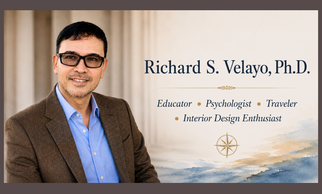

"A Life of Curiosity, Learning, and Discovery."

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Welcome!

Thank you for stopping by.

This website is a reflection of the many experiences that have shaped my life—from decades of teaching psychology and working with colleagues around the world to discovering new passions through travel, digital art, interior design, and activities of interest that promote lifelong learning.

I've always believed that curiosity is one of life's greatest gifts. Whether exploring another culture, creating digital artwork, designing beautiful spaces, or simply appreciating a quiet sunset, I continue to find inspiration in everyday experiences.

I invite you to browse, explore, and perhaps discover something that speaks to you as well.

Warm regards,

Richard S. Velayo, Ph.D.

Contact Me

Reflection of the Month

August 2026 – *Inspiring Discovery*

"A meaningful life is measured not only by what we accomplish, but by what we inspire others to discover."

— Rich Velayo

Browse Previous Reflections

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Digital Legacy Archive

To help preserve this website for future generations, archival editions are periodically deposited with the **Internet Archive**.

View the August 2026 Website Archive: https://archive.org/details/richard-s-velayo-website-archive-august-2026

[This archive preserves the appearance and content of this website as it existed in August 2026.]

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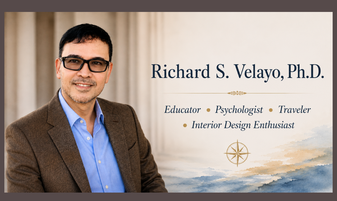

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About Me

Life's most meaningful journeys often begin with a simple curiosity to learn, explore, and grow.

I'm **Richard S. Velayo, Ph.D.**, Professor Emeritus of Psychology at Pace University in New York City. Welcome to my website—a place where I've brought together the different chapters of my life, the work that has shaped me, and the interests that continue to inspire me.
For more than three decades, my **academic journey** centered on teaching psychology, mentoring students, conducting research, and collaborating with colleagues around the world. My professional interests in international psychology, education, and cross-cultural understanding gave me opportunities to learn from people and perspectives far beyond the classroom.
Retirement opened a new chapter—**life beyond academia**. I now have more time to travel, explore new cultures and places, pursue creative interests, and simply remain curious about the world around me. I've discovered that leaving the classroom didn't mean leaving learning behind; it simply gave learning a different form.
At the same time, I've become increasingly interested in **my roots**—the people, places, experiences, and Filipino heritage that helped shape who I am. Looking back has given me a greater appreciation for where my journey began, while traveling and exploring continue to remind me how much there is still to discover.
This website brings these parts of my life together. Whether you're a former student or colleague, a fellow traveler, or simply a curious visitor, I invite you to explore. I hope you'll find something here that informs, inspires, or perhaps simply brings a smile.
Thank you for stopping by. I'm glad you're here.

Warm regards,

Richard S. Velayo, Ph.D.

Quick Links

My Academic Journey

A Lifetime of Learning, Teaching, and Service

For more than three decades, I had the privilege of teaching psychology, mentoring students, conducting research, and serving in leadership roles at Pace University. My work also provided opportunities to collaborate with psychologists and educators around the world, reinforcing my belief that psychology is strengthened by diverse perspectives and cultural understanding.

Although I have retired from full-time teaching, I remain deeply grateful for the experiences, friendships, and collaborations that shaped my career. This section highlights the academic journey that has been such an important part of my life.

Education is not simply about sharing knowledge—it's about inspiring curiosity that lasts a lifetime.

Explore this section to learn more about my academic career, publications, presentations, leadership, and professional service.

Life Beyond Academia

A New Chapter of Discovery

Retirement has given me the freedom to pursue many of the interests that have inspired me throughout my life. In addition to psychology, I enjoy traveling, photography, digital artwork, architecture, interior design, and mindfulness.

Every new place, experience, and creative project reminds me that learning never truly ends. This section reflects the personal side of my journey and the joy of continuing to explore the world with curiosity and gratitude.

Retirement is not the end of learning; it is the beginning of learning by choice.

My Roots

Honoring My Heritage

My Filipino heritage has been an important influence throughout my life, shaping my values, appreciation for education, and sense of family and community.

Exploring my ancestry has become a meaningful way to honor those who came before me and to better understand my own journey. I hope this section offers a glimpse into the family history and traditions that continue to inspire me today.

Our roots tell us where we began, but they also help us understand where we're going.

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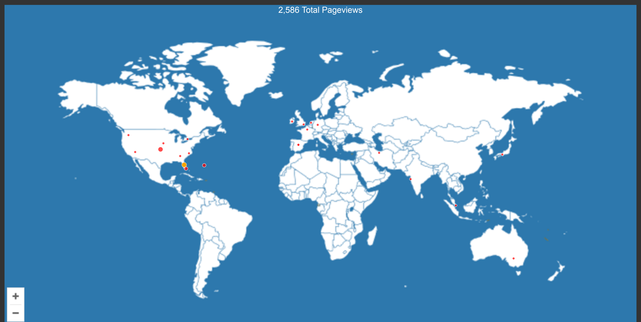

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Academic

For me, education has never been simply about teaching—it has always been about inspiring curiosity and opening doors to new possibilities.

A Lifelong Commitment to Learning

Education has been one of the greatest privileges of my life. Throughout my academic career, I had the opportunity to teach and mentor students, pursue research and scholarship, and contribute through leadership and service. Each of these experiences reinforced my belief that learning is a lifelong journey—one that grows through curiosity, collaboration, and the exchange of ideas.

Teaching and mentoring gave me the opportunity to encourage curiosity and help students discover their own potential. **Research and scholarship** allowed me to explore questions about psychology, culture, education, and learning. And through **leadership and service**, I was fortunate to contribute to my university, my profession, and the broader international psychology community.

Together, these three dimensions tell the story of my academic journey. I invite you to explore them below and learn more about the experiences, people, and ideas that shaped my career.

Quick Links

Teaching & Mentoring

Inspiring Curiosity Through Education

Teaching was always much more than sharing information—it was about encouraging students to ask questions, think critically, and discover their own potential. Whether in the classroom, advising students, or developing innovative learning experiences, my goal was to create an environment where curiosity could flourish.

The opportunity to learn alongside my students remains one of the most rewarding aspects of my academic career.

Research & Scholarship

Exploring Questions That Matter

Research allowed me to better understand human behavior while contributing to the advancement of psychology. My interests have included areas such as cross-cultural psychology, international psychology, teaching and learning, and the thoughtful integration of technology in teaching and learning.

.

For me, research has always been about more than publishing findings—it's about asking meaningful questions, expanding knowledge, and encouraging continued exploration.

Leadership & Service

Giving Back to the Profession

Service has been an important and rewarding part of my professional journey. Beyond teaching and research, I was fortunate to contribute through leadership, committee work, professional organizations, mentoring, and collaborations with colleagues around the world.

These experiences strengthened my appreciation for the importance of community, shared purpose, and working together to advance psychology and higher education.

Academic Biography - At a Glance

Richard S. Velayo, Ph.D.

Professor Emeritus of Psychology

Pace University, New York City

Richard S. Velayo, Ph.D., is Professor Emeritus of Psychology at Pace University in New York City. During a career spanning more than three decades, his work encompassed teaching, research, academic leadership, international collaboration, and professional service. He retired from full-time teaching in 2017, but his longstanding interests in psychology, education, international and cross-cultural perspectives, and lifelong learning continue to shape his interests today.

Academic Leadership (Select)

During his tenure at Pace University (1994–2017), Dr. Velayo served as:

- Associate Chair, Psychology Department (NYC Campus)
- Director, Master of Arts in Psychology Program (2014–2017)
- Director, Dyson College Center for Global Psychology
- Editor-in-Chief, *Psychfye* (Department Newsletter)

He previously taught at:

- De La Salle University (Manila)
- Montana State University
- University of Michigan (Ann Arbor)

Scholarly Contributions (Select)

Dr. Velayo's scholarship focuses on:

1. Development of assessment tools for multimedia learning
2. Applications of Internet-based technologies (IBTs) in teaching and research
3. Pedagogical strategies to internationalize the psychology curriculum

He has authored:

- 47 peer-reviewed journal articles
- 4 book chapters
- 30+ non-peer reviewed publications
- 305+ scholarly presentations
- 78+ workshops, panels, and invited addresses
- 120+ organized symposia and conferences

His work has appeared in leading journals including:

- *American Psychologist* (APA flagship journal)
- *Teaching of Psychology*
- *Psychology Learning and Teaching*
- *Educational Technology*
- *International Psychology Bulletin*
- *International Psychologist*

He has supervised over 60 doctoral dissertations and master's theses.

Courses Taught

Graduate and undergraduate courses include:

- Experimental Psychology
- Cognitive Psychology
- Instructional Psychology: Multimedia Applications
- Research Design and Statistics
- Psychology of Learning
- Developmental Psychology
- Behavior Modification
- Critical Thinking and Problem Solving
- Introduction to International Psychology
- Psychology at the United Nations
- Professional Seminar

Honors and Awards (Select)

Dr. Velayo's honors include:

- Virginia Staudt Sexton Award for Early Career Contributions (1997)
- Distinguished Service Award, NYSPA (2002)
- Wilhelm Wundt Award for Outstanding Research and Service (2007)
- Distinguished Award for Outstanding Service, Pace University (2000)
- Guest of Honor, Greater New York Conference on Behavioral Research (2012)
- Henry P. David International Mentoring Award, APA Division 52 (2013)

Professional Affiliations and Leadership (Select)

Dr. Velayo is a Fellow of multiple divisions of the American Psychological Association (Divisions 1, 2, 46, and 52), as well as the Eastern Psychological Association. His service includes:

- Past President, APA Division 52 (International Psychology)
- Past President (twice), NYSPA Academic Division
- Past Chair, Psychology Section, New York Academy of Sciences
- Chair, Communications and Publications Committee, International Council of Psychologists
- Co-Director, International Social and Behavioral Research Alliance
- NGO Representative to the United Nations (2009–2017)

He has served in numerous leadership roles involving curriculum development, publications, international psychology, fellows committees, and United Nations psychology initiatives.

Complete Academic Biography

For a more detailed account of my academic career—including my education, teaching, scholarship, leadership, professional service, and honors—my Complete Academic Biography is available for download below.

Complete Academic Biography - Richard S. Velayo, Ph.D.
RSV-CompleteAcademicBiography.pdf
Adobe Acrobat Document [47.5 KB]

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International Psychology

Every culture has something to teach us, and every international experience broadens our understanding—not only of psychology, but also of ourselves.

Psychology in a Global Community

"Psychology becomes even more meaningful when we learn from one another across cultures and around the world."

Psychology does not exist in isolation. It is shaped by culture, history, language, and the unique experiences of people around the globe. International psychology encourages us to look beyond national boundaries, embrace diverse perspectives, and work collaboratively to address shared global challenges.

Whether you're a student, educator, researcher, or practicing psychologist, I hope this section inspires you to explore how psychology can contribute to a more connected, compassionate, and culturally informed world.

Featured Resource #1: PSYCHOLOGY ATLAS

I created the Psychology Atlas and its interactive Google My Maps as resources to help psychology educators incorporate international and cross-cultural perspectives into their courses. By exploring these maps, teachers can discover psychologists, organizations, heritage sites, conferences, and global initiatives that bring psychology to life from a worldwide perspective.

Explore Psychology Atlas

Featured Resource #2: The Handbook of International Psychology

Bullock, M., Stevens, M. J., Wedding, D., & Clinton, A. (Eds.). (2024). *The Handbook of International Psychology* (2nd ed.). Routledge.

I found *The Handbook of International Psychology* to be a comprehensive and valuable overview of how psychology has developed and is practiced across countries and cultures around the world. I particularly appreciated its international and cross-cultural perspective, which illustrates how history, culture, social conditions, and political contexts influence psychological research, education, training, and professional practice, while reinforcing the importance of understanding psychology as a truly global discipline.

Recommended Resources for teaching INTERNATIONAL PSYCHOLOGY

Contained here is a collection relevant resources I use in teaching "Introduction to International Psychology", a graduate level course at Pace University (NYC).

A Course on "International Psychology"

Syllabus (sample)
This sample syllabus was used in a 15-week online (asynchrounous) course last offered in the Spring 2025 semester at Pace University (NYC campus) in which the textbook above was used. Instructors may use this syllabus as a basis from which to develop their own.
PSY603syllabus(generic).pdf
Adobe Acrobat Document [158.5 KB]

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Textbook

Shealy, C. N., Bullock, M., & Kapadia, S. (Eds.). (2023). *Going Global: How Psychologists Can Meet a World of Need.* American Psychological Association
[ISBN: 978-1433836435]

Textbook Introduction Video: https://www.dropbox.com/scl/fi/rd2dzr8oy9kmdp05zmj42t/GG-Textbookintro-720p.mp4?rlkey=053f43nsw jjgwgjkw f0x14q1o&st=2qksnb1p&dl=0

Quick Links to Books Chapters

Below are the sections of the textbook that comprise the contents of this course. Each contain resources and materials relevant to key topics about international psychology.

International Psychology?

International psychology is more than studying psychology in different countries—it is about understanding how psychological science and practice can contribute to addressing the opportunities and challenges that affect people around the world.

As our world becomes increasingly interconnected, psychologists have unique opportunities to promote well-being, advance human rights, strengthen education, and collaborate across cultures. This section introduces the growing field of international psychology and highlights the many ways psychologists can make a meaningful global impact.

Intro. to Global Psychology

Global psychology provides a roadmap for applying psychological knowledge to today's most pressing international issues. From advocacy and leadership to research, teaching, and service, psychologists have many opportunities to contribute beyond traditional professional roles.

The following sections introduce ten areas in which psychology can make a meaningful difference, while encouraging collaboration, cultural humility, and responsible global engagement.

Advocacy

Advocacy gives psychologists an opportunity to apply their knowledge in support of human dignity, social justice, education, mental health, and other issues affecting communities around the world. By combining scientific evidence with compassion and ethical responsibility, psychologists can help influence positive change at both local and global levels.

Assessment

Assessment extends well beyond testing and diagnosis. In international settings, psychologists use assessment to better understand individuals, communities, educational systems, and organizations while ensuring that methods remain culturally appropriate and scientifically sound.

Thoughtful assessment provides the foundation for effective decision-making, research, and intervention across diverse populations.

Consultation

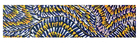

Psychological expertise can benefit governments, schools, businesses, nonprofit organizations, healthcare systems, and international agencies. Consultation allows psychologists to work collaboratively with diverse organizations, offering evidence-based guidance that helps improve programs, policies, and services around the world.

Intervention

Psychological interventions promote resilience, well-being, and positive change for individuals, families, organizations, and communities. In global settings, successful interventions require cultural sensitivity, collaboration, and an appreciation for local values, traditions, and resources.

Effective intervention is not simply about applying existing knowledge—it is about adapting that knowledge to meet the unique needs of each community.

Leadership

Leadership in psychology involves more than managing organizations—it means inspiring collaboration, encouraging innovation, and helping others work toward shared goals. Around the world, psychologists contribute their expertise to strengthen institutions, resolve complex challenges, and promote positive organizational change across cultures.

Policy

Psychologists can make valuable contributions to public policy by applying research and psychological science to important societal issues. Whether working with governments, educational institutions, healthcare systems, or international organizations, psychologists help shape policies that improve the lives of individuals and communities.

This section explores how psychological knowledge can inform thoughtful, evidence-based decision-making on a global scale.

Research

International research expands our understanding of human behavior by bringing together diverse cultures, perspectives, and experiences. Collaborative research not only strengthens psychological science but also helps ensure that discoveries are relevant to people around the world.

This section explores opportunities for psychologists to engage in meaningful international research partnerships and contribute to solving global challenges.

Service

Professional service is one of the most rewarding ways psychologists can contribute beyond the classroom or consulting office. Through volunteerism, leadership, international organizations, and community engagement, psychologists can use their knowledge to support meaningful change while building lasting professional relationships around the world.

Service reflects psychology's commitment to improving lives through collaboration, compassion, and shared purpose.

Teaching

Teaching offers a unique opportunity to prepare the next generation of globally minded psychologists. By incorporating international perspectives, diverse cultural viewpoints, and innovative learning experiences, educators help students develop the knowledge, skills, and cultural awareness needed to thrive in an increasingly interconnected world.

For me, internationalizing the teaching of psychology has been one of the most meaningful and rewarding aspects of my career.

Concluding Thoughts

Psychology has the potential to make a meaningful difference far beyond the boundaries of any one country. As our world continues to evolve, opportunities for international collaboration, cultural understanding, and global engagement will become increasingly important.

I hope the resources and ideas presented throughout this section encourage students, educators, researchers, and practitioners to think more globally, embrace diverse perspectives, and recognize the many ways psychology can contribute to building a healthier, more compassionate, and more connected world.

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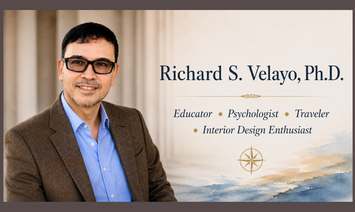

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Life & Interests

Retirement has given me the freedom to pursue many of the interests that have inspired me throughout my life. Every new experience reminds me that learning doesn't end—it simply takes new and exciting directions.

While psychology and education will always be an important part of who I am, retirement has opened the door to new opportunities for exploration, creativity, and personal growth. Today, I enjoy traveling, cruising, digital artwork, interior design, architecture, personal finance, genealogy, and the practice of mindfulness.

Whether I'm discovering a charming coastal town, photographing a beautiful sunset, designing a welcoming living space, or simply enjoying a quiet cup of coffee while reflecting on life's experiences, I continue to find inspiration in the people, places, and moments that surround me.

The pages in this section offer a glimpse into the interests that enrich my life beyond academia. Together, they reflect my belief that curiosity, lifelong learning, and meaningful experiences continue to shape who we are—at every stage of life.

I hope these pages encourage you to celebrate your own interests, embrace new experiences, and continue discovering the joy of lifelong learning.

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Florida Homes

Florida Favorites

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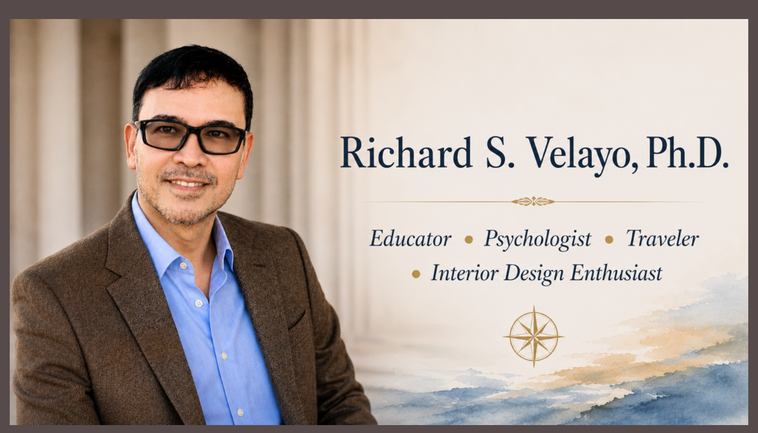

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Galleries

Digital artwork allows me to preserve moments of discovery and share the beauty I find in everyday life.

My digital artwork explores structure, color, and spatial balance through a lens shaped by psychology and global experience. Working primarily with digital composition, I am drawn to contrasts—abstraction and order, geometry and emotion, interior stillness and expansive landscapes.

These works are not simply visual experiments but reflections on perception, cultural memory, and aesthetic harmony. Influenced by travel, architecture, and curated design environments, I approach each composition as both observer and constructor—seeking balance, clarity, and quiet resonance.

The gallery reflects a lifelong engagement with visual form as another language of reflection.

Quick Links

DESIGN HOME Gallery

Digital Artwork

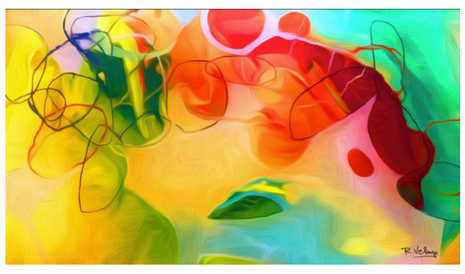

Self-Portraits

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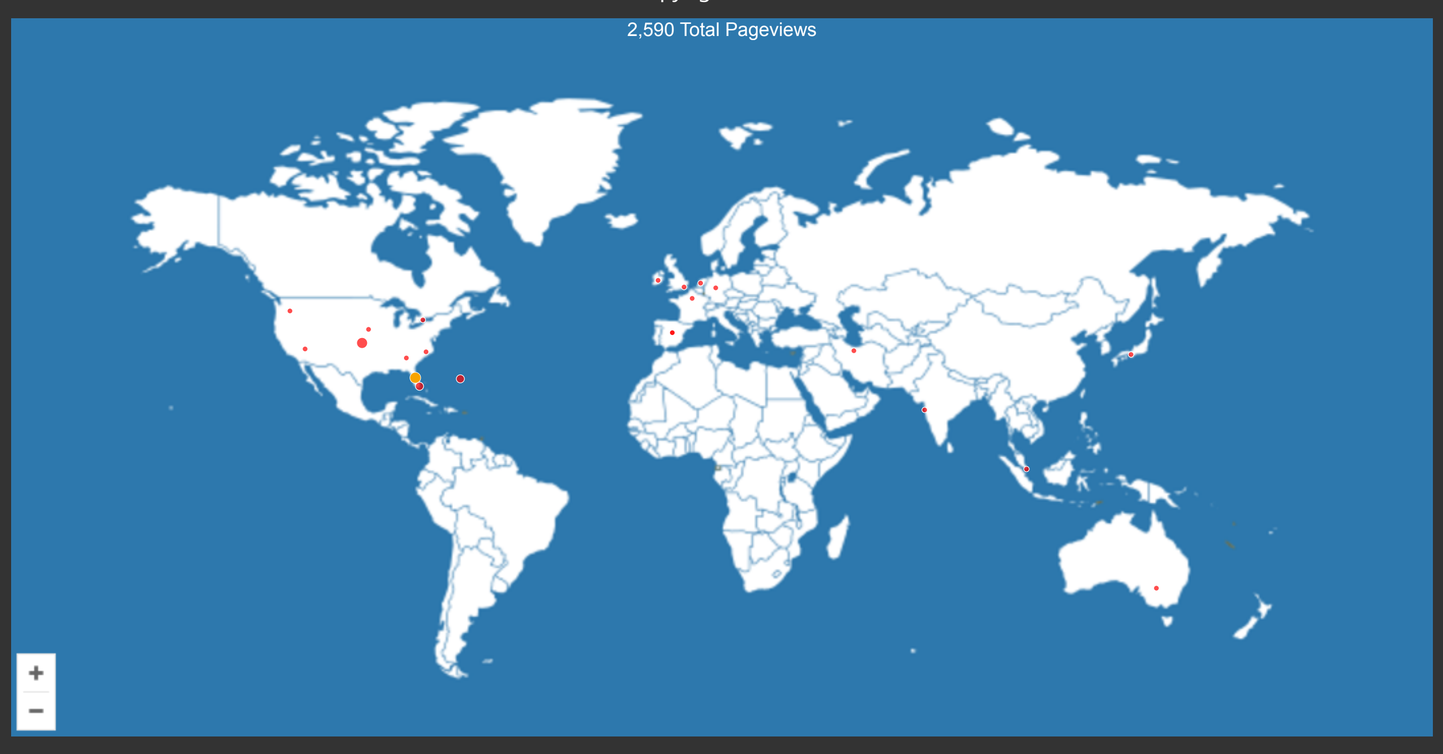

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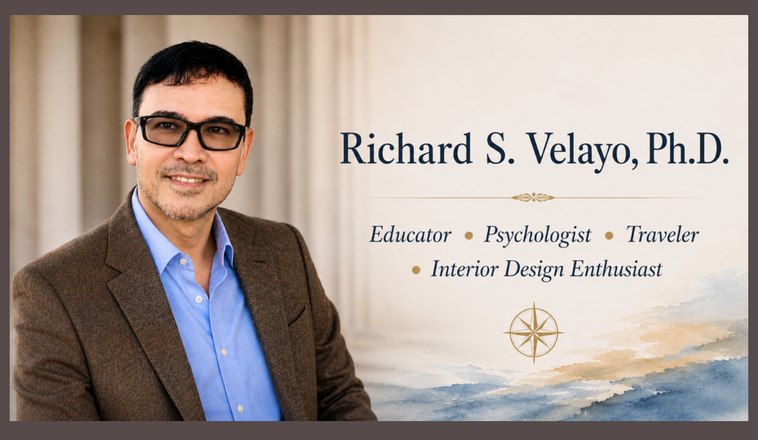

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My Maps

Explore the places, journeys, and experiences that have shaped a lifetime of curiosity, learning, and discovery.

Maps tell stories. Every place we visit, every community we call home, and every journey we undertake becomes part of our personal story. This collection of interactive Google My Maps brings together many of the places that have shaped my life—from psychology and education to travel, photography, and retirement adventures. I invite you to explore these maps, click on the markers, and discover the people, places, and experiences that have fueled my lifelong curiosity.

Psychology Atlas Florida Maps U.S. Maps World Map

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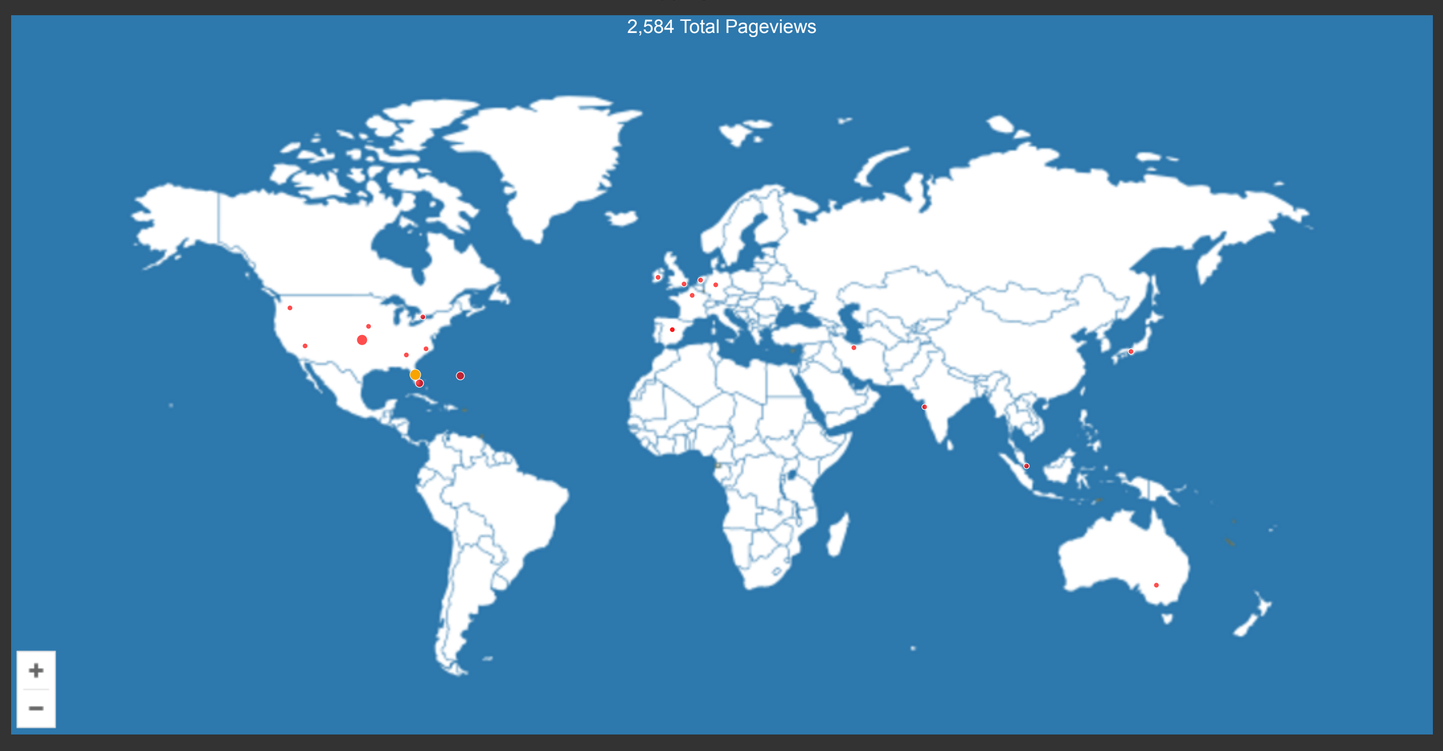

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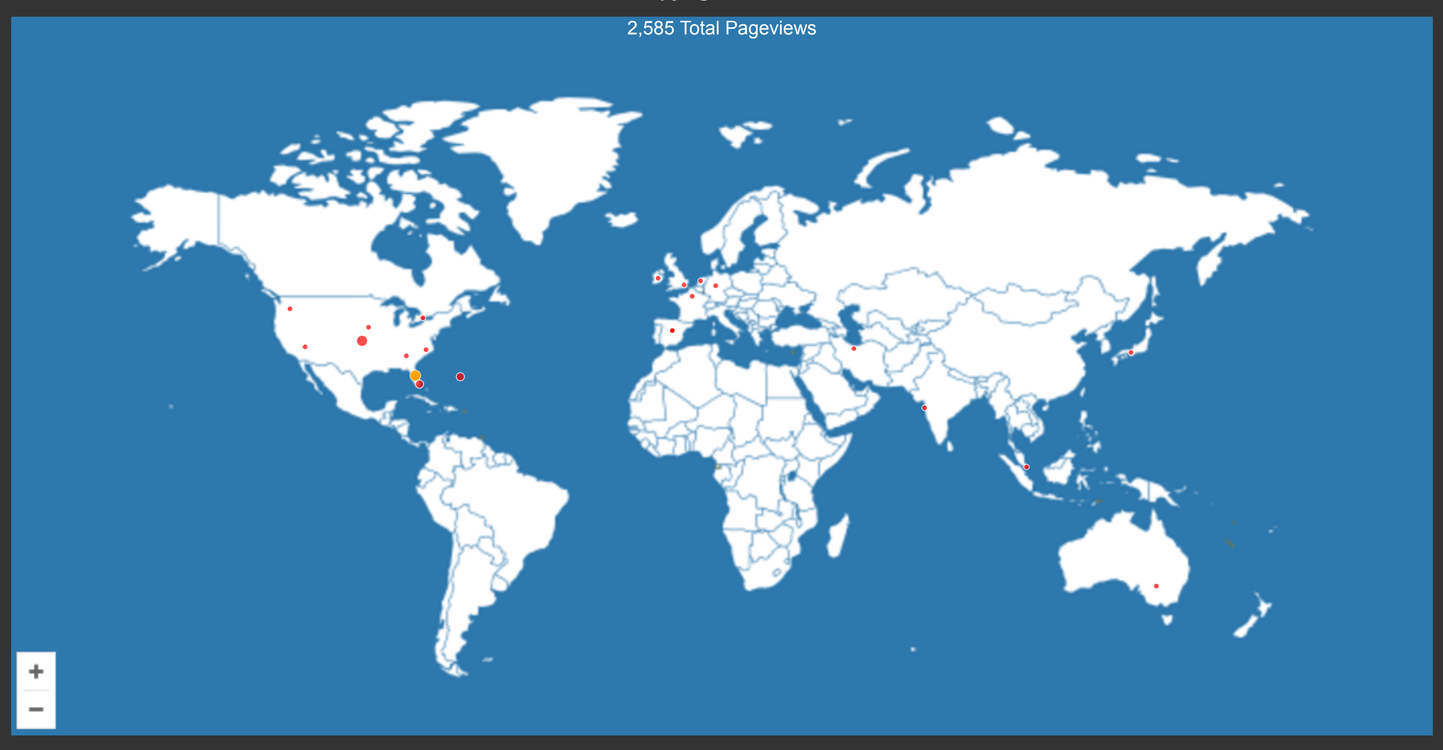

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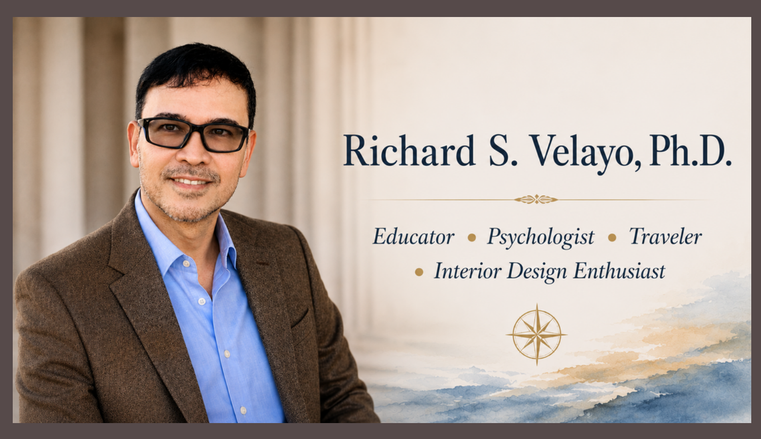

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Contact Me

Thank you for visiting. I hope something on this website has sparked your curiosity or inspired you to continue your own journey of learning and discovery.

CONTACT INFORMATION:

Email: rvelayo@gmail.com

If you wish to leave a note for Dr. Richard Velayo, please type it below.

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Email *

Message *

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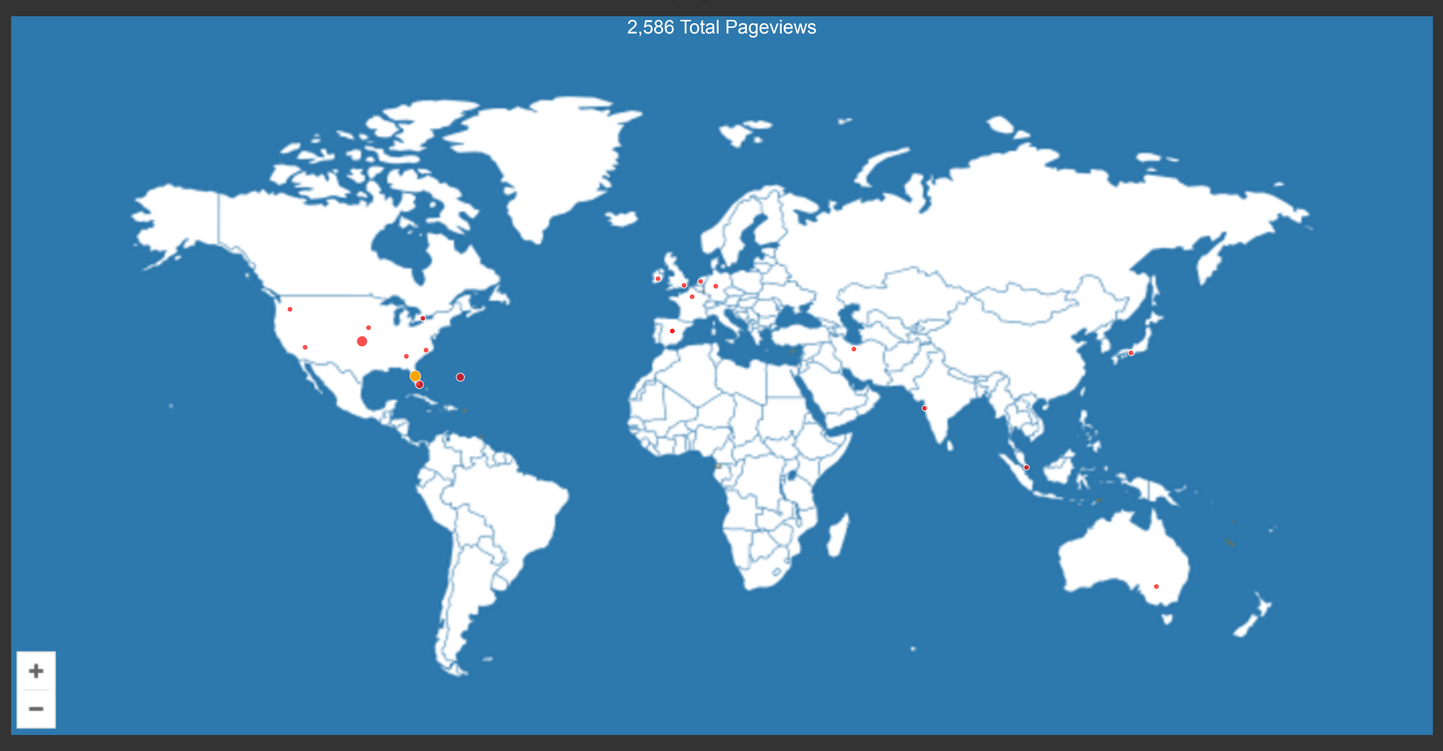

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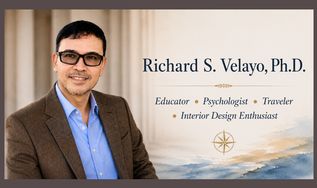

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Reflections (Archive)

Life is a continuous journey of learning, growth, and discovery. These reflections share some of the experiences, lessons, and perspectives that have shaped my personal and professional life.

These monthly reflections are inspired by my journey as an educator, psychologist, traveler, and lifelong learner. Each offers a brief pause to consider an idea, an experience, or a lesson that has shaped my life and continues to inspire me.

I hope these reflections encourage you to pause, reflect, and discover something meaningful in your own journey.

August 2026 – *Inspiring Discovery*

"A meaningful life is measured not only by what we accomplish, but by what we inspire others to discover."

— Rich Velayo

July 2026 – *The Journey Begins with Curiosity*

Every journey begins with curiosity. Whether we are exploring a new country, learning a new language, or simply seeing the familiar with fresh eyes, we continue to grow. Some of life's greatest rewards come not from reaching a destination, but from remaining open to the people, places, and ideas we encounter along the way.

— Rich Velayo

June 2026 – *Trying Something New*

Some of life's greatest adventures begin with a simple question: "What if I tried something new today?" Curiosity encourages us to step beyond the familiar and discover opportunities we might otherwise have missed.

— Rich Velayo

May 2026 – *The Joy of Learning*

Education is not simply about acquiring knowledge; it is about developing the curiosity and wisdom to use that knowledge well. Lifelong learning keeps our minds open and our lives continually enriched.

— Rich Velayo

April 2026 – *Growing Every Day*

Spring reminds us that growth is often quiet. Small steps taken consistently can transform our lives in ways we never expected. Curiosity and patience often lead to our greatest discoveries.

— Rich Velayo

March 2026 – *Travel as a Teacher*

Travel teaches us that the world is both larger and smaller than we imagine—larger in its beauty and diversity, yet smaller in the kindness shared between people. Every journey leaves us with memories, friendships, and a deeper appreciation for different cultures.

— Rich Velayo

February 2026 – *The Gift of Connection*

The strongest connections in our lives are built not only through love and friendship, but also through kindness, understanding, and genuine curiosity about one another. Every meaningful conversation has the potential to broaden our perspective.

— Rich Velayo

January 2026 – *New Beginnings*

A new year reminds us that learning has no finish line. Every beginning offers another opportunity to grow with curiosity, purpose, and gratitude. Each day presents a chance to discover something new about ourselves and the world around us.

— Rich Velayo

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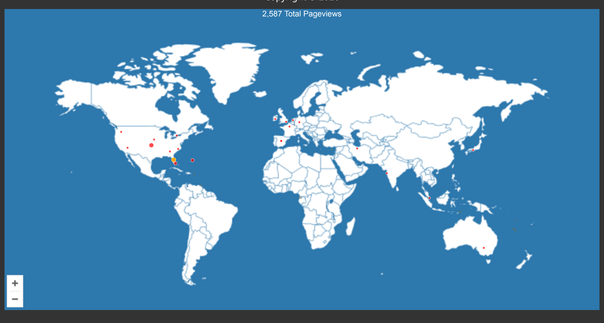

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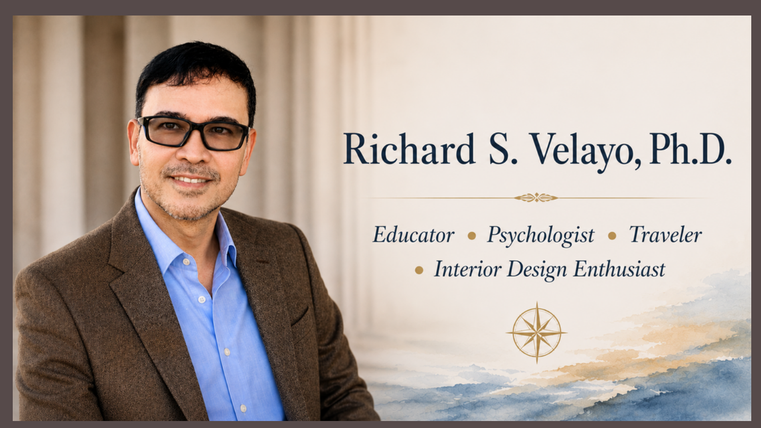

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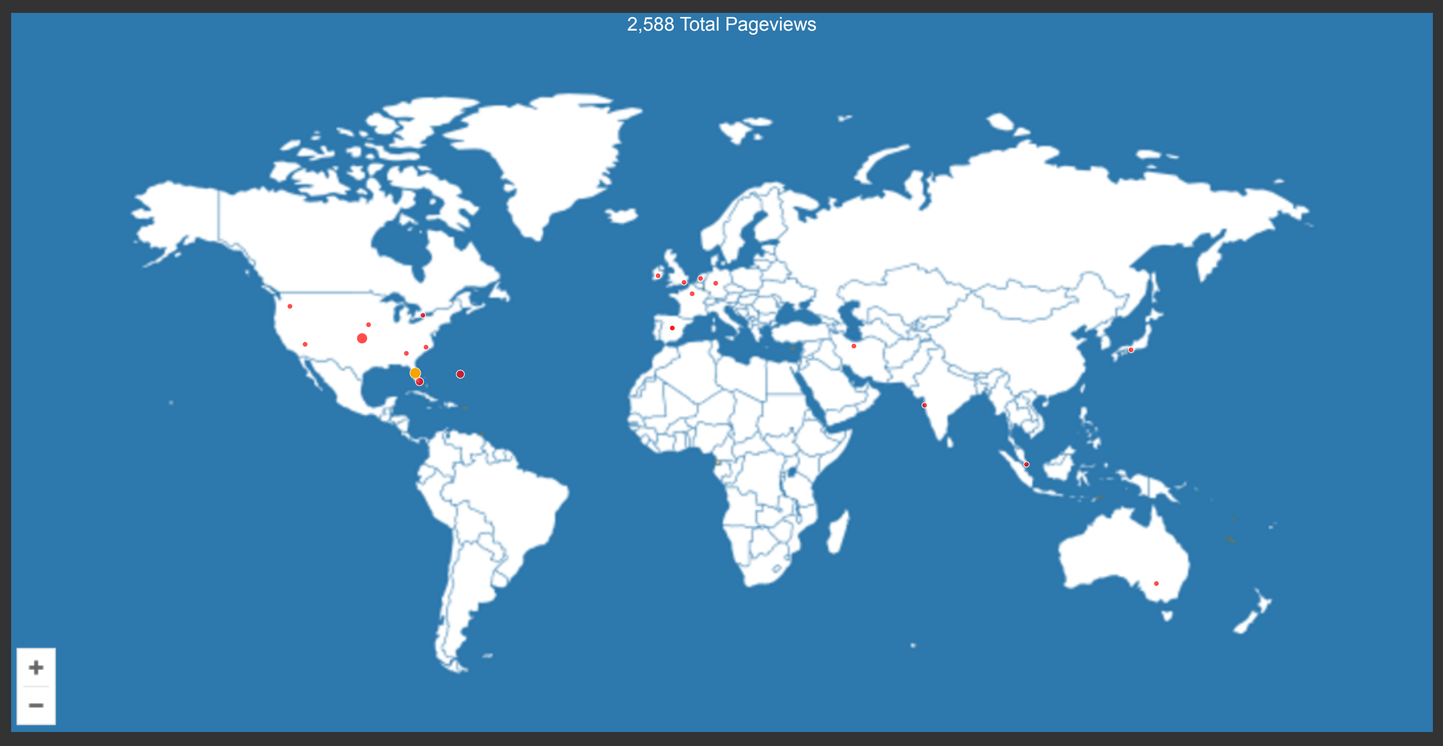

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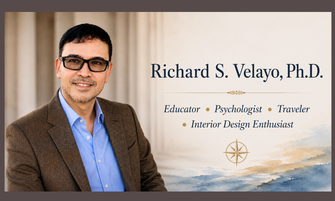

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My Roots

Learning about our roots helps us better understand ourselves and appreciate the journeys of those who came before us.

Taking Pride in My Heritage

My heritage is rooted in the Philippines, a country whose history reflects centuries of cultural exchange and resilience. The Philippines has been shaped by indigenous traditions as well as Spanish and American influences, creating a unique cultural blend that values family, education, community, and respect for others. Growing up in Quezon City, in the Manila metropolitan area, I experienced firsthand the energy and diversity of Filipino life — a place where modern urban living exists alongside strong cultural traditions. The richness of Filipino culture, from language and food to social values and community ties, helped shape my early understanding of identity and belonging in a world influenced by many cultures.
I remain deeply proud of my Filipino heritage, which has instilled in me a lasting appreciation for cultural diversity and human connection. At the same time, I have fully embraced my life as an American citizen, grateful for the opportunities for education, professional growth, and global engagement that the United States has provided. In many ways, my life reflects the blending of these two worlds — the cultural roots of the Philippines and the opportunities and perspectives of America — and this dual identity has strongly influenced both my personal outlook and my professional commitment to international and cross-cultural understanding.

Ancestry DNA Results Summary (As of October 2025)

Go to Ancestry DNA

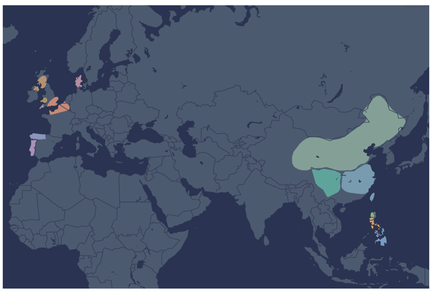

Richard's 13 ancestral regions

Southeast Asia

Luzon	38%
Central & Southern Philippines	34%
Northern & Central Philippines	7%

England

Cornwall	5%
Southeastern England & Northwestern Europe	1%

Celtic & Gaelic

Central Scotland & Northern Ireland	3%
Southern Wales	2%

East Asia

Central & Eastern China & Taiwan	2%
Southwestern China	2%
Northern China	1%

Iberian Peninsula

Portugal	2%
Northern Spain	1%

Nordic

Denmark	2%

Updated October 2025. View previous results and FAQs

Click here to go to Ancestry DNA.

Richard Velayo

DNA inheritance

These are the ethnicity regions Richard inherited from each parent

Region	Parent 1	Parent 2	RV
Total: 11	**50%**	**50%**	**100%**
Northern Philippines	4%	32%	36%
Central & Southern Philippines	36%	0%	36%
Western Philippines	6%	3%	9%
England & Northwestern Europe	0%	5%	5%
Scotland	0%	5%	5%
Southwestern China	2%	0%	2%
Germanic Europe	0%	2%	2%
Spain	0%	2%	2%
Basque	1%	<1%	1%
Wales	0%	1%	1%
Ireland	1%	0%	1%

Ethnicity Inheritance by Parents

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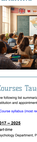

Explore representative course syllabi and reflections that illustrate my approach to teaching, student learning, and psychology education throughout my academic career.

My teaching interests center on international and cross-cultural psychology, integrating global perspectives into undergraduate and graduate education courses, and developing students' critical thinking and research skills. Throughout my career, I have been committed to innovative pedagogy, curriculum internationalization, and preparing students to apply psychological knowledge thoughtfully in diverse and global contexts.

Courses Taught

The following list summarizes the undergraduate, graduate, and doctoral courses I taught during my academic career, organized chronologically by institution and appointment.

Course syllabus (most recent) for some courses available for download in PDF. (Scroll further down this page to access.)

2017 – 2020
Part-time
Psychology Department, Pace University, NY

Graduate:
- Introduction to International Psychology (Master's) NEW
  - Link to my International Psychology Webpage
- Instructional Psychology: Multimedia Applications (Master's) NEW
- Psychology at the United Nations (Master's) NEW

1994 – 2017
Full-time
Psychology Department, Pace University, NY

Graduate:
- Human Learning (Master's) NEW
- Psychological Research Methods (Master's) NEW
- Research Design and Statistics II (Master's)
- Cognitive Psychology (Master's) NEW
- Psychology of Personality (Master's)
- Instructional Psychology: Multimedia Applications (Master's)
- Mentored Lab Class (1 and 2) (Master's)
- Independent Study (Master's) NEW
- Professional Seminar (Master's) NEW
- Instructional Psychology: Technology (Master's)
- Psychology at the United Nations (Master's)
- MA Thesis (Master's) NEW
- Advanced Seminar: Theories and Applications (Doctoral) NEW
- Doctoral Seminar: Year 1 (PSY8104) and Doctoral Research Colloquium (PSY8105) (Doctoral) NEW

Undergraduate:
- General Psychology I NEW
- General Psychology II NEW
- Experimental Psychology I NEW
- Experimental Psychology II NEW
- Cognition, Perception, Motivation, and Mind Fields
- Cognitive Psychology
- Mentored Lab Class (1 and 2)
- Senior Seminar, Ms NEW
- Independent Study

2000 – 2005
Part-time
School of Computer Science and Information Systems, Pace University, NY

Undergraduate
(These three courses offered through the NACTEL's (National Coalition for Telecommunications Education and Learning) Associate of Science in Applied Information Technology and the Accelerated Criteria B.S. in Telecommunications degree programs.)
- Critical Thinking and Problem Solving
- Psychology of Personal Adjustment
- Psychology of Learning (NACTEL Program, Pace University) NEW

1992 – 1994
Full-time
Psychology Department, Monterey State University, Bozeman, MT

Undergraduate:
- Introductory Psychology
- Thinking Skills: (Critical Thinking Skills and Cognitive Psychology)
- Introductory Psychology (as a secondary course)
- Developmental Psychology
- Behavior Modification
- Independent Study

1989 – 1992
Psychology Department, University of Michigan, Ann Arbor

Undergraduate: (as a Graduate Research Assistant)
- Introduction to Psychology
- Learning to Learn (Cognitive and Motivational Psychology)

1986 – 1988
Part-time
Psychology Department, University of the Pacific, Stockton, CA

Undergraduate: (as a Graduate Teaching/Research Assistant)
- Experimental Psychology

1984 – 1985
Part-time
Department of Psychology and Behavioral Sciences, De La Salle University, Manila, Philippines

Undergraduate:
- Introductory Psychology (as a Lecturer)
- Introduction to Sociology (as a Lecturer)
- Industrial Psychology and Human Engineering (as an Undergraduate Teaching Assistant)

Course Syllabi (in PDF)

During my tenure at Pace University, I taught undergraduate and graduate courses in psychology at several institutions. The syllabi below illustrate my approach to course design, student learning, and assessment. While policy and schedules changed from semester to semester, these documents provide a representative snapshot of my teaching philosophy and expectations.

[NOTE: These syllabi are presented as historical documents reflecting the courses I taught during the indicated semester. University policies, textbooks, prerequisites, and schedules may have changed since then.]

Graduate Courses (Master's and Doctoral)

#1 - Introduction to International Psychology (MA)
Spring 2019
PSY636 syllabusSpr2019.pdf
Adobe Acrobat Document [163.6 KB]
Download

This graduate-level online course entails reading, discussing, and writing about a variety of contemporary topics in the relatively new specialty of international psychology. You will examine mainstream as well as alternative theoretical, methodological, and applied approaches that are relevant to the study and practice of international psychology. The topics selected offer a broad and deep understanding of this field, specifically, an appreciation of psychology's relevance to the understanding and solution of global problems, as well as of how psychology itself is affected by worldwide events and forces.

- Link to my International Psychology Webpage

#2 - Instructional Psychology: Multimedia Applications (MA)
Summer 2 2017
PSY636 syllabusSum2017.pdf
Adobe Acrobat Document [209.4 KB]
Download

This 3-credit web-enhanced (online) course is designed as an advanced learner course in instructional design principles associated with learning from media (text, visual, and audio presentations) and the application of these principles in designing multimedia instruction for effective learning and teaching. Drawing from years of research in cognitive science and educational psychology, this course provides materials based on the cognitive theory of multimedia learning and principles for the design of multimedia presentations. It aims to help students realize the potential of multimedia instruction for effective learning and teaching and to understand the research that underlies this potential. Students learn about the basic principles of multimedia instructional design and to demonstrate their knowledge by completing a multimedia project that adheres to these principles.

#3 - Psychology at the United Nations
Fall 2015
PSY645 syllabusFall2015.pdf
Adobe Acrobat Document [168.9 KB]
Download

The United Nations (UN) is a complex, somewhat mythical world which serves as the meeting ground for political powers from around the world. It is a place where international relations are conducted, and where the fate of the world is in the balance. Psychology's relevance to the UN is therefore unique and important rule in the global community. "Global" is a word that is used to refer to issues and concerns of two or more countries. While not always successful in implementation, the UN does provide a forum for the discussion of issues, the development of international agreements, and the coordination of the activities of nations, and the role of psychology and psychologists at the United Nations. Guest speakers who are active in the United Nations will be invited to speak to the class. Students will be assigned UN-relevant topics to present in class.

#4 - Human Learning (MA)
Fall 2005
PSY715 syllabusFall1999.pdf
Adobe Acrobat Document [321.8 KB]
Download

This course introduces both basic and advanced principles and theories of learning and motivation, including cognition, Conditioning, Behavior Modification, Internalization and discrimination, information processing, and complex cognitive functioning are some of the topics discussed. Research on learning theory and their general application in a variety of contexts will be covered.

#5 - Research Design and Statistics II (MA)
Spring 2016
PSY616 syllabusSpr2016.pdf
Adobe Acrobat Document [295.3 KB]
Download

This is an intensive three-hour per week graduate course that will introduce you to psychological research design, descriptive and inferential statistical techniques in psychology, and other topics pertinent to conducting research in psychology. The major objectives of this course are to learn how to design, conduct, and report the results of psychological research. Students will also learn how to use inferential and descriptive statistical information, and to develop the critical thinking skills to determine when and how to use a particular statistical technique given a specific research problem.

#6 - Cognitive Psychology (MA)
Spring 2014
PSY626 syllabusSpr2014.pdf
Adobe Acrobat Document [280.9 KB]
Download

This graduate-level course examines cognitive processes, often called "higher mental processes." Cognitive psychology includes topics such as perception, memory, language, and thinking. This course will give you an appreciation of research and theory in cognitive psychology, an understanding of the methods used to gather and evaluate evidence about cognitive processes, and an understanding of the ways in which knowledge of these processes has been applied to solve problems and improve the quality of life. Through this course requires a fairly sophisticated background in psychology, it will begin with a basic overview of cognition. Discussion of key research on cognition is covered. Note that much of the research in cognitive psychology is methodologically complex, especially because of the challenge of assessing covert mental processes.

#7 - Personality Theories (MA)
Spring 2011
PSY625 syllabusSpr2011.pdf
Adobe Acrobat Document [263.8 KB]
Download

This graduate-level course provides an overview of current thinking and research about personality. Personality psychology includes topics such as personality development, personality assessment, and personality theories. Personality theories include psychodynamic, humanistic, biological and other relevant factors (interpersonal, contextual, and developmental), and assessment. This course will give you an appreciation of research and theory in personality psychology, an understanding of the methods used to gather and evaluate evidence about personality constructs, and an understanding of the ways in which knowledge of these constructs has been applied to various settings. Though this course requires a fairly sophisticated background in psychology, it includes a basic overview of personality theory. Discussion of key research on personality theories and research is covered.

#8 - Independent Study (MA)
Spring 2016
PSY699 syllabusSpring2016.pdf
Adobe Acrobat Document [142.6 KB]
Download

This course requires the student to (1) Select a relatively specific topic/project you are interested in and that is flexible to do conduct a research on. The supervising faculty must approve your chosen topic/project, (2) Survey and gather the relevant research on the topic. Most of the related articles should be recent and published in psychological literature/journals, (3) Summarize the research trends on the topic and site the research literature, and (4) Identify three suggestions for future research based on your paper that may be pursued based on the research literature you have surveyed.

#9 - Professional Seminar (MA)
Fall 2016
PSY698 syllabusFall2016.pdf
Adobe Acrobat Document [205.1 KB]
Download

The purpose of this non-credit bearing course developed for students in the MA in Psychology program is to develop skills for life-long learning and professionalism. Important criteria by which Graduate Programs are assessed for their effectiveness in preparing young professionals in life-long learning and skills that including professional networking, mentorship, and professionalism.

#10 - 6th Thesis (MA)
PSY6MA3MA Thesis syllabus.pdf
Adobe Acrobat Document [152.7 KB]
Download

With the approval of the appropriate faculty member and coordinator of the MA in Psychology Program in Chairperson, students may conduct an original research project with the supervision of a faculty member. The student meets and regularly consults with the faculty member to provide guidance and to review progress on the research project. A research paper must be submitted upon completion of the course.

#11 - Psychology of Learning (MA/PsyD)
PSY715 syllabusFall2015.pdf
Adobe Acrobat Document [1.2 MB]
Download

This course is intended to provide students with information regarding major theories of learning (e.g., social cognitive, cognitive developmental, information-processing, behavioral). The first half of the course will focus on basic principles of behavior modification and its application to educational instruction and psychological interventions. The second half of this course will present the basic principles of various learning theories. Consideration will be given to how the principles discussed relate to effective teaching and learning.

#12 - Doctoral Project Seminar + Doctoral Project Colloquium (PsyD)
Spring 2014
PSY8104-8105syllabusSpr2014.pdf
Adobe Acrobat Document [81.3 KB]
Download

PSY8104 - Doctoral Project Seminar (Psy.D.)
This seminar provides a structured framework for the completion of the Psy.D. doctoral project. Issues regarding the statistical analyses and interpretation of research findings are of primary concern for discussion. Research results are presented to faculty and peers and are rigorously critiqued. The completion of the Psy.D. doctoral project is contingent upon faculty approval.
Prerequisite: PSY8104

PSY8105 - Doctoral Colloquium (Psy.D.)
This seminar provides a structured framework for the completion of the Psy.D. doctoral project. Issues regarding the statistical analyses and interpretation of research findings are of primary concern for discussion. Research results are presented to faculty and peers and are rigorously critiqued. The completion of the Psy.D. doctoral project is contingent upon faculty approval.
Prerequisite: PSY8104

Undergraduate Courses

#13 - General Psychology I (Undergraduate)
PSY115 syllabusSum1 2006-Online.pdf
Adobe Acrobat Document [154.5 KB]
Download

An introduction to the science and profession of psychology including coverage of research, cognitive abilities, human development, personality, testing and assessment, abnormal psychology, treatment of psychopathology, health and wellness, personality, abnormal psychology, social cognition, and social influence.

#14 - General Psychology II (Undergraduate)
PSY115 syllabusFall2015.pdf
Adobe Acrobat Document [117.9 KB]
Download

An introduction to the science and profession of psychology including coverage of research, cognitive abilities, human development, personality, testing and assessment, abnormal psychology, treatment of psychopathology, health and wellness, personality, abnormal psychology, social cognition, and social influence.

#15 - Experimental Psychology I (Undergraduate)
PsyBK syllabusFall2015.pdf
Adobe Acrobat Document [152.1 KB]
Download

This is an intensive, six hours per week course that introduces research methodology in psychology. It will include theoretical and practical aspects of behavioral research. The primary activity for this seminar will be the development of an original scientific research proposal. You will conduct the research and complete the research paper based on this proposal when you take PSY301: Experimental Psychology 2. For the following spring semester, Blackboard will be utilized to help disseminate announcements, archive course materials, supplement instruction, and update grades.

#16 - Experimental Psychology 2 (Undergraduate)
PsyBK syllabusSpr2016.pdf
Adobe Acrobat Document [160.1 KB]
Download

This is an intensive six hours per week course that aims to develop critical thinking skills in psychological research and to carry out the research proposal you have developed in PSY280. In PSY280, there is greater focus on the use of the SPSS statistical software. The primary activity for this seminar will be the completion of an original scientific research study and to present it at a formal undergraduate psychology conference. Blackboard will be utilized to help disseminate announcements, archive course materials, supplement instruction, and update grades.

Special Topics

#17 - Immersion 101 (Undergraduate)
Fall 2000
PsyBK syllabusFall2000.pdf
Adobe Acrobat Document [205.7 KB]
Download

This course is designed for first-year undergraduate students. It aims to:
• To help make the transition into college life easier.
• To help pick a major course of study and/or affirm the major that you have chosen.
• To develop a sense of community among the students and faculty.
• To develop time management, decision making and critical thinking skills.
• To help one be more mature and be more responsible.
• To be able to bond with Pace through closer advisement and interaction with your peers and peer leaders.

#18 - Psychology of Learning (NACTEL Program)
Fall 2004
PSY320syllabusFall2004.pdf
Adobe Acrobat Document [220.4 KB]
Download

This graduate-level course examines cognitive processes, often called "higher mental processes." Cognitive psychology includes topics such as perception, memory, language, and thinking. This course will give you an appreciation of research and theory in cognitive psychology, an understanding of the methods used to gather and evaluate evidence about cognitive processes, and an understanding of the ways in which knowledge of these processes has been applied to solve problems and improve the quality of life. Though this course requires a fairly sophisticated background in psychology, it will begin with a basic overview of cognition. Discussion of key research on cognition is covered. Note that much of the research in cognitive psychology is methodologically complex, especially because of the challenge of assessing covert mental processes.

A Final Reflection

Looking back, teaching has been one of the most rewarding aspects of my academic career. If these syllabi or course materials inspire even one educator to adapt an idea or encourage one student to explore psychology more deeply, then they have continued to serve their purpose beyond the classroom.

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Educator • Psychologist • Traveler
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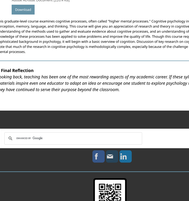

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RESEARCH

Research begins with curiosity. Asking thoughtful questions, exploring new ideas, and sharing knowledge have been among the most rewarding aspects of my academic journey.

My research interests focus on international psychology, cross-cultural understanding, and the global application of psychological knowledge to promote well-being and social responsibility. I enjoy exploring how psychological concepts, culturally responsive frameworks, and the practical orientation of research intersect meaningfully local and global issues.

Prior to my retirement in 2017, my research focused on the internationalization of psychology education, with particular emphasis on helping instructors integrate international perspectives into undergraduate and graduate psychology curricula.

- Internationalizing Psychology Courses: Identifying effective pedagogical strategies to internationalize psychology courses.
- Assessment: Developing a set of assessment tools for an international psychology course.
- Educational Technology: Applying Internet-based technologies (IBTs) as teaching and research tools to help infuse international perspectives into psychology courses.

This research projects generally involve the design and development of online surveys, identification of pilot sites for measures (e.g., instructors, courses, multimedia materials), and curriculum-based applications of IBTs. Students who have been involved in his research are provided with training in the ethical conduct of human research, data management, and data analysis. Students who have been absent or have traveled extensively or other countries are especially welcome.

My publications are organized below by publication type. Stakeholders PDFs are provided whenever available. Additional publications and citation information are also available through the Google Scholar profile. ORCID: https://orcid.org/0000-0002-0000-0000 Scholar

For more information, please contact me at velayo@gmail.com.

Research at a Glance

Research Interests

- International Psychology
- Teaching of Psychology
- Cross-Cultural Psychology
- Global Citizenship
- Learning and Cognition
- Higher Education

Publications

A selection of my scholarly work is organized below by publication type. Whenever permitted, downloadable PDFs are provided for educational and personal scholarly use. Publications are organized chronologically within each category. Full-text PDFs are provided when copyright permits. Publications without downloadable PDFs include a DOI or publisher link instead.

Categories:

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- Book Chapters (4)
- Selected Conference Papers (2)
- Other Publications (28)
- Theses & Dissertations (2)

JOURNAL ARTICLES (47)

Peer-Reviewed

*(Student co-authors * = undergraduate student involvement, ** Graduate student involvement, ***PhD)*

Click the "Download" button beneath a citation to access the full text PDF when available. Publications without a downloadable PDF include a DOI or publisher link instead.

1. Sebastian, R., Golden, H., Berlo, N., & Velayo, R. S. (2024). Internationalizing the teaching of psychology. *Oxford Bibliographies*. New York, NY: Oxford University Press. DOI: 10.1093/obo/9780199828340-0300 https://academic.oup.com/obo/obo/9780199828340/obo-9780199828340-0300/oxfordbibliography.pdf?disableRedirect=true&wtokenSSO0001=JW
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2. **Pettijohn, R., Frank, L., Ghaffarpilah, S., Jewett, S., & Siddiqui, H. (2019). Tirfusing Global Perspectives: Providing Students with Skills to Conduct International Psychology Research. *The International Psychologist: International Understanding, Part B, 34*(3), 14-20.
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3. **Pettijohn, R., Pettijohn, T., Ward, M., & Brannigan, S. (2019). Internationalizing the Teaching of Psychology (TOP) Research Team: Providing A Global Perspective in Students' Developmental Psychology Bulletin, 2(62), 46-47.
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A Final Reflection

Research is ultimately a conversation that extends beyond the time and place in which it was conducted. By preserving these publications, I hope they remain accessible to future students, educators, researchers, and anyone interested in the ideas they contain.

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Richard S. Velayo, Ph.D.
Professor Emeritus of Psychology
A Life of Curiosity, Learning, and Discovery
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SERVICE (Selected Positions)

Working alongside colleagues around the world taught me that some of life's greatest discoveries come through collaboration, service, and learning from one another.

My service interests center on advancing international psychology through leadership, advocacy, and collaboration while professionally representing my field. I also have a strong commitment to culturally informed practice, fostering international partnerships, and promoting psychological knowledge as meaningful service at local, national, and international levels.

Throughout my career, service has been an extension of my teaching and research. Whether mentoring students, collaborating on professional organizations, or helping shape the future of psychology through governance, I remain committed to strengthen the profession and support the broader psychological community.

Many of these service activities tied directly to collaborative publications described on my Research page.

Several of these service activities also illustrate my commitment to development of the courses described on my Teaching page.

Service at a Glance

- Leadership in national and international psychological organizations
- University committees and program service
- Peer review and manuscript editorships
- Conference planning and professional presentations
- Faculty, student, and international mentoring
- Community outreach and professional development

Academic and Professional Psychology Organizations

American Psychological Association (APA) (FULL MEMBER)

- Committee on Disorders/APA Relations (COD/APA)
  - Member (2014 - 2017)
  - Alternate (COD/APA) (2005, 2006, 2007 - 2009)
- Society for General Psychology (Division 1)
  - Member, Cross-Psychology Award Committee (2011)
  - Chair, Fellows Committee (2012 - 2014)
  - Member, Fellows Committee (2009 - 2011)
  - Member, Fellows Committee (2005 - 2015)
  - Fellow (2005 - Present)
  - Chair, Nominations Committee (2005)
  - Chair, Technology Committee (2004 - 2006)
- Society for the Teaching of Psychology (Division 2)
  - Chair, International Teaching of Psychology Task Force (2006 - 2008)
  - Fellow (2005 - Present)
- International Psychology (Division 52)
  - Member-at-Large (2010 - 2013)
  - Chair, Nominations Committee (2010)
  - Co-Editor, Handbook Committee (2011 - 2013)
  - Co-Editor, Handbook Committee (2005 - 2007)
  - Member-at-Large (2007 - 2009; 2012 - 2015)
  - Member, Nominations Committee (2008)
  - Member, Nominations and Bylaws Committee (2006, 2007)
  - Member, Awards Committee (2006)
  - Co-Chair, Psychology Around the World Handbook Book Award Committee (2007 - 2010)
  - Co-Editor, Curriculum and Teaching Committee (2006 - 2007)
  - Member, Ageing Committee (2006 - 2012)
  - Member, Ethics Committee (Ad Hoc Committee) (2006 - 2010)
  - Australian Ethics International Psychology Reporter (2005 - 2010)
  - Chair, Website Technology Task Force (2005 - 2012)
  - Fellow (2005 - Present)
  - Member, Communications Committee (2004 - 2010)
  - Member, Fellows Committee (2004 - 2006)
  - Member, Ethics International Psychology Reporter (Interim) (2004)
  - Member, Fellows Committee (2003)
  - Member, Nominations Committee (2002)
  - Past President (2000)
  - President-Elect/President-Elect (2000 - 2012)
  - Fellow (2000 - Present)
  - President (2000); President-elect (2001)
  - Co-Chair, Membership Committee (2000 - 2001)
  - Co-Chair, Membership Committee (2000 - 2001)
  - Chair, Program Committee (1998 - 1999)
  - Co-Chair, Program Committee (1996 - 1998)

Eastern Psychological Association (EPA)

- EPA Liaison to Rand Corporation Peer Review Committee (Ad Hoc) (2014 - 2017)

International Council of Psychologists (ICP), Full Member

- Member/Member Facilitator/Leader for Advanced International Psychology Research and Service (2016)
- Member, Ethics Committee (2015 - 2016)
- Member, Long Range Planning Committee (2012 - 2014)
- Member, Nominations and Elections Committee (2010 - 2012; 2015 - 2017)
- Member, Publicity Committee (2011 - 2012)
- Member, Program Committee (2008 - 2009; 2011)
- Chair, Communications Committee (2006 - 2009)
- Member, Continuing Education Committee (2006 - 2009)
- Member, Nominations and Elections Committee (2006 - 2009; 2012 - 2014)
  - Member, Nominations and Elections Committee (2012 - 2014)
- Member, Nominations and Elections Committee (2006)
- Member, Awards Committee (2006)
- Co-Editor, Handbook Committee (2005 - 2007)
- Co-Chair, Membership Committee (2004 - 2006)
- Member, Membership Committee (2004 - 2006)
- Co-Chair, Program Committee (1998 - 1999)
-

A Study of Religion and Parenting
Author: Elisheva Konstam (Completed May 2011)

Mommy Dearest, Abba Almighty: Parenting Perceptions and Styles Across Christian Denominations
Author: Elizabeth Dale Langley (Completed May 2011)

Relational Aggression in Middle School: Gender, Grade, Self-Esteem, and Narcissism
Author: Etty Mizrahi (Completion December 2011)

Personality traits and perceptions of parenting, as assessed by the PBIQ-R
Author: Andrea Kops (Completed January 2012)

Parenting Perceptions and Adult Attachment: The Intergenerational Effects of Parenting
Author: Malky Klein (Completed May 2012)

Parenting Behaviors: Their Relationship to Children's Perceived Social Support and Academic Achievement.
Author: John Perez (Completed May 2012)

Consuming Concepts: The Hedonic and Utilitarian Effects of Perceived in a Digital Information Products Context
Author: Colleen P. Kirk (Completed August 2012) – Doctoral degree in Professional Studies (DPS)

Random Number Generation as a Function of Mode of Production
Author: Abraham Lipton (Masters Thesis) (Completed May 2013)

Trans Video Blogs on Social Networking Sites and the Solidification of Identity and Community Among its Users
Author: Stephanie Scrofani (Masters Thesis) (Completed May 2013)

The Relationship between 'OCEAN' Personality Dimensions, Demographics, and Online Dating Attitudes and Behaviors
Author: Karen Marks Pinto (Completed August 2013)

Importance of Parenting Behaviors in an Early Childhood Separation Program
Author: Hope Baker (Spring 2014)

Religious Identity, Perceived Discrimination, and Psychological Well-Being in Sikh Americans
Author: Gurleen Saini (Completed Spring 2014)

Program Evaluation of Positive Behavior Intervention System (Gender and Setting as Variables)
Author: Rotem Dayan (Completed Spring 2014)

Examining the Relationship Between On-line Gaming and Perceptions of Parenting
Author: Smith Kidkarndee (Completed Summer 2014)

Multidimensional Assessment of Psychologists' Multicultural Competency
Author: Tanya Regis (Completed Summer 2014)

Women's Fashion Styles: Personality and Shopping Behavior vs. Feeling of Objectification
Author: Maria Corazon Reano (Masters Thesis) (Completed Fall 2014)

Screening for Developmental Delay in At-Risk Children: Ages and Stages Questionnaire in an Adolescent Primary
Author: Jordan Zelinger (Completed Fall 2014)

Social Cues in a Textual World: Impact on Comprehension and Perceived Understanding
Author: Jenicka Hornung (Completed Spring 2015)

Parenting Childhood Victims of Sexual Abuse: A Comparative Study of Mothers With and Without Histories as Victims
Author: Talia Kaplan (Completed Fall 2015)

Spiritual Well-Being and Entheongen Substance Therapy: An Explorative Survey-Based Study of Individual's Level of Spiritual

Well-Being and Their Attitude towards the Use of Entheogenic Substances (Masters Thesis) (Completion pending)
Author: Wallis Back (Completed Fall 2015)

Memory for Concept Pairs as a Function of Bimodality Type, Educational Background, and Culture
Author: Michael Trush (Completed Summer 2016)

⭐ Other Service Activities

Cattell Award Dissertation Competition

- Reviewer, "James Cattell Dissertation Award" for the Psychology Section of the New York Academy of Sciences. Reviewed finalist for this award. Dissertations reviewed were from Psychology-Department endorsed outstanding dissertations from the U.S. and other countries. (2000 – 2017)

PSYCHE Speakers Bureau (APA Divisions 1 and 52)

- Member, "PSYCHE Speakers Bureau" Team. This APA project involved the construction of a zip-code ordered document containing geographic network of 200 outstanding psychology experts in diverse specialties across North America, who are prepared to visit area schools or community groups to speak on their topics of expertise. (2007 – present)

International Psychologists at Work: A Video

- Member, "International Psychologists at Work" is a video project of the APA Division of International Psychology to produce on videotape several interviews and feature events while attending various international psychology conferences (2007 – 2010).

National Institute on the Teaching of Psychology

- Member, "Textbook Donation Initiative" from the National Institute on the Teaching of Psychology (2007 - 2011).

Division of International Psychology, American Psychological Association

- Sponsor, "Adopt a Psychologist Program" Initiative, International Liaisons Committee (Adoptee: Dr. Ivana Petrovic, Servia) (2005 - 2006)

United Nations – NGO Committee on Ageing

- Co-Chair, 16th Annual Celebration of the International Day of Older Persons (October 5, 2006)
- Editor and Producer, Proceedings of the 14th Annual Celebration of the International Day of Older Persons (2004 – 2014)

American Psychological Association, Washington, DC

- Co-Chair, Committee on Divisions and APA Relations (2010)
- Member, Committee on Divisions and APA Relations (2005 - 2009)
- Member, Task force on the Internationalization of the Psychology Curriculum (2004 - 2005)

Chinese American Planning Council Volunteer Faculty, New York, NY

- Faculty Supervisor and Mentor, Asian American high school students in the NYC area (2004)

A Final Reflection

Service has always been about contributing to something larger than oneself. Whether through professional organizations, mentoring, editorial work, or university committees, I have valued every opportunity to support colleagues, students, and the discipline of psychology.

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Visits

Richard S. Velayo, Ph.D.
Professor Emeritus of Psychology
A Life of Curiosity, Learning, and Discovery
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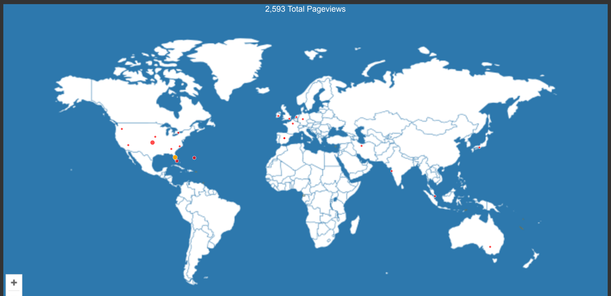

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HONORS

Explore the honors, awards, grants, fellowships, and distinctions that marked significant milestones throughout my academic career.

Throughout my academic career, I have been honored to receive honors, awards, grants, fellowships, and other forms of recognition from universities, professional associations, and philanthropic organizations. These recognitions reflect my contributions to teaching, research, and service within psychology and related fields, and I have deeply grateful for the colleagues, students, and organizations that made these experiences possible.

Selected Distinguished Honors

- APA Fellow
- APA Divisional Fellow
  - Division 1 (General Psychology and Interdisciplinary Inquiry)
  - Division 2 (Society for the Teaching of Psychology)
  - Division 46 (Media Psychology and Technology)
  - Division 52 (Society for Global Psychology)
- Fellow, Eastern Psychological Association
- Wilhelm Wundt Award
- Henry P. David International Mentoring Award
- Virginia Slouth Senior Award
- Pace University Teaching or service awards
- APA Presidential recognitions

Early Academic Honors (1985–1994)

- Magna Cum Laude
- Outstanding Undergraduate Thesis
- Phi Kappa Phi Honor Society
- Fordham Fellowship
- Dissertation Fellowship
- Dissertation Grants
- APA Students Fund Award
- Science Directions Award

Professional Recognition and Growing Scholarship (1995–2003)

- Virginia Slouth Senior Award
- University Distinguished Service Award
- Phi Eta Research Award
- Phi Eta Grant Award
- Travel Grants
- Early Mentoring Awards
- NYSPA Distinguished Service Award

National Leadership and Professional Recognition (2004–2010)

- APA Fellow
- Division Fellowships
- Division Travel Grants
- Presidential Awards
- Eastern Psychological Association Fellow
- Dissertation Grants
- International Council of Psychologists Awards

International Leadership and Recognition (2011–Present)

- Henry P. David Award
- APA Presidential Recognition
- International Grants
- Travel Grants
- CODAPSY Grant
- Teaching Online Recognition
- New York Academy of Sciences Appreciation Award

Professional Fellowships

- American Psychological Association
- Eastern Psychological Association
- Society for the Teaching of Psychology (Division 2)
- Media Psychology and Technology (Division 46)
- Society for Global Psychology (Division 52)
- Eastern Psychological Association

Research and Faculty Development Grants

- Pace University Summer Research Grants
- Scholarly Research Grants
- Human Fund Awards
- Faculty Development Grants
- APA Division Grants
- Internationalizing the Curriculum Grant
- Learning Assessment Grant

Professional Recognition

- Marquis Who's Who
- Marquis Who's Who Leaders of the 21st Century
- Outstanding Scientists of the 21st Century
- America's Registry of Outstanding Professionals
- Deans' Distinguished Educators
- Sweetmore's Who's Who

Complete List [Honors/Awards/Grants/Recognitions]

2018

- APPRECIATION AWARD, New York Academy of Science, Psychology Steering Committee (New York City, April 2018)

2017

- Recipient, Certificate of Completion/Recognition, "Teaching Online Seminar Program", Pace University (August 2017)

2016

- Recipient and Rubrics Team Member, 2016 CODAPSY Committee on Divisions and APA Relations/International Grant from the American Psychological Association (Collaborative grant between APA Division 1, 2, and 52. Project title: "International Expansion in Project Syllabus" (Collaborative project between Division 2 (Society for the Teaching of Psychology) Division 52 (Division of International Psychology), and Division 1 (Society for General Psychology)

2015

- **PRESIDENTIAL RECOGNITION AWARD** (in recognition of Outstanding Service to the Discipline) Division of International Psychology (APA Division 52) (August 8, 2015)
- Kenya Fund Recipient, Presentation at the 2015 Convention of the Association for Psychological Science, Marriott Marquis, New York City (May 2015)
- Certificate of Appreciation (for outstanding service and dedication to the Society for General Psychology, APA Division 1) in the role of Representative-at-Large (August 2015)
- Recipient, 2015 Quinn Sanders Research Grant on Research Project titled "Psychological Predictors of Stress and Health" (with Dr. Sonia Suchday, Arendta Rau, and Lynne Levine)
- Certificate of Contribution in recognition of contributions in research and scholarship for 2015, Office of Sponsored Research, Pace University, NYC (April 20, 2015)

2014

- Certificate of Recognition in recognition of significant research contributions to International Psychology, 20th Annual Greater New York Conference on Behavioral Research, New York, NY (November 9, 2014)
- **Presidential Citation Award (in recognition of Outstanding Service to the Division), Society for General Psychology (APA Division 1)** (August 2014)
- Kenya Fund Recipient, Keynote Speaker at the 4th Annual International Conference on Psychology Education, Nairobi, Nairobi, Kenya (August 4, 2014)
- **Pace University Teaching Pioneer Award Winner**, "Tools and Strategies for an International Psychology Course", Presented at the 2014 Convention of the International Conference on Psychology, Paris France (July 2014)
- Certificate of Recognition (in recognition of contributions to International Psychology), Manhattan Psychological Association (MPA) and the Society for the Teaching of Psychology (Division 2) Joint Conference, Manhattan College, Riverdale, New York (April 26, 2014)
- Certificate of Contribution (in recognition of contributions in research and scholarship for 2014), Office of Sponsored Research, Pace University, NYC (April 9, 2014)
- Recipient, Certificate of Appreciation of the Eastern Psychological Association, Boston, MA (March 13-16, 2014)
- Featured Senior Participant, FIRST CONNECT Site, 8th Annual Division of International Psychology (February 2014)

2013

- **AWARDEE, Henry P. David INTERNATIONAL MENTORING AWARD (American Psychological Association, Division of International Psychology)** (Recognizes exceptional mentoring and leadership in fostering the professional development of psychologists from around the world)
- Kenya Fund Recipient, 2013 Convention of the American Psychological Association, Honolulu, HI (July 31 - August 3, 2013)
- Summer Research Grant Recipient, Pace University, "A Review of European and United States Psychologists' Views of Internationalizing the Curriculum: Preliminary Survey Findings" (2013)

2012

- Distinguished "SUPER" OF HONOR" for Outstanding Contributions to Psychology (24th Annual Greater New York Conference on Behavioral Research, Fordham University, New York)
- Recipient, 2013 Division International Awards Grant (DIAG) from the American Psychological Association - Project title: "Internationalizing the Curriculum: Preliminary Survey Findings" (2012)
- Silver Leadership Recognition, Pace City Film International Honors Society in Psychology (2011 - 2012)
- Certificate of Outstanding Service, Fellows Committee, Society for General Psychology (2012)
- Kenya Fund Recipient, 2012 Meeting of Society for Cross-Cultural Research (March 28 - 22 - 25, 2012)

2011

- TORRENTY INSTITUTE Grant Recipient - Version 2011-2012 - Project title: "Behavioral Lab for Conducting Experiments in Marketing and Psychology"
- Summer Research Grant Recipient, Pace University, "Online Assessment Survey to Evaluate International Psychology Courses" (2010)

2010

- **FELLOW, Eastern Psychological Association** (Awarded in recognition of sustained and distinguished contributions to psychological science and to the profession of psychology)
- **PRESIDENT'S AWARD 2010** (International Council of Psychologists, Pace University, Pace University, Pleasantville, NY)
- RECOGNITION AWARD, 25th Anniversary of the United Nations International Day of Older Persons (for outstanding generosity and commitment to the United Nations Mission and Millennium Development Goals, Pace University, NY)
- Summer Research Grant Recipient, Pace University, "The Potential of Second Life as a Research and Teaching Tool" (2010)
- SABBATICAL LEAVE (Fall 2010)

2009

- Certificate of Appreciation for Outstanding Contributions, United Nations NGO Committee on Aging (New York,July 24, 2009)
- Certificate of Appreciation for United Nations Representative, International Council of Psychologists (Presented at the 67th Convention, Mexico City, on July 4, 2009)
- **EDITORIAL BOARD APPOINTMENT AWARD as Director of Communications and Publications Committee** and an active voice beyond the Board of Directors, International Council of Psychologists (Presented at the 67th Convention, Mexico City, on July 4, 2009)
- TORRENTY INSTIUTOR Grant Recipient - Version 2010-2011 - Project title: "Exploring Web_2.0 Technologies to Internationalize the Curriculum"
- Summer Research Grant Recipient, Pace University, "Exploring the Use of Clickers in Assessing Multimedia Presentations in the Classroom" (2009)
- **PAST PRESIDENT AWARD (Academic Division, New York State Psychological Association)**

2008

- **PAST-CHAIR AWARD (New York Academy of Sciences, Psychology Section)**
- Certificate of Recognition, Fordham University Graduate School of Psychology, Greater New York Conference on Behavioral Research, Fordham University, New York, November 10, 2008
- Summer Research Grant Recipient, Pace University, "Multimedia Learning Experience Survey Project"
- Kenya Fund Recipient, 2008 Meeting of Society for Cross-Cultural Research Convention, Cooperstown, NY, May 2-3, 2008 (Conference Theme: "Twenty First Psychology for a Twenty First Century World")
- Scholarly Research Grant Recipient, Pace University, "Development of an Assessment Tool for the Multimedia Learning Experience"

2007

- **WILHELM WUNDT AWARD for Outstanding Research Contributions to Academic Psychology** (awarded by the New York State Psychological Association)
- **FELLOW, Society for the Teaching of Psychology (American Psychological Association, Division 2)**
- Recipient, Pace University Faculty Development Grant, "Exploring Web_2.0 Technologies for Instruction and Research"
- Recognition Award as Chair Task Force, Internationalizing the Teaching of Psychology (presented by the Society for the Teaching of Psychology)
- Marquis Who's Who in Science and Engineering (1th Anniversary Edition, 2008-2009)
- Marquis Who's Who in America (51st Edition)
- Marquis Who's Who in American Education (9th Edition, 2007-2008)

2006

- **FELLOW, Media Psychology (American Psychological Association, Division 46)**
- Presidential Certificate of Recognition, American Psychological Association Division of International Psychology, Volunteer Meeting, San Francisco, CA, August 2006 (for outstanding contributions to the Division of International Psychology)
- Kenya Fund Recipient, American Psychological Association Expert Summer on Evaluation "Distance Learning: Pedagogy and Transitions", San Antonio, TX, February 2-3, 2006.
- Recipient, Pace University Faculty Development Grant, "Exploring Cognitive and Organizational Strategies in Managing Electronic Mail: Developing an Assessment Tool"
- Marquis Who's Who in the World (24th Edition)
- Marquis Who's Who in Science and Engineering (5th Edition, 2006-2007)
- Marquis Who's Who in American Education (8th Edition, 2006-2007, 2007-2008)

2005

- **PRESIDENTIAL AWARD, American Psychological Association Division of International Psychology** (Awarded in recognition of outstanding service to the Division of International Psychology and to the American Psychological Association)
- Presidential Citations from the APA Division of International Psychology
  - Website Technology Website Committee
  - Nominations Committee (2005)
  - Bylaws/Rules Committee
- Recognition Award, 17th Annual Greater New York Conference on Behavioral Research, John Jay College, CUNY (November 4, 2005)
- **FELLOW, Eastern Psychological Association** (Awarded in recognition of sustained and distinguished contributions to psychological science and to the profession of psychology)
- Kenya Fund Recipient, 49th Annual Convention of the New York State Psychological Association, Niagara Falls, New York (March 17-19, 2005)
- Marquis Who's Who in American Education (7th Edition, 2005)
- Commercial Mini's Who of National Leaders Registry

2004

- **FELLOW, American Psychological Association** (Fellow status is one of the highest professional distinctions awarded by the American Psychological Association to its members who have made outstanding contributions to psychology)
- **PRESIDENTIAL AWARD, Division of International Psychology (American Psychological Association, Division 52)**
- Internationalizing the Curriculum Project (American Psychological Association Grant: $100,000 (total amount)
- Marquis Who's Who in America (59th Edition)
- University Associates, Faculty Resource Network (New York University, NY)

2003

- **RECOGNITION AWARD, Phi Chi (the National Honor Society in Psychology)**, 50th Anniversary Mega-Induction of the joint Iota-City Induction of the Phi Chi Chapters held at Hunter College, NY, Sponsored by Phi Chi chapters at Fordham University, Hunter College, Long Island University, Pace University, and Pratt Institute
- University Associates, Faculty Resource Network (New York University, NY)
- American Registry of Outstanding Professionals
- Marquis Who's Who in Science and Engineering (1st Edition, 2004-2005)
- Marquis Who's Who in American Education (5th Edition, 2003, 2004-2005)
- SABBATICAL LEAVE (Spring 2003)

2002

- Scholar Faculty Resource Network (NYU Faculty Enrichment Program on "Instructional Design for the World Wide Web" (New York University, NYU (June 2002)
- University Associates, Faculty Resource Network (New York University, NY)
- **2002 DISTINGUISHED SERVICE AWARD (New York State Psychological Association)**
- **PAST-PRESIDENT AWARD (Academic Division, New York State Psychological Association)**
- Pace University Faculty Development Grant, "Exploring Cognitive and Organizational Strategies for the research titled "Learning Outcome Measures and Usage of Features Associated with the Use of a Website Management Tool" (with undergraduate students Lilian Kal, and Sigve Brand-Mayo), 2002
- Pace University Grant, "Exploring Web Course in Psychology" (Annual Conference of the New York State Psychological Association, Vienna, NY, July 2-7, 2002)
- Marquis Who's Who in the World (19th Edition, 2002)
- Marquis Who's Who in America (56th Edition, 2002)

2001

- Orthorhythm Course Development Grant, Dyson College of Arts and Sciences, Pace University, NYC, to develop an online course for General Psychology I (\$3,000)
- Pace University Faculty Development Grant, Pace University, NY (\$6,500) (Major"Learning Assessment Tool for Evaluating the Pedagogical Effectiveness of Online Teaching"
- Pro Co Grant Recipient Award for Outstanding Research on "Declarative Memory as a function of Dual-Orientation and Gender" (Sponsored by the Pace University Chapter of the Phi Chi Honor Society in Psychology, Pace University, NY, April 2001) (Co-Author: Dean Porter, Ronald Bishop, as Function of Thinking Style "Presented at the 75th Annual Conference on Undergraduate Teaching of Psychology: Ideas and Innovations, Newel Grande, Ellenville, NY, (with undergraduates Mehlbaum, B., Zahnapel, K., and Kaufman, J.)
- **THELMA SUTT AWARD and Grant Recipient** for the research project titled "Undergraduate Research Mentors: Learning Outcomes, what impacts?" Awarded by Pro Chi, The National Honors Society in Psychology ($3,000). Award was shared with Drs. Harold Takooshian and Dr. Lynne Levine (Pace University, NY)
- Scholarly Research Grant Recipient, Pace University, "Pace Laws of Control and Learning Strategy Type Indicative of the Ability to Associate Concepts"
- Kenya Fund Recipient, National Institute on the Teaching of Psychology (Co-Contributor), St. Petersburg, FL, January 5 - 6, 2001
- Marquis Who's Who in America (55th Edition, 2001)

2000

- Award Recipient, 2000 Outstanding Intellectuals of the 21st Century, First Edition (International Biographical Centre, Cambridge CB2 3QP England)
- Award Recipients, Who's Who in the 21st Century, First Edition (International Biographical Centre, Cambridge CB2 3QP England)
- Directory of American Scholars (15th Edition) - Gale Group, Farmington Hills, MI
- **UNIVERSITY AWARD FOR DISTINGUISHED SERVICE** (Outstanding Contribution Awards, Pace University Downtown Theater, December 2000)
- (This University Award for Distinguished Service is presented to faculty members who have shown unusual initiative in creativity in giving outstanding services to students, meeting special needs, or in contributing to the attainment of the University's mission and goals.)
- **NEW YORK STATE PSYCHOLOGY DISTINGUISHED SERVICE** (New York State Psychological Association's Award for Outstanding Contributions to its Academic Division)
- 2000 Outstanding Scientists of the 21st Century (1st Edition) - International Biographical Centre, Cambridge CB2 3QP England
- **NEW YORK STATE PSYCHOLOGY DISTINGUISHED SERVICE** - Society for International Psychology, American Psychological Association, Washington, DC
- **PSI CHI NATIONAL RESEARCH AWARD** for Research on "Gender and Mediated Strategies" from the American Psychological Association Division of Teaching of Psychology (Co-Author: Dean Porter, Sofia Kanaan and Dominic Fabio)
- Sweetmore's Who's Who (2000-2001 Millennium Edition)
- Sloan Foundation Grant to the Office of Information Systems (OIS) of Pace University (Participated in the design and development of a Web-based course in Introductory Psychology offered to students in the Master's in Science: Applied Information Technology Program - Telecommunications Track)
- **PSI CHI NATIONAL RESEARCH AWARD** for Research on "Gender Gender Mediated Strategies" from the American Psychological Association Division of Teaching of Psychology" (Eastern Psychological Association Convention, Baltimore, MD (with undergraduate students Dominic Fabio and Yuliya Kanaan)
- Directory of American Scholars (15th Edition)
- Kenya Fund Recipient, National Institute on the Teaching of Psychology (Co-Contributor), St. Petersburg, FL, January 2-5, 2001.
- **SOCIETY OF FELLOWS, Dyson College** (Inducted April 20, 2000)
- Marquis Who's Who in the World (17th/Millennium Edition, 2000)
- Marquis Who's Who in America (54th Edition, 2000)
- Marquis Who's Who in Science and Engineering (5th Edition, 2000-2001)
- Scholarly Research Grant Recipient, Pace University, "Assessing the Design and Use of Multimedia and Web Technology as a Classroom Teaching Tool"

1999

- Dancers Who Who (USA) - Outstanding Americans for the Twenty First Century
- Pace Psychology Club Service Award
- Kenya Fund Recipient, National Institute on Teaching Constructions, Pro Chi / American Psychological Association Convention, Boston, MA (August 1999)
- National Endowment for the Humanities (NEH) Grant to Dyson College (Spring 1999)
  - Participated in a "writing assistive program" to help improve the writing skills of students enrolled in courses that utilize technology as a tool for instruction. Participants were given a stipend to develop a "writing assistive" component to their courses. Project title: "Pedagogy and Use of the on-campus classroom with a "Related" system was integrated in the teaching of the course. (Primary Investigators: Linda Kotovsky, Ph.D. and Eugene Richie, Ph.D.)
- Marquis Who's Who in the World (16th Edition, 1999) (1 June 1, 1998
- Summer Research Grant Recipient, Pace University, "Pedagogy and Technology: Assessing the Design and Use of Multimedia and Web Technology as a Classroom Teaching Tool"
- Scholarship Recipient, Pace University, "Pedagogy and Technology: Assessing the Design and Use of Multimedia and Web Technology as a Classroom Teaching Tool" (supplemental funding)

1998

- Marquis Who's Who in the Media and Communications (1st Edition, 1998-1999)
- Marquis Who's Who in the South and Southwest (26th Edition, 1998)
- **PSI CHI NATIONAL RESEARCH AWARD** for Research on "The Effects of Feedback on Awareness of Letters Orientation Stimuli" (Co-Author: Dean Porter, Doctoral Unit President "Eastern Psychological Association Convention, Boston, MA
- Outstanding Young American
- Summer Research Grant Recipient, Pace University, "Audio-Visual Learning as a Function of Stimulusby Sequence Presentation and Type of Content Organizing Tool"

1997

- **VIRGINIA SLOUTH SENIOR AWARD FOR EARLY CAREER CONTRIBUTIONS TO ACADEMIC PSYCHOLOGY**, New York State Psychological Association (Presented by the New York State Psychological Association to recognize outstanding early-career contributions to academic psychology by a psychologist who is a member of the Association)
- Summer Research Grant Recipient, Pace University
- Scholarly Research Grant Recipient, Pace University, "Multimedia Learning: Introducing, Presentation Sequence, and Content Dependency Factors"
- Kenya Fund Recipient, APA Society for the Teaching of Psychology Convention, Chicago, IL, August, 1997
- Kenya Fund Recipient, National Institute on the Teaching of Psychology, St. Petersburg, FL, January, 1997

1996

- Kenya Fund Recipient, National Institute on the Teaching of Psychology, St. Petersburg, FL, January, 1996.

1995

- Summer Research Grant Recipient, Pace University, "Exploring the Use of Interactive Multimedia Instruction as a Classroom Teaching Tool"
- Scholarly Research Grant Recipient, Pace University, "Student-Dual Orientation and Instructional Evaluation of Computer-Assisted Instruction"
- Kenya Fund, The Scientific Research Society
- Dyson Research Recipient
- Kenya Fund Recipient, Kenya Fund Recipient, National Institute on the Teaching of Psychology Conference, St. Petersburg, FL, January, 1995.

1993 - 1994

- Phi Chi, The National Honor Society in Psychology (1994)
- Dyson Research Grant Recipient, Dyson College Research Council (1993)
- Student Dissertation Fellowship, Fordham University (1993)

1991 - 1992

- American Psychological Association (APA) Student Travel Award
- American Psychological Association (APA) Science Directorate Award
- School of Education Fellowship Award
- University of Michigan Rackham Travel Grant (1991, 1992)

1985 - 1989

- University of Michigan Rackham Fellowship, Block Grant Recipient (1989)
- Graduate Assistant - Project Head Start, Dunkirk, CA (1988)
- **MARIAN CORE LEADER** (with distinction in Psychology, Sociology and Anthropology), Graduation Honor (De La Salle University, Manila, Philippines)
- **Most Outstanding Undergraduate Thesis**, Graduation Honors (De La Salle University, Manila, Philippines)(1985)
- **Jose Rizal National Honors Society** (De La Salle University, Manila, Philippines)(1985)

A Final Reflection

While I am grateful for the recognition represented by these honors, the personal rewards of my career have been the friendships, collaborations, and opportunities to make a positive difference in the lives of students and colleagues.

Richard S. Velayo, Ph.D.
Professor Emeritus of Psychology
A Life of Curiosity, Learning, and Discovery
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Updated on 8/11/2026

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Professor Emeritus of Psychology
Pace University, New York City

Richard S. Velayo, Ph.D., is Professor Emeritus of Psychology at Pace University (New York City). He happily retired in Florida (Orlando Metro area) in 2017 though occasionally teaches online graduate courses. When he was a full-time tenured full professor at Pace University, he served as Associate Chair of the Psychology Department (NYC) and Director of the Master of Arts (M.A.) in Psychology Program from 2014-2017. In 1993, he obtained his doctorate in the Combined Program in Education and Psychology from the University of Michigan (Ann Arbor), and specialized in the areas of Cognitive Psychology and Educational Technology. He obtained his M.A. degree in Applied Behavioral Analysis from the University of the Pacific (Stockton, CA), a B.A. in Psychology / B.A. in Sociology-Anthropology from De La Salle University (Manila, Philippines) (Magna Cum Laude), and at Colegio de San Juan de Letran (Manila, Philippines) for his elementary and high school education. His scholarly interests and publications focus on pedagogical strategies to internationalize the psychology curriculum, and on the use of multimedia and internet-based technologies as pedagogical tools. More specifically, his scholarly interests included: (1) development of an assessment tool for multimedia learning, (2) applications of Internet-based technologies (IBTs) as teaching and research tools, and (3) pedagogical strategies to internationalize psychology courses. He has 47 peer-reviewed publications in journals such as American Psychologist (the flagship journal of the American Psychological Association (APA), Teaching of Psychology, The International Journal of Instructional Media, Journal of Instructional Psychology, Reading Improvement, NYS Psychologist, Educational Technology, Psychology Learning and Teaching, International Psychology Bulletin, and the International Psychologist. He also has 4 book chapters and 30 non-peer reviewed publications. Moreover, he has 305+ scholarly presentations, 78+ workshops/panels/invited addresses, 120+ symposia/conferences organized at various regional, national, and international psychology conferences including (but not limited to) those of the American Psychological Association (APA), the American Psychological Society (APS), the Eastern Psychological Association (EPA), the National Institute on the Teaching of Psychology (NIToP), the International Council of Psychologists, and the Greater New York Conference on Behavioral Research. He has also been involved in the supervision of over 60 doctoral dissertations and masters theses.

The courses he has taught at the graduate and undergraduate levels include Experimental Psychology, Cognitive Psychology, Instructional Psychology: Multimedia Applications, Research Design and Statistics, General Psychology, Psychology of Learning, Developmental Psychology, Behavior Modification, Critical Thinking and Problem Solving, Introduction to International Psychology, Psychology at the United Nations, and Professional Seminar (for Masters Students). Dr. Velayo has taught at De La Salle University (Manila), Montana State University, University of Michigan (Ann Arbor), before coming to Pace University (New York City Campus) in 1994 as a full-time faculty member of the Psychology Department. In addition to being the Editor-in-chief of the “PsychEye” newsletter (official newsletter of Pace University’s Psychology Department, NYC), he was also an editorial board member of the International Psychologist and International Understanding. He has also served as a reviewer for a number of publications which includes the following: International Psychology Bulletin (APA Division 52), International Journal of Instructional Media, Journal on School Education, and Computers in Teaching Section of the Teaching of Psychology (APA Division 2). The New York State Psychological Association awarded him the Virginia Staudt Sexton Award for Early Career Contributions to Academic Psychology (1997), the Distinguished Service Award (2002), and the Wilhelm Wundt Award for Outstanding Research Contributions to Academic Psychology and Service to NYSPA (2007). He is also the recipient of the 2000 Distinguished Award for Outstanding Service at Pace’s Employee Recognition Ceremony. In 2012, he was recognized as a “Guest of Honor” for Outstanding Contributions to Psychology at the 24th Annual Greater New York Conference on Behavioral Research (Fordham University, New York). In 2013, he received the "Henry P. David International Mentoring Award" from the Division of International Psychology of the American Psychological Association.

His professional service affiliations include: the American Psychological Association (Fellow of Divisions 1, 2, 46, and 52), the International Council of Psychologists (ICP), International Association of Applied Psychologists (IAAP), the New York Academy of Sciences (NYAS), the New York State Psychological Association (Academic Division and the Social Issues Division), the Eastern Psychological Association (Fellow), PSI CHI (The International Honors Society in Psychology), and Sigma Xi (The Scientific Research Society). He was Past-President (2004), and Member-at-Large (2008-2009) for the Division of International Psychology (Division 52) of the APA in which he has also served as chair of the Membership Committee, Program Committee, the Website Committee, Associate Editor of the International Psychology Bulletin, and an active Member of its Curriculum and Training

Committee. His other positions include Fellows Chair (2005-2007) for The Society for General Psychology (APA Division 1), Fellows Chair (2008) for The Division of International Psychology (APA Division 52), Chair (2006-2009) of the Communications and Publications Committee for the International Council of Psychologists (ICP) (2006-2009), served twice as Past-President (2001 and 2008) of the New York State Psychological Association's Academic Division, Past-Chair (2006-2008) of the Psychology Section of the New York Academy of Sciences, Past Co-Chair (2009) of APA's Committee on Divisions/APA Relations (CODAPAR), and Member-at-Large for the NGO Committee on Ageing (2007-2009), and Executive Committee Member (2009-2012) of the Eastern Regional PSI CHI Steering Committee. He has served as the Chair of the Publication and Registration Subcommittee for the United Nations Psychology Day Organizing/Planning Committee. At Pace University, he is the Director of Masters Program(s) and Associate Chair of the Psychology Department (NYC campus). Additionally, he has served as the Secretary and Webmaster (2000-2005) of the New York Faculty Council, Chair (2000-2001) of the Academic Resources Committees of Dyson College and NY Faculty Council, and Chair (January 2000 - August 2002) of the Communication Studies Department (NYC campus) of Pace.

Dr. Velayo also served as the NGO Representative (2009-2017) of the International Council the International Council of Psychologists to the United Nations, Treasurer (2009-2013) of the NGO Committee on Ageing, Webmaster (2005-2014), Fellows Chair and Member-at-Large of the Society for General Psychology (2012-2014), Curriculum and Training Committee Chair and Member-at-Large for the International Psychology Division of APA (2012-2016), Liaison of the Eastern Psychological Association to Pace University's Psychology Department (2010-2016), and one of the three Co-Directors (2010-2017) of The International Social and Behavioral Research Alliance. At Pace, in addition to being the Associate Chair of the Psychology Department and Director of the M.A. in Psychology Program (2014 - 2017), he also serves as a Director of the Dyson College Center for Global Psychology (DCCGP), a member (2004-2017) of the Kenan Development Fund Committee for Faculty Development, and a Fellow (2000-present) of the Dyson College Society of Fellows.

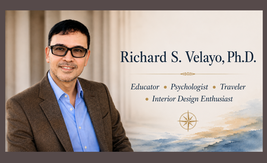

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TOPIC: What is International Psychology?

1. What is International Psychology?
2. Video on ***"International Psychology: What's Students Want to Know?"***
3. How can this course be beneficial to your psychology education?

Professor's Brief Self-Introduction:
https://drive.google.com/file/d/12LmLcMBGpSzesHCyXn9IzeSVgbjs6T3S/view?usp=drive_link

Assigned Reading/s: Syllabus

Supplementary Materials:

ARTICLE: Internationalizing Your Psychology Course
Velayo, R. (2011). Internationalizing Your Psychology Course. Essays from *E-xcellence in Teaching, 10*, 25-31.
To download full-text, go to the link below and see pp 25-31 https://www.researchgate.net/publication/324113288_Internationalizing_Your_Psychology_Course

AUDIO: International Psychology Career Options *(Oct 2014, 27 min 34 sec)*
https://www.youtube.com/watch?v=bnm2aJMnKGU

VIDEO: International Psychology: What Students Need to Know *(May 2016, 35 min 57 sec)*
https://www.youtube.com/watch?v=oENWIDiFIic&t=20s

VIDEO: Maryam N. Tafreshi, Ph.D.: What is international psychology?
https://www.youtube.com/watch?v=LuQhS53OhWA
Dr. Tafreshi was born in Iran before emigrating to the United States. Although she grew up during the Iran and Iraq war, she experienced a closeness with her family in Iran. In addition to Iran and the U.S., she has lived in Chile, Brazil, Singapore, China, and Dubai. This experience has contributed to her completing her Ph.D. in International Psychology from The Chicago School as well as her work as a faculty member in mind-body medicine at Saybrook. Dr. Tafreshi discusses multicultural understanding, development of initiatives related to improved health and wellbeing to those around the globe.

WEBSITE: International Psychology (Wikipedia)
https://en.wikipedia.org/wiki/International_psychology

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Annual Psychology Day at the United Nations

Psychology Day at the United Nations is a celebration of psychology in the context of the UN. It provides an opportunity for psychology to share with U.N. Permanent Missions, U.N. Agencies, NGOs and the private sector the activities of psychologists at the U.N. and the role of psychology in addressing concerns of global importance.

19th Annual Psychology Day at the U.N. (April 23, 2026)
Theme: *Psychological Contributions to Fostering Collective Action in Uncertain Times*
Webcast Link: https://youtu.be/Mc4Rps_GdM?si=JjjuNBHS1Rd2b01Z

18th Annual Psychology Day at the U.N. (April 24, 2025)
Theme: *From Crisis to Growth: Psychological Contributions to Building Global Resilience*
Webcast Link: https://youtu.be/mXgtqG9fRoY?si=vJdXBnxtH7rO1Ws

17th Annual Psychology Day at the U.N. (April 25, 2024)
Theme: *Reducing Global Inequalities Through Education: Psychological Contributions*
Website Link: https://psychologycoalitionun.org/psychology-day-un/

16th Annual Psychology Day at the U.N. (April 27, 2023)
Theme: *Psychological Contributions to Global Peace, Conflict Resolution and Equity*
Webcast Link: https://youtu.be/A4mA9nYNa5U

15th Annual Psychology Day at the U.N. (April 21, 2022)
Theme: *Building Hope: Contributions to a Roadmap for Climate Change*
Webcast Link: https://www.youtube.com/watch?v=hQwXPt28mz4U

14th Annual Psychology Day at the U.N. (April 15, 2021)
Theme: *Psychological Contributions to Building Back Better In A Post-Pandemic World*
Webcast Link: https://youtu.be/z9xR-99lvEs

13th Annual Psychology Day at the U.N. (May 27, 2020)
Theme: *UN75: The Multilateralism We Want: Psychological Contributions to Building Bridges Among and Within Nations*
Webcast Link: https://register.gotowebinar.com/recording/viewRecording/6161065434192697099/5678870212515006466/takoosh@aol.com?registrantKey=3357184339558304524&type=ATTENDEEEMAILRECORDINGLINK

12th Annual Psychology Day at the U.N. (April 25, 2019)
Theme: *The Time is Now: Psychological Contributions to Global Gender Equality*
Webcast Link: https://media.un.org/en/asset/k1m/k1mc9dj0a6

11th Annual Psychology Day at the U.N. (April 12, 2018)
Theme: *Climate Change: Psychological Interventions, Promoting Mitigation and Adaptation*
Webcast Link: https://media.un.org/en/asset/k1q/k1q67mfo3p

2007-2025 EVENT PROGRAMS (Psychology Day at the U.N.)
- 2007 UN Psychology Day Program.pdf
- 2008 UN Psychology Day Program.pdf
- 2009-2010 UN Psychology Day Program.pdf
- 2011 UN Psychology Day Program.pdf
- 2012 UN Psychology Day Program.pdf
- 2013 UN Psychology Day Program.pdf
- 2014 UN Psychology Day Program.pdf
- 2015 UN Psychology Day Program.pdf
- 2016 UN Psychology Day Program.pdf
- 2017 UN Psychology Day Program.pdf
- 2018 UN Psychology Day Program.pdf
- 2019 UN Psychology Day Program.pdf
- 2020 UN Psychology Day Program.pdf
- 2021 UN Psychology Day Program.pdf
- 2022 UN Psychology Day Brochure.pdf
- 2023 UN Psychology Day Program (website link)
- 2024 UN Psychology Day Program.pdf
- 2025 UN Psychology Day Program.pdf
- 2026 UN Psychology Day Program.pdf

Suggested Discussion Questions:

1. Watch the video - "What is International Psychology" and How Can Students Get Involved".
Link to video - https://www.youtube.com/watch?v=oENWIDiFIic
What did you find most interesting in this video? Explain why.

2. In what way do you think this course may be valuable to you given your educational and professional goals?

3. Do you think that the courses you have taken in psychology have sufficient "international" content (e.g., cross-cultural comparisons between cultures/countries, non-Western psychology, psychologists abroad)? Briefly explain.

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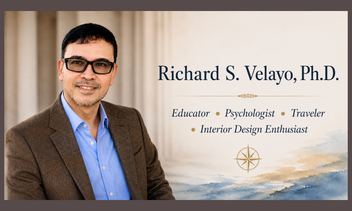

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TOPIC: INTRODUCTION to Global Psychology: Why Psychologists Should Meet a World of Need

Professor's Brief Introductory Video:
https://drive.google.com/file/d/1ruXBxSxn2IECUYht8xwX3s3CZ1IWhD_5/view?usp=drive_link

Assigned Reading/s: TEXTBOOK, pp. 3 - 13 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Why a Unified Theory of Psychology Is Impossible
https://www.psychologytoday.com/blog/theory-knowledge/201202/why-unified-theory-psychology-is-impossible
by Gregg Henriques, PhD (2012)

ARTICLE: Marsella (2015)
https://openjournals.bsu.edu/jsacp/article/view/359
Trends, Changes, Challenges in North American (Eurocentric) Psychology: Rethinking Assumptions, Practices, and Organization in Socio-Political Contexts

Other Articles of Interest

Arnett, J. J. (2008). The neglected 95%: Why American psychology needs to become less American. *American Psychologist, 63,* 602-614.

Gergen, K. J. (2001). Psychological science in a postmodern context. *American Psychologist, 56,* 803-813.

GEOGRAPHY QUIZ: Countries of the World
https://lizardpoint.com/geography/world-countries-magnifier-quiz.php?qid=1806

VIDEO: The need for an international psychology model | Dr. Paul T. P. Wong
https://www.youtube.com/watch?v=3K0pyWOGRnM
Dr. Paul T. P. Wong Ph.D., C. Psych talks about the important topic of indigenous psychology and international or universal psychology.

VIDEO: The Handbook of International Psychology
https://www.youtube.com/watch?v=-mePoypMcGU
Edited By Merry Bullock, Michael Stevens, Danny Wedding, Amanda Clinton This second edition of The Handbook of International Psychology chronicles the discipline of psychology as it evolves in different regions, from the perspective of those living and working in the countries they write about. This comprehensive handbook is essential for students and teachers of psychology, as well as professionals wanting to develop their understanding of psychology around the world. "This is a substantially updated, expanded, and enhanced edition of the dated Handbook of International Psychology. It now reflects the global spectrum of modern psychology. The four distinguished editors have direct deep knowledge of the substantial variations in how psychology developed, is conceived, situated, and practiced around the world and have structured the contributions of international authors to capture these features as well as their commonalities. Readers will benefit from learning how varied are the organizations and practices of psychology. This important seminal work belongs on every psychologist's desk."

Suggested Discussion Questions:

1. The textbook editors wrote the introductory section of the textbook (pp. 3 – 13). Which of the following parts of this section (pick only 1) did find most interesting or intriguing? Explain why. [NOTE: Indicate which one (a), (b), or (c) you picked to respond to.]
(a) Going Global in the Past, Present, and Future
(b) Going Global as Psychology and Psychologists: Realizing Our Promise and Potential
(c) Concluding by Beginning: How Will you Meet a World of Need?

2. Test your knowledge of where countries are located on a world map.
Link - https://lizardpoint.com/geography/world-countries-magnifier-quiz.php?qid=1806
There are three modes in which you may take this test – practice, test, and strict test. It's up to you which mode to take. After you take this test, assess your performance. How well did you do? Do you think others in class may have done better (or worse) than you? Mention some of the interesting things you learned after having done this activity.

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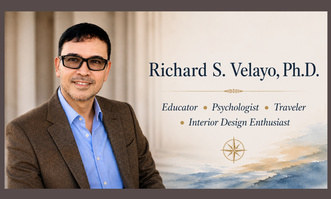

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TOPIC: ADVOCACY: Global Opportunities and Responsibilities for Psychologists

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1-mWaYt2BhfapXoqzmEngmo9kQgW2OTP1/view?usp=drive_link

Assigned Reading/s: CHAPTER 1, pp. 15 - 36 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Eye of Psi Chi: International Social Justice: How Do I Make a Difference in My Country?
https://www.psichi.org/page/244EyeSummer20Paralkar

DOCUMENT: ICP Position on Responding to World Events (PDF)
https://icpweb.org/wp-content/uploads/2024/03/ICP-position-on-statements-2024-final.pdf
The ICP board has been approached to make statements about current world events. Many of our members, in reading about world events, want to take action as a measure of their concern and care about dignity, justice, and human rights the world around. In response to these requests, ICP formed a task group to consider the ICP mission, vision and values as expressed in the ICP bylaws, and to make recommendations for ICP actions going forward.

WEBPAGE: International Council of Psychologists (ICP) and Advocacy
https://icpweb.org/advocacy/
In 2024 ICP reviewed its role in promoting human rights, dignity and justice, and developed a statement of how it would address current world events.

WEBSITE: APA Office of International Affairs
https://www.apa.org/international
APA strives to be a global partner and leader in the promotion of psychological practice, science and education to address personal, societal and global challenges. The mission of the Office of International Affairs (OIA) is to advance psychology globally through international engagement, association efforts, meaningful collaborations and enhance APA's role as a partner and leader in global health.

WEBSITE: International Association of Applied Psychology (IAAP)
https://iaapsy.org/iaap-and-the-united-nations/reports-meetings-events/mental-health-well-being-advocacy-and-programs-implementing-the-global-agenda/
Mental Health & Well-Being Advocacy and Programs Implementing the Global Agenda, and A Spotlight on Mental Illness and Minority Identities

WEBSITE: Global Network of Psychologists for Human Rights
https://humanrightspsychology.org/home/about/
The Network of Psychologists For Human Rights is open to all psychologists around the world who are interested in Human Rights. This includes the application of psychological science to human rights issues; human rights abuses; advocacy for respect for human rights; and human rights of psychologists.

WEBSITE: Psychology Coalition of NGOs at the United Nations Having Consultative Status with ECOSOC
https://psychologycoalitionun.org/
Psychology Day at the United Nations is a celebration of psychology in the context of the UN. It provides an opportunity for psychology to share with U.N. Permanent Missions, U.N. Agencies, NGOs and the private sector the activities of psychologists at the U.N. and the role of psychology in addressing concerns of global importance.

VIDEO: Psychology's contribution to global human rights: A focus on social inequity." What aspect of this video did you find interesting or intriguing?
Link to video *(Runtime: 8 min, 20 sec)* **-** https://www.youtube.com/watch?v=DJ4eenHrwiI&t=66s
[Presenter: Darren Bernal, PhD, from the American Psychological Association, explains how psychology can address poverty and socioeconomic inequity. June 24, 2021, APA]

Suggested Discussion Questions:

1. In the chapter's section on "Become Cognizant of Your Own Interests (pages 24-25), the authors list eight (8) broad categories of issues that psychologists can advocate for. These are: (1) Human rights, (2) Criminal justice, (3) Health and well-being, (4) Education, (5) Sustainability, (6) Conflict resolution, (7) Economic Justice, and (8) Religious and cultural understanding.
Pick only one (1) of these issues. Provide a SPECIFIC example of how you may advocate for that issue. Explain your answer.

2. Watch this brief video titled "Psychology's contribution to global human rights: A focus on social inequity." What aspect of this video did you find interesting or intriguing?
Link to video (Runtime: 8 min, 20 sec) - https://www.youtube.com/watch?v=DJ4eenHrwiI&t=66s
[Presenter: Darren Bernal, PhD, from the American Psychological Association, explains how psychology can address poverty and socioeconomic inequity. June 24, 2021, APA]

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TOPIC: ASSESSMENT: The Power and Potential of Psychological Testing, Educational Measurement, and Program Evaluation Around the World

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1oSHJXF5Or9vhlrcw2YXxCFs6epsAxzA5/view?usp=drive_link

Assigned Reading/s: CHAPTER 2, pp. 37 - 58 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Global and regional perspectives on testing children: An Empirical Study
https://onlinelibrary.wiley.com/doi/10.1080/00207594108246857
The results of an international survey of test use in 44 countries are reported. Data are presented and discussed for six groupings: highly industrialised, less industrialised Western, developing Third World, socialist, Middle East, and least developed nations. A total of 740 tests were identified. A number of similarities exist among the six groupings in their test use. Intelligence tests are most commonly used followed by personality and achievement tests. Important differences also exist. For example, the developing Third World and Middle East nations use more group than individually administered tests and fewer achievement tests. Many tests lack reliability and validity studies and norms. Additional tests are needed to assess achievement, intelligence, social development, personality, and vocational interests and aptitudes. Tests are especially needed for children and youth who are learning disabled, mentally retarded, and slow learners. Problems created by these conditions and implications of the frequent use of foreign developed tests are discussed.

ARTICLE: Beyond Western, Educated, Industrial, Rich, and Democratic (WEIRD) Psychology: Measuring and Mapping Scales of Cultural and Psychological Distance
https://journals.sagepub.com/doi/full/10.1177/0956797620916782
In this article, we present a tool and a method for measuring the psychological and cultural distance between societies and creating a distance scale with any population as the point of comparison. Because psychological data are dominated by samples drawn from Western, educated, industrialized, rich, and democratic (WEIRD) nations, and overwhelmingly, the United States, we focused on distance from the United States. We also present distance from China, the country with the largest population and second largest economy, which is a common cultural comparison. We applied the fixation index (F_{ST}), a meaningful statistic in evolutionary theory, to the World Values Survey of cultural beliefs and behaviors. As the extreme WEIRDness of the literature begins to dissolve, our tool will become more useful for designing, planning, and justifying a wide range of comparative psychological projects. Our code and accompanying online application allow for comparisons between any two countries. Analyses of regional diversity reveal the relative homogeneity of the United States. Cultural distance predicts various psychological outcomes.

ARTICLE: Top ten standardized tests used internationally with children and youth by school psychologists in 64 countries: A 24-year follow-up study
https://journals.sagepub.com/doi/10.1177/0734282915595303
This article provides a 24-year update on the 10 standardized tests used most frequently with children and youth by school psychologists. Data were acquired from 64 countries through an international survey, with one respondent from each country. The informants were solicited due to their expertise in the area of assessment. The data from the current 2013 survey are described and discussed as well as contrasted with the 1989 survey data. The 2013 survey data led to the following rank order of tests based on data from the 64 countries: the Wechsler Intelligence Scales for Children, Ravens Progressive Matrices, Wechsler Preschool and Primary Scales of Intelligence, Child Behavior Checklist, Bender–Gestalt Test, Child and Adult Apperception Tests, Kaufman Assessment Battery for Children, Draw-a-Person Test, Stanford–Binet Intelligence Scales, and the Wechsler Adult Intelligence Scales. Survey data from advanced, developing, and emerging counties also are compared and discussed. Results are discussed in the broader context of international test development and use.

BOOK: The ITC International Handbook of testing and assessment
https://academic.oup.com/book/1027
Embedded within the globalization movement, the internationalization of testing and assessment has encouraged scholars, professionals, and practitioners to work together to enhance our research and practice in the cross-cultural context. The International Test Commission (ITC) was formed to serve this need. The ITC seeks to facilitate the exchange of information among members and stimulate cooperation on problems related to the construction, distribution, and use of psychological tests and other psycho-diagnostic tools. The ITC has also sought to advance knowledge and best practices related to international testing by the publication of guidelines and of a journal, the *International Journal of Testing*. Consistent with these aims, the executive council of the ITC decided to launch a Handbook to present a state-of-the-art review on international testing. *The ITC International Handbook of Testing and Assessment* has been published to address the many challenges facing the cross-cultural applications of psychological and educational testing in this era of globalization. It also represents and showcases the concerted efforts of the ITC in tackling the wide range of problems and complexities in international psychological testing. Finally, the *Handbook* has been designed to provide information and resources to help guide professionals and graduate students regarding testing and assessment from an international and global perspective.

BOOK: Clinical Assessment in International Settings
https://academic.oup.com/book/1027/chapter-abstract/137929813?redirectedFrom=fulltext
The adaptation of psychological tests that were developed in one language and country into a different language and culture is expanding in contemporary international psychological assessment. This chapter addresses the need for psychological tests to be carefully developed in order to be effectively employed in cultures and languages different from their country of origin. Before a psychological test, based upon item content from the initial culture, can be adapted in other cultures, it is important to assure that linguistic equivalence has been attained through effective translation and adaptation procedures. Several psychometric procedures that are crucial to developing effective test adaptation are provided in this chapter, such as the strategy of using multiple translations to ensure general accuracy, doing a careful back-translation study, conducting a bilingual test-retest evaluation of translated items and scales to further ensure translation accuracy, developing appropriate in-country norms, and conducting external validation of tests.

BOOK: Assessment: The power and potential of psychological testing, educational measurement, and program evaluation around the world.
https://psycnet.apa.org/record/2023-04288-003
Assessment is a broad, globally relevant, and much-needed area of inquiry and practice—with tremendous power and potential. Psychologists are leaders and experts in assessment, with specialized knowledge in research design; statistics; and, of course, psychological testing, measurement, and evaluation. This chapter discusses assessment broadly, focusing on its centrality to psychology and research. It also discusses contemporary national assessment practices considering the "big four" specialties: clinical, counseling, school, and industrial/organizational psychology. The chapter presents basic competencies, including what applied psychologists do in the United States. It discusses three important international assessment topics: psychological testing, educational measurement, and program evaluation. The chapter explains cross-cultural issues in assessment, including test translation and adaptation. It highlights challenges, opportunities, and cutting-edge exemplars, including therapeutic assessment, formative educational testing and item development, and transformative program evaluation. The chapter offers practical suggestions for developing global assessment competencies and participating in the international assessment community. (PsycInfo Database Record (c) 2024 APA, all rights reserved)

BOOK CHAPTER: Positive Psychological Assessment in an Increasingly Diverse World.
https://psycnet.apa.org/record/2003-02181-003
The purpose of this chapter is to discuss our capacity to assess positive characteristics of individuals from all populations and to examine the interpretation and generalizability of these findings from one culture to another. Specifically, we will review the history of cross-cultural psychological assessment, issues related to cross-cultural measurement, and the applications of positive psychological constructs across cultures. Finally, we will describe a model for positive psychological assessment with cross-cultural populations and provide recommendations for future developments in the assessment of positive psychological constructs. (PsycInfo Database Record (c) 2024 APA, all rights reserved)

DOCUMENT: Going International: A Practical Guide for Psychologists Book 2: Engaging in International Collaborative Research
https://www.apa.org/international/resources/publications/research.pdf
The goal of this booklet is to provide an introductory guide for U.S. based psychologists, graduate students and early career psychologists interested in pursuing international research opportunities. It is written to help span the gap between knowledge of sound research practices, knowledge of local ethical and regulatory processes, and the application of that knowledge in international collaborative research.

WEBPAGE: The Standards for Educational and Psychological Testing
https://www.testingstandards.net/open-access-files.html

The Testing Standards is a joint product of the American Educational Research Association *(AERA)*, the American Psychological Association *(APA)* and the National Council on Measurement in Education *(NCME)*. Published collaboratively by the three organizations since 1966, it represents the gold standard in guidance on testing in the United States and many other parts of the world.

Suggested Discussion Questions:

1. Pages 50 – 54 is about "Developing Global Assessment Competencies". The authors pointed out nine (9) of the most important skills in developing such competencies (See Exhibit 2.1 on page 51). Which one (1) do you find most interesting or relevant? Explain why AND give your own unique example (hypothetical or not).

2. Watch this brief video titled "The Myth of Culture Fair Tests". What do you find interesting or intriguing in relation to the use of standardized psychological testing/assessment? Explain why.
Link to video (Runtime: 7 min, 11 sec): https://www.youtube.com/watch?v=Rbx3hY3tTZg

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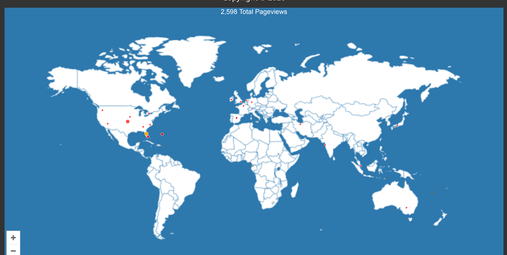

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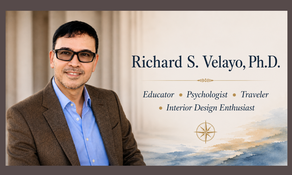

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TOPIC: CONSULTATION: Who Needs Psychological Expertise Around the World and Why?

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1vV7m0sTWqdFwusyAmlOFq2IX_TAL-V/view?usp=drive_link

Assigned Reading/s: CHAPTER 3, pp. 59 - 74 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Introduction to the Special Issue on International Organizational Consulting: Consulting Psychology Goes Global
https://www.apa.org/pubs/journals/features/cpb-a0031584.pdf
This Special Issue of the Consulting Psychology Journal: Practice and Research on "International Organizational Consulting: Consulting Psychology Goes Global" provides highlights of experienced practitioner consulting psychologists' work in a variety of multinational contexts. A brief description of the context for the Special Issue is provided, followed by an outline of the articles the special issue contains. Questions addressed by the articles include the following: how do the assumptions of organizational consulting psychology as taught and practiced in the United States need to be changed when applied to individual, group, and organizational consultation in other countries? Are there issues specific to international organizational consulting psychology different from those addressed by existing cross-cultural psychology findings? How do practicing consulting psychologists learn how to negotiate international consulting projects from start to finish? What kind of overarching templates are useful when entering a new country of international practice?

ARTICLE: Frontier No More: International Consulting Skills as Necessary Minimal Competencies for Consulting Psychologists
https://www.researchgate.net/publication/263937931_Frontier_no_more_International_consulting_skills_as_necessary_minimal_competencies_for_consulting_psychologists
This article identifies and comments on several themes that derive from the Special Issue on International Organizational Consulting: Consulting Psychology Goes Global. Six issues are identified that are intended to help integrate the Special Issue articles and to extend the four factors each article addressed: (1) how can we generalize from cases to actionable propositions?; (2) does corporate culture trump national culture?; (3) Is country an individual difference variable?; (4) are there international metacompetencies that consulting psychologists must know?; (5) who or what is the ethical arbiter in international contexts?; and (6) how can international organizational consulting psychology skills become routinized?

WEBSITE: Society of Consulting Psychology (APA Division 13)
https://www.societyofconsultingpsychology.org/

ARTICLE: Global Consulting in a Culturally Diverse World: Ethical and Legal Implications
https://psycnet.apa.org/doiLanding?doi=10.1037%2Fa0031675
This article presents an overview of the ethical and ethically related legal dilemmas faced by organizational consultants in global environments. It describes the critical factors that make the practice of global consulting complex, ambiguous, and challenging. It offers recommendations as to organizational strategies, guiding principles, and competencies that can help global consultants better navigate the ethical maze their clients face, or that they themselves face as they work with diverse cultures and organizations. We analyze the root cause of failures by global organizational management consultants and consider the difficulty of determining the right approach for all stakeholders within the broader global system.

BOOK CHAPTER: Consulting Psychology in the Business World
https://academic.oup.com/book/1321/chapter-abstract/140303209?redirectedFrom=fulltext
Consulting psychologists working in the private sector of the business world have many roles. This chapter discusses several types of business consulting engagements. The differences between psychotherapy practice and business consulting are explained. Case illustrations are supplied based on the authors' more than 30 years of experience. Information is given about the type of additional training required to become a consultant. Topics covered are executive coaching, leadership development, family business consulting, executive selection, team building, leadership succession, organizational analysis and design, mergers and acquisitions, and strategic planning.

BOOK: Internationalizing the Curriculum in Organizational Psychology
https://www.researchgate.net/publication/296341860_Internationalizing_the_Curriculum_in_Organizational_Psychology
Since the days of silk roads and spice routes, international commerce has been essential to business. Today, from air travel to the Internet, advances in technology have served to make the business world smaller. Yet, despite the real world's march towards globalization, organizational psychology as an academic discipline has yet to incorporate these developments into its degree programs. Internationalizing the Curriculum in Organizational Psychology counters this resistance with a flexible floor plan to bring practical cross-cultural content into education and training. An expert international panel offers guidance on key aspects of curriculum design, including subject matter, learning objectives, competencies, and experiential learning, with here-and-now global insights and business as well as pedagogical savvy. The approach is far from monolithic, as these diverse contributors challenge readers to embrace complexity, surprise, and the inevitable humorous moments that come with cultural exchanges. Among the areas featured: Meaningfully applying cultural knowledge. The dominance of Western perspectives and assumptions. Core competencies for the cross-cultural curriculum. Tools for implementing internationalism in course content. Educational models from abroad. Internationalizing faculty development. For faculty and administrators in industrial/organizational psychology, organizational behavior, work psychology, and applied psychology programs who wish to incorporate an international component to their curriculum or courses, Internationalizing the Curriculum in Organizational Psychology occupies the ground floor of the next major paradigm shift.

DOCUMENT: Guidelines for Education and Training at the Doctoral Level in Consulting Psychology (CP)/Organizational Consulting Psychology (OCP)
https://www.apa.org/about/policy/education-training.pdf

VIDEO: Industrial/Organizational Psychology and Globalization
https://study.com/academy/lesson/video/industrial-organizational-psychology-globalization.html
Globalization is an increasingly important concept to businesses today. In order to compete, a business must consider its world-wide markets and be aware of cultural differences. Inclusiveness in the workplace helps a business reach beyond its borders and become more successful. Businesses with international presences often use virtual teams who may rarely meet in person but work together using modern technology. Industrial/organizational psychologists (I/OPs) are vital players on this global field.

Suggested Discussion Questions:

Read the section on "Competencies of International Consulting (pp. 60 – 65) which describes four (4) core competencies that are integral to effective consulting. These are (i) Awareness of Self, Others, and the Larger World, (ii) Cultural Agility, (iii), Affective Capacity, and (iv) Personality Variables. Then, on pages 65 – 68, you will see case studies that illustrate how these competencies were demonstrated. Choose only one:

(1) Of the case studies that you find interesting. Which of the core competencies do you think was demonstrated by the consultant? Explain your answer.
(IMPORTANT: DO NOT choose Case Study 1. Your instructor will be the only one to provide a response to this case.)
Case Study 2: Learning by Teaching
Case Study 3: Bridging Boundaries
Case Study 4: Handling Trauma
Case Study 5: "Well, That Didn't Work"

2. Watch this video podcast titled "Practicing Consulting Psychology Internationally" in which Dr. I-Ching Grace Hung shares with Dr. Len Wysock about her experience as a consulting psychologist practicing internationally. What aspect/s of the video do you find interesting? Explain why.
[Link to video (Runtime: 17 min, 7 sec): https://www.youtube.com/watch?v=_eUALtILCzY]

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TOPIC: INTERVENTION: Enhancing Mental Health and Well-Being Around the World

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1ZVxVMu3g160-bBI6hsLa1f2UM9Y64E1A/view?usp=drive_link

Assigned Reading/s: CHAPTER 4, pp. 75 - 97 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Ethical Principles of Psychologists and Code of Conduct
http://www.apa.org/ethics/code/index.aspx
The American Psychological Association's Ethical Principles of Psychologists and Code of Conduct provides guidance for psychologists in professional, scientific and educational roles. The Ethics Code also outlines standards of professional conduct for APA members and student affiliates.

ARTICLE: International practitioners
http://www.apa.org/gradpsych/2009/03/cover-abroad.aspx
What does it take to practice psychology abroad? Cultural competence is always in demand; educational requirements vary widely.

ARTICLE: Employing Psychotherapy Across Cultures and Contexts
https://pmc.ncbi.nlm.nih.gov/articles/PMC3868079/
Psychotherapy and psychological interventions are practiced across diverse cultural and health settings, for a variety of emotional distress and among very heterogeneous groups of people. Different schools of psychotherapy exist and are employed across regions, contexts, and cultures. However, they have been criticized for the failure to appreciate the ethnocentricity of their approaches.[1] The apparent contradictions between the theory and methods of individual schools of psychotherapy and their use in diverse social and ethnic environments are often emphasized. Nevertheless, a diligent examination of the issues suggests that many so-called "unresolvable" tensions between the standard psychotherapies and their use in diverse contexts are explained by the form-content dichotomy related to psychological therapy.[2] This editorial highlights some issues related to the use of psychotherapy across cultures.

ARTICLE: International Themes in Psychotherapy Integration
https://psycnet.apa.org/record/2019-28355-021
Integrative psychotherapies have grown significantly worldwide since the 1980s and currently hold a central place on most continents. This chapter presents a landscape of practice, training, and research in psychotherapy integration in select countries in Asia, Latin America, and Europe. Psychotherapy is defined by common features throughout the world and, at the same time, is practiced differently according to geographical regions and cultural contexts. The chapter provides brief descriptions of integrative psychotherapy movements and contributions in different world regions in order to furnish a view of integration at an international level. It provides overviews of integration in their respective countries in terms of specific models, training programs, and research programs, concluding with the current state of psychotherapy integration. Following summaries of integration in Asia-Pacific, Latin America, and Europe and select countries therein, the chapter highlights recurrent themes across countries. The landscape includes considerations about incentives and challenges to the growth of psychotherapy integration in every region as well as obstacles to address. In the future, psychotherapy around the world will undoubtedly become more fully integrative, not only in terms of blending theoretical perspectives, but also in mutually beneficial collaborative efforts between practitioners and researchers.

WEBPAGE: World Health Organization: Department of Mental Health, Brain Health and Substance Abuse
https://www.who.int/teams/mental-health-and-substance-use/treatment-care/innovations-in-psychological-interventions
This page provides a link to key WHO resources related to the delivery of psychological interventions.

WEBPAGE: IUPsyS - Universal Declaration of Ethical Principles for Psychologists
http://www.iupsys.net/about/governance/universal-declaration-of-ethical-principles-for-psychologists.html

WEBSITE: EAP: Situation of Psychotherapy in various countries on Quality Standards
https://www.europsyche.org/situation-of-psychotherapy-in-various-countries/
https://www.europsyche.org/quality-standards/eap-standards/

VIDEO: Dr. Janel Gauthier on the "Universal Declaration of Ethical Principles for Psychologists"
https://youtu.be/LqBO9pjMvsM
Published on Mar 31, 2012
Dr. Gauthier about the Universal Declaration of Ethical Principles for Psychologists
Critical Thinking Question: *What are your thoughts about "Individual Human Rights" vs. "Cultural Rights" between Nations?*

VIDEO: Multicultural Competence in Counseling and Psychotherapy
https://www.youtube.com/watch?v=4sCvBlb6JP0
Published on Apr 11, 2014
In this provocative interview with multicultural expert Derald Wing Sue, learn about the history of multicultural counseling, the unmet needs of diverse clients, and ways to counter the culture-bound values that may be impacting your work. This video may also be viewed at: http://www.psychotherapy.net/video/multicultural-competence-psychotherapy-sue

Suggested Discussion Questions:

1. This chapter covers several areas in which psychological intervention/s can help enhance mental health and well-being around the world. In the Applications section (pp. 84 – 93), there are eight (8) examples/exhibits of intervention settings that present opportunities for psychologists to intervene. Choose only one (1) example/exhibit from the list below (except Exhibit 4.1). In your own words, briefly summarize the problem situation AND the intervention used. What other intervention/s would you suggest?
XHIBIT 4.2: Benefiting families in Mexico City: Adaptation of a Parenting Intervention in School Setting
EXHIBIT 4.3: Empowerment in the Aftermath of an Earthquake: A Lay-Led Psychosocial Initiative in Haiti
EXHIBIT 4.4: Collaborative Healing in Post-conflict Angola
EXHIBIT 4.5: Addressing the Global Crisis of Depression: Interpersonal Therapy
EXHIBIT 4.6: ACT for All: A Conceptual Approach to Acceptance and Commitment Therapy
EXHIBIT 4.7: Investment in Early Child Development
EXHIBIT 4.8: Dealing with Disasters: International Interventions and Development of the Disaster Mental Health Institute

2. Watch this brief 2012 video which featured Dr. Janel Gauthier (Canada) who spearheaded this effort for the Universal Declaration of Ethical Principles for Psychologists.
Link to video (Runtime: 8 min, 25 sec): https://youtu.be/LqBO9pjMvsM
Professional psychology (particularly in the areas of clinical, counseling, school, and perhaps industrial/organizational psychology) is growing rapidly, though unevenly, in various regions of the world. As a result, one of the major concerns of various international psychology organizations is the development of ethical guidelines across nations. The International Union of Psychological Sciences (IUPsyS) in 1976, urged its member nations to develop codes of ethics that prohibited psychologists from abusing human rights. In 2008, it was completed and adopted.
Link to document: https://www.iupsys.net/about/declarations/universal-declaration-of-ethical-principles-for-psychologists/

Do you think this document sufficiently addresses the issue of a shared ethics and moral values across cultures/nations? Explain your answer.

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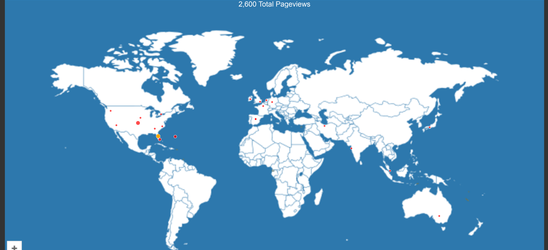

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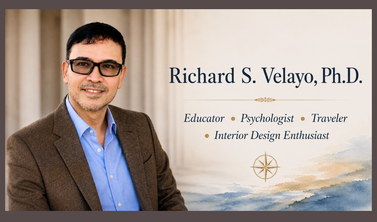

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TOPIC: LEADERSHIP: How Psychology and Psychologists Develop Global Leaders and Leadership

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1dqaqYdSiTC-1R_2bDYO2dO0heBJfMjlB/view?usp=drive_link

Assigned Reading/s: CHAPTER 5, pp. 99 - 120 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Steering Global Leadership
https://www.apa.org/monitor/2024/07/international-leadership-psychologists
Expertise in human behavior and well-being shapes governance and policy-making on a global scale

WEBPAGE: Global Psychology Alliance
https://www.apa.org/international/networks/global-psychology-alliance
The Global Psychology Alliance actively addresses global issues using psychological science to elevate the field and enhance human well-being around the world.

WEBPAGE: Psychology Societies Outside the U.S.
https://www.socialpsychology.org/inter.htm
This page contains an international listing of general psychology societies that have web sites. For information on other organizations

WEBPAGE: Global Psychology Learning Leadership Institute
https://www.apa.org/international/networks/global-psychology-alliance/learning-leadership-institute#:~:text=The%20Global%20Psychology%20Learning%20Leadership,established%20leaders%20in%20the%20field.
The Global Psychology Learning Leadership Institute (LLI) began in 2021 as a Presidential Initiative of APA 2020 President, Sandra Shullman, PhD, with the support of the Global Psychology Alliance (GPA). The LLI brings together established and emerging leaders in the field from across the world with the aim of creating a leadership pipeline and ensuring the voices of future leaders of psychology are represented in global efforts. Through cross-cultural mentorship, engagement with expert speakers and invited guests, the development of leadership projects, and contributions to the 2022 International Summit on Psychology and Global Health: Leadership for Emerging Challenges, young leaders from GPA associations continue to impact their countries, expand the global psychology community, and shape the direction of our science and profession alongside established leaders in the field.

WEBSITE: International Union of Psychological Science (IUPsyS)
https://www.iupsys.net/
The International Union of Psychological Science (IUPsyS) was established in 1889 during the First International Congress of Psychology in Paris. With 82 country members and 20 affiliated organizations the IUPsyS represents over a million psychologists worldwide. As such it acts for psychology in its full breadth as a science and as a profession.

Suggested Discussion Questions:

1. The section on "Global Leadership Development" (pp. 110 – 114) describes three applications/practices that exemplify global leadership. These are:

- Practice 1: Attend to Values and Ethics
- Practice 2: Clarify Processes and Goals
- Practice 3: Learn to Navigate Paradoxes

Which of these interested you the most? Pick only one (1). Briefly explain why AND provide your own example (hypothetical or not).

2. "Featured International Psychologist" PROJECT
(a) Indicate the NAME and COUNTRY of your "Featured International Psychologist" and provide a brief paragraph (100 - 150 words) on the biographical information about this person.
(b) Mention one (1) noteworthy accomplishment (e.g., an award, a scholarly publication) related to international psychology. Why did you choose this particular accomplishment? [IMPORTANT: Include the link/source where you found this information.]

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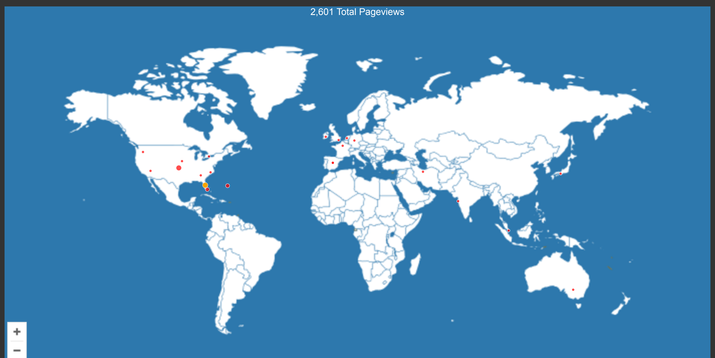

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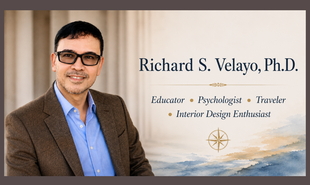

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TOPIC: POLICY: Why and How to Become Engaged as an International Policy Psychologist

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1mTHRaaiBHh3FhJsP7rP85hhj18AJE9P9/view?usp=drive_link

Assigned Reading/s: CHAPTER 6, pp. 121 - 142 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Steering global leadership
https://www.apa.org/monitor/2024/07/international-leadership-psychologists#:~:text=They%20are%20also%20consulting%20on,global%20lens%2C%E2%80%9D%20she%20said.
Expertise in human behavior and well-being shapes governance and policy-making on a global scale

ARTICLE: International psychological research that matters for policy and practice
https://psycnet.apa.org/doiLanding?doi=10.1037%2F0003-066X.64.8.825
After a brief history of the Committee on International Relations of the American Psychological Association, 3 points are made about international psychological research that matters. First, it matters when the definition of the research problem area and the findings can potentially be reflected in policy change, in the practice of educators or psychologists, or in the mindsets of a new generation of researchers. Person-centered analysis of adolescents' social and political attitudes has this potential and can complement variable-centered analysis. A cluster analysis of the IEA Civic Education Study's data in 5 Western European and 5 Eastern European countries illustrates this. The following 5 clusters of adolescents were identified: those supportive of social justice but not participative, those active in conventional politics and the community, those indifferent, those disaffected, and a problematic cluster of alienated adolescents. Second, research that matters is situated in a cultural context. It is proposed that publications using data from any single country be required to include information about the cultural context in which the research was conducted. Finally, it matters that attention be given to the dynamics of the collaborative international research process, not only to research results.

BLOG: The Role of Political Psychology in Diplomacy
https://online.maryville.edu/blog/the-role-of-political-psychology-in-diplomacy/
Fundamentally, psychology is focused on better understanding the human mind and human behavior. Political psychology seeks to apply the same principle to the world of politics, examining the interplay between how people think, feel, and act — and the impact that has on how they approach political considerations. Through political psychology, individuals can gain deeper insight into different political ideologies, personalities, and policies — both for the public and political figures.

BOOK: Psychology and Foreign Policy
https://www.oxfordbibliographies.com/display/document/obo-9780199743292/obo-9780199743292-0252.xml
The use of psychological concepts to explain the behavior of individuals and groups that shape foreign policy is centuries old. Thucydides in his great *History of the Peloponnesian War* explored the impact of the fear of decline on leaders' decisions to go to war. Barbara Tuchman in *The Guns of August* demonstrated how misperception and miscalculation by leaders in the summer of 1914 led to an accidental war that no leader wanted or expected. During and after World War II, political scientists began to draw systematically on psychological concepts to explain foreign policy behavior. Scholarship advanced when the International Society of Political Psychology was founded in 1978 along with a specialized journal, *Political Psychology*. Early scholarship focused on leaders' personalities and their impact on the foreign policy choices they made, with special attention devoted to decisions to go to war or make peace. A second wave of scholarship drew on the work of cognitive psychologists who had identified heuristics and biases to explore the impact of the way leaders thought on the foreign policy decisions that they made and examined pairs of interacting leaders to explain spirals of escalation. Scholars mined cognitive psychology to explore decisions to cooperate or compete, the success and failure of deterrence and compellence, and bargaining and signaling behavior by leaders. A third wave of scholarship drew on psychological research on emotion and examined how the emotional states of leaders influenced foreign policy choices. Scholars moved beyond leaders to study elite and group attributes to explain foreign policy behavior. In doing so, they confronted the central problem of aggregation; cognition and emotion are embedded in the individual. When they move to explain group behavior, scholars deepened psychological concepts by adding a broader social dimension to the analysis. Research in the last decade situates feeling and thinking in a larger social and cultural context in a more contextualized explanation of foreign policy behavior. Research is increasingly multidisciplinary, drawing on neuroscience, evolutionary biology, evolutionary psychology, and behavioral economics to explain foreign policy behavior.

BOOK: The Psychology of Foreign Policy
https://link.springer.com/book/10.1007/978-3-030-79887-1
This book focuses on foreign policy decision-making from the viewpoint of psychology. Psychology is always present in human decision-making, constituted by its structural determinants but also playing its own agency-level constitutive and causal roles, and therefore it should be taken into account in any analysis of foreign policy decisions. The book analyses a wide variety of prominent psychological approaches, such as bounded rationality, prospect theory, belief systems, cognitive biases, emotions, personality theories and trust to the study of foreign policy, identifying their achievements and added value as well as their limitations from a comparative perspective. Understanding how leaders in world politics act requires us to consider recent advances in neuroscience, psychology and behavioral economics. As a whole, the book aims at better integrating various psychological theories into the study of international relations and foreign policy analysis, as partial explanations themselves but also as facets of more comprehensive theories. It also discusses practical lessons that the psychological approaches offer since ignoring psychology can be costly: decision-makers need to be able reflect on their own decision-making process as well as the perspectives of the others. Paying attention to the psychological factors in international relations is necessary for better understanding the microfoundations upon which such agency is based.

WEBPAGE: International Society of Political Psychology
https://ispp.org/

Suggested Discussion Questions:

1. The section on "How to Get Started" (pp. 134– 136) provides nine (9) suggestions/opportunities for psychologists to become more engaged in international policy through their education and training. Which of these interest you the most? Pick only one (1). Briefly explain why AND provide your own example (hypothetical or not).

2. As you may know, the final paper for this course involves writing a critique of a particular national/regional psychology organization that is part of the Global Psychology Alliance (GPA). This alliance is a global psychology leadership team formed to take action in addressing global issues as described in the video titled "Global Psychology Coming Together". What aspects of the video AND/OR the GPA website did you find most interesting? Explain why.
Link to Video (Runtime: 3 min, 11 sec): https://youtu.be/GlxbJDlxV10?si=TebziIbqhpRI4TPT
Link to Website: https://www.apa.org/international/networks/global-psychology-alliance

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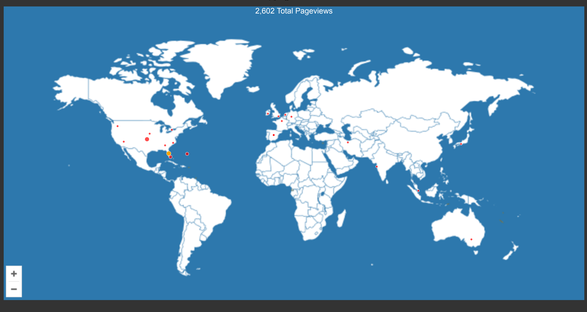

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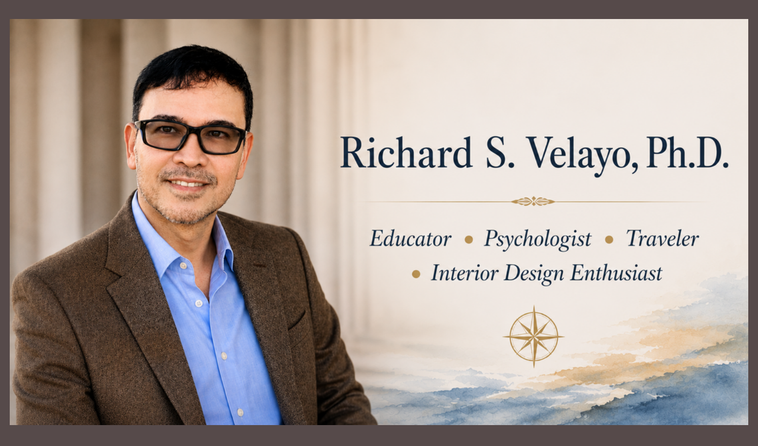

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TOPIC: RESEARCH: International Possibilities and Partnerships for Psychologists

Professor's Brief Video Introduction:
https://drive.google.com/file/d/187TW1aQU4YsIUecPRqlAWNYnS5pX2Iix/view?usp=drive_link

Assigned Reading/s: CHAPTER 7, pp. 143 - 165 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Psychology Takes a Global View
https://www.apa.org/monitor/2025/01/trends-global-view
Global research collaborations are seeking larger, more representative samples in investigating shared urgent challenges

ARTICLE: Guidelines to Improve Internationalization in the Psychological Sciences
https://compass.onlinelibrary.wiley.com/doi/10.1111/spc3.12847
This commentary is based on the hackathon titled "Guidelines on Including Non-WEIRD Populations in Psychological Science" presented at the 2021 meeting of the Society for the Improvement of Psychological Science. This was also presented as a paper at the 60th Annual Conference of the Taiwan Psychological Association in October 2021.

JOURNAL: International Perspectives in Psychology: Research, Practice, Consultation
https://www.hogrefe.com/us/journal/international-perspectives-in-psychology-research-practice-consultation
Official Journal of Division 52 (Society for Global Psychology) of the American Psychological Association

WEBSITE: Going International: A Practical Guide for Psychologists
https://www.apa.org/international/resources/info/academics-abroad
The goal of this guide is to provide an introductory guide for U.S. academics going outside the country for research and scholarship. It is written to fill the gap between general, country-level information typical of travel books or country websites, and specific details of the universities, cities or programs with which you may become involved.

WEBSITE: Challenges and Opportunities for Psychological Research in the Majority World
https://online.ucpress.edu/collabra/article/10/1/123703/203452/Challenges-and-Opportunities-for-Psychological
How can psychology transform itself into an inclusive science that engages with the rich cultural diversity of humanity? How can we strive towards a broader and deeper understanding of human behavior that is both generalizable across populations and attentive to its diversity? To address these major questions of our field, relying on scholars from different world regions, we outline first the opportunities associated with conducting psychological research in these and other majority world regions, highlighting international collaborations.

Suggested Discussion Questions:

Presume that you are the principal investigator/research in charge of conducting a cross-national psychology research project (e.g., college students' perceptions about school-related stress).

1. Pick two (2) countries to study/compare for this research project. Explain why you picked these countries.

2. Pages 155 – 160 presents several questions and offer suggestions to help initiate your research project. Pick only one (1) of these questions that you think is most interesting or important given your research project. Briefly explain your answer.

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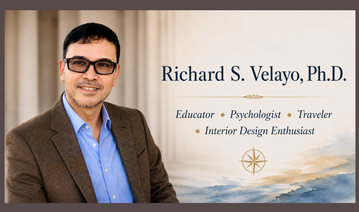

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TOPIC: SERVICE: Toward a Global Psychology of Collaboration, Counterflow, and Capacity Building

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1fbFv1ZTuEFyuIanb2yOMnCL9rnVAaU9Z/view?usp=drive_link

Assigned Reading/s: CHAPTER 8, pp. 167 - 182 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: International humanitarian careers
https://www.apa.org/monitor/2024/09/international-humanitarian-careers
Blending Western psychology with local knowledge, mental health professionals are driving positive change around the world.

ARTICLE: Humanitarian activities of psychologists are a vital step for the globalization of psychology
https://www.apa.org/international/global-insights/humanitarian-activities-psychologists
How engaging in humanitarian activities can promote acceptance, empathy, and a global psychology.

ARTICLE: Volunteer Abroad in Mental Health, Psychology and Special Needs
https://www.volunteerforever.com/article_post/volunteer-abroad-in-mental-health-psychology-and-special-needs/
Mental health and special needs are important issues everywhere, and in many countries around the globe, there is still much work to be done to combat pervasive social stigma, discrimination and low quality of life.

ARTICLE: Serving Abroad
https://www.apa.org/gradpsych/2014/04/serving-abroad
International assignments offer career opportunities and cultural insights

ARTICLE: Humanitarian Work Psychology
https://www.apa.org/monitor/2016/04/humanitarian
This new psychology field focuses on underserved populations.

VIDEO: SIOP UN Committee: Applying Humanitarian Work Psychology for the Eradication of Poverty
https://youtu.be/fekE6NuYPuQ?si=r9io5TK5W9UBTpLX

VIDEO: Global Organization for Humanitarian Work Psychology
https://www.youtube.com/watch?v=lKB6bxmxYp4

WEBSITE: Psychology and Mental Health Volunteer Programmes
https://vocationalimpact.org/psychology-mental-health-programmes/
Kickstart your career in psychology and mental health while making a lasting difference. Contribute to meaningful projects in Ghana, India, and South Africa aligned with your studies and career goals.

Suggested Discussion Questions:

1. It is important to reflect on whether undertaking humanitarian service in global psychology is for you. One can expect to encounter challenges and meet essential requirements to prepare for such venture. Pages 174 – 177 provide five (5) advice for psychologists who want to work in global humanitarian service. Choose only one (1) of these and give your OWN example. Briefly explain why.

2. The Society for Industrial and Organization Psychology (SIOP) is an international psychology organization that has consistently been doing humanitarian service around the world. The link below is a video of one other their projects. What did you find most interesting? Briefly explain why.
Link to Video - https://youtu.be/fekE6NuYPuQ?si=r9io5TK5W9UBTpLX (Runtime: 3 min. 31 sec.)

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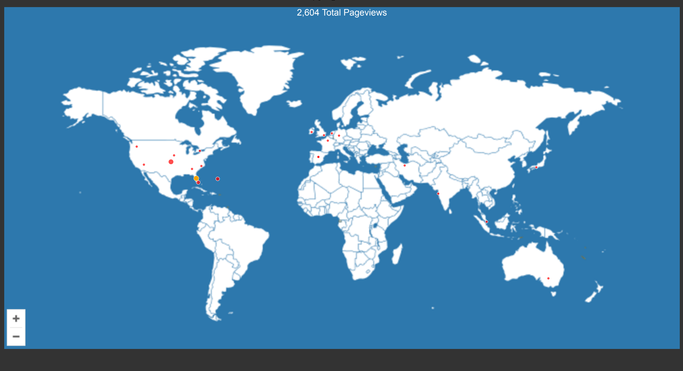

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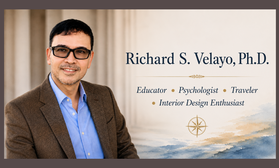

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TOPIC: TEACHING: Opportunities and Recommendations for Internationalizing Psychology Education

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1tY8RtL2hW1J37-wO1ZouUzm4x2-sF0pa/view?usp=drive_link

Assigned Reading/s: CHAPTER 9, pp. 183 - 206 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: Internationalizing Undergraduate Psychology Education: Trends, Techniques, and Technologies
https://psycnet.apa.org/record/2016-06476-005
Takooshian, H., Gielen, U. P., Plous, S., Rich, G. J., & Velayo, R. S. (2016). Internationalizing undergraduate psychology education: Trends, techniques, and technologies. *American Psychologist, 71*(2), 136-147.

ARTICLE: How Do We Create Transformative Global Citizens (Bosio, 2018)
https://www.academia.edu/35340771/How_do_we_create_transformative_global_citizens_Bosio_2018_?email_work_card=view-paper
Why are we in teaching and learning if not to be able to help enrich the lives of our students? This article builds on a 'transformative value-creating' dimension of global citizenship education. The word transformative refers to a clear focus on self-reflection and awareness, while the words value-creating denote taking actions in order to create value in society. Findings suggest there are three emerging interconnected dimensions of implementing the notion of global citizenship into universities' curricula, namely: social contribution, civic commitment, and global disposition. These dimensions can be summarized in the following equation: Social contribution + civic commitment + global disposition (the development of knowledge, skills and values) = students' 'personal transformation' and evolution towards value-creation within society.

ARTICLE: American Psychological Association Working Group on Internationalizing the Undergraduate Psychology Curriculum: Report and Recommended Learning Outcomes for Internationalizing the Undergraduate Curriculum (Nov. 2005)
https://www.researchgate.net/publication/324112757_American_Psychological_Association_Working_Group_on_Internationalizing_the_Undergraduate_Psychology_Curriculum_Report_and_Recommended_Learning_Outcomes_for_Internationalizing_the_Undergraduate_Curricu
This document represents the work of the APA Working Group on Internationalizing the Undergraduate Psychology Curriculum. The document does not represent policy of the American Psychological Association.

Neil Lutsky, Carleton College
Judith Torney-Purta, University of Maryland College Park
Richard Velayo, Pace University
Val Whittlesey, Kennesaw State University
Linda Woolf, Webster University
Maureen McCarthy, American Psychological Association

ARTICLE: Internationalizing Your Psychology Course
https://www.researchgate.net/publication/324113288_Internationalizing_Your_Psychology_Course
Velayo, R. (2011). Internationalizing Your Psychology Course. Essays from *E-xcellence in Teaching, 10*, 25-31.
To download full-text, go to the link below and see pp 25-31

ARTICLE: APAGS article on "Students from Abroad"
http://www.apa.org/gradpsych/2015/09/international-students.aspx

VIDEO: How to International Your Teaching and Learning in Psychology
https://youtu.be/LNlI0tbCSrs?si=Y5724_x5nPKdyjC3
Susan Nolan talks about the field of international psychology and how it is relevant to a number of courses across the psychology curriculum. She discusses ways in which psychology learning and teaching can be enhanced by consideration of current global events, international research and researchers, and applications of psychology to social change.

VIDEO: DePaul University - Internationalization
https://www.youtube.com/watch?v=gXDqwM4w4tY
This video explores the education of students for an increasingly globalized world, focusing specifically on international initiatives and how they impact the student experience.

WEBPAGE: Resources for Teachers of Psychology
https://teachpsych.org/page-1603066#international
The Society for the Teaching of Psychology (STP) curates and distributes teaching and advising materials to all teachers of psychology (e.g., 4-year instructors, 2-year instructors, and high-school teachers). The resources available below are documents that can pertain to any aspect of teaching. (NOTE: Syllabi have their own listings under Project Syllabus.)
Instructors have generously shared classroom activities, annotated bibliographies, film guides, lab manuals, advising aids, textbook compendiums, and much more. Notations indicate those that developed from Instructional Resource Awards.

WEBPAGE: Resources to Help Internationalize Psychology Courses/Curricula
https://teachpsych.org/page-1588335
This resource includes books, chapters, articles, and other materials related to the internationalization of the psychology curriculum. The resource is organized topically as follows: Cognitive, Developmental, General Cross-Cultural, General International, Global Issues, Health, History, Industrial/Organizational, Intergroup Relations, Introductory, Mental Health and Clinical, Psychology and Law, School, Social, Teaching, Women, and additional resources.

WEBPAGE: International psychology. Oxford Bibliographies.
https://www.oxfordbibliographies.com/view/document/obo-9780199828340/obo-9780199828340-0184.xml

WEPBAGE: Internationalizing our psychology courses: Resources for faculty
http://www.apa.org/education/undergrad/internationalize.aspx
Velayo, R. S. (2016). *Internationalizing our psychology courses: Resources for faculty*.

WEBPAGE: InterTOP (International Teaching of Psychology Network)
Main Page for InterTOP
Link to webpage: http://interteachpsy.org
Resource page of InterTOP
Link to webpage: http://interteachpsy.org/Main/ Resources

WEBPAGE: Wikipedia entry on "International Psychology"
Link to webpage: https://en.wikipedia.org/wiki/International_psychology

Suggested Discussion Questions:

1. Pages 191 - 196 of the chapter presents four (4) best practices and specific activities for the classroom that help infuse an international perspective in the psychology classroom. Pick one (1) that you think would be most beneficial to you as a graduate (or undergraduate) student. Briefly explain why.

2. Here is an article published in APA's flagship journal – The American Psychologist.
Takooshian, H., Gielen, U. P., Plous, S., Rich, G. J., & Velayo, R. S. (2016). Internationalizing undergraduate psychology education: Trends, techniques, and technologies. American Psychologist, 71(2), 136-147.
https://www.researchgate.net/publication/294276539_Internationalizing_undergraduate_psychology_education_Trends_techniques_and_technologies
On pages 143 - 145 of this article, fourteen (14) recommendations are presented that help support the internationalization of undergraduate psychology in the U.S. Pick one (1) recommendations that you think may be most beneficial for "undergraduate" students at Pace. Briefly explain why.

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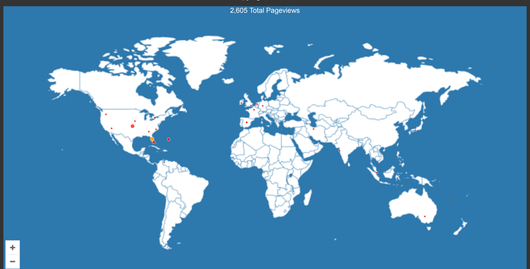

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TOPIC: CONCLUDING THOUGHTS: on Going Global: How Psychologists Should Meet a World of Need

Professor's Brief Video Introduction:
https://drive.google.com/file/d/1vYNISLFb62ImfPxacZq9XaS4EI2eNuCw/view?usp=drive_link

Assigned Reading/s: CHAPTER 10, pp. 207 - 227 [Shealy, Bullock, & Kapadia (Eds.) (2023)]

Supplementary Materials:

ARTICLE: A Global Perspective
https://www.apa.org/gradpsych/2006/01/perspective
Experts and students offer tips on adding an international focus to your psychology work.

VIDEO: Global Psychology Coming Together
https://www.youtube.com/watch?v=G9dvJDkXY10
APA is committed to working with our global partners to promote the use of psychological science to improve lives worldwide.

WEBPAGE: Society for Global Psychology (APA Division 52_
https://div52.net/
Division 52: The Society for Global Psychology seeks to develop a psychological science and practice that is contextually informed, culturally inclusive, serves the public interest and promotes global perspectives within and outside of APA. The Division of International Psychology represents the interest of all psychologists who foster international connections among psychologists, engage in multicultural research or practice, apply psychological principles to the development of public policy or are otherwise concerned with individual and group consequences of global events.

EPILOGUE: A Final Note about "International Psychology" - WHAT's NEXT?...
"*The answers and other developments in theory, research, intervention, and pedagogy, will certainly advance the field of global psychology greatly over the next few years. While it is an exciting period for psychologists and psychology students who are interested in global psychology, it is also a challenging one. There are myriad forces and events that could influence the direction of the specialty, some of which can be dimly envisaged (e.g., the expected course of globalization) and others which cannot be anticipated. The future course of global psychology also rests on the awareness and commitment of psychologists to communicate and collaborate in a horizontal and multidisciplinary fashion on various levels in an effort to understand and address the shared concerns and issues that face humankind. Perhaps, the most telling question that remains to be answered concerns the foundation and identity of the discipline of psychology as we know it. As the process of globalizing psychology ensues, how will its science and practice be transformed from the form in which it is currently constituted? Psychology will continue to evolve as it has in the past. Although this inevitable evolution can be forecast with limited accuracy, it would seem that the beliefs and customs of other cultures will be incorporated more extensively into the fabric of scientific and professional psychology in the future. Conversely, as psychology becomes more globally integrated, the history of psychology will be reconceptualized as transnational and multilingual, rather than as Western and English-dominated. New books that deconstruct the history of psychology (e.g., Brock, in press) will play a significant role in how psychologists and psychology students construe the discipline of psychology and their own identity within it.*" (Stevens & Gielen, 2007, pp. 397-399)

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Annual Psychology Day at the United Nations

Psychology Day at the United Nations is a celebration of psychology in the context of the UN. It provides an opportunity for psychology to share with U.N. Permanent Missions, U.N. Agencies, NGOs and the private sector the activities of psychologists at the U.N. and the role of psychology in addressing concerns of global importance.

19th Annual Psychology Day at the U.N. (April 23, 2026)
Theme: *Psychological Contributions to Fostering Collective Action in Uncertain Times*
Webcast Link: https://youtu.be/MTo4Rps_GdM?si=JtjuNBHS1Rd201Z

18th Annual Psychology Day at the U.N. (April 24, 2025)
Theme: *From Crisis to Growth: Psychological Contributions to Building Global Resilience*
Webcast Link: https://youtu.be/mXgtoG9fRoY?si=vJdIXBnxtH7rO1Ws

17th Annual Psychology Day at the U.N. (April 25, 2024)
Theme: *Reducing Global Inequalities Through Education: Psychological Contributions*
Website Link: https://psychologycoalitionun.org/psychology-day-un/

16th Annual Psychology Day at the U.N. (April 27, 2023)
Theme: *Psychological Contributions to Global Peace, Conflict Resolution and Equity*
Webcast Link: https://youtu.be/A4mA9nYNa5U

15th Annual Psychology Day at the U.N. (April 21, 2022)
Theme: *Building Hope: Contributions to a Roadmap for Climate Change*
Webcast Link: https://www.youtube.com/watch?v=NQwXPQ8mz4U

14th Annual Psychology Day at the U.N. (April 15, 2021)
Theme: *Psychological Contributions to Building Back Better In A Post-Pandemic World*
Webcast Link: https://youtu.be/z9xR-99IvEs

13th Annual Psychology Day at the U.N. (May 27, 2020)
Theme: *UN75: The Multilateralism We Want: Psychological Contributions to Building Bridges Among and Within Nations*
Webcast Link: https://register.gotowebinar.com/recording/viewRecording/6160654341926970991/5678870212515006466/takoosh@aol.com?registrantKey=3357184339558304524&type=ATTENDEEEMAILRECORDINGLINK

12th Annual Psychology Day at the U.N. (April 25, 2019)
Theme: *The Time is Now: Psychological Contributions to Global Gender Equality*
Webcast Link: https://media.un.org/en/asset/k1m/k1mcd9d0a6

11th Annual Psychology Day at the U.N. (April 12, 2018)
Theme: *Climate Change: Psychological Interventions, Promoting Mitigation and Adaptation*
Webcast Link: https://media.un.org/en/asset/k1q/k1q67mfo3p

2007-2025 EVENT PROGRAMS (Psychology Day at the U.N.)
- 2007 UN Psychology Day Program.pdf
- 2008 UN Psychology Day Program.pdf
- 2009-2010 UN Psychology Day Program.pdf
- 2011 UN Psychology Day Program.pdf
- 2012 UN Psychology Day Program.pdf
- 2013 UN Psychology Day Program.pdf
- 2014 UN Psychology Day Program.pdf
- 2015 UN Psychology Day Program.pdf
- 2016 UN Psychology Day Program.pdf
- 2017 UN Psychology Day Program.pdf
- 2018 UN Psychology Day Program.pdf
- 2019 UN Psychology Day Program.pdf
- 2020 UN Psychology Day Program.pdf
- 2021 UN Psychology Day Program.pdf
- 2022 UN Psychology Day Brochure.pdf
- 2023 UN Psychology Day Program (website link)
- 2024 UN Psychology Day Program.pdf
- 2025 UN Psychology Day Program.pdf
- 2026 UN Psychology Day Program.pdf

Suggested Discussion Questions:

1. This final chapter provides a fitting summation and conclusion for our textbook. On pages 209 – 214, the book's editors presented four (4) fundamental questions to consider if we (as proponents of internationalizing psychology) want to "go global" and "meet a world of need".
Question 1: Can We Believe in Something Bigger Than Ourselves?
Question 2: What is our Capacity for Complexity?
Question 3: Can We Cultivate Mind and Heart?
Question 4: What Will We Do With Our Lives?
Choose only one (1) that you find interesting? Briefly explain why you chose it.

2. Do you remember the video you watched from our WEEK 1 discussion forum? - "How Can Students Get Involved in International Psychology?" (https://www.youtube.com/watch?v=oENWlDiFIjc). With the exception of taking this course, specify ONE (1) other relevant way that you can do (or wish you can) to obtain a more international perspective about psychology as it relates to YOUR career/professional objective? Explain why.
(NOTE: Please specify your career/professional objective. If you are unsure of what this may be, base your explanation on how it may benefit your personal life.)

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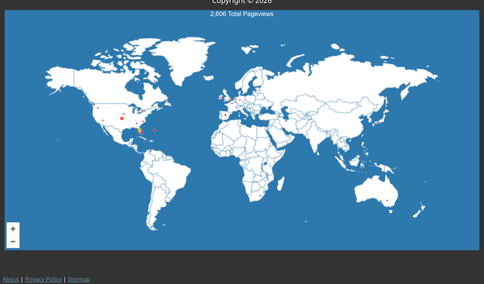

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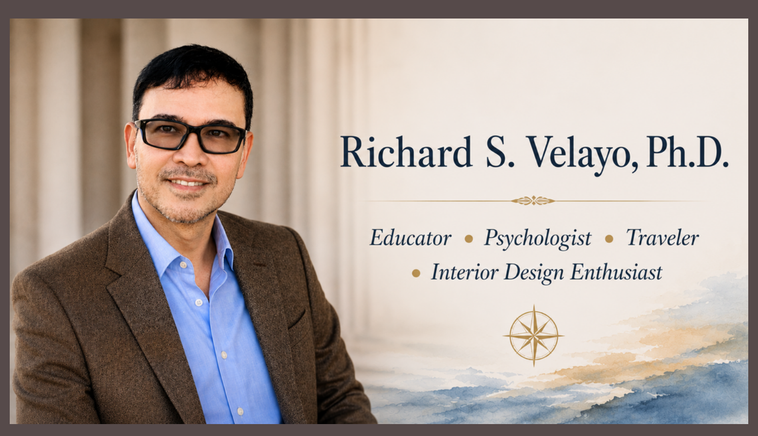

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Psychology Atlas

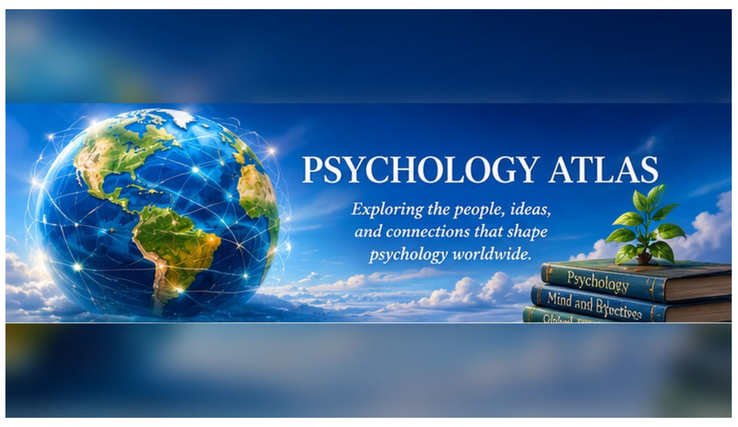

Psychology has been my lifelong profession and one of my greatest passions. These maps highlight the people, organizations, universities, and international collaborations that have contributed to the growth of psychology around the world. Together they illustrate how ideas cross borders and how the science of behavior truly belongs to a global community.

MAP 1 - Foundations of Psychology

Contents (9 layers):

1. World History of Psychology
2. Great Psychologists
3. Psychology Heritage Sites
4. Psychology Museums
5. Nobel Laureates & Psychology
6. Positive Psychology
7. Psychology & the United Nations
8. Psychology & Climate Change
9. Cross-Cultural Psychology

MAP 2 - International Psychology and the World

Contents (7 layers):

10. Indigenous Psychology
11. Psychology Around the World
12. Psychology Organizations
13. Psychology Conferences
14. Psychological Tests Around the World
15. Psychology and Human Rights
16. Psychology in Literature and Film

MAP 3 - Global Psychology Alliance

Explore the organizations and partnerships that unite psychologists in advancing the science and practice of psychology worldwide.

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PSYCHOLOGY 603
Introduction to International Psychology

Instructor:
Email:
Office Hours:
Credits:
Course Format:

Course Description
This graduate-level online course entails reading, discussing, and writing about a variety of contemporary topics in the relatively new specialty of international psychology. You will examine mainstream as well as alternative theoretical, methodological, and applied approaches that are relevant to the study and practice of international psychology. The topics selected offer a broad and deep understanding of this field, specifically, an appreciation of psychology's relevance to the understanding and solution of global problems, as well as of how psychology itself is affected by worldwide events and forces. There will be a Final Paper in the form of an in-depth critique on a topic relevant to the internationalization of psychology.

Prerequisite
There are no graduate course prerequisites. This course is required for students in the "Global Psychology Research track within the MA in Psychology Program (Pace Psychology Dept., NYC campus).

Learning Outcomes
Students in this course will develop and demonstrate competencies in the following areas:
- Knowledge of current foci and future directions of this rapidly growing specialty in the discipline.
- Ability to evaluate critically the appropriateness and consequences of mainstream psychological theory, research, and practices within a global context;
- Familiarity with alternative models, methods, and interventions that have their roots in cultural, economic, historical, political, religious, and social contexts and their relevance to understanding and addressing global phenomena;
- Sensitivity to how global events and forces impact the psychosocial and sociocultural realities of diverse populations; *and*
- Understanding the education and training requirements for a career in international psychology.

Class Delivery Format/Location (General description only)
Online: Course is delivered fully remotely with no on-campus components.
- Asynchronous (ASYNC): CLASSES will be utilized for this course. There will be assignments, quizzes/tests, projects and/or discussions that students have the flexibility to complete within a set period **each week**.

How Do I login to CLASSES (also called "Brightspace")?
This online course is taught using CLASSES which may be accessed at CLASSES.pace.edu. Enter your username and password and click the login button; use your MyPace Portal username and password to login (e.g., cw94975n, tr87689w and jc73732p).

Course Materials (Required text and other materials)

- Shealy, C. N., Bullock, M., & Kapadia, S. (Eds.). (2023). *Going Global: How Psychologists Can Meet a World of Need.* American Psychological Association [(ISBN: 978-1433836435)
  (NOTE: Below are links to two formats of this book. The Kindle format is recommended.)

- Additional relevant readings may be assigned.

Course Requirements

In CLASSES, the course materials are organized within the **TABLE OF CONTENTS.**

1. DISCUSSIONS (Weekly)

Each week begins on (day of the week) and ends on the following (day of the week).
The main purpose of the online discussions is to enhance your learning of the concepts and applications presented in this course, and to further your thinking and writing skills. Discussions are meant to be insightful, reflective, lively, and thought provoking.

Every Monday, your instructor will post a few questions pertaining to the assigned chapter and/or course requirement. You are expected to actively read and comprehend the materials assigned for that week.

INITIAL Response/s: You are expected to regularly and to actively participate in all the weekly discussions by responding (completely and thoroughly) to each question posted.

FEEDBACK Responses: You are also required to provide "quality" feedback to **at least 2** of your other classmates' and/or instructor's initial postings in a way that makes the discussions intellectually stimulating. You are encouraged to respond to more postings if you want a better participation grade for that week.

Grading of Weekly Discussions:
Grading rubric. This form will be used by your instructor.
[NOTE 1: It will be up to your instructor to determine the quality and frequency of your initial responses to the questions and your feedback to your classmates' (including instructor's) postings. This rubric will serve as a basis for the grading of your discussion forum participation.]
[NOTE 2: Responses deemed to be inappropriate may be deleted by your instructor.]

2. ASSIGNMENTS

The two assignments for the course are (1) "Featured International Psychologist" Project, and (2) Final Paper.

- **"Featured International Psychologist" Project –** PowerPoint (10 - 12 slides)

  Your instructor will provide a list of names of relevant international psychologists from which each student in class may choose from. You are required to create a **report in the form of a PowerPoint presentation** (or a comparable/compatible presentation software) that highlights the relevant background and contributions of an esteemed individual on the field of international psychology. In addition to the background information that you find about this person, you are also expected to include relevant images, videos, and audio narration of your voice in your presentation. The more multimedia your presentation, the better. You may use the "add notes" feature of PPT and/or insert your recorded voice/narration if you wish. (*Let me know if you have any questions regarding this.)*

  Your PowerPoint presentation/slides should contain the following information.

1. Background information of Featured Psychologist (with face photo if available)
2. Contributions to International Psychology
3. List of scholarly publications
4. Additional Information of Interest
5. COMMENTARY

In addition, your project will also be evaluated on the following: (i) Quality of slides, and (ii) Notes and/or Audio content.

Grading of "Featured International Psychologist" Project:
Grading rubric. This form will be used by your instructor.
[NOTE: Details about the grading of your final paper will be presented during the semester.]

- **Final Paper** (4 - 5 pages, single-spaced)

Your instructor will provide you with a list of more than 70+ national, regional and international psychological associations that are part of the ***Global Psychology Alliance*** (https://www.apa.org/international/networks/global-psychology-alliance). Each student will be required to write an in-depth critique (reaction paper) on a particular national psychology organization from this list.
[NOTE: The CRITIQUE section of your final paper may include your own comments about the organization, which includes your thoughts and recommendations about its activities and contributions to the internationalization of psychology. Incorporate what you have learned from the textbook and discussion forums. The number of relevant ideas you include will significantly contribute to the grading of your paper.]

Turnitin will be used to submit papers.

The structure and contents of the paper MUST be organized using the following headings.
1. Description of the organization *(approx. 1 page)*
2. Leaders of the organization *(approx. 1 page)*
3. Membership *(approx. 1 page)*
4. Recent news, events, and activities *(approx. 1 page)*
5. CRITIQUE (Commentary about the organization) *(approx.1- 2 pages)*

In addition, your project will also be evaluated on the following: (i) Writing quality, and (ii) Organization of paper.

Grading of Final Paper:
Grading rubric. This form will be used by your instructor.
Student Grade Form: This form will be used by you and your classmates to help grade your paper.
[NOTE: Details about the grading of your final paper will be presented during the semester.]

Grading System

DISCUSSIONS (Weekly)*		
(20 points per week/forum; 14 weeks/forums)	56%	280 points
ASSIGNMENTS**		
"Featured International Psychologist" Project	14%	70
Final Paper		
Instructor Evaluation	20%	100
Student Grade Form (grades are averaged)	8%	40
Submission of Student Grade Form	2%	10
Total Points:		**500**

** 1 point deducted for each day late. (Per initial response and per feedback response.)*
*** 3 points deducted for each day late.*

Letter-Grade Equivalent
("Strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

SCHEDULE

WEEK	TOPIC/s	READING/s*
1	What is International Psychology? Video on "International Psychology: What Student Want to Know"	Syllabus; Additional readings
2	IINTRODUCTION to *Global Psychology:* Why Psychologists Should Meet a World of Need	Textbook (pp. 3 - 13)
3	ADVOCACY: Global Opportunities and Responsibilities for Psychologists	Ch. 1 (pp. 15 - 36)
4	ASSESSMENT: The Power and Potential of Psychological Testing, Educational Measurement, and Program Evaluation Around the World	Ch. 2 (pp. 37 - 58)
5	CONSULTATION: Who Needs Psychological Expertise Around the World and Why?	Ch. 3 (pp. 59 - 74)
6	INTERVENTION: Enhancing Mental Health and Well-Being Around the World	Ch. 4 (pp. 75 - 97)

7	LEADERSHIP: How Psychology and Psychologists Develop Global Leaders and Leadership **DUE: "Featured International Psychologist" Project**	Ch. 5 (pp. 99 - 120)
8	POLICY: Why and How to Become Engaged as an International Policy Psychologist **DUE: TOPIC for FINAL PAPER** *(NOTE: Your topic is one of the participating national psychology associations from the Global Psychology Alliance.)*	Ch. 6 (pp. 121 - 142)
9	NO CLASS (Spring Break)	
10	RESEARCH: International Possibilities and Partnerships for Psychologists	Ch. 7 (pp. 143 - 165)
11	SERVICE: Toward a Global Psychology of Collaboration, Counterflow, and Capacity Building	Ch. 8 (pp. 167 - 182)
12	TEACHING: Opportunities and Recommendations for Internationalizing Psychology Education	Ch. 9 (pp. 183 - 206)
13	CONCLUDING THOUGHTS on *Going Global:* How Psychologists Should Meet a World of Need	Ch. 10 (pp. 207 - 227)
14	**DUE: FINAL PAPER** **DUE: STUDENT GRADE FORM** (for Final Paper)	Final Papers
15	FINAL COURSE GRADES	

**Supplementary readings may be assigned.*

University Policies and Resources

- ***Academic Integrity***

Students in this course are required to adhere to Pace University's Academic Integrity Code, which supports honesty and ethical conduct in the educational process. It educates students about what constitutes academic misconduct, helps to deter cheating and plagiarism, and provides a procedure for handling cases of academic misconduct. Students are expected to be familiar with the Code, which can be found in University Policies, Disciplinary and Grievance Procedures. Individual schools and programs may have additional standards of academic integrity. Students are responsible for familiarizing themselves with the policies of the schools, programs, and courses in which they are enrolled.

[Pace Graduate Students]
Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any academic paper, report, or submission for academic credit without the appropriate acknowledgement is plagiarism. It is also academically dishonest to submit anything in electronic form as one's own that is the work, either fully or in part, of someone else. It is unethical to present as one's own work, the ideas, words, or representations of another without the proper indication of the source. Therefore, it is the student's responsibility to give credit to any quotation, idea or data borrowed from an outside source. Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension, dismissal, or expulsion from the University. (L-54)

- ***Learning Commons***

The Learning Commons uses an array of programs and a holistic approach to assist students with academic skills and content knowledge. We are dedicated to developing independent learners through purposeful interactions with trained, well-qualified peer and professional staff. Services offered:

- Content Support Services including, content tutoring, exam review sessions, & content preparation/support workshops
- Academic Skills Services including small group peer mentoring, academic skills workshops, and individual academic development
- Writing Support Services including, writing tutoring & writing preparation/support workshops

- ***Procedure for Students Who Wish to Obtain Reasonable Accommodations for a Course***

The same rigorous standards for admission apply to students with and without a disability. In order to support the continued success of students with disabilities, the University prohibits discrimination on the basis of disability and is committed to ensuring equal access for students with disabilities to its facilities, programs, and activities. The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities.

To request an accommodation for a qualifying disability, a student must self-identify and register with the Disability Services Office for his or her campus. The Office of Disability Services is housed in the Counseling Center on the New York City and Pleasantville campuses. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see Information for Students with Disabilities page.

- ***Technological Resources***
  - List of all Pace Information Technology Services.
  - For assistance with a technological concern contact the Pace Helpdesk at (914) 773-3648 or create a help desk ticket.
  - Visit the Learning Remotely website

- ***Appropriate Use Policy for Information Technology***

Pace endorses the following statement on software and intellectual rights distributed by EDUCAUSE, the non-profit consortium of colleges and universities, committed to the use and management of information technology in higher education. The statement reads:

> *Respect for intellectual labor and creativity is vital to academic discourse and enterprise. This principle applies to work of all authors and publishers in all media. It encompasses respect for the right to acknowledgment, right to privacy and right to determine the form, manner and terms of publication and distribution.*
>
> *Because electronic information is volatile and easily reproduced, respect for the work and personal expression of others is especially critical in computer environments. Violations of authorial integrity, including plagiarism, invasion of privacy, unauthorized access and trade secret and copyright violations, may be grounds for sanctions against members of the academic community.*

See Pace's IT appropriate use policy.

- ***Sex-Based Misconduct Policy and Procedure***

Pace University is committed to providing a safe environment for every member of its community and to ensuring that no student, faculty, or staff member is excluded from participation in or denied the benefits of any University program or activity on the basis of sex. Accordingly, the University prohibits the following forms of Sex-Based Misconduct: sexual assault, sexual harassment, gender-based harassment, dating violence, domestic violence, sexual exploitation, and stalking.

Instructors are a **non-confidential** resource and have an obligation to report any information about sexual assault with the Executive Director of Institutional Equity and Title IX Coordinator – Bernard Dufresne, bdufresne@pace.edu, 163 Williams Street, Room 1017, (212) 346-1310. The Title IX/Affirmative Action Office is responsible for investigating violations of the sexual misconduct policy. Go here for more information about the Pace University sexual misconduct policy.

Members of the University community who believe that they have been subjected to Sex-Based Misconduct are encouraged to report such incidents to the University and, where applicable, to local law enforcement. **Confidential** resources include the **University Counseling Centers, Offices of Sexual and Interpersonal Wellness** and **University Healthcare**. Contact information for those offices may be found in the self-care section below.

- ***Self-Care***

Your academic success in this course and throughout your college career depends heavily on your personal health and well-being. Stress is a common part of the college experience, and it often can be compounded by unexpected life changes outside the classroom. The Pace Community strongly encourages you to take care of yourself throughout the term before the demands of midterms and finals reach their peak. Please feel free to talk with me about any difficulty you may be having that may impact your performance in this course as soon as it occurs and before it becomes unmanageable. Please know there are a number of other support services on campus that stand ready to assist you. You are strongly encouraged to contact them when needed as well.

The Counseling Center "Just In Case" information supplies potentially life-saving mental health information to Pace University students, staff, and faculty, putting vital information and support options at your fingertips, just in case you or a friend needs help. Go to the Just in Case page on the Pace website or go to "Counseling Center" on the MyPace or the Pace Safe app.

Department	**Pleasantville**	**New York City**
Advising Center for Exploring Majors	First-year: (914) 773-3756 | (914) 773-3757	(212) 346-1798
Affirmative Action Office	(914) 923-2610	(212) 346-1310
Center for Spiritual Development	(914) 773-3767	
College of Health Professions Academic Advisement	UG (914) 773-3961 UG (914) 773-3347 Grad (914) 773-3114	UG (212) 618-6027 Grad (914) 773-3114
Counseling Center	(914) 773-3710	(212) 346-1526
Dean for Students Office	(914) 773-3351	(212) 346-1306
Dyson College Academic Advisement	(914) 773-3781	(212) 346-1518
International Student/Scholars	(212) 346-1368	
Lubin School of Business Academic Advisement	UG (914) 773-3531	UG (212) 618-6550 Grad (212) 618-6440
Office of Multicultural Affairs	(914) 773-3628	(212) 346-1546
Office of Sexual and Interpersonal Wellness	(212) 346-1931	
Office of Student Assistance (OSA)	(877) 672-1830	
Pace Women's Justice Center	(914) 287-0739	
Pforzheimer Honors College Academic Advisement	(212) 346-1697	
Residential Life	(914) 597-8777	(212) 346-1295
Seidenberg School Academic Advisement	SeidenbergInquiry@pace.edu	
Sexual Assault Prevention & Education	(212) 346-1931	
Study Abroad	(212) 346-1368	
Student Accessibility Services	(914) 773-3710	(212) 346-1526
Student Engagement	(914) 773-3767	(212) 346-1590
University Health Care	(914) 773-3760	(212) 346-1600

-End-

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Florida Homes

My Florida homes reflect the peaceful lifestyle I enjoy in retirement. From lakeside living to Gulf Coast sunsets, these places have become personal retreats for relaxation, reflection, and everyday happiness.

My Zen Island Beach Havens

Florida has become an important part of my life's journey. I fondly refer to my two homes as my **Zen Island Beach Havens—or simply my Zenis.** Each offers its own character and rhythm of life, while sharing the sense of comfort, tranquility, and connection to nature that I value.

MAP - Florida Homes

Zeni 1 - Central Florida Home

Zeni 1, located in the Metro Orlando area, is my primary Florida home—a warm, tropical-inspired retreat for everyday living, family gatherings, and enjoying the many attractions of Central Florida.

The Zeni 1 aesthetic blends warm contemporary design with subtle tropical and coastal influences. Neutral tones, natural textures, dark wood, greenery, and touches of aqua and coral create a relaxed, resort-inspired atmosphere. The design emphasizes comfort, visual balance, and an easy connection between indoor and outdoor living—reflecting both Florida life and a lifelong appreciation for travel, welcoming spaces, and the places that feel like home.

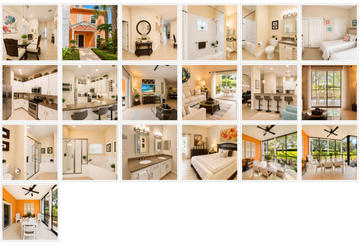

Clubhouse & Main Pool

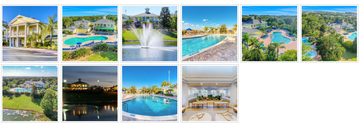

Lake Davenport & Private Pier

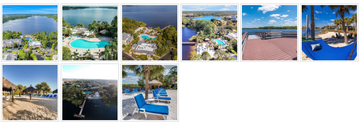

Recreation

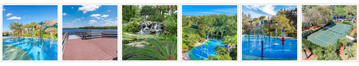

Spa & Wellness

Tropical Grounds & Nature Trail

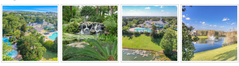

Zeni 2 - Gulf Coast Retreat

Zeni 2, located in St. Petersburg, is my Gulf Coast retreat—a relaxed, light-filled home for enjoying beaches, breathtaking sunsets, waterfront parks, and the easygoing character of coastal Florida.

The Zeni 2 aesthetic reflects a relaxed coastal-contemporary style inspired by Florida's Gulf Coast. Soft neutrals, warm wood tones, shades of blue and aqua, natural textures, and simple furnishings create an airy, casual atmosphere. The design emphasizes comfort, light, and an easygoing connection to the outdoors—evoking the feeling of a coastal retreat shaped by sunshine, water, and the slower rhythm of St. Petersburg living.

Clubhouse & Pool

Grounds

Two Homes, Two Rythms.

Together, my Zenis represent two sides of the Florida life I have come to enjoy—one centered on the familiarity and energy of Central Florida, the other on the relaxed coastal character of St. Petersburg. Both are places where I can slow down, appreciate my surroundings, and simply enjoy being home.

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Florida Favorites

These are some of my favorite places in Florida—destinations that I enjoy returning to for their beauty, history, culture, and the simple pleasures they bring to everyday life.

MAP - Florida Favorites

Places I Return To

Some places become favorites not because they are famous, but because something about them keeps drawing us back. These are a few of the places that have become part of my experience of living, exploring, and enjoying Florida.

St. Petersburg

Favorite Florida City

St. Petersburg is one of my favorite Florida cities, combining a beautiful waterfront, a walkable downtown, interesting neighborhoods, museums, restaurants, and the relaxed atmosphere of Florida's Gulf Coast.

What I especially enjoy is the variety. A visit can include walking along the waterfront, exploring downtown, enjoying a meal, visiting one of the city's museums, or simply spending time outdoors. It is a place that feels both lively and relaxed, and one I continue to enjoy returning to.

Featured Video

Celebration

Favorite Florida Town

Celebration has always interested me because it feels quite different from most communities in Central Florida. Originally developed by The Walt Disney Company, it combines traditional architecture, tree-lined streets, lakes, walking paths, shops, and restaurants within a carefully planned town.

I especially enjoy its walkability and welcoming atmosphere. It is the kind of place where simply strolling around the lake, exploring the town center, having a meal, or sitting outdoors can be the experience itself. Its distinctive character makes Celebration one of the Florida communities I enjoy visiting again and again.

Featured Video

Clearwater Beach

Favorite Florida Beach

Clearwater Beach represents much of what I enjoy about Florida's Gulf Coast—white sand, warm water, beautiful sunsets, and an easygoing seaside atmosphere. It offers the pleasures of a beach destination while still having plenty of restaurants, activities, and places to explore nearby.

For me, however, its greatest appeal is much simpler: being near the water. There is something restorative about looking across the Gulf, walking along the beach, and watching the sun set over the horizon. Sometimes the simplest experiences become the most memorable.

Featured Video

Wat Florida Dhammaram

Favorite Spiritual Place

Wat Florida Dhammaram is one of the more unexpected and peaceful places I have discovered in Central Florida. The Buddhist temple and monastery provide a quiet setting surrounded by statues, gardens, and representations of Buddhist traditions.

What I appreciate most is the contrast between this peaceful setting and the busy attractions for which Central Florida is better known. It offers an opportunity to slow down, observe, reflect, and experience a different cultural and spiritual tradition. Places like this remind me that meaningful discoveries can sometimes be found surprisingly close to home.

Featured Video

Nipa Hut

Favorite Filipino Restaurant

Nipa Hut is one of my favorite places to enjoy Filipino food in Central Florida. Its casual atmosphere and familiar dishes offer something beyond simply going out for a meal—they provide a connection to the tastes, traditions, and culture of the Philippines.

Having grown up in the Philippines, Filipino food carries memories and associations that make the experience especially meaningful to me. Places such as Nipa Hut are reminders that even after making a home somewhere new, familiar flavors can provide a small but comforting connection to where one's journey began.

Featured Video

More Florida Favorites to Come

Florida continues to surprise me, and this collection will undoubtedly grow as I discover new places—and return to old favorites—along the way.

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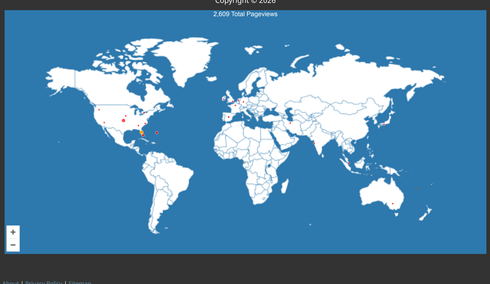

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Cruises

Cruising has taken me to remarkable destinations and created some of my most memorable travel experiences. Each voyage has offered new adventures and opportunities to discover the world from a different perspective. From short escapes close to home to journeys across Europe, the Caribbean, Hawaii, and Asia, this page traces those travels through the ships, destinations, and experiences that have become part of my journey.

Cruises Through the Years

The voyages that have taken me to destinations near and far.

MAP - Placed Visited

MAP - Future Trips

Upcoming Cruises (4)

Mariner of the Seas
(Royal Caribbean Cruise Line)
July 23 - 30, 2027

Itinerary: Barcelona, Spain | Palma de Mallorca, Spain | Malaga, Spain | Casablanca, Morocco | Tangier, Morocco | Lisbon, Portugal

Navigator of the Seas
(Royal Caribbean Cruise Line)
March 9 - 13, 2027

Itinerary: Singapore, Singapore | Penang, Malaysia | Phuket, Thailand | Singapore, Singapore

Valiant Lady
(Virgin Voyages Cruise Line)
December 12 - 19, 2026

Itinerary: San Juan, Puerto Rico | Philipsburg, St. Maarten | Bridgetown, Barbados | Castries, St. Lucia | Fort-de-France, Martinique | Basseterre, St. Kitts and Nevis | San Juan, Puerto Rico

Valiant Lady
(Virgin Voyages Cruise Line)
August 20 -27, 2026

Itinerary: Portsmouth, UK | Zeebrugge (Bruges), Belgium | Amsterdam, Netherlands | Hamburg, Germany | Hamburg, Germany | Portsmouth, UK

Cruises Through the Years (16)

Islander
(Margaritaville at Sea)
March 9 - 13, 2026

Itinerary: Tampa, FL | Progreso/Merida, MX | Tampa, FL

Brilliant Lady
(Virgin Voyages)
December 7 - 18, 2025

Itinerary: Miami, FL | Oranjestad, Aruba | Cartagena, Colombia | Ochos Rios, Jamaica | George Town, Grand Cayman Islands | Miami, FL

MSC Seashore
(MSC Cruise Line)
August 28 - 31, 2025

Itinerary: Orlando (Port Canaveral), FL | Nassau, Bahamas | Ocean Cay MSC Marine Reserve (Bahamas) | Orlando (Port Canaveral), FL

Utopia of the Seas
(Royal Caribbean Cruise Line)
January 10 - 13, 2025

Itinerary: Orlando (Port Canaveral), FL | Nassau, Bahamas | Perfect Day Coco Cay (Bahamas) | Orlando (Port Canaveral), FL

Resilient Lady
(Virgin Voyages Cruise Line)
May 4 - 11, 2025

Itinerary: Athens (Piraeus), Greece | Split, Croatia | Dubrovnik, Croatia | Kotor, Montenegro | Mykonos, Greece | Athens (Piraeus), Greece

Valiant Lady
(Virgin Voyages Cruise Line)
December 15 - 20, 2024

Itinerary: Miami, FL | Puerto Plata, Dominican Republic | Bimini, Bahamas | Miami, FL

Scarlet Lady
(Virgin Voyages Cruise Line)
May 19 - 26, 2024

Itinerary: Barcelona, Spain | Toulon, France | Marina di Carrara, Italy | Civitavecchia (Rome), Italy | Ibiza, Spain | Barcelona, Spain

Norwegian Bliss
(Norwegian Cruise Line)
January 7-12, 2024

Itinerary: Los Angeles, CA | Cabo San Lucas, Mexico | Los Angeles, CA

Scarlet Lady
(Virgin Voyages)
December 13 - 17, 2023

Itinerary: Miami, FL | Key West, FL | Cozumel, Mexico | Miami, FL

Norwegian Escape
(Norwegian Cruise Line)
January 7 - 14, 2023

Itinerary: Orlando (Port Canaveral), FL | St. Thomas, US Virgin Islands | Tortola, British Virgin Islands | Orlando (Port Canaveral), FL

Brilliance of the Seas
(Royal Caribbean Cruise Line)
December 15 - 19, 2022

Itinerary: Tampa, FL | Key West, FL | Nassau, Bahamas | Tampa, FL

Disney Dream
(Disney Cruise Line)
May 13 - 16, 2022

Itinerary: Orlando (Port Canaveral), FL | Nassau, Bahamas | Castaway Cay, Bahamas | Orlando (Port Canaveral), FL

Norwegian Sun
(Norwegian Cruise Line)
January 3 - 8, 2020

Itinerary: Orlando (Port Canaveral), FL | Costa Maya, Mexico | Cozumel, Mexico | Orlando (Port Canaveral), FL

Mariner of the Seas
(Royal Caribbean Cruise Line)
November 18 - 18, 2019

Itinerary: Orlando (Port Canaveral), FL | Nassau, Bahamas | Perfect Day Coco Cay, Bahamas | Orlando (Port Canaveral), FL

Pride of America
(Norwegian Cruise Line)
August 3 - 10, 2013

Itinerary: Honolulu, Oahu | Kahului, Maui | Hilo, Hawaii | Kona, Hawaii | Nawiliwili, Kauai | Honolulu, Oahu

Pride of Aloha
(on Norwegian Sky)
(Norwegian Cruise Line)
July 31 - August 7, 2004

Itinerary: Honolulu, Oahu | Nawiliwili, Kauai | Hilo, Hawaii | Kona, Hawaii | **Kahului, Maui** | Honolulu, Oahu

The Journey Continues

What began as another way to travel has become one of my favorite ways to experience the world. Each voyage has brought something different—new destinations, familiar places seen from another perspective, and memories created along the way. As long as there are new places to discover, I hope there will always be another journey ahead.

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Travel

Travel has enriched my life by introducing me to new places, cultures, and perspectives. Every journey has deepened my appreciation for the diversity, beauty, and shared humanity of our world.

Travel has been one of the great teachers in my life, offering opportunities to experience new places, encounter different cultures, and see the world from new perspectives. From exploring the communities of Florida to traveling across the United States and abroad, each journey has added something to my understanding of the places we call home and the wider world we share.

The sections below trace those journeys—from places close to home to destinations around the world—and the maps offer another way to explore where I've been and where I hope to go next.

Florida Travels

31 Cities & Communities

Florida has been home for many years, but it has also been a place of continuing discovery. From the communities where I've lived to favorite destinations and places discovered along the way, these travels reflect my experience of exploring the state I now call home.

MAP - Florida Homes

MAP - Florida Favorites

MAP - Florida Cities Visited

Northwest (7)

Escambia County
- Pensacola

Santa Rosa County
- Milton
- Navarre
- Pace

Okaloosa County
- Crestview

Bay County
- Panama City

Leon County
- Tallahassee

North (7)

Alachua County
- Gainesville

Clay County
- Fleming Island
- Oakleaf Plantation

Duval County
- Jacksonville

Marion County
- Ocala

St. Johns County
- St. Augustine
- St. Augustine Beach

Central (36)

Brevard County
- Cocoa
- Melbourne
- Palm Bay
- Titusville

Flagler County
- Palm Coast

Lake County
- Clermont
- Eustis
- Leesburg
- Mount Dora
- Tavares
- The Villages

Orange County
- Apopka
- Ocoee
- Orlando
- Winter Garden
- Winter Park

Osceola County
- Kissimmee
- St. Cloud

Polk County
- Auburndale
- Bartow
- Davenport
- Haines City
- Lakeland
- Winter Haven

Seminole County
- Altamonte Springs
- Casselberry
- Longwood
- Oviedo
- Sanford
- Winter Springs

Volusia County
- Daytona Beach
- DeLand
- Deltona
- New Smyrna Beach
- Ormond Beach
- Port Orange

West/Southwest (38)

Charlotte County
- Port Charlotte
- Punta Gorda

Citrus County
- Homosassa Springs

Hernando County
- Brooksville
- Spring Hill

Hillsborough County
- Brandon
- Carrollwood
- Plant City
- Riverview
- Tampa
- Town 'n' Country
- Valrico

Lee County
- Bonita Springs
- Cape Coral
- Estero
- Fort Myers
- Lehigh Acres
- San Carlos Park

Manatee County
- Bradenton
- Lakewood Ranch
- Palmetto

Pasco County
- Holiday
- Land O' Lakes
- New Port Richey
- Wesley Chapel

Pinellas County
- Clearwater
- Dunedin
- Largo
- Palm Harbor
- Pinellas Park
- Seminole
- St. Petersburg
- Tarpon Springs

Sarasota County
- Englewood
- North Port
- Sarasota
- Venice

South (48)

Collier County
- Naples

Indian River County
- Vero Beach

Martin County
- Palm City
- Stuart

Monroe County
- Key West

Palm Beach County
- Boca Raton
- Boynton Beach
- Delray Beach
- Greenacres
- Jupiter
- Lake Worth Beach
- Palm Beach Gardens
- Riviera Beach
- Royal Palm Beach
- Wellington
- West Palm Beach

Broward County
- Coconut Creek
- Coral Springs
- Davie
- Deerfield Beach
- Fort Lauderdale
- Hallandale Beach
- Hollywood
- Lauderhill
- Margate
- Miramar
- Oakland Park
- Pembroke Pines
- Plantation
- Sunrise
- Tamarac
- Weston

Miami-Dade County
- Coral Gables
- Country Club
- Cutler Bay
- Doral
- Fontainebleau
- Hialeah
- Homestead
- Kendall
- Kendall West
- Miami
- Miami Beach
- Miami Gardens
- North Miami
- North Miami Beach

St. Lucie County
- Fort Pierce
- Port St. Lucie

U.S. Travels

30 States

Follow my travels across the United States, including the states I've visited and the places I've lived.

MAP - States Visited

MAP - States Lived In

West (7)

- **Fort Pierce**
- **California**
- **Colorado**
- **Hawaii**
- **Montana**
- **Nevada**
- **Washington**
- **Wyoming**

Southwest (2)

- **Arizona**
- **Texas**

Midwest (5)

- **Illinois**
- **Michigan**
- **Missouri**
- **Ohio**
- **South Dakota**

Southeast (7)

- **Florida (HOME)**
- **Georgia**
- **Louisiana**
- **Mississippi**
- **North Carolina**
- **South Carolina**
- **Virginia**

Northeast (9)

- **Connecticut**
- **Delaware**
- **Maryland**
- **Massachusetts**
- **New Hampshire**
- **New Jersey**
- **New York**
- **Pennsylvania**
- **Rhode Island**

World Travels

31 Countries & Territories

International travel has given me some of my most memorable experiences and has deepened my appreciation for different cultures, histories, and ways of life. These destinations trace my travels beyond the United States, as well as some of the places I hope to discover in the years ahead.

MAP - Places Visited

MAP - Future Trips

North America / Caribbean (15)

Bahamas
(Bimini, Nassau)

Barbados (TBV)
(Bridgetown)

British Virgin Islands
(Tortola)

Canada
(Toronto)

Cayman Islands
(George Town)

Dominican Republic
(Puerto Plata)

Jamaica
(Ochos Rios)

Martinique (TBV)
(Fort-de-France)

Mexico
Baja California Sur (Cabo San Lucas, San Jose del Cabo
Quintana Roo (Cancun, Costa Maya, Cozumel, Playa del Carmen, Tulum)
Yukatan (Izaua, Merida, Progreso, Valladolid)

Puerto Rico (TBV)
(San Juan)

St. Kitts & Nevis (TBV)
(Basseterre)

St. Lucia (TBV)
(Castries)

St. Maarteen (TBV)
(Philipsburg)

United States
(Home)

US Virgin Islands
(St. Thomas)

Europe (10)

Belgium (TBV)
(Zeebrugge)

Croatia
(Split, Dubrovnik)

France
Eu
(Castelet, Marseille, Toulon)

Germany (TBV)
(Hamburg)

Greece
(Athens, Piraeus, Mykonos)

Italy
(Florence, Marina di Carrara, Pisa, Rome, Vatican City)

Montenegro
(Kotor)

Netherlands (TBV)
(Amsterdam)

United Kingdom (TBV)
(London, Portsmouth, Westminster)

Spain
(Barcelona, Ibiza, Sitges)

Asia (4)

China
(Hong Kong, Macau)

Japan
(Tokyo, Tsukuba)

Philippines
(Metro Manila, Baguio, Pangasinan, Tagaytay)

Singapore
(Central Area)

South America (2)

Aruba
(Oranjestad)

Colombia
(Cartagena)

Africa (0)

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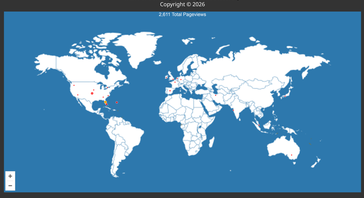

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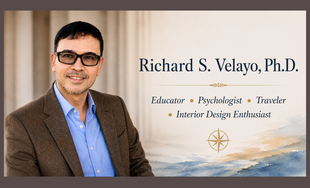

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Zen Living & Wellness

Living well is about finding balance, purpose, and peace in everyday life. This page reflects some of the practices, ideas, and resources that inspire me to nurture physical health, emotional well-being, and a more mindful way of living.

My Approach to Living Well

For me, living well means finding a comfortable balance among physical health, emotional well-being, meaningful relationships, personal growth, and simply enjoying life. I value moments of quiet and reflection, but also travel, learning, new experiences, and time spent with people who matter to me. I try to appreciate the present while remaining curious about what life still has to offer.

"What if our religion was each other? If our practice was our life? What if the temple was the Earth? If forests were our church? If holy water - the rivers, lakes, and oceans? What if meditation was our relationships? If the Teacher was life? If wisdom was knowledge? If love was the center of our being."
— Ganga White

Finding Calm & Balance

Quiet moments can provide an opportunity to slow down, clear the mind, and reconnect with the present. Music, nature, and peaceful surroundings are some of the simple ways I enjoy creating a sense of calm and balance in everyday life.

Stingray Naturescape

A relaxing combination of beautiful natural scenery and soothing music that can provide a peaceful background for reflection, relaxation, or simply unwinding.

Ideas That Inspire Me

Over the years, I have found value in ideas that encourage reflection, personal growth, emotional well-being, and a greater appreciation of everyday life. The following are a few resources and perspectives that I have found interesting or meaningful.

17 Zen Tips for Practicing Gratitude All Day Long (Sifu Anthony Korahais)
https://flowingzen.com/18103/17-zen-tips-for-practicing-gratitude-all-day-long/

The Beginner's Guide to Zen Living: 10 Steps to Transforming Your Life with the Spirit of Zen (Matt Valentine)
https://buddhaimonia.com/blog/zen-living

How to Create a Mini-Retreat at Home (The Buddhist Review: Tricycle)
https://tricycle.org/trikedaily/home-meditation-retreat/

Free template: The half-day (and full-day) at-home meditation retreat (A Life of Productivity)
https://alifeofproductivity.com/free-template-at-home-meditation-retreat/

The Fear of Being Alone (Leo Babauta)
https://zenhabits.net/joy-of-one/

Videos & Channels I Enjoy

The following are a few channels I enjoy for their perspectives on mindfulness, philosophy, emotional well-being, and living a more thoughtful life.

Share Ideas
Thought-provoking short films exploring spiritual, psychological, intellectual, and philosophical ideas.

The School of Life
Explores psychology, philosophy, relationships, and emotional well-being with an emphasis on understanding ourselves and living more thoughtfully.

Philosophies for Life
Presents wisdom from ancient philosophers and applies their ideas to the challenges and opportunities of modern life.

Plum Village
Offers teachings and practices inspired by Zen Master Thich Nhat Hanh, with an emphasis on mindfulness, compassion, peaceful living, and connection with others and the natural world.

For me, living well is less about seeking perfection than about appreciating the present, remaining open to growth, and finding meaning and joy along the way.

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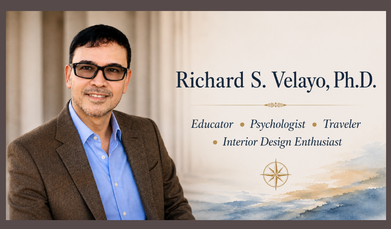

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Finance

Financial well-being provides the freedom and security to pursue the experiences that matter most. This page reflects some of the principles, ideas, and resources that have helped me plan for a secure, independent, and fulfilling retirement.

My Approach to Financial Well-Being

For me, financial well-being is not simply about accumulating wealth. It is about creating security, maintaining independence, and having the freedom to enjoy life. Thoughtful saving, investing, and retirement planning have allowed me to focus more on the experiences I value—travel, learning, relationships, and making the most of retirement—while also preparing responsibly for the future.

Financial Resources I Have Found Useful

Over the years, I have used a variety of resources to learn more about retirement planning, investing, and financial independence. The following are a few that I have found particularly useful.

Financial Samurai

A personal-finance resource offering perspectives on investing, retirement planning, financial independence, real estate, and other financial topics.

Boldin

A comprehensive retirement-planning resource that offers tools for exploring retirement income, spending, investments, taxes, and long-term financial scenarios.

Empower

A financial planning and investment-management resource with tools for tracking investments, retirement accounts, spending, and overall financial progress.

Financial security has never been an end in itself for me. Its greatest value is the freedom it provides—to make choices, enjoy meaningful experiences, help others when possible, and approach the future with greater confidence and peace of mind.

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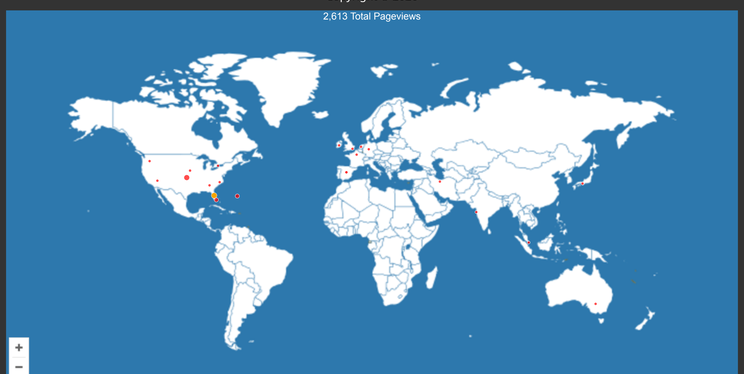

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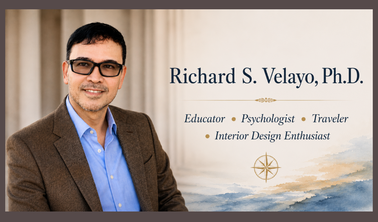

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Giving

Giving back is one of life's most meaningful rewards, reflecting the values of compassion, gratitude, and a desire to make a positive difference in the lives of others.

Why Giving Matters to Me

I believe that even modest acts of generosity can make a meaningful difference. The causes I have chosen to support reflect concerns that are personally important to me—including helping children overcome poverty, protecting animals from cruelty, supporting people in vulnerable circumstances, and promoting dignity, acceptance, and opportunity for LGBTQ individuals. Giving is one way I can express gratitude for what life has given me while helping others along the way.

Causes and Organizations I Support

children international™

Children International

An organization dedicated to helping children and families overcome poverty through access to education, health care, nutrition, and opportunities for a better future.

HUMANE SOCIETY INTERNATIONAL

Humane World for Animals

formerly Humane Society International

An international animal-welfare organization working to protect animals from cruelty, improve their well-being, respond to disasters, and strengthen the bond between people and animals.

Nazareth House - Catholic Worker (Bahay Nazareth)

A house of hospitality in the Philippines serving people in vulnerable circumstances, including individuals living with HIV or AIDS who may lack adequate housing or family support. Its commitment to compassion, dignity, inclusion, and care for those in need makes its mission especially meaningful.

Email: bahaynazareth@gmail.com
Nazareth House Facebook Page: https://www.facebook.com/groups/1083887471739199/

THE TREVOR PROJECT
saving young lives

The Trevor Project

An organization dedicated to supporting LGBTQ young people through crisis services, advocacy, education, and efforts to create a safer and more accepting world.

Giving reminds me that a meaningful life is measured not only by what we experience and accomplish for ourselves, but also by the kindness, compassion, and opportunities we are able to extend to others.

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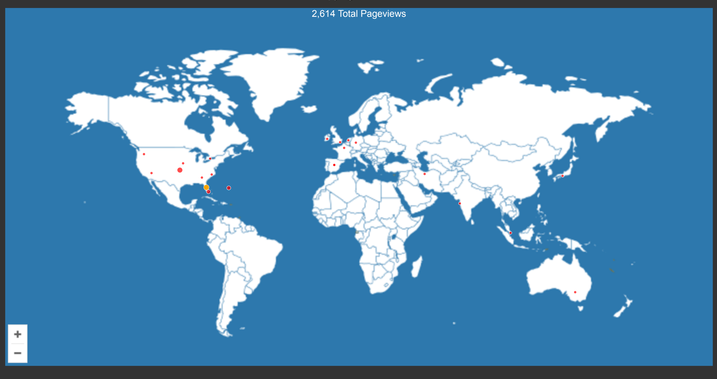

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DESIGN HOME Gallery

Beautiful spaces have the power to inspire, comfort, and spark creativity.

Design Home has become one of my favorite creative hobbies, allowing me to explore interior design in a fun, relaxing, and imaginative way. Although I have no formal training in interior design, I enjoy experimenting with color, texture, balance, lighting, and furnishings to create spaces that are both comfortable and visually appealing. The homes featured in this gallery represent some of my favorite designs created using the Design Home app and reflect a variety of architectural styles and locations from around the world. Earning a 5-star rating is always rewarding, but even more enjoyable is the creative process itself and the opportunity to express my own sense of style through each room I design. Every room begins with imagination, where creativity transforms an empty space into a place that feels like home.

FEATURED VIDEOS: The Design Home App

Featured Video 1

Link: https://youtu.be/y2RlDuW6KA

Featured Video 2

Link: https://youtube.com/shorts/qNfzuAMdCIA?si=RqHPZMWCOvNcr9ua

Displayed below are my home design spaces generated by the Design Home App.
(1) My 5-Star Designs (Slideshow)
(2) My Featured Homes (Click each photo to view the slideshow of the home...)

My 5-Star Designs (n=160)

DESIGN HOME™

OUT IN THE FIELD ★ 5.00!

Featured Homes

Here are various types of virtual homes from different parts of the world that I have designed using the Design Home app. The rooms (interiors) for each home features my various design aesthetic.
Click the "Slideshow" button to view each area of the home.

Deluxe Townhome 1
(Santa Monica, California)

Slideshow

Townhouse 2
(Norwalk, Connecticut)

Slideshow

Dream Home 3
(Eagle, Idaho)

Slideshow

Main Home 4
(Vancouver, Canada)

Slideshow

Coastal House 5
(Montauk, New York)

Slideshow

Penthouse 6
(Miami, Florida)

Slideshow

Tropical Villa 7
(Sao Paulo, Brazil)

Slideshow

Mountain Lodge 8
(Sao Paulo, Brazil)

Slideshow

Mid-Century Style Home 9
(Palm Springs, California)

Slideshow

Chateau 10
(Loire Valley, France)

Slideshow

Industrial Loft 11
(Montreal, Canada)

Slideshow

Tree House 12
(Whistler, Canada)

Slideshow

Greek Villa 13
(Santorini, Greece)

Slideshow

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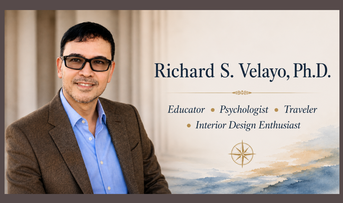

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Digital Artwork

Creativity continues to evolve, and technology has opened exciting new ways to imagine, create, and share ideas.

My Digital Canvas Photos are created by transforming original photographs into digital artwork, many of which are stylized to resemble oil paintings on canvas. I enjoy creating images that are colorful, bold, and vibrant, often featuring soft, flowing brushstrokes that give each piece a painterly feel. Most of my artwork is presented in a 16:9 widescreen format, making it well suited for display on computer monitors and televisions. My favorite subjects include abstract compositions, close-ups, interiors, landscapes and cityscapes, self-portraits, and still life. From time to time, I also create pieces that do not fit neatly into a single category but simply capture a scene, pattern, or moment that inspires me.
Creating these digital artworks allows me to combine my interests in photography, creativity, and technology while exploring new ways of seeing familiar subjects.

FEATURED ARTWORK

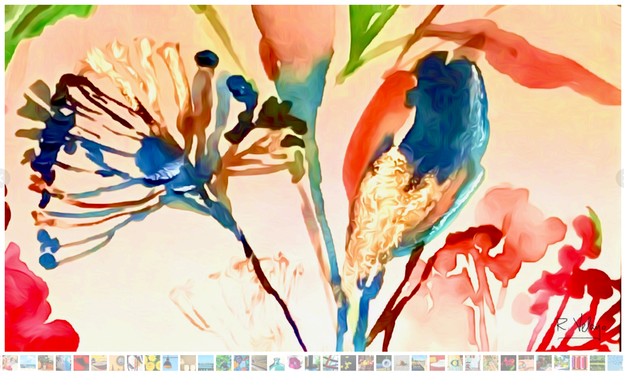

ART GENRES COLLECTION

Abstract

Close Ups

Interiors

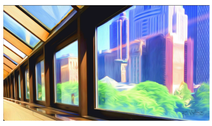

Scapes

Still Life

Others

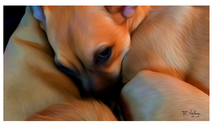

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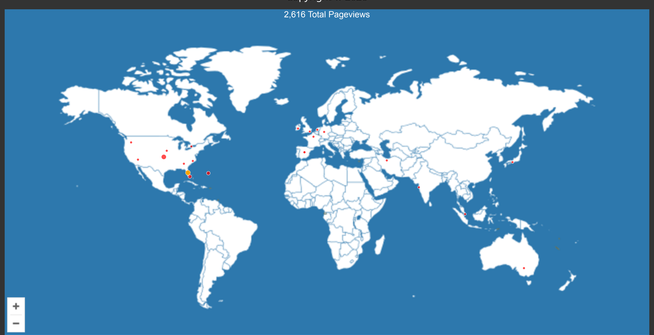

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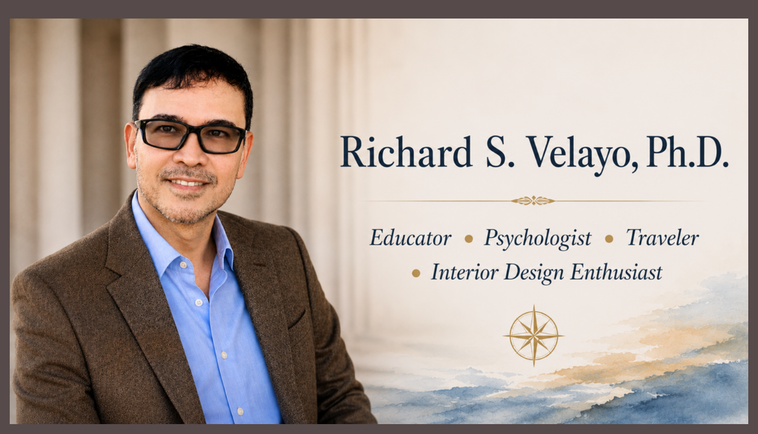

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Self-Portraits

Every portrait tells a story—not only of how we look, but of who we are becoming.

This gallery features AI-generated self-portraits inspired by some of my recent photographs. Rather than serving as traditional portraits, these images represent a creative and playful exploration of how artificial intelligence can reimagine familiar photographs through a variety of artistic styles and interpretations. As someone who has always enjoyed learning about emerging technologies, I created this collection to better understand the creative possibilities of AI and its potential for personal expression. Over time, I hope to expand this gallery with AI-generated portraits inspired by photographs from different stages of my life, creating a visual journey that combines memory, creativity, and technology.

Note: *The images in this gallery are AI-generated artistic interpretations inspired by my photographs and are intended as a creative exploration rather than actual photographic portraits.*

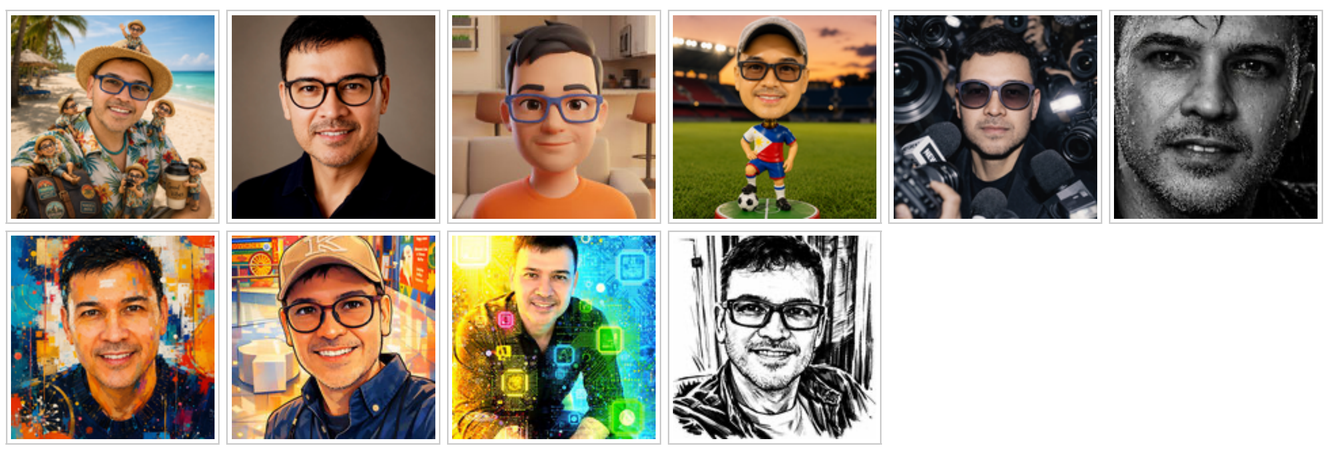

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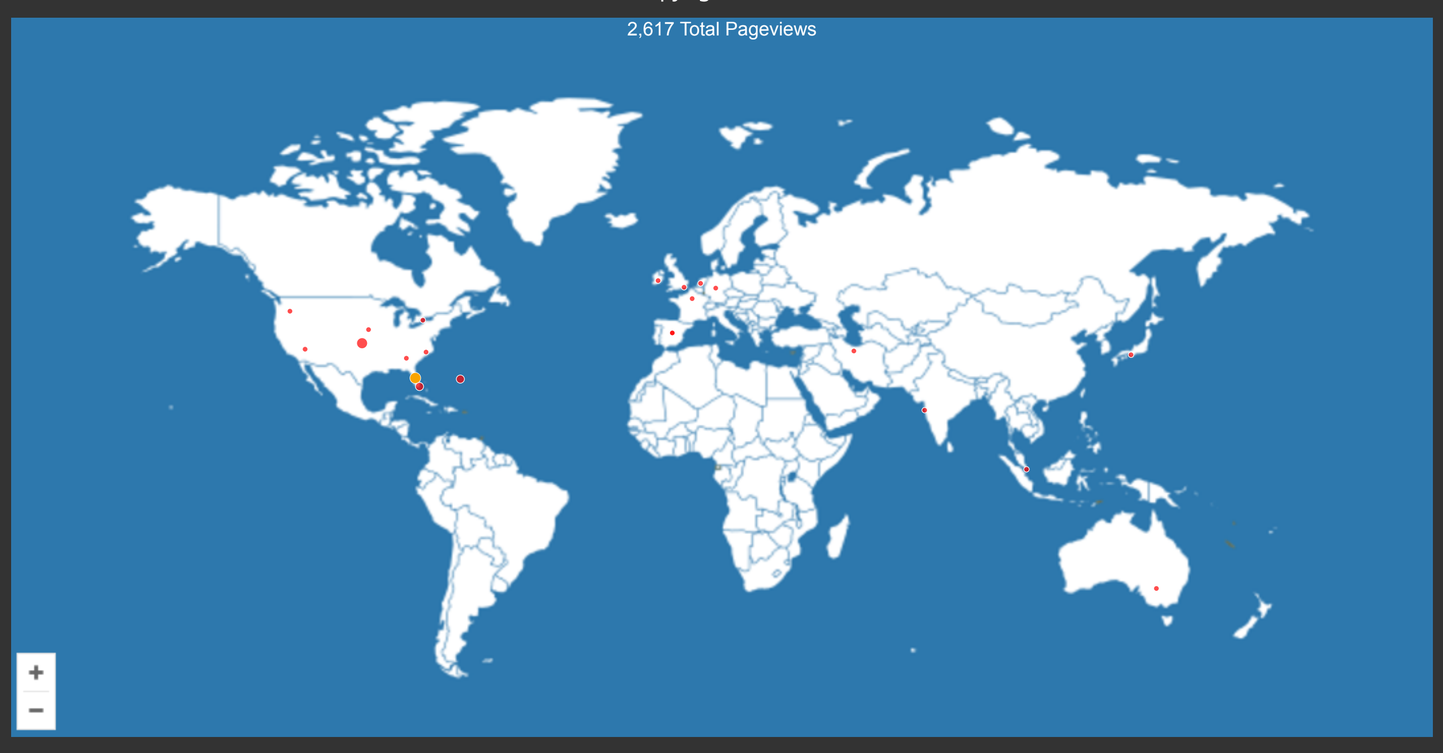

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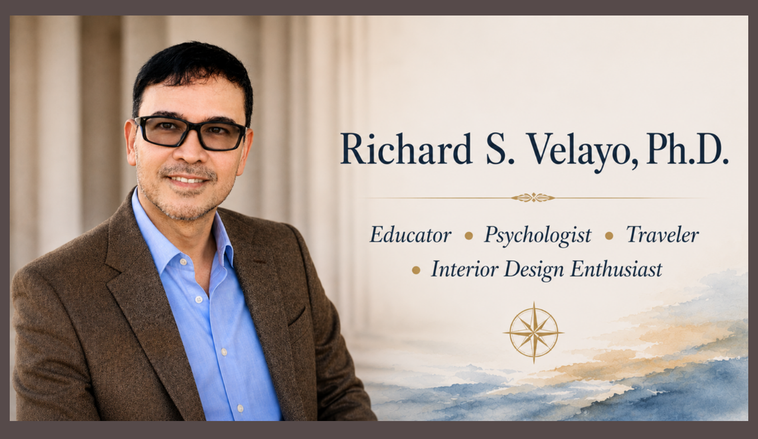

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Florida Maps

Florida has been my home for many years, but it has also been a place of continual discovery. From favorite restaurants and hidden gems to communities I've visited and places I've lived, these maps reflect countless day trips, weekend adventures, and memorable experiences throughout the Sunshine State.

MAP - Florida Homes

MAP - Florida Favorites

MAP - Florida Cities Visited

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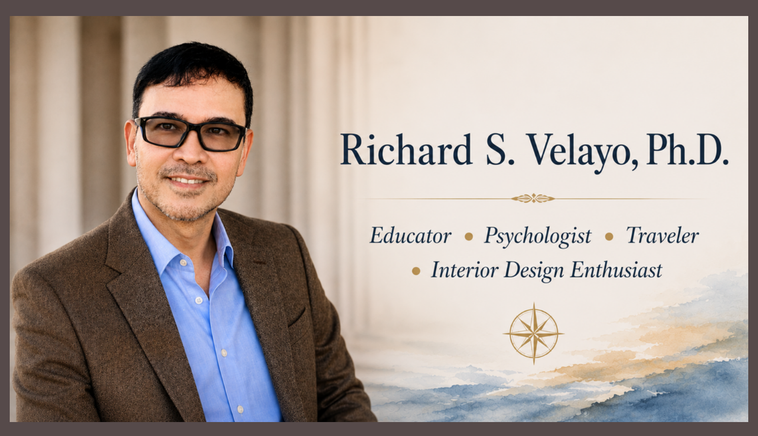

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U.S. Maps

Although Florida is home, my travels throughout the United States have taken me to many remarkable places. These maps trace both the places I've visited and the states I've called home over the years.

MAP - States Visited

MAP - States Lived In

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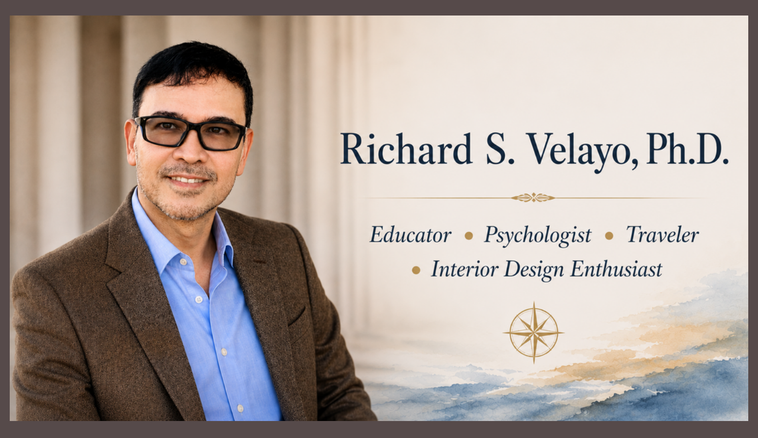

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World Map

Traveling internationally has broadened my appreciation for history, culture, and the remarkable diversity of our world. This interactive map includes countries and cities I have visited, along with destinations that remain on my travel wish list. Every journey offers an opportunity to learn something new—not only about the places we visit, but also about ourselves.

MAP - Places Visited

MAP - Future Trips

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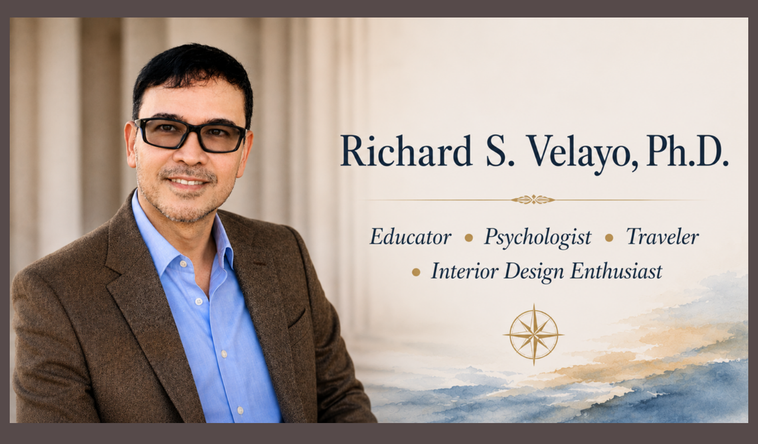

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Interiors

Finding inspiration... in awe-inspiring interior spaces. Notice the harmony in form and in function of objects in the space. Laud the use of color, proportion, symmetry, contrast, and brightness of the space. Feel yourself immersed in these spaces.

Featured INTERIORS Art...

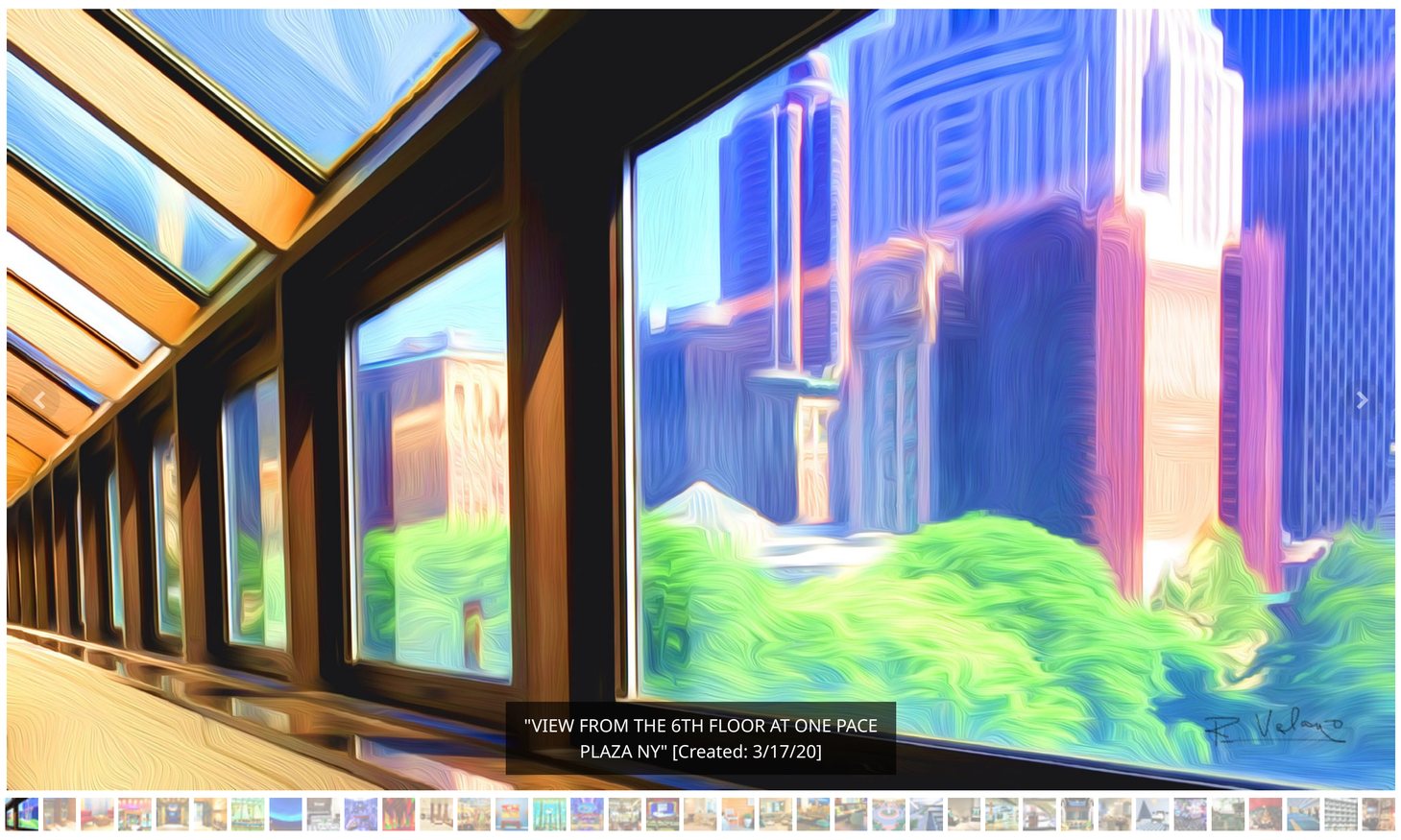

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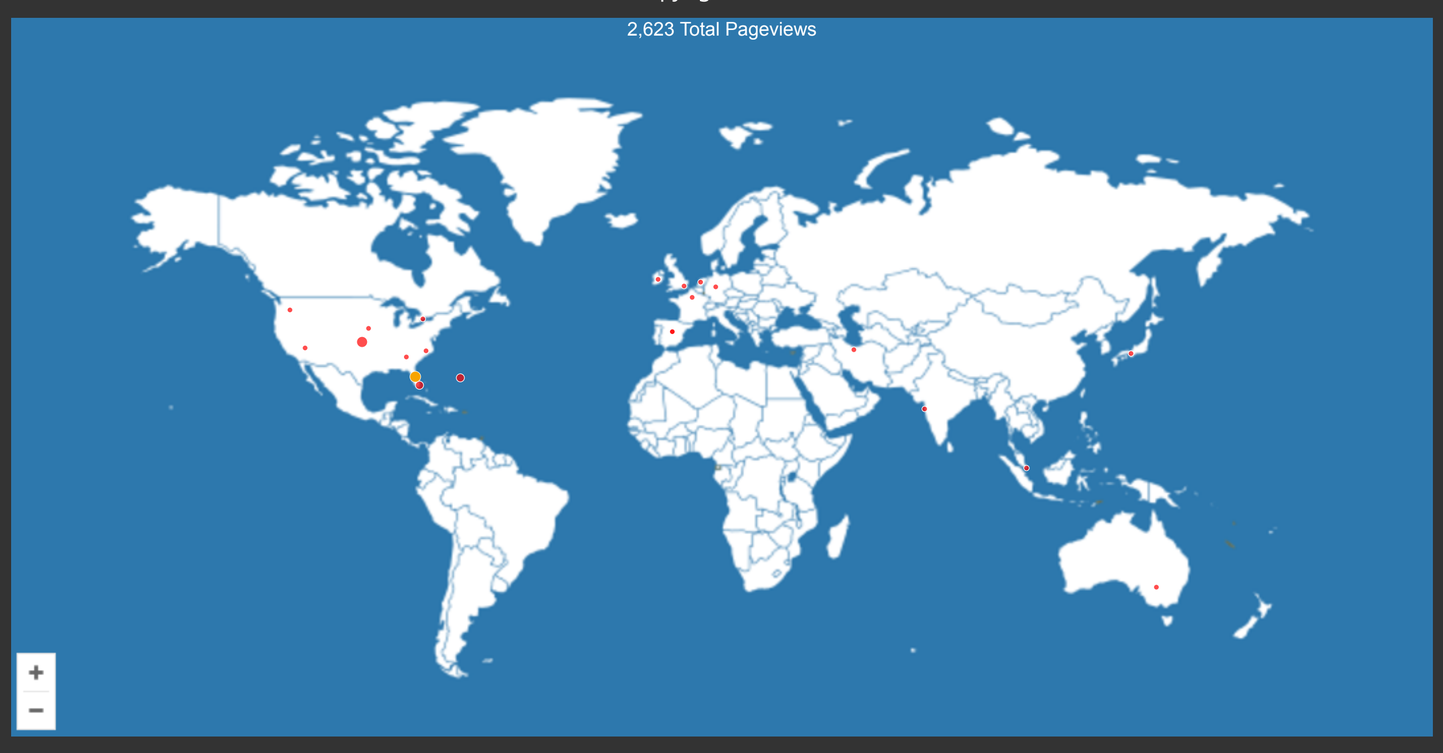

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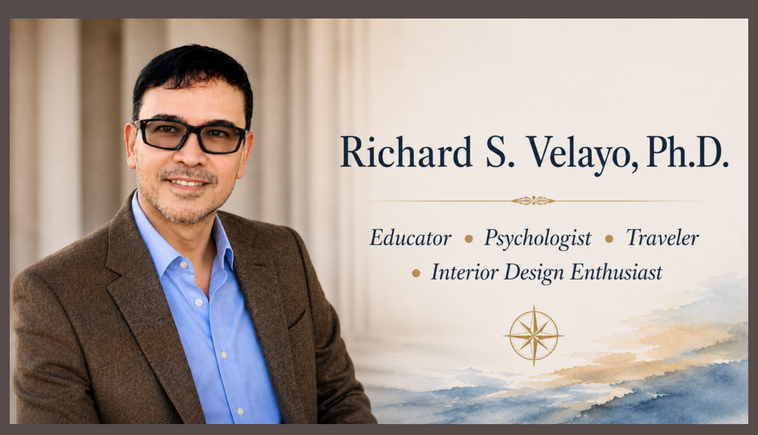

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Close Ups

Finding inspiration... in the minute, and the seemingly mundane and insignificant. Beauty and meaning can be found almost anywhere, even in the small things that we rarely notice around us. Look closer at the many beautiful little things around you. Experience the joy they bring to the moment.

Featured CLOSE UP Art...

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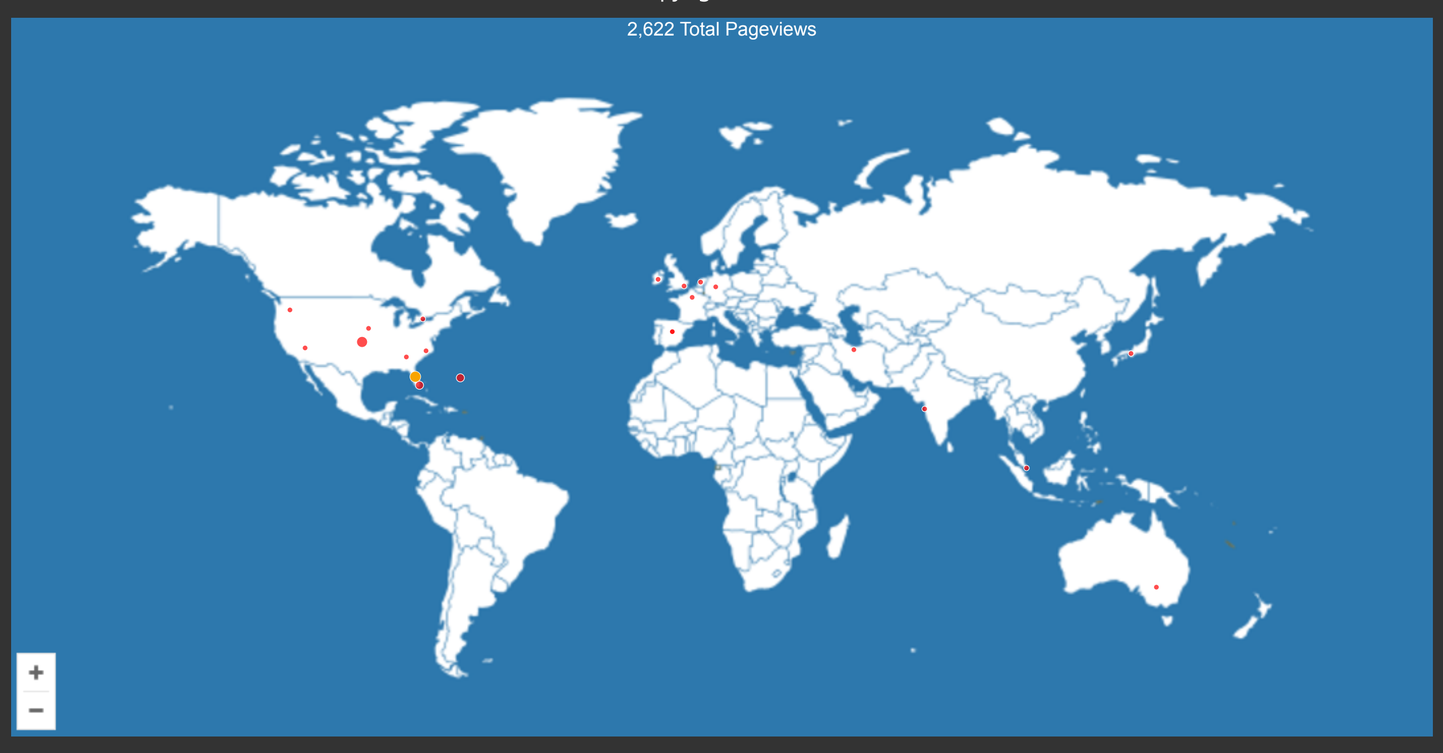

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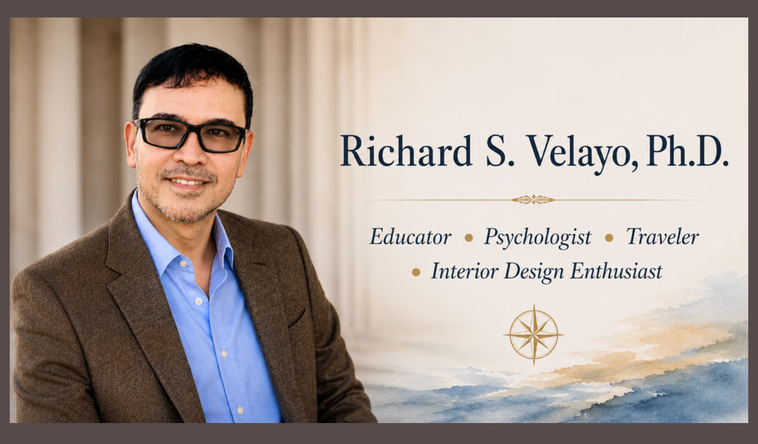

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Abstract

Finding inspiration... in the flow, the texture, the subjective. Appreciate that we often experience reality from our own interpretation of the world. These are photos of objects taken using a digital microscope, then magnified to up to 1000x, then digitally manipulated with a burst of saturated colors and wavy textures.

Featured Abstract Art...

"BUDDING CACTUS" [Created: 9/08/20]

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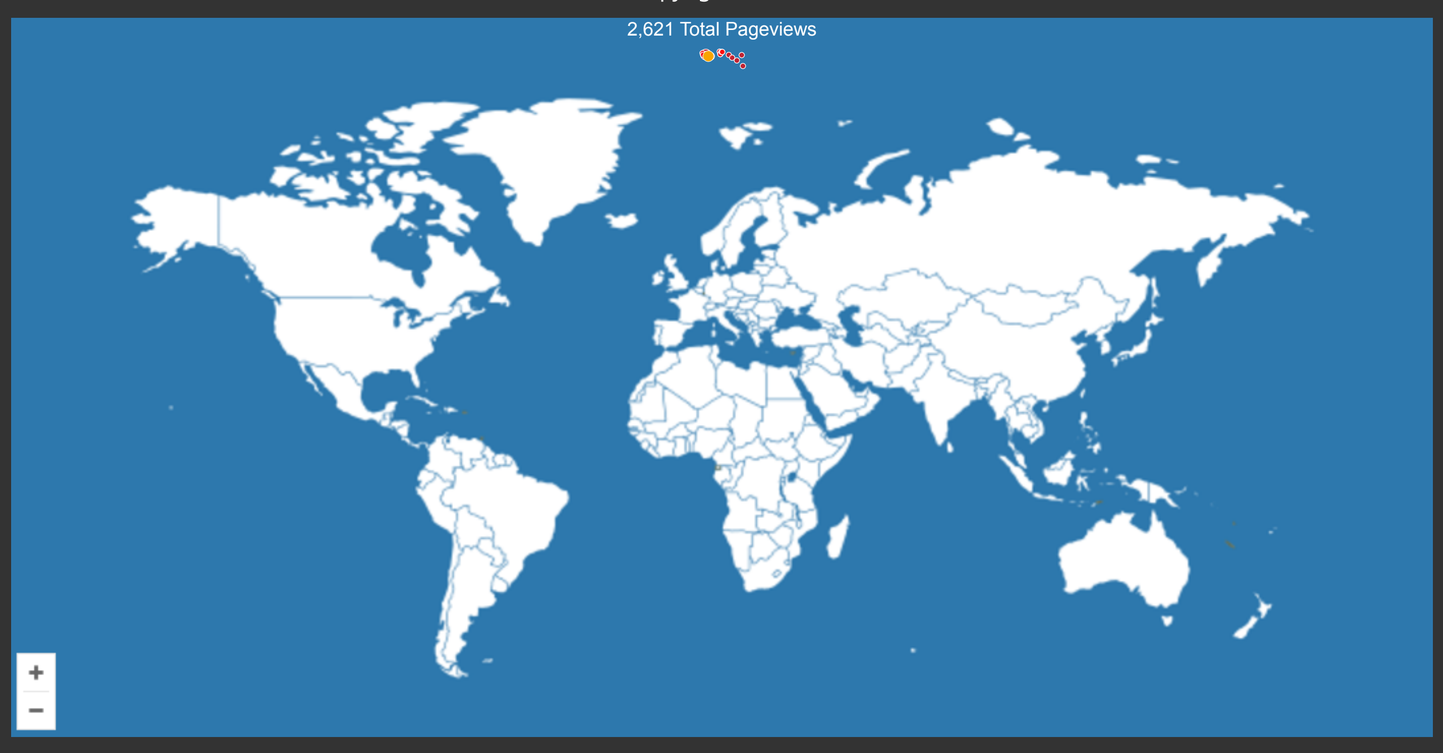

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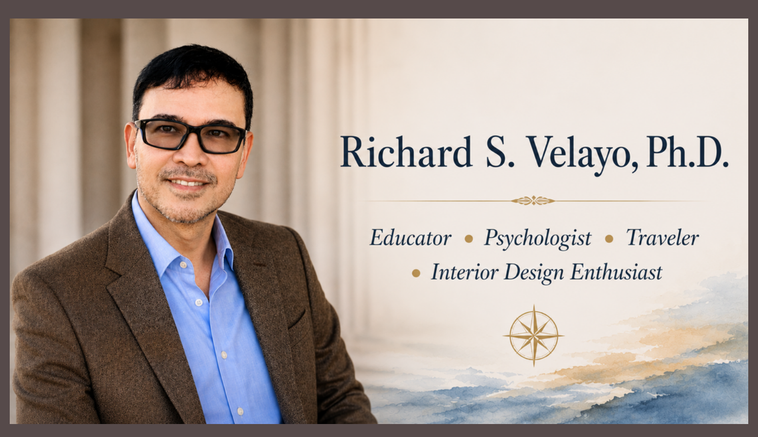

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Scapes

Finding inspiration... in the outdoor views that surround us, whether they be formed by nature, by man, or some combination of both. Experience the vibrant colors of the elements you see. Stop for a moment and find serenity in the scene. Let it breathe life in you.

Featured SCAPES Art...

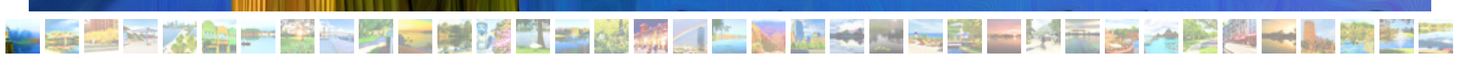

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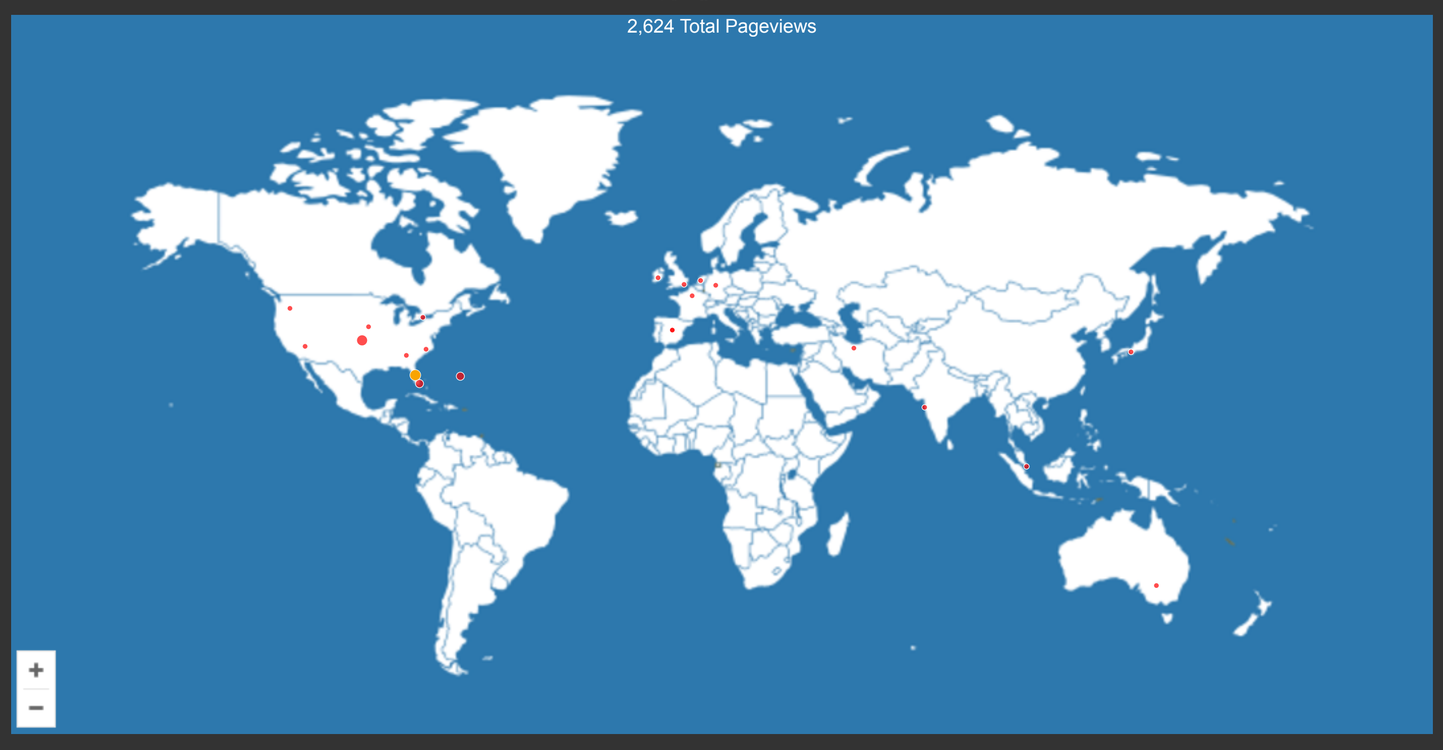

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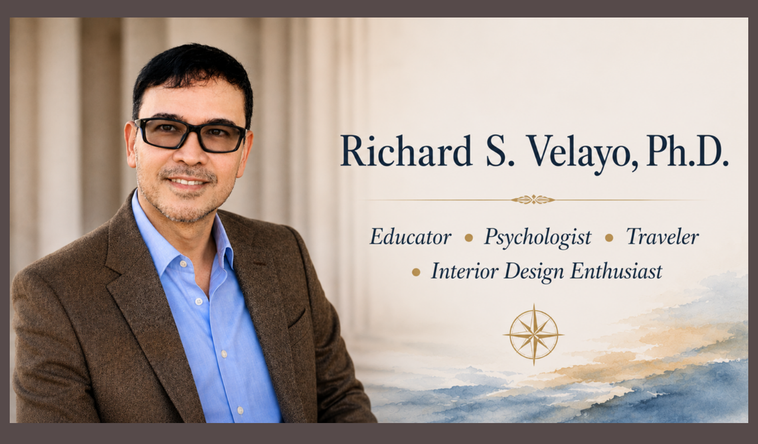

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Still Life

Finding inspiration... in the stillness and placement of objects within the confines of a limited space. Let yourself be fully aware of the present moment. Reflect on emotions these elicit in you.

Featured STILL LIFE Art...

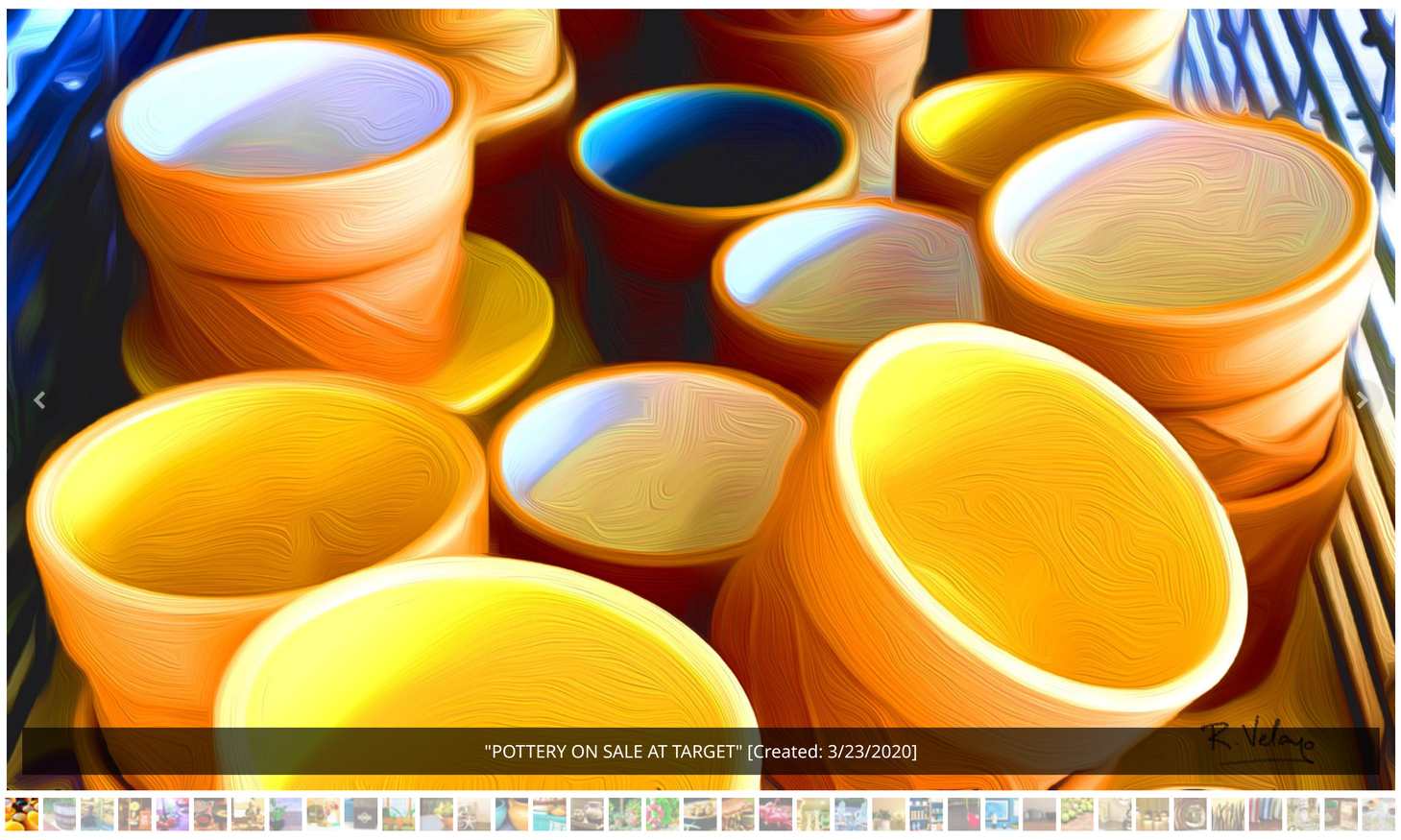

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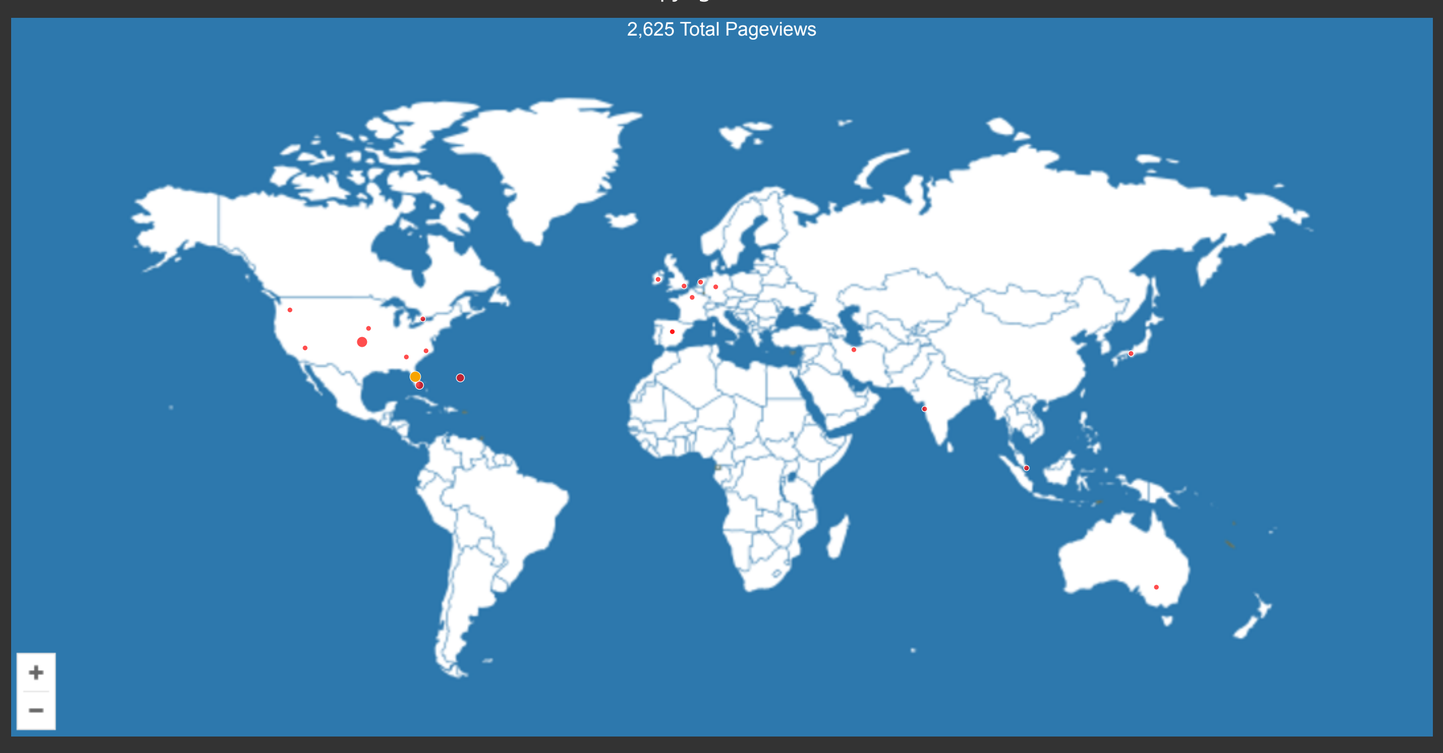

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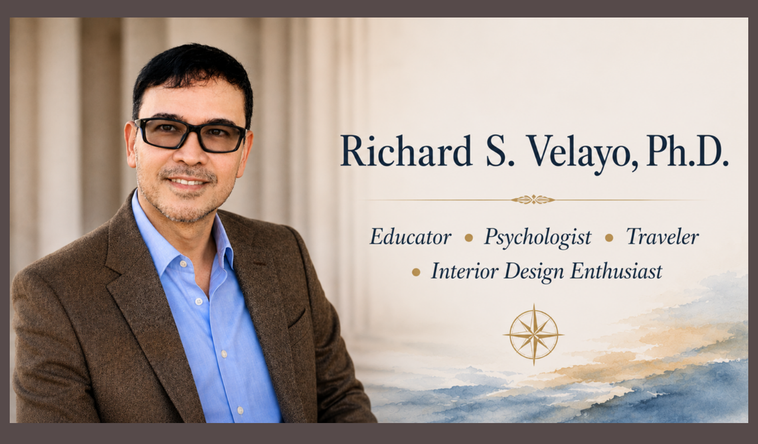

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Others

Finding inspiration... in the candid, the unusual, the organic, or whatever you find to be meaningful in your own life. These digital artwork were created from the less common subjects of my photography. The subject may be abstract, wildlife, pets, portraits, etc.

Featured OTHERS...

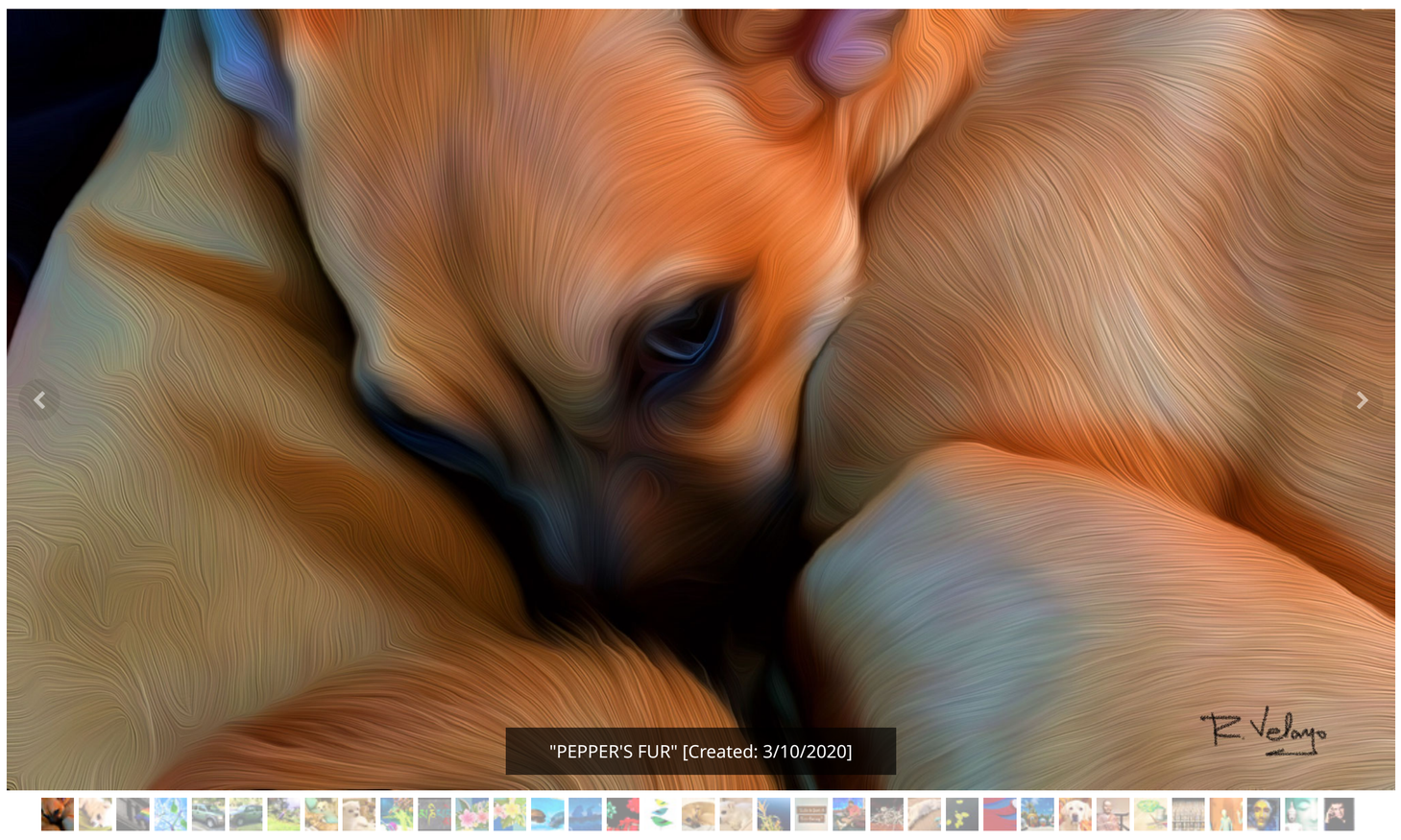

"PEPPER'S FUR" [Created: 3/10/2020]

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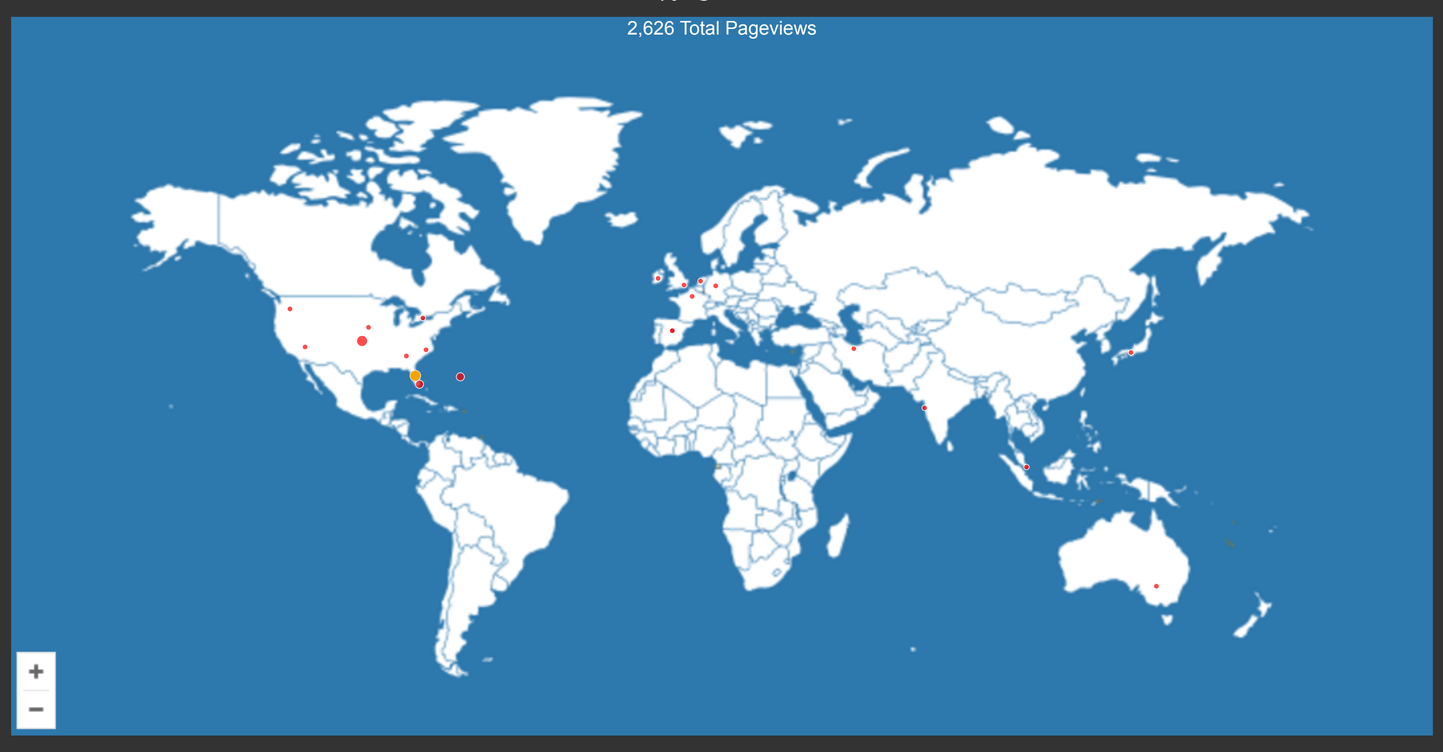

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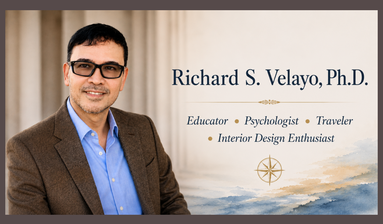

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MAP 1 - Foundations of Psychology

Every field has pioneers whose ideas continue to influence generations of scholars and practitioners. This map recognizes many of the individuals, institutions, and historic locations that helped establish psychology as a scientific discipline.

Explore This Map

This interactive map includes the following layers:

- World History of Psychology
- Great Psychologists
- Psychology Heritage Sites
- Psychology Museums
- Nobel Laureates & Psychology
- Positive Psychology
- Psychology & the United Nations
- Psychology & Climate Change
- Cross-Cultural Psychology

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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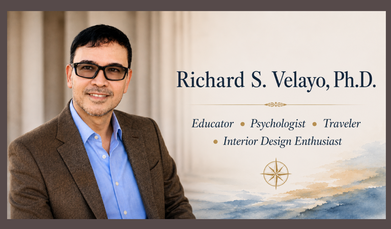

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MAP 2 - International Psychology

Psychology is practiced in virtually every country, yet each culture brings its own perspectives and traditions. This map celebrates the worldwide reach of psychology and the diversity that strengthens our understanding of human behavior.

Explore This Map

This interactive map includes the following layers:

- Indigenous Psychology
- Psychology Around the World
- Psychology Organizations
- Psychology Conferences
- Psychological Tests Around the World
- Psychology and Human Rights
- Psychology in Literature and Film

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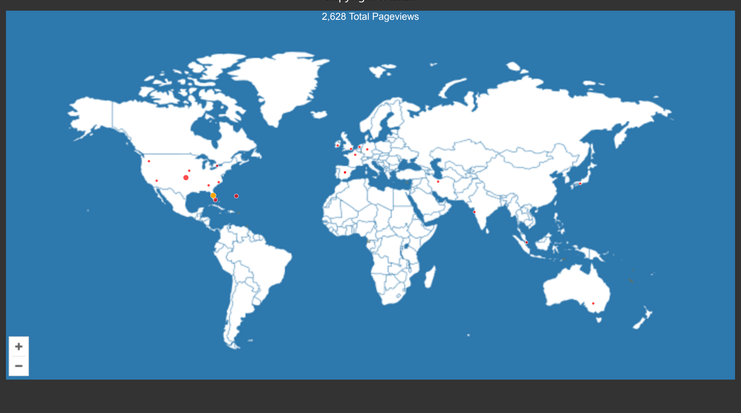

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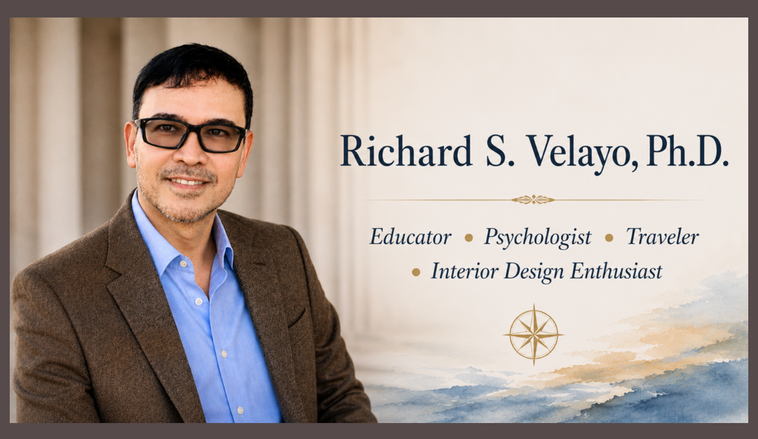

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MAP 3 - Global Psychology Alliance

Progress in psychology depends upon collaboration. This map highlights organizations and partnerships that bring psychologists together across national boundaries to address shared challenges and advance psychological science and practice.

Explore This Map

This map contains a single layer:

- Global Psychology Alliance

The **Global Psychology Alliance** highlights the worldwide network of psychological organizations working together to strengthen international collaboration, advance psychological science and practice, support human rights, and address shared global challenges.

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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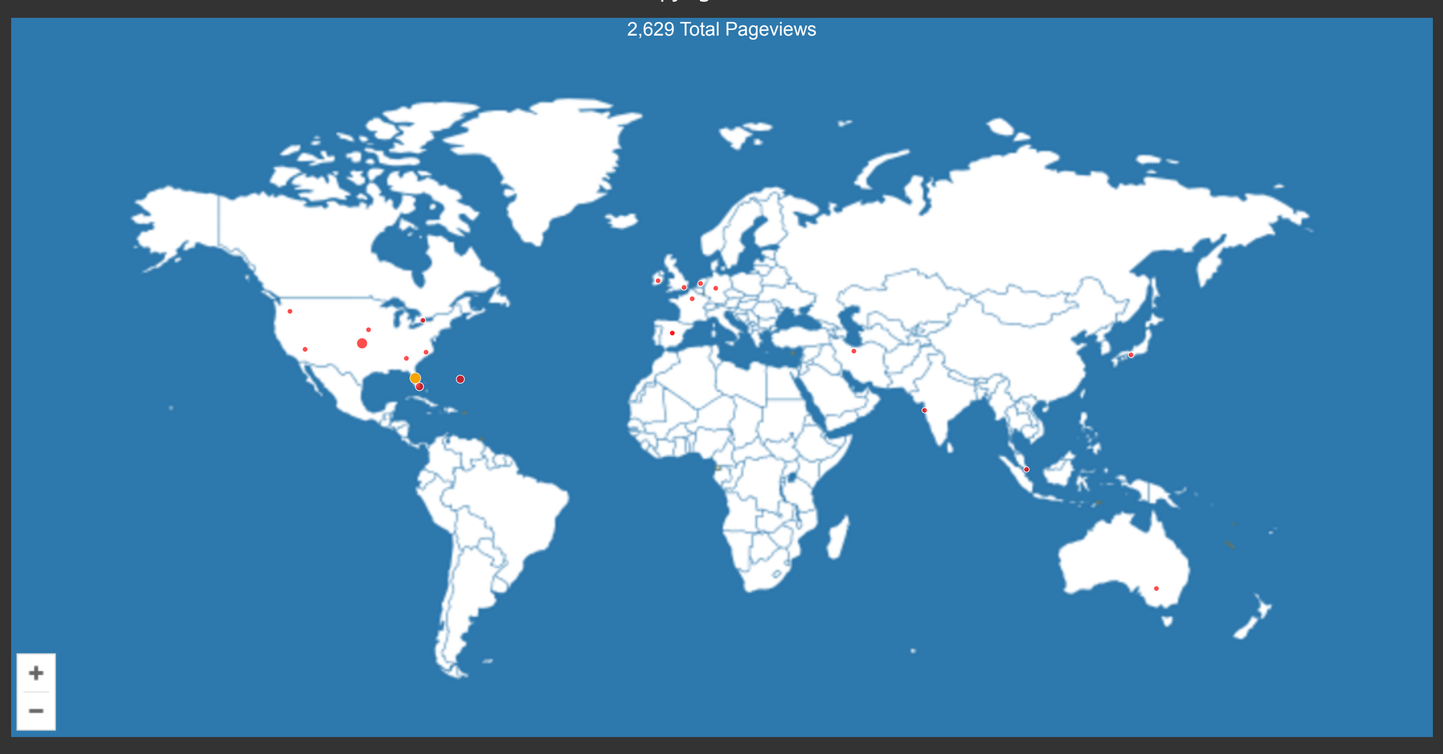

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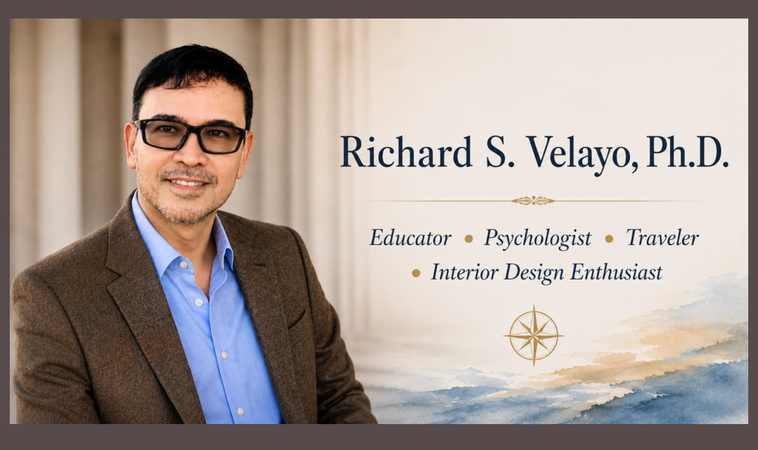

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MAP - Florida Homes

Home is more than an address. These locations represent different chapters of my life and the places where new memories, friendships, and adventures began.

Explore This Map

This interactive map highlights the Florida communities that I have called home throughout different stages of my life. Each location represents a chapter in my personal journey and reflects the experiences that have shaped my life in the Sunshine State.

This interactive map includes the following layers:

- Florida Homes

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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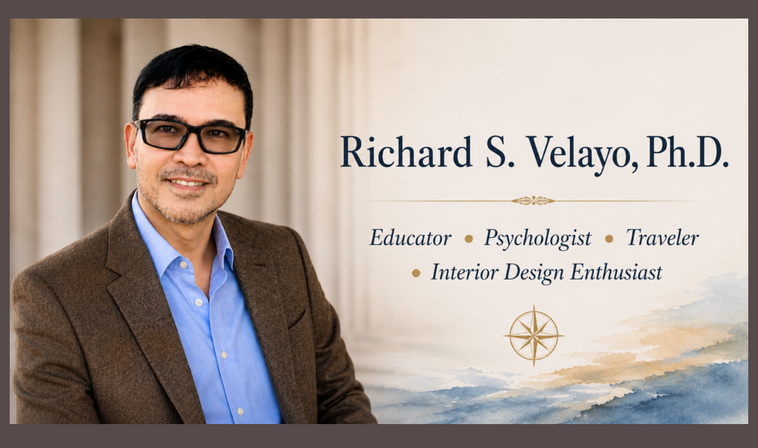

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MAP - Florida Favorites

Some places simply invite you back again and again. Whether for their scenery, history, food, or personal memories, these are among my favorite destinations throughout Florida.

Explore This Map

This interactive map features some of my favorite places throughout Florida, including communities, restaurants, attractions, cultural sites, parks, and other destinations that have provided memorable experiences and continue to inspire return visits.

This interactive map includes the following layers:

- Florida Favorites

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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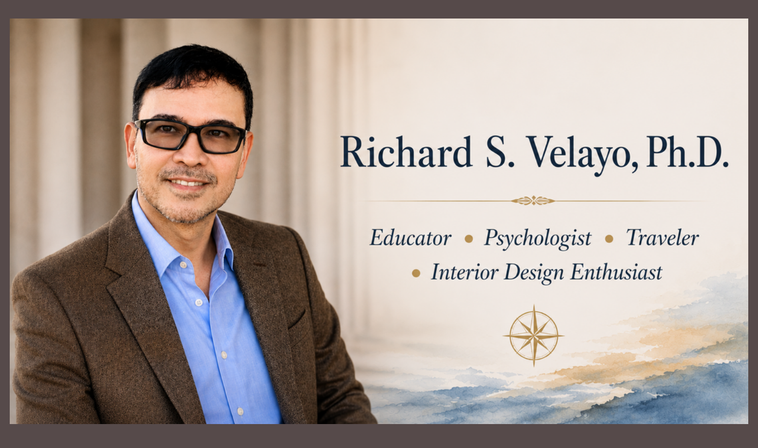

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MAP - Florida Cities Visited

Exploring Florida has been one of the great pleasures of retirement. This map continues to grow as I discover new communities, historic towns, parks, beaches, and hidden treasures across the state.

Explore This Map

This interactive map showcases the many Florida cities and communities I have visited over the years. From historic towns and vibrant cities to scenic coastal communities and hidden gems, each marker represents another step in my ongoing exploration of Florida.

This interactive map includes the following layers:

- Florida Cities Visited

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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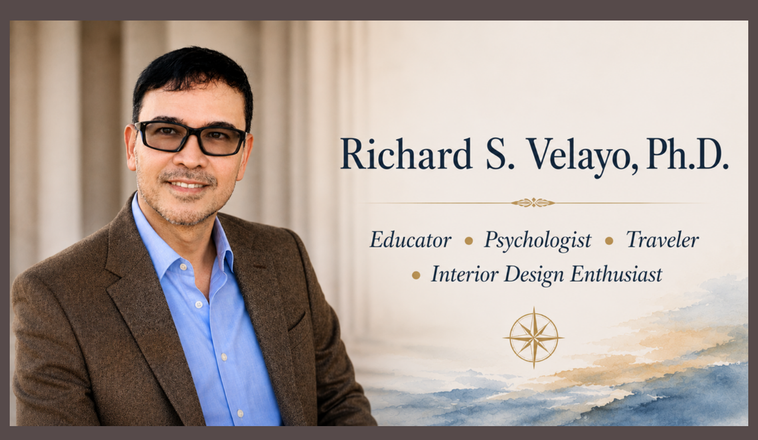

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MAP - States Visited

Every state has its own personality. This map represents the growing list of places I've explored across the United States, each adding another chapter to my journey.

Explore This Map

This interactive map highlights the U.S. states I have visited throughout my lifetime. Each state represents a unique travel experience and an opportunity to discover America's diverse landscapes, history, cultures, and communities. As I continue exploring the country, this map will continue to grow.

This interactive map includes the following layers:

- US States Visited

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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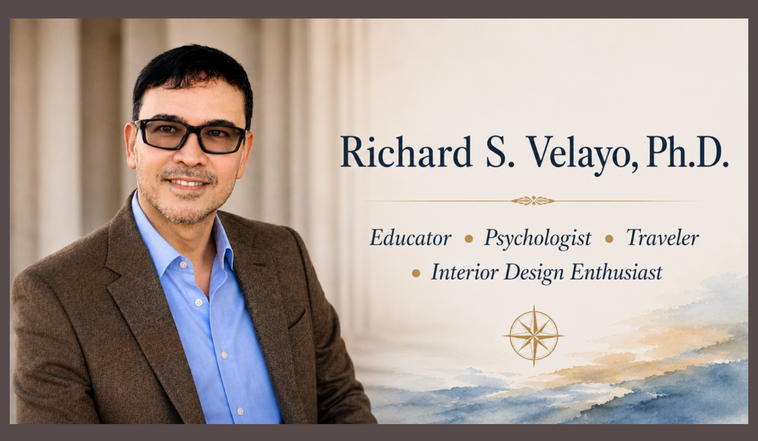

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MAP - States Lived In

Our homes help shape who we become. These states mark the places where I have lived throughout my life, each contributing in its own way to my personal and professional development.

Explore This Map

This interactive map traces the states that I have called home during different stages of my life. Each location represents an important chapter in my personal and professional journey, illustrating how the places where we live help shape our experiences, relationships, and perspectives over time. The markers are arranged chronologically, illustrating the geographic journey of my life from childhood through retirement.

This interactive map includes the following layers:

- US States Lived In

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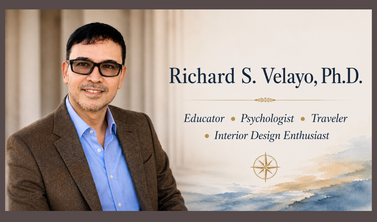

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MAP - Places Visited

Every journey leaves a lasting impression.
One of the greatest joys of travel is discovering that every destination has its own story to tell. Whether exploring a vibrant city, standing before a historic landmark, or simply enjoying the beauty of everyday life in another culture, each place has broadened my perspective and deepened my appreciation for our remarkable world. This map highlights many of the countries and cities I have been fortunate to visit over the years. I hope it inspires you to explore, reflect, and perhaps begin planning your own next adventure.
Travel has taught me that while every destination is unique, people everywhere share far more in common than they often realize. Those discoveries have become some of life's greatest rewards.

Explore This Map

This interactive map highlights the countries, cities, and destinations I have visited throughout my travels around the world. Each location represents a memorable experience and an opportunity to appreciate the history, culture, natural beauty, and diversity that make every destination unique.

This interactive map includes the following layers:

- The World (Cities/Countries Visited)

To view the map layers, click or tap the small rectangular icon in the upper-left corner of the map. The layer panel will open, allowing you to view the individual layers; on a computer, you can also click the expand icon in the upper-right corner to open a larger map view.

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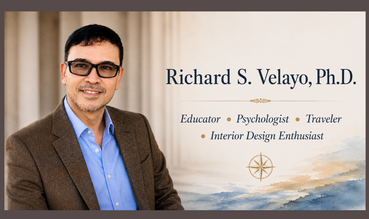

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MAP - Future Trips

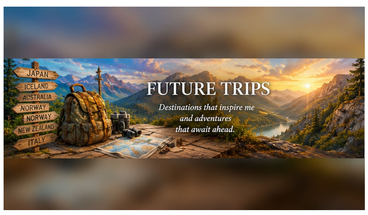

The world still has many stories waiting to be discovered. Retirement has given me something that is both exciting and precious—time to continue exploring. This map represents places that have long captured my imagination, whether because of their history, natural beauty, cultural traditions, or personal significance. Some destinations have been on my travel list for decades, while others are more recent discoveries. I hope, one by one, these markers will eventually move from my "Future Trips" map to my "Places Visited" map.

Explore This Map

This interactive map features destinations that I hope to visit in the future. Each marker represents a place that has captured my curiosity through its history, culture, scenic beauty, or significance, reminding me that there is always something new to discover and another adventure waiting to begin.

This interactive map includes the following layers:

- The World (Future Trips)

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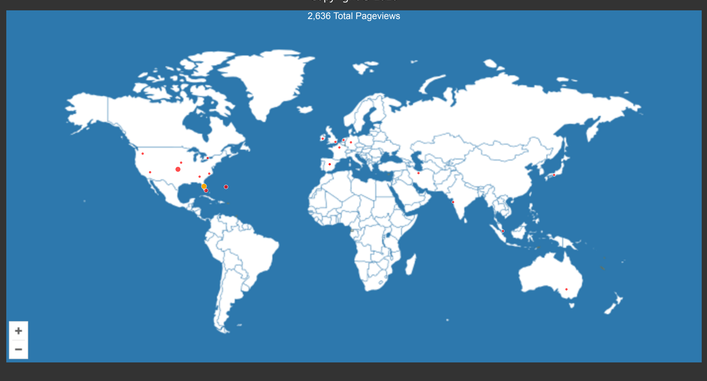

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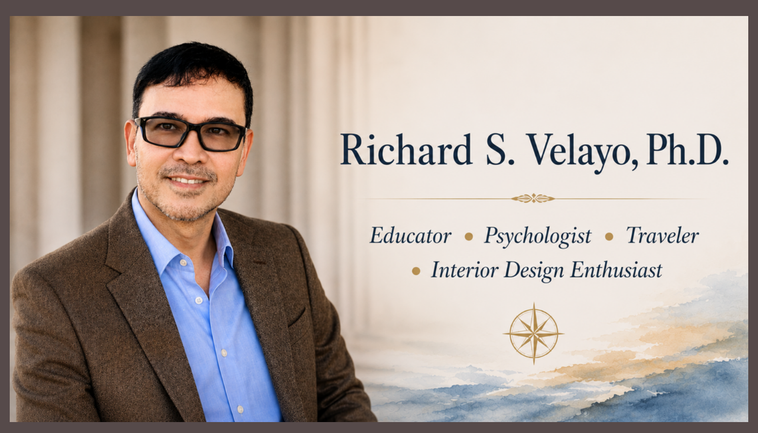

"A Life of Curiosity, Learning, and Discovery."

Reflections & Legacy

Looking Back with Gratitude, Looking Forward with Meaning

As the years pass, I find myself thinking less about what I have accomplished and more about what life has taught me. This page is a place for those reflections—on gratitude, identity, relationships, vulnerability, resilience, circumstance, and even the role of luck in shaping a life. It is also a place to remember the people who made a difference in mine and to consider what I hope may remain after I am gone. These are not intended as final answers, but as personal reflections on what I have experienced, what I have come to value, and what I believe has made my life meaningful.

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Visits

Richard S. Velayo, Ph.D.
Professor Emeritus of Psychology
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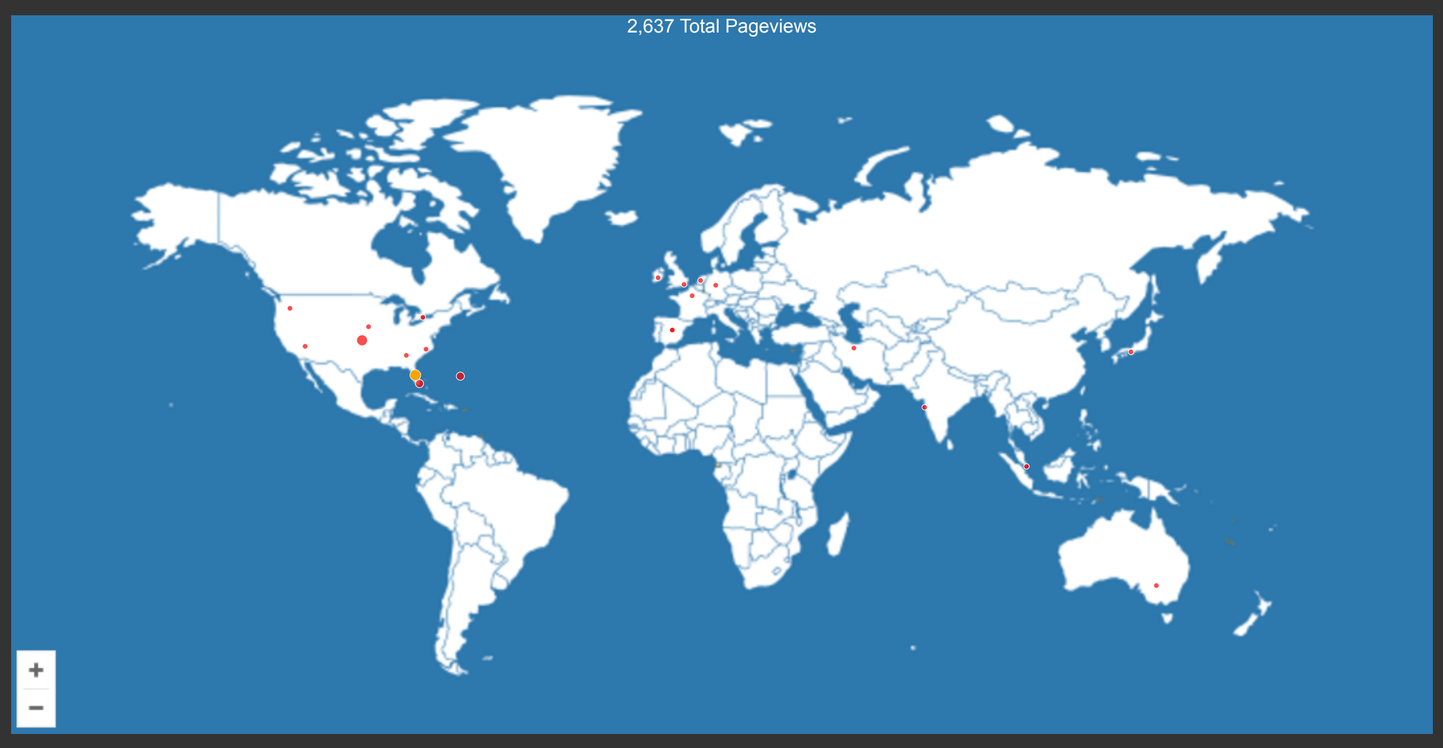

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PSYCHOLOGY 603

Introduction to International Psychology

(CRN #21243)
(Spring 2025)

Instructor: Richard Velayo, Ph.D.
Email: rvelayo@gmail.com or rvelayo@pace.edu
Office Hours: by appointment (phone)
Credits: 3
Course Format: Online (Asynchronous)

Course Description

This graduate-level online course entails reading, discussing, and writing about a variety of contemporary topics in the relatively new specialty of international psychology. You will examine mainstream as well as alternative theoretical, methodological, and applied approaches that are relevant to the study and practice of international psychology. The topics selected offer a broad and deep understanding of this field, specifically, an appreciation of psychology's relevance to the understanding and solution of global problems, as well as of how psychology itself is affected by worldwide events and forces. There will be a Final Paper in the form of an in-depth critique on a topic relevant to the internationalization of psychology.

Prerequisite

There are no graduate course prerequisites. This course is required for students in the "Global Psychology Research track within the MA in Psychology Program (Pace Psychology Dept., NYC campus).

Learning Outcomes

Students in this course will develop and demonstrate competencies in the following areas:

- Knowledge of current foci and future directions of this rapidly growing specialty in the discipline.
- Ability to evaluate critically the appropriateness and consequences of mainstream psychological theory, research, and practices within a global context;
- Familiarity with alternative models, methods, and interventions that have their roots in cultural, economic, historical, political, religious, and social contexts and their relevance to understanding and addressing global phenomena;
- Sensitivity to how global events and forces impact the psychosocial and sociocultural realities of diverse populations; *and*
- Understanding the education and training requirements for a career in international psychology.

Class Delivery Format/Location (General description only)

Online: Course is delivered fully remotely with no on-campus components.

- Asynchronous (ASYNC): CLASSES will be utilized for this course. There will be assignments, quizzes/tests, projects and/or discussions that students have the flexibility to complete within a set period **each week**.

How Do I login to CLASSES (also called "Brightspace")?

This online course is taught using CLASSES which may be accessed at CLASSES.pace.edu. Enter your username and password and click the login button; use your MyPace Portal username and password to login (e.g., cw94975n, tr87689w and jc73732p).

Course Materials (Required text and other materials)

- Shealy, C. N., Bullock, M., & Kapadia, S. (Eds.). (2023). *Going Global: How Psychologists Can Meet a World of Need.* American Psychological Association [(ISBN: 978-1433836435)
  (NOTE: Below are links to two formats of this book. The Kindle format is recommended.)
  Kindle format:
  Link to purchase Kindle format:
  https://www.amazon.com/Going-Global-Psychologists-Meet-World-ebook/dp/B0B11X9RH2/ref=tmm_kin_swatch_0?_encoding=UTF8&qid=&sr=
  Paperback format:
  Link to purchase Paperback format:
  https://www.amazon.com/Going-Global-Psychologists-Meet-World/dp/1433836432/ref=tmm_pap_swatch_0?_encoding=UTF8&qid=&sr=

- Additional relevant readings may be assigned.

Course Requirements

In CLASSES, the course materials are organized within the **TABLE OF CONTENTS.**

1. DISCUSSIONS (Weekly)

Each week begins on a Monday and ends on the following Sunday.
(NOTE: The discussion forum for the first week of the semester starts on Tuesday, Jan. 21.)
The main purpose of the online discussions is to enhance your learning of the concepts and applications presented in this course, and to further your thinking and writing skills. Discussions are meant to be insightful, reflective, lively, and thought provoking.

Every Monday, your instructor will post a few questions pertaining to the assigned chapter and/or course requirement. You are expected to actively read and comprehend the materials assigned for that week.

INITIAL Response/s: You are expected to regularly and to actively participate in all the weekly discussions by responding (completely and thoroughly) to each question posted.

FEEDBACK Responses: You are also required to provide "quality" feedback to **at least 2** of your other classmates' and/or instructor's initial postings in a way that makes the discussions intellectually stimulating. You are encouraged to respond to more postings if you want a better participation grade for that week.

Grading of Weekly Discussions:
Grading rubric. This form will be used by your instructor.
[NOTE 1: It will be up to your instructor to determine the quality and frequency of your initial responses to the questions and your feedback to your classmates' (including instructor's) postings. This rubric will serve as a basis for the grading of your discussion forum participation.]
[NOTE 2: Responses deemed to be inappropriate may be deleted by your instructor.]

2. ASSIGNMENTS

The two assignments for the course are (1) "Featured International Psychologist" Project, and (2) Final Paper.

- **"Featured International Psychologist" Project –** PowerPoint (10 - 12 slides)

  Your instructor will provide a list of names of relevant international psychologists from which each

student in class may choose from. You are required to create a **report in the form of a PowerPoint presentation** (or a comparable/compatible presentation software) that highlights the relevant background and contributions of an esteemed individual on the field of international psychology. In addition to the background information that you find about this person, you are also expected to include relevant images, videos, and audio narration of your voice in your presentation. The more multimedia your presentation, the better. You may use the "add notes" feature of PPT and/or insert your recorded voice/narration if you wish. (*Let me know if you have any questions regarding this.)*

Your PowerPoint presentation/slides should contain the following information.
1. Background information of Featured Psychologist (with face photo if available)
2. Contributions to International Psychology
3. List of scholarly publications
4. Additional Information of Interest
5. COMMENTARY

In addition, your project will also be evaluated on the following: (i) Quality of slides, and (ii) Notes and/or Audio content.

Grading of "Featured International Psychologist" Project:
Grading rubric. This form will be used by your instructor.
[NOTE: Details about the grading of your final paper will be presented during the semester.]

- **Final Paper** (4 - 5 pages, single-spaced)

Your instructor will provide you with a list of more than 70+ national, regional and international psychological associations that are part of the ***Global Psychology Alliance*** (https://www.apa.org/international/networks/global-psychology-alliance). Each student will be required to write an in-depth critique (reaction paper) on a particular national psychology organization from this list.
[NOTE: The CRITIQUE section of your final paper may include your own comments about the organization, which includes your thoughts and recommendations about its activities and contributions to the internationalization of psychology. Incorporate what you have learned from the textbook and discussion forums. The number of relevant ideas you include will significantly contribute to the grading of your paper.]

Turnitin will be used to submit papers.

The structure and contents of the paper MUST be organized using the following headings.
1. Description of the organization *(approx. 1 page)*
2. Leaders of the organization *(approx. 1 page)*
3. Membership *(approx. 1 page)*
4. Recent news, events, and activities *(approx. 1 page)*
5. CRITIQUE (Commentary about the organization) *(approx.1- 2 pages)*

In addition, your project will also be evaluated on the following: (i) Writing quality, and (ii) Organization of paper.

Grading of Final Paper:
Grading rubric. This form will be used by your instructor.
Student Grade Form: This form will be used by you and your classmates to help grade your paper.
[NOTE: Details about the grading of your final paper will be presented during the semester.]

Grading System

DISCUSSIONS (Weekly)*		
(20 points per week/forum; 14 weeks/forums)	56%	280 points
ASSIGNMENTS**		
"Featured International Psychologist" Project	14%	70
Final Paper		
Instructor Evaluation	20%	100
Student Grade Form (grades are averaged)	8%	40
Submission of Student Grade Form	2%	10
Total Points:		**500**

** 1 point deducted for each day late. (Per initial response and per feedback response.)*
*** 3 points deducted for each day late.*

Letter-Grade Equivalent
("Strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

SCHEDULE

WEEK	TOPIC/s	READING/s*
1 *(1/21 – 1/26)*	What is International Psychology? Video on "International Psychology: What Student Want to Know"	Syllabus; Additional readings
2 *(1/27 – 2/02)*	IINTRODUCTION to *Global Psychology:* Why Psychologists Should Meet a World of Need	Textbook (pp. 3 - 13)
3 *(2/03 – 2/09)*	ADVOCACY: Global Opportunities and Responsibilities for Psychologists	Ch. 1 (pp. 15 - 36)
4 *(2/10 – 2/16)*	ASSESSMENT: The Power and Potential of Psychological Testing, Educational Measurement, and Program Evaluation Around the World	Ch. 2 (pp. 37 - 58)
5 *(2/17 – 2/23)*	CONSULTATION: Who Needs Psychological Expertise Around the World and Why?	Ch. 3 (pp. 59 - 74)

6 *(2/24 – 3/02)*	INTERVENTION: Enhancing Mental Health and Well-Being Around the World	Ch. 4 (pp. 75 - 97)
7 *(3/03 – 3/09)*	LEADERSHIP: How Psychology and Psychologists Develop Global Leaders and Leadership **DUE: "Featured International Psychologist" Project**	Ch. 5 (pp. 99 - 120)
8 *(3/10 – 3/16)*	POLICY: Why and How to Become Engaged as an International Policy Psychologist **DUE: TOPIC for FINAL PAPER** *(NOTE: Your topic is one of the participating national psychology associations from the Global Psychology Alliance.)*	Ch. 6 (pp. 121 - 142)
9 *(3/17 – 3/23)*	NO CLASS (Spring Break)	
10 *(3/24 – 3/30)*	RESEARCH: International Possibilities and Partnerships for Psychologists	Ch. 7 (pp. 143 - 165)
11 *(3/31 – 4/06)*	SERVICE: Toward a Global Psychology of Collaboration, Counterflow, and Capacity Building	Ch. 8 (pp. 167 - 182)
12 *(4/07 – 4/13)*	TEACHING: Opportunities and Recommendations for Internationalizing Psychology Education	Ch. 9 (pp. 183 - 206)
13 *(4/14 – 4/20)*	CONCLUDING THOUGHTS on *Going Global:* How Psychologists Should Meet a World of Need	Ch. 10 (pp. 207 - 227)
14 *(4/21 – 4/27)*	**DUE on 4/22: FINAL PAPER** **DUE on 4/27: STUDENT GRADE FORM** (for Final Paper)	Final Papers
15 *(4/28)*	FINAL COURSE GRADES	

**Supplementary readings may be assigned.*

University Policies and Resources

- ***Academic Integrity***

Students in this course are required to adhere to Pace University's Academic Integrity Code, which supports honesty and ethical conduct in the educational process. It educates students about what constitutes academic misconduct, helps to deter cheating and plagiarism, and provides a procedure for handling cases of academic misconduct. Students are expected to be familiar with the Code, which can be found in University Policies, Disciplinary and Grievance Procedures. Individual schools and programs may have additional standards of academic integrity. Students are responsible for familiarizing themselves with the policies of the schools, programs, and courses in which they are enrolled.

[Pace Graduate Students]
Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any academic paper, report, or submission for academic credit without the appropriate acknowledgement is plagiarism. It is also academically dishonest to submit anything in electronic form as one's own that is the work, either fully or in part, of someone else. It is unethical to present as one's own work, the ideas, words, or representations of another without the proper indication of the source. Therefore, it is the student's responsibility to give credit to any quotation, idea or data borrowed from an outside source. Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension, dismissal, or expulsion from the University. (L-54)

- ***Learning Commons***

The Learning Commons uses an array of programs and a holistic approach to assist students with academic skills and content knowledge. We are dedicated to developing independent learners through purposeful interactions with trained, well-qualified peer and professional staff. Services offered:

- Content Support Services including, content tutoring, exam review sessions, & content preparation/support workshops
- Academic Skills Services including small group peer mentoring, academic skills workshops, and individual academic development
- Writing Support Services including, writing tutoring & writing preparation/support workshops

- ***Procedure for Students Who Wish to Obtain Reasonable Accommodations for a Course***

The same rigorous standards for admission apply to students with and without a disability. In order to support the continued success of students with disabilities, the University prohibits discrimination on the basis of disability and is committed to ensuring equal access for students with disabilities to its facilities, programs, and activities. The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities.

To request an accommodation for a qualifying disability, a student must self-identify and register with the Disability Services Office for his or her campus. The Office of Disability Services is housed in the Counseling Center on the New York City and Pleasantville campuses. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see Information for Students with Disabilities page.

- ***Technological Resources***
  - List of all Pace Information Technology Services.
  - For assistance with a technological concern contact the Pace Helpdesk at (914) 773-3648 or create a help desk ticket.
  - Visit the Learning Remotely website

- ***Appropriate Use Policy for Information Technology***

Pace endorses the following statement on software and intellectual rights distributed by EDUCAUSE, the non-profit consortium of colleges and universities, committed to the use and management of information technology in higher education. The statement reads:

> *Respect for intellectual labor and creativity is vital to academic discourse and enterprise. This principle applies to work of all authors and publishers in all media. It encompasses respect for the right to acknowledgment, right to privacy and right to determine the form, manner and terms of publication and distribution.*
>
> *Because electronic information is volatile and easily reproduced, respect for the work and personal expression of others is especially critical in computer environments. Violations of authorial integrity, including plagiarism, invasion of privacy, unauthorized access and trade secret and copyright violations, may be grounds for sanctions against members of the academic community.*

See Pace's IT appropriate use policy.

- ***Sex-Based Misconduct Policy and Procedure***

Pace University is committed to providing a safe environment for every member of its community and to ensuring that no student, faculty, or staff member is excluded from participation in or denied the benefits of any University program or activity on the basis of sex. Accordingly, the University prohibits the following forms of Sex-Based Misconduct: sexual assault, sexual harassment, gender-based harassment, dating violence, domestic violence, sexual exploitation, and stalking.

Instructors are a **non-confidential** resource and have an obligation to report any information about sexual assault with the Executive Director of Institutional Equity and Title IX Coordinator – Bernard Dufresne, bdufresne@pace.edu, 163 Williams Street, Room 1017, (212) 346-1310. The Title IX/Affirmative Action Office is responsible for investigating violations of the sexual misconduct policy. Go here for more information about the Pace University sexual misconduct policy.

Members of the University community who believe that they have been subjected to Sex-Based Misconduct are encouraged to report such incidents to the University and, where applicable, to local law enforcement. **Confidential** resources include the **University Counseling Centers, Offices of Sexual and Interpersonal Wellness** and **University Healthcare**. Contact information for those offices may be found in the self-care section below.

- ***Self-Care***

Your academic success in this course and throughout your college career depends heavily on your personal health and well-being. Stress is a common part of the college experience, and it often can be compounded by unexpected life changes outside the classroom. The Pace Community strongly encourages you to take care of yourself throughout the term before the demands of midterms and finals reach their peak. Please feel free to talk with me about any difficulty you may be having that may impact your performance in this course as soon as it occurs and before it becomes unmanageable. Please know there are a number of other support services on campus that stand ready to assist you. You are strongly encouraged to contact them when needed as well.

The Counseling Center "Just In Case" information supplies potentially life-saving mental health information to Pace University students, staff, and faculty, putting vital information and support options at your fingertips, just in case you or a friend needs help. Go to the Just in Case page on the Pace website or go to "Counseling Center" on the MyPace or the Pace Safe app.

Department	**Pleasantville**	**New York City**
Advising Center for Exploring Majors	First-year: (914) 773-3756 | (914) 773-3757	(212) 346-1798
Affirmative Action Office	(914) 923-2610	(212) 346-1310
Center for Spiritual Development	(914) 773-3767	
College of Health Professions Academic Advisement	UG (914) 773-3961 UG (914) 773-3347 Grad (914) 773-3114	UG (212) 618-6027 Grad (914) 773-3114
Counseling Center	(914) 773-3710	(212) 346-1526
Dean for Students Office	(914) 773-3351	(212) 346-1306
Dyson College Academic Advisement	(914) 773-3781	(212) 346-1518
International Student/Scholars	(212) 346-1368	
Lubin School of Business Academic Advisement	UG (914) 773-3531	UG (212) 618-6550 Grad (212) 618-6440
Office of Multicultural Affairs	(914) 773-3628	(212) 346-1546
Office of Sexual and Interpersonal Wellness	(212) 346-1931	
Office of Student Assistance (OSA)	(877) 672-1830	
Pace Women's Justice Center	(914) 287-0739	
Pforzheimer Honors College Academic Advisement	(212) 346-1697	
Residential Life	(914) 597-8777	(212) 346-1295
Seidenberg School Academic Advisement	SeidenbergInquiry@pace.edu	
Sexual Assault Prevention & Education	(212) 346-1931	
Study Abroad	(212) 346-1368	
Student Accessibility Services	(914) 773-3710	(212) 346-1526
Student Engagement	(914) 773-3767	(212) 346-1590
University Health Care	(914) 773-3760	(212) 346-1600

-End-

PSY634
INSTRUCTIONAL PSYCHOLOGY: Multimedia Applications

(CRN #50279)

Summer 2 2021

Instructors: Richard Velayo, Ph.D.
Course Format: Online (Asynchronous)
Office Hours: by appointment – Zoom or phone
Credits (graduate): 3

Description

This 3-credit web-enhanced (online) course is designed as an advanced level course on cognitive principles associated with learning from media (visual, textual, and audio presentations) and the application of these principles in designing multimedia instruction for effective teaching and learning. Drawing from years of research in cognitive and educational psychology, this course provides materials based on the cognitive theory of multimedia learning and principles for the design of multimedia presentations. It aims to help students realize the potential of using words (text and/or audio material) and visual elements (pictures, videos, icons) to promote learning. Students will learn about the basic principles of multimedia instructional design and to demonstrate their knowledge by completing a multimedia project that adheres to these principles. This course relies heavily on the use of Blackboard's discussion board.

Goals and Objectives

- To be knowledgeable and critically think about important concepts in multimedia learning and their applications.
- To understand how people process verbal and visual information based on psychological and educational research and the research that help explain them.
- To demonstrate the principles of effective multimedia learning and presentations by designing and completing a "multimedia project" (e.g., a PowerPoint presentation, website) on a particular topic approved by the instructor.

Prerequisite

Registration for this course requires approval (instructor or program coordinator), including those students who are not matriculated in the MA in Psychology program.

There are no prerequisite course/s required within the MA in Psychology Program. Basic knowledge of and ability to use a presentation software (e.g., PowerPoint, Keynote, Prezi, VoiceThread) or a website-authoring program (e.g., WordPress, Jimdo, Wix) is preferred.

Course Materials

Required Textbook:
Mayer, R. E. (2020). *Multimedia Learning (2nd ed.)*. UK: Cambridge University Press.
(ISBN for Paperback: 978-1316638088; **ISBN for eTextbook:** 978-1107187504**)**

In addition to the required textbook, there may be supplemental materials (which you do not need to purchase) utilized by your instructor which are derived from, but not limited to, the following:

Clark, R. C. & Mayer, R. E. (2016). *E-Learning and the Science of Instruction: Proven Guidelines for Consumers and Designers of Multimedia Learning (4rd ed.).* NJ: Wiley. (ISBN: 978-1119158660)

Kosslyn, S. M. (2007). *Clear and to the Point: 8 Psychological Principles for Compelling PowerPoint Presentations.* Oxford University Press. (ISBN: 978-0195320695)

Mayer, R. E. (2014). *The Cambridge Handbook of Multimedia Learning (2nd ed.).* NY: Cambridge University Press (ISBN: 978-1107610316)

Class Delivery Format/Location

Online: Course is delivered fully remotely with no on-campus components.
Asynchronous (ASYNC): Course is taught online with students participating at their own times. There will be assignments, quizzes/tests, projects and/or discussions that students have the flexibility to complete within a set period **each week**.

How Do I login to CLASSES (also called "Brightspace")?

This online course is taught using CLASSES which may be accessed at CLASSES.pace.edu. Enter your username and password and click the login button; use your MyPace Portal username and password to login (e.g., cw94975n, tr87689w and jc73732p).

CLASSES Resource Center

If you need help with CLASSES, go to https://www.pace.edu/its/learning-management-system/resources. The 24-hour phone support for students is 1-877-325-7778.
Below are links to videos designed for Pace for students on the use of CLASSES.

- **Navigation Overview**: https://mediaspace.pace.edu/media/Classes+Student+Navigation+Overview/1_4gqt84m7
- **Video Tutorial**: https://mediaspace.pace.edu/media/Classes+Student+Video+Tutorial/1_vubjrq05

Pace University COVID-19 Safety

CDC guidelines and University policy require proper face covering use in all classrooms, conference rooms, hallways, elevators, and other common areas. Face coverings are required even if you are more than 6 feet from another individual in a common indoor area. We must work together to protect others and ourselves from the transmission of COVID-19. Any student entering class without a face covering will be asked to: a) wear a face covering or b) go to Security to obtain a face covering if the student does not have one. Students who do neither of these things will be asked to leave class and they will be marked absent for the session. Students are expected to be familiar with the current COVID-19 regulations, which are posted on the Return to Campus website. See also up-to-date policies and announcements and more information about Pace University's response to COVID-19.

Course Documents

Course materials are organized into weekly folders located within the **COURSE DOCUMENTS** button of **Blackboard**. ***Course documents are organized on a weekly basis (beginning on Monday and ending the following Sunday).*** You will see weekly folders that contain the readings/assignments for that week. You are expected to actively read through and comprehend the materials assigned for that week.

COURSE REQUIREMENTS

DISCUSSIONS (WEEKLY)

Every Monday, your instructor will post a few questions pertaining to the assigned chapters to motivate your learning of the course content. Facilitation of a discussion forum will be based on one (or a few) of the chapters from the textbook. For example, Chapter 4 (Coherence Principle) discussion board questions may be as follows:

- *Imagine that you are in a class in which the instructor presents the material on the different parts and function of the human brain in lecture-style format. You find the lecture to be somewhat boring and difficult to understand. How may you, as a learner, enhance your understanding of the lecture using the Coherence Principle in the way you take notes? Explain your answer clearly.*
- *According to Coherence principle number 1, "learning is improved when interesting but irrelevant words and pictures are excluded from a multimedia presentation". Give a specific example of this and explain how you would "redesign" instruction to enhance student learning. Explain the rationale for your "redesign"?*

You are expected to regularly and to actively participate in all the weekly discussions by responding to each of the questions posted. The quality and frequency of your responses will be taken into account towards your grade. You are also expected to provide feedback to other students' responses. Discussions are meant to be *insightful, reflective, lively, and thought provoking.*

Your participation in the weekly discussion contributes significantly toward your final grade. You should respond completely and thoroughly to each of the posted question for the week's discussion board questions. ***Providing "quality" feedback to at least 3 of your other classmates' and/or instructor's initial postings*** in a way that makes the discussions intellectually stimulating will constitute sufficient participation, although you are encouraged to respond to more postings if you want a better participation grade for that week. It will be up to your instructor to determine the quality level of your postings and feedback to determine the appropriate grade for weekly participation in the discussion boards.

The main purpose of the online discussions is to enhance your learning of the concepts and applications presented in this course, and to further your thinking and writing skills.

There is no need to submit a written report for this requirement.

MULTIMEDIA PROJECT

You will be required to develop a multimedia project (which may take the form of a PowerPoint presentation, a website/webpage, a video, or any other format that incorporates the multimedia principles learned from this course. The content material of the multimedia presentation should be clearly defined, specific, uncomplicated, and of interest to you. Your instructor must approve your chosen topic.

In addition, you are required to submit a paper ***(no more than 8 pages, double-spaced)*** that describes how your multimedia project addresses each of the 12 research-based principles in the design of multimedia instruction/messages AND how you think your project may be further improved. Therefore, you are expected to respond to the following four (4) questions:

A. Briefly describe the content material of your project? *(no more than 1 page)*

B. Who is your intended audience AND how is your project meant to be presented (e.g., lecture format in a classroom, individualized instruction over the Internet)? *(no more than 1 page)*

C. How has your multimedia project incorporated each of Mayer's 12 principles of multimedia learning? Provide a specific example for each principle that you applied to your project. *(approximately 4 – 5 pages)*

1. ***Coherence Principle***
2. ***Signaling Principle***
3. ***Redundancy Principle***
4. ***Spatial Contiguity Principle***

5. ***Temporal Contiguity Principle***
6. ***Segmenting Principle***
7. ***Pre-training Principle***
8. ***Modality Principle***
9. ***Personalization Principle***
10. ***Voice Principle***
11. ***Image Principle***
12. ***Embodiment Principle***
13. ***Immersion Principle***
14. ***Generative Activity Principle***

D. How could you make your multimedia project even better? *(approximately 1 page)*

After you have completed your project, your classmates will be given the opportunity to provide you with feedback and to have your project evaluated by them. You will do the same for your classmate's projects. Thus, all projects will be made accessible online and will be evaluated by students using the ***Student Grade Form*** (This form will be made available online). Your instructor will also provide you with feedback/comments. Details on the technical aspects of this requirement will be discussed in the course of the semester.

An ***Individual Member Evaluation*** form must also be submitted. (This form will be made available online). This will allow you to evaluate your own project.

Your Final Project is intended to supplement your learning of the course and to demonstrate your knowledge of important multimedia principles in presenting multimedia instruction.

FINAL EXAM

The ***Final Exam*****,** which will be administered online, shall cover all the chapters of your textbook. It is designed to test your knowledge of the material discussed in the assigned readings and to apply what you have learned from the course. The format may include multiple-choice, true-false, and short answer questions.

Communication

Discussion

The ***Discussion Board*** area has been set up in an asynchronous online format in which students (and the instructor) answer questions, ask questions, comment on the responses of your fellow classmates and instructors. This area can be very valuable to you if you encounter difficulty during the course. Check the Discussion area frequently. Your participation is part of your grade.

If you have personal and/or on-the-job experience relevant to a discussion topic or to a question from one of your fellow students, please do share your experiences as it relates to the chapter/topic covered. Active participation by everyone contributes to a more intellectually stimulating and engaging online learning experience.

Email

Please feel free to contact your instructor or your classmates via **email** at any time if needed. My email address is rvelayo@gmail.com. You classmates' (and instructor) email(s) may be accessed under the "Email" button on the PSY634 Blackboard site.

Course Topics and Schedule

WEEK	TOPIC	REQUIREMENT DUE
1 (July 14 - July 20)	***COURSE INTRODUCTION*** **<u>SECTION 1</u>: Introduction to Multimedia Learning** CHAPTER 1: The Promise of Multimedia Learning CHAPTER 2: Science of Learning: Determining How Multimedia Learning Works CHAPTER 3: Science of Instruction: Determining What Works in Multimedia Learning CHAPTER 4: Science of Assessment: Determining What Was Learned in Multimedia Learning CHAPTER 5: Multimedia Principle	**Post your self-introduction on Discussion Board forum called "PSY634 Lounge"** **(Due: July 20)**
2 (July 21 - July 27)	**<u>SECTION 2</u>: Principles for Reducing Extraneous Processing in Multimedia Learning** CHAPTER 6: Coherence Principle CHAPTER 7: Signaling Principle CHAPTER 8: Redundancy Principle CHAPTER 9: Spatial Contiguity Principle CHAPTER 10: Temporal Contiguity Principle	
3 (July 28 - August 3)	**<u>SECTION 3</u>: Principles for Managing Essential Processing in Multimedia Learning** CHAPTER 11: Segmenting Principle CHAPTER 12: Pre-training Principle CHAPTER 13: Modality Principle	**TOPIC for Multimedia Project** **(Due: August 3)**
4 (August 4 - August 10)	**<u>SECTION 4 (Part 1)</u>: Principles for Fostering Generative Processing in Multimedia Learning** CHAPTER 14: Personalization Principle CHAPTER 15: Voice Principle CHAPTER 16: Image Principle	

5 (August 11 - August 17)	**<u>SECTION 4 (Part 2):</u> Principles for Fostering Generative Processing in Multimedia Learning** CHAPTER 17: Embodiment Principle CHAPTER 18: Immersion Principle CHAPTER 19: Generative Activity Principle	**Multimedia Project** **(Due: Aug. 17)**
6 (August 18 - August 24)	**<u>SECTION 5</u>: Conclusion** CHAPTER 20: Principles of Multimedia Design ***COURSE Wrap-up and EVALUATION***	**Final Exam** **(Due/Complete by Aug. 24)** **Student Grade Form for Multimedia Project** **(Due: Aug. 24)** **Self-Evaluation Form for Multimedia Project** **(Due on Aug. 24)**

Grading

Each of the activities below constitutes part of your grade. Failure to participate in one or more activities may result in a significant reduction in your grade.

Final grades are calculated as follows:

Participation (Weekly Discussion Board) *(15 points per chapter; 14 chapters)*	42%	210 points
Final Project:		
Feedback from Class	10%	50
Feedback from Instructor	20%	100
Self-Evaluation Form	4%	20
Submission of Student Grade Form (SGF)	4%	20
Final Exam	20%	100
Total	**100%**	**500 points**

<u>Note</u>: *Three (3) points are subtracted for each day a course requirement is submitted late.]*

Letter-Grade Equivalent
("Strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

Attendance

Attendance is in the form of participation in the discussion board. Successful online learning requires that a student actively participates in each week's learning materials including:

- **Reading** textbook chapters, plus any articles and/or web materials assigned.
- **Submission** of assignments, projects and papers on time.
- **Completion** of the course requirements (e.g., exams, final project).
- **Participation** in the weekly discussion board forums, and other activities.

Excessive non-participation and failure to keep up with the course pace may result in a decreased or failing course grade. This is ***not a self-paced course***. Within each week, assignments may be worked on at times convenient to the student. However, the assignments are to be completed by the end of that academic week If you are unable to participate during a particular week, please contact the instructor beforehand.

Academic Integrity Code (Graduate)

Students in this course are required to adhere to Pace University's Academic Integrity Code. The Academic Integrity Code supports honesty and ethical conduct in the educational process. It educates students about what constitutes academic misconduct, helps to deter cheating and plagiarism, and provides a procedure for handling cases of academic misconduct. Students are expected to be familiar with the Code, which can be found under "University Policies" in the Student Handbook. You may also access it at http://www.pace.edu/student-handbook/university-policies-disciplinary-and-grievance-procedures

Individual schools and programs may have additional standards of academic integrity. Students are responsible for familiarizing themselves with the policies of the schools, programs, and courses in which they are enrolled.

[Pace Graduate Students]
Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any academic paper, report or submission for academic credit without the appropriate acknowledgement is plagiarism. It is also academically dishonest to submit anything in electronic form as one's own that is the work, either fully or in part, of someone else. It is unethical to present as one's own work, the ideas, words or representations of another without the proper indication of the source. Therefore, it is the student's responsibility to give credit to any quotation, idea or data borrowed from an outside source. Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension, dismissal or expulsion from the University. (L-54)

Indigenous Land Acknowledgement

The Pace University NYC campus and its surroundings are located on the traditional lands of the Lenape people.

Students with Disabilities

The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities. To request a reasonable accommodation for a qualified disability a student with a disability must self-identify and register with Student Accessibility Services for their campus. (NYC Campus: 212-346-1526; 156 William St., 8th floor). No one, including faculty, is authorized to evaluate the need for or grant a request for an accommodation except Student Accessibility Services. Moreover, no one, including faculty, is authorized to contact Student Accessibility Services on behalf of a student. For further information, please see Resources for Students with Disabilities page at https://www.pace.edu/counseling/student-accessibility-services

Justice, Equity, Diversity, and Inclusion

This course covers some topics that may be personal, upsetting, unfamiliar, and/or difficult for us, making it especially important that we all treat each other with compassion and respect. Disagreement and debate are good and encouraged, and they should focus on the issue, not attacking any individual. While we discuss and debate different points of view, we are all expected to contribute to justice, equity, and inclusion, and to support everyone feeling welcome to share, explore, learn, and grow together in this course. Comments that are stigmatizing based

on identities/positionalities, such as ability, age, ethnicity, gender/sex identity/expression, immigration status, national origin, race, religion, sexual orientation, social class, or weight/physical appearance, among others, are not welcome in class. Sometimes without intending to or being aware, we commit microaggressions, which involve saying or doing things that are stigmatizing and harmful to members of a marginalized group. It helps us all learn if we inform each other when we commit microaggressions or say something discriminatory. If you are ever upset with any comments made (including by me) in class or any other aspect of the course, please communicate this in some way, either to the entire class or me individually.

Pace University is committed to preventing and provides support for survivors of sexual assault and gender-based harassment. For more information: https://www.pace.edu/sexual-wellness

Pace University has an Office of Multicultural Affairs (https://www.pace.edu/multicultural-affairs/nyc) that provides support in the area of diversity broadly and an LGBTQA & Social Justice Center (https://www.pace.edu/lgbtqa-center) that provides support in the areas of sexual and gender identity and expression. Both of these offices are located on the 9th floor of 41 Park Row, but will likely be operating primarily remote/online for the Fall 2020 semester.

Pace University provides support for international students and scholars: https://www.pace.edu/international-students-scholars

Pace University allows students to use the name and salutation of their choice for some campus systems (e.g., campus ID, academic record/transcript/diploma). For more information: https://www.pace.edu/lgbtqa-center/resources-services/preferred-first-name-procedure

Title IX Coordinator: Title IX makes it clear that violence and harassment based on sex and gender are Civil Rights offenses subject to the same kinds of accountability and the same kinds of support applied to offenses against other protected categories such as race, national origin, etc. If you or someone you know has been harassed or assaulted, you can contact Juliette Verrengia, MSW, jverrengia@pace.edu, 212-346-1931 (Director, Office of Sexual Assault Prevention and Education) or A. Lisa Miles, 212-346-1310, amiles@pace.edu (Title IX Coordinator). If you have any questions about Title IX, I invite you to speak with me or to contact Ms. Verrengia or Ms. Miles.

Other University Resources

I also encourage students to take advantage of the following other resources that Pace University offers:

- Information Technology Support and Services: https://www.pace.edu/its/it-services-and-support/students-resources
- The Counseling Center: https://www.pace.edu/counseling
- The Library: https://libguides.pace.edu/?group_id=6678
- International Student Services: https://www.pace.edu/admission-aid/graduate-admission/international/international-student-services
- The Writing Center: https://www.pace.edu/dyson/centers/writing-center
- The Learning Center: https://www.pace.edu/center-academic-excellence/tutoring-center/new-york-city-campus
- The Center for Academic Excellence: https://pace.smartcatalogiq.com/en/2017-2018/Graduate-Catalog/General-University/Academic-and-Co-Curricular-Services/The-Center-for-Academic-Excellence-CAE
- Career Services: https://www.pace.edu/career-services/
- The Office of Student Development and Campus Activities: https://www.pace.edu/student-development/nyc

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PSYCHOLOGY 643

Psychology at the United Nations

(CRN #71411)
(Fall 2023)

Class Schedule

Days/Times: Fridays, 1:20pm – 4:20pm (via ZOOM)

Instructors

Florence L. Denmark, Ph.D.
Email: fdenmark@pace.edu
Office Hours: by appointment (by phone)
Phone: 646-983-0890

Richard S. Velayo, Ph.D.
Email: rvelayo@gmail.com or rvelayo@pace.edu
Office Hours: by appointment (remote or by phone)

Course Description

The United Nations (UN) is a complex, somewhat mythical world which serves as the meeting-ground for political powers from around the world. It is unique among international institutions, considering the vast array of tasks entrusted to it. The UN is involved in all aspects of human activity; it therefore plays an important role in the global community. "Global" is a word that is used to refer to issues and concerns of the entire world while "international" is a term that is used to refer to issues and concerns of two or more countries. While not always successful in implementation, the United Nations takes a global stance on world issues.

This 3-credit graduate-level course will consider the history of the United Nations, how it functions, and the role of psychology and psychologists at the United Nations. Guest speakers who are active in the United Nations will be invited to speak to the class. Students will be assigned UN-relevant topics to present in class.

Prerequisite

There are no graduate course prerequisites.

Learning Objectives

At the end of this course, a student should be able to demonstrate the following competencies:

- Identify and describe key events and structures related to the history of the United Nations.
- Determine the function and structure of the United Nations.
- Describe and appraise one's tour (guided or virtual) of the United Nations Headquarters (in NY).
- Assess psychology's impact on United Nations objectives.
- Apply, examine, and assess the role of psychologists/psychology at the United Nations.

Class Delivery Format/Location

Online: This course is delivered fully remotely with no on-campus components.

- Synchronous (SYNC): This course is taught online in real time using *ZOOM*. Students will be required to participate at set times from their own home/residence hall or remote location. *[NOTE: CLASSES will also be utilized for this course. Students are responsible for assuring that they have access to both CLASSES and ZOOM.]*

Course Materials (Required text and other materials)

1. United Nations Website

Web-based materials derived from the website of the United Nations (www.un.org) will be utilized. Other relevant online sources will be included as determined by the instructors.

2. Textbook

Congress, E.P., Takooshian, H., & Asper, A. (Eds.). (2020). *Behavioral Science in the Global Arena: Addressing Timely Issues at the United Nations and Beyond*. Information Age Publishing.

(NOTE: Below are links to two formats of this book. The Kindle format is recommended.)

Kindle format (ISBN: 978-1-64802-082-1)

Link to purchase Kindle format:
https://www.amazon.com/Behavioral-Science-Global-Arena-International-ebook/dp/B08B2RSGZ3/ref=sr_1_1?crid=XTLG7VLXYJPV&keywords=Behavioral+Science+in+the+Global+Arena&qid=1691948134&s=digital-text&sprefix=behavioral+science+in+the+global+arena%2Cdigital-text%2C157&sr=1-1

Paperback format (ISBN: 978-1-64802-082-7)

Link to purchase Paperback format:
https://www.amazon.com/Behavioral-Science-Global-Arena-International/dp/1648020828/ref=tmm_pap_swatch_0?_encoding=UTF8&qid=1691948134&sr=1-1

Course Requirements

1. PARTICIPATION

- **Attendance (via ZOOM)**
  Students are expected to be connected to Zoom during the entirety of each class meeting. Points may be deducted for late attendees or those who only attend part of the meeting. Instructor/s will set the policy on the use of chat, video, and audio functions.

- **Discussions**
  There will be weekly questions posted on CLASSES for students to respond to.

- **In-class Topic Presentations**
  [See Grading rubric for this requirement.]
  Each student will present (via Zoom) at least two (2) topics covered in the course.
  TOPIC #1: U.N. website (https://www.un.org/)
  TOPIC #2: Select textbook chapter
  Chapter 2: **Aging**
  Chapter 3: **Child Welfare and Well-Being**
  Chapter 4: **Migrant Adaptations and Well-Being**
  Chapter 5: **Gender Equity and Reproductive Justice**
  Chapter 6: **Poverty and Inequality**
  Chapter 7: **Social Protection**

Chapter 8: **Freedom and Democracy**
Chapter 9: **Human Rights**
Chapter 10: **Counter-Terrorism**
Chapter 11: **Crime Prevention and Control**
Chapter 12: **Mental Health: Happiness and Well-Being**
Chapter 13: **Physical Health**
Chapter 14: **Disaster and Trauma Intervention**
Chapter 15: **Promoting Environmental Health**
Chapter 16: **Reducing Urban Noise**

2. PAPERS

- **Tour (Guided or Virtual) of U.N. Headquarters (NYC)** – Reaction Paper (1-page, single-spaced)

- **Interview a Psychologist involved with the U.N.** – Written Report (2 - 3 pages, single-spaced)
  - A list of interview questions to be provided by your instructor/s.
  - The psychologist to be interviewed must be approved by your instructor/s.
  - A write-up of the interview AND a brief in-class presentation of the write-up are required.

- **NGO Committee meeting/event** – Reaction Paper (1-page, single-spaced)

- **Final Paper** (3 - 4 pages, single-spaced) *[See Grading rubric for this requirement.]*
  - The final paper is a critique on one of the chapters from the course textbook.
  - There shall be NO duplication of topics/chapters between students.
  - Final papers will be submitted via *Turnitin.*
  - Students will present their final papers in class (via ZOOM) towards the end of the semester.

Grading System

Course Requirements	**Points**
PARTICIPATION (Weekly)	
Attendance (24%)	120
10 points subtracted for each meeting absent.	
5 points subtracted if more than 30 minutes late.	
Discussions (weekly) (6%)	30
Late postings are NOT accepted.	
Three (3) points subtracted for not posting on a forum.	
In-class Topic Presentations (via ZOOM) (20%)*	
Topic #1: A topic from the U.N. website	50
Topic #2: A chapter from the textbook	50
PAPERS*	
Tour (Guided or Virtual) of the U.N. Headquarters (NYC) – Reaction Paper (6%)	
Written Report	25
Brief (in-class) presentation (via ZOOM)	5
"Interview a Psychologist Involved with the U.N." (11%)	
Written Report	50
Brief (in-class) presentation (via ZOOM)	5
NGO Committee Meeting or Event – Reaction Paper (6%)	
Written Report	25
Brief (in-class) presentation (via ZOOM)	5
Final Paper (27%)	
Instructor Evaluation *(See Grading Rubric)*	80
Student Grade Form *(Grades are averaged)*	20
Submission of Student Grade Form	10
Paper Presentation (In-class) *(via ZOOM)*	25
Total points	**500**

***[Note:** Two (2) points subtracted for each day a course requirement is late.]*

Letter-Grade Equivalent
("Strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

SCHEDULE

General outline of class meetings:

1. Reminders + Instructor introduction to the topic(s) *(20 min.)*
2. Featured Speaker *(60 min.)* (and/or class activity/discussion)
3. Break (Optional) *(10 min.)*
4. Student In-class Presentation/s of assigned weekly topic/s *(40+ min.)* (and/or class activity/discussion)
   [NOTE: PowerPoint file must be sent to instructors the day prior to the presentation date. It will be uploaded to CLASSES by your instructor.]

(Times indicated above are approximate.)

WEEK 1 & 2 (9/08, 9/15): **COURSE OVERVIEW**
Overview of the UN website
History of the UN (including *League of Nations*)
Behavioral Sciences at the U.N. *(Chapter 1 of textbook)*

WEEK 3 & 4 (9/22, 9/29): **ABOUT THE U.N.**
- Member States
- Main Bodies
- Secretary-General
- Secretariat
- UN System
- History
- Emblem and Flag
- UN Charter
- UDHR (Universal Declaration of Human Rights)
- ICJ (International Court of Justice) Statute
- Nobel Peace Prize

WEEK 5 & 6 (10/06, 10/13): **Part 1: WHAT DOES THE U.N. DO?**
- Peace and Security
- Human Rights
- Humanitarian Aid
- International Law

WEEK 7 (10/20): **PART 2a: WHAT DOES THE U.N. DO?**
- Support Sustainable Development (UN Sustainable Development Goals) and Climate Action

WEEK 8 (10/27): **PART 2b: WHAT DOES THE U.N. DO?**
Support Sustainable Development (UN Sustainable Development Goals) and Climate Action

DUE 10/27: Tour (Guided or Virtual) of the U.N. Headquarters (NYC) (Reaction Paper)

WEEK 9 (11/03): **PART 3: WHAT DOES THE U.N. DO?**
- Global Issues
- Documents
- Official Languages
- Observances

WEEK 10 (11/10): **OTHER TOPICS ABOUT THE U.N.**
- Events and News
- Get Involved

DUE 11/10: Interview a Psychologist Involved with the U.N. (Written Report)
In-class presentation of Interview write-up (via ZOOM)

WEEK 11 (11/17): **Psychology and the Future of the UN**
- Annual Psychology Day at the U.N.
- What is the APA and other international psychology organizations doing?
- Engaging Students in the work of the U.N.

DUE 11/17: NGO Committee Meeting/Event (Reaction Paper)

WEEK 12 (11/24): **NO CLASS** (Thanksgiving Break)

WEEK 13 (12/01): **FINAL PAPER Presentations** (via ZOOM)

DUE 12/01: FINAL PAPER

WEEK 14 (12/08): **NO CLASS [Tentative; possible "snow day"]**

DUE 12/06: STUDENT GRADE FORM *(Part of FINAL PAPER requirement)*

WEEK 15 (12/15): **NO CLASS**

University Policies and Resources

- ***Academic Integrity***

Students in this course are required to adhere to Pace University's Academic Integrity Code, which supports honesty and ethical conduct in the educational process. It educates students about what constitutes academic misconduct, helps to deter cheating and plagiarism, and provides a procedure for handling cases of academic misconduct. Students are expected to be familiar with the Code, which can be found in University Policies, Disciplinary and Grievance Procedures. Individual schools and programs may have additional standards of academic integrity. Students are responsible for familiarizing themselves with the policies of the schools, programs, and courses in which they are enrolled.

[Pace Graduate Students]
Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any academic paper, report, or submission for academic credit without the appropriate acknowledgement is plagiarism. It is also academically dishonest to submit anything in electronic form as one's own that is the work, either fully or in part, of someone else. It is unethical to present as one's own work, the ideas, words, or representations of another without the proper indication of the source. Therefore, it is the student's responsibility to give credit to any quotation, idea or data borrowed from an outside source. Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension, dismissal, or expulsion from the University. (L-54)

- ***Learning Commons***

The Learning Commons uses an array of programs and a holistic approach to assist students with academic skills and content knowledge. We are dedicated to developing independent learners through purposeful interactions with trained, well-qualified peer and professional staff. Services offered:

- Content Support Services including, content tutoring, exam review sessions, & content preparation/support workshops
- Academic Skills Services including small group peer mentoring, academic skills workshops, and individual academic development
- Writing Support Services including, writing tutoring & writing preparation/support workshops

- ***Procedure for Students Who Wish to Obtain Reasonable Accommodations for a Course***

The same rigorous standards for admission apply to students with and without a disability. In order to support the continued success of students with disabilities, the University prohibits discrimination on the basis of disability and is committed to ensuring equal access for students with disabilities to its facilities, programs, and activities. The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities.

To request an accommodation for a qualifying disability, a student must self-identify and register with the Disability Services Office for his or her campus. The Office of Disability Services is housed in the Counseling Center on the New York City and Pleasantville campuses. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see Information for Students with Disabilities page.

- ***Technological Resources***
  - List of all Pace Information Technology Services.
  - For assistance with a technological concern contact the Pace Helpdesk at (914) 773-3648 or create a help desk ticket.
  - Visit the Learning Remotely website

- ***Appropriate Use Policy for Information Technology***

Pace endorses the following statement on software and intellectual rights distributed by EDUCAUSE, the non-profit consortium of colleges and universities, committed to the use and management of information technology in higher education. The statement reads:

> *Respect for intellectual labor and creativity is vital to academic discourse and enterprise. This principle applies to work of all authors and publishers in all media. It encompasses respect for the right to acknowledgment, right to privacy and right to determine the form, manner and terms of publication and distribution.*
>
> *Because electronic information is volatile and easily reproduced, respect for the work and personal expression of others is especially critical in computer environments. Violations of authorial integrity, including plagiarism, invasion of privacy, unauthorized access and trade secret and copyright violations, may be grounds for sanctions against members of the academic community.*

See Pace's IT appropriate use policy.

- ***Sex-Based Misconduct Policy and Procedure***

Pace University is committed to providing a safe environment for every member of its community and to ensuring that no student, faculty, or staff member is excluded from participation in or denied the benefits of any University program or activity on the basis of sex. Accordingly, the University prohibits the following forms of Sex-Based Misconduct: sexual assault, sexual harassment, gender-based harassment, dating violence, domestic violence, sexual exploitation, and stalking.

Instructors are a **non-confidential** resource and have an obligation to report any information about sexual assault with the Executive Director of Institutional Equity and Title IX Coordinator – Bernard Dufresne, bdufresne@pace.edu, 163 Williams Street, Room 1017, (212) 346-1310. The Title IX/Affirmative Action Office is responsible for investigating violations of the sexual misconduct policy. Go here for more information about the Pace University sexual misconduct policy.

Members of the University community who believe that they have been subjected to Sex-Based Misconduct are encouraged to report such incidents to the University and, where applicable, to local law enforcement. **Confidential** resources include the **University Counseling Centers, Offices of Sexual and Interpersonal Wellness** and **University Healthcare**. Contact information for those offices may be found in the self-care section below.

- ***Self-Care***

Your academic success in this course and throughout your college career depends heavily on your personal health and well-being. Stress is a common part of the college experience, and it often can be compounded by unexpected life changes outside the classroom. The Pace Community strongly encourages you to take care of yourself throughout the term before the demands of midterms and finals reach their peak. Please feel free to talk with me about any difficulty you may be having that may impact your performance in this course as soon as it occurs and before it becomes unmanageable. Please know there are a number of other support services on campus that stand ready to assist you. You are strongly encouraged to contact them when needed as well.

The Counseling Center "Just In Case" information supplies potentially life-saving mental health information to Pace University students, staff, and faculty, putting vital information and support options at your fingertips, just in case you or a friend needs help. Go to the Just in Case page on the Pace website or go to "Counseling Center" on the MyPace or the Pace Safe app.

Department	**Pleasantville**	**New York City**
Advising Center for Exploring Majors	First-year: (914) 773-3756 | (914) 773-3757	(212) 346-1798
Affirmative Action Office	(914) 923-2610	(212) 346-1310
Center for Spiritual Development	(914) 773-3767	
College of Health Professions Academic Advisement	UG (914) 773-3961 UG (914) 773-3347 Grad (914) 773-3114	UG (212) 618-6027 Grad (914) 773-3114
Counseling Center	(914) 773-3710	(212) 346-1526
Dean for Students Office	(914) 773-3351	(212) 346-1306
Dyson College Academic Advisement	(914) 773-3781	(212) 346-1518
International Student/Scholars	(212) 346-1368	
Lubin School of Business Academic Advisement	UG (914) 773-3531	UG (212) 618-6550 Grad (212) 618-6440
Office of Multicultural Affairs	(914) 773-3628	(212) 346-1546
Office of Sexual and Interpersonal Wellness	(212) 346-1931	
Office of Student Assistance (OSA)	(877) 672-1830	
Pace Women's Justice Center	(914) 287-0739	
Pforzheimer Honors College Academic Advisement	(212) 346-1697	
Residential Life	(914) 597-8777	(212) 346-1295
Seidenberg School Academic Advisement	SeidenbergInquiry@pace.edu	
Sexual Assault Prevention & Education	(212) 346-1931	
Study Abroad	(212) 346-1368	
Student Accessibility Services	(914) 773-3710	(212) 346-1526
Student Engagement	(914) 773-3767	(212) 346-1590
University Health Care	(914) 773-3760	(212) 346-1600

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PSYCHOLOGY 617*

HUMAN LEARNING

(NY 90856)

Fall 1999

Instructor:	Richard S. Velayo, Ph.D.
Lecture Meetings:	Wednesdays, 5:30 pm - 8:10 pm
Office:	41 Park Row, Room 1601A 346-1506 (office phone)
Office Hours:	T, R 2:30 pm - 5:00 pm (or by appointment)
Prerequisite:	None (but preferably an undergraduate course on Learning Theory)
URL:	http://webpage.pace.edu/rvelayo/fall1999.htm
Web Board:	http://webboard.pace.edu:8080/~velayo
E-mail:	rvelayo@pace.edu

Brief Course Description

This course introduces both basic and advanced principles and theories of learning and motivation, including cognition. Conditioning, behavior systems, generalization and discrimination, information processing, and complex cognitive functioning are some of the topics discussed. Research on learning theory and their general application to a variety of contexts will be covered.

Classes will generally have a discussion format in which students actively participate by asking questions, thinking critically about the concepts presented in the course, and determining appropriate ways to apply such concepts. You are also expected to have read the assigned materials prior to a class meeting and be prepared to answer questions posed.

Your enrollment in this course will require intensive reading and understanding of the text and assigned readings. There may be some small group or individual exercises, presentations, and a final project that will test your ability to apply concepts learned from the course. Details regarding these requirements will be explained in the course of the semester.

In addition, films relating to some of the topics covered may be shown occasionally.

The specific objectives of this course are as follows:

- Demonstrate understanding of the basic "learning" concepts and principles of both by answering questions on exams and by appropriate application of these principles and concepts to a variety of contexts.
- Ask and answer questions in class that correctly use basic concepts, terms, and principles from the field of applied behavior management.
- Evaluate practical problems in behavior management and thereby identify the objective target behaviors (responses), the environmental conditions (stimuli), and the significant consequences (reinforcers, punishers, and other contingencies) that require change.
- Be aware of the ethical considerations regarding the applications and techniques discussed in the course, given a specified context.
- Be able to critique research on the use of behavior modification techniques.
- Determine the feasibility of implementing a behavior modification program.

- Write a behavior modification program/proposal for intervention and behavior change in an actual problem situation.

Text (Required):

Lieberman, D. A. (2000). Learning: Behavior and Cognition. (3rd ed.). Pacific Grove, CA: Brooks/Cole.

Other readings may be assigned.

You are expected to have read the assigned textbook chapters prior to a class meeting. As a graduate course in psychology, you are expected to come to class prepared to learn by discussing issues and principles that you find particularly interesting or difficult.

Exams

There will be two exams, a Midterm and a Final (125 points each) that will cover the chapters in the text and lecture materials. The format will be short answer, multiple-choice, and possibly some true-or-false items.

Make-up exams will be given only for excused absences (e.g., medical reasons and the like) and will obviously be different from the exam administered during the scheduled time (and generally require more in-depth knowledge of the material). Missing an exam will require a valid written excuse. Arrangements for a make-up exam must be made within one week following the test date or a grade of 0 may be given.

Session Facilitation

This activity will primarily require you to facilitate a discussion session based on a textbook chapter assigned in class. For each session, you will be in charge of facilitating discussion on the topic to be covered that day. You may be creative in doing this. For example, you may have the class do an exercise, evaluate literature, critique a film, discuss a controversial topic, etc., so long as you cover the major concepts in that chapter.

You are also expected to develop an "activity" for the entire class using the WEB BOARD (http://webboard.pace.edu:8080/~velayo). This will help not only enhance your knowledge and critical thinking skills on some content area covered in the course but also to learn about the use of technology as a pedagogical tool.

The class will also provide you with brief written feedback form with a corresponding grade based on your facilitation of the session.

I will provide the class with a discussion sheet a week prior to the discussion of the chapter to make it easier to focus on the more important concepts. Use this sheet to prepare yourself for each session.

The other members of the class are expected to actively contribute.

Presentation of Behavioral Technique/s

Teams (or an individual) will be formed to introduce and demonstrate certain behavior modification techniques to the class. You may do your presentation in whatever format you think will motivate the class to learn, but it should not be solely based on the textual readings. You may present these techniques through demonstrations, role-playing, skits, brief surveys, etc. Nonetheless, it is important that you let me know one week ahead of time the format and added content (if any) of your team's presentation. Time limit: 15 minutes

You may also use the WEB BOARD (http://webboard.pace.edu:8080/~velayo) to supplement your presentation.

The behavioral techniques that will be covered for presentation is listed at the end of this syllabus.

Behavior Modification Project (Group or Individual)

A major requirement of this course is to develop a proposal for a behavior modification program for a problem situation in a context of your choice. This will involve determining a feasible program to modify a problem behavior. Details on possible topics, and how to do the program will be discussed during the semester.

The behavior modification project may be done as a team (2 or 3 people) or individually. The project's topic must be submitted for approval on or before **October 6** (Wednesday).

An oral presentation of your project is expected before the end of the semester. This should last no longer than 30 minutes and should follow the format of the write-up. Allow some time for other members of the class to ask questions about your project.

The write-up of the program should be typewritten, double-spaced, and should be written in the following outline format:
(Important Note: Each component part of each section of the write-up should be incorporated in one paragraph, if possible. Otherwise, make sure that each component part is clearly labeled.)

I. Problem Description and Assessment (20 pts.)
- Define important terms.
- Present related literature.
- Describe, in detail, the subject/individual with the behavioral problem.
- How will you assess if the problem involves a behavioral excess, deficiency, or inappropriateness?
- Analyze the antecedents and consequences of the problem behavior.
- What are some of your behavioral assessment sources?
- Why is it feasible to use behavior modification in such situation?

II. Baseline Data (10 pts.)
- Include a "behavioral recording chart" to assess the target behavior.
- Gather preliminary data on the rate, frequency, duration, magnitude, and/or latency of the target behavior over a period of time in which it occurs.
- Present the data using tables, graphs, and relevant descriptive statistics. Describe them thoroughly.

III. Intervention Planning (20 pts.)

Formulate specific behavioral goals of the program including initial, intermediate, and long-term ones.

Describe the concepts and techniques used and why you think this is (these are) the most feasible to use.

Speculate on the amount of time and what resources are necessary to undertake the program.

What specific behaviors will you keep a record of and how?

How will you evaluate the effectiveness of the program?

What are the ethical considerations you need to observe?

Plan for generalization and maintenance of the behavior change.

IV. Potential Problems (10 pts.)

Enumerate some of the methodological, contextual, and ethical problems you may encounter in the implementation of your program. In what way could these be potential problems to your program?

How do you plan on minimizing or eliminating them?

V. References (5 pts.)

Writing Quality (5 pts.)

- Grammar, spelling, coherence, etc.

Note: ***Late submissions will not be accepted*** *unless due to unavoidable circumstances.*

An **individual member evaluation form** must also be submitted (separately or with the write-up) on or before **December 22** (Wednesday). You will be given this form sometime during the semester. This will allow you to evaluate each member of your group, including yourself.

Extra Credit Work

You may choose only one of the following for extra credit:

(i) **Article Critique** (? points)

This optional requirement is based on outside reading and evaluation of psychological literature that is related to the course. You must first obtain approval from me regarding the article you have chosen. Choose an empirical article of interest to you that has appeared in the last five or six years (1993 - present).

If you choose to do an article critique for extra credit, you are expected to write a 3-4 page critique (typewritten, double-spaced) of the article you have chosen and approved by me. This must be turned in by **December 22** (Wednesday). Late submissions will NOT be accepted. It should contain a full citation and attach a copy of the article to your critique. The format of your paper should contain the following:

1) Problem - Describe the nature of the problem or main research question in and motivation that the author is addressing.
2) Method/s - Describe the methods (subjects, apparatus, procedures) that the author use to answer the experimental question.
3) Results - Describe the most important key results, particularly those that answer the main experimental question.
4) Implications - What are the implications of the results for theories of learning, especially in relation to relevant text chapters.

I suggest that you do not wait until the last minute to do the article critique because this may interfere with studying for your Final Exam.

(ii) **Participation in a Research Project** (? points)

You are encouraged to participate in a research project involving some aspect of learning, memory, and cognition. Details on some of these projects will be made available in the course of the semester.

Other Reminders

- You may find some of the answers to your questions pertaining to this course in this syllabus. . . so read it carefully!
- Ask me if something isn't clear. I'm quite approachable. . . really! . . . well, most of the time :)
- Keep all papers returned to you.
- There is no such thing as bargaining for a grade. . . unless there is an error in correction or computation.
- During our class meetings, I encourage you to share some of your experiences and/or expertise as it relates to this course.
- Put a smile on your face . . . it cools the brain! (see research by Zajonc)

Grading System

MIDTERM Exam	125
FINAL Exam	125
Session Facilitator	50
Class Feedback of Session	40
Presentation of Behavioral Technique	30
Behavior Modification Project:	
Oral Presentation	40
Write-up	70
Individual Member Evaluation	20
Extra Credit Work:	
Article Critique	?
Participation in Research Project	?
Total points	**500+**

Letter-Grade Equivalent
(will be "strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449		
B	400-424		
B-	375-399	F	below 325

SCHEDULE

Date/s	Topic	*Readings
Sep 15	Introduction to Psychology 617 What is "Psychology of Learning"? What is Behavior Modification (BM)? What is BM for?	Syllabus
Sep 22	SOME BASIC ASSUMPTIONS	1

Sep 29	FOUNDATIONS OF CLASSICAL CONDITIONING Behavioral Techniques: *(i) Discrimination Training Procedure and Stimulus Generalization* *(ii) Fading*	2
Oct 6	PRINCIPLES AND APPLICATIONS Behavioral Techniques: *(i) Systematic Desensitization and In Vivo Desensitization* *(ii) Flooding and Aversion Therapy* **Due: Topic for Behavior Modification Project**	3
Oct 13	THEORIES OF CONDITIONING Behavioral Technique: *(i) Extinction*	4
Oct 20	No Classes	
Oct. 27	REINFORCEMENT	5
	APPLICATIONS OF REINFORCEMENT Behavioral Techniques: *(i) Positive Reinforcement* *(ii) Intermittent Reinforcement Schedules* *(iii) Contingency Contracting and Premack Principle* *(iv) Shaping and DRO Procedure*	6
Nov. 3	**MIDTERM Exam** (Coverage: Chapters 1-6, Lieberman) Lecture**: - Elements of Behavioral Assessment - Conducting a Behavioral Assessment - Intervention Planning and Evaluation	
Nov 10	PUNISHMENT AND EXTINCTION Behavioral Technique: *(i) Time-out and Overcorrection*	7

Nov 17	THE ROLE OF MEMORY AND ATTENTION	9
	Behavioral Techniques: *(i) Conditioned Reinforcement* *(ii) Chaining and Token Economy* *(iii) Modeling Procedure and Assertiveness Training* *(iv) Negative Reinforcement - Escape and Avoidance Conditioning*	
Nov 24	No Classes	
Dec 1	THE ROLE OF THE REINFORCER	10
	CONCEPT LEARNING: ASSOCIATIVE AND COGNITIVE PROCESSES	12
	Behavioral Techniques: *(i) Cognitive Restructuring* *(ii) Stress Inoculation Training* *(iii) Thought Stopping* *(iv) Covert Sensitization*	
Dec 8	IS ASSOCIATIVE LEARNING SIMPLE OR COMPLEX?	13
Dec 15	**Oral Presentations: Behavior Modification Projects** (max. of 30 min./pres.) Course Wrap-up	
Dec 22	**FINAL Exam** (Coverage: Chapter 7, 9, 11-13, Lieberman) **Due: Write-up of Behavior Modification Project** **Due: Article Critique (optional)**	

*Lieberman, D. A. (2000). Learning: Behavior and Cognition. (3rd ed.) Pacific Grove, CA: Brooks/Cole.
**based on Sundel & Sundel, M. (1993). Behavior Modification in the Human Services (3rd ed.). Newbury Park, CA: Sage.

Presentations of Behavioral Techniques

(Time Limit: 15 min./ presentation)

Topics	Chapter**	Presentation Date
Positive Reinforcement	2	10/27
Extinction	3	10/13
Contingency Contracting and the Premack Principle	4	10/27
Intermittent Reinforcement Schedule	5	10/27
Shaping and DRO Procedure	6, 12	10/27
Discrimination Training Procedure and Stimulus Generalization	7	09/29
Fading	7, 8	09/29
Conditioned Reinforcement	8	11/17
Chaining and Token Economy	8	11/17
Modeling Procedure and Assertiveness Training	9	11/17
Time-out and Overcorrection	10	11/10
Negative Reinforcement - Escape and Avoidance Conditioning	11	11/17
Systematic Desensitization and In Vivo Desensitization	12	10/06
Flooding and Aversion Therapy	12	10/06
Cognitive Restructuring, Stress Inoculation Training, Thought Stopping, and Covert Sensitization	13	12/01

**based on Sundel & Sundel, M. (1993). Behavior Modification in the Human Services (3rd ed.). Newbury Park, CA: Sage.

-End-

PSYCHOLOGY 615*

Research Design and Statistics 1

(NY 44986)

Spring 2000

Instructor:	Richard S. Velayo, Ph.D.
Meetings:	Wednesdays, 5:30pm - 8:10pm, Birnbaum Electronic Classroom or TBA
Office:	41 Park Row, Rm. 1601-A 346-1506 (office phone)
Office Hours:	T, R 2:30 p.m. – 5:00 p.m. (or by appointment)
Prerequisite:	None
URL:	http://courseinfo.pace.edu/courses/psy615/
E-mail:	rvelayo@pace.edu

Course Objectives

This is an intensive three-hour per week graduate course that will introduce you to psychological research design, descriptive and inferential statistical techniques in psychology, and other topics pertinent to conducting research in psychology. The major objectives of this course are for you to become aware of the process in doing psychological research, become familiar with written communication and interpretation of statistical information, and to develop the critical thinking skills to determine when and how to use a particular statistical technique given a specific research problem.

Films and the use of statistical software will supplement your learning in the course.

Texts (Required)

Leong, F. & Austin, J. (1996 or latest edition). The Psychology Research Handbook: A Guide for Graduate Students and Research Assistants. Thousand Oaks, CA: Sage.

Hurlburt, R. (1998). Comprehending Behavioral Statistics (2nd edition). Pacific Grove, CA: Brooks/Cole.

Kirkpatrick, L. & Feeney, B. (2000). A Simple Guide to SPSS for Windows for Versions 8.0 & 9.0 (Revised Edition). Pacific Grove, CA: Wadsworth.

Statistical Package (Recommended):

SPSS-PC statistical software (latest Windows version if possible)

Supplementary Films

Annenberg/CPB Collection. (1990). Against all odds: Inside statistics. [Videotapes.]

*http://courseinfo.pace.edu/courses/psy615/

Chapter Presentations (team project)

You will be assigned to present some chapters (out of the 24 chapters of Parts I - V) from The Psychology Research Handbook (Leong and Austin, 1998) in class. The presentation should be about **15 minutes** and should conform to the following format:

- A summary of the important points of the chapter/s supplemented with examples, demos, etc.
- An open forum to allow you to respond to questions from the class and the instructor
- Distribute a "summary" of the content of your presentation.

Assignment of chapters to be presented will be done early during the semester. There is no need to submit a written report for this requirement.

A Student Feedback form will be distributed to other members of the class to evaluate your presentation. This will constitute part of your grade for this requirement.

Class Research Project (CRP) (team project)

This requirement involves the entire class undertaking a research project designed by your instructor. You will collect data, analyze the part of the CRP data of interest to you, and gather literature related to the research data you will or have analyzed. In addition, you (and your partner/s) will be given the opportunity to present your statistical analyses of the research data and the related literature you have gathered during the last few class meetings. You will be given **20 minutes** to present your work pertaining your statistical analyses of the CRP data. Additional time will be allotted for open discussion. You are advised to utilize useful paraphernalia to supplement your presentation (e.g., audio-visual aids, demonstration activities, etc.).

[NOTE: There should be NO duplication of that part of the CRP data that the teams will present.]

A written paper on the content of your presentation is required. It must be typed in APA-style format. This will be discussed in the course of the semester.

Your conduct in carrying out your research is very important and will contribute towards a significant part of your grade.

Statistics Exercises (individual project)

There are **5 statistics exercises** in this course. You are expected to submit 4 of the 5 exercises. No makeup exercise/s will be given. If you decided to do all 5 exercises, the lowest grade is eliminated from the computation of the final grade. Each exercise is worth 15 points. 2 points are deducted for each day the exercise is turned in late.

In addition, you will be required to present a brief demonstration of one of the chapters in the SPSS for Windows text (Kirkpatrick & Feeney, 2000). This SPSS statistical package will be used as an integral part of this requirement.

These exercises are meant to further develop your understanding of statistics in psychological research and to critically think about when to appropriately use each statistical tool in analyzing research data.

Class Participation

This requirement will be based on your in-class participation and your responses to the "Discussion Forum" set up for this class at http://courseinfo.pace.edu/courses/psy615/. Details pertaining to the Discussion Forum will be discussed in class.

Final Exam

There is a Final Exam, each of which will cover ALL the chapters of your textbooks (Leong and Austin, 1998; Hurlburt, 1998). The exam will test your knowledge of how to apply what you have learned in class. The format may include multiple-choice, true-false, and short-answer questions. A review sheet will be provided about a week prior to the scheduled exam.

Grading System

Requirement/s	Points
CHAPTER PRESENTATION/S STUDENT FEEDBACK OF PRESENTATION/s	75 25
STATISTICS EXERCISE 4 out of 5 exercises, no makeup/s given (@15 points each) SPSS Presentations	 60 25
CLASS PARTICIPATION	40
CLASS RESEARCH PROJECT (CRP) CRP Paper CRP Presentation	 100 75
FINAL EXAM	100

TOTAL POINTS: 500

Letter-Grade Equivalent (will be "strictly" followed)			
A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

NO CLASSES

March 15
April 19

SCHEDULE

Note: Do the assigned readings before the scheduled discussion of the topic/s.

DATE	TOPIC	READING/s	Presenter/s
Jan 26	Introduction to PSY615	Syllabus	Velayo
Feb 2	Research Planning *Chapter Presentations (1, 2, 3, 4)*	Part 1, Leong & Austin	Velayo
Feb 9	Design, Instrument Selection, and Sampling *Chapter Presentations (5, 6, 7, 8)*	Part II, Leong & Austin	_____ (Ch 5, 6) _____ (Ch 7, 8)
Feb 16	Data Collection *Chapter Presentations (9, 10 , 11, 12)*	Part III, Leong & Austin	_____ (Ch 9, 10) _____(Ch 11,12)
Feb 23	Data Analyses *Chapter Presentations (13, 14)* **SPSS Presentation: Chapter 1, 2, 3, 4, 5**	Part IV, Leong & Austin Kirkpatrick & Feeney	_____(Ch 13,14) Velayo

Mar 1	Data Analyses (continued) *Chapter Presentations (15, 16, 17, 18, 19, 20)* Variables, Frequency Distributions, Central Tendency, Variation	Part IV, Leong & Austin Chapters 1-5, Hurlburt	_____(Ch 15,16) _____(Ch 17,18) _____(Ch 19,20) Velayo
Mar 8	Using Frequency Distributions, Sampling, and Parameter Estimation **Due: Statistics Exercise #1** **SPSS Presentation: Chapter 6, 7**	Chapters 6-8, Hurlburt Kirkpatrick & Feeney	_____ _____
Mar 15	NO CLASSES		
Mar 22	Data Analyses (continued) **Due: Statistics Exercise #2** **SPSS Presentation: Chapter 8, 9**	Chapter 9-11, Hurlburt Kirkpatrick & Feeney	_____ _____
Mar 29	Data Analyses (continued) **Due: Statistics Exercise #3** **SPSS Presentation: Chapter 10, 11**	Chapter 12-15, Hurlburt Kirkpatrick & Feeney	_____ _____
Apr 5	Data Analyses (continued) **Due: Statistics Exercise #4** **SPSS Presentation: Chapter 12, 13**	Chapter 16-17, Hurlburt Kirkpatrick & Feeney	_____ _____

Apr 12	Research Writing *Chapter Presentations (21, 22)* **Due: Statistics Exercise #5** **SPSS Presentation: Chapter 14, 15**	Part V, Leong & Austin Kirkpatrick & Feeney	_____ (Ch 21,22) _____
Apr 19	NO CLASSES		
Apr 26	Research Writing (continued) *Chapter Presentations (23, 24)* **SPSS Presentation: Chapter 16, 17**	Part V, Leong & Austin Kirkpatrick & Feeney	_____ (Ch 23,24) _____
May 3	**CRP Presentation/s**		
May 10	**FINAL EXAM** **Due: CRP Paper**		

-End-

PSYCHOLOGY 624

Cognitive Psychology

(CRN #20949)
(Spring 2014)

Instructor:	Richard Velayo, Ph.D.
Meetings:	Wednesdays, 5:40pm - 8:30pm, Room E101 (Birnbaum Electronic Classroom)
Office Hours:	Tuesdays and Thursdays, 3:00pm - 5:30pm (by appointment)
Office Location:	Psychology Dept., 41 Park Row, Rm. 1310, New York, NY 10038
Office Phone:	(212) 346-1558
Credits:	3
Course URL:	http://blackboard.pace.edu/
E-mail:	rvelayo@pace.edu

Course Description

This graduate-level course examines cognitive processes, often called "higher mental processes." Cognitive psychology includes topics such as perception, memory, language, and thinking. This course will give you an appreciation of research and theory in cognitive psychology, an understanding of the methods used to gather and evaluate evidence about cognitive processes, and an understanding of the ways in which knowledge of these processes has been applied to solve problems and improve the quality of life. Though this course requires a fairly sophisticated background in psychology, it will begin with a basic overview of cognition. Discussion of key research on cognition is covered. Note that much of the research in cognitive psychology is methodologically complex, especially because of the challenge of assessing covert mental processes.

The content material covered in this course will require your active reading of the assigned materials (i.e., textbook chapters, assigned articles) and your regular class participation. You will also be required to write an in-depth written critique of an article that is of interest to you. In addition, there is a Midterm exam and a Final exam based on the concepts covered in the textbook and on the application of the key concepts covered.

Blackboard, a distance learning software program, will be utilized to supplement regular classroom meetings.

Prerequisite

There are no graduate course prerequisites.

Course Objectives

As the course instructor, I have several goals that I hope each of you will be able to accomplish during the course of this semester:

1. An appreciation of the basic information in cognitive psychology, including research and theory, as well as an understanding of the complexity of cognitive processes.
2. An understanding of research methods in cognitive psychology, together with the ability to evaluate research in this area critically.
3. An ability to apply your knowledge to your own cognitive processes (for example, in studying for exams and in solving problems) and to professional areas such as education, speech pathology, law, clinical psychology, communication, business, and social relations.
4. An ability to write a review of an article on a topic of your choice, related to Cognitive Psychology, that demonstrates an understanding of the research, an ability to synthesize information, and a mastery of writing style.
5. **Important Note:** A distinct objective of this course is to incorporate an "international perspective" as part of learning various relevant concepts. Given the interdisciplinary and empirically-based nature of psychology, it has become increasingly important to demonstrate how current topics may be relevant to understanding human behavior and thinking from a global perspective. Thus, we shall attempt to infuse

such perspective in our understanding of various constructs presented in each chapter and in your final paper. In addition, before the end of the semester, we shall assess the extent in which the strategies used were effective in "internationalizing" the course and to identify other strategies to further achieve this objective.

Course Materials (Required text and other materials):

1. Matlin, M. W. (2013). *Cognition* (8th ed.). NJ: Wiley.
   [ISBN: 978-1-118-148969 for print version OR 978-1-118-545560 for e-text version]

2. Selected articles/readings will be distributed/assigned.

Assignments / Course Requirements

- **Participation (170 points)**
  - *Chapter Presentation(s)* – This is a "team" activity. Make your presentation(s) fun, creative, and informative. Your group will be assigned chapters from the main PSY624 textbook/s to present in class. The assignment of chapters will be done early during the semester. An **outline of your presentation** (which may be in the form of a PowerPoint presentation) must be posted on the appropriate Blackboard discussion forum prior to your in-class presentation. There is no need to submit a written report for this requirement. Your in-class presentation should conform to the following format:
    (i) 40-minute presentation (e.g., chapter summary, video clips, demonstrations, games, and other relevant materials/activities)
    (ii) Implement a strategy that helps provide an "international perspective" of the constructs in your presentation. (See *E-xcellence* handout.)
    (iii) An open forum to allows you to respond to questions from the class and the instructor

    NOTE: Both instructor and other students in class will evaluate chapter presentations. (Instructor will explain this requirement in greater detail.)

  - *Attendance*– For attendance, five (5) points are deducted for each meeting absent. Less points may be deducted if you are late to class. Proof for excused absences is required.

- **Final Paper (180 points)**

  The final paper (an individual project) is an in-depth critique of a journal article (theoretical and/or empirical) on a course-related topic that is of interest to you. The paper should be no longer than 7 pages, single-spaced (or 14 pages double-spaced).

  The article you choose requires your instructor's approval. You can find relevant articles by searching the PsycINFO and/or the PsycArticles database. [Go to http://library.pace.edu to access these databases.] The article should be derived from an academic or professional journal in **psychology** published **within the last 5 years**.

  An APA style formatted paper is preferred. The structure of the paper should be as follows:

  I. Cite the Journal Article
  Example:
  Zhang, Y., Yu, J., & Boland, J. (2010). Semantics does not need a processing license from syntax in reading Chinese. *Journal of Experimental Psychology: Learning, Memory, and Cognition, 36,* 765-781.

  II. Summary of the Journal Article *[no longer than one (1) page, single-spaced]*

III. Critique/Review *[approximately 5 pages]*

This is primarily opinion-based, but you are also expected to demonstrate your knowledge of cognitive psychology by using the concepts and terms covered in the course. Citing references is encouraged but not required.

IV. Implications for International Psychology *[approximately 1 page]*

Answer these questions:

A. What may be the potential relevance of this article on the internationalization of Cognitive Psychology?

B. If this study was done (or to be done) in another country/nation, to what extent do you think the findings or the basic ideas of the article apply to other cultures/nations? Explain why.

This course requirement is intended to supplement your learning of the course content and to enhance your ability to apply the concepts learned.

You will be given the opportunity to have your written critique read by other members of the class sometime during the latter part of the semester. Thus, your paper will be accessible online for other students to evaluate using the Student Grade Form. (This form is available on our course's Blackboard site). Other students in the course, including your instructor, will then provide feedback/comments to your paper. Details about this requirement will be discussed in the course of the semester.

An Individual Member Evaluation form must also be submitted. (This form is available on our course's Blackboard site). This will allow you to evaluate yourself given your perceived quality and/or effort you place in doing the paper.

A Final Paper Presentation Session (in-class) is scheduled during the latter part of the semester. You will be given the opportunity to orally present your paper. The length of the presentation may vary depending on the number of student groups scheduled to present during the day(s) of presentation.

- **Exams (150 points)**

  There will be a Midterm and a Final Exam. This exam will mostly contain multiple-choice questions plus 1 - 2 essay questions. A review sheet will be provided about a week prior to the scheduled exam.

Grading System

Course Requirements	**Points**
Participation = 170 points (34%)	
Chapter Presentation(s):	
Feedback from Class (grades are averaged)	40
Feedback from Instructor (grades are averaged)	60
Individual Member Evaluation	20
Attendance	50
Final Paper = 180 points (36%)	
Instructor Evaluation	80
Individual Member Evaluation (grades are averaged)	20
Student Grade Form (grades are averaged)	40
Submission of Student Grade Form	10
Paper Presentation Session (In-class)	30
Exams = 150 points (30%)	
Midterm (15%)	75
Final (15%)	75
Total points	**500**

Letter-Grade Equivalent
("strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

Academic Integrity Policy

Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in the academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any paper, report or submission for academic credit without the appropriate acknowledgment is **plagiarism**. It is unethical to present as one's own work the ideas, words, or representations of another without proper indication of the source. Therefore, it is the student's responsibility to give credit for any quotation, idea, or data borrowed from an outside source.

Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension or dismissal from the University. Individual schools and programs may have more specific procedures for violations of academic integrity. Therefore, students are encouraged to familiarize themselves with the academic integrity policies of the University and of individual schools and programs in which they are enrolled. Students penalized for failing to maintain academic integrity who wish to appeal such action must follow the appeal procedure outlined below in the "Grades Appeal Process" section or that of the individual school or program in which they are enrolled if such school or program has a separate appeal procedure in place.

Students with Disabilities

The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities. To request an accommodation for a qualifying disability, a student must self-identify and register with the Coordinator of Disability Services for his or her campus. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see *Information for Students with Disabilities* on the University's web site.

Pace University Writing Center

The Pace University Writing Center offers tutorial services in writing as well as handouts and reference materials on writing for student use in person or via the web at www.pace.edu/dyson/writingcenter. The staff of instructor and student tutors can assist students in understanding writing assignments and criteria and can help students with any stage of the writing process, from brainstorming topics to revision of rough drafts. Students may be referred to the Writing Center as part of this course, or students may seek assistance with course writing on their own via web-based tutoring or by visiting the Writing Center in person (NY-Birnbaum Library, 2nd Floor, 346-1085; PLV-Mortola Library, 3rd Floor, 773-3942). Please refer to the Writing Center's website for information about polices and hours of operation.

SCHEDULE

Note: Read the assigned chapter/s and other assigned readings before the scheduled presentation date.

WEEK	TOPIC/s	READING/s
1 *(01/29)*	What's PSY624 all about? Class Roster Information How may we "internationalize" this course? (Distribute *E-xcellence* article.) (Show Survey to assess an "Internationalized" psychology course.)	Syllabus; Additional handouts
2 *(02/05)*	An Introduction to Cognitive Psychology	Ch. 1
3 *(02/12)*	*NO CLASS (Instructor is away.)*	
4 *(02/19)*	Perceptual Processes 1: Visual and Auditory Recognition Perceptual Processes 2: Attention and Consciousness	Ch. 2 Ch. 3
5 *(02/26)*	Working Memory Long-Term Memory	Ch. 4 Ch. 5
6 *(03/05)*	Memory Strategies and Metacognition Mental Imagery and Cognitive Maps	Ch. 6 Ch. 7
7 *(03/12)*	**MIDTERM EXAM (Chapters 1-7)** **Due: TOPIC for FINAL PAPER** (NOTE: The article that will be critiqued must be submitted to the instructor for approval.)	
8 *(03/19)*	*NO CLASS (Spring Break)*	
9 *(03/26)*	General Knowledge	Ch. 8
10 *(04/02)*	Language 1: Introduction to Language and Language Comprehension Language II: Language Production and Bilingualism	Ch. 9 Ch. 10
11 *(04/09)*	Problem Solving and Creativity	Ch. 11

12 *(04/16)*	Deductive Reasoning and Decision Making Cognitive Development Throughout the Lifespan	Ch. 12 Ch. 13
13 *(04/23)*	**Due: FINAL PAPER + Individual Member Evaluation Form** **Part 1: FINAL PAPER PRESENTATIONS (In-class)**	
14 *(04/30)*	**Part 2: FINAL PAPER PRESENTATIONS (In-class)**	
15 *(05/07)*	**FINAL EXAM (Chapters 8 -13)** **Due: STUDENT GRADE FORM** (for Final Paper)	

*****Assigned supplementary articles/readings will be assigned for each chapter.*

-End-

PSYCHOLOGY 625

Personality Theories

(CRN #20568)
(Spring 2011)

Instructor:	Richard Velayo, Ph.D.
Meetings:	Wednesdays, 5:30pm - 8:15pm, Room E101 (Birnbaum Electronic Classroom)
Office Hours:	M, W 3:15pm - 5:15pm (by appointment)
Office Location:	Psychology Dept., 41 Park Row, Rm. 1324, New York, NY 10038
Office Phone:	(212) 346-1558
Credits:	3
Course URL:	http://blackboard.pace.edu/
E-mail:	rvelayo@pace.edu

Course Description

This graduate-level course provides an overview of current thinking and research about personality. Personality psychology includes topics such as the major personality theories (psychoanalytic, phenomenological, trait, biological, behavioristic, cognitive, and social-cognitive), and other relevant factors (interpersonal, contextual, and developmental, and assessment). This course will give you an appreciation of research and theory in personality psychology, an understanding of the methods used to gather and evaluate evidence about personality constructs, and an understanding of the ways in which knowledge of these constructs has been applied to various settings. Though this course requires a fairly sophisticated background in psychology, it includes a basic overview of personality theory. Discussion of key research on personality theories and research is covered.

The content material covered in this course will require your active reading of the assigned materials (i.e., textbook chapters, assigned articles) and your regular class participation. You will also be required to write an in-depth written critique of an article that is of interest to you. In addition, there is a Midterm exam and a Final exam based on the concepts covered in the textbook and on the application of the key concepts covered.

Blackboard, a distance learning software program, will be utilized to supplement regular classroom meetings.

Prerequisite

There are no graduate course prerequisites.

Course Objectives

As the course instructor, I have several goals that I hope each of you will be able to accomplish during the course of this semester:

1. An appreciation of current psychological approaches to theorizing about personality.
2. An understanding of research methods in personality psychology, together with the ability to evaluate research in this area critically.
3. An ability to apply independent, creative, and critical thinking of personality constructs to everyday life and in relevant professions.
4. An ability to write a review of an article on a topic of your choice, related to Personality Psychology, that demonstrates an understanding of the research, an ability to synthesize information, and a mastery of writing style.

5. **Important Note:** A distinct objective of this course is to incorporate an "international perspective" as part of learning various relevant concepts. Given the interdisciplinary and empirically-based nature of

psychology, it has become increasingly important to demonstrate how current topics may be relevant to understanding human behavior and thinking from a global perspective. Thus, we shall infuse such perspective in our understanding of various constructs presented in each chapter and in your final paper. In addition, before the end of the semester, we shall assess the extent in which the strategies used were effective in "internationalizing" the course and to identify other strategies to further achieve this objective.

Course Materials (Required text and other materials):

1. Cervone, D. & Pervin, L. (2010). *Personality: Theory and Research* (11th Ed). NJ: Wiley. [ISBN 978-0-470-48506-4]

2. Selected articles/readings will be distributed/assigned.

Assignments / Course Requirements

- **Participation (170 points)**
  - *Chapter Presentation(s)* – This is a group activity. Make your presentation(s) fun, creative, and informative. Your group will be assigned chapters from the main PSY624 textbook/s to present in class. The assignment of chapters will be done early during the semester. An **outline of your presentation** (which may be in the form of a PowerPoint presentation) must be posted on the appropriate Blackboard discussion forum prior to your in-class presentation. There is no need to submit a written report for this requirement. Your in-class presentation (which may be videotaped) should be about 30 minutes AND should conform to the following format:
    (i) 30-minute presentation (i.e., chapter summary, video clips, and other relevant materials/activities)
    (ii) Implement a strategy that helps provide an "international perspective" of the constructs in your presentation. (See *E-xcellence* handout.)
    (iii) An open forum to allow you to respond to questions from the class and the instructor

  - *Attendance / Participation* – Five (5) points are deducted for each meeting absent or late. Proof for excused absences is required. Included in this grading is the completion of a presentation feedback form to be completed each class meeting by all students who are not assigned to present a chapter for that class session. (Instructor will explain this requirement in greater detail.)

- **Final Paper (180 points)**

  You are required to write an in-depth critique paper (no longer than 7 pages, single-spaced) of a journal article (theoretical and/or empirical studies) on a course-related topic, which is of interest to you. Your choice of a journal article requires your instructor's approval. You can find relevant articles by searching the PsycINFO and/or the PsycArticles database. [For questions or assistance on accessing the Pace University Library Resources, go to http://library.pace.edu]

  Your final paper should be a review or critique of an academic or professional journal article in psychology published within the last 5 years. The structure of the paper should be as follows:

  I. Cite the Journal Article
  Example: Walker, B. M., & Winter, D. A. (2007). The elaboration of personal construct psychology. *Annual Review of Psychology, 58*, 453-477.

  II. Summary of the Journal Article [no longer than two (2) pages, single-spaced]

  III. Critique/Review [This is primarily opinion-based, but you are also expected to demonstrate your knowledge of personality psychology by using the concepts and terms covered in the course.

Citing references is encouraged but not required.]

IV. Implications for International Psychology [What may be the potential relevance of this article on the internationalization of Personality Psychology? Briefly discuss the extent to which the constructs and/or findings in the article apply to other cultures/nations.]

This course requirement is intended to supplement your learning of the course content and to enhance your ability to apply the concepts learned.

You will be given the opportunity to have your written critique read by other members of the class sometime during the latter part of the semester. Thus, your paper will be accessible online for other students to evaluate using the Student Grade Form. (This form is available on our course's Blackboard site). Other students in the course, including your instructor, will then provide feedback/comments to your paper. Details about this requirement will be discussed in the course of the semester.

An Individual Member Evaluation form must also be submitted. (This form is available on our course's Blackboard site). This will allow you to evaluate yourself given your perceived quality and/or effort you place in doing the paper.

A Final Paper Presentation Session is scheduled during the latter part of the semester. You will be given the opportunity to present your paper in class for no longer than ten (10) minutes. (This amount time of time may vary depending on the number of students scheduled to present during the day of presentation).

- **Exams (150 points)**

  There will be a Midterm and a Final Exam. This exam will mostly contain multiple-choice questions plus 2 – 3 essay questions. A review sheet will be provided about a week prior to the scheduled exam.

Grading System

Course Requirements	**Points**
Participation = 170 points (34%)	
Chapter Presentation(s):	
Feedback from Class (grades are averaged)	40
Feedback from Instructor (grades are averaged)	60
Individual Member Evaluation	20
Attendance	50
Final Paper = 180 points (36%)	
Instructor Evaluation	80
Individual Member Evaluation (grades are averaged)	20
Student Grade Form (grades are averaged)	40
Submission of Student Grade Form	10
Paper Presentation Session (In-class)	30
Exams = 150 points (30%)	
Midterm (15%)	75
Final (15%)	75
Total points	**500**

Letter-Grade Equivalent

(will be "strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

Academic Integrity Policy

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Pace University Writing Center

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SCHEDULE

Note: Read the assigned chapter/s and other assigned readings before the scheduled presentation date.

WEEK	TOPIC/s	READING/s
1 *(01/24)*	What's PSY625 all about? Class Roster Information How may we "internationalize" this course? (Distribute *E-xcellence* article.) (Show Survey to assess an "Internationalized" psychology course.)	Syllabus; Additional handouts
2 *(01/31)*	Personality Theory: From Everyday Observations to Systematic Theories	Ch. 1
3 *(02/07)*	The Scientific Study of People	Ch. 2
4 *(02/14)*	A Psychodynamic Theory: Freud's Psychoanalytic Theory of Personality Freud's Psychoanalytic Theory: Applications, Related Theoretical Conceptions, and Contemporary Research	Ch. 3 Ch. 4
(02/21)	*NO CLASSES (President's Day)*	
5 *(02/28)*	A Phenomenological Theory: Carl Roger's Person-Centered Theory of Personality Roger's Phenomenological Theory: Applications, Related Theoretical Conceptions, and Contemporary Research	Ch. 5 Ch. 6
6 *(03/07)*	Trait Theories of Personality: Allport, Eyesenck, and Cattell Trait Theory: The Five-Factor Model; Applications and Evaluation of Trait Approaches to Personality **Due: TOPIC for FINAL PAPER** (NOTE: The article that will be critiqued must be submitted to the instructor for approval.)	Ch. 7 Ch. 8
03/14	*NO CLASSES (Spring Break)*	
7 *(03/21)*	**MIDTERM EXAM on Chapters 1 - 8**	
8 *(03/28)*	Biological Foundations of Personality	Ch. 9
9 *(04/04)*	Behaviorism and the Learning Approaches to Personality	Ch. 10

10 *(04/11)*	A Cognitive Theory: George A. Kelly's Personal Construct Theory of Personality	Ch. 11
04/18	*NO CLASSES (Passover Eve, No Evening Classes)*	
11 *(04/25)*	Social-Cognitive Theory: Bandura and Mischel Social-Cognitive Theory: Applications, Related Theoretical Conceptions, and Contemporary Research	Ch. 12 Ch. 13
12 *(05/02)*	Personality in Context: Interpersonal Relations, Culture, and Development Across the Course of Life Assessing Personality Theory and Research **Due: FINAL PAPER + Individual Member Evaluation**	Ch. 14 Ch. 15
13 *(05/09)*	**FINAL PAPER PRESENTATIONS (In-class)**	
14 *(05/11) (Wed.)*	**FINAL EXAM on Chapters 9 -15** **Due: Student Grade Form** (for Final Paper)	

**Assigned supplementary articles/readings will be assigned for each chapter.*

-End-

PSYCHOLOGY 695 – INDEPENDENT STUDY (MA in Psychology)

Instructions:

1. Select a relatively specific topic/project you are interested in and that is feasible to do conduct a research on. The supervising faculty must approve your chosen topic/project.

2. Survey and gather the relevant research on the topic. Most of the related articles should be recent and published in psychological literature/journals.

3. Summarize the research trends on the topic and cite your references.

4. Provide at least three suggestions for future research based on your paper that may be pursued based on the research literature you have surveyed.

Independent Study: Literature Review and/or other written/tangible project

Due Date for PAPER: 5/09/16 (Monday)

General Format and Style: APA Style; must be typed and double-spaced

GRADING SYSTEM

		Points
Paper*		
Title Page	10	
Introduction (1 paragraph)	20	
Summary of research trends (based on at least 15 articles)	100	
3 Suggestions for further research	30	
References (Only articles cited in the research paper should be included in this list); (List at least 15 references)	20	
Overall Quality	20	**200**
Weekly Updates / Meetings / Consultations (15 pts. /week) [Note: Grades for this requirement is based on written updates sent by email (10 pts/wk) and attendance at weekly research meetings (5 pts/wk)]		**200**
Conference Presentation [Venue to be determined by your instructor]		**100**
TOTAL POINTS		**500**

**Note: Approximate length of paper: 10-15 pages, excluding references section*

Letter-Grade Equivalent
("strictly" followed)

A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

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Request for an Accommodation

To request an accommodation for a qualifying disability, a student must self-identify and register with the Office of Disability Services for his or her campus. The Office of Disability Services is housed in the Counseling Center on both the New York City and Pleasantville campuses. The Coordinator of Disability Services for the New York City campus may be contacted at 212-346-1526 or 156 William Street, 8th Floor. The Coordinator of Disability Services for the Westchester campuses may be contacted at 914-773-3710 or the Administration Center at 861 Bedford Road, Pleasantville. Notifying other University offices, faculty or staff does not constitute giving notice to the University of a request for an accommodation. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student.

It is the student's responsibility to request an accommodation. Because some accommodations may take considerable time to arrange, students are urged to contact the Coordinator of Disability Services in order to request an accommodation as soon as possible after receiving notice of admission to the University. Untimely requests may result in delay, substitution, or an inability to provide an accommodation. If a request for an accommodation is submitted late, the Coordinator of Disability Services will, nevertheless, make every reasonable effort to process the request for an accommodation.

Before an accommodation will be provided, the student may be required to submit medical and/or other diagnostic information concerning the student's impairments and limitations. If the information provided is unclear or incomplete, the student may be required to provide additionalinformation or participate in further evaluations.

The Coordinator of Disability Services will, in conjunction with others as may be appropriate, evaluate the information provided by the student and health care providers; refer the student for additional testing and evaluation as may be necessary; make recommendations for the accommodations to be provided to the student; and, assist in arranging for the implementation of the accommodation to be provided.

If a student experiences difficulties with the implementation of the accommodation or, if after it has been implemented, a student has concerns that the expected results of the accommodation are not being met, the student

must promptly notify the Coordinator of Disability Services. The Coordinator of Disability Services will, as may be appropriate, endeavor to remedy the situation.

If a student disagrees with the accommodation recommended by the Coordinator of Disability Services, he or she should promptly appeal the recommendation to the Interim Director for Compliance at 914-923-2892.

Faculty members who have concerns about a reasonable accommodation recommended by the Coordinator for Disability Services for his or her class, should contact the Coordinator on the appropriate campus.

Depending on the nature of the disability and the accommodation provided, a student may be required periodically to submit medical and/or diagnostic information demonstrating the current status of the disability and/or to renew the request for an accommodation.

Any questions about the services offered by the University to students with disabilities or the procedures for requesting an accommodation should be directed to the Coordinator of Disability Services for the New York City campus at 212-346-1526 or for the Westchester campuses at 914-773-3710.

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-End-

PSYCHOLOGY 698

Professional Seminar

(CRN #73454)
(Fall 2016)

INSTRUCTOR:

Richard S. Velayo, Ph.D.
Email: rvelayo@pace.edu
Phone: 212-346-1558
41 Park Row, 13th floor, Room 1308
Office Hours: Wednesday, 1:00pm – 3:30pm (by appointment)

Class Meetings: Dates: Wednesdays (See class meeting schedule on page 3 of this syllabus.)
Times: 11:00am – 12:20pm
Location: Psychology Dept. Conference Room (Room 1321)

Course Description and Objectives

The purpose of this non-credit bearing course developed for students in the MA in Psychology program is to develop skills for life-long learning and professionalism. Important criteria by which Graduate Programs are assessed for their effectiveness in preparing young professionals is life-long learning and skills that including professional networking, mentorship, and professionalism.

Students will meet at designated days/times during the semester. Activities planned for this time throughout the year will include colloquia, professional discussion of "real world" issues, and any other professional activities deemed appropriate and necessary. These activities may be formal (such as colloquia) or informal such as a brown bag lunch to discuss an area of professional interest with students and faculty (e.g., licensure). In addition, each student will have two individualized consultation sessions with the instructor: (1) an advising session to discuss each student's educational and/or career goals, and (2) a feedback session to discuss each student's professional portfolio.

Learning Outcomes

This course is offered every semester to benefit students in the MA in Psychology Program. It provides a venue for students to learn and be updated on relevant and current information about the field, and help them realize how the MA in Psychology program may address their own professional goals as they go through the program. Students should therefore:

- Be able to have sufficient knowledge about contemporary real world issues that face the field of psychology.
- Perceive their education in the program as providing them with relevant life-long learning and skills that including professional networking, mentorship, and professionalism.
- Be prepared to determine what area of psychology, a related field, or professional/academic area to pursue in the context of the general psychology masters program.
- Be prepared to discuss an area of professional and/or research interest.

Prerequisite

There are no graduate course prerequisites.

Course Materials

Relevant resource materials may be disseminated to students during each seminar/meeting and/or posted on the Blackboard site dedicated for this course.

Course Requirements

Matriculated full-time students in the MA in Psychology program are required to enroll in the Professional Seminar for each fall and spring semesters in which they are enrolled in the program. (Note: The MA program is designed to be completed in two years – Fall 1, Spring 1, Fall 2, and Spring 2 semesters). For students who plan to complete the program in less than two years, those students must register for the Professional Seminar during each fall and spring semesters they are matriculated in the program.

Matriculated part-time students in the MA in Psychology program should take this course for at least 4 semesters (Fall/Spring). It is strongly advised that all part-time students take this course in their first semester that they have matriculated into the program and in their last semester prior to graduation.

1. Attendance/participation at scheduled classes
   - Make up for a maximum of three missed meetings per semester is possible by writing an additional reaction paper for each missed meeting.

2. Attendance in at least two (2) instructor-approved events (colloquia, seminars, lectures, talks related to Psychology, either at Pace or anywhere else).
   - Your instructors will inform you of which events are approved. You may also propose events, which require the approval by your instructor/s. Approval of such events is based on the discretion of your instructor.
   - Students will write no more than a 1-page reaction for each of the two "events" attended. One paragraph summarizing the topic and another paragraph summarizing what you thought of the event and what you learned from it.
     [IMPORTANT: You need to indicate the source (e.g., URL) and/or title/date/time of the event.]
   - You may write your Reaction Papers on any event or activity posted on Blackboard (e.g., Psy.D. doctoral project presentations, colloquia/talks sponsored by the Psychology Department). In addition, if there are Psychology-related talks/events around town that you may be interested in attending, you may write your reaction paper on those events. If you attend any regional conferences (e.g., Eastern Psychological Association) or national (e.g., American Psychological Association) or international conferences (International Council of Behavioral Medicine), you may base these reaction papers on DIFFERENT events at the conference.

3. Development/Updates on Your Professional Portfolio which includes:
   - A personal (narrative) statement of previous experiences as well as personal/educational/professional goals related to the degree being pursued OR a cover letter for a job.
   - Updated Curriculum Vitae / Resume

   [NOTE: You may also include other relevant supplemental materials such as syllabi of all classes taken, assignments at classes, record of any professional publications or presentations, etc.]

4. Two (2) one-on-one consultation sessions with your instructor during the semester. (You and your instructor will coordinate the dates/times to meet.)
   - Advising session on your educational and/or career goals
   - Feedback session on your Professional Portfolio

Grading System

Pass (P) or Fail (F) as determined by compliance with course requirements specified above.

SCHEDULE

NOTE: For each semester of PSY698, there will be a different "Featured Discussion Topic". Students are encouraged to suggest other topics that may be of interest for discussion.

Meeting	DISCUSSION TOPIC/s
1 *(09/14)*	**What is this course about?** **Traditional and Alternative Career Paths in Psychology;** **Building your Portfolio** Featured Discussion Topic: *Graduate course grades, GRE scores, and recommendations letters.*
2 *(09/28)*	**The Relevance of Joining Psychology Organizations;** **Academic Integrity, Professionalism, Collegiality, & Diversity;** **Time Management** Featured Discussion Topic: *Plagiarism: What is it and how can you avoid committing it?*
3 *(10/19)*	*What you need to know about…* **RESEARCH in Psychology** Featured Discussion Topic: *Mentored Lab and Independent Study*
4 *(11/02)*	*What you need to know about…* **PROFESSIONAL PRACTICE in Psychology** Featured Discussion Topic: *Internships, Practicum, and other field-based opportunities*
5 *(11/16)*	*What you need to know about…* **TEACHING in Psychology** Recommended Discussion: *Strategies for Improving Public Speaking Skills*
6 *(12/07)*	**Strategies for Applying to Doctoral Programs** **Strategies in Applying for Jobs** **Your Portfolio (Revisited)** Featured Discussion Topic: *Your Cover Letter and/or Personal Statement*

7 *(12/21)*	**NO CLASS MEETING** **DUE: Your Portfolio (Updates)** **DUE: Two (2) Reaction Papers**

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If a student experiences difficulties with the implementation of the accommodation or, if after it has been implemented, a student has concerns that the expected results of the accommodation are not being met, the student must promptly notify the Coordinator of Disability Services. The Coordinator of Disability Services will, as may be appropriate, endeavor to remedy the situation.

If a student disagrees with the accommodation recommended by the Coordinator of Disability Services, he or she should promptly appeal the recommendation to the Interim Director for Compliance at 914-923-2892.

Faculty members who have concerns about a reasonable accommodation recommended by the Coordinator for Disability Services for his or her class, should contact the Coordinator on the appropriate campus.

Depending on the nature of the disability and the accommodation provided, a student may be required periodically to submit medical and/or diagnostic information demonstrating the current status of the disability and/or to renew the request for an accommodation.

Any questions about the services offered by the University to students with disabilities or the procedures for requesting an accommodation should be directed to the Coordinator of Disability Services for the New York City campus at 212-346-1526 or for the Westchester campuses at 914-773-3710.

Pace University Writing Center

The Pace University Writing Center offers tutorial services in writing as well as handouts and reference materials on writing for student use in person or via the web at www.pace.edu/dyson/writingcenter. The staff of instructor and student tutors can assist students in understanding writing assignments and criteria and can help students with any stage of the writing process, from brainstorming topics to revision of rough drafts. Students may be referred to the Writing Center as part of this course, or students may seek assistance with course writing on their own via web-based tutoring or by visiting the Writing Center in person (NY-Birnbaum Library, 2nd Floor, 346-1085; PLV-Mortola Library, 3rd Floor, 773-3942). Please refer to the Writing Center's website for information about polices and hours of operation.

- End -

REQUIREMENTS FOR THE M.A. THESIS
MA in Psychology Program
Psychology Department

PSY699 – M.A. THESIS
3 credits

Current Catalogue Description
Prerequisite: Department approval required.
Course Description: With the approval of the appropriate faculty member and coordinator of the M.A. program or Department Chairperson, students may conduct an original research project with the supervision of a faculty member. The student meets and regularly consults with the faculty member to provide guidance and to review progress on the research project. A research paper must be submitted upon completion of the course.
Course Rotation: TBA.

Proposed Requirements:

- Prerequisite Course/s: Research Design and Statistics I (PSY615) AND Research Design and Statistics (PSY616) NOTE: PSY616 may be taken concurrently with PSY699.

- Approval to take this course must be obtained from at least two full-time faculty members of the MA Committee. The necessary approval forms must be signed by the student's thesis advisor prior to initiation and completion of the project.

- Students must have a thesis advisor [i.e., a f/t Pace Psychology faculty (NYC campus) faculty who is responsible for the supervision of the student's thesis]. The student is expected to have regular consultations with the advisor.

- The MA thesis must be written in APA style format.

- The MA thesis should an empirical study and involves the completion of a paper for publication consideration to a psychology journal (or a journal in a related field as deemed appropriate by the thesis advisor).

- The MA thesis must be presented at a conference (e.g., Pace Psychology Conference) OR to at least two full-time faculty (including the thesis advisor) of the Psychology Department sometime before the end of the semester.

- A "K" grade may be given to a student until the all the necessary requirements associated with the thesis are completed.

- The MA Thesis will be archived and made available on the MA in Psychology (NYC) Blackboard site.

-End-

MA Thesis
Dr. Velayo

General Format and Style

Typed and double-spaced
APA Style (Refer to APA Publications Manual)

Organization and Descriptions of Sections of the Proposal

TITLE PAGE

This will serve as the first page of your proposal. (Refer to the APA Publication manual.)

ABSTRACT

This section is a summary of your proposal. (Limit: 100 words)

INTRODUCTION

(The general goal of this section is to present the theoretical and empirical scientific literature justifying the proposed study, culminating in a statement of the purpose of the study and specific hypotheses.)

Overview

This section is a general introduction orienting the reader to the rationale and purpose underlying the proposed research study.

Literature Review

This section contains presents the relevant research literature, which may include a conceptual or theoretical framework underlying the development of your research. The review should be organized from general to specific -- presenting research covering broad theoretical issues pertinent to your proposed project, moving to research more specific to your study, culminating in a description of the specific study of studies upon which your project is built. This review should lead logically to your statement of purpose and hypotheses. Add a summary/ concluding paragraph at the end of this section.

Significance of the Study

Write a paragraph pointing out the relevance of this study as it pertains to its theoretical or practical significance or both. In other words, how would this research contribute to psychological knowledge and its application/s to the real world.

Statement of Purpose

This section should contain a specific statement, based on the cited literature, of the justification for your proposed project, complete with an outline of the project itself.

Hypotheses

This section is a formal set of statements of specific hypotheses, clearly articulated and logically derived from the literature you have cited.

METHOD

(The general goal of this chapter is to describe the methodology to be used in the study with such clarity that the reader could replicate your study.)

Participants

This section contains a relatively complete description of the participants in the study, including (a) the rationale for the type of population that will be used, (b) sample size considerations, and (c) sampling plan.

Experimental Design

This section specifies the experimental design of your study, identifies and operationally defines the independent and dependent variables. A visual representation of your design that shows the distribution of participants to each condition in your study is a good supplement to this section.

Materials

This section should contain complete descriptions of all research materials (i.e., stimuli, equipment, scales) to be used in the study. Included in this section are (a) the rationale for the choice of independent and dependent variables, as well as their operational definitions, and (b) description of all measurement instruments (e.g., questionnaires, apparatus). If you are going to develop a specific instrument, you must describe it in detail, including an assessment of its reliability and validity. All materials, letters of consent, scales, and others must be placed in appendices.

Procedure

All relevant instructions to participants need to be documented, including how informed consent will be obtained. All details concerning the experimental design of the proposed study (e.g., manipulation of the independent variables, use of control features, counterbalancing) must be spelled out.

RESULTS

The general goal of this section is to present appropriate statistical analyses to be used in the evaluation of your research hypotheses. It is important that each statistical procedure to be used be clearly linked to the appropriate hypothesis. This section should present the relevant descriptive (e.g., means and standard deviations) and inferential statistics (e.g., ANOVAs, t-tests, paired comparisons tests, regression analysis) pertaining

to your hypotheses. Link each statistical result to a specific hypothesis and present any theoretically interesting results that go beyond the hypotheses tested.

DISCUSSION

The general goal of this section is to discuss the theoretical and practical implications of the results of your research. It is also strongly suggested that you do the following: a) summarize key findings of your study and the probable explanations for these, b) relate your findings based on the previous literature you had reviewed, c) indicate the key limitations of the study that may have contributed to the results, and d) suggest what future research on your topic should focus on.

REFERENCES
(Minimum of 15 articles required)

All relevant research literature cited within the research proposal should be included in the reference list. Make sure you follow proper APA style format.

APPENDICES

All stimulus materials, letters of consent, detailed descriptions of psychological instruments, raw data, coding guide, data sheets, etc. should be included in separate appendices.

- End -

Pace University
PSY 717: The Psychology of Learning: Theory and Applications

Fall 2012
Wednesdays 1:00-3:40p.m.
Instructor: Richard Velayo, Ph.D.

Instructor Information:
Office Hours: M 12:00-3:00p.m., W 4:00-5:00p.m., & F 12:00-3:00
(by appointment)
Phone: 212-346-1506 or 212-346-1801
Email: ayasik@pace.edu

Prerequisite: Undergraduate Learning Theory course.

Course Description

This course is intended to provide students with information regarding major theories of learning (e.g., social-cognitive; cognitive developmental; information-processing; behavioral). The first half of the course will focus on basic principles of behavior modification and its application to educational instruction and psychological intervention. The second half of this course will present the basic principles of various learning theories. Consideration will be given to how the principles discussed relate to effective teaching and learning.

Course Objectives

1. Students will demonstrate an understanding of basic behavioral principles.
2. Students will demonstrate an understanding of behavioral observation techniques including recording procedures and interpretation of data.
3. Students will demonstrate the ability to conduct a functional behavioral assessment.
4. Students will demonstrate an understanding of methods to increase and reduce various behaviors.
5. Students will demonstrate the ability to devise behavior modification plans.
6. Students will demonstrate an understanding of data analytic procedures to determine the efficacy of behavioral treatments.
7. Students will gain knowledge of behavioral techniques applied in the classroom as well as in clinical settings.
8. Students will demonstrate an understanding of ethical issues related to the use of behavioral techniques.
9. Students will demonstrate an understanding of basic theoretical concepts of various learning theories.
10. Students will demonstrate an understanding of key components of information processing theory and it's relation to classroom instruction.
11. Students will demonstrate an understanding of developmental changes in information-processing and it's relation to classroom instruction.
12. Students will demonstrate an ability to critically analyze current research related to learning and/or instructional techniques.

Student attainment of these objectives will be assessed through class examinations, student research papers, and student behavior modification plans.

Course Requirements:

1. **Participation**. Students are expected to have completed assigned readings before coming to class. Students should be prepared to discuss and respond to questions about the readings.

2. **Research Paper & Presentation** (30% of course grade). Each student is required to prepare a 10-15 page double-spaced paper that focuses on a research topic related to educational psychology (e.g., expert vs novice teachers, achievement motivation, instructional approaches). Specifically, each student will review research related to the chosen topic. The topic and references will be discussed and agreed upon by the instructor. The following outline should be followed:
   a. Introduction (topic explained, importance discussed)
   b. Review of relevant research
   c. Conclusions and implications for school-clinical child psychology.
   d. References (in current APA style)

   The following due dates apply to the research paper requirement:

   9/19/12 Topic/research question (Include: tentative title and one paragraph summarizing topic area)(Posted to blackboard)
   10/17/12 Review of one journal article (Include: complete reference in APA style and a copy of the article)(Posted to blackboard)
   11/14/12 First draft or outline of paper (Posted to blackboard)
   12/12/12 Final paper (Posted to blackboard AND double-sided hard copy to instructor)

   In addition, each student will prepare a 15-minute, in-class presentation that summarizes the key findings of their research paper. The presentation will be factored into the final grade for the research paper. The dates for in-class presentations are **12/05/12, 12/12/12,** and **12/19/12.**

3. **Behavior Modification Paper** (30% of course grade). Each student is required to prepare a 10 page double-spaced paper that involves planning, applying, and evaluating a behavior modification treatment program. Students should follow the guidelines presented in Chapter 24 of Martin and Pear (2011). Topics for this paper need to be approved by the course instructor. Published research results denoting the efficacy of the chosen behavioral treatment should be presented.

   The following due dates apply to the behavior modification paper requirement:

   10/03/12 Topic & Assessment Proposal (Include: operational definition of behavior to be modified and a one to two page description of the assessment methods to be utilized). [Posted to blackboard AND hard copy submitted to instructor)]
   10/17/12 Intervention Proposal (Include a one to two page description of behavioral techniques you will be implementing) [Posted to blackboard AND hard copy submitted to instructor]
   12/12/12 Final draft of paper (Posted to blackboard AND hard copy submitted to instructor)

4. **Exam** (40% of course grade). A final cumulative examination will be given on **November 28, 2012**. The format of the exam will be a combination of multiple choice, definitions, short answer, and/or essay questions. The exam will cover

materials discussed in class as well as materials from readings. Please note that questions will be both theoretical and applied. A list of exam objectives will be distributed prior to the exam.

Required Texts:

Martin, G., & Pear, J. (2011). *Behavior modification: What it is and how to do it* (9th ed.). Upper Saddle River, NJ: Prentice-Hall.

Required Readings:

Additional articles &/or chapters will be assigned throughout the course of the semester. Students are responsible for all reading materials assigned even if the material is not formally discussed in class. Articles and chapters other than from required texts are available on E-reserve from the Pace University Library.

Recommended:

American Psychological Association. (2010). *Publication manual of the American Psychological Association* (6th ed.). Washington, DC: Author.

Policy regarding Assignments and Exams:

All written assignments are to be type-written. Handwritten assignments will not be accepted. Furthermore, late assignments will not be accepted unless due to unavoidable circumstances which have been discussed with the instructor. Assignments, supplementary readings, and changes to this syllabus will be announced in class. Students are responsible for these changes.

All papers should follow the American Psychological Association (APA) style as presented in the *Publication Manual of the American Psychological Association* (6th ed.). Students at this level of training are expected to utilize primary sources from peer-reviewed publications as their main type of references. Use of secondary sources (e.g., book chapters) should be limited.

Make-up exams will be given only for excused absences (e.g., medical excuses) and are at the discretion of the instructor. Please note that any make-up exam will differ from the exam given during the regularly scheduled class period. It is the student's responsibility to contact the professor to make such arrangements prior to the date of the in-class exam.

Students with Disabilities

If you have a disability for which you are or may be requesting an academic accommodation, you must register with the Coordinator of Services for Students with Disabilities. You can contact the Coordinator at 212-346-1526.

Course Outline:

Date	Topics	Readings[1]
9/5	Course Introduction Historical overview of Behavioral Theories	Martin & Pear Chap. 29
9/12	Behavior Modification Approach Behavioral Assessment	Martin & Pear, Chaps. 1, 2, & 20-22 Gresham et al. (2001) Ervin, Ehrhardt, et al. (2001) Ervin, Radford, et al. (2001) Sterling-Turner et al. (2001)
9/19	Behavioral Intervention Plans Positive reinforcement, extinction & punishment **(Research Paper: Topic Due)**	Martin & Pear, Chaps. 3, 5 & 12 Little & Kelley (1989)
9/26	**No Class**	
10/3	Existing stimulus control & schedules of reinforcement **(Behavior modification topic & assessment proposal due)**	Martin & Pear, Chaps. 6, 7, 17, & 18 Ogier & Hornby (1996)
10/10	Shaping, discrimination, & fading Conditioned reinforcement, chaining, & generalization **(Research Paper: Article review due)**	Martin & Pear, Chaps. 8-10 Meyer et al. (1999)
10/17	Token Economies Behavior Modification Designs Clinical behavior therapy overview & Ethical issues	Martin & Pear, Chaps. 4, 11, 16, 23, 25-28, & 30 **Hargett & Webster (1996)** Drasgow & Yell (2001)
10/24	Socio-cultural Theories of Learning **(Behavior modification intervention proposal due)**	Schunk (2004) Chap. 3 Steiner & Mahn (2003)
10/31	Information Processing Theories & Cognitive Learning Processes	Derry (1990) Leighton & Sternberg (2003) Mayer (2003), Mayer (1996) McCormick (2003) Paris & Winograd (1990)
11/7	Information Processing Theories & Cognitive Learning Processes (cont.)	

[1] Additional readings may be assigned throughout the course of the semester. Students are responsible for all readings unless otherwise specified.

11/14	Motivation & Self-Regulation **(Research Paper: Outline/draft due)**	Pintrich (2003) Ryan et al. (2001) Schunk & Zimmerman (2003) Tollefson (2000)
11/21	**No Class**	
11/28	Final Exam	
12/5	Instructional Issues **Student Research Presentations**	Borko & Shavelson (1990) Dart et al. (1999) Pressley et al. (2003) Slavin et al. (2003)
12/12	**Student Research Presentations** **(Research Paper Final Version Due)** **(Behavior Modification Final Paper Due)**	
12/19	**Student Research Presentations**	

References:

Borko, H., & Shavelson, R. J. (1990). Teacher decision making. In B. F. Jones & L. Idol (Eds.), *Dimensions of thinking and cognitive instruction* (pp. 311-346). Hillside, NJ: Erlbaum.

Dart, B., Burnett, P., Boulton-Lewis, G., Campbell, J., Smith, D., & McCrindle, A. (1999). Classroom learning environments and students' approaches to learning. *Learning Environments Research, 2*, 137-156.

Derry, S. J. (1990). Learning strategies for acquiring useful knowledge. In B. F. Jones & L. Idol (Eds.), *Dimensions of thinking and cognitive instruction* (pp. 347-379). Hillside, NJ: Erlbaum.

Drasgow, E., & Yell, M. L. (2001). Functional behavioral assessments: Legal requirements and challenges. *School Psychology Review, 30*, 239-251.

Ervin, R. A., Ehrhardt, K. E., & Poling, A. (2001). Functional assessment: Old wine in new bottles. *School Psychology Review, 30*, 173-179.

Ervin, R. A., Radford, P. M., Bertsch, K., Piper, A. L., Ehrhardt, K. E., & Poling, A. (2001). A descriptive analysis and critique of the empirical literature on school-based functional assessment. *School Psychology Review, 30*, 193-210.

Gresham, F. M., Watson, T. S., & Skinner, C. H. (2001). Functional behavioral assessment: Principles, procedures, and future directions. *School Psychology Review, 30*, 156-172.

Hargett, M. Q., & Webster, R. E. (1996). Treatment integrity and acceptability with families: A case study of a child with school refusal. *Psychology in the Schools, 33*, 319-324.

Leighton, J. P., & Sternberg, R. J. (2003). Reasoning and problem solving. In I. B. Weiner (Series Ed.) & A. F. Healy (Vol. Ed.), *Handbook of Psychology: Vol. 4. Experimental Psychology* (pp. 623-648). New York: Wiley.

Little, L. M., & Kelley, M. L. (1989). The efficacy of response cost procedures for

reducing children's noncompliance to parental instructions. *Behavior Therapy, 20*, 525-534.

Mayer, R. E. (1996). Learners as information processors: Legacies and limitations of educational psychology's second metaphor. *Educational Psychologist, 31*, 151-161.

Mayer, R. E. (2003). Memory and information processes. In I. B. Weiner (Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 47-57). New York: Wiley.

McCormick, C. B. (2003). Metacognition and learning. In I. B. Weiner (Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 79-102). New York: John Wiley & Sons, Inc.

Meyer, E. A., Hagopian, L. P., & Paclawskyji, T. R. (1999). A function-based treatment for school refusal behavior using shaping and fading. *Research in Developmental Disabilities, 20*, 401-410.

Ogier, R., & Hornby, G. (1996). Effects of differential reinforcement on the behavior and self-esteem of children with emotional and behavioral disorders. *Journal of Behavioral Education, 6*, 501-510.

Paris, S. G., & Winograd, P. (1990). How metacognition can promote academic learning and instruction. In B. F. Jones & L. Idol (Eds.), *Dimensions of thinking and cognitive instruction* (pp. 15-51). Hillside, NJ: Erlbaum.

Pintrich, P. R. (2003). Motivation and classroom learning. In I. B. Weiner (Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 103-122). New York: Wiley.

Pressley, M., Roehrig, A. D., Raphael, L., Dolezal, S., Bohn, C., Mohan, L., et al. (2003). Teaching processes in elementary and secondary education. In I. B. Weiner

(Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 153-175). New York: Wiley.

Ryan, A. M., Pintrich, P. R., & Midgley, C. (2001). Avoiding seeking help in the classroom: Who and why? *Educational Psychology Review, 13*, 93-114.

Slavin, R. E., Hurley, E. A., & Chamberlain, A. (2003). Cooperative learning and achievement: Theory and research. In I. B. Weiner (Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 177-198). New York: Wiley.

Schunk, D. H. (2004). Learning theories: An educational perspective (4th ed.)(pp. 83-135). Upper Saddle River, NJ: Prentice-Hall.

Schunk, D. H., & Zimmerman, B. J. (2003). Self-regulation and learning. In I. B. Weiner (Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 59-78). New York: Wiley.

Steiner, V. J., & Mahn, H. (2003). Sociocultural contexts for teaching and learning. In I. B. Weiner (Series Ed.) & W. M. Reynolds & G. E. Miller (Vol. Eds.), *Handbook of Psychology: Vol 7. Educational Psychology* (pp. 125-151). New York: Wiley.

Sterling-Turner, H. E., Robinson, S. L., & Wilczynski, S. M. (2001). Functional assessment of distracting and disruptive behaviors in the school setting. *School Psychology Review, 30*, 211-226.

Tollefson, N. (2000). Classroom applications of cognitive theories of motivation. *Educational Psychology Review, 12*, 63-83.

PSY834: Doctoral Project Seminar **Spring 2014**
PSY835: Doctoral Colloquium
Blackboard Community Name: Psy.D. Doctoral Projects
[To access, go to http://blackboard.pace.edu and look under "My Organizations".]

INSTRUCTORS

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DESCRIPTION OF COURSES

PSY834 - Doctoral Project Seminar (Psy.D.)
This seminar provides a structured framework for the development of the Psy.D. doctoral project. Quantitative, methodological, and ethical issues relevant to students' research proposals are discussed. Fully developed research proposals are presented to faculty and peers and subjected to rigorous review. Implementation of their proposed research is contingent upon faculty approval.

PSY835 - Doctoral Colloquium (Psy.D.)
This seminar provides a structured framework for the completion of the Psy.D. doctoral project. Issues regarding the statistical analyses and interpretation of research findings are of primary concern for discussion. Research results are presented to faculty and peers and are rigorously critiqued. The completion of the Psy.D. doctoral project is contingent upon faculty approval. Prerequisite: PSY834

[NOTE: Please check the Blackboard Community called "Psy.D. Doctoral Projects" for all procedures, documentation, schedules, research proposals, and results summaries. Sample resources, suggested readings, and weblinks may also be accessed through this online community.

CALENDAR

2/05 *(Wednesday)* 7:30pm – 9:30pm Location: To be determined	**CLASS MEETING #1:** General Overview, Paperwork, and other Course Requirements *(See Note 1 for attendance requirements.)*
2/10 *(Monday)* 7:30pm – 9:30pm Location: To be determined	**CLASS MEETING #2:** General Overview, Paperwork, and other Course Requirements *(See Note 1 for attendance requirements.)*
2/28 *(Friday)*	**DEADLINE:** Submission of materials for students planning to present on 3/14 *(See Note 2 for submission requirements.)*
3/14 *(Friday)*	**PSY.D. PRESENTATIONS:** Psychology Lab & Conference Room
3/24 *(Monday)*	**DEADLINE:** Submission of materials for students planning to present on 4/04 *(See Note 2 for submission requirements.)*
4/04 *(Friday)*	**PSY.D. PRESENTATIONS:** Psychology Lab & Conference Room
4/25 *(Friday)*	**DEADLINE:** Submission of materials for students planning to present on 5/09 *(See Note 2 for submission requirements.)*
5/09 *(Friday)*	**PSY.D. PRESENTATIONS:** Psychology Lab & Conference Room

Note 1
- Psy.D. students who plan to present their PSY834 proposals or PSY835 papers are REQUIRED to attend either *Class Meeting #1* or *Class Meeting #2*, AND to schedule a brief (15 - 20 minute) consultation meeting with Dr. Velayo and/or Dr. Rosenthal *after* having attended one of the class meetings but *before* their presentation. A Psy.D. student may present their proposal (PSY834) or paper (PSY835) in one of the presentation dates ONLY when this attendance requirement is satisfied.
- PSY834 students must also attend at least 3 presentation sessions (excluding their own) on at least one of the Psy.D. presentations dates scheduled for this semester. Attendance will be taken.
- PSY835 students must also attend at least 3 presentation sessions (excluding their own) on the Psy.D. presentation date they are scheduled to present their results. Attendance will be taken.

Note 2
- Two weeks prior to the date you wish to present, the Psy.D. student must submit:
  1) Approval forms signed by your advisor and consultant (needed for both PSY834 and PSY835)
  2) An electronic file (in MS Word format) of your doctoral project proposal (PSY834) or doctoral project paper (PSY835) must be sent as an email attachment to Dr. Velayo at rvelayo@pace.edu.

PSY111
Introduction to Psychology 2
(CRN#40741)
Summer 1 2008

Instructor:	Richard S. Velayo, Ph.D.
Office Location:	41 Park Row, Rm. 1324
Office Phone:	(212) 346-1558
E-mail (preferred):	rvelayo@pace.edu

Credits: 3

Description

An introduction to the science and profession of psychology including coverage of research, cognitive abilities, human development, personality, testing and assessment, abnormal psychology, treatment of psychopathology, health and wellness, personality, abnormal psychology, social cognition, and social influence.
[Note: The Introductory Psychology course sequence (PSY110 and PSY111) introduces students to psychology as a science, a profession, and as a means of promoting human welfare. These courses are required for all Psychology and Applied Psychology and Human Relations majors and are considered Area of Knowledge 5 of Pace's Core Curriculum. All sections of PSY110 and PSY111 use the same textbook and each course covers specific content areas.]

This course, together with PSY110, provides you with an introduction to psychology, the scientific study of behavior and mental processes. (In PSY110, the focus is on the biological aspects of psychology, sensation, perception, learning, memory, cognition and language, consciousness, and motivation and emotion.) In each section we will examine the kinds of questions asked, methods used, and assumptions made by researchers. PSY110 and PSY111 are prerequisites for all advanced courses in psychology.

Many students come to introductory psychology courses more interested in the application of psychology than in its scientific basis. Psychology is relevant to the personal and social issues you confront. Students are expected to be able to connect the basic concepts we examine to their personal experience. An important aim of the course is to assist you in developing the critical thinking skills necessary for dealing with psychological issues, and becoming an informed consumer able to evaluate the many claims about psychology appearing in the media. Students are expected to take an active role in thinking about and questioning the matters addressed in the text and in class.

Prerequisite

There are no prerequisite course/s required.

Course Materials

Required Textbooks:

- **Bernstein, D., Penner, L., Clarke-Stewart, L., & Roy, E., (2006). *Psychology* (7th ed.). Boston, MA: Houghton-Mifflin. [ISBN: 0-61867483-2]**

Note: Books for Pace online courses are available through the Pace Online Bookstores or you may visit an on campus bookstore. To purchase your textbooks online go to http://pace.bncollege.com. You may also purchase the textbook at the Pace campus bookstore:

New York City Barnes & Noble @ Pace University
41 Park Row, New York, NY 10038
(212) 346-1605

Blackboard Resource Center

If you need help with Blackboard, go to: **http://www.pace.edu/blackboardhelp**

Course Topics and Schedule

WEEK	TOPIC	ASSESSMENTS
1 (May 29 – June 4)	***COURSE INTRODUCTION*** ***PSY111 SYLLABUS*** **CHAPTER 1: Introducing Psychology**	
2 (June 5 – June 11)	**CHAPTER 2: Research in Psychology** **CHAPTER 10: Cognitive Abilities**	**TOPIC for FINAL PAPER** **(Due on June 11)**
3 (June 12 – June 18)	**CHAPTER 12: Human Development** **CHAPTER 13: Health, Stress, and Coping**	
4 (June 19 – June 25)	**CHAPTER 14: Personality** **CHAPTER 15: Psychological Disorders**	
5 (June 26 – July 2)	**CHAPTER 16: Treatment of Psychological Disorders** **CHAPTER 17: Social Cognition**	**FINAL PAPER** **(Due on July 2)**
6 (July 3 – July 12)	**CHAPTER 18: Social Influence** ***COURSE Wrap-up and COURSE EVALUATION***	**Final Exam** **(Due/Completed by July 10)** **Student Grade Form for FINAL PAPER** **(Due on July 12)** **Individual Member Evaluation Form for FINAL PAPER** **(Due on July 12)**

Course Documents

Course material is organized into weekly folders located within the **COURSE DOCUMENTS** button of **Blackboard**. On each Thursday, by midday, a new folder will be made available for you to actively read through and comprehend the material. You have an entire week (Thursday through the following Wednesday) to go through the information. Once available, folders will remain active throughout the duration of the course for you to review material on your own.

Assignments

Discussion Board

Participation
As a student in the course, you are expected to ***regularly*** and to ***actively*** participate in all the weekly discussions by responding to each of the questions posted. The quality and frequency of your responses will be taken into account towards your grade. You are also encouraged to provide feedback to other students responses. Discussions are expected to be *insightful, reflective, lively, and thought provoking.*

As for the grading of your weekly participation, you should respond completely and thoroughly to each of the posted question for the week discussion board questions. ***Providing quality feedback to at least 5 of your other classmates and/or instructor postings*** in a way that makes the discussions intellectually stimulating will constitute sufficient participation although you are encouraged to respond to more postings. It will be up to your instructor to determine the quality level of your postings and feedback to determine the appropriate grade for weekly participation in the discussion boards.

These online discussions will focus not only on enhancing your learning of the concepts and applications presented in this course, but also to further your thinking and writing skills.

Facilitation of Discussion Forum
Each week, an assigned student facilitator (or your instructor) will be in charge of developing and posting a few questions to motivate your learning of the course content.

You will be required to facilitate a discussion forum on a topic in one of the chapters from the textbook, including the assigned article for the week. This will involve ***posting questions and/or an interesting activity on or before the first day (Thursday) that your assigned topic is covered***. For example, if you were assigned to facilitate Chapter 2 (Research in Psychology), your set of questions should be posted by Thursday morning. Your goal is to generate a lively online discussion on the chapter topic. Examples of discussion questions that may be posted are:

Imagine that a psychologist asked you to participate in his/her experiment. You were presented with an Informed Consent Form in compliance with ethical guidelines in conducting research with human participants. Why is it important for you to read this form before signing? What information should you expect to read in the form?

There were a number of research methods presented in the textbook. Let presume that a psychologist would like to determine if a new therapeutic approach to depression may work best for a particular client who has recently been diagnosed with depression. Which research method do you think would be best? Why so?

The chapter(s) that you will facilitate is assigned to you early during the semester. Procedurally, you will be asked to send your instructor your questions(s) first via e-mail so that these may be looked over prior to posting. Your instructor may need to modify or make changes so that about 2-4 discussion questions are posted. Your instructor will post these questions for you. As a discussion board facilitator, you are expected to actively respond and provide feedback to your classmates responses, particularly the initial set of responses to the discussion questions for each student. [***Note:*** You are also expected to respond to the questions posted for the week you are assigned to facilitate.]

There is no need to submit a written report for this requirement.

Final Paper (individual project)

You will be required to write an in-depth critique (no longer than 5 pages, single-spaced) of a journal article (theoretical and/or empirical) on a topic covered in the course (based on the textbook) which is of interest

to you. Your choice of a journal article requires your instructor6 approval. You can find relevant articles by searching the PsycINFO and/or PsycArticles database. These contain psychology journals and full-text versions of these articles. [For questions or assistance on accessing the Pace University Library Resources, go to http://library.pace.edu
Your final paper should be a review or critique of an academic or professional journal article in psychology published within the last 5 years. The structure of the paper should be as follows:

I. Cite the Journal Article
Example: Zimbardo, P. G. (2004). Does psychology make a big difference in our lives? *American Psychologist, 59,* 339-351.
II. Summary of the Journal Article (no longer 1 page, single-spaced)
III. Critique/Review [This is primarily opinion-based, but you are also expected to demonstrate your knowledge of general psychology by using the concepts and terms covered in the course/textbook.]

This course requirement is intended to supplement your learning of the course content and to enhance your ability to apply the concepts learned.

You will be given the opportunity to have your paper read by other members of the class sometime during the latter part of the semester. Thus, your paper will be accessible online for other students to evaluate using the **Student Grade Form**. Other students in the course, including your instructor, may then provide feedback/comments to your paper. Details on the specific and technical aspects of this requirement will be discussed in the course of the semester.

An **Individual Member Evaluation Form** must also be submitted. (This form will be made available online). This will allow you to evaluate yourself given your perceived quality and/or effort you placed on doing the paper.

Final Exam

The **Final Exam,** which will be administered online, shall cover all the chapters covered in the course. This is designed to test your knowledge of the material discussed in the assigned readings and to apply what you have learned from the course. The format may include multiple-choice, true-false, and short answer questions.

Communication

Discussion

The **Discussion Board** area has been set up to operate like a live classroom; answer questions, ask questions, comment on the responses of your fellow classmates and instructors. This area can be very valuable to you if you encounter difficulty during the course. Check the Discussion area frequently. Your participation is part of your grade.

If you have personal and on-the-job experience relevant to a discussion topic or to a question from one of your fellow students, please share your knowledge. Active participation by everyone makes the class better for everyone.

Virtual Chat (also called ´ollaboration3accessible under ωCommunication)

This feature is optional. You may use this area to work **synchronously** with your classmates and/or the instructor. This feature in Blackboard may not be used in this course.

Email

Please feel free to contact your instructor or your classmates via **email** at any time.

Grading

Each of the activities below constitutes part of your grade. Failure to participate in one or more activities may result in a significant reduction in your grade.

Final grades are calculated as follows:

Participation (Weekly Discussion Board) *(20 points per chapter; 10 chapters; plus 1 discussion forum)*	44%	220 points
Facilitation of Discussion Forum	12%	60
Final Project:		
Feedback from Class	8%	40
Feedback from Instructor	14%	70
Individual Member Evaluation	4%	20
Submission of Student Grade Form	4%	20
Final Exam	14%	70
Total	**100%**	**500 points**

Note: *One (1) point is subtracted for each day late for each of the related grade associated with a particular course requirement.*

Grading Scale

Note: This will be strictly enforced.

LETTER	POINTS	QUALITY POINTS
A	475 - 500	4.0
A-	450 - 474	3.7
B+	435 - 449	3.3
B	415 - 434	3.0
B-	400 - 414	2.7
C+	380 - 399	2.3
C	350 - 379	2.0
C-	335 - 349	1.7
D+	315 - 334	1.3
D	300 - 314	1.0
F	0 – 299	0.0

Attendance

Successful online learning requires that a you actively participate in each weekó learning materials which include:

- **Reading** course documents, textbooks, articles and web materials assigned.
- **Submission** of homework assignments, projects and papers.
- **Completion** of the course requirements (e.g. exams, written critique paper).

- **Participation** in the weekly discussion board forums, team activities, and email.

Excessive absences and failure to keep up with the course pace may result in a decreased or failing course grade. This is ***not a self-paced course***. Within each week, assignments may be worked on at times convenient to the student. However, the assignments are to be completed by the end of that academic week (Wednesday at midnight). If you are unable to participate during a particular week, please contact the instructor beforehand.

Disabilities

The University¿ commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities. To request an accommodation for a qualifying disability, a student must self-identify and register with the Coordinator of Disability Services for his or her campus. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see *Information for Students with Disabilities* on the University¿ web site.

Academic Integrity Policy

Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in the academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any paper, report or submission for academic credit without the appropriate acknowledgment is plagiarism. It is unethical to present as one¿ own work the ideas, words, or representations of another without proper indication of the source. Therefore, it is the student¿ responsibility to give credit for any quotation, idea, or data borrowed from an outside source. Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension or dismissal from the University. Individual schools and programs may have more specific procedures for violations of academic integrity. Therefore, students are encouraged to familiarize themselves with the academic integrity policies of the University and of individual schools and programs in which they are enrolled. Students penalized for failing to maintain academic integrity who wish to appeal such action must follow the appeal procedure outlined below in the ˜rades Appeal ProcessM section or that of the individual school or program in which they are enrolled if such school or program has a separate appeal procedure in place.

Students can get help on how to use resources properly in their research and writing from many sources. This site (http://www.pace.edu/library/pages/instruct/plaig.html) provides links to useful information.

Pace University Writing Center

The Pace University Writing Center offers tutorial services in writing as well as handouts and reference materials on writing for student use in person or via the web at www.pace.edu/dyson/writingcenter. The staff of instructor and student tutors can assist students in understanding writing assignments and criteria and can help students with any stage of the writing process, from brainstorming topics to revision of rough drafts. Students may be referred to the Writing Center as part of this course, or students may seek assistance with course writing on their own via web-based tutoring or by visiting the Writing Center in person (NY-Birnbaum Library, 2nd Floor, 346-1085; PLV-Mortola Library, 3rd Floor, 773-3942). Please refer to the Writing Center¿ website for information about polices and hours of operation.

-End-

PSYCHOLOGY 112*
Introduction to Psychology
(CRN #73672)
Fall 2011

Instructor:	Richard S. Velayo, Ph.D.
Meetings:	T, R - 6:00pm - 8:45pm, Birnbaum Electronic Classroom (E101)
Office Location:	41 Park Row, Room 1324
Office Phone:	(212) 346-1506
Office Hours:	W, R - 3:00pm - 5:00pm (by appointment)
Course URL:	http://blackboard.pace.edu
E-mail:	rvelayo@pace.edu (preferred mode of communication)

Description

This web-enhanced (online) course introduces the student to the scientific study of behavior and mental processes. Modern psychology is broad in scope and rich in detail. The topics in this course have been chosen to provide a representative sample of important areas of active interest in psychology today. Topics include: introduction and research methods, neurosciences and biological foundations, sensation and perception, learning, memory, life span development, motivation and emotion, personality, psychological disorders, therapy, and social psychology.

This course requires your active reading of the assigned materials (i.e., textbook chapters), participation in online discussions, and two online exams (a Midterm and a Final). You will also be required to write a final paper in the form of a journal article critique on a course-related topic of interest to you.

Blackboard, a distance learning software program, will be utilized as the primary mode of instruction in order to disseminate information and to serve as the medium for discussion.

Textbook (Required)

Schacter, D. L., Gilbert, D. T., & Wegner, D. M. (2009). *Psychology*. New York, NY: Worth. [ISBN-13: 978-1-4292-3719-2]

Blackboard Resource Center

If you need help with Blackboard, go to: http://www.pace.edu/online-learning/online-help-students

How Do I login to Blackboard?

Go to http://blackboard.pace.edu. Click on the login button and enter your username and password; use your MyPace Portal username and password to login (e.g., cw94975n, tr87689w and jc73732p). If you do not know your username, you can search it at whitepages.pace.edu.

Online Learning Community & Orientation (Blackboard)

If you feel that you need more information on how to use Blackboard, there is a self-paced tutorial available to you. This tutorial may be accessed as follows: When you have successfully logged-on to Blackboard, you

will see a category called "My Organizations". You will see that one of the organizations listed underneath this is called "Online Learning Community". This is a self-paced program designed to prepare students for the online learning experience. It also provides information about the resources available to online students. All students enrolled in online courses are automatically placed in this community.

Course Documents

Course coverage is based on the chapters in the required textbook. Supplementary materials are organized into weekly folders located within the **COURSE DOCUMENTS** button of our **PSY112 Blackboard course**. These supplementary materials are organized on a weekly basis (generally beginning on Thursday and ending the following Wednesday).

Assignments

Discussion Board

Participation (Weekly)
Every week, your instructor will post a few questions pertaining to the assigned chapter(s) to motivate your learning of the course content. Each discussion forum will be based on the assigned chapter readings for the week. For example, the Chapter 3 (Neuroscience and Behavior) discussion board questions may be as follows:

- *To what extent do you think neuropsychology (neuroscience in general) may adequately explain how we think, feel , and behave? Explain your answer.*

- *There are many misconceptions surrounding the brain and its functioning. Pick at least two from the list of common perceptions about the brain and present your thoughts pertaining to them. You may find information sources on the web the support your ideas.*
  (a) The human brain is gray in color and firm to the touch.
  (b) Most people use only 10% of their brain
  (c) Functions are localized in either the left or rigth hemisphere.
  (d) Neurons cannot be newly created; they can only die with age.
  (e) Alcohol kills brain cells.

You are expected to ***regularly*** and to ***actively*** participate in all the weekly discussions by responding to each of the questions posted. The quality and frequency of your responses will be taken into account towards your grade. You are also expected to provide feedback to other students' responses. Discussions are meant to be *insightful, reflective, lively, and thought provoking.*

Your participation in the weekly discussion contributes significantly toward your final grade. You should respond completely and thoroughly to each of the posted question for the week's discussion board questions. ***Providing "quality" feedback to at least 4 of your other classmate's and/or instructor's initial postings*** in a way that makes the discussions intellectually stimulating will constitute "sufficient" participation, although you are encouraged to respond to more postings if you want a better participation grade for that week. It will be up to your instructor to determine the quality level of your postings and feedback to determine the appropriate grade for weekly participation in the discussion boards.

The main purpose of the online discussions is to enhance your learning of the concepts and applications presented in this course, and to further your thinking and writing skills.

There is no need to submit a written report for this requirement.

Final Paper

You are required to write an in-depth critique paper (**no longer than 6 pages, single-spaced**) of a journal article (theoretical and/or empirical studies) on a course-related topic, which is of interest to you. Your choice of a journal article requires your instructor's approval. You can find relevant articles by searching the PsycINFO and/or the PsycArticles database. [For questions or assistance on accessing the Pace University Library Resources, go to http://library.pace.edu]

Your final paper should be a review or critique of an academic or professional journal article in psychology published within the last 5 years. The structure of the paper should be as follows:

I. **Cite the Journal Article**
Example: Arnett, J. J. (2008). The neglected 95%: Why American psychology needs to become less American. *American Psychologist, 63*, 602-614.

II. **Summary of the Journal Article** [1 – 2 pages]

III. **Critique/Review** [3 – 4 pages]
[This is primarily opinion-based, but you are also expected to demonstrate your knowledge of psychology by using the concepts and terms covered in the textbook. Citing references is encouraged but not required.]

IV. **Implications for International Psychology** [1-page]
[What may be the potential relevance of this article on the internationalization of psychology? In other words, comment/discuss the extent to which the constructs and/or findings in the article apply to other cultures/nations.]

This course requirement is intended to supplement your learning of the course content and to enhance your ability to apply the concepts learned.

You will be given the opportunity to have your written critique read by other members of the class sometime during the latter part of the semester. Thus, your paper will be accessible online for other students to evaluate using the Student Grade Form. (This form is available on our course's Blackboard site). Other students in the course, including your instructor, will then provide feedback/comments to your paper. Details about this requirement will be discussed in the course of the semester.

An Individual Member Evaluation form must also be submitted. (This form is available on our course's Blackboard site). This will allow you to evaluate yourself given your perceived quality and/or effort you place in doing the paper.

A Final Paper Presentation Session is scheduled during the latter part of the semester. You will be given the opportunity to present your paper in class for no longer than ten (10) minutes. (This amount time of time may vary depending on the number of students scheduled to present during the day of presentation).

Exams

A **Midterm Exam** and a **Final Exam** will each be administered online. Each exam will cover specific chapters of your textbook assigned by your instructor. The exams are designed to test your knowledge of the material discussed in the assigned readings and to apply what you have learned from the course. The exams are in multiple-choice format.

Communication

Discussion

The **Discussion Board** area has been set up to operate like a live classroom; answer questions, ask questions, comment on the responses of your fellow classmates and instructors. This area can be very valuable to you if you encounter difficulty during the course. Check the Discussion area frequently. Your participation is part of your grade.

If you have personal and/or on-the-job experience relevant to a discussion topic or to a question from one of your fellow students, please do share your experiences as it relates to the chapter/topic covered. Active participation by everyone contributes to a more intellectually stimulating and engaging online learning experience.

Email

Please feel free to contact your instructor or your classmates via **email** at any time if needed. My email address is rvelayo@gmail.com. You classmates' (and instructor) email(s) may be accessed under the "Email" button on the PSY112 Blackboard site.

Course Topics and Schedule

WEEK	TOPIC	REQUIREMENT DUE
1 (Sep 7 – Sep 14)	***COURSE INTRODUCTION*** **CHAPTER 1: Psychology: The Evolution of a Science (including Historical Foundations)**	**PSY112 Syllabus**
2 (Sep 15 – Sep 21)	**CHAPTER 2: Methods in Psychology**	
3 (Sep 22 – Sep 28)	**CHAPTER 3: Neuroscience and Behavior** **CHAPTER 4: Sensation and Perception**	
4 (Sep 29 – Oct 5)	**CHAPTER 5: Consciousness** **CHAPTER 6: Memory**	**TOPIC for FINAL PAPER** **(Due on Oct 5)**
5 (Oct 6 – Oct 12)	**CHAPTER 7: Learning** **CHAPTER 8: Emotion and Motivation**	
6 (Oct 13 – Oct 19)	**CHAPTER 9: Language and Thought**	
7 (Oct 20 – Oct 26)	**MIDTERM EXAM**	**MIDTERM Exam** **(Due/Completed by Oct 26)**
8 (Oct 27 – Nov 2)	**CHAPTER 10: Intelligence** **CHAPTER 11: Development**	**ARTICLE for FINAL PAPER** **(Due on Nov 2)**
9 (Nov 3 – Nov 9)	**CHAPTER 12: Personality**	
10 (Nov 10 – Nov 16)	**CHAPTER 13: Social Psychology (including Gender and Multicultural Issues)**	

11 (Nov 17 – Nov 23)	**CHAPTER 14: Psychological Disorders**	
12 (Nov 24 – Nov 30)	***NO CLASS (Thanksgiving Break)***	
13 (Dec 1 – Dec 7)	**CHAPTER 15: Treatment of Psychological Disorders**	**FINAL PAPER** **(Due on Dec 7)**
14 (Dec 8 – Dec 14)	**CHAPTER 16: Stress and Health**	
15 (Dec 15 – Dec 21)	**FINAL EXAM** ***COURSE Wrap-up and EVALUATION***	**FINAL Exam** **(Due/Completed by Dec 21)** **Student Grade Form for FINAL PAPER** **(Due on Dec 21)** **Individual Member Evaluation Form for FINAL PAPER** **(Due on Dec 21)**

Grading

Each of the activities below constitutes part of your grade. Failure to participate in one or more activities may result in a significant reduction in your grade.

Final grades are calculated as follows:

Participation (Weekly Discussion Board) *(15 points per chapter; 16 chapters)*	48%	240 points
Final Project:		
Feedback from Class	4%	20
Feedback from Instructor	14%	70
Individual Member Evaluation	2%	10
Submission of Student Grade Form	2%	10
Midterm Exam	15%	75
Final Exam	15%	75
Total	**100%**	**500 points**

***Note**: One (1) point is subtracted for each day a course requirement is submitted late.*

Grading Scale

Note: This will be strictly enforced.

LETTER	POINTS	QUALITY POINTS
A	475 - 500	4.0
A-	450 - 474	3.7
B+	435 - 449	3.3
B	415 - 434	3.0
B-	400 - 414	2.7
C+	380 - 399	2.3
C	350 - 379	2.0
C-	335 - 349	1.7
D+	315 - 334	1.3
D	300 - 314	1.0
F	0 – 299	0.0

Attendance

Successful online learning requires that a student actively participates in each week's learning materials including:

- **Reading** course documents, textbooks, articles and web materials assigned.
- **Submission** of projects and papers on time.
- **Completion** of the course requirements (e.g. exams, written journal critique paper).
- **Participation** in the weekly discussion board forums and other activities

Excessive non-participation and failure to keep up with the course pace may result in a decreased or failing course grade. This is ***not a self-paced course***. Within each week, assignments may be worked on at times convenient to the student. However, the assignments are to be completed by the end of that academic week **(Wednesday by midnight).** If you are unable to participate during a particular week, please contact the instructor beforehand.

Academic Integrity Policy

Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in the academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any paper, report or submission for academic credit without the appropriate acknowledgment is **plagiarism**. It is unethical to present as one's own work the ideas, words, or representations of another without proper indication of the source. Therefore, it is the student's responsibility to give credit for any quotation, idea, or data borrowed from an outside source.

Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension or dismissal from the University. Individual schools and programs may have more specific procedures for violations of academic integrity. Therefore, students are encouraged to familiarize themselves with the academic integrity policies of the University and of individual schools and programs in which they are enrolled. Students penalized for failing to maintain academic integrity who wish to appeal such action must follow the appeal procedure outlined below in the "Grades Appeal Process" section or that of the individual school or program in which they are enrolled if such school or program has a separate appeal procedure in place.

Students with Disabilities

The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities. To request an accommodation for a qualifying disability, a student must self-identify and register with the Coordinator of Disability Services for his or her campus. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see *Information for Students with Disabilities* on the University's web site.

Pace University Writing Center

The Pace University Writing Center offers tutorial services in writing as well as handouts and reference materials on writing for student use in person or via the web at www.pace.edu/dyson/writingcenter. The staff of instructor and student tutors can assist students in understanding writing assignments and criteria and can help students with any stage of the writing process, from brainstorming topics to revision of rough drafts. Students may be referred to the Writing Center as part of this course, or students may seek assistance with course writing on their own via web-based tutoring or by visiting the Writing Center in person (NY-Birnbaum Library, 2nd Floor, 346-1085; PLV-Mortola Library, 3rd Floor, 773-3942). Please refer to the Writing Center's website for information about polices and hours of operation.

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PSYCHOLOGY 380*
Experimental Psychology 1
(CRN #70230)
Fall 2014

Instructor:	Richard S. Velayo, Ph.D.
Meetings:	M, W - 6:10pm - 8:10pm, W200B (1 Pace Plaza)
Office Location:	41 Park Row, Room 1308
Office Phone:	(212) 346-1506
Office Hours:	M, W - 3:30pm - 5:30pm (by appointment)
Prerequisites:	PSY112 and PSY205
Course URL:	http://blackboard.pace.edu
E-mail:	rvelayo@pace.edu (preferred mode of communication)

Course Description:

This is an intensive, six hours per week course that introduces research methodology in psychology. It will include theoretical and practical aspects of behavioral research. The primary activity for this semester will be the development of an original scientific research proposal. You will conduct the research and complete the research paper based on this proposal when you take PSY381: Experimental Psychology 2, for the following spring semester. Blackboard will be utilized to help disseminate announcements, archive course materials, supplement instruction, and update grades.

Objectives of Experimental Psychology 1 and 2:

The primary goal of the Experimental Psychology sequence (PSY380 and PSY381) is to develop the critical thinking skills necessary for students to:

- Critically evaluate primary, empirical research in psychology,
- Translate theoretical ideas into testable research hypotheses, and
- Evaluate these hypotheses by means of a logically developed research plan

To meet these goals, specific pedagogical material to be covered and activities to be carried out for this semester include:

- Conducting and reporting the results of a class research project.
- Theoretical coverage of the process of scientific inquiry and the logic of the empirical method.
- Coverage of the major experimental designs and methods used in psychology.
- Familiarization with the major statistical techniques used in analyzing behavioral data.
- Development of an original scientific research proposal.

[Note #1: Other sections of PSY380 may differ in their specific course requirements, course activities, and grading system. The general course objectives, however, should be similar.]

[Note #2: You will need to enroll with the same instructor for PSY380 and PSY381.]

** This syllabus may be accessed from the PSY380 Blackboard site at* http://blackboard.pace.edu/

Texts (Required):

Smith, R. & Davis, S. (2013). *The Psychologist as Detective: An Introduction to Conducting Research in Psychology* (6th Edition). NJ: Pearson/Prentice-Hall. (ISBN: 978-020585907-8)

Cronk, B. C. (2014). *How to Use SPSS: A Step-by-Step Guide to Analysis and Interpretation (8th Edition).* CA: Pyrczak. (ISBN: 978-1-936523-26-9)

American Psychological Association (2009). *Publication Manual of the American Psychological Association* (6th ed.). Washington, DC: American Psychological Association. (ISBN: 978-1-4338-0561-5)

Statistical Package: SPSS statistical software (More details will be provided…)

Course Requirements:
This course is organized into three "modules" that consist of the following:

1. **EXAMS Module** (150 points) - There is a Midterm and a Final Exam, each of which will cover specific chapters of your text/s (which may include the APA Publication Manual). The exam format may include multiple-choice and short-answer questions. A review sheet will be provided about a week prior to the scheduled exam.

2. **PARTICIPATION Module** (170 points) - This module is composed of 3 parts namely:
   - *Attendance* – Three (3) points are deducted for each meeting absent or late. Proof for excused absences is required.
   - *Chapter Presentation(s)* – Each student will be assigned selected sections of the textbook (Smith & Davis, 2013) to present in class. The assignment of chapters will be done early during the semester. The use of PowerPoint is required.
     [Note: There is no need to submit a written report for this requirement.] The in-class presentation should be about 30 minutes in length and should conform to the following format:
     (i) A summary of the chapter (Use examples in your presentation)
     (ii) Try to integrate examples or discussion that help provide an international or cross-cultural perspective in understanding the constructs and/or research methodology, associated with your assigned chapter/section.
     (iii) An open forum for questions from the students and the instructor
   - *Research Exercises* - In order to better illustrate psychological research, we will conduct, as a class, some designated class research project or projects. You will learn hypothesis-testing, experimental design, and data analyses (using SPSS), and data interpretation. Critically evaluating experimental methodology is also a major part of this exercise.

3. **RESEARCH PROPOSAL Module** (180 points) – Your team (up to 4 persons) will be required to undertake a research project that is of interest. In the course of developing your proposal, you will need to consult with the instructor regarding your topic and how the proposal is developing. Your conduct in carrying out your research is very important and will contribute towards a significant part of your grade. Your proposal must be typed in APA-style format (See Publication Manual of the American Psychological Association).
   This is a group activity, which is composed of 3 parts/phases, namely:

- *Draft of your Research Proposal* - This written project represents your team's first attempt at writing your proposal, which includes a title page, abstract, introduction (with literature review), methods, references, and accompanying appendices. Your proposal should be written in APA style. This requirement will be discussed in greater detail during the course of the semester.
  [Note: An important part of your draft is the *Literature Review*. Submission of the Literature Review is optional. However, for the draft of your Research Proposal, you are required to gather and cite literature/articles that are relevant to your proposed topic. A minimum of 15 references (i.e., journal articles) is required as part of your team's Final Research Proposal.]
- *Final Research Proposal* – This written project represents the final revisions made of ALL sections of your draft and must be written in APA style format.
- *Presentation of Research Proposal* – This involves presenting your Research Proposal in class during the latter part of the semester. Prepare for no more than 20 minutes to present your work and additional time will be allotted for open discussion. You are advised to use paraphernalia that supplement and enhance your presentation (e.g., audio-visual aids, demonstration activities, etc.)

[Note: Students and the instructor are involved in the grading of the Research Proposal Module. This will be explained in greater detail during the semester.]

Grading System

EXAMS Module = 150 points (30%)	
Midterm Exam	75
Final Exam	75
PARTICIPATION Module = 170 points (34%)	
Attendance	50
Chapter Presentation(s) (Instructor Evaluation)	50
Research Exercises (Class Research Project)	70
(7 exercises at 10 pts. each)	
RESEARCH PROPOSAL Module = 180 points (36%)	
Draft of Research Proposal	
Individual Member Evaluation	10
Instructor Evaluation	40
Final Research Proposal	
Individual Member Evaluation	10
Instructor Evaluation	40
Student Grade Form	20
Submission of Student Grade Form	10
Presentation of Research Proposal	
Individual Member Evaluation	10
Instructor Evaluation	40
TOTAL POINTS	**500**

** This syllabus may be accessed from the PSY380 Blackboard site at* http://blackboard.pace.edu/

Letter-Grade Equivalent ("strictly" followed)			
A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

Course Evaluation:
In order to improve our Dyson College courses we look to you, the students, for feedback. Near the end of the semester you will be asked to fill out an online evaluation form regarding your experience in this course.

Dyson College is "going green" so we have made this a paperless process, but we need your help to make this eco-friendly solution a success. You will receive an email directing you to the IOTA course evaluation site http://paceevals.com where you will find the Dyson courses that you are enrolled in for the current semester.

Your feedback is very important and your response will remain confidential. If you have any questions about the online evaluations, please contact Martina Blackwood at mblackwood@pace.edu.

Thank you for your participation in this important process.

Academic Integrity Policy:
Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in the academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source in any paper, report or submission for academic credit without the appropriate acknowledgment is **plagiarism**. It is unethical to present as one's own work the ideas, words, or representations of another without proper indication of the source. Therefore, it is the student's responsibility to give credit for any quotation, idea, or data borrowed from an outside source.

Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension or dismissal from the University. Individual schools and programs may have more specific procedures for violations of academic integrity. Therefore, students are encouraged to familiarize themselves with the academic integrity policies of the University and of individual schools and programs in which they are enrolled. Students penalized for failing to maintain academic integrity who wish to appeal such action must follow the appeal procedure outlined below in the "Grades Appeal Process" section or that of the individual school or program in which they are enrolled if such school or program has a separate appeal procedure in place.

Students with Disabilities:
The University's commitment to equal educational opportunities for students with disabilities includes providing reasonable accommodations for the needs of students with disabilities. To request an accommodation for a qualifying disability, a student must self-identify and register with the Coordinator of Disability Services for his or her campus. No one, including faculty, is authorized to evaluate the need and arrange for an accommodation except the Coordinator of

Disability Services. Moreover, no one, including faculty, is authorized to contact the Coordinator of Disability Services on behalf of a student. For further information, please see *Information for Students with Disabilities* on the University's web site.

Pace University Writing Center:

The Pace University Writing Center offers tutorial services in writing as well as handouts and reference materials on writing for student use in person or via the web at www.pace.edu/dyson/writingcenter. The staff of instructor and student tutors can assist students in understanding writing assignments and criteria and can help students with any stage of the writing process, from brainstorming topics to revision of rough drafts. Students may be referred to the Writing Center as part of this course, or students may seek assistance with course writing on their own via web-based tutoring or by visiting the Writing Center in person (NY-Birnbaum Library, 2nd Floor, 346-1085; PLV-Mortola Library, 3rd Floor, 773-3942). Please refer to the Writing Center's website for information about polices and hours of operation.

Other Reminders:

- You may find some of the answers to your questions pertaining to this course in this syllabus, so read it carefully!
- Regularly check the PSY381 Blackboard site to preview next meeting's topic/s, activities, and important announcements.
- Ask me if something isn't clear. I'm quite approachable . . . really! ...well, most of the time :)
- Keep all papers returned to you.
- There is no such thing as bargaining for a grade in this course . . . unless there is an error in correction or computation.
- One (1) point is subtracted for each day a particular course requirement is late. Note that it is possible that a course requirement is graded from multiple sources. In this case, one (1) point is subtracted from each grading source. This will be explained in greater detail during the semester.
- Put a smile on your face . . . it cools the brain! (See research by Zajonc.)

PSY380 SCHEDULE

[Note: Read the assigned chapter(s), if any, before the scheduled class meetings.]
Some class meeting may include consultations and updates regarding your team group's Research Projects.

DATE/s	TOPIC/s	READING/s
Sep 3	***About PSY380... Course Introduction*** ***Class Roster Information*** ***What is Experimental Psychology?*** ***What is its relevance?***	Course Syllabus
Sep 8	***Psychological Research and the Research Methods Course***	*Chapter 1
Sep 10, 15	***Library Information Session***	
Sep 17	***Developing a Good Research Idea and Conducting an Ethical Project***	*Chapter 2
Sep 22	***Overview of Research Paper & Writing in APA Style*** ***APA Mastery Test #1*** ***RESEARCH PROPOSAL*** ***- DUE: Topic for Research Proposal***	APA Style Manual
Sep 24	NO EVENING CLASSES (Rosh Hashanah)	
Sep 29	***Qualitative Research Methods***	*Chapter 3
Oct 1, 6	***Nonexperimental Methods:*** ***Descriptive Methods, Correlational Studies,*** ***Ex Post Facto Studies, Surveys and Questionnaires, Sampling, and Basic Research Strategies***	*Chapter 4
Oct 8	***Using the Scientific Method in Psychology***	*Chapter 5
Oct 13	***Conducting a Good Experiment 1: Variables and Control***	*Chapter 6

** This syllabus may be accessed from the PSY380 Blackboard site at* http://blackboard.pace.edu/

Oct 15	***Conducting a Good Experiment 2: Final Considerations, Unanticipated Influences, and Cross-Cultural Issues*** ***RESEARCH PROPOSAL*** ***- DUE on 10/18: Literature Review Paper (optional)***	*Chapter 7
Oct 20	***MIDTERM EXAM*** ***(Chapters 1 - 7, Smith and Davis)*** ***(6:00pm – 8:00pm)***	
Oct 22	***Internal and External Validity***	*Chapter 8
Oct 27	***Using Statistics to Answer Questions (Part 1)***	*Chapter 9 (Part 1)
Oct 29	***Using Statistics to Answer Questions (Part 2)***	*Chapter 9 (Part 2)
Nov 3	***Designing, Conducting, Analyzing, and Interpreting Experiments with Two Groups***	*Chapter 10
Nov 5	***Designing, Conducting, Analyzing, and Interpreting Experiments with More than Two Groups***	*Chapter 11
Nov 10	***Designing, Conducting, Analyzing, and Interpreting Experiments with Multiple Independent Variables***	*Chapter 12
Nov 12	***Alternative Research Designs***	*Chapter 13
Nov 17	***Writing and Assembling an APA-Format Research Report*** ***APA Mastery Test #2***	*Chapter 14 APA Style Manual
Nov 19	***RESEARCH PROPOSAL*** ***- UPDATES AND CONSULTATIONS WITH GROUPS***	
Nov 24	***RESEARCH PROPOSAL*** ***- DUE: DRAFT of RESEACH PROPOSAL*** *(Title Page, Abstract, Introduction, Method, References, Appendices)* ***- DUE: Individual Member Evaluation Form (for Draft)*** ***Sample IRB (Research Review) Form***	

** This syllabus may be accessed from the PSY380 Blackboard site at* http://blackboard.pace.edu/

Nov 26	NO CLASSES (Thanksgiving Break)	
Dec 1	***RESEARCH PROPOSAL*** ***- FEEDBACK AND CONSULTATIONS WITH GROUPS***	
Dec 3, 8	***RESEARCH PROPOSAL*** ***- In-class Group Presentations*** ***- DUE: Individual Member Evaluation Form (for Presentation)***	
Dec 10	***RESEARCH PROPOSAL*** ***- DUE: Final Research Proposal*** NO PSY380 CLASS SESSION	
Dec 15 or Dec 17	***FINAL EXAM*** ***- Coverage: Chapters 8 - 14, Smith and Davis)*** ***(6:10pm – 8:10pm)*** ***RESEARCH PROPOSAL*** ***- DUE on 12/19: Individual Member Evaluation Form*** ***(for Final Research Proposal)*** ***- DUE on 12/19: Student Grade Form***	

* Smith, R. & Davis, S. (2013). *The Psychologist as Detective: An Introduction to Conducting Research in Psychology* (6th Edition). NJ: Pearson/Prentice-Hall. (ISBN: 978-0205859078)

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** This syllabus may be accessed from the PSY380 Blackboard site at* http://blackboard.pace.edu/

PSYCHOLOGY 381*

Experimental Psychology II

(CRN # 20290)

Spring 2015

Instructor:	Richard S. Velayo, Ph.D.
Meetings:	M, W - 6:10pm - 8:10pm, Birnbaum Electronic Classroom (E101)
Office Location:	41 Park Row, Rm. 1308 346-1506 (office phone)
Office Hours:	M, W - 3:00 p.m. - 5:30 p.m. (by appointment)
Prerequisite:	PSY380
URL:	http://blackboard.pace.edu
E-mail:	rvelayo@pace.edu (preferred mode of communication)

Course Description

This is an intensive six hours per week course that aims to develop critical thinking skills in psychological research and to carry out the research proposal you have developed in PSY380. In PSY381, there is greater focus on the use of the SPSS statistical software. The primary activity for this semester will be the completion of an original scientific research study and to present it at a formal undergraduate psychology conference. Blackboard will be utilized to help disseminate announcements, archive course materials, supplement instruction, and update grades.

Objectives of Experimental Psychology I and II

The primary goal of the Experimental Psychology sequence (PSY380 and PSY381) is to develop the critical thinking skills necessary for students to:

- Critically evaluate primary, empirical research in psychology,
- Translate theoretical ideas into testable research hypotheses, and
- Evaluate these hypotheses by means of a logically developed research plan.

To meet these goals, specific pedagogical material to be covered and activities to be carried out for this semester include:

- Taking SPSS exercises that help demonstrate knowledge of SPSS (statistical analyses and interpretation of findings)
- Collecting and organizing data followed by analyzing and reporting the results of class research project/s through statistical analyses and graphical representations.
- Completion of the written scientific research report
- Presentation of a completed scientific research project at the Pace Psychology Conference.
- Possibly the submission of the research project to a local, regional, or national conference, or for publication.

Texts (Required):

Smith, R. & Davis, S. (2013). *The Psychologist as Detective: An Introduction to Conducting Research in Psychology* (6th Edition). NJ: Pearson/Prentice-Hall. (ISBN: 978-020585907-8)

Cronk, B. C. (2014). *How to Use SPSS: A Step-by-Step Guide to Analysis and Interpretation (8th Edition).* CA: Pyrczak. (ISBN: 978-1-936523-26-9)

American Psychological Association (2009). *Publication Manual of the American Psychological Association* (6th ed.). Washington, DC: American Psychological Association. (ISBN: 978-1-4338-0561-5)

**This syllabus may also be accessed from the PSY381 at* http://blackboard.pace.edu

Statistical Package: SPSS statistical software (More details will be provided…)

Course Requirements:
This course is organized into three "modules" that consist of the following:

1. **EXAMS Module** (150 points) - There is a Midterm and a Final Exam, each of which will cover your knowledge of hypothesis testing, identification and operationalization of the independent and dependent variables, statistical analyses, and interpretation of statistical results. The exam format will be short-answer essay questions.

2. **PARTICIPATION Module** (150 points) - This module is composed of 3 parts namely:
   - *Attendance, Classroom Conduct and Demeanor* – Three (3) points are deducted for each meeting absent or late. Proof for excused absences is required. Conduct and demeanor in the classroom are also evaluated by the instructor.
   - *SPSS Chapter Presentation(s)* – You will each be assigned a chapter from our SPSS textbook (Cronk, 2014) to present in class using the SPSS for Windows software package. The assignment of chapters will be done early during the semester. There is no need to submit a written report for this requirement. The presentation is approximately 15 - 20 minutes and should conform to the following format:
     - **(i) Demonstrate the step-by-step procedure on the use of the SPSS statistical package as shown in the chapter.**
     - **(ii) Explain when and under what situations will the statistical test(s) and procedure(s) you demonstrated may be used. You may describe other examples in the use of these test(s) or procedure(s)**
     - **(iii) Extra time may be allotted to allow for questions from the class and the instructor.**
   - *SPSS in-class exercise(s)* – These exercises are meant to reinforce your understanding and skill in using SPSS.

3. **RESEARCH PAPER Module** (200 points) – Your team (up to 4 persons) will be required to collect and statistically analyze data, write up a complete research paper, and formally present your paper based on the research proposal you developed in PSY380. In the process of completing this requirement, you consult with the instructor regarding your project and how it is developing. Your conduct in carrying out your research and working with your group is very important and will contribute towards your final grade for this module. Your paper must be typed in APA-style format (See Publication Manual of the American Psychological Association).

   This is a group activity, which is composed of 3 phases, namely:
   - *In-class writing exercises* – These exercises are meant to help your group complete certain requirements/sections of your research paper.
   - *Draft of your Research Paper* – This written project represents your team's first attempt at writing your paper, which includes a title page, abstract, introduction (with literature review), methods, results, discussion, references, and accompanying appendices. Your paper should be written in APA style. This requirement will be discussed in greater detail during the course of the semester.
   - *Final Research Paper* – This written project represents the final revisions made of ALL section of your draft and must be written in APA style format.
   - *Presentation of Research Paper* – This involves presenting your Research Paper in class during the latter part of the semester. You will be given 20 minutes to present your work and additional time will be allotted for open discussion. You are advised to use useful

paraphernalia to supplement your presentation (e.g., audio-visual aids, demonstration activities, etc.) In addition, you are required to present your paper at a formal undergraduate psychology conference.

[Note: Students and the instructor are involved in the grading of the Research Paper module. This will be explained in greater detail during the semester.]

Grading System

EXAMS Module = 150 points (30%)	
Midterm Exam	75
Final Exam	75
PARTICIPATION Module = 150 points (30%)	
Attendance	50
SPSS Chapter Presentation(s) (Instructor Evaluation)	30
SPSS in-class exercises (7 exercises at 10 pts. each)	70
RESEARCH PAPER Module = 200 points (40%)	
In-class writing exercises (4 exercises at 5 pts. each)	20
Draft of Research Paper	
Individual Member Evaluation	10
Instructor Evaluation	40
Final Research Paper	
Individual Member Evaluation	10
Instructor Evaluation	40
Student Grade Form	20
Submission of Student Grade Form	10
Presentation of Research Paper	
Individual Member Evaluation	10
Instructor Evaluation (Pace Conference)	40
TOTAL POINTS	**500**

Letter-Grade Equivalent ("strictly" followed)			
A	475-500	C+	350-374
A-	450-474	C	325-349
B+	425-449	C-	300-324
B	400-424	D	275-299
B-	375-399	F	below 275

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Course Evaluation:
In order to improve our Dyson College courses we look to you, the students, for feedback. Near the end of the semester you will be asked to fill out an online evaluation form regarding your experience in this course.

Dyson College is "going green" so we have made this a paperless process, but we need your help to make this eco-friendly solution a success. You will receive an email directing you to the IOTA course evaluation site http://paceevals.com where you will find the Dyson courses that you are enrolled in for the current semester.

Your feedback is very important and your response will remain confidential. If you have any questions about the online evaluations, please contact Martina Blackwood at mblackwood@pace.edu.

Thank you for your participation in this important process.

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- Put a smile on your face . . . it cools the brain! (See research by Zajonc.)

PSY381 SCHEDULE

[Note: Read the assigned chapter(s), if any, before the scheduled class meetings.]
Each class meeting may include consultations and updates regarding your team's Research Projects.

DATE/s	TOPIC/s	SPSS Textbook Chapters*
Jan 26	***INTRODUCTION*** *- Experimental Psychology II* ***Sample Video of Pace Conference Presentation*** ***RESEARCH PROPOSAL*** *- Group Consultations: Do Revisions* *- IRB Application: UPDATES* ***- Qualtrics***	Course Syllabus IRB application packet
Jan 28	***RESEARCH PROPOSAL*** ***- Do Revisions*** (Continued) ***- Qualtrics***	
Feb 2	***RESEARCH PROPOSAL*** ***- In-class Pilot Testing*** (Continued) ***- Qualtrics***	

**This syllabus may also be accessed from the PSY381 at* http://blackboard.pace.edu

Feb 4	***RESEARCH PROJECT*** ***- In-class Pilot Testing*** (Continued) ***SPSS Chapter Presentation*** *1. Getting Started* *2. Entering and Modifying Data* ***SPSS In-class Exercise #1***	Chapter 1 Chapter 2
Feb 9	***SPSS Chapter Presentation*** *3. Descriptive Statistics* *PART 1 (Sections 3.1, 3.2, 3.3)* *PART 2 (Sections 3.4, 3.5)* ***SPSS In-class Exercise #2***	Chapter 3 (Part 1) Chapter 3 (Part 2)
Feb 11	***SPSS Chapter Presentation*** *4. Graphing Data* *PART 1 (Sections 4.1, 4.2, 4.3)* *PART 2 (Sections 4.4, 4.5, 4.6)* ***SPSS In-class Exercise #3***	Chapter 4 (Part 1) Chapter 4 (Part 2)
Feb 16	**NO CLASS (President's Day)**	
Feb 18	***SPSS Chapter Presentation*** *5. Prediction and Association* ***SPSS In-class Exercise #4***	Chapter 5
Feb 23	***SPSS Chapter Presentation*** *6. Parametric Inferential Statistics* *PART 1 (Sections 6.1, 6.2, 6.3, 6.4)* *PART 2 (Sections 6.5, 6.6)* ***SPSS In-class Exercise #5***	Chapter 6 (Part 1) Chapter 6 (Part 2)
Feb 25	***SPSS Chapter Presentation*** *6. Parametric Inferential Statistics* *PART 3 (Sections 6.7, 6.8)* *PART 4 (Sections 6.9, 6.10)* ***SPSS In-class Exercise #6***	Chapter 6 (Part 3) Chapter 6 (Part 4)

**This syllabus may also be accessed from the PSY381 at* http://blackboard.pace.edu

Mar 2	***SPSS Chapter Presentation*** *7. Nonparametric Inferential Statistics* *PART 1 (Sections 7.1, 7.2, 7.3)* *PART 2 (Sections 7.4, 7.5, 7.6)* ***SPSS In-class Exercise #7***	Chapter 7 (Part 1) Chapter 7 (Part 2)
Mar 4	***SPSS Chapter Presentation*** *8. Test Construction* ***RESEARCH PROJECT*** *- Each group provides summary updates to the entire class.)* *- Data collection must be completed.* *- Begin data entry and organization* ***MIDTERM EXAM REVIEW***	Chapter 8
Mar 9	***RESEARCH PROJECT*** *- Data entry and organization* *- Qualtrics*	
Mar 11	***MIDTERM EXAM (6:10pm – 8:10pm)***	
Mar 16, 18	**NO CLASS (Spring Break)**	
Mar 23	***RESEARCH PROJECT*** *- Data entry and organization* *- Qualtrics*	
Mar 25	***RESEARCH PROJECT*** *- Data analyses* *- SPSS*	
Mar 30	***RESEARCH PROJECT*** *- Data analyses* *- SPSS* ***APA Mastery Test #3*** *(non-graded)*	
Apr 1, 6	***RESEARCH PROJECT*** *- "Interpreting the Data": Writing RESULTS Section*	

**This syllabus may also be accessed from the PSY381 at* http://blackboard.pace.edu

Apr 8, 13	***RESEARCH PROJECT*** *- "Explaining the Results": Writing DISCUSSION Section*	
Apr 15	***RESEARCH PROJECT*** ***- DUE: DRAFT of Research Paper*** ***- DUE: Individual Member Evaluation Form*** ***APA Mastery Test #4*** *(non-graded)*	
Apr 20	***RESEARCH PROJECT*** ***- In-class Group Presentations***	
Apr 22	***RESEARCH PROJECT*** ***- DUE: FINAL VERSION of Research Paper*** ***- DUE: Individual Member Evaluation Form***	
Apr 27	***RESEARCH PROJECT*** ***- Preparing for the Pace Psychology Conference***	
Apr 29	***FINAL EXAM REVIEW*** ***End-of-semester Drawing***	
May 4	***CLASS (To be determined)*** ***RESEARCH PROJECT*** ***- DUE: Student Grade Form***	
May 6 or 13	***FINAL EXAM (6:00pm – 8:00pm)***	
May 9 (Saturday)	***PACE UNIVERSITY PSYCHOLOGY CONFERENCE*** ***Formal (oral or poster) presentations*** ***Attendance is required and graded.***	

* Cronk, B. C. (2014). *How to Use SPSS: A Step-by-Step Guide to Analysis and Interpretation (8th Edition).* CA: Pyrczak. (ISBN: 978-1-936523-26-9)

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**This syllabus may also be accessed from the PSY381 at* http://blackboard.pace.edu

UNIVERSITY 101

UNV 101
(CRN# 46326)
Fall 2000

Instructor:	Richard S. Velayo, Ph.D.
Meetings:	Mondays, 5:30pm – 7:30pm
Instructor's Office:	41 Park Row, Rm. 1324 346-1506 (office phone)
Instructor's Office Hours:	T, R 3:00pm - 5:30pm (or by appointment)
Instructor's E-mail:	rvelayo@pace.edu
Peer Leader:	Omar Kennedy
Peer Leader's E-mail:	bajan_roman@yahoo.com
Peer Leader's Office Hours:	T, R 10:00am – 11:30am
CourseInfo Website:	http://courseinfo.pace.edu/courses/UNV-101-46326/

Course Objectives

- To help you make the transition into college life easier;
- To help you pick a major course of study and/or affirm the major that you have chosen;
- To develop/improve academic skills to assist with the college workload;
- To develop time management, decision making and critical thinking skills;
- To help you mature and be more responsible;
- To bond you to Pace through closer advisement and interaction with your peers and peer leaders.

Texts (Required):

Crawford, S. & Zeigler, M. (2000). Connections: A text compiled for Pace University's Freshman Seminar (2nd Edition). Boston, MA: Pearson Custom Publishing.

Reminders

This is a 13-week "Pass/Fail" course, 1-credit
You CANNOT DROP Unv101
Mandatory attendance (3 absences = Fail)
Attendance of three Pace events (To be announced)
Mandatory 5-minute oral presentation project
Weekly readings of the New York Times + written critique
Weekly readings of the "Connections" textbook

Weekly Readings of the New York Times

Before each class meeting, you are required to write a 1-page critique opinion paper of an article published in any of the past week's issue of the NY Times. Your written work should be posted in the UNV101 Discussion Board via CourseInfo (http://courseinfo.pace.edu/courses/UNV-101-46326/). The purpose of this activity is to provide you with awareness and experience on current events that are happening around you and to develop an appreciation for reading and writing. Your peer leader will provide you with feedback on your work.

Fall 2000 Schedule

Note: *You are required to do the assigned readings before the scheduled class meeting.*

Date	Topic	Readings*
Sept 11	Peer Introductions Course Expectations	pp. 6-11 ("Pace Univ. is…")
Sept 18	High School and College – What's the difference? The Core Curriculum: Why is "liberal arts" important for everyone? Preparing your Oral Presentation	pp. 20-26 pp. 48-53 pp. 69-72
Sept 25	Technology at Pace Discussion: Undergraduate Catalogue	pp. 168-180
Oct 2	Library Orientation (5:30pm-6:30pm)	pp. 159-167
Oct 9	No classes	
Oct 23	Academic Integrity Time Management	pp. 54-58 pp. 64-68
Oct 30	Diversity	pp. 80-92, 93-106
Nov 6	Wellness and Academic Success	pp. 108-117
Nov 13, 20	Career Planning Registration Information Oral Presentations	pp. 124-129, 139-152
Nov 27	Career Services and Cooperative Education Oral Presentations	pp. 130-138
Dec 4	Oral Presentations	
Dec 11	Oral Presentations (continued…) Wrap-up and Evaluations	

**Crawford, S. & Zeigler, M. (2000). Connections: A text compiled for Pace University's Freshman Seminar (2nd Edition). Boston, MA: Pearson Custom Publishing.*

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PSY 323y– Psychology of Learning

PACE UNIVERSITY	NACTEL PROGRAM
BS in Professional Technology Studies: *Telecommunications Concentration*	Semester: Fall 2005

Credits: 4

Description

This course addresses traditional and contemporary theories of learning, conditioning. and memory processes. It surveys some of the important theories and findings in the psychology of learning. A historical look at the development of behavioral and cognitive theories, including current-based research as well as connectionism and models of memory, motivation, and social learning are presented. In addition, this course aims to enable students and professionals to apply the concepts learned more effectively in their work setting or in their personal lives. Students are expected to write a thorough review/critique of a journal article on a topic (or topics) covered.

Goals and Objectives

- To demonstrate understanding of the basic learning, conditioning, and memory concepts and principles of both by answering questions on exams and by appropriate application of these principles and concepts to a variety of contexts.
- To understand the theoretical and empirical studies that support the principles and concepts associated with each chapter.
- Be aware of the ethical considerations regarding the applications and techniques discussed in the course, given a specified context.
- Write a write a thorough review/critique of a journal article on a topic (or topics) covered. Both the topic and the journal require the instructor's approval.

Prerequisites

- There are no prerequisites.

Course Materials

All Books and Materials are available via the Pace University/ NACTEL Program online bookstore at: http://support.csis.pace.edu/nactel/program/bookstore.cfm

Required Books and Materials

Textbooks:

Lefrancois, G. R. (2006). *Theories of Human Learning: What the Old Woman Said* (5th Ed.). CA: Wadsworth [ISBN #0-534-64152-8]

Course Topics

WEEK	TOPIC	ASSESSMENTS
1	CHAPTER 1: Human Learning: Science and Theory	
2	CHAPTER 2: Early Behaviorism: Pavlov, Watson, and Guthrie	
3	CHAPTER 3: The Effects of Behavior: Thorndike and Hull	
4	CHAPTER 4: Operant Conditioning: Skinner's Radical Behaviorism	Topic for Journal Article Critique
5	CHAPTER 5: Evolutionary Psychology: Learning, Biology, and the Brain	
6	CHAPTER 6: A Transition to Modern Cognitivism: Hebb, Tolman, and the Gestaltists	
7	CHAPTER 7: Three Cognitive Theories: Bruner, Piaget, and Vygotsky	
8	CHAPTER 8: Neural Networks: The New Connectionism Chapter 9: Learning and Remembering	Approval of Journal Article (A copy of the article must be sent to the instructor.)
9	CHAPTER 10: Motivation	
10	CHAPTER 11: Social Learning: Bandura's Social Cognitive Theory	
11	CHAPTER 12: Analysis, Synthesis, and Integration	DUE: Journal Article Critique
12	Evaluation of PSY 323y	Proctored Final Exam; Student Grade Form for Journal Article Critique; Individual Member Evaluation Form Due

Course Documents

Course material is organized into weekly folders located within the **COURSE DOCUMENTS** button of **Blackboard**. Each Thursday, by midday, a new folder will be made available for you to actively read through and comprehend the material. You have an entire week (Thursday through the following Wednesday) to go through the information. Once available, folders will remain active throughout the duration of the course for you to review material on your own.

Assignments

Discussion Board

Participation

As a student in the course, you are expected to regularly and to actively participate in all the weekly discussions by responding to each of the questions posted. The quality and frequency of your responses will be taken into account towards your grade. You are also encouraged to

provide feedback to other students' responses. Discussions are expected to be *insightful, reflective, lively, and thought provoking.*

These online discussions will focus not only on enhancing your learning of the concepts and applications presented in this course, but also to further your thinking and writing skills.

Facilitation of Discussion Forum
Each week, there will be assigned student facilitator(s) or your instructor will post a few questions to motivate your learning of the course content.

You will be required to facilitate a discussion forum on a topic in one of the chapters from the textbook. This will involve posting questions and/or an interesting activity on or before the first day (Thursday) that your assigned topic is covered. For example, if you were assigned to facilitate Chapter 3 (The Effects of Behavior: Thorndike and Hull), your set of questions should be posted by Thursday morning. Your goal is to generate a lively online discussion on the chapter topic. Examples of discussion questions that may be posted are:

"What do you think are the implications of the concepts learned in the chapter with regards to the "No Child Left Behind Act" requirements."

"In an aside, the Old Woman stands and swats a spider from her arm. How would learning theories discussed thus far best explain her reaction to the arachnid? The author watches the spider and is curious about the spider's reaction to its altered external environment. Do you think behavioristic learning theories address external environmental influences? Explain your answer.

The chapter(s) that you will facilitate is assigned to you early during the semester. Procedurally, you will be asked to send your instructor your questions(s) first via e-mail so that these may be looked over prior to posting. Your instructor may need to modify or make changes so that about 2-4 discussion questions are posted. Your instructor will post these questions for you. As a discussion board facilitator, you are expected to actively respond and provide feedback to your classmates' responses. [**Note:** You are also expected to respond to the questions posted for the week you facilitate.]

There is no need to submit a written report for this requirement.

Projects

Journal Article Critique (Individual project)
You will be required to write an in-depth critique (no longer than 4 pages, single-spaced) of a journal article (theoretical and/or empirical studies) in which the topic is covered in the course and is of interest to you. Your choice of a journal article requires your instructor's approval. You can find many article by searching the PsychINFO and/or PsycArticles database . These contain psychology journals and full-text versions of these articles. [For questions or assistance on accessing the Pace University Library Resources, go to http://support.csis.pace.edu/nactel/gotoclass/library.cfm]

The paper should be a review or critique of an academic or professional journal article in psychology published within the last 5 years. The structure of the paper should be as follows:

I. Cite the Journal Article

Example:

Gershoff. E. T. (2002). Corporal Punishment by parents and associated child behaviors and experiences: A meta-analysis and theoretical review. *Psychological Bulletin*, 128, 539-579.

II. **Summary of the Journal Article** (no longer than half a page, single-spaced)

III. **Critique/Review** [This is primarily opinion-based, but you are also expected to demonstrate your knowledge of this course by using the concepts and terms covered.]

This course requirement is intended to supplement your learning of the course content and to enhance your ability to apply the concepts learned.

You will be given the opportunity to have your written critique read by other members of the class sometime during the latter part of the semester. Thus, your paper will be accessible online for other students to evaluate using the Student Grade Form. Other students in the course, including your instructor, will then provide feedback/comments to your paper. Details on the technical aspects of this requirement will be discussed in the course of the semester.

An Individual Member Evaluation form must also be submitted. (This form will be made available online). This will allow you to evaluate yourself given your perceived quality and/or effort you placed on doing the paper.

Exams

Final Exam

There is a **proctored Final Exam**, which will cover all the chapters of your textbook. This is designed to test your knowledge of the material covered in the assigned readings and to apply what you have learned from the course. The format may include multiple-choice, true-false, and short answer questions. A review sheet will be posted about a week prior to the scheduled exam.

Communication

Discussion

The **Discussion Board** area has been set up to operate like a live classroom; answer questions, ask questions, comment on the responses of your fellow classmates and instructors. This area can be very valuable to you if you encounter difficulty during the course. Check the Discussion area frequently. Your participation is part of your grade.

If you have personal and on-the-job experience relevant to a discussion topic or to a question from one of your fellow students, please share your knowledge. Active participation by everyone makes the class better for everyone.

Email

Please feel free to contact your instructors or your classmates via **email** at any time.

Grading

Each of the activities below constitutes part of your grade. Failure to participate in one or more activities may result in a significant reduction in your grade.

Final grades are calculated as follows:

Participation *(10 points for each of the 15 weekly discussion boards)*	30%	150 Points

Facilitation of Discussion Forum	20%	100
Journal Article Critique:		
Feedback from Class	6%	30
Feedback from Instructor	8%	40
Individual Member Evaluation	4%	20
Student Grade Form	2%	10
Final Exam (proctored)	30%	150
Total	**100%**	**500 Points**

Grading Scale
[Note: This will be strictly enforced.]

LETTER	POINTS	QUALITY POINTS
A	465 - 500	4.0
A-	450 - 464	3.7
B+	435 - 449	3.3
B	415 - 434	3.0
B-	400 - 414	2.7
C+	380 - 399	2.3
C	350 - 379	2.0
C-	335 - 349	1.7
D+	315 - 334	1.3
D	300 - 314	1.0
F	0 - 300	0.0

Proctoring

Please note that this course **requires a proctor**. You can read more about the proctoring program and steps needed to obtain an approved proctor by clicking on this link: Proctoring Program.

There will be a one proctored examination (Final Exam) for this course. Specific details will be provided once classes begin.

Attendance

Successful online learning requires that a student actively participate in each week's learning materials which may include:

- **Reading** course documents, textbooks, articles and web materials
- **Submission** of homework assignments, projects and papers
- **Completion** of any available quizzes, exams and laboratories
- **Participation** in the weekly discussion board forums, team activities and email.

Excessive absences and failure to keep up with the course pace may result in a decreased or failing course grade. Recall that this is **not a self-paced course**. Within each week,

assignments may be worked on during times convenient to the student. However, the assignments are to be completed by the end of that academic week (Wednesday at midnight). If you are unable to participate during a particular week, please contact the instructor beforehand.

Disabilities

If a student believes that he/she has a disability that may affect academic performance, that student should notify Pace University's Counseling Center for assessment and advisement. If a student tells the instructor that he/she has a disability, the instructor is bound by University policy to notify the appropriate University representative of such disability.

Academic Integrity Policy

Students must accept the responsibility to be honest and to respect ethical standards in meeting their academic assignments and requirements. Integrity in the academic life requires that students demonstrate intellectual and academic achievement independent of all assistance except that authorized by the instructor. The use of an outside source, including electronic sources, in any paper, report or submission for academic credit without the appropriate acknowledgment is **plagiarism**. It is unethical to present as one's own work, the ideas, words or representations of another without the proper indication of the source. Therefore, it is the student's responsibility to give credit for any quotation, idea or data borrowed from an outside source.

As a student, you cannot copy work from someone else's disk to your own or print two copies of the same assignment to be handed in by two individuals. Each student must do his/her own work. It is easy for instructors to tell when data has been duplicated between students. All instructors reserve the right to challenge work they feel has not been completed independently.

Students who fail to meet the responsibility for academic integrity subject themselves to sanctions ranging from a reduction in grade or failure in the assignment or course in which the offense occurred to suspension or dismissal from the University.

The **first time** that a student submits an assignment or an assessment that is not completely his or her own at Pace University, the student will receive a **0 grade** for that individual assignment/assessment.

The **second time** that a student submits an assignment or an assessment that is not completely his or her own at Pace University, the student will receive an **F for that course**.

The **third time** that a student submits an assignment or an assessment that is not completely his or her own at Pace University, the student will be **dismissed from the University**.

The process will be monitored by the NACTEL Academic Review Committee. Students penalized for failing to maintain academic integrity who wish to appeal such action may petition the Department Chair to request a hearing on the matter.

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Internationalizing Undergraduate Psychology Education: Trends, Techniques, and Technologies

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How can we best internationalize undergraduate psychology education in the United States and elsewhere? This question is more timely than ever, for at least 2 reasons: Within the United States, educators and students seek greater contact with psychology programs abroad, and outside the United States, psychology is growing apace, with educators and students in other nations often looking to U.S. curricula and practices as models. In this article, we outline international developments in undergraduate psychology education both in the United States and abroad, and analyze the dramatic rise of online courses and Internet-based technologies from an instructional and international point of view. Building on the recommendations of the 2005 APA Working Group on Internationalizing the Undergraduate Psychology Curriculum, we then advance 14 recommendations on internationalizing undergraduate psychology education—for students, faculty, and institutions.

Keywords: undergraduate education, international psychology, teaching psychology, diversity, MOOC

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> On U.S. college campuses, we psychologists should be teaching our undergraduates about human behavior, not just behavior in North America.
>
> —David G. Myers

Psychology is a highly popular subject of study for American undergraduates. Between 1.2 and 1.8 million U.S. students enroll in the introductory course each year (Gurung et al., 2016). More than 100,000 U.S. students earn their bachelor's degrees in psychology annually (Norcross et al., 2016)—114,450 degrees in 2013 (National Center for Education Statistics, 2015).

It is, however, less well known that in recent decades, psychology has been expanding apace in many corners of the world, making undergraduate education in psychology hugely popular around the globe (McCarthy, Dickson, Cranney, Trapp, & Karandashev, 2012). American psychologists now account for only an estimated 21% to 24% of the world's psychologists (Bullock, 2012a; Zoma & Gielen, 2015), down sharply from an estimated 80% in the 1980s (Rosenzweig, 1984). Increasingly, the educational practices and knowledge base of psychology are constructed on a worldwide basis, yet current American psychology curricula insufficiently reflect this trend.

This article describes how international and cross-cultural contributions can be purposefully integrated into undergraduate psychology education so that undergraduates both in the United States and elsewhere are better prepared for an

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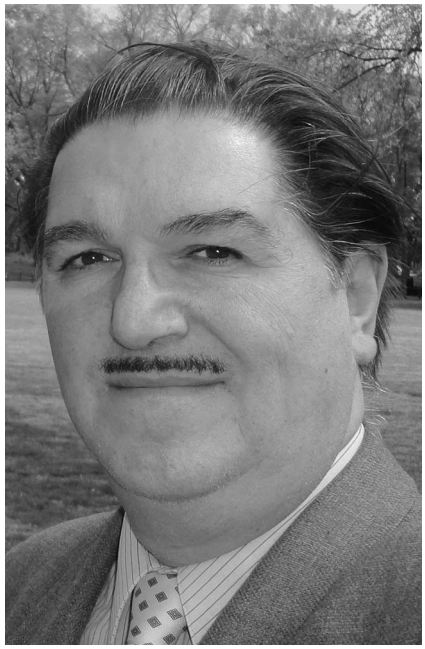

Harold Takooshian

increasingly interdependent world. In addition, this article describes how a modern psychology curriculum can enable students to gain international experience by facilitating their interactions with overseas students and faculty either in person or via electronic means, such as online courses and Internet-based technologies. The Internationalization of Curricula (IoC) is a movement affecting many fields (Leask, 2015), and is especially valuable for undergraduate psychology in more than one way, to increase (a) our understanding of human behavior in general, across diverse nations and cultures; and, (b) the "world-consciousness" of all psychology students in the United States and elsewhere—to nurture what has been termed "global psychological literacy" (Cranney & Dunn, 2011; Dunn, 2015).

In the following, we provide a brief history of the international growth of psychology, followed by how these international developments and new forms of diversity relate to undergraduate psychology education. Because the recent dramatic growth of international education is driven to a significant degree by technological changes, we address massive open online courses (MOOCs) and the pervasive influence of Internet-based technologies on students and faculty. These sections are followed by a set of 14 recommendations outlining how undergraduate psychology education might best be internationalized on three levels—by undergraduate students, their faculty, and institutions.

The Growth of Psychology as an International Discipline

Psychology as a discipline with a firm, institutional identity was born in the 1870s in Germany, spread to other European countries and the United States within the next few years, and soon thereafter also became known in some Asian and Latin American countries, such as Japan, China, Mexico, and India (Stevens & Wedding, 2004). Thus, Western-style psychology had an international dimension from its beginnings, but it would grow into a full-blown global discipline in the late 20th and early 21st centuries (Rich & Gielen, 2015).

After Wilhelm Wundt established the first psychological institute in Leipzig in 1879, his highly popular lectures and his laboratory soon attracted students from numerous Western as well as several non-Western countries. Many of these international students accepted his vision of a new, scientific discipline and returned home to establish laboratories and institutes in their own countries. By 1897, Wundt's laboratory expanded to 14 rooms, filled with students from 20 nations—from Japan to Chile (Misiak & Sexton, 1966).

Wundt had many American students and assistants, such as James McKeen Cattell. Although most of them rejected or ignored Wundt's theoretical outlook, they nevertheless formed an important part of the founding generation that would soon, together with William James and others, help American psychology assume worldwide leadership. By 1900, there were 40 doctoral programs and 41 laboratories at American universities, whereas only 10 laboratories could be found in Europe (Benjamin, 2000). Moreover, psychology was rapidly becoming one of the most popular subjects at the undergraduate level, while intriguing the general public (Schultz & Schultz, 2012).

In addition, during the 1930s and 1940s, many elite Austrian and German psychologists migrated to the United States. After 1945, American psychology began to dominate the worldwide scene not only based on its sheer number of psychologists but also through its journals, scientific research, textbooks, the growing dominance of English in scientific publications, and the country's economic and political power. There were now more psychological scientists, practitioners, and educators in the United States than in all other nations combined—to the point where some began to fault American psychology as being "self-absorbed" (Rosenzweig, 1984) or even "xenophobic" (Sexton & Misiak, 1984). These American critics argued that American psychology was assuming a monocultural and monolingual character while ignoring many new developments, especially in the non-English-speaking countries.

But this trend has changed dramatically since the 1990s, as psychology now grows faster outside than inside North America (Bullock, 2012a, 2012b), and colleagues inside and outside the United States seek greater communication. By integrating data from diverse sources (e.g., Bullock, 2013; Cooper, 2014; Lunt, Peiró, Poortinga, & Roe, 2015; Stevens & Gielen, 2007; Stevens & Wedding, 2004), one may estimate conservatively that there are 1 million psychologists worldwide: roughly 230,000 in the United States,

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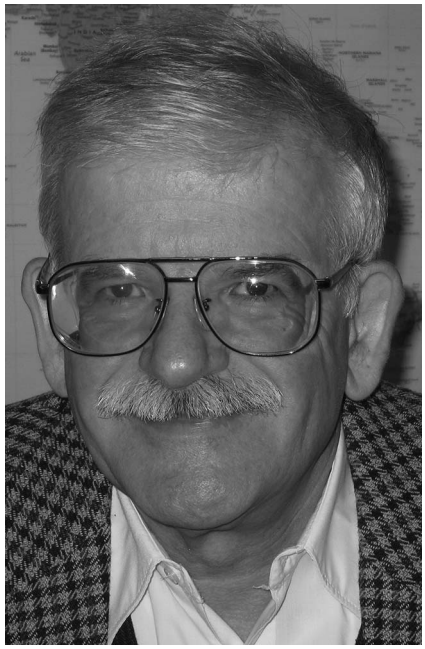

Uwe P. Gielen

330,000 in Latin America, 330,000 in Europe, and 100,000 in the rest of the world (Zoma & Gielen, 2015).

International Diversity in U.S. Psychology Education

Although discussions about *diversity* are now frequently included in U.S. psychology courses, this was not always the case. Through most of the 20th century, the classic psychology experiments that American instructors present to their undergraduates—such as Solomon Asch's (1955) study on conformity and Philip Zimbardo's (1972) study of prisoners—were based on small samples that were intentionally homogeneous: White male U.S. college students. This control for gender, age, and race was an easy way to reduce confounding variables, tacitly leaving it to other researchers to cross-validate how much these findings on White male students might generalize to the other 99.9% of humanity—women, nonstudents, other ages, ethnicities, or nations. As late as 1986, an analysis of U.S. social psychology journals found that 72% of articles used North American undergraduates as subjects (Sears, 1986), and it concluded that this narrow database was giving our undergraduates a distorted picture of human nature. One psychologist wryly noted that in psychology experiments, "Even the rat was white" (Guthrie, 1998).

The 1991 Saint Mary's conference on the undergraduate curriculum noted the importance of diversity to "ensure that psychology courses more accurately reflect the diversity of humankind, including ethnic, social, cultural, and gender diversity" (McGovern, 1993, p. 179), as well as greater inclusion of underrepresented minority students and faculty in the psychology pipeline. Then in 2008, the inclusion of "sociocultural diversity" in the undergraduate curriculum became a major emphasis through the Puget Sound conference (Landrum et al., 2010), including the promotion of "psychological literacy" among citizens worldwide (Halpern, 2010). In fact, the American Psychological Association's (APA's) Board of Educational Affairs "noted that diversity is a particularly important aspect of the *Guidelines*" (Hailstorks & Boenau, 2013), and the revised *APA Guidelines for the Undergraduate Psychology Major 2.0* (APA, 2016) feature "Ethical and Social Responsibility in a Diverse World" as the third of its five broad learning goals. The "sociocultural diversity" in these *Guidelines 2.0* includes both multicultural diversity within the United States as well as international diversity across nations—which is the central focus of this article.

APA has a long history of promoting international psychology education, even before the formation of its Committee on International Relations in Psychology in 1944 (Fowler, 2000). The APA Office of International Affairs, formed in 1971, offers a website rich with global resources, travel funding, and a bimonthly bulletin (*Psychology International*). In 2008, the APA Education Leadership Conference focused its annual meeting on this theme of internationalizing psychology education (Torney-Purta, 2008), on the heels of an APA Working Group on Internationalizing the Undergraduate Psychology Curriculum (2005).

Because the question of educational "outcomes" is important, the 2005 APA Working Group identified five valuable goals of IoC in psychology, each with five measurable outcomes. Examples of these 25 outcomes include an increase in students' sociocultural awareness (Outcome 1.1); understanding of research methods applied across cultures (Outcome 2.3); knowledge of the field of psychology in other nations (Outcome 3.2); cross-cultural competence of students on a personal level (Outcome 4.4); and appreciation of global issues of human rights and social justice (Outcome 5.4). These 25 outcomes are not yet documented, but are best seen as an agenda for future researchers, to assess the actual impact of IoC on students' knowledge, attitudes, and actions.

Of course, U.S. undergraduate psychology courses should be relevant to the 95% of the human population living outside the United States, but creating such a cross-national science of behavior has been a challenge (Rosenzweig, 1984). Unlike physical sciences such as chemistry, which share a "periodic table" across nations, psychology lacks a solid core that is recognized cross-nationally (Howell, Collisson, & King, 2014).

To borrow from the concepts of Newtonian physics, we can see the challenge of a transnational psychology as a tension between two opposing forces. These are (a) the strong "centrifugal" (outward) forces that divide cross-national psychology and include the familiar obstacles of language, distance, cost, sociocultural variations, and ide-

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Scott Plous

ology (Draguns, 2001); and (b) the strong "centripetal" (inward) forces that increasingly bind cross-national psychology: quadrennial and other world congresses, journals, cross-national educational and research efforts (such as Fulbright scholarships and study abroad), and now the Internet.

The Growth of Psychology Education Outside the United States

Since the 1990s, the numbers of psychologists, psychology programs, and course enrollments have increased rapidly around the globe. In 2012, over 4 million tertiary-level students were studying psychology and other subjects outside their own nation, up from 2 million in 2000 (UNESCO Institute for Statistics, 2014). And in the academic year 2013–2014, 886,052 international students were enrolled in U.S. institutions of higher education (4.2% of all students)—up 72% from 1999–2000 (Institute of International Education, 2014). Moreover, 289,408 U.S. students were studying overseas in the 2012–2013 academic year.

A growing number of international conferences, publications, and other resources support instructors who seek to internationalize their undergraduate courses. For instance, *Psychology Resources Around the World*, a web-based compendium of psychology in nearly every nation in the world, has been developed by the International Union of Psychology Science (IUPsyS: Bullock, 2012b). McCarthy and colleagues have produced three volumes of an edited series, *Teaching Psychology Around the World* (McCarthy et al. 2007, 2009, 2012), describing both education requirements and best practices in many nations. Six International Conferences on Psychology Education have been held since the first one in Russia in 2002. Psi Chi, the once-U.S. Honor Society for Psychology, voted in 2009 to expand into the International Honor Society for Psychology, and formed chapters in 10 nations within 5 years (McCormick et al., 2014).

Psychology education is flourishing in Western and non-Western countries alike. One clear example is Indonesia—the world's fourth most populous nation, with 252 million inhabitants. For decades, psychology was largely unknown among Indonesia's general public, until its first psychology department was founded in 1960 at the University of Indonesia. Yet by 2011, Indonesian students could study psychology in 95 departments across the country, and Indonesian psychologists appear so often on national TV and radio, and in newspapers and popular magazines, that the "psychological literacy" of the Indonesian public may now surpass that of the American public (Sarwono, 2011).

In some nations (such as Argentina, Brazil, Indonesia, Israel, and the Netherlands), psychology is taught to large numbers of psychology "undergraduates," and it has also entered the popular culture. In other countries (such as Cameroon, Mexico, Philippines, South Korea, and Taiwan), efforts are underway to "indigenize" psychology theories and research to reflect a region's unique cultural, social, and linguistic traditions. Many scholars in these non-Western countries believe that psychology education must be indigenized so that undergraduates can better understand psychology's relevance to their own lives. Some members of this movement aim to create a unified global psychology that can integrate diverse cultures and contributions from psychologists across many nations, whereas others emphasize the cultural embeddedness of almost all psychological processes (Kim, Yang, & Hwang, 2006).

It is valuable for U.S. and other psychology students to learn about these struggles to create both locally meaningful and globally unifying forms of psychological science. After all, many of these struggles revolve around the central psychological question of whether there is a universal human nature—and whether Western psychology has been successful in identifying most of its essential aspects, or whether it has been (partially) led astray by implicit but powerful cultural perceptions and norms (as described in www.indigenouspsych.org/). In international circles, some scholars have described North Americans as demographically "WEIRD"—White, Educated, Industrious, Rich, Democratic (Henrich, Heine, & Norenzayan, 2010), and thus not representative of populations in "ROW" (the Rest of World).

Although psychology has been growing rapidly outside the United States, the definitions and credentialing practices associated with the term "psychologist" vary considerably between nations. As a consequence, we lack sound global data comparable with the United States. The American system draws a clear distinction between undergraduate and

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graduate education based on the structure of the American university and college system. Most American 4-year college students pursue a liberal arts education in which required courses for their major occupy no more than 20% to 30% of coursework. The baccalaureate degree is prerequisite for future graduate education. In contrast, most psychology students in South America do (or did) not "major" in psychology. Instead, upon graduation from a selective high school, they enter a university to pursue a professional degree for about five years, and graduate with a professional bachelor's degree in psychology that, together with a period of supervised practice, allows them to practice psychology. (This degree is more comparable with a U.S. master's degree.) However, only a small fraction of these licensed psychologists will later pursue a master's or doctoral degree (Klappenbach, 2004).

In Europe, undergraduate education has been changing dramatically since the 1990s under the so-called Bologna process. Now, the 36 countries in the European Federation of Psychologists' Associations (EFPA) have been developing unified systems and standards for education and credentialing that are transforming psychology in Europe. In 2000, EFPA launched its "tuning" process to address the needs of students and employers for "transparent and reliable information as to what a degree qualification stands for in practice" (Lunt et al., 2015, p. 70). This process covers all education levels in Europe, including Levels 6 (baccalaureate), 7 (master's), and 8 (doctorate).

The EuroPsy Basic Certificate specifies outcomes for a 3-year program leading to a bachelor's degree, followed by a 2-year master's degree, and a 1-year period of supervised practice (Lunt, 2014; Lunt et al., 2015). At the same time, the EuroPsy initiative endeavors to protect "the rich diversity of European education . . . and in no way seeks to restrict the independence of academic and subject specialists or undermine local and national academic authority" (EuroPsy, 2011, p. 6). This effort is supported by 36 national psychology associations representing more than 300,000 psychologists who, in turn, serve more than 740 million people. Over time, this EuroPsy initiative may well shape undergraduate and graduate education in psychology outside Europe as well. This EuroPsy initiative moves European psychology education one step closer to the American educational model with its clear separation between undergraduate and graduate education. However, this movement has not been welcomed by everybody.

In addition to the EuroPsy efforts in Europe and the *APA Guidelines 2.0* (APA, 2016) in the United States, a third effort to enunciate a set of the goals for a diverse psychology education has been pursued by the International Baccalaureate Organization (IBO). Since 1960, the IBO is an independent multinational association that has developed international curricula and exams for 26 fields, including psychology. Like the U.S. Advanced Placement (AP) program, the IB Diploma gives motivated secondary school students, Ages 16 to 19, a chance to earn college-level credits. As of 2014, 1.1 million students at 3,789 schools in over 40 nations have studied for IB exams, including 17,200 IB exams in psychology (11,300 of these in the United States; IBO, 2009). So far, there appears to be little direct contact between leaders of these three independent efforts, though this may change with time, given their common goals to develop a solid undergraduate curriculum that also incorporates global diversity.

The role of new instructional technologies is especially relevant in supporting the goal of internationalizing psychology and other curricula. Just as new technologies in the 21st century are transforming higher education, one impact is to reduce these centrifugal barriers to internationalization—travel, cost, and language. By all accounts, technologies such as open online courses and Internet-based technologies will play a major role in the future of undergraduate education worldwide, including psychology.

MOOCs

One of the most notable developments in global education has been the rise of MOOCs, with important implications for undergraduate education and global psychological literacy. Although definitions vary, MOOC generally refers to a free or low-cost Internet-based course taken by a large number of people. These courses first garnered widespread media attention in the fall of 2011, when a Stanford University computer science professor enrolled more than 160,000 students in a MOOC on artificial intelligence, and 23,000 completed the course. A year later, an article in the

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New York Times dubbed 2012 "the year of the MOOC," with good reason. By then, newly formed MOOC providers such as Udacity, edX, and Coursera had already enrolled millions of students, and the largest of these organizations, Coursera, reported growing at a rate faster than Facebook (Pappano, 2012).

The first MOOCs offered by Udacity, edX, and Coursera were in computer science, but today psychology-related MOOCs are among the most popular online courses, just as psychology courses have long been popular on college campuses. In fact, based on student registration figures that combine the first and second run of each course, four of Coursera's six most heavily enrolled MOOCs have focused on psychology, thinking, or behavior. These four Coursera courses include Social Psychology, with an initial enrollment of 633,131 students; Think Again: How to Reason and Argue (376,629 students); A Beginners Guide to Irrational Behavior (357, 511 students); and Learning How to Learn: Powerful Mental Tools to Help You Master Tough Subjects (321,617 students). Since 2012, MOOCs have also grown more international. For example, Coursera began exclusively with U.S. partner schools and instructors, yet nearly 40% of its 900 courses are now from partners outside the United States, and only 29% of its students are American.

Of course, distance learning—whether domestic or international—is not a new phenomenon. For most of the 20th century, correspondence courses taken through the mail were quite popular (Kett, 1996), and since 1990, The Teaching Company has offered more than 500 college-level Great Courses in a variety of audio and video formats. The video series *Discovering Psychology* has reached millions of PBS viewers since 1990, and has been taken as a tele-course for college credit by more than 500,000 students worldwide (Philip Zimbardo, personal communication, October 29, 2014). With the Internet, millions of online learners began watching educational videos and taking self-paced courses through KhanAcademy.com, lynda.com, and hundreds of other distance learning websites. It remains unclear what long-term impact this online explosion will have on traditional undergraduate psychology courses, but at the very least, MOOCs appear to be increasing psychological literacy worldwide.

What distinguishes MOOCs from other forms of online learning is that MOOCs usually take place with a large cohort of online learners from around the world. Typically, MOOCs include a combination of "courseware" (online course content) and elements of real-time traditional college courses, such as peer interaction, teaching assistants, and homework deadlines. Most often, MOOCs release course materials one week at a time, thereby allowing students in different time zones to learn about topics together as the course unfolds, help each other in online forums, and in some classes, assess one another's work.

Why this meteoric rise of MOOCs since 2012? The most obvious answer is that the technology has only recently become available—including global high-speed Internet access, bandwidth to stream videos, cloud storage of data, and the ability to create interactive online lectures that require students to answer questions before the video will advance. Yet technology is only part of the answer; MOOCs also provide a variety of economic and pedagogical benefits over traditional forms of education, particularly when it comes to internationalization.

The Benefits of MOOCs

On a per student basis and compared with traditional undergraduate courses, MOOC technology "can be used to enhance productivity in higher education by reducing costs without compromising student outcomes" (Griffiths, Chingos, Mulhern, & Spies, 2014, p. 4). Given the soaring costs of higher education in many countries, including the United States, it will become increasingly difficult for universities to ignore the economy of scale of these MOOCs.

MOOCs also offer benefits from the perspective of students. Not only are the courses less expensive and more accessible than most traditional classes, but for low-income students or people who live in a low-income nation, MOOCs may represent the only affordable opportunity for higher education. (In 2014, nearly half of all students in Coursera's Social Psychology MOOC were in countries with an emerging economy.) Since MOOCs are accessible around the clock, students can watch the lectures and receive online help from fellow classmates at any hour—a key advantage for students who are single parents, full-time workers, or homebound because of disability or illness.

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For international students not fluent in the instructor's language, MOOCs offer several other advantages over traditional instruction. First, videotaped lectures can be watched with subtitles, often in the student's native language. Second, students taking a MOOC can replay the lectures as many times as they like. Third, MOOC lectures usually have an option that allows students to slow down the video when needed. And fourth, students can use the class forums to study and help one another in their native language.

Indeed, because the students who enroll in MOOCs come from so many countries, the need for language support is even greater than in traditional classroom settings. In the Coursera Social Psychology MOOC, students came from more than 200 countries, spoke more than 40 different primary languages, and listed a primary language other than English nearly half of the time. To meet the needs of these students, lecture subtitles were available in 27 languages, thanks to volunteer translators who donated their services. On average, according to Coursera, the enrollment of students who speak a non-English primary language triples when a MOOC offers subtitling in their language (Andreina Parisi-Amon, personal communication, November 1, 2014).

These enrollment patterns highlight the central role of language in international psychology education, and they suggest the importance of incorporating pedagogical practices that meet the linguistic and cultural needs of students. Whether courses are online or on campus, internationalizing psychology education will require platforms that facilitate peer interaction, language support such as video subtitling, visual and nonverbal demonstrations of key principles, and the inclusion of diverse cross-cultural examples that engage students regardless of nationality. Such practices are consistent with recent research on effective undergraduate education in psychology (Halpern, 2010), and their adoption stands to benefit not only students abroad but international and domestic students studying in the United States as well.

Learning Outcomes

Critics of MOOCs note that course completion rates are very low, and that it is hard to assess the learning that takes place. Of the estimated 33,000 to 43,000 students who enroll in an average-size MOOC, only 60% or so of students return to the course when it begins, and only 6% to 10% complete the course, depending on how the completion rate is defined (Jordan, 2014)—making a 90% to 94% incompletion rate a source of concern for educators. In response to these criticisms, MOOC supporters argue that course completion rates are the wrong metric to measure educational success. In the words of the founders of Coursera, "the goal of education is to provide students with the skills they need to achieve their own life goals, not to retain individuals in a classroom" (Koller, Ng, Do, & Chen, 2013, p. 1).

Outcome studies comparing online and traditional learning have shown promising results. For instance, one study found that when an electrical engineering course incorporated content from an edX Circuits and Electronics MOOC, the percentage of students passing the course went from as little as 55% to 91% (Fowler, 2013). An especially encouraging result was reported by University of Texas researchers who compared the effectiveness of an online version of introductory psychology with a traditional version (Pennebaker, Gosling, & Ferrell, 2013). Not only did psychology exam scores increase by approximately half a letter grade when the course was taught online—the socioeconomic achievement gap in course grades was cut in half.

How effective are MOOCs or other new technologies in internationalizing undergraduate education in developing regions? Current opinions are divided. On the positive side, educators such as David Myers (2009) foresee how new technologies can segue into a "pedagogical utopia," in which "web-based e-books may deliver state-of-the-art, interactive, low-cost, locally adapted content to students who cannot afford books" (p. 99). On the negative side, Kentaro Toyama (2015), from his experience with undergraduates in India, concluded that "the primary effect of free online courses is to further educate an already well-educated group who will pull away from less-educated others. The educational rich just get richer." The long-term impact of MOOCs is clearly an open question awaiting empirical study.

Internet-Based Technologies

In addition to MOOCs, various Internet-based technologies and systems—such as Twitter, Facebook, blogs, wikis, Skype, videoconferencing, podcasts, YouTube, and virtual worlds—are revolutionizing how disciplines internationalize their undergraduate programs and curricula (Velayo, 2010; Velayo & Trush, 2012). Through such web-based systems, instructors in different nations can work together, often in real time, on joint activities. Undergraduates are generally well-acquainted with these sites and technologies (at times, more so than faculty), and their thoughtful use is valuable in guiding education, supplementing lessons, improving research and collaboration, and pursuing the larger goal of IoC (Velayo, Oliva, & Blank, 2008). Moreover, Moodle, Blackboard and other online teaching platforms can facilitate a web-enhanced class, which enables students from different institutions across the world to interact in real time. Such technology is now commonplace in most schools in the United States and other nations.

Internet-based technologies are increasingly popular to incorporate international content into the psychology curriculum (Grenwald, Oberlechner, & Velayo, 2012; Grenwald & Velayo, 2011; Velayo, 2012). One key reason is cost-effectiveness—especially for community college and other students with family, work, or financial limitations

(Guerin, 2009). The Internet offers interaction with people from other cultures and countries, journal articles written by individuals from diverse backgrounds, and countless opportunities for cross-cultural collaboration—all at little cost.

Social media refer to Internet-based technologies that enable users to interact by sharing information, ideas, images, or videos. Facebook, YouTube, Twitter, blogs, and wikis are among the most common social media platforms used to enhance collaboration and share knowledge among learners from different parts of world. Social media exemplars in internationalizing undergraduate education include virtual psychology labs (e.g., Gao & Wang, 2010), international mentoring (Stevens & Wedding, 2009), and collaborative online research with participants across nations. One example of a popular virtual lab is APA's Online Psychology Laboratory (http://apaonlineacademy.bizvision.com/), with almost a million views per year.

Another way that Internet-based technologies incorporate international content is through the sharing of materials. It is increasingly easy to share material with peers or colleagues and work collaboratively. Many instructors now use social networks and videoconferencing to participate in lecture exchanges (e.g., Longview Foundation for Education in World Affairs and International Understanding; www.longviewfdn.org). Internet-based technologies can also help supplement textbooks which may lack international content, with articles from international journals to supplement the texts.

There are also many content-based resources that provide information for undergraduate instructors who wish to infuse international content in their courses (Velayo, Grenwald, & Manfred, 2012). Probably the most comprehensive collection of psychology resources focused specifically on internationalization are Psychology Resources Around the World (http://resources.iupsys.net/iupsys/index.php/patw-resources) and International Teaching of Psychology Network (http://interteachpsy.org/). Instructors can help update these and other sites by contributing resources as well as reviewing the materials. Just as emerging technologies are transforming undergraduate education in general, these technologies promise to be a valuable centripetal force to reduce barriers to global education.

14 Recommendations to Support the Internationalization of Undergraduate Psychology

Internationalizing undergraduate psychology is an ambitious but highly desirable goal that needs the concerted efforts of students, faculty, departments, and educational institutions. Institutions must help create the right educational atmosphere as well as provide the necessary organizational support and financial incentives to enable faculty and departments to engage in the necessary efforts. Departments must see internationalization as an overarching goal that cuts across the curriculum. Faculty members must see themselves as eager learners who consider the internationalization of their own courses and research efforts a challenging but rewarding task. Finally, although students may at first be reluctant to leave their comfort zone to gain international experience, once they do they can expect to grow intellectually, emotionally, socially, and perhaps spiritually. Some of them will find their life's calling precisely by seeing themselves in new and surprising situations, whereas others will see their career options enlarged in a world shaped by the forces of globalization.

How timely, then, that the *APA Guidelines 2.0's* (APA, 2013) third goal of "Ethical and social responsibility in a diverse world" can help guide individual faculty, students, and educational institutions to develop an international outlook and acquire the necessary skills to cross cultural borders. To make this broad goal more specific, we offer 14 suggestions that address three levels—undergraduate students, faculty, and institutions.

Undergraduate Students

1. Cross-national research. Because most undergraduate curricula mandate a research experience, why not a cross-national one? A student guide (Shvets, 2007) offered six reasons for students to collaborate in cross-national research and four low-cost ways to do so. For one example, without funding, a researcher completed an extensive field experiment on prosocial behavior, comparing 36 U.S. cities and 23 nations, by training student tourists who valued this chance to get research experience (Levine, 2003).

2. Study/work abroad. The numerous U.S. students studying abroad do so typically for one summer, semester, or full year, through one of the increasing number of study abroad programs (Soto, 2014). In addition, "work abroad" programs (such as teaching English) offer income along with cultural immersion (Murray, 2005). Such study abroad programs offer ideal opportunities to conduct cross-national research and to create personal contacts for future collaborative research projects.

3. Conferences. One simple yet valuable international experience is for undergraduates to attend one of the many global psychology or education conference each year, most of which offer a reduced fee for students. Moreover, many conferences now allow undergraduate and graduate students to present posters, thereby reinforcing the challenges and excitement to conduct and present cross-cultural research.

4. Organizations. Undergraduates can benefit from joining an international organization as student members (Takooshian & Stambaugh, 2007)—be this a large group (such as the International Association of Applied Psychology or the International Association of Cross-Cultural Psychology) or one of the 100 smaller specialty groups, such as forensic or school psychology (Bullock, 2012a).

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5. Funding. There are at least 50 major sources of funding for student and faculty international activities—such as Boren, Coro, and Open Society. In fact, one analysis found that "funding for international activities has risen sharply since the 1990s, now accounting for 15% of all foundation-grant dollars . . . as more U.S. foundations are 'going global,' up from 46% in 1994 to 63% in 2001" (Takooshian & Takooshian, 2012, p. 54). Students frequently report profound experiences after completing a Fulbright or similar program (Zoma et al., 2012).

6. Internships. Whether for credit or not, students can seek multicultural field placements as part of their undergraduate degree. Most cities have multicultural service centers that can offer a psychology placement, such as Los Angeles' Institute for Multicultural Education and Services. In New York City, the United Nations offers an increasing number of internships (Takooshian & Campano, 2008), participation in Model U.N. sessions, and other international experiences for undergraduates (Roberts, 2014). Many internships provide students with the opportunity to interact with children and/or adults of numerous immigrant backgrounds that can prepare them for subsequent international experiences.

Faculty

The revised version of the *APA Guidelines 2.0* (APA, 2016) seeks to infuse "sociocultural learning outcomes" across the major, rather than in a separate course to produce "global psychological literacy" (Cranney & Dunn, 2011). Individual faculty can do much to adapt their existing courses, develop new ones, experiment with new technologies in the classroom, and participate in cocurricular activities outside the classroom (Velayo, 2016).

7. Syllabi. Faculty may integrate into their current courses more research based on non-U.S. participants or by non-U.S. authors (Woolf, Hulsizer, & McCarthy, 2002). One volume offers a dozen practical chapters on how to integrate cross-cultural work into traditional courses such as developmental, social, personality, and health psychology, as well as 52 ways to internationalize the psychology curriculum (Leong, Pickren, Leach, & Marsella, 2012). An increasing number of cross-cultural textbooks are appearing for teachers of these courses (e.g., Gielen & Roopnarine, 2016). One offers "111 experiences for multicultural learning" inside the classroom (Pedersen, 2004).

8. Courses. Some faculty might develop a new course, using one of the many textbooks available for international (Eysenck, 2004) and cross-cultural psychology (Shiraev & Levy, 2012). The APA Society for Teaching of Psychology offers a variety of model syllabi in its Project Syllabus. Faculty can tap the IUPsyS resource center (cf. Stevens & Wedding, 2006), the nine volumes on international psychology (in Baker, 2012), or any of a dozen cross-cultural psychology periodicals, such as the *International Journal of Psychology* or the *Journal of Cross-Cultural Psychology* (Simonian, 2014).

9. Remote courses. In addition to MOOCs and other online and other distance-learning courses (Velayo, 2011), faculty may now use Skype, Polycom, or similar technologies to offer simultaneous cross-national courses (Chia & Poe, 2004).

10. Cocurricular activities. Over 1,300 U.S. undergraduate institutions have a chapter of Psi Chi or Psi Beta (for community colleges), which commonly offer cocurricular activities that complement classroom learning (McCormick et al., 2014). These include international activities such as lectures or workshops by international travelers, programs focused on global topics, and using Skype to hold shared sessions between American and overseas chapters of Psi Chi.

Departments and Institutions

11. Institutes for international and cross-cultural psychology. An institute focused on global psychology can broaden the curricular offerings of psychology programs, involve undergraduate students in international research and other internationally oriented activities, and broaden their horizons. An example of such a center at a predominantly undergraduate institution is the Institute for International and Cross-Cultural Psychology at St. Francis College, New York (www.iiccp.org).

12. International activities on campus. In order to promote international activities on campus, a school may foster creative collaborations among existing campus groups: the psychology department, offices for international students and study abroad (Roberts, 2014), and the Psi Beta or Psi Chi chapter (Russo & Takooshian, 2002). Such activities might include lecture series, interdisciplinary workshops for students, receptions, awards, faculty development workshops, or press releases highlighting global work.

13. Fulbrights and faculty abroad. Schools would do well to encourage and support faculty who consider applying for Fulbrights to do research or teach overseas. Since 1946, over 110,000 faculty have served as U.S. Fulbright Scholars overseas, often with life-changing experiences (Takooshian et al., 2011). In addition, over 183,000 international faculty members have served in the United States. There are a growing number of overseas programs besides Fulbright. Over 1 million "alumni" and "alumnae" have been funded by one of the dozens of other U.S. State Department programs—such as the Humphrey, Gilman, and UGRAD programs (Barton, 2013). Over 7,500 psychologists have directly benefitted from one of these programs (Takooshian, 2013).

14. Administrative support. Ask deans, directors, provosts, and other administrators to support programs and events that internationalize psychology education. When feasible, familiarize administrators can also familiarize themselves with resources to internationalize the school's curricula (IoC, in Leask, 2015), or Internationalize at Home (in Barker & Mak, 2013). Because educational institutions are frequently under pressure to internationalize their offerings, administrators may be willing to provide organizational, financial, and moral support for this effort.

Concluding Comments

Contemporary undergraduate psychology education in the United States is being powerfully affected by at least two forces: the sharp growth of psychology outside its borders and the emergence of new technologies in the classroom. Separate but parallel efforts are underway—*APA Guidelines 2.0* (APA, 2016) in the United States, and the EuroPsy "tuning process" in Europe—to encourage greater cultural diversity in undergraduate education, as psychologists around the world seek to develop educational practices that reflect a cross-national science of behavior. These efforts are supported by the sustained commitment of APA to further the goals of internationalization, and the dedicated efforts of faculty members and other psychologists both in the United States and abroad, to get their psychology undergraduates ready for the future.

What will this future look like, and how can we best prepare our students for it? *APA Guidelines 2.0* (APA, 2016) emphasizes that our undergraduates today are entering an ever more diverse and multicultural world. As noted by the past CEO of APA, Raymond Fowler (2000, p. 11), "new psychologists who do not have the benefit of a sophisticated orientation to international issues will be severely handicapped in their career options." Psychology undergraduates must develop *global psychological literacy*—to think in broad international terms, communicate across cultural borders, integrate multiple identities in themselves, and support others in their efforts to achieve goals that are in part culturally shaped. Our recommendations are intended to help psychology undergraduates and faculty to prepare for a "glocal" world—that is, a world that is simultaneously global and local in nature.

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INTERNATIONAL UNDERSTANDING

an ICP, Inc. publication

Part B: International Psychologist IP 56.2 Edition

Dr. Ann Marie O'Roark, Editor

St. Augustine, Florida. June 2016.

IP56.2 Part B: INTERNATIONAL UNDERSTANDING is dedicated to Ludwig Frederick Lowenstein, PhD., ICP, Inc. President 2011-2013. Ever the optimistic motivator, Dr. Lowenstein contributed the most articles for the INTERNATIONAL UNDERSTANDING, ICP, Inc.'s informal journal that encourages students and professionals from all nations who are new to the international association community opportunities to begin publishing in English.

Ludwig became an ICP, Inc. member in 1977. He organized two annual conferences in England and led the Forensic Research Interest Group in presenting symposia at each scientific conference. He attended the Paris conference, but could not attend Toronto last year. He planned a presentation for Yokohama, and it is hard for me to imagine ICP conferences without his presence. His lovely wife Kathleen and devoted partner in his lifework and his ICP, Inc. work, notified us of his peaceful passing on April 9, 2016.

On the next page you will read some messages to Kathleen, sent by ICP friends around the world.

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April 10, 2016
Dear ICP, Inc. Colleagues
With heavy heart, I forward this message [about the passing of Ludwig Lowensterin on April 9] from Kathleen Lowenstein.
We will dearly miss ICP's gallant and ever-optimistic *man of energy and empathy*, of independent thought and interesting work, of good cheer and good writings.Ave etque Vale Ann Marie O'Roark [USA]

Dear Kathleen
I am sorry to find out about Ludwig's death. I have fond memories of him. My condolences,
Varda Muhlbauer [Israel]

Dear Kathleen, I am honored and blessed to have known Dr Lowenstein. My most heartfelt condolences to you and your family. Warmest regards, Cecilia [Cheng] [Hong Kong]

Ann, thanks for sharing the sad news of Ludwig's passing on April 9.
Do you think IP will be collecting memories of Ludwig? I have a good photo or two.
In Paris, Ludwig + I were surprised that we graduated there same NYC high school,
but slightly different years.
Harold Takooshian, PhD Fordham University, New York NY 10023, USA

Dear Kathleen:
It was a great sorrow to me to learn of Dr.Ludwig Lowenstein's passing away.
I would like to express my sincere condolence on this sad event. From bottom of my heart, I have appreciated Ludwig's long-term friendship and encouragement given to me: I will miss him in Japan, while he has been eager to prepare for the Conference. He will be remembered in my heart. I hope Kathleen will take care in this grief situation.
With deepest sympathy, Machiko Fukuhara [Japan]

Ann Marie, Thank you very much for your letting me know of Ludwig's passing away. With deep sympathy, I pray for the repose of late Ludwig Lowenstein. I hope my message has arrived to Kathleen. I have a thought that at the opportunity of 74th ICP,Inc.Conference Yokohama, we will have a ceremony in memory of Ludwig. Looking at a tentative program, there is a paper session prepared for him, 11:30a.m.-12:00m. on July 23. It might be an appropriate time to do it. Machiko Fukuhara [Japan]

Dear ICP colleagues
Our hearts go out to Ludwig's family. He was such a wonderful gentleman and was a loyal ICP member and friend. He will be missed.
Best,
Janet [Sigal] Sent from my iPad [USA]

Dear Kathleen, I'm so sorry to hear about Ludwig. I knew him for many years, and always found him to be a wonderful person, a great leader, and a dear friend. He loved you very much. I remember the time he and my husband Bob both compared notes on "what wonderful wives they had." I will always remember him and all that he meant to ICP.
With deepest sympathy, Florence Denmark

Dear Kathleen, I think of Ludwig as an ICP icon over the many years met annually in so many conferences all over the globe. My wife and I remember his cheerful friendliness and kindness.Saddened and heartfelt condolences for your loss but he will always live on as one of the greats of ICP. Chok Hiew [Canada]

Dear Kathleen,
With deepest sympathy, I share your sorrow of Ludwig's passing.
This very difficult time must include meaningful memories. I always remember Ludwig's admiration of you as a unique, supportive partner in life. His legacy remains as an optimistic, engaging communicator.
Long live you and Ludwig's legacy.

An Idea: At the deepest sorrow about Ludwig's passing, it made me think of reversing our usual tradition of honoring people after they pass. I think it would have been so meaningful for Ludwig to have heard the wonderful words of acknowledgement that were expressed by our members when he was with us, especially as he was challenged by illness and suffering toward the end of his life.
Inspired by Ludwig and others who recently passed away, I propose to develop a new tradition of honoring and acknowledging our ICP colleagues/members during their life with us. I believe end of life on this Earth is inevitable, regardless of age and other factors. I would like to propose that we dedicate a section in our IP based on some order (alphabetical or other) to recognize and acknowledge our members/colleagues' participation/contributions by asking everyone for statements about them. We/ICP would also put these together as a nice presentable letter to the individual and keep a copy for our archive.
Please let me know what you think.
Warm regards,
Tara [Pir] [USA]

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~Dear Tara, I like your idea very much. Donna [Goetz] [USA]
~A wonderful idea Tara and thanks to the wonderful man that inspired it and who will remain a part of us forever. Consuelo [Barreda-Hansen, PhD. Australia]
~I will be happy to initiate the process. Love, Florence [Denmark, USA]

Dearest Kathleen, We are so very sad to learn of Ludwig's death. He meant so much to Bob and me , friend, companion, lover of life, a man much greater than most, above all always loyal to us from the 1980s onwards.I would like to write an obituary for him. As you know Kathleen I was writing the introduction and Practice notes to his second book "Surviving in Families" after his first book, "Parental Alienation". I will continue that with your permission. I will write to you when I can have my mind less frazzled by his loss.
With condolences and love, Sandra and Bob.
Dr. Sandra E. Neil, FAPS [Australia]

Dear Kathleen and ICP family..
Ludwig lives on through all the lives he touched and directed to brighter paths and in our hearts, always. How fortunate we all are that his gallantry graced our lives...
Sherri
Dr. Sherri McCarthy, Ph.D [USA]

Dear Kathleen, I join other colleagues members of the ICP to give you our heartfelt condolences. A kiss! Ana Guil, PhD. [SPAIN]

Dear Kathleen,
Please accept my sincere condolences. Ann Marie could not have said it better; we will always remember dear Ludwig as " *ICP's gallant and ever-optimistic man of energy and empathy, of independent thought and interesting work, of good cheer and good writings*."
In sympathy, Joy Rice [USA]

Dear Friends and Fellow ICP Members,
Thank you so much for your tributes to Ludwig in the current IP. They are appreciated and welcomed by myself and his family. I will indeed include them in our tribute book to him when we have a memorial service for him on 9th July 2016. I am only sorry that I cannot extend an invitation to you all as you are all so far away.
I would wish President Sigal to give my apologies to the Board and to Machiko for not being able to attend this year's conference in Japan. Ludwig and I were so looking forward to it, especially as we missed the last conference in Japan also. I still have a commitment to my mother now aged 92 which Ludwig and I took on 2 years ago.

I would also like to take this opportunity to thank you for the gift of flowers that you so kindly sent to me on behalf of ICP. I should have sent my thanks long ago and for this I apologise to you all. There is a memorial tribute to Ludwig on the British Psychological Society's website which you may like to view. The link is https://thepsychologist.bps.org.uk/dr-l-f-lowenstein-1928-2016
All best wishes to you all for a successful conference.
Kathleen [England]

Please send your favorite story about Ludwig to Florence Denmark for the MEMORY BOOK:

fdenmark@pace.edu

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Long Ago and far away vs Today and yesterday

The INTERNATIONAL UNDERSTANDING, IP56.2, Spring-Summer 2016, opens with the article Ludwig Lowenstein sent titled, "What is there to know about memory." This is a technical and cognitive review of the two types of individual's memories: short term and long term. Ludwig extrapolates from physical functionings of the brain to current cognitive disabilities, dementia, Alzheimer's, verbal fluency and executive functioning and problems such as depression and false childhood memories of abuse. The second article is an excerpt from a chapter I prepared for an African book, here titled: The Editing of Who-I-Am. It is included as a compliment to my colleague Ludwig with whom I held numerous dialogues about self concept. This review of over 100 years of thinking about self concept pays special attention to the importance of self concept maintenance in later years of life and of finding ways to link the global sets of "self ways." The first section concludes with Anna Laura Comunian's presentation about differences and similarities in human values across cultures, about the emic and etic dimensions, and about conducting scientific research into the values phenomena, which some consider the heart of the self concept and a key cohesive factor in memory stability.

The Future: Students, Sustainabilities, and Longitudinal Milestones

The next set of articles begin with the Velayo, Forti, Ghahghahi, Javani and Siddiqui paper illustrating how next generation psychologists are taking advantage of technology to examine a variety of scientific psychology's mysteries in an international context while infusing the curriculum with the value of conducting international research [e.g., mood disorders, depressive rumination, facilitating international communications about leadership]. The next paper is from Dr. Roswith Roth about UN NGOs and securing a sustainable future, about working toward shared ideals, shared values and shared futures. She also notes the70th year of NGOs being associated with the UN, and the 60th Session of the Commission on the Status of Women. Florence Denmark presents her 2016 UN ICP report summarizing the varied activities of the members of the ICP, Inc. UN NGO and DPI representatives for the year.

Special Books

The third section includes two book reviews. First, Dr, Sandra Neil describes a pair of books that enable development of a therapeutic deradicalizing method for assisting terrorists to adjust perspective and behavior patterns. The first book is by ICP, Inc. member Roseline Davido of Paris: *The Davido-CHaD in Practice: A clinical and projective personality test.* The second is by another ICP, Inc. member, Sarlito Sarwono of Jakarta, *Indonesian Terrorists in Psychoanalytical Perspectives.* Neil concludes that "Overall, these two books are convincing…."

Dr. Judy Kuriansky submits a review of "The Psychosocial Issues in Ebola: From the Psychology Coalition forum to Boots on the Ground" to an anthology chronicling the Psychosocial issues. She sees relevance to the contemporary concerns about a potential Zika epidemic. Fear, stigma and discrimination are key aspects of these world health emergencies.

THE 2016 BOARD ELECTION BALLOT

Dr. Tara Pir is presenting the 2016 Board Election in two Components. The first set of nominees will be for the Board Secretary and Directors At Large: 2 seats open for Professionals and 2 seats open for Graduate Student Representatives.

With Warm Regards

Ann Marie O'Roark, PhD, ABAP
IP Editor

2016 Publications Deadlines

IP56.3 Part A: **August 30, 2016**
IP56.4 Part A: **November 30, 2016**
IP56.4 Part B. International Understanding: **12/10/16**

All submissions should be sent via email to Dr. Ann Marie O'Roark. Her email is **annoroark@bellsouth.net**

Convention photos appreciated!

WHAT IS THERE TO KNOW ABOUT MEMORY

Ludwig F. Lowenstein, Ph. D.
Past-President
Southern England Psychological Services, UK

Abstract

The memories that individuals possess are based on both short and long-term memory. Certain parts of the brain interacting with one another are responsible for memory. As we are currently living longer there is likely to be an increase in memory problems leading to cognitive disabilities and frequently dementia and Alzheimer's disease. Due to the process of ageing firstly the immediate or working memory suffers and this is followed by deterioration of long-term memory. Older people also suffer from lack of verbal fluency and executive functioning. Psychological problems such as depression are likely to interfere with memory functioning. Amnestic disorders are briefly discussed along with depression and false childhood memories of abuse.

What is there to know about memory?
(The past and recent research)

The picture of the brain which follows will be discussed in some detail.

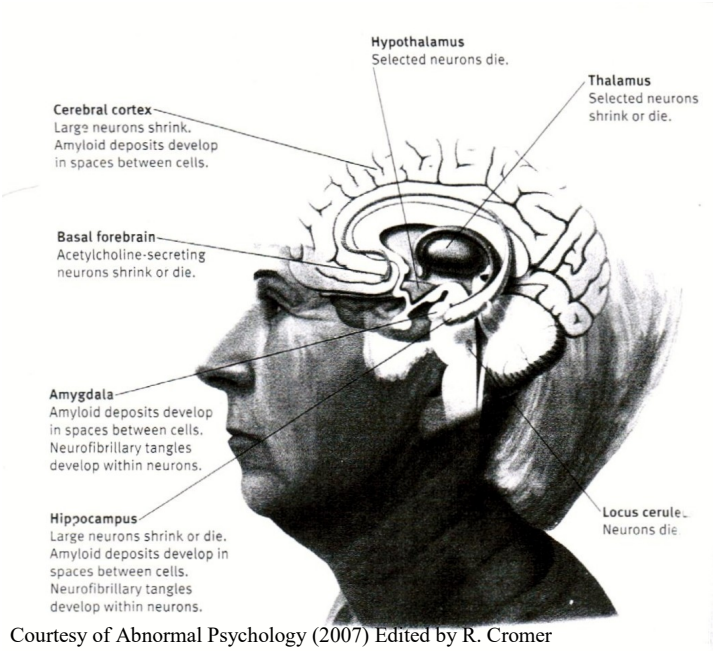

Courtesy of Abnormal Psychology (2007) Edited by R. Cromer

Fig. 1 Parts of the Brain

Memory is affected by a number of events such as traumatic psychological problems and of course through the process of ageing. It occurs in dementia and Alzheimer disease. It has been estimated that 25% of the population over 85 will suffer from cognitive disabilities, especially a deterioration in memory (Itua & Naderali, 2010). This is especially illustrated by the increase of the aged due to better care received.

Two forms of memory have been identified: short-term or working memory and long-term memory. New information is gathered via short term memory, but it can only be retained when it is transferred into long term memory. It can be retrieved or remembered. It has been noted that music, somantic memory and other types appear to be preserved in a moderate form of Alzheimer's disease (Cuddy et al., 2012).Particular parts of the brain are involved in the obtaining of working memory. They are the pre-frontal lobes, just behind the forehead (Jiang et al., 2000). Other areas important in the gathering of information by short-term memory are the temporal including the hippocampus and amygdala. Also important structures dealing with short-term memory are the diencephalon including the mammillary bodies, the thalamus and the hypothalamus. These structures transfer the short-term memory into long-term retained memory. (Please see Fig. 1 as to where these structures reside).

As a result of the aging process these areas are sometimes damaged (Van der Flier et al., 2005).

The aging process and memory loss

Genoe & Dupuis (2014) noted the importance for the elderly suffering from dementia being unable to retain their memory better. It is important and helpful for the elderly to be engaged in meaningful activities such as work and having good relationships with others. When there is increased working memory demand difficulties will increase eventually being unable to remember sentences (Gross et al, 2012). Patients attending memory clinics were found to benefit as measured via the Cornell Scale for Depression and Dementia (Hancock & Larner, 2015; Knapskog, 2014).

Jones et al., (2015) considers that many aged individuals begin to suffer from dementia. They frequently forget their medical condition and the medication they require to deal with it. Of 99 patients interviewed only 22% were able to remember the names of the medications they were using. Only 34% understood their medical condition. Only 49% remembered the number of drugs they were taking (Kohler et al., 2013).

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It was also found in a Dutch study that when individuals aged they increasingly suffered from deterioration in immediate and delayed memory recall, and delayed recognition and information processing speed. They also suffered from lack of verbal fluency and executive functioning. Other deficits in some cases included the impaired ability to recognise faces due to neurodegeneration (Kumfor et al., 2015).

It was also noted that those individuals who attended a memory clinic alone and not with a caregiver or friend were found to be cognitively healthier with an absence of dementia in many cases (Larner, 2014). Those suspected of suffering from dementia were likely to over-estimate their memory and were unaware of their deficits (Lindquist et al., 2014). This included their deficits in memory (Lin et al., 2010).

The elderly whose memory has been thus affected appear to have the ability to discriminate between memories recalled and not recalled (Mammarella et al., 2012). It has also been proposed their needs to be an observation of memory functioning over a period of time in order to note deterioration occurring (Persoon et al., 2011).

Working or immediate memory is often affected in Alzheimer's disease. This is often termed 'central executive impairment' due to the lack of frontal lobe functioning (Stopford et al., 2012). This is not the case in all instances. The dysfunction appears to be in the posterior hemisphere and not the frontal lobes. A study by Terry et al (2013) suggests that the personality of aging individuals is a strong predictor of memory functioning. Other factors where the age, gender and the estimated premorbid IQ and symptoms of depression (neuroticism of the 5-factor model). Openness is associated with better memory functioning. Tsang et al. (2013) also found that depression is associated with memory impairment.

It has also been found that chemical factors, especially biochemical changes, affect memory. Acetylocholine glutamate (RNA, ribonucleic acid) and calcium are responsible for the formation of memory-linked proteins. The improper secretion of proteins may be prevented interfering with the developing of memories (Wu et al., 2008) especially short-term memories. It is the same case when there is a blocking of cellular production of the RNA (ribonucleic acid) or of calcium., There could also be failure to develop long-term memories in that case (Berridge, 2011). Such abnormal development can lead to Alzheimer's disease.

There are also substances found in nature that can act as toxins and damage the brain leading to Alzheimer's disease. This is especially when there are high levels of zinc in the brain (Schrag. 2011). The same can be said about the toxin lead (Ritter, 2008). As a result of petrol being unleaded in 1976 and 1991 there was a reduction of lead by 80% in the blood. In the 1960s and 1970s, there was destruction of the neurons due to inhalation of pollutions. These toxins came from automobile exhaust. This is likely to have affected the cognitive ability of those who constitute the elderly population today (Ritter, 2008). The absorption of lead was measured by assessing the shin bone of the elderly (Schwartz & Stewart, 2007). There appears to be direct effect on the memory and language tests. Symptoms presented such as forgetfulness occur due to the destruction of brain cells many years after the pollutant has been absorbed (Landrigan, 2007).

Another aspect affecting the brain cells is the immune system. This occurs when the immune system response occurs acting upon itself (Zipp & Aktas, 2006). The viral theory states that a virus is slow acting much as in the Kreutzfeldt Jakob disease. This leads to the Alzheimer condition and this leads to a deterioration of memory. It can be measured via the Memory for Names Test (Brouillette et al., 2011). Another test for memory is Memory Orientation and Screening Test (MOST) by Clionsky & Clionsky (2010).

A rarely occurring disease is Pick's Disease which affects the frontal and temporal lobes. This is due to a slow acting virus which lives in the body, often for many years. Genetic factors often play a role as illustrated by Huntington's disease which is progressive and affects both the memory and personality via unexplained mood changes. There is also a 50% chance that those suffering with this condition may in 50% of cases develop Parkinson's disease with such symptoms as twitching, spasms, rigidity, and being unsteady on their feet.

Amnestic disorders

Amnestic disorders occur as a result of a brain disease due to direct injuries to the brain (Bigler, 2009). This disorder develops in both young an older people when they are injured due to head trauma (King & Kirwilliam, 2011).

Half of the more severe head injuries result both in learning problems as well as memory deficits. Such deficits mainly occur due to car accidents and falls. This affects both the anterograde and the retrograde memory. We will define each of these now:

1. Retrograde amnesia – this occurs in the inability to remember what has happened in the past.
2. Anterograde amnesia – this occurs when an individual is unable to form or hold on to new memories. This results in individuals being unable to allow short-term

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memories to develop into long-term memories. Thereby the individual forgets all recent events and forgets all that has occurred it being immediately forgotten. The IQ however, remains unchanged. In severe cases individuals they have met, including their names, are immediately forgotten.

The effect of dissociative disorder on memory

Under normal circumstances most individuals have a sense of who they are, that is, their identity. We have our own expectations, values and goals. We are aware of past, present and likely future. Our past experience influences our present events, helping us to make decision now and in the future. Memory helps one to remember individuals with whom we have, and will continue, to interact. When we fail to remember what has gone on before, and new information just learned, we may suffer from a dissociative disorder. This occurs when one part of the individual's memory is dissociated or separated from the rest resulting in the inability to remember personal events and information. Anyone with this affliction forgets the past and travels to a new location and even assumes a new identity. This condition is also called "multiple personality disorder" whereby the person has two or more separate identities that are not necessarily known to each other. Such problems are rare. It can also be called a "deep personalization disorder" (Brockmeier, 2014).

Such individuals may see themselves from outside as they have become "detached" from their own mental processes or body. Their own bodies feel unreal. They are suffering from "dissociative amnesia", often termed "dissociative fugue or "dissociative personality disorder". This is caused by the individual experiencing a traumatic event leading to confusion and shock and an inability to recall traumatic events or information from the past (Kikuchi, et al., 2010). They can however remember what occurred before the traumatic event leading to this selective amnesia. It could lead to the individual failing to recognise even family and friends he/she has known for many years.

Depressed or false childhood memories

This is another form of memory loss which is somewhat in dispute. In the 1990s there were reports that memories from childhood concerning physical and sexual abuse of children have been recovered. Memories were recovered while undergoing therapy. The manner in which these buried memories were obtained came into dispute. There were those who claimed that these "memories" were not memories at all. They had been inculcated or induced by therapy (Balash et al., 2013) were the repercussions of such earlier forgotten abusive events. Other experts argued against such assertions (Birrell, 2011; Haaken & Reavey, 2010). A dispute arose between those who believed these memories were real and true and those who did not believe this. Loftus & Cahill, (2007) believed such real abuse is only too well remembered without therapy and is unlikely to be repressed and not remembered. Finally, many believed that past memories are often not based on real events (Haaken &Reavey, 2010). The results, according to Loftus & Cahill (2007) came from such individuals being suggestive personalities and the therapists inducing these non-existent memories on their clients.

In recent times efforts have been made to develop better memory or prevent further deterioration of memory. One such approach has been Cognitive Training Intervention (Materne et al., 2014; Creighton et al., 2013). Fiksdal et al. (2012), found that memory enhancement procedures known as "spaced retrieval" help an individual in early stages of dementia to retain meaningful information learned.

Memory club support groups also help individuals with memory loss (Gaugler et al., 2011). Other ways to enhance memory and reduce speed of deterioration is to stimulate cognitive ability via such strategies as crossword puzzles (Pillai et al., 2011). When one member of a couple suffers from memory loss and the other does not then much help can be provided by the person who has not suffered such loss.

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THE EDITING OF WHO-I-AM

Ann Marie O'Roark, PhD

From birth to death each of us strives for maximum organization and integration of experience and information, always directed toward four goals: survival, adequacy, growth, and meaningfulness (Gordon, 1962; Combs, Miser, Whitaker, 1999; O'Roark, 2000). Survival and growth depend on a continuous editing of the self and its awareness of who-I-am. Accurate updating efforts result in more effective strategic mapping-and-selection of behavioral options and choices.

Neisser & Jopling conclude that self-concept is conceptualized in many different ways across cultures, that there exists a wide variability in how individuals experience their self, and that, at times, there is noticeable disjunction between self-concept and self. Should other scholars and researchers offer overwhelming support for these hypotheses, we are not at the mercy of postmodernism or nihilistic existentialism. Quite to the contrary, such evidence may culminate in

1. increased respect for self, others and work tasks,
2. increased openness to learning and conscious editing of the self-concept in healthy, productive directions across the life span, and,
3. increased understanding of cross-cultural differences, interpersonal conflicts, mental health and dysfunctional behavior.

THE EDITING OF THE SELF-CONCEPT: WHO-I-AM

The *who* function of self-concept provides a mirrored reflection of *who-I-am in this place at this time*. This collage of nouns and adjectives is organised, dynamic, and has positive and/or negative valence (Purkey, 1970). According to some self-concept theorists, the self-view is the key to understanding the multitude of puzzling behaviors displayed by a single person. Therefore, these researchers propose the self-concept, defined as the view or perception an individual holds of him/herself, as the most important single human attribute.

OVER 100 YEARS OF THINKING ABOUT SELF-CONCEPT

Such pre-eminence for *self-concept* as delimited in the definition above is not universally proclaimed. A blizzard of *self* words emerged in the more than 100 years of psychological attention to the nature and function of a sense of *self*. James (1890) was first to note that the self is multifaceted. He maintained that the self has two primary dimensions - a *spiritual self* and a *social self*. The *spiritual self*, a likely ancestor of the current personal *private self*, was described as the inner, subjective being and included a person's dispositions. This manifested self works as the control center of perception and behavior and determines whether experiences are welcomed or rejected. James (1890) postulated that the *social self* is in charge of recognition of others and determining how to respond to other people. The social self has the ability to behave in diverse ways, responding to each person or clusters of people as deemed appropriate. James was the first to describe the self and its constituents, the connections between self and feelings, and the actions of self-seeking and self-preservation.

The term *self* has come to have two distinct meanings, namely:

1. A person's attitudes and feelings about her/himself (who), and
2. a group of psychological processes which govern behavior and adjustment (how).

The second is known as the *self-as-process*, and the first is typically referred to as the *self-as-object*. Each meaning has been elaborated in theory and empirical study, but no scientific school of thought holds that there is a spiritual or psychic agent, an 'inner manikin', a soul or an independent *homunculus*, i.e., 'a [person] man within the breast' (Hall & Lindsey, 1970).

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In 1935 Koffka elaborated on and extended the notion of the *self-as-object* as a knowable collection of conscious experiences that constitute the *phenomenal ego*. He conceptualized the ego as a doer as well as an object and hypothesized these functions as tension systems that interact with the environment. Koffka was the first to introduce the *executive* aspect of the self as a controller of behavior which is separate from the ego, that powerful concept developed by Freud, which continues to imprint thinking about the self (Hall, 1954). Koffka placed the *self* at the core or nucleus of the *ego,* referencing the concept to a basic science model. Erickson (1947), on the other hand, reserved the word *self* for the *object* aspect and used ego to refer to the central, organizing agent. Erickson's developmental model proceeds to track ego development through eight stages of priorities found to characterize the life span (Hall & Lindsey, 1970).

Allport (1943) gathered up all the meanings of ego and self into the term *propriate function.* Under this rubric he discussed bodily sense, self-identity, self-esteem, self-extension, sense of selfhood, rational thinking, self-image, propriate striving, cognitive style and the function of knowing. Sullivan (1953) considered the self to be a dynamism, the smallest unit and enduring pattern of energy transformation which recurrently characterize the organism in its duration as a living entity. He hypothesized that the dynamism develops as a result of anxiety and refers to that pattern of energy as the self or the self system. Buhler (1962) introduced the phenomenal self as all self-perceptions and self-concepts. She considered the core self to include life's basic processes, need satisfactions, adaptation, creative expansion, and internal order (Hall & Lindsey, 1970).

At the turn of the twentieth century, Jung (1921, 1971) described the self as equivalent to the *psyche* or *total personality*. For Jung, self is the mid-point of personality around which all of the other systems are constellated while it provides unity, equilibrium, and stability. Later on, Adler (1956) proposed the *self* as a personalized subjective system which interprets and makes meaningful the experiences of the organism. He introduced the notion that the self also searches for experiences that will end in fulfilling the person's unique style of life. He went on to say that if the necessary experiences were not found in the world about that individual, the self tries to create them, hence his introduction of the *creative self*. He wrote about the consequences of being *self- conscious*, which he concluded made one capable of planning and guiding actions toward *self-realization*. The motivation substrata of the self soon became a central research interest.

Maslow (1967) stated his now classic heuristic model of self that tracked his concept of an inner nature pressing for actualization. Depending on an individual's access to survival essentials (food, water, shelter), the self's motivational attention moves beyond basic security to belonging and culminates in full realization of individual human potentialities. Maslow later added a final motivational impetus - appreciation of others.

Rogers (1959) elaborated on Maslow's thinking, writing that the self or self-concept denotes an 'organized, consistent conceptual gestalt composed of perceptions of the characteristics of the ***I*** or ***me*** and the perceptions of the relationships of the *I* or the *me* to others and to various aspects of life, together with the values attached to these perceptions. It is a gestalt that is available to awareness, though not necessarily in awareness. It is a fluid and changing gestalt, a process, but at any given moment it is a specific entity' (1959, p.200). Rogers' definition of self-concept reveals a clear and striking similarity to quantum physicists' descriptions of an electron's two manifestations - *particle* and *wave*.

USING SELF-CONCEPT AS A THERAPEUTIC CONSTRUCT

Rogers (1959) became most interested in congruence and incongruences - the disjunctures between self and ideal self, between an individual's phenomenal field (subjective reality) and the external reality (the world as seen by others). Combs (Snygg & Combs, 1949) elaborated the phenomenal self as an object and a doer, concluding that what a person thinks and feels determines what a person will do. His research established a list of perceptual characteristics, as inferred from an individual's behaviors and statements, as observed by trained panels of raters. The *self-as-adequate* was most often associated with successful individuals in the helping professions (e.g., clinical psychologists, counselors, teachers, health care specialists, government service providers) (Combs, Richard, & Richards, 1976).

In my own research (1975, 1982), *self-as-open-to-experience* was the perceptual characteristic that discriminated between counselors and legislators who were identified as most or least effective. Other salient perceptual variables that have been found to be characteristic of

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successful individuals include: self-as-dependable, self-as-worthy, self- as-wanted, self-as-identified-with-others, self-as-internally-motivated, others-as- worthy/able/ dependable, and tasks-as-larger/freeing/meaning-oriented (Combs, Miser, & Whitaker,1999; Combs, Soper, Gooding, Benton, Dickman, & Usher,1971).

Wylie (1968) reviewed the literature on self-concept and found support for viewing this concept as comprising a matrix of social and private conceptions of the self, both actual and ideal. She concluded that the trend was for self-concept constructs to include a stronger 'sense of individualized goals' as opposed to James's 'centre of experience'. A summary of psychological principles associated with the perceptual-humanistic theories of the mid-1900s is provided by Purkey (1972).

THE SELF-CONCEPT: ASSUMPTIONS IN PERCEPTUAL/HUMANISTIC PSYCHOLOGY

Adapted from Purkey (1972) Personality Course Handout '... distillation of thought from Rogers, Allport, Festinger, Combs, Diggory, Lecky, Jerslid, Jourard, and Purkey'.

1. The self-concept is the awareness an individual has of one's role and place among living beings and influences behaviour and affect; personality and well-being.
2. The self-concept generates intelligence, motivation, productivity, and creativity. It is an inner manager of the daily flow of perception and action and is influenced by external and internal conditions.
3. The humanistic theorists state: Nothing is so highly personal as 'reality'. Reality is understood in relation to the self. Central to all perception is a person's perception of *self*. The self consists of attitudes, beliefs, and opinions that a person considers true about his or her personal existence.

- The maintenance, protection and enhancement of *self* is the basic motive for behavior.
- The *self* is usually more important than the physical body.
- We learn to perceive/understand ourselves, others and the world as a result of experience.
- The *self* is a continuous process experienced as a steady state, at a point of time in a lifelong evolution of *who-I-am*. This flow includes constant assimilation of new ideas and expulsion of old ideas. The healthy, productive *self* is a product of self- regard and regard from others.
- As *self* perceptions change, behavior changes.
- Behavior is determined by perceptions and not by facts, i.e., objective or collectively determined reality.
- An individual perceives different aspects of *self* at different times with varying degrees of clarity.
- The *self* maintains coherent productivity by striving for consistency, stability and predictability and therefore resists change.
- The more central a belief about the *self*, the more resistant the *self* is to change.
- The *self* is active as a whole. Ideas included in the self system must seem to the individual to be consistent with one another.
- Any experience which is inconsistent with the organization or structure of the *self* may be perceived as a threat, and the more of these perceptions there are, the more rigidly the self-structure is organized to maintain itself.
- Experiences of failure and success generalize throughout the self system.
- Psychological problems arise when a person cannot integrate the centrally held beliefs, attitudes and interests co-existing within the self-concept.
- Defending the *self* from internal and/or external threat restricts healthy development and awareness of growth opportunities.

These principles were reiterated or reinvented in academic-generic format as *Learner-Centered Psychological Principles* by the Division of Educational Psychology of the American Psychological Association (*Newsletter for Educational Psychlogists*,1995). Like the nineteenth century bifaceted construct of self-concept, these principles are presented as having two dimensions: one is the *substantive content* of the principles, and the second is the *learning process* (p. 4).

At the end of the twentieth century, self-concept constructs were just beginning to emulate models of natural processes, from quantum physics such as particle and wave functions, to cybernetics, the science of communication and control, i.e. negative and positive feedback loops. Both of these information loops operate from *reference values*. The negative input loop is like a thermostat that causes air conditioners to go to work to adjust temperatures that vary from a preset value, i.e. they precipitate movement toward a *desired goal*. The positive feedback loop is generated by a preset reference value

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that is to be avoided, initiating action to move away from a *repellant goal*. Consequently the self-concept's governance activities can be described in cybernetics language, as activation (motivation) of approach-avoidance processes according to self-concept contents, preset reference values and goals for the future (realization of the ideal-self, achieving specific objectives: family, career, health, homes, cars, boats, etc.).

Actions taken to attain specific objectives, each of which could be assigned to be associated with the general goals of survival, adequacy, growth, and meaningfulness, fall under a category of How-I-Behave, or the *self-as-process*. Wheatley suggests that it is only at the end of our lifetime that we are able to discern our individual *basins of attraction*, i.e., the strange attractors that shaped the fractal coastlines of our self's voyage across the years. Then, and perhaps only then, we can see the meaning and purpose (motivations, strange attractors) of our time of being.

We are fortunate if we can catch a glimpse of our attractors interacting with counterpoint resellers in mid-stream life. According to *catastrophe theory*, it is in these moments of non-linearity that a small change in one major variable produces an abrupt and usually large change in another variable. With logical ways to interpret the meaning and cause of drastic changes in self-concept and behavior, these sudden dysfunctions may lose some of their post-traumatic effects.

VITAL-SIGN CHARACTERISTICS OF THE SELF-CONCEPT

For most of us it is enough to know that complexities when found in self-concepts and personalities are associated with less vulnerability to depression and illness in response to life stressors. It is more practical for counselors and consultants to recognize the connections between the *vital-sign emotions*, i.e., curiosity, anxiety, and anger (Spielberger, Ritterband, Sydeman, Reheiser, & Unger, 1995; Spielberger & Starr, 1995; Spielberger, Reheiser, & Sydeman, 1994) and their motivational impact on the individual self-system. The links between health conditions and individual personality traits are becoming clearer (Spielberger & London, 1982, 1983, 1990).

Our self-concept travels along with us on the human growth and development paths detailed by Erickson, Freud, Kagan, Levinson, Piaget, and Vygotsky. Ausubel (1963) described the progress of *self* in terms of *satelizers* and *incorporaters*. *Satelisers* are more followers or absorbers of significant others' opinions.

Incorporaters take information or feedback and work it into their own schema, thus making them more likely to become independent, individualistic and / or leaders. A widely accepted child development model articulates normative phases, tracing maturation in self from behaviors characterized as *dependent, counter dependent, independent*, and into *interdependent* activities. This life pathway gained secular, popular recognition in the writings of Covey (1990). Such models provide ways of sorting out cross-cultural issues reflected in contrasting self-concepts and discrepant psychometric results. Cross-cultural issues are deferred to the next section, and the universal matter of disengagement, disease and death will conclude this section. Once again, Carver and Scheirer (1998) provide compelling new science imports to shed light on relevant self-concept issues.

The term *defaults* in the computer environment refers to preset decisions for computer operations, an automatic way of system functioning when not given an overriding instruction by the operator. As the self grows into adulthood a number of skills are acquired and so well practiced that they can be carried out without conscious planning or thinking. We all have experiences with such *defaults*, i.e., driving a car, playing a piano, and typing on the computer keyboard, and they save us time. They are shortcut efficiencies in our work and daily living. There are plenty of 'important' problems for our mind to deal with on a conscious level during the mid-life time, i.e., getting an education, rearing a family, building a career and carrying out multiple civic and social responsibilities. Later in life, there are fewer and fewer decisions to be worked through. Life gets to be routine and more and more decisions are default acts, i.e., we become 'set in our ways'.

The hypothesis is that movement toward goals that require effortful thinking results in a sense of subjective well-being. The older self that begins to disengage from the struggle of life, putting all decisions into default mode, or into the hands of others, is more likely to enter into a phase of hopelessness, pessimism and decreased ability to recover from illness or surgery (Carver & Scheirer, 1998, p. 357). The sense of importance attached to self and goals is diminished as more defaults take over governing action patterns until there is nothing that needs our attention-demanding decision-effort. American nursing care facilities are already overcrowded with the rapidly increasing population of older Americans.

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Gerontologists alert us to the fact that it is critical to find ways to allow the elders to be involved in real-time problem solving and decision making. As my father entered his golden period, it was my role to help him navigate the years with dignity. Insisting that care givers call him by his full name and career-earned title of address did not win me popularity with rehabilitation staff and home care providers who wanted to use first names, driving for instant friendship and intimacy.

The practice in Western cultures of treating an older adult like a child rushes a *self* into default activity and precipitates a cusp catastrophe shift of self-concept back into early life phases of dependency. Elderly people cling to survival since they have been robbed of working on their basic goals, i.e., adequacy, growth, and meaningfulness that produce the sense of importance. We are cultivating a mounting population with untapped resources, wasting irreplaceable talent and energy. Taking over problem-solving activities and importance from tenured selves destroys identity and purpose, hastening the end of the person(ality).

LIFETIME ACHIEVEMENTS AND TRACK RECORDS: WHAT-I-PRODUCE

The who-how-what model of self-concept is inspired by something-old and something- new. The something-old is one of my long time favorite teaching *tools*. Participants in the leadership development courses I teach never fail to respond to a simple three-level chart I sketch to remind them that their job requires attention to the 3 Ps:

1. Product (task, mission: *what* we are doing or producing)
2. Process (relationships, interactions, methods: *how* we are doing it)
3. Persons (individual skills, well-being, interests: *who* is doing it)

The typical European-American self-concept reflects belief that a personal *self* is the primary agent. The individual is responsible for actions and for maintaining internal consistency. Self-ways of Japanese, Korean, and Chinese groups included in these studies are described as the person perceiving their self as embedded within relationships. The individual assumes responsibility for behaving flexibly in their particular community in order to maintain and further the welfare of their relationships and the larger community. In the Asian self way, priority attention is given to interactively defined meanings over the private meanings held by any individual self.

European-American self-concepts are organized to be aware of how the social order can be reconciled with what these researchers called an 'all-important individual order'. In contrast, the self- ways of Korean, Chinese, and Japanese persons who come from the Confucian tradition will emphasize achievement of virtue through development of the individual into a socialized person, a self that assures that maintenance of social order will prevail over individual rights or divergent opinions. This sounds similar to the work objective of the psychologist from the iron -curtained Russia who stated in personal conversations during the 1983 International Union of Psychology convention that the job of the Soviet psychologist was to shape individuals into model communist citizens.

The studies of African self-ways, generalised across 47 countries, multiple religions and ethnic groups, indicate more similarity to the Asian self-way than to the Euro-American self way, but includes several distinct characteristics. For example, the African self-way is reported to place greatest emphasis on *what-I-produce,* i.e., add to the group. Personhood and individuality were reported to emerge late in life, based on achievements such as children and contributions to the maintenance of the community. Given present data, most likely the strong hierarchical and longitudinal *reference values* prevent fostering of selfhood until the end of the life span. In many African groups, it is considered rude or dangerous to talk about the self. Many African social systems seem to be vertically organized collectives that ascribe active responsibility for self-way management to deceased ancestors, who are believed to afflict people who have been disruptive to 'right relationships within the social order'. (Markus, Mullally, & Kitayama, 1997, p. 43.)

The globalisation of daily news, electronic mail communications and multinational business alliances may usher in a new era of self-ways. Undoubtedly, it will be a very long time developing a cultural climate to support a self-concept in which the 'hometown' identification embraces the 'global village' that gives priority to being a 'world citizen'. Nevertheless, it would be worthwhile and interesting to track the gradual merging and integration of self -ways, a progression that may have to follow a route similar to one suggested for classifying *globalisation* stages of development in business environments (Ayman, Kreiker, & Masztal, 1994) as indicated [below] on the next page.

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INTERNATIONAL ORGANISATIONS		GLOBAL ORGANISATIONS	
Stage 1	**Stage 2**	**Stage 3**	**Stage 4**
Ethnocentric	Polycentric	Regiocentric	Geocentric
Export-import	Offices in	Strategic plans	Multinational
National controls	Several countries	Made regionally	Equal status
Self-ways separated	Self-ways respected	Balancing of private and social in all self-ways	

Plotting a course of self-way adjustments that would enable individuals to adapt, survive, and thrive in an era of global consciousness is, admittedly, is an ambitious undertaking. Self-concept change is considered to be hard work and painful, but possible. It is predicted to be easiest if one reference value (goal) is set aside and another is at hand to take its place. It is important that there is a link from the new reference value (i.e., action goal) to higher-order values and goals. In the process of making such links more visible and accessible, models of global self-concept development may play an increasingly important role in shifting national and cultural self-ways away from extremes of private and social self-ways, that serve as substrata for aggression and war (Groebel & Hinde, 1989, 1991; Spielberger, Reheiser, & Sydeman, 1995). New self- ways will assign to the self a creative function, tasked with the job of effortful problem solving to find ways for expressing anger in productive-constructive modes (Pelligrin & Spielberger, 1995, O'Roark, 1988, 1989, 1990, 1992).

The innovative effortful thinking products of a self, of a social group, or of an era can contribute more or less to survival of the species. Some of the more compelling questions an American therapist or consultant asks a client are: How do you want to be remembered when you are dead?; What is it you wish to achieve/accomplish/do before you die?; If you were told you would die in six months, how would you use your time? Answers vary depending on the individual, and according to the self-way. Our products, artifacts, knowledge, children or students are tracks we leave in the sand. These are the bones and fossils of a self-concept.

REFLECTING ON GLOBAL SELF-CONCEPT

Criteria for a good theory in science call for the conceptualization to be a logical set of related assumptions that explain a set of observations, is built on previous knowledge, and is simple and testable. Aldefer (1956) simplified the thinking about universal needs of the self (security, relatedness, growth). Jung (Myers & Myers, 1980; Myers & McCaulley, 1989) simplified the self-as-process by proposing that we all have two tasks in life: to gather information (perception) and to make decisions about what to do based on that information (judgement). Einstein (*Time,* 1979) and Wilson (1998) simplified the universe by conceptualising the unity of knowledge (fundamental principles are at work everywhere).

These foundations imply that a sensible understanding of the self-concept is possible. Sophisticated theorems and evidence of the power of the unconscious mind and of external manipulators over judgement and behavior (Azar, 1996; Skinner, 1956; Levinson, 1973) do not take away from the power of hope (Snyder, Cheavens, & Sympson, 1997; Snyder, Irving, & Anderson, 1991; DeAngelis, 1991; Frankel, 1957; McClelland, 1965), or the need for trust (Gibb, 1978; Jourard, 1964; McDonald, Kessel, & Fuller, 1972; Pelligrin & Spielberger, 1995; O'Roark, 1999 in press).

What the new science principles teach us about the self-concept is that there is order, even in chaos and catastrophe, that there are universal goals (reference values) that serve as the GPS calculators for the self-concept's life journey, that we are growing or dying (Eiseley, 1946, 1957). Dying is the clogging up of the mind with established defaults (Carver & Sheier, 1998) that are no longer questioned nor examined.

Fortunately, the nature of the self-concept is dynamic, a vehicle for conveying a continuous self-identity across the developmental phases of the life cycle. It is likely that there are 'set points' in the culturally divergent self-concept systems that endorse greater or lesser levels of positive regard, for greater or lesser degrees of dependence and independence, for greater or lesser degrees of ambiguity, or authority, or other social status variables.

How do we discover the optimal combination of valences within a self-concept system in order to reduce hostility, aggression, violence, hatred, and xenophobia? How can the inner editing of *who I am* be infused with productive optimism, adequate humility and generous attitudes? How can the self-concept system promote the creative survival mix of the elemental emotions such as curiosity, anxiety, anger, affection?

It is not spurious that ancient wisdom concluded that God goes by the name of Elohim - 'I am who I am', and that this self-way is important for people to keep in mind as they strive to survive, co-exist and collaborate. As new science psychologists work out the underlying mechanisms of human well-being and quality of life, the best theories will build on accumulated wisdom and evidence,

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while opening new paradigms and delving deeper into how people go about editing *who-I-am*.

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EXPLORE DIFFERENCES AND SIMILARITIES IN HUMAN VALUES: CULTURAL AND CROSS-CULTURAL RESEARCH APPROACH

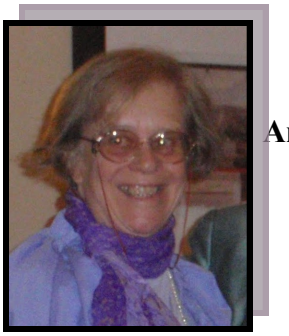

Anna Laura Comunian, Ph.D.
Director at Large, ITALY

" I am not an Athenian, or a Greek, but a citizen of the world"
Socrates

Cultural and Cross-Cultural Research Approach explore differences and similarities in human values. Each of the approaches has a place in the attempt to relate culture and psychological processes.

Cultural psychology refers to the branch of psychology that holds that human behavior is significantly influenced by cultural differences, meaning that psychological phenomena can only be compared with each other across cultures to a very limited extent. Cultural Psychology has continued to expand, incorporating culture and diversity into studies.

Cross-cultural psychology is the scientific study of human behavior and mental processes, including both their variability and invariance, under diverse cultural conditions.

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Examination of the kinds of the people who are studied by cross-cultural psychologists suggests that they considered the construct of "cultural distance" as reflecting differences in language, social structure, religion, political system, level of literacy etc. Cross-cultural psychology includes a search for possible universals in behavior and mental processes.

Psychologists have used the *emic/etic distinction* for some time. The *emic* approach studies behavior from within the culture, and mostly is based on one culture; the *etic* approach studies behavior from outside the culture system, and is based on many cultures. Researchers working across cultures need recognize and protect their own and their partners "cultural autonomy", their social goals, knowledge and values. One reason to collaborate across cultures is that many global problems –diseases, conflict and inequity without global partnerships.

Currently, many psychologists conducting cross-cultural research use what is called a pseudoetic approach. This pseudoetic approach is actually an emic based approach is designed to work as an etic approach.

The relationship of culture and psychology is conceived rather differently by different kinds of psychologists. In this paper some of these conceptions are presented and a possible synthesis among the points of view is proposed.

Researchers working across cultures

Hofstede's cultural dimensions theory. One of the most active research traditions in cross-cultural psychology is Hofstede's cultural dimensions theory. This theory found that cultures differ on four dimensions: power distance, uncertainty avoidance, masculinity-femininity, and individualism-collectivism (Hofstede, 2001). Alternative measures to assess individualism and collectivism were proposed (McSweeney, 2002). Indeed, the individualism-collectivism debate has itself proven to be problematic. Strong individualistic and collectivistic orientations can coexist in various countries.

Personality Factors. How to compare traits across cultures have often questioned. To examine this question, studies measuring personality factors, using trait adjectives from various languages, are known as lexical studies (McCrae, 2012). Over time these studies have concluded that Extraversion, Agreeableness, and Conscientiousness factors almost always appear, but Neuroticism and Openness to Experience sometimes do not. Nevertheless it has been determined that the Five-Factor Model is a universal structure and can be used within cross-cultural research and research studies in general.

Emotions. People emotions have been interpreted in similar ways across various cultures. In the field of cross-cultural psychology Ekman et al. (1987) have conducted research examining judgments in facial expression cross-culturally. One of his studies included participants from ten different cultures. They were required to indicate emotions and the intensity of each emotion. In result, the study showed that there was agreement across cultures as to which emotion was the most intense and the second most intense. These findings provide support to the view that some cross-cultural psychologists hold in which there are universal facial expressions of emotion.

Facial Expressions. Facial expressions are said to be universally: Huang and his colleagues (2001) performed research that looked at how a culture may put different labels on certain expressions of emotions. Their findings show support for the notion that there is a cross-cultural difference present in emotional judgement. Also, because every culture has different values and norms, it is important to analyze those differences in order to gain a better understanding as to why certain emotions are interpreted differently or not at all.

Subjective Well-being. Also the term "subjective well-being" is frequently used throughout psychology research and is made up of three main parts: a) life satisfaction (as cognitive evaluation of one's overall life), b) the presence of positive emotional experiences, and c) the absence of negative emotional experiences (Suh & Oishi, 2012). Across cultures people may have different opinions on the "ideal" level of subjective well-being. When comparing subjective well-being cross-culturally it appears important to take into account how the individuals in one culture may rate one aspect differently from individuals from another culture.

Social Conflict. How cultures differ in the ways they approach social conflict and how culture continues to be an important factor in human development even into old age was also evidenced. For example Grossmann et al. (2012) found that Americans emphasize individuality and solve conflict in a direct manner, while the Japanese place an emphasis on social cohesion and settle conflict more indirectly. The Japanese are motivated to maintain interpersonal harmony and avoid conflict, resolve conflict better, and are wiser earlier in their lives. Americans experience conflict gradually, which results in continuous learning about how to solve conflict and increased wisdom in their later years. The current study supported the concept that varying cultures use different methods to resolve conflict.

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Differences in conflict resolution

Differences in conflict resolution across cultures can also be seen with the inclusion of a third party. These differences can be found when the third party becomes involved and provides a solution to the conflict (Lieche, 1992).

Gender roles. Williams and Best (1990) have looked at different societies in terms of prevailing gender stereotypes, gender-linked self-perceptions and gender roles. They both find universal similarities as well as differences between and within more than 30 nations. One of the main findings overall was that under the topic of sex and gender pan-cultural similarities were shown to be greater than cultural differences. Furthermore, across cultures in social groups the way in which men and women relate to one another has shown to be similar. Further calls have been made to examine theories of gender development as well as how culture influences behavior of both males and females.

Childrearing practices. Berry et al.(1997; 1992) refer to evidence that a number of different dimensions have been found in cross-cultural comparisons of childrearing practices, including differences on the dimensions of obedience training, responsibility training, nurturance training (the degree to which a sibling will care for other siblings or for older people), achievement training, self-reliance, and autonomy. On cross-cultural influences on child development, the following topics were shown to consistently come up: a)to conceptualize variability within and across cultural settings, b) to characterize activities of the child's mind, and c) to improve methodological research in culture and development (Super & Harkness,1997).

Future developments

The future of the relationship of culture and psychology may include more investigations which use methods of both cultural and cross cultural psychology and collaborations between cultural psychologists providing the data from one culture and cross-cultural psychologists utilizing the data of cultural psychologists from many culture to understand both universal and culture-specific influences of culture on psychological processes.

The rise of cross-cultural psychology reflects a general process of globalization in the social sciences that seeks to purify specific areas of research which have western biases. In this way, cross-cultural psychology aims to make psychology less ethnocentric in character than it has been in the past. Cross-cultural psychology is now taught at numerous universities located around the world, both as a specific content area as well as a methodological approach designed to broaden the field of psychology.

The psychologists can help to solve global problems depend on the ability to collaborate with colleagues of other cultures and promote more and better cultural and cross cultural research, increasing capacity, empowered colleagues, personal growth, and a stronger and healthier global community.

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INFUSING GLOBAL PERSPECTIVES: PROVIDING STUDENT WITH OPPORTUNITIES TO CONDUCT INTERNATIONAL PSYCHOLOGICAL RESEARCH

Richard Velayo, Ph. D., Lucio Forti, Simin Ghahghahi, Sonia Javani and Hina Siddiqui
Pace University, New York

(From left to right): Sonia Javani, Hina Siddiqui, Richard Velayo, Ph.D., Simin Ghahghahi, Sarika Persaud (PsyD student in School-Clinical Psychology program), and Lucio Forti

Within the last two decades, there has been a noticeable increase in the number of psychology instructors who are exploring ways to incorporate a greater international content and infuse enhanced international perspectives in the courses they teach. One key strategy in achieving this goal is by providing students to join research teams that encourage international and cross-cultural research in psychology.

At Pace University in New York City, there are several

More specifically, 5 of the 11 active faculty-led research teams (http://www.pace.edu/dyson/academic-departments-and-programs/psychology---nyc/research-groups) provide valuable research mentorship for student academic and professional development. Students may become involved in any or some of research teams as part of their major or program of study by registering for an independent study course, a mentored lab class, or through a thesis or dissertation project. One of the research teams worth noting is called the "Internationalizing the Teaching of Psychology (IToP) team led by Dr. Richard Velayo, Professor of Psychology at Pace University. His research group called "Internationalizing the Teaching of Psychology (IToP) Team (http://rvelayo.jimdo.com/itop-team/) involves research that focus on strategies that help infuse international content and promote a global perspective within the discipline of psychology at the higher education level. More specifically, IToP's research involves projects related to the following: (1) identifying effective pedagogical strategies to internationalize psychology courses, (2) developing of an assessment tool for an internationalized psychology course, and (3) applying Internet-Based Technologies (IBTs) as teaching and research tools to help infuse international content. Research projects generally involve looking at cross-national differences of psychological constructs, psychological practices and perspective in countries other than the U.S., the design and development of online surveys administered to various countries, identification of and access to resources (e.g., instructors, courses, multimedia materials), and curriculum-based applications of IBTs. Students involved in his team get to present their individual or group projects at local, regional, national, and/or international conferences. Some of the psychology conferences in which the IToP team has presented in include the annual meetings of the American Psychology Psychological Association, Eastern Psychological Association, Greater New York Conference on Behavioral Research, Hunter College Psychology Conference, International Council of Psychologists, and Pace University Psychology Conference.

Since fall 2015, there have been 12 students who have been part of the IToP research team. There are currently 4 individuals (one masters alumnus and three current masters students) this spring. Each student is actively undertaking research projects of interest to them, which ties in one of the topics related to the IToP team research subtopics (as mentioned above). At each weekly meeting, students provide the entire team with updates about their individual work and discuss preparations for presentations (e.g., poster, paper, symposium) at an upcoming confer-

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ence. Students are encouraged to present their work at student-focused, local, and/or regional conference held during the latter part of that semester or the following semester. This fall 2015 semester, the IToP team highlights three student research projects. Below are brief descriptions written by current IToP students about their projects:

Lucio Forti (lforti@pace.edu) (Alumnus, MA in Psychology)

"Designing an Internet-Based Infrastructure for an International Leadership Network"

This project will review currently existing technologies that may be used by leaders in the field to establish a network through communication and collaboration among psychologists, psychology students. Elements of a modern workflow for collaboration will be presented as well as tips for successfully managing tools and user training. The feasibility of using webconferencing tools (e.g., GoToMeeting, Blackboard Collaborate) to facilitate meetings and presentations and to archive these in video, audio, and chat formats will also be explored as a way to make them to those unable to attend, or used for further collaboration and training.

Simin Ghahghahi (sg71695n@pace.edu) (Student, M.A. in Psychology)

"Cross-cultural examination of depressive rumination in college students: Brooding versus reflection"

This research project will examine studies on rumination in college students, focusing on depressive rumination and its two subtypes: brooding and rumination. There have been studies done on how gender, mental disorders, etc. play a role in rumination, but there is little research on how race, ethnicity, and culture play a role in rumination -- depressive rumination to be specific. This paper will also provide a review of how culture plays a role in type of rumination a person uses and will compare results of studies done from people in the United States versus people in other countries such as Japan, Russia, and the United Kingdom.

Sonia Javani (sj09763n@pace.edu) (Student, M.A. in Psychology)

"Cross-cultural study of Autism Spectrum Disorder: Review and recommendations on closing the gap among developed and developing countries"

This research project will review the differences in prevalence rate, management, and support programs that are available to individuals with Autism Spectrum Disorder and their families among developed and developing countries. The lack of prevalence studies in developing countries is believed to account for the limited information on the identification of children with this condition, the dearth of support services, and insufficient management of this disorder. Educating the society to break the stigma, delivering culturally competent screening tools, and promoting international organizations to increase advocacy action for individuals with ASD are some of the recommendations mentioned to assist and close the gaps.

Hina Siddiqui (hs80890n@pace.edu) (Student, M.A. in Psychology)

"Comparison of Diagnosis and Treatment of Mood Disorders between Pakistan the United States"

There have been several studies on the diagnosis and treatment of major mood disorders in the United States and drawing a clear and concise association and comparison between the methods used in the United States with the methods used in Pakistan would be beneficial. This research project will focus on some of the symptoms associated with these disorders, and briefly touch upon suicidal ideations. Diagnostic and treatment approaches used in Pakistan versus those in the United States will be compared. Suggestions on future research and clinical practices that address cross-national and cross-cultural variations will be presented.

These student-initiated projects exemplify research that contributes to international content that may be infused in the teaching of courses in psychology. Such research projects provide not only content that may be shared with other research team members, but will also be archived as student research projects accessible to other students and instructor in the departmental for instructional purposed or to motivate further international research. Additionally, these projects help cultivate a more international perspective about the discipline of psychology and a greater appreciation for psychological constructs taking into consideration the cross-cultural and cross-national contexts in which it applies. There is tremendous value in getting students involved in the internationalization the teaching of psychology, particularly in the U.S. More importantly, it is essential to prepare them for a society that is increasingly becoming global.

For more information about this presentation and of the IToP team, please contact Dr. Richard Velayo at rvelayo@pace.edu.

ICP INC ACTIVITIES AT THE UNITED NATIONS-VIENNA, AUSTRIA

Roswith Roth, PhD.
UN Representative—Vienna
Austria

I attended the **Conference of NGOs in Consultative Relationship with the United Nations** (**CoNGO**) a celebration of "**70 Years United Nations and Cooperation with NGOs: Shared Ideals, Shared Values, Shared Futures ,The Role of NGOs in Securing a Sustainable Future"** on Monday 5 October 2015 at the Vienna International Centre (VIC).

This event was celebrated in New York and Geneva earlier this year. The program consisted of a welcome address of **Wolfgang Beigelboeck**, the CoNGO Vice-President, Vienna, an introduction **by Cyril Ritchie**, President of Congo, with the title "Shared Ideals, Shared Values, Shared Futures" and two keynotes by **Martin Nesirsky**, Director, United Nations Information Service (UNIS) Vienna and **Stefano Prato**, Managing Director, Society for International Development (SID), Rome. After the keynotes statements were given by **chairs of the NGO Committees in Vienna.**

Mr Beigelboeck stated that October 5, 2015 is this year the "World Habitat Day". In Resolution 40/202 of 17 December 1985, the UN General Assembly designated the first Monday of October of every year as World Habitat Day. In 2015, the United Nations chose the theme ***Public Spaces for All.*** The World Habitat Day 2015 campaign aims to recognize the challenges and issues around Public Spaces. The streets and public spaces have often been overlooked and undervalued, but are increasingly being considered the backbone of cities. Public spaces are places which are accessible and enjoyable by all without a profit motive and take on various spatial forms, including parks, streets, sidewalks, markets and playgrounds. Good public spaces enhance community cohesion and promote health, happiness, and well-being for all citizens as well as fostering investment, economic development and environmental sustainability. Additional he stated that UN is working in dangerous situations, doing dangerous work at dangerous places and fosters the relationship between local and international NGOs. Above all the UN is expected to be the governor of peace and human rights. The diversity of NGOs is both strength and weakness at the same time they give a vital contribution for the citizens of the world.

Mr Ritchie talked about "Shared Ideals, Shared Values, Shared Futures": these lead to shared actions. Actions depend on the courage of NGO members. Many or most UN conventions come from NGO initiatives. NGOs have to be vigilant to spread good practices. But there are obstacles: (1) money: UN has serious problems to get money from members, (2) implementation - NGOs have to put pressure on governments to implement the UN decisions and resolutions and (3) increasing restrictions of NGOs. Considering shared futures NGOs have been coming an immensely long way as a voice of the people. For 2030 - we should plan implementations and actions for shared responsibility we not only want but we need!

Mr Nesirsky said CONGO is nurturing and fostering cooperation of UN-NGOs and civil society. Civil society is the oxygen of the society, peace and human rights. No country can do this alone. NGOs are supporting UN and they also monitor the work, analyze it and evaluate failure and success. Peace to the People and the Millennium Goals aim that less than 10% of people will live in poverty soon. The extreme poverty rate has been halved, but major challenges remain. This is done jointly, done together, evaluating the shortcomings, taking actions to prevent backslide, securing the chance for the future.

Mr Prato talked about the theory of change which is unfolding around us 7 pillars - growing and expanding goods - water today, air tomorrow - forms of homogenizations: you find all the same products at the Amazonas or in New York - cooptation of science - decreasing role of the state - loss of serenity - shrinking of democratic space - numbers over voices - pressure of media - progressive capture of public space - use of law as instrument of power - nutrition. Several challenges are related to modernity: existential challenges, second causes of deaths are suicide, 800.000/yrs., ethical aspects of science and technology, poverty, violence and culture of violence, kids are daily exposed, data revolution etc. "Non-state actors (NGOs)" are merging private and public interests, are a public - private relationship, with no conflict of interests.

The following NGO Committees reported and gave statements:

- Committee on Aging
- Committee on the Status of Women
- Committee of Peace
- Committee on Sustainable Development
- The conference gave a good overview of the challenges and success of NGOs in the UN.

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I attended the 60th Session of the Commission on the Status of Women which included a Live Stream session of the CSW60 Opening Ceremony at the UN in New York.

The Program consisted of a welcome remark of Anne Thomas, the Deputy Director of the United Nations Information Service (UNIS) Vienna, Focal Point for Women for UNOV and UNDOC.

The Chair of the NGO Committee on the Status of Women, Vienna Martina Gredler, gave an introduction. Marlene Parenzan, a member of the NGO Committee on the Status of Women at the UN Vienna, a former chair of the NGO Committee on the Status of Women Vienna gave a speech about Some thoughts of a long-term observer and activist and Eva Maria Burger, Deputy Head of the Department for Socio-Economic Equality, International and EU Affairs at the Austrian Federal Ministry of Education and Women's Affairs gave a Keynote. Then we attended the Live Stream Opening Session of the Opening of the 60th Session of the Commission on the Status of Women. All attendants expected to see in New York a female chair and more female speakers.

ICP INC ACTIVITIES AT THE UNITED NATIONS-NEW YORK, USA

Florence Denmark, PhD
Main Representative UN
New York

In the past year, as usual, ICP representatives have been very active at the United Nations. They have been active participants of various committees such as the NGO Committee on the Family, the Ageing Committee, Migration Committee, Human Rights Committee, and the Committee no the Status of Women.

In New York, we have the following NGO Representatives: Martin Butler, Florence Denmark, Eva Sandis, Norma Simon, Richard Velayo, and Pete Walker .

Florence Denmark, the Main Representative for the ICP NGO UN Committee, is serving as the co-chair of the UN NGO Family Committee. In addition to her active role in the Family Committee, Florence Denmark has been holding monthly meetings for the New York Representatives and interns. Florence also is active on the Executive Committee on Ageing. She served on the International Day of Older Persons (IDOP) Committee and the Administrative Committee for the Psychology Day Program (having chaired or co-chaired the Psychology Day for its initial 3 years).Florence is also active on the Psychology Coalition at the UN (PCUN) chairing the Nominating Committee. Florence represented ICP on the CONGO Committee Board. CONGO represents all the NGO Committees and ICP was one of the few NGOs to be elected to the CONGO Board.

Martin Butler served on the Psychology Day Planning Committee for the 2015 Psychology Day. He was also a member of the Psychology Coalition, and he helped interview potential interns for ICP. he was also a member of the Committee on Migration.

Norma Simon serves as the Corresponding Secretary of the UN NGO Family Committee. Dr. Simon has served as a member at large for the NGO Committee on Ageing. She has also served on the Post 2015- agenda subcommittee, the Hazzard subcommittee, and the website subcommittee. She was active on the International Day of Older Persons Committee and arranged the luncheon for 80-100 people for the event. Furthermore, she was an active participant on the sub-committee for Psychology Day at the UN and arranged the reception for the event.

Pete Walker has concluded a two year term as a founding officer and Treasurer for the Psychology coalition at the United Nations (PCUN) and has rejoined the NGO Committee on Ageing-NY, where he participated in preparation for the 25th annual Internal Day of Older Persons (IDOP). In this capacity, Dr. Walker has made a substantive historical contribution to the Planning Committee, which this year is focusing on UN Habitat III, to be held in 2016. Additionally, he has been participating in the NGOCOA-NY Website Committee, which will see the launch of the new NGOCOA-NY website in early May. Recently nominated to serve a two year term on the NGOCOA Executive Committee as Member-at-Large, he also serves on the Virginia Hazzard Fund Committee, which is now seeking a new project regarding older persons' literacy. Also as a past co-chair of the second Psychology Day at the United Nations, Dr. Walker participated on this year's Advisory Committee, planning the 9th Annual event that was held in late April. In mid-April he was a panelist in a Health Cities Lecture for the Urban Studies Program at Fordham University in New York. His topic was "Coastal Cities and Climate Change".

Eva Sandis has been very active on the Migration Committee, having been a former chair. She has been focused on two principal items:

1. Advocating for the post-2015 agenda, especially on interventions for the human rights of migrants and their families worldwide: at NGO Briefings, whether with ECOSOC or at the UNGA

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Intergovernmental Negotiations or in preparation for the Commission on Population and Develop ment.

2. Pushing advocacy on migrants in transit, especially women and children. Her subcommittee is preparing an advocacy brief both for the UNHCR NGO Consultations in Geneva in July and for the GFMD in Turkey in October. Eva will attend the meeting at Geneva. We are fcalling for a Comprehensive plan, which includes protections for migrants and their families before they are in transit, during transit, and post-transit (similar to the comprehensive plan that States adopted for Vietnamese refugees).

Richard Velayo was part of the Planning Committee for the 9th Annual Psychology Day, which was held on April 28, 2016. The theme of the conference was "From Vulnerability to Resilience: Using Psychology to Address the Global Migration Crisis." He presented at the 2015 ICP Conference in Toronto. The title of his presentation was "Importance of Psychology Day at the United Nations, which was also part of the panel session about ICP at the UN this past academic year.

In Geneva, Anna Laura Comunion has been serving on the Human Rights Committee, and Roswith Roth is active in the UN headquarters in Vienna, serving on the Committee on the Status of Women.

We are also very proud of our interns at the United Nations" Massoma Alam, Tamara Alaryan, Niki Davis, Amanda Gooden, and Sonia Javani. They were selected by a committee, headed by Norma Simon, who coordinated intern activities. They have been involved at the UN through attending and participating in many NGO Committee meetings, DPI briefings, Psychology Coalition meetings, and the planning of the ninth Annual Psychology Day at the UN. The interns were, in particular, very active in the family Committee and the Ageing Committee. They had the opportunity to work closely with the APA interns in assisting and planning numerous events such as International Day of Older Persons, Family Committee end of the year event, and the ninth annual Psychology Day at the UN.

IDOP was a great conference at the beginning of their internship and exposed them to the operational details of holding a large conference. Their responsibilities included data analysis and inputting with managing the guests that have registered either for the main event held at the UN headquarters, and guests that have registered for the reception following at another location. This experience exposed the interns to the populations of which The Committee on Ageing effects and individuals that work to help with their cause. The following reception was a warm welcome for the interns. They were able to hear speeches from the sponsors and organizations, as well as network with members of the executive committee. Before it began, the interns were integral in organizing seating plans and registration. They coordinated with the restaurant staff to ensure all was set and ready before any guests began to arrive.

Other activities that the interns participated in was creating flyers for events for the Family Committee and Ageing Committee, assisting the IDOP luncheon, and serving as guides to help participants find the location of the event. Furthermore, the interns participated in discussions, asked questions, and also made suggestions at executive meetings. The ICP interns along with the APA interns were required to an hour presentation along with Q&A related to family for an event by the Family Committee. The name of the presentation is "Different Causes of Family Trauma: Finding Resiliency on a Global Scale," and includes three subcategories including "Effects of Sexual Violence in War and Conflict on Families, Forced Political Migration, Trauma and the African American Diaspora.

As a final challenge, the interns were asked to assist in the organization of our Annual Psychology day at the UN. As many of them had previously participated in Psychology Days as guess,. There inputs were valuable in continuing and exceeding the expectations of previous yars. Many interns committed themselves to the publicity committee, ensuring that the event was widely marketed and trending. Many held other roles in programming, fundraising, and all played a hand in logistics on the day of. It is with the help of the ICP interns that all of our guests feel welcome and are guided through the UN headquarters to the conference room where speakers and presentations await them.

BOOK REVIEWS

Sandra E. S. Neil, PhD.
ICP, Inc. Director at Large
World Area Chair Coordinator
2014-2017

Sarwono, S. W. (2015). *Indonesian Terrorists in Psychoanalytical Perspectives.* SWAN World: Paris. ISBN: 978-2-84924-426-5.

In Professor Sarlito Sarwono's (2015) book, he explores this notion of 'the hand that disturbs' as a representation; sometimes of the devils' hand, the monster in us, against existing norms. He then presents us with the deradicalisation program for ten ex-terrorists (who were terrorists in Indonesia), and includes Davido's interpretation of each one. There are some very interesting facts that emerge. For example, in a case of a young man who was studying Islam and became a radical, Professor Sarlito Sarwono writes: '..his childhood experience was not that good. He was born in a middle-class highly educated family. His father was an engineer, graduated from a famous engineering institute at Bandung, and worked as a staff at the local government of Jakarta. All his five children has good education….But MI became radical as a reaction formation toward the abusive treatment from his father. He was the only child (amongst five children of his fathers) who was maltreated…' (p.70).

I am totally convinced by this particular projective method, as I have used it myself to trace multicultural families, to trace people who are in blended families, and, in adoptive families, who bring young children into their already succinct family that has grown up. I've have pictures shown to me by two little Thai children, with little language (from age 3 onwards), their pictures of their family, and the moment that disturbed them. I had one little boy showing me how his family was before the second adoption and how it changed for him completely when the second child was adopted (age 3), within the CHaD drawings.

As far as projective testing goes, it is difficult to give the inner and the outer interpretations and diagnostics without making reference to all kinds of aspects, like: pathognomonic signs, the isolation of the person, the mistreatment, the guiltiness of people, their hyper-control, the relationship with each person (including children) to death, the depression in the person, and their mental deterioration, and, isolation anxiety. It's also possible to look to the absence of psychopathology.

Overall, these two books [*The Davido-CHaD in Practice* and *Indonesian Terrorists in Psychoanalytical Perspectives]* are convincing in the effectiveness of the use of the Projective Personality Test. I would recommend them to anyone who deals with families, children and adults. I believe both, adults and children, together in family therapy make a very convincing statement using this test about their own, and, family functioning.

Publisher note: Dr. Neil's review of Dr. Davido's book was published in the *International Psychologist 56.1*. That issue can be found at the ICP, Inc. website: ICP-WEB.ORG.

Judy Kuriansky, PhD
Editor

Many of us around the world struggle with flu season, and know the discomfort and distress associated with that infection. Sadly, in recent times, we became aware of an extreme viral disease, the Ebola epidemic, that ravaged West Africa and threatened many other countries around the world. Initially a mystery, and not declared the world health emergency it actually was, information ultimately circulated about medical issues like symptoms, causes of contagion, and (lack of) cure. However, our international psychology community became alert to the psychosocial issues of this virulent disease that was not getting the attention it deserved. Fear, stigma and discrimination reigned. While media was blamed for causing widespread panic, psychological science and practice needed to be highlighted.

For this reason, the Psychology Coalition of NGOs accredited at the United Nations (PCUN) held a forum in September, 2015, on the topic of "**Eradicating Stigma & Promoting Psychosocial Wellbeing, Mental Health and Resilience in the Ebola Epidemic:** *Policies and Practices to Protect the Global Community."* This forum emanated from the Ebola Task Force, chaired by Dr. Corann Okorodudu, that I convened in my role as PCUN Chair.

Continued next page

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A brilliant collaborative effort put together a stellar event, sponsored by the Mission of Liberia to the United Nations (Corann's home country, and also one of the three most-affected countries)), and co-sponsored by other missions, including Guinea (also among the three most-affected countries), Uganda, Nigeria, the Netherlands and the USA. This was a precedent for our international psychological community at the UN. Moderated by Okorodudu, the panel had exceptional multi-stakeholder representation, including, speakers from UN agencies (UNICEF, UN Women and WHO), the NGO Committee on Health, a report by Skype from Sierra Leone by Yotam Polizer who is the head of psychosocial programming for IsraAid, an Israel-based international humanitarian NGO, as well as a presentations comparing Ebola to HIV/AIDS by PCUN member Miriam Vega, and an overview and commentary by me about media involvement (in my role also as a journalist) and implications for the Sustainable Development Goals. The panel was held in Conference Room 7 of the UN Conference Building, to full capacity.

The perspectives from top-level UN policy makers and NGOs on the panel and participants in the discussion illustrated to the entire conference how imperative it is that psychosocial issues be addressed in any health crisis.

As a result of the connection with Polizer, I went to Sierra Leone shortly thereafter, during the epidemic, to help them develop and implement psychosocial workshops and trainings for survivors, children, communities, burial teams, hotline operators, social work students, first responders and other helpers who could carry on the work to make it sustainable. Many valuable programs were initiated, and connections made with an extended community of responders from local and international NGOs.

After the epidemic subsided, I returned to Freetown, to participate in the Conference on Mental Health – appropriately called Build Back Better – and to further the earlier work and consolidate connections, since we know from a psychological perspective that the healing process goes on for years after an immediate crisis has abated. In between those times, many conferences of high-level officials, panels, and multistakeholder partners were held at the United Nations concerning Ebola, that I attended.

The goal of keeping the awareness alive about the psychosocial issues – of what I call the 3 S's (stigma, silence, shame) as well as the pain, mourning losses of loved ones and livelihood, ongoing trauma, and rebuilding personal life, relationships, and community – led me to put together a volume titled **The Psychosocial Aspects of a Deadly Epidemic: What Ebola Has Taught Us About Holistic Healing.** See: http://bit.ly/1o4c3wK. Given the traumatic feelings triggered by the epidemic, and the cultural relevance of music in the region, a song was co-written for the workshops (with my co-lyricist Russell Daisey, an international composer) called "Hope is Alive", that became a theme song for many groups, as it stimulated hope and created joyful connections between people who had felt so alienated from each other by the fear of infection. The book has just been released. It includes an impressive collection of chapters by outstanding experts, addressing the issues faced by children, women, survivors, hotline operators, and many other constituents, as well as perspectives of cultural competence, education and public service campaigns, the UN response, and policy recommendations.

The issues are relevant to many other diseases, including the recent ravage of the Zika virus, that has devastated families in Brazil and elsewhere in the world. Videos that dramatically show some of the workshop materials from my work related to Ebola recovery, and also the situation during and after the height of the epidemic, can be seen at http://bit.ly/1KVHgqA (about a workshop with a burial team), and at http://bit.ly/207xXL7 (about Ebola in Sierra Leone: Psychosocial Issues During and After the Outbreak). Do contact me if you are doing work in the area: DrJudyK@aol.com

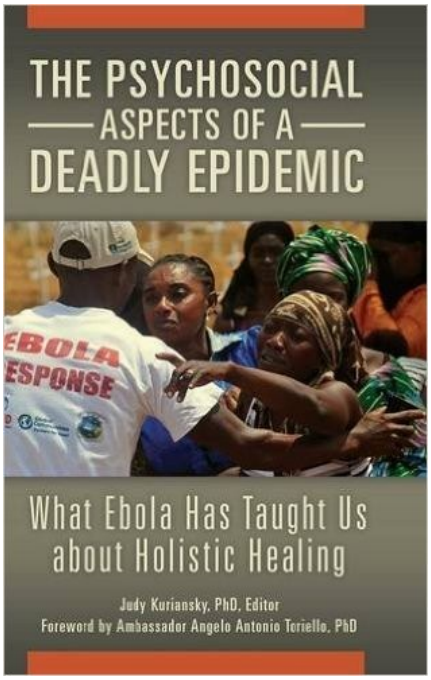

74th ICP INC ANNUAL CONVENTION AWARD WINNERS 2016

Josephine Tan, PhD.
ICP, Inc. Awards Chairperson

Every year, ICP, Inc. accepts nominations for several awards. Each award has a chair person who works tirelessly to be sure candidates are vetted for that award. It is with great appreciation that I announce the winners of this year's awards and express my heartfelt thanks to all of the chairs for their hard work. The winners will receive a small stipend, a certificate of achievement, a one-year paid membership into ICP, Inc. and a beautiful plaque. The awards will be handed out at the annual convention at the Membership Meeting which will be held on July 24 in Yokohama, Japan.

And the winners are . . .

Seisoh Sukemune/Bruce Bain Encouragement of Early Career Research Award

Award recipient:
Dr. Hiroaki Kawamichi. Gunma University, Japan
Award chair:
Dr. Cecilia Cheng

Denmark-Grunwald Feminist Research and Service Award

Award recipient:
Dr. Joan Chrisler
Award chair:
Dr. Donna Goetz

Fukuhara Advanced International Research and Service Award

Award recipient:
Dr. Janel Gauthier
Laval Univérsite, Quebec, Canada

Award chair:
Dr. Ann Marie O'Roark

Frances Mullen Distinguished Contribution to International Psychology Award

Award recipient:
Dr. Anna Laura Comunian, Padua University, Italy
Award chair:
Was Dr. Comunian but Dr. Tan stepped in as chair for this year because Dr. Comunian is the listed chair.

Dr. Comunian was selected by 3 individuals - A.M. O'Roark, E. Margaona, D. Goetz.

Happy 75th Birthday, ICP, Inc. (1941 –2016) and we wish all a wonderful 74th Annual Convention and Board Meeting in Yokohama, Japan.

75 years of psychology worldwide, 1941-2016
International Council of Psychologists ICP
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2017 dues are due no later than December 31!

Easy to pay at the website—just go to **www.icpweb.org** and click on the MEMBERSHIP tab at the top! From there, just fill in your dues amount and payment type. Thank you.

Members of ICP, Inc., look for your election ballot via email, soon! Please complete and return your ballot as quickly as possible!

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Please submit manuscripts using APA style, MS Word, 11 pt. Times New Roman to the Editor at annoroark@bellsouth.net. The *IU* is published two to four times yearly, according to the number of manuscripts received. *IU* submissions are screened for style and professional content. Submissions may be returned for revisions as needed. We invite your participation.

Ann O'Roark, Editor

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International Psychology Bulletin

Volume 20 No. 2 Spring 2016

Editor
Vaishali V. Raval

Associate Editors
Radosveta Dimitrova
Genomary Krigbaum

Official Bulletin of the Division of International Psychology [Division 52 of the American Psychological Association]
div52.org

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Submission Deadlines
International Psychology Bulletin
Vaishali V. Raval, Editor, ravalvv@miamioh.edu

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to the appropriate section editor.
Guidelines for submission to peer-reviewed research article or theoretical review sections, please see the next page.

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- *Heritage Mentoring Project:* Neal Rubin, nealrubin@hotmail.com

Submission Deadlines:
Spring issue March 31st
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Submission Guidelines for
Peer-reviewed Articles
International Psychology Bulletin

The *IPB* publishes peer-reviewed research articles that focus on important issues related to international psychology. The review process takes approximately two months.

Please submit the following three documents in Microsoft Word format to Dr. Vaishali Raval at ravalvv@miamioh.edu:

- A cover letter
- A title page with the title of the manuscript, author names and institutional affiliations, and an author note that includes name and contact information of corresponding author
- A blinded manuscript that does not include authors' names or any identifying information

Cover letter

- In your cover letter be sure to include the author's postal address, e-mail address, and telephone number for future correspondence
- State that the manuscript is original, not previously published, and not under concurrent consideration elsewhere
- State that the manuscript adheres to APA Ethical Principles (Ethical Principles of Psychologists and Code of Conduct), and all co-authors are in agreement about the content of the manuscript
- Inform the journal editor of the existence of any published manuscripts written by the author that is sufficiently similar to the one submitted (e.g., uses the same dataset).

Blinded Manuscript

- Prepare manuscripts according to the *Publication Manual of the American Psychological Association (6th edition)*.
- Check APA Journals Manuscript Submission Instructions for All Authors
- The entire manuscript should be formatted in 12-point Times New Roman font, 1 inch margins, and double-spaced submitted as Microsoft Word document. The entire manuscript should be up to 4000 words.
- The first page of the manuscript should include a title of the manuscript (no more than 12 words)
- The second page of the manuscript should include an abstract containing a maximum of 250 words, followed by up to five keywords brief phrases
- The remaining pages should include the text of the manuscript. For research articles, include introduction, method, results, and discussion. The format of a review paper will vary, and may include a brief introduction to the topic, review of the literature, and conclusions and future directions.
- Provide a full reference list as per the *Publication Manual of the American Psychological Association (6th edition)*.
- Present tables and figures as per the *Manual, if you have any, at the end of the manuscript.*
- Review APA's Checklist for Manuscript Submission before submitting your article.

Upon acceptance

Please note that if your article is accepted for publication in *International Psychology Bulletin*, you will be asked to download the copyright transfer form, complete and sign it, and return to the editor (ravalvv@miamioh.edu) before the manuscript can be published.

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Division 52 IPB Spring Edition 2016

Jean Lau Chin, Ed.D.
APA 2016 Division 52 President
chin@adelphi.edu

Division 52 Executive Committee gathered at Pace University in New York City on March 2, 2016 for its Midwinter Meeting. This was an inaugural meeting as Lucio Forti, our new Webmaster and Richard Velayo, our Education and Training Chair helped to launch our first attempt to make these meetings available virtually to promote greater access for our members who could not join us face-to-face from all parts of the world.

International Leadership Network

My presidential initiative is to develop this network to promote mutual exchange and collaborate for scholarship, research, education and training on global and diverse leadership. Potentially, this network can: build a critical mass of scholars internationally to collaborate on issues in leadership, build a pipeline for leaders in psychology, create leadership development activities and training for new and existing leaders, and to address disparities in leadership via training, policy, and research.

We have created and grown our database of about 50 members and a working committee to plan the International Leadership Network. We are excited to have several meetings of the International Leadership Network in 2016 to plan and development this network and its activities at local and international conferences to include: APA, EPA, IUPsyS, and ICP. We hope to promote the visibility and availability of the Network through social media, APA, Monitor, and division publications.

Several virtual planning and development meetings and the symposium at the recent Eastern Psychological Association identified the following domains for 2016:

1. Training Network: Nancy Sidun and Linda Garcia Shelton are working to develop a mutual exchange for training of psychologists between institutions of higher education.
2. Leadership Research: Jean Lau Chin is working on building a network of cross-national research collaboration on Global and Diverse Leadership. Craig Shealy is doing the same on Authentic Leadership.
3. Leadership Training and Network development at international conferences (e.g., ICP, IUPsyS, IAAP): Richard Velayo is planning several symposia with virtual access and webcasting to develop training opportunities for leadership development, and development of the network. Our goal is to use web conferencing and archiving through video and chat so that the meetings can be made available to those unable to attend, or used for further collaboration and training.
4. Pipeline issues: We intend to promote the development of a younger generation of leaders. Using our division CONNECT and ECP committee, Craig Shealy and Cidna Valentin will explore this issue.
5. Other Suggestions:
   a. Internationalize Curriculum Development
   b. Start a blog to promote dialogue on leadership training, research collaboration, or curriculum development
   c. Develop a database of Leadership Success Stories
   d. Develop a compendium of psychologists in leadership roles
   e. Identify Leadership dilemmas

2016 Events for the International Leadership Network: Launched at the March EPA meeting, we videoconferenced and archived the meeting so that it would be accessible to those unable to attend in person. Please let us know if you would like to attend any of the meetings below.

1. Saturday, March 5 at 3:30 PM EST at the Eastern Psychological Association Convention, New York, NY, USA
2. July 22-July 25 at the International Council of Psychologists Conference, Yokohama, Japan (specific day/time to follow)
3. July 24-July 29 International Union of Psychological Science Conference, Yokohama, Japan (specific day/time to follow)
4. Saturday, August 6 at 10:00 AM UTC at the American Psychological Association Conference, Denver, CO, USA

You can also join our database (which will eventually be transferred to an online searchable database) by filling out a brief survey on: https://www.surveymonkey.com/r/IntnlDatabase

Strategic Planning

We began a planning process to develop a Strategic Plan which will be a blueprint for our division's future to identify "Where have we been?, Where are we now?, and Where might we go? in order to actualize the division's potential on international psychology". This process will continue into 2017 during Craig Shealy's presidency with more specific objectives to promote membership outreach, to revisit the division's identity, and to expand the division's international presence. As Craig says, if our outcome is "to draw upon the extraordinary knowledge, experience, and connections of our distinguished leaders, to create a prominent space for our students and early career colleagues to contribute and be heard, and to be supportive and listen deeply and respectfully to one another, we not only can fulfill our potential as *the* division of international psychology, but also chart a dynamic course together over the next two decades."

Two key questions posed to our EC which I ask all members to also respond to are:

1. What is your vision for how you and the activities you do can help to advance the mission of Division 52 or International Issues?
2. How might Division 52 promote the visibility of international issues specifically as it relates to what you are doing?

Strategic Planning Issues identified at Midwinter included:

1. Being *the* International Division:
   a. How can Division 52 weigh in on APA's role on international issues given that there are Memoranda of Understanding with about 15 psychological associations internationally?
   b. Should we revisit our mission as a division in the 21st century?
   c. How do we strengthen our identity of the division?
   d. How do market our division to be more visible, have our voice heard, and disseminate our positions?
2. Collaboration for research, training and practice:
   a. How do we engage psychologists internationally for research, training, and practice?
   b. Can we create an incentive system for international research collaboration for non-US based APA members to join our division? Many non-US based members are often looking for opportunities to publish in English and U.S journals. For example, a match system to connect US-based psychologists with non-US based psychologists with similar interests.
3. Supporting students and ECPs:
   a. Can we create opportunities both in the US and internationally? For example, international internships, international accreditation.
4. Policy:
   a. Where do we stand on policy and position statements on international issues? For example, advocacy, trauma, humanitarian, immigration, social justice, diversity.
5. Membership Outreach:
   a. How do we capitalize on those attending our Social Hours at conventions to become members of our division, especially the international guests?
   b. We have a much greater readership on our journal than membership in our division. We have more hits on our webpage, followers on our Facebook that is greater than the numbers of our membership. How do we reach them to join?
   c. Include information about the membership benefits on the membership page.
6. Communication and Publications: Promoting International Issues
   a. How can we grow Division 52's capacity to broadcast our EC meetings, convene groups and symposia to enhance our accessibility and importance as an international division? Lucio Forti and Richard Velayo are already beginning to do this and have recorded the EC meeting and International Leadership Network meeting to be made available to members.
   b. How do we promote visibility of our division through our major publication outlets, the newsletter, journal, and book series? It was suggested to have each of our publications promote the products of one another, and cross solicit proposals and submissions.
   c. Division 52 International Psychology Book Series is an untapped resource of the Division. How do we get the word out to solicit more book proposals, mentor potential authors, and be more proactive in making the book series more visible through our website and newsletter? Suggest topics like an internationally oriented multicultural book? Interview individuals using a high quality qualitative method to find out best practices for international psychology?
   d. Increase the use of Social Media to promote the division's visibility and connection with international members, and to promote membership. Announce progress of projects and what's going on in the division on the website and newsletter.

Contact Us

The Division 52 leadership looks forward to engaging with our member to achieve our goals. As president, I especially invite you to join the ongoing discussion through the open forum on the Div52 Listserv or contact me at: ceoservices@yahoo.com If you are not currently a member of the listserv, please send a request to lforti@pace.edu

Call for Nominations
APA Division 52 Henry David International Mentoring Award

Henry David was a founding member of Division 52 and a significant contributor to international psychology. In honor of his contributions, Division 52 established the Henry David International Mentoring Award.

The recipient of this prestigious award will be honored at the 2015 APA Convention in Toronto. Nominations, including self-nominations, are welcomed. The Division 52 Henry David International Mentoring Award is presented annually to a member or affiliate of Division 52, who plays an exceptional mentoring role in an international context. Mentoring may be defined by any of the following activities:

(1) A psychologist who has served as a mentor for international students or faculty member for at least three years.

(2) A psychologist who has mentored students in the area of international psychology, by training, educating, and/or preparing students to be active participants in international psychology.

(3) A senior psychologist who has mentored early career psychologists who are now functioning as international psychologists.

OR

(4) An international psychologist working outside of the United States who serves as a mentor on his/her campus or at his/her agency.

Nominations should include a cover letter, vitae, and at least 3 letters of endorsement from former or current mentees. **Questions about the application procedure and nominations should be emailed to the Henry David International Mentoring Award Committee Chair, Lawrence Gerstein at lgerstein@bsu.edu.** The Committee will review the nominations. The Committee's recommendation will be reported to the Division 52 Board of Directors. **The deadline to submit materials is April 1, 2016.**

The Anne Anastasi Graduate Student Research Award Nomination - International Psychology -

Two Graduate Student Research Awards

Anne Anastasi was president of the American Psychological Association in 1965 and was awarded the National Medal of Science in 1987. She made major conceptual contributions to the understanding of the manner in which psychological development is influenced by environmental and experiential factors. Her writings have provided incisive commentary on test construction and the proper application of psychological tests. She drew attention to the individual being tested and therefore to the responsibilities of the testers. She called for them to go beyond test scores, to search the assessed individuals' history to help them to better understand their own results and themselves. This award is thus named after her and was funded by the Anne Anastasi Foundation.

All Div52 applicants will be considered for this award, however the ones who demonstrate research that focus on psychometrics and differential psychology in respect to Anne Anastasi contributions to the field from an international perspective will be highly considered.

Each awardee will receive $300 and a certificate. The winner will be decided based on the student's vitae and research plan, plus a supporting letter from the student's advisor. There are no restrictions on nominees, self-nominations, as well as nominations by others.

- Deadline: June 7 -

Please send the following materials electronically to the 2016 Chair of the Committee, Suzana Adams, PsyD (suzea@mac.com) and to the members of the Committee, Mercedes A. McCormick PhD (mampsyyoga@aol.com) and Zhipeng Gao (gzhipeng@yorku.ca)

I. Cover Letter with the following information. **Please attach the following checklist with your application.**

- Name
- Email
- Institution
- A mentor's name and his/her email
- Focus of research and title
- There are 2 levels of the Anastasi Award: Students with 2 years or less of graduate study and those with more than 2 years of graduate study. Please indicate (check off) in your cover letter the one that best applies to you:

___Two years or less of study beyond the baccalaureate or

___More than two years beyond the baccalaureate.

- If applicable, year in which masters' degree was completed or projected year in which masters' degree will be completed.

  _____

II. Please add to the Cover Letter the following attachments:

1. Research statement on your past/present/future work (2-3 pages, with limited number of important citations)
2. Your Curriculum Vitae
3. Supporting letter from one mentor, either attached or sent separately

Division 52/Psi Chi International Conference Travel Grant $1,500 US

Call to students living outside the US who are interested in the field of international psychology and plan to attend the August 4-7, 2016 APA Convention in Denver, Colorado!

In 2015, APA Division 52, International Psychology and Psi Chi, the International Honor Society in Psychology, collaborated through the D52 Building Bridges Committee to offer the inaugural **Division 52/Psi Chi International Conference Travel Grant.** In 2016 the travel grant will continue to provide assistance with travel costs to Psi Chi students who live outside the US,are interested in international psychology, and plan to attend and present at the APA convention in Denver, Colorado August 4-7 , 2016.

Eligibility:

1. Must be a current undergraduate psychology major or a student in a graduate psychology program outside the US or a recent graduate (defined as having completed an undergraduate psychology degree between November 1, 2015 and May 1, 2016.
2. At the time of submission, must be currently – and at least through August 2016 – living, working, and/or studying outside the US.
3. Must be a member of Psi Chi at the time of submission.
4. Must be a member of D52 at the time of submission (students may join at any time).
5. Must be able to cover any travel expenses beyond the $1,500 provided by the grant.
6. Must agree to attend and talk for 5-10 minutes about personal interests in international psychology at the D52 Awards Ceremony/ Hospitality Suite Program at the 2016 APA convention.
7. Must attend at least one other D52 session.
8. May not win more than one D52 travel grant.
9. May not win more than one Psi Chi travel grant that can be used to attend APA.
10. Must provide proof of acceptance to present research at the 2016 APA convention in Denver, CO.
11. Acceptance of research for presentation in any format (poster, talk) and within any division or affiliated group (such as Psi Chi) program at the 2016 APA Convention.

To Apply, Students Need to Submit:

I. Description of Interest (maximum 275 words, double-spaced):

1. A description of
   a. your interest in international psychology,
   b. how your participation at the APA Convention will strengthen your professional interest in the field of international psychology,
   c. meaningful experiences in psychology courses,
   d. volunteer experience,
   e. Psi Chi involvement,
   f. Division 52 involvement, if any

II. Eligibility Information:

1. A document or email text providing:
   a. Full name
   b. Contact information (email & phone)
   c. Name of university/college
   d. Name of the undergraduate/graduate department program
   e. Year in the program
   f. Expected graduation date
   g. Member status with D52
   h. Psi Chi member ID
   i. Full name and title of endorsing faculty mentor
   j. Endorsing faculty mentor email address

III. Faculty Mentors submit directly to Drs. McCormick and Zlokovich:

A brief (200 words maximum) document or email that includes:

1. A statement endorsing you for the travel grant,
2. Confirmation that your interest and academic efforts in international psychology will be enhanced by attending the APA convention, and
3. Assurance of your good standing as a student in the undergraduate/graduate psychology program.

Deadline: Before midnight (Eastern Standard Time) June 30, 2016.

Email all application materials to the Building Bridges Committee Chair:

Mercedes A. McCormick, Ph.D.
Chair of APA Div. 52 Committee on Building Bridges With Psi Chi
2013 President of APA Div. 52
Pace University, New York 10038
mmccormick2@pace.edu

Application and Review Process:
Applications will be reviewed by the committee according to completeness of submission and strength of the description of interest in international psychology.

Winner Notification and Obligations:

The grant winner will be notified no later than May 30, 2016 and will be recognized in person at the Division 52 Awards ceremony in Denver, Colorado on August 6th. The winner will present a 5-10 minute talk at the D52 Awards Ceremony on August 6, 2016 on the benefits of being awarded the travel grant. In addition, the grant winner will be featured in an issue of the International Psychology Bulletin.

D52 and Psi Chi will present the winner with a check at the D52 Awards Ceremony after the winner has met all obligations. Obligations are attending the APA convention, attending at least one D52 presentation, presenting research included as part of the travel grant application, and speaking at the D52 Awards Ceremony. Any winner who does not attend the APA convention or D52 Awards Ceremony will not receive the grant funding.

LEAVING A LEGACY TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Susan Nolan at (973) 761-9485 or at susan.nolan@shu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

A DVD about International Psychology: Perspectives and Profiles

Uwe P. Gielen
St. Francis College

Judy Kuriansky
Columbia University

As members of APA's International Psychology Division (52), we have created a DVD that informs students, faculty, professionals and others about the exciting new field of International Psychology. The DVD can be used in the classroom setting or for individual viewing.

The DVD's first section includes a 35-minute documentary entitled *International Psychology: What Students Need to Know*. It includes profiles of various international psychologists; advice for students from international psychologists in different parts of the world; students' descriptions of their international projects and how they have obtained funding; starting a career in International Psychology; activities and opportunities for students at the United Nations; resources to find out about International Psychology; and guidelines about whether International Psychology is a field that fits the student.

The DVD's second section offers an overview of *Pathfinders in International Psychology*, a recent book that traces the history of psychology through profiles of known and not-as-well-known, yet important, psychologists and psychiatrists from different regions of the world. The editors of the volume are leading international psychologists, Dr. Grant J. Rich and Dr. Uwe P. Gielen, who were interviewed by Dr. Judy Kuriansky.

In the 20-minute interview, the book editors offer fresh and illuminating views of historical figures in international psychology as conceived by an international group of contributors. The editors describe the biographies and contributions of 17 psychologists, psychiatrists, and healers who have been active in 14 countries around the world. The recounting begins with the colorful figure of Franz Anton Mesmer (1734-1815) who created and practiced Mesmerism in Austria, France, Germany, and Switzerland, and ends with a recounting of the inspiring biography of the South African anti-apartheid activist and clinical psychologist Sathasivan Cooper (*1950; also known as "Saths"), the current president of the International Union of Psychological Science. Altogether, the book covers a timespan of more than 250 years.

A brief additional video tracks the dramatic life and career of Dr. Cooper by tracing his life as a student in South Africa through his days in the struggle against apartheid, his imprisonment on Robben Island where he shared a cell block with Nelson Mandela, and his evolving career as a noted psychologist.

In Dr. Kuriansky's interview with Dr. Cooper, he discusses the development of psychology in Africa. In this process, he has accomplished many "firsts": he served as the President of the International Congress of Psychology (in 2012) that was held in Africa for the first time; he is currently the first President of the International Union of Psychological Science from the continent of Africa; and he is playing a crucial role in the foundation of the Pan African Psychology Union. The video ends with his hopes for psychology in the future.

A copy of the DVD can be ordered from Uwe P. Gielen (ugielen@hotmail.com). Please include your postal address in your email. The DVD will be sent free of charge (as long as supplies last).

References

Rich, G., & Gielen, U. P. (Eds.). (2015). *Pathfinders in international psychology.* Charlotte, NC: Information Age Publishing. [APA Division 52/IAP Book Series on International Psychology].

International Perspectives on Humanity's Sustainable Development Goals

Stuart C. Carr

Incoming Editor for *International Perspectives in Psychology* (IPP, 2016)
Poverty Research Group
End Poverty & Inequality Cluster (EPIC)
Massey University
Aoteaoroa/New Zealand

Source: United Nations, 2016

Why is it that the people I meet and show *International Perspectives in Psychology* (IPP) always, palpably, react with excitement? Perhaps it has something to do with the fact that no other journal in psychology has such an ambitious and inspiring goal, or rather, set of goals. The role that this journal has set for itself - becoming the primary source for state-of-the-art information on how psychology can help to tackle human well-being and development - is quite simply unique.

This is certainly a focus with which our New Zealand-based, interdisciplinary team of 20+ academics in the self-explanatory *End Poverty & Inequality Cluster* (EPIC, 2015) identify. Like IPP, EPIC has a focus on global and local issues in everyday life. Our guestimate here in the Western Pacific is that there are many more networks and groups like ours 'out there' internationally, and that IPP is a natural home for us as readers, writers, and contributors.

As Professor Gibbons (2011) cogently captured in her inaugural Editorial, IPP is a journal that will "confront global problems such as poverty, economic disparity, health crises, intergroup antipathy, conflict and natural disasters." IPP promises - like the Division itself - to take psychology beyond its often quite personal individualized outlook towards broader and often structural issues shaping human life. We can do so by "promoting greater global awareness throughout the discipline" and by engaging directly with some of the 21st century's 'wicked issues' (e.g., "initiatives on human rights, international ethics, immigration, women in developing countries… global trauma and disaster, collaboration with international organizations"). IPP is thereby not a repository for cross-country comparisons unless they speak to the well being of the world's citizens; its ethos is heavily applied and inclusive of research, policy and everyday professional practice ("create, distribute, and apply knowledge globally…leave global citizens a bit more connected and adept at solving the world's problems").

In keeping with this vision, the journal and Division's mission includes connecting with practice, policy development and implementation. In the past, Psychology has arguably struggled with this pivotal phase of taking research to society, for evaluation by society and for implementation in society. More recently however, the APA, in collaboration with other groups in Psychology, has made great strides and commitments in convening regularly with major multilateral agencies for human development at the United Nations (UN). The latter are effectively our 'global civil service,' which includes the UN's diverse chapters from UNDP through to ECOSOC.

Collectively these UN chapters have this year launched the "Sustainable Development Goals" (or SDGs). These SDGs have been put together with much international consultation, including some with our own profession. They will guide the resourcing and focus for global human development plans for the next 15 years. Crucially for IPP, and as the graphic at the head of this article indicate, the SDGs overlap remarkably, and perhaps not coincidentally, *with the very goals and mission that IPP has set for its own development*.

Granted that the world's wicked problems like poverty reduction, war and conflict, climate change, gender inequity and socio-economic inequality are inherently interdisciplinary, their solutions must be too. Expanding on IPP's readership and outreach to wider human development circles, for example in development economics, sociology anthropology and community development will enhance IPP's impact. This will enable fulfilment of its mission and purpose. Themed special issues and sections would be one way of enabling people working outside as well as inside of Psychology to easily locate and secure the best possible source of advice on the SDG that matters most to them. In our experience at EPIC there is a huge unmet demand globally regionally and locally for this kind of information, from the academy to the community, which reflects the multidisciplinary ethos of modern policy and practice.

In our view, Editors can and should play an active role in facilitating such outreach and impact, alongside their duties vis-à-vis the psychological community of research practice. Together with Editorial Board members we can be connected with policy-makers, think tanks and networks and be ready to act as a 'connector' between their profession and other networks in research, practice and consultation. This I will endeavour to do during my tenure as Editor of IPP.

Obviously, and as signalled in the inaugural editorial, Special Issues with a single theme are one way to group the material for instant access by focused readers, policy makers, practitioners and consultants. This initiative is already underway. In any case, it can create the journal equivalent of a 'point person' for specific issues on which psychologists and other professionals want information on evidence-based practice. A robust variation on the same basic option might be to include smaller Special Sections within single issues of the journal. These are normally focused on a single topic or sub-group of topics - say three or four papers, sometimes with a lead article and commentaries. This format was successfully applied for instance in the recent "Global Special Issue on Psychology and Poverty Reduction," as reviewed in IPP. The special sections format has also been engagingly applied in Division 14 - SIOP in its official journal *Industrial and Organizational Psychology: Perspectives on Science and Practice*. Decent work, living wages, and sustainable livelihood, clearly have a resonance with IPP and D52's ambit.

The future of any community of applied research practice rests on its early career scholars and practitioners. For the past two decades I have had the privilege to spend a lot of time building friendships and working relationships with emerging career researchers and practitioners from a diverse range of economies, political systems and cultures - including many materially marginalised groups and societies. Such connections are the lifeblood of any journal. They may add an additional pool, actually waves of talent who can be reviewers and proposers of special issue sections, lead articles and reviews for the journal. This kind of carrying capacity broadens international orientation; capacitates. Ultimately it can only enrich the perspectives that frame our research, practice and consultation, and the problems that face Humanity.

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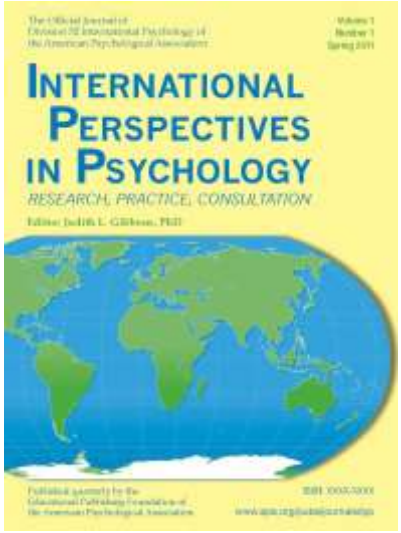

APA Council of Representatives Report

Harold Takooshian
D52 Representative, 2010-2015

On 1/1/2016, Neal Rubin began his three-year term as our D52 Representative to APA Council, as I ended my six-year term of 2010-2015. I am reporting here on Council activities up to 2016, and how much our division 52 has changed during these six years, from 2010-2016.

In 2015, we all saw the 160-member Council's near-total focus on "restructuring" eclipsed by another focus--the Hoffman Report--which resulted in one termination and several high-level retirements/resignations/recusals. APA President (and D52 Fellow) Barry Anton presided over a turbulent August meeting of Council in Toronto, where media assembled to broadcast the final vote (photo below). This Hoffman Report will continue to reverberate in Council in coming months (APA, 2015).

What is less publicized is the financial aspects of the Hoffman report. This was not clear at first, until Council requested and received a break-down of expenses to the Association, noted in Table 1 below. It was reported that APA Counsel's office, under attorney Nathalie Gilfoyle, initially allocated an estimated $400,000 for the cost of this independent report. When David Hoffman's law firm of Sidley Austin soon informed APA that this sum was inadequate, it was not feasible for APA to do anything but continue funding this IR, which eventually swelled ten-fold to $4-million. There were also ancillary expenses, which brought the total closer to $5-million, and rising. APA hopes to develop some strategy to replenish this unexpected expenditure in coming years. APA later posted 42 changes in the original report, now posted at http://www.apa.org/independent-review/index.aspx.

Table 1. Costs of the Investigative Report, as of 2015

	Hours	Fees	Expenses
Sidley Austin (David Hoffman)	10,0002	$3,945,692	$142,173
Wilmer Hale (APA outside counsel)	877	$654,369	$6,093
Powell Tate (Public relations)	492	$174,264	$632
Covington & Burlington (Insurance)	28	$16,233	$116
Transperfect (Transcription)		$2,415	$0
TOTAL	11,399	$4,792,973	$149,014

In my six years on Council in 2010-2015, I have seen our fine D52 change in many ways. Back on March 5, 2010, at our D52 board dinner at Saint Francis College, during the EPA meeting in Brooklyn NY, then-President Danny Wedding was cheered as he described D52 as "the friendliest division in APA." A NYU student from Italy, Guilia Landi, wrote in our *International Psychology Bulletin* how attracted she was at EPA by the large room full of smiling faces. "Going to EPA and discovering all the opportunities within Division 52... I am extremely grateful to Dr. Rivka Meir... and would like to share the Division's vibrant and wide-reaching initiatives with other students" (Landi, 2010, p. 9). At EPA 2010, our D52 hosted ten packed sessions in two days, where, like Jennifer Doran (Stowell & Doran, 2010), Ms. Landi was one of over 50 students and professionals who submitted a D52 application to our Outreach Chair Rivka Meir to join D52.

Growth. As of 2010, D52 was a friendly and growing division, for many reasons. (1) Thanks to our past-President Gloria Gottsegen, our bylaws are highly democratic and transparent, requiring open meetings of the board (section 4.4), and a transparent election process where the candidates with the most nominations are put on the slate (section 7.3). (2) Semi-annual board meetings resembled reunions of old friends, and board minutes were published in the D52 Bulletin. (3) There was a healthy succession system, where students and ECPs were welcome to join committees and gain experience in D52 before becoming chairs, then stand for election as officers and possibly President.

Decline. As of 2016, it is sad to see so many negative trends in our division. Most obviously, APA (2016) data finds our D52 membership is now plummeting since 2011. When Table 2 compares four APA divisions formed since 1996, three have grown over 1,000 paid members, while D52 is now dropping since 2011, from 629 to 543. The same is true of our annual D52 apportionment ballot, where each member has 10 votes, and D52 has been plummeting towards zero votes: from 442 (2013), to 425 (2014), to 376 (2015), 330 (2016), to 305 (2017). Not least of all, board meetings since 2013 are often less than friendly, when some hard-working members are involuntarily removed from their roles, leaving others to avoid the division and its meetings. At our August 2014 board meeting, someone posted a uniformed guard at the door to eject unwanted members, while an APA lawyer actively participated in the meeting. Some are now proposing that D52 changes its democratic bylaws (above) in ways to reduce transparency (though this first requires a 2/3 vote of the membership). In March of 2016 at EPA, with no D52 outreach committee, the D52 room was virtually empty for most of two days, with not a single D52 application in sight--so different from EPA 2010 and 2013 (Takooshian, 2013).

At a time when psychology now grows faster outside than inside North America (Zoma & Gielen, 2015), it is a sad irony that our growing division is now losing members (APA, 2016). Happily, our sedulous President Jean Chin has proposed a bold new International Leadership Network (ILN), to engage nonmembers. Sadly, more reforms are clearly needed, to re-create the value of D52 that attracted students like Giulia Landi in 2010.

On a personal note, it has been my pleasure to serve Division 52 as its Council representative the past six years. As one of the co-founders of our Division in 1997, I was honored to serve faithfully the Division on Council the past six years.

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Zoma, M., & Gielen, U. P. (2015). How many psychologists are there in the world? *International Psychology Bulletin, 19,* 47–50.

Table 2. Number of paid members of four APA divisions formed after 1996

	1999	2011	2012	2013	2014	2015
52: International	802	629	608	582	581	543
53: Clinical child	1,300	1,768	1,809	1,773	1,767	
54: Pediatric	1,235	1,040	1,040	1,072	1,118	
56: Trauma	---	1,038	1,058	1,102	1,068	

Mapping People's Views Regarding Physician Assisted Suicide: A Five-Country Study

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Jean-Jaurès University, France

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Abstract

Whether physicians or other caregivers should intervene to end terminally-ill patients' lives has always been controversial. In euthanasia, physicians intervene directly and purposely to end patients' lives whereas in physician-assisted suicide (PAS) physicians provide patients with the means to end their lives by themselves. Studies examining the circumstances under which lay people consider PAS as acceptable and using the same set of realistic vignettes were conducted in five countries with quite different cultures: France, India, Kuwait, Togo, and Turkey. The vignettes depicting the condition of terminally-ill patients included information about the patient's age, the level of incurability of the illness, the type of suffering, and the extent to which the patient requests a life-ending procedure. A single cluster analysis performed on these five sets of data found eight qualitatively-different positions among participants: (a) PAS is never acceptable, (b) it is not very acceptable, (c) it depends on the type of suffering, (d) it depends on the level of curability, (e) it depends on the patient's age, (f) it depends on the patient's request and age, (g) it depends on the patient's request, and (h) it is mainly acceptable. Most participants were not systematically opposed to PAS. The most important factor in providing acceptability was advanced age. The dominant principle guiding participants' views was non-malevolence (not jeopardizing the patient's access to heaven). This principle tended to be superseded by principles of benevolence, autonomy and justice as religious beliefs vanished.

Keywords: physician-assisted-suicide, France, India, Kuwait, Togo, Turkey

The most controversial end-of-life decisions are those in which physicians actively help patients to die. In the case of physician-assisted suicide (PAS), patients are provided with the means to end their own life. Since patients themselves perform the lethal action – for example, by ingesting a solution of sodium pentobarbital -- the procedure is at their request and with their consent. In euthanasia, the physician either directly intervenes to end the patient's life (active euthanasia) or withholds or withdraws treatment needed to maintain life (passive euthanasia). The current study is a reanalysis of previously published data on people's views regarding the acceptability of PAS gathered in five culturally very different countries: France, India, Kuwait, Togo, and Turkey. Its main findings are discussed in lights of the four principles of bioethics suggested by Beauchamp and Childress (2001): autonomy, benevolence, non-malevolence and justice.

Legislation has been passed recently to permit and regulate euthanasia and PAS in the Netherlands and Luxembourg; euthanasia in Belgium and Colombia; and PAS in Germany and in the United States of California, Montana, Oregon, Vermont, and Washington (Steck, Egger, Maessen, Reisch, & Zwahlen, 2013; State-by-State Guide to Physician-Assisted Suicide, 2015). Similar legislation is under discussion in other U.S. states and elsewhere in the world, including in India (Mahapatra, 2011). It is important, therefore, for caregivers and policy makers around the world to appreciate the conditions under which end- of-life decisions are or are not acceptable to the public.

Assessing People's Views

Varied methodologies have been used to assess the overall level of acceptability of helping to end a patient's life and the main factors that affect people's acceptability judgments. Most investigators have used questionnaires. For instance, in the study by Cohen, van Landeghem, Carpentier and Deliens (2014), participants from 47 European countries were asked: "Please tell me whether you think euthanasia (terminating the life of the incurably sick) can always be justified, never be justified, or something in between"? (p. 144). The mean ratings in each country ranged from 1.52 to 6.79 (out of 10), indicating much greater acceptance in some countries (e.g., France: 6.75) than in other countries (e.g., Turkey: 2.21).

Other researchers have focused on the circumstances under which end-of-life decisions are considered as acceptable or not, using realistic vignettes (Anderson, 2008). For example, Kamble, Sorum, and Mullet (2012) presented Indian students with 36 scenarios depicting the condition of terminally ill patients, composed according to a four within-subject factor design. The information included (a) the patient's age (35, 60, or 85 years), (b) the level of incurability (or curability) of the illness (completely incurable or extremely difficult to cure), (c) the type of suffering (extreme physical pain or complete dependence), and (d) the extent to which the patient requests a life-ending procedure, euthanasia or PAS (no request, some form of request, or repeated formal requests). The authors observed wide differences in participants' response patterns, which they examined through cluster analysis. They found three contrasting positions. For 42%, PAS was clearly unacceptable if the patient was young, but it was clearly acceptable if elderly, and more so if the patient requested it. For 29%, it was mainly acceptable, but less so if the patient was younger or did not request it. For another 29%, it was mainly unacceptable, but less so if the patient was older or requested it. The material used by Kamble and colleagues (2012) in India has also been applied to samples of people in four other countries: (a) Kuwaiti students (Ahmed, Sorum, & Mullet, 2010), (b) French adults (Munoz Sastre, Gonzales, Lhermite, & Mullet, 2010), (c) Togolese adults (Kpanake, Sorum, & Mullet, 2013), and (d) young Turks (Bugay, Sorum, & Mullet, 2014). In each case, qualitatively different positions have also been found, and these positions are summarized in Table 1.

Table 1

Positions Regarding End-of-Life Decisions Observed in Previous Studies and Countries in which the Position has been Observed

Position	Overall Range of Ratings	Effects Observed	Countries
A. Never acceptable	All ratings very close to the zero end of the acceptability scale	No effects	Kuwait, Togo
B. Not very acceptable	All ratings in the unacceptability side of the response scale	Weak effect of patient's age	Kuwait, India
C. Type of suffering	Most ratings in the unacceptability side of the response scale except in the case of complete dependence	Effects of type of suffering, request and incurability	Kuwait
D. Incurability of the Illness	Ratings ranging between the two ends of the scale	Effects of incurability of the illness, patient's request and patient's age	Togo
E. Patient's Age	Ratings ranging between the two ends of the scale	Strong effect of patient's age, weak effect of request	India, Kuwait
F. Patient's Request	Ratings ranging between the two ends of the scale	Strong effect of patient's request	France
G. Mainly Acceptable	Most ratings in the acceptability side of the response scale	Weak effects of patient's request and patient's age	France, India

They varied from not acceptable irrespective of circumstances (the majority position in Kuwait), to mainly acceptable if patients requested it (the majority position in France), or acceptable if patients were elderly people (a common position in India). In Togo, the curability factor had a stronger impact than in other countries: when the illness was not completely incurable, the acceptability level was lower than when the illness was difficult to treat. For some people, the type of suffering matters, as among a minority of Kuwaiti for whom acceptability was lower in case of physical pain than in case of complete dependence.

A Reanalysis

Since the data from these studies were analyzed separately, however, direct comparisons between countries are difficult. In this article, we present the results of a single cluster analysis conducted on the whole set of data gathered in these five countries (Table 2). An analysis performed on a larger sample may, in addition, allow the detection of positions, especially minority positions that were missed in each separate analysis conducted at a country level. Furthermore, such an analysis may offer the common framework that is needed when direct international comparisons are made.

The five countries differ considerably in religious and philosophical backgrounds regarding life and death issues. According to Islamic bioethics, "the killing of a terminally ill person, whether through voluntary active euthanasia or physician-assisted suicide, is judged an act of disobedience against God" (Sachedina, 2005, p. 779). In the Hindu tradition, death is not the end of life but a transition through rebirth, between two successive lives in two different bodies (Desai, 1988). As a result, maintaining life at all costs is not viewed as an imperative. In Togo, the death of an old person, in contrast to the death of a young person, is considered a great blessing for the whole society since it is seen as a ritual of passage into becoming an ancestor; that is, into the highest stage of the developmental trajectory of personhood (Moore, 2007). France is now a largely secular country where, regarding end-of-life issues, most people believe in the right to self-determination (Cohen et al., 2014). Finally, Turkey has a predominantly Muslim population, but, in contrast to Kuwait, a secular civil society, leading to divisions of many social issue, including end-of-life decision making (Karadeniz et al., 2008). As a result and as already shown in Table 1, a rich diversity of positions may be expected even if the number of countries considered is small.

Method

The participants in the five subsamples were either (a) adults in countries in which surveying people on societal issues was feasible and relatively common practice (France, Togo) or (b) university students in countries where surveying adults was not feasible (Kuwait, India). The material was described in the Introduction: a set of 36 scenarios indicating the patient' age, the level of incurability (or curability) of the illness, the type of suffering, and the extent to which the patient requests a life-ending procedure. An example of a vignette is the following: "Mrs. Silva is 85 years old. She has a serious illness, totally incurable given current knowledge. She is currently receiving the best possible treatment. She is completely dependent; she cannot breathe by herself and she cannot feed herself. She has asked clearly and repeatedly to resort to euthanasia or physician assisted suicide. Do you think physician assisted suicide would be an acceptable procedure in this case"? Adults were contacted in the streets of big cities, and university students were contacted on campus.

Table 2

Demographic Characteristics of the Five Subsamples

Country	*N*	Type of Participants	Mean Age (*SD*)	Percent. Females	Percent. Believers	Percent. Attendees
Kuwait	330	Students	20.80 (1.77)	67	100	100
Togo	302	Adults	32.35 (12.19)	52	96	
Turkey	129	Young people	25.92 (9.22)	48	100	
India	293	Students	22.86 (2.50)	62		92
France	292	Adults	35.59 (14.94)	53	48	9

Note: When data were not available, cells were empty. "Believers" refers to believers in God. "Attendees" refers to worship's regular attendees.

Results

A cluster analysis was performed on these data in accordance with the recommendations of Hofmans and Mullet (2013); that is, we used K-means clustering (Euclidian distances), a nonhierarchical centroid-based method. Nine clusters of participants were identified. Six of them are shown in Figure 1, with the mean acceptability ratings pooled across the levels of incurability and types of suffering. The three remaining ones are shown in Figure 2. Table 3 shows the percentages of participants from each country in each cluster.

The first cluster (n = 270) was the *Never Acceptable* cluster expected on the basis of prior studies (see Table 1). The responses were always very close to the unacceptability side of the scale (M = .21, SD = .29), and no effect of any factor was detected. The second cluster (n = 132) was the *Not Very Acceptable* cluster. The responses were mostly low but nevertheless significantly higher than in the first cluster (M = 1.80, SD = .54). The request by age interaction was significant, $F(4, 520) = 10.89$, $p < .001$, $\eta_p^2 = .08$.

The third cluster (n = 60, see Figure 2) was the *Type of Suffering* cluster (M = 3.03, SD = 0.65). Suffering was significant, $F(1, 118) = 109.65$, $p < .001$, $\eta_p^2 = .65$, as well as the Suffering x Request interaction, $F(2, 118) = 12.94$, $p < .001$, $\eta_p^2 = .18$. The fourth (n = 45) was the expected *Incurability of Illness* cluster (M = 4.80, SD = .90). Incurability was significant, $F(1, 44) = 395.37$, $p < .001$, $\eta_p^2 = .90$, as well as Request and Age, $F(2, 88) = 33.46$ and 32.40, respectively, $p < .001$, $\eta_p^2 = .43$ and .42.

The fifth cluster (n = 242, see Figure 1) was the expected *Patient's Age* cluster (M = 5.16, SD = 1.07). Request and Age were significant, $F(2, 482) = 105.95$ and 1,285.00, respectively, $p < .001$, $\eta_p^2 = .31$ and .84. The sixth cluster (N = 73) was not expected (see Figure 2). The response pattern was similar to the one observed in the *Not Very Acceptable* cluster except that most values were higher (M = 4.54, SD = .75). It was termed *Request* x *Age* because of the strong interaction between these factors, $F(4, 288) = 46.58$, $p < .001$, $\eta_p^2 = .39$.

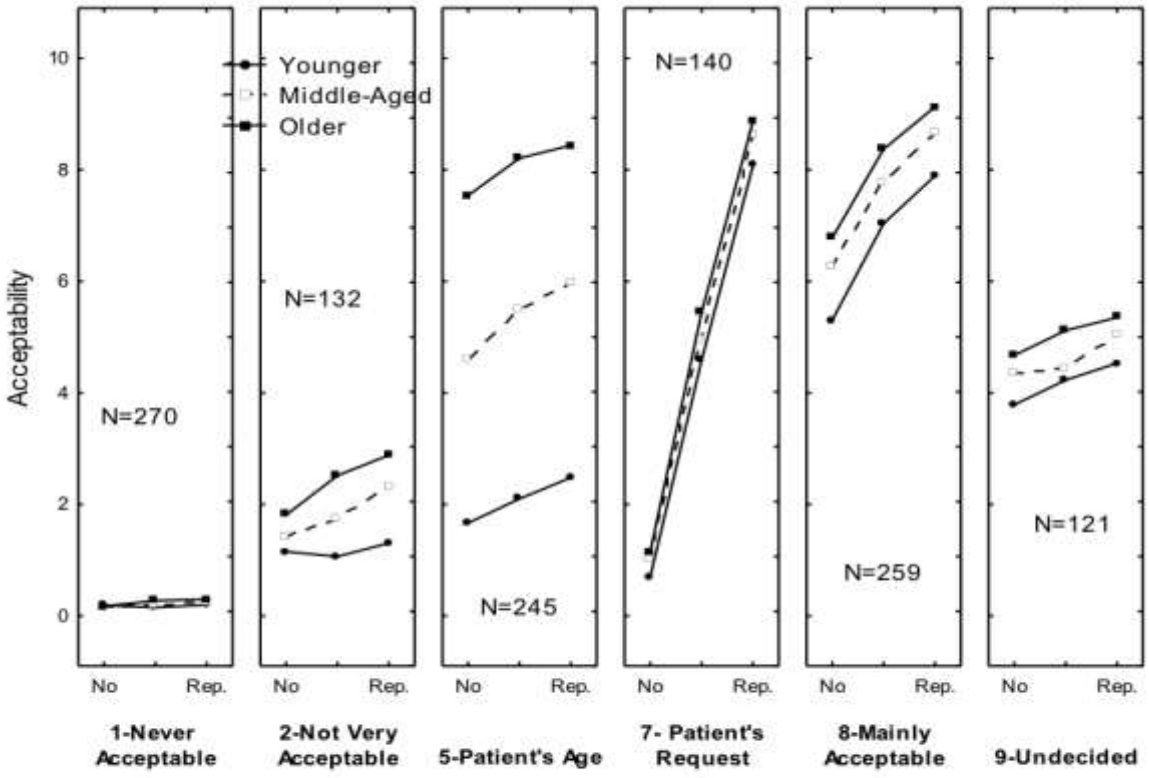

Figure 1

Patterns of Results Corresponding to Six of the Nine Clusters

Note: In each panel, the mean acceptability judgments are on the y-axis, the three levels of patient request (No = No request, and Rep. = Repeated request) are on the x-axis, and the three curves correspond to the three levels of patient age.

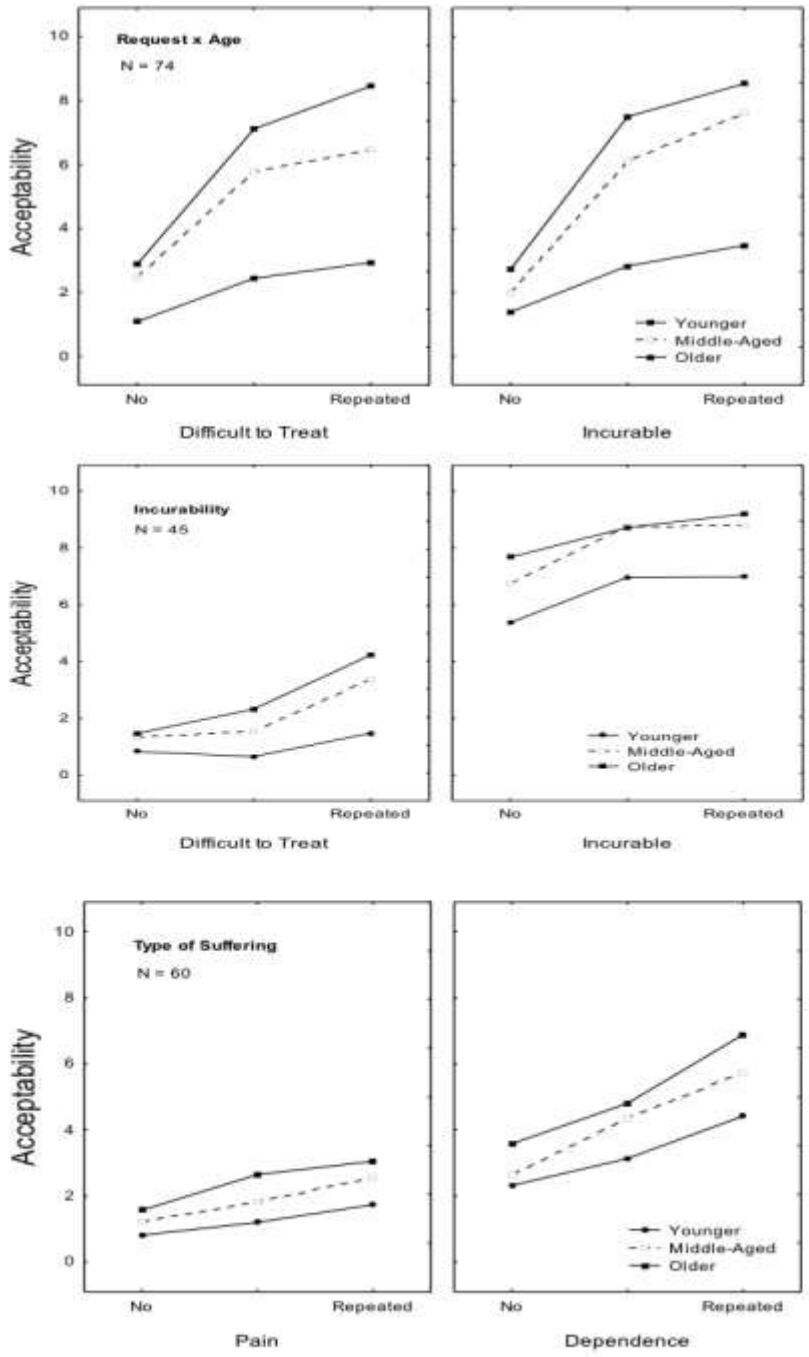

Figure 2.

Patterns of Results Corresponding to the Three Additional Clusters. *Note*: In each panel, the mean acceptability judgments are on the y-axis, the three levels of patient request are on the x-axis, and the three curves correspond to the three levels of patient age. The two panels in each row correspond to the two levels of the Curability factor or of the Type of Suffering factor.

Table 3

Number and Percentage of Participants in the Nine Clusters per Country

Cluster	Kuwait	Togo	Turkey	India	France	Total
1-Never Acceptable	*159 (59)*	72 (27)	27 (10)	4 (1)	8 (3)	270
2-Not Very Acceptable	*65 (49)*	36 (27)	6 (5)	15 (11)	10 (8)	132
3-Type of Suffering	*20 (33)*	*25 (42)*	8 (13)	7 (12)	0 (0)	60
4-Incurability	0 (0)	*40 (89)*	1 (2)	1 (2)	3 (7)	45
5-Patient's Age	30 (12)	55 (22)	31 (13)	*118 (48)*	11 (4)	245
6-Request x Age	8 (11)	20 (27)	4 (5)	*35 (47)*	7 (9)	74
7-Patient's Request	12 (9)	12 (9)	18 (13)	5 (4)	*93 (66)*	140
8-Mainly Acceptable	9 (3)	29 (11)	26 (10)	54 (21)	*141 (54)*	259
9-Undecided	27 (22)	13 (11)	8 (7)	*54 (45)*	19 (16)	121
Total	330	302	129	293	292	1346

The seventh cluster (n = 140) was the expected *Patient's Request* cluster (M = 4.82, SD = 1.19). Request and Age were significant, $F(2, 278) = 939.70$ and 49.80, respectively, $p < .001$, $\eta_p^2 = .87$ and .26. The eighth (n = 259) was the expected *Mainly Acceptable* cluster. The responses were always much closer to the acceptability than to the unacceptability side of the scale (M = 7.47, SD = 1.13). Request and Age were significant, $F(2, 510) = 344.04$ and 179.62, respectively, $p < .001$, $\eta_p^2 = .57$ and .41. Finally, the ninth cluster (n = 121) was not expected. It was termed *Undecided* because the responses were always close to the middle of the scale (M = 4.62, SD = .69). Request and Age were, however, significant, $F(2, 236) = 10.98$ and 23.58, respectively, $\eta_p^2 = .09$ and .17.

Figure 3 shows the Euclidian distances between the clusters' profiles of mean ratings. Three meta-positions can be distinguished: Not acceptable (including Depends on type of suffering), Mainly acceptable, and Depends on circumstances. Figure 4 shows the distances between countries' mean profiles of ratings. India and France were clearly at variance from the other three countries.

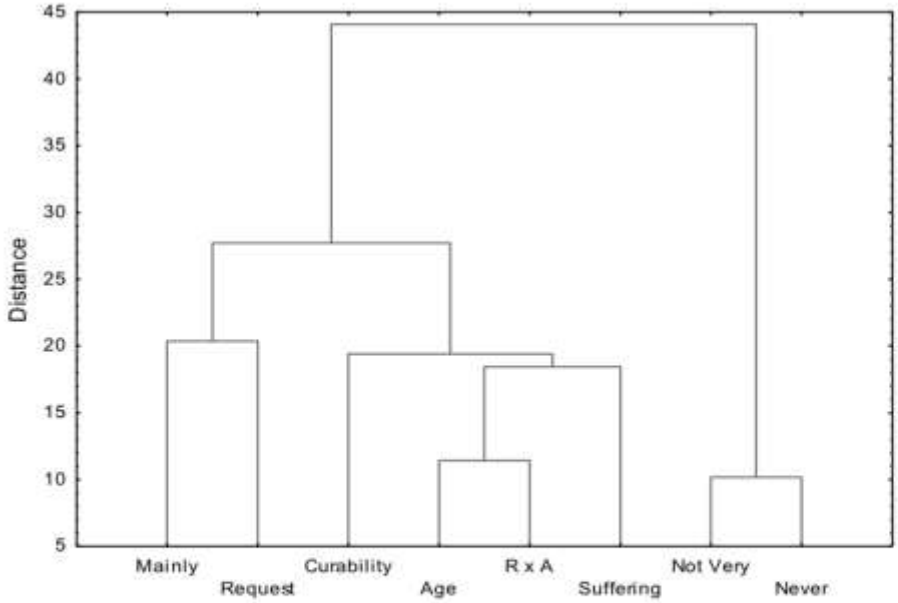

Figure 3.

Dendogram Showing the Euclidian Distances between the Eight Clusters Corresponding to a Clear Position. Note: Mainly = Mainly acceptable, Request = Depends on patient's level of request, Curability = Depends on the level of curability of the illness, Age = Depends on patient's age, R x A = Depends interactively on patient's age and request, Suffering = Depends on type of suffering, Not Very = Not very acceptable, Never = Never acceptable.

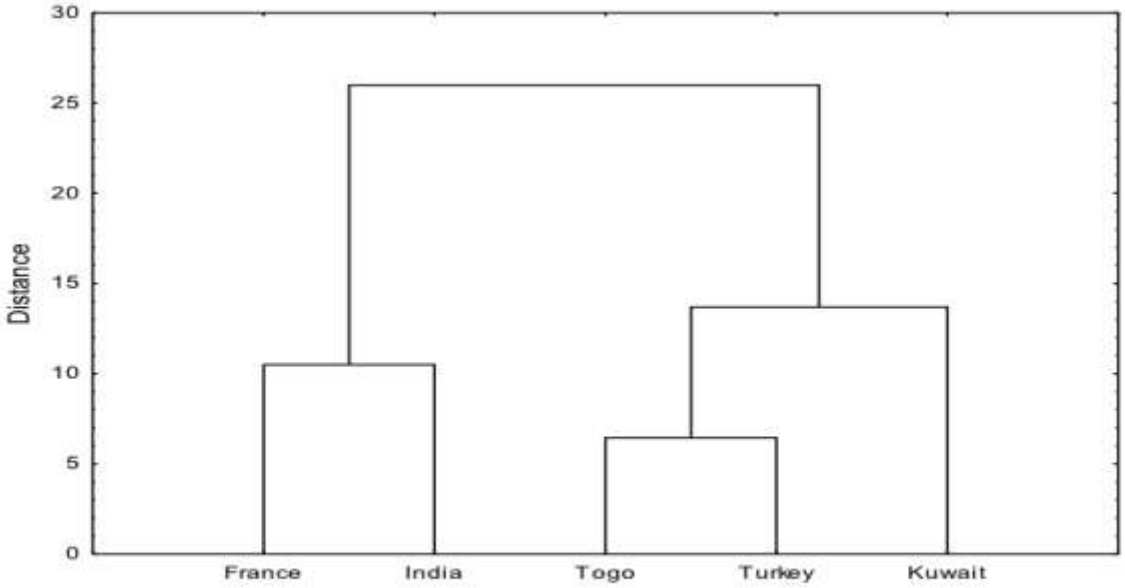

Figure 4.

Dendogram Showing the Euclidian Distances between the Five Countries

Discussion

The study compared the views on the acceptability of PAS of people from five culturally very different countries. It is clear that these views cannot be summarized easily as single values along an acceptability/unacceptability dimension. Most of the time, circumstances mattered, and the circumstances that mattered most differed from one person to another, and all the more so if these persons lived in different countries. These findings are consistent with the view of Cohen et al. (2014, p. 150) that "euthanasia attitudes should be seen as a complex, multi-faceted concept."

Only in Kuwait, where most participants were practicing Muslims, did circumstances matter little: for 68% of them, PAS was never acceptable. Nonetheless, for a minority of them, one circumstance was decisive: the patients' age. When an elderly patient was suffering unbearable pain, they considered PAS as acceptable.

Among Togolese participants, the impact of circumstances was stronger than among the Kuwaiti. Although 36% of them also considered that PAS was not acceptable, 51% took at least one circumstance into account--the patient's age, the level of curability of the illness, or the type of suffering. The great importance given to patient's age by some participants is consistent with the traditional Western African view that, as indicated earlier, the death of an old person is considered a great blessing for the whole society. The importance given to the curability of the illness may reflect a tendency in a country where medical resources are scarce to interpret "difficult to treat" as indicating instead the difficulty of obtaining the treatment or its high cost to the family.

Among Turkish participants, circumstances also mattered more than among the Kuwaiti. If 26% were hostile to PAS, 48% took, like Togolese participants, at least one circumstance into account. In addition, 20% per cent were of the view that PAS was a quite acceptable procedure in all the cases presented. The sensitivity of some participants to the request factor was consistent with findings from a study of Turkish students (Özkara, 2004) showing that about nine out of ten of them agreed with the view that "everyone has the right to decide about his or her own life and health."

Among Indian participants, the most frequent position (52%) was that acceptability depended on the patient's age (except for some participants for whom age made no difference if the patient made no explicit request). In addition, 18% were of the view that PAS was quite acceptable in all the cases presented. The importance given to the patient's age was consistent with the idea that death can, from a traditional Hindu viewpoint, be either good or bad (Firth, 2005). Good deaths are non-violent deaths that occur at the right time, that is, in old age, when the dying person has had time to resolve conflicts. The high percentage of undecided people (18%) might, however, stem from the absence of an official body to define Hindu orthodoxy, which allows people to take different positions on end-of-life questions and, in some cases, to remain undecided. Finally, among French participants, the most frequent positions were that PAS was a quite acceptable procedure in all the cases presented (48%) and that acceptability largely depended on patient request (32%). This finding was consistent with those of Cohen et al. (2014).

The study has limitations. First, the groups of participants were always convenience samples, of moderate size, and, in two cases, restricted to university students from only one site. Generalizations must, therefore, be made with care, especially since the variance in responses might reflect the difference in developmental stage of the participants and not the difference in the culture in which they lived. It would be important, therefore, to repeat the study in India, Kuwait, and Turkey, as well as in other countries, using old as well as young participants. Second, the participants responded to realistic vignettes but not to real patients. Third, the researchers did not ask further questions to elucidate, from the participants' perspectives, the reasons for the responses given in each case.

Owing to the great diversity of positions found, it may seem that the four principles of bioethics suggested by Beauchamp and Childress (2001) may fail to offer a convincing interpretative framework. We do not think so, however. In our view, when Kuwaiti participants considered that in no case was PAS acceptable, they applied their own version of the non-malevolence principle: (a) it would be risky for the ill person to disobey God's command because access to heaven could, as a result, be denied, and (b) it would be risky to the physician, for the same kind of reason, to help the patient to die (Sachedina, 2009). In the same vein, when Indian participants considered that the patient's age was the main determinant of acceptability, they also applied their own version of this principle: in the case of a young patient who is going to experience "bad death", any human intervention runs the risk of introducing severe perturbations into the karmic cycle of life (Desai, 1988). Table 4 presents an interpretation, in terms of the four principles, of the various positions found in the present study. This table shows, in particular, that the autonomy principle, which is highly valued in western countries, rarely applies.

In summary, (a) most participants did not appear to be systematically opposed to PAS; (b) the most important factor, overall, in providing acceptability was advanced age; (c) additional acceptability was, in some cases, provided by the patient's request or the type of suffering or the level of curability of the illness; (d) the dominant principle of bioethics intuitively applied by participants was the principle of non-malevolence, the meaning of which appeared to be not to interfere with God's or the gods' plan; (e) this principle tended to be superseded by the other principles as religious beliefs vanished; and (f) it was only in a secular country (France) that the principle of autonomy was dominant.

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Table 4

Analysis of the Eight Positions in Terms of the Four Principles of Bioethics

Position	Overall Percentage	Main Principles Involved	Rationale
1-Never Acceptable	20	Non-malevolence	Not interfering with God's commands, which would be risky for the patient after her death (and also for the helper).
2-Not Very Acceptable	10	Non-malevolence and Benevolence	Not interfering with God's commands although it is tempting to put an end to the patient's suffering
3-Type of Suffering	4	Non-malevolence and Benevolence	Not interfering with God's commands although it is tempting to put an end to the patient's life when it has become meaningless
4-Incurability	3	Non-malevolence and Justice	Not killing a patient who could be cured if adequate care was available
5-Patient's Age	18	Non-malevolence	Not interfering with Karma; that is, when the patient is too young to experience "good death".
6-Request x Age	5	Non-malevolence and Autonomy	Not interfering with Karma and, at the same time, respecting the patient wishes
7-Patient's Request	10	Autonomy and Justice	Strictly respecting the patients' wishes, irrespective of their personal characteristics
8-Mainly Acceptable	19	Benevolence	Putting an end to the patient's suffering

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Experience of Chinese Immigrant Parents in the United States in an Advocacy-Based Group (POWER) during Initial Settlement

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Abstract

Migration is often a disorienting experience for immigrants, especially for new immigrants who migrate with children as they have additional challenges to ensure that their children's needs are met. Research recommends the advocacy-based theory for social services when working with new immigrants. The purpose of this study was to evaluate one such social services program, the POWER parent program, from the perspectives of new immigrant parents. The goal of this program was to strengthen the college-going culture for low-income immigrant communities in NYC by focusing on promoting advocacy and leadership skills among new parent immigrants with high-school aged children. Using a focus group and the method of content analysis, this study aimed to evaluate the experience of the new Chinese immigrant parents (n = 12) who attended POWER, the advocacy-based leadership program in New York City, between 2010-2012. Qualitative content analysis yielded 6 main themes. The emerging themes revealed that the parents have a strong desire and expectations of themselves to be both a good parent and a good US citizen, and attending POWER helps them increase necessary knowledge and skills, address the communication problem with their children, and empowers them to help other immigrant parents in their community.

Keywords: New Immigrants, Parent-Child Relationship, Advocacy-based Social Services, School Achievement, Cultural Competence

People are moving across the globe in unprecedented rates and numbers, with an estimate of over 200 million migrants in the world, and the U.S. has more migrants than any other country in the world (United Nations Population Fund [UNPF], 2015). Global migration has increased and become a complex issue that requires the evolution of public policies, including policies concerning social services, to address the complex needs of migrants. Migrants relocate for many reasons. Many relocate in order to escape persecution or to obtain better living conditions and opportunities. The experience of migration itself presents a challenge in terms of adjusting to a new country and culture, as well as doing so with limited resources. Recognizing new immigrants as change agents for the success of their community's settlement, advocacy-based approaches of services such as the community-organizing model (Biklen, 1983) may be used to improve immigrants' quality of life and success in settlement in the host country (Chang-Muy & Congress, 2009). These advocacy-based approaches strive to address immigrants' needs, empower them to recognize sociopolitical and structural aspects of their lives, and eventually become an advocate for themselves and their communities in their endeavor to become American. There is little research in general on the experience of new immigrant parents, especially those immigrating with children as they try to settle in the U.S., trying to meet the needs of their own and their children. The purpose

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of this study was to examine the experience of immigrant parents with high school-aged children who participated in a New York-based advocacy program, POWER.

The Needs of New Immigrants with Children

For migrants, no matter what type of migration, settlement can occur in three stages: pre-settlement, on arrival or initial settlement, and post settlement (Singer & Wilson, 2006). Each stage may require a varying amount of time for each immigrant and family. Settlement and integration services targeting immigrant parents and children need to recognize these stages and aim to provide assistance unique for each stage. For many, pre-settlement is fraught with trauma and hardship. When immigrant families, especially low-income and poorly educated families, first attempt to settle in the new country, they may need substantial assistance just to survive (Yoshikawa, Weiland, Ulverstad, Perreira, & Crosnoe, 2014). Literature shows that at the intial settlement, many new immigrants may have unrealistic and often inaccurate expectations of life in their new country (Newland, Tanaka, & Barker, 2007). These expectations may in part be fueled by the host community's general expectation that the migrant become independent after the initial settlement stage (The Department of Labour, 2008). These expectations may cause added and intensified distress to the immigrants upon their arrival as well as tensions between them and the services of the host community.

New immigrants are uniquely challenged by many immediate needs, such as housing, food, employment, learning the new language, culture, and system, and many experience social isolation, culture shock, and discrimination from anti-migrant sentiment in the host country (Meleis, 2010). Immigrants with children also have their children's needs to be concerned about, especially high school-aged children, who may have more difficulty adjusting to the linguistic, social, and cultural challenges than younger children (Goldner & Epstein, 2014). Suárez-Orozco & Suárez-Orozco (2002) stated that immigrant parents often hold the belief that their children will have better educational opportunities and these parents begin to focus sharply on their children's education and schooling for a better future, which in the minds of the parents will make their sacrifice of leaving their home country worthwhile. The adjustment outcomes of immigrant parents are often related to the academic success of their children (Pong & Landale, 2013; Shields & Behrman, 2004). When settlement presents these parents with roadblocks, such as the challenging path to citizenship, unemployment, difficulty with acculturation, then the success of their children becomes these parents' main aspiration and hope (Goldenberg, 2001). While research has suggested that the intergenerational relationships between immigrants and their children in the U.S. have positive predictive effects for the health and wellbeing for both (Crosnoe, 2010), many Chinese immigrants experience extreme parental pressure that may be counterproductive for their growth (Zhou, 1997). This issue is even more likely to be intensified among recent immigrants with limited financial and informational resources who live at or below the poverty line.

Among new immigrants living in poverty in the U.S., high rates of problems have been documented, including mental health and impaired academic functioning (Pumariega, Rothe, & Pumariega, 2005). Research shows that immigrant students are among the populations that have the highest premature school dropout rates (Goldner & Epstein, 2014). For parents with high school-aged students, the needs of their children often involve important issues that the parents do not know how to remedy, such as how to navigate the American school system, the standardized tests, and college and financial aid applications (i.e., the Free Application for Federal Student Aid or FAFSA). These issues are substantially more difficult for immigrant parents with limited English proficiency. In addition, there are other needs of adolescents/emerging young adults that immigrant parents have to be aware of, such as peer relationships, potential dating issues, and cultural adaptation in the school environment (Juang, Syed, & Takagi, 2007). Social service programs that work with immigrant parents of high school-aged children may encounter these complex needs in their clients (Morse, 2005).

Advocacy-based programs for marginalized populations often aim to increase a sense of hope and a belief that every family and community has strengths, despite their compromised situation (Bruner & Rapp, 2001), through community engagement and organizing (Biklen, 1983). Specifically for immigrants, the advocacy-based approach entails a practice that examines ecological resources to support change and growth and manages to meet immigrants' unique needs (Cicchetti, Rappaport, Sandler, & Weissberg, 2000), and fosters cultural competence to target needs and strengths that exist in the minority children's cultural group (Cross, Bazron, Dennis, & Isaacs, 1989; Niessen & Schibel, 2007). A longitudinal study examining the effectiveness of a community-based advocacy and learning program for Hmong refugees found that over the course of the intervention, the migrants' levels of distress decreased, and the following outcomes increased: participants' quality of life, satisfaction with resources, English proficiency, and knowledge for the U.S. citizenship exam (Goodkind, 2005).

Overall, the effectiveness of these services are contingent upon the clarity and timeliness of the targeted needs of both the parents and their children and the connection they have with other community members within a specific location in which they are being settled.

New Wave of Asian American Immigrants in New York City

Immigrants have increasingly comprised the large portion of the U.S. population. As a racial group, Asian Pacific Americans (APA) have the highest percentage growth (46%) between the 2000 and 2010 censuses compared to other major race groups (U.S. Census, 2012). New York City (NYC) has the largest APA population of any U.S. city, making up approximately 15% of the city's population (Asian American Federation, 2012). According to the latest census, Chinese are the largest Asian group in New York City, with

more than a half million residents and expanding 34% from 2000 to 2010 (Asian American Federation, 2012). About one quarter of APA children in NYC are foreign born, and about half of APA youth live below the poverty line and in linguistic isolated households (CEO, 2013). The new wave of Chinese immigrants in the past decade is mostly from the Fuzhou province in China (Guest, 2003), who tend to speak solely Mandarin and the Fuzhou dialect at home.

Despite the illusion that Asian immigrants represent a 'model minority' and fare better than other ethnic minority groups, there is large variation along the lines of class and history of migration in Asian populations (Abelmann & Lie, 1995; spiritu, 1997; Kao & Tienda, 1998; Sue & Okazaki, 1990). Chinese immigrant workers in NYC are nearly twice (1.8 times) as likely to earn minimum wages as native-born workers (US Census, 2006). In NYC, foreign-born adults with low incomes are less likely to have Medicaid than the U.S.-born (29% vs. 42%; NYC Department of Health and Mental Hygiene, 2006).

Considering these needs, many immigrants face particular challenges when it comes to supporting their children in schools. Immigrant families often lack the knowledge of systems and resources, leaving their children in school feeling isolated and marginalized as they navigate the system alone. NYC Department of Education (2006) reported that 1 in 4 APA high school students does not graduate on time or at all; 1 in 5 APA students is an English language learner (ELL); and 30% of APA ELL students prematurely dropped out of schools in 2005-2006.

The POWER group

To address the needs of APA families, a program titled POWER was launched by the Coalition of Asian American Children and Families (CACF). Based in NYC and formed in 1986, CACF is a pan-Asian children's advocacy organization that fights for improved policies, services and funding for APA youth and families. In partnership with a local community site, Asian Americans for Equality (AAFE), the POWER group was CACF and AAFE's parent leadership program focused specifically on APA immigrant parents in the community of Flushing, Queens. The goal of this program was to strengthen the college-going culture for low-income minority communities in NYC, particularly in the targeted neighborhood of Flushing, Queens. Flushing is home to one of the largest dynamic Asian communities in NYC, with Asians comprising 71% of the residents (Asian American Federation, 2012).

As a concentrated immigrant population in the area, many residents in Flushing face challenges in pursuing education due to linguistic, cultural and economic barriers. CACF and AAFE worked with the administration, staff, youth and parents of 2 local high schools in the community. Many of the families that CACF and AAFE worked with are not just the first to be en route to attend college in the US, but the first in their family to attend any type of higher education. Each year, this POWER group consists of 12-15 parents, all of whom are living at or below the poverty line and speak solely Chinese-Mandarin and Fuzhou dialect at home. Since it is based in Flushing, this particular program cohort, the POWER parents, were recruited from the 2 local high schools. There was a multi-prong approach in recruitment for the POWER parents. There were recruitment workshops held throughout the first year of our Flushing program aimed for parents to participate at the start of the next academic year. The CACF's staff managing this program was bilingual, and the workshops were held in Chinese, and all of the recruitment materials sent out were translated into Chinese. Flyers and recruitment information were also mailed and sent home to every Asian parent. In addition to recruitment workshops, CACF staff also attended the Parent-Teacher Association meetings and the Parent-Teacher conferences at the schools. At the parent teacher conference, CACF staff would assist in interpretations at the meetings. This provided more face-time with the parents while generating trust and buy-in from the immigrant parents, as they now would perceive the CACF staff member as a resource at the school. In doing so, a relationship was formed, and parents became more inclined to attend school events whenever the outreach was performed by the CACF staff member, in addition to enrolling in the POWER leadership program. The POWER program recommended that the parents commit to one full academic year by attending a 2-hour session each month. The parents were also encouraged to attend their child's parent teacher conferences and their PTA meetings. One of the goals for this program was to increase parent engagement in both formal and informal settings. During the monthly sessions, a variety of topics were covered. There were know-your-rights workshops for parents attending a NYC public school, which would entail their rights to language access in schools, the structure of public school systems, as well as pathways to graduation. There were also workshops on college readiness, which included financial aid, the different types of colleges, and the different criteria that colleges look for. Other workshops entailed parent engagement, financial literacy, cultural competency, and advocacy. These included information on the larger community and on the history of Asians in the United States and examined the different values and cultural expectations between an Asian context and an American context. In addition to these monthly meetings, there were supplemental events such as the program launch event, graduation event, free English language courses and college trips. In Flushing, one of the events the POWER parents organized was a college workshop for other Asian immigrant parents. The goal of the POWER program was to develop the parents' capacity in their own active engagement as members and organizers of the program, enable them to better support their immigrant families at home, in the school, and in the larger community, and focus on long terms goals such as college readiness.

Purpose of the present study

The present study aimed to explore the experience of new immigrant parents who migrated within the last two years of the study and participated in the POWER program,

an advocacy-based group. Specifically, the study proposed to examine (1) the needs and challenges of new Chinese immigrant parents and (2) ways in which their participation in POWER helped address these needs and challenges. The study gathered data from a focus group conducted with Chinese-speaking immigrant parents from the two high schools located in the neighborhood of Flushing, Queens and analyzed that data using content analysis methodology (Elo & Kyngas, 2007).

Method

Participants

The participants were 8 females and 4 males with the mean age of 41.9 (*SD* = 4.8, rage 35-50); 90% completed only high school or less. All of the participants were Chinese immigrants from China and spoke Mandarin and the Fuzhou dialect as their primary languages and lived at or below poverty line, based on their reported income (ranging from $8,000-$22,000 per household with an average of 2-3 people in the household). Nine out of twelve (75%) participants had lived in the U.S. for less than one year and all of them had been in the US for less than two years.

Procedure

After CACF's Review Board approved the study, flyers about the focus group were given to all the POWER parents, and those interested in participating contacted the program coordinator to sign up. A total of 12 Chinese immigrant parents out of 20 who attended the POWER group from 2011-2012 volunteered to participate in one two-hour focus group, designed to examine their experiences as POWER group attendees. The author facilitated several open-ended questions with a bi-lingual Mandarin Chinese/English facilitator, who translated the questions to the participants, and four other bilingual translators sitting next to every three parents to actively ensure that every parent's responses were accurately translated back to the author in real time. Prior to the beginning of the focus group, both verbal and written consent in Chinese was obtained by the program coordinator (co-author) from every participant.

The focus group interviews were audiotaped, transcribed, and translated into English by two bi-lingual volunteers, blind to the study. Following the content analysis strategies described in Elo & Kyngas (2007), the first author coded the transcripts and developed salient emerging themes by selecting key words and recurring words as the unit of analysis. Based on the limited knowledge of the experience of Asian immigrant parents in advocacy-based groups, the author chose to analyze the data using the inductive analysis method of content analysis. This process involves open coding, creating categories of themes, and abstraction (Creswell, 2003; Elo & Kyngas, 2007; Polit & Beck, 2004). The abstraction step refers to the fact that subthemes are selected to be grouped under a main theme on the basis that they "belong" to that particular group (Elo & Kyngas, 2007). The transcripts were then coded by the second author using the same process. Any discrepancies were discussed until a final set of themes was agreed upon by the two coders.

Measure

A semi-structured interview guide with 7 open-ended questions (see Appendix A for the questions) was used in the focus group to collect perspectives of all participants regarding their experience of attending the POWER group.

Results

The focus group was structured in a way to ensure that every participant was able to voice their opinion by going around the room for each question. The participants were given the choice to pass, but none of them took the offer, and 100% of the participants answered all the questions. As a result of the open coding, category building, and abstraction, there were a total of 6 main themes, representing salient perspectives of the focus group interviews.

Theme 1: Desire to be a good resident in the U.S. as a new immigrant

All parents agreed that it is very important for them to be informed and made more aware of American culture, including values, the legal system, and financial and housing situations. This knowledge reflects the importance of having their basic needs addressed, in addition to helping their children focus on attending a good college. Some of the participants' responses that illustrated this theme were:

"We just got in America without knowing about American's situation, and we wanted to learn all different things like the houses, loans and banks...to be successful" (F, 50).

"I want to understand the system here, so I can be a good American" (F, unknown age).

"I want to know about tax returns" (F, 39).

"Chinese and American have different cultures, we as parents, we won't know these if we don't attend the meeting, like, we understand after the person explained to me" (M, 37).

Theme 2: Desire to be an informed and good parent

All participants stated that one of the main reasons that they attended the POWER group concerned their desire to be a good parent for their children and want to be informed of the college preparation process in order to help their and to select the best college for them. Some of the participants' responses that illustrated this theme were:

"I also want to know about the school, and the tips on college (after entering college), and help my kids easier and

quicker to get into colleges" (F, 44).

"Me too - for kids, we don't know about the situations about American and American schools, I want to know more about it to help my kid go to a good college" (M, 37).

Theme 3: Gaining financial, linguistic and informational resources about the US educational system

Many parents stated that challenges as an immigrant parent for them mainly included the lack of knowledge about college preparation in the U.S. and the inaccessibility of financial resources due to their own and their children's limited English proficiency. Some of the participants' responses that illustrated this theme were:

"Just… know nothing. For example what score does a college need – we don't know about it. And we don't have money for top colleges, just want to know what are the ways to help him/her go to a good college and save money at the same time" (M, 43).

"We can ask many questions. If we have anything we don't understand we can ask them [the group leaders]. Like last time, I have question on loans and schools my children can go to" (F, 39).

"My child is still a ninth grader; I don't know what's going to happen to him next" (M, 37).

"I don't have a reliable job. Coming here helps me know more about options" (M, 36).

Theme 4: Addressing the lack of parent-child communication upon migration

10 out of 12 parents stated that the lack of parent-child communication was a challenge. Some of the parents expressed that their children are not likely to share with them the information or experience that they have at school. These parents agreed that it is difficult to be a good parent for them without their children sharing their experience with them. Attending the POWER group is an opportunity that these parents have to hear and learn from other parents and from the facilitators about common issues related to the American school system and the challenges that their children may face. Some of the participants' responses that illustrated this theme were:

"I know lot of things that I can't know in school (from the meeting), because my child does not necessarily tell me everything in school. He handles things by himself, I get information from here." (F, unknown age).

"Sure it is about communication with children. Parents and children think differently. That's common, because the age gap is a lot - we understand the society differently" (F, 39).

Theme 5: Solution for current challenges

All parents agreed that the POWER group is one of the reliable places to receive information. It is one of the significant solutions for their current challenges in relation to the lack of knowledge and information, the limited financial and linguistic resources for themselves and their children, and the lack of communication between them and their children. Some of the participants' responses that illustrated this theme were:

"We asked Teacher XX, what score ranges fit to which college, and he answers us almost every problem" (F, 35).

"I was told just what the process of applying for college is, and what academic score he needs" (M, unknown age).

"Yes, we can tell my friends about college applications, and we believe everything we heard from here is true. We can't tell if it is true if not from here" (F, 43).

Theme 6: A shift from receiving to giving: The opportunity to help others and exercise community engagement

When asked about the meaning of advocacy, all of the parents endorsed the opportunity to give back to the community and help other immigrants in their community by passing on the knowledge they learned from the POWER group. In addition, through helping other parents in the community, the parents acknowledged their voice as valuable and empowering for other immigrant parents facing similar issues. Some of the participants' responses that illustrated this theme were:

"We learned a lot, this place not only helped my kid, but also other parents and children" (M, 37).

"To me, advocacy means to speak out for your community about concerns that are important" (F, 39).

"Because I have lots of new immigrant friends who are struggling, their kids are not from these two high schools therefore they cannot attend the meeting. We should expand it to the larger society" (F, 45).

"I like the opportunity to help other parents in our community who do not attend this group. They need help with their kids too" (F, unknown age).

Discussion

This study sought to understand the experiences of new Chinese immigrant parents about their participation in an advocacy-based group during their initial settlement in NYC. The emerging themes revealed that the parents have a strong desire to be both a good parent and a good citizen, despite limited necessary knowledge and assis-

tance. These expectations, while they may not be unrealistic, require targeted support from the host community to materialize. The current challenges that they experienced as immigrant parents with children preparing for college mainly included the lack of information and knowledge about college preparations in the U.S. and their limited English proficiency as a barrier to fully understand the process. In addition to language and cultural barriers, many immigrant parents had a limited financial literacy of the U.S. system and did not know how to open savings and checking accounts, how to complete tax return information, or how to build financial histories in order to achieve financial independence and accumulate wealth (Amuedo-Dorantes & Pozo, 2002). A lack of options for viable employment is also a daunting issue to many new immigrants. These barriers make it distressful for new immigrants, who are expected to be financially independent soon after their settlement, based on the U.S.'s policy on immigration (The Department of Labour, 2008). All of the parents come from low-income backgrounds, and most of them never attended college in China. These needs are consistent with well-documented needs for new immigrants (Meleis, 2010). The POWER program provides information intended to strengthen knowledge in these areas. POWER provides workshops and educational presentations to increase knowledge of basic US financial literacy.

The barriers of class, language, and culture all contribute to parenting challenges for parents. Many immigrant parents do not know how or have the time to engage in their child's school-related activities. Many studies show a positive link between parental engagement and student academic success and achievement (Schaller & Rocha, 2007; Sobel, Kugler, 2007), including among Asian immigrant families (Crosnoe, 2010). However, this link is interrupted by the generational gap between the new immigrants and their children in this sample. Unaddressed intergenerational gap may lead to intergenerational conflicts, which are negatively associated with mental health outcomes among immigrants and their children (Ansary, Scorpio, & Catanzariti, 2012; Buki et al., 2003). The POWER program provides a safe space for parents to share their feelings and experiences and ask questions regarding the common needs that their children may have. This type of safe space provides validation, knowledge exchange, and emotional support (Seif, 2005). A safe space is also supported in the literature of adult learning as an essential element for transformative learning because ideal learning conditions promote a sense of safety, trust, and openness (Nino, Cuevas, & Loya, 2011).

Drawing from these challenges, the participants acknowledged that the variety of services for parents, including college preparation, legal and financial counseling, and English proficiency classes, are important for their success in building a new life in the U.S. As the lack of bilingual staff for these supports is one of the major barriers for the success of the immigrants and their children in school (Lake Snell Perry Mermin/Decision Research, 2005), attending the POWER group became very essential for the participants in this sample.

The shift from being the recipient of help to being the helper is another thematic response from this study's participants, which confirmed the importance of advocacy and leadership elements for new immigrants (Chang-Muy & Congress, 2009). All of the parents in this study acknowledged that attending this group empowered them to become an advocate for their community by passing on the information to other new parents who are not in the group. Throughout the year, the POWER parents were asked to create a college readiness campaign for the larger immigrant community. This is one of the activities that accentuates the community engagement and advocacy skills among the POWER parents. The desire and motivation to give back to the community is echoed by other immigration studies as well (Findley & Martos, 2015; Weng & Lee, 2015). For example, a recent study (Weng & Lee, 2015) on the civic engagement experience of giving back to the community among new immigrants found a desire to maintain ethnic identity and connection, seeing ethnic community as an extension of family, and a sense of duty and connection as major themes. The parents in this study expressed the desire to expand this group to make it available for other parents not living in their immediate community. This activated motivation for civic engagement proves the effectiveness of such an advocacy-based program for its ability to serve a wider range of immigrants through empowerment and leadership of the program participants. This internal motivation to help and connect with their ethnic community appeared to be activated by their participation in the group and drove them to engage in civic engagement plans as one protective factor for their settlement in the U.S.

POWER is not the only parent group serving new immigrants in NYC. There are other available parent programs for immigrants in NYC (NYC Mayor's Office of Immigrant Affairs, 2015); however, most programs provide specific services, such as English as a second language classes, job training workshops, and early childhood development. Because new immigrants with high school-aged children often face several unique challenges, POWER aims to be a well-rounded and advocacy-based program for financial literacy and college readiness and to play an essential role in increasing parent engagement and empowerment during the initial settlement stage. Advocacy-based organizations can not only provide linguistically and culturally appropriate services to connect with immigrant parents and their children, but also empower these parents to become leaders and advocates for members of their community who are faced with similar settlement challenges.

Limitations and Future Research

There are several limitations to be noted of this study. First, it consisted of only one group of 12 participants. More focus groups of the participants from different cohorts in the program are recommended to increase the representativeness of the findings. Second, the findings might not generalize to other new immigrants in other settings. These experiences may be unique to the participants included in the study. A replication of a similar study is recommended in new immigrant parents from the Fuzhou province who attend similar

programs. Third, a self-select bias may be at play as these participants volunteered to be in the study. Their experience may be qualitatively and characteristically different from parents who attended the group but were not in the study. Lastly, while the first author is an outside researcher contracted to conduct focus group interviews, the second author is part of the CACF's POWER program. Several strategies were used to minimize the effects of the authors' personal biases (e.g., the author's use of extensive journaling and memos throughout the study to reflect on and minimize the influence of these possible biases, and the use of bi-lingual volunteers who were blind to the study, and the study's participants to be involved in the translation and coding of the data). However, it is important to acknowledge that despite these strategies the second author's connection to the POWER group may have influenced the participants' responses and the focus group process.

Future research that explores the following issues would be beneficial: (1) long-term outcomes of advocacy-based services for new immigrants and their children, (2) the effects of participation in advocacy-based services on mental health outcomes among immigrants and academic outcomes among their children, (3) factors that are necessary for addressing intergenerational gaps and strengthening parent-child relationship among new immigrants to prevent intergenerational distress. Lastly, there should be further systematic exploration of the development, maintenance, and use of internal motivation in civic engagement as part of settlement for new immigrants.

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Appendix A: Semi-structured interview guide

1. What are the reasons that you joined the POWER group?
2. What do you get from attending the POWER meetings?
3. What did you expect to learn in the POWER group? And what do you still want to learn in this group?
4. What are the difficulties and challenges you have faced when you help your children apply for college?
5. You've all talked about the difficulties and challenges, what do you think might be the solutions for these challenges?
   a. Probing question: What have you tried to do to solve these difficulties?
6. What do you think will help parents advocate for their children who are applying for college?
7. In what ways can the POWER group improve in order to help more new immigrant parents with children?

Closing question: Is there anything else you would like to share with me in regards to your participation in the POWER program?

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Parent-Child Representations in Children's Family Drawings in Bulgaria, Italy and the Netherlands

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Abstract

We investigated cultural variations in parent-child representations of Dutch (n = 112), Italian (n = 82), and Bulgarian (n = 121) children's family drawings. The drawings were selected to represent highly individualistic (Dutch), individualistic (Italian), and collectivistic (Bulgarian) cultures. Using the Pictorial Assessment of Interpersonal Relationships (PAIR, Bombi, Pinto, & Cannoni, 2007), all drawings were coded with regard to Cohesion, Distancing, Similarity, and Value in parent-child representations. Dutch children scored higher on Distancing and lower on Cohesion, compared to the Italian and Bulgarian children, whereas Bulgarian children scored higher on Cohesion and lower on Distancing compared to the other two samples. We conclude that children's drawings represent individualistic and collectivistic traits in the relationship between self and parental figures.

Keywords: Children's drawings, parent-child representation, Bulgaria, Italy, the Netherlands

This study investigates the representation of parent-child relationships in children's drawings across three European cultures by exploring potential cultural variations underlying these representations. Research has consistently found that children's drawings provide a window into the child's view of family dynamics and self-perception within the family. Children draw their environment and relationships in socially and culturally relevant ways (Dennis, 1966). Research has also shown that culture and embedded local values within social and cultural systems affect the representations of children's drawings (LaVoy et al., 2001; Nuttall et al., 1988; Rübeling et al., 2010). For instance, LaVoy and colleagues (2001) compared Japanese and North-American children's drawings showing that Japanese children drew significantly fewer smiles than North-American children. Presumably, Japanese children have developed boundaries between the private self and public self, whereas the American children have been taught the value of social emotion. The Japanese culture emphasizes group identification and a strong feeling of belonging. Such society's high social values are reflected in the Japanese drawings, showing larger figures as the self in comparison to the American children (LaVoy et al., 2001). The comparison between Chinese and U.S. children's drawings made this distinction even clearer. American children expressed a greater sense of individualism, seen by depicting themselves alone, whereas the Chinese children expressed a greater sense of collectivism, drawing significantly more figures as part of their family than the US children (Nuttall et al., 1988). These studies show that children's drawings can be used as a valid tool to explore culturally relevant representations across cultures.

Cultural differences have also been ascribed to the distinction made between cultures of individualism (independence) and collectivism (interdependence). Individualism can be defined as a complex set of behaviors based on the concern for oneself detached from the immediate family or social environment (e.g., Western cultures; Shiraev & Levy, 2010)The self-construal related to individualism is characterized by an emphasis on personal accomplishments, success and the development of a unique personality (Shiraev & Levy, 2010). Collectivism, on the other hand, is characterized by "strong ties" where individuals subordinate their personal goals to the goals of some collective, which is usually a stable in-group, like their family (e.g., Asian cultures; Hofstede, Hofstede, & Minkov, 2010). In this line of reasoning, parent-child relationships may be related to independent or interdependent self-construal. Parents from individualistic cultures focus on parenting the child as an independent self, whereas parents from collectivistic cultures emphasize interdependent upbringing (Rübeling et al., 2010). As the relationship between parent and child differs between cultures, it would be reasonable to expect that these differences are expressed in children's drawings. A more detailed description of parent-child relationships of the target groups and study context is presented below.

The Present Study

This study explored cultural variations in representations of parent-child relationships in drawings of children in three European countries (i.e., Bulgaria, Italy, and the Netherlands) as representatives of individualistic and collectivistic cultures. Bulgaria, an Eastern European country, represents a collectivistic culture in comparison to the other two Western European countries. Bulgaria has been rated with 49 out of 100 points on individualism and showing a higher degree of un-

equal power in comparison to the Netherlands and Italy. Bulgaria is described as having strong family ties (Davidkov, 2004). Characterized by long term commitment and loyalty towards the family (nuclear and/or the extended family) and belongingness to the family is high (Hofstede, 2010). Bulgarian parents teach their children to obey and children are thought to treat their parents with respect. There are tight rules for children, they are encouraged to think in term of "we" and respect and harmony between the family members are important (Davidkov, 2004). Studies have shown that collectivism has a strong presence in Bulgaria, presumably because of the communistic and totalitarian systems of the past (Kulkarni et al., 2010).

The Netherlands is one of the most individualistic countries in Europe and scores 80 out of 100 points on individualism with strong equal power distribution (Davidkov, 2004). In comparison to Bulgaria, Dutch parents teach their children in terms of "I". Children treat their parents as equals and vice versa. Dutch family ties can be described as weak. Parents have lenient rules towards their children and they stimulate their children to speak their minds. Young adults are encouraged to leave the house. Parents see this as part of their education; acquiring the experiences they need to handle life as autonomous individuals (Reher, 1998).

Italy has been scored 76 out of 100 points on individualism due to the fact that large cities became more individualistic in recent years (Davidkov, 2004; Hofstede et al., 2010). However, Italy is more collectivistically oriented compared to the Netherlands and less than Bulgaria (Smith, Dugan, Peterson, & Leung, 1998). Similar to Bulgarian family ties, the Italian family ties are described as strong. Children from Italian families live longer within the household compared to their Dutch counterparts. Parents support and protect their children until the child is ready to leave the household, normally for marriage or when financially independent (Reher, 1998).

This study investigates cultural variations in parent-child representations in Bulgarian, Dutch and Italian family drawings. Dutch children's drawings have been chosen as representative of an individualistic culture, Italian drawings represent an individualistic culture but less individualistic than the Dutch, and Bulgarian drawings represent a collectivistic culture. The following hypotheses were tested:

Hypothesis 1: Bulgarian drawings will show higher cohesion compared to Italian and Dutch drawings, denoting higher interdependence in the parent-child relationship.

Hypothesis 2: Dutch drawings will show higher distancing compared to Bulgarian and Italian drawings, expressing higher independence in the parent-child relationships.

Hypothesis 3: Bulgarian drawings will show higher similarity and collectivistic features compared to Italian and Dutch drawings.

Hypothesis 4: Bulgarian children's will show higher value compared to Italian and Dutch, conveying higher degree of power distance among family members.

Method

Participants and Procedure

Participants were 338 children (184 female, 154 male) aged 7 to 14 years of whom 123 were Dutch, 94 were Italian, and 121 were Bulgarian (Table 1). Drawings were collected as part of a larger multi country projects in Bulgaria, Italy and the Netherlands. Based on Bombi, Pinto, and Cannoni' method (2007), all children were given an A4 sheet of white paper and were asked to draw their family. The children were free to use the sheet as they wanted, horizontally or vertically, and to use crayons, pencils or pens provided to them. The children were free to draw what they thought was their family, including pets, surroundings, activities, or attributes. A time limit of thirty to forty-five minutes was set. Afterwards, children were asked to identify the figures (e.g., self, mother, father, peers, etc.).

The Pictorial Assessment of Interpersonal Relationships (PAIR; Bombi et al., 2007) was used to code children's representation of family relationships. PAIR explores the differences between one pair of individuals in this case the mother-child and father-child dyad. The four PAIR scales that were used in this study were: Cohesion, Distancing, Similarity and Value. *The Cohesion Scale* measures the degree of interdependence among partners with 6 subscale. Three out of the six subscales refer to the direction of partner's action. *C1 Looking at*: Is one figure looking at the other? *C2 Moving towards*: Does the posture of one figure tend to reduce space between two figures? *C3 Coordinated activity*: Is the activity of one figure coordinated with the activity and/or presence of the other figure? Three of the six subscales of Cohesion refer to the organizational space. *C4 Proximity*: Are the two figures near one another? *C5 Common area*: Are the two figures both located in a shared area, distinct from the remaining space in the sheet? *C6 Union*: Are the two figures united by a graphic element? Each subscale provides a dichotomous score with higher scores indicating high interdependence and lower scores - more independent, individualistic view of the relationship (Bombi et al., 2007). *The Distancing Scale* measures the degree of autonomy among partners, comprising 6 subscales. Three of the six subscales refer to the direction of the partner's action and not to its content. *D1 Looking away*: Does one figure actively avoid looking at the other? *D2 Moving away*: Does the posture of one figure tend to increase the space between two figures? *D3 Independent activity*: Does one figure act by itself? Three of the six subscales refer to the organizational space. *D4 Remoteness*: Are the two figures far apart? *D5 Individual area*: Is one figure set in an area of its own distinct from the remaining space in the sheet? *D6 Separation*: Are the two figures separated by a graphic element? The subscale provides dichotomous score with high scores indicating higher degree of autonomy or independence, and low scores - an interdependent view of the relationship. Simultaneous presence of indices in cohesion and distancing is possible (Bombi et al., 2007). The *Similarity Scale* measures the psychological affinity among figures and consists of 5 subscales each scored from 0 (little or no simi-

larity) to 2 (strong similarity). Two of the five overall subscales refer to stable aspects of the figures. *S1 Height*: Are the two figures of the same height? *S2 Position*: Are the two figures in the same position? Three of the five subscales refer to changeable aspects of the figures. *S3 Body*: Do the two figures have the same face and body form? *S4 Attributes*: Do the figures show attributes of the same type and form? *S5 Colors*: Are the colors of the two figures' body and attributes the same? A high score on similarity indicates a more identical pair of figures, which is a collectivistic trait; a more diverse pair of figures reflects individualistic features (Bombi et al., 2007). The *Value Scale* measures the comparative value among figures. It comprises 5 subscales, each given a score from 0 (identical or very similar value) to 2 (value disparity). Three of the five subscales refer to the figures' importance. *V1 Space occupied*: Do the two figures occupy an equal amount of space? *V2 Dominant position*: Is the relative location of the figures on the page equal? *V3 Body detail*: Do the two figures have an equal number of body parts? The remaining two subscales refer to the figures' elaboration. *V4 Number of attributes*: Do the two figures have the same number of attributes? *V5 Number of colors*: Do the two figures have the same number of colors? High scores indicate a difference in power that the pair of figures display (Bombi et al., 2007).

Table 1

Sample Description by Gender, Age and Country

	Bulgaria	Italy	The Netherlands	Total	Group differences
	(n = 121)	(n = 94)	(n = 123)		
Gender, n (%)					
Female	64 (52.9%)	50 (53.2%)	70 (56.9%)	184 (54.4%)	χ^2 (1, 338) = .72
Male	57 (47.1%)	44 (46.8%)	53 (43.1%)	154 (45.6%)	
Age					
Mean (SD)	12.45 (1.44)	9.24 (1.55)	9.79 (1.80)		F(2,338) = 123.81*
PAIR, Mean (SD)					
Cohesion	.90 (.90)	.80 (.76)	.58 (.71)		F(2,353) = 5.83* η^2 = .03
Distancing	1.75 (.86)	1.82 (.79)	2.20 (.90)		F(2,353) = 10.37* η^2 = .06
Similarity	7.02 (1.86)	7.74 (1.47)	6.17 (1.54)		F(2,353) = 11.47* η^2 = .06
Value	1.51 (1.42)	2.24 (1.56)	1.82 (1.44)		F(2,353) = 6.63* η^2 = .03

Note: PAIR = Pictorial Assessment of Interpersonal Relationships. * $p < .001$.

Results

Analyses were conducted in three steps. First, all drawings were coded by two independent raters whose inter-rater reliability ranged between .86 and 1.00. Second, bivariate Pearson correlations between mother-child and father-child dyads on every PAIR scale were conducted. There were positive and significant correlations between mother and father dyads on cohesion ($r(338) = .56$, $p < .001$), distancing ($r(338) = .24$, $p < .001$), similarity ($r(338) = .74$, $p < .001$) and value, $r(338) = .73$, $p < .001$. Therefore, composite variables were created for all the scales consisting of a total score of each scale regarding mother-child and father-child comparisons. Third, Multivariate Analysis of Covariance (MANCOVA) was performed with Cohesion, Distancing, Similarity and Value as dependent variables and Italian, Dutch and Bulgarian culture as the independent variables and with age as the covariate. There were significant effects for cohesion ($F(2, 338) = 5.834$, $p < .003$, $\eta^2 = .03$), distancing ($F(2, 338) = 10.37$, $p < .001$, $\eta^2 = .06$), similarity, ($F(2, 338) = 11.47$, $p < .001$, $\eta^2 = .06$), and value ($F(2, 338) = 6.63$ $p < .001$. $\eta^2 = .03$) (see Table 1). Post-hoc Bonferonni comparisons showed that in line with the first hypothesis, cohesion was higher in drawings of Bulgarian children, denoting a higher degree on interdependence among family members. Similarly, as expected, the independence among family members was higher in the Dutch drawings compared to the Italian and Bulgarian ones, which confirms the second hypothesis (Figure 1). Contrary to the third hypothesis, similarity was highest in Italian rather than in Bulgarian drawings. The last hypothesis was also not confirmed as Italian rather than Bulgarian drawings had higher scores on value between parents and children.

Figure 1

Examples of Family Drawings of Bulgarian, Dutch and Italian Children

Figure 1a

Drawing of Bulgarian girl (second figure from left), age 10, representing high Cohesion, low Distancing, low Similarity and high Value

Figure 1b

Drawing of Dutch girl (third figure from the left), age 11, representing low Cohesion, high Distancing and low Value

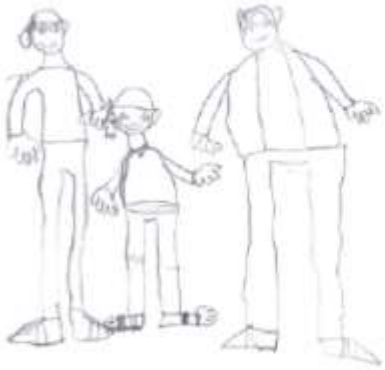

Figure 1c

Drawing of Italian boy (middle figure), age 9, representing high Cohesion, low Distancing, high Similarity and high Value

Discussion

The purpose of this study was to explore cultural variations in representations of parent-child relationships in drawings of children with different cultural backgrounds. We found that Dutch children's drawings represented high individualistic features and Bulgarian children demonstrated high collectivistic features, whereas the Italian sample represented moderate individualistic combined with collectivistic traits. In fact, in line with the first hypothesis, Bulgarian children's drawings showed a significantly higher score on cohesion (e.g., proximity and union between child and parents) compared to the Dutch, indicating a higher degree of interdependence. In line with the second hypothesis, we found that Dutch children's drawings were scored significantly higher on distancing in comparison to the Bulgarian and Italian drawings. The Netherlands is a highly individualistic country, where the self is perceived as autonomous and separate. Dutch children drew more distance between the child and parent, depicting independent activities, reflecting autonomy and independence of the child. Drawings provided by Bulgarian children showed the opposite, confirming a more interpersonal bond and cohesion between parents and child (Rübeling et al., 2010).

With regards to the third and fourth hypotheses, no significant differences were found between Bulgarian and Dutch children's drawings on similarity and value in parent-child representations. Possible explanations for these discrepancies could be found in the characteristics of autonomy and relatedness. It has also been suggested that individualistic and collectivistic traits may coexist at the same time in different situations (Sahin & Mebert, 2013). Yet, with regard to similarity in parent-child representations, a significant cultural group difference emerged. The Italian drawings showed a higher degree of similarity among figures compared to Bulgarian and Dutch. Italy has been considered as an individualistic country with collectivistic traditions, especially in terms of family relationships. Traditionally, the immediate family is a tight unit of relevant representation in sharing values and traditions (Rabaglietti et al., 2012), possibly explaining such strong similarity in parent-child dyads drawn by Italian children.

Significant cultural differences were also found between Italian and Bulgarian drawings on the value scale (denoting power distance relationships). Unequal power is a characteristic for collectivistic cultures, therefore, it would have been expected to be high in Bulgaria, but instead, was found to be high in Italy. As explained by Hofstede (2001), Italians believe in hierarchy and accept different power distributions. Another alternative explanation could be found in some details when scoring similarity and value scales, namely, the diversity of color. The Italian children drew mostly in black and white compared to the Bulgarian and Dutch who used different colors. The lack of color could result in a higher overall score on similarity and value scales, which would not necessarily explain cultural differences but use of diverse materials.

In summary, the results showed cultural variations in parent-child representations among Dutch, Italian and Bulgarian children. Overall, the Dutch scored low on cohesion and high on distancing (low on similarity and value), according to expectations and evidence that the Netherlands is an individualistic culture. The scales of cohesion and distancing indicate that Bulgarian families tend to be more collectivistic and interdependent compared to the Italian and Dutch. On the other hand, the Italian sample showed more collectivistic traits than previously expected, indicating a seemingly collectivistic culture on some aspects, but also having individualistic traits as seen in the cohesion and distancing scores.

The study has some limitations. First, future research could expand on different developmental stages. The PAIR uses different coding schemes for complex and elementary drawings drawings to control for age differences. However, age could still have an effect on how individuals perceive their culture. For example, older children could have

a different understanding of the parent-child relationship in terms of power. Adolescents go through a period of change needing more freedom and autonomy (Noller & Callan, 1986). Thus, expressing more freedom and autonomy means a change in power, and not necessarily an individualistic trait. Further studies should use the PAIR in different age groups of children and adolescents. Second, although PAIR has shown to be a good tool to detect how children understand interpersonal relationships and how they discriminate between different categories of relationships, it would be useful to add other methodological tools. As Bombi and colleagues (2007) pointed out, drawing and language are both able to understand central aspects of parent-child relationships, but also differ in their sensitivity to specific aspects of the relational experience. For example, verbal report of a relationship may focus more on doing things together, or being near each other. Drawings, on the other hand, depict other relational indices, such as looking at each other and sharing a common area. It would be interesting to explore if children's verbal narratives would resemble individual aspects of family life (e.g., "I") or collective joint activities (e.g., "we"). It is also important to note that even though statistical significance was reached in testing our hypotheses, the substantive significance of these effect sizes was small to medium. Arguably, other factors may contribute to explain the variance in drawings, such as age or developmental period, drawing ability, or dynamics related to interpersonal relationships within the family. Despite these limitations, we can conclude that this study showed unique aspects as well as interesting similarities and differences among children's family drawings. The method used to examine these aspects, the PAIR, showed to be a good instrument to explore cultural variations in parent-child relationships in Bulgarian, Italian and Dutch children's drawings.

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Experiencing the Dynamics of Cultural Identity

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Contemporary developments such as globalization and technological advancements require the discipline of Cross-Cultural Psychology to adjust its operationalization of culture. Whereas it was viable to define cultural groups alongside national borders (i.e., "being Turkish, due to being *from* Turkey), and to study culture and acculturation as categorical and static entities in the last few decades (e.g., by using the acculturation model of Berry, 1997), such an operationalization does not seem valid anymore (van de Vijver, Blommaert, Gkoumasi, & Stogianni, 2015). Cross-border migration and web-based communication have led to more faded and permeable cultural boundaries. Today, an increased number of individuals negotiate various cultural identities and identify as "multicultural" (e.g., Chen, Benet-Martínez, & Bond, 2008; Hong, Morris, Chiu, & Benet-Martinez, 2000); thereby challenging traditional conceptualizations of culture. My personal experiences from childhood to present day illustrate the drawbacks of static and categorical approaches, and highlight the need for truly dynamic conceptualizations of culture and multiculturalism (Aydinli & Bender, 2015).

Culture has always played an important role in my life. Being born to Turkish parents in South-Western Germany made it impossible for me to escape the process of acculturation. I had to explain to others how to pronounce my first name correctly as early as kindergarten and this quickly made me realize that "I am somehow different from others". Experiences such as those shaped my cultural identity. They taught me that I am Turkish-German, or rather only Turkish, as it was the "Turkishness" that set me apart from other children in kindergarten, from classmates at school, and from fellow students at university. This distinctiveness unwittingly led others to categorize me as *"the Turkish"*, which in turn affected how I viewed, identified, and labeled myself. Driven by these experiences, I developed a genuine interest in studying culture. As a result, I attended a joint PhD in Social/Cross-Cultural Psychology between Tilburg University (the Netherlands) and Koç University (Turkey).

Before I moved to the Netherlands, I had primarily considered myself *"Turkish",* while knowing that, at times, I can also be German, or at least think and behave like a German, even without considering myself German. After arriving at the department of Cross-Cultural Psychology at Tilburg University, the way I viewed and perceived myself changed. There was no distinctiveness anymore. I was faced with a multicultural environment consisting of Dutch, German, Turkish, Bulgarian-Italian, Chinese, South African, Kenyan, Indonesian, and Spanish colleagues and friends. I once again experienced acculturation, but this time from a different perspective. For the first time I felt to be Turkish, German, everything and nothing *at once*. I literally felt like myself, "Arzu", rather than the Turkish girl in kindergarten, school or university. Going beyond these artificially drawn boundaries of cultural groups (i.e., breaking through cultural group borders that were created by the environment and assumed impermeable) has been an invaluable gift for me; it has been a genuine experience of how context and cultural identity work together.

After I spent two years in Tilburg, in February 2013, I moved to Turkey to complete my PhD studies at Koç University. Again, my distinctiveness reappeared, and my German accent when speaking Turkish revealed that I am different. People around me, both within and outside the university, considered me as assertive, direct and cold, as disrespectful of hierarchies, as sticking too much to rules and principles, as being over-concerned with work and so on. Simply, for them I was *German,* which also affected how I have been viewing and defining myself: Each time when I met German students in the hallways of Koç University, I experienced feelings of sympathy. We apparently had something in common; being distinctive (as Germans) in a primarily Turkish context.

Today, as an Assistant Professor of Psychology at Bahçeşehir University in Turkey, I am again acculturating; especially to my role as a lecturer which offers numerous opportunities of experiencing culture. For instance, I recently learned that for my students "asking the instructor for feedback" means criticizing, questioning or rejecting the instructor's evaluation; hence, a clearly inappropriate act. This clarification provided me with insight why very few students request feedback on their papers or assignments.

I truly consider myself lucky for these experiences as a child, student, PhD candidate, and assistant professor. They substantially shaped my personal understanding of culture and cultural identity, as well as my research agenda. To me, culture is not static anymore; it is in constant interaction

with various contexts, roles, and cultures that we find ourselves in (Oyserman, 2011). Now, I realize that I am actually more than just "the Turkish" or "the German", and that it is my environment and the (non-) distinctiveness in it that determines how I view, identify, and label myself, resonating with the call for a more dynamic approach to study culture (see "polycultural psychology" by Morris, Chiu, & Liu, 2015). Contemporary cross-cultural research should do justice to the requirements of a globalized world and move beyond a static understanding and assessment of culture that merely offer a snapshot of cultural identities and orientations. Instead, research should acknowledge that culture is a dynamic construct, which strongly interacts with the different contexts in which we find ourselves throughout our lives. Examining the interplay between culture and context will enhance our notion of culture and multicultural identity, advance the practices that we apply for their assessment, and eventually lead to more valid predictions.

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LEAVING A LEGACY TO DIVISION 52

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The Ph.D. Experience in Sweden: Having it "Just Right" and Applying "the Fika Model"

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First of all, I am very honored to be invited to share my experiences with students and colleagues from APA Division 52 International Psychology about being a Ph.D. student in Sweden. Since the Ph.D. program may look different depending on the university or department at which you are enrolled, I will share my experiences of being a doctoral student at the Department of Psychology in Sweden's second largest city, Gothenburg. The best way to describe what it is like to be a doctoral student in Sweden is to provide a brief introduction to Sweden's cultural context. So what makes Sweden so special besides being the home of ABBA, IKEA, Pippi Longstocking, and the Nobel Prize?

Often, Swedes themselves call their country "the land of the *just right,*" which means that Swedes live by the motto of not having anything too much or too little – we simply want everything to be *just right*. Thus, Sweden may be viewed as Northern Europe's own Goldilocks. However, when we look at Sweden's cultural context, Sweden is anything but *just right*; *extreme* might be a more suiting label. According to the World Value Survey (WVS6, 2015), which measures different aspects of culture, Sweden differs significantly from all other countries in the world, even our closest neighbors Denmark, Norway, and Finland. Sweden stands out as having the most beliefs in emancipative values and as the second most secular-rational country in the world. In other words, Sweden is a country that does not emphasize the importance of religion, traditional family values, or deference to authority; instead it is a country that values equality, whether it is about gender, ethnic background, or sexuality. In addition, Sweden has a well-established well-fare system with paid sick leave, paid parental leave, and subsidized health care. All Ph.D. students are employees with paid salary from day one and are allowed benefits such as free health care, paid prescription drugs, as well as being guaranteed at least 28 paid vacation days a year. Therefore, being a doctoral student in Sweden is a privilege.

To be admitted to the doctoral program at my department, candidates are required to have a Master's degree in Psychology and to submit a dissertation plan along with their applications. Then, a selection committee reads and evaluates the quality of the applications and the candidates who are valued as suitable for the doctoral program are invited to interviews. Usually, the Ph.D. program takes four years in Sweden. At my department, all new doctoral students take compulsory courses in statistical methods the first semester. Then, it is up to the student, together with his or her supervisor, to choose which courses to take. Quite a few of these courses are reading courses created by the students themselves in order to get an in-depth knowledge in areas related to their dissertation. Within the four years of the Ph.D. program, the students are supposed to conduct and report a minimal of three studies, at least one of which is required to be accepted by and published in a peer-reviewed journal.

I got accepted to the Ph.D. program in August 2014 and I am currently in my second year. Doing reaserch on identity has been my dream since I figured out that identity has been the common topic of over ten years of prior studies in psychology, sociology, history of ideas, social anthropology, and musicology. And the dream came through. I am a member of the Gothenburg Research unit on Youth development (GReY) where I am fortunate to have Professor Ann Frisén (University of Gothenburg) and Associate Professor Moin Syed (University of Minnesota) as my supervisors. Currently, I am working simultaneously in two very interesting projects named GREEN and GoLD. GREEN (Gothenburg Research on Ethnicity-related Experiences and identity Narratives) is a project investigating young people's identity and experiences related to ethnicity. GoLD (the Gothenburg Longitudinal study of Development) is a longitudinal study that has been continuing for more than 30 years with the overall goal to investigate cross-generational patterns of identity and personality development in early adulthood. In addition to these research projects, I am currently taking a course on scientific communication, in which we learn ways to better communicate our research to the broader society.

Being a Ph.D. student, diving into the things that interest you the most, trying to find answers to the questions you have, travelling all around the world to hear about the latest research findings, and meeting international students and scholars; these are the aspects of research that drive and motivate me the most. However, being a doctoral student is not all milk and honey. It is a constant questioning of yourself, your abilities, and the work that you do. It is an emotional rollercoaster, with ups and downs, where you just have to buckle up and try to enjoy as much of the ride as possible. I think these struggles are universal and that many Ph.D. students around the world would agree.

At times, it may be easier to feel isolated and alone as a Ph.D. student at my department since there are very few mandatory courses we take together with other students. Therefore, it is especially important to have a surrounding social support system of colleagues and friends that keeps you going. Fortunately, we have a very strong cultural practice that may serve as a protective factor against these potential feelings of loneliness. It is called a *fika.* A fika has been described as a Swedish practice where all employees, professors and students take a pause together over a cup of coffee and a pastry (or two), and engage in conversations (McLean & Syed, 2015). Taking a fika with people from other areas of research and at different stages of their scientific careers often provide new angles and ideas for your research, and is something I would encourage every Ph.D. student to engage in.

If you are interested in becoming a doctoral student in Sweden, the first step is to connect with a Professor, learning about what they are working with, and investigate if they are searching for a Ph.D. student. Since all departments tend to have slightly different procedures, it is good to learn about the specific application and acceptance procedure at that particular department. Most importantly, do not forget to follow the instructions. For Swedes, not following the rules is a deal breaker and a common reason to why many applications are denied according to our Head of Department. I would recommend inviting for a fika where you and the Professor can discuss mutual research interests.

Going forward, I still have both my Licentiate defense (a half term exam) and my final dissertation defense ahead of me. What happens after the years as a Ph.D. student is hard to anticipate. As a doctoral student, without a clinical background, it is sometimes hard to see how to continue and move forward in your career. Probably, I will apply for a Post-Doc, either in Sweden or abroad. Hopefully by then, I will have built a rich network with fellow researchers with potential for future collaborations and research projects. My goal is to be able to continue having it just right and spreading the word about the fika model wherever I go.

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PhD in Psychology: An Experience from Portugal

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I am grateful for the opportunity to share my PhD experience in Portugal and I would like to start by affirming that I am a doctor since I finished my bachelor's degree in Psychology. This might sound strange, but in Portugal, it is something normal to occur. When addressing someone unknown, for example in an e-mail, a person's name does not seem to be enough, so "Dr." is usually placed before it. Titles are used on a daily basis and, according to Hofstede (1994) this might be due to Portugal's high score on power distance. This result indicates that hierarchy is extremely present and accepted in the Portuguese culture, leading to an unequal distribution of power. Therefore, individuals holding a bachelor's degree are admitted to have privileges for their position, at least in the way they are addressed. Consequently, my perception is that in Portugal, there are as many doctors as there are women named Maria (*i.e.* the most popular female name). However, I am aware that, although many people are called doctors due to the Portuguese culture, the number of individuals pursuing a PhD degree has been constantly increasing. Data shows that in the last ten years, the number of completed PhD degrees doubled, and the last available data point out that in 2013, there were 2668 Portuguese holding a PhD degree (PORDATA, 2015). Having this in mind, and not forgetting the aim of this short article – to share my PhD experience in Portugal – next I am going to answer the following two questions: What is needed to be a PhD student in Portugal, and what is it like to be a PhD student in Portugal?

What is Needed to Be a PhD Student in Portugal?

In order to apply for a PhD program in Psychology at ISCTE-IUL, it is necessary to hold a master's degree in Psychology and to design a PhD project planned to be conducted over a period of three years. A supervisor should approve the PhD project and afterwards a panel evaluates it, along with the candidate's resume. Based on this evaluation, the candidate may be admitted for the PhD program and then the adventure begins.

During the first year, a PhD student is required to attend different courses and complete the correspondent assignments, covering thematic (*e.g.* health psychology) and methodological seminars (*e.g.* SEM, meta-analysis) as well as receive training in academic skills (*e.g.* academic and scientific writing). Besides this, students enrolled in the first year of the PhD program are required to organize a conference aimed at bringing together national and international PhD students, in a context of scientific exchange and discussion. Students have the opportunity to present and discuss their research project with a senior researcher. This public presentation of the PhD project is the one to which the students commit themselves to complete over the upcoming three years, after successfully completing the first curricular year of the PhD program. Besides conducting the PhD project, at the end of each one of the three years, students are required to complete a report describing the progress made with the research project and what they plan to do next. The supervisor and a senior scholar evaluate the report independently and provide some feedback. Then, PhD students are ready to advance to the next year.

What is it Like to Be a PhD Student in Portugal?

I consider that dedicating three years to the PhD project may be a solitary process. That's why I believe it is important to adopt some useful habits which can lead to a successful end of this journey. Some of the habits which I embraced and which help me see the light at the end of the tunnel are related with my professional and private life.

Regarding the professional life habits, I considered that after completing the curricular year of the PhD program, it could be useful to continue attending some of the thematic and methodological seminars offered at ISCTE-IUL. They provide me with the opportunity of learning about others' research and different ways of analyzing data. At the same time, I found out that the pre-conference workshops are very interesting ways of improving my knowledge about a specific topic and of sharing ideas with other PhD students/early career scholars. Having this in mind, every time I hear about an interesting conference where I could disseminate my research, I check the conference website in search of the offered pre-conference workshops, lunch with senior scholars or other activities which may contribute to the development of my PhD career and make it less solitary.

In this sense, I consider that networking is a powerful tool which can be developed through the professional life habit of attending conferences and becoming a member of one or more associations. On one hand, conferences bring together scholars who work in a similar area as mine and provide the opportunity for presenting and discussing the encountered results with other PhD students and senior scholars. On the other hand, associations help me know about the upcoming conferences and other important events in the specific research area they are promoting. Therefore, in my opinion, it is very important to wisely choose the association you would like to become a member of, so that you receive useful information related to your own research area. For example, my research is about the contemporary Portuguese migrants' cross-cultural adaptation in the United Kingdom. By taking into account its cross-cultural aspect, I decided to become a member of the International Association for Cross-Cultural Psychology (IACCP). Then, after conducting a qualitative study and consulting the most recent statistics about the contemporary Portuguese migration, I realized that it is mostly composed by young (under 30 years old) and highly qualified individuals; hence I considered that it would be interesting to become a member of the Society for the Study of Emerging Adulthood (SSEA) as well as the European Association of Developmental Psychology (EADP). Besides being a member of the EADP, I had the opportunity of being a member of its Early Researchers' Union, where I represented Portugal and participated in the 3rd Writing Week Event. This was an extremely enriching experience, since I had the opportunity to share research experiences with other PhD students, participate in several lectures given by very successful scholars and contribute to the writing of a systematic review article on immigration paradox and morbidity hypotheses. Another valuable output of my association membership is the participation at the 3rd IACCP Summer School, where I was fortunate to work with other PhD students on the elaboration of a research project, which brings together our research interests.

Participating in research projects related to my research interests is another professional life habit that I adopted. My supervisor, Dr. Marta Gonçalves has been challenging me to broaden research horizons and make the most of these three years of doctoral studies, by acquiring new skills and constantly training the existing ones. Therefore, she invited me to participate as a research assistant in several research projects related to family, mental health and intergeneration relations, and encouraged me to apply for a post-graduate grant for lecturing activities. As a result of this, besides carrying out the studies proposed in my PhD project, I was fortunate to participate in the whole research process of other research projects and to provide lectures to several classes of graduate and undergraduate students.

So far, the described professional life habits seem to follow an internationalization path. This is not by accident that it happened, and I believe that it is the direction that we are mostly encouraged to follow. When looking back to the opening ceremony of the PhD program, I clearly remember one of the expressions used by the director: "Spread your wings and fly!" Therefore, going abroad, getting to know other researchers who work on a similar topic and possibly establishing cross-cultural collaborations is extremely valued in Portugal. In my opinion, this actually makes sense since most of the grant opportunities appreciate international collaborations.

Nonetheless, I should not forget to mention that, at the national level, there are some professional life habits that I adopted, which to some extent complement the previously mentioned ones. For example, when looking for associations to become a member, I decided to explore the existent ones in Portugal. Through this search, I found out that there is an Emigration Observatory which aims to collect relevant information for the characterization of the Portuguese emigration and make a contribution to the definition of public policies in this area. Regarding policies, there is also a government organization named High Commissioner for Migration, which I decided to follow closely, since I believe that research results should be disseminated to policy makers, in an attempt to promote change in the field.

Besides this, another professional habit I adopted at the national level goes back to the first year of the PhD program, when I joined one of the research groups present at the Center for Social Research and Intervention (CIS-IUL). It is called Health for All (H4A) and aims to bring together junior and senior scholars whose research interests focus on one of the following four areas: 1) risk perception and health communication; 2) health of social minorities; 3) equality promotion and participation in the health-care processes; 4) health and places. During regular meetings, we present and discuss research projects and manuscripts (ready to be submitted) elaborated by H4A's members or invited scholars.

The PhD project and all the other professional habits I adopted, compose my job at the moment. Therefore, I usually go to my office on a daily basis. Sharing the office with other PhD students is an enriching experience because we can share our doubts, distresses and victories. Having lunch together is also nice, because we take a break from work and come back more refreshed to continue it. Nonetheless, there is life outside of work, and this way of thinking may also contribute to making the PhD project a less solitary one. The private life habits I adopted involve mainly being around loves ones (friends and family) and engaging in activities that I enjoy (*e.g.* sports, dancing lessons, travelling and knowing other cultures). My aim is to divide the 24 hours per day between professional and personal life habits as well as sleeping. Nonetheless, I must confess that this is something I am constantly working on, since just as the participants in my master's thesis mentioned: The work-life conflict requires lots of skills to master it; practice and patience being only two of them.

Conclusions

I believe that equilibrium between the adopted professional and private life habits will continue making the PhD project a less solitary one. In addition, it may contribute to its successful completion. As soon as this happens, I could officially be addressed as a doctor, contrary to what has been happening so far in Portugal: Being addressed as a doctor due to holding a bachelor's degree.

Having this in mind, my advice for an international student who would wish to complete his/her doctoral degree in Portugal are:

1) Accept the possibility of your title being "Dr." even when you just started your doctoral degree. Consequently, expect a lot of formality and bureaucracy, combined with a high degree of tolerance and will to help. Portuguese are known for their hospitality, so although there are a lot of rules and procedures that are followed, whenever something cannot be solved, Portuguese are willing to help you.
2) Search the several doctoral degrees offered by most Portuguese universities, in order to identify the one which interests you the most. Usually on the university's website you can find a full description of the PhD degree, its requirements, offered grants and some testimonials. Nonetheless, for more opinions you can search for groups formed in the social networks or ask your professors if their academic and research networks include someone from Portugal who you can contact and ask for some advice.
3) Check the professional life habits I adopted, which include joining various organizations locally and internationally for networking, research and continuing education purposes. Maybe you could adopt some of them, but do not forget the personal life habits! Try your best to find equilibrium between the two of them.
4) Enjoy Portugal's beautiful weather, with its illuminated capital, Lisbon, which was considered Europe's Leading City Break Destinations in 2013 (World Travel Awards, 2015).

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"Internationalizing the Teaching of Psychology (IToP)" Research Team: Promoting A Global Perspective in Students

Richard Velayo, Ph.D., Sarika Persaud, Wallis Back, and Sahiba Bhatnagar
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There are a growing number of psychology instructors and researchers who are exploring ways to incorporate greater international content and infuse enhanced international perspectives in the courses they teach. One strategy in achieving this goal is by providing students the opportunity to join research teams that encourage international and cross-cultural research in psychology.

At Pace University (New York City), there are several full-time faculty members who mentor both undergraduate and graduate students as an important part of their academic experience. In fact, of the 18 full-time faculty members who represent a variety of scholarly interests, at least seven consider themselves as having interests in the areas of cultural and/or international psychology. More specifically, 5 of the 11 active faculty-led research teams (http://www.pace.edu/dyson/academic-departments-and-programs/psychology---nyc/research-groups) provide valuable research mentorship for student academic and professional development. Students may become involved in any or some of research teams as part of their major or program of study by registering for an independent study course, a mentored lab class, or through a thesis or dissertation project. One of the research teams worth noting is called the "Internationalizing the Teaching of Psychology (IToP) team led by Dr. Richard Velayo, Professor of Psychology at Pace University. His research group called "Internationalizing the Teaching of Psychology (IToP) Team (http://rvelayo.jimdo.com/itop-team/) involves research that focuses on strategies that help infuse international content and promote a global perspective within the discipline of psychology at the higher education level. More specifically, IToP's research involves projects related to the following: (1) identifying effective pedagogical strategies to internationalize psychology courses, (2) developing an assessment tool for an internationalized psychology course, and (3) applying Internet-Based Technologies (IBTs) as teaching and research tools to help infuse international content. Research projects generally involve the design and development of online surveys, identification of and access to resources (e.g., instructors, courses, multimedia materials), and curriculum-based applications of IBTs. Student involved in his team get to present their individual or group projects at local, regional, national, and/or international conferences. Some of the psychology conferences at which the IToP team has presented include the annual meetings of the American Psychology Psychological Association, Eastern Psychological Association, Greater New York Conference on Behavioral Research, Hunter College Psychology Conference, International Council of Psychologists, and Pace University Psychology Conference.

Since fall 2014, there have been 10 students who have been part of the IToP research team. There are currently 3 students (one doctoral and two masters) this fall, and at least three others (masters-level) will be joining in the spring semester. Each student is actively undertaking research projects of interest to them, which ties in with one of the topics related to the IToP team research subtopics (as mentioned above). At each weekly meeting, students provide the entire team with updates about their individual work and discuss preparations for presentations (e.g., poster, paper, symposium) at an upcoming conference. Students are encouraged to present their work at student-focused, local, and/or regional conference held during the latter part of that semester or the following semester. This fall 2015 semester, the IToP team highlight three student research projects. Below are brief descriptions written by current IToP students about their projects.

Wallis Back (wb94354n@pace.edu)(M.A. in Psychology)

"Exploring Attitudes Toward Entheogen Therapy as a Means of Improving Spiritual Well-being"

The integration of spirituality into modern western psychological therapy practices has rapidly been gaining relevance, as recent research findings show it to be an integral part of an individual's overall well being. Simultaneously, the increasing approval and funding for entheogenic substance research has re-opened the doors into psychedelic studies and their immense potential for improving spiritual well-being. There lacks research however, on the relationship between an individual's level of spiritual well being and their attitude towards the use of entheogenic substances in therapy. My current research study aims to explore the relationship between these two constructs in both users and non-users of entheogenic substances, in order to better define and understand differences and relationships that emerge between them. I have created and administered an online questionnaire, and I am currently in the process of data analyses for data collected from over 350 participants. Further research may provide a means to more effectively develop and target therapy training and programs to help facilitate higher levels of spiritual and over all well-being.

Sahiba Bhatnagar (sb17859n@pace.edu) (M.A. in Psychology Student)

"Exploring the Integration of Eastern Mindfulness Practices into Western Approaches to Therapy"

My independent study explores perceptions of implementing eastern mindfulness practices in western therapy. After conducting a literature review I found research has shown that despite a participant's perceptions of mindfulness and meditation before experiencing it, almost all experiences of mindfulness were found to be positive when practiced in a therapeutic setting. Additionally, I explored populations that these new therapeutic interventions could be beneficial for. Incoming first year undergraduate students are vulnerable to experiencing depression and anxiety from the life transition. Through surveys, this population also expressed a desire for more education of their faculty and staff on mental health practices as well as peer led mental health groups. With this information I have proposed two research questions: How is mindfulness perceived among the undergraduate college population in America? Using these perceptions, what are the best ways to implement mindfulness based therapy onto campuses? I plan to conduct this research with a combination of surveys and interview/focus groups. The surveys I plan to use are the Five Facet Mindfulness Questionnaire and The College Adjustment Scale.

Sarika Persaud (ap75294n@pace.edu) (Psy.D. student in School Clinical Child Psychology)

"Adolescent Mental Health in the Caribbean: Integrating Religion & Psychoeducational Training"

My experiences growing up as a part of the Indo-Carribean community have led me to take a personal interest in the alarming rates of suicide and depression in Guyana. My research focuses on developing psychoeducational interventions for adolescence, which can be implemented in local schools as a way of providing grassroots mental health services in Guyana. I am exploring the potential of integrating local religious communities as a way of empowering post-colonial communities to find value in their own systems, and using existing methods of healing to supplement the use of evidence-based practices. This preliminary research on this topic will eventually lead into my doctoral dissertation in the Psy.D. Program in School Clinical-Child Psychology program at Pace University.

These student-initiated projects exemplify research that contributes to international content that may be infused in teaching. Such research projects provide not only content that may be shared with other research team members, but also be archived as student research projects accessible to other students and instructors in the departmental for instructional purposes or to motivate further international research. Additionally, such projects help cultivate a more international perspective about the discipline of psychology and a greater appreciation for psychological constructs taking into consideration the cross-cultural and cross-national contexts in which they apply. There is tremendous value in involving students in the process of internationalizing the teaching of psychology. More importantly, it is essential to prepare them for a society that is increasingly becoming global.

For more information about this presentation and of the IToP team, please contact Dr. Richard Velayo at rvelayo@pace.edu or Sarika Persaud (Dr. Velayo's graduate research assistant and Psy.D. student) at ap75294n@pace.edu.

(From left to right): Sarika Persaud, Wallis Back, Sahiba Bhatnagar, and Richard Velayo, Ph.D.,
(Photo taken at 27th Annual Greater New York Conference on Behavioral Research, St. Francis College, Brooklyn Heights, NY)
[Photo taken by Sheriney Frederick, *MA in Psychology student*.]

Phases of Public and Private Education at University Level in Mexico: A Local Teaching Experience

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In Mexico, out of the 100,000,000 applicants in higher education, only 10 % are the lucky ones who enter one of the public universities, research centers or federal polytechnics. Due to the lack of space in the public institutions, the private sector has grown considerably. There are many different academic demands between these two sectors that require different strategies for career success as a lecturer in Mexico. Public institutions, like state universities or the National University, receive a specific public budget. In contrast, private institutions have earned prestige and gained private tuition support over the years through their appealing offerings for students.

In this paper, I discuss the implications of private and public alternatives. I base these insights on my 14 years of teaching experience in psychology. Currently, I have a full time position in one of the most renowned private universities. At the same time, I am also a lecturer at the National University, the biggest and most prestigious public university in the country.

Private universities are sustained through tuition paid directly by students. This creates a great deal of pressure on teachers from university authorities. Teachers are pressured to balance between entertaining students, being mentors, and being friends with them while at the same time demanding discipline and performance. For obvious reasons, these things are very difficult to do at the same time. The students have the right to demand a good quality of education, which is reasonable but often misinterpreted. Some students interpret this right as the teacher is there to give them all the benefits and best grades, and they expect the teacher to be subordinate. This creates a great deal on pressure on professors, especially at the end of the semester, when students evaluate their professors. Through this evaluation, students have significant influence. If a professor is graded badly (regardless of how many years of teaching and experience) she or he runs the risk of being denied a promotion or in the worst case scenario – of being fired.

Private universities have smaller numbers of students per classroom. This is in contrast with public universities where auditoriums are used for teaching more often than are classrooms, especially in the first semesters. Thanks to the small groups in private universities, there is an atmosphere of interaction and intimacy between professors and students. At their best, small classes improve the learning environment and help to hold all the students´ attention. At the same time, because of this type of interaction, the role boundary between professor and student may erode.

In the public sector, there is a big distance between professor and students not only in the physical dimensions of the teaching space but also in the large number of students per instructor. Enrollment can be above 50 students in classes and can be 100 in medical classes. In public institutions the professor may adopt a cold and strict attitude towards students without repercussions since student evaluations do not affect his or her job.

In the private sector, curriculum changes take place more easily, due to the need to recruit students. In contrast, in the public sector, this process is slower since more people compose the council board and they have more complicated and restrictive regulations. Private education gives more importance to popular subjects. Both systems support lecture freedom for professors. Private education assures a whole content curriculum that meets program standards due to students' course evaluations. In public education, the professor has the freedom to include or change any subject without running the risk of being fired. A student's learning experiences depends on the quality and skill of the professor.

In private universities, the range of research is very limited since they support their own philosophy or meet popular needs. However, the public universities can provide financial support for any idea in order to develop proposals, as long as it does not exceed the university budget. Private full time professors can develop academic, research and management jobs while public professors can focus in just one field. Still, professors try to work in more than one field in order to get job promotions.

Good and bad students are found in both types of institutions. In my experience, I have students who need to work and study at the same time. The difference is that the students in private schools work to pay their tuition. In public institutions, students work in order to survive. In conclusion, both types of education have advantages and disadvantages. I enjoy and learn a lot from being among these two worlds.

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The Tragedy and Legacy of Phineas Gage

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On September 13, 1848, Phineas Gage, the 25-year old foreman of a railroad construction crew in Cavendish, Vermont, USA, suffered a horrific accident and, inadvertently, made history. As it turned out, the accident he experienced on that fateful day would have important implications for psychology, neurology, and related fields. In fact, his case would end up playing a crucial role in the entire history of brain science.

The job of Phineas Gage and his crew was to prepare the railroad bed for the Rutherford & Burlington Railroad. The boulder impeding their progress was to be blasted away using gunpowder. Phineas was in charge of the explosives. His usual procedure was to drill a hole in the offending rock, fill the hole with gunpowder and sand, and tamp the mixture down with a three and a half foot long tamping iron – the smaller the space the greater the explosion. After alerting his fellow workers, he would light the fuse and run for cover. He had done this many times before, with great success. This time things did not go so smoothly.

On this occasion, after filling the hole with gunpowder, Phineas apparently turned away from the rock, distracted. The tamping iron, still in his left hand, touched the rock and created a spark, igniting the gunpowder. The resulting explosion sent the sharp end of the tamping iron through his left cheek, into his head, exiting at the top. Phineas was thrown back, although he never lost consciousness. The tamping iron was later found more than thirty yards away, encrusted with brain matter.

Phineas spoke immediately after the accident, fully aware of what had happened to him. His fellow workers, aghast at the obvious damage to him, put him on a cart and brought him three-quarters of a mile to the tavern where he had been boarding. Two doctors eventually tended to him, positioning the large skulls fragments back into place and removing the smaller ones. Neither doctor had any hope that Phineas would survive. Phineas, on the other hand, was more optimistic – he spoke of going back to work the next day.

Phineas soon developed a fever – infections were major killers in those days. Other signs suggested he was in great physical distress. The local undertaker even measured Phineas for a coffin. But one of the attending physicians, Dr. John Harlow, refused to give up, working with Phineas day after day, trying everything in his medical arsenal. To almost everyone's surprise, including his family, by November Phineas was well enough to travel to his mother's home in nearby New Hampshire. Harlow visited him there shortly after the New Year. Although he had lost the sight of one eye and the opening in his skull had not completely closed, Phineas appeared to have regained much of his strength and Harlow declared him to be in good health.

After only a short convalescence, Phineas was eager to return to his old job. But now he had a new problem. The railroad declined to hire him back. They realized that his personality had changed. While he had once been one of their best workers -- industrious, friendly, and well-organized, he had become argumentative and short-tempered, and his language had become vulgar and profane. He had difficulty planning and his friends no longer cared to be with him. His personality had changed so much that Harlow would later write "he was no longer Gage."

Phineas was the object of much scientific inquiry and observation as the news of his accident and recovery became known. One important result of the accident was to demonstrate that a brain could suffer tremendous damage, but the person could still survive, largely intact. A logical conclusion was that it was possible to operate on the brain. The second major discovery was to strongly suggest that personality could be found in the brain – something that seems obvious to contemporary thought, but was much less obvious then.

Information on Phineas after the initial excitement is not well-documented and is based almost entirely on the account of his mother and Dr. Harlow. It is known that he participated in one of P. T. Barnum's exhibitions -- a poster has been found describing his appearance. It is also known that he traveled to Chile to become a stage coach driver on the route between Valparaiso and Santiago, a distance of 75 miles. Stage coaches in that part of the world typically used six horses, and managing them would have taken considerable skill. Gage's mother said that Phineas was very good working with animals. Still, it would have been a strenuous job. After seven years in Chile, Phineas returned to the U.S. in somewhat fragile health.

At first Phineas stayed with his mother who had moved to San Francisco to be near her daughter. He briefly held several jobs, but began suffering from seizures that became increasingly debilitating. When he died on May 20, 1860, age 36, the cause of death was listed as epilepsy. The usual assumption is that his death was the result of the earlier brain injury, with his deterioration due to the subsequent scarring and other changes in the brain that took place over time. He was buried in San Francisco, with his tamping iron at his side. But his story does not end there.

Dr. Harlow had lost contact with Phineas when he was in Chile. When Harlow later contacted Gage's mother and found out that Phineas had died, he made an unusual request. Would his mother consider having the body exhumed and the skull and tamping iron sent to Harlow for further examination? Gage's mother, clearly understanding the scientific importance of her son's accident, complied with his request.

Harlow conducted a number of measurements of the skull. One of the first things he noticed was that even though Gage lived long after the accident, his skull had not completely healed. When Harlow completed his work with the skull, both it and the tamping iron were deposited in the Warren Anatomical Museum of the Harvard University Medical School. There they remain, a reminder of the continuing quest to understand the relationship between brain and behavior.

Places to Visit

The town of Cavendish is located in Windsor County, Vermont. The population was 1,367 at the 2010 census. The town is approximately 95 miles northeast of Albany, NY, and 160 miles northwest of Boston, MA. In the Cavendish Town Green, at the intersection of High St. and Rt. 131, there is a Memorial to Gage, placed there at the 150th anniversary of the accident. It gives directions to several locations relevant to the story of Phineas Gage.

The Warren Anatomical Museum is part of the Countway Library of Medicine's Center for the History of Medicine at Harvard University, Cambridge, MA. The Museum's Exhibition Gallery is located on the 5th floor of the Countway Library and displays 300 cases and artifacts from the larger collection, including the skull and tamping iron of Phineas Gage. The Museum Gallery is open to the public, free of charge, Monday through Friday, 9:00am-5:00pm. The Exhibition Gallery is closed on weekends and during certain Harvard University holidays.

Phineas Gage

Village Green in Cavendish

Site of the Accident

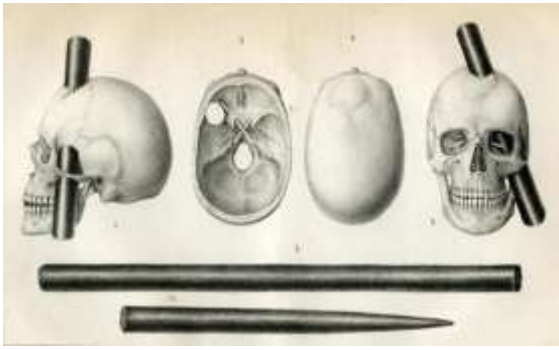

Skull and Tamping Iron

Articles

Diversified path to the psychological career: Europe vs. USA

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Abstract

Written from the social psychological perspective of social representations, this review paper presents some aspects of the current situation of European psychologists. Opportunities and challenges of academic path and private practice as a psychotherapist are outlined in four countries: France, Italy, Poland and Romania, based on interviews with recent psychology graduates and examination of the official information in original languages in each geo-cultural context. Starting from education, through career choices, numerous possibilities of professional affiliation to the larger context of the general public, a comparison of Europe with the United States brings about a number of surprises and recommendations for enriching intercultural interaction.

Keywords: psychologist, psychotherapist, social representations, psychological associations, European psychology

Introduction

If there were a continuum from unity to diversity in psychology on a given continent, most probably the majority of continents would opt for a position much closer to diversity. In fact, European psychology tends to be considered as diverse as its countries or even regions.

This review paper is written from the theoretical perspective of social representations (Moscovici, 1976, 1988), which used to be considered primarily as a French tradition of research (Farr, 1987) that is slowly becoming a more diffused, genuinely European alternative to the dominant social cognition approach imported from the United States. In line with the indigenous psychology (Kim, Yang, & Hwang, 2006), it pays attention to the context where commonsense knowledge is transmitted and transformed. Since it is impossible to take into account every single European country, four contexts of France, Italy, Poland and Romania have been chosen. While the authors interviewed students who graduated in psychology in each of these countries, they also gathered the official information from national psychological associations and government websites in original languages. Given the diversity among European countries, the choice of these four contexts was thus due to the authors' linguistic abilities and knowledge about conditions in each country. Such awareness of context appears as necessary when the researchers (who are also products of culture) assess social representations since "it is hard to remove the powerful lenses of individualism from our sense making – in both everyday and research contexts" (Howarth, 2002, p. 258).

Clearly, psychology is not all about research. Therefore, in the contemporary scenario of economic difficulties faced by Europe, this review paper presents some perspectives of young people who decide to embark on the diversified path to the career as a psychologist. It includes the required education, possible further steps, prospective employment and options of professional affiliation, specifically in two cases: of a psychotherapist primarily involved in private practice and of a researcher in academic setting. In the United States, in 1973 it was proposed to use different degrees to designate the practitioner's role (PsyD) from the scientist role (PhD); the former focuses primarily on clinical service and less on research (Norcross et al, 2004) by training students to practice what they learn about the full spectrum of psychological science, while the latter gives the fundamentals of practice, but its primary job is training students to conduct research (Peterson, 1997).

Realizing a bit more about the challenges that European psychologists are facing and being aware of some underlying assumptions that many of them may have concerning the discipline, can be useful when implementing international relations on a professional level or simply travelling to Europe for private reasons and successfully managing personal encounters.

Literature review

The recent literature on the career path of a psychologist in research and private practice that compares the situation in the United States and in Europe is not yet very extensive, probably due to dynamic and ongoing changes in various European countries. Arnett (2008) points out to the need of studies in psychology that are not solely focused on the "rich who get researched", while Donn and colleagues (2000) specifically compare North America with Europe. In terms of psychology and psychotherapy in health care, Van Broeck and Lietaer (2008) propose a review of legal regulations in 17 European countries. Another way to assess differences between the two continents consists of pointing out the competences that a psychologist should possess according to pre-established standards (Bartram & Roe, 2005) and his or her career prospects (Sternberg, 1997). More detailed comparisons of approaches to psychotherapy in Europe and United States include relational (Aron, 2007), experiential (Greenberg, Watson, & Lietaer, 1998), cognitive-behavioral (Hoffman et al, 2012) and psychoanalytic psychotherapy (Jacobs, 2002), to mention just a few. On the other hand, some authors focus on career prospects of psychology students in Europe (Knight & Vainre, 2011) and in the United States (Borden & Rajecki, 2000). Last summer in Canada the topic of this article has been treated by Giua and Dryjanska (2015).

North American standards

The American Psychological Association (APA) provides clear and comprehensive information concerning the career path in psychology (APA, 2011). In the United States, it is possible to earn bachelor's and master's degrees in psychology. While some doctoral programs require a master's degree in psychology, more commonly applicants can enroll in the doctoral programs with a bachelor's degree and work directly on a doctoral degree. The majority of doctoral degrees take 5–7 years to complete, and a one-year internship is necessary in order to become a professional clinical psychologist. According to the APA (2011), "some universities and professional schools offer a PsyD degree in lieu of the traditional research doctoral degree (PhD) or EdD degree. These PsyD degrees, with their emphasis on clinical psychology, are designed for students who primarily want to do clinical work exclusively." Moreover, one has to be licensed as a psychologist to exercise independent practice of psychology anywhere in the United States. The state licensing boards review applicant's educational background and their successful completion of at least two years of supervised professional experience before granting the permission for him or her to take the licensing exam. Information about state and provincial licensing requirements is provided by the Association of State and Provincial Psychology Boards (ASPPB).

Diversity of psychology in four European countries

Four European countries discussed in this review paper include France, Italy, Poland and Romania – diverse contexts that nonetheless present some similarities when it comes to a career path in psychology, often thanks to the processes prompted by the European Union, of which all of these states are members. Each one with distinct language, customs, history and other aspects of culture offers a unique context for the development of self as a psychologist. In line with the recommendations of Hermans (2001), this paper emphasizes increasing complexity and shifts attention from core to contact zones, discussing the social representations of North American psychologists by their European colleagues.

Education

At least in its early stages, the education required of a European psychologist is currently quite similar across different countries, at least concerning the number of years of study required. This fairly recent situation concerns current psychologists in their early thirties and younger. In 1999 almost thirty European ministers responsible for higher education signed a joint declaration – the official starting point of the so-called Bologna Process, aimed at creation of a common European Higher Education Area by 2010. As a result, "governments have developed policies that fit the European agenda towards converging systems of higher education'' (Huisman & Wende, 2004, p. 355). Their main focus - the introduction of the three-cycle system (bachelor/master/doctorate), strengthened quality assurance and easier recognition of qualifications and periods of study – brought about the fairly unified length and requirements of the early stages of career in psychology: from three to four years to earn a bachelor degree in psychology, one to two years for a master degree in psychology and a minimum of three years for a doctorate in psychology.

While the Bologna Process regulates quite well the academic career in psychology focused on research (on a doctorate level, a PhD), more ambiguity concerns the private practice career in psychology focused on psychotherapy (on a doctorate level, a PsyD). Typically, the latter have a tougher admission process and the programs tend to be more expensive. It is worth mentioning that while the term "PhD" is familiar to the majority of psychologists, "PsyD" tends to be less known in continental Europe where these types of programs are often known as "specializations" ("spécialisation en psychothérapie" in French, "specializzazione in psicoterapia" in Italian, "specjalizacja" in Polish and "specializare în psihoterapie" in Romanian). In general, European PhD programs in psychology are accredited by the national ministries of education, as opposed to "specialization" programs in psychology (mainly in psychotherapy) accredited by the national ministries of health.

Table 1 summarizes the minimum number of years necessary to complete different types of degrees in psychology, based on national legislation.

Table 1. Comparison of the minimum number of years necessary to get a degree in countries under scrutiny, based on national legislation (Civic Impulse, 2016; Lege nr. 288 din 24, 2004; Loi n° 2013-660, 2013; D.M. 270/04, 2004; Dz. U. 2005 Nr 164 poz. 1365, 2005)

COUNTRY	BACHELOR	MASTER	DOCTORATE
France	≤ 3 years	≤ 2 years	≤ 3 years
Italy	≤ 3 years	≤ 2 years	≤ 3 years
Poland	≤ 3 years	≤ 1.5 years	≤ 2 years; ≥ 4 years
Romania	≤ 3 years	≤ 1 year	≤ 4 years
USA	≤ 4 years	≤ 1 year	≤ 4 years

Career in private practice

In Europe, a person is generally considered as a psychologist upon completion of their master degree in psychology or a minimum of five years of university training (Van Broeck, & Lietaer, 2008). Italy constitutes an exception: holders of a degree must pass a state examination, complete a one-year supervised internship and register as a member of the National Council of Psychologists ("Ordine degli Psicologi" in Italian). Following this first step, those interested in private practice need to obtain a license or a title of a psychotherapist. A close equivalent of the North American PsyD, the "specialization" tends to be awarded by specific schools of thought, such as specialization in cognitive-behavioral therapy, systemic-relational therapy, hypnosis, psychodynamic therapy, etc. Schools that integrate more approaches have become more popular, especially in Eastern Europe, not to mention specific concentrations or sub-specializations that apply a certain kind of therapy to children, adolescents or other specific groups of clients or patients. However, historically the origins of training in psychotherapy in Europe are marked by a "solitary supremacy of psychoanalysis" (Gemignani & Giliberto, 2005, p. 171).

Once the expensive and lengthy supervised training is completed, a young psychotherapist faces the challenge of finding the recipients of his or her services. In France, the situation is particularly unstable (Bernaud, Cohen-Scali, & Guichard, 2007) due to the decrease in state involvement (various French ministries used to clearly define qualifications, recruitment processes, career conditions and monitoring of activities of French psychologists) and the pressure from the European Union to start establishing new standards, often from Northern Europe.

Based on the results of a national survey conducted in 2012-2013 with 1500 Italian psychologists registered as members of the National Council of Psychologists ("Ordine degli Psicologi" in Italian), Bosio and Lozza (2013) reported that the average annual income of recent graduates is slightly above the poverty threshold defined by the Italian National Institute of Statistics (ISTAT). Simply put, employment opportunities for psychologists are scarce and not very attractive. Due to the financial crisis, it is also difficult to find and/or keep clients in private practice, which results in unemployment and underemployment. Notwithstanding, the number of Italian graduates in psychology has been declared as "very high, considering the Italian population as a whole" (Job, Tonzar, & Lotto, 2009, p. 311), with the increase of approximately 10% per year.

In Poland, where psychology is a fairly new discipline for decades restricted by Marxist philosophical approach (Kaczkowski, 1967), professional psychologists face the challenge of the lack of legal regulations that would protect them from the infiltrations of pseudo-scientific methods and diagnostic tools (Brzezinski, 2014). In turn, this has negative consequences on the social representations of psychologists among the general public. Various myths penetrate Polish society, such as "psychologists always analyze everything and everyone around them", "every psychologist is a psychotherapist", "those who study psychology do it to solve their own mental problems", etc.

Similarly, in Romania the levels of stigma and discrimination against people with mental illness and therefore a shame attached attending psychotherapy are quite high (Evans-Lacko et al., 2012). School/educational psychology tends to be a popular orientation among students since parents often declare to be more willing to invest in psychotherapy for their children rather than themselves (Negovan & Dincă, 2014).

As in Poland, myths and erroneous perception of psychotherapy cause potential patients or clients to turn to other types of therapy, such as complementary and alternative, instead of psychotherapy (Dumitrașcu, 2014).

In general, in Europe there is a plethora of psychotherapy approaches and various entities that offer supervised training. On the other hand, due to negative attitudes of the general public towards the mental healthcare including interventions by psychotherapists, ongoing efforts through large nationally and locally based programs that fight the stigma shall be further implemented and monitored (Evans-Lacko et al., 2012).

Overall, in Europe the differentiation between a psychologist (someone who has a degree in psychology) and psychotherapist (someone who is licensed to run a private practice) is not very clear among lay people. For the most part, they do not realize that it is necessary to be a psychologist in order to become a psychotherapist, and the two terms are used interchangeably, which creates confusion and contributes to some myths about the profession. Moreover, the media have widely contributed to the social representation of a psychotherapist anchored in the figure of a psychoanalyst, the use of a couch and specific setting, making it more difficult to convey to the general public how diverse and dynamic are the numerous approaches to psychotherapy.

Academic career

As a result of the Bologna Process, European psychologists involved in research have a much more linear career path. Mainly affiliated with universities, upon completion of a doctorate program, successful candidates enter highly competitive academic career, usually at first benefitting from post-doc positions or research grants. Across Europe, they dedicate time to research and teaching, publishing results and presenting them at national and international conferences.

What differs them from their counterparts in the United States? A study of personal homepages of European academic psychologists revealed that they almost exclusively offer information about result-oriented research activities and publications. Additionally, it is common for them to provide links that demonstrate a network of academic connections. According to Dumont and Frindte (2005), self-presentation is limited to information about academic work, possibly due to their understanding of personal homepages that follows "the common ethos of science, that is to say, scientific results

should be independent of the scientists who produce them" (Dumont & Frindte, 2005, p. 81).

Another issue concerns the choice between publishing in English (encouraged by many European monitoring and evaluation entities) or native language. Being able to read and write scientific papers in English is a must to join the global discourse, yet at the same time researchers from non-English speaking countries have the duty to publish in their native languages in order not to lose considerable part of their native audience (Brzeziński, 2014).

Thanks to the international language of science and opportunities of funding from the EU (unlike private practice), academic career tends to be more international and involves significant mobility opportunities across Europe. Alongside numerous benefits, some authors nevertheless point out the challenges of this situation, such as transience and risk identified by Richardson and Zikic (2007) as two important dimensions of the "darker side" of pursuing an international academic career.

Professional affiliations

Virtually every European country has some sort of a national entity for psychologists. Their authority, function and character vary considerably within Europe.

Among the four countries considered in this paper, Italy stands out as one with the most developed and complex structure of possible professional affiliations open to graduates in psychology. On the one hand, practitioners are obliged to become a part of the National Council of Psychologists ("Ordine degli Psicologi" in Italian) that requires a five-year diploma in psychology, proof of at least one-year supervised practice, satisfactory grade on the national examination and payment of annual membership fees. On the other hand, those interested in the academic career have an easier path of simply applying for the membership of the Italian Psychological Association (AIP in Italian) following the acquisition of a PhD degree and payment of annual membership fees. While the National Council of Psychologists ensures recognition of a professional (dealing mainly with the Italian Ministry of Health), the Italian Psychological Association (AIP) provides opportunities for the exchange of research during conferences and gives voice to the academic community in discussions with the Italian ministry of education.

The French scenario somewhat mirrors the Italian one, with the Federation of French Psychologists ("Fédération Française des Psychologues et de Psychologie" in French) for practitioners (but also open to academicians and students) and the French Psychological Society ("Societé Française de Psychologie" in French) that caters mainly to psychologists in the world of higher education.

In Poland and Romania, national psychological associations recognize respective national diplomas in psychology and offer opportunities for further training, dialogue with governmental entities and professional growth. Polish Psychological Association ("Polskie Towarzystwo Psychologiczne" in Polish) and College of Romanian Psychologists ("Colegiul Psihologilor din România") try to appeal to both academicians and practitioners, also providing lists of available opportunities of further training.

Each one of the associations (except for the National Council of Psychologists) publishes scientific journals and belongs to the European Federation of the Psychologists' Associations. This entity has the ambition to appeal to all psychologists by promoting the EuroPsy, a European qualification standard for psychologists and a registry of European professionals who have achieved it. However, for example in case of Italy the Federation did not partner with the National Council of Psychologists (which would be the best choice, given its authority over examinations and official Italian registry). Moreover, it is not very well known and many psychologists may not see a point of acquiring additional certification beyond national standards, especially since the procedure requires time and money necessary for obtaining official translations and notarized paperwork.

Throughout Europe, specific associations that often (but not always) correspond to the APA divisions exist in an independent way on different levels: regional, national, European and international. For example, in case of psychotherapists, a school that offers specialization in systemic-relational therapy may belong to the European Family Therapy Association. Similarly, academicians usually have a specific area of interest in psychology and tend to be active within that area on different levels. For instance, a social psychologist from Poland may choose to become a member of the Polish Society of Social Psychology (PSPS) as well as the European Association of Social Psychology. A fairly common practice in scientific societies is the requirement of presenting recommendations from two active members in order to apply.

Overall, the world of associations and societies is quite complex. There is no simple rule that would apply to all countries. While generally in Europe being a psychologist still means having graduated after five years of studies in this discipline, in Italy it additionally requires being enlisted in the national registry of the National Council of Psychologists. All other associations are on a voluntary basis and the fact that someone's name cannot be found on the list of members does not mean that they cannot legally present themselves as psychologists.

Social representations of psychologists

Introduced by Moscovici (1976), social representations were a construct that encompassed commonsense knowledge and lay theories about a new phenomenon in France in the fifties – psychoanalysis. Shared by certain groups of society, these opinions, judgments, images and metaphors served the function of familiarization and enabled communication. Moscovici realized that social representations could be extended to other phenomena, since they reflect how people think and interpret surrounding reality using a number of processes. Since then, Moscovici has considerably elaborated his theory (1988, 1998, 2011) and many social scientists have used social representations in their research.

Recently, de Rosa, Fino and Bocci (2013) have taken the original object of the seminal study – psychoanalysis and psychoanalysts to examine their social representations in France and Italy, also taking into account the information from various sources in the Internet. Without doubt, among the general public in Europe the distinction between a psychologist and psychotherapist is not very clear, let alone familiarity with different types of therapies. Movies, in particular by Woody Allen (Gordon, 1994), constitute a source of images that nurture laymen thinking about psychotherapy.

How about European psychologists themselves? Professionals are not free from commonsense thinking about their occupation. Romaioli and Contarello (2012) have conducted interviews with cognitive-behavioral, constructivist, psychodynamic and systemic-relational therapists in order to identify the representational processes that they employed to organize knowledge about change in their clients' lives. Social representations of therapists would often reify the metaphors used, showing their ideological attachment to the system of thought of a specific school. As shown by Romaioli and Contarello (2012), reified metaphors are the phenomenological description of different kinds of psychological problems, enabling the identification of linguistic repertoires more practicable for the therapist, aimed at constructing effective communication during therapy sessions. For example, cognitive-behavioral therapists represented change in terms of a slow and cumulative acquisition of instruments with which to cope with everyday difficulties (a metaphor of an encyclopedia); while psychodynamic therapists represented change as a regeneration of one's own roots that enables new growth (a metaphor of a tree). Such research (Romaioli & Contarello, 2012) is an example of the application of a narrative or conversational approaches to the study of social representations of a specific object – in this case the process of change in the lives of clients of psychotherapists. It also has an added value of appealing to metaphors that are likely used in other cultures, such as the metaphor of a tree (Raval, & Kral, 2004), in order to understand the process of socially constructing reality.

Overall, the European general public as well as psychologists themselves faced with the complex world of psychology and psychotherapy have developed articulate ways of thinking and representing these phenomena, rich in images, metaphors and rhetoric devices. In Europe, there are multiple points of reference on various levels and the lack of a single firmly established authority concerning standards, accreditation, monitoring, definitions and ethics. In North America, the American Psychological Association constitutes such a point of reference to universities and practitioners. Unsurprisingly, many Europeans turn to its standards, especially when it comes to the publication manual.

Conclusions

While this review paper concentrates on educational input rather than performance output, the authors recognize the need for considering both aspects, following the definition of the content of psychologist's profession and its various specializations across Europe (Roe, 2002). Considerable differences persist between North American and European models of clinical psychology training (Donn, Routh, & Lunt, 2000), although efforts are being made towards the standardization of the profession of a psychologist and continued professional development (Poortinga, 2015), yet for some common standards (especially publication manual), the American Psychological Association is a firm point of reference.

What are some practical recommendations to a North American psychologist when interacting with her European colleagues? First, instead of referring to a "PsyD" it is much better to ask about a "specialization" of a psychotherapist, enquiring about her particular school of thought or approach, years of study and supervised practice. Concerning a "PhD", misunderstandings are not very likely. However, while throughout the entire Europe someone is a doctor in psychology only after obtaining a doctorate degree, Italy constitutes an exception: even a BA in psychology legally entitles a person to the title of a doctor in psychology ("dottore" in Italian, abbreviated "Dott." or "Dr").

Asking about a license in Europe can also be tricky. Each country has different regulations and it is safest to first enquire about what are some national regulations concerning private practice and if there is an obligatory, public national registry of psychologists and psychotherapists. A conversation about different associations and societies could also open up a whole new world, quite distinct from the American Psychological Association and its divisions. Moreover, there seems to be a tendency among European psychologists not to go into as many personal details as their colleagues from the United States, emphasizing the results of their research, publications and professional status.

In sum, when interacting with European psychologists it is wise to first define and explain both contexts. The efforts to overcome the human tendency to ethnocentrism in psychology should be mutual and conscious (Takooshian, 2003). Such exchange among researchers probably brings fewer surprises than among psychotherapists, but will surely be fruitful, eye opening and stimulating in both cases.

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The Development of Psychology in Brazil: Its Early History

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The history of Brazil and of Brazilian Psychology are intrinsically related. The political, economic, social, educational, juridical and philosophical aspects had a grand influence in the development process of the Psychology. Earlier psychology themes were learned with the Jesuits (1500 – 1808) at the catechesis of natives and children at settlers, encompassing emotion, memory, behavior and adaptation. Provisions made by the Portuguese Court to live in Brazil in 1808, involved concern about public health and hygiene. Psychopathological disturbances involving addictive behavior and mental disabilities were treated by psychiatry hospitals or led to prison – with the medical support of the Brazilian Social Hygiene Movement (Furtado, 2012; Mitsuko, 2012; Vilela, 2012).

During the period of 1808-1900, philosophical and physiological knowledge from Europeans and North American professors, provided important information for Brazilians, involving psychological topics related with passion and emotion, assessment and possible treatment for mental hallucinations, epilepsy and hysteria (Soares, 2010; Vilela, 2010; CRPSP, 2011). Pioneers who made early studies in Brazil about Psychology were self-taught and started to study psychological knowledges in the Teacher Training Institutions. It is impossible to mention all the pioneers, and some remain anonymous. To mention a few: Anita Paes Barreto (1907 – 2003); Annita de Castilho e Marcondes Cabral (1924 – 2004); Aníbal Cipriano da Silveira (1902-1979); Antonio G. Penna (1917 – 2010); Dante M. Leite (1928 – 1976); Durval Marcondes (1899 – 1981); Eliezer Schneider (1910 - 1998); Emilio Myra y Lopes (1896 – 1964); Father Antonius Benkö (1920 – 2013); Franco Lo Presti Seminerio (1923 – 2003); Paulo Rosas (1930 – 2003); Mathilde Neder (1923 -); Mother Cristina S. Doria (1916 – 1997); Nise da Silveira (1905 -1999); Raul Carlos Bricquet (1887 – 1953); Silvia Tatiane Maurer Lane (1933 – 2006); Therezinha Lins de Albuquerque (1926 -); and Ulisses Pernambucano de Melo Sobrinho (1892 – 1943). The pioneers were responsible for important landmarks of psychology in Brazil, as noted in Table 1 (Furtado, 2012; Mitsuko, 2012; Vilela, 2012; Lisboa & Barbosa, 2009).

Table 1. *Landmarks of Psychology in Brazil*

1890's	Earlier dissertation thesis by physicians to conclude Medical Schools with psychological themes
1906	First Experimental Psychology Brazilian Lab
1930's	First classes of Psychology – Graduate courses of Philosophy, Educational and Medical Graduation Courses
1940's	First scientific journals in Psychology First societies of psychology
1950's	First Psychology graduate courses in the Universities of Sao Paulo, Minas Gerais, and Rio de Janeiro
1960's	First post-graduate programs in Psychology
1962	Officially recognition by the President Joao Goulart of the Psychology in Brazil as a science and a professional practice (August 27, 1962)
1971	Creation of the Councils of Psychology

Psychologists' discussion of abuses in the political practices within the society has been one of the important issues for the social psychology. The Brazilian League of Mental Hygiene, founded in 1923, created a psychology laboratory for psychiatry studies that later on became influenced by eugenic practices, leading the exit of many psychologists of the league. By the 1940's, most of the abusive practices of the Brazilians Social Hygiene Movement became extinct. (Furtado, 2012; Mitsuko, 2012).

Another roadblock for the development of the psychology and its benefits for society was the military dictatorship (1964 - 1985). It induced a socially committed psychology practice. The abusive political practices included threat, exile and torture of many psychology professors. After this dark period, by the 1990's there was an increased number of Psychology courses and post-graduate programs with more published studies--a scenario that continues until today (Soares, 2010; Vilela, 2012).

Nowadays, Brazil has 270.605 psychologists, 23 Regional Psychology Councils and a Federal Council of Psychology (CFP, 2016). There are 401 Courses of Psychology and 64 Post-graduation Programs. Many discussions of possible improvement of practices and research remain (Tourinho & Bittencourt, 2010). Nevertheless, one must consider all the victories over past challenges to Psychology in Brazil since its inception, becoming nationally and internationally recognized as a respected science and profession.

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Reports

Volunteering in the Kingdom of Bhutan

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For many travelers who are into "off the beaten path" types of destinations, the Kingdom of Bhutan, a nation of around 600,000 nestled in the Himalayas, represents the holy grail of destinations. It is a nation seldom visited by tourists, a large part of that likely due to the approximately $250USD/day fee imposed on travelers for a mandatory guide, accommodations, and food. As such, the culture remains comparatively uninfluenced by the Western world. It is a nation that welcomed television and the internet as recently as 1999, and where both men and women wear traditional Bhutanese clothing as part of their everyday dress.

So, in the summer of 2014 when the opportunity arose to volunteer at the Jigme Dorji Wangchuck National Referral Hospital (JDWNRH) in Thimphu, the capital city, I jumped at it. I was there for almost 3 months, and it was an unforgettable experience for which I'll always be grateful to Health Volunteers Overseas (HVO), the organization which arranged my placement, provided my accommodation, and allowed me to experience this fascinating country without the exorbitant tourist fees.

The mission of HVO centers around empowering local healthcare professionals in developing nations and furthering the quality of healthcare provided. It accomplishes this by sending licensed healthcare professionals from a number of different countries to various locations around the globe to work alongside local professionals, provide didactics, presentations, and make suggestions as treatment situations arise. It also provides fantastic opportunities for healthcare professionals from Western nations to learn about the culture and healthcare practices of the locals and to exchange knowledge. As such, the aim is much less about imposing one's own ways and training on local healthcare workers than it is about collaboration and mutual learning.

The hospital I was placed at has a small psychiatric and substance detox unit that accepts volunteer therapists (psychologists, social workers, MFT's, etc.) or psychiatrists for 3-month placements. When I was there, there were 2 psychiatrists in the entire country, both located at JDWNRH, and no graduate-level trained psychologists, or graduate schools that offered such training.

The psychiatrists, one Bhutanese and the other foreign-born, principally saw patients on an outpatient basis but would also make rounds on the inpatient unit. The hospital itself is a referral hospital that sees patients from across the country. And although Bhutan is small, the infrastructure- namely the oftentimes windy, dirt roads- makes traveling to the hospital for treatment a long and trying ordeal for many of the patients.

For me, this meant that the patients I saw- both on the inpatient unit and on an outpatient basis- were often from distant locales and would only be in Bhutan to receive treatment for short periods of time. This of course provided its own set of unique challenges, as did the fact that most patients spoke Dzongkha (the official language), Nepalese, or some local dialect much more fluently than English.

Thankfully, I had Ugyen, the local therapist with whom I worked most closely. Upon receiving his bachelor's degree in psychology in India and returning home to take a position at the hospital, he became the defacto therapist on the unit. I can't imagine being thrust into that role after my bachelor's degree! Luckily for me and for the patients he served, Ugyen is a wonderfully personable, intelligent, and empathic person. And, through his various interactions with HVO volunteers, readings done in his own time, and his undergraduate training, he is quite a solid therapist.

Ugyen and Myself In Front of JDWNRH

Being that my work there would take place over just a short period of time, my focus was not on direct patient care but in working with Ugyen in a collaborative, supervisory role to improve his skills as much as possible in the three months I had with him. He also served as a capable translator when I needed one!

During our time together, I worked with Ugyen on developing Cognitive Behavioral Therapy skills. This approach seemed to fit well with the shorter-term nature of the therapy that was often conducted in our outpatient setting. And, not unlike the patients we might see in the West, many who presented for treatment had some variations of anxiety or depressive disorders that seemed to be quite amenable to CBT treatment.

In spite of its international reputation as one of the the "happiest nations on earth" (Bhutan is the country whose government actually measures Gross National Happiness) and a peaceful Buddhist nation, Bhutan struggles with many of the same mental and behavioral health issues as other countries, sometimes to an extreme extent. Alcoholism is rampant, as is domestic violence, physical and sexual abuse of minors (often at the hands of those most trusted such as teachers and monks), and so forth. (Arora, 2013; Dorji, 2014; Global Initiative, 2016; Kelly, 2013; Royal Government of Bhutan, n.d.; Sundas, 2016.). This meant that we saw a steady stream of such cases in both the inpatient and outpatient settings, which was both discouraging but also heartening in that it meant that people were reaching out and accessing these relatively novel resources available to them.

In addition to many of the mental health and social issues I was accustomed to seeing in the USA, there were also various fascinating, unique, and culturally laden cases, which often didn't fit neatly into any DSM diagnosis that I was familiar with. Among these were several cases that were understood locally as possession. Prior to my experience in Bhutan, I had assumed that what was known in some quarters of the world as spiritual possession could most likely be classified as some type of psychotic disorder such as schizophrenia, well-known to the west. While such cases certainly were brought to our attention, other cases could not be so easily categorized.

For instance, I saw a 10th grade boy in the hospital following a suicide attempt. He was admitted first into intensive care after trying to hang himself, being found unconscious by his brother. He was not able to talk for some time, and in addition to the bruising on his neck appeared to have some residual cognitive impairment due to hypoxia. Interestingly, he seemed to be just as happy as could be and denied any kind of difficulty in school, personal, or family life. His family members denied noticing any change in behavior or depression leading up to the event. He had no memory of hanging himself and was absolutely puzzled about why he would attempt such a thing, particularly because everything seemed to be going well for him. He was quite surprised when he woke up in the hospital and heard about what had happened.

When I met with the attending physician who was treating him, he explained to me that many Bhutanese people, himself included, believe that the soul of someone else who has died may inhabit the body of a living person, causing them to act as the deceased person had acted. The doctor explained to me that what had probably happened was that since the boy was attending a school where a female student had hanged herself recently, her spirit likely then possessed him, causing him to hang himself.

Needless to say, it was fascinating to see how culture, religion, and traditional medicine interacted in case conceptualization and treatment. Unfortunately, all too often I did observe instances where people with sometimes severe mental illness were deprived of treatment in favor of exorcisms or isolation and inhumane treatment. Psychology and psychiatry are very new disciplines in the country, and for them to become known, understood, and accepted will take many more years, I suspect.

In other ways, however, Bhutan has a lot to teach the West when in comes to family and community support of patients with severe mental illness. I was always impressed by how the patients on the inpatient and detox wards always had some family members or friends at their side. I was also impressed with the general compassion with which the staff treated patients.

Outside of my work at the hospital, I passed a simply amazing time with the wonderful, hospitable, and friendly people of Bhutan. Some of the best hiking and trekking in the world can be found there, and some of the scenery- monasteries built high up in the mountains seemingly clinging to the very ledges they overlook- is breathtaking.

Tiger's Nest Monastery, Bhutan

I encourage anyone who is interested in this volunteer possibility to check out the HVO program: https://hvousa.org/ourwork/programs/special-projects/

I continue to volunteer with HVO in helping to screen potential volunteers, and would be happy to speak with anyone who would like more information. I can be reached at darrenkensmith@gmail.com

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Dr. Pir receives Organization of the Year award for IMCES, the organization she founded in 1989, for her tireless commitment to serving the culturally and linguistically diverse communities in Los Angeles.

Dr. Pir Honored with "Organization of the Year" Award for Commitment to Diversity

Tara Pir, PhD

Founder and President, Institute for Multicultural Counseling and Education Services, Inc. (IMCES)

Dr. Pir was recently honored with the prestigious "Organization of the Year" award presented in Washington, D.C. by PR News in recognition of the demonstrated commitment to diversity by her organization, the Institute for Multicultural Counseling and Education Services, Inc. (IMCES).

IMCES was selected for this distinction from a long and impressive list of organizations, agencies, academic institutions, professional associations and other nonprofits that have demonstrated a commitment to diversity and excelled at communicating their diversity achievements, such as Covered California, Anthem Foundation, the Canadian Alliance on Mental Illness and Mental Health, the California Endowment, and the Medical University of South Carolina. Entries were judged by a blue-chip panel of public relations executives, the staff of PR News, and peers.

Dr. Pir made the strong commitment to contribute to the community in two major domains:

Commitment to Providing Comprehensive Services to the Community

IMCES, a nonprofit organization as a community clinic that Dr. Pir established in 1989 has, from its beginning, demonstrated a strong commitment to promote social justice and human rights in action on a day-to-day basis, based on the principle of inclusion by design. From day one, IMCES has focused on addressing disparities in access to health, mental health, social and legal services among culturally diverse communities.

Dr. Tara Pir at Awards Ceremony with Organization of the Year award in recognition of her demonstrated commitment to serving the health, mental health, social, and legal services needs of diverse target population in Los Angeles County through professionals with cultural and linguistic expertise in over 10 languages.

IMCES receives the Organization of the Year award for its commitment to diversity with the focus on practicing the principle of inclusion by design demonstrated throughout its organization.

Dr. Pir consistently moves from vision to action. For example, with the belief that health and mental health is the human right of everyone, she creates an even ground for everyone to walk on by providing the highest standard clinical services and advocacy programs for the most needy, underserved, vulnerable, diverse populations in Los Angeles County through professionals with cultural and linguistic expertise in over 10 languages.

Commitment to Professional Workforce Development

Dr. Pir's strong commitment to high standard, relevant workforce development for the helping professions in community based services led to the developing of doctoral and residency programs with a focus on leadership and practicing inclusion, accredited by the American Psychological Association (APA). Her programs have been recognized as unique, futuristic models for clinical training in psychology nationally and internationally. For more information about IMCES, please visit our website at www.imces.org.

Dr. Pir meeting with Congresswoman and former Speaker of the House, Nancy Pelosi, at U.S. Capital event, describing IMCES's commitment to service provision as well as high standard workforce development, the APA accredited clinical training program for the helping profession of psychology.

Dr. Pir and staff demonstrating the power of commitment to diversity and inclusion for multicultural, multilingual needed service provision to our vulnerable population in Los Angeles County.

Tara Pir Received National Award for Pioneering International Service

Leland Keel
lelandkeel@imces.org

Dr. Pir was recently honored with the prestigious "Organization of the Year" Award presented in Washington, D.C. by PR News, in recognition of the demonstrated commitment to diversity by her organization, the Institute for Multicultural Counseling and Education Services, Inc. (IMCES).

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IMCES was selected for this distinction from a long and impressive list of organizations, agencies, academic institutions, professional associations and other nonprofits that have demonstrated a commitment to diversity--such as Covered California, Anthem Foundation, the Canadian Alliance on Mental Illness and Mental Health, the California Endowment, and the Medical University of South Carolina. Entries were judged by a blue-chip panel of public relations executives, PR News staff, and peers.

IMCES was also recognized for its workforce development. IMCES has developed doctoral and residency programs accredited by the American Psychological Association (APA), with a focus on leadership and inclusion. Her programs have been recognized as unique, futuristic models for clinical training in psychology nationally and internationally. For more information about IMCES, please visit our website at www.imces.org.

Many government officials saluted Dr. Pir and IMCES at the Awards reception, such as former House Speaker Nancy Pelosi. For any details, check wwww.imces.org

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Note: **S. Leland Keel, JD, MBA**, is General Counsel for the IMCES in Los Angeles CA.

PHOTO caption (l to r): Congresswoman Nancy Pelosi congratulates Dr. Tara Pir.

Dr. Tara Pir with her award-winning IMCES staff in Los Angeles.

Announcements

Meaning Conference 2016 - Call for Papers

The International Network on Personal Meaning (INPM) is pleased to announce the **9th Biennial International Meaning Conference** (Second Wave Positive Psychology Summit) to be held July 28-31, 2016 in Toronto, Canada.

This is the only international conference focusing on **second wave positive psychology** (PP2.0), which embraces the dark side of life and empowers humanistic values. It emphasizes cutting-edge research and innovative positive interventions from the world's leading psychologists, including **Michael Steger**, **Carol Ryff**, **Clara Hill**, **Itai Ivtzan**, **Piers Worth**, **Veronika Huta**, **William Breitbart**, **Crystal Park**, **Dmitry Leontiev, Robert Neimeyer**, **Mick Cooper, Kirk Schneider**, **Suemay Chan**, **Paul T. P. Wong**, and more.

In addition to several pre-conference workshops for professionals in mental health and the workplace/organizations, the highlights of the conference include:

Second Wave Positive Psychology Summit to explore the new frontiers of positive psychology in research and applications,

Panel on Meaning-Centered Interventions in professional practices, and a multi-disciplinary

Panel on Terrorism and Heroism consisting of **Jordan Peterson, Michael Lerner, Alex Batthyany,** and **Alex Pattakos**.

To encourage research in PP2.0, we invite graduate students to enter a **Scholarship Competition**; for details, click here.

To submit a **Proposal (Symposium, Workshops, Papers, or Posters**), click here. The submission deadline is April 30, 2016, and notifications will be sent before May 25, 2016. Please note that the early bird registration deadline is May 31, 2016.

For more information on the conference, pre-conference workshops, and registration, click here.

The Role of Psychology in Positive Social Change

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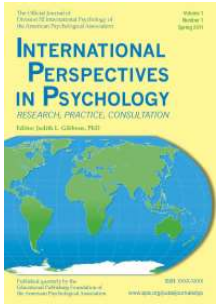

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Internationalizing Undergraduate Psychology Education: Trends, Techniques, and Technologies

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How can we best internationalize undergraduate psychology education in the United States and elsewhere? This question is more timely than ever, for at least 2 reasons: Within the United States, educators and students seek greater contact with psychology programs abroad, and outside the United States, psychology is growing apace, with educators and students in other nations often looking to U.S. curricula and practices as models. In this article, we outline international developments in undergraduate psychology education both in the United States and abroad, and analyze the dramatic rise of online courses and Internet-based technologies from an instructional and international point of view. Building on the recommendations of the 2005 APA Working Group on Internationalizing the Undergraduate Psychology Curriculum, we then advance 14 recommendations on internationalizing undergraduate psychology education—for students, faculty, and institutions.

Keywords: undergraduate education, international psychology, teaching psychology, diversity, MOOC

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> On U.S. college campuses, we psychologists should be teaching our undergraduates about human behavior, not just behavior in North America.
>
> —David G. Myers

Psychology is a highly popular subject of study for American undergraduates. Between 1.2 and 1.8 million U.S. students enroll in the introductory course each year (Gurung et al., 2016). More than 100,000 U.S. students earn their bachelor's degrees in psychology annually (Norcross et al., 2016)—114,450 degrees in 2013 (National Center for Education Statistics, 2015).

It is, however, less well known that in recent decades, psychology has been expanding apace in many corners of the world, making undergraduate education in psychology hugely popular around the globe (McCarthy, Dickson, Cranney, Trapp, & Karandashev, 2012). American psychologists now account for only an estimated 21% to 24% of the world's psychologists (Bullock, 2012a; Zoma & Gielen, 2015), down sharply from an estimated 80% in the 1980s (Rosenzweig, 1984). Increasingly, the educational practices and knowledge base of psychology are constructed on a worldwide basis, yet current American psychology curricula insufficiently reflect this trend.

This article describes how international and cross-cultural contributions can be purposefully integrated into undergraduate psychology education so that undergraduates both in the United States and elsewhere are better prepared for an

Editor's note. This article is one of a collection of four articles published with undergraduate education guidelines in a special issue of *American Psychologist*, "Undergraduate Education in Psychology: Current Status and Future Directions" (February–March 2016). John C. Norcross and Robin Hailstorks provided scholarly lead for the special issue.

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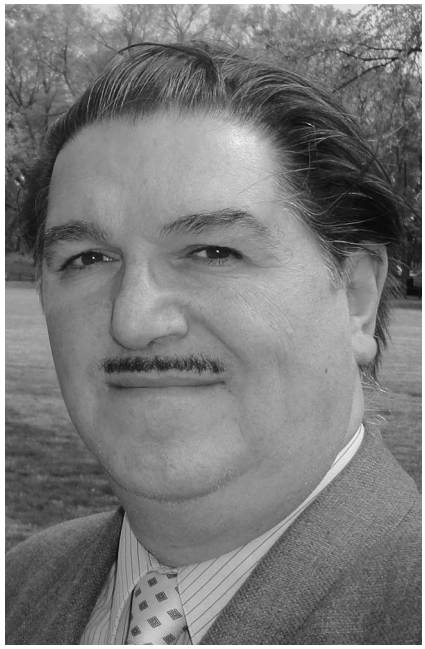

Harold Takooshian

increasingly interdependent world. In addition, this article describes how a modern psychology curriculum can enable students to gain international experience by facilitating their interactions with overseas students and faculty either in person or via electronic means, such as online courses and Internet-based technologies. The Internationalization of Curricula (IoC) is a movement affecting many fields (Leask, 2015), and is especially valuable for undergraduate psychology in more than one way, to increase (a) our understanding of human behavior in general, across diverse nations and cultures; and, (b) the "world-consciousness" of all psychology students in the United States and elsewhere—to nurture what has been termed "global psychological literacy" (Cranney & Dunn, 2011; Dunn, 2015).

In the following, we provide a brief history of the international growth of psychology, followed by how these international developments and new forms of diversity relate to undergraduate psychology education. Because the recent dramatic growth of international education is driven to a significant degree by technological changes, we address massive open online courses (MOOCs) and the pervasive influence of Internet-based technologies on students and faculty. These sections are followed by a set of 14 recommendations outlining how undergraduate psychology education might best be internationalized on three levels—by undergraduate students, their faculty, and institutions.

The Growth of Psychology as an International Discipline

Psychology as a discipline with a firm, institutional identity was born in the 1870s in Germany, spread to other European countries and the United States within the next few years, and soon thereafter also became known in some Asian and Latin American countries, such as Japan, China, Mexico, and India (Stevens & Wedding, 2004). Thus, Western-style psychology had an international dimension from its beginnings, but it would grow into a full-blown global discipline in the late 20th and early 21st centuries (Rich & Gielen, 2015).

After Wilhelm Wundt established the first psychological institute in Leipzig in 1879, his highly popular lectures and his laboratory soon attracted students from numerous Western as well as several non-Western countries. Many of these international students accepted his vision of a new, scientific discipline and returned home to establish laboratories and institutes in their own countries. By 1897, Wundt's laboratory expanded to 14 rooms, filled with students from 20 nations—from Japan to Chile (Misiak & Sexton, 1966).

Wundt had many American students and assistants, such as James McKeen Cattell. Although most of them rejected or ignored Wundt's theoretical outlook, they nevertheless formed an important part of the founding generation that would soon, together with William James and others, help American psychology assume worldwide leadership. By 1900, there were 40 doctoral programs and 41 laboratories at American universities, whereas only 10 laboratories could be found in Europe (Benjamin, 2000). Moreover, psychology was rapidly becoming one of the most popular subjects at the undergraduate level, while intriguing the general public (Schultz & Schultz, 2012).

In addition, during the 1930s and 1940s, many elite Austrian and German psychologists migrated to the United States. After 1945, American psychology began to dominate the worldwide scene not only based on its sheer number of psychologists but also through its journals, scientific research, textbooks, the growing dominance of English in scientific publications, and the country's economic and political power. There were now more psychological scientists, practitioners, and educators in the United States than in all other nations combined—to the point where some began to fault American psychology as being "self-absorbed" (Rosenzweig, 1984) or even "xenophobic" (Sexton & Misiak, 1984). These American critics argued that American psychology was assuming a monocultural and monolingual character while ignoring many new developments, especially in the non-English-speaking countries.

But this trend has changed dramatically since the 1990s, as psychology now grows faster outside than inside North America (Bullock, 2012a, 2012b), and colleagues inside and outside the United States seek greater communication. By integrating data from diverse sources (e.g., Bullock, 2013; Cooper, 2014; Lunt, Peiró, Poortinga, & Roe, 2015; Stevens & Gielen, 2007; Stevens & Wedding, 2004), one may estimate conservatively that there are 1 million psychologists worldwide: roughly 230,000 in the United States,

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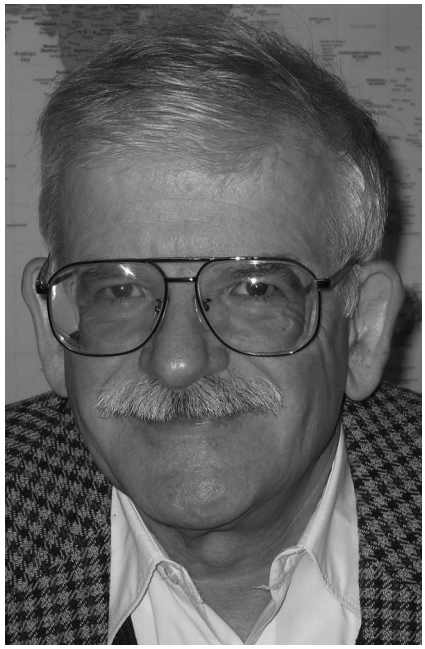

Uwe P. Gielen

330,000 in Latin America, 330,000 in Europe, and 100,000 in the rest of the world (Zoma & Gielen, 2015).

International Diversity in U.S. Psychology Education

Although discussions about *diversity* are now frequently included in U.S. psychology courses, this was not always the case. Through most of the 20th century, the classic psychology experiments that American instructors present to their undergraduates—such as Solomon Asch's (1955) study on conformity and Philip Zimbardo's (1972) study of prisoners—were based on small samples that were intentionally homogeneous: White male U.S. college students. This control for gender, age, and race was an easy way to reduce confounding variables, tacitly leaving it to other researchers to cross-validate how much these findings on White male students might generalize to the other 99.9% of humanity—women, nonstudents, other ages, ethnicities, or nations. As late as 1986, an analysis of U.S. social psychology journals found that 72% of articles used North American undergraduates as subjects (Sears, 1986), and it concluded that this narrow database was giving our undergraduates a distorted picture of human nature. One psychologist wryly noted that in psychology experiments, "Even the rat was white" (Guthrie, 1998).

The 1991 Saint Mary's conference on the undergraduate curriculum noted the importance of diversity to "ensure that psychology courses more accurately reflect the diversity of humankind, including ethnic, social, cultural, and gender diversity" (McGovern, 1993, p. 179), as well as greater inclusion of underrepresented minority students and faculty in the psychology pipeline. Then in 2008, the inclusion of "sociocultural diversity" in the undergraduate curriculum became a major emphasis through the Puget Sound conference (Landrum et al., 2010), including the promotion of "psychological literacy" among citizens worldwide (Halpern, 2010). In fact, the American Psychological Association's (APA's) Board of Educational Affairs "noted that diversity is a particularly important aspect of the *Guidelines*" (Hailstorks & Boenau, 2013), and the revised *APA Guidelines for the Undergraduate Psychology Major 2.0* (APA, 2016) feature "Ethical and Social Responsibility in a Diverse World" as the third of its five broad learning goals. The "sociocultural diversity" in these *Guidelines 2.0* includes both multicultural diversity within the United States as well as international diversity across nations—which is the central focus of this article.

APA has a long history of promoting international psychology education, even before the formation of its Committee on International Relations in Psychology in 1944 (Fowler, 2000). The APA Office of International Affairs, formed in 1971, offers a website rich with global resources, travel funding, and a bimonthly bulletin (*Psychology International*). In 2008, the APA Education Leadership Conference focused its annual meeting on this theme of internationalizing psychology education (Torney-Purta, 2008), on the heels of an APA Working Group on Internationalizing the Undergraduate Psychology Curriculum (2005).

Because the question of educational "outcomes" is important, the 2005 APA Working Group identified five valuable goals of IoC in psychology, each with five measurable outcomes. Examples of these 25 outcomes include an increase in students' sociocultural awareness (Outcome 1.1); understanding of research methods applied across cultures (Outcome 2.3); knowledge of the field of psychology in other nations (Outcome 3.2); cross-cultural competence of students on a personal level (Outcome 4.4); and appreciation of global issues of human rights and social justice (Outcome 5.4). These 25 outcomes are not yet documented, but are best seen as an agenda for future researchers, to assess the actual impact of IoC on students' knowledge, attitudes, and actions.

Of course, U.S. undergraduate psychology courses should be relevant to the 95% of the human population living outside the United States, but creating such a cross-national science of behavior has been a challenge (Rosenzweig, 1984). Unlike physical sciences such as chemistry, which share a "periodic table" across nations, psychology lacks a solid core that is recognized cross-nationally (Howell, Collisson, & King, 2014).

To borrow from the concepts of Newtonian physics, we can see the challenge of a transnational psychology as a tension between two opposing forces. These are (a) the strong "centrifugal" (outward) forces that divide cross-national psychology and include the familiar obstacles of language, distance, cost, sociocultural variations, and ide-

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Scott Plous

ology (Draguns, 2001); and (b) the strong "centripetal" (inward) forces that increasingly bind cross-national psychology: quadrennial and other world congresses, journals, cross-national educational and research efforts (such as Fulbright scholarships and study abroad), and now the Internet.

The Growth of Psychology Education Outside the United States

Since the 1990s, the numbers of psychologists, psychology programs, and course enrollments have increased rapidly around the globe. In 2012, over 4 million tertiary-level students were studying psychology and other subjects outside their own nation, up from 2 million in 2000 (UNESCO Institute for Statistics, 2014). And in the academic year 2013–2014, 886,052 international students were enrolled in U.S. institutions of higher education (4.2% of all students)—up 72% from 1999–2000 (Institute of International Education, 2014). Moreover, 289,408 U.S. students were studying overseas in the 2012–2013 academic year.

A growing number of international conferences, publications, and other resources support instructors who seek to internationalize their undergraduate courses. For instance, *Psychology Resources Around the World*, a web-based compendium of psychology in nearly every nation in the world, has been developed by the International Union of Psychology Science (IUPsyS: Bullock, 2012b). McCarthy and colleagues have produced three volumes of an edited series, *Teaching Psychology Around the World* (McCarthy et al. 2007, 2009, 2012), describing both education requirements and best practices in many nations. Six International Conferences on Psychology Education have been held since the first one in Russia in 2002. Psi Chi, the once-U.S. Honor Society for Psychology, voted in 2009 to expand into the International Honor Society for Psychology, and formed chapters in 10 nations within 5 years (McCormick et al., 2014).

Psychology education is flourishing in Western and non-Western countries alike. One clear example is Indonesia—the world's fourth most populous nation, with 252 million inhabitants. For decades, psychology was largely unknown among Indonesia's general public, until its first psychology department was founded in 1960 at the University of Indonesia. Yet by 2011, Indonesian students could study psychology in 95 departments across the country, and Indonesian psychologists appear so often on national TV and radio, and in newspapers and popular magazines, that the "psychological literacy" of the Indonesian public may now surpass that of the American public (Sarwono, 2011).

In some nations (such as Argentina, Brazil, Indonesia, Israel, and the Netherlands), psychology is taught to large numbers of psychology "undergraduates," and it has also entered the popular culture. In other countries (such as Cameroon, Mexico, Philippines, South Korea, and Taiwan), efforts are underway to "indigenize" psychology theories and research to reflect a region's unique cultural, social, and linguistic traditions. Many scholars in these non-Western countries believe that psychology education must be indigenized so that undergraduates can better understand psychology's relevance to their own lives. Some members of this movement aim to create a unified global psychology that can integrate diverse cultures and contributions from psychologists across many nations, whereas others emphasize the cultural embeddedness of almost all psychological processes (Kim, Yang, & Hwang, 2006).

It is valuable for U.S. and other psychology students to learn about these struggles to create both locally meaningful and globally unifying forms of psychological science. After all, many of these struggles revolve around the central psychological question of whether there is a universal human nature—and whether Western psychology has been successful in identifying most of its essential aspects, or whether it has been (partially) led astray by implicit but powerful cultural perceptions and norms (as described in www.indigenouspsych.org/). In international circles, some scholars have described North Americans as demographically "WEIRD"—White, Educated, Industrious, Rich, Democratic (Henrich, Heine, & Norenzayan, 2010), and thus not representative of populations in "ROW" (the Rest of World).

Although psychology has been growing rapidly outside the United States, the definitions and credentialing practices associated with the term "psychologist" vary considerably between nations. As a consequence, we lack sound global data comparable with the United States. The American system draws a clear distinction between undergraduate and

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graduate education based on the structure of the American university and college system. Most American 4-year college students pursue a liberal arts education in which required courses for their major occupy no more than 20% to 30% of coursework. The baccalaureate degree is prerequisite for future graduate education. In contrast, most psychology students in South America do (or did) not "major" in psychology. Instead, upon graduation from a selective high school, they enter a university to pursue a professional degree for about five years, and graduate with a professional bachelor's degree in psychology that, together with a period of supervised practice, allows them to practice psychology. (This degree is more comparable with a U.S. master's degree.) However, only a small fraction of these licensed psychologists will later pursue a master's or doctoral degree (Klappenbach, 2004).

In Europe, undergraduate education has been changing dramatically since the 1990s under the so-called Bologna process. Now, the 36 countries in the European Federation of Psychologists' Associations (EFPA) have been developing unified systems and standards for education and credentialing that are transforming psychology in Europe. In 2000, EFPA launched its "tuning" process to address the needs of students and employers for "transparent and reliable information as to what a degree qualification stands for in practice" (Lunt et al., 2015, p. 70). This process covers all education levels in Europe, including Levels 6 (baccalaureate), 7 (master's), and 8 (doctorate).

The EuroPsy Basic Certificate specifies outcomes for a 3-year program leading to a bachelor's degree, followed by a 2-year master's degree, and a 1-year period of supervised practice (Lunt, 2014; Lunt et al., 2015). At the same time, the EuroPsy initiative endeavors to protect "the rich diversity of European education . . . and in no way seeks to restrict the independence of academic and subject specialists or undermine local and national academic authority" (EuroPsy, 2011, p. 6). This effort is supported by 36 national psychology associations representing more than 300,000 psychologists who, in turn, serve more than 740 million people. Over time, this EuroPsy initiative may well shape undergraduate and graduate education in psychology outside Europe as well. This EuroPsy initiative moves European psychology education one step closer to the American educational model with its clear separation between undergraduate and graduate education. However, this movement has not been welcomed by everybody.

In addition to the EuroPsy efforts in Europe and the *APA Guidelines 2.0* (APA, 2016) in the United States, a third effort to enunciate a set of the goals for a diverse psychology education has been pursued by the International Baccalaureate Organization (IBO). Since 1960, the IBO is an independent multinational association that has developed international curricula and exams for 26 fields, including psychology. Like the U.S. Advanced Placement (AP) program, the IB Diploma gives motivated secondary school students, Ages 16 to 19, a chance to earn college-level credits. As of 2014, 1.1 million students at 3,789 schools in over 40 nations have studied for IB exams, including 17,200 IB exams in psychology (11,300 of these in the United States; IBO, 2009). So far, there appears to be little direct contact between leaders of these three independent efforts, though this may change with time, given their common goals to develop a solid undergraduate curriculum that also incorporates global diversity.

The role of new instructional technologies is especially relevant in supporting the goal of internationalizing psychology and other curricula. Just as new technologies in the 21st century are transforming higher education, one impact is to reduce these centrifugal barriers to internationalization—travel, cost, and language. By all accounts, technologies such as open online courses and Internet-based technologies will play a major role in the future of undergraduate education worldwide, including psychology.

MOOCs

One of the most notable developments in global education has been the rise of MOOCs, with important implications for undergraduate education and global psychological literacy. Although definitions vary, MOOC generally refers to a free or low-cost Internet-based course taken by a large number of people. These courses first garnered widespread media attention in the fall of 2011, when a Stanford University computer science professor enrolled more than 160,000 students in a MOOC on artificial intelligence, and 23,000 completed the course. A year later, an article in the

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New York Times dubbed 2012 "the year of the MOOC," with good reason. By then, newly formed MOOC providers such as Udacity, edX, and Coursera had already enrolled millions of students, and the largest of these organizations, Coursera, reported growing at a rate faster than Facebook (Pappano, 2012).

The first MOOCs offered by Udacity, edX, and Coursera were in computer science, but today psychology-related MOOCs are among the most popular online courses, just as psychology courses have long been popular on college campuses. In fact, based on student registration figures that combine the first and second run of each course, four of Coursera's six most heavily enrolled MOOCs have focused on psychology, thinking, or behavior. These four Coursera courses include Social Psychology, with an initial enrollment of 633,131 students; Think Again: How to Reason and Argue (376,629 students); A Beginners Guide to Irrational Behavior (357, 511 students); and Learning How to Learn: Powerful Mental Tools to Help You Master Tough Subjects (321,617 students). Since 2012, MOOCs have also grown more international. For example, Coursera began exclusively with U.S. partner schools and instructors, yet nearly 40% of its 900 courses are now from partners outside the United States, and only 29% of its students are American.

Of course, distance learning—whether domestic or international—is not a new phenomenon. For most of the 20th century, correspondence courses taken through the mail were quite popular (Kett, 1996), and since 1990, The Teaching Company has offered more than 500 college-level Great Courses in a variety of audio and video formats. The video series *Discovering Psychology* has reached millions of PBS viewers since 1990, and has been taken as a tele-course for college credit by more than 500,000 students worldwide (Philip Zimbardo, personal communication, October 29, 2014). With the Internet, millions of online learners began watching educational videos and taking self-paced courses through KhanAcademy.com, lynda.com, and hundreds of other distance learning websites. It remains unclear what long-term impact this online explosion will have on traditional undergraduate psychology courses, but at the very least, MOOCs appear to be increasing psychological literacy worldwide.

What distinguishes MOOCs from other forms of online learning is that MOOCs usually take place with a large cohort of online learners from around the world. Typically, MOOCs include a combination of "courseware" (online course content) and elements of real-time traditional college courses, such as peer interaction, teaching assistants, and homework deadlines. Most often, MOOCs release course materials one week at a time, thereby allowing students in different time zones to learn about topics together as the course unfolds, help each other in online forums, and in some classes, assess one another's work.

Why this meteoric rise of MOOCs since 2012? The most obvious answer is that the technology has only recently become available—including global high-speed Internet access, bandwidth to stream videos, cloud storage of data, and the ability to create interactive online lectures that require students to answer questions before the video will advance. Yet technology is only part of the answer; MOOCs also provide a variety of economic and pedagogical benefits over traditional forms of education, particularly when it comes to internationalization.

The Benefits of MOOCs

On a per student basis and compared with traditional undergraduate courses, MOOC technology "can be used to enhance productivity in higher education by reducing costs without compromising student outcomes" (Griffiths, Chingos, Mulhern, & Spies, 2014, p. 4). Given the soaring costs of higher education in many countries, including the United States, it will become increasingly difficult for universities to ignore the economy of scale of these MOOCs.

MOOCs also offer benefits from the perspective of students. Not only are the courses less expensive and more accessible than most traditional classes, but for low-income students or people who live in a low-income nation, MOOCs may represent the only affordable opportunity for higher education. (In 2014, nearly half of all students in Coursera's Social Psychology MOOC were in countries with an emerging economy.) Since MOOCs are accessible around the clock, students can watch the lectures and receive online help from fellow classmates at any hour—a key advantage for students who are single parents, full-time workers, or homebound because of disability or illness.

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For international students not fluent in the instructor's language, MOOCs offer several other advantages over traditional instruction. First, videotaped lectures can be watched with subtitles, often in the student's native language. Second, students taking a MOOC can replay the lectures as many times as they like. Third, MOOC lectures usually have an option that allows students to slow down the video when needed. And fourth, students can use the class forums to study and help one another in their native language.

Indeed, because the students who enroll in MOOCs come from so many countries, the need for language support is even greater than in traditional classroom settings. In the Coursera Social Psychology MOOC, students came from more than 200 countries, spoke more than 40 different primary languages, and listed a primary language other than English nearly half of the time. To meet the needs of these students, lecture subtitles were available in 27 languages, thanks to volunteer translators who donated their services. On average, according to Coursera, the enrollment of students who speak a non-English primary language triples when a MOOC offers subtitling in their language (Andreina Parisi-Amon, personal communication, November 1, 2014).

These enrollment patterns highlight the central role of language in international psychology education, and they suggest the importance of incorporating pedagogical practices that meet the linguistic and cultural needs of students. Whether courses are online or on campus, internationalizing psychology education will require platforms that facilitate peer interaction, language support such as video subtitling, visual and nonverbal demonstrations of key principles, and the inclusion of diverse cross-cultural examples that engage students regardless of nationality. Such practices are consistent with recent research on effective undergraduate education in psychology (Halpern, 2010), and their adoption stands to benefit not only students abroad but international and domestic students studying in the United States as well.

Learning Outcomes

Critics of MOOCs note that course completion rates are very low, and that it is hard to assess the learning that takes place. Of the estimated 33,000 to 43,000 students who enroll in an average-size MOOC, only 60% or so of students return to the course when it begins, and only 6% to 10% complete the course, depending on how the completion rate is defined (Jordan, 2014)—making a 90% to 94% incompletion rate a source of concern for educators. In response to these criticisms, MOOC supporters argue that course completion rates are the wrong metric to measure educational success. In the words of the founders of Coursera, "the goal of education is to provide students with the skills they need to achieve their own life goals, not to retain individuals in a classroom" (Koller, Ng, Do, & Chen, 2013, p. 1).

Outcome studies comparing online and traditional learning have shown promising results. For instance, one study found that when an electrical engineering course incorporated content from an edX Circuits and Electronics MOOC, the percentage of students passing the course went from as little as 55% to 91% (Fowler, 2013). An especially encouraging result was reported by University of Texas researchers who compared the effectiveness of an online version of introductory psychology with a traditional version (Pennebaker, Gosling, & Ferrell, 2013). Not only did psychology exam scores increase by approximately half a letter grade when the course was taught online—the socioeconomic achievement gap in course grades was cut in half.

How effective are MOOCs or other new technologies in internationalizing undergraduate education in developing regions? Current opinions are divided. On the positive side, educators such as David Myers (2009) foresee how new technologies can segue into a "pedagogical utopia," in which "web-based e-books may deliver state-of-the-art, interactive, low-cost, locally adapted content to students who cannot afford books" (p. 99). On the negative side, Kentaro Toyama (2015), from his experience with undergraduates in India, concluded that "the primary effect of free online courses is to further educate an already well-educated group who will pull away from less-educated others. The educational rich just get richer." The long-term impact of MOOCs is clearly an open question awaiting empirical study.

Internet-Based Technologies

In addition to MOOCs, various Internet-based technologies and systems—such as Twitter, Facebook, blogs, wikis, Skype, videoconferencing, podcasts, YouTube, and virtual worlds—are revolutionizing how disciplines internationalize their undergraduate programs and curricula (Velayo, 2010; Velayo & Trush, 2012). Through such web-based systems, instructors in different nations can work together, often in real time, on joint activities. Undergraduates are generally well-acquainted with these sites and technologies (at times, more so than faculty), and their thoughtful use is valuable in guiding education, supplementing lessons, improving research and collaboration, and pursuing the larger goal of IoC (Velayo, Oliva, & Blank, 2008). Moreover, Moodle, Blackboard and other online teaching platforms can facilitate a web-enhanced class, which enables students from different institutions across the world to interact in real time. Such technology is now commonplace in most schools in the United States and other nations.

Internet-based technologies are increasingly popular to incorporate international content into the psychology curriculum (Grenwald, Oberlechner, & Velayo, 2012; Grenwald & Velayo, 2011; Velayo, 2012). One key reason is cost-effectiveness—especially for community college and other students with family, work, or financial limitations

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(Guerin, 2009). The Internet offers interaction with people from other cultures and countries, journal articles written by individuals from diverse backgrounds, and countless opportunities for cross-cultural collaboration—all at little cost.

Social media refer to Internet-based technologies that enable users to interact by sharing information, ideas, images, or videos. Facebook, YouTube, Twitter, blogs, and wikis are among the most common social media platforms used to enhance collaboration and share knowledge among learners from different parts of world. Social media exemplars in internationalizing undergraduate education include virtual psychology labs (e.g., Gao & Wang, 2010), international mentoring (Stevens & Wedding, 2009), and collaborative online research with participants across nations. One example of a popular virtual lab is APA's Online Psychology Laboratory (http://apaonlineacademy.bizvision.com/), with almost a million views per year.

Another way that Internet-based technologies incorporate international content is through the sharing of materials. It is increasingly easy to share material with peers or colleagues and work collaboratively. Many instructors now use social networks and videoconferencing to participate in lecture exchanges (e.g., Longview Foundation for Education in World Affairs and International Understanding; www.longviewfdn.org). Internet-based technologies can also help supplement textbooks which may lack international content, with articles from international journals to supplement the texts.

There are also many content-based resources that provide information for undergraduate instructors who wish to infuse international content in their courses (Velayo, Grenwald, & Manfred, 2012). Probably the most comprehensive collection of psychology resources focused specifically on internationalization are Psychology Resources Around the World (http://resources.iupsys.net/iupsys/index.php/patw-resources) and International Teaching of Psychology Network (http://interteachpsy.org/). Instructors can help update these and other sites by contributing resources as well as reviewing the materials. Just as emerging technologies are transforming undergraduate education in general, these technologies promise to be a valuable centripetal force to reduce barriers to global education.

14 Recommendations to Support the Internationalization of Undergraduate Psychology

Internationalizing undergraduate psychology is an ambitious but highly desirable goal that needs the concerted efforts of students, faculty, departments, and educational institutions. Institutions must help create the right educational atmosphere as well as provide the necessary organizational support and financial incentives to enable faculty and departments to engage in the necessary efforts. Departments must see internationalization as an overarching goal that cuts across the curriculum. Faculty members must see themselves as eager learners who consider the internationalization of their own courses and research efforts a challenging but rewarding task. Finally, although students may at first be reluctant to leave their comfort zone to gain international experience, once they do they can expect to grow intellectually, emotionally, socially, and perhaps spiritually. Some of them will find their life's calling precisely by seeing themselves in new and surprising situations, whereas others will see their career options enlarged in a world shaped by the forces of globalization.

How timely, then, that the *APA Guidelines 2.0's* (APA, 2013) third goal of "Ethical and social responsibility in a diverse world" can help guide individual faculty, students, and educational institutions to develop an international outlook and acquire the necessary skills to cross cultural borders. To make this broad goal more specific, we offer 14 suggestions that address three levels—undergraduate students, faculty, and institutions.

Undergraduate Students

1. Cross-national research. Because most undergraduate curricula mandate a research experience, why not a cross-national one? A student guide (Shvets, 2007) offered six reasons for students to collaborate in cross-national research and four low-cost ways to do so. For one example, without funding, a researcher completed an extensive field experiment on prosocial behavior, comparing 36 U.S. cities and 23 nations, by training student tourists who valued this chance to get research experience (Levine, 2003).

2. Study/work abroad. The numerous U.S. students studying abroad do so typically for one summer, semester, or full year, through one of the increasing number of study abroad programs (Soto, 2014). In addition, "work abroad" programs (such as teaching English) offer income along with cultural immersion (Murray, 2005). Such study abroad programs offer ideal opportunities to conduct cross-national research and to create personal contacts for future collaborative research projects.

3. Conferences. One simple yet valuable international experience is for undergraduates to attend one of the many global psychology or education conference each year, most of which offer a reduced fee for students. Moreover, many conferences now allow undergraduate and graduate students to present posters, thereby reinforcing the challenges and excitement to conduct and present cross-cultural research.

4. Organizations. Undergraduates can benefit from joining an international organization as student members (Takooshian & Stambaugh, 2007)—be this a large group (such as the International Association of Applied Psychology or the International Association of Cross-Cultural Psychology) or one of the 100 smaller specialty groups, such as forensic or school psychology (Bullock, 2012a).

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5. Funding. There are at least 50 major sources of funding for student and faculty international activities—such as Boren, Coro, and Open Society. In fact, one analysis found that "funding for international activities has risen sharply since the 1990s, now accounting for 15% of all foundation-grant dollars . . . as more U.S. foundations are 'going global,' up from 46% in 1994 to 63% in 2001" (Takooshian & Takooshian, 2012, p. 54). Students frequently report profound experiences after completing a Fulbright or similar program (Zoma et al., 2012).

6. Internships. Whether for credit or not, students can seek multicultural field placements as part of their undergraduate degree. Most cities have multicultural service centers that can offer a psychology placement, such as Los Angeles' Institute for Multicultural Education and Services. In New York City, the United Nations offers an increasing number of internships (Takooshian & Campano, 2008), participation in Model U.N. sessions, and other international experiences for undergraduates (Roberts, 2014). Many internships provide students with the opportunity to interact with children and/or adults of numerous immigrant backgrounds that can prepare them for subsequent international experiences.

Faculty

The revised version of the *APA Guidelines 2.0* (APA, 2016) seeks to infuse "sociocultural learning outcomes" across the major, rather than in a separate course to produce "global psychological literacy" (Cranney & Dunn, 2011). Individual faculty can do much to adapt their existing courses, develop new ones, experiment with new technologies in the classroom, and participate in cocurricular activities outside the classroom (Velayo, 2016).

7. Syllabi. Faculty may integrate into their current courses more research based on non-U.S. participants or by non-U.S. authors (Woolf, Hulsizer, & McCarthy, 2002). One volume offers a dozen practical chapters on how to integrate cross-cultural work into traditional courses such as developmental, social, personality, and health psychology, as well as 52 ways to internationalize the psychology curriculum (Leong, Pickren, Leach, & Marsella, 2012). An increasing number of cross-cultural textbooks are appearing for teachers of these courses (e.g., Gielen & Roopnarine, 2016). One offers "111 experiences for multicultural learning" inside the classroom (Pedersen, 2004).

8. Courses. Some faculty might develop a new course, using one of the many textbooks available for international (Eysenck, 2004) and cross-cultural psychology (Shiraev & Levy, 2012). The APA Society for Teaching of Psychology offers a variety of model syllabi in its Project Syllabus. Faculty can tap the IUPsyS resource center (cf. Stevens & Wedding, 2006), the nine volumes on international psychology (in Baker, 2012), or any of a dozen cross-cultural psychology periodicals, such as the *International Journal of Psychology* or the *Journal of Cross-Cultural Psychology* (Simonian, 2014).

9. Remote courses. In addition to MOOCs and other online and other distance-learning courses (Velayo, 2011), faculty may now use Skype, Polycom, or similar technologies to offer simultaneous cross-national courses (Chia & Poe, 2004).

10. Cocurricular activities. Over 1,300 U.S. undergraduate institutions have a chapter of Psi Chi or Psi Beta (for community colleges), which commonly offer cocurricular activities that complement classroom learning (McCormick et al., 2014). These include international activities such as lectures or workshops by international travelers, programs focused on global topics, and using Skype to hold shared sessions between American and overseas chapters of Psi Chi.

Departments and Institutions

11. Institutes for international and cross-cultural psychology. An institute focused on global psychology can broaden the curricular offerings of psychology programs, involve undergraduate students in international research and other internationally oriented activities, and broaden their horizons. An example of such a center at a predominantly undergraduate institution is the Institute for International and Cross-Cultural Psychology at St. Francis College, New York (www.iiccp.org).

12. International activities on campus. In order to promote international activities on campus, a school may foster creative collaborations among existing campus groups: the psychology department, offices for international students and study abroad (Roberts, 2014), and the Psi Beta or Psi Chi chapter (Russo & Takooshian, 2002). Such activities might include lecture series, interdisciplinary workshops for students, receptions, awards, faculty development workshops, or press releases highlighting global work.

13. Fulbrights and faculty abroad. Schools would do well to encourage and support faculty who consider applying for Fulbrights to do research or teach overseas. Since 1946, over 110,000 faculty have served as U.S. Fulbright Scholars overseas, often with life-changing experiences (Takooshian et al., 2011). In addition, over 183,000 international faculty members have served in the United States. There are a growing number of overseas programs besides Fulbright. Over 1 million "alumni" and "alumnae" have been funded by one of the dozens of other U.S. State Department programs—such as the Humphrey, Gilman, and UGRAD programs (Barton, 2013). Over 7,500 psychologists have directly benefitted from one of these programs (Takooshian, 2013).

14. Administrative support. Ask deans, directors, provosts, and other administrators to support programs and events that internationalize psychology education. When feasible, familiarize administrators can also familiarize themselves with resources to internationalize the school's curricula (IoC, in Leask, 2015), or Internationalize at Home (in Barker & Mak, 2013). Because educational institutions are frequently under pressure to internationalize their offerings, administrators may be willing to provide organizational, financial, and moral support for this effort.

Concluding Comments

Contemporary undergraduate psychology education in the United States is being powerfully affected by at least two forces: the sharp growth of psychology outside its borders and the emergence of new technologies in the classroom. Separate but parallel efforts are underway—*APA Guidelines 2.0* (APA, 2016) in the United States, and the EuroPsy "tuning process" in Europe—to encourage greater cultural diversity in undergraduate education, as psychologists around the world seek to develop educational practices that reflect a cross-national science of behavior. These efforts are supported by the sustained commitment of APA to further the goals of internationalization, and the dedicated efforts of faculty members and other psychologists both in the United States and abroad, to get their psychology undergraduates ready for the future.

What will this future look like, and how can we best prepare our students for it? *APA Guidelines 2.0* (APA, 2016) emphasizes that our undergraduates today are entering an ever more diverse and multicultural world. As noted by the past CEO of APA, Raymond Fowler (2000, p. 11), "new psychologists who do not have the benefit of a sophisticated orientation to international issues will be severely handicapped in their career options." Psychology undergraduates must develop *global psychological literacy*—to think in broad international terms, communicate across cultural borders, integrate multiple identities in themselves, and support others in their efforts to achieve goals that are in part culturally shaped. Our recommendations are intended to help psychology undergraduates and faculty to prepare for a "glocal" world—that is, a world that is simultaneously global and local in nature.

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Part B: International Psychologist IP 55.4 Edition

Dr. Ann Marie O'Roark, Editor

January 17,2016. St. Augustine, Florida USA. Themes in the IU55.4 move from innovative interdisciplinary client services to activities that highlight the value priorities of the International Council of Psychologists, Inc., and conclude with attention to the association's constitution, the articulation of its *raison d être*.

Providing Interdisciplinary Client Services: Using Assessment to Testify in Forensic Community Matters

Information from **Dr Tara Pir**, ICP, Inc. Past President, describes innovative approaches to education and counseling services offered at the Institute For Multicultural Counseling and Education Services, Inc. (IMCES). She and members of her multidisciplinary staff, **Marc Borkheim**, PhD, **George Gharibian**, PhD and **Ardalan Zamani,** Esq., presented papers on several of their studies during the 2015 annual conference. In *"Breaking the Cycle of Recidivism Among the Mentally Ill Population,"* Dr. Pir discusses the purpose of IMCES research work which is designed to stop recidivism among people with mental illness. IMCES is one of the first psychological firms to design services that actively include attorneys on multidisciplinary teams offering health, mental health, as well as social services to clients, and this time including legal advocacy.

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Dr. Ludwig Lowenstein, former ICP Inc. president [2011-13] and an independent practitioner in England, is a faithful contributor to the **IU**, a semi-journal section of the International Council of Psychologists, Inc., newsletter, **IP**. In *"Value of Psychological Testing in Forensic Cases Before the Courts,"* Lowenstein describes his special services to clients who face legal and courtroom challenges. He conducts psychological assessments of parties involved in legal actions for barristers and judges' decision making.

Highlighting ICP, Inc.'s Core Values: Wellbeing and Women's Challenges

Dr. Chok Hiew, ICP, Inc. President 2007-08**,** describes his rehabilitation work with the elderly and victims of natural disasters. He has promoted work merging eastern and western healing knowledge and application. Co-Author of books on qigong, the ancient Chinese healing method, he recently developed his own research backed methods and techniques. **Dr. Jennifer Boyce**, Toronto licensed psychologist, is in the early phase of a newly launched private practice providing well being and stress reduction services to individual clients. The section concludes with an excerpt from **Dr. Jan Yoder's** Denmark-Gunwald Award address. She was awarded ICP, Inc.'s feminist research and service award for her long term work as a feminist educator and researcher and raising visibility for issues related to social justice for women. She recently moved from the University of Akron to Kent State University.

Advancing Psychology: Comparison of Applied Services in two countries; Applying Innovative Methods

Two articles by ICP, Inc. members, both participants in an research interest group headed by Dr. Frances Culbertson that made cross cultural comparisons of stressors of professional women, present articles on "consulting psychology" as an important competency for all psychologists and as a rapidly expanding area of service.

Continued next page

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Dr. A. M. O'Roark traces the shifting focus and priorities of consulting and consultation during 100 years of efforts by the American Psychological Association to establish "who can call themselves a consulting psychologist?"

Dr. Machiko Fukuhara, President Elect of ICP, Inc., and chair of the 2016 annual conference, provides a cross cultural counterpoint review of the evolution and status of "consulting to organizations" in Japan. Only recently have psychologists been involved in organizational consulting, previously included by financial and business specialists. Consulting is an interdisciplinary activity slowly gaining in visibility. polarizing cultural views cloud current purpose and functionings as a 501c3 incorporation and unified, collaborative group. A committee was appointed during the Toronto 2015 Board meetings to work on collating and refining the scattered and usually ignored agreements included in the Board Rules [administrative procedures and policies. The scientific methodology of approaching the current disarray and centrifugal-centralpedal currents in the group would be to collect all recent minutes where Board adjustments to Rules are recorded and results of membership votes on any changes in the Bylaws by the Board secretary. The Secretary's reports are published in the newsletter. The 2015-16 Bylaws and Rules Committee includes: Dr. Robert Silverberg, chair; and three members – Dr. Florence Denmark, Dr. Tara Pir and Dr. Ann Marie O'Roark. Dr. Pir presented the technical version of bylaws adjustments to the Board in Toronto. Her material is presented here. Dr. Silverberg is preparing a review and message that will include beginning the refinement of bylaws by reviewing philosophical foundations behind governance documents.

A Poem; A Fictional Interview; A Letter from the Past

One colleague said that 2016 feels like a "spooky" year. Perhaps with the reality horror film, *The Revenant*, winning so many Hollywood awards in the cinema arena, the spooky part of 2016 is out of the way and less brutal flights of fantasy and recollections can fill the rest of the new year with more optimism, humor and fresh ideas for meaningful engagement with environments and revengeful social entities. This group of writings illustrates creative flairs of ICP members.

Dr. Ani Kalayjian, former ICP, Inc. Treasurer**,** shares a poem from her ever hopeful and caring heart. **Dr. David Y.F. Ho,** President of ICP, Inc. 1989, writes a dialogue between his two "selves": David and Y.F. He recalls intercultural exchanges during some of his many travels around the globe. The varied incidents of misunderstandings might be a little hard to follow at times [they are taken from a larger work of fiction Dr. Ho published recently] but his genuineness is unmistakable. His effort to poke fun at himself illustrates mid-depth cultural faux pas. **Dr. Bruce Bain's** letter is a relic from the time he was ICP Inc. president, 1998, some ten years after Dr. Ho's term. Dr. Bain writes about his travels during his presidency and, ever the educator, gives us a glimpse into the work and "world" of ICP colleagues in far flung places.

Looking Forward

This section calls attention to ICP, Inc. Bylaws, the association constitution. It is the governance document that serves as the glue that prevents the ICP melting pot membership constituency from flying apart. Unfortunately, polarizing cultural views cloud current purpose and function as a 501c3 incorporation and unified, collaborative group. A committee was appointed during the Toronto 2015 Board meetings to work on collating and refining the scattered and usually ignored agreements included in the Board Rules [administrative procedures and policies]. The scientific methodology of approaching the current disarray and centrifugal-centripetal currents in the group would be to collect all recent minutes where Board adjustments to Rules are recorded and results of membership votes on any changes in the Bylaws by the Board secretary. The Secretary's reports are published in the newsletter.

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The issue closes with updates about the 2016 ICP, Inc. annual conference and board meetings in Yokohama, Japan, next July.

Appreciations / Citations

With appreciation, we list here the articles included in INTERNATIONAL UNDERSTANDING for 2014 and 2015. Manuscripts are sent to the Editor in APA publication format. A Review Panel considers the submissions in light of the stated mission and purpose of the association and the values endorsed in policies.

Deadline Schedule times for IP 56. Part A and B are:

Continued next page

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IP56.1 Part A: **February 10, 2016**

IP56.2 Part A: **May 10, 2016**

IP56.2 Part B. International Understanding: **5/20/16**

IP56.3 Part A: **August 30, 2016**

IP56.4 Part A: **November 30, 2016**

IP56.4 Part B. International Understanding: **12/10/16**

With Warm Regards and Wishes for a year of Health, Happiness and Harmony,

Ann Marie O'Roark, PhD, ABAP
IP Editor

Providing Interdisciplinary Client Services

Breaking the Cycle of Recidivism Among the Mentally Ill Population

By Tara Pir, PhD

The focus of this article is the interconnectedness of public policy and psychology with the aim of developing a bridge of connectedness rather than isolation, helping to return individuals with mental illness from the criminal justice system back into mental health care. The special problem of recidivism among those with mental illness is well documented and studied. However, the proposed strategies and interventions to address this serious problem have focused on the period of time following imprisonment.

In order to address the special needs of this vulnerable and especially challenged population, I developed a comprehensive approach to stopping recidivism that includes the following components: (i) prevention and early intervention; (ii) multidisciplinary care teams including attorneys; and (iii) culturally and linguistically appropriate service provision, practicing the principle of inclusion.

History

In the decades since the Reagan administration closed community mental health clinics and the national mentally ill inmate population soared, the prevailing school of thought among mental health advocates was that medicating offenders upon their release from prison and connecting them with psychiatric services would ensure that they would never come into contact with the justice system again. (How To Break The Cycle Of Imprisonment For Mentally Ill American, Sam P.K. Collins, 2015.)

However, with recidivism rates among the mentally ill reaching more than 50 percent, some health experts are seeking another approach. They want to change the manner in which parole officers, judges, employers, and mental health care professionals help mentally ill ex-offenders reintegrate into their communities. (Collins, 2015.)

To get a sense of the extent of the problem of the incarceration of the mentally ill, consider that by the mid-1970s, studies in some states suggested that about 5% of jail inmates were seriously mentally ill. A study of five California county jails reported that 6.7% of the inmates were psychotic. A study of the Denver County Jail reported that 5% of prisoners had a "functional psychosis." Such figures contrast dramatically with studies from the 1930s that reported less than 2% of jail inmates as being seriously mentally ill. In 1973 the jail in Santa Clara County, which included San Jose, "created a special ward . . . to house just the individuals who have such a mental condition"; (Dr. E. Fuller Torrey, "Ronald Reagan's shameful legacy: Violence, the homeless, mental illness" Salon, 2013.)

Not only is there a tremendous human toll involved when mentally ill individuals are incarcerated rather than receive mental healthcare; but, from a public policy perspective, the state unwittingly ends up investing in recidivism rather than recovery. The price tag for housing, feeding and caring for a prisoner in California has climbed to almost $64,000 annually, up from $49,000 five years ago. Per prisoner, the state spends more than three times the amount it did 20 years ago when the population was a similar size. (Reuters US, Wed Jan 6, 2016, "California prison reforms have reduced inmate numbers, not costs" Robin Respaut.)

A well-known approach to addressing recidivism

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among this community is the establishment of Mental Health Courts. Mental health courts divert offenders with mental illness away from incarceration in return for their participation in monitored mental health treatment. Since their inception in the late 1990s, the proliferation of these problem-solving courts has outpaced the research on their effectiveness. (PsycINFO Database Record (c) 2015 APA.)

At the present time, mental health courts still represent an emerging practice, but have not yet reached the level of an evidence-based model. Existing studies of mental health courts suffer from methodological limitations, specifically, a lack of experimental design, use of non-representative samples, and assessment over short timeframes. Moreover, the inherently idiosyncratic nature of these courts and the variance in reporting of court-specific eligibility criteria make cross-article comparison more difficult. (PsycINFO Database Record (c) 2015 APA.)

Over the past decade, Mental Health Courts have spread rapidly across the United States. Research suggests that Mental Health Courts can be effective in reducing recidivism, but also demonstrates that their effectiveness varies as a function of characteristics of the participants (e.g., criminal history) and the program (e.g., coercion). Less is known regarding the extent to which process-related factors (e.g., length of participation, time between referral and receipt of services) impact effectiveness.

Overall, results provide some evidence supporting the effectiveness of Mental Health Courts. Participants had significantly fewer jail days, but not charges or convictions, relative to participants who were receiving treatment as usual (TAU). Among Mental Health Court participants, graduation from the Mental Health Court, presence of co-occurring substance use, and longer length of Mental Health Court participation were associated with greater reductions in jail days. Other process factors were unrelated to reductions in recidivism. Findings suggest that Mental Health Courts may be particularly effective for high-risk participants and that time spent in a Mental Health Court has positive effects on recidivism, regardless of graduation status. (PsycINFO Database Record (c) 2015 APA.)

Evidence-based practices (EBP) with track records of effectiveness in treating serious mental illness, co-occurring substance abuse, trauma, and motivational challenges have been utilized with some success in forensic populations (CMHS National GAINS Center, n.d.). However, recent reviews of offender-focused and jail diversion programs found that many EBPs, such as Assertive Community Treatment, may achieve symptom reduction but not decrease criminal recidivism. (Morrissey, 2007; Case, 2009; Skeem, 2009.) In fact, studies indicate that offenders with mental illness share diagnoses and treatment needs similar to those of individuals with mental illness who do not commit crimes. However, with reference to recurrent criminal behavior, offenders with mental illness share the same risk factors for offending as their non-mentally ill counterparts. (Reducing Criminal Recidivism for Justice-Involved Persons with Mental Illness**,** Rotter, Carr, 2013.)

Although connecting individuals with mental illness to appropriate and effective community care is clearly good in and of itself, the failure of traditional case management and clinical services to fully address criminal justice recidivism in the mentally ill offender population challenges providers to adopt and adapt best practices that may be ultimately more effective in decriminalizing persons with mental illness. These practices include Risk-Need-Responsivity (RNR)-based recidivism-focused assessment and clinically sensitive, mandated community case management, such as probation officers with specialized caseloads and mental health courts; criminal-thinking and behavior-focused structured clinical interventions; and an awareness of how to maximize the likelihood that an offender will take advantage of these interventions. Integrating these approaches with existing assessments and interventions for individuals with mental illness is also necessary and is beginning to receive attention in research, clinical, and policy forums. (Osher, 2012.)

The Need For Early Intervention

By incarcerating a mentally ill individual rather than providing them with appropriate mental health care, they are not able to learn new skills and behavior toward joining the workforce. Rather, the opposite takes place, with the individual acquiring the skills and behavior of a criminal, setting them further on the road to recidivism. The critical importance of timing and, specifically, the value of a program that precedes and precludes incarceration is demonstrated in a special Mental Health Diversion program begun in 2007 in the District of Columbia Superior Court.

One study tracked mentally ill defendants in the pro

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gram and compared their re-arrest record with mentally ill defendants who were not part of the program, which involves greater court supervision and the incentive of having criminal charges dismissed. (Tillman, 2013.) Mentally ill criminal defendants who completed the program were less likely to reoffend, compared with mentally ill defendants who went through traditional criminal proceedings, according to a recent study. (Zoe Tillman, 2013. blog of legal times, an ALM Publication.)

Following arrest, defendants on pretrial release are placed under the supervision of the Pretrial Services Agency, which tries to connect mentally ill defendants with treatment and other support. Since both groups in the study—those in the diversion program and those not—were getting the same access to mental health services through the agency, the study's authors said they were bet ter able to identify the effects of being in the diversion program. (Tillman, 2013)

The District has made some advancements in deterring mentally ill ex-offenders from prison. A 2013 study of the city's mental health courts found that those proceedings positively affected the life outcomes of defendants by dropping their charges and connecting them with mental health services. For mentally ill inmates entering the system for the first time, the D.C. Department of Corrections provides mental health screenings during the intake process and secures individual counseling and prescription medication if needed.

However, Tammy Seltzer, director of the University Legal Services D.C. Jail and Prison Advocacy Project, said that those services will not suffice for mentally ill offenders and ex-offenders who need more than medication to lead a normal life.

"Based on research, medication is the least likely indicator of whether someone will commit an offense. We know that people with a serious mental illness are more likely to have their probation revoked for minor, technical infractions. It shows that we are more afraid of what's going to happen if they don't show up their appointment. We're driven by fear and that continues the cycle." (Seltzer)

Although diversion programs such as this one in D.C. have resulted in some limited success, this model does not take into consideration the additional complication that cultural and linguistic differences introduce, which can compromise an individual's ability to understand the circumstances they are in and the ability to be heard. As Heathcote Wales, a professor at Georgetown University Law Center and one of the study's lead authors observed, "these folks have just not been treated like responsible human beings or people who are worth listening to."

Community clinics have unique advantages in their ability to address the challenge of recidivism among individuals with mental illness. In contrast with other responses to the problem of recidivism among persons with mental illness, the approach I propose incorporates a multidisciplinary approach, focuses on prevention and early intervention, and takes linguistic and cultural characteristics into consideration. Also, as part of the training that I provide on an ongoing basis to staff, interns, and clinicians at IMCES, we practice the principle of inclusion.

In addition to their clinical presenting problems, many of our clients already face cultural and linguistic challenges as well as a lack of knowledge of the legal system. The addition of legal challenges, which includes dealing with the judicial system, compounds their difficulties. Often invisible and overlooked during initial assessment, are the feelings of rage associated with being considered "undesirable" or "defective" as a person with mental health challenges in the eyes of the judicial system.

Research indicates that legal aid/advocacy services included as an integral part of a multidisciplinary intervention plan are virtually nonexistent. At IMCES, we conducted a study examining the improvements of overall client psychological health recovery goals during the course of mental health treatment, when legal aid is included. The study measured the comparative mental health improvement of these two groups. The result demonstrated our desired outcome of reaching recovery goals by the group that used the multidisciplinary care plan. We practically helped our clients break through the vicious cycle of recidivism.

Using Assessment to Testify in Forensic Community Matters

Value of Psychological Testing in Forensic Cases Before the Courts

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Abstract

This article considers the role of expert witnesses be they psychiatrists, psychologists and others in carrying out forensic reports for the courts. The courts require certain ethical and objective criteria being presented. This includes psychological testing of alleged criminal offenders and those suffering from neuropsychological injuries due to accidents. Personal injury is an area where there is often a considerable degree of malingering for obvious reasons, i.e. compensation payments etc. The role of the expert witness using such tests and measurements as well as interviews with adults and children are considered as is the potential for malingering using any psychological test that exists. Much more research is required to make certain that assessments carried out are indeed objective, accurate and valid.

Psychologists, more than anyone, rely heavily on objective and projective personality testing as well as the interview. It is an area in which psychologists, especially clinical and forensic psychologists, as well as educational psychologists, are trained. This work adds substance to what is provided in the court where frequently it is objective evidence which is required for the benefit of the court rather than opinions based on interviews or other matters. In what follows we will consider psychological assessments first followed by the role of the expert witness in carrying out forensic assessments and reports for the court. This will be followed by work that psychologists do regarding alleged criminality, neuropsychology, and personal injury cases. The information discussed will be based on recent research carried out worldwide.

Some specific areas will be covered including malingering, ADHD (attention deficit and hyperactive disorder) and work with children. We will begin with basic principles involved in the use of psychological testing in cases before the courts.

Basic principles

Buchanan (2013) reviews expert evidence providing psychological and psychiatric evidence in the court. He considers it a necessary requirement to act in the best interest of the person being assessed. This ultimately outweighs any duty of confidentiality to the instructing party. As pointed out by McAuliff (2009) judges depend on expert evidence from psychologists and others for the purpose of making the most appropriate decisions. Following such reports being provided to the court both psychologists and psychiatrists are sometimes asked to testify. According to Sadoff (2011) "*the proper role of the expert is to describe the relevant abilities, disabilities, symptoms and diagnostic conditions in clinical and behavioural terms, leaving to the court to weigh these observations in the context of legal concept and standards*".

Psychological testing in the reports that follow for the court

Much as possible empirical evidence needs to be provided by psychologists carrying out testing and providing psychological testimony in the court (Woody, 2013). The expert witness who will be discussed later, seeks to provide clinical and statistical predictions of future behaviour for the court. Some psychologists, more than others, follow the system of Achenbach & Rescorla (2013) of providing empirically based assessments (ASEBA). Actual scores are displayed in these reports relating to age, gender and other criteria.

A large number of tests are used but some of the more common ones are the MMPI-2 in criminal cases (Barber-Rioja et al., 2009). Of particular importance in criminal offence assessment is elevation of scores in criminal defendants in certain area such as the FC scale. The relationship between the Psychopathy Checklist-Revised and the MMPI-2 was considered by Hansen et al (2013). The goal of this study was to note the relationship between Hare's four-facet model of psychopathy and the Minnesota Psychopathic Inventory-2 (MMPI-2) in a forensic sample. This consisted of 22 male prisoners from Bergen prison.

The MMPI-2 and the MMPI-2 Restructured Form was also used by Hoelzle et al. (2012) relying somewhat heavily on the validity scale in these tests. The MMPI-2 and the MMPI-2-RF validity scales appeared to be particularly well suited to assess symptom validity and the psychological status in secondary gain settings. It was noted by Sellbom et al. (2010) that the MMPI-2 was also used to detect feigned psychopathology. In the MMPI they used a structured interview of reported symptoms (SIRS). It was sought to establish whether malingering or non-

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(2012). Over-reporting litigants were compared with under -reporting.

Fluttert et al. (2013) sought to assess whether forensic early warning signs of aggression could be noted by using the Forensic Early Warning Signs of Aggression Inventory (FESAI) which could them lead to early detection plans to deal with this (EDP). Such early warning signs could prevent damage and harm being done to other individuals with whom such persons interacted. Some of the traits noted that provided information concerning early warning were those who were prone to anger, social withdrawal and those who had superficial contact and showed signs of non-aggressive antisocial behaviour.

The Rorschach test was used to good effect by Erard (2012) to provide expert testimony in the assessment of a psychological injury due to an accident. According to this research the Rorschach Performance Assessment System (R-PAS) offers an alternative to self-report methods which adds to the validity of the assessment. It also provides a useful check against exaggerated or minimised symptom presentation. It generates evidence concerning implicit traits and behavioural tendencies, and offers techniques for adjusting for abnormal response sets. Despite the criticism of others of the Rorschach test it is used in many cases as support rather than providing a single assessment based on its own findings alone.

Khadivi & Evans (2012) had a similar view as to the value of using Rorschach performance assessments. Khadivi and Evans concluded by commenting on the advantages of incorporating the use of the Rorschach test to verify self-report methods.

Another approach is the use of the Clinical and Risk Management (HCR-20) to assess violence risks. According to Jung et al (2013) researched into use of this method in order to conclude on the possibility of future violence of offenders. They sought to investigate the validity of the HCR-20 method in order to provide the necessary risk management for individuals with tendencies towards violence. The validity of the HCR-20 was also used by Vojt et al. (2013). Again to predict that likelihood of violence occurring among 109 male mentally disordered offenders in a high security forensic hospital. Their result indicated that the HCR-20 did not predict future violence regardless of setting i.e. in the community or as an in-patient. Data on violent incidents including reconviction were collected from a variety of sources. However, systematic tailoring of care and treatment plans were found to result in the reduction of violent incidents. They considered that further research was required to better understand this practice leading to violent behaviour.

Gowensmith et al. (2013) asked how reliable forensic evaluations were of legal sanity. It appears that when different clinicians evaluate the same criminal defendant's legal sanity they do not always agree. This Hawaiian study points out that its laws require multiple, independent evaluations when there is a question of "legal sanity". They examined 483 evaluation reports by psychiatrists and psychologists addressing the defendant's legal sanity in 165 criminal defendants. The reports did not however, always reach a unanimous agreement. There was however, a unanimous agreement regarding the legal sanity in only 55.1% of cases. Evaluators tended to disagree about a defendant's sanity when drugs and alcohol were involved in the offence committed. They did however, agree on the diagnosing of psychotic disorders and judges followed the majority opinion among the evaluators in 91% of cases. When judges disagreed with the outcome of the evaluations they tended to find defendants 'sane' rather than 'insane'. The authors point out that their study showed that reliability among practicing forensic evaluators into "legal sanity" was not as exact, and did not agree, as often as might be the case. The authors also recommended better and deeper training practices as being necessary to overcome these differences in the evaluation.

A structured interview of reporting symptoms, and its accuracy, was considered by Green et al. (2013). He investigated the use of the Structured Interview Reported Symptoms (SIRS). The SIRS-2 yielded an impressive specificity rate (94.3%) which was beyond the original SIRS score method of 92%.

Lander & Heilbrun (2009) considers the expanding practice of forensic mental health assessment (FMHA). He recommends the need for more detailed guidelines into use of such assessments. Five individuals are considered being helpful to indicate whether such reports are of value. These include a Judge, a Law Professor, a practicing Attorney, a Psychiatrist, and a Psychologist. There appeared to be limited consistency of these individuals with FMHA principles. There were however, significant correlations between a number of FMHA principles and a rating of report relevance and helpfulness to the court.

The value of the forensic mental health assessment was also considered by McLaughlin & Kan (2014). They studied the use of assessment tools regarding the competence of individuals to stand trial based on their mental state and the time of the alleged offence. They considered 4 instrument types used. These were the multi-scale inventories, forensic assessment and instruments used, cognitive neural psychological instruments and projective tech-

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niques. They found that projective techniques were used by investigators.

A number of investigators including Zapf & Pirelli (2012) emphasised the importance of using multiple pieces of relevant data and for these to support one another. The use of such assessments with juveniles will be discussed in another section.

The evaluation specifically of individuals accused of criminal activities

The relationship between the Psychopathy Checklist-Revised and the MMPI-2 was carried out by Hansen et al. (2013). The goal was to investigate the relationship between Hare's Four Faceted Model of Psychopathy and the MMPI-2. They studied 22 male prisoners. Facet 4 of the PCL-R was the only facet that correlated statistically significantly with the scores on the psychopathy deviate scale of the MMPI-2. It has been well established that there is a relationship between psychopathy and serious criminality which includes violence. Psychologists and psychiatrists need to establish that psychopathy exists with some degree of certainty as it is a form of mental disorder (Hart & Storey, 2013). Among the assessment procedures used are diagnostic interviews, self-report questionnaires, and inventories.

Lander & Heilbrun (2009) carried out forensic mental health assessments (FMA). Their study examined the content of adult's criminal FMHA reports. As mentioned earlier they used a Judge, a law professor, a practicing lawyer, a psychiatrist and a psychologist to establish the validity of FMHA approaches. It is also vital to establish whether the alleged perpetrator of a crime is capable of standing trial or may suffer from insanity, as well as the predicted future dangerousness (Miller, 2013).

A study by Viljoen et al. (2010) surveyed 199 forensic clinicians about the practice of assessing 'violent risk' in juvenile and adult offenders. The importance of measuring the individual for psychopathy could not be underestimated. 79% of the clinicians reported using psychopathy measures in order to carry out risk assessments. Clinicians did not feel that juveniles should not be labeled psychopaths due to their ages.

It was noted by Weiss et al. (2011 that many of those evaluated suffered from intellectual disabilities. This being initially established through structured interviews and later through psychological testing using intelligence tests. Many of these individuals had co-morbid psychiatric diagnoses making it difficult to establish whether their intelligence was an important factor or the psychiatric illness.

Neuropsychology and the assessment of personal injuries

Psychologists and psychiatrists are frequently involved in cases dealing with the need for neuropsychological assessments. Uncredible performances have to be carefully assessed as there may be an element of malingering involved and this then needs to be carefully scrutinised (this will be discussed later). Neuropsychological assessment is particularly important when there is evidence that the individual suffers from mild traumatic brain injury (Boone, 2013). The objective is to ascertain whether cognitive impairment has occurred as a result of an accident. Kamper & Axelrod (2014) considers it important to detect cognitive impairment and its degree in quality.

Expert witnesses trained in the use of neuropsychological tests are frequently requested to ascertain the causes and prognosis of brain injuries (Larrabee, 2012). Their expertise is essential in helping the court make decisions concerning the future of such individuals and the impact of brain dysfunction. It is important also to assess the possible contributing factors of malingering. Frequently, experts are asked to assess traumatic injury and perinatal injury. With an aging population, elderly individuals frequently need to be assessed for dementia.

Psychometric testing must be carried out to establish the validity and reliability of disorders of higher cortical functions. This must be done both in adults and in children and the elderly (Reynolds & Horton, 2012). Pediatric neuropsychology is particularly concerned with children and adolescents. Emphasis has been given to the importance of these reports referring to neuropsychological testing being clear and understandable for the general public, including juries, lawyers and judges so that appropriate judicial decision can be made. In the addition to the use of psychological tests experts frequently use structured interviews of reported symptoms (SIRS). Great care must be taken to be aware of a feigned cognitive impairment (FCI) when compared with genuine presentations (GEN-C). There is a special need to identify cognitive disorders due to dementia, amnestic disorders, or specific cognitive disorders due to traumatic brain injuries.(Rogers et al.,2009).

Sometimes it is necessary to consider who should be held responsible for tort actions, and to define negligence torts (Foote & Lareau, 2013). These investigators consider it vital to seek information from records, plaintiff interviews, collateral interviews, and psychological testing.

Boone (2013) considering the clinical practice of forensic neuropsychology emphasises the importance of obtaining adequate evidence paying special attention to assessing when the individual does not perform credibly,

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possibly due to malingering. Personality testing is of special importance in such cases, especially testing for malingering which will be discussed later. Malingering frequently occurs in some mild traumatic brain injury cases. Again, there should be an emphasis on the avoidance of 'jargon' and the end reports must be clear to the ordinary person or interpreting what has been provided in the court (Demakis, 2009). Mention has already been made earlier of the use of the Rorschach Performance Assessment System (R-PAS) by Erard (2012).

The use of legally protected test materials must be emphasised and has been studied by Kaufman (2012). It was noted that solicitors frequently seek consultation from a neuropsychological expert, using both objective testing such as the MMPI-2 with a symptom validity scale (SBS), and projective techniques. It was pointed out that courts painstakingly avoid philosophical debates to focus on justifiable issues in cases that have been appropriately assessed by competent expert witnesses be they psychologists or psychiatrists. Legal claims can only be settled effectively when there is expert opinion based on objective and projective testing in relation to traumatic brain injuries (Kaufman, 2013).

Neuropsychologists practice in both civil and criminal courts. Some experts concentrate only on civil cases (Duke et al. (2012). These experts normally receive graduate and post doctoral training in neuropsychology. Personal injuries occur and the disability which can result needs to be carefully identified and measured using well validated psychological objective and projective testing (Rogers et al. 2009). Frequently there are other aspects that need to be assessed including post-traumatic stress disorders, and cognitive disorders.

Principles and practice of the independent forensic expert witness

Greenfield (2014) considers that many experts working with the courts in forensic cases achieve their goal of bridging the gap between clinical thinking and legal thinking. This results in an inability of the legal audience within the courts understanding many of the clinical and forensic psychologist's basis for their views. It is vital that expert witnesses are capable of explaining the evidence for their views and writing their clinical forensic reports for the courts (Karson & Nadkarni, 2013).

Mental health professionals appear to have three different sorts of information. There is the clinical interview, collateral information which provides useful background information, and the third area is psychological testing. It is the improper use of psychological testing that sometimes causes problems in the courts (Lareau & Ahern, 2012). McAuliff (2009) considers that psychologists attempt to testify in the court and base their evidence on clinical assessments and social framework evidence. Judges frequently fail to understand what is provided by experts and consider certain evidence inadmissible in the court. There appears to be some differences between clinical versus actuarial predictions in the assessment of individuals especially in regard to risk of violence and other serious offences occurring again. These are the contemporary issues that cause difficulties for the court when assessing the validity of forensic psychological reports (Ogloff & Douglas, 2013).

Recupero (2008) notes that forensic experts need to understand how clinical practice guidelines function in the court room, and the role they play. Courts are therefore much more cautious and show a high level of scrutiny when reports are presented by experts in the court. Scientific evidence is not always considered reliable or relevant in some of the cases being presented by experts. Of particular concern are reports by psychologists and psychiatrists based on opinions rather than objective expert evidence. There appears to be a difference between forensic reports and ordinary clinical reports. Sometimes there is a conflict of interest when experts present cases in court. This has the potential of encouraging what Reid (2011) considers misguided and even unethical behaviour, when in fact such experts should provide reports that are both honest and objective.

A study by Taylor et al. (2012) of 27 member states of the European Union (EU) shows legal differences between experts of these countries. Forensic psychiatrists were studied from Austria, Belgium, Denmark, Germany, Hungary, the Netherlands, Switzerland and the UK. The result of this study appears to indicate that a treating clinician can never be totally independent as an expert in carrying out both roles of the assessment and treatment of individuals. Taylor et al. (2012) emphasises the necessity of experts showing clarity and therefore being ethical in the manner in which they deal with the various roles vis a vis the forensic courts.

Specific areas of expertise in which expert witnesses function

There are a number of areas in which expert witnesses function including when assessing malingering, dealing with children and assessing such diagnostic categories as Attention Deficit and Hyperactive Disorder (ADHD).

Reference has already been made to the possibility or the potential for malingering especially in cases of neuropsychological accidents and also in cases of criminality.

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Barber-Rioja et al. (2009) recognised this point when using the Minnesota Multiphasic Personality Inventory (MMPI-2) in the case of criminal offenders. Rogers et al. (2010) also noted the tendency towards malingering possibly interacting with confusion or insight into symptoms of a particular problem. Rogers et al. (2010) used a Structured Interview of Reported Symptoms (SIRS) and concluded that malingering is a possibility even with repeat administration. Frequently, individuals feigned psychopathology both in the use of MMPI-2-RF and other testing carried out (Selbourne et al., 2010). The author of this article recommends in such cases that specific tests be used to assess malingering rather than relying on the MMPI-2 and other tests such as Structured Interviews. Some of the useful tests to be considered are the Wildman Symptom Checklist and other specific tests geared to identifying malingering.

In the case of the assessment of children, clinical interviews are frequently used asking the child to draw figures doing something to reveal emotional experiences they may have had (Macleod et al., 2013). Alleged juvenile offenders were assessed by Spice et al. (2010) using the Risk Sophistication Treatment Inventory (RSTI) and the Structured Assessment of Violence Risk in Youth (SAVRY). 74 adolescents being considered for transfer to less secure units were assessed. Scores on the RSTI, Criminal Sophistication and Treatment Amenability Scales, were considered appropriate for sentencing decisions.

The author of this article prefers the use of the Eysenck Personality Inventory for Juniors since it has good norms by ages and sex. It also has a 'Lie score' which can be effective in identifying the possibility of malingering or the desire to deceive the result. ADHD is frequently associated with pathological behaviour in children. Kingston et al (2013) noted that assessment of ADHD frequently revealed dysfunctional anger, and impulsive aggression. The assessment result was based on self-report and observation reports of others in schools and elsewhere. Such assessments have been primarily used with adults but could possibly also be used with children and adolescents.

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##

Highlighting ICP Inc.'s Core Values: Wellbeing and Women's Challenges

Qi Gong Training in Self Care

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Qi Gong is a complementary form of Eastern medicine that has been practiced since ancient times to promote healthy aging and emotional wellbeing as well as to overcome adversities such as pain and disease (Hiew, 1998; 2006a). Researchers have long documented that Qi Gong training regulates the heart beat or rhythm, normalizes blood pressure and pulse rate as well as the enhancement of the immune system and vital organs functioning. The practice utilizes a set of meditative therapeutic exercises to enhance protective resilience and self-regulation of one's emotional and physical states. Qigong as a form of meridian therapy enables practitioners, through the letting-go action, to release and eliminate trapped stressful energy stemming from accumulated cognitive-emotional and biological stressors. They are the source of a disruption of the body's normal healthy functioning and of one's emotional equilibrium. The body's inherent self-repair response is activated to restore resilient life and blood flow and rebound back to health (Hiew, 2005a; 2006b).

Over the past decade, I have offered brief evidence based Qi Gong training that has been effective for people suffering from a wide range of problems such as emotional trauma and PTSD, refugees in war torn countries, child sexual exploitation and natural disasters such as earthquakes and tsunamis (Hiew, 2001; 2002; 2005b). Qi Gong has proven to be a very cost effective intervention for medically difficult to treat diseases such as fibromyalgia. Clinical trials have shown that after nine hours of Qigong training (by the author), together with daily Qi Gong self-practice over four weeks, fibromyalgia (characterized by chronic pain, fatigue, insomnia and depression) produced changes and benefits beyond standard medication (Lynch, et. al., 2012). In a subsequent case report, those who continued their daily practice over a 1-year period had their chronic condition completely resolved (Sawynok & Hiew, 2012).

More recently I have designed a tested system of meditative Qi Gong exercises or WHQ (www.wisdomheartqigong.com) for those interested in self-care. It is especially matched to populations like the elderly or those with body pain and/or limited physical ability or in poor health. A controlled study using an Indonesian sample of elderly in nursing homes found clear evidence of balanced standing, improved ability in walking, muscle strength (hand grip), positive mood, relaxation and wellbeing (Hiew 2015).

Participants can readily learn the prescribed user-friendly gentle movements, physical breathing, and detachment from negative thoughts processes. The exercises can be done standing for short periods of time and/or sitting comfortably. For the exercises to be effective, it is essential to train the person's to be skillful in shifting out of the normal ongoing mental state by sensing one's physical body and to feel and spread the radiant heart energy flowing to every part of the head, torso and limbs. In a demonstration of WHQ exercises at the 2015 Toronto ICP conference, participants after a 20 minute practice, have expressed experiencing a sense of serenity, relaxation, and evident physical and emotional wellbeing.

Training workshops normally have a duration of 12 hours over two days. After each practice session of 30-60 minutes most participants can readily feel physical changes such as elevated electromagnetic flow, warmth and tingling especially in the hands (from increased blood flow), heightened relaxation and deepened respiration. There is often a rapid relief of pain, fatigue and sleeplessness overnight and persistent practice over a few weeks. The practitioner experiences the healing process from the enhanced qi and blood flow that leads to a harmonious and coherent state of wholeness.

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MINDFULNESS FOR PSYCHOLOGISTS: HEALING YOURSELF FIRST

Jennifer Boyce, PhD., C. Psych.
CANADA

Presentation notes from the ICP, Inc. annual convention, August 1 -3, 2015, Toronto, Canada

PSYCHOLOGISTS & STRESS

- To what extent do you consider that you have been under stress as a result of your job?
- 75% of psychologists said that they were moderately or very stressed
- In a survey of 155 psychologists, 1/3 experienced anxiety or depression & 40% reported episodes of exhaustion in the previous year (Cushway & Tyler, 1994)
- One out of 8 psychologists was worried about their alcohol consumption (Mahoney, 1997)

SOURCES OF STRESS FOR PSYCHOLOGISTS

- Workload
- Client related difficulties
- Organization structure or processes
- Relationships/Conflicts with other Professionals
- Lack of resources
- Professional self-doubt (Delardo, 2008)

PSYCHOLOGISTS' STRESS & WORK SETTING

- Practicing psychologists report more stress than research psychologists but also more positive influence from work
- Solo practitioners reported less support than either group practice or agency responders
- Psychologists in private practice were significantly less stressed and more satisfied than those working in either institutional settings
- Across all work settings men worked more hours, spent more time in therapy, and reported more negative client behaviours (Wise, Hersh, & Gibson, 2012 or cited in Wise, E., Hersh, M., & Gibson, C. 2012)

PSYCHOLOGISTS & PERFECTIONISM

- Psychotherapists reporting burnout reported beliefs such as '*I must be totally competent, knowledgeable and able to help everyone.'*
- Psychologists with higher levels of perfectionism reported higher stress & higher levels of burnout
- Only adaptive perfectionism (e.g. setting high standards) correlated with burnout (cited in D'Souza, Egan & Rees, 2011)

PSYCHOLOGISTS' SELF-CARE STRATEGIES

- Talking to other psychologists
- Exercise
- Talking to partner (Cushway & Tyler, 1994)
- Personal therapy
- Reducing caseload (Hirsch, 2009)
- Adjusting work-life balance (Coster & Schwevel, 1997)

A survey of 500 psychologists nationwide revealed 6 key strategies to maintaining a positive attitude and functioning well at work

- Self-awareness/Self-monitoring
- Sense of humor
- Maintain profession identity/values
- Maintain balance between personal and professional lives
- Spend time with spouse or partner
- Engage in hobbies (Ruper, P. & Kent, J., 2007)

PSYCHOLOGISTS—MEDITATION & YOGA

- Half of psychologists reported practicing meditation or prayer (Mahoney, 1997)
- A qualitative study interviewed 12 licensed psychologists with a yoga practice a minimum of 30 minutes/ week for at least 6 months (Hirsch, 2009)

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- Subjects reported that yoga (as distinct from exercise), increased awareness, decreased reactivity, & enhanced ability to be empathetic & present with clients.

PSYCHOLOGISTS & MINDFULNESS

- Mindfulness is being fully aware of whatever is happening in the present moment, without filters or judgement
- Observing, watching, examining. You are not a judge but a scientist
- Mindfulness involves the cultivation of
  1. Intention—purposeful and conscious
  2. Attention
  3. Attitude—non-striving, acceptance, and curiosity
- Ethical behavior is considered essential for the development of mindfulness because it frees the individual from the agitation that unethical behavior produces. (Grossman, 2010)
- Traditionally, behaviours unconducive to a calm mind include killing, lying, stealing, sexual misconduct & use of intoxicants
- Important to nurture an affective state of kindness, patience, tolerance, compassion, acceptance, and openness

Mindfulness Based Stress Reduction for Psychologists (cited in Wise, Hersch, & Gibson, 2012)

- Positive effect on psychologists' perceived stress
- Decreased psychological distress—trait depression, anxious affect, remuneration
- Increased empathy & self-compassion
- Increased sense of spirituality and interconnectedness

Results of study on 7-week loving-kindness meditation workshop (Cohn & Fredrickson, 2010)

- Greater resilience traits
- Reduced illness symptomatology
- Improved interactions
- Mindfulness predicted greater life satisfaction & reduced depression
- Benefits sustained 1 year later

Double blind study: One group of psychotherapists were taught meditation by a Zen master for 9 weeks for 1 hour & a control group (Grepmair, Mitterlehner, Loew, Bachler, Rother & Nickel, 2007)

- Researchers measured symptoms in patients seen by psychotherapists over the course of the study
- These were psychiatric inpatients in a hospital with the most prominent diagnoses being severe adjustment disorders, mood disorders, personality disorders, anxiety disorders, substance abuse & obsessive-compulsive disorder

Results:

- Patients of the Zen-trained therapists were more likely than patients of the non-Zen-trained therapists showed significantly better results at the T2
- Lower levels of somatization, insecurity in social contact, obsessiveness, anxiety, anger, phobic anxiety, paranoid thinking and psychoticism
- Patients better understood their own psychodynamics, and the characteristics of their difficulties, and the possibilities and goals of their development.

MINDFULNESS EXERCISE

1. Lay down with your knees bent & feet flat on the ground
2. Observe your breath for 6 breaths
3. Exhale by gently contracting lower abdomen inward & upward for 6 breaths
4. Exhale using above technique for 4, 5, 8, 10 seconds, etc. to maximum comfort level for 2 breaths per interval
5. Stay at maximum for 6 breaths
6. Rest
7. Sit up and inhale freely and exhale at maximum for 6 breaths

"There is no way to peace. Peace is the way." - Thich Naht Hahn

##

2015 DENMARK-GRUNWALD FEMINIST RESEARCH AND SERVICE AWARD WINNER

Asking "So what?" about our Scholarship: Why Values Matter When Planning, Doing, and Disseminating Research

Janice D. Yoder, PhD
Kent State University

Author Note

Versions of this talk were also presented at the meetings of the Canadian Psychological Association, Ottawa, July 2015 (sponsored by the Society for Women in Psychology, SWAP) and were included in my final editorial for *Psychology of Women Quarterly*, December 2015. [Excerpt here]

A brief history of the psychology of women begins with studies making simple gender comparisons — that is, men do this and women do that — summarized by Maccoby and Jacklin in their 1974 seminal narrative review, "The Psychology of Sex Differences." Since then, the field has obviously burgeoned, becoming more sophisticated about how we summarize gender differences (with meta-analysis and now even metasynthesis) as well as becoming more critical about what is to be gained from difference

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thinking. With the rise of social constructionist thinking in our field has come the realization that at least some differences between women and men derive from the different social contexts in which each is socialized and in which, even as adults, each of us is immersed (Yoder & Kahn, 2003). For example, as adults, contexts shaped by forces, large as well as small and subtle (e.g., task instructions, the expectations of others, and differences in social statuses) can affect how women and men operate and are perceived by others.

In my text, I contend that being able to think critically about these gendered contexts and their impacts on us as women and men is a key skill that we should nurture in our students (Yoder, 2013). Gender matters. It, along with age and race, is a first impression that people encode about each of us, and it plays a pervasive, but often hidden, role in most, if not all, of our social interactions. This is the meta-message that underlies the first half of my textbook and course, and it lays a foundation on which we build to explore topics critical to women's and men's lives (e.g., body image, violence, close relationships, work, and mental and physical health).

Although much of this supposition about these extracurricular teaching goals is justifiable from what we discuss in the field, as a teacher-scholar I knew I needed empirical evidence. So my co-authors and I surveyed five different Psychology of Women classes taught at three different universities by three different instructors using two different texts (Yoder et al., 2007). We conducted these surveys both at the start and then again at the end of the course. As we'd expect given prior studies of the impact of women's studies classes, students' feminist identification intensified from the start to the end of the course.

But our "So what?" question urged us to explore what drove these changes so we tapped into students' thinking about gender differences. We did this by focusing in on specific cognitive abilities (math, spatial, verbal, and memory skills), social skills (aggression, activity, empathy, and smiling), and motor skills (throwing velocity and flexibility) identified through existing meta-analyses to document gender differences. Half of these skills favored women; the other half, men. We also knew from research on stereotype accuracy that students are often accurate at picking up on gender differences that meta-analysts confirm (Hall & Carter, 1999).

We created a measure of students' endorsement of these explanations, crossing each skill with four plausible explanations focused on biology, personality, socialization, and social context. Students were presented with an opening stem (e.g., "Men are better at math than women because…"), and then they were given four possible explanations and asked to rate how likely it was that each explanation was correct. For the math stem for example, the biological possibility stated that "Men's and boys' brains are better suited to doing math"; the personality explanation: "Men's and boys' personalities are more logical and analytic"; the socialization explanation: "More parents and teachers encourage boys in math"; and finally social context: "People don't expect women to do well in math."

Pooling data from all students together, biological and personality thinking declined from the start to the end of the semester whereas endorsement of socialization and social contextual explanations increased. Both biological and personality explanations assume that differences reside within people, representing essentialist thinking. In contrast, socialization and social contextual explanations focus on the influences of contexts external to the person, suggesting constructionist thinking. The general pattern then is that students' essentialist thinking declined whereas their constructionist thinking expanded across the course.

Our next step was to link the two, exploring whether changes in difference thinking were related to changes in feminist identity. We found this connection for both personality and social context explanations. Declines in students' endorsement of personality explanations were associated with declines in non-feminist passive acceptance of the status quo and in pro-feminist increases in students' desires to immerse themselves in materials and experiences related to women. Even more pervasively, greater endorsement of social contextual explanations was associated with strengthened feminist identification across the full spectrum of identity dimensions.

But even more heartening for me as a throw-back second-wave feminist believer in the importance of making the personal political, students' endorsement of essentialist thinking was linked to beliefs about not being able to eliminate social and cognitive differences between women and men whereas constructionist thinking was linked to students' beliefs in the possibility of social changes across the full range of skills we studied. Activism is futile if one believes that something cannot be changed so I was especially delighted when what changed in students' essentialist and constructionist thinking across these courses was consistent with beliefs in the potentialities of social change. Add to this students' stronger feminist identification, and they have both the motivation and the direction to make a difference.

So far I have argued that we need to ask "So what?" when we plan and do our research, including when that

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research extends to understanding our teaching. My final piece related to asking "So what?" today has to do with dissemination. As an editor, I came to realize that part of my responsibility to *PWQ* was to disseminate the work published in it more broadly than to other scholars (although certainly impact factors remain quite influential in the world of publishing and *PWQ*'s is strong). I had the additional motivation of editing a feminist journal and hence a feminist obligation to put good research into the hands of people who might put it to good use in the service of girls and women.

But many, many more of us are scholars, not editors, so that my point today has to extend to authors who themselves can play an active role in getting their good work into the hands of people who can use it, as well as take this process a step farther by exploring what happens when their work is shared. Indeed, this is the next step that Corinne Moss-Racusin and her colleagues (took with their own research area (Moss-Racusin, Molenda, & Cramer, 2015). Prior experimental work on gender bias in STEM (science, technology, engineering, and math) fields, including research conducted by the current authors, was picked up and disseminated in three online articles which attracted 831 written comments from readers, both professional and lay. The authors in their *PWQ* paper used both thematic and quantitative analyses to explore patterns in these posted comments.

Their thematic analysis revealed 433 negative and 754 positive comments, with some postings obviously including a mix of both. These negative comments included expected sexist remarks directed to women (e.g., "In every competitive situation, with a few exceptions, the women I worked with were NOT competent, by comparison with the men") along with occasional sexist remarks directed at men (e.g., "For an equally skilled man or woman, I would prefer the woman"). A significant proportion (41%) of these negative comments offered some justification for the readers' bias, drawing on biological explanations (e.g., "I think one of the largest subconscious factors here is that women get pregnant"), personality and other non-biological factors (e.g., "The successful males I train simply seem to be hungrier and more willing to make the per sonal sacrifices required to get ahead of the competition"), and women as perpetrators of their own failings (e.g., "Women have expectations of men to be financially successful and then complain about more men at the top").

Of all the negative comments, the ones that had to be most disturbing for the authors were from commenters who refused to accept their results. These disagreements with the results relied on personal opinions that gender bias no longer really exists (as in "I am a scientist and most of my co-workers are as well — No gender bias at my job!"), flipped the findings by insisting that gender bias targets men, not women (as in the lament that it would be: "Harder for me to get a job at Hooters"), and critically nit-picked at the study as a way to discredit it (e.g., "Why are your y-axes not labeled?").

On a brighter note, there were more positive than negative comments, with these positive comments clustering around two themes: agreement with the results and constructive responses that expressed gratitude for the study, reported occasional opinion change, and called for social change. The most pervasive theme expressing agreement with the results, appearing in fully 560 comments, validated the study's evidence of the persistence of bias with commenters' own experiences (e.g., "I am a female scientist, and even I sometimes struggle with bias against women"). Although similarly validating, another subset of agreeing comments added pessimism about possible improvement, with 74 comments like this one: "There is a bias and that will not change. At least not for a couple of decades."

Interestingly, when the authors compared those comments from readers obviously affiliated with a STEM field with those who were not, they found no differences, suggesting that responses were similar both within and outside the STEM community. And when they could determine the gender of the commenters, the patterns were pretty predictable with more negativity expressed by men and more confirmation of the persistence of sexism expressed by women.

The reason their study made my list of "So what?" exemplars is because the authors took the effect their work had on the general public seriously, capitalizing on its dissemination in public venues to use their skills as researchers to better understand its impact. By doing so, they began to see their own research as more than another source of evidence of sexist bias in STEM fields; rather, their study's dissemination itself became an intervention targeting prejudice-reduction. As they go on to point out in their Practice Implications section of their paper, "…many current STEM diversity initiatives rest on the theory that exposing participants to evidence of gender bias will ultimately reduce bias and enhance diversity" (Moss-Racusin et al., 2015, p. 206). However their analysis of comments about their original study calls for diverse approaches for targeting sexism in STEM that are tailored to specific audiences.

For example, comments from most women working in

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STEM areas suggest that they already are aware of the existence of persistent gender biases so that practitioners might focus less on awareness per se and more on how to translate women's awareness into effective action. Furthermore, the greater likelihood that negative reactions came from men than women highlights the need to tackle how exposure of unfairness might threaten men and male privilege, making it likely that evidence, no matter how sound, will be denied or diminished by some men. My guess is that it takes quite a bit of open-mindedness to make one's research so publically open to criticism and even more stoicism to actually read and think dispassionately about all that is said. I applaud Moss-Racusin and her co-authors (2015) for putting their passion for making a difference for women in STEM ahead of their own egos; in other words, for their courage to ask "So what?" and to learn from the answer.

It obviously is easier on the academic publish-or-perish treadmill to just "crank it out." In fact, I have one colleague who has advised doctoral students that the fastest and most likely-to-be-accepted path to publication is to create a scale: It's easy to recruit respondents and gather data online, data analyses are likely to impress reviewers because they are statistically formulaic and sophisticated, one's paper is likely to be widely cited if the scale catches on, and so on. But, "So what?" I have this nagging sense that we are being inundated by measures that will never be put to good use (Yoder, 2016b), although I certainly will acknowledge that a few scales, such as the Ambivalent Sexism Inventory (Glick & Fiske, 1996), have made important leaps toward refining and expanding our understandings of some important phenomena (such as sexism). And I certainly don't want to confine my call to asking "So what?" of any single research area nor do I want to get into finger-pointing at existing work, including those *PWQ* papers that never made it to my family's dinner table or to my students' blogs. I also don't want to patrol what does and does not find its way into print in scholarly journals based on whether or not the findings have practice implications.

I also don't want to suggest that garnering media attention should drive the publication process or our research agenda. The widely cited journal, *Science*, finds itself at the center of a media maelstrom, making the front page of *The New York Times* over a paper the journal has now retracted and about which the author has admitted to lying about some aspects (Scheiber, 2015). The newspaper article goes on to insinuate that scholars' job and funding prospects may be enhanced if their work attracts media attention, suggesting that media visibility can trump sound scholarship in influencing the work researchers elect to pursue.

But I do want to argue that as feminist scholars and in our feminist publications, including journals, books, and texts, we do have an obligation to ask "So what?" of our research, our teaching, and the dissemination of what we do. In fact, I believe that, by adopting this imperative, we will necessarily have to be better researchers and better educators simply because we have more riding on our work than another notch in our publication belt and another batch of students making it through our classes. By putting our work out there for others to use, we have a heightened responsibility to make that work sound. So, I call on you to, every now and then, step back from what you are doing to distill it down to a few sentences in everyday language, to take it to the dinner table, and to run it by your students to gauge its meaningfulness and to help guide your time and energies toward moving forward in meaningful directions.

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CONSULTING PSYCHOLOGY

A CENTENNIAL: The First 100 Years of Consulting Psychology in APA 1915—2015

Ann Marie O'Roark, PhD, ABAP

My story for you today begins and ends with questions. The question that started this story was posed in the days of the "war to end all wars," World War I, 1915, "Who can call themselves a consulting psychologist." The story continues through the time known as the "winds of war" and World War II. The Consulting Psychology first 100 years story includes a climatic dénouement during an era of regionally contained wars, and concludes in the current time of endless wars and intimations of fresh questions that consulting psychologists might choose to address, along with a reprisal of what appear to be sustainable results of a longitudinal investment by psychologists in consulting as a critical function within the discipline.

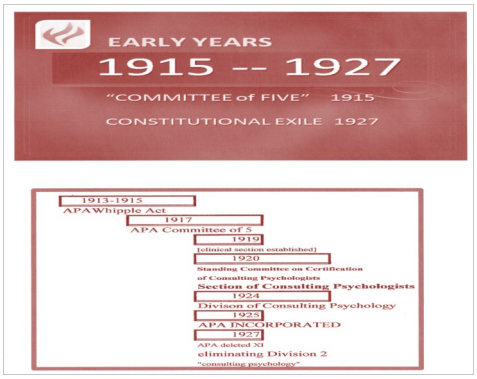

This walk-though synopsis of consulting psychology's first100 years is divided into five sections, determined by zeitgeist and ortgeist more than even numbers of years. 1915-1927; 1927-1946; 1946-1987; 1987-2007; 2007-2016.

At the time of the first World War, when US soldiers and their families were struggling with the hardships and consequences of sending troops to Europe to engage the Kaiser's attempt to conquer and rule Europe and beyond, American newspapers began asking various "experts" and specialists in mental health for opinions about the problems being encountered. The American Psychological Association, founded in July 1892 by G. Stanley Hall at Clark University, was 23 years old when the leaders decided that there needed to be some way to assure that the public's questions and concerns were addressed by those most qualified and knowledgeable about human behavior and mental status.

The men who spearheaded the movement to identify who could announce themselves as psychological experts were the leading experts in intellectual and personality assessment. Three also served as APA presidents: Guy Montrose Whipple, who made the initial Council proposal, Lewis Terman who was a member of the Committee of Five, and James McKeen Cattell was a member of the 1920 Standing Committee on Certification. After becoming a Section of Consulting Psychology, in 1924 it became a Division. The next year, in 1925, APA incorporated.

In those years, as remains a reality today, psychologists held strong and polarized opinions about science, theory and, of course, who had the right to determine who was and who was not qualified to give "expert opinions." As a result, in 1927, APA Bylaws were edited to eliminate Consulting Psychology as a division and as a certification group.

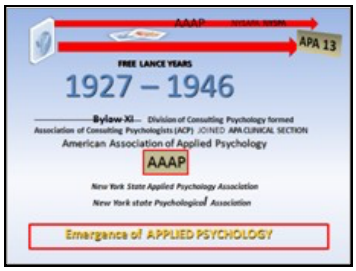

The years between 1927 and 1946, known as the "winds of war" era and culminated in World War II, saw the emergence of applied psychology. 1 The exiled Division of Consulting Psychology continued as a free lance group and became the Association of Consulting Psychologists (ACP). 1 They soon joined with the former APA clinical section/division and became the American Association of Applied Psychology. In this period of

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mergers and spin offs, the AAAP helped organize a New York State Applied Psychology Association which in turn developed the New York State Psychological Association. At the end of WWII, APA reorganized and the Consulting Psychologists, AAAP, were included as Division 13.

If you are attending the American Psychological Association Convention, please accept my invitation to attend the APA Division 13, now called Society of Consulting Psychology, for their Centennial symposium where John Hogan, History and Obituary Editor for the American Psychologist, will discuss these mergers and spin offs which included the development of the first ethics code for psychologists.

The post war era, including times of regionally contained "conflicts" [small wars], saw the emergence of consulting theories and techniques, especially in the areas of mental health, group dynamics, educational consulting.

The first president of the new Division, APA13, was Jack W. Dunlap (1902–1977), who also served as president of the Psychometric Society, the Human Factors Society, the Military Division and the I/O Division. Dunlap served in the military and was prominent in military research and assessment advancements. After a time with the Psychological Corp, a computer testing and scoring organization, he started his own company, Dunlap and Associates, which he headed until his retirement in 1966. The company was quite successful, specializing principally in human factors work for industry and government on a variety of problems, including highway safety, emergency medical care, and flight training. Donald Super, whose early career was with the YMCA, also served in the military and as a president of the Military Division, APA18. He said that "one of the great things about NVGA [National Vocational Guidance Association] is the friendships which activity in the Association fosters. [NVGA] not only helps improve services to youth, adults, and the aging, it provides a focus for friendship." He received the 1983 APA Award for distinguished scientific contributions to applications of psychology.

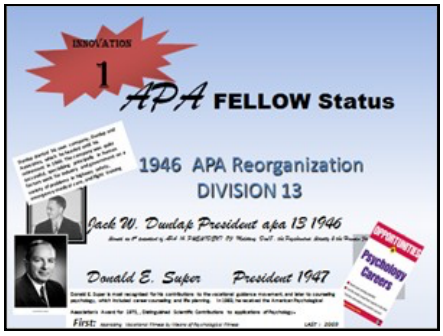

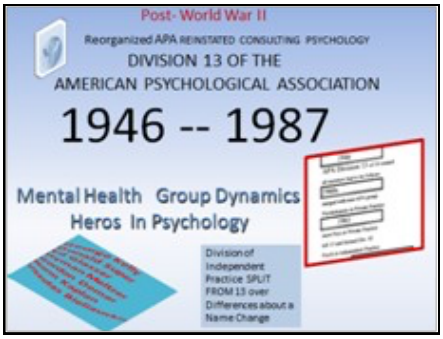

Process consulting and organizational culture, leadership and followership, and international awareness began to flourish in the Consulting Psychology Division. After a disagreement about the name of the Division, a group split off from 13 to form the Psychologists in Independent Practice, Division 42. Several of the influential division 13 presidents and theorists of that time of fermenting and formulating were: George A. Kelly, Albert Ellis, Gordon Derner, Norman Kaplan, Ray Fowler and Vytautas Bielauskas. Vy, a recognized WWII hero, left Lithuania the day the Russian troops arrived, to craft a career in psychology; completing academic studies in northern Europe, moving to the US and finally serving as Chairman of the Xavier University Psychology Department 1959-78.

The fourth phase of consulting psychology as an interest group/division in APA is based on a major "paradigm" shift: From individual's in leadership roles who were recognized for their unique and outstanding contributions to the discipline of Psychology to the election of presidents some of whom were already Fellow status, but some who were not. All had a special interest in and gave attention to the development of the division, and dedicated time to activities aimed at fulfilling its purpose.

Clyde Crego, who died just two months ago, was interested in continuing education workshops being approved by APA to award CE credits, and had a glint in his eye about a midwinter event. Each one in this montage added to the strengthening of the division and movement toward achievement of the 1915 mandate to find a way for APA to determine who could call themselves a consulting psychologist.

The growth began with Goal Setting at a Board Retreat planned by Paul Lloyd and Ken Bradt. Diversity of Membership was a priority and establishing the consulting psychology knowledge base was a close second. Another critical incident was the initiation of the midwinter conference, but equally relevant to stabilizing of the group was conceptualizing the operations and constituencies of the group, which included attention to publishing knowledge

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and information about consulting psychology. The culmination and denouement moment in this story of the 100 years came in 2006, when the Education and Training Guidelines for doctoral and postdoctoral level consulting psychology, organizational consulting, were approved by APA Council as APA Policy. This seven year composition by the division E&T Committee came about after the division shifted attention from seeking APA approvals as a specialty, a proficiency or a certification agent.

The fifth phase of the first 100 years leaves important questions to be answered in the next 100 years. Since endorsement of the E&T Guidelines for organizational consultants and achieving what was initially intended to be the first of a series of E&T guidelines for consulting done by those not fully invested in a career in organizational consulting psychology, but more often consulting on their specialty topic, the group, by this time renamed the Society of Consulting Psychology, both expanded and contracted. More members and reducing attention to organizational –primarily businesses, industry and services – and to "coaching" approaches.

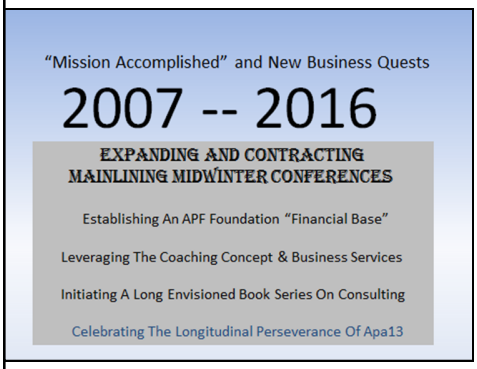

To recapitulate and consider what sustainable solutions may have been produced through the longitudinal perseverance of the group and dedication to finding a solution to a problem that was "global" for APA and arose out of global conflicts:

1. E&T Guidelines for determining who can call themselves a Consulting Psychologist [CP].
2. Beginning the Organized Collections of CP knowledge.
3. WILL THE NEXT CENTURY PRODUCE A LIBRARY OF CP THAT INCLUDES a Super's Rainbow Model and Killberg's Model of Psychoanalysis and Systems Theories, Freedman's Phoenix Model of the adjustment process in technological changes in large organizations?
4. Frameworks for Consulting Psychologists to use when diagnosing and planning interventions.
5. WILL THE NEXT CENTURY BE ABLE TO COMPILE AND CLASSIFY THE FULL RANGE OF Consulting LENSES?
6. Overcoming the stigma of working with a "psychologist-shrink" by putting on the COACHING CLOAK-with shoulder-pads.
7. WILL THE NEXT CENTURY FIGURE OUT HOW TO SORT OUT THE KINDS OF COACHING BEST DONE BY GREYHAIRS, BY FRESH PHDS, BY TRANSITIONERS?
8. Beginnings of strategies for consulting in diverse cultures, countries, populations.
9. WILL CP BEGIN TO DEVELOP THE CONCEPTS OF HOW TO AND WHEN TO INTRODUCE VARIOUS INTERVENTIONS INTO A PARTICULAR GROUP IN A PARTICULAR PLACE?

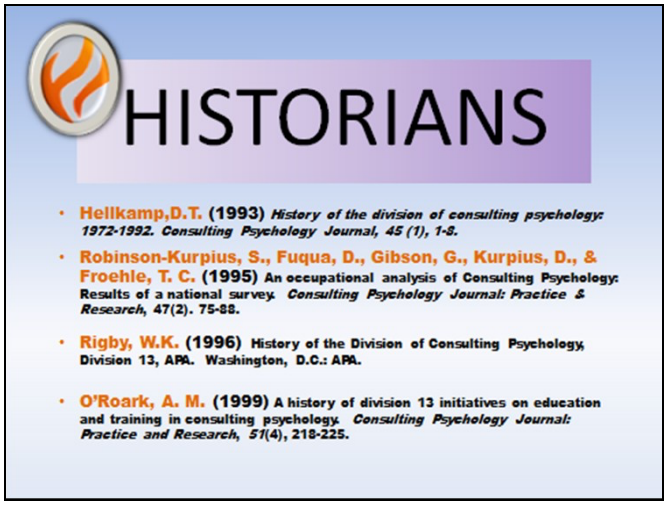

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Worth asking . . .

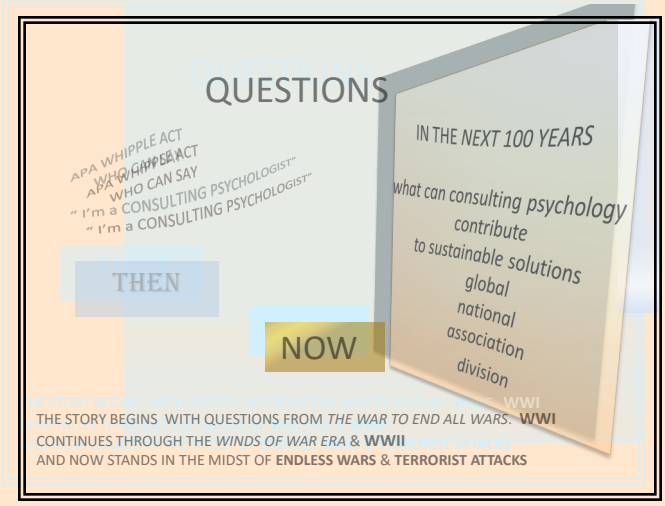

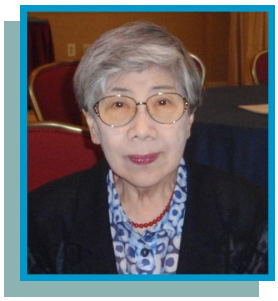

Congratulations from Japan on APA's 100th Year of Defining Consultating Psychology and 75th Anniversary of ICP, Inc.

Machiko Fukuhara, PhD., President, MicroCounseling Institute of Japan, Tokyo, Japan; ICP, Inc. President-Elect

I feel honored to be able to participate in this celebration symposium.
Consultation has played an important role for human beings. People need to live with others, asking for any help when needed.

1. I understand that the Consulting Psychology Division (Div.13) in APA was established early about the same time with the divisions for Clinical Psychology, School Psychology and Counseling Psychology. Consultation played an important role in those professional helping relationships. Before those helping-professionals were introduced in Japan, around the middle of 20th century, consultation (sodan in Japanese) by laymen done mainly at working places played helping roles to employees for their problems at work or even for their personal problems. Later the function of consultation systems in the business world became familiar among people as a sort of Guidance which helped them handle finances, manage the organization, etc. Those consultants were not necessarily professional personnel in terms of carrying psychology-based services.
2. Along with the introduction of professional psychology in helping such as, Counseling, School Psychology, etc., psychological services came to be recognized in Japan, especially in educational settings. And consultations to, for instance, teachers at schools, were carried by counselors and/or clinical psychologists. (At present the Industrial Counseling Association is offering certificates after some training, and psychologists play roles for training.)
3. Since the beginning of the 21st century, consideration for the mental health of the individuals and groups has been strongly voiced for their wellness. Caring for one from this viewpoint might not be done by only one professional or institution. Consultation or supervision is needed by counselors for their satisfactory works: Individuals, wherever they live, are multicultural beings. Being included in this idea, as a recent trend in Japan, are the various areas of helping professions, such as doctors, nurses, nutrients, occupational therapists, counselors, psychologists, etc. who are encouraged to work cooperatively in the respective institute and/or community to support different kinds of individuals for their wellness. Those professions consult with each other within this kind of cooperative linkage. One example, is caring for the old. In Japan, the number of elders has increased (in a few years one forth of the population will be over 65 years old), and in the near future, they could be taken care of through this system in the community.
4. ICP, Inc., with its long history, has contributed to human beings for keeping up with human rights and being sensitive to the needs of the times. It is amazing that it continues to hold an annual conference every year since its establishment in 1941. And seeing the theme of each conference, you will see how we are sensitive to the trend of the times and how we have challenged helping individuals for their mental health and well being.
5. One individual cannot live alone. One has to be strong to support him/her self, of course, but he/she needs social support in order to meet the challenges to "quality of life." Roles of consultation will become more important there.
6. It is an honor for us, the Japanese members, to work for the 75th Conference in Yokohama which will be held in conjunction with ICP2016, the Congress. It has been 26 years since our 48th Conference was held in Tokyo. People all over the world are facing challenges from disasters of many kinds, wars, etc. but we have to live with these things and go forward towards wellness for people and for the world. Even after many years of desiring this change for all human beings, the challenges to the rights of human beings all over the world have not changed. Let us work on our common issues and do whatever we can.

We, Local Arrangement Committee, Drs. Katou, Nagy-Tanaka and myself, representing the Japanese, are welcoming you. We look forward to seeing you here. We are hoping to set many opportunities when our members will talk together in person which is one of the traditions of the ICP, Inc.

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History of Psychological Associations related to Counseling/Clinical Certificate (1/2)

Name of Association	Year of foundation	Year of Certificate started
The Japanese Psychological Association	1927	1990
The Japanese Association of Applied Psychology	1931	1995
The Japanese Association of Student Counseling	1955	2002
The Japanese Association of Educational Psychology	1959	1997**
The Japanese Association of Clinical Psychology	1964	
* Counseling Psychology was introduced to Japan 1951 – 1953 with the Educational Reformation		
The Japanese Association of Counseling Science	1967	1986
The Association of Japanese Clinical Psychology	1982	
* Board of Certificate (joined by 30 related Associations) started to offer License for Clinical Psychologists		1988**

* significant event related to counseling development and certificate
** a minimum education requires Master - level.

History of Psychological Associations related to Counseling/Clinical Certificate (2/2)

Name of Association	Year of foundation	Year of Certificate started
The Japanese Association of Educational Psychology	1959	2001 }
The Japanese Association for the Study of Developmental Psychology	1988	2001 }
The Japan Association for Personality Psychology	1992	2001 }
Japan Society for Research on Emotion	1992	2001 }
The Japanese Association for the Study of Developmental Psychology	1988	2002 }
The Japanese Academy of Learning Disabilities	1992	2002 }
The Japanese Association for the Study of Developmental Disabilities	1996	2002 }
The Japanese Association of Health Psychology	1988	1997
The Association of Industrial Counseling	1996	

} collaboratory certificate

Dimensions of Globalization Among Urban Indian Youth

Sonia Suchday, Ph.D.
Richard Velayo, Ph.D.

India is a fast-globalizing economy where young people make up 65% of the population. Globalizaiton has brought with it rapid and inequitable development and has impacted on the lives of young people, particularly emerging adults. The current study evaluated the dimensions along which globalization impacted young people.

Young college students from Mumbai (n=56) provided written descriptions of how globalization has changed their lives – and impacted on families and society. Content analysis of participants written responses by three independent raters provided a series of themes regarding the impact of globalization. Additional participants (n=211, 42 males, age=18.65 years) responded to each theme on a Likert scale "never", "sometimes", "often", "always" as a part of a larger study on globalization and health.

Factor analysis of the responses yielded four factors with eigenvalues >1 and high internal reliabilities. Sociocultural changes (alpha=.95) – described growth in egalitarian values, adoption of western popular culture - music & clothing; increased unhealthy behaviors (alpha=.84) included items that described acceptance of smoking, drinking and use of "vulgar" language; materialism (alpha=.61) described less time for family; and deterioration of traditional values (alpha=.70) defined less respect for age, traditions.

Clearly, globalization has positive and negative effects including exposure to multiple cultures and growth of egalitarianism. Aspects of globalization such as increased smoking and drinking may be associated with health consequences for individuals and societies, and may conflict with traditional values (e.g., spiritual growth versus materialism).

These many aspects of globalization need to be explored to define their impact on health and well-being.

BOOK REVIEW

(Publisher note: Part of this review was published in IP 55.4, December 2015.)

The MultiGradeMultiLevel-Methodology and its Global Significance: Ladders of Learning - Scientific Horizons - Teacher Education (Theory and Practice of School Pedagogics Book 34)
Authors: Müller, Thomas, Ulrike Lichtinger & Ralf Girg (2015)
Publisher: Prolog-Verlag Immenhausen, 266 pages

What if children loved going to school? What if they enjoyed learning according to their lives and interests? What if their learning processes were supported in a way that they corresponded to their abilities and needs? What if they learned in their own rhythm and pace? What if teachers were able to support such learning through an individualized arrangement of learning materials and showed an attitude of appreciation? What if schools were maintained mostly by the students themselves and were surrounded by flowering gardens full of herbs and vegetables and fruit? If schools taught students how to live their lives in a sustainable way? Is that utopian? A non-existent paradise of learning? Does that sound like an exclusively perfect world that can only be found in upper class schools and would never be affordable for anybody else?

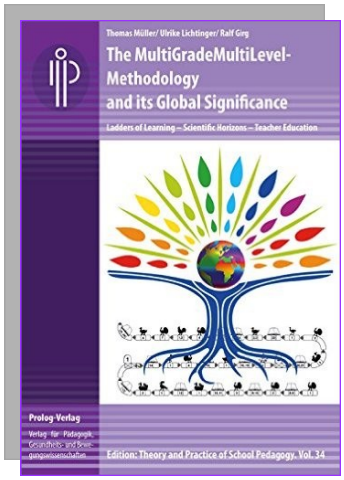

Thomas Müller, Ulrike Lichtinger and Ralf Girg of the universities of Regensburg and Würzburg describe such a learning and teaching culture, that has been practiced for thirty years in rural South India at Rishi Valley, in the state of Andhra Pradesh. The authors convey vividly an exemplary modern, inclusive, community-based and environmentally sustainable school culture, we, in many places in the so-called western world, are far away from. Each child there, so the book plausible emphasizes, is respected in its uniqueness. And it is encouraged and educated to cooperate responsibly with a sense for the whole community. At the same time the children show high learning performances.

The Rishi Valley approach has been developed by Padmanabha Rao, Anumula Rama and their team since the 1980s, inspired by the ideas of the philosopher Jiddu Krishnamurti (1895 – 1986). The so-called MultiGrade-MultiLevel-methodology (MGML) has won many national and international prizes for education, sustainability and social entrepreneurship. Today this approach can be found in more than 250,000 primary schools in India and in more than 10,000,000 children benefit from it. It has also been spreading out to many countries in the world and is thereby one of most innovative and effective developments in school education worldwide.

The authors of the book, who - for many years - have been cooperating with their Indian partners at Rishi Valley, step by step reveal the secrets of this success to the reader. Their book of 200 pages is deeply exciting because it reminds the reader of his own educational ideals.

The secret of the MGML-Methodology evidently can be found in the individualized student centered learning in mixed age groups with the help of highly structured pathways, the so-called “ladders of learning”, through prepared material collections, and accompanied by teachers, whose interactions are inspired by deep appreciation and mindfulness.

In the last part of the book the authors give examples of successful adaptations in German and international primary, secondary, higher and special needs education. Thomas Müller, Ulrike Lichtinger and Ralf Girg themselves have been using and evaluating this approach in their own teachings at the educational faculties in Regensburg and Würzburg for a decade now.

Both the methodology and the attitude may serve as models for a truly modern education, because individual differences and needs in learning speed are globally becoming more and more acknowledged. The MGML-approach allows for teaching formats that take these differences into account and at the same time foster children´s ability to support each other in learning groups. This book is an inspiration to all who want to strengthen schools as spaces of learning and teaching that truly meet the needs and challenges of the 21st century.

Reviewer:
Nils Altner, PhD, researches, teaches and publishes on education, mindfulness, health and personal development at the University of Wurtzberg.

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A Poem; A Fictional Interview; A Letter from the Past

The Autumn Leaves

Dr. Ani Kalayjian

The autumn leaves are around me, I step on them carefully,
I cannot help it, as they are fallen all around me.
Of course, its autumn, I convince myself…
Perhaps that's why they call it the Fall,
As so many leaves fall all around ...

I am scared to walk…to crush the leaves…
Like I'm crushing the fragile heart of Mother Nature…
When I step on the leaves I see you coming alive…
I hear the soft crying sound of the leaf
and I feel you in my soul even more deeply...

Then I see a resilient rose...
In spite of all the harsh winds,
one determined rose has made it through…
I think of you once again and I wonder…
Are you that resilient rose I see?

I feel your gentle spirit like a halo around me,
then I see you once again in the petals
of the one strong and resilient rose...

I am now passing through the streets of New York,
Here is a child crying for Mom,
You come alive in my mind once again...
as I wonder if you are too crying for unity?

Do you feel lost while searching?
Are you tired and resting by a tree?
Or are you transformed to a red rose?
An aromatic and resilient rose,
amongst the thousands of the fallen leaves...

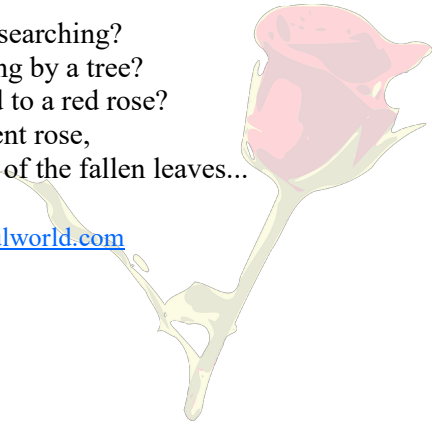

DrKalayjian@Meaningfulworld.com

Life as a Playful Journey: Intercultural Encounters

David Y.F. Ho, PhD
ICP, Inc. President 1989-90
Program Chair 1988: "East -West Dialogue: The Role of Psychologists in Promoting Health and Well Being."

Abridged excerpt from "Enlightened or Mad? A Psychologist Glimpses in Mystical Magnanimity"
Publisher: Dignity Press in 2014.

The excerpt, as do other parts of the book, takes the form of an imaginary interview, in actuality, an internal dialogue between my two selves: David and YF, different but complementary.

David is my Western-educated self, analytic, informed, and thoughtful. He sees things from different perspectives, Eastern and Western. He puts things in context and spells out their implications. He functions as a detached observer, summarizing periodically and giving feedback to YF. He tempers YF's extremist proclivities and keeps him on track. Occasionally, he functions as a therapist for YF. He acts as a catalyst, challenging YF to go deeper or to clarify issues, thus pushing the interview forward.

YF is my Chinese self, born and raised in Hong Kong. He derives knowledge from firsthand experiences, including those of "madness." His mind is complexity itself, critical, incisive, and self-reflective. Characteristically direct, he minces no words. He is intense in both action and thought, single-minded in the pursuit of his goals. He has a low threshold for enthusiasm and is almost incapable of doing things halfway.

David: A spiritual quest does not have to be a journey of solemn, staid drudgery, but of dedication
intermingled with playfulness. You were born in the Year of the Rabbit, according to the Chinese zodiac.

What do rabbits do? They leap about and frolic in merriment. So naturally life to you is a gamble. One of my episodes of madness took place in a luxurious setting, on board the Queen Victoria and land excursions around the

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Mediterranean. The experiences I gained could fill a travelogue. They illustrate our worldviews as a world citizen. They serve to redirect attention from abnormality to the rich diversity of normality, in which madness may be embedded. More important, they demonstrate that spiritual journeys can indeed be playful.

YF: Life on board the Queen Victoria was anything but boring. One day, the captain broadcasted an announcement about security measures against terrorism, while crew members went around checking for hidden bombs. The announcement went something like this:

We take terrorist threats seriously…. So take note and report to the authorities if you see someone who looks suspicious, or if you see someone who does not look suspicious but has been seen in the company of people, among some of whom might have been seen together with someone who does look suspicious.

Upon hearing this, I blurted out, "Ridiculous!" Whereupon, an Englishman nearby was sufficiently amused to initiate conversation with me. I introduced myself as "Double-Oh-Seven"; he introduced himself as "Double-Oh -Six." Thus, both of us were working for Her Majesty's government, in search of potential terrorists on board.

Later, he introduced me to his wife. I ran into her over breakfast one morning but failed to recognize her. She was visibly peeved. I thought to myself, "Now you know what it's like not to be recognized by people who ought to have recognized you. I have had plenty of experiences of not being recognized, intentionally or unintentionally, by Westerners."

David: Ah, don't all Orientals look alike?

YF: Mentally settled a moment later, I took corrective action and went over to the table where she and her husband were sitting. I said to her husband, "007 reporting to 006." I then asked his wife not to take to heart behaviors natural to secret agents that probably look unnatural to normal people. This seemed to placate her. The English couple were curious about my occupation.

I said, "You mean besides being a secret Agent? You may ask me any question, to which I am bound to give a truthful answer. You have five guesses."

I did give truthful answers, but with nuances calculated to mislead. I talked about various occupations with authority, coupled with counter questions to suggest that I knew a lot more than I actually did.

David: This comes naturally to you after years of teaching practice: The art of teaching is not to conceal the teacher's ignorance, or to show his knowledge, but to demonstrate how knowledge may be generated through dialogue.

YF: The Englishman came close but missed the target. Finally, I told the couple that I was a professor of psychology.

His wife professed disbelief. She asked in a sarcastic tone, "You have a certificate to prove it?" She then took another good look at me and noticed the Gucci shoes I was wearing. "Ah, I believe you. Those expensive shoes befit a professor."

At that moment, I didn't know whether I was amused or vexed. I have seldom bought expensive items for myself. I bought the Gucci shoes so I could dance, not to impress people.

David: Apparently, the Chinese saying "Respect the person's attire, before respecting the person" is not confined to Chinese people. Such great regard for worldly concerns is symptomatic of spiritual emptiness. Sadly, to many, materialistic pursuits offer more attraction than spiritual quests.

YF: Nonetheless, I was very pleased to have met the English couple. Both thought that English was my mother tongue! For the first time in my life, I passed the test of being a native speaker. Nothing made me happier.

Another linguistic encounter was a surprise. After talking with a hairstylist for a while, I asked her what her native tongue was.

She replied, "English."

This answer instantly embarrassed me, for having possibly embarrassed her. Fortunately, she wasn't. She explained that, being Scottish, she was used to not being understood by the English. It took me a while to get used to her accent. I still remember the way she pronounced *but*, which sounded very strange to my ears. Accent was certainly no barrier to communication. I sensed that there was something troubling her.

After discovering that I was a psychologist, she wanted to talk with me about that something. We had a heart-to-heart talk for about thirty minutes and got to the bottom of it. It turned out that she was concerned about her relationship with her boyfriend's mother, who she felt was rather possessive of her son.

David: So the classic antipathy between mothers-in-law and daughters-in-law is not unique to the Chinese.

YF: I felt gratified that we had both transcended our backgrounds. Indeed, kindred souls countenance no linguistic or cultural barriers to communication.

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Displayed inside the ship's gallery were photographs of passengers dressed in utmost elegance. A Chinese couple was looking at some of the photographs, and the lady aimed her camera at one. A staff member dashed in front of the couple and bawled out a pointed threat with an Australian accent: "These photos are copyrighted. If I see you doing this again, I'm going to confiscate your camera."

David: Typical Western active-aggressiveness!

YF: She had a build that dwarfed the Chinese lady. Standing nearby, I could imagine how the Chinese woman reacted, and I approached her to see if I could help. She explained that she didn't really intend to take a photograph of the photograph on display. I said that I would talk with the staff member concerned. In a typical Chinese fashion, she said, "Never mind."

I saw an opportunity to be an agent of intercultural understanding in action. In a typically atypical Chinese fashion, I approached the staff member and relayed to her what the Chinese lady said.

The staff member explained: "You know, some people actually steal photographs from the gallery. We have to protect our copyrights."

I replied, "I understand. However, the couple feel offended. You could have explained to them in a nicer way."

She then went over to the couple and apologized for her ill manners. Later, I talked to some Chinese passengers about the incident.

One reacted: "I'll intentionally take photographs of photographs in the gallery, just to vex them."

I thought to myself: Typical Chinese passive-aggressiveness! I was witness and intervener to numerous similar incidents of intercultural strain during the entire cruise. Neither Eastern nor Western I had found myself but a supracultural agent of understanding.

David: So you treated the Queen Victoria as a perfect place for conducting field research on intercultural communication, organizational behavior, customer relations, and so forth.

YF: Too busy enjoying myself, I did nothing by design. Still, a generalization forced its way into my scientific consciousness: There was an inverse relation between status and friendliness or pleasantness among the staff.

The high-status staff were typically European and fluent speakers of English. Some displayed condescending attitudes toward passengers who didn't speak English.

The low-status staff came from the Philippines, India, or other third-world countries. Some had substandard proficiency in English. One waiter asked, for instance, "Are you all right?"

David: When what he meant was, "Is the food all right?"

YF: I discovered to my amazement, however, that those who came from Mauritius were articulate in multiple languages, although they had completed only secondary education. This would put Hong Kong to shame.

I found out that the low-status staff were not as well paid as one would imagine. This meant that I had paid less for the cruise on their account. Almost without exception, they were helpful and friendly. To repay them in a small measure, I would hoard chocolates given only to passengers and redistribute them among the staff. They showed grateful delight, far beyond the chocolates' value.

David: Without loving actions in the concrete, talks of universal love in the abstract sound hollow.

YF: Part of the cruise involved land excursions in Egypt and Italy. I visited the world renowned Library of Alexandria, where I saw groups of Egyptian schoolchildren on tour with their teachers. Like schoolchildren elsewhere, they were fun-loving, noisy, and not as attentive as demanded. Their teachers, mostly men, watched over them like hawks over chickens. They had no hesitation in delivering a hefty blow to the head of a child whom they considered to be out of line.

I followed the children around for a while. Occasionally, I caught their attention by making funny faces to reflect how scary the teachers were. They were greatly amused.

David: You had to be cautious, for nothing would infuriate teachers, in Egypt or elsewhere, more than someone who succeeded in distracting students from the crutch of their authority.

YF: In Italy, I saw an entirely different pattern of teacher-student relationships. Groups of schoolchildren were led by their teachers around to tour galleries and museums. The children were jovial and showed no fear of their teachers. I saw students and teachers joking around together, enjoying each other's company.

David: All your life, you have had a special interest in the socialization of children in different cultures. Here was socialization observed in person. You have often said: The destiny of a nation is conditioned by the manner in which its children are socialized. Remember, even as a child, you thought that traditional Chinese upbringing "produces enslaved nations."

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YF: I saw busloads of tourists on their way to the Egyptian Museum in Cairo. Most of them seemed to show more interest in Egypt's antiquity than in its modern history, more fascination with dead mummies than with the living. Few showed understanding of, let alone empathy toward, life outside the museum.

I noticed, however, that the squalid conditions under which teeming masses of people lived did not seem to have taken the spirit out of them. Everywhere I went, people responded cheerfully to gestures of goodwill. I asked someone to write down on a piece of paper the equivalent of "Greetings, and thank you for your help" in Egyptian Arabic. All I had to do was to show it to people around when I got lost (sometimes in pretense) and they would come to my aid.

David: That piece of paper is a passport to pleasant and meaningful intercultural interactions. Serendipitous encounters tend to be the most interesting when you travel in another country.

YF: Inside the museum, I took a special interest in the death mask of King Tutankhamun, particularly the hieroglyphics inscribed on it.

A young Egyptian woman appeared unexpectedly and asked, "Would you like some help?" It turned out she was a university student majoring in history. She could read the hieroglyphics, which she translated into English for my benefit! She then took my hand and gave me a personal guided tour around the museum. Pointing to a statue of a cat, she explained that it was crying with tears because it wanted another "man." Perplexed, I endeavored to discover the mystery behind such feline desire. It then dawned on me that she meant "meal."

Her name was Amany. Her stature was as diminutive as her charm was immense. Her head was covered with a hijab, which did nothing to conceal her facial expressiveness. Her large, enchanting eyes, like a pair of black pearls, would move even the most unmovable Bodhisattva. She taught me to write my name in hieroglyphics, and I showed her how to write hers in Chinese.

When it was time to depart, I took out a banknote of twenty euros and gave it to her. She asked me to write my Chinese name on it, which I did.

"I will treasure this for the rest of my life," she said. At that moment, I felt what began as a casual contact had turned into a communion between two ancient civilizations, of which we were ambassadors.

David: A woman in a Muslim country taking initiative to approach a man in public? And taking his hand to go around? This defies the stereotype of heterosexual relations in Muslim societies.

YF: I remember my visit years ago to Mindanao State University in the Autonomous Region in Muslim Mindanao of the Philippines. On the way there, my travel companion, a Christian, warned me repeatedly: "Don't ever touch any woman, not even accidentally. Otherwise, dire consequences will follow!"
However, Amany showed no unease and must have felt that her behavior was perfectly acceptable. As a matter of fact, nobody around paid much attention to our interaction. She provided a living demonstration of how misleading stereotypes can be.

David: The Muslim world is not monolithic. It is far more heterogeneous than is acknowledged by most outsiders.

YF: More fundamentally, my past encounters in diverse cultures give me little or no reason to be surprised: Everywhere, women governed by strict codes of conduct will, nonetheless, find ways to express their humanity.

David: Manuals in the form of do's and don'ts written for tourists often perform a disservice: They reinforce common ethnic or cultural stereotypes and put tourists too much on guard. Now you have published many scholarly papers on transcultural psychology. Are you guided by your extensive knowledge of how people from different cultures interact when you travel to foreign lands?

YF: Having traveled around the world three times, I can say that attitude matters much more than academic knowledge. People all over the world appreciate gestures of good will. Ultimately, I have only one basic principle: Be yourself, whether you are living in your own country or traveling abroad.

David: Are you saying, in effect, that there is no distinction to be made between traveling as a tourist for pleasure and traveling as a pilgrim for spiritual fulfillment? If so, you have taken a radical stance, in conformity with your identity as a world citizen.

But "be yourself" also means being occasionally mad. Did you scare anyone around the Mediterranean?

YF: Being myself, I was playful. Not surprisingly, my playfulness was amplified by a measure of madness. Significantly, none of the people I interacted with thought I was mad. So, it is possible to control or conceal my madness during episodes.

A LETTER FROM THE PAST

From: Bruce.Bain@(Bruce Bain)
Subject: 1998

Dear friends,

On New Year's Eve '97, at the midnight minute, Bruce and Agnes were on a dance floor, on a ship, in the Straits of Malacca, hugging and kissing, doing all those wonderfully silly things one does at the auspicious hour. Set civilization stamps out primitive ritual?

We were on sabbatical, Agnes for the first time, Bruce for the umpteenth time, and the start of a long shared dream of traveling together around the world. Joining us on the cruise from Singapore to Puket was Parisian friend Marlene Dolitsky, and her son Dexter—a child, who, at his best, is a great and endearing boy, and in other times, well, Golding must have had the other times in mind when he wrote Lord of the Flies. The best will win out, we're sure.

Puket was sad: so much natural beauty, so much human potential being wasted, so many young Thai girls and boys in the sex trade, catering mostly to drunken Germans, Japanese, and Australians. The Asian economic meltdown has hit Thailand so hard that this business is the only recourse for so many. When and by what means does this sickness end?

While on a cruise, we met three ladies from Singapore, and the mom of two of them, and became good friends. This is interesting, because some years ago, at Versailles, we met three other young ladies from Malta, and became enduring friends. What is it Jung said about synchronicity and serendipity? Jung seems intuitively right and empirically wrong about many things. Agnes appreciates his mystical insights. Bruce is less sure. But who can argue with Jung and Agnes?

January and February were spent mostly in Singapore, visiting profs at the National Institute of Education. It was a productive time. Bruce completed a number of manuscripts, and Agnes wrote some and met many informed people in the Singaporean school psychology fields. Singapore has good feng shui for Bruce and Agnes.

Side trips were made to Malacca, a handsome, sedate, and historic place; and to Bali, which has the most and unpleasant hawkers we ever encountered. Mahathir, the Malaysian President and self-appointed Messiah, was (and is still) railing against foreigners (which seemed to be anyone who disagrees with him), and Suharto, the Indonesian President and self-appointed Messiah (since replaced by his deputy Messiah Habibi) was (and still is) railing against foreigners (which seemed to be ethnic Chinese, and anyone who disagrees with him/them). Singapore was/is a calm island sea. One holds otherwise, but suspects contrarily that the storm is not over.

A short family-and-friends visit to Hong Kong rounded out the Asian part of the sabbatical. One of the essays Bruce wrote is, The renaissance of psychology in Hong Kong, which is now published in the bulletin of the Hong Kong Psychological Society, 1997, 38/39, pp 149/162. On a slow night, over a sherry or two or three you may wish to read it.

Then, it was on to South Africa, Johannesburg, visiting professors at Rand Afrikaans University, for the month of March. Jacobus and Susann Kok greeted us and treated us like long-lost cousins — a feeling that was spontaneously mutual. RAU colleagues were equally effusive in their concern for our well-being. During the week, Bruce was busy writing and occasionally lecturing; and Agnes was busy writing and visiting schools around Johannesburg. The weekends were something else.

One weekend, the Kok's took us to their farm near Witburg for a weekend of sightseeing, food, drink and chat with a cast of engaging friends. Another weekends they took us to Margate, a country cottage town on the Indian Ocean, south of Durban, where we walked on the beach, visited an alligator farm, and eats like Epicureans. The third weekend we went to Kruger National Park, one of the world's great sites: lions, elephants, zebras, baboons, all manner of birds, hippos, giraffes, one leopard; the only big game animal we did not see was the rhinoceros.

The fourth and final weekend was a trip to Cape Town by train, and back by plane. Cape Town is truly spectacular: Table Top Mountain, Cape of Good Hope, a dramatic harbor, Robben Island, long sweeping beaches, fascinating houses clinging to mountainsides, and food worthy of the gods. South Africa possesses some of the most dramatic scenery in the world. Every turn in the road or twist of thetrain seemed to bring with it another breathtaking scene. We used up eighteen rolls of film in South Africa alone!

The magic moment of our South African sojourn was an evening visit to Pretoria, with the Koks of course, to see/experience the opera Rigoletto, one of our favorites, followed by a visit to a planetarium, on a farm east of Pretoria, operated by a group of fellow amateur astrophysicists (stargazers to the uninitiated; Peeping Toms to the cruel). To our surprise, like the earthly Agnes, the celestial Agnes is a twin! Joan seems right on, again. Nine months later we still talk about it and likely will for the rest of our

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lives. It was evident that South Africa is having serious civil, political, and economic problems. It was also evident that, if people like the Koks and others with a similar moral compass are given a chance to help guide the future, South Africa will find a harmonious path to the promised land.

The promised land of Israel was our next stop. A Canadian proverb has it that Canadians have roots in two cities, Paris and their own; and in two nations, Israel and their own. It was like stepping into part of our collective past to actually see the Galilee, the Jordan River, the hills of Judea, Caesaria, the Dead Sea, Masada, and of course, Jerusalem. And Passover and Easter in the holy land as well!

The first week we stayed with old friends, Roberta and Noach Milgram, who live near Tel Aviv. They took us on a grand tour of Israel, from the church of the Beatitudes on the shores of the Galilee, to the source of the Jordan River which, surprisingly, is freezing cold, to Vad Mordecai.

The next two weeks were centered in Jerusalem, guests of Bruce's former student and loving friend, Sam Hazanovitz, and his new scriptwriter wife, Hadas.

No sooner had we settled in than the four of us were off to Istanbul to see the sights: the Topaki Palace, the Blue Mosque, the Golden Horn, Asian and Western Istanbul, the Grand Bazaar. Istanbul is a surprisingly easy place to get around. The airport is a nightmare. But the Turks on the street are helpful. We left wanting to see more, and promising ourselves that one day we will return.

Back in Jerusalem, we visited all the historical sites in the old city: the Western Wall, the Church of the Holy Sepulchre, the El Aksa Mosque and the Mosque of the Golden Dome, the Way of the Cross, and scores of churches and synagogues. Bruce "prayed" at the Western Wall. He solemnly uttered "quaequmque vera" and "Lotto 649." "Whatsoever be true" likely will be, but Bruce is yet to win the lotto.

In the old city we found that Judaism, Christianity, Islam have a strong common root: ripping off the tourist. We're not sure why this surprised us. We've seen " holy places" of all denominations and scores of sites around the world; yet, we were. We seemed uncontrollably to hold a higher standard for this holy place and for the others — Jerusalem does that one.

We also felt sorry for believers of a gentle spirit for whom the old city must be a disappointment. The good Jew, Christian, or Muslim must be appalled by all the crass larceny. But if one can hold one's nose about the vulgar commercialism surrounding the holy sites, and if one can ignore the intolerant few of all three faiths, the Old City is a wondrous place. Our own philosophy of life is to carry Jerusalem around in our hearts. But the geo-political-physical Old City of Jerusalem captures the imagination directly.

Avi and Sara Habinski, friends from Edmonton, expatriot Israelis, on sabbatical in Israel, took us to Masada, the Dead Sea, and scores of fascinating places that only the seem to know. The pictures of us covered with Dead Sea mud is a sight worthy of Punch

Banff and Jasper overwhelm with their eternal beauty. Harris puts one in touch with romance and, in a sardonic way, reason. But Israel is alive with some indefinable essence. And the falafel is great! Again Jung would understand.

Before going to Israel we knew of the protracted turmoil — who doesn't? But we worry because we know and love some of its potential victims.

From Israel we went to New York, one of our favorite places, for a couple of weeks of theater, sightseeing, shopping, visiting friends Selma Sapir and Kate Greene, and just winding down (or is it up) before getting back home, and back to work. Bruce, back to supervising graduate students, teaching large classes, researching and writing; and, Agnes, back to the schools and problem learners. Agnes has the more difficult job.

In July, Bruce went on his own to the International Council of Psychologists convention in Melbourne, where, after three sometimes-tumultuous years at the "high table" he stepped down as Past President. ICP is one of Bruce's passions, it's not up there with opera or food or hockey, but a passion nonetheless. Unlike most psychology associations, this one has real feeling and caring if sometimes erratic people in it. The feeling and caring make it worthwhile.

After Melbourne, back to Singapore to help out the National Institute of Education with their new applied psychology program. And then back home sweet home to be greeted by a nephew, Paul, and his new bride, Rebecca, and Paul's mom, Margaret, Agnes' sister, visiting from Adelaide. We took them to (where else) to Jasper and Banff – our holy places. We had a family reunion, with family arriving from Adelaide, Houston, Vancouver, to celebrate Agnes' mother's eightieth birthday, a moving event for a grand lady.

Politics in Canada was normal in nineteen ninety-eight. The federal government governed by not governing. The provincial governments governed by appealing to the federal government to government, according to each province is provincial agenda. The provincial election in

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Québec produced characteristic Canadian answers: the Parti Quebecois (the separatist party) won 43% of the popular vote, and won 78 seats; the Liberal Party (the non-separatist party) won 47% of the popular vote and won 32 seats; the other small parties (Marxist-Leninists, Action Quebec, The Rhinoceros, The Green Party, etc.) won 10% of the popular vote and 1 seat (for Action Quebec.) And again the United Nations voted character as the most desirable country in the world in which to live. Are we missing something?

On the health front, Agnes is, as always, in good shape. Bruce, well, good health is not part of Bruce's karma.

His MS has reached a favorable remission point (score one for Bruce) such that, after seventeen years, he was taken off of steroids. But, as we found out, withdrawal from prolonged steroid use is something like withdrawal from alcoholism. It did odd things to Bruce's mind (such as it is) and body (such as it is). May to September was the worst: dizziness, disorientation, weight gain, heart palpitations, reflux, and wild and erratic mood swings. All this was to be expected Bruce was told by his neurologists. But between expectation and reality were many anxious moments. The withdrawal screaming-meemies seem to be over, we hope. Though now Bruce has tinnitus symptoms!

The nineteen ninety-eight New Year's Eve will be less spectacular than nineteen ninety-seven's. We are off to a warm family new year in damp and chilly Vancouver, where, at the midnight minute, we will drink a heartfelt toast — to each of you.

In ending the '98 year-end tour d'horizon, we would like to share a poem that captures our evolving sense of ourselves at this stage of our lives:

A Prince said, "A painted rice cake does not satisfy hunger."

A Buddha replied, "There are a few who have even seen this 'painting of a rice cake' and none of them has thoroughly understood it.

"The paints for painting rice cakes are the same as those used for painting mountains and waters. If you say the paintings are not real, then the material phenomena world is not real, the Dharma is not real.

"Unsurpassed enlightenment is a painting. The entire phenomenal universe and the empty sky are nothing but a painting.

"Since this is so, there is no remedy for satisfying hunger other than a painted rice cake. Without painted hunger you never become a true person."

May there be a painted rice cake in your New Year.

Be well, Bruce and Agnes, and Suki

Looking Forward

The following suggestions made by Past President Tara Pir during her By Laws review were presented to the ICP, Inc. Board of Directors at the 2015 Annual Board Meeting in Toronto, Canada on August 3, 2015. Member comments welcome. Email Dr. Florence Denmark at: fdemark@pace.edu and copy Dr. Ann Marie O'Roark at: annoroark@bellsouth.net. Thank you.

ARTICLE 1. CERTIFICATE OF INCORPORATION
CONNECTICUT CERTIFICATE OF INCORPORTATION

1.1 The name of the corporation is the International Council of Psychologists, Inc.
Proposed name change to "International Council of Psychologists & Allied Professionals." (TP)

1.2 The duration of said corporation is unlimited.

1.3 The International Council of Psychologists, Inc. is a nonprofit corporation, governed by the bylaws, organized exclusively for educational and scientific purposes. Its purpose is to advance psychology and the application of its scientific findings throughout the world.

1.4 The Board of Directors consists of the Officers and Directors-at-Large of the Board of Directors, elected in accordance with the Bylaws.

1.5 The officers are the President, President-Elect, Past President, Secretary, and Treasurer, all of whom are elected from Members of the International Council of Psychologists, Inc. in accordance with the Bylaws.

1.6 A meeting of the Board of Directors and a general membership meeting both will occur at ~~the International Council of Psychologists, Inc. Convention site~~ annually(TP). The Board of Directors may hold additional meetings as needed either in a single location or viaelectronic means.

1.7 No part of the Council's income is distributed to its members, directors, or officers, and the Council shall not have to issue shares of stock or pay dividends.

1.8 Upon the dissolution or other termination of the Council, the Board of Directors will select another organization dedicated to educational or scientific purposes in the field of psychology, to which to

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transfer such assets as remain after the payment of

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all liabilities.

ARTICLE 2. MEMBERSHIP

2.1 ~~Types of Membership~~. There are two ~~classes~~ categories of membership: Individual and Organizational. Individual Members include Allied Members and Student Affiliates. (TP)

2.2 Members are health, mental health professionals, ~~and~~ social scientists, and others from diverse helping professions (e.g., attorneys, physicians, chiropractors) from both traditional and nontraditional practices (TP) who (a) hold or are eligible to hold membership in their discipline related national professional association,and (b) have been actively engaged for a period of not less than two years, prior toapplication for membership, in professional work or study that advances the science andpractice of psychology and supports the use of psychological, health, and other helping professional (TP) knowledge to promote socialhealth and justice globally. This is consistent with the ICP Mission.

2.3 Student Affiliates are graduate students enrolled in an academic program leading to an advanced degree in psychology or in an allied ~~mental health~~ helping profession or social science.

2.3.5 Organizational Members are academic and other service organizations that share the mission of ICP. Member organizations and ICP make a commitment to mutually promote the mission of the respective organizations in their networking contexts, inclusive of websites, conventions, conferences, etc. Each organization would identify a Liaison to represent the organizational member at ICP and provide status reports on an annual basis of their activities. (TP)

2.4 Privileges and Benefits of Members.

Full Members in good standing, inclusive of allied members, (TP) are entitled to:

2.4.1 Vote in all member elections and on all propositions submitted to the membership

2.4.2 Receive regularly issued publications free of charge; receive discounts on other publications or on registration fees as may be established by the Board

2.4.3 Hold elective or appointive office, and receive other privileges granted by theBoard or specified in the Bylaws.

2.4.4 Student Affiliates receive all the privileges of Members, except the rights to v~~ote and h~~old elective office.

2.5 Applications for Membership. Each must be submitted with first year dues and are reviewed by the Membership Committee for recommendation to the Board of Directors for membership status approval.

2.6 ~~Resignation, Termination and Reinstatement of Membership~~. Termination of membership occurs under the following conditions: (1) for nonpayment of dues; (2) for unethical practice or unprofessional behavior, or conduct reflecting unfavorably upon the association or scientific psychology.

2.7 Reinstatement of a former member whose resignation had previously been accepted, or who has been terminated, is considered by the membership Committee. Upon receipt of the reinstatement request, submission of a new application for membership and the payment of dues, the Membership Committee shall act upon the request.

2.8 Members may not act as a representative or agent of the International Council of Psychologists, Inc. without specific, written authorization by the President or as specifiedin these Bylaws.

ARTICLE 3. EXECUTIVE COMMITTEE & BOARD OF DIRECTORS

3.1 The Board of Directors consists of five Officers comprising the Executive Committee and 6 six (TP) Directors-at-Large. The President, President-Elect, Past-President, Secretary and Treasurer comprise the Executive Committee of the association.

3.2 The President is the executive-in-charge of management and leadership of the association and has just completed an elected term as President-Elect. Following the Presidential ~~year~~term, this officer serves as Past President in the next term. (The term is presently two years. There is a motion before the Board to change this to a one-year term.) (TP)

3.3 The Secretary and Treasurer are elected for terms of three years. The Secretary and Treasurer are elected in different years so their terms are overlapping but not identical years. The Secretary and Treasurer can serve consecutive terms.

3.4 Board members are elected annually from a slate of candidates who have agreed to be nomi-

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3.5 Two Directors-at-Large of the Board are elected each year to serve three-year terms.

3.6 Board members are installed during the outgoing Board meeting that follows their election. They serve until successors are duly elected and installed, or are replaced byappointment by the President after being absent for two consecutive board meetings.

3.7 Board Meetings

3.7.1 It is mandatory that elected Officers of the Board of ICP attend two annual Board Meetings, either in person or electronically. ~~The Outgoing Board session is scheduled for a day and a half prior to the opening of the convention.~~ Board Members are required to correspond, communicate, and respond to email on an ongoing basis.

3.7.2 Both the Outgoing Board session and the Incoming Board session may or may not be scheduled to occur in conjunction with our annual Convention (TP), as determined by the Board of Directors. The Incoming Board session is scheduled following the outgoing Board and Membership Meeting, but within the convention period. ~~The Incoming Board session is scheduled following the outgoing Board and the Membership Meeting, but within the convention period. When business before the Incoming Board is completed, the Board adjourns sine die.~~

3.8 ~~Additional~~ Special meetings of the Board may be called at any time at the discretion of the President with the concurrence of at least ~~four~~ two (TP) members of the Board Directors. Formal notice of a Special Meeting must state~~s~~ its purpose and only business related to that purpose should be transacted at that Special Meeting.

3.9 Open Board Meetings. Members of ICP are encouraged to attend Board Meetings as observers. Observers do not speak except upon specific invitation of the President. Meetings are to be held in rooms of a size to accommodate observers.

3.10 Quorum. Decisions at meetings of the Board are made by majority vote of the Directors present and voting. No policy or action can be approved that could endangerICP's status as a : Non-profit 501(c)3 educational organization recognized by the Internal Revenue Service of the United States of America.

3.11 The Executive Committee of the Board consists of the five elected officers. They are responsible for conducting the business of the association between regular Board meetings.

3.12 Each officer prepares an Annual Report to the Board in advance of the Annual Board Meeting in time for inclusion in the Annual Board Agenda Book.

3.13 The Board of Directors amends Board Rules as needed, submits changes in bylaws, incorporation, or policies for membership vote, assures conduct of Board and Membership meetings in accord with Robert's Rules of Order, and ensures that AP&P procedures and rules are followed by officers, committees, agents, delegates, and staff except that, where there is a conflict between either Robert's Rules of Order or AP&P procedures and ICP's Bylaws, the latter will control. (TP)

3.14 The Board reviews, amends, and approves the annual operating budget presented by the Treasurer for the coming calendar year.

3.15 The Board receives and approves Convention proposals [sites, dates, hotel, budget projections,]

3.16 The Board reviews proposals for regional meetings, inter-convention workshops, other area chair meetings, and authorizes the President to appoint *ad hoc* ~~ad hoc~~ committees as deemednecessary. The Board may establish or eliminate *ad hoc* committees as necessary. (TP)

3.17 The President is Chief Executive Officer and Chairman of the Board for the International Council of Psychologists, Inc.

3.18 The President Elect [PE] assumes duties of President in the event of the latter's absence, resignation, or inability to perform the duties of office.

3.19 The Past President [PP] manages the Nomination and Election (N&E) process.

3.20 The Secretary is responsible for the preparation of all minutes of Board meetings, Executive Committee meetings/issues dialogues/votes, and Annual Membership Business Meetings. As required by federal and state incorporation regulations, the Secretary signs or cosigns official correspondence, resolutions and documents with the President or other designated agents of the association.

3.21 The Treasurer has primary fiduciary responsibility for ICP financial operations, presents accounting reports and operating budgets to the Board, reviews ~~conference~~Convention (TP)

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budgets and manages reserve funds.

3.22 The Board of Directors functions in conformity with the Certificate of Incorporation, the By-laws, Board Rules, and ~~Council~~ ICP (TP) Policies.

3.23 The responsibilities of Board as a whole include: monitoring and oversight of the work of ICP ~~the Council~~ (TP); determining general policies, making and amending rules for the conductof governance meetings, procedures established for ICP ~~Council~~ (TP) programs and activities, and procedures established to guide officers, committees, agents, delegates, and staff; and forsubmission of an annual report to the President andBoard.

3.24 The Board reviews and approves the association's annual operating budget, investments, and annual accounting reports, IRS reports, and convention hosting proposalsand budgets.

3.25 Each Board member keeps a current record of procedures and a compilation of the papers of the office, which are transferred to the successor in the role.

3.26 ~~The Board may establish or eliminate ad hoc committees as necessary.~~ (moved to 3.16.) (TP)

ARTICLE 4. CENTRAL OFFICE OR SECRETARIAT

4.1 The Board may establish a central office or Secretariat to support the mission of the association by supporting elected Board members and appointed leaders in the conduct oftheir duties.

4.2 A central office may serve as the clearing house for communications and information exchange.

4.3 The manager of the central office is responsible directly to the ~~President~~ Executive Committee. (TP).

ARTICLE 5. STANDING COMMITTEES AND WORKGROUPS

5.1 The Standing Committees of ICP are: Archives; Area Chairs; Continuing Education; Finance Committee; ~~Conference~~ Convention (TP) Long Range Planning Committee; Nominations & Elections, and United Nations Committee. Standing committee chairs are appointed by thePresident to three year renewable terms and presented for Board approval at the IncomingBoard meeting.

~~8.2 10~~.5.2 (TP) Working Groups and Task Forces include Professional Concerns; Liaisons; Bylaws; and Policies and Procedures Updating.

ARTICLE 6. CONVENTIONS AND MEETINGS

6.1 A convention is held annually, unless ~~prevented by natural disaster, war, or decision of~~ decided by the Board. ICP Conventions may not be limited to an annual convention. Through collaboration and sponsorship with organizational members from many parts of the world, ICP may conduct as many regional Conventions (TP) throughout the year in order to create opportunities for our world members to attend one or as many as they choose. (TP)

6.2 The annual convention may include some or all of the following: Board Meetings; a Membership Business Meeting; a Scientific Program, professional development and Continuing Education.

6.3 The annual convention schedule is developed under the leadership of a ConventionArrangements and Program Chair, appointed by the President-Elect, who chairs the Annual ~~Conference~~ Convention (TP) Working Group with the support of the Local Arrangements Chair and ~~Conference~~ Convention (TP) Long-Range PlanningCommittee.

6.4 Annual Convention, Regional and Ancillary or Embedded program proposals are presented to the President, Long Range ~~Conference~~ Convention (TP) Planning Chair, and Treasurer for review and authorizations.

ARTICLE 7. FISCAL YEAR, DUES, AND DONATIONS

7.1 The ICP fiscal year is the calendar year.

7.2 Annual dues are determined and approved by the Board and solicited on a calendar year basis.

7.3 Donations or contributions are accepted, recognized and acknowledged with the non-profit laws and rules.

ARTICLE 8. COMMUNICATIONS AND PUBLICATIONS

8.1 The International Psychologist (IP) is the official newsletter for ~~the Council~~ ICP. (TP)

8.2 The IP newsletter is disseminated quarterly ~~three times a year~~ with supplements as authorized by the President.

8.3 The ICP Journal [WORLD PSYCHOLOGY], Membership Directory & Leaders Guide are prepared, published and disseminated as authorized by the Board

8.4 ICP's Annual Convention Proceedings are published as feasible.

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8.5 ICPweb.org is the official internet website for ~~the Council~~ ICP.

8.6 ICP will develop a LISTSERV and email addresses associated with ICP's website. (See my motion.) (TP)

ARTICLE 9. AMENDMENTS

9.1 The ~~Council~~ ICP (TP)Board of Directors may submit for membership vote amendments to the Bylaws that are consistent with ICP's ~~the Council's~~ Certificate of Incorporation, which are ~~and~~ (TP) deemed necessary for the efficient management of the affairs of ~~the Council~~ICP.

9.2 Adoption of amendments is determined by a majority vote of those members voting.

9.3 Amendments to the Bylaws may be proposed by any member of the ~~Council~~ Board of Directors.

9.4 Votes of the membership are conducted under confidentiality conditions and may be executed through either print or electronic means.

9.5 Proposed changes to Certificate of Incorporation or Federal Tax Exemption status are reviewed and approved by the certifying agencies prior to submission for membershipvoting.

* * * * * *

Notes on changes:

1. Recommended deletions are identified by strike-out (~~Example~~).
2. Recommended additions are identified by red type (Example).
3. Paragraph 2.1. there is repetition
4. Paragraph 2.2. is self explanatory
5. Paragraph 2.4 the word Full is redundant
6. Paragraph 2.5 Correction of plurality. By deleting 'each' and combining the two statements it reads easier.
7. Paragraph 2.6 This is redundant as it goes on to explain each category independently.
8. Paragraph 3.1 **Nine** has been changed to **six** as it is believed that for the current size of ICP six is sufficient. Additionally it has the advantage of making decisions easier and in less time along with alleviating the need to find so many willing to serve asboard members. With the current size of ICP having one board member for every ten or so people is viewed as unwieldy and unnecessary.
9. Paragraph 3.2 Since the President Elect is by definition the next president, stating that the term follows the term of President Elect is viewed as redundant.
10. Paragraph 3.3 While it is nice to have the Secretary and Treasurer re-elected, past history would suggest that consecutive terms is not only advisable but practical.
11. Paragraph 3.5 by electing two each year instead of four there will be a naturalattrition from the current level to the recommended level over the next years with everyone currently in position able to finish their term of office.
12. Paragraph 3.8 Additional changed to 'Special' to conform to the rest of the paragraph.
13. Paragraph 3.8 the addition of must requires inclusion of purpose and the deletion of the 's' is to match plurality.
14. Paragraph 5.2 Numbers were changed to maintain continuity as it appears thoseparagraphs were copied over from another source. The insertion of 'include' is stylistic in that it helps the paragraph read easier.
15. Paragraph 6.1 Since the Board will ultimately make the decision, and since a Board Meeting does not really qualify for a conference, "prevented by natural disaster, war, or decision of" is replaced with "decided by".
16. Paragraph 8.2 It is recommended that the IP come out three times a year as it is already in the by-laws that supplements can be made. Also, there is historically difficulty in getting articles or meeting deadlines for the IP.
17. Paragraph 9.2 The addition of, "of those members voting" precludes the argument that a decision was made by few if only a few choose to vote.
18. Paragraph 9.3 The term "Council" is redundant.
19. Paragraph 9.4 The 'ity' deleted, as confidential is an adverb describing the conditions
20. The AP&P are generally contained within the current by-laws. Since the by-laws state that all decisions are made by the Board or the President, the manner in which those decisions are made will generally be determined at that time by the President or Board respectively. When ICP was larger and more people were involved in the decision process, there was a need for the AP&P. A perusal of the AP&P would suggest that most of the contents are either repeating the by-laws or are common sense. Additionally, each major sub-committee answers to the Board so decisions made within those committees are overseen by the Board and any discrepancy or alteration in form can be discussed and determined or corrected at that time. Finally, those currently active in ICP have demonstrated a strong commitment to the organization and it is unlikely that they would attempt to function in a way inconsistent with the goals or interests of ICP. Therefore it is recommended that the AP&P be retired and the organization function on a less structured basis.

# #

UPDATES REGARDING THE 2016 74th ICP, INC. ANNUAL CONFERENCE and BOARD MEETING

MACHIKO FUKUHARA,
PhD, JAPAN
Local Area Chair, Scientific Chair,
President-Elect

Since I wrote the P-E Column for IP55.4, one month has already passed. At the beginning of this New Year, I pray for peace in the world and for all peoples' well-being.

The 74th annual conference, ICP, Inc., Yokohama, is coming closer. With the LAC, I am working very hard on the preparation so that it will be an exciting and informative event for all of the participants. A draft of the entire program for the Conference has just been completed.

We are receiving Proposals for Presentations for symposia and papers. Together with those of the invited speakers, we have many responses from people who wish to contribute to the sessions. The diversity of their academic interests tells us that our Association's philosophy of multicultural and interdisciplinary approach to human beings is resulting in a wide interest among our participants.

I wish to thank those who have applied and I am encouraged by your interest in our Association. We still encourage your participation in the Workshop (during the afternoon of the 22nd), and the Conversation Hour (on the afternoon of the 25th). These sessions are planned especially for early career scholars and practitioners, including those from both underdeveloped and developed countries. We would like to encourage an exchange of scholarly discussions and friendship on an international level. This is one of the features of this Conference. We welcome you!

Blessings to you for your well-being,
Machiko Fukuhara, Ph.D.
P-E and Chair, Local Arrangement Committee

(For more information, please contact the Tokyo Office, ICP, Inc. at icpinc.tky-office16@nifty.com). Also, we encourage you to apply for Poster and Inabsentia Poster presentations, (For these, please contact one of the following annoroark@bellsouth.net or annalaura.comunian@uipd.it).

HOW TO REGISTER FOR THE JAPAN CONFERENCE(S) & HOTEL

Those attending **both** ICP2016 and ICP, Inc. are allowed to pay ONE registration fee to cover both. [Registration rates will vary with registration period. Also, check exchange rates at time of payment for accurate conversion values.]

To register, open the ICP2016 home page [The ICP2016 website address is: http://www.icp2016.jp/] and complete your Registration. THEN, *email your ICP, Inc. registration form to Ms. Nancy Quatrano,* for participation in our conference. Nancy@OnTargetWords.com.The form is on our website. Click on DOWNLOAD REGISTRATION FORM under the Membership tab.

You can enjoy the entire program and social events (July 24-29) planned by the Congress (ICP2016). In addition, ICP, Inc. will have 2 rooms (for July 23-24) independent from ICP2016.

Those attending only the ICP, Inc. Conference (July 22-25) can participate in the cultural tours ICP2016 has planned by contacting Japan Tourist Bureau (JTB) at their venue desk and by paying the necessary fees.

Both ICP2016 and ICP, Inc. participants can book accommodations by contacting hotels contracted by JTB for reduced prices. They are listed at **the ICP2016 home page.** (You can open the ICP2016 Homepage and choose a hotel of your choice listed there.) http://www.icp2016.jp/accommodation.html You must make your own hotel arrangements.

Please do that as quickly as possible. The deadline is June 1, but rooms may sell out before that date.

We hope to see you there for this very exciting time!

Machiko Fukuhara, Ph.D.
P-E and Chair, Local Arrangement Committee

~CORRECTION~

In the International Understanding 55.2, the order of presenters was incorrect for one of the abstracts presented. Here is the correct information for that article:
2015: *Relationship Among Sense of Coherence, Gratitude and Well-Being,* Tomoko Fujitani, Ami Kojima, Dr. Yoshiko Kato
73rd Annual ICP, Inc. Conference, Toronto, Canada, Aug 1-3, 2015

NEW: PLEASE NOTE SPECIAL ARRANGEMENTS

International Council of Psychologists (ICP, Inc.)
74th Annual Conference
22-25 July 2016, Yokohama, Japan

Conference Theme: Psychology for World Equality, Access and Well-Being

Conference date

The 74th Annual Conference of the International Council of Psychologists (ICP Inc.) will be held on 22-25 July, 2016, in Yokohama, Japan. Don't miss this excellent opportunity to share ideas and to engage in face-to-face discussions with fellow colleagues! The International Congress of Psychology (ICP2016) will be held at the same place during and after our meeting, so there will be ample opportunities to meet psychologist colleagues from all over the world.

Conference venue

Pacifico Yokohama is one of the most distinguished convention centers in Japan. It is located in the waterfront of Yokohama Bay and consists of a Conference Center, an Exhibition Hall, a hotel and the National Convention Center of Yokohama. The buildings, modeled after a yacht sail and a shell, are impressive from both the sea and land sides.

Conference registration special

SPECIAL ARRANGEMENTS HAVE BEEN MADE FOR ATTENDANCE AT BOTH OF THESE CONFERENCES! If you will be attending both events, you will only pay *ONE FEE* for the two conferences. That must be done at the ICP2016 (Congress) website where you will indicate that you are attending both ICP2016 and ICP, Inc. Then notify Nancy Quatrano by email that you will be attending the 74th ICP, Inc. conference and send her your registration form, but do NOT pay any additional fee. *ALL HOTEL ARRANGEMENTS MUST BE MADE BY THE ATTENDEE.*

IF you are attending ONLY the 74th ICP, Inc. conference, you will complete your registration form and then you'll need to pay the appropriate fee at the ICP, Inc. website via the button provided there. That link is: ICPWEB.ORG

Country category	A	B & C
Membership category	US$	US$
Full member	300	200
Allied professionals – non member	350	350
Student		
Member	100	100
Non-member	130	130
Accompanying person	150	150
After June 1, 2016 (including On-site registration) Add $50.00		

Registration fees include admission to all scientific sessions, reception, tea breaks and conference material. For accompanying person, registration fees include admission to the reception.

DEADLINES TO REMEMBER:

JANUARY 15, 2016 – SCIENTIFIC PROPOSALS ARE DUE

JUNE 1, 2016 – REGULAR REGISTRATION FEES ARE DUE

FOR MORE INFORMATION, EMAIL: ICPINC.TKY-OFFICE16@NIFTY.COM

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Please visit the website for ICP, Inc. information and conference updates at ICPWEB.ORG
Email address: ICPINCUN@Gmail.com

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2016 dues are LATE after January 30, 2016! The fee for paying late is $15 extra. Why not pay them now?

Easy to do at the website—just go to **www.icpweb.org** and click on the MEMBERSHIP tab at the top! From there, just fill in your dues amount and payment type. Thank you.

ICP, Inc NEEDS YOU for the ICP board in 2016! Contact Past-President Tara Pir via email if you are interested. Email: TaraPirImces@msn.com

CALL FOR MANUSCRIPTS

Please submit manuscripts using APA style, MS Word, 11 pt. Times New Roman to the Editor at annoroark@bellsouth.net. The *IU* is published two to four times yearly, according to the number of manuscripts received. *IU* submissions are screened for style and professional content. Submissions may be returned for revisions as needed. We invite your participation.

Ann O'Roark, Editor

Continued next page

American Psychology Association (APA)
A Publication of the Society of General Psychology - Division 1

The General Psychologist

American Psychology Association (APA)
Society for General Psychology

Volume 49, Issue 2 April 6th, 2015

Stop! Don't flip that electric switch!

Chronicling the experience of Ed English - Camera-man for Stanley Milgram's experiment

As cameraman and editor for Stanley Milgram's original documentary "Obedience," I have, over the years, come to believe that his experiment never attained the impact on society at large that it might have had. I suggest, in this personal comment, that it was too powerful to receive acceptance at a time when the authority of the government and military establishment were being challenged. The many comparisons of the study to the tragedy of the Holocaust overshadowed most applications of the study to the war in Vietnam. Sadly, the more sensational aspects of the study were emphasized, often out of context, except among an informed minority. My hope is that scholars will work to correct this for Milgram himself, the psychology profession, and the good of society.

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Stop! Don't flip that switch!

By Edward English

Introduction

On August 28, 2013, I was surprised to hear a review on National Public Radio by Leonard Lopate of Gina Perry's book on Stanley Milgram's "Obedience" experiment. Serendipitously, the author requested an interview with me the next day. She did extensive research for her book, and, she was interested in speaking with me because I'm listed in the film credits of "Obedience", a documentary record of the Milgram experiment.

The title of Gina Perry's book "Behind the Shock Machine: The untold story of the notorious Milgram psychology experiments" (2013) indicates how the publisher may be trying to capitalize on the sensationalism that has undermined Milgram's powerful experiment through the years. The psychology profession has frequently debated the controversial ethical aspects of the experiment, thereby not encouraging further research except for "Milgram lite," (Burger, 2009; Elms, 2009). Ms. Perry told me that she had studied Milgram in her early psychology courses and was intrigued, as many other students were, with the set-up for the experiment.

In 1960, when I graduated from the free, public City College of New York, I was fortunate to land an assignment at the prestigious Yale University, to make Russian language training films for the US Office of Education. The University also gave me the opportunity to work with Stanley Milgram. He explained that the experiment he was conducting may expose the inherent dangers in blindly obeying authority. Publically, two subjects were recruited for the experiment to investigate if electric shock given as punishment can improve learning. The "leader" of the experiment asked the two subjects to draw slips of paper to decide who will be the "learner" and who will be the "teacher." The drawing was rigged so the newcomer was always the "teacher" and the actual "subject" of the experiment. The "learner" and the "leader" were both trained as confederates (acting according to Milgram's instructions). I understood the experiment was really designed to find out if, and how far the newcomer or "teacher/subject" was willing to follow orders from the "leader/actor" even when it seemed increasingly apparent that the "learner/actor" was experiencing pain. Predictions, prior to the actual experiment, even by psychiatrists, stated that only a pathological fringe of one or two percent would continue through to the maximum shock of 450 volts, (Milgram, 1973a). Astonishingly, the results of the experiment showed that almost half of the "teachers" across different experimental variations willingly inflicted electric shock punishment on the "learners," (Milgram, 1973a).

> Filming secretly over 50 years ago, behind a two-way mirror, I could not believe as I was zooming in on the faces of many of the "teachers", that they could conceivably flip to the next higher voltage switch to shock the poor "learner,".

Filming the 'subject' experience

Ms. Perry said she was greatly influenced by the 1975 CBS TV program, "The Tenth Level," featuring William Shatner playing Stanley Milgram. The film opened dramatically with a camera shot of a train transporting Jews to the gas chamber. Much later when she began her research and diligently interviewed all the participants in Milgram's experiment, she learned how deeply the subjects felt the shame of being compared on national television to people who allowed the atrocities of the Holocaust because they claimed to be just obeying orders. This raised serious doubts for her about Milgram's experiment that she detailed in her book.

I told Ms. Perry I was very grateful to her for explaining the plight of the participants to me. I had not thought of this specifically before and am deeply sympathetic to them. (I never saw the CBS TV version.) I still vividly remember many of the people she interviewed and I too have had troubling thoughts over the years but from a decidedly different perspective.

Filming secretly over 50 years ago, behind a two-way mirror, I could not believe as I was zooming in on the faces of many of the "teachers", that they could conceivably flip to the next higher voltage switch to shock the poor "learner". Their actions continued even after escalating calls from the 'learner' asking to stop, demanding to be let go, crying out in agony, pleadings because of a heart condition, to ultimately non-responsiveness. At this point only the sound of the switch being clicked at 450 volts was heard. And all this merely because of routine-sounding prompts to continue by a man in an off-white lab coat with a clip board who sat nonchalantly behind the "teachers."

This took place *after* I had filmed the "teachers" undergoing a slight shock themselves to feel what would be given to the "learner." Each "teacher" was asked to sit in an old-fashioned, wooden chair with flat arm supports. Some special electrode paste was applied to the arm that was to be shocked. It was explained that the paste would help to avoid blisters and burns. A mild shock was given and each subject said they definitely felt it. The leader told them it was only 45 volts. Casually, the "teachers" were given a paper towel to wipe their forearm and then led into an adjacent room in order to administer the test objectively apart from the "learner" who had been left strapped into what resembled an electric chair.

Continued on page 15

President's Column
Joan C. Chrisler, Ph.D.

It is difficult to believe that my presidential year is more than half over already! The time has flown by, but a lot has been accomplished. Here I will share some of the highlights with you.

Our energetic program chair, Maria del Pilar Grazioso, has put together a diverse and interesting set of papers, posters, symposia, and conversation hours for the Toronto APA convention. In addition, of course, we have invited addresses by last year's award winners, and several other invited addresses and invited panels. She and her team of student assistants are at work now planning activities to take place in our divisional hospitality suite. I hope that many of you will be able to be in Toronto to enjoy the program.

2015 marks the 70th anniversary of the founding of Division 1, and we will be celebrating 70 years of bringing psychology together. If you will be in Toronto, please plan to join us at the Division 1 Social Hour to eat anniversary cake and share your favorite memories of the division's activities and accomplishments at our open mic. We will offer a ticket for a free drink to the first 70 students and early career psychologists to arrive at the social hour. Information about the history of the division, including daily trivia sheets (Come every day to collect them all!), will be available in our hospitality suite. So, please, spread the word that Division 1's Social Hour and Hospitality Suite are the places to be in Toronto this August. *We're number one!*

On February 28th, at the APA building in Washington, Division 1 held an unusual midwinter meeting of the extended executive committee. Sixteen of us attended. It proved to be an excellent opportunity for us to develop our working relationships (the EC has many new members), to plan the anniversary celebrations, review what we are currently doing as a division, and to consider what we might like to do in the future. All of us agreed that the meeting was a success.

One of the things we did at the meeting was to revise our division's mission statement and develop a set of goals. (You will be able to read these documents elsewhere in this issue of the newsletter.) The goals we developed are intended to be both descriptive and aspirational. That is, they cover all of our current, traditional activities (i.e., our awards, the newsletter, the journal, the convention program, the Staats lecture), and they are broad enough to encompass new program initiatives we might take (some of which were discussed at the meeting, but others we have not yet imagined).

Our treasurer, Deborah Johnson, reported to us that we are in excellent financial shape, and she presented us with a 2015 budget, which we tweaked a bit and then voted to implement. We agreed that we would use our newly established goals to guide our budgeting so that we spend our funds primarily on projects and activities that contribute to the achievement of our goals. Our treasurer expressed concern that we have too much money in our checking account, and we agreed to seek information and advice about investing it more wisely. If any of you have experience with investment committees in other divisions, please write to Deb with your ideas for how we should proceed: djohnson@usm.maine.edu. We also discussed the possibility of setting up a fund with the American Psychological Foundation (APF). Our president-elect, Nancy Baker, is heading up an ad hoc committee to discuss the cost and feasibility of such a program. Several ideas were entertained about how we could allocate money from the fund once it is established. We will be sure to let you know the outcome of these discussions after the ad hoc committee reports back to us at our August meeting.

We heard interesting reports from our Membership Chair, Mark Sciutto, and our Student Representative, Emily Dow. Both told us that the most frequent reason why people join Division 1 is because someone asked them (or told them!) to do so. Like many (if not most) APA divisions, our division's membership is skewing older than the traditional retirement age of 65. If we are going to survive and thrive for the next 70 years, we need to recruit and retain new members, especially those at the beginning of their careers. If you want to celebrate Division 1's anniversary, whether you can attend the party or not, the best way to do so is to reach out to a colleague or student and invite her or him to join Division 1. Look for a membership form elsewhere in this newsletter. Feel free to copy the page and distribute it.

We discussed membership trends at length during our meeting, and we decided to do several things: 1) to survey members who have left the division to find out why they did not renew; 2) to do more membership outreach (such as communication via our divisional list serve) to engage members in divisional activities; 3) to launch a membership drive targeted at faculty who teach at small, primarily undergraduate, colleges and universities, as those faculty are often generalists of necessity, if not by choice. We will be reaching out to Psi Chi and to Division 2 (Teaching of Psychology) as we plan our membership drive. If you would like to join the Membership Committee to work on this initiative, or have ideas to advance the committee's work, or both, please contact Mark: mark.sciutto@gw.muhlenberg.edu.

Continued on page 4

President's Column - Joan C. Chrisler, Ph.D.

..... Continued from page 4

Student members of Division 1 would like more interaction through social media. Our tech-saavy newsletter editor, Alicia Trotman, volunteered to set up a Division 1 YouTube channel. Look for details about her plans and how you can contribute to them elsewhere in this issue of the newsletter. If you are willing to set up a Facebook or Research Gate page for the division, please contact me: jcchr@conncoll.edu. These activities also require a few creative thinkers who can develop and maintain the pages once they are set-up. These do not have to be time-consuming projects, but they do mean looking for ideas to post and thinking about how to make the pages interesting. If that sounds like something that you (or you and a team of your students could do – maybe as a class project?), we want to hear from you!

Increasing our Social Media Presence

If you are willing to set up a Facebook or Research Gate page for the division, please contact me: jcchr@conncoll.edu

The Division's Portraits of Pioneers in Psychology book series continues to sell well and provide us with annual royalties. The most recent volume, Portraits of Pioneers in Developmental Psychology, was published in 2011. Over the past few years, we have talked during our meetings about a desire to develop new volumes for this series, but we have not progressed beyond discussion. What we need is a series editor to take charge, give this some thought, propose topics, solicit people to edit books on those topics, and serve as liaison with our publisher. This is a great job for someone with an interest in the history of psychology, as the books contain biographies of major contributors to the field. If you are interested, please contact me: jcchr@conncoll.edu. If you know colleagues who might be interested, please ask them to contact me.

As I close, I would like to express my thanks to the extended executive committee of our division for their work, advice, and support during my presidential year. I am grateful to them all! In addition to those mentioned above, I thank Janet Sigal, Anita Wells, Jocelyn Turner-Musa, Richard Velayo, Mindy Erchull, Gerianne Alexander, John Hogan, Carrol Perrino, Sue Dutch & Sue Frantz, Terece Bell & Nicholas Noviello, and Wade Pickren.

Happy spring, everyone! See you in Toronto, eh?

American Psychology Association (APA)
Society for General Psychology

Why should I become a Member of Division 1

Because we are number 1!!!

Contact Emily Dow if you are a student! She is featured on page 9!

Otherwise if you have any questions, check out our membership brochure on page 10 designed by our Membership Chair: Mark Sciutto (mark.sciutto@gw.muhlenberg.edu)!

Division 1 Mission Statement and Goals

Mission

The Society for General Psychology (APA Division 1) is concerned with creating coherence among psychology's diverse specialties by encouraging members to incorporate multiple perspectives from psychology's sub-disciplines into their research, theory, and practice . Division 1 welcomes membership from academics, scientists, practitioners, psychologists whose main concern is the public interest, and students of psychology.

Goals

The goals of the Society for General Psychology (APA Division 1) are to:

1. Promote awareness of general psychology as an integrative approach to the field of psychology;
2. Advocate for connection and coherence among psychology's diverse specialties;
3. Provide opportunities for integration of multiple perspectives in education, research, practice, and psychology in the public interest;
4. Recognize excellence in general psychology and in the integration of multiple perspectives;
5. Provide networking opportunities to support integrative activity for psychological scientists, practitioners, educators, theorists, historians, public policy advocates, and students of psychology;
6. Support the development of the next generation of general psychologists;
7. Collaborate and cooperate with other APA divisions to develop programs and projects designed to integrate multiple concepts, perspectives, and theories.

Approved March 2015

2015-16 Election Statements

These are the two nominees for the president-elect position.

Irene Hanson Frieze, Ph.D.

Irene Hanson Frieze, Ph.D., is a Professor of Psychology at the University of Pittsburgh. Her current research areas include intimate partner violence, motivation and the migrant personality, and cross cultural work on changing gender-related beliefs. Her work is widely cited [h index=49, with over 10,000 citations]. Her most recent book is Hurting the One You Love: Violence in Relationships, published in 2005. She is working now on a revision and update. She was Editor of the Journal of Social Issues from 2001 to 2005, and is currently Editor of Sex Roles: A Journal of Research (beginning in 2007). Her Division 1 service includes membership on the William James Award Committee this year. She is a Fellow of Divisions 8, 9, 34, 35 and 52, and also is a member of 1 and 51. She has served in many roles for Division 9, including being President in 2006-7. She has also been active in Division 35, serving as President from 1983-84. Currently, she chairs the International Committee for Women for Division 52. She hopes to bring her experiences with other Divisions to help build additional networks for Division 1.

Josephine Tan, Ph.D.

Josephine Tan is an APA Fellow with Divisions 1, 12, 35, and 52, and a tenured clinical faculty at Lakehead University, Canada. She is active in research and has published in areas related to psychopathology, gender, and culture. She has received national research grant funding, presented at scientific meetings and other events including at the United Nations, and served as a journal and grant reviewer. Her service record includes President of the Canadian Council of Professional Psychology Programs (CCPPP, 2009-2010), Council Member of the College of Psychologists of Ontario (2004-2007), and more recently, as Member-at-Large and Awards Coordinator for Division 1 (2011-2014). As the Awards Coordinator, she regularly updated the Awards Manual, ran the Awards program, and liaised with APA, APF, APS, award committee chairs, and award winners. She received the Division 1 Presidential Award for her work. She continues to serve Division 1 in a joint task force with Division 2 on core curriculum in introductory psychology. She has received other Division 1 awards, the 2008 CCPPP Award of Excellence in Professional Training (Academic), and was recently selected as one of Lakehead University's 50+ research success stories in its 50-year history. She is also a Psi Chi faculty advisor and active mentor. Her vision for Division 1 includes the promotion of integrative work across subfields and encouraging participation from early career psychologists and students in divisional matters. She considers both to be important to the continued vitality and future of Division 1.

2015-16 Election Statements

These are two of the three nominees for the member-at-large position.

Mark Sciutto, Ph.D.

I am honored to be considered for a member at-large position in Division 1. I have been actively involved in Division 1 for the past few years. I served as the Division 1 program co-chair at the 2010 APA convention and I am currently serving as the Division's membership chair. The goals of Division 1 (elsewhere in this newsletter) speak to the importance of coherence and connection among the diverse areas of psychology. As a faculty member at a small liberal arts college, the Division's commitment to integration in education, research, and practice are particularly valuable for me; working with undergraduate students in my classes and in my research frequently demands that I be a "generalist". In a field that seemingly is becoming more specialized, I see great value in Division 1 and I hope to have the chance to support the Division's activities as a member at-large. As member at-large, I will be a strong advocate for improving Divisional resources that promote integration, collaborating with other APA Divisions, and reaching out to the next generations of psychologists.

Lisa M. Osbeck, Ph.D.

Lisa Osbeck is Professor of Psychology at the University of West Georgia, where she teaches courses historical and philosophical foundations and comparative theories of psychology. She holds a PhD in General Psychology from Georgetown University. She is the lead author of Science as Psychology: Sense-Making and Identity in Science Practice (Cambridge, 2011), which was co-winner of the William James Book Award from APA Division 1 for 2012 (General Psychology), and co-editor of Rational Intuition: Philosophical Roots, Scientific Investigations (Cambridge, 2014), with Barbara Held. Lisa is a Fellow of the American Psychological Association (APA Division 24) and the Center for Philosophy of Science, University of Pittsburgh. She received the Sigmund Koch award for Early Career Contributions to Psychology in 2005 and the Theodore Sarbin award from Division 24 in 2012. Her involvements with APA governance include several positions on the executive committee of Division 24, including program chair, secretary/treasurer, and Council representative. She was program chair for Division 1 in 2013.

2015-16 Election Statements

This is the third nominee for the member-at-large position.

Maria del Pilar Grazioso, Ph.D.

Maria del Pilar Grazioso is currently the director of a recently approved doctoral program in Applied Psychology at Universidad del Valle de Guatemala. She has continuously strived to foster and develop international collaborations to enhance the training and enhancement of General Psychologists at the research, teaching, and practitioner levels who can consequently further advance the integration and foundations of our discipline.

Her formal international education at the undergraduate, graduate, doctoral and post-doctoral level in Guatemala, United States and Argentina, was complemented by training opportunities in Canada and Europe provided her with an enormous array of perspectives that can enrich her possibility to serve as a Non US based, member-at-large in Division 1. She has been an active member in Division 52, 17 and continuously collaborated with other divisions and associations. She has served in academic, professional, administration, and leadership positions in Guatemala as well as internationally; her work in the Interamerican Society of Psychology attests for this as well as recognitions she has received for her continuous work in favor of the development of the Psychological science, discipline and profession.

She is active in conducting research in cultural, supervision, prevention, family, training, gender, ethics, and community research. She targets funding, publishing, and dissemination as top priorities of her endeavors not only for coordinating efforts but working collaboratively with teams, editorial boards, and task forces.

As a member at large for division 1 she will commit her efforts to enhance diversity in a culturally respectful manner serving to achieve the integrative, generic, and fundamental goals of our division.

APA Presidential Nomination Ballot

The following candidates (in order of number of nominations received) have been nominated to run for president of the American Psychological Association:

Antonio E. Puente, Ph.D.
Jessica Henderson Daniel, Ph.D.
Todd E. Finnerty, PsyD.
Jack Kitaeff, Ph.D. J.D.
Sharon L. Bowman, Ph.D.

Dr. Puente is a Fellow of Division 1.

Ballots will be sent to APA members on September 15th; voting closes on October 29th.

DIVISION ONE STUDENT CORNER

Dear student members of Division 1,

I hope this finds you well into your spring semester! I would like to thank everyone who responded to the brief survey I circulated in January. I presented the results to the Executive Committee Board at the mid-winter meeting, and we discussed the composition of the student membership and student needs in great detail.

Networking seemed to be a priority for many students. As a result, a **social hour just for students** in the Division 1 suite will be scheduled for the APA Convention in Toronto. More details about the social hour will be distributed via the listserv once the suite schedule has been finalized. Similarly, in order to develop networking opportunities outside of the APA Convention, I will be **spotlighting various members of the EC** via the student listserv over the next couple of months. Please keep an eye out for these virtual meet-and-greets! In the meantime, if you have not already done so, please be sure to join our Student Division 1 listserv through the APA listerserv portal (http://lists.apa.org/).

While I am excited to support and promote these initiatives for student members, my term as the Division 1 Student Representative will come to an end in August. I will be circulating a call towards the end of the semester for a new student representative. If you are interested, please email me directly. From personal experience, I can tell you it is a great opportunity to develop professionally and meet some amazing mentors in the field!

I will be at the Convention in Toronto this year, and hope to see you at the student social hour!

-Emily

Emily A. A. Dow, MA

Doctoral Candidate

Developmental Psychology

The Graduate Center, City University of New York

emilydow@gmail.com

Become a member of Division 1 today!

The Society of General Psychology, Division 1 of the APA, encourages students, academicians, and professionals in psychology to be educated and trained across the broad areas of the discipline and to promote unity and coherence in psychology.

To this end, we would like to offer you a **free 1-year membership to Division 1**.

By accepting this free offer you will:

⇒ Receive our biannual newsletter, The General Psychologist;

⇒ Be added to our email list to receive announcements about the society;

⇒ Be cordially invited to involve yourself in all of the activities of the division, such as serving on committees of the society, presenting your research and scholarship at the annual APA convention, and enjoying the congenial fellowship of like-minded colleagues.

Benefits of Ongoing Membership:

⇒ The General Psychologist, the Division 1 newsletter — the best newsletter in psychology

⇒ A subscription to the Review of General Psychology, Division 1's outstanding journal (this can be added to the free membership for an additional $22.00)

⇒ Discounts on Division 1 books, which includes six volumes of Pioneers in Psychology

⇒ Exciting programs at APA that present distinguished award winners

⇒ Great people who support coherence among psychology's many subfields

⇒ Low dues

Please visit www.apadivisions.org/division-1/membership for more information on this exciting offer.

Alicia Trotman, PhD - Newsletter Editor

This issue begins with Ed English's experience filming Milgram's experiment. Here we attain a 'behind the scenes' understanding of the pervasive influence of authority. Social interest under an Adlerian scope clearly was not a motivation for most participants, as we slowly comprehend via Eva Dreikurs Ferguson's article. However, thanks to our historian, John Hogan, we learn that academic freedom, as championed by one of our past Presidents of Division 1, Edward Tolman, was indeed crucial to Milgram's research.

Distinguishing the influence of authority from many different perspectives, including those that are international may be vital to the growth of psychology. Richard Velayo's research with his students on internationalizing the curriculum in psychology may be the first step in that direction. Secondly, reciting Shakespeare plays may help with discerning one's emotional status in charged roles as gleaned form Patrick O'Reilly's article. Thirdly and more importantly, Morton Ann Gernsbacher , our Ernest R. Hilgard winner in 2014, argues in her lecture that there is a need to move beyond dualistic thought to recognize cognitive obstacles that persons may face may actually *not* be obstacles but advantages. The brain automatically rewires itself to cope with loss and gain simultaneously; and dis/ability is redefined. Finally, an opportunity to learn about mindfulness-based practices may be instrumental to comprehending how existence without force is closely and uniquely tied to the present moment transforming thought and action.

Book Review

I had the sincere pleasure reading this book written by Susan M. Pollak, Thomas Pedulla and Ronald D. Sigel. New to this form of therapy, thebook informed me of practices that are proving effective in healing persons with psychological illness, destabilizing anxieties and chronic pain. The authors have utilized their years of experience treating patients and have conducted substantial historical research to compile a volume that details a gradual process of utilizing mindfulness base therapy. They provide a historical basis for every practice and instructional guidelines. In addition, they include a clinical illustration to address when the practice should be used, and with whom it may be most effective. As a result, I find this book to be accessible to anyone who has a keen interest incorporating a new form of therapy or wanting to elevate their current practices with a focus on the 'present'.

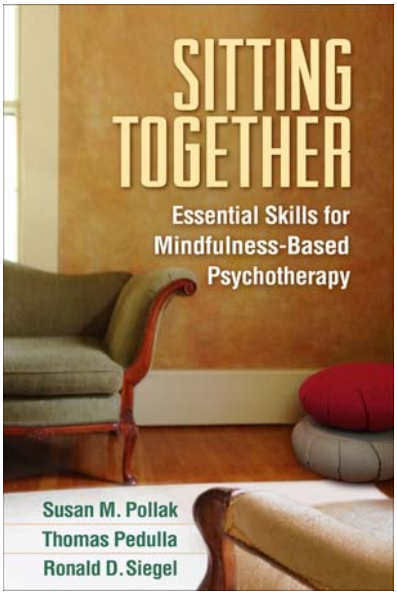

I was fortunate to have the opportunity to interview the first author, Susan M. Pollak, MTS, EdD.

1: *You stated in your preface that the book was intended to provide mindfulness skills to psychotherapists who may encounter different individuals that will require a practice suited to remediating their development. Since its publication, did you witness the book being helpful to other populations as well? If so, in what way?* While the Sitting Together was written for therapists, we are delighted that it is now being used as a textbook in undergraduate and graduate courses. Some professors are assigning a chapter each week to teach the fundamental skills of mindfulness, help students establish their own practice, and safely introduce mindfulness to their patients. Our hope is that Sitting Together will continue to be an accessible, hands-on guide for beginning as well as experienced therapists who want to bring the power of mindfulness into their clinical practice.

2: *There seems to be a mental trend that resisting discomforting memories and experiences spark their persistence. In resisting, we engage in bombastic and pleasurable behaviors to escape the pain that in reality never leaves. As a result, you mention that patients' minds 'create suffering'. Thus, how does mindfulness-based therapy help a patient recognize that the pain is still present? Furthermore, when the pain is recognized, what are some common behaviors patients have consequentially engaged in to manage the pain?* A useful maxim in mindfulness is, "What we resist persists." Or as many meditation teachers put it, "Pain is inevitable, but suffering is optional."

Continued on page 12

2: We are not going to be able to avoid pain, just as we won't be able to avoid sickness, old age, and death. However, we try not to add on to the pain. For example, I am working with someone who sustained an injury while training for a marathon. Before consulting a doctor, she spent hours on the internet diagnosing the problem, and was convinced that she had fractured her hip. She then began to worry that she would never run again, and was sure that if she couldn't run she would never be happy. Clearly, although she was only 23, her life was ruined. As we worked with this situation, she realized that not only was she anticipating the worst outcome but also was adding emotional upset to the physical pain. As we reflected on this, she realized this was a pattern that dated back to childhood. When she saw her doctor and had an MRI, it turned out that her fears were just fears and the injury was not debilitating.. One practice that is very effective for people in pain is the Body Scan, part of the MBSR (Mindfulness-Based Stress Reduction) course developed by Jon Kabat-Zinn. By staying with sensations in the body, bringing kind and gentle attention to them, not resisting or exaggerating them, but simply being with them, many people find that the perception of pain, along with the mental proliferation that often accompanies the pain, decreases and they subsequently have more resources to manage it.

3: *Mindfulness-based therapy involves many meditation practices. Is there yet any experimental data that show the effects these practices have on patients' ability to face painful memories?* This is an excellent question that brings us to the issue of traumatic memories and how to treat them. While MBI's (Mindfulness-Based Interventions) can help with symptom stabilization and reducing hyperarousal, current research suggests that the traumatic memories remain relatively intact. Researchers are now thinking of MBI's as useful adjunctive treatments, in addition to EMDR and exposure-based treatments, which can reduce re-experiencing symptoms. One excellent new book on this subject is Mindfulness-Oriented Interventions for Trauma: Integrating Contemplative Practices., edited by Follette, Briere, et al. (Guilford, 2014). David Kearney's chapter on working with Veterans speaks to this specific question.

4: *There appears to be a heightened bodily awareness that arises as persons engage in mindfulness-based therapy. They feel the sensations from painful emotions and are able to stay with those feelings as opposed to only thought or solely 'thinking about a narrative' that can be destructive to themselves and/or others without feeling. Through the therapy, have you seen patients' ability to stay with these emotions increase, and are they able to apply this skill in different situations? More importantly, when they do face a distressing situation, does 'feeling' come before 'thought' or do they work in conjunction?* Yes, through therapy and continued daily mindfulness practice there is often increased bodily awareness. Patients can learn to stay with painful emotions, learning to ride the waves of strong feelings. One phrase from a meditation teacher that we have found useful is, "You can't stop the waves but you can learn to surf." Mindfulness practice teaches us is that no thought, no feeling, lasts forever. Like a wave, or the breath, thoughts arise and then pass away. Rather than shut off painful emotions that emerge during challenging situations, patients can learn to work skillfully with the thoughts and feelings that they evoke. Rather than allowing our feelings to dominate our thoughts, or vice versa, we learn to be with both. One useful mindfulness exercise that we often teach is the practice of "labelling" thoughts, available on our website www.SittingTogether.com. When it comes to thoughts and feelings, psychiatrist Dan Siegel puts it succinctly: We name them to tame them.

5: *Now you stated that there is a balancing act between knowing when a patient needs to stay with the narrative or the experience. I can guess patients who decide to stay with the narrative that gives rise to painful or pleasant feelings benefit from labeling which is a meditation practice that labels the experience and has been amply researched. Do you find that there are a particular group of patients based on their backgrounds/identities that gravitate more towards the narrative than the experience? Or vice-versa? Or it does not matter – each patient takes a different pathway with narrative and/or experience?* There is a balancing act between the narrative and the experience, and every clinician needs to find a balance that works for both patient and therapist. I have learned to be with the patient where he or she is, rather than impose my agenda.

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5: In one workshop we gave a few months ago, one participant commented, "My therapist keeps pushing mindfulness, but I just want to talk! I need someone to hear me." Since psychotherapy is the "talking cure," we don't want to neglect the importance of giving voice to experience so that it can be acknowledged and understood. It's always important, as in any therapy, to really listen to the patient, and not think that there's one "right" way to heal, or that mindfulness is a magic bullet that will cure all ills if only the patient will cooperate and meditate. It's always hard to generalize, but I find that patients who have experienced neglect or abuse in childhood often need to develop a narrative relationship with what happened to them, which in itself becomes an emotionally reparative experience. For most patients, it's important to start by building a strong, trusting alliance before introducing mindfulness. I think of the interpersonal relationship as the foundation of therapy, even mindfulness-based therapy.

6: *Meditation does not always work. As you stated, there are a number of reasons stated in the book where meditation practices are used as 'counterproductive defenses'. Also in many of the clinical illustrations mentioned in the book, a number of patients leave therapy and then return. Do you think these defenses emerge more with persons unfamiliar with meditation? And those who are experts in mediational practices, do these defenses arise as well but with less frequency?* As with any type of therapy, one size does not fit all. Mindfulness does not work for every patient. Defenses and transference do not magically disappear when you introduce mindfulness into the clinical hour. Often, patients turn to meditation as a defense against trauma or interpersonal distress, seeking some refuge from the misfortunes and hardship of life. I don't think we can accurately say that defenses are greater for those unfamiliar with meditation, or less frequent in those who meditate. We have all suffered, we have all been wounded, and we all construct defenses to help us navigate through the storms of life.

7: *In part of the book it is mentioned that therapy is more an art than a science because truths become more relative than absolute when working with patients. In addition, there is a quote from Freud stating that therapy, in particular 'psychotherapy' as an "impossible profession" (Freud, 1937). It appears that there are many uncertainties, so why continue if not only for the love of the profession? There appears to be 'compassion fatigue' or burnout that is experienced by some who do this work. As a result, what have been your rationales for continuing psychotherapy coupled with mindfulness practices?* And for those who do have burnout, do you find that many return to the profession? Therapy is often more art than science, and Freud, who advised us to turn to the works of the poets and novelists to understand the human heart, understood this well. He stated that therapy (along with raising children and governing of nations), is an impossible profession. Many therapists continue out of love of the work, and because they feel that they can make a difference in many, though not all, lives. When the work is going well, it can be enormously rewarding, and can at times feel sacred. As we discuss in Sitting Together, recent research suggests that what we call "compassion fatigue" may in fact be "empathy fatigue," if caring for others is not balanced by self-compassion and equanimity. Mindfulness and compassion can help clinicians mediate burnout in the workplace.

"It's always important, as in any therapy, to really listen to the patient, and not think that there's one "right" way to heal, or that mindfulness is a magic bullet that will cure all ills if only the patient will cooperate and meditate."

8: *In Chapter 2 of the book, you outline the benefits of practicing mindfulness-based therapies for the therapist. It appears that the effectiveness of these therapies increase once the therapist makes mindfulness practice part of their daily lifestyle. In making mindfulness a habit, what exercises or recommendations does the clinician find most difficult?* Mindfulness is most effective when it becomes a daily practice. In talking to clinicians, one theme that often arises is the difficulty of practicing alone. Mindfulness doesn't have to be a solitary pursuit, and traditionally it was done with the support of a community. So I encourage folks to find a community of mindfulness practitioners, even if it's a virtual one, if they possibly can. And when people worry that they aren't doing it "right," I like to remind them of something one of my meditation teachers often says, which is that you can't fail at mindfulness. Unlike academia and clinical work, where we often don't feel that we are good enough, effective enough, or powerful enough, mindfulness allows us to let go of the "comparing mind" and relax in the present moment without grasping and without needing things to be different from the way they are.

9: *Besides reading this comprehensive book, what advice would you have for therapists now seeking to learn and engage with mindfulness practices?* I would also suggest to therapists that they listen to talks (so many are available for free, online) from meditation masters who are also psychologists such as Tara Brach and Jack Kornfield.

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Book Review - Sitting Together: Essential Skills for Mindfulness Based Psychotherapy

.....Continued from page 13

10:*Besides reading this comprehensive book, what advice would you have for students who may be seeking to incorporate these practices into their educational trajectory? What resources (e.g. internships, scholarships, etc.) are available to them?* At this point, there are only a few programs that offer internships, scholarships, or rigorous training in integrating mindfulness with psychotherapy. However, hopefully this will be changing soon. We have started a new Center for Mindfulness and Compassion at Cambridge Health Alliance, http://www.challiance.org/ForProviders/CMC.aspx., which we hope will become a model for ways to bring mindfulness into a clinical setting.

11:*Any closing thoughts?* People may also be interested in following my blog on Psychology Today, which has many new practices and applications that are not in Sitting Together, https://www.psychologytoday.com/blog/the-art-now.

New Book Releases from our Members

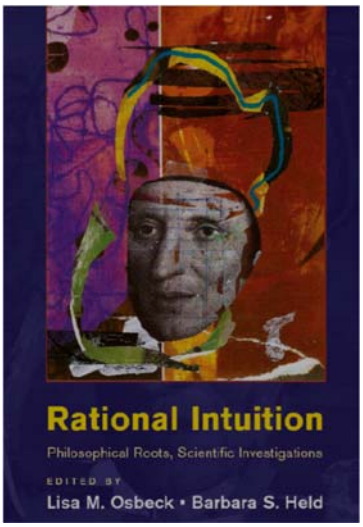

Rational Intuition: ***Philosophical Roots, Scientific Investigations***

Edited by *Lisa M. Osbeck*, University of West Georgia & *Barbara S. Held*, Bowdoin College, Maine

What is intuition? What constitutes an intuitive process? Why are intuition concepts important? After many years of scholarly neglect, interest in intuition is now exploding in psychology and cognitive science. Moreover, intuition is also enjoying a renaissance in philosophy. Yet no single definition of intuition appears in contemporary scholarship; there is no consensus on the meaning of this concept in any discipline. Rational Intuition focuses on conceptions of intuition in relation to rational processes. Covering a broad range of historical and contemporary contexts, prominent philosophers, psychologists, and cognitive scientists explore how intuition is implicated in rational activity in its diverse forms. In bringing the philosophical history of intuition into novel dialogue with contemporary philosophical and empirical research, Lisa M. Osbeck and Barbara S. Held invite a comparison of the conceptions and functions of intuition, thereby clarifying and advancing conceptual analysis across disciplines.

Train Your Mind for Peak Performance: A Science-Based Approach for Achieving Your Goals

Authors: *Lyle E. Bourne, Jr. & Alice F. Healy*

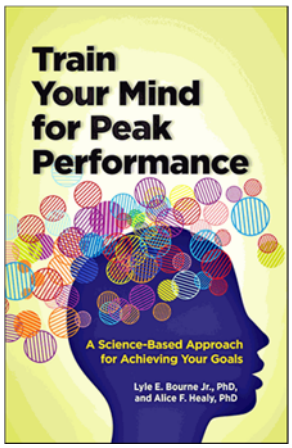

Whether you're training to play the piano, speak a foreign language, shoot a target with a bow and arrow, or master the techniques of fine carpentry, the conditions of your training will affect how successfully you learn and perform.

- How can you process new information in order to remember it better and use it in the future?
- How long should you work, study, or practice before taking a break?
- Is it desirable or even possible to "overlearn"?
- How can you counteract fatigue and boredom to improve performance if the task is tedious?

Cognitive psychologists Lyle Bourne and Alice Healy have studied these and other questions for decades to determine the best training conditions for learning and job performance. Readers will learn how best to acquire, retain, and transfer knowledge and skills to new situations.

More book releases and profiles from our members on page 40...

..... Continued from page 2

The door between them was closed and the "teacher" was seated at a table in front of a very large, imposing, highly scientific looking electric-shock machine. Watching unnoticed behind the two-way mirror, I thought, how could anyone who had just received a mild electric shock not question or at least express some doubt about administering shocks from a machine labeled "Shock Generator" with switches running incrementally from 15 to 450 volts and with corresponding descriptors starting with "Slight Shock" and progressing to "Intense Shock", "Extreme Intensity Shock", "Danger Severe Shock", and the "XXX" at the highest range? Nonetheless, everyone during the filming proceeded as they were instructed.

Even though I had been told that no one was actually going to be progressively shocked and that this was essential for the bona fide scientific experiment, I felt queasy about filming. A few years earlier in a college course, I had studied the role of the cameraman in intense situations like riots and war, and I had made a documentary inside the violent prison at Riker's Island, NY, so I continued filming the subjects in the experiment.

I also remembered, as a very young student in parochial school, how ineffective it was being struck by a teacher with a ruler across my hand, and how it made me suspicious of teachers who did it. So, in a strange way I was curious about how these "teachers" would administer punishment during Milgram's experiment.

The implication of war with Milgram's experiment

I told Ms. Perry who was a journalist, psychology researcher, and Australian citizen and was most likely young at the time of the Milgram experiment, how American college students felt in the 1960's. What was uppermost on every young man's mind was his draft status with the Selective Service System. (Milgram had joined the Air Force ROTC in 1951 at Queens College and served his time (Blass, 2004).)

We all knew that if Elvis Presley – the King - could be drafted away a few years earlier from millions of his adoring fans to serve in the military, what chance did anyone of us have as the path to war in Vietnam seemed to be inexorably heating up? I told her that, like other recent college graduates, I had a deferment from the military to work on a government contract, and so I was at Yale

Edward English

available to work on Milgram's experiment as well.

Ms. Perry told me about one of the subjects in her book, who participated in the early experiments. Herb Weiner, who quit before finishing because of the intense pressure he felt upon being prompted to administer the shocks even after the "learner" expressed pain. After the experiment, Weiner bitterly complained to Milgram about his own reaction and voiced his ethical concerns. He was proud of that, and rightly so, but being a member of the Yale faculty, Weiner could easily disobey because he had the higher authority of the institution on his side. He was an assistant professor at Yale when he entered the experiment. Ms. Perry said she wasn't sure if Weiner mentioned this when he signed up. Most subjects chosen for the experiment were just ordinary Americans from diverse backgrounds unaffiliated with the University. It proved to be far more difficult for these individuals to disobey authority on their own, which was exactly the purpose of the experiment, (Milgram, 1973a).

More pointedly, could the short prompts that were unemotionally spoken to Weiner prod him to continue the experiment by the "leader/actor" in a lab coat with a clipboard sitting behind him, be as threatening as a uniformed SS officer barking orders backed by the Third Reich? Yet this comparison between the pre-Vietnam War Americans and the World War II Germans was very commonly drawn with the Milgram experiment. Obviously, this comparison was, I believe, to be highly offensive to Americans.

Clearly, with Stanley Milgram's background, this was implausible. His parents were Jews who left Eastern Europe before the Holocaust. His father still had relatives there during the war, so they were acutely aware of the evils of the Nazis. (Blass, 2004). He was not trying to make the case to restore the reputation of the "good" Germans.

Neither was Milgram directly implicating Vietnam War era Americans. Yet the results of the experiment were overshadowed by the comparison to the Holocaust almost from the beginning. Some of this may be due to the notoriety of the trial of Adolphe Eichmann, which had begun with much publicity shortly before the Milgram experiment. On the one hand, Milgram's studies were influenced by the bedrock of irrefutable evidence on the Holocaust in European culture. On the other hand, should Americans have introspectively linked themselves to these horrendous events? Hadn't many of the 'greatest generations' fought and died to defeat Hitler and win the Second World War? Milgram's studies might have been received better if he had deemed them applicable to the authority of the military-industrial complex that President Eisenhower warned about in his farewell address in 1961. However, that connection was overlooked in his book Obedience to Authority published in 1974, where Eichmann is referred to at least seven times.

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In the early 1960's, some of us naively thought the Milgram experiment might be used as a rationale to stay out of the draft. I thought of being a conscientious objector, but realized that such a sudden shift would not be consistent with my history. I joined the Universal Life Church and paid for a card and certificate that said I was a religious minister, but that attempt to avoid the draft would have certainly been obvious to my draft board. I asked to join the Peace Corps, but was told I might be drafted afterwards anyway. I would not lie to dodge the draft, and even though I felt we were making a terrible mistake in Vietnam, I wanted to serve my country in some way, so I enlisted in the US Army Reserves. There was a real sense of desperation everywhere among young people and even some parents. The whole country seemed to be falling apart, and "revolution" was shouted out as if it were a real possibility. The draft had burrowed into our collective gut; the Eichmann trial was only, rarely, a very, small part of a specific conversation.

Conclusion

Milgram's experiment could have been used to help power the anti-Vietnam War movement. Had he directly confronted the war establishment, and received support outside the psychology profession, his work might not have been subjected to the endless rounds of discussions by the profession over ethical and methodological concerns, (Elms, 2009).

Thinking back over all the enormous amount of criticism Milgram got for his experiment, he might have spared himself a lot of grief if he had just stopped the experiment as soon as the door closed on the "learner" and the "teacher/subjects" agreed to the casual prompt by the "leader" to administer the first shock. At that instant, it was obvious to me behind the two-way mirror that when the "teachers" took their seat right in front of the imposing shock machine, that they were willing to ignore any cautions of good conscience they might have had to obey the flimsiest of authority under a barely credible scientific rationale.

With the tumult of the civil rights and early, anti-war protests still rumbling in my mind, when the door shut and the first switch was about to be activated, I can distressingly remember squelching my own inner commands to run into the room and shout, "Stop, don't flip that electric switch!" Had I done this, however, and the experiment was halted just before the first switch, most of the same professionals clamoring that he went too far, would probably have scoffed at those results and Milgram's experiment would not have been so significant.

> If Stanley Milgram could respect these people who had spontaneously revealed, on film, after varying protestations, such an unambiguous obedience to, at best, a perfunctory and questionable, minor authority, surely, he was committed to probing the darker side of our nature for the benefit of all of us.

But what has made the most sense for me over all the years is remembering, from the time of the filming, how compassionately Stanley Milgram would debrief the subjects after the experiment. If he could respect these people who had spontaneously revealed, on film, after varying protestations, such an unambiguous obedience to, at best, a perfunctory and questionable, minor authority, surely, Stanley Milgram was committed to probing the darker side of our nature for the benefit of all of us.

We do not want to believe that our authorities are out to control us and Milgram doesn't blame our authorities either. His experiment delineates in numerous variations, that it is our complicity with authority that is the crux of the problem. People are relieved, in trying situations, when someone in authority takes responsibility for their actions. (Milgram, 1973b).

Many of the subjects in the Milgram experiment, Ms. Perry told me, have had a difficult time trying to understand what they went through and what it meant. Personally, I have lasting memories, but always with the understanding that the experiment I was participating in was of valid scientific concern. This has only deepened over the years, even as the psychology profession has continued to flounder with how to further build on his results. Ms. Perry said her opinion of Milgram deteriorated after she spoke with many of the participants in the experiments as they recounted the emotional stress they had endured. It would be a very sad irony if her book "Behind the Shock Machine" confirmed their worries and they believed that their participation was for naught.

In 1984, at Stanley Milgram's funeral, his colleague, Irwin Katz, reflected on the obedience experiment, "After two decades of critical scrutiny and discussion, there remains one of the most singular, most penetrating, and most disturbing inquiries into human conduct that modern psychology has produced in this century. Those of us who presume to have knowledge of man are still perplexed by his findings, with their frightful implications for society," (Blass, 2000, p. 136).

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CALL FOR BOOK SERIES EDITOR

PORTRAITS OF PIONEERS IN PSYCHOLOGY

Are you a generalist with an interest in the history of psychology? Do you have editorial skills and experience? If so, we have a job for you! The Society for General Psychology (APA Division 1) is calling for a volunteer to serve as Editor of our book series, known as *Portraits of Pioneers in Psychology*. The most recent volume, *Portraits of Pioneers in Developmental Psychology*, was published in 2011. Duties of the series editor are to: serve as liaison with our publisher; prepare a list of topics for potential volumes; recruit experts to serve as volume editors; and coach less experienced potential volume editors through the prospectus writing and editing phases. Interested parties should send a cover letter and c.v. to Joan C. Chrisler, Ph.D. at jcchr@conncoll.edu. Review of candidates will begin in May and continue until the position is filled.

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Historical note

Making 16 mm documentaries in the 1960's, meant that directors and producers often were their own cameramen and editors because of the physical, hands-on technology. (Purists like Frederic Wiseman have only recently switched to digital.) Stanley didn't really shoot or edit himself; consequently 'Obedience' is a classic well-constructed, powerful documentary without any special effects. This editing style reflected the scientific rigor Stanley strove for at Yale. At the very end of the later version re-edited, narrated, and distributed by Pennsylvania State University, there is an artistic visual and narration sequence that steps outside the strict documentary form and points the finger at "governments." Milgram did not receive adequate additional funding for future obedience experiments and ever the brilliant scientist, he moved on. (Blass, 2011.)

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'Milgram lite' is a term coined by Alan C. Elm to describe the tasks executed by participants in replicated studies of Milgram's experiment to be less nocuous. Compared to the higher degree of shock levels administered in Milgram's experiment, the tasks in these subsequent studies had to comply with institutional review boards ensuring participants were not subjected to possible stress or trauma.

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Alfred Adler's profound understanding of social motivation

By *Eva Dreikurs Ferguson, Ph.D.*

Abstract

Alfred Adler (1870 -1937) developed a holistic and dynamic theory that emphasized social motivation and goals as the basis of thought, emotion, and actions. For Adlerans, Gemeinschaftsgefühl (Social Interest) is the key to mental health and is inextricably interwoven with the need to belong, and democratic relationships with equality of value of each individual help enhance well being.

Alfred Adler's profound understanding of social motivation

Early in the 20th century, Alfred Adler, a Viennese psychiatrist, postulated that humans, and social animals generally, have a basic need to belong that has evolutionary and survival value (Ferguson, 1989). Adler's theory is built on the concept that humans, as part of their evolutionary heritage, have a need to feel belonging (Ferguson, 2010). When they feel belonging they thrive, and they feel inadequate when they do not feel belonging. Well-being occurs when one feels belonging, of having value as an equal among equals. Malaise occurs when one feels one does not belong. Although it is called a 'feeling' it contains cognitions ("I am convinced I do not belong") and emotions ("I feel hurt"). Feeling one does not belong can lead to various emotional and behavioral disorders. Long before Baumeister and Leary (1995) wrote their seminal paper on the need to belong, Adlerian counselors, educators, and psychotherapists identified the symptoms of discouragement and disorder in children and adults as a result of the feeling that one does not belong.

Equality and need to belong

According to Adlerian psychology, the feeling of belonging involves a conviction that the person has value as an equal among equals (Dreikurs, 1999). The feeling that one has value is amplified when one's contributions to the 'greater good' of the community in which one lives is valued.

Whereas much of psychology in the past century has focused on negative emotions, in part stemming from the influence of Freud (1900, 1936a, 1936b), Adlerians can be said to be the first 'positive psychologists' (Ferguson, 2009). Aggression as behavior and anxiety, fear, and alienation as emotions were viewed by Adlerian psychologists as outward symptoms of a more fundamental process of discouragement with respect to being valued and feeling belonging. Adler (1929, 1931, 1933) viewed humans as fundamentally social beings, and their motivation, thought, emotion, and action can be understood only in social terms. Because humans live in groups, they share characteristics with other social animals, as Seyfarth and Cheney (2012, 2014) and de Waal (2013), among others, have notably indicated.

Adler (1933) postulated that Gemeinschaftsgefühl (loosely translated as Social Interest) was the crucial motivation that assures well being. When humans have high social interest, of caring for and being committed to the welfare of all members of the community, physical and mental health are increased.

Early social psychologists, like Kurt Lewin (1948), understood the link between personality, social identity, and various psychological processes. Years before Lewin, but congruent with him, Adlerians emphasized the importance of 'equality' as essential for well being. One cannot feel 'belonging' if one does not feel 'equal.' The work of Kenneth Clark (1967), in providing research evidence that led to the end of segregation in public schools in the USA, was based on Adler's concept of the need to belong and the importance of feeling equal with others.

Adler and his younger colleague Rudolf Dreikurs (1999) recognized that 'well being' and 'belonging as an equal' were irrevocably linked. Adler (1933) postulated that Gemeinschaftsgefühl (loosely translated as Social Interest) was the crucial motivation that assures well being. When humans have high social interest, of caring for and being committed to the welfare of all members of the community, physical and mental health are increased. Social interest is a potential in all humans, but like language, it needs to be taught. Without social interest, humans become self-oriented. This in the long run leads not only to poor social relationships but to diminished health. Social interest is reciprocally related to the human need to belong as an equal. The process involves a positive spiral: when humans feel belonging and equal they are more likely to have high social interest and seek to contribute to the larger community, and when they have strong social interest this is likely to lead them to increase their feeling of belonging as equals.

For Adlerians, social relationships that involve reciprocity, collaboration, and mutual support are more likely to occur when humans in their beliefs and actions relate to each other as equals. This is also found in non-human social animals (de Waal, 2013). Autocratic relations among human beings, based on an 'obedience' model (Milgram, 1974), do not involve equality nor mutual support, and thus, in terms of Adlerian psychology, the autocratic process leads not only to social and societal difficulties but also to various kinds of psychological disturbances.

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The importance of goals

Adler's theory is teleological in the sense that human motivation, emotions, and actions are goal-directed (Ferguson, 2014). Whereas other theories emphasize a variety of sources for motivation and emotion, Adlerians postulate that human motivation and emotion is a function of goals the individual is seeking. If one wishes to change the motivation or the emotion it is necessary to change the goal. Goals within Adlerian psychology are primarily based on 'private logic,' which is the private reasoning each person gives to the immediate situation. Adler showed that one is not necessarily aware of one's goals and private logic nor, ordinarily, need one have such awareness. However, when one faces life problems that one tends not to be able to solve readily, understanding one's private logic and unaware goals helps one find solutions.

Educators and parents, especially, have gained increased benefit by learning about the mistaken goals of children (Dreikurs, 1947, 1958). Children's disturbing behavior can be readily altered if the adults understand the mistaken goals of the child and if the adults have learned effective ways of dealing with these goals. The effective solutions have the aim of increasing the child's social interest and increasing the child's feeling of belonging. Specific Adlerian methods have been developed that help children meet the challenges they encounter (Dreikurs, Cassel, & Ferguson, 2004; Dreikurs & Soltz, 2014; Gfroerer, Nelsen, & Kern, 2013; Nelsen 2011).

Democratic processes increase mental health

According to Adlerian psychology, just as autocratic processes diminish the sense of being an equal among equals, democratic process more likely increase the feeling of belonging. According to Dreikurs (1958; Dreikurs, Grunwald, & Pepper, 1999), democratic processes involve freedom with order. This contrasts to the obedience-based autocratic processes, in which there is order without freedom. In the third kind of process, called 'laissez faire,' people do as they like without regard to others and there is freedom without order. The parenting and education methods developed by Adlerians separate these three styles of leadership. The Adlerian model, which emphasizes the democratic style of leadership, shows the kinds of problems that occur with autocratic and laissez faire styles of parenting and education.

In his writings and teachings, Dreikurs showed that problems in homes and schools would occur when parents and teachers used autocratic and laissez faire methods that minimized the feeling of belonging and equality. When children are trained to be responsible and caring with high social interest, and when they understand the consequences of their behavior, they feel encouraged and function in prosocial ways. This requires democratic procedures, in which the children are partners in the rules and decision making. In autocratic homes and schools, the children follow rules set by the authorities. They are not contributing as equals to the life of the community.

In an obedience-oriented home or school the child tends to have two possible behavior routes: to obey or to rebel. Dreikurs warned in his writings and speeches that until homes and schools learn democratic leadership and the methods developed by Adlerians, children are increasingly likely to rebel. Whereas in centuries of punitive control the authorities could beat the children into submission and obedience, in the democratization of modern society, when such punitive methods were removed, new methods of democratic parenting and leadership were required. Countless books and articles were written by Adlerians (e.g., Dreikurs, 1958; Dreikurs & Soltz, 2014; Nelsen, 2011) that described Adlerian methods for parenting and educating children and youths. These methods were based on the democratic model of 'freedom with order.' In his description of methods, Dreikurs (Dreikurs, Grunwald, & Pepper, 1999) credits the work of Lewin, Lippit, and White (1939) for demonstrating the crucial elements of autocratic, democratic, and laissez faire styles of leadership.

Research by Ferguson, Hagaman, Grice, and Peng (2006) has found that modern parenting styles are likely to be a mixture of democratic and laissez faire styles. Follow up studies verified that not only do young adults, when reporting how their parents raised them, show confusion between the democratic and laissez faire styles but that parents themselves have this confusion. Parents who themselves were raised by autocratic methods know they do not wish to adopt these methods in raising their own children, and so they follow what they consider to be the opposite styles of parenting. In the process, although they often call their parenting style 'democratic,' they in fact follow many laissez faire procedures. The data obtained by Ferguson, Hagaman, Maurer, Mathews, and Peng (2013) and in many related studies showed that parents and their young tend to have a 'binary' set of concepts, that parenting is either autocratic and based on obedience or it is what they call 'democratic' and based on unlimited freedom given to children.

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This binary belief system leads to many homes having a laissez faire and not a democratic style of parenting, as defined by Lewin (1948) and Dreikurs (1958). In the Adlerian approach, a clear distinction is made between democratic methods, that involve freedom with order, and laissez faire methods that involve freedom without order.

From the point of view of Adlerian psychology, just as social interest can be learned, democratic methods of human relationships also can be learned (Ferguson, 2007). Thousands of parents and teachers in the United States and abroad have followed the methods offered by Adlerians and have found that unruly and disgruntled children become cooperative and appreciative members of the family or school community. They grow up to be responsible and caring members of the larger society, in work and in their many personal relationships. The Adlerian methods apply equally to the workplace and to international relations (Ferguson, 2012), and they are used effectively in many treatment programs in counseling and psychotherapy (e.g., Shulman & Mosak, 1988; Sperry, 2009, Walton, 2012).

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General Psychology Trivia Quiz **Part 2**
By John D. Hogan, PhD *

The brief descriptions below all refer to past-presidents of the APA. How many can you identify? (Correct answers can be found on p. xx. Don't peek! :)

1. His first name was Burrhus but he preferred to be called Fred.
2. She was the first woman to receive a PhD degree in psychology.
3. More APA presidents received their doctoral degrees from this university than any other.
4. William James referred to this as a "bloated tumefied mass." What was he referring to?
5. One past-APA president wrote this to another past-APA president about the book of a third past-APA president: "It is chock full of errors, masturbation, and Jesus. The man is a mad man." The people involved? The book?
6. She was likely the oldest member of APA ever.
7. This highly regarded U.S. Western university, home to several APA presidents, is so large, it resides in two different zip codes.
8. She was the only woman to receive a PhD degree under the mentorship of Wilhelm Wundt.
9. The brain of this pioneer psychologist is on display in a case outside the psychology department of his home university.
10. The birth name of this future psychologist was Harold Israel, but he was known professionally by a different name.

Bonus Question: Josiah Royce was a Harvard faculty member and a president of the APA. His home in Cambridge, MA was later bought and lived in by a very prominent television personality. Which TV personality lived in Josiah Royce's house?

*John D. Hogan is the historian for APA Division One.

Edward C. Tolman

Eminent Learning Theorist and Outspoken Supporter of Academic Freedom

by John D. Hogan and Nate Frishberg - *St. John's University*

Edward C. Tolman was one of the most prominent learning theorists of the 1930s and beyond. Although he was a behaviorist, his theory incorporated some strikingly non-behavioral elements. One of his most important creations was the notion of "intervening variables," a concept that was immediately taken up by other learning researchers. As an educator, Tolman also became embroiled in a political brouhaha regarding academic freedom. His stand on the issue eventually earned him high marks and the praise of many of his contemporaries. Tolman was president of APA Division 1 from 1947-48, and again from 1952-53, one of only two presidents in the Division's 70 year history to serve two terms.

Early life and education.

Tolman was born on April 14, 1886, in Newton, Massachusetts, the son of a well-to-do rope manufacturer and a Quaker mother. Although his father encouraged him to enter the family business, Tolman chose instead to become an academic. At first he studied engineering at the Massachusetts Institute of Technology (MIT) but, after reading works by William James, he found himself drawn to philosophy and psychology. Immediately following graduation from MIT in 1911 with a BS degree in electrochemistry, he entered the psychology doctoral program at Harvard University, where he was exposed to the work of many prominent psychologists of his day, including Robert Yerkes, Hugo Münsterberg, and Herbert Langfeld.

In the summer following his first year at Harvard, Tolman went to Germany to prepare for the language requirement of the doctoral degree. (For many years, one of the requirements for a U. S. doctoral degree was familiarity with French and/or German.) In Germany, he had his first encounter with Kurt Koffka, the Gestalt psychologist, who would later have such an influence on his learning theory. Indeed, in 1923, he would return to Germany for further study of Gestalt theory. Upon graduating from Harvard in 1915, he was hired as an instructor at Northwestern University where he taught for three years until he was dismissed—in part, he thought, due to his pacifist beliefs. Following that, he became a faculty member of the University of California, Berkeley, where he remained for the rest of his professional life.

Theory and professional accomplishments.

Although Tolman was educated in the behaviorist tradition, he nonetheless remained interested in the concept of introspection. It was during his early years at Berkeley that he began to develop the learning theory for which he would become famous. He established an animal laboratory in which he and his students studied the ability of rats to learn mazes. Unlike prominent theorists of his era, most notably E. L. Thorndike and John B. Watson, Tolman extended learning beyond simple stimulus-response connections. He emphasized that stimuli and responses exist in a given context, that is, they relate to other stimuli and responses as opposed to being isolated phenomena. He also argued that learning is purposeful rather than consisting of simple repetition of stimulus-response pairings -- that it can be conceived of as consisting of a series of "sign-gestalt-expectations." (This term is exemplary of Tolman's fondness for constructing hyphenated neologisms.) In 1932, he published his theory in a book titled, Purposive Behavior in Animals and Men.

Expanding on these ideas, Tolman introduced a concept he called "intervening variables." Intervening variables are hypothesized internal states of a human or animal that are proposed to link stimuli (or independent variables) with responses (or observable, behavioral outcomes). Although Tolman remained a behaviorist who believed that all of learning could be understood by studying a rat in a maze, his formulations were a departure from the strict behaviorist position so common then. Instead, his theory is seen as a precursor to the cognitive movement that would later come to dominate the field. Some commentators have characterized his theory as the best theory of learning to emerge in the 1930s. In 1936, at age 51, he was honored by his fellow psychologists by being elected the 46th president of the American Psychological Association.

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EDWARD C. TOLMAN

Eminent Learning Theorist and Outspoken Supporter of Academic Freedom

by John D. Hogan and Nate Frishberg - *St. John's University*

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For all his important contributions, Tolman's legacy is not solely the result of his achievements in psychology. In the late 1940s, U.S. Senator Joseph McCarthy drew great public attention when he charged that government institutions and academia were filled with Communists and other individuals disloyal to the country. As a result of his accusations, some state legislatures required loyalty oaths from their employees. In 1949, consistent with state law, Berkeley required its faculty members to sign such an oath.

Tolman's loyalty to the United States had never been in question and he had never given evidence of political beliefs that were considered "radical." Nonetheless, he objected to the oath and refused to sign it. His resistance was based on both personal liberty and the idea of academic freedom—that external pressure on educators decreases their ability to learn and teach accurate, objective truth. Indeed, academic freedom carried particular significance for Tolman as well; throughout his life as an academic, he had felt a sense of personal release in being able to conduct research and publish his ideas freely and openly. In his defiance, he became a leader of those opposing the oath.

University officials threatened Tolman with dismissal. In response to this threat, he sued the university, taking the case to the Supreme Court of California. In the 1952 decision, Tolman vs. Underhill, the requirement of the loyalty oath was removed. Tolman's courage in standing up against this rule cannot be understated. Indeed, the climate of McCarthyism made it very dangerous for anyone to take such a stance—even in the absence of Communist beliefs. In 1959, ten years after his refusal to sign the oath, Tolman was awarded an honorary LLD degree from Berkeley. A few years later, a new Psychology and Education building at Berkeley was named Tolman Hall in his honor.

In summary.

Not all of Tolman's ideas have stood the test of time. In particular, his belief that laws of learning applied equally to all living creatures, is dated. Still, his legacy is strong -- found not only in his theory and its anticipation of cognitive psychology, but in his students, many of them distinguished, who benefitted from his kindness and from the intellectual stimulation he provided. Unlike other learning theorists, he did not demand loyalty to his system. He has been remembered as a gifted and passionate teacher who placed great value on his students. Moreover, as one of his students has pointed out (Gleitman, 1991), he was always open to new ideas and willing to draw from all parts of psychology as well as other disciplines – the least dogmatic of theorists. Perhaps this openness and commitment to the exchange of ideas is what gave him the courage to stand up against the impact of McCarthyism in academia. Edward Chace Tolman died in Berkeley, California, on November 19, 1959, at the age of 73.

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Internationalizing the Psychology Curriculum through Mentored Student Research

(From left to right): Sarika Persaud, Richard Velayo, Ph.D., Wallis Back, Ranya Marjieh, and Lucio Forti.

(Not in photo: Suchun Dong and Michael Trush)

At Pace University's Psychology Department (New York City Campus), one of the recently developed course offerings for its psychology undergraduate and graduate students is a "mentored lab" course. This course, which may be taken for a maximum of two semesters, allows students to be involved in faculty research as research assistants but with the benefit of obtaining credit towards their degree. Such hands-on and active learning experience has become highly sought after by students who wish to continue in their psychology education at the masters or doctoral level.

Dr. Richard Velayo, Professor of Psychology at Pace University, is one of the instructors involved in this mentored lab initiative. His research group called "Internationalizing the Teaching of Psychology (IToP) Team (http://rvelayo.jimdo.com/itop-team/) focuses on exploring and assessing strategies that help infuse international content and promote a global perspective within the discipline of psychology at the higher education level. The essential requirements for this mentored lab involve a weekly meeting with the principal researcher/faculty and other research assistants/students involved in the research, and a 10-page experiential final paper. In addition, each student member develops a proposal or research project related to one of the following subtopics: (1) identifying effective pedagogical strategies to internationalize psychology courses, (2) developing of an assessment tool for an internationalized psychology course, and (3) applying Internet-based technologies (IBTs) as teaching and research tools to help infuse international content.

Their projects are presented at an u coming research psychology conference. Some of the psychology conferences in which the IToP team has presented include the annual meetings of the American Psychology Psychological Association, Eastern Psychological Association, Greater New York Conference on Behavioral Research, Hunter College Psychology Conference, and Pace University Psychology Conference.

There are currently 5 students actively involved in Dr. Velayo's mentored lab class. Each student is actively undertaking research projects of interest to them, which ties in one of the topics related to the IToP team research subtopics (as mentioned above). At each weekly meeting, students provide the entire team with updates about their individual work and discuss preparations for presentations (e.g., poster, paper, symposium) at an upcoming conference.

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Internationalizing the Psychology Curriculum through Mentored Student Research

Richard Velayo, Ph.D., Sarika Persaud, Lucio Forti, Wallis Back, Ranya Marjieh, Michael Trush, and Suchun Dong ~ *Pace University, New York*

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Below are brief descriptions of each of the student-initiated research projects:

Lucio Forti (lf72881n@pace.edu) - "*Incorporating an International Perspective in the Classroom Through Web-based Technology: Best Practices and Demo*"
Recent advances in technology have contributed toward an increase in the availability and usage of web-based collaborative tools in higher education. Previous research has examined how internet based strategies can be used to cultivate critical thinking, engagement, discussion, and improve learning outcomes in the classroom. This presentation will focus on a summary of best practices gathered from the current literature for instructors seeking to leverage technologies in order to incorporate an international perspective in psychology courses. Challenges and potential barriers to success will also be explored as well as how to navigate the plethora of choices in collaborative tools available online. A brief live demonstration will highlight how strategies can be applied as well as how to find additional resources for those interested in exploring how an internet based strategy can be integrated into a course. Directions for future research aimed at examining tools and pedagogy will be discussed.

Wallis Back (wb94354n@pace.edu) – "*Shamanic Healing Techniques: An Exploratory Case Study on Its Implications To Western Approaches to Therapy*"
There is a growing interest within modern Western society to explore implications of ancient Eastern practices and traditional Shamanic healing techniques. Preliminary research has emerged on the benefits of mindfulness practices such as mediation and herbal alternatives to pharmaceutical medication. However, there lacks psychological research, on the how spirituality and the significance of incorporating non-Western therapeutic approach into the psychological healing process. A review of the current academic literature on the post-psychological effects of a traditional Shamanic "ayahuasca" ceremony and the perceived importance of a deeper sense of spiritual connection, suggest a viable means of integration into Western therapy. In addition, a personal explorative case study will be conducted in order to assess pre and post quantitative measures of neurotransmitter levels, quantitative measures of anxiety, depression, spiritual connection and overall subjective well-being after participating in a traditional Shamanic ayahuasca ceremony in Peru.

Ranya Marjieh (rm52659p@pace.edu) - "*How are Graduate Psychology Programs Becoming Internationalized? A Side-by-side Comparison of Programs in Transpersonal Psychology and Cross-Cultural Psychology*."
This literature review and critique provides a comparison of curricula between transpersonal psychology and cross-cultural psychology graduate programs - two programs deemed to inherently infuse an international psychology perspective in the education and training of the graduate students in each of these programs. In addition, a listing of graduate programs that offer these two graduate degrees, with relevant background information, history, similarities and differences in curricula will be presented. Moreover, descriptions of how these two programs differ in the way they integrate an internationalized perspective will be provided. Suggestions and implications for further for curricular reform will be incorporated in the report.

Suchun Dong (sd76217n@pace.edu) - "*An Investigation Into The Use of Active Learning Approach To Teaching Graduate Psychology Courses in China*"
Psychology in China has received unprecedented attention in recent years. At the same time, there is an increasing number of psychology programs are provided in graduate schools to train students to be psychologists. However, the approach to teaching that professors tend to utilize in these programs to encourage students' active learning in China remains unclear. The current study will collect and analyze graduate program training information from selective ten official graduate school websites in China, interview twenty Chinese psychology professors via email about their training plans and teaching methods, and will also conduct an online survey regarding program evaluation to fifty psychology graduate students in China.

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Internationalizing the Psychology Curriculum through Mentored Student Research

Richard Velayo, Ph.D., Sarika Persaud, Lucio Forti, Wallis Back, Ranya Marjieh, Michael Trush, and Suchun Dong ~ *Pace University, New York*

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Michael Trush (mt09725n@pace.edu) - *"Memory for Concept Pairs as a Function of Participant Culture and Bimodality Type"*

This internet-based study will commence with the participant providing consent, and completing demographic information, including the culture(s) that they most closely identify with. Participants will then be encouraged to select a recall strategy they deem will be most effective in remembering visual concept pairs. Participants will randomly be assigned the presentation in a visual-textual format, or the visual -textual presentation with an auditory component, in which the name prescribed to each picture will be presented auditorily. Following the concept pair presentation, subjects will be presented with one of the two associated concepts, and tested as to which image appeared alongside the testing item. The participant will be asked to select the associated pair from five multiple-choice options. Lastly, the subject will complete The Cultural Orientation Scale, to determine their orientation towards either a collectivistic or individualistic culture, and if they tend towards a horizontal (egalitarian) or vertical (hierarchical) nature. Descriptive statistics and correlations will be run in order to determine the relationships between, memory strategy, culture, and bimodality type.

These student-initiated research projects exemplifies what could be an effective strategy to get students to develop a more international perspective about psychology and a greater appreciation of how the psychological constructs we learn need to take into consideration the cross-cultural and cross-national contexts in which it applies. There is tremendous value in involving students in the process of internationalizing the teaching of psychology. More importantly, it is essential to prepare them for a society that is increasingly becoming global.

For more information about this presentation and of the IToP team, please contact Dr. Richard Velayo at rvelayo@pace.edu or Sarika Persaud (Dr. Velayo's graduate research assistant) at ap75294n@pace.edu.

Division 1
70th
Anniversary

Mark your calendars!

2015 marks the 70th anniversary of the founding of Division 1.

We will be celebrating 70 years of *bringing psychology together*.

If you will be in Toronto, please plan to join us at the Division 1 Social Hour!

Shakespeare Plays

By Patrick O'Reilly, Ph.D.

I am a clinical psychologist at Napa State Hospital in Napa, California. The hospital is a locked facility housing over a thousand adults who have been diagnosed with serious and long-lasting biological mental disorders. Patients receive psychiatric services and individual and group psychotherapy. Group therapy at Napa is intensive and includes groups modeled on Dialectical Behavioral Therapy (DBT) and Cognitive-Behavioral Therapy (CBT), substance abuse relapse prevention skills training, identifying and correcting criminal thinking, and psycho-educational classes. In addition to these groups, normally facilitated by psychologists, psychiatrists and social workers, Napa State Hospital also has a vibrant recreational therapy program.

"To thine own self be true" (Hamlet)

In a departure from my scheduled psycho-education, identifying criminal thinking and substance abuse relapse prevention groups, I applied to facilitate a group I had long wanted to do. I had been an undergraduate English major and had often thought that Shakespeare could be both psychotherapeutically helpful and entertaining to the patients if presented in the right way, and so, with the permission of my supervisor, I started a Shakespeare group. To my delight, several patients quickly enrolled in this time-limited group. It is also worth noting that because the great majority of our patients experienced their first psychotic break while in their late teens and early twenties, most had not been exposed to Shakespeare's plays. I thought that providing genuine intellectual stimulation in conjunction with psychotherapy could be a valuable learning experience for them.

My justification in facilitating this group, which was done in collaboration with Napa State Hospital psychologists Doctors Ian Chapman and Thomas Knoblauch, was that Shakespeare's characters represent the gamut of moral strength, moral weakness and human emotion. Maybe, I thought, the patients could find a way to relate personally to the situational challenges faced by the characters in the plays and in the process, acquire insight into their own behavior and the way they face adversity and temptation. We chose five plays for the group (Macbeth, Hamlet, A Midsummer's Night Dream, Romeo and Juliet and Much Ado About Nothing) that we thought were easily accessible to people unfamiliar with Shakespeare's work and had plot lines that were fairly straight forward.

Thought this be madness, there is method in it" (Hamlet)

The majority of the group members were diagnosed with schizophrenia and many were dually diagnosed, and, even though medication compliant, they continued to experience intense internal stimuli. For that reason, the format of the group was purposely uncomplicated. I typed a brief (less than one page) synopsis of the play that included a description of the play's characters, which I passed out to the patients at the start of each group. Dr. Chapman, Dr. Knoblauch, or I would then ask for a volunteer from the group to read the synopsis aloud. A separate volunteer would read the descriptions of the characters. The group met weekly and each group meeting consisted of reading and listening to one act of the play. The group members were each provided with a print out of the act we were covering that week and after reading the synopsis, the group listened to an audio CD of the play while reading along with their printed copies. The CD was paused frequently so that the patients could discuss what they were reading and hearing, ask questions of each other as to the play's meaning up to that point and speculate about possible plot twists or motivations of the characters. Most of the patients were quite engaged in this process and at the conclusion of the weekly group would often express disappointment that they would need to wait a week before continuing. When the entire play had been read and listened to, the group watched a DVD of the play, also pausing the DVD frequently to encourage discussion.

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Shakespeare Plays

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"For man is a giddy thing, and this is my conclusion." (Much Ado About Nothing)

What was gratifying to Doctor s Chapman, Knoblauch and myself was the depth of connection the patients felt towards the characters in the plays and the surprising interpretations they gave to plot development, all of which they related to their own experiences in the mental health system and their often chaotic and trauma filled lives in the community prior to their current hospitalization. The group discussions were lively and often quite detailed and it is worth noting just a few of the reactions the patients expressed as the group progressed.

By far, the patients' favorite play was *Macbeth*. One patient, who spent years as a homeless drug addict, said early on in the play that Macbeth was "on a slippery slope." He explained to us that Macbeth "had it all – riches, a castle, a beautiful wife" and then threw it all away because, the patient explained, once somebody started sliding down the slippery slope, there was no going back. The patient equated Macbeth's downfall to the patient's own years of addiction, saying that before the patient began using drugs, he had subsidized housing, a monthly disability check and friends. He told us that the drug use was a slippery slope for him because he lost everything to his addiction just as Macbeth had once he killed King Duncan. A female patient commented that she could relate to Lady Macbeth's obsessive hand washing and ultimate suicide because before being hospitalized at Napa she had been "a cutter" and had attempted suicide multiple times. Her final comment was "maybe Lady Macbeth should have tried DBT."

Hamlet, which we felt surely would be a success with the patients, was more problematic. We had purposely left the concluding act of the play off the synopsis given to the patients each week and the comments during discussion were relevant and occasionally surprising. One patient pointed out that Hamlet's faked madness would not have fooled any of the group members and nodding to the facilitators added "but you guys would probably have bought it." Since many of the patients in the group, the female patients especially, had experienced serious trauma in their lives, they were able to express empathic compassion for Ophelia and found Hamlet's treatment of her reminiscent of abusive relationships they'd experienced. The most surprising comments made during the discussion of the play's conclusion were by two male patients who'd said very little in the group up to that point. One statement, made with considerable indignation, was "I didn't know Hamlet was going to die! Hamlet wasn't supposed to die!" The other patient, when asked if he wanted to add to the group conversation said "I didn't really understand the play but I liked the sound of the words."

Oh, I am fortune's fool!" (Romeo and Juliet)

Romeo and Juliet was especially easy for the patients to understand and they related to the play in interesting and insightful ways. One male patient thought that the dilemma faced by Romeo and Juliet would be the equivalent of a patient and a nurse at the hospital falling in love. He explained that their love could be real but no one would understand it, and both would be punished by the hospital administration. When we explained to him that such a relationship would be an abuse of authority on the part of the nurse and would be viewed as he or she taking advantage of the patient, he said simply "if it's real love, it's real love, just like Romeo and Juliet."

The patients' observations about *A Midsummer Night's Dream* were also interesting, particularly because they felt a connection to the magical elements of the play. One patient explained that had he been a character in the play, he would not have been one of the "rich" characters or one of the lovers, nor would he have been a member of the fairy world. He thought that being in the mental health system brings with it its own degradations (although he did not use that word) and it would be foolhardy to imagine that he could be someone of importance. He added that if he was in the play he would certainly be one of the tradesmen who were laughed at and mocked during their serious attempt to stage Pyramus and Thisbe. Another patient said that there is a fine line between the magic world (in her case the auditory hallucinations she experiences daily) and the real world and that the line was easy to cross. She finished up by adding that her observation was the only thing she felt like saying about A Midsummer Night's Dream.

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Shakespeare Plays

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While it appeared that the patients enjoyed Much *Ado About Nothing*, mostly they said that there was nothing particularly complicated about the story and they didn't relate to the characters in a personal way. One patient commented that it was immediately apparent that Benedick and Beatrice loved each other and the patient found their bickering pointless, adding "why waste all that time if you love somebody." Another patient said that he's known "lots of people just like" Don John, the villain of the play and was at a loss to understand why people are mean to each other. The group members all enjoyed the character Dogberry the policeman and pointed out that because he was not a rich man and because he was different and clumsy he had been underestimated by the wealthy and better educated characters in the play. I believe they were making a pointed reference to themselves in relation to hospital staff.

The patient observations that I noted in this paper are a miniscule sampling from often remarkably detailed and animated group discussions. The patients' ability to analyze the plays from their own life experiences – and do this in ways that were immediately relevant to their own lives, was both gratifying and humbling to the group facilitators, and for those reasons we considered the group successful and have discussed repeating the group with five different Shakespeare plays.

Patrick O'Reilly, Ph.D. is a clinical psychologist at Napa State Hospital in Napa, California and is an Assistant Clinical Professor of Psychiatry at the University of California, San Francisco School of Medicine.

2014 Ernest R. Hilgard's Award Lecture

Diverse Brains

By *Morton Ann Gernsbacher, PhD*

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What a great era it is to be involved in brain research, because the public loves brains. From just the books that are sold on Amazon.com, you can learn how to Use Your Brain (Amen, 2013), Use Both Sides Of Your Brain (Buzan, 1991), and Challenge Your Brain (Tuller & Rios, 2005). You can also find out how to Boost Your Brain's Power (Pasinski, & Neporent, 2012), Feed Your Brain (McCleary, 2011), Power Up Your Brain (Perimutter, 2012), even Beef Up Your Brain (Noir, 2009). But just remember: You Are Not Your Brain (Schwartz, & Gladding, 2012).

However, if you want to, you can Change Your Brain, indeed, Change Your Brain To Change Your Body (Amen, 2010). You can Save Your Brain (Nussbaum, 2010), Rewire Your Brain (Arden, 2010), and more specifically, Rewire Your Brain For Love (Lucas, 2013). You can Educate Your Brain (Brown, 2012), Entertain Your Brain (Stickels, Harris, & Christin, 2007), Stress Proof Your Brain (Hanson, 2010), Evolve Your Brain (Dispenza, 2008), Unchain Your Brain (Amen & Smith, 2010), even Outsmart Your Brain (Reynolds, 2004).

But Don't Check Your Brains At The Door! (McDowell & Hostetler, 2011), because you need to Train Your Brain about food (Hughes, 2012), Train Your Brain For Success (Seip, 2012), Train Your Brain For Wealth, Prosperity, and Financial Security (Aubele, 2011), Train Your Brain the Green Beret Way (Martel, 2012), and Train Your Brain More (Kawashima, 2008). If all of this is confusing, you are in luck because Amazon also sells a Training Your Brain for Dummies manual (Alloway, 2011).

These book titles illustrate just how much the public wants to read about anything to do with the brain. Journalists are also aware of our passion for reading about the brain. Riffing off the 1980s Public Service Announcement, "This is your brain. This is your brain on drugs" (Suddath, 2009), we now have a whole slew of articles, proclaiming "This is your brain. This is your brain on love" (Popular Science, n.d.).

A few years ago, the New York Times offered us "Your Brain on Computers" (2010) and followed that offering with "Your Brain on E-Books and Smartphone Apps" (Bilton, 2012). TIME Magazine offered us "Your Brain on Laughter" (Szalavitz, 2013); NPR offered us "Your Brain on God" (2009) and Psychology Today, "Your Brain on Food" (Wenk, 2010). Even TED conferences got into the act, with "Your Brain on Improv" (Limb, 2010).

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By *Morton Ann Gernsbacher, PhD*

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Websites are also honed into our love of the brain, and they seem to be mining the 'your-brain-on' meme for click bait. For example, Mashable.com, which covers social media, lured readers with the headline, "My Brain on YouTube" (Erickson, 2012). For the Scholastic Corporation, it was "Your Brain on Reading" (Cunningham & Rose, n.d.). For a website called The Credits, "Your Brain on the Movies" (Nuwer, 2013), and from Coupons.com, "Your Brains on Coupons" (Pavini, 2012).

During the 2012 election cycle, there was great interest in your brain on politics. A Science Daily press release claimed that, "Neuroscience reveals brain differences between Democrats and Republicans" (University of South Carolina, 2012). A research study described in USA Today claimed that brain differences can be found based on faith (Shimron, 2011). A study reported in PositScience claimed brain differences between morning people and night owls (Fitzgerald, 2012).

In my presentation, I outlined when, we as scientists, should accentuate brain differences, and when we probably should resist doing so; why we, as individuals, should accept the brain differences that truly exist; and, how, we as a society, can accommodate those brain differences.

Scientists Should Resist Over-Hyping Brain Differences

I began my presentation by focusing on an area of putative diversity that has held popular mystique for centuries: the potential differences between male versus female brains. A 2007 issue of Scientific American (Halpern et al., 2007b), to which I contributed, was based on a juried review of scientific evidence that we had previously published in the APS journal, Psychological Science in the Public Interest (Halpern et al., 2007a). The starting point for our scholarly review was the stereotypic assumption that men's brains are best suited for analytical careers, such as being math and science professors at Harvard (Summers, 2005).

In another APS journal, Current Directions, author Cordelia Fine (2010), had reminded the public that centuries before our current stable of high-tech brain imaging tools, such as MRI scanners, other tools were used to identify brain differences, such as scales. In the Victorian era, the 'missing five ounces,' the difference in weight between the average male and female brain, was considered the source of women's intellectual inferiority.

On average, female brains still weigh less (Ruigrok et al., 2014), and, on average, a female brain has a thicker cortex, which is the outermost sheet of neural tissue (Im et al., 2008; Luders et al., 2006; Preul et al., 2006; Sowell et al., 2007). But, these days, most neuroscientists no longer interpret the fact that women have thicker cortices than men – or conversely, that men have thinner cortices than women – as a deficit. It is simply a difference. However, such a progressive interpretation of difference as diversity rather than different as always deficient does not extend to all other groups.

As I reviewed in one of my APS Presidential columns (Gernsbacher, 2007b), when one research study reported that autistic persons have thicker cortices than non-autistic persons, the finding was interpreted as an autistic deficit (Hardan et al., 2006). When other research studies reported the opposite finding, autistic persons have thinner cortices, that finding was also interpreted as an autistic deficit (Chung et al., 2005; Hadjikhani et al., 2006). In neither case, was the effect size larger than what is observed between average males and females, but such heads you lose, and tails you also lose interpretations that pervade the neuroimaging-of-autism literature (Gernsbacher, 2006; 2007a; 2010).

Indeed, a few years ago, one of my PhD students, Jennifer Stevenson examined all of the autism-related neuroimaging studies in the literature at that time. The list included 36 studies with data on the cerebellum; 32 studies with data on the Superior Temporal Gyrus and Sulcus; 30 studies with data on the inferior frontal gyrus; 29 studies with data on the amygdala; 27 studies with data on the fusiform gyrus; 24 on the striatum; another 24 on the cingulate gyrus; and another 24 on the hippocampus.

To make a long story of meta-analyses short, for none of these brain regions was there a consistent pattern of results across studies. There were inconsistent findings among the functional imaging studies; there were inconsistent findings among the structural, volumetric, imaging studies. Not one brain region showed a consistent pattern across studies. But, whenever a difference between autistic and non-autistic participants was reported, even if the direction of the difference conflicted with the finding of another study, the difference was always interpreted as an autistic deficit.

For example, among studies examining the volume of the hippocampus, six studies reported that autistic participants had larger hippocampi than non-autistic participants. In each of those six studies, the autistic participants' larger hippocampi were interpreted as an autistic deficit. Another three studies reported just the opposite: that autistic participants had smaller hippocampi than non-autistic participants. In each of these studies, the autistic participants' smaller hippocampi were also interpreted as a deficit. Another study reported no difference between autistic and non-autistic participants' hippocampi. This study suggested that it must be other brain regions that are to blame for autistic participants' deficits.

As another example, among studies examining task-related functional activation in the superior temporal sulcus or gyrus, nine studies reported that autistic participants produced greater task-related activation, and that greater activation was interpreted as an autistic deficit. Another seven studies reported just the opposite – that autistic participants produced less task-related activation, and that was considered a deficit. And two other studies split the difference.

As a third example, among studies examining task-related functional activation in the amygdala. Five studies reported that autistic participants produced greater task-related activation, and that was a deficit. Three studies reported less activation, and that was a deficit. And seven studies found no difference between autistic and non-autistic participants, with some of these studies suggesting that the autistic participants must have been 'compensating for there to be no differences.

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Inconsistency characterized all the brain regions that Jennifer Stevenson reviewed. Such inconsistencies might be due to methodological pitfalls that can befall cognitive and affective neuroscience, for example, small sample sizes and what's known as p-hacking. Indeed, in research made possible by the Simons Foundation, Haar et al. (2014) drew similar conclusions.

Examining a collection of neuroimaging data from nearly a thousand autistic and non-autistic participants, made possible by Autism Brain Imaging Data Exchange, and motivated by the fact that previous findings "have not been replicated consistently in the literature" most likely due to "small samples of participants," Haar et al. (2014, p. 1, 9) found "no evidence for between-group differences in any measures of gross anatomy or in specific brain regions including the amygdala, hippocampus, most segments of the cerebral cortex, and the cerebellum".

However, in all the previous, less-powered studies, whenever a difference was observed, regardless of whether it was consistent with the previous literature or not, the difference was always attributed to an autistic deficit. Similarly, a few years ago in the APS journal Perspectives on Psychological Science, I reviewed the evidence for whether mirror neuron dysfunction underlies autism (Gallese, Gernsbacher, Heyes, Hickok, & Iacoboni, 2011). This body of data was also riddled with inconsistencies.

For example, one study measured autistic and non-autistic participants' brain activity during imitation and reported that autistic participants demonstrated greater task-related activity in the inferior parietal region. That greater task-related activity was interpreted as evidence that autistic persons have broken mirror neurons (Williams et al., 2006). But another study, also using an imitation task, reported that autistic participants demonstrated less task-related activity in the inferior parietal region, and that finding was also interpreted as evidence that autistic persons have broken mirror neurons (Dapretto et al., 2006).

I think we as neuroscientists can do better; I think we can be more sophisticated when we conceptualize diverse brains. Attributing every difference, regardless of the direction of the effect, to a minority group's deficit is cheap – and boring. A considerably more fruitful, approach has been demonstrated by an exciting series of neuroimaging studies of blind individuals (Bedny, Pascual-Leone, Dravida, & Saxe, 2012; Bedny, Pascual-Leone, Dodell-Feder, Fedorenko, & Saxe, 2011; Burton, Snyder, Diamond, & Raichle, 2002; Ofan & Zohary, 2007; Röeder, Stock, Bien, Neville, & Rösler, 2002; Watkins et al., 2012).

Although the brain is not nearly as regionally functional as our color-coded schematics lead us to believe, some of the most explicit functional specificity is found in the lobe farthest to the back, the occipital lobe. In sighted people, the occipital lobe shows strong specificity for processing visual information. But what about blind people, particularly people like Stevie Wonder, who have been blind since birth? If the occipital lobe's usual job is to handle visual processing, what do the occipital lobes of blind people do?

In the Victorian era, the 'missing five ounces,' the difference in weight between the average male and female brain, was considered the source of women's intellectual inferiority.

It would be boring and rather foolish to give blind people a bunch of visual stimuli, and when the blind participants' occipital lobes showed less task-related activity than that of sighted participants, pop the champagne, write up the study, and conclude that one has found a blind deficit. A more interesting approach is to investigate what type stimuli the occipital lobes of congenitally blind persons do respond to, and several recent neuroimaging studies have done just that.

These studies show that the brains of blind people are amazingly flexible organs. They take that prime brain real estate known as the occipital lobe, and they use it for other functions, like higher-order reasoning, judgment and decision-making, and spoken language comprehension. From my vantage point, that discovery provides a stellar model for how we as neuroscientists can more fruitfully go about studying brain differences. Similarly fruitful models have also been demonstrated recently by developmental psychologists who study children with disabilities other than autism.

For example, Susan Goldin-Meadow has demonstrated a masterful approach to studying deaf children (2003). Most compelling to Susan Goldin-Meadow are deaf children who neither are exposed to a spoken language, because they are deaf and cannot hear a spoken language, nor are these children exposed to a signed language, because their hearing parents resist using it. These deaf children develop what is known as home sign, a unique gesture system, which does not resemble their hearing parents' gestures. Rather, deaf children's home signs resemble other deaf children's home signs – even deaf children halfway around the world.

Thus, instead of describing deaf children as having a deficit in learning their parents' spoken language, and instead of describing deaf children as having a deficit in learning their speaking parents' gestures, Susan Goldin-Meadow describes deaf children's home signing as a masterful demonstration of their cleverness. Susan Goldin-Meadow appreciates that deaf children's home signing can provide an informative window into the resilience of human communication.

Another example of a more fruitful model for how to study differences without calling everything a deficit is represented by Miguel Perez-Perera and Gina Conti-Ramsden's book analyzing Language Development and Social Interaction in Blind Children (1999). As one of this book's reviewers notes: "This book summarizes and discusses the existing and very often conflicting literature and concludes that blind children's language development is not just a slower version of 'normal' development. Rather, blind children's language acquisition follows a different route" (Schleef, 2002, p. 589). A different route, not a deficit route.

Members of another minority have also witnessed a progression from their neuroanatomy and behavior being defined as a deficit to simply a difference. I am referring to left-handers. In the 19th-century, left-handedness was considered extremely pathologic (Kushner, 2011; 2013); it was assumed to be an indicator of primitivism, savagery, possession by the devil, and criminality, hence the term, sinister (Goodman, 2014).

By the middle of the 20th century, some of the cruelest of those assumptions had attenuated, at least in Western societies. As developmental psychologist Gertrude Hildreth reported in 1949, parents had become a bit more willing to accept that their left-handed children must have been, presaging the words of Lady Gaga, "born that way" (Hildreth, 1949, p. 213).

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Diverse Brains

By *Morton Ann Gernsbacher, PhD*

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Nonetheless, when over 100 upper-middle class parents were asked whether they would prefer that their child be right-handed, all but 2% of the parents indicated a preference for right-handed children. Similarly, when parents were asked if their child showed a left-handed tendency would they make the child shift to the right hand, nearly three fourths of parents said yes. And when parents were asked if their child showed a left-handed tendency would they help him become a better left-hander, only a minority of parents said that they would (Hildreth, 1949).

Times have changed, and in Western societies, attitudes toward left-handedness now epitomize the United Nations Convention on the Rights of Persons with Disabilities, which prescribes "respect for difference and acceptance of persons with disabilities as part of human diversity and humanity," which led me to the second part of my presentation.

Individuals Should Accept Their Brain Differences

I described a bountiful literature of behavioral studies, because these studies empirically document the robust, positive effects of accepting disability as diversity. The statement "It is important for me to accept myself as I am" is one of the key items on the Acceptance of Disability Scale, which was constructed over 40 years ago, and has been used in numerous research studies around the world (Linkowski, 1971). The Acceptance of Disability scale also includes other items, such as "I feel ok talking about my disability with others," "There are more important things in life than those my disability prevents me from doing," and "Because of my disability, I have a lot to offer other people."

As with most psychological scales, the Acceptance of Disability Scale comprises both positively scored items, like these items, for which acceptance of disability is indicated by a person's agreement with the item, and negatively scored items, such as "My disability affects aspects of my life that I care the most about," "My disability prevents me from doing the things I want to do," and "My disability has disrupted my life greatly." For these items, agreeing with the statement indicates a lack of acceptance of disability.

Using the Acceptance of Disability Scale, and other measures like it, a wealth of scientific data has been collected from persons of all ages, with various disabilities, in numerous countries. Unlike the morass of inconsistent brain imaging data, the body of data on acceptance of disability is remarkably consistent. Each study demonstrates a positive association between acceptance of disability and positive psychological states.

For example, one large-scale study of nearly 1300 individuals in the U.S, with a wide range of various disabilities, demonstrates that disabled persons' acceptance of their disability is highly and positively correlated with their self-esteem (Li & Moore, 1998). The more the individuals accept their disability, the more positive their self-esteem. This strong positive relation between acceptance of disability and self-esteem, for persons with disabilities, is independent of the person's gender, race, level of education, or marital status, and it is only weakly a function of whether the person has multiple disabilities or just one (see also Belgrave, 1991; Heinemann & Shontz, 1982; Linkowski & Dunn, 1974; Starr & Heiserman, 1977).

Other studies measuring acceptance of disability demonstrate a related, positive effect. Persons who accept their disabilities have better psychological well-being, as demonstrated in a U.S. study of nearly 120 Polio Survivors (Tate et al., 1994) and a Belgian study of nearly 100 individuals with Chronic Fatigue Syndrome (Van Damme, Crombez, Van Houdenhove, Mariman, & Michielsen, 2006). A Dutch study of nearly 600 persons with Spinal Cord Injury also demonstrates a strong, positive correlation between acceptance of disability and psychological well-being (Wollaars, Post, van Asbeck, & Brand, 2007).

This Dutch study, as well as a Thai study (Attawong & Kovindha, 2005), and an Australian study (Snead & Davis, 2002) with persons with Acquired Brain Injury, also illustrate another important principle: Acceptance of disability is frequently independent of severity of disability. There are individuals with severe spinal cord or brain injury who fully accept their disability and reap those positive benefits of acceptance. And there are individuals with much milder injury who resist accepting their disability and therefore, they miss out on the benefits of acceptance.

Independence between acceptance of disability and severity of disability has also been shown in a Polish study of 115 persons with chronic lower back pain (Janowski, Steuden, & Kurylowicz, 2010) and a U.S. study of 50 persons with pain from a spinal cord injury (Summers, Rapoff, Varghese, Porter, & Palmer, 1991).

Multiple studies also demonstrate that quality of life for persons with disabilities is also independent of the severity of the person's disability. For example, a British study of nearly 50 adults who were disabled by prenatal exposure to thalidomide demonstrates that their quality of life is independent of the severity of their disability (Bent, Tennant, Neumann, & Chamberlain, 2007).

In this British study, severity of disability was precisely determined because of the long-term financial compensation provided by the UK Thalidomide Trust. There were individuals with severe levels of impairment due to their exposure to thalidomide as well as individuals with only minor levels of impairment. A U.S. study of nearly 100 adults with Parkinson's also demonstrates that quality of life is independent of degree of or severity of disability (Gruber-Baldini, Ye, Anderson, & Shulman, 2009). Rather, the primary predictor of quality of life was the person's optimism.

All the studies that I reviewed pertain to individuals themselves accepting their own disability and reaping positive effects on their own self-esteem and their own quality of life. But frequently I am asked to speak to parents of children with disabilities, perhaps because in addition to being a researcher in this field, I too am a parent of an offspring with a disability.

An area in which parents are deeply interested, particularly parents of children with disabilities, is stress. And the data could not be clearer that for parents of children with a wide range of disabilities and medical conditions, parents' stress is not related to objective measures of their children's impairments. That is, parents' stress is not a function of, it is independent of, the severity of their children's disabilities.

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For example, in a US study of nearly 100 parents of children with congenital heart disease, parents' subjectively reported stress was unrelated to objective measures of their child's illness, including the number of hospitalizations, operations, catheterizations, outpatient visits, or a cardiologist's independent rating of the severity of the child's illness (DeMaso et al., 1991). In a Canadian study of 53 mothers of children with intractable epilepsy, parents' subjectively reported stress was unrelated to seizure type, seizure frequency, number of failed treatments and surgeries (Wirrell, Wood, Hamiwka, & Sherman, 2008).

In a US study of 63 parents of children with intellectual disability, parents' subjectively reported stress was unrelated to objective measures of their children's functioning levels, for instance, whether their children were so-called high functioning or low functioning (Guralnick, Hammond, Neville, & Connor, 2008). For 70 Taiwanese parents of children with Duchenne muscular dystrophy (Chen & Clark, 2007), and for 270 US parents of children with cerebral palsy (Manuel, Naughton, Balkrishnan, Smith, & Koman, 2003), parents' subjectively reported stress was unrelated to objective measures of their children's disability.

The same, highly consistent pattern has been shown for the disability of autism. Although parents of autistic children sometimes report experiencing even more stress than parents of children with other disabilities, parents' stress is unrelated to every objective measure of autism. Parents' stress is unrelated to their autistic children's level of social interaction (Davis & Carter, 2008), receptive and expressive language (Davis & Carter, 2008; Kasari & Sigman, 1997), IQ and cognitive abilities (Baker-Ericzen et al., 2005; Bishop, Richler, Cain, & Lord, 2007; Kasari & Sigman, 1997), and even the degree of or severity of their children's objectively measured autistic traits (Baker-Ericzen et al., 2005; Davis & Carter, 2008; Epstein et al., 2008).

In contrast to objective measures of impairment, for children with autism, and for children with other disabilities, their parents' stress is related to parents' subjective judgments of their children's impairments. The more stress the parents feel, the more impaired they judge their children to be (Arnaud et al., 2008; Beck et al., 2004; Benson et al., 2006; Benson & Karlof, 2009; Ekas & Whitman, 2011; Georgiades et al., 2011; Kasari & Sigman, 1997).

Given the powerful role of affect on perception, the strong relation between parents' subjectively reported stress and their subjective evaluations of their children's abilities and disabilities is not surprising. But the strong relation between parents' subjectively reported stress and their subjective evaluations of their children's abilities should throw caution to any researcher who relies on parent report for any aspect of assessment in their studies.

The United Nations prescribes "respect for difference and acceptance of persons with disabilities as part of human diversity and humanity."

If parents' stress is not a function of how disabled their children are, at least not as objectively measured, then what can attenuate parents' stress? In collaboration with fellow University of Wisconsin Psychology professor, Hill Goldsmith, and former graduate student Emily Schweigert, we investigated whether parents' acceptance of their children's disabilities attenuated those parents' subjective levels of stress. The disability we worked with was autism, and we modified items from the Acceptance of Disability Scale (Linkowski, 1971).

For example, rather than parents responding to the item, "It is important for me to accept myself as I am," we asked them to respond to the item, "It is important for me to accept my child with autism as they are." Rather than "My disability prevents me from doing the things I want to do," the item was stated as, "My child's autism prevents me from doing the things I want to do." Rather than "My disability affects aspects of my life that I care the most about," the item was "My child's autism affects aspects of my life that I care the most about." And rather than "Because of my disability, I have a lot to offer other people," "Because my child has autism, they have a lot to offer other people."

Our participants were parents of twins, one or both of whom were objectively diagnosed as autistic. In this way, we could investigate whether parents' stress was compounded by having two children with autism. It was not. In fact, as countless other studies have shown, parents' subjectively reported stress was not related to any objective measure of their children's disabilities – even, as our study demonstrated, when those disabilities were doubled. Rather, parents' subjectively reported stress was solely a function of their acceptance of their children's disabilities.

By acceptance, I surely do not mean doing nothing. Indeed, the parents, in our study, who scored high on acceptance of their children's disability reported enrolling their children in just as many conventional therapies as the parents who scored low on acceptance.

But the parents in our study who scored high on acceptance of disability, as well as persons with disabilities who score high on acceptance of disability, are adept at reframing their situation (Gerber, Reiff, & Ginsberg, 1996; Hastings, Allen, McDermott, & Still, 2002; King et al., 2006). Reframing is the art of stepping back from the current frame or lens through which one is viewing a situation, reconsidering that frame, and reconstructing a new frame, as the adage recommends: "Life may not be the party we hoped for. But while we're here we should dance."

Reframing is illustrated by a flyer from the Canadian Association for Community Living: Superimposed over a full-page photo of a school-age boy with Down syndrome, the caption reads, "Chances are he'll never cure cancer, walk on the moon, or be Prime Minister. Then again, neither will you."

Reframing is also illustrated by a case study of a pair of identical twins who were raised apart (Neubauer & Neubauer, 1996). That is, through adoption, each twin was raised in a different family. When one of the adoptive mothers was asked if her adopted child was a picky eater, the mother responded with frustration, consternation, and exasperation, saying something akin to, "Oh! My goodness, yes!" She is such a picky eater! She won't eat anything unless – unless – I put cinnamon on it. She wants to have cinnamon on everything she eats. It's bizarre, and it tries my patience on a daily basis."

When the adoptive mother of this child's identical co-twin was asked the same question about her adopted daughter's eating habits, she responded calmly and evenly, with a response such as, "No, she's not a very picky eater at all. In fact, she's a great little eater, with a very healthy appetite. I bet she'd eat just about anything — well, just as long as I put some cinnamon on it." This cinnamon anecdote illustrates the heart and soul of the concept of accommodation, which is the last topic I spoke about.

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2014 Ernest R. Hilgard's Award Lecture

Diverse Brains

By *Morton Ann Gernsbacher, PhD*

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Society Should Accommodate Brain Differences

Accommodation is key to supporting disability and enabling the diversity that disability affords. We can classify accommodations into two broad categories. There are accommodations such as curb cuts, which were initially established to level the playing ground – literally level the playing ground – for one minority group, namely persons with mobility disabilities. But in reality, although curb cuts have been incredibly important for improving the mobility of wheelchair users and scooter users, look at any street corner, and you'll see that the overwhelmingly vast majority of persons who benefit from curb cuts are not persons with disabilities, but rather bicyclists, people pushing strollers, and people pushing dollies.

Similarly, closed captions have been incredibly important for improving access to entertainment and education for deaf and hard of hearing people. But the majority of people who benefit from captions are not deaf or hard of hearing. Rather, the majority of people who benefit from captions are hearing people – and not just hearing people at bars, airports, or work cubicles who want to watch YouTube without getting caught by their boss.

Numerous studies show that captions increase literacy skills for hearing children learning to read (Linebarger, 2001; Linebarger, Piotrowski, & Greenwood, 2010). Other studies show that captions increase language comprehension skills for hearing persons learning a second language (Garza, 1991; Neuman, & Koskinen, 1992). And still other studies show that captions increase language comprehension and memory for hearing people of all ages (Bean & Wilson, 1989; Griffin & Dumestre, 1993; Kruger & Steyn, 2013).

Indeed, every study ever conducted demonstrates that captions are beneficial to a wide range of hearing people because bimodal redundancy almost always trumps unimodal presentation (Bird & Williams, 2002; Hinkin, Harris, & Miranda, 2014).

In contrast to accommodations like captions and curb cuts, which although implemented initially to aid only disabled people are now used predominantly by non-disabled people, are accommodations that remain specific to a disability, such as Braille for blind people and sign language for deaf and hard of hearing people. Accommodations, like Braille and sign language that remain specific to disability groups are often, still shrouded, in stigma.

> ***Accommodation is the key to supporting diversity; without accommodation we cannot level the playing field for our diverse society.***

A prime example of the stigma that still surrounds disability-specific accommodations is provided by hearing aids. A 2014 article on the Mayo Clinic's website provides potential hearing aid consumers with the following advice: "Perhaps you've thought about getting a hearing aid, but you're worried about how it will look." The article explains: "All hearing aids contain the same parts to carry sound from the environment into your ear. However, hearing aids ... differ in size ... Some are small enough to fit inside your ear canal, making them almost invisible."

The Mayo Clinic article further explains that in general, the smaller a hearing aid is, the less powerful it is, the shorter its battery life, the harder it is to use, and the more it will cost. Yet, that is what the Mayo Clinic, as well as every other hearing aid website I have perused, assumes that consumers prioritize: the least visible hearing aid. Can't we, as a society, agree to not be prejudiced about the visibility of a person's hearing aid? I think we can, given the strides, all puns intended, that we as a society have made in overcoming prejudice about the form of prosthetic limbs.

For centuries, the overarching goal was to create a prosthetic that most closely resembled a flesh limb. But prosthetics that prioritized the superficial aspects of a flesh limb, were bulky, often quite uncomfortable, and not very functional (Oatman-Stanford, 2012). We now prize function over form.

Indeed, some prosthetic wearers like Dan Horkey, who runs a business creating "prosthetic tattoo art" want their prosthetics to be noticed. After avoiding showing his prosthetic for two decades, decorating it was a way to be proud of it, Horkey said. "It was instant – it just made me feel good. When I walked around in public, people wouldn't look away and avoid eye contact. Instead it would provoke compliments. I was proud of my leg for the first time" (Perez, 2013). Kiera Roche wears a floral prosthetic leg, sculpted by hand, because "it's personal, it's a fashion statement" (Schweitzer, 2012).

Speaking of fashion brought me to clothing tags. For years, persons like me, persons with enhanced tactile sensitivity, what diagnosticians call "sensory defensiveness," told garment producers that clothing tags were annoying (Goldsmith, van Hulle, Arneson, Schreiber, & Gernsbacher, 2006). For such persons, our only recourse was to perform meticulous apparel surgery, being careful to remove each offending tag without creating a hole in its garment. But a few years ago, clothing manufacturers finally listened to this neural minority of consumers, and guess what they learned? Like curb cuts and captions, it is not only a minority of people who benefit from the accommodation, it is a lot of people (Murphy, 2011).

Lastly, I turned to discuss one more accommodation, quite familiar to those of us on university campuses. As chair of my University's Committee on Access and Accommodation in Instruction, I have received a lot of boots on the ground experience with regard to accommodating diverse brains. The most frequently requested accommodation made by students at my university is not Braille or sign language, which is not surprising, because the most frequent disability among students at my university, and most other universities, is not visual or hearing disabilities.

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Indeed, at my university, students with vision disabilities comprise less than 2% of the population of students with disabilities. And students with hearing disabilities comprise less than 3%, as do students with the disability of autism. Students with mobility disabilities comprise 7% and students with chronic health disabilities comprise 13%. The highest frequency disabilities on my university campus and other campuses are learning disabilities, such as dyslexia and ADHD, and the most frequent disabilities are psychological disabilities, such as anxiety and depression.

Therefore, it is not surprising that the most frequently requested accommodation is not Braille, not sign language, and not curb cuts. It is extended time on in-class exams and tests, what is often called 'time and a half.' But the terms, extended time and time and a half, are misnomers. When students request extended time or time and a half, what they really want is to take the quiz or exam without the pressure of being timed. From everything we know about the psychometrics of testing, these students are barking up the right tree.

Psychometrically, tests can be classified into speeded tests, which as the name implies, test how rapidly the examinee can complete all of the items, and power tests, which are designed to measure the examinees' power – their skill or knowledge, regardless of speed of performance (Gulliksen, 1950).

Because speeded tests are timed, speeded tests typically contain more items than every examinee can complete during the testing time. Therefore, the number of items completed during a fixed period of time is expected to vary among examinees. In contrast, power tests have no time limit whatsoever. All examinees are allowed as much time as they need. All examinees are not expected to answer correctly all items on a power test, but that is not because they run out of time. Rather it is because they do not know the information.

Most of us who teach on college campuses assume when we administer an in-class test, we are administering a power test, not a speeded test. We assume we are measuring how well the students have learned the material and how skillfully they can apply what they have learned. But if an in-class exam has a stop time, it is by definition a speeded test.

When students request extended time or time and a half, what they are really requesting is not to feel the pressure of time ticking off; not to experience anxiety about running out of time; not to have a power test administered as a speeded test. And just like curb cuts, captions, and tagless clothes, power tests, that is, tests without time limits, aid everyone.

Numerous studies across all age ranges, indicate that removing time limits not only decreases students' anxiety, but also increases the tests' validity and reliability (Attali, 2005; Elliott & Marquart, 2004; Lovett, 2010; Lu & Sireci, 2007; Scrams, & Schnipke, 1999). A decade ago, the tenth version of the Stanford Achievement Test removed all time limits for all of its subtests. This decision was based on data from 360,000 students (Brooks, Case, & Young, 2004).

Therefore, if you use in-class exams, and you too want to measure power, I have two suggestions: Either allow all students to remain as long as they want to finish every exam, or if that is infeasible, design exams that last no longer than two thirds of a class period, and tell students that. Announce to all students that everyone is welcome to remain for the entire class period, if they so desire. You will be accommodating all students, those with and without disabilities, and you will be increasing the validity and reliability of your exams (Attali, 2005).

Students, use that extra time, to review your answers and change them if you are not sure. Every research study in the literature shows that the majority of changes on tests are from wrong to right, rather than right to wrong (Fischer, Herrmann, & Kopp, 2005; Higham & Gerrard, 2005; Lynch & Smith, 1975; McMorris, DeMers, & Schwarz, 1987; Schwarz, McMorris, & DeMers, 1991; Vispoel, 1998).

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Division One Crossword Puzzle

Author: Stephanie Schwartz, *St. John's University*

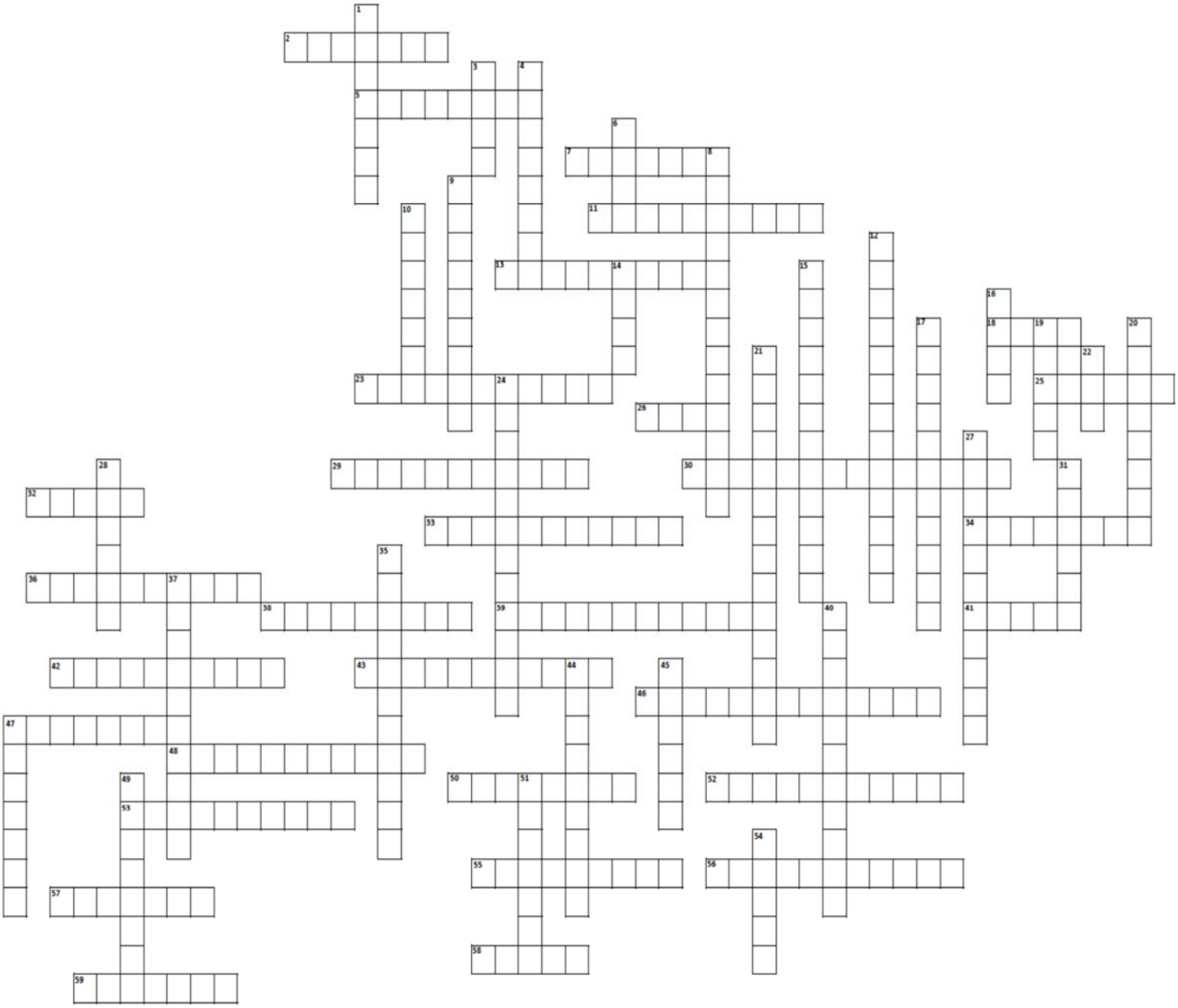

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Division One Crossword Puzzle

Author: Stephanie Schwartz, *St. John's University*

ACROSS

2. Using successive approximation to gradually reinforce behavior tendencies in a desired direction
5. Part of the brain that deals with emotions
7. Core units of the nervous system
11. The adjustment of people's behavior, attitudes, and beliefs to a group
13. _____ desensitization
18. Initials that identify a dimplomat in psychology
23. A relationship or association between two variables, scale of -1 to +1
25. Promoted a form of person-centered psychotherapy
26. Founder and first president of APA
29. Animal researchers who stressed the importance of critical periods and early experience
30. Freud's therapeutic approach
32. First psychology laboratory at Harvard (1875). William _____
33. Ability of a test to produce similar results over time
34. Seligman's Psychology
36. A proposed relationship between two variables
38. A type of intelligence that includes identifying the emotions of others
39. Young-Helmholtz theory
41. Goal-oriented, humanistic psychologist, stressed organ inferiority
42. Knowledge is derived through experience
43. School of psychology founded by John Watson
46. Increases the likelihiood that a response will occur
47. Immersion into the feared situation as an intervention to decrease the feared response
48. Tendency for the body (person) to want to maintain a state of constancy
50. First woman to receive a PhD in psychology
52. Ability to identify previously encountered information
53. Mental shortcuts that guide us in problem solving and decision making
55. The study of the meaning of words/combinations/sentences
56. An individual's pattern of behavior, thoughts, motives, and emotions; consistent over time
57. First woman president of APA
58. First psychology laboratory. Wilhelm _____
59. Openness, conscientiousness, extroversion, agreeableness, neuroticism

DOWN

1. Disorder characterized by the inability to use language
3. The ninth International Congress of Psychology held here
4. Ability of a test to measure what it purports to measure
6. _____ Münsterberg; author of "On the Witness Stand"
8. Titchener's version of voluntarism
9. Items under consideration in a study; can change
10. First African American woman to receive a PhD degree in psychology
12. Competing school to structuralism
14. The average of a set of numbers
15. A form of learning; classical _____
16. Considered the founder of the phrenology movement
17. Genetically identical twins
19. First International Congress Meeting Location
20. Smallest unit of meaning in a language
21. Repeated behavior as a penalty for inappropriate behavior
22. Mediates id and superego
24. In Piagetian theory using existing ideas in new situations
27. Part of the brain involved in memory
28. Individual cells which receive, integrate, and transmit information
31. The founder of school psychology
35. Tests that use unstructured or ambiguous stimuli
37. Studied memory using nonsense syllables
40. Variable that is manipulated
44. Drug that speeds up activity in the central nervous system
45. An involuntary response
47. Created the formula: S= k log P
49. Strategy which helps us hold information; group things together
51. _____ von Helmholtz
54. The co-author of "Studies of Hysteria" (1895)

New Book Releases from our Members

Women and Aging

An International, Intersectional Power Perspective

Edited by Varda Muhlbauer, *Netanya Academic College*, Joan C. Chrisler, *Connecticut College*, & Florence L. Denmark, *Pace University*

This book is focused on women over 60, a group who have pushed against age and gender restrictions and challenged the traditional construction of gendered age identity and stereotypes. The authors of the chapters take a feminist/power perspective as they examine such topics as body image, economics and purchasing power, multiple roles, leadership and encore careers, sexuality and romance, older lesbians, and clinical interventions to empower older women. The book includes a foreword by Jamila Bookwala.

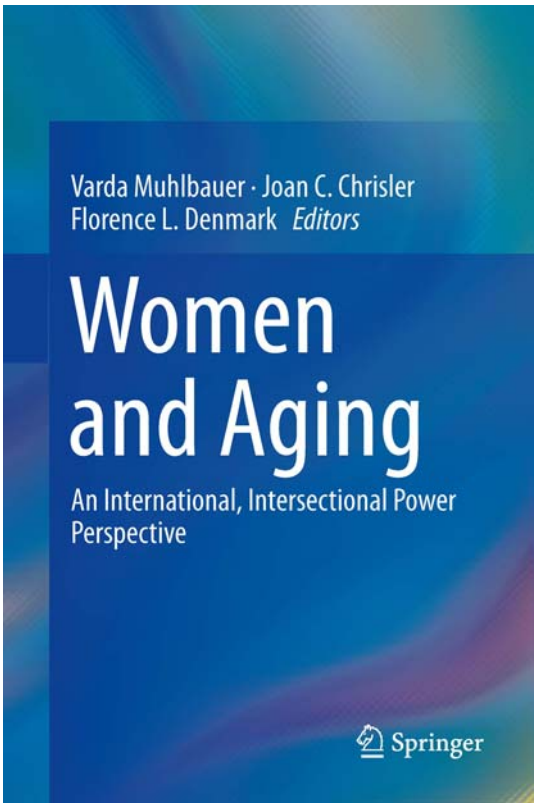

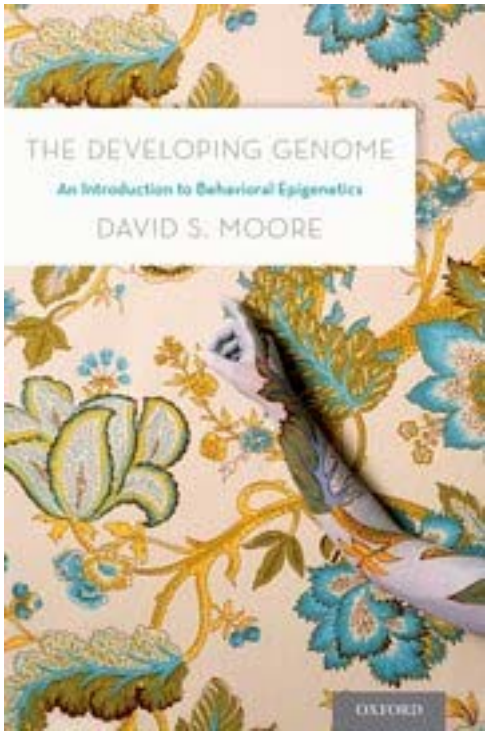

David S. Moore, Ph.D. , Professor of Psychology
Pitzer College and Claremont Graduate University
Claremont, CA 91711

I am pleased to announce the release of my new book, The Developing Genome: An Introduction to Behavioral Epigenetics (Oxford University Press, 2015). Behavioral epigenetics is important because it explains how our experiences get under our skin and influence the functioning of our genes. Because research in behavioral epigenetics has demonstrated that experiences influence genetic activity, this work has the potential to change how we think about nature, nurture, and human development. My goal in writing this book was to offer an introduction to this emerging field, which would be useful to any interested party, from undergraduates to established research scientists. As such, the book is structured to allow readers without a strong background in biology to understand the momentous implications of behavioral epigenetics; at the same time, specific chapters offer readers with more training in biology access to the latest molecular details associated with this ascendant discipline. In addition to critical background information, the book has dedicated chapters on topics such as stress, memory and learning, the effects of abusive parenting, nutrition, and transgenerational inheritance.
Please feel free to contact me if you have any questions!

Member Profiles

David S. Moore is a Professor of Psychology at Pitzer College and Claremont Graduate University in Southern California. He received his B.A. in psychology from Tufts University and his M.A. and Ph.D. in developmental and biological psychology from Harvard University; he also completed a postdoctoral fellowship at the City University of New York. He is a developmental cognitive neuroscientist with expertise in perceptual and cognitive development in infancy. His empirical research has produced publications on infants' reactions to infant-directed speech, on the development of spatial cognition, and on infants' rudimentary perception of numerical quantities. His theoretical writings have explored the contributions of genetic, environmental, and epigenetic factors to human development. His first book, The Dependent Gene (2001), was widely adopted for use in undergraduate education, was translated into Japanese, and was nominated for the Cognitive Development Society's Best Authored Volume award. His new book on behavioral epigenetics, The Developing Genome, was published by Oxford University Press in 2015. For more information on his new book, see the announcement in this newsletter!

Dr. Hanley is a Licensed Clinical Psychologist in Michigan who works with adults, adolescents, children, and couples. He specializes in outpatient psychotherapy with individuals struggling with depression, anxiety, relationship issues, addictions, trauma, and more. In addition to his psychotherapy work, Dr. Hanley is an Adjunct Instructor at the University of Detroit Mercy. He has taught undergraduate and graduate courses in Adult Development and Aging, Death and Dying, and Personality Disorders. He has published in the areas of self-actualization, psychoanalytic theory, and psychotherapy. Dr. Hanley has a warm demeanor and a particular knack for helping people figure out what has gotten in the way of living happier, less conflicted, and more fulfilled lives. His training includes a Ph.D. in clinical psychology from the University of Detroit Mercy, a B.A. in psychology from the University of Michigan, and extensive post doctorate training in psychoanalytic theory and practice. He takes an eclectic and client-centered approach to his work.

Feature Articles/Books from our Members

Eddy, B., & Kreger, R. (2014). Splitting: Protecting yourself while divorcing someone with borderline or narcissistic personality disorder. Retrieved from http://www.stevenjhanleyphd.com/blog/book-review-splitting-protecting-yourself-while-divorcing-someone-with-borderline-or-narcissistic-personality-disorder/

Klinger, E. (2013). Goal commitments and the content of thoughts and dreams: Basic principles. Frontiers in Psychology, 4(415), 1-17. Retrieved from https://edutrotea.edublogs.org/files/2015/04/Klinger2013-18f5oye.pdf

General Psychology Trivia Quiz: Part 2 **Answers**

1. B(urrhus) F(rederic) Skinner.
2. Margaret Floy Washburn, 1894, from Cornell University.
3. Columbia University. (Harvard is second.)
4. His book "The Principles of Psychology" published in 1890.
5. Edward Thorndike wrote this to James McKeen Cattell after reviewing G. Stanley Hall's Adolescence (1904).
6. Lucy May Day Boring, the wife of psychology historian E. G. Boring and a psychologist in her own right, was a few weeks shy of her 110th birthday at the time of her death.
7. Stanford University.
8. Anna Berliner who received her doctorate in 1914, near the end of Wundt's career.
9. Edward B. Titchener's brain is on display outside the Psychology Office in Uris Hall, Cornell University.
10. Harry Harlow.

Bonus Question:

11. The French Chef, Julia Child. In fact, many of her later TV shows were broadcast from the house. .

Readers are encouraged to submit their favorite psychology trivia to John Hogan at hoganjohn@aol.com. If their trivia is used, they will be acknowledged in a future "answer' section.

Welcome to our Members who have signed up for our Online Newsletter!

1. Dr. Mindy Erchull
2. Dr. Lori Ellingford
3. Richard Meegan
4. Dr. David Leary
5. Mr. Robert Dumond
6. Mark Sciutto
7. Katarzyba Kościcka
8. Dr. Richard Velayo
9. Barry Klein
10. Dr. Jeffery Mio
11. Dr. Raymond Fancher
12. Mrs. Rhonda Dreggors-Newport
13. Dr. Lyle Bourne
14. Mr. Ray Browne
15. Dr. Steven Hanley
16. Dr. Lisa Osbeck
17. Dr. Thomas Faschingbauer
18. Professor David Moore
19. Alan Feldman
20. Dr. Alan Skidgell
21. Dr. Andrew Bland
22. Eric Klinger
23. Dr. Joelle Mast

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2. Adler [Photo]. Retrieved from http://www.oigarden.com/adlerimages/home.jpg

Division One Crossword Puzzle - Answers

Author: Stephanie Schwartz, *St. John's University*

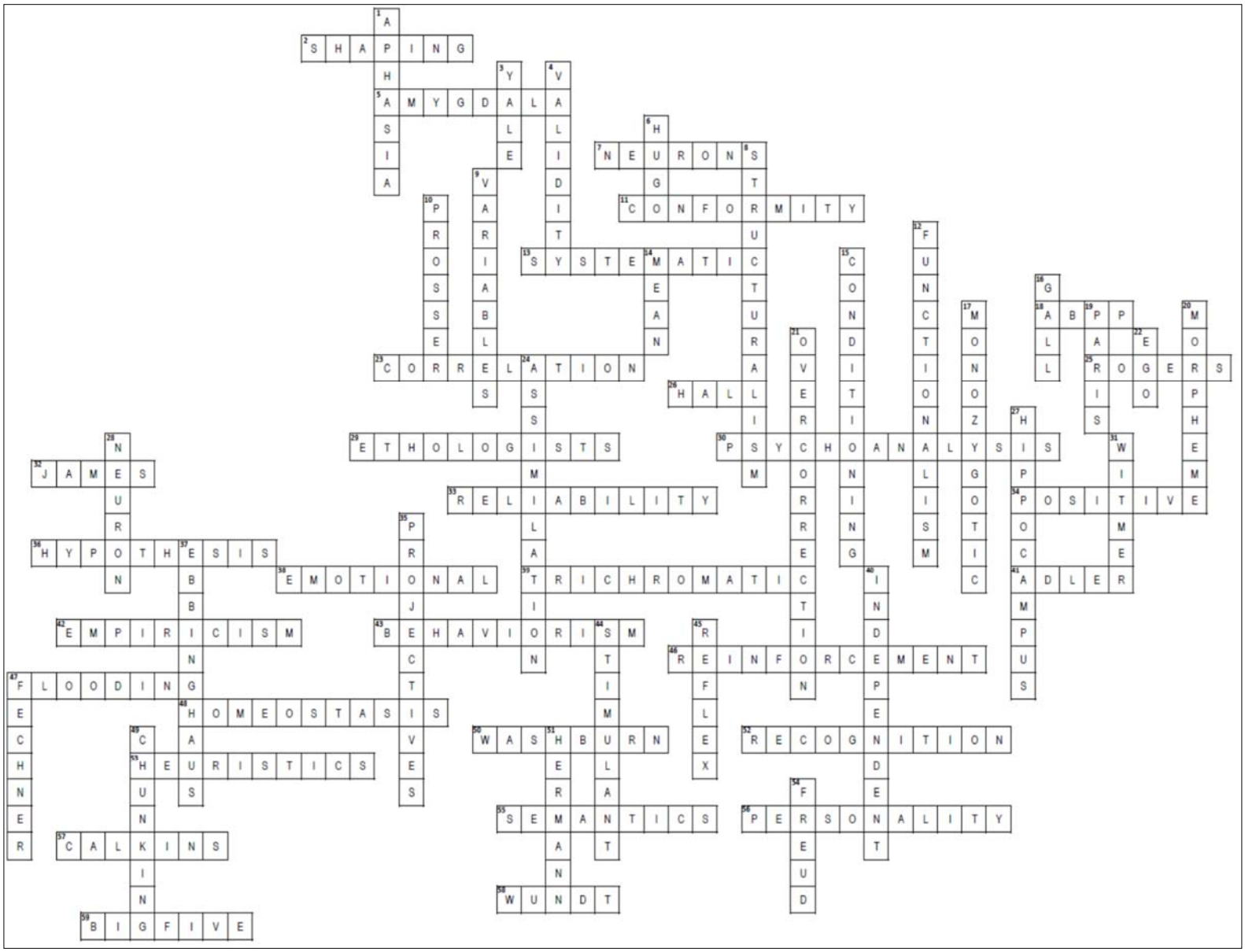

American Psychology Association (APA)
Society for General Psychology

Quote from Morton Ann Gernsbacher, PhD:

"These studies show that the brains of blind people are amazingly flexible organs. They take that prime brain real estate known as the occipital lobe, and they use it for other functions, like higher-order reasoning, judgment and decision-making, and spoken language comprehension. From my vantage point, that discovery provides a stellar model for how we as neuroscientists can more fruitfully go about studying brain differences."

Thank you to those who signed up with our online subscription! Currently, the most popular theme is *The Myth of the Golden Years* for Fall 2014. Eating Disorders, Racism/Prejudice and Parenting/Fatherhood/Single Families tied for second, third and fourth respectively. If you have not signed up with our newsletter, please do so now:

https://division1apa.wufoo.com/forms/m1isbaac0l7bqe7/

Our theme will coincide with the celebration of our 70th anniversary. Details will be sent out in July. Submission deadline for Fall Newsletter: **Friday September 4th**. Please do not hesitate to contact me if you have any questions/concerns (ali.trot@gmail.com).

See you in Toronto for the 70th Anniversary of Division 1!

American Psychology Association (APA)
Society for General Psychology

Email: ali.trot@gmail.com

It may be that we are puppets-puppets controlled by the strings of society. But at least we are puppets with perception, with awareness. And perhaps our awareness is the first step to our liberation.

-Stanley Milgram

International Psychology Bulletin

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Editor
Vaishali V. Raval

Associate Editors
Harold Takooshian
Richard Velayo

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div52.org

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Submission Deadlines

International Psychology Bulletin

Vaishali V. Raval, Editor, ravalvv@miamioh.edu

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to the appropriate section editor.

Guidelines for submission to peer-reviewed research article or theoretical review sections, please see the next page.

- *Book Reviews, Current Issues Around the Globe, Division 52 News,* and *Peer-Reviewed Research Articles:* Vaishali V. Raval ravalvv@miamioh.edu
- *Early Career Professional Column*: Genomary Krigbaum , genomary.krigbaum@my.gcu.edu
- *Student Column:* Valerie Wai-Yee Jackson vjackson@alliant.edu
- *Teaching International Psychology:* Gloria Grenwald grenwald@webster.edu
- *Travels in the History of Psychology:* John D. Hogan, hoganj@stjohns.edu
- *Heritage Mentoring Project:* Neal Rubin, nealrubin@hotmail.com

Submission Deadlines:

Spring issue March 31st
Summer issue June 30th
Fall issue September 15th
Winter issue December 15th

Issues typically will be published about 4 weeks after the deadline.

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Submission Guidelines for
Peer-reviewed Research Articles & Theoretical Reviews
International Psychology Bulletin

The *IPB* publishes peer-reviewed research articles and theoretical reviews that focus on important issues related to international psychology. The review process takes approximately two months.

Please submit the following three documents in Microsoft Word format to Dr. Vaishali Raval at ravalvv@miamioh.edu:

- A cover letter
- A title page with the title of the manuscript, author names and institutional affiliations, and an author note that includes name and contact information of corresponding author
- A blinded manuscript that does not include authors' names or any identifying information

Cover letter

- In your cover letter be sure to include the author's postal address, e-mail address, and telephone number for future correspondence
- State that the manuscript is original, not previously published, and not under concurrent consideration elsewhere
- State that the manuscript adheres to APA Ethical Principles (Ethical Principles of Psychologists and Code of Conduct), and all co-authors are in agreement about the content of the manuscript
- Inform the journal editor of the existence of any published manuscripts written by the author that is sufficiently similar to the one submitted (e.g., uses the same dataset).

Blinded Manuscript

- Prepare manuscripts according to the *Publication Manual of the American Psychological Association (6th edition)*.
- Check APA Journals Manuscript Submission Instructions for All Authors
- The entire manuscript should be formatted in 12-point Times New Roman font, 1 inch margins, and double-spaced submitted as Microsoft Word document. The entire manuscript should be up to 4000 words.
- The first page of the manuscript should include a title of the manuscript (no more than 12 words)
- The second page of the manuscript should include an abstract containing a maximum of 250 words, followed by up to five keywords brief phrases
- The remaining pages should include the text of the manuscript. For research articles, include introduction, method, results, and discussion. The format of a review paper will vary, and may include a brief introduction to the topic, review of the literature, and conclusions and future directions.
- Provide a full reference list as per the *Publication Manual of the American Psychological Association (6th edition)*.
- Present tables and figures as per the *Manual, if you have any, at the end of the manuscript.*
- Review APA's Checklist for Manuscript Submission before submitting your article.

Upon acceptance

Please note that if your article is accepted for publication in *International Psychology Bulletin*, you will be asked to download the copyright transfer form, complete and sign it, and return to the editor (ravalvv@miamioh.edu) before the manuscript can be published.

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Welcome From the Incoming Division 52 President

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APA 2015 Division 52 President
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I would like to express my appreciation and excitement to serve as your 2015 President of Division 52 of the APA. I have thoroughly enjoyed being part of the division and am honored that you selected me to serve in this challenging position. I have benefitted greatly from the support of many colleagues and divisional leaders, but really want to acknowledge and thank our immediate past-President, Dr. Senel Poyrazli. Senel was a consistent guiding force for the division this past year. I learned a great deal from her and am pleased to call her a friend.

I looked back at my nominating statement to remind myself what I said 18 months ago when I decided to run for president of Division 52. I wanted to take this opportunity to briefly discuss my background, what led me down the international psychology path and what my goals are for the upcoming year. If I get poetic license to change the title of a popular children's' book, my interest in international psychology came about through "*A Series of Fortunate Events*".

Having earned my doctorate in clinical and school psychology I was fortunate enough to get a position as a faculty member at St. John's University in Queens, New York. Queens county is the most diverse county in North America and I found that I would often learn from our students about how psychology is seen from an international perspective. At the beginning of my career, I recall using the terms "international psychology" and "cross-cultural psychology" interchangeably, but quickly learned the important distinction. Having had the opportunity to train with Dr. Albert Ellis, the founder of Rational Emotive Behavior Therapy (REBT), I was asked by the Albert Ellis Institute to provide a number of international trainings over the past 15 years. What I quickly found was that I needed to give up my "Western creation philosophy" that the areas of clinical assessment and intervention started and ended in the United States. I learned a great deal from my travels about the history of psychology from an international perspective. This began to impact upon my research and teaching while increasing my interest in international psychology.

My interest in international psychology was further piqued by a former Dean at my university who gauged my interest in working with faculty at a University in Vietnam to develop the first school psychology program. This has probably been the most personally meaningful professional activity of mine, as it allowed me to bring my knowledge of school psychology to Vietnam and learn from and collaborate with faculty there to build something that is sustainable. I am hopeful that this will have a long-term impact on the educational and social development of youth in Vietnam.

My colleague and friend at St. John's, Dr. John Hogan (past president of Division 52) was influential in getting me involved in the Division and continues to educate me about the decidedly international focus of psychology from the beginning. By becoming involved in the division I have witnessed first-hand the dedication and commitment of many individuals to the field of international psychology and the opportunities to "build bridges" (to borrow from Division 52 Past-President Dr. Mercedes McCormick). One would think that with individuals from very diverse backgrounds both geographically and professionally that there would be a potential for these differences to cause friction within the division. I have found the opposite to be true within the division, as the individuals that I have had the opportunity to work with have been caring and supportive, and I actively encourage others who are considering becoming involved in the division to do so. I believe that while my formal education may have ended almost 20 years ago, I continue to learn and understand the true internationalization of psychology. I often find myself considering: where will the future of international psychology go?

When you look at the field of psychology, international psychology is everywhere! The membership of the APA is becoming more international (7000 international members at last estimate) as are those who attend the conference (about 600 yearly) (CIRP, 2014). Further, the APA graduate student association (APAGS) has an active international email list. The growth in the published literature is quite impressive, with a 27.5% increase in citations that come up after the search "international psychology" for the last five years *in comparison* to the previous ten. In addition to our excellent division journal, many divisions of the APA have international committees (14 of the 56 divisions at last count) and many dedicate a special section of the journal to an international theme.

In trying to understand this growth and interest in international psychology, I imagine that there are many variables that may be predictive of this. I am of the belief that there is one variable that directly and indirectly contributed to this: technology. In society as a whole, we are at quite an interesting time with regard to how technology has afforded us better access to information as well as an opportunity for researchers to understand more about the human condition from a medical model to a psychological one. The opportunity to share resources through advanced technological tools for data collection and analysis may help us answer some age-old questions related to psychology as well as create new ones. I am highly skeptical that any of the projects that I have done with my international collaborators could have been done in the absence of technology as it is today. While the reflection of the blue screen of Facebook on my students glasses while I teach may frustrate me, I think we have to recognize the power of social media and embrace these technological advances to further international psychology and our division. The use of technology to further education can be seen in the expansion of the Massive Open Online Courses (Moocs). In 2014, the number of MOOCs doubled to over 400 universities with a doubling in the number of cumulative courses to 2400. These courses are being offered from 22 of the top 25 US universities in US News World Report rankings and social sciences makes up approximately 6% of the course offerings (Shah, 2014).

Given these advances and the potential benefit for our field, technology to promote international psychology will be my theme for my Presidential term. I want our division to *make technology matter* to further international psychology education, practice, and research. I want us to consider how do we bring technology into the classroom, how might technology be utilized to foster international practice, and share resources and information to develop collaborative research programs. Drs. William Pfohl and Monica Thielking are serving as our program chairs and have actively worked to promote this within the conference. The division has a technology task force that we hope will continue to build our divisions' use of technology. The Early Career Psychologists subcommittee successfully launched our first Division sponsored webinar this past December. Division 52 along with Division 2 and Psi Chi received an APA grant to promote the internationalization of "Project Syllabus" to encourage the submission of syllabi from different countries and in different languages.

So much like international psychology is everywhere, so is technology. I am hopeful that many of you will continue to embrace technology while also considering how it can be expanded within the division as well as in the field of international psychology. I am grateful to be able to serve the division as President this year, I look forward to working with many of you and am hopeful that I am able to support your faith in me.

References

Committee on International Relations in Psychology (CIRP). (n.d.). Retrieved December 20, 2014, from http://www.apa.org/international/governance/cirp/index.aspx

Shah, D. Online Courses Raise Their Game: A Review of MOOC Stats and Trends in 2014. (n.d.). Retrieved December 20, 2014, from https://www.class-central.com/report/moocs-stats-and-trends-2014/

APA Office of International Affairs

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UN MATTERS

Nelson Mandela's Legacy, the United Nations and the APA— Parallel and Intersecting Lines

The latest issue of *Psychology International* can be accessed on the Web at: http://www.apa.org/international/pi

International Research Award for Graduate Students in Psychology

Call to students engaged in international psychology research!

Division 52, International Psychology, is offering an International Research Award for graduate students in psychology. This award has been established to encourage and recognize promising graduate student research in international psychology.

On or before Sunday midnight (PST), **May 3th, 2015**, interested students should submit:

- Four page double-spaced summary of research that describes the purpose, method, analysis, results, and discussion of your international research (excluding references and one table or figure). Please also exclude all identifying information on research summary document.
- Curriculum Vitae.
- One-paragraph email endorsement from faculty research advisor/sponsor providing:
  - Endorsement for the award;
  - Confirmation that research was an independent project, thesis, or dissertation effort conducted during graduate program; and
  - Assurance of student's good standing in the graduate program.
- Two-paragraph cover email from the student:
  - First paragraph should provide: contact information (email & phone), name of graduate program and research advisor, year in the program, expected graduation date, as well as member status with Div. 52. Student must be a member of Div. 52 as of application deadline.
  - Second paragraph should assure the committee that student's independent research project, thesis or dissertation is nearing completion and that student is not applying simultaneously for another similar APA research award. At least preliminary analysis and results must have been completed by May 2015.

Please note that submissions exceeding the paragraph or page limits will be disqualified.

Email all application materials BEFORE MIDNIGHT, Pacific Standard Time, on **MAY 3, 2015**, to the Chair of the Division 52 Student International Research Award: Daria Diakonova-Curtis, PhD, St. Petersburg State University; E-mail: daria.diakonova@gmail.com

The two-tiered blind rating process is designed to will evaluate the award applications under double-blind review based on: (a) the degree of relevance to international psychology, (b) progress to completion, (c) adherence to APA Style, (d) originality of research, (e) clarity of design and method, (f) complexity of analysis, (g) quality of findings, (g) recognition of limitations, (g) insight in the discussion, and (h) brevity and clarity.

Awardees will be notified no later than Monday June 8, 2015, awarded in person at the Division 52 APA Convention awards ceremony in Toronto, Canada, and featured in an issue of the International Psychology Bulletin.

Call for Nominations APA Division 52 Henry David International Mentoring Award

Henry David was a founding member of Division 52 and a significant contributor to international psychology. In honor of his contributions, Division 52 established the Henry David International Mentoring Award. The recipient of this prestigious award will be honored at the 2015 APA Convention in Toronto. Nominations, including self-nominations, are welcomed. The Division 52 Henry David International Mentoring Award is presented annually to a member or affiliate of Division 52, who plays an exceptional mentoring role in an international context. Mentoring may be defined by any of the following activities:

(1) A psychologist who has served as a mentor for international students or faculty member for at least three years.

(2) A psychologist who has mentored students in the area of international psychology, by training, educating, and/or preparing students to be active participants in international psychology.

(3) A senior psychologist who has mentored early career psychologists who are now functioning as international psychologists.

OR

(4) An international psychologist working outside of the United States who serves as a mentor on his/her campus or at his/her agency.

Nominations should include a cover letter, vitae, and at least 3 letters of endorsement from former or current mentees. **Questions about the application procedure and nominations should be emailed to the Henry David International Mentoring Award Committee Chair, Lawrence Gerstein at lgerstein@bsu.edu.** The Committee will review the nominations. The Committee's recommendation will be reported to the Division 52 Board of Directors. **The deadline to submit materials is April 1, 2015.**

What are Rights? Definitions and Perspectives from the Global South

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Abstract

The purpose of this exploratory study was to analyze definitions of "rights" from the Global South, which has been too often neglected by researchers addressing constructs with universal implications. A convenience sample of 747 participants from Brazil, Colombia, The Philippines, India, Algeria, and Ghana, which were once colonies of Western nations, provided definitions in their own words of the term "rights." These definitions were coded for basis (inherent, legal, or moral), nature (freedoms, rights, or other specifications), and outcome/function/purpose. Basic descriptive analyses indicated that the basis of rights was more often described as inherent or moral than legal, and that the nature of rights more often took the form of individual freedoms and social duties to the individual than of individual duties to society or the government. Our findings suggest a common core in conceptions of rights, with subtle variations across countries in some of the elements of those conceptions. They also add normative support from the overlooked Global South for the salience of human rights, and may contribute to the development of peace protocols that incorporate local definitions of individual rights and institutional responsibilities. Finally, they suggest that future research, as well as interventions aimed at peacekeeping and supporting human rights, should focus more on the fostering of universal human values and ethics and less on policy and governmental action, regulation, and law.

The United Nations Declaration of Human Rights, adopted by the United Nations General Assembly on December 10, 1948, is a remarkable document, globally revolutionary on several points. First, it anchors the foundation of human rights in "the equal and inalienable rights of all members of the human family"; thus, in regard to the longstanding debate as to whether human rights are inherent in every human or derive from legal documents promulgated by appropriate authorities, the Universal Declaration comes down solidly on the inherency of human rights. However, the Universal Declaration also indicates that "human rights should be protected by the rule of law" and that not only are people

born "free and equal in dignity and rights," but are also "endowed with reason and conscience and should act towards one another in a spirit of brotherhood." Thus, the document adds a moral as well as a legal dimension to the foundations of human rights. Second, this crucial document, originally named the Declaration of Human Rights and Freedoms, enshrines at least three fundamental types of freedom: freedom to have, freedom to do, and freedom from inhumane and unjust behavior from ruling parties.

The universality of human rights is made explicit in the Universal Declaration, and talk of human rights and human rights violations is part of the contemporary global discourse. However, rarely have ordinary people around the world been asked to provide, in their own words, their personal beliefs, understandings, and definitions regarding human and governmental rights. In particular, researchers have paid little attention to the Global South, which is an area that has been subjugated and exploited by Western powers since colonial times. The Global South has also been afflicted by violence and oppression from within, as members of privileged classes often oppress their poor and disenfranchised counterparts. With the exception of the work done by the Group on International Perspectives on Governmental Aggression and Peace (GIPGAP), little voice has been given to individuals afflicted by violence in the Global South. The GIPGAP provided a platform to researchers by publishing a four volume series on *State Violence and the Right to Peace* (Malley-Morrison, 2009a, b, c, d), the *International Handbook on War, Torture, and Terrorism* (Malley-Morrison, Hines, & McCarthy, 2013) and the *International Handbook on Peace and Reconciliation* (Malley-Morrison, Mercurio, & Twose, 2013). The current study, which grows out of that larger international collaborative project, is an exploratory study of definitions of "rights." In particular, we investigated lay persons' definitions of rights from an idiographic approach with a focus on their phenomenological understanding; a major goal was to give voice to a part of the world that has long been neglected in comparison to the richer and more powerful countries of the northern hemisphere.

Learning more about contemporary understandings of human rights in the Global South seems particularly important. According to Nault (2011): 1) The common emphasis on human rights as a Western invention neglects the contributions arising out of resistance in the Global South to Western imperialism; 2) Global South countries made larger contributions to the United Nations Charter and the Universal Declaration of Human Rights than is generally recognized; 3) "Examples of human rights abuses linked to Western nations' domination of their formal and informal empires are too numerous to recount..." (p. 13); and 4) much of the Global South continues to be subject to human rights abuses (e.g., human trafficking, in which Western organizations and governments have been complicit). Moreover, research with young people from Western countries such, as Canada, indicates that they view human rights problems as more of an issue in "Third World" and in former Soviet Union countries than in the West (Moghaddam & Vuksanovic, 1990), with very little understanding, we suggest, of the role the "developed" countries have played in the abuses experienced in those "developing" countries.

Perspectives on the Universality of Human Rights

It would be difficult to establish empirically that human rights are "inherent" in human beings; however, several researchers have made the case that human rights have a normative basis that is prior to their codification in conventions and legal and judicial documents. Doise (2003), for example, argued that there is considerable evidence supporting the idea that human rights are much more than just legal rights. Spini and Doise (2005) asserted that declarations of human rights are formal expressions or codifications of principles built into (inherent in) human interactions. Moghaddam (2000) made a similar argument, stating that certain fundamental relations (e.g., cooperation) are inherent in human social life and predate legislated ("black letter") rights and duties.

Much of the research conducted by Doise and associates consists of survey research, often of multi-national samples, to explore the nature of lay theories of human rights and duties, and the extent to which these lay theories correspond to those of experts. In one survey of participants from 35 countries from the Americas, Africa, Asia, Europe, and the Pacific, Doise, Spini, and Clémence (1999) found that participants from those diverse regions shared similar understandings and evaluations of various articles in the Universal Declaration of Human Rights. For example, in each national group there was greater agreement with the most basic rights (freedom from torture and slavery) than with such social and economic rights as equal access to public services and opportunities to rest and leisure.

The counterpart of universalism is cultural specificity. As Hoppe-Graff and Kim (2005 p. 53) point out, "rights and duties may mean different things in different cultures." In their study of definitions of rights from adolescents from an individualistic culture (Germany) and a collectivistic culture (Korea), they found that the German teens were more likely than the Korean teens to equate rights with being permitted by an authority to do something, whereas the Korean teens were more likely to associate rights with feelings of obligation, responsibility, being respected, and being treated correctly. Hoppe-Graff and Kim also emphasized that underlying the understanding of rights in young persons from both cultures were the concepts of self-determination, obligation, and responsibility.

Rights and Duties

As is true in regard to rights, there has been a growing effort to establish the universality of duties and an argument for the inherency of duties in human interactions. For example, Moghaddam, Slocum, Finkel, Mor, and Harré (2000) described duties, like rights, as having their origins in long-standing social psychological aspects of social interactions. In their "cultural theory of rights and duties," Moghaddam and Riley (2005) suggested that a small number of basic universal rights and duties emerge from "primitive social

practices" such as turn taking (p. 78).

To explore nuances in the balance between rights and duties, Moghaddam and Finkel (2005, p. 281) recommended using "qualitative methods and critical assessment" rather than traditional survey methods. Following their recommendations, the present study utilized qualitative techniques to assess definitions of rights in areas of the world very much neglected by Western researchers (i.e., areas of the Global South subjected to long-lasting human rights violations both from imperialistic occupiers and anti-colonial revolutions that failed to bring about fundamental changes in the rights and perceived duties of civil society in those countries). In particular, we addressed the following research questions: Would samples from the Global South characterize rights as inherent, legal, or moral? Would their definitions emphasize freedoms or duties? Or would their spontaneous and personal definitions utilize constructs quite different from those addressed, however meagerly, in Western social science literature? Given that the international organizations most concerned with ensuring "rights" have adopted a universalistic conception of inherent human rights, it seems important to consider the extent to which that universalistic conception has validity for parts of the world where large portions of the population were long considered to have no rights.

Method

Participants

A convenience sample of 747 participants was recruited largely through snow-balling techniques from six Global South countries formerly occupied by Western nations: Brazil (Portugal), Colombia (Spain), The Philippines (Spain, Japan, and the United States), India (England), Algeria (France), and Ghana (England and the Netherlands). See Table 1 for age and gender information by country.

All participants responded, in writing, to the Personal and Institutional Rights to Aggression and Peace Survey (PAIRTAPS), generally in their home countries, with the survey available both in English and in a native language (Portuguese in Brazil, Spanish in Colombia, Filipino in the Philippines, English in India, Arabic in Algeria, and Ewe in Ghana[1]). Each translation was done by a native speaker of the language and checked by at least one other native speaker in the country in which the survey was being administered. Discrepancies between translations were resolved through discussion in order to achieve consensus. The translations for the term "rights" were: *direitos* in Portuguese, *karapatan* in Filipino, حقوق in Arabic, and *derechos* in Spanish.

The 36-item PAIRTAPS survey, developed by the GIPGAP, includes rating scale and open-ended items regarding level of support for various forms of governmental aggression as well as items asking for definitions of terms such as "rights," "terrorism," and "justice." The survey took about 30-40 minutes to complete. For the current study, we focused only on the item asking participants to define the term "rights."

The methods by which the survey was administered and completed varied somewhat across countries. For example, in Brazil, surveys about "*direitos humanos"* were distributed by teaching assistants and students to peers, family, and associates, and completed anonymously, in writing, in Portuguese. Responses were then back-translated to English. The Philippine dataset was gathered through distribution of printed surveys, English and Filipino translations, in selected cities and schools in metro Manila, the Cordillera Region in the North, and Davao City in the South. A portion of the responses was also collected from the online survey. Three researchers in India recruited participants independently, using a number of different methods, including snowballing techniques in

Table 1
Demographics by Country

	n	Mean Age	Range Age	n Females	n Males	n Protestors
Philippines	256	30	18-69	155	98	46
India	230	31	18-75	95	132	42
Colombia	69	31	18-78	36	31	13
Brazil	105	26	19-69	79	24	26
Ghana	44	36	18-63	8	33	3
Algeria	43	25	18-48	27	16	10
Total	747	30	18-78	400	334	140

which the survey was sent to people via email, and the recipients were asked to fill it out anonymously and send it as an attachment to a "warandpeace" gmail account.

Coding

The coding system for the definitions of "rights" was derived in part by a grounded theory approach (Glaser, 1992; Glaser & Strauss, 1967), but informed by the literature regarding the inherency of human rights and the connection between rights and duties. Our approach was consistent with what Gilgun (2005) called *deductive qualitative analysis* and Mayring (2000) called *deductive category application*. Following exactly the steps outlined by Mayring, we began with a research question, identified the units of analysis (every unit of meaning rather than the entire definition), created main categories and subcategories, randomly selected an international coding manual sample from the full project sample, formalized definitions, selected examples, clarified coding rules, and incorporated all of this material into a coding manual. Our evaluation of intercoder reliability was a continuous process not accompanied by formal statistical assessment. Responses (translated into English) were coded by two of the co-authors of this paper (Gutowski from the United States and Estuar from the Philippines) with successive subsamples from each co-author also coded by the lead author (Malley-Morrison, from the United States) both to establish intercoder reliability and to assure consistency in the final codes assigned to each response. Discrepancies between coders were resolved through discussion and the coding manual was refined in places where additional examples and explanations of criteria improved reliability.

Three major sets of categories were identified in the qualitative responses: a) *basis*, b) *nature*, and c) *outcome/purpose/function*. Responses identifying a presumed source of rights were coded into one of three *basis* categories: *inherent*, *moral,* and *legal*. Consistent with the perspective of Hoppe-Graff and Kim (2005), we considered inherent and moral responses to be more internal in their orientation, and legal to be more externally oriented. The second set of categories, *nature,* included: *freedoms*, *duties*, and *other specifications.* The *freedoms* category, reflecting a major portion of the rights identified in the Universal Declaration, included subcategories for *freedom to have* (e.g., an identity), *freedom to do* (e.g., assemble), and *freedom from* (e.g., torture). The *duties* category had two subcategories: *social duties* (duties society owes to the individual) and *individual duties* (duties of the rights holder to the society). The *other specifications* category included subcategories for *entitlement*, *privilege*, *need*, and *unrealized ideal*. All responses in the final category, *outcome/purpose/function*, associated rights with positive outcomes, purposes, or functions (e.g., "democracy)."

For purposes of coding, definitions were first segmented into codeable units. For example, the definition "entitlements guaranteed by law" has two codeable units: 1) "entitlements" (coded into the *nature other specifications* category for *entitlements*) and 2) "by law" (coded into the *basis* category for *legal*). Generally, for purposes of analysis, two scores were computed—a presence/absence (1, 0) score depending on whether a particular code was or was not assigned to each codeable unit and, where appropriate, a count score indicating how many times a particular code was assigned to the codeable units within a definition. For ease of reporting, we refer to codeable units as "responses" in the remainder of the paper.

Results

Table 2 indicates by country the percentage of total responses (codeable units) falling into the different subcategories of the three major sets of categories (*basis, nature,* and *outcomes).* In the following sections, we provide examples of responses falling into major and subordinate categories, and elucidate response patterns in the Global South sample as a whole.

The Basis of Rights

Approximately 35% of all Global South responses to the definition of rights item were coded into one of the *basis* subcategories. Table 2 shows that at least 30% of the responses from every country sample identified a *basis* for rights, with Brazil having the highest percentage in this category. Within that major category, 41% of all Global South responses indicated that the *basis* for rights was *legal*; that is, rights were said to be something "granted" by a governing body. For example, according to one Indian man, rights are "conditions of living guaranteed to all individuals and communities by society at large." The Algerian sample had the largest number of *basis* responses coded into the *legal* subcategory, followed by Ghana, Colombia, Brazil, India, and the Philippines.

Thirty-two percent of all *basis* responses indicated that individuals possess rights by virtue of being human; that is, they described rights as *inherent*. For example, a woman from the Philippines stated, "These are not 'awarded' by any power; rather, these are inherent to human life and intrinsic to all human beings." The Philippines had the highest percentage of *basis* responses attributing an *inherent basis* to rights, with lower percentages from India, Colombia, Brazil, Ghana, and Algeria. A *moral* basis for rights (e.g., "norms that guarantee the integrity of the person") was identified in 27% of all *basis* responses, with Ghana and Brazil having the highest percentages and Columbia the lowest.

The Nature of Rights

Fifty-one percent of all Global South responses were coded into the *nature* category set, which included *freedoms, duties*, and *other specifications*. Responses coded into one of the *nature* subcategories accounted for at least 30% of responses in every country sampled, with the Philippines having the highest percentage and Brazil having the lowest.

Freedoms. Within the major *nature* category, 44% of all Global South responses equated rights with *freedoms*—something people are *free to have*, *do*, or *be protected from*. More specifically, the proportion of *nature* responses coded for freedom ranged from a high of 43% of responses in Ghana down to 14% in Brazil. The subcategory *free to do*, exemplified by a Brazilian woman who said that rights mean,

Table 2
Percentages, by Country, of Responses Coded into Definitional Subcategories in Relation to Total Number of Responses for Each Country and for the Major Category in Each Country to which the Subcategories Belong

Major Category Sets & Subcategories	**Algeria**		**Ghana**		**Brazil**		**Colum-bia**		**India**		**Philippines**	
	% of Algeria Rs	% of Major Categ.	% of Ghana Rs	% of Major Categ.	% of Brazil Rs	% of Major Categ.	% of Columbia Rs	% of Major Categ.	% of India Rs	% of Major Categ.	% of Philip-pines Rs	% of Major Categ.
Basis	3	7	5	15	11	23	13	38	14	41	13	44
Inherent	26	64	16	46	18	38	15	45	12	36	8	25
Legal	11	29	13	38	18	38	6	17	8	23	9	31
Moral												
Nature												
Freedoms												
Free	6	11	5	10	0	0	0	0	3	6	4	6
Freedom to have	9	16	9	17	4	9	7	17	4	8	6	9
Freedom to do	3	5	9	17	11	27	7	17	16	30	17	27
Freedom from	3	5	0	0	0	0	1	3	3	5	2	3
Duties												
Duty	3	5	3	5	0	0	0	0	0	0	2	3
Individual duties	11	21	5	10	4	9	7	17	6	12	4	6
Social duties	11	21	4	7	4	9	8	19	6	12	8	12
Other specifications												
Entitlement	0	0	5	10	7	18	1	3	4	8	17	27
Privilege	6	11	12	21	0	0	1	3	1	2	2	3
Need	3	5	3	5	0	0	2	6	6	11	0	0
Unrealized ideal	0	0	0	0	11	27	7	17	3	6	2	3
Outcome												
Positive Outcome	6	100	12	100	14	100	24	100	14	100	8	100

Note: The first column for each country (titled "% of [Country] Respon.") indicates the percentage of all national responses that identified a *Basis*, *Nature*, or *Outcome* subcategory within their definitions of rights (e.g., 3% of all Algerian responses attributed an *inherent basis* to rights).
The second column for each country (titled "% of Major Categ.") indicates the percentage of national responses coded under each major category set (*Basis*, *Nature*, or *Outcome*) that indicated a related subcategory within their definition of rights (e.g. 7% of Algerian responses coded under the major category *basis* indicated an *inherent* basis to rights).
Columns may not add up to 100 percent because of rounding.

"being able to speak and do what you believe" was coded most frequently for the *nature* responses from India, followed by Brazil and the Philippines, Colombia and Ghana, and Algeria. A smaller proportion of Global South responses within the *nature* category set were coded as *free to have.* An Indian man said, rights "include but are not limited to the right to food, the right to equality, etc.," and a Ghanaian man defined rights as "having access to natural and artificial wealth of the land." Participant responses categorized as *freedom from* (e.g., "antisocial" activities), which equated rights with protection from something unwanted, were relatively rare. Of all *nature* responses, only 3% were coded as *freedom from*; 6% were categorized as general *freedoms.*

Duties. Twenty-seven percent of Global South responses within the *nature* category set associated rights with *duties*, which included *social duties, duties of the rights holder,* and *duties* in general. By country, Algeria had the highest percentage of *duties* responses within the major *nature* category, followed by Columbia, India, Ghana, the Philippines, and Brazil.

Of all Global South *nature* responses, 13% had a theme of *social duty*, specifically, a duty of the state or society as a whole to the individual or an indication that rights cannot be taken away or infringed upon. A Colombian woman explained, "Rights are something we are given by our country that people should respect." Algeria had the highest percentage of *social duty* responses in the *nature* category set, and Ghana had the lowest. Examples of the second *duty* subcategory, *duty of the rights-holder* (e.g., "what an individual needs to do in society"), were found in 12% of all *nature* responses. The Algerian sample also had the highest percentage of *duty of the rights holder* responses in the *nature* cate-

-gory set, followed by Columbia, India, Ghana, Brazil, and the Philippines. Additionally, small percentages of *nature* responses from the Algeria, Ghana, and Philippines samples related rights with *duties* in general; however, this theme was not found in the responses from the other countries.

Other specifications. Twenty-nine percent of all *nature* responses were coded into the category for *other specifications* of rights, such as rights being an *unrealized idea, privilege, need,* or *entitlement.* Seven percent of these *nature* responses were coded into the subcategory *unrealized ideal*. As one Indian woman proclaimed, "Wish we could have them!!!!" The frequency of this theme within the *nature* responses varied greatly by country, with higher percentages from South America, lower percentages from Asia Pacific, and no examples from either African country. Six percent of all *nature* responses defined rights as a *privilege* (e.g., "opportunities to be enjoyed"), a theme found more frequently in the African samples than the others, which had fewer than 10% of responses coded for this theme. Seven percent of all *nature* responses described rights as a *need* (e.g., "necessary conditions for a normal life") and another 7% described it as an *entitlement* (e.g., "a person's due").

The Outcome of Rights

Outcome. Responses referring to a *positive purpose, outcome, function, or goal* of having rights constituted only 14% of the Global South responses. A Filipino man explained that rights "allow a person to live a full and human life" and a Colombian man stated that rights are "that which allows people to live in harmony." Columbia had the highest number of *outcome* responses, followed by India and Brazil, Ghana, the Philippines, and Algeria.

Modal Patterns within and across Countries

Based on frequencies of responses, Table 3 indicates by country the first and second most common major categories and subcategories found within participant definitions of rights. As can be seen, *nature* responses predominated in both the Global South sample as a whole and in all country samples except Brazil (where *basis* responses were most common). Within the *nature* category, themes focusing on *freedoms* predominated in the total sample and in all countries except for Colombia (where responses coded for *freedoms* were tied with responses coded for *duties*) and Algeria (where *duties* were predominant among the nature responses). For Brazil, *legal* and *moral* responses tied for the most common theme within the *nature* category.

The major category *basis* ranked second in frequency of responses in all national samples except Brazil, where *nature* was the second most common major category and themes emphasizing *other specifications* predominated. Among the responses coded into a *basis* category, the *legal* theme predominated in the total sample, Algeria, Ghana, and Colombia, and the *inherent* theme predominated in India and the Philippines.

Discussion

In the current study, we found that when asked to provide a personal definition of the term "rights," participants from six Global South countries emphasized the presumed foundations of rights. Although about one-third of those responses attributed a *legal* basis to rights, a majority of them, consistent with the Universal Declaration of Human Rights, identified the basis of rights as *inherent* or *moral*. Thus, to the extent that participants referred to foundations of rights, their beliefs provide some limited agreement with the views of Doise (2003) and Moghaddam (2000) that human rights are perceived as more than just legal rights.

Also consistent with the Universal Declaration, many participants associated rights with particular freedoms and the duty of society to insure those freedoms. Very few respondents mentioned any sort of duty of individual rights holders toward their governments or society. Specifically,

Table 3
Modal Definitional Categories and Subcategories by Country.

	Algeria	Ghana	Brazil	Colombia	India	Philippines	Total
Modal Major Category	Nature (54%)	Nature (55%)	Basis (46%)	Nature (42%)	Nature (53%)	Nature (62%)	Nature (51%)
Modal Subcategory	Duties (47 %)	Freedoms (43%)	Legal (38%)	Freedoms (36%)	Freedoms (49%)	Freedoms (45%)	Freedoms (44%)
			Moral (38%)	Duties (36%)			
Second Most Common Major Category	Basis (40%)	Basis (34%)	Nature (39%)	Basis (34%)	Basis (34%)	Basis (30%)	Basis (35%)
Second Most Common Subcategory	Legal (64%)	Legal (46%)	Other Specifications (45%)	Legal (45%)	Inherent (41%)	Inherent (44%)	Legal (41%)

20% of the Global South responses equated rights with the *freedom to have, to do,* or *to be protected from* something and 6% equated rights with *duty* on the part of *society* to the individual. Only 5% of all responses referred to *duty* on the part of the rights holder.

This emphasis on individual rights seems unsurprising in samples from countries long subjected to despotic rule by foreign powers and, in most cases, continued despotic rule following "independence." Moghaddam et al. (2000) have suggested that "after achieving equal rights in black-letter law, minorities should shift their focus to the correlative duties that arise from their change in moral status" (p. 275). Our Global South participants, although not minority groups within their own countries, might perhaps be persuaded that their "moral status" has changed, but feel quite unwilling to give up their fight for equal rights in practice. According to Rose (1996; cited in Moghaddam et al., 2000), rights cannot be exercised successfully until the people with the power to concede those rights accept it as a duty to enable them. Ordinary people in many Global South countries—and perhaps in many Western countries as well—may want to see more concessions regarding their rights before considering whether they have duties to the controllers of those rights.

Our study has the common limitations of a convenience sample such as limits to generalizability, compounded by difficulties with linguistic and conceptual equivalence of the various translations of the term "rights" into the different languages and of translations of the participants' definitions into English for coding. Data collection methods as well as heterogeneity of samples varied from country to country. Despite these limitations, the survey empowered ordinary people to define, in their own words, the term "rights" and provides rich qualitative data for the generation of new research questions (e.g., the extent to which emphases on particular components of rights vary consistently and meaningfully across Global South countries that may share a history of colonization, but differ in other important ways). The finding that the nature of rights more often took the form of individual freedoms and social duties than individual duties to society or the government suggests that future research as well as interventions aimed at peacekeeping, and supporting human rights around the globe should focus more on universal human values and ethics and less on policy and governmental action, regulation, and law. Countries engaging in interventions to support human rights and freedom need to be aware of differences in perception from region to region in order to avoid alienating those they seek to help. Research such as this is an important first step in raising awareness of the importance of these perceptions.

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[1]Analyses for Ghana were done only on the sample that completed the English version of the survey because the Ewe surveys have not yet been translated.

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Finding Harmony with Indirect Directivity: Cognitive-Behavioral and Psychoanalytic Approaches to Counseling in China

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Over the past decade, counseling psychology has pushed for an international perspective (Forrest, 2011; Heppner, 2006; Leung, 2003; Leong & Bluestein, 2000; Leung, Guo, & Lam, 2000; Nutt, 2007). At the 2008 International Counseling Psychology Conference, over one-third of the conference was focused on international programming and landmarked an internationally themed conference. Leung (2003) noted that cultural encapsulation of the profession may give a *false sense of self-sufficiency* and lead to an avoidance of looking outward for ideas. Leong and Bluestein (2000) asserted that in order to achieve and sustain a truly multicultural perspective, we must avoid seeing Western scholarship as the ideal or *truth* to be imparted to the rest of the world; instead we need to move beyond a national multicultural perspective toward a global vision for the field. Western scholarship can contribute to the growing need for culturally appropriate training and treatment in other countries and yet benefit from research beyond its borders (Leung et al., 2000). Counseling exists in a cultural context, and in order to understand both the culture-general and culture-specific aspects of counseling, we need to take a global and comparative approach to counseling (Leong & Bluestein, 2008).

Heppner (2006) stressed the importance of incorporating the international perspective in training of counseling psychologists, arguing for action ensuring that training and research occur in a richly diverse cultural environment, such as immersion experiences, collaboration with colleagues from other countries, student/faculty exchanges with other countries, and incorporating international readings into training curriculum. These activities promote specific cultural issues both intellectually and experientially. Further, as the economic expansion of China continues, the associated growth will result in an increased demand for mental health and other professionals. In the absence of established standards for theoretical approaches to counseling in China, this article is expected to be particularly useful for those early career professionals intending to work and network with Chinese clients. This article reflects the multicultural training of two early career counseling psychologists in collaboration with a Chinese tenured faculty member working at an American university. It incorporates both our reflection on our own experiences in China and a literature review of counseling in China. It is our hope that, through the unique combination of our experience and literature review, we will be able to convey the importance of intellectual and experiential multicultural training.

Mental Health in China

As China continues to rapidly expand its international and economic ties, the need for mental health services is also increasing. A recent article on CNN.com describes the adverse effects of the economic boom on mental illness (FlorCruz, 2011). In the aftermath of several tragic homicidal attacks on the public by Chinese citizens with mental illness, FlorCruz (2011) interviewed Chinese counselors to demonstrate the need for appropriate mental health prevention and intervention services in China. Although China's population accounts for one-fifth of the world's population, there is a staggering lack of counselors available to offer culturally appropriate mental health treatment (about 215 psychiatric patients to every one mental health professional according to the Ministry of Health's Center for Statistics Information, as cited by FlorCruz, 2011). The alarmingly high suicide rate in China is another critical reason to improve culturally appropriate mental health intervention (Miller, 2006).

To address the growing need for mental health services, the Chinese government had called for an increased focus on psychological treatment to promote health harmony (Schlosser, 2009). Although transplanting pre-established methods of counseling from the West into China may appear to be a quick and easy fix, doing this without modifications based on cultural considerations may do the field a disservice. Despite the general consensus that the globalization process has brought some individualistic values to the east (Kwan, 2009; Schlosser, 2009), Duan and Wang (2000) noted the importance of knowledge and understanding of both the traditional and transforming collectivistic culture in providing culturally appropriate counseling for Chinese clients.

Cognitive-Behavioral Therapy in China

Many authors have suggested that cognitive-

behavioral therapy (CBT) is especially suited for work with Chinese clients (Chen & Davenport, 2005; Hwang, Wood, Lin, & Cheung, 2006; Lin, 2002; Williams, Foo, & Haarhoff, 2006). Lin (2002) pointed out that Chinese individuals function well in structured, clearly defined roles within authoritarian, hierarchical relationships. Chinese clients respect authority and expertise in therapists and are likely to perceive them as more competent when they take a directive, advising, and problem-solving approach. Practical solutions may be preferred over discussing intense emotions because these solutions are a way of engaging clients by giving a "gift" of symptom reduction, consistent with the gift-giving culture (Hwang et al., 2006). Based on our discussions with many counselors and psychologists in China, CBT training was indeed highly desired and sought after.

However, the traditional CBT model may require several modifications to fully fit Chinese cultural values (Chen & Davenport, 2005). Although respect for experts may lead the Chinese to initially seek a directive therapist, this teaching role may create hesitance to express disagreement and lead to early termination. The use of Socratic questioning to challenge dysfunctional thinking may cause anxiety for clients to deliver a "correct" answer, and assertiveness training may violate values of harmony, deference to authority, and avoiding confrontation.

Psychoanalysis in China

Like CBT, the emphasis of the therapist as expert in psychoanalysis fits well with the Chinese emphasis on the student-teacher relationship (Halberstadt-Freud, 1991; Schlosser, 2009). Additionally, both *Zen* Buddhism and psychoanalysis can be viewed as effortful studies in attention, making psychoanalysis a natural fit in Buddhist influenced China. Concepts such as unconscious activity, defense mechanisms, and the superego seem to be well-received among Chinese psychiatrists (Joseph, 1986).

However, psychoanalysis has been criticized for being overly Eurocentric and insensitive to the role of family and community (Prochaska & Norcross, 2007). Expressive sharing of free association may be a mismatch for the cultural de-emphasis on excessive emotionality. Moreover, the psychoanalytic distinction between the pain of psychological conflict and physical pains was not seen as a good fit for the Chinese holistic perception of mind and body (Halberstadt-Freud, 1991).

Previously Overlooked Cultural Considerations

Collectivism. It is well-established that the Chinese may represent the prototypical example of collectivism, in which the group takes precedence over the individual (Triandis, 2001). Collectivistic cultures also emphasize relationships above tasks and achievement. Through cooperation, conformity, obedience, and avoiding conflict, relationships become stable and long-lasting. As such, the absence of interpersonal harmony may be the locus of distress for Chinese clients (Hsiao, Klimidis, Minas, & Tan, 2006). Core Chinese values, rooted in Confucianism, include filial piety, compliance with authority, conservatism and endurance, fatalism, and male dominance (Kwan, 2009). This manifests as structured vertical relationships and strictly obeyed norms (Triandis, 2001). Other values include the limited expression of emotion (Shibusawa & Chung, 2009), *renqing* (an interpersonal relationship defined in doing and returning favors), saving face, non-verbal communication (Hsiao et al., 2006), indirect verbal communication, and a holistic view of the mind and body (Sue & Sue, 2008).

Even the traditional manner of eating represents a collectivistic orientation. During our visit to mental health facilities in China, our gracious hosts treated us to several traditional meals, which were served on a large, rotating turntable in the center of a round table that was spun to bring the desired dish close enough to reach chopsticks into the dish and take enough for one or two bites. This tradition of food service is very communal, with every person sharing equally. The message is "what's mine is yours." Western individualists might shudder at this method of delivering food, since every person returns their chopsticks into the community dishes over and over. The collectivist, however, values these shared experiences.

The sense of connectedness appears related to the cultural values of personal space and privacy (Lomranz, 1976). We noticed that privacy appeared to be much less important in China than in the West. It was not uncommon for clients in psychiatric hospitals to be asked about their diagnosis and treatment. As beginning Western psychologists, this exchange was surprising because the clients did not seem to have any qualms about openly discussing their mental health with apparent strangers. While Chinese neighbors often live very close and share communal gardens or courtyards, Westerners tend to have privacy fences around their yards. We also witnessed several other examples of the de-emphasis on privacy and personal space. For instance, mothers showed no discomfort in carrying their nude infants in public. Chinese tourists were not hesitant in taking a foreign tourist by the hand for a photograph. Finally, most young adults shared a physical closeness with each other that is reserved for only very close relationships in the West.

Approaches such as CBT and psychoanalysis focus on the individual rather than the system. Early career psychologists wishing to apply theoretical approaches in China should choose or modify the approach to fit with a systemic understanding. Furthermore, psychological health should be defined in terms of the collectivistic culture. Factors such as apparent low-self esteem, submissiveness, conformity/compliance to authority, male dominance, and filial piety should be viewed as culturally appropriate rather than signs of pathology. Finally, homework should be assigned with caution that it may interfere with the client's in-group system. Optimal homework assignments are those that facilitate interpersonal harmony.

Face and modesty. One concept that has been largely overlooked in discussions of particular therapy models with Chinese clients is the importance of Face. Face is a social-psychological concept that is universal to all cultures, but holds great significance in Chinese culture (Yabuuchi, 2004). In Western culture it is most often related to "saving face"

and is largely an unconscious phenomenon. However, in Chinese culture, Face goes beyond "saving" and is something that can be given, projected, promoted, struggled for, lost, borrowed and underlies all social interactions. Another importance distinction in Face between cultures is where it exists. In the American culture, Face, is possessed and taken with one into various situations. In the Chinese culture, Face is dynamic and must be built and maintained within each relationship. Maintaining Face is of utmost importance for regulating social interactions within Chinese culture and helps to build *guanxi* (social network and connections), which *renqing (*emotions and social resources) flow through. Loss of Face leads to shame and can harm a person's *guanxi*.

During our stay in China, we witnessed many examples of how Face influenced social interactions. While many Westerners may carry their reputation with them into a meeting with new colleagues and rely on it to speak for them, a Chinese person will attempt to promote their Face with the new contact in order to build *guanxi* with them, regardless of what their reputation is with others. This was apparent in our visits to universities, hospitals, and counseling centers. Nearly everywhere we went, our hosts immediately extended hospitality to promote their Face and build a positive *guanxi* with us. This hospitality often took the form of being served tea or meals, depending on the time of day, and always being served first. Our hosts would also extend hospitality by giving gifts and offering the prime seats to us. We were surprised at the treatment we received from important researchers and practitioners, being merely students from a small university. However, we soon realized that regardless of the Face each party possessed before meeting, our hosts felt the need to build Face in order to begin a relationship with us.

Not only is it important to promote and protect your own Face, the Chinese are also concerned with the Face of others. A number of young Chinese women we met discussed struggles maintaining an "appropriate" appearance of being thin and feminine as their appearance was a reflection of their parents and significant others. Therefore, this pressure was directed at protecting the Face of important people in their life. We also witnessed people protecting the Face of strangers and acquaintances, not just loved ones. The most vivid example happened while visiting a university of Traditional Chinese Medicine (TCM). A member of our group stated, in the presence of the TCM students, that she did not trust TCM to work. Following this remark, the Chinese woman in our group defended TCM, describing how she trusts her health to TCM and regularly takes TCM herbs. For several minutes she excessively praised TCM and discussed the problems with Western medicine. Later on the ride back, she explained that she felt embarrassed for the TCM students and exaggerated her reliance on TCM in order to protect their Face.

CBT may offer initial problem solving and symptom relief, but some aspects of CBT may not fit with norms of Face. Because it consists of social interactions, the therapeutic relationship with Chinese clients may be largely influenced by Face. Chinese clients might be concerned with protecting their own Face, as well as that of the therapist, in order to build *guanxi*. To protect Face, a client might be hesitant to express emotions or discuss psychological distress. A client concerned with protecting the therapist's Face may also find it difficult to disagree with the therapist.

Chinese individuals value modesty and may feel uncomfortable directly discussing their own positive behaviors. This has potential application in CBT if a beginning therapist expects clients to disclose the behavioral improvements they have made since the last session. CBT focuses on out of session homework and positive reinforcement for improvements made by clients. Driven to protect their Face and display modesty, the direct communication style of CBT may be problematic in work with Chinese clients.

Traditional authoritarian techniques of psychoanalysis also may violate the principle of Face. An authoritarian relationship that focuses on transference can violate the reciprocity that is desired in relationships to maintain Face. Also, a focus on sexual drives may be seen as damaging to the client's Face. Although both CBT and psychoanalysis offer some benefits for the Chinese client, many aspects may violate cultural norms. Therefore, early career counselors should not restrict themselves to these approaches and should be open to using the indirect methods of communication discussed in the next section to help clients maintain their Face.

Indirect communication style. Indirect communication is the chief communication tool in collectivistic cultures. In the West, "reading between the lines" is rarely required, but is "normative and intentional" in collectivism cultures (Fong & Phillipsen, 2000). Peeling back the layers of nonverbal and indirect communication to reveal the hidden meaning of a message is like ceremoniously unwrapping a gift (Shibusawa & Chung, 2009).

During our brief yet enlightening time in China, we quickly learned to recognize some of the non-verbal forms of this indirect communication. Personal space was one of the first values we recognized as different from the West. After some time, we began to recognize that the physical closeness may have been a way of communicating welcoming affection or curiosity in the absence of verbal speech. Once, while riding in a taxi, one of us noticed an unexpected feeling of unease. After a moment of introspection, it became evident that the discomfort was due to the surprising physical closeness between she and the Chinese guide despite the relative plethora of space in the backseat of the taxi. Interpreting this closeness as a means of communicating trust and affection, the feeling of unease dissipated and a new understanding of the evolving relationship was established.

Apparently the personal space that we witnessed among young people not only represents feelings of affection, but also an understanding of the type of relationship between individuals. While the affection between friends is apparent by the small amount of interpersonal space, the affection between hierarchical relationships (e.g., parents and children) cannot be judged the same way. In other words, horizontal relationships may minimize personal space to indirectly communicate positive feelings. Meanwhile, vertical relationships

(e.g., parent-child, employer-employee, older brother-younger brother) maintain a fair amount of personal space and communicate emotional responses in an entirely different nonverbal way. In counseling, the amount of physical space allotted by the client may give beginning counselors a clue to the clients' perception of the relationship.

In their deconstruction of the popular film Dim Sum, which depicts a Chinese American girl's relationship with her aging mother, Fong and Philipsen (2000) outlined several types of persuasive indirect communication. The first attempt at persuading the other person requires the individual to communicate their desires using one of four tactics. These tactics include discussing their wishes for the target to a 3rd party while in earshot of the target, asking indirect questions aimed at guiding the conversation without clearly asking for information, making comparisons of the target to someone else (perhaps a sibling or neighbor) who possesses the desired trait, or to make implied statements requiring some action commitment from the target.

A second approach to indirect communication described by Fong and Philipsen (2000) is the use of an intermediary or "go-between" who communicates the wishes of the individual to the targeted other. The third dimension of indirect communication refers to unspoken action, which encompasses not only nonverbal communication such as eye-contact, facial expressions, and body language, but also symbolic action. In the film Dim Sum, the mother, who wants her daughter to marry before her death, uses the unspoken action strategy to communicate this by hanging the daughter's wedding dress up next to the mother's intended funeral dress. The fourth and final dimension of communication is direct communication (e.g., "I'd like you to marry before I die") and is typically a last resort because it risks the development of conflict, which is in contrast to interpersonal harmony.

Because Chinese clients expect to preserve Face and social harmony, counselors should not demand direct communication. Overt expression of emotion is an undesirable behavior in collectivistic cultures, therefore directly discussing distressing emotions in counseling has the potential to impede therapeutic progress. Instead, beginning counselors should expect to validate clients' experiences without explicitly discussing them (Shibusawa & Chung, 2009). Chinese clients expect to share *guanxi* with their counselors, reciprocally extending Face to each other. This means that the counselor will be expected to understand the client and show empathy to their experiences by not demanding a direct discussion of the burdens of the situation.

The open nature of communication in directive approaches such as CBT may be perceived as abrasive to a Chinese client. Therefore, counselor should consider communicating with their Chinese clients in indirect ways. Direct questioning should be a last resort and information should be obtained using other approaches as much as possible. For instance, early career professionals might use one of the indirect linguistic strategies offered by Fong and Phillpsen (2000) such as the use of a 3rd party proxy, making comparisons, or using implied statements.

In traditional psychoanalysis, the psychoanalyst usually has some recommendations in mind for relief of patient neurosis, but they typically avoid openly sharing this prescription so that the client can come to their own solution. A modification of this might require the analyst to remain open about their interpretations and recommendations while sharing them in an indirect way. This meets two of the Chinese client's cultural needs: direct advice from the expert and indirect communication.

Process issues such as failure to progress in therapy may not be openly addressed as it would be with Western clients. Concern should be addressed with an indirect linguistic strategy or with the use of an intermediary. The use of intermediaries offers the opportunity to involve the client's social system and protect the client's Face. In addition, client gratitude and affection will be uniquely expressed. This may involve nonverbal action, gift-giving, or indirect speech. Early career psychologists should expect to look for these expressions and respond reciprocally to maintain and deepen therapeutic relationships.

Finally, couples and family therapy will be very important with Chinese clients. When conducting such therapies, modifications of Western approaches will likely be most beneficial. For instance, rather than asking clients to directly express their concerns to each other, it may be more appropriate for beginning therapists to take the role of 3rd party intermediary. In this manner, clients can express their concern to the therapist who may offer a gentle interpretation to the other party.

Conclusions

Since the opening of China to the West, psychotherapy has made some impressive advancements in an underserved and barely understood area. Scholars have done well to consider pre-existing therapeutic approaches and aspects of those orientations that fit with the Chinese culture. Elements of CBT and Psychoanalysis have been used with varying degrees of popularity. However, the growth process is still in its infancy and counseling psychology is in a prime position to advance the mental health services in the country. For instance, due to the importance of Face, outcome research based on the Western measures that focus on client's direct report will be difficult to obtain as a means of validating the success of any therapeutic approach. Culturally sensitive outcome measures should be developed to aid clinicians in measuring the effectiveness and acceptability of their interventions.

In addition, therapeutic approaches other than CBT and Psychoanalysis may have vital contributions to offer. Values such as Face, indirect communication, and modesty should be thoroughly explored in consonance with values imbedded in other therapeutic approaches such as self-enhancement in person-centered-therapy, direct in touch with personal experience of emotions in acceptance and commitment therapy. Furthermore, an emphasis on training in basic common factors micro-skills may also facilitate social skills such as attention to non-verbal and indirect communication. Culturally sensitive therapeutic approaches should be

explored both conceptually and quantitatively in Chinese counseling settings.

The results of our review indicate that the East and West have much to learn from each other regarding the ways in which people experience and respond to treatment for psychological distress. In China, the influence of collectivistic values and focus on harmony runs deep. The current psychoanalysis and CBT models offer the directivity and authoritarian relationship desired by Chinese clients. However, they do not adequately protect a client's Face or use the indirect communication style that is common in China. Therefore, counseling psychologists will need to learn to work within rather than against this worldview by helping the Chinese client find harmony through indirect directivity.

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The Importance of International Immersion Experiences in Developing Cultural Competence

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In my experience, if you ask any psychologist or mental health professional whether they think that cultural competence is important, they will most likely say yes. But what does it mean to be culturally competent and why do we need it? Whether or not we like it, the world is becoming smaller every day through the process of globalization. More and more, individuals from different cultural backgrounds are beginning to come in contact with one another and are forced to navigate increasingly complicated relationships. Both within and outside of the United States, mental health professionals are more frequently interacting with clients who are from a different cultural background than them, however racial/ethnic disparities in quality of health care continue to be an issue (Betancourt, Green, Carrillo, & Ananeh-Firempong II, 2003). Specifically, one particular challenge related to this disparity involves providing *quality care* that incorporates both best practices and an understanding of specific client characteristics in order to provide effective and relevant interventions.

In response to the increasing demand of being able to work with diverse client populations, the American Psychological Association (APA) and the Council for Accreditation for Counseling and Related Educational Programs (CACREP) have made a large push to provide a cultural basis for the application of research and clinical work, and in turn mandated multicultural training as part of graduate study within accredited training programs (APA, 2003; Speight, Thomas, Kennel, & Anderson, 1995; Sue, Arredondo, & McDavis, 1992). In order to assist programs with developing multicultural training, both governing bodies have provided similar frameworks that include three general areas including cultural awareness and beliefs, cultural knowledge, and cultural skills (Sue, 2006). Although all accredited programs have mandated multicultural training, there has been difficulty in translating theory into clinical skills, training, and practice, which has resulted in inconsistencies across training in different programs (Sue, 2006). Training programs range from mandating only one multicultural course to having several mandated courses with multicultural issues woven throughout every other course offered. Differences in training produce psychologists with a wide range in skill and understanding of multicultural issues, leading to continued disparities in providing ethical and effective treatments to diverse populations (Smith, Constantine, Dunn, Dinehart, & Montoya, 2006).

So, how do we know if the training we are receiving is adequate to conduct ethical treatment of diverse populations? Multiculturalism is a social-intellectual movement that not only demands that all groups be treated with equal respect, but also places value on diversity, tolerance, human rights, and authenticity (Fowers & Richardson, 1996). Cultural competence, which stemmed from the adoption of multiculturalism within the mental health field, may therefore be defined as the ability to engage in actions or create conditions that maximize the optimal development of the client and client systems. Multicultural counseling competence is thus achieved by the counselor's acquisition of awareness, knowledge, and skills needed to function effectively in a pluralistic democratic society (e.g., ability to communicate, interact, negotiate, and intervene on behalf of clients from diverse backgrounds) and on an organizational/societal level, advocating effectively to develop new theories, practices, policies, and organizational structures that are more responsive to all groups (Sue & Torino, 2005).

In line with this understanding, several studies have attempted to evaluate important characteristics of individuals who are viewed as culturally competent, as well as the effectiveness of various training experiences. Key characteristics of individuals who presented as culturally competent included the ability to acknowledge, accept, and value the cultural differences of others. More specifically, individuals were able to develop the skills and knowledge that allowed them to appreciate, value, and celebrate both similarities and

differences within, between, and among culturally diverse groups (Bhui, Warfa, Edonya, McKenzie, & Bhugra, 2007). Training models developed to address the development of these characteristics include a wide variety of approaches including lectures, case study discussions, role plays, video materials and video feedback, and study abroad / immersion experiences (Bhui et al., 2007; Kitsantas, 2004). Overall, research has supported that various methods of cultural competence training improve cultural competence and have resulted in increases in treatment provider knowledge, attitude, and skills (Beach et al., 2004; Cooper et al., 2004; Smith et al., 2006). Although choice in training experiences is greatly impacted by specific factors such as specific sociohistorical experiences including colonial rule and immigration, national attitudes towards migrants, citizenship, and how best to address racial and cultural integration (Bhui et al., 2007), immersion experiences or direct exposure to individuals from other cultures provide some of the largest benefits and improvement in key cultural competence characteristics in all three areas (i.e., awareness, knowledge, and skills; Beach et al., 2005; Kitsantas, 2004).

In particular, immersion experiences, such as study abroad programs, have been shown to enhance students' cross-cultural skills, global understanding, as well as self-awareness and knowledge of a particular group (Kitsantas, 2004), all of which are important in developing cultural competence. My own experiences as a graduate student, who has engaged in international immersion experiences while in graduate training, are consistent with the conclusions of Kitsantas (2004). This past summer I was given the opportunity to attend a three week study abroad experience in Japan that was tailored towards my research interests: violence against women. Although I expected to gain a deeper understanding of what Japanese women in urban areas face when exposed to violence, I could not have predicted the immersion experiences that would change the way that I view psychopathology and cultural competence as a whole.

During the trip, I experienced for the first time what it felt like to be an "outsider" in the community I resided. As the ethnic make-up of Japan is 98% Japanese, it was clear from the very beginning that I was an anomaly and was thus treated as an outsider (also known as Gaijin). People would often stare, take pictures, and whisper around me. Although the Japanese culture as a whole was very welcoming, these experiences made me feel unwelcome and created a sense that I did not belong. After the first few days, I was desperate for anyone who could speak my own language or understand the experiences that I was having. I felt alone, misunderstood, and lost, and felt a constant yearning to be around others similar to myself. Upon reflecting on these experiences, I began to think about how marginalized groups within the U.S. are treated differently due to norms and values that deviate from the dominant culture. This further solidified my perspective that we must understand cultural differences from a strengths versus deficiency perspective, in order to understand, validate, and effectively treat individuals from marginalized groups.

In addition to my experiences as an outsider, I also found that most of the theories and research related to violence against women generated in North America were not applicable within the Japanese culture. After meeting with several agencies and non-government organizations, I quickly realized that our understanding of women's experiences are heavily influenced by our own sociohistorical experiences, current laws, and cultural norms and practices. For instance, due to stricter laws in Japan related to physically harming a woman, most perpetrators of domestic violence within the Japanese culture revert to other forms of harm that cannot be as readily physically identified such as control of finances, severe emotional abuse, and forms of sexual violence that could be construed as consensual within a relationship. Although there are laws within the U.S. against physically harming women, a violation for breaking the law in Japan, especially related to violence against women, not only heavily impacts the individual, but also destroys the reputation of the family and has wide-reaching consequences for all members of the family including negatively impacting the ability to find a job and rent/own a home. In addition to differences in laws, social norms and practices, which ascribe gender roles within Japanese society, which are largely different from the dominant culture within Western societies, also contribute to understandings of violent experiences women have and motivations for perpetrators to engage in violent behaviors. As dominant theories related to violence against women in psychology are based on the sociohistorical experiences, cultural norms and values, and laws that exist within the U.S. and Europe, these theories and conceptualization become largely unhelpful when attempting to understand experiences that women have within Japanese culture. Although I have studied and read research pertaining to the importance of understanding these factors, it was not until this experience that I fully grasped the critical importance of developing an understanding and awareness of these systems when working with specific groups within diverse populations.

Since my return, the way that I view psychopathology and cultural competence as a whole has shifted, and in turn it has impacted my research and clinical work. More specifically, I have developed a deeper understanding of how the many systems and sociohistorical experiences impact individuals and the experiences that they have. I now view the Western understanding of psychopathology as relevant and important for *specific* groups in *certain* contexts (i.e., European American, middle-class individuals, who ascribe to the dominant norms and practices). As such, I have come to the understanding that because social constructions of psychopathology are imbedded within a cultural context, we cannot fully understand experiences that individuals have without first considering their sociohistorical context and the many systems within which they reside. Although cultures have *some* similarities, we cannot assume that psychological constructs, or "universal" constellations of symptoms, represent similar phenomena in different regions and populations around the world.

Considering the impact that this immersion

experience has had on my graduate training, I would highly recommend that both Clinical and Counseling psychology training programs invest in more experiential exercises and opportunities with diverse populations in order to strengthen students' awareness of the impact of culture, as well as the importance of developing cultural competence. Although not every program could afford to fund an international experience, such as the one I engaged in, programs could develop activities that integrate diverse populations from the local community in order to better understand experiences of individuals who do not hold similar beliefs or values to the dominant culture. Additionally, graduate training programs could integrate activities that involve interacting with international students or other immigrant groups on campus. These activities or exercises could be utilized to help training clinicians develop important skills such as learning new customs, cultural values and norms, and what it means to be culturally competent with particular populations. Lastly, I would highly encourage training programs to build relationships and develop training opportunities, whether on a domestic or international level, with diverse communities. These training opportunities could serve as immersion experiences in themselves to help further develop insight and awareness of the heterogeneous nature of diverse populations, as well as critical transferrable skills that could be utilized when working with future diverse populations.

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Checking On-line Psychology Graduate Degrees: Five Points to Consider

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"How can an international of U.S. student select a high-quality on-line psychology program to complete their master's degree?" This is a common but challenging question for an increasing number of students, who can easily find themselves scouring the internet for many hours to find information on available degrees programs.

When I was near the completion of my Bachelors, it was natural for me, like many others, to start looking into graduate-level programs. I was moving from Germany back to the United States where my work schedule would vary, so I needed an online program. I spent countless hours researching schools and programs and there are five things I learned throughout my search.

1. Use your goals to determine the right school and program. What do you want to do with your degree? There are a number of different masters and doctoral degrees and it is important that you understand where you want to go with your education and career. Do you want to be a licensed counselor or therapist? Do you want to enter the world of School or Clinical psychology? What about Forensics, Behavioral therapy, or Industrial Organizational Psychology? Maybe you are pursing a Masters program in hopes of making yourself a better candidate for a PhD or PsyD program? The first step in finding an online psychology program is to determine whether you need a PhD or a Masters to reach your goals. Psychology has many sub-fields knowing what sub-field you want to move into will help you determine what school and program will work best. A good online source for some basic information on Masters and Doctorates in Psychology can be found here: http://www.alleydog.com/psychology-degrees.php

2. Not all schools are equal. Once you decide between a Masters and a Doctorate you need to find a school. If you take one thing away from this article, let it be this. You will find a lot of schools offer online programs in today's technology driven age. The easiest to find using a basic search will be for-profit schools. Be careful when choosing a for-profit institution, as there has been an issue with some for-profit institutions parent companies losing financial aid funding. This has caused mass closures of campuses. There is nothing worse than getting into a program and taking out massive student loan debt to have your school close down mid way through a degree. Some students also found out that their classes did not transfer over to any other programs. Students using VA benefits found out that their benefits were completely lost and they no longer had enough left over to complete a degree. More on this situation can be found here: http://www.npr.org/blogs/ed/2014/07/16/331700270/students-react-to-the-closure-of-a-giant-for-profit-college

This is not to say that all for-profit institutions are bad; in fact, I have heard great things about some, but that you really need to do your research on a potential institution. Take the time to understand the difference between for-profit and not-for-profit schools (www.franklin.edu/blog/non-profit-vs-for-profit-colleges-what-you-need-to-know/), as well as public and private schools (www.collegeconfidential.com/dean/000294/). Understanding these differences can help you choose the right school for your needs.

3. A program may not be what you think. This is through no fault of the institution, but is a problem still. The best example I can provide is Forensic Psychology. My Masters is in Forensic Psychology and I am constantly asked if I want to be a criminal profiler. The chance of becoming a criminal profiler as a forensic psychologist is extremely slim. This is a common misconception due to current TV shows such as *Criminal Minds*. Finding out mid-way through a program that you wont be chasing serial killers can be quite upsetting and leave you having to decide between finishing a degree you do not want, and withdrawing with no degree and large student debt. Do your homework and be sure that the sub-field is what you think it is before racking up those student loans.

4. Just because a program is available, does not mean it is useful. Some schools have created programs that will bring in money, but are essentially useless. If you come across an uncommon program it could very well be a new and emerging field that can be useful, but it could also be useless. This is not always the easiest information to find, but if you decide the degree falls into the "new and emerging" field rather than useless; decide if you are willing to do the work that is necessary to make others see the usefulness of your degree. These fields are harder, but not impossible, to break into.

5. Know your state requirements if you plan to get licensure. Each state has different requirements and it is important to know if your program will set you up for licensure. Many programs claim to prepare a graduate for licensure, but no program covers all 50 states requirements, at least not that I have found. More than one state requires an APA accredited Clinical Psychology program in order to apply for licensure at the doctoral level. If you want a PhD or PsyD in clinical psychology an APA accreditation is necessary in some states and for some jobs.

I had decided early on not mention any particular school while writing this article, but I am going to make one exception based on lesson number 5. If you want to pursue a PhD in Clinical Psychology online there is only one school that is APA accredited: Fielding Graduate University. Fielding may or may not work for you, but that is for you to decide. Also, it is not fully online. There are monthly meet ups as well as yearly conference attendance requirements. This can be costly, but well worth it if you cannot attend a traditional brick and mortar institution.

Once you have decided on the right degree and program, you can begin researching schools. Many traditionally brick and mortar schools offer online programs that do not show up in a basic web search. Try going to a potential schools website and searching from there. Finally, be persistent in your search for the right school. There are many schools out there that did not come up in my searches but were found in discussion boards; which can be used to gain information guidance from other people who have already done the research. I hope this article helps proves useful in your search for online graduate degrees, but essentially, you will need to do some homework.

Note: Jolene Caro is a PhD Student of International Psychology at The Chicago School of Professional Psychology in Washington DC, and is the President of its Psychology Without Borders student club.

Learning by Doing: Transnational Social Justice Consultation in Kyrgyzstan

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This past May, eight second-year doctoral students and four faculty members in the Counseling and School Psychology Ph.D. program at the University of Massachusetts Boston (UMass) embarked on the program's first transnational social justice trip. The group traveled to Kyrgyzstan, where they worked with the American University of Central Asia (AUCA) in Bishkek. They gave presentations and workshops to students related to resume building, cover-letter writing, work-life balance, and applying to graduate school. They also implemented individual and group interventions to help students with career decision-making. In addition, they met with faculty in the Psychology Department at AUCA to discuss their plans for establishing an Assessment and Consultation Center to meet community needs for testing for autism, learning disorders, and other issues. In the following paragraphs, three students will share their personal impressions of the trip.

Melanie Cadet:

Our 10 day trip to Kyrgyzstan was an eye opening experience for me on personal, educational, and professional levels. As counseling psychologists in training who are keen on social justice work, I believe that our job is not to swoop in like knights in shining armor to provide a service or quick fix/band-aid solution. This trip has helped me understand that there is a difference between working *for* a population and working *with* a population (Biddle, 2014; Corey, Corey, & Callanan, 2011). Our role, rather, is to collaborate with the group/population in question to identify the needs that exist, how to address thier needs, and to provide assistance in implementing changes that allow that group to continue addressing that need without further assistance.

For instance, we met with the faculty of the Psychology Department at AUCA and in a collaborative endeavor, both groups tried to discern how we could be most helpful regarding their assessment needs. Instead of imposing our way of doing things, we had a wonderful discussion during which both groups put forth and considered different potential options. In this collaboration, the AUCA faculty members were the experts who made the final decision about which option would be feasible or ideal within the Kyrgyz context. In addition, we implemented career adaptability training for interested AUCA students, which resulted in a wonderful collaborative discussion with the students. After the training, we worked together with the students to identify which aspects of the training were helpful, unhelpful, and/or could be improved for future practice with students in Kyrgyzstan and elsewhere. For instance, students suggested that an increased emphasis on the influence of family history may be particularly valuable in future vocational trainings with Kyrgyz students. I learned from the students that socio-cultural factors, such as, the family, play a very important role in in influencing the career path of Kyrgyz students. Based on anecdotal evidence, it appears that family variables have a different role in the vocational lives of Kyrgyz students as compared to U.S. American students.

Overall, traveling to Kyrgyzstan and working with AUCA provided me with an example of how to walk the walk of social justice. It is not enough to assume that a need exists or to presume that we have the knowledge to know exactly what their need is. As a future counseling psychologist, I have a responsibility not to "give a voice" or speak on behalf of a group/population/community, but rather to be collaborative and offer assistance in any way that a group considers appropriate or useful. My responsibility is not to impose best practices but to provide collaborative assistance and advocacy to empower communities to address their needs independently. On an individual counseling level, I feel an even greater responsibility towards tailoring counseling interventions in ways that are relevant and useful for my clients. My goal is to make efforts to be more collaborative with clients in the future and to seek assistance and supervision on how to do that in the most culturally-appropriate manner.

Emily E. Wheeler:

It is my belief that social justice work begins and ends with individual relationships while operating on many levels. One of the most powerful components of this trip/experience was in reflecting on how I could relate to the individuals I met and collaborated with while in Kyrgyzstan. In their chapter on international consultation from a multicultural-feminist framework, Mathews and Horne (2005) contend that a position of not-knowing with regards to other cultures is important for consultants who are working across borders in order to collaborate in an open and unbiased manner. In doing so, Mathews and Horne (2005) argue against using a framework of cultural competence, as we do in the United States. Rather, they argue that a critical and non-defensive examination of power in these relationships, including the current and historical power held by Western countries, allows for a more appropriate starting place that will aid in building a collaborative working relationship.

In the process of self-reflection during this trip, I realized that my culturally-based assumptions were a near-constant filter that I had to work through and attempt to unlearn cultural assumptions. Although multiculturalism and social justice work have been given consistent emphasis in

our coursework and training at UMass, this was my first experience of moving from discussion to direct experience in an international context. In conversations with students and faculty at AUCA, the challenge of not-knowing became clear to me, as did the potential rewards of using not-knowing to achieve a productive working relationship with international colleagues. I was struck by the effort required in working towards a collaborative, not-knowing stance. This stance was essential not just in the moment but also across time, in periods of preparation and reflection, as well as in the context of ongoing relationships.

Although I valued the preliminary research I had completed before the trip about Kyrgyzstan and the field of counseling within it, I learned on this trip a new appreciation for the role of lived experiences in constructing an understanding of something new. The insight that derives from experience is invaluable, and this trip provided me with the extraordinary gift of the means to learn about international psychology and consultation through lived experiences and from the wonderful faculty and students whom I met at AUCA. These learning experiences have already changed the way I approach working relationships after my return to the U.S., and it has spurred in me the desire to think forward to the relationships I will build in the future.

Aleksandra Plocha:

The opportunity to be immersed in the Kyrgyz culture provided a context for social justice considerations in our field that I have never experienced before. Throughout my graduate training at UMass, I have read and discussed many aspects of social justice, including the stigma of seeking mental health care. During my trip in Kyrgyzstan, I was able to understand the context of this issue in more depth. There is a tremendous need for mental health services in Kyrgyzstan due to "the multidimensional consequences of interethnic tensions, violence, and mass panic [that] included not only political, economic, and health costs, but also mental health repercussions including increased rates of reported depression, anxiety, somatoform, and posttraumatic stress disorders" (Malchonova et al., in press, p. 4). Despite this need, many barriers exist to accessing mental health care in Kyrgyzstan.

The current state of mental health services in Kyrgyzstan reflects the complex history of the country, including the intersection of the traditional culture with modern developments in this arena (Molchanova et al., in press). The concept of counseling, as a separate entity, did not exist prior to 2009, and as such, the notion of psychotherapy is very new in Kyrgyzstan. There are an estimated 32 psychologists in the entire country, or one psychologist for approximately every 171,176 individuals. There are only three university departments that currently provide education for counselors, which means that opportunities for training new counseling professionals are extremely limited. Furthermore, the training models for counseling psychology and psychotherapy are not uniform and vary greatly (Molchanova et al., 2009).

Language and cultural background pose other barriers to accessing mental health care in Kyrgyzstan. The Kyrgyz language has limited vocabulary for emotional states and concepts like *depression* and *anxiety*, which makes communication about mental health concerns and diagnosis of mental health disorders challenging (Molchanova et al., 2009). This difficulty is compounded by the lack of professionals in Kyrgyzstan who speak both Russian and Kyrgyz. Furthermore, a majority of ethnically Kyrgyz people prefer to seek treatment from traditional healers.

Developing a better understanding of the contextual factors that have shaped and continue to influence the field of psychology in Kyrgyzstan, and the barriers to accessing mental health care, is important in framing solutions to these barriers which may be more complex than they might initially seem. I realized that when we limit our understanding of social justice to what we read in published works, from the confines of our classroom, we may misperceive systemic changes as being overly simplistic. Being immersed in a culture, however, elucidates the multidimensional attention that social justice initiatives require.

The trip to Kyrgyzstan with my doctoral program offered a once in a lifetime opportunity for personal and professional growth. It also represented a rare chance to apply my learning of social justice concepts outside of the classroom and to dynamically interact with counseling professionals in a culture very different from my own. It was a privilege to represent UMass Boston's Counseling and School Psychology Ph.D. program on its first transnational trip.

Conclusion

In sum, our cohort's trip to Kygyzstan and our collaborations with AUCA highlighted the importance of international travel and immersion in Counseling Psychology training, particularly from a social justice perspective. With this experience, we were able to supplement and give deeper meaning to our rich classroom discussions and readings about psychology and social justice in the context of internationalization of counseling psychology. This experience helped us become more aware of personal assumptions and biases in a unique and valuable way. We learned the importance of individual relationships, collaboration, and, perhaps most importantly, finding a shared lived experience and understanding of multiple worldviews. We returned from our trip to Kyrgyzstan feeling inspired, with a greater sense of meaning, purpose, and passion with regard to the field of counseling psychology.

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International Graduate Student's Experience of the 2014 APA Convention

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In many ways, this year's APA Convention in Washington, D.C. was different than the previous two that I had attended. As an international student from the United Arab Emirates who has been living in Boston, MA, for almost seven years, I was glad to find that the Convention hosted more events related to psychology in the Middle East. Furthermore, I had the opportunity to present in the convention for the first time in the form of an informal discussion. Similar to previous years, I attended the events related to international and cross-cultural psychology as well as psychology of religion and spirituality.

This year, I attended the International Mentoring & Orientation Committee (IMOC), which is part of the International Section of Division 17 (Counseling Psychology), Roundtable Discussion. At that event, I received valuable advice from psychologists, both clinicians and scholars, who used to be international students like myself during their training years in the United States. The most surreal part for me was to meet two of the discussion leaders, namely Dr. Stefania Aegisdottir and Dr. Ayse Ciftci, whose publications I had read and had felt inspired by their work. It was great to have the opportunity to meet them in person!

While many topics were discussed during this event, I especially learned from listening to the differing opinions about the value of taking time off to gain clinical or/and research experiences between a master's and doctoral degree. Whether this time off is spent in one′s home country, in the U.S., or both, all attendees agreed that doctoral programs will likely be interested in how this time was spent and how it advanced the development of the applicant. I heard caution against exclusively spending this time in clinical pursuits if one is interested in a research-oriented program and vice-versa. Another discussion that interested me was that of transitioning to professional life back in one′s home country after years of studying abroad in the United States. Discussion leaders highlighted how this process can be seen as one of rediscovery as a global citizen rather than that of merely "going back home." Among the proposed suggestions of performing this transition smoothly, the discussants suggested reading media about psychology in the native language, especially introductory books on psychology. Another proposed suggestion entailed conducting site visits of local community centers and practitioners to form connections and to map resources in one′s home country.

I further attended the board dinner and board meetings of Division 52 (International Psychology) and a business meeting of the International Section of Division 17. In fact, it was not until this year that I learned that students are allowed to attend some of the divisions′ board and business meetings. It was

Fellows Committee with President of the Division 52 (International Psychology) and me (right).

Student Column

During the Division 17 International Section Business Meeting, I asked attendees about an issue that concerns me as an international masters-level counseling psychology student who has one more year of graduate school and who hopes to obtain a Licensed Mental Health Counselor (LMHC) license in Massachusetts. I asked how does the section, and similar APA divisions, address the lack of agencies and organizations willing to sponsor international students for an H1-B work visa upon completion of their studies and Optional Practical Training (OPT). Without such sponsorship, recent graduates with F-1 student visa, like myself, are unable to gain needed post-graduate clinical hours for clinical licensure in the United States. For instance, one of the requirements of obtaining an LMHC license in Massachusetts is full time clinical work with supervision for a minimum of two years. In contrast, the OPT only allows international students on F-1 visa to work full time in the U.S. for one year upon graduation. This issue is especially difficult for F-1 visa students in the masters-level who do not have the privilege of doing something similar to a post-doctorate student who can extend their stay. Post-doctorate students have the option to apply for a J-1 research/scholar status, which is easier to get than an H1-B work visa.

Nonetheless, despite the hard work of the section, and similar APA Divisions, in this area, this challenge still exists. I was further surprised to learn that many U.S. universities do not properly caution their international students about working beyond the maximum hours of pre-graduation practicum/internship and part-time employment that are allowed to remain eligible to apply for OPT upon graduation. Fortunately, the attendees of the meeting gave me some helpful suggestions. They advised that I look for a mentor in Massachusetts, who would be willing to advocate for me, and that I pay attention to how much the agency or organization welcomes diversity. They also suggested that I make the most of my OPT period with my employers in the hopes that their positive appraisal and recommendation of my candidature will convince them to sponsor me. During the IMOC Roundtable Discussion, I learned that, unlike not-for-profit organizations, universities and some hospitals (not VA ones or those with low funds) are more likely to sponsor an H-1B visa. I further learned there that one could consider having a letter from the government of one′s home country or one′s university advocating to extend one′s stay in the U.S.

One of the Division 36 (Religion & Spirituality) Hospitality Suite events I attended was an informal discussion about the ethics of doing international research in the psychology of religion and spirituality. Participants of the discussion highlighted the need to genuinely learn the community′s interests first instead of coming in with an agenda. I was surprised to learn that even when doing international research, the Institutional Review Board (IRB) will still ask non-American co-researchers to go through the IRB research training. This makes me wonder about the cultural appropriateness of this practice and how to navigate cultural and ethical clashes in research. While my master′s program is clinically focused and I have yet to take the research classes this year, I wished that I had learned the contents of this discussion in a formalized way during my undergraduate research classes. Unfortunately, my undergraduate psychology program only briefly mentioned multicultural psychology topics in small sections of book chapters, not as a mindset to be practiced at all times as a researcher. Indeed, as a person who has been living in the U.S. for almost seven years and who was born and raised in the U.A.E., I have an interest in potentially exploring international research and this information would be highly valuable for me to gain..

This year′s convention was especially unique for me as it was the first one in which I did a presentation thanks to the immense help of my mentor, Dr. Ani Kalayjian. Dr. Kalayjian and I were among the panel presenters on *Ethnic Psychology Associations* in the Division 1 (General Psychology) Hospitality Suite. In this panel, each presenter briefly discussed the history and current status of an ethnic psychological association that they had led or were researching on. Apart from my presentation, I learned about the Asian American Psychological Association from Dr. Jeff Rey S. Mio, Italian American Psychological Society from Dr. Bernando Carducci, Greek American Behavioral Sciences Institute from Dr. Thomas Mallios, Armenian Behavior Sciences Association from Drs. Harold Takooshian and Ani Kalayjian, and Association for Trauma Outreach & Prevention (ATOP) Meaningful World from Dr. Kalayjian. This discussion has implications for assessing the growing role of U.S. ethnic psychology associations in U.S. psychology. In addition, by possessing the knowledge about active ethnic associations abroad, psychology associations in the U.S. can enhance international collaborations. Fostering these collaborations is important for the development of a global perspective in psychology and in being global citizens overall in our role as psychologists.

Division 1 Conversation Hour participants (from right to left): Drs. Harold Takooshian, Bernardo Carducci, Ani Kalayjian, Thomas Mallios, Ray Paloutzian, & me)

I presented an introductory review that I wrote and that was edited by Dr. Kalayjian The introductory review was about psychological associations in the Middle East. We hope to submit this for publication in the *International Bulletin*, a newsletter by Division 52, and to then work on a more comprehensive review for publication in an academic journal. We will then present updates in next year's *Ethnic Psychology Associations* panel in the next Convention where we will also be updated about other ethnic psychological associations from fellow panel presenters. We therefore hope that the information that we are gathering will be beneficial to both Divisions 1 and 52, especially in fostering cross-national collaborations. I had never imagined I would be presenting in the Convention and working on submitting to APA publications as a masters-level student!

Among the Convention events related to my region, I found myself feeling inspired in the first meeting of the Arab/ Middle Eastern American Psychology group which met in the Division 45 (Culture, Ethnicity, & Race) Hospitality Suite. Listening to a number of inspiring Arab psychologists who introduced themselves and their work in this meeting made me think about how much expertise already exists in my region even though there is a lack of avenues in which students can connect with them. Consequently, I liked the idea of a new group proposing to create a database of Arab psychologists and students, creating a listserv for members and listserv rules to moderate it, and to meet annually during APA Conventions. Meeting attendees also proposed the idea of dividing the group into smaller working groups.

As a student, it was interesting to gain an understanding of the variables that are considered when starting a group affiliated with APA. In particular, it was interesting to hear about the difficulties in assessing the number of APA members who identify as Arab or Middle Eastern. This difficulty arises because some members are hesitant about disclosing such information due to concerns about how APA will use this information. It is particularly a sensitive issue for Middle Eastern members whose identities are marginalized in the U.S. In the U.S. Census, Arabs and Middle Eastern people are automatically labeled as "white" even if they choose to indicate that their race is "other." Dr. Germine Award, the meeting leader, is trying to address this issue. Although the group currently aims to focus on Arab Americans, it plans to branch out to an international focus in the future. It also does not exclude people who are non-American or non-Arab/Middle Eastern.

Another event relating to my region was a symposium about Creating Peace in the Middle East. This event was chaired by Dr. Laura Miller and Dr. Wael Mohamed. The other speakers were Dr. Kalayjian, who led the discussion and Q&A in the end, and Dr. Shuki Cohen.

In this symposium, I liked hearing about the updates on Dr. Kalayjian's ATOP Meaningful World services in the Middle East this year. Her organization is not-for-profit and is affiliated with the United Nations. She has written two books that describe how her 7-Step Biopsychosocial and eco-spiritual model has been used in over 45 countries to help survivors of trauma due to natural and human-made disasters heal in a holistic way and to also prevent violence. Apart from connecting survivors with needed resources, Dr. Kalayjian's model incorporates meaning-making (based on Frankl's logotherapy), simple movement exercises (such as yoga and Tai Chi), breathing exercises, meditation, aromatherapy, and practices indigenous to the region being served. In addition, her model encourages survivors to heal their environment, both its ecological and social senses . It was interesting for me to learn about how her model was successfully used in the Arab countries that she visited this year. This inspires me to explore how this model can be used in my country and in Gulf Arab countries, both for trauma survivors and for survivors of other struggles.

Symposium presenters of Peace in the Middle East (from left to right): Drs Cohen, Kalayjian, Stout, Miller, and Wael

Dr. Laura Miller presented on the topic of trauma and ecologically informed humanitarian interventions in Egypt. I was most intrigued by her presentation when she pointed out that PTSD is associated with strictly categorical views (i.e. black and white) of reality which influences how people respond to reality. She added that this phenomenon, along with how violence is not experienced separately from other forms of violence and systemic issues, needs to be understood in order to understand the trends of interpersonal violence in Egypt. I also learned about how interventions that used the local *Imams* (religious priest or worship leader of a mosque) to teach content material of treatments were found to be most successful. I personally believe that it is important to map community resources, to gain trust from, and to collaborate with community leaders. I think that collaboration with religious leaders is particularly important in a community where religion is central to everyday life and to the cultural fabric of the country.

Aside from the symposium and meetings, I attended the APA Career Fair. The Career Fair was a miniature reflection of the reality I will be facing while looking for post-graduation jobs to sponsor me in the U.S. to obtain the

required hours for a LMHC license. On the bright side, I left my mark on artist Mark Cooper's sculpture, which was a collaborative art project among Convention attendees.

Despite my busy convention schedule, I had the opportunities to engage in sightseeing in Washington D.C. Overall, I hope that next year's Convention will continue to host events pertinent to international students, and to conduct events related to international research, Middle Eastern psychology, and ethnic psychology broadly. I am particularly interested in attending more discussions relating to international psychology students' transitions back to their home countries after graduation. I believe that such discussions can lead to a supportive community of likeminded international students and early career professionals committed to being global citizens rediscovering their home countries. I further hope that next year's Convention will include more events of relevance to non-Arab Middle Eastern countries, and not be restricted to Arab countries. Finally, I am curious if next year's Convention can host a more in-depth discussion about the lack of organizations and agencies that are willing to sponsor recent international graduates in psychology so that they can obtain their postgraduate clinical hours for licensure. Perhaps this could be accomplished in the form of a panel featuring advocates in this area, international students and early career professionals, hiring agencies in the field, APA leadership, and representatives from the US Department of Homeland Security Citizenship & Immigration Services.

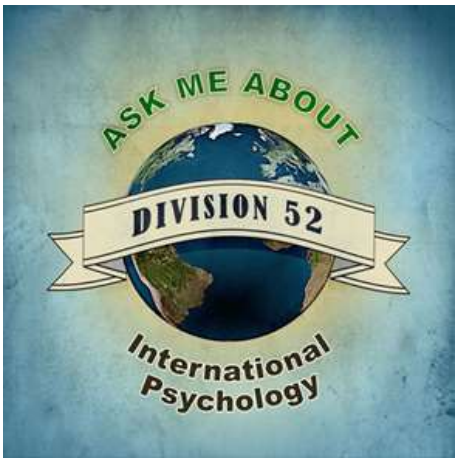

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Our Webmaster Ji-yeon Lee sends out her listserv monthly, rich with useful news, http://div52.org/announcements/div-52-announcements/ Are you missing this? If you are not now receiving this monthly, be sure to register with Emily Laumeier at APA today: elaumeier@apa.org

To find out about free international activities in greater New York, check Ji-yeon's "NY-52" webpage at: http://div52.org/committee/committee-news/division-52-in-greater-ny/

Would you like to see the history of our D52 in several diverse languages, from Hindi to Somali? If so, check: http://div52.org/about-us/a-brief-history-of-division-52/

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Giving Away a World of Psychology: Reflections on Curricula, Training, and the Larger Field

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I am pleased to accept an invitation to write for the

Teaching International Psychology column, as it provides a great forum by which to share some of the work of the Division's Curriculum and Training Committee as well as my own interests in this essential area of inquiry and practice. First though, we all owe Dr. Gloria Grenwald, immediate past chair of the C&T Committee, a deep debt of gratitude, not only for the substantive accomplishments under her tenure, but for her warm and inclusive leadership. I would not have assumed this position if she had not reached out in her characteristically open and encouraging manner, first vis-à-vis a symposium proposal on global education that colleagues and I conducted under the auspices of Division 52 in 2011, and in subsequent correspondence over the past few years.

So who and where are we now? As to who, I'm delighted at the composition of the C&T Committee, which includes a mix of new and familiar names to Division 52, including Drs. Merry Bullock, Gloria Grenwald, Craig Shealy, Lee Sternberger, and Rich Velayo along with Dr. Devi Bhuyan, as our early career member, and Pat Kenny, as student representative. As to where we are now, building upon the work of Gloria and her team, the C&T Committee continues to support an ongoing project to "internationalize psychology syllabi," which is gathering and disseminating examples of courses that emphasize the relevance and role of a global psychology for the next generation of psychologists. Along similar lines, in support of President Elect, Dr. Mark Terjeson's dynamic initiative to develop more web-based educational and training materials, we are participating in the proposal and assemblage of topic areas that are of greatest relevance to our current and future members. We also continue the tradition of coordinating and/or participating in the submission of annual symposia to APA, most recently via the newly developed collaborative system by which two or more divisions develop a proposal. Thus far, this process resulted in a joint submission with Division 32, Humanistic Psychology, entitled *International Humanistic Psychology: Implications and Applications from Research and Practice*, which was accepted and subsequently presented at the APA's 2014 annual conference in Washington, DC. As a final area of emphasis, the overarching goal of the C&T Committee – which includes the development and dissemination of relevant educational and training materials, experiences, and opportunities – is furthered via representation by Division 52 at a forthcoming summit series (described below) at my home institution of James Madison University, where I am a professor in our Combined-Integrated Doctoral Program in Clinical and School Psychology, which also has a strong commitment to international engagement. If you are interested in participating in any of the above activities of the C&T Committee – or would like to propose others that may be of relevance to Division 52 – please don't hesitate to contact me directly at shealycn@jmu.edu. In my relatively brief time thus far as C&T Chair, I have found the Division 52 Board and members to be a highly engaged and creative group of individuals, who are devoted completely to our larger and shared goal of "giving away a world of psychology" to the larger profession, other disciplines, and the public at large.

In inviting this column, Gloria suggested that I might offer some information about my own background and interests. I am happy to do so since it's important, I think, that we share our perspectives and experiences, as such information can provide helpful context and support to one another in the pursuit of our shared goals. For myself – and like many of us – I certainly did not imagine during my training as a clinical psychologist at Auburn University in the late 1980s and early 1990s that my own professional identity, teaching, and scholarship ultimately would become so deeply embedded in all things international. In retrospect, I suppose the signs might have been clear, from participation in a semester abroad program in London as an undergraduate, to the three or so years I spent in South Korea and Germany through the University of Maryland's system for teaching college courses

to military personnel, which culminated in running a small counseling center at UMUC's international campus located in Schwäbisch Gmünd, Germany. But even with these experiences, I didn't see myself at the time as an "international psychologist" per se, but rather as someone who simply had deep interests in understanding how the experience of different life events, cultures, and contexts affected who we become as human beings.

More specifically, like many who are drawn to our field, I always had been interested in why we experienced ourselves, others, and the larger world as we do; I was – and am – fascinated by the stories we tell ourselves about the nature of reality vis-à-vis the beliefs and values we declare to be self-evident. An early manifestation of these interests emerged even before doctoral level training, in comparing the beliefs of soap viewers and non-viewers in my master's thesis, via the Jones Irrational Beliefs Test (and yes, the former group did show "more" irrational beliefs, with all the requisite caveats regarding the need for more study). These preoccupations continued throughout my own graduate training, and were piqued that much more during internship and my postdoctoral year. Overall, the more I attended to the belief-statements from my clients, the more it became obvious that the stories we tell ourselves and others mediated every aspect of human functioning, from our implicit and explicit formulations regarding etiology, to attributions regarding why we think, feel, and behave as we do, to the assessment questions and treatment interventions we ultimately employed. So, beginning in my internship year, I simply began to take notes regarding the belief statements individuals, couples, and families made about the nature of reality. This practice continued during my teaching, scholarship, and practice overseas, and was extended to include belief statements uttered by other prominent humans (e.g., politicians), which resulted in hundreds of such statements over time. Ultimately, this content was adapted in the early 1990s into the first version of an assessment measure called the Beliefs, Events, and Values Inventory or BEVI, which since has been used in a wide range of contexts, from assessment, therapy, forensics, and leadership, to a multi-year, multi-site study of international, multicultural, and transformative learning (e.g., www.forumea.org/research-bevi-project).

Prompted by work with the BEVI, as well the terrorist attacks of 9/11, an interdisciplinary group of colleagues and I established the International Beliefs and Values Institute or IBAVI in 2004, which has as its mission "to explore beliefs and values and how they influence actions, policies, and practices around the world" (www.ibavi.org). Findings from many dissertations and other studies from the BEVI, and our ongoing work through the IBAVI, culminated most recently in an edited book with Springer Publishing called *Making Sense of Beliefs and Values* (www.springerpub.com/making-sense-of-beliefs-and-values.html). Among other initiatives, a similarly titled course was developed under the auspices of the IBAVI, and has been taught for many years now through the Madison International Learning Community at JMU, for which I serve as Academic Coordinator (www.jmu.edu/international/mi). And here is where paths directly converge, since another initiative of the IBAVI was the development of *Cultivating the Globally Sustainable Self*, a three-year summit series beginning in March of 2015, which examines and pursues a range of initiatives in research and practice (www.jmu.edu/summitseries). As mentioned above, Division 52 – along with additional partners in APA and other organizations – will participate in this summit series, which should help in the identification and development of teaching, training, and learning activities that are highly congruent with the mission and goals of our division.

From my perspective, the common denominator across all of the above work is a threefold contention: first, we can and must do a much better job of identifying the factors and forces that "make us who we are" as human beings, a goal that is best pursued by examining the similarities and differences among us around the world; second, we must juxtapose such understanding with other disciplinary perspectives if we are to apprehend the nature of human nature, and address the most pressing issues of our day; third, as educators, scholars, and practitioners, we have an obligation to engage one another as well as the next generation of psychologists and citizens in this essential dialogue as our world ineluctably is becoming more interdependent.

Within psychology, Division 52 – along with APA's Office of International Affairs, a key partner in this process (www.apa.org/international/) – offers a world of possibilities by which current and future psychologists may pursue these means and ends. Such perspective is advanced further by a forthcoming volume with APA Books, called *Going Global: How Psychology and Psychologists Can Meet a World of Need* – which focuses on who we are, what we do, and all we may become across nine interrelated areas of emphasis: advocacy, assessment, consultation, intervention, leadership, policy, research, service, and teaching. As co-editors, Dr. Merry Bullock, Senior Director of APA's Office of International Affairs, and I have been privileged to work with an extraordinary cohort of psychologists in the States and internationally, and can report unequivocally that the international future of our discipline and profession is as bright and promising as it is inevitable and necessary. In the context of Division 52, the C&T Committee will do its part to identify how, when, and why we may operationalize these aspirations and meet these needs that much more, and we warmly welcome your presence and perspective along the way.

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Darwin's Country Retreat: Down House

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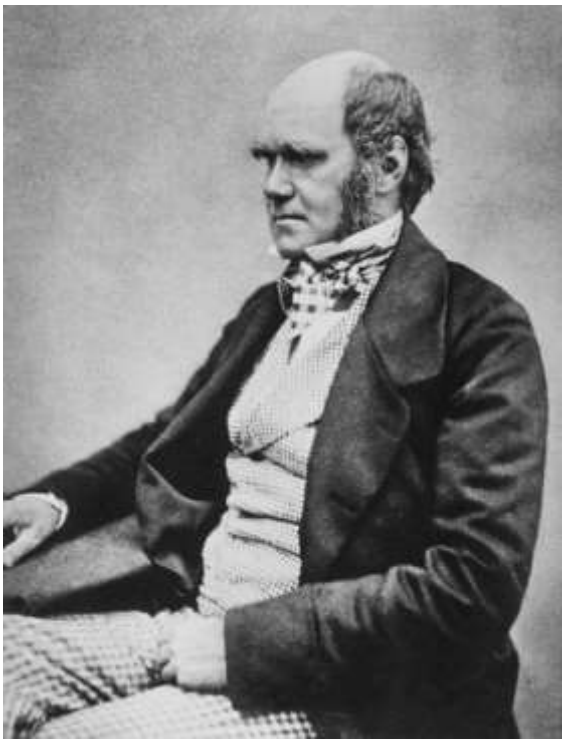

Charles Darwin about the time "Origin of Species" was published (photo by Maull & Fox)

For the last forty years of his life, Charles Darwin (1809-1882) lived in a large rambling house in a small village located about 16 miles southeast of London. It was here that he raised his children and wrote his books, including *On the Origin of Species* (1859). But his home was also a refuge. Although he had literally traveled around the world, once he moved into his country home he rarely even ventured into London. He preferred the company of his large family and adoring wife – and the geographic isolation that allowed him more time for his studies.

Darwin's theory of evolution is recognized as a unifying construct for all of the life sciences. Nonetheless, it may be surprising to learn that his impact on psychology was particularly important. More than anyone, his half-cousin, Francis Galton, was responsible for bringing his ideas into psychology. While Darwin barely discussed the human condition in *Origin of Species*, Galton immediately saw the human implications of his work. Soon after reading the book, Galton began to develop his ideas about improving the human race, an effort that he labeled *eugenics.* And while eugenics itself has long fallen out of favor, it led to Galton's search for an intelligence test, his focus on individual differences, and his development of many statistical procedures still in use today. Many historians feel that the content of U.S. psychology owes a greater debt to Galton than to anyone else, emphasizing, as it does, adaptation and individual differences. Along with Galton, other pioneer psychology luminaries who identified Darwin as important to their work included Sigmund Freud, Ivan Pavlov, William James, James McKeen Cattell, and G. Stanley Hall.

Darwin's famous voyage on HMS The Beagle lasted from 1831 to 1836. It was during that 5-year journey around the world that he gathered the specimens that helped to establish his early scientific reputation. And although he did not speak of it publicly for several decades, his theory of evolution began to form during that journey. When he returned to England in 1836, he had changed from a young man without direction to a respected naturalist. His older friends had been sharing his letters and their insights with the larger scientific community. His father, who had once been so dubious about young Darwin's future, helped arrange his finances so he could pursue the life of a gentlemen scientist.

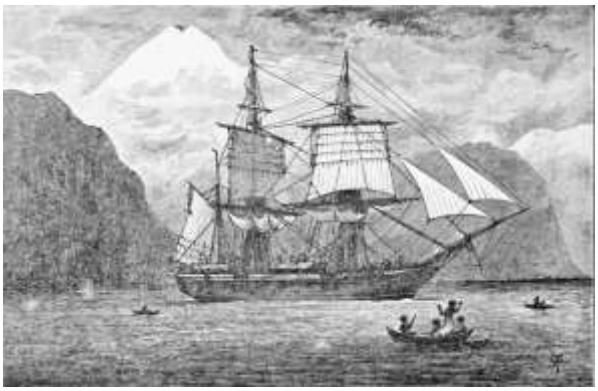

HMS The Beagle (sketch by R. T. Pritchett).

Charles debated whether he should marry, and only after making pro and con lists and considering all the possibilities did he decide to go forward with it. He proposed to his cousin Emma Wedgewood, she accepted, and they were married in 1839. They lived for the next three years in London

Finally, in 1842, with Emma pregnant with their third child, they bought a house in the village of Downe, sixteen miles southeast of London. (Soon after the Darwins moved to their new home, the village decided to change its name from Down to Downe so as not to be confused with County Down in Ireland. The Darwins stuck with their first name for Down House.)

Originally, their home was a box-like structure, probably dating from the early 1700s. On several occasions as the family became larger, the Darwins hired an architect to modify and increase the living space. Over the years it grew into an expansive and multi-faceted structure. (The Darwins would eventually have ten children in all, although three of them died in childhood.)

Down House

After Darwin's death in 1882, his widow moved closer to one of her sons and lived in the house in Downe during the summer only. After her death in 1896, the family rented the house. For two different periods, it was the site of a girl's school. In 1927, the home was purchased from the Darwin heirs with the specific intent of making it a museum to honor Darwin and his work. When the decision was made to turn it into a museum, one of the Darwin children, Leonard, was still alive. With his help, the home was restored with many of the original furnishings. The museum was opened to the public for the first time in 1929. In 1996, English Heritage, an arm of the government, took over the care of the house. They restored it even further and finally reopened it to the public in 1998.

Visiting the house and grounds is a rare opportunity to learn more about one of the most influential scientists of all time. A particular highlight of the site is his study where the bulk of Darwin's writing took place. It contains most of the original furniture. Also of note are the gardens in which Darwin took his daily walks, both for reasons of health but also to ponder his latest scientific questions. Audio tours are available. Between September and March, visitors may catch a glimpse of sheep grazing in the fields. Special events, such as stargazing nights, are held regularly on the grounds; a calendar is listed online.

Visiting Details:

Website: http://www.english-heritage.org.uk/daysout/properties/home-of-charles-darwin-down-house/

Hours: Open Saturday and Sunday, 10 AM to 4 PM (last admission at 3:30). Closed on major holidays.

Admission:

- Adult: £10.30
- Child: £6.20
- Student/Senior: £9.30
- Family (2 adults, 3 children): £26.80

Address: Luxted Road, Downe, Kent - BR6 7JT

Public Transport from central London:

- Take the National Rail (Southeastern Line towards Ramsgate) from London Victoria Station to Bromley South Station. Transfer to the 146 Bus. Exit the bus at Downe Church and walk up Luxted Road for about ½ mile.
- Take the National Rail (Southeastern Line towards Tunbridge Wells) from London Bridge Station to Orpington Station. Transfer to the R8 Bus. Exit the bus at Downe Church and walk up Luxted Road for about ½ mile.

Driving: Off the A21 or A233. Parking is available on site free of charge.

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Live, Learn, and Love Haiti: Profile of Haitian Clinical Psychologist Guerda Nicolas

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Introduction

The life and work of Haitian clinical psychologist, Guerda Nicolas, is perhaps best captured by the South African principle *Ubuntu*. Ubuntu, deriving from the language of Nguni people in southern Africa (Kamwangamalu, 1999), refers to values of interdependence, fraternity, and humanity (Swanson, 2007). Although phonetically varied across other African regions (Kamwangamalu, 1999), the essence of the term remains the same in any language and can be translated in English as, "I am because we are" (Kidjo, 2014). Dr. Nicolas' 20 years of professional and personal contributions to advancing the study and practice of psychology in Haiti and among the Haitian diaspora in the United States is an impressive illustration of this profound and deeply meaningful concept.

After the January 2010 earthquake in Haiti, Dr. Nicolas was the premier expert on Haitian mental health sought by news media including CNN, BBC, NPR, and Haitian radio broadcasts *Radio Solidarite* and *Tele Diaspora*. Her poignant views on the post-earthquake response could also be read in articles written for the wider audiences of the *Caribbean Journal* and *Times Magazine*. Although her service to Haiti began many years prior to the earthquake, she has dedicated the past 10 years of her scholarship to making her work on Haiti more accessible to the academic community as well as the general public. In the 20 years since completing her doctoral training, Dr. Nicolas' professional profile includes over 50 scholarly publications, 100 professional presentations, workshops, and trainings, and 15 years of leadership in various capacities for several organizations including the *American Psychological Association* (APA), the *Institute for the Study and Promotion of Race and Culture* (ISPRC) at Boston College, the *Haitian Studies Association* (HSA), the *Haitian Psychological Association* (HPA), and the *Caribbean Psychological Association* (CPA), to name just a few. She has also been successful securing substantial funds for several youth-related projects through prestigious federal and private grants, with two of her six ongoing research and mentorship projects funded by the National Institute of Health (NIH) and the National Center for Minority Health and Health Disparities (NCMHD). Additionally, she has held academic appointments at Iona College, College of Saint Elizabeth, and Boston College. In 2008 she joined the faculty of the Educational and Psychological Studies Department at the University of Miami. She was soon named chair of the department in 2009 and recently completed her 5-year term.

An avid reader, Dr. Nicolas enjoys biographies and books grounded in history. She likes to "learn lessons" from the life stories of others. During the interview for this Heritage Mentoring Project article, she recommended, because she is always and foremost an educator, *Silencing the Past: Power and the Production of History*, by Haitian anthropologist and historian, Michel-Rolph Trouillot (1997). Trouillot's acclaimed work encourages readers to ascertain and apply the accounts of diverse "voices" in recording history. Fittingly, Dr. Nicolas' personal and professional history provides important insights and lessons for our international community of psychologists.

"I am"

The mother of two musically and theatrically talented daughters, 14 year-old Tatyana and 11 year-old Alexis, Dr. Nicolas teases that her daughters' musical and theatrical gifts were not inherited from her or her former husband. Describing her daughters as "amazing," "grounded," and "leaders in their own right," she boasts about Tatyana and Alexis' astuteness and mastery of issues related to social justice. Conceivably, the girls' interest in these topics can be traced to their mother's career-long commitment to the same issues, which Dr. Nicolas would attribute to the women who came before her.

Like in many Haitian families, Dr. Nicolas' grandmother held a major role during her upbringing in Grand-Goave, Haiti, where Dr. Nicolas was born and raised. "Gran-Grann," as Dr. Nicolas refers to the presently 97 year-old matriarch, helped define her identity and imparted values about community and spirituality. "She reminded me that I am a child of God and that I was meant to live a life of purpose. She taught me about life and about connecting with people," said Dr. Nicolas. She remembers vividly that Gran-Grann's wise words were delivered after a near-death experience during her childhood, in which a pot of hot soup accidentally fell on to her. Hospitalized for a year, Dr. Nicolas' grandfather began to prepare for the funeral, while her grandmother continued to treat the burns through Haitian ethnomedical methods. Thankfully, the coffin that her grandfather built was never used, as Gran-Grann's herbal remedies healed the severe burns to 90% of Dr. Nicolas' skin. Dr. Nicolas attests that presently there "are no visible signs" of the injury on her body.

Never having met her father, Dr. Nicolas' mother and grandmother were the pillars, or *poto mitan* in Haitian Kreyol, of the family that included Dr. Nicolas and her two younger siblings, Yveline and Kevin Jean. At the age of 14, Dr. Nicolas and her mother immigrated to the United States,

where she reunited with her mother and met her sister Yveline for the first time. The family soon settled in Brooklyn, a borough of New York City that she still considers home. She entered high school with future ambitions of working with children and families as a pediatrician. She recalls amusingly that those dreams came to a halt when she was assigned in an advanced biology class to dissect a human brain. Fortunately, her experience as a peer counselor, also during high school, steered her towards psychology.

When she started her undergraduate studies, Dr. Nicolas knew that she desired to work with people directly. She explains that at that time, clinical psychology was the most popular career choice for the professional practice of psychology and she was inspired by the many clinical psychologists within her academic network who modeled for her the type of professional she wanted to become. She suspects that she might have chosen differently had she been more exposed to counseling psychologists at this juncture in her education. She would later in her profession come to identify more strongly with counseling psychology's strong orientation in multiculturalism and social justice. Ultimately, Dr. Nicolas graduated from Rutgers University with bachelor's degrees in psychology, French, and Spanish. She then went on to pursue a master's degree at Fairleigh Dickinson University and a PhD at Boston University, with both graduate degrees in clinical psychology. It was while she was completing her pre-doctoral internship at Columbia University that she considered exploring more seriously a career in academia.

From the beginning, Dr. Nicolas envisioned herself as a community psychologist who cared for children and families through practice. Before internship, she was certain that she would return to Brooklyn and become what she had originally intended. The idea of becoming a researcher and teacher was first sparked while a 2nd year doctoral student at Boston University. Lecturing a course on Physiological Psychology, it was the feedback from students who enjoyed her dynamic teaching style that would force her to reflect on her career goals. She realized that she had never considered an academic career because she had never "seen" anyone who looked like her in the academy. In other words, she had lacked examples of scholars of ethnic and racial minority backgrounds throughout her academic training.

Dr. Nicolas' career in academia began with the intent of being a model for upcoming scholars of color. In addition, she felt an obligation to "do the work and do it right because it has implications." Following internship, Dr. Nicolas accepted a postdoctoral fellowship at Columbia University, where she would first learn how to "do the work." The work, for which she felt greatly responsible, would involve instruction and research on issues pertaining to mental health services for ethnic and racial minority groups. Remaining committed to children, families, community, spirituality, and social systems, she studied in Philadelphia at the *Minuchin Center for the Family* after her postdoctoral training.

Since her doctoral training, Dr. Nicolas' scope of research has derived from many perspectives and has followed a variety of directions. She has maintained her commitment to communities of color, in spite of the negative response she received initially about her interest in marginalized groups. In the brief period that she has devoted to writing peer-reviewed articles, book chapters, and for print media, Dr. Nicolas has investigated with rigor complex psychosocial issues. Whether she is addressing the ontology of PTSD and resilience in Haiti (Nicolas, Wheatley, & Guillaume, 2014), depression in Haitian women (Nicolas et al, 2007), or the validation of psychological instruments for youth of color (Nicolas, DeSilva, Houlahan, & Beltrame, 2009), she has remained focused on populations under-examined and often misunderstood. Fluent in Haitian Kreyol, Spanish, and French, she is a strong advocate for interventions oriented in the culture of its recipients and uses her multilingualism to discern and represent the needs of the communities she serves through practice and scholarship.

In the early stages of her career, Dr. Nicolas attempted to broaden her research inquiry to include studies of popular interest at that time. Yet, her desire to be more proactive in deconstructing the common narrative about populations of color drove her back to her original aims. She became interested in producing a body of literature that would contribute to understanding the mental health experiences of people of color. She became especially dedicated to voicing the experiences of Haitian people in the US.

"We are"

Dr. Nicolas credits her enormous productivity in the past two decades to her heritage. She says modestly, "I have a lot that I owe Haiti for," although she does not consider her dedication to Haiti an obligation. She believes deeply that Haiti and being Haitian has greatly influenced the person and professional that she has become. Her work in Haiti began as a personal quest to "give back" to a beloved country and people. Her strong sense of identification with a "group of warriors and fighters" sculpted her determination to continue in spite of challenges in life. These same qualities were never more evident among the millions of Haitians living in Haiti, the US, Canada, Europe, Latin America, Africa, and elsewhere than on January 12th, 2010.

"The 12th", "goudou-goudou," or "tranbleman te," as the 2010 Haitian earthquake is referred to among Haitians, marked a critical point in Haitian history. With over 300,000 Haitians killed and 1.3 million displaced (USGS, 2011), the 7.0 magnitude earthquake devastated the nation. While the international response was widely covered in news media globally, much less reported was the response of local Haitians as well as Haitians from the diaspora.

Dr. Nicolas had returned to Miami from Haiti just two days before she received a call from a friend wanting to know her current location on that Tuesday afternoon. The friend informed her of the news and because Dr. Nicolas traveled to Haiti often, the friend worried that she might have been affected. Feelings of powerlessness and anger overwhelmed Dr. Nicolas in the days after the earthquake as she followed graphic news stories and attempted to connect with family in Haiti. For many, the first week after the quake was torturous as mass telecommunication delays prevented

families from corresponding with relatives on the island. She later learned that some friends and an uncle had been victims of the disaster.

Soon after, Dr. Nicolas became compelled to initiate a community healing process among Haitians in South Florida. *The Healing Little Haiti Project* provided a space for Haitians of all generations to discuss their concerns about the earthquake and its impact on their families. Tablets in-hand, community health workers with the project met with community members of the predominately Haitian neighborhood of "Little Haiti" in Miami to assess how they were coping with the event. *Vicarious trauma*, *re-traumatization*, and *acute distress* evidenced as the major themes of discussions with community members. The team also held meetings with key stakeholders to educate on related mental health topics, such as PTSD, and to provide more accurate information on the relief response.

In addition to *The Healing Little Haiti Project*, Dr. Nicolas extended her knowledge and perspective after the earthquake to two other projects upholding the values of community-driven programs. *Rebati Sante Mentale Haiti*, or Rebuilding Haiti's Mental Health, was formed by Haitian mental health professionals in Haiti, the US, and Canada in response to the lack of mental health services for those affected by the earthquake. Convened at a summit at the University of Miami in June 2010, the group originated as a taskforce and soon evolved into a structured nonprofit organization with projects targeting Haiti's mental health policies. Since 2010, the group has continued to hold conferences annually. The organization works closely with the Haitian Ministry of Health to meet their objectives, establishing themselves as a multilateral clearinghouse and a resource bank for international groups planning to implement mental health programs in Haiti.

Residents of the northern Haitian cities of Arcahaie and Cap-Haïtien have also benefited from programs led by Dr. Nicolas. In partnership with the Massachusetts School of Professional Psychology (MSPP), and Haitian clinical psychologist Gemima St. Louis of the *Haitian Mental Health Network* (HMHN), the *Teachers Mental Health Training Program* (TMHT) was developed to offer teachers in Arcahaie and Cap-Haitien comprehensive training on various mental health topics to better serve students in Haiti (St. Louis, 2014). The program was designed in close collaboration with community members, thus lending to the creation of culturally-relevant and sustainable interventions. In addition, MSPP graduate students participate in the program through a week-long service learning component of a summer course offered at MSPP. The course introduces students with interest in Haitian populations in the US and Haiti to Haitian culture, history, and current issues. While in Haiti, graduate students work alongside the program directors, Haitian teachers, and local non-profit representatives to facilitate relationships and expand networks among community members.

The Haiti Legacy Project is another example of Dr. Nicolas' commitments to Haiti, psychology, and education. Established in 2013 and funded by the Kellogg Foundation, the primary purpose of the project is to promote awareness of Haitian history and its inclusion in curricula, particularly for Haitian educators. Visitors can find academic and non-academic articles, sample curricula, links to documentaries, music, and art on the project's website. Through education, the project aims to provide ample insight into Haitian culture and psychology, while forging links between generations of Haitians. These linkages, by Dr. Nicolas' assessment, have been difficult to form due to the preceding generations' discontents and fears of sociopolitical issues in Haiti. In spite warnings from their parents about being involved in Haiti, Dr. Nicolas observes that the current generation of professionals of Haitian descent in the US has been "relentless." From practice to scholarship, Haitian-Americans proudly stand at the forefront with more senior professionals in reconstructing the narrative about Haiti. The team of early career and senior professionals who direct *The Haiti Legacy Project* serves as testament to intergenerational collaboration among Haitians.

Dr. Nicolas' effort to expand networks among generations of professionals has not been limited to Haiti. The *Caribbean Alliance of National Psychological Associations* (CANPA) was first conceived 10 years ago at an APA symposium. The founders, Dr. Nicolas and Bahamian psychologist Dr. Ava Thompson, grew dissatisfied with the lack of organization and representation of Caribbean psychological associations at annual APA conventions. With the support of APA's Office for International Affairs, in addition to much diligence and undertaking, CANPA was officially launched in 2013 at the *Caribbean Studies Association* (CSA) annual conference in Grenada. In 2014, the alliance hosted its first conference in Suriname under the theme, "Caribbean Psychology: Unmasking the past and claiming our future." The national psychology associations of Puerto-Rico, the US Virgin Islands, Martinique, and Jamaica are also represented in the association. Dr. Nicolas believes that the alliance provides a platform for building bridges as well as the capacity of psychological organizations in the Caribbean.

When asked what she has found to be her most important contribution to Haitian mental health, Dr. Nicolas responded, "Designing projects that are not 'Guerda-dependent.'" Although she has sought to discourage developing projects that solely rely on her involvement, her community-focused and action-oriented attitude has spurred the same dedication in those who have benefited from her work. Perhaps, constituents of her projects have become "Guerda-inspirited" instead of dependent. By upholding her commitment to her lineage, culture, and personal values, Dr. Nicolas has achieved enormous success in creating interventions that are collectively inspired and motivated.

Conclusion

It is through Dr. Nicolas' strong devotion to family, community, and Haiti that her professional story has come to embody the values of the South African world-view of Ubuntu. Firmly believing in partnership and the collective responsibility of groups to affirm, educate, and empower one another, Dr. Nicolas has exemplified this cultural perspective throughout her career with her many contributions to Haitian mental health.

Gardening, one of her favorite hobbies, has also been a great source of inspiration for her life. She likens the process of nurturing rare flowers in her home garden to the "tilling" and "watering" of relationships. In the relationships with her daughters, grandmother, students, and colleagues, Dr. Nicolas has sown several seeds, the harvest of which many will reap. It appears that Dr. Nicolas' grandmother, Gran-Grann, was responsible for planting the first seeds. Although Gran-Grann might not quite understand the broad impact of Dr. Nicolas' professional activities, Dr. Nicolas knows that she is proud.

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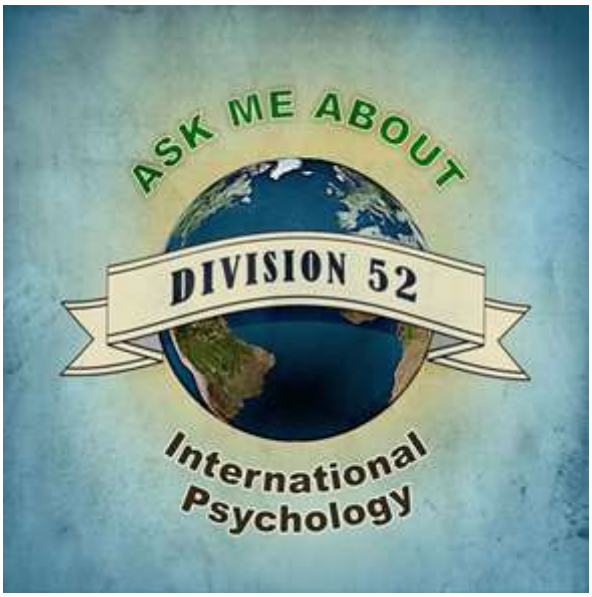

Encountering Culture: Psychotherapy and Counseling Practice in India

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Western or scientific psychology was introduced in India in 1905 at Calcutta University (Prasadrao & Sudhir, 2001). In 1915 a full-fledged department of psychology was instituted and Girindrashekhar Bose, a practicing Indian physician, became the first recipient of a doctorate in psychology in 1921. In 1922, Bose founded the Indian Psychoanalytic Society. After India became an independent democracy in 1947, premier mental health institutions were set up for providing preventive, curative and rehabilitative health care. National Institute for Mental Health and Neurosciences (NIMHANS) in Bangalore and Central Institute of Psychiatry in Ranchi were the earliest centres offering higher education in psychiatry, psychiatric social work and clinical psychology. Psychotherapy became an essential component of these qualifications (Neki, 1995). Fifty years down the line, the earlier trend of medicalized treatment has given way to counseling services (George & Thomas, 2013). There is greater mobility of Indians within the country and abroad, and people in larger cities and towns are asking for therapeutic counseling, to deal with emotional issues. Modernization and changing lifestyles seem to increase the need for therapy and also make it an acceptable form of help.

A Changing Society

Globalization has transformed the cultural landscape of India. Growth of industries and migration from rural to urban centers has created the promise of economic wellness as well as disappointments. Education and employment of women, especially in urban areas, call for reorientation of roles, responsibilities and power between genders, a welcomed shift for many women. Availability of mass media and modern communications has exposed people to ideas from western societies that led to a shift towards pursuit of personal goals and profit making enterprise (Carson & Choudhray, 2000). Among the concerns of current times are marital strain, parent-child conflicts, domestic violence, delinquency, substance abuse, low achievement in poorer families, and stress for high academic achievement in the higher income groups. Family bonds are affected because the joint family system that promotes collectivist values such as cohesion and interdependence is no longer the norm, especially in cities. Child rearing practices foster earlier independence for young adults. Indians who come to therapy may have worldviews that are very traditional, quite modern or a mix of both. There are clients in difficult marriages yet avoiding the stigma of divorce. There are progressive young adults living together without being married and talk openly about cohabiting. In addition, there are joint families where couples struggle to save their marital relationships in the face of intergenerational conflicts. Interdependence also continues by elders being involved in arranging marriages, helping in child rearing, and old parents living with adult children and being cared by them. 'Compartmentalization', the ability to function with newer skill sets or values in one area of life and retain the older values in another area, serves well as an adaptation to modernisation (Singer, 2007).

Evolving Culture of Psychotherapy

Systemic theories from the West are fairly applicable but certain peculiarities of Indian families call for slightly modified treatment strategies. Nath and Craig (1999) remind us that marriages in India have always been more than an alliance between the spouses unlike the West where it is a bond between two 'individuated' persons. The conflicts that clients present can challenge the counselor to examine their own value system. The effort to preserve the resilience of families and mental health of individuals against stresses of modern times has resulted in a significant development in family therapy services. Family therapy in modern India offers ways to strike a balance between the "tyranny of the collective and the alienation of individualism" (Oommen, 2000; as cited in Carsen & Chowdhury, 2000, p. 398). Mental health professionals have been able to engage families as an effective system of care when treating individuals with mental illness such as Schizophrenia (Chadda & Deb, 2013).

Training of counselors has received more attention only in the last two decades although there were many established departments of academic psychology in the country. The need for counseling and guidance for a growing population in schools and colleges has led to starting a number of postgraduate courses in counseling psychology (Arulmani, 2007). Institutions such as *Parivarthan* in the south Indian city Bangalore, offer training in counseling for mature middle-aged individuals from non-psychology background and ensure rigor through appropriate supervision (www.parivarthan.org). There are other practitioners oriented towards Transactional Analysis and maintain allegiance to the international TA association. A committed group of professionals has meticulously introduced EMDR training to psychologists, counselors and social workers (www.emdrindia.org). There is renewed interest in psychoanalysis in various metropolitan locations such as Delhi and Ahmedabad. One can also meet Jungian analysts in India who advocate the healing potential of dreams and mythological motifs. Service providers and users are capitalizing on the technologies available for long distance counseling. The variety of professionals available in urban India matches the plurality of the culture itself.

Cultural psychology is an emerging field and many of those who come to study bring their individual concerns reflecting social realities (Sapru, 1998). Psychology helps the students to articulate these concerns and find ways to cope, which in turn contributes to wider social transformation. Counselors trained in Western models effectively assimilate the cultural context in helping individuals and couples to find a balance between their relational and individual needs (Bala, 2007). Reviewing literature on psychotherapy practice in India, Manickam (2010) observes that while the authors' theoretical orientation to therapy varied over the years, a consistent concern for most of them was to assimilate indigenous concepts to meet client needs. Smoczyinski (2012) explores how counselors trained in Western approaches to counseling adjust their practice at an urban counseling center in Bangalore according to the local context. She views this process of adaptation in terms of *glocalisation,* drawn from the field of social constructionism. According to this concept, practice from one part of the world is transferred as an abstract idea to another part where it is actively received, modulated and put into further practice in this other context. Another critical concern facing professional therapists across the country is to collaborate towards consolidation of ethical guidelines and regulation of counseling and psychotherapy practice in India.

Encounters with Culture in the Therapy Space

India is a multilingual society. Training at universities and training institutes is conducted mostly in English due to availability of standard texts and training resources. Neki (1995) urged his contemporaries to attend to psycholinguistics because how people speak can say much about the mind structure and cultural stance towards life and living. A few professionals have undertaken translation of psychological concepts into a vernacular form despite some inherent challenges. Many English terms such as 'shame' cannot be substituted with Indian words conveying the same connotations just as certain cultural expressions cannot be expressed accurately in English. Nonetheless, a majority of therapists are likely to be conversant with at least one Indian language and do not hesitate to tune into a client's preferred mode of communication. Therapy in context, then, truly becomes the co-creation of all participants. Some lighter moments are experienced when the client can sense the therapist's genuine effort and correct their vocabulary, making for warm bonding between both.

The role of emotions in human experiencing is an important issue to contend with when applying constructs originating from a different culture. While physiological processes involved in regulation of emotions may be the same for all people, it is increasingly acknowledged that *cultural regulation* plays a significant mediating role (De Leersynder, Boiger, & Mesquita, 2013). Indian art and literature offer an enormous vocabulary and discussion on affect and emotion. Yet like other Asians, traditional Indians believe that emotions such as anger are damaging to relationships and are to be avoided in everyday life. It is hard for them to participate in exploration of feelings. Indian therapists of yesteryears who noticed this in their clients called it a 'cultural defence' (Varma, 1986). In such cases, mythological stories or fables allow for a profound sublimation of difficult emotions in the presence of a compassionate observer. Stories with relevant themes or characters can be spontaneous expressions from clients (Ramnathan, 2013). At other times, the therapist takes a lead to evoke the necessary image and aspired coping (Bhatt, 2010).

The egalitarian stance advocated by Western approaches is a much debated issue and many therapists have written that it is unhelpful and ineffective in the Indian context (Neki, 1979). In contemporary times, such difficulties are seen less frequently yet not completely absent. Clients asking for advice and anticipating direction is not uncommon. In a study by Smoczyski (2012), several counselors describe how they manage such a challenge by carefully exploring the client's worldview to elicit the advice or solution being sought and offer it back in in a constructive form. Arulmani (2009) has proposed that *cultural preparedness* is a necessary condition for counseling to be effective in non-western communities. He describes it as the ability to provide culturally relevant counselling that matches the client's expectation. A therapist may find herself being greeted with a handshake by a man and with a *Namaste* (i.e., joining both hands) from his wife (Bhatt, 2010). Some clients, including English-speaking individuals, can be at a loss when asked to address the therapist by first name because it is a practice that is common only between equals. Indians amongst other Asians who grow up in a Western environment often seem to function independently in some areas of life and yet in other spheres demonstrate deep-seated hierarchical attitudes as inculcated in their families (Kakar, 2003). In a society that has a hierarchical structure, tradition assigns roles, tasks and position, based on age and gender. Men, older members and individuals with valued qualities or qualifications are ascribed a higher place. The person lower down in the order expresses deference and the other in the higher role reciprocally offers caring and protection. Chin (1993) observes a 'hierarchical transference' when working with Asian clients in America. She suggests that for some clients it is facilitative to transcend the hierarchy and for some it is beneficial to reciprocate as expected.

Neki, a leading psychiatrist in the 1970s, observed that Indian clients often tended to look up to the therapist as a *Guru* (Neki, 1979). According to him, Indian society traditionally promotes social dependency and dependability. Within this cultural context it was reasonable, that clients considered a therapist as a teacher who could show them a way out of dilemmas. However, this attitude seems to be waning. Today's therapist is more likely to be seen as a consultant or a collaborator, going by the comment, "If the middle mental space between the body and the soul needs repair, the doctor or the guru is no use, it needs its own specialist to heal it" (Vishwanathan, 2005, as cited in Wadhwa, 2005). Based on conversations with professionals across several cities of India, Wadhwa (2005) reports that over the last decade urban Indians openly acknowledge their vulnerabilities and seek therapy proactively compared to earlier days when many

patients were referred by their doctor. Some clinicians still maintain that talk therapy is less effective when patients present with physical complaints, which are more socio-culturally acceptable ways to receive attention. These individuals speak less and still expect the doctor to understand their mental state (Wasan, Neufeld, & Jayaram, 2008). When hard pressed for time, many psychiatrists are likely to use medications to get maximum impact in shorter time. There are, however, psychiatrists who keenly practice psychotherapy or refer their patients to counselors (Bhatt, 2010). Furthermore, there are therapists who also advocate other forms of healing that their clients can benefit from. The alternate methods are seen to address the person's inner conflicts through different but equally plausible interpretations mediated by metaphors and archetypes relevant to their cultural identity. Moodley (1999) describes how an Indian client who lived in the West could be helped through talk therapy up to a point and was further healed successfully by an indigenous 'doctor'. In retrospect, he believes, it was wise to hold back an interpretation of 'splitting' because the client found an integration of his 'divided selves' with the other practitioner.

Integration and Grounding

The acceptability of Western psychotherapy and counseling professionals has not diminished the popularity of older healing practices (Arulmani, 2007). The Eastern approach cannot conceive of a separation between psychology and spirituality since both are concerned with the study and understanding of human nature (Varghese, 1998). According to Ayurveda, a traditional system of life science in India, wellness is a delicate balance between the mind, body, and spirit. Yoga offers time tested means to regulate the body, the breath and the mind leading to stillness- "observing transforms the observer- a radical resolution for inner discord and almost a God experience", describes Rao (2008, p. 299). Yoga and *Vippasna*, another Eastern discipline, commonly referred to as Mindfulness, are being incorporated into psychotherapy in the West as they overlap in their goals of helping a person to develop unconditional friendliness to oneself. Folk wisdom directs people to undertake regulated activities through social, vocational, creative and religious commitments, as meaningful engagement in life can help to develop equanimity. Communal practices such as musical chanting or attending discourses based on various philosophical texts remain popular for seeking solace or insight. Other sources of support are Meditation, *Pranic* healing, and Astrology. The cultural tradition of India is spiritual and this tradition includes influences of religions, religiosity, practice of various rituals and festivals (Arulmani, 2009; Thomas, 2010). It is not unusual for a Hindu to consult a Fakir (i.e., a Muslim sage) or visit particular churches associated with healing images of a Christian god or saint. Psychotherapy and counseling practice in India is positioned to be enriched by all streams of knowledge. Western psychotherapy offers a way to address the panic in the journey towards the unknown and strengthen an ego, which can only then be surrendered in the spiritual quest (Varma, 2004).

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The 24th U.N. International Day of Older Persons

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On October 9th, 2014, the annual celebration of Older Persons was held in the ECOSOC chamber of the United Nations HQ in New York, as several attendees filed in for this year's International Day of Older Persons event, themed "Leave No One Behind." This year's conference was presented by the NGO Committee on Ageing/New York as well as UNDESA (UN Department of Economic and Social Affairs) and was sponsored by the Permanent Missions of Argentina, El Salvador, Slovenia, South Africa, and Thailand as well as Pfizer Inc.

James Collins, the Chair of the NGO Committee on Ageing/New York, began the introduction of the programme at 10 a.m., introducing other introductory panel members as well as the day's mission: to include the interests of older persons in national decisions make ageing an inter-generational as well as an international issue. He acknowledged the diverse ages in his audience. Mr. Collins is also a representative of the International Council on Social Welfare at the UN, and a member of the NGO Committee for Social Development, as well as having been actively involved in several public service organizations, advocating for older persons.

Following his presentation, Mateo Estrémé presented his message on the theme "Leave No One Behind." Mr. Estrémé discussed the importance of distinguishing age from its social construction that 60-65 is the threshold after which one becomes an older person. Rather, Mr. Estrémé recognized the importance that this threshold is vastly changing and that it may be different for everyone. He also advocated the fact that social rights and benefits should be more accessible and available to older persons as the number of older persons continues to increase. The inclusion of older persons will be incorporated in the post-2015 agenda of the UN.

Daniela Bas, the Director of the Division for Social Policy and Development (DSPD), relayed a message from Ban Ki-Moon, the highly regarded Secretary-General of the United Nations. Ms. Bas noted that as healthcare is constantly and exponentially improving, the human lifespan is increasing, and so naturally the number of older persons is also constantly increasing. In fact, Ms. Bas declared that by 2050, the number of older persons is expected to double to 2 billion. As the elderly continue to make up a larger and larger part of the population, it is counter-intuitive to exclude them and their interests in any way; yet this discrimination continues to persist. With the post-2015 agenda, Ms. Bas remarked that the UN wishes to take into account the rights and securities of older persons and "leave no one behind."

The original keynote speaker Amina Mohammed was unable to reach the conference, so Paul Ladd, the head of the UNDP's organization team for the post-2015 development agenda, spoke in her stead. Addressing the subject "Older Persons and the Post-2015 Agenda," he noted that the post-2015 agenda would be age-blind. He also promoted "A Million Voices: The World We Want" that was published and that surveyed voices around the world on the topics people felt were important to address. In this, the top 7 priorities for all, including older persons, were about the

same: education, healthcare, that the government needed to be more caring and inclusive, the job sector, food, water and sanitation, and protection from crime and violence. He also noted several things to benefit older persons, such as green spaces and transportation systems. Overall, Mr. Ladd promoted the universality of the post-2015 agenda, and that all people want to and should be part of its creation and implementation.

After a short break, Sering Falu Njie introduced and began moderating the interactive panel session themed "Breaking Barriers: Sharing Successful Innovative Approaches to Ageing." As well as introducing the panelists, he introduced the Millennium campaign as well as the "A Million Voices: The World We Want" website containing all things happening related to the post-2015 agenda.

The first panelist was Marta Benavides, a human rights advocate for the Alliance for Sustainability for Sustainable Peace, who provided her own words as well as translating those of Cesar Cartagena, the Executive Director of the 'Asociacion Nueva Vida Pro-Ninez y Juventud.' She emphasized the importance of creating the world that is "needed" and not necessarily the one that is wanted. Ms. Benavides also stressed that civil society should direct government to carry out what is needed for society, and it is important to work together for the "manifestation of peace."

After Ms. Benavides' message, she translated for Cesar Cartagena, who spoke about both of their presences at the UN, and how they represent the intergenerational aspect of ageing. He acknowledged the existing mentality, that when youth are old enough, older persons should move out of the way and hand everything over to younger persons. He stressed the fact that the post-2015 agenda was created for those who suffer exclusion. It is important to educate people and bring diversity of all types, including age, to the table, and make the agenda transparent so as not to exclude older persons.

After Mr. Cartagena's speech, Mr. Njie remarked once again that Ms. Benavides and Mr. Cartagena so relevantly demonstrated an "intergenerational alliance" as they presented together.

Vladimir Cuk, the Executive Director of the International Disability Alliance, spoke next on the "Intersection of Ageing and Disabilities." He noted that older persons are more susceptible to disabilities, so the voices of people with disabilities should also be heard, because older persons and the disabled "naturally" support each other's goals.

The next presenter was Akiko Ito, the Chief of the Secretariat for the Convention on the Rights of Persons with Disabilities/DSPD/DESA at the United Nations. She addressed "Leading the Way – Older Persons with Disabilities"--continuing the conversation that Mr. Cuk began. She offered inspiring examples of older persons who are in art, politics, and other fields, highlighting that disabilities are a "cross-cutting issue" with ageing and that the relation stems from the belief that everyone should be valued regardless of age, disability, or anything else.

David Ryan came from Intel to speak about the innovative and technological future for older persons. He noted that older persons should not be stereotyped as people who cannot do much, but rather should be seen as still fully active, and socially connected--those who *can* do rather than *cannot*. He introduced the RealPad, an AARP tablet that is an accessible, in-hand technology for older persons that can be easily used in the home. Mr. Ryan also remarked that most older persons will suffer a disease of the nervous system sometime in their lives, and since physicians can usually tend to patients no more than once a week, he initiated the idea that technology should exist to constantly track health. To wrap-up, he summarized that care should be everywhere for older persons to access, so that seniors can live an "independent life."

The last panelist, Stephen Johnston, continued Mr. Ryan's conversation about ageing and technology. He provided the interesting fact that there are around 4 billion toothbrushes in the world, but around 5 billion electronic devices, which shows that the world is moving towards "super-connectivity." Mr. Johnston introduced Telehealth, a technology that uses facial expressions to interact with older persons, and advocated for the use of virtual reality to produce joy, as well as the social interaction of older persons in senior housing communities or even with robots that are used as company.

Following the panel, an interactive question and answer session was moderated by Mr. Njie. The panelists answered questions from the audience, remarking on the disparities in technology access and communication around the world; the importance of a global network; discrimination that occurs in the senior community among the disabled, LGBT community, and those suffering from HIV/AIDS; as well as partnership and the inclusion of all people and generations.

Last but not least, Mateo Estrémé, the Chair of the Open-Ended Working Group on Ageing, provided a 'status report.' He noted some conflict in that some countries believe the situation is well as it is, while others see the need to improve. Mr. Estrémé said that now that the issue of the exclusion of older people is being addressed in the post-2015 agenda, the UN will "continue to be engaged" until the problem is resolved.

Katherine Kline, the Chair of IDOP 2014, made closing remarks, to thank the panelists, and encourage countries present for IDOP to help this issue gain more visibility. Details appear at http://www.un.org/en/events/olderpersonsday/

Note: *Priyanka Srinivasan is a student at Fordham University studying Psychology, with interests in public health and gender studies.*

Examining mental health effects of the Ebola crisis in West Africa

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Overview

In 2014, the Ebola virus disease erupted, causing worldwide illness, mortality, and fear of a potentially fast-spreading pandemic. The virus spreads through human-to-human transmission via direct contact (through broken skin or mucous membranes) with contaminated areas. The time from infection to the onset of symptoms (the incubation period) is two to 21 days, with symptoms becoming increasingly worse with time. The fatality rate averages 50%, while past outbreaks have shown fatality rates between 25-90%. The current Ebola outbreak occurred in West Africa in March 2014 and has been the largest and most complex outbreak since the virus was first discovered in 1976. The most severely impacted countries are Guinea, Sierra Leone, and Liberia; and very weak health care systems and the lack of resources have made the outbreak most challenging (WHO, 2014). While fear has been in the forefront of what the WHO declares is a Public Health Emergency of International Concern, what have been the primary mental health and psychological impacts and how are they culturally responded to?

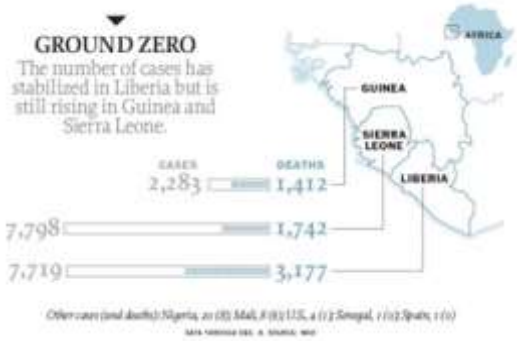

Figure 1.Statistics as of December, 2014. TIME, 2014. Source: WHO

Impact on individuals and communities

The impact of the outbreak has created devastating effects on systemic levels, which is of particular consideration, as community plays a strong role in life in these Western African areas. In affected communities, in order to prevent Ebola from spreading, individuals who may be infected are placed into quarantine for 21 days. As family and community systems in West Africa serve as important practical, social and emotional supports, such an isolation period has serious consequences. Separation from quarantine can often lead to sadness and feelings of hopelessness. Isolated individuals may inherit feelings of guilt and shame if they feel they could endanger family members or are unable to work to support them (IFRC, 2014). The actual quarantine conditions have also produced severe psychological stress for patients, including feelings of humiliation and shame (Persaud & Morris, 2014). A study in 2004 of SARS quarantines showed that the psychological distress of quarantine includes symptoms of PTSD and depression (Hawryuck, 2004). Furthermore, patients might lose their jobs and livelihood. While sick and isolated, patients lose the hope of recovery.

Additionally, post quarantine, integration back into the community often invoke challenges. Members of the community may shun not only the victim, but also the victim's family, by acts such as refusing to let individuals into markets. Because of this harsh response from the community, individuals who are infected may try to hide their symptoms rather than seeking medical attention. Those affected by other medical concerns, such as cholera and malaria, may also hesitate to receive medical attention, as their symptoms are similar to those of Ebola and they fear being ostracized by the community (IFRC, 2014). Stigmatization from community also presents a harsh circumstance, as Sierra Leone, Guinea, and Liberia are all countries that have experienced violence, displacement, and country conflict. Therefore, while recovery and healing from psychological symptoms related to violence and displacement may still be present for some, rejection from society can result in a drawback and uncover distress.

A study by Omidian, Tehoungue, and Monger (2014) on psychosocial support in Liberia following the Ebola outbreak found that the greatest stress and emotional pain revolved around death and burials. Because communities could not carry out traditions for loss and burials, a large portion of their regular emotional healing was lost. Denial, which serves as a fear response, was also found commonly, in that some people did not believe the virus existed. This was also supported by the fact that the Liberian government initially denied the issue of Ebola when it first evolved (Omidian, Tehoungue & Monger, 2014).

Hopelessness is found significantly at community levels. As described by Chernor Bah (2014), a former Sierra Leone refugee who returned to the Pork Loko recently, 500,000 civilians in the district had been sealed off from the world and stigmatized, as if criminals, with little or no help. Many other districts similarly have been held under quarantine with approximately a third of the nation unable to move freely. People exhibit fear, suspicion, and desperation in a nation that has already experienced civil war and displacement. With lockdowns, there is a parallel that people have also shut down [emotionally].

For children, many have lost one or both parents to Ebola and have been subjected to seeing family members taken away "by people effectively in astronaut suits looking like crop sprayers. And the affect of this is deeply distressing for children. Children who have been exposed to the virus

are facing deep stigma and nobody wants to take them on because there is this terribly psychosis of fear around the Ebola virus" (Schlein, 2014). Another major result of the crisis has been the closing down of schools to lessen the chances of contact; however, it is questionable whether children are in fact better off at home, where there is very little food, almost no mental stimulation, and decreased safety. While most humanitarian crises keep children in schools, where they can receive care from adults, have some protection against outside turmoil, and build resilience, this strategy of closing schools has presented a hindrance to recovery. More children will be subject to illiteracy, which is already high in some areas, which raises the question: How can public health messages on safety against Ebola be beneficial if they cannot be read? The government has made efforts to broadcast lesson plans over radio. However, the programs do not distinguish different grade levels, are unexciting, and the poorest families do not own radios (Schlein, 2014).

Widespread reports have shown girls have become victims of rape, as they are cooped up in homes rather than school . With a lack of sufficient health care workers in these communities, girls and women who are subjected to sexual violence cannot reach medical treatment. In addition, females have higher chances of contracting the virus, as they are likely to be pressed into taking care of sick family members with Ebola. It is also noticed that nurses and those involved in burial processes are mainly female (IASC, 2014), which has the potential to increase psychosocial distress, as does having constant, direct contact with patients and deceased victims.

Mental health and psychosocial response

Local health care systems in West Africa have been ill-equipped to manage such an outbreak. While international NGOs have sent humanitarian response teams to help manage the crisis, challenges are presented with cultural considerations. Psychological First Aid (PFA) has been implemented in communities hit by the Ebola crisis. "PFA describes a humane, supportive response to someone who is suffering and may need support" (World Health Organization, CBM, World Vision International & UNICEF, 2014). It involves providing non-intrusive care and support, evaluating needs, assisting people to access basic needs such as food and water, listening, comforting and encouraging a sense of calm, helping connect the community to information, services, and social support, and protecting the community against further harm. PFA can be beneficial to anyone impacted by the crisis, such as Ebola victims, health care providers, community members, and people fearing they have Ebola even if told they do not. PFA is based on a pyramid of intervention, in which a small number of people (about 7-10%) fall into the category of needing specialized mental health services, as many are able to cope (World Health Organization, CBM, World Vision International & UNICEF, 2014). The purpose of PFA is to facilitate resilience through a wellness approach without relying on specialized care (Omidian, Tehoungue, & Monger, 2014); as such, non-professionals can implement the services.

A challenge for implementing PFA in areas of West Africa has been the cultural factors for which these services

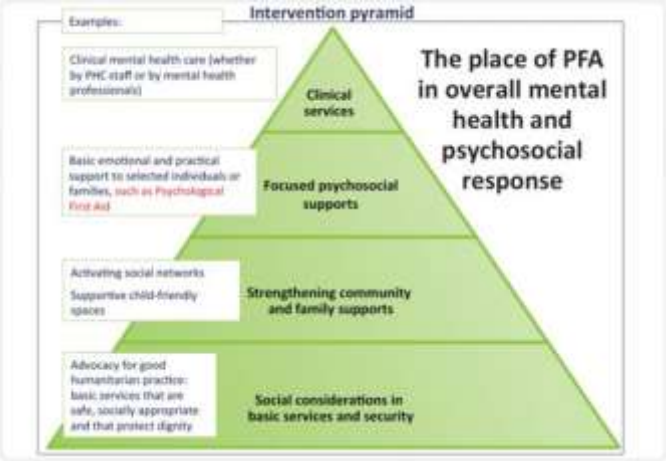

Figure 2. World Health Organization, CBM, World Vision International & UNICEF, 2014

need to be adapted. Distributing information has been particularly vital, as many rumors, misconceptions, and misinformation about Ebola and how it's prevented have spread in communities. Common rumors and beliefs include: Ebola is caused by witchcraft or a snake biting those for revenge, international NGO workers have brought the disease to communities as a way of spraying, white men have brought the disease to get money from institutions or for the purpose of collecting organs for science, and the dead victims of Ebola are beheaded, which is why relatives cannot see the bodies (IFRC, 2014). Active agencies have trained volunteers to provide information and sensitization campaigns, identify and track suspected cases, disinfect homes of patients, and raise awareness on how to protect against infection. However, communities have been hesitant to listen to awareness campaigns, which has caused challenges for ensuring they receive accurate information. In addition, communication barriers, illiteracy, and those living in remote areas may be seen as additional difficulties in addressing public health education (IFRC, 2014).

On an individual level, psychosocial support programs that include psychological counseling have been assisting recovered patients in regaining their lives. The waiting period for test results can bring on psychological stress. To cope during this waiting period, individuals are encouraged to set goals, keep active, look for humor, exercise, maintain hope by believing in something meaningful (such as family, God, or an ideal), and to utilize stress management techniques (IFRC, 2014). While a number of resources are available for managing psychosocial support in humanitarian crises, adaptation to cultural considerations is essential, and the Ebola crisis presents this clearly.

For women and girls, it is suggested that community groups provide meaningful support to survivors of sexual violence and emerging issues. Women may also benefit from

the creation of new economic opportunities, which can empower and strengthen their mental wellness (IRC, 2014). The Inter-Agency Standing Committee (2014) recommends that social mobilization and community engagement efforts be developed by women and young females, and that women are equally represented in recovery and coordination activities (IASC, 2014). These types of actions could provide a source of empowerment and resilience for females who are especially vulnerable in this crisis.

Mental health considerations for responders and health care workers

TIME honored Ebola fighters as "person of the year" (2014), recognizing the courageous efforts of local and international doctors, nurses, health care workers, ambulance drivers, and volunteers, who decided to attend to this dangerous work. In addition to the threat to their own health and of contracting the highly contagious disease, which many did, these individuals also faced resistance, and at times, hostile reactions from communities who were skeptical about Ebola. They also witnessed constant deaths of patients, especially those on burial teams, while struggling to maintain hope about the epidemic.

As described by psychologist Dr. Theresa Jones, who went to Liberia to help, the physical challenges of this crisis held distress for health care workers. At one point, a health care facility in Liberia had to turn people away, as the Ebola center simply did not have enough space; "to have to turn people, who are often unwell and desperate, away from the treatment center is terrible" (VICE). Psychosocial groups and workshops on well-being are particularly important for health care workers, especially since many have been evicted from their homes and rejected by their communities as a result of working with the Ebola crisis. Jones (2014) states that for medics, small acts of kindness can by very meaningful in a situation that seems hopeless. "Shaking hands is of huge importance in Liberia. Friendships are formed between the doctors and patients, and when a patient whom they got on with particularly well is discharged, you see the medical staff running over to shake their hand. It really creates a wave of positive feelings when you see this" (Jones & Nianias, 2014).

International volunteers and responders also face fear and stigma after returning home from missions. As seen in events across the U.S., the widespread panic of communities has taken a harsh toll on individuals completely removed from the Ebola situation but perceived to be threats. Ebola has certainly shaken up the world. While mental health and psychosocial responses are continuing to address patients, communities, and health care workers, hope remains one of the strongest facets of recovery from this crisis.

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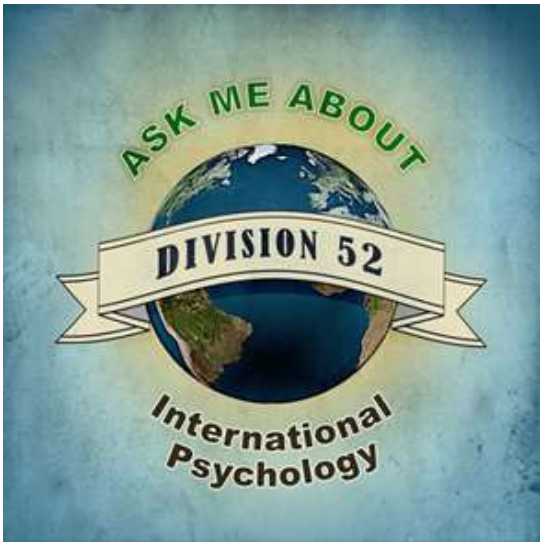

Internationalizing Psychology: The Importance of Student Research

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"To internationalize the teaching of psychology, how can we involve more students in cross-cultural research?" This question was the focus of a forum offered at the 26th Greater New York Conference on Behavioral Research on November 9, 2014.

This forum was chaired by Professor **Richard Velayo** (rvelayo@pace.edu), who is the Director of the Masters Psychology Programs at Pace University, his graduate assistant **Sarika Persaud** (ap75294n@pace.edu), and five members of Dr. Velayo's student research team called the IToP (Internationalizing Teaching of Psychology) team, with diverse messages.

The three major goals of the IToP team are to (a) identify effective pedagogical strategies to internationalize psychology courses, (b) develop assessment tools for an internationalized psychology course, and (c) apply Internet-based technologies (IBTs) as teaching and research tools to help infuse international content. Dr. Velayo noted, currently the internationalization strategies, and initiatives are mainly coming from major international organizations, but it is also important to involve students in this work. In Dr.Velayo's mentor laboratory, student researchers came up with topics of their own interest, and proposed research project carefully mentored by the professor.

Lucio Forti (lf72881n@pace.edu) presented his research proposal on *"Internet-Based Technologies in an Internationalized Classroom."*He explored the usage of technology to infuse international content, the types of IBT strategies that instructors used to incorporate international perspectives, and the challenges and benefits associated with these strategies. Some possible tools in an instructor's digital toolbox are: Face-to-Face, Social Media, Learning Management Systems (BB, WebCT; Moodle), Online Collaboration (wiki-based), and Digital Narratives (Prezi, YouTube, Blogs).

Lauren Lambert (ll97492n@pace.edu) researched *"Social Media and Culture: Factors that Influence Classroom Learning*." She sought to figure out how technology negatively and positively impacted learning in the classroom, mainly looking into the possible usage of a Facebook group to enhance learning in the classroom for a semester.

Yuting Dai (yd65442n@pace.edu) decided to look into the "*Current Status of Psychology Programs in China*." As an international student from China, she would like to learn about what advantages and disadvantages the psychology curriculum in her home country have in meeting the public needs of mental health service.

Matilda Koroma (mk53787n@pace.edu) talked about "*Culturally-sensitive Teaching Strategies for Third Culture Adolescents* (TCAs)". She explained to the audience, the Third Culture Adolescents are those who were raised in a culture outside of their parents' culture for a significant part of their development years, so that basically there 1st culture is where their parents are from, their 2nd culture is the current one in which they were raised up, and the 3rd culture would be the mixture of the first two. Matilda Koroma was specifically interested in the ways in which we could develop culturally-sensitive teaching strategies which catered to the unique cognitive and developmental needs of TCAs.

Michael Trush's proposed research examines the "*Interaction between Learning Strategy, Modality Presentation, and Cultural Background on Memory*." His hypothesis was that cultural background would significantly moderate learning as a function of modality presentation and type of learning strategy.

Students' projects provoked a lively audience discussion--particularly on the pros and cons of using IBT in teaching, including social media platforms. Though face-to-face communication is still the most effective type of communication, the development of the IBT has enabled instructors and students to do many activities distantly, along with internationalizing and expending the "classroom" experience.

In regards to the development of psychology in China, it was pointed out that many psychological issues were neglected in China in earlier days, and even now psychology has not drawn a proper attention to itself. Many psychological issues carry a lot of stigma in the society and are not spoken of. Moreover, the number of universities offering psychology programs is quite limited, and if they do, they offer only 2 types of psychology programs: general psychology and applied psychology. Even though the situation is gradually changing the progress is slower than expected.

Due to the aforementioned reasons, there exists a huge gap in terms of the small ratio of trained psychologists to the vast population of China. Thus, there is a greater need for internationalizing teaching of psychology, and making it

more accessible for different people all around the world.

Furthermore, the discussion of incorporating the perspectives of Third Culture Adolescents raised the question about the sense of "being everywhere and nowhere," causing possible issues with personal identity, which should be taken into consideration when developing culturally-sensitive teaching strategies.

Dr. Velayo summarized the value of involving students in the process of internationalizing the teaching of psychology. Despite all the differences between people from various cultures, we should not overlook the commonalities. There is way more out there that makes us similar to each other, than what makes us different. Those commonalities

Speakers (l to r): Matilda Koroma, Lauren Lambert, Yuting Dai, Richard Velayo, Ph.D., Sarika Persaud, and Lucio Forti.

might also help us to achieve the goal of internationalizing psychology teaching and developing corresponding strategies to do so.

For more information about this presentation and of the IToP team, please contact Dr. Richard Velayo at rvelayo@pace.edu.

Note: Originally from Russia, Yulia Kamenskova is now a student in the M.A. in Psychology Program of Dyson College, Pace University, yulia.kamenskova@gmail.com.

How Many Psychologists Are There in the World?

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"How many psychologists are in the world today?" The answer to this simple question is as elusive as the question itself is common. This brief report reviews: (a) the problems faced when attempting to answer this question, (b) reasons why this answer is so elusive, and (c) sources of information on cross-national psychology today.

In the United States, there is a plethora of data by a variety of sources tracking and updating the number of psychologists, psychology undergraduate and graduate students, professors, and members of professional psychological associations in the country. This information can be found in the US labor statistics data (Bureau of Labor Statistics, 2014), university data on the number of students in their psychology programs, on the American Psychological Association (2014) website, and elsewhere. (See Figure 1). There might be some variations in these numbers, due to the varying criteria on who is considered a psychologist, and differences in each state on educational and professional requirements for state licensing exams.

However, do these statistics exist for countries outside of the United States? Are there any data sets showing the number of psychologists or psychology students in Europe, South America, Africa, the Middle East, and Asia? Although this question appears to be quite straightforward, the answer to this question is actually quite elusive (Bullock, 2012a). Even if such a dataset did exist, it might not be able to

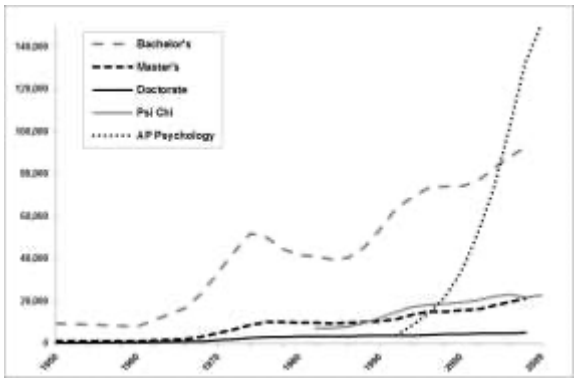

Figure 1. Trends in U.S. psychology bachelor's, master's, and doctorates awarded, new Psi Chi memberships, and high school AP psychology examinations, 1950-2009. (Adapted from Takooshian & Landi, 2011).

provide much detail about the educational qualifications required to be considered a psychologist in these countries, and what are the requirements to join a country's psychological association. In addition, it is likely the statistics might under- or over-represent the number of psychologists. Although there are psychologists who are involved in conducting research, teaching, and practicing worldwide, the definition of a psychologist may vary in different countries. These definitions may not be consistent with the United States's definition of a psychologist or psychology student, thus making comparisons between countries incredibly difficult or impossible (Bullock, 2012b, 2013).

Though it was difficult to find definitive data on the number of psychologists in the world, there exist some valuable resources that can provide information about the criteria for being considered a psychologist in a country or region.

Who is a Psychologist?

The definition of a psychologist varies from country to country. Developing nations or countries where psychology is a fairly new field may be at different stages of professionalization. Although these countries may have data on the number of psychologists in their respective countries, this number may include people who are psychiatrists or other mental health practitioners. Countries may not distinguish between these varying professions, thus inflating the number of psychologists recorded. International bachelor's, master's, and doctoral psychology programs may offer different courses and trainings than US programs, again making it difficult to compare these numbers. In addition, countries and universities may offer certificates or short-term training programs in psychology and may count these individuals as students or psychologists. Some individuals may have the title of psychologist at their place of employment, without obtaining an education in psychology or providing psychological services. In many countries, an individual with a bachelor's degree in psychology may be considered a psychologist.

For example, in some countries, such as Egypt, individuals may be providing psychological services without much training or education, and traditional healers, social workers, or sociologists might be administering these services (Ahmed, 2004). Moreover, in the Middle East some individuals might be working as school psychologists with a bachelor's degree in counseling and education and providing counseling services, or education and tutorial services. Although they may have the title of school psychologist at their place of employment and may be counted as a psychologist in the country or regional dataset, they may not be providing any psychological services or working in the capacity of a psychologist.

Some inconsistencies also include conflicting information from different data sets. For example, the maps below created with data on psychologists and European Federation of Psychologists' Associations (EFPA) members from Lunt, Pieró, Poortinga, and Roe (2015) show that Turkey has 1,300 psychologists; however Jimerson, Stewart, Skokut, Cardenas, and Malone's (2009) article on school psychology indicates that there are 11,327 school psychologists in Turkey.

Map 1
Estimated Number of Psychologists in Europe per Country

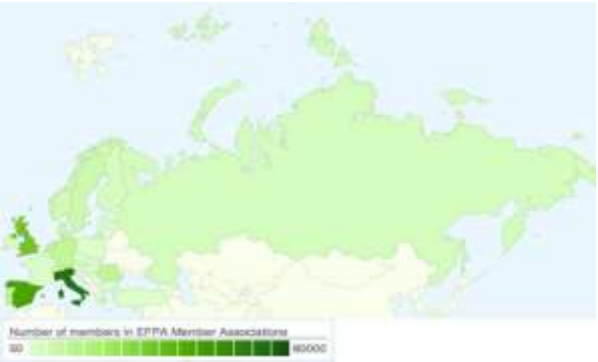

Map 2
Number of Members in EFPA Member Associations per Country

Useful Resources

Even though data may not be consistent or inflated, there are some useful resources available providing estimates on the number of psychologists worldwide. These resources include:

- **The World Heath Organization (WHO) Mental Health Atlas**: In 2001, 2005, and 2011, the WHO collected information on mental health resources in 184 countries, covering 98 percent of the world's population. Each country profile has information on the number of mental health facilities, psychologists, psychiatrists, social workers, and people treated in mental health facilities.
- http://www.who.int/mental_health/evidence/atlasmnh/en

- **Professional Psychological Associations**: Some professional psychological associations keep a record of their members and psychologists in their country or region.
- http://www.socialpsychology.org/inter.htm
- http://www.efpa.eu
- http://www.efpsa.org
- http://www.iupsys.net/about/members/national-members/index.html

It is important to realize that national membership organizations may include or represent quite varied proportions of the psychologists practicing or being active in the respective countries. Two highly divergent examples found on the website of the International Union of Psychological Science (IUPsyS) may illustrate this point. On one hand, The British Psychological Society (BPS) is said to represent "over 42,000 psychologists, and over 7,300 students and affiliates" (IUPsyS, 2013a). Clearly, the number of 42,000 suggests that BPS does, in fact, represent most active psychologists in the United Kingdom. For Argentina, however, the website lists as the "Adhering Member" Association the Argentinian Association of Behavioral Science/Asociación Argentina de Ciencias del Comportamiento (AACC), with 213 members (IUPsyS, 2013b). Yet, there are probably more than 40,000 psychologists active in Argentina, with the large majority of them endorsing a variety of psychoanalytic traditions (e.g., those founded respectively by Freud and Lacan). One wonders in this context how a small, behaviorally oriented organization can be said to represent Argentinian psychology in IUPsyS.

Recommendations and Further Research

Additional research needs to be conducted with universities, professional psychological associations, and country labor departments to obtain reliable data and cross-reference information on the number of psychologists worldwide. If further research is to be done on this topic, researchers must be very clear about the data they want to collect and create consistent guidelines as to who is counted or considered a psychologist. In addition, researchers conducting this work may want to consider the following questions when developing their research and data collection strategies and measurement tools:

- What does psychology mean in a cross-cultural context?
- Should individuals who provide clinical services and work as a psychologist, but do not have the training or educational background, not be considered a psychologist?
- If a local community recognizes an individual as a psychologist, should the international community also recognize them as a psychologist?

Publications such as the *Handbook of International Psychology* (Stevens & Wedding, 2004), *Psychology & Developing Societies*, *International Perspectives in Psychology: Research, Practice, Consultation*, and *International Journal of Psychology*, can provide useful information, data, and background on the aforementioned questions.

Another way to help gain more consistent data from countries is to possibly work with them in standardizing and professionalizing the field in their country, especially if psychology is a fairly new field, while also recognizing the local context and meaning of psychology in these countries. This work could be done with universities with a focus on curriculum development, conducting needs assessments, and starting local Psi Chi chapters.

Conclusion

During the last few decades, the discipline of psychology has grown at a rapid pace in many parts of the world. Even though in the immediate post-World War II era psychology had its center in the United States, by the end of the 20th century psychology had become a very popular discipline in Europe, Latin America, Australia, and increasingly also in some parts of Asia and the Middle East. Today, colleges and universities around the world offer more than 4,000 psychology programs.

Despite this, we do not have a clear picture of how many psychologists there are. Recent estimates by Merry Bullock (personal communication, October 3, 2014) and Stevens and Gielen (2007) indicate that the worldwide number of psychologists has probably surpassed one million. But for reasons delineated in this article, these estimates are no more than crude approximations depending not only on variable and at times missing local estimates, but also on varying definitions of who should or could be called a "psychologist." We hope that as international psychology organizations gain in scope, vitality, and rigor, a more precise and inclusive picture of the worldwide status of psychology and psychologists will emerge.

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The United Nations Association: Helping students at the UN

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How can students get more involved in international activities at the United Nations? This can be quite a challenge. Students can greatly benefit from UN activities (Martinez, 2014), but often do not know where to start (Roberts, 2014), and the number of seats are typically limited for U.N. internships and other programs (Takooshian & Campano, 2008).

The brief report reviews a valuable but little-known resource for students: the network of United Nations Associations (UNAs) that support UN activities--their origins, purpose, and how students especially can benefit from joining the UNA.

The United Nations Association of the United States is a program of the United Nations Foundation. UNA works unflaggingly to support the mission of the United Nations by connecting and keeping Americans informed of the work of the United Nations, and advocating for strong US leadership within the UN. The UNA-USA grew from the American Association of the United Nations, which originated from the League of Nations Association in 1943. This organization was established by a group of prominent citizens, which included the first executive director, Clark M. Eichelberger, who sought to promote acceptance of the Dumbarton Oaks proposals in the late years of the World War II. One of the first Association's early actions was a national tour by a number of US representatives to spread the word and gain support for American adherence to the Dumbarton proposals, which would later lead to the creation of the UN.

For 70 years, UNA-USA has worked to accomplish its mission through its national network of UNA chapters, youth engagement, advocacy efforts, education programs, and public events. The New York chapter (UNA-NY) - one of the many nation-wide UNA-USA Chapters - similarly seeks to educate and galvanize New Yorkers to support the principles and pivotal work of the United Nations. Though becoming involved United Nations activities can be quite a challenge, the UNA is one of the best ways to do this.

Joining the UNA-USA is very easy. If you are a student, this is free. If you feel passionate about human rights, international affairs, complex social and political issues, and are interested in informing and working together with your community to bettering these issues, this is the perfect way of getting involved. As an active member of the UNA-USA, you commit to stimulate international cooperation and community education on international affairs. UNA-USA members and their chapters work with their local communities and elected officials to support the UN. For members, there are monthly events that you can attend at no cost. For example, the New York Chapter offers a stimulating selection of events and activities suited to the interest range of its lively constituency. Some of these events include:

The Ambassador Series. A favorite- the UNA-NY ambassador series presents well-attended programs in partnership with the Columbia Club of New York. Several ambassadors are hosted every years, and are invited to discuss current events and relevant issues from their past experiences and the background of their respective regions. There is a reception where you get the opportunity to network with all the invitees and in turn let them know about your concerns, work and interests.

Screening the issues. The UNA-NY provides a series of films and discussion events that are designed to promote the work of the United Nations in an engaging way. Featured are recently produced films which address some

of the many crucial issues which concern the United Nations, made by enthusiastic, passionate filmmakers who are invited to each screening to involve and motivate an ethically aware New York audience in discussing the issues illustrated in the films.

BookTalkUNA. One of the newest, this bright new compliment to the screening presentations, features books and their authors, whose work is in-depth, politically and ethically engaged, and often quite controversial. These writers and thinkers illuminate many complex social and political realities that challenge assumptions, while offering inspiration, ideas and understanding. This can create possibilities for a better world. These book talks are quite useful since they complement the far-reaching work of the United Nations and are suitable for those who enjoy reading.

One of the best things about being a member and attending these events is that students are reminded of the ability and power that they have to seek change and better the world. Students also have the ability to advocate and inform others of the issues they learn about. By becoming a UNA member, students are able to join a chapter or create their own chapter. Once a student is a chapter leader, s/he can advocate for a strong United Nations in their local community or school.

To become a member, you can join here. Membership in the United Nations Association of the USA is open to any U.S. citizen or resident who is committed to the purposes of the United Nations Association of the USA. If you are a student 25 years or younger you can join the USA-UNA for FREE. You can also gift someone interested in being in UNA -USA.

Since only a tiny fraction of U.S. students are aware of the UNA, the UNA is almost a "secret"--but such an invaluable secret for those who want to be involved in the UN. Every student should join, if interested in the United Nations and the pressing issues that face us every day in our troubled world. Not only do you learn, become inspired and network, but you also are a step closer of making a change.

Some useful links.
UN Associations: http://www.unausa.org/
The UN mission: www.un.org/en/documents/charter/
Origins in 1945: www.un.org/en/aboutun/history/dumbarton_yalta.shtml
UNA application: http://www.unausa.org/membership

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Caribbean Regional Conference of Psychology Meets in Suriname

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Did you know that there are 26,000 psychologists in the Caribbean and that half of those are in Cuba? Did you know that Barbados has the highest rate of publications per capita among psychologists in the Caribbean? These are just a few of the facts that were revealed in a recent conference.

This November psychologists from around the Caribbean and the world met in Paramaribo, Suriname for the second Caribbean Regional Conference of Psychology (CRCP2014) under the theme of "Caribbean Psychology: Unmasking the Past and Claiming Our Future."

SVPO members: Fourth from right, LOC Chair Maja Heijmans-Goedschalk

The event was sponsored by the Caribbean Alliance of National Psychological Associations (CANPA) and hosted by the Suriname Association of Psychologists and Special Educators (SVPO). CRCP2014 follows the landmark first Caribbean Regional Conference of Psychology held in the Bahamas in 2011, where the Nassau declaration was signed by many Caribbean countries to agree in principle to establish a Caribbean Psychology Organization to promote the development of psychology as a science and practice. Subsequently, CANPA was launched in Grenada on June 5, 2013.

Ava Thompson, CANPA President Pro Tem, and Guerda Nicolas, CANPA Vice-President Pro Tem, seemed to be everywhere at the conference, as did CRCP2014 Conference co-chairs Donna-Maria Maynard and Keith Lequay, as well as the Surinamese local organizing chair Maja Heijmans-Goedschalk. They are all to be commended for working diligently and going above and beyond the call of duty to assemble this truly extraordinary event.

CRCP2014 Co-Chairs Donna-Maria Maynard and Keith Lequay

CANPA members began their CRCP2014 week with a one-day capacity building pre-conference workshop, which was followed by a community symposium on non-communicable diseases for Suriname's health, social services and education providers. CRCP2014 participants had a number of half-day workshops on Behavior Change Interventions, Education and Training, and Mastering the Research and Publication Processes, held at the Anton de Kom University and which were well attended.

The Surinamese Minister of Health, Dr. M. Blokland, opened the conference; and among the guests in attendance were the Chair of the National Assembly, Dr. J. Simons, and the heads of the International Union of Psychological Sciences, the European Federation of Psychologists' Associations, and the International Association of Applied Psychology, the past-president of the Association of Black Psychologists, and the president-elect of the American Psychological Association.

Several major awards were presented at CRCP 2014. The Pioneer awards--given to psychologists in the host country who have been fundamental and formidable in developing, promoting, and sustaining psychology in the country--were given to Lillian Ferrier, Tobi Graafsma, and Hank E. Essed. Educated at the University of Leiden in the Netherlands, Ferrier has 37 years of professional experience and is the current chair of the presidential taskforce for young children and adolescents. Her work in Suriname has focused on many topics, including early child development, malnutrition, sexual abuse, domestic violence, HIV policy development, and domestic violence. Educated at Groningen University and the Psychoanalytic Institute in Amsterdam in the Netherlands, Graafsma has 43 years of professional experience and is currently Bascule Chair at the Institute for Graduate Studies and Research at Anton de Kom University in Suriname. He has played a leading role in research in Suriname on suicide prevention and on prevention of violence against children. Educated at the University of Utrecht in the Netherlands, Essed has 39 years of professional experience and is currently a psychologist working in the Suriname prison system. Essed played a central role in creating the SVPO, and has also worked as a lecturer at the Anton de Kom University of Suriname and with the Roman Catholic Church in a program for people living in Suriname's interior regions. Kudos to all!

From left to right: Hank E. Essed, Lillian Ferrier, and Tobi Graafsma with their Pioneer awards.

Invited speakers included Yovanska Duarté-Vélez on suicidality among Latino/a adolescents from Puerto Rico to the mainland USA, Janel Gauthier (President of the International Association of Applied Psychology) on using the universal declaration of ethical principles to promote just and ethical policies in the Caribbean, Robert Roe (President of the European Federation of Psychologists' Associations) on diversity and collaboration in psychology, Danny Wedding (American University of Antigua) on movies and mental illness, and anthropologist Angela Roe (Curaçao), who presented her excellent debut film *Sombra di Koló* (Shadow of Color), which examined issues of race and color through interviews of 30 Curaçaoans of different ages, genders, and classes from five different neighborhoods.

Saths Cooper, President of IUPsyS, offered an inspiring plenary lecture entitled, "Critical Issues Psychologists Must Confront." Peter Weller (University of the West Indies) and Guillermo Bernal (University of Puerto Rico) offered an invaluable session on Caribbean Psychology Education and Training. Weller's presentation "Whither Caribbean Clinical Psychology?" helped situate the issue relative to the colonial heritage of the region and the post-colonial present and future. Bernal offered a thoughtful and data rich analysis of "Indigenization of Psychology in the Caribbean: Progress and Status in Scholarship, Research, and Education," with some helpful statistics on numbers of psychologists in the region, and the relevance of impact factors for Caribbean scholars. Omowale Amuleru-Marshall offered a powerful plenary on health psychology, demonstrating a point of view rooted in a psychology aimed to empower and to enhance well-being across the region. Other plenaries included Gloria Wekker on relations between Afro-Surinamese mothers and their children and Gail Ferguson (University of Illinois at Urbana Champaign) on "Remote Acculturation and the Birth of a New Bicultural Caribbean Youth Identity."

Saths Cooper Introduction

CRCP 2014 opened with keynote sessions by Barbados based attorney-at-law and political activist David Commissiong, a Pan-Africanist who covered the Reparations Movement, and Professor Marcia Sutherland, a Jamaican born psychologist at SUNY, Albany, USA, who spoke on a Pan-Caribbean Psychology as a tool for regional development.

A number of Division 52 members presented at CRCP 2014. Judith Gibbons and Merry Bullock presented on publication opportunities. Danny Wedding offered an excellent presentation on the portrayal of psychopathology in contemporary cinema. Grant Rich and his colleagues (Lynn McCutcheon, USA, Maria Wong, USA, Joan Black, Jamaica, Donna-Maria Maynard, Barbados and Rosemary Frey, New Zealand) presented their cross-national analysis of the relationship between celebrity attitudes and sensation seeking. Frank Worrell and his colleagues presented on school psychology in Trinidad and Tobago.

A sampling of other valuable presentations must include Olivia Edgecombe-Howell's comprehensive presentation on Fetal Alcohol Syndrome in small, vulnerable developing Caribbean countries. She is clearly a go to person on this critical issue. A Thursday afternoon session on youth and children offered a veritable plethora of insights, with presentations on mental health professionals' experiences counseling young sexual abuse survivors in the Cayman Islands, the high prevalence of child maltreatment in Suriname, and neuropsychological performance of former street children in Ecuador. There were also a number of interesting paper presentations, symposiums, roundtable discussions, and poster sessions.

Given that the conference was so stimulating, few had the time or inclination to experience Suriname more broadly while sessions were being offered. That said, some participants did have the opportunity before or after the conference to take a city tour or visit the vast interior of this nation, where they were treated to Suriname's many attractions, from food, dance, and music, to such wonders as the inner city of Paramaribo, a UNESCO World Heritage Site, Fort Zeelandia, the 19th century Roman Catholic St. Peter and Paul Cathedral, one of the largest wooden structures in the Americas, and a mosque right next to a synagogue, emblematic of the unity that comes from Suriname's diversity. Those unable to leave the conference were treated to a special evening cultural event, featuring impressive drumming and dancing from many of Suriname's cultural groups. Seventeen types of percussion instruments performed, with accompanying traditional dances. Suriname, a former Dutch colony, became independent in 1975. Located in South America, where it is bordered by French Guiana, Guyana, Brazil, and the Atlantic Ocean, its heritages, and CARICOM membership, situate it in many ways, in the Caribbean both historically and in terms of contemporary politics. While its official language remains Dutch, a number of other languages are spoken including Sranantongo creole, Hindi, and Javanese, and the population of just under 600,000 is richly diverse (East Indian, Maroon, Afro-Creole, Javanese, Amerindian, Chinese, Mixed).

Cultural Evening at CRCP

Currently, CANPA has 13 national members (the Bahamas, Barbados, Cuba, Haiti, Dominican Republic, Puerto Rico, U.S. Virgin Islands, Trinidad and Tobago, Jamaica, Guyana, Grenada, Suriname, and Martinique). One would not be surprised if the enthusiasm and expertise stimulated by the recent Suriname CRCP leads more member nations to join in time for the next Caribbean Regional Conference of Psychology – CRCP2016, which is scheduled for November 7 to 11, 2016 in Haiti.

The theme of CRCP 2014, Unmasking the Past and Claiming our Future, was consistently addressed throughout the conference. While many scholars have recognized that most of psychology is limited by its WEIRD emphasis, the organizers and presenters at CRCP moved well beyond that recognition. Speakers made strides towards identifying the nature of an emerging Caribbean psychology. In a workshop Ava Thompson outlined the process for indigenizing a curriculum. In a plenary session Guillermo Bernal provided a path for developing "a creole or autochthonous psychology through the process of indigenization in the Caribbean." Lillian Ferrier chaired a panel on the factors that make our children vulnerable. Posters presented by students and young scholars maintained the theme. Ayodele Harper of the University of the West Indies and co-authors described some uniquely Caribbean aspects of the grieving process.

Most notable about the CRCP 2014 conference were the warm and welcoming atmosphere, the enthusiasm of the attendees, stimulating discussions, and the positive contributions to knowledge. For those who missed this wonderful opportunity, you can view the program at http://canpanet.org/index.php/crcp2014-programme.

From left to right: Rita Dudley-Grant (USVI), Milagro Mendez (Puerto Rico), Omowale Amuleru-Marshall (Grenada), Guillermo Bernal (Puerto Rico), Deidre Blom, (Suriname) Ava Thompson (Bahamas) and Guerda Nicolas (Haiti)

Milgram Conference Convened in Russia

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Regina V. Ershova,
Moscow Regional State Institute (MGOSCI)

On December 9-11, 2014, the ancient city of Kolomna was the site for the international conference on "Obedience to Authority." The conference produced a 284 -page English-Russian volume, collecting 16 chapters by 25 Milgram scholars in four nations: Russia, USA, UK, France. More details on this conference appear at www.milgram.ru/en

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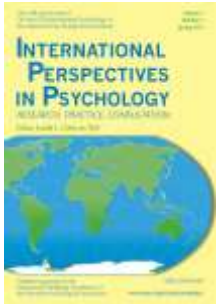

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AN INTERDISCIPLINARY ASSOCIATION

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PRESIDENT'S COLUMN

Tara Pir, Ph.D.

President, USA

As we approach the transitional bridge from one year to the next, there is a time for reflection on our experience and collective wisdom of insight. That process of reflection must certainly include celebrating our successes and accomplishments. One of those successes was the outstanding ICP conference that was held in Paris, in conjunction with the 28th International Congress of Applied Psychology. Our conference provided an opportunity to reach out to professionals from around the world to share knowledge, to collaborate, and promote our collective wisdom.

Throughout my presidency, I have presented initiatives and motions aimed at supporting and expanding our organization's ability to achieve its mission and goals, as well as its sustainability. Our gathering in Paris also provided the opportunity for our Board to consider and discuss a number of these.

One of these motions was my proposal to restructure our membership and provide one universal membership fee to encourage more individuals in our profession and allied professions to join ICP. At a time when many professionals are already members of one or more organizations, the proposed fee would make becoming an ICP member more accessible for a greater number of professionals globally.

Also, with the aim of expanding on the principle of inclusion by design, I proposed to have at least five different regional centers, one in each continent, and have each region promote our mission locally in their network and provide regional conferences in addition to our annual ICP

ICP 2015 ELECTIONS
CALL FOR NOMINATIONS
for
PRESIDENT ELECT, TREASURER and
TWO (2) DIRECTORS AT LARGE
N & E Committee:
Ludwig Lowenstein, Chair
Members: Naty Dayan, Dennis Trent, Chik Hiew, Anna Laura Comunian, Ann M. O'Roark

PAST PRESIDENT REPORT

Ludwig F. Lowenstein, Ph.D.
U.K.

SEASONAL GREETINGS

The report from the Past President is rather short as nothing much has occurred in ICP upon which to comment. There have been few nominations for office made to me over the past months but I am hoping that if there are more nominations you will contact me soon. I take this opportunity to call for nominations for future ICP Board Members.

(See the blue box above!)

[continued on next page]

PRESIDENT, from page 1

conference. However, our Board meeting would continue to be held in conjunction with APA's timeline to support Board Members' availability for participation at this time. This is aimed to decentralize and promote more local engagement and involvement with our fellow professionals around the world. As you can tell, all of these motions are aligned with ICP's mission "to foster international professional development, networking, communication, mentor, and friendship among psychologists and allied mental health professionals."

Although we have to do everything within the context of procedural, organizational process, I am inviting and encouraging all of you to provide your feedback to these motions that have been approved practically by everyone. I am confident that, as we continue to open the doors of inclusiveness and move forward with changes such as these, ICP's continued expansion and sustainability will be assured.

Wishing you a Happy New Year,
With warm regards,

Tara Pir, PhD

PAST PRESIDENT, from page 1

I had the opportunity of visiting New York in November and was meant to visit the United Nations where an arrangement had been made for Kathleen and I to attend. For various reasons this unfortunately did not take place and our ICP representatives were all busy with their various tasks. My apologies to my colleagues that we could not get together. I would very much like to continue with some involvement with the UN which I would term personally a "disunited nations" rather than a "united nations". I do not see any positive aspects on the horizon until great powers such as America, Russia and China begin to see things similarly and cooperate to keep peace in the world instead of taking sides.

We have recently seen a great deal of commotion regarding the torture of prisoners. I know psychologists on the whole are opposed to any form of torture or physical pressure whatsoever.

I myself feel very much like the CIA and also ex Vice President Chaney. When thousands of lives are at stake as was the case at 9/11 there may be, at times, a necessity for getting information using less ethical methods than anyone would like to impose. This is my private opinion. I still see the twin towers falling and 3,000 people dying needlessly and cruelly due to the fact that America was not alert enough at the time to obtain information which could have prevented such tragic events from occurring. I shall never forget the loss of life due to the events of 9/11 and the shock that reverberated around the world.

I have over the last couple of years been engaged in writing a number of articles including one on terrorism and how to deal with it as effectively as possible. I have noted in the research that there is no easy answer. The old saying that "you cannot make an omelette without breaking eggs" in my opinion, deals very much with how to deal with potential or real terrorists who have information which could be useful in saving thousands of live. I know for a fact that most psychologists are totally opposed to any form of pressure being imposed on prisoners, especially enhanced torture. We are a caring profession and this has resulted in us always using the soft option.

What is most tragic however, in recent days, is that now it is children who are being targeted which is of grave concern to all in the civilised world.

Unfortunately, in my view at least, and I am only one voice speaking, sometimes one has to be extremely hard on a few to save many, many lives. Failing to do so is a dereliction in the duty to save the most lives.

I realise by saying what I have said I am leaving myself open to considerable criticism from other members of my profession. The world is currently in such turmoil and suffering that we need to work hard as professionals to adjust this situation with good will, cooperation and working together for a better end.

As I come towards the end of my term as Past President I wish all ICP members the best of good fortune in the future, and may our tribe increase, especially with young psychologists joining us. We older psychologists will have to hold the fort until we have achieved that end.

It only remains for me to wish you all a very Merry Christmas and Happy New Year and Peace and Good Will to all men.

Your Past President,

Ludwig Lowenstein

NEXT IP DEADLINE is March 15, 2015. All submissions should be sent to Managing Editor Ann O'Roark, at annoroark@bellsouth.net by that date..

PRESIDENT ELECT REPORT

Janet Sigal, Ph.D
USA

December 22, 2014

As ICP President-Elect, and the Coordinating Chair, I am working with closely with the ICP Conference Co-Chairs, Ann Marie O'Roark and Florence Denmark to organize the International Council of Psychologists 73rd Annual Meeting on August 1, 2, and 3 in Toronto, Canada. The Theme of the Meeting will be: PSYCHOLOGICAL CONTRIBUTIONS TO SOLVING GLOBAL PROBLEMS IN THE 21st CENTURY.

We plan to organize the ICP conference prior to the APA Convention which begins on Thursday August 5, 2014. Other satellite meetings are being scheduled on August 4th and 5th.

At present, we are contacting hotels to secure a venue for our August meeting. Once the venue is secured, we will send out a CALL for submissions for the meeting. The CALL will be sent out in January. A Scientific Review Committee will be established to review the submissions. Students will also be encouraged to submit posters for the Meeting.

We are also in the process of establishing a local arrangements committee for the meeting.

At this time I wish all ICP members and their families a wonderful holiday and a Happy New Year. Thank you for your support for ICP.

Janet Sigal

DIRECTOR AT LARGE REPORT

Yoshiko Kato, Ph.D
JAPAN

Thank you ICP Inc. !

This summer I visited Graz University and Goethe University with my students. I organized this study tour to present our research on metabolic syndrome and life satisfaction in Japan and to encourage cross-cultural research collaboration on well-being. We presented our findings to Austrian and German professors and students and discussed cultural and global implications of this research. This international academic exchange was very fruitful and led to new insights and possibility for future collaboration.

Recently universities have the big responsibilities to foster globalization in Japan. The study tour is evaluated as a representative successful educational program in my department. I was able to organize this study tour based on ICP network especially with Dr. Roswith Roth in Graz and Dr. Diana Boer in Frankfurt. I appreciate ICP Inc. very much for enabling such international collaborations and exchanges. I hope we will have further fruitful relationship through ICP Inc. in the future.

Graz University, 2014

Goethe University, 2014

DIRECTOR AT LARGE REPORT

Richard Velayo, Ph.D.
USA

A "Mentored Research Team" on International Psychology:

Helping Internationalize the Student Learning Experience

Richard Velayo, Ph.D., Sarika Persaud, Lucio Forti,
Lauren Lambert, Yuting Dai
Matilda Koroma, and Michael Trush
Pace University, New York

At the New York City campus of Pace University, the Psychology Department prides itself with offering a course called "Mentored Lab class" in which students at the graduate and undergraduate levels are able to gain supervised research experience in psychology by becoming involved in faculty research work. Students have one-on-one mentored and individualized experience with faculty on active research projects, and will prepare students for future graduate work as well as their own independent study and research projects. Students also gain the opportunity to participate in weekly lab meetings and learn about broader theory and pragmatics of research through meetings with faculty members and other research assistants conducting research in psychology out of their primary area. *One such mentored lab course is through Dr. Richard Velayo's research group referred to as the Internationalizing the Teaching of Psychology (IToP) team.*

Speakers (l to r): Matilda Koroma, Lauren Lambert, Yuting Dai,

This brief paper describes a one-hour panel symposium on the current work of the IToP team which was presented at the 26th Greater New York Conference on Behavioral Research on November 9, 2014.

"To internationalize the teaching of psychology, how can we involve more students in cross-cultural or cross national research?" This question was the focus of this symposium, which was chaired by Professor ***Richard Velayo*** *(rvelayo@pace.edu) (Director of the Masters Psychology Programs at Pace University), with his graduate assistant* ***Sarika Persaud*** *(ap75294n@pace.edu) who is his graduate assistant and PsyD student in the School-Clinical Child Psychology Program). There were five members of Dr. Velayo's IToP team, each presenting their own proposed research projects as a function of their involvement in this mentored research group.*

The three major goals of the IToP team are to (a) identify effective pedagogical strategies to internationalize psychology courses, (b) develop assessment tools for an internationalized psychology course, and (c) apply Internet-based technologies (IBTs) as teaching and research tools to help infuse international content. As Dr. Velayo noted, currently the internationalization strategies and initiatives are mainly coming from major international organizations, but it is also important to involve students in this work. In this mentor lab team, student researchers came up with topics of their own interest (in relation to one or more of the team's research goals), and proposed research project mentored by the professor. Below is a brief synopsis of each student's presentation.

Lucio Forti *(lf72881n@pace.edu), MA in Psychology student, presented his research proposal on "Internet-Based Technologies in an Internationalized Classroom." He looked into the usage of technology to infuse international content,* the types of IBT strategies that instructors used to incorporate international perspectives, and what the challenges and benefits associated with these strategies were. Some possible tools in an instructor's digital toolbox are: Face-to-Face, Social Media, Learning Management Systems (e.g., Blackboard, Moodle), Online Collaboration (wiki-based), and Digital Narratives (Prezi, YouTube, Blogs).

Lauren Lambert *(ll97492n@pace.edu), MA in Psychology student, researched* "Social Media and Culture: Factors that Influence Classroom Learning." She sought to explore how technology negatively and positively impacted learning in the classroom, mainly looking into the possible usage of a Facebook group to enhance learning in the classroom for a semester.

Yuting Dai *(yd65442n@pace.edu), MA in Psychology student,* decided to look into the "Current Status of Psychology Programs in China." As an international student

 [continued on next page]

from China, she would like to learn about what advantages and disadvantages of the psychology curriculum in her home country have in meeting the public needs of mental health service. She provided information about the history and state of psychology training and education in China in contrast to the psychology education in the United States.

Matilda Koroma *(mk53787n@pace.edu), Communication Studies major,* talked about "Culturally-sensitive Teaching Strategies for Third Culture Adolescents (TCAs)". She explained to the audience, the Third Culture Adolescents are those who were raised in a culture outside of their parents' culture for a significant part of their development years, so that basically their first culture is where their parents are from, their second culture is the current one in which they were raised up, and the third culture would be the mixture of the first two. Matilda was specifically interested in the ways in which one could develop culturally-sensitive teaching strategies that cater to the unique cognitive and developmental needs of TCAs.

Michael Trush *(mt09725n@pace.edu), PsyD in School-Clinical Child Psychology student,* proposed to look into the "Interaction between Learning Strategy, Modality Presentation, and Cultural Background on Memory." His hypothesis was that cultural background would significantly moderate learning as a function of modality presentation and type of learning strategy.

Following the presentations, there was time devoted to a Q & A session. Students' projects provoked a lively audience discussion--particularly on the pros and cons of using IBTs (Internet-Based Technologies) in teaching, including social media platforms. Though face-to-face communication is still the most effective type of communication, the development of the IBTs has enabled instructors and students to do many activities distantly, along with internationalizing and expending the "classroom" experience.

As for the development of psychology in China, it was pointed out that many psychological issues were neglected in China in earlier days, but even now psychology has not drawn a proper attention to itself. Many psychological issues are still considered stigmas in the society and are not spoken of. The number of universities offering psychology programs is quite limited, and if they do, they offer only 2 types of psychology programs: general psychology and applied psychology. The situation is gradually changing, but the process is going very slow. This highlights a huge gap between the small number of psychologists for the vast population in China, proving the importance of internationalizing teaching of psychology, making it more accessible for different people all around the world.

The discussion of incorporating the perspectives of Third Culture Adolescents raised the question about the sense of "being everywhere and nowhere," causing possible issues with personal identity, which should be taken into consideration when developing culturally-sensitive teaching strategies.

Dr. Velayo summarized the value of involving students in the process of internationalizing the teaching of psychology in that despite the differences between people from various cultures, we should not overlook the commonalities among the people worldwide. He emphasized that cross-cultural and cross-national research may also emphasize how people in different cultures may similar to each other, rather than looking at their differences as the driving force of psychological inquiry. Those commonalities might also help us to achieve the goal of internationalizing psychology teaching and developing corresponding strategies to do so.

For more information about this presentation and of the IToP team, please contact Dr. Richard Velayo at *rvelayo@pace.edu*

ICP 2014 CONFERENCE WRAP UP

Dayan-O'Roark InAbsentia Poster Awards International Council of Psychologists

Paris, France, July 13-15, 2014

Anna Laura Comunian

Joshua Wright and Jason Young were the recipients of the first place award for the Dayan-O'Roark InAbsentia Poster Awards hosted at the 2014 International Council of Psychologists (ICP) conference in Paris, France past July. Joshua Wright and Jason Young's poster, *Religious Identity, Aggression, and Attitudes towards Violence: Implications for Intergroup Conflict* reported an experimental study with 150 religiously oriented persons in New York City that included Christians, Muslims, and persons of other religious affiliations.

In addition to experimentally manipulating the salience of membership in a given religious group, the authors also assessed the subjects' religious involvement, religious commitment, and perceived collective self-esteem of their religious in-group. The research results indicated that Muslims in particular responded with lower levels of anger and hostility in situations where their religious identity was salient in a situation of (perceived) threat.

Dr. Harold Takooshian of Fordham University, New York, and of Council of Representatives American Psychological Association (International Division), presented the certificates and award funds to Joshua and Jason on-behalf of all the ICP family in November.

 [continued on next page]

The second place winners of the competition were Claudia Zago and Paolo Francesco Cottone who displayed a poster entitled *Shaking Violence with Laws.* In addition, they gave a presentation about the study that they had described in their poster. The poster explored how Portuguese laws could influence representations of domestic violence after Portugal had introduced a law stating that domestic violence constitutes a crime that can be prosecuted. Their study included a review of pertinent Portuguese legislation, ethnographic research, and participant observation together with four interviews with police officers and four in-depth interviews with members of relevant Portuguese organizations.

Zago and Cottone concluded that the aforementioned changes in Portuguese law helped to empower women who had been victims of domestic violence, made people in general more aware of the nature and complexity of domestic violence together with the social networks involved, and also led to a greater awareness among the public and the victims' neighbors. The Director of the Department, Dr Egidio Robusto, and Dr Anna Laura Comunian presented the certificates and award funds to Claudia and Paolo Francesco during a ceremony organized at the Department of Psychology, University of Padua, Italy.

During the ceremony were also distributed the certificates "Dayan-O'Roark InAbsentia Poster participation ICP 2014" to the other exhibitors of posters. Their topics presented different psychological research. They were from Spain, Italy, Hong Kong, USA. The authors were the followings: *Psychological resilience at University of Seville: a comparison study between male and female students* by Sara Vera Gil, University of Seville; *Expectations of well-being and happiness at the beginning and at the end of the career path: a survey of Italian and Romanian youth and seniors* by Raluca Levonian, Eleonora Bordon& Mariselda Tessarolo, University of Padua; *A sector study on employability of women in post-modern society* by Maria Concepción Mimbrero Mallado, Ana Guil, University of Seville; *Youths think to the future: economic crisis and new definitions of self and social, by* Eleonora Bordon, Mariselda Tessarolo, Anica Lazic.University of Padua, *Tell me what different languages you speak: Perception and representation of foreign languages in university students* by Magali Boureux, Eleonora Bordon, University of Padua; *Recalling 'Thanks' for good: The effects of gratitude recall on appraisals of psychological well-being* by Bobo Hi-Po Lau & Cecilia Cheng, The University of Hong Kong; *Why are obese kids thin in mums' eyes? Transnational survey on mothers' evaluation bias while estimating their children's weight* by Alexander Hochdorn, Dario Gregori, Ileana Baldi & The Obey-Ad Study Group, University of Padua; *Goals and Strategies for "Internationalized" Psychology Course: An Online Assessment Survey* by Richard Velayo, Pace University, New York.

The Evaluation Commission for the Dayan-O'Roark InAbsentia Poster Awards included Uwe P. Gielen and Roswith Roth, both past presidents of the International Council of Psychologists.

Photos from Paris, courtesy of Anna Laura Comunian

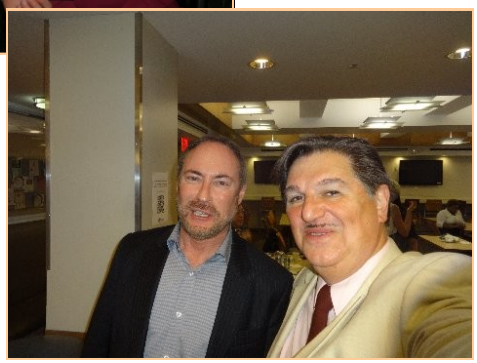

Shown directly above: Jason Young with Harold Takooshian, in New York. Joshua Wright was unable to attend as he is now in grad school in Canada.

UNITED NATIONS REPORT

UN NGO Representative
Florence L. Denmark, PhD
USA

In New York, we have the following NGO Representatives: Norma Simon, Richard Velayo, Martin Butler, Eva Sandis, Pete Walker, and Florence Denmark as the Main Representative. We are active on many committees such as Florence Denmark being co-chair and Norma Simon serving as the Corresponding Secretary of the Family Committee. On the Ageing Committee, both Norma Simon and Florence Denmark (as past chair) are on the Executive Committee. Richard Velayo and Pete Walker are also active on this committee. Eva Sandis is very active on the Migration Committee, having been a former chair. Martin Butler is also active on the Migration Committee.

Anna Laura Comunian serves on the Human Rights Committee at the UN headquarters in Geneva, and Roswith Roth is active in the UN headquarters in Vienna.

ICP Interns (from left to right): Lucio Forti, Eve Mitchell, Pancho Diaz, and Alaa Alhomaizi.

I am very proud of our interns at the United Nations: Alaa Alhomaizi, Pancho Diaz, Lucio Forti, and Eve Mitchell. They are active and involved. They were selected by Norma Simon, who coordinates the intern activities, Pete Walker, and Florence Denmark. Following is a brief biography of each intern.

Alaa Alhomaizi: Alaa Alhomaizi is pursuing a Masters degree in Clinical Psychology at Teachers College, Columbia University majoring in Global Mental Health and investigator of a study focusing on Arab women's stress, adjustment, and mental health at the Global Mental Health Lab at Teachers College. Her primary research interests are maternal and child mental health, stress and resilience, and global mental health. Alaa is originally from Kuwait. She is the co-founder of the Standing for Psychological Education and Awareness in Kuwait (SPEAK) anti-stigma campaign, the first and only campaign of its kind in Kuwait. Upon completing her masters, Alaa plans to pursue a PhD in Clinical Psychology and eventually return to Kuwait as a practicing clinician as well as an advocate for the rights of people living with mental illness in Kuwait.

Pancho Diaz: Pancho Diaz Jr. has recently graduated with a MA in Psychology from Pace University. He has been living in New York for the past four years, and has been involved with the International Council of Psychologists for the past two. Over those two years, he has participated in and helped organize various events at the United Nations, such as Psychology Day and the International Day of Older Persons. He is also active in the Family Committee, assisting with things such as website development. In the near future, he plans to continue his education in the areas of public health and quantitative research.

Lucio Forti: Lucio Forti is a Master's student in Psychology at Pace University where he is a member of Dr. Richard Velayo's IToP research team (Internationalizing the Teaching of Psychology). His background in systems engineering at a custom software developer has led him to investigate internet-based strategies that instructors use to incorporate international perspectives in the classroom. A member of the Academic Technology Department at Pace, Lucio works closely with faculty and students to design strategies that leverage technology in order to cultivate a rich learning environment. His current research interests also include the cross-cultural study of perception and affective priming.

Eve Mitchell: Eve Mitchell is a first-year Master's student in Psychology at Hunter College. As a post-baccalaureate student, her research at Hunter College focused on identity and self-structure. She began her foray into psychology as a research intern for The Family Center, working on projects that focused on the efficacy of social and educational programs offered to families around New York City. She trained for two years under a learning specialist and currently works with children ages 10-16 as a private tutor. Her interests include the ideographic structure of behavior, the relationship between self-structure and authenticity, and valid, reliable measures of the self. She has a cat whom she loves dearly, a soft spot for eastern philosophy, and very strong feelings

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about 19th century art.

Interns and representatives all look forward to an active 2015.

UN reps meet in New York, Fall 2014: Pete Walker, Harold Takooshian, Florence Denmark

[*Publisher's Note: More intern notes and information in the upcoming International Understanding. NQ]*

SECTION II: INTERNATIONAL

WORLD AREA CHAIR REPORT

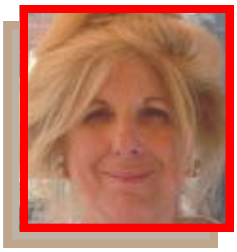

Dr. Sandra E. S. Neil

World Area Chair Coordinator
AUSTRALIA

In Graz Austria

International Satir Model Training

Dr Sandra E. Neil and Dr. Robert L Silverberg will present a 5 day workshop "Satir Model Family Psychology & Therapy Training Programme: Toward Healthy Families 2020" from 24th – 28th August 2015 at Institut Für Kind Jugend Und Familie Austria. This is a Satir Model Family Psychology & Therapy Training Programme:

The programme is not limited to and includes:

Systemic Transformational Change Processes
The Hierarchical vs The Seed Model for Growth
The Satir Model Towards Congruence
Three Generational Family Maps
Tools and Vehicles of Satir Therapy
The Survival Stances
The Transformation Process
The Parts Party, Ropes, Metaphors, Family Chessboard
Family Reconstruction
What Children need for Self Esteem

In Gold Coast, Australia

Australian Psychological Society

The 50th Anniversary Annual Conference of the Australian Psychological Society will be held at The Gold Coast, Queensland, Australia, 28th September -2nd October 2015. The conference Chair and team are developing an enriching program for this Golden anniversary. Website link:
http://www.psychology.org.au/conference2015/?utm_source=Homepage&utm_medium=Hero&utm_campaign=2015APSConference

Australiawide

National Psychology Week 9-15 November 2014 generated nation-wide media coverage, with an estimated 360 media pieces across print, television, online and radio outlets (including 240 radio news pieces) reporting findings from the APS Stress and Wellbeing survey, as well as APS member events, to highlight the contribution of psychology to community wellbeing.

Melbourne, Victoria, Australia

Australian Psychological Society, Victorian Section Clinical College AGM and Dinner held at The Point, Albert Park, Melbourne, November 27th 2014. Presentation by Dr Sandra Neil, Title: "Midnight Musings of a Clinical Psychologist in the World of International Psychology". Dr Neil spoke about her experiences and collaborations with international psychologists. This Presentation was a resounding success with many young PHD Students and prize winners excited by the talk, both content and style.

This talk would be very effective if presented at an ICP conference or other gathering to attract new members, especially from young professionals and graduate students.

Kuala Lumpur, Malaysia

International Family Therapy Association (IFTA) 23rd World Family Therapy Congress 10-14 March 2015 Kuala Lumpur, Malaysia

Dr. Sandra E. S. Neil, PhD, MA, BEd, BA, FAPS and Dr

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Emotional Abuse A Group Therapy Method For Healing Family Abuse: Can the Leopard Change His Spots?

This group psychotherapy method for healing abuse describes types of traumatic abuse, representing: the Man, the Child, the Family, the Self, and Tools of Abuse. The group process resulted in the transformation of the emotional signature of an adult man who wishes to never repeat family patterns of abuse.

The Psyche and The Soma - A Satir-Based "Body Parts Party" for Diagnosis of a Brain Tumour

"The Psyche & the Soma" is a group therapy method assisting early diagnosis. A multidisciplinary team used the Body Parts Party indicating a combined physical-psychological pattern. After early detection in Group Therapy, a cerebello-pontine angle brain tumour was diagnosed by a Neurosurgeon. A twenty-year follow-up revealed permanent remission.

International Council of Psychologists (ICP) World Peace Summit – the Endangered People and Children Human Rights World Summit 2015.

This important symposium will be presented by the International Relations and Human Rights Interest Group for the 73rd Annual ICP (International Council of Psychologists) Conference to be held in Toronto Canada in August 2015. The Human Rights Summit will be chaired by Dr. Sandra E. S. Neil (Australia) World Area Chair Coordinator ICP.

Panel members are being invited and so far those who are confirmed to attend are: Emerita Professor Florence Denmark (USA) as discussant, Dr. Tara Pir (USA), Dr. Ann Marie O'Roark (USA), Dr. Ani Kalayjian (USA), Professor Dr. Roswith Roth (Austria), Professor Dr. Anna Laura Comunian (Italy), Dr. Machiko Fukuhara), Dr. Sandra Neil (Australia). Further details will be available in early 2015 when we have all our replies.

Finally, in conclusion could all the Area Chairs please send a few lines to me; DrNeil@satiraustralia.com about their own area of the world. All your news is of interest to other psychologists.

Submitted respectfully,

Dr. Sandra E. Neil
World Area Chair Coordinator,
International Council of
Psychologists 2014-2017

LIAISONS

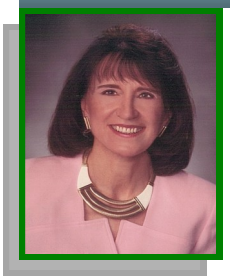

Joy K. Rice, Ph.D.
ICP Liaison Coordinator
USA

On behalf of the Presidents of the Congress, I send you this invitation:

It is our pleasure to welcome all of you to the World Congress of the World Federation for Mental Health WFMH 2015 in Cairo, Egypt on 16-19 October, 2015.

This Congress is being organization by WFMH, the Royal College of Psychiatrists—Middle East Division, the Behman Hospital Egypt and the Egyptian Society for the Rights of People with Mental Illness.

We promise to produce a rich scientific, clinical and practice-based program with contributions from service users, their families and caregivers, as well as an interesting introduction to the culture, arts and social life of the local community in Cairo via several social, cultural and artistic events.

For more information, please visit the website at:

Www.WFMH2015.com.

Hope to see you there!

Sincerely,

Dr. Joy K. Rice
ICP Liaison to WFMH

LONG RANGE PLANNING

ICP, INC TO MEET IN YOKOHAMA JAPAN IN 2016

Dr. Machiko Fukuhara, 2016 Local arrangements Committee Chair and former ICP, INC Treasurer, invites ICP INC MEMBERS TO VISIT YOKOHAMA IN 2016. Dr. Fukuhara is also an advisory member of committees of the International Union of Psychological Science's 2016 CONGRESS being held in Yokohama CONGRESS, July 24-28, 2016. She and her Committee, Yoshiko Kato and Edit Nagy-Tanaka, are in negotiations with hotels and congress planners to confirm the site for the ICP, INC meeting in 2016. They expect to submit a proposal with budget to the Board of Directors soon and to have plans confirmed at the ICP, INC 2015 Toronto Annual Conference and Board Meetings.

Yokohama Landmark Tower

Dr. Fukuhara coordinated local arrangements for the ICP, INC ANNUAL CONFERENCE AND MEETING in Tokyo when Dr. Tsuni Shirai was President in 1989-90

Views of the Yokohama region of Japan

CALLS FOR 2017 CONFERENCE PROPOSALS

ICP INC MEETS IN THE GENERAL VICINTY AND TIME FRAME AS OTHER INTERNATIONAL PROFESSIONAL ASSOCIATIONS

ICP, INC ESPECIALLY INVITES PROPOSALS FOR 2017 THAT COULD CONNECT WITH:

- 2017 European Congress of Psychology in Amsterdam : July 11-14, 2017
- The InterAmerican Society of Psychology
- The International Association of School Psychologists
- A major congress of an Allied Discipline Association of Mental Health or Counseling or Academic Professionals.

PLEASE FORWARD ALL PROPOSALS TO PRESIDENT TARA PIR at tarapirimces@msn.com.

MEMBER AND INTERNATIONAL NEWS

Dr. Ani Kalayjian, November 2014

The Advisory Board of the University of Missouri International Center for Psychosocial Trauma (UMICPT) awarded the 2014 Humanitarian Award to Dr. Ani Kalayjian. This award is given annually to an individual who has made significant contributions throughout his/her professional career to promote the mental health of children and their families. The ICPT board recognized Dr. Kalayjian's lifelong contribution in the field of mental health and its impact on the lives of children worldwide. UMICPT had selected Dr. Kalayjian from amongst a large number of peers to receive the 19th Annual Humanitarian Award.

Also, Dr. Kalayjian contributed to a timely article regarding Seasonal Affective Disorder (SAD) - something many people suffer with during the shorter, colder, darker days of the winter seasons. The article can be read at:

http://dailyburn.com/life/lifestyle/sad-cope-with-seasonal-affective-disorder/

Dr. Chris Stout, founding director of the Center for Global Initiatives was delighted to report that the CGI was honored with the designation of 2014 TOP-RATED NonProfit by GreatNonProfits.com.
https://www.linkedin.com/redirect?url=http%3A%2F%2Flnkd%2Ein%2FbighaQ3&urlhash=-jPe&_t=commentary-share-link&trk=commentary-share-link

Dr. Roberto Velasquez, Riverside California, USA

Member Roberto Velasquez, PhD, working with Dr. Eduardo Gamarra (Florida International University), Dr. Jeanett Castellanos (University of California Irvine), Susana Mendez of Tijuana, Mexico and Sequoia Kermott (Alliant International University) has completed a study regarding the Cuban Mariel Boatlift of 1980.

April 15, 2015 marks the 35th anniversary of what is regarded in many circles as the most controversial wave of refugees to arrive on American shores. The impact of the event was widespread for both refugees and Americans and has lasted into current times.

Claudia Zago, Student Member 2014 and InAbsentia Poster finalist writes (November 26, 2014):

Dear Dr. O'Roark and Dr. Dayan,

I am Claudia Zago, one of the Italian participants of the ICP conference in Paris, the wonderful capital of France, last July 2014.

This week there was the meeting with Dr. Comunian and she gave me the certificate of 2nd award for my poster titled, "Shaking Domestic Violence with Laws" and the relative bank check.

I really feel glad and proud for this acknowledgement and for the precious opportunity I had to present directly at the ICP convention, the research I realized in Portugal. Not only was ICP a great opportunity for me, but to be one of the speakers at the Symposio, "Gender identities around the world: an international challenge between culture, society and everyday practices" [which was] well organized by Hochdorn Alexander, allowed my international academic experience to grow a lot.

I really want to thank you and the ICP committee, also in the name of my co-author Paolo Cottone, for this great result.

Best regards,

Claudia

MEMBER PUBLICATIONS

Uwe Gielen and **Grant Rich**. Editors for an in-process volume, "Pioneers in International Psychology". **Ann O'Roark** is author of a chapter on Charles D. Spielberger, ICP, Inc. president 1987-88. Publisher: Information Age Publishing

Ana Guil, Anna Laura Comunian and Ann M. O'Roark. Editors for an in-process proceedings book: ICP, Inc. Conferences 69 & 70. Publisher: University of Seville, Spain.

Sandra E.S. Neil and Ludwig Lowenstein. Collaborators for a book: "Families in Turmoil" featuring the very learned work of Ludwig Lowenstein, and a preface and chapter on Further Therapy for the Alienated Family by Dr. Sandra E.S. Neil. 2014

Ani Kalayjian. *From War to Peace: Ancestral Meditation Transforming Generational Trauma.* Meditation CD. *(2010)*

Ani Kalayjian. *Post Trauma, Crisis, or a Disaster: Chakra and Energy Balancing Techniques.* Workbook. (2014)

A. Kalayjian, R. Paloutzian. *Forgiveness & Reconciliation: Psychological Pathways for Conflict Transformation and Peace Building.* Publisher: Springer (2010)

R. Davido. *The Davido-CHaD Test in Clinical Practice.* Projective clinical drawing test. *Le Davido-CHaD Test en Pratique Clinique. Editions due Cygne, Paris, France.* Forward by Sarlito Sarwono, Indonesia. A dual language guidebook for using the CHaD. (2013)

INTERNATIONAL NEWS

CALL FOR ABSTRACTS—9TH EUROPEAN CONGRESS ON VIOLENCE

22-24 October 2015
Copenhagen, Denmark
9th European Congress on Violence in Clinical Psychiatry
"Advancing knowledge—Transforming Practice"

SUBMIT ALL ABSTRACTS BY MARCH 1, 2015. Must be submitted electronically. Poster abstracts can be submitted until August 1, 2015.

To submit, register and attend go to:
http://www.oudconsultancy.nl/Copenhagen2015/

CALL FOR PAPERS—6TH INTERNATIONAL CONFERENCE ON DISABILITIES

July 6-9, 2015
Tel Aviv, Israel
"Unity and Diversity in Action"

SUBMIT ALL PAPERS BY JANUARY 31, 2015

Register today and save!! http://eng-conf.beitissie.org.il/

FIRST 100 YEARS OF CONSULTING PSYCHOLOGY CELEBRATIONS PLANNED

ICP's Ann O'Roark and Florence Denmark are involved in the planning of the three 100-year celebration events planned for the Society of Consulting Psychology during the 2015 year.

Special celebrations will begin with the February conference, Excellence Across Borders: Fit to Consult? being held in San Diego, California from the 3rd through the 8th.

For more information on the conference, visit: http://societyofconsultingpsychology.org/

From Madrid:

PSYCHOSOCIAL INTERVENTION Vol 23. No. 03 (2014)

Dimensiones del sentido de comunidad que predicen la calidad de vida residencial en barrios con diferentes posiciones socioeconómicas
Isabel Hombrados-Mendieta, Trinidad López-Espigares
Psychosocial Intervention 23 (2014) 159-67
Resumen - Texto Completo - PDF

Sentido de comunidad, empoderamiento psicológico y participación ciudadana en trabajadores de organizaciones culturales
Ignacio Ramos-Vidal, Isidro Maya-Jariego
Psychosocial Intervention 23 (2014) 169-76
Resumen - Texto Completo - PDF

For more about this journal, go to:
http://www.psychosocial-intervention.org/&lang=en&numero=&articulo=&secc=all

FROM INTERNATIONAL TO TRANSNATIONAL:

TRANSFORMING THE PSYCHOLOGY OF WOMEN

International Summit before the 2015 APA Convention in Toronto, Canada, August 4-5.

SUBMISSION DEADLINE: January 15, 2015

To submit a proposal, register to attend or for other information regarding the summit, visit:

For information, registration and submissions, visit:

http://www.intlpsychwomensummit.com/

And from Chris Stout's newsletter from the Center for Global Health, a good deal of study, conversation and communication about the relationship between man and animals:

January 7, 2015, Chicago, Illinois

Monthly meeting of the Center for Global Health Network will present Dr. John Arthur Herrmann: "One Health: We're all in this Together."

Discussion regarding how human, animal and ecosystem health are interrelated; identify the need for effective communication between health care providers in humans, animals and with public health professionals; describe how surveillance systems for infections and non-infectious diseases across human and animal populations within critical ecosystems can be integrated to predict and manage outbreaks effectively.

Meeting at Gerald Moss Auditorium, 909 S. Wolcott, Chicago, Illinois. 1 CME credit eligible.

The Executive Committee of Non-Governmental Organizations Associated with the United Nations Department of Public Information

HAPPY HOLIDAYS!

Dear Fellow NGO Representatives:

As another successful year comes to a close we wish you and your families a happy holiday season.

The NGO/DPI Executive Committee, (DPI), of which I am Chair, works in close partnership with the United Nations Department of Public Information (DPI). It is comprised of eighteen NGO representatives elected by organizations officially associated with DPI. The Executive Committee was founded to provide leadership and strategic direction for the NGOs with respect to their association with DPI and to help NGOs become more knowledgeable about, and make effective use of, information on the U.N.'s purpose, policies, program and activities. We represent you.

Organizing the NGO/DPI conference is one of the many activities the Executive Committee undertakes to represent the concerns and interests of over 1,500 non-governmental organizations (NGOs) associated with DPI. The conference held in August this year was a great success and its report and Declaration is mentioned in the Secretary-General's recent report **on "The Road to Dignity by 2030: Ending Poverty, Transforming All Lives and Protecting the Planet,"** which exemplifies the important role and contribution of non-governmental organizations and civil society to the post-2015 sustainable development agenda.

Other activities undertaken by the Executive Committee to benefit the NGO community include organizing the popular communications workshops, youth programs, networking events and outreach to NGOs associated with DPI throughout the world.

Building on our past success, we are planning a full program of NGO activities next year and we need your help. The intensive efforts needed to mount a successful conference; providing opportunities for NGOs in developing countries to participate and other activities that we provide; imposes significant financial burdens on the all-volunteer DPI/NGO Executive Committee.

The NGOs are critical to the success of the United Nations. We are the voice of **Civil Society**. It is through all of our efforts that the U.N. and its member states succeed.

Yours sincerely,
Anne-Marie Carlson
Chair, NGO/DPI Executive Committee

Merry Christmas and Happy 2015 from the Ecadoc European Research Community!

To see what the Padua Ecadoc community is up to, visit them at: http://larios.psy.unipd.it/ecadoc/pages/1_summer_school.php

CALL FOR ARTICLES

This newsletter is your publication. While we hope to provide resources and information that are helpful to our global community, YOUR news is very valuable to fellow ICP members and to all of those who receive this newsletter around the world. Many organization leaders receive this newsletter quarterly and take note of your accomplishments, studies, and commitment to a healthier global community. We all learn, inspire and encourage each other with this sharing of information!

In addition to the *International Psychologist* (aka the IP), a semi-annual journal-type publication is also put out to showcase articles, papers, and studies longer than the average 350-500 words desired for the IP. This publication is known as the *International Understanding*.

Please send your inquiries or submissions to Dr Ann O'Roark, at **annoroark@bellsouth.net**. The guidelines are pretty simple. Save text in MS Word format (.doc or .docx) 11pt. Times New Roman and prepare the work using the current APA style. Photos also appreciated. Submit those in a jpeg format and send as attachments as well.

Nancy Quatrano, Publisher

SECTION III: ADMINISTRATIVE

EDITOR'S REPORT

ICP, INC CELEBRATES 73 YEARS OF ANNUAL MEETINGS: UNIQUE PERSON TO PERSON SHARING OF PSYCHOLOGICAL KNOWLEDGE, ETHICS AND VALUES REQUIRES ACTIVE PARTICIPATION FROM MEMBERS EACH AND EVERY YEAR

Ann Marie O'Roark, Ph.D., ABAP

St. Augustine, Florida. For those of us committed to discovering ways to continue the contributions of ICP, Inc. to the community of international associations, a new year offers a fresh vista of opportunities. One of the oldest / first organizations to be global in psychological membership (1941) ICP, Inc. became one of the earliest to embrace interdisciplinary membership in 2011.

Being innovative and inclusive are hallmarks of ICP's culture, which has always been values based: peaceful resolution of national differences; individual collaboration and respect across national boundaries; and contributing to the wellness and education for citizens of every country.

In addition to aspirational motivations for quality of life for people served by psychologists, ICP's founding members began with commitment to highest of standards in educational preparation for those who teach, conduct research and practice in the area of human behavior, treatment or theory.

In order to promote deeper cross-cultural understanding and collaborations, ICP follows a path that results in smaller-sized membership constituency and conference gatherings. That distinctive desire for more than a casual acquaintance with international colleagues is worth the membership fee and time necessary to be an active contributor to ICP's annual conference and newsletter.

Moreover, the unique history, role and incubator functions of ICP in the community of international associations is an opportunity that is unavailable in groups that are intentionally focused on specializations within the discipline or activities in one geographic region. In

[continued on next page]

keeping with its larger role, ICP introduced a number of activities and structural features currently popular in liaison organizations, such as liaisons, UN NGO and DPI participation; Regional and Area Chairs for communications and conference announcements; newsletter and publication opportunities for newcomers to international concepts and scientific writing; InAbsentia graduate student posters for those who cannot afford to travel internationally yet.

The Universal Declaration of Ethical Principles for Psychologists (2008) is fundamental "common ground" for ICP members and a bond with members of liaison organizations, especially IAAPsy, IUPsyS, SIP, EPA, American Psychological Association, Canadian Psychological Association, International Cross Cultural Association, International Association of School Psychologists. [note: IAAP recently changed its internet identity to IAAPsy].

Universal Declaration of Ethical Principles for Psychologists

Adopted by the Assembly of the International Union of Psychological Science in Berlin on July 22nd, 2008.

Adopted by the Board of Directors of the International Association of Applied Psychology in Berlin on July 26, 2008.

Preamble

Principle I: Respect for the Dignity of Persons and Peoples

Principle II: Competent Caring for the Well-Being of Persons and Peoples

Principle III: Integrity

Principle IV: Professional and Scientific Responsibilities to Society

Preamble:
Ethics is at the core of every discipline. The Universal Declaration of Ethical Principles for Psychologists speaks to the common moral framework that guides and inspires psychologists worldwide toward the highest ethical ideals in their professional and scientific work. Psychologists recognize that they carry out their activities within a larger social context. They recognize that the lives and identities of human beings both individually and collectively are connected across generations, and that there is a reciprocal relationship between human beings and their natural and social environments. Psychologists are committed to placing the welfare of society and its members above the self-interest of the discipline and its members. They recognize that adherence to ethical principles in the context of their work contributes to a stable society that enhances the quality of life for all human beings.

The objectives of the Universal Declaration are to provide a moral framework and generic set of ethical principles for psychology organizations worldwide:

1. to evaluate the ethical and moral relevance of their codes of ethics;
2. to use as a template to guide the development or evolution of their codes of ethics;
3. to encourage global thinking about ethics, while also encouraging action that is sensitive and responsive to local needs and values; and
4. to speak with a collective voice on matters of ethical concern.

The Universal Declaration describes those ethical principles that are based on shared human values. It reaffirms the commitment of the psychology community to help build a better world where peace, freedom, responsibility, justice, humanity, and morality prevail. The description of each principle is followed by the presentation of a list of values that are related to the principle. These lists of values highlight ethical concepts that are valuable for promoting each ethical principle.

The Universal Declaration articulates principles and related values that are general and aspirational rather than specific and prescriptive. Application of the principles and values to the development of specific standards of conduct will vary across cultures, and must occur locally or regionally in order to ensure their relevance to local or regional cultures, customs, beliefs, and laws.

The significance of the Universal Declaration depends on its recognition and promotion by psychology organizations at national, regional and international levels. Every psychology organization is encouraged to keep this Declaration in mind and, through teaching, education, and other measures to promote respect for, and observance of, the Declaration's principles and related values in the various activities of its members.

You can read the full declaration at the IAAPsy web site at **www.iaapsy.org/**

We welcome your annual contribution to the ICP mission: proposals for the 2015 conference; articles for the *IP International Understanding ;* nominations for the spring Board elections.

Warm Wishes for a happy year ending and year beginning,

BANKING AND RECORDS MANAGEMENT

Ms. Nancy L. Quatrano, USA

BANKING AND RECORDS MANAGEMENT JUNE—NOVEMBER 2014

Hastings, Florida. The ICP net worth is stable at $86,097 as of December 1, 2014:

The PayPal account balance is $916.00 and is comprised of both membership dues and some conference payments due back to the operations account. Still outstanding is $1264 of invoiced fees expected to be paid by end of the year, which belong to the operations account for conference expense reimbursements.

The convention account balance of $2,537 represents unspent funds from the Jakarta-Hawaii conference of 2013. The Paris conference did not realize a profit. This balance has been committed to the 2015 convention chair for the Toronto, Canada area conference budget which is still being developed.

The operations account balance is at $22,432.93. To that balance, the PayPal amount of $826 and $600 from the award fund will be added by year end. There is $1250 due to contractors for work being done for banking and records and organization's publications, and another $100 due to the State of Connecticut for our corporation reports and fees. This does not reflect the payment of dues (PayPal) which at this time is for 2 new student members only. No existing members have renewed their dues at this time.

The escrow (awards/reserve) account balance is at $60,211.01 but I'll be transferring $600 of that into the operations account on behalf of the Fukuhara fund payments. The awards of 2013 and 2014 need to be withdrawn to reimburse the ICP for the award checks issued. Interest has been minimal at approx $2.51 per month.

The year has been full to say the least. Work on the needs of the 2014 conference consumed more than 240 of my hours. I also handled membership information, sent *Welcome* emails, scanned applications and managed the email inquiries when there were issues. One prospective member who lives in a country that has almost no financial structure tried his best to pay dues to become a member, but after all his attempts the result was a fraudulent money order that cost him $40, the ICP organization a $12 fee for the returned item, and me approximately 10 hours of trying to resolve the situation with him, banks, attorneys, etc. Membership rosters are updated monthly and the email addresses for our various mailings are updated as I am notified of changes.

And so, as this year closes on our calendar, I still have a few things to do. January will mean preparation of the tax documents (1099) for the contractors, a summary of income and expenses for the 2014 filing of the 501(3c) annual reports with the State of Connecticut and the IRS filing for 2014 which I'll visit the CPA for.

And now, there's Toronto in 2015 and I'm just sure you'll be sending all of your dues in to me this week, right?

Wishing you all a happy, healthy, prosperous and blessed holiday season and 2015! See you in the spring!

Respectfully,

Nancy Quatrano

Banking and Records Manager

2nd NOTICE OF 2015 DUES

Go today to the website at www.ICPWEB.ORG and complete your renewal/membership form and submit your payment via the easy PAY NOW buttons wonderfully worked out by our webmaster, JP Abilla, a team member with the IMCES organization. You'll be all done in just a matter of a few minutes!

And if you'd prefer to complete your membership form (used for updating our records if you are renewing) manually and send it to me with a check that's perfectly fine, as well! My address is on the form. And, the form is also located here in this section of the IP as well!

Before the rush of new year things becomes overwhelming, and before the late fees kick in on January 31, 2015, get those dues paid so we can build a budget that will keep ICP healthy and moving forward. Thank you!

Nancy Quatrano

ICP, INC. 2015 ANNUAL CONFERENCE AND MEETING

TORONTO CANADA

7-31 .. 8-4 2015

PLANNING COMMITTEE

2015 COORDINATOR: Dr. Janet Sigal, President Elect

Co- Chairs: Dr. Janet Sigal, Florence Denmark, Ann Marie O'Roark

LOCAL ARRANGEMENTS COMMITTEE

Co-chairs: Dr. Mark Mrazik, ICP Liaison to Canadian Psychological Association, and Dr. Chok Hiew, President ICP INC 2005-6

Consultant Member: Dr. Jennifer Boyce, Registered Psychologist, Integra Health and Wellness Clinic, Toronto Canada

Long Range Planning Committee Members: Dr. Machiko Fukuhara, Dr. Edit Nagy-Tanaka, Dr. Yoshiko Katu [Japan 2016 Conference]

ADVISORY: Former Conference Planners: Dr. Elisa Margaona, Dr. Sarlito Sarwono, Dr. Anna Laura Comunian

AWARDS CHAIRS: Advanced International Research and Service; Gender Research & Service; Early Career; Distinguished Contributions; InAbsentia Graduate Student Poster Exhibit

EXOFFICIO: President Tara Pir, Past President Ludwig Lowenstein

CONFERENCE PREPARATIONS:

Call for Proposals and Review Panel. To be announced

Conference Program Book: Preparation and Publication. TBA

Conference Amenities. TBA

Conference Public Information: ICP Area Chairs, Liaisons and TBA

73rd year

International Council of Psychologists

A non-governmental organization in Special Consultative Status with the Economic and Social Council and the Department of Public Information of the United Nations. Website: http://www.ICPweb.org

73RD Annual ICP Conference, Canada

Scientific Program

Caring for Individual Well-being and Advancement of Psychology

Guidelines:

Only typed abstracts in English will be considered. Use Word, Word Perfect or Plain Text, Times New Roman font in 10 or 11 point size.

- **Abstract is to fit inside the box on the right and may be provided on a separate sheet using those parameters and the following guidelines:**
- **Title: ten words or less in UPPER CASE that clearly indicates the content of the contribution.**
- **Skip a line, 3rd /4th Line:Your full name, Degree, institution or Practice, city and country**
- **Skip a line. Abstract single spaced , limit to 250 words, avoid abbreviations**
- **Abstracts should include problem or objectives, methods, results, and Conclusions. Do not include references, charts or graphs.No attachments will be accepted**

Submission of the abstract constitutes agreement to register, arrange for own travel and lodging plans, and to be present at the scheduled time and place for the session. Requests for schedule changes can not accepted. Letters of invitation will be provided.

Select one

Paper (15 or 20 Min) __Symposium (15 or 20 Min per presenter) (all names of & one abstract for each r)
Conversation Hour [all names and contact info]
Poster [registrant. Identify student, early career, or professional

Request for Technical Support.

Note: hotel resources may limit what can be provided

- **Slide projector ___Overhead projector**
- **SVGA projector/computer/multimedia**
- **(Word/Power Point will be supported)**
- **VHS video player**

Can you bring your own?

- **Projector ___computer ___flash drive**

GUARANTEE OF CONFERENCE REGISTRATION IS A CONDITION FOR ABSTRACT CONSIDERATION & INCLUSION IN PROGRAMME.

- **Program Chair and Committee will group proposals by category topics into thematic sessions in order to promote communication among presenters and to allow for inspiring discussions.**
- **Scientific Committee will notify the FIRST AUTHOR OR MODERATOR of acceptance and time of session within the overall program. Chair or moderator is to notify other participants in the session.**
- **Acceptance does not include any financial assistance or fee reduction.**

Insert submission here!

CALL FOR AWARD NOMINATIONS

CALL FOR PAPERS
The Seisoh Sukemune/Bruce Bain Encouragement of Early Career Research Award 2014-15

Submission Deadline: May 1, 2015

Purpose
The Award for Research in International Psychology recognizes outstanding early career contributions to scholarly endeavors addressing psychological issues of a universal or multinational significance. It is designed to encourage research that systematically addresses the psychological dimensions affecting the quality of human life, and to enhance and reinforce the mission and goals of ICP (http://www.icpweb.org/). For the purpose of this award, "research" is broadly defined to include all paradigms of scholarly endeavor, such as laboratory experiments, field experiments, field studies, correlation and evaluation studies, historical studies and case histories. The recipient is expected to present an address at the ICP annual convention that relates to his/her research.

Criteria for eligibility
The recipient must be a psychologist (including a student).

Paper selection criteria

The paper's logic, its purpose, its methodology, its universal or multinational significance, contribution to the development of international psychology, and contribution to the development of human well-being. The recipient must be the first or sole author of the paper; her/his contribution must be greater than 50%.

Submission procedure & requirements
Candidates *from all over the world* are invited to submit a paper and a cover letter by e-mail (to **ceci-cheng@hku.hk**) to Prof. Cecilia Cheng, Chair of the ICP Research Awards Committee, not later than May 1, 2014 (date of email or postal delivery).

NOTICE OF SELECTION: JUNE 1, 2015

Prof. Cecilia Cheng

Chair of the ICP Research Awards Committee
Department of Psychology
The University of Hong Kong
Pokfulam Road
Hong Kong

Paper and application must meet the following requirements:

1. The research must be based primarily on the candidate's own work, and must be considered distinguished. The candidate must be the first or sole author of the paper. Her/his contribution to the paper must be greater than 50%.

2. The paper must not have been published elsewhere, but may be based on the applicant's unpublished bachelor, master, diploma or dissertation research.

3. The paper must be prepared in the style and format specified for journal articles by APA (Publication Manual).

4. The length of the paper is limited to 25 typed, double-spaced pages (maximum), including abstract, references, figures and tables.

5. One attached file accompanied by a **cover letter** which provides the following information: (1) Title of the paper, author's name, institutional affiliation, mailing address, telephone and fax numbers, and email address. (b) Applicant's curriculum vitae (CV). (2) Two letters of support which stipulate why the applicant is deserving of the award. (3) A statement signed (electronically or by hand) by the candidate applying for the award certifying that (a) the material presented is original and is primarily the candidate's own work, and the material has not been previously published; (b) the contribution of the candidate to the paper is greater than 50% (in case of multiple authorship and he/she is the first of two or more authors); (c) additionally, if the paper is judged to be the winner of the competition, the candidate agrees to present it at the next annual convention of ICP.

Main selection procedure
1. The Research Awards Committee evaluates papers according to a standard point system.

2. The Chair assures that results are reported to the ICP-Board.

Prize
The prize for winning the research award will consist of

- a certificate
- US$ 200.00
- an invitation to present the research at the upcoming ICP convention
- there will be no registration charge at the upcoming ICP convention (registration waived)
- membership in ICP, Inc. for 18 months

Watch the website for updates throughout the year.

 [continued on next page]

Distinguished Contribution Award: Frances Mullen Award
Submission Deadline: May 20, 2015

This award is presented to honour a member of the ICP who has a long and distinguished history of research or applied contributions to one or more of international areas. Previous recipients include Dr. Frances Mullen, first ICP Secretary General; Dr. Elisa Margaona, Mexico; and Dr. Frances Culbertson, USA, former president of ICP.

Nominees must be (a) either 20 years past the granting of their doctoral degree or at least 50 years old at the time of nomination, and (b) a Member of ICP. The award recipient will be asked to serve on a committee to select subsequent award winners.

Anyone, including a candidate him or herself, may nominate an ICP member for the award.

Nomination material includes: (a) nominee's curriculum vitae and (b) name, address, phone, fax, and email of nominator and nominee. Please send your letter of nomination and address any queries to:

Dr. Anna Laura Comunian, 2014-15 Chair.

E-Mail: **annalaura.comunian@unipd.it**

The Fukuhara Advanced International Psychology Research and Service Award

Submission Deadline: May 20, 2015

This award is given to a midcareer or senior level psychologist with distinguished contributions to international psychology in research and service and is funded through an ICP, Inc. Award Fund established by Dr. Machiko Fukuhara, past Treasurer of ICP, Inc., Organizer of the 1990 ICP conference in Tokyo, research collaborator with past president Charles D. Spielberger on State-Trait Measures of Anxiety, Anger, Curiosity, and Depression.

Dr. Fukuhara served two terms on the Board of the International Association of Applied Psychology and is Director of the Japanese Association of Microcounseling , Director of Psychoeducation Institute, and Honorary Professor of Tokiwa University. Dr. Fukuhara epitomizes the standards of excellence that ICP, Inc. and this Advanced International award is accompanied by a check, a certificate, conference registration for participation and presentation at the annual conference, and the next year's dues for ICP membership.

Please send your letter of nomination and address any queries to: Dr. Ann O'Roark., 2014-15 Chair.
Email: **annoroark@bellsouth.net**

The Denmark-Grunwald Award for Gender Research and Service

Submission Deadline: June 1, 2015

The Denmark-Grunwald Award for Feminist Research and Service is presented to honor a member of ICP who has the history of research and service that directly benefits the health, promotion and well-being of women in the world.

Anyone, including a candidate him or herself, may nominate an ICP member for the award.

Nomination material includes: (a) nominee's curriculum vitae and (b) name, address, phone, fax, and email of nominator and nominee. Please send to Dr. Donna Goetz, at **donnag@elmhurst.edu**

The Dayan-O'Roark InAbsentia Poster Awards

Chair: Dr. Anna Laura Comunian

Submission Deadline: July 20, 2015

These awards are to encourage participation by those students who are unable to attend the conference and want to present a pictoral abstract of their research work.

Judges are ICP members in attendance who have been professionals in the their field for a number of years.

The posters submitted remain on display throughout the duration of the Annual Meeting and Conference for all attendees to view. Winners are awarded a check and a certificate for their work.

ICP CALLS FOR SERVICE

CALL FOR APPLICATIONS FOR SERVICE AS SECRETARY GENERAL/ADMINISTRATIVE OFFICER

The International Council of Psychologists, Inc. Board of Directors authorized the re-opening of a call for applicants for the role of Secretary General for the association. Applications for this administrative role are not restricted by citizenship, race, gender, age or sexual orientation. Special consideration will be given to persons with experience in office management, background in a professional discipline associated with health and wellness, as well as experience in professional associations. *The position is not full time, compensation will be discussed related to expected operating expenses and some travel allotment.*

Interested members should contact Board Secretary Cecilia Cheng at cec.cheng@gmail.com

IP EDITOR WANTED

CALL FOR APPLICATIONS FOR IP EDITOR

1.1] The IP editor is selected from applicants responding to a public "call" for applicants presented in the IP, the ICP website, and several newsletters of other international and professional associations. The Outgoing Editor and C&P Chair serve on the Selection Committee with other ICP Members appointed by the President.

- The Selection Committee rank orders applicants and submits a report to the President. Following Board approval, the President, Secretary, and next IP Editor sign a letter of agreement for a term of three years, renewable for a second term.
- The IP Editor reminds leaders and members of upcoming submission deadlines and contacts particular leaders directly for timely submissions related to their responsibility areas.
- The IP Editor is guided by the newsletter protocol and special requests from the President, the Convention Chair, and the members.

Interested parties should contact Ann O'Roark at

annoroark@bellsouth.net.

CALL FOR 2015 NOMINEES

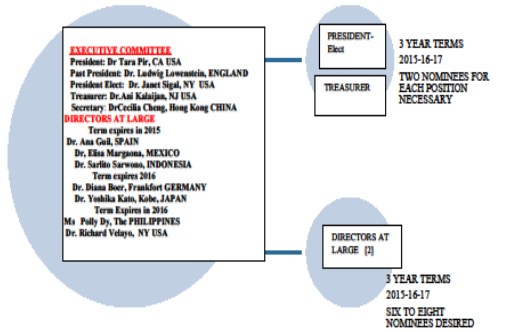

ICP, INC. BOARD OF DIRECTORS 2015 VACANCIES FOR SPRING BALLOT 2015

All must be members in "good standing" – dues paid. President and Treasurer are typically individuals who have served on ICP INC board previously, or held similar positions in comparable associations. The composition of the ballot intentionally represents the global nature of ICP, INC.

All nominations should be sent to Dr. Ludwig Lowenstein, ICP Past president as soon as possible. Elections need to be held in the spring months. At this time there are nominations needed for President Elect, Treasurer and two directors at large. (We have a few, but not enough!)

Please send nominations to:

Ludwig.lowenstein@BTinternet.com and copy Ann M. O'Roark (annoroark@bellsouth.net), Naty Dayan, Dennis Trent, Chik Hiew, and Anna Laura Comunian.
Thank you!

Views of Toronto, Canada

GUIDELINES FOR HOSTING AN INTERNATIONAL COUNCIL OF PSYCHOLOGY ANNUAL CONFERENCE AND BOARD MEETING

The International Council of Psychology, Inc holds an annual scientific program and Board meeting each year in accord with the policy of freedom of movement of scientists . The conference host (local arrangements committee) must be a member of ICP,Inc. To establish the feasibility of submitting an application, a potential applicant might begin with an overview of some logistical issues for proposing a Congress venue:

- Is there a conference venue to host at least 100 participants? (50)? (30)?
- Are there sufficient hotel rooms close to the conference venue
- Is there a scientific community to develop or sponsor the program?

Proximity in time and site to other major professional congresses. ICP operates in alliance with the International Association of Applied Psychology [IAAP, quadrennial congresses], the International Union of Psychological Science [IUPsyS, quadrennial congresses that meet in between the IAAP cycles]; the American Psychological Association or the Canadian Psychological Association; with options for meeting near allied professional association on intervening years.

Proximity in time and site to other major professional congresses. ICP operates in alliance with the International Association of Applied Psychology [IAAP, quadrennial congresses], the International Union of Psychological Science [IUPsyS, quadrennial congresses that meet in between the IAAP cycles]; the American Psychological Association or the Canadian Psychological Association; with options for meeting near allied professional association on intervening years.

Geographical Rotation among continents and countries attempts to guarantee broad geographical coverage, proximity to other major professional conferences, or in regions where psychologists may not have presented a scientific program previously.

The scientific community in the conference country is especially invited to participate in the scientific program.

Communication: There is a requirement for intensive and frequent communication between the Board President, Scientific Program Chair, Local Arrangements Chair, Workshops Chair, InAbsentia Student Posters Chair, and Awards Chairs.

Costs for participating in the Congress are another factor. The Board will expect that the registration fee will be reasonable, that there is a range of good hotel rates (particularly including inexpensive ones), and that travel costs can be kept as low as possible. Despite efforts to keep costs low, travel is expensive for **young psychologists**, and for psychologists from the **developing world and transition countries**. It is therefore important to provide a plan that will guarantee special fees, housing, and support for those colleagues.

A **balanced budget** needs to be provided in outline. It is important to show realistically how the income (registration fees and other) will cover your costs. It may be helpful to consult the preceding organisers of Conferences in drafting the budget. The budget is reviewed by the President and the Treasurer, who can offer advice.

ICP, Inc. is a volunteer organization. There are vacancies on the list below that you may be able to fill! If so, please contact President Tara Pir and let her know your interest. Her email is tarapirimces@msn.com.

ICP 2014-2015 APPOINTMENTS
STANDING COMMITTEES & Working Groups

Archives: Akron University Archives	Donna Goetz
Area Chairs, World Area Chairs Coordinator	Sandra E. S. Neil
Awards…Coordinator	Ann Marie O'Roark
Early Career *Bain-Sukemune Award*	Cecilia Cheng
Gender Research/ Service *Denmark-Gunwald*	Anna Laura Comunian
Distinguished Contributions *Mullin*	Anna Laura Comunian
InAbsentia Student Posters *Dayan-O'Roark-Hansen*	A.L. Comunian ; N. Dayan; A. M. O'Roark
Advanced International Research	Ann Marie O'Roark
Annual Appreciations/ Ambassadors	Annual President [Pir]
Communications and Publications	
News letter. *International Psychologist*	Editor: A M O'Roark. Contract Publisher: N Quatrano
Website. ICPWEB,COM	Manager: Contract: J.P.Abilla
Directory	VACANT
Proceedings	
Board Agenda Book	President [Pir]
Conference Program Book	President Elect [Sigal]
World Psychology [journal. On hold]	VACANT
Research articles: *International Understanding*	Editor: O'Roark; Publisher: Quatrano
Continuing Education	VACANT
Conference	
Coordinator and Scientific Program Chair	Janet Sigal, PE -President
Conference Local Arrangements Chair 2015	VACANT
Conference Long Range Planning	VACANT
Finance Committee	VACANT
Interest Groups Coordinator	Varda Muhlbauer
Liaisons Coordinator	Joy K. Rice
Membership Committee Chair	VACANT
Student Members Recruitment	Harold Takooshian
Nominations and Elections	Past President [Lowenstein]
Organizational Development	VACANT
Public Information Coordinator	VACANT
Parliamentarians	Florence Denmark; A. M. O'Roark
United Nations Committee Chair	Florence Denmark

ECOSOC Representatives

Florence Denmark, Main ECOSOC Representative	
Richard Velayo, PhD.	rvelayo@gmail.com
Janet Sigal, PhD.	janet2822@aol.com
Norma Simon, PhD.	normasimon@aol.com
Martin Butler, PhD.	butlerpsych@cs.com
DPI Representatives	
Pete Walker,PhD.	petewalker@aol.com
Vienna Main Representative	
Roswith Roth, PhD.	Roswith.roth@uni-graz-at
Geneva Main Representative	
Anna Laura Comunian, PhD	annalaura.comunian@unipd.it
Association Officers Registered	
Tara Pir, PhD.	tarapirimces@msn.com
Ludwig L. Lowenstein, PhD.	Ludwig.lowenstein@btinternet.com
Janet Sigal, PhD.	Janet 2822@aol.com
Ann Marie O'Roark, PhD.	annoroark@bellsouth.net
Student Representatives	
World Area Chairs	

INTERNATIONAL COUNCIL OF PSYCHOLOGISTS, INC.

Membership Application

ICP Banking and Records Assistant: Ms Nancy Quatrano

4625 Cedar Ford Blvd., Hastings, FL USA 32145

nancy@ontargetwords.com

MEMBERSHIP STATUS IS REVIEWED BY THE ICP MEMBERSHIP COMMITTEE AND BOARD CONFIRMED

_____ **A MEMBER** is a psychologist or professional in an allied discipline field who (a) holds or is eligible to hold membership in a national psychological association affiliated with the International Union of Psychological Science (IUPsyS), or (b) meets comparable requirements in their discipline or in a particular country, as determined by the application review agent, and (c) has been actively engaged for a period of not less than two years prior to application for membership in professional work or study that is primarily focused on quality of life, wellness, and is psychological in nature.

_____ **A STUDENT AFFILIATE** is a graduate student or full-time undergraduate student actively working toward a degree or certificate in psychology or in an area of study involving major emphasis on psychological aspects of a related field of study.

PREFERRED TITLE: Dr ___Prof ___ Mr. ___ Mrs. ___ Ms ___ Other_____

Languages spoken_____

FULL NAME (Print)_____

PREFERRED MAILING ADDRESS (Print)

City _____State _____Zip/Mail Code_____----_____

Country_____

TELE Home_____ TELE Work_____

CELL PHONE_____ FAX_____

E-MAIL_____ (all ICP communication is done via email. Please provide an address)

HIGHEST APPROPRIATE DEGREE OR CERTIFICATE (Degree, Date, Major Subject, Institution, Location)

_____

OTHER DEGREES

Student Affiliate applicant—you must provide (1) the name and address of your university, (2) name and address of your major professor, (3) your anticipated degree or certificate, and (4) your anticipated date of graduation.

_____

_____

ENDORSERS: all applicants (one or two—see instructions below): Names, addresses, and EMAIL addresses

_____

_____

_____

If you are a member of a national psychological association affiliated with the International Union of Psychological Science (IUPsyS), and are endorsed by at least one current ICP Board Member and/or Area Chair, you do not need to provide any other endorsement than the typed full name of that endorser or endorsers on the application.2. Other applicants: Please ask two professional persons to sign as endorsers on the other side of this application, or have them send a letter of endorsement directly to the ICP Secretariat (address at the top of this page). These endorsers should be familiar with your training and/or experience in psychology, and should either be members of ICP or be recognized professional persons who can be identified by the Membership Application Processing Committee.

If endorsers are not available, please submit a complete curriculum vitae or resume with your application.

[continued on next page]

PAYMENT: The ICP Membership year is January 1 – December 31. Late fees effective February 1

Country of residence determines dues category. Please write "yes" in front of one category.

_____CATEGORY "A" COUNTRIES OR AREAS: $100 (U.S. DOLLARS)

(Australia, Austria, Bahrain, Belgium, Brunei, Canada, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong, Iceland, Ireland, Israel, Italy, Japan, Kuwait, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Qatar, Saudi Arabia, Singapore, Spain, Sweden, Switzerland, Taiwan, United Arab Emirates, USA)

_____ CATEGORY "B" COUNTRIES: $60 (U.S. DOLLARS)

(Antigua & Barbuda, Argentina, Bahamas, Barbados, Brazil, China, Croatia, Cyprus, Czech Republic, Iran, Korea, Malaysia, Malta, Mexico, Oman, Poland, Seychelles, Slovakia, Slovenia, South Africa, Suriname, Turkey, Venezuela, Yemen)

_____CATEGORY "C" COUNTRIES: $40 (U.S. DOLLARS) (All other countries)

____ STUDENT AFFILIATE: _____Category A: $10 US _____Category B: $10 US _____

Category C: $10 US _____

APPLICATION AMOUNT DUE $_____

PAYABLE TO: INTERNATIONAL COUNCIL OF PSYCHOLOGISTS, INC.

See HTTP://WWW.ICPWEB.ORG for Credit Card & PayPal plus Background Form

Send Application and Payment or Confirmation of Payment To:

Ms. Nancy Quatrano Via Street Or Email Address Given At Top Of Application

A COPY of application will be sent to Board Secretary:

Dr. Cecilia Cheng, Hong Kong, China

Credit Card payments accepted at http://www.ICPWEB.ORG

Use PAYPAL options for dues payments.

Complete background information form online.

If you would like to volunteer for a committee assignment (recommended) fill out the Committee Assignment Worksheet (below) and submit with this application form.

See next page for committee volunteer opportunities

[continued on next page]

Applicant Committee Assignment Worksheet

_____ I volunteer for the Committee assignment shown.

_____ Please send more information on the Committee assignment shown.

____ **Archives Committee**:
Committee Chair is liaison to and communicates with the Archives of the History of American Psychology at the University of Akron, Ohio. Information about AHAP is provided in the newsletter several times a year along with instructions for how members are to ship ICP records, older than three years to the Archives
.

_____ **Area Chair**:
Area Chairs represent ICP, Inc. in a specified geographic region. Country or State Area Chairs are coordinated by the World Area Chairs Coordinator and submit reports twice a year to the WACC for publication in the newsletter and for an annual report to the President and Board. Disseminating information about ICP, Inc. conferences, recruiting members, and organizing regional meetings are typical activities of Area Chairs.

____ **Awards:**
Committee members issue calls for nominations in relevant newsletters and websites, solicit several candidates, review documents submitted, arrange certificates and stipends if provided, arrange for appropriate time allocations in the annual conference scientific program, prepare newsletter and regional announcements of recipients, in order of establishment by ICP, Inc.

___**Distinguished Contributions and Outstanding Service to International Psychology**. Frances Mulen Award [1986]
___**Gender Research and Service**: Denmark-Grunwald Award
____**Early Career Research**: Bain-Sukemune Award [1996]
____**InAbsentia Student Poster Exhibit and Awards**: Dayan-O'Roark-BarredaHansen-Comunian [2005]
____**Latin Student Research Paper** presentation at Annual conference: Ernesto Gonzalez Rosales Alvarez / McCarthy Award [2009]
____**Advanced International Research and Service**: Fukuhara Award [2011]

____ **Membership Committee**:
Committee Chair provides recruitment literature, records application information, updates contact data and membership details for newsletter publication, and welcomes new members, contacts non-continuing members and provides statistics on membership constituencies to the President and Board. Committee members assist the Chair with recruiting and maintenance activities in their regions.

____ **Continuing Education:**
Committee members meet via telephone and email to develop call for proposals for workshops for the annual scientific conferences. CE administers the necessary documentations for awarding continuing education credits. In addition to developing the ICP, Inc. World CE program, the American Psychological Association CE sponsor authorization is maintained or arranged with allied organizations..

____ **Finance Committee**:
Committee members review the annual budget and assist the Treasurer as requested. FC oversees and makes recommendations for ICP, Inc.'s financial investments and award programs. The FC audits the tasks of the Treasurer annually.

____ **Interest Groups:**
Interest Groups are formed to enable collaborations on topics of professional concern or research. Groups plan joint research and/ or program events for the annual scientific conference. Papers are presented in the International Understanding section of the newsletter.
Currently active groups are:

____ Creativity & Education [Milgram]
____ Forensic [Lowenstein]
____ Health [Pir]
____ Peace and Human Rights [Neil]
____ Religion & Spirituality [Rayburn]
____ Women's Issues [Muhlbauer]

____ **Liaison Representatives**
Individuals who are members of professional associations other than ICP, Inc. submit articles to the Liaison Coordinator for presentation of information about that organization in the newsletter and submit ICP, Inc. information to the association in which they hold membership/represent.

____ **Long Range Conference Planning:**
Committee members solicit and review proposals for ICP, Inc. annual conferences 3 to 5 years in advance. Timing and sites are coordinated with major professional congresses. LRCP presents completed proposals from the proposal submitters. Once a Local Arrangement Committee (LAC) is established, LRCP provides information and assistance. The LAC makes arrangements for meeting site, hotel information, tours, banquet, and promotional materials.

International Council of Psychologists, Inc. 2014

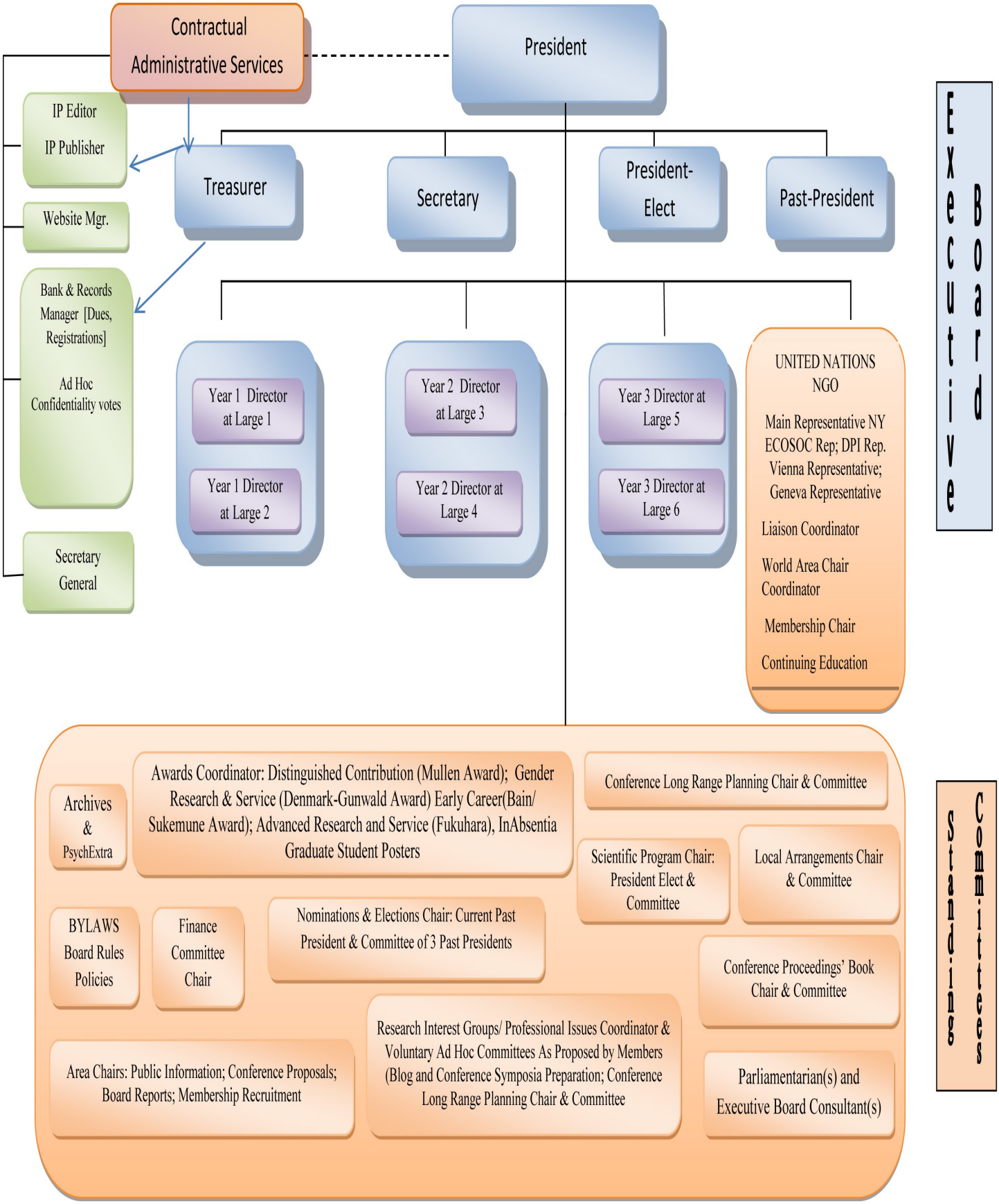

WWW.ICPWEB.ORG

INTERNATIONAL COUNCIL OF PSYCHOLOGISTS, INC. DIRECTORY 2014-15

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Tara Pirhekayaty, PhD
3580 Wilshire Blvd #2000
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tarapirimces@msn.com

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1000 River Road
Teaneck, NJ 07666 USA
Janet2822@aol.com

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drkalayjian@meaningfulworld.com

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Psychology Department
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Hampshire, SO50 7DE, UK
Ludwig.lowenstein@btinternet.com

Directors at Large (Exp. 2015)
Ana Guil
C/ Columbia N. 8,Urb:Maestranza de Simon Verde
Gelves, Sevilla 41120 Spain
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МЕЖДУНАРОДНОЕ НАУЧНОЕ СОТРУДНИЧЕСТВО

BUILDING BRIDGES: PSI CHI AND INTERNATIONAL PSYCHOLOGY

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"How can Psi Chi best partner with international psychologists to expand the honor society worldwide?" This has been an important question since 2009, when the 1,100 chapters of Psi Chi in the United States voted to become "The International Honor Society in Psychology". This report updates and expands on a unique symposium offered at the 120th meeting of the American Psychological Association in Orlando, Florida, in August of 2012 — the first symposium on the Presidential theme of "Building Bridges" between Psi Chi and international psychology [8]. Here, seven leaders in international psychology in North and South America join to address different aspects of this timely question--with many suggestions on how to "build bridges" to expand Psi Chi globally. It was in part due to this historic symposium that in 2013 Guatemala became the first nation in Latin America, and Russia the first nation in mainland Europe to launch a chapter of Psi Chi.

Key words: International Honor Society in Psychology Psi Chi, American Psychological Association (APA), international psychology, student scientific society, scientific work of students.

OVERVIEW

(by Martha S. Zlokovich)

The field of international psychology is expanding as people around the world connect to share ideas about psychological and social issues, psychology education, and psychological interventions. In 2009 Psi Chi, the National Honor Society in Psy-

chology — founded in 1929 in the US — became Psi Chi, the *International* Honor Society in Psychology. The purpose of this symposium was to learn more about the internationalization of Psi Chi including how and why the Society has been welcoming international Psi Chi chapters. The individual presentations were followed by discussion of the issues brought up by the symposium presenters.

Many of the contacts Psi Chi makes outside the US are dependent on the time, effort, and dedication of international psychologists who spread the word about Psi Chi when they travel. Since 2009 the first two international chapters (affiliate chapters in Canada and Ireland that became full chapters at that time) have expanded to 15. These include 12 chapters in ten countries, and another three chapters outside the 50 states. As of September 2014, additional applications were in progress from faculty in Australia, Ecuador, India, Indonesia, Italy, Kuwait, Malaysia, The Netherlands, Puerto Rico, and Serbia [20; 21].

WHAT IS INTERNATIONAL PSYCHOLOGY?

(by Alvin Y. Wang)

What is International Psychology? What are reasons for Psi Chi to become an international organization? How can chapter advisors help internationalize their chapters?

In 2009, after several years of deliberation, Psi Chi's Board of Directors elected to "*go global.*" It is interesting to note that Psi Chi was founded at the Ninth International Congress of Psychology which took place on September 4, 1929 at Yale University. So 80 years after its founding, Psi Chi returned to its international roots.

Psi Chi's Purpose Statement was revised to reflect its global aspirations: *Psi Chi is an international honor society whose purpose shall be to encourage, stimulate, and maintain excellence in scholarship of the individual members in all fields, particularly in psychology, and to advance the science of psychology.* With this global vision, Psi Chi began to rebrand its logo, redesign its website, and update its marketing efforts to better serve the international psychology community.

Since 2009, Psi Chi expanded its outreach efforts to cultivate new friends and partnerships with organizations that share Psi Chi's vision for advancing psychology in the international arena. In this regard Psi Chi views APA Division 52 as a steadfast partner who has helped us build bridges across international waters. Several members of Division 52 were instrumental in these efforts. Dr. Harold Takooshian (former Psi Chi President) promoted Psi Chi to four Russian institutions in Moscow including: the Higher School of Economics (HSE), HSE's International Laboratory of Socio-cultural Research, the People's Friendship University of Russia, and the Russian Academy of Science's Institute of Psychology. Also instrumental in our friend-raising efforts was Dr. Mercedes McCormick, who is incoming President of Division 52 and Psi Chi Vice-President for the Eastern Region. Dr. McCormick promoted and implemented joint programming between our two organizations at the 2012 annual meeting of APA as well

as past meetings of the Eastern Psychological Association. Psi Chi is also appreciative of the support and sage advice concerning internationalization provided by two of Psi Chi's past-presidents: Dr. Florence Denmark and Dr. John Davis.

Psi Chi's Executive Director Dr. Martha Zlokovich has racked up her frequent flier miles while travelling overseas to promote our organization. In November of 2011, she attended the Caribbean Regional Conference on Psychology in the Bahamas and in July 2012 she attended the annual meeting of the International Association of Cross-Cultural Psychology in South Africa. This was followed by a Psi Chi presentation she made at the annual meeting of the International Congress of Psychology which was also in South Africa. There were several co-presenters including Psi Chi President Dr. Susan Amato-Henderson and Psi Chi President-Elect Dr. Maria Lavooy. It is also noteworthy that Dr. Zlokovich is incoming chair for the International Relations Committee of Division 2 and she is also a member of the Division 52 International Committee for Women.

Early Psi Chi's efforts began showing results, with the first five international chapters established in Canada (2), Ireland, New Zealand, and Egypt. We also have chapters in Puerto Rico (2) and in the U.S. Virgin Islands. Two chapters have been approved for University of the West Indies campuses (Barbados and St. Augustine), and several other international chapters are in various stages of the review process including: Russia, Guatemala, Australia, and England.

As with any organizational expansion, growing pains are to be expected. Psi Chi's Board of Directors is currently discussing several issues related to our international efforts. Perhaps the most critical is how we can meaningfully integrate international chapters into the governance structure of our society. One possibility is that an international region is created in additional to the six regions that currently exist. Another issue is that Psi Chi must improve its IT infrastructure to better meet the needs of our international chapters. Finally, Psi Chi's Board of Directors has been discussing ways in which our international chapters can participate in the numerous grants and awards programs that are available to students and faculty members.

As I pointed out earlier in my presidential message to Psi Chi members, "the time is right for Psi Chi to sit at the global table and join the transnational discourse that already exists through organizations such as Division 52..." [19. P. 4]. I am pleased to report that as of now Psi Chi has made significant advances in its efforts toward internationalization.

COMMUNITY INTERNSHIPS: STRENGTHENING MULTICULTURAL COMPETENCIES THROUGH INTERNATIONAL COLLABORATIONS

(by Maria del Pilar Grazioso)

In my Universidad del Valle de Guatemala (UVG), our students and faculty have a long tradition of working together on community partnerships. In 2013, after three years of effort, our UVG successfully formed the first chapter of Psi Chi in Latin America. One key project we hope to pursue is culturally-appropriate Spanish-language materials

to help introduce the Psi Chi concept to the hundreds of four-year colleges throughout Latin America. In July of 2014, our chapter was pleased to release a five-minute, Spanish-language video that is suitable to show throughout Spanish-speaking Latin America, www.youtube.com/watch?v=xo2lsDKtiw4&feature=youtu.be.

We hope to expand on this early effort, to promote Psi Chi globally.

PSI CHI OUTREACH TO THE EASTERN HEMISPHERE

(by Harold Takooshian)

How can Psi Chi best expand beyond North America? Though Psi Chi had its origins at an international meeting in 1929, it has been limited to the USA for its first 80 years [15]. Yet Psi Chi has long been interested to open its benefits to the fast-growing number of psychology students and faculty outside the USA [5], to the point of inspiring a new international student group on its 70th anniversary in 1999 — the International Psychology Student Organization, or IPSO [16]. We know Psi Chi's immense role in shaping psychology in the USA [6], which it portends to do in other nations [10; 12; 14].

On its 80th year in 2009, when Psi Chi chapters voted to "Go global," many leaders of the APA international division were also past national officers of Psi Chi. Prime among these in 2012 was Psi Chi Eastern Vice President and Division 52 President-elect Mercedes McCormick, who chose her timely Presidential theme for 2013: "Building Bridges between Psi Chi and international psychology" [8].

In 2013, the Psi Chi Board appointed 14 Psi Chi "International Ambassadors" within the APA Division of International Psychology, to spread the word about Psi Chi while traveling abroad [13]. These 14 Ambassadors were: Bernardo J. Carducci, Lauren Crane, Dwayne Crites, John M. Davis, Florence L. Denmark, Melanie Domenech Rodríguez, Joseph R. Ferrari, Gina Grimshaw, Paul I. Hettich, Hy Le Xuan, Mercedes McCormick, David Skeen, Michael J. Stevens, Harold Takooshian.

As of 2014, the 1,100 Psi Chi chapters at U.S. campuses include nearly 90 percent of eligible U.S. four-year colleges. In contrast, Psi Chi has barely a dozen chapters among the thousands of campuses now eligible on six other continents.

Russia. In 2010, to mark the 125th anniversary of the origin of psychology in Russia in 1885, Professor Alexander Voronov integrated Psi Chi into his five-day multi-city conference [18]. Hundreds of students and faculty at five institutions in two cities appeared visibly excited to learn about the benefits of Psi Chi. One professor, Alexey Sozinov of the Russian Academy of Sciences in Moscow, went further to produce a nine-minute Russian-language DVD describing Psi Chi in detail--its origin, growth, procedures, benefits. This DVD was posted on YouTube, http://youtu.be/1t63fKZ1OPY. Teams of Russian students and faculty began to participate in Psi Chi programs in the USA in the 2011 EPA in Cambridge, 2012 EPA in Pittsburgh, 2013 EPA in New York, 2014 EPA in Boston [1; 11].

In 2012, when I returned to Russia as a Visiting Professor at the Higher School of Economics (HSE), I could see changes within just two years. Students at a few Russian

schools had formed active psychology clubs. (One chapter application requirement is having had an active psychology club for at least one year.) Students were becoming more involved in co-curricular research and other activities [4]. The People's Friendship University of Russia (PFUR) hosted co-curricular activities for its 20,000 students from 140 nations (www.rudn.ru/en/). The Institute of Psychology at the Russian Academy of Sciences (IPRAS) hosted co-curricular activities that brought together students and faculty from diverse institutions, http://ipras.ru/cntnt/rus/novosti/rus_news1/n3468.html. Each of the four institutions I visited was pleased to receive a copy of President-elect Mercedes McCormick's personal invitation to the next Eastern Psychological Association meeting in New York City on 1—4 March 2013, and many came in 2013 in New York and 2014 in Boston.

Russia's land area of 6.6 million square miles makes it the "world's largest nation", and one where Psi Chi may grow rapidly among Russia's 1,100 HEIs (higher education institutions). Hopefully, Psi Chi may use the internet and this Russian outreach model to develop culturally-appropriate DVDs in other languages (Spanish, Arabic, Chinese, French) to reach the countless students and faculty who do not yet know what awaits them in Psi Chi.

In 2013, history was made on October 11, when the Peoples' Friendship University of Russia installed the first chapter of the Society in Russia and mainland Europe [2; 3]. Details on-line: www.youtube.com/watch?v=ggtdPVAPjJY. In that same week in October of 2013, PFUR appeared in the roster of "the world's top 500 universities" in the *QS World University Rankings* for 2013 (www.rudn.ru/?pagec=3372).

WHAT AN INTERNATIONAL UNIVERSITY/COLLEGE NEEDS TO KNOW TO APPLY TO BECOME AN INTERNATIONAL PSI CHI CHAPTER

(by Mercedes A. McCormick)

How does an international university/college start an international chapter in Psi Chi International Honor Society, and foster Psi Chi connection with APA Division 52, International Psychology? In the 21st century, it is fitting for Division 52 and Psi Chi to connect and collaborate on issues important to undergraduate and graduate students as they embark in careers in psychology [8]. It is clear that "the recent expansion of Psi Chi internationally promises to offer student members assistance on the path to academic excellence, exciting research possibilities, leadership opportunities, mentorship for career advancement, and opportunities to provide service to their communities" [9. P. 112].

Background. Psi Chi's international connections stretch back to its very formation on September of 1929, during the Ninth International Congress of Psychology in New Haven-the first world congress on U.S. soil [7].

In 1963, Psi Chi sent psychology textbooks overseas, published a special global issue of its *Psi Chi Newsletter*, and hosted overseas students at the APA meeting. In 1964, Executive Director Ruth Cousins joined a 20-person world tour with the International Council of psychologists (ICP), which later appointed an ICP liaison to Psi Chi. In 1984,

Psi Chi changed its bylaws to allow international chapters, and in 1990s, another push saw Psi Chi welcome applications from schools in Canada, though none completed the chapter process.

In 1994, Psi Chi formed an international committee with a liaison to APA's CIRP, and the committee's chair visited the ICP meeting in Lisbon, Portugal to inform colleagues in other nations about the "impact of a student honor society on a nation's psychology" [12]. Among other things, this committee also worked with APA's Joan Buchanan to conduct two surveys of 75 national psychology associations, to find which nations had student psychology groups like the USA; although no nation reported an independent student group. 15 (20%) permitted some students to affiliate with their national association.

In 1996, Psi Chi invited 50 Canadian schools to its first student mini-convention outside the USA (*Upward Bound*), hosted by the University of Toronto on the Thursday before the APA meetings, and a small cadre of Canadian students joined about 80 U.S. participants.

In 1999, past-President Slater Newman organized a session at APA exploring the formation of the first international student group, close on the heels of his 1998 article in the International *Journal of Psychology* detailing Psi Chi as a "model [that] might well be adapted by leaders in other nations to promote student excellence" [14. P. 367]. In Spring of 2000, *Eye on Psi Chi* published a special issue on international psychology edited by Kay Wilson and Dan Bockert, bringing together original articles by several key cross-cultural figures — Walter J. Lonner, John Davis, Leonore Loeb Adler--and launching the Eye's new International Notes column.

How can Psi Chi members become more involved in this growth of international psychology while still students? Let us see.

Psi Chi's International Connection. In 2012, APA's Division 52 of International Psychology marks its 15th anniversary. In 1997, APA approved this new Division. It quickly grew into a large and active force within US psychology and now internationally. It is important to note that Psi Chi members and Chapter Advisors have been so much at the forefront of this effort.

Several Division 52 Presidents also have been President of Psi Chi. These respected international psychologists include: Florence Denmark (Division 52 President in 1999, Psi Chi President in 1978—80), and Harold Takooshian (Division 52 President in 2003, Psi Chi President in 1998—1999.)

In 2009, Psi Chi went international. In Psi Chi bylaws, the name of the organization was changed to *Psi Chi International* with the mission to be a society in psychology to promote student excellence, leadership, research, and service learning internationally. Since 2009, Psi Chi International has encouraged international colleges and universities to petition to open a Psi Chi chapter. Already a dozen chapters started with the National University in Galway, Ireland; American University in Cairo, Egypt; University of West Indies; Peoples' Friendship University of Russia; and more--as Psi Chi expands globally.

The Psi Chi website has instructions to start a Psi Chi Chapter, www.psichi.org.

INTERNATIONALIZING PSI CHI

(by Florence L. Denmark)

Thank you to our esteemed panel of presenters who have spoken on the psychological and social issues that impinge on Psi Chi students in a world that is becoming increasingly more global.

In 2009 Psi Chi, the Honor Society in Psychology in the US became the *International Honor Society of Psychology,* an impressive accomplishment. This will truly help the next generation of psychologists create a cohesive field of psychology internationally.

The field of International Psychology is expanding as the world connects globally about issues regarding coping with psychological and social issues and learning about interventions that may help others in our global society.

Division 52 is the primary Division within APA with a focus on internationalization of Psychology, whereas Psi Chi is the biggest and newest "international" psychology organization with students, faculty, and other professionals comprising its membership worldwide.

Psi Chi and Division 52 were represented in the conference of the International Congress of Psychology and the International Council of Psychologists recently held in Cape Town, South Africa (July 22—27, 2012).

Going forward, it is our goal to build bridges between Psi Chi and Division 52. We can begin by focusing on the following.

1. *Membership/Outreach*

Assist each other in helping establish chapters during travels abroad.

Sharing resources with each other to help internationalize psychology and outreach for members (collaborative membership drive)

Division 52 members in institutions with Psi Chi Chapters can encourage students to join Division 52. Conversely, Psi Chi chapters can help Division 52 recruit Psi Chi students as student affiliates.

2. *Meetings and events*

Share a suite and collaborate on suite activities

Division 52 may give reports on its activities relevant to Psi Chi members through meetings (and vice-versa)

Having joint session such as this one in future APA meetings

Psi Chi programs can include Division 52 — featured events, talks (and vice-versa)

Speakers Network — focus on student-relevant matters

3. *Mentorship opportunities*

Division 52 members can mentor students

Psi Chi students may become involved in international research and internship opportunities with Division 52 members

4. *Publications*

Psi Chi Journal of Psychological Research, International Psychology Bulletin, International Perspectives in Psychology: Research, Practice, Consultation — provide opportunities to publish collaborative international research

Division 52 President (and perhaps other leaders of Division 52) may write articles on *Eye on Psi Chi.* Conversely, Psi Chi leadership may publish in the *International Psychology Bulletin.*

5. *Grants/Funding Opportunities for mutually beneficial projects*

Collaborative research grants between Psi Chi students and Division 52 members

Division 52 and Psi Chi can pool resources to help fund projects between its members.

6. *Awards*

Recognition given by both Psi Chi and Division 52 to recognize collaboration on research work between students and international psychologists on topics that promote international psychology.

7. *Governance*

Encourage Psi Chi and Division 52 to have representatives/liaisons to attend their midwinter or annual meetings

BUILDING BRIDGES WITH TECHNOLOGY

(by Richard S. Velayo)

I thank our outstanding panel members for their informative presentations. Their information and recommendations will certainly strengthen the international reach of Psi Chi, contribute to building bridges between Psi Chi and Division 52 and more importantly, help promote the internationalization of psychology.

Psi Chi and APA Division 52 can benefit from each other in so many ways. In a way, we are meant for each other. We share an important goal of internationalizing psychology and providing opportunities for students, faculty, practitioners, researchers, and advocates for internationalization to be able to collaborate and share experiences and expertise with each other.

What I would like to emphasize here is how internet-based technologies may help build bridges between Psi Chi and Division 52, which, in turn, further the internationalization efforts of both organizations. In other words, we can go global by going virtual! Internationalization efforts by Psi Chi and Division 52 may continue to explore further innovative ways to collaborate and do outreach.

Many organizations effectively utilize social media in their attempt to reach out to other nations. Psi Chi and Division 52 are no exception. For example, as of March, 2012, both have Facebook group pages effectively establishes their web presence to the world. Facebook, the most popular social networking site, had over 835 million active users worldwide. Of the 835 million users, 233 million came from Europe, 196 million from Asia, 173 million from North America, 113 million from South America, 41 million from Central America, 40 million from Africa, 20 million from the Middle East, 40 million from Oceana and Australia, and about 6 million from the Caribbean (*http://www.internetworldstats.com/facebook.htm*).

Facebook is also accessible in more than 70 different languages. An average of 500 million people log on to use Facebook everyday. The percentage of users in various

countries who are on Facebook are astonishing: 80 percent of all Internet users in Chile, Turkey, and Venezuela, 60 percent of all Internet users in the U.S. and U.K., 20—30 percent of all Internet users in Brazil, Germany, and India, and 15 percent of all Internet users in Japan, Russia, and South Korea. Unsurprisingly, there is less than 0.1 percent in countries that restrict Facebook (like China) [17].

Nonetheless, the global usage and reach of Facebook, and many other Internet-based technologies, is tremendous. Its use by so many students and various academic, professional, and business organizations is indicative of the future of inter-organizational communications in a world that is increasingly global and interconnected.

Also note that there are various other forms of Internet-based technologies: teleconferencing (e. g., Skype), Twitter, Blogs, GoogleTalk and Google+, Wikis, YouTube, and even FaceTime (for Mac, iPhone and iPad users), all of which can facilitate internationalization efforts and outreach.

Bridges. Below are a variety of ways to build bridges between Psi Chi and Division 52 through shared objectives related to membership, meetings and events, mentorship opportunities, publications, grants and funding opportunities, awards, and governance. All of these objectives are feasible and may be efficiently and effectively facilitated, in part, through electronic communications. These are some practical recommendations on how the Internet may build bridges given the shared objectives of both organizations.

1. *Membership and Outreach*

Recruitment efforts may be shared and be done virtually through social media and other internet-based communications. Having membership application forms that encourage dual membership, can be created. Such forms may even be completed online and perhaps presented in different languages.

Division 52 members can send out information regarding Psi Chi activities and events, through their social media accounts and through departmental listservs/emails/ and electronic newsletters. Psi Chi can do the same with Division 52 activities and events.

International Psi Chi chapters can regularly and efficiently keep in touch with the Psi Chi central office, mutually providing each other updates of news, events, and other activities. Selected news may be shared among various Psi Chi chapters and international psychology organizations.

2. *Meetings and events*

Members can participate (and perhaps even present) in activities through Skype, webinars, or even through blogs. Videos of collaborated events may even be posted on YouTube. Facilitating meetings, coordinating events and activities, can be conveniently and easily shared.

There may be times in which students abroad are unable to attend a conference or to be recognized for their leadership or scholarship. Perhaps Division 52 and Psi Chi may explore ways in which members can participate and even present their work through

online meetings, webinars, or even through Skype. Such sessions can be highly interactive between participants and presenters, wherever in the world they may be as long as they have internet access.

3. *Mentoring.* Division 52 members may be able to do their mentoring online.

4. *Research and Grants*

Division 52 and Psi Chi can collaborate on developing a web-based repository of reviewed projects and articles by students from various parts of the globe.

Use of wikis or Google docs to work on electronic documents and projects may be utilized in preparing publications or presentations.

Division 52 members and Psi Chi can work collaboratively on applying for and carrying out grant projects.

Students may help with creating online surveys and in data collection through social media sites.

5. *Governance and Committee involvement.* Members of both organizations may contribute their time and participate in meetings online, which may be an efficient and lower-cost alternative to meeting in person at conferences or midwinter meetings.

In spite of these recommendations, it is wise to keep in mind at least two anticipated difficulties that will likely be encountered. First is that access to the Internet may be limited in other countries, reducing their ability to communicate internationally. Second, language barriers can certainly be problematic between certain nations. Online translation software is becoming more sophisticated to help people to communicate, but it has not reached that level in which we can completely trust this technology to translate one language to another.

In conclusion, Psi Chi and Division 52 are a natural match. It is reassuring to know that a number of its leaders (including our esteemed panelists), continue to serve as important conduits to strengthen the bridges that have been built between our two organizations.

If there are those of you who are not yet members of Psi Chi or of Division 52, I urge you to join both, and to join now, to be part of this tandem force. Given this bridge that has been established, you can expect both our organizations to continue to be at the forefront in the effort to internationalize psychology.

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ПСИХОЛОГИЧЕСКОЕ ОБЩЕСТВО ПОЧЕТА PSI CHI И МЕЖДУНАРОДНАЯ ПСИХОЛОГИЯ: УСТАНОВЛЕНИЕ КОНТАКТОВ

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Статья посвящена поиску ответа на вопрос о том, как партнерство с международными психологами может помочь интернализации Психологического общества почета Psi Chi. Этот вопрос стал актуальным начиная с 2009 г., когда 1100 отделений Psi Chi в США проголосовали за то, чтобы стать «международным» обществом. Статья представляет собой обновленный и расширенный отчет об уникальном симпозиуме, состоявшемся на 120-м съезде Американской психологической ассоциации (АПА) в Орландо (штат Флорида) в 2012 г. Это был первый симпозиум по предложенной Президентом АПА теме «Наведение мостов» между Psi Chi и международной психологией [8]. На симпозиуме выступили семь лидеров международной психологии из Северной и Южной Америки со своими предложениями о глобализации Psi Chi. Отчасти благодаря этому историческому симпозиуму в 2013 г. Гватемала первой из стран Латинской Америки, а Россия первой из стран континентальной Европы открыли свои первые отделения Psi Chi.

Ключевые слова: Международное психологическое общество почета Psi Chi, Американская психологическая ассоциация (АПА), международная психология, студенческое научное общество, научная работа студентов.

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Part B: International Psychologist Spring 2014 Edition

By Dr. Ann Marie O'Roark, Editor
International Psychologist A/B

This Part B is intended to be used for longer reports and as a place for the ICP's Research Interest Groups to present their collaborative work. One expectation is that *IU* can be a linking pin between print media and electronic communications offered through the ICPWEB.ORG site. Dr. Varda Muhlbauer [Israel] is exploring ways with the help of new Director at Large Diana Boer [Germany] to implement a blog for scientific conversations and professional discussions, as well as using it for planning conference symposia and joint research projects.

We certainly hope that you will enjoy this ICP publication and consider contributing to future issues. This is a fine venue for sharing your work with others in our field.

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Helping Prevent Elder Abuse Globally Through the Use of Social Media

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Elder abuse is a single or continuous exploitative behavior, or failure to take an appropriate action (as expected) in a relationship, which involves trust, and eventually causes distress or psychological harm to an elderly person. This form of mistreatment can occur at home within a family, care givers/assistants, friends, etc. or in an institution such as a nursing home in the hands of a professional caregiver. Approximately 2.1 million elderly people in America are victims of elder abuse yearly. Neglect and failure to carry out a responsibility towards an elderly person are the most common forms of abuse. Other forms of abuse which often cause psychological and emotional harm include lack of respect and denying the elderly freedom (e.g. freedom of expression and doing what makes them happy like listening to music), controlling all their moves and making all decisions for them, threatening to withdraw care, bullying, financial exploitation (e.g. misappropriation of the wealth of an elderly person, exploiting their finances and depriving them the right to use their wealth as desired, denying them access to their property and giving them false reports regarding their wealth). Other forms of elder abuse include physical abuse like beat-

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ing or slapping, unnecessary medical sedation, and physical restraint, as well as sexual abuse (Bagshaw, Wendt & Zannettino, 2007). This paper explores the various forms of elder abuse and how social media can be useful in reversing this vice.

Statistics indicate that women are more commonly the victims of elder abuse and perpetrators of this abuse are mostly men, particularly family members, partners or spouses. People aged 85 years and above are more likely to undergo elder abuse than those aged between 65 and 84. Moreover, exploitation increases as the health of victims deteriorates. Also, elderly people who have a lower socio-economic status are more likely to experience elder abuse. Other aspects like psychological disorders, physical injury, cognitive impairment, restricted mobility, fear of isolation, ignorance of their rights and social isolation can increase the risk of an elderly person being mistreated (Bagshaw, Wendt & Zannettino, 2007). Some individuals hold the belief that elderly people are weak, helpless and less significant in society. These are ageist attitudes, which make society more tolerant of elder abuse and ignore the detrimental consequences faced by the elderly. However, the good news is that elder abuse can be prevented. Although few studies have been put forward on prevention of elder abuse, there is still hope for the elderly. This paper explains how social media can be used to prevent the pervasive problem of elder abuse.

Social media, the society, and prevention of elder abuse

Social media is a technology, which uses web-based techniques to offer information and create awareness on several issues. Social media can also be used as a tool that creates dialogue among front-line employees looking for support and professional assistance on how to stop elder abuse. Caregivers from rural areas and remote places often feel isolated, unappreciated and unmotivated in their profession. Continued communication among caregivers is important because they can share information, encourage each other and share updates on what is happening in their local areas. This is where social media comes in handy though avenues like "exploring the space between" (an experimental blog that invites communication for professional and caregivers for the elderly), "CHNET-Works" (a conference system for health professionals) and "USTREAM TV" (a live streaming resource used on various geographic levels). Chat services enable immediate and prompt communication between individuals and they can also share photos. This increases support for other caregivers and gives them an opportunity to obtain professional guidance from others. When caregivers and professionals who deal with the elderly connect, they can share information, which will be useful in eliminating elder abuse in the society (Cooper, Selwood & Livingston, 2008).

Currently, statistics indicate that more elderly people are using the Internet and social media than ever before. Statistics Canada (2011) reported that age is a significant factor in determining Internet use regardless of the other factors being taken into account such as income and education levels. In 2010 alone, 80% of Internet users over 45 years old were between 45 and 64 years. Those aged 65 and above were less likely to use the Internet and the percentage of Internet users declined with age (Kathryn & Mary, 2012). However, current statistics indicate that the elderly are increasingly using the Internet and social media, and they are the fastest growing category of Internet users. In a 2012 survey by American Life Project and the Pew Internet, 34% of those aged 65 and above used the Internet and another study by Ipsos Reid research firm indicated that 44% of those aged 55 and above used the Internet. Of the people who contribute to blog content, take part in discussions, upload photos and participate in social networking, 9% of them are aged between 55 and 65 (Ipsos, 2011). This trend is a clear indication that the Internet and social media is an important tool for creating awareness about elder abuse and offering advice through current support services (Kathryn & Mary, 2012).

Social media creates forums and groups where individuals can hold discussions, share information, communicate, and work together towards a common goal. Social media includes blogs, twitter and Facebook. People have the opportunity to share personal opinions and professional recommendations on blogs. Facebook gives individuals an opportunity to meet friends and create a group where people can form a network, which they use to share information, photos

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and post updates. Twitter is a short instant messaging network, which gets updated immediately as a message is uploaded. These social networks are often free of charge and even if they have to charge, the cost is very little. They are also accessible from any place, at any time. Moreover, the elderly need to get awareness about what they should tolerate and what not to. For instance, a support group can start a blog, which posts articles or provides information that highlight behaviors and actions that the elderly should accept from caregivers and what they should report as abuse. This blog can offer advice and help to locals in knowing what is acceptable; hence, increasing awareness (Cooper, Selwood & Livingston, 2008).

The fundamental issue that has given birth to the spread of elder abuse in society is the negative attitude that people often carry towards the elderly. The first step is therefore, creating an atmosphere, which encourages a positive attitude towards the elderly. Many people, especially the youth have stereotypes, negative attitudes, and discrimination towards the elderly. The elderly are believed to be of no great significance to the society because they are thought to basically rely on others for physical assistance, housing, financial support, medical help, among others. Since they are physically frail and worn out, they have little control over their own life (including personal activities like physical hygiene, feeding, etc.) and are therefore believed to be of little value to the society. This reasoning affects the way relatives, caregivers, friends, and society as a whole treats the elderly (Kathryn & Mary, 2012).

Interventions that encourage people to have more respect and warmth for the elderly are a major step towards eradicating elder abuse. This comes in the form of public education where the social media is used to raise awareness of elder abuse in the society. Knowledgeable people make informed decisions, which are likely to bring transformation in the society. Movements that support the elderly have started campaigns and have groups online, which create awareness. Some important elements highlighted in these social networks are increasing respect for the elderly, seeing the valuable experiences, skills and abilities in the elderly people, and treating them as fellow human beings who can make a change in the society. Social media can also be important in increasing identification and the referral of elderly people who have been abused. This will make it easier to report a case of abuse or suspected abuse because all you would need to do is log in and post the information after which the support group can do a follow-up. This means that even if the person being abused is afraid of taking action, the support group can help them to bring the case to the attention of the authorities (Outreach Gide, 2013).

Everyone can participate in this fight; it can be as simple as liking a Facebook page for the fight against elder abuse or 'tweeting' your friends about it. You can post photos with elderly people with smiles to show your friends that older people are interesting and "older is wiser". You can make a poster about prevention of elder abuse and post it on your Facebook wall. Start an awareness group on your social network and invite friends to join. Inform your friends in your social networks about rallies, conferences or public forums on prevention of elder abuse. Chat with your online friends or group members and make arrangements to visit a local nursing home or a homebound senior adult and engage in games, picnic or a barbecue. Post articles in a blog about elder abuse prevention, mentioning the rights of the elderly and why they deserve better. Visit organizations featured in your social network and partner with them for more opportunities to collaborate and raise awareness for eradication of elder abuse.

Conclusion

It is hard to measure the effectiveness of social media in preventing elder abuse. However, the fundamental idea is to make an effort to challenge the negative attitudes that people have towards the elderly, increasing protection for the abused and informing people that such behavior is harmful to our aged generation and should not be tolerated. Social media provides numerous opportunities for caregivers, organizations, society, and the elderly themselves to take a stand against elder abuse. Visit organizations featured in your social network and partner with them for more opportunities to collaborate and raise awareness for eradication of elder abuse. All in all, older people must be given the opportunity to live in dignity, free

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of exploitation and mistreatment, and participate in cultural, economic and spiritual activities.

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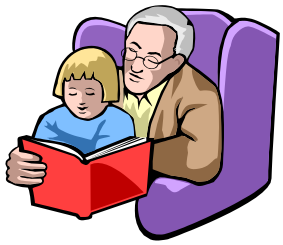

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Alzheimer's Disease and Dementia

(Past and Current Reserach)

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Abstract

This article seeks to investigate dementia via past and current research. The condition of Alzheimer Disease and dementia is described. The causes, incidence, and signs and repercussions of dementia are delineated. Finally, there is a brief section dealing with the diagnosis and treatment of the condition. Much needs to be done to identify early dementia and seek new and more effective treatment for this condition.

Introduction

It has long been known that people live longer now than in the past. This is partly due to the better medical services that they now have than they did in the past. It is also due to the attitude and behaviour or many individuals such as changing of lifestyles, including working longer, taking more exercise, eating more healthy foods, avoidance of smoking and reduction of alcohol intake etc. etc. Efforts have been made, without total success, in differentiating Alzheimer Disease from Vascular Dementia (Laukka et al., 2012). It was only found that those suffering from dementia deteriorated more quickly than those with Alzheimer Disease and that Alzheimer Disease is a form of dementia. Also included as forms of demential are vascular dementia, dementia with Lewy bodies and frontal temporal dementia.

Longer life means that many will reach their 80s and 90s and beyond. This naturally puts considerable pressure on the medical profession, Social Services and the relations of those having to care for those suffering from dementia. It also puts pressure on individual who may ultimately develop Alzheimer Disease. The two conditions, as already mentioned, are similar. Others consider them identical, due to similarities in their causes and symptoms, and the fact that like many causes they are difficult to prevent. Hence, there is a need for early detection via screening (Fowler, 2012). At this stage certain therapeutic strategies and medications can be used as soon as possible.

Little at present can be done except to try to slow down the condition for a time. This is because genetics plays such an important role in determining dementia (Williams, 2003). Therapeutic methods may be said to be working against genetic predispositions. Many individuals consider dementia a form of a 'death sentence'. Affected are the individual's memory and other cognitive functions. There are still many who hope that some form of genetic manipulation can in future improve the dismal ultimate outcome of deterioration.

Brain abnormalities in the form of tangles and plaques are responsible for the causes of dementia as well as high levels of zinc which affect memory and other functions. It is especially likely to affect short term memory or working memory, and less so long term memory. Long term memory can be divided into procedural memory and declarative memory. Procedural memory is still performed without needing to think, such as walking. Declarative memory involves remembering names, dates and other facts. Declarative memory is more affected than procedural memory by dementia.

Areas of the brain responsible for memory are the pre-frontal lobes and other important structures are the diencephalon including the mammillary bodies, the thalamus and hypothalamus. These organs transform short term memory into long term memory (Van der Flier et al., 2005). There are also chemical changes which occur in the brain including proteins that run amok.

Incidence of dementia

Being over the age of 65 is usually considered to be old age. There are however, many in society who function well and work successfully beyond that age and into their 80s. In the USA those deemed to be aged over 65 are 13% of the population. This constitutes an 11-fold increase since 1900 (Webster, 2005; Dietch, 2001). There are still a larger number of females that live longer than males by a ratio of 3:2. Hence dementia is more common in females. Only 2-5% of people under 65 suffer from dementia.

Repercussions of signs of developing dementia

Among the repercussions of growing older is the

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greater susceptibility to illness, physical injuries, psychological stress (Nordhus & Nielson, 2005), a loss of hope due to becoming depressed and suicidal. Part of this is undoubtedly due to a lack of purpose and motivation after unwanted retirement (Inselmann, 2004).Many, at least 50% of individuals would benefit from mental health treatment, yet only 20% seek such help (Aldwin, Spiro & Park, 2006).

Gero-psychology or dealing with the mental health of aging is only 50 years old, but only 5% of clinicians work in this area (Birren & Schroots, 2001). The most common problems of the aged are depression, anxiety and substance abusing of their medication or alcohol (Biringer et al., 2005; Devanand, 2002). Depression is associated with feelings of hopelessness and having low self-esteem (Knight et al., 2006). Many of the elderly suffer from low self-esteem, emptiness and sleep disturbances including insomnia (Chong, 2005). They often suffer from loss of appetite, feeling guilty, and pessimistic (Nelson et al., 2005). Many experience trauma and loss such as the loss of a spouse, or other members of one's family, and friends (Alexopoulos, 2005; Freyne et al., 2005). It has been well established that the elderly recover less quickly from physical illnesses such as heart failure, hip and other fractures, pneumonia and other infections. The other aspect related to frequency of physical illness and depression are increased likelihood of feeling suicidal, and actually committing suicide (Preville et al., 2005; Fisher et al., 2001).

The suicide rate is 19 per 100,000 among the elderly in the United States. This is much higher than among the normal population. In the normal population it is 12 per 100,000. For those over the age of 85 the suicide rate is 65 per 100,000 (Fisher et al., 2001).

Another sign of dementia is a decline in cognitive ability, that is, intelligence and memory (Ancelin et al., 2012; Sorbi et al. 2012).This is due to frontal temporal lobe neuro-degeneration (Sperling & Johnson, 2012). Sometimes this is associated with Parkinson's, and Huntington's Disease. Decline in cognitive ability may be rapid as noted in 32.7% of cases (Sona et al., 2012).

Another development in some of the elderly, especially those who have a tendency towards substance abusing is the excessive use of medication and alcohol. This is used by them to reduce anxieties and stress (Jeste et al., 2005; Knight et al., 2006). The most common substance abuse is likely to be alcohol and the misuse of the patient's own medication in the form of prescription drugs (Beckman, Parker & Thorslund, 2005). These medications are often supplied by the medical profession not being aware of the tendency of the elderly to abuse their use.

Another reaction, but somewhat rarer, due to aging, is the development of psychotic symptoms or disorders. These include delusional disorders and schizophrenia (Fisher et al., 2001). These conditions frequently have been present before the aging process commenced. Such individuals also suffer from paranoid ideations such as feeling they are being persecuted, cheated, or maligned. This feeling is frequently expressed toward well intentioned family members.

Many suffer from cognitive disorders most especially short term memory deficits and attention (Hoyer & Verhaeghen, 2006) as well as delirium sometimes. This affects the capacity to concentrate, focus, attend and to think clearly (Kempler, 2005). Such individuals become confused about where they are and there can be frequent changes in their personality due to brain disease and stroke. Fewer than 1% suffer from dementia at aged 60, while 50% suffer from this condition after the age of 85 (Cowley, 2000). Other signs of dementia are poor judgement and suffering from disorientation, confusion, delusions and incoherent thinking. Eventually such individuals require almost constant care (Shenk, 2001). Fowler (2012) emphasizes the importance of screening the elderly in order to provide treatment as early as possible, this being either medication, psychological treatment, or both.

The DSM Checklist indicates that those suffering from dementia of the Alzheimer type also develop, in addition, memory loss, aphasia, apraxia, agnosia and executive functioning problems. Social and occupational functions also become impaired and there is a gradual decline in every day functioning. Early diagnosis of the condition is necessary to hold or slow down the process of deterioration (Getsios, et al., 2012; Genius, et al., 2012; Perneczky & Kurz, 2012).

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Diagnosing dementia

A number of diagnostic assessments have been used to identify, as early as possible, those suffering from Alzheimer Disease. These include the Alzheimer Disease Knowledge Scale (ADKS) consisting of 30 true and false items covering risk factors, assessment and diagnosis symptoms. Another useful test is the Clinical Dementia Reading Sum of Boxes (CDR-SB) measuring the symptoms of Alzheimer Disease. Agreement on diagnosis is important in order to develop the most effective treatment approach possible (Zaleta et al., 2012).

Treating dementia and its effects

Other than medication, there is the use of multisensory training approaches which can be of value in slowing the ravages of dementia (Lippa, 2013). Many who suffer from Alzheimer Disease or another illness that causes dementia are cared for by their families. This however, is very demanding and stressful for the family members and there is the need to consider the emotional needs of these care-givers (Zarit & Talley, 2013).

Many investigators and researchers are currently seeking to curb the growing population of individuals suffering from dementia (Lyketsos & Miller, 2012; Naylor et al., 2012). Many researchers are currently looking for new innovative methods to prevent, delay and deal with dementia. One researcher who is undoubtedly optimistic has stated "Twenty years from now dementia as a disease may be a distant memory. The best is yet to come." (Reiman & Jagust, 2012). At this point in time however, there is still a heavy reliance on nursing homes and hospitals where 60% of these individuals spend their final days (Nichols, 2013).

The treatment of the depressed elderly consists mainly of the use of anti-depressant and other medication (Annweiler et al., 2012) as well as the use of statins (McGuiness et al., 2013). Cognitive therapy, interpersonal therapy, group therapy or an eclectic use of all of these approaches has also been of value (Knight et al., 2006). In some cases ECT or electroconvulsion therapy has also been used (Blazer, 2002), mainly to combat severe depression and tendencies towards suicide. One hopes current research will bring about a revolution in new therapeutic rehabilitation approaches.

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ANGER: Heroic Idealism in Action

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[Excerpt with author's permission]

What we love and what we get most angry about tells a tale of the hero within. Anger reveals our ideals, our goals, and our grand passions. Angers are indelible character markers. We go to war to defend beliefs and persons we cherish. We fill with outraged determination when an obstacle interrupts progress toward our goals.

The Anger Leitmotiv

Anger is a normal survival emotion. Yet, we treat anger as if it were Pandora's box. If we dare open it, to see what's inside, we believe we will let loose a horde of evils. That apprehension is not without reason. Court dockets are overloaded with testimony of negative consequences of anger. As far back as our earliest memories of elementary schooldays, we recall encounters with troublemakers who were quick to get mad and pick-a-fight. Children, at predictable ages, tend to take immediate action to resolve conflict or disappointment, fists flying, tears flowing, feet kicking. As adults, we hear news reports of how often anger is the motive for criminal acts.

Ironically, and appropriately, anger is described by some as the moral, judicial emotion. Anger motivates acts of heroism as well as acts of mayhem. Especially, when love is involved. Strong attachment, as in grand passion, inspires both grand arts and folk arts. Do Greek theater, Wagnerian opera, country pickin-music, and western guitar songs possibly have anything in common? Yes: Love, honor, anger, and death.

Judicial Anger in Greek Tragedy and Grand Ole Opry

Oedipus Rex, the tragic hero in a classic 5th century BC Greek drama, is remembered as a model leader-king, yet one who inadvertently killed his father and married his mother. In mid-life, Oedipus learned that the menacing traveler he battled to the death when he was a youth was actually the king of Thebes, the husband of the woman he later met and married, and a man whose murder he vowed to avenge to honor his bride. His shock deepened when he further learned that the king and queen of Thebes were the parents he had been separated from in infancy. Ethically-bound to carry out his pledge of vengeance, Oedipus gouged out his eyes and went into exile with his daughter to guide him. His wife committed suicide. A Freddie Kruger-Halloween plot of ancient times.

This story became a favorite example for psychoanalysts. It was elaborated into the Oedipus Complex, which is used to diagnose and explain a particular kind of love-anger conflict. This condition is diagnosed when a male child's attraction for the mother, innocent or not, is complicated by rivalry with, or anger toward the father. Another classic tragedy, based on events that took place more than a millennium later, is immortalized in the 18th century opera, *Tristan and Isolde,* where Wagner's love-honor-anger-and-death leitmotiv probed medieval erotic desire and death wishes of a heroic dragon slayer and a beautiful Irish princess. Later, in the opera *Parsifal*, Wagner dares compare emotional similarities of love as aroused in sexual experiences with religious experiences. He explores the subtleties of the diverting and perversion of emotions and, always, harsh consequences of denial of emotions.

Grand passions and perversions are no less traumatic among the poor and the untitled. From the stage at the Grand Ole Opry in Nashville, Tennessee and from roadhouse music-circuits, simple ballads passed down through ordinary folk are full of the tragic, the sadistic, and the forbidden. Country-singer Johnny Cash made Folsom prison famous as a homeplace of love-stricken suitors. Cash also sang about desire, anger, and death wishes -- homey tales of jealous rages, of murders of rivals, and of unobtainable loved-ones. Even before Johnny Cash topped the hit parade, two unextrordinary but ill-fated lovers, *Frankie and Johnny,* were immortalized in song and dance by Gene Kelly, who staged the now famous bluegrass ballad as a musical spectacular for the 1951 film, *American In Paris*. Kelly's fusion of life's common passages into memorably innovative contexts earned him a place in history books, and speaks volumes about universality of a love-anger connection.

Continued next page

Justified Anger

Passionate love endures in spite of, and sometimes because of, hardships, separations, and anger-arousing experiences. Such passion inspires the extraordinary in science as well as operas, ballads, and paintings. A love-anger motif became the driving force behind Marie Curie's efforts to extract radium from pitchblende. Madam Curie [1867-1934] loved her work and her teacher who, later, became her husband. Together, the Curies made discoveries that won them Nobel Prizes.

Yet, Marie's greatest work was done after her husband's tragic death. He was run over on a Paris street by a heavily loaded dray transporting commercial goods. Madam Curie's impassioned anger at this untimely loss had far-reaching consequences, inspiring her single-purposed dedication to completing their unfinished research. Her life of love, loss, sadness, anger, and purposeful work is a tale which could fit easily into Wagner's favorite plot: redemption through love. Her story equally well illustrates effective use of justified anger.

Justified Anger Is The Unsung-Hero Emotion

Anger receives little praise because it is a closet emotion. Stress researchers early-on found anger to be a hard-wired signal occurring in animals and humans, a distinctive neurochemical survival mechanism. Cannon was the first to associate anger with a biologically determined fight-or-flight response observed in all forms of life. Across the ages since prehistoric eras, adults had experiences that suggested it was best to avoid the painful, often irreparable consequences of fighting, at least with members of one's own tribe. Societies worked to eradicate or ignore the presence of anger. Children who showed their anger were quickly, sternly punished. A noticeable side effect of generations of effort to civilize angry behavior is under-appreciation of anger, and failure to recognize anger as a built-in problem detector.

Anger sends us signals that it's time to attend to justice, or love, or integrity. Anger's normal job is to increase chances of survival by adjusting attention to matters of immediate importance, and to work in concert with the two other stress emotions--curiosity and anxiety. Curiosity gets us moving and exploring, finding nourishment for body and mind, and anxiety keeps us from being foolishly naive, reminding us the duty officer on *Hill Street* Blues advises us to "be careful out-there on the street." Anger fires us up to be sure things are right for ourselves and our loved ones. Anger motivates us to pursue truth, beauty, and excellence.

In order to recover an appreciation for anger's intended beneficial function, it is necessary to look directly at anger, to acknowledge anger's presence and it's relationship to perfectionism, health, and happiness. We begin by taking a fresh look at anger. Everybody knows what anger is, even those who say that they never get angry. Everyone has experienced frustration, exasperation, and irritation.

Problems arise when anger is confused with hostility and aggression. Overlaps in the daily use of these terms contributes to a common misperception sometimes referred to as an *AHA Syndrome*. The acronym suggests Anger is automatically infused with Hostility and destined to culminate in acts of Aggression. In contrast, behavioral scientists make distinctions between anger and hostility. Hostility, like anger, is considered to be an emotional condition that can vary in intensity from annoyance to rage. But hostility, unlike anger, incorporates permissive attitudes toward destroying objects and injuring others. Hostility also involves disliking others and evaluating them negatively. Anger does not.

Aggression is behavior that results in punitive effects on persons or objects. Some aggressive acts are carried out to achieve desirable, generative outcomes. Harmful or destructive side effects are unintended. This type of goal-driven aggression is called "instrumental aggression" in contrast to "hostile aggression." Hostile aggression is behavior that is punitive, and sometimes destructive, proceeds out of negative evaluations. For example, sporting competitions that shift from competitive, instrumental-aggression into hostile-aggressive fighting are most likely to occur when team rivalries include a preconditioned hatred, contempt, or disrespect for the opposing group.

The fresh look at anger, in its natural form, shows it to be a survival emotion that motivates actions of innovators and idealists. Anger is a quality assurance emotion: *If I point out flaws when I see them; if I re-*

Continued next page

dress insults, then the good things of life can be won. Anger signals that quality of life is being threatened, and that corrective, sometimes punitive, action may be required.

Anger, recognized as a *stop-look-listen* message, means it is time to get clear about what we are expecting or are hoping for that is not happening. Stop and reassess the situation to be sure it is currently realizable and appropriate, or if it is an out of date expectation or objective. What is a reasonable goal in terms of fairness or improvement? Then, with that reasonable goal in mind, formulate an *instrumental* action plan, one that moves toward a constructive goal. Infusing Anger with Hope followed by Action produces a different kind of AHA Syndrome.

To re-claim the natural power [adrenal energy/ motivation] of the anger emotion involves the shift in expression of anger from the hostility to the hope mode. Experiences of anger, once acknowledged, are found to be neither a Pandora's box of evils nor a Medusa's head. We do not let loose a horde of horrors or turn into stone when we look deeply at anger. Instead, what researchers noticed is that anger experiences come in two related, but noticeably different ways. One, a broad-band signal, is called *angry temperament*, and the second, a personal protection signal, is called *angry reaction*. Individuals vary in their tendency to see a lot of situations as unfair, which is reflected by their reporting high or low levels of angry temperament. We also vary in the intensity of our reaction to being criticized, to not receiving recognition, or to being slowed down in pursuit of a goal. Angry reaction, while related to angry temperament, is triggered primarily by a perception of unfairness that strikes close to home-- nsults to the self.

More surprises awaited researchers who investigated what happens following an experience of anger. The expression of angry emotions has two separate, independent pathways. Anger expressed inwardly and anger expressed outwardly are not polar opposites of one trait. I could, for example, score high on one scale and not on the other, high on both scales, or low on both scales. Anger-in is when I know I am experiencing a mild to intensely angry emotion, but I do not express this directly to others. Anger-out is when I know I'm feeling angry emotion and I verbally or non -verbally let others know it. I speak-up, I strike others, I throw things.

The anger emotion impacts us in three ways -- mind, body and behavior. The experience starts with a mental signal that something is wrong. The autonomic nervous systems kicks into action and neurochemicals flow through the body. Energized by the emotional state, we shape mental conclusions [i.e., apperceptions] about the meaning of what we are perceiving. Finally we select a behavioral action. That action depends on available resources, knowledge, recent experiences, and creative thinking skill.

New ways of thinking about anger began with attention to stress, Type-A behavior, workaholics, and heart diseases. Surprise findings and subsequent changes in how researchers understood anger reshaped insights about longevity and vitality. Once anger proved to be the most salient emotional factor effecting heart disease patients, it wasn't long before scientific explorers mapped out topographic features of the emotion.

A scientific *Anger Box* replaces Pandora's Box to illustrate Spielberger's research findings about the experience and expression of angry emotions. Notice a strong separation of **state** from **trait** anger. State-anger describes variations of *intensity* of angry emotion being experienced in the present. Trait-anger looks at differences in the *frequency* that angry emotions are experienced in an extended time frame. State-anger may, or may not, reflect an individual's typical intensity of experience, and state intensity does not look at source or provocations of anger. State anger reflects *current circumstances*. Trait-anger suggests how often and how easily the **control** lid on anger **expression i**s likely to be raised. Trait anger does sort between generic provocations: Temperament-no specific provocation; and Reaction-receiving negative evaluation or being treated badly.

Since one person's boiling over point is likely to be quite different from another's, it became important to assess anger control. Measures reflect how much effort is expended to manage experiences of anger and subsequent expression of anger. Heroes who address every flaw, who always point out how things can be improved, may be acting out of love and loyalty, wanting only the best possible for others, push-

The Tyranny of Perfectionism

Few things in life attain the perfection of a first love. Few people fail to remember the first love-of-their-life. Frequently, it's a memory from high school years spiced with first kisses and first proms and first heartbreaks. Recalling first-loves may bring flash-backs of hard-won baseball games, or a shiny used-car, or frequently played tunes on a cherished guitar. Love at first sight may be best represented by the famous photograph showing sociologist Konrad Lorenz striding across a marshy field with a row of baby ducks following along behind him. Lorenz was the first thing these duckling saw when they opened their eyes, so they followed him wherever he went. Other new-born ducks follow a mother duck who is sitting by their eggs as they hatch.

First Impressions, Admirations, Irritations, and Trust

How long does a first impression influence where one goes? Some believe *reward-and-punishment* make the difference in how long a first love lasts. Others suggest it depends on the quality of trust in early relationships. Either way, a current reading of your early imprinting is easy: what do you most admire? What are you most proud of about yourself? What makes you angry? What about others irritates you most? Angers and irritations may give the best clues to deeper roots of your own characteristics.

Externally caused surprises, like falling and loud noises which Karen Horney said invoked the earliest experiences and expressions of anger, bring on internal feelings of disequilibria: Something is wrong. I must stop this. I must regain balance...must not fall. I must keep out the strong sounds. I must resist invasion. Why is someone/thing causing abuse to my body? It makes me angry.

Not everyone interprets imbalances or counter intuitive sensations as a call to aggressive behavior. Rather than instrumental or hostile acting-out, Einstein took a fresh approach to surprising external movement. Near the end of his life, he declared that his most happy moment came when he conceived of a man falling from the roof who simultaneously dropped an object he had been holding. As the man and the object continued to fall, the man was in motion, falling from the roof--yet he was in a state of non-motion or a stable, unchanging state in relationship to the object falling beside him at the same rate of speed. As a result, Einstein formulated his theory of relativity, a startling breakthrough in the science of physics, releasing scientists from Newtonian expectations. Visions of a dual state of being, without Einstein's insight, might generate more questions about one's sanity than about relativity.

Editing is Better than Denying

Like Einstein, we can control how we respond to our emotional signals. We can decide not to deny anger signals. We can *edit* how we behave after we get a surprising signal: *Something is not moving as expected. Perhaps it needs some fixing.* Or, even better, *we need to consider relativity*.

Denial may bring short term relief, but is long range trouble and reduces survival probabilities. Editing, on the other hand, maximizes survival potentials, in a relativity context. Editing responses to emotional signals involves intentional thinking about immediate actions compatible with future benefits for all.

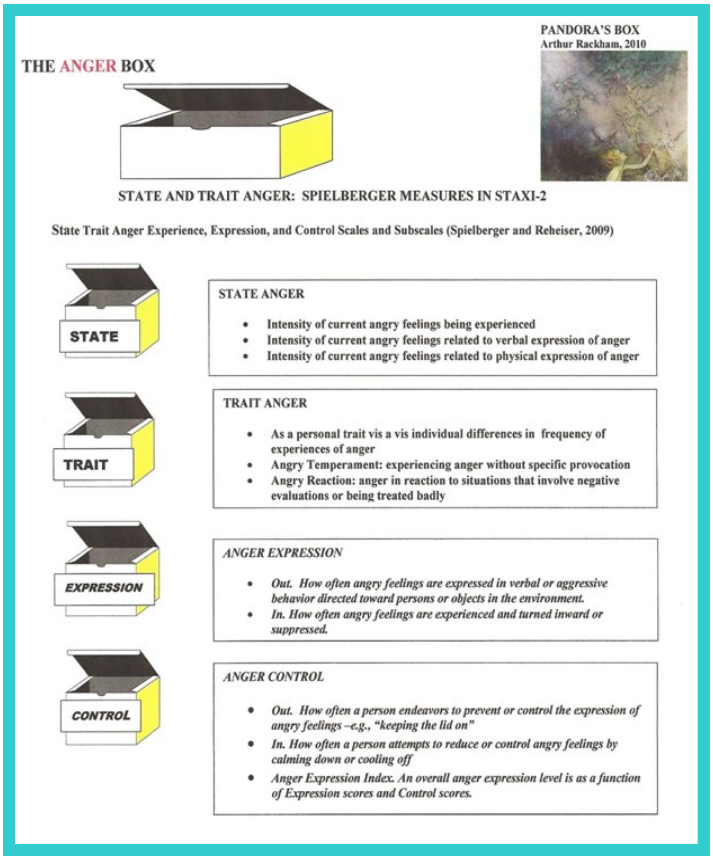

This flow chart suggests it's best to accept sensations for what they are. Recognize when something is falling, invading, or moving in a surprising direction. Notice how anger can be used radar-like, to show when the ship is veering off-course. Never loosing sight of the fact that if anger is allowed to be king among emotions, to dominate curiosity and anxiety, then, anger's quality assurance perceptions can turn ugly. Or, if anger is allowed to disguise itself in robes of honorable perfectionism, it begins planting seeds of depression.

Anger and Depression In Second Generation Corporate Leaders

Harry Levinson, one of the wisest US therapists who worked primarily with executives, understood that depression and psychological illness is one of the most important problems associated with failures in corporations. He argues that understanding depression is the first step in resolving complex psychological issues inherited by second & third-generation leaders, especially in giant corporations. Levinson found that, too often, individuals groomed for succession leadership and even newly-hired talented technicians were vulnerable to depressive rage in the aftermaths of abrupt or dramatic changes in corporate operations.

Less than two years after the downsizing rush, popular management publications reported that reengineering advocates were reversing pattern and rushing to aid beleaguered staff in human resources departments. These once hard-nosed, time-task neo-Taylorites reported feeling pain, anger, and guilt. The corporate reengineers suffered emotions they denounced while arousing them in others.

Unattended Anger, Injustices, and Depressions are Dangerous

What's the problem with just ignoring the distress felt when something we advocate ardently doesn't turn out to be perfect? What's the cost of executive depression, burnout, heart attack, suicide? A classic example from the 1980's is Vincent Foster, the accomplished attorney who was deputy counsel to President Clinton. Psychological autopsy of this suicide suggests it was perfectionism that led to the depression that ended with a solitary gunshot. Yale's Sid Blatt describes Foster as a pillar of strength, a portrait of poise, and a person of impeccable integrity, someone who seemed outwardly successful in both his professional and personal life.

It was the intensity of his perfectionist standards and his vulnerability to personal and public criticism that allowed his inner voices to stalk him relentlessly. There were observable symptoms: He lost weight, his mood was low, he spent weekends in bed with the shades pulled, he told the graduating class at the University of Arkansas Law School a few months before his death that "The reputation you develop for intellectual and ethical integrity will be your greatest asset or your worst enemy."

Executive suicides represent an extreme resolution of severe depression. More frequently, high achievers survive the periods when they experienced some or all of the criteria used to diagnose major depression and the time of reduced productivity. Many more endure episodic experiences of one or two of the critical symptoms: diminished interest and pleasure; significant increase or decrease in weight; chronic fatigue; inability to sleep or over-sleeping; agitation; sense of worthlessness or guilt; reduced thinking or concentration abilities; thoughts of death.

Living in Beautiful Surroundings Is Not Protection from Machismo Thinking

In New Zealand, recently reported to have highest suicide rate in the industrialized world, it's the young men who are six times more likely to kill themselves. Analysts conclude that they are trying to conform to exaggerated standards of masculinity. They are expected to excel in school and in sports and to never give vent to their emotions. No wonder the families are often surprised by their suicides. Self-criticism, a key aspect of perfectionism, plays a central role in depressions and in suicide.

Blatt points out that Perfectionism, in some forms and to a certain degree, can contribute to high achievement. He suggests that perfectionism comes in three varieties: socially prescribed perfectionism, other-oriented perfectionism, and self-oriented perfectionism. Of the three, self oriented perfectionism is the one closely linked to executive effectiveness. High personal standards, a need for order and organi-

zation seem to go along with good work habits, striving, and high achievement. Executives with strong self oriented perfectionism characteristics, as in an active striving for improving performance to the point of being flawless, are typically managers who have been seen as resourceful and engaged in constructive problem solving activity. Executives who set high expectations and standards for others, Blatt's third face of perfectionism, when those expectations are realistic and presented in supportive ways, are identified as charismatic leaders and mentors in studies reported by Bernard Bass. They inspire others to achieve even more than they ever imagined they could achieve.

Beneficial vs Debilitative Perfectionism

Beneficial perfectionism, a condition found in hardy executives, is characterized by a sense of pleasure from painstaking effort, rather than a feeling of anger with oneself or others if an outcome is not perfect. These persons are flexible, adaptable leaders who seek excellence while being able to be less precise when necessary or appropriate. For example, an anonymous saying advises the busy person that "some things are worth not doing well."

Perfectionism coupled with fear of failure or with stressor conditions which limit the level or nature of achievement is a prelude to a number of disorders, especially depression. Negative conditions intensify when self-oriented perfectionism is influenced by socially prescribed perfectionism. The perfectionist harbors a belief, real or imagined, that others are expecting difficult or impossible achievements and will withhold acceptance or approval until these imposed demands are met. Such external expectations are felt to be uncontrollable. They generate, as in an experience of falling, feelings of anxiety, helplessness, and anger.

Debilitating perfectionism is found in persons who have excessive concern over mistakes, who perceive high parental expectations along with strong criticism, and who struggle with doubts about the quality of their actions. These people carry an intense need to avoid failure, nothing is quite good enough, and there is an endless cycle of over-striving and distress. Health problems linked to debilitating perfectionism, in addition to depression, are eating disorders, obsessive-compulsive disorders, anxiety, panic disorder, migraine, sexual dysfunction, and Type A Behavior.

Death, Divorce, Abandonment, Self-Criticism

Depressions that are not caused by chemical imbalances in the body are believed to be activated from two sources, either interpersonal relationships or self-definition issues. Inner questioning is either about *who we are*, or *who I am*. Depression arising from interpersonal relationships is often related to a loss of a significant other who was greatly depended upon. This type of depression can be noticed after a death of a significant other and after a divorce. Likewise, it underlies the abandonment experiences of employees fired or retired from companies after many years of employment. A second source of depression is associated with autonomous responsibility, self-criticism, and guilt. There is continuous harsh self-scrutiny and evaluation, plus a chronic fear of criticism. They make many demands upon themselves and are often highly competitive, with others and with themselves.

Assessments of health-care mid-level managers and of local pastors from two major Protestant denominations reflected higher-than-average levels of assessed trait anger. Both mid-level managers and local pastors reported noticeably higher anger levels when contrasted with executive level or regional administrative staff, who reported higher levels of trait anxiety. One explanation is that senior executives and administrators know that no one has neat solutions to industry or profession-wide issues, while new managers and professionals, frequently selected for front-line positions because they are fired-up go-getters, experience impatient frustration. They assume those in seats-of-power are hoarding information, or else they are incompetent to produce decisions on timely basis. *These executives and administrators are keeping me from doing perfect work*.

Helping-professionals and therapists coined and applied the term *burnout* to negative, depressive periods in the careers of professionals of all types. These intervention specialists determined that the way to reduce depressive episodes for professionals and executives is for organizational leaders to recognize the

symptoms of depression in persons like Vincent Foster, and use their authority to take action to provide assistance to individuals struggling against burnout or depression.

Too Little Control, Too Much Control Exact a Price

Type-A behavior patterns show that hard-driving individuals liked to gain and maintain control over their environment. Assessment of anger control shows that persons with high anger control scores are those who invest a great deal of energy in gaining and maintaining control over their expression of anger-in and, or out. If there is a high level of angry temperament, anger is predicted to show through as authoritarian behavior with deliberate use of expression of anger to intimidate others. On the other hand, observers and predictors, also see that excessive control can at times result in passivity. High anger-out control levels and high anxiety scores are also considered conducive to depressive states.

Suppressed anger, as measured on the anger-in scale, is associated with hypertension, especially in Black males. Interpretation of anger-in control is underway and is expected to also impact elevations in depression. A tendency to work hard at control of anger expression conforms to Pandora-Box beliefs about keeping anger in the closet. Excesses in anger control are not more prevalent in either male or female populations. Gender differences on anger measures do show up in questions about particular situations. Women experience more intense anger when criticized in front of others, and males are more angry when slowed by others mistakes. Men are much more likely to report expressing anger out physically or verbally, e.g. when I get angry I say nasty things.

While women generally seem more able to tolerate higher levels of anger without becoming ill, recurring patterns are similar in both gender groups. High trait anger, high anger control is associated with recurrence of breast cancer in women. A high trait anger, high angry reaction, and high anger-out is an at-risk factor for myocardial infarcts, heart attacks, and cardiovascular accidents, strokes. These later findings are not news when we recall the tale of Rip Van Winkle. This fictional New Englander got home after a 20 -year nap and learned that his ill-tempered wife had died of apoplexy. Internal physical disasters are known to happen in the wake of frequent and intense bouts of fury.

Fifty Plus Years of Investigation into Executive Stress

Specific insights into the role of anger in health have been a long time in the making. At the end of World War II the US male was twice as likely to be struck down by heart failure as a Dane, a Swede or a Norwegian, and five times as likely as a Japanese man. Deaths from strokes and heart attacks had risen from 20% in 1900 to 55% in the 1950s. The federal government launched the first longitudinal study of the causes of heart attacks. With more specific information about risk factors like tobacco use and cholesterol, the general public gradually became less fatalistic about heart diseases.

Changing behaviors--stopping smoking, exercising, watching the diet--was accepted as a means to preventing heart attacks in people with basic good health. Next came the study of nonphysical risk factors, and close attention to the fact that many heart disease patients were ambitious, competitive, and highly stressed. The direct comparison of Type As with Type Bs showed that over a period of eight-and-one-half years the Type As were more than twice as likely to suffer heart attacks as the Type Bs, even with other risk factors like cholesterol and smoking were taken into consideration. Major components were found to be the competitive way of life, the sense of time urgency, and an excessive involvement with one's job. Factors were refined to hostility, irritability, impatience, and competitiveness. Under scrutiny, the underlying factor distills into anger and its power to activate the autonomic nervous system.

Physiological Pathways from Anger to Heart Disease

Anger fires-up a signal that travels down the pituitary, hypothalamus, adrenal cortex pathway and puts into production excess catecholamine which in turn are what put the plaque on the inside of the blood vessels and give the heart a hard time. This is one way that perception of external irritation brings about internal actions that wear down and burnout physical beings. Other emotions collude with anger, to our det-

riment and to our benefit: Anxiety boosts the anger signal into a bigger wallop. Curiosity tones things down by revving up proteins in the brain and strengthening the auto-immune system.

Cynicism, an acquired attitude, is believed to stimulate production of additional fight-or-flight hormones [catecholamines, i.e., adrenalines] that accelerate buildup on artery walls, causing hardening of the arteries. Following the cynicism etiology school-of-reasoning, hostility questionnaires measure, primarily, mistrust. The assertion is that those who have untrusting hearts, who believe it is safer to trust nobody, who say "most people will tell a lie to get ahead," are, perhaps, not angry, just cynical. It's hard to believe that those who find it safer to trust nobody would not have an emotional history dominated by anger and anxiety. Darwin and Freud recognized that depression generally resulted from the interaction of anxiety and anger. Spielberger and Reheiser {2009) further trace the history of theory and research on depression, which carries symptoms that vary in severity and can include sadness, guilt, hopelessness, gloomy attitudes [cynicism] and even thoughts of suicide.

Disturbances of Normal Processes

Hostile aggression begins with a negative attitude about the object of the invasive behavior, a cynical attitude. Evaluating others negatively escalates the dislike, which is manifested in harmful ways as sanctioned by permissive attitudes toward destroying objects and injuring others. If anger is a neurochemical process proceeding from experiences of a hardwired emotion, then hostile aggression is an aberration of normal survival function. Normal processes gone haywire are examined for characterizing features and classified as disorders.

Classification of disturbances of natural processes, physical and mental, is not a new idea. Medical libraries are full of volumes describing the physical parts, their workings, their interactions, and their abnormalities. Mental workings and abnormalities are more recent targets of diagnostic and prognostic knowledge seekers. Four revisions with another in-process of the initial 1952 Diagnostic and Statistical Manual of Mental Disorders have been produced since 1968. While not one addresses anger directly, acute anger is frequently listed as a symptom and as a primary diagnostic criteria in a wide range of disorders -- affective, organic, neurotic, psychotic.

Panic Attacks

Panic attacks, an unpleasant and acute anxiety episode, offers a prototype for thinking about "anger attacks." Panic attacks, described frequently in popular magazines, are DSM listed as a unique anxiety disorder.

Symptoms include difficulty breathing, palpitations of the heart, chest pains, dizziness, hot and cold flashes, sweating, fainting, trembling, fear of dying or going crazy. A panic attack brings sudden and intense apprehension, fear, or terror. These moments occur unpredictably, yet may become attached to certain situations -- i.e., driving a car. The disorder often begins in late adolescence or early adult years. It may be limited to a single brief period, or become chronic. It is rarely incapacitating unless complicated by severe phobia, abuse of alcohol, or drugs and medications. Early warning clues are experiences of separation anxiety in childhood and or sudden loss of significant others.

Anger Attacks

Temper tantrums are recognized in children, and can continue as an adult behavior pattern. In an early consulting assignment, I learned about both the tantrum and the perfectionist. Contracted to provide organization development services, my monthly activities were periodically side-tracked to attend to special situations identified by the Vice-President. One month, I talked with a computer specialist who was kicking the main-frame computer and screaming at it several times a week. Another month, I spent time with a supervisor who was being heard down the hallways venting her anger at her staff. She berated them about inappropriately dressing for work and excessively wasting time.

The computer specialist was intentionally venting his frustration and anger in order to send a message upstairs that he wanted a new computer. The woman supervisor, with no daughters of her own, was unaware that her voice tone and affect conveyed anger at her young staffers. This supervisor-perfectionist

not only wanted to shape her employees into top performing employees. She wanted them to make a good appearance by being professionally well-groomed. Most of all, she wanted to protect them, fearing that they were at-risk wearing short, short skirts in the dominantly male environment of their heavy-industry workplace. She was trying to warn them that, at the very least, they could evoke insults and undesirable sexual attention. Of course, at her more settled, less adventuresome stage of life, she failed to see that attention from the male workers may have been an important goal for the younger women.

After those early assignments, I began to notice that my organizational consultation assignments frequently involved [a] cleaning-up after an employee's expression of anger and [b] communications training to prevent angry exchanges. Looking back, I see that many of the anger incidents I witnessed or intervened with were similar in many ways to panic attacks. Angry behaviors, however, in my experience, occurred more frequently in work settings than panic attacks and had more after effects than did panic attacks. I observed that:

Anger attacks include labored breathing, flaring of nostrils, narrowed eye focus, pounding of the heart, clenching of head, arm, and leg muscles, clutching of the chest, hot flashes, going cold, and loss of concern for personal safety, life, or others at risk, a tunnel vision awareness.

An anger attack begins with a sudden and intense sense of frustration, deprivation, or insult. These moments occur unpredictably, yet may attach to certain situations, e.g., an umpire's ruling in a baseball game. The disorder often begins in childhood or preadolescent years. Anger attacks may be limited to a single brief period, or become chronic. Anger attacks are rarely incapacitating unless complicated by particularized hostility, abuse of alcohol, drugs, or medication. Early warning clues that an anger attack is imminent can be similar to aura precursors of an epileptic seizure: onset of sensory hallucinations of smells, colors, or pains in parts of the body where tension is maintained, such as the jaw or the neck. Etiologies of chronic anger attacks include a history of severe parental punishment and / or criticism, sibling fighting, or severe deprivation in childhood and early life. Anger expression is influenced by family and social norms, and may be effected by genetic factors.

How Do I Love Thee? Let Me Count the Angers

Anger, like love, can be personal, professional, and generic, for example, as defined by erotic, filial, and agape types of love. Things that make us angry enough to take action at home, at work, or as a citizen reveal the hero within. Angers are indelible character markers of what it is that we value and love.

Examples of Filial and Agape Angers

Martin Luther King said, "I have a dream." A legendary Mexican contemporary, Don Juan was a very different type of visionary. Made famous in the writings of Carlos Castaneda, Don Juan understood individual, separate realities and taught the importance of controlled folly. King loved his kinfolk: filial love. Don Juan loved all folk: agape love. One advocated an instrumental, non-aggressive anger-out strategy for demonstrating ways of protecting and loving others. The second plumbed the depths of anger-in strategies, ways of controlling fascinations and frustrations that inhibit our ways of respecting and loving all life. King was angry about racial prejudice against his brothers. Don Juan was angry about social norms and biases that inhibit talent utilization, and respect for life potentials in each individual.

King, full of righteous *filial anger*, spoke about injustices done to people with black skin by people with white skin. He harnessed and channeled the anger of many people to move society toward the dream of equality, his goal was justice. Don Juan spoke of mastery over anger through intensive, individualized training. Don Juan's students were challenged to let go of externally imposed perspectives, and to train the powers within to extend their idiosyncratic capabilities into the world. He taught that cultivation of inner strength let's one achieve beyond ordinary expectations and goals. He was full of agape anger about people enslaved to things, people or ideas. Both were charismatic participators in the quest for quality of life.

Continued next page

Erotic Anger

Most of us fall somewhere between the activist and the individualist, and all of us have at least a glimpse of what personal, erotic anger is about. Freud's love-anger-deathwish notions make sense even for those who disagree with elaborate psychoanalytic assumptions and conclusions. For the less fatalistic, living beyond first impressions and first loves is a matter of putting new spins on emotional experiences. Anger signals a time-out for planning. Refocusing gets us to be at-rest with what's beside us, here and now. Like Einstein, we shift an internal sense of falling into one of moving relative to another person or object of our love or anger.

Concentration on goals, much like Marie Curie's determination to complete the research work she began with her husband, becomes a stabilizing influence as we adapt in response to anger's alert that it's time for a perceptual shift. Executives and managers who refuse to accept new goals, new technologies, new assignments are difficult, sometimes impossible, to motivate. They are using their anger to dig their heels in, to stay right where they are for the rest of their days. Some call it being in a rut, others consider it digging an early grave.

We know, first or second-hand, the debilitating consequences of a wrong choice in a career or in a marriage partner. Struggles come either way, staying in a bad job or marriage, and when divorcing or starting over. Over-estimating and relying on first impressions is a matter of doing more wishful thinking than data gathering. First impressions seldom include all relevant and accurate details. Mistaken first loves, as well as long-lasting loves, show themselves in our angers and too often lead to our sadness and depression, which in extreme situations culminate in suicide or hostile aggression.

As we live out our days in the non-stop stream of experiences, emotions, and behaviors, we can count on anger to be an informed ally bent on improving and perfecting things. We can tune into what our angry temperament and our angry reaction points out. We can edit our behavior, pausing the spontaneous flow of anger-out or anger-in long enough to determine the behavior that will maximize survival potentials when we lift the lid of the anger box.

Anger As Political Advisor: Constant Campaign for Justice, Fairness, Improvement

Beneficial anger in it's intended form keeps us from being walked on, abused by the systems around us, and increases our energy for achievement. Anger makes it possible for us to survive, to feel adequate, to grow, and to make meaningful contributions to life around us. In fact, our anger can be compared to a politician who runs for office every two, four, or six years, and knows staying relevant means being on a *constant campaign*. To hold your place of influence and get re-elected, the politician must be alert to what is lacking and needed, and must stay publically visible. Like anger, the elected official will be constantly pointing out what's wrong with the way things are in the present and how to make it better in the future.

> *Anger, like love, is a moral emotion...We are ambivalent about anger because sometimes it is effective and sometimes it is not, because sometimes it is necessary and sometimes it is destructive. . . anger is ultimately an emphatic message: Pay attention to me. I don't like what you are doing. Restore my pride. You're in my way. . . Give me justice.*
>
> *Anger, The Misunderstood Emotion. Carol Tavris*

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Establishing Forgiveness and Peace Gardens Around the Globe

Dr. Ani Kalayjian
ATOP Meaningfulworld, USA

Forgiveness is not an occasional act.
It is a permanent attitude.
Martin Luther King, Jr.

Although an abundance of peace organizations, non-governmental, as well as related university affiliations exist; conflict continues to flourish around the world. The roots of these conflicts and violence may be political, religious, territorial, tribal, generational, as well as those motivated by greed, rigidity, ego centrism, and shortsightedness. Since 1988 I have organized and delivered programs in over 45 countries to bring peace, conflict resolution, post trauma healing, forgiveness, and meaning-making through our organization, the Association for Trauma Outreach & Prevention, Meaningfulworld (www.meaningfulworld.com). We have noticed repeatedly that in spite of the establishment of a number of peace centered groups there are at least a handful of oppositional groups, or extremist groups being formed in opposition to another extremist group. In addition, many states have used extreme force, slavery, and violence in the name of peace and security.

Only in the Middle East, we have seen Israeli government building a wall all around Palestine and complicating and delaying the check points. We have also seen many Islamic extremist groups formed to defy these new developments. Similar oppositional groups are formed in Africa, such as in Kenya, Somalia, the Democratic Republic of Congo, and Burundi, all in the name of peace and security while destroying lives and ecology.

In addition to our educational and empowerment programs, we have recently integrated the establishment of Forgiveness and Peace Gardens around the world, in countries where we have collaborative centers and programs. These gardens have been welcomed as an alternative ecological connection, as well as a reinforcement of our educational programs. Forgiveness & Peace Gardens are a place where people can visit privately, or in a group, to renew their commitment to peace, and to be mindful of the importance forgiveness plays in establishing peace within, and all around. We can use these gardens to gather around and have educational, ecological, and emotional healing programs, especially on United Nations International Day of Peace annually 21 September. Peace begins in every individual, first on a personal level, and then spreads through our actions, behaviors, thoughts, and intentions. This extension happens both energetically as well as in learned and reinforced behaviors.

Many individuals, as well as States, are not mindful of inconsistencies they engage in; they may talk about, yet yell, hit, or destroy in anger and rage. If one's thoughts, actions and intentions are not harmonized we will not be able to establish peace on any level. We need to harmonize our head (thoughts), heart (intentions), and hands (actions) in order to be in peace.

Central to our educational programs is the 7-Step Integrative Healing Model (Kalayjian 2002, Sofletea & Kalayjian 2012). This innovative model incorporates various theories including: psychodynamic (Freud, 1910), interpersonal (Sullivan, 1953), existential and humanistic (Viktor Frankl, 1962), electromagnetic field balancing (EMF, Dubro & Lapierre, 2002), learning theory, ecology, forgiveness (Kalayjian & Paloutzian, 2010), flower fssences (Bach & other flower remedies), essential oils, physical release (yoga, martial arts), and mind-body-spirit chakra balancing exercises, prayers, meditation, indigenous rituals and celebration.

The 6th step of this Model integrates ecological principles of Mother Earth, for engendering inner peace, peace all around, as well as physical, mental & spiritual health. Creating gardens as sanctuaries is important to reconnect with Mother Nature and honor our presence in this world in harmony with our Mother. Whether we have a window seat, a terrace, a porch, a corner in our room, or a garden is irrelevant; instead, what matters is a corner that we create with thoughtfulness, intention, and love to house a work of art that celebrates our connection with the earth and our unconditional love. Our feelings of fear,

Continued next page

isolation, hopelessness, and uncertainty will decrease immensely once we establish and frequent this special sanctuary. We may explore a variety of themes, such as angels, flowers, wood, trees, bells, gongs, candles or colorful flags or scarves, with each theme representing an aspect of the earth. We need to be mindful to include something to represent love, something for passion, another for forgiveness, love, nurturing abundance, gratitude, and compassion.

Therefore, we are mindful of including 7 elements: Water, such as a fountain or running water; earth, such as a plant with a planter; fire, such as candles, wind, created with chimes; rocks and crystals, especially rose quartz, jade or turquoise; sculptures, representing peace and forgiveness, and incense. We have sown the seeds to create these ecological peaceful places for students, faculty, clinics, hospitals, and community centers in eight countries in the Middle East, Haiti and Africa. Community is invited to gather around the garden to engender inner peace, to help forgive oneself and others, to raise consciousness on being mindful of one's own feelings, managing and transforming negative feelings of anger, rage, envy, and greed, and replacing them with positive and uplifting feelings such as love, gratitude, forgiveness, empathy, compassion, abundance, and acceptance. These gardens will be in every house, in front of every university, secondary and primary schools and kindergartens, including in the slums, refugee centers, and other open community centers.

Garden description

The garden should be circular, representing natural space. Evergreen short bushes are to be placed all around to mark the circularity, which represents unity, as well as follows the shape of a medicine wheel. Large river stones or rocks could be placed around the perimeter for definition and grounding. A small cedar tree could be central. The following flowers and herbs are recommended, with special attention to perennials for their endurance and practicality.

- Hybrid Tea Roses, such as Peace, Pope John Paul II, Our Lady of Guadalupe, and Innocence
- Baby's Breath, to connect us with our innocence and purity of our heart
- Gardenias, for purity of purpose
- Magnolias, to activate our heart
- Allium Gigantean, for nurturing unity
- Gladiolas, for sincerity
- Bird of Paradise, central for meditation
- Iris, for appreciation of friendship and instilling hope
- Blue Scylla, for forgiveness
- Honey Suckle, for letting go
- Jasmine, for transformation
- Lily of the Valley, to open our heart to let love in
- Lilies in general, to strengthen our commitment to be the change we want to see,
- Larkspur, to open our heart even when we are in pain, and we have been hurt
- Clematis, for nurturing peaceful thoughts
- Hosta, for devotion to our inner health
- Yarrow, for healing
-

Other flowers could be added based on your garden's exposure to sun, type of soil, water needs, and season. I encourage you to add tulips, daffodils, crocus, iris, bergamot, butterfly catcher, bearberry bush, lobelia, evening primrose, poppies, mums, bachelor buttons, and so forth. Inside the circle I recommend to plant the following healing herbs: lavender, mint, rosemary, sage, thyme, and other local healing herbs.

Other flowers could be added based on your garden's exposure to sun, type of soil, water needs, and season. I encourage you to add tulips, daffodils, crocus, iris, bergamot, butterfly catcher, bearberry bush, lobelia, evening primrose, poppies, mums, bachelor buttons, and so forth. Inside the circle I recommend to plant the following healing herbs: lavender, mint, rosemary, sage, thyme, and other local healing herbs. If the Forgiveness and Peace Garden is within an institution, all departments would get involved in the establishment of this garden by donating one of the flowers or herbs mentioned above. The art department could be asked to conduct a contest for the best sculpture signifying peace and forgiveness. The winner's sculpture would be placed in the center of the garden with a plaque that states:

Continued next page

Meaningfulworld Ecology Project Forgiveness & Peace Garden (name of institution, city & state)

Brochures and informational material could be prepared to have an opening of the Forgiveness and Peace Garden, and press releases sent to the community at large, to disseminate this concept widely. Liaisons will be assigned to mentor community members on the importance of these gardens, how to start them in their homes, how to begin a practice of mindfulness for peace and forgiveness, and how to utilize these gardens in a meaningful way. Forgiveness is shifting from the automatic ego reaction (anger/self-protection, hurting back), to a non-reactive conscious response of empathy; considering that the other person is ALSO a human being, perhaps not mindful, and there is no peace without forgiveness (Kalayjian, 2010).

How to use the Forgiveness and Peace Garden

Meaningfulworld liaisons will mentor the community on how to use this garden daily for prayers, meditation, and a time for refuge, silence, renewal, commitment and mindfulness. This Forgiveness and Peace Garden could signify that no matter how challenging life circumstances become, we can surround ourselves with love, peaceful plants, herbs and flowers, and reinforce the importance of peace for our health, for generations of healthy people who are guided by peace, forgiveness and love. For forgiveness is not an innocent act of Pollyanna but rather is self-love above and beyond anything else, as well as love of others, engendering inner peace as well as peace all around us.

Gratitude: special gratitude to Antonia Gentile, Sandra Delcioppio, and Leysa Cerswell.

For further information on how to start your own garden contact the author Dr. Kalayjian at DrKalayjian@Meaningfulworld.com selective gardens would be displayed at our website: www.Meaningfulworld.com

Kitty Genovese Forum Convened in New York City

Harold Takooshian, Ph.D.
New York, New York, USA

On March 8-9, 2014, 150 people gathered in the rooftop conference center of Fordham University in New York City, to hear 24 experts address the "The Kitty Genovese Memorial Conference: 50 years later." These 24 speakers included journalists, scholars, activists, and Genovese family members--most of them meeting for the first time. Participants heard each expert speak with passion for 15 minutes, presenting their new information or insights, on one of three themes: (1) a celebration of young Kitty's life, (2) a re-examination of the facts in her senseless death, or (3) the many ways society has changed for the better after Kitty's tragedy.

When Kitty was fatally stabbed outside her New York City home at 3 am on March 13, 1964, her little-known death soon exploded into headlines world-wide, when journalist A.M. Rosenthal's bold book, THIRTY EIGHT WITNESSES, asked this simple question: "If many of Kitty's neighbors saw or heard her screaming for her life, why did none of them help her, or even phone the police in time?" Even a half-century later, we continue to learn new facts about Kitty and her iconic tragedy. Inexplicably, not one biography of Ms. Genovese has appeared these past 50 years--yet this conference included the voices of authors of at least five powerful new or forthcoming books this year about Kitty and her tragedy. A list of these books appears in the conference program, at http://file-id.org/140310/13688.

One question probed in this conference was whether knowledge of Kitty's tragedy has changed bystander behavior since 1964? A blog seeks people's views on this question, http://psyccritiquesblog.apa.org/2009/04/what-is-the-value-of-the-genovese-parable.html.

For any details, contact the forum's co-chairs: Attorney Joseph F. DeMay of New York City, or Professor Harold Takooshian of Fordham University, kgconf@gmail.com.

ICP, Inc. 2014 ANNUAL MEETING: JULY 13-15 PARIS, FRANCE

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If you would like information regarding the International Council of Psychologists, Inc., the conference, or any of the publications for the organization, please feel free to visit the website at http://www.ICPWeb.org. Membership and registration forms reside there as well as a great deal of information about the organization.

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Part B: International Psychologist Spring 2014 Edition

By Dr. Ann Marie O'Roark, Editor
International Psychologist A/B

This Part B is intended to be used for longer reports and as a place for the ICP's Research Interest Groups to present their collaborative work. One expectation is that *IU* can be a linking pin between print media and electronic communications offered through the ICPWEB.ORG site. Dr. Varda Muhlbauer [Israel] is exploring ways with the help of new Director at Large Diana Boer [Germany] to implement a blog for scientific conversations and professional discussions, as well as using it for planning conference symposia and joint research projects.

We certainly hope that you will enjoy this ICP publication and consider contributing to future issues. This is a fine venue for sharing your work with others in our field.

CALL FOR MANUSCRIPTS

Please submit manuscripts using APA style, Word, 12 pt. Times New Roman to the Editor at annoroark@bellsouth.net. The *IU* is published two to four times yearly, according to the number of manuscripts received. An Editorial Review Panel reviews all material submitted for the International Psychologist for readability and consistency with ICP, Inc policies. *IU* submissions are screened for style and professional content. Submissions may be returned for revisions as needed. We invite your participation. While *IU* is not a formal journal, it may set the stage for re-activating *World Psychology.*

Helping Prevent Elder Abuse Globally Through the Use of Social Media

Richard Velayo, Ph.D. and Michael Trush
Pace University, New York City

Elder abuse is a single or continuous exploitative behavior, or failure to take an appropriate action (as expected) in a relationship, which involves trust, and eventually causes distress or psychological harm to an elderly person. This form of mistreatment can occur at home within a family, care givers/assistants, friends, etc. or in an institution such as a nursing home in the hands of a professional caregiver. Approximately 2.1 million elderly people in America are victims of elder abuse yearly. Neglect and failure to carry out a responsibility towards an elderly person are the most common forms of abuse. Other forms of abuse which often cause psychological and emotional harm include lack of respect and denying the elderly freedom (e.g. freedom of expression and doing what makes them happy like listening to music), controlling all their moves and making all decisions for them, threatening to withdraw care, bullying, financial exploitation (e.g. misappropriation of the wealth of an elderly person, exploiting their finances and depriving them the right to use their wealth as desired, denying them access to their property and giving them false reports regarding their wealth). Other forms of elder abuse include physical abuse like beat-

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ing or slapping, unnecessary medical sedation, and physical restraint, as well as sexual abuse (Bagshaw, Wendt & Zannettino, 2007). This paper explores the various forms of elder abuse and how social media can be useful in reversing this vice.

Statistics indicate that women are more commonly the victims of elder abuse and perpetrators of this abuse are mostly men, particularly family members, partners or spouses. People aged 85 years and above are more likely to undergo elder abuse than those aged between 65 and 84. Moreover, exploitation increases as the health of victims deteriorates. Also, elderly people who have a lower socio-economic status are more likely to experience elder abuse. Other aspects like psychological disorders, physical injury, cognitive impairment, restricted mobility, fear of isolation, ignorance of their rights and social isolation can increase the risk of an elderly person being mistreated (Bagshaw, Wendt & Zannettino, 2007). Some individuals hold the belief that elderly people are weak, helpless and less significant in society. These are ageist attitudes, which make society more tolerant of elder abuse and ignore the detrimental consequences faced by the elderly. However, the good news is that elder abuse can be prevented. Although few studies have been put forward on prevention of elder abuse, there is still hope for the elderly. This paper explains how social media can be used to prevent the pervasive problem of elder abuse.

Social media, the society, and prevention of elder abuse

Social media is a technology, which uses web-based techniques to offer information and create awareness on several issues. Social media can also be used as a tool that creates dialogue among front-line employees looking for support and professional assistance on how to stop elder abuse. Caregivers from rural areas and remote places often feel isolated, unappreciated and unmotivated in their profession. Continued communication among caregivers is important because they can share information, encourage each other and share updates on what is happening in their local areas. This is where social media comes in handy though avenues like "exploring the space between" (an experimental blog that invites communication for professional and caregivers for the elderly), "CHNET-Works" (a conference system for health professionals) and "USTREAM TV" (a live streaming resource used on various geographic levels). Chat services enable immediate and prompt communication between individuals and they can also share photos. This increases support for other caregivers and gives them an opportunity to obtain professional guidance from others. When caregivers and professionals who deal with the elderly connect, they can share information, which will be useful in eliminating elder abuse in the society (Cooper, Selwood & Livingston, 2008).

Currently, statistics indicate that more elderly people are using the Internet and social media than ever before. Statistics Canada (2011) reported that age is a significant factor in determining Internet use regardless of the other factors being taken into account such as income and education levels. In 2010 alone, 80% of Internet users over 45 years old were between 45 and 64 years. Those aged 65 and above were less likely to use the Internet and the percentage of Internet users declined with age (Kathryn & Mary, 2012). However, current statistics indicate that the elderly are increasingly using the Internet and social media, and they are the fastest growing category of Internet users. In a 2012 survey by American Life Project and the Pew Internet, 34% of those aged 65 and above used the Internet and another study by Ipsos Reid research firm indicated that 44% of those aged 55 and above used the Internet. Of the people who contribute to blog content, take part in discussions, upload photos and participate in social networking, 9% of them are aged between 55 and 65 (Ipsos, 2011). This trend is a clear indication that the Internet and social media is an important tool for creating awareness about elder abuse and offering advice through current support services (Kathryn & Mary, 2012).

Social media creates forums and groups where individuals can hold discussions, share information, communicate, and work together towards a common goal. Social media includes blogs, twitter and Facebook. People have the opportunity to share personal opinions and professional recommendations on blogs. Facebook gives individuals an opportunity to meet friends and create a group where people can form a network, which they use to share information, photos

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and post updates. Twitter is a short instant messaging network, which gets updated immediately as a message is uploaded. These social networks are often free of charge and even if they have to charge, the cost is very little. They are also accessible from any place, at any time. Moreover, the elderly need to get awareness about what they should tolerate and what not to. For instance, a support group can start a blog, which posts articles or provides information that highlight behaviors and actions that the elderly should accept from caregivers and what they should report as abuse. This blog can offer advice and help to locals in knowing what is acceptable; hence, increasing awareness (Cooper, Selwood & Livingston, 2008).

The fundamental issue that has given birth to the spread of elder abuse in society is the negative attitude that people often carry towards the elderly. The first step is therefore, creating an atmosphere, which encourages a positive attitude towards the elderly. Many people, especially the youth have stereotypes, negative attitudes, and discrimination towards the elderly. The elderly are believed to be of no great significance to the society because they are thought to basically rely on others for physical assistance, housing, financial support, medical help, among others. Since they are physically frail and worn out, they have little control over their own life (including personal activities like physical hygiene, feeding, etc.) and are therefore believed to be of little value to the society. This reasoning affects the way relatives, caregivers, friends, and society as a whole treats the elderly (Kathryn & Mary, 2012).

Interventions that encourage people to have more respect and warmth for the elderly are a major step towards eradicating elder abuse. This comes in the form of public education where the social media is used to raise awareness of elder abuse in the society. Knowledgeable people make informed decisions, which are likely to bring transformation in the society. Movements that support the elderly have started campaigns and have groups online, which create awareness. Some important elements highlighted in these social networks are increasing respect for the elderly, seeing the valuable experiences, skills and abilities in the elderly people, and treating them as fellow human beings who can make a change in the society. Social media can also be important in increasing identification and the referral of elderly people who have been abused. This will make it easier to report a case of abuse or suspected abuse because all you would need to do is log in and post the information after which the support group can do a follow-up. This means that even if the person being abused is afraid of taking action, the support group can help them to bring the case to the attention of the authorities (Outreach Gide, 2013).

Everyone can participate in this fight; it can be as simple as liking a Facebook page for the fight against elder abuse or 'tweeting' your friends about it. You can post photos with elderly people with smiles to show your friends that older people are interesting and "older is wiser". You can make a poster about prevention of elder abuse and post it on your Facebook wall. Start an awareness group on your social network and invite friends to join. Inform your friends in your social networks about rallies, conferences or public forums on prevention of elder abuse. Chat with your online friends or group members and make arrangements to visit a local nursing home or a homebound senior adult and engage in games, picnic or a barbecue. Post articles in a blog about elder abuse prevention, mentioning the rights of the elderly and why they deserve better. Visit organizations featured in your social network and partner with them for more opportunities to collaborate and raise awareness for eradication of elder abuse.

Conclusion

It is hard to measure the effectiveness of social media in preventing elder abuse. However, the fundamental idea is to make an effort to challenge the negative attitudes that people have towards the elderly, increasing protection for the abused and informing people that such behavior is harmful to our aged generation and should not be tolerated. Social media provides numerous opportunities for caregivers, organizations, society, and the elderly themselves to take a stand against elder abuse. Visit organizations featured in your social network and partner with them for more opportunities to collaborate and raise awareness for eradication of elder abuse. All in all, older people must be given the opportunity to live in dignity, free

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of exploitation and mistreatment, and participate in cultural, economic and spiritual activities.

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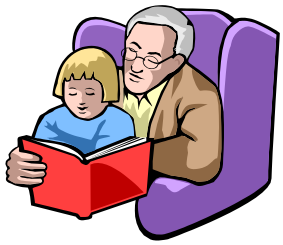

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Alzheimer's Disease and Dementia

(Past and Current Reserach)

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Abstract

This article seeks to investigate dementia via past and current research. The condition of Alzheimer Disease and dementia is described. The causes, incidence, and signs and repercussions of dementia are delineated. Finally, there is a brief section dealing with the diagnosis and treatment of the condition. Much needs to be done to identify early dementia and seek new and more effective treatment for this condition.

Introduction

It has long been known that people live longer now than in the past. This is partly due to the better medical services that they now have than they did in the past. It is also due to the attitude and behaviour or many individuals such as changing of lifestyles, including working longer, taking more exercise, eating more healthy foods, avoidance of smoking and reduction of alcohol intake etc. etc. Efforts have been made, without total success, in differentiating Alzheimer Disease from Vascular Dementia (Laukka et al., 2012). It was only found that those suffering from dementia deteriorated more quickly than those with Alzheimer Disease and that Alzheimer Disease is a form of dementia. Also included as forms of demential are vascular dementia, dementia with Lewy bodies and frontal temporal dementia.

Longer life means that many will reach their 80s and 90s and beyond. This naturally puts considerable pressure on the medical profession, Social Services and the relations of those having to care for those suffering from dementia. It also puts pressure on individual who may ultimately develop Alzheimer Disease. The two conditions, as already mentioned, are similar. Others consider them identical, due to similarities in their causes and symptoms, and the fact that like many causes they are difficult to prevent. Hence, there is a need for early detection via screening (Fowler, 2012). At this stage certain therapeutic strategies and medications can be used as soon as possible.

Little at present can be done except to try to slow down the condition for a time. This is because genetics plays such an important role in determining dementia (Williams, 2003). Therapeutic methods may be said to be working against genetic predispositions. Many individuals consider dementia a form of a 'death sentence'. Affected are the individual's memory and other cognitive functions. There are still many who hope that some form of genetic manipulation can in future improve the dismal ultimate outcome of deterioration.

Brain abnormalities in the form of tangles and plaques are responsible for the causes of dementia as well as high levels of zinc which affect memory and other functions. It is especially likely to affect short term memory or working memory, and less so long term memory. Long term memory can be divided into procedural memory and declarative memory. Procedural memory is still performed without needing to think, such as walking. Declarative memory involves remembering names, dates and other facts. Declarative memory is more affected than procedural memory by dementia.

Areas of the brain responsible for memory are the pre-frontal lobes and other important structures are the diencephalon including the mammillary bodies, the thalamus and hypothalamus. These organs transform short term memory into long term memory (Van der Flier et al., 2005). There are also chemical changes which occur in the brain including proteins that run amok.

Incidence of dementia

Being over the age of 65 is usually considered to be old age. There are however, many in society who function well and work successfully beyond that age and into their 80s. In the USA those deemed to be aged over 65 are 13% of the population. This constitutes an 11-fold increase since 1900 (Webster, 2005; Dietch, 2001). There are still a larger number of females that live longer than males by a ratio of 3:2. Hence dementia is more common in females. Only 2-5% of people under 65 suffer from dementia.

Repercussions of signs of developing dementia

Among the repercussions of growing older is the

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greater susceptibility to illness, physical injuries, psychological stress (Nordhus & Nielson, 2005), a loss of hope due to becoming depressed and suicidal. Part of this is undoubtedly due to a lack of purpose and motivation after unwanted retirement (Inselmann, 2004).Many, at least 50% of individuals would benefit from mental health treatment, yet only 20% seek such help (Aldwin, Spiro & Park, 2006).

Gero-psychology or dealing with the mental health of aging is only 50 years old, but only 5% of clinicians work in this area (Birren & Schroots, 2001). The most common problems of the aged are depression, anxiety and substance abusing of their medication or alcohol (Biringer et al., 2005; Devanand, 2002). Depression is associated with feelings of hopelessness and having low self-esteem (Knight et al., 2006). Many of the elderly suffer from low self-esteem, emptiness and sleep disturbances including insomnia (Chong, 2005). They often suffer from loss of appetite, feeling guilty, and pessimistic (Nelson et al., 2005). Many experience trauma and loss such as the loss of a spouse, or other members of one's family, and friends (Alexopoulos, 2005; Freyne et al., 2005). It has been well established that the elderly recover less quickly from physical illnesses such as heart failure, hip and other fractures, pneumonia and other infections. The other aspect related to frequency of physical illness and depression are increased likelihood of feeling suicidal, and actually committing suicide (Preville et al., 2005; Fisher et al., 2001).

The suicide rate is 19 per 100,000 among the elderly in the United States. This is much higher than among the normal population. In the normal population it is 12 per 100,000. For those over the age of 85 the suicide rate is 65 per 100,000 (Fisher et al., 2001).

Another sign of dementia is a decline in cognitive ability, that is, intelligence and memory (Ancelin et al., 2012; Sorbi et al. 2012).This is due to frontal temporal lobe neuro-degeneration (Sperling & Johnson, 2012). Sometimes this is associated with Parkinson's, and Huntington's Disease. Decline in cognitive ability may be rapid as noted in 32.7% of cases (Sona et al., 2012).

Another development in some of the elderly, especially those who have a tendency towards substance abusing is the excessive use of medication and alcohol. This is used by them to reduce anxieties and stress (Jeste et al., 2005; Knight et al., 2006). The most common substance abuse is likely to be alcohol and the misuse of the patient's own medication in the form of prescription drugs (Beckman, Parker & Thorslund, 2005). These medications are often supplied by the medical profession not being aware of the tendency of the elderly to abuse their use.

Another reaction, but somewhat rarer, due to aging, is the development of psychotic symptoms or disorders. These include delusional disorders and schizophrenia (Fisher et al., 2001). These conditions frequently have been present before the aging process commenced. Such individuals also suffer from paranoid ideations such as feeling they are being persecuted, cheated, or maligned. This feeling is frequently expressed toward well intentioned family members.

Many suffer from cognitive disorders most especially short term memory deficits and attention (Hoyer & Verhaeghen, 2006) as well as delirium sometimes. This affects the capacity to concentrate, focus, attend and to think clearly (Kempler, 2005). Such individuals become confused about where they are and there can be frequent changes in their personality due to brain disease and stroke. Fewer than 1% suffer from dementia at aged 60, while 50% suffer from this condition after the age of 85 (Cowley, 2000). Other signs of dementia are poor judgement and suffering from disorientation, confusion, delusions and incoherent thinking. Eventually such individuals require almost constant care (Shenk, 2001). Fowler (2012) emphasizes the importance of screening the elderly in order to provide treatment as early as possible, this being either medication, psychological treatment, or both.

The DSM Checklist indicates that those suffering from dementia of the Alzheimer type also develop, in addition, memory loss, aphasia, apraxia, agnosia and executive functioning problems. Social and occupational functions also become impaired and there is a gradual decline in every day functioning. Early diagnosis of the condition is necessary to hold or slow down the process of deterioration (Getsios, et al., 2012; Genius, et al., 2012; Perneczky & Kurz, 2012).

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Diagnosing dementia

A number of diagnostic assessments have been used to identify, as early as possible, those suffering from Alzheimer Disease. These include the Alzheimer Disease Knowledge Scale (ADKS) consisting of 30 true and false items covering risk factors, assessment and diagnosis symptoms. Another useful test is the Clinical Dementia Reading Sum of Boxes (CDR-SB) measuring the symptoms of Alzheimer Disease. Agreement on diagnosis is important in order to develop the most effective treatment approach possible (Zaleta et al., 2012).

Treating dementia and its effects

Other than medication, there is the use of multisensory training approaches which can be of value in slowing the ravages of dementia (Lippa, 2013). Many who suffer from Alzheimer Disease or another illness that causes dementia are cared for by their families. This however, is very demanding and stressful for the family members and there is the need to consider the emotional needs of these care-givers (Zarit & Talley, 2013).

Many investigators and researchers are currently seeking to curb the growing population of individuals suffering from dementia (Lyketsos & Miller, 2012; Naylor et al., 2012). Many researchers are currently looking for new innovative methods to prevent, delay and deal with dementia. One researcher who is undoubtedly optimistic has stated "Twenty years from now dementia as a disease may be a distant memory. The best is yet to come." (Reiman & Jagust, 2012). At this point in time however, there is still a heavy reliance on nursing homes and hospitals where 60% of these individuals spend their final days (Nichols, 2013).

The treatment of the depressed elderly consists mainly of the use of anti-depressant and other medication (Annweiler et al., 2012) as well as the use of statins (McGuiness et al., 2013). Cognitive therapy, interpersonal therapy, group therapy or an eclectic use of all of these approaches has also been of value (Knight et al., 2006). In some cases ECT or electroconvulsion therapy has also been used (Blazer, 2002), mainly to combat severe depression and tendencies towards suicide. One hopes current research will bring about a revolution in new therapeutic rehabilitation approaches.

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ANGER: Heroic Idealism in Action

Ann M. O'Roark, Ph.D., ABAP
St. Augustine, Florida, USA
[Excerpt with author's permission]

What we love and what we get most angry about tells a tale of the hero within. Anger reveals our ideals, our goals, and our grand passions. Angers are indelible character markers. We go to war to defend beliefs and persons we cherish. We fill with outraged determination when an obstacle interrupts progress toward our goals.

The Anger Leitmotiv

Anger is a normal survival emotion. Yet, we treat anger as if it were Pandora's box. If we dare open it, to see what's inside, we believe we will let loose a horde of evils. That apprehension is not without reason. Court dockets are overloaded with testimony of negative consequences of anger. As far back as our earliest memories of elementary schooldays, we recall encounters with troublemakers who were quick to get mad and pick-a-fight. Children, at predictable ages, tend to take immediate action to resolve conflict or disappointment, fists flying, tears flowing, feet kicking. As adults, we hear news reports of how often anger is the motive for criminal acts.

Ironically, and appropriately, anger is described by some as the moral, judicial emotion. Anger motivates acts of heroism as well as acts of mayhem. Especially, when love is involved. Strong attachment, as in grand passion, inspires both grand arts and folk arts. Do Greek theater, Wagnerian opera, country pickin-music, and western guitar songs possibly have anything in common? Yes: Love, honor, anger, and death.

Judicial Anger in Greek Tragedy and Grand Ole Opry

Oedipus Rex, the tragic hero in a classic 5th century BC Greek drama, is remembered as a model leader-king, yet one who inadvertently killed his father and married his mother. In mid-life, Oedipus learned that the menacing traveler he battled to the death when he was a youth was actually the king of Thebes, the husband of the woman he later met and married, and a man whose murder he vowed to avenge to honor his bride. His shock deepened when he further learned that the king and queen of Thebes were the parents he had been separated from in infancy. Ethically-bound to carry out his pledge of vengeance, Oedipus gouged out his eyes and went into exile with his daughter to guide him. His wife committed suicide. A Freddie Kruger-Halloween plot of ancient times.

This story became a favorite example for psychoanalysts. It was elaborated into the Oedipus Complex, which is used to diagnose and explain a particular kind of love-anger conflict. This condition is diagnosed when a male child's attraction for the mother, innocent or not, is complicated by rivalry with, or anger toward the father. Another classic tragedy, based on events that took place more than a millennium later, is immortalized in the 18th century opera, *Tristan and Isolde,* where Wagner's love-honor-anger-and-death leitmotiv probed medieval erotic desire and death wishes of a heroic dragon slayer and a beautiful Irish princess. Later, in the opera *Parsifal*, Wagner dares compare emotional similarities of love as aroused in sexual experiences with religious experiences. He explores the subtleties of the diverting and perversion of emotions and, always, harsh consequences of denial of emotions.

Grand passions and perversions are no less traumatic among the poor and the untitled. From the stage at the Grand Ole Opry in Nashville, Tennessee and from roadhouse music-circuits, simple ballads passed down through ordinary folk are full of the tragic, the sadistic, and the forbidden. Country-singer Johnny Cash made Folsom prison famous as a homeplace of love-stricken suitors. Cash also sang about desire, anger, and death wishes -- homey tales of jealous rages, of murders of rivals, and of unobtainable loved-ones. Even before Johnny Cash topped the hit parade, two unextrordinary but ill-fated lovers, *Frankie and Johnny,* were immortalized in song and dance by Gene Kelly, who staged the now famous bluegrass ballad as a musical spectacular for the 1951 film, *American In Paris*. Kelly's fusion of life's common passages into memorably innovative contexts earned him a place in history books, and speaks volumes about universality of a love-anger connection.

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Justified Anger

Passionate love endures in spite of, and sometimes because of, hardships, separations, and anger-arousing experiences. Such passion inspires the extraordinary in science as well as operas, ballads, and paintings. A love-anger motif became the driving force behind Marie Curie's efforts to extract radium from pitchblende. Madam Curie [1867-1934] loved her work and her teacher who, later, became her husband. Together, the Curies made discoveries that won them Nobel Prizes.

Yet, Marie's greatest work was done after her husband's tragic death. He was run over on a Paris street by a heavily loaded dray transporting commercial goods. Madam Curie's impassioned anger at this untimely loss had far-reaching consequences, inspiring her single-purposed dedication to completing their unfinished research. Her life of love, loss, sadness, anger, and purposeful work is a tale which could fit easily into Wagner's favorite plot: redemption through love. Her story equally well illustrates effective use of justified anger.

Justified Anger Is The Unsung-Hero Emotion

Anger receives little praise because it is a closet emotion. Stress researchers early-on found anger to be a hard-wired signal occurring in animals and humans, a distinctive neurochemical survival mechanism. Cannon was the first to associate anger with a biologically determined fight-or-flight response observed in all forms of life. Across the ages since prehistoric eras, adults had experiences that suggested it was best to avoid the painful, often irreparable consequences of fighting, at least with members of one's own tribe. Societies worked to eradicate or ignore the presence of anger. Children who showed their anger were quickly, sternly punished. A noticeable side effect of generations of effort to civilize angry behavior is under-appreciation of anger, and failure to recognize anger as a built-in problem detector.

Anger sends us signals that it's time to attend to justice, or love, or integrity. Anger's normal job is to increase chances of survival by adjusting attention to matters of immediate importance, and to work in concert with the two other stress emotions--curiosity and anxiety. Curiosity gets us moving and exploring, finding nourishment for body and mind, and anxiety keeps us from being foolishly naive, reminding us the duty officer on *Hill Street* Blues advises us to "be careful out-there on the street." Anger fires us up to be sure things are right for ourselves and our loved ones. Anger motivates us to pursue truth, beauty, and excellence.

In order to recover an appreciation for anger's intended beneficial function, it is necessary to look directly at anger, to acknowledge anger's presence and it's relationship to perfectionism, health, and happiness. We begin by taking a fresh look at anger. Everybody knows what anger is, even those who say that they never get angry. Everyone has experienced frustration, exasperation, and irritation.

Problems arise when anger is confused with hostility and aggression. Overlaps in the daily use of these terms contributes to a common misperception sometimes referred to as an *AHA Syndrome*. The acronym suggests Anger is automatically infused with Hostility and destined to culminate in acts of Aggression. In contrast, behavioral scientists make distinctions between anger and hostility. Hostility, like anger, is considered to be an emotional condition that can vary in intensity from annoyance to rage. But hostility, unlike anger, incorporates permissive attitudes toward destroying objects and injuring others. Hostility also involves disliking others and evaluating them negatively. Anger does not.

Aggression is behavior that results in punitive effects on persons or objects. Some aggressive acts are carried out to achieve desirable, generative outcomes. Harmful or destructive side effects are unintended. This type of goal-driven aggression is called "instrumental aggression" in contrast to "hostile aggression." Hostile aggression is behavior that is punitive, and sometimes destructive, proceeds out of negative evaluations. For example, sporting competitions that shift from competitive, instrumental-aggression into hostile-aggressive fighting are most likely to occur when team rivalries include a preconditioned hatred, contempt, or disrespect for the opposing group.

The fresh look at anger, in its natural form, shows it to be a survival emotion that motivates actions of innovators and idealists. Anger is a quality assurance emotion: *If I point out flaws when I see them; if I re-*

Continued next page

dress insults, then the good things of life can be won. Anger signals that quality of life is being threatened, and that corrective, sometimes punitive, action may be required.

Anger, recognized as a *stop-look-listen* message, means it is time to get clear about what we are expecting or are hoping for that is not happening. Stop and reassess the situation to be sure it is currently realizable and appropriate, or if it is an out of date expectation or objective. What is a reasonable goal in terms of fairness or improvement? Then, with that reasonable goal in mind, formulate an *instrumental* action plan, one that moves toward a constructive goal. Infusing Anger with Hope followed by Action produces a different kind of AHA Syndrome.

To re-claim the natural power [adrenal energy/ motivation] of the anger emotion involves the shift in expression of anger from the hostility to the hope mode. Experiences of anger, once acknowledged, are found to be neither a Pandora's box of evils nor a Medusa's head. We do not let loose a horde of horrors or turn into stone when we look deeply at anger. Instead, what researchers noticed is that anger experiences come in two related, but noticeably different ways. One, a broad-band signal, is called *angry temperament*, and the second, a personal protection signal, is called *angry reaction*. Individuals vary in their tendency to see a lot of situations as unfair, which is reflected by their reporting high or low levels of angry temperament. We also vary in the intensity of our reaction to being criticized, to not receiving recognition, or to being slowed down in pursuit of a goal. Angry reaction, while related to angry temperament, is triggered primarily by a perception of unfairness that strikes close to home-- nsults to the self.

More surprises awaited researchers who investigated what happens following an experience of anger. The expression of angry emotions has two separate, independent pathways. Anger expressed inwardly and anger expressed outwardly are not polar opposites of one trait. I could, for example, score high on one scale and not on the other, high on both scales, or low on both scales. Anger-in is when I know I am experiencing a mild to intensely angry emotion, but I do not express this directly to others. Anger-out is when I know I'm feeling angry emotion and I verbally or non -verbally let others know it. I speak-up, I strike others, I throw things.

The anger emotion impacts us in three ways -- mind, body and behavior. The experience starts with a mental signal that something is wrong. The autonomic nervous systems kicks into action and neurochemicals flow through the body. Energized by the emotional state, we shape mental conclusions [i.e., apperceptions] about the meaning of what we are perceiving. Finally we select a behavioral action. That action depends on available resources, knowledge, recent experiences, and creative thinking skill.

New ways of thinking about anger began with attention to stress, Type-A behavior, workaholics, and heart diseases. Surprise findings and subsequent changes in how researchers understood anger reshaped insights about longevity and vitality. Once anger proved to be the most salient emotional factor effecting heart disease patients, it wasn't long before scientific explorers mapped out topographic features of the emotion.

A scientific *Anger Box* replaces Pandora's Box to illustrate Spielberger's research findings about the experience and expression of angry emotions. Notice a strong separation of **state** from **trait** anger. State-anger describes variations of *intensity* of angry emotion being experienced in the present. Trait-anger looks at differences in the *frequency* that angry emotions are experienced in an extended time frame. State-anger may, or may not, reflect an individual's typical intensity of experience, and state intensity does not look at source or provocations of anger. State anger reflects *current circumstances*. Trait-anger suggests how often and how easily the **control** lid on anger **expression i**s likely to be raised. Trait anger does sort between generic provocations: Temperament-no specific provocation; and Reaction-receiving negative evaluation or being treated badly.

Since one person's boiling over point is likely to be quite different from another's, it became important to assess anger control. Measures reflect how much effort is expended to manage experiences of anger and subsequent expression of anger. Heroes who address every flaw, who always point out how things can be improved, may be acting out of love and loyalty, wanting only the best possible for others, push-

The Tyranny of Perfectionism

Few things in life attain the perfection of a first love. Few people fail to remember the first love-of-their-life. Frequently, it's a memory from high school years spiced with first kisses and first proms and first heartbreaks. Recalling first-loves may bring flash-backs of hard-won baseball games, or a shiny used-car, or frequently played tunes on a cherished guitar. Love at first sight may be best represented by the famous photograph showing sociologist Konrad Lorenz striding across a marshy field with a row of baby ducks following along behind him. Lorenz was the first thing these duckling saw when they opened their eyes, so they followed him wherever he went. Other new-born ducks follow a mother duck who is sitting by their eggs as they hatch.

First Impressions, Admirations, Irritations, and Trust

How long does a first impression influence where one goes? Some believe *reward-and-punishment* make the difference in how long a first love lasts. Others suggest it depends on the quality of trust in early relationships. Either way, a current reading of your early imprinting is easy: what do you most admire? What are you most proud of about yourself? What makes you angry? What about others irritates you most? Angers and irritations may give the best clues to deeper roots of your own characteristics.

Externally caused surprises, like falling and loud noises which Karen Horney said invoked the earliest experiences and expressions of anger, bring on internal feelings of disequilibria: Something is wrong. I must stop this. I must regain balance...must not fall. I must keep out the strong sounds. I must resist invasion. Why is someone/thing causing abuse to my body? It makes me angry.

Not everyone interprets imbalances or counter intuitive sensations as a call to aggressive behavior. Rather than instrumental or hostile acting-out, Einstein took a fresh approach to surprising external movement. Near the end of his life, he declared that his most happy moment came when he conceived of a man falling from the roof who simultaneously dropped an object he had been holding. As the man and the object continued to fall, the man was in motion, falling from the roof--yet he was in a state of non-motion or a stable, unchanging state in relationship to the object falling beside him at the same rate of speed. As a result, Einstein formulated his theory of relativity, a startling breakthrough in the science of physics, releasing scientists from Newtonian expectations. Visions of a dual state of being, without Einstein's insight, might generate more questions about one's sanity than about relativity.

Editing is Better than Denying

Like Einstein, we can control how we respond to our emotional signals. We can decide not to deny anger signals. We can *edit* how we behave after we get a surprising signal: *Something is not moving as expected. Perhaps it needs some fixing.* Or, even better, *we need to consider relativity*.

Denial may bring short term relief, but is long range trouble and reduces survival probabilities. Editing, on the other hand, maximizes survival potentials, in a relativity context. Editing responses to emotional signals involves intentional thinking about immediate actions compatible with future benefits for all.

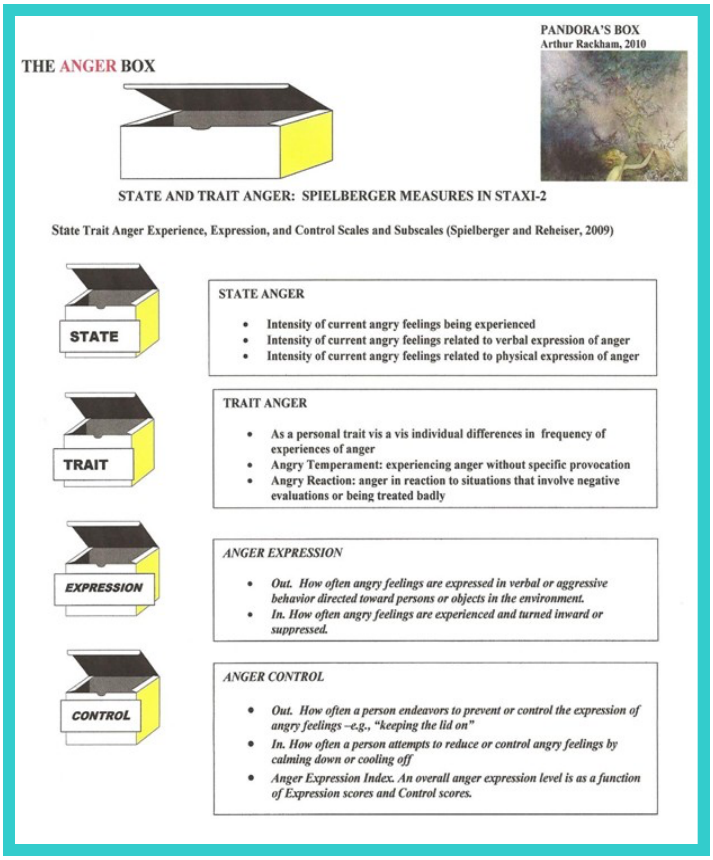

This flow chart suggests it's best to accept sensations for what they are. Recognize when something is falling, invading, or moving in a surprising direction. Notice how anger can be used radar-like, to show when the ship is veering off-course. Never loosing sight of the fact that if anger is allowed to be king among emotions, to dominate curiosity and anxiety, then, anger's quality assurance perceptions can turn ugly. Or, if anger is allowed to disguise itself in robes of honorable perfectionism, it begins planting seeds of depression.

Anger and Depression In Second Generation Corporate Leaders

Harry Levinson, one of the wisest US therapists who worked primarily with executives, understood that depression and psychological illness is one of the most important problems associated with failures in corporations. He argues that understanding depression is the first step in resolving complex psychological issues inherited by second & third-generation leaders, especially in giant corporations. Levinson found that, too often, individuals groomed for succession leadership and even newly-hired talented technicians were vulnerable to depressive rage in the aftermaths of abrupt or dramatic changes in corporate operations.

Less than two years after the downsizing rush, popular management publications reported that reengineering advocates were reversing pattern and rushing to aid beleaguered staff in human resources departments. These once hard-nosed, time-task neo-Taylorites reported feeling pain, anger, and guilt. The corporate reengineers suffered emotions they denounced while arousing them in others.

Unattended Anger, Injustices, and Depressions are Dangerous

What's the problem with just ignoring the distress felt when something we advocate ardently doesn't turn out to be perfect? What's the cost of executive depression, burnout, heart attack, suicide? A classic example from the 1980's is Vincent Foster, the accomplished attorney who was deputy counsel to President Clinton. Psychological autopsy of this suicide suggests it was perfectionism that led to the depression that ended with a solitary gunshot. Yale's Sid Blatt describes Foster as a pillar of strength, a portrait of poise, and a person of impeccable integrity, someone who seemed outwardly successful in both his professional and personal life.

It was the intensity of his perfectionist standards and his vulnerability to personal and public criticism that allowed his inner voices to stalk him relentlessly. There were observable symptoms: He lost weight, his mood was low, he spent weekends in bed with the shades pulled, he told the graduating class at the University of Arkansas Law School a few months before his death that "The reputation you develop for intellectual and ethical integrity will be your greatest asset or your worst enemy."

Executive suicides represent an extreme resolution of severe depression. More frequently, high achievers survive the periods when they experienced some or all of the criteria used to diagnose major depression and the time of reduced productivity. Many more endure episodic experiences of one or two of the critical symptoms: diminished interest and pleasure; significant increase or decrease in weight; chronic fatigue; inability to sleep or over-sleeping; agitation; sense of worthlessness or guilt; reduced thinking or concentration abilities; thoughts of death.

Living in Beautiful Surroundings Is Not Protection from Machismo Thinking

In New Zealand, recently reported to have highest suicide rate in the industrialized world, it's the young men who are six times more likely to kill themselves. Analysts conclude that they are trying to conform to exaggerated standards of masculinity. They are expected to excel in school and in sports and to never give vent to their emotions. No wonder the families are often surprised by their suicides. Self-criticism, a key aspect of perfectionism, plays a central role in depressions and in suicide.

Blatt points out that Perfectionism, in some forms and to a certain degree, can contribute to high achievement. He suggests that perfectionism comes in three varieties: socially prescribed perfectionism, other-oriented perfectionism, and self-oriented perfectionism. Of the three, self oriented perfectionism is the one closely linked to executive effectiveness. High personal standards, a need for order and organi-

zation seem to go along with good work habits, striving, and high achievement. Executives with strong self oriented perfectionism characteristics, as in an active striving for improving performance to the point of being flawless, are typically managers who have been seen as resourceful and engaged in constructive problem solving activity. Executives who set high expectations and standards for others, Blatt's third face of perfectionism, when those expectations are realistic and presented in supportive ways, are identified as charismatic leaders and mentors in studies reported by Bernard Bass. They inspire others to achieve even more than they ever imagined they could achieve.

Beneficial vs Debilitative Perfectionism

Beneficial perfectionism, a condition found in hardy executives, is characterized by a sense of pleasure from painstaking effort, rather than a feeling of anger with oneself or others if an outcome is not perfect. These persons are flexible, adaptable leaders who seek excellence while being able to be less precise when necessary or appropriate. For example, an anonymous saying advises the busy person that "some things are worth not doing well."

Perfectionism coupled with fear of failure or with stressor conditions which limit the level or nature of achievement is a prelude to a number of disorders, especially depression. Negative conditions intensify when self-oriented perfectionism is influenced by socially prescribed perfectionism. The perfectionist harbors a belief, real or imagined, that others are expecting difficult or impossible achievements and will withhold acceptance or approval until these imposed demands are met. Such external expectations are felt to be uncontrollable. They generate, as in an experience of falling, feelings of anxiety, helplessness, and anger.

Debilitating perfectionism is found in persons who have excessive concern over mistakes, who perceive high parental expectations along with strong criticism, and who struggle with doubts about the quality of their actions. These people carry an intense need to avoid failure, nothing is quite good enough, and there is an endless cycle of over-striving and distress. Health problems linked to debilitating perfectionism, in addition to depression, are eating disorders, obsessive-compulsive disorders, anxiety, panic disorder, migraine, sexual dysfunction, and Type A Behavior.

Death, Divorce, Abandonment, Self-Criticism

Depressions that are not caused by chemical imbalances in the body are believed to be activated from two sources, either interpersonal relationships or self-definition issues. Inner questioning is either about *who we are*, or *who I am*. Depression arising from interpersonal relationships is often related to a loss of a significant other who was greatly depended upon. This type of depression can be noticed after a death of a significant other and after a divorce. Likewise, it underlies the abandonment experiences of employees fired or retired from companies after many years of employment. A second source of depression is associated with autonomous responsibility, self-criticism, and guilt. There is continuous harsh self-scrutiny and evaluation, plus a chronic fear of criticism. They make many demands upon themselves and are often highly competitive, with others and with themselves.

Assessments of health-care mid-level managers and of local pastors from two major Protestant denominations reflected higher-than-average levels of assessed trait anger. Both mid-level managers and local pastors reported noticeably higher anger levels when contrasted with executive level or regional administrative staff, who reported higher levels of trait anxiety. One explanation is that senior executives and administrators know that no one has neat solutions to industry or profession-wide issues, while new managers and professionals, frequently selected for front-line positions because they are fired-up go-getters, experience impatient frustration. They assume those in seats-of-power are hoarding information, or else they are incompetent to produce decisions on timely basis. *These executives and administrators are keeping me from doing perfect work*.

Helping-professionals and therapists coined and applied the term *burnout* to negative, depressive periods in the careers of professionals of all types. These intervention specialists determined that the way to reduce depressive episodes for professionals and executives is for organizational leaders to recognize the

symptoms of depression in persons like Vincent Foster, and use their authority to take action to provide assistance to individuals struggling against burnout or depression.

Too Little Control, Too Much Control Exact a Price

Type-A behavior patterns show that hard-driving individuals liked to gain and maintain control over their environment. Assessment of anger control shows that persons with high anger control scores are those who invest a great deal of energy in gaining and maintaining control over their expression of anger-in and, or out. If there is a high level of angry temperament, anger is predicted to show through as authoritarian behavior with deliberate use of expression of anger to intimidate others. On the other hand, observers and predictors, also see that excessive control can at times result in passivity. High anger-out control levels and high anxiety scores are also considered conducive to depressive states.

Suppressed anger, as measured on the anger-in scale, is associated with hypertension, especially in Black males. Interpretation of anger-in control is underway and is expected to also impact elevations in depression. A tendency to work hard at control of anger expression conforms to Pandora-Box beliefs about keeping anger in the closet. Excesses in anger control are not more prevalent in either male or female populations. Gender differences on anger measures do show up in questions about particular situations. Women experience more intense anger when criticized in front of others, and males are more angry when slowed by others mistakes. Men are much more likely to report expressing anger out physically or verbally, e.g. when I get angry I say nasty things.

While women generally seem more able to tolerate higher levels of anger without becoming ill, recurring patterns are similar in both gender groups. High trait anger, high anger control is associated with recurrence of breast cancer in women. A high trait anger, high angry reaction, and high anger-out is an at-risk factor for myocardial infarcts, heart attacks, and cardiovascular accidents, strokes. These later findings are not news when we recall the tale of Rip Van Winkle. This fictional New Englander got home after a 20 -year nap and learned that his ill-tempered wife had died of apoplexy. Internal physical disasters are known to happen in the wake of frequent and intense bouts of fury.

Fifty Plus Years of Investigation into Executive Stress

Specific insights into the role of anger in health have been a long time in the making. At the end of World War II the US male was twice as likely to be struck down by heart failure as a Dane, a Swede or a Norwegian, and five times as likely as a Japanese man. Deaths from strokes and heart attacks had risen from 20% in 1900 to 55% in the 1950s. The federal government launched the first longitudinal study of the causes of heart attacks. With more specific information about risk factors like tobacco use and cholesterol, the general public gradually became less fatalistic about heart diseases.

Changing behaviors--stopping smoking, exercising, watching the diet--was accepted as a means to preventing heart attacks in people with basic good health. Next came the study of nonphysical risk factors, and close attention to the fact that many heart disease patients were ambitious, competitive, and highly stressed. The direct comparison of Type As with Type Bs showed that over a period of eight-and-one-half years the Type As were more than twice as likely to suffer heart attacks as the Type Bs, even with other risk factors like cholesterol and smoking were taken into consideration. Major components were found to be the competitive way of life, the sense of time urgency, and an excessive involvement with one's job. Factors were refined to hostility, irritability, impatience, and competitiveness. Under scrutiny, the underlying factor distills into anger and its power to activate the autonomic nervous system.

Physiological Pathways from Anger to Heart Disease

Anger fires-up a signal that travels down the pituitary, hypothalamus, adrenal cortex pathway and puts into production excess catecholamine which in turn are what put the plaque on the inside of the blood vessels and give the heart a hard time. This is one way that perception of external irritation brings about internal actions that wear down and burnout physical beings. Other emotions collude with anger, to our det-

riment and to our benefit: Anxiety boosts the anger signal into a bigger wallop. Curiosity tones things down by revving up proteins in the brain and strengthening the auto-immune system.

Cynicism, an acquired attitude, is believed to stimulate production of additional fight-or-flight hormones [catecholamines, i.e., adrenalines] that accelerate buildup on artery walls, causing hardening of the arteries. Following the cynicism etiology school-of-reasoning, hostility questionnaires measure, primarily, mistrust. The assertion is that those who have untrusting hearts, who believe it is safer to trust nobody, who say "most people will tell a lie to get ahead," are, perhaps, not angry, just cynical. It's hard to believe that those who find it safer to trust nobody would not have an emotional history dominated by anger and anxiety. Darwin and Freud recognized that depression generally resulted from the interaction of anxiety and anger. Spielberger and Reheiser {2009) further trace the history of theory and research on depression, which carries symptoms that vary in severity and can include sadness, guilt, hopelessness, gloomy attitudes [cynicism] and even thoughts of suicide.

Disturbances of Normal Processes

Hostile aggression begins with a negative attitude about the object of the invasive behavior, a cynical attitude. Evaluating others negatively escalates the dislike, which is manifested in harmful ways as sanctioned by permissive attitudes toward destroying objects and injuring others. If anger is a neurochemical process proceeding from experiences of a hardwired emotion, then hostile aggression is an aberration of normal survival function. Normal processes gone haywire are examined for characterizing features and classified as disorders.

Classification of disturbances of natural processes, physical and mental, is not a new idea. Medical libraries are full of volumes describing the physical parts, their workings, their interactions, and their abnormalities. Mental workings and abnormalities are more recent targets of diagnostic and prognostic knowledge seekers. Four revisions with another in-process of the initial 1952 Diagnostic and Statistical Manual of Mental Disorders have been produced since 1968. While not one addresses anger directly, acute anger is frequently listed as a symptom and as a primary diagnostic criteria in a wide range of disorders -- affective, organic, neurotic, psychotic.

Panic Attacks

Panic attacks, an unpleasant and acute anxiety episode, offers a prototype for thinking about "anger attacks." Panic attacks, described frequently in popular magazines, are DSM listed as a unique anxiety disorder.

Symptoms include difficulty breathing, palpitations of the heart, chest pains, dizziness, hot and cold flashes, sweating, fainting, trembling, fear of dying or going crazy. A panic attack brings sudden and intense apprehension, fear, or terror. These moments occur unpredictably, yet may become attached to certain situations -- i.e., driving a car. The disorder often begins in late adolescence or early adult years. It may be limited to a single brief period, or become chronic. It is rarely incapacitating unless complicated by severe phobia, abuse of alcohol, or drugs and medications. Early warning clues are experiences of separation anxiety in childhood and or sudden loss of significant others.

Anger Attacks

Temper tantrums are recognized in children, and can continue as an adult behavior pattern. In an early consulting assignment, I learned about both the tantrum and the perfectionist. Contracted to provide organization development services, my monthly activities were periodically side-tracked to attend to special situations identified by the Vice-President. One month, I talked with a computer specialist who was kicking the main-frame computer and screaming at it several times a week. Another month, I spent time with a supervisor who was being heard down the hallways venting her anger at her staff. She berated them about inappropriately dressing for work and excessively wasting time.

The computer specialist was intentionally venting his frustration and anger in order to send a message upstairs that he wanted a new computer. The woman supervisor, with no daughters of her own, was unaware that her voice tone and affect conveyed anger at her young staffers. This supervisor-perfectionist

not only wanted to shape her employees into top performing employees. She wanted them to make a good appearance by being professionally well-groomed. Most of all, she wanted to protect them, fearing that they were at-risk wearing short, short skirts in the dominantly male environment of their heavy-industry workplace. She was trying to warn them that, at the very least, they could evoke insults and undesirable sexual attention. Of course, at her more settled, less adventuresome stage of life, she failed to see that attention from the male workers may have been an important goal for the younger women.

After those early assignments, I began to notice that my organizational consultation assignments frequently involved [a] cleaning-up after an employee's expression of anger and [b] communications training to prevent angry exchanges. Looking back, I see that many of the anger incidents I witnessed or intervened with were similar in many ways to panic attacks. Angry behaviors, however, in my experience, occurred more frequently in work settings than panic attacks and had more after effects than did panic attacks. I observed that:

Anger attacks include labored breathing, flaring of nostrils, narrowed eye focus, pounding of the heart, clenching of head, arm, and leg muscles, clutching of the chest, hot flashes, going cold, and loss of concern for personal safety, life, or others at risk, a tunnel vision awareness.

An anger attack begins with a sudden and intense sense of frustration, deprivation, or insult. These moments occur unpredictably, yet may attach to certain situations, e.g., an umpire's ruling in a baseball game. The disorder often begins in childhood or preadolescent years. Anger attacks may be limited to a single brief period, or become chronic. Anger attacks are rarely incapacitating unless complicated by particularized hostility, abuse of alcohol, drugs, or medication. Early warning clues that an anger attack is imminent can be similar to aura precursors of an epileptic seizure: onset of sensory hallucinations of smells, colors, or pains in parts of the body where tension is maintained, such as the jaw or the neck. Etiologies of chronic anger attacks include a history of severe parental punishment and / or criticism, sibling fighting, or severe deprivation in childhood and early life. Anger expression is influenced by family and social norms, and may be effected by genetic factors.

How Do I Love Thee? Let Me Count the Angers

Anger, like love, can be personal, professional, and generic, for example, as defined by erotic, filial, and agape types of love. Things that make us angry enough to take action at home, at work, or as a citizen reveal the hero within. Angers are indelible character markers of what it is that we value and love.

Examples of Filial and Agape Angers

Martin Luther King said, "I have a dream." A legendary Mexican contemporary, Don Juan was a very different type of visionary. Made famous in the writings of Carlos Castaneda, Don Juan understood individual, separate realities and taught the importance of controlled folly. King loved his kinfolk: filial love. Don Juan loved all folk: agape love. One advocated an instrumental, non-aggressive anger-out strategy for demonstrating ways of protecting and loving others. The second plumbed the depths of anger-in strategies, ways of controlling fascinations and frustrations that inhibit our ways of respecting and loving all life. King was angry about racial prejudice against his brothers. Don Juan was angry about social norms and biases that inhibit talent utilization, and respect for life potentials in each individual.

King, full of righteous *filial anger*, spoke about injustices done to people with black skin by people with white skin. He harnessed and channeled the anger of many people to move society toward the dream of equality, his goal was justice. Don Juan spoke of mastery over anger through intensive, individualized training. Don Juan's students were challenged to let go of externally imposed perspectives, and to train the powers within to extend their idiosyncratic capabilities into the world. He taught that cultivation of inner strength let's one achieve beyond ordinary expectations and goals. He was full of agape anger about people enslaved to things, people or ideas. Both were charismatic participators in the quest for quality of life.

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Erotic Anger

Most of us fall somewhere between the activist and the individualist, and all of us have at least a glimpse of what personal, erotic anger is about. Freud's love-anger-deathwish notions make sense even for those who disagree with elaborate psychoanalytic assumptions and conclusions. For the less fatalistic, living beyond first impressions and first loves is a matter of putting new spins on emotional experiences. Anger signals a time-out for planning. Refocusing gets us to be at-rest with what's beside us, here and now. Like Einstein, we shift an internal sense of falling into one of moving relative to another person or object of our love or anger.

Concentration on goals, much like Marie Curie's determination to complete the research work she began with her husband, becomes a stabilizing influence as we adapt in response to anger's alert that it's time for a perceptual shift. Executives and managers who refuse to accept new goals, new technologies, new assignments are difficult, sometimes impossible, to motivate. They are using their anger to dig their heels in, to stay right where they are for the rest of their days. Some call it being in a rut, others consider it digging an early grave.

We know, first or second-hand, the debilitating consequences of a wrong choice in a career or in a marriage partner. Struggles come either way, staying in a bad job or marriage, and when divorcing or starting over. Over-estimating and relying on first impressions is a matter of doing more wishful thinking than data gathering. First impressions seldom include all relevant and accurate details. Mistaken first loves, as well as long-lasting loves, show themselves in our angers and too often lead to our sadness and depression, which in extreme situations culminate in suicide or hostile aggression.

As we live out our days in the non-stop stream of experiences, emotions, and behaviors, we can count on anger to be an informed ally bent on improving and perfecting things. We can tune into what our angry temperament and our angry reaction points out. We can edit our behavior, pausing the spontaneous flow of anger-out or anger-in long enough to determine the behavior that will maximize survival potentials when we lift the lid of the anger box.

Anger As Political Advisor: Constant Campaign for Justice, Fairness, Improvement

Beneficial anger in it's intended form keeps us from being walked on, abused by the systems around us, and increases our energy for achievement. Anger makes it possible for us to survive, to feel adequate, to grow, and to make meaningful contributions to life around us. In fact, our anger can be compared to a politician who runs for office every two, four, or six years, and knows staying relevant means being on a *constant campaign*. To hold your place of influence and get re-elected, the politician must be alert to what is lacking and needed, and must stay publically visible. Like anger, the elected official will be constantly pointing out what's wrong with the way things are in the present and how to make it better in the future.

> *Anger, like love, is a moral emotion...We are ambivalent about anger because sometimes it is effective and sometimes it is not, because sometimes it is necessary and sometimes it is destructive. . . anger is ultimately an emphatic message: Pay attention to me. I don't like what you are doing. Restore my pride. You're in my way. . . Give me justice.*
>
> *Anger, The Misunderstood Emotion. Carol Tavris*

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Establishing Forgiveness and Peace Gardens Around the Globe

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Forgiveness is not an occasional act.
It is a permanent attitude.
Martin Luther King, Jr.

Although an abundance of peace organizations, non-governmental, as well as related university affiliations exist; conflict continues to flourish around the world. The roots of these conflicts and violence may be political, religious, territorial, tribal, generational, as well as those motivated by greed, rigidity, ego centrism, and shortsightedness. Since 1988 I have organized and delivered programs in over 45 countries to bring peace, conflict resolution, post trauma healing, forgiveness, and meaning-making through our organization, the Association for Trauma Outreach & Prevention, Meaningfulworld (www.meaningfulworld.com). We have noticed repeatedly that in spite of the establishment of a number of peace centered groups there are at least a handful of oppositional groups, or extremist groups being formed in opposition to another extremist group. In addition, many states have used extreme force, slavery, and violence in the name of peace and security.

Only in the Middle East, we have seen Israeli government building a wall all around Palestine and complicating and delaying the check points. We have also seen many Islamic extremist groups formed to defy these new developments. Similar oppositional groups are formed in Africa, such as in Kenya, Somalia, the Democratic Republic of Congo, and Burundi, all in the name of peace and security while destroying lives and ecology.

In addition to our educational and empowerment programs, we have recently integrated the establishment of Forgiveness and Peace Gardens around the world, in countries where we have collaborative centers and programs. These gardens have been welcomed as an alternative ecological connection, as well as a reinforcement of our educational programs. Forgiveness & Peace Gardens are a place where people can visit privately, or in a group, to renew their commitment to peace, and to be mindful of the importance forgiveness plays in establishing peace within, and all around. We can use these gardens to gather around and have educational, ecological, and emotional healing programs, especially on United Nations International Day of Peace annually 21 September. Peace begins in every individual, first on a personal level, and then spreads through our actions, behaviors, thoughts, and intentions. This extension happens both energetically as well as in learned and reinforced behaviors.

Many individuals, as well as States, are not mindful of inconsistencies they engage in; they may talk about, yet yell, hit, or destroy in anger and rage. If one's thoughts, actions and intentions are not harmonized we will not be able to establish peace on any level. We need to harmonize our head (thoughts), heart (intentions), and hands (actions) in order to be in peace.

Central to our educational programs is the 7-Step Integrative Healing Model (Kalayjian 2002, Sofletea & Kalayjian 2012). This innovative model incorporates various theories including: psychodynamic (Freud, 1910), interpersonal (Sullivan, 1953), existential and humanistic (Viktor Frankl, 1962), electromagnetic field balancing (EMF, Dubro & Lapierre, 2002), learning theory, ecology, forgiveness (Kalayjian & Paloutzian, 2010), flower fssences (Bach & other flower remedies), essential oils, physical release (yoga, martial arts), and mind-body-spirit chakra balancing exercises, prayers, meditation, indigenous rituals and celebration.

The 6th step of this Model integrates ecological principles of Mother Earth, for engendering inner peace, peace all around, as well as physical, mental & spiritual health. Creating gardens as sanctuaries is important to reconnect with Mother Nature and honor our presence in this world in harmony with our Mother. Whether we have a window seat, a terrace, a porch, a corner in our room, or a garden is irrelevant; instead, what matters is a corner that we create with thoughtfulness, intention, and love to house a work of art that celebrates our connection with the earth and our unconditional love. Our feelings of fear,

Continued next page

isolation, hopelessness, and uncertainty will decrease immensely once we establish and frequent this special sanctuary. We may explore a variety of themes, such as angels, flowers, wood, trees, bells, gongs, candles or colorful flags or scarves, with each theme representing an aspect of the earth. We need to be mindful to include something to represent love, something for passion, another for forgiveness, love, nurturing abundance, gratitude, and compassion.

Therefore, we are mindful of including 7 elements: Water, such as a fountain or running water; earth, such as a plant with a planter; fire, such as candles, wind, created with chimes; rocks and crystals, especially rose quartz, jade or turquoise; sculptures, representing peace and forgiveness, and incense. We have sown the seeds to create these ecological peaceful places for students, faculty, clinics, hospitals, and community centers in eight countries in the Middle East, Haiti and Africa. Community is invited to gather around the garden to engender inner peace, to help forgive oneself and others, to raise consciousness on being mindful of one's own feelings, managing and transforming negative feelings of anger, rage, envy, and greed, and replacing them with positive and uplifting feelings such as love, gratitude, forgiveness, empathy, compassion, abundance, and acceptance. These gardens will be in every house, in front of every university, secondary and primary schools and kindergartens, including in the slums, refugee centers, and other open community centers.

Garden description

The garden should be circular, representing natural space. Evergreen short bushes are to be placed all around to mark the circularity, which represents unity, as well as follows the shape of a medicine wheel. Large river stones or rocks could be placed around the perimeter for definition and grounding. A small cedar tree could be central. The following flowers and herbs are recommended, with special attention to perennials for their endurance and practicality.

- Hybrid Tea Roses, such as Peace, Pope John Paul II, Our Lady of Guadalupe, and Innocence
- Baby's Breath, to connect us with our innocence and purity of our heart
- Gardenias, for purity of purpose
- Magnolias, to activate our heart
- Allium Gigantean, for nurturing unity
- Gladiolas, for sincerity
- Bird of Paradise, central for meditation
- Iris, for appreciation of friendship and instilling hope
- Blue Scylla, for forgiveness
- Honey Suckle, for letting go
- Jasmine, for transformation
- Lily of the Valley, to open our heart to let love in
- Lilies in general, to strengthen our commitment to be the change we want to see,
- Larkspur, to open our heart even when we are in pain, and we have been hurt
- Clematis, for nurturing peaceful thoughts
- Hosta, for devotion to our inner health
- Yarrow, for healing
-

Other flowers could be added based on your garden's exposure to sun, type of soil, water needs, and season. I encourage you to add tulips, daffodils, crocus, iris, bergamot, butterfly catcher, bearberry bush, lobelia, evening primrose, poppies, mums, bachelor buttons, and so forth. Inside the circle I recommend to plant the following healing herbs: lavender, mint, rosemary, sage, thyme, and other local healing herbs.

Other flowers could be added based on your garden's exposure to sun, type of soil, water needs, and season. I encourage you to add tulips, daffodils, crocus, iris, bergamot, butterfly catcher, bearberry bush, lobelia, evening primrose, poppies, mums, bachelor buttons, and so forth. Inside the circle I recommend to plant the following healing herbs: lavender, mint, rosemary, sage, thyme, and other local healing herbs. If the Forgiveness and Peace Garden is within an institution, all departments would get involved in the establishment of this garden by donating one of the flowers or herbs mentioned above. The art department could be asked to conduct a contest for the best sculpture signifying peace and forgiveness. The winner's sculpture would be placed in the center of the garden with a plaque that states:

Continued next page

Meaningfulworld Ecology Project Forgiveness & Peace Garden (name of institution, city & state)

Brochures and informational material could be prepared to have an opening of the Forgiveness and Peace Garden, and press releases sent to the community at large, to disseminate this concept widely. Liaisons will be assigned to mentor community members on the importance of these gardens, how to start them in their homes, how to begin a practice of mindfulness for peace and forgiveness, and how to utilize these gardens in a meaningful way. Forgiveness is shifting from the automatic ego reaction (anger/self-protection, hurting back), to a non-reactive conscious response of empathy; considering that the other person is ALSO a human being, perhaps not mindful, and there is no peace without forgiveness (Kalayjian, 2010).

How to use the Forgiveness and Peace Garden

Meaningfulworld liaisons will mentor the community on how to use this garden daily for prayers, meditation, and a time for refuge, silence, renewal, commitment and mindfulness. This Forgiveness and Peace Garden could signify that no matter how challenging life circumstances become, we can surround ourselves with love, peaceful plants, herbs and flowers, and reinforce the importance of peace for our health, for generations of healthy people who are guided by peace, forgiveness and love. For forgiveness is not an innocent act of Pollyanna but rather is self-love above and beyond anything else, as well as love of others, engendering inner peace as well as peace all around us.

Gratitude: special gratitude to Antonia Gentile, Sandra Delcioppio, and Leysa Cerswell.

For further information on how to start your own garden contact the author Dr. Kalayjian at DrKalayjian@Meaningfulworld.com selective gardens would be displayed at our website: www.Meaningfulworld.com

Kitty Genovese Forum Convened in New York City

Harold Takooshian, Ph.D.
New York, New York, USA

On March 8-9, 2014, 150 people gathered in the rooftop conference center of Fordham University in New York City, to hear 24 experts address the "The Kitty Genovese Memorial Conference: 50 years later." These 24 speakers included journalists, scholars, activists, and Genovese family members--most of them meeting for the first time. Participants heard each expert speak with passion for 15 minutes, presenting their new information or insights, on one of three themes: (1) a celebration of young Kitty's life, (2) a re-examination of the facts in her senseless death, or (3) the many ways society has changed for the better after Kitty's tragedy.

When Kitty was fatally stabbed outside her New York City home at 3 am on March 13, 1964, her little-known death soon exploded into headlines world-wide, when journalist A.M. Rosenthal's bold book, THIRTY EIGHT WITNESSES, asked this simple question: "If many of Kitty's neighbors saw or heard her screaming for her life, why did none of them help her, or even phone the police in time?" Even a half-century later, we continue to learn new facts about Kitty and her iconic tragedy. Inexplicably, not one biography of Ms. Genovese has appeared these past 50 years--yet this conference included the voices of authors of at least five powerful new or forthcoming books this year about Kitty and her tragedy. A list of these books appears in the conference program, at http://file-id.org/140310/13688.

One question probed in this conference was whether knowledge of Kitty's tragedy has changed bystander behavior since 1964? A blog seeks people's views on this question, http://psyccritiquesblog.apa.org/2009/04/what-is-the-value-of-the-genovese-parable.html.

For any details, contact the forum's co-chairs: Attorney Joseph F. DeMay of New York City, or Professor Harold Takooshian of Fordham University, kgconf@gmail.com.

ICP, Inc. 2014 ANNUAL MEETING: JULY 13-15 PARIS, FRANCE

THEME: INTERNATIONAL PERSPECTIVES ON GLOBAL ISSUES

President-Elect and Scientific Program Chair: Dr. Janet Sigal
Conference Committee: Florence Denmark (Co-chair), Joy Rice

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Non-Member	**125.00**	$150.00	
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4625 Cedar Ford Blvd., Hastings, FL 32145 USA

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If you would like information regarding the International Council of Psychologists, Inc., the conference, or any of the publications for the organization, please feel free to visit the website at http://www.ICPWeb.org. Membership and registration forms reside there as well as a great deal of information about the organization.

International Psychology Bulletin

Volume 17 No. 4 Fall 2013

Editor
Grant Rich

Associate Editors
Harold Takooshian
Richard Velayo

Official Bulletin of the Division of International Psychology [Division 52 of the American Psychological Association]
http://div52.org

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Submission Guidelines for
Research Articles
International Psychology Bulletin

Research article submissions: The *IPB* publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association, 6th Edition. Please submit it as a Microsoft Word document, not as a pdf file.

Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, e-mail address, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://www.apastyle.org If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method. *Improperly formatted submissions may be returned unread to the author and/or may delay the review and publication process.*

To submit manuscripts to the Division's peer-reviewed quarterly journal, *International Perspectives in Psychology: Research, Practice, & Consultation*, contact Editor Judith Gibbons at gibbonsjl@slu.edu.

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Submission Deadlines

International Psychology Bulletin

Grant J. Rich, Editor, optimalex@aol.com

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to the appropriate section editor.

- *Book Reviews, Current Issues Around the Globe, Division 52 News, International Employment Opportunities,* and *Peer-Reviewed Research Articles:* Grant J. Rich optimalex@aol.com
- *Student Column:* Valerie Wai-Yee Jackson vjackson@alliant.edu
- *Teaching International Psychology:* Gloria Grenwald grenwald@webster.edu

Submission Deadlines: Spring issue March 31st

Summer issue June 30th

Fall issue September 15th

Winter issue December 15th

Issues typically will be published about 4 weeks after the deadline.

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President's Reflections: Building Bridges When East Meets West—Psychologists and Students at the 2013 APA Convention in Honolulu, Hawaii

Mercedes A. McCormick, Ph.D.
Division 52 President
mmccormick2@pace.edu

In preparing to write this 2013 fall presidential column, I thought intently about meeting wonderful colleagues at the 2013 APA convention in Honolulu who shared camaraderie with smiles and laughter. I hope your time in Hawaii allowed you to combine professional interests with experiencing the Polynesian culture and sightseeing paradise.

As you know, APA is a hectic time. You need to develop your own system to navigate APA activities and events. Many 2013 APA events and activities in the exhibition hall, convention center, and APA Divisions' hospitality suites programs were informational and motivational.

The 2013 APA Div. 52 program and hospitality suite events emphasized Div. 52's mission to develop a psychological science and practice that is contextually informed, culturally inclusive, serves the public interest, and promotes global perspectives within and outside of APA. In addition, my 2013 Div. 52 Presidential Initiative to *Build Bridges* intertwines well with Div. 52's mission and lends itself to Div. 52 program planning. (Please refer to the detailed International Psychology 2013 APA Convention Program and International Psychology Hospitality Suite program in the *International Psychology Bulletin* (Volume 17, No. 3, Summer 2013).

The purpose of this column is to reflect on the highlights of the 2013 APA convention as they relate to the 2013 Div. 52 Presidential Initiative "Building Bridges…" The following content will be addressed: (1) APA Division 52 opening symposium—*Building Bridges Between Div. 52 and Psi Chi to Promote Student Excellence and Leadership*; (2) *2013 Division 52 Presidential Address: Lessons Learned...to Lead*; and (3) *Div. 52's Building Bridges Initiative*—demonstrated by key hospitality events.

1) **APA Division 52 Opening Symposium:** The opening symposium's purpose was to advance the ideas and endeavors that were described at the 2012 APA convention symposium *"Building Bridges between Division 52 and Psi Chi International."* Speakers dialoged about partnering with Division 52 through their international psychology professional experiences. Current symposium speakers were identified as ambassadors to represent Div. 52 and Psi Chi's mission to promote academic leadership and leadership in educational institutions throughout the world. At the 2013 opening symposium, speakers discussed such topics as: *Using the Internet to Build Bridges to Enhance Student Involvement in International Psychology* (Harold Takooshian, Fordham University); *Innovative Approaches to Conducting International Research with Students* (Jason Young, 2013 President of Psi Chi, the International Honor Society of Psychology, CUNY -Hunter University, NYC); *Division 52's Student Committee's History, Role, and Lessons Learned for Psi Chi International Chapters Membership* (Laura Reid Marks, Div. 52 Student Committee Co-Chair, Purdue University); *Thinking Globally, Acting Locally: Building Bridges Italian Style* (Bernardo Carducci, Div. 52 Chair Clearinghouse, Indiana University Southeast); and *Psi Chi Debuts in South Africa-Summer 2012* (Martha S. Zlokovich, Executive Director of Psi Chi International Advisory Board and Maria Lavooy, 2013 President-Elect of Psi Chi International, Florida Institute of Technology). Additionally, officers of Psi Chi, the International Honor Society in Psychology, mentioned that Psi Chi has opened chapters in eleven countries around the globe. Psi Chi will continue to mention APA Division 52's mission to build bridges to Psi Chi chapters' advisors around the globe.

2) **Presidential Address:** A highlight of the 2013 APA convention was my Division 52 Presidential Address. Kindly go to the links below to read my introduction and PowerPoint presentation. Overall my presidential presentation is presented from a personal career developmental perspective. Please keep in mind that the live presentation at the convention provided nuances, gestures, and remarks that are difficult to capture in connecting to hyperlinks. However this is a good understanding of my career and presidential address: *Lessons Learned...to Lead.*

   Introduction can be viewed at: http://internationalpsychology.files.wordpress.com/2012/09/division_52__presidential_address_introduction.docx

   PowerPoint presentation can be viewed at: http://internationalpsychology.files.wordpress.com/2012/09/div-_52_presidential_address_submitted_to_ipb.pptx

3) ***Building Bridges* Hospitality Suite Event:** The *Building Bridges* initiative was welcomed by APA Division 39, Psychoanalysis, Psi Chi International Honor Society, the Korean Network of Psychologists, and the Taiwanese Psychologists' Association. Each organization held a networking event during the Division 52 Hospitality Suite Program.

Division 52 opened its hospitality programing to host the Korea and Taiwanese Psychology Associations. This was the first time both Asian organizations attended the APA convention, and Division 52 International Psychology program events. Both organizations were appreciative that Div. 52 hosted these collaborative events.

Division 52's networking opportunities allowed Asian psychologists to present their views on important issues confronting their membership in the field of international psychology. Each organization's theme involved building a strong network of psychologists through improving communication skills among membership. Several members of these organizations expressed an interest to become a Div. 52 international affiliate and to build mentoring relationships with Div. 52 board members to provide them with advice for future career development.

The Korean Psychologists Network (KPN) is a network of Korean/Korean American psychologists, and is welcome to anyone who is interested in the KPN in counseling psychology or in a related mental health field. The KPN mission aims to help members to connect with one another in order to share support and validation of their unique issues and challenges, as well as to offer the opportunity to collaborate. For more information about the Korean network contact the President Jinhee Kang at jkang@umbc.edu and go to the website https://www.facebook.com/pages/Korean-Psychologist-Network/168405583246409 For information about the Taiwanese Psychology Association go to http://taiwanpsy.wordpress.com/

Also, a Presidential Breakfast was held at a Div. 52 hospitality suite event to honor Asian psychologists and officers of Asian Psychological Associations. Psychologists from Korea, Japan, and China attended the breakfast event. The breakfast event provided an outstanding opportunity for Div. 52 to connect with psychologists from the East region of the globe who are interested in international psychology. Several personal and professional connections were initiated. These relationships were developed on similar research interests, sharing of global teaching strategies, and the implication of intervention techniques to improve adolescent mental health issues, reduce family violence, women abuse and women's career advancement.

Furthermore Division 52 also connected with other interested like-minded partners to *Build Bridges*. Two interested collaborators are APA's Division 39 in regard to Global Treatment Practices and the Interamerican Society of Psychology (SIP).

In closing, it is evident that the initiative regarding *Building Bridges* was widely accepted at the 2013 APA Convention. This positive interest is providing an exceptional opportunity for psychologists from the East and West regions of the globe to collaborate about issues and concerns in regard to international psychology. Division 52 is available to mentor psychologists to *Build Bridges of Collaboration about International Psychology*.

As President of APA Division 52, I would like to hear from you about your experiences of international collaboration in international psychology. You may contact me through mmccormick2@pace.edu and/or contact Division 52 for more information at http://div52.org/ I look forward to hearing from you.

LEAVING A LEGACY TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Susan Nolan at (973) 761-9485 or at susan.nolan@shu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

Division 52 Images from the APA Convention, Honolulu, Hawaii USA

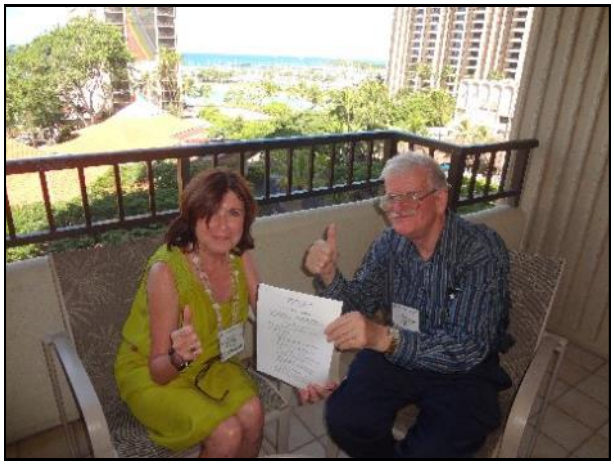

New Fellows in International Psychology: The Class of 2013

Harold Takooshian, Ph.D.
Chair, Fellows Committee
takoosh@aol.com

In 2013, 14 psychologists were elected Fellows of the Division of International Psychology, based on their "unusual and outstanding contributions to international psychology." Five of these were elected as new Fellows of APA, and nine were current APA fellows elected by the Division. For APA, "Fellow status requires that a person's work has had a national impact on the field of psychology beyond a local, state, or regional level." Of 84,000 APA members, about 6 percent are Fellows.

The D52 Fellows Committee works hard to use a rigorous and transparent procedure to elect new fellows. In 2013, six fellows independently rated each nominee on 15 criteria. The three-person Fellows Committee was **Kurt F. Geisinger, Senel Poyrazli,** and **Harold Takooshian** (Chair). The Fellows Committee thanks its three consulting fellows for 2013: **Bernardo J. Carducci, Ani Kalayjian,** and **Mercedes A. McCormick**. We congratulate all new Fellows of the Class of 2013.

Five members were elected a Fellow of APA and its International Division:

Stefanía Ægisdóttir, PhD
Ball State University

Rita Chi-Ying Chung, PhD
George Mason University

Ayşe Çiftçi, PhD
Purdue University

Abdel-Sattar Ibrahim, PhD, AABMCP, ABMPP
President, Egyptian Union for Psychological Specialties

Mark D. Terjesen, PhD
Saint John's University

Nine current APA Fellows were elected as a new Fellows in International Psychology:

Gonzalo Bacigalupe
University of Massachusetts-Boston

Bernardo M. Ferdman
Alliant International University

Lisa L. Harlow
University of Rhode Island

Shane R. Jimerson
University of California-Santa Barbara

Mark M. Leach
University of Louisville

Rodney L. Lowman
CSPP/Alliant International University

Bonnie K. Nastasi
Tulane University

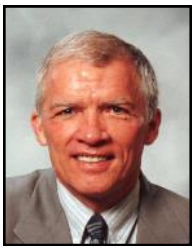

Dean Keith Simonton
University of California-Davis

Thomas R. Zentall
University of Kentucky

Congratulations Fellows!

Fellows Committee Report **

APA Division of International Psychology
August 2013, APA, Honolulu

Harold Takooshian (Chair), **Kurt F. Geisinger, and Senel Poyrazli**

The year 2013 was an active year for D52 fellows, in three ways:

1. **New fellows.** D52 received 8 completed nominations by its 12/2/2012 deadline. These were independently vetted by our three-person fellows committee, plus three consultants (note 2 below). All 8 were recommended to the APA fellows committee, with mean ratings of 7.3 up to 9.2 on our 0–10 scale. We learn the final outcomes at APA in Honolulu.

2. **Current fellows.** A total of 8 current APA Fellows were elected to Fellow status in D52, based on their outstanding international or cross-cultural work. Our congratulations to **Gonzalo Bacigalupe, Bernardo M. Ferdman, Lisa L. Harlow, Shane R. Jimerson, Mark M. Leach, Bonnie K. Nastasi, Dean Keith Simonton,** and **Thomas R. Zentall**.

3. **Recognition.** Once again, D52 will host a breakfast reception and conversation hour for new fellows at the August APA meeting, at 9–10 am Sunday August 4 in its international suite. This breakfast is kindly funded by The College Board. In addition, Editor Grant Rich will again publish a list and photo of all new D52 fellows in the fall 2013 issue of *International Psychology Bulletin*.

For 2014, **Ani Kalayjian** has agree to chair the Fellows Committee (note 4 below).

Since 1999, D52 has elected a total of 184 fellows—about 25% of the division's paid membership, compared with 6% of fellows among APA's 84,000 members (Note 1 below). The D52 fellows committee has been an unusually hardworking committee because of its pro-active work, to draw talented new fellows into our D52 work. (Note 3 below.) Nominations are now welcome for 2014.

*** Notes:** *1. D52 fellows elected in 1999 = 72, 2000 = 18, 2001 = 36, 2002 = 1, 2003 = 5, 2004 = 3, 2005 = 1, 2006 = 4, 2007 = 7, 2008 = 5, 2009 = 19, 2010 = 2, 2011 = 9, 2012 = 11.*

2. Our thanks to three independent consulting fellows for 2013: ***Bernardo Carducci, Ani Kalayjian,*** *and* ***Mercedes McCormick****.*

3. With sadness, since its formation in 1997, D52 has recognized that many APA fellows who do outstanding international research, teaching, or service are not yet members of D52, but should be involved in our work. Thus, the second half of our Committee's work is in the spring, when we identify current APA fellows in other divisions who have done outstanding international or cross-cultural work. The fellows committee has developed a three-step system to bring them in: (a) identify these outstanding non-members of D52 in

February, (b) vet them in March, then (c) invite them to join D52 as fellows-elect in April, to submit their names to APA by June 1. Since people must be a member for 1 year before becoming a division fellow, this becomes effective on January 1.

4. ***Call for fellows 2014:*** *Members of APA Division 52, are now invited to nominate others or themselves for election as a fellow of Division 52, based on "unusual and outstanding contributions" to international psychology. Contact Dr. Kalayjian soon for details and our Division's 15 criteria. This year all completed materials must be submitted online by* ***5 pm Friday, 6 December 2013****—including the nominee's vita, personal statement, and endorsements from 3 current APA fellows. At least 2 of the 3 endorsers must be a fellow of Division 52. (Those already a fellow of another APA division can ask about a streamlined procedure.)—****Ani Kalayjian,*** DrKalayjian@meaningfulworld.com

Congratulations to Student Awardees at Division 52's Second Annual Student Poster Competition at APA 2013

Lynette H. Bikos, Ph.D.
Seattle Pacific University
lhbikos@spu.edu

Thirteen posters (of the 40 exhibited during the poster session) left APA with commendations after the Division 52 Student Poster Competition at APA 2013. During the Friday afternoon poster session, posters with student first-authors were evaluated and awards were distributed during the Saturday afternoon awards ceremony and reception. Awardees were e-mailed a certificate of achievement.

Many thanks go to the panel of judges who volunteered to visit with the poster exhibitors and score the posters. Judges included Sheila Henderson, MBA, Ph.D., California School of Professional Psychology at Alliant International University—San Francisco; Juliana Yam, M.A., Alliant International University—San Francisco; Celso S. Oliveira, Ph.D., University of the State of São Paulo; Bernhard Seubert, Ph.D., Universidad Regional del Sureste and Clinic of Pediatrician, Asthma, Allergy and Medical Specialties, Oaxaca, Mexico; Mark Terjesen, Ph.D., St. John's University; Yu-Wei Wang, Ph.D., Southern Illinois University; and Greg M. Kim-Ju, Ph.D., California State University, Sacramento. The poster competition was coordinated by Lynette Bikos, Ph.D., Seattle Pacific University, Seattle, WA.

First Placings:

Positive and Protective Factors in the Psychological Well-Being of Refugees From Burma. Maha See & Sheila Henderson. California School of Professional Psychology at Alliant International University—San Francisco, CA.

Emotional Distress and Binge Drinking in College Students: Cognitions As Mediators A Cross-Cultural Study. Fabian Agiurgioaei Boie, Alina Agiurgioaei Boie, & Lavinia Marchis. St. John's University, New York, NY.

Moderation Effect of Korean Emerging Adults' Identity Acquisition Between Stress and Satisfaction. Yoo Sun Ahn & Joohee You. Ewha Womans University, Seoul, Republic of Korea.

Second Placings:

Autism in China: Moderators and Mediators in the Parental Perceived Needs—Mental Health Link. Ge Song & Cirleen DeBlaere. Lehigh University, Bethlehem, PA.

Cultural Beliefs About Diabetes Predict HBA1C Among Type 2 Diabetics in Chile. Gregory Regts, Sonika Ung, Hector Betancourt, & Patricia Flynn. Loma Linda University, Novato, CA.

Exemplar Zambian Caregivers Narratives of Caring for the Grief of Orphaned Children. Julie Rabb & Cynthia Neal Kimball. Wheaton College, Wheaton, IL.

Third Placings:

Risk Pathways From 1994 Rwandan Tutsi Genocide Exposure to Distress and Traumatic Stress. Lauren Ng, Beth Meyerowitz, & Donald Miller. Harvard University, Cambridge, MA.

Mental Health Implications in International Older Chinese Adults' Role Loss. Joe Nee, Hollis Tsoi, & Michi Fu. Alliant International University—Los Angeles.

Honorable Mentions:

Role of Culture in Mental Illness Stigma: A Multinational Perspective. Valerie Jackson, Monica Martinez, Chak Wong, Melinda Wong, Shayla Cashwell, Annie Liang, Jenny Kim, Jeanette Chong, Lawrence Yang, & Eduardo Vega. Alliant International University—San Francisco, Mental Health Association of San Francisco.

Guatemalan Indigenous Youth: Experiences of Ethnic Discrimination and Its Impact. Heather Mitchell, Kelly Flanagan, Elizabeth Moore, Rebecca Loveall, & Rachael Post. Wheaton College, Wheaton, IL.

Object Relations of Korean Depressive Patients. Junglim Lee, Donghyuck Lee, & Seokhyeon Kim. Konkuk Universi-

ty, Seoul, Republic of Korea.

The Reason for Living and Suicidal Behavior of Korean Adolescents. Tae Hee Kim, Donghyuck Lee, Ji Hee Chung, Suk Yeong Lee, & Sha Sha Lee. Konkuk University, Seoul, Republic of Korea.

Spirituality, Optimism, Self-Identity, and Career Maturity. Yi Seul Min, Donghyuck Lee, Tae Seung Kim, & Eun Mi Doo. Konkuk University, Seoul, Republic of Korea.

Similar competitions are planned for the 2014 WPA and APA Conventions. Those interested in competing should identify their posters as student-authored (students should be first authors, faculty and non-students can be subsequent authors) and indicate that international psychology is their first programmatic choice.

Present Your *Internationally Focused* Work at the Western Psychological Association

April 24 – 27, 2014, Portland, OR
Deadline: 15 November 2013 (midnight PST)

With an annual offering of 30+ poster presentations, 12 hours of symposia/papers (many offering CE), and a Saturday evening dinner with engaging international conversations, WPA is becoming *the place* to showcase your international work.

In addition to posters, consider organizing international symposia or selecting the *one-speaker paper* option (*one-speaker papers* are assembled into a panel of papers with related topics).

To be reviewed for the *international program*, use the WPA Call-for-Paper submission process (http://www.westernpsych.org/convention/call.cfm) and select *International Psychology* from the topics.

WPA requires that at least one of the authors of each submission should be registered for the conference. Conference registration fees are lower for WPA members and registration for the convention and membership can both be accomplished when you register for the convention.

Student poster competition! Posters with students-as-first-authors (faculty and non-students are allowed as co-authors) are eligible for commendations for their internationally-focused posters. When submitting the proposal, PLEASE identify that it is a student submission and that the topic is primarily international. To ensure inclusion in the competition, please e-mail Lynette Bikos (lhbikos@spu.edu) when the date/time/poster ID number is confirmed by the WPA program committee.

Contact Lynette Bikos, Ph.D., Div. 52@WPA Program Chair, if you are a student or professional member who:

- wants to find co-presenters for internationally focused symposia;
- is interested in serving on a Division 52/International Psychology *Western Region Outreach Committee* (primarily promoting D52 and international psychology at WPA);
- would like to volunteer as a poster judge for the student poster competition; or
- has other questions.

To learn more about Division 52/International Psychology, or to join the division: http://div52.org/

INVITATION: All students and faculty who present international research at WPA 2014, and are (or become) members of the APA International Division, can submit their 300-word abstract by 15 September 2014 for publication in the APA *International Psychology Bulletin* in fall 2014. For any details, contact Editor Grant Rich at optimalex@aol.com

Psi Chi International Ambassadors, 2013

Harold Takooshian
Fordham University
takoosh@aol.com

How can we promote student excellence internationally? Since Psi Chi voted to expand from a national to an international honor society in 2009, its Board appointed a team of "International Ambassadors" to promote globally the International Honor Society for Psychology, (www.psichi.org). In 2011, as the incoming President of our APA Division 52, **Mercedes McCormick** developed a dynamic "Building Bridges" program, in which many in D52 became involved to help expand Psi Chi globally. Below is contact information for some of the 14 Psi Chi International Ambassadors, as of August, 2013. **

Bernardo J. Carducci, PhD, Indiana University Southeast, New Albany, IN President of the Italian American Psychology Assembly (IAPA), Past-President of the Council of Teachers of Undergraduate Psychology (CTUP), his books on shyness have been translated into eight languages.

Webpage: www.ius.edu/shyness
Contact: bcarducc@ius.edu

Dwayne R. Crites, MA, Korea University, Seoul, Republic of Korea
Psi Chi chapter President (1998–1999) and Summa Cum Laude graduate of Southeast Missouri State University, he holds three university degrees, and has taught at five universities, including two in South Korea.
Webpage: www.korea.ac.kr or www.korea.edu
Contact: dwaynecrites@korea.ac.kr

John M. Davis, PhD, Texas State University, San Marcos, TX
Past-President and Southwestern Vice President of Psi Chi, and former Executive Officer of the International Council of Psychologists.
Contact: jd04@txstate.edu

Florence L. Denmark, PhD, Pace University, New York City, NY
Past-President of the APA (1980–1981), Psi Chi (1978–1980), International Council of Psychologists (1989–1990), APA Division 52, and currently the main ICP representative to the United Nations, as well as the International Association of Applied Psychology.
Contact: fdenmark@pace.edu

Joseph R. Ferrari, PhD, DePaul University, Chicago, IL
Joe is the Vincent dePaul Distinguished Professor of Psychology, a teacher, researcher, consultant, and Editor of the *Journal of Prevention and Intervention in the Community.*
Contact: JFERRARI@depaul.edu

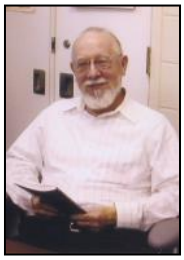

Paul I. Hettich, PhD, DePaul University (emeritus), Chicago, IL
Paul taught overseas at the University of Stirling (Scotland) and elsewhere, and writes the Eye on Psi Chi column on "Wisdom from the workplace," on workplace readiness and transition issues for college graduates.
Contact: PHETTICH@depaul.edu

Lê Xuân Hy, PhD, Seattle University, Seattle, WA.
Vietnamese, former Fulbright Fellow to the Middle East and grade school teacher in Central America, Hy (given name) is associate professor, and directs the Institute for Human Development.
Contact: HYL@seattleu.edu

Mercedes A. McCormick, PhD, Pace University, New York City, NY
President of the APA Division of International Psychology (2013), Eastern Vice President of Psi Chi (2011–2013), she is the architect of "Building Bridges."
Contact: mmccormick2@pace.edu

Melanie M. Domenech Rodríguez, PhD, Utah State University, Logan, UT
Melanie is the Editor of the *Psi Chi Journal of Psychological Research* and a former Vice President for the Rocky Mountain Region, with active research collaborations in Mexico, Puerto Rico, and the US.
Webpage: http://psychology.usu.edu/people/Melanie-Domenech-Rodriguez/
Contact: Melanie.Domenech@usu.edu

Michael Stevens, PhD, DHC, Illinois State University, Normal, IL
An author of 4 books, Michael's many leadership roles include Past-President of the APA International Division, and now Executive Secretary for North America of *Sociedad Interamericana de Psicología.*
Webpage: http://psychology.illinoisstate.edu/mjsteven/
Contact: mjsteven@ilstu.edu

Harold Takooshian, PhD, Fordham University, New York City, NY
A past Board Member and President of Psi Chi (1993–2000), he has taught at 12 universities in 5 nations, and is Past-President of the APA Division of International Psychology.
Webpage: http://takooshian.socialpsychology.org
Contact: takoosh@aol.com

** All 14 current Psi Chi International Ambassadors, as of August, 2013:

Bernardo J. Carducci, PhD
Lauren Crane, PhD
Dwayne Crites
John M. Davis, PhD
Florence L. Denmark, PhD
Melanie Domenech Rodríguez, PhD
Joseph R. Ferrari, PhD
Gina Grimshaw, PhD
Paul I. Hettich, PhD
Lê Xuân Hy, PhD
Mercedes McCormick, PhD
David Skeen, PhD
Michael J. Stevens, PhD
Harold Takooshian, PhD

Remembrances of Charles D. Spielberger 1927–2013

Compiled by Ann Marie O'Roark, Ph.D., ABAP
annoroark@bellsouth.net

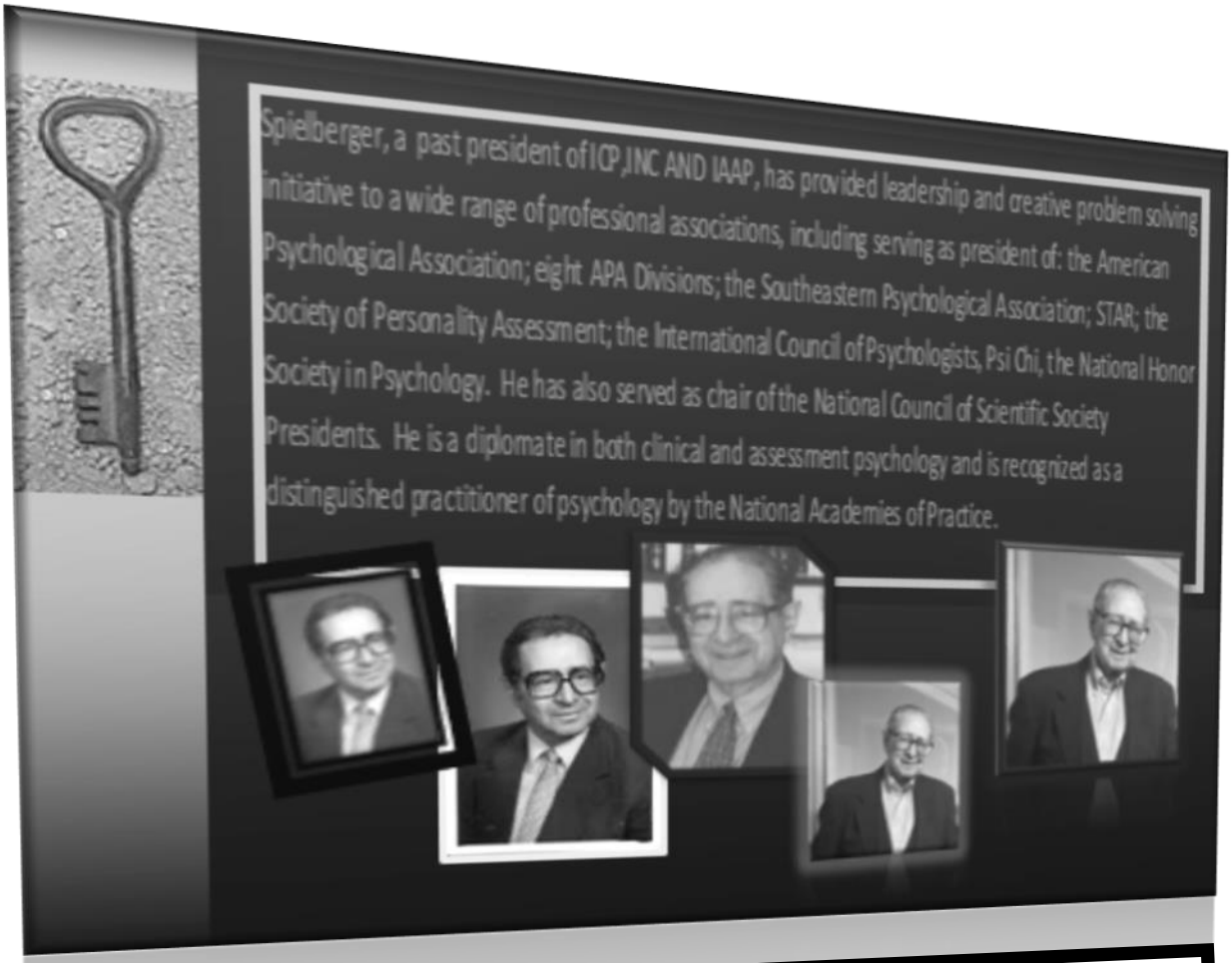

The American Psychological Association Division of International Psychology celebrates the life and contributions of former APA and Division President
CHARLES DONALD SPIELBERGER

The following remembrances and tributes are made to a psychologist colleague who enriched lives while energizing an international perspective with his extraordinary vision of human emotions and the importance of scientific psychology for enhancing quality of life. Remembrances come from fellow presidents of the American Psychological Association, international associations, APA Divisions, other professional associations; from co-authors, former doctoral students and psychologists whose careers he impacted.

Florence L. Denmark, Ph.D.
Robert S. Pace Distinguished Research Professor
Pace University, New York, NY

Following are some of my memories with Charlie Spielberger:

I knew Charlie very well. We were both Presidents of APA, and attended the broom closet dinners (for past Presidents) with our spouses. We also served on the national council of Psi Chi, the international psychology honor society. We worked together, and followed each other as national president. We were also both active in the International Council of Psychologists. I remember 6 of us, including Charlie and me, and you Ann, going for tea in Halifax, Nova Scotia, where we all shared a 6 pound lobster! In addition to these more formal activities, Charlie and I shared many dinners together with our spouses. Charlie was a good friend, and someone I could always count on for advice or help when necessary.

Sandra M. Fowler
La Jolla, CA, USA

Charlie Spielberger, winner of the Wundt-James Award, was the apotheosis of an international psychologist. He could be seen at psychological meetings all over the world. Very often when he attended the APA convention in the United States, you found him in deep conversation with an international psychologist. He mentored international psychologists, making sure they connected with the people they needed to meet. He and Carol have probably been in more psychologists' homes throughout the world than any other psychologist in history.

Charlie and Ray Fowler were good friends for over a half century. First meeting in 1954 when they arrived at the Worcester State Hospital in Massachusetts for their internship, their friendship and close professional association continued throughout their careers. Ray loved to tell about the time he visited Charlie and Carol at their home on Carollwood Drive. Charlie proudly showed off their dock and boat which he said was so relaxing to take out on the lake. Carol whispered to Ray that Charlie had gone out exactly once. Charlie was not known for relaxing. I know that if he could, Ray would say that the world of psychology will miss Charlie as much as he misses his treasured colleague and friend.

Harold Takooshian
Fordham University
New York, NY, USA

Charlie Spielberger, Southern gentleman

Charlie and I met in New York City in 1987, at the magnificent International Council of Psychologists' conference. Like many, I was entertained to meet a Jewish colleague whose voice exuded southern charm. Of course Charlie stood out in many ways—a gifted teacher, researcher, practitioner, administrator. We worked most closely in 2002, when he was my immediate predecessor as President of the APA International Division. All of us have Charlie stories, and I would share these two:

Productivity. When I asked Charlie for advice on how he was so versatile and productive, he credited his "daily system." He told me his USF secretaries would print his average of 800 daily e-mails into his "in box" each day, and he made sure to quickly sort and reply by day's end, in between his more scholarly work of teaching, research, editing.

Patience. Charlie's cross-national research on STAI made him a globe-trotter. He told me his worst trip was visiting a psychology conference in India, where he was not allowed out of the airport due to a typo in his visa. I naturally asked him if he was furious, or overcame the error. He calmly said no, he stayed 3 days in the airport, where conferees had to come to meet him to do their business, and then he flew home on schedule from a successful series of meetings. Here was an expert on anger who could stay calm even in such a miserable circumstance.

In both cases, Charlie was a model of an unstoppable yet gracious colleague—a remarkably productive Southern gentleman.

Danny Wedding, Ph.D.
California School of Professional Psychology
Alliant International University
San Francisco, CA, USA

Charlie Spielberger, Ray Fowler and I all loved to travel, and the three of us were fortunate enough to be invited to present papers at a conference sponsored by the International Association of Applied Psychology, the International Union of Psychological Science, and the Bombay Psychological Association in December, 2001. The conference was held in Mumbai, India, and it was well attended. It was a genuine pleasure for me to "hang out" with these two psychology luminaries. I especially recall one night when three of us were stranded together for several hours after a reception held in a remote location, waiting for a taxi that never showed up. Charlie put this time to good use – he taught me everything he thought I should know about the assessment of anxiety! It was a rare opportunity to be tutored by one of the giants in psychological assessment.

Paul J. Lloyd, Ph.D.
Professor Emeritus
Southeast Missouri State University
Cape Girardeau, Missouri, USA

Going back to my days as an undergraduate psychology major, I was familiar with Dr. Spielberger's publications and used the STAI in my own research. It was through Psi Chi, The National Honor Society in Psychology, that I became personally acquainted with Charlie when we both served on the Psi Chi National Council including three terms each as National President. I followed Charlie after serving three years as a region vice-president.

Dr. Spielberger has a well-deserved reputation for his research and as one of the icons of psychology. It was my privilege to work with Charlie and witness his leadership skills in recognizing outstanding Psi Chi student members and leading the largest honor society in the world. Dr. Spielberger was a powerful force in shaping policy both in Psi Chi and APA.

Dr. Spielberger was a mentor for many young psychologists by shepherding their research interests as well as their professional development as leaders in their profession. For me, one of Charlie's most impressive traits was his ability to keep the political infighting that is ever present in professional associations, in perspective. Charlie would lead a pitched battle to fight for his position, but when it was over, win or lose, he appreciated his opponents and was ready to sit down and break bread together. He was a role model as an outstanding leader. He has left psychology an outstanding legacy as a human being, who cared deeply for his students and for the future of psychology.

Peter R. Vagg, Ph.D.
Psychological Consultant
Tampa, Florida, USA

When we look at Charlie's body of work, we are impressed by the sheer number of books and articles he produced. Anyone who worked with Charlie was aware of his love of editing and wordsmithing to improve clarity and flow. What we forget is the enormous amount of time and energy it took to produce these results. When we worked together on papers, it was not unusual to produce 20 to 40 drafts, and usually each one was better than the one it succeeded. Charlie was a man who loved his work.

Machiko Fukuhara, Ph.D.
Professor Emeritus, Tokiwa University
Tokyo, Japan

Since 1990 when the Congresses of the IAAP and the ICP were held in Japan, Dr. Spielberger visited Japan several times. Thus he has contributed greatly to the development of Japanese Psychology.

With his co-authorship, there is a Japanese version of STAI-FormY (STAI-JYZ). On the process of translation, I was motivated to explore more of the multicultural issues of the individuals. I was honored to work under his presidency as a BOD in the IAAP. He supported me for the development of my scholarship and career.

He is a great person and respected scholar whom I will never find easily in this world.

Anna Laura Comunian, Ph.D.
Professor Emeritus, Padua University
Padua, Italy

Dr. Spielberger was a guest in Padua University. My work in Test Italian Adaptation: ***Test Anxiety Inventory*** (1988; 1992); ***State Trait Anger Expression Inventory*** (2004); ***State Trait Anger Expression Inventory-2*** (1980); and in research reports about ***State Trait Personality Inventory***, ***Lifestyle Defence Mechanisms Inventory*** and ***Italian Job Stress Survey***. C. D. Spielberger was always my wise guide and sensible friend.

Dr. Comunian, ICP past president and APA Division 52 member, sends her "Thank You" to Charles for these special programs she hosted and the research projects that she sponsored at the University of Padua: Comunian, A. L. (1980). ***Italian Job Stress Survey***. Conference Papers. Research reports. Comunian, A. L. (1985). ***State Trait Personality Inventory***. Conference Papers. Research report. Spielberger, C. D. (1988). ***Test Anxiety Inventory***. Questionario d'ansia al test. Firenze: Organizzazioni Speciali. Spielberger, C. D. (1988). **Lifestyle Defence Mechanisms Inventory**. Conference Paper. Research reports. Spielberger, C. D. (1992). **STAXI Manual**. ***State Trait Anger Expression Inventory***. Firenze: Organizzazioni Speciali. Comunian, A. L. (2004). ***Adattamento Italiano dello State Trait Anger Expression Inventory-2***. Firenze: Organizzazioni Speciali.

Francis Macnab, Ph.D.
Cairnmillar Institute, Director Emeritus
Melbourne, Australia

Charles Spielberger was a man with broad shoulders. He was a colossus of a man who could stand above the many differences of first, second, and third world issues, and foster a sense of common causes.

In my time as ICP President (1982–1983) the world was troubled by many tensions: of peace and war, race and colour, east and west, male and female, politics and religion, old and new. An international body of psychologists could try to hold these concerns above conflict, but realities were never far away. Psychologists themselves added their own prejudices and persuasions to the complexities of these concerns.

Charlie brought a strong and wise perspective and patience to each situation. Along with his dedication to research scholarship, we saw his humour and kindness, and many benefitted from his enthusiasm and enjoyment. He pursued his interests with his own singleness of purpose, and he was also fun to be with.

Although he knew some difficulties were insurmountable, Charlie embraced diversity with a strong desire to make a worthwhile difference. And we who shared his commitment to international psychology honour the significant contribution and the very real difference he made.

Rubin Ardila, Ph.D.
University of Colombia
Bogotá, Colombia

Charlie Spielberger and Latin America

The news of Charles D. Spielberger´s death has been received with sadness by many psychologists around the world including Latin America. Charlie was a good friend of

Latin America's, was very well informed about scientific and professional developments in this part of the world, and visited several Latin American countries along the years.

I invited him to Colombia as the main speaker for the 8th Colombian Congress of Psychology (April 30 to May 3, 1998). He gave several lectures on psychological factors on stress, cancer, cardiac diseases, hostility, anger and other issues concerning the most recent advances in health psychology. His ideas on cross-cultural measurement of personality traits were very influential in Colombia and gave origin to research work and practical applications. I had met Charlie many years before in Mexico, with Rogelio Díaz-Guerrero and his group. The standardization and validation of Charlie's tests in Mexico and other Latin American countries helped to advance psychological assessment and provided important clinical instruments to professional psychologists.

We miss Charlie very much. and colleagues around the world will keep his memory alive for the years to come.

Chok C. Hiew, Ph.D.
University of New Brunswick Professor (retired)
Visiting Professor: University of Malaya

My first recall of Dr. Spielberger was during my grad student years in CU, Boulder. I had used his State Anxiety Scale for my Master's thesis research in 1970. I have admired his influence in the psychology I taught ever since. Years later, I met him personally when he was President of ICP and I was a Board member. I helped organize the annual convention in Asia then. He is a genuine international psychologist roaming the world and sharing his knowledge with passion and patience. I have lost count of the many budding Asian researchers and professors he has touched. I attribute my lifelong research interest in emotions and health over the decades and my professional life as a academic and practitioner to his presence and work. Dr. Spielberger will be missed for long by the many admirers for his kindness, mentorship and dedication to psychology.

Mary Banks Gregerson, PhD,
President and CEO**,** Health Environment Professional Psychology
Leavenworth, Kansas, USA

Charles D. Spielberger - A Giant among Psychologists, and a Towering Person

A true "gentleman and scholar," Charlie significantly differentiated trait from state anxiety to hone our understanding of essential human nature. His professional support instrumentally brought the Ugandan Minster of State for Health to the 2006 APA Convention (New Orleans) to speak on countering in children the adversities of terrorism. For those legions of psychologists touched by Charlie, I offer welcome solace emanating from this Theodore Roethe poem:

[Untitled]
A lively understandable spirit
Once entertained you.
It will come again.
Be still. Wait. ...

Judith Albino, PhD
President Emerita and Professor
University of Colorado
Director, Center for Native Oral Health Research
Denver, Colorado, USA

I met Charlie Spielberger at my first APA Annual Convention. I was a graduate student at the time, and the only thing I remember about that conference was meeting Charlie. A group of us sat around a table in a restaurant talking about measuring state and trait anxiety. I felt privileged to be there, because I knew even then that I was learning directly from one of the greatest voices in Psychology. I haven't missed an APA meeting since, but I always felt that the experience wasn't complete unless I saw Charlie. Later, when I was treasurer of APA, I served on the Board with Charlie; that meant getting to know both Charlie and Carol—they were a great team! My career has taken many twists and turns, but Charlie was one of those individuals who always served as an "indirect mentor" for me. And that won't change just because Charlie is no longer physically among us. Faced with challenges, I will continue to ask myself, "How would Charlie have handled this?"

James Campbell (Jim) Quick
Professor of Leadership & Organizational Behavior
The University of Texas at Arlington
Arlington, Texas, USA

I met Charlie through the APA-NIOSH Project and the birth of the *Journal of Occupational Health Psychology*. I came to deeply admire and respect him as a person, and for his work. An amusing exchange occurred between us, after his APA presidency, when he learned I was a third generation Freudian. He cocked his head, smiled, and said "If I'd known you were a Freudian, I'd have been much more suspicious of you sooner." Our last visit together was when he visited the UT Arlington campus. Charlie left psychology and the world a great legacy!

Henry C. Ellis
Distinguished Research Professor of Psychology, Emeritus
University of New Mexico
Albuquerque, NM, USA

I am very pleased to comment on Charlie Spielberger. I knew and worked with Charlie on a number of activities in APA. Charlie was an outstanding President of APA as well

as a very active participant on many boards and committees. He was dedicated to Psychology and did excellent work in Anxiety and Anger. Charlie had broad interests in various areas of research. Finally, Charlie was a delightful colleague and excellent company.

Howard Kassinove, PhD, ABPP
Director, Institute for the Study and Treatment of Anger and Aggression
Hofstra University
Hempstead, NY, USA

In 1992, I was putting together a book on the definition, diagnosis and treatment of anger disorders. I didn't know Charlie at all, and sheepishly cold called to ask if he would contribute a chapter on measurement. "Sure," he said. I certainly felt happy that the famous Dr. Spielberger would be part of my text. Later, in correspondence and at a lunch at an APA convention, he helped me understand some of the pitfalls with cross-cultural translations of the STAXI that I was developing. For such a major figure, he was always available to me. I am saddened by his loss.

Diane J. Willis, Ph.D.
Professor Emeritus, Department of Pediatrics
University of Oklahoma Health Sciences Center
Norman, OK, USA

I first met Charlie in Nashville when I was a Master's level student at George Peabody College. I was fortunate enough to take a Personality course taught by Charlie, through Vanderbilt University, where he was then a Professor. Over the years, I was fortunate to get to know Charlie and his wife at a more personal level. Not only was Charlie a well read, scholarly man who mentored younger psychologists, but he also seemed to have contacts around the world. I once had a German student whose husband was in the U.S. Air Force, and she wanted to work on a graduate degree in clinical psychology. Charlie gave me the names of colleagues with whom he had worked who were faculty members at the University of Heidelberg, Germany. Charlie was also a generous man who donated monies to numerous organizations, including the American Psychological Foundation. This productive, scholarly, and gentle man will be missed by all who knew him. He served as a role model to many psychologists over the years.

Thomas M. Brunner, Ph.D.
Clinical, Forensic, and Consulting Psychology
Tucson, AZ, USA

I am deeply saddened that the life of one of our field's greatest diplomats to the world has ended: Charlie Spielberger, Emeritus professor at the University of South Florida, past American Psychological Association President, recipient of countless lifetime achievement awards. Charlie's prolific influence on our field and on society is impossible to measure. His body of work is staggering in breadth and depth. I was one of his final graduate students, and I still remember fondly working with him on Saturdays, poring over manuscripts, learning his way of viewing personality assessment.

Charlie was vigilant about the task list of conceptualizing complex phenomena clearly and in a way that could be soundly measured using brief self-report questionnaires. His background in chemistry showed through his work in psychology in this way. He really inspired me to think about how our field could be used to comprehensively yet concisely assess almost any phenomena that we tackled. And he tackled many! His State Trait Anger Expression Inventory went on to be adapted into over 26 languages, and is likely the most widely used measure of anger in the world today. Many of you have used or heard of the State Trait Anxiety Inventory, an amazingly brief but useful tool is also used worldwide. Clearly relevant to consulting psychology, the Job Stress Inventory was also one of the many measures he authored or co-authored. He also made contributions to Positive Psychology through his assessment of curiosity.

He published nearly 1,000 articles and up until his death continued to go into the office early and leave late. He truly gave his life to psychology, and that is not a metaphor, it is a fact. Charlie was one of the most highly cited psychologists in the world, and he truly has forwarded our field internationally.

If you read anything Charlie has written, you'll notice that is amazingly easy to read! He really took time to write things out clearly. He never tried to rush things out the door. Everybody has a Charlie Spielberger story and here is mine: he was having a party at his house and I was given the task of writing a map to his house. It went through eight iterations before it was acceptable! But boy was it a great map by the end!!!! His commitment to producing the very best intellectual work and to approaching things from the big picture perspective is inspiring and definitely influenced me to become who I am.

Charlie's core emphasis on the importance of distinguishing between assessing a state versus a trait has impacted our field and become a benchmark for evaluating new assessment tools. I will miss him greatly as I am sure so many graduate students will who came before me—and so many people whose lives he touched in such innovative ways. After burning so brightly for so many decades, may he rest in Peace.

Rodney L. Lowman, Ph.D.
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San Diego, CA, USA

Charlie was a world renowned researcher widely recognized for his contributions to assessment and stress but he was also a highly effective contributor to a number of psychological associations, including APA.

I worked with him closely while serving as APA's representative to the last revision of the *Standards for Educational and Psychological Tests* and also when I served as chair of

BPA. He was extraordinarily talented at bringing people from diverse backgrounds together to a sometimes fragile but almost always workable consensus. He could always hear multiple viewpoints and was remarkably adept at figuring out a way to find compromises through the common interests. When a number of scientists were leaving APA for a then-new alternative professional organization, he helped engineer a way to devote more of APA's budget and resources to science. He helped those more oriented to practice than to science see how psychology would be diminished without a robust science and without scientists feeling like they had a home in APA.

A colleague of mine who knew him well said that Charlie was still working furiously on his writing and research almost to his end. He wrote, co-authored and edited an astonishing number of articles, chapters, books, book series and widely used (and widely translated) psychological tests. He always created multiple drafts of everything he wrote or edited and the result is clear prose that stands the test of time.

Psychology is greatly in Charlie's debt, but so too is the APA—and so are the many of us all over the world who had the privilege of benefiting from his mentoring and cheerful good will.

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Assessment theorists and leadership trainers suggest first impressions set the stage for all that follows. My first impression of Charles Spielberger was imprinted while sitting by a stone fireplace in a dark paneled British hotel lobby, listening to his enthusiastic description of his research findings. It was a compelling psychological adventure-mystery.

Following a workshop Stress Management in Southampton, England on at the annual meeting of the International Council of Psychologists, Charlie talked of scientific sleuthing that began by following clues he discovered in streams of literature developed by psychology's pioneers. Insights from William James, Daniel Berlyne, Anne Anastasia, and Janet Spence were advanced by data generated in his research laboratory, in collaboration with doctoral students and international colleagues.

Even the brilliant fictional detective Hercule Poirot could not have disentangled any more complex mystery of human interaction than Charles' intriguing discovery of how three *vital sign* emotions, anxiety, anger and curiosity mediated stress, heart diseases, cancers and executive well-being. The importance of the motivational impact of these hard-wired human motivators set the stage for my work in organizational consulting and leadership development workshops across the next 30 years.

In addition to using the Spielberger assessment instruments in batteries for management development programs and our collaborations in analyzing those data, we worked together to advance the Society of Personality Assessment. When he became president, he convinced me to move the SPA office into my practice office, across Tampa Bay from his office. His influence on my career direction and success culminated in my book, the *Quest for Executive Effectiveness, Part II,* which is about motivation and the constructive application of anger, anxiety, and curiosity. We were still working on a manual for consulting psychologists with guides for using the *Job Stress Survey*. It was to be called: Creating the Optimal Challenge. Indeed, from the first impression in Southampton Charles provided that optimal challenge in my career. Thank you, Mentor, Role Model, Colleague and Friend. *Ave atque Vale*.

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Peer-Reviewed Research Article

Stress and Well-Being Among Minorities: Turkish-Armenian and German-Turkish Adolescents

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This research compares majority (Turkish, German) and minority (Turkish-Armenian, German-Turkish) adolescents, regarding stress, coping, psychological well-being and self-construal. The sample was 1,192 high school students from grades 8 to 12 (500 Turkish, 253 German, 147 German-Turkish, and 292 Turkish-Armenian). The results showed that both minority groups' adolescents as well as Turkish adolescents experience higher levels of distress than German adolescents. Regarding coping strategies, both minority groups (German-Turkish and Turkish-Armenian adolescents) show increased values for developing social support. These groups (and also the Turkish adolescents) also showed an increased preference for solving family problems as a coping strategy. In line with this result, they rated an interdependent self-construal higher in comparison to German adolescents. Moreover, adolescents in Turkey reported higher levels of relational interdependence, compared to adolescents in Germany. Regression analyses showed that stress level and well-being can be predicted by coping and self-construal variables, but most predictions are independent of a minority or majority status. The discussion focuses on implications for the acculturation of minority group adolescents in a majority group context.

Keywords: stress, coping, self-construal, minority groups, adolescence

Editor's Note

Researchers vary in their use of the terms German-Turkish and Turkish-German to refer to Turks living in Germany. Similarly, there is variation in the usage of Armenian-Turkish vs. Turkish-Armenian to refer to adolescents in Turkey of Armenian background.

Introduction

The term ethnicity refers to groups of people from the same cultural background with a common historical heritage, shared language, or religious background (Betancourt & Lopez, 1993; Phinney, Horenczyk, Liebkind, & Vedder, 2001). The importance of a child's ethnicity or sense of belongingness to a cultural group grows more salient in adolescence. Especially, being aware of the attitudes toward immigrants and minorities leads minority youths to pay more attention to their ethnic identity (Phinney, 1989). Having a minority status may cause social isolation, which in turn increases the level of stress (Smith, 1985).

According to the transactional stress model, cognitive appraisals (i.e., subjective interpretations of events) are the basis for the experience of stress (Lazarus & Folkman, 1984). There are two stages of cognitive appraisal, namely primary and secondary appraisal. Primary appraisal is related to the evaluation of an event as a potential stressor. If the situation is perceived as stressful, the secondary appraisal follows, which is an assessment of one's coping resources and coping options. Not having appropriate coping strategies results in stress. Coping strategies are cognitive and behavioral efforts to overcome a stressful situation.

The preference for specific coping strategies is affected by cultural and personal differences. Members of non-Western cultures define themselves according to their social roles and social group memberships, which may be summarized to indicate an interdependent self-construal (Kitayama & Markus, 2000). In addition, the self-definitions in non-Western cultures are characterized by relational-interdependent self-construal, which is derived from an interdependent self-construal. Interdependent self-construal emphasizes group relationships as a part of the self, while relational self-construal emphasizes the importance of close relationships with specific others as part of the self-definition (Brewer & Gardner, 1996). Previous research found that in a stressful situation, members of non-Western cultures prefer to change themselves rather than change the situation in coping. On the other hand, Western cultures prefer to change the situation instead of changing themselves (Bond, Wan, Leung, & Giacalone, 1985).

The aim of the current study is to investigate the relationship between stress, well-being, coping, and self-construal among minorities and the majority groups to which they belong. The focused upon minority groups are Armenian adolescents in Turkey, and Turkish adolescents in Germany. Although both are minority groups, a main difference between Armenian adolescents living in Turkey and Turkish adolescents living in Germany however, is that the Turkish adolescents in Germany are confronted not only with the status of belonging to a minority, but also of being immi-

grants.

According to the population census from 2012, approximately 75 million people live in Turkey (Turkish Statistical Institute, 2013) and 60 thousand of them are Armenian people (Hofmann, 2002). Historical information indicates that Armenian people have settled in Turkey for about one thousand years. According to the Treaty of Lausanne, Armenian people are one of the three officially recognized minority ethnic groups in Turkey (besides Greeks and Jews). Around 45 thousand of them are located in Istanbul. Most Armenians are Christians (Hofmann, 2002).

The immigration of Turkish people to Germany started in the beginning of the 1960s, due to high unemployment in Turkey, and a need for labor in other parts of Europe, especially in Western Europe (Levinson, 1998). At that time, the number of Turkish immigrants in Germany was about five thousand, but the population with a Turkish background topped three million 50 years later (Statistisches Bundesamt, 2012). The Turkish people are the largest minority group in Germany. Most of the Turkish people have an Islamic religious background (Levinson, 1998).

In this study it is hypothesized that Turkish-Armenian and German-Turkish adolescents experience more stress in comparison to Turkish and German adolescents (Hypothesis 1). Moreover, it is predicted that adolescents from minority groups experience less well-being than adolescents who belong to the majority cultures (Hypothesis 2). Due to a non-Western background it is expected that Turkish-Armenian, German-Turkish, and Turkish adolescents rate an interdependent self-construal higher than German adolescents (Hypothesis 3). Having a minority status leads young people to have stronger ties with their families (Harrison, Wilson, Pine, Chan, & Buriel, 1990). As a consequence, it is expected that the minority groups (Turkish-Armenian and German-Turkish) use more social support (as a form of coping strategy) than Turkish adolescents and German adolescents (Hypothesis 4). As a result of the different expectations between the minority and majority groups regarding self-construal and coping, it is expected that these constructs show differential relations to stress and well-being in the different subgroups (Hypothesis 5).

Method

Participants

A survey was completed by 1,192 high school students in grades 8–12, in one of four cultural groups: (a) 500 Turkish, (b) 253 German, (c) 147 German-Turkish (adolescents in Germany of Turkish background), and (d) 292 Turkish-Armenian (adolescents in Turkey of Armenian background). Ages ranged from 13 to 22 ($M = 17.0$, $SD = 1.38$). Age and sex were included as covariates in all analyses reported below because of significant age ($F(3, 1184) = 73.408$, $p < .001$, $\eta = .157$) and sex ($\chi^2(3) = 19.74$, $p < .001$) differences between the subsamples. The Turkish and Turkish-Armenian participants were in Istanbul, and the German-Turkish and German participants were in the state of North Rhine-Westphalia, Germany.

Table 1
Sample Sizes and Mean Ages of the Subsamples

Sample	Male			Female			Total		
	N	Mean Age	*SD*	*N*	Mean Age	*SD*	*N*	Mean Age	*SD*
Turkish	228	17.54	1.08	272	17.50	0.99	500	17.52	1.04
German-Turkish	89	17.35	2.02	58	17.28	1.96	147	17.32	1.99
German	121	16.14	0.88	132	16.09	1.29	253	16.12	0.92
Turkish-Armenian	112	16.93	1.42	180	16.99	1.29	292	16.96	1.34

Measures

The questionnaire contained scales related to perceived stress, coping, well-being, and self construal. Because participants with different languages were involved, the questionnaires were administered either in German or Turkish. If a Turkish or German version was not available, the respective scales were translated using the Brislin translation method (Brislin, 1980). All scales were assessed using 5-point Likert scales (1 = never, 2 = hardly, 3 = sometimes, 4 = often, and 5 = most of the time). For all scores reported below, the mean score across the scale items was taken as the total scale score.

Perceived Stress Scale. To understand how an adolescent appraises the amount of experienced stress, the Perceived Stress Scale (PSS) was used (Cohen, Kamarck, & Mermelstein, 1983). In total this scale includes ten items including six positive items (e.g., "In the last month, how often have you felt that things were going your way") and four negative items (e.g., "In the last month, how often have you felt that you were unable to control the important things in your life?"). The original language of the scale was English. The scale has been used previously both in Turkish and German languages (Erci, 2006; Gräßel, Bock, & Rosanowski, 2006). In the current study, Cronbach's alpha was .81.

Well-Being. Ryff's Psychological Well-Being scale was used to investigate the psychological well-being of the adolescents (Ryff, 1989). The scale consists of six dimensions (autonomy, environmental mastery, personal growth, positive

relations with others, purpose in life, and self-acceptance) and each dimension includes 14 items. Because of having an adolescent sample, the current study focused on the dimensions of positive relationships (e.g., "Most people see me as loving and affectionate"), autonomy (e.g., "Being happy with myself is more important to me than having others approve of me"), purpose in life (e.g., "I enjoy making plans for the future and working to make them a reality"), and self acceptance (e.g., "In general, I feel confident and positive about myself"). Some items of the other two subscales seem to be more appropriate for adults and these scales were thus excluded. Cronbach's alpha for the total well-being score was .91.

A-COPE. The A-COPE scale (Adolescent Coping Orientation for Problem Experiences), developed by Patterson and his colleagues (Patterson & McCubbin, 1987), was used to analyze which strategies were applied by the adolescents to overcome stressful situations. In the total scale are 54 items in 12 subscales. The current study focuses on the subscales related to developing social support (e.g., "Talk to a friend about how you feel") and solving family problems (e.g. "Talk to your mother about what bothers you"). Cronbach's alpha of the scores for developing social support was .53, and for solving family problems .75.

Independent-Interdependent Self-Construal Scale (SCS). To be able to assess the self-construal types the scale developed by Singelis was used (Singelis, 1994). The scale consists of two subscales that are independent (e.g., "I am the same person at home that I am at school") and interdependent (e.g., "I will sacrifice my self-interest for the benefit of the group I am in") self-construals. Each subscale includes 12 items. The German translation of the questionnaire was provided by Hannover and her colleagues (Hannover, Kühnen, & Birkner, 2000). In the current study, Cronbach's alpha was .61 for independence and .68 for interdependence.

Relational-Interdependent Self-Construal (RISC) Scale. To understand the significance of close relationships in adolescents' self-definitions, the RISC scale was used (Cross, Bacon, & Morris, 2000). The scale includes two negatively (e.g., "Overall, my close relationships have very little to do with how I feel about myself") and nine positively (e.g., "My close relationships are important to my sense of what kind of person I am") phrased items. Both Turkish and German translations of the scales were available (Akin, Eroglu, Kayis, & Satici, 2010; Ringeisen, 2008). In the current study, Cronbach's alpha was .76.

Procedure

The heads of the schools in Turkey and Germany were contacted and informed about the study and asked for participation. At the arranged date, surveys were distributed. The participants were allowed to complete the questionnaire at school. The adolescents' participation in the study was on a voluntary basis and required their parents' permission. Completing the questionnaires took approximately 45 minutes.

Statistical Analyses

Multivariate analysis of variance (MANOVA) was applied to understand the differences between the subsamples regarding stress, well-being, coping, and self-construals (Hypotheses 1 to 4). Regression analyses were used for the prediction of the reported stress level and well-being by the coping and independence-interdependence scales. Nation (Turkey versus Germany) and status (minority versus majority) were included as moderator variables. This means that the interaction terms defined as predictor variable x moderator variable were included additionally (as two-way and also higher order interactions). The moderator variables were coded as -1 and +1. In the case of nation, Turkey was coded as -1 and Germany as +1. For status, the values are -1 for a majority and +1 for a minority status. Age and sex were included in all analyses to control for possible age and sex effects. Due to numerous tests used for the analyses, alpha was generally set to $\alpha < .01$.

Results

Hypothesis 1 and 2: Stress and Psychological Well-Being

It was predicted that Turkish-Armenian and German-Turkish minority adolescents would experience higher levels of stress (Hypothesis 1) and less well-being (Hypothesis 2) than adolescents who belong to the majority cultures, namely Turkish and German adolescents. A multivariate analysis of variance was calculated to address this hypothesis. The independent variable was related to the four cultural groups, while the level of perceived stress and well-being were dependent variables. Age and sex were included as covariates. The results showed that there was a significant multivariate between-subjects effect ($F(6, 2362) = 9.29$, $p < .001$, $\eta = .02$). The univariate results showed that there is a significant difference between the sample with regard to perceived stress ($F(3, 1182) = 11.66$, $p < .001$, $\eta = .03$). A Tukey post-hoc test for perceived stress showed that German adolescents perceive less stress than Turkish, German-Turkish, and Turkish-Armenian adolescents. No differences were found between Turkish, German-Turkish, and Armenian adolescents. In addition, there were no differences with regard to well-being. The results are summarized in Table 2.

Hypothesis 3 and 4: Self-Construal and Coping

Hypothesis 3 predicted that adolescents with a non-Western background, namely Turkish, German-Turkish, and Turkish-Armenian adolescents will evaluate an interdependent self-construal higher than German adolescents. Using the self-construal scales as dependent variable, a multivariate analysis of variance (MANOVA) was calculated to analyze cultural group differences among the adolescents (with age and sex as covariates). The results revealed a significant main effect indicating differences between the four samples regarding the self-construal scales ($F(9, 2869) = 8.27$, $p < .001$, $\eta = .02$). When the scales were considered separately in univariate analyses there were significant differences for the relational-interdependent self-construal ($F(3, 1181) = 6.30$, $p < .001$, $\eta = .02$) and the interdependent self-construal ($F(3, 1181) = 17.29$, $p < .001$, $\eta = .04$). As expected, the post-hoc test (Tukey) showed for the interdependent self-construal

Table 2
Mean Scores and Standard Deviations (SD) of Perceived Stress, Psychological Well-Being, Developing Social Support, Solving Family Problems, and Self-Construals Among Turkish, German-Turkish, German and Turkish-Armenian Adolescents

	Turkish		**German-Turkish**		**German**		**Turkish-Armenian**	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Perceived Stress	2.99	0.66	2.97	0.49	2.74	0.65	2.93	0.65
Well-Being	3.64	0.44	3.51	0.43	3.57	0.46	3.61	0.43
Developing Social Support	3.11	0.67	3.30	0.81	3.08	0.69	3.26	0.61
Solving Family Problems	2.92	0.77	2.97	0.86	2.53	0.72	3.02	0.79
Independent Self-Construal	3.48	0.43	3.47	0.51	3.47	0.40	3.47	0.45
Interdependent Self-Construal	3.48	0.50	3.47	0.55	3.21	0.47	3.47	0.50
Relational Self-Construal	3.71	0.54	3.53	0.50	3.56	0.56	3.71	0.56

that German adolescents reported lower levels of interdependent self-construal than Turkish, German-Turkish, and Turkish-Armenian adolescents. The mean scores for relational-interdependent self-construal indicated that Turkish and Turkish-Armenian participants reported higher levels of relational-interdependent self-construal than German and German-Turkish participants. The results are summarized in Table 2.

To address Hypothesis 4, the preference for social support and solving family problems as coping strategies was investigated among Turkish, German, German-Turkish, and Turkish-Armenian adolescents. A multivariate analysis of variance was calculated with the cultural groups as independent variable and the scales social support and solving family problems as dependent variable. The results indicated a significant difference between the groups regarding their preferred coping strategies ($F(6, 2362) = 11.48$, $p < .001$, $\eta = .03$). The univariate analyses showed significant effects for both social support ($F(3, 1182) = 7.47$, $p < .001$, $\eta = .02$) and solving family problems ($F(3, 1182) = 18.48$, $p < .001$, $\eta = .05$). The results of Tukey post-hoc tests showed that there were significant differences between adolescents from minority groups (German-Turkish and Turkish-Armenian youth) and adolescents from majority groups (Turkish and German youth). According to the mean differences, minority group adolescents use more social support than majority groups. On the other hand, not only German-Turkish and Turkish-Armenian adolescents, but also Turkish adolescents, show an increased preference for solving family problems in comparison to German adolescents (see Table 2).

Hypothesis 5: Prediction of Stress and Well-Being by Nation and Status (Minority/Majority)

To analyze the predictability of stress and well-being, the coping variables (social support and solving family problems) and the independence-interdependence variables were used as predictor variables, while nation and status were used as moderator variables. Table 3 provides an overview for the variables with significant associations to the criteria (stress level and well-being). As can be seen from the Table, the most powerful predictions for stress as well as well-being are related to non-moderated associations. Thus, most predictions are independent of nation and status (minority/majority).

With regard to the reported stress level, 12.3% of the variance is explained by the predictor variables ($F(22, 1164) = 7.41$, $p < .001$). Male sex, solving family problems, and an independent self-construal are related to decreased stress levels, while social support and an interdependent self-construal are related to an increased stress level. There is only one moderated relation regarding the association between solving family problems and nationality. As an analysis of the slopes shows, there is a significant negative correlation between solving family problems and stress in the Turkish sample ($r = -.23$, $p < .001$), but an insignificant correlation in the German sample ($r = -.07$, $p > .01$). With regard to well-being, 24.1% of the variance is explained by the predictor variables ($F(22, 1164) = 16.80$, $p < .001$). Solving family problems, a relational-interdependent self-construal, and an independent self-construal are related to increased well-being, while an interdependent self-construal is related to a decreased well-being. In addition there are two moderated relations: (a) One of the moderated relations is associated to an independent self-construal and nation. As an inspection of the slopes shows, there is a positive correlation of $r = .26$ ($p < .001$) in Turkey, but an even more positive correlation of $r = .44$ ($p < .001$) in Germany. Thus, although there is a significant correlation in both nations, the slope is steeper in Germany. (b) The results showed that the association between a

Table 3
The Prediction of the Reported Stress Level and Well-Being by Coping Variables and Independence-Interdependence with Nation, Location, and Sex as Moderators (Included Are Only Significant Predictions)

Stress Level	*B*	*SE*	β	*p*
Sex	-.091	.019	-.142	< .001
Social support	.101	.022	.158	< .001
Solving family problems	-.129	.021	-.203	< .001
Interdependent self-construal (SCS)	.069	.020	.108	< .01
Independent self-construal (SCS)	-.097	.020	-.152	< .001
Solving family problems x nation	.070	.021	.108	< .01
Well-Being	***B***	***SE***	**β**	***p***
Solving family problems	.110	.014	.250	< .001
Relational-interdependent self-construal (RISC)	.113	.016	.256	< .001
Interdependent self-construal (SCS)	-.076	.016	-.173	< .001
Independent self-construal (SCS)	.141	.013	.319	< .001
Independent self-construal x nation	.042	.013	.095	< .01
Relational-interdependent self-construal x status	.040	.016	.019	< .01

relational self-construal and well-being is dependent on status (minority versus majority). In the minority sample, the correlation is $r = .31$ ($p < .001$), while the correlation is $r = .23$ ($p < .001$) for the majority sample.

Discussion

The aim of the current study was to analyze differences between minority group adolescents (German-Turkish and Turkish-Armenian) and majority group adolescents (Turkish and German) with regard to stress, psychological well-being, coping strategies, and self-construals.

Previous research found that people who belong to minority groups are more vulnerable to stressful situations (Thoits, 1995). The current results indicated that German-Turkish and Turkish-Armenian adolescents as minority group members, and also Turkish adolescents, perceive higher levels of stress than German adolescents. For minority adolescents, stress may be significantly predicted by differences in cultural backgrounds, beliefs, languages, and traditions, in addition to challenges resulting from the period of adolescence, for instance cognitive, emotional, attitudinal, and physical changes. Moreover, negative stereotypes and discrimination could be salient factors that potentially explain why adolescents experience high stress. It was also found that Turkish adolescents in general perceive more stress than German adolescents. Thus, there may be additional differences between Turkey and Germany, which may contribute to the increased stress experiences of Turkish adolescents in general. Especially in non-Western cultures, parents are interested in maintaining control over the child. When children reach adolescence, they want to have their own rights and freedom, while parents want to maintain control. The parents, however, are interested in maintaining close family relationships, which is consistent with a self-construal based on interrelatedness. This may lead to more conflicts, especially if adolescents are influenced by Western culture. As a consequence, the experienced stress levels may be higher in Turkish adolescents in general, and not only in Turkish adolescents with a minority status. Although there were differences between the samples with regard to stress experiences, this was, however, not reflected in differences regarding well-being.

Individuals' adaptation to an environment is mainly affected by how they define themselves. A self-conception as being interdependent with other people may influence their attitudes. Previous research showed that people from non-Western cultures define themselves as part of a group and give more importance to social norms (Markus & Kitayama, 1991; Cross, Gore, & Morris, 2003). On the other hand, individual goals play a more crucial role for people from Western cultures. It was hypothesized in the current study that German-Turkish, Turkish-Armenian, and Turkish adolescents, because of having a non-Western background, evaluate an interdependent self-construal higher than German adolescents. Results confirmed this hypothesis. As can be seen, cultural background plays an important role in one's self-definition. Even German-Turkish adolescents, although liv-

ing in a Western culture (German culture), still prefer to think and behave according to the norms of their original culture (Turkish culture). Although German-Turkish adolescents emphasize the importance of group relationships while defining themselves, the results showed that Turkish-Armenian and Turkish adolescents put additional emphasis on the importance of close relationships with specific others as a part of their self-definition.

As noted above, German-Turkish, Turkish-Armenian, and Turkish adolescents rated an interdependent self-construal higher than German adolescents. Moreover, the results found that they try to solve family problems to overcome stressful events more than German youth. Having an interdependent self-construal could be the key to understand why they put emphasis on solving family problems to cope with stressful situations. For people with an interdependent self-construal, it may be important to maintain their relationships and to take care not to destroy them (Cross, Bacon, & Morris, 2000). Having an interdependent self-construal could be a protective resource, because this would provide a means to get support when a person is faced with stressful events (Eschenbeck, Heim-Dreger, Tasdaban, Lohaus, & Kohlmann, 2012). The results of this study found that adolescents belonging to minority groups (German-Turkish, and Turkish-Armenian adolescents) use more social support to cope with threatening situations than adolescents from majority groups (Turkish and German adolescents). Thus, the study indicates that minority groups may need more social resources to cope with stressful experiences, because they belong to a vulnerable group experiencing an increased level of distress.

The fifth hypothesis examined the prediction of stress and well-being by self-construals and coping strategies. The results indicated general sex effects on stress with female adolescents reporting more stress than male adolescents. Previous studies showed that concerns about physical appearance are more salient for female adolescents (Allgood-Merten, Lewinsohn, & Hops, 1990; Frydenberg, 1997). Moreover, female adolescents may be more willing to report their stress experiences than male adolescents in correspondence with gender role expectations. Thus, concerns regarding physical appearance and gender role expectations could be explanations for these sex differences.

Results also revealed that an independent self-construal has a buffering effect on stress and that it is related to increased psychological well-being in all samples. Although there are cultural differences regarding the self-construal types, independence plays generally an important role in adolescence. An independent self-construal emphasizes the uniqueness and individuality while defining the self (Markus & Kitayama, 1991; Cross, Gore, & Morris, 2003). Adolescents want to gain more autonomy and freedom. Therefore, making decisions and having their own responsibilities could increase their self-esteem. Though an independent self-construal is related to an increased well-being of adolescents in Turkey as well as in Germany, it has even more positive effects on adolescents in Germany.

Furthermore, the results found that an interdependent self-construal and social support are related to lower psychological well-being and higher stress levels. Although it may be expected that an interdependent self construal and the availability of social support are related to decreased stress and increased well-being, it is also possible that adolescents who experience increased stress search for more social support to cope with their stress experiences. It should be noted that this study was based on a cross-sectional design, which does not allow determining the causal direction of the effects. Thus, this interpretation may be in line with the results.

There was, on the other hand, a positive relation between psychological well-being and solving family problems as well as relational self-construal. Solving family problems and relational self-construal both emphasize close relationships (Cross, Bacon, & Morris, 2000). Many studies emphasize the importance of close relationships for well-being (Baumeister & Leary, 1995). Moreover, previous studies found that increased conflicts with parents during adolescence might threaten adolescents' self-esteem and self-confidence, which are important components of well-being (Burke & Weir, 1978). Although the relation between solving family problems and well-being is significant for all subgroups, solving family problems has a buffering effect on stress only for participants from Turkey. In non-Western countries like Turkey, people give more importance to maintaining family ties. Therefore, experiencing fewer problems in families may be associated with decreased stress experiences. The results showed in addition that maintaining close relationships has a more positive impact on well-being for minority adolescents in comparison to majority adolescents. Thus, the effect of close relationships may be even increased in adolescents with a minority status.

In conclusion, the results found differences between the four subsamples, in coping and self-construal. These concepts play important roles in predicting stress and psychological well-being. With few exceptions, these influences are, however, independent of having a minority or majority status.

Limitations and Implications

The data were collected at high schools in Turkey and Germany. However, the Turkish-Armenian sample was collected from Armenian-only high schools in Turkey, but there are no such Turkish-only schools in Germany. As a consequence, the German-Turkish data were collected from general schools. These differences regarding schooling could have had effects on the results. On the other hand, the samples were comparable in other regards. For example, the study was carried out in developed cities both in Turkey and Germany. This, however, leads to a second limitation: the study omits adolescents from rural regions in Turkey and Germany.

It should also be noted that the reliability score of the A-COPE scale related to developing social support was rather low. It is unclear why the respective value was so low in the current study, but it should, on the other hand, also be noted that the analyses related to this subscale represent only a small part of the current study. Thus, the majority of the results are not affected by a low reliability of this subscale.

In general, research about the acculturation process of minority youth could provide further information about their stress levels and preferred coping strategies. This information may be valuable in prevention efforts, to support adolescents in adjusting to their specific situations, if they belong to a minority group. Preventive efforts to reduce the level of experienced stress and to supply effective coping strategies could be useful to help adolescents in minority group situations to reduce their stress level and help to develop strategies to overcome stressful situations successfully. The study underlines especially the importance of close relationships for minority groups for their well-being when they are faced with a new cultural surrounding.

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Psychology, National Politics, Genetics, and *The Myth of Race*

Fish, J. M. (2013). *The myth of race.*
New York, NY: Argo Navis.
154 pp., ISBN 978-0786754366, Price US $19.95

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The Myth of Race by Jefferson Fish seeks to draw on scientific knowledge to debunk a series of myths about the concept of race that pass as facts in mainstream U.S. culture. The book seeks to correct false assumptions and clarify cultural misunderstandings for a general audience, but it may also be useful reading for students in seminars about developmental diversity, social and political psychology, psychometrics, and other areas. For psychologists and students outside of the United States, it might also provide an interesting window into the dynamics of racial politics for Black Americans at a time in history when these issues are especially salient.

I was living and working in Brazil shortly after the Supreme Court in that country ruled race was not a legitimate concept, had no scientific support or validation and, as such, could not be introduced as a category on any legally-recognized document in that country, including college admission forms, job applications, or census surveys. I found the logic inherent in that ruling refreshing at the time. Unfortunately, U.S.-style westernization, cross-cultural data collection, private educational institutions based in the United States operating in Brazil, and affirmative action policies rooted in this culture have long since supplanted that decision in the ensuing decades. Still, the experiences I have had throughout my life living and working in Brazil and other countries, as well as the stark contrasts in racial assumptions I noted while spending parts of my childhood and adolescence in Canada and Ireland while being raised by a Canadian grandfather in Kansas during the landmark *Brown vs. Board of Education* case that desegregated U.S. public schools, make the topic of this book particularly interesting to me.

Prior to *The Myth of Race,* Fish had already written two comprehensive books on the same subject, *Race and Intelligence: Separating Science from Myth* (Fish, 2002) and *Concept of Race and Psychotherapy* (Fish, 2011), both of which I am familiar with. These books were technical volumes clearly directed toward psychologists, therapists, and psychometricians. His current book, however, is aimed at a more general audience. *The Myth of Race* primarily summarizes social interactions that Fish, of Russian Jewish descent, and his biracial family (a commonly-used descriptive term in U.S. counseling literature that I acknowledge has no basis in science), experienced over the years relating to culturally-embedded concepts about race, both in the United States and while he and his wife were visiting scholars in Brazil. His first introduction to Brazilian culture was fairly early in their marriage when he assisted his wife as she completed anthropological field work interviewing Brazilians in the Amazon region about their conceptions of race—a popular topic with U.S. social scientists at the time. Race continued to be a particularly salient concept to both of them throughout their marriage and careers. She is an African-American anthropologist, and they were married in the United States during the height of the civil rights movement when both were graduate students, he in psychology and she in anthropology. Both have since enjoyed long, productive academic careers in this country, during which they periodically returned to work in Brazil. They are still married and have now retired. Their daughter, who was a toddler and preschooler the first time they visited Brazil, is now grown and married to an African American in the United States.

The Myth of Race subjectively recounts how concepts and attitudes toward race affected their family life while in this country and in Brazil. The book highlights the differences they noted between the two countries on this dimension. Although the contrast may be useful to illustrate how the concept of race is intertwined with the history and culture of a particular country, I think it is important to note that I consider it a mistake to present the United States and Brazil as two separate cultures. Both countries are extremely large, diverse areas which include many different cultures, languages, traditions, and values existing in parallel. What a particular individual or family experiences in either country is heavily dependent on the region they are in, level of education, profession, income, expectations, familiarity with language(s) and local norms, purpose(s) of stay, and a myriad other factors. It is far too simplistic to simply contrast Brazil and the United States on attitudes and concepts regarding race—or any other construct because of the multicultural variation within each. Bearing that criticism in mind, I still think the book effectively presents several of the myths about race that permeate many of the currently-existing subcultures within the United States and northern Europe. In an interesting, engaging manner understandable to educated laypeople, without specialized terminology from psychology or anthropology for the most part, Fish debunks the turn-of-the 18th century English anthropological notion that humans are divided into Caucasoid, Negroid, and Mongoloid races. Through the experiences he recounts, it becomes evident that the idea

of race is generally rooted in political motivations aimed at dehumanizing certain groups for economic or other political purposes. Race is conceptualized quite differently from one historical era to the next and from one political system within any given country or location to the next. He demonstrates that, given this, one's race is a mutable concept that can generally be changed by any given individual simply by changing locations or editing the information given about heritage. The power of race resides in the impact it has on self-image and expectations and the false categories it creates. The book also, in a relatively jargon-free manner, debunks the myth of biologically-based arguments about differences in intelligence between races the era of *The Bell Curve* (Hernstein & Murray, 1994) ushered in.

Fish presents race as a confused mixture of two different concepts, biological race and social race. As with the general contrast between Brazil and U.S. attitudes, I find this limitation to only two concepts overly simplistic, but perhaps it adequately serves the purposes of the book. He notes that biological race does not exist in the human species, but what does exist is gradual variation in what people look like (e.g., skin color and facial features) and in their genes as you travel around the planet—with more distant populations appearing more different from each other than closer ones. If you travel in different directions, the populations look different in different ways. This anthropological explanation is confounded, especially recently, by mobility and travel patterns, immigration trends in various countries, and changing weather patterns, so the time spent on this concept, in my opinion, could have been better approached through modern genetic data and truncated to leave more room to address the second concept he identifies, social race.

As Fish presents it, social race is a set of cultural categories for labeling people based on how their ancestors were classified, selected aspects of appearance, or various combinations of both. These categories vary widely from one culture to the next. In *The Myth of Race*, Fish gives lots of attention to post-civil war census categories such as quadroon and octoroon, focusing specifically on Black vs. White in the context of U.S. culture. Thus, his presentation of social race is extremely limited— to one group, one country, and one historical period, with little accounting for some of the economic and political motivations for the categories that could also have provided relevant data about how Native Americans were categorized and presented in order to serve land acquisition in this country, or how various groups of Hispanics were categorized in different regions and at different times relevant to similar political and economic agendas. Instead, he focuses specifically on Black Americans, but then fails to show any reasonable parallel extension of the concept that applies within Brazil. He also overlooks the history of slavery in Brazil, and barely treats the preferences within that country for fair skin or how historically this connection was tied to economics and power, becoming more of a class issue than a caste issue. He overlooks how miscegenation was encouraged in part because of the way it was connected to the system of slavery in Brazil. Slavery thrived there for nearly 400 years and Brazil was, in fact, the last country in the American continents to abolish slavery, in 1888 (see McCarthy, Rose, & Castenheira, 2009). There was no Civil War over slavery fought there, however; no carpetbaggers, no refusal to acknowledge votes based on race, no gerrymandering, and no need to justify a notion such as "manifest destiny" resulted in the necessity for such a concept to develop. This information would have been rich to present and explore in developing the notion of "social race," but is noticeably absent.

In short, a collaborative effort with a biologist and a sociologist or social historian—at least one of whom was a Brazilian—would have improved the book, but it is still worth reading and deserves a favorable review. I am not the only one offering praise, and I think it will be very useful in my own graduate seminars on developmental diversity and related topics. Psychologists, and those of us in academic psychology at universities around the world, will find it useful, and I recommend it to colleagues and students. Colleagues in sociology, history, ethnic studies, and other disciplines may also find it helpful. Praise for *The Myth of Race* already has come from anthropologists and politicians. Anthropologist Audrey Smedley, author of *Race in North America* (1975), recommends the book. Former U.S. Secretary of Defense William Cohen, has said, "Writing with stunning clarity, Dr. Fish poses profound and perturbing questions about race...*The Myth of Race* is must reading." I agree with his assessment of the book.

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How Can We Internationalize Psychology Curricula? A Review of *Internationalizing the Psychology Curriculum in the United States*

Leong, F. T., Pickren, W. E., Leach, M. M., & Marsella, A. J. (Eds.). (2012). *Internationalizing the psychology curriculum in the United States*. New York, NY: Springer.
375 pp., ISBN 978-1461400721, Price US $129

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"Now is the time to open ourselves to other psychologies with different epistemologies, different assumptions about personhood, and different ways of discovering and applying psychological knowledge" Leong, Pickren, Leach, and Marsella (2012, p. 310) write in their volume on internationalizing the psychology curriculum in the United States. In this book, the first of its kind, Leong and colleagues (2012) address the fundamental issue of adapting the psychology curriculum to reflect the ever-changing and global nature of the field. How can the psychology curriculum in the United States become more international, less ethnocentric, and more open to the contributions of foreign scholars?

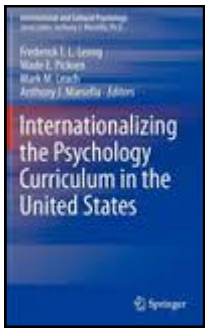

This 15-chapter volume examines this question across several major subfields of psychology—history of psychology, ethics, personality theory, testing and assessment, and psychology of women and gender, as well as developmental, social, clinical, counseling, school, organizational, health, and peace psychology. In total, 22 scholars contributed to the book, each with impressive expertise in their respective subfields, as well as extensive international experience, whether through direct experience abroad, collaboration with foreign scholars, or significant contributions to the knowledge base on international issues. Leong et al. (2012) introduce the challenges to internationalizing the curriculum in Chapter 1, including discussion of such topics as (1) "overcoming our ethnocentrism," (2) "enhancing cross-cultural competence," (3) "cultural sensitivity versus imposed etics in theory development," (4) "supporting and extending indigenous psychologies," (5) "promoting the integration of multicultural and cross-cultural foci," (6) "promoting cross-national research collaborations," (7) "promoting culturally valid practice around the globe," (8) "enhancing and promoting international education," and (9) "collaboration among counseling organizations" (pp. 4–5).

In the chapters that follow, specific challenges within the various subfields are carefully examined. In Chapter 2, the Western bias in our historical accounts of psychology as a science is explored, and Pickren calls for the inclusion of indigenous histories in our curriculum. In Chapter 3, international ethics documents are introduced (e.g., *Universal Declaration of Human Rights*; United Nations, 1948) and ethical codes and standards are compared internationally. The authors aptly identify issues with applying national ethics codes to international contexts; for example, codes that protect the rights of individuals over the rights of groups typically reflect a Western bias, where more collectivist values are excluded from the ethical language.

In their chapter on developmental psychology, White and Schnurr examine the context of culture through three specific developmental issues: co-sleeping, attachment, and parenting styles. In evaluating international findings on these issues, the authors question findings typically reported in U.S. textbooks, and urge readers to consider the contextual nature of developmental theory. In Chapter 5, Lee, Fathali, Moghaddam, and Harré examine the social patterns of importing and exporting psychological theory; they describe the US as the "sole superpower" and the "First World of psychology," while Western Europe and other industrialized nations are the "Second World" and developing nations the "Third World" (p. 76).

Perhaps one of the strongest chapters in the book is that of Draguns (Chapter 6), who compiled a wealth of interviews with personality researchers conducted in German, French, and Russian. Draguns evaluates universal findings on personality (e.g., results on the Big Five Inventory), the impact of culture, and the appropriateness of measures developed in the US for use in other countries. He outlines 14 areas for future research in the study of personality and refers to the importance of qualitative methods.

Four chapters are devoted to applied fields—clinical, counseling, school, organizational, and health psychology. Marsella discusses the history of training in clinical psychology and emerging changes, such as the increased attention to culture in clinical care and the feminization of the profession. As Marsella astutely identifies, the historical roots of psychology are wedded to Western philosophies of science, particularly "logical positivism" (p. 184). He calls for changes to the curriculum, writing that "Internationalizing the clinical psychology curriculum will require adjustments and changes consistent with cultural variations in ways of knowing (i.e., epistemology), ways of practicing (i.e., praxiology), and ways of constructing human nature (i.e., ontology)" (p. 184). Chapter 10 traces the internationalization of counseling psychology as a discipline. Leong, Leach, and Malikioso-Loizos review international contributions to counseling psychology publications and discuss a number of recommendations for internationalization. First and foremost, they refer to the diversification of methods of psychological science, which is consistent with Marsella's assertion. Other recommendations included inviting international scholars onto the editorial boards of American journals, holding the APA convention

internationally, and creating training opportunities abroad for graduate students.

Another highlight of the book was the inclusion of a chapter on peace psychology. Christie and Noor offer a number of perspectives on peace, including the ways in which particular cultural values or practices may promote peace (e.g., harmony within oneself in Indian culture). They compare Western notions of peace (i.e., absence of violence) to those of other cultures (e.g., positive peace), a particularly relevant topic to both domestic and international audiences.

Internationalizing the Psychology Curriculum in the United States is a must-have for educators, training programs, and program developers. The authors offer a wealth of resources for curriculum planning: suggestions for assignments (pp. 45–46), a cultural competence self-assessment (p. 193), training scenarios (pp. 249–250), recommendations for future research, readings and websites, and recommendations to the APA and departments of psychology (pp. 317–319). The book also includes a comprehensive appendix titled "Fifty Ways to Internationalize the Curriculum of 'Western' Psychology."

Leong et al.'s (2012) volume offers a solid review of research published in the English language on the internationalization of a number of subfields in psychology. A resounding theme in the volume was the need to evaluate Western approaches to science. Western philosophies predominate our development of theory and methods of scientific inquiry. Embedded in these philosophies are assumptions about the ways in which we acquire knowledge (epistemology) and our understandings of the nature of reality (ontology); these in turn inform our heavily quantitative methods of scientific investigation and empirically-based forms of practice (praxiology). Are these methods akin to the philosophies of other cultures? From their review, Leong et al. (2012) appear to repeatedly suggest a need for more contextual approaches to the study of human behavior, including generating empirical data within cultural contexts (pp. 63, 149), reducing reliance on causal explanations (p. 86), balancing nomothetic and idiographic methods (p. 113), and incorporating qualitative methodologies (e.g., oral histories, biographies, ethnography, case study, phenomenology, grounded theory; pp. 120, 206). In a future edition, perhaps this theme could be further developed into a chapter on underlying philosophies of science (cf. Ponterotto, 2005).

Furthermore, the hegemony of Western philosophies in U.S. psychology has created a power imbalance in the consumption of knowledge in the field, where in the US, foreign knowledge consumption is nearly nonexistent. Lee, Moghaddam, and Harré seem to accurately describe this phenomenon in their chapter on social psychology. Bridging our understanding of power dynamics to the process of internationalization is yet another strength of the book. Concepts from feminist theory and the psychology of women can further our understanding of these dynamics (see Russo, Pirlott, & Cohen's chapter).

The power imbalance appears to be maintained through the predominance of English language literature in the scientific community. Although identified by Leong et al. (2012, p. 213), this challenge is not overcome in this volume. Very few foreign language resources were cited in the text. In the next edition, this author suggests following the lead of Draguns and incorporating more foreign citations. Similarly, of the 22 contributors, only five were international (three of whom were from Canada). Though Leong et al. (2012) repeatedly recommend the inclusion of foreign scholars in scientific collaborations, this volume is lacking in this area. This speaks to the difficulties of forming international collaborations.

Several authors stressed the importance of speaking a foreign language as a means of increasing international contact; however, the preponderance of English language publications remains an issue. In their chapter on counseling psychology curriculum, Leong et al. (2012) address this issue: "Our experience is that…it is to the best of our interests to master the English language since the bulk of the scientific literature is in English" (p. 210). This author agrees that language barriers are among the most difficult obstacles to effective international collaborations; however, in the interest of reducing ethnocentrism, is it not incumbent upon researchers in the US to consume literature in other languages? Should we not learn to read and speak more languages as so much of the world has done to consume our wealth of psychological knowledge? I leave these questions for future consideration in the development of curricula in psychology.

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Call for Book Review Editor

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Who can you nominate to serve as the next Book Review Editor, effective in winter of 2014? I hereby welcome nominations. The editor should be a fellow or member of Division 52 who is comfortable with APA style and quarterly deadlines. S/he works with the Editor-in-Chief, to solicit, edit, and submit 2–4 book reviews per issue—a total of about 10 per year. For details, just contact me. Please submit your nomination(s) to me as soon as possible, for appointment in time for the February board meeting.

A Review of the *International Handbook of Peace and Reconciliation*

Malley-Morrison, K., Mercurio, A., & Twose, G. (Eds.). (2013). *International handbook of peace and reconciliation*. New York, NY: Springer.
700 pp., ISBN 978-1461459323, Price US $229

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Humans have developed many approaches to regulating violence, including religious and cultural principles of moral conduct, social norms, laws, and a variety of enforcement mechanisms and degrees of punishment. But when it comes to war and its variants, most of the violent behaviors that are illegal or immoral in times of peace become part of the means by which competing rivals seek to dominate and subordinate their opponents. Until relatively recently, there was little attempt to impose any regulatory limits on the conduct of war and that which has been done seems to have met with very limited success, as anyone can see if they look at the brutality of recent conflicts in most any part of the world. And because war and other types of violent conflicts have long lasting consequences for societies and the individuals of which they are composed, they leave indelible scars and cast a long shadow over human relationships. What sometimes passes at the surface as peace may only thinly mask legacies of hostility, hatred, desires for revenge, social pain, regret, guilt, shame, trauma, and persistent fears of recurrences. These types of ongoing feelings and the oppositional perspectives they reflect can act as impediments to achieving an authentic and durable reconciliation. The ideal of peace requires something more harmonious than merely a suspension of overt violence, and following upon the horrifying infliction of grievous harm it is supremely challenging to find our way to truly reconcile with those who were previously perceived as our lethal enemies. To the extent that peace and reconciliation are collective states of mind, whatever progress is made in their direction is fragile and vulnerable to setbacks when perceptions of threats motivate acts of defensiveness, which in turn are perceived as offensive triggers for an escalating cycle of hostility. And yet if we are to counteract the trends toward perpetual war and low intensity conflict, we must develop determination and the effective means by which peace and reconciliation become likely.

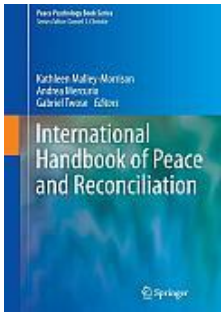

Peace scholars have dedicated considerable study to understanding the factors that differentially promote either violence or peace, suspicion or trust, or antagonism or reconciliation. A new edited volume of scholarly chapters regarding peace and reconciliation has been published this year (2013) by Springer, under the title of *International Handbook of Peace and Reconciliation*, with the promise of gathering in one place the collective knowledge and wisdom of about 120 authors in the adjoining realms of peace psychology and international relations. This book is a new entry in the Peace Psychology Book Series edited by Daniel J. Christie, a founding member and former president of Division 48 (Peace Psychology) of the American Psychological Association. The editors are Kathleen Malley-Morrison (Boston University), Andrea Mercurio (Boston University), and Gabriel Twose (Society for the Psychological Study of Social Issues). Those who authored and edited this book have produced a remarkably well designed volume of chapters systematically addressing distinctive aspects of how approaches to peace-building vary in eight regions of the world in which conflict has been all too prevalent.

The editorial team and the authors they selected to contribute chapters bring to the book an impressive range of experiences with violence, conflict resolution, peace-building, and the truth and reconciliation process applied across a variety of cultures and contexts. Their collective purpose is to identify variations in: (1) What "peace and reconciliation" mean to ordinary people; (2) Factors believed necessary for promoting reconciliation; (3) Beliefs about the rights of those who protest in matters of war and peace; (4) Beliefs about the role of apologies in reconciliation; (5) Beliefs about the best ways for achieving peace; and (6) Beliefs about the achievability of world peace. The methodology is extensive and elegant, drawing upon researchers from the Group on International Perspectives on Governmental Aggression and Peace (GIPGAP) to administer a survey to volunteers from over 40 countries. The volume is organized such that the responses to the survey are summarized and analyzed by both country and by theme. Integrative chapters provide an up-to-date overview of historical and current events relevant to peace and reconciliation and a grounded theory analysis of definitions of peace and reconciliation and of the role of apology in reconciliation. In addition to describing the major themes emerging from the responses in each region, the volume reports on some exploratory analyses addressing the extent to which differences were found in patterns of responding based on characteristics such as gender, military experience, and involvement in anti-war protest activity. The *International Handbook on Peace and Reconciliation* allows ordinary citizens from around the world to voice their views on peace and related issues, and examines the context of these views. Thus, it offers researchers in political science, peace psychology, social psychology, social justice, and anthropology a comprehensive resource for a changing global landscape.

The book contains 43 chapters divided into four topical sections. The first section, Definitions of Peace and Reconciliation, establishes the conceptual foundation for under-

standing the general descriptive terminology while also addressing distinctive variations of perception and meaning across nations, regions, and cultures. This approach is one in which a section topic is described in terms of how it is perceived and manifested in one or another geographical sector of the world. The geographical divisions are "Western Europe," "Great Britain, Northern Ireland, Canada, the United States, and Australia," "Russia and the Balkans," "the Middle East," "Africa," "Latin America," "South and Southeast Asia," and "China, Japan, and Korea," followed by a more integrative treatment comparing information regarding peace and reconciliation from every region of the world. This template is followed with only a small degree of variation in subsequent sections describing "Perspectives on Protest," "Apology and Reconciliation," and "Perspectives on Achieving Peace." There are also some excellent integrative chapters that draw together the strands of commonality and diversity of experiences to distill essential insights.

The approach taken is an elegant variation on one seen in a number of other books describing historical, cultural, religious, and nationalistic variations in perceptions and behaviors of one type or another across the global diversity of social groups. The utility of this model is clear, for we do in fact tend to perceive the world in terms of a map of geographical locations that correspond to the ways in which our cultures, languages, belief systems, political perspectives, industries, and wealth are distributed. Political leaders, the news media, and most individuals speak often of Eastern and Western viewpoints and divides, and Northern and Southern hemispheric differences in wealth and industrial development. Very large and diverse continents such as Africa, Europe, and Asia, and the geo-linguistically defined region of Latin America are used as shorthand for the perception of an implicit typology corresponding to comparatively higher homogeneity. This is not a salient weakness in this admirable volume, but instead seems to be the prominent framework for describing and analyzing human behavior and belief. Perhaps addressing conflicts and their outcomes in geographical terms is the most reliable current method of capturing salient variables such as history and culture, or religious divisions, or resource availability, or the relative credibility or effectiveness of healing interventions. But given the extensive amount of upheaval that has taken place around the world over the past century, and the pace of environmental and technological trends with the potential to stimulate even more forced and volitional migration, and the churning and blending of cultures, it seems important that we keep improving upon our ways of understanding populations, cultures, and the human experience. That is to say, the frames of reference and models of analysis to which we have long been accustomed may not continue to serve us well, if in fact they ever did.

Among the qualities that will make this book one that peace scholars will treasure is the brilliantly well-designed approach to empirically examining what people from various parts of the world mean and believe about peace, conflict, violence, protesting, apologizing, and reconciling. The result is a broad and diverse collection of studies, each with their own discoveries, that taken together allow for an integration of threads of wisdom and insight that can then be woven together as a tapestry. Indeed, this very metaphor is invoked in the book's afterword and brought to life in the final integrative chapter. Each chapter has great merits of its own, and in some instances serve individually to meet a reader's needs. But the true beauty of this lies in the achievement of rendering such a complex story of human loss, survival, and resilience with scholarly integrity, scientific rigor, and the compelling eloquence that keep the reader in touch with the humanity at its core. Too many people have paid too high a price throughout this war torn world to expect anything less, and the authors and editors of this book are to be commended for this unique and compelling contribution to peace studies.

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At the end of 2013, the student committee will be experiencing some organizational changes as Laura Reid Marks moves to the position of past-chair. We would both like to reflect upon on our experiences in the student committee, as well as describe some of the committee's current and future projects.

Lessons Learned as a Division 52 Student Committee Chair

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As my time serving as a chair of the Division 52 student committee comes to an end, I find myself reflecting on things I have learned over the last 2 years. In this article, I discuss these lessons. I share my knowledge on the importance of: (a) getting involved in a professional organization early, (b) finding a voice in that organization, (c) not being afraid to try things, and (d) learning from your mistakes.

Getting Involved Early in a Professional Organization

Getting involved with a professional organization early is more important than one might realize. When you get involved early, you develop relationships with other students who are passionate about the same things that you are passionate about, and you also develop relationships with senior members of the organization, who may end up mentoring you or serving as influential role models. I became involved with Division 52, as a chair of the student committee when I was in the second year of my graduate program. I remember feeling nervous and unsure of what to do in my new role. I utilized information from the chairs that came before me, Jennifer Doran and Jenna Stowell, and with my co-chair, Daria Diakonova-Curtis, we worked together to acclimate to our new roles. We also received a lot of guidance from the division president at the time, Neal Rubin, and the next year, the new co-chair and myself received guidance from the new division president, Mercedes McCormick. In sum, the earlier you get involved, the more relationships you will develop, and the more time you will have to learn the other lessons I share below.

Find Your Voice

As an introvert, finding a voice has always been challenging for me. However, being a member of a professional organization can provide you with opportunities where you can share your voice in a safe environment. I remember my first Division 52 executive board meeting. I recall feeling intimidated being one of the few students in the room, surrounded by the "big names" in international psychology. At first, I remember wondering what important knowledge I would have to share. Soon, I learned my voice was important to everyone in the room, because I shared the voice of students (i.e., their questions, their concerns, and their suggestions), and you can only be an expert on students when you are a student.

Don't Be Afraid to Try New Things

This next lesson might be a difficult one to learn in the beginning. You want to impress people, and sometimes trying new initiatives might not go as you planned. Trying new things means you are being risky. One of the new things I tried with the student committee was developing a campus representative network. By having a campus representative network, Division 52 would potentially have a network of students around the country, and around the world, who are tasked with making the division more visible. In this position, students meet other students who are passionate about international psychology. Further, if you attend big conferences, such as the American Psychological Association (APA) convention, you have the opportunity to meet these representatives in person and develop a relationship with them. In this case, my initiative was successful, but I could imagine it going the other way as well.

Learn From Your Mistakes

This last lesson is a hard one. With taking risks comes the actuality that you may not accomplish what you set out to do in the first place. I think one of the biggest mistakes I made in my leadership was not speaking up soon enough at division board meetings. It took me a while to realize that my voice is valued. I think this lesson is one I will carry with me forever as I move forward with my graduate student career, and eventual career as a psychologist interested in international issues. Don't be afraid to speak up!!!

In Conclusion

Students, I hope you will learn from the lessons I have learned and presented in this article. Before I make a decision I always ask myself, "What do I have to lose?" Often not much, so go for it. I wish you all good luck in your educational endeavours, and, as you get involved in a professional organization early, find a voice in that organization, try

things without fear, and learn from your mistakes.

Student Leadership: Past, Present, and Future

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As I complete my first year and enter my final year as co-chair of the Division 52 student committee, I would like to share some reflections as well as comment on future directions of the student committee. I will speak to my own path in entering the student committee, some of the benefits I have experienced so far, and my goals for the upcoming year. My hope is to share my experiences, encourage current students to join and participate, and inform senior members of student endeavours to promote mentorship and interaction.

Past: The Many Benefits of Student Leadership Involvement

I began serving on the committee in early 2011 by referral of a past president, Danny Wedding. I had just begun my doctoral program after returning from a year in China, where I worked for a public health non-governmental organization. I was looking for a way to continue my international interest and engagement during graduate school, and Dr. Wedding encouraged me to participate in student leadership to stay connected. This proved to be a great idea, as I gained experience in leadership, access to excellent mentorship, as well as exposure to APA as an organization.

Looking back, I want to share a few of the many benefits of joining a student leadership position in hopes of encouraging other students to become more involved with our student committee. In my first 2 years on the committee, I served as Public Relations Chair, focusing on outreach. This allowed me to interact with several senior and student members, as well as to develop my communications skills. Furthermore, as a result of my involvement with the student committee, I was asked to write my first submission to the *International Psychology Bulletin* (*IPB*), which is an excellent opportunity to publish early in a student's career.

Additionally, students can make connections through Division 52 that will endure throughout their careers as well, even if not directly related to international psychology. For instance, I met Jennifer Doran when she was chair of the Division 52 student committee in 2011. Despite being on opposite coasts of the US, we were able to collaborate on a symposium that we presented at APA this year in Hawaii. While the presentation was not related to our work on the student committee, we were able to learn enough about each other and the quality of our work that we were able to continue our professional relationship beyond Division 52. In addition to the exposure to senior members and experts in international psychology, I had the benefit of meeting peer collaborators as well.

Present: A Period of Growth

Various members of the student committee shifted roles this year, leading to my current role as editor of the student column, another one of the many diverse opportunities for leadership with Division 52. I worked closely with Daria Diakonova-Curtis, who was the previous editor of the column and helped me transition to this new responsibility, with the help of senior members like Grant Rich and Harold Takooshian. I certainly experienced the stress and growth associated with holding up to the high standards of an APA publication, but I was able to leverage support from other leadership. Being an editor for an official APA publication is a unique opportunity to learn about the publishing process, work with experienced senior editors, as well as get a window into the reviewer's perspective. I strongly encourage students to send me their ideas for submissions and to take advantage of this opportunity to publish.

Another initiative I participated in this year is an excellent project called "Fast-Connect" by Early Career Professional (ECP) chair, Suzana Adams. Briefly, the project involves interviewing different student, ECP, and senior members of Division 52, increasing interaction between members, and creating member profiles. I found this to be a wonderful experience as a whole, in which I was able to speak with an ECP and senior member of the division, learn about their paths to international psychology, and benefit from informal mentorship. This is an opportunity open to all student members, and I would encourage interested parties to get involved.

A final area I would like to mention is mentorship. This is one of the reasons many students get involved with professional organizations, and I can't emphasize enough how truly useful this can be. This year was my first in organizing division events for the annual APA convention, including a mentorship hour with chair of the Mentoring Committee, Nancy Russo. Not only did I learn about the organizational aspects of division programming, but I had the pleasure of meeting a wide variety of members interested in networking and mentorship. One of the main recommendations of mentors from this event was "Don't be afraid to ask"; something I would like to pass on to student readers and hope to continue to learn to do better myself.

Future: Directions for the Student Committee

Among the many goals of the student committee, I aim for the coming year to bring even more interaction between student, ECP, and senior members. We will continue initiatives such as the Campus Representatives Program to improve outreach and visibility of Division 52, as well as grow our student membership, including for undergraduate students. With ongoing feedback from other student members,

we will continue to revise our website to suit the needs of students. A key goal is to start fundraising for student travel grants to conferences, and we are open to ideas.

In conclusion, it has been an exciting path so far on the student committee. As I begin my final year as chair of the student committee, I would like to thank my co-chair Laura Reid Marks for her mentorship, openness, and great support throughout the past year. I look forward to working with the student committee and other Division 52 members in 2014!

Editor's Note

This column is geared towards our student committee members and all students of international psychology. All Division 52 student members are invited to submit ideas or drafts for future articles, as well as questions they would like to see addressed in future columns – such as overseas internship opportunities, study abroad availability, cross-cultural research, etc. Contact Student Column Editor Valerie Wai-Yee Jackson at vjackson@alliant.edu to submit an idea or a question.

Translators Wanted

A one-page overview of the history of the APA Division of International Psychology was co-authored by its Presidents John Hogan and Harold Takooshian. It is located on our website at: http://div52.org/about-us/a-brief-history-of-division-52/

We now seek global colleagues to translate this sheet into other languages, with themselves as the author, to circulate to colleagues and students globally. As of October 2013, this sheet appears in 26 languages: Amharic, Armenian, Chinese (Mandarin), Dutch, English, Estonian, Finnish, French, Greek, Hindi, Indonesian, Japanese, Kinyarwanda, Korean, Latvian, Malaysian, Norwegian, Polish, Portuguese, Russian, Sinhalese, Somali, Spanish, Swahili, Thai, and Ukrainian.

Can you translate this into another language? If so, contact Dr. Rivka Bertisch Meir at winsuccess@aol.com or Dr. Harold Takooshian at takoosh@aol.com.

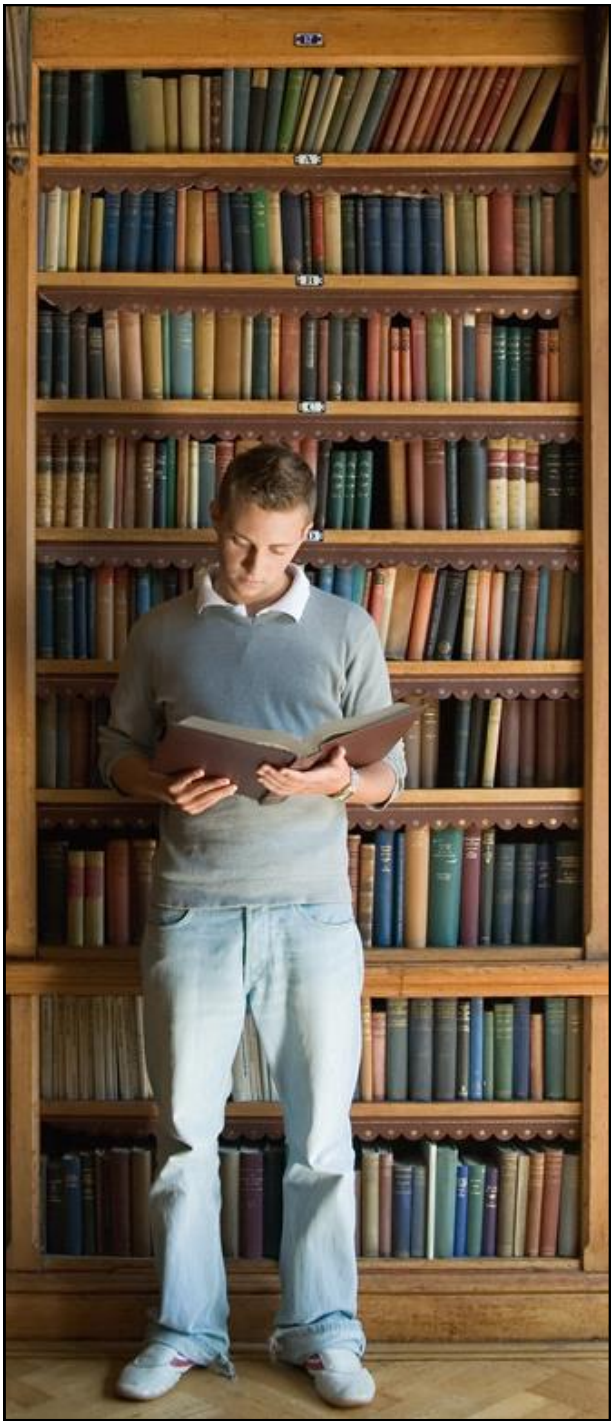

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International Mentoring: Recommendations for a Successful Mentor-Mentee Relationship

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International mentoring is probably one of the most gratifying experiences for an international psychologist who advocates for and values the internationalization of psychology as a discipline. A mentoring relationship is important to the career success of both the mentor and mentee. In conventional mentoring relationships, it is customary for the mentor and mentee to be in one location to facilitate face-to-face interaction. With e-mail, video conferencing, and other web-based ways of communicating, mentoring international psychology mentees has become not only feasible, but more common.

The Internet has greatly facilitated and expanded the opportunity for a mentor to be available to a number of mentees in different parts of the world. This is important to psychology students and mentees in communities or countries where mentors may not be readily available locally.

In the field of psychology, mentoring is a supportive and nurturing process in which psychologists connect to offer encouragement, guidance, and support (American Psychological Association, 2013). A psychologist mentor serves as an advocate, resource, and role model, who stimulates the mentee to build the skills required for work in the field of psychology, whether in private practice, academic, forensic, medical, or community settings. Mentoring is not therapy or supervision. The mentor-mentee relationship can be as familiar and intimate as sharing dreams and dinner, or as simple as the mentor being the 'go-to' person whenever the mentee has a question.

Mentorship is an important aspect of career success. However, the relationship is not accessible to all potential mentees. It is therefore important to find ways and resources for connecting individuals with potential mentors. These methods may involve blending current technology and social media with old-fashioned networking. Mentors can find mentees through mentoring programs such as the APA's Division 2 (Society for the Teaching of Psychology), and by attending conferences organized by or for student clubs and organizations. Collaborating on cross-cultural research, applying for international research and teaching opportunities, and joining professional psychology organizations are some of the ways that students can find mentors. Outlined below are some recommendations on how to ensure that international mentor-mentee relationships are successful (Hill, Castillo, Ngu, & Pepion, 1999; Roy & Linendoll, 2008).

Developing a Relationship of Trust

In international and multicultural mentorship relationships, there may be a greater chance of failure, poor results, or misunderstanding because of cultural expectations and language differences. Therefore, the most important step in establishing a successful mentoring relationship is for both the mentor and mentee to honestly define, identify, and clearly articulate their individual and common motives and goals (Chan, 2008). Before any mentoring can take place, the relationship must be based on an environment of mutual understanding and trust. It is essential for the mentor and mentee to get to know each other. The following are some examples of how a mentor may help to build a mentorship relationship based on trust.

- The mentor could check the level of understanding of the mentee by asking the mentee to provide an example of what she understands the mentor to be saying.
- The mentor may start each mentorship relationship with a get-to-know-you session.
- By establishing a warm, accepting relationship, the mentor helps the mentee to identify his or her professional goals and needs.
- The mentor may share information about her own experience and background as well as learn about the mentee's experience and educational background.
- Throughout the mentoring period, the mentor may focus on assessing the needs and building the strengths and goals of the mentee.

Defining Roles and Responsibilities

To build a strong and successful relationship, the mentor and mentee should have clearly defined roles. Naturally, a mentee is likely to be more receptive to feedback from the mentor if he or she is perceived as an active member in the relationship. Some of the recommendations to consider are:

- Defining the role of the mentor.
- Analyzing the type of mentoring that will be most appropriate.
- Defining the responsibilities of the mentor and mentee.

For instance, the mentor may require the mentee to complete a given number of goals or attend a specific training during the mentoring period.

Establishing Short-Term and Long-Term Goals

Mentors and mentees should collaborate and work together to come up with mutually agreed upon goals. The goals then become the basis for the mentoring process. For example, mentors should offer mentees constructive feedback on goal progression. In return, the mentees should be given an opportunity to reflect on their actions. The mentor can then note his or her observations in a constructive and positive manner as well as discuss any actions that the mentee takes with regards to the established goals. Afterwards the mentor and mentee may review the observations and decide on the next step (Fulton et al., 2007). While establishing short-term and long-term goals, there is a need for supportive, respectful and open communication. Thus,

- Mentors must be active listeners. According to Allen and Poteet (2013), feelings are very important, and it is only when mentees feel that they can share their feelings and thoughts with the mentor that greater trust is established.
- It is important for mentors and mentees to be responsive and value each other's feedback since even the most experienced teachers can learn novel ways of thinking and doing things.

Collaborating to Solve Problems

Mentors should give mentees the opportunity to identify potential solutions and concerns. It is the responsibility of mentors to encourage mentees to embrace risks and do things in a different way through the implementation of creative solutions (Roy & Linendoll, 2006). To improve the results of mentoring and to develop a successful relationship,

- The mentor should identify the precise concern and brainstorm possible solutions.
- The mentor should come up with a plan to try, discuss the preferred results, and implement the plan. The mentor should be encouraging and supportive as well as ensure the plan is completed successfully.
- The mentor and mentee should assess the outcome of the relationship together, discuss its effectiveness, be reflective of the activity, and make adjustments if need be.
- Mentors should not shy away from trying another solution. It is important to appreciate that there are several ways to address an issue, and thus the mentor's preference might not be the most suitable solution for the mentee.

Honoring Commitments

Mentors often have very demanding jobs. Mentees need to show their appreciation for the time mentors have invested in them by, at the very least, responding to the mentor's comments and questions in a timely manner. Through mentoring, mentees are able to learn and grow under the guidance of mentors. They are able to experiment with creative solutions to problems within a supportive and safe environment. It is through mentoring that less experienced individuals are able to progress and develop in their profession (American Psychological Association, 2013). Thus, one important strategy to establishing a successful international mentor-mentee relationship lies in establishing short-term and long-term goals, creating a relationship of trust, collaboratively solving problems, using open and supportive communication, and clearly defining roles and responsibilities.

A mentorship relationship may not work all the time. However, by using emerging social networking and communication media, international mentoring relationships are facilitated. In an international mentorship, the mentor and mentee may be from different countries or have different cultures (Hill et al., 1999). Thus the success of the mentoring relationship lay in the building of direction, confidence, and self-esteem, both professionally and personally, by expanding possibilities and sharing ideas. A successful international mentorship plays an important part in guaranteeing career success and satisfaction for mentees and mentors.

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Author's Note

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Community Healing and Evolution of Psychology: 25 Years Post-Earthquake in Armenia

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On December 7, 1988 at 11:41 a.m. (Viviano, 2004), a devastating earthquake disrupted northern Armenia, Soviet Armenia at that time. The earthquake measured 6.9 on the Richter scale and killed at least 25,000 people, according to Soviet records. According to European sources however, as many as 100,000 Armenians died, and 530,000 people were left homeless (Kalayjian, 1995). Unfortunately, this was not the only source of devastation. During this time, tension was also growing between ethnic Armenians in Nagorno-Karabakh and military forces of Soviet Azerbaijan. As a result, 200,000 refugees fled to Armenia, settling in the earthquake zone (Viviano, 2004). The country was left in shambles and in the midst of a serious conflict, both natural and human-made. Many survivors were affected, and as a result, developed many emotional reactions, including posttraumatic stress disorder (PTSD) and depression. The author has organized the Mental Health Outreach Project (MHOP) (Kalayjian, 1995) for Armenia and has sent over 50 professional volunteers to Armenia since the earthquake.

Mount Ararat, pride of Armenians.

Mental Health Outreach Project

After the earthquake in Armenia the Mental Health Outreach Project (MHOP) was established by the author to assess levels of PTSD in the surviving community, and to establish a rehabilitation program. MHOP was comprised of eight stages including: pre-assessment, assessment, analysis, community diagnosis, planning, implementation, evaluation, and remodification (Kalayjian, 1991b).

Group and individual therapies have been used to help survivors, especially children, and adolescents. The survivors were given the Child Posttraumatic Stress Reaction Index and the Depression Self-Rating Scales. The survivors were assessed 1.5 years and 5 years after the earthquake. The untreated survivors were at risk for chronic PTSD and depressive symptoms, whereas the treated ones found that they had better chances at relieving the symptoms of PTSD (Kalayjian, 2005; Goenjian et al., 2009).

MHOP included assessment in these four areas: (1) Assessment of survivor characteristics, (2) Assessment of event characteristics, (3) Issues during disaster relief, and (4) Pre- and post-disaster sociopolitical and economic climate.

Survivor Characteristics in Armenia

Who were the survivors of the 1988 earthquake in Armenia? They were intelligent, hard-working, peaceful, religious, family-oriented, and hospitable people (Jordon, 1978). The Republic of Armenia is geographically the smallest of the former Soviet Republics, with a population of approximately four million, and it is the most entrepreneurial and economically fastest-growing republic (Walker, 1991). The historical record shows an Armenian presence in the general region of Asia Minor and the Caucasus dating back over three millennia (Ishkhanian, 1989). Its history throughout the centuries is one of enduring oppression, war, relocation, and survival. From the end of the fourteenth century until 1991, Armenia had only 2 years of independence (1918–1920), yet its people, culture, and language have survived. On September 23, 1991, Armenia once again declared independence. For the first time in 71 years, the Armenian people freely elected a President and Representatives to the Republic's Parliament, the Supreme Soviet, from a slate of candidates representing a variety of political movements and organizations.

In discussing their history, Armenians mention three things. First, they mention their religion. This is a point of great pride since Armenia became the first nation to adopt Christianity in 301 A.D. as its national religion. Second, they mention their language. The Armenian language is a distinct branch of the lndo-European family of languages, with a unique 38 character alphabet. Last, they mention their survival of the Ottoman-Turkish Genocide. From 1894 to 1923, the Armenian Nation was brought to the brink of annihilation as almost two million Armenians, more than half the Armenian population, were massacred by the Ottoman Turkish rulers. To this day, the Genocide is denied by the current Turkish government. This denial causes tremendous feelings of anger and resentment, with no reparation or resolution (Kalayjian, 1991a). During World War II, and for over seventy years under Communism, Armenians experienced yet more pain and suffering. This was a system that relied on oppression of individual needs for the sake of the party and any rebellious gesture could lead to one's disappearance. Pain and suffering continued on in the post-independence era (after 1991), due to territorial conflict within Azerbaijan over Nagorno-Karabagh. Adding to the suffering has been the Azeri and Turkish blockade of Armenia which began in 1988 and as of today (2013), is yet to be lifted.

The literacy rate is comparatively high in Armenia, as virtually all Armenian children attend school for 8 to 10 years

from age 6 to 16.

People are industrious yet poor as the economy has been decimated by decades of Soviet rule, further exacerbated by the Azeri and Turkish blockade.

Event Characteristics in Armenia

On Wednesday, December 7, 1988, at 11:41 AM, a devastating earthquake shook the Republic of Armenia for 40 seconds. This catastrophic destruction occurred in a zone where several plates of the earth's surface converge, which occasionally results in disastrous consequences when movement occurs. Although the quake did not come as a total surprise to American and Soviet experts in the field, according to Purkaru of the geological institute in Frankfurt (Sullivan, 1988), due to gross unpreparedness and lack of emergency and evacuation plans, the community experienced the quake as a total nightmare.

Measuring 6.9 on the Richter scale, the quake occurred in an area highly vulnerable to seismic activity. It destroyed two-thirds of Leninakan, Armenia's second-largest city (now Gumru, population about 300,000), half of Kirovakan (now Vanatzor, population 150,000), obliterated Spitak—the epicenter (a town of about 30,000), and heavily damaged some fifty-six of 150 villages and towns in the northwest corner of Armenia, near the Turkish border. Initial reports of casualties spoke of "thousands" which soon became "tens of thousands" and went on to climb day-by-day to 130,000. In the end, there were about 500,000 people handicapped, approximately 500,000 children orphaned, and over 500,000, one sixth of Armenia's population, left homeless. The physical damage was estimated at $20 billion (US).

Assistance from all over the world poured into Armenia. Within the first 10 days, $50,000,000 worth of goods, food, and supplies were delivered to Yerevan's airport from around the world, overwhelming the damaged distribution system. This airlift marked the first time since World War II that the Soviet government had accepted disaster assistance from the United States. In all, the American government spent about four million U.S. dollars, and U.S. Air Force and National Guard planes were used to fly in the relief supplies. Private contributions from Americans in the first 4 weeks following the earthquake reached about 34 million dollars. The grand total given by all countries outside the Soviet Union reached 106 million dollars (Simon, 1989). According to U.S. Senator Simon, in view of the fact that the United States represents 20 percent of the world's economy, what the US did as a nation was not that impressive. However, aid sent by the U.S. government to the Soviet Union and its acceptance was unprecedented. When the Marshall Plan was announced in 1948, the Soviets would accept no American aid whatsoever. Therefore, the fact that aid was given and received was a healthy sign (Simon, 1989).

Issues During Disaster Relief

The disaster response was somewhat different in Armenia compared to natural disasters in Florida and California. Overwhelming international attention was received due to the interruption of President Gorbachev's visit to the United States. Unfortunately, this did not result in an organized rescue effort. Efforts were extremely disorganized, began too late, and resulted in chaos. The warning system was outdated, old-fashioned or just dysfunctional, and the rescue equipment was either broken or insufficient. The then Soviet governments were centralized and every little decision had to come from Moscow.

Pre- and Post-Disaster Sociopolitical and Economic Climate

During the 10 months preceding the quake, Armenia was experiencing sociopolitical tension and was economically drained. This was due to the conflict with neighboring Azerbaijan over Nagorno-Karabagh, a 4,000 square kilometer enclave mostly populated by Armenians and locally ruled by Armenians until 1923, when Josef Stalin gave it to Soviet Azerbaijan. In early 1988, Armenia challenged Gorbachev and put "Glasnost" and "Perestroika" to their first true test, but failed. As a result, over 200,000 Armenian refugees from Azerbaijan came to already overcrowded Armenia. In February 1988, there was yet another massacre in Sumgait, Azerbaijan, where dozens of Armenians were killed, houses were burned and women were raped and set on fire (V. Manookian [the then Prime Minister of Armenia], personal communication, 1991). Noteworthy is that seismologists described the quake area as a "structural knot," engendered by the interaction of several rigid plates (Sullivan, 1988). Ironically, this paralleled the sociopolitical and emotional situation: political agitation, tension, anger, resentment, disappointment and mistrust, due, at least partly, to rigid attitudes (Kalayjian, 1995).

Analysis

Psychological and behavioral symptoms were first assessed by the author 6 to 8 weeks after the earthquake. Over 200 adults and 200 adolescents and children constituted the assessment sample. The site of the assessments varied. Several different layers of the community were observed in their natural environments, i.e., school age children and adolescents in their classrooms during recess, in hospitals, in shelters or in their homes; adults at their work places (if they were still employed), in hospitals, at government shelters or at the homes of their relatives. Geographically, emphasis was placed on the quake zone in Armenia: Leninakan, Kirovakan, Spitak, and a few of the villages that were en route to the larger cities. Data from the assessment were used for this analysis.

Short-Term Impact of the Earthquake Manifested in Children and Adolescents in Armenia

Assessment of children. Eighty-six percent of the children interviewed or observed ($N = 122$, $F = 60\%$), displayed at least four of the following 10 symptoms: separation anxiety intensified during the night; refusing to go to school; refusing to sleep or to be left alone; conduct disorders; sleep disturb-

ances manifested by bad dreams, frequent awakenings, and difficulty falling asleep; regressive behavior manifested by thumb sucking, enuresis, and clinging behaviors; hyperactivity; withdrawal; inability to concentrate; and somatic complaints. Utilizing the Reaction Index Scale (Frederick, 1986), 82.8% of the adolescents interviewed ($N = 62$, $F = 55\%$) scored over 50, indicating severe levels of posttraumatic stress disorder (PTSD). The most common psychological and behavioral symptoms observed in adolescents were as follows: withdrawal, lack of concentration, aggressive tendencies, nightmares, unusually poor grades in courses in which they had excelled prior to the earthquake, irritability, and increased reports of episodic daydreaming (Kalayjian, 1995).

Dr. Kalayjian training children's centers staff.

Assessment of adolescents. Responses of adolescents differ somewhat from those exhibited by children and adults. Although a few research findings indicate the short-lived nature of responses by adolescents to disaster, very few studies focus on the frequency and the intensity of those responses. Milgram, Toubiana, Klingman, Raviv, and Goldstein (1988) studied seventh graders 9 months after a school bus disaster and found they had very few psychological symptoms. Nader, Pynoos, Fairbanks, and Frederick (1990) assessed children and adolescents after a sniper attack at their school and similarly found their posttraumatic stress symptoms decreased within 14 months after the trauma.

The adolescent disaster stress response differs from that of adults and children. Developmentally, adolescents are in a unique and inherently stressful stage, with distinct emotional and psychological needs (Rutter, Izard, and Read, 1986). In addition, adolescents do not have the advantage of increased age and multiple life experiences to rely on, as do adults. According to Hardin, Weinrich, Weinrich, Hardin, and Garrison (1994), who studied 1,482 South Carolina high school students a year after Hurricane Hugo, as exposure to the hurricane increased, so did symptoms of psychological distress. However, the study by Hardin et al. was limited, as are almost all the studies on natural disasters, by its inability to compare the baseline psychological distress scores of adolescents before and after the disaster. As a whole, the study revealed that social support and self-efficacy are inversely related to psychological distress, which reinforced studies of Baum, Fleming, and Davidson (1983), Fleming, Baum, Gisriel, and Gatchel (1982), and Murphy (1987). Social support was even a better protector against psychological distress than self-efficacy, reinforcing studies by Fleming et al., Berndt and Ladd (1989), and others, who found peer support to be essential for teens in distress.

Assessment of adults. Two hundred twelve adults (62% female) were interviewed in Armenia. The Reaction Index Scale was utilized. Over 80% scored in excess of 50 on the Reaction Index Scale, indicating severe levels of posttraumatic stress disorder (PTSD). Over 80% of those interviewed admitted to having at least five of the psychological symptoms listed (Kalayjian, Shigemoto, & Patel, 2010).

Community diagnoses. Community diagnosis is a term describing a community's response to a disaster. Diagnoses are utilized as classifications to express conclusions based on the data gathered in the pre-assessment, assessment, and analysis phases.

Diagnoses generally are abstract and broad labels, or definitions of phenomena that health professionals use to help clients, as well as communities, to change and improve. These labels, or inferences, are utilized to assist professionals in their planning and implementations of care (Kalayjian, 1995; Kalayjian & Eugene, 2010).

A thorough analysis of the assessment of the impact of the earthquake in Armenia and individual interviews conducted by the author revealed several diagnoses.

Community findings in Armenia Post-1988 Earthquake indicate that:

1) 86% of the children interviewed had severe PTSD.
2) 83% of the adolescents interviewed had severe PTSD.
3) 81% of the adults interviewed had severe PTSD.
4) 80% of the teachers interviewed in Leninakan (now Gumru) were survivors themselves.
5) Over 79% of the leaders and government officials interviewed from the quake zone were survivors themselves.
6) 80% of the mental health professionals interviewed from the quake zone exhibited signs of burnout.
7) 98% of the survivors in the earthquake zone did not have a mental health professional available to provide care.
8) There was only one community mental health outpatient clinic in Leninakan (Gumru) established by the first author.
9) Spitak and some 56 affected villages had no mental health providers or centers.
10) There were 39.2 physicians for every 10,000 people in Armenia (Kalayjian & Eugene, 2010).

Mental Health Outreach Project: Short-Term Planning

The author coordinated the dispatch to Armenia of teams of Armenian-speaking mental health professionals from the United States, Canada, and Europe, necessary to provide direct patient care. Fluency in the Armenian language, some knowledge of the culture, and emotional stability were key criteria in the selection of the volunteers. Based on the author's experience, those without knowledge of the language and culture arrived at erroneous conclusions in their assess-

ments of the survivors' mental health and further drained the limited resources of the community by requiring translators. Over 50 professionals were deployed over a 1-year period.

Each interdisciplinary team included a psychiatrist, a psychologist, and a psychiatric nurse or psychiatric social worker. Interdisciplinary groups were helpful in many ways. First and foremost, they were to be role models for the professionals in Armenia, where not only did the psychiatrists and psychologists not work collaboratively, but they were also supervised by different governmental ministries. Psychiatry was supervised by the Ministry of Health, but Psychology was supervised by the Ministry of Education. At that time psychologists were not permitted to care for clients, and there were no psychiatric nurses or social workers. There were a handful of psychotherapists in Yerevan who were psychiatrists with a year of post-psychiatry training, which frequently took place in Moscow or Leningrad. Each mental health outreach team remained in Armenia for 15–22 days and provided services at the major disaster sites.

Each team was also joined by a psychiatrist and/or a psychologist from Armenia for the purposes of training, education, and role modeling. This was a successful attempt at involving and empowering the survivor community, and expanding the knowledge and practice of psychology.

The author provided orientation sessions and workshops in the United States for the volunteer professionals who agreed to serve in Armenia. These sessions were designed to inform, educate, and empower the volunteers. These goals were accomplished through a step-by-step plan using the seven-step Biopsychosocial and Eco Spiritual Model (Meaningfulworld.com, n.d.).

Implementation

Implementation means putting a plan into effect. This phase directly follows planning, and is followed by the evaluation phase. Implementation is based on specific, unique needs of survivors and their community.

It is absolutely essential to have highly trained and expert mental health professionals conducting the interventions and implementing the plan of care. The planning phase, emphasizing the short-term goals, began in February 1989 and was re-evaluated and modified 6 months later, in August 1989, and repeated with each team of MHOP outreach. During this initial planning phase, six mental health teams were sent to Armenia to help the survivors of the earthquake, with a total of around 50 volunteers. Each team helped over 3,500 earthquake survivors in Yerevan, Leninakan, Kirovakan, Spitak, and five other villages.

The Mental Health Outreach volunteers possessed expertise in a variety of theoretical methods, and thus clinical approaches also varied. Therapeutic techniques utilized included art therapy, biofeedback, a coloring storybook, drawings (structured and unstructured), family therapy, group therapy, instruction booklets, logotherapy, meditation, play therapy, pharmacotherapy, and short-term psychotherapy. No single clinical intervention alone would have been successful to treat all post-quake symptomatology (Kalayjian, 1995).

Dr. Kalayjian engaging in movement therapy.

Six Month Follow-Up

A 6 month follow-up evaluation conducted by the first author in Armenia revealed that those survivors (n = 180) who received care from the MHOP's professional teams were:

1) Coping more effectively (78%), based on one-to-one interviews and the survivors' own anecdotal reports.
2) Less depressed (50%), based on the interview process and the survivors' own observations.
3) Scored lower on the PTSD Reaction Index Scale (80%) (Kalayjian, 1994).

In comparison, those survivors who did not receive care from the MHOP's professional teams expressed feelings of hopelessness, helplessness, anger, despair, and apathy. These same survivors, immediately after the quake, were working together cohesively, struggling to survive, helping one another and hoping that, with the coming of spring, they would spring back to a more stable life. Instead, they had nothing but tanks, tents and makeshift sheds for basic shelter, air polluted with dust due to the rubble, no running water in many places for 15 hours a day, and no electricity for several hours a day. Only about 50% of the survivors had homes, 30% were in shelters, and the remaining 20% had relocated to other parts of what was then the Soviet Union or to the United States (Kalayjian, 1995).

The author then recommended the following interventions:

1) Collaborate with and motivate American philanthropic organizations which have enormous resources at their disposal to expedite the reconstruction process.
2) Continue on-site clinical interventions using the MHOP professional teams for longer stays. The longer time would allow for follow-up and long-term treatments.
3) Engage in on-site education and training of teachers, psychologists, psychiatrists, and other health professionals, as well as invite them to the United States. The purpose of this emphasis is to reach a larger num-

ber of survivors and to empower Armenia's professionals by providing them with the necessary instruments, knowledge, and expertise in PTSD to help themselves and their communities.

4) Develop community mental health clinics in the affected cities of Leninakan, Kirovakan, and Spitak in order to provide easy access to care for the community.
5) Collaborate with the mental health professionals in Armenia and Moscow to conduct joint scientific research studies.
6) Provide training and orientation for those professionals providing field relief work in Armenia; upon their return, provide them with support groups and debriefing sessions.

One Year Follow-Up

The author returned to Armenia in April 1991 to evaluate the MHOP and gather more data for the ongoing research. The outpatient clinics in Leninakan (managed by Earthquake Relief Fund for Armenia (ERFA)) and Kirovakan were in place and both clinical care and training were taking place. Two MHOP team members stayed in Armenia for 1 year, to supervise, train, and conduct clinical work. About 40% of the survivors who visited the clinic had severe PTSD and 15% suffered from major depressive disorders. According to Vasken Manoukian (Kalayjian, 1995), the then Prime Minister of Armenia, only 19% of the housing had been completed, leaving thousands of Armenian refugees in need of homes. About 90% of the refugees interviewed by the author had severe levels of PTSD. They had escaped the beating, rapes, and torture by the Azerbaijanis.

Survivors who attributed a positive meaning to their experiences focused instead on the present moment and the meaningful experiences they had gained by helping or receiving help from one another and from the world. One survivor from Armenia stated: "Look at how the world has come to help us (the Armenians); the closed Soviet system has opened its doors; there is more communication, caring, and sharing" (Kalayjian, 1995).

According to the author's research findings (1991b), 20% of the survivors in Armenia were convinced that they were indomitable, echoing the words of Nietzsche (1956), who said, "That which does not kill me makes me stronger."

Dr. Kalayjian giving a radio interview.

Use of Humor

Black humor was used generously to distance survivors from the enormity of the trauma and from the crippling pain of multiple losses and to help them transform their suffering. The following is an example of such humor: "Ara, a survivor, is half buried under a massive boulder. His brother is standing on top of the boulder, engaging him in conversation to keep him alive until rescue forces arrive. After a couple of hours Ara moans "I am cold, I am cold!" His brother replies jokingly: "Shall I throw another boulder onto you?"

Five Year and 10 Year Follow-Up

The author returned to Armenia every 3 years to continue the educational programs, to supervise the MHOP teams, as well as to conduct healing circles. Due to the conflict with Azerbaijan, the Armenian government was placing priority on protecting the borders rather than focusing on the survivors' needs. The levels of PTSD had decreased to 25%; those who had received emotional healing previously reported functioning much better, with fewer symptoms of trauma. The MHOP teams extended the outreach to other groups of people, such as refugees from Baku and Azerbaijan.

Twenty Year Follow-Up

The author returned with her team for another follow-up in 2009. Other refugees were expressing tremendous need for emotional healing. Horizontal violence had set in, as the local Armenians were angry at the refugees, while the refugees were feeling left out, and discriminated against. Many programs were set in place for post-trauma healing, empowerment, and education.

The author helped establish several psychological centers to work with earthquake survivors, including mobile clinics in a minivan driving around the villages. Stress centers and psychological centers were established in cities affected by the earthquake—such as Stepanavan, Vanadzor, and Gyumri. A Mental Health Foundation was established (A. Vardanyan) specifically to raise funds and awareness for the mentally challenged. Many psychological associations, such as the Psychoanalytical Association, although not organized well, were established. The author emphasized the importance of media exposure, to make psychology a household word. She appeared on television and radio, and gave public speeches to emphasize how to prevent mental illness, how to mitigate and intervene effectively, what signs to look for, etc. Media continue to have psychologists interviewed on talk-shows, and feature scenes with psychologists on TV shows.

Advances in Psychology and Mental Health

Throughout the 25 years post-earthquake, psychology and mental health awareness have advanced tremendously. While pre-quake, psychologists did not engage in clinical practice, and instead worked in schools and research, and were supervised by the Ministry of Education only, now there are many psychologists in private practice, and there are many programs in psychology in several universities. Pre-

earthquake there were no programs in social work and advanced psychiatric nursing; now there are a few programs in each area that have been developed, and more are on the way.

After the quake, since 1990 academia has included the applied and clinical fields. Since 1992, a Department of Psychology was established at Yerevan State University (YSU) providing undergraduate and graduate programs. Students can pursue bachelor's and master's degrees in General, Social, and Personality Psychology. There are Master's Programs in the following areas: Organizational and Management Psychology, Psychology of Emergency and Crisis situations, Clinical Psychology and Psychotherapy, Political Psychology, Social Psychology, and Psychological Counseling.

Providing a training program at the State University of Armenia.

Discussion

The author's most recent humanitarian outreach programs in Armenia in 2009 and 2011 revealed a continued need for psychological interventions for the following reasons: remaining fear and trauma from the earthquake, generational transmitted trauma of the Ottoman Turkish Genocide, ongoing Azeri conflict, challenges in the post-Soviet reconstruction, horizontal violence, influx of Armenian refugees from Iraq and Syria escaping the wars, and issues in practicing democracy in leadership.

Advancement in psychology has been consistent with the increased demands of the people of Armenia, as the aforementioned list of needs attests. Universities, communities, NGOs, and government have attempted to address the growing mental health needs of the people. Diasporan organizations also assisted in the healing process, such as the ABSA (Armenian Behavioral Science Association). ABSA completed a census of 304 U.S. behavioral scientists, which it published as the first Directory of Armenian-American Behavioral Scientists (Takooshian, 1989). The Association for Trauma Outreach and Prevention (Meaningfulworld.com) was the organization founded by this author, and it organized the first Mental Health Outreach Program post-quake in Armenia, which continues until today. The next humanitarian outreach program, assessing the 25 year impact of the earthquake, will take place in October 2013.

Recommendations for the Future

According to the author's observations and evaluations, there is the need for at least 20 year continued on-site clinical intervention programs with several vulnerable groups:

1) The earthquake survivors;
2) The refugees from Azerbaijan, Iraq, and Syria; and
3) The leadership.

To conclude, in Armenia, when addressing psychological needs, it is recommended that a 20-year plan be established for schools in clinical psychology, public health, social work, and nursing, on clinical, applied, and research levels. Although there are many new developments, such as the fact that the Armenian General Benevolent Union and the University of California have founded the American University of Armenia, many doctoral programs in psychology and behavioral health are needed. Also needed is the establishment of a central clinical certification process. More programs are needed in clinical psychology as well as in other specialty programs, such as social work, counseling, and psychiatric nursing.

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Psychology in Armenia After the 1988 Earthquake: 25 Years Later

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Abstract

How is psychology developing in the fast-changing Republic of Armenia? This brief overview describes the past 25 years, since the monumental earthquake of December 7, 1988 devastated this tiny Republic. This report combines published with unpublished sources to offer an unusual look at the intersection of events, programs, and people shaping psychology in this beleaguered region.

How was psychological science and practice in the Republic of Armenia developed since the immense earthquake of 1988? In 1992, psychologist Hagop Pambookian predicted this:

> The developments in psychology in Armenia will likely include (a) an emphasis on the application of psychology to everyday life and on psychology practica in the psychology curriculum; (b) the organization of activities and seminars/ workshops for psychology students, and other interested scientists and individuals; (c) an expansion of information and instructional psychology programs in television; (d) the translation, adaptation and/or development of psychological tests for use ... (e) the easy availability of psychological services to those in need and (f) the reorganization of Armenian Psychological Association (pp. 23–24).

A look back 25 years later confirms Pambookian's original vision. Two major events—the 1988 earthquake and the 1991 collapse of the Soviet Union—deeply impacted the development of psychology in Armenia, in at least a few ways: (a) an influx of volunteer experts from Russia, Europe, and the USA, (b) opening of new centers, and (c) expansion of existing institutions. This brief report offers an overview of this post-earthquake era.

The Earthquake and a New Era of Psychology

At 11:41 am on December 7, 1988, a massive earthquake struck the Caucasus region, including Armenia. This measured 6.9 on the Richter scale, destroying 40% of the Republic in the northwestern regions (Spitak, Gyumri, and Vanadzor), killing over 25,000 people, and traumatizing untold thousands who lost their families, friends, and homes. It was morning, so children were in school, and people at work. Buildings were frail, and rescue attempts were hampered by a lack of resources (Moro, 2004). People lacked knowledge about behaving in emergencies, and the country itself lacked post-disaster experts to cope with such a tragedy—including psychologists to counsel survivors. This tragedy was so cataclysmic that the world press that day were stunned to watch Soviet Premier Mikhail Gorbachev suddenly flee his long-awaited "power lunch" in New York City with U.S. President Ronald Reagan, in order to rush to remote Armenian villages to view this tragedy firsthand.

Armenia and the Soviet Union quickly sought humanitarian help from all over the world. Many international humanitarian organizations came to provide essential triage. Doctors from *Médecins Sans Frontières* (MSF), a global organization working in this region, reported profound psychological problems among survivors (especially children), which engaged psychologists and psychiatrists from these organizations. Russian psychologist Konkov also emphasized the urgency of psychological help to survivors, because many of them might have psychological trauma (Cooper, 1988). In addition to a shortage of local specialists, those available were lacking in experience working with disaster survivors. One psychologist in the affected region in an interview with *The New York Times* emphasised that "psychologists and psychiatrists from other countries could be a great help, especially Armenian psychologists and psychiatrists who live and work in other countries" (Cooper, 1988). Indeed, this help followed shortly, with Armenian-ancestry therapists volunteering to train indigenous specialists.

Moro (2004), the technical head of MSF in Armenia, documented the situation in Armenia after the earthquake, and the steps that were undertaken to simultaneously provide psychological support to families (especially children), and train specialists to provide further services. She emphasized the shortage of practical psychologists to provide psychological help and counseling to those traumatized from the earthquake. She found there was a "devitalised concept of psychoanalysis" which was not acceptable for such professional intervention programs.

On one hand, there was a high demand for psychological counseling, but on the other hand, foreign psychologists faced a number of obstacles. First, people were skeptical that Western psychologists could help them. Second, it was nearly impossible to provide psychological services, because foreign psychologists were unable to understand the Armenian mentality (Moro, 2004). However, enormous efforts had been invested to ensure the provision of psychological help to survivors and allocation of necessary time to train Armenian specialists for further work.

In 1989 several psychological centers were established, to work with earthquake survivors. Stress centers and psychological centers in cities affected by the earthquake—such as Stepanavan, Vanadzor and Gyumri—were established right after the earthquake. Some psychological services such as "Apaga"("Future") in Yerevan, and "Arevamanuk" in Gyumri evolved into multi-purpose psychological services.

Within these developments, many practical psychologists started to work in the areas of behavioral psychology (Samvel Khudoyan), neurolinguistic programming (NLP) (Ruben Nagdyan), and psychoanalysis (Anjela Vardanyan and Ara Chalikyan). Many psychological associations such as the Psychoanalytical Association were established, with a goal to promote practical psychology in Armenia. Media also promoted practical psychology by involving psychologists in talk shows, providing columns for psychologists in magazines and newspapers, and even featuring scenes with psychologists in TV series.

Based on these developments, there is now "*an emphasis on the application of psychology to everyday life"* and an *"easy availability of psychological services to those in need."* However, the lack of quality assurance and a professional certification system for practical psychologists makes it impossible to speak about the quality of these psychological services.

Applied Psychology in University Curricula

The fall of the "Iron Curtain," open exchange with Western societies, and media influence have also raised interest in psychology as a profession in the general public, and triggered the development of psychology educational programs in universities.

Psychology as an academic discipline dates from the early 20th century when Gurgen Edilyan founded the first psychology laboratory in Armenia. But for many years, applied psychology as a scientific discipline was highly underdeveloped. During the Communist period psychology was influenced by Russian psychological schools focused mainly on education (pedagogical psychology) and developmental psychology (Jeshmaridian & Takooshian, 1994). Other areas such as sports and personality psychology have become the subject of scholarly interest after the 1960s (Nalchajyan & Takooshian, 1997; Pambookian, 1992). Furthermore, since 1990 academe has also included the applied fields of psychology in the research and teaching agenda following the establishment of psychological services after the earthquake.

Along with increased interest in counseling psychology, other fields of applied psychology have also grown popular—such as legal, military, forensic, and management psychology—leading to new undergraduate psychology programs in both public and private universities.

One key educational institution awarding degrees in psychology is the Armenian State Pedagogical University (formerly Institute, hereinafter ASPU). At ASPU prior to 1990, teaching and research in the area of psychology had been mainly conducted within the Faculty of Preschool Pedagogy and Psychology. A new Faculty of Psychology and

Pedagogy (currently a Faculty of Psychology of Education and Sociology) provides a specialized 5-year degree in psychology, founded in 1996. Faculty members (Sergey Arzumanyan, Srbuhi Gevorgyan, and others) collaborated with the Ministry of Defense and law enforcement agencies to start new programs training psychologists for these areas. Chairs of Developmental and Applied Psychology, Theory and History of Psychology, Age and Pedagogical Psychology have major input in the development of specific fields of psychology, such as legal, social, and military psychology.

Since 1992, a newly founded Department of Psychology at Yerevan State University (YSU) has been providing psychology education—first as a 5-year degree, which was then transformed to undergraduate and graduate programs. Within three Chairs of Psychology—General, Social, and Personality Psychology—students pursue bachelor's and master's degrees. There are Master's Programs in the following areas: Organizational and Management Psychology, Psychology of Emergency and Crisis situations, Clinical Psychology and Psychotherapy, Social and Political Psychology, Psychology of Personality, and Psychological Counseling. Moreover, a Center for Applied Psychology adjacent to the YSU Department of Psychology was founded in 2008 to provide training and seminars for students, employees, and the general public.

In response to public interest in the specialization of psychology, Faculties/Departments providing psychology education have been formed in other universities as well. From 2002, Russian-Armenian (Slavonic) State University established a Faculty and Department of Psychology providing education in psychology. Since 2009 it has awarded master's degrees in Personality Psychology, Psychology of Management, and Political Psychology.

Yerevan State Linguistic University after V. Bryusov, and State Pedagogical Universities in Gyumry and Vanadzor have programs awarding the degree of Psychologist-Pedagogue. Furthermore, master's degree programs are available at the Public Administration Academy of RA and at the International Scientific–Educational Center at the National Academy of Science of RA. There is also a Department of Medical Psychology at Yerevan State Medical University.

Apart from the state universities, specialization in psychology can be pursued at private universities as well. Most of them have established Faculties/Departments of Psychology and Pedagogy which are currently undergoing accreditation processes. Among key private universities is "Urartu" University of Practical Psychology and Sociology, which was established in 1991, and recently accredited by the Ministry of Education and Science. Indeed, psychology education in Armenia has made a great step forward and the "*emphasis on the application of psychology on psychology practica in the psychology curriculum"* is evident.

All contemporary developments have widened opportunities for scholars to receive doctoral degrees in psychology. As noted earlier (Jeshmaridian & Takooshian, 1994), research degrees in all scientific disciplines in Armenia still have a two level structure: Candidate of Sciences (equivalent to a PhD degree) and Doctor of Psychology. In Armenia before 2000, there were only two doctors of psychology, Karlen Voskanyan and Sergey Arzumanyan. Now there are 10 Doctors of Psychology in different fields (Vladimir Karapetyan, Gayane Shahverdyan, Mels Mkrtumyan, Naira Hakobyan, Hrant Avanesyan, Srbuhi Gevorgyan, Svetlana Harutyunyan, Asya Babayan, Samvel Khudoyan, and Vazgen Margaryan). Moreover, there is a scientific committee eligible to award a "Candidate of Psychological Sciences" degree in several fields, such as developmental and educational psychology, theory and history of psychology, legal psychology, political psychology, and social psychology, without involving external members. This committee is also eligible to award Doctor of Psychology degrees after involving eligible academics from abroad. However, this system is centralized, and remains unreformed since establishment in the Communist period.

Development of Psychology Research

In the Communist era, education and research focused mainly on issues of education (pedagogical psychology) and development (Jeshmaridian & Takooshian, 1994). However, individual efforts have been made to advance psychology research also in other directions.

Since 1970 Professor Sergey Arzumanyan has been actively engaged in research on juvenile offenders. He developed a psychological concept of "criminogenic" attitudes, the process of becoming an offender, and an early psycho-social prevention approach to criminal behavior with a new area of Legal Psychology in Armenia—Psychology of Social Pathologies.

Organizational or management psychology—specifically psychological causes of conflicts in civil service organizations—in Armenia and other related topics of social psychology were the focus of research of Professor Srbuhi Gevorgyan, who conducted large-scale research on interpersonal conflicts in civil servants in Armenia. The latter work led to a new system introduced in Armenia since 2000.

As noted in a few reports (Jeshmaridian & Takooshian, 1994; Nalchajyan & Takooshian, 1997; Pambookian, 1992), the most popular fields before 1988 were developmental (age) and educational (pedagogical) psychology. The popularity of these areas did not diminish with the development of applied psychology. Issues of child development, teaching, and learning were discussed in scientific articles. Recently, Dr. Samvel Khudoyan introduced his theory of "functional periodization of lifelong development and crisis of life span development."

Military psychology is the focus of research by Vazgen Margaryan, Zarzand Asatryan, and others. The Ministry of Defense is very interested to facilitate the development of military psychology.

Still, experimental and laboratory research remains underdeveloped in Armenia. The Experimental Laboratory at ASPU, the Scientific-Research Laboratory on Psychology of Personality and Professional Activities, and the Laboratory of Experimental Psychology at YSU, all lack funding and modern equipment (e.g. EEG, AM Tracks, and other modern tech-

niques) that inhibit work in neuropsychology, in brain/cognition, and on other contemporary topics in psychology.

Cooperation with Diaspora Armenians

For most of the 20th Century—following the massive 1915 genocide of Armenians in Turkey—about half of the world's five million Armenians have lived in a global diaspora, outside the Republic of Armenia—nearly one million of these in North America (Takooshian, 1995). When the earthquake struck in 1988, there was a massive outpouring of assistance by governments and hundreds of private organizations.

One of these was the new Armenian Behavioral Science Association (ABSA). By good coincidence, ABSA was launched 13 months earlier—on August 21, 1987 in New York City—by six scientists representing six fields: psychology, psychiatry, political science, social statistics, sociology/anthropology, and social science. Though Armenian-American behavioral scientists are few in number, many of these are leaders in their specialty, such as: Hagop Akiskal (emotions), Harout Armenian (public health), Seth Arsenian (humanistic psychology), Edmund S. Gergerian (EMDR/psychotherapy), Armen Goenjian (psychiatry), Harold Goolishian (family therapy), Ani Kalayjian (disaster/trauma), and Alen J. Salerian (forensic psychiatry). As one of the six co-founders of ABSA in 1987, psychologist Harold Takooshian spent 4 months on a Fulbright to the USSR in 1987–1988, where he conducted an unprecedented census of psychologists in the Republic of Armenia.

When the earthquake struck in 1988, ABSA provided a timely framework for well-intentioned U.S. scientist-practitioners to reach out to their colleagues in Armenia on two levels, and in several ways.

First, ABSA arranged several programs for U.S. experts to work with Armenia. (a) **U.S. census.** ABSA completed a census of 304 U.S. behavioral scientists, which it published as the first *Directory of Armenian-American Behavioral Scientists* (Takooshian, 1989). This number grew from 304 in 1989, to 433 in the second edition in 1991, then 506 in the third edition in 1995. (b) **Programs.** ABSA members also published a national *ABSA Bulletin*, presented awards to outstanding scientists, and sponsored professional workshops and public symposia at local, regional, and national meetings. (c) **Outreach.** Several U.S. teams visited Armenia as short-term or long-term volunteers, either in direct service/consultation, or as trainers of Armenian colleagues. The heads of these teams included key U.S. experts like Armen Goenjian, Haikaz Grigorian, Shakeh Kaftarian, Ani Kalayjian, Meliné Karakashian, Shaké Toukmanian, and A. Diana Zacarian.

Second, ABSA encouraged specialists in Armenia to cooperate with U.S. colleagues. (d) **Census in Armenia.** ABSA completed a census of 130 psychologists in Armenia, which was published as a *Directory of Psychologists in the Republic of Armenia* (Vardanian, 1990). This number grew from 130 psychologists in 27 programs in 1990, to 167 psychologists in 38 programs in the second edition in 1992. ABSA also published a *Directory of Sociologists in the Republic of Armenia* (Pogosian, Kalayjian, & Takooshian, 1991), which grew from 53 sociologists in 15 programs in 1991, to 71 sociologists in 19 programs in the second edition in 1992. (e) **Training.** In 1990, ABSA received training grants from two sponsors—the Armenian Relief Society (ARS) and the Armenian Missionary Association of America (AMAA). In cooperation with the American Psychological Association (APA) and many volunteer experts, a team of eight specialists from Armenia addressed the 1990 APA meetings in Boston, while spending 1 month in the USA training with such mentors as therapist Albert Ellis, and hypnotists Herbert Robbins and Gabrielle Stutman (DeAngelis, 1990).

In the quarter century since 1988, psychologists in the USA and Armenia have grown visibly closer on many levels. For example, the American University of Armenia (AUA), launched on September 21, 1991, has become a premier graduate institution affiliated with the University of California system, which now links experts in the USA and Armenia. For many years AUA was headed by Haroutiune K. Armenian, MD, DrPH—a brilliant behavioral scientist-practitioner with Johns Hopkins University.

Publications and Other Scholarly Activities in the Field of Psychology

In early 1990s there were no psychology textbooks in the Armenian language. The textbooks for students were Armenian translations of two Russian books. The decentralization of science, the war, continued blockade, and Western influences on the development of science increased the need to have publications in Armenian. In the early 1990s Samvel Khudoyan had published the "Hogi" yearbook, where different scientific problems were introduced from other than a Soviet perspective. This was soon followed by other publications, such as *Handbook on General Psychology* (Albert Nalchajyan) in 1991 and then in 1997, *Handbook of Psychology* (Sergey Arzumanyan, 2002), *Practicum of Applied Psychology* (Sergey Arzumanyan, Vahan Sargsyan, & Sokrat Mkrtchyan, 2002), *Forensic Psychology Handbook* (Sergey Arzumanyan & Elda Grin, 2004), and *The Critical Ages of Individual Development* (Samvel Khudoyan, 2004).

Around 2000, new scientific peer-review journals on psychology started, such as *Psychology and Life* (founder Sokrat Mkrtchyan, "Zangak" Publishing house) and *Issues of Pedagogy and Psychology* (founder and editor Prof. N. Hakobyan). There are also other journals where psychologists can publish their papers. Several scholars (Armen Nersisyan, Samvel Khudoyan, and others) initiated production of psychotherapy CDs.

Besides publications, psychology scholars realized the need to exchange research results and to engage in scientific collaboration. For that purpose, a number of national and international conferences are organized each year in Armenia. Recent topics have included Contemporary Issues of Psychology Teaching in 2007 at YSU; The Problems of Personal Development in 2009; Contemporary Problems of Theoretical

and Applied Psychology in 2011 at YSU; and Crossroads of Psychology and Law at AUA in 2011. These events have definitely facilitated interdisciplinary dialogues between specialists in different areas of the social sciences. They bring together many prominent and well known scholars from all over the world, which enable Armenian scholars to have a clear understanding of global developments in psychology.

Conclusion

The past 25 years have seen the growth of applied psychology in Armenia. Indeed, the devastating earthquake emphasized the need for psychological services, and triggered a change in public attitudes toward psychology, abetting the rapid development of applied fields. Moreover, the collapse of the Soviet Union led to the elimination of censorship of academe, and to an open exchange with Western scholars—so local scholars became familiar with Western psychology, and implemented these approaches in their teaching and research.

The services of psychologists have become widely available to the public. Departments of applied psychology have opened in many universities, offering diverse degrees in psychology. Research in applied psychology has become more popular among scholars, resulting in journal publications (though mostly local). Still, many areas of applied psychology remain underdeveloped—especially areas involving neuropsychology and brain science, due to lack of funding and modern laboratories.

Despite the fall of the "Iron Curtain," and the lack of formal obstacles for collaborating with established research institutions and scholars from the West, not many cross-cultural studies have been conducted in Armenia, and fewer studies have been published in highly-ranked international peer-review journals. Furthermore, despite being widely available, psychological practices lack a quality assurance mechanism. No institution is charged with certification and accreditation of practicing psychologists, who register their entities as companies with limited liability, and conduct their professional activity with a license designed for entrepreneurs. Despite these problems, we remain hopeful that psychology in Armenia has a bright future.

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Links to Some Current Psychology Resources in the Republic of Armenia

Therapists: http://doctors.am/en/doctors/category/180?page=1
Disabilities: http://sgmf.am/en/
Psychology Centers: http://www.doctors.am/en/doctors/yerevan/214
Armenian State Pedagogical University: http://www.armspu.am/faculties/ln/en/f/25
Yerevan State University: http://www.ysu.am/faculties/en/Philosophy-and-Psychology
American University of Armenia: http://aua.am/

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ICAP: Call for Presentations

On July 8–13, 2014, Paris is the site of the next historic International Congress of Applied Psychology. Many members of the APA international division will participate, and students are most welcome. The deadline to submit individual posters/papers is December 1, at www.icap2014.com/call-for-individual-papers-and-posters/68

XXXV Interamerican Congress of Psychology in Lima, Peru

Sixty-Two Years Building Psychological Bridges Across the Americas
July 12-16, 2015

Prof. Dr. Sheyla Blumen
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Every 2 years, the Interamerican Society of Psychology (known as SIP for its acronym in Spanish: *Sociedad Interamericana de Psicología*), which gathers the main academic and professional psychologists of the Americas and Spain, organizes an Interamerican Congress of Psychology (ICP), involving approximately 3,000 participants, in one of the main cities of North, Central, or South America. In July 2015, after 12 years, Lima, Peru will become again the venue of an Interamerican Congress of Psychology (ICP). Peru has the distinction of having been the country that gathered the highest number of attendees in SIP's ICP history, reaching 4,000 participants in 1979. Furthermore, the 2003 ICP in Lima reached a high quality level, both in terms of the conference administration, as well as in the academic level achieved. Therefore, the current Organizing Committee is working tirelessly, in order to provide an excellent congress that surpasses expectations and welcomes all colleagues of the Americas.

This academic, professional, and cultural event will mark the 62nd Anniversary of the ICP, which began in 1953. The conference will feature parallel meetings, and host international symposia, round tables, oral presentations, workshops, and poster presentations, as well as offer special conversation spaces focused on the big issues of International Psychology. Keynote speakers will be invited following the International Scientific Committee's advice, and will consider the different topics and research lines of contemporary psychology.

Taking into consideration the cultural and touristic richness of Peru, spaces to facilitate guided visits to museums, galleries, and cultural centers will be offered, and there will be opportunities for participation in social activities alongside the Congress. Moreover, tours to visit the main touristic centers of Peru, before, and after the scientific event, will be offered. We welcome all researchers and professionals interested in submitting original scientific proposals that contribute towards the advancement of psychology to be considered by the Scientific Committee.

The main goals of SIP's XXXV Interamerican Congress of Psychology are as follows: (a) To promote psychological research and prevention and intervention programs in behavioral science developed in Peru and in the Americas; (b) To establish links among the organizations and participants to facilitate collaboration in projects of common interest; (c) To promote the development of scientific and academic psychology in Peru and the Americas; (d) To facilitate the exchange of information and the establishment of networking among people interested in psychology; and (e) To support the community from the psychology perspective.

Peru is an ethnically and linguistically diverse and modern democratic country that promotes freedom of expression and freedom of gathering, as well as warmly welcomes tourists from every part of the world. Peru combines the richness of ancient cultures with the needs of a modern society that projects towards the future, and it is included in the international tourist circuit. Access to information and communication technology (ICT) is satisfactory, and there is relatively easy access to the Internet, even from the public cabins, and some open parks in the city of Lima. Moreover, Lima is a lively modern and beautiful city which copes with challenges including its Pre-Inca, Inca, and Viceroy Legacies, and which reflects the Spanish influence, as well as the Republican development which extends until the present day. Furthermore, Lima offers a variety of lodging facilities that fit every budget as well as world class museums. Moreover, Lima is a world renowned culinary destination.

Peru is a centralized country, and 25 out of 48 psychology programs nationally accredited (CONAFU, 2013) function in the city of Lima. Moreover, there are three psychology programs that are internationally accredited, including the Pontificia Universidad Católica del Perú (PUCP), which was the first to be accredited, in 2010, for 6 years. Among the scientific peer-reviewed indexed publications, only the Revista de Psicología (PUCP) which is celebrating its 30th Anniversary of continuing publishing since 1983, is indexed in PsycINFO (since 1993).

Peru has successfully organized three Interamerican Congresses, under the presidencies of Dr. Alberto Seguín (†) (1967), Dr. Reynaldo Alarcón (1979), and Dr. Cecilia Thorne (†) (2003), following scientific rigor, and collaborative work among universities, and societies of psychology, both in and out of Peru. Three thousand participants are expected from the diverse Societies of Psychology, from the representatives of the main scientific societies of the Americas, and from professionals and students of the behavioral sciences, both from the Americas and from Spain.

The Organizing Committee started its functions in August 2013 with a call to collaborate sent to every Peruvian Program of Psychology, inviting the deans and heads of departments to join us. Also, the representatives and presidents of the main scientific societies, psychology unions, and the APA branch in Peru, were invited, along with the representatives of the public and private institutions linked with the psychological activities in Peru. Under the current presidency of Dr. Judith Gibbons, President of SIP, the following positions were elected for the next XXXV Interamerican Congress of Psychology: Dr. Matilde Raez as Honorary President, Dr. Sheyla Blumen as the President of the Organizing Committee, Dr. Reynaldo Alarcón as the President of the Interna-

tional Scientific Committee, and Dr. Patricia Martinez as the President of the National Scientific Committee.

The Pontificia Universidad Católica del Perú (PUCP), ranked No. 23 in Latin America (QS World University Rankings, 2013) and No. 1 in Peru, will be the venue of SIP's XXXV Interamerican Congress of Psychology. The PUCP is the academic leader in the formation of psychologists in Peru, and was the first to become internationally accredited. It has modern installations, free Wi-Fi all throughout the campus, as well as cafeterias, restaurants, wide green areas, and spaces for collaborative and virtual work. Moreover, the PUCP provides high quality tertiary education, promotes research and scientific publications, as well as social responsibility, towards the building of new knowledge, establishing a leadership with legitimacy among its peers and society at large. Furthermore, the PUCP promotes academic and scientific development in the country, and is a legitimate authorized source of opinion when discussing the main problems of Peru. It has consolidated its relevant social actor role towards development and democracy in Peru. Also, the PUCP has established alliances and agreements among the main public and private universities nationwide that provide an important platform to facilitate services in the organization and execution of an international conference of high quality, as is the tradition in the Interamerican Congresses of Psychology. Moreover, the PUCP has officially given its support as the venue of SIP's XXXV Interamerican Congress of Psychology.

In conclusion, we hope that Lima will constitute an excellent intercontinental scientific space for discussion of the most significant topics of contemporary psychology, for establishing and consolidating social and professional networks, and for facilitating theoretical and practical interchange, relevant to psychologists and health professionals, as well as to policy makers on the impact of psychology in the Americas as well as in Peru. You are cordially invited to contribute to SIP's XXXV ICP scientific program by submitting your work for review and by attending the Congress .

Meanwhile in the Fertile Crescent: The Role of INGOs to Promote Peace, Charity, and Healing in the Middle East

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Abstract

Since the creation of the United Nations, countries around the world have championed the cause of human rights. Human rights are so pertinent to the survival of the human race that they are enforced by and through international law, and occasionally through military intervention. The burden of liberation and human rights activism has been shifted in part to the realm of International Non-Governmental Organizations (INGOs), which provide for displaced and disenfranchised peoples, among other activities. The Association for Trauma Outreach & Prevention (ATOP), Meaningfulworld, is an example of how effective an INGO can be in developing a standard of reconciliation, forgiveness, and activism that is required by all parties in need of healing. In addition to Palestine, ATOP Meaningfulworld also contributes to aid campaigns in Haiti, Israel, Syria, Lebanon, Kenya, Rwanda, Burundi, DR Congo, Sierra Leone, and Jordan among other countries.

Since the creation of the United Nations, countries around the world have championed the cause of human rights. Human rights are pertinent to the survival of the human race, and are enforced by and through international law. Yet we are ever so cognizant of the deteriorating state of human rights in Palestine, Syria, and the greater Middle East, as well as in Africa. It has been 65 years since al-Nakba (the 1948 Palestinian exodus), and 77 years since Syrian Independence from France, and yet today the story of these two countries is about the worsening situations of their people(s). And yet as we applaud and praise the work of the United Nations and its efforts to ensure human rights in every corner of the globe, we are ever more drawn to the harrowing plight of dead infants, mothers, and children almost every single night while watching the news. It is not so much about the validity of an international organization to police, protect, and provide for the human race, rather it concerns the current situation and International Non-Governmental Organizations (INGOs) like Meaningfulworld, and the questions about how quickly one can help. What is the most efficient way to serve the needs of those underserved? The purpose of this paper is to examine and discuss the human rights situations in both Palestine and

Syria and the rights of those people(s) to peace.

Of all the peoples in the entire world perhaps none other than the Palestinians have come to define the human rights struggle. Displaced, disenfranchised, and disregarded, the Palestinians continue to persevere in the face of great oppression. It has been 5 years after the diamond anniversary of al-Nakba but all Palestine receives is coal, on a good day. Even with Articles 1 and 55 of the Charter of the United Nations affirming the right of self-determination for the Palestinian people, they are merely an observer. It should be carefully noted that despite the United Nations' assertion of Palestine as an observer state, the majority of countries voted for the right of self-determination for the Palestinian people(s). Again it is the Charter of the United Nations that affirms the trajectory of the Palestinian territories to not be occupied but to be granted independence from Israel, thus affirming the two state solutions. At the 50th meeting of the Human Rights Council in March of 2013, countries overwhelmingly voted to support and champion the cause of the Palestinian people as seen by the following quote: "All Member States and relevant bodies of the United Nations system to support and assist the Palestinian people in the early realization of their right to self-determination" (United Nations, Human Rights Council, 2013b). While this statement brings joy to the hearts of those who support human rights, it is the lack of universal support that remains troubling. Although the United States at the current moment does not support the proposition to amend Palestine as a free state, ATOP Meaningfulworld works on emotional healing, peace building, and humanitarian work.

It is paramount to the cause of the Palestinians that one recognizes the hegemonic practices of the Israeli government. The Charter of the United Nations has explicitly stated that it does not recognize the acquisition of Palestinian land through force via settlements. The United Nations has "an obligation to promote and protect human rights and fundamental freedoms" (United Nations, Human Rights Council, 2013a). This obligation is not limited to the illegality of the Israeli settlements, and yet still the Palestinian people continue to be disenfranchised. The position of the United Nations is strong, as evident here: "Affirming that the Israeli settlement activities in the Occupied Palestinian Territory, including in East Jerusalem, are illegal under international law and constitute very serious violations of international humanitarian law and of the human rights of the Palestinian people therein, and undermine international efforts" (United Nations, Human Rights Council, 2013b). Yet still over a million of the Palestinian people are in a Gaza prison, and others have to go through long check points daily to get to work and school, and they are without their own country.

One source of complication is the ambivalence and mistrust on both sides. Due to such factors as the expansion of Israeli settlements on the West Bank, the construction of separate roads and security fences, the confiscation of land, the proliferation of checkpoints, and the gradual development of Israeli building projects, both Israel and Palestine often have given up hope that peace is a possibility (Kalayjian, 2012).

Among those attempting peace and negotiation, it becomes clear that both sides see themselves as victims, which makes it difficult to move forward, or to mindfully negotiate (Kalayjian, 2012). The Israeli community lives in fear due to being surrounded by Islamic Arab countries, while the Palestinians feel alone in their Arab world because they view themselves as victims of Israeli oppression, Arab oppositions, and an indifferent world. What brings the conflict to a deeper level is that other countries benefit from this conflict. Israel continues to benefit from the expansion, threatening Turkey and other Arab countries, and as long as any country is benefiting, there is less motivation to change the status quo (Kalayjian, 2012). Michael Neumann (2002) summed up this vicious cycle: "The worse things get for the Palestinians, the more violently they must defend themselves, and the more violently Israel can respond."

Currently the Middle East is in the headlines for all the wrong reasons. Syria is disintegrating and with that has come an immense amount of civilian causalities. Just this last week (August 25th), the United States government confirmed that the Syrian government has been using chemical weapons against its own people. The Syrian government disputes these claims, and reaffirms that it is in fact the opposition extremist groups that have done the crime. The extremist groups have flooded Syria, and are using this chaotic war to ransack and take advantage of the minorities, such as the Armenians and other Christians. The question at hand for members of the INGO community has less to do with the actualities of the plight of the Syrian people, and more to do with the eventual emotional rehabilitation of those innocent people.

At some point there will have to be a discussion regarding the future of peoples in countries affected by recent violence. The United Nations is actively participating in trying to set in place measures to protect people from oppression. The United Nations Report of the Open-ended Inter-Governmental Working Group on the Draft United Nations Declaration on the Right to Peace (United Nations, Human Rights Council, 2013c), is an example of how INGOs can influence "peace policy." Of course, there are several obstacles that INGOs will face in the attempt to implement said policy. The report concluded with the parties agreeing that there needs to be more of a discussion concerning the definition of "right to peace" as it is not legally clear what that means.

Since both Israelis and Palestinians feel like they are victimized, any mindful negotiation becomes challenging. Each side believes that they are giving more than receiving. When the circularity and balance of giving and receiving is disrupted, one can become vindictive and move from giving, to endless retaliation, and to the viewpoint of "if you hurt me, I will hurt you 100 times more." This perception serves as one of the most serious obstacles to reconciliation and peace in the Middle East, as well as in other chronic, malignant conflicts. It fuels the thought of being a victim, not a victimizer, and shields a person from experiencing any remorse for one's own unfairness. This thought will often not remain confined only to individuals, but may extend out to groups

and communities, adding stronger, harder to change attitudes that prevent peace building.

In addition to Palestine and Israel, ATOP Meaningfulworld has also conducted humanitarian outreach, healing, and peace building in Jordan, Lebanon, Israel, Syria, Africa, and Haiti. In Haiti, it has become increasingly necessary that INGOs that operate without contributions from USAID or other government sponsored organizations become involved. The 2010 earthquake, which devastated the already impoverished capital, Port Au Prince, has brought Haiti again to the forefront of charity and, unfortunately, humanitarian aid corruption. Since ATOP Meaningfulworld professionals are volunteers and receive no pay, it becomes easier to build instant trust in the communities that they work in.

The work of ATOP Meaningfulworld is dedicated to fostering a meaningful, peaceful, and just world, in which every individual enjoys physical, mental, social, economic, and spiritual health (www.meaningfulworld.com). A sense of meaning, peace, and justice, although unique to each individual, is achieved through a transformative journey that integrates knowledge and experience with a sense of responsibility and reflection. This transformative process is also disseminated through lectures, workshops, and healing circles, to establish healthy relationships that nurture open, honest, and transparent communication, offer insights into forgiveness, love and spiritual connections, and promote active collaborations. This process of transformative healing and forgiveness is only applicable if all countries recognize and support the cause of the Palestinians as well as other vulnerable citizens from around the world. It is to the betterment of the progress of humanity that organizations such as ATOP Meaningfulworld not only spread the values of human rights but also actively practice them. It has become increasingly clear in this day and age that INGOs remove the capital gain aspects of philanthropy, instead returning to a selfless desire to give. Therefore, contributors to ATOP Meaningfulworld are guaranteed that their sponsorships are not going to pay a salary, but directly are used to deliver a humanitarian aid project.

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Who Admires Raymond Corsini? Seeking Contributions in Recognition of the 100th Birthday of Ray Corsini

The late, great psychologist Raymond J. Corsini (1914–2008) of Hawaii was a brilliant author, teacher, and mentor. Many of Ray's friends gathered at APA in Honolulu, where Division One Awards Chair Josephine Tan announced the launch of a new Corsini student research award to mark the centenary of Ray's birth in 2014. Ray's career is described in the *American Psychologist* (January 2010, p. 54).

Help *The General Psychologists* to Honor Ray Corsini

For a tribute to Ray in 2014, *The General Psychologist* seeks brief remembrances from Ray's students, colleagues, and friends. Did Ray's life touch yours somehow? If so, please send us this information by November 15, 2013: your name, current affiliation, photo, and 1–3 paragraphs on how Ray's life touched yours. If you have a good photo or two of Ray, please add these. These edited remembrances will appear in a tribute to Ray in *TGP* in 2014. Direct any questions to Corsini Committee Chair Bernardo Carducci: bcarducc@ius.edu

2014 APA Symposium Honoring Ray Corsini Seeking Participants

In addition to the tribute to Ray Corsini to appear in *TGP* in 2014, efforts are being made to organize a symposium in Ray's honor at the 2014 APA Convention in Washington, DC. We are seeking individuals who will be attending this meeting and have a desire to be part of this symposium to discuss Ray's impact on their work and his contribution to psychology. If you are interested in participating in this symposium, direct questions to Corsini Symposium Chair Bernardo Carducci: bcarducc@ius.edu before November 1, 2013.

In Hawaii, Dr. Vernon Thompson's family joins the salute to their friend Ray.

Division 52 Participates in International Conference…Italian Style

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The International Conference 'Life Design and Career Counseling: Building Hope and Resilience' was held at the University of Padua from June 20 to 22. The conference, organized by ***Larios Laboratory***, saw the participation of more than 600 delegates, of which more than 60% were from outside of Italy.

Larios Laboratory — Università degli Studi di Padova

Representatives of 34 countries from all continents had the opportunity to discuss theoretical and applied aspects focusing on how to deal with the difficult times we are going through. The international and multidisciplinary nature of this event was evident in the plenary sessions that were attended by psychologists, philosophers, and economists, which included debating such issues such as hope, self-determination, work, and career adaptability.

As the first of three speakers in the opening plenary session, **Shane J. Lopez**, of the Clifton Strengths Institute in the USA, presented a lecture titled "Hope for Tomorrow Pays Off Today." The second speaker, **Jean Guichard**, of Cnam–INETOP in France, discussed "Forms of Reflexivity and Transformations of Systems of Subjective Identity Forms During Life Designing Dialogues." In the third presentation, **Salvatore Soresi**, of the University of Padova in Italy, invited participants to reflect on the importance of "Helping People Build Their Future."

The second day of the conference was devoted to presenting different perspectives about the future. **Annelies van Vianen**, of the University of Amsterdam in The Netherlands, discussed "Creating and Conserving Resources for Career Self-Regulation." **Stefano Zamagni**, of the University of Bologna in Italy, discussed "What Makes the Young Unemployable and Why Businesses Continue to Believe in Taylorism?" **Michael L. Wehmeyer**, of Kansas University in the USA, presented **"**Beyond Pathology: Positive Psychology and Disability." The last presentation by **Luciano L'Abate**, of Georgia State University in the USA, underscored "The Future is Now: Online Interventions are Here to Stay and to Grow."

Prof. Luciano L'Abate (extreme left) and Michael L. Wehmeyer (extreme right).

Also on the second day, **Bernardo J. Carducci**, President of the *Italian American Psychology Assembly* and Fellow of Division 52, **Bradley T. Erford**, President of the *American Counseling Association*, and **Mercedes A. McCormick**, President of *Division 52: International Psychology Division of the American Psychological Association*, **Christiane Schiersmann**, Coordinator of the *Network for Innovation in Career Guidance & Counselling in Europe*, and **Susan Whiston**, Chair of the *Society of Vocational Psychology*, brought greetings to all the attendees. In remembering his Italian origin and his family history during his remarks, Bernardo Carducci discussed the cycle of life design and career choice as experienced through the process of loss of ethnic identification through cultural assimilation, the role of education and vocational aspirations, and the desire to reconnect with one's ethnic heritage through his involvement with the Italian American Psychology Assembly and

Prof. Bernardo J. Carducci presents the Italian American Psychology Assembly, scientific partner of the Conference.

APA's Division 52. Although based on his own cycle of life design and career choice, Carducci's presentation resonated with many members of the audience who, along with their students and clients, are now facing their own ethnic identity vs. assimilation career dilemma.

The plenary session of the last day was dedicated to career adaptability and life designing. Maria E. Duarte, of the University of Lisbon in Portugal coordinated an international symposium in which **Mary McMahon**, of the University of Queensland in Australia, **Guðbjörg Vilhjálmsdóttir**, of the University of Iceland, **Marcelo A. Ribeiro**, of the University of San Paulo in Brasil, **Frederick T. L. Leong & Catherine Ott-Holland**, of Michigan State University in the USA and **Laura Nota**, of the University of Padova, discussed the issue of "Adaptability and Personal Promotion." Finally, in his presentation, **Mark L. Savickas**, of the Northeast Ohio Medical University in the USA, encouraged the participants to reflect on "Life Designing: Balancing Work and Love."

Both in plenary sessions and in the parallel and poster sessions, which saw the presentation of more than 300 contributions, there was a great deal of interest in the topics addressed and a lively desire to participate by all delegates. Throughout the presentations and the debates, it was agreed that in times of high uncertainty, such as those we are experiencing, even the theoretical models and the professional practices of those involved in choice and life designing must radically change and deal with the promotion of well-being and quality of life of those more exposed to the deleterious effects that the crisis is causing in different parts of the world.

At the end of the conference **Jean-Pierre Dauwalder**, of the Lausanne University and President of the European Society for Vocational Designing and Career Counseling, presented awards to **Dr. Aysenur Buyukgoze-Kavas**, of Ondokuz Mayıs University in Turkey, and **Maria Chiara Pizzorno**, of the University of Valle d'Aosta. The awards were presented to "... these two young researchers who have distinguished themselves with their research projects so early in their careers."

The conference concluded with a special award on behalf of the ESVDC being presented by Prof. Jean-Pierre Dauwalder to **Salvatore Soresi** "for his scientific and human contribution to our field." In his remarks, Prof. Dauwalder listed the "Top-Ten Reasons" why Salvatore is receiving the award. Most importantly, he recalled that Salvatore Soresi, during the 1970s, actively took part in the struggles of scholars and researchers to support the inclusion of children with disabilities in regular schools and inclusion of adults with disabilities in competitive work settings, by carrying out demonstrations and hunger strikes, actively promoting the deinstitutionalization of persons with disability in Italy. He also said that Salvatore Soresi, at the beginning of the 1990s, created the *LaRIOS* (*Laboratory for Research and Intervention in Vocational Designing and Career Counseling*) and the *Center for Research and Services on Disability, Rehabilitation and Inclusion* at the University of Padova, with the aim of stimulating and developing research on these difficult but important topics. Salvatore Soresi participated in the birth of *Life Design International Research Group* and of the *International Collaborative Group on Adaptability Research*. For his efforts, he received the Award for Distinguished Contributions from the Society of Counseling Psychology (APA Division 17). He recently founded the *International Hope Research Team* (IHRT) that involves Italian and foreign scholars interested in studying hope.

With great satisfaction to the organizers of the conference, they received more than 100 e-mails of thanks sent by conference participants from different parts of the world expressing their gratitude to the conference organizers for their tremendeous efforts and wonderful contribution to the success of the conference!

For those who are interested in contacting members of the *LaRIOS* team, visit the *LaRIOS* website at http://larios.psy.unipd.it/ze-index.php to find out more about their onging activities and learn about what the *International Hope Research Team* is doing to trigger international cross-culturalresearch with several countries.

the motto of the conference ...

"hope has two beautiful offspring: disdain and courage. The former confronted by how things are going, the latter to change them"; *"die Hoffnung hat zwei schöne Töchter: Wut und Mut - Wut darüber, wie die Verhältnisse sind, und Mut, sie zu bekämpfen"; "la esperanza tiene dos hijas hermosas: la displicencia y la valentía. La displicencia ante el estado de las cosas y la valentía para cambiarlas"*; "l'espoir a deux beaux enfants: le dédain et le courage. Le premier face à l'état des choses, le second pour les changer"; *"la speranza ha due bellissimi figli: la rabbia e il coraggio. La prima per come vanno le cose, il secondo per cambiarle"; "nadzieję ma dwie piękne córy - pogardę i odwagę; pogarda spogląda na stan rzeczy, a "*; "الأمل له ابنتان جميلتان الازدراء والشجاعة. الأول في مواجهة الأمر الواقع والثاني من أجل تغييره"; *"espero havas du belegajn filojn: indigno kaj kuraĝo. La unua konsideras kiel iras la ajoj, la dua kiel ŝanĝi ilin"*.
Sant'Agostino (354-430)

Prof. Jean-Pierre Dauwalder presents an award to Prof. Salvatore Soresi.

A Photographic Post Script
Some Scenes From the Last Day of the Conference

On the last day of the conference, Bernie Carducci congratulates Laura Norta, of the University of Padov and one of the primary organizers of the conference, on a job well done and to thank her for allowing Division 52 to be part of this highly successful international conference.

Bernie Carducci spends time during a break on the last day of the conference to chat about Division 52 with (left photo) René Angeramo, an Italian psychologist –psychotherapist from Rome, and (right photo) Gloria Marsay, an educational psychologist in Johannesburg with special interests in career development and neuropsychology.

A Post-Conference Celebration in the Italian Countryside

To celebrate the success of the conference, as well as to take some time to relax, Division 52 members Mercedes A. McCormick and Bernie Carducci were invited by the organizers of the conference to a special Italian family-style Sunday dinner in the countryside at the home of Savatore Soresi. Mercedes and Bernie spent the next 6 hours feasting on a multiple-course dinner featuring a variety of nuts, home-grown vegetables, a traditional meat course, seafood course, a few pasta dishes, a salad, a fresh fruit course, multiple home-made desserts, and, of course, many different wines throughout the afternoon.

Mercedes begins to enjoy a day in the Italian countryside with fellow presenters from the conference.

Bernie takes a short break in between one of the many courses being served thorughout the afternoon.

As the food, wine, and conversation continue to flow, Mercedes has the look of pure relaxation that only an afternoon in the Italian countryside can provide.

Bernie unwinds late in the afternoon with one of his favorite cigars and some new friends.

Neurophenomenology and Its Applications to Psychology

Susan Gordon, *Editor*
susan.gordon@snet.net

Neurophenomenology combines phenomenology and neuroscience to study experience. The term *neurophenomenology*, first used by Laughlin, McManus, and d'Aquili (1990), was distinguished as a new research direction for the neuroscience of consciousness by Chilean biologist Francisco Varela (1996) and colleagues. The field of neurophenomenology has expanded internationally around the central question of how consciousness and subjective experience relate to the brain and body or the *embodied mind* (Gallagher, 2005; Thompson, 2007; Varela, Thompson, & Rosch, 1991; Zahavi, 2008). While the "easy problems" for neuroscience pertain to questions about the difference between wakefulness and sleep and the mechanisms that allow us to focus our attention, the "hard problem" is the relationship between objective knowledge and subjective experience.

Neurophenomenological methods integrate interdisciplinary knowledge within the fields of psychological theory, research, and practice by combining Rogers' (1964) "three ways of knowing," subjective, objective, and interpersonal: first-person accounts of phenomenological lived experience and third-person neurophysiological data as co-emergent enactive processes (Lutz & Thompson, 2003; Petitot, Varela, Pachoud, & Roy, 1999; Thompson, 2001). Varela's work combined experimental studies of multiple electronic recordings, mathematical analysis of large-scale neuronal integration in cognitive processes, and phenomenological studies of human consciousness. Foundational to neurophenomenology; however, is the second-person perspective: the empathic, interpersonal, intersubjective dimensions of conscious experience in which the person *enacts* experience in interdependency with surroundings from which meaning become inseparable.

Varela believed that scientific research needs to be complemented by detailed phenomenological investigations of human experience as it is lived and verbally articulated in the first person. Also, that the study of consciousness had the potential for inciting a major revolution in what science is about and how it is practiced, by going beyond subject-object dualism, to the *embodied enactive* self. By *embodiment*, I refer to the bodily aspect of human subjectivity; the biological and physical presence of our body as the precondition for the experience of emotion, language, thought, and social interaction; and our kinesthetic awareness of the body as the vehicle through which we experience the sensorimotor, perceptual, and non-conceptual lived world that is tacit, prereflective, and intersubjective. By *enactive*, I refer to the self that brings forth its own cognitive domains. The nervous system does not process information, it creates meaning. Thus, cognition, as embodied action is a relational domain enacted by a being's autonomous agency and autopoietic mode of coupling with their environment.

In my quest to learn more about Francisco Varela, I read his dissertation on the phenomenology of perception in the insect retinas of the honey bee from the Library of Molecular & Cellular Biology at Harvard. I also traveled to Paris to meet Varela's wife Amy Cohen, a psychoanalytic psychologist, and his colleagues at Centrede Recherche en Epistémologie Appliquée (CREA), École Polytechnique during the summer of 2011, where he began writing *The Embodied Mind: Cognitive Science and Human Experience* (Thompson, Varela, & Rosch, 1991) in 1986. I also met with Michel Bitbol, Director of Research at Centre National de la Recherche Scientifique (CNRS) and reviewed many of Varela's writings in French at the Bibliothèque François Mitterrand.

Varela explored ontogenic developmental learning, perception-action in the synchronous coupling of neuronal cell assemblies, and present-time consciousness philosophically rooted in the functionalism of William James and the European Continental traditions of Edmund Husserl, Martin Heidegger, Maurice Merleau-Ponty, and Jean Paul Sartre in existential-phenomenology foundational to many international psychologists. By combining these perspectives, neurophenomenology introduces an approach to philosophy, psychology, and human science that is able to articulate the ontological ground upon which science itself operates in ways that are not accessible to positivist science. Phenomenology studies consciousness, both the rational waking state as well as dynamics of the unconscious, as it is experienced from the first-person point of view. Experience must be grasped holistically as a relationship in which the subject relates to an object through its meaning.

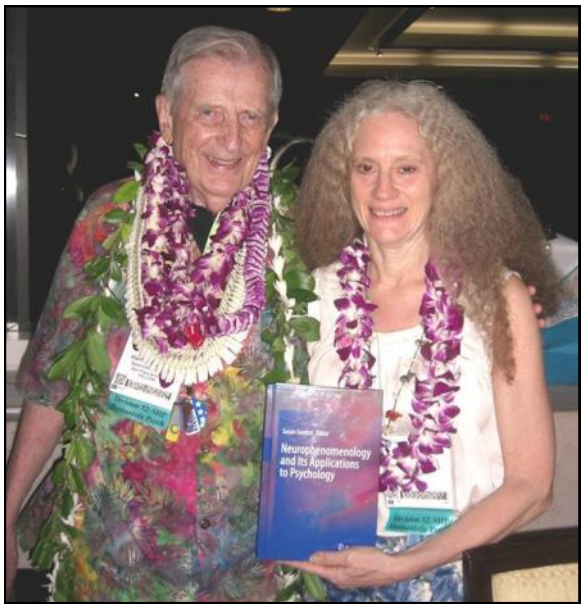

Susan Gordon and Stanley Krippner, 121st APA Convention, Honolulu, HI

Cognitive behaviorism, the standard in mainstream theoret-

ical and clinical psychology, founded on reductionistic positivism, can neither address the implications of the neuroscience revolution regarding the phenomenology of consciousness nor the relationship between the mind and the brain because it lacks a self-reflective element. Science needs grounding in self-reflection, contemplation, and an embodied approach to experience that is unrestricted to the study of behavior and a phenomenologically-oriented psychology that is foundational to the sciences (Gordon, 2013; Taylor, 2009, 2010).

Neurophenomenology provides a theoretical and practical framework that integrates the natural and human sciences to consciousness inviting an interdisciplinary dialogue on the nature of awareness, the ontological primacy of experience, the perception of the observer, and the mind-brain relationship that is shaping the future of psychological theory, research, and practice. Integrating Western Anglo-American and Continental phenomenology, with cognitive science, and Eastern contemplative experience and practices, neurophenomenology provides an interdisciplinary bridge that neither reduces the mind to the physiology of the brain, nor the living organism to cause and effect relationships.

About This Book

This book grew out of a symposium that I chaired at the annual convention of the APA in Toronto, Canada (2009) titled, "Neurophenomenology and the Enactive Approach to Cognition." The book is composed of five chapters. In Chapter 1, "Enactive Cognition and the Neurophenomenology of Emotion," Brent Dean Robbins argues that an account of emotion needs to preserve the meaning of experience as it appears in the life-world of the person, rather than being based on inferences drawn from laboratory conditions. We need to step back to examine how form is constituted as an object for cognition. In Chapter 2, "Neurophenomenological Praxis: Its Applications to Learning and Pedagogy," Robert McInerney introduces neurophenomenology to the psychologist-educator, and a prereflective, situated, enactive assessment of learning and thinking. In Chapter 3, "Mutual Enlightenment: Cognitive Phenomenology in the Study of Tibetan Meditation," Olga Louchakova-Schwartz presents original research of visuospatial processing in Tibetan monks using *phenomenological-cognitive mapping* of awareness during meditation. In Chapter 4, "Déjà-Vu: William James on 'The Brain and the Mind,' 1878. A Comment on Current Trends in Neurophenomenology Defining the Applications of James's Radical Empiricism to Psychology," Eugene Taylor explores the historical and theoretical basis of James' philosophy of radical empiricism for present day neuroscience, and its implications for the 'hard problem' of consciousness with regard to the intersubjective presence of the experimenter on the outcome of what he or she studies. In Chapter 5, "Psychoneuro-intracrinology: The Embodied Self," I introduce an autopoietic model of the mind-brain continuum: the confluence of psychological, neurological, and intracrinological (intracellular hormonal) processes modulated by the person's perception of experience and sense of well-being in the development of meaning and emergence of self.

Dedicated to Francisco J. Varela and to Eugene I. Taylor, this book begins with an *In Memoriam* for Eugene, my dear friend, and mentor, and contains his last published work. Stanley Krippner, discussant for the original symposium, wrote the Foreword. The Editor's Preface explores the book's progression of ideas. The Editor's Introduction is a tribute to Francisco Varela. The contributors introduce steps towards a more experiential, non-reductive, holistic, phenomenologically-oriented, descriptive psychology of immediate experience, and a person-centered science.

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For more information about this book, please see:

Springer: http://www.springer.com/psychology/cognitive+psychology/book/978-1-4614-7238-4

Amazon: http://www.amazon.com/Neurophenomenology-Applications-Psychology-Susan-Gordon/dp/1461472385/ref=sr_1_1?s=books&ie=UTF8&qid=1366555130&sr=1-1&keywords=neurophenomenology+and+its+applications+to+psychology

Milgram Obedience Conference Success: 50 Years on, Milgram's Research Draws an International Crowd

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Fifty years after they were first published, Stanley Milgram's most famous and controversial experiments were the topic of a world-first conference in Canada in August. The conference attracted around 100 delegates and Milgram experts from around the globe who gathered to reappraise the value and meaning of psychology's most famous research.

Organized by Nipissing University's Nestar Russell and the University of Melbourne's Gina Perry, "Obedience to Authority, Milgram's Experiments 50 Years" was held at Nipissing University's Muskoka campus in Bracebridge, near Toronto, on August 6–8.

The program featured Milgram experts and delegates from Russia, Australia, the UK, France, Italy, New Zealand, and the Netherlands, as well as from Canada and the United States.

Ethics panel delegates from left to right: Jill Morawski, Andrew Perlman, Arthur G. Miller, Herbert Kelman and Patricia Werhane.

Delegates left at the end of the conference 'raving' about it, according to co-convener Gina Perry. "We've had a series of e-mails from participants who said it was the best conference they'd ever been to," Perry said. "The beautiful setting of lakeside Bracebridge, the specific focus of the conference, and an opportunity for all delegates to meet and mingle were all factors in its success," Perry added. "Anybody who's anybody in Milgram research presented. And those that couldn't attend in person presented via Skype."

"It was a very interdisciplinary crowd, with political scientists, ethicists, social psychologists, historians, sociologists, and environmentalists. It was just fantastic," co-convener Nestar Russell said.

Kevin Corti's contemporary take on Milgram's cyranoid study.

Such a mix of perspectives naturally generated some heated debate, particularly given the more critical assessments of the research in light of new archival research, but the overall atmosphere was of respectful collegiality.

This was borne out by feedback from delegates, including the following from Emeritus Professor Augustine Brannigan from the University of Calgary: "I want to thank Nestar and Gina for organizing one of the best conferences I have ever attended. I was thrilled to meet people whose work I have read and admired, but never met or heard in person. I was also inspired by the thinking of younger generations of social scientists who bring a fresh perspective to old problems. It was difficult to come away without revising one's views of Milgram, while appreciating even more so the magnitude of his influence on our views of the world."

George Mastroianni introducing panelists from L to R: Thomas Blass, Nestar Russell, Stephen Gibson, Ian Nicholson, and Gina Perry.

Presenters included Professor Thomas Blass, Milgram's biographer and author of *The Man Who Shocked the World*, Emeritus Professor Arthur Miller, author of *The Obedience Experiments: A Case Study of Controversy in Social Science*, and Australian author Gina Perry, whose book *Behind the Shock Machine*, has just been published in the USA and Canada.

Various presentations included critical assessments of the obedience experiments (Gina Perry, Ian Nicholson, Hank Stam, and Augustine Brannigan), several theoretical re-interpretations (Neil Lutsky and Ed Erdos), reports on attempted replications (Wim Meeus, Alexander Voronov, and Clifford Stott) and the application of the studies to corporate authority, identity theft, climate change, and children's fantasy fiction (Josef Brody, Marianne Miserandino, Kenneth Worthy, and Sarah Winters).

With over 25 presentations, four panel sessions, opening and closing addresses, and all the intervening debates and discussions over break times, it was impossible for delegates to experience all that was on offer. To remedy this, Russell and Perry are planning to publish a selection of conference proceedings.

For more information contact Gina Perry and Nestar Russell.

Scenes of Psychology Students in Russia

Photos by Constantin Zyev at:
http://ip-ras.livejournal.com/4383.html

At Peoples' Friendship University of Russia, students of Professor Elena Chebotareva (far right) send a thumbs-up to the APA Division of International Psychology.

At Moscow State University, student Lera Lyanguzova shows a photo of 300 people attending a lecture on hypnosis organized by PRAXIS, her MSU psychology student group.

At the Moscow School of Higher Economics, the student psychology group SPIRITUS screens the D52 film by Judy Kuriansky on "international psychology students."

Students and faculty from many schools meet at city-wide Academy of Science events.

COMING IN WINTER '13 - '14:

International Psychology Pioneers: Portraits and Perspectives

Editors

(Grant J. Rich, Ph.D. & Uwe P. Gielen, Ph.D.)

OUTLINE

PART I: Introduction

PART II: Enlightenment Philosophy and the Emergence of Psychology

PART III: Psychology as an International European Science

PART IV: The Worldwide Expansion of Psychology

PART V: Recent Developments in International Psychology

PART VI: Overcoming Africa's Colonial Heritage and Racism

PART VII: Epilogue

INTERNATIONAL PSYCHOLOGY PIONEERS: PORTRAITS AND PERSPECTIVES

This book provides a global overview of pioneers in international psychology with contributions from distinguished authors from representative nations around the world. Chapters offer biographical profiles describing the personal histories and professional contributions of leading figures in psychology from across the globe that represent the diversity of psychology. This volume can serve as a core or supplemental text for a broad range of courses in Psychology, International Studies, and Education, with particular interest to those teaching international psychology, cross-cultural psychology, and history of psychology.

IAP INFORMATION AGE PUBLISHING

Australia

Australian Catholic University (Australia), Lecturer/Senior Lecturer in Psychology: As the Lecturer/Senior Lecturer in Psychology, you will contribute to teaching and curriculum development in both undergraduate and postgraduate Psychology programs. You will also supervise postgraduate research and conduct research in Psychology in an area of relevance to the School.

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A range of generous conditions of employment and entitlements are provided, these include: generous leave conditions; flexible working arrangements; salary packaging benefits and comprehensive staff development programs.

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For more details visit www.acu.edu.au/careers

Curtin University (Perth, Australia), Lecturer - School of Psychology and Speech Pathology:

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Curtin University's School of Psychology and Speech Pathology is committed to excellence and innovation in teaching and research with the majority of the School's research recognised as 'above world ranking'. Receiving a rating of 4 (out of 5) in the recent Excellence in Research for Australia scale the University had made significant investment in research facilities such as the Curtin Neuroscience Laboratory, a Motor Learning Laboratory, and the recently developed Health Psychology and Behavioural Medicine Laboratory.

Offering a Bachelor of Psychology degree programme accredited by the Australian Psychology Accreditation Council, our lecturers make a substantial contribution to the research profile of the University. As Lecturer you will undertake research and teaching duties in the undergraduate psychology programmes offered by the school and maximise opportunities for interdisciplinary collaboration. Your research will ideally complement existing areas of expertise within the School including Health Psychology and Behavioural Medicine, Cognition and Psychopathology, Language and Speech Sciences, Teaching and Internet Behaviour, and Community Psychology.

You will possess a Doctoral degree in a relevant area of psychology and be eligible for membership of the Australian Psychological Society. An excellent research and publication profile in an area of psychology is essential as is demonstrated commitment to Curtin's values of integrity, respect, fairness and care.

Applications close: 5pm, Monday, November 11, 2013

Application URL: https://webkiosk.curtin.edu.au/pls/prd/wk8127$.startup

Internal Number: 3023

onPsych (Australia), Clinical Psychologist: onPsych is a company in Australia, seeking Clinical psychologists to live and work "down under" for a minimum of three years. We have offices across Australia and have visas available for individuals and families. Applicants must be able to be registered in Australia as a "Clinical" Psychologist. Excellent holidays (12 weeks) and salary ($80 to $130K). E-mail jobs@onpsych.com.au.

Notes: 20 openings
Internal Number: 457/13
Required Education: Master's Degree
Salary: $70,000 - $130,000

onPsych is a company in Australia which employs clinical psychologists who work in schools across Australia. We work with children, teachers and parents and deal with many types of mental health problems, from anxiety, anger management to bullying and disability.

University of Melbourne (Australia), Lecturer or Senior Lecturer in Clinical Psychology: The Melbourne School of Psychological Sciences at the University of Melbourne, Australia, is seeking to make a continuing (tenure-track) appointment at the lecturer or senior lecturer level in clinical psychology.

The Melbourne School of Psychological Sciences is one of the leading schools of Psychology in Australia with active research programs in Behavioural Neuroscience, Cognitive

Psychology, Clinical Psychology, Clinical Neuropsychology, Developmental Psychology, Quantitative and Mathematical Psychology, and Social Psychology.

We are seeking to appoint an outstanding individual who can complement and extend our research strengths in clinical psychology, contribute to our undergraduate and postgraduate clinical psychology teaching program, and provide professional leadership in a public health setting.

For more information on the Melbourne School of Psychological Sciences, visit psych.unimelb.edu.au

Salary: AU$87,334 - AU$103,705 p.a. (Level B) or AU$106,980 - AU$123,353 p.a. (Level C) plus 17% superannuation. Level of appointment is subject to qualifications and experience.

To apply, use the following link: http://go.unimelb.edu.au/74sn

Applications Close: November 4, 2013 11:55 pm Australian Eastern Standard Time

University of Tasmania (Australia), Senior Lecturer in Psychology: Applications are invited for appointment to this position, which will be offered on a full-time continuing basis.

The University is seeking to appoint a Senior Lecturer with the capacity to align with health and aging, human neuroscience or applied research theme areas and the competence to teach across a range of core undergraduate topics, including research methods. They will also have the knowledge, skill and willingness to embrace contemporary approaches and technology to develop and enhance high quality online learning. Travel to other campuses is required.

Applicants will have a Ph.D. in a relevant area of psychology with postdoctoral research and/or teaching experience. In addition the applicant will undertake high-quality research of national and increasingly of international standing, secure external competitive and other funding, publish research findings and contribute to the successful supervision of research higher degree students.

Women are particularly encouraged to apply as the University is seeking to increase the number of women in senior academic and administrative positions.

The appointment will be at Academic Level C and will have a total remuneration package of up to $134,559 per annum (comprising salary within the range $100,368 - $115,008 plus 17% superannuation, with the option of an additional 3% salary loading in exchange for 14% instead of 17% superannuation).

For further information about the position, contact Associate Professor Jenn Scott, Acting Head, School of Psychology, University of Tasmania on +61 3 6226 2245 or e-mail Jenn.Scott@utas.edu.au.

The closing date for applications is September 30, 2013.

Internal Number: 410

Location: Launceston, Australia

University of Tasmania (Australia), Lecturer in Psychology: Applications are invited for appointment to this position, which will be offered on a full-time continuing basis.

The University is seeking to appoint a lecturer with the capacity to align with either the health and aging or human neuroscience research theme areas and the competence to teach across a range of core undergraduate topics, including research methods. They will also have the knowledge, skill and willingness to embrace contemporary approaches and technology to develop and enhance high quality online learning.

Applicants will have a Ph.D. in a relevant area of psychology with postdoctoral research and/or teaching experience. In addition the applicant will undertake high-quality research of national and increasingly of international standing, secure external competitive and other funding, publish research findings and contribute to the successful supervision of research higher degree students.

The appointment will be at Academic Level B and will have a total remuneration package of up to $113,952 per annum (comprising salary within the range $82,602 - $97,395 plus 17% superannuation, with the option of an additional 3% salary loading in exchange for 14% instead of 17% superannuation).

For further information about the position, contact Associate Professor Jenn Scott, Acting Head, School of Psychology, University of Tasmania on +61 3 6226 2245 or e-mail Jenn.Scott@utas.edu.au.

The closing date for applications is 30 September 2013.

Internal Number: 411

Location: Hobart, Australia

Bermuda

Ministry of Public Safety (Bermuda), Psychologist: Applications are invited for the post of Psychologist in the Department of Corrections. The successful applicant will work under the direction of the Assistant Commissioner to provide a range of professional psychological assessments and treatment services to inmates and their families in accordance with

the relevant legislation, Departmental policies and procedures and professional standards, designed to bring about positive changes in their behavior so that they are not likely to re-offend.

Applicants must be a graduate from an accredited college or university with advanced course work in psychology, as received in a clinical psychology Doctoral level program; Ph.D. or equivalent in psychology required (for example, U.K. Chartered Psychologist with a Master's Degree in Psychology). The applicant must be a registered practitioner and meet the local registration criteria (The Psychological Practitioners Registration Regulation 2003). A minimum of five years' relevant experience is required for the post. Experience working in a correctional environment with a focus on one or more of the following areas: adult or young offenders, sex offenders, low functioning populations, habitual and/or violent offenders and substance abuse facilitation is preferred.

This post is offered on a two year contract. Qualified persons wishing to be considered for the post may apply online at www.govtcareers.gov.bm by the specified closing date of **September 27, 2013**. Short listed applicants will be required to pass an extensive medical examination.

Government of Bermuda - The Cabinet Office
Department of Human Resources
Psychologist (Temporary Additional—Two Years)
PS 34-36 $105,765 - $113,480 (=US$ equivalent)
Department of Corrections

Internal Number: DHR00128 (250364A/OS)

Canada

IWK Health Centre (Canada), Clinical Psychologist - Residential Treatment: Located in Halifax, Nova Scotia, the IWK Health Centre provides quality care to women, children, youth and families in the Maritime provinces and beyond. In addition to providing highly specialized (tertiary) care, the IWK also provides primary care services. The IWK is also engaged in leading-edge research; works to promote healthy lifestyles for families; and supports education opportunities for health professionals and other learners.

Clinical Psychologist - Residential Treatment
Regular Full-Time (1.0 FTE)

Annual Salary: $80,210 - $100,263

Competition #: L-2013-1166

Applications will be accepted until
this position has been filled

Position Summary: The IWK Mental Health & Addictions Program is recruiting a Clinical Psychologist with experience working with youth in residential, day treatment, and/or outpatient services to work within the Adolescent Centre for Treatment (ACT). The Mental Health and Addictions Program at the IWK Health Centre provides a residential treatment centre (ACT) for youth aged 13 to 19 years presenting with severe and persistent disruptive behaviours and/or severe and persistent mental illness. ACT has a capacity for 16 youth at any given point, offering a combination of residential and day treatment options. The length of the service is between 3 to 4 months of intensive service, followed by a period of transition support. Transition support is designed upon admission into the service. Psychologists in this service provide clinical program planning, individual and group treatments, family interventions including family therapy and service evaluation. The Psychologist is a member of an interdisciplinary team that provides milieu and specific interventions consistent with the Connect Model. This model is a relationship based model steeped in attachment theory. Parents are provided training in the model through a Connect Parenting Program.

The Adolescent Centre for Treatment provides evidence-based best practice Mental Health Services to youth and families. The youth often present with emotional and behavioral dysregulation and cognitive and behavioural methods are engaged to help youth self-regulate. The Doctoral Psychologist is a member of an interdisciplinary team of service providers, which includes other doctoral prepared psychologists, master's prepared clinical social workers, registered nurses, licensed practical nurses, transition support workers, youth care workers, occupational therapy, recreation therapy, teachers, educational support workers, administrative support, and psychiatry. The Psychologist's responsibilities include psychological assessments, (including diagnostic assessment where indicated), evidence-based mental health treatment (focused on rehabilitation/ reintegration into community), program development, program evaluation, staff development and clinical leadership for service improvement. Treatments include individual, group, and family interventions.

The IWK Health Centre Predoctoral Residency Program in Pediatric and Child-Adolescent Psychology is both APA and CPA accredited. All Psychologists at the IWK are expected to actively participate in training residents. Candidates for Psychology positions who have the appropriate credentials may be considered for academic adjunct appointment in an appropriate university department at Dalhousie University. Further information about these appointments can be obtained from Vicky Veitch Wolfe, Ph.D., Psychology Professional Practice Chief, at (902) 470-8458 or vicky.wolfe@iwk.nshealth.ca

Applicants are asked to include a copy of his/her curriculum vitae, pertinent scientific publications and three letters of recommendations from professionals attesting to the applicant's clinical training, clinical skills and character. For individuals with less than three years of experience, an additional

letter must be provided, from the Director of Clinical Training, at the institution where the applicant completed his/her clinical internship.

Qualifications:

- Ph.D. / Psy.D. Degree in Clinical Psychology from an accredited university program.
- Registered, or eligible to be registered, with the Nova Scotia Board of Examiners in Psychology.
- Minimum five (5) years of formal training and clinical experience in child/adolescent mental health.
- Demonstrated ability to treat a highly disregulated youth population.
- Demonstrated ability to consult with professional and para-professional staff.
- Demonstrated ability to diagnose and formulate treatment protocols for a wide range of adolescent mental health problems.
- Demonstrated ability to effectively consult with other health, social service and education agencies.
- Demonstrated knowledge in the area of ecological intervention preferred.
- Demonstrated ability to work well as part of an interdisciplinary team required.
- Demonstrated excellent verbal and written communication skills required.
- Ability to participate in the clinical training activities of the Psychology Discipline.
- Education, experience, or training in the related subspecialty area preferred.
- Competencies in other languages an asset; French preferred.

To apply for this position, forward your application to Amanda.gerrits@iwk.nshealth.ca

IWK Health Centre (Canada), Clinical Psychologists - Youth Forensics: Located in Halifax, Nova Scotia, the IWK Health Centre provides quality care to women, children, youth and families in the Maritime provinces and beyond. In addition to providing highly specialized (tertiary) care, the IWK also provides primary care services. The IWK is also engaged in leading-edge research; works to promote healthy lifestyles for families; and supports education opportunities for health professionals and other learners.

Clinical Psychologists - Youth Forensics
Regular Full-Time (1.0 FTE)

Annual Salary: $80,210 - $100,263

Competition #: L-2013-1161

Applications will be accepted until
this position has been filled

Position Summary: Currently the IWK has openings for several Forensically Trained Clinical Psychologists with experience working with youth in forensic mental health settings. Psychologists in these services focus on Forensic Mental Health Assessment for Youth Court as well as Forensic Rehabilitation Services. This specialized interdisciplinary team offers assessment and treatment that is primarily geared to identifying and reducing risk factors for criminal activity, including psychosocial and mental health factors that impact upon risk to reoffend. The IWK offers a range of services under the umbrella of Youth Forensic Services that include: youth court liaison service, intervention services dedicated to the community corrections, clinical case management, forensic rehabilitation for youth found unfit to stand trial or not criminally responsible, subspecialty services for youth who are sexually aggressive, a secure care unit providing assessment and rehabilitation, and clinical services delivered to incarcerated youth at the Nova Scotia Youth Facility in Waterville, Nova Scotia. While the focus of psychology is on youth court assessment, opportunities exist to work across the service continuum.

The mission of Youth Forensic Service is to provide evidence-based, best practice Health and Mental Health Services to youth and families involved in the criminal justice system. The Doctoral Psychologist is a member of an interdisciplinary team of service providers, which includes both master and doctoral prepared Psychologists, masters prepared Clinical Social Workers, Registered Nurses, Licensed Practical Nurses, Community Support Workers, administrative support, and Psychiatry. The Psychologist's responsibilities include section 34 psychological assessments and evidence-based mental health treatment that is focused on reducing the risk of reoffending. Treatments include individual, group, and family interventions. Consultation with IWK Forensic colleagues and community service partners and providers is expected. Testifying in court is also expected when required.

The IWK Health Centre Predoctoral Residency Program in Pediatric and Child-Adolescent Psychology is both APA and CPA accredited. All Psychologists at the IWK are expected to actively participate in training residents. Candidates for Psychology positions who have the appropriate credentials may be considered for academic adjunct appointment in an appropriate university department at Dalhousie University. Further information about these appointments can be obtained from Vicky Veitch Wolfe, Ph.D., Psychology Professional Practice Chief, at (902) 470-8458 or vicky.wolfe@iwk.nshealth.ca

Applicants are asked to include a copy of his/her curriculum vitae, pertinent scientific publications and three letters of recommendations from professionals attesting to the applicant's clinical training, clinical skills and character. For individuals with less than three years of experience, an additional letter must be provided, from the Director of Clinical Training, at the institution where the applicant completed his/her

clinical internship.

Qualifications:

- Ph.D. / Psy.D. Degree in Clinical Psychology from an accredited university program.
- Registered, or eligible to be registered, with the Nova Scotia Board of Examiners in Psychology.
- Minimum five (5) years of formal training and clinical experience in child/adolescent mental health.
- Minimum five (5) years of formal training and clinical experience in assessing risk for sexual and violent recidivism.
- Demonstrated ability to treat a youth forensic population.
- Demonstrated ability to consult with professional and para-professional staff.
- Demonstrated ability to diagnose and formulate treatment protocols for a wide range of adolescent mental health problems.
- Demonstrated ability to effectively consult with other health, social service and education agencies.
- Demonstrated knowledge in the area of ecological intervention preferred.
- Demonstrated ability to work well as part of an interdisciplinary team required.
- Demonstrated excellent verbal and written communication skills required.
- Ability to participate in the clinical training activities of the Psychology Discipline.
- Education, experience, or training in the related subspecialty area preferred.
- Competencies in other languages an asset; French preferred.

To apply for this position, forward your application to Amanda.gerrits@iwk.nshealth.ca

Notes: 4 openings.

Additional Salary Information: Relocation allowance if relocating from out of province.

Internal Number: L-2013-1161

McGill University (Canada), Assistant Professor in Clinical Psychology: The Department of Psychology of McGill University seeks applicants for a tenure-track position as Assistant Professor in Clinical Psychology with an anticipated starting date of Sept. 1, 2014. An ideal candidate will be conducting research in a major area of psychopathology. The McGill program in Clinical Psychology is strongly committed to the clinical-science model and is accredited by the Canadian Psychological Association and Psychological Clinical Science Accreditation System.

Candidates will have a Ph.D. from a CPA- or an APA-accredited doctoral program and will also be expected to demonstrate the potential to establish a record of significant, externally-funded research. Candidates are also expected to have an aptitude for both undergraduate and graduate teaching. The psychology department has excellent facilities for interdisciplinary research with other McGill departments and other universities in Montreal.

Applications will be considered beginning Nov. 1, 2013 and continue to be evaluated until the position is filled. Applicants should arrange for the following materials to be sent in electronic format to clinical-search@psych.mcgill.ca: (1) curriculum vitae; (2) description of current areas of research; (3) relevant reprints or pre-prints; (4) three confidential letters of recommendation; (5) description of teaching competencies, interests and approaches.

McGill University is committed to equity in employment and diversity. It welcomes applications from Aboriginal persons, persons with disabilities, ethnic minorities, persons of minority sexual orientation or gender identity, visible minorities, women, and others who may contribute to diversification. All qualified applicants are encouraged to apply; however, Canadians and permanent residents will be given priority.

Internal Number: 4671

Memorial University of Newfoundland (Canada), Clinical Psychologist: The Department of Psychology at Memorial University of Newfoundland invites applications for a tenure track position in Clinical Psychology at the rank of Assistant Professor (VPA-PSYC-2012-001). The successful candidate (1) will have a doctorate from a CPA or APA-accredited clinical psychology programme, (2) will have completed a CPA or APA-accredited internship in clinical psychology, (3) will be Registered or eligible for Registration in Newfoundland and Labrador, and (4) will have the potential for establishing an externally-funded research programme. In addition to teaching undergraduate courses, the successful candidate will also teach core courses in the Psy.D. programme, and will help supervise and mentor the clinical graduate students.

Applicants should submit (1) curriculum vitae; (2) a statement of their approach to clinical training and clinical practice; (3) a statement of their research interests and selected reprints; (4) a statement of their teaching interests and evidence of effective teaching; and (5) letters from three referees to: Dr. Gerard Martin, Head, Department of Psychology, Memorial University of Newfoundland, St. John's, NL, A1B 3X9. Electronic submissions are strongly encouraged and may be sent via e-mail to Psychology.Head@mun.ca The deadline for receipt of all materials is September 30, 2013. The appointment will begin on July 1, 2014.

All qualified candidates are encouraged to apply; however, Canadians and permanent residents will be given priority. Memorial University is committed to employment equity and

encourages applications from qualified women and men, visible minorities, aboriginal people and persons with disabilities. Informal inquiries are welcomed. This position is subject to final approval.

Memorial University is the largest university in Atlantic Canada. As the province's only university, Memorial plays an integral role in the education and cultural life of Newfoundland and Labrador. Offering diverse undergraduate and graduate programmes to almost 18,000 students, Memorial provides a distinctive and stimulating environment for learning in St. John's, a very safe, friendly city with great historic charm, a vibrant cultural life, and easy access to a wide range of outdoor activities.

Internal Number: VPA-PSYC-2012-001

The Ontario Institute for Studies in Education, University of Toronto (Canada), Applied Psychology & Human Development Assistant/Associate Professor - School Psychology:

Closing Date: November 15, 2013

The Ontario Institute for Studies in Education, University of Toronto invites applications for a tenure-stream appointment at the rank of Assistant or Associate Professor commencing on July 1, 2014 in the Department of Applied Psychology and Human Development (APHD).

We seek applicants with expertise in child clinical, developmental or school psychology. Successful candidates will have a doctoral degree.

Consideration may be given to applicants who will complete their doctoral degree by the appointment date or shortly thereafter. Successful candidates must be registered or eligible for registration with the College of Psychologists of Ontario. We welcome applications from candidates with research interests in any of the following areas: learning; typical or atypical cognitive or socio-emotional development; assessment, prevention, consultation or intervention in childcare, school, community or health settings; cognitive, biological or environmental risks for learning difficulties and psychopathology and the assessment, prevention, and treatment of these risks; developmental disabilities; or internalizing or externalizing disorders. Salary will be commensurate with qualifications and experience.

Candidates should be outstanding scholars as evidenced by their areas of research, grant and publication records, and their collaborations. We look for evidence of excellence in teaching and student training, excellence in research and the capacity for collegial service and service to the profession. The successful candidate will contribute primarily to the School and Child Clinical Psychology (SCCP) program, which is the only Canadian Psychological Association (CPA)-accredited doctoral program that explicitly provides combined professional training in school and clinical child psychology. The specific mission of the SCCP Program is to provide students with theoretical, research, and professional training in preparation for leadership positions in academic and applied settings. The framework for the program is the scientist practitioner model.

Applications should include a cover letter, curriculum vitae, three recent research publications, results of teaching surveys (or equivalent evidence, such as a teaching dossier), and a statement outlining current and future research interests. If you have questions about this position, please contact Professor Lana Stermac at: aphdchair.oise@utoronto.ca The review of applications will begin on November 1, 2013, and will continue until the closing date of November 15, 2013. All application materials should be submitted online at: http://uoft.me/academicopportunities

The U of T application system can accommodate up to five attachments (10) MB per candidate profile; please combine attachments into one or two files in PDF/MS Word format. Submission guidelines can be found at: http://uoft.me/how-to-apply

Applicants should ask three referees to send letters directly to the department via e-mail to aphdchair.oise@utoronto.ca by November 15, 2013.

Established in 1827, the University of Toronto is Canada's largest and most research-intensive university and the only Canadian University to be named in the top 25 in the Times Higher Education World University Rankings. Located in and around Toronto, one of the world's most diverse regions, the University of Toronto's vibrant academic life is defined by the cultural diversity in its community.

The Ontario Institute for Studies in Education (OISE) has, for more than a century, made a major contribution to advancing education, human development and professional practice around the world. With more than 72,000 alumni, close to 3,000 students and 20 research centres, ours is an intellectually rich and supportive community, guided by the highest standards of scholarship and a commitment to equity and social justice.

For more information visit the Ontario Institute for Studies in Education homepage and the Department of Applied Psychology and Human Development website at: http://www.oise.utoronto.ca/aphd

The University of Toronto is strongly committed to diversity within its community and especially welcomes applications from visible minority group members, women, Aboriginal persons, persons with disabilities, members of sexual minority groups, and others who may contribute to the further diversification of ideas. All qualified candidates are encouraged to apply; however, Canadians and permanent residents will be

given priority.

University of Calgary (Canada), Tier II Canada Research Chair in Determinants of Healthy Development: The Department of Psychology at the University of Calgary invites applications for a tenure-track Tier II Canada Research Chair in the Determinants of Healthy Development. The focus of the Chair in the Determinants of Healthy Development addresses a major priority identified in the University's Research Plan, the understanding of Brain and Mental Health, Optimizing Child and Adolescent Development and Behaviour. Specific area of research is open within the broad domain of healthy development. We are seeking individuals with strong research records appropriate to a research-oriented doctoral program and who have strong commitments to teaching and research supervision of undergraduate and graduate students.

The successful applicant will be expected to establish a successful and externally funded program of research in healthy development. Excellent candidates with active research programs in any area of healthy development will be considered. The position involves teaching, research, and supervision of graduate students.

The successful applicant will be appointed within the Faculty of Arts, Department of Psychology. This tenure track appointment will made at the rank of **Assistant or Associate Professor**. The successful applicant should be within ten years of completing doctoral training. Although not required for the position, having accredited clinical training (including an APA- or CPA-accredited internship) and being eligible for registration as a psychologist in the province of Alberta would be an asset.

Send letter of application, statement of research interests, statement of teaching philosophy and interests, curriculum vitae, representative reprints/preprints, and three letters of recommendation to:

Dr. David Hodgins, Chair of the CRC Psychology Search
Department of Psychology
University of Calgary
Calgary, AB, Canada, T2N1N4
E-mail: dhodgins@ucalgary.ca

Review of applications will begin immediately and continue until the position is filled.

About the University of Calgary
The University of Calgary is a leading Canadian university located in the nation's most enterprising city. The university has a clear strategic direction to become one of Canada's top five research universities by 2016, where innovative teaching and groundbreaking research go hand in hand, and where we fully engage the communities we both serve and lead. The strategy is called Eyes High, inspired by our Gaelic motto, which translates to 'I will lift up my eyes'.

To succeed as one of Canada's top universities, where new ideas are created, tested and applied through first-class teaching and research, the University of Calgary needs more of the best minds in our classrooms and labs. We're increasing our scholarly capacity by investing in people who want to change the world, bringing the best and brightest to Calgary to form a global intellectual hub and achieve advances that matter to everyone.

About Calgary
Named a cultural capital of Canada and one of the best places to live in the world, Calgary is a city of leaders - in business, community, philanthropy and volunteerism. Calgarians benefit from the strongest economy in the nation and enjoy more days of sunshine per year than any other major Canadian city. Calgary is less than an hour's drive from the majestic Rocky Mountains and boasts the most extensive urban pathway and bikeway network in North America.

All qualified candidates are encouraged to apply; however, Canadians and permanent residents will be given priority. The University of Calgary respects, appreciates, and encourages diversity.

Internal Number: 5268

University of Toronto Scarborough (Canada), Multiple Academic Positions in Psychology: The Department of Psychology at the University of Toronto Scarborough invites applications for two tenure-stream appointments in the fields of: Social Psychology (#1301313) and Developmental Neuroscience (#1301323). The appointments will be at the rank of Assistant Professor and will begin on July 1, 2014.

All qualified candidates are invited to apply by clicking on the University of Toronto Faculty Careers Page at http://www.uoftcareers.utoronto.ca/ and submitting your application online. Refer to the job posting numbers above and pay close attention to individual closing dates and application requirements.

Job Posting: 1301313
https://utoronto.taleo.net/careersection/10050/jobdetail.ftl?job=1301313

Closing Date: November 12, 2013

Job Posting: 1301323
https://utoronto.taleo.net/careersection/10050/jobdetail.ftl?job=1301323

Closing Date: November 13, 2013

For more information about the Department of Psychology, University of Toronto Scarborough visit our homepage:

http://www.utsc.utoronto.ca/~psych/

The University of Toronto is strongly committed to diversity within its community and especially welcomes applications from visible minority group members, women, Aboriginal persons, persons with disabilities, members of sexual minority groups, and others who may contribute to the further diversification of ideas.

All qualified candidates are encouraged to apply; however, Canadians and permanent residents will be given priority.

Egypt

The American University in Cairo (Egypt), Clinical or Counseling Psychologist, Community Psychologist and Research Psychologist:

Company Description: Founded in 1919, AUC moved to a new 270-acre state-of-the-art campus in New Cairo in 2008. The University also operates in its historic downtown facilities, offering cultural events, graduate classes, and continuing education. Student housing is available in both downtown Zamalek and New Cairo. Among the premier universities in the region, AUC is Middle States accredited; its Engineering programs are accredited by ABET, its Chemistry program is accredited by the Canadian Society for Chemistry, and the Management program is accredited by AACSB. The AUC Libraries contain the largest English-language research collection in the region and are an active and integral part of the University's pursuit of excellence in all academic and scholarly programs. AUC is an English-medium institution; eighty-five percent of the students are Egyptian and the rest include students from nearly ninety countries, principally from the Middle East, Africa and North America. Faculty salary and rank are based on qualifications and professional experience. All faculty receive generous benefits, from AUC tuition to access to research funding; expatriate faculty also receive relocation benefits including annual home leave, and tuition assistance for school age children.

Job Description: CLINICAL OR COUNSELING PSYCHOLOGIST, COMMUNITY PSYCHOLOGIST AND RESEARCH PSYCHOLOGIST. The Psychology Unit at AUC is poised to establish its own department and is looking for psychologists to join our team who are excited by the opportunity to create a world-class program that will serve as a leader in meeting the unique needs and demands of the Egyptian community and the Middle East and North Africa (MENA) region. We are searching for a number of full-time, possibly visiting, and tenure-track Assistant Professors and/or Professor of Practice. Positions will start in January/February and/or in fall of 2014.

Requirements: Applicants must have a doctorate in Psychology and a demonstrated commitment to undergraduate education. Between the positions, teaching needs include: Introduction to Psychology, Statistics, Research Methods, Social Psychology, History and Systems, Cognitive Psychology, Community Psychology and Systems Theory, Fundamentals of Counseling, Psychological Assessment, Ethics, and Internship Supervision. One position involves master's thesis advising. Candidates should show significant promise as a scholar. AUC offers a BA in Psychology, a MA in Community Psychology, and a MA in Counseling Psychology.

Additional Information: Review of applications will begin immediately and continue until the positions are filled.

Application Instructions: Send the following application materials via our online portal: current curriculum vitae; a letter of interest; a completed Personal Information Form; official graduate transcript(s), (p)reprints of publications, teaching evaluations, and at least three reference letters from referees sent directly to hussref@aucegypt.edu

Review our list of offered classes [http://catalog.aucegypt.edu/content.php?catoid=15&navoid=476] and indicate in your application which psychology classes you are prepared to teach; psychology courses have the prefix PSYC.

Apply Here

PI67592114

Germany

Korn/Ferry International (Germany), Leadership Assessment Psychologist: Korn/Ferry International is the executive search industry's leader and innovator, and has evolved as the world's premier provider of executive talent management solutions. Today, Korn/Ferry has conducted more successful executive searches globally than any other recruiting firm in history.

Understanding that the business community is now facing many more challenges in attracting, retaining and developing senior managers, Korn/Ferry's services range from executive recruitment to corporate governance and CEO recruitment, outsourced recruiting, management assessment, and executive coaching and development.

Our executive recruitment professionals, many of whom joined our firm from senior positions in the industry sectors they now serve, conduct more than 10,000 senior-level searches for clients worldwide each year. Our consultants are based in nearly 80 offices in 40 countries in the Americas, Asia Pacific, Europe, the Middle East and Africa. The industry-sector knowledge and global reach of our firm ensures that our clients have access to the most qualified candidates for every position.

Responsibilities:

- Assist with the successful recruitment of key corporate executives by providing leadership assessment support to both internal customers and external clients
- Provide both written and verbal assessment interpretation to clients, search committees, consultants, and executive candidates
- Provide coaching and support to executives around onboarding/transition into new client organizations
- Provide trouble-shooting and technical assistance to internal and external users of the on-line assessment
- Market the assessment to both internal and external users. This will include conducting presentations, preparing consultants to successfully market the tool to their clients, and continuously developing, updating, and improving marketing materials
- Contribute to both organizational and database research aimed at improving the assessment tool and increasing its use
- Create thought leadership

Who Should Apply?: Ph.D. in Clinical or Counseling psychology, or a related discipline, is preferred.

This position is best suited for a Counseling or Clinical Psychology Ph.D. or Psy.D. looking to transition out of more traditional clinical/consulting/assessment work into work more aligned with executive assessment and organizational consulting. If the doctorate is recently earned, experience working in a large organization is strongly preferred.

This position is located in our Frankfurt, Germany office. **Note:** To ensure your application materials reach those directly leading the search, please utilize **ONLY** APA's PsycCareers website at http://jobs.psyccareers.com/jobs/ for questions or submission of applications and **do not contact a Korn/Ferry office directly.**

Unique Skills Required:

- **Must be fluent in German**, as well as English
- Comfort and capability with psychometric testing and with Excel, Word and PowerPoint applications
- Excellent verbal and written communication skills
- Strong social/relationship-building/outreach/ networking skills
- Comfort and capability with social-science research methods, organizational research, and database management

Why is This a Great Opportunity?:

- This is a position that will waste little time in putting the right individual on the front line working at the executive level. As skills develop, there is opportunity to expand the scope of the role over time.
- This is a dynamic position that will draw on a wide range of skills that include assessment, research, written and verbal communication, marketing, and consultation.
- Competitive compensation
- Attractive benefits package
- Significant opportunities for growth

Japan

MedPro Technologies, LLC (Japan), Clinical Psychologist (Civilian Position):

OVERSEAS PSYCHOLOGICAL HEALTH SUPPORT SERVICES (OPHSS)
Misawa AB, Japan

Competitive Salary plus full benefits; will provide allowance for housing/cost of living and assist with relocation costs.

MedPro Technologies, LLC is a provider of direct healthcare services to government agencies, including Military Treatment Facilities (MTF) both stateside and overseas and is nationally recognized for excellence in supporting, managing and staffing, the mission of our customers through medical, applied sciences and research and development. Visit our website www.medpro-tech.us

Scope: In order to support the Air Force Psychological Health Program, the Air Force Medical Service (AFMS) has nine (9) clinical psychologists, six (6) clinical social workers and two (2) Psychiatrists for 17 overseas medical treatment facilities (MTFs) in seven (7) countries for the United States Air Forces in Europe (USAFE) and Pacific Air Force (PACAF) commands.

Background: The mission of the Air Force Medical Operations Agency (AFMOA) is to support Department of Defense (DoD) health professionals in optimizing the health and wellness of their populations through appropriate, effective and efficient healthcare practices and service delivery. AF readiness targets combat stress reactions, deployment environment and deployment-related stressors. It also provides tailored support of the base helping agencies (Community Resources such as the Airman and Family readiness center, Chaplains, Health and Wellness centers), targets deployment challenges and engages the services of these base helping agencies. The AF community is represented by several agencies, one of which is AFMOA, Mental Health Division (SGHW). AFMOA/SGHW provides military readiness support through management of various programs engaged in individual, family and community health initiatives. These programs include Family Advocacy; Alcohol and Drug Abuse Prevention and Treatment/Demand Reduction; Education and Development Intervention Services/ Special Needs Identification and Assignment Coordination; and Suicide Prevention. Their objective is to address intervention and prevention strategies for

common modifiable behavioral risk factors.

Must Have Requirements (clearly show on resume):

- Have a Doctor of Philosophy (Ph.D.) or (Psy.D.) degree in clinical or counseling psychology from an APA-accredited psychology program (or a program acceptable to the Office of the Surgeon General, U.S. Air Force in accordance with AFI 44-119).
- Shall have completed an APA-accredited internship/residency in clinical psychology (or an internship/residency acceptable to the Office of the Surgeon General, U.S. Air Force in accordance with AFI 44-119).
- Have and maintain a current license to practice psychology in any one of the 50 states, the District of Columbia, Puerto Rico, or the U.S. Virgin Islands.
- Clinical/Counseling Psychology. Responsible for and applies psychological procedures and techniques, including interviewing, behavioral assessment, cognitive-behavioral therapy, and psychological testing/psycho diagnostic testing, in the evaluation, diagnosis, and treatment of psychological and neuropsychological disorders.
- Conduct individual, family and group psychotherapy, and couples therapy, alcohol and drug treatment evaluations.

Additional Information:

- Conduct applied research and clinical investigations in clinical/behavioral health psychology.
- Attend and participate in meetings during normal duty hours and professional staff conferences and other appropriate professional activities such as, but not limited to the following: Quality Improvement meeting, professional staff meetings, Commander's staff meetings, Department meetings, and others required by applicable regulations, MTF guidance, or as directed by the Chief, Department of Psychology or his/her designated representative.
- Consult with medical personnel, legal authorities, military commanders and school districts, as required.
- Maintain accurate and current notes in both the Department of Psychology records and patient medical records of all patients seen, as appropriate, and produces reports of evaluation and/or treatment, as required.
- Participate in military specific training (for example, training to perform Command Directed Evaluations, security clearances, Military Training Instructor clearances, pre-post deployment screening, PTSD, combat stress, etc.)
- Will provide allowance for HOLA/COLA and assist with relocation costs.
- MedPro Technologies, L.L.C. is an Equal Opportunity Employer.

If interested, forward curriculum vitae/resume to Tammie.simon@eagle-app-sci.com for consideration or contact me at (210) 387-8727.

Internal Number: 009-MED-XJ0-13

NES Health Care Group (Japan), Clinical Psychologist: NES Government Services is seeking a licensed clinical psychologist to work with active duty military personnel and dependents at the 35th Medical Group, Misawa, Japan. This contract position is full time for two years. Workdays are Monday through Friday, eight hours per day with no overtime or on call. Position is out-patient, with duties performed at primary care/mental health clinics.

Misawa is located about 400 miles north of Tokyo, and is not in a location affected by the Fukushima accident.

If you are seeking an adventure job, and wish to support our military, this may be just the position for you!

For more details, contact Mary Holland at NES Government Services, 1-800-637-3627 x 237 or mholland@neshold.com

Notes: Employer will assist with relocation costs.

Okinawa Institute of Science and Technology Graduate University (Japan), Clinical Psychologist: The Okinawa Institute of Science and Technology Graduate University (OIST) will become a model for change in education and research with the best international graduate students, working side by side with world-class faculty in modern well-equipped laboratories. Beautifully situated on the island of Okinawa, OIST relies on a cross-disciplinary approach, with an emphasis on creativity and exchange, to offer unique, individualized graduate training. OIST is a university with no departments, eliminating artificial barriers between people working in different fields, but many nationalities, with students and faculty being attracted from all over the world. Concentrating initially on Neuroscience, Molecular Sciences, Mathematical Sciences, Environmental and Ecological Sciences and Physical Sciences, OIST is bringing some of the best brains in the world to Okinawa to transform the way science and education is done in the global academic world.

Position: Clinical Psychologist

Working Location: Onna-son, Okinawa, Japan

Responsibilities: The Okinawa Institute of Science and Technology Graduate University (OIST) is seeking a mid to senior level licensed/registered Clinical Psychologist to establish and direct its outpatient mental health and counseling services.

The successful applicant will provide clinical leadership and supervision to a small team of psychology/counseling staff; psychological assessment and evidence based therapy in English for OIST graduate students, staff and their families pre-

senting with a wide range of clinical issues; and contribute to the development of student and staff support networks and mental health workshops.

Qualifications: Applicants must have a Ph.D. in Clinical Psychology or a Postgraduate Diploma in Clinical Psychology together with an Advanced Research Degree and be licensed/registered to practice as a clinical psychologist in the country in which they completed their graduate training. It is expected that applicants will have at least five years' experience working as a Clinical Psychologist and possess excellent clinical and administrative skills.

Term: Full-time, fixed term appointment for three years contract initially with three month probationary period. This contract may be renewed.

Working Hours: Flextime (core time 10:00-15:00) 7.5 hrs. per day

Compensation: In accordance with the OIST Employee Compensation Regulation

Benefits: Annual paid leave, summer holidays, Private School Mutual Aid, commuting allowances and relocation allowances.

Submission Documents:
1) Letter of Intent
2) Curriculum vitae
3) Copy of License/registration as a Clinical Psychologist
4) Names of three references who can be contacted for letters of recommendation

Starting Date: As early as possible

Application Due Date: Applications deadline will continue until the position is filled.

Application Address: Submit all required application materials by e-mail to: recruiting@oist.jp

Or send documents via post mail to:
Recruiting Team, HR Management Section
Okinawa Institute of Science and Technology
Graduate University
1919-1, Onna, Onna-son, Okinawa 904-0495, Japan

OIST is an Equal Opportunity/Affirmative Action Employer.

Information provided by applicants or references will be kept confidential, documents will not be returned. All applicants will be notified regarding the status of their applications.

Further details about the Institute can be viewed on our website (www.oist.jp).

Notes: Employer will assist with relocation costs.

Additional Salary Information: In accordance with the OIST Employee Compensation Regulation

Sterling Medical Corporation (Japan), Clinical Child Psychologists: Clinical Child Psychologist Needed in Japan Working with US Military Families/Special Needs Children. Benefits: Excellent compensation package, Medical, Dental, Vision, Life, 401K and provided. Relocation expenses provided. Requires two years working with special needs children and their families. Interested candidates call Lynn Romer at 1 (800) 852-5678 ext. 156 or e-mail a resume to LynnR@MagnumMedicalOverseas.com

Notes: Employer will assist with relocation costs.

Macau

The University of Macau (Macau), Full Professor in Psychology: The University of Macau is a leading higher educational institution in Macao and is making strides towards becoming internationally recognized for its excellence in teaching, research and service to the community. The University is growing rapidly with a number of new strategic initiatives including the relocation to a new campus and the establishment of the largest Residential College system in Asia. The new campus is 20 times larger than the present one with a projected fast growth of student intake and faculty size. English is the University's working language.

The Department of Psychology of the Faculty of Social Sciences (FSS) offers programmes at the BSS, MSS and Ph.D. levels. The Department invites applications for the position of Full Professor in Psychology with expertise in any of the applied fields or sub-disciplines of Psychology.

Qualifications: In addition to a Ph.D. in Psychology, applicants should have an excellent record of scholarship in the field of Psychology, a keen interest in contributing to the research productivity in the department, and should be committed to teaching excellence, research and community service. Registration/licensing in any field of expertise in psychology will be an advantage.

The selected candidate is expected to assume duty in August 2014.

Consider joining our motivated and enthusiastic faculty members who believe they are making a difference in Macao and in the larger community of Asia. To discover more about the Department of Psychology visit the department website at http://www.umac.mo/psychology/

Position and Remuneration: Remuneration and appointment rank offered will be competitive and commensurate with the successful applicant's academic qualification, current position

and professional experience. The current local maximum income tax rate is 12% but is effectively around 5% - 7% after various discretionary exemptions.

Application Procedure: Applicants should visit http://www.umac.mo/vacancy for more details, and apply **ONLINE** at **Jobs@UM** (https://isw.umac.mo/recruitment) (Ref. No.: FSS/DPSY/FP/09/2014). Review of applications will commence on **October 1, 2013** and continue until the position is filled. Applicants may consider their applications not successful if they were not invited for an interview within three months of application. Other contact points are:

Human Resources Office
University of Macau, Av. Padre Tomás Pereira, Taipa, Macau
Website: https://isw.umac.mo/recruitment;
E-mail: vacancy@umac.mo
Tel: +853 8397 8593 or +853 8397 8592;
Fax: +853 8397 8694

The effective position and salary index are subject to the Personnel Statute of the University of Macau in force. The University of Macau reserves the right not to appoint a candidate. Applicants with less qualification and experience can be offered lower positions under special circumstances.

Personal data provided by applicants will be kept confidential and used for recruitment purpose only

Norway

Norwegian University of Science and Technology (Norway), Professor/Associate Professor in Developmental Psychology: The Department of Psychology at the Faculty of Social Sciences and Technology Management, Norwegian University of Science and Technology is announcing two permanent positions as Professor of Developmental Psychology, Associate Professor of Developmental Psychology, or temporary positions to qualify for Associate Professor of Developmental Psychology.

The Norwegian University of Science and Technology (NTNU) in Trondheim represents academic eminence in technology and the natural sciences as well as in other academic disciplines ranging from the social sciences, the arts, medicine, teacher education, architecture to fine art. Cross-disciplinary cooperation results in innovative breakthroughs and creative solutions with far-reaching social and economic impact.

For more information about the positions, see complete announcement at www.jobbnorge.no, position number SVT-1135.

Further information about the position is available by contacting Head of Department Magne Arve Flaten, phone 73 59 74 68, e-mail: magne.a.flaten@svt.ntnu.no, or head of office Tore Amundsen, phone 73 59 19 70, e-mail: tore.amundsen@svt.ntnu.no

An application including attachments should be sent electronically through: www.jobbnorge.no Mark the application SVT -1135.

Location: Trondheim, Norway

Application Deadline: November 24, 2013

Internal Number: SVT-1135

Russia

The National Research University Higher School of Economics (Moscow, Russia), Assistant Professor in Psychology: The Faculty of Psychology of the National Research University Higher School of Economics in Moscow, Russia invites applications for full-time, tenure-track positions of Assistant Professor, or higher, in all subfields, and notably in cognitive psychology.

The HSE is a young, dynamic, fast-growing Russian research university providing unique research opportunities (http://hse.ru/en and http://psy.hse.ru/en/).

Work Conditions:

- Internationally competitive compensation package, 13% flat income tax rate and other benefits
- Generous travel support and research grants provided by the university's Centre for Advanced Studies (www.cas.hse.ru)
- Low teaching load, minimal service required
- Heavy emphasis on high quality research

Requirements:

- Ph.D. in Cognitive psychology or related fields
- Fluent English (knowledge of Russian is not required)
- Ability and high motivation to conduct high-quality research publishable in reputable peer-reviewed journals and international university presses

Generally appointments will be made for an initial three-year period and upon successful completion of an interim review, contracts would normally be extended for a further three years until the tenure review.

Provide curriculum vitae, at least two letters of reference forwarded directly, a statement of research interest and a recent research paper. All materials should be addressed to Martin Gilman, Director, Centre for Advanced Studies at cas@hse.ru no later than December 18, 2013.

Saudi Arabia

King Fahd University of Petroleum & Minerals (Saudi Arabia), Assistant/Associate Professor Positions:

College of Applied & Supporting Studies
DEPARTMENT of GENERAL STUDIES

The Department of General Studies at *King Fahd University of Petroleum & Minerals* (KFUPM) in Dhahran, Saudi Arabia invites applications for full-time faculty positions with the rank of Assistant/Associate Professor in the following field:

Psychology

Applicants are expected to hold a Ph.D. degree with a strong commitment to research and teaching. Applicants are also expected to be proficient in English (spoken and written) as the language of instruction at KFUPM is English. Candidates with Middle East expertise and experience are encouraged to apply.

Salary and Benefits: These positions are full-time two-year renewable contracts with competitive tax free salary based on qualifications and experience, free furnished air-conditioned on-campus housing unit with free essential utilities and maintenance. Subject to University policy, the appointment includes the following additional benefits: Air ticket/s to Dammam on appointment; annual repatriation air tickets to Dammam for the faculty and up to three of his dependents; tuition fees for school-age dependent children enrolled in local schools; local transportation allowance; Two months' paid summer vacation, end-of service benefits, and free access to recreation facilities. KFUPM campus has a range of facilities including medical & dental clinic, teaching and research support facilities such as an extensive library acquisitions and library databases, computing facilities, smart classrooms, and research and teaching laboratories. The campus is within a very short distance from the cities of Dammam and Al-Khobar.

Review of applications will continue until the positions are filled.

To Apply: Send cover letter, updated/detailed curriculum vitae/resume, completed KFUPM application form with copies of credentials (academic degree/s & transcript/s) and three (3) signed reference/recommendation letters from your referees to:

Dean of Faculty & Personnel Affairs
DEPT. REF. No. DGS-PSY-141
KFUPM Box 5005, Dhahran 31261, Saudi Arabia
E-mail: *faculty@kfupm.edu.sa* **or** *c-gsd@kfupm.edu.sa*
Fax: +966-3-860-2429 or 860-2442

To download the KFUPM application form, click on the link

Quote DEPT. reference no. DGS-PSY-141 in your initial application
http://www.kfupm.edu.sa/fpa/serv/InfApplicFacPosi.mht

For more information, visit the following links:
KFUPM Web Site: http://www.kfupm.edu.sa
Deanship of Faculty & Personnel Affairs: http://www.kfupm.edu.sa/fpa

Application Deadline: Open until filled
Internal Number: DGS-PSY-141

Singapore

Nanyang Technological University (Singapore), Assistant Professor in Clinical/Health, Cognitive, Developmental or Forensic Psychology: The School of Humanities and Social Sciences at Nanyang Technological University (NTU), Singapore, invites qualified academics to apply for faculty positions as Assistant Professor in Clinical/Health, Cognitive, Developmental or Forensic Psychology.

Candidates should possess a Ph.D. in Psychology or in a closely related discipline. The areas of specialization include, but are not limited to clinical/health, cognitive, developmental or forensic Psychology. Candidates should possess strong research track records, including publications in international peer reviewed journals, and should demonstrate a commitment to effective teaching and administrative service. Interest in Asian cultures and languages is a plus. He or she is expected to have successfully completed the requirements for the Ph.D. degree and will be required to show evidence of potential for high-quality research. Relevant post-doctoral experience will be significant advantage.

The Division of Psychology in the School of Humanities and Social Sciences is a very cohesive group of research scholars. It was recently ranked number 38 in the world (http://www.topuniversities.com/university-rankings/university-subject-rankings/2013/psychology) and is enjoying a period of continued expansion. For further information about the Division, refer to the following website: http://psychology.hss.ntu.edu.sg/Pages/Home.aspx

To apply, refer to the Guidelines for Submitting an Application for Faculty Appointment (http://www.ntu.edu.sg/ohr/CareerOpportunities/SubmitanApplication/Pages/FacultyPositions.aspx) and e-mail your application package [consisting of a cover letter, curriculum vitae, personal particulars form, teaching and research statements, three selected reprint/preprints of publications, and the names and e-mail addresses of three potential referees] to: H-DPSY@ntu.edu.sg

Applications may also be submitted by regular mail to:

Head, Division of Psychology
School of Humanities and Social Sciences

Nanyang Technological University
14 Nanyang Drive
Singapore 637332

Review of applications will begin upon receipt and will continue until the positions are filled. Only shortlisted candidates will be notified.

Yale-NUS College (Singapore), Psychology Faculty: The newly established Yale-NUS College (www.yale-nus.edu.sg) in Singapore, a collaboration between the National University of Singapore (NUS) and Yale University, seeks to hire one or more psychologists in social, developmental, and/or abnormal/clinical psychology. The search is open with regard to rank. We are particularly interested in candidates who combine an active research agenda with interest in a collegiate liberal arts environment and a demonstrated commitment to creative and effective undergraduate teaching and mentoring.

In addition, the College seeks to hire two distinguished senior scholars to serve as the inaugural JY Pillay-Global Asia Professors of Social Science. We encourage applicants in any area of the Social Sciences including areas that can serve our majors in Global Affairs/Political Science, Economics, Psychology, Anthropology, Urban Studies, Environmental Studies, and Philosophy, Politics and Economics (PPE). Within these broad areas, we are open to sub-specialty.

Yale-NUS College seeks outstanding teacher-scholars, who are committed to innovative pedagogy and curriculum development, who are active researchers, and who enjoy closely mentoring students. Regardless of their field of specialization, candidates should be enthusiastic about contributing to an interdisciplinary common curriculum in the liberal arts.

Salary, benefits, and leave policies will be competitive at an international level. The College expects further rounds of hiring over the next few years as the student body increases. Yale-NUS College is committed to supporting faculty research through generous startup grants, annual research and travel budgets, and sabbatical leave.

For all general inquiries, contact yale-nus.college@yale.edu
Review of applications will begin November 15, 2013, and continue until the positions are filled.

The College values diversity and is committed to equality of opportunity. For additional information about Yale-NUS College and the faculty hiring process, including submission guidelines, and to apply, we invite you to our web site at: http://www.yale-nus.edu.sg/prospective-faculty.html

Turkey

Bilkent University (Ankara,Turkey), Chairperson of the Department of Psychology: The Faculty of Economics, Administrative and Social Sciences at Bilkent University is inviting applications for the position of Department Chair of Psychology. We are seeking a dynamic leader and scholar to facilitate the Psychology Department's vision in research and teaching. The Psychology Department is comprised of a rapidly growing team of international academics and currently has a strong focus on cognitive, developmental and social psychology. Bilkent University is committed to expanding the department into other domains in psychology and the chairperson will have an opportunity to shape the department for the future. Psychology Department faculty members are internationally-recognized scientists that have well-funded research programs and publish extensively in ISI-indexed journals. As well as publishing in high-impact journals, Bilkent University expects faculty to perform superior teaching and mentoring for undergraduate students. Thus, the Psychology Department faculty members are dedicated to excellence in teaching in addition to their successful research programs. Bilkent University, located in Ankara, the capital city of Turkey, is a leading private research institution and the language of teaching is English.

Responsibilities and Qualifications: The Chairperson should build upon the department's vision of excellence in research and teaching. Additional key responsibilities include budget administration and management, faculty development and evaluation, and general management of the department. Moreover, the candidate must actively help expand the department and develop the post-graduate program, which is planned to be opened in the near future. Successful candidates will be internationally-recognized scholars with a history of excellence in research and teaching, as well as administrative experience. Candidates must have a Ph.D. or equivalent degree in Psychology and hold the rank of Full or Associate Professor, as well as a strong track record in research as evidenced by the quality of publications and success in obtaining research grants.

Appointment and Application Procedure: The appointment for the Department Chairperson is a 12-month position and the salary for this position is commensurate with qualifications and experience. Bilkent University faculty are offered rent-free housing and various other benefits including private health insurance. Inquiries should be directed to Prof. Dilek Önkal, Dean of the Faculty of Economics, Administrative and Social Sciences (onkal@bilkent.edu.tr). Applications should include a letter of interest describing qualifications, a personal statement of leadership skills and experience, curriculum vitae, and names of three references. Application materials should be sent electronically to Executive Secretary Eser Berkel Sunar (sunar@bilkent.edu.tr). Review of applications will begin immediately and continue until the position is filled. For more information about the Psychology Department and Bilkent University visit the websites for the Department (http://www.psy.bilkent.edu.tr/), Faculty of Economics, Administrative, and Social Sciences (http://feass.bilkent.edu.tr/) and the University (http://

www.bilkent.edu.tr/).

United Arab Emirates

New York University Abu Dhabi (UAE), Faculty Positions in Sociology, Social Research, and Public Policy: New York University has established itself as a Global Network University, a multi-site, organically connected network encompassing key global cities and idea capitals. The network has three degree-granting campuses—New York, Shanghai, and Abu Dhabi—complemented by 12 additional academic centers across five continents. Faculty and students will circulate within the network in pursuit of common research interests and cross-cultural, interdisciplinary endeavors, both local and global.

Entering its fourth year, NYU Abu Dhabi has recruited a cohort of faculty who are at once distinguished in their research and teaching. Our students are drawn from around the world and surpass all traditional recruitment benchmarks, both US and global. NYU Abu Dhabi's highly selective liberal arts enterprise is complemented by an institute for advanced research, sponsoring cutting-edge projects across the Arts, Humanities, Social Sciences, and Physical and Engineering Sciences.

NYU Abu Dhabi is currently inviting applications for faculty positions at any level (assistant, associate or full professor) for appointment to its program in Social Research and Public Policy. One opening at the Full Professor level is for the Foundation Chair of the Department of Sociology and Public Policy; we seek a distinguished senior scholar who will also assume a leadership role in the program. For the positions at all levels, we encourage applications from candidates with outstanding teaching and research records across the social sciences (Sociology, Demography, Political Science, Economics, Social Psychology, Public Policy). We will consider applications from all areas of theoretically-informed policy-relevant social research, including urban studies, immigration, public health, organizations, and inequality.

You may visit the Social Research and Public Policy Program's website for a description of its innovative curriculum: http://nyuad.nyu.edu/academics/undergraduate-programs/majors/social-research-and-public-policy.html

The terms of employment are competitive and include housing and educational subsidies for children. Faculty may also spend time at NYU New York and other sites of the global network, engaging in both research and teaching opportunities. The appointment might begin as soon as September 1, 2014, or could be delayed until September 1, 2015.

The review of applications is underway, and will continue until the positions are filled. To be considered, applicants need to submit curriculum vitae, statement of research and teaching interests, representative publications and three letters of reference in PDF format. Visit our website at http://nyuad.nyu.edu/about/careers/faculty-positions.html for instructions and other information on how to apply. If you have any questions, e-mail nyuad.socialscience@nyu.edu

NYU Abu Dhabi is an Equal Opportunity/Affirmative Action Employer.

Internal Number: NY98090

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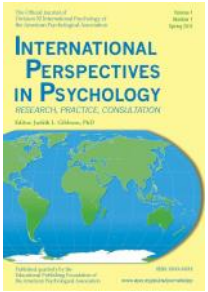

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PART B: INTERNATIONAL UNDERSTANDING

ICP RESEARCH AND INTEREST GROUPS

International Understanding (IU) is the name given to ICP, Inc.'s first publication of papers and research by members to the larger psychological community at national and international conferences, conventions and congresses. ICP members first published the IU in 1962-63. It merged with the ICP newsletter, the *INTERNATIONAL PSYCHOLOGIST*, in 1966.

Until 1970, ICP members met and read papers in conjunction with each annual meeting of the American Psychological Association (APA). ICP continues to meet annually during the APA convention and co-sponsors the International Reception for international visitors with APA International Affairs CIRP committee and the APA Division of International Psychology (Div.52).

A 2010 initiative reactivated IU to enable those who cannot attend annual conferences to be informed about the research and interests of ICP members. IU's purpose is to fill a void in association benefits that came about when the ICP journal, *WORLD PSYCHOLOGY*, was unable to continue into the 21st century.

The millennium transition to electronic communications and "global psychology" resulted in a proliferation of international associations and journals. In the wake of the rush into worldwide economics, knowledge, and resources, ICP maintained a person-to-person, face-to-face value-centered general psychology orientation with a strong commitment to honoring peace/wellbeing and human rights of, by and for all peoples.

We hope that you will enjoy the papers and information presented here that are too long for our regular quarterly newsletter format, and would not be well-served by minimization.

Best wishes to all!

Ann Marie O'Roark, Ph.D.
Editor, International Psychologist

Ten Strategies for Psychology Instructors to Internationalize Their Courses

by
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Introduction

Psychology, as a discipline, is undergoing a transformation that will inevitably make it more international; therefore, it is important to determine how to internationalize the way psychology is taught to students. Psychology instructors play a central role in this endeavor, and many are exploring ways to effectively infuse international content in their courses through student classroom experience. Given the steady influx of people from abroad, our international travels, and interactions with others from various countries, it is crucial that our students are prepared to function effectively in an increasingly global society… to become global citizens. Certainly, there is a need for educational institutions to prepare their students for such a world, for them to be able to communicate and work with each other, and learn how to accommodate changes brought forth by a society that is progressively becoming more global. Proposed here are ten strategies that can be useful to instructors seeking to internationalize their courses. The order in which these strategies are presented is based, presumably, on the extent in which it may be feasible to implement in a course - from the least feasible to the most feasible. Combining any number of these suggested strategies can potentially make efforts to internationalize a psychology course more effective.

#10: Establish a relationship with an international university

Instructors can establish a relationship with an international university that has a psychology department.

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This relationship can be made through an instructor's professional network, such as an affiliation with an international psychology organization or group. By doing so, students have the opportunity to connect with each other and discuss their academic and/or research interests. This may also expand student and instructor access to resources that would otherwise be unknown to them. Lutsky et al (2005) suggest that connecting with others abroad may help students recognize demographic, socio-cultural, economic, political, religious, ethnic, and other potential sources of variability in psychological phenomena. The idea is to have students in different regions across the world communicate and provide feedback among each other in a context by which psychological constructs are presented and discussed. By receiving feedback from the students and instructors abroad, instructors are in a position to foster better understanding of perspective about psychology and world views about psychological phenomena. Lutsky et al (2005) indicated that familiarity with international approaches and practices may also enrich students' understanding of Psychology and help them become more aware of the assumptions, they bring to Psychology.

Similarly, the instructor also gains from receiving feedback from students from other cultures, allowing him/her ways to tailor strategies that best complement communication and collaboration between students from different cultures (Lutsky et al, 2005; Stevens, 2007). One example of implementing this strategy is to have a faculty member from different countries agree to bring their students and have them meet at an international psychology conference for an informal meet-and-greet event. A less-expensive alternative is to have their students interact with each other via the Internet, perhaps through videoconferencing or through correspondences via various forms of social media (e.g., Facebook, Twitter). Students can collaborate on papers or perhaps work on projects that they may present at the end of the course or even in conferences.

A relationship with other international universities may be established through inter-university faculty exchanges, international psychology scholarship and grants. For instance, the Fulbright student scholarship program may facilitate the internationalization of the psychology course at both the undergraduate and graduate levels. Beneficiaries of this scholarship are exposed to different studying and learning opportunities abroad and in addition to the regular psychology curriculum, the students benefit from extensive practicum and teaching experience. Inter-university collaborations in research and learning between universities provide for better internationalization of psychology curricula as colleagues, students and institutions are better placed and share varied knowledge and perspectives.

#9: Encourage students to join organizations and attend psychology conferences.

Students can have a better understanding of psychology as an international discipline if they experience attending a psychology conference. Many U.S.-based psychology organizations with many student members [e.g., Psi Chi (The International Honors Society in Psychology), APAGS (American Psychological Association of Graduate Students), Psi Beta (The National Honors Society in Psychology for Community and Junior Colleges)] sponsor talks that highlight psychologists' international experiences and knowledge as it relates to their areas of expertise. International psychology organizations such [e.g., The International Division of the American Psychological Association (Division 52); International Council of Psychologists (ICP)], can be requested to recommend speakers that highlight and/or promote international psychology. According to Takooshian and Stambaugh (2007) there are roughly 200 cross-national psychology organizations that fall into four major categories: national, regional, specialty, and student. Although these 200 groups are largely independent of one another, they all share a mission to globalize psychology in distinct ways.

Many, if not all, have members (who are foreign-born, have interests in international and cross-cultural research in psychology or have taught abroad) who would be willing to be guest speakers in class. Similarly, instructors may encourage (or even require) students to attend talks at various conferences that focus on cross-national research on global issues relevant to psychologists. Exposing students to such talks may also encourage them to join these organizations. According to Hogan and Vaccaro (2007), one of the most effective ways to share information about psychology across nations has been through face-to-face encounters in forums provided by such groups. These encounters include formal presentations at meetings as well as fewer formal social gatherings. Both types of situations present enormous opportunities for learning about psychology in other countries. The participation in several diverse organizations helps increase one's multicultural awareness.

Educational institutions and other psychology professional psychology groups may opt to offer incentives to psychology students and members from the faculty who attend international conferences or join psychology organizations. For faculty, this helps towards their professional development, tenure and promotion. Universities may help

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students to reach out to international psychology groups and organizations that are important in expanding institutional objectives to prepare students to become better global citizens. Encouragement and support from professional bodies and organizations (e.g., APS, APA, Psi Chi, and SIOP) are also critical in broadening the scope of psychology education.

#8: Offer an elective course in Global Psychology.

In order to offer a course in Global Psychology (or International Psychology), the course must be implemented appropriately and taught effectively with the endorsement of the psychology department and curriculum. When it comes to educating and training an instructor in teaching such a course, Marsella (2007) suggests that psychology departments in universities must emphasize three components: person, philosophy, as well as process and content. An instructor must understand that there are a variety of cultures and that these cultures have distinctive ideals and principles. Knowing this, the instructor should be open-minded and accepting of other ways of teaching and communicating with students from different backgrounds. Marsella (2007) believes that in this global age, psychologists must live their profession; and their profession must be an integral part of their lives, an extension of what they value and are willing to commit themselves to, in order to find purpose, meaning, and fulfillment. Understanding a person's beliefs, their culture and history behind them are essential in determining how an instructor will educate the students in a Global Psychology course. Spariosu (2004) is optimistic in addressing global challenges through education. He believes that the emphasis on values, content, and the processes that are rooted within an increased awareness of the global context of our lives will create possibilities for a peaceful, just, and harmonious future.

Thus, offering a global psychology course will allow for the exploration and promotion of different psychological theories, and an appreciation that these different perspectives may be viewed differently in different countries or world regions. Instructors may become involved in liaising with publishers to create and increase international content in psychology textbooks. In addition, students may take part in international practicum experiences, such as working in refugee camps on unpaid internships.

#7: Collaborate with multicultural groups in the university that are outside the Psychology department.

Collaborating with multicultural groups within the university to promote cultural events in the Psychology department can be effective in spreading multicultural and international awareness. Ho, Bulman-Fleming, and Mitchell (2003) suggest that multicultural groups allow students to learn how to communicate, interact, and solve problems with people from other cultures, and also allow students to learn from the course material from other perspectives. Ho et al. (2003) mentioned that focus groups in the University of Waterloo reported that multicultural group work is an excellent way to learn from and learn about students with different cultural experiences. More specifically, these students felt that this type of small-group learning is effective for idea-sharing and the facilitation of opportunities for students to learn from other cultures and to learn how to communicate with people from other countries. Furthermore, Boehringer (2002) pointed out that this type of interaction also provides the students with the skills to communicate and understand people from various backgrounds. The incorporation of monthly or bimonthly workshops that focus on different cultures and non-western psychological theories is an effective way to promote multicultural group participation and awareness. By enhancing the integration and collaboration of multicultural groups, students are able to appreciate, celebrate and recognize the missions and contribution to international organizations. Arrangements between multicultural groups outside the university that are outside the psychology department can be an interesting course activity that allows students to discuss about with non-U.S. students about various topics in a psychology course.

#6: Work with professors currently working on international research.

Encouraging students to work with a psychology instructor who is currently working on international research is another strategy that promotes the internationalization of psychology. Searight, Ratwik, and Smith (2010) view this as an opportunity for the integration of coursework and allows for inquiry that is specific to a particular discipline. Evaluations of student involvement in curricular projects have found that they positively impact students' knowledge and skills in that discipline. Students who work with professors can spread information about such ongoing international research and can also encourage other students to become involved in it. This can potentially encourage student participation at conferences, events, and promote multicultural and global issues.

An example of student-professor collaboration involves distributing surveys (or conducting interviews) from population sources that are culturally diverse. Having a student obtain data one way (i.e., survey distribution and/

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or conduct interviews) while the instructor obtains data in other ways (i.e., provide existing data and/or multicultural resources), will not only allow for more efficient statistical data collection, but the student will be more motivated to spread the word of multiculturalism and how important it is to the community as well. The collaboration of students with professors conducting international psychological research is a huge opportunity for both the students and the faculty to experience firsthand diverse cultures. If students do not have the opportunity to work directly with international psychologists at their university, the faculty may encourage students in various ways (i.e., extra credit) to use and cite international literature on potential research conducted by certain professors.

#5: Create an online social media group.

Another strategy to help in internationalizing psychology is to create a university psychology group via social media as a means to discuss international issues relevant to a psychology course. As Velayo (2011) indicates, students tend to be relatively more comfortable and more engaged with new technologies than their instructors. Technology-savvy students can be wonderful allies to help instructors learn ways to use these technologies in their courses. Students may serve as collaborators to integrate such technologies in ways they think may be most engaging to their peers. There are a range of benefits when an instructor creates groups in a Facebook account, a twitter account, or a blog, specifically for the class. This will allow students to check their group page and engage in online discussions. In turn, sending information to students via social media will spread news and events related to global psychology quickly and efficiently. In addition to the students, the instructor will be able to share their most current research interests and pursuits easily with the tech-savvy generation, especially since the majority of students have active Facebook's accounts.

One group that exemplifies the benefits of using social media as a networking tool is the Facebook group for "American Psychological Association of Graduate Students (APAGS)," which is officially sanctioned by professional organizations and provides valuable information for trainees (Myers et al., 2012). The APAGS group post information online that includes psychology-related discussions, such as transitioning from a student to licensed practitioner, information related to postdoctoral positions, and tips for obtaining research funding. In addition, the general aspect of blog-writing can increase class participation outside of a classroom setting. For example, if an instructor were to set up a blog journal entry on a cultural issue or cultural belief, this creates the opportunity for an open discussion among the students and to provide/receive feedback to others. It is an effective and convenient way for students to share their experiences.

In regard to utilizing one of the most popular forms of social media, Facebook, to benefit international psychology, an instructor can create a Facebook page that only pertains to the field of psychology (research work, facts, etc.) where students can log in and post comments and interact with other psychology students in other countries. Students can also use Facebook to aid their adding a cross-cultural dimension to their research; in which those who need to distribute surveys for their research can easily acquire the data online from the millions of Facebook users from all over the world who are willing to participate. The instructor can also use special features in Google groups or LinkedIn to create restrictions where only psychology students can access the site and obtain information related to the field. For example, a topic on developmental psychology can be started in a Facebook community page where users from various cultures can comment. This is another convenient way to broaden our scope of various cultures.

#4: Show relevant videos.

Having instructors implement the use of online videos that depict international or cross-cultural differences in class for students to understand diversity can help to internationalize the curriculum. Mays, Rubin, Sabourin, and Walker (1996) pointed out that the United States is increasingly becoming internationalized as a result of the development of better communication devices, connecting larger and smaller, lesser-known countries. Velayo (2011) indicates that not only do these technologies allow for greater and faster communication between psychologists and students residing in different nations and different regions within a country, but they also provide for greater cross-national understanding, increased curricular and scholarly collaborations, and an enhanced level of experience that goes beyond just reading about another culture. The idea of using technology as a means of internationalizing the teaching of Psychology will serve as a key component in how to internationalize the discipline of psychology. Through the use of online-based videos, instructors will be able to show supplemental videos, which will contribute to understanding of other beliefs in an international point of view.

You Tube is a great multimedia tool that communicates effectively with millions of people through video, and may be accessed anytime. You Tube videos can also

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originate from non-U.S. sources and an instructor may present constructs relevant from such videos for class discussion. More specifically, Instructors are able to show students videos from all over the world, such as interviews from different psychologists and points of views. This helps students become more aware of psychological perspectives from cultures and/or countries beyond their own. In a History of Psychology class, for example, the speaker or instructor may use videos to show students a virtual tour of a related historical site, or display an archival collection of psychological things that are relevant for the class. Furthermore, in a cross-cultural psychology class, videos that display family dynamics in various countries can be informative to other cultures and help to spread multicultural awareness.

#3: In-class group discussions on personal experiences.

Universities in the U.S. tend to be demographically diverse and there may be students from a variety of cultures in any given classroom, who may share their own unique experiences with other students in the class. Generally, the in-class discussions of one's travels can also provide an opportunity for discussion of such experiences. Ho et al. (2003) suggest that facilitating critical in-class discussion and encouraging students with different international and cultural perspectives is a straightforward and relatively simple way to draw upon student experiences. The instructor may initiate a multicultural discussion and to encourage students from other countries or cultures to share their thoughts and opinions Bond, Qian, and Huang (2003) state that many instructors attempt to include diverse perspectives in class discussions, but that it may be difficult, using only visual cues, to identify students from a different cultural background or who have traveled abroad.

Therefore, it is important to get to know students' backgrounds, to be a proponent of diversity, and to establish rapport with the students in order to encourage participation and a civil exchange of ideas. The best way to explore one's background might be to have students complete an assignment on the first day of class indicating their personal cultural background and to discuss any international experiences abroad. They can include in this assignment a brief history of their family and origin. In addition, it is important to note whether any of their family members currently live abroad and the comparison of those members' experiences overseas to their own in the United States. By encouraging everyone to participate in the discussion of their cultural background and experiences, either through their travels abroad or familial history peers and faculty will reach a better understanding of each other. It will also provide more of an understanding among each other with regards to the differences in cultural beliefs.

From such a personal assignment, the instructor can choose several international students who have suffered from a common condition, say depression at one point, or a member of their family has suffered from depression. Given the topic of depression, they can all share with the entire class how they coped with the situation, what caused it, and what measures they took to avoid going back to a similar state. Since one issue will be discussed by various students with diverse backgrounds, students can compare and see the similarities and differences of how different cultures handle a similar issue.

#2: Encourage international students to be guest speakers.

Given that much of the content in textbooks (e.g., cited research, theory) is from authors in Western countries, particularly from the United States and those from Western Europe. It would be interesting to have someone with enough background about another country, share their thoughts about how constructs presented in class applies (or does not apply) to other nations or cultures abroad. There are psychological theories and phenomenon that are taught in one's country of origin, that may be considerably different (or similar) from how Western psychologists view them. Thus, one relatively easy and effective strategy that can be used to internationalize a psychology course is to encourage international students to volunteer as guest speakers in the classroom (or in conferences) to talk about their experiences in their own countries within the context of the course material. Having international students share their experiences can help promote students' more international perspective on the way they view and critically think about course material presented to them.

Having international students and domestic students speak and discuss with each other cross-cultural and cross-national variations in terms of how psychological constructs are perceived can be a very interesting way to see the differing perspectives in which students view such constructs in the context of their own culture. Moreover, having students do such presentations in class allows them to gain presentation experience, and to learn about an aspect of the course material from a unique point of view (Pickert and Turlington 1992; Schoorman 2000). During such discussions, students who have studied or lived abroad can elaborate on similar or differing experiences

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that occur in comparison to their own country. For instance, on the topic of how culture influences suicide patterns in the society, a student from China can illustrate how factors that influence suicide are the same or different in relation to other societies. Encouraging a student to talk about their experiences not only caters to an increased level of willingness to share, but it will serve as a more enriching experience to non-native listeners as well.

While it can be a good idea as instructors to ask students to participate as guest speakers, it is important to note that sometimes there are many factors that play a role into what possibly will lead the student to refuse to be a guest speaker. Ho et al. (2003) noted that although students from the University of Waterloo focus groups were generally very eager to participate as guest speakers, and cited increased experience in presentation skills and cultural sharing as main motivations for serving in this capacity, several international students cited language difficulties as a potential barrier in volunteering to be a guest lecturer. On the other hand, they also acknowledged that public speaking would help their communication skills. Ultimately, language difficulties may be a potential barrier, but having other non-international students initially present as guest speakers can easily reduce the anxiety that international students may experience.

#1: Dedicate a class meeting to discuss what international psychology is.

Devoting at least one class period to discussing the relevance of international psychology and what it is can be effective. One example of how this can function well is by selecting a topic within that course and relating it to an issue with global significance. For example, discussing the psychological effects of the Tsunami that occurred in Southern Asia and how it may have affected other regions around the world indirectly may trigger an interesting class discussion about the extent to which people around the world are interconnected. Such a discussion may provoke students to share their own experiences in light of universal events. Before the meeting, the instructor can ask the students to think of various events or situations that exist on a global scale and have affected people psychologically in one way or another. Such an idea can trigger further ideas from students, which could be encouraged for discussion in class. This will be a good starting point for the introductory meeting because you will use what the students know to make them see the universality of psychological issues. The instructor can also present a question to trigger debate at the meeting. For instance, a good question could be, "From a psychological perspective, how did the 9/11 terrorist attacks in the United States affect the world? And how can you compare the effects of these attacks to those in other countries like Israel?" In general, a question related to international psychology that spurs on debate, and discussion is encouraged to generate activity in the classroom.

Conclusion

The American Psychological Association has over the years, prioritized on initiatives and strategies that instructors and learners can adopt to internationalize the psychology curriculum. In addition, many colleges and universities have reverberated similar initiatives as reflected in their mission aimed at offering students the kind of educational experience that prepares them to competently work and function in a more globalized society. As students plan to work and live in a multicultural and global society, it is expected that the curriculum will provide them with the necessary tools and knowledge to fast track their transformation into culturally and globally competent citizens.

Many psychology students may not have the privilege to work or study abroad and therefore, the internationalization of a course is important to all students to develop international knowledge and multicultural awareness. In addition to establishing relationships with other international universities, institutions of higher education should encourage their students and the faculty to join psychology organizations and attend international conferences. There is a long listing of germane resources to assist instructors to internationalize their courses such as collaborations with other multicultural groups outside the psychology department, working with psychology instructors on international research, facilitating learning, and relevant psychological knowledge through social media platforms and even Internet-based videos.

Instructors should be open to examine and carefully assess the effectiveness of the strategies, they use to internationalize their courses and to see which strategy or strategies work best for them and their students. Obtaining students' feedback through student–led discussions and forums is one of the effective ways of assessing the level of "international perspective" and awareness they have gained from the course (Stevens, 2007). Through interfaculty exchanges and collaborations, instructors may share teaching strategies that they deem efficient in helping to internationalize their psychology course. This also promotes the sharing of perspectives between institutions, students, and colleagues.

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Preparedness, Impact, and Coping: Lessons from Hurricane Sandy
by Dr. Ani Kalayjian

Production Editor's Note: An excerpt of this paper was published in the IP 52.4. Here it is presented in it's entirety, as promised. N. Quatrano

While the media was obsessively warning people about the importance of getting ready for Hurricane Sandy, I observed mixed behaviors around me. This was going to be a category 1 hurricane, a 300-mile-long swath of devastation packing 90 mph winds starting from Virginia and stretching all the way to New England. In the wake of the destruction, Sandy claimed the lives of many in New York and Long Island, destroyed significant properties such as houses and cars, resulted in power outages affecting millions, left debris and devastation galore, and portions of our infrastructure and many businesses are crippled. Recovery will be a slow, arduous process.

Meaningfulworld had scheduled an autumn-foliage hot air balloon ride for Sunday morning, and we rescheduled it to Saturday instead. In spite of all the concerns, fears, and

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threats of inclement weather, we were able to fly and had a great time. Even then our discussions turned to subjects such as how the youth will be able to cope with no electricity for a week to 10 days. Would they able to converse, play cards, read a book, or just tell stories around candlelight?? Many have told us that they could not imagine life without the Internet, let alone without electricity.
The Hurricane did strike as strongly as they expected in the South Jersey area. In Northern New Jersey we received a hard hit with high winds, but not as much rain as forecasters expected. We had actually placed empty containers in our garden to collect the rainwater for flushing toilets, but there was only about 2 inches of rain. Mostly we experienced high winds, lots of trees falling, electrical poles down, trash cans flying, as well as the foliage swirling and piling up all around. I am grateful for what we had, as I am not sure we are able to cope with any catastrophes in our area. First, we have no evacuation plan nor evacuation route; second, we do not conduct any emergency- evacuation drills, and third, we are not ready emotionally, as well as practically.

It was so interesting to observe people's reactions to the preparation phase of the Hurricane. People were in these three categories:

A. Those who obsessively over-bought everything they needed or did not even need – Such as a trunk full of batteries, even for sizes that they had no need of like AAA. They bought groceries and blankets and left the shelves at the supermarket totally bare.

B. Those who did absolutely nothing, reassuring themselves that in fact we had never had a category 1 hurricane, and that it would be a light storm and nothing to worry about. They reasoned along the lines that we had never had a hurricane except the past year's Hurricane Irene, which was not so bad, and we still had electricity in our area.

C. Those who put all their kids in their vehicles and drove away, some to Florida, some to Arkansas, others to the Catskills or wherever they could run away to and still have electricity and daily comfort.

Group B then began panicking after Monday night, when in fact the hurricane hit so hard, from Cape May, Sandy Hook, all the way up north to Connecticut, that it flooded coastal areas, ripping electrical posts as well as 100-year-old trees from their roots, killing some people in their own bedroom while they were watching TV, as others were washed out along the shore. Pieces of beach boardwalks were found 10 blocks inland, and hospitals by the Hudson and East Rivers had to be evacuated both in New York and New Jersey. This group embarked on a search spree for a generator, gasoline, batteries, and candles, now paying double prices for all. The lines for to buy generators comprised more than 100 people; they were punctuated by fights erupting here and there, and the waiting list was up to 500 people in the Home Depot in Paramus. In other stores they promised that they would have generators, asked for pre-payment, and told buyers to return the next morning at 5 A.M. after waiting on the queue for over four hours. The next morning they walk up at 5 A.M. and wait on long lines again, only to be told to return in the afternoon, and in the afternoon they were told the truck was held up in the hurricane aftermath in Virginia.

While some of them were waiting for generators, other family members were waiting for gas, since the generator won't run without gasoline. Gas stations were closed from Bergen County all the way down south in Hudson County. Even at my friend's gas station, although it had gasoline, the police had placed barricades and told us that the remaining gasoline was for the police and emergencies. Then they received word that there was some gas in North Bergen so everyone rushed over there, only to find 50 people on line and another 50 cars as well wrapped around four city blocks. In this panic, Group B was driving recklessly, cursing their luck, and wishing that they had paid attention and gotten ready BEFORE the hurricane.

Those few who were fortunate enough to still have electricity were diligently sending text messages and inviting their friends to come and have a hot shower, charge their phones and laptops, and drink some hot tea. This invitation was so appreciated. Without communication it is difficult to know how your loved ones are doing, if they need help, etc. I was so happy when my friend texted me with an invitation, I hustled over to Ridgefield to charge my phone and four other phones. When I got there she was glued to the news, and I got sucked into watching it as the

Examples of destruction in our area, and people waiting on lines for 5-10 hours for gasoline.

TV were a magnet. I saw eyewitnesses from Seaside Heights crying while describing what they have witnessed and experienced. There was no longer a boardwalk, and there was extreme helplessness, despair, and resignation in their expressions. "You build for years and then in two

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hours everything is gone, destroyed, transformed into a pile of debris and sand."

Though disasters differ in their intensity, impact, and experience, my research finds these are universal reactions to disasters (Kalayjian, 1995):

1.**Shock and disbelief.** In stage one of a trauma, survivors are in shock – emotionally numb, and in some cases in denial because the pain is too severe for any human to bear. Many people expressed thoughts such as, "It was surreal, like a nightmare."

2.**Strong emotional response**. In the second stage, the survivor is emotionally aware of the problem and feels overwhelmed and unable to cope with it.

Common Reactions in Children: 1. separation anxiety; 2. refusing to sleep or be left alone; 3. disorderly conduct; 4. regressive behaviors (thumb sucking, wetting the bed, clingy behavior); 5. hyperactivity; 6. withdrawal; 7. somatic complaints (stomachache, headache, joint aches, etc.); 8. sleep disturbances.

It is recommended that parents maintain calmness, compassion, and patience. If you are calm, open to questions, and focus on the facts, you can ease the anxiety of children who are worried about the storm. Once again, please turn off that TV, you will be traumatizing your children.

Common Reactions in Adolescents: 1. withdrawal; 2. anger; 3. increased aggression; 4. regression; 5. sleep disturbances and nightmares; 6. increased daydreaming; 7. inability to concentrate; 8. irritability; 9. drug use and addiction.

Destruction in my gratitude garden

Common Reactions in Adults: 1. uncertainty and fear; 2. anger expressed toward builders and government officials; 3. feeling tense, edgy and jumpy; 4. loss of appetite; 5. sleep disturbances and nightmares; 6. withdrawal; 7. loss of concentration; 8. inability to make decisions; 9. aggression (domestic violence, increased alcohol/drug use, etc.).

3.Acceptance. In this stage the survivor begins to accept the magnitude of the disaster and makes an appropriate effort to address it. Survivors feel more hopeful and goal-oriented. At this time survivors may take more specific actions to help themselves and their families. Many of us are not yet at this stage.

4.Recovery. Last but not least, is the recovery stage, in which survivors feel they have returned to their pre-disaster level of functioning. A sense of adjustment and well- being is restored, and realistic memories of the traumatic experience are developed.

I began helping people in my neighborhood; some needed gasoline, and others needed candles or batteries. While driving through the streets in Bergen and Hudson Counties in New Jersey, where the traffic lights were not functioning, there were once again three types of drivers:

a. Those who just drove through, as if they had the green light, without consideration for others;

b. Those who stopped for a long time and let everyone else drive through while frustrated motorists piled up behind them;

c. Those who stopped, got out, helped direct the traffic, helped others, and helped the elderly cross the street safely.

We at home welcomed Hurricane Sandy with a potluck dinner and live music. My friends, who live nearby, gathered around, ate, played the guitar and the accordion as others sang and joined in with percussion. I remembered the Armenian song, "I don't care about palaces, caviar, and diamonds – my best friends are priceless jewels for me."

We created joy within and released it and expressed it to one another, multiplying the joy, and it was amazing. It reminded me of our Meaningfulworld motto: "Shared sorrow is half sorrow, while shared joy is double joy."

In the morning it was unbelievable to witness the extent of the damage. It reminded me of Hurricane Andrew in Southern Florida in 1992, where we went to help. There as well, many people didn't evacuate, thinking it would not be a strong hurricane and then were left devastated. I would not recommend complacency, denial, or disbelieve as one never knows how strong and how long a hurricane will impact a region. Have you ever wondered why they call it the "weather"? Well, because we never know with certainty "whether" it's going to rain, how hard it's going to rain, or how many inches of rain we will get. Meteorologists are the only professionals who are respected even when they change their mind constantly, and even if they are wrong.

In these difficult days, I was pleasantly surprised to receive calls of concern from friends, colleagues, and family from around the world: Pakistan, Armenia, California,

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Syria, Germany, England, Virginia, and more. It was refreshing to feel that people cared, not only nationally but internationally.

Though we had no electricity, it was so enlightening to feel the serenity after seven when everything was dark – no electricity, no computers, no appliances running. The darkness silenced people, as they began whispering, slowing down, staying indoors, even altering their circadian rhythm (our inner biological clock). I noticed people went to sleep earlier and woke up earlier with the sunrise. We had no desktops, laptops, BlackBerries, Bluetooth, Kindles, iPads, iPhones (or other cellular phones), pagers, or faxes. Until, of course, the generators began polluting the air with their exhaust and harsh sound.

Instead we had iHeal, and we used our inner skills to entertain ourselves. We planned events with one another (those in proximity) such as walks, and while walking we helped people in need in our neighborhood; we did yoga with friends, we gathered around candles and told jokes and stories. We stayed calm, meditating and praying. Of course without electricity we could not watch TV, which was a blessing. Others were glued to their TV sets, bearing witness to the media sensationalizing all the atrocities, crying, and getting more and more upset with each news story and eyewitness account.

Kids and teenagers were not functioning well without their electrical and Internet-enabled gadgets. They could not fathom life without electricity. I sat a few of them down and had generational storytelling nights, explaining to them how people in the past lived this way, with no electricity, refrigerators, or computers. I also told them how in Africa and other countries of the developing world the people still live without the comforts by which we are spoiled. The youth have lost their ability to converse and tell a story or a joke. They were depressed and had cabin fever. They also realized that they had not learned any phone numbers by heart – even family members could not call one another because their phones had lost battery power and they could not remember any phone numbers to call from someone else's phone. They kept on repeating, "I cannot live another day without my phone and the Internet."

This was an incredible educational experience for us all, individually, within families, community wide, as well as on the state and federal level. How many times have articles been written indicating that New York City is not ready for any natural disasters, but no one, including government officials, had incorporated this as a priority for planning. Planning does not start four days before a hurricane – it starts today, and it continues until there is a disaster pending.

Now, five days after the devastation, we are faced with the challenges of cleaning up, putting things in order, getting rid of all the spoiled perishable food, dealing with thousands of unread e-mails, and informing concerned communities nationally and internationally about the ordeal we faced. Sometimes I found myself not answering phone calls, because I had no energy left to repeat the same observations. Then I said to myself, why don't you write, and then you can e-mail it to them?

The most challenging issue at this time, besides the financial loss, is the emotional drain: a week of fear, suspense, threats, and orders to fulfill, then three days of being battered by fierce winds and further terrorized by shaking buildings, apartments, walls, and roofs, as well as losing daily comforts such as showers, heat, phone, and Internet access. By the way, our rehabilitation programs in Africa, Haiti, and the Middle East, helped me tremendously to cope with these daily discomforts. Now we are literally trying to warm ourselves, wash off the dirt, leaves, and sewage, and moving on having learned valuable lessons.

While the Global Fever has pulled our comfort away, destroyed our beaches and structures that have stood for centuries, we are resilient and we will always rebuild, start over again. Yes, governors, mayors, and emergency rescue officials are reassuring us that we will rebuild, better than before, but the sad reality is that it will not be the same, it will not have the memories and energies of lovers hugging around the trees, carving in their initials with a heart around it to show how much they loved each other. We need time to mourn for all these losses, if we are sad we need to express that and even cry if we feel like it. Expression of sad or negative feelings is very important, especially when it is followed by validation and then lessons learned (as indicated in the 7-step Integrative Healing Model [Kalayjian, A. 1990, 2002, 2012]). It is very important to reach out and be with your loved ones, family, friends, neighbors – anyone you feel comfortable with and free to be yourself around.

In the end it is important to learn the lessons, discover a new meaning, or recover a refreshing point of view. I learned to be mindful and help others prepare better, even if they get upset with me. What is your lesson?? Share it with us, your lessons will be useful guidance and enlightenment for those who are seeking to make sense but are lost in their fear and anxiety-provoking thoughts.

In addition, we cannot drive anywhere because we have a gasoline shortage. We must drive from town to town, and if we're lucky wait five hours for a few gallons of gasoline for our vehicles or generators. We cannot drive

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to work to New York as we must have three people in the vehicle, and tunnels and several bridges are closed (only the Lincoln Tunnel is open at times).

The wounds are fresh, so we are all making sense of the disaster, searching to find our feelings, being grateful, patient, and compassionate. "That which does not kill us makes us stronger," said the philosopher Friederich Nietzsche.

Although I have worked in the field of disaster relief,

preparedness, recovery, and rehabilitation since 1988, I echo what Socrates said:

Whatever authority I may have, Rests solely on knowing how little I know

Here are some useful resources for emotional preparedness:

Mental Health Preparedness: Hurricane Season

As hurricane season begins, it is important to be both physically and psychologically prepared. The following resources can help prepare you and your family for the potential arrival of a hurricane.

American Psychological Association:

- Prepare Now for Hurricane Season
- Preparing Mentally for Disasters
- Tips to Strengthen your Emotional Well-Being before the Arrival of a Hurricane
- The Road to Resilience

American Red Cross:

- **Hurricane Safety Checklist**
- New York - from Governor Cuomo

FEMA:

- Hurricane Preparedness Tips

CDC:

- Hurricanes

National Weather Service:

- National Hurricane Center
- Hurricane Preparedness

ADDITIONAL RESOURCES:

Be Red Cross Ready: Hurricane Safety Checklist. Red Cross. Accessible at http://www.redcross.org/www-files/Documents/pdf/Preparedness/checklists/Hurricane.pdf

Emergency Preparedness and Response: Hurricanes, Cyclones, Typhoons, and other Tropical Storms. Centers for Disease Control. Accessible at http://emergency.cdc.gov/disasters/ hurricanes/

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From PSYCHOLOGY DAY at the UN

Top: Co-chairs Janet Sigal and Martin Butler

Right: Dr. Florence Denmark, delivering the closing remarks at Psychology Day event.

ICP at the United Nations
by Florence L. Denmark
ICP Main Representative to the UN

From left to right - Alishia Kiiza, Annie Chai, Dr. Florence Denmark, Pancho Diaz

I am happy to report on the activities of our outstanding ICP members, as well as the excellent interns who represent ICP at the United Nations. Martin Butler is active on the Committee on Migration and chairs the committee's task force on human trafficking. Florence Denmark is the immediate past Chair for the Ageing Committee, corresponding secretary for the Committee on Mental Health, and treasurer of the Family Committee; Norma Simon is the recording secretary for the Committee on Ageing, a Member-at-Large on the Committee on Mental Health, and a member of the Executive Committee of the Family; Richard Velayo is completing his term as treasurer of the Committee on Ageing; and Pete Walker is the treasurer of the Psychology Coalition and a Member-at-Large on the Sustainable Development Committee. We are all also active on the Psychology Coalition and involved in the planning of Psychology Day.

In addition to ICP's representatives at the UN, ICP member Janet Sigal is completing her term as co-chair of the Family Committee, and is also serving as vice-chair of the Committee on Ageing. Janet is the main representative for APA at the UN. ICP member Neal Rubin is also a member of APA's team at the United Nations.

We also have five interns, plus one intern-in-training. All of the interns attend and are active on various committees at the UN. These committees include Ageing, Family, Mental Health, Migration, Sustainable Development, and Women. All also attend meetings of the Psychology Coalition and the Psychology Day planning committee. Annie, Rich, and Kristin are in their second year as interns; the others are in their first year. Following is a list of the background and education of our current group.

- Annie Chai was born in Malaysia and has spent most of her life overseas. She received her BA at Pace University in Psychology. She has been a UN intern for a year and has done research in Web 2.0 and food consumption around the world. She has been published in different fields in Psychology including Positive Psychology and elderly care. She is currently finishing her MA in Psychology and works as a Teacher's Assistant in Social Psychology. She also works on Pace's Legal Counsel; her goal for the future is to do a combined clinical program with law.
- Richard Cresswell was born in North Carolina but lived in New Haven, Connecticut for most of his adolescence. He graduated from Skidmore College in 2006 with a BA in Religious Studies, during which time he did a lot of work on neo-paganist belief systems such as Wicca and Odinism. Since then, he's been a traveling salesman, provided live-in childcare, and worked in an outpatient after-school program for at-risk adolescents. He is now currently finishing his MA in Psychology at Pace University.
- Pancho Diaz Jr., an intern in training, is currently a first year master's student at Pace University. He was born and raised in Los Angeles, California and earned his BA in psychology at Cal Poly Pomona. Since then, he has moved to New York City and has been living here for the past 3 years to continue his education. He grew up with a younger brother who has autism, and his experiences in dealing with the disorder in his family led him to become interested in the field of psychology. He is also currently a part of the Web 2.0 research team at Pace University.
- Alishia Kaikara Kiiza was born in Uganda. She completed her undergraduate schooling with a degree in Psychology and French from the University of Nevada Las Vegas before coming to New York City to attend the MA Psychology program at Pace University. She hopes to one day obtain a PhD in Psychology and take information back to Uganda regarding mental health and Psychology in general. It is still taboo in Africa to have any mental health problems, she hopes one day to change this to help the continent prosper. She finds that working with the diverse group of people at the United Nations has helped her to acquire more knowledge on how to do so.
- Cory Reano graduated from the University of California, Los Angeles in 2008 with a major in Psychology and double minors in Educational Studies and Applied Developmental Psychology. After college, she worked as an International Service-Learning Tutor for Lingnan University in Hong Kong. She is currently enrolled in the MA Psychology Program at Pace University and works Full-time as a Program Coordinator for NYU

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School of Medicine.

- Kristin Thies is currently in the second year of the School-Clinical PsyD program at Pace University. She was born in Illinois, and received her BS in psychology from the University of Illinois at Urbana-Champaign in 2010. In addition to working as an intern at the UN, Kristin also interns at an elementary school in Long Island. Kristin hopes to work both as a school psychologist, as well as a clinical psychologist, following the completion of her PsyD program in 2016.

ICP Conference: 2012
Sevilla, Spain
O'Roark-Margaona Symposium
Women and Immigration

Impact of Leader Personality and on Social–Economic Justice

Presentations by Drs. O'Roark, Comunian and Gamache were included in the Fall *2012 International Understanding IP52.3* Part B.

Presentations by Drs. Barreda-Hansen and Margaona are included here following an introduction to the topic by Dr. O'Roark.

Annual meetings of the International Council of Psychologists, Inc., began with the 1942 meeting of the National Council of Women Psychologists, established within the American Psychological association to provide women opportunities to apply scientific knowledge and competencies to the war effort after the establishment by APA of an all-male Emergency Committee in Psychology. The intent was to be a temporary group and to dissolve when WWII ended. Instead, NCWP decided to become ever more inclusive, first inviting women psychologists from Canada and establishing liaison relationships with several northern European countries; next the group opened membership to men and changed the name to ICP. Soon, ICP incorporated independent of APA and established UN NGO status. Most recently, in 2011, ICP, Inc. membership was opened to allied discipline members.

ICP, Inc began crossing borders in 1970, holding its annual meeting in Tel Aviv. While maintaining headquarters in the USA, ICP, Inc served as an educational non-profit incorporation, transporting ideas and information about scientific psychology, concepts about well being, peace, clinical therapies, and professional ethics. This purpose distinguished the group from the activist-feminist movement.

One of the two themes for the 70th ICP, Inc. annual meeting [was] "Immigrants." The traditional image of immigrants is one of adventurous, courageous individuals, or of starving families whose homes and livelihood had been overtaken by invading foreigners, or, of undesirables like criminals and prisoners, or, of religious pilgrims and missionaries. However, seldom considered as "immigrants" per se, commercial tradesmen were crossing borders and establishing businesses for centuries.

The far eastern Silk Road may be the earliest recorded passageway across borders for entrepreneurs. And the Dutch East India Company established in the 1500s in Amsterdam may have been the first modern day trading market for commodities, futures and stocks. The Olympics may be the earliest sporting exchanges. The middle ages' Knights Templar may have been first to guard the trade routes and become a powerful international militia and financial management influence. These are the ancestors of today's immigrant corporations that influence both national cultures and social well being.

In our 21st century era, the power of economic needs and speed of technological communications multiplied the border crossers: franchised businesses. Corporations, and agencies are rapidly becoming visible and influential *immigrants*. In this Sevilla symposium, presenters [offered] case examples and the psychologists' perspective on issues pertinent in understanding and advising immigrant organizations and their host countries.

Dr. Barreda-Hanson tells the story of an individual immigrant trying to start up his family business in a new land. Dr. Margaona addresses the influence of executive personality on the corporation functioning in Latin and South America.

Previously reported: Dr. Comunian wrote about resilience of leaders in organizations that move into another culture; Dr. Gamache presented issues related to government and agency decision making when responding to national disasters with global impact; and, I wrote about the importance of extending information bases comparing and contrasting cultures, in the context of a corporate responsibility for ethical leadership and trust building.

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ICP Conference: 2012
Sevilla, Spain
IMPOTENT CLIENT or IMPOTENT THERAPIST
by Dr. Maria Consuelo Barreda-Hanson

INTRODUCTION:

Disorders of secondary erectile dysfunction with no clear organic explanation are often seen in clinical settings and frequently accompany other psychological symptoms. Their frequency and severity are known to vary within and across cultural groups. Though its relationship to stress factors and depression has been well researched since early 70s (e.g. Kaplan, 1974 and Surridge, Condran and Morales, 1983) its relationship to cultural or migration stressors is not well known. Yet, we know that migration is a major life change and that life changes are psychological transitions with built-in stressors that have been related to onset of emotional symptomatology and problems (Roskin and Edleson, 1984).

If this is so, it can then be safely assumed that sexual dysfunction could be the consequence of migration stressors. The question still remains, however, as to possible mechanisms of action. I shall attempt to answer this question in the present paper. I shall do so by drawing on my experiences with Hispanic clients in the United States of America and Australia.

Firstly, I will summarize the presentation and historical background of one of my clients as an illustration of this symptom and then outline the phases of migration he went through and the variables that affect "acculturation". I shall then end my presentation by suggesting a schema for therapeutic interventions.

CLIENT PRESENTATION:

Mr. Jaime, an attractive, presentable, 35 year old man, employed as a "body painter" in a car factory, was referred by his General Practitioner for emotional assessment and therapy. Mr Jamie had been diagnosed by his G.P. as suffering from "impotence". Depression was queried. The G.P. could find no organic basis for either disorder. Socio-sexual and educational histories were non-significant (fig. 1)

On presentation Mr. Jamie was rather depressed and complained of sleep difficulties, nightmares and headaches. He was also concerned that he was loosing his temper, becoming aggressive, particularly against his son, with whom he had triangulated the relationship with his wife. He was wondering if he had done the right thing by migrating to Australia and though unsure if he should return to his native land, Argentina, he spoke highly, in unrealistic and nostalgic terms about his country.

CLIENT'S HISTORICAL PROFILE AND MIGRATION PHASES:

Background history:

Mr. Jaime's life history indicated early aspirations and expectations from life than did the others. Similarly, he had not been able to form a good relationship with his mother. He considered her a "bad mother" and blamed this on her "war trauma" when young. Mr Jaime related better to his father, though he considered him distant and saw little of him as he was often away from home at work. It was his father, however, who had first introduced him to mechanics by offering him his first job in the mechanic's department of a car industry.

Mr. Jaime's developmental history was non-eventful. He had been a good student, completed year three in High School and later attained a Certificate in Motor Mechanics. He described a healthy, happy satisfying socio-sexual history, with "no girl problems". Mr. Jaime had started to be sexually active before his 15th birthday and considered his potency to be the "centre of his life."

Mr. Jaime met his wife, Mrs. Juana, in his mid twenties. They sexualized the relationship after a short courtship. Mrs. Juana remained living in the parental home until the day they married. They married in 1981, when he was 29 years of age. Shortly thereafter they migrated to Australia. The reasons for migration was "to establish his own mechanics shop and provide well for his wife and future children". He sold his home in Argentina and brought the proceedings of the sale plus a small amount of savings he had managed to accumulate through his working years. This, he thought, would give him a "good start."

PHASES OF MIGRATION: (figs. 2, 3 and 4)

A. Arrival Phase:

Mr. Jaime and his wife arrived at Australia in 1981. He was full of hope, motivation and high expectations. Yet, it was not easy.

Continued next page

Consequences of migration were numerous. They had become uprooted, created a great geographical distancing between themselves and their loved ones and had lost support and reference groups. They felt some discrimination and were disappointed with the environment which they had visualized quite different. Furthermore, they were not prepared for some of the role changes they had to make, particularly for Mr. Jaime, who for the first time had to start relying on his wife for some help. This was a great blow for his "macho image".

Symptoms of migratory stress started early in this phase. Mr. Jaime felt a sense of loss and would occasionally feel nostalgic about his home land.

B. Cultural Adaptation Phase:

This phase of acculturation/adaptation process began as soon as they arrived at the hostel, where they had to first get used to the migrant subculture and start learning English. He found this very difficult. He felt "lumped" together with people culturally and politically offensive to him and could not learn English well. Mrs. Juana did better, particularly with English, and he found himself frequently having to rely on his wife for translations. Furthermore, they found Australia much more expensive than they had imagined, their money less valuable and they had to start using some of their savings for living essentials.

Consequences at this phase repeated the above phase but emphasized the difficulties with learning English and the economical strain.

Symptoms were kept at bay but he started to feel fear of failure and would occasionally become stressed.

C. Gaining Self Sufficiency Phase:

During this phase of taking steps at gaining power and exercising the controls they had temporarily given up Mr. Jaime attained full time employment. This however, was at a factory, far below his level of expertise and did not pay near as much as he had expected. His wife had to get part time employment in order to safe their saving and eventually buy the house they had planned.

Consequences of this phase were deeply felt. Mr. Jaime had to abandon English classes and felt professionally "demoted". He felt different to his co-workers and inadequate as a husband. Because of his wife's job he had to start sharing some household responsibilities, something he was not use to and did not see as a "male role". He started to become more isolated from Hostel friends and felt unable to attain a support group. He had no reference group.

Symptoms greatly augmented in this phase. He felt ashamed and guilty. His sense of frustration rose highly and his nostalgic feelings for Argentina became frequent. He was perplexed at his environment, which he tended to see as hostile and became stressed. He had some sleeping problems, feelings of uneasiness and some minor signs of depression. At this time he had his first one or two episodes of impotence. He started to worry about his health and for the first time visited a health service.

D. Recuperating Status Phase:

During this phase Mr. Jaime made great attempts at recuperating migration losses and to regain the power, control and the level of living he had lost. After much struggles he bought their home in 1983. His job, however, continued to be a point of stress. It did not pay enough and did not provide the opportunity to make the "right type" of friends. He felt forced to take on an extra part-time job to complement his full time salary. His wife had to increase her work to full time; otherwise they would not have been able to pay the high mortgage rates.

Consequences of this stage developed from the prior phase. He eventually lost contact with Hostel friends, isolated himself socially and started to wonder who he really was and what he was all about. He started to loose hope in fulfilling his migration goals and his first marital conflicts took place.

Symptoms became more severe. He felt stressed, tired and started to be afraid that he was losing controls over his feelings. He burst out angrily at times, mostly against his wife, which made him feel guilty. He became preoccupied with himself and started to loose more sleep, to have nightmares and have feelings of depersonalization. He started to make a few more visits to the Health Service, where Doctors continued to find nothing wrong with him that a "good rest would not cure".

E. Maintaining Status Phase:

During this phase Mr. Jaime started to gain the power and controls he had lost and for the first time felt he was on the road to attaining the future he wanted. He left the factory job for a setting-floors one, whilst continuing his part time job. His wife left work and gave birth to their first child – a son.

Consequences of this rewarding event created somewhat like "a flight to health". His hopes were renewed, his motivation came back and he reached out socially. He joined a Spanish club and made new friends. The birth of his son overjoyed him and he had more job satisfaction. Going back to his "male role" of a Bread Winner and "man of the house" as well as a son, proving

Continued next page

his masculinity was more satisfying.

Symptoms during this time were non-existing, at least that he remembered. The so many positive events overshadowed any negative experiences.

F. Disillusionment Phase:

This phase had two stages and was most traumatic for Mr. Jaime. He started to loose his controls and the independence he had so hard tried to acquire. Expenses surmounted, his new job did not provide enough work as it was on contractual bases. In 1985 he had to return to factory work but kept both past jobs on part time bases. His wife also had to start part time work but raised it to full time in 1986.

Consequences of this phase were mostly in the family. Mr. Jaime's role changed dramatically to that of a father with parental responsabilities, particularly in 1986 when Mrs. Juana had to work full time nights. He resented the care of the child as he felt this should not be a man's job. There were renewed marital problems, social isolation and he stopped going to the club. By 1986 he had lost his hope for gaol attainment and lost motivation to keep trying. He started to reconsider his stay in Australia but was not sure they should leave. Yet, he started to glorify the cultural values of Argentina, ignoring the reasons that brought him to Australia.

Symptoms resurged with great strength. He felt very stressed and tired. Started again to loose control over his feelings and was especially aggressive towards his wife and son. He also started to dislike the child and to see him as a rival with his wife. He was disappointed at himself and at his failed expectations. He began to think often with nostalgia about Argentina, his loved ones and friends there and had odd episodes of depression, with an occasional crying spell. He once more had sleeping difficulties, nightmares and the odd experience of impotence. He again visited his G.P., with little satisfaction on his part. By 1986, soon after his wife took on the full time job, his impotence became a serious concern. He eventually became insomniac, suffering nightmares when he slept and developed headaches. He became depressed and felt guilty and ashamed. He then started frequent visits to his G.P.

G. Giving Up Phase:

This last stage was the most painful for Mr. Jaime as he had come to the realization that he had lost the power and controls over his life and what he had worked so hard for. He lost his factory job because of" illness" and was unable to attain extra part time employment. His home and sex roles had by now dramatically changed and it was his wife who was supporting the family financially and emotionally.

Consequences of this final phase were most devastating. He had feelings of depersonalization and role confusion, which were carried out in dreams of homosexual behaviour, which greatly scared him. He acquired strong feelings of dislikes towards his son, whom he saw as taking his wife away from him. Mr. Jaime totally isolated himself, even at home, and started to have strong desires to relocate again but was ambivalent about returning to Argentina.

Symptoms became quite serious and Mr. Jaime for the first time became very afraid. He was by now fully impotent and depressed. He also had severe insomnia problems and headaches. He continued to loose his temper, particularly with his son and had started to withdraw from family interactions. He was psychologically disoriented and saw his environment as threatening. He kept thinking about Argentina with an unrealistic, glorified nostalgia. His Doctor became concerned at this time and referred him for a Psychological assessment and therapy for impotence. He also queried "depression as a consequence of the impotence".

FORMULATION OF DYSFUNCTIONAL CAUSATION:

In this case, as in many other cases of erectile dysfunction, the symptom was a somatic one, disguising the more profound depression that was not properly identified until "impotence" had become a serious problem. Given the client's past history and lack of pre-existing symptomatology prior to migration, it seems to suggest that the occurrence of the condition was due to migration stressors.

Mr. Jaime, as all the other migrant Hispanic men, had at least a secondary education and belonged to a comfortable socio-economic class. He, as others, had migrated against family and friends' wishes, in order to achieve a "higher level of life and provide better for a family". Mr. Jaime was a high achiever. He had always been in control of his life and had the power to act on his decisions. As the other men, Mr. Jaime came from a male-oriented society with sex related stereotypes, and, as he said, had "potency as the centre of his life".

Potency was, to Mr. Jaime, equated to his maleness, his controls and his power. His job and status in the family and society were an important part of his "potency". Because of this he was very vulnerable to the various psychosocial stress factors that operated in "liberated, free Australia". Migration changed all that he valued. Firstly, it separated him from his reference and support groups; secondly, it took away from him the con-

Continued next page

trols he had had over his life, job and finances; and thirdly, it disempowered him from his male role, as "bread winner" and "man of the house". He had lost much and gained nothing (fig.5). Most importantly, he had lost his controls, a crucial factor highly correlated with emotional health (Meyers, 1971; Paykel, 1979); had felt disappointed with the environment and failed to keep a job and achieve his migration goals. He felt a failure and feared public humiliation and accusation, particularly back in Argentina, by friends and relatives. All these variables have also been highly associated to emotional health and sexual activity (Kaufman, 1982; Kelvin, 1985; Mckinley, 1975; Morrison, 1973).

Whilst Mr. Jaime lost much, Mrs. Juana, on the other hand had gained more controls and independence. These further affected Mr. Jaime's self esteem as it shifted familial roles. The interaction of all these factors seriously affected his sense of being, caused depersonalization, depression and finally the physical impotence that paralleled his psycho-social impotence.

SUGGESTED INTERVENTION SCHEMA:

I have found it helpful to formulate the problem as an interactional causation model. Thus, I avoid conceptualizing causation in a linear fashion, as "his problem", and see impotence in migrants as a series of variable that affect each other and are affected in turn by self and environmental feedback cues. Thus, it is a complex, interactional process that demands careful assessment of the individual and the couple. (Fig. 6)

It is important that a good historical overview of the client be attained with particular focus on those variables affecting migration (Fig 7). Not only are client characteristics and sexual identity important but also is the dissonance between reality and expectations; past and present experiences; and between both cultures, as the greater the difference, the higher the effect on the psychological health.

The assessment should not ignore the sexual partner, but ensure she is an integral part of the intervention program, particularly as partners, specially if they are sensitive, are affected by the client's feelings and may also be depressed.

A helpful schema is one consisting of six stages, as presented in Figure 8, with clear, concrete definitions of problem, hypothesis, desired changes, attainable goals, formulation and re-formulation of therapy plans and implementation of plans, at each stage.

Therapeutic interventions should be at four levels (Fig 9).

Firstly there should be the focus on the client's sexual adequacy, which should start with the urological examination to rule out any physiological condition. Secondly, there should be the focus on sexual therapy, which involves the client's partner. Thirdly, there should be a focus on the stressful life events of the client, with emphasis on the positive health practise, stress management techniques, increased control over situations, positive reframing and preparation and prevention of future stressors. And fourthly, there should be the focus on Migration Therapy, with emphasis in re-structuring perceptions and migration goals, whilst aiming at enhancing self-esteem as well as regaining controls and power.

Therapeutic interventions with these clients, particularly those presenting in the last phase of migration – the "Giving up Phase" is most disheartening as many have already decided they do not want to remain in their adopted country but are afraid to return home and have further humiliations if they do so. Thus, they can be very resistant to therapy. At these times I have found useful to give a "prescription that saves face" and gives them a good reason to return home. Saying they are Dr's orders: "I can not help you anymore. It might help if you returned home". It has worked! Some clients have gone home to return at a later date "cured" but with re-defined goals and more realistic expectations. Others have stayed home and the few that wrote back had also been "cured with the prescription".

PRESENTATION:
Medical referral – "Impotence"
Urologic report – No physical cause
Symptoms:

- Impotence
- Depression
- Insomnia
- Nightmares
- Headaches
- Loss of temper
- Aggressive to wife and son
- Some dependency on wife
  Isolated with son

PAST SOCIO-SEXUAL HISTORY:
A "mixer" – many friends
Popular
Sexually active –"healthy"
Potency "centre of my life"

Continued next page

EDUCATION:
Completed 3rd year high school
Certified Mechanic

REASON FOR MIGRATION:
"To establish own business and provide well for his family."

Figure 1

A CASE OF MIGRANT IMPOTENCE
MR. JAIME

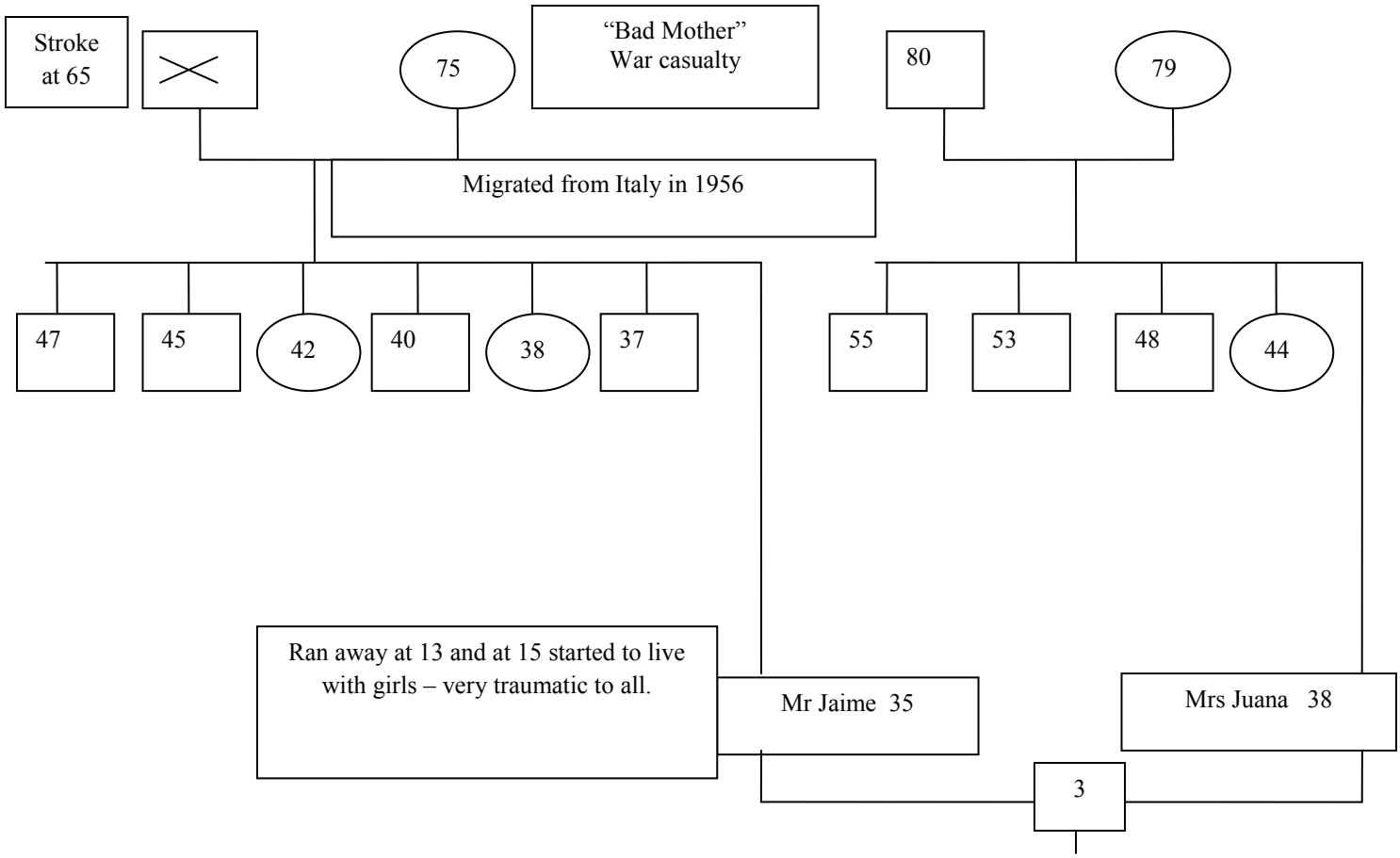

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Figure 2a

ARRIVAL PHASE

Sequence	Events	Consequences	Symptoms
1981	Married and migrated to Australia	Uprooting Change of roles	Some nostalgia
	Arrival		
	High expectations		
1981 A	High motivation	Geographical distancing Loss of support groups Unexpected socio-economic environment Discrimination Loss of reference group	Sense of Loss

Figure 2b

CULTURAL ADAPTATION PHASE

Sequence	Events	Consequences	Symptoms
1981 B	Acculturation/Adaptation Process Hostel culture	Difficulty learning English (wife did better) Had to use savings allocated for their new home	Fear of failure Some stress

Figure 2c

GAINING SELF SUFFICIENCY PHASE

Sequence	Events	Consequences	Symptoms
1982 C	Steps at Gaining Power and Exercising Controls	Stopped English classes-relied on wife Felt "demoted" professionally and socially	Some feelings of shame and guilt Frustration
	Full time employment-factory work	Felt was not "good enough husband"	Nostalgia Perplexity at environment
	Wife commenced part-time employment in child care	Unable to regain reference group Unable to regain support group Some changes in gender roles	Stressed Some sleepiness Feelings of uneasiness and slight signs of depression One or two minor episodes of impotence

Continued next page

Figure 2d

RECUPERATING STATUS PHASE

Sequence	Events	Consequences	Symptoms
1983 D	Attempts at Recuperating Losses Through Attainment of Power and Control	Lost contact with Hostel friends- Social isolation Change in family roles-some marital conflict	Stress Tiredness Occasional insomnia
	Brought home-high mortgage	Feeling of loss of identity	Rare episodes of impotence
	Took extra part-time job		Feelings of lacking control Guilt and preoccupations
	Wife increased to full time job		Depersonalization Occasional visits to Health Service

Figure 3a

MAINTAINING STATUS PHASE

Sequence	Events	Consequences	Symptoms
1984 E	Gaining Power, Taking and Starting a Future	Renewal of hope and motivation Elation at birth of son	Asymptomatic
	Left factory for new job-setting floors	Changes in family roles Regaining status as "bread winner"	
	Continued part-time jobs	Greater job satisfaction	
	Wife left job	New friends	
	Birth of son	Social activities joined Spanish Club	

Figure 3b

DISILLUSIONMENT PHASE

Sequence	Events	Consequences	Symptoms
1985 F	Losing Independence and Controls	Changes in family roles Shared more child responsibilities	Stress and tiredness Feeling loss of control
	Went back to factory	Renewal of isolation	Occasional episodes of impotence
	Kept two part-time jobs	Stopped club activities	Occasional insomnia
	Wife started part-time job	Some marital conflicts	Disappointment at failed expectations One nightmare about son Nostalgia Odd depressive episodes Odd visits to health service

Continued next page

Figure 3b, con't.

DISILLUSIONMENT PHASE

Sequence	Events	Consequences	Symptoms
1986 F	Wife took full time job	More parenting demands Increased household responsibilities Feelings of loss of identity Loss of hope to attain goals Loss of motivation Reconsideration of status in Australia Resurgence of cultural values	Impotence now a serious concern Insomnia Nightmares quite often Guilt and shame Depression Frequent visits to Health Services Frequent visits to G.P. Headaches

Figure 3c

GIVING UP PHASE

Sequence	Events	Consequences	Symptoms
1987 G	Loss of Power and Controls	Total change of Gender roles- wife kept family together (emotionally and economically)- role confusion	Clinically depressed Impotent Insomniac and bad headaches
	Lost factory work because of "illness"	Child demanding of mother and becoming rival to father	Loss of temper, particularly with son Unrealistic, glorified nostalgia
	Unable to attain extra part time job	Dislike of child Total isolation, even at home Desires to relocate in native land but ambivalent	Unrealistic, glorified nostalgia Psychosocial disorientation Isolation Frequent visits to medical services Referral to therapy

Figure 4

PHASES TOWARDS "MIGRANT IMPOTENCE"

A. ARRIVAL PHASE (REGRESSION TO STAGE OF DEPENDENCY AND NO CONTROLS)

- Major life change
- Loss of reference group/models
- Loss of support systems and networking

Continued next page

Figure 4, con't.

PHASES TOWARDS "MIGRANT IMPOTENCE"

B. CULTURAL ADAPTATION PHASE (DEPENDENCY WITH SLOW RE-ACQUISITION OF CONTROLS)

- Social re-adjustment
- Political awareness
- Acquisition of new language
- Acquisition of cultural competence
- Environmental perplexity
- Loss of self esteem and self identity/identification

C. GAINING SELF SUFFICIENCY PHASE (ATTAINING INDEPENDENCE AND ACQUIRING CONTROLS)

- Job/professional re-adjustment
- Gender/familial role change(s)
- Working out support groups

D. RECUPERATING STATUS PHASE (INDEPENDENCE AND CONTROLS)

- Regaining socio-economic level to prior migration
- Work towards attainment of migration goals
- Establishing new social roles

E. MAINTAINING STATUS QUO PHASE (SHARING INDEPENDENCE AND CONTROLS)

- New job(s)/career
- Continue goal attainment efforts
- Family focus
- Social focus

F. DISILLUSIONMENT PHASE (LOSING INDEPENDENCE AND CONTROLS)

- Realization of unmet expectations
- Unrealistic, glorified nostalgia
- Uneasiness with self
- Depersonalization
- Loss of dignity
- Cognitive changes of perception –negative focus
- Depression ("atypical depressive characteristics")

G. GIVING UP PHASE (LOOSING INDEPENDENCE AND LOSS OF CONTROLS)

- Loss of power and controls
- Loss of faith, hope and motivation
- Acceptance of failure
- Depression ("atypical depressive characteristics")
- Impotence
- Experience environment as hostile and alienating
- Other psychosomatic symptoms- headaches, etc

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Figure 5

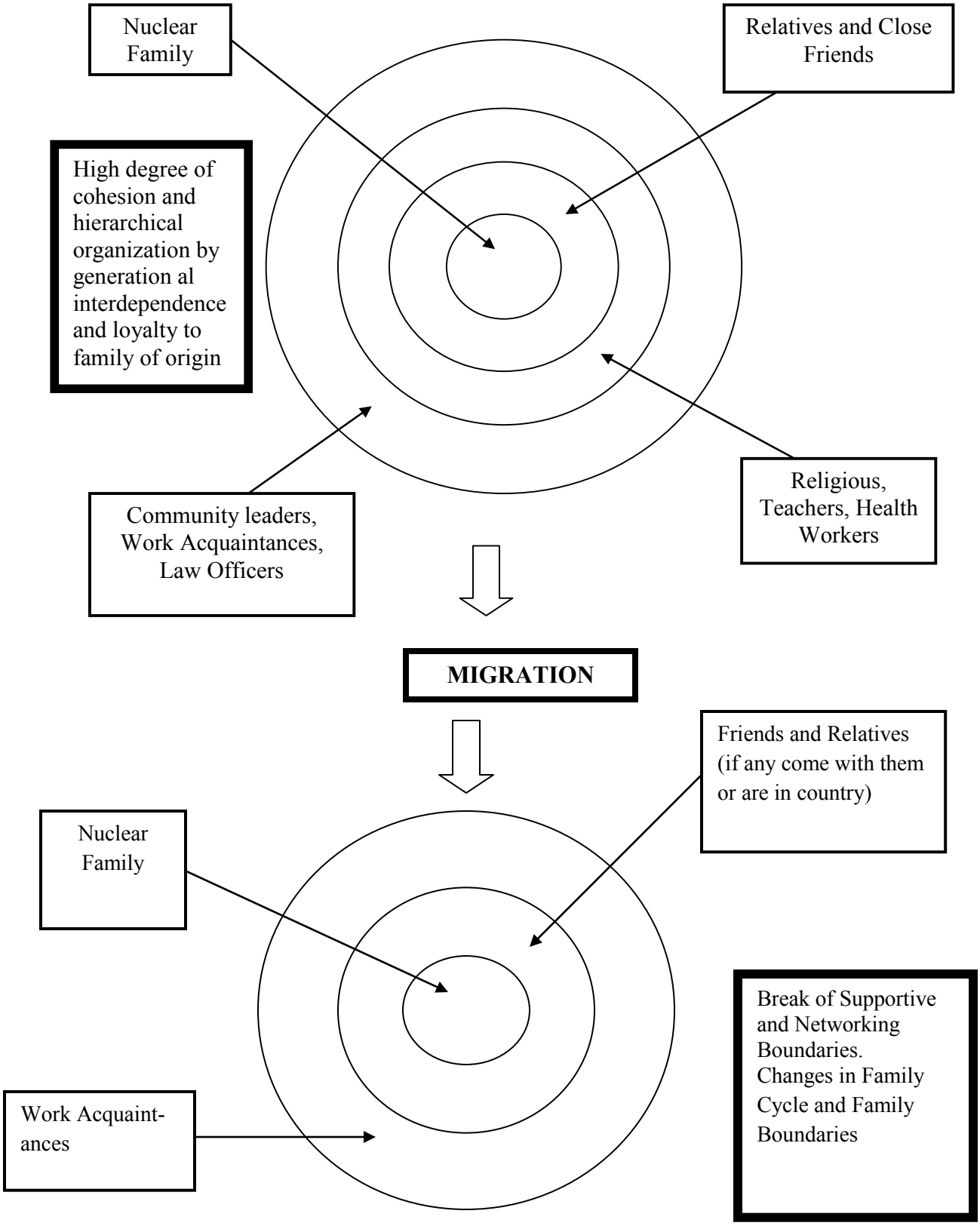

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Figure 6

INTERACTIONAL CONCEPTUALIZATION OF MIGRANT SECONDARY IMPOTENCE

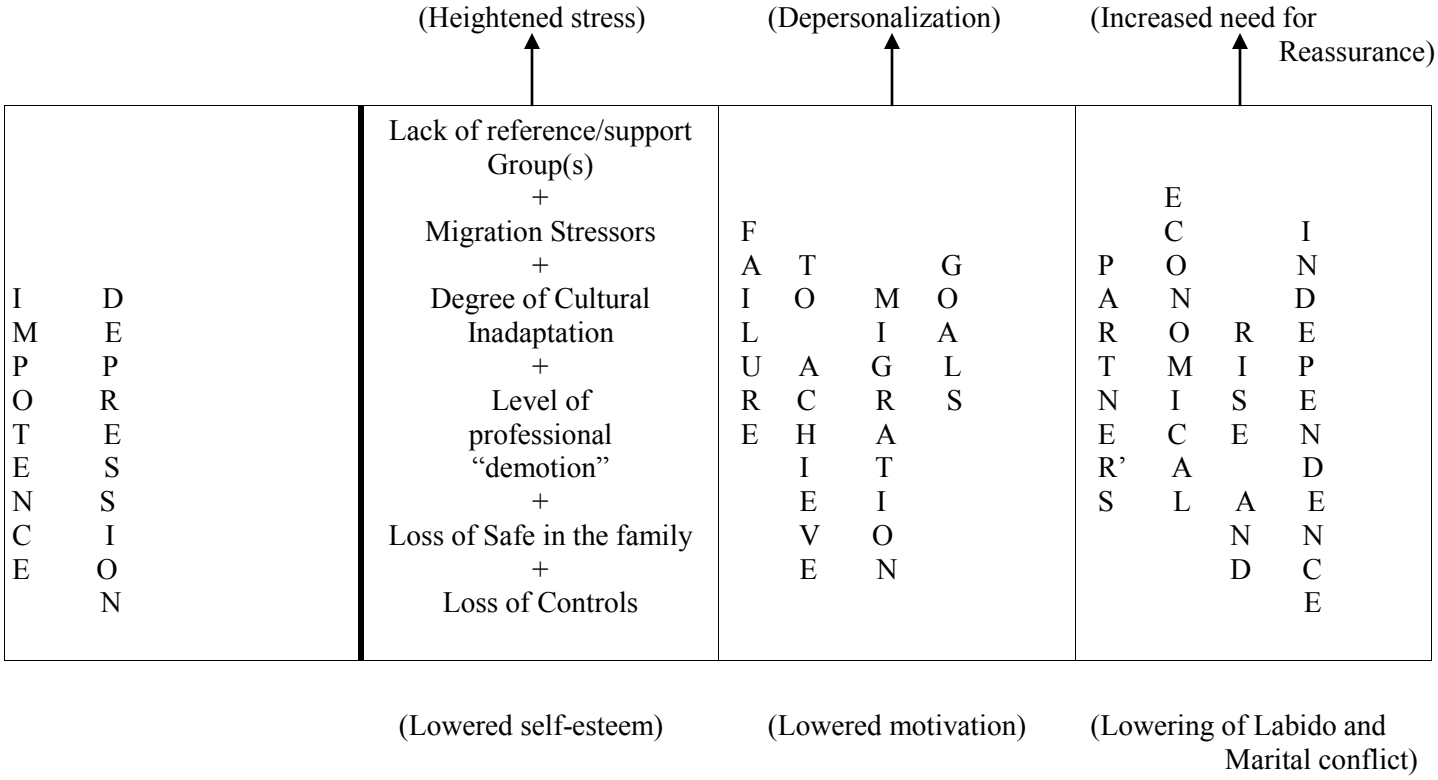

Figure 7

Variables Affecting Migration

PRIOR TO MIGRATION:
Cultural background
Socio-economic position
Religious Affiliation
Educational/professional level
Life experiences
Support systems
Networking
Personality Characteristics
Reasons for leaving homeland (voluntary or involuntary)
Reasons for moving to new location
Circumstances in which migration took place

DURING MIGRATION:
Age/life phase
Marital and family status
Single or accompanied
Expectations
Relocation stresses
Support systems
Knowledge/Understanding of Host Country
Ability to adapt to a different culture (any previous experience?)

Continued next page

Figure 7, con't.

Variables Affecting Migration

AFTER MIGRATION:
Type of migration (permanent or temporary)
Socio-cultural and political differences (degree and quality of changes)
Ability to recreate support group (same culture/other)
Speed and degree of adjustment
Perceptions of the environment
Environmental attitudes
Socio-economic opportunities
Work employment opportunities
Personality Characteristics
Fulfilment of expectations and aspirations

Figure 8

SCHEMA FOR IMPLEMENTING THERAPY

Stage	Data	Required
1. Pre-acceptance	Medical check up Urologic diagnosis	Rule out organic causes
2. Background Information	*Presenting problem *Detailed sexual history and assessment of emotional and cognitive responses to sexual situation and interpersonal social situation *Psychosocial, Familial, Professional and Medical history *Importance of sexual identity in his self image *Migration history and goal attainment *Personality assessment (MMPI) *Life events scale *Indicators of present environmental stressors ("Stress Audie")	*Interview of couple together and individually *Knowledge of cultural background *Language facility *Experience with sexual therapy *Experience with Psychosomatic therapy *Experiences with migration variables and migrant issues
3. Treatment History	*Previous involvement of family members in treatment *Previous treatment efforts *Contract between therapist and client(s) *Expected stance of partner *Status of current treatment *Therapist's formulation of case *Goals for therapy *Fit between possible recommendations and	*Detailed and structured history *Openness to therapeutic intervention *Therapist support systems *Skills in couple therapy
4. Formal Therapy Sessions: Initial Stages	*Check pre-session hypotheses by observing couple interaction *Clarity of couple goals; area of disagreement *Relationship between couple and therapist *Rigidity and responsiveness of couple system	*Clarity of goals and contract *Checking client(s) ability to achieve goals or any needed support

Continued next page

Figure 8, con't.

SCHEMA FOR IMPLEMENTING THERAPY

Stage	Data	Required
5. Possible interventions	*Test response of couples to stronger interventions based on previous stages *Modify intervention based on previous responses	*Clear therapy outline *Check client response to intervention
6. Terminating	*Develop plan for termination that is consistent with conceptualization of case and therapy goals	*Possible closure with optimistic outcome

N.B. BARRIERS TO THERAPY:
1. Poor diagnostic reliability when dealing with migrants.
2. Language barriers and cultural communication patterns.
3. Understanding of specific culturally determined differences affecting problem presentation and diagnosis.
4. Understanding the complexity of "mixed cultures" migrants live in.
5. Understanding the difficult issues confronted by migrants, from different cultural backgrounds at different times.

Figure 9

COMPONENTS FOR SUCCESSFUL THERAPY

CLIENT ADEQUACY IN ALL SEXUAL FUNCTIONS
- Adequate physiology
- Adequate stimulation
- Positive reinforcement history
- Positive psychological and cognitive frame of mind

SEXUAL THERAPY
- Establishing mutual responsibility for satisfaction
- Correcting myths and misinformation through education and improvement of couple communication
- Ensuring patient receives a high level of physical and psychological stimulation by increasing couple's sexual repertoire and communication about sexual matters
- Eliminating cognitive interference in the form of performance demand, anxiety, or negative evaluations

STRESSFUL LIFE EVENTS MANAGEMENT
- Positive health practices
- Stress management and relaxation techniques
- Increased control over situation
- Positive reframing of goals and situation
- Acquiring alternative solutions and goals
- Enhancing support systems

Preparation and prevention of future stressors

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MIGRATION THERAPY

- Regaining controls, power and independence
- Reframing environment and understanding it
- Cognitive reframing of migration
- Building up self esteem and identity
- Focusing on the positive and pleasurable - day to day positives (Short term to long term positives)
- Day to day positives (Short term to long term positives)
- Acquiring reference groups and supports
- Re-socialization and Club joining
- Re-interpreting and re-setting migration goals
- Vocational re-orientation/rehabilitation

Family therapy in cultural context(s) and "cultural blending"

WHEN NOTHING WORKS
Prescribe a return to homeland with "face saving" instructions.

Adapted from Alma Dell Smith. "Psychological factors in the multidisciplinary evaluation of treatment of erectile dysfunction", Urologic Clinics Of North America Vol 15., No. Feb.1989, pp 41-51.

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ICP Conference: 2012
Sevilla, Spain
DECISION MAKING DIRECTIVE CRITERION: ITS COMPLEXITY
by Elisa Margaona, Ph.D.

Abstract: The relationship between organizational psychology and the complexity of developing a decision making directive criterion will be discussed in this presentation. Several studies have analyzed in the past the relationship between the directive organizational functions with cognitive elements, which are required to be a director of a firm. (Haslam S.A, Reicher S., Platow M. (2010); Barlett and Ghoshall, 1989; Hedberg and Johnson, 1978; Hooijberg. R.Quinn,R..E. (1992); Thomas and Gioia, 1991; Huff, 1990). Empirical information of living experiences in companies of five different countries will be added to analyze changing environments, with different problems facing a global economy. Successful cases will be presented to determine the type of decisions which favored results and others which caused great losses.

Introduction:
Strategic alliances and acquisitions have been the result of an international market. The organizations are facing an everyday harder global competition which has stimulated the interest in organizational culture and studies directed to

Continued next page

develop individuals with leadership and directive abilities. The industries expansion requires an increase in the thinking capacity and creativity of its leaders, to be able to excel the strategies of competitors, the face constant change and to master new technologies. Also, it is necessary to be able to interpret market signs to decide between its contradictions and transform them in organizational decisions with adequate behavior mechanisms, capable of interpreting the international complexity and its meanings. (Riveline, 1991; Van Muijen, etc.1999).

Some theories mention that it is the responsibility of organizational psychology to provide the tools required to define the different propositions to approach this matter. Neves (2000) suggests ideas based on a conceptual basis and an analysis of the symbolic characteristics of each organization and its strong characteristics, including previous historical facts that can be studied with qualitative and quantitative methods.

At present, leaders of organizations require the ability to interpret the structure of problems originated from lack or wrong information. that include contradictory data which do not allow the correct decisions. Also, leaders have to have flexible and open thinking, the capacity to integrate thoughts in single sentences and being critical without antagonizing leadership, understanding the exterior surrounding signs. All these, at the end, have to be integrated in practical solutions that will represent a return on investments.

The above represent a very difficult profile and several studies have tried to find the relationship between cognitive elements and personality to define the individual responsible to fulfill the organizational functions of today. (Prahalad, C.K., Hamel, G. 1990; Thomas and Gioia, 1991; Huff, A.S. 1990). Investigations on this area have structured development programs at executive level within the organizational structure. However, much has yet to be done to be able to determine the cognitive capacity of individuals capable to fulfill these functions.

Discussion

Within this conceptual approach, studies have being added (Hooijberg, R. Quinn, R.E. 1992) describing the behavioral complexity of managers within a multi-organizational level perspective. The environment in each company, with its foreseeable and unforeseeable circumstances, demand that a director had sufficient abstract thinking to determine the right action when facing a problem and demand understanding how individual personalities interact in a given group.

To succeed. leaders need to originate and embed a group identity to create an understanding of "us", making a material difference to the organizations and societies that they lead. (S.Alexander Haslam, S. Reicher, M.J.Platow. 2010). These authors provide an insight in the new approach for organizational psychologists and their research for years to come, citing 400 empirical studies and texts, spanning 170 years, from 1840 to 2010.

One of their conclusions is that there is not a specific set of stereotypical leadership qualities, although they point out that one of the most important is motivation. Cost of employing has increased dramatically and employers expect individuals to be committed to the organization and get the job done, placing work as the most important thing in their lives, not minding the time invested in achieving success. Creativity and drive innovation is also in constant demand and it also stresses the fact that working environment have to provide the structure, the methods, the basic ideas and the tools that will allow their collaborators to be creative and innovative.

There are in the market workshops that claim to develop a creative mindset. Personality tests are so popular that there are books providing information on how the tests should be answered to project the right image. A theoretical space is open for organizational psychology.

In this presentation, cases will be analyzed which decisions, when studied through time, have proved to be right and others wrong, pointing out the importance of the criterion of leaders and the factors which contribute to the results. The cases presented are related to strategies used by executives in the retailing industry in the last one hundred years in Latin America (Margaona, 2003) and include international strategic alliances, development of new markets, financial and human resource problems. The discussion will be based on the characteristics of the individuals making the decisions.

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The Syrian Situation: A Personal Perspective

by

Dr. Ani Kalayjian

Editor's Update: I am relieved to report that after this letter was submitted, and after the 52.4 IP was released, Dr. Kalayjian's kidnapped cousin was released. I have no other details. Because the situation is still volatile and relevant to the work and commitment of the ICP members, I have published Dr. Kalayjian's original letter here. It has not been edited. *N. Quatrano, production editor.*

My cousin, a 60 year-old diabetic male, was kidnapped from his own mechanic shop in Aleppo, Syria, by the Syrian opposition asking for $150,000 US dollars. For the last five months the opposition has been targeting the Armenian Christian minority in Aleppo, Damascus, Azez, and Der Zor, and have kidnapped and killed hundreds of Armenians. They have systematically destroyed Armenian churches, Armenian schools, nursing homes, and Armenian neighborhoods. I called my other cousin and could hear the bombs blasting at any hour of the day and night. The opposition is waging war against the Assad government, but Armenians have nothing to do with this war. Although loyal to their country's government, Armenians are also loyal to their neighbors, and humanity at large. My other cousin has been hiding in the basement of her daughter's house, in fear, with the house shaking from the blasts, afraid they can no longer live there. Just a day ago they blasted a huge truck in the middle of a courtyard in Aleppo, killing many innocent people. The government is not the force behind all this destruction—it is the Syrian opposition that we Americans are supporting.

In 1915 Syria opened its arms when Ottoman Turks were annihilating Armenians and throwing them out of their homes of 3,000 years. One-and-a half million Armenians were systematically annihilated, and others walked across the Arabian deserts to make it to Syria. Since 1915, Armenians have been building Aleppo, Azez, Latakia, Damascus, Kesab, Der Zor, and other parts of Syria. Armenians have their own private schools, churches, and community centers. Now in 2012, 97 years after the Genocide, Armenians are being subjected to another mass trauma of murder, destruction, ransacking, kidnapping, and torture. The Syrian opposition is backed by Saudi Arabia, Qatar, and Turkey. Turkey has been selling arms to the opposition and finding any excuse to attack the border in northern Syria, which is populated by Christian minority Armenians. Turkey has taken advantage of this chaotic war situation and has destroyed the Genocide memorial and the Armenian Church in Der Zor.

The opposition also threw elderly Armenian residents out of the Armenian Elders Home in Bostampasha and turned it into their headquarters to send bombs and missiles to destroy the rest of the Armenian community. These older Armenian adults had been thrown out of their homes at the beginning of their lives by Ottoman Turks, and now, once again, at the last stage of their lives, they are being thrown out of their homes by Syrian opposition forces and Turkish criminals.

I am a humanitarian worker and President of Meaningfulworld, a charitable organization, servicing the world in over 45 countries, and it hurts me in the core to not be able to go to Syria and help the surviving community that is in shell shock, experiencing severe trauma. Here in the US, my family and I have been feeling the

Continued next page

surge of the unresolved generational trauma of the Ottoman Turkish Genocide and the generalized helplessness we feel from not being able to help my cousin. Where is the UN Declaration for Human Rights? When we contacted the United Nations High Commissioner for Human Rights, their response was that their office is in the dark and cannot help. Where is justice? What can we do to stop this madness? Why is the opposition destroying the Armenian community? If they want to lead Syria, they should oppose the Syrian government and not attack innocent Armenian people who are the Christian minority. How many times does a nation gets displaced?

Please help in any way you can, pray for the Christian Armenian minority that is innocently being targeted by the Syrian opposition, hold prayer circles, send us donations to help feed our family, talk with your congressional representative, tell him or her what is REALLY going on in Syria—a totally different story than what the opposition and mainstream media are broadcasting to convince the world. Please educate your circle of Americans and others so they will stop supporting and sponsoring the opposition.

Ani Kalayjian
President, Armenian American Society for Studies on Stress & Genocide
http://drkalayjian.com
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Guam and Singapore: The Brown Tree Snake Invasion to Suicide Prevention by Dr. Robert F. Morgan

Note: Portions of this international material and related context may be found in my 2008 book, a fairly new Cambridge University Press online journal article (Morgan 2011), and a new 2012 international text: *Trauma Psychology in Context: International Vignettes and Applications from a Lifespan Clinical-Community Psychology Perspective*.

Cultural adaptation to a brown tree snake invasion

Guam is a beautiful tropical western Pacific island with a rich multi-cultural history. Residents often give driving directions along the lines of "go past the corner where the school used to be.." Although it is a United States Territory, it is nearly in Asia, as far from Hawaii to the west as California is to the east. In this land of super typhoons, earthquakes, military buildups, and irresistible . courtesy and friendship, chaos theory applies at least as much as anywhere else.

Anybody familiar with science fiction knows that going back in time is risky for the future. The accidental death of a small animal or the crumpling of a tiny piece of vegetation could, over sufficient cumulative time, change everything. Today the public is well aware of this possibility, in current real time, as the "*Butterfly Effect"*. The flapping of a Butterfly's wings could, with enough time and distance, lead to a typhoon or … nothing of consequence.

The Butterfly lives a short decorative life, mainly to reproduce, and along the way does some useful pollination. If flapping its wings ultimately brings about a major storm, it really doesn't care. Its collective impact is not aggressively purposive. Any grand consequences of its actions would be part of a pattern so complex humans have yet to understand it. The intentionality of a Butterfly on world events is neutral (Butz 1997; Butz and Schwinn 2004).

On the other hand, the Bee Moth has a more focused destructive effect on others. Like the Butterfly, the Bee Moth lives to reproduce. It neither eats nor drinks in its short life span of three to four weeks. A single female with only about a 4 cm wingspan lays up to 1000 eggs. In a few days these hatch into voracious caterpillars. The diminutive mother lays them in a bee hive, usually one weakly defended (possibly due to some external stressor). When the larvae hatch, they begin burrowing through the hive walls in search of food. Eventually they will destroy the entire hive. The Bee Moth, a small creature, has a powerful ultimate impact on the hard-working bees. In this it has specific purpose, useful for its own survival, but at the parasitic cost of another community.

Continued next page

While the *Butterfly Effect* is initially neutral and without specific eventual outcome, the *Bee Moth Effect* is one with specific purpose, initially through small effort, that over long chains of events can become a behemoth in damaging others. Danger can be an impetus for transcending trauma. But applied to the human species and magnified by the ripple effect of billions of individuals, the *Bee Moth Effect* is the Shadow side of this opportunity. Undercutting human progress, it is a manipulation for the gain of a few in a way that is exponentially destructive for others (Morgan 2008).

(Note: As early as 2007, it was noted that more than half the American domestic bee population had suddenly disappeared and that this seriously threatened the food supply for humans across the globe. This crisis was variously blamed on pesticide or cell phone towers or a warming climate, but at least metaphorically it certainly fit the accelerating zeitgeist of traumatic corporate Bee Moth greed across the planet.)

When the communities of a species confront crises, their survival may depend on how long the crisis endures. Unresolved crises are exhausting over long periods of time. This chronic trauma can be deadly. The emergency system of living organisms can battle so long that its hyper-metabolic response becomes locked into high gear. This is why birds, for example, surviving an unusually long harsh winter, tend to die in the Spring when the weather is warm once again.

Leaving the bees and the birds, communities of people have a similar response. They can be so locked into conflict that it becomes a way of life and, eventually, death by exhaustion. Benjamin Tong (2005) discovered a high early mortality among Chinese American males, linking this interestingly to a life-long destructive "positive racist stereotype" which, when combated effectively, saved lives. In our present Procrustean culture, we have traveled many years into an era of terrorism, both from genuine external enemies and from the Bee Moth political manipulations of fear from within.

At this writing, the crisis has not been transcended. Although we have become used to stress, we seem to have almost lost, as a national community, the essential belief in ourselves to return to a more secure and generative life. After years of externally induced stress, lethargy sets in. With each new alarm, real or manipulated, we are, again 'shaken but not stirred'. An existentialist community therapist might say: What will we do about it?

Guam was having an epidemic of Brown Tree Snakes. In the early 1990s these aggressive animals were to be found everywhere on this United States territory. In that helpful

They were seen on public streets, private lawns, and in what seemed like every tree. There were no birds anymore to be seen on the island, the snakes having eaten them all.

A psychologist friend had seen one jump from the plumbing of her toilet where she immediately dispatched it with a ready machete. Children were warned away from them as they attacked anything that moved in their direction. Tourism, particularly plentiful from Japan in prior years, was declining rapidly as word of the swarm spread.

But by the time I came to work at the University of Guam in 1999, the epidemic was over. In my years there I saw only one Brown Tree Snake and that was in a cage. It was thought that, running out of birds, they had begun to eat their own young and so had reduced their numbers drastically. Others thought they had just stopped reproducing so prolifically. The frequent power outages were regularly still blamed on the snakes, but with a smile, as most Guamanians knew, the faulty equipment and maintenance was the true culprit. My students asked me, since I was new to Guam, if I was afraid of Brown Tree Snakes. No, I told them, I just stay away from brown trees.

Where had these snakes come from and why had they swarmed? Why had their numbers retreated to near invisibility? My answers were heavily based on a book of Guam History called "*Destiny's Landfall*" (Rogers 1995) that was cheekily referred to locally as 'Destiny's Landfill'. In that helpful volume we have these disparate facts: volume we have these disparate facts:

1. Aggressive Brown Tree Snakes first appeared in Guam in the 1940s after stowing away on planes from Indonesia.
2. These stealthy hitch-hikers settled quietly into a small colony near the airport and were curiosities.
3. Decades later the radioactive refuse from nuclear submarines was stored near the home of the snakes.
4. In time the surviving traumatized snakes multiplied and swarmed the island.
5. Once relocated throughout Guam, particularly in the jungle habitats friendly to snakes and away from people, they eventually stopped over-

Continued next page

breeding and faded into quiet lives.

This may sound like a grade B movie: radiation creates monsters! Instead, the behavior of these animals is quite typical for many living (surviving) populations, including humans.

The traumatized snakes were likely all but destroyed by the radiation dump. The survivors did what animals do under decimating conditions. They moved away and reproduced exponentially. In animal populations this would usually lead to larger families and shorter life spans.

The aggressiveness may have come from pain or fear: attack as a defense.

Their swarm of the island was partially reversed by a unique intervention: a project by the U.S. Department of Agriculture Wildlife Service used mice stuffed with acetaminophen -- the active ingredient in many headache medicines -- to poison the snakes in an effort to cut down the population of the invasive species. About 280 mice were dropped from a helicopter with their legs glued to cardboard "flaggers," which are designed to hook on the jungle canopy and suspend the mice in treetops, where only the snakes can reach them. The 80 mg of acetaminophen in each mouse is enough to kill any brown tree snake and took out a large swath of survivors (*Pacific Daily News*, September 20, 2010). The remaining survivors of the brown tree snake population are hard to find, and may well avoid mice in trees. Once safe again, they may well have done what human populations do: smaller families and longer individual life spans.

Human populations that face deadly trauma produce extra progeny (remember the Baby Boom of post-WWII?) and extraordinarily larger families reduce longevity (Morgan & Wilson 2005). In quieter eras, less "interesting times", families are smaller and interest in life extension proliferates. Applied Gerontologists know this.

In thinking about our own future as a species, facing the recurrent challenges of 21st century eras, we see a time of struggle between liberal and conservative philosophies, science and scientism, ecology and greed. As has been noted earlier, the cars are typically black, silver, gray and white: a colorless temporal culture; a definitely "interesting time" where traumatic crisis is equated with opportunity (but for who?) and even this opportunity has its shadow. The Butterfly of chaos theory fame is in danger of extinction by the devouring Bee Moth of contemporary chaos emergence (Morgan 2008).

###

Suicide from the top and its prevention

On February 1, 1990, hours before Ricky Bordallo was scheduled to report to a minimum-security federal prison, the popular former Governor of Guam, committed suicide. He had wrapped himself in a Guam flag, chaining himself to the statue of Guam's first native chief to adopt Christianity, a statue located on the island's primary thoroughfare, and shot himself in the head with a .38-calibre pistol, all during rush hour traffic. In addition to wrapping himself in the Guam flag, Bordallo had set up four placards, one of which said: "***I regret that I only have one life to give to my island.***"

Despite the Catholic disapproval of suicide, the much loved Governor was given a church burial with honor. A decade later, during my work with mental health counselors at the University of Guam, the graduate students said the island community's number one prevention problem had become teen suicide. Even a depressed homicidal citizen, before gunning down people at his former workplace (and then himself), loudly proclaimed, "***I do this for the people of Guam".***

My counselor education graduate students did some good prevention work by a media campaign recognizing that suicide is not glamorous and, in fact, is a 'loser's choice'. They promoted quick counseling intervention, including ventilation of bottled up rage and compassion from friends. Not only did their interventions prevent some suicides, but the process of organized intervention transformed the students, helping all to generate more and better choices. '***Confronted with two dismal alternatives, choose a third"*** was a slogan and they became adept at generating many more.

Yet, in January 2009 a survey called "A Profile of Suicide on Guam" noted that there was an average of 23 suicide deaths per year on island between 2000 and 2007, or about one every two weeks. The survey also stated that nearly 60 percent of all suicide deaths on Guam in that time involved people younger than 30 years old. (*Pacific Daily News,* September 20, 2010).

Clearly, despite ongoing effective interventions, the trauma remains, probably intergenerational by now, and there still is work to be done.

Teenagers are so far from a time of old age and death that they can develop an illusion of immortality: what is distant seems non-existent. From that perspective, should they be in a circumstance, continuing or acute, that is overwhelmingly traumatic, they may feel trapped in an

Continued next page

eternity of suffering. A good therapist will help them see fresh options for action and the temporal reality that situations often change over time. Absent that intervention, that key insight, suicide may appear to be the only exit from pain.

Of course such sad feelings can be magnified iatrogenically.

In nearly every school shooting incident in the United States in the past 15 years, the children involved were already taking one or more psychiatric drugs, had the dose increased, or had just stopped taking them abruptly (Ross, 20006). As we have seen, recently published evidence suggests that the death rate on the more expensive newer drugs, the "atypical" anti-psychotics (Risperdol, Zyprexa, Seroquel, etc.) is twice that of patients taking the older much cheaper typical anti-psychotics (Haldol, Thorazine, etc); even though multiple studies have verified this (Whitaker, 2005), these drugs are still on the market and are the drugs of choice for current federally funded suicide screening programs (Ross, 2006).

David Healy, the psychiatrist whose research was responsible for the British banning antidepressants for children and the United States placing Black Box warnings on them, found that the suicide rate for "treated" schizophrenics has increased *20 fold* since the introduction of psychotropic drugs; he also found major increases in diabetes (Healy, 2006).

Is the crisis the diagnosis or its treatment, cause or effect? Clearly, this is a factor to consider in understanding the multiple causality of contemporary suicide. Drugs are definitely a key component of the Propane Decade: their use is exponential, heavily marketed directly to the consumer. Legal or illegal, the epidemic use of toxic drugs can be a Bee Moth for suicide-challenged communities. Psychiatrist Leonard Miller took a more nonlinear existential approach to a community's suicide prevention. At San Francisco's Center for Special Problems, he held a Contact Group the same night each week. Contact groups are walk-in opportunities for people in crisis: no paper is ever filled out, no records kept.

Leonard was ahead of his time in many ways. He prescribed drugs only as a last resort. He was the most articulate and acidic critic of any prevailing iatrogenic practice of the medical community, of which the targets were many.

Dr. Miller lived on a houseboat in Sausalito with an eclectic community of thinkers including Alan Watts. The staff at the Center could choose any client group to work with and the Contact Groups were organized accordingly. If a sly intern wrote in that his group was only for "Left -Handed Hermaphrodites", then the group might still fill with left-handed hermaphrodites, drawing on San Francisco's legendary diversity.

Another psychiatrist who we will call Harvey (much as his mother did) suddenly announced that his cooking could cure any diagnostic category and offered a Contact Group afternoon picnic to test his theory: Harvey challenged Leonard to find him clients for this healing picnic without Harvey knowing in advance what their problems were. Harvey was a great believer in excessive medication and eternal slide shows of his vacations. Leonard was a poor choice to mediate this opportunity for poor Harvey. Dr. Miller chose all self-identified bulimics for the picnic. We looked forward to Harvey's slides but none were forthcoming.

In his own group, advertised for those considering suicide, Leonard Miller excelled. We sat in and watched him take walk-in clients from "**I have no reason to live"** to the search for their own specific best reason to live. In very Ericksonian fashion, he would say:
"**Congratulations. Not having a reason to live is a great insight. Finding the best reason to live is why we are alive. Your search can begin now."**

The group helped each member, session after session, find their own individual purpose for living. The choices varied but were all admirable and suicide was quickly discarded as a good path. Leonard promised them that they would all die and most sooner than they meant to: the purpose of life was to use the window of opportunity we have to find our own purpose. Leonard was an Elder, semi-retired, and had clearly found his own purpose.

At a more recent event in 2010 for Suicide Prevention Week at Australia's James Cook University in Singapore, a very moving presentation was made by a suicide survivor. She was the mother of a much loved teenage girl who had killed herself unexpectedly at the age of 15 and mom now wrapped herself in the best memories of this child while sharing her most effective methods of trauma reduction.

This was followed by two more such presentations from trauma survivors of the families of attempted and completed suicides. In the very large crowd, many were tearful and struggling with their own survivor trauma. The mood was intense and to many it was overwhelming. I began my own serious remarks with music from Peggy Lee's "*Is that all there is?"* record which didn't help much. So I detoured the mood with the following story, recently circulating from unknown origins on the internet:

Continued next page

The Reframe

"There I was sitting at the bar staring at my drink when a large, trouble-making biker steps up next to me, grabs my drink and gulps it down in one swig.

"Well, whatcha gonna do about it?" he says, menacingly, as I burst into tears.

"Come on, man," the biker says, "I didn't think you'd CRY. I can`t stand to see a man crying."

"This is the worst day of my life," I say. "I'm a complete failure. I was late to a meeting and my boss fired me. When I went to the parking lot, I found my car had been stolen and I don't have any insurance. I left my wallet in the cab I took home. I found my old lady in bed with the gardener and then my dog bit me. So I came to this bar to work up the courage to put an end to it all. I buy a drink, I drop a capsule in and sit here watching the poison dissolve; then you, you jack-ass, show up and drink the whole thing! … But enough about me, how's your day going?"-Anonymous

The entire massive audience roared with laughter and the laughter continued on, uninterrupted by me, for what seemed like a minute or two. I knew this was not a particularly funny joke, kind of sadistic really. But this is one of the elements of successful healing from suicide trauma, as well as other fairly traumatic events.

Fighting back in a good way and on target humor can be powerful access signs to healing, both in therapy and in lecture halls. The feedback after the event was that this was a very helpful comment, although many were somewhat puzzled why that might be.

Sometimes, trauma and depression so suppress the joy in life that the right combination of turning the tables and laughter can be liberating. It can help prevent suicide or the impact of secondary trauma from a family suicide. Or so it seemed that evening.

On the other hand, sometimes even some health professionals "assist" suicide. To live or die is a fundamental existential choice. So who gets to decide, if not you? For me, the best choice is life, brief as this unmatched opportunity is.

Once again: ***"If that's all there is, let's keep on dancing."*** **(Peggy Lee, 1969)**

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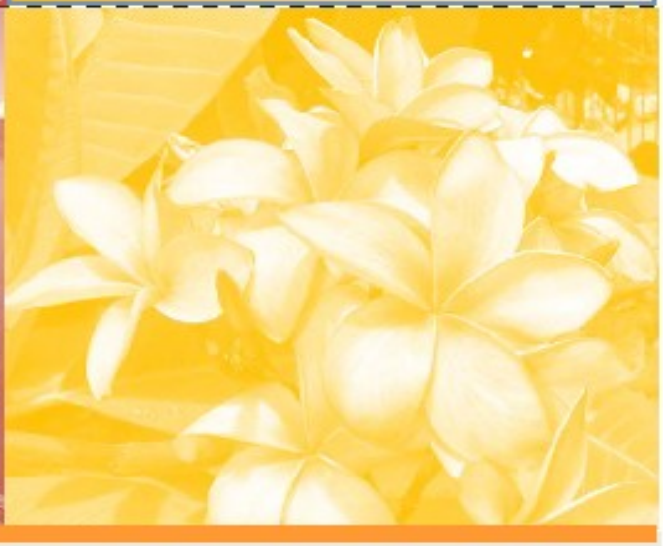

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PSYCHOLOGY Learning & Teaching

Internationalizing Postsecondary Education in Psychology: a global endeavor

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ABSTRACT The twenty-first century has witnessed a widespread call for internationalizing postsecondary psychology education. The authors discuss the rationale for recent efforts to enrich psychological contents, methods, and practices by internationalizing the teaching of psychology. They present aims and results of an online survey on how psychology instructors, primarily in the United States, can make psychology education more international. They also discuss strategies to incorporate international psychology perspectives in such aspects of teaching as lectures, classroom activities, assignments, and the use of Internet-based technologies. They describe the aims of a second online survey that compares European and US faculty perspectives on internationalization in psychology. Future research should empirically explore the effectiveness of instructional strategies and assess specifically defined learning outcomes of an internationalized psychology education.

Many psychologists in the United States are calling for the internationalization of the psychology curriculum to better prepare students for practice, research, and service in the twenty-first century (Leong, Leach, Marsella, & Pickren, 2012; Lutsky et al., 2005). Faculty face challenges that include the changing political, economic, social, and environmental forces, which cause them to re-think their teaching goals and methods so as to make psychology more relevant to global problems (Hogan & Vaccaro, 2007; Marsella, 2007). In this article, we present (a) a rationale for expanding the way psychology is typically taught in the United States; (b) a description of a survey administered to members of the American Psychological Association's (APA) International Psychology Division (52) and other APA members on international listservs (nearly all respondents were psychology instructors) and of another survey currently under way for psychology instructors in the United States and Europe; and (c) specific teaching strategies to help faculty incorporate a deliberately international perspective in their psychology courses.

Rationale for Internationalizing Psychology Education in the United States

Western, including US, psychology is often presented as universal to students in classrooms across the country. In reality, it is a psychology that reflects values and norms of the dominant social culture in its accumulated knowledge, methods used to acquire knowledge, and the perceptual frameworks through which content and process are understood. Although it is reasonable to expect psychology to reflect the normative culture of those by whom it is developed and for whom it is practiced, it typically is taught in a manner that divorces it from the cultural context in which it was created (Grenwald & Velayo, 2011).

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Through their learning experiences, students of psychology are enculturated into a psychological perspective, just as they are enculturated into a language community. Students and their professors rarely examine cultural influences on the epistemology of psychological knowledge. Thus, the social-cultural framework is rendered invisible by its familiarity. Only when one steps outside one's culture of origin by being exposed to other cultural milieus does the previously invisible framework begin to take shape. For example, when students learn about indigenous psychologies in other parts of the world, they begin to understand the peculiar cultural configurations of psychology in the United States.

In recent years, many voices (Marsella, 2007; Marsella & Pedersen, 2004; Stevens & Wedding, 2004) have called for psychologists in the United States to acknowledge the hegemonic position of US psychology, and of western psychology more generally, and to enrich its content, methods, and practice by incorporating diverse cultural perspectives and values so that a 'universal' psychology might be more fully realized. On this view, universals in psychology, should they emerge, will be taught side by side with culturally specific theories, methods, and practices. Students of international psychology will learn to appreciate the cultural specificity of psychology as well as its universality, and will have the appropriate skills to determine which is which.

Psychologists of tomorrow must be ready to understand and intervene in societal problems that impact individuals, families, and communities, such as war and conflict, terrorism, global climate change, disease, and the needs of the global poor, refugees, and immigrants (Marsella, 2007). Students who successfully complete an internationalized psychology program should have not only an increased knowledge base and expanded skills but also the motivation and ability to continue professional development that is internationalized (Yershova, DeJaeghere, & Mesterhauser, 2000).

Surveying Psychology Instructors about Making Psychology Education More International

Early in 2009, we developed and administered an online survey to learn more about how psychology faculty are internationalizing their courses. We sent the survey to the International Psychology Division members of the APA's Division 52 and to other APA members on international listservs. More than half of our 128 respondents had begun to internationalize how they teach psychology. Of those respondents, full professors were the largest group (nearly half). Associate and assistant professors followed, with just under 20 percent for each group. Adjunct and other instructors, some in secondary education settings, made up the remainder of respondents who were internationalizing their teaching. In descending order, faculty at comprehensive institutions, community colleges and liberal arts institutions (tie), research institutions, and other types of institutions reported that they had begun to internationalize the courses they teach (see also Grenwald & Velayo, 2011).

Our current online survey (Grenwald, Oberlechner, & Velayo, 2012) allows us to compare and contrast perspectives on an internationalized curriculum from psychology faculty in the United States and in various European countries. Among the questions we hope to answer are: Is the concept of 'internationalizing the psychology curriculum' familiar in Europe? How interested are psychology faculty in more broadly preparing their students to participate in an increasingly interconnected world? In which ways are they already doing it? What geographic differences exist in views and practices regarding a more international psychology education? With provisions of the Bologna Accord under way, there will be increasing conformity to an agreed-upon model for European higher education, and for both undergraduate and graduate degrees (European Commission: Education & Training, 2011). What are the implications for internationalizing psychology education under the Bologna Accord?

Recommendations for Psychology Instructors

Internationalization is more than the inclusion of international content into courses. It also involves the development of internationalized instructional strategies (Fraser & Bosanquet, 2006). The major goal of internationalizing psychology education is to increase student competence to do

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research and to practice psychology in a global setting. This goal can be achieved through lectures, classroom activities, out-of-class assignments, and Internet-based technologies. Accordingly, student-learning outcomes and their assessment should also reflect such competence. What follows reflects findings from the first survey of APA Division 52 members and selected others described above (Grenwald & Velayo, 2011).

Lectures

Lectures are a straightforward way to integrate international content into psychology courses. Cultural and ethnic references may be woven into lectures to illustrate the international diversity in psychology (Marsella & Pedersen, 2004). Some instructors compare and contrast issues related to gender and education in the United States with those in other countries or examine child-rearing practices across cultures. Other instructors use case examples from other countries, international data sets, or personal international experiences. Including contributions of non-US psychologists is another way to internationalize lectures. Guest lectures by individuals with international expertise or who represent another culture also internationalize course content. International students may be invited to provide guest lectures in which they share personal experience and background related specifically to course content (Gurung & Prieto, 2009; Ho, Bulman-Fleming, & Mitchell, 2003).

Classroom Activities

Classroom activities can serve as an important adjunct to lectures in promoting international perspectives. Faculty may employ activities that require the integration of cultural information, such as applying selected concepts and research findings to individuals in a different country. For example, the discussion of attachment theory may include differences in child-rearing practices that vary in terms of the extent to which parents teach autonomy to their children.

Discussion of world events helps students understand how those events impact psychological well-being and development in diverse communities. Such activities may draw from international data sets and from international news. For example, how do natural disasters or political unrest affect a population's mental health and attitudes toward life? Incorporating films into courses can enhance an international perspective on psychology (Meiners, 2009). Activities such as autoethnography (the cultural analysis of one's own culture) might be beneficial at the outset of a course, because first knowing one's own culture is an important part of understanding and appreciating others' (Marsella & Pedersen, 2004). Asking students at the beginning of the course about the culture(s) with which they identify and the countries they have visited can provide useful information for the instructor's inclusion of student cultural experiences during the course.

Student Assignments

Our survey results indicated that instructors often assign research papers about psychology and psychologists in other countries in order to broaden students' exposure to alternative views. Requiring students to read international news, interview someone from another culture, or conduct collaborative projects with students from other countries (either in person or via the Internet) may also be valuable.

Internet-based Technologies

Internet-based technologies are becoming increasingly popular as a means to incorporate international content into psychology courses (Velayo, 2011; Wankel, 2010). These resources enable many of the teaching strategies mentioned earlier, and are accessible and cost-effective (Guerin, 2009). Not all students are able to travel or study abroad due to the cost involved or to personal circumstances. Internet access allows psychology students a wide range of opportunities for cross-cultural collaboration without having to leave the country. It provides access to the international literature and to multimedia materials created by individuals in other countries.

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Videoconferencing (e.g., Skype) allows instructors in different countries to lecture jointly and students to participate in discussions with peers from other countries. Because many textbooks used for psychology courses include little, if any, international content (Woolf, Hulsizer, & McCarthy, 2002), international electronic databases, e-books, and e-articles can be useful supplements.

Recommendations for Future Research on Internationalizing Psychology Education

We offer two recommendations for internationalizing psychology education: (a) exploring the effectiveness of instructional strategies; and (b) assessing student-learning outcomes.

Exploring the Effectiveness of Instructional Strategies

It is important to determine the effectiveness of instructional strategies used to bring international content into the psychology classroom. Students who have completed a psychology course with an international component could be surveyed about their learning and, specifically, their classroom experience. Possible questions to be addressed are: does student interest increase when lectures include international content? What types of assignments do students find most effective for developing an international perspective? What can instructors do to increase student involvement in meaningful discussions about issues from an international perspective?

Similarly, instructors who incorporate international content in their courses could be surveyed by researchers to identify specific effective strategies. Empirical research on the use of specific instructional strategies could examine the context of specific courses, demographic characteristics of the students, pre-post levels of international psychological knowledge, and resources available to the instructor.

Assessing Student-learning Outcomes

Instructors need to specify student-learning outcomes that will help them determine whether students meet the international goals for a course. Such outcomes alert students to the fact that international content is not merely an add-on to the course but in fact is central to it (Bartolini, Gharib, & Phillips, 2009). The APA asserts 'international awareness' as one of its official goals for the undergraduate psychology major. In a 2004 collaboration with the American Council on Education, the APA formed a task force to help suggest ways to internationalize the undergraduate psychology curriculum (see Lutsky et al., 2005). The final report delineated goals and student-learning outcomes in five domains of psychology instruction: knowledge; methodology; discipline of psychology; interpersonal understanding; and global issues (Belar, 2008; Lutsky et al., 2005).

The future of psychology will be realized by today's students. Internationalizing the curriculum will prepare them to competently understand and potentially intervene in global problems. Many faculty members already are heeding the call to incorporate international content and themes in the courses they teach (e.g., Belar, 2008; Grenwald & Velayo, 2011; Guerin, 2009; Leong et al., 2012). We hope this brief review of models for curricular internationalization and available resources will encourage others to follow suit in the best interests of the psychologists of tomorrow.

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МЕЖДУНАРОДНОЕ НАУЧНОЕ СОТРУДНИЧЕСТВО

BUILDING BRIDGES: PSI CHI AND INTERNATIONAL PSYCHOLOGY

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"How can Psi Chi best partner with international psychologists to expand the honor society worldwide?" This has been an important question since 2009, when the 1,100 chapters of Psi Chi in the United States voted to become "The International Honor Society in Psychology". This report updates and expands on a unique symposium offered at the 120th meeting of the American Psychological Association in Orlando, Florida, in August of 2012 — the first symposium on the Presidential theme of "Building Bridges" between Psi Chi and international psychology [8]. Here, seven leaders in international psychology in North and South America join to address different aspects of this timely question--with many suggestions on how to "build bridges" to expand Psi Chi globally. It was in part due to this historic symposium that in 2013 Guatemala became the first nation in Latin America, and Russia the first nation in mainland Europe to launch a chapter of Psi Chi.

Key words: International Honor Society in Psychology Psi Chi, American Psychological Association (APA), international psychology, student scientific society, scientific work of students.

OVERVIEW

(by Martha S. Zlokovich)

The field of international psychology is expanding as people around the world connect to share ideas about psychological and social issues, psychology education, and psychological interventions. In 2009 Psi Chi, the National Honor Society in Psy-

chology — founded in 1929 in the US — became Psi Chi, the *International* Honor Society in Psychology. The purpose of this symposium was to learn more about the internationalization of Psi Chi including how and why the Society has been welcoming international Psi Chi chapters. The individual presentations were followed by discussion of the issues brought up by the symposium presenters.

Many of the contacts Psi Chi makes outside the US are dependent on the time, effort, and dedication of international psychologists who spread the word about Psi Chi when they travel. Since 2009 the first two international chapters (affiliate chapters in Canada and Ireland that became full chapters at that time) have expanded to 15. These include 12 chapters in ten countries, and another three chapters outside the 50 states. As of September 2014, additional applications were in progress from faculty in Australia, Ecuador, India, Indonesia, Italy, Kuwait, Malaysia, The Netherlands, Puerto Rico, and Serbia [20; 21].

WHAT IS INTERNATIONAL PSYCHOLOGY?

(by Alvin Y. Wang)

What is International Psychology? What are reasons for Psi Chi to become an international organization? How can chapter advisors help internationalize their chapters?

In 2009, after several years of deliberation, Psi Chi's Board of Directors elected to "*go global.*" It is interesting to note that Psi Chi was founded at the Ninth International Congress of Psychology which took place on September 4, 1929 at Yale University. So 80 years after its founding, Psi Chi returned to its international roots.

Psi Chi's Purpose Statement was revised to reflect its global aspirations: *Psi Chi is an international honor society whose purpose shall be to encourage, stimulate, and maintain excellence in scholarship of the individual members in all fields, particularly in psychology, and to advance the science of psychology.* With this global vision, Psi Chi began to rebrand its logo, redesign its website, and update its marketing efforts to better serve the international psychology community.

Since 2009, Psi Chi expanded its outreach efforts to cultivate new friends and partnerships with organizations that share Psi Chi's vision for advancing psychology in the international arena. In this regard Psi Chi views APA Division 52 as a steadfast partner who has helped us build bridges across international waters. Several members of Division 52 were instrumental in these efforts. Dr. Harold Takooshian (former Psi Chi President) promoted Psi Chi to four Russian institutions in Moscow including: the Higher School of Economics (HSE), HSE's International Laboratory of Socio-cultural Research, the People's Friendship University of Russia, and the Russian Academy of Science's Institute of Psychology. Also instrumental in our friend-raising efforts was Dr. Mercedes McCormick, who is incoming President of Division 52 and Psi Chi Vice-President for the Eastern Region. Dr. McCormick promoted and implemented joint programming between our two organizations at the 2012 annual meeting of APA as well

as past meetings of the Eastern Psychological Association. Psi Chi is also appreciative of the support and sage advice concerning internationalization provided by two of Psi Chi's past-presidents: Dr. Florence Denmark and Dr. John Davis.

Psi Chi's Executive Director Dr. Martha Zlokovich has racked up her frequent flier miles while travelling overseas to promote our organization. In November of 2011, she attended the Caribbean Regional Conference on Psychology in the Bahamas and in July 2012 she attended the annual meeting of the International Association of Cross-Cultural Psychology in South Africa. This was followed by a Psi Chi presentation she made at the annual meeting of the International Congress of Psychology which was also in South Africa. There were several co-presenters including Psi Chi President Dr. Susan Amato-Henderson and Psi Chi President-Elect Dr. Maria Lavooy. It is also noteworthy that Dr. Zlokovich is incoming chair for the International Relations Committee of Division 2 and she is also a member of the Division 52 International Committee for Women.

Early Psi Chi's efforts began showing results, with the first five international chapters established in Canada (2), Ireland, New Zealand, and Egypt. We also have chapters in Puerto Rico (2) and in the U.S. Virgin Islands. Two chapters have been approved for University of the West Indies campuses (Barbados and St. Augustine), and several other international chapters are in various stages of the review process including: Russia, Guatemala, Australia, and England.

As with any organizational expansion, growing pains are to be expected. Psi Chi's Board of Directors is currently discussing several issues related to our international efforts. Perhaps the most critical is how we can meaningfully integrate international chapters into the governance structure of our society. One possibility is that an international region is created in additional to the six regions that currently exist. Another issue is that Psi Chi must improve its IT infrastructure to better meet the needs of our international chapters. Finally, Psi Chi's Board of Directors has been discussing ways in which our international chapters can participate in the numerous grants and awards programs that are available to students and faculty members.

As I pointed out earlier in my presidential message to Psi Chi members, "the time is right for Psi Chi to sit at the global table and join the transnational discourse that already exists through organizations such as Division 52..." [19. P. 4]. I am pleased to report that as of now Psi Chi has made significant advances in its efforts toward internationalization.

COMMUNITY INTERNSHIPS: STRENGTHENING MULTICULTURAL COMPETENCIES THROUGH INTERNATIONAL COLLABORATIONS

(by Maria del Pilar Grazioso)

In my Universidad del Valle de Guatemala (UVG), our students and faculty have a long tradition of working together on community partnerships. In 2013, after three years of effort, our UVG successfully formed the first chapter of Psi Chi in Latin America. One key project we hope to pursue is culturally-appropriate Spanish-language materials

to help introduce the Psi Chi concept to the hundreds of four-year colleges throughout Latin America. In July of 2014, our chapter was pleased to release a five-minute, Spanish-language video that is suitable to show throughout Spanish-speaking Latin America, www.youtube.com/watch?v=xo2lsDKtiw4&feature=youtu.be.

We hope to expand on this early effort, to promote Psi Chi globally.

PSI CHI OUTREACH TO THE EASTERN HEMISPHERE

(by Harold Takooshian)

How can Psi Chi best expand beyond North America? Though Psi Chi had its origins at an international meeting in 1929, it has been limited to the USA for its first 80 years [15]. Yet Psi Chi has long been interested to open its benefits to the fast-growing number of psychology students and faculty outside the USA [5], to the point of inspiring a new international student group on its 70th anniversary in 1999 — the International Psychology Student Organization, or IPSO [16]. We know Psi Chi's immense role in shaping psychology in the USA [6], which it portends to do in other nations [10; 12; 14].

On its 80th year in 2009, when Psi Chi chapters voted to "Go global," many leaders of the APA international division were also past national officers of Psi Chi. Prime among these in 2012 was Psi Chi Eastern Vice President and Division 52 President-elect Mercedes McCormick, who chose her timely Presidential theme for 2013: "Building Bridges between Psi Chi and international psychology" [8].

In 2013, the Psi Chi Board appointed 14 Psi Chi "International Ambassadors" within the APA Division of International Psychology, to spread the word about Psi Chi while traveling abroad [13]. These 14 Ambassadors were: Bernardo J. Carducci, Lauren Crane, Dwayne Crites, John M. Davis, Florence L. Denmark, Melanie Domenech Rodríguez, Joseph R. Ferrari, Gina Grimshaw, Paul I. Hettich, Hy Le Xuan, Mercedes McCormick, David Skeen, Michael J. Stevens, Harold Takooshian.

As of 2014, the 1,100 Psi Chi chapters at U.S. campuses include nearly 90 percent of eligible U.S. four-year colleges. In contrast, Psi Chi has barely a dozen chapters among the thousands of campuses now eligible on six other continents.

Russia. In 2010, to mark the 125th anniversary of the origin of psychology in Russia in 1885, Professor Alexander Voronov integrated Psi Chi into his five-day multi-city conference [18]. Hundreds of students and faculty at five institutions in two cities appeared visibly excited to learn about the benefits of Psi Chi. One professor, Alexey Sozinov of the Russian Academy of Sciences in Moscow, went further to produce a nine-minute Russian-language DVD describing Psi Chi in detail--its origin, growth, procedures, benefits. This DVD was posted on YouTube, http://youtu.be/1t63fKZ1OPY. Teams of Russian students and faculty began to participate in Psi Chi programs in the USA in the 2011 EPA in Cambridge, 2012 EPA in Pittsburgh, 2013 EPA in New York, 2014 EPA in Boston [1; 11].

In 2012, when I returned to Russia as a Visiting Professor at the Higher School of Economics (HSE), I could see changes within just two years. Students at a few Russian

schools had formed active psychology clubs. (One chapter application requirement is having had an active psychology club for at least one year.) Students were becoming more involved in co-curricular research and other activities [4]. The People's Friendship University of Russia (PFUR) hosted co-curricular activities for its 20,000 students from 140 nations (www.rudn.ru/en/). The Institute of Psychology at the Russian Academy of Sciences (IPRAS) hosted co-curricular activities that brought together students and faculty from diverse institutions, http://ipras.ru/cntnt/rus/novosti/rus_news1/n3468.html. Each of the four institutions I visited was pleased to receive a copy of President-elect Mercedes McCormick's personal invitation to the next Eastern Psychological Association meeting in New York City on 1—4 March 2013, and many came in 2013 in New York and 2014 in Boston.

Russia's land area of 6.6 million square miles makes it the "world's largest nation", and one where Psi Chi may grow rapidly among Russia's 1,100 HEIs (higher education institutions). Hopefully, Psi Chi may use the internet and this Russian outreach model to develop culturally-appropriate DVDs in other languages (Spanish, Arabic, Chinese, French) to reach the countless students and faculty who do not yet know what awaits them in Psi Chi.

In 2013, history was made on October 11, when the Peoples' Friendship University of Russia installed the first chapter of the Society in Russia and mainland Europe [2; 3]. Details on-line: www.youtube.com/watch?v=ggtdPVAPjJY. In that same week in October of 2013, PFUR appeared in the roster of "the world's top 500 universities" in the *QS World University Rankings* for 2013 (www.rudn.ru/?pagec=3372).

WHAT AN INTERNATIONAL UNIVERSITY/COLLEGE NEEDS TO KNOW TO APPLY TO BECOME AN INTERNATIONAL PSI CHI CHAPTER

(by Mercedes A. McCormick)

How does an international university/college start an international chapter in Psi Chi International Honor Society, and foster Psi Chi connection with APA Division 52, International Psychology? In the 21st century, it is fitting for Division 52 and Psi Chi to connect and collaborate on issues important to undergraduate and graduate students as they embark in careers in psychology [8]. It is clear that "the recent expansion of Psi Chi internationally promises to offer student members assistance on the path to academic excellence, exciting research possibilities, leadership opportunities, mentorship for career advancement, and opportunities to provide service to their communities" [9. P. 112].

Background. Psi Chi's international connections stretch back to its very formation on September of 1929, during the Ninth International Congress of Psychology in New Haven-the first world congress on U.S. soil [7].

In 1963, Psi Chi sent psychology textbooks overseas, published a special global issue of its *Psi Chi Newsletter*, and hosted overseas students at the APA meeting. In 1964, Executive Director Ruth Cousins joined a 20-person world tour with the International Council of psychologists (ICP), which later appointed an ICP liaison to Psi Chi. In 1984,

Psi Chi changed its bylaws to allow international chapters, and in 1990s, another push saw Psi Chi welcome applications from schools in Canada, though none completed the chapter process.

In 1994, Psi Chi formed an international committee with a liaison to APA's CIRP, and the committee's chair visited the ICP meeting in Lisbon, Portugal to inform colleagues in other nations about the "impact of a student honor society on a nation's psychology" [12]. Among other things, this committee also worked with APA's Joan Buchanan to conduct two surveys of 75 national psychology associations, to find which nations had student psychology groups like the USA; although no nation reported an independent student group. 15 (20%) permitted some students to affiliate with their national association.

In 1996, Psi Chi invited 50 Canadian schools to its first student mini-convention outside the USA (*Upward Bound*), hosted by the University of Toronto on the Thursday before the APA meetings, and a small cadre of Canadian students joined about 80 U.S. participants.

In 1999, past-President Slater Newman organized a session at APA exploring the formation of the first international student group, close on the heels of his 1998 article in the International *Journal of Psychology* detailing Psi Chi as a "model [that] might well be adapted by leaders in other nations to promote student excellence" [14. P. 367]. In Spring of 2000, *Eye on Psi Chi* published a special issue on international psychology edited by Kay Wilson and Dan Bockert, bringing together original articles by several key cross-cultural figures — Walter J. Lonner, John Davis, Leonore Loeb Adler--and launching the Eye's new International Notes column.

How can Psi Chi members become more involved in this growth of international psychology while still students? Let us see.

Psi Chi's International Connection. In 2012, APA's Division 52 of International Psychology marks its 15th anniversary. In 1997, APA approved this new Division. It quickly grew into a large and active force within US psychology and now internationally. It is important to note that Psi Chi members and Chapter Advisors have been so much at the forefront of this effort.

Several Division 52 Presidents also have been President of Psi Chi. These respected international psychologists include: Florence Denmark (Division 52 President in 1999, Psi Chi President in 1978—80), and Harold Takooshian (Division 52 President in 2003, Psi Chi President in 1998—1999.)

In 2009, Psi Chi went international. In Psi Chi bylaws, the name of the organization was changed to *Psi Chi International* with the mission to be a society in psychology to promote student excellence, leadership, research, and service learning internationally. Since 2009, Psi Chi International has encouraged international colleges and universities to petition to open a Psi Chi chapter. Already a dozen chapters started with the National University in Galway, Ireland; American University in Cairo, Egypt; University of West Indies; Peoples' Friendship University of Russia; and more--as Psi Chi expands globally.

The Psi Chi website has instructions to start a Psi Chi Chapter, www.psichi.org.

INTERNATIONALIZING PSI CHI

(by Florence L. Denmark)

Thank you to our esteemed panel of presenters who have spoken on the psychological and social issues that impinge on Psi Chi students in a world that is becoming increasingly more global.

In 2009 Psi Chi, the Honor Society in Psychology in the US became the *International Honor Society of Psychology,* an impressive accomplishment. This will truly help the next generation of psychologists create a cohesive field of psychology internationally.

The field of International Psychology is expanding as the world connects globally about issues regarding coping with psychological and social issues and learning about interventions that may help others in our global society.

Division 52 is the primary Division within APA with a focus on internationalization of Psychology, whereas Psi Chi is the biggest and newest "international" psychology organization with students, faculty, and other professionals comprising its membership worldwide.

Psi Chi and Division 52 were represented in the conference of the International Congress of Psychology and the International Council of Psychologists recently held in Cape Town, South Africa (July 22—27, 2012).

Going forward, it is our goal to build bridges between Psi Chi and Division 52. We can begin by focusing on the following.

1. *Membership/Outreach*

Assist each other in helping establish chapters during travels abroad.

Sharing resources with each other to help internationalize psychology and outreach for members (collaborative membership drive)

Division 52 members in institutions with Psi Chi Chapters can encourage students to join Division 52. Conversely, Psi Chi chapters can help Division 52 recruit Psi Chi students as student affiliates.

2. *Meetings and events*

Share a suite and collaborate on suite activities

Division 52 may give reports on its activities relevant to Psi Chi members through meetings (and vice-versa)

Having joint session such as this one in future APA meetings

Psi Chi programs can include Division 52 — featured events, talks (and vice-versa)

Speakers Network — focus on student-relevant matters

3. *Mentorship opportunities*

Division 52 members can mentor students

Psi Chi students may become involved in international research and internship opportunities with Division 52 members

4. *Publications*

Psi Chi Journal of Psychological Research, International Psychology Bulletin, International Perspectives in Psychology: Research, Practice, Consultation — provide opportunities to publish collaborative international research

Division 52 President (and perhaps other leaders of Division 52) may write articles on *Eye on Psi Chi.* Conversely, Psi Chi leadership may publish in the *International Psychology Bulletin.*

5. *Grants/Funding Opportunities for mutually beneficial projects*

Collaborative research grants between Psi Chi students and Division 52 members

Division 52 and Psi Chi can pool resources to help fund projects between its members.

6. *Awards*

Recognition given by both Psi Chi and Division 52 to recognize collaboration on research work between students and international psychologists on topics that promote international psychology.

7. *Governance*

Encourage Psi Chi and Division 52 to have representatives/liaisons to attend their midwinter or annual meetings

BUILDING BRIDGES WITH TECHNOLOGY

(by Richard S. Velayo)

I thank our outstanding panel members for their informative presentations. Their information and recommendations will certainly strengthen the international reach of Psi Chi, contribute to building bridges between Psi Chi and Division 52 and more importantly, help promote the internationalization of psychology.

Psi Chi and APA Division 52 can benefit from each other in so many ways. In a way, we are meant for each other. We share an important goal of internationalizing psychology and providing opportunities for students, faculty, practitioners, researchers, and advocates for internationalization to be able to collaborate and share experiences and expertise with each other.

What I would like to emphasize here is how internet-based technologies may help build bridges between Psi Chi and Division 52, which, in turn, further the internationalization efforts of both organizations. In other words, we can go global by going virtual! Internationalization efforts by Psi Chi and Division 52 may continue to explore further innovative ways to collaborate and do outreach.

Many organizations effectively utilize social media in their attempt to reach out to other nations. Psi Chi and Division 52 are no exception. For example, as of March, 2012, both have Facebook group pages effectively establishes their web presence to the world. Facebook, the most popular social networking site, had over 835 million active users worldwide. Of the 835 million users, 233 million came from Europe, 196 million from Asia, 173 million from North America, 113 million from South America, 41 million from Central America, 40 million from Africa, 20 million from the Middle East, 40 million from Oceana and Australia, and about 6 million from the Caribbean (*http://www.internetworldstats.com/facebook.htm*).

Facebook is also accessible in more than 70 different languages. An average of 500 million people log on to use Facebook everyday. The percentage of users in various

countries who are on Facebook are astonishing: 80 percent of all Internet users in Chile, Turkey, and Venezuela, 60 percent of all Internet users in the U.S. and U.K., 20—30 percent of all Internet users in Brazil, Germany, and India, and 15 percent of all Internet users in Japan, Russia, and South Korea. Unsurprisingly, there is less than 0.1 percent in countries that restrict Facebook (like China) [17].

Nonetheless, the global usage and reach of Facebook, and many other Internet-based technologies, is tremendous. Its use by so many students and various academic, professional, and business organizations is indicative of the future of inter-organizational communications in a world that is increasingly global and interconnected.

Also note that there are various other forms of Internet-based technologies: teleconferencing (e. g., Skype), Twitter, Blogs, GoogleTalk and Google+, Wikis, YouTube, and even FaceTime (for Mac, iPhone and iPad users), all of which can facilitate internationalization efforts and outreach.

Bridges. Below are a variety of ways to build bridges between Psi Chi and Division 52 through shared objectives related to membership, meetings and events, mentorship opportunities, publications, grants and funding opportunities, awards, and governance. All of these objectives are feasible and may be efficiently and effectively facilitated, in part, through electronic communications. These are some practical recommendations on how the Internet may build bridges given the shared objectives of both organizations.

1. *Membership and Outreach*

Recruitment efforts may be shared and be done virtually through social media and other internet-based communications. Having membership application forms that encourage dual membership, can be created. Such forms may even be completed online and perhaps presented in different languages.

Division 52 members can send out information regarding Psi Chi activities and events, through their social media accounts and through departmental listservs/emails/ and electronic newsletters. Psi Chi can do the same with Division 52 activities and events.

International Psi Chi chapters can regularly and efficiently keep in touch with the Psi Chi central office, mutually providing each other updates of news, events, and other activities. Selected news may be shared among various Psi Chi chapters and international psychology organizations.

2. *Meetings and events*

Members can participate (and perhaps even present) in activities through Skype, webinars, or even through blogs. Videos of collaborated events may even be posted on YouTube. Facilitating meetings, coordinating events and activities, can be conveniently and easily shared.

There may be times in which students abroad are unable to attend a conference or to be recognized for their leadership or scholarship. Perhaps Division 52 and Psi Chi may explore ways in which members can participate and even present their work through

online meetings, webinars, or even through Skype. Such sessions can be highly interactive between participants and presenters, wherever in the world they may be as long as they have internet access.

3. *Mentoring.* Division 52 members may be able to do their mentoring online.

4. *Research and Grants*

Division 52 and Psi Chi can collaborate on developing a web-based repository of reviewed projects and articles by students from various parts of the globe.

Use of wikis or Google docs to work on electronic documents and projects may be utilized in preparing publications or presentations.

Division 52 members and Psi Chi can work collaboratively on applying for and carrying out grant projects.

Students may help with creating online surveys and in data collection through social media sites.

5. *Governance and Committee involvement.* Members of both organizations may contribute their time and participate in meetings online, which may be an efficient and lower-cost alternative to meeting in person at conferences or midwinter meetings.

In spite of these recommendations, it is wise to keep in mind at least two anticipated difficulties that will likely be encountered. First is that access to the Internet may be limited in other countries, reducing their ability to communicate internationally. Second, language barriers can certainly be problematic between certain nations. Online translation software is becoming more sophisticated to help people to communicate, but it has not reached that level in which we can completely trust this technology to translate one language to another.

In conclusion, Psi Chi and Division 52 are a natural match. It is reassuring to know that a number of its leaders (including our esteemed panelists), continue to serve as important conduits to strengthen the bridges that have been built between our two organizations.

If there are those of you who are not yet members of Psi Chi or of Division 52, I urge you to join both, and to join now, to be part of this tandem force. Given this bridge that has been established, you can expect both our organizations to continue to be at the forefront in the effort to internationalize psychology.

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ПСИХОЛОГИЧЕСКОЕ ОБЩЕСТВО ПОЧЕТА PSI CHI И МЕЖДУНАРОДНАЯ ПСИХОЛОГИЯ: УСТАНОВЛЕНИЕ КОНТАКТОВ

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Статья посвящена поиску ответа на вопрос о том, как партнерство с международными психологами может помочь интернализации Психологического общества почета Psi Chi. Этот вопрос стал актуальным начиная с 2009 г., когда 1100 отделений Psi Chi в США проголосовали за то, чтобы стать «международным» обществом. Статья представляет собой обновленный и расширенный отчет об уникальном симпозиуме, состоявшемся на 120-м съезде Американской психологической ассоциации (АПА) в Орландо (штат Флорида) в 2012 г. Это был первый симпозиум по предложенной Президентом АПА теме «Наведение мостов» между Psi Chi и международной психологией [8]. На симпозиуме выступили семь лидеров международной психологии из Северной и Южной Америки со своими предложениями о глобализации Psi Chi. Отчасти благодаря этому историческому симпозиуму в 2013 г. Гватемала первой из стран Латинской Америки, а Россия первой из стран континентальной Европы открыли свои первые отделения Psi Chi.

Ключевые слова: Международное психологическое общество почета Psi Chi, Американская психологическая ассоциация (АПА), международная психология, студенческое научное общество, научная работа студентов.

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Psychology Is a **Contact Sport**

I am just beginning my year as President of Psi Chi, and I'm excited at the prospect of some major developments opening up for the organization this coming year. One of the biggest changes will be the development of a new Psi Chi website to allow access to more information in an easier to navigate format. In addition, you will see the membership application process shift from faculty data entry to online application by prospective students, interactive features within each region, and continual improvement of online submissions for awards and grants.

But it is the development of some other new initiatives that I want to highlight here to support one of the most important experiences you can gain during your time in college. Sure, everyone tells you to "get involved," and most of you, by dint of being a Psi Chi member, likely already fall into the "well-connected" category.

There is, however, an increasing truism about best preparing for any career involving the application of psychology: you must gain some form of research or internship experience (e.g., Giordano, Davis, & Licht, 2012; Wegenek & Buskist, 2010). Taking classes is not enough to cultivate the variety of skills you will need for the specific research or practitioner environs to which you may aspire.

Psychology is a contact sport. You must directly, viscerally encounter the specific settings in which psychology is studied and applied in order to a) acquire helpful research- or practitioner-related skills that future graduate programs and employers will value, and, equally importantly, b) assess early enough in your student career whether or not these psychology-relevant experiences are a "good fit" for your own career goals. In other words, fully immerse yourself in these experiences in order to appreciate the challenges and demands of being a researcher and/or practitioner. If that feels enlightening and exciting, go forward; if not, speak with an advisor immediately to re-evaluate your career course.

Where does Psi Chi fit into this process? Everywhere. One of the central goals of Psi Chi (in addition, of course, to honoring your excellent progress in your psychology work) is to provide monetary support to help our members conduct research and present that research at conferences.

With respect to research support, Psi Chi offers a number of awards and grants (see http://www.psichi.org/awards/data_sheet.aspx for a quick overview) that help fund specific research projects, summer research experiences, and research and practitioner-related internship opportunities.

What if research opportunities on your campus are limited? One option is to contact area research institutions. This could include other colleges and universities, as well as hospitals, clinics, government-run health agencies, and sometimes even private industries that may have in-house research divisions.

More persistent students, who are often more assertive about their education, will take the initiative to find out about these off-campus opportunities. There is no rulebook here other than conducting yourself as a professional as you seek out these experiences.

In addition, Psi Chi is working to help provide some online research opportunities that would allow our members to collect data at their own campuses for larger projects being conducted at multiple sites. Some of these projects may also offer publication opportunities for participating researchers. As one example, our Western Regional Vice-President, Jon Grahe, is currently working with Psi Beta (the psychology honor society for community college students) to develop an online National Research Project. Details on this project were included in regional vice-presidents' fall 2012 letters, and more will be sent to Psi Chi members in coming weeks.

With respect to presenting your research, Psi Chi in recent years has made special efforts to listen to its members and has been increasing the number and variety of travel grants to psychology conferences. Regional travel grants help with costs associated with attending and presenting at any of the six regional psychology conventions. More of our members attend these conventions than any other type of conference. Deadlines for these grants vary by region. Check http://www.psichi.org/Regions/ for details on your region's travel grants.

In addition, Psi Chi recognizes that there are many other more specialized conferences that our members would like to attend. Some of these hosted by the Society for Research in Child Development, the Psychonomics Society, the Society for Personality and Social Psychology, and a large number of other research- and practitioner-oriented conferences. To help our members attend these conferences, we have made available our new *Unrestricted Travel Grant*; details are available at http://www.psichi.org/awards/forms/Unrestricted_Travel.aspx.

Going forward, in line with Psi Chi's continuing expansion as an international society, we will be working to increase support for international and cross-cultural research opportunities. Look for invitations to connect with Psi Chi's international chapters and students in a variety of ways in the coming year.

We continually seek your input, and I hope that during the coming year I will have the opportunity to help shepherd many new initiatives into fruition that directly influence the professional growth of our members. Here's to a promising year!

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Past President's Message

Outgoing President Shares 'Behind Scenes' Appreciation

Susan Amato-Henderson, PhD
Psi Chi Past-President
Michigan Technological University

My year serving as President of the Psi Chi Board of Directors has been invigorating, challenging, and eye opening. As I move comfortably to my new role as past president, I recognize just how much I will miss my day-to-day involvement in Psi Chi. In this column, I hope to enlighten you on the amount of work done "behind the scenes" by the staff, executive staff, and the Board of Directors to keep Psi Chi on track to achieve the goals of our strategic plan.

The Central Office in Chattanooga, TN, is abuzz with a flurry of activity every day. Our staff, although small in number compared to other honor societies and nonprofit membership organizations, are the most committed, caring, and compassionate people that I have ever had the pleasure to work with. If not for them, Psi Chi's ability to serve the needs of our members would suffer. Our phenomenal staff include Susan Iles and her interns in Communications; Kat Bozeman and Linda Williams in Membership Services (and merchandise); Jennifer Baldwin and her intern in Awards and Grants; Kevin Germain and Chris Smith in IT; Dael Hoyt in Finance; and Debbie Garvich who provides administrative assistance.

These people are truly amazing, and their commitment to Psi Chi is clear in all that they do. EVERY STAFF MEMBER has stepped up into new roles or is new to our organization during the past year. Times of transition can be quite disruptive, so I wish to publicly thank each and every staff member for his or her willingness to take charge, transition into new roles, and work in, sometimes, less than ideal conditions. The next time you have the pleasure to interact with any of them, I encourage you to give them your thanks and appreciation. I have learned a lot about the inner workings of Psi Chi during the past year, and will forever be grateful that these wonderful people are part of our family!

Our organization maintains its operation and vision through the hard work of Executive Director Martha Zlokovich, PhD and Chief Operating Officer Michele Rumpf. Both Martha and Michele work hard every day to maintain the vision of the Board of Directors, of which they are nonvoting members. Martha is Psi Chi's liaison to universities and psychology organizations around the world, and Michele manages staff in the Central Office. Their time is spread thin, and their efforts are relentless. The dynamics of their jobs change annually, as new Boards come in with new visions and priorities. Both executives also deserve public recognition for their ability to keep "the ship sailing" through the rough waters of transition and the ever-increasing demands of providing quality services to more than 660,000 members.

Finally, my colleagues on the Board of Directors are driven, ambitious, goal-oriented individuals. It is clear that their primary concern is to enhance membership benefits while being fiscally responsible. The strategic planning that was conducted a year ago is in place, and much of this past year was spent reframing priorities and directing efforts toward the following strategic initiatives:

1) **Raising Central Office capacity**

   This goal focuses on our ability to continue offering quality services to our members through IT infrastructure, website redesign, staffing demands, and increased/improved services.

2) **Improving the logistics of internationalization**

   This goal focuses on developing new processes and changing old ones in an effort to be sensitive to the needs of ALL members, including those from other countries. This initiative is far reaching and includes things as simple as updating our process for mailing (we now mail internationally) to programming online forms to allow for various phone number and zip code formats. It also involves developing methods to assess our progress with internationalization and laying the foundation for long-term goals.

3) **Enhancing and promoting value of Psi Chi to both current members and potential new members**

   This has kept the Board of Directors busy enhancing existing benefits (such as increased travel grant funding), designing new opportunities for members (such as new research grants), and communicating these to members in different ways (such as Facebook and Twitter).

4) **Encouraging and providing support for faculty advisors**

   Providing support, recognition, and incentives for faculty advisors allow them to better support their student and alumni members.

As Psi Chi continues to grow and become a premier international honor society, please remember that the Board of Directors and staff are open to hearing your suggestions, ideas, and needs. While we have not changed Psi Chi's mission, we are always open to ideas for improving the route through which we achieve that mission!

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Martha S. Zlokovich, PhD
Psi Chi Executive Director
Associate Editor

Psi Chi and International Psychology

Even though Psi Chi only became an international society in 2009, it has long been a part of international psychology. In fact, it was officially founded at the 9th International Congress of Psychology (ICP), held for the first time in the United States in 1929 at Yale University (Lewis, 1950/1979). Psi Chi has grown in many ways since it began with the signatures of faculty from 14 universities. These 14 charter members accepted another eight universities by January 1, 1930, increasing the number of charter chapters to 22.

By 2002, Psi Chi had 1,000 chapters, and it currently has 1,129. By 1970, there were 61,588 lifetime members of Psi Chi (Hunt, 1979), and now there are more than 660,000! Psi Chi has more chapters than any other university honor society; it's the largest honor society—in both number of chapters and number of members—specific to one major.

Even though Psi Chi has only been an international organization since 2009, it has maintained a tie to international psychology throughout its existence. For example, when ICP came to the United States in 1963, once again Psi Chi was there (Portenier, 1969/1979). Psi Chi's Board of Directors (called the National Council then) named 1963 Psi Chi's International Year and encouraged chapters to participate in ICP events in Washington, DC. Psi Chi members attending the meeting had the opportunity to "learn of recent contributions to the field of psychology by other countries, and the program and activities of Psi Chi became known to countries around the world" (Portenier, pp. 21).

Most recently, Psi Chi was present at the July 2012 ICP held in Cape Town, South Africa. Past and current Psi Chi Board members met with students and faculty from all over the world to let them know about Psi Chi and learn about psychology programs in their countries. Drs. Susie Amato Henderson (Board President at the time), Maria Lavooy, (Southeastern Regional Vice-President at the time, now Board President-Elect), Past-Presidents John Davis and Florence Denmark, Randall Osborne (past Southwestern Regional Vice-President), along with Chief Operating Officer Michele Rumpf and I attended and participated in the event.

Dr. Amato and I also attended the International Association for Cross-Cultural Psychology meeting in Stellenbosch, South Africa the week before ICP. This meeting was held on the University of Stellenbosch campus and provided lots of opportunities to talk about Psi Chi with students and faculty from psychology departments around the world. Since these two meetings (and the efforts of Psi Chi Ambassadors Drs. Florence Denmark, Harold Takooshian, Bernardo Carducci, Susan Becker, Gina Grimshaw, John Davis, Mercedes McCormick, Joseph Ferrari, Melanie Domenech-Rodríguez, and Paul Hettich), Psi Chi has received requests for applications from universities in South Africa, Zimbabwe, Nigeria, New Zealand, Columbia, Russian Federation, Italy, the United Kingdom, and Brazil. Currently, Psi Chi has applications in progress from universities in Guatemala, Russia, New Zealand, Puerto Rico, South Africa, and Australia. Psi Chi has also forged more opportunities to work with APA's Division 52, International Psychology, and enjoys the advice of its President-Elect Dr. Mercedes McCormick who is currently Psi Chi's Eastern Regional VP.

Starting with one affiliate chapter before 2009 at the University of Victoria in Canada, Psi Chi has also grown with regard to international chapters. Today, Psi Chi has three chapters outside the 50 U.S. states—two chapters in Puerto Rico and one in the U.S. Virgin Islands. In addition, five new international chapters have joined Psi Chi since the University of Victoria was awarded full chapter status including a second chapter in Canada, and one in Egypt, Ireland, and New Zealand. Two other chapters, in Barbados and in Trinidad and Tobago, have been approved but not yet installed their chapter.

There are many reasons for students, faculty, and alumni to be proud members of Psi Chi, and one of these is how Psi Chi has continued to grow internationally. As more chapters from other countries join Psi Chi, all U.S. chapters should consider how their members might reach out to a chapter outside the United States to exchange ideas and encourage new chapters to make the most of their Psi Chi memberships. If your chapter would like to partner with another chapter via Skype or similar social media, please e-mail Martha.Zlokovich@psichi.org.

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Building Bridges:
Psi Chi and International Psychology

(The following are excerpts from a larger work.
To read the entire article visit http://www.psichi.org/pdf/building_bridges_aug2012.pdf)

Mercedes A. McCormick, PhD—Psi Chi Eastern Regional Vice-President
"How can Psi Chi best partner with international psychologists to expand the honor society worldwide? This question was the theme of a symposium at the 120th meeting of the American Psychological Association in Orlando, FL, in August 2012. This symposium brought together six outstanding psychologists in international psychology from North and Central America to offer their suggestions."

Martha S. Zlokovich, PhD—Psi Chi Executive Director and Past-President (2003–04)
"Since 2009 the first two international chapters (affiliate chapters in Canada and Ireland that became full chapters at that time) have expanded to ten. These include seven chapters in six countries, and another three chapters outside the 50 states. Additional applications are in progress from faculty in Guatemala, Russia Federation, Italy, South Africa, Zimbabwe, Puerto Rico, United Kingdom, New Zealand, Nigeria, and Australia."

Alvin Y. Wang, PhD—Psi Chi Past-President (2009–10)
"Psi Chi's Board of Directors is currently discussing several issues related to our international efforts. Perhaps the most critical is how we can meaningfully integrate international chapters into the governance structure of our society."

Maria del Pilar Grazioso, PhD
—Universidad del Valle de Guatemala Professor of Psychology
"Efforts to develop opportunities for collaboration between Psi Chi International and Division 52 might entail a wide array of projects. As a means to foster a sustainable possibility for the enhancement of training, research, international relationships, and community outreach, our program at Universidad del Valle de Guatemala has a long tradition of working together on community partnerships."

Harold Takooshian, PhD—Psi Chi Past-President (1998–99)
"In 2010, to mark the 125th anniversary of the origin of psychology in Russia in 1885, Professor Alexander Voronov integrated Psi Chi into his 5-day multi-city conference. Hundreds of students and faculty at five institutions in two cities appeared visibly excited to learn about the benefits of Psi Chi."

Florence Denmark, PhD—Psi Chi Past-President (1978–80)
"Division 52 is the primary Division within APA with a focus on the internationalization of psychology, whereas Psi Chi is the largest and newest international psychological organization with students, faculty, and other professionals comprising its membership worldwide. Going forward, it is our goal to build bridges between Psi Chi and Division 52."

Richard S. Velayo, PhD—Past President of the APA Division of International Psychology
"What I would like to emphasize is how Internet-based technologies may help build bridges between Psi Chi and Division 52 which will further the internationalization efforts of both organizations. In other words, we can go global by going virtual! Internationalization efforts by Psi Chi and Division 52 may continue to explore innovative ways to collaborate and perform outreach."

Chapters Outside the 50 states

University of Puerto Rico Mayagüez
University of Puerto Rico Río Piedras
University of the Virgin Islands

International Chapters

Barbados; The University of the West Indies–Cavehill*
Canada; University of Victoria
Canada; University of British Columbia–Vancouver
Egypt; American University in Cairo
Ireland; National University of Ireland–Galway
New Zealand; Victoria University of Wellington
Trinidad and Tobago; The University of the West Indies–St. Augustine*

*Charter approved but not yet installed at time of publication.

American University of Cairo (Egypt) Psi Chi Chapter's induction ceremony

Chapter members from the **University of Victoria (Canada)**

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The Real and Unreal Worlds of College

"College is *not* the real world!" How many times have you heard someone speak these words or, similarly, "Wait until you get to the real world!"? I concurred with these messages in "School-Smart but Culture-Dumb" (Hettich, 2011) in which I summarized three real-life examples of recent college graduates to illustrate inappropriate behavior in the workplace. Table 1 in that article compared college and workplace settings on 16 dimensions that represent important differences in organizational cultures and practices. For example, in the workplace, compared to college, you can expect less concrete feedback, less control over your schedule, less personal support, less structure in your assignments, fewer right answers, and less time off. In addition, you will experience high expectations from your boss for consistently excellent performance, productive teamwork, active participation in your tasks, application of your knowledge, and adaptability to changes. Such comparisons are the ways in which college is *not* the real world.

New graduates are likely to encounter serious problems if they cannot quickly discern and adapt to these discrepancies. Not only are the differences real, but also the distinctions reveal that some aspects of college (e.g., expectations of frequent feedback, its focus on your personal development, the academic calendar) actually counter-prepare you for the workplace, or instill habits and expectations that are opposite workplace practices. Elwood Holton and Sharon Naquin (2001) pinpoint the nature of these differences.

> College and work are fundamentally different. The *knowledge* you acquired from college will be critical to your success, but the *process* of succeeding in school is very different from the process of succeeding at work. Certain aspects of your education may have prepared you to be a professional, but evidence from the workplace indicates that this is not enough for professional success. …Worse yet, the culture of education is so different from the culture of work that if you continue to have the same expectations of your employer that you did of your college and professors, you'll be greatly disappointed with your job and make costly career mistakes. (p. 7).

To reduce the effects of college's counter-preparation practices, I highly recommend (and employers agree) that you complete at least one internship (Hettich, 2012) preferably in a nonacademic setting, acquire diverse part-time job experiences, complete job-related courses such as management, marketing, economics, and communications, and become involved in extracurricular and volunteer activities to develop interpersonal and leadership skills. Coursework alone is a necessary but inadequate preparation for the workplace.

Yet, College *is* the Real World

In his annual hiring survey of employers for the Collegiate Employment Research Institute, Philip Gardner (2007) sought explanations for why recent graduates are disciplined or fired from their jobs and why others are promoted or given new assignments. Table 1 lists several reasons why new hires are disciplined, ranked in order by mean score and showing the corresponding percentage of occurrence at the high end of the scale; behaviors shown in bold are also reasons for being fired. As you examine Table 1 note how easy it is to identify college situations that are counterparts of workplace behaviors. Yet, a student can possess a mediocre work ethic, show minimal initiative, be late for class, fail to follow instructions in an assignment, text-message during class—in general, do just enough to get by—and still receive a passing grade. In the workplace such behaviors could be cause for termination—a consequence drastically different from receiving a C or D grade. In short, behaviors (whether in corporate or in graduate/professional school settings) that lead to discipline or termination are the same behaviors students should avoid during college.

A major factor that accounts for the seemingly harsh consequence of being fired is a person's accountability to others. For instance, the disinterested student who ignores instructions, arrives late to class, and submits assignments late is usually harming just one person. On the job, however, such actions can affect the performance and evaluation of coworkers and the supervisor. Remember: College is all about your personal development, but the workplace is about organizational productivity and making the boss look good. The transition from college to workplace involves a major switch from being

Table 1 | Factors That Influence the Disciplining and Termination of New Hires

Reasons for Discipline	Occurrence: Fairly Very Often (%)	Mean Score
Lack of work ethic/commitment	52	3.46
Unethical behavior	46	3.22
Failure to follow instructions	41	3.21
Ineffective in teams	41	3.19
Failure to take initiative	26	3.10
Missing assignments/deadlines	33	2.98
Unable to communicate effectively—verbally	32	2.97
Inappropriate use of technology	34	2.90
Being late for work	28	2.83
Unable to communicate effectively—writing	28	2.81

Note: Occurrence: Percentage at the high end of the scale.
Mean Score: 5 = highest
Behaviors in boldface are also reasons for terminating new hires.

Note: From *Moving Up or Moving Out of the Company? Factors That Influence the Promoting or Firing of New College Hires* (Research Brief 1-2007) by P. Gardner. 2007. Adapted with permission.

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Paul Hettich, PhD, Professor Emeritus at DePaul University (IL), was an Army personnel psychologist, program evaluator in an education R&D lab, and a corporate applied scientist—positions that created a "real world" foundation for his career in college teaching and administration. He was inspired to coauthor *Connect College to Career: A Student Guide to Work and Life Transitions* (2005) by graduates and employers who revealed a major disconnect between university and workplace expectations, cultures, and practices.

You can contact Paul at phettich@depaul.edu

self-centered to other-centered. Teachers, staff, and administrators who enforce high standards for performance and accountability are not simply being "hardnosed," they are doing you a favor—preparing you for the real world after college.

From a positive perspective, Gardner (2007) also asked employers to identify characteristics that lead to promotions and new assignments. Table 2 lists the top ten characteristics (from a group of 1500 that respondents named) by relative frequency and integrates them with a series of work strategies identified by Robert Kelly as "Star Performers." These qualities are also essential for success in graduate and professional school and are defined in Table 3.

As you study the definitions, identify those aspects of your coursework, extracurricular and volunteer pursuits, jobs, and other daily activities that enable you to establish and practice these characteristics. Why not tape this list by a mirror or computer as a set of personal goals? Or discuss it at your next Psi Chi meeting? If you can firmly establish the values these characteristics reflect while you are in college, chances are you will apply them successfully in your professional and personal life. The list is certainly not complete but it is a good start.

Your coursework and college life in general are teaching you to distinguish among a diverse array of values, theories, ideas and concepts. Along the way, you can jumpstart your professional preparedness by learning to discriminate among those aspects of college life that do and do not reflect the other real world you will enter after graduation. You can do this now— paying forward—or put it off until you enter the workplace and pay the price of an early career setback.

Table 2 | Characteristics That Lead to Promotion and New Assignments

Characteristics	Relative frequency (%) identified by employers
Taking initiative	16
Self-management	13
Personal attributes	9
Commitment	9
Leadership	8
"Show and tell"	7
Technical competence	7
Organizational savvy	5
Learning	5
Critical thinking/cognitive abilities	5

Note: From *Moving Up or Moving Out of the Company? Factors That Influence the Promoting or Firing of New College Hires* (Research Brief 1-2007) by P. Gardner. 2007. Adapted with permission.

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Table 3 | Definitions of Characteristics That Lead to Promotions and New Assignments

Term	Definition
Taking initiative	Accepting responsibility above and beyond the stated job, volunteering for additional activities, promoting new ideas, being self-motivated, a self-starter.
Self-management	Regulating your own work commitments, time management, completing work on time, handling stress, customer service orientation, ability to handle change, accountability.
Personal attributes	Being friendly, dependable, patient, flexible, reliable, and respecting diversity.
Commitment and Passion	Working with a positive attitude, demonstrating work ethic, enthusiasm, and dedication.
Leadership	Formulating, starting and building consensus on common goals, working to accomplish them, developing management skills, recognizing the need to develop people.
Show and tell	Presenting one's ideas persuasively in written and oral forms.
Technical competence	Possessing core knowledge in an area of study, demonstrating core acumen appropriate for position, obtaining mastery of current position, displaying high level of competence.
Organizational savvy	Navigating the competing interests in an organization, promotion corporation, addressing conflicts and working well with others (interpersonal skills), fitting with the organization, getting things done.
Learning	Showing an eagerness to learn and to pursue new ideas, willing to obtain additional knowledge for next position.
Critical thinking/ cognitive abilities	Thinking critically and analytically, evaluating data, being innovative, creative, and open-minded.

Note: From *Moving Up or Moving Out of the Company? Factors That Influence the Promoting or Firing of New College Hires* (Research Brief 1-2007) by P. Gardner. 2007. Adapted with permission.

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Questions (and Answers) About **Graduate School**

Dear readers,
In this issue's "Three-Headed Advice" column, we have adapted the questions we were asked at our last in-person gig at the Midwestern Psychological Association meeting May 2012 in Chicago. We appreciate our continued opportunity to serve by answering your questions of interest.

What is a good way to narrow down the search of professors to work with in graduate school?

Landrum: Nice question! First, it is good you are thinking ahead and know to do your research about the professors already at a particular university. As with so much of the graduate school admissions process, this too is about match-and-fit. After you have read about all of the faculty in your program of interest (including what's on their web site as well as some author-based PsycINFO searches), you need to seriously self-reflect about what your interest areas are and what they might be in the future. Then, it is about match-and-fit. But let's say you want the answer to this question as you are writing your personal statement for your graduate admission package. The additional piece of advice I would offer would be to not put all your eggs in one basket; that is, do not limit yourself to wanting to work with only one graduate faculty member. You may not know if that faculty member is about to retire, go on sabbatical, or enter the job market. Always include two to three faculty members you would be most interested in working with; that way, you can avoid any eggs-in-one-basket situations.

VanderStoep: I agree with Dr. Landrum. Let me add a couple of other thoughts. First, I encourage students to consider sending an email to potential faculty advisors. Make sure this email is carefully prepared and professional. It is your first impression and it must be done well. Ask the professor if she/he will be taking students next year. This is where you will get insight into sabbaticals, leaving for another institution and other constraints to which Dr. Landrum referred.

Second, picking a professor within a program should be an important criterion, but let me offer other criteria. First, location is a big deal to some and irrelevant to others. If you think there is a zero percent chance you would ever live in *fill in the blank* then save their time and your money and do not apply. Second (this may sound like I am speaking out of both sides of my mouth), have a broad and diverse portfolio of schools. Many students suffer from what might be called an ESPN worldview of higher education. That is, unless a university appears regularly on College Game Day, students assume it is not worth considering. In fact, having a broad and diverse set of schools will allow you to find some schools that you have never heard of. It is far better to be happy and perform high-quality work with a stellar advisor at a lesser-known institution than to be miserable and perform marginal work at a well-known institution.

Handelsman: As usual, my colleagues have nailed this one! I would concur and add simply that you can also have a diverse portfolio of professors to work with in each program you apply to. Define your interests as broad (not diffuse, but broad). In some programs you may wind up working with more than one professor and thus learn a range of research skills.

I originally graduated with a BA and a low-ish GPA. Now my GPA is climbing higher as I finish two more BAs. How will this be viewed?

Landrum: First, good for you for being so persistent. Generally graduate programs concentrate most on what you did last. Although the graduate program will probably request transcripts from all of your bachelor's degrees and undergraduate institutions, they tend to value most that which you have completed most recently. This is why a master's degree is often a great stepping-stone to a doctoral degree program. Sometimes undergraduates with a less-than-stellar undergraduate transcript enter a master's program to "prove themselves," then apply to a doctoral degree once the master's is complete. In your particular case, you substituted two additional bachelor's degrees as your stepping stone. Also,be sure to be fair with the data. Do not gloss over that first degree with the low-ish GPA. If asked about it, tell the story; perhaps you were not a serious student when you first arrived to college, but your record since that time proves otherwise. Do not leave your first degree off of your CV in an attempt to hide it—always be fair with the data.

VanderStoep: Interestingly, I just had an advising appointment with a student last week who had a poor first-year GPA. He has now hit his stride academically and is doing much better. I told him not to ignore his first-year GPA when writing his personal statement; people will notice it so there is no sense in pretending it is not there. This is similar to your experience, in the sense that my student's first-year GPA is roughly equivalent to your first BA and his later GPA is equivalent to your subsequent degrees. Thus, I agree with Dr. Landrum that you should not ignore something in your past.

The trick will be to describe carefully what was going on in your first degree. Was the topic of study different/more difficult/not something you enjoyed? Did you have self-assessed maturity issues that prevented you from achieving? Describing this academic transformation might help you because it will show a positive

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change. Conversely, it also might hurt you because sometimes programs are so competitive they are just looking for reasons to eliminate people because there are so many strong applicants in the pool.

Handelsman: Let me balance this discussion a bit by encouraging you to not pay too much attention to your first degree. Because of the recency effect that Dr. Landrum explained, I would spend more time detailing the graduate-study-related experiences you have had in your last two degree programs including internships, research experience (in detail), development of career goals, and writing ability. Another way to put this: SHOW them what you have done rather than telling them too much about why you started slowly.

Should I self-disclose my own mental illness in my essay?

Landrum: This is a complicated question, and I am so glad to have trusted colleagues to also weigh in on any potential advice to offer here. First, congratulations on making so much progress given the situation. The ability to treat and cope with a mental illness is admirable, and even more so if you are able to seriously consider graduate school with the motivation of helping others; your perspective could be extremely valuable and insightful. As for disclosure, I lean toward encouraging disclosure; this will avail you to some of the positive impacts of the protections offered by the Americans with Disabilities Act., I think this is a delicate balance; you want to disclose (which also allows you to be fair with the 'data'), but if you over-emphasize this, some on the faculty might begin to question whether the mental illness might overshadow your ability to benefit from graduate education and successfully enter the profession. Of course, all of this would be context dependent on such factors as to the type of mental illness, its severity, if remission is possible, and so on. Consultations with your undergraduate faculty mentor and advisors will be key for you to be able to navigate this delicate situation.

VanderStoep: I tend to recommend more limited disclosure than Dr. Landrum is recommending. First, prevalence rates for mental illness are very high, especially for anxiety and depression. Using mental illness to make the case for graduate admission to clinical psychology could be seen as analogous to a medical school applicant saying she is more qualified because she is diabetic. I know this is an extreme analogy, but the argument seems plausible. Second, my fear is that such disclosure creates certain impressions that might not be helpful.

However, the one exception to my own rule would be if your particular condition makes you a particularly unique applicant for a particular program. For example, a diagnosis of PTSD might benefit someone who is applying to a program in trauma psychology. But overall, I am concerned that a general diagnosis of mental illness may draw unnecessary and unwanted attention to your application.

Fortunately, our Three-Headed Advice panel has a clinical psychologist, who can now break the tie between me and Dr. Landrum. Dr. Handelsman, the floor is yours.

Handelsman: I have another analogous question: If you were applying to a graduate program in chemistry, would you disclose your mental illness? The key point is that experiencing a mental illness, in and of itself, is not a qualification for graduate study. Having said that, many people who experience mental illness learn a lot about themselves and a lot about mental illness. What you know about yourself and mental illness might be good to include in your statement, but you may not need to discuss any details of how you know it!

One mistake that I have seen in some personal statements is students who write that because they had success with a particular treatment (cognitive-behavioral therapy, Paxil, dance therapy, mindfulness, whatever), they know that that particular treatment will work for anybody with that illness. That is, they overgeneralize from their experience. In this case, they still need to learn the research behind various treatments and understand that there are unique elements to peoples' experience with mental illness that may influence treatment decisions and effectiveness.

However you decide to proceed, make sure you get several experienced people to read and comment on your draft statements. They can tell you if they see any red flags regardless of the level of detail you choose to present.

Scott VanderStoep, PhD, previously served as Psi Chi Midwest Regional Vice-President from 2002–06 and President from 2008-09. His educational journey began in the same place where he currently works—Hope College (MI)—and where he is associate professor and Dean of Social Sciences. In his 18 years of college teaching, he has taught introductory, developmental, social, cognitive, industrial/organizational, research lab, psychology of religion, and advanced data analysis.

Mitch Handelsman, PhD, is currently professor of psychology and a CU President's Teaching Scholar at the University of Colorado Denver, where he has been on the faculty since 1982. In 2003–04, he was president of the Rocky Mountain Psychological Association. He is a licensed psychologist and a fellow of APA. He currently writes the quarterly column Ethics Matters for *Eye on Psi Chi*. His blog, "The Ethical Professor," can be found at psychologytoday.com.

A frequent contributor to *Eye on Psi Chi*, **R. Eric Landrum, PhD**, is a former Psi Chi Rocky Mountain Regional Vice-President (2009–11). A professor at Boise State University (ID) and the chapter's faculty advisor, Dr. Landrum often give talks about issues such as graduate school admissions. He has over 225 professional presentations at conferences and published over 20 books or book chapters, and has published over 65 professional articles in scholarly, peer-reviewed journals.

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Avoiding the Nightmare & Worry of Plagiarism

Richard Bromfield, PhD
Harvard Medical School (MA)

There is something you should know about your professors. Their passion is their subject matter, not teaching students how to write. However much students hate their professors marking their papers up in red and downgrading for weak writing or citing, their professors hate it even more. Professors have plenty to do without being the grammar or plagiarism police. In a perfect world imagined by professors, all students would come to their classes knowing how to write and cite properly. When reading your writing, it is what you have learned and what you have to say that interests them. Unfortunately, in a real world, professors cannot help but collide with, trip on, and suffer writing and citing that distracts from and undermines what a student like you tries to convey. (Bromfield, 2011, p. 5-6)

Like much in human psychology, plagiarism is a funny thing, full of paradox and contradiction. A majority of students judge it to be wrong and a form of cheating. Yet, despite this moral awareness and their dread of failure or expulsion, plagiarism remains an ever present threat, risk, and temptation. How can we account for this?

Some suggest that cheating and plagiarism are such a visible part of modern society that they inevitably pervade the culture and life of a university. This might be true. However, there may be an alternative explanation. Most students do not wish to cheat and want no part of academic trouble or misdeed. Their flirtations with plagiaristic misdeeds may stem from misunderstanding and confusion as to why and how one properly cites and references when writing essays, research papers, and theses.

Many students begin their writing missions with a noble and clear determination to write a paper that is honestly their own, but then, harsh reality sets in. They encounter a web site that doesn't seem to fit their criterion for citation. They find that someone else already said what they, the students, thought were their own ideas. They reread what they've written and find that it seems so boring and repetitive that they cannot bear to stick with their own writing. As the hour grows late and exhaustion sets in, or other work waits, students' resolve and resourcefulness wane. Discouraged or no longer caring, they give up, settle for indecision, and let their citing or referencing slide. "Who cares," that devilish little guy on their shoulder urges, and; "what difference does it make?" So the students submit something they do not feel confident about, hoping not to be accused of plagiarism.

You do not need to suffer such agony, hardship, frustration, and possibly the tough consequences of plagiarism. All that is required is some clarity regarding proper academic citation. Remember, American Psychology Association (APA) style has a purpose; it was not devised as a modern form of torture.

The purpose of APA style is to give credit where credit is due. It is really not so complex or obscure. Take this example from a recent book on introverts by Susan Cain.

She writes, "Heritability statistics derived from twin studies show that introversion-extroversion is only 40 to 50 percent heritable" (Cain, 2012, p. 108). Consider the many ways in which you can refer to Cain's sentence and idea:

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- Cain says, "introversion-extroversion is only 40 to 50 percent heritable" (2012, p. 108).
- In 2012, Cain suggested that whether an individual is introverted or extroverted is "only 40 to 50 percent heritable" (p. 108).
- A person's tendency to be introverted or extroverted cannot wholly be explained by genetics (Cain, 2012).
- Heredity, so claims Susan Cain (2012), probably accounts for no more than half of any one child's being introverted or extroverted.
- Is introversion perfectly determined by genetics? Not at all, according to Susan Cain and the findings of twin studies (2012).

The possibilities are endless.

It is up to you whether you state it as Cain *claims, says, writes, proposes, hypothesizes, wonders, assumes, thinks,* etc. You can mention Cain at the beginning of the sentence, in the middle, or at the end. You can use her exact words, or use your own. You, as the writer, can state it almost any way you choose in order to best make your argument and express your own genuine voice. All you need to do is give credit to the original scholar or writer by quoting exact statements or paraphrasing (i.e., putting into your own words) those same ideas. All that matters is that you give Cain the credit and make clear which words are precisely hers and which are yours. It is that easy and direct.

By understanding why you cite, you will find yourself free and flexible to write papers that are accurate and APA approved. Most of all you will be able to express yourself in ways that are interesting, engaging, and convincing. And, not to be dismissed, accurate citation will allow you to feel proud of your work and to sleep well after it is done.

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Richard Bromfield, PhD, is a psychologist on the clinical faculty of Harvard Medical School. He is author of several books for clinicians and parents, including: *Doing Therapy With Children and Adolescents With Asperger Syndrome; Teens in Therapy; Embracing Asperger's;* and, *How to Cite APA [Style]–6th in Psychology Social Work, Education, and the Social Sciences.*

Plagiarism Q&A

1. What do I do if I am unsure about a citation?

When in doubt, cite. Though your writing may bog down unnecessarily from an overabundance of citing, you will never get into trouble for doing so.

2. What if I truly come up with an idea, and then discover that someone else already said it, or something like it?

This is a common experience for all of us. Unfortunately, the original source still gets the credit and needs to be cited. However, you can always add a footnote to your paper that describes to your professor what your thinking was and how you came to it on your own. Most professors will find your thinking process interesting and will appreciate your revealing it while also taking care to do the proper citing of the original source.

3. Sometimes, I find that a lot of different people or studies came to the same conclusion. How many of these do I need to cite?

Again, when writing about a rich area of study or research, you may find too many references to cite. You need not cite all or even most of them. Your job is to merely show the official source for your statement or idea. In terms of substance, cite perhaps two sources, especially the most recent and well researched

4. Plagiarism scares me. Should I just quote the whole paper and leave my own thinking out of it?

A paper that is virtually a listing of block or lengthy quotes strung together can, while properly cited, be boring for you to write and boring for your professor to read. It is important that you learn how to cite in ways that integrate your own thinking.

5. What do I do when I am really stumped by some detail of citation or referencing?

This is sure to happen. Consult the APA manual or guidebooks. Google your dilemma. Frustrating as it is, strive to learn the right way to handle the source in question. If you cannot find a solution, add a footnote or bracketed comment in your paper that explicitly explains your problem and best efforts to your professor. You will never be penalized or accused of plagiarism if you make a good and open effort to cite properly.

6. Is it worth my time to master APA style?

It absolutely is. By coming to understand and use APA style comfortably, your writing (and citing) will grow easier and more flexible. The more you know how to cite and reference, the better you become at reading and taking notes on potential source material, saving yourself that familiar and awful task of going back to relocate original sources.

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Transitioning From College to the Great Beyond

Marisa T. Cohen St. Francis College (NY)

The transition between college and the "real world" can be one of the most daunting times in an individual's life. Even with the assistance of great mentors and a supportive college career counseling program, it still can create a sense of uneasiness. During these uncertain economic times, students may have trouble deciding what path to follow, whether it is a career or continuing their education by enrolling in a Masters or Doctoral program. Some may even consider enrolling in school while working a job simultaneously, making them a more competitive candidate for positions in academia down the road.

There are many books that help transitioning students prepare for graduate school, ranging in topics from acing the GREs to writing the most attention grabbing and effective personal statement. Also helpful are guides and manuals that discuss the benefits of shadowing professionals before committing to a career path. Despite the multitude of resources available, often the richest source of information comes from individuals who have previously gone or are now going through a transition themselves. Who better to ask than peers who are preparing for the future, transitioning, and flourishing?

No Time for Senioritis

Don't assume your senior year will be a time that you can devote all of your energy and attention to job and graduate school applications. While these forms need to be filled out and submitted, schoolwork keeps coming. Senior year in college is much different than in high school; the classes are harder, senior theses need to be completed, and the prospect of entering the "real world" approaches. Many students wish they had spent the summer prior to their senior year getting "ahead" by researching potential employment opportunities and graduate programs.

The 'Fit' Needs to Work Two Ways

Most students were shocked that their graduate school interviews did not only focus on why they wanted to attend the school, but also on why it would be a good "fit" for them. Unlike applications to undergraduate institutions, graduate admissions interviewers look for a well thought-out 5 to 10 year plan and clearly defined examples of how the graduate program will fit into your current life.

It is important to not only research the program or company you are applying to, but to look up "key players" (professors, potential supervisors, etc.) and discuss how their accomplishments have personally influenced you. For example, read research papers of a professor you hope to work with, paying special attention to the sections outlining directions for future research. Consider what you can add to their agenda, and take it another step further. The better you can articulate the working relationship you hope to have with the professors, the more successful a contender you will be.

Seek Support

While the decision about your future is ultimately in your hands, it is important to communicate with others during such a formative time. Students stressed the importance of being proactive to seek out opportunities and helpful resources.

Help at College

Within their college, students noted many sources of help, such as workshops, career fairs, and networking opportunities, in addition to access to faculty members. Most described relying heavily on their academic advisors, starting as early as their sophomore year. With their advisors, students were able to craft a schedule that gave them depth of knowledge in their field of interest, but also a well-rounded education ranging from the social to "hard" sciences. The academic advisors also made sure that the students were on track towards graduation.

Faculty members were also a great support. While students counted on their favorite professors for recommendations, they also looked to them for career advice. Remember, most of the faculty members in your subject area went through the same process as you. By approaching counselors and other faculty on your own, you get advice tailored to your personal needs, and you can also voice any of your concerns.

Finally, students revealed that the career counseling center was one of the most important sources of information. Students were able to set up appointments to practice interviewing techniques, review their applications, as well as network during career fairs. For example, two students discussed making appointments with the career counseling center to review general interview approaches for graduate and employment opportunities, and to schedule times to have their resumes edited. One even said that the individual he contacted at the career center was so obliging that she set up a series of mock interviews which really helped him learn how to talk to others.

Help at Work

Not only did students rely on their college for help, but they also received support from outside their university. Many turned to their supervisor and fellow workers for job connections and advice. If you want to ask your supervisor for a recommendation, it is important to approach them at least a month or two before applications are due so they

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have time to evaluate you. Chances are they will be writing several recommendations, so it is better to be proactive and give them the time they need. It is also helpful if you provide them with a copy of the courses you took in school, a short description of where you plan to apply, as well as a list of all your awards, accomplishments, and extracurricular activities. This information can help your supervisor tailor a letter to highlight everything you have achieved.

Start Early

Many students echoed the same sentiment that they felt they had started their search late in the game. Most noted the reasons for starting at the end of their junior and senior years as being bogged down by work and other commitments as well as being uncertain of exactly what they wanted to do upon graduation. These students agreed that had they looked earlier into programs in their general area of interest and contemplated specific geographic regions , they would
have saved a lot of time during the search process later.

Students felt they should have begun their admissions essays during their junior year, using the summer prior to their final college year as a time to edit and perfect their work. This way, instead of scrambling to complete applications while balancing school work and other commitments, they could devote their energy and focus to their interviews and last minute preparations.

Take Advantage of All Opportunities

Of the students interviewed for this article, all were active in several clubs, jobs, teams, and honor societies. Surprisingly, they all said they wish they had taken part in more. One student who already has a lot on her plate said she wished she had gotten involved with internships, even if it meant less time for schoolwork. While she wants to enter the mental health counseling field, she fears she will proceed down this path and later decide it is not for her. Had she been able to work in the field, perhaps she would have been more certain in her career choice. Another student also affirmed this belief saying he worked six part time jobs in different areas of psychology. This was his conscious choice and gave him great exposure to opportunities available in the future,despite giving him less time for other activities.

It's Up to You

While everyone's journey is unique, the ideas students expressed regarding their futures share many common themes. All students emphasized the need to prepare early, take advantage of all of the support available, and explore all options when preparing for the future. No matter what is in store for you on your personal search, remember that this is an important time for self-exploration, reflection, and growth. Good luck!

Editor's Note: In talking with some of her most reflective and thoughtful students, Marisa T. Cohen, PhD, shares what her students say they wish they had known or done in their transition from college to beyond.

Marisa T. Cohen, PhD, is an assistant professor of psychology at St. Francis College in Brooklyn, New York. She teaches educational psychology, social psychology, general psychology, and research methods courses.

Dr. Cohen has several lines of research, all with the focus of improving learning in the classroom. She has continued with her dissertation work, which centered on imagery interventions for teaching students novel vocabulary in the science content area. She has also worked with colleagues to examine misconceptions students hold in science. Finally, her current research focuses on the ability of students to assess their own knowledge, self-regulate, and adequately prepare for exams.

Beyond her teaching commitments, Dr. Cohen has served on the Graduate Student Issues Committee for the Northeastern Educational Research Association, and is the cochair of the National Graduate Student Committee for Kappa Delta Pi, an honor society in education.

Going **Global** by Going **Virtual**:

Internationalizing Student Psychology Organizations

Richard Velayo PhD and Michael Trush
Pace University (NY)

In this day and age, students tend to be quite comfortable with and may even prefer to use Internet-based technologies to communicate with one another. Extending the use of various forms of online communication (e.g., Facebook, Skype, teleconferencing, blogs) to student groups is a natural extension of the way students use technology for corresponding with their classmates and friends. The Internet has enormous potential for assisting in internationalization efforts among student psychology organizations through online collaboration and exchange of ideas and resources.

There continues to be a growing trend with the use of the Web to internationalize the psychology curriculum (Power & Velayo, 2006; Velayo, 2004). For instance, many psychology instructors use social media in their teaching in an effort to internationalize their courses (Velayo, 2011). Going virtual can contribute to going global. Student psychology organizations can provide the extra-curricular means to infuse a more international perspective about psychology in their communications with their members. Presumably, many of their members already have the necessary technological knowledge and skills to communicate via the Web. Students are therefore resources that may be tapped by these organizations to help extend their reach to other student groups around the world.

Benefits of an Internationalized Student Psychology Organization

Through Internet-based technologies, students from different locations are able to collaborate on projects and groups can interact across the globe toward a common goal. There are numerous student organizations that would benefit from the use of such collaborative technologies. Some of these organizations include: Psi Chi (The International Honor Society in Psychology), APAGS (American Psychological Association of Graduate Students), and the APSSC (Association for Psychological Science Student Caucus), as well as university psychology clubs and student groups that share common interests in psychology. The use of collaborative technologies allows for electronic files to be shared and even viewed almost instantly in correspondence. Besides convenience and efficiency, how else does the Internet enhance interorganizational communications? O'Brien (2007) pointed out that "Globally-distributed teamwork mediated by effective use of digital technologies can motivate and influence people to approach cross-cultural communication and cultural exchanges with greater sensitivity, understanding, and ethical awareness in order to bring about positive international and social relations" (p. 4). Students are able to examine the information exchanged from a number of contexts and viewpoints. Additionally, they derive more immediate feedback from each other and allow for decisions to be made efficiently and problems to be solved more effectively.

The Internet can provide a bridge between student organizations in different universities and countries, allowing them to communicate freely. Technology can act as "a foundation for global collaborations later on in life" (O'Brien, 2007, p. 5). "The use of the Internet in education, and the doors it opens [...] gives the student 'global experience' not only through the social factor but also in a technical way" (O'Brien, 2007, p. 5). For example, some of the more readily accessible instant messaging technologies (e.g., Skype, GoogleTalk, FaceTime, GoToMeeting) have textual, audio, and video capabilities that can be used for meetings with student leaders from around the world to share ideas, research, and new developments (Bekkering, 2006). Student groups can conveniently and easily share meetings, events and activities, announcements, and recognition for students in different countries for their leadership and scholarship. Moreover, students can participate and even present their work at meetings held online. Interactive sessions allow for questions and feedback at such events from anywhere in the world provided participants have Internet access.

Recommendations for Student Psychology Organizations

Many student psychology organizations and groups are affiliated with institutions of higher learning or are under the umbrella of professional psychology organizations. It is therefore imperative that specific goals associated with the use of such technologies be clearly defined in order to decide which specific technologies may be needed and determine how these may be best used by the organization. There are hardware, software, and bandwidth requirements associated with using the Internet. In order for cross-national communications to be efficient, the technologies used should be available to the students in the student organization all participating countries. Open-source communication platforms should not only be relatively easy to learn and use, but must also be compatible with the technologies in other countries. User knowledge and familiarity must be established. Examples of these kinds of platforms are in the form of social media —Facebook, Twitter, Blogger, Skype, GoogleTalk, and YouTube. The technologies must be in place before

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addressing the issue of how communications may be made more effective when corresponding online.

In order for psychology organizations to successfully manage and use technology efficiently and effectively, a high level of organization and coordination is crucial. A centralized source of IT (Information Technology) personnel is needed to monitor how these technologies are being used and to routinely obtain feedback from its users on how they may be better implemented or whether there are other, more worthy technologies available. Motivated students who are familiar with the use of social media can effectively help facilitate and monitor the use of social media to reach out to members around the globe. Nonetheless, it is important to keep in mind that students who serve as IT personnel may be limited in the duration of their involvement in the organization, such as when they graduate. It is therefore important to establishing a system of training and a set of protocols in the use of these technologies to assure a smooth transition between student IT personnel.

Psi Chi, for example, continues to expand with chapters in Canada, Ireland, New Zealand, Egypt, Puerto Rico, U.S. Virgin Islands, and two more approved in Barbados and in Trinidad and Tobago. Psi Chi may encourage collaborations between its international chapters, by promoting submissions for inter-chapter grants on collaborative projects that utilize Web-based technologies. Having virtual meetings and conferences, informal meet-and-greet sessions, utilizing Facebook as a way for members to discuss relevant psychology-related issues or using Web-based online surveys to collect data from various regions of the world, are some examples by which the Web may be used to promote inter-chapter collaborations.

Anticipated Difficulties in Implementation

Access to Internet-based technologies may be limited in other countries, reducing their students' ability to communicate internationally. Furthermore, language barriers could potentially serve as an issue for communication between cultures. In addition, cultural and sociopolitical views regarding technology may hinder individuals from accessing certain information or software on the Internet because of government regulations.

Assessing Internationalization Efforts

The effectiveness of using Internet-based technology may be based on identifiable outcome measures. A strong indicator of success would be the development of international communication and conferences. Another positive outcome is an increase in the number of coordinated virtual presentations and publications that ensue from long-distance collaboration between students. Moreover, if collaborative use and production of wikis and Google documents between students in multiple cultures expands, it bodes well for the continued use of the technology to facilitate cross-cultural collaborations. Other indicators may include the following: an increase in international student attendance and involvement in international, national, regional, and in-state psychology conferences; more cross-national research collaborations between students; and greater number of student-authored research related to international and cross-cultural psychology.

Global Reach of Facebook

Cheredar (2012) pointed out that Facebook, the most popular social networking site, had over 825 million active users worldwide as of December 31, 2011, and can be accessed in more than 70 different languages. An average of 483 million people log on to Facebook every day (Cheredar, 2011). Of this number, 161 million come from the U.S., 46 million from India, and 37 million from Brazil. The percentage of Facebook users in various countries is astonishing: 80% of all Internet users in Chile, Turkey, and Venezuela, 60% of all Internet users in the U.S. and U.K., 20-30% of all Internet users in Brazil, Germany, and India, and 15% of all Internet users in Japan, Russia, and South Korea. Unsurprisingly, there is zero percent penetration in countries that restrict Facebook, such as in China. The global reach of Facebook, and many other Internet-based technologies, is tremendous. Its use by so many students and various academic, professional, and business organizations is indicative of the future of interorganizational communications in a world that is increasingly becoming more global and interconnected. Many student psychological organizations routinely use collaborative technologies to share ideas, collect data, hold virtual conferences, and more. The burning question is how can we best utilize these powerful communication tools to aid with internationalizing our student psychology organizations, and in turn, internationalize psychology. Let us begin to explore the ways.

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Richard Velayo, PhD, is a professor of psychology at Pace University. He received his PhD in education and psychology (combined program) from the University of Michigan, Ann Arbor). His scholarly interests include the pedagogical application of multimedia and internet-based technologies, instructional psychology, and the internationalization of the psychology curriculum. He is a fellow of the American Psychological Association and the Eastern Psychological Association. Dr. Velayo is past-president and current webmaster for the APA Division of International Psychology, past-president of the Academic Division of the New York State Psychological Association, past-chair of the Psychology Section of the New York Academy of Sciences, NGO representative to the United Nations for the International Council of Psychologists, and a member of the Eastern Regional Psi Chi Steering Committee. He has published in several journals and presented in numerous local, regional, national, and international conferences. You can contact him at rvelayo@pace.edu

Michael Trush is a doctoral candidate in the PsyD in the School-Clinical Psychology Program at Pace University, New York City. He was participating in the MA degree in general psychology at Pace University prior to getting accepted in the PsyD program. Mr. Thrush is also Dr. Velayo's graduate assistant who is involved with research on strategies to internationalize the psychology curriculum. He is also the associate editor of *Psych Eye*, the newsletter of Pace's Psychology Department in the New York City campus.

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The Gospel According to Josh:

An Interview With Professional Actor and Playwright Josh Rivedal

Merry Sleigh, PhD
Winthrop University (SC)

Your chapter probably begins the academic year in the same way that our chapter does, with the officers brainstorming possible activities and setting goals. Last year, we were doing this planning process—pulling out our "tried and true" ideas while simultaneously attempting to think outside the box—when I received an e-mail from Josh Rivedal. Josh described a one-person show he developed in conjunction with Baruch College and offered to perform for interested Psi Chi chapters. I almost deleted the e-mail, but I am so glad that I did not.

Our chapter sponsored Josh's performance in spring 2012. Almost 200 students across campus gathered in the student center for a 50-minute show that literally made us laugh and cry throughout. Josh played multiple characters, bringing each to life in a unique way, and revealed his complicated relationship with his father who died by suicide. Following the performance, Josh spoke with us about suicide prevention and willingly answered very personal questions about the impact of suicide on survivors and communities. The total production lasted about 75 minutes, and the audience's attention never waned.

After watching the audience respond to Josh's show in such a positive way, I could not believe that just a few months earlier, I had almost banished Josh to my junk mail

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folder. The words he used in that initial e-mail could not convey the power of his performance. *The Gospel According to Josh* was education and entertainment at its best. I asked Josh if he would sit down for an interview in the hopes that other Psi Chi chapters would not accidentally miss out on this opportunity.

Josh, thanks for your willingness to be interviewed today.

My pleasure, Merry. I never pass up the chance to talk, and I had such a great time working with you at Winthrop University this past spring. It is always nice speaking with you.

What inspired you to create *The Gospel According to Josh*?

My initial inspiration to create *The Gospel According to Josh* was my desire to simply write a play in which I could star. After some early success, my acting career was on life support back in 2009, and my writing career was not doing much better. I saw people like Whoopi Goldberg, Camryn Manheim, and John Leguizamo who created solo shows for themselves and achieved some wonderful career success after performing their one-person shows.

I started writing *The Gospel According to Josh* right after my dad took his life in 2009, and I had no idea what direction I was going with it. But it quickly turned into an autobiographical comedy that details the strained relationship I had with my dad and all of the quirky and awkward things I went through to go into show business—things like starring on an episode of the *Maury Povich Show* where I had to pretend to date a 450-pound woman, auditioning for a creepy film director in the middle of a forest in New Jersey, and accidentally costarring on a reality TV show that featured Erik Estrada from TV's *CHiPS*. However, the show does take a poignant turn at the end when I find out in the play that my dad killed himself. It is a real portrayal of how someone has to deal with emotional repercussions when one of their loved ones dies by suicide. And I deal with the topic of suicide in a sensitive and non-sensationalist manner.

After producing the show in New York and Philadelphia, and shortly thereafter going through my own bout of clinical depression and a near suicide attempt, it dawned on me that I can use this show to start helping people. I can help people like myself and like my father who did not speak out and ask for help because of the stigma surrounding talking about and getting help for suicide and mental health issues. It is pretty incredible that from my initial desire to revive my acting career came a play that has transformed into something that is able to help tens of thousands of students all across the world.

At first, we thought you might be offering to do a religious presentation on our campus, because of your play's title. How did you come up with the title, *The Gospel According to Josh*?

That's a great question and one that I get all the time. My dad happened to be a religious man, and his beliefs affected his persona, how I wrote his character in the play, and how I portray him as an actor. I do not make fun of his beliefs, and I do not promote them either. They are just part of the story. If my dad was a fisherman, then I'm sure the title would have Tilapia in it or something. "Gospel" is also a bit of a double entendre. It means "good news," and my good news is that suicide is preventable, and any and all of us can get help for it.

What made you reach out to Psi Chi as an avenue to get your production to college campuses?

The issue of suicide is one that affects a large number of college students (it is the second leading cause of death for 18- to –24-year-olds), so I looked into college clubs and organizations whose success was driven by its students. After investigating www.psichi.org, I realized that Psi Chi was a natural fit. I saw that Psi Chi was founded with the purpose of "advancing the science of psychology," and I know that mental illnesses and suicide prevention research are aspects of psychological science that need a lot more advancement and funding.

Upon further research, I also read that one of Psi Chi's major goals is to "nourish and stimulate professional growth through programs designed to augment and enhance the regular curriculum." *The Gospel According to Josh* seemed like a perfect vehicle for chapters to accomplish this goal. Because Psi Chi officers are known for their leadership abilities, they seemed like an ideal resource to utilize for putting together a social advocacy event.

How did you first link up with the Psi Chi chapter at Baruch College?

I was able to first link up with the Baruch College Psi Chi chapter through a gentleman, Dr. David Sitt, who works in the Department of Psychology at Baruch College and is also the faculty advisor for Psi Chi. I had initially sent out some very discombobulated pitch e-mails to psychology professors all across the United States that outlined my ideas on the way I wanted to develop a program that combined *The Gospel According to Josh* with education on suicide prevention and mental wellness.

Not many people were responding. After about a month of revising my pitch e-mail and resending, Dr. Sitt called me with questions about my idea of pairing live theatre with suicide prevention education. After a few meetings with Dr. Sitt and his colleague, Professor Sapolsky, they decided to green-light the project and have the Baruch Chapter of Psi Chi and the Baruch Department of Psychology sponsor the premiere of *The Gospel According to Josh* with suicide prevention and mental wellness education.

What happened after this initial performance?

I am very fortunate to have gotten the

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opportunity from Dr. Sitt and the Baruch College chapter of Psi Chi to do this work because it has grown exponentially. In the 2011–12 school year, I was able to go to more than 20 schools across the country and present my work—places like Arizona State University; University of Nevada, Reno; Yeshiva University; and Florida Memorial University. I have also presented *The Gospel According to Josh* on high school and middle school campuses and have worked with the Hawaii Department of Education. I've been fortunate to have my audiences consist of low-income and at-risk-youth, Native Americans, faith and nonfaith based schools, and people ages 8 to 68. It is pretty amazing to be able to reach such a wide demographic of people in such a positive way.

What type of feedback have you gotten from your production?

I have gotten some tremendous feedback from my production and suicide prevention work. I've received e-mails from some very brave young people who have lost loved ones to suicide or have made their own attempts and are working on getting help for their suicide ideations. In some schools, I have actually witnessed students making appointments to see their school psychologist after my show. Others have told me that I am promoting healing in their family after they've lost a loved one to suicide. I have been able to hug students and educators who have felt comfortable sharing their stories of suicide attempts. People have told me that I am helping them cope with their mental health issues or the way they're dealing with having lost a friend or family member to suicide. One young lady even quoted something I said verbatim and mentioned in her e-mail to a counselor that what I said was the reason she was getting help. Basically, this is the best and most fulfilling work I have ever done. I'm able to be a working artist while helping people deal with their issues and stay alive.

What do you think your father would think about your work on behalf of suicide prevention?

We did not have the best relationship when he was alive, but I think he would be happy and proud of the work I am doing. I'm doing it for him and for me. He grew up in a time when it was not okay to talk about how you feel or get help if you need it. But I am working to change that, and I think he is able to rest a little more peacefully knowing, that, in some way, his death and my work may help prevent other people from ever having to go through the emotional and physical pain he experienced when he took his life.

What does a Psi Chi chapter need to do to bring this type of event to its campus?

There are a variety of ways you can bring an event to your campus. For example, you can pair the event with a psychology class on mental disorders, such as Abnormal Psychology. Ninety percent of suicides are the result of an untreated mental health issue like clinical depression, Post Traumatic Stress Disorder (PTSD), Obsessive Compulsive Disorder (OCD), and bipolar disorder.

You can also offer to partner with the counseling center, student government, the psychology department, social work department, residence life, Greek organizations, or all of the above. Good times of year to bring events like this to your campus are

- National suicide prevention week—always the week surrounding September 10, which is World Suicide Prevention Day.
- The week preceding Suicide Survivor Day—November 17.
- Early December before the stress of finals.
- Late January at the start of the spring semester.
- March during social work month.
- Late April or early May before the stress of finals.

What does the chapter need to do to prepare in advance for this type of production?

Setting up this kind of event is a relatively easy process. There are really just a few basic steps:

- Set up a venue with someone in campus activities or the student life center. The venue could be a theatre, a lecture hall, a classroom, or an auditorium.
- Make sure your Psi Chi officers and advisor are all helping with the planning of the event (many hands make light work).
- Advertise. Many speakers have template flyers that can help with this or assist in setting up events via social media. Interview the speaker for the school newspaper or a school radio show in anticipation of the event. You could also advertise through your psychology professors, and ask them to offer extra credit to students that attend.
- (Optional) Find a person or two on campus to serve on the panel to answer questions from the audience at the end of the event. It is always nice to have either someone from the psychology department or counseling center to answer the very difficult clinical questions audiences may have.

Our chapter has a small operating budget, and I know the cost of events is a concern for us. How can chapters keep the costs manageable?

There are a few options:

- Often student clubs like Psi Chi collaborate with the counseling center or student government, their psychology department, or an Active Minds club to help with funding and promotion.
- Speakers can help the Psi Chi chapter find the most affordable means of transportation to get to their college or university; time of day permitting, some will fly in and out on the same day to negate the cost of a hotel.
- Chapters can charge admission to help offset the cost of the program.

Josh, thanks for your time and your contributions to this important topic.

Anytime. Thank you!

In 2009, **Josh Rivedal** wrote and developed the play, *The Gospel According to Josh* for the commercial stage. In May of 2011 at Baruch College in New York City in conjunction with the Baruch College Chapter of Psi Chi, Josh launched *The Gospel According to Josh: Youth Suicide Prevention* program to promote suicide prevention, good mental health, and a help seeking culture among college students. This program has played to colleges in more than twenty states and two Canadian provinces. Josh also works full time as an actor and playwright in New York City. He volunteers for the Trevor Project and serves on the board of the New York City chapter of The American Foundation for Suicide Prevention.

For more information about the Youth Suicide Prevention Program, go to http://www.yspp.org/

To contact Josh: josh@gospeljosh.com

Merry Sleigh received her PhD in developmental psychology from Virginia Tech in 1996 and has been involved with Psi Chi for over 20 years. Dr. Sleigh currently teaches at Winthrop University and is honored to serve as the Psi Chi Southeastern Regional Vice-President.

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Psi Chi is pleased to offer over **$350,000** in awards and grants to its members each year. Don't miss the exciting opportunities and funding these programs provide!

Go to **http://www.psichi.org/awards/faqs/awards.aspx** to learn more.

Here are some upcoming deadlines to add to your chapter calendar or website:

December 1

Paper/Poster submissions for the **APA/Psi Chi Society Annual Convention**

Poster submissions for the **APS National Convention**

Denmark Faculty Advisor Award

Kay Wilson Officer Team Leadership Award
To award the best chapter officer team for exceptional leadership as a group. One award of $2,000 is available annually. The chapter retains $1,000 of the award and the faculty advisor divides the remaining $1,000 among the officers.

Regional Chapter Awards

Regional Faculty Advisor Awards

January 20

Collaboration Grants
In order to encourage collaborative and cooperative activities and projects between Psi Beta and Psi Chi chapters, this grant has been established to help collaborating chapters achieve their goals with support from both societies. This grant program will provide seed funding for up to four collaborating chapter pairs. All applicants for the Collaboration Grant will automatically be entered in the Building Bonds Award competition.

RA = Research Advisor

Kay Wilson Leadership Award

Psi Chi is pleased to announce the 2011–12 Kay Wilson Leadership Award for Outstanding Chapter President, Michael Kersten, of California State University, Dominguez Hills. The Kay Wilson Leadership Award was established to honor Kay Wilson, the Executive Officer of Psi Chi from 1991–2003. Under Kay's leadership, Psi Chi doubled its membership and increased its grants, awards, and visibility. Kay not only demonstrated excellence in leadership but also realized the role Psi Chi plays in developing future leaders in psychology. This award is dedicated to her commitment to leadership. The award is presented annually to one chapter president who demonstrates excellence in leadership of the local chapter. Such leadership should assist Psi Chi in achieving its purpose "to encourage, stimulate, and maintain excellence in all fields, particularly in psychology, and to advance the science of psychology." As the winning Psi Chi chapter president, Michael Kersten received a cash award of $500 and travel expenses to attend the Psi Chi/American Psychological Association Annual Convention in Chicago to receive an engraved plaque commemorating the award. Please see Michael Kersten's personal statement about his role as chapter president.

When I was elected president of the Psi Chi chapter, the organization only had four remaining members after thirty-six of the members had graduated. For 40 years, Psi Chi had been a very active and well-respected honor society on campus known for its academic achievements. Now it was lacking leadership and on the verge of collapse. Immediately, I knew that it was my responsibility to recruit new members and to keep Psi Chi alive as an organization. Although the chapter advisor was on sabbatical during my first semester as president, I still singlehandedly recruited 39 new members (more than a 1000% increase in membership size), and hosted an induction that attracted hundreds of guests including psychology professors and the Dean of the College of Natural and Behavior Sciences.

As president, one of my primary goals was to help students get into graduate school. This meant informing members of the research opportunities on campus as well as the various local and national psychological conferences. I made every attempt to encourage participation in the 7th annual Student Research Day event on campus. To my amazement, over 20 of the oral/poster presentations at Student Research Day came from current Psi Chi members. Most of these students are now active in research labs and are present at other conferences as well. For example, many Psi Chi members attended both the WPA and APA conventions during my presidency. I also hosted graduate school workshops to inform students about personal statements, curriculum vitae, letters of recommendation, required research/internship experience, and the different degrees, subfields, and careers available in psychology.

Michael Kersten was presented the Kay Wilson Leadership Award plaque by Dr. Susie Amato Henderson at the APA Convention in Chicago.

To me, leadership is not just about scheduling meetings and promoting psychology on campus. Leadership is about being able to encourage others to engage in academic excellence and to test the concept of what is possible to achieve as a student. Group leadership is about helping every individual realize their strengths and how those strengths are applicable to the successes of the individual and the entire group. While president, I have witnessed all of my fellow members become leaders. The support, encouragement, and commitment of our members are congruent with the qualities of those successful in both academia and research.

As a graduating senior, I am delighted to say that my Psi Chi chapter has nearly 60 current members and continues to be active on campus, in the community, and at psychological conferences. I am also happy to say that our chapter made a $250 donation to Student Research Day because we consider it to be a vital research opportunity for undergraduates. My appreciation for my Psi Chi chapter grew when we won the Presidential Award for Outstanding Academic Achievement out of all of the organizations on campus. Most importantly, I am happy to feel that I, along with my fellow members, have positively contributed to the growth and development of such a prestigious honor society.

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PSI CHI/FBI NCAVC Internship Grant

The Psi Chi Research Grants Committee is pleased to announce the winner of the Psi Chi/FBI National Center for the Analysis of Violent Crimes (NCAVC) Internship Grant. Adrienne Hoffman-Lewis of Marymount University (VA) is the grant recipient for the spring 2012 internship. The grant's purpose is to further the goals of Psi Chi by providing funds for undergraduate or graduate Psi Chi members to conduct research at the FBI NCAVC. The NCAVC conducts empirical research on factors involved in violent crime (e.g., maternal filicide, sexual exploitation of children, domestic violence homicide, child abduction/homicide, and serial murder). Interns participate as team members in all aspects of the research. Psi Chi has formed a partnership with the NCAVC to provide grants for NCAVC interns who are Psi Chi members. Up to two $7,000 grants will be awarded annually to support living expenses for Psi Chi members who are selected for one of the 14-week unpaid NCAVC internship positions.

Adrienne Hoffman-Lewis

Adrienne Hoffman-Lewis was the recipient of the 2011–12 Psi Chi/FBI National Center for the Analysis of Violent Crimes Internship Grant. She graduated *magna cum laude* from California State University, Los Angeles, with a BA in psychology in December 2004. Ms. Hoffman-Lewis was granted a Psi Chi membership in October of 2010 and graduated from Marymount University in May of 2012 with an MA in forensic psychology. She has accepted a fellowship as a research analyst with the Oak Ridge Institute for Science and Education at the FBI's Behavioral Analysis Unit 3.

My internship at the FBI's National Center for the Analysis of Violent Crime (NCAVC) has been an enriching experience, both personally and professionally. I was very excited when I received the call that I had been selected as an intern, and was able to work from an off-site location with the Innocent Images Intelligence Unit (IIIU). This arrangement allowed me to work with both the BAU-3, which handles crimes against children, and the IIIU on projects that inform child sex offender research and assist in protecting children.

Working with my mentor, agents, and research analysts in the BAU-3, I contributed to a literature review of an in-press study by summarizing articles on suicide notes. Additionally, I was tasked with transcribing suicide notes left by child sex offenders. These notes were often very intimate and allowed me to gain personal insight into the minds of the offenders.

At the IIIU, I was asked to assist in a large-scale initiative to identify online threats and vulnerabilities to children. My duties included classifying and categorizing websites that were reported to the National Center for Missing & Exploited Children's (NCMEC) CyberTipline for future analysis.

Perhaps even more exciting, however, were the perks that came along with the internship. I was given the opportunity to attend a lecture at the National Academy on the DC Sniper case and tour Quantico, and was able to tour the FBI's Headquarters at the J. Edgar Hoover Building. I was also invited to attend a presentation on suicides by child sex offenders and the dangers that these subjects may present to law enforcement officials.

The knowledge and experience I have gained during my internship at the NCAVC has been extremely rewarding. The people I met were willing to discuss their careers with me, allowing me an insider's view of the various positions available within the FBI. My time as an intern with the FBI's NCAVC was invaluable, enabling me to polish my skills, meet new people, and learn more about careers with the Bureau.

Model Chapter Awards

For 2011–12 academic year, 56 Psi Chi chapters qualified for recognition as Model Chapters. The Model Chapter Awards Program annually recognizes and rewards those chapters that consistently maintain outstanding records of membership inductions, chapter correspondence, service projects, and other criteria associated with being an outstanding chapter. All chapters meeting the criteria are designated as winners and receive a check for $100 noting their achievement as a Model Chapter. In addition, the winning chapters are eligible to win subsequent years. Eligibility is determined after the end of the fiscal year (June 30). The 2011–12 Model Chapter Award winners are:

2011-12 Model Chapter Award Winners

Adams State College (CO)
Adelphi University (NY)
Agnes Scott College (GA)
Baruch College, CUNY
Bradley University (IL)
Cal State University, San Bernardino
Catawba College (NC)
Central Michigan University
Claremont Graduate University (CA)
Colorado State University
Davidson College (NC)
Dominican College (NY)
Drury University (MO)
Eastern Michigan University
Eastern University (PA)
Emporia State University (KS)
Fairleigh Dickinson University (NJ)
Florida Institute of Technology
George Mason University (VA)
Hawaii Pacific University
Hendrix College (AR)
Indiana University Southeast
Michigan Technological University
Morningside College (IA)
Northwestern College
Nova Southeastern University (FL)
Regis University (MA)
Saint Vincent College (PA)
Southern Connecticut State University
Southern Oregon University
Southwestern University (TX)
SUNY at New Paltz
Texas State University, San Marcos
The George Washington University (DC)
Trinity Washington University (DC)
University of Akron (OH)
University of Central Arkansas
University of Central Florida at Cocoa
University of Central Missouri
University of Illinois at Chicago
University of La Verne (CA)
University of Louisville (KY)
University of Mary Washington (VA)
University of Missouri, Kansas City
University of Northern Colorado
University of Puerto Rico, Rio Piedras
University of San Diego (CA)
University of San Francisco (CA)
University of South Carolina
University of Texas at Tyler
University of Toledo (OH)
University of Wisconsin–Green Bay
Vanderbilt University (TN)
Westfield State University (MA)
West Virginia University
Winthrop University (SC)

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Cousins Chapter Award: West Virginia University

Congratulations to the Psi Chi Chapter at West Virginia University for winning the 2011–12 Ruth Hubbard Cousins Chapter Award. This award recognizes the chapter that best achieves Psi Chi's purpose, which is "to encourage, stimulate, and maintain excellence in all fields, particularly in psychology, and to advance the science of psychology." This award was established to honor Psi Chi's former executive director Ruth Hubbard Cousins for her 33 years of dedicated service. This award-winning chapter received a $3,500 check and paid travel expenses to the 2012 APA/Psi Chi Society Annual Convention where the award was presented. West Virginia University was chosen as the winning chapter because of the outstanding accomplishments and activities of its members during the past three academic years. The award is granted to the chapter that excels in the following areas: effective programming of chapter activities, effective membership practices, and participation in Society and regional activities. Read further about the chapter's outstanding activities and their essay on how to build an effective chapter.

Building an Effective Chapter

Successful Psi Chi chapters are active beyond their college walls, encouraging interactions not only in their home department, college, and university, but also in local, state, regional, national, and international communities. The West Virginia University (WVU) chapter has, as its foundation, an ongoing presence in the WVU Department of Psychology. Chapter members go to great lengths to focus on undergraduate issues, as well as incorporate graduate students, faculty, and departmental staff. The collaboration encourages wonderful opportunities for all parties. The chapter keeps the department current on all Psi Chi and Psychology Club events through posted flyers around the department building, our Psi Chi chapter website, and emails sent to undergraduates, graduates, staff, and faculty. The chapter has a guest speaker at each monthly meeting, providing students with new information from diverse areas of psychology. Faculty are invited to speak at some of these meetings, as well as Psi Chi initiations, but members also engage the local psychology community by inviting as speakers psychological scientists and practitioners from outside the Department of Psychology and WVU. Additionally, to encourage relationship-building, faculty and undergraduates participate in the chapter's annual student/faculty pool tournament. The chapter sponsors social events such as an annual trip to the local haunted attraction and frequent "psychological" movie nights to help students build lifelong relationships.

To be a successful chapter, an environment must be created in which all its students can be involved. To encourage involvement, the WVU Psi Chi chapter works hand-in-hand with the WVU Psychology Club. Such collaboration allows students the opportunity to become involved in our activities from the start of their education. Members of both organizations work together and the combination is a stepping stone, allowing club members to easily apply to Psi Chi. The chapter president and other officers speak to both Introductory Psychology and Psychology as a Profession classes, in order to spread the purpose and mission of Psi Chi and the Psychology Club to all interested psychology students. Additionally, Psi Chi officers' names, emails, and office hours are posted on the website and outside the Psi Chi office door, which is located in the Department of Psychology, to promote contact with members.

To reach out to the local community, the chapter cooks dinner each month for the Ronald McDonald House and for families attending the West Virginia Family Grief Center after the loss of a loved one. Chapter members annually participate in Relay for Life, the Linus Project, and help sponsor the Polar Bear Plunge, which benefits the local Special Olympics. Holding Every Life Precious (HELP) mental health awareness and suicide prevention program has been a valuable way for the chapter to reach out to the campus and its communities. The mission of HELP is to promote positive mental health, to destigmatize help-seeking, to promote awareness of suicidal risk, and to prevent suicide. The chapter, through the HELP program, sponsors monthly awareness activities and works closely with the WVU counseling center.

A successful chapter must not only contribute locally, but regionally, nationally, and even globally, particularly given Psi Chi's new international chapters. The WVU chapter attends national conferences and actively participates in the Tri-State Undergraduate Psychology Research Conference. WVU has hosted the Tri-State conference on two occasions in recent years, and began the intercollegiate Psychological Jeopardy competition at the conference. Globally, the WVU chapter advisor, Dr. Daniel W. McNeil, provided consultation and support during his sabbatical in New Zealand to a school of psychology in their development of a psychology club and the initial steps to establish a Psi Chi chapter. He is an advocate for our chapter's active involvement with Psi Chi as an international organization. It is essential to have an active, invested, and dedicated faculty advisor who helps establish and maintain a successful chapter, and to encourage continuity across academic years.

In conclusion, members believe that to be successful, a Psi Chi chapter must create an environment in which all who are interested have a way to be meaningfully active. Moreover, the chapter is nourished by engagement in service at all levels, starting at home and branching out to serve the university, local community, state, regional, national, and international levels.

Sincerely,
West Virginia University Psi Chi Chapter

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Newman Graduate Research Award

Cynthia J. Najdowski
University of Illinois at Chicago
RA: Bette L. Bottoms, PhD

Understanding Jurors' Judgments in Cases Involving Juvenile Defendants

Juveniles, particularly intellectually disabled juveniles, are at heightened risk for falsely confessing to crimes. Thus, we conducted a mock trial experiment to investigate how a juvenile defendant's confession and disability influence jurors' decision making. As expected, jurors discounted a juvenile's coerced confession, rendering similar judgments for a juvenile who confessed under coercion and a juvenile who did not confess. The juvenile's disability status did not moderate these effects, nor did it influence jurors' neither verdicts nor suspicions of guilt. Jurors who suspected the juvenile was guilty, however, were less likely to vote guilty when the juvenile was intellectually disabled rather than nondisabled. We used attribution theory and the discounting principle to identify the psychological mechanisms underlying these effects.

Cynthia J. Najdowski

Cynthia J. Najdowski is a doctoral student majoring in social and personality psychology and minoring in psychology and law at the University of Illinois at Chicago. Her research examines social influences on sexual abuse victims' psychological recovery, public and jurors' perceptions of juvenile offenders, and how social psychological theories can be used to understand racial disparities in the criminal justice system. Ms. Najdowski will begin an appointment as assistant professor in the University at Albany's School of Criminal Justice in spring 2013.

Bandura Graduate Research Award

Christopher Conway
University of California, Los Angeles
RA: Constance Hammen, PhD

Expanding Stress Generation Theory: Test of a Transdiagnostic Model

The original stress generation (SG) hypothesis states that people with a history of depression, compared to never-depressed counterparts, experience more stressors that are dependent, at least in part, on their own actions. However, recent studies on anxiety and externalizing disorders suggest that SG is not unique to depression. We propose a transdiagnostic SG model that identifies SG effects that are due to depression-specific pathology versus pathology shared across multiple disorders. Analyses revealed that both transdiagnostic and syndrome-specific pathology play complementary roles in the SG process. At the disorder level, depression- and panic-specific pathology contributed incrementally to the prediction of acute stress even after accounting for transdiagnostic pathology. This hierarchical framework is discussed as an integrative model for SG research.

Christopher Conway joined Psi Chi at Duke University in 2006 and graduated in 2007 with a BS degree in psychology. For the past five years, he has worked under the mentorship of Dr. Connie Hammen at UCLA to study the social and genetic origins of psychopathology. Currently, he is completing a predoctoral clinical psychology internship at the Veterans Affairs hospital in San Diego.

Intel International Science & Engineering Fair Awards

Psi Chi presented awards at the Intel International Science & Engineering Fair (ISEF) for three high school presentations in the field of psychology. Drs. Maria Lavooy of Florida Institute of Technology (Psi Chi President-Elect), Jason Young of Hunter College, CUNY (Psi Chi President), and Joyce Jagielo of Edinboro University of Pennsylvania (local Psi Chi primary faculty advisor) served as judges for these awards.

First Place

Megan Smith
Shawnee Mission West High School
Overland Park, KS

The Effect of Coffee Extract and Caffeine on the Locomotory Rate and Basal Slowing Response of a LRRK2 Transgenic Caenorhabditis elegans (G2019S Mutation) Model of Parkinson's Disease

This project investigated the effects of caffeinated coffee, decaffeinated coffee, and caffeine on the dopamine controlled behaviors in transgenic Caenorhabditis elegans(C. elegans) with the G2019S mutation in leucine-rich repeat kinase 2 (LRRK2), one of the most common mutations linked to Parkinson's disease (PD). These C. elegans, with movement dysfunction resulting from decreased dopamine levels, were exposed to 10%(v/v) caffeinated or decaffeinated coffee or 3.6mM caffeine from hatching. Significant improvements ($p < .01$) in the locomotory rate and basal slowing response were noted in G2019S C. elegans treated with caffeinated coffee or decaffeinated coffee from day 3 on and in those treated with caffeine from day 9. All improvements occurred after the L4 molt.

Megan Smith is from Lenexa, KS, where she is a senior in the Biotechnology Signature Program at Shawnee Mission West High School. She has been named a Kansas BioGENEius finalist, a Presidential Scholar, a National Merit Finalist, and was the Kansas female recipient of the Siemens Award for Advanced Placement. In addition to her scientific research, she enjoys her participation in the Girls Grant Project with the Women's Foundation of Greater Kansas City, Academic Decathlon, and piano. In her free time, she enjoys spending time with her four younger siblings, baking, and reading. In the fall she plans to attend the University of Pennsylvania where she will pursue a dual-degree in the Life Sciences and Management Program.

Third Place

Mimi Yen
Stuyvesant High School
New York, NY

Characterizing the Behavior and Genetics of Headplugging in *C. elegans*

Headplugging is a variation of mating behavior observed in *C. elegans* resulting from large-scale evolutionary change. Hermaphroditic development has eliminated the need for males and caused mutant behaviors in the low male population to be overlooked by natural selection. One such behavior is the deposition of mucus plugs, normally deposited onto hermaphrodite vulvae, onto male excretory pores by other males in all-male environments. The headplugging gene was mapped to a 0.699 Mb region on chromosome II. Behavioral assays show that headplugging tendencies result from the absence of hermaphroditic secretions that promote normal mating behavior and do not negatively affect a male's mating capabilities. Further studies may reveal biochemical circuits that govern mating, many of which are preserved in other species.

Mimi Yen was born in Honduras and raised in New York. She conducted her C. elegans headplugging behavioral study under Drs. Matthew Rockman and Audrey Chang at the NYU Genomics and Systems Biology Center over the course of two years and will be continuing her research this summer. She has entered her research in the Intel Science Talent Search, where she placed third in the nation. In addition to research, Ms. Yen enjoys helping others at soup kitchens, where she prepares food for those on special medical diets. She was a member of the Service Events Committee in her school's national honor society and president of the Research Team. She graduated from Stuyvesant High School in June 2012 and will be attending Harvard University in the fall, where she plans on majoring in biology.

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Allyn & Bacon Awards

The Allyn & Bacon Awards are named for the publisher of the same name. Cash awards were given to the winners as follows: $1,000 for first place, $650 for second place, and $350 for third place.

First Place:
Richard Chambers
University of Wisconsin–River Falls
RA: Lisa Isenberg, PhD

Top-Down Influences and Inversion Effects on Stereopsis

Second Place:
Lane Nesbitt
University of Michigan
RA: Sari van Anders, PhD

Jealousy as Competition: Imagined Partner Flirting Behavior Increases Testosterone in Partnered Women

Third Place:
Jason Parad
Yale University (CT)
RA: James Leckman, PhD

Mind-Body Dualism in Beliefs About Tic Disorders

Mind-body dualism presents an enduring challenge to psychiatry in that mental disorders can be perceived as psychological or biological. Although past research shows that this distinction inappropriately invites discrepant clinical recommendations and social judgments, these effects are contingent upon explicit suggestions about disorder etiology. Of greater concern is whether the symptoms, rather than the causes, of disorders generate similarly biased attitudes. The present study tests this possibility using the psychiatric phenomenon of tics. In line with dualism, our results demonstrate that whereas vocal tics precipitate beliefs about psychological etiology and recommendations for psychotherapy, motor tics engender beliefs about biological etiology and recommendations for medication. These findings call for increased attention to the selection of treatment plans across all psychiatric disorders.

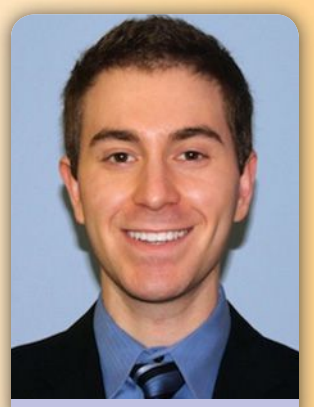

Jason Parad

Jason Parad graduated *summa cum laude* and Phi Beta Kappa from Yale University where he received distinction in the biology and psychology majors. He founded the Yale Undergraduate Psychological Society and served as executive editor of the *Yale Review of Undergraduate Research in Psychology.* He is the recipient of the William R. Belknap Prize, the Fellows' Prize, the Yale College Writing Prize, and the Yale Science & Engineering Association Senior High-Scholarship Award. Mr. Parad has conducted psychology-based fieldwork in Malaysia, Mexico, and South Korea with fellowships from the Charles H. Siegel and Paul K. & Evalyn Cook Richter Memorial Funds as well as with grants from the Korea Foundation and Psi Chi. His published research on psychological biases in medical intervention has also been presented at the 30th International Congress of Psychology in Cape Town, South Africa. He continues his studies in the Perelman School of Medicine at the University of Pennsylvania.

Travel Grants

The Psi Chi Board of Directors began sponsoring Travel Grants for the 2011 Regional Conventions. Each Regional Vice-President provides guidelines specific to his or her region, and each recipient receives from $100 to $350 in funding to support travel to the regional conference. The 2011–12 Travel Grant Winners are listed below:

Eastern Region
Daniel Albohn, Eastern University (PA)
Elphys Alvarez, Dominican College (NY)
Kellye Bageon, Southern Connecticut State University
Kelly Brown, Saint Vincent College (PA)
Mary Buckingham, St. Joseph's College (NY)
Sally Capanzano, Pace University (NY)
Lydia Eisenbrandt, SUNY Potsdam
Adam Fine, Georgetown University (DC)
Hannah Frank, Georgetown University (DC)
Marie Fuga, Saint Vincent College (PA)
Stephanie Goldstein, Drexel University (PA)
Katelyn Gormley, Lasell College (MA)
Monica Jimenez, Montclair State University (NJ)
Alyssa Matteucci, Drexel University (PA)
Melanie Oxendine, Trinity Washington University (DC)
Ruth-Anne Poli, Temple University (PA)
Alexis Rodgers, Saint Vincent College (PA)
Anna Rutledge, Saint Vincent College (PA)
Megan Slater, State University of New York at Potsdam

Midwestern Region
Juliana Black, University of Toledo (OH)
Heather Burcham, University of Michigan
Julia Capstrain, University of Illinois at Springfield
Carolyn Davidson, Ohio University
Rachel Kauffman, University of Missouri, Kansas City
Hayley Vaske, St. Cloud State University (MN)

Rocky Mountain Region
Tyler Broderick, New Mexico Highlands University
Joseph Clyde, Utah State University
Jessica Christensen, Utah State University
James Estes, Regis University (MA)
Megan Hart, Adams State College (CO)
Laura Hopkins, Adams State College (CO)
Tucker Jones, Adams State College (CO)
April Knight, Weber State University (UT)
Rebecca Mecham, Weber State University (UT)
Chris Olance, Adams State College (CO)

Southeastern Region
Janae Bonsu, University of South Carolina
David R. Bowling, Catawba College (NC)
Rachel Cook, Agnes Scott College (GA)
Elizabeth Ann Brashier, Agnes Scott College (GA)
Amanda Fisher, Drury University (MO)
Lauren Hayes, Florida Institute of Technology
Daniel Keller, Davison College (NC)
Michelle Lyons, Catawba College (NC)
Katherine Ness, Davidson College (NC)
Maura L. Pantone, Catawba College (NC)
Kyle Piecora, Florida Institute of Technology
Samantha Yung, University of Louisville (KY)
Katherine Zink, Catawba College (NC)

Southwestern Region
Marisol Cervantes, University of Texas at Brownsville
Lauren Eberting, Kansas State University
Jonathan English, Hendrix College (AR)
Abimbola Farinde, Walden University (MN)
Mariam Khan, University of Central Arkansas
Mandi Laurie, Texas State University–San Marcos
Stacey O'Leary, Walden University (MN)
Sarah Stegall, University of Texas–Pan American
Angela Welborn, Southeastern Oklahoma State University

Western Region
Ashlee Baker-Davis, Southern Oregon University
Tyler Broderick, New Mexico Highlands University
Caitlin Brown, Southern Oregon University
Coral Bruni, Claremont Graduate University (CA)
Anita Chen, University of California, Irvine
Elizabeth Conkey, Western Oregon University
Emma Fraser, University of Victoria (BC)
Lavina Ho, University of California, Irvine
Roanne Tiongson, University of Nevada, Las Vegas
Timothy Williamson, Pitzer College (CA)

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PSI CHI Awards and Grants

Psi Chi sponsors a variety of award competitions each year. Listed below is a brief overview.
For more information, please visit **www.psichi.org/Awards**

Name of Award	Submission Deadline	Who Can Apply?
Bandura Graduate Research Award	February 1	• Graduate
Cousins Chapter Award	February 1	• Chapter
Newman Graduate Research Award	February 1	• Graduate
Kay Wilson Leadership Award	April 1	• Chapter President (chapter nomination)
Allyn & Bacon Psychology Awards	May 1	• Undergraduate
Guilford Undergraduate Research Awards	May 1	• Undergraduate
Building Bonds Awards	June 1	• Chapter
Model Chapter Awards	June 30	• Chapters
Diversity Article Awards	July 1	• Graduate • Undergraduate
Regional Research Awards	Deadlines Vary, Fall/Winter	• Graduate • Undergraduate
Denmark Faculty Advisor Award	December 1	• Faculty Advisor (chapter nomination)
Kay Wilson Officer Team Leadership Award	December 1	• Chapter
Regional Chapter Awards	December 1	• Chapter
Regional Faculty Advisor Awards	December 1	• Faculty Advisor (chapter nomination)
Society Annual Convention Research Awards	December 1	• Graduate • Undergraduate

Name of Grant	Submission Deadline	Who Can Apply?
Graduate Assistantship Grants	January 1	• Graduate
Collaboration Grants	January 20 June 1	• Chapter
FBI NCAVC Internship Grants	February 1 June 1	• Graduate • Undergraduate
APS Summer Research Grants	March 1	• Undergraduate
CUR Summer Research Grants	March 1	• Undergraduate
SRCD Summer Research Grants	March 1	• Undergraduate
Summer Research Grants	March 1	• Undergraduate
Faculty Advisor Research Grants	June 1	• Faculty Advisor
STP Assessment Resource Grants	June 1	• Psi Chi Faculty Members
APAGS/Psi Chi Junior Scientist Fellowships	June 30	• Psi Chi Members • APAGS Members
SuperLab Research Grants	October 1	• Graduate • Undergraduate
Thelma Hunt Research Grants	October 1	• Faculty • Graduate • Undergraduate
Undergraduate Psychology Research Conference Grants	October 1	• Sponsor(s) of local and regional conference
Regional Travel Grants	Deadlines Vary, Winter/Spring	• Graduate • Undergraduate
Graduate Research Grants	November 1 February 1	• Graduate
Mamie Phipps Clark Reseach Grants	November 1 February 1	• Faculty • Graduate • Undergraduate
Undergraduate Research Grants	November 1 February 1	• Undergraduate

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With over 1,000 chapters, Psi Chi members can make a significant impact on their communities. Let us know what your chapter has been doing and share your fund-raiser ideas with others. See submission information listed below.

Submission deadlines*
Fall: June 15
Winter: October 15
Spring: December 15
Summer: February 15

* Reports received (postmarked) after the deadline will appear in the next issue of *Eye on Psi Chi*.

Submission specifications

- Only activities that have already occurred and are submitted in paragraph form will be published.
- Do not send future plans, calendars, or summarized lists.
- Limit reports to 250 words. If you wish to report more extensively on a special activity, series of programs, etc., contact the Central Office at psichieye@psichi.org.
- Write your report in the third person rather than the first person (e.g., "the chapter sponsored" vs. "we sponsored").
- Include full names, degrees, and titles of speakers/leaders, their institutions, and their topics.
- Report chapter events such as: discussions, lectures, meetings, socials, fund-raising events, conventions, field trips, and honors received by students, faculty members, and/or the chapter.
- Report attempted solutions to chapter problems—those that were effective and those not so effective.
- Color photos are welcomed; the number of photos per chapter is limited to two per issue. Include accurate, typed captions. Photos may be mailed (include a self-addressed, stamped envelope for returned photos) or emailed to psichieye@psichi.org. For digital photos, email only high-quality resolution images (600KB) using a 5-or-higher megapixel camera. Do not send digital printouts from a photo quality printer.
- Photographs and chapter reports submitted to *Eye on Psi Chi* may be featured on our website (www.psichi.org).

ABBREVIATIONS:

ACHS	Association of College Honor Societies
APA	American Psychological Association
APS	Association for Psychological Science
EPA	Eastern Psychological Association
MPA	Midwestern Psychological Association
NEPA	New England Psychological Association
RMPA	Rocky Mountain Psychological Association
SEPA	Southeastern Psychological Association
SWPA	Southwestern Psychological Association
WPA	Western Psychological Association

East

Adelphi University (NY)

The chapter hosted its biannual colloquium on March 21; Dr. Joanne Gerenser from the Eden II Programs supporting the autistic community gave a talk entitled "Understanding Autism: An Overview of Diagnosis and Intervention." On March 26, the chapter inducted 45 new members in a beautiful ceremony and celebrated afterward with food, cake, family, and friends. For the first time in the chapter's history, masters and doctoral students were among the inductees. During the semester the chapter also sponsored two brown bag lunch meetings, where Adelphi faculty members Drs. Carolyn Springer and Kate Szymanski presented their research. Finally, the chapter participated in the National Alliance on Mental Illness walk at Jones Beach on May 5.

Fordham College of Liberal Studies, Westchester (NY)

The chapter mourned the passing of its founding president, Jason S. Pryce, on May 9, 2012, at age 28. The son of Sandra Pryce and Kenneth Dwyer, Jason was a star athlete when he graduated Iona Prep in 2002, then Fordham in 2010. Jason also played saxophone and sang in the choir of his Full Gospel Church. His inspiring four-year battle with a rare carcinoid syndrome is described in many News-12 TV reports that also appear on YouTube.

Saint Vincent College (NY)

In the months of September and October, the chapter held its major fund-raiser which is a Halloween treat bag sale. Parents of all students had the opportunity to purchase a large trick-or-treat bag which was delivered to their student on Halloween. Psi Chi members stuffed over 170 bags. The fall semester also included a service project for Saint Anne Home, which is a local assisted-living facility. Each member of Psi Chi purchased a gift or gifts from the resident's wish list.

On March 1–3, 10 Psi Chi members attended the annual meeting of the EPA Convention. Six senior Psi Chi members presented their research theses at the conference. One senior member also presented research with a senior Psi Chi member and the chapter advisor, Dr. Mark Rivardo, who was presented with the Regional Faculty Advisor Award.

Also in the month of March, Psi Chi invited Tara Karns, a fellow Psi Chi member and 2009 graduate of the university, to campus. Tara is currently a graduate student in a clinical program at West Virginia Univeristy. The chapter sponsored a luncheon to allow students the opportunity to ask Tara their questions about graduate school and the

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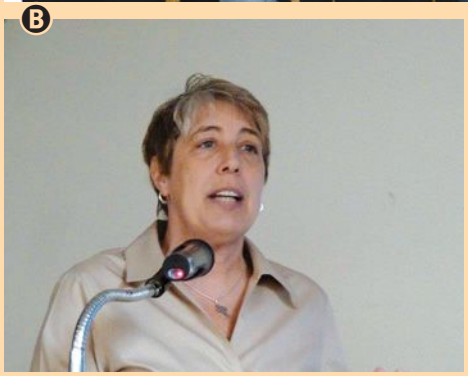

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application process.

On April 15, the chapter inducted 14 new members, who joined in time to participate in a needs list drive for the Blackburn Center Against Domestic and Sexual Violence.

Westfield State University (MA)

Members held the annual induction ceremony on April 21, 2012, at which time they held a food drive for the homeless shelter in town. Lauren Rachel (secretary) volunteered at the shelter on a weekly basis during the spring semester of 2012. Dr. Jason Young, Psi Chi President-Elect, was the guest speaker at the induction ceremony.

Members of the chapter attended NEPA along with the Psychology Club. Two members presented at the Massachusetts state-wide undergraduate research conference along with the Honors Program. In addition, meetings were held twice a month and an e-newsletter was sent out after each meeting with the minutes and the agenda for the next meeting. The members also helped each other apply for awards and grants from Psi Chi.

Midwestern

Bradley University (IL)

The chapter started the semester with its semi-annual pizzapalooza where all psychology students had dinner with psychology department faculty. The chapter continued its peer mentor program in which freshmen psychology majors are paired with Psi Chi members in order to help the incoming students get involved with the opportunities the psychology department offers. In February, the peer mentor group met with Psi Chi members in order to make Valentine's Day cards for sick children in a local hospital. They also hosted two separate movie nights where the movies *Shutter Island* and *A Dangerous Method* were shown and discussed. The members were very involved in the American Cancer Societies' annual Relay for Life and came in second place for the most money raised campus wide. They also hosted Dr. Jean Twenge, professor at San Diego State University and author of *Generation Me* and *The Narcissism Epidemic*, at the chapter's annual Honors Colloquium.

College of Wooster (OH)

During the spring semester, the chapter and Psychology Club hosted Dr. Karl Rosengren (professor and director of undergraduate studies at Northwestern University and a College of Wooster alumnus) for an invited lecture on April 24. The title of the talk was "The Magic of Children;" Dr. Rosengren shared his innovative research on the development of magical thinking, beliefs, and superstitions in children.

The chapter conducted its annual induction ceremony on April 18, 2012, welcoming 14 new members to Psi Chi.

Eastern Michigan University

Many chapter officers and members presented research at the 32nd Annual Undergraduate Symposium. The chapter has been active in its community, participating in local charities and fund-raisers including volunteering at a soup kitchen in Detroit and raising awareness about and participating in a suicide prevention walk. They also had fund-raisers and participated in the 24-hour Relay for Life to benefit the American Cancer Society. During the year, the chapter held the Networking Party and Raffle to benefit Ozone House, a local nonprofit for youth and families in crisis, and allowed undergraduate students to meet graduate students and faculty in the psychology department at the university.

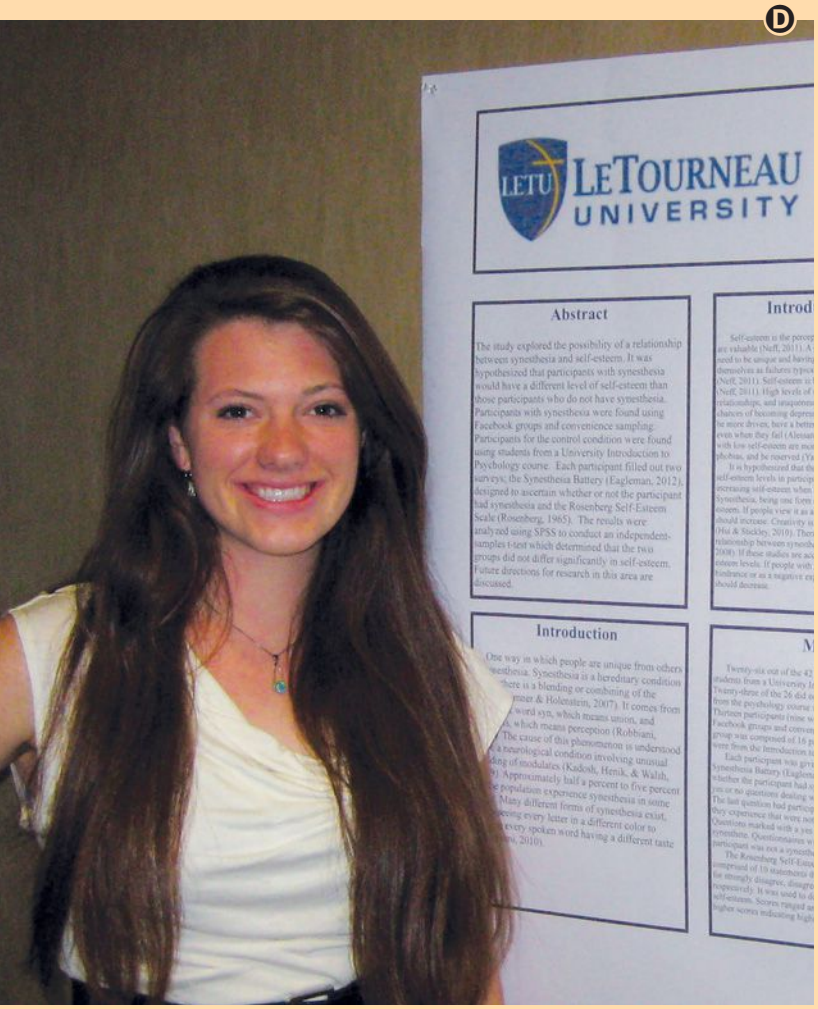

A Members of the **Saint Vincent College (NY)** Chapter with faculty at EPA in Pittsburgh, PA.

B Dr. Joanne Gerenser speaking at the biannual Psi Chi colloquium hosted by the chapter at **Adelphi University (NY)**.

C **Adelphi University's (NY)** faculty advisor with the officers at the March 21 induction.

D Anna Crawford (vice-president) of **LeTourneau University's (TX)** Psi Chi Chapter presented the poster, "The Effects of Synesthesia and Self-Esteem," which won the Award of Merit at the 4th Annual East Texas Psi Chi Student Research Conference.

E **Adelphi University's (NY)** new inductees, officers, and faculty advisor at the March 21 induction.

F **Fordham College of Liberal Studies' (NY)** Psi Chi Chapter founding president, Jason S. Pryce at his 2009 induction; he passed away in May 2012.

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The chapter held bi-weekly meetings to educate students on topics such as how to get into graduate school, taking the GRE, different degrees that can be achieved, and various career paths in the field of psychology.

Emporia State University (KS)

The members have been continuously offering their time and resources to the society and the community, beginning the semester with tornado clean up in Harveyville, KS. Other community service projects included judging a grade school science fair, highway clean up, and making May Day cards for residents of a local retirement home. The chapter earned money through a chili cook-off and a "Kiss the Animal" contest that involved the university's psychology professors. Additionally, members were able to gain research experience by surveying the community with other psychology organizations on campus as a fund-raiser. The spring semester ended with an initiation banquet and a record-breaking number of initiates! Major George M. Boyd, who served with the Tuskegee Airmen in WWII, was the honored banquet speaker. The chapter also created a Facebook page and a blog in a continued effort to be visible to members and the community.

Friends University (KS)

Throughout the year, members involved themselves in a variety of fund-raisers such as football game food sales, coffee and snacks at the monthly jazz concerts, faculty/staff auction, and Halloween baskets. The chapter was also active in community service activities such as cooking dinner once a month at the Anthony Family Shelter and participated in campus events such as the homecoming parade, student government-sponsored events, club fairs, and the annual Christmas tree decorating contest. The chapter also sponsored its own campus events such as lectures, the annual coat drive, and many other activities.

In November Jeremy, Lyne (president) presented a paper at the annual Association for Psychological & Educational Research in Kansas Convention. Jeremy and Caitlin Burk presented their senior research projects at the Great Plains Students' Psychology Convention in March. Jeremy won a first place award.

This year over 300 students from area high schools attended the 4th Annual Psych Fair in April. On April 15, the chapter held its annual spring induction, welcoming 25 new members, including Professor Jennifer Jay. Friends University's new president, Dr. T.J. Aarant, was the invited lecturer, and Jeremy Hickey provided the welcome to new members on behalf of the chapter's alumni. Many members won several honors at the university-wide annual awards ceremony and awards for a variety of academic and athletic achievements.

Marian University (IN)

The chapter welcomed seven new members during a fall induction ceremony. Chapter members worked with the Psychology Club throughout the year on many service activities including a cleanup project with Keep Indianapolis Beautiful, forming a team for the Komen Race for the Cure 5K walk, and distributing Easter baskets to children at two local shelters. The most successful project was a Christmas pizza party for homeless residents of the Holy Family Shelter. Five senior Psi Chi members attended the Butler

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Ⓐ Emporia State University (KS) fund-raiser with Psi Chi Chapter members.

Ⓑ Emporia State University (KS) chapter members at a fun night out.

Ⓒ Emporia State University (KS) initiation banquet at the end of spring semester.

Undergraduate Research Conference, three of whom gave presentations of their independent research studies. In addition, 11 psychology students and a faculty advisor traveled to the College of DuPage to attend the Midwest Institute for Students and Teachers of Psychology Conference to learn about topics related to psychology education. Finally, chapter picnics as well as dinner at an Ethiopian restaurant provided amazing culinary and social experiences.

Michigan Technological University

The chapter assisted the Psychology Club on campus along with Counseling and Wellness Services with many events including: National Depression Screening Day and *America the Beautiful* and *America the Beautiful 2*. For *America the Beautiful 2*, the producer, Darryl Roberts, was brought to campus to premier his documentary. In addition, the chapter participated in Make a Difference Day and multiple social events in conjunction with the Psychology Club throughout the academic year.

One chapter member received the graduate research grant. The chapter also held a formal induction in the spring to induct seven new members into the chapter. To end the academic year, 10 of the chapter's members attended the APS Convention, where two members presented posters.

University of Michigan-Flint

Throughout the year, the chapter worked to expand connection between officers and members by increasing communication and transparency. The chapter established a blog (http://umflintpsichi.blogspot.com/), increased membership on the chapter's Facebook page, released meeting minutes through email to each member, and created a page on Blackboard so members could conveniently keep tabs on the organization alongside their coursework. The chapter also put into motion a plan to establish a Psi Beta chapter at the local Mott Community College to help students planning to transfer to the university. Volunteering was a primary goal of the chapter, and they helped out at a water station for the Crim Festival of Races, volunteered at Walk for Autism, and members also assisted in a basketball program for autistic children at Grand Blanc Academy. The chapter also created a Take the Stairs campaign, posting signs encouraging people to forgo the elevator in favor of the stairs, in hopes that the simple increase in activity would lead to healthier lifestyles. With regards to psychology students' future plans, the chapter hosted a Graduate School Event where the university's Director of Academic Advising, Aimi Moss, gave a presentation on preparing for and applying to graduate schools in psychology.

Rocky Mountain

Adams State College (CO)

The Adams State College Psi Chi/Psychology Club has participated in many events this year. During the week of homecoming, many different activities take place, such as "chalk the walk," the homecoming parade, and the biggest event, the Medicine Show (a skit that must combine the yearly homecoming theme and our club's academic area). Following homecoming, the chapter volunteered at the local garden and helped pick vegetables, pull weeds, and build an entirely new fence!

Psi Chi/Psychology Club has also participated in fund-raisers throughout

D Fall 2011 inductees from **Marian University (IN).**

E **Marian University (IN)** Psi Chi members Elizabeth Campbell, Ally Higgenbottom, and Sarah McGary after presenting at the Butler Undergraduate Research Conference.

F Psi Chi members of **Eastern Michigan University** at a fund-raising booth for Relay for Life.

G Psi Chi members of **Eastern Michigan University**.

H Psi Chi members of **University of Mary Washington (VA)** with President Hurley, the university's president.

the year to help members attend the RMPA. This year, the chapter was able to send six people, four of whom were granted Psi Chi money to help pay for transportation to the event. Two members presented original research. As an academic event, the chapter recently hosted a faculty lecture. Dr. Nate Pipitone, new faculty at Adams State, spoke about evolutionary psychology and the human voice.

Southeast

Davidson College (NC)

This spring, members volunteered at the Mooresville Christian Mission, sorting clothes and nonperishable food and drink items to be made available to local individuals in need. At the spring induction ceremony, eight new members were welcomed into Psi Chi. Also at the ceremony, four new officers were inducted for the 2012–13 academic year. At the Senior Psychology Major Banquet, four Psi Chi members were among those honored. Katherine Ness received the Sigma Xi Award for the highest quality of psychological research. Dan Keller received the Dr. Edward L. Palmer Award for his extraordinary service to the psychology department and the larger community. And finally, Nadia Brashier and Jen Green were corecipients of the Dr. William Gatewood Workman Award for highest excellence and achievement in psychology.

The University of Alabama in Huntsville

The chapter hosted two LifeSouth Blood Drives on campus in the fall and spring semesters. The chapter sponsored a trunk for the community-wide Trunk or Treat Festival, on October 26, where the chapter won second place for the best decorations. The chapter also volunteered at the WAFF-48 Can-a-thon in December, helping collect and box cans of food, and volunteered at the Walk for Autism in April. Psi Chi members also served as moderators at the Alabama Gerontological Society Conference in Huntsville, April 11–13, 2012, which offered both volunteer and educational opportunities to the students by giving them exposure to careers in aging. The chapter hosted three other educational events this year. The first was a GRE Preparation Tutorial given last fall by the university's assistant professor of psychology, Dr. Marita O'Brien. This spring, Dr. Eric Seemann (assosciate professor of psychology) gave a talk on how to apply to graduate programs in psychology. Psi Chi members also facilitated discussion at the movie night of *The Soloist* to raise introductory psychology students' awareness of psychological disorders. The chapter held a coffee and doughnut fund-raiser on campus in February. Chapter members also had fun participating in the Psi Chi/Psychology Club bowling nights in the fall and spring. The year concluded with the annual induction ceremony on April 25, during which new officers and 10 new members were inducted.

University of Louisville (KY)

Under the direction of Dr. Melinda Leonard (faculty advisor) and Samantha Yung (president), the chapter received the 2012 Southeastern Regional Chapter Award.

The chapter inducted 25 new members at the annual induction ceremony on February 25. Dr. Jay Irby, Department of Psychological and Brain Sciences, was the keynote speaker.

The chapter also hosted a morning GRE workshop (Kaplan conducted),

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followed by lunch, and a practice exam on March 3. Registration was open to all post-baccalaureate, and current graduate and undergraduate students. The first annual spring event was attended by 24 students.

University of Mary Washington (VA)

To focus their efforts on connecting with the community, the chapter participated in the Spring Forward Festival, a school-run event that has Easter crafts for parents and children of the community to do together. Psi Chi members also worked on selling the Psi Chi Powercard, a discount card for local businesses. To further publicize the card, university President Hurley bought one! In addition, the chapter held its 27th annual research symposium where psychology students share their research with one another, friends, and professors. The chapter also held its annual potluck where members, psychology department faculty, and their families can socialize with one another while enjoying delicious food. The chapter later selected Bragg Hill Family Life Center, a local organization that provides different afterschool activities for children and their families, to receive a donation of one hundred dollars. Finally, the chapter elected new officers for the 2012–13 school year.

West Virginia University

The chapter was thrilled to receive the Psi Chi/Ruth Hubbard Cousins Chapter Award for 2012! The chapter's award was featured on the university's website and in an article in the city newspaper.

The formal spring initiation ceremony was conducted with the Department of Psychology's awards event. New faculty member Natalie Shook, PhD, was the keynote speaker, addressing the chapter on a topic highly relevant to college students, "Roommate Relationships: The Good, the Bad, and the Uniting."

Throughout the semester, weekly pizza sales were held to fund scholarships for members and to financially support buying food to prepare and serve meals on a monthly basis at the West Virginia Grief Center.

The chapter contributed to the department's recycling efforts by collecting printer toner cartridges throughout the year and then donating them to the local Ronald McDonald House. A new student and faculty bowling event was added and the chapter hosted the Senior Send-Off Dinner for graduating seniors and incoming chapter officers and committee chairs. With faculty-undergraduate student teams of two, the annual pool tournament was held this term. The winners were Steve Kinsey, PhD, assistant professor in the Department of Psychology, and Anthony Arthur, committee chair for the chapter's Holding Every Life Precious (HELP) suicide prevention and mental health awareness program; their names are engraved on a permanent trophy displayed in our Department of Psychology.

Southwest

Cameron University (OK)

On April 19, 2012, the chapter was awarded status as a Four Star Organization. The Star rating system is used by Cameron University to denote organizations that are active on campus and meet a number of other specific criteria (fund-raising, involvement with student government, etc). The highest rating is five stars. The chapter was able

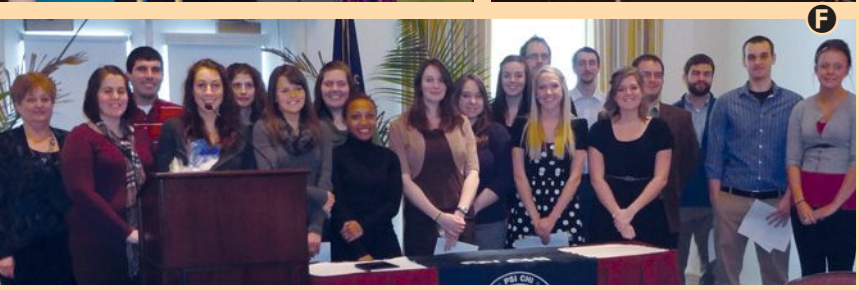

A University of Alabama in Huntsville Psi Chi member Tiffany Sledge at the Trunk or Treat Festival.

B Friends University (KS) Chapter of Psi Chi spring induction ceremony.

C University of Louisville (KY) Melinda Leonard (faculty advisor) and Samantha Yung (president) with the 2012 Southeastern Regional Chapter Award.

D Psi Chi President Susan Amato-Henderson with **Michigan Technological University** Psi Chi members.

E Michigan Technological University Psi Chi members with bobo doll.

F University of Louisville (KY) induction ceremony.

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to go from an inactive organization to a Four Star organization in one year!

Additionally, Dr. Jenel Cavazos was awarded the Faculty Advisor of the Year award for her work as the chapter's advisor. This award is university wide and must be nominated and voted on by the students themselves. She was honored to receive the award and is extremely proud of all the members of the chapter for their dedication and hard work this past year.

LeTourneau University (TX)

The 4th Annual East Texas Psi Chi Student Research Conference was held on the campus of the University of Texas at Tyler on April 28, 2012. The conference allows undergraduate and graduate students from East Texas universities to come together and learn more about research in psychology. The final project submissions of four members, Emily Aitken (president), Anna Crawford (vice-president), Ricky Farris, and Sydni James (president-elect), were accepted for Statistics and Research Methods II.

The keynote speaker for the conference was Dr. Nadja Schreiber Compo (assistant professor at Florida International University) who gave a talk entitled, "Legal Psychology and Investigative Interviewing: Research on Intoxicated Witnesses."

There were morning and afternoon student presentations, as well as a competition in which Awards of Merit were given for the best spoken presentation and the best poster presentation. For the third year in a row, the chapter members won Awards of Merit for the poster presentation competition. Anna Crawford won for her poster entitled, "The Effects of Synesthesia and Self-Esteem," and Emily Aitken won for her poster entitled, "The Effects of Religious Affiliation on Attitudes Toward Psychotherapy." The students were accompanied by Dr. Vicki Sheafer, faculty advisor and chair of the psychology department.

Southeastern Louisiana University

On March 24, the chapter participated in Rock N' Roar Fest. Rock N' Roar Fest is an event the university hosts for over 2,000 high school students from surrounding communities in attendance for the literary rally. The students were provided with food and entertainment. The chapter set up a booth that entertained the students with inversion goggles and a realistic brain.

In April, Dr. Paula Varnado-Sullivan (graduate coordinator for the psychology department) gave a guest lecture at the chapter meeting entitled "How to Get Into Grad School."

Throughout the semester, members were asked to collect soda can tabs to donate to St. Jude's Hospital for "Pop It for a Cure." The chapter was able to donate a substantial amount of tabs toward assisting those in need of cancer treatment.

In May, guest speaker, Dr. Sara Sohr-Preston (psychology professor), spoke about developmental psychology. The chapter also held a raffle and a psychology T-shirt sale to raise money for induction.

During the last week of classes, induction was held at Jacmel Inn Restaurant in Hammond, Louisiana. The chapter inducted 12 new members and installed new officers for the next school year. Also, the chapter awarded the spring 2012 Outstanding Member Award to Jamie Corkern.

Ⓐ Psi Chi members (left to right) Ashley Freitas, Jeremy Connolly, Keshawn Johnson, and Anna Ellis smile for a photo while working **Southeastern Louisiana University's** Rock N' Roar Fest.

Ⓑ **Southeastern Louisiana University's** Dr. Varnado-Sullivan (faculty advisor) awards member Jamie Corkern, Outstanding Member at the spring semester induction.

Ⓒ **Fielding Graduate University (CA)** Psi Chi members at Saint Elizabeth's Hospital, a public psychiatry facility for those with serious and persistent mental illness.

Ⓓ A student uses the inversion googles and attempts hop-scotch at the **Southeastern Louisiana University** Rock N' Roar Fest.

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West

Fielding Graduate University (CA)

At the chapter's Summer Session 2012 in Alexandria, Virginia, the chapter members held their second annual service drive for Saint Elizabeth's Hospital, the District of Columbia's public psychiatric facility for individuals with serious and persistent mental illness who need intensive inpatient care to support their recovery. The donations focused on CDs and DVDs to be used for music therapy, dance therapy, and recreation therapy. Cash donations were also accepted to support these services as well. This year was a huge success as they collected even more donations than the previous year. In addition, members were then graciously invited to participate in a private tour of the Saint Elizabeth's facility. Throughout the tour, members were educated on the therapeutic learning centers that offer individuals receiving care with recreational, educational, and therapeutic opportunities to improve their well-being, strengthen their social skills, and allow them to connect with the community. Members also learned about the rich history of the facility, as it once was the nation's first federal psychiatric institution dating back to 1852. The members who were eligible to participate received an invaluable experience that enhanced their own knowledge of the world of psychology while giving back to the community.

Portland State University (OR)

The chapter established a donation-based library of psychology textbooks and GRE study materials to loan these items to students who would normally have trouble affording them on their own. The chapter also reached out to the community with The Road Back Home, a grass roots initiative that seeks to provide Portland's many homeless with resources and information that may help them get back on their feet.

In order to get students on campus thinking critically and seriously about the discipline of psychology, the chapter also hosted a DSM-V discussion panel, which encouraged participants to voice comments and concerns regarding the upcoming edition of the DSM, as well as to submit a series of suggestions and critiques to the DSM-V committee.

Finally, the chapter, in conjunction with members of the Moving to the Beat Project, organized a conference to promote the curriculum and documentary developed from the endeavor. Moving to the Beat was a project developed to bring awareness to how hip-hop music is being used to express political and cultural identities in Sierra Leone.

Whittier College (CA)

The chapter hosted a wide range of social and academic events during 2011–12. Some highlights included a barbecue at the faculty advisor's beach house, movie nights, a grad school panel, and a student achievement lunch at which students presented information about recent research and internship experiences. Additionally, the chapter inducted 26 new members on March 21, 2012; six undergraduates presented research with faculty members at professional conferences; and 28 undergraduate students from Whittier and 11other local colleges presented their own research at the 11th annual Psi Chi Whittier Undergraduate Research Conference, which was hosted by the chapter on April 21, 2012.

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The Little Train That Could

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More than seventy years ago an organization began, which from its start had an uncertain future. In 1941 it was founded in New York City as the National Council of Woman Psychologists, and was supposed to be dissolved once World War II ended (Gielen, Adler, & Milgram, 1992). According to Ann Marie O'Roark, immediate Past President of the International Council of Psychologists, Inc. (ICP) and superb historian, it was started to give more of a voice to women psychologists, who at that time were excluded from a male-only APA committee, "Emergency Committee in Psychology." The Council was continued post-wartime to broaden the scope of psychology by providing opportunities for fledging psychologists around the world. Intentionally establishing an evermore inclusive membership, three name changes later, it became the ICP that we know today, at www.icpweb.org/.

Almost every issue of the *International Psychology Bulletin* contains either pictures or articles about joint members of Division 52 and ICP, but it is beneficial to recount ICP's purpose and inclusiveness. Over the last few years, as psychology became globalized, ICP bylaws have reflected our universal educational and mentoring capacities, while at the same time our membership has been strengthened by including allied disciplines. Over the past decade, membership in ICP has continued to decline from 1,600 to 125 today. Recruitment and marketing are constant concerns as we move forward into the future.

In 2011, ICP President-Elect Tara Pir and I conducted a joint activity in Los Angeles for ICP, APA Division 52 members, and the Western Psychological Association. Tara received a well-deserved fellowship award from Division 52.

ICP continues to be a beacon of nourishment to mental health practitioners and an "incubator" for graduate students, as well as for early and late career psychologists as we celebrate our 70th annual convention in Seville, Spain September 11-13, 2012. Award recipients include in absentia graduate students and seasoned advanced researchers like Charles D. Spielberger and Elisa Margoana, both past presidents of ICP, Inc. Sixty-nine previous conventions have been held around the world, in Asia, Europe, South America, and the USA.

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How Psychology Instructors Internationalize Their Courses: Strategies, Perspectives, and Implications

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Abstract

Many instructors emphasize the importance of international knowledge and understanding in their students. For this reason, an increasing number of instructors have started to incorporate international content in their psychology courses. The present study looked at the strategies and methods used by instructors who have already internationalized their courses. Responses to a survey distributed by the Curriculum and Training Committee of the APA Division of International Psychology (52) were monitored in an attempt to provide strategies for instructors who may be looking to internationalize a course. Most of the respondents had internationalized at least one psychology course at the time of the survey. The strategies that were most frequently used by respondents fit into the categories of student assignments, lectures, classroom activities, and Internet-based technologies. Differences were also found in faculty ranking and number of international activities participated in by instructors.

"What students lack most, in my view, is an understanding of the living system that is psychology. We teach students the methodology and content of the discipline, but we rarely teach them its inherent diversity, versatility, and capacity for change" (Hogan, 1996, p. 45). Hogan is expressing that students are given all of the tools they need to practice psychology, but they are usually not aware of alternative ways that psychology is practiced or how it varies as a field

from place to place. Hogan made this statement in 1996, over ten years ago, but the effort to internationalize the curriculum of psychology has been very gradual. A desire to prepare students for practice, research, and service in the 21st century in order to competently contribute to understanding and intervene in global problems has caused a growing number of psychologists to call for the internationalization of the psychology curriculum. There is a growing need for effective teaching strategies to better incorporate international perspectives into psychology courses.

In the past, there has been a focus on learning about cross-cultural perspectives. Psychology from a cross-cultural perspective involves teaching students about similarities and differences between different cultures, learning about the values of other cultures, confronting biases, and challenging assumptions. Recently, there has been a shift from the study of cross-cultural psychology to international psychology (Gerstein, 2007).

International psychology has several qualities that differentiate it from a traditional approach in that it examines the impact of evolving contexts on human behavior (Velayo, 2005). It recognizes the contributions of scholarly articles written in languages other than English (Adair, Coelho, & Luna, 2002). International psychologists attend international conferences to gain a broader perspective and to learn how to integrate international material into traditional understandings of psychology (Gerstein, 2007).

Psychology faculty members strive to incorporate international content into the curriculum to increase students' global competence. Students benefit greatly from an increased knowledge base, as well as the skill and motivation to look for international content on his or her own (Yeshova, DeJaeghere, & Mesterhauser, 2000). The APA Task Force on Internationalizing the Undergraduate Psychology Curriculum (2005) has outlined five main internationalizing goals for psychology courses. These goals include gaining psychological knowledge in an international perspective, being aware of methodological issues in conducting international research, an awareness of the discipline of psychology in an international perspective, an awareness of global issues as they pertain to psychology, and finally, the ability to use psychological knowledge to gain interpersonal understanding.

International content can be infused into a psychology course through lectures, classroom activities, writing assignments, and the use of technology.

Lectures

Lectures are important for integrating international content into psychology courses in many ways. First, lectures serve to inform the students. If the instructor infuses international content into a lecture, the student will be able to learn about cultural, ethnic, and international variations in psychology. In a class on abnormal psychology, for example, students may learn about disorders that are bound to certain cultures, or the implications of world citizenship in terms of the treatment of psychopathology (Marsella & Pederson, 2004).

Bartolini, Gharib, and Phillips (2009) give examples of attempts to internationalize the curriculum of a Psychology of Learning course as well as a course on Abnormal Psychology. A key aspect of their attempt involves outlining student-learning outcomes (SLOs) at the beginning of the course that indicate what the student should be able to take away from the course when it is finished. It sets the goals for what is to be achieved through the course. Incorporating SLOs in the syllabus that indicate international concepts to be learned alerts the students to their importance.

For their course in "Learning," Bartolini, Gharib, and Phillips (2009) incorporated an SLO that stated, "Students shall demonstrate an understanding of how principles of learning shall be applied in the international area to solve real world problems" (p. 186). The aim in developing this SLO was to add a real-world application component to the student understanding of international perspectives. Students would be able to use knowledge acquired in the course to apply potential solutions to real problems throughout the world.

For the "Abnormal Psychology" course, a student learning outcome (SLO) was added, "Students will be able to demonstrate how one mental illness is diagnosed, assessed, and treated globally" (Bartolini, Gharib, & Phillips, 2009, p. 185). Their aim is to establish an eclectic way of thinking about mental illness. It allows students to realize that certain methods of treatment are more or less appropriate depending on the context or country of the person who has the illness.

These two examples show a starting point for introducing international content and perspectives into a course. The lecture is a key component in making sure the SLOs that instructors set can be achieved. The lecture serves as an example for the student. Students are able to see how international content is infused and why this is important; this opens the student up to the idea of looking at issues from an international perspective. For example, for their "Learning" course, Bartolini, Gharib and Phillips (2009) suggested that instructors provide examples throughout the course of different culturally specific behavioral modification methods as well as reinforcers and punishments. The lectures should serve as a model students can follow. If students hear lectures that model topics from an international perspective, they may automatically begin to think from a broader perspective when they are working independently.

Classroom Activities

Gurung and Prieto (2009) suggest that a relatively untapped resource in internationalizing the psychology curriculum is the student. At this point in time, universities are seeking and admitting more international students than ever before. There have also been increased opportunities for students to travel, including work and study abroad. International students and those who have traveled abroad are becoming increasingly valuable assets in the classroom (Ho, Bulman-Fleming, & Mitchell, 2002).

Using the student as a resource can be accomplished in many ways. Possibly the most obvious way to do this would be to engage the class in group discussion (Ho, Bulman-

Fleming, & Mitchell, 2002). The role of the instructor is as facilitator, guiding the discussion in the desired direction. The students are then encouraged to take responsibility for their own learning. Students can gain international understanding by listening to one another's experiences, history, and background.

One way to engage students in class discussion pertaining to international content would be to assign oral presentations. A 2002 study by Hull found that when introducing international content, students were able to retain information for a longer period of time when they completed an assignment, such as an oral presentation. Oral presentations, followed by question and answer sessions, coupled with the valuable student resources that are already in the classroom, can lead to meaningful and informative discussion of international content.

Guest lecturers could be a way to infuse international content into a course. What is unique about this topic is that anyone can be an expert on his or her own country or culture. This makes guest lecturers easier to find. Again, students can be looked upon as resources (Ho, Bulman-Fleming, & Mitchell, 2002).

Marsella and Pedersen (2004) suggest that an important part of introducing international content into a course is first knowing one's own culture. We must know who we really are before we can fully begin to understand others. A class activity such as an auto-ethnography of one's own culture might be a beneficial way to begin a course. Students can share their results with one another, thus learning more about each other while learning about themselves at the same time.

Writing Assignments

According to Bartolini, Gharib, and Phillips, the writing assignment can be used as a form of assessment. This is where the instructor can determine if the SLOs outlined in the syllabus were achieved (Bartolini, Gharib, & Phillips, 2009). In their "Learning" course, SLOs were assessed through a paper assignment in which each student was assigned to a social or health problem that is specific to a culture or geographic region. Students were then asked to determine the behavioral modification methods that would be used to treat this problem. The behavioral modification methods suggested by the student were to be appropriate for the culture or region that they were dealing with (Bartolini, Gharib, & Phillips, 2009). Writing assignments are important because at this point in the course, students have been given all of the tools that they need to think about a problem from an international perspective. What they ultimately produce for the assignment demonstrates what they have learned and their ability for independent thought when infusing international perspectives and practices.

Bartolini, Gharib, and Phillips (2009) also give an example of writing assessments that would be used to assess learning in their "Abnormal Psychology" course. For this course, the writing assignment challenged students to look at a specific mental illness and find out how it is written about in other countries. This is a useful exercise because it involves students looking at international journals, and helps students to realize that disorders are not conceptualized the same way in every country or culture. The second part of the assignment was to focus in on one country and look at the prevalence rate of the specific mental illness, as well as how it would be diagnosed and treated in that country. This aspect of the assignment challenges students to think about disorders that they have previously learned about in a different way. They come to realize that what they learn in the U.S. is not the only way. Prevalence rates, diagnoses, treatments, etc., vary depending on geographic region and culture.

Hull (2001) suggested that writing assignments are beneficial when incorporating international content because completing a writing assignment helps the students to retain the information that they have learned for longer periods of time. In this sense, the SLO outlines the goals of incorporating international content, the lecture provides the examples and the tools that are necessary for thinking from an international perspective, and the writing assignment serves as a form of assessment of what has been accomplished throughout the course and helps to reinforce the information that was learned for longer retention.

Internet-Based Technologies

Internet-based technologies are becoming increasingly popular for incorporating international content into the psychology curriculum. Guerin believes that one possible reason for this is that it is cost-effective (Guerin, 2009). Not all students can afford to travel or study abroad. This becomes especially true for the community college or graduate student who may have family and work obligations in addition to financial limitations (Guerin, 2009). The Internet is able to provide the student with interaction with people from other cultures and countries, journal articles written by individuals from diverse backgrounds, and countless opportunities for cross-cultural collaboration without having to leave the country.

One way that Internet-based technologies can serve to incorporate international content is through the sharing of material. It is becoming increasingly easy to share material with peers or colleagues and work collaboratively. Many instructors are already participating in lecture exchange (Longview Foundation for Education in World Affairs and International Understanding, Inc., http://www.longview.fdn.org). Instructors can use social networks to share their lectures with global educators. Instructors can also implement other interactive technologies such as videoconferencing (e.g., Skype), and perhaps instructors from two different countries could lecture together, allowing students to participate in discussions with peers from other countries.

Another way that Internet-based technologies can serve to incorporate international content is as a supplement to textbooks. Many textbooks that are used for courses in psychology today do not have sections on international content, and if they do, it is usually limited. Articles from international journals help to supplement these texts and provide more diverse perspectives on topics and issues.

Present Study

The present study investigated methods employed by psychology instructors at the graduate and undergraduate level used to internationalize psychology courses. In 2009, the Curriculum and Training Committee of the American Psychological Association's Division 52 developed and administered an online survey, which was published in the *International Psychology Bulletin* (Grenwald & Velayo, 2011). Results of this study indicated that more than half of the respondents had begun to internationalize their courses. The most common teacher strategies to internationalize courses that were indicated could be categorized into lectures, classroom activities, student assignments, and use of Internet-based technologies. In 2011, a revised online survey was administered which aimed to learn more about the teaching strategies that psychology instructors use to internationalize courses. The goals of instructors in internationalizing their courses were also examined. The importance of classroom activities, writing assignments, lecture, and Internet-based technologies were measured in terms of internationalizing a psychology course. The goal of this study was to determine which methods were used most by instructors and how they were put into use.

Method

Participants

A total of 149 respondents completed an Internet-distributed survey sent by the Curriculum and Training Committee of the International Psychology Division (52), American Psychological Association. Respondents were instructors of psychology courses at the graduate and undergraduate level. Responses were received from instructors from a variety of geographic regions, including Asia (n = 8), Europe (n = 7), Latin America and the Caribbean (n = 9), North America (n = 124) and Oceania (n = 1). Respondents also differed in faculty ranking with the largest number being full professors (n = 48), then associate professors (n = 29), adjunct professors (n = 25), assistant professors (n = 22), and other (n = 24). Institutional affiliations included comprehensive (n = 40), research (n = 30), liberal arts (n = 28), community college (n = 21), and other (n = 27).

Materials and Procedure

An online survey called "Survey to Internationalize the Psychology Curriculum 2" was developed and administered in the spring of 2010. This survey was a revised and extended version from the original version (see Grenwald & Velayo, 2011) in that respondents were asked to rate the level of importance of certain strategies (lectures, classroom activities, student assignments, and Internet-based technologies) identified as having been used to internationalize courses, based on the courses they teach. The survey was sent to members of Division 52 and select nonmembers who were identified as potentially implementing ways to internationalize course(s) that they teach.

An Internet-distributed survey was sent by the Curriculum and Training Committee of the International Psychology Division (52), American Psychological Association. The weblink to the online survey was announced to various APA divisions through listservs and e-mails. The survey was based on and designed as a follow-up to a previous online survey administered in 2009 and completed in 2010 (Grenwald & Velayo, 2011). This survey was a revised and extended version from the original version (see Grenwald & Velayo, 2011) in which respondents were asked to share information on how they have tried as well as strategies that they may have used to internationalize course(s) they teach. Findings from the original survey indicated that more than half of the respondents had begun to internationalize their courses, and that their strategies for internationalizing their courses were categorized into lectures, classroom activities, student assignments, and the use of Internet-based technologies. The revised survey consisted of 46 questions. Demographic information was taken such as institution, institution type, faculty rank, number of international organizations that the respondent participates in, number of courses revised to include an international perspective, number of courses the respondent would like to revise to include an international perspective, international activities that the respondent has participated in, the effort made by the institution to internationalize the curriculum, and the effort made by the department to internationalize the psychology curriculum.

Results

Many respondents indicated that they had revised their course to include an international perspective. The percentage of participants who had not revised any courses to include an international perspective was 23.5%, while 26.8% had revised at least one course, 24.2% had revised two, 11.4% had revised three, and 14.1% had revised four or more.

In terms of international activities that respondents had participated in, frequency tests indicated that the activities with the highest participation were international research (53.7%), internationalizing courses (51.7%), and international campus activities (51.7%). Respondents also participated in teacher exchange programs (23.5%), leading study abroad trips (16.8%), and international service learning (10.7%).

Respondents were asked to indicate their goals for psychology students with regard to internationalism. The goals were coded based on the goals and learning outcomes from a report by the APA Task Force Report (Lutsky et al., 2005). The goal that was most frequently stated was to gain psychological knowledge in an international perspective (30.2%). Many respondents indicated multiple goals for their students (20.8%), while others had goals such as gaining knowledge of psychology as it related to interpersonal understanding (10.1%), knowledge of psychology as it related to global issues (6.7%), knowledge of methodological issues in international research (6%), and understanding of the discipline of psychology in the international perspective (6%).

Most respondents indicated that they infused international content throughout the course (69.1%) as opposed to incorporating content in a module format (18.1%). Courses were

internationalized in a variety of different ways, including content (71.1%), student assignments (49.7%), Internet-based technologies (24.8%), pedagogy (22.8%), and methodology (18.1%).

Respondents recommended useful resources that could be helpful for psychology faculty who wish to internationalize a similar course, including technology-based resources (10.1%), text-based resources (6%), and experiential resources (3.4%). Ten point one percent recommended multiple resources.

Instructors rated lecture strategies relatively high in importance on a 4-point scale when internationalizing their courses. Among these strategies, using cultural examples ($M = 3.64$, $SD = .55$), taking a comparative approach ($M = 3.10$, $SD = .97$), international case studies ($M = 3.10$, $SD = .97$), and using personal examples ($M = 3.06$, $SD = .73$) were rated the highest. Instructors also indicated the importance of using, international data sets ($M = 2.85$, $SD = .99$), anthropology sources ($M = 2.68$, $SD = .89$), and international films ($M = 2.39$, $SD = 1.03$) when internationalizing their courses.

Instructors also rated student assignments as being important when internationalizing their courses. The strategies with the highest ratings of importance were research by non-U.S. psychologists ($M = 3.44$, $SD = .76$), readings in "international psychology" ($M = 3.04$, $SD = .99$), papers on psychology in other countries ($M = 3.03$, $SD = .89$), readings from other disciplines ($M = 2.84$, $SD = .98$), and interviewing someone from another culture ($M = 2.81$, $SD = 1.03$). These strategies were followed by investigating international organizations ($M = 2.73$, $SD = 1.01$) and projects with students in other countries ($M = 2.46$, $SD = 1.04$).

Using Internet-based technologies was rated relatively low in importance for internationalizing courses. Media sharing had the highest rating ($M = 2.25$, $SD = 1.36$), followed by wikis ($M = 1.82$, $SD = 1.17$), social networks ($M = 1.81$, $SD = 1.12$), blogs ($M = 1.79$, $SD = 1.16$), social bookmarking ($M = 1.63$, $SD = 1.10$), and virtual worlds ($M = 1.40$, $SD = 1.09$).

The average importance of lecture in internationalizing psychology courses was positively correlated with the average importance of classroom activities in internationalizing the courses, $r = .78$, $p < .05$. There was also a positive correlation between the average importance of lecture in internationalizing the course and the average importance of student assignments, $r = .77$, $p < .05$.

The effect of faculty rank on the total number of international activities participated in was analyzed using a one-way analysis of variance. The ANOVA revealed that the different faculty rankings differed significantly in the number of international activities that they had participated in $F(4, 143) = 5.20$, $p < .05$. More specifically, Scheffe's posthoc tests indicated that full professors had participated in significantly more international activities as compared to assistant professors.

Respondents were asked to explain what it means to be a "global citizen" in the context of an internationalized psychology curriculum. Findings indicated that 27.5% of participants did not give a response or were not sure of the answer to the question, while 22.1% of the respondents believed that "global citizenship" related to psychological knowledge in an international perspective, 8.7% made reference to psychology as it relates to interpersonal understanding, 8.1% stated that it relates to knowledge of the discipline of psychology in the international perspective, 6% defined it as knowledge of psychology as it relates to global issues, and 1.3% defined it in terms of knowledge of methodological issues in international research.

Discussion

Essentially, this present survey complements and provides greater insight into the findings from the original survey by Grenwald and Velayo (2011). Psychology instructors of various ranks from various institutions and geographic regions are exploring and perhaps fine-tuning their use of instructional strategies to help internationalize their courses. Most of the respondents in this study indicated that they had internationalized at least one psychology course. Among the most important strategies for internationalizing courses indicated were student-based assignments such as research by non-U.S. psychologists and readings in "international psychology", lecture strategies such as using cultural and personal examples, and classroom activity strategies such as discussions with an international focus. These findings would seem to make sense as classroom discussion serves as a great way to delve into sensitive and unfamiliar topics.

Instructors most frequently stated that their goal in internationalizing their courses was for their students to gain psychological knowledge in an international perspective. International content was most often infused throughout the course as opposed to introducing it in a module format. The most common method employed by instructors in internationalizing their courses was to use student assignments. Examples of specific student assignments used included research projects using international journals and informants and projects which encourage students to further explore their ethnic roots. Surprisingly, the use of Internet-based technology and social media strategies were rated relatively low in importance for internationalizing courses. This finding was unexpected. However, it would seem to make sense, as use of these strategies in the classroom is somewhat new in general. It is possible that instructors are still learning how to incorporate these strategies into their courses and as a result, they are not yet crucial strategies employed for incorporating international content. Another interesting though unanticipated finding is that full professors participated in the greatest number of international activities compared to other faculty ranks. It is possible that full professors in the sample have had more opportunities to participate in international activities.

Strategies identified as most effective for incorporating international content included student assignments, choosing textbooks that are internationalized or contain international content, and supplementing class materials with articles published in international journals. Further recommendations for instructors may include creating a portal for sharing materials and ideas on internationalizing courses. With such a portal,

faculty could share syllabi and innovative ideas for student assignments. Another recommendation would to derive and assess student feedback about their learning experiences. Students could be a valuable source in designing and implementing new strategies.

A limitation of this study is that the survey used was distributed by Division 52 of the American Psychological Association. Since this is the international psychology division, it is possible that the respondents were more likely to have an interest in international issues, thus making it more likely that they would have internationalized a course than the general population of instructors. It may be beneficial in the future to send the survey to a selected sample of psychology departments or schools throughout the world.

The majority of respondents in this study had only taught courses in the United States. Future studies may speak to the differences of methods employed between U.S. instructors and instructors in other countries. In addition to looking at differences, surveying instructors from a variety of institutions may be helpful in acquiring new and innovative methods to internationalize psychology courses.

Further recommendations for future research involve student input. Getting student feedback can be an effective way to research the internationalization of the psychology curriculum. As suggested by Ho, Bulman-Fleming, and Mitchell (2002), the student can be considered a valuable resource within the classroom. It would be beneficial to get student feedback on which methods of internationalizing the curriculum work best for them. Possible questions to consider would be: Do students prefer lectures that incorporate an international component? What types of assignments do students find to be the most effective? What can the instructor do to gain student interest? What can the instructor do to increase student involvement in meaningful discussions regarding international content and issues? This can be accomplished through surveying students who have recently completed a course with an international component. A possible strategy might be to use the American Psychological Association's student outcomes survey from the task force on internationalizing the undergraduate curriculum (Appendix B).

Another strategy would be conducting experiments of student learning outcomes based on courses they have taken with international content. This could be accomplished through studies similar to Hull's 2001 study which illustrated that students are able to retain information for longer periods of time when completing a writing assignment on the international content that they were intended to learn. Studies could test a variety of methods for learning international content on students to see which are the most effective.

Conclusion

There is a growing need to prepare students for practice, research, and service in the 21st century to competently contribute to understanding and intervening in global problems. For this reason, a growing number of psychologists in the U.S. have called for the internationalization of the psychology curriculum. There is a need for effective teaching strategies to better incorporate international perspectives into psychology courses. This study found that many instructors of various ranks from various types of institutions have already incorporated international content into their courses, and are further exploring and perhaps fine-tuning different instructional strategies in doing so. Most frequently, instructors have indicated using student assignments and class discussion with an international focus as their main strategies. It may be important to further assess how these specific strategies can be implemented and measure their success with student feedback.

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Submission Guidelines for
Research Articles
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Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.

Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

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For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

Submission Deadlines: Spring issue March 31st

Summer issue July 31st

Fall issue September 15th

Winter issue December 15th

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Presidential Column

John D. Hogan, PhD
President, Division 52

Greetings to everyone. I'm pleased to report that we had a very productive mid-winter meeting in Cambridge, MA, from March 10-12, in conjunction with the annual meeting of the Eastern Psychological Association (EPA). Thanks to Harold Takooshian and others, we've built a strong relationship with EPA over the years. We even shared a coffee break with their Executive Board during our own Board meeting. We are particularly grateful to Fred Bonato, the EPA Executive Officer, and Diane Finley, the Chair of the EPA Program Committee, for their hospitality.

The lead EPA speaker this year was Elizabeth Loftus who presented an enthralling opening address as she reviewed her research on "manufacturing memories" to a crowded ballroom. Of course, our Division had its own two-days of well-attended programming blended into the larger convention. Among the programs we presented were sessions on international publishing opportunities, the United Nations, internationalizing the psychology curriculum, disaster relief, and psychology in Russia today. We continue to develop a relationship with Psi Chi, the (now) International Honor Society in Psychology. We even shared a session with them in which we addressed issues related to becoming an international society.

The Div. 52 Board meeting was held on Thursday afternoon from 12 noon to 5pm. Our Board meetings always remind me of what an active and wide-ranging division we are. I've listed a few of the highlights of the meeting in the following paragraphs.

Early in the meeting we learned that our financial health is strong, thanks in large part to the excellent treasurers we have had through the years. The term of Michael Stevens, our current treasurer (and past-president), will end this year and he has decided not to seek another term. We owe him an enormous debt for the service he has given to the division. His will be a hard act to follow.

After finances, we discussed another priority – membership – an important issue that is not confined to our division. The membership of APA is aging and, although we have received some mixed messages, it is clear that the organization is not enrolling new and younger members at the level it thinks it should. We believe our division has a great deal to offer students and ECPs (Early Career Psychologists) and we are determined to become more proactive in welcoming them to the division.

Division President-elect Neal Rubin made several proposals to address our membership concerns. Among them, he proposed two changes to the bylaws. The first proposal is that we establish a position for a student representative on our Board, with voting privileges. The second is that we agree to set aside one of our member-at-large board positions for an early career psychologist. Both proposals were accepted unanimously by the Board and will be presented to the membership for their vote. (See elsewhere in this issue for further clarification of the proposed change in bylaws.) Our thanks, as always, to Joy Rice, member-at-large and past president, who guided us through the process of clarifying the bylaws and arranging the vote from the membership.

The Board agreed to rename our international mentoring award in honor of Henry David, one of the founding members of the Division. Henry, who died on December 31, 2009, at age 86, is best known for his international contributions to population issues, women's issues, and mental health. A warm and gentle man, he received a number of honors from APA in the past including the APA Award for Distinguished Contributions in the International Advancement of Psychology (1992) and the APF Gold Medal Award for Life Achievement in Psychology in the Public Interest (2001). We are so grateful that Henry was part of our lives and the life of our Division. We're pleased to honor him in this small way.

Our program for the APA Convention in Washington, DC (August 4-7, 2011), looks strong, thanks to our program chairs, Senel Poyrazli and Mark Terjesen. They reported that we received 25 paper submissions, 92 poster submissions, and 22 symposia for the Convention. Because of the limited number of program hours allotted to us, many of the submissions had to be rejected. Fortunately, some of the papers could be turned into posters and were accepted on that basis. We will be hosting a suite at the convention again this year and we will be able to use it for some additional programming. But I hope that many of you will make use of it for purely social purposes as well, and come by for a visit during the convention.

As always, I welcome any comments and/or concerns you might have regarding the Division. You can reach me at hoganjohn@aol.com I hope to see you in Washington in August!

Best wishes, John

John D. Hogan, PhD
Professor, Dept. of Psychology
St. John's University
Queens, NY 11439

International Programs @ WPA 2011
At a Glance!

	Thursday April 28, 2011	Friday April 29, 2011	Saturday April 30, 2011	Saturday April 30, 2011 *Concurrent Programs
8:00-8:15		Symposia (Westwood Rm): ***Global Disasters and Trauma: Preparation, Coping, and Psychosocial Responses*** Chair: Roxane Cohen Silver, University of California, Irvine Discussant: E. Alison Holman	Symposia (Fernwood Rm): ***International Immersion Learning Experiences in Higher Education: Program Outcomes and Recommendations*** Chair: Lynette H. Bikos, Seattle Pacific University Discussant: M.C. Gilberto Manuel Galindo, Universidad Autónoma de Baja California	
8:15-8:30				
8:30-8:45				
8:45-9:00				
9:00-9:15				Invited Presentation (Golden State Rm): ***Intimate Partner Violence: A Global Mental Health Priority*** Gaithri Fernando, California State University, Los Angeles
9:15-9:30				
9:30-9:45				
9:45-10:00		Symposia (Westwood Rm): ***Four Research Reports from a Summer Research Training Program on Latino Mental Health in Puebla, Mexico*** Chair: Steven R. Lopez, University of Southern California		
10:00-10:15				
10:15-10:30				
10:30-10:45				Invited Presentation (Golden State Rm): ***Making Culture Usable for a Scientific Social Science by Unweaving its Rainbow.*** Michael Harris Bond, Hong Kong Polytechnic University.
10:45-11:00				
11:00-11:15				
11:15-11:30				
11:30-11:45		Symposia (Westwood Rm): ***Addressing Hawai`i in Theories of Culture, Dating, and Microaggressions.*** Chair & Discussant: Alyson L. Burns-Glover, Pacific University Oregon	Symposia (Fernwood Rm): ***Beyond Borders: Recognizing the Validity of Psychologies Across National Lines*** Chair: Jason J. Platt, CSPP at Alliant International University	
11:45-12:00				
12:00-12:15				
12:15-12:30				
12:30-12:45				
12:45-1:00				
1:00-1:15				

International Programs @ WPA 2011
At a Glance!

	Thursday April 28, 2011	Friday April 29, 2011	Saturday April 30, 2011	Saturday April 30, 2011 *Concurrent Programs
1:15-1:30			Symposia (Fernwood Rm): ***International Perspectives on Positive Psychology*** Chair & Discussant: Douglas C. Smith, Southern Oregon University	
1:30-1:45				
1:45-2:00				
2:00-2:15				E.E. Jones Award Presentation (Rosewood Rm): ***How Do We Culturally Adapt Psychotherapy? Let's Get Down to the Specifics***. Wei-Chin Hwang, Claremont McKenna College & Independent Practice
2:15-2:30				
2:30-2:45				
2:45-3:00		Symposia (Fernwood Rm): ***Challenges in Conducting Cross-Cultural Research: Professional and Student Perspectives*** Chair: Eric L. Kohatsu, California State University, Los Angeles		
3:00-3:15	Symposia (Westwood Rm): ***Threats to Family Wellness in Immigrant Communities: Hopes and Challenges.*** Chair: Marcel Soriano, California State University, Los Angeles		Symposia (Fernwood Rm): ***Mixed Methodologies and Multigroup Structural Equation Modeling in Cultural and Health Research*** Chair: Patricia Flynn, Loma Linda University	
3:15-3:30				
3:30-3:45				Poster Session: International Psychology (Wilshire Rm). 50 posters!
3:45-4:00				
4:00-4:15				
4:15-4:30				
4:30-4:45				
4:45-5:00			Symposia (Fernwood Rm): ***Family Conflict and Sociological Imagination in Mexican Immigrant Families*** Chair: Carrie L. Saetermoe, California State University, Northridge Discussant, Gabriela Chavira	
5:00-5:15				
5:15-5:30				
5:30-5:45				
5:45-6:00				
6:00-6:15				
6:15-6:30				
6:30	**Saturday 6:30pm, lobby:** Interested in socializing with other psychologists/psychology students who are interested in international issues? Please RSVP in advance to Lynette Bikos (lhbikos@spu.edu), or alert one of Saturday's International Programming Hosts so that we can get a count and make reservation at a restaurant that will accommodate all of us.			

International Programming: A Pre-Conference Primer Western Psychological Association Los Angeles, CA April 28 – May 1, 2011

Invited Presentations

Intimate Partner Violence: A Global Mental Health Priority
Presenter: Gaithri Fernando, California State University, Los Angeles
Saturday, 9:00-10:00 Golden State

Making Culture Usable for a Scientific Social Science by Unweaving its Rainbow
Presenter: Michael Harris Bond, Hong Kong Polytechnic University
Saturday, 10:30-11:30 Golden State

How Do We Culturally Adapt Psychotherapy? Let's Get Down to the Specifics
Presenter: Wei-Chin Hwang, Claremont McKenna College & Independent Practice
Saturday, 2:00-3:00 Rosewood

Symposia

Threats to Family Wellness in Immigrant Communities: Hopes and Challenges
Chair: Marcel Soriano, California State University, Los Angeles
Thursday, 3:00-4:30 Westwood

UNDERSTANDING TREATMENT NEEDS OF A TRAUMATIZED POPULATION: POLITICAL ASYLUM SEEKERS, *Audrey Ham (CSU Los Angeles)*

PROMOTING FAMILY WELLNESS IN IMMIGRANT COMMUNITIES: PSYCHOLOGISTS AS CHANGE AGENTS, *George K. Hong (CSU Los Angeles)*

DUAL STATUS LATINO FAMILIES: DETENTION/ DEPORTATION IMPACT ON FAMILY WELLNESS, *Marcel Soriano (CSU Los Angeles)*

GANGS: A THREAT TO THE WELLNESS OF ASIAN AMERICAN FAMILIES, *Stephen Cheung (Azusa Pacific University)*

Global Disasters and Trauma: Preparation, Coping, and Psychosocial Responses
Chair: Roxane Cohen Silver, University of California, Irvine
Discussant: E. Alison Holman
Friday, 8:00-9:30 Westwood

POST-DISASTER OUTCOMES ASSOCIATED WITH THE 2010 CHILEAN EARTHQUAKE, *Dana R. Garfin, Roxane Cohen Silver, (University of California, Irvine), Francisco Ugalde Bilbao & Heiko Linn (Universidad Andrés Bello)*

PREPARATION TYPE MATTERS: IMPLICATIONS FOR TARGETING POPULATIONS FOR PERSONAL PREPAREDNESS FOR NATURAL DISASTERS, *Kristen L Gamble, Roxane C. Silver, Dana Garfin, Scott Blum (University of California, Irvine) & Michael Poulin (University of Buffalo)*

POST TRAUMATIC STRESS AMONG INDONESIAN CHILDREN: THREE YEARS AFTER A MAJOR EARTHQUAKE, *Edwin T. Tan (University of California, Irvine), Conor Seyle (Psychology Beyond Borders), C. Siswa Widyatmoko (Universitas Sanata Dharma), Suman Lam & Roxane Cohen Silver (University of California, Irvine)*

EMOTIONAL SUPPRESSION, PROBABLE POST-TRAUMATIC STRESS DISORDER, AND THE CORTISOL AWAKENING RESPONSE FOLLOWING EXPOSURE TO REPEATED NATURAL DISASTERS, *Suman Lam (University of California, Irvine), D. Conor Seyle (Psychology Beyond Borders), C. Siswa Widyatmoko (Universitas Sanata Dharma), Edwin Tan & Roxane Cohen Silver (University of California, Irvine)*

DYADIC DISTRESS IN THE FAMILY: THE INTER-DEPENDENCE BETWEEN PARENTAL AND CHILD RESPONSES FOLLOWING A NATURAL DISASTER IN INDONESIA, *Vanessa Juth, Roxane Cohen Silver (University of California, Irvine), Conor Seyle (Psychology Beyond Borders), Edwin Tan (University of California, Irvine), Siswa Widyatmoko & Suman Lam (Sanata Dharma University, University of California, Irvine)*

Four Research Reports from a Summer Research Training Program on Latino Mental Health in Puebla, Mexico
Chair: Steven R. Lopez, University of Southern California
Friday, 9:45-11:15 Westwood

NORMATIVE DIFFERENCES IN THE U.S. WAIS-III AND SPANISH LANGUAGE ADAPTATIONS, *Cynthia M. Funes (Georgia State University), Juventino Hernandez Rodriguez (Arizona State University) & Steven R. Lopez (University of Southern California)*

INCREASING PSYCHOSIS LITERACY OF SPANISH-SPEAKING ADULTS IN MEXICO, *Erendira Aldana (California State University, Long Beach), Edlin Gonzalez (Columbia Teachers College) & Steven Lopez (University of Southern California)*

ATTRIBUTION-AFFECT-HELPING MODEL IN SCHIZOPHRENIA: PATIENT AND CAREGIVER PERSPECTIVES, *Yu T. Wang (University of California, Los Angeles), Bianca Villalobos, (CSU Channel Islands), Darcy Alcántara, (University of Massachusetts, Boston) & Steven R. López (University of Southern California)*

HACIA UN PUNTO DE VISTA DIÁDICO DE EMOCIÓN EXPRESADA / TOWARDS A DYADIC VIEW OF EXPRESSED EMOTION, *John P. Keefe (University of Southern California), Denisse Tiznado (San Diego State University), Evelyn Mendoza (California State University, Los Angeles), Cristina Medina (Autonomous University of Barcelona) & Steven R. Lopez (University of Southern California)*

Addressing Hawai`i in Theories of Culture, Dating, and Microaggressions
Chair & Discussant: Alyson L. Burns-Glover, Pacific University Oregon
Friday, 11:30-1:00 Westwood

THE HAWAIIAN EXPERIENCE OF

MULTICULTURALISM AND MICROAGGRESSIONS, *Elinor Marie P. Butay, Chelsea Y. J. Wong & Alyson Burns-Glover (Pacific University Oregon)*

INTERETHNIC DATING: CULTURAL

ORIENTATIONS AND DATING CHOICES, *Christopher Ferrante & Jordana Ferreira*

KOKO OR CULTURE? RACE, ETHNICITY, CULTURE AND DATING IN HAWAI'I, *Jasmine Eugenio, & Alyson Burns-Glover (Pacific University Oregon)*

Challenges in Conducting Cross-Cultural Research: Professional and Student Perspectives
Chair: Eric L. Kohatsu, California State University, Los Angeles
Friday, 2:45-4:15 Fernwood

CASE EXAMPLES OF CROSS-CULTURAL RESEARCH, *Eric L. Kohatsu, Shizue Mizukami, Patricia Singim, Kayin Ho, Marlene Gonzalez, Monique Ervin, Aaliyah Muhammad & Stacy Scates (California State University, Los Angeles)*

PROBLEMATIC ISSUES IN RESEARCH, *Eric L. Kohatsu, Shizue Mizukami, Patricia Singim, Kayin Ho, Marlene Gonzalez, Monique Ervin, Aaliyah Muhammad & Stacy Scates (California State University, Los Angeles)*

LEARNING CROSS-CULTURAL RESEARCH: AN ANALYSIS OF STUDENT EXPERIENCES, *Shizue Mizukami, Patricia Singim, Kayin Ho, Marlene Gonzalez, Monique Ervin, Aaliyah Muhammad, Stacy Scates & Eric L. Kohatsu (California State University, Los Angeles)*

International Immersion Learning Experiences in Higher Education: Program Outcomes and Recommendations
Chair: Lynette H. Bikos, Seattle Pacific University
Discussant: M.C. Gilberto Manuel Galindo, Universidad Autónoma de Baja California
Saturday, 8:00-9:30 Fernwood

ADVOCACY FOR INTERNATIONAL IMMERSION LEARNING EXPERIENCES IN DOCTORAL PSYCHOLOGY CURRICULA, *Kim H. Huynh, Kara L. Pegram, Nicola F. De Paul & Lynette H. Bikos (Seattle Pacific University)*

OUTCOMES ASSOCIATED WITH UNDERGRADUATE-LEVEL INTERNATIONAL INTERNSHIPS, *Kari Knutson Miller (California State University, Fullerton), Amber M. Gonzalez (University of California Santa Barbara), Ashleigh Bauserman, Megan C. Mclaughlin & Peggy B. Shoar (California State University, Fullerton)*

DEVELOPING MEANINGFUL CROSS-CULTURAL EXCHANGE EXPERIENCES: A STUDENT AND FACULTY PANEL DISCUSSION, *Sherri McCarthy (Northern Arizona University - Yuma), Alfredo Padilla Lopez (Universidad Autonoma de Baja California), Albertina Aros (Northern Arizona University - Yuma) & Susanna M. Pino Velazquez (Arizona Western College)*

Beyond Borders: Recognizing the Validity of Psychologies Across National Lines
Chair: Jason J. Platt, CSPP at Alliant International University
Saturday, 11:30-1:00 Fernwood

CRITICAL PATRIOTISM: EXPLORING NATIONALITY IN PSYCHOLOGY EDUCATION, *Jason J. Platt (Alliant International University)*

RECLAIMING HUMANITY: IDEAS FROM LIBERATION AND LATIN AMERICAN PSYCHOLOGIES, *Jason J. Platt (Alliant International University)*

BEYOND BORDERS: RECOGNIZING THE VALIDITY OF PSYCHOLOGIES ACROSS NATIONAL LINES, *Tatiana Glebova (Alliant International University)*

International Perspectives on Positive Psychology
Chair & Discussant: Douglas C. Smith, Southern Oregon University
Saturday, 1:15-2:45 Fernwood

This symposium will feature both research and practice efforts with cross-national or international samples in the areas of psychological health and well being, resiliency, vitality, emotional intelligence, mindfulness, and related areas of positive psychology. Speakers will report on the development of a multi-dimensional scale to measure positive traits and dispositions in adolescents and young adults and will discuss comparative research conducted in the Untied States and in Japan. Additionally, research on emotional intelligence, self-esteem, self-confidence and social adaptation comparing adolescents from Barcelona –Spain

and Mexicali –Mexico will be reported and discussed. Finally, the symposium will present research exploring the efficacy of mindfulness meditation for aging adults and its effects on self-esteem, self-awareness and a more positive perception of themselves.

Mixed Methodologies and Multigroup Structural Equation Modeling in Cultural and Health Research
Chair: Patricia Flynn, Loma Linda University
Saturday, 3:00-4:30 Fernwood

MULTIGROUP STRUCTURAL EQUATION MODELING IN CULTURAL RESEARCH: FATALISM, EMOTIONS AND SCREENING, *Patricia Flynn (Loma Linda University)*

LATINO AND ANGLO WOMEN'S CULTURAL STEREOTYPES ABOUT HEALTHCARE PROFESSIONALS, *Jael Amador, Troy Davis & Patricia Flynn (Loma Linda University)*

CULTURE AND DIABETES TREATMENT ADHERENCE AMONG MAPUCHE AND MAINSTREAM CHILEANS, *Manuel Ortiz (Universidad de La Frontera, Chile / University of California, Los Angeles), Tamara Hernandez (Universidad de La Frontera, Chile), Jaime Silva (Universidad de La Frontera, Chile), Pablo Vera-Villaroel (Universidad de Santiago, Chile) & Hector Betancourt (Universidad de La Frontera, Chile / Loma Linda University)*

CULTURAL AND PSYCHOLOGICAL FACTORS IN HEALTH DISPARITIES: AN INTEGRATING MODEL, *Hector Betancourt (Loma Linda University & Universidad de La Frontera, Chile)*

Family Conflict and Sociological Imagination in Mexican Immigrant Families
Chair: Carrie L. Saetermoe, California State University, Northridge
Discussant, Gabriela Chavira
Saturday, 4:45-6:15 Fernwood

FAMILIES AND SOCIOLOGICAL IMAGINATION: BACKGROUND AND METHOD, *Carrie L. Saetermoe (CSU Northridge)*

FAMILIES AND SOCIOLOGICAL IMAGINATION: SYNTHESIS, *Carrie L. Saetermoe (CSU Northridge)*

EXAMINING FAMILIAL CONFLICT AND ACADEMIC MOTIVATION OF MEXICAN IMMIGRANT PARENTS, *Carrie Saetermoe (CSU Northridge), Katie Young (UC Davis/CSU Northridge) & James Garcia (CSU Northridge)*

ACADEMIC MOTIVATION WITHIN FAMILIAL CONTEXT OF MEXICAN IMMIGRANT FAMILIES, *Carrie Saetermoe (CSU Northridge), Kaitlyn Young (UC Davis/CSU Northridge) & James Garcia (CSU Northridge)*

Interested in socializing with other psychologists/psychology students who are interested in international issues? If so, we can meet Saturday, 6:30pm in the lobby. Please RSVP in advance to Lynette Bikos (lhbikos@spu.edu), or alert one of the Saturday's International Programming Hosts so that we can get a count and make reservation at a restaurant that will accommodate all of us.

Posters: International Psychology, Social Issues 1
Saturday, 3:30-4:45 Wilshire

19-1 INTER-ETHNIC DATING AND NATIVE HAWAIIANS: ALOHA, HISTORY AND MULTICULTURALISM, *Jasmine Eugenio, Jordana Ferreira, Christopher Ferrante, Alyson L. Burns-Glover & Alicia Kepa (Pacific University Oregon)*

19-2 RAPE MYTH ACCEPTANCE AND RELIGIOSITY, TRADITIONALISM, & PARENTAL IMMIGRANT STATUS, *Cheryl Groskopf & Heidi R. Riggio (CSU Los Angeles)*

19-3 CHANGE IN THE MEANING OF DATING AND MARRIAGE OF TURKISH GRADUATE STUDENTS: DOES GENDER PLAY A ROLE?, *Raquel Delevi (CSU Los Angeles)*

19-4 OVERLOOKED CHALLENGES OF INTERNATIONAL PSYCHOLOGY STUDENTS, *Kin Cheung Lee (CSPP at Alliant International University)*

19-5 VALUES EXTOLLED IN INDIAN INDEPENDENCE DAY PRIME MINISTERIAL ADDRESSES, *David Hauser & Richard Kinnier (Arizona State University)*

19-6 EXPLORING THE ACHIEVEMENT/ ADJUSTMENT PARADOX IN BRITISH-CHINESE UNIVERSITY STUDENTS, *Jacqueline Lee Tilley (University of Southern California) & Ruth Kershner (University of Cambridge)*

19-7 AN ANALYSIS OF NATIONAL FOOTBALL LEAGUE'S SPECTATOR BEHAVIOR IN CHINA, *Yiu-Ni Judy Chen, Mathew Curtis (University of Southern California) & Doug Stenstrom (California State University, Los Angeles)*

19-8 CULTURAL COMPETENCY EDUCATION: LATINO CULTURE AND SPANISH LANGUAGE IMMERSION TRAINING, *Janese Olalde, John K. Miller (University of Oregon) & Jason J. Platt (Alliant International University Mexico Campus)*

19-9 INTERNATIONAL RELOCATION AND REPATRIATION EFFECTS ON FAMILY IDENTITY, *Kelsey Getz, Jenna Dumpit, Anna Taylor & Deborah Wiese (Whitman College)*

19-10 CORRELATES OF MARRIAGE AND DIVORCE RATES IN 86 COUNTRIES, *Cornelia Brentano, Christian Ducree, Claudia Flores & Martha Yepez (California State University, Dominguez Hills)*

19-11 THE ROLE OF LOR AND AGE OF ARRIVAL ON ACCULTURATION, *Dan Airth, Chi-Ah Chun, James Amirkhan & Young-Hee Cho (CSU Long Beach)*

19-12 TOWARDS A THEORY OF HEALTH BEHAVIOR CHANGE FOR THE DEVELOPING WORLD, *Kaile Brake, Trina Demirer, Christian Washburn, Sonya Gotts, Charles Kirkwood, Marzieh Forghany & Suni Petersen (CSPP at Alliant International University)*

19-13 IMPACT OF CIVIL WAR: TRAUMA IN SOUTHERN SUDAN, *Chad Houchin, Rodger K. Bufford, Rusty Smith, Heather Mackay (George Fox University) & George Rhoades (GAiN Canada)*

19-14 IMPACT OF NATURAL TRAUMA: HAITI'S 2010 EARTHQUAKE, *Kristie Knows-His-Gun, Rodger K. Bufford, TaJuana Wade, Chad Houchin (George Fox University) & George Rhoades (GAiN Canada & Ola Hou Clinic)*

19-15 HEALTH LOCUS OF CONTROL AMONG NEPALI CHILDREN, *Jessica L. Petzold (San Diego State University), Rina M. Sobel (SDSU/UCSD Joint Doctoral Program in Clinical Psychology), Vanessa L. Malcarne (San Diego State University; SDSU/UCSD Joint Doctoral Program in Clinical Psychology; Rebecca & John Moores UCSD Cancer Center), Geargia Robins Sadler (Rebecca & John Moores UCSD Cancer Center) & Amanda Mia Marin (San Diego State University)*

19-16 COMPARISON OF THE POSITIVITY EFFECT IN US AND AFGHANISTAN, *Christie Chung & Frishta Sharifi (Mills College)*

19-17 LANGUAGE PROFICIENCY AND INTERCULTURAL ADAPTATION, *Victor Savicki (Western Oregon University) & Maria Nelida de Juano (Universidad Nacional de Rosario)*

19-18 EVOLVING BUSINESS ETHICS IN EASTERN EUROPE, *John Kantor (CSPP at Alliant University) & Michelle Kantor (University of San Diego)*

19-19 PERCEPTIONS OF RACIAL MICROAGGRESSIONS ON UNDERGRADUATE COLLEGE CAMPUSES, *Arlyn Madsen-Bond (Scripps College)*

19-20 THE FORMATION AND EFFECTS OF MULTIRACIAL IDENTITY, *Allyson Yuen (Whittier College)*

19-21 FRIENDS, FACEBOOK, AND OTHER SOCIAL NETWORKS, *Ian Roberson (California State University, Fullerton)*

19-22 COLLEGE STUDENTS ATTITUDES TOWARD ALCOHOLICS, *Elizabeth Bandy (Dominican University of California)*

19-23 THE ROLE OF ORGANIZATIONAL NETWORKS ON STUDENT MOBILIZATION IN ORANGE COUNTY, CA, *Burrel J. Vann, Jr. (California State University, Fullerton)*

19-24 RELIGION AND PSYCHOSIS: PERCEPTIONS OF RELIGIOUS BELIEFS, *Julie Stevenson (Dominican University of California)*

19-25 ADOLESCENTS WITH GAY, LESBIAN, OR HETEROSEXUAL PARENTS: STIGMATIZATION AND FUNCTIONING, *David Mendelsohn & Allen Omoto (Claremont Graduate University)*

19-26 EFFECTS OF FRAMING: CULTURAL VS. MORAL DIVERSITY ON INTERGROUP BIAS, *Nicole Nordello & Azenett A. Garza (Weber State University)*

19-27 WHAT MAKES YOUR WORLD PERFECT? AN EXAMINATION OF MILITARY PERSONNEL, *Joshua Lewandowski & Benjamin Rosenberg (Claremont Graduate University)*

19-28 PREDICTING ATTITUDES TOWARD AFFIRMATIVE ACTION WITH PERCEIVED POLICY PRACTICES, *Leah Ozeroff & Chris Aberson (Humboldt State University)*

19-29 THE ROLE OF THREAT IN ATTITUDES TOWARD SAME-SEX MARRIAGE, *James P Clifton & Christopher L. Aberson (Humboldt State University)*

19-30 THE IMPACT OF PARENTAL DIVORCE ON OFFSPRINGS' ADULT ROMANTIC RELATIONSHIPS, *Genevieve V. Lam & Connie Shears (Chapman University)*

19-31 THE LINKS BETWEEN BODY DISSATISFACTION AND RELATIONSHIP SATISFACTION, *Amelia S. Moghaddam Jafary & David A. Frederick (University of California, Los Angeles)*

19-32 SENSATION SEEKING AND IMPULSIVITY AS PREDICTORS OF ADOLESCENTS RISK TAKING, *Meagen A. Higgins & David V. Chavez (California State University, San Bernardino)*

19-33 THE EFFECTS OF PRIMING STEREOTYPES ON JUROR ATTENTION AND MEMORY, *Kristen Adams, Dayna Gomes & Douglas Senstrom (California State University, Los Angeles)*

19-34 TEXT MESSAGING VS. TALKING BETWEEN GENDERS, AND PERCEPTIONS OF SUCCESS, *Tiffani Lewis & Diana Kyle (Fullerton College)*

19-35 ADULT DAY CARE UTILIZATION AND CAREGIVER WELL-BEING AMONG ASIAN AND NON-ASIAN AMERICANS, *Stephanie R. Ramirez & Laura Zettel-Watson (California State University, Fullerton)*

19-36 SEX TRAFFICKING: KNOWLEDGE AND ATTITUDES OF SOUTHERN CALIFORNIA COLLEGE STUDENTS, *Susan L. Nelson (University of California, Irvine) & Stacy J. Bacigalupi (Mount San Antonio College)*

19-37 HAWAIIAN EXPERIENCE OF MICROAGGRESSIONS: DEVELOPING THE CONCEPT OF AMBASSADOR FATIGUE, *Elinor Marie P. Butay, Chelsea Y. J. Wong & Alyson Burns-Glover (Pacific University Oregon)*

19-38 EFFECT OF CULTURAL SENSITIVITY IN AN IMMERSED ABROAD EXPERIENCE, *Christina Keys, Paul Neis, Tim Hall & Holly Irwin-Chase (Point Loma Nazarene University)*

19-39 PREDICTORS OF SELF-PERCEIVED CULTURAL COMPETENCE IN MENTAL HEALTH PROVIDERS, *Victoria Keyser, Glenn C. Gamst, Aghop Der-Karabetian (University of La Verne) & Gloria Morrow (Private Practice)*

19-40 NATIVE AMERICAN SPIRITUALITY AND NONVIOLENCE: EMPIRICAL RELATIONSHIPS, *Michelle L. Cutfinger, M. Zachary Brink, Kayla D. Burke, Jessica A. Berghammer, Amber L. Stafford, Elaine B. Dufford & Daniel M. Mayton II (Lewis Clark State College)*

19-41 A SOCIAL RELATIONSHIPS INTERVENTION PROGRAM FOR BULLYING: LIFESKILLS ADVENTURE DAY, *Alyson Burns-Glover, Leah Kresse, Scott Imanaka, Aes Ferrer & Jayson Fukumoto (Pacific University Oregon)*

19-42 GENERATIONAL DIFFERENCES OF EUROPEAN IDENTITY IN CENTRAL AND EASTERN EUROPE, *Natalia Waechter (Institute for Advanced Studies, Vienna)*

19-43 A PROGRAM ASSESSMENT OF LOCAL SERVICES FOR HUMAN TRAFFICKING VICTIMS, *Brianna Hodge & Andrew Downs (University of Portland)*

19-44 RELIGION AND EMOTIONS, *Heather L. Porter & Diane J. Pfahler (Crafton Hills College)*

19-45 COMMUNITY VIOLENCE EXPOSURE IN HMONG YOUNG ADULTS, *Susan Her & Greg M. Kim-Ju (Calfornia State University, Sacramento)*

19-46 CULTURAL COMPETENCY: AN UNATTAINABLE GOAL, *Patricia Kyle & Paul Murray (Southern Oregon University)*

19-47 ATTITUDES TOWARD ARRANGED MARRIAGE: COURTESY BIAS?, *Zeenath Bozorgmehr & T.L. Brink (Crafton Hills College)*

19-48 EXAMINATION OF SUICIDALITY AMONG MILITARY SERVICE MEMBERS, *Katherine Fox, Katie Diershaw & Samantha Forsythe (Pacific University Oregon)*

19-49 CLIMATE CHANGE DENIERS: ROLE OF AVOIDANCE DENIAL AND POLITICAL IDEOLOGY, *Suzanne Thompson (Pomona College), Danielle Manning (Claremont McKenna College) & Alexandra Cone (Pomona College)*

19-50 MATURE CINEMATIC CONTENT FOR IMMATURE MINDS, *Lauren Elizabeth Skidmore (California State University, San Bernardino), Dean Keith Simonton (University of California, Davis) & James C. Kaufman (California State University, San Bernardino)*

This pre-conference summary is prepared by Lynette H. Bikos, Ph.D., Division 52/International Psychology Western Region Outreach Chair, lhbikos@spu.edu.

To join D52, visit the membership page of the Division's website: http://www.itopwebsite.com/InternationalPsychology/Membership.html.

Heritage Mentoring Project: Volunteers Needed

Neal S. Rubin, Ph.D., ABPP
Argosy University, Chicago

In conjunction with Dr. Grant Rich and the *International Psychology Bulletin* (IPB) and on behalf of the Board of the Division of International Psychology (Division 52), I am pleased to announce the launching of the Heritage Mentoring Project (HMP). This endeavor will result in the publication of a series of articles in the IPB consisting of brief biographies of luminaries in the field of International Psychology. The HMP has at least two central purposes. First, it is time for us to celebrate the contributions of pioneers in the field of International Psychology. Second, we seek to promote connections between senior members of our field and those more recently engaged in International Psychology through the vehicle of scholarly mentorship. It is our hope that facilitating these collaborative connections will engender meaningful mentoring relationships and as a product enrich our appreciation of our own history and of those women and men worldwide whose scholarship has been foundational to our field.

For this project to be a success, we need your help. Drs. Chalmer Thompson, Uwe Gielen, John Hogan, and Wade Pickren have offered to provide guidance in the selection of subjects for these biographies. Together, they will provide a list of international psychologists from around the world who have made seminal contributions to our field. For example, current proposals include biographies of recipients of the Committee on International Relations in Psychology's (CIRP) award for Distinguished Contributions to International Psychology, Division 52's Distinguished International Psychologist Award (U.S. and non-U.S. awardees) and former Presidents of Division 52. Additionally, we will seek to identify subjects who are diverse scholars whose work may not have, as yet, reached mainstream Western publications. In this way we will enhance our knowledge of, for example, scholars of color worldwide who may have had a significant impact on their particular local or cultural context, but who may not have received international attention. The coordinator for the HMP, Dr. Chalmer Thompson, will facilitate connecting members interested in engaging in collaborating on a biographical article. The senior member of the pairing will guide the project, providing mentoring in the selection of the subject and in the development of the publication, and the junior member will research and possibly interview the subject (if they are available), and serve as the primary author of the piece.

Therefore, what we need from you as either seasoned members of our field or as newcomers to International Psychology are volunteers to serve as co-authors of these biographies: one established psychologist in a mentoring role and one student or early careerist as a primary investigator. Collaborators will design the structure and content of each biography to be submitted to the IPB in 1,500 – 3,000 words. These articles will be submitted to Dr. Grant Rich and will appear as part of a continuing series in the IPB. Additionally, authors will be asked to give their permission for these biographies to be posted on line on the Division 52 website by Dr. Richard Velayo, division webmaster.

If you would like to help us develop a greater appreciation of our heritage, while engaging in enriching mentoring collaborations and publishing in the International Psychology Bulletin in the Heritage Mentoring Project, please contact the HMP coordinator, Chalmer Elaine Thompson, Ph.D., Associate Professor of Counseling and Counselor Education at the Indiana University School of Education, Indianapolis, Indiana: chathomp@iupui.edu.

Division of International Psychology Nominees for Elected Offices

Nominations were solicited for Division 52 President-Elect, and two Treasurer. The names are listed below in alphabetical order.

President-Elect (2012)
Mercedes A. McCormick, Ph.D.
Senel Poyrazil, Ph.D.

Treasurer (2012-2014)
Cristina L. Magalhaes, Ph.D.
Susan Nolan, Ph.D.

All candidates were asked to submit their statements for inclusion in the International Psychology Bulletin.

Candidates for President-Elect

Mercedes A. McCormick, Ph.D.

I am on the psychology faculty at Pace University, New York City where I teach psychology courses that focus on the internationalization of psychology. I also coordinate the MA Program in General Psychology and am the advisor for Psi Chi, the International Honor Society of Psychology. I coordinate the Annual Pace Psychology Conference that highlights international psychology research and issues. I mentor international students to promote their development as global psychologists. My own research interests include *Internationalizing the Curriculum* and I presented research in Russia, Mexico City, Portugal and Canada.

I joined Division 52 in 2005 and have been actively involved. I serve as Member-at-Large on the Executive Committee (2010-2012), D52 Liaison for the Committee on LGBT Concerns, Chair of Outreach Committee 2005-2011 and was 2010 Chair of the International Mentoring Award Committee. I created digital resources for our Division explaining the field of international psychology 2008.

I am enthusiastic about serving as president and look forward to continuing the work of former leaders. If elected, I will promote the following goals to:

- Build stronger partnerships with international organizations of psychology and APA Divisions to advance the mission of international psychology.
- Survey the membership to collect demographic data and learn about their satisfaction in order to develop initiatives and motivate members.
- Ongoing support of the techniques and methods to internationalize the psychology curriculum.
- Enhance international collaboration via web-based technologies.

Senel Poyrazli, Ph.D.

I am an APA Fellow and associate professor at the Pennsylvania State University, Harrisburg campus. I internationalize all of my courses in an attempt to help my students become global citizens. My research is directly involved with international psychology. I study international students' and immigrants' psychosocial adjustment and acculturation processes, and have published substantially in this area. I also have a forthcoming book entitled, International Case Studies in Mental Health: An International Perspective in Counseling and Psychology, by Sage Publications. I collaborate with international psychologists in the U.S. and abroad (e.g., Sweden, Turkey, Canada).

I have been a member of our Division since 1998. I recently completed a 5-year term as the editor of the International Psychology Bulletin and have been the chair of the Long Range Planning Committee for the past two years. I have co-chaired the Division's APA program for 2010 and serve as the current chair for its APA 2011 program in Washington, D.C. In addition, I was a member of the Website Task Force and the Mentorship Committee. For these contributions, I received two presidential citations and a recognition award for extraordinary service.

I am very excited about serving as your president, continuing the work of the previous leaders of our Division, and advancing international psychology. If elected, the following will be among my goals:

- Increasing the visibility of our Division
- Continuing the work of infusing an international perspective in all APA divisions
- Supporting efforts to internationalize the psychology curriculum worldwide
- Increasing the number of members and leaders from countries outside of the U.S.

Candidates for Treasurer

Cristina L. Magalhaes, Ph.D.

Cristina L. Magalhaes, PhD, is Assistant Professor in the PsyD program at Alliant International University, Los Angeles, and faculty affiliate of the Multicultural Community Psychology Emphasis and the university's Rockway Institute for LGBT Psychology. Her research and teaching experience/interests focus in areas that fall under the larger umbrella of multicultural/diversity and international psychology. These include socio-cultural considerations in assessment and treatment, translation and adaptation of measures for cross-cultural use, immigration issues, LGBTQ issues, and the intersection of multiple aspects of identity. Her work has been presented at several international conferences including the Interamerican Congress of Psychology, International Congress of Psychology, World Conference on Psychology, Counseling and Guidance, and the World Professional Association for Transgender Health.

Dr. Magalhaes' career started in Brazil where she completed her *Licenciatura em Psicologia* and *Formação de Psicólogo* degrees in 1991. Her clinical training and work experiences in Brazil were primarily in psychiatric hospital and outpatient community-based settings. She earned her MS (2000) and PhD (2005) degrees in clinical psychology from Nova Southeastern University in Fort Lauderdale, Florida. In the United States, she provided administration, supervision and direct clinical services in community mental health, child residential programs, and private practice since 1997. She is member of several APA divisions and currently serves as Treasurer for Division 12, Section IV (Women in Clinical Psychology). As a psychologist with an international identity, she looks forward to the opportunity to join other Division 52 members in their efforts to advance knowledge of issues impacting the practice of psychology worldwide.

Susan Nolan, Ph.D.

I received a Ph.D. in Clinical Psychology from Northwestern University, and am an Associate Professor and Chair of the Department of Psychology at Seton Hall University. I live in Jersey City, NJ, and have a house in Bosnia-Herzegovina, where I spend part of each summer.

Why Division 52? Division 52 is the professional organization that best bridges the increasingly interna-

tional nature of my research, teaching, and service. For example, I study gender differences in STEM careers and have incorporated international perspectives, including in an NSF-funded symposium (2003) and subsequent co-edited book (2006) that included international contributors. With respect to teaching, I developed an International Psychology course at Seton Hall that received approval as a behavioral science core course. In terms of service, I am an NGO representative to the United Nations and Chair of Division 52's International Committee for Women. I look forward to continued involvement in Division 52, with an emphasis on creating connections among the varied arenas in which international psychologists work and involving students more directly.

Why Treasurer? I believe my experience will enable to me to carry out the duties of Treasurer. First, I enjoy quantitative tasks, as evidenced by my co-authored statistics textbooks. Second, I have held administrative positions at Seton Hall since 2001 (Director of Women's Studies, Associate Dean of Graduate Studies, and Department Chair), all with budget-related duties. Third, I served for two years as Treasurer and an Executive Board Member of the New Jersey Coalition Against Sexual Assault (budget of over $700,000).

Learn More About the New Division 52 Journal

Visit http://www.apa.org/pubs/journals/ipp/index.aspx.

International Perspectives in Psychology: Research, Practice, Consultation is committed to publishing conceptual models, methodologies, and research findings to help study and understand human behavior and experiences around the globe from a psychological perspective. It publishes intervention strategies that use psychological science to improve the lives of people around the world.

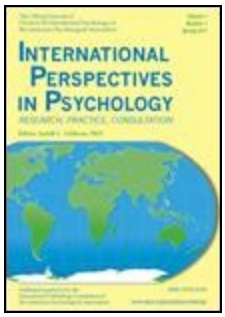

The journal promotes the use of psychological science that is contextually informed, culturally inclusive, and dedicated to serving the public interest. The world's problems are imbedded in economic, environmental, political, and social contexts. *International Perspectives in Psychology* incorporates empirical findings from education, medicine, political science, public health, psychology, sociology, gender and ethnic studies, and related disciplines.

The journal addresses international and global issues, including

- inter-group relations
- disaster response
- societal and national development
- environmental conservation
- emigration and immigration
- education
- social and workplace environments
- policy and decision making
- leadership
- health care
- poverty and economic justice
- the experiences and needs of disadvantaged groups

LEAVING A LEGACY

TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

Division 52 – International Psychology
2011 APA Convention Program

	Wednesday August 3rd	Thursday August 4th	Friday August 5th	Saturday August 6th	Sunday August 7th
8:00-8:50				Understanding Autism in Vietnam: Implications for Psychologists and Educators (SYM)	
9:00-9:50		International Psychology Paper Session I	Paradigm of Intersectionality: Promoting Asian Women's Physical, Mental, and Reproductive Health (SYM)	Division 52 Business Meeting	International Psychology Paper Session II
10:00-10:50		Where is Ellis? Where and how is RBT Practiced Internationally? (SYM)	Taxonomy of Sexual Trafficking: Treating Survivors and Exploiters of Sexual Abuse (SYM)	Psychological Impacts of the January 2010 Earthquake in Haitian Survivors (SYM)	Sustainable Visions and Values for Psychology and Psychologists: Current Needs and Emerging Opportunities for Global Teaching, Research, and Practice (SYM)
11:00-11:50		Advancing International North-South-North Dialogues in Psychology in the Americas (SYM)	Intergenerational Consequences of Intercommunal Political Violence (SYM)	Division 52 Presidential Address: Teaching the History of Psychology From an International Perspective: A Few Recommendations (John D. Hogan)	
12:00-12:50		Dissemination of Evidence Based Practice Internationally (SYM)			
1:00-1:50		Examine Cross-Cultural Applicability of Adult Attachment Theory to Asian Populations (SYM)		Research in International Psychology Poster Session II	
2:00-2:50	Executive Meeting	Integrating Mental Health into the Primary Care Setting in Africa: Lessons from Rural Senegal (SYM)			
3:00-3:50					
4:00-4:50			Research in International Psychology Poster Session I		

This is a tentative program. APA may make changes to it. For questions, please email Senel Poyrazli, Ph.D. at poyrazli@psu.edu or Mark D. Terjesen, Ph.D. at terjesem@stjohns.edu

Proposed Bylaws Changes Re: Student and Early Career Representation on the Division 52 Board

March 28, 2011
Joy K. Rice, Bylaws/Handbook Chair

In mid April, as a member of Division 52, you will receive an electronic vote email from APA that will ask you to vote on some changes to the Bylaws of Division 52 that were approved by the Board of Directors at the 52 MidWinter meeting in March. The issue is student and early career psychologist representation on our Board of Directors. Please take minute to read the rationale and proposed bylaws changes and be sure to vote in April. The additions are in red.

Rationale

Students and early career psychologists represent the future of psychology and of our Division. In order to assure that Division 52 remains a vibrant and viable organization, we need to continuously nurture the development of new members of our field. Designating a voting membership role on the board of directors for both a student and an early career member explicitly defines a meaningful place for these individuals as valued members of our Division. Providing a voice for students on the boards of divisions has become increasingly common among APA divisions who report they are gratified by the dynamic contributions of their younger members. Additionally, we have much to offer students and young professionals in the way of mentorship. Involvement with the board will enhance their organizational experience, provide needed seasoning, create new career opportunities and hopefully propel their career trajectories toward significant contributions to the field of international psychology. Having student and early career representatives with a vote on the board will benefit these constituencies, the division, our field and ourselves.

The proposed bylaws changes in Article IV are essentially two: Designating that one of the four elected Members-at-large will be an Early Career Member and adding a new elected board position of Student Representative with vote.

Article IV: Board of Directors

Section 1

There shall be a Board of Directors of the Division. Its membership shall consist of the following persons:

1) The elected officers of the Division as specified in Article III, Section 1 of these Bylaws;

2) There shall be four Members-at-large who shall be Members of the Division, elected for three-year terms in staggered sequence. Members-at-large shall be members of the Board of Directors with vote. The terms of the initial Members-at-large shall be set by the Board of Directors for one, two, or three years so as to implement staggered terms. They shall assume office on January 1 of the year following their election. One of the Members-at-Large shall be an Early Career Member. A Member-at-large initiates or works on at least one special project that furthers the goals of the division and reports on the progress annually.

3) The Division shall elect that number of Representatives to APA Council necessary to fill vacancies created by ending terms of current Representatives and/or vacancies created by changes on the APA Apportionment Ballot. Representatives to Council must be Members or Fellows of the Division and are ordinarily elected to serve a three-year term. The Division's Representative(s) to Council shall be members of the Board of Directors with vote.

4) The Division shall elect a Student Representative who is a Member of the Division, elected for a two year term. The Student Representative shall be a member of the Board of Directors with vote.

If the membership approves these changes, we will also add information to our Division 52 Handbook that will indicate a) that the Early Career MAL is expected to chair the Early Career Committee; b) that the definition of an Early Career Psychologist is up to ten years post graduate status and c) that in terms of rotation, every third year one of the two MAL nominations will go to an early career psychologist, ensuring that there will always be one MAL ECP representative on the board. In addition, the Handbook will note that the Student Representative a) is expected to chair the Student Committee and b) will generally be a graduate student, but that a particularly outstanding psychology undergraduate may be nominated for the position.

International 2011 Research Award for Doctoral Students in Psychology

Call to Students Engaged in International Psychology Research!

Division 52, International Psychology, is offering an International 2011 Research Award for doctoral students in psychology. This award has been established to encourage and recognize promising doctoral student research in international psychology.

Please submit:

a) Four page double-spaced summary* of research (including references) that describes the purpose, method, analysis, results, and discussion of your international research. Please exclude all identifying information on research summary document.
b) Student's Curriculum Vitae
c) One-paragraph email* endorsement sent directly from faculty research advisor/sponsor providing:
   1. Endorsement for the award
   2. Confirmation that research was an independent project, thesis, or dissertation effort conducted during doctoral program, and
   3. Assurance of student's good standing in the doctoral program.
d) Two-paragraph cover email from student applicant*
   1. First paragraph should provide all contact information, name of doctoral program and institution, name of research advisor, year in the doctoral program, expected graduation date, as well as member status with Div 52. (Student applicant must be a member of Div 52 as of the award application deadline.)
   2. Second paragraph should assure the committee that the independent research project, thesis or dissertation is nearing completion. At least preliminary analysis and results must be completed by early May 2011.

***Please note that submissions exceeding the paragraph/ page limits will be disqualified. Brevity is valued!**

Email all application materials BEFORE MIDNIGHT ON SUNDAY, May 15th, 2011 to the Chair of the International Research Award for Doctoral Students (late applications will not be reviewed):

Sheila J. Henderson, MBA, Ph.D., Visiting Associate Professor, California School of Professional Psychology & Associate Director, I-MERIT, Alliant International University, 1 Beach Street, San Francisco, CA 94133, shenderson@alliant.edu.

The award committee will evaluate the award applications under blind review based on: (a) the degree of relevance to international psychology, (b) progress to completion, (c) adherence to APA Style, (d) originality of research, (e) clarity of design and method, (f) complexity of analysis, (g) quality of findings, (h) recognition of limitations, (i) insight in the discussion, and (j) brevity and clarity.

Awardees will be notified no later than May 31st, 2011, awarded in person at the Division 52 APA Convention Awards ceremony in Washington D.C., and featured in the Fall issue of the Division 52 newsletter.

Eastern Psychological Association 2011 International Conference

Harold Takooshian

On March 10-12, 2011, over 1,800 psychologists and students from as far as Moscow gathered at the Hyatt Regency Cambridge for the 82nd annual meeting of the Eastern Psychological Association. Once again, for the ninth year since 2003, this included the semi-annual program and meeting of the 25-person board of directors of the APA Division 52, International Psychology (D52). Thanks to EPA, D52 had its board meeting from noon till 5 pm on March 10, then a two-day program of 10 symposia and poster sessions on March 11 -12, presenting work by D52 members and others. The 30 seats in the Hyatt Cambridge room were often filled by a steady stream of students and professionals hearing about a variety of global topics: publishing opportunities in international psychology, the United Nations, Fulbrights, international collaborations on TAT scoring, internationalizing the teaching of psychology, and intervening after natural and human-made disasters.

Some images of these sessions appear at www.picasaweb.com/takoosh. This program had some unusual features.

The D52 board met in Cambridge MA (photo by Michael Meir)

During the two-day conference, conferees closely followed media news of a deadly 8.9 earthquake in Japan, while teams of experts at EPA discussed their work after past disasters in Haiti, Pakistan, Sri Lanka, Armenia, Lebanon, Sierra Leone and elsewhere.

Officers of Psi Chi, the international honor society for psychology, joined D52 for a joint session on "Psi Chi: Moving from a national to an international society in psychology."

Under Russian professor Alexander Voronov, a team of seven faculty and students from Moscow visited EPA, and offered a symposium on "Russian psychology today: Current trends." This included the debut of a nine-minute DVD, "Psi

Chi: Student excellence," translated into the Russian language by Dr. Alexey Sozinov of the Academy of Sciences of Russia.

On behalf of D52, President John Hogan thanked the EPA Board of Directors for hosting such a full program on international psychology, and presented his Presidential Citation to EPA Executive Officer Frederick Bonato and Program Chair Diane Finley for their efforts to make EPA a model among the seven U.S. regional psychology associations.

Thanks to the efforts of D52 secretary Ayse Çiftçi, about 30 members shared a wonderful international supper at the exotic Elephant Walk in Cambridge

To give the EPA presentations a wider audience, Editor Grant Rich invites session chairs or presenters to consider adapting their presentation for possible publication this year in the APA *International Psychology Bulletin.* Contact Dr. Rich at optimalex@aol.com

EPA 2011: How Moscow Met Massachusetts

Grant J. Rich

Back in 1998, the American Psychological Association hosted its first annual Division 52 program in Washington DC (Takooshian, 1998). Since then, D52 has now grown to offer at least three annual international programs each year—at APA, then EPA in the East (since 2003), now WPA in the West (since 2009). After 14 years, the D52 board now tries to host its midwinter board meeting every other year at a new regional or other venue, to inspire more U.S. international programs.

Still, it remains unusual for overseas presenters to participate in these D52 meetings, due to the familiar challenges of distance, cost, and language. In addition, some nations like Russia also require a special visa to travel to the USA.

At EPA, Russians present their research findings.

The recent and model exception was the 2011 EPA meeting in Cambridge, where 4 professors and 2 students from Moscow managed to present their work--thanks to unusual teamwork between EPA, Moscow Professor Alex Voronov, and the national board of Psi Chi, the international honor society in psychology.

In Cambridge, Russian scientists meet Psi Chi national officers and psychologists. (l t o r): Elena Chebotareva, Irina Novikova, Mercedes McCormick, Tatyana Al-Batal, Alexander Voronov, Grant Rich, Anastasia Chebotareva, Alexey Novikov, Rivka Bertisch Meir, Michael D. Hall, Martha Zlokovich, Susan Iles, Harold Takooshian. (Photo by Michael Meir, MD)

Back in November of 2010, the All-Russian conference was taking place to mark the 125th anniversary of native experimental psychology. A.Voronov organized a six-day international seminar "To the 50th anniversary of the first obedience experiments of Stanley Milgram" in Russian cities Moscow and Kolomna, which happened simultaneously with the conference. Five Russian universities cooperated in an unusual multi-site, cross-national meeting, using technology to bring together 300 Russian faculty and students with American and British colleagues. Psi Chi past-President Harold Takooshian gave talks at each of these five universities on three topics: 1) Stanley Milgram as researcher, teacher, mentor: Beyond the controversy; 2) Promoting student excellence in psychology: 80 years of Psi Chi, including discussion of the offer on the organization of the first Euro-Asian chapters; 3) Russian and American psychologists: Traditions and prospects of contacts (including survey of Russian staff and students about their familiarity with the "top 10" psychologists most often cited by American and Soviet textbooks, the results were compared with the analogous results in the US) (Voronov & Takooshian, 2011). There, Takooshian furnished to his many hosts the timely invitations their government required, to participate in EPA in March 2011. Several of them succeeded, with encouragement from EPA and from Psi Chi--which had voted in 2009 to become an international organization.

Russian professors visiting New York City for the first time.

At EPA, the D52 presenters included Russian professors Elena Chebotareva, Irina Novikova, Alexey Novikov, Alexander Voronov, and students Anastasia Chebotareva and Tatyana Al-Batal. Voronov also debuted a new 9-minute Russian-language DVD on Psi Chi, prepared by Alexey Sozinov of the Russian Academy of Sciences. In addition to presenting their research findings at EPA, and meeting officers of D52 and Psi Chi, the Russian scientists toured nearby MIT and Harvard University. The team of four from the People's Friendship University of Russia also managed to visit New York City for three days, where they were registered as D52 members at the home of Rivka Meir, and greeted at Fordham University by psychology Deans Vincent Alfonso and Mark Mattson. Their Russian university's psychology program cooperates with European schools, and now hopes to link with U.S. schools in the future (www.rudn.ru/en/).

Such cross-national cooperation of psychology programs is more possible now, with the continued encouragement of all involved—EPA, APA, Psi Chi, and willing institutions.

References

Takooshian, H. (1998, July). The 1998 convention program. *International Psychology Reporter, 2* (2), 3-6.

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Assessing Psychology in Thailand

Bruce B. Svare
State University of New York at Albany

As a Fulbright senior scholar to Thailand in 2006-2007, I had the opportunity to examine the status of psychology in this country's system of higher education and to explore its role in Thai mental health care.

Psychology is not a well developed discipline in Thailand and only a few elite institutions have stand alone psychology departments with significant undergraduate and graduate course offerings. Notably absent are programs in clinical and experimental psychology. Faculty who teach psychology are very dedicated and have for the most part received their graduate training in the United States, Canada, the United Kingdom, or Australia. Many Thai faculty are still heavily invested in rote learning strategies but new faculty development programs are emphasizing more cooperative learning approaches. Thai interpersonal strategies that emphasize respect for seniority and the suppression of boastful/leadership behaviors are significant cultural impediments to more effective classroom teaching and student learning. A new emphasis upon English taught coursework in Thailand's higher education system reflects this country's desire to become less insular and more oriented toward globalization.

The severely strained Thai mental health care system is dominated by psychiatrists who adhere to a medical model of mental illness. Thai psychologists are poorly trained by western standards with most possessing only an undergraduate degree. They are considered to be "paramedical professionals" by the psychiatric community. In spite of their deficient training and education, Thai psychologists increasingly are being asked to serve on the frontlines of the diagnosis and treatment of mental illness.

Psychology can grow in Thailand and eventually become a greater force in academia and the clinical mental health community. This will only occur if a western educational curriculum is more fully adopted at both the undergraduate and graduate level and many more colleges and universities develop their own psychology departments. Once this infrastructure is in place and levels of training and licensing are simultaneously upgraded, psychology academics and practitioners can begin to contribute more effectively to the Thai mental health care system. While there are significant economic and cultural challenges to advancing modern psychology in this country, the potential rewards for the quality of living among Thai people are enormous.

Key words: Thailand, higher education, history of psychology, teaching of psychology, faculty development, mental health and psychology, reform measures for growth of psychology

Background

I was named a Fulbright senior scholar to Thailand in 2006. The mission for my yearlong assignment was simple: Promote the development of psychology in the Thai higher education system by bringing my specialization to the country. To that end, I taught behavioral neuroscience and assisted with curriculum development at Chulalongkorn University in Bangkok, and lectured widely in the country at other universities and medical schools.

During my stay in Thailand, I learned that the field of psychology is still in its infancy. Most universities in this beautiful country have little in the way of a formal psychology curriculum. Moreover, the profession of clinical psychology and the role that it plays in the diagnosis and treatment of mental illness is almost nonexistent. As a result, Thailand's mental health care system is burdened with increasing numbers of mentally ill patients receiving little in the way of professional care or, worse yet, no care at all.

This was never more evident than 2004 when a tsunami struck Phuket, Thailand. Overwhelmed by the physical and emotional devastation, Thailand's compassionate but largely untrained mental health care professionals were often helpless in assisting survivors who were psychologically damaged by the disaster. Thanks to the benevolence of the United States and many other countries, trained psychologists descended on the country to provide needed assistance and comfort.

After completing my Fulbright stay, I have sought new ways of contributing to their higher education system and the

development of psychology. I return yearly to teach intensive short-term courses at various Thai universities and medical schools, and continue to promote the exchange of Thai students to the United States for doctoral training in psychology. I have also spearheaded fund-raising efforts in the United States to enable more Fulbright scholars to come to Thailand to teach and conduct research.

I recently attended the 60th anniversary celebration of the Fulbright Program in Thailand. It was held at the Thai Ministry of Foreign Affairs in Bangkok. As a senior scholar to Thailand, I was one of only a few former Fulbrighters given the honor of describing my mission to Her Royal Highness Princess Sirindhorn. I came away from our discussion knowing that the princess understood my work and appreciated my efforts to help build the discipline of psychology in her country.

I was also given an award by the Thai-U.S. Educational Foundation (TUSEF) and U.S. Ambassador to Thailand, Eric John, in recognition of my fund-raising efforts on behalf of the Fulbright Program in Thailand. I am grateful for this distinction, for it has motivated me to work even harder to promote psychology in this country.

Bruce Svare, former Fulbright senior scholar to Thailand, is recognized for his fund-raising efforts on behalf of the Thai-U.S. Educational Foundation (TUSEF). Pictured are, from left, Svare, Deputy U.S. Secretary of State Alina Romanowski, His Eminence Manaspas Xuto, former Thai ambassador to the United States and adviser to the Thai minister of foreign affairs, and U.S. Ambassador to Thailand. Eric John. Svare is a Fellow of the American Psychological Association (APA) and the Association for Psychological Science (APS) and professor of psychology and neuroscience at the State University of New York at Albany.

My experiences in Thailand since 2006 have contributed in part to the present analysis. What follows is an assessment of psychology's status in this country. This includes an examination of its relatively brief history, an exploration of the general culture of college teaching and faculty development, an assessment of the role of psychology in the mental health care system in this country, and an analysis of reforms in psychology that are needed if the discipline is to continue to grow and ultimately benefit the Thai people.

Psychology in Thailand: Past and Present

The arrival of Buddhism in Thailand took place approximately 700 years ago. Because a major focus of Buddha's teaching included the nature and function of the mind, it could be said that psychology had its beginning in this country long ago. Modern psychology did not become established in Thailand until about 60 years ago when the western education system was adopted and schools of education were first established for the training of teachers. These schools included a basic psychology curriculum with a heavy emphasis upon child development. There are approximately 200 institutions of higher learning in Thailand today with half private and half public. Only a few of the leading institutions offer undergraduate degrees in psychology and even fewer offer graduate degrees.

Clearly, psychology in Thailand is still in its infancy as a well developed discipline. Some specialties are represented better than others such as social, developmental, industrial, educational, school and counseling psychology. The absence of clinical psychology in this early development is particularly noteworthy. This has been due in large part to the fact that mental health care in Thailand has traditionally been considered the province of the medical psychiatric community. Also, owing to the strong influence of Buddhism on all aspects of Thai life and the stigma associated with mental disorders, monks are often sought out by those needing help in contrast to trained professionals. This factor alone has had a major impact upon the development of clinical psychology as a discipline and a profession. In Thailand today there are only about 400 practicing clinical psychologists (Tapanya, 2010) and the requirements are minimal: Only an undergraduate degree is required and the passing of a licensing exam. Overworked psychiatrists and a largely untrained clinical psychology community cannot begin to take care of the needs of a country consisting of 63 million people.

As noted above, psychology as a formal discipline grew from education departments. Such was the case at Chulalongkorn University in Bangkok, considered along with Thammasat University, to be an elite institution of higher learning in Thailand. In 1996, Chulalongkorn University became the first Thai university to establish a comprehensive psychology program with its own faculty strictly dedicated to graduate and undergraduate training in the discipline. At present it offers undergraduate training in many but not all of the traditional sub-disciplines in psychology. Notably absent are courses that normally are considered to be essential for psychology as a modern experimental discipline: experimental psychology, sensation and perception, research methods and design, psychopharmacology, behavior genetics, developmental psychobiology, behavioral neuroendocrinology, and advanced behavioral neuroscience. Chulalongkorn also has masters programs in social, counseling, developmental, and industrial/organizational psychology and doctoral programs in social, counseling and developmental psychology. Absent from Chulalongkorn's graduate degree offerings

is a doctoral program in clinical psychology. Students with advanced degrees typically find employment as counselors in mental health settings, hospitals, schools, colleges and clinics. They also find employment in government agencies as well as in the private sector as research assistants in marketing and advertising depending upon their graduate specialization.

In recent years, the growth of undergraduate programs in Thai universities has stagnated. Most psychology courses in Thai universities and colleges continue to be taught as part of education or social science departments. Unlike Chulalongkorn and Thammasat Universities with established curriculums and significant enrolled majors each year, psychology offerings at other universities are minimal and typically do not go beyond standard 100 and 200 level courses (e.g., introductory and developmental psychology). One notable exception to this is the development of a clearly identified undergraduate clinical psychology track at Chiang Mai University in northern Thailand. Interestingly, graduate programs in psychology have actually grown somewhat. For example, in Bangkok, Assumption and Thammasat Universities now have doctoral programs in counseling psychology while Mahidol University has a master's degree in clinical psychology. This is an interesting development in Thai higher education since some of these institutions (Assumption and Mahidol) do not have undergraduate psychology departments with significant course offerings.

There are four professional societies for psychologists in Thailand: the Thai Clinical Psychologists Association, the Thai Psychological Association, the Thai Guidance Counselor Association, and the Thai Mental Health Association. There are very few psychology journals and they are all in Thai. A few of the journals are *The Journal of Clinical Psychology*, *Psychology Journal*, and the *Guidance Journal.*

Observations on Teaching Psychology in Thailand

Some comments regarding the professional status of college teaching in Thailand as well as issues surrounding faculty development are also relevant. Thai college professors are not well paid by Western standards but none-the-less are revered in the culture of this country. Teachers Day or "Wan-Kruu" is celebrated every January 16th and college students remember their professors with gifts such as flowers and food. This is a tradition that is seen throughout the educational system in Thailand and is a reminder of how deeply Thais respect their elders.

Psychology faculty, indeed faculty throughout the Thai higher education system, are very hardworking and thoughtful teachers and scholars. They are justifiably proud of the accomplishments they have made in building their respective departments and universities over the past 60 years. Psychology faculty routinely receive their doctoral training in institutions outside their country with the US, Canada, the UK and Australia being the most frequent destinations. They return to Thailand in order to fulfill obligations they have as the result of government grants and to join with other colleagues in the teaching of the next generation of Thai students. It is important to note that Thai psychology faculty are strongly committed to each other, their students and their institutions. This is especially admirable since, as noted above, levels of compensation are universally low.

Professors in Thailand are viewed with unquestioned authority when they teach in the classroom. While this certainly is not unique to Thailand, it poses a striking contrast to expectations in the United States where students and faculty are taught to speak their minds openly and invite discourse regardless of status. An understanding of the concepts of "man-sai" and "kreng-jai", interpersonal strategies for dealing with those in a position of power and authority, are keys to understanding how the avoidance of shame and saving face play a central role in determining the college classroom environment in Thailand. Belonging to a larger group, especially a family group, is a key to happiness and feeling at ease in Thai culture. Indeed, Thais are known for having fun ("sanuk") and keeping everyone in their social and family group happy. At times, this is counterproductive to learning in the classroom since no student wants to stand out too much as a leader for fear of being regarded as boastful and showing off to the rest ("man-sai"). With the risk of not belonging so great, Thais are often reticent in the classroom to express their opinions. This factor, coupled with respect for seniority, promotes a cultural habit where Thais rarely challenge an authority figure ("kreng-jai") for fear of making them look bad. These are challenges that both Thai and foreign professors frequently acknowledge. They are impediments to educational environments that promote a more active and cooperative learning milieu where professors are not just there to dispense information but also serve as facilitators of a collaborative classroom experience. Not surprisingly, in spite of advances to encourage more cooperative learning approaches as noted below, Thai pedagogy is still heavily embedded with rote learning strategies.

Thailand, like many developing countries, has experienced a shift from elite to mass education. Student enrollments have dramatically expanded in this country and a much more diverse student body is now represented in many Thai universities, especially those with open enrollments. Because student centered learning approaches are being promoted as part of a larger educational reform effort, there are new and significant challenges for both faculty and students in this country. Thai faculty are now being encouraged to adopt teaching approaches that include active learning, collaborative learning and problem based learning (Brody, 2008). Faculty are being asked to adjust their curricula and develop, in some cases, radically different approaches to the presentation of classroom material and methods of assessment. Because the hierarchical structure of Thai higher education is more extreme than that of the United States, the implementation of the changes above present problems of their own. For the most part, Thai faculty appear to be overworked. However, they have a strong sense of obligation to accept all assignments regardless of whether or not they have the time or support. Faculty development programs have emerged on a limited basis, most notably at Burapha University. Clearly, this is an area that should receive much more emphasis and re-

sources than it currently does. However, the cultural factors noted above as well as the inertia of tradition and lack of administrative leadership have prevented further development.

Lastly, the availability of technology in Thai higher education, like that of many countries, is highly variable depending upon the discipline as well as the institution and its location. In urban areas such as Bangkok, elite universities such as Chulalongkorn and Thammasat enjoy reasonably good educational technology with smart classrooms, numerous computer stations for students and faculty, wireless service in designated areas, and online software (e.g., Blackboard, Web CT, E-res and other software for web based learning and library access). Although universities in areas outside Bangkok (especially in rural areas), are not as well equipped for educational technology, there seems to be momentum for investment as a result of Thai educational reform. Whether or not faculty make use of this technology is another matter; My observations in psychology indicated that very few used it on a regular basis while most others never used it. Likewise, my observations indicated that the utilization for teaching purposes of YouTube, professional society websites, and web based pedagogical resources was minimal.

Observations on the Role of Psychology in the Thai Mental Health Care System

The most recent World Health Organization assessment of Thailand's mental healthcare system (2006) states that the country has 7.29 mental health providers (e.g., psychiatrists, psychologists, nurses, social workers, and occupational therapists) for every 100,000 people. By any standard of comparison, this is an alarmingly low figure especially when one considers that many of the providers included in the analysis lack any significant training in psychology.

Psychology as a profession in Thailand's mental health care system has not grown substantially in the last 50 years. This follows from a number of factors including the dominance of psychiatry and the medical model, limited opportunities for clinical training comparable to what is seen in the United States, limited educational and training opportunities at both the undergraduate and graduate levels, the lack of rigorous licensing standards, and cultural factors that promote Buddhist monks as defacto counselors. Over 80% of Thai psychologists have only an undergraduate degree, about 15% have earned a master's degree, and about 5% have a doctoral degree (all from overseas and none with internships or post-doctoral training) (Tapanya, 2001, 2010).

Psychologists in Thailand today are considered to be "paramedical professionals" by the psychiatric community (WHO-AIMS, 2006; Tapanya, 2001). Their role is usually limited to being a technician that is ordered by psychiatrists to administer tests and develop reports. However, because increasing numbers of Thais are seeking help from professionals and because there are so few psychiatrists (only about 300 with 80% practicing in urban areas), their role has expanded more recently into areas of treatment, promotion of mental health, and research (Tapanya, 2010). In spite of their lack of education, training and experience, Thai psychologists increasingly are on the front lines of care helping with group and individual therapy, community mental health promotion, and counseling of drug addicts and HIV positive patients. Unfortunately, this development frequently occurs in the absence of supervision from experienced psychiatrists and psychologists. Moreover, the pay in these positions is very low and the opportunities for advancement are almost non-existent.

An important outcome of the heavy emphasis on the medical model approach to mental illness in Thailand is the devaluing and underrepresentation of behavioral science in their curriculum (Tapanya, 2010). There are no departments of psychology or behavioral science in medical schools. Because the six year medical education for Thais begins right after high school, there is little opportunity for psychology and sociology coursework. As a result, Thai medical students who ultimately specialize in psychiatry do not have the benefit of a broad perspective on mental health and illness that their American counterparts usually have from a broad based, undergraduate, liberal arts experience. This is unfortunate since it is well known that medical problems such as heart disease, drug addictions, and sexually transmitted diseases have strong behavioral components. Here again, the growth of clinical psychology and enhanced psychology curriculum in Thai colleges, universities and medical schools could have a major impact upon improving prevention and treatment in their mental health care system.

Cultural factors also play a significant role in the extent to which Thais seek out mental health care (Tapanya, 2001, 2010; WHO-AIMS, 2006). For example, Thais prefer living in extended families and typically build houses in groups where they are in close proximity to relatives. If there is a relative with a mental disorder, families take care of these individuals rather than risk the stigma associated with seeing a psychologist or psychiatrist. Even when a family member is seen by a professional, every effort is made to bring this individual home as quickly as possible. Also, as noted above, Buddhist monks, especially in rural areas, are as likely as a mental health care professional to see and treat those suffering from behavioral problems. Buddhist monks are highly respected in Thai culture and are regularly sought out for assistance with psychological problems. With a small donation, certainly much less than a payment to a psychologist or psychiatrist, a Thai person can simultaneously gain merit for the afterlife while also receiving counseling for a behavioral problem. Additionally, Buddhism advocates meditation and it is well known that this practice alone can ameliorate some problems associated with stress and emotional change.

Though the stigma associated with seeing a mental health care professional in Thailand is significant, the question remains as to how effective a Buddhist monk can be in successfully diagnosing and treating the whole spectrum of behavior disorders that are commonly recognized in the Diagnostic and Statistical Manual (DSM). Notwithstanding the important role that monks play in some areas of counseling and behavioral treatment, they have, for the most part, re-

ceived little in the way of professional training. While some small programs have attempted to train Buddhist monks in basic counseling skills, such training is not widespread and there is little empirical evidence to date that it has had a significant impact on servicing those with mental health care needs (Tapanya, 2010). With the important evidence based advances that are an accepted part of professionalized mental health care in other parts of the world, it remains to be seen whether the continuation of these alternative approaches can produce the kind of quality diagnosis, treatment and care that those suffering from mental illness deserve.

The Thai mental health care system is also limited by the fact that there is no universal insurance in this country. Government officials and their families have extensive health care coverage as do employees of private companies. Some coverage is available to laborers and low income citizens free of charge in government hospitals but the care is considered to be substandard by the public. Importantly, psychological assessment and therapy are not reimbursable and mental health care services usually are limited to acute psychotic episodes where immediate hospitalization is required (Tapanya, 2010). Clearly, a more fully developed discipline of psychology could have a major positive impact upon the mental health care system in Thailand. This is especially true in underserved rural areas where the presence of trained professionals is extremely limited.

Needed Reforms for Continued Growth

There is a tremendous need in Thailand for the development of curriculum that meets western standards for undergraduate and graduate training in psychology as well as faculty development that replaces rote learning pedagogical strategies with more collaborative, student centered learning. Clearly, many more institutions, both public and private, need to develop stand alone psychology departments that present modern psychology in all of its specialties, but most critically in clinical psychology. Once this infrastructure is in place, a concerted effort needs to be placed upon improving the education and training opportunities for those seeking to pursue the profession of clinical psychology. While training overseas is an option in combination with the development of joint programs with other countries, a tactic employed at Chiang Mai University, homegrown (Thai) Ph.D. programs in clinical psychology should be the ultimate goal. Indeed, the professionalization of Thai psychologists and their ultimate ability to shed the status of "second class citizen" to psychiatrists is critically dependent upon growing the psychology infrastructure in higher education.

An untapped but potentially important area for building psychology in Thailand is to encourage the development of the discipline in high school curriculums. Presently, little is done to present the discipline of psychology below the college level. This stands in marked contrast to the United States where close to 370,000 high school students annually are enrolled in psychology classes (APA, 2005).

A developing emphasis in Thai higher education is instruction in English. The Thai government is placing special emphasis upon these programs because of a renewed interest in Thailand becoming a center for higher education in Southeast Asia. Because English is the language of opportunity and is universally recognized as the world-wide language of education, health, science, engineering, finance and commerce, this commitment needs even greater attention. Pockets of progress are evident at some institutions. For example, at Chulalongkorn University, a number of academic units, including psychology, now offer separate instruction for those who want to be taught in English. Called the "International Program," these students are admitted to Chulalongkorn University separately from students who want to be taught in Thai. Very few students come from other countries. Indeed, almost all of the International Program students are Thais coming from elite international high schools in Thailand (mostly Bangkok) that feature intensive instruction in English starting in the earliest grades. Tuition for International Program students is much higher than that of their Thai taught counterparts and there is a tendency for International Program students to have lower entrance exam scores. Nevertheless, if the ultimate goal of Thai higher education is to elevate its people to compete more effectively in a global economy, then a much greater emphasis must be placed on college coursework taught in English.

In the larger context of higher education in Asia, Thailand's desire to become a hub that will attract students from the entire region has a ways to go (Purnell, 2010, World Bank Group, 2009). While Singapore, Japan and Hong Kong have already become leading regional centers for higher education, Thailand has lagged behind. As noted above, the lack of English speaking instruction is a major barrier for drawing a more international student body. This is especially true in the case of psychology where students are more likely to seek graduate education in English speaking countries such as Australia and the United States.

As noted elsewhere, the governing organizations for psychology in Thailand presently are mixed among 4 separate organizations. If these organizations combined and formed one umbrella organization of both academicians and practitioners with various divisions like that of APA, the discipline of psychology in Thailand could function more effectively and grow more rapidly in the future. This should become a major goal in this country if it is to develop the capacity to educate and train more students in the discipline and ultimately serve more of its people whose mental health care needs will increasingly depend upon trained professionals.

Lastly, the economic recession in Thailand, like that of many countries, has forced significant reductions in spending for higher education and has curtailed the development of many new programs. Clearly, a more fully developed discipline of psychology combined with other educational reforms would seem to be worthy goals. However, a fluctuating economic picture will ultimately dictate whether or not and to what extent the aforementioned changes will materialize in the future.

Conclusions

My teaching and lecturing experiences in Thailand provided an important perspective for evaluating the role of psychology in the higher education and mental health care systems of this country. The weaknesses I have identified in both academic and applied vocations in psychology in Thailand are not unique to this country. Indeed Thailand has come a very long way in developing this discipline and its higher education system over a relatively short period of time. It is clear that the trajectory of continued improvement is one that will be realized as more young Thais become educated in the basic principles of this important discipline and ultimately seek more advanced training in their own country and abroad. There are enormous opportunities for the growth of psychology in Thailand, especially for those who understand its history, culture, and traditions. Though the challenges are formidable, the potential payoff from a modernized, more fully developed, psychology discipline may be critical for the future quality of living in this country.

Lastly, I am humbled by my Thai colleagues in psychology who carry out their work with enormous dedication and pride. Many remarked to me that they felt called to the profession as a means to help their country's future development. With this collective positive attitude, psychology in Thailand is sure to thrive in the future.

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The History of Psychology Is Not What It Used to Be!

Lawson, R. B., Graham, J. E., & Baker, K. M. (2007). A history of psychology: Globalization, ideas, and applications. Upper Saddle River, NJ: Pearson Prentice Hall. ISBN: 0-13-014123-2.

Pickren, W. E., & Rutherford, A. (2010). A history of modern psychology in context. Hoboken, NJ: Wiley. ISBN: 978-0-470-27609-9.

Shiraev, E. (2011). A history of psychology: A global perspective. Los Angeles: Sage. ISBN: 978-1-4129-7383-0.

Reviewed by John D. Hogan, Ph.D.
St. John's University, New York, U.S.A.

It is surprising to realize that some of the most dramatic developments in psychology are taking place in the history of psychology. Readers who think of history as simply a recitation of established facts will be taken aback by some of the new directions that are currently being promoted. Nowhere is this more evident than in the recent wave of textbooks.

Since E. G. Boring wrote his classic text: *A History of Experimental Psychology* (1929/1950), the field has gone through remarkable changes. One obvious example can be found in the title of Boring's book. He was specifically addressing the dominant form of psychology of his time; he had little interest in applied aspects of the field. Today, more than three-quarters of the new doctoral degrees are given in applied fields, and traditional experimental psychology, while still regarded as an important and necessary foundation, is clearly in the minority.

But the new history of psychology is about more than the experimental/applied dichotomy. Contemporary historians of the social sciences have become increasingly sensitive to the role that context has played in determining the direction of the discipline. They view much of psychology as deeply embedded in the culture in which it arises. As a result, context becomes an important source of discussion. The new history also asks about the role of underrepresented groups in contributing to the discipline. Among the more obvious changes has been the large percentage of women currently entering the profession. Their greater presence leads to some obvious questions. Why were women denied entry to the profession in the early days? Who were the successful pioneer women? Who were the pioneers from other minority groups? These kinds of queries no longer represent Boring's history!

There is still another question about the new history that is probably the one of most interest to the international community. To what extent is the history of psychology as usually presented in the U.S. a genuine history of the field? Adrian Brock (2006) has established several "rules" for the way in which the history is typically portrayed. He argues -- perhaps overstating his point on purpose -- that U.S. history ignores any developments that did not have a local impact. He adds that although we in the U.S. may have some historical knowledge of European psychology, our knowledge of psychology in the rest of the world is all but non-existent. In short, he is proposing that the typical history of psychology, as taught in U.S. colleges and universities, is strongly geocentric and, thus, severely limited. He is not the only one to voice these concerns.

Three new recently published texts have arrived to address many of these issues. Each is successful in its own way. To be clear, the intention of these "new" histories is not to throw out the old history, at least not entirely. There is, after all, some value to be found even in an indigenous history. The problem arises if it is viewed as the only history, with no other possibilities presented.

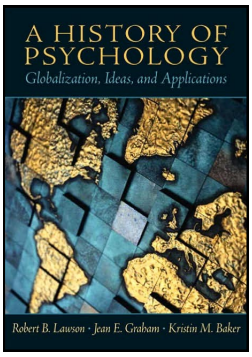

Lawson et al. are explicit in calling for a psychology that is multi-paradigmatic, with a diversity of world views. From the outset, they challenge many of the Western assumptions about science and its role in the discovery of truth. At the same time, a large middle section of their text is devoted to a somewhat traditional U.S. history, with a heavy focus on biography. But then their postmodern and global interests strongly reemerge. The final section of their book, five chapters out of eighteen, presents material on women in psychology and on racial diversity, followed by individual chapters on psychology in Russia, China, and indigenous psychologies. All in all, the text is a useful blend of the old and the new. Readers are exposed to the more traditional parts of the history, but are also given a glimpse of what is likely to be the future of the field.

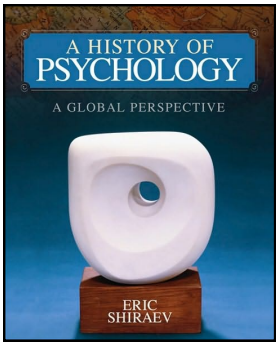

Shiraev brings a fresh approach to his text. A Russian-born American professor, with academic degrees from St. Pe-

tersburg and post-doctoral study at UCLA, he is in a strong position to deviate from the traditional U.S. text, and in many ways he does. His review of the history of early psychological knowledge addresses several non-Western traditions – not a typical feature of U.S. texts. I particularly enjoyed his chapters on clinical research and on psychology after "the Great War." I would have preferred if he had devoted a little more space to Francis Galton. But, instead, he offers a trade-off -- an extensive and very worthwhile section on Vladimir Bekhterev, the Russian behavioral psychologist. As with each of the texts being discussed here, when something is added, it is likely that something else will be taken away, or at least given reduced coverage. Overall, Shiraev often surprised me (pleasantly) with his choices. Even many of the photographs were new to me.

Pickren and Rutherford have put together what strikes me as the least traditional text of the three. They have clearly made an effort to stay away from the commonly used "schools" approach to organizing the history. Instead, their chapter headings suggest a very different organization, e.g. "Internationalization and indigenization of psychology after World War II" (chapter 10) and "Inclusiveness, identity, and conflict in late 20th century American psychology" (chapter 12). Maybe the most telling chapter heading of all is chapter 2: "Everyday life and psychological practices," a title that would have had Boring scratching his head! Although they manage to touch on many of the traditional topics, their stated emphasis is to attend to "the ways that culture, race, ethnicity, and gender have contributed to the making of psychology's history" (p. xv). And, indeed, international and feminist issues play a particularly strong role throughout the text. I looked for any major topics and persons that they missed, but came up empty handed. Instead, I found sections on such novel topics as psychoanalysis outside of Europe and the U.S., and testing and Dutch society. At the end of each chapter, the authors discuss their sources, a device that I have seen before but which I found particularly valuable here. In short, I found their text both satisfying and inventive, virtually from start to finish.

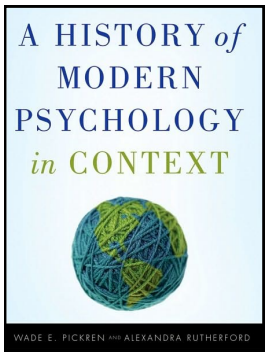

So what does this all amount to? From my perspective, these texts suggest a new and exciting time for those of us who teach the history of psychology, a wake-up call and a time to start rewriting syllabi. It will be interesting to see how extensively these texts are adopted for the classroom. We learned some time ago that most instructors in the history of psychology rely heavily on their texts to organize their courses for them (Hogan et al., 1998). It is hard for me to see how instructors could go back to the old way of teaching once they have viewed these new directions.

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ANNOUNCING THE PUBLICATION OF ...

Curriculum for culturally responsive health care: The step-by-step guide for cultural competence training
Ring, J.M., Nyquist, J.G., Mitchell, S.M., Flores, H., Samaniego, L.
Publisher: Oxford: Radcliffe Publishing (2008)
ISBN: 978-1-84619-294-4

This is a creative, comprehensive and user-friendly manual comprising a curriculum for residencies and medical schools looking to implement new, or enhance existing, curricula in culturally responsive care. It meticulously describes teaching strategies that will prove engaging to learners and faculty alike, challenging them to grow in their attitudes, awareness, desire, knowledge and skills to effectively practice culturally responsive medicine. It demonstrates commitment to teaching culturally responsive medicine towards the elimination of health disparities, be they related to gender, race/ethnicity, income, sexual orientation, religious background or world view.

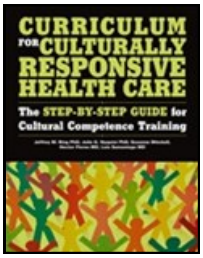

The manual includes a step-by-step guide for each year of the curriculum, with detailed session descriptions, and sections on teaching techniques, evaluation tools, cultural competence exercises, together with information on further resources. The curriculum provides a solid foundation upon which educational programs can build as they evolve to meet the needs of patients and their communities toward preventing and treating illness, and improving access to excellence in medical care.
http://www.radcliffe-oxford.com/books/bookdetail.aspx?ISBN=1846192943

Handbook of research on civic engagement in youth
Sherrod, L., Torney-Purta, J. & Flanagan, C. (Eds.)
Publisher: John Wiley and Sons
ISBN: 978-0-470-52274-5

This 24 chapter handbook represents a multi-disciplinary set of reviews of research in this rapidly growing field. Many of the chapters take an international perspective. Of particular interest are the chapter by Amna and Zetterberg who describe

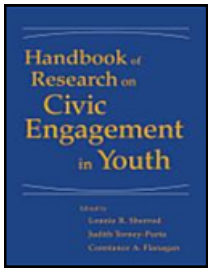

the "stand by" citizen among youth in the Nordic countries, lacking in civic engagement most of the time but ready to respond if there is a concern; and the chapter by Kassimir and Flanagan on the role of engagement for youth in the developing world. There are also chapters on immigrants, LGBT political socialization, and the participatory media culture, to give an example of current concerns that are covered. In the area of psychological theory, the chapter on developmental theory considers the theoretical base of the international IEA Civic Education Study, while the chapter by Beaumont presents a conceptual integration of efficacy as it is considered in psychology and political science with illustrations from multi-method data from PEP (Political Engagement Project. Contact jtpurta@umd.edu for more information.

Building multicultural competency: Development, training, and practice
White, Joseph. L. and Henderson, Sheila. J. (Eds.)
Publisher: Rowman & Littlefield Publishers (2008)
ISBN-10: 0-7425-6420-7
ISBN-13: 978-0-7425-6420-6

Building Multicultural Competency answers this need by providing a new Multiracial/Multiethnic/Multicultural Competency Building Model--a model that, in great detail, provides relevant solutions to this growing problem. This book will supply individuals, students, professionals, educators, and administrators who are involved in the field of psychology with a map on how to build the multicultural competency skills that will allow them to function cross-culturally. The resolutions are personally enriching, helpful to diverse peoples, and influential to other individuals, groups, and institutions.

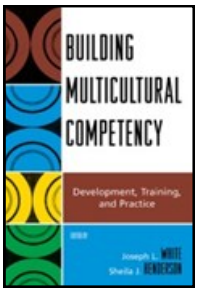

Addressing cultural complexities in practice: Assessment, diagnosis, and therapy
Hays, P. A.
Publisher: American Psychological Association (2008, 2nd ed.)
ISBN: 978-1-4338-0219-5

This engaging book helps readers move beyond one-dimensional conceptualizations of identity to an understanding of the complex, overlapping cultural influences that form each of us. Hays's "ADDRESSING" framework enables therapists to better recognize and understand cultural influences as a multidimensional combination of Age and generational influences, Developmental and acquired Disabilities, Religion, Ethnic and racial identity, Socioeconomic status, Sexual orientation, Indigenous heritage, National origin, and Gender.

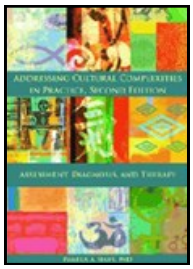

Unlike other books on therapy with diverse clients, which tend to focus on working with one particular ethnic group, this volume presents a framework that can be used with a person of any cultural identity. Organized according to the flow of clinical work (in contrast to the one chapter-per-group approach), the book's contents are summarized in handy Key Tables at the end of each chapter for ease of use in education and supervision. This stimulating book will be an important resource for counselors, clinicians, and mental health professionals working with clients from a variety of backgrounds.

Culturally responsive cognitive-behavioral therapy
Hays, P. A., & Iwamasa, G. Y. (Eds.) (2006).
Publisher: American Psychological Association
ISBN: 978-1-59147-360-2

This is the first book to integrate cultural influences into cognitive-behavioral therapy (CBT). This engagingly written volume describes the application of CBT with people of diverse cultures and discusses how therapists can refine cognitive-behavioral therapy to increase its effectiveness with clients of many cultures. The contributing authors examine the characteristics of some of the most common cultural groups in the United States including American Indian, Latino, Asian, and African American, as well as groups less commonly considered in multicultural psychology books: people of Alaska Native, Arab, and Orthodox Jewish heritage. The volume also describes the use of CBT with older adults, people with disabilities, and gay and lesbian individuals, including examples of people who hold bicultural and multicultural identities. A chapter on culturally responsive assessment, with an emphasis on the most frequently used cognitive-behavioral assessment scales, and a chapter on supervision round out this volume. Numerous case examples provide practical information grounded in an empirically supported theory, making this book a practical resource for every therapist.

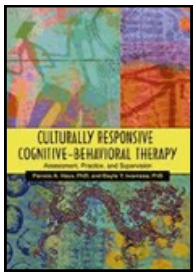

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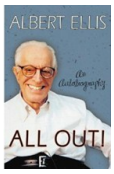

All out ! An autobiography
Albert Ellis, with Debbie Joffe Ellis
Publisher: Prometheus Books, Amherst New York (2010)
ISBN: 978-1-59102-452-1

Relational being, beyond self and community
Gergen, K.J. (2009)
Publisher: New York: Oxford University Press.
ISBN: 978-0-19-530538-8

The latest issue of *Psychology International* can be accessed on the web at: http://apa.org/international/pi

Wise Words from Veterans in the Field: Gaining International Research Experience Early in Your Career

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Within recent years, the internationalization of psychology has become more prolific in the United States with an increase in students and early career psychologists becoming interested in global research and work. Although the field is moving towards a more international perspective, it can be challenging for students to gain relevant experiences during graduate school. In addition to coursework, teaching obligations, completing the dissertation, and maintaining an active caseload of therapy clients, it can be a daunting task to try to find the time and funding to explore opportunities abroad, particularly for students who may not have mentors at their university interested in international experiences. This article tackles this dilemma by providing recommendations and ideas to initiate these opportunities from two seasoned psychologists with very diverse backgrounds in international psychology.

Dr. Charles Abramson

Dr. Charles Abramson is a comparative physiological-psychologist at Oklahoma State University where he also holds adjunct appointments in the departments of Zoology and Entomology. He is recognized internationally for his work with studying behavior in a wide range of organisms including Africanized honey bees, flatworms, ants, crabs, elephants, and humans among others. Dr. Abramson has acted as a visiting professor and conducted research in a number of countries including Brazil, Greece, Italy, Japan, Russia, Turkey, Slovenia, and Venezuela. He has taken undergraduate students to Brazil, Venezuela, Greece and Turkey as part of a National Science Foundation sponsored program to provide research experiences. Dr. Abramson serves on the editorial board of five international journals and is the author of several books including a Slovene phrasebook that has been translated into Italian and German, two animal behavior activity books that have been translated into Slovene, and a children's book that has been translated into French. When Dr. Abramson moved from the culturally-diverse state of New York to a very small college-town in rural Oklahoma, he found it quite challenging to have foreign visitors wanting to come to Oklahoma. He quickly realized that if he initiated contact and conducted interesting, well-designed research studies, people would begin to seek him out for international collaborations. For early career psychologists interested in international research, he recommends deciding where you want to go and what research you would like to conduct and then contacting psychologists, either abroad or domestically, who do similar research. Many universities offer visiting student or faculty members financial assistance in exchange for research. By contacting faculty at universities in the country you would like to work, they can assist you in finding funding and research collaborations.

With his diverse background in international research, Dr. Abramson provides a unique perspective to the field of psychology. Over the course of his international collaborations, he has come to believe that psychologists who lack international experience have a more challenging time "deviating from their network." In other words, international experiences allow for the development of entrepreneurial thinking and collaborations with professionals from diverse backgrounds and worldviews. These experiences create the opportunity for important global scientific advances and allow psychologists to expand their network of colleagues to include non-Western perspectives and theories.

Dr. Abramson, along with his international colleagues, is in the process of creating a "super-laboratory." These international researchers are developing a system of student exchanges to increase opportunities for students to work in different countries through the same research lab. Through the advancement of technology and the use of Skype, it is possible to hold research meetings with lab members from all over the globe. These collaborations allow ample opportunities for publications and research experiences. It also gives the student an opportunity to make international collaborations early in their career and experience the challenges and rewards associated with international work.

Dr. Abramson has found that the growth of these collaborations into friendships is by far the best reward of international work. Additionally, being able to teach a new way of conducting research in various countries and providing opportunities to increase science and education in less developed

countries is a passion of his. Dr. Abramson previously initiated a "Books for Brazil" program in which he partnered with sororities and fraternities on OSU's campus to gather educational books to send to schools in Brazil that lack these resources. He is committed to providing resources, which we so often take for granted, to countries that lack those essentials to help advance education and research.

One of the most important lessons learned from Dr. Abramson on working internationally is that you have to be careful to not force your views onto members of other cultures. Respect for varying world views is important in maintaining collaborations. Further, it is important to include as many collaborators from the country you are working with as possible to demonstrate that you are a "true partner" in advancing scientific knowledge.

As graduate students, it is often difficult to find the funding to travel internationally. Additionally, gaining extensive international experience during graduate school may ultimately delay graduation. According to Dr. Abramson, the only thing students really needs is "the will to do it and the right people" to help get them there. It is easy to get frustrated when there appear to be so many challenges to gaining international experience while in graduate school. Surrounding one's self with colleagues of similar interests can help keep that passion for international psychology alive.

In our second interview, we found that Dr. Kathryn Norsworthy is much more than an international researcher in the field of counseling psychology – she is an international advocate, collaborator, and friend to those with whom she works. Dr. Norsworthy has spent over a decade working in South and Southeast Asia addressing a number of topics, including ethno-political conflict, peace-building, HIV/AIDS, and violence against women (Norsworthy & Gerstein, 2003; Norsworthy & Khuankaew, 2004; Norsworthy & Khuankaew, 2008). In collaboration with her partner, Ouyporn Khuankaew, of Thailand, Dr. Norsworthy has worked with communities primarily from Burma, Thailand, Cambodia, and with members of the Tibetan community in exile. She currently teaches at Rollins College and has taken her students to India, Thailand, to the Burma communities in exile, and to the migrant and farm worker communities of Florida to develop international skills and perspectives.

Dr. Kathryn Norsworthy

During this interview, Dr. Norsworthy provided a wealth of information for graduate students and early career psychologists wanting to work in international settings and with international individuals. First, Dr. Norsworthy described what she learned from her many years in the field. She emphasized that in the beginning, she and her American colleagues assumed a power position as "the expert, common for Western psychologists entering non-Western settings." She stated, "I learned that I needed to unlearn my training regarding the superiority of U.S. mainstream values – the ethnocentric perspective - and I needed to be willing to approach situations from a beginner's mind while also recognizing that I do have knowledge and skills that may be of value in the international contexts in which I work and conduct research." Dr. Norsworthy emphatically described how important it is for those collaborating internationally to *not* assume this expert role and to engage in difficult dialogues with international colleagues around potential power issues and in the service of working from a power-sharing framework. Additionally, when working with international colleagues, it is critical to value multiple ways of knowing and epistemologies, and to "make space for people on the ground with whom we collaborate to put forward their real questions and concerns since they are really the experts on their own lives, communities, and cultures."

In making recommendations to graduate students and early career psychologists engaging in international psychology research, Dr. Norsworthy noted the importance of being aware of one's own enculturation. She said being able to shift one's worldview enough to understand where people come from and openly learn about others' values and worldviews is the first stepping stone to creating lifelong, collaborative relationships with other international researchers. Further, Dr. Norsworthy made a practical recommendation to students – to simply "go over and hang out at first." Prior to working professionally in South and Southeast Asia, she spent a lot of time with locals and opened herself up to the beliefs and practices of local cultures. After being immersed in a new culture personally, one can pursue professional relationships through local organizations, working voluntarily, and perhaps writing small grants to assist with associated expenses. From these small beginnings, one can then begin to network and form the relationships necessary to gain the funding for larger projects.

Dr. Norsworthy also commented on the role of training programs in fostering international experiences for students. She acknowledged the recent push for the internationalization of psychology and spoke with caution regarding this movement, stating that "we want to avoid a colonizing, imperialist model of internationalization, but instead it is to center the cultures, worldviews, issues and concerns of people on the ground in the countries in which we do research and practice." It is important that students gain an intellectual understanding of the issues in internationalizing psychology by reading works that critique the uncritical exportation of U.S. psychology, as well as how we can remedy the effects of this exportation. For further reading, she recommended students and educators begin with Chapter 4 of the *International Handbook of Cross-Cultural Counseling: Cultural Assumptions and Practices Worldwide* (2009), which she co-authored alongside Dr. Lawrence Gerstein, Dr. P. Paul Heppner, Dr. Stefanía Ægisdóttir, and Dr. Seung-Ming Alvin Leung. Second, she described opportunities that need to be made available to students, which she called "community engaged models

of international experiences." She described these experiences as projects in which local people and students collaborate in the development and implementation of projects that are of real value to those in the communities and cultures in which the projects take place and emphasized the importance of having local and faculty mentors and supervisors with a critical consciousness regarding cross cultural research and practice.

These interviews provide a snapshot of Drs. Abramson and Norsworthy's experiences, knowledge, and recommendations regarding international psychology research. The veterans of the field have a vast array of experiential knowledge and most are eager to share that knowledge and help those early in their careers to build upon that knowledge base. This article provides a brief framework for those interested in international research and will hopefully assist others in building on the international research and advocacy these psychologists have devoted their careers towards.

For more information on mentoring opportunities within Division 52, check out the Division 52 website (www.internationalpsychology.net). Doran and Stowell (2011) offer perspective on both the formal and informal mentoring opportunities available, and those interested in mentoring may contact the chair of the mentoring committee, Dr. Ani Kalayjian (drkalaykian@gmail.com). For those of you interested in serving as a mentor to international students, we recommend Wedding, McCartney, & Currey (2009).

Further Reading

Gerstein, L.H., Heppner, P.P., Ægisdóttir, S., Leung, S.A., & Norsworthy, K.L. (2009). *International handbook of cross-cultural counseling: Cultural assumptions and practices worldwide.* Thousand Oaks, CA: Sage Publications

Wedding, D., McCartney, J.L., & Currey, D. E. (2009). Lessons relevant to psychologists who serve as mentors for international students. *Professional Psychology: Research and Practice*, *40* (2), 189-193.

Additional Resources

www.internationalpsychology.net
www.apa.org/international
www.psychologystudents.org
http://www.internationalcounselingpsychology.org/

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Editor's Note: *This column is geared towards our student committee members and all students of international psychology. All Div52 student members are invited to submit ideas or drafts for future articles, as well as questions they would like to see addressed in future columns – such as overseas internship opportunities, study abroad availability, cross-cultural research, etc. Contact the Editor at optimalex@aol.com to submit an idea or a question.*

Division 52 Membership Survey

Dear 52 Member:
We have developed a survey to measure your opinions of your membership in Division 52. The purpose of the survey is to determine how we can improve the services that the Division provides to enhance your membership in the division. Please send any comments or questions to Janet2822@aol.com and susan.nolan@shu.edu

We welcome your input.

We appreciate your participation in this survey.

Fulbright Awards at 65: A Year Teaching at Istanbul University and Beyond*

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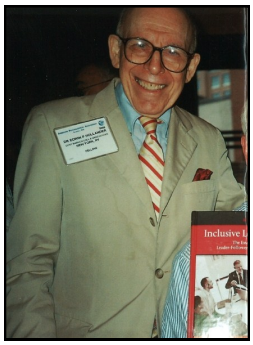

*Note: This paper was prepared for a Division 52 International Psychology Panel, March 11, 2011, Eastern Psychological Association, Cambridge, MA. The author thanks David Adams and Esther Boyd of the Institute of International Education for providing information and handouts about the Fulbright Awards. I am particularly indebted to Prof. Harold Takooshian, my friend and fellow Fulbrighter, who joined in an effort to honor the program and make its opportunities more accessible to our membership.

Background

Since its inception in 1946, the Fulbright Program has sponsored 294,000 faculty and students in the Fulbright Scholar Program and the Fulbright Student Program, currently with 7,500 grants in 155 nations. Regrettably, the Program is continually under threats of severe budget cuts, though its total cost is miniscule within our nation's international programs.

Students from Abroad

In addition to those of us who have had the benefit of time abroad from awards, there are countless students who have come to study for advanced degrees here on awards and gone back to productive careers in their home countries. My two Fulbright doctoral students, S.K. Dani from India and Barry Fallon from Australia, completed their Ph.D.s at SUNY Buffalo. At home, Dani became a much honored Dean of a College of Psychology, and Fallon was Professor of Psychology at the University of Melbourne, and elected President of the Australian Psychological Society. I mainly credit their success to the selection process of Fulbright Commissions, rather than to my influence, because they came as mature, dedicated students, and soon good friends. We maintained contact, and both returned to visit me years later. I now want to give some grateful glimpses of an exceptionally revealing year at Istanbul and beyond, some of which appears in the Afterword of my book, *Inclusive Leadership* (2009).

A Fulbright Year Teaching at Istanbul University and Beyond

My international interests brought me to apply for a Fulbright Lectureship in Europe for the 1957-58 academic year, when I was an assistant professor at Carnegie Tech (now Carnegie-Mellon University). The small number of social psychology teaching positions made for limited choice, so when I was offered such a post at Istanbul University I was glad to accept. It turned out to be a marvelous opportunity, very worthwhile in many ways, including learning about Turkey, its culture and politics, and the Islamic religion, with early visits to two monumental mosques, Aya Sofia, which had been a church under the Byzantines, and the fabled Blue Mosque. I also gave lectures in seven countries.

In July 1957, at the International Congress in Brussels, I was the guest at breakfast of Sir Fredrick Bartlett, the first Cambridge professor of experimental psychology, a great and very genial, but rare psychologist with a knighthood, chairing our social psychology session. It included Leon Festinger speaking about (you guessed it) "cognitive dissonance." I gave my first overview paper on my "idiosyncrasy credit (IC) model of leadership" at this international meeting, published the next year in the *Psychological Review* (Hollander, 1958a). I then travelled briefly, including to England with a stop to visit Bartlett's Applied Psychology Research Unit at Cambridge, at his invitation. On returning home, I soon began studying the language with a Turkish student. I had received leave from Carnegie Tech, and confirmation from Istanbul University of my appointment as a Visiting Professor, with a letter from my gracious and supportive host, the Professor of Psychology and Chair, Mumtaz Turhan. Coincidentally, he had earned his Ph.D. with Bartlett at Cambridge, as well as having studied in Germany.

The University had been founded in 1492 as a mosque school and had become a major twentieth century institution in the Middle East, with a fully developed set of professional schools and the usual undergraduate arts and sciences college. Interestingly, the medical school had almost as many women as men students, at a time when in the United States women students were in a small minority. I lectured in English, which at least half the students understood, but had sequential translation into Turkish every paragraph or so. Two graduate assistants, Iffet Dinc and Yilmaz Ozakpinar, a woman and a man, were marvelous young colleagues who very capably did the translating as well as aiding me with my research and other academic contacts and writing needs. He did analyses with me for a study I had underway, and eventually earned his doctorate at Cambridge University. She helped translate a paper I wrote for a French journal (Hollander, 1958b), and came to the USA to visit us, and then earned a doctorate at Florida State University. The Istanbul campus had many older but some newer buildings surrounded by greenery, and a familiar feel. The students wore distinctly modern, western attire. I taught a large undergraduate class in social psychology, another in research methods, and a graduate seminar in personality and social psychology.

I found interacting with the students very refreshing, for

their earnestness, and evident motivation, with good performance skills, even with the need for translation. At least half of them knew English well enough to understand it, and almost as many could speak it. Few ever talked Turkish with me since what I'd learned was largely oriented to outside life, such as buying things in stores, or making other needs known. The University faculty were almost always multilingual and also wanted to speak English with me. If not able to, then even my rusty high school French and college German helped many times to bridge the language gap.

I was not then married, and lived alone on a hillside on the Bhosporus, the central straits that separated Europe from Asia, in a two-room frame cottage that had a basic kitchen and a bathroom. Istanbul is on the same 42nd parallel as New York City, and can get cold, so heating with the kerosene heater that was the sole source was essential. However, it could not always function in cold weather because of all too frequent fuel shortages. I did get to travel to other parts of Turkey, including the capital city of Ankara, which is relatively modern and set in the central Anatolian plain, the Aegean Coast in the South, and Black Sea region in the North, from which the Soviet naval ships and oil tankers came through these straits in a daily procession that I could view from my cottage.

The Fulbright Commissions in other countries invited me to come to give guest lectures at universities and colleges elsewhere, and in the course of the academic year I visited Greece, Austria, Germany, France, Holland, England, and late in my stay, in June, Israel. My network of acquaintances abroad grew considerably, and I enjoyed seeing old and making new friends. I had some eye-opening experiences, given that the late 1950s were stimulating times, and cross-national contacts could be a challenge. In public places, I met a number of people in Britain who were angry at the American stand in the recent Suez Crisis, and said so as soon as they identified my accent. There was outspoken criticism there of President Eisenhower for withholding support for the British and French forces when they took control of the Suez Canal with Israel. It was not personalized to me though and I felt no threat. Colleagues were cordial at the British Psychological Society (BPS) annual meeting in April, 1958, at Birmingham when I came to give an invited address on interpreting conformity behavior, which subsequently was published in the British journal, *Sociological Review* (Hollander, 1959). My talk afterward generated much interest, and to my delight friendly, probing discussions.

At the Sorbonne in Paris, the director of the laboratory of social psychology was Robert Pages who invited me to do a seminar that Spring with his advanced students and colleagues, in English with occasional translation. It proved to be very lively, with continuing conversation while socializing afterward. He and I became good friends, as did others there whom I saw at meetings later, even during the difficult period of the late 1960s with upheaval on campuses. While lecturing and giving seminars in the Fulbright year of 1957-58, I had an interest in a dynamic conception of personality that takes account of social interaction. It led to a chapter I wrote for a book on personality research (Hollander, 1960), coedited by a life-long friend from graduate school days, Henry P. David, whose doctorate was in Clinical Psychology at TC. The book came from a session at the 1957 Brussels International Congress, and was also published in German in 1961 in Switzerland. Among my publications in that language are a chapter on the IC Model of leadership, and a 1978 Munich Applied Congress keynote address on applied social psychology (Hollander, 1979).

Another year spent studying and speaking abroad

In 1966-67, this time in London, with my wife Pat and our son Peter, I was fortunate to receive an NIMH Senior Fellowship at the Tavistock Institute on a sabbatical from SUNY at Buffalo. Among my lectures, I spoke at a time of great involvement by students at the London School of Economics, invited by the psychology chair, a friendly Hilde Himmelweit.

Elsewhere, I gave talks in Paris on leadership at the Institute of American Studies, and then one on organizational conformity and independence. It was to an amphitheater of masters students at the School of Economic and Social Sciences. They are said to be a tough audience, so when they stomped their feet afterward as a traditional sign of appreciation, I was very grateful, and also for their interesting questions. Another highpoint was to be invited back to speak and conduct a seminar at Istanbul University in the Spring of 1967, where we were greeted warmly and met many of my former students, some of whom had become academics.

Conclusions

These international, scholarly exchanges and subsequent contacts can be priceless experiences for all concerned. That is certainly so for this writer as an awardee, who gladly gained a more rounded, worldly perspective. Our nation would be well served doing more of this, not less, as I fear could be happening.

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Fulbright Scholar Program & Psychology from IIE - Given out at 2011 EPA Division 52 Meeting For 2012-13 Program

Finding an Award

Here are some points that deserve particular attention.

Prospective applicants should not limit their search to only awards with psychology in the title because they will find there are only a few. In 2011-12, only three awards had the word "psychology" in the award title and in the 2012-13 catalog only two do.

This should not discourage people. They need to seek opportunities through what are called "All Discipline Awards" or "Multiple Discipline Awards."

There is a search function built into the awards catalog. Searching by country/program or by "key word" is the best approach. If the "discipline" search function is used, it will bring up every "All Discipline Award". Some of these will not be appropriate for scholars or professionals in psychology.

The better approach is to use the "key word" search function. If you type in psychology here, it will only bring up awards that have "psychology" in the description of the award. Or, the prospective applicant might type in counseling, or child psychology, etc.

Alternatively, search by country and have a look at the "All Discipline Awards." If it is not clear whether psychology is included, contact the program officer listed for that country.

CIES (Center for International Exchange of Scholars) Assistance

Applicants should keep in mind that it is very good idea to be in touch with the program staff member that administered a country's program to discuss how what the prospective applicant has in mind fits with a particular country's program. The names of the program staff and their contact information can be found in each of the country entries in the online awards catalog.

Applicants are encouraged to avail themselves of the live Webinars that CIES offers each week during the spring and summer. These cover awards in particular sets of disciplines, particular countries or regions as well as how to prepare a successful application. Information about the schedule can be found on the CIES website, www.cies.org. Archived Webinars from the 2011-12 competition are also available on the CIES website. There are also some examples of key parts of well-prepared project statements.

If you are interested in applying for a Fulbright Grant, contact a program officer at 202-686-4000 and/or peruse the Catalog of Awards at www.iie.org/cies.

The Status of Public Mental Health Services in South Africa

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University of Texas School of Public Health

The Status of Public Mental Health in South Africa

South Africa, located at the southern tip of the African continent, is an independent country of approximately 48.7 million people. Based on recent health statistics, the country's life expectancy is low, at 53.4 years of age. The World Health Organization (WHO) estimates both opportunities and challenges for adequate health and development in the country. Among the opportunities are "well developed health policies" and "a National Health Act in place providing legislation" for a structured and uniform health system in the country. These opportunities are tempered by challenges including "equitable provision of health services", "heavy burden of disease" (including HIV/AIDS, tuberculosis and malaria) and "inadequate health services for health affecting service delivery" (World Health Organization, 2009, p. 1).

In addition to a high burden of disease in South Africa, there is also a high burden of mental illness in the country. According to the WHO World Mental Health Survey Initiative, the lifetime prevalence of any DSM-IV disorder among South Africans is 30.3% while lifetime risk for development of a disorder is 47.5%. The survey showed that, of the 17 countries reporting at the time, prevalence of mental disorders ranged from 47.4% in the US to 12% in Nigeria while projected lifetime risk ranged from 55% in the US and Colombia to 18% in the People's Republic of China (Kessler, et al., 2007).

The high prevalence of HIV and AIDS in South Africa contributes to the landscape of public mental health in the country. With a large proportion of people living with HIV/AIDS in South Africa, mental health disorders associated with the disease are important to consider. As many as 19% of HIV-infected South Africans also have a mental illness as defined by the Mini-International Neuropsychiatric Interview (MINI). Of all mental disorders measured by the MINI, post-traumatic stress disorder, depression and alcohol abuse/dependence were major mental illness categories discovered as prevalent among HIV-infected individuals. Of these illnesses, depression was the most prevalent (Myer, Smit, Le Roux, Parker, Stein, & Seedat, 2008).

Depression is also correlated with other physical illnesses. Naidoo and Mwaba's (2010) research indicates depression is a major factor among tuberculosis patients in South Africa. Those South Africans living in poverty and lacking sufficient resources may feel even more vulnerable upon contracting an infectious disease. For tuberculosis patients, the assumption

by community members that they are also HIV positive is an additional stressor. The interaction of these factors contributes to high rates of depression among these individuals.

On the international level, it is generally recognized that the right to health includes mental health. For example the Constitution of the World Health Organization states that "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (World Health Organization, 1946). Several international charters, also explicitly recognize the right to mental health. The International Covenant on Economic, Social, and Cultural Rights proclaims "the right of everyone to the…highest attainable standard of physical and mental health" (The United Nations, 1966). Regionally, the African Banjul Charter on Human and People's Rights requires that "every individual shall have the right to enjoy the best attainable state of physical and mental health" and that states party to the charter should "take the necessary measures to provide for the health of their people" (Organization of African Unity, 1981).

More recently, South Africa has promulgated new legislation around mental health, the Mental Health Care Act of 2002 (MCHA 2002). This Act aligns mental health services with the human rights granted by the national Constitution which provides that every South African citizen has "the right to have access to health care services" (Mkhize & Kometsi, 2008, p. 7). The Act further aims to create access to care near the homes and within the communities of mental health care users (Burns, 2008). Most importantly, however, the MHCA 2002 has an ultimate goal of making "mental health a health issue like any other, and not separate it out as something totally different from other illnesses" (Strachan, 2000, p. 5).

While strides have been made in South Africa toward a return to primary health care and legislation for a national health insurance is currently being developed, the integration of mental health into this system and into the general health care debate has been poor. Moreover, as a consequence of low prioritization by government and international donors, mental health rights issues have lagged behind others such as HIV/AIDS and the public mental health system struggles to provide adequate services to its users (Lund, et al., 2008).

The substandard provision of mental health care services, as compared to general health care services in South Africa, has been documented. While expenditure on mental health is not known at the national level, a few of the provinces have been able to report on their local expenditures. Of those provinces, only 5% of their health budgets is spent on mental health care; however, 86% of those funds are spent on mental hospitals as opposed to the desperately needed mental health services at local clinics and in the community (Lund, et al., 2008).

In addition to the low expenditures on mental health, human resources are a challenge. Most nurses in the primary health care system have an already extremely heavy workload and are sometimes resistant to the addition of mental health care users being added to their roles. Further, inadequate training and efficacy building for general PHC nurses "may lead to a loss of professional identity and job security" (Mkhize & Kometsi, 2008, p. 107). Additionally, stigma by health professionals leads to poor performance of services and often leads to mental health care users not seeking treatment (Lund, et al., 2008). While a 2010 study suggests that not all South Africans suffering from mental illness internalize negative stigma, the perception that "the general public are rejecting of people with mental illness" may still create a negative impact towards treatment (Sorsdahl, Kakuma, Wilson, & Stein, 2010, p. 6).

Moreover, many South Africans with severe psychiatric disturbances find it difficult to receive adequate mental health services at community-based facilities. A study conducted in the Western Cape, in 2010, suggests that those persons with schizophrenia spectrum disorders do not receive adequate community based care. The study suggests that although many of these individuals seek out services in community clinics, they do not receive necessary services at the primary care level and are often referred on to specialists. This is of some concern, especially in light of the MHCA 2002 which requires that "mental health services should be integrated into primary and secondary care and that patients should use tertiary care (psychiatric hospitalization) as a last resort" (Lund, et al., 2010, p. 236). A considerable number of South Africans find themselves seeking out indigenous healing practices when they themselves, or their family members, experience mental health issues and concerns. These "Traditional healers" use a variety of practices, including Traditional herbal remedies and religious/spiritual practices, to treat mental disorders. Focus groups conducted with Traditional healers (Sorsdahl, Stein, & Flisher, 2010) indicate they do not often refer patients who present with mental health related symptoms, to Western practitioners. Traditional healers in this study felt they were not treated with sufficient respect by Western practitioners, despite their contributions to the health and welfare of their respective communities.

There is some speculation that a collaborative model for mental health provision between Traditional healers and Western practitioners might be successful. A collaboration in this sector must include "evidence-based models of collaboration which promote a reciprocal collaboration at district level and which is respectful of both healing systems" (Campbell-Hall, Petersen, Bhana, Mjadu, Hosegood, & Flisher, 2010, p. 62). In order to be effective, these collaborative models must include Western practitioners who hold respect for Traditional healers and healing practices, and accommodate culturally diverse explanations of mental illness.

With myriad structural and financial challenges presenting to the health system in South Africa, it is important that the mental health of South Africans is adequately provided for and not overlooked by the public health sector. The high burden of mental illness and co-morbidity with other prevalent diseases, which aggravates the situation, calls for mental health to receive prompt and serious attention in the health care debate and in the struggle for the right to health. It is imperative that mental health as a key element of "health" overall is acknowledged and given proper positioning in the programming and advocacy activities of NGOs, the govern-

ment and activists alike.

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ATOP Meaningfulworld's Psychosocial Rehabilitations Trainings and Healing Groups

One-Year Follow-Up to the Earthquake in Haiti

January 12, 2011, Port au Prince, Haiti

Dr. Ani Kalayjian
Meaningfulworld

A solemn yet celebratory day in Haiti marks the one-year anniversary of the January 12, 2010, earthquake. 230,000 people lost their lives in this devastating earthquake, 2.3 Million people are still missing; over half of the Haitian population found themselves without homes, 70% of people's homes were destroyed. Although thousands are angry since they cannot get out of the tent-city. Today, on 12 January 2011, streets of Port au Prince were flooded with a sea of hundreds of thousands people dressed in black and white, with some mournful colors like blue and purple or bright forbidden colors sprinkled throughout the crowd.

We began the day with a march to a variety of town centers, churches, community centers, and streets at large. We went to the FOKAL Knowledge and Freedom Foundation where a select group of NGOs, artists, poets, and many other citizens reflected on their feelings of survival and remembered their losses while reinforcing their devotion to hope. "Kanpe Pale" ("Stand up and talk") was the theme for the day, which meant express yourself, and discharge emotions, while others in the audience empathically witnessed the events. We then went to pay our respects to Magalie Marcelin, a prominent figure in the women's right movement. We first cleaned up the area around the tomb, where human remains continued to be burned, releasing a strong toxic odor

that was difficult to inhale. The scent weighed heavily on my heart because it reminded me of how fragile people can be. We placed flowers on the grave, burned candles, planted an avocado tree, held hands as we prayed, sang, and then sang and prayed some more.

The afternoon was emotionally moving: We nurtured our body and soul as we sat on the terrace to witness the exact time of the anniversary of the earthquake, 4:47 P.M.. At this time, everyone stood in unison, vehicles stopped moving, and bicycles and motorbikes stood still on the roads. Everyone came out and put their hands up in the air and chanted "Jesus," then sang the Haitian anthem and continued with their marches, memorials, collective meals, and remembrance plans. The sun set very quickly, and people began dancing in the streets in the dark as candles were being lit everywhere. Driving to Jacmel, the beautiful mountains on the southeast side of Haiti, we could not believe the hundreds of thousands of people still in the streets singing, dancing, celebrating their survival, expressing gratitude to one another, and embracing one another.

The Association for Trauma Outreach & Prevention (ATOP) of Meaningfulworld is a charitable 501 c (3) organization founded in 1990, to address the psychosocial and eco-spiritual needs of surviving communities globally. Specifically, it aims to promote the advancement of knowledge about the immediate and long-term human consequences of traumatic events and promotes effective methods of prevention, relief and restoration to those traumatized and to those treating traumatized populations. This goal is accomplished through the recognition of achievement in the advancement of knowledge in the area and through dissemination of knowledge through discussion, education, training, networking, support of professionals, and collaboration with other trauma organizations, and the use of knowledge transfer media. ATOP has served in over 29 missions in 25 countries around the world post natural and human-made disasters, the recent ones being: Haiti, Kenya, Sierra Leone, Mexico, Lebanon, and Armenia. The next ATOP Humanitarian Missions are in Niger Delta in June, Congo in July, Romania in October, and Lebanon in December.

We, the ATOP Team, began our work immediately, surveying Haitians about their feelings and their continued challenges on the day of the earthquake anniversary. Haitians call one another "emotional" but at the same time, it is taboo to express one's emotions or discharge negative feelings, unless it is through reactive behaviors. The next day our ATOP team trained more than 30 students of social work and psychology from several universities, including the University of Notre Dame. Initially, an annual conference was organized to address the emotional and spiritual impact of the earthquake, but due to election upheaval as well as the cholera epidemic, the conference was cancelled. We decided to go on with our humanitarian mission and one-year follow-up evaluation as planned and were grateful for the local coordination of efforts by Fr. Wismick, Jean Yves Valcour, and Sister Lamercie. The training utilized the 7-step Biopsychosocial and Eco-Spiritual Model. This seven-step model has been utilized in over 25 countries and 30 calamities, both natural and human-made, with excellent response. Through this model various aspects of the disaster are assessed, identified, explored, processed, worked through, released, and a new meaning achieved. This innovative model incorporates various theories including: psychodynamic, interpersonal (Sullivanian), existential and humanistic (Viktor Franklian), electromagnetic (EMF), Learning theory, flower essences, essential oils, physical release (Bessel van der Kolk), mind-body-spirit continuum, chakra balancing, prayers and meditation.

Although the roads are still unpaved and rubble caused by the quake still blocks many streets, people have the determination to get to their destinations. Of course, some streets were unpaved and difficult to drive or walk through even before the earthquake, but more deterioration is taking place each day. The majority of the group expressed how the training made them feel better physically: headaches have gone away, body aches transformed, shoulders feel released of all stress; and emotionally: frustration is transformed; hope is strengthened, and plans for action solidified. Everyone prayed to have a smooth election without further violence. Haitians are a fun-loving, honest, sharing, and caring people who are tired of being used by opportunistic dictators. I then invited previous team members Junior Duplier and "Billy" Carl Prophet, who functioned as our interpreters and coordinators of transportation.

On day four we went to the elementary school in Petionville to teach on the subjects of love, nonviolent communication, assertiveness, and forgiveness. More than 200 students standing in rows in the courtyard listened attentively; it was extremely heartwarming to witness their hunger to hear, their curiosity to observe, and their commitment to the messages of love. They were asked to repeat each message after hearing it, and they did so loudly and with conviction. At the end the students surrounded me, asking me what my name was, where I live, and so on! They sang and took photos in groups. We then met with the teachers. I observed that the teachers were using physical punishment (hitting, pinching, slapping) for disciplining purposes. I then conducted a class on disciplining strategies, mindfulness, love, and forgiveness.

On day five we visited the Community Hospital that we worked in last year. We met with the directors and physicians, made an evaluation and comparison, and donated bags of medicine.

On day six we visited Complexe D'orchidee, another primary school, which is located in the heart of a debilitated neighborhood, Delmar 2—perhaps the second-poorest area in Port au Prince. This school is supported by Rose, a Haitian-American who now lives in Boston. Traveling through the neighborhood, one would never imagine there is a school in this area; in fact, the local driver insisted that we must have been given the wrong address, as there could be no school in this neighborhood. Then we turned right and went through an alley and heard the beautiful voices of the children. When we entered we were shocked to see how respectfully the students stood up in unison and began singing a "welcome to our school" song in Creole as well as in English, which brought tears to our eyes. We then visited each and every classroom, spoke with the teachers, hugged the children, and at the end, the team donated a bag of crayons, paper, and other goods to the school. The tuition for each student is $100 a year, therefore, ATOP is asking your help to support a child in Haiti by paying for one child's tuition, so they can be educated. I have attached a photo from this very school. Education is the key to the salvation of the next Haitian generation.

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The Practice of Psychology in Greece

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Psychology first appeared as an academic discipline in Greece in 1926, when a psychology course was first taught at the University of Athens by Theofilos Voreas. Since then, it has been developing slowly in Greece. It was not until recently that psychology received more attention.

Nine years ago, psychology was not a very popular field of study. If somebody were to see a psychologist to ask for help, he or she would have felt the need to hide this fact from other people. A common perception that people had was that seeking help from a psychologist meant that one must have psychological problems. It was commonly believed that one should have something very serious before seeking help from a psychologist. Even today, people harbor prejudice towards psychologists and those that seek their services. This may result from a lack of knowledge about both psychologists and psychological disorders.

Psychology is a relatively young discipline and profession in Greece. In 1979, a law was issued to acknowledge and establish the profession of the psychologist in Greece. Psychology has a 17-year "official" history as an applied professional practice. It was in 1993 when the first licenses in psychology were issued. In order for somebody to become a psychologist in Greece, he or she has to complete a four-year degree in psychology at an accredited university.

Now that licensure has been established, the question is how somebody in Greece can obtain a degree in psychology. While in the United States students usually get into a university first and then declare their majors as sophomores, in Greece, students have to decide what they want to do before entering the university. In other words, in Greece students have to know if they want to become a lawyer or a psychologist as soon as they graduate from high-school. In order to get admitted to a psychology program in a higher education institution, applicants have to take the National Level Examination. The exam typically takes place after students graduate from high-school, and performance on the National Level Examination determines if a student will be offered admission to a certain program in one of the accredited universities. If, for example, somebody fails the National Level Examination or gets a lower score than requirements for acceptance into one of the Psychology programs, he or she will have either to retake the examination or make another career choice. Since the final grade on the examination is the criterion for acceptance to the psychology programs or to any other program, there is a lot of competition. Basically, the idea is that as a future psychologist, one has to score above the average to make one's dream come true. The National Level Examination takes place only once a year and all applicants across the

country are tested on the same questions. This examination is difficult, and in order to prepare for that, applicants take private classes throughout their last year of high-school. There are even cases of students who begin preparing for the exam two years before the actual exam day. There is a lot of pressure on students to perform well on the examination because their future depends on their exam score.

Currently, there are four different universities in Greece that offer a recognized degree in psychology: the University of Crete, the Panteion University of Athens, the National and Kapodistrian University of Athens, and the Aristotelian University of Thessaloniki, which is the largest university in Greece. The duration of psychology courses of study without specialization is usually four years (approximately eight semesters). For successful completion of studies, it is important to complete 180 hours, including 160 hours (40 courses) attending classes, thesis (10 hours) and a practical training (10 hours). 75% of the classes are directly related to psychology, while the other 25% are related to other aspects, such as Philosophy and Education.

Although pursuing a Master's in psychology is not required to practice psychology in Greece, it is considered highly desirable these days. There are a few postgraduate courses in psychology offered in Greece right now. The duration of the programs is about two years, including one year of practice. Currently, there are postgraduate courses in exercise psychology, school psychology, clinical psychology, developmental-cognitive psychology, and organizational-industrial psychology. Doctoral programs in these fields of Psychology are available as well.

In case somebody has completed a psychology degree abroad and wants to work as a psychologist in Greece, he or she will have to make sure that the degree is recognized. There is an organization called the Hellenic National Academic Recognition Information Center (Hellenic NARIC). This organization works under the Hellenic Ministry of Education and is responsible for the recognition of university degrees that are awarded by accredited foreign Higher Education Institutions. The documents that are required for recognition of degrees from foreign institutions are listed on the official website: http://www.doatap.gr/en/dikaiolog.php. In the case of non-European applicants, a work permit is also necessary in order to practice psychology in Greece.

In Greece, anybody with a four-year degree in psychology can call himself or herself a psychologist. However, getting a Bachelor's in Psychology does not automatically mean that anyone can practice psychology. In order to practice psychology or use the title "psychologist", a person would have to hold a psychology license. The Greek professional license that allows practice of psychology is given to all individuals who have graduated from a psychology program with a bachelor's degree after the completion of some paperwork. It seems that this criterion is extremely low compared to what is required in the U.S. in order to become a licensed psychologist. In the United States, a Ph.D. from an APA-accredited psychology program is typically required.

According to the law, there are no official specializations in Greece. Therefore, somebody who has earned a Bachelor's in psychology and licensure along with a Master's in Sport Psychology is considered to be a psychologist with a Master's in Sport Psychology and not a Sport Psychologist. Usually, psychologists in Greece claim a specialty in some psychology area such as school or clinical psychology although the State has not yet issued an official specialty certificate. Greece is in the process of adopting the EuroPsy Certificate which is a European Certification program that was established across Europe. The purpose of EuroPsy is to define the standards in regards to the application of the profession of Psychologist in more than one setting. These standards define the requirements in order to practice the job of psychologists. The EuroPsy is not a license for the practice of psychology and is not intended to substitute for the laws in each nation for granting licensure. It is basically a set of criteria that defines the tasks of a psychologist. The EuroPsy is issued for a limited period of time and has to be renewed. In order to get the EuroPsy, one has to provide documentation of successful completion of an academic program in psychology. He or she also would have to demonstrate successful completion of supervised practical training. Last but not least, he or she would have to accept the European Code of Conduct for Psychologists.

Various associations have also been founded to represent psychologists of different disciplines in Greece, such as the Association of Greek Psychologists, the Panhellenic Psychological Association, the Greek Psychological Association (ELPSE), the Greek Association for Behavioral Modification (member of EABCT), and the Greek Psychoanalytic Association.

Although there has been a lot of progress in the field of psychology in Greece, it seems that there are many changes that need to occur in terms of the requirements for licensure and specializations for psychologists. The criteria to become a licensed psychologist have to be reviewed and should follow the standards that exist in the U.S. If the criteria were more uniform across nations, a person who is a psychologist in Greece could also be considered a psychologist in the USA.

Further Reading

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Family Influences on the Career Choices of International Undergraduate College Students

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Abstract

A literature review, consisting of books and peer-reviewed empirical research studies, was conducted on how families influence international college students' career choices. Due to the limited studies related to international students, parental influences related to other student groups were also examined to draw conclusions regarding international students. Results of the review indicated that parents play a major role in children's gender-role socialization and cultural socialization, which may affect adolescents' and subsequently college students' career choices. We discussed two cultures (individualistic and collectivistic) and how the degree of parental influence on international students' career choice may be different depending on to which culture the student might belong. Implications of our findings and suggestions for future research studies regarding international students are provided.

Family Influences on the Career Choices of International Undergraduate College Students

Despite the fact that there have been many literature reviews written over the years pertaining to college students and the career decision-making process, most of these literature reviews focus on U.S. students. There are very few literature reviews with an emphasis on international students. A majority of the U.S. colleges and universities, however, host international students; thus it is important to understand how international students choose a career in order for college career counselors and advisors to effectively provide these students with assistance. Previous research (e.g., Bright, Pryor, Wilkenfeld, & Earl, 2005; Lent et al., 2002) indicates that the student's family plays an influential role during the career decision-making process. The purpose of this review is to identify how the family may be affecting an international student's career choice, and to propose suggestions to researchers regarding future research studies that could be conducted. International students in this review refer to foreign undergraduate college students, with a particular emphasis on students from more collectivistic cultures, who were studying in the United States. Because studies were limited, it was necessary to also include research studies that looked at college students from the U.S. and in other foreign countries so that we could draw additional conclusions regarding international students. The definition of family in this review pertains to the students' parents or legal guardians, as well as to their extended family. In the following sections, gender-role socialization and cultural socialization will be discussed to determine how an international student's family may influence his or her career choice.

Family and Gender-Role Socialization

In order to understand how family might be influencing college students' career decisions, it is important to look at how these students might be socialized into their gender roles as children. Socialization is "the way in which individuals are assisted in the acquisition of skills necessary to function in their social group" (Grusec, 2002, p. 143). Gender socialization occurs when children and adolescents learn about and develop gender roles (Cobb, Walsh, & Priest, 2009). Wood and Eagly (2002) indicate that gender socialization begins in infancy and that as children grow up they develop gender schemas in which they discover the concept of being men and women. The most important gender socializing medium for children is family, especially parents. West and Zimmerman (1987) state that the conception of gender develops on a daily basis through "social interactions" in order to develop differences between men and women (p.136). Based on this premise, children learn and establish gender role identities through the constant interactions they have with their parents. Gelman, Taylor, and Nguyen (2004) also indicate that children learn gender roles by watching their parents and other adult family members. Leaper (2002) indicates that parents teach their children values and attitudes about gender, as well as what they consider being appropriate gender roles by mentioning or enforcing gender stereotypes.

Children's and adolescents' gender development may affect their career development, which begins during middle childhood and early adolescence. Parents are the most influential factor regarding children's career development because they pass on career information as well as their beliefs regarding certain careers in relation to gender to their children (Bryant, Zvonkovic, & Reynolds, 2006). One of the main ways parents influence career development is by influencing their children's academic development based on their attitudes toward gender and gender stereotypes, which may affect children's perception of their level of competence in different academic subjects (Wigfield, Battle, Keller, & Eccles, 2002).

Recent research in a western cultural context has examined how parents socialize their sons and daughters regarding math and science. Tenenbaum and Leaper (2003) discovered that sons and daughters are treated differently by parents. They found that fathers gave sons more explanations and used more scientific vocabulary than daughters during a physical science lesson. Lindberg et al. (2008) found gender differences in mother-child interactions they observed during a math assignment. Mothers who believed in gender equality gave equal support and teaching to both boys and girls, whereas mothers who believed in traditional gender roles and

who were more educated in math gave girls more coaching and help than they gave the boys. Thus, both mothers and fathers may encourage or inhibit their children's attitudes and future career interests in different subjects. Based on these research studies, female international students from a western culture may believe that they are not as good as male students in math and science careers and may become less likely to pursue these majors. In fact, UNESCO (2008) found that women worldwide are underrepresented in the field of science. Out of 121 countries surveyed, only 15% of the countries have reached gender equality in science; most are located in Central Asia.

Family and the Cultural Socialization

Like gender socialization, cultural socialization is a type of socialization children and adolescents are exposed to predominantly by their families. Rothbaum and Trommsdorff (2007) state that there are two different types of culture children and adolescents are socialized into: individualism and collectivism. More individualistic cultures emphasize autonomy and independent decision making, whereas more collectivistic cultures focus on interdependence and having close social relationships (Rothbaum & Trommsdorff, 2007; Triandis, 1995).

A family's involvement in a child's cultural socialization starts during infancy through the process of parental attachment (Bridges, 2003). According to several researchers (e.g. Harwood et al., 2002; Keller et al., 2004), more collectivistic parents spend more time together with their young children, such as holding them, which helps the children develop close relationships. More individualistic parents help their children develop autonomy by being more separated from their children and encouraging them to make their own decisions.

Parents also culturally socialize their children through their parenting styles. The authoritative parenting style is considered to be the best parenting style for more individualistic cultures because it encourages children to be independent, whereas the authoritarian parenting style is considered to be the best for more collectivistic cultures because it emphasizes discipline and the importance of having close social relationships (e.g. Baumrind, 1971; Chao & Tseng, 2002).

Mazzarol and Souter (2002) found that international students' families are a major factor in decisions to study abroad. Once international students arrive in the United States, Poyrazli, Kavanaugh, Baker, and Al-Timimi (2004) found that they begin going through the process of acculturation, which is the process of having to adjust to a new culture. Not only do international students have to adjust to American culture, they have to become fluent in English and adapt to the U.S. education system as well (2004). Yeh and Inose (2003) said that acculturation may be more difficult for international students who come from more collectivistic cultures because more differences exist between international students from more collectivistic cultures and international students from more individualistic cultures.

Yi, Lin, and Kishimoto (2003) stated that succeeding academically is the most important concern international students have. This could be due to the fact that, according to Popadiuk and Arthur (2004), international students feel considerable pressure from their families to do well. Even though international students want to achieve their academic goals, Prue (2004) indicated they may have a hard time adjusting to the U.S. education system due to different teaching styles. Zhang and Dixon (2003) indicated that how international students deal with their acculturative issues can affect whether or not they will academically succeed. Therefore, students who struggle with acculturation may not do well in college.

It is important to present a major recent research study by Singaravelu, White, and Bringaze (2005) that compared more individualistic cultures to more collectivistic cultures regarding college students' career choice. They compared U.S. students to international students in order to look at how satisfied these students were with their major/career choices. The international student group was divided into Asian and non-Asian groups. All of the students indicated that their family, particularly their fathers, was an important influencing factor when they were choosing a major/career. Family influence was considered to be a stronger factor for the non-Asian international students, whereas it was considered the lowest by the U.S. students. Constantine, Wallace, and Kindaichi (2005) state that particularly college students from more collectivistic cultures are socialized to consider how their decisions will affect other people, so they will choose careers that will satisfy their parents. Tang (2002) points out that college students from more collectivistic cultures are more willing to compromise with their parents regarding their career choice. Therefore, international students from more collectivistic cultures may defer their career choice to their parents or feel that they need to strongly consider their family's wishes regarding their career choice, whereas the ones from more individualistic cultures may feel that they have more control over their career choice.

Conclusions

Based on the research studies in this literature review, it appears that families influence international college students' career choices through gender-role socialization and cultural socialization. Families, especially parents, start giving their young children messages about gender roles and what each gender stereotypically might want to choose as a career. In addition, families in more individualistic cultures tend to encourage their children to make their own decisions with some guidance, while families in more collectivistic cultures may expect that the child gives more weight to his or her parents' wishes. Therefore, counselors, student advisors, and college faculty who work with international students may need to consider the influence of the family when helping these students to make the decision to declare, stay in, or change a major.

One limitation of this literature review is the fact that few research studies related to career choice have been conducted on undergraduate international students who are studying in the United States. Because there is a lack of research

regarding the career decision-making process of international students, there are several research studies that researchers should consider conducting. The first research study could be a longitudinal study that looks at undergraduate international students. Researchers could begin to follow the students from the time they enter college in the United States, and they could look to see what the international students' majors are when they begin their college education in the United States. The students could be followed throughout their undergraduate education in order for the researchers to explore their patterns of choosing a major. Researchers should also look at the frequency with which international students change their majors. A second research study researchers could conduct is a study that compares U.S. and international undergraduate students in order to see if there are any possible differences regarding how often the students change their majors while they are in college. If the researchers find any differences between the U.S. and international students they should explore the reasons why the differences exist.

Finally, there is still a lack of research regarding the specific ways in which international students' families influence their career decisions. Therefore, more research needs to focus on how the family influences international students' career choices. In order to do this, researchers should conduct a mixed method study. During the first part of the study the researchers could interview the international students to see how their families might be influencing their career choices. The researchers would then administer a career choice survey to the international students to answer questions about their major choice. Both the interview and career choice survey questions should be based on the Chope's Family Protocol, which provides ways of assessing how the family influences the career decision-making process of college students (Chope, 2005). Chope's Family Protocol has been used with many different cultures and ethnic groups, which makes it a good assessment to use with international students. Because Chope's Family Protocol is one of the few assessments that measures how the family influences college students' career choices, developing measures to explore how the family influences the career decision-making process of college students should be an important part of career development research. Due to the fact that more recent research has begun to focus on the career decision-making process of international students, this is likely to continue to become a popular research topic in future studies for years to come.

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Social Psychology and International Conflict Resolution

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For almost 25 years, I sometimes tolerated, sometimes enjoyed, a typical academic career in social psychology, teaching at five universities, publishing a textbook and research papers, and even serving as a department chair. During those years, having arrived in academia mostly by chance (Gross, 1998), it occasionally occurred to me that ivory tower scholarship was not my natural calling. For one thing, I often found myself diverted off campus by forays into political campaigns, business deals, and social causes. For another, I was afflicted by writer's block and almost perished on the tenure track.

As a grad student at Stanford, during some very difficult years at the University of Wisconsin in the late 60s (where the three "colleagues" closest to my interests were unavailable and unsupportive), and even after becoming tenured, I continued to feel tension between relatively pure science shared only with interested colleagues, and applied work with potential to impact and benefit non-academics and the general society.

My first attempts to stray from the rigorous laboratory work that defined the experimental social psychology of the 1960s were ventures into field studies inspired by the work of Donald Campbell and others. Abandoning the Psychology 101 subject pool yielded results with increased external validity, created interesting work for my collaborators and me and provided fodder for some papers and talks (Gross & Doob, 1976; Doob & Gross, 1968; Gross, 1975). However, despite some interest by the media including a mention in Playboy, the impact of these field studies on society was hardly noticeable.

Prior to relatively recent involvement in international work, my most extensive attempt at applied research began during the painful years at Wisconsin in collaboration with social work colleague, Irving Piliavin. Based on earlier laboratory work demonstrating that people often do not ask for needed help (e.g. Broll, Gross, & Piliavin, 1974), we successfully applied for a federal grant to study the effects of different methods for delivering service to a population of welfare mothers in Minneapolis. An extensive three-year field study yielded results that clearly identified a means of service delivery that greatly benefited the recipients compared to the standard method in use at the time. Subsequently, we prepared the results for publication in a major social work journal, (Piliavin & Gross, 1977), and sent several copies to the U.S. Department of Health Education and Welfare.

We anticipated that it would be difficult to obtain the attention of busy policy makers, but surprisingly we found that our results were read and understood. Naïvely, however, we had failed to recognize that our interests and values differed from those with power to implement and act. We had inadvertently delivered a template that allowed bureaucrats to determine how they could conserve funds, mainly by retaining the programs *least* likely to result in more aid for the needy target group. Because this and other attempts at applied research failed to have a desirable impact on various social problems, I came to recognize that academic research without opportunity to implement results was inadequate to affect real world phenomena.

A fortuitous diversion into a lucrative business in the mid 80's provided an opportunity for me to finally resign my academic position and to dedicate more of my time to applied problems, especially in the international arena. This travel-related business also provided cheap or free airfare that allowed me to become familiar with cultures on several continents.

Although I had previously devoted some time to projects outside the USA including airline consulting in Ethiopia and teaching English in Mexico, I was formally introduced to international conflict scholarship and peacemaking applications during an intensive summer fellowship at the Solomon

Asch Center for Ethnopolitical Conflict at the University of Pennsylvania in the late 1990's (http://www.brynmawr.edu/aschcenter/about/index.htm). Visitors to the Asch workshops included many international scholars, including psychologists Paul Rozin and Clark MacCauley who co-directed the program, and Herbert Kelman, Ervin Staub, Michael Wessels, among many others. Roy Eidelson, past president of Psychologists for Social Responsibility, served as Executive Director of the Asch Center until it moved to its present location at Bryn Mawr College in 2008.

In addition to the excellent lectures, stimulating discussions and extensive readings, the Asch center experience led to a number of collegial connections, some of which resulted in interesting and challenging international work. For example, Shanee Stepakoff invited me to offer mediation training to her staff at the UN Special Court in Freetown, Sierra Leone; Charles Malcolm asked me to deliver a research colloquium on help-seeking in Cape Town; and Thomas Hill opened the door to my current adjunct professorship at New York University's Center for Global Affairs where I offer applied courses in mediation skills.

Having devoted much of my volunteer time after retirement from academia to conflict resolution work, especially mediation (Gross, 2007), I often attended professional ADR (Alternative Dispute Resolution) conferences. While attending one of these meetings a few years ago, I heard Kenneth Cloke, co-founder of Mediators Beyond Borders (MBB) (www.mediatorsbeyondborders.org), speak about his vision for the new organization. The opportunity to combine my international interests with the conflict resolution skills I had acquired from many trainings and volunteer work, mainly with the Safe Horizon Mediation Program in New York City[1] , became apparent immediately.

During the past few years, in collaboration with MBB teams, I have developed and worked on a number of projects designed to build conflict resolution capacity in locations around the world. My involvement with MBB as a project leader and as a board member, has included working with Liberian refugees and child soldiers, Hurricane Katrina victims, villagers in Colombia and members of the Iraqi Peace Network. In addition, I have advocated for the use of mediation to resolve conflicts with delegates and others attending UN climate change conferences, and with Ghanaian attorneys and land settlement officers.

At first, I viewed my ventures into peace making and conflict management as a separate career almost completely divorced from the many years endured within psychology departments. However, it soon became apparent that important principles derived from social psychological research could be applied during MBB and other interventions.

One of the most basic principles, and one often ignored when dealing with groups in conflict, is that all stakeholders must be invited to participate in facilitated discussions, meetings and other activities. Although sometimes impractical when dealing with very large populations, I consider it critical to ensure that those who are likely to affect decisions and actions be strongly encouraged to attend and participate in all meetings. Inclusion of relevant stakeholders has almost become a standard practice, but this was not always the case. My consciousness for this critical factor had been raised by one of the studies assigned in my first year of social psychology grad school!

Although some have criticized the interpretation of its results, the classic study at Harwood Mills (Coch & French 1948) indicates that decisions reached with full group participation were more likely to be accepted and implemented. The Coch and French results are not directly relevant to conflict situations, but there is a strong implication that people not present or even those represented by others are less likely to buy into whatever agreements or decisions are made during group meetings. As a consequence of the Harwood Mills research combined with much group work experience, I now delay, reschedule, move venues, and take whatever actions are necessary to encourage full attendance of all who are involved in a conflict. One of the first tasks in mapping a conflict, and planning for useful interventions, is to identify all of those involved or affected. The identification process often involves intense interviewing and networking to make sure that all of the critical players are invited to the table and strongly encouraged to attend.

Another important strategy borrowed from social psychological theory and research is closely related to the popular and widely tested "contact hypothesis" and the renowned Robber's Cave study (Allport, 1954, Sherif, M, Harvey, O.J., White, B.J. Hood, W.R. & Sherif, C.W., 1969/1988) that predict that when parties work on a common problem, they often develop more positive attitudes towards each other. Allport and others have proposed and demonstrated that properly managed contact between adversarial groups working on a common problem can lead to better interactions. Some necessary conditions for the effectiveness of intergroup contact include equal status between groups or parties; common superordinate goals for the task at hand; and an interdependent task structure that requires cooperation between groups to perform the task well.

Because of the potential benefits of such contact, we have recently introduced pre-mediation training as warm-up exercises in large multi-party conflicts. In addition to the usual advantages of trainings, especially those that include interactive skill exercises, these exercises also offer benefits derived from simply engaging disputants in a common task not directly related to the conflict that brought them to the table. This method has been employed successfully among groups involved in New York City community disputes and in a recent MBB intervention between two potentially violent student groups at a West African University.

In the West African sessions, we successfully risked including some content material in the training exercises that related to issues at conflict. After the training, which included tasty food, videos, handouts with major take-away points and certificates of completion, many of the participants recog-

[1] After July 1, 2011, this Program will become independent and be renamed "New York Peace Institute".

nized that they had survived, tolerated, and in many cases enjoyed mutual activities with others previously identified only as adversaries. In a sense we had successfully channeled the spirit of the camp boys at Robber's Cave (Sherif et al., 1948) who had first despised and shunned boys assigned to competing teams, but later learned to cooperate with them after collaborating on common tasks.

Although we have consciously borrowed major principles from social psychological research related to the Harwood Mills and Robber's Cave studies, many of our other international practices have benefited more subtly from social psychological theory and data. For example, when we are able to successfully engage adversaries in dialog or other peaceful mutual activities, their cognition that "I worked/ talked with them successfully" can be viewed as inconsistent with the cognition that "I hate them" or " I should shun them". When opposing parties engage in mutual activities, negative beliefs become inconsistent or dissonant (Festinger, 1957) with the positive behavior and are likely to change.

As another example, we often encourage disputing parties to understand the other side's point of view, and to empathize with their feelings when mediating or facilitating dialog among adversaries. And when asking our clients to consider an intervention or training, we usually include both potential benefits and costs or risks. These mediation and presentation practices are at least tenuously related to the finding that two-sided communications are usually more credible and often more persuasive than a one-sided sales pitch (Hovland, Lumsdaine, & Sheffield, 1949).

Our international work is certainly not the first or only application of psychological principles related to conflict, negotiation, and peacemaking (e.g. Pruitt 2011; Rubin 1981; Kelman, 2010). Many prominent social psychologists have produced excellent research and writing that is directly relevant to negotiation, conflict management and peacemaking. And a number of academic journals[2] regularly publish articles applying psychological data and theory to peacemaking and conflict resolution.

The empirical frame inculcated via a solid education and extensive experience in academic psychology does more than make it likely that we will apply concepts like inclusion and equal status contact. In addition, a scientific background leads to better understanding of the utility of systematic data collection that can be used effectively in evaluating projects to determine whether they should be continued, adjusted or abandoned. Lastly, experimental social psychology's focus on how situational variables frequently overwhelm individual differences leads us to consider the impact of various interventions and/or causes of problems in general (for more on this issue see Zimbardo, 2007).

[2] See for example *Peace and Conflict: Journal of Peace Psychology*, The Journal of the Society for the Study of Peace, Conflict, and Violence: Peace Psychology Division of the American Psychological Association; and *Conflict Resolution Quarterly*, a publication of the Association for Conflict Resolution http://www3.interscience.wiley.com/journal/97519532/home.

Looking back on my career change from academic to applied and international work, it seems less an abrupt break and more a fortunate transition. It has become increasingly clear that my peacemaking colleagues and I often build elements of our interventions and projects on the solid foundation of academic research.

Note: *Thanks to Harold Takooshian for suggesting that I contribute this piece and to Sarah Davies for helpful comments.*

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A Brief Experiment in China: A Western-Style Department of Psychology at Fu Jen Catholic University, 1929-1933

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In 1932 the *American Journal of Psychology* published a review of recently established psychology laboratories in China (Chou, 1932). As an update to this publication Gregory J. Schramm, a Benedictine monk and experimental psychologist, published a brief report in the journal *Child Development* describing the psychology laboratories that he helped establish at Fu Jen Catholic University in Beijing. Among the three laboratories at the university Schramm identified the child study laboratory as most distinguished, "… believed to be the first and only one in China, which was originally erected and completely controlled by a department of psychology without school system connections" (Schramm, 1933, p. 279).

Gregory J. Schramm was born in Newark, New Jersey on January 9, 1898. Schramm completed his AB degree in St. Vincent's College in Beatty, Pennsylvania (1920) and was ordained in the order of St. Benedict (O.S.B.) in 1925 after completing S.T.B. and S.T.L. degrees at St. Vincent's Seminary in Latrobe, Pennsylvania (Curtis & Elder, 1960). After earning an MA from Catholic University of America, Schramm continued his training in experimental psychology in two influential American departments of psychology. He attended Columbia University at a time when the "Columbia School of Psychology" under W. S. Woodworth had already established itself as one of the "Seven Psychologies" (Heidbreder, 1933). Schramm's (1927) thesis "The Relative Affectivity of Association and Personal Reference Stimuli as Measured by the Psycho-galvanic Reflex and Introspection" was within the framework of Woodworth's dynamic psychology which supported the use of introspective and objective response measures (Graham, 1967).

Figure 1 – Catholic University of Peking changed its name to Fu Jen Catholic University when the Chinese Ministry of Education officially approved the university in 1927. The Cassinese-Benedictines of St. Vincent Archabbey purchased the Beile Tao Palace in Beijing as its campus and constructed the main building in 1930. (Courtesy of St. John's Abby, Collegeville, Minnesota)

Schramm continued his training in experimental psychology at Johns Hopkins University but shifted his interest to child development, earning his Ph.D. in 1929. His dissertation, *Direction of movements of children in emotional responses,* was a systematic examination of children's approach and avoidance responses to animals. Schramm systematically exposed children 3 to 6 years of age to a rabbit, rat, frog and parakeet at successively varying distances as they were confined to a high chair or free to walk in the room. The high chair used in the confined condition contained four pneumatic sensors that measured gross body movements. Among his observations was one of the earliest descriptions of habituation in children. His dissertation work was not published immediately, however, appearing in the journal *Child Psychology* six years after earning his doctorate (Schramm, 1935). But there was good reason for the delay in publication. Shortly after earning his Ph.D. the Cassinese-Benedictines of St. Vincent Archabbey (Latrobe, Pennsylvania) appointed Schramm acting dean of the College of Education in a new university in China– Catholic University of Peking (Beijing).

Two Chinese Catholic scholars from Beijing petitioned Pope Pius X in Rome in 1912 to establish a Catholic university in China that would integrate Christian faith in its curriculum with Chinese intellectual and western scientific thought. At the request of the Holy See the Cassinese-Benedictines of St. Vincent Archabbey established the university in 1925 beginning with an affiliation with Fu Jen Academy (also named McManus Academy of Chinese studies). The university's duality as a western Catholic and Chinese university was achieved successfully by introducing western science

Figure 2. Gregory Schramm in the general psychology laboratory of the Psychology Department at Fu Jen Catholic University. (Courtesy of St. John's Abby, Collegeville, Minnesota)

while preserving an appreciation of Chinese culture (Chen, 2004).

In 1927 a reformed Ministry of Education under a new Chinese National Government forced expansion of the university from 1 to 3 schools and a name change to *Fu Jen Catholic University*. One of the added schools was the School of Education consisting of a Department of Pedagogy and a Department of Psychology. Schramm was acting dean of the School of Education the first year but served as the chair of the Department of Psychology his remaining years at the university (Chen, 2004; Wu, 1993). The department curriculum was described as offering "… all the important fields in the realm of Psychology at the collegiate level. The varieties of psychologies spread over the four-year course" (Fu Jen News Letter, April 1931, p. 7). In the early days of experimental psychology Catholic psychologists at Christian institutions had to come to terms with the new scientific psychology by defending its legitimacy while arguing against assertions that the new science demanded an atheistic or agnostic philosophy (Misiak & Staudt, 1954). With training in experimental laboratories at three different American psychology departments Schramm was in an excellent position to introduce the science of psychology to Chinese students within a Catholic context.

Schramm designed the child study laboratory primarily to observe and test preschool children under controlled laboratory conditions. The young American psychologist's efforts as director of a "pioneer child study laboratory" in an exotic land even made notice in the popular press (The Science News-Letter, 1932). However by 1933 as a result of the hardships of the Great American Depression the Cassinese Congregation of Benedectine Monasteries could no longer finance Fu Jen Catholic University, transferring operation to the care of the *Divine World Fathers* (Wu, 1993). When the Chinese Communist Government took power in 1949 the Ministry of Education dismantled Fu Jen Catholic University, annexing what remained to the Beijing Normal University in 1952. Fu Jen Catholic University would be re-established in Taiwan in 1961.

With St. Vincent Archabbey no longer involved in Fu Jen Catholic University Schramm returned to America. In 1937 he was hired as a lecturer of psychology in the urban division of Seton Hall College in New Jersey (Setonian, Feb 8, 1937). The urban division of the college was established in 1936 as an extension college to provide men and women unable to attend the program at the main South Orange campus (which at the time was exclusively male) an opportunity to attend college in Newark and Jersey City. By the next academic year Schramm was appointed professor of psychology on the South Orange campus in the newly named Department of Philosophy and Psychology. He would establish a laboratory and teach experimental psychology and child psychology. But by 1940 there was no longer a Department of Psychology on the South Orange campus and Schramm had left to teach for two years in the graduate program at Fordham University. He would eventually return as a faculty member in a newly formed Psychology Department at Seton Hall University and retire in the late 1960s. Schramm died September 15, 1972.

Figure 3. Gregory Schramm testing a child participant in the gardens of the Child Study Laboratory. (Fu Jen News Letter, April 1931, p. 14)

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The January 2011 issue of *Interpersonal Acceptance*

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Thoughts on the Status of the Mental Health Psychologies in Thailand

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Introduction

In an attempt to promote the development of Psychology in Thailand, and especially those disciplines dealing with mental health as Clinical Psychology, Counseling Psychology, Social Work and Marriage and Family Therapy, senior scholars from the US have been annually invited to lecture or teach mini-Psychology courses, consult on curricular development and promote the exchange of Thai students to the US for advanced doctoral training (Svare, 2011). Among the intended audience of these top-down efforts, it is presumed would be Thai administrative personnel who are in the position to initiate and establish the necessary structural organizations to implement new Psychology programs and Departments at various institutions of higher education in Thailand. Not only are advanced programs at the Master's and Doctoral levels needed, but a dynamic and flourishing undergraduate college level curricular is a sine qua non to provide a broad based feeder system into the yet-to-be established graduate programs. This is an important step in the revitalization of

the profession of Clinical/Counseling Psychology in the Thai Mental Health Care System without which jobs taken over by other mental health professionals would override and make superfluous the Thai Psychologist, or at least relegate them to technician status, similar to the first generation of Thai psychologists (Tapanya, 2004).

Impediments

However, there are at least five deterrents/impediments for the growth and development of Clinical/Counseling Psychology in Thailand. These may be broadly categorized into the following areas: cultural, religious, educational, economic, and the influence of the family.

The cultural area involves the attitude ingrained in young Thais from very early on to respect their elders, to treat them with deference and unquestioned obedience. These concepts are expressed in the Thai term *kao rop* meaning *respect*. In a much broader sense it is expressed in the relationship between *phuu yai* (big person) and *phuu nawy* (little person) along the lines of social rank defined by age (adults vs. children, elder vs. younger siblings), wealth (haves vs. have-nots), occupational status (employers vs. employees), education (highly educated vs. less educated), political power (elected vs. appointed), law enforcement (military/police vs. civilians), nationality (Thais vs. farangs or foreigners), etc.

In the religious arena, it is not uncommon for young Thai males to enter a Buddhist Wat (temple) for a short period (1week up to 3 mos.), and this brings great merit for the family. Here the novitiate is exposed to a set of monastic vows imposing disciplinary rules accompanied by meditation and religious (Dharma) study. During the day, barefoot robed monks may be seen receiving gifts (food or money) in their bowls, and through this process, much merit is accorded the donor. Monks are often brought into homes to bless and recite prayers for anniversaries as for a respected and departed member; into Universities to religiously celebrate auspicious occasions, into political (see Fig. 1) and monarchy-related events. The ever pervasive appearance of monks is a constant reminder of the role of Buddhism in the daily life of all Thais. Monks are sought out for counseling on a variety of psychological issues or emotional problems, and the donation can be much less than the cost of seeing a Clinical Psychologist or a Psychiatrist, depending on the generosity of the donor. There is still a strong stigma attached to seeking mental health services, so it is more socially acceptable for Thais to seek help from monks.

Fig.1 The interior of Wat Luang in the city of Phrae (Northern Thailand) where a wealthy merchant from Chonburi has made a large donation to the monks in the presence of local government officials, bringing together the religious, political and familial influences ever present in Thai society.

In addition, there is a famous Wat in Saraburi Province that has a reputation for helping people who are suffering from drug (heroin/opium) addiction by employing traditional Thai herbal medicine, psychological support and aspects of Dharma. Wat Tham Krabawk claims a success rate of 70 to 80% with treatment lasting up to 6 months, initially involving emetic herbs to detoxify the body. Upon completing the program, patients ingest a sacred paper inscribed with a vow to remain drug free, which if broken would incur the wrath of the spirit world. In 1975, after 57,000 addicts were treated, the respected head of this Temple was awarded the Magsaysay Prize. Thus, because of the manner, style, discipline and the respect accorded the Buddhist monks, the Thai people, in general, believe that Monks can help solve or ameliorate their everyday problems, more so than psychologists and/or psychiatrists.

Thai people have their own way of dealing with stress and emotional problems. They practice meditation as prescribed by Buddhism. It would be difficult to scientifically prove that this technique has validity but the incontrovertible fact is that the growth of people from all walks of life practicing meditation suggests the use of this technique is considered a practical way of dealing with emotional issues, perhaps by leading to an increase in self-awareness.

The current Thai system of higher education with its emphasis on not questioning or challenging the authority of the Professor directly, because it is improper or impolite, is well known. This stifles creativity and independent thinking, while simultaneously encouraging rote learning where, in many cases, the notes of the Professor become the notes of the student without passing through the brains/minds of either. It would be interesting to note if there are any seminar courses or independent research courses both on an undergraduate level as well as in those Psychology programs offering a Ph.D. degree (like Chulalongkorn Univ.). It would be interesting to specify the courses constituting a Psychology major in the undergraduate curriculum. For instance, are there courses in Abnormal Psychology, Tests and Measurements, Internships or Clerkships, Biological Bases of Behavior, Theories of Personality, Social Psychology, etc.? Is a Senior Research Project in the college curricula required before graduating? This offers an opportunity for the student to actually get involved in designing/ planning and carrying out his/her own research. If a senior Project is required, are

there opportunities for these studies to be presented? This could easily be accommodated at Mahidol University (See Fig. 2) where many such conferences are annually hosted. Alternatively, is there a national honor society serving as a venue for such an activity, similar to the US Psi Chi Society that is strictly for undergraduates? There are a number of advantages for such a formation, not the least of which is identification with the discipline, coupled with an increase in motivation to study further by working for an advanced degree. This bottom-up approach would further strengthen the development of Psychology.

Fig. 2 An aerial view of Siriraj Hospital and Mahidol University on the banks of the Chao Phraya River, Bangkok, Thailand

Another important element having a detrimental effect on the formation of new programs concerns the recent Thai economic situation. A change in the government's policy toward funding higher education programs occurred at and around 2004. Prior to that, public universities were under the jurisdiction of the Ministry of Education and received financial support from them. Since then, the economic recession in Thailand mandated a reduction in subsidies, thereby forcing all public universities to initiate fund-raising activities. In addition to curtailing new programs, all employees of public universities hired after 2004 were no longer considered civil servants, and therefore, were not entitled to health care or retirement benefits. Without money, it is impossible to hire the necessary faculty to staff new programs to meet the need of an expanding student enrollment. While recognizing the need for development in the direction of Psychology, its growth seems to be halted or at best, severely curtailed. Unless the Thai people are aware of the importance of Psychology in their everyday life, the chance for expansion is minimal, regardless of the money. Other programs focusing on public health issues (lymphatic filariasis, HIV-AIDS, mosquito allergies, malaria, parasitic infectivity, etc.) are considered more important, and therefore, are more likely recipients of the limited financial aid that is available.

Finally, the role of the family impacts the type of care received by the mentally ill. At the center of Thai society is the family unit consisting of all blood relatives and those who marry into the family. In the next strata, are friends, professional colleagues, and close acquaintances. Beyond this circle is everyone else. When anything goes awry within the family circle, the members close ranks and attempt to ameliorate or lessen the negative impact. The Thais have great respect for the family unit. Therefore, in many cases, when one member is stricken with a mental illness, instead of seeking long-term care in a mental hospital, home care is the preferred mode of treatment. This obviates, to a certain degree, the stigma associated with "losing face" by having a mentally ill family member, even though hospitalization and the treatments they offer are recommended. Also, since most Thai parents want their children to be well, seeking mental health services may bring shame and guilt to the family. Consequently, people with mental health concerns may exhibit reluctance in seeking parental advice/support, and would more likely seek out friends. Thus, the concept of peer counselors becomes critical in the advancement of Psychology in Thailand. China and Taiwan have already adopted this model under the supposition that it increases/improves mental health more effectively. It also may help in "planting seeds" to germinate interest in a new generation of students to pursue their education in this important field, reasoning that they also can make a difference.

Conclusions

These impediments are not written in stone. They can be overcome but the process is long and arduous. There is no quick easy fix. The establishment of new curricula in new programs is a combination of a top-down effort by administrators and a bottom-up approach by the undergraduate departments. This will strengthen a broad-based foundation for the implementation of graduate level training that is currently lacking. Marketing is needed to inform and educate the Thai people about Psychology. This may be realized through (a) advertizing and public relations efforts through local media outlets, (b) showcasing to the public at University/Collegiate events, the research efforts of Psychology majors, (c) highlighting specialized interests that characterize particular Psychology Departments. All of these activities would be aimed at explaining the technical aspects of Psychology in a jargon-free manner to the Thai public. At the same time, this is a two-way street. Scholars in the US can learn much from what has already existed in Thailand. It is more about collaboration and learning from one another, rather than "having them to be more like us."

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Internationalizing Your Psychology Course: Preliminary Survey Findings

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Colleges and universities across the country are internationalizing their campuses and curricula. Increasing numbers include the goal of developing global citizens in their mission statement. There are many compelling reasons why a growing number of instructors have tried to internationalize their courses in some way. These include the need to develop intercultural awareness, sensitivity, and knowledge among students, the lack of "Cross-national" knowledge, research, and perspectives about psychology, and that psychology is inherently an international or global field of study (Stevens & Gielen, 2007). There has been an increasingly urgent call by prominent psychologists in the U.S. to internationalize the U.S. psychology curriculum (e.g., Bartolini, Gharib, & Phillips, 2009, Grenwald-Mayes & Moore, 2002; Hogan, 1996; Marsella, 2007; Stevens & Gielen, 2007; Stevens & Wedding, 2004; Takooshian, 2004; Velayo, Oliva, & Blank, 2008).

In 2004, the American Psychological Association was one of the grant recipients from the American Council on Education (ACE) funded through the Carnegie Foundation. APA formed a small task force of psychologists with an international perspective and relevant expertise to determine ways to promote the internationalization of the teaching and learning of psychology at colleges and universities in the United States (APA Task Force on Internationalizing the Undergraduate Psychology Curriculum, 2005).

Internationalization of the psychology curriculum has been an important concern of Division 52, International Psychology, since its inception in 1997. The Division's Curriculum and Training Committee is charged with promoting and supporting internationalization of psychology across the educational span, including high schools, colleges and universities, graduate school, and specialized training programs. As part of this effort, several APA Convention panels have been offered along with hospitality suite conversations to promote internationalization of the curriculum. Lively discussions among panel audiences and hospitality suite attendees suggested a number of psychology faculty are very interested in finding ways to incorporate global perspectives into the courses they teach. We hoped that from a survey of faculty who are currently internationalizing their psychology courses we would learn something about the methods and approaches they use. The Curriculum and Training Committee conducted a survey to discover how psychology faculty members have attempted to internationalize the courses they teach.

Description of Survey Project

The online survey "Internationalizing the Psychology Curriculum" began early in 2009. The survey was sent to members of Division 52 and select non-members through the teaching of psychology listserv administrated by the Office of Teaching Resources. There were 128 respondents to the survey by the end of 2010. More than half of the survey respondents had begun to internationalize courses they teach. Survey responses in this article have been edited.

International and Internationalized Courses

Courses inherently international, such as cross-cultural, international, and peace psychology, were most frequently mentioned as courses taught with international content. Of courses not traditionally thought of as international, survey respondents had internationalized courses in developmental, research methods, abnormal, gender, history, introductory, organizational, educational, cognitive, neuro/physiological, and personality. The method used most often (91.7%) to revise courses to include global perspectives was infusion of international content throughout the course. Far fewer (16.7%) added international content in a module format. Several individuals had both infused and added modules to internationalize courses.

How Faculty Internationalized Courses

When survey respondents gave specific examples of how they had internationalized psychology courses, nearly all responses corresponded to one or more of the following categories: lectures, classroom activities, and student assignments. Many responses reflected a desire to expose students to greater diversity in areas such as cultural, economic, education systems, and gender relations.

How Faculty Internationalize Lectures:

- Use a comparative method, United States compared to another country, such as in teaching gender and educational systems
- Include contributions of non-United States psychologists
- Infuse cultural content into all examples
- Use case studies from other countries
- Include anthropology sources and concepts
- Use international data sets
- Draw from personal cultural and international experience
- Include indigenous psychologies

How Faculty Internationalize Classroom Activities:

- Show films that enhance an international perspective and critical thinking pertaining to psychological constructs
- Post a global map to point out world areas
- Invite guest speakers such as visiting scholars, international students, and study-abroad returnees
- Students discuss how given information applies internationally
- Discuss methodologies used in other countries
- Assign exercises using international data sets
- Discuss world events and current issues
- Fields trips such as to the United Nations

International Student Assignments:

- Research and papers on psychology in other countries
- Research on psychologists from other countries
- Readings in the field of international psychology
- Readings from other disciplines
- Read news from other countries
- Interview someone from another culture
- Collaborative project with students in another country

There also seems to be a growing number of psychology instructors who recognize the importance of using Internet-based technologies in the classroom as an efficient and convenient way to help internationalize their courses (Power & Velayo, 2006). Such technologies can be particularly relevant and effective pedagogical devices in internationalizing the psychology curriculum (Velayo, Oliva, & Blank, 2008). Blogs, wikis, Facebook, Google groups, LinkedIn, Twitter, YouTube videos, and Skype are among the more common web platforms used to enhance lectures, classroom activities, and student assignments. Given that many students are relatively familiar with many of these technologies, their use can facilitate readiness to seek international content to infuse in the course, and also to communicate and collaborate with others across geographical regions of the world.

Goals for Psychology Students with Respect to Internationalization

Stated goals for psychology students reflected four main areas; content knowledge, perceptual framework, skills, and experiences. Representative responses are included below:

Content Knowledge

Survey respondents want their students to know psychology is an international discipline and to understand what makes it so. Following are representative comments regarding what faculty want their students to know with respect to international content knowledge in psychology:

- Awareness of limitations of current state of psychological research, that the vast majority of research has been conducted by Western researchers with Western college students
- Understand the issues surrounding psychological universals and cultural specifics
- Understand that culture not only affects the subjects we study in textbooks, but it affects how researchers establish hypotheses and methods, and how clinicians try to reach people across cultures
- Help students understand the influence of growing up in other nations on peoples' thinking and behavior
- Help students understand things American psychology and psychology in other nations have in common and how they differ. Provide students information on the historical impact of other nations on American psychology
- Awareness of broader world of psychology and opportunities for teaching, research, and service in other countries
- Know how to do international research

Perceptual Framework

In addition to content knowledge, many faculty expressed a desire for students to develop an open, non-ethnocentric framework through which to view international content. They wanted students to appreciate how the lens through which differences are viewed impacts understanding. Several survey respondents suggested that students need to first examine their own life history and context in order to appreciate how an interpretive lens is formed and how it filters perceptions. While some respondents mentioned conceptual framework in a general manner, others specifically linked conceptual framework to psychology. Selected responses reflecting this theme include:

- Become aware that the United States' view is only one view

- To realize that culture and context affect behavior
- Diminish American ethnocentrism in the profession
- To gain non-U.S. perspectives and appreciate different outlooks on key psychological concepts
- Appreciation of similarities and differences. Respect for diversity reduces ethnocentricity
- A growing sense of cosmopolitanism, marked by increased tolerance and openness
- To adopt a comparative/anthropological perspective when traveling and studying psychology

Skills

Several survey respondents' goals for students included skills needed presently and in the future for international psychology practice and research. Competency in applying psychological principles to individuals in countries worldwide and the ability to work with individuals from other countries or cultures are representative of skill-related goals mentioned by survey respondents.

Experiences

A number of faculty recommended that their students participate in international and cultural experiences. These experiences were sometimes included in a course such as service learning or a field trip, but more often were extracurricular. Study abroad, participation in cultural events, attendance at international conferences, and service learning offered through other parts of the university were suggested as ways for students to gain international experience.

What It Means to be a Global Citizen in the Context of an Internationalized Psychology Curriculum

The American Council on Education, Center for Global Initiatives worked with a number of colleges and universities between 2002 and 2007 to develop strong international outcomes goals for their students in its Global Learning for All initiative (2006). Institutions developed goals and outcomes that addressed both framework and content for international education. Most of the institutions embodied the notion of global citizenship preparing students to be competent and compassionate individuals who participate in the world in a manner that betters life for people and the planet. Although a common definition of global citizenship has not been adopted for psychology students, Hobbs and Chernotsky (2007) propose a three-part definition for students in interdisciplinary international studies programs that may have some relevance to psychology. First, students need an awareness of complexity and interdependence in the world. Second, students need a perceptual framework that reflects openness and appreciation of difference. Finally, students must be able to effectively communicate across cultures. A number of survey responses included these and other ideas of global citizenship in the context of an internationalized psychology curriculum. This question elicited particularly rich answers. Following are several representative responses:

- I think to be a "global citizen" means to have some understanding of how the rest of world works; to be aware of other cultures and how those cultures influence behavior and cognition; and to be able to accept that differences do not mean inferiority. Global citizens should be able to communicate a sense of understanding and respect for each other even though they may speak different languages.
- It is important that psychology professors and students seek information on research, teaching, and practice internationally. We should reach out to like-minded colleagues abroad; seek the findings of research conducted in other cultures and countries; attend international conferences where possible; and teach our students how to acquire knowledge about psychology internationally.
- A Global Citizen/Psychologist is one who has the philosophy of psychology as a transformational discipline focusing on broad competencies rather than narrow skills or type of education. A Global Citizen/ Psychologist conducts her/himself in ways that are culturally sensitive, multimodal, and reflective of multiple ways of knowing, cognizant that behavior cannot be considered apart from specific contexts.
- The competent Global Citizen/Psychologist must have both a broad knowledge of the scientific and theoretical principles of psychology from a global perspective and the ability to apply that knowledge in culturally sensitive ways and in diverse settings. The Global Citizen/Psychologist is flexible and open to new developments in the field and in personal behavior exercises critical thinking, practices in ways sensitive to social justice and universal ethical principles, examines critically the role of personal values, and appreciates cultural diversity.
- Global Citizen: a World citizen. Somebody who belongs to several countries and cultures at the same time. Somebody who doesn't identify with one citizenship as their primary citizenship, but feels they belong to several places in the world. A psychology graduate who has the knowledge and the competence to be able to work and generate knowledge in more than two places, countries, cultures in the world.
- To have an openness to different perspectives, research orientations and varied understandings of psychology, depending on one's cultural background. To be able to impart in the classroom psychological research and practice that accounts for differences and similarities on an international landscape. To get away from the notion that Americanized psychology is somehow superior to alternate approaches around the world.

Faculty who Internationalized Courses

Survey respondents were varied with respect to institution type (figure 1), faculty rank (figure 2) and courses taught (table 1). The greatest number were from comprehensive universities. Next, were equal numbers from community

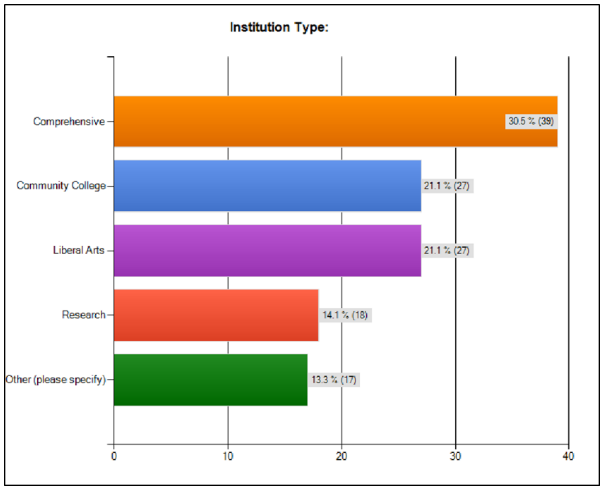

Figure 1. Bar graph showing institutional affiliation type of survey respondents

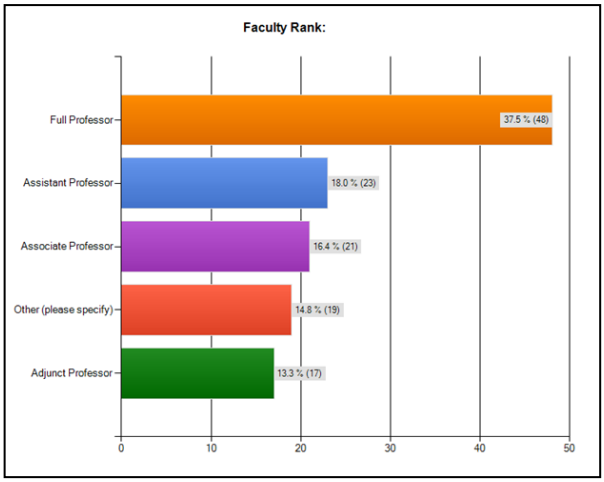

Figure 2. Bar graph showing faculty ranks among survey respondents

colleges and liberal arts institutions. Fewer respondents were from research institutions. Others were from more than one institution type, a high school, or other combination of research and private practice.

In terms of faculty rank, Full Professors were by far the largest groups of survey respondents. Assistant and Associate Professors were nearly equal in number. In addition, there were adjunct professors who responded to the survey.

Survey respondents have engaged in a broad range of international experiences and activities (table 2). However, it is interesting to note that only 25% had been involved with an interdisciplinary international committee or task force at their institution. Approximately three fourths had not been involved with such a group.

When asked the extent to which respondents' institutions encourage internationalism, approximately half identified a

"Internationalized" Course	Created	Revised
Cross-cultural/multicultural	29	14
Other (Psych)	13	21
Other (Non-psych)	7	9
Developmental	5	18
Research Methods/Statistics	5	8
Abnormal	4	16
Gender	3	9
History	3	6
Introductory/General	3	13
Social	3	15
Organizational	2	1
Educational	1	2
Cognitive	0	2
Neuro/Physiological	0	2
Personality	0	4

Table 1 List of "internationalized" courses that survey participants had created or revised

International Activities of Respondents	Frequency	Percentage
International Faculty Teaching Exchange	26	24.8
International Research	63	60
Leading Study Abroad Trip	20	19
Internationalize Courses Taught	61	58.1
Participation in Campus International Activities	51	48.6
International Service Learning as Part of Class	12	11.4
Other(s) (e.g., international conferences, U.N. involvement, studied abroad, Fulbright, international committees, international travel, lived abroad, course development in other countries, foreign national)	38	36.2

Table 2 List of international activities of survey respondents

high level of institutional commitment across the campus to internationalism. Twenty percent identified a more limited commitment to internationalism. Seventeen percent perceived no overt commitment to internationalism, and four percent reported their institutions to be antagonistic toward international efforts.

With respect to support from respondents' academic departments in internationalizing the curriculum, approximately 55% perceived no support or encouragement, 29% reported a high level of encouragement, 15% perceived some encouragement, and 2% perceived hostility toward efforts to internationalize the psychology curriculum. However, as some faculty who perceived high or moderate encouragement to internationalize were quick to point out, encouragement does not always mean monetary support or release time. The picture that emerges is that many psychology faculty members are making significant independent efforts to internationalize their teaching.

Despite challenges, internationalization of the psychology curriculum is solidly underway. The Curriculum and Training Committee has revised its survey and is in the process of collecting more data. Many survey respondents expressed a desire for resources to help with international

course creation and revision. Sample syllabi, curriculum guidelines, reading lists, model programs, recommended textbooks, release time and funding were most often mentioned as needed resources. A number of respondents suggested that internet based resources would be the most helpful.

The Curriculum and Training Committee encourages faculty who have internationalized teaching resources to share these by sending them to the chair of the Committee, Gloria Grenwald at grenwald@webster.edu or to Division 52 webmaster, Richard Velayo at rvelayo@gmail.com. The resource bank will eventually be posted on the APA Division 52 (International Psychology) website.

Recommended Resources to Internationalize the Teaching of Psychology

There are abundant resources that can be very useful in incorporating international content into a psychology course but these are not generally available through a single published resource. For those who wish to read more about internationalizing the psychology curriculum, Velayo (2011) lists recommended resources (listed alphabetically based on authorship) to help you gain more knowledge and develop your own unique approach to internationalizing your courses.

1. APA Task Force on Internationalizing the Undergraduate Psychology Curriculum. (2005). *Report and recommended learning outcomes for internationalizing the undergraduate curriculum.* Retrieved on July 11, 2010 from http://www.acenet.edu/Content/NavigationMenu/ProgramsServices/cii/ current/past/APAFinalACEReportjtp.doc [This document recommends five relevant goals and associated learning outcomes for internationalizing the undergraduate psychology curriculum in the United States.]
2. International Journal of Psychology (2006, Volume 41, Issue 1). [This special issue of the journal published on behalf of the International Union of Psychological Science (IUPsyS) features the topic on "International Practices in the Teaching of Psychology" with guest editors, Victor Karandashev and Sherri McCarthy.]
3. *International Psychology Information Clearinghouse.* Retrieved on July 11, 2010 from http://www.internationalpsychology.net/resources/ [This 100+ page comprehensive listing of relevant resources has been compiled by Michael Stevens, PhD (Professor of Psychology at Illinois State University) and made accessible on the website of APA's Division of International Psychology. It contains general resources - accessible via the web or in print form - including career information, international psychology organizations, work opportunities for academic, research, and clinical settings, potential funding sources for US and non-US instructors and students, books, articles, syllabi, conference presentations, and many other resources.]
4. McCarthy, S., Newstead, S., Karandashev, V., Prandini, C., Hutz, C., & Gomes, W. (Eds.) (2007). *Teaching psychology around the world, Volume 1.* Newcastle upon Tyne, UK: Cambridge Scholars Publishing. [This book provides an overview of teaching psychology internationally by incorporating research and perspectives from psychologists in more than 30 countries. It also includes relevant information for secondary, undergraduate, and post-graduate psychology programs.]
5. McCarthy, S., Karandashev, V., Stevens, M., Thatcher, A., Jaafar, J., Moore, K., Trapp, A., & Brewer, C. (Eds.) (2009). *Teaching psychology around the world, Volume 2.* Newcastle upon Tyne, UK: Cambridge Scholars Publishing. [This book includes current information on the teaching and practice of psychology collected by experts in the field throughout the world. It is highly recommended by prominent U.S. psychologists. One of the chapters from this book that you may find useful is by Meiners (2009) titled "Viewing films to build 'global competence': A case study."]
6. Woolf, L. M., Hulsizer, M. R., & McCarthy, T. (2002a). *International psychology: A compendium of textbooks for selected courses evaluated for international content.* Retrieved March 31, 2011 from http://teachpsych.org/otrp/resources/index.php?category=International%20Psychology [This electronic resource contains a compilation of information on textbooks in introductory, social, and lifespan developmental psychology, which have been evaluated for international content. It includes comparative tables (amount of international coverage per textbook and per chapter, total number of chapters, number and gender of authors, etc.), plus narrative reviews of each of the textbooks given these three content areas.]
7. Woolf, L. M., Hulsizer, M. R., & McCarthy, T. (2002b). *International psychology: Annotated bibliography, relevant organizations, and course suggestions.* Retrieved March 31, 2011 from http://teachpsych.org/otrp/resources/index.php?category=International%20Psychology [This contains a diverse set of resources including sample syllabi, annotated bibliographies, and video suggestions to help you incorporate international content into selected existing courses. It may also be useful to those who wish to develop a course on international psychology.]
8. Pawlik, K., & d'Ydewalle, G. (2006). *Psychological concepts: An international historical perspective.* Hove, UK: Psychology Press. [This book provides an international perspective on each of the core psychological concepts, describing and analyzing them from a historical point of view. Authors from 11 countries and 4 continents, all distinguished in their respective research areas, contributed the 14 chapters.]
9. Stevens, M. J., & Wedding, D. (Eds.). (2004). *Handbook of International Psychology.* New York: Brunner-Routledge. [This book chronicles the evolution of psychology in different world regions for the purpose of reducing the ethnocentric nature of the western

psychology. Each chapter follows a uniform outline, unifying the volume as a whole, but allowing for the cultural diversity and status of psychology in each country.]

10. Stevens, M. J., & Gielen, U. P. (Eds.). (2007). *Toward a global psychology: Theory, research, interventions, and pedagogy*. Mahwah, NJ: Erlbaum. [This book is a thorough review of the existing literature on international psychology from around the world and provides the knowledge needed to successfully engage in the science and practice of psychology in an increasingly globalized society. It provides an overview of conceptual models, research methodologies, interventions, and pedagogical approaches related to international psychology.]
11. Wedding, D., & Stevens, M. J. (2009). *Psychology: IUPsyS global resources.* [CD-ROM (8th ed.)]. Hove, UK: Psychology Press. [This resource contains a set of tools covering all aspects of psychology around the world. New material is added to this CD-ROM and existing sections are updated and/or expanded annually.]

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Request for Info: Department Study Abroad Opportunities

Hello Division 52 members:

The student committee of Division 52 is seeking to gather information on what types of study abroad and/or international immersion experiences are available across psychology programs. We hope to use this information to create a resource for students and/or faculty to find information on what types of study abroad experiences exist around the world. If you could take a few minutes and answer the below questions, we would greatly appreciate any information you can provide on what study abroad experiences exist around the globe! Responses can be sent back to me, at anhutchison@bsu.edu.

Please provide the following information, if available:

1. What types of study abroad or immersion experiences does your psychology department offer to your students (e.g. target student population, undergraduate or graduate focus, location, length of time, activities completed during experience, etc.)?
2. How do these opportunities further students' education?
3. How do these opportunities contribute to the study of psychology?
4. Any other information that you feel would contribute to this project.

Again, thank you so much for taking the time to provide this valuable information!

Ashley Hutchison, M.S.
Student Committee of Div. 52 - Member at Large
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Psychologists' Role in Advancing the Agenda and STEM Education for Girls and Women at the United Nations: A New Agency and Psychologists' Events at the Commission on the Status of Women

The following three articles describe psychologists' role in new developments at the United Nations regarding the women's agenda.

The New "UN Women" at the United Nations

Judy Kuriansky, Ph.D. (DrJudyK@aol.com)

Mary O'Neill Berry, Ph.D.

The global women's movement now has a rare opportunity to participate in building a new UN agency focused on leading the UN to improve the lives of girls and women worldwide. That hope lies in the creation of a new United Nations organization -- the United Nations Entity for Gender Equality and the Empowerment of Women, known as UN Women (www.unwomen.org) that was formed in July 2010, became operational January 1, 2011 and was formally launched in March 2011 in conjunction with the Commission on the Status of Women annual meeting at UN headquarters in New York.

Psychologists representing psychology-related NGOs at the United Nations were present at various ceremonies for the launch of UN Women, and are actively preparing to contribute psychological research and best practices relevant to the mission of the new agency.

At the launch luncheon for UN Women (seated from left to right) APA UN Representatives Janet Sigal and Susan Nolan; colleague Cecilia Marzabadi; and (standing) APA Main UN Representative Deanna Chitayat and APA Div 52 CIRP liaison and IAAP UN Main Representative Judy Kuriansky

One major event was a luncheon at UN headquarters, with the new head of UN Women, Michelle Bachelet, former President of Chile, as the main speaker. Women and men representing over 200 organizations worldwide were present, along with representatives of psychology associations accredited at the United Nations, and UN dignitaries. The Main UN Rep from the International Association of Applied Psychology and APA Division 52 liaison to CIRP, Judy Kuriansky, and the Main UN Rep from the American Psychological Association, Deanna Chitayat, spoke briefly with the President of the New York Chapter of UN Women and with Mrs. Ban Ki-Moon, wife of UN Secretary-General Ban Ki-Moon.

The UN Secretary-General's wife, Mrs. Ban Ki-Moon (left) with APA Div 52 CIRP liaison Judy Kuriansky (middle) and APA UN rep Deanne Chitayat (right)

UN Women is composed of four previously separate groups: UNIFEM (United Nations Development Fund for Women, founded in 1976), DAW (Division for the Advancement of Women, founded in 1946), OSAGI (Office of the Special Advisor on Gender Issues and Advancement of Women, founded in 1997) and INSTRAW (International Research and Training Institute for the Advancement of Women, founded in 1976). The new Executive Board consists of 41 elected people, headed by an Under Secretary General *Michelle Bachelet*. Four seats on the Executive Board are reserved for the highest donors, two from the developing world and two from the traditional major donor countries (one of the latter will be the United States).

The functions of UN Women are:

- to provide substantive support to UN bodies
- to support national efforts to promote/enhance gender equality through country-driven programs
- to undertake advocacy at regional and national levels
- to support Member States in implementing and monitoring the 12 areas of the Beijing Platform for Action and CEDAW (*Committee on the Elimination of Discrimination against Women*)

- to undertake research and analytical work and act as a knowledge hub on gender equality and women's empowerment
- to lead and coordinate the UN system's strategies, policies, and actions in this arena
- to strengthen the accountability of the UN system, including providing oversight/monitoring/ reporting on system-wide performance regarding gender equality and to monitor and report on system-wide compliance with intergovernmental mandates on gender balance, including at senior and decision-making levels

The budget was estimated to amount to USD 500 million annually.

Why UN Women came about: While many organizations had been active in women's issues at the UN and in civil society, and while NGOs had achieved some progress by putting forth statements, declarations, platforms, and conferences related to women's rights and issues, there was great frustration about lack of implementation due partly to lack of resources and the low level authority of women's voices in the UN. The new agency was formed with the promise to be a true "game-changer" -- a new way for women's issues to be talked about and acted upon at the United Nations in a both effective and efficient way. An added advantage is having a high level UN official put in place at the helm, with the high grade of "Under Secretary General."

The challenge is daunting. To help, the GEAR campaign (standing for Gender Equality Architecture Reform) was also launched (www.gearcampaign.org). This network of over 300 women's, human rights and social justice groups and NGOs has four mandates, to: (1) establish meaningful, systematic, and diverse civil society participation; (2) help shape UN Women to play a critical role in the 21st century global women's movement, by ensuring that UN Women becomes a coordinated, strong, and strategic organization that further advances the UN's work on gender equality and women's empowerment and improves the daily conditions of girls and women's lives; (3) pressure donors to aim for USD 1 billion in funding; and (4) seek powerful, capable and effective leadership at every regional and country level.

Enthusiasm about UN Women is high.

A Celebration of the Launch of UN Women and a Special Tribute to Women in Technology & Science

The luncheon celebrating UN Women on February 25, 2011, in the UN Delegates Dining Room, was hosted by the Metro New York Chapter of the US National Committee for UN Women. Many of the luncheon attendees were in New York attending the UN's annual Commission on the Status of Women, whose theme this year was increasing the participation of women and girls in technology and science.

In her welcome, the Chapter President, Cheryl Benton, called the luncheon "an historic occasion celebrating the launch of UN Women, and a significant step by the UN to improve and enhance the lives of women and girls everywhere." Expressing enthusiasm over the new organization, she noted that the theme of the chapter conference and of the luncheon is consistent with the theme of this year's conference on the Status of Women: "Access and Participation of Women and Girls in Science and Technology," by honoring women in technology and science.

In an unusual opening for the afternoon's presentations, Saranne Rothberg, Founder and CEO of The Comedy Cures Foundation, performed a comedy routine, noting that she has also performed at the launch in February 2008 of UN Secretary-General Ban Ki-Moon's Global Campaign to UNite To End The Violence Against Women, and was the first therapeutic humor consultant called to Ground Zero after September 11th. The audience was moved as she shared her story as a survivor of breast cancer, going on to create her foundation to bring joy, laughter, and therapeutic humor programs to kids and grown-ups living with illness, depression, trauma and disabilities. The recipient of several humanitarian awards, Saranne has been featured by media worldwide, including CNN, PBS, NPR and The New York Times, and as a "Hero" in Oprah's book, "Live Your Best Life."

The audience was awed when Saranne introduced the next performer, her 17 year old daughter, Lauriel Harte Marger, who is a partner in Comedy Cares as well as a United Nations Youth Advisor and a World Health Organization Health Champion who helped launch this year's UN International Year of Youth. With her two best friends, Lauriel launched a socially conscious singing group, "The Bonde", with their adaptation of an African chant, "Kamwanna" which protests the rape of young girls. At the luncheon they performed an original song, "Behind The Lies," which is a protest anthem to end Female Genital Mutilation.

The stage was set to introduce the keynote speaker, Michelle Bachelet, the new UN Under Secretary General and Executive Director of UN Women. The audience audibly gasped when it was announced that among Ms. Bachelet's many credits, she had an 82% approval rating when she recently stepped down as the President of Chile.

The head of UN Women, Michelle Bachelet, addresses the luncheon gathering at UN headquarters during the Commission on the Status of Women meetings

Bachelet noted in her speech that her training as a pediatrician made her sensitive to the importance of women in

STEM (science, technology, engineering and mathematics) – the theme of the CSW conference.

There is widespread agreement that Ms. Bachelet is the right woman for the job with a rich background to help her accomplish UN women's goals. A pediatrician, with graduate studies in Military Sciences, she speaks Spanish and English and has a command of German, French and Portuguese. A dynamic global leader with highly honed political skills, she served as the region's first female minister of defense and as the first women elected as President in the history of Chile, for a full four-year term from February 2006 to March 2010 -- with the greatest approval from people in the history of Chile – after which she founded Dialoga Foundation, to support new ideas, action, and leadership in Chile.

Bachelet pledged to involve all women at all levels in achieving UN women's goals and to do more than just "talk" but to accomplish action items and advance the empowerment of women at the UN and globally. She was pleased that the creation of UN Women gives women more political weight and voice and noted that "women all over the world are very powerful agents of development, agents of change, peacebuilders, and peacekeepers. They are also essential…because they have good ideas and proposals and they are hard workers in their communities."

Bachelet has been quoted as saying that women have said to her, "I can die now because I know that my daughter has a better future." She is also proud that holding the highest office in Chile as a woman made her sensitive to women's problems. As a result, she gave pensions for housewives to collect when they reached 65 years old so they would not need to depend on their husbands for everything; developed a network of nurseries and kindergartens to help working mothers; and presented bills to Parliament requiring equal salaries for women and men.

The last speaker was Susan Hassler, Editor-in-Chief of a monthly magazine, IEEE Spectrum, the publication for the IEEE (the world's largest technology association) read by over 385,000 technology professionals and senior executives worldwide in the high technology sectors of industry, government, and academia. With her more than 20 years of experience as a science editor and journalist dealing with a wide range of complex topics from developmental neurobiology to genetic and metabolic engineering, Hassler talked about the positive impact of women in the fields of technology and science.

Chapters of UN Women, such as the Metro New York Chapter, advocate, educate, and raise funds on behalf of UN Women. To join UN Women's chapters, go online at www.unwomen-usnc.org/chapters. Chapter members participate in educational and informational programs, fundraisers and other events, and receive notices about the progress of UN Women. National Committee Chapters are in New York, Atlanta, Georgia; Chicago, Illinois; East Florida; Gulf Coast, Florida; National Capital; New Haven, Connecticut; North Carolina; and the San Francisco Bay Area. New chapters can also be formed.

A Contribution of Psychology to UN Women: Women and Organizational Leadership

Walter Reichman Ed.D.
Mary O'Neill Berry Ph.D.
Judy Kuriansky, Ph.D.
Florence Denmark, Ph.D.
UN Representatives for the International Association of Applied Psychology

In response to the call by UN Women for contributions to help their mission, representatives to the United Nations from the International Association of Applied Psychology prepared the below document about the role of women in organizational leadership. The document represents an important example of how psychologists can impact the mission of UN agencies, by providing research and best practices in our area of expertise, in this case focused on organizational psychology.

This report was delivered to the office of the head of UN Women, Michelle Bachelet, which then sent a response email of appreciation for the submission, inviting IAAP to comment on their first strategic plan when it is published on their Website.

The report read as follows:

A major goal of the United Nations is to bring about gender equality; in fact, Millennium Development Goal # 3 is to "promote gender equality and empower women." Psychologists have long been researching the role of women in all aspects of life, including their role in organizations. Psychologists join other disciplines in asserting that the achievement of gender equality requires that women have the same opportunity as men to be leaders in organizations, both as entrepreneurs and also within existing organizations.

Presently the number of women leaders in organizations lags behind men in developed countries such as the United States and the United Kingdom, as well as in the developing countries. In the United States only 2% of the Fortune 1000 companies have chief operating officers who are female and of the top 280 companies listed on the London Stock Exchange less than 28% have female top executives. In China, women comprise less than 18% of heads of government departments (United Nations, 2009).

Despite these discouraging statistics there are still sufficient numbers of women in leadership positions for psychologists to be able to research their development into such positions as well as to examine their leadership style and effectiveness. The considerable body of psychological research on leadership has defined the activities and criteria of effective organizational leadership in the 21st century. These activities include: emphasizing task accomplishment, considerate behavior toward employees who carry out the required tasks,

and the ability to inspire and motivate employees to higher levels of effort and dedication. This model is known as *transformational* leadership in contrast to *transactional* leadership which emphasizes reward and punishment for following directions. Transformational leadership demands a relationship between leaders and followers directed at bringing about change that is in the best interest of both (Ayman and Korabik, 2010).

With regard to differences between men and women in leadership positions, a review of research indicates that some studies find that males and females do not differ on the degree to which they focus on task completion or the degree of consideration they show their employees, while other studies have found that women are higher in both skills, e.g. that women focus more on tasks and are more considerate of employees. These studies also show that women tend to be more transformational in their leadership than men. A key component of transformational leadership is better communication and more positive negotiations among leaders and subordinates (Ayman and Korabik, 2010). Research also indicates the benefits of female leadership for company success in that there is a statistically significant relationship between the number of women in top management and the financial performance of the company (Bowers, 2009).

The leadership style of women, which promotes organizational success, is in keeping with the cultural changes of the 21st century. In our ever-changing world, flexibility in thinking and performing and an emphasis on consultation are necessary ingredients for success. In addition, under globalization the business leader must have an ability to confront and appreciate increasing diversity and negotiate with and understand those who differ from us. This too, is a component of transformational leadership.

Despite these leadership advantages, there are many blocks to women gaining leadership positions in organizations. Although women in organizations demonstrate all the appropriate attitudes and skills, they are still disadvantaged in both securing and maintaining leadership positions (Kent and Moss, 1994). Even though women demonstrate their leadership ability, they are not perceived as having or being credited with that ability. Psychologists believe that this is due to stereotyping in that leadership is more often associated with male roles and behavior than with female behavior (Ayman and Korabik, 2010). A study by Catalyst on women executives at the vice president level and above in Fortune 1000 companies cited stereotyping and pre-conceptions of women as one of the most significant barriers to women advancing in the workplace (cited in Sanchez-Hulces and Davis, 2010). Even more troublesome is that when women gain positions of leadership, they almost always encounter resistance to carrying it out (Eagly and Chin, 2010). It is uncomfortable for people to see a stereotype broken and will require steps to be taken to promote favorable stereotypes.

Women who achieved leadership positions described their careers as progressing through a labyrinth of hurdles, discrimination, stereotyping and challenges. Those who make it past the proverbial "glass ceiling" often find themselves on what has been termed the "glass cliff." A female leader is on a glass cliff when she is promoted to a leadership position to deal with a problem that was not of her making and has a low probability of a positive solution. Those who survive the glass cliff say they did so by working hard and working smart (Sanchez-Hulces and Davis, 2010). Working smart usually involves seeking allies, negotiating and collaborating to reach a solution.

In further research on successful female leaders, these women attribute their success to parental encouragement during their childhood, which fostered a sense of self-worth and a belief they could accomplish their goals. In the business world, they report learning from role models and mentors, networking and developing relationships and partnering with accomplished associates. In life in general, they report having developed life skills and guidelines for melding their personal and professional lives. Their experiences drew them to develop a transformational way of dealing with people that evolved into a transformational leadership style (Cheung and Halpern, 2010).

The barriers to women's success in top levels of organizations also have roots in childhood, since that is when stereotypes begin to form. For example, the stereotype that leadership is associated with men and masculinity begins as early as age five. Also, this stereotype seems to be held more strongly by boys than girls, making it more difficult for women to overcome since men in most cultures are given higher status and greater privilege than women and their prejudices carry more weight (Ayman and Korabik, 2010).

From this overview of the psychological research on women and organizational leadership, we can conclude that the skills and attributes of women are invaluable for the success of organizations in the global world economy of the 21st century.

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The Contributions of Psychology to the Commission on the Status of Women 2011 Conference Focusing on Education of Women and Girls in STEM (science, technology, engineering and mathematics): Two Parallel Events by Psychologists

Megan Lytle
UN Intern for the International Association of Applied Psychology

Judy Kuriansky
APA Division 52 Liaison to the Committee on International Relations and UN Main Representative for the International Association of Applied Psychology

Event #1: Workshop and Demonstration of STEM Education: Best Practices and Products

A parallel event organized by psychologists for the 2011 conference of the Commission on the Status of Women was entitled "Workshop and Demonstration of STEM Education: Best Practices and Products." Held on February 24, the presentation focused on techniques and teaching strategies to encourage women and girls to get involved with careers in STEM (science, technology, engineering, and mathematics). Sponsored by the International Association of Applied Psychology at the request of APA, other psychological association co-sponsors included APA, IUPsyS (the International Union of Psychological Science) and ICP (the International Council of Psychology).

APA Main United Nations representative Deanna Chitayat opened the event at the Salvation Army auditorium (a United Nations satellite venue), mentioning how we must question why not as many women as men are involved in STEM careers and introducing that in this program, teachers and students will present best practices and programs involving females in these pursuits.

Glen Schuster, a representative from the NASA Endeavor Science Teaching Certificate Project developed by NASA through a US Satellite partnered with Columbia University Teachers College, reported that this day marked the last scheduled launch of the Discovery Shuttle and then proceeded to describe the Endeavor fellowship and recent graduates' successes. The Endeavor program is a fellowship for K-12 formal educators whereby fellows take five courses online, earn graduate credit, and receive a certificate in STEM education upon completion (see www.us-satellite.net/endeavor).

The next speaker, Sharika Castronovo, a teacher from the Environmental Science Manhattan School for Children, presented how she has adjusted her curriculum to motivate female students in her classroom to get actively involved in STEM activities. These include to:

- make science fun (e.g. making baking soda rockets)
- help girls develop personal connections to show them that they have the skills
- have students write about science though journaling
- have students discuss their ideas to explore successes as well as mistakes
- make it "cool" to participate
- include families by providing worksheets with projects to do at home (e.g. a night at the observatory)
- create school-wide projects to help to get more girls involved

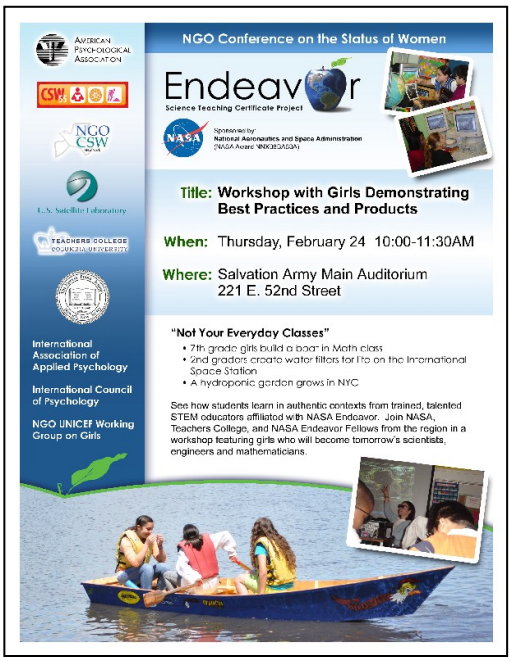

Two girls from her class described their experiences making an energy bike by connecting a bike to water and then to a battery, as well as their greenhouse projects (e.g. developing a hydroponic greenhouse for the classroom, allowing students to develop experiments). In other projects using technology in the classroom, a conference call was made with a female marine biologist and the students made a newscast about endangered animals. Such projects motivate the students to learn science and to use technology.

Louise McMinn, a math and science coach in Stamford, Connecticut at the Scofield Magnet Middle School, then described the after-school STEM programs she developed. She reported that (1) recently the number of women in STEM programs has started to decrease; (2) it is hard to find women actively engaged in science since they often get in administrative positions; and (3) there is a need to get more girls interested in STEM careers. Since after-school programs allow

more freedom to get girls interested in STEM skills and careers – compared to in-class programs which not only need to engage students but have to meet specific educational standards -- McMinn created an after-school program in astrobiology, for girls only. This program was developed after she noticed that even though girls in her class admit that they like to do experiments, they tend to take less active roles in the project.

The astrobiology after-school program for girls utilizes NASA programs found online for content. Recently, her students tested soil samples to decide if there was life present which allowed the girls to reconsider the question, "What is the meaning of life?" The curriculum also includes: extremophiles (examining microorganisms that live in extreme environments); AstroVenture (a simulator to determine what conditions are required to sustain life); rocketry, specifically a design challenge to land a rocket (e.g. make a shock-absorbing container to protect an item such as an egg from breaking); and a waste limitation management and recycling design challenge. Her students studied the water quality in five sites in their town of Stamford, Connecticut and then developed a digital presentation about their study. McMinn reiterated that the NASA website offers design challenges and is a great resource for classroom activities.

The next speaker, Marylin Ortiz is a 5th grade inclusion teacher in Newark (i.e., her class has special education students in addition to general education students). She emphasized the need to encourage girls to become involved with STEM activities and to consider STEM careers. She developed a course, called "Inspiring Girls in Engineering," which provides female role models in the field of engineering, and teaches about how men and women are built differently; for example, engineers have been involved in modifying snowboarding equipment for women. Although STEM activities promote the genders working together, Ms. Ortiz separates girls from boys during science projects, creating classroom competition in order to get more students involved, especially since girls usually take a less active role in science projects. She concluded with a quote from Hillary Clinton: "The future of women and girls are tied together. Girls cannot advance without the advancement of women and no improvement in the lives of women will be sustained unless girls are given the tools and opportunity to reach their potential. For they are the women of tomorrow."

The fifth presenter, Linda Richardson, is the Principal of Ann Street School in Newark, New Jersey, a school that has received the National Blue Ribbon of Excellence by the United States Department of Education (the highest award an American school can receive). She shared personal reflections about being a product of the women's movement and her challenge of becoming a principal in a male-dominated field. Emphasizing the need to have women in STEM programs and how to foster this goal, she reported that her district has provided opportunities for girls to set up and participate in math and science fair projects, such as building model boats, that require developing drafts, making models, and taking measurements to build a 15-foot skiff boat.

Four of her students in this project shared their experience in making a full-size functional boat within the time period of 12 weeks. In a dramatic moment, two of the male teachers brought the boat down the aisle and placed it in the front of the auditorium. The students reported that although they were not initially enthused about the project, they quickly became motivated once they realized that they would be building a real boat. Also, the girls were more excited and involved in this project than the boys, and enthusiastically described their experience in working with power tools (e.g. a belt sander and drills) for the first time, their struggles with using math to obtain the correct measurements, and the decision-making process and teamwork required to successfully build the boat. In addition, their class took a field trip to a yacht company in New Jersey and learned how the father who owned the company designed the boats, however, his daughter utilized the computer to implement her father's designs. The girls concluded by describing how their class launched the boat, amusing the audience by noting that the male teachers who assisted overturned the boat and needed to be rescued while the girls successfully rowed the boat and kept it afloat.

Female students who built a boat (pictured against the wall)

Dr. Felicia Moore Mensah from Columbia University Teachers College, in concluding the program, described how she used to dream about becoming an astronaut and shared her experiences of incorporating science into her life. She emphasized the importance of bringing STEM experiences to females, whether they live in a rural or urban environment. Telling girls and women that they are already scientists, she said, can help them expand their career options. Given that there are a number of STEM-focused scholarships, the opportunities for young women are plentiful.

All involved agreed that the event was not only successful but inspirational, especially given the related experiences of the young girls themselves.

In the question and answer session, a representative from the World Association of Girl Guides and Scouts said that the

girls inspired her and that she was looking forward to sharing what she learned. A representative from the World Federation of Mental Health noted that the program helps young women develop dignity and inquired about how the programs relate to psychological wellbeing. Principal Richardson responded that the projects also develop moral character and acknowledged that affective as well as academic aspects need to be recognized. She said that while the girls building the boat were stressed (as well as challenged), they (and the teachers) managed the stress well. In addition, the project won first place at the Algebra Olympics (beating out high school students). One of the male faculty members supervising the boat building described that he managed his stress during the process by considering the benefits the students were deriving from the project and remembering that while the girls might not remember how they did in 8th grade, they would undoubtedly remember the experience and pride in building a boat. Dr. Chitayat commented on how upbeat the students were in discussing their experience and how this relates to increasing self-esteem and self-efficacy.

Regarding funding, Ms. Ortiz reported that a grant funded the water filtration system but in the past she paid for the projects out of her own pocket. Ms. Castronovo said she received donations from her students' parents as well as outside contributions to fund the $800,000 greenhouse she now uses as an interactive classroom. Ms. McMinn suggested that education programs include grant writing to secure necessary finding for such projects. The boat project was funded partly by community resources, with networking being crucial to establish relationships to make companies with products and services related to the project aware of the project and how they can contribute.

In response to Dr. Kuriansky's query about future plans to promote the projects digitally, a faculty member reported that he has been working with NASA to post all their projects online to share with educators.

Regarding how the projects are eco-friendly, Ms. Castronovo reported that she teaches in an eco-friendly greenhouse, and a faculty member described how the students engaged in the boat building were encouraged to use natural lighting and to recycle, and were required to take care of their own garbage.

In describing how they are ambassadors of science education, one student said her girl scout troop does science projects with the brownies and juniors, including showing them what they can do with science. Another student described her involvement with a science contest outside of school and her participation in an event about how crime scene investigators work on forensic cases.

It was suggested in conclusion that in-school as well as broad after-school, programs as well as an interdisciplinary approach, are crucial in getting female students interested in STEM skills and careers.

Parallel Event #2: What Psychology Offers to the Education of Women and Girls

Another psychology-related event at the CSW was a caucus on "What Psychology Offers to the Education of Women and Girls." A panel of three psychologists included two representatives from the American Psychological Association team at the United Nations, Deborah L. Vietze, Ph.D., Professor of Psychology at the City University of New York and a member of the Ph.D. faculty in Social Psychology, Developmental Psychology and Urban Education and Beatrice J. Krauss, Ph.D., a Professor of Urban Public Health and Executive Director at Hunter College Office of Faculty Research and Project Development and the Center for Community and Urban Health, as well as Judy Kuriansky, Ph.D., the United Nations representative for the International Association of Applied Psychology and Division 52 liaison to the APA Committee on International Relations.

The aim of the Caucus was to indicate what psychology has done and can do for STEM education, and to create discussion and action steps. Dr. Krauss focused on education and health; Dr. Vietze addressed education in general and access to vocations; and Dr. Kuriansky described the interrelationship between health and financial empowerment of girls, giving examples of field projects. Intended as a workshop, the event evoked lively discussion from the attendees, who represented a wide range of ages, gender and countries. Several CSW delegates from Africa were particularly keen about how to encourage more women to be involved in STEM education and careers and their desire to collaborate on projects.

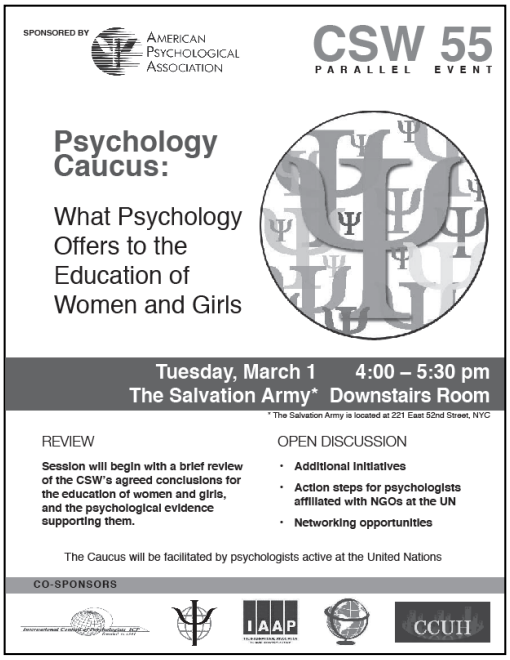

Presenters from APA and IAAP with attendees at the Commission on the Status of Women parallel event on the role of Psychology in the Education of Girls

Young women in the audience of the parallel event

Youth from European Lawyers Youth Group describing their intention to further include women

APA Division 52 CIRP liaison Judy Kuriansky presenting about female entrepreneurship at the APA-sponsored CSW Parallel event on "The Role of Psychology in the Education of Women and Girls"

Aftermath of the Japanese Earthquake and Tsunami: Immediate Response and Impact of Events as Healing Efforts

Judy Kuriansky, Ph.D.
DrJudyK@aol.com

From a psychological point of view, when a crisis strikes one part of the world, global solidarity and support – both heartfelt as well as financial – are important in healing. These have been extended to Japan in the wake of the 9.0 magnitude earthquake and subsequent devastating tsunami.

Immediately after the environmental tragedies hit Japan, health professionals and the interfaith community throughout the world started mobilizing special events to help and international psychologists like myself began contacting local mental health professionals and organizations. This report summarizes immediate efforts in New York City to express solidarity and support through fundraising concerts and vigil ceremonies.

Exactly one week after the tragedy, a Prayer Service and Candlelight Vigil for Japan was held at the Church Center for the United Nations at UN Plaza in New York City. An overflowing audience of the interfaith community, UN officials and concerned citizens came to "mark the first week anniversary" showing their solidarity.

Sitting in a row of Buddhist monks and next to my friend Jean-Pierre Amisi Ramazani who had just interviewed me about my IAAP project in Lesotho Africa for UN radio, I was moved to tears not only at the tragedy, but at the cruel irony of this nuclear disaster happening in a country where so much anti-nuclear war effort is being put forth. For example, Mayor Tadatishi Akiba of Hiroshima has been the head of Mayors for Peace for years, and spoke eloquently against nuclear armament at the 2009 Department of Public Information/NGO Conference about disarmament, where my own "Stand Up for Peace Project' has performed as well as participated in annual peace and anti-nuclear concerts and symposia throughout Japan including for the Dalai Lama and Reverend Desmond Tutu.

This solemn event opened with an incense offering and welcome by co-organizers Reverend T. Kenjitsu Nakagaki, Buddhist priest and Vice President of the Interfaith Center for New York, and Reverend Kathleen Stone from the UN Church Center. Meditations and prayers were then offered by Japanese Religious Leaders from different sects, including Reverend Nakagaki representing Jodoshinshu Buddhism, Reverend Masafumi Nakanishi from Shintoism, Reverend Shogun Kumakura from Nichirenshu Buddhism, Reverend Yugo Suzuki from Christianity, and Reverend Masamichi Kamiya from Rissho Kosei-kai Buddhism.

Welcome by Reverend Nakagaki and incense lighting by Reverend Shogun Kamakura at prayer service at the United Nations Church Center one week after the 3/11 tragedy in Japan.

Messages were delivered from leaders of the Japanese community, including Riki Ito, President of the Japanese Lions Club and Gary Moriwaki, President of the Japanese American Association of New York. In a statement on behalf of the Consulate General of Japan, Fumiho Suzawa explained that 6,500 lives were lost, 10,000 people were still missing and hundreds of thousands of people had been evacuated. Tears have been shed, she said, but the government expresses "gratitude for the outpouring of kindness and support towards all the people."

A message was read on behalf of the Sri Lankan community in New York, expressing sadness since they "know the suffering caused by this event first-hand since we also experienced a similar event…[thus] sending sincere and heartfelt sympathy towards the Japanese community worldwide."

Pianist Taka Kigawa performed J.S. Bach's Prelude in C major from "Well Tempered Clavier Book I" and Chopin's Prelude in C-sharp minor, Op 45; and Maurice Ravel's "Pavane pour une infante défunte."

A silent prayer and mediation, and traditional incense offering, was followed by a candlelight vigil. Holding lights and paper Japanese flags, we walked in silence from the church to Dag Hammarskjöld Plaza a few blocks away, to share testimonials and to network. There, I connected with many people from the health sector to determine the best way to help. Emiko Nagano, volunteer community organizer of the Humanist Movement, said that if we send love to the people of Japan they will feel our love.

Starting the prayer vigil at the UN Church Center in support of Japan: from left, Russell Daisey, international composer; UN Radio reporter Jean-Pierre Amisi Ramazani; Russ Jennings, owner of Common Soul Productions; Dr. Judy Kuriansky, IAAP UN rep and APA Division 52 member; Universal Peace Initiative founder SuZen.

Candlelight ceremony and testimonials at UN Dag Hammarskjöld park in honor of Japan

As a psychologist who has been at many disaster sites around the world, I know that people in crisis appreciate knowing that others care.

The strong message that resonated throughout was that "Japan will overcome" and that the "people of Japan are facing this tragedy with dignity" but that support is direly needed.

The next week, an "Interfaith Time of Reflection for Japan" was held at the majestic Riverside Church near Columbia University in New York City. The event was led by Reverend Nakagaki and co-sponsored by The Mission and Social Justice Ministry of The Riverside Church, the Universal Peace Initiative and its co-founder SuZen; and the Interfaith Center of New York. The large gathering was in part a result of networking through the Japanese community and through social media by volunteers trained by Columbia Journalism School Professor and social media expert Sree Sreenivasan. The solemn afternoon, in a perfectly respectful and moving tone, began with a processional, greetings from Reverend Nakagaki, a musical offering from pianist Masayo Ishigure playing "Yomigaeru-Rising Phoenix," and offerings to the altar with candlelight, incense, flowers and fruits by SuZen and mothers and children. Welcomes were offered by Reverend Robert Coleman of The Riverside Church and Reverend Chloe Breyer of the Interfaith Center of New York who said movingly that we "come together to pray in shared presence in sacred space, to give thanks [to all supporters and to honor the Japanese people who] through great suffering have an example of grace and dignity."

The theme of grace and dignity of the Japanese people in the face of such tragedy prevailed – an important testimony to psychological resilience.

Interfaith prayers were offered in many religious traditions, including Muslim (by Iman Shamsi Ali of the Islamic Cultural Center of New York); Jewish (by Rabbi Harlan Wechsler of the New York Board of Rabbis); Sikh (by Bhupinder Singh of UNITED SIKHS); Hindu (by Chan Jamoona of the United Hindu Cultural Center); Christianity (by Reverend Dr. Arnold Thomas of The Riverside Church); and Buddhism (by Reverend Shogen Kumakura of the Buddhist Council of New York).

Religious leaders offer prayers at The Riverside Church "Interfaith Time of Reflection for Japan"

Exceptionally moving reflections were offered by the Presidents of three Japanese Prefectures affected by the earthquake and tsunami, including Kenjjiro Sasaki from the Miyagi Perfecture in Sendai; Ypji Shikama from the Fukushima Perfecture; and Robert Iwasaki from the Iwate Perfecture. Their first-hand stories about the suffering of the people from the loss of loved ones, homes and livelihood, the threat from food shortage and radiation, and fears for the future, were heart-wrenching. As one ever-so-dignified gentleman cried, many others gasped empathically.

Several musical offerings including "Tamuke-Giving Hands" were performed, Candles of Hope were lit, and Japanese poet Popona Tsukino read two of her haiku poems about the tragedy, followed by silent prayer and mediation. Everyone was then invited to offer incense in the front of the church.

Division 52's Judy Kuriansky lighting incense at the "Interfaith Time of Reflection for Japan" at Riverside Church

It is significant to note psychologically that the prayer services and invocations emphasized "gratitude" to those who are supporting Japan through this crisis. This emphasis on gratitude reminded me of the song my "Stand Up for Peace Project" co-founder Russell Daisey and I wrote and have performed in Japan many times that is called "Appreciation." When we perform it, I explain that it was inspired from my years in Japan – teaching, doing TV shows, and live broadcasts of my New-York based advice radio show – where I learned about Japanese Naikan therapy which is based on expressing thanks to people and things in your life. It is consistent with Buddhist tradition to offer gratitude rather than make requests.

That same evening, I attended a concert held at Columbia University Miller Theatre headlined by Yoko Ono. The noted performance artist opened her set with a song written about the loss of John Lennon with lyrics like "He is Gone," accompanied by her son with Lennon (Sean Lennon) on guitar. The other acts were eclectic, including grunge band Sonic Youth.

At the end of the concert, Yoko announced, "Give, and you will get back." As a psychologist, I note that unconditional giving without concern for return is more powerful.

Ironically a fire alarm cleared the hall immediately after the performance, causing some mayhem outside as many fire trucks arrived, which some equated to the emotionality of the disaster. Fortunately most people had already exited.

Two days later, another concert was held to raise funds particularly for the children who have been affected by the catastrophe. Everyone was invited to "Stand With Japan in its hour of crisis" and "Let's remind everyone in despair that they are not alone in their time of need."

The evening opened with the national anthems of Japan and the United States of America, and featured twenty diverse musical acts, including traditional Japanese drums, opera arias, jazz piano and vocals, a four-person cello recital, duets and solos of classical music (e.g. Chopin, Bach and Rachmaninoff) and modern styles as well as original compositions (e.g. "Stand With Japan" and "I Do What I Can" songs). In the finale performance, jazz pianist Davell Crawford, hailed as the "Prince of New Orleans," noted the solidarity he feels for Japan given his hometown's devastation after Hurricane Katrina. Having led "Wellness Workshops" in Louisiana after Hurricane Katrina, with APA member and Louisiana psychologist Darlyne Nemeth, I was powerfully reminded of the connection not only between these two experiences involving such destructive floods, but the universality of so many natural disasters suffered by so many people in so many countries throughout the world in recent years.

One guitarist made a particularly moving dedication in my estimation, noting that while we are far away from Japan at this moment geographically, the energy of the message of support and love, and offerings from the heart, can still be felt by the people who are suffering.

Performances at the Concert for Japan Earthquake and Tsunami Victims in New York City at First Church of Christ, Scientist

The concert was organized by Nozomi Terao, who had two months earlier founded a non-profit organization called "Happy Dolls" linking children with dolls as messengers of hope. A similar concept evolved after 9/11 where young children sent toys and cards to children who had suffered losses of loved ones from the World Trade Tower attacks. My colleagues and I at the International Association of Applied Psychology had done a similar project for children in post-earthquake Haiti, where we had second graders in a New York City public school make cards, and youth in Japan send cranes (a traditional peace symbol), to children in Haiti.

Concerts are useful at these times of crisis since psychologically music is a universal language that reaches across cultures.

Upcoming concerts in New York include a series of 5 "Save Japan Benefits" throughout April; and the Japan-US Chorus Charity Concert to be held at Carnegie Hall on May 20th featuring men's glee clubs, with free admission and donations going to the Sendai Relief Fund.

Funds are of course direly needed for recovery in Japan as in all disasters. Tickets for the Yoko Ono concert were $50 and $100. While the concerts at the UN Church Center and The Riverside Church were free, offerings were made at the latter. Proceeds went to several organizations: the New York Japanese-American Lions Club Japan Earthquake Fund (as there are already many clubs in the affected area), with the promise that all donations would go directly to the affected area; the Religious NGO Network on Humanitarian Support (a cooperative system of NGOs); the United Church of Christ and American Baptist Church (that is on the ground and affiliated with the interdenominational Riverside Church); and the Humane Society International (organizing to shelter affected animas). About $30,000 was raised at the March 29th concert at the First Church of Christ with all the proceeds promised to be sent to SAVE THE CHILDREN Japan Earthquake Tsunami Relief. Other donation organizations recommended were the Japanese American Association and others listed on www.jaany.org.

The heartfelt expressions and actions of these events greatly affected all those involved, and serve as an example of immediate responses and outpourings of support and solidarity that are healing for individuals, communities and the world in these times when we are all so inter-connected globally.

Special Issue on Psychological Consequences of 2010 Chile Earthquake

Dear Colleagues,

For those of you interested on this subject, let me bring your attention to the following:

Vogel and Vera-Villarroel, the invited editors of a special issue of *Terapia Psicologica* write, "this special issue is an attempt to organize preliminary information collected by researchers on the psychological consequences of the natural disaster that occurred in Chile's south central area on February 27, 2010. This issue focuses on the types of psychological interventions that have been conducted in the affected areas, while emphasizing the need to define intervention strategies for middle- and long-term effects. Finally, some intervention strategies applied in other countries are reviewed." To see the website of the *Journal* and the special issue on Chile's earthquake and disasters please visit http://teps.cl/en/ (*Terapia Psicologica* 2010, Vol. 28, #2).

Most cordially,

Andres Consoli and Wilson Lopez

Presidente Saliente/Past President (2009-2011) SIP
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Sociedade Interamericana de Psicologia
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American Psychological Association 2011 APA Convention Travel Awards for Early Career Professionals

The Board of Convention Affairs along with the Board of Scientific Affairs and the Committee on Early Career Psychologists are pleased to announce a travel award program for early career members from all areas of psychology (education, practice, public interest and science) to attend the 2011 APA Annual Convention in Washington, D.C., August 4-7, at the Washington Convention Center.

Thirteen award recipients will receive $750 to be applied toward their 2011 APA convention expenses. The program is designed to encourage attendance and increase representation of early career members at this year's APA convention.

All early career APA members (within seven years receipt of their doctorate) are encouraged to apply. Preference will be given to applicants who are first-time attendees, or whose primary work is in basic psychological science or those who will be presenting at the 2011 convention. The submission package must include the following information:

1. Brief statement (maximum one page) about your interest in attending the convention and how you will use this award to support your attendance. Please highlight any significant achievements in your career as well as any leadership positions you have held as an early career psychologists (within APA, other related scholarly or professional organizations such as state and local psychological associations) and indicate how you believe you would benefit from attending the convention. Also, please include in your statement if the 2011 convention will be your first APA convention and if you will be receiving other funding to help cover your expenses.
2. If you are presenting at the 2011 APA convention, please include an abstract of your presentation along with the title and the names of co-presenters. Please note that you do not need to be a presenter to be eligible for this travel award.
3. Include your Curriculum Vitae (the year you were awarded a doctorate in psychology should be clearly stated).

Electronic submission instructions: Please submit all materials in a single Word document. Put your name and the name of the award in the subject line (e.g. Jane Smith, Early Career Travel Award).

The deadline for submission of materials is April 25, 2011, midnight (EST). Email or fax all materials to Kraig Scott (kscott@apa.org); fax # 202-216-7628. Award winners will be notified in May 2011 and will be acknowledged during the Early Career Social Hour sponsored by the Committee on Early Career Psychologists at the APA convention on Friday, August 5, 2011 at 6PM.

Janet Hyde Graduate Student Research Grant

Proposals are being sought for Hyde Graduate Student Research Grants. These grants, each up to $500, are awarded to doctoral psychology students to support feminist research. The grants are made possible through the generosity of Janet Shibley Hyde, Ph.D., who donates the royalties from her book, *Half the Human Experience*, to this fund. Past recipients of Hyde Graduate Student Research Grants are not eligible to apply. Because the purpose of this award is to facilitate research that otherwise might not be possible, projects that are beyond the data analysis stage are not eligible.

Please send all application materials attached to a single e-mail message to both of the Hyde Award Co-chairs at the following addresses by March 15, 2011 (or September 15th for the fall deadline):

Dr. Mindy J. Erchull, merchull@umw.edu and Dr. Olivia Moorehead-Slaughter, oms@parkschool.org

Requirements:

1. Cover page with project title, investigator's name, address, phone, fax, and e-mail address
2. A 100-word abstract
3. A proposal (5-pages maximum, double-spaced) addressing the project's purpose, theoretical rationale, and procedures, including how the method and data analysis stem from the proposed theory and purpose.
4. A one-page statement articulating the study's relevance to feminist goals and importance to feminist research.
5. The expected timeline for progress and completion of the project (including the date of the research proposal committee meeting). The project timeline should not exceed two years.
6. A faculty sponsor's recommendation, which includes why the research cannot be funded by other sources. This letter should be attached to the e-mail with the application materials. Please do not send it separately.
7. Status of IRB review process, including expected date of IRB submission and approval. Preference will be given to proposals that have received approval.
8. An itemized budget (if additional funds are needed to ensure completion of the project, please specify sources)
9. The applicant's curriculum vitae
10. All sections of the proposal should be typed and prepared according to APA style (e.g., please use 12-point font)

Proposals that fail to meet the guidelines described above will not be reviewed.

Review Process

A panel of psychologists will evaluate the proposals for theoretical and methodological soundness, relevance to feminist goals, applicant's training and qualifications to conduct the research, and feasibility of completing the project.

Other Requirements

Only one application will be accepted per student, for each application deadline. Applicants who are involved in multiple projects that meet the submission requirements should choose the project that best fits the evaluation criteria (see "Review Process").

Within 24 months of receipt of the grant, recipients are expected to submit to the Hyde committee co-chairs a complete and final copy of the research document (e.g., a copy of the thesis, dissertation or journal manuscript based on the sponsored research), along with a 500-word abstract for publication in Division 35 newsletter. In addition, grant recipients shall acknowledge the funding source in the author's notes in all publications. Hyde award winners will be announced at the APA convention during Division 35 Social Hour. The names of the Hyde award winners may also be posted in Division 35 newsletter as well as on Division 35 web page and listserv.

Questions and other communications may be sent to the committee co-chair:

Mindy J. Erchull, Ph.D.
Co-Chair, Hyde Research Award Committee
Department of Psychology
University of Mary Washington
1301 College Avenue
Fredericksburg, VA 22401-5300
Phone: (540) 654-1557
E-mail: merchull@umw.edu

Congratulations to Division 52 Fellow Judy Kuriansky

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Friends of the UN Announces 2011 Tolerance Awardees: Honors Dr. Judy Kuriansky with 2011 Lifetime Achievement in Global Peace and Tolerance, Nejeed Kassam as first Youth Ambassador, and Launches Tolerance Awareness Campaign, "Wear My Hat" with Awards

New York, NY 1/21/11 – Dr. Noel Brown, President of 'Friends of the UN' (FOTUN) announces that as Friends of the UN grows to become the world's largest and most connected community of global citizens working to support the achievement of the Millennium Development Goals and the ideals of the United Nations, the association has named its two new honorees for 2011's Global Peace and Tolerance Awards.

"To help people see that fundamentally all people are the same, though we wear different hats, have different lives and grow up culturally different, then we might begin to realize we can take deeper steps of global engagement towards a more peaceful, tolerant world. Further, we can get things done to overcome dire global circumstances, and achieve these goals together," says Dr. Brown.

The first hat to symbolize the worldwide campaign will be awarded to Dr. Judy Kuriansky, the 'Friends of the UN' 2011 Awardee for a Lifetime Achievement in Global Peace and Tolerance at a ceremony at the 8th Annual United Nations Youth Assembly, taking place at UN headquarters in New York January 20-21, hosted by the Friendship Ambassador Foundation. Kuriansky, an internationally acclaimed clinical psychologist, humanitarian, journalist and Main United Nations NGO representative for the International Association of Applied Psychology and the World Council of Psychotherapy, will address the youth participants about field models in Haiti and Africa that advance the MDGs, as well as the role of youth and the importance of tolerance in such efforts.

"Dr. Judy Kuriansky is the epitome of the global, responsible citizen we want all people on the planet to strive to be. For years she has tirelessly given her talent and time to causes of peace which make the world a better and more tolerant place for many," said Dr. Brown.

In receiving the prestigious honor, Judy Kuriansky joins luminaries such as Dr. Michael E. DeBakey, the Honorable Mikhail Gorbachev, Melba Moore, Maestro Zubin Metha, Arnold Schwarzenegger, Alanis Morissette, Kyai Haji Abdurrahman Wahid and Sergio Vieira de Mello (Posthumous) who signify what being a 'Friend of the UN' means, and becomes an Ambassador for its ideals and goals.

A well know radio call-in advice host for decades, Kuriansky is on the adjunct faculty of Columbia University Teachers College and Columbia College of Physicians and Surgeons and a Visiting Professor at Beijing Health Science Center, and has done disaster relief worldwide including after the Asian tsunami and earthquakes in Haiti and China. She also serves on the Boards of the Peace Division of the American Psychological Association and U.S. Doctors for Africa.

"My first event with my 'new hat' of Tolerance as a 'Friends of the UN' Ambassador," says Dr. Kuriansky, *"will be to announce a 'call to action' at the upcoming Youth Assembly at the United Nations, inviting young people to join me in becoming a Friend of the UN, to work together to foster mutual understanding and appreciation of diversity,"* says Kuriansky whose recent book "Beyond Bullets and Bombs" about grassroots peacebuilding chronicles youth efforts towards mutual understanding, tolerance and cooperation. *"Youth have an important role to play in promoting and em-*

bodying the ideals which the UN charter set out 60 years ago." The United Nations International Year of Youth began in August 2010.

Additionally, in her new role, Dr. Kuriansky will 'Share Her Hat' with 'Friends of the UN' 2011 Youth Ambassador Nejeed Kassam who, at 24 embodies the hope and acceptance that we want to see in the future world.

Dr. Kuriansky says, *"Nejeed is an aspiring change-maker devoted to helping other youth to appreciate diversity. At a young age he is the creator and director of the High on Life campaign and the editor of the book, 'High on Life: Stories of Hope, Change, and Leadership'. He is the founder of the international NGO 'End Poverty Now' where he continues to work as the organization's Executive Director, as well as Networks for Change".*

Adds Dr. Brown, *"Nejeed Kassam IS the change we want to see in the world. As a young person who will inherit the world we are proud to name him as a Youth Friend of the United Nations and believe his own future actions will benefit the whole world, as his current initiatives at such an early age have shown".*

As an Ambassador for Friends of the UN, Dr. Kuriansky will wear her Tolerance hat at many events and invite others to 'Wear My Hat' as a symbol of their commitment to tolerance. For example, models, designers and attendees at the upcoming February Fashion Week in New York City will be invited by Dr. Judy to 'Wear My Hat'.

"I want to show that tolerance and peace is chic," says Kuriansky, whose Stand Up for Peace Project plays at peace concerts and has done seminars about peace and conflict resolution worldwide.

Friends of the United Nations will further its mission with events, media campaigns and dialogue conferences related to important issues world peoples must face together, asking individuals, corporations, NGOs and governments alike to become a member and partner in its goals for the future.

"We have only one world in this life, and for now, only one planet on which to live together," says Dr. Brown. "For the foreseeable future, we must find new ways to create, collaborate and move forward – in tolerance and peace – or, I fear we won't."

Founded in 1985, Friends of the United Nation (FOTUN) is an independent, non-partisan organization dedicated to increasing awareness of the United Nations' activities through partnerships with educational institutions, corporations, media, international governments and NGOs to bridge the gap between ideas necessary to achieve global progress and collaboration of people worldwide in actual work on issues of peace, human rights, the environment, children and responsible social and economic development.

For more information and to join Friends of the UN, visit www.fotun.org or Facebook at http://on.fb.me/g8JaSu.

Correspondence related to this article should be sent to:
Donnetta Campbell, donnettacc@yahoo.com

The Florence L. Denmark and Mary E. Reuder Award for Outstanding International Contributions to the Psychology of Women and Gender

Purpose

The award is named for two charter members of Division 52 who are known for their scholarly contributions, international outlook, and outstanding mentoring. The award's purpose is to recognize and encourage other outstanding psychologists who have made similar international contributions to further the understanding of women and/or gender. The outstanding contributions can be cross-cultural studies of women and gender, the mentoring of young colleagues across borders, the training of psychologists to do international work, or other areas deemed important by the Award Committee.

Criteria for Eligibility

The recipient must be a psychologist with a demonstrated interest in international or cross-cultural psychology. Current membership in Division 52 is not a requirement. The Committee will make up to one award per year.

The Award

The award shall consist of a plaque. The winner will be announced during the Division's annual business meeting at the APA convention.

Submission Requirements and Procedure

Submission requirements are a copy of the candidate's c.v. and a letter of nomination setting forth the most outstanding contributions of the candidate.

Six copies of the materials should be sent to:
Joan C. Chrisler, Ph.D.
Department of Psychology
Connecticut College
New London, CT 06320
USA

Deadline: All materials must be received by May 1, 2011.

E-mail questions to Dr. Chrisler at jcchr@conncoll.edu.

Fourth Annual Psychology Day at the United Nations

Reach Them, Teach Them:
The Role of Psychology in Achieving Universal Access to Education

United Nations Headquarters and Surrounding Venues
New York, New York

Thursday, 14 April 2011
10:00am – 5:00pm

Morning DPI Briefing
Reach Them, Teach Them

Afternoon Concurrent Workshops
Innovative Ideas
Innovative Technologies
Challenging Places and Situations

To register, go to http://sites.google.com/site/unpsychday/

Nominations for International Union of Psychological Science Awards

Nominations are invited for the following International Union of Psychological Science sponsored awards to be given at the 2012 International Congress of Psychology in Capetown, South Africa. Deadline for nominations is only 6 months away. More details at http://www.iupsys.net/index.php/prog-awards or by following the hotlinks below.

Mattei Dogan Prize: Recognizes a contribution that represents a major advancement in psychology by a scholar or team of scholars of high international reputation.
Young Investigator Awards: Recognize young post-doctoral scientists who have already made a significant contribution to psychological science.
Achievement Against the Odds Award: Honors a researcher or team of researchers who succeeded in conducting research under extremely difficult circumstances.

Lifetime Career Award: Honors distinguished and enduring lifetime contributions to international cooperation and advancement of knowledge in the field of psychological science.

The deadline for receipt of nominations for the 2012 Awards is 30 September 2011.

Call for Student Research Manuscripts on Women and Gender

Deadline April 1, 2012

The Society for the Psychology of Women (SPW) of the American Psychological Association and the Association for Women in Psychology (AWP) seek research manuscripts for the 2012 Annual Student Prize for Psychological Research on Women and Gender.

Research Topics

The student research manuscript should focus on women's lives and issues, or more generally, on gender ideologies and behavior, from a feminist perspective.

Eligibility

Jointly-authored papers are eligible, but the first author must have been a student at the time the research was conducted, as indicated by a statement by the first author, in a cover letter accompanying the submission, specifying when and from what institution the first author obtained the degree, the name of the faculty who supervised the research, and the department of the supervising faculty. Entries should be of journal length and in *APA* style. Eligible papers include unpublished manuscripts as well as papers that have been submitted or accepted for publication. Published or presented papers are also eligible as long as they have a date of 2011 or 2012. All papers should be submitted in manuscript form, not as pre-prints or prints with information about submission and publication status provided in the cover letter.

Evaluation

Entries will be judged on theoretical creativity, methodology, clarity and style, and social importance of the research questions and findings for the psychology of women and gender.

Awards

A $250.00 prize will be awarded to the best paper. First and alternate winners will be announced at the 2012 meeting of the American Psychological Association.

Submission Procedure

Please attach a copy of your paper to an e-mail sent to the address below. Also, please send four (4) copies of the paper, a self-addressed, stamped postcard, and a self-addressed stamped business size envelope by April 1, 2012 to: Silvia Sara Canetto, Ph.D., Department of Psychology, Colorado State University, Fort Collins, CO 80523-1876 (silvia.canetto@colostate.edu)

The Submission Deadline for the 2011 AWP/SPW Student Research Manuscript Prize is April 1, 2012

Call for Papers: Journal of Asia Pacific Counseling (JAPC)

www.kcajournal.org

Deadline: April 30, 2011

The Journal of Asia Pacific Counseling (JAPC) is an official publication of the Korean Counseling Association (KCA) that has more than 8,000 South Korean counselors and counseling psychologists as its members. Korean Counseling Association has long recognized the need for having an outlet for scholarly work that gives special attention to the applications of counseling with diverse populations in the Asia Pacific region. In setting up the Journal of Asia Pacific Counseling, many internationally renowned scholars have provided invaluable input regarding the title of the journal, potential editors, and the target audience.

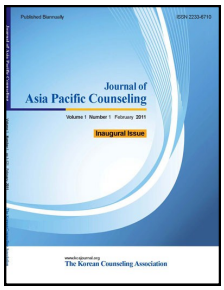

JAPC is intended for both researchers and practitioners, and includes theoretical, empirical, and methodological articles in the areas of counseling interventions, prevention, career development and vocational psychology, supervision and training, assessment, multicultural aspects of counseling, and consultation.

All articles are published in English, and JAPC is issued twice a year in February and August. The inaugural issue has just been released in the past month. Please visit the homepage of the Journal of Asia Pacific Counseling (www.kcajournal.org) for full details on aims and scope, editorial policy, and article submission.

The next due date for manuscript submission is on April 30, 2011. Please submit manuscripts via e-mail (japc@snu.ac.kr), following the guidelines described on the homepage of the journal.

We hope you will seriously consider JAPC for your scholarship.

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Graduate Student Scholarships To Be Offered for Teaching the Psychology of Men Continuing Education Program at the APA Washington D.C. Convention

Teaching the Psychology of Men will be a Continuing Education Program during the APA Convention in Washington, D.C. Eleven scholarships will be awarded to graduate students who want to attend the workshop free of charge.

The purpose of this introductory workshop will be to assist psychologists in developing course work on the psychology of men using the theoretical and empirical literature on men and masculinity. Participants will learn basic knowledge on how to create a psychology of men course or how to infuse this content into existing courses on gender or the psychology of women. Each presenter will share their syllabi, reading materials, class manuals, evaluation processes, and other resources. The workshop will discuss pedagogical processes such as traditional lecturing, psychoeducational techniques, group discussion approaches, use of video media, student assessment techniques, managing classroom problems, and the infusion of diversity and multiculturalism as critical content.

The goals of the workshop are to help psychologists:

1) Design a psychology of men course or incorporate the psychology of men into existing courses;
2) Locate syllabi, core concepts, readings, media, self assessments, and other resources to teach the psychology of men;
3) Utilize multiple teaching methods when teaching the psychology of men including psychoeducational and multicultural approaches; and
4) Enumerate the critical problems/dilemmas and solutions when teaching the psychology of men.

The teaching faculty for the workshop include: James M. O'Neil, Ph.D., University of Connecticut, Storrs, CT; Christopher Kilmartin, Ph.D., Mary Washington University, Fredericksburg, VA; James Mahalik, Boston College, Chestnut Hill, MA.

Information about the graduate student scholarships, how to apply, criteria for selections, and the deadline date can be obtained by emailing Jim O'Neil, Chair, Committee on Teaching the Psychology of Men, Society for the Psychological Study of Men and Masculinity (SPSMM), Division 51 of APA, at jimoneil1@aol.com.

Registration For APA Continuing Education Programs Begins April 15, 2011: Call 1-800-374-2721, ext. 5991 or register online at apa.org/ce.

The Institute for the Study and Promotion of Race and Culture 2011 Diversity Challenge: Intersections of Race or Culture and Gender or Sexual Orientation October 28-29, 2011

Each year the Institute for the Study and Promotion of Race and Culture addresses a racial or cultural issue that could benefit from a pragmatic, scholarly, or grassroots focus through its Diversity Challenge conference. The theme of the 2011 conference is the examination of intersecting identities from multiple frameworks. The two-day conference held at Boston College includes panel discussion/symposia, workshops, structured discussions, a poster session, and individual presentations by invited experts and selected guests including educators, administrators, researchers, mental health professionals, and community organizations. Individuals interested in presenting should check the ISPRC website where the Call for Proposals is posted, http://www.bc.edu/schools/lsoe/isprc/dc2011.html. The proposal deadline is May 2, 2011.

General information about the conference including pre-registration will also available on the website. For all inquiries feel free to email isprc@bc.edu.

International Employment Opportunities

Michael J. Stevens, PhD, DHC
Illinois State University
mjsteven@ilstu.edu

Murdoch University, School of Psychology: The School of Psychology at Murdoch University seeks applications for a senior lectureship in clinical psychology. The appointee will have a primary responsibility for teaching and supervising in the postgraduate clinical psychology program. The appointee will also be expected to conduct research and supervise student research. Applicants should hold relevant postgraduate qualifications in psychology, be registered or registrable as psychologists within Australia, and be eligible for membership of the College of Clinical Psychologists in the Australian Psychological Society. They should have experience in providing clinical supervision and teaching in an academic environment. Knowledge and expertise in the area of psychological assessment would be an advantage. The School has a tradition of excellence in research and teaching, particularly in areas of applied psychology and offers a range of accredited courses in psychology (including specializations in clinical and organizational psychology at the postgraduate level). Information about the School of Psychology can be found at http://www.psychology.murdoch.edu.au/. Information about this position and other upcoming positions in the School of Psychology can be obtained from Associate Professor Max Sully, Dean of the School of Psychology, at +08 9360 2253 or M.Sully@murdoch.edu.au. Application procedures and a position description with detailed selection criteria are available from the University's web site at http://jobs.murdoch.edu.au/. All applicants should address the selection criteria within their application. Please send applications to recruitment@murdoch.edu.au. Closing date: March 2011

University of New England, Clinical Psychology Program: Join the UNE Clinical Psychology Program to strengthen and expand the University's research and teaching capacity in this area and to serve the needs of education in clinical psychology in regional Australia. This Program is well-established and popular with students, particularly those wanting to live and work in rural and regional areas. The Clinical Program at UNE has five full-time staff, a part-time clinic receptionist, and contributions from the other fifteen psychology staff as well as from adjunct practitioner-educators. The Clinical Program staff work closely with the other academics in Psychology and the program is integrated with the general psychology program in regards to teaching and research collaboration. There are 12 Commonwealth supported student places per year. The program provides a key pathway for education and training in clinical psychology in a major rural and regional centre in Australia. The successful applicant may have teaching and research interests in any area of clinical psychology including (but not limited to) child clinical psychology, adult mental health, clinical neuropsychology, and health psychology.

Further information about psychology at UNE, including the Clinical Program is available at www.une.edu.au/bcss/psychology/. Informal enquiries may be directed to Dr. Tanya Hanstock, Director of the Clinical Psychology Program, Tel: +61 2 6773 2871, E-mail: thansto2@une.edu.au

Salary: AUD$90,977 to $104,763 per annum (Senior Lecturer level); or AUD$74,438 to $88,222 per annum (Lecturer level) plus 17% employer superannuation and optional salary packaging. A 15% market loading currently applies to this position. This loading is subject to review from time to time.

Closing date: April 11, 2011

An application package, including selection criteria that must be addressed, may be obtained from www.une.edu.au/recruit/ or by phoning Human Resource Services, +61 2 6773 3972. Applications will be received up to 5 pm on the closing date.

Macquarie University, Department of Psychology: An outstanding opportunity exists for two clinical neuropsychologists and one organizational psychologist to join one of the leading psychology departments in Australia. The organizational position is Level B (Lecturer) and the Neuropsychology positions are at Level B or C (Lecturer/ Senior Lecturer) and Level D or E (Associate Professor/Professor). Located on the north shore of Sydney, the Psychology Department at Macquarie University is a research intensive department that is home to the Centre for Emotional Health, a newly planned Centre for Elite Performance, Expertise, and Training, and other highly productive research groups and laboratories. It is also closely affiliated with the Macquarie Centre for Cognitive Science (MACCS), the Centre of Excellence in Cognition and its Disorders (a national centre of excellence), the Macquarie University Hospital (which specializes in neurosurgical research and practice), and the Mild Traumatic Brain Injury Clinic at Westmead Hospital. The Psychology Department has outstanding undergraduate and post-graduate programs, and a large number of excellent higher-degree research students. The successful applicants will contribute to the undergraduate curriculum and to the postgraduate programs in clinical neuropsychology or organizational psychology. The successful applicants will be expected to teach and carry out research in a relevant area, supervise research students, and seek external research funding and will have the opportunity to maintain a neuropsychology or organizational psychology practice.

Neuropsychology positions:
For the Level B or C appointment available teaching areas include behavioral management and psychopathology, and

psychological assessment. The Level D or E will have the relevant professional expertise to provide academic leadership for the program. Candidates must have a PhD in psychology and be eligible for membership to the Australian Psychological Society's College of Clinical Neuropsychologists, and for endorsement as a clinical neuropsychologist with the Psychology Board of Australia.

Organizational Psychology position:
Candidates must have a PhD in psychology and be eligible for membership of the Australian Psychological Society's College of Organizational Psychologists, and for endorsement as an organizational psychologist with the Psychology Board of Australia.

For full details of the positions and selection criteria, please visit http://www.mq.edu.au/jobs/. Anticipated start date for these roles is from July 2011.

Appointment: Full-time, continuing (permanent)

Inquiries: Professor Bill Thompson on +61 2 9850 9949 or E-mail: bill.thompson@mq.edu.au

Package: Salary level dependent on level of appointment

Applications close: March 2011

University of British Colombia, School of Arts & Sciences: The Irving K. Barber School of Arts & Sciences invites applications for a tenured or tenure-track position in the area of clinical psychology at the rank of associate professor, to begin with a possible start date of January 1, 2012. The position will be held in Psychology (http://web.ubc.ca/okanagan/psyo/welcome.html) within the Barber School. The successful candidate will assume the role of clinical training director, and will provide leadership, guidance, direction, and coordination and inspiration to students/interns, members of the training committee, and other program staff on matters relating to training in professional psychology. Minimum Qualifications: A PhD in clinical psychology from an APA/CPA-accredited university; minimum 4 years of full-time university teaching at the rank of assistant professor (or equivalent) or higher; evidence of scholarly achievement comparable to peers at major research universities; a productive research program; experience and skills in teaching and mentoring within a university-based clinical psychology PhD program; and licensed or license eligible in clinical psychology in British Columbia. The Barber School (http://web.ubc.ca/okanagan/ikbarberschool/welcome.html) - the largest faculty in the University of British Columbia, Okanagan Campus - offers opportunities for world-class research that spans the sciences, social sciences, and humanities within an intimate teaching and learning environment. UBC is consistently ranked among the world's top 40 universities, and the UBC system comprises two distinct and autonomous campuses in the province of British Columbia - one in Vancouver and the other in Kelowna. Applicants should provide a cover letter, curriculum vitae, evidence of teaching ability (e.g., course evaluations), program of research, and the names and contact information of three referees. All documents must be submitted as E-mail attachments and sent to recruitment.bsas@ubc.ca. For additional information, go to http://web.ubc.ca/okanagan/facultystaff/prospective/recruitment/tenuretrack.html#bsas. Applications will be reviewed starting April 30, 2011.

Pine River Institute, Chief Executive Officer: Pine River Institute is a residential treatment center and outdoor leadership experience for youth 13 to 19 struggling with mental health issues, and specifically, substance abuse. Their campus is located on a 200-acre site 100 kilometers northwest of Toronto, Ontario, and includes a residential program for 36 adolescents, an eight-bed therapeutic wilderness program near Algonquin Park, an aftercare program, and a head office in Toronto. Its family-centered program is innovative and highly structured, and creates opportunities for troubled teens to engage in a focused transformation process through a fusion of education, therapy, recreation, and life skills. The majority of its students is from Ontario and funded by the Ministries of Health and Education. They also work with families from across Canada and internationally. The organization has been in operation for 4.5 years, and has achieved stable funding from the Ministries of Health and Education. The current CEO and the Board have developed a 10-year developmental trajectory (strategic plan). A collaborative, relational therapeutic milieu culture has been achieved, and the new CEO will implement the growth strategy within the context of ensuring the integrity of the Institute's integrated educational and therapeutic program (the Pine River Model - comprehensive developmental-systemic approach). Reporting to the Board of Directors, and working collaboratively with the Institute's Executive Director, Clinical Director, and staff, the new CEO will lead the organization through its next stage of growth and success. To meet the challenges of this position, candidates should meet the following criteria:

- Relevant graduate degree (psychology, social work, mental health, health sciences, Public policy, etc.).
- Professional affinity with the Pine River treatment model;
- Proven ability to build organizational capacity with clinical and service excellence, and ensure accountability for such; an excellent manager and coach for staff;
- Demonstrated ability to develop, foster and nurture strong working relationships with external stakeholders (local community, government(s), other leading clinical/professional organizations, relevant community organizations, business, key funders/donors) to advance an organization's mission, and plans. Proven ability to be an effective champion and advocate for an organization, its plans and its people; become a valued "go-to" thought leader;

- Proven senior leadership/management experience in a mental health, addiction treatment, adolescent health organization.

Please forward your resume, in confidence, to Heather Connelly, Managing Director, Kinley & Connelly, Stanton Chase International (Toronto), 220 King Street West, Toronto ON, M5H 1K4, (416)593-5550, hconnelly@kinleyconnelly.com or to Cheryl Lai, clai@kinleyconnelly.com.

***Science Applications International Corporation (Germany), Addictions Counselor*:** Develop and implement a community -based adolescent substance abuse prevention and treatment program on U.S. military base overseas (Netzaberg, Germany). The duties include intake, screening, assessment, case management, providing AOD training and specialized education on a variety of topics, treatment planning, discharge and continuing care planning, records management, and participation in quality assurance. The essential prevention and education role includes classroom education for adolescents, in-service training to community agencies, community education, screening for and facilitation of prevention support groups for youth from high risk environments, and participate in community awareness campaigns. Also, obtain and maintain written referral agreements with all community agencies, briefing referral agencies about the ASACS program and how to transfer adolescents for assessment and case record management and documentation, maintaining program statistics maintaining Continuous Quality Improvement Manual; maintain valid license. Required Education: Masters

NOTES: 4 openings. US Residents Only. Employer will assist with relocation costs. Two-part compensation package includes salary plus Living Quarters Allowance. Foreign-Earned income (U.S. Federal and State Tax Exempt).

Sterling Medical, Child Psychologist: Civilian opportunity for a child Psychologist to provide EDIS services to the U.S. Navy located in Okinawa, Japan. Sterling Medical offers excellent compensation, relocation, paid time off and holidays off, CEU allowance, health/dental/life/ADD and disability insurance, and tax advantages. For more information, please contact Rochelle Myers at (800)852-5678 x.323 EST, or E-mail rmyers@sterlingmedcorp.com. Fax number is (727)821-0711. Child psychologist must have a doctorate in clinical or counseling psychology from an APA-approved program, and completed an APA-approved internship, with a fellowship in child psychology. Must have 2 years experience in family-centered services to children with disabilities and/or behavioral disorders.

New Zealand, Clinical Psychologists: We have full-time clinical psychologist vacancies to fill for community mental health and other service organizations. You must have: Ph.D. in clinical psychology; current practicing license. A minimum of two-years post-supervisory experience. The ability to receive your New Zealand psychologist registration with clinical scope; the desire to commit two years or longer. E-mail: office@alignrecruitment.com; Phone: +64 3 366 8779: Fax: +64 3 377 6770; Web www.alignrecruitment.com. An expatriate American is available to assist with all enquiries.

University of Otago, Department of Psychological Medicine: Applications are invited for the part-time position of associate professor/senior lecturer in the Department of Psychological Medicine from graduates with relevant specialty qualifications in clinical psychology. Duties include contributing to: undergraduate medical school teaching, relevant specialist topic(s) in the postgraduate programs in cognitive behavior therapy and psychiatry, Departmental and Faculty examination duties, developing a personal research program and making applications for external funding support within 1 year of appointment. Those appointed at associate professor level will be expected to have already developed a substantive research program of at least national standing. The appointment will be for up to 0.8 FTE for a senior lecturer or up to 0.7 FTE for an Associate professor. This position offers an exciting academic opportunity to contribute to the development of undergraduate and postgraduate mental health education, and to mental health research, within the School of Medicine and Health Sciences, University of Otago, Wellington.

Specific enquiries may be directed to Professor Peter Ellis, Head, Department of Psychological Medicine, University of Otago, Wellington, P.O. Box 7343, Wellington South, New Zealand, Tel: +64 4 385 5656, Fax: +64 4 385 5877, E-mail: pete.ellis@otago.ac.nz

To see a full job description and to apply online go to: www.otago.ac.nz/jobs

Nanyang Technical University, Business School: The Nanyang Business School (NBS) invites applications for assistant professor/research scientist with the Culture Science Institute in the area of social neuroscience, in the Division of Strategy, Management and Organization. Applicants should hold a doctorate degree with expertise in social neuroscience (broadly defined) and research interests in culture, social cognition, behavioral economics, and other business related topics. The Culture Science Institute (CSI) is a newly developed research institute at NBS, Nanyang Technological University in Singapore. It aims at conducting cutting-edge transdisciplinary research on culture and business. The school has recently built a research laboratory equipped with state-of-the-art ERP/EEG system, bio-physiological system, eyetrackers, and other facilities for acquiring behavioral data. Functional MRI facility will also be available at a later stage. Successful candidates will be offered an internationally competitive salary commensurate. International faculty will enjoy subsidized housing in a 500-acre residential campus environment, on-campus childcare center, and children's educational allowances for Singapore's acclaimed international schools. Applicants should submit (1) a curriculum vitae with a full list of publications, (2) statements of teaching and research

interests, (3) representative publications, and (4) three references and letters of recommendation. Applications will be screened until positions are filled. Please send application package electronically (PDF documents) to HeadSMO@ntu.edu.sg, and addressed to:
Professor Soon ANG
Goh Tjoei Kok, Endowed Chair & Professor in Management
Head, Division of Strategy, Management & Organization
Nanyang Business School, Nanyang Technological University
Singapore 639798

Nanyang Technological University, School of Humanities and Social Sciences: The School of Humanities and Social Sciences at Nanyang Technological University (NTU), Singapore, invites qualified academics to apply for a faculty position as assistant professor. Applications are welcome from any area of academic psychology, though preference will be given to social psychology and/or areas that complement the research foci in Psychology at NTU. Successful candidates should possess strong research track records, including publications in international peer reviewed journals, and should demonstrate a commitment to effective teaching. The successful candidate is expected to have completed the requirements for the PhD degree in psychology, or a cognate discipline, and post-doctoral experience will be a significant advantage. A visiting appointment, particularly in social psychology, will also be considered. Salary will be competitive and will commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package. Further information about the University and the Division of Psychology can be viewed at the following websites: NTU: www.ntu.edu.sg. Division of Psychology: http://www.ntu.edu.sg/hss/psychology/Pages/default.aspx.

To apply, please refer to the Guidelines for Submitting an Application for Faculty Appointment (http://www.ntu.edu.sg/ohr/career/submitApplications/pages/faculty.aspx) and E-mail your application package [consisting of cover letter, curriculum vitae, personal particulars form, teaching and research statement, three selected reprints/preprints of publications, and the names and email addresses of three potential referees] to:
Head, Division of Psychology
School of Humanities and Social Sciences
Nanyang Technological University
14 Nanyang Drive
Singapore 637332
E-mail: H-DPSY@ntu.edu.sg

Review of applications begins on April 4, 2011 and we will continue until the position is filled. Only short-listed candidates will be notified.

Özyegin University, Department of Psychology: Özyegin University invites applications for an assistant professor position in psychology. A PhD degree is required. Applicants must have a strong commitment to teach at both the undergraduate and graduate levels, to conduct theoretical as well as applied research, and to provide community service. Özyegin University is a private, not-for-profit university located in Istanbul, at the crossroads of Europe and Asia. Founded in 2008, Özyegin University aims to be a "Third Generation University" that facilitates the transformation of knowledge to economic and societal value. Internationally competitive salaries and benefits are offered to qualified candidates. The language of education is English. Currently, Özyegin University has undergraduate and graduate programs in engineering, business, and hotel management. Plans are under way to start programs in law, economics, international business, entrepreneurship, finance, civil aviation management, as well as psychology. Following the successful launch of the undergraduate program in 2011, we plan to launch graduate programs within 3 years. Our intent is to have particular strengths in clinical psychology as industrial/organizational psychology, while serving all areas of the discipline. Candidates should submit a cover letter, together with their curriculum vitae, teaching and research statements, and complete contact information of three professional references. Please direct questions and submit applications by E-mail to Prof. Erhan Erkut, Rector (rector@ozyegin.edu.tr), +90 216 559 2300. Review of applications will continue until the position is filled.

Accredited Internship Training Programs – Canada:

Alberta Children's Hospital
1820 Richmond Road, SW
Calgary, Alberta
Canada T2T 5C7
Accredited: June 30, 1992
Next site visit scheduled 2008

British Columbia Children's Hospital
4480 Oak Street
Vancouver, British Columbia
Canada V6H 3V4
Accredited: May 19, 1995
Next site visit scheduled 2012

Center for Addiction and Mental Health, Clarke Division
(formerly listed as The Clarke Institute of Psychiatry)
250 College Street
Toronto, Ontario
Canada M5T 1R8
Accredited: May 23, 1991
Next site visit scheduled 2007

Children's Hospital of Eastern Ontario
401 Smyth Road
Ottawa, Ontario
Canada K1L 8L1
Accredited: May 4, 1990
Next site visit scheduled 2012

The Hospital for Sick Children
Department of Psychology
555 University Avenue
Toronto, Ontario
Canada M5G 1X8
Accredited: August 10, 2001
Next site visit scheduled 2011

IWK–Grace Health Center
(formerly listed as IWK Children's Hospital)
5850 University Avenue
P.O. Box 3070
Halifax, Nova Scotia
Canada B3J 3G9
Accredited: January 9, 1996
Next site visit scheduled 2006

London Health Sciences Center
339 Windermere Road
London, Ontario
Canada N6A 5A5
Accredited: May 13, 1999
Next site visit scheduled 2007

University of Manitoba Counseling Service
474 University Center
Winnipeg, Manitoba
Canada R3T 2N2
Accredited: June 30, 1992
Next site visit scheduled 2012

University of Manitoba Faculty of Medicine
Department of Clinical Health Psychology
PZ-350, 771 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 3N4
Accredited: May 1, 1979
Next site visit scheduled 2011

McGill University Psychology Internship Consortium
(This program is affiliated with the McGill University doctoral training program in clinical psychology)
Department of Psychology
1205 Dr. Penfield Avenue
Montreal, Quebec
Canada H3A 1B1
Accredited: September 1, 1972
Next site visit scheduled 2007

University of Ottawa
(This program is affiliated with the University of Ottawa doctoral training program in clinical psychology.)
Center for Psychological Services
School of Psychology
11 Marie Curie
Ottawa, Ontario
Canada K1N 6N5
Accredited: October 27, 1987
Next site visit scheduled 2007

Queen Elizabeth II Health Sciences Center
(formerly listed as Camp Hill Medical Center)
1763 Robie Street
Halifax, Nova Scotia
Canada B3H 3G2
Accredited: October 23, 1992
Next site visit scheduled 2006

Royal University Hospital
Department of Clinical Health Psychology
Saskatoon, Saskatchewan
Canada S7N OW8
Accredited: May 12, 1994
Next site visit scheduled 2011

St. Joseph's Healthcare
Anxiety Treatment and Research Center
6th Floor, Fontbonne Building
50 Charlton Avenue, East
Hamilton, Ontario
Canada L8N 4A6
Accredited: July 15, 2005
Next site visit scheduled 2010

Vancouver Hospital and Health Sciences Center—UBC Hospital (formerly listed as University Hospital—University of British Columbia Site)
Internship Training Program in Professional Psychology
2211 Wesbrook Mall
Vancouver, British Columbia
Canada V6T 2B5
Accredited: November 6, 1987
Next site visit scheduled 2006

CANADEM JPC International Internships: CANADEM is looking for qualified Lawyers, MAs and other university graduates interested in development, human rights and peace building to work overseas starting in June with the following international organizations:

- Sierra Leone Special Court
- UNDP (United Nations Development Programme) - Central Asia, Africa
- UNESCO (United Nations Educational, Scientific, and Cultural Organization) - Thailand
- OSCE (Organization for Security and Cooperation in Europe) - Balkans
- IOM (International Organization for Migration) - Washington DC, Ukraine
- UNHCR (United Nations High Commissioner for Refugees) - Geneva, Croatia
- IFES (International Foundation for Election Systems) - Congo (Kinshasa)

- UN ODC (United Nations Office on Drugs and Crime) - Uzbekistan

CANADEM is sponsoring up to 40 internship placements, pending funding notice from the Department of Foreign Affairs and International Trade (DFAIT) and the Canadian International Development Agency (CIDA). You must be under 30, underemployed and meet all other eligibility criteria (for more information please visit our website at www.canadem.ca).

Of the over 120 JPCs placed by CANADEM over the past four years, most found relevant employment after completing their internships. Many continued working as full-time staff members with their host organization.

On-Going Support: CANADEM interns are given assignments and responsibilities commensurate with their academic, working and volunteer experiences. Contracts include:

- An in-Canada pre-departure orientation (early summer);
- A six months overseas posting;
- On-going follow-up while an intern (including job leads); and
- A final in-Canada debriefing session.

Throughout the internships, the Program Coordinator remains in contact with the JPCs and, as the internships draw to a close, provides assistance in reworking and updating resumes.

Funding: This project is undertaken within the Government of Canada's Youth Employment Strategy (YES) with contributions from DFAIT and CIDA. CANADEM provides its interns with a $12,000 stipend out of which all direct expenses are paid (e.g. travel, health insurance, briefing sessions, accommodations, etc).

For Application, Eligibility and Additional Information Visit: www.canadem.ca

"A national roster of Canadian skilled in human rights, peace building, democratization, admin-logistics, security, reconstruction and other field expertise." tel: (613) 789-3328, fax: (613) 789-612, e-mail: neil.burron@canadem.ca , web: www.canadem.ca

Please send all completed applications to: jpc@CANADEM.ca.

The Seeds of Sustenance Fellowship Program: The Seeds of Sustenance (SOS) Fellowship Program is a unique cross-sectoral and sustainable training program providing skills and practical information in food production, nutrition, AIDS prevention, and income generation to rural African communities affected by HIV/AIDS. Through this program, Global Service Corps recruits, prepares, and trains pairs of Local and Visiting Fellows to become qualified instructors in HIV/AIDS prevention and care, nutrition, and sustainable agriculture methods. Visiting Fellows and Local Fellows receive a one-month initial training in Arusha, Tanzania. Following this training, Fellow pairs work with Participating Organizations (POs) for five to eleven months. Fellows assist POs with the development of community training and education programs, and facilitate in-depth field seminars for local communities. http://www.globalservicecorps.org/d/levelsofservice.html#internship

St. Francis College, Department of Psychology: The Department of Psychology at St. Francis College invites applicants for a tenure-track Assistant Professor position to begin September, 2011. The College seeks a highly motivated professional with a Ph.D. in Developmental, Social or Experimental Psychology. The successful applicant must be qualified by training and experience to teach both undergraduate and graduate level courses in general psychology, developmental psychology, social psychology, statistics, experimental psychology, and to provide supervision to students. The successful applicant will work with a diverse faculty and student body and is expected to teach 12 credit hours (or graduate equivalent) per semester, provide advising and research mentoring for undergraduate and graduate students and serve on departmental and college committees. Preference will be given to applicants who demonstrate a history of experience and proficiency in conducting research and have prior experience in teaching upper-division undergraduate courses.

St. Francis College is a Franciscan founded, coeducational, liberal arts institution of higher learning in which teaching, research, and service are central to its total learning environment. Located in Brooklyn Heights, and with Manhattan just one subway stop away, the entire spectrum of art, culture, and educational/research facilities is at your fingertips. St. Francis College has been recognized by U.S. News & World Report as one of the top Baccalaureate Colleges in the North and ranked on the Forbes.com list of America's Best Colleges. The psychology department has six full-time faculty members (five tenured), 250 undergraduate majors, and as of September 2011, will have students enrolled in a new five-year combined BA/MA program in General Psychology.

Candidates should submit a statement of teaching/research interest, curriculum vitae, and three letters of reference. All applications should be emailed to the address listed below to the attention of Dr. Michele Hirsch, Chair of the Search Committee.

Review of applications will continue until the position is filled. Apply for this position through My HigherEdJobs. Contact: Dr. Michele Hirsch, Chair of the Search Committee St. Francis College, e-mail hr@stfranciscollege.edu.

International Employment Opportunities

The **Graduate School of Professional Psychology (GSPP) at the University of Denver** is seeking 2 core faculty members specializing in international disaster psychology. The full-time position is tenure-track; the half-time position is a clinical appointment. Salary and rank will depend on academic and clinical or field experience. There are numerous practice opportunities in Denver. Duties include teaching in the Master's Program in International Disaster Psychology, advising, supervising local and/or overseas practica, and participating as a core member of the GSPP. The applicant should have sufficient academic background and field experience in international disaster psychology to be able to teach a variety of courses in the program. Preference will be given to license or license eligible applicants. A doctorate in clinical psychology is preferable. The University of Denver is an EEO/AA Employer. Minorities are strongly encouraged to apply. Please apply at: http://www.du.edu/hr/employment/jobs.html. Inquiries may be addressed to Dr. Judith Fox, Director, Master's Program in International Disaster Psychology, at jufox@du.edu. Applications will be reviewed beginning February 1, 2011. Subject to budget availability, preferred starting date is September 2011.

Board Members

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***Award, Book**
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Submission Guidelines for
Research Articles
International Psychology Bulletin

Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.

Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

To submit manuscripts to the Division's new peer-reviewed quarterly journal, *International Perspectives in Psychology: Research, Practice, & Consultation*, contact Editor Judith Gibbons at gibbonsjl@slu.edu.

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SUBMISSION DEADLINES

International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

Submission Deadlines: Spring issue March 31st

Summer issue June 30th

Fall issue September 15th

Winter issue December 15th

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Looking Back/Looking Ahead

John D. Hogan, PhD
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This is my last column as the Division 52 president. It is amazing how quickly the year has gone by! But, as most of you are aware, presidential terms these days are really three years long – comprised of terms as president-elect, president, and past-president – each year with specific duties. So I am not going away just yet! ☺

2012 Awards

As past –president, I will oversee the various awards that the Division gives, and chair the committee for the Internationalist Psychologist Award. We give two awards each year in this category, one for an outstanding international psychologist from the U.S., the other for a non-U.S. outstanding psychologist. We seek to honor individuals who have made outstanding contributions to international psychology either through significant research, teaching, advocacy, and/or contributions to international organizations. I hope you'll consider making a nomination in one or both of these categories. Our members have always been an excellent source for nominations. Please send your nominations, with a brief letter of support, to me at: hoganjohn@aol.com. I will need the nominations by February 1, 2012.

Our other Division Awards include the Henry David International Mentoring Award, the Florence L. Denmark/ Mary E. Reuder Award for Outstanding Contributions to the Psychology of Women and Gender, the Ursula Gielen Global Psychology Book Award, and the Awards for Student International Research. Please check our website for further information about the awards, as well as the due date for nominations and the email addresses of the appropriate award chairs: www.internationalpsychology.net.

2012 Elections/ Committee Participation

As past-president, I will also Chair the Nominations and Elections Committee. This year we will be voting on two upcoming openings for member-at-large positions. One of these openings will be reserved for an Early Career Psychologist (ECP), that is, a psychologist who is within ten years of receiving the doctoral degree. Members-at-large are voting members of the Executive Committee of the Division and typically focus on an area of special interest to the Division during their term.

Of course, there will also be an election for president-elect during 2012, as there is every year. Nominations are welcome for this position as well. Although any Division member may be nominated, the final nominees are typically individuals who have been active in the Division over a period of time. Obviously, some experience with the Division is necessary before an individual can become an effective leader of it. So perhaps this is a good time to remind all of our members that we encourage your participation in the Division's governance. A good place to start is to become a member of one or more of our various committees. By the time you read this, Neal Rubin, our president for 2012, will have already begun to make committee assignments, but I am certain he would welcome any offers of committee participation: nealrubin@hotmail.com

New Officers/Future Plans

Speaking of Neal Rubin (Argosy University, Chicago), our newly elected officers will begin their terms at the beginning of the calendar year, January 1. In addition to Neal as president of the Division, Mercedes McCormick (Pace University) will become president-elect, and Susan Nolan (Seton Hall University) will become the Division treasurer. Each one of them has a substantial history with the Division, as well as more than enough energy and enthusiasm to safely carry the Division through their respective terms of office. Neal has already begun to plan our mid-winter meeting, to be held in Las Vegas, NV, from February 22-25, 2012. He has discussed the meeting elsewhere in this newsletter.

With all that we have coming up, I want to be certain to remind everyone of our new journal – *International Perspectives in Psychology: Research, Consultation, Practice* which will be launched in the new year and which is being edited by Judith Gibbons of St. Louis University. By all accounts, we are off to a good start, with many worthwhile submissions. The journal is an important extension of the mission of the Division and we are very excited about its future.

Looking Back

It's been a wonderful year for me. I've had the opportunity to share the work of our Division with a terrific group of active, hard-working, and committed individuals. I've been particularly impressed with those members whose work is so often behind the scenes and yet is so crucial to keeping our Division running efficiently. I hesitate to name any

names for fear of leaving some people out, but I will risk naming a few: Richard Velayo, who has done such wonderful work with our website and has calmed us whenever we have had electronic concerns; Joy Rice, who oversees our Handbook and bylaws and, in general, makes certain we abide by the "rules" and know what we are doing; and our recently "retired" treasurer , Michael Stevens, who has been a wise and extraordinarily efficient treasurer as well as a counselor *par excellence.*

I must also mention the work of our program committee: Senel Poyrazli (Pennsylvania State University, Harrisburg) was in charge of the "regular" convention planning, and Mark Terjesen (St. John's University, NY) supervised the suite programs. The Suite planning has become increasingly important as APA divisions are being allotted fewer and fewer hours. The suite also affords a more intimate venue for our attendees, as well as the opportunity to interact more easily with the presenters. They've done a wonderful job in both venues. Mark will be in charge of the "regular" programming this coming year: terjesem@stjohns.edu. Robyn Kurasaki will be in charge of the suite programs.

Finally, many thanks to all of the members of the Division for their support during 2011. It has been a privilege to serve the Division as president, and I remain very grateful for the opportunity.

John

NEWS AND UPDATES FROM THE AMERICAN PSYCHOLOGICAL ASSOCIATION OFFICE OF INTERNATIONAL AFFAIRS July-August 2011

Psychology International

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An Interview with 2011 APA President Melba Vasquez

2011 APA President Melba Vasquez, PhD is an independent practitioner in Austin, Texas. Her expertise is in the areas of ethics, multicultural psychotherapy, the psychology of women, supervision and training. Before receiving a doctorate in Counseling Psychology from the University of Texas at Austin, Dr. Vasquez taught English and political science to middle school students. She has since served as a member of the APA Minority Fellowship Program; and as a chair of numerous APA boards, committees, and task forces. Major projects included co-founding Division 45—Society for the Psychological Study of Ethnic Minority Issues, Division 56—Trauma Psychology, and the National Multicultural Conference and Summit. Dr. Vasquez has received many awards for her work, including both the Heiser Award and the AAP Advocacy Award for her role in advocating for psychology at the state and federal legislative levels. She has published 3 books and more than 65 articles and book chapters.

PI: Some APA members are excited about the prospects of international outreach and activities; others believe that APA, as a national organization, should focus within its own borders and leave international activities to international organizations. How do you feel about these two perspectives?

Vasquez: The question implies that the two activities could be exclusive of each other; I am a firm believer that APA can do a good job of both focusing on psychology at the national level, within our borders, as well as engage in international outreach. The APA members reflect a wide range of career paths, research areas, applications and interest, and some of those include interest in the use of psychological knowledge internationally. We live in a time where technology facilitates a global understanding in many areas, including psychology. Learning about psychology outside our borders can also enrich our understanding of our discipline within our borders.

PI: In your candidate statement, you wrote that psychology is an increasingly global discipline and pledged to focus APA's efforts to "increase communication and collaboration with international psychologists, develop student and professional exchange programs, and continue its response during times of disaster." In your opinion, how has APA succeeded in these objectives, and what can still be done to continue on this path?

Vasquez: The first ever strategic plan conducted by the governance of the APA was finalized in 2010. The process resulted in the development of a mission statement, a vision statement, and the identification of core values. The vision statement of the APA is that it "...aspires to excel as a valuable, effective and influential organization advancing

The latest issue of *Psychology International* can be accessed on the web at: http://apa.org/international/pi

LEAVING A LEGACY

TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

Division 52 Midwinter Meeting in Las Vegas, Nevada

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The Board of the Division of International Psychology (Division 52) has decided to hold its yearly midwinter meeting from February 22 through February 25, 2012 at the Riviera Hotel in Las Vegas, Nevada. We are delighted to be meeting in conjunction with the Society for Cross Cultural Research's annual conference (SCCR) www.sccr.org. Also meeting jointly with Division 52 and SCCR will be the Society for Anthropological Science (SASCI) http://anthrosciences.org/ and the American Anthropological Association's Children and Childhood Interest Group (AAACIG) http://www.aaacig.org/. We are hoping that meeting with a range of social scientists that share many of our international and cross cultural interests will provide an opportunity for lively exchange and for possibilities for collaboration, during and beyond the conference.

Together with William Jankowiak, President-elect of SCCR and Professor of Anthropology and Ethnic Studies at the University of Nevada, Las Vegas, we are planning a number of avenues to promote stimulating interaction. For example, we have proposed a scholarly exchange in which an SCCR speaker will be scheduled in the Division 52 program and a Division 52 speaker scheduled similarly in the SCCR program. We are also designing a joint symposium that will feature prominent speakers from each group presenting on the same panel. Additionally, our schedule will free up Division 52 members to hear the keynote speakers* in the SCCR program. Of course, numerous opportunities for more informal exchanges will be available throughout the conference including opening ceremonies, conference banquet and a Board dinner.

Initial information on the SCCR program, along with information on accommodations and tourism, can be accessed @ www.sccr.org/sccr2012.

Regarding the Division 52 schedule, our Board meeting will be held in the Riviera on Wednesday 2/22/12 from noon to 5 pm. Following the SCCR opening ceremonies on Thursday morning 2/23/12, our Division 52 program will begin at 1 pm and conclude at 5 pm. We will continue on Friday 2/24/12 with a day long series of presentations from 9 am to 5 pm. Division 52 members interested in submitting a proposal for the midwinter program should send a brief summary of your proposed presentation to nealrubin@hotmail.com. Presenters are strongly encouraged to design panels that include students and/or early careerists on their programs, or as co-authors of their presentations. In this way we hope to encourage increased interaction between our more established members and members who have more recently joined our division. We appreciate your consideration of this request as our valued senior members can so impressively serve as role models for our early careerists, students and prospective members.

We are hoping that our Midwinter Meeting will be a stimulating opportunity for new connections, collaborations, and creative problem solving as we review our work together, engage in strategic planning and problem solving, and as always, as we renew valued friendships.

*Keynote speakers:

2/23/11 "History of Las Vegas"
Eugene P. Mohring
Professor of History
University of Nevada, Las Vegas

2/23/11 "Legalize Prostitution in Nevada"
Barbara G. Bents
Professor of Sociology
University of Nevada, Las Vegas

2/24/11 "Unpacking Female Sexual Desire: Desire for What, for Whom and When?"
Marta Meana
Professor of Psychology
University of Nevada, Las Vegas

The Division 52 Poster at the International Poster Session at the 2011 APA Convention

Judy Kuriansky, Ph.D., Richard Velayo, Ph.D.,
Neal Rubin, Ph.D., Brian Davis, and Rebecca Houran

This August 2011, the American Psychological Association Conference featured a poster session for which all divisions were invited to participate, to present their international work. The session was launched by the APA Office of International Affairs, evolving out of discussions of the APA Committee on International Relations (CIRP) about the international connections, membership and activities of the various APA divisions.

An email was sent to all the APA division Presidents to invite their division to participate. The email described the purpose of the poster – "to provide information and to foster interaction among Divisions around international activities" – and suggested content. The session was called "Psychology Around the World – APA Divisions Reach Out" and took place on Friday, August 5 from 1:00-1:50 PM at the Convention Center Halls D and E.

Division 52 enthusiastically agreed to participate. Division 52 CIRP liaison Judy Kuriansky convened a committee comprised of Division 52 Past-President Richard Velayo, President-elect Neal Rubin, APA United Nations student representative and NYU graduate student Brian Richard Davis and recent Smith College graduate Rebecca Houran, a psychology major, Division 52 student member and Dr. Judy's summer intern.

The committee worked together throughout many months, and many nightly long evening sessions, in person and on Skype, to create an interesting design (greatly enhanced by Brian Davis' creative skills) and to honor as much work of division members as possible.

The Division 52 Poster is titled *"One World Psychology: Global Connections and International Psychology in APA Division 52."*

Whatever information could not be included on the poster itself, was presented on an exceptionally unique feature – an interactive kiosk presented via an iPad attached in the center of the poster. The iPad provided an interactive way in which viewers could interact with the poster. It contained information presented in the poster, including the Division 52 video on "International Psychology: What Students Want to Know".

Several emails were sent to all the members of the division to solicit their information in many categories of international work. Several members replied with extensive information, and these responses were honored as much as possible by being included in the poster itself and also placed in full on the iPad.

Given the extent of interesting international work by division members, it was challenging to organize the efforts. The design decided upon consisted of five main sections, each with subsections. These are:

1. Teaching activities (teaching appointments; seminars, workshops and presentations; teaching-related committees; books; and developing courses);
2. Science activities (presentations at international conferences; publications; and research projects and scholarship);
3. Basic information and demographics about the Division (mission; membership; programs including international liaisons, adopt-a-psychologist, clearinghouse, and heritage mentoring project; and opportunities including speakers network, student activities, cross-divisional collaborations; book series and international awards);
4. Service (humanitarian field projects; international organizations and committees; editorial board appointments; organization board appointments; guidelines; manuscript reviewing; and policy/public interest/ advocacy); and
5. Other international activities (grants and fellowships; awards; media; and organizations founded).

Dr. Judy Kuriansky at the Division 52 Poster at the International Poster Session (APA 2011).

The Division 52 poster was exceptionally well-received, with many visitors viewing the poster and enjoying the iPad.

The poster may be accessed on the Division 52 website at: http://www.itopwebsite.com/InternationalPsychology/Media.html. The interactive kiosk, which was presented through an iPad at the poster session, may also be downloaded in PDF format.

Given the great success of the poster session, APA and the CIRP committee agreed to repeat such a session at next year's convention.

Call for *Internationally Focused* Papers Western Psychological Association

April 26 – 29, 2012, San Francisco, CA
Deadline: 15 November 2011

The 2011 WPA Convention will be in San Francisco from April 26-29, 2012 at the Hyatt Regency. For the fourth year, WPA leadership has allotted some convention time and space for internationally/cross-culturally focused presentations. The deadline is 15 November 2011 (midnight PST).

The WPA Call for Papers is located at: http://www.westernpsych.org/convention/call.cfm

To be reviewed for the *international program*, please use the WPA Call-for-Paper submission process and select *International Psychology* from one of the "topic" areas listed within the on-line submission process.

Please consider organizing international symposia or selecting the "one-speaker paper" option. The "one-speaker paper" option will alert the program committee of your interest in being assembled into a panel of papers with related topics. The online process for submitting symposia requires two-steps (first, the chair submits the proposal for the symposium and receives a symposium number; second each of the speakers submits a paper proposal and identifies the symposium number in one of the submission form fields).

WPA requires that at least one of the authors of each submission should be registered for the conference; conference registration fees are lower for WPA members.

For questions (or to provide suggestions) about the international sessions, activities, and events at WPA, please contact Lynette H. Bikos, Ph.D., Div52@WPA Program Chair, lhbikos@spu.edu.

To learn more about Division 52/ International Psychology, or join the division: www.internationalpsychology.net

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INVITATION: All students and faculty who present international research at WPA, and are (or become) members of the APA International Division, can submit their 300-word abstract by 30 June 2012 for publication in the APA *International Psychology Bulletin* in summer 2012. For details, contact Editor Grant Rich at optimalex@aol.com.

Call for Fellows 2012

Members of APA Division 52 are now invited to nominate others or themselves for election as a fellow of Division 52, based on "unusual and outstanding contributions" to international psychology. Phone or write soon for a packet of forms for APA, and our Division's 15 criteria. This year all completed materials must be submitted by 5 pm Friday, 2 December 2011 -- including the nominee's vita, personal statement, and endorsements from 3 current APA fellows. At least 2 of the 3 endorsers must be a fellow of Division 52. (Those who are already a fellow of another APA division can ask about a streamlined nomination procedure). A roster of D52 fellows now appears at: www.internationalpsychology.net.

Contact:
Harold Takooshian
D52 Fellows Chair
314 Dartmouth
Paramus, NJ 07652, USA
Phone 212-636-6393
takoosh@aol.com

Translators Wanted

A one-page overview of the history of the APA Division of International Psychology was co-authored by its Presidents John Hogan and Harold Takooshian. We now seek global colleagues to translate this sheet into other languages, with themselves as the author, to circulate to colleagues and students in their nation. As of October 2011, this sheet appears in 14 languages: Armenian, Chinese (Mandarin), Dutch, English, Estonian, French, Korean, Polish, Russian, Somali, and Spanish.

Can you translate this into another language this month? If so, contact the Chair of International Liaisons, Rivka B. Meir, at: winsuccess@aol.com.

Division 52 National Speaker Network

Harold Takooshian, Rivka Bertisch Meir,
and Ronald G. Shapiro (co-chairs)

What do these three experts have in common: **Drs. Florence Denmark** in New York, **Norman Abeles** in Michigan, and **Diane Halpern** in California? Besides being past-Presidents of APA and fellows of our APA International Division, they also kindly registered for the new APA Speaker Network, to share their expertise as speakers to local student and community groups.

If you would you like to find a local psychology expert or two this year, to speak to your school, community group, or corporation, here is good news. At APA in Washington, D.C. this August, our international suite again hosted its annual gathering of the APA Speaker Network—a national roster of 212 APA fellows, arranged in zip code order, who are prepared to share their "unusual and outstanding" expertise with local audiences. In addition, many of these indicate they are also prepared to host visits to their lab or clinic, speak with the media, or advise younger colleagues or students. These 212 gracious experts include five past-Presidents of APA, several textbook authors, and some of the leaders of US and international psychology. To download a PDF of this free list, simply check our website, http://web.mac.com/rvelayo/Div52Announcements/Speakers.html.

This PSYCHE network—Psychology Speakers You Can Hear Easily—was first arranged in 2006 with a CODAPAR mini-grant. It currently spans four APA divisions—1 (general), 2 (teaching), 21 (human factors), 52 (international)—and will expand to include other APA divisions in 2012. It also cooperates with other speaker networks, including ROMEO for international speakers, at www.apa.org/international.

Pictured from left to right: Florence Denmark, Ph.D., Norman Abeles, Ph.D., and Diane Halpern, Ph.D. Three of the 212 distinguished experts in the APA national speaker network.

Be Sure to "Stay Connected"

Our webmaster Richard Velayo sends out his listserv monthly, rich with useful news, http://www.rvelayo.com/Div52Announcements. Are you missing this? If you are not now receiving this monthly, be sure to register with Keith at APA today: kcooke@apa.org.

To find out about free international activities in greater New York, check Richard's "NY-52" webpage at: http://web.mac.com/rvelayo//Div52/Div52-NY.html.

Would you like to see the history of our D52 in several diverse languages, from Hindi to Somali? If so, check: http://web.mac.com/rvelayo/Div52/Div52HistoryTranslations.html.

Call for 2012 EPA International Proposals

The 2012 meeting of the Eastern Psychological Association is set for 1-4 March, at the Westin Convention Center in Pittsburgh PA. Once again, for the eighth year, EPA welcomes proposals from all students and professionals interested in international and cross-cultural psychology, due by **15 November 2011**. A low fee of US $45 also includes one year membership in EPA ($25 for students). The 2013 meeting will be at the Marriott Marquis in Manhattan.

In 2011 at EPA in Cambridge MA, many of 1,800 psychologists and students shared two full days of global programs—invited international speakers, symposia, papers, posters, and organizations.

*To submit proposals by **11/15/2011**: www.easternpsychological.org.*

For any details, check www.internationalpsychology.net, or contact the EPA International Program: Harold Takooshian at takoosh@aol.com

INVITATION: All students and faculty who present international research at EPA, and are (or become) members of the APA International Division, can submit their 300-word abstract by 31 March 2012 for publication in the APA *International Psychology Bulletin* in spring 2012. For details, contact Editor Grant Rich at optimalex@aol.com.

Division 52 Images from the APA Convention, Washington, D.C. USA

The D52 board meets.

In the international suite, Drs. Michael and Rivka Meir host a one-hour Skype session with Dr. Noach Milgram in Tel Aviv.

The international suite was shared by Division One (General Psychology), where President Russo presented a book award to the Editors of the International Handbook of Applied Psychology.

The D52 board members share an international supper at the exotic Marrakesh restaurant.

In the suite, the officers of Psi Chi, the international honor society in psychology, present their annual awards.

A conversation hour with the Ursula Gielen Book Award winners in the APA international suite.

Many officers worked hard to help purchase the lavish snacks that kept the suite well-stocked.

Late into the night, some members enjoyed the Renaissance suite's magnificent veranda overlooking Washington.

In the APA suite, two Fulbright officers were recognized for their presentations on the U.S. Fulbright program.

The international suite was the site of many awards and receptions.

Division of International Psychology
American Psychological Association
Annual Board Meeting Minutes
Wednesday, August 3, 2011
2 – 6 pm
Renaissance Washington Hotel,
Meeting Rooms 10 & 11

Present: John Hogan (President), Ayse Çiftçi, Andrés Consoli, Judith Gibbons, Uwe Gielen, Gloria Grenwald, Ani Kalayjian, Mercedes McCormick, Rivka Bertisch Meir, Susan Nolan, Ann O'Roark, Wade Pickren, Artemis Pipinelli, Senel Poyrazli, Joy Rice, Grant Rich, Neal Rubin, Janet Sigal, Michael Stevens, Harold Takooshian (late, coming from Council), Mark Terjesen, Richard Velayo, Danny Wedding.

Guests: Merry Bullock, Anna Laura Comunian, Michael Meir, Tara Pir, Karin Vann.

Absent: Norman Abeles, Fred Bemak, Joan Chrisler, John Davis, Florence Denmark, Sharon Horne, Judy Kuriansky, Jennifer De Mucci, Roberta Nutt.

The meeting was called to order at 2:07 pm and President John Hogan welcomed all board members and guests. All individuals attending the meeting introduced themselves.

1) **Changes to the Agenda:** The agenda was unanimously approved.

2) **Approval of the Minutes** from the Mid-Winter Board Meeting in Cambridge (3/10): The minutes were unanimously approved.

3) **President's Report:** John Hogan reviewed some of the major issues that have come up in previous months. He expressed concern about a possible decline in memberships related to increased dues associated with the new journal. He explained that this decline is typical when new dues are introduced. He reported that we have new officers elected for the Division. He also discussed different awards given by the Division. He had previously suggested the need for an "awards-coordinator", but noted that the Handbook indicates that past-presidents serve in this position. He expressed special thanks to Senel Poyrazli and Mark Terjesen for the convention programming and special thanks to Michael Stevens for his contributions to the Division. Michael is leaving the Division board this year.

4) **Past-President's Report:** Danny Wedding announced election results: Mercedes McCormick is the president-elect and Susan Nolan is the treasurer. They assume their positions on January 1, 2012. As the awards coordinator, Wedding announced the recipients of the Outstanding International Psychologist Awards: Michael Stevens for the US based award and Narasappa Kumaraswamy for the non-US based award. Three awardees for the Henry David International Mentoring award were Larry Gerstein, Tara Pir and Harold Takooshian. The Gielen Book Award went to the editors of the *International Handbook of Cross Cultural Counseling: Assumptions and Practices Worldwide* (Gerstein, L. H., Heppner, P. P., Ægisdóttir, S., Leung, S. A., & Norsworthy, K. L.).

5) **President-elect Report:** Neal Rubin discussed the concerns about membership, specifically issues related to early career psychologists (ECPs). He reported several initiatives to recruit and engage more ECPs in the Division: (1) recent changes on the board (voting seat for an ECP and non-voting seat for a student representative), (2) newly proposed ECP award, (3) dedicated ICP regular column for students and ECPs, (4) recruiting one student and one ECP member for each committee, (5) Heritage Mentoring Project. Rubin also reminded that next year will be the 15th anniversary of the Division. He invited members to make recommendations regarding the anniversary. He proposed bringing together all the past-presidents of Division 52 as a part of the 15th anniversary celebration. Rubin reported that the student committee applied for a National APAGS award. Even though Division 52 didn't receive the award, students put together an excellent proposal. One of the concerns about the application/selection process was that our Division doesn't require students to be APA members. Rubin also reminded the Board members about the poster session that will take place on Friday at 1pm. Division 52 prepared a very impressive, interactive poster. Finally, he presented two options for the mid-Winter meeting: SCCR (Las Vegas, February 22-25) and WPA (San Francisco, April 26-29). A straw vote was taken regarding the location of the 2012 mid-winter meeting.

   The board members clearly indicated preference for SCCR (14 votes) over WPA (7 votes).

6) **Policy Changes Re Early Career and Student Board Representatives:** Joy Rice reported the proposed bylaws changes regarding student and early career representation on the Division 52 board. The purpose of these proposed changes were not only to increase the number of ECPs and students but also to get them more involved in the Division. Rice reported that both changes were approved (95% for the early career representative and 92% for the student representative) and the changes are reflected in the bylaws. Further discussion on the following items took place:

a) the Early Career MAL is expected to chair the Early Career Committee;

b) the definition of an Early Career Psychologist is up to ten years post graduate status; and

c) in terms of rotation, every third year one of the two MAL nominations will go to an early career psychologist, ensuring that there will always be one MAL ECP representative on the board.

d) the Student Representative will generally be a graduate student, but that a particularly outstanding psychology undergraduate may be nominated for the position, and

e) the Student Representative is expected to chair the Student Committee.

All items were discussed separately and unanimously approved. Rice will reflect the changes in the Handbook.

7) **Presentation of Denmark-Reuder Award:** John Hogan presented the Denmark-Reuder Award to Joy Rice. This award is named after two founding members of Division 52, Florence Denmark and Mary Reuder. Rice thanked the committee and the board.

8) **Division 52 Budget:** Michael Stevens discussed the changes between 2011 and 2012. He discussed the expenditures due to the Journal (i.e., office expenses and subscription fees). For the long term investments, Stevens suggested to be on the safe side and keep the accounts in the same place due to the current economy. He suggested that we continue our discussions as the economy changes. Stevens reported that Division 52 received support (grants and donations) for the hospitality suite from Division 1, the College Board, and Psi Chi. Finally, there was a discussion over ISCP funds (approximately $3,100). Stevens expressed his concerns about the legitimacy of the funds-whether this organization is really dead or not? Gloria Gottsegen and Danny Wedding were the past-presidents of the group. However, there is still some confusion about the organization. It is recommended that it will be best for Gloria Gottsegen to write a check to APF indicating that the money is for Division 52.

The budget was unanimously approved.

9) **Discussion About Committees and Survey Results:** Wade Pickren summarized the history of the long-range committee and the need to review the subcommittees and ad hoc committees. Pickren reported that based on the survey, we have 11 active ad hoc committees. Multiple recommendations were made to follow up on the report. One recommendation was that appointments be considered division appointments, not ad hoc committees, e.g., webmaster, student coordinator, and ECP coordinator. These appointments may be for 2- or 3-year terms. Another recommendation was that ad hoc committees be reviewed periodically. All appointments should have terms associated with their appointments. Finally, there were some requests/discussions to re-group some of our committees such as awards or communication and publication (journal, website, and newsletter). Rubin will continue to work with Pickren during his presidential year to review committees.

10) **Discussion on Eligibility Henry David International Mentoring Award:** Mercedes McCormick raised some concerns about the eligibility of this award whether mentoring is separate from international work. It is decided that mentoring is different from international mentoring and it will be up to the committee to evaluate the relevant qualifications. There was a consensus that the award is best served by being awarded to one person each year, although it is understood that multiple awards may be necessary based on the quality of the nominations.

11) **Discussion on Eligibility for Student Research Award:** Danny Wedding raised some questions about whether undergraduate students are eligible for this award. Based on the Handbook, this award can be given separately for graduate and undergraduate submissions. Furthermore, the student is required to be a student affiliate of APA or Division 52.

12) **Webmaster Committee:** Richard Velayo reported on the increasing web presence of Division 52, including our use of other social media (Facebook, YouTube, Twitter). Currently, there are four listservs: announce only, open discussion (51 subscribers), ECP (13 subscribers), and student (0 members). With the increasing need for social media and IT, Velayo expressed a need to create a committee. The board supported Velayo developing a Webmaster committee.

13) **Membership:** Janet Sigal reported two new membership co-chairs: Josephine Tan, the Canadian Coordinator and Julia Rose, the UK Coordinator. Sigal also provided information on the proposed ECP award: the ECP award committee can be co-chaired by one ECP and another committee member. The President-elect will appoint the committee chairs.

This new award was unanimously approved.

14) **Policy about registration waiver** for the outstanding international psychologist award (non-US). In order to be able to have a possible registration waiver for the awardee and meet the APA deadlines, the deadline for this award will change. The deadline will be much earlier in order to have the opportunity to submit the awardee name to APA in March, if needed.

15) **Update with the New Journal:** Judith Gibbons provided information about the current state of the journal. She

received 78 submissions in 7 months with none yet accepted for publication. (Most are currently under review.) She has established an editorial board of 43 scholars, with primary affiliations in 32 countries. Even though most of these submissions are from the US, an effort has been made to reach out to non-US authors. Gibbons praised APA and the efforts they have made toward publishing a successful journal. A "mock" issue of the journal has been constructed, with published articles from other APA journals as an example of what the journal will look like.

16) **Merry Bullock (APA Office of International Affairs)** distributed copies of the Office's annual international Convention program book, that includes all programs with an international focus and a list of all international presenters. She also distributed the first brochure in a new APA publication series of interest to Division 52: "Going International: a Practical Guide for Psychologists". Bullock informed the Board of a new web based resource called Psychology Resources Around the World that is being developed to be the repository of information on organized psychology in every country in the world. Two international conferences of note are: Caribbean Regional Conference of Psychology in November, 2011 and the 30th International Congress of Psychology in July 2012. APA has just been awarded a $25,000 grant to fund travel and a mentoring program for the ICP (up to 16 students/ECPs, and up to 10 more senior mentors) by NSF. Finally, Bullock reported that in 2012 the APA President will invite all the presidents of national psychology organizations around the world to a special Presidents' Initiative at the Convention.

17) **Program Committee:** Senel Poyrazli and Mark Terjesen updated the board on the program. The suite will be opening on Thursday. Board members thanked them for the wonderful programming they developed.

18) **International Psychology Bulletin:** Grant Rich updated the board about the Bulletin that is published four times a year. Rich reported the changes from the previous year such as the new regular student column. The next deadline for submissions is September 15th.

19) **Council:** Division 52 Council representative Harold Takooshian reported that the Council unanimously approved all six D52 nominations for new Fellows of APA: William R. Herkelrath, Samvel S. Jeshmaridian, Tahereh Pirhekayaty, Grant J.M. Rich, Mihaela Robila, Nancy Sidun. The suite hosts a breakfast reception and conversation hour to salute these six, and other fellows in the APA speaker network.

The meeting was adjourned at 5:50pm.

Respectfully submitted, Ayse Çiftçi, Ph.D.

Local Networking Event in Los Angeles: APA Division 52 International Psychology & International Council of Psychologists (ICP)

Dr. Tara Pir
Institute for Multicultural Counseling and Education Services, Inc.
tarapirimces@msn.com

A local networking social event was coordinated between Dr. Tara Pir (ICP long range planner and area chair for ICP, and Division 52 member) and Dr. Lynette Bikos (Division 52 program chair for the Western Psychological Association). The purpose of the event was to bring together local members of the International Council of Psychologists and APA Division 52 International Psychology. This event took place after the 2011 conference for the Western Psychological Association at the Bonaventure Brewing Company located in downtown Los Angeles. The event was well attended and well received by participants who took advantage of the opportunity to network and connect with members of both organizations who shared the common interest of international psychology. As a result, we were able to recruit new members for both ICP and APA Division 52.

Dr. Tara Pir and Dr. Lynette Bikos received certificates of appreciation from APA Division 52 International Psychology.

New members of APA Division 52 and International Council of Psychologists (ICP) in Los Angeles.

Member Profile

Members of Division 52 could not be more richly diverse in every way: nationality, specialty, age, gender, heritage, ethnicity, lifestyle, and worldview. This new column profiles the work of some of our most active members. For details or suggestions, contact Editor Grant Rich at optimalex@aol.com.

Naji Abi-Hashem, Ph.D., a long time member of Division 52, had three projects completed:

A large book chapter on, "Working with Middle Eastern Immigrant Families," published in an edited volume entitled *Working with Immigrant Families: A Practical Guide for Counselors*. While the book focuses on immigrants from all continents of the world and on their mixed cultures and identities, adaptations and acculturation, needs and struggles, this particular chapter focuses on people from various Arabic, Muslim, and Middle Eastern backgrounds. Also, it explains the similarities and differences among the countries and societies of the East Mediterranean region and Gulf-Peninsula area, versus those of North Africa. The chapter is divided into several sections and covers a host of topics, timely matters, and sociocultural dynamics. The table of contents includes the following: Introduction; Migration, Survival, and Coping; History and Demography [in the USA & North America]; Counseling and Psychotherapy in the Middle East and Arabic Countries; Major Religions and Social Meanings; Tenets of Faith and Modes of Religious Practice; Generational Gaps, Cultural Trends, and Counseling Considerations; Born and Raised in North America [1st, 2nd, & 3rd generations, socioeconomics, and mixed marriages]; Multi-Identity or Multiple Identity; The Concept of Cultural Self; Suggested List of Proper Etiquette and Behavior; Integration Versus Alienation; Therapeutic Modalities and Orientations; Insights and Guidelines for Counseling and Caregiving Among the Culturally and Religiously Diverse Middle Eastern and Arab American Populations; and finally, the References.

The last section of this chapter is an extensive list of practical hints and suggestions on how to help and relate to all types of immigrants and refugees, including the people from Middle Eastern, Arabic, or Islamic descent. Many of these insights and skills can also apply to other minorities, diverse populations, global travelers, and all kinds of internationals. After all, every encounter we experience these days, anywhere in the world, can be qualified as a *cross-cultural encounter!*

Reference

Abi-Hashem, N. (2011). Working with Middle Eastern Immigrant Families. In A. Zagelbaum & J. Carlson (Eds.), *Working with immigrant families: A practical guide for counselors* (pp. 151-180). New York, NY: Routledge Press.

"Working With Arab Americans," a professional DVD produced by APA that includes interviews, analysis, a live session, and commentaries, with an informative website and coverage. It is a part of the *APA Multicultural Counseling Video Series* and can be found at the following link: http://www.apa.org/pubs/videos/4310843.aspx.

Abi-Hashem demonstrates his approach to working with clients with Middle-Eastern and Arab backgrounds in this closed captioned DVD. He explains in detail about the so-called Arab Americans. He shows that Middle-Easterners living in the West are a heterogeneous group that includes people from two continents and the three major world religions. They originate from a dozen countries and have diverse subcultures and backgrounds. Abi-Hashem suggests a general way of working with Arab American people that touches on certain commonalties across these cultures and that is relevant to their particular generation, such as greeting clients with respect regardless of age, increasing cultural awareness for personal behaviors and boundaries, and resolving potential internal conflicts about living in the West, as they try to reconcile their own heritage and tradition with the American culture at large.

Reference

Abi-Hashem, N. (2008). Psychotherapy with Arab Americans. *APA Training Videos: Multicultural Counseling Series.* Hosted by Jon Carlson, PsyD, EdD. Washington DC: American Psychological Association. http://www.apa.org/pubs/videos/4310843.aspx

"On Cultural Resiliency," a journal article that has just appeared in *The Australian Community Psychologist,* which is a peer-reviewed, yet open access periodical (the new trend of professional writing).

The article tries to revisit the subject of resilience and emphasizes its psycho-emotional and sociocultural roots. It explores the major themes, dimensions, and conceptualizations of resiliency from a communal, psychological, spiritual, existential, and cultural perspective. The article discusses the interplay among social norms, tradition, and religion and their implications on surviving, coping, and thriving. Also, it ponders how to remain resilient in this globalized and fast changing 21st century. This article argues that, in addition to all the other factors and mediators, resiliency is a function of culture, wisdom, and generational heritage and identity.

The article is divided into the following sections: Introduction; Is There an Adequate Definition of Resilience?; Conceptual Considerations of Resiliency; Is There an Adequate Definition of Culture?; Resiliency and Cultural Competency; Spiritual and Existential Aspects of Resiliency; Resiliency in the 21st Century; References.

Reference

Abi-Hashem, N. (2011). On cultural resiliency. *The Australian Community Psychologist, 23* (2), 23-31.

Links

http://www.groups.psychology.org.au/GroupContent.aspx?ID=883
http://www.groups.psychology.org.au/Assets/Files/Abi-Hashem%20ACP%202%2011[1].pdf

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Peer-Reviewed Research Article

Challenges and Effective Strategies For Conducting International Research

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Despite increasing diversity and widespread interest in cultural and international issues in the field of psychology, the difficulties of conducting international research have not been adequately addressed in the literature. Key challenges in international work are addressed, and an eight-step guide is introduced to assist in navigating these challenges. International research is important to the field of psychology and emerging scholars need access to information and resources to make such pursuits possible.

Keywords: international research, challenges, cultural sensitivity, guide

International research is of paramount importance to the field of psychology. America continues to become increasingly diverse, and it is projected that by the year 2060 Caucasians will become a minority, making up less than 50% of the overall U.S. population (U.S. Census Bureau, 2011). As the cultural milieu changes, more research on international or cross-cultural populations will be needed. Additionally, increasing numbers of international students are enrolling in U.S. academic institutions, with around 1/3 of international graduate students majoring in psychology (Koh Chin & Bhandari, 2007; National Science Foundation, 2007). Wedding, McCartney, & Currey (2009) state that as international students and interest increase, more internationally proficient mentors will be needed to guide such students in their careers. International research is critical to helping us understand global issues such as war, terrorism, the falling economy, and ways to improve international relations. Furthermore, knowledge of international psychology can prove invaluable for individuals pursuing careers in business, social work, education, and all other professions that require interaction with diverse people (Russo & Takooshian, 2002).

Despite increasing globalization and the importance of international research, the topic is under-researched and little information is provided to emerging scholars on why this research is important, how one can go about doing it, and what challenges can be expected along the way. In a 2010 Members Survey conducted by the Student Committee of APA's Division 52 (International Psychology), students of the division reported that there is a lack of information available to them and that they wanted additional resources on international opportunities and how to go about conducting international work (Doran & Stowell, 2010).

The following article discusses key challenges and offers a practical, eight-step guide for how to navigate these challenges in international research and prepare oneself for success in the field of international psychology.

Key Challenges

Language Barriers. In all populations where English is not the primary language, issues of translatability arise. Translation can be problematic in a variety of ways. Different spoken languages may make it difficult (or impossible) for the researcher and the target population to interact in a meaningful way. The researcher, if not fluent in the native language, will require a translator or collaborator who can communicate with the population in an accurate and efficient way. Of note, while most words will translate, not all *concepts* will, and researchers need to consider if a construct translates validly into another language and culture. For example, there is no word for *assertiveness* in many languages, such as Armenian, Turkish, Arabic, and Swahili.

Cultural Differences. Differences regarding the perceptions of test and assessment may come into play in many cultures. While testing is common in Western societies and prevalent in our educational system, this is not the case in more underdeveloped areas. Tests may produce unnecessary anxiety in international populations and this can impact participant's responding or performance. In some areas, stigma and fear of evaluation will play a role, or the participant may be overly concerned about providing 'right' answers. Social desirability can also play a role in disclosure. The appropriateness of self-disclosure and the expression of feelings vary across cultures, and not all participants will be used to talking about or answering questions about themselves. They may perceive personal questions as uncomfortable and intrusive. All of these factors can impact the validity of an assessment. In research conducted by the second author, it was observed that in certain countries (Sri Lanka, DR Congo, Haiti, and

Sierra Leone), participants were looking over at one another's responses to see if their responses were 'right' or the same as others'.

Feasibility of Research. In order to conduct international research, one needs to obtain funding to travel to the country under study. Often times multiple trips or an extended visit will be required, which can be a financial burden to the researcher. Careful planning will likely be required to ensure that financial means are available to cover the associated costs of the study, including translation fees and travel expenses. For a successful international research collaboration is recommended while inviting professors or researchers from another country to join and assist in the data gathering process.

Clinical/Research Divide. Many clinical or community services will aim to collect data to determine if the services they are offering are effective in international populations. However, many individuals seeking services may not want to participate in the research component of the clinic or center, leaving the service provider unable to determine if the treatment methods being provided are efficacious in this population or tailor interventions appropriately. In populations that are unfamiliar with scientific research, there may be a lack of understanding about the research process, the importance of data collection, the meaning behind the assessment, and concerns about the confidentiality of information they provide and how that information might be used in the researcher's home country.

Finding Appropriate Psychometric Tools. Perhaps the biggest challenge is locating appropriate assessment tools for use in the target population. While most assessment tools have been created and validated in the United States, very few psychometric investigations have occurred outside of this country. There is a dearth of information about the reliability and validity of popular tests outside of the United States, particularly in underdeveloped areas. This is problematic because what may measure *depression* or *intelligence* in the researcher's country may not measure the same construct in an outside population. Lack of data on the international reliability and validity of popular measures makes research studies that use them in other contexts questionable.

8-Step Guide to Conducting International Research

1. *Find International Collaborators.* In order to be most effective in designing and executing research studies, it would be ideal for researchers to have connections with other scholars in the target country, particularly those who conduct research in the same discipline. International collaborators would be useful to assist with recruitment, ensure the fidelity of any translated materials and constructs, and act as a liaison between the researcher and the target population. Having a collaborator of the same racial or ethnic background may help alleviate any cultural mistrust. They may also provide valuable connections to local guides and translators. International collaborators may be found by researching authors who have published data on countries you are interested in studying, or looking on international university websites for local scholars.

2. *Funding Travel and Associated Costs.* It is ideal for the researcher to spend considerable time in the country in which they would like to undertake a study. However, repeated or extended travel may not always be possible. Fundraising needs to be a priority in advance of any international research study. The researcher should seek out funds, in the forms of grants or travel scholarships, to partially support travel costs associated with their research. Collaborators may be able to assist in hosting outside researchers as visiting scholars at their institutions. Where travel is not possible, it may suffice to work closely with an international collaborator who can oversee the project in the target country. Modern technology also makes it possible for the researcher to conduct studies electronically from home (Takooshian & Stevens, 2001), though this method does present unique challenges (e.g. verification of data).

3. *Research Design.* Research should be viewed through a "cultural lens" perspective (APA, 2003). The researcher needs to be aware of their own cultural framework and should try to avoid bias in study design and interpretation. They should also endeavor to balance finding both similarities and differences across cultures. Researchers need to take care to learn about and incorporate cultural practices and idiosyncrasies to increase the validity of tests, and make sure to respect the culture in which they plan to study. If there is no IRB in the target country, make sure the home institution reviews and approves the research and consider creating a workgroup in the target country to review the study as well. Outcome research associated with clinical interventions may need to include a psychoeducational component about the importance of conducting research to examine the efficacy of treatment for the population under study. Information about these studies may make participants more likely to participate in research associated with clinical interventions.

4. *Combat Western Superiority Bias.* As most tests were created and normed on Caucasian samples in America, "Americentrism" can occur. Researchers need to be aware of and strive to combat the Western superiority bias (the way things are done in the *West* is not always *best*). Cultural *differences* should not automatically imply inferiority; the difference should be investigated and understood, and the researcher should avoid making a distinction between which cultural response pattern is "better." Researchers are advised to be mindful of the fact that a psychology based solely on meanings in Western cultures misses the larger picture (Russo &

Takooshian, 2002) and to consider the various ways in which their findings can be interpreted.

5. *Psychometric Translation.* Finding an appropriate assessment battery can be a challenge. The first step is figuring out if an appropriate tool exists. Are there measures that have successfully been used in the target population in the past? Have any measures actually been validated for this sample? Psychometric theory dictates that scales should only be used on populations they have been validated and standardized on (Gregory, 2004). When this is not possible, the researcher should be sure to include reliability and validity statistics in any research they publish, to demonstrate the effectiveness of the scale in the population of interest and provide some material for researchers seeking to conduct similar research in the future. If scales require translation, they should be translated and then back-translated to ensure fidelity (Beaton, Bombardier, Guillemin, & Ferraz, 2002). A local scholar or consultant should also ensure if all concepts and constructs can be understood and investigated cross-culturally. For example, in Eastern countries, where somatic symptoms of depression are more common than affective ones, a scale should be used that asks about somatic symptoms. It can be difficult to determine how much one can or should adapt a measure (should somatic symptoms be added to a preexisting depression scale?). This may change the reliability and validity of a measure, so this technique should be used only when necessary and should always be accompanied by appropriate reliability and validity assessment and reporting.

6. *Considering Cultural Differences.* Cultural differences should always be thoroughly considered and evaluated at all phases of research. Are there any meanings of tests or attitudes towards evaluation that may be playing a role in the results? Could cultural mistrust (Terrell & Terrell, 1984) be present and could this impact honest reporting? In cultures where biases may exist, could stereotype threat confirmation (Steele & Aronson, 1995) play a role (e.g. an African American examiner is anxious about an IQ test because he does not want to "prove" the stereotype that African Americans perform more poorly on intelligence tests). When children are being evaluated, it is important to understand how children are treated in the target population, and if it is common or disrespectful to look at or speak freely to adults (Kalayjian & Eugene, 2010). Finally, social desirability is a concern, and care should be taken to understand any attitudes towards sharing and disclosure that may impact a respondent's willingness to share information.

7. *Field Work.* International researchers should spend as much time in the field as possible, and should become familiar and comfortable with any areas they wish to study. Researchers should visit target countries as often as is possible and immerse themselves in the cultures and customs of the people there. The more information the researcher has about a particular cultures norms and beliefs, the more able they will be to conduct meaningful and culturally sensitive research. Field work should also be supplemented with outside reading and education, and past studies on the target population should be evaluated.

8. *Balance the Results.* Researchers should always strive for balanced reporting of both similarities and differences they find in cross-cultural studies. The researcher should take care to not assume that a cultural difference implies a deficiency or inferiority, and alternative explanations should also be considered (what other reasons can you think of for why African-Americans traditionally achieved lower IQ scores on standardized intelligence tests?). Researchers should be aware of the Western superiority bias so they can aim to avoid it, and should always consult local scholars about the meanings of their findings and possible alternative explanations. Researchers should carefully consider how their research will impact the target population, and should not publish any findings they would not be comfortable directly sharing with the target population themselves. The international researcher has a large responsibility to be unbiased, culturally sensitive, and fair in all assessments.

International research remains a challenge, yet these eight steps can help in the design, execution, and interpretation of research studies. While it can be difficult to translate research across cultures, the effort is ultimately rewarding and necessary if the field is going to conduct valid and meaningful international research. Recommendations for aspiring international researchers are: to learn as much as possible about the target population, through research, ecological observations, and collaboration with local scholars; to get involved in organizations dedicated to furthering international work, such as Division 52 or APAGS International Division within APA; Association for Trauma Outreach & Prevention, to find a research mentor who conducts international work, which can be facilitated through joining the Division 52 mentoring program; and to strive to take a cultural lens perspective to conducting and analyzing research studies.

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Dr. Ani Kalayjian conducting outreach work and research in Sierra Leone.

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ANNOUNCING THE PUBLICATION OF ...

The new humanitarians: Inspiration, innovations, and blueprints for visionaries
Volume 1, Changing global health inequities
Volume 2, Changing education and relief
Volume 3, Changing sustainable development and social justice
Chris E. Stout; foreword by Mehmet Oz
Publisher: Westport, CT: Praeger Publishing (2008)
ISBN-10: 0-275-99768-5; **ISBN-13:** 978-0-275-99768-7

"All of us aspire to someday "make a real difference" in the world yet, caught up in our own day-to-day personal crises and seemingly pressing obligations, very few of us ever fulfill this important human dream. Chris Stout is a world class humanitarian who has taken the time to vividly explore the inside world of those who have succeeded. Perhaps with this new appreciation for how to succeed, more of us will eventually fulfill our own personal quest to make the world just a little bit better."
- Pat DeLeon, Ph.D., M.P.H., JD, Past President of the American Psychological Association

Moral judgment and social education (2nd ed.)
Georg Lind, Hans A. Hartmann, & Roland Wakenhut (Eds.)
Publisher: Edison, NJ: Transaction Publisher (2010)
ISBN-10: 1412813395; **ISBN-13:** 978-1-4-4128-1339-6

The study of morality is an empirical as well as conceptual task, one that involves data collection, statistical analysis, and the formulation and rigorous testing of hypotheses. The book relates this directly to the work of Jean Piaget, Jürgen Habermas, and Lawrence Kohlberg, who wrote the introduction to the book. The contributors are psychologists, sociologists,

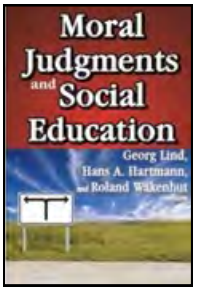

and philosophers of morality, most of whom have collaborated on long-ranged research projects in Europe involving socialization. Though the contributors represent diverse disciplines, they have as their common concern the two basic aspects of moral behavior and development, and the implications of dual-aspect theory for moral and social education. Although deeply involved in empirical research, they maintain that research on moral development can be pursued properly only in conjunction with a well-formulated theory of the relationship between society, cognition, and behavior.

Pain medicine: Philosophy, ethics and policy [paperback]
J. Giordano & M.V. Boswell
Publisher: Urbana, IL: Linton Atlantic Books, Ltd. (2009)
ISBN-10: 0981785441; **ISBN-13:** 978-09817854

This book, edited and written by leading scholars in the field (s) of neuroscience, ethics, law and healthcare policy, provides a unifying perspective of how a philosophical understanding of pain and medicine gives rise to the ethics and policies of pain care. Toward these ends, the chapters shed light on how pain and the experience of the patient and clinician establish the moral obligations of pain medicine, and the conditions necessary to enact pain care on a global scale. In this context, the authors consider possible ethical systems and approaches that are important to, and viable for pain medicine, and provide perspectives into the ways that moral obligations and practical realties are wedded to (and should underscore) any and all practice guidelines, health policy, and laws. In these ways, this volume provides erudite discussions of how contemporary knowledge of pain could and should influence the moral values, and conduct, tenor and value(s) of medical practice, and how this knowledge might serve as a foundation upon which to construct policies toward a more meaningful, patient-centered pain medicine in the future.

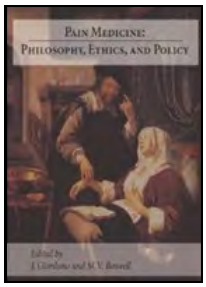

The cinematic mirror for psychology and life coaching [paperback]
Mary Banks Gregerson (Ed.)
Publisher: New York: Springer (2010)
ISBN-10: 144198156X; **ISBN-13:** 978-1441981561

Cinema both reflects life and contours life—that is its psychological power. And for decades, clinicians and educators have recognized the value of this power, using it to respectively heal in therapy and educate in the classroom. This volume mines the illustrative value of cinema, offering therapists and life coaches access to ideas that can motivate and

enlighten clients. Although many movie guides exist, this volume complements the available literature by adding positive psychology, mental health, and wellness perspectives to the clinical/educational/coaching mix. The serious intent to cull from cinema its underlying psychological value has motivated noted clinicians, life coaches, and cultural critics to offer science-based analysis and intervention strategies. Readers may add their own movie insights and professional expertise to this rich foundation. The volume covers international as well as domestic cinema in a variety of genres, providing a range of film choices relevant to clients' lives. Beyond this, it expands on universal concepts of strengths, capabilities, and coping methods.

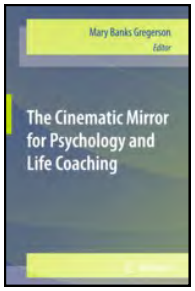

Technology innovations for behavioral education
Mary Banks Gregerson (Ed.)
Publisher: New York: Springer Publishing (2011)
ISBN-10: 1441993916; **ISBN-13:** 978-1-4419-9391-5

Evolving alongside technological advances is a new generation of tech-savvy, media-attuned students, particularly in graduate and medical programs. But while much is being made of a growing digital divide between teachers and learners, inventive instructors are using the new electronic media to design educational strategies that are creative and practical, engaging and effective. *Technology Innovations for Behavioral Education* documents these successful strategies emphasizing both technology-powered breakthroughs and psychology-driven instructional techniques reflecting the quantum leap in how students learn and what they have come to expect in the classroom. In these pages, multimedia pedagogy in itself involves multitasking, as competency development encourages technological development and improvements in health care education translate into improvements in client care.

ALSO ANNOUNCING THE PUBLICATION OF...

International perspectives in psychology: Research, practice, consultation
Judith L. Gibbons (Ed.)
Published: Quarterly, beginning in Spring 2012
ISSN: 2157-3883; **eISSN:** 2157-3891

This journal is a publication of APA Division 52 (International Psychology). *International Perspectives in Psychology: Research, Practice, Consultation* is committed to publishing research that examines human behavior and experiences around the globe from a psychological perspective. It publishes intervention strategies that use psychological science to improve the lives of people around the world.

The journal promotes the use of psychological science that is contextually informed, culturally inclusive, and dedicated to serving the public interest. The world's problems are imbedded in economic, environmental, political, and social contexts. *International Perspectives in Psychology* incorporates empirical findings from education, medicine, political science, public health, psychology, sociology, gender and ethnic studies, and related disciplines. The journal addresses international and global issues, including inter-group relations, disaster response, societal and national development, environmental conservation, emigration and immigration, education, social and workplace environments, policy and decision making, leadership, health care, poverty and economic justice, and the experiences and needs of disadvantaged groups.

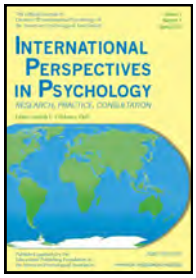

If you would like to include a book in a future issue of the *International Psychology Bulletin* and have not already done so, please email information to Jennifer Lancaster at jlancaster@stfranciscollege.edu.

Please note that at least one author/editor must be a member of Division 52 and the work must have been published in the last three years.

Reflection on Division 52 Activities at the 2011 APA Convention

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Reflecting on my experience at the 2011 APA Annual Convention in Washington D.C., I am glad I attended early in my career. After just finishing the first year of my doctoral program, I am thankful to Division 52 for not only the opportunity to present my research for the first time at the APA convention, but also for providing a broad range of programming that inspired, taught, and motivated me. In the sea of programming offered at the convention, it was incredibly useful having a guide of hand-picked interesting presentations as well as self-selected internationally-minded attendees. As many of you know, reviewing the telephone book-sized convention program is the first of several daunting aspects of attending a multi-day conference with several thousand participants. By using sessions related to Division 52 as a road map, I navigated my way through the convention, managing to cover a breadth of topics that where held together by their international focus.

As a member of the Division 52 student committee, I attended a diverse set of international psychology programs and events that put me in touch with several peers and mentors. Through this, I discovered many research areas that I would have otherwise not known about. From examining the psychological aspects of immigration to the international dissemination of evidence-based practices, this broad exposure to the possibilities of working in psychology was inspiring, and something I would have not encountered at a smaller conference or in a school course.

Presenting at the Division 52 poster session was also quite the experience. While I have presented my research at other smaller conferences, I was not prepared for the amount of exposure I would receive by merely having a poster up for an hour. The foot traffic at APA was constant, and I surprisingly received more than polite questions and brief glances. From suggestions for alternative interpretations of my results to offers to collaborate on other international research projects, I was shocked at how much came out of that brief poster session.

One thing that stood out to me about the International Psychology Division poster sessions was that several other students were walking around, mostly all looking for answers to the same question: how did you get involved with international research in psychology? With very few psychology programs in the United States having an international focus or having international liaisons for student research and training experiences, coming to APA is one of the best ways for students to reach out to psychologists worldwide. In my own (limited) experience, it seems that aside from international researchers conducting research in their country of origin, American students and professors come across opportunities to work abroad by happenstance—perhaps a colleague knows someone abroad looking for research support in your particular area of research, or—in my case—one of my professors knew of my interest in China and put me in touch with a visiting professor in our department. This repeated questioning from students about how to get involved with international research and clinical training led me to think that mentorship in the field of international psychology is especially important, as the path is largely undefined. We know that in order to have people follow in our footsteps, it helps to create a path. In an era of increasing globalization and ability to collaborate cross-nationally, I encourage leaders to reach out and make yourselves available to students and share your stories of how you became involved in your current position. In a time of rapid change in the way we communicate and work, I encourage students to not be afraid to reach out to professors and psychologists and ask questions and offer your unique perspective. Our division is a place to start this dialogue.

The social hour sponsored by Division 52 was a great way for me to meet both seasoned psychologists and other students along various steps of their graduate programs. For example, I met division members who took alternate paths with their graduate degrees in psychology, such as working as an international mental health advocate or being a Fulbright Teaching Fellow in a developing country. Being a PhD student in an academic setting, it can be difficult to envision working as a psychologist outside of a traditional path. I found such conversations were eye-opening to various non-academic career paths that I would not have encountered otherwise. Networking at APA through specific divisions was both helpful for professional development because of shared interests, as well as a common connection that is personally relevant. I had the pleasure of meeting in person with some peers that I have already been in contact with through my involvement in Division 52. Actually attending the convention and meeting other members in person has had a great impact on how connected I feel to the division.

Based on my interactions with other students at the Division 52 student committee meeting, I found that we had a small but motivated group of minds hoping to be the next generation of practitioners, teachers, and research scientists. A unanimous buzz amongst the students highlighted how exciting the entire convention was for a group new to this process. For young investigators, it is inspiring to see so many like-minded people who have established their careers in improving research and practice of psychology. It was

encouraging to observe a senior generation of psychologists collaborate so easily, share ideas, and support each other in research and friendship. There was not only a professional relationship among many members of Division 52, but a clear camaraderie that had formed over years of being a part of this community.

Overall, my first in-person experience with Division 52 was positive one, and I intend to continue involvement throughout the rest of my graduate career, as well as into the future. It is my hope that during my time as Co-Chair of Student Public Relations, I can help increase outreach and student membership in our community. I look forward to carrying the optimism I picked up at the convention, sharing it with colleagues, and helping maintain and expand the next generation of international psychologists. In sum, a sincere thank you to those at the 119th APA Annual Convention who provided an exceptional opportunity to meet other students already involved in impressive and exciting work in the field, as well as a network of psychologists willing to share their experiences and offer their time and support. I look forward to seeing you all at next year's convention in Orlando.

Editor's Note: *This column is geared towards our student committee members and all students of international psychology. All Div52 student members are invited to submit ideas or drafts for future articles, as well as questions they would like to see addressed in future columns – such as overseas internship opportunities, study abroad availability, cross-cultural research, etc.*

Contact the Editor at optimalex@aol.com to submit an idea or a question.

The September 2011 issue of *Interpersonal Acceptance*

(Newsletter of the International Society for Interpersonal Acceptance and Rejection) is now available for viewing at http://www.isipar.org/Newsletter.html.

This issue contains: A review of *Interpersonal acceptance and rejection: Social, emotional, and educational contexts*; information on the Seminar on Paternal Love & Psychological Adjustment held in Dhaka, Bangladesh; information on the International Association for Cross-Cultural Psychology Regional Conference held in Istanbul, Turkey; a review of *Social pain: Neuropsychological and health implications of loss and exclusion*; activities and accomplishments of ISIPAR members as well as other items you might find interesting and useful.

Please share the newsletter with anyone you know who might like to know about it or about the Society. Membership information is available at www.isipar.org.

You can read all prior issues of *Interpersonal Acceptance* by going to www.isipar.org and clicking on Newsletter in the left navigation pane.

How Do U.S. Fulbright Scholarships Change Lives?

Harold Takooshian, takoosh@aol.com &
Anne Stout, AnneStout@aol.com

In August of 2011 in Washington, D.C., many faculty and students at the 119th annual meeting of the American Psychological Association had to bypass dozens of other fine sessions to reach the APA international suite, for an unusual briefing by four experts about the U.S. Fulbright Scholars program.

The report that follows was inspired by that lively Fulbright briefing, to share practical information about Fulbrights here with the much larger readership of the APA *International Psychology Bulletin*. The briefing addressed participants' most common questions: "Why should a U.S. professor apply for a Fulbright award?" "How competitive are such awards?" "Do these Fulbright awards change lives?"

The four speakers in August were: (1) **Andy Riess, Ph.D.**, Fulbright Assistant Director for Outreach and Communication; (2) **David B.J. Adams, Ph.D.**, former Fulbright Senior Program Officer for Outreach and Public Affairs; (3) **Danny Wedding, Ph.D.**, a two-time Senior Fulbright Scholar to Thailand and Korea; (4) **Harold Takooshian, Ph.D.**, a Senior Fulbright Scholar to the USSR who later hosted multiple Fulbrights to the USA.

The U.S. Fulbright program was launched by U.S. Senator J. William Fulbright in 1946, just after the devastation of World War Two, as an effective way for the USA to increase global harmony, with an exchange of faculty and students. In 65 years, a staggering 110,000 U.S. Fulbrights have served overseas, and another 183,000 from 155 nations have served in the USA. As of 2011, the program now serves 7,500 scholars annually, and is fully detailed at the website of the Council for International Exchange of Scholars, www.cies.org.

As a long-time outreach officer, Dr. Andy Riess noted three clear trends that he has seen the past 22 years: (1) **Reticence.** Many U.S. faculty are unduly wary to apply as Fulbright Scholars, because they wrongly assume they have little chance to succeed among the Nobel Laureates and other celebrities who have served as past Fulbright Scholars. (2) **Gratification.** Yet those who go on to Fulbrights typically report the experience as one of the highlights of their lives, if not the lives of their families as well. (3) **Surprise.** It is common for Fulbrights to look back 10 years later with surprise, at how much their career has been transformed by their overseas experience.

As detailed in the expanded essays below, the advice is the same for all these Fulbright panelists: for each professor or graduate student to seriously consider the great adventure that lies ahead if they apply for a Fulbright experience overseas by the annual August 1 deadline.

Here, Andy Riess shares Fulbright materials. Dr. Riess completed his Ph.D. in Russian History, then joined the Council for International Exchange of Scholars in 1989, where he is currently the Council's Assistant Director for Outreach.

Behind the Scenes at the U.S. Fulbright Program

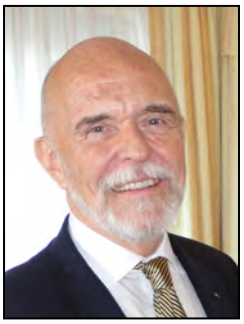

Andy Riess, Ph.D.
Council for International Exchange of Scholars
ariess@iie.org

It is difficult not to be impressed by the Fulbright Programs' list of grantees—43 Nobel Prize laureates, 78 Pulitzer Prize winners (with a total of 82 awards) and 28 heads of state. For many, such statistics are not inspirational, but forbidding. They look at Fulbright and decide, without further consideration, that they would never be competitive and should, therefore, not bother applying. Many take an almost hubristic attitude toward a grant. They are not worthy.

In fact, each year the Scholar Program awards grants of varying length to nearly 1,100 American academics and professionals. Not surprisingly, the recipients are not all laureates, presidents, or prime ministers. Rather, they run the gamut of academic and professional positions. There are university presidents, deans, chairs, tenured and non-tenured faculty, lawyers, research scientists, government workers, unaffiliated scholars and artists of all types. Each competition's grantees represent over 500 different institutions and every field one can imagine.

Fulbright scholars are the same people who sit in the office next door, teach a course in the adjoining classroom, serve on campus committees and labor to keep up-to-date in their fields. The distinguishing factor between them and non-Fulbrighters is that they applied for and won a grant. As a

result, it is fair to suggest that they also changed their lives based on living, teaching, and conducting research abroad. They almost certainly created new friendships and established ties with scholars and students they might never have known otherwise. Upon returning to their home classrooms, it is likely they entered them with renewed vigor and a different sense of how their academic specializations relate to the wider world and their local teaching. If they traveled with their families, the impact of the grant was shared even more broadly. The power of Fulbright can be exponential. It all depends on the grantees.

The view of Fulbright from the stratosphere is always bracing. But for the individual scholar/applicant, the point of view that counts is at ground level. What do Fulbright grantees in psychology "look" like? In the academic years 2006-2007 to 2010-2011 there were 96 Fulbright grants awarded to individuals who identified themselves as specialists in psychology. The grantees spent time in 64 different countries ranging from India to Russia, Australia to Norway, Japan to El Salvador. Together, they represented 86 different educational institutions and governmental entities. Their homes were major research institutions, liberal arts colleges, community colleges, and local, state and national governmental agencies. They were drawn from 36 states and the District of Columbia. In short, Fulbright scholars, affiliated and unaffiliated, truly represent America in all its facets. The talents and interests they bring to the program are of extraordinary breadth.

It is important to note that Fulbright awards are designed, each year, in the hosting countries. There is no great bureaucratic machine in Washington, D.C., that instructs our overseas partners as to what their interests should be. The programs, administered either through 51 Fulbright commissions or the local American embassies, create their award programs based on local interests, needs and priorities. That is the reason why the programs vary dramatically, country by country, and why topics currently of interest in one country may not show up in another. Fulbright is a cooperative effort and the annual competitions represent that fact. Awards and interests often change with time and each new competition will, in some degree, look quite different from the one before and the one to follow.

For all applicants, there is a variety of activities covered by the awards. Some are exclusively for teaching, others solely for research. There is a combined field (teaching/research) for which an applicant designs a program that covers both. Many awards will offer options as to the activity and in a number of cases, all three possibilities are available. It is up to the applicant to decide what seems best and then to make a case for that choice. For the period 2006-2011, 29 psychology grantees conducted research, 23 chose to teach (including 3 Distinguished Chair awards), and 44 used the combined teaching/research category.

The specific topics of these cohorts of Fulbright scholars can be found at the Council for International Exchange of Scholars website (www.iie.org/cies) and are well worth looking through. Fulbright depends on the imaginations and scholarly interests of the applicants to shape not only the program but to describe what is happening within their fields of specialization. Among the grantees in psychology, the scope of the work done has been truly impressive. Fulbrighters focused on neuroscience, cultural memory, mental health services for youths, drug and alcohol dependence, street children, health policy regulation, multi-ethnic community issues, solution-focused therapy, psychodrama, etc. The full roster of the topics covered by Fulbright grantees is truly a fascinating read. As it is with psychology, so it is with all academic fields. The world has much to learn from Fulbrighters. And Fulbrighters have much to learn from the world.

One aspect of Fulbright that may be overlooked by some is that it brings over 800 scholars from abroad to the United States each year. Hosting scholars at American universities and colleges is an excellent way to create ties; to build them, to rebuild them, to maximize non-Fulbright grants; to encourage others to become globalized and to construct a framework that might lead to a Fulbright grant for an American scholar. In the period 2006-2007 through 2009-2010, 79 scholars of psychology were hosted at American universities through the Core and the Scholar-In-Residence programs. They came from 42 different countries including Yemen, Kyrgyz Republic, Nigeria, Qatar, Peoples Republic of China, Norway, Panama, and Latvia and were hosted in 21 states. As with American Fulbrighters, they worked in widely divergent aspects of psychology and were able to interact, on a daily basis, with fellow academics and students. Simultaneously, many had their first experiences with American university and community life.

In terms of outcomes, they are so varied and so individual that is difficult to characterize them. Statistical surveys make clear that Fulbright recipients conduct research and teach in new academic and governmental environments. They publish, they make conference presentations, they travel, they build bridges to their home institutions. Returning to the United States, they often reevaluate elements of their course presentations, adding new topics, including innovative points of view. A major outcome is their inspiring students to become global. Between 40% and 70% of student Fulbright applicants note that their teachers were the ones who directed them to apply for an overseas grant. Fulbrighters speak to other faculty, to administrators, and to the wider community about their experiences and the importance of linking to the world.

Fulbright grants are not always easy, but years of experience have confirmed the profound impacts that grants have on the personal level. The CIES Website has a number of scholar experiences for reading and viewing. In dealing on the personal level with Fulbrighters, the years have made clear that the impact is profound; but it is wonderful to hear, again and again, comments such as "the most important thing I have ever done," "I shall never be the same person," "how can I possibly summarize what the grant has meant to me?" Fulbright is all about personal diplomacy and over 300,000 Americans have already taken the opportunity to represent their country and its academic strengths abroad. The people

who undoubtedly will never have this opportunity are the people who never apply.

A Cultural Lens on Social Relations

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Lebanon, 2008
U.S. Senior Fulbright Scholar to *Haigazian University*

My Fulbright experience in Lebanon has played a transformative role in my life personally and professionally. It provided me with an experience that has enriched my understanding of social relations, both practically and theoretically. This extends into my personal relationships—particularly how I interact with others, as well as into the research I have been carrying out on social relations over the past ten years.

Through my social outings, teaching experience, and research project, I came to recognize the importance of an overlapping sense of self in Lebanon. The ties that bind extend beyond family, and are achieved through various interactional norms within the society that cut across religion, gender, class, and age. Learning this fact, and in many ways living it, provided insight useful for understanding cultural differences which in turn helps me to be aware of how social relations vary, and are similar, across countries.

I have plenty of personal experiences that demonstrate this point (i.e., students' feeling they have the right, indeed a duty, to negotiate assignments, due dates, etc. with their professors is a case in point). For illustrative purposes I would like to present the sample case of driving in Lebanon as a microcosm of social relations.

I absolutely loved driving in Lebanon. I could drive as fast as I dared and that there were seemingly no clear rules on the road-- I found it liberating to have the freedom to negotiate the road based on my needs and goals. I also had no problem yielding to others when it was clear they had a need greater than mine. The way Lebanese drive is often joked about by those living in the country. For instance, a student at Haigazian University (where I taught and conducted research during my Fulbright) wrote an article in the university newspaper in December 2007 that identified what she observed to be unique to Lebanon. In that list of distinctive characteristics she frames as: *Where else in the world…* she included the following observation "would a driver illegally enter a one-way street and then yell at people moving WITH traffic?" Note that it is not just the act of doing something "illegal," but the fact that the driver who turned into a one-way street is yelling at those driving in the correct direction! This scene perfectly captures the issue. It is not simply the fact that rules are broken, but that the person breaking the rule feels justified, and makes the others out to be wrong. Though seemingly chaotic to the unaccustomed observer, there is order to this seeming madness. The order, however, is a negotiation that happens with each and every encounter. How and whether one moves depends on one's skill to maneuver around the other. Driving is a game of give and take. There must be a willingness to give, as well as the courage to take. Accountability does not exist at the macro level, but is achieved each and every time one person on the road comes into contact with another person on the road. The lessons learned from driving in Lebanon extend to interpersonal relationships as well as a deeper understanding of the ties that bind groups of people.

Having the privilege to carry out a Fulbright has contributed to a heightened awareness of how norms within a society shape the nature of social relations, which after all, are the foundation of human existence. This experience impacted my career in numerous ways, from new opportunities to conduct funded research, to collaborations with colleagues across disciplines and countries. A Fulbright award is, indeed, a life changing experience.

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Linking American and Post-Soviet States of Mind

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Russia, 1994
U.S. Senior Fulbright Scholar to Russia

I first visited the Soviet Union in 1990. Only a year later the Soviet Union began its tortuous march toward capitalism. The official belief system of approximately 200 million Soviet citizens was abandoned as the principles of free enterprise

replaced those of a planned economy. It was my incredible honor to witness the transformation first hand as a Fulbright scholar at Moscow State University in 1994.

Being a Fulbright scholar in Russia in 1994 was an incredible experience. I came to realize that political belief systems are, at their heart, psychological theories. They are implicit theories of motivation, personality, mental health, human development, education, and social interaction--topics that are the very lifeblood of psychology. My work with colleagues in Russia led to life-long collaborations and friendships. Alexander Voiskounsky, my host at Moscow State University, and I received a Rockefeller Foundation Scholar-In-Residence Award in 1995, where we lived for a month at the Rockefeller International Center in Bellagio, Italy. We co-edited a book that compared American and Post-Soviet Perspectives on many issues in psychology including political psychology, inter-ethnic conflict, truth and lies, mental health, and other key concepts.

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Contributing to Psychology in Turkey and Beyond

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Turkey, 1957-58
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Long-time interests in world affairs led me to join the International House at Columbia University as a doctoral student, in the late 1940s, until early 1951, when I left for three-years' duty as a Navy Research Psychologist during the Korean War. Otto Klineberg, a venerable international social psychologist, was a major mentor of mine, and at the "I House" I met and conversed with students from around the world. My desire to be directly involved abroad was realized in 1957-58 when teaching at what is now Carnegie Mellon University (CMU).

I received a Fulbright Lectureship Award to Turkey as a Visiting Professor at Istanbul University, a modern academic center, with equality of women and men, founded in 1492. I recently wrote an article for *International Psychology Bulletin* about my experience there, to celebrate the Program's 65th Anniversary (Hollander, 2011). As detailed in it, I taught graduate and undergraduate psychology students, supervised research, and lectured in seven other countries. I lived alone in a small cottage on the Bosporus, and experienced daily life as a resident, far different from what a tourist would, including frequent shortages of heating fuel, in a climate like New York City, on the same 42nd parallel. The people were friendly, though the Turkish I had studied was limited. At the University, most spoke English. The memorable impression I had was of students' high motivation and earnestness, truly eager to learn. My two graduate assistants, Ms. Iffet Dinc, and Mr. Yilmaz Ozakpinar, were superb doing sequential translations of my lectures, a paragraph or two at a time. Both were extremely helpful and caring, and our friendships went on for years as they both earned doctorates, she at Florida State and he at Cambridge. My genial host, Professor Mumtaz Turhan, respected Chair of Psychology, had his doctorate from Cambridge with Sir Frederic Bartlett. He was friendly from the moment my appointment was underway, and facilitated my activities and awareness, with marvelous support from Fulbright Commissions of the nations involved. Nine years after leaving him and the University, Turhan invited me back to give lectures and do a seminar session in the spring of 1966-67 when I was on a year's Senior Post-Doctoral NIMH Fellowship at London's Tavistock Institute. By then married, my wife Pat came with our son, Peter, then six. Yilmaz Ozakpinar, now on the faculty, was among many former student greeters. That year, I also returned to lecture again at many places I had gone in my Fulbright year, and in Paris visited as a Fellow of the Institute of American Studies.

The academic year in Turkey broadened my horizons considerably, experiencing a crisis between Turkey and Greece in the Aegean Sea that led to martial law for a time, fortunately with reduced threats, so I did lecture in Athens. A backdrop to these events was reading the foreign press and hearing multi-national shortwave broadcasts. Among the effects was a deeper sense of shared human conditions and concerns, but also the differences in living of those relatively comfortable in America and people elsewhere, and how they saw our nation. However, personally, the warmth I encountered from students and colleagues was memorable.

Professionally, this was one of the richest years of my over half a century in academe, meeting others, giving talks. In the summer of 1957, before going to Istanbul that October, after returning home to prepare, I presented a paper at the International Congress of Psychology in Brussels, on a panel chaired by Bartlett, who invited me to visit his research center at Cambridge, which I did. It was the second Congress I attended, having gone to Montreal in 1954, taking some of my graduate students from CMU. In the decades since, among many, I participated in Congresses in Rome 1958, Bonn 1960, Paris 1976, Munich 1978, where I gave a keynote

address, Brussels 1992, Montreal 1996, and Athens 2006. There, I reconnected with Jim Georgas from the University, my host almost 50 years before, and received an honor at the Congress for the "international advancement of applied psychology." Grateful for this, I'd gladly been singing my songs of leadership-followership, conformity-independence, and the utility of positive peer nominations, at national psychology meetings abroad, such as the British Psychological Society. In spring 1973, I was glad to be a visiting professor at Oxford for the Trinity Term, with students in Michael Argyle's Laboratory of Social Psychology, and invited to speak elsewhere in the UK. My textbook in social psychology (Hollander, 1967) was then in its second edition, and in Spanish, and later in Chinese. Other translations of my books include Korean and Norwegian.

In the APA at home, I continued to be oriented to international relations, and had the privilege of being appointed to its then new Committee on Psychology in National and International Affairs for 1960-63. It focused mainly on international conflict reduction, including research for the UN (Kelman & Hollander, 1964; Hollander, 2005a,b). Its first chair was Charles Osgood, and I chaired it in my third year, having served in its first, 1960-61, as Interim Executive Secretary, while on the faculty of American University's School of International Service (SIS) in Washington, D.C. At SIS, I taught graduate and undergraduate courses in the behavioral science curriculum that I participated in developing for these international relations students, many entering diplomacy. I also conducted research, including a world-wide study of newspaper stories about UN activities, and a cross-national study of college student attitudes toward atomic power, under UNESCO auspices.

For 1981-84, as a member of the APA Committee on International Relations in Psychology (CIRP), I arranged a convention program on international tension-reduction. As president of APA Division 1 (General Psychology) in 1980-81 I welcomed participants from abroad to the Annual Convention, and facilitated their visiting campuses and particular laboratories in their fields of interest. At EPA, where I was president in 1988-89, I have participated in the Annual Meetings' international psychology sessions, earlier organized by Florence Denmark, now by Division 52, including this year's Fulbright awards panel.

Finally, the Fulbright experience significantly affected my scholarly work on leadership, and its relationship to followership. Beyond my laboratory and field studies, I observed further that the basic "reciprocity norm" operates widely, and does underlie and facilitate good leadership. Among its implications in practice, it means Respect for others, Recognition of their contribution, Responsiveness to them, and Responsibility in both directions. I refer to these fundamentals as the "Four Rs" of "Inclusive Leadership," in my latest book, so titled (Hollander, 2009). As a small sign of their wider relevance, this new book is being published now in Korean, as was an earlier leadership book of mine (Hollander, 1978). I am grateful that my international outreach continues, and may be beneficial.

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From the Soviet Union to the USA: An American Dream

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USA, 1996-97
Senior Fulbright Scholar
to the USA

Did Fulbright change my life? Absolutely. My career could not be more transformed after serving as a Fulbright Scholar to the USA in 1996-97.

From 1983 to 1994 in the Soviet Union, I was the Scientific Secretary of an Institute within the National Academy of Sciences of Armenia. During that decade, I met a series of Fulbrights to the USSR, including Harold Takooshian of Fordham University.

Before being awarded a Fulbright in 1996 to study in the United States, I had received an IREX (International Research and Exchanges) Scholarship to Fordham University with Professor Takooshian in 1993. Though I completed a Ph.D. (Kandidat) in Psychology from the Academy of Sciences of the Soviet Union, I gained practical post-doctoral training in psychology field research from Professor Takooshian. By 1996, on my return to the USA as a Fulbright, I already regarded myself as a researcher with professional experience. Both Professor Takooshian of Fordham University and Pro-

fessor Uwe Gielen (of St. Francis College, Brooklyn Heights, NY), hosted me as a Fulbright, and gave me confidence as a professional in the field. I participated fully in U.S. psychology—as a writer, reviewer, speaker, editor, organizer, and participant in the vibrant psychology community in New York—becoming active in such U.S. organizations as Psi Chi and the Society for Psychological Study of Social Issues.

After developing a few research papers together with my U.S. colleagues, I returned in 1997 to Armenia, my home country, to be useful to the field of psychology. But as Jesus said, "A Prophet is not without honor except in his own country" (Mark 6:4)—which seemed true for me as well. I found greater success abroad in the first half decade of the 21st century. I visited European countries (Germany, Sweden, Hungary, The Netherlands, Spain) for lecturing and research purposes--some of this financed by Soros Foundation--while continuing to grow professionally in psychology and sociology. My goal remained "The American Dream": living and working here in the USA. In 2005, I was awarded a Kennan Scholarship at the Woodrow Wilson Center for International Scholars in Washington, D.C., a highly prestigious scholarship. The Director of the Kennan Institute told me that only two persons from Armenia had received a Kennan Scholarship – Hon. John Marshall Evans (Former US Ambassador to Armenia) and me. What an honor.

I am now a professor and department chair at Technical Careers Institute in New York City — an unique college founded by Nobel Laureate Guglielmo Marconi in 1909, and now known for serving the needs of first-generation inner-city college students.

Without the life-changing experience of Fulbright, I cannot picture the direction my professional career would have taken. I have become a citizen of the world, with many experiences back home in Armenia, Russia, Europe, and the United States of America. The help of the colleagues I have met and who have mentored me along the way has been invaluable. Although my heart remains in my beloved Armenia, I have made the United States my home – truly a land of opportunity.

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Applying Psychology in the Soviet Union

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Soviet Union, 1987-88
U.S. Fulbright Scholar
to the USSR

Back in 1987, I had to switch my application from terror-ridden Sri Lanka to the USSR, and was lucky to be among the 15% who were chosen for the USSR. Fordham President Joseph O'Hare personally intervened to grant a sabbatical to allow Assistant Professor Takooshian to travel to the USSR with my dear wife Silva and our three-year-old Lori. Thanks to Alan Campbell at CIES, I was able to arrange visas for 5 universities in 3 republics: Leningrad, Moscow, Novosibirsk, Tblisi, Yerevan.

During my five months, this Fulbright could not have had more diverse impacts: (a) **Family.** My family savored a wealth of new experiences with U.S. Embassy officials and others, as my trilingual three-year old Lori translated for her monolingual dad. We spent precious time as house guests of gracious families like that of Sue and Max Robinson, the U.S. Consul in Moscow, Nana Sumbadze in Tbilisi, Vladimir Trusov in Leningrad, and Artaches Emin in Yerevan. (b) **Teaching.** My hosts in 3 republics received much new information about U.S. applied psychology--I-O, forensic, psychometrics, behavioral research. (c) **Learning.** I learnt much about Soviet psychology, and did a census of Soviet psychologists. (d) **Career.** I published research comparing Russian and U.S. psychology, starting with my essays co-authored with the heads of social psychology at Leningrad State University (Takooshian & Trusov, 1992) and the Academy of Sciences in Armenia (Nalchajian et al., 1997).

Long after 1988, I am surprised how my life was totally transformed by this Fulbright, at several turns. (a) Within APA, I was propelled to pioneer the new specialty of "international psychology," as the first program chair (1998), then President (2003) of the new APA International Division, then a member of the new six-person APA team at the United Nations (2003-2008). (b) I edited a series of five unprecedented directories of psychologists and sociologists in Armenia (Vardanian, Takooshian, & Karakashian, 1990), which proved useful after the deadly 1988 earthquake in the Caucasus. (c) Dozens of Soviet colleagues visited the USA over 25 years, including two Fulbrights hosted by Fordham in the 1990s. In November of 2010 I was invited back to Moscow as a guest lecturer at five institutions. I had no idea how

much 5 months in the USSR would alter my life for the better, leaving me grateful to become part of Senator J.W. Fulbright's bold vision for a better world.

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Two Critical (Fulbright) Steps in a Lifetime Journey

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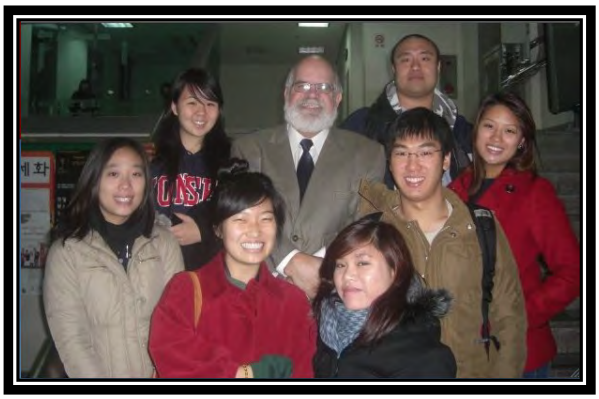

Danny with his psychology students in Korea

After a contentious divorce in 1999, I had the good fortune to be selected as a Fulbright Senior Scholar teaching psychotherapy to psychiatry residents in the Chiang Mai University School of Medicine (Thailand); a decade later I had an incredible experience spending ten months as a Fulbright Distinguished Lecturer teaching graduate and undergraduate psychology students at Yonsei University in Seoul, South Korea. These two experiences shaped my

- **professional activities** (e.g., serving as President of Division 52 in 2010, and as a member of the APA *Committee on International Relations in Psychology*);
- **scholarship** (e.g., I coedited the *Handbook of International Psychology* with Michael Stevens);
- **subsequent travel** (e.g., participation in International Psychology conferences in Athens, Berlin, Beijing, Mexico City and Cape Town);
- **career** (I'm currently responsible for CSPP programs in Mexico City, Hong Kong and Tokyo, and for investigating new opportunities for international education for our students);
- and my **spiritual journey** (I began a serious study of Buddhism while living in Thailand).

On my first Fulbright I lectured in every medical school and most of the major universities in the country, as well as in Australia and New Zealand; on my second Fulbright I lectured at all the leading universities in Korea, and I presented a U.S. state department sponsored series of lectures on suicide prevention at universities in Osaka, Okinawa and Tokyo.

At Yonsei, I taught classes on Tuesday and Thursday, and used Wednesday to meet with students and prepare lectures. This left me with a four-day weekend each week, and I used this time to visit dozens of other Asian countries (e.g., I finally made it to Angkor Wat).

Anyone interested in learning more about my Fulbright in Korea can review a photo journal describing the experience by simply entering "**Sojourn in Seoul**" into a search engine like Google.

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7 Projects for a Healthy and Prosperous Democratic Republic of Congo: Peace Building, Empowerment, and Forgiveness Projects

New York – Kigali, Rwanda and Bukavu, Congo – July 2011 – Dr. Ani Kalayjian

The sky was overcast and the weather was hot as we arrived at the border of DR Congo after driving seven hours from Kigali in Rwanda, traversing the mountainous, debilitated roads, which made for a bumpy ride that shook us the whole way. We are the ATOP Meaningfulworld volunteer Team (myself and Mr. David Melvin Pressley), joined by our partners from the DR Congo Peace and Conflict Resolution Team (Pastor Samuel and Mrs. Faida). Kigali was active, with many construction projects underway; the Chinese have been fixing the roads, so it is all smooth and beautiful. In contrast to those qualities of the road, the Genocide museums were emotionally tumultuous places that paid tribute to the 1994 massacres that in 3 months' time resulted in the brutal deaths of 800,000 Tutsis and empathic Hutus; others were left maimed, their limbs hacked off, disabling them for life. The Genocide museums were a testament to the horrors that we had read about and seen on our televisions in 1994: The skulls were lined up along one area, the bulging eyes conveying the horrors that were endured. We could see how the machetes cut into them in three or four places. The limbs were in another section, and there were photos of terrified children showing the wounds they endured, as well as a pregnant women who was brutally killed on a church altar where she was kneeling and praying to God, and other women raped and killed in front of their parents and siblings.

Few countries have seen the amount of violence that the Democratic Republic of Congo (DRC) has witnessed in the past few decades. Exacerbated after the Genocide in Rwanda in 1994, the fourth largest African state has endured wars with its neighbors, civil wars, and other forms of violence that have proliferated immense poverty and famine, an HIV/AIDS epidemic, increasing rape rates, and gender intolerance. The International Rescue Committee estimates more than 5.4 million people have died from the prolonged conflict, a conflict that Nicholas D. Kristof of the *New York Times* says is being ignored by the international community.

Having arrived at the border of Bukavu and Kigali, we had to exit the vehicle with our seven trunks of donations for the needy. A large group of Congolese had gathered around us to transport our luggage across a bridge. Our main partner was the Peace and Conflict Resolution Project (PCR), spearheaded by Pastor Samuel Muderhwa and Faida Mutula. Their friends met us at the border and calmly took care of the mob of Congolese wanting the opportunity to get a tip. They then escorted us to the immigration office and from there, to the customs office. We had to walk across a debilitated wooden bridge guarded by police with machine guns and stern faces while the seven women who were with us carried the heavy luggage on their heads, backs, and shoulders. It was surreal, and we could not even take photos to record our observations, because we would be imprisoned. The sky got cloudier as we walked across the bridge and entered Bukavu, there to have our visas verified at the immigration office. We were greeted with a warm "karibu" and "jombo" ("welcome" and "hello" in Swahili). I was so excited that I was able to respond in kind, since I still remembered my Swahili from our humanitarian program in Kenya: "Jombo Sana, habari," I said, which means "Hello to you, and how are you?"

While we were walking to our friend's vehicle we encountered many adults and children calling out "muzungu" ("white person"), and extending their open palms to ask for money and food. To the Congolese, a white person is associated with money, prosperity, and wealth. Congo was a colony of Belgium, which is why the second language (after Swahili, Lingala, KiKongo, etc.) is French, while across the bridge in Rwanda, people are picking up the English language more and more to benefit from English speaking universities in neighboring Uganda, as well as in Canada and USA. Congo got its independence in 1960 and just celebrated its 50th anniversary.

ATOP's Meaningfulworld Peace Building, Conflict Transformation, and Forgiveness Program began immediately as our team (myself and M. David Pressley) met our partners at PCR, which is under the leadership of Pastor Samuel Muderhwa and his wife, Faida Mutula. They reviewed our program for each day, and each day the program was packed with daily trainings followed by visiting refugee camps as well as various victimized individuals such as displaced people, rape victims, orphaned children, single mothers, and those in the maternal ward for rape victims. As we traveled to Pastor Samuel's home, we witnessed extreme poverty and slums, young men and women sitting around with nothing to do, nowhere to go, and no food to eat. They looked emaciated and dehydrated as they attempted to give a warm welcoming smile to the "muzungus."

We began at the Pentecostal Church where I spoke as the guest to deliver a message of love and forgiveness. There were more than 500 people packed into the Church, drums beating fast and passionately, a chorus singing, and all kinds of musical instruments vibrating the space. The message was well taken, and members of the congregation came to me and told me they had come to Church with headaches and stomachaches, and they left nourished and in peace. I was in awe of their belief system, as they were all praying with such a deep faith, hope, love, and connection. We then went to another Church where well over a thousand people were gathered. I wondered why the poorest are often the most faithful or religious…

We provided two days of intense trainings, lectures, and discussions on peace building, conflict transformation, assertiveness, and anger management. Each day more than 50 professionals, students, activists, police officers, soldiers, chief officers, religious leaders, people from the media, local community leaders, women and youth groups, disabled persons, among others joined us. Their questions indicated a deep search for peace and empowerment. We had seven projects developed while we were addressing the needs of the Congolese. We started working with the PCR's HIV/AIDS women's group, who were struggling without medications and reporting weakness, severe symptoms, and helplessness. The Netherlands NGO was providing them with food and medications, but they withdrew about a year ago, and no one replaced them. We gave them protein bars, gifts, and valuable guidance, and we made plans to follow up in order to provide them with continued support.

The second project was educating boys and men. Early unwanted pregnancies and STDs such as the deadly HIV continue spreading. Condoms are not available, and anyway, it's taboo to ask for one, as you would be considered "a loose person." Unwanted pregnancies will continue if males are not educated about the consequences of their actions and empowered to respect and care for themselves as well as the women in their communities.

We visited the slums of Bukavu, and while of course you may say there are slums in every country (Kenya, Sierra Leone, Haiti, etc.), it was still an unbelievable scene: Millions of people lived in these tiny tin-and-mud houses the size of a small tool shed, with bare walls and no furniture, food, or books inside – just a few plastic containers to fetch water or perhaps an old calendar from 2009 collecting a lot of dust. We listened to their plights, witnessed the long lines of children with runny noses and flies all over their faces, each with a yellow container clutched in both hands, each struggling to fetch water for their family or looking for cooking wood before sunset.

The next project was in the maternity ward of Dr. Rau Hospital in Chiriri/Kasha. We were reaching out to the women in the maternity ward, listening to their experiences, their needs, and their pain, as we were empowering them. PCR had a supply of donated birthing kits from an Australian NGO. The fresh blood on the floor from a C-section, the smell of the sweat of labor mingling with the odors of urine and placenta permeating the ward compelled me to exit for a breath of fresh air to prevent myself from fainting. At this hospital the new mothers were crying out for soap to wash the dried blood, as well as their newborns. We supplied one of the PCR staff with money and sent him to the market to buy a large quantity of soap. At that time we had the opportunity to speak with the head nurse as well as the director, who took us to their bare supply room, which lacked such basics as syringes, gloves, sanitary napkins, and antibiotics. The soaps arrived and we were on the verge of tears as we watched how the women's eyes lit up with joy and gratitude, as if we were distributing bars of gold.

The fourth project was giving a follow-up training in the 7-Step Biopsychosocial and Eco-Spiritual Healing Model for about 30 PCR staff members. The Meaningfulworld Humanitarian Outreach Program (Kalayjian, 2010) has focused upon national & international mediation through conflict transformation workshops conducted in over 25 nations. At the core of all workshops is the seven-step Biopsychosocial and Eco-Spiritual Model, through which various aspects of trauma, dispute, conflict, or disagreements are assessed, identified, explored, processed, worked through, and released, and a new meaning achieved. This innovative model incorporates various theories including: psychodynamic, interpersonal (Sullivan, 1953), existential and humanistic (Viktor Frankl, 1962), Electromagnetic Field Balancing (EMF, Dubro & Lapierre, 2002), Learning Theory, Flower Essences, Essential Oils, physical release and mind-body-spirit chakra balancing, prayers, and meditation. The questions were insightful; people were tired of 20 years of war, corruption, and now the Hutu Militia. Some just wanted to let go of everything, to forgive, and move on and sacrifice their human rights, while others asked for revenge and justice, and a third group wanted to leave everything up to God's will. It was an opportunity to discuss the importance of assertiveness, of not giving up one's rights as specified in the UN Human Rights Declaration and the Millennium Development Goals (which is signed by all governments in the world, including the Congolese government), and the importance of healing before taking a blind leap into forgiveness.

The fifth project was visiting refugees (displaced people) in Mudaka village, where people came from Bunyakiri, Gahutu, Luhinja, and many other villages that were ransacked by the Hutu Militia (which killed parents, raped young girls, and set villages on fire). These Hutus have escaped the Gacaca Court and some, led by General Mudacumura, exploit the weak presence of the UN Peace-Keeping Forces while exploiting the wealth of minerals, gold, and diamonds in Congo. We interviewed more than 50 women ages 14–38, as well as a few men who witnessed these horrific experiences. Their stories greatly distressed us. Some had walked for 18 days, others for 2 months to arrive at this camp. All too often it reminded me of what my grandmother had told me about what the Armenians went through during the Ottoman Turkish Genocide in 1915. Almost 100 years later, the world is still witnessing horrific acts of violence inflicted by one human being upon another. It is surreal, it is unbelievable, and it is a disgrace. When are we going to learn the lessons of history and embrace one another?

We brought healing Bach Flower Remedies made in England and distributed and donated by Nelsons. These remedies are formulated specifically for trauma (such as Rescue Remedy and Star of Bethlehem). We also brought donated clothing, toothpaste and brushes, and Zone protein bars. These people need continued support and collective healing. These flower remedies have been trusted for over seventy years in over 66 countries. Rescue Remedy, for example, helps alleviate the shock and helplessness of trauma, and contains the following natural ingredients: Helianthemum nummularum, Clematis vitalba, impatiens glandulifera, Prunus cerasifera, and Ornithogalum umbellatum.

The sixth project was with the displaced children in Bagira (they came from Funu, others are from Tchimpunda, Kaza-Roho, Chiriri and Essance). PCR had been working with more than 500 children. 279 are orphans, while others were economic orphans. When we arrived they had banners welcoming us with messages such as "God Bless You and Keep You Safe," and "Dr. Ani, King David, Pastor Samuel, and Faida, God Bless You." They sang, we all danced, and we talked about love, compassion, sharing, and working hard and doing the best we can. We were amazed at how attentively they were listening, repeating our words with conviction. We also engaged them in activities such as art therapy and storytelling. The contents of another suitcase of gifts were shared, including crayons, clothes, and protein bars. With your support, these healing groups and art and play therapy sessions will continue.

We spent a few hours each day counseling individuals

with specific needs such as family issues, health issues, nutritional issues, and identity issues. Many of the complaints were on the somatic levels: Tachycardia, hypertension, heart palpitation, and chest pain, which may be related to their unresolved trauma. We taught them about the limbic breathing (diaphragmatic breathing) method, healthy nutritional intake, and creating inner peace with visualization and meditation.

David Pressley characterized the journey as a rewarding experience. "While it was emotionally extremely draining, I was happy to be there and share the sorrow of the Congolese. I wish we could do more, and we are planning to do more. I was also angry with the extent of the suffering, as there was an underlying helplessness and resignation with their plight instead of reaching in and discovering solutions and working steadily to reclaim their basic human rights."

The next invitation was from the Université de la Paix in Bukavu. We later found out that there are three universities for peace in Bukavu, in a country that is struggling for peace. More than 50 students, faculty, and administrators had gathered. They were listening attentively, raising their hands, and sharing their concerns: Can we forgive before healing the wounds of rape and murder? Which comes first, forgiveness or justice? How can we help our rape victims whose families have abandoned them? How can we enforce our rights to free access to primary education and decent roads? How can we empower people when they are hungry? (The Congolese have a saying, "An empty stomach doesn't have ears," which means hungry people cannot listen, understand, and be empowered- their basic needs have to be met first.) They asked many questions, indicating their desire to move out of

this mode of helplessness, pain, corruption, and suffering.

The seventh project was teaching yoga stretches and chakra balancing movements, especially those for reinforcing trust: opening the fourth chakra for unconditional love, strengthening the third chakra for empowerment and the fifth chakra for self-expression and demanding basic human rights, and the sixth chakra for insight and strengthening inner resolve. In the future we are planning to start tennis courts for the slums, to empower, engage, discipline, and train youth in a constructive sport.

With your support, we can continue our 7 Projects for a Healthy and Prosperous Congo. Education is the key to growth, empowerment, and confidence. $325 will educate a child in Congo for an entire year (10 months). **Together we can make a difference in Congo**. Please send your check (made out to ATOP, DRC Sponsor a Child) to 135 Cedar St, Cliffside Park, NJ 07010, or donate online at www.meaningfulworld.com.

Cost of Conflicts in Organizations: Review of Research and Recommendations for a Healthy Organizational Environment

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Conflict is inevitable in businesses, non-profit and for profit organizations, as well as countries. Depending upon connotation, severity, length and extent of conflict, conflict-transformation skills can have drastically different impacts on employees, organization, and individuals. It is critical to first define conflicts and differentiate them from similar concepts such as disagreements or problems. While disagreements occur when there are opposing opinions that do not directly impact behavior, decisions, and organizational effectiveness and are viewed as healthy; problems occur when there are differences of opinion which have a functional impact on these areas. A conflict arises when this impact occurs as well as a belief that one's interests or goals would not be able to be accomplished (Cram & MacWilliams). There are "positive conflicts," which are well-managed and involve an augmentation in efficiency and strengthening of relationships, as well as "negative conflicts," which are poorly-managed and often lead to lower productivity and damaging of interpersonal relationships (Buss, 2011). Klynveld, Peat, Marwick, Goerdeler or KPMG, an American division of an audit, tax and advisory firm, conducted a Conflict Cost Study demonstrating functional versus dysfunctional conflict costs, in which the first helps an organization, allowing parties to openly express themselves, use active listening, and maintain an open mind while dysfunctional conflict costs are damaging and often involve personal attacks and involve personal pain and suffering (Blees, 2009). In this paper, the authors review and report on negative impacts of dysfunctional conflict and offer strategies to transform conflicts while reducing the costs.

Often businesses and non-profit organizations do not take into consideration low morale or unhealthy conflict and do not actively measure and collect the costs of conflict in the workplace. On the organizational level, conflict costs can be found in low productivity, absenteeism, rapid turnover, low reputation, burnout, theft and damage. Lack of productivity arises with unhealthy conflict. A study by OPP Limited, an international business psychology consultancy of European countries and Americas, surveyed 5,000 employees, and found that approximately 2.3% to 8.3% of weekly working hours were spent on badly managed conflicts (McHenry, 2008 http://www.opp.cu.com/conflict.aspx). Distancing disputing employees from working with one another leads to inefficiency in obtaining organizational goals (Buss, 2011). Absenteeism, or the number of unscheduled days a person takes off from work due to badly managed conflict, has been correlated with increased workers' stress. Presenteeism is the presence of an employee who is working while sick or not suitable to work, while maintaining a defeatist attitude causing greater workload for other employees. While difficult to quantify, presenteeism may result in greater costs than absenteeism (DeVol & Bedroussian, 2007). Another organizational cost is turnover and research shows that at least 50% of voluntary departures are because of unresolved conflicts. The results from a Canadian study showed that replacing an employee costs approximately 150% of their yearly salary (Philips, 1990). According to a global staff survey on recruitment and retention (2011) within the United Nations, chronic unresolved conflict is not as prevalent for reasons of employ-

ees voluntarily leaving the organization. The diminished productivity, poorly managed conflicts, lowered motivation and service, all too often devastate an organization's reputation through weakened cohesiveness. About 80% of employees affected by negative conflict criticize the organization, which can have negative impacts in an organization maintaining well-skilled employees or obtaining financial support from stakeholders or donors. Lastly, theft and damage by employees has been quantified by the UN within areas of: paying for employees who are on sick leave, replacing employees in conflict, or providing counseling during work hours (Buss, 2011).

In regards to the employee, poorly managed conflict can lead to greater stress, anxiety, frustration, physical illnesses, humiliation, and excessive concern about the self. It can also lead to lower confidence and occupational motivation for employees. Interpersonal connections can be hindered from behaviors of withdrawal, interruption, not listening, or negative biasing (Buss, 2011). Presenteeism only exacerbates medical conditions, quality of life at work and job inefficiency. Based on a take-home survey sent to 500 international United Nations High Commissioner for Refugees (UNHCR) employees with a 42% response rate, seven out of ten individuals felt they experienced burnout because of unmanaged conflict. More than 50% believed that the conflict impacted their mood which is consistent with research findings that connect workplace conflict with emotional exhaustion and potentially absenteeism, burnout, and turnover (Buss, 2009).

Employees' compromised health, due to stress from workplace conflict, can be alleviated by social support. Social support can improve one's health via the body's cardiovascular and immune systems. It may diminish behaviors like smoking and drinking while accelerating positive behaviors of the body like exercising, stress management, etc. Social support can be obtained from empathic peers or supervisors. Collective esteem is determined by characteristics, achievements, and evaluations of one's in-group by the person and society. This differs from self-esteem which is determined by the same individuals about one's personal characteristics, achievements, and evaluations. Results from James' (1997) study showed that when faced with value conflicts and maintaining high levels of collective esteem, African American workers' health improved while it did not have a similar impact on European-Americans. Also, perceived support predicted better health outcomes only for European-Americans, but not for minority subjects. Thus, having social supports can mitigate some of the negative health consequences of organizational conflict (James, 1997).

Simons and Peterson (2000) demonstrated the different impacts of task conflict (or cognitive conflict), which involves perceiving disagreements in views, ideas, or opinions among group members about content of decisions, as compared to relationship conflict (emotional conflict), which pertains to perceiving interpersonal issues, often including tension and aggravation. Task conflict among groups often makes group members engage in better decision making which may be due to stronger cognitive understanding needed in order to overcome the task conflict (Putnam, 1994; Fiol, 1994). In a study using CEOs of US-based hotel companies, Simons and Peterson (2000) showed that intra-group trust negatively moderated the relationship between task conflict and relationship conflict. The mechanism of misattribution tries to explain this process. For example, group members infer the intentions of others to be negative towards themselves through personal attacks or hidden agendas. Processes of negatively-biased information processing and self-fulfilling prophecy aid in the progression of task conflict to relationship conflict. Simons and Peterson (2000) demonstrated that at low levels of intra-group trust there was a stronger direct correlation of task conflict and relationship conflict as compared to groups with high levels of intra-group trust. In addition, aggressive conflict management technique of loudness positively moderated the relationship of task conflict and relationship conflict was only marginally supported. Therefore, task conflict has a higher likelihood of a transition to relationship conflict when arguments are expressed as compared to average or low volume. This is potentially due to the consequence of loud harsh language which can hurt others' feelings and be interpreted as disrespectful and as personal attack. Therefore, trust at a group level has a critical importance in preventing an escalation of task conflict to relationship conflict and more research is needed to support harsh task conflict tactics as a mechanism by which relationship conflict arises (Simons and Peterson, 2000).

In regards to the individual, some costs of unmanaged conflict may include dissatisfaction and scarred reputation. Furthermore, costs which are less easy to quantify include lower value products or services leading to potentially life threatening situations (i.e. humanitarian workers assisting refugees).

Buss (2011) provides a flexible method to analyze both the negative consequences and poorly managed conflict using a Conflict Visibility and Measurability Matrix. The matrix shows how easy visibility of negative consequences of conflict is not commensurate with costs and that "hidden" consequences can be more easily computable. An example of this may be accidents in the work place (Buss, 2011). Another tool for measuring costs is Dana's formula which takes into account variables such as number of individuals, average number of hours per week, average annual salary of employee, duration of conflict and time management systems (i.e. time sheets) if available. It was suggested to collect and analyze information of costs of: legal proceedings and judgments of the employee against the organization, temporary staff to cover for absent employees, sick leave records, systematic employee interviews who want to horizontally move within the organization, recruitment and staff training, managing theft and sabotage and occasional surveys on sources of conflict and decision making (Dana, 2001).

Nowadays, conflict in organizations is often dealt with in a hierarchical manner or through organizational structures (i.e. liaisons) which allow a neutral third-party to make decisions and resolve disputes (Brett, 1984; Szilagyi & Wallace, 1980). Brett, Goldberg, and Ury (1990) suggested seven

principles of dispute resolution to lower the costs of conflict of intra- and inter-organizational disputes. The first included consultation prior to disputation because conflict is often a precursor for a need for change. Furthermore, feedback after a conflict can assist in the prevention of it repeating in the future. The second principle involves maintaining a focus on interests during negotiation. This can be accomplished using a cooperative approach by sharing information or proposals (Pruitt, 1981; Puitt & Carnevale, 1982). Training of negotiation skills for managers can be helpful and allow norms to develop around the manner by which conflicts are resolved (Fischer & Ury, 1981; Lax & Sebenius, 1986). The third principle involves loop-back procedures back to negotiations to avoid power struggles. A cooling-off period and third party interventions allows parties to resume talks. The fourth principle utilizes low-cost rights to dissolving disputes based on rights or power. The fifth principle is arranging procedures from low to high cost, beginning with arbitration and voting. Principle six includes training of negotiation skills in a manner that seeks joint gains or integrative bargaining. This is accomplished through post-settlement settlements, which try to minimize cognitive biasing when obtaining joint solutions (Raiffa, 1982). Furthermore, providing employees resources, such as information that can be useful in loop-back procedures and motivation with incentives can be useful in having them utilize the steps to lessen the costs of disputes. Lastly, the seventh principle involves providing parties a voice to dispute the conflicts, provide their perspectives, and express their feelings (Brett, Goldberg, & Ury, 1990).

The COPE Model (Kalayjian, 2009) offers a communication style to transform conflicts into lessons learned. The COPE model has four steps, first to connect with positivity, compassion and gratitude, then to present one's own observations with objectivity and "I" statements, third to express one's feeling, and finally to make a constructive win-win recommendation, where both parties can gain something and learn from one another. The other model is the 7-step Biopsychosocial and Eco-Spiritual Model (Kalayjian & Eugene 2010), which not only focuses on release of stress but also on lessons learned, forgiveness and transformation.

Therefore, cost of conflicts can be viewed on the organizational as well as individual level. Organizations can take a stronger stand on monitoring and measuring factors in order to prevent conflict in arising or mitigating that which already occurred. Utilizing the COPE model or the 7-step model will not only assist in conflict transformation and cost reduction; it will also help build inter-group esteem, productivity, and cohesion.

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Visitors from Hong Kong Share with Division 52 Members at the United Nations

A group of social workers from the YANG Memorial Methodist Social Service in Hong Kong came to the United States for a short visit to exchange about their work in the area of protection of youth, and their interests in issues like prostitution, trafficking, and violence against girls and women. They had met Division 52's Judy Kuriansky in Hong Kong the year before when she was the keynote speaker for the Family Planning Association of Hong Kong at their 4th Asian Conference on Sexuality Education in August, 2010, in Hong Kong. Dr. Judy hosted the delegation at the United Nations in New York, where they shared about the 'C.A.R.E. Project', a service on teenage prostitution, also called "Compensated Dating." Their service is a first and major project dealing with new cyber-related behaviors in Hong Kong, which have become a major social problem. They also shared about their work concerning Cyber Addiction of Children in Hong Kong that has caused various mental health problems. Dr. Judy Kuriansky shared that teen cyber-addiction and cyber-bullying are major problems in the United States, and also issues that have been addressed at conferences at the United Nations.

The delegation of social workers from the YANG Memorial Methodist Social Service in Hong Kong, with Division 52's Judy Kuriansky and Richard Velayo (4th and 5th from left).

On their short trip, they visited the following agencies:

In Boston

'My Life My Choice' – to gain an overview of commercial sexual exploitation and trafficking issues in USA.

'The van der Kolk Centre Glenhaven Academy' – to learn more about trauma-informed treatment for adolescents.

In New York

'The Children's Aid Society: Carrera Adolescent Pregnancy Prevention Program' – to learn about programs for preventing teenage pregnancy.

'United Nations' – to exchange sharing with Dr. Judy Kuriansky on Mental Health issues in the U.S. and Hong Kong, and with several representatives of the Psychology NGOs accredited at the United Nations, who were having a meeting about the upcoming Psychology Day. These individuals and groups included the UN American Psychological Representative Deborah L. Vietze, the UN International Association of Applied Psychology representative Martin Butler, Ph.D. and the International Council of Psychology representative Richard Velayo. As a member of the UN NGO Committee on Mental Health (CMH), Dr. Judy invited them to attend the CMH meeting about 'Healthy Ageing: The Value of Social Support' held by the NGO Committee on Mental Health." At UNICEF they also were introduced to some high level officials.

In sum, their visit was a big success and promises future exchanges.

First International Conference on Restoring Life and Maintaining Hope in Port-au-Prince: Establishing a New "Center for Spirituality and Mental Health" in Haiti

Wismick Jean-Charles
Fordham University

The first International Conference on Restoring Life and Maintaining Hope in Haiti was held at the University of Notre-Dame, in Port-au-Prince, on June 25-26, 2011. The purpose of this conference was twofold: first, to launch the first National Center for Spirituality and Mental Health in the country; second, to bring together various international psychologists who had conducted research and provided training in Haiti in the aftermath of the devastating January 12, 2010 earthquake.

When responding to trauma, research suggests that religion and spirituality play a pivotal part in helping people cope with and make meaning of, the event. Haiti is a country where the population is very religious and primarily turns to their religious leaders for counseling and healing in times of distress and trauma, yet to date, no center for spirituality and mental health has been available to serve and to address, in a scientific manner, the needs of citizens. Thus, the development of such an initiative was deemed critically needed.

The primary goals of this new Center for Spirituality and Mental Health (called CESSA according to the French name, Centre de Spiritualité et de Santé Mentale) include the following:

- Equip and empower Haiti's spiritual leaders, clergy, congregations, and community stakeholders to respond to the long term mental health and spiritual needs in the wake of the January 12, 2010 earthquake.
- Develop infrastructures by encouraging ongoing collaborative meetings held bi-monthly for spiritual leaders, clergy, and other community stakeholders to get together for trainings and sharing resources and information.
- Provide training about psychological first-aid for religious communities, churches, and spiritual and religious leaders about subjects related to trauma recovery (e.g. peer-listening, and self-care).
- Adopt culturally relevant curricula for community stakeholders, youth leaders, and teachers with a focus on training the trainers and empowering them to be able to continue the work at tent cities and remote villages.
- Conduct research that will help communities identify needs, lead to targeted training and build local capacity.
- Organize and convene an annual conference on disaster mental/spiritual health, run and attended by Haiti's community stakeholders.

Given the scarcity of local resources in this field, it goes without saying that the viability and the sustainability of such an ambitious initiative lies on a prolonged collaborative partnership with international experts.

Indeed, in this spirit of partnership, more than 200 attendees came to this first Conference, including local psychologists, professors, students, clergy, religious leaders of various denominations, and international researchers. They came from various parts of Haiti as well as from the international community for this launch of the new Center for Spirituality and Mental Health and to kick-off the first annual international conference.

The President of the University of Notre-Dame, His Excellency Monsignor Pierre-André Pierre, welcomed the participants and stated that the University of Notre-Dame is considered honored and blessed to host this first international conference. The Provincial of the Montfort Order, Very Reverend Laurent Pierre, explained the mission of the center and pointed out the key areas of focus of this new institution, entrusted under the leadership of Father Wismick Jean-Charles as the founding director. The keynote address, entitled: "Rebuilding Haiti on the Rock" was given by the Archbishop Emeritus of Port-au-Prince, His Excellency Most Reverend Francois Wolf Ligondé. His successor was killed in the earthquake.

Presenters gave reports of their work after the earthquake, including numerous guest psychologists from various North American Universities and international organizations, such as Regent University (Dr. Donald Walker); Fordham University/Association for Trauma Outreach and Prevention (Katherine Kaze representing ATOP founder Dr. Ani Kalayjian); Loyola University (Dr. Kari O'Grady); and the International Association of Applied Psychology IAAP (Wismick Jean-Charles/Dr. Judy Kuriansky). Other researchers from institutions of higher learning in Canada (e.g. Professor Luc Corriveau of the Institut de Formation Humaine Intégrale de Montréal: IFHIM; and Kim/Dr Beth Hedva of the Canadian Institute for Transpersonal and Integrative Sciences) also provided data about the effectiveness of their interventions after the earthquake and offered brief training based on their psychological models which use spiritual resources.

Local psychologists played an important role, delivering impressive presentations and discussing a large range of critical issues. These included, Dr. Herold Toussaint, Professor at the University of Notre-Dame, who gave a presentation on "Logotherapy and Exercises of Saint Ignace de Loyola"; Dr. Michel Eugene, the Director of the Cellule d'Aide Psychologique, (CAP), a national NGO, who chaired a symposium on "Recovery in the context of poverty"; and Professor Ronald Jean-Jacques, from the State University of Haiti, who

presented about the realities and the complexities of the psychological needs in Haiti in the aftermath of the earthquake. Father Wismick Jean-Charles, an IAAP NGO UN representative, gave a training on self-care, entitled "Healing the Wounded Healer".

At the end of this two-day Conference, Father Wismick Jean-Charles, the coordinator of this international gathering, presented a lifetime Award to Reverend Godefroy Midy, Ph.D. (GSAS Fordham'71), in honor of his being the first Haitian to receive a degree in Counseling and Spirituality. He is one of the leading figures in the psychotherapy-spirituality integration initiative in the country and has been making

priceless contributions to this burgeoning field in Haiti.

At the end of this international gathering, the attendees rendezvoused for meetings looking ahead to early 2012, since the center is planning to implement two projects in Port-au-Prince and in other cities in the country: (1) a one-long day meeting on January 11, 2012 (the anniversary of the earthquake) whose purpose is to bring together leaders of different faiths to explore opportunities for mutual actions and identify collaborative initiatives that create peace building and enhance local capacity, (2) a two-day workshop for teachers and youth leaders to take place on January 14-15, 2012.

Finally, special thanks were extended to Dr. Judy Kuriansky, the main NGO representative to the United Nations for the International Association of Applied Psychology (IAAP). This well-known clinical psychologist, the first one to arrive on the ground after the devastating earthquake, was instrumental in helping bring this project to its fruition. Helpful during the early stages of this initiative, she currently serves as Senior Consultant for training for CESSA.

This center, which is providing comprehensive, integrated, innovative service to the Haitian people, is an important asset for the country and sets the tone for a unique, exciting, and new direction for the field of psychology in Haiti.

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Canadian Position on American Psychological Association Membership Dues

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A recent review by the American Psychological Association's (APA) Membership Committee resulted in a recommendation to the Board of Directors (BoD) to stop reduced membership dues for psychologists holding joint membership in other select organizations. This recommendation resulted in controversy and debate in Canada. The ensuing debate has touched on the nature of the relationship between some Canadian provincial associations of psychologists with both APA and with the Canadian Psychological Association (CPA) and has extended to question who are the appropriate constituents of APA's Committee of Representatives (CoR). The current paper attempts to outline the reason for the current debate, the historical antecedents, and to reflect on what the future might hold.

The APA Membership Committee plan to rescind all dues reduction policies would harmonize APA dues, simpli-

fying administration procedures and costs, and would benefit all members rather than just a few. The BoD saw that the rescinding plan had merit and began acting on it by notifying partner organizations that the fee reductions previously enjoyed were to be rescinded.

At the February 2011 CoR meeting the BoD put forward a motion to ratify the decision to rescind all dues reduction plans currently in effect. In the ensuing discussion it became clear that the CPA had been informed of the decision to rescind the dues agreement by letter and that the decision was made unilaterally by the APA BoD without negotiation with CPA.

The CPA President, Doctor Peter Graf, and the CPA Executive Director, Doctor Karen Cohen, petitioned the APA BoD for an opportunity to address CoR at the February 2011 meeting in Washington. Their request was granted. This request was necessary since currently CPA does not have a seat on CoR.

The proposal to rescind the mutual dues reduction policy between the APA and the CPA was problematic for CPA and for those Canadian provincial associations having CoR representation. All Canadian members of CoR spoke to the issue resulting in the matter being deferred to allow negotiations to take place between the APA BoD and the Executive of the CPA.

To assess this reciprocal dues issue properly it is necessary to review the long history between psychologists in the United States and in Canada. In 1892 at a conference held in Dr. Granville Stanley Hall's study at Clark University[1] a proposal was entertained for the development of APA. At the time, APA was conceived as a North American association and for many years national American and international Canadian fraternal support for psychologists in North America was only through the APA.

For many years the APA functioned unopposed by any national Canadian psychological association. The impetus behind the development of a national Canadian association was the fact that Canada entered World War II much before the United States[2]. The inception of CPA followed a preliminary meeting in Ottawa in 1938 with the first meeting being held in Toronto in April 1939. Thus, from 1892 until 1939 the APA served as a true North American psychological association.

Even after the creation of the CPA, many Canadian psychologists continued to see the APA as their 'home' association because of the availability of leading scientific journals and the annual learned conferences. The APA continued to support actively its Canadian members. In the 1940s the APA created a seat on CoR for the Dominion of Canada[3].

The mutual fees reduction policy between the APA and the CPA has continued to represent a tangible way in which the APA supports its Canadian members. The membership fee reduction between APA and CPA had been in place for decades and was reciprocal. Thus, Canadian psychologists having membership in CPA could join APA with a 50% reduction in fees. Similarly an American psychologist having membership in APA could join CPA with a 50% reduction in fees.

Currently the CPA does not maintain a seat on the CoR. It believes that it would be inappropriate for a national association to maintain a seat on a committee of a different national association. However, some Canadian provinces do have seats on CoR.

It may be helpful to understand Canadian demographics to understand better the issues now being discussed in Canada. The Canadian governance experience is similar to that found in the United States. Psychologists may join the APA, Provincial or State Associations, or the CPA, or other specialized associations.

Membership in regulatory boards throughout North America is mandatory for most psychologists offering public service. Membership in fraternal organizations is voluntary.

Many psychologists in Canada with membership in the APA do not also have membership in either the CPA or in any of the regional associations. There are only 1,100 psychologists in Canada with joint membership in the APA and the CPA[4].

While Canada is a larger country in terms of land mass than is the U.S., it is diminutive in terms of its population. Specifically, Canada has about 1/10th of the American population (the US population is 308,745,538[5] compared to the Canadian population of 33.74 million[6]).

Canada is divided geopolitically into 10 Provinces and three Territories. Currently five Canadian Provincial Associations have seats on the APA CoR. They are: the Ordre des Psychologues du Quebec (the Province of Quebec), the Ontario Psychological Association, the British Columbia Psychological Association, the Manitoba Psychological Association, and the Association of Psychologists of Nova Scotia. A sixth province, represented by the Alberta Psychological Association, continues to be listed as a provincial affiliate of APA but it has declined a seat on CoR.

The subdivision of Canada into 10 provinces and 3 territories represent vastly variable land areas and populations. For example, the largest in terms of land area is the Territory of Nunavut in the far north of Canada with a land mass of over 2 million square kilometres. It has the smallest population: 32 thousand people representing 0.10% of the population of Canada. The next largest in area is the Province of Quebec with 1.5 million square kilometres. Its population is 7.8 million people comprising 23.19% of the Canadian population. In terms of population the largest population is found in the Province of Ontario; which has 13 million people comprising 38.73% of the total population of Canada. My own

[1] Boring, Edwin G. (1950). A History of Experimental Psychology (2nd ed.). New York: Appleton-Century Crofts, Inc. Page 521.
[2] See Luc Granger, www.thecanadianencyclopedia.com/index.cfm?PgNm=TCE&Params=A1ARTA0006538
[3] Over time the formal title 'The Dominion of Canada" has fallen into disuse. The formal title of the Country is now 'Canada.'

[4] Current CPA data.
[5] According to the USA Census Bureau for 2010.
[6] According to the World Bank for 2010.

Province, that of Nova Scotia, is small with a population of 940,000 people representing 2.78% of the total population of Canada.

Given the different population sizes in provinces, each Canadian member of CoR represents a different number of APA Psychologists. Some of the smaller Canadian jurisdictions have concerns about losing their CoR seat if the numbers of APA psychologists within their boundaries shrink.

The dues reduction agreement policy is between the APA and the CPA. There are no comparable dues reduction agreements between the APA and any of the provincial or territorial psychological associations. In order for any provincial or territory association member to take advantage of the dues reduction that individual must be a full member of their local association, the CPA, and the APA.

Thus, to understand the debate it is necessary to understand that there are divisions of interest between the CPA and those Canadian Provinces with CoR seats. Several of the Provinces wish to maintain their CoR seats while the CPA has no interest in holding a committee seat.

The CPA believes that it is able to offer a "made in Canada" service that would be of great value to all psychologists working in Canada. The provinces with seats on CoR do not appear ready to give up the opportunity to influence North American psychology and see continued involvement on CoR as providing ongoing value.

The Canadian provincial psychological associations tend to be comprised primarily of psychologists having an applied focus of interest. Academic psychologists tend not to join the Provincial associations. Thus in Canada, as in the U.S, academic psychologists tend not to be represented by the State or Provincial Associations of psychologists. Psychologists in Canada who have only APA membership or even with combined CPA membership but not provincial membership do not enjoy newsletters and other forms of information dissemination that comes from the provincial associations. Thus, in all practical matters CoR members in Canada represent those APA members who live in Canada, and are members of a provincial association that maintains a CoR seat. It is possible that the number of academic psychologists with APA membership could outnumber the APA psychologists who are also members of a provincial association.

The initial negotiations between the BoD of the APA with the Executive of the CPA suggested that the American position was intractable. The Executive of the CPA reported that there was no wish on the part of the APA BoD to maintain the status quo.

This seeming intransigence led the Executive of the CPA to consider asking the APA for a change in policy which would allow Canadian members to apply for affiliation with APA as Foreign Members. Quite simply, CPA decided that it was illogical for members in Canada to be treated differently in the APA than psychologists from other foreign countries. There was the potential for a very large cost savings with foreign affiliate membership since the Annual Fees for membership in the APA is $50.00.

Just before the 2011 CoR meetings, CPA and the Ordre des Psychologues du Quebec agreed that their APA members should be surveyed and given the opportunity to vote on the issue. These two associations favoured pressing for an APA by-law change allowing psychologists in Canada to opt for foreign affiliate or for full membership just as is possible with psychologists from all other non-American countries.

The CPA position has merit. However, four of the five provincial associations wished to maintain their close ties with APA. Initially CPA was trying to present a collective voice that represented a strong voice of solidarity: This was not achieved.

However the provinces of Ontario, British Columbia, Manitoba and Nova Scotia all opted to maintain their ties with APA and to maintain their seats on CoR. None of these provinces surveyed their APA members. Thus the debate turned divisive in Canada with allegations that these provinces were acting in the best interest of their respective associations and not necessarily in the best interest of their individual APA psychologists. This, however, is a moot point, since CPA had already surveyed these psychologists since the only psychologists anywhere in Canada that have the fee reduction were those who were also full members of CPA.

At the August meeting of CoR it appeared that the BoD may have softened their stand on the CPA/APA dues reduction issue. Informal discussions with various members of the BoD suggested that the status quo was found acceptable.

The issue has yet to come before CoR for a decision. The information item was not raised during the August meetings. This allows more time for deliberation and thought about what the future of the Canadian position will be in APA.

There are important implications should the APA By-Laws be rewritten to allow foreign affiliate status for psychologists in Canada. One implication is that if many of the Canadian psychologists opted to become foreign affiliate members of the APA then there is a strong possibility that some Canadian provinces could lose their seats on CoR because of the reduction of APA full members.

Unfortunately, no matter what the outcome there may be hard feelings. Consider, if the four provinces with CoR seats are successful in arguing that the status quo should be maintained then there may be an impression that these provinces were able to protect the self-interests of their associations at the financial expense of individual APA psychologists within their jurisdiction.

For the four provinces who enjoy and value their APA interaction the best course is to maintain the status quo. Failing that there is need for agreements between individual provinces and APA rather than the provinces and territories of Canada falling under the CPA umbrella.

The conclusion of the debate is uncertain. At this time, the APA by-laws do not allow Canadian members to have foreign affiliate status. Thus, the position of CPA and of the Ordre des Psychologues du Quebec is based on the premise of being able to successfully negotiate a change in the APA By-

Laws and to successfully validate it with a 2/3-majority vote of the APA Membership.

The differences in interests between some of the provincial associations and with the CPA suggest that a formal agreement between these jurisdictions and the APA may be necessary rather than relying on the agreement the APA has with the CPA. This seems all the more likely since the position of the CPA is to celebrate their role as a national Canadian body. However, the separation of the two national associations, while understandable, plays down the over 100-years of partnership in developing a North American voice for psychology.

Request for Information: Department Study Abroad Opportunities

Hello Division 52 Members:

The student committee of Division 52 is seeking to gather information on what types of study abroad and/or international immersion experiences are available across psychology programs. We hope to use this information to create a resource for students and/or faculty to find information on what types of study abroad experiences exist around the world. If you could take a few minutes and answer the below questions, we would greatly appreciate any information you can provide on what study abroad experiences exist around the globe! Responses can be sent back to me, at anhutchison@bsu.edu.

Please provide the following information, if available:

1. What types of study abroad or immersion experiences does your psychology department offer to your students (e.g. target student population, undergraduate or graduate focus, location, length of time, activities completed during experience, etc.)?
2. How do these opportunities further students' education?
3. How do these opportunities contribute to the study of psychology?
4. Any other information that you feel would contribute to this project.

Again, thank you so much for taking the time to provide this valuable information!

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Barack Hussein Obama: The Making of a Global President

Joseph C. Giardino & Harold Takooshian
Fordham University

"How has Barack Obama's unusual childhood impacted his Presidency?" This question was the focus of a public forum in New York City on October 14, 2011. It was co-sponsored by three local APA divisions (International Psychology, Social Issues, and General Psychology), and hosted by the Fordham University chapter of Psi Chi, the International Honor Society in Psychology. For this forum, the principal speaker was author **Dinesh Sharma**, who began a national book tour in October of 2011, upon the release of his new volume, *Barack Obama in Hawai'i and Indonesia: The making of a global President* (2011). Other participants in the forum were developmental psychologists **Uwe P. Gielen** of Saint Francis College, and **Joshua L. Brown** of Fordham University. Despite torrential rain that Friday evening, the Fordham room filled with over 50 students and professionals from across New York City.

In his introduction of Sharma, Gielen noted two points. (1) First, Sharma's new psychobiography is unique among the many books on President Obama, that critique Obama's policies. Rather, Sharma's book is the first to consider the President's childhood development from a cultural psychology perspective, for a more scientific and dispassionate understanding of Obama the person. (2) Second, Sharma comes well-trained to this task. He completed his doctorate in psychology and human development at Harvard University, with psychological anthropologist Robert Levine, and has been a Senior Fellow at the Saint Francis College Institute for International and Cross-Cultural Psychology. To prepare this volume, Sharma travelled world-wide to interview dozens of Obama family and associates.

Psychobiography. For Sharma, Barack Hussein Obama is much more than the first black U.S. President. His very name, derived from Swahili and Arabic, reflects the multiple identities that make him a "first" among the heads of state of any Western democracy: An African-American, biracial, multiethnic person raised in Southeast Asia. Obama uniquely represents globalization. His formative years in Hawai'i and Indonesia laid the groundwork for a resilient, charismatic, and global leader. The book offers an "empathic look" at the formative years that are so crucial to identity development. Sharma views Obama's development through an Eriksonian lens (Erikson, 1950), looking at early stage conflicts during his youth in Hawai'i and Indonesia. "Barry," as he was known in youth, developed trust (Erikson, 1950) from the women in his life – his mother and grandmother – which "gave him a head start," a foundation to meet other developmental challenges.

Barry's early years in Jakarta, Indonesia from ages 6 to

10 marked the start of his global schooling. Reports from teachers and classmates recounted stories of Barry imitating Indonesian Prime Minister (PM) Suharto, and saying that he "wanted to be PM." Sharma offers an analytic interpretation of this event as a harbinger for Obama's future presidency. Obama's time in Indonesia was also the only time he spent in a nuclear family. His stepfather was critical in his life during this time. According to Sharma, support from his nuclear family instilled industry (Erikson, 1950) in young Barry.

At age 10, Barry returned to Hawai'i to attend an elite prep school, Punahou, with an idyllic campus that was a stark contrast with the streets of Jakarta. It was here that Barry began to explore his racial identity. He was the only Black student, yet being in Hawai'i and the culturally diverse Punahou, he was protected from negative stereotypes of African-American men. He later began reading the works of prominent Black leaders, such as Martin Luther King and Malcolm X. In recognizing his difference and turning inward for exploration, Sharma describes Obama as having developed a "deep introspective core." Consistent with ethnic identity development in minority adolescents (Phinney, 1989), Barry's explorative stage during adolescence can be described as moratorium.

Sharma continued the exploration of Obama's "globe-trotting" and developmental journey through his college years and after on the mainland U.S., in Los Angeles, New York, and Chicago. Learning of his father's death shortly after his arrival in New York City sent him on an exploration of life's existential meanings. He learned his identity (Erikson, 1950) on the streets of Harlem among African Americans. Social interaction with African-Americans likely provided the external validation (Rockquemore, 1999) necessary to assume his

At the New York City forum (l to r): Joseph Giardino, Uwe Gielen, Dinesh Sharma, Joshua Brown

ethnic identity. As with many other African Americans, spirituality was salient (Wheeler, Ampadu, & Wangari, 2002) in reaching the achievement stage of ethnic identity development (Phinney, 1989). Upon learning his identity, Barry fully assumed his father's name, Barack. Described by Sharma as a "rite of passage," this critical event in Barack's development set the groundwork for his later career.

Barack moved to Chicago's South Side and began working in the African-American community as an organizer. For Sharma, it was here that he became a "true reformer" and "change-maker of global proportions." Sharma related Obama's leadership prowess to common threads in his family history, including his mother's work throughout the world, and his father's work with the Kenyan government. Despite not knowing his father, Obama inherited the family legacy (McGoldrick, Giordano, & Garcia-Preto, 2005) of reform and change-making.

President Obama not only inherited the family legacy, but his "genealogical roots are spread throughout the world," declared Sharma. His unique form of multiculturalism, inherited through genetics, culture, and familial experience, has been instilled since his formative years in Hawai'i and Indonesia. Sharma claims that it is precisely this multiculturalism that appealed to the American people. Immigration and the tanning of the American people have caused a shift from Western canon to multiculturalism--a true "shift in the American psyche." Global changes through immigration patterns and the Internet age have opened the American mind. According to Sharma, Obama embodies globalization and is himself a conduit for global change.

As the discussant, Joshua Brown commended Sharma for applying Eriksonian theory to understand Obama's life, and raised a few issues for listeners. (1) Since we know nature and nurture both shape adult development, and Barack senior and junior were both charismatic, what neurological endowment did Barack inherit from his father? This question is as unanswerable as it is important. (2) In Erikson's stages, how much was Obama's entry into community organizing in Chicago his attempt to find "community" to replace the isolation in his life? (3) Since Erikson contrasts "generativity vs. stagnation," how much is Obama motivated to surpass the struggles of his own childhood by preparing a bright future for the world's youth?

For further discussion, the audience was directed to Sharma's website, www.dineshjsharma.com

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Humanitarian Tool Kit

There seems to be a wonderful phenomenon afoot in what appears to be a significant up-tick in interest in volunteerism. Books like Allison Thompson's *The Third Wave* (Spiegel & Grau, 2011) highlight many people's desire to help post catastrophe (e.g., 9/11, Sri Lankan Tsunamis, and Haitian earthquakes). Rock stars such as Bono and Peter Gabriel, along with film-stars like Mark Walberg and Sean Penn, also add to the media attention and thus perhaps fuel some volunteers' motivations. I, too, have found that via many of my talks, expositions, and dealings with graduate students (psych, social work, public health), pre-med and med -students as well as mid-career and senior psychologists, that there is a wonderful level of interest in doing more for others.

I know from the work in my three volumes of *The New Humanitarians* (Praeger, 2009), that many individuals who I had met in Davos at the annual meetings of the World Economic Forum, or perhaps at a TED conference, or a Renaissance Weekend, or a Bolivian prison, or an abandoned hospital in Halong Bay, were not satisfied helping various causes by just writing checks of support or volunteering, these individuals preferred to actually start their own organizations—to enact their passionate humanitarian interests.

Now while these impressive individuals come from varied backgrounds—cashing out of start-ups, flush with equal amounts of cash and talent—to those with less money but a willingness to have skin in the game in order to make a difference—they all share the common denominator of changing the world. Not in a pretentious, abstract cliché, but really, honestly, changing the world.

I founded the Center for Global Initiatives (CGI), somewhat accidentally (as was publicly discussed at the 2011 Annual Convention of the APA). While I am nowhere close to the amazing people I interviewed for *The New Humanitarians*, I found that via an organization, mentorship, and some cool-tools (thank you Web 2.0), a lot can be leveraged and done to make real and significant differences in peoples' lives. You'd be surprised.

The mission of the Center for Global Initiatives is to create self-sustaining programs that improve access to healthcare in underserved communities throughout the world. We believe in the "power of the small project," wherein generally we do this by:

- Serving as an incubator for new initiatives that creatively solve health care inequities throughout the world.
- Acting as a collaborator with individuals and organizations in developing and launching projects that address the needs of medically impoverished populations.
- Functioning as a facilitator in directing public and private resources towards programs aimed at improving health.
- Working as an educator to provide new information and tools to empower others.

I was asked to help with projects in Bolivia, Cambodia, India, Tanzania, and Benin. And we did it! It wasn't too difficult, but it also wasn't obvious on how structure things state -side in order to be of help to those in need and to be able to have donors rightfully gain a tax-deduction for their support.

Tyranny of the 501(c)(3)

I had no idea how difficult it is to establish a not-for-profit, let alone the costs involved, the tax-reporting requirements (hey, I thought this was a tax-EXEMPT organization and we still have to file federal and state taxes, and they are not 1040 forms but 990s?? What's a 990???). CGI is an all volunteer organization, so once we hit our capacity-limit of five projects we could manage on-going, and others were still in need of out help, we decided to help others capacity!

I began to realize that it would be great if there was a website where you could find out about all the places on the internet that help you learn how to fundraise, connect to other not-for-profit organizations, or teach you how to set-up your own..?! These were the questions I found myself fielding on a weekly basis.

And most people do not want to have to create their own 501(c)(3), recruit a board of directors, host a website and build its content, fundraise, get a PayPal account, do audit-worthy financial reporting and tax-accounting, and spend all the months and thousands of dollars needed to get going. They just wanted to do the work!

Thus the Tool Box…!

In response to this demand, we developed a set of tools that are freely available to anyone for the surfing to come to our site and download medial libraries:

- Spanish, English, and Multi-lingual medical dictionaries, translators, glossaries, and search engines.
- Downloadable Medical Library that includes:
  - A Book for Midwives,
  - A Health Handbook for Women with Disabilities,
  - A Workers Guide to Health and Safety,
  - Community Guide to Environmental Health,
  - Helping Children Who Are Deaf,
  - Helping Children Who Are Blind,
  - HIV, Health and Your Community,
  - Where There Is No Dentist,
  - Where There Is No Doctor,
  - Where Women Have No Doctor, and
  - Women's Health Exchange

Flight Discounts

If someone is volunteering on a CGI project or any other recognized international project or conference they may qualify for discounted roundtrip airfare via our relationship with

www.flyforgood.com, where airlines select routes around the world that are common for humanitarian travelers and discount them based upon season and availability and so some routes do not have discounted fares, just so you know. Additionally helpful benefits include:

1. Changes to airline tickets with reduced fees 50-75% lower than regular tickets.
2. Refundable fares with reduced penalties 50-75% lower than regular tickets.
3. Free stopovers to cities while traveling internationally at no cost (in case you need a break).
4. Add additional piece of luggage beyond the normal 2 piece rule.

CGI also has helpful travel-related links on:

- Traveling Carbon Neutral
- Luggage Requirements
- State Department Warnings
- Airline Toll Free Numbers
- World Weather
- Customs Service
- Travel Documents
- FAA - Travel Advisories
- Currency Converter, and
- International Travel Health

Last Piece(s) of Advice

Through my research in *The New Humanitarians,* I learned that while most of the approaches of the organizations were different, they do share a number of commonalities. At the time they formed their entities, they were novel in their approach to dealing with the problems they address. They were not restricted with past ways of thinking or acting, nor should you be. They created innovative approaches to make something real and actionable from a concept and a vision, as can you. They developed practical approaches to solutions, some complex, some elegant, but are all robust and lasting, and replicable.

You don't have to be a MacArthur "Genius" Award winner to make a real difference, and we can help. CGI is a ladder that can help you reach beyond where you could otherwise.

Hey. You know what? Now you don't have any more excuses… Check us out… CenterForGlobalInitiatives.org.

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Co-Chair, APA's Committee for International Relations in Psychology, 2010-2012
APA International Humanitarian Award Winner, 2004
Author, *The New Humanitarians*
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Call for Student Research Manuscripts on Women and Gender

Deadline April 1, 2012

The Society for the Psychology of Women (SPW) of the American Psychological Association and the Association for Women in Psychology (AWP) seek research manuscripts for the 2012 Annual Student Prize for Psychological Research on Women and Gender.

Research Topics

The student research manuscript should focus on women's lives and issues, or more generally, on gender ideologies and behavior, from a feminist perspective.

Eligibility

Jointly-authored papers are eligible, but the first author must have been a student at the time the research was conducted, as indicated by a statement by the first author, in a cover letter accompanying the submission, specifying when and from what institution the first author obtained the degree, the name of the faculty who supervised the research, and the department of the supervising faculty. Entries should be of journal length and in *APA* style. Eligible papers include unpublished manuscripts as well as papers that have been submitted or accepted for publication. Published or presented papers are also eligible as long as they have a date of 2011 or 2012. All papers should be submitted in manuscript form, not as pre-prints or prints with information about submission and publication status provided in the cover letter.

Evaluation

Entries will be judged on theoretical creativity, methodology, clarity and style, and social importance of the research questions and findings for the psychology of women and gender.

Awards

A $250.00 prize will be awarded to the best paper. First and alternate winners will be announced at the 2012 meeting of the American Psychological Association.

Submission Procedure

Please attach a copy of your paper to an e-mail sent to the address below. Also, please send four (4) copies of the paper, a self-addressed, stamped postcard, and a self-addressed stamped business size envelope by April 1, 2012 to: Silvia Sara Canetto, Ph.D., Department of Psychology, Colorado State University, Fort Collins, CO 80523-1876 (silvia.canetto@colostate.edu)

The Submission Deadline for the 2011 AWP/SPW Student Research Manuscript Prize is April 1, 2012

International Activities from APA Division 6 (Behavioral Neuroscience and Comparative Psychology)

Mauricio R. Papini, PhD
Division 6 President
m.papini@tcu.edu

Division 6 was founded in 1944 and has as a focus the biological basis of perception, learning, memory, cognition, motivation, and emotion. Its main interests are in brain-behavior relationships and evolution, abnormalities and repair, interactions with the immune, cardiovascular, and energy regulation systems, species similarities and differences in behavior, and the evolution and development of behavior.

As Division 6 President, I intend to have a strong international presence in our Convention program for 2012. My own background is very influenced by international activities. I was born and educated in Argentina, I have developed extensive research links to colleagues in a variety of countries (Argentina, Colombia, England, Japan, Mexico, and Spain), and I have served as president of the *International Society for Comparative Psychology* (2008-2010) and Editor of the *International Journal of Comparative Psychology* (2000-2005). I believe that it is time that our division benefits from globalization trends that can give us a boost in membership and greatly expand the realm of our influence.

The two journals most closely associated with Division 6 (although they are not division journals strictly speaking) are *Behavioral Neuroscience* and the *Journal of Comparative Psychology*. A survey of the national origin of authors for the 2010 volume of these journals indicates that whereas the US is the country with the highest representation, there is a widespread distribution across the world. Authors from Europe, Asia, Australia, Canada, and Latin America are routinely represented in both journals, in that order of frequency.

Many of our members also come from an international background or are collaborating with researchers abroad to explore various research topics. Among the first category, a very incomplete list includes such names as Ruben Ardila (Colombia), Josep Call (Germany), Victoria Chamizo (Spain), Sergio Pellis (Canada), and Sara Shettleworth (Canada). Among those who are or have been involved with researchers from other countries are Gordon M. Burghardt, who has collaborated with colleagues from Australia, Japan, Panama, and Venezuela; Donald Dewsbury, who has collaborated with Canadian colleagues; Karen Hollis, who is developing research in collaboration with colleagues from France and Slovenia; and Charles Snowdon, who has done extensive work in Argentina, Belize, Brazil, Colombia, Ecuador, Kenya, Peru, Rwanda, and Tanzania.

Division 6 is planning a program for the 2012 APA Convention that will draw heavily from researcher working in Asia, Europe, and Latin America. There are exciting opportunities for interaction between scientists from different national origins that can be strengthened during the APA Convention. Victoria Chamizo (University of Barcelona, Spain) is program chair for the 2012 Division 6 scientific program.

APA-USNC International Travel and Mentoring Program

The APA Office of International Affairs, in conjunction with the U.S. National Committee for Psychological Science, is pleased to announce its upcoming **International Travel & Mentoring Program**, for those wishing to attend the 30th International Congress of Psychology in Cape Town, South Africa on July 22-27, 2012.

Student and Early-Career awardees will be paired with Mid- and Senior psychologists who have experience in international research and collaboration, and will participate in networking and mentoring activities prior to, during, and following the ICP2012. The program will award $1,500 to Student and Early-Career participants and $1,000 to Mid- and Senior-level participants.

Awardees must be enrolled at or employed by a U.S. institution and do research in areas supported by the National Science Foundation: Perception, Action & Cognition, or Social Psychology.

For more information on this program, please visit the Office of International Affairs website. **The deadline for application is December 1, 2011.**

Call for Reviewers *Journal of Latina/o Psychology*

The National Latina/o Psychological Association (NLPA) and the Journals Program of the American Psychological Association (APA) have joined together to launch the *Journal of Latina/o Psychology*, a peer-reviewed journal publishing scholarly writing on research, practice, advocacy, education, and policy relevant to Latino communities. *The Journal of Latina/o Psychology* will

publish empirical, theoretical, methodological, and applied research. The journal will focus on articles that contribute to knowledge of Latina/o psychology through research, methodological innovation, and inquiry; develop and advance theories pertinent to Latinas and Latinos; promote education and training of psychologists to work with Latinas and Latinos; address issues of social justice and advocacy in Latina/o communities; promote the application of research and training to advancement of policy related to Latino individuals and communities; and use quantitative, qualitative, or mixed method approaches. Articles on topics such as immigration and its impact, health and wellness, spirituality, mental health issues, Latina/o identity, and multigenerational families will be of particular interest. The journal will officially begin receiving manuscripts on October 1, 2011. The first issue will be published in Spring 2013.

We are seeking reviewers with expertise in these topics for the journal. We welcome students to serve as co-reviewers of manuscripts. If you are interested in reviewing manuscripts for the *Journal of Latina/o Psychology*, please send a list of 6 or 7 phrases that indicate your areas of expertise and 2 or 3 words that represent your preferred methodologies to:

Azara Santiago-Rivera, Ph.D.
The Chicago School of Professional Psychology
901 15th Street, NW
Washington, DC 20005
Email: azararivera@thechicagoschool.edu

Please note that this is a 2 year commitment to serve as a reviewer for the journal. We also welcome ad hoc reviewers who will serve on an "as needed" basis.

About the Editor

Azara L. Santiago-Rivera, PhD, NCC, is the Inaugural Editor of the *Journal of Latina/o Psychology*. Her publications and research interests include multicultural issues in the counseling profession, bilingual therapy, Latinos and depression, and the impact of environmental contamination on the biopsychosocial well-being of Native Americans. She has presented on these topics at major conferences and has published in peer-reviewed journals such as the *Journal of Professional Psychology: Research and Practice, the Journal of Counseling and Development*, the *Journal of Community Psychology*, the *Journal of Environment of Psychology*, and *Psychotherapy: Theory, Research, Practice, Training*. She is a Fellow of Divisions 45 and 17 of APA.

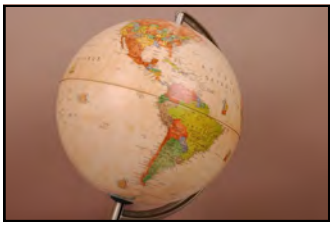

AMERICAN PSYCHOLOGICAL FOUNDATION

PSYCHOLOGY PHILANTHROPY

Request for Proposals: Francis M. Culbertson Travel Grant

American Psychological Foundation (APF) provides financial support for innovative research and programs that enhance the power of psychology to elevate the human condition and advance human potential both now and in generations to come. It executes this mission through a broad range of scholarships and grants. For all of these, it encourages applications from individuals who represent diversity in race, ethnicity, gender, age, disability, and sexual orientation.

The Francis M. Culbertson Travel Grant supports women from developing countries who are in the earliest stages of their careers. Its description, application requirements, and procedures appear below.

APF supports original, innovative research and projects. Although APF favors unique, independent work, the Foundation does fund derivative projects that are part of larger studies.

Description

Limited resources in developing countries make it difficult for early-career psychologists to keep abreast of the latest information in psychology. In many of these countries, women are at a special disadvantage. By providing travel funds to attend international and regional conferences, the Culbertson Grant affords opportunities to women in developing countries.

NOTE: APF does not fund applicants from countries that do not have diplomatic relations with the United States.

Program Goals

- Enable promising early career women psychologists to enhance their careers through conference attendance.

Funding Specifics

- Up to $1,500 reimbursement for actual travel and registration expenses, offered biannually;
- Two-year international affiliate membership in the American Psychological Association included.

We do not allow indirect costs to be taken out of grant monies, although applicants can use grant monies for stipend support and other administrative costs (software, materials, etc.). Our policy on this is as follows, from the grant terms and conditions document:

No Institutional Indirect Costs. The entire grant must be provided to the individual grantee for the stated purpose. The grant may not be used to pay institutional indirect costs or

overhead. If funds will be administered by the grantee's institution, the institution must affirm in writing that it will waive all administrative fees and charges for indirect costs. This assurance may be provided through the signature of a responsible official on this agreement. This assurance must be received before the funds can be released.

Eligibility Requirements

- Woman from a developing country, as defined by The World Bank;
- Five to ten years post-doctoral degree;
- Preference for attendance at the following conferences:
  - International Council of Psychologists (ICP);
  - International Congress of Applied Psychology (sponsored by the International Association of Applied Psychology (IAAP));
  - International Congress of Psychology (sponsored by the International Union of Psychological Science (IUPsyS));
- Participation in the conference program is not required.

Evaluation Criteria

- Conformance with stated program goals and qualifications;
- Applicant's demonstrated scholarship and competence, including potential for carrying the conference experiences forward through teaching, research, or other scholarship.

Proposal Requirements

- Completed application form;
- Current CV;
- One letter of recommendation from a supervisor certifying present position.

Submission Process and Deadline

Submit a completed application online at http://forms.apa.org/apf/grants/ **by February 15, 2012**.

Questions about this program should be directed to Parie Kadir, Program Officer, at pkadir@apa.org.

Sunday, November 20, 2011
Lander College for Women,
225 West 60 St., NYC

12:30: **Registration, Refreshments**, Room 301
Welcome, meet people from area schools.

1 pm: **Scientific research panels**, in Rooms 301, 302, 322, 323
At 1-2:05 pm, 2:15-3:20 pm, 3:30-4:35 pm, 12 panels and workshops with presenters from 14 institutions

4:45: **Awards**, on floor 3 terrace, presentation of Certificates to presenters, and Scarpetta/ Toth/ Guzewicz/ Witmer/ Parker/ Lander Awards.

5 pm: **Gala reception**, conversation hour with distinguished Guests of Honor:

Elena Agadullina, *Professor, State U. Higher School of Economics, Moscow*

Robert V. Levine, *author, Professor, California State University-Fresno*

Dinesh Sharma, *author, Barack Obama in Hawai'i and Indonesia (ABC-CLIO, 2011)*

Vladimir Stroh, *Dean of Psychology, State U. Higher School of Economics, Moscow*

Richard H. Wexler, *President, Personnel Systems Inc.*

Admission is free. All are welcome.

This Conference is endorsed by specific units within several organizations which welcome student participation: *Society for Psychological Study of Social Issue, Association for Psychological Science, American Psychological Society (APS), APA International Division, APA Society for General Psychology, Eastern Psychological Association, Manhattan Psychological Association, METRO Applied Psychologists, NYS Psychological Association, Psi Beta, Psi Chi.* This Conference is hosted by Touro College (**Dean Louis Primavera**) and Lander College for Women. Any details: gnyc@fordham.edu , or 212-636-6393.

Conference Chair: **Rivka Bertisch Meir,** *CUNY*
Awards Chair: **Arthur P. Sullivan,** *Touro*
Conference Director: **Harold Takooshian**, *Fordham*
Committee: **Vincent R. Brown**, *Hofstra*
Victoria Comerchero, *Touro*
Giuseppe Costantino, *Touro*
Dominick Fortugno, *Touro*
Amy Gross, *Landers*
Andrew Karmen, *John Jay*
Lloyd Klein, *Fordham*
Giuliana Losapio, *Touro*
Karen Magee, *Touro*
Yair Maman, *Touro*
Pascal E. Sauvayre, *WA White Institute*
Henry Solomon, *Marymount Manhattan*
Kyle Stout, *Bergen Community*

International Employment Opportunities

Michael J. Stevens, PhD, DHC
Illinois State University
mjsteven@ilstu.edu

University of New South Wales (Australia). School of Psychology: The School of Psychology is seeking to make an academic appointment in clinical psychology at the level of lecturer or senior lecturer. The successful applicant will carry out independent research, teach courses and supervise research projects in the School's undergraduate and postgraduate programs.

The School of Psychology at UNSW is located in the Faculty of Science and is recognized nationally and internationally for its excellence in research and teaching. It is a leading Australian Psychology Department on all quality measures such as research publications and competitive grant funding. The School has well equipped research and teaching facilities and offers a comprehensive range of undergraduate and postgraduate programs that attract outstanding students from Australia and overseas. The School's postgraduate programs include the masters of psychology in clinical, forensic, and organizational psychology, and matching combined PhD/Masters programs. UNSW is located five km from the center of Sydney and is close to other research centers, teaching hospitals, transport, shopping, and beaches.

This position is designed to augment and complement the School's existing strengths in clinical psychology and to extend the clinical group's tradition of collaboration with researchers in other relevant areas such as neuroscience, forensic, health, social, developmental, and experimental psychology. The School has an in-house clinic that sees both children and adults with emotional and/or behavioral problems, with associated testing rooms, and specialized research laboratories in a range of areas. The School also has collaborative research links with the Faculty of Medicine and the adjacent Sydney Children's Hospital and Prince of Wales Hospital, with access to further resources such as genetic and imaging facilities.

The position is full time with provision for conversion to continuing after three years, subject to satisfactory performance (approximately equivalent to a North American assistant / associate professor tenure-track appointment). Preferred starting date is July 2012 (negotiable).

Applicants should address the selection criteria found within the position description, in their online application.

Applications close: November 11, 2011

For further information about the position, contact the Head of School, Professor Simon Killcross at E-mail s.killcross@unsw.edu.au or phone (+61 2) 9385 3034.

University of New South Wales (Australia), School of Psychology: The School of Psychology is seeking to make an academic appointment in clinical psychology at the level of associate professor or professor. The successful applicants will carry out independent research, teach courses and supervise research projects in the School's undergraduate and postgraduate programs.

The School of Psychology at UNSW is located in the Faculty of Science and is recognized nationally and internationally for its excellence in research and teaching. It is a leading Australian Psychology Department on quality measures such as research publications and competitive grant funding. The School has well equipped research and teaching facilities and offers a comprehensive range of undergraduate and postgraduate programs that attract outstanding students from Australia and overseas.

The School's postgraduate programs include the masters of psychology in clinical, forensic, and organizational psychology, and matching combined PhD/Masters programs. UNSW is located five km from the centre of Sydney and is close to other research centers, teaching hospitals, transport, shopping, and beaches.

This position is designed to augment and complement the School's existing strengths in clinical psychology and to extend the clinical group's tradition of collaboration with researchers in other relevant areas such as neuroscience, forensic, health, social, developmental, and experimental psychology. The School has an in-house clinic that sees both children and adults with emotional and/or behavioral problems, with associated testing rooms, and specialized research laboratories in a range of areas. The School also has collaborative research links with the Faculty of Medicine and the adjacent Sydney Children's Hospital and Prince of Wales Hospital, with access to further resources such as genetic and imaging facilities.

Outstanding candidates with a proven track record in research with funding support are strongly encouraged to apply. Senior appointments are expected to have a national/international reputation in their relevant discipline. Subject to appropriate experience the position will be full time continuing (approximately equivalent to a North American 'tenured' position). The preferred starting date is in the latter half of 2012 (negotiable).

The salary range (effective 08/07/2011) for associate professor is A$120,987 - $132,898 per year and for professor is from A$154,741 per year, depending on qualifications and experience, plus 17% employer superannuation plus leave loading.

Applications close: November 11, 2011

Applicants should systematically address the selection criteria in their application.

Enquiries may be directed to the Head of School, Professor Simon Killcross (Tel: +61 2 93853034; E-mail: s.killcross@unsw.edu.au).

For further information about the School, visit: www.psy.unsw.edu.au.

University of British Columbia (Canada), School of Arts & Sciences: The Irving K. Barber School of Arts and Sciences at the University of British Columbia, Okanagan Campus, invites applications for a professorial appointment (clinical psychology) at the rank of assistant professor or, in the exceptional case, an associate professor to begin with a possible start date of July 1, 2012. The position will be held in Psychology (http://www.ubc.ca/okanagan/psyo/welcome.html) in the Barber School (http://www.ubc.ca/okanagan/ikbarberschool/welcome.html).

In January 2011, we expanded our existing experimental psychology graduate program to include a masters/doctoral clinical program with a targeted implementation date of Autumn, 2013. The program has been developed to meet the requirements of CPA accreditation and acceptance by the College of Psychologists of BC. This program is based on the scientist-practitioner model and therefore is research-oriented.

We are seeking to fill a position in clinical psychology with a candidate who is registered or eligible to register as a psychologist in the province of British Columbia. Candidates with a strong commitment to teaching and an established research program in developmental psychology or neuropsychology would best meet our program needs; however, individuals with other research interests are welcome to apply. The successful candidate will be expected to contribute to our clinical program and to graduate and undergraduate teaching and supervision.

Applicants to the rank of associate professor may also be considered for a limited-term, renewable, appointment as Director of Clinical Training. The Director of Clinical Training will provide leadership, guidance, direction, coordination, and inspiration to students/interns, members of the training committee, and other program staff on matters relating to training in professional psychology. The Director of Clinical Training assumes overall responsibility for the program. He or she provides the leadership and coordination necessary to obtain and maintain accredited status.

Applications will be reviewed beginning November 15, 2011. Applicants should provide a cover letter, curriculum vitae, evidence of teaching ability (e.g., course evaluations), program of research, and the names and contact information of three referees. All documents must be submitted as e-mail attachments and sent to recruitment.bsas@ubc.ca. Preferred formats are Microsoft Word (.doc) and Adobe Acrobat (.pdf). Put the competition title on the subject line of the E-mail and declare whether you are legally entitled to work in Canada. The process will continue until the position is filled.

Carleton University (Canada), Department of Psychology: The Department of Psychology at Carleton University invites applications from qualified candidates for a preliminary (tenure-track) appointment in occupational health psychology at the rank of assistant professor beginning July 1, 2012.

Applicants must have a PhD, have demonstrated excellence in teaching and possess a strong commitment to research and scholarship, as reflected in publications, in the area of occupational health psychology. The successful candidate will have the ability to develop an externally-funded, high quality research program, will be committed to excellence in teaching at the undergraduate and graduate levels, and will contribute effectively to the academic life of the Department.

The Department is interested in candidates with an established or developing research program in the area of occupational health psychology. Preference will be given to candidates whose health-related research expands our current graduate field of applied psychology and who has some knowledge and experience in personnel selection.

The Department of Psychology offers opportunities to explore psychology's major fields including health, developmental, cognitive, applied, forensic, and personality/social. We also have intellectual ties with academic units offering degrees in cognitive science, child studies, human computer interaction, and neuroscience. Carleton has offered undergraduate degrees in psychology since 1953 and graduate degrees in psychology since 1961. The Department of Psychology currently offers undergraduate programs in the Faculty of Arts and Social Sciences, as well as the Faculty of Science. Graduate programs in psychology are offered at the master's and doctoral level. Further information on the department is available at http://www2.carleton.ca/psychology.

Please send applications to Chair, Department of Psychology, Carleton University, 1125 Colonel By Drive, Ottawa, ON, K1S 5B6. Fax 613-520-3667. Applications and reference letters can be sent by email to psychchair@carleton.ca. Applications should include a curriculum vitae, a statement outlining current and future research interests, examples of publications and materials relevant to teaching experience. Interviews will include both a research talk and a lecture on a topic in occupational health psychology. Applicants should ask three referees to write letters directly to the Chair. Applications will be considered after January 1, 2012 or until the position is filled.

University of Waterloo (Canada), Department of Psychology: As part of the clinical psychology program, this position will support the University of Waterloo Centre for Mental Health Research (CMHR). The CMHR combines in-house opportunities for research concerning the nature and treatment of psychological disorders with graduate training and psychological services to the surrounding community. Candidates must have a PhD from an accredited clinical psychology program, an accredited internship, and should be registered or eligible for registration with the College of Psychologists of Ontario. Responsibilities will include undergraduate and graduate teaching, supervision of graduate students' clinical and research work, and an ongoing research program. We welcome applicants who have a strong, theory-driven, research investment that will be attractive to graduate students. Applicants with a research focus consistent with the aforementioned aims of the clinical division and the CMHR will be considered. Information about the clinical program, the CMHR, and the Psychology Department can be found at: http://www.psychology.uwaterloo.ca. Information regarding Waterloo can be found at: http://www.region.waterloo.on.ca.

The anticipated starting date for the position is July 1, 2012. Review of applications will begin October 15, 2011 and will continue until the position is filled. Applicants should electronically submit curriculum vitae, a statement of research and teaching interests, reprints or preprints of recent papers, and the names and contact information for three referees (including their e-mail addresses) to: clinicalpsychology@uwaterloo.ca.

University of Calgary (Canada), Department of Psychology: The Department of Psychology at the University of Calgary in collaboration with the Alberta Children's Hospital Research Institute for Child and Maternal Health (ACHRI), the Southern Alberta Cancer Research Institute (SACRI), and the Childhood Cancer Collaborative funded by the Alberta Children's Hospital Foundation is seeking applications for a tenure-track clinical psychology professorship at the assistant professor level in the field of pediatric psychosocial oncology.

The successful applicant will be expected to: establish a successful, collaborative, multi-disciplinary and externally funded program of research in psychosocial oncology; participate in the scholarly activities, including knowledge generation and translation, of ACHRI and SACRI; and supervise graduate students in the clinical psychology program. Applicants for this position will have accredited training in clinical psychology (including an APA- or CPA-approved internship) and will be able to obtain registration as a psychologist in the province of Alberta. The position offers 75% protected research time, with a one course teaching requirement per academic year, for a period of four years. After the expiration of the four year term, the appointee duties will be discussed with the Dean, including modification of the protected research time.

The successful applicant will be appointed within the Faculty of Arts, Department of Psychology with cross-appointment in Pediatrics and Oncology, Faculty of Medicine.

Send letter of application, statement of research interests, statement of teaching philosophy and interests, curriculum vitae, representative reprints/preprints, and at least two letters of recommendation to, Dr. Tavis Campbell, Chair of the Clinical Psychology Search, Department of Psychology, University of Calgary, Calgary, AB, Canada, T2N1N4; E-mail: t.s.campbell@ucalgary.ca. Review of applications will begin immediately and continue until the position is filled.

University of Toronto (Canada), Department of Psychology: The Department of Psychology at the University of Toronto Scarborough (UTSC) invites applications for a tenure-stream appointment in the field of cognitive neuroscience. The appointment will be at the rank of assistant professor and will begin on July 1, 2012. We encourage applications from candidates with a strong research record in cognitive neuroscience, especially with a strong research record in neuroimaging broadly defined.

The successful candidate will be expected to excel in teaching at the graduate and undergraduate levels, to develop courses that contribute to our proposed masters program in contemporary neuroimaging, to build an externally funded vibrant research program and laboratory centered at UTSC, and to undertake undergraduate and graduate research supervision and teaching. The successful candidate also will be expected to perform standard professional and administrative activities typical of a department and/or university.

The successful candidate must have a PhD in cognitive neuroscience (or in Psychology with the required neuroimaging experience), an established record of excellent scholarly research and publications, and demonstrated commitment to and innovation in teaching. Salary will be commensurate with qualifications and experience.

The closing date for applications is **November 30, 2011**.

We encourage you to submit your application online by visiting the University of Toronto Faculty Careers Page http://www.jobs.utoronto.ca/faculty.htm, and combine PDF or MS Word documents into one or two files. Applicants should submit a complete and current curriculum vitae, a statement outlining current and future research interests, three recent publications, and a teaching portfolio. Applicants should also arrange for three confidential letters of recommendation to be sent directly to: Professor John Bassili, Chair; Department of Psychology, University of Toronto Scarborough; 1265 Military Trail, Toronto; Ontario, Canada, M1C 1A4.

Reference letters and large documents may also be submitted electronically to: *psychology-applications@utsc.utoronto.ca*.

The University of Toronto has three campuses, Scarborough, Mississauga and St. George, each with its own Department of Psychology. Members of the three Psychology departments are also members of the tri-campus graduate Department of Psychology.

For more information about the Department of Psychology, University of Toronto Scarborough visit our home page: http://www.utsc.utoronto.ca/~psych/.

American University of Cairo (Egypt), SAPE Department: The Psychology Program, SAPE Department, at the American University in Cairo is seeking applications for an assistant professor to begin fall 2012. The Department is looking for excellent candidates in the fields of counseling, community, or applied psychology. Candidates should have a strong record of applied work and university level teaching experience. Successful candidates will be able to teach undergraduate and graduate courses in statistics and research methods. Ability to teach cognitive psychology and/or biopsychology is a plus.

A completed PhD and university level teaching experience are required. Successful candidates should have an ongoing program of applied work and a demonstrated commitment to excellence in teaching. Responsibilities include undergraduate as well as graduate teaching, and service to the Department and the University.

All applicants must submit the following documents online: a current curriculum vitae, a letter of interest, a statement of teaching philosophy, a completed Personal Information Form, and at least three referees familiar with your professional background to send reference letters directly to hussref@aucegypt.edu, and a complete list of AUC Psychology courses you are qualified to teach typed in a Word document (course list is available at http://catalog.aucegypt.edu/content.php?filter[27]=PSYC&filter[29]=&filter[course_type]=-1&filter[keyword]=&filter[32]=1&cpage=1&cur_cat_oid=15&expand=&catoid=15&navoid=476&search_database=Filter&filter[exact_match]=1)

Faculty salary and rank are based on qualifications and professional experience. All faculty receive generous benefits, from AUC tuition to access to research funding; expatriate faculty also receive relocation benefits including housing, annual home leave, and tuition assistance for school age children.

Baumholder Army Health Clinic (Germany), Clinical Child Psychologists: Clinical child psychologists needed to work with active duty military dependents at the Baumholder Army Health Clinic in southwestern Germany on a full time contract basis. Minimum one year commitment, paid relocation, tax incentives, paid malpractice insurance. Position includes on-base privileges such as commissary, exchange, gasoline purchase, officers clubs, recreational facilities, etc. Come experience the excitement of living in Europe, while helping our soldiers and their families! Must be licensed in any state, have completed an APA-accredited pre-doctoral internship (no exceptions) and a fellowship in child psychology.

For more details, send curriculum vitae to Mary Holland at mholland@neshold.com. Fax is (757) 420-6616.

Anderson Air Force Base (Guam), Clinical Social Worker: Andersen Air Force Base at Yigo, Guam. Licensed clinical social worker case manager. Full-time position providing civilian services at this military medical treatment facility. Please send resumes by E-mail to: hr@rlmservices.net or by fax to: 305-576-5864.

University of Hong Kong (China), Department of Psychology: Applications are invited for appointment as post-doctoral fellow in personality/social psychology in the Department of Psychology, from as soon as possible, for a period of 19 months.

Applicants should have a PhD degree in psychology, or a related discipline, an active research record, and an interest in personality/social psychology or applied social psychology. The appointee will work on a project in social and health psychology with Professor Cecilia Cheng. Further information can be obtained at http://www.hku.hk/psychology.

A globally competitive remuneration package commensurate with the appointee's qualifications and experience will be offered. At current rates, salaries tax does not exceed 15% of gross income. The appointment carries leave, and medical/dental benefits.

Review of applications will begin immediately upon receipt and will continue until the post is filled. Candidates who are not contacted within two months of the date of their applications may consider their applications unsuccessful.

Chinese University of Hong Kong (China), Department of Psychology: The Department is keen to enhance its reputation as a source of world-class research and delivery of knowledge through teaching and conference participation. It hopes that new appointees can embrace that agenda with the support of the abundant facilities provided at the Department to all faculty members. Further information about the Department and its programs is available at www.psy.cuhk.edu.hk/. For enquiries, contact the Department via e-mail at: info@psy.cuhk.edu.hk.

Applicants should have excellent academic qualifications including a doctoral degree (PhD, DClinPsy, or PsyD) in clinical psychology, with a background in research as well as clinical experience in clinical psychology; strong commitment to excellent teaching and research; and a track record of research ability and publication. The appointee will participate in teaching undergraduate and postgraduate courses,

including an undergraduate course in psychology and law, supervise theses of students, assist in administrative duties. Appointment will initially be made on contract basis for up to two years commencing August 2012, which, subject to mutual agreement, may lead to longer-term appointment or substantiation later.

Salary will be highly competitive, commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package, including medical care, a contract -end gratuity for an appointment of two years, and housing benefits for eligible appointee. Further information about the University and the general terms of service for appointments is available at http://www.cuhk.edu.hk/personnel. The terms mentioned herein are for reference only and are subject to revision by the University.

Send full resume, copies of academic credentials, a publication list and/or abstracts of selected published papers, together with names, addresses and fax numbers/e-mail addresses of three referees to whom the applicants' consent has been given for their providing references (unless otherwise specified), to the Personnel Office, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong (Fax: 852 3943 1462) by the closing date. The Personal Information Collection Statement will be provided upon request.

University of Otago (New Zealand), Department of Psychology: Applications are invited for two confirmation path positions at the lecturer / senior lecturer level (equivalent to North American tenure-track assistant professor/associate professor) in the Department of Psychology. The area of research is open. The main selection criterion for the position is the potential for international distinction in research, provided that there is flexibility in teaching. The University of Otago is New Zealand's top-ranked university for research. The Department of Psychology supports highly rated research programs in several areas, including neuroscience, experimental, clinical, developmental, cognitive, social, and applied psychology. The teaching program emphasizes the development of student research skills, and thus the ability to attract and supervise student researchers is critical. In addition to undergraduate, master's and PhD degrees in psychology, the Department offers postgraduate training in clinical psychology and contributes to interdisciplinary courses in cognitive science and neuroscience. Excellent computing and technical facilities support the teaching and research programs in the Department. The Department has recently undergone a major building project that provides state-of-the-art teaching and research facilities. Specific enquiries may be directed to the Head of Department, Department of Psychology, Tel: 03 479 7644, E-mail psyhod@psy.otago.ac.nz. Applications close on November 11, 2011. To see a full job description and to apply online go to: www.otago.ac.nz/jobs.

New Zealand, Clinical Psychologists: We have full-time clinical psychologist vacancies to fill in the areas of general community mental health, forensic, neuropsychology, pain management, alcohol/drug services for adults and/or children and adolescents. You must have a PhD/PsyD in psychology, current practicing license, a minimum of five years' post-license experience, and able to commit at least two years or longer. All positions include four weeks' paid annual leave/ vacation, 9-11 paid public holidays, option to participate in retirement savings and other benefits plus the adventure of a lifetime to live and work in beautiful, nuclear-free New Zealand and enjoy our unique Kiwi lifestyle.

Contact Larry Beck via e-mail at larry@alignrecruitment.com or give him a call on his US/Canada toll-free phone number, 1-800-511-6976, which rings into Align's office in Christchurch.

Nanyang Technical University (Singapore), Psychological Studies Academic Group: The Psychological Studies Academic Group (PS) at the National Institute of Education, Nanyang Technological University, Singapore, invites applicants who possess a PhD or PsyD in clinical, counseling or school psychology to apply for a faculty position within the academic group in the following priority areas: school psychology, school counseling, and multicultural counseling.

We are looking for candidates with a proven track record in research and teaching at the university, and a minimum of five years' experience providing direct services to children, families or adults. Appointments may be made at the level of associate professor or assistant professor, depending on the candidate's qualifications and experience. Associate professor appointment will be expected to assume a higher level of administrative and leadership responsibilities.

Successful candidates will be able to provide clinical supervision to trainee psychologists and counselors and teach graduate level coursework in psychological testing, evidence-based intervention, or counseling. In addition, candidates must demonstrate an established or promising record of research productivity and have experience working with culturally and linguistically diverse populations. Further information about the psychological studies academic group is available at http://www.nie.edu.sg/psychological-studies/about-ps?url=http://www.ps.nie.edu.sg/.

Applications will be accepted until the position is filled. Only shortlisted applicants will be contacted for an interview.

Interested applicants may write to Associate Professor Maureen Neihart, Head of Psychological Studies. Her E-mail address is maureen.neihart@nie.edu.sg.

National University of Singapore (Singapore), School of Business: NUS Business School seeks to fill two research fellow / post-doctoral fellow positions.

Candidates should possess a PhD from a reputable university.

The candidate should be well versed in designing and running laboratory experiments. Fresh doctoral graduates with outstanding academic records, proven research capability, and a strong interest in developing an academic career are welcome to apply. Interest and background in behavioral and experimental economics are desirable, but not required. Successful candidates are expected to join a team of passionate researchers to work on pre-specified projects. They will also be given the opportunity and resource to develop their own research agenda.

Appointments will be on a term-contract of one to three years, and renewable depending on performance and project requirements. Remuneration package is globally competitive and commensurate with candidate's qualifications, track record, potential, experience and level of appointment.

Applications will be accepted until the positions are filled or until November 15, 2011, whichever is earlier.

Interested applicants should send a cover letter, curriculum vitae and publication list, the names of three to six referees with complete contact information and any other supporting documents to the following:
Professor Ho Teck-Hua
(c/o Jothi S)
NUS Business School
15 Kent Ridge Drive
Singapore 119245

National University of Singapore (Singapore), Social Sciences: The newly established Yale-NUS College in Singapore announces the availability of faculty positions at all ranks and in all areas of the social sciences. Yale NUS College seeks outstanding teacher-scholars at all career stages who are eager to be part of the inaugural faculty, who are committed to innovative pedagogy, who are active researchers and who enjoy close mentoring of students.

The field is open. Candidates should be enthusiastic about contributing to an interdisciplinary common curriculum in the liberal arts. New faculty may start their appointment either in mid-2012 or mid-2013. Salary and leave policies will be competitive at an international level. Review of applications begins on November 1, 2011 and will continue until positions are filled.

E-mail: bizhoth@nus.edu.sg or mktsec@nus.edu.sg.

Istanbul Sehir University (Turkey), Department of Psychology: The Department of Psychology at Istanbul Sehir University has a faculty position opening for its new MA in Social psychology program, beginning September 2012. The successful candidate is expected to take a leadership role in the establishment of a master's program in social psychology (curriculum development, teaching masters-level social psychology courses, and chairing thesis committees). Additional responsibilities include engaging in high quality research and performing administrative duties.

Applications received by December 1, 2011 will receive full consideration, but review of applications will continue until a suitable candidate is identified. Qualifications for the position include a doctorate in social psychology or a related field. Additionally, previous experience as the primary advisor on a masters or doctoral thesis is required. Salary is competitive and will be commensurate with candidate experience and credentials. Applicants should send a cover letter describing their research and teaching experience, curriculum vitae, three current letters of reference, and representative publications or pre-prints to: Dr. Medaim Yanik via e-mail at medaimyanik@sehir.edu.tr.

Bahcesehir University (Turkey), Department of Psychology: Bahcesehir University in Istanbul, Turkey is seeking to fill two positions in the Department of Psychology. One of the positions is in clinical or counseling psychology, the second is open specialization. Bahcesehir is located at the heart of Istanbul and has very strong international collaborations. We are looking for dynamic scholars who can help build a strong research capacity and play an integral part in our international projects. Applications will be accepted until the positions are filled. Send a cover letter, curriculum vitae, description of research and teaching interests, and the names of three references to: sirinbahcesehir@gmail.com.

Bilkent University (Turkey), Department of Psychology: Applications are invited for multiple posts (hiring at all levels) in all areas of psychology, commencing September 2012. Applicants with backgrounds in learning and memory, psycholinguistics, theory of mind or developmental psychology are particularly encouraged. The Psychology Department at Bilkent University is a young and growing institute, with an emphasis on cognitive psychology and cognitive neuroscience in research and teaching. Facilities available to our faculty members include a 3Tesla MR scanner, several fully equipped cognition and perception labs, as well as animal facilities. Current faculty members are well supported through national and international funds, and collaborate nationally and internationally. Our students are highly motivated and are ranked among the highest percentile in the Turkish university entrance examination.

Candidates should have at least a PhD at the time of appointment and show evidence of outstanding research potential. The teaching load is two courses per semester. The language of teaching is English across the university. The salary is competitive and commensurate with credentials. Rent-free furnished apartment on campus are available. Informal enquiries and applications in the form of curriculum vitae, research statement, and three confidential letters of recommendation should be sent to psy@bilkent.edu.tr. For more information visit www.psy.bilkent.edu.tr.

University of Alberta (Canada), Department of Psychology: The Department of Psychology at the University of Alberta has an opening for a full-time faculty lecturer effective July 1, 2012. Faculty lecturer positions are for 5-year renewable terms. Primary responsibilities associated with this position, in addition to teaching introductory psychology, are teaching undergraduate courses in personality, abnormal and clinical psychology. The successful applicant must have earned a PhD in psychology and be able to demonstrate teaching effectiveness. Preference will be given to individuals registered, or eligible to be registered, as psychologists in the Province of Alberta.

Salary for this faculty lecturer position begins at $71,544 per annum (on the 2011-12 salary scale), and the position includes a full range of benefits. Hiring decisions for this position will be made on the basis of demonstrated teaching ability and fit with departmental needs.

A curriculum vita, three letters of reference, a teaching dossier and evaluations of teaching performance should be sent to:
Dr. Thomas L. Spalding, Acting Chair
Department of Psychology
P217 Biological Sciences Building
University of Alberta
Edmonton, AB Canada T6G 2E9
E-mail: psychair@ualberta.ca
Fax: (780) 492-1744

Review of applications will begin on December 1, 2011, however the position will remain open until filled.

University of British Columbia (Canada), Department of Educational and Counselling Psychology, and Special Education: The Department of Psychology at the University of British Columbia (www.psych.ubc.ca) invites applications for a tenure-track assistant professor position in behavioral neuroscience, which will begin July 1, 2012. Candidates must have a PhD before commencing the position. We are seeking an individual who can add to the departmental strength in animal-based behavioral neuroscience. Particular areas of interest include: epigenetics, behavioral genetics, developmental psychobiology, addiction, interactions between the immune system and behavior, and learning. Note that primate facilities are not available. We are seeking an individual who has a strong commitment to teaching and a strong research record appropriate to a research-oriented doctoral program. The successful candidate will be expected to maintain a program of effective teaching, departmental service, graduate and undergraduate research supervision, and scholarly research that leads to publication. The starting salary for the position will be commensurate with experience. This position is subject to final budgetary approval. The closing date for applications is October 31, 2011. Applicants for the position should upload a single PDF file (containing a cover letter, curriculum vitae, research statement, teaching statement, evidence of teaching effectiveness, and three publications) to https://websec1.psych.ubc.ca/internal/faculty/jobappl/ and complete the brief form found on that webpage. Next, applicants should arrange to have at least three confidential letters of recommendation submitted online (details provided at the above webpage).

University of British Columbia (Canada), Department of Educational and Counselling Psychology, and Special Education: The Department of Educational and Counselling Psychology, and Special Education at the University of British Columbia invites applications for an assistant professor or an associate professor tenure track appointment in school psychology. This position is part of a program expansion initiative undertaken by the Province of British Columbia. Applicants need a doctoral degree in school psychology or a closely related area, preferably from a CPA, APA, or other nationally-accredited program or from a major research university. Evidence of research and scholarly achievement, and experience and commitment to excellence in teaching and clinical supervision are required. Preference will be given to individuals with research, teaching and supervisory experience in assessment, and interventions with school-age children, youth, and their families, with a focus on one or more of the following areas: child/youth neuropsychology, academic performance and assessment, school/child-clinical psychological services, and/or intervention. In addition to contributing to both graduate and undergraduate teaching and service within the department, the successful applicant is expected to have a strong commitment to research and training in school psychology, to pursue an active program of research, seek research funding, provide clinical and research supervision of masters and doctoral students, and pursue registration with the College of Psychologists of British Columbia. The appointment will be effective July 1, 2012, or as soon as the position is filled. Review of the applications will begin on October 17, 2011, and will continue until the position is filled. UBC offers the only school psychology program in British Columbia, with a current enrollment of 13 PhD and 38 MA and MEd degree students. The school psychology program is dedicated to optimizing the development of children, youth, and families within their social systems by creating a community of learners with foundational knowledge and respect for diverse theoretical orientations and empirical literatures. Training and practice integrate developmental, social-ecological, cognitive, and social-behavioral perspectives, with a focus on being able to utilize multiple frameworks to understand the development of individuals and groups within complex systems in a diverse society. Graduate training at UBC is distinguished in its strong appreciation for diversity, in terms of the populations served, the students recruited and admitted, the issues and elements of the practice examined and trained, and the provision of skills and experiences in working with a broad range of students and families across numerous settings. There are five program areas in the Department, including Counselling Psychology, Human Development, Learning and Culture, School Psychology, Special Education, and Measurement, Evaluation and Research Meth-

odology. Over 400 graduate students, including 95 PhD students, are enrolled in the Department. The Department has strong ties to schools, community and governmental agencies, and oversees the Faculty of Education's Psychoeducational Research and Training Centre which provides resources and materials as well as facilities for the school psychology program. Both the ECPS Department and the school psychology program have outstanding records of student and faculty research funding.

Salary and rank are commensurate with the candidate's background and experience. Applicants should send a cover letter, current curriculum vitae, a statement of research interests, a sample of recently published work, evidence of teaching effectiveness, and the names of three references together with their addresses, phone numbers, and e-mail addresses. Questions regarding the position should be directed to: William Borgen, PhD, Head, ECPS at (604)822-5261 or william.borgen@ubc.ca; or William McKee, PhD, Coordinator, SCPS Program at (604)822-6572 or william.mckee@ubc.ca.

Applications should be directed to:
Dr. Bill Borgen, Head
Department of Educational and Counselling Psychology, and Special Education
Faculty of Education
University of British Columbia
2125 Main Mall
Vancouver BC, Canada V6T 1Z4
william.borgen@ubc.ca.

University of Western Ontario (Canada), Department of Psychology: Applications are invited for a tenure stream appointment in I/O psychology at the rank of assistant professor in the Department of Psychology at the University of Western Ontario, effective July 1, 2012. We have a particular interest in applicants who specialize in topics that are typically associated with the "I" side of I/O psychology and who have a solid background in statistics/research methodology, but applicants trained in any area of I/O psychology are strongly encouraged to apply. Applicants must have a PhD or be very close to completing a PhD by July 1, 2012, and the selected candidate will be expected to maintain an active research program, teach undergraduate and graduate courses in I/O psychology topics, and provide graduate student supervision.

Applicants should submit curriculum vitae, a statement of research interests and teaching experience (including teaching ratings, if available), copies of representative publications, and arrange to have three letters of recommendation sent to: Dr. Albert Katz, Chair, Department of Psychology, University of Western Ontario, London, Ontario, Canada N6A 5C2.

Consideration of applications will commence on September 15, 2011, and will continue until the position is filled. This position is subject to budgetary approval. Applicants should have fluent written and oral communication skills in English.

The Psychology Department has approximately 50 faculty members, 20 staff members, and over 100 graduate students enrolled in the Masters and PhD programs. It is one of the most distinguished psychology departments in Canada and has a very strong I/O psychology group. Further information about psychology, and the I/O psychology group, at Western may be found at http://www.ssc.uwo.ca/psychology/ and http://psychology.uwo.ca/IO, respectively.

York University (Canada), Department of Psychology: York University's Faculty of Health has an ambitious mission to be an integrative force for promoting health and improving health care, locally and globally. Our vision is to educate future global leaders who will redefine and advance health and human science.

Positions will commence July 1, 2012 and are subject to budgetary approval. Salaries will be commensurate with qualifications and experience. The successful candidates must be suitable for prompt appointment to the Faculty of Graduate Studies.

Cultural Psychology
Applications are invited for a full-time tenure-track appointment in cultural psychology, at the assistant professor level. The successful candidate will have a PhD in psychology or a relevant field. We are seeking a scholar with extensive research experience in working on the dynamics of culture within a psychological framework. This position is not tied to a specific area of the graduate program areas of the psychology department, as cultural psychology cuts across many areas of research – cognition, clinical, developmental, personality, and social. Applications will be considered from candidates with a strong publication record in the area of cultural psychology, although we particularly welcome applications from those working in the area of mental health, broadly defined. The position will involve graduate teaching and supervision, as well as undergraduate teaching and research.

Applicants should send a signed letter of application, their curriculum vitae and a statement of teaching and research interests and experience, three reprints and the names of three referees, by November 1, 2011, to: Chair of the Cultural Psychology Search Committee, Department of Psychology, Faculty of Health, York University 4700 Keele Street, Toronto, Ontario M3J 1P3. Tel: (416)736-5116 Fax: (416)736-5814

Cognitive Aging
Applications are invited for a full-time tenure-track appointment in cognitive aging, at the assistant professor level. The successful candidate will have a PhD in psychology or a relevant field. Applicants should have an ongoing program of research in cognitive aging and specialize in one or more of the following areas: memory, attention, language, or higher-

order cognitive processes. Research should investigate the processes of change across the adult lifespan as they relate to the function of specific cognitive abilities. Research relating to healthy and successful aging is a priority. Candidates should show excellence or promise of excellence in teaching and in scholarly research and publication. The position will involve graduate teaching and supervision, as well as undergraduate teaching and research.

Applicants should send a signed letter of application, their curriculum vitae and a statement of teaching and research interests and experience, three reprints and the names of three referees by November 1, 2011, to: Chair, Cognitive Aging Search Committee, Department of Psychology, Faculty of Health, York University, 4700 Keele Street, Toronto, Ontario M3J 1P3. Tel: (416)736-5116 Fax: (416)736-5814

IWK Health Centre (Canada), Clinical Psychologist: Early Intensive Behavioural Intervention (EIBI) Treatment Program, Children's Neurosciences, Surgical and Rehabilitation Care

Salary: $39.9277 - $ 49.9098 /hour
Union Status: Non-Union
Closing Date: Open Until Filled
Start Date: ASAP

Position Summary
The EIBI Treatment Program provides intervention to preschool aged children diagnosed with autism spectrum disorder (ASD) ideally in naturalistic settings to achieve greater generalization of skills. The EIBI model is developed from evidence-based, best practices, which encompass both the principles of applied behavior analysis (ABA), including positive behavioral support, and advances in communication intervention and pivotal response treatment (Koegel & Koegel, 2006).

The EIBI clinical psychologist provides leadership, supervision, and support to the EIBI clinical interventionist and EIBI program implementers. The clinical psychologist coordinates and integrates the delivery of service in collaboration with the family, EIBI clinical leader and other team members, and plays a consulting role in adapting client-specific programs to meet the unique needs of individual children. The psychologist participates in local data collection as determined by provincial process, and maintains fidelity and consistency of the program in conjunction with the EIBI clinical leader. The clinical psychologist participates in training and program evaluation and makes recommendations to the EIBI clinical leader for ongoing training needs of intervention providers. The clinical psychologist also participates in the EIBI clinical network, EIBI team and administrative meetings, meetings and activities of the discipline of psychology, as well as Health Centre committees and community partnerships as appropriate. As one of the members of professional practice group in psychology, the successful candidate will have opportunities to work collaboratively on projects and share experiences with other psychologists in different fields of practice. The discipline of psychology is strong and vibrant at IWK Health Centre, with over 50 psychologists who provide services in both child health and mental health and addictions programs (www.iwk.nshealth.ca/index.cfm?objectid=A291305D-B904-ABEC-2740C4FDDA521C72).

The residency program in pediatric and child-adolescent psychology at the IWK Health Centre is both APA- and CPA-approved. The successful candidate will be expected to actively participate in training residents. Candidates with appropriate credentials may be considered for academic adjunct appointment in an appropriate university department at Dalhousie University. Further information about this position can be obtained from Vicky Veitch Wolfe, PhD, Psychology Professional Practice Chief, (902)470-8458, vicky.wolfe@iwk.nshealth.ca.

Qualifications

- PhD or PsyD in a CPA/APA-accredited clinical psychology program required.
- Completion of a CPA/APA pre-doctoral internship/ residency required.
- Registered, or eligible for registration, with the Nova Scotia Board of Examiners in Psychology (NSBEP) required.
- Two years formal training and clinical experience working with young children with developmental disabilities, specifically autistic spectrum disorder (ASD) required.
- Demonstrated excellence in clinical care required.
- Demonstrated knowledge of best practices in intervention for young children with ASD; commitment to evidence-based treatment strategies required.
- Demonstrated excellence in leadership of program development and evaluation as well as ongoing training and support of treatment providers required.
- Demonstrated ability to formulate and implement treatment programs to promote positive adaptive behaviors, independence, and skill development in preschool-aged children, specifically children with autism spectrum disorder required.
- Demonstrated ability to work as part of a collaborative, interdisciplinary team in a variety of settings as well as the ability to work independently required.
- Demonstrated excellent interpersonal, presentation, and communication (verbal and written) skills required.
- Demonstrated ability to develop and maintain internal/ external partnerships required.
- Demonstrated excellent time management, organization, and problem-solving skills required.
- Demonstrated commitment and champion of family-centered care required.
- Valid minimal Class five Nova Scotia driver's license

and reliable transportation required.

- CPR certification within the last 12 months and current First Aid Certification required.
- Knowledge and experience in applied behavior analysis preferred.
- Demonstrated experience in pivotal response treatment (PRT) preferred.
- Demonstrated experience in picture exchange communications system (PECS) preferred.
- Demonstrated experience in positive behavioral support (PBS) preferred.
- Knowledge of program-based care an asset.
- Competencies in other languages an asset; French and/or Arabic preferred.

It is the responsibility of IWK employees to self identify as internal applicants. At the time of application submission, each applicant will be asked if they are a current IWK employee. All application information submitted for this posting may be viewed by IWK Human Resources Employees, IWK Hiring Managers, and/or their delegates. The information submitted will be retained in the CareerBeacon database, and the IWK may also store and retain application information on secure computers, or within locked filing systems for up to 5 years.

***Marine Corps Community Services (Japan), Clinical Counselor*:** Marine Corps Community Services (MCCS) located at Marine Corps Air Station (MCAS) Iwakuni, Japan, is seeking a highly qualified clinical counselor who provides comprehensive case management services that require coordinating with collateral resources to assure that the health/safety of clients is maintained. Develops and monitors the treatment process to ensure that it is appropriate and evaluates effectiveness through follow-up services. Maintains case records of all client contacts and ensures case records are in compliance with department standards. Maintains a resource file of collateral resources providing treatment, education, or other support services. Develops, implements, and conducts a wide variety of clinical education and prevention classes, briefings and training of military and civilian personnel and families. Prevention/education activities are program-related and focus on each of the programs under the Counseling Services Branch. This includes training other service providers to identify high-risk behavior which tend to indicate individual or family dysfunction and determining intervention protocols for community resources (i.e., Provost Marshal's Office, etc.).

Serves as Team Leader for one or more programs or subject areas such as:

Family Advocacy Program Case Manager (FAP-CM): Conducts psychosocial assessments on cases involving child and spouse abuse. Conducts interviews with individuals and families involved in child/spouse abuse situations. Provides detailed social histories as appropriate. Develops and implements appropriate treatment plans for victims of abuse or neglect in accordance with the decisions of the Case Review Committee. Conducts intake interviews for advocacy-related programs. Counsels individuals and families experiencing family violence, emotional abuse and neglect. Provides short term, non-medical individual, marital or family counseling to active duty and DoD civilian clients and/or families who may be experiencing family breakdown and coordinates referrals to appropriate community agencies. Conducts interviews, counsels, and processes case management tasks according to recognized professional techniques and procedures in order to assist clients' attempts to effect changes, make decisions and resolve problems while maintaining client privacy and confidentiality according to legal and Counseling Services Program requirements. FAP-CM is available for follow-up, and on a rotating, on-call basis, to provide crisis intervention after regular work hours when required and/or appropriate.

General Counselor: Counsels individuals and families experiencing problems such as significant trauma, sexual assault, combat operational stress, complicated bereavement, suicidal ideation, marital distress, financial hardship, parenting difficulties, cultural adaptation, adjustment to family separations, due to TAD's, deployments, and overseas assignments. Counseling is non-medical and usually short-term. Conducts professional counseling assessments, formulates treatment plans based on presenting problems to assist clients in decision-making, problem-solving and effecting change, evaluates efficacy of service, maintains professional 'best practice' standards for documentation of all services provided, and participates in quality assurance reviews of case files. Counseling service delivery is consistent with recognized professional counseling/social work practice, and is within the ethical boundaries of the profession. Performs duties of the family advocacy counselor when client caseloads or staff shortages demand. Determines and analyzes needs of military families and recommends courses of action the Counseling Center may take to meet those needs. Develops, facilitates, and conducts programs for the Counseling Center. Included are programs designed to assist with marriage preparation, enhancing communication, effective parenting, financial management, preparation for family separation and reunions, cultural adaptation, intercultural relationships, and other programs that extend and enhance support to the community. Interacts with higher echelon authority in regards to confidential clinical cases, and acts as an advocate for the military member and his/her family while adhering to the policy of the command and HQMC directives. Participates in one or more advisory committees, such as the FAP Case Review Committee (CRC) meetings and Family Advocacy Program Committee (FAC) meetings, on an as needed basis. Effectively supports the Marine Corps Equal Employment Opportunity policy, and ensures compliance with fire, safety, and other environmental issues. Manages new property resources and provides advice on renovations and improvements. Maintains and enforces security of funds, merchandise, supplies, and equipment to

preclude or minimize the potential for fraud, waste, and abuse.

Due to the nature of work in this position, the incumbent may serve in an "on call" duty status outside of normal work hours that includes: remaining in a reasonable call-back radius, carrying a cell phone or pager, or regularly checking email to respond to emergencies; remaining in a state of readiness to perform work with limitations on pursuing outside leisure activities, and/or reporting to a designated post of duty to be ready to or to perform work.

Education
This position has a positive education requirement. You must submit a copy of your transcripts with your application to be considered for this position. At the time the education was obtained, the entire institution, applicable school within the institution, or the applicable curriculum was appropriately accredited by the U.S. Department of Education. Application materials will not be returned.

Licensure
All applicants must be licensed as a professional counselor by the recognized licensing agency of a U.S. state or the District of Columbia with one of the following: LCSW, LMFT, LPC, LMHC, or clinical psychology. Candidates must have the most independent license for their state.

Credentialing
All applicants must be able to be credentialed as a condition of employment. For candidates with a LPC or LMHC, only the following states have been approved for credentialing: Arizona, Delaware, Florida, Hawaii, Illinois, Louisiana, Maryland, New Jersey, Ohio, South Carolina, Texas, Virginia, Washington, and Wyoming.

Selective Placement Factor
Providers who are state licensed or state certified (or were granted a license or a certificate by a U.S. territory) to provide independent clinical care. These providers are eligible to apply for clinical privileges to functions as independent practitioner. Must possess a current, valid, unrestricted license or certification which grants independent status to be eligible for professional staff appointment with clinical privileges. Failure to submit the required documents with the resume will cause the individual to be ineligible for consideration.

This position is an overseas assignment tour of duty which includes the following benefits: relocation costs, transportation agreement, travel expenses, shipment of household goods, off-base housing living quarters allowance, post-allowance (COLA), annual leave, sick leave, 401(K), retirement plan, medical, dental, life and long-term insurances. MUST BE A UNITED STATES CITIZEN. This position is subject to random drug testing.

***Singapore Management University (Singapore), School of Social Sciences*:** The School of Social Sciences (SOSS), Singapore Management University, invites applications for tenure-track positions in psychology at the assistant, associate, or full professor rank, to begin in July 2012. Positions are available in cognitive psychology (with focus on judgment and decision-making), industrial and organizational psychology, quantitative psychology, and social psychology. The positions require a doctorate in psychology by the date of appointment. We are seeking candidates with a demonstrated record of, or high potential of, scholarly research commensurate with the rank and a strong ability or aptitude to teach a wide range of undergraduate and postgraduate courses. The SOSS, which has a strong record of attracting the best students in Singapore and the region, is committed to an interdisciplinary and integrated undergraduate curriculum. The ideal candidate will have a strong commitment to excellence in research and teaching at both undergraduate and postgraduate levels. A research interest in Singapore and the Asian region will be an advantage. The teaching load is light compared to many research universities. The research support is excellent and salary and benefits are highly competitive.

Full evaluation of applications will start December 1, 2011, and on-campus interviews will typically be conducted in the period from January to March 2012. However, submission of applications is open and evaluation will continue until the positions are filled. Applicants must submit, in electronic form (Word or PDF file), a detailed curriculum vitae, a description of research interest and philosophy, and a statement of teaching interests and philosophy to the following address: socialsciencescv@smu.edu.sg. Applicants should also send hardcopies (if not available in electronic form) of selected publications and teaching evaluations. Applicants should arrange for three confidential letters of recommendation to be sent directly to: The Dean's Office, School of Social Sciences, Singapore Management University, 90 Stamford Road, Level 4, Singapore 178903. Information about the University and the School can be found at www.socsc.smu.edu.sg.

National Taiwan University (Taiwan), Department of Psychology: The Department of Psychology at the College of Science, National Taiwan University is inviting applications for faculty positions at all levels in the following areas: psychobiology/cognitive neuroscience, industrial and organizational psychology, personality/social psychology, clinical psychology, cognitive/perceptual psychology, developmental psychology, and psychometrics.

Application deadline will be September 30, 2011, for the spring appointment at February 1, 2012. Application deadline will be January 31, 2012 for the fall appointment at August 1, 2012. Applicants (PhD required, post-doctoral training preferred) should indicate the area(s) applied. This department focuses on both research and teaching. The appointee is expected to teach in Mandarin or English at both graduate and undergraduate levels. A complete application dossier

should include: curriculum vitae (including a full publication list), proof of PhD and employment records (if applicable), publication(s) within the last seven years, three copies each (please mark one to three representative article(s) published within five years from the appointment date), at least three letters of reference, letter of interest, including statement of research and teaching experiences and/or potentials, and others (official post-graduate transcripts for applicants of assistant professorship). Send the above application materials to: Professor Chih-Wei Hue, Chairperson, Department of Psychology, National Taiwan University, No.1, Sec. 4, Roosevelt Road, Taipei, Taiwan 10617, ROC.

University of York (United Kingdom), Department of Psychology: The Department seeks two individuals with international reputations who will complement or extend existing strengths. The successful candidates will have outstanding publication records alongside proven abilities in leadership in research and in the acquisition of research funding. Applicants should also demonstrate a strong commitment to the promotion of teaching and learning. Salaries will be commensurate with experience on the professorial scale (current minimum £54,133 per annum). Closing date: October 21, 2011.

University of Western Australia (Australia), School of Psychology: The University of Western Australia is seeking to appoint a senior academic in psychology to a newly created tenurable position in the School of Psychology. The appointed person will be a leader in the field with an international reputation for research, a track record in attracting significant research funds, and the capacity to develop a team of world-class researchers and educators of clinical psychologists. The appointee will play a key role in the integration of clinical research and teaching with the existing research clusters in the school. Applications from those with specialist expertise in pediatric clinical psychology, clinical neuropsychology, or clinical health psychology are particularly encouraged to apply. Although a higher-level Winthrop Professorial appointment is preferred, applicants may be considered for a slightly more junior professorial position depending on their level of experience. In the recent (January 2011) Excellence in Research for Australia (ERA) assessment, psychology at UWA achieved the highest ERA rating of 5 and was one of only three psychology schools in Australia to achieve this level. The school hosts research programs in Australian Research Council funded centers, including the Centre of Excellence in cognition and its disorders and the Bushfire Co-operative Research Centre. Additionally, the school has a number of staff funded by the Australian Research Council on prestigious professorial or future fellowships. The school has research and teaching strengths in cognitive science and cognitive neuroscience (including developmental psychology, developmental disorders, neuropsychology, and perception), abnormal cognition and clinical psychology, and social psychology and organizational psychology.

For further information regarding the positions contact: Winthrop Professor, David Morrison, Head of the School of Psychology on Tel: +61 8 6488 3240, or via e-mail at david.morrison@uwa.edu.au.

The University offers an attractive salary with benefits including 17% employer superannuation, generous leave provisions, fares to Perth (if applicable) for the appointee and dependents, together with a substantial relocation allowance. The information for candidates' brochure which includes details to lodge your application may be found via a link at http://jobs.uwa.edu.au/; or at https://www.his.admin.uwa.edu.au/Advertising/3541CandidateInformation.pdf; or by contacting Ms. Toni Pilgrim, Human Resources, via e-mail at toni.pilgrim@uwa.edu.au.

Website: www. jobs.uwa.edu.au

University of Sydney (Australia), Faculty of Health Sciences: The Faculty of Health Sciences is a world leader in health sciences and allied health education and research, with research programs spanning disability, rehabilitation, health and functioning. The Faculty of Health Sciences is well-established internationally as a leading contributor to the WHO Family of Classifications and, relevant to this new professorial position, the International Classification of Functioning, Disability and Health (ICF), and the development of the International Classification of Health Interventions (ICHI). The ICF is fundamental to understanding and documenting activity limitations and participation restrictions in everyday life. The Faculty is leading the development of the evidence base utilizing the ICF as a monitoring framework for the implementation of internationally accepted services such as Community-Based Rehabilitation (CBR).

This new professorial position in disability and mental health offers the opportunity for a leading researcher to consolidate and expand research on everyday functioning in the disability and mental health field and to lead curriculum development, particularly in the areas of mental health, CBR and ICF application, all in the context of the UN Convention on the Rights of Person with Disabilities. You will play a key role in initiating a multidisciplinary graduate-level program in health, rehabilitation, and disability. You can enjoy strong collaborative relationships with the Brain and Mind Research Institute, the Sydney Medical School, the Faculty of Education and Social Work, and the Faculty of Arts and Social Sciences at the University of Sydney relevant to disability and mental health.

To succeed, you will:

- have a strong record in mental health research with a focus on functioning in the community evidenced by competitive grant success, seminal publications, and graduate student completions,
- have advanced knowledge of ICF in research and in-

formation development, and preferably in diverse communities including in lower income countries,
- ideally possess knowledge of Community-Based Rehabilitation (CBR), with familiarity with developments in CBR in the Asia Pacific region an advantage, and
- have proven ability to collaborate with people with disabilities and mental health difficulties and other stakeholders in disability and mental health including government agencies and non-government organizations in Australia and internationally.

This is an opportunity to contribute to the Faculty's goal to further enhance its teaching in mental health, commensurate with the scope of mental ill-health as a proportion of public health disability.

The position is full-time, continuing appointment subject to the completion of a satisfactory probation period for new appointees.

For general enquiries about the recruitment process please contact Mr. Rodney Waterson, Acting Senior Recruitment Manager, Sydney Recruitment, at +61 2 8627 1214 or rodney.waterson@sydney.edu.au.

All applications must be submitted via the University of Sydney's careers website. Visit http://sydney.edu.au/positions/.

University of Tasmania (Australia), School of Psychology: Applications are invited for appointment to this position, which will be offered on a full-time tenurable basis. The position of lecturer in psychology will primarily involve teaching core and applied psychology topics in undergraduate and honors programs, and the pursuit of a productive program of research.

The School of Psychology is a large cross-campus School offering undergraduate study on three Tasmanian campuses and postgraduate professional training programs in clinical psychology, counseling, and rehabilitation counseling on the Hobart campus. The School's research program is focused on four main theme areas: health and aging, human neuroscience, developmental psychology and psychopathology, and community and environmental psychology. Within each of the theme areas are established areas of research strength which form the basis of the School's current and future research endeavors.

Applications are invited from persons with knowledge and ability in core and applied areas of psychology, together with experience in the effective delivery of tertiary teaching and supervision of honors and postgraduate research projects.

The successful applicant will have a PhD in psychology and will demonstrate a commitment to the development of a strong and productive, nationally or internationally competitive research program in an area associated with one of the School's research themes.

The appointment will be at Academic Level B and will have a total remuneration package of up to $107,211 per annum (comprising salary within the range $77,715 - $91,633 plus 17% superannuation, with the option of an additional 3% salary loading in exchange for 14% instead of 17% superannuation). Employer will assist with relocation costs.

For further information about the position, the School's teaching programs and research plan, contact the Head of School, Associate Professor Greg Hannan, Tel: (03) 6324-3267 or E-mail G.Hannan@utas.edu.au or visit our website at: www.utas.edu.au/psychol.

For further details and an application package go to http://jobs.admin.utas.edu.au/positions/.

Carleton University (Canada), Department of Psychology: The Department of Psychology at Carleton University invites applications from qualified candidates for a preliminary (tenure-track) appointment in quantitative methods at the rank of assistant professor beginning January 1, 2012. Applicants must have a PhD., demonstrated excellence in teaching statistics and methodology, and must possess a strong commitment to research and scholarship, as reflected in publications, with preference to publications in health, environment, or digital media. The successful candidate will have the ability to develop an externally-funded, high quality research program; will be committed to effective teaching at the undergraduate and graduate level; and will contribute effectively to the academic life of the Department. The Department is interested in candidates who are able to teach advanced statistics at the graduate level including ANOVA, regression, multivariate statistics, and other advanced statistical techniques (e.g., HLM, SEM), and basic and advanced statistics at the undergraduate level. The successful candidate will have a program of research applying their methodological skills to areas of psychological research that contribute to Carleton's strategic research direction in health, environment, or new digital media.

The Department of Psychology offers opportunities to explore psychology's major fields including health, developmental, cognitive, applied, forensic, and personality/social. We also have intellectual ties with academic units offering degrees in cognitive science, child studies, human-computer interaction, and neuroscience. Carleton has offered undergraduate degrees in psychology since 1953 and graduate degrees in psychology since 1961. The Department of Psychology currently offers undergraduate programs in the Faculty of Arts and Social Sciences as well as the Faculty of Science. Graduate programs in psychology are offered at the master's and doctoral levels. Further information on the department is available at http://www2.carleton.ca/psychology/.

Please send applications to Chair, Department of Psychology, Carleton University, 1125 Colonel By Drive, Ottawa, ON. K1S 5B6. Fax: (613)520-3667. Applications and reference letters can be sent by email to psychchair@carleton.ca. Applicants should include a curriculum vitae, a statement outlining statistical expertise, a statement describing current and future research interests, examples of publications, and materials relevant to teaching experiences. Interviews will include both a research talk and a lecture on an advanced statistical method. Applicants should ask three referees to write letters directly to the Chair.

Carleton University is a dynamic research and teaching institution with a tradition of leading change. Its internationally recognized faculty, staff, and researchers provide more than 24,000 full- and part-time students from every province and more than 100 countries around the world with academic opportunities in more than 65 programs of study. Carleton's creative, interdisciplinary, and international approach to research has led to many significant discoveries and creative work in science and technology, business, governance, public policy, and the arts. As an innovative institution, Carleton is uniquely committed to developing solutions to real world problems by pushing the boundaries of knowledge and understanding daily.

University of Toronto (Canada), Department of Psychology: The Department of Psychology and the Rotman School of Management at the University of Toronto invite applications for a tenure-stream position in social/personality neuroscience, at the rank of associate professor, to commence July 1, 2012. The successful candidate should have a PhD, an established research program that includes such topics as affect, attitudes, and/or motivation. In addition, candidates should be able to bridge their research to the social, cognitive, and cognitive-neuroscience researchers in the two units. The ability to teach advanced undergraduate and graduate statistics is an important component of this position, and experience with more than one neuroimaging methodology is preferred. Candidates must show evidence of successful, externally funded research programs and commitment to both undergraduate and graduate education. Evidence of excellence in teaching and research is required.

Applicants should submit curriculum vitae, a statement of research interests, copies of representative publications, and arrange for at least three letters of recommendation to be sent directly to Chair Jay Pratt. Alternatively, applications may be mailed to the Social/Personality Neuroscience Search Committee, Department of Psychology, St. George Campus, 100 St. George Street, Toronto, Ontario M5S 3G3, or by E-mail to chair@psych.utoronto.ca.

Potential applicants may contact Professor Jay Pratt, Chair at chair@psych.utoronto.ca for additional information. Salary will be commensurate with experience and qualifications. For more information on the Department of Psychology, visit our homepage at www.psych.utoronto.ca.

Cape Breton District Health Authority (Canada), Clinical Psychologists: The Cape Breton District Health Authority, Sydney, Nova Scotia, has immediate openings for permanent full-time clinical psychologists. The successful candidates will have doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology. They must be registered or eligible for registration with the Nova Scotia Board of Examiners in Psychology.

The positions in Child & Adolescent Mental Health Services require the candidates to work in a multidisciplinary team to provide assessment, individual and group treatment to children and adolescents patients aged 0-19 years with a variety of mental health disorders. Our multi-disciplinary approach involves services within our district as well as within the community, including consultation to schools, daycares, children's aid services, and group homes.

The Autism Intervention Program again involves a multidisciplinary team approach including in-home behavioral interventionists, psychiatry, social work, psychology, and occupational therapy. The program requires a candidate that can provide clinical leadership in the areas autism assessment and diagnosis, pre-school assessment, behavioral intervention, and the provincial EIBI program, as well as help facilitate the transition to schools for children with autism both in an outpatient and home setting. The Autism Program is part of a province wide initiative and utilizes the pivotal response therapy (PRT) model for early intervention. There are also opportunities to be part of larger, multi-site research projects within this program.

The Eating Disorders Clinic involves a multi-disciplinary team approach including diagnostic assessment, consultation and direct treatment services for individuals with eating disorders across the lifespan. Consultation service is also provided to pediatrics, inpatient psychiatry, and primary care physicians for patients requiring inpatient admission and treatment. Clinical supervision is provided to the dietitian assigned to the Eating Disorders Clinic.

The Adult Outpatient Mental Health Clinics are an outpatient service involving a multidisciplinary team approach, individual and group treatment, consultation, and education. The team may involve psychiatry, psychology, social work, nursing, and occupational therapy.

For further information, or to apply with cover letter and resume please contact: Janine Hussey Manager, Recruitment & Retention Cape Breton District Health Authority, 1482 George Street, Sydney, NS, B1P 1P3; Fax: (902)567-7224; E-mail: husseyjan@cbdha.nshealth.ca.

Universidad Icesi (Colombia), School of Business:
Online only:
Faculty positions: Management and Marketing
Institution: Universidad Icesi
Location: Cali, Colombia
Type: Full-Time
Minimum Qualifications: PhD in business, business management, business administration, organizational behavior, marketing, consumer behavior, consumer psychology, business education, or the equivalent.
Departments: Business Administration, Marketing & International Business
Application Procedures: The number of faculty hired varies from semester to semester, depending upon the needs of the Business School. Your resume will be maintained in this adjunct pool for 12 months.
Send resumes to: Silvio Borrero, Chair, Department of Management, Universidad Icesi, Calle 18 # 122-135, Cali, Colombia; Tel: +(572)555-2334, ext. 8231.

Employment acceptance or rejection shall be based on job-related qualifications. More information on Universidad Icesi at www.icesi.edu.co.

Employer will assist with relocation costs. Salaries are competitive, and will be negotiated depending on qualifications and level of experience.

Ross University (Dominica), School of Medicine: Ross University School of Medicine invites applications for a faculty post as Chair of Behavioral Sciences. Our mission is to prepare highly dedicated students to become effective, successful physicians in the United States. Foundations of Medicine and Integrated Medicine coursework is taught in Dominica and students then complete their clinical studies in the United States. After passing all prerequisite examinations, Ross graduates are licensed to practice medicine in all 50 states of the U.S. Ross University School of Medicine is a division of DeVry, Inc. (NYSE:DV).

Education is the primary focus of the faculty. The academic year is divided into three semesters with a new class of students admitted each semester. Teaching and other responsibilities continue throughout the year. Effective teachers are sought, particularly individuals who are interested in improving medical education and who work well on a team. Research opportunities exist and are encouraged in the area of medical education.

Job Description:
The Chair of Behavioral Sciences is responsible for ensuring that faculty, in addition to excellent teaching, are mentoring and advising students, and is providing examinations that monitor the progress of students. The Chair is responsible for faculty recruitment, retention, and development along with performance management of faculty, and facilitation of faculty in the development of curricular innovation and improvement that aligns with the goals of the overall curriculum. The Chair is responsible for ensuring that systems are in place to provide faculty time and resources that facilitate collaboration between basic and clinical faculty to produce a highly integrated curriculum. The Chair reports to the Senior Associate Dean for Academic Affairs and will be responsible for fulfilling any other duties as requested by the Senior Associate Dean and/or Dean of the Medical School.

Essential Duties and Responsibilities:

- Oversee the overall operation of affairs related to the Department of Behavioral Sciences
- Recruit, interview, and hire faculty within the Department
- Mentor and provide support for faculty members toward promotion within the Department
- Evaluate and recommend to the dean merit increases of faculty based on performance
- Supervise the implementation of policies and procedure for educational and administrative affairs and maintain currency of procedures and programs
- Participate in faculty and chairs meetings with the Senior Associate Dean and Executive Dean
- Make recommendations regarding appropriate faculty appointments to committees at the request of the Dean
- Foster faculty participation in a well-integrated medical curriculum
- Hold regular departmental meetings
- Prepare the annual budget for the Department
- Facilitate departmental contribution to continuing medical education and clinical grand rounds
- Participate in teaching within the department, in PAcE, and in Problem-Based Learning (PBL)
- Advocate for integration of material with basic science disciplines and clinical science, active learning (including use of audience response systems), adult learning methods, and use of technology such as e-learning
- Contribute to curricular development
- Work to achieve improvement in departmental performance
- Participate in learning about the science of education
- Establish departmental goals aligned with institutional goals
- Assign faculty appropriately to cover curricular needs
- Contribute to community
- Promote academic scholarship in self and faculty within the Department

Qualifications:
To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the

essential functions.

- A record of outstanding achievement as a scholar with evidence of teaching success or as a senior-level academic administrator
- A demonstrated ability to effectively communicate verbally and in writing with outside constituencies, such as business and governmental leaders, on issues vital to the university
- A well-organized and self-directed individual who is a team player. The ability to think strategically, build consensus, and engage the faculty, staff, and administration in collegial and constructive decision-making.
- Desire for self-improvement
- Strong leadership and human relations skills that promote dedication, team orientation, creativity, and growth.
- Strong communication skills in English
- Ability to communicate effectively with employees, faculty, staff, and community groups
- Experience with assessment programs and a record of leading successful curricular and programmatic changes based upon assessment results
- The desire to advance the University in curricular and other academic initiatives
- Understanding of ways in which technology can support learning and a record of support for technological advancements
- Technological skills, including use of e-learning management systems, audience response systems, online examinations, and videoconferencing
- Experience in computer-assisted delivery and active learning of course content
- An articulate individual with excellent negotiating and presentation skills
- Must be flexible, possess high energy level, and promote a collaborative team-oriented environment
- Experience with problem-based learning and team-based learning
- Strong teaching skills and experience or evidence of potential
- Ability to initiate, complete, and present results of medical education research projects and to demonstrate ongoing faculty development in medical education
- Demonstration of DeVry *TEACH* values: teamwork and communication, employee focus, accountability, continuous improvement, and helping our students achieve their goals

Education, Experience, Knowledge, and Skills:

- We are looking for a psychiatrist with an earned M.D. from an APA-accredited institution of higher education with a strong record of scholarly achievement and progressive teaching/leadership related experience in a postsecondary institution. The candidate should qualify for the level of full professor.
- Experience in academic administration or equivalent experience at a North American or United Kingdom medical school
- Demonstrated managerial and leadership skills in the area of academic programs
- Experience as a faculty member
- Budget management experience

Ross University offers a competitive potentially tax-free annual salary, relocation assistance to and from the island, a retirement program, tuition assistance benefit, scholarship program for dependents, 100% medical benefits paid for the employee, travel benefits, a living allowance, 25 days of paid annual leave is provided along with opportunities for professional development, which includes a conference and book allowance.

Jacobs University of Bremen (Germany), School of Humanities and Social Sciences: The School of Humanities and Social Sciences at Jacobs University Bremen invites applications for a professorship in psychology in social psychology at the assistant or associate professor level. Applicants should have a specialization in social neuroscience or social cognition and/or judgment and decision-making. The successful candidate must hold a Ph.D. degree at the time of the application. He/she will contribute to teaching programs of the School of Humanities and Social Sciences, specifically to the undergraduate program, Integrated Social and Cognitive Psychology. In addition, he/she will be involved in the further development of the Bremen International Graduate School of Social Sciences (BIGSSS) and is expected to participate actively in one of the recently created research centers.

Salary and professorial rank will be commensurate with qualification and experience. The annual teaching load is three courses at three hours each. The language of instruction is English. The successful candidate shall begin in February 1, 2012. An initial contract will cover seven years and can be prolonged.

Applications should include one single PDF attachment containing a letter of motivation, copies of certificates and diplomas, curriculum vitae, a record of teaching, three exemplary publications, a statement on current and future research interests, and the names and addresses of three referees.

The Chinese University of Hong Kong (China), Department of Educational Psychology: Founded in 1963, The Chinese University of Hong Kong aspires to be acknowledged regionally and internationally as a first-class comprehensive research university marked for the bilingual and multicultural dimensions of its consistently excellent student education, scholarly output and contribution to the community. The University offers a broad spectrum of programs up to Ph.D. level in various disciplines and boasts a team of over 2,000 full-time teaching and research staff.

The Department invites applications for several positions with prospect for substantive appointments in counseling psychology, including school guidance, school/educational psychology, special needs and learning difficulties, and other areas of psychology. Ranks are open with preference given to assistant and associate professor levels.

Applicants should have (1) excellent academic qualifications including a doctoral degree in psychology or education, (2) a strong research background in areas that will contribute or add to the existing strengths of the Department, (3) strong commitment to excellence in teaching and scholarship, and (4) a track record of programmatic research and publications. The appointees will (1) teach postgraduate and undergraduate courses (including theory and applied courses for postgraduate degree programs), (2) supervise postgraduate students, and (3) assist in administrative matters. Both English and Chinese are used as the medium of instruction.

Further information about the Department is available at http://www.fed.cuhk.edu.hk/eps/.

Salary will be highly competitive, commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package, including medical care, plus a contract-end gratuity for appointments of 2 years, and housing benefits for eligible appointees. Further information about the University and the general terms of service for appointments is available at http://www.cuhk.edu.hk/personnel. The terms mentioned herein are for reference only and are subject to revision by the University.

Send full resume, copies of academic credentials, a publication list and/or abstracts of selected published papers, together with names, addresses and fax numbers/e-mail addresses of three referees to whom the applicants' consent has been given for their providing references (unless otherwise specified), to the Personnel Office, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong (Fax: +(852)2696-1462). The Personal Information Collection Statement will be provided upon request.

Sterling Medical Corporation (Japan): Two positions are currently available to work with children of American military families stationed in Japan as a clinical child psychologist. Full relocation and benefits are available with excellent compensation. Requirements include a doctorate degree in psychology from an APA-accredited program, an active license, and a minimum of two years pediatric psychology experience. Call Lynn Romer at (800) 852-5678 x 323 EST. Employer will assist with relocation costs. Additional Salary Information: Salary is negotiable at this time travel may be reimbursed.

US International University (Kenya), Clinical Psychology Program: USIU is a private, not-for-profit, chartered university located on the outskirts of Nairobi, Kenya, accredited by the Western Association of Schools and Colleges and The Commission for Higher Education in Kenya. USIU boasts a diversified faculty and student body from over 40 nations, with a vibrant history of growth and development.

We are expanding our psychology programs to offer our first doctorate degree in clinical psychology (PsyD), and we are also expanding our master of arts in psychology to include an MA in clinical psychology and an MA in marriage and family therapy.

We have four openings for full-time faculty who are licensed psychologists with an earned PhD or PsyD to start with us in September 2011 or early 2012, preferably with a two-year renewable contract. We seek faculty who meet three or more of the following criteria:

- Licensed clinical psychologists, who hold an earned doctorate in psychology.
- Direct clinical expertise to include assessment, diagnoses, psychotherapeutic treatment, and general scope of practice in individual and group therapy.
- Direct family therapy expertise with families, couples, and children.
- Academia/faculty experience in clinical psychology, preferably at the doctorate level.
- Clinical supervision experience and continuing education preferably with pre-doctorate or post-doctorate students, or with private practice consultation and supervision expertise.
- Psychometric expertise in application of objective, cognitive, and projective testing.
- Direct research experience and expertise in clinical psychology.

Applicants are requested to email a letter of interest and resume/curriculum vitae to Dr. Carol J. Watson, USIU Coordinator of Psychology Programs, E-mail: cwatson@usiu.ac.ke, Website: www.usiu.ac.ke.

Victoria University (New Zealand), School of Psychology: We have an exciting opportunity for an early-to-middle career academic to contribute to the School's teaching and research program in cognitive neuroscience. You will be expected to conduct research in one or more areas related to cognitive neuroscience (broadly interpreted), to provide teaching at undergraduate and postgraduate levels in cognitive psychology and cognitive neuroscience, and to supervise research students. In particular, you will be expected to contribute to teaching and research supervision in the Masters of Cognitive and Behavioural Neuroscience program.

You will possess a PhD in cognitive neuroscience and/or a related area, a demonstrated record of research publication in

this general area, a proven ability to teach psychology at university level, and a willingness to contribute to the administrative functioning of the School and the University. The term "cognitive neuroscience" will be interpreted to include any research program aimed at investigating human cognition, whether by conventional behavioral methods, eyetracking techniques, electrophysiological methods ERP, EEG, and TMS, neuroimaging techniques, or the study of special patient populations. For appointment within the senior lecturer range, you would also need to demonstrate an established record as an independent researcher and demonstrated success in postgraduate research supervision.

For more information and to apply online visit http://vacancies.vuw.ac.nz.

Victoria University (New Zealand), School of Psychology: Victoria University of Wellington, from its location in Wellington, the capital city, undertakes teaching and research to maintain, disseminate and advance knowledge. Victoria provides worldwide opportunities for its staff as members of the international network of scholars, scholarship, and research, providing diversity and depth to our perspectives. Internationally Victoria is recognized as a leading University in New Zealand and Australia, and as a world leader in a number of areas of scholarship and enquiry. The appointee will contribute to teaching at the undergraduate level, teach adult clinical psychology at the graduate level, supervise postgraduate research, and assist with the administration of the clinical program. Qualifications required include a PhD, a postgraduate qualification in clinical psychology and recent clinical practice experience, as well as evidence of successful teaching and research. Eligibility for registration as a psychologist under the Psychologists' Act (1981) is also required.

We are particularly interested in appointing someone with expertise in the following areas: adult mental health and psychological assessment. For more information and to apply online visit http://vacancies.vuw.ac.nz.

RMIT International University (Vietnam): RMIT International University Vietnam (RMIT Vietnam) is an integral part of RMIT University, a global university of technology and design, focused on creating solutions for the benefit of people and their environments. RMIT Vietnam is leading the way in creating an innovative research, teaching and learning culture. It is committed to providing internationally recognized high-quality education and professional training for its students, clients and members of the community. Since commencing operations in 2001, RMIT Vietnam has grown rapidly to a current student population of approximately 6,000 studying in Ho Chi Minh City and Hanoi.

RMIT Vietnam is seeking qualified staff for Ho Chi Minh City Campus for the position of Manager, Well-being and Counselling Services. The Manager is responsible for the delivery of services which support the mental and physical health and well-being of students and staff. The most significant component of this position is the function of Chief Psychologist or Counselor of RMIT Vietnam, managing the day to day operations of the RMIT Vietnam Counselling Service at all sites. In addition, this position will manage the relationship with external health care providers, including the provider of the on-campus medical services, develop and contribute to the Employee Assistance Program, and chair the Health, Safety, and Wellbeing Committee.

To obtain a copy of the position description visit www.rmit.edu.vn.

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Internationalizing the Teaching of Psychology by Using Emerging Social Media

A growing number of psychology instructors recognize the importance of incorporating a more global perspective in the courses they teach, especially as people become increasingly interconnected and interdependent with the growth of Internet-based technologies worldwide (Power & Velayo, 2006; Velayo, 2000).

Social media technologies provide opportunities that help internationalize the education and training experience of students. Blogs, wikis, Facebook, Google groups, LinkedIn, Twitter, YouTube, and Skype are among the more common web platforms used to enhance collaboration and sharing among learners. As a result, the instructor's role is changing more towards facilitation and mentoring in a collegial atmosphere supported by these kinds of technologies (Wankel, 2010).

Below is a list of the most common social media technologies with links to their main sites.

Blog (www.blogspot.com; www.blogger.com, http://wordpress.com)
Facebook (www.facebook.com)
Google Groups (http://groups.google.com)
LinkedIn (www.linkedin.com)
Second Life (http://secondlife.com)
Skype (www.skype.com)
Twitter (http://twitter.com)
Wiki (www.wikispaces.com; www.wikispaces.com; pbworks.com)
YouTube (www.youtube.com)

Psychology instructors may not use all of these technologies, but knowing what the technologies can do is important in determining which ones are useful for integrating a more international perspective in teaching. The proposed approach is not necessarily for the instructor to add or incorporate international content in a course, but to facilitate collaboration and engagement using social media technology to further student learning.

Why Use Social Media to Internationalize the Teaching of Psychology?

Now, widespread use of the Internet to educate and train students allows for a greater rate of knowledge sharing and understanding among people of various nations. Emerging social, cultural, environmental, and political issues impose complex challenges and demands on our discipline. There is a growing need to be responsive to the demands of a growing multiracial, multiethnic, and multinational network of people within the field. By promoting greater appreciation and understanding of people worldwide, instructors can efficiently internationalize teaching using these newer collaborative technologies.

As with many other disciplines, psychology has begun to tap into social media technologies to engage students and to provide them with the kind of "international experience" that would otherwise be relatively difficult, time-consuming, and more expensive with traditional approaches such as inviting a speaker from abroad, engaging in student travel abroad programs, or changing an established curriculum.

In general, students tend to be relatively more comfortable and more engaged with new technologies than their instructors. Technology savvy students can be wonderful allies to help instructors learn ways to effectively use these technologies in their courses. Students may even enjoy serving as collaborators to integrate such technologies in ways they think may be most engaging to their peers.

Some Strategies to Internationalize Teaching

For colleges and psychology departments to internationalize their curricula, faculty members need to find effective and creative ways to incorporate new material into their lesson plans (Grenwald-Mayes & Moore, 2000). Internet-based technologies continue to significantly impact the globalization of psychology in training and education, practice of psychology, and psychological research (Velayo, 2000). These technologies promise to be particularly relevant and effective pedagogical devices in internationalizing the psychology curriculum (Velayo, Oliva, & Blank, 2008).

Blogs and Wikis

Blogs are generally web pages that contain journal-like entries on any topic and can archive relevant comments from students and instructors around the world. Instructors can create a blog for students to share their international experiences in relation to course content.

For example, in a social psychology course, students can comment on various theories of interpersonal attraction given their own unique experiences. They may be required to ask someone they know from another country to do the same. Such blogs can generate interesting discussions and a realization that there are cross-national differences in what others consider attractive.

In another example, students, and even professionals, from different cultures or nations could discuss whether a particular behavior or belief is *emic* (culture specific) or *etic* (culture neutral). Instead of lecturing or providing notes, it may be more effective if material were gathered in a blog for discussion. The instructor, and students could read the comments and contribute to an enhanced discussion given the myriad of interesting responses.

Wikis are generally web pages in which students work collaboratively online. For example, a student group in a psychotherapy course could collaboratively work on a web page or write on the topic of cultural differences in treating depression. Students could continually comment and revise the page. It would be interesting to have them ask other students taking a similar course in another country to also comment and/or collaboratively work on the web page.

Social Networking Sites

Social networking sites (e.g., Facebook, LinkedIn, and Google groups) are commonly used Internet-based media that allow people with similar interests to find, interact, and share ideas and resources with each other.

For example, an instructor in research methods can create a Facebook group as a way for students to interact and post updates of their research work for others to see. Students can also solicit

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comments from others and collect survey data online by tapping into the huge number of Facebook members who wish to respond.

Research can also be done with other social networking sites such as LinkedIn and Google groups. Several features in these sites allow an instructor to tailor the sites to the course. For instance, the instructor can restrict access to specified information on a page to certain individuals.

An eye-opening and engaging way to get students to learn another culture in a developmental psychology course is to create a Facebook community page designed around cross-national differences in child-rearing practices.

Twitter

Twitter is a microbloging technology that allows one to send and receive messages, usually through some mobile device, in which each message (or tweet) is no more than 140 characters. In addition to text, Twitter can now contain embedded photos, videos, and other media. A day or two prior to each class session, the instructor can send students a "tweet" such as a brief description of a current world event related to the topic to be discussed. In a community psychology course, for example, tweet to students, "Hurricane destroys homes in Haiti! What can psychologists do to help the community affected by this disaster?" Presumably, this will prompt students to think about the topic prior to class and be prepared to share their thoughts in the context of other cultures or countries.

Skype and YouTube

Using Skype for videoconferencing or showing talks or interviews that have been recorded on YouTube can be an interesting student project. Guest experts from other countries may wish to show relevant locations or some psychosocial phenomenon in another country. For example, in a History of Psychology course, instructors may use Skype or even record interviews of other psychologists, go on a virtual tour of a historical location relevant to psychology, or perhaps show a collection of psychology paraphernalia that are part of an archival collection of psychology instruments. Using Skype may even allow students to interact with the guest. Recorded footage made available on YouTube can be used for future class discussions and presentations.

In another example, a comparative study in a cross-cultural psychology course could require students to virtually observe the family dynamics in different cultures and directly inquire about the participants' points of view through video clips posted on YouTube. Subsequently, students could organize all information online to share for discussion.

By using these technologies, instructors can archive correspondences and make them available for future instructional use. The rising use of Internet-based technologies is opening new avenues for teaching international materials (Takooshian & Velayo, 2004; Velayo, Oliva, & Blank, 2008). These technologies contribute to the growing number of resources that instructors may use for course development. Such resource clearinghouses may be accessed through the APA Division of International Psychology website at http://internationalpsychology.net/resources/ (e.g., Stevens, 2007) and from APA's Society for the Teaching of Psychology Office of Teaching Resources in Psychology (OTRP) at http://teachpsych.org/otrp/resources/resources.php? category=International Psychology (e.g., Woolf, Hulsizer, & McCarthy, 2002a, 2002b).

A Way to Assess If a Psychology Course is Internationalized

A report from the APA Working Group on Internationalizing the Psychology Curriculum (Lutsky, Torney-Purta, Velayo, Whittlesey, Woolf, & McCarthy, 2005) may be used to assess the extent to which a psychology course is "internationalized." The authors of the report recommended five goals and associated learning outcomes: psychological knowledge in international perspective; methodological issues in international research; the discipline of psychology in the international perspective (i.e., awareness of how the discipline of psychology is developed, studied, and applied in and across cultures); psychology and interpersonal understanding; and psychology and global issues. The report also provides suggested student learning outcomes for each goal to assist with course design and for use as a checklist to assess the effectiveness of the strategies at the end of the course.

Innovative ways to utilize social media technologies as pedagogical and training tools need to be further explored. Not only do these technologies allow for greater and faster communication between psychologists and students residing in different nations and different regions within a country but they also provide for greater cross-national understanding, increased curricular and scholarly collaborations, and enhanced level of experience that goes beyond just reading about another culture. Such transformation necessitates changes to the broader psychology curriculum and requires assessment on a regular basis to determine whether students have sufficiently obtained a level of international perspective and knowledge base.

There is no doubt that currently used and emerging internet-based technologies shall continue to contribute significantly to the globalization of psychology, in general, and the psychology curriculum in particular.

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Submission Guidelines for
Research Articles
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Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.

Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

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International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

Submission Deadlines: Spring issue March 31st

Summer issue July 31st

Fall issue September 15th

Winter issue December 15th

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Presidential Column

John D. Hogan, PhD
President, Division 52

Greetings to everyone. I'm pleased to report that we had a very productive mid-winter meeting in Cambridge, MA, from March 10-12, in conjunction with the annual meeting of the Eastern Psychological Association (EPA). Thanks to Harold Takooshian and others, we've built a strong relationship with EPA over the years. We even shared a coffee break with their Executive Board during our own Board meeting. We are particularly grateful to Fred Bonato, the EPA Executive Officer, and Diane Finley, the Chair of the EPA Program Committee, for their hospitality.

The lead EPA speaker this year was Elizabeth Loftus who presented an enthralling opening address as she reviewed her research on "manufacturing memories" to a crowded ballroom. Of course, our Division had its own two-days of well-attended programming blended into the larger convention. Among the programs we presented were sessions on international publishing opportunities, the United Nations, internationalizing the psychology curriculum, disaster relief, and psychology in Russia today. We continue to develop a relationship with Psi Chi, the (now) International Honor Society in Psychology. We even shared a session with them in which we addressed issues related to becoming an international society.

The Div. 52 Board meeting was held on Thursday afternoon from 12 noon to 5pm. Our Board meetings always remind me of what an active and wide-ranging division we are. I've listed a few of the highlights of the meeting in the following paragraphs.

Early in the meeting we learned that our financial health is strong, thanks in large part to the excellent treasurers we have had through the years. The term of Michael Stevens, our current treasurer (and past-president), will end this year and he has decided not to seek another term. We owe him an enormous debt for the service he has given to the division. His will be a hard act to follow.

After finances, we discussed another priority – membership – an important issue that is not confined to our division. The membership of APA is aging and, although we have received some mixed messages, it is clear that the organization is not enrolling new and younger members at the level it thinks it should. We believe our division has a great deal to offer students and ECPs (Early Career Psychologists) and we are determined to become more proactive in welcoming them to the division.

Division President-elect Neal Rubin made several proposals to address our membership concerns. Among them, he proposed two changes to the bylaws. The first proposal is that we establish a position for a student representative on our Board, with voting privileges. The second is that we agree to set aside one of our member-at-large board positions for an early career psychologist. Both proposals were accepted unanimously by the Board and will be presented to the membership for their vote. (See elsewhere in this issue for further clarification of the proposed change in bylaws.) Our thanks, as always, to Joy Rice, member-at-large and past president, who guided us through the process of clarifying the bylaws and arranging the vote from the membership.

The Board agreed to rename our international mentoring award in honor of Henry David, one of the founding members of the Division. Henry, who died on December 31, 2009, at age 86, is best known for his international contributions to population issues, women's issues, and mental health. A warm and gentle man, he received a number of honors from APA in the past including the APA Award for Distinguished Contributions in the International Advancement of Psychology (1992) and the APF Gold Medal Award for Life Achievement in Psychology in the Public Interest (2001). We are so grateful that Henry was part of our lives and the life of our Division. We're pleased to honor him in this small way.

Our program for the APA Convention in Washington, DC (August 4-7, 2011), looks strong, thanks to our program chairs, Senel Poyrazli and Mark Terjesen. They reported that we received 25 paper submissions, 92 poster submissions, and 22 symposia for the Convention. Because of the limited number of program hours allotted to us, many of the submissions had to be rejected. Fortunately, some of the papers could be turned into posters and were accepted on that basis. We will be hosting a suite at the convention again this year and we will be able to use it for some additional programming. But I hope that many of you will make use of it for purely social purposes as well, and come by for a visit during the convention.

As always, I welcome any comments and/or concerns you might have regarding the Division. You can reach me at hoganjohn@aol.com I hope to see you in Washington in August!

Best wishes, John

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International Programs @ WPA 2011
At a Glance!

	Thursday April 28, 2011	Friday April 29, 2011	Saturday April 30, 2011	Saturday April 30, 2011 *Concurrent Programs
8:00-8:15		Symposia (Westwood Rm): ***Global Disasters and Trauma: Preparation, Coping, and Psychosocial Responses*** Chair: Roxane Cohen Silver, University of California, Irvine Discussant: E. Alison Holman	Symposia (Fernwood Rm): ***International Immersion Learning Experiences in Higher Education: Program Outcomes and Recommendations*** Chair: Lynette H. Bikos, Seattle Pacific University Discussant: M.C. Gilberto Manuel Galindo, Universidad Autónoma de Baja California	
8:15-8:30				
8:30-8:45				
8:45-9:00				
9:00-9:15				Invited Presentation (Golden State Rm): ***Intimate Partner Violence: A Global Mental Health Priority*** Gaithri Fernando, California State University, Los Angeles
9:15-9:30				
9:30-9:45				
9:45-10:00		Symposia (Westwood Rm): ***Four Research Reports from a Summer Research Training Program on Latino Mental Health in Puebla, Mexico*** Chair: Steven R. Lopez, University of Southern California		
10:00-10:15				
10:15-10:30				
10:30-10:45				Invited Presentation (Golden State Rm): ***Making Culture Usable for a Scientific Social Science by Unweaving its Rainbow.*** Michael Harris Bond, Hong Kong Polytechnic University.
10:45-11:00				
11:00-11:15				
11:15-11:30				
11:30-11:45		Symposia (Westwood Rm): ***Addressing Hawai`i in Theories of Culture, Dating, and Microaggressions.*** Chair & Discussant: Alyson L. Burns-Glover, Pacific University Oregon	Symposia (Fernwood Rm): ***Beyond Borders: Recognizing the Validity of Psychologies Across National Lines*** Chair: Jason J. Platt, CSPP at Alliant International University	
11:45-12:00				
12:00-12:15				
12:15-12:30				
12:30-12:45				
12:45-1:00				
1:00-1:15				

International Programs @ WPA 2011
At a Glance!

	Thursday April 28, 2011	Friday April 29, 2011	Saturday April 30, 2011	Saturday April 30, 2011 *Concurrent Programs
1:15-1:30			Symposia (Fernwood Rm): ***International Perspectives on Positive Psychology*** Chair & Discussant: Douglas C. Smith, Southern Oregon University	
1:30-1:45				
1:45-2:00				
2:00-2:15				E.E. Jones Award Presentation (Rosewood Rm): ***How Do We Culturally Adapt Psychotherapy? Let's Get Down to the Specifics***. Wei-Chin Hwang, Claremont McKenna College & Independent Practice
2:15-2:30				
2:30-2:45				
2:45-3:00		Symposia (Fernwood Rm): ***Challenges in Conducting Cross-Cultural Research: Professional and Student Perspectives*** Chair: Eric L. Kohatsu, California State University, Los Angeles		
3:00-3:15	Symposia (Westwood Rm): ***Threats to Family Wellness in Immigrant Communities: Hopes and Challenges.*** Chair: Marcel Soriano, California State University, Los Angeles		Symposia (Fernwood Rm): ***Mixed Methodologies and Multigroup Structural Equation Modeling in Cultural and Health Research*** Chair: Patricia Flynn, Loma Linda University	
3:15-3:30				
3:30-3:45				Poster Session: International Psychology (Wilshire Rm). 50 posters!
3:45-4:00				
4:00-4:15				
4:15-4:30				
4:30-4:45				
4:45-5:00			Symposia (Fernwood Rm): ***Family Conflict and Sociological Imagination in Mexican Immigrant Families*** Chair: Carrie L. Saetermoe, California State University, Northridge Discussant, Gabriela Chavira	
5:00-5:15				
5:15-5:30				
5:30-5:45				
5:45-6:00				
6:00-6:15				
6:15-6:30				
6:30	**Saturday 6:30pm, lobby:** Interested in socializing with other psychologists/psychology students who are interested in international issues? Please RSVP in advance to Lynette Bikos (lhbikos@spu.edu), or alert one of Saturday's International Programming Hosts so that we can get a count and make reservation at a restaurant that will accommodate all of us.			

International Programming: A Pre-Conference Primer Western Psychological Association Los Angeles, CA April 28 – May 1, 2011

Invited Presentations

Intimate Partner Violence: A Global Mental Health Priority
Presenter: Gaithri Fernando, California State University, Los Angeles
Saturday, 9:00-10:00 Golden State

Making Culture Usable for a Scientific Social Science by Unweaving its Rainbow
Presenter: Michael Harris Bond, Hong Kong Polytechnic University
Saturday, 10:30-11:30 Golden State

How Do We Culturally Adapt Psychotherapy? Let's Get Down to the Specifics
Presenter: Wei-Chin Hwang, Claremont McKenna College & Independent Practice
Saturday, 2:00-3:00 Rosewood

Symposia

Threats to Family Wellness in Immigrant Communities: Hopes and Challenges
Chair: Marcel Soriano, California State University, Los Angeles
Thursday, 3:00-4:30 Westwood

UNDERSTANDING TREATMENT NEEDS OF A TRAUMATIZED POPULATION: POLITICAL ASYLUM SEEKERS, *Audrey Ham (CSU Los Angeles)*

PROMOTING FAMILY WELLNESS IN IMMIGRANT COMMUNITIES: PSYCHOLOGISTS AS CHANGE AGENTS, *George K. Hong (CSU Los Angeles)*

DUAL STATUS LATINO FAMILIES: DETENTION/ DEPORTATION IMPACT ON FAMILY WELLNESS, *Marcel Soriano (CSU Los Angeles)*

GANGS: A THREAT TO THE WELLNESS OF ASIAN AMERICAN FAMILIES, *Stephen Cheung (Azusa Pacific University)*

Global Disasters and Trauma: Preparation, Coping, and Psychosocial Responses
Chair: Roxane Cohen Silver, University of California, Irvine
Discussant: E. Alison Holman
Friday, 8:00-9:30 Westwood

POST-DISASTER OUTCOMES ASSOCIATED WITH THE 2010 CHILEAN EARTHQUAKE, *Dana R. Garfin, Roxane Cohen Silver, (University of California, Irvine), Francisco Ugalde Bilbao & Heiko Linn (Universidad Andrés Bello)*

PREPARATION TYPE MATTERS: IMPLICATIONS FOR TARGETING POPULATIONS FOR PERSONAL PREPAREDNESS FOR NATURAL DISASTERS, *Kristen L Gamble, Roxane C. Silver, Dana Garfin, Scott Blum (University of California, Irvine) & Michael Poulin (University of Buffalo)*

POST TRAUMATIC STRESS AMONG INDONESIAN CHILDREN: THREE YEARS AFTER A MAJOR EARTHQUAKE, *Edwin T. Tan (University of California, Irvine), Conor Seyle (Psychology Beyond Borders), C. Siswa Widyatmoko (Universitas Sanata Dharma), Suman Lam & Roxane Cohen Silver (University of California, Irvine)*

EMOTIONAL SUPPRESSION, PROBABLE POST-TRAUMATIC STRESS DISORDER, AND THE CORTISOL AWAKENING RESPONSE FOLLOWING EXPOSURE TO REPEATED NATURAL DISASTERS, *Suman Lam (University of California, Irvine), D. Conor Seyle (Psychology Beyond Borders), C. Siswa Widyatmoko (Universitas Sanata Dharma), Edwin Tan & Roxane Cohen Silver (University of California, Irvine)*

DYADIC DISTRESS IN THE FAMILY: THE INTER-DEPENDENCE BETWEEN PARENTAL AND CHILD RESPONSES FOLLOWING A NATURAL DISASTER IN INDONESIA, *Vanessa Juth, Roxane Cohen Silver (University of California, Irvine), Conor Seyle (Psychology Beyond Borders), Edwin Tan (University of California, Irvine), Siswa Widyatmoko & Suman Lam (Sanata Dharma University, University of California, Irvine)*

Four Research Reports from a Summer Research Training Program on Latino Mental Health in Puebla, Mexico
Chair: Steven R. Lopez, University of Southern California
Friday, 9:45-11:15 Westwood

NORMATIVE DIFFERENCES IN THE U.S. WAIS-III AND SPANISH LANGUAGE ADAPTATIONS, *Cynthia M. Funes (Georgia State University), Juventino Hernandez Rodriguez (Arizona State University) & Steven R. Lopez (University of Southern California)*

INCREASING PSYCHOSIS LITERACY OF SPANISH-SPEAKING ADULTS IN MEXICO, *Erendira Aldana (California State University, Long Beach), Edlin Gonzalez (Columbia Teachers College) & Steven Lopez (University of Southern California)*

ATTRIBUTION-AFFECT-HELPING MODEL IN SCHIZOPHRENIA: PATIENT AND CAREGIVER PERSPECTIVES, *Yu T. Wang (University of California, Los Angeles), Bianca Villalobos, (CSU Channel Islands), Darcy Alcántara, (University of Massachusetts, Boston) & Steven R. López (University of Southern California)*

HACIA UN PUNTO DE VISTA DIÁDICO DE EMOCIÓN EXPRESADA / TOWARDS A DYADIC VIEW OF EXPRESSED EMOTION, *John P. Keefe (University of Southern California), Denisse Tiznado (San Diego State University), Evelyn Mendoza (California State University, Los Angeles), Cristina Medina (Autonomous University of Barcelona) & Steven R. Lopez (University of Southern California)*

Addressing Hawai`i in Theories of Culture, Dating, and Microaggressions
Chair & Discussant: Alyson L. Burns-Glover, Pacific University Oregon
Friday, 11:30-1:00 Westwood

THE HAWAIIAN EXPERIENCE OF

MULTICULTURALISM AND MICROAGGRESSIONS, *Elinor Marie P. Butay, Chelsea Y. J. Wong & Alyson Burns-Glover (Pacific University Oregon)*

INTERETHNIC DATING: CULTURAL

ORIENTATIONS AND DATING CHOICES, *Christopher Ferrante & Jordana Ferreira*

KOKO OR CULTURE? RACE, ETHNICITY, CULTURE AND DATING IN HAWAI'I, *Jasmine Eugenio, & Alyson Burns-Glover (Pacific University Oregon)*

Challenges in Conducting Cross-Cultural Research: Professional and Student Perspectives
Chair: Eric L. Kohatsu, California State University, Los Angeles
Friday, 2:45-4:15 Fernwood

CASE EXAMPLES OF CROSS-CULTURAL RESEARCH, *Eric L. Kohatsu, Shizue Mizukami, Patricia Singim, Kayin Ho, Marlene Gonzalez, Monique Ervin, Aaliyah Muhammad & Stacy Scates (California State University, Los Angeles)*

PROBLEMATIC ISSUES IN RESEARCH, *Eric L. Kohatsu, Shizue Mizukami, Patricia Singim, Kayin Ho, Marlene Gonzalez, Monique Ervin, Aaliyah Muhammad & Stacy Scates (California State University, Los Angeles)*

LEARNING CROSS-CULTURAL RESEARCH: AN ANALYSIS OF STUDENT EXPERIENCES, *Shizue Mizukami, Patricia Singim, Kayin Ho, Marlene Gonzalez, Monique Ervin, Aaliyah Muhammad, Stacy Scates & Eric L. Kohatsu (California State University, Los Angeles)*

International Immersion Learning Experiences in Higher Education: Program Outcomes and Recommendations
Chair: Lynette H. Bikos, Seattle Pacific University
Discussant: M.C. Gilberto Manuel Galindo, Universidad Autónoma de Baja California
Saturday, 8:00-9:30 Fernwood

ADVOCACY FOR INTERNATIONAL IMMERSION LEARNING EXPERIENCES IN DOCTORAL PSYCHOLOGY CURRICULA, *Kim H. Huynh, Kara L. Pegram, Nicola F. De Paul & Lynette H. Bikos (Seattle Pacific University)*

OUTCOMES ASSOCIATED WITH UNDERGRADUATE-LEVEL INTERNATIONAL INTERNSHIPS, *Kari Knutson Miller (California State University, Fullerton), Amber M. Gonzalez (University of California Santa Barbara), Ashleigh Bauserman, Megan C. Mclaughlin & Peggy B. Shoar (California State University, Fullerton)*

DEVELOPING MEANINGFUL CROSS-CULTURAL EXCHANGE EXPERIENCES: A STUDENT AND FACULTY PANEL DISCUSSION, *Sherri McCarthy (Northern Arizona University - Yuma), Alfredo Padilla Lopez (Universidad Autonoma de Baja California), Albertina Aros (Northern Arizona University - Yuma) & Susanna M. Pino Velazquez (Arizona Western College)*

Beyond Borders: Recognizing the Validity of Psychologies Across National Lines
Chair: Jason J. Platt, CSPP at Alliant International University
Saturday, 11:30-1:00 Fernwood

CRITICAL PATRIOTISM: EXPLORING NATIONALITY IN PSYCHOLOGY EDUCATION, *Jason J. Platt (Alliant International University)*

RECLAIMING HUMANITY: IDEAS FROM LIBERATION AND LATIN AMERICAN PSYCHOLOGIES, *Jason J. Platt (Alliant International University)*

BEYOND BORDERS: RECOGNIZING THE VALIDITY OF PSYCHOLOGIES ACROSS NATIONAL LINES, *Tatiana Glebova (Alliant International University)*

International Perspectives on Positive Psychology
Chair & Discussant: Douglas C. Smith, Southern Oregon University
Saturday, 1:15-2:45 Fernwood

This symposium will feature both research and practice efforts with cross-national or international samples in the areas of psychological health and well being, resiliency, vitality, emotional intelligence, mindfulness, and related areas of positive psychology. Speakers will report on the development of a multi-dimensional scale to measure positive traits and dispositions in adolescents and young adults and will discuss comparative research conducted in the Untied States and in Japan. Additionally, research on emotional intelligence, self-esteem, self-confidence and social adaptation comparing adolescents from Barcelona –Spain

and Mexicali –Mexico will be reported and discussed. Finally, the symposium will present research exploring the efficacy of mindfulness meditation for aging adults and its effects on self-esteem, self-awareness and a more positive perception of themselves.

Mixed Methodologies and Multigroup Structural Equation Modeling in Cultural and Health Research
Chair: Patricia Flynn, Loma Linda University
Saturday, 3:00-4:30 Fernwood

MULTIGROUP STRUCTURAL EQUATION MODELING IN CULTURAL RESEARCH: FATALISM, EMOTIONS AND SCREENING, *Patricia Flynn (Loma Linda University)*

LATINO AND ANGLO WOMEN'S CULTURAL STEREOTYPES ABOUT HEALTHCARE PROFESSIONALS, *Jael Amador, Troy Davis & Patricia Flynn (Loma Linda University)*

CULTURE AND DIABETES TREATMENT ADHERENCE AMONG MAPUCHE AND MAINSTREAM CHILEANS, *Manuel Ortiz (Universidad de La Frontera, Chile / University of California, Los Angeles), Tamara Hernandez (Universidad de La Frontera, Chile), Jaime Silva (Universidad de La Frontera, Chile), Pablo Vera-Villaroel (Universidad de Santiago, Chile) & Hector Betancourt (Universidad de La Frontera, Chile / Loma Linda University)*

CULTURAL AND PSYCHOLOGICAL FACTORS IN HEALTH DISPARITIES: AN INTEGRATING MODEL, *Hector Betancourt (Loma Linda University & Universidad de La Frontera, Chile)*

Family Conflict and Sociological Imagination in Mexican Immigrant Families
Chair: Carrie L. Saetermoe, California State University, Northridge
Discussant, Gabriela Chavira
Saturday, 4:45-6:15 Fernwood

FAMILIES AND SOCIOLOGICAL IMAGINATION: BACKGROUND AND METHOD, *Carrie L. Saetermoe (CSU Northridge)*

FAMILIES AND SOCIOLOGICAL IMAGINATION: SYNTHESIS, *Carrie L. Saetermoe (CSU Northridge)*

EXAMINING FAMILIAL CONFLICT AND ACADEMIC MOTIVATION OF MEXICAN IMMIGRANT PARENTS, *Carrie Saetermoe (CSU Northridge), Katie Young (UC Davis/CSU Northridge) & James Garcia (CSU Northridge)*

ACADEMIC MOTIVATION WITHIN FAMILIAL CONTEXT OF MEXICAN IMMIGRANT FAMILIES, *Carrie Saetermoe (CSU Northridge), Kaitlyn Young (UC Davis/CSU Northridge) & James Garcia (CSU Northridge)*

Interested in socializing with other psychologists/psychology students who are interested in international issues? If so, we can meet Saturday, 6:30pm in the lobby. Please RSVP in advance to Lynette Bikos (lhbikos@spu.edu), or alert one of the Saturday's International Programming Hosts so that we can get a count and make reservation at a restaurant that will accommodate all of us.

Posters: International Psychology, Social Issues 1
Saturday, 3:30-4:45 Wilshire

19-1 INTER-ETHNIC DATING AND NATIVE HAWAIIANS: ALOHA, HISTORY AND MULTICULTURALISM, *Jasmine Eugenio, Jordana Ferreira, Christopher Ferrante, Alyson L. Burns-Glover & Alicia Kepa (Pacific University Oregon)*

19-2 RAPE MYTH ACCEPTANCE AND RELIGIOSITY, TRADITIONALISM, & PARENTAL IMMIGRANT STATUS, *Cheryl Groskopf & Heidi R. Riggio (CSU Los Angeles)*

19-3 CHANGE IN THE MEANING OF DATING AND MARRIAGE OF TURKISH GRADUATE STUDENTS: DOES GENDER PLAY A ROLE?, *Raquel Delevi (CSU Los Angeles)*

19-4 OVERLOOKED CHALLENGES OF INTERNATIONAL PSYCHOLOGY STUDENTS, *Kin Cheung Lee (CSPP at Alliant International University)*

19-5 VALUES EXTOLLED IN INDIAN INDEPENDENCE DAY PRIME MINISTERIAL ADDRESSES, *David Hauser & Richard Kinnier (Arizona State University)*

19-6 EXPLORING THE ACHIEVEMENT/ ADJUSTMENT PARADOX IN BRITISH-CHINESE UNIVERSITY STUDENTS, *Jacqueline Lee Tilley (University of Southern California) & Ruth Kershner (University of Cambridge)*

19-7 AN ANALYSIS OF NATIONAL FOOTBALL LEAGUE'S SPECTATOR BEHAVIOR IN CHINA, *Yiu-Ni Judy Chen, Mathew Curtis (University of Southern California) & Doug Stenstrom (California State University, Los Angeles)*

19-8 CULTURAL COMPETENCY EDUCATION: LATINO CULTURE AND SPANISH LANGUAGE IMMERSION TRAINING, *Janese Olalde, John K. Miller (University of Oregon) & Jason J. Platt (Alliant International University Mexico Campus)*

19-9 INTERNATIONAL RELOCATION AND REPATRIATION EFFECTS ON FAMILY IDENTITY, *Kelsey Getz, Jenna Dumpit, Anna Taylor & Deborah Wiese (Whitman College)*

19-10 CORRELATES OF MARRIAGE AND DIVORCE RATES IN 86 COUNTRIES, *Cornelia Brentano, Christian Ducree, Claudia Flores & Martha Yepez (California State University, Dominguez Hills)*

19-11 THE ROLE OF LOR AND AGE OF ARRIVAL ON ACCULTURATION, *Dan Airth, Chi-Ah Chun, James Amirkhan & Young-Hee Cho (CSU Long Beach)*

19-12 TOWARDS A THEORY OF HEALTH BEHAVIOR CHANGE FOR THE DEVELOPING WORLD, *Kaile Brake, Trina Demirer, Christian Washburn, Sonya Gotts, Charles Kirkwood, Marzieh Forghany & Suni Petersen (CSPP at Alliant International University)*

19-13 IMPACT OF CIVIL WAR: TRAUMA IN SOUTHERN SUDAN, *Chad Houchin, Rodger K. Bufford, Rusty Smith, Heather Mackay (George Fox University) & George Rhoades (GAiN Canada)*

19-14 IMPACT OF NATURAL TRAUMA: HAITI'S 2010 EARTHQUAKE, *Kristie Knows-His-Gun, Rodger K. Bufford, TaJuana Wade, Chad Houchin (George Fox University) & George Rhoades (GAiN Canada & Ola Hou Clinic)*

19-15 HEALTH LOCUS OF CONTROL AMONG NEPALI CHILDREN, *Jessica L. Petzold (San Diego State University), Rina M. Sobel (SDSU/UCSD Joint Doctoral Program in Clinical Psychology), Vanessa L. Malcarne (San Diego State University; SDSU/UCSD Joint Doctoral Program in Clinical Psychology; Rebecca & John Moores UCSD Cancer Center), Geargia Robins Sadler (Rebecca & John Moores UCSD Cancer Center) & Amanda Mia Marin (San Diego State University)*

19-16 COMPARISON OF THE POSITIVITY EFFECT IN US AND AFGHANISTAN, *Christie Chung & Frishta Sharifi (Mills College)*

19-17 LANGUAGE PROFICIENCY AND INTERCULTURAL ADAPTATION, *Victor Savicki (Western Oregon University) & Maria Nelida de Juano (Universidad Nacional de Rosario)*

19-18 EVOLVING BUSINESS ETHICS IN EASTERN EUROPE, *John Kantor (CSPP at Alliant University) & Michelle Kantor (University of San Diego)*

19-19 PERCEPTIONS OF RACIAL MICROAGGRESSIONS ON UNDERGRADUATE COLLEGE CAMPUSES, *Arlyn Madsen-Bond (Scripps College)*

19-20 THE FORMATION AND EFFECTS OF MULTIRACIAL IDENTITY, *Allyson Yuen (Whittier College)*

19-21 FRIENDS, FACEBOOK, AND OTHER SOCIAL NETWORKS, *Ian Roberson (California State University, Fullerton)*

19-22 COLLEGE STUDENTS ATTITUDES TOWARD ALCOHOLICS, *Elizabeth Bandy (Dominican University of California)*

19-23 THE ROLE OF ORGANIZATIONAL NETWORKS ON STUDENT MOBILIZATION IN ORANGE COUNTY, CA, *Burrel J. Vann, Jr. (California State University, Fullerton)*

19-24 RELIGION AND PSYCHOSIS: PERCEPTIONS OF RELIGIOUS BELIEFS, *Julie Stevenson (Dominican University of California)*

19-25 ADOLESCENTS WITH GAY, LESBIAN, OR HETEROSEXUAL PARENTS: STIGMATIZATION AND FUNCTIONING, *David Mendelsohn & Allen Omoto (Claremont Graduate University)*

19-26 EFFECTS OF FRAMING: CULTURAL VS. MORAL DIVERSITY ON INTERGROUP BIAS, *Nicole Nordello & Azenett A. Garza (Weber State University)*

19-27 WHAT MAKES YOUR WORLD PERFECT? AN EXAMINATION OF MILITARY PERSONNEL, *Joshua Lewandowski & Benjamin Rosenberg (Claremont Graduate University)*

19-28 PREDICTING ATTITUDES TOWARD AFFIRMATIVE ACTION WITH PERCEIVED POLICY PRACTICES, *Leah Ozeroff & Chris Aberson (Humboldt State University)*

19-29 THE ROLE OF THREAT IN ATTITUDES TOWARD SAME-SEX MARRIAGE, *James P Clifton & Christopher L. Aberson (Humboldt State University)*

19-30 THE IMPACT OF PARENTAL DIVORCE ON OFFSPRINGS' ADULT ROMANTIC RELATIONSHIPS, *Genevieve V. Lam & Connie Shears (Chapman University)*

19-31 THE LINKS BETWEEN BODY DISSATISFACTION AND RELATIONSHIP SATISFACTION, *Amelia S. Moghaddam Jafary & David A. Frederick (University of California, Los Angeles)*

19-32 SENSATION SEEKING AND IMPULSIVITY AS PREDICTORS OF ADOLESCENTS RISK TAKING, *Meagen A. Higgins & David V. Chavez (California State University, San Bernardino)*

19-33 THE EFFECTS OF PRIMING STEREOTYPES ON JUROR ATTENTION AND MEMORY, *Kristen Adams, Dayna Gomes & Douglas Senstrom (California State University, Los Angeles)*

19-34 TEXT MESSAGING VS. TALKING BETWEEN GENDERS, AND PERCEPTIONS OF SUCCESS, *Tiffani Lewis & Diana Kyle (Fullerton College)*

19-35 ADULT DAY CARE UTILIZATION AND CAREGIVER WELL-BEING AMONG ASIAN AND NON-ASIAN AMERICANS, *Stephanie R. Ramirez & Laura Zettel-Watson (California State University, Fullerton)*

19-36 SEX TRAFFICKING: KNOWLEDGE AND ATTITUDES OF SOUTHERN CALIFORNIA COLLEGE STUDENTS, *Susan L. Nelson (University of California, Irvine) & Stacy J. Bacigalupi (Mount San Antonio College)*

19-37 HAWAIIAN EXPERIENCE OF MICROAGGRESSIONS: DEVELOPING THE CONCEPT OF AMBASSADOR FATIGUE, *Elinor Marie P. Butay, Chelsea Y. J. Wong & Alyson Burns-Glover (Pacific University Oregon)*

19-38 EFFECT OF CULTURAL SENSITIVITY IN AN IMMERSED ABROAD EXPERIENCE, *Christina Keys, Paul Neis, Tim Hall & Holly Irwin-Chase (Point Loma Nazarene University)*

19-39 PREDICTORS OF SELF-PERCEIVED CULTURAL COMPETENCE IN MENTAL HEALTH PROVIDERS, *Victoria Keyser, Glenn C. Gamst, Aghop Der-Karabetian (University of La Verne) & Gloria Morrow (Private Practice)*

19-40 NATIVE AMERICAN SPIRITUALITY AND NONVIOLENCE: EMPIRICAL RELATIONSHIPS, *Michelle L. Cutfinger, M. Zachary Brink, Kayla D. Burke, Jessica A. Berghammer, Amber L. Stafford, Elaine B. Dufford & Daniel M. Mayton II (Lewis Clark State College)*

19-41 A SOCIAL RELATIONSHIPS INTERVENTION PROGRAM FOR BULLYING: LIFESKILLS ADVENTURE DAY, *Alyson Burns-Glover, Leah Kresse, Scott Imanaka, Aes Ferrer & Jayson Fukumoto (Pacific University Oregon)*

19-42 GENERATIONAL DIFFERENCES OF EUROPEAN IDENTITY IN CENTRAL AND EASTERN EUROPE, *Natalia Waechter (Institute for Advanced Studies, Vienna)*

19-43 A PROGRAM ASSESSMENT OF LOCAL SERVICES FOR HUMAN TRAFFICKING VICTIMS, *Brianna Hodge & Andrew Downs (University of Portland)*

19-44 RELIGION AND EMOTIONS, *Heather L. Porter & Diane J. Pfahler (Crafton Hills College)*

19-45 COMMUNITY VIOLENCE EXPOSURE IN HMONG YOUNG ADULTS, *Susan Her & Greg M. Kim-Ju (Calfornia State University, Sacramento)*

19-46 CULTURAL COMPETENCY: AN UNATTAINABLE GOAL, *Patricia Kyle & Paul Murray (Southern Oregon University)*

19-47 ATTITUDES TOWARD ARRANGED MARRIAGE: COURTESY BIAS?, *Zeenath Bozorgmehr & T.L. Brink (Crafton Hills College)*

19-48 EXAMINATION OF SUICIDALITY AMONG MILITARY SERVICE MEMBERS, *Katherine Fox, Katie Diershaw & Samantha Forsythe (Pacific University Oregon)*

19-49 CLIMATE CHANGE DENIERS: ROLE OF AVOIDANCE DENIAL AND POLITICAL IDEOLOGY, *Suzanne Thompson (Pomona College), Danielle Manning (Claremont McKenna College) & Alexandra Cone (Pomona College)*

19-50 MATURE CINEMATIC CONTENT FOR IMMATURE MINDS, *Lauren Elizabeth Skidmore (California State University, San Bernardino), Dean Keith Simonton (University of California, Davis) & James C. Kaufman (California State University, San Bernardino)*

This pre-conference summary is prepared by Lynette H. Bikos, Ph.D., Division 52/International Psychology Western Region Outreach Chair, lhbikos@spu.edu.

To join D52, visit the membership page of the Division's website: http://www.itopwebsite.com/InternationalPsychology/Membership.html.

Heritage Mentoring Project: Volunteers Needed

Neal S. Rubin, Ph.D., ABPP
Argosy University, Chicago

In conjunction with Dr. Grant Rich and the *International Psychology Bulletin* (IPB) and on behalf of the Board of the Division of International Psychology (Division 52), I am pleased to announce the launching of the Heritage Mentoring Project (HMP). This endeavor will result in the publication of a series of articles in the IPB consisting of brief biographies of luminaries in the field of International Psychology. The HMP has at least two central purposes. First, it is time for us to celebrate the contributions of pioneers in the field of International Psychology. Second, we seek to promote connections between senior members of our field and those more recently engaged in International Psychology through the vehicle of scholarly mentorship. It is our hope that facilitating these collaborative connections will engender meaningful mentoring relationships and as a product enrich our appreciation of our own history and of those women and men worldwide whose scholarship has been foundational to our field.

For this project to be a success, we need your help. Drs. Chalmer Thompson, Uwe Gielen, John Hogan, and Wade Pickren have offered to provide guidance in the selection of subjects for these biographies. Together, they will provide a list of international psychologists from around the world who have made seminal contributions to our field. For example, current proposals include biographies of recipients of the Committee on International Relations in Psychology's (CIRP) award for Distinguished Contributions to International Psychology, Division 52's Distinguished International Psychologist Award (U.S. and non-U.S. awardees) and former Presidents of Division 52. Additionally, we will seek to identify subjects who are diverse scholars whose work may not have, as yet, reached mainstream Western publications. In this way we will enhance our knowledge of, for example, scholars of color worldwide who may have had a significant impact on their particular local or cultural context, but who may not have received international attention. The coordinator for the HMP, Dr. Chalmer Thompson, will facilitate connecting members interested in engaging in collaborating on a biographical article. The senior member of the pairing will guide the project, providing mentoring in the selection of the subject and in the development of the publication, and the junior member will research and possibly interview the subject (if they are available), and serve as the primary author of the piece.

Therefore, what we need from you as either seasoned members of our field or as newcomers to International Psychology are volunteers to serve as co-authors of these biographies: one established psychologist in a mentoring role and one student or early careerist as a primary investigator. Collaborators will design the structure and content of each biography to be submitted to the IPB in 1,500 – 3,000 words. These articles will be submitted to Dr. Grant Rich and will appear as part of a continuing series in the IPB. Additionally, authors will be asked to give their permission for these biographies to be posted on line on the Division 52 website by Dr. Richard Velayo, division webmaster.

If you would like to help us develop a greater appreciation of our heritage, while engaging in enriching mentoring collaborations and publishing in the International Psychology Bulletin in the Heritage Mentoring Project, please contact the HMP coordinator, Chalmer Elaine Thompson, Ph.D., Associate Professor of Counseling and Counselor Education at the Indiana University School of Education, Indianapolis, Indiana: chathomp@iupui.edu.

Division of International Psychology Nominees for Elected Offices

Nominations were solicited for Division 52 President-Elect, and two Treasurer. The names are listed below in alphabetical order.

President-Elect (2012)
Mercedes A. McCormick, Ph.D.
Senel Poyrazil, Ph.D.

Treasurer (2012-2014)
Cristina L. Magalhaes, Ph.D.
Susan Nolan, Ph.D.

All candidates were asked to submit their statements for inclusion in the International Psychology Bulletin.

Candidates for President-Elect

Mercedes A. McCormick, Ph.D.

I am on the psychology faculty at Pace University, New York City where I teach psychology courses that focus on the internationalization of psychology. I also coordinate the MA Program in General Psychology and am the advisor for Psi Chi, the International Honor Society of Psychology. I coordinate the Annual Pace Psychology Conference that highlights international psychology research and issues. I mentor international students to promote their development as global psychologists. My own research interests include *Internationalizing the Curriculum* and I presented research in Russia, Mexico City, Portugal and Canada.

I joined Division 52 in 2005 and have been actively involved. I serve as Member-at-Large on the Executive Committee (2010-2012), D52 Liaison for the Committee on LGBT Concerns, Chair of Outreach Committee 2005-2011 and was 2010 Chair of the International Mentoring Award Committee. I created digital resources for our Division explaining the field of international psychology 2008.

I am enthusiastic about serving as president and look forward to continuing the work of former leaders. If elected, I will promote the following goals to:

- Build stronger partnerships with international organizations of psychology and APA Divisions to advance the mission of international psychology.
- Survey the membership to collect demographic data and learn about their satisfaction in order to develop initiatives and motivate members.
- Ongoing support of the techniques and methods to internationalize the psychology curriculum.
- Enhance international collaboration via web-based technologies.

Senel Poyrazli, Ph.D.

I am an APA Fellow and associate professor at the Pennsylvania State University, Harrisburg campus. I internationalize all of my courses in an attempt to help my students become global citizens. My research is directly involved with international psychology. I study international students' and immigrants' psychosocial adjustment and acculturation processes, and have published substantially in this area. I also have a forthcoming book entitled, International Case Studies in Mental Health: An International Perspective in Counseling and Psychology, by Sage Publications. I collaborate with international psychologists in the U.S. and abroad (e.g., Sweden, Turkey, Canada).

I have been a member of our Division since 1998. I recently completed a 5-year term as the editor of the International Psychology Bulletin and have been the chair of the Long Range Planning Committee for the past two years. I have co-chaired the Division's APA program for 2010 and serve as the current chair for its APA 2011 program in Washington, D.C. In addition, I was a member of the Website Task Force and the Mentorship Committee. For these contributions, I received two presidential citations and a recognition award for extraordinary service.

I am very excited about serving as your president, continuing the work of the previous leaders of our Division, and advancing international psychology. If elected, the following will be among my goals:

- Increasing the visibility of our Division
- Continuing the work of infusing an international perspective in all APA divisions
- Supporting efforts to internationalize the psychology curriculum worldwide
- Increasing the number of members and leaders from countries outside of the U.S.

Candidates for Treasurer

Cristina L. Magalhaes, Ph.D.

Cristina L. Magalhaes, PhD, is Assistant Professor in the PsyD program at Alliant International University, Los Angeles, and faculty affiliate of the Multicultural Community Psychology Emphasis and the university's Rockway Institute for LGBT Psychology. Her research and teaching experience/interests focus in areas that fall under the larger umbrella of multicultural/diversity and international psychology. These include socio-cultural considerations in assessment and treatment, translation and adaptation of measures for cross-cultural use, immigration issues, LGBTQ issues, and the intersection of multiple aspects of identity. Her work has been presented at several international conferences including the Interamerican Congress of Psychology, International Congress of Psychology, World Conference on Psychology, Counseling and Guidance, and the World Professional Association for Transgender Health.

Dr. Magalhaes' career started in Brazil where she completed her *Licenciatura em Psicologia* and *Formação de Psicólogo* degrees in 1991. Her clinical training and work experiences in Brazil were primarily in psychiatric hospital and outpatient community-based settings. She earned her MS (2000) and PhD (2005) degrees in clinical psychology from Nova Southeastern University in Fort Lauderdale, Florida. In the United States, she provided administration, supervision and direct clinical services in community mental health, child residential programs, and private practice since 1997. She is member of several APA divisions and currently serves as Treasurer for Division 12, Section IV (Women in Clinical Psychology). As a psychologist with an international identity, she looks forward to the opportunity to join other Division 52 members in their efforts to advance knowledge of issues impacting the practice of psychology worldwide.

Susan Nolan, Ph.D.

I received a Ph.D. in Clinical Psychology from Northwestern University, and am an Associate Professor and Chair of the Department of Psychology at Seton Hall University. I live in Jersey City, NJ, and have a house in Bosnia-Herzegovina, where I spend part of each summer.

Why Division 52? Division 52 is the professional organization that best bridges the increasingly interna-

tional nature of my research, teaching, and service. For example, I study gender differences in STEM careers and have incorporated international perspectives, including in an NSF-funded symposium (2003) and subsequent co-edited book (2006) that included international contributors. With respect to teaching, I developed an International Psychology course at Seton Hall that received approval as a behavioral science core course. In terms of service, I am an NGO representative to the United Nations and Chair of Division 52's International Committee for Women. I look forward to continued involvement in Division 52, with an emphasis on creating connections among the varied arenas in which international psychologists work and involving students more directly.

Why Treasurer? I believe my experience will enable to me to carry out the duties of Treasurer. First, I enjoy quantitative tasks, as evidenced by my co-authored statistics textbooks. Second, I have held administrative positions at Seton Hall since 2001 (Director of Women's Studies, Associate Dean of Graduate Studies, and Department Chair), all with budget-related duties. Third, I served for two years as Treasurer and an Executive Board Member of the New Jersey Coalition Against Sexual Assault (budget of over $700,000).

Learn More About the New Division 52 Journal

Visit http://www.apa.org/pubs/journals/ipp/index.aspx.

International Perspectives in Psychology: Research, Practice, Consultation is committed to publishing conceptual models, methodologies, and research findings to help study and understand human behavior and experiences around the globe from a psychological perspective. It publishes intervention strategies that use psychological science to improve the lives of people around the world.

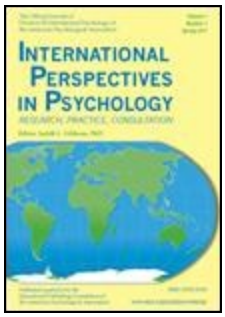

The journal promotes the use of psychological science that is contextually informed, culturally inclusive, and dedicated to serving the public interest. The world's problems are imbedded in economic, environmental, political, and social contexts. *International Perspectives in Psychology* incorporates empirical findings from education, medicine, political science, public health, psychology, sociology, gender and ethnic studies, and related disciplines.

The journal addresses international and global issues, including

- inter-group relations
- disaster response
- societal and national development
- environmental conservation
- emigration and immigration
- education
- social and workplace environments
- policy and decision making
- leadership
- health care
- poverty and economic justice
- the experiences and needs of disadvantaged groups

LEAVING A LEGACY

TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

Division 52 – International Psychology
2011 APA Convention Program

	Wednesday August 3rd	Thursday August 4th	Friday August 5th	Saturday August 6th	Sunday August 7th
8:00-8:50				Understanding Autism in Vietnam: Implications for Psychologists and Educators (SYM)	
9:00-9:50		International Psychology Paper Session I	Paradigm of Intersectionality: Promoting Asian Women's Physical, Mental, and Reproductive Health (SYM)	Division 52 Business Meeting	International Psychology Paper Session II
10:00-10:50		Where is Ellis? Where and how is RBT Practiced Internationally? (SYM)	Taxonomy of Sexual Trafficking: Treating Survivors and Exploiters of Sexual Abuse (SYM)	Psychological Impacts of the January 2010 Earthquake in Haitian Survivors (SYM)	Sustainable Visions and Values for Psychology and Psychologists: Current Needs and Emerging Opportunities for Global Teaching, Research, and Practice (SYM)
11:00-11:50		Advancing International North-South-North Dialogues in Psychology in the Americas (SYM)	Intergenerational Consequences of Intercommunal Political Violence (SYM)	Division 52 Presidential Address: Teaching the History of Psychology From an International Perspective: A Few Recommendations (John D. Hogan)	
12:00-12:50		Dissemination of Evidence Based Practice Internationally (SYM)			
1:00-1:50		Examine Cross-Cultural Applicability of Adult Attachment Theory to Asian Populations (SYM)		Research in International Psychology Poster Session II	
2:00-2:50	Executive Meeting	Integrating Mental Health into the Primary Care Setting in Africa: Lessons from Rural Senegal (SYM)			
3:00-3:50					
4:00-4:50			Research in International Psychology Poster Session I		

This is a tentative program. APA may make changes to it. For questions, please email Senel Poyrazli, Ph.D. at poyrazli@psu.edu or Mark D. Terjesen, Ph.D. at terjesem@stjohns.edu

Proposed Bylaws Changes Re: Student and Early Career Representation on the Division 52 Board

March 28, 2011
Joy K. Rice, Bylaws/Handbook Chair

In mid April, as a member of Division 52, you will receive an electronic vote email from APA that will ask you to vote on some changes to the Bylaws of Division 52 that were approved by the Board of Directors at the 52 MidWinter meeting in March. The issue is student and early career psychologist representation on our Board of Directors. Please take minute to read the rationale and proposed bylaws changes and be sure to vote in April. The additions are in red.

Rationale

Students and early career psychologists represent the future of psychology and of our Division. In order to assure that Division 52 remains a vibrant and viable organization, we need to continuously nurture the development of new members of our field. Designating a voting membership role on the board of directors for both a student and an early career member explicitly defines a meaningful place for these individuals as valued members of our Division. Providing a voice for students on the boards of divisions has become increasingly common among APA divisions who report they are gratified by the dynamic contributions of their younger members. Additionally, we have much to offer students and young professionals in the way of mentorship. Involvement with the board will enhance their organizational experience, provide needed seasoning, create new career opportunities and hopefully propel their career trajectories toward significant contributions to the field of international psychology. Having student and early career representatives with a vote on the board will benefit these constituencies, the division, our field and ourselves.

The proposed bylaws changes in Article IV are essentially two: Designating that one of the four elected Members-at-large will be an Early Career Member and adding a new elected board position of Student Representative with vote.

Article IV: Board of Directors

Section 1

There shall be a Board of Directors of the Division. Its membership shall consist of the following persons:

1) The elected officers of the Division as specified in Article III, Section 1 of these Bylaws;

2) There shall be four Members-at-large who shall be Members of the Division, elected for three-year terms in staggered sequence. Members-at-large shall be members of the Board of Directors with vote. The terms of the initial Members-at-large shall be set by the Board of Directors for one, two, or three years so as to implement staggered terms. They shall assume office on January 1 of the year following their election. One of the Members-at-Large shall be an Early Career Member. A Member-at-large initiates or works on at least one special project that furthers the goals of the division and reports on the progress annually.

3) The Division shall elect that number of Representatives to APA Council necessary to fill vacancies created by ending terms of current Representatives and/or vacancies created by changes on the APA Apportionment Ballot. Representatives to Council must be Members or Fellows of the Division and are ordinarily elected to serve a three-year term. The Division's Representative(s) to Council shall be members of the Board of Directors with vote.

4) The Division shall elect a Student Representative who is a Member of the Division, elected for a two year term. The Student Representative shall be a member of the Board of Directors with vote.

If the membership approves these changes, we will also add information to our Division 52 Handbook that will indicate a) that the Early Career MAL is expected to chair the Early Career Committee; b) that the definition of an Early Career Psychologist is up to ten years post graduate status and c) that in terms of rotation, every third year one of the two MAL nominations will go to an early career psychologist, ensuring that there will always be one MAL ECP representative on the board. In addition, the Handbook will note that the Student Representative a) is expected to chair the Student Committee and b) will generally be a graduate student, but that a particularly outstanding psychology undergraduate may be nominated for the position.

International 2011 Research Award for Doctoral Students in Psychology

Call to Students Engaged in International Psychology Research!

Division 52, International Psychology, is offering an International 2011 Research Award for doctoral students in psychology. This award has been established to encourage and recognize promising doctoral student research in international psychology.

Please submit:

a) Four page double-spaced summary* of research (including references) that describes the purpose, method, analysis, results, and discussion of your international research. Please exclude all identifying information on research summary document.
b) Student's Curriculum Vitae
c) One-paragraph email* endorsement sent directly from faculty research advisor/sponsor providing:
   1. Endorsement for the award
   2. Confirmation that research was an independent project, thesis, or dissertation effort conducted during doctoral program, and
   3. Assurance of student's good standing in the doctoral program.
d) Two-paragraph cover email from student applicant*
   1. First paragraph should provide all contact information, name of doctoral program and institution, name of research advisor, year in the doctoral program, expected graduation date, as well as member status with Div 52. (Student applicant must be a member of Div 52 as of the award application deadline.)
   2. Second paragraph should assure the committee that the independent research project, thesis or dissertation is nearing completion. At least preliminary analysis and results must be completed by early May 2011.

***Please note that submissions exceeding the paragraph/ page limits will be disqualified. Brevity is valued!**

Email all application materials BEFORE MIDNIGHT ON SUNDAY, May 15th, 2011 to the Chair of the International Research Award for Doctoral Students (late applications will not be reviewed):

Sheila J. Henderson, MBA, Ph.D., Visiting Associate Professor, California School of Professional Psychology & Associate Director, I-MERIT, Alliant International University, 1 Beach Street, San Francisco, CA 94133, shenderson@alliant.edu.

The award committee will evaluate the award applications under blind review based on: (a) the degree of relevance to international psychology, (b) progress to completion, (c) adherence to APA Style, (d) originality of research, (e) clarity of design and method, (f) complexity of analysis, (g) quality of findings, (h) recognition of limitations, (i) insight in the discussion, and (j) brevity and clarity.

Awardees will be notified no later than May 31st, 2011, awarded in person at the Division 52 APA Convention Awards ceremony in Washington D.C., and featured in the Fall issue of the Division 52 newsletter.

Eastern Psychological Association 2011 International Conference

Harold Takooshian

On March 10-12, 2011, over 1,800 psychologists and students from as far as Moscow gathered at the Hyatt Regency Cambridge for the 82nd annual meeting of the Eastern Psychological Association. Once again, for the ninth year since 2003, this included the semi-annual program and meeting of the 25-person board of directors of the APA Division 52, International Psychology (D52). Thanks to EPA, D52 had its board meeting from noon till 5 pm on March 10, then a two-day program of 10 symposia and poster sessions on March 11 -12, presenting work by D52 members and others. The 30 seats in the Hyatt Cambridge room were often filled by a steady stream of students and professionals hearing about a variety of global topics: publishing opportunities in international psychology, the United Nations, Fulbrights, international collaborations on TAT scoring, internationalizing the teaching of psychology, and intervening after natural and human-made disasters.

Some images of these sessions appear at www.picasaweb.com/takoosh. This program had some unusual features.

The D52 board met in Cambridge MA (photo by Michael Meir)

During the two-day conference, conferees closely followed media news of a deadly 8.9 earthquake in Japan, while teams of experts at EPA discussed their work after past disasters in Haiti, Pakistan, Sri Lanka, Armenia, Lebanon, Sierra Leone and elsewhere.

Officers of Psi Chi, the international honor society for psychology, joined D52 for a joint session on "Psi Chi: Moving from a national to an international society in psychology."

Under Russian professor Alexander Voronov, a team of seven faculty and students from Moscow visited EPA, and offered a symposium on "Russian psychology today: Current trends." This included the debut of a nine-minute DVD, "Psi

Chi: Student excellence," translated into the Russian language by Dr. Alexey Sozinov of the Academy of Sciences of Russia.

On behalf of D52, President John Hogan thanked the EPA Board of Directors for hosting such a full program on international psychology, and presented his Presidential Citation to EPA Executive Officer Frederick Bonato and Program Chair Diane Finley for their efforts to make EPA a model among the seven U.S. regional psychology associations.

Thanks to the efforts of D52 secretary Ayse Çiftçi, about 30 members shared a wonderful international supper at the exotic Elephant Walk in Cambridge

To give the EPA presentations a wider audience, Editor Grant Rich invites session chairs or presenters to consider adapting their presentation for possible publication this year in the APA *International Psychology Bulletin.* Contact Dr. Rich at optimalex@aol.com

EPA 2011: How Moscow Met Massachusetts

Grant J. Rich

Back in 1998, the American Psychological Association hosted its first annual Division 52 program in Washington DC (Takooshian, 1998). Since then, D52 has now grown to offer at least three annual international programs each year—at APA, then EPA in the East (since 2003), now WPA in the West (since 2009). After 14 years, the D52 board now tries to host its midwinter board meeting every other year at a new regional or other venue, to inspire more U.S. international programs.

Still, it remains unusual for overseas presenters to participate in these D52 meetings, due to the familiar challenges of distance, cost, and language. In addition, some nations like Russia also require a special visa to travel to the USA.

At EPA, Russians present their research findings.

The recent and model exception was the 2011 EPA meeting in Cambridge, where 4 professors and 2 students from Moscow managed to present their work--thanks to unusual teamwork between EPA, Moscow Professor Alex Voronov, and the national board of Psi Chi, the international honor society in psychology.

In Cambridge, Russian scientists meet Psi Chi national officers and psychologists. (l t o r): Elena Chebotareva, Irina Novikova, Mercedes McCormick, Tatyana Al-Batal, Alexander Voronov, Grant Rich, Anastasia Chebotareva, Alexey Novikov, Rivka Bertisch Meir, Michael D. Hall, Martha Zlokovich, Susan Iles, Harold Takooshian. (Photo by Michael Meir, MD)

Back in November of 2010, the All-Russian conference was taking place to mark the 125th anniversary of native experimental psychology. A.Voronov organized a six-day international seminar "To the 50th anniversary of the first obedience experiments of Stanley Milgram" in Russian cities Moscow and Kolomna, which happened simultaneously with the conference. Five Russian universities cooperated in an unusual multi-site, cross-national meeting, using technology to bring together 300 Russian faculty and students with American and British colleagues. Psi Chi past-President Harold Takooshian gave talks at each of these five universities on three topics: 1) Stanley Milgram as researcher, teacher, mentor: Beyond the controversy; 2) Promoting student excellence in psychology: 80 years of Psi Chi, including discussion of the offer on the organization of the first Euro-Asian chapters; 3) Russian and American psychologists: Traditions and prospects of contacts (including survey of Russian staff and students about their familiarity with the "top 10" psychologists most often cited by American and Soviet textbooks, the results were compared with the analogous results in the US) (Voronov & Takooshian, 2011). There, Takooshian furnished to his many hosts the timely invitations their government required, to participate in EPA in March 2011. Several of them succeeded, with encouragement from EPA and from Psi Chi--which had voted in 2009 to become an international organization.

Russian professors visiting New York City for the first time.

At EPA, the D52 presenters included Russian professors Elena Chebotareva, Irina Novikova, Alexey Novikov, Alexander Voronov, and students Anastasia Chebotareva and Tatyana Al-Batal. Voronov also debuted a new 9-minute Russian-language DVD on Psi Chi, prepared by Alexey Sozinov of the Russian Academy of Sciences. In addition to presenting their research findings at EPA, and meeting officers of D52 and Psi Chi, the Russian scientists toured nearby MIT and Harvard University. The team of four from the People's Friendship University of Russia also managed to visit New York City for three days, where they were registered as D52 members at the home of Rivka Meir, and greeted at Fordham University by psychology Deans Vincent Alfonso and Mark Mattson. Their Russian university's psychology program cooperates with European schools, and now hopes to link with U.S. schools in the future (www.rudn.ru/en/).

Such cross-national cooperation of psychology programs is more possible now, with the continued encouragement of all involved—EPA, APA, Psi Chi, and willing institutions.

References

Takooshian, H. (1998, July). The 1998 convention program. *International Psychology Reporter, 2* (2), 3-6.

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Assessing Psychology in Thailand

Bruce B. Svare
State University of New York at Albany

As a Fulbright senior scholar to Thailand in 2006-2007, I had the opportunity to examine the status of psychology in this country's system of higher education and to explore its role in Thai mental health care.

Psychology is not a well developed discipline in Thailand and only a few elite institutions have stand alone psychology departments with significant undergraduate and graduate course offerings. Notably absent are programs in clinical and experimental psychology. Faculty who teach psychology are very dedicated and have for the most part received their graduate training in the United States, Canada, the United Kingdom, or Australia. Many Thai faculty are still heavily invested in rote learning strategies but new faculty development programs are emphasizing more cooperative learning approaches. Thai interpersonal strategies that emphasize respect for seniority and the suppression of boastful/leadership behaviors are significant cultural impediments to more effective classroom teaching and student learning. A new emphasis upon English taught coursework in Thailand's higher education system reflects this country's desire to become less insular and more oriented toward globalization.

The severely strained Thai mental health care system is dominated by psychiatrists who adhere to a medical model of mental illness. Thai psychologists are poorly trained by western standards with most possessing only an undergraduate degree. They are considered to be "paramedical professionals" by the psychiatric community. In spite of their deficient training and education, Thai psychologists increasingly are being asked to serve on the frontlines of the diagnosis and treatment of mental illness.

Psychology can grow in Thailand and eventually become a greater force in academia and the clinical mental health community. This will only occur if a western educational curriculum is more fully adopted at both the undergraduate and graduate level and many more colleges and universities develop their own psychology departments. Once this infrastructure is in place and levels of training and licensing are simultaneously upgraded, psychology academics and practitioners can begin to contribute more effectively to the Thai mental health care system. While there are significant economic and cultural challenges to advancing modern psychology in this country, the potential rewards for the quality of living among Thai people are enormous.

Key words: Thailand, higher education, history of psychology, teaching of psychology, faculty development, mental health and psychology, reform measures for growth of psychology

Background

I was named a Fulbright senior scholar to Thailand in 2006. The mission for my yearlong assignment was simple: Promote the development of psychology in the Thai higher education system by bringing my specialization to the country. To that end, I taught behavioral neuroscience and assisted with curriculum development at Chulalongkorn University in Bangkok, and lectured widely in the country at other universities and medical schools.

During my stay in Thailand, I learned that the field of psychology is still in its infancy. Most universities in this beautiful country have little in the way of a formal psychology curriculum. Moreover, the profession of clinical psychology and the role that it plays in the diagnosis and treatment of mental illness is almost nonexistent. As a result, Thailand's mental health care system is burdened with increasing numbers of mentally ill patients receiving little in the way of professional care or, worse yet, no care at all.

This was never more evident than 2004 when a tsunami struck Phuket, Thailand. Overwhelmed by the physical and emotional devastation, Thailand's compassionate but largely untrained mental health care professionals were often helpless in assisting survivors who were psychologically damaged by the disaster. Thanks to the benevolence of the United States and many other countries, trained psychologists descended on the country to provide needed assistance and comfort.

After completing my Fulbright stay, I have sought new ways of contributing to their higher education system and the

development of psychology. I return yearly to teach intensive short-term courses at various Thai universities and medical schools, and continue to promote the exchange of Thai students to the United States for doctoral training in psychology. I have also spearheaded fund-raising efforts in the United States to enable more Fulbright scholars to come to Thailand to teach and conduct research.

I recently attended the 60th anniversary celebration of the Fulbright Program in Thailand. It was held at the Thai Ministry of Foreign Affairs in Bangkok. As a senior scholar to Thailand, I was one of only a few former Fulbrighters given the honor of describing my mission to Her Royal Highness Princess Sirindhorn. I came away from our discussion knowing that the princess understood my work and appreciated my efforts to help build the discipline of psychology in her country.

I was also given an award by the Thai-U.S. Educational Foundation (TUSEF) and U.S. Ambassador to Thailand, Eric John, in recognition of my fund-raising efforts on behalf of the Fulbright Program in Thailand. I am grateful for this distinction, for it has motivated me to work even harder to promote psychology in this country.

Bruce Svare, former Fulbright senior scholar to Thailand, is recognized for his fund-raising efforts on behalf of the Thai-U.S. Educational Foundation (TUSEF). Pictured are, from left, Svare, Deputy U.S. Secretary of State Alina Romanowski, His Eminence Manaspas Xuto, former Thai ambassador to the United States and adviser to the Thai minister of foreign affairs, and U.S. Ambassador to Thailand. Eric John. Svare is a Fellow of the American Psychological Association (APA) and the Association for Psychological Science (APS) and professor of psychology and neuroscience at the State University of New York at Albany.

My experiences in Thailand since 2006 have contributed in part to the present analysis. What follows is an assessment of psychology's status in this country. This includes an examination of its relatively brief history, an exploration of the general culture of college teaching and faculty development, an assessment of the role of psychology in the mental health care system in this country, and an analysis of reforms in psychology that are needed if the discipline is to continue to grow and ultimately benefit the Thai people.

Psychology in Thailand: Past and Present

The arrival of Buddhism in Thailand took place approximately 700 years ago. Because a major focus of Buddha's teaching included the nature and function of the mind, it could be said that psychology had its beginning in this country long ago. Modern psychology did not become established in Thailand until about 60 years ago when the western education system was adopted and schools of education were first established for the training of teachers. These schools included a basic psychology curriculum with a heavy emphasis upon child development. There are approximately 200 institutions of higher learning in Thailand today with half private and half public. Only a few of the leading institutions offer undergraduate degrees in psychology and even fewer offer graduate degrees.

Clearly, psychology in Thailand is still in its infancy as a well developed discipline. Some specialties are represented better than others such as social, developmental, industrial, educational, school and counseling psychology. The absence of clinical psychology in this early development is particularly noteworthy. This has been due in large part to the fact that mental health care in Thailand has traditionally been considered the province of the medical psychiatric community. Also, owing to the strong influence of Buddhism on all aspects of Thai life and the stigma associated with mental disorders, monks are often sought out by those needing help in contrast to trained professionals. This factor alone has had a major impact upon the development of clinical psychology as a discipline and a profession. In Thailand today there are only about 400 practicing clinical psychologists (Tapanya, 2010) and the requirements are minimal: Only an undergraduate degree is required and the passing of a licensing exam. Overworked psychiatrists and a largely untrained clinical psychology community cannot begin to take care of the needs of a country consisting of 63 million people.

As noted above, psychology as a formal discipline grew from education departments. Such was the case at Chulalongkorn University in Bangkok, considered along with Thammasat University, to be an elite institution of higher learning in Thailand. In 1996, Chulalongkorn University became the first Thai university to establish a comprehensive psychology program with its own faculty strictly dedicated to graduate and undergraduate training in the discipline. At present it offers undergraduate training in many but not all of the traditional sub-disciplines in psychology. Notably absent are courses that normally are considered to be essential for psychology as a modern experimental discipline: experimental psychology, sensation and perception, research methods and design, psychopharmacology, behavior genetics, developmental psychobiology, behavioral neuroendocrinology, and advanced behavioral neuroscience. Chulalongkorn also has masters programs in social, counseling, developmental, and industrial/organizational psychology and doctoral programs in social, counseling and developmental psychology. Absent from Chulalongkorn's graduate degree offerings

is a doctoral program in clinical psychology. Students with advanced degrees typically find employment as counselors in mental health settings, hospitals, schools, colleges and clinics. They also find employment in government agencies as well as in the private sector as research assistants in marketing and advertising depending upon their graduate specialization.

In recent years, the growth of undergraduate programs in Thai universities has stagnated. Most psychology courses in Thai universities and colleges continue to be taught as part of education or social science departments. Unlike Chulalongkorn and Thammasat Universities with established curriculums and significant enrolled majors each year, psychology offerings at other universities are minimal and typically do not go beyond standard 100 and 200 level courses (e.g., introductory and developmental psychology). One notable exception to this is the development of a clearly identified undergraduate clinical psychology track at Chiang Mai University in northern Thailand. Interestingly, graduate programs in psychology have actually grown somewhat. For example, in Bangkok, Assumption and Thammasat Universities now have doctoral programs in counseling psychology while Mahidol University has a master's degree in clinical psychology. This is an interesting development in Thai higher education since some of these institutions (Assumption and Mahidol) do not have undergraduate psychology departments with significant course offerings.

There are four professional societies for psychologists in Thailand: the Thai Clinical Psychologists Association, the Thai Psychological Association, the Thai Guidance Counselor Association, and the Thai Mental Health Association. There are very few psychology journals and they are all in Thai. A few of the journals are *The Journal of Clinical Psychology*, *Psychology Journal*, and the *Guidance Journal.*

Observations on Teaching Psychology in Thailand

Some comments regarding the professional status of college teaching in Thailand as well as issues surrounding faculty development are also relevant. Thai college professors are not well paid by Western standards but none-the-less are revered in the culture of this country. Teachers Day or "Wan-Kruu" is celebrated every January 16th and college students remember their professors with gifts such as flowers and food. This is a tradition that is seen throughout the educational system in Thailand and is a reminder of how deeply Thais respect their elders.

Psychology faculty, indeed faculty throughout the Thai higher education system, are very hardworking and thoughtful teachers and scholars. They are justifiably proud of the accomplishments they have made in building their respective departments and universities over the past 60 years. Psychology faculty routinely receive their doctoral training in institutions outside their country with the US, Canada, the UK and Australia being the most frequent destinations. They return to Thailand in order to fulfill obligations they have as the result of government grants and to join with other colleagues in the teaching of the next generation of Thai students. It is important to note that Thai psychology faculty are strongly committed to each other, their students and their institutions. This is especially admirable since, as noted above, levels of compensation are universally low.

Professors in Thailand are viewed with unquestioned authority when they teach in the classroom. While this certainly is not unique to Thailand, it poses a striking contrast to expectations in the United States where students and faculty are taught to speak their minds openly and invite discourse regardless of status. An understanding of the concepts of "man-sai" and "kreng-jai", interpersonal strategies for dealing with those in a position of power and authority, are keys to understanding how the avoidance of shame and saving face play a central role in determining the college classroom environment in Thailand. Belonging to a larger group, especially a family group, is a key to happiness and feeling at ease in Thai culture. Indeed, Thais are known for having fun ("sanuk") and keeping everyone in their social and family group happy. At times, this is counterproductive to learning in the classroom since no student wants to stand out too much as a leader for fear of being regarded as boastful and showing off to the rest ("man-sai"). With the risk of not belonging so great, Thais are often reticent in the classroom to express their opinions. This factor, coupled with respect for seniority, promotes a cultural habit where Thais rarely challenge an authority figure ("kreng-jai") for fear of making them look bad. These are challenges that both Thai and foreign professors frequently acknowledge. They are impediments to educational environments that promote a more active and cooperative learning milieu where professors are not just there to dispense information but also serve as facilitators of a collaborative classroom experience. Not surprisingly, in spite of advances to encourage more cooperative learning approaches as noted below, Thai pedagogy is still heavily embedded with rote learning strategies.

Thailand, like many developing countries, has experienced a shift from elite to mass education. Student enrollments have dramatically expanded in this country and a much more diverse student body is now represented in many Thai universities, especially those with open enrollments. Because student centered learning approaches are being promoted as part of a larger educational reform effort, there are new and significant challenges for both faculty and students in this country. Thai faculty are now being encouraged to adopt teaching approaches that include active learning, collaborative learning and problem based learning (Brody, 2008). Faculty are being asked to adjust their curricula and develop, in some cases, radically different approaches to the presentation of classroom material and methods of assessment. Because the hierarchical structure of Thai higher education is more extreme than that of the United States, the implementation of the changes above present problems of their own. For the most part, Thai faculty appear to be overworked. However, they have a strong sense of obligation to accept all assignments regardless of whether or not they have the time or support. Faculty development programs have emerged on a limited basis, most notably at Burapha University. Clearly, this is an area that should receive much more emphasis and re-

sources than it currently does. However, the cultural factors noted above as well as the inertia of tradition and lack of administrative leadership have prevented further development.

Lastly, the availability of technology in Thai higher education, like that of many countries, is highly variable depending upon the discipline as well as the institution and its location. In urban areas such as Bangkok, elite universities such as Chulalongkorn and Thammasat enjoy reasonably good educational technology with smart classrooms, numerous computer stations for students and faculty, wireless service in designated areas, and online software (e.g., Blackboard, Web CT, E-res and other software for web based learning and library access). Although universities in areas outside Bangkok (especially in rural areas), are not as well equipped for educational technology, there seems to be momentum for investment as a result of Thai educational reform. Whether or not faculty make use of this technology is another matter; My observations in psychology indicated that very few used it on a regular basis while most others never used it. Likewise, my observations indicated that the utilization for teaching purposes of YouTube, professional society websites, and web based pedagogical resources was minimal.

Observations on the Role of Psychology in the Thai Mental Health Care System

The most recent World Health Organization assessment of Thailand's mental healthcare system (2006) states that the country has 7.29 mental health providers (e.g., psychiatrists, psychologists, nurses, social workers, and occupational therapists) for every 100,000 people. By any standard of comparison, this is an alarmingly low figure especially when one considers that many of the providers included in the analysis lack any significant training in psychology.

Psychology as a profession in Thailand's mental health care system has not grown substantially in the last 50 years. This follows from a number of factors including the dominance of psychiatry and the medical model, limited opportunities for clinical training comparable to what is seen in the United States, limited educational and training opportunities at both the undergraduate and graduate levels, the lack of rigorous licensing standards, and cultural factors that promote Buddhist monks as defacto counselors. Over 80% of Thai psychologists have only an undergraduate degree, about 15% have earned a master's degree, and about 5% have a doctoral degree (all from overseas and none with internships or post-doctoral training) (Tapanya, 2001, 2010).

Psychologists in Thailand today are considered to be "paramedical professionals" by the psychiatric community (WHO-AIMS, 2006; Tapanya, 2001). Their role is usually limited to being a technician that is ordered by psychiatrists to administer tests and develop reports. However, because increasing numbers of Thais are seeking help from professionals and because there are so few psychiatrists (only about 300 with 80% practicing in urban areas), their role has expanded more recently into areas of treatment, promotion of mental health, and research (Tapanya, 2010). In spite of their lack of education, training and experience, Thai psychologists increasingly are on the front lines of care helping with group and individual therapy, community mental health promotion, and counseling of drug addicts and HIV positive patients. Unfortunately, this development frequently occurs in the absence of supervision from experienced psychiatrists and psychologists. Moreover, the pay in these positions is very low and the opportunities for advancement are almost non-existent.

An important outcome of the heavy emphasis on the medical model approach to mental illness in Thailand is the devaluing and underrepresentation of behavioral science in their curriculum (Tapanya, 2010). There are no departments of psychology or behavioral science in medical schools. Because the six year medical education for Thais begins right after high school, there is little opportunity for psychology and sociology coursework. As a result, Thai medical students who ultimately specialize in psychiatry do not have the benefit of a broad perspective on mental health and illness that their American counterparts usually have from a broad based, undergraduate, liberal arts experience. This is unfortunate since it is well known that medical problems such as heart disease, drug addictions, and sexually transmitted diseases have strong behavioral components. Here again, the growth of clinical psychology and enhanced psychology curriculum in Thai colleges, universities and medical schools could have a major impact upon improving prevention and treatment in their mental health care system.

Cultural factors also play a significant role in the extent to which Thais seek out mental health care (Tapanya, 2001, 2010; WHO-AIMS, 2006). For example, Thais prefer living in extended families and typically build houses in groups where they are in close proximity to relatives. If there is a relative with a mental disorder, families take care of these individuals rather than risk the stigma associated with seeing a psychologist or psychiatrist. Even when a family member is seen by a professional, every effort is made to bring this individual home as quickly as possible. Also, as noted above, Buddhist monks, especially in rural areas, are as likely as a mental health care professional to see and treat those suffering from behavioral problems. Buddhist monks are highly respected in Thai culture and are regularly sought out for assistance with psychological problems. With a small donation, certainly much less than a payment to a psychologist or psychiatrist, a Thai person can simultaneously gain merit for the afterlife while also receiving counseling for a behavioral problem. Additionally, Buddhism advocates meditation and it is well known that this practice alone can ameliorate some problems associated with stress and emotional change.

Though the stigma associated with seeing a mental health care professional in Thailand is significant, the question remains as to how effective a Buddhist monk can be in successfully diagnosing and treating the whole spectrum of behavior disorders that are commonly recognized in the Diagnostic and Statistical Manual (DSM). Notwithstanding the important role that monks play in some areas of counseling and behavioral treatment, they have, for the most part, re-

ceived little in the way of professional training. While some small programs have attempted to train Buddhist monks in basic counseling skills, such training is not widespread and there is little empirical evidence to date that it has had a significant impact on servicing those with mental health care needs (Tapanya, 2010). With the important evidence based advances that are an accepted part of professionalized mental health care in other parts of the world, it remains to be seen whether the continuation of these alternative approaches can produce the kind of quality diagnosis, treatment and care that those suffering from mental illness deserve.

The Thai mental health care system is also limited by the fact that there is no universal insurance in this country. Government officials and their families have extensive health care coverage as do employees of private companies. Some coverage is available to laborers and low income citizens free of charge in government hospitals but the care is considered to be substandard by the public. Importantly, psychological assessment and therapy are not reimbursable and mental health care services usually are limited to acute psychotic episodes where immediate hospitalization is required (Tapanya, 2010). Clearly, a more fully developed discipline of psychology could have a major positive impact upon the mental health care system in Thailand. This is especially true in underserved rural areas where the presence of trained professionals is extremely limited.

Needed Reforms for Continued Growth

There is a tremendous need in Thailand for the development of curriculum that meets western standards for undergraduate and graduate training in psychology as well as faculty development that replaces rote learning pedagogical strategies with more collaborative, student centered learning. Clearly, many more institutions, both public and private, need to develop stand alone psychology departments that present modern psychology in all of its specialties, but most critically in clinical psychology. Once this infrastructure is in place, a concerted effort needs to be placed upon improving the education and training opportunities for those seeking to pursue the profession of clinical psychology. While training overseas is an option in combination with the development of joint programs with other countries, a tactic employed at Chiang Mai University, homegrown (Thai) Ph.D. programs in clinical psychology should be the ultimate goal. Indeed, the professionalization of Thai psychologists and their ultimate ability to shed the status of "second class citizen" to psychiatrists is critically dependent upon growing the psychology infrastructure in higher education.

An untapped but potentially important area for building psychology in Thailand is to encourage the development of the discipline in high school curriculums. Presently, little is done to present the discipline of psychology below the college level. This stands in marked contrast to the United States where close to 370,000 high school students annually are enrolled in psychology classes (APA, 2005).

A developing emphasis in Thai higher education is instruction in English. The Thai government is placing special emphasis upon these programs because of a renewed interest in Thailand becoming a center for higher education in Southeast Asia. Because English is the language of opportunity and is universally recognized as the world-wide language of education, health, science, engineering, finance and commerce, this commitment needs even greater attention. Pockets of progress are evident at some institutions. For example, at Chulalongkorn University, a number of academic units, including psychology, now offer separate instruction for those who want to be taught in English. Called the "International Program," these students are admitted to Chulalongkorn University separately from students who want to be taught in Thai. Very few students come from other countries. Indeed, almost all of the International Program students are Thais coming from elite international high schools in Thailand (mostly Bangkok) that feature intensive instruction in English starting in the earliest grades. Tuition for International Program students is much higher than that of their Thai taught counterparts and there is a tendency for International Program students to have lower entrance exam scores. Nevertheless, if the ultimate goal of Thai higher education is to elevate its people to compete more effectively in a global economy, then a much greater emphasis must be placed on college coursework taught in English.

In the larger context of higher education in Asia, Thailand's desire to become a hub that will attract students from the entire region has a ways to go (Purnell, 2010, World Bank Group, 2009). While Singapore, Japan and Hong Kong have already become leading regional centers for higher education, Thailand has lagged behind. As noted above, the lack of English speaking instruction is a major barrier for drawing a more international student body. This is especially true in the case of psychology where students are more likely to seek graduate education in English speaking countries such as Australia and the United States.

As noted elsewhere, the governing organizations for psychology in Thailand presently are mixed among 4 separate organizations. If these organizations combined and formed one umbrella organization of both academicians and practitioners with various divisions like that of APA, the discipline of psychology in Thailand could function more effectively and grow more rapidly in the future. This should become a major goal in this country if it is to develop the capacity to educate and train more students in the discipline and ultimately serve more of its people whose mental health care needs will increasingly depend upon trained professionals.

Lastly, the economic recession in Thailand, like that of many countries, has forced significant reductions in spending for higher education and has curtailed the development of many new programs. Clearly, a more fully developed discipline of psychology combined with other educational reforms would seem to be worthy goals. However, a fluctuating economic picture will ultimately dictate whether or not and to what extent the aforementioned changes will materialize in the future.

Conclusions

My teaching and lecturing experiences in Thailand provided an important perspective for evaluating the role of psychology in the higher education and mental health care systems of this country. The weaknesses I have identified in both academic and applied vocations in psychology in Thailand are not unique to this country. Indeed Thailand has come a very long way in developing this discipline and its higher education system over a relatively short period of time. It is clear that the trajectory of continued improvement is one that will be realized as more young Thais become educated in the basic principles of this important discipline and ultimately seek more advanced training in their own country and abroad. There are enormous opportunities for the growth of psychology in Thailand, especially for those who understand its history, culture, and traditions. Though the challenges are formidable, the potential payoff from a modernized, more fully developed, psychology discipline may be critical for the future quality of living in this country.

Lastly, I am humbled by my Thai colleagues in psychology who carry out their work with enormous dedication and pride. Many remarked to me that they felt called to the profession as a means to help their country's future development. With this collective positive attitude, psychology in Thailand is sure to thrive in the future.

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The History of Psychology Is Not What It Used to Be!

Lawson, R. B., Graham, J. E., & Baker, K. M. (2007). A history of psychology: Globalization, ideas, and applications. Upper Saddle River, NJ: Pearson Prentice Hall. ISBN: 0-13-014123-2.

Pickren, W. E., & Rutherford, A. (2010). A history of modern psychology in context. Hoboken, NJ: Wiley. ISBN: 978-0-470-27609-9.

Shiraev, E. (2011). A history of psychology: A global perspective. Los Angeles: Sage. ISBN: 978-1-4129-7383-0.

Reviewed by John D. Hogan, Ph.D.
St. John's University, New York, U.S.A.

It is surprising to realize that some of the most dramatic developments in psychology are taking place in the history of psychology. Readers who think of history as simply a recitation of established facts will be taken aback by some of the new directions that are currently being promoted. Nowhere is this more evident than in the recent wave of textbooks.

Since E. G. Boring wrote his classic text: *A History of Experimental Psychology* (1929/1950), the field has gone through remarkable changes. One obvious example can be found in the title of Boring's book. He was specifically addressing the dominant form of psychology of his time; he had little interest in applied aspects of the field. Today, more than three-quarters of the new doctoral degrees are given in applied fields, and traditional experimental psychology, while still regarded as an important and necessary foundation, is clearly in the minority.

But the new history of psychology is about more than the experimental/applied dichotomy. Contemporary historians of the social sciences have become increasingly sensitive to the role that context has played in determining the direction of the discipline. They view much of psychology as deeply embedded in the culture in which it arises. As a result, context becomes an important source of discussion. The new history also asks about the role of underrepresented groups in contributing to the discipline. Among the more obvious changes has been the large percentage of women currently entering the profession. Their greater presence leads to some obvious questions. Why were women denied entry to the profession in the early days? Who were the successful pioneer women? Who were the pioneers from other minority groups? These kinds of queries no longer represent Boring's history!

There is still another question about the new history that is probably the one of most interest to the international community. To what extent is the history of psychology as usually presented in the U.S. a genuine history of the field? Adrian Brock (2006) has established several "rules" for the way in which the history is typically portrayed. He argues -- perhaps overstating his point on purpose -- that U.S. history ignores any developments that did not have a local impact. He adds that although we in the U.S. may have some historical knowledge of European psychology, our knowledge of psychology in the rest of the world is all but non-existent. In short, he is proposing that the typical history of psychology, as taught in U.S. colleges and universities, is strongly geocentric and, thus, severely limited. He is not the only one to voice these concerns.

Three new recently published texts have arrived to address many of these issues. Each is successful in its own way. To be clear, the intention of these "new" histories is not to throw out the old history, at least not entirely. There is, after all, some value to be found even in an indigenous history. The problem arises if it is viewed as the only history, with no other possibilities presented.

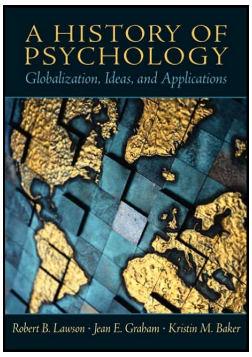

Lawson et al. are explicit in calling for a psychology that is multi-paradigmatic, with a diversity of world views. From the outset, they challenge many of the Western assumptions about science and its role in the discovery of truth. At the same time, a large middle section of their text is devoted to a somewhat traditional U.S. history, with a heavy focus on biography. But then their postmodern and global interests strongly reemerge. The final section of their book, five chapters out of eighteen, presents material on women in psychology and on racial diversity, followed by individual chapters on psychology in Russia, China, and indigenous psychologies. All in all, the text is a useful blend of the old and the new. Readers are exposed to the more traditional parts of the history, but are also given a glimpse of what is likely to be the future of the field.

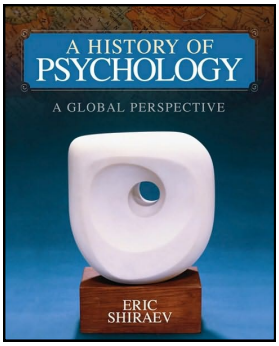

Shiraev brings a fresh approach to his text. A Russian-born American professor, with academic degrees from St. Pe-

tersburg and post-doctoral study at UCLA, he is in a strong position to deviate from the traditional U.S. text, and in many ways he does. His review of the history of early psychological knowledge addresses several non-Western traditions – not a typical feature of U.S. texts. I particularly enjoyed his chapters on clinical research and on psychology after "the Great War." I would have preferred if he had devoted a little more space to Francis Galton. But, instead, he offers a trade-off -- an extensive and very worthwhile section on Vladimir Bekhterev, the Russian behavioral psychologist. As with each of the texts being discussed here, when something is added, it is likely that something else will be taken away, or at least given reduced coverage. Overall, Shiraev often surprised me (pleasantly) with his choices. Even many of the photographs were new to me.

Pickren and Rutherford have put together what strikes me as the least traditional text of the three. They have clearly made an effort to stay away from the commonly used "schools" approach to organizing the history. Instead, their chapter headings suggest a very different organization, e.g. "Internationalization and indigenization of psychology after World War II" (chapter 10) and "Inclusiveness, identity, and conflict in late 20th century American psychology" (chapter 12). Maybe the most telling chapter heading of all is chapter 2: "Everyday life and psychological practices," a title that would have had Boring scratching his head! Although they manage to touch on many of the traditional topics, their stated emphasis is to attend to "the ways that culture, race, ethnicity, and gender have contributed to the making of psychology's history" (p. xv). And, indeed, international and feminist issues play a particularly strong role throughout the text. I looked for any major topics and persons that they missed, but came up empty handed. Instead, I found sections on such novel topics as psychoanalysis outside of Europe and the U.S., and testing and Dutch society. At the end of each chapter, the authors discuss their sources, a device that I have seen before but which I found particularly valuable here. In short, I found their text both satisfying and inventive, virtually from start to finish.

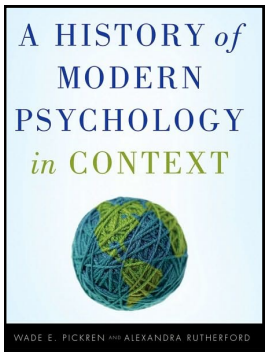

So what does this all amount to? From my perspective, these texts suggest a new and exciting time for those of us who teach the history of psychology, a wake-up call and a time to start rewriting syllabi. It will be interesting to see how extensively these texts are adopted for the classroom. We learned some time ago that most instructors in the history of psychology rely heavily on their texts to organize their courses for them (Hogan et al., 1998). It is hard for me to see how instructors could go back to the old way of teaching once they have viewed these new directions.

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ANNOUNCING THE PUBLICATION OF ...

Curriculum for culturally responsive health care: The step-by-step guide for cultural competence training
Ring, J.M., Nyquist, J.G., Mitchell, S.M., Flores, H., Samaniego, L.
Publisher: Oxford: Radcliffe Publishing (2008)
ISBN: 978-1-84619-294-4

This is a creative, comprehensive and user-friendly manual comprising a curriculum for residencies and medical schools looking to implement new, or enhance existing, curricula in culturally responsive care. It meticulously describes teaching strategies that will prove engaging to learners and faculty alike, challenging them to grow in their attitudes, awareness, desire, knowledge and skills to effectively practice culturally responsive medicine. It demonstrates commitment to teaching culturally responsive medicine towards the elimination of health disparities, be they related to gender, race/ethnicity, income, sexual orientation, religious background or world view.

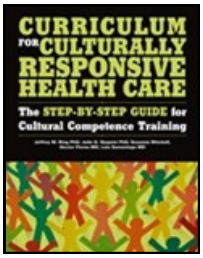

The manual includes a step-by-step guide for each year of the curriculum, with detailed session descriptions, and sections on teaching techniques, evaluation tools, cultural competence exercises, together with information on further resources. The curriculum provides a solid foundation upon which educational programs can build as they evolve to meet the needs of patients and their communities toward preventing and treating illness, and improving access to excellence in medical care.
http://www.radcliffe-oxford.com/books/bookdetail.aspx?ISBN=1846192943

Handbook of research on civic engagement in youth
Sherrod, L., Torney-Purta, J. & Flanagan, C. (Eds.)
Publisher: John Wiley and Sons
ISBN: 978-0-470-52274-5

This 24 chapter handbook represents a multi-disciplinary set of reviews of research in this rapidly growing field. Many of the chapters take an international perspective. Of particular interest are the chapter by Amna and Zetterberg who describe

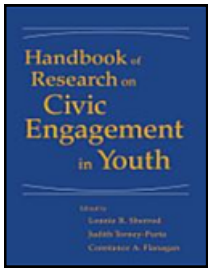

the "stand by" citizen among youth in the Nordic countries, lacking in civic engagement most of the time but ready to respond if there is a concern; and the chapter by Kassimir and Flanagan on the role of engagement for youth in the developing world. There are also chapters on immigrants, LGBT political socialization, and the participatory media culture, to give an example of current concerns that are covered. In the area of psychological theory, the chapter on developmental theory considers the theoretical base of the international IEA Civic Education Study, while the chapter by Beaumont presents a conceptual integration of efficacy as it is considered in psychology and political science with illustrations from multi-method data from PEP (Political Engagement Project. Contact jtpurta@umd.edu for more information.

Building multicultural competency: Development, training, and practice
White, Joseph. L. and Henderson, Sheila. J. (Eds.)
Publisher: Rowman & Littlefield Publishers (2008)
ISBN-10: 0-7425-6420-7
ISBN-13: 978-0-7425-6420-6

Building Multicultural Competency answers this need by providing a new Multiracial/Multiethnic/Multicultural Competency Building Model--a model that, in great detail, provides relevant solutions to this growing problem. This book will supply individuals, students, professionals, educators, and administrators who are involved in the field of psychology with a map on how to build the multicultural competency skills that will allow them to function cross-culturally. The resolutions are personally enriching, helpful to diverse peoples, and influential to other individuals, groups, and institutions.

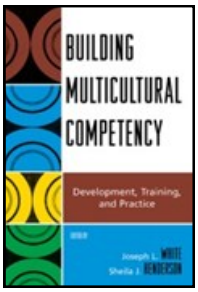

Addressing cultural complexities in practice: Assessment, diagnosis, and therapy
Hays, P. A.
Publisher: American Psychological Association (2008, 2nd ed.)
ISBN: 978-1-4338-0219-5

This engaging book helps readers move beyond one-dimensional conceptualizations of identity to an understanding of the complex, overlapping cultural influences that form each of us. Hays's "ADDRESSING" framework enables therapists to better recognize and understand cultural influences as a multidimensional combination of Age and generational influences, Developmental and acquired Disabilities, Religion, Ethnic and racial identity, Socioeconomic status, Sexual orientation, Indigenous heritage, National origin, and Gender.

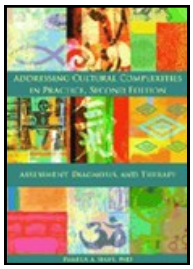

Unlike other books on therapy with diverse clients, which tend to focus on working with one particular ethnic group, this volume presents a framework that can be used with a person of any cultural identity. Organized according to the flow of clinical work (in contrast to the one chapter-per-group approach), the book's contents are summarized in handy Key Tables at the end of each chapter for ease of use in education and supervision. This stimulating book will be an important resource for counselors, clinicians, and mental health professionals working with clients from a variety of backgrounds.

Culturally responsive cognitive-behavioral therapy
Hays, P. A., & Iwamasa, G. Y. (Eds.) (2006).
Publisher: American Psychological Association
ISBN: 978-1-59147-360-2

This is the first book to integrate cultural influences into cognitive-behavioral therapy (CBT). This engagingly written volume describes the application of CBT with people of diverse cultures and discusses how therapists can refine cognitive-behavioral therapy to increase its effectiveness with clients of many cultures. The contributing authors examine the characteristics of some of the most common cultural groups in the United States including American Indian, Latino, Asian, and African American, as well as groups less commonly considered in multicultural psychology books: people of Alaska Native, Arab, and Orthodox Jewish heritage. The volume also describes the use of CBT with older adults, people with disabilities, and gay and lesbian individuals, including examples of people who hold bicultural and multicultural identities. A chapter on culturally responsive assessment, with an emphasis on the most frequently used cognitive-behavioral assessment scales, and a chapter on supervision round out this volume. Numerous case examples provide practical information grounded in an empirically supported theory, making this book a practical resource for every therapist.

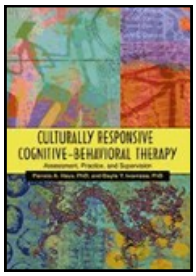

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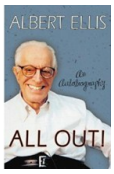

All out ! An autobiography
Albert Ellis, with Debbie Joffe Ellis
Publisher: Prometheus Books, Amherst New York (2010)
ISBN: 978-1-59102-452-1

Relational being, beyond self and community
Gergen, K.J. (2009)
Publisher: New York: Oxford University Press.
ISBN: 978-0-19-530538-8

The latest issue of *Psychology International* can be accessed on the web at: http://apa.org/international/pi

Wise Words from Veterans in the Field: Gaining International Research Experience Early in Your Career

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Within recent years, the internationalization of psychology has become more prolific in the United States with an increase in students and early career psychologists becoming interested in global research and work. Although the field is moving towards a more international perspective, it can be challenging for students to gain relevant experiences during graduate school. In addition to coursework, teaching obligations, completing the dissertation, and maintaining an active caseload of therapy clients, it can be a daunting task to try to find the time and funding to explore opportunities abroad, particularly for students who may not have mentors at their university interested in international experiences. This article tackles this dilemma by providing recommendations and ideas to initiate these opportunities from two seasoned psychologists with very diverse backgrounds in international psychology.

Dr. Charles Abramson

Dr. Charles Abramson is a comparative physiological-psychologist at Oklahoma State University where he also holds adjunct appointments in the departments of Zoology and Entomology. He is recognized internationally for his work with studying behavior in a wide range of organisms including Africanized honey bees, flatworms, ants, crabs, elephants, and humans among others. Dr. Abramson has acted as a visiting professor and conducted research in a number of countries including Brazil, Greece, Italy, Japan, Russia, Turkey, Slovenia, and Venezuela. He has taken undergraduate students to Brazil, Venezuela, Greece and Turkey as part of a National Science Foundation sponsored program to provide research experiences. Dr. Abramson serves on the editorial board of five international journals and is the author of several books including a Slovene phrasebook that has been translated into Italian and German, two animal behavior activity books that have been translated into Slovene, and a children's book that has been translated into French. When Dr. Abramson moved from the culturally-diverse state of New York to a very small college-town in rural Oklahoma, he found it quite challenging to have foreign visitors wanting to come to Oklahoma. He quickly realized that if he initiated contact and conducted interesting, well-designed research studies, people would begin to seek him out for international collaborations. For early career psychologists interested in international research, he recommends deciding where you want to go and what research you would like to conduct and then contacting psychologists, either abroad or domestically, who do similar research. Many universities offer visiting student or faculty members financial assistance in exchange for research. By contacting faculty at universities in the country you would like to work, they can assist you in finding funding and research collaborations.

With his diverse background in international research, Dr. Abramson provides a unique perspective to the field of psychology. Over the course of his international collaborations, he has come to believe that psychologists who lack international experience have a more challenging time "deviating from their network." In other words, international experiences allow for the development of entrepreneurial thinking and collaborations with professionals from diverse backgrounds and worldviews. These experiences create the opportunity for important global scientific advances and allow psychologists to expand their network of colleagues to include non-Western perspectives and theories.

Dr. Abramson, along with his international colleagues, is in the process of creating a "super-laboratory." These international researchers are developing a system of student exchanges to increase opportunities for students to work in different countries through the same research lab. Through the advancement of technology and the use of Skype, it is possible to hold research meetings with lab members from all over the globe. These collaborations allow ample opportunities for publications and research experiences. It also gives the student an opportunity to make international collaborations early in their career and experience the challenges and rewards associated with international work.

Dr. Abramson has found that the growth of these collaborations into friendships is by far the best reward of international work. Additionally, being able to teach a new way of conducting research in various countries and providing opportunities to increase science and education in less developed

countries is a passion of his. Dr. Abramson previously initiated a "Books for Brazil" program in which he partnered with sororities and fraternities on OSU's campus to gather educational books to send to schools in Brazil that lack these resources. He is committed to providing resources, which we so often take for granted, to countries that lack those essentials to help advance education and research.

One of the most important lessons learned from Dr. Abramson on working internationally is that you have to be careful to not force your views onto members of other cultures. Respect for varying world views is important in maintaining collaborations. Further, it is important to include as many collaborators from the country you are working with as possible to demonstrate that you are a "true partner" in advancing scientific knowledge.

As graduate students, it is often difficult to find the funding to travel internationally. Additionally, gaining extensive international experience during graduate school may ultimately delay graduation. According to Dr. Abramson, the only thing students really needs is "the will to do it and the right people" to help get them there. It is easy to get frustrated when there appear to be so many challenges to gaining international experience while in graduate school. Surrounding one's self with colleagues of similar interests can help keep that passion for international psychology alive.

In our second interview, we found that Dr. Kathryn Norsworthy is much more than an international researcher in the field of counseling psychology – she is an international advocate, collaborator, and friend to those with whom she works. Dr. Norsworthy has spent over a decade working in South and Southeast Asia addressing a number of topics, including ethno-political conflict, peace-building, HIV/AIDS, and violence against women (Norsworthy & Gerstein, 2003; Norsworthy & Khuankaew, 2004; Norsworthy & Khuankaew, 2008). In collaboration with her partner, Ouyporn Khuankaew, of Thailand, Dr. Norsworthy has worked with communities primarily from Burma, Thailand, Cambodia, and with members of the Tibetan community in exile. She currently teaches at Rollins College and has taken her students to India, Thailand, to the Burma communities in exile, and to the migrant and farm worker communities of Florida to develop international skills and perspectives.

Dr. Kathryn Norsworthy

During this interview, Dr. Norsworthy provided a wealth of information for graduate students and early career psychologists wanting to work in international settings and with international individuals. First, Dr. Norsworthy described what she learned from her many years in the field. She emphasized that in the beginning, she and her American colleagues assumed a power position as "the expert, common for Western psychologists entering non-Western settings." She stated, "I learned that I needed to unlearn my training regarding the superiority of U.S. mainstream values – the ethnocentric perspective - and I needed to be willing to approach situations from a beginner's mind while also recognizing that I do have knowledge and skills that may be of value in the international contexts in which I work and conduct research." Dr. Norsworthy emphatically described how important it is for those collaborating internationally to *not* assume this expert role and to engage in difficult dialogues with international colleagues around potential power issues and in the service of working from a power-sharing framework. Additionally, when working with international colleagues, it is critical to value multiple ways of knowing and epistemologies, and to "make space for people on the ground with whom we collaborate to put forward their real questions and concerns since they are really the experts on their own lives, communities, and cultures."

In making recommendations to graduate students and early career psychologists engaging in international psychology research, Dr. Norsworthy noted the importance of being aware of one's own enculturation. She said being able to shift one's worldview enough to understand where people come from and openly learn about others' values and worldviews is the first stepping stone to creating lifelong, collaborative relationships with other international researchers. Further, Dr. Norsworthy made a practical recommendation to students – to simply "go over and hang out at first." Prior to working professionally in South and Southeast Asia, she spent a lot of time with locals and opened herself up to the beliefs and practices of local cultures. After being immersed in a new culture personally, one can pursue professional relationships through local organizations, working voluntarily, and perhaps writing small grants to assist with associated expenses. From these small beginnings, one can then begin to network and form the relationships necessary to gain the funding for larger projects.

Dr. Norsworthy also commented on the role of training programs in fostering international experiences for students. She acknowledged the recent push for the internationalization of psychology and spoke with caution regarding this movement, stating that "we want to avoid a colonizing, imperialist model of internationalization, but instead it is to center the cultures, worldviews, issues and concerns of people on the ground in the countries in which we do research and practice." It is important that students gain an intellectual understanding of the issues in internationalizing psychology by reading works that critique the uncritical exportation of U.S. psychology, as well as how we can remedy the effects of this exportation. For further reading, she recommended students and educators begin with Chapter 4 of the *International Handbook of Cross-Cultural Counseling: Cultural Assumptions and Practices Worldwide* (2009), which she co-authored alongside Dr. Lawrence Gerstein, Dr. P. Paul Heppner, Dr. Stefanía Ægisdóttir, and Dr. Seung-Ming Alvin Leung. Second, she described opportunities that need to be made available to students, which she called "community engaged models

of international experiences." She described these experiences as projects in which local people and students collaborate in the development and implementation of projects that are of real value to those in the communities and cultures in which the projects take place and emphasized the importance of having local and faculty mentors and supervisors with a critical consciousness regarding cross cultural research and practice.

These interviews provide a snapshot of Drs. Abramson and Norsworthy's experiences, knowledge, and recommendations regarding international psychology research. The veterans of the field have a vast array of experiential knowledge and most are eager to share that knowledge and help those early in their careers to build upon that knowledge base. This article provides a brief framework for those interested in international research and will hopefully assist others in building on the international research and advocacy these psychologists have devoted their careers towards.

For more information on mentoring opportunities within Division 52, check out the Division 52 website (www.internationalpsychology.net). Doran and Stowell (2011) offer perspective on both the formal and informal mentoring opportunities available, and those interested in mentoring may contact the chair of the mentoring committee, Dr. Ani Kalayjian (drkalaykian@gmail.com). For those of you interested in serving as a mentor to international students, we recommend Wedding, McCartney, & Currey (2009).

Further Reading

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Wedding, D., McCartney, J.L., & Currey, D. E. (2009). Lessons relevant to psychologists who serve as mentors for international students. *Professional Psychology: Research and Practice*, *40* (2), 189-193.

Additional Resources

www.internationalpsychology.net
www.apa.org/international
www.psychologystudents.org
http://www.internationalcounselingpsychology.org/

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Editor's Note: *This column is geared towards our student committee members and all students of international psychology. All Div52 student members are invited to submit ideas or drafts for future articles, as well as questions they would like to see addressed in future columns – such as overseas internship opportunities, study abroad availability, cross-cultural research, etc. Contact the Editor at optimalex@aol.com to submit an idea or a question.*

Division 52 Membership Survey

Dear 52 Member:
We have developed a survey to measure your opinions of your membership in Division 52. The purpose of the survey is to determine how we can improve the services that the Division provides to enhance your membership in the division. Please send any comments or questions to Janet2822@aol.com and susan.nolan@shu.edu

We welcome your input.

We appreciate your participation in this survey.

Fulbright Awards at 65: A Year Teaching at Istanbul University and Beyond*

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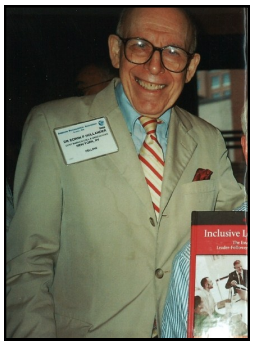

*Note: This paper was prepared for a Division 52 International Psychology Panel, March 11, 2011, Eastern Psychological Association, Cambridge, MA. The author thanks David Adams and Esther Boyd of the Institute of International Education for providing information and handouts about the Fulbright Awards. I am particularly indebted to Prof. Harold Takooshian, my friend and fellow Fulbrighter, who joined in an effort to honor the program and make its opportunities more accessible to our membership.

Background

Since its inception in 1946, the Fulbright Program has sponsored 294,000 faculty and students in the Fulbright Scholar Program and the Fulbright Student Program, currently with 7,500 grants in 155 nations. Regrettably, the Program is continually under threats of severe budget cuts, though its total cost is miniscule within our nation's international programs.

Students from Abroad

In addition to those of us who have had the benefit of time abroad from awards, there are countless students who have come to study for advanced degrees here on awards and gone back to productive careers in their home countries. My two Fulbright doctoral students, S.K. Dani from India and Barry Fallon from Australia, completed their Ph.D.s at SUNY Buffalo. At home, Dani became a much honored Dean of a College of Psychology, and Fallon was Professor of Psychology at the University of Melbourne, and elected President of the Australian Psychological Society. I mainly credit their success to the selection process of Fulbright Commissions, rather than to my influence, because they came as mature, dedicated students, and soon good friends. We maintained contact, and both returned to visit me years later. I now want to give some grateful glimpses of an exceptionally revealing year at Istanbul and beyond, some of which appears in the Afterword of my book, *Inclusive Leadership* (2009).

A Fulbright Year Teaching at Istanbul University and Beyond

My international interests brought me to apply for a Fulbright Lectureship in Europe for the 1957-58 academic year, when I was an assistant professor at Carnegie Tech (now Carnegie-Mellon University). The small number of social psychology teaching positions made for limited choice, so when I was offered such a post at Istanbul University I was glad to accept. It turned out to be a marvelous opportunity, very worthwhile in many ways, including learning about Turkey, its culture and politics, and the Islamic religion, with early visits to two monumental mosques, Aya Sofia, which had been a church under the Byzantines, and the fabled Blue Mosque. I also gave lectures in seven countries.

In July 1957, at the International Congress in Brussels, I was the guest at breakfast of Sir Fredrick Bartlett, the first Cambridge professor of experimental psychology, a great and very genial, but rare psychologist with a knighthood, chairing our social psychology session. It included Leon Festinger speaking about (you guessed it) "cognitive dissonance." I gave my first overview paper on my "idiosyncrasy credit (IC) model of leadership" at this international meeting, published the next year in the *Psychological Review* (Hollander, 1958a). I then travelled briefly, including to England with a stop to visit Bartlett's Applied Psychology Research Unit at Cambridge, at his invitation. On returning home, I soon began studying the language with a Turkish student. I had received leave from Carnegie Tech, and confirmation from Istanbul University of my appointment as a Visiting Professor, with a letter from my gracious and supportive host, the Professor of Psychology and Chair, Mumtaz Turhan. Coincidentally, he had earned his Ph.D. with Bartlett at Cambridge, as well as having studied in Germany.

The University had been founded in 1492 as a mosque school and had become a major twentieth century institution in the Middle East, with a fully developed set of professional schools and the usual undergraduate arts and sciences college. Interestingly, the medical school had almost as many women as men students, at a time when in the United States women students were in a small minority. I lectured in English, which at least half the students understood, but had sequential translation into Turkish every paragraph or so. Two graduate assistants, Iffet Dinc and Yilmaz Ozakpinar, a woman and a man, were marvelous young colleagues who very capably did the translating as well as aiding me with my research and other academic contacts and writing needs. He did analyses with me for a study I had underway, and eventually earned his doctorate at Cambridge University. She helped translate a paper I wrote for a French journal (Hollander, 1958b), and came to the USA to visit us, and then earned a doctorate at Florida State University. The Istanbul campus had many older but some newer buildings surrounded by greenery, and a familiar feel. The students wore distinctly modern, western attire. I taught a large undergraduate class in social psychology, another in research methods, and a graduate seminar in personality and social psychology.

I found interacting with the students very refreshing, for

their earnestness, and evident motivation, with good performance skills, even with the need for translation. At least half of them knew English well enough to understand it, and almost as many could speak it. Few ever talked Turkish with me since what I'd learned was largely oriented to outside life, such as buying things in stores, or making other needs known. The University faculty were almost always multilingual and also wanted to speak English with me. If not able to, then even my rusty high school French and college German helped many times to bridge the language gap.

I was not then married, and lived alone on a hillside on the Bhosporus, the central straits that separated Europe from Asia, in a two-room frame cottage that had a basic kitchen and a bathroom. Istanbul is on the same 42nd parallel as New York City, and can get cold, so heating with the kerosene heater that was the sole source was essential. However, it could not always function in cold weather because of all too frequent fuel shortages. I did get to travel to other parts of Turkey, including the capital city of Ankara, which is relatively modern and set in the central Anatolian plain, the Aegean Coast in the South, and Black Sea region in the North, from which the Soviet naval ships and oil tankers came through these straits in a daily procession that I could view from my cottage.

The Fulbright Commissions in other countries invited me to come to give guest lectures at universities and colleges elsewhere, and in the course of the academic year I visited Greece, Austria, Germany, France, Holland, England, and late in my stay, in June, Israel. My network of acquaintances abroad grew considerably, and I enjoyed seeing old and making new friends. I had some eye-opening experiences, given that the late 1950s were stimulating times, and cross-national contacts could be a challenge. In public places, I met a number of people in Britain who were angry at the American stand in the recent Suez Crisis, and said so as soon as they identified my accent. There was outspoken criticism there of President Eisenhower for withholding support for the British and French forces when they took control of the Suez Canal with Israel. It was not personalized to me though and I felt no threat. Colleagues were cordial at the British Psychological Society (BPS) annual meeting in April, 1958, at Birmingham when I came to give an invited address on interpreting conformity behavior, which subsequently was published in the British journal, *Sociological Review* (Hollander, 1959). My talk afterward generated much interest, and to my delight friendly, probing discussions.

At the Sorbonne in Paris, the director of the laboratory of social psychology was Robert Pages who invited me to do a seminar that Spring with his advanced students and colleagues, in English with occasional translation. It proved to be very lively, with continuing conversation while socializing afterward. He and I became good friends, as did others there whom I saw at meetings later, even during the difficult period of the late 1960s with upheaval on campuses. While lecturing and giving seminars in the Fulbright year of 1957-58, I had an interest in a dynamic conception of personality that takes account of social interaction. It led to a chapter I wrote for a book on personality research (Hollander, 1960), coedited by a life-long friend from graduate school days, Henry P. David, whose doctorate was in Clinical Psychology at TC. The book came from a session at the 1957 Brussels International Congress, and was also published in German in 1961 in Switzerland. Among my publications in that language are a chapter on the IC Model of leadership, and a 1978 Munich Applied Congress keynote address on applied social psychology (Hollander, 1979).

Another year spent studying and speaking abroad

In 1966-67, this time in London, with my wife Pat and our son Peter, I was fortunate to receive an NIMH Senior Fellowship at the Tavistock Institute on a sabbatical from SUNY at Buffalo. Among my lectures, I spoke at a time of great involvement by students at the London School of Economics, invited by the psychology chair, a friendly Hilde Himmelweit.

Elsewhere, I gave talks in Paris on leadership at the Institute of American Studies, and then one on organizational conformity and independence. It was to an amphitheater of masters students at the School of Economic and Social Sciences. They are said to be a tough audience, so when they stomped their feet afterward as a traditional sign of appreciation, I was very grateful, and also for their interesting questions. Another highpoint was to be invited back to speak and conduct a seminar at Istanbul University in the Spring of 1967, where we were greeted warmly and met many of my former students, some of whom had become academics.

Conclusions

These international, scholarly exchanges and subsequent contacts can be priceless experiences for all concerned. That is certainly so for this writer as an awardee, who gladly gained a more rounded, worldly perspective. Our nation would be well served doing more of this, not less, as I fear could be happening.

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Fulbright Scholar Program & Psychology from IIE - Given out at 2011 EPA Division 52 Meeting For 2012-13 Program

Finding an Award

Here are some points that deserve particular attention.

Prospective applicants should not limit their search to only awards with psychology in the title because they will find there are only a few. In 2011-12, only three awards had the word "psychology" in the award title and in the 2012-13 catalog only two do.

This should not discourage people. They need to seek opportunities through what are called "All Discipline Awards" or "Multiple Discipline Awards."

There is a search function built into the awards catalog. Searching by country/program or by "key word" is the best approach. If the "discipline" search function is used, it will bring up every "All Discipline Award". Some of these will not be appropriate for scholars or professionals in psychology.

The better approach is to use the "key word" search function. If you type in psychology here, it will only bring up awards that have "psychology" in the description of the award. Or, the prospective applicant might type in counseling, or child psychology, etc.

Alternatively, search by country and have a look at the "All Discipline Awards." If it is not clear whether psychology is included, contact the program officer listed for that country.

CIES (Center for International Exchange of Scholars) Assistance

Applicants should keep in mind that it is very good idea to be in touch with the program staff member that administered a country's program to discuss how what the prospective applicant has in mind fits with a particular country's program. The names of the program staff and their contact information can be found in each of the country entries in the online awards catalog.

Applicants are encouraged to avail themselves of the live Webinars that CIES offers each week during the spring and summer. These cover awards in particular sets of disciplines, particular countries or regions as well as how to prepare a successful application. Information about the schedule can be found on the CIES website, www.cies.org. Archived Webinars from the 2011-12 competition are also available on the CIES website. There are also some examples of key parts of well-prepared project statements.

If you are interested in applying for a Fulbright Grant, contact a program officer at 202-686-4000 and/or peruse the Catalog of Awards at www.iie.org/cies.

The Status of Public Mental Health Services in South Africa

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The Status of Public Mental Health in South Africa

South Africa, located at the southern tip of the African continent, is an independent country of approximately 48.7 million people. Based on recent health statistics, the country's life expectancy is low, at 53.4 years of age. The World Health Organization (WHO) estimates both opportunities and challenges for adequate health and development in the country. Among the opportunities are "well developed health policies" and "a National Health Act in place providing legislation" for a structured and uniform health system in the country. These opportunities are tempered by challenges including "equitable provision of health services", "heavy burden of disease" (including HIV/AIDS, tuberculosis and malaria) and "inadequate health services for health affecting service delivery" (World Health Organization, 2009, p. 1).

In addition to a high burden of disease in South Africa, there is also a high burden of mental illness in the country. According to the WHO World Mental Health Survey Initiative, the lifetime prevalence of any DSM-IV disorder among South Africans is 30.3% while lifetime risk for development of a disorder is 47.5%. The survey showed that, of the 17 countries reporting at the time, prevalence of mental disorders ranged from 47.4% in the US to 12% in Nigeria while projected lifetime risk ranged from 55% in the US and Colombia to 18% in the People's Republic of China (Kessler, et al., 2007).

The high prevalence of HIV and AIDS in South Africa contributes to the landscape of public mental health in the country. With a large proportion of people living with HIV/AIDS in South Africa, mental health disorders associated with the disease are important to consider. As many as 19% of HIV-infected South Africans also have a mental illness as defined by the Mini-International Neuropsychiatric Interview (MINI). Of all mental disorders measured by the MINI, post-traumatic stress disorder, depression and alcohol abuse/dependence were major mental illness categories discovered as prevalent among HIV-infected individuals. Of these illnesses, depression was the most prevalent (Myer, Smit, Le Roux, Parker, Stein, & Seedat, 2008).

Depression is also correlated with other physical illnesses. Naidoo and Mwaba's (2010) research indicates depression is a major factor among tuberculosis patients in South Africa. Those South Africans living in poverty and lacking sufficient resources may feel even more vulnerable upon contracting an infectious disease. For tuberculosis patients, the assumption

by community members that they are also HIV positive is an additional stressor. The interaction of these factors contributes to high rates of depression among these individuals.

On the international level, it is generally recognized that the right to health includes mental health. For example the Constitution of the World Health Organization states that "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (World Health Organization, 1946). Several international charters, also explicitly recognize the right to mental health. The International Covenant on Economic, Social, and Cultural Rights proclaims "the right of everyone to the…highest attainable standard of physical and mental health" (The United Nations, 1966). Regionally, the African Banjul Charter on Human and People's Rights requires that "every individual shall have the right to enjoy the best attainable state of physical and mental health" and that states party to the charter should "take the necessary measures to provide for the health of their people" (Organization of African Unity, 1981).

More recently, South Africa has promulgated new legislation around mental health, the Mental Health Care Act of 2002 (MCHA 2002). This Act aligns mental health services with the human rights granted by the national Constitution which provides that every South African citizen has "the right to have access to health care services" (Mkhize & Kometsi, 2008, p. 7). The Act further aims to create access to care near the homes and within the communities of mental health care users (Burns, 2008). Most importantly, however, the MHCA 2002 has an ultimate goal of making "mental health a health issue like any other, and not separate it out as something totally different from other illnesses" (Strachan, 2000, p. 5).

While strides have been made in South Africa toward a return to primary health care and legislation for a national health insurance is currently being developed, the integration of mental health into this system and into the general health care debate has been poor. Moreover, as a consequence of low prioritization by government and international donors, mental health rights issues have lagged behind others such as HIV/AIDS and the public mental health system struggles to provide adequate services to its users (Lund, et al., 2008).

The substandard provision of mental health care services, as compared to general health care services in South Africa, has been documented. While expenditure on mental health is not known at the national level, a few of the provinces have been able to report on their local expenditures. Of those provinces, only 5% of their health budgets is spent on mental health care; however, 86% of those funds are spent on mental hospitals as opposed to the desperately needed mental health services at local clinics and in the community (Lund, et al., 2008).

In addition to the low expenditures on mental health, human resources are a challenge. Most nurses in the primary health care system have an already extremely heavy workload and are sometimes resistant to the addition of mental health care users being added to their roles. Further, inadequate training and efficacy building for general PHC nurses "may lead to a loss of professional identity and job security" (Mkhize & Kometsi, 2008, p. 107). Additionally, stigma by health professionals leads to poor performance of services and often leads to mental health care users not seeking treatment (Lund, et al., 2008). While a 2010 study suggests that not all South Africans suffering from mental illness internalize negative stigma, the perception that "the general public are rejecting of people with mental illness" may still create a negative impact towards treatment (Sorsdahl, Kakuma, Wilson, & Stein, 2010, p. 6).

Moreover, many South Africans with severe psychiatric disturbances find it difficult to receive adequate mental health services at community-based facilities. A study conducted in the Western Cape, in 2010, suggests that those persons with schizophrenia spectrum disorders do not receive adequate community based care. The study suggests that although many of these individuals seek out services in community clinics, they do not receive necessary services at the primary care level and are often referred on to specialists. This is of some concern, especially in light of the MHCA 2002 which requires that "mental health services should be integrated into primary and secondary care and that patients should use tertiary care (psychiatric hospitalization) as a last resort" (Lund, et al., 2010, p. 236). A considerable number of South Africans find themselves seeking out indigenous healing practices when they themselves, or their family members, experience mental health issues and concerns. These "Traditional healers" use a variety of practices, including Traditional herbal remedies and religious/spiritual practices, to treat mental disorders. Focus groups conducted with Traditional healers (Sorsdahl, Stein, & Flisher, 2010) indicate they do not often refer patients who present with mental health related symptoms, to Western practitioners. Traditional healers in this study felt they were not treated with sufficient respect by Western practitioners, despite their contributions to the health and welfare of their respective communities.

There is some speculation that a collaborative model for mental health provision between Traditional healers and Western practitioners might be successful. A collaboration in this sector must include "evidence-based models of collaboration which promote a reciprocal collaboration at district level and which is respectful of both healing systems" (Campbell-Hall, Petersen, Bhana, Mjadu, Hosegood, & Flisher, 2010, p. 62). In order to be effective, these collaborative models must include Western practitioners who hold respect for Traditional healers and healing practices, and accommodate culturally diverse explanations of mental illness.

With myriad structural and financial challenges presenting to the health system in South Africa, it is important that the mental health of South Africans is adequately provided for and not overlooked by the public health sector. The high burden of mental illness and co-morbidity with other prevalent diseases, which aggravates the situation, calls for mental health to receive prompt and serious attention in the health care debate and in the struggle for the right to health. It is imperative that mental health as a key element of "health" overall is acknowledged and given proper positioning in the programming and advocacy activities of NGOs, the govern-

ment and activists alike.

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ATOP Meaningfulworld's Psychosocial Rehabilitations Trainings and Healing Groups

One-Year Follow-Up to the Earthquake in Haiti

January 12, 2011, Port au Prince, Haiti

Dr. Ani Kalayjian
Meaningfulworld

A solemn yet celebratory day in Haiti marks the one-year anniversary of the January 12, 2010, earthquake. 230,000 people lost their lives in this devastating earthquake, 2.3 Million people are still missing; over half of the Haitian population found themselves without homes, 70% of people's homes were destroyed. Although thousands are angry since they cannot get out of the tent-city. Today, on 12 January 2011, streets of Port au Prince were flooded with a sea of hundreds of thousands people dressed in black and white, with some mournful colors like blue and purple or bright forbidden colors sprinkled throughout the crowd.

We began the day with a march to a variety of town centers, churches, community centers, and streets at large. We went to the FOKAL Knowledge and Freedom Foundation where a select group of NGOs, artists, poets, and many other citizens reflected on their feelings of survival and remembered their losses while reinforcing their devotion to hope. "Kanpe Pale" ("Stand up and talk") was the theme for the day, which meant express yourself, and discharge emotions, while others in the audience empathically witnessed the events. We then went to pay our respects to Magalie Marcelin, a prominent figure in the women's right movement. We first cleaned up the area around the tomb, where human remains continued to be burned, releasing a strong toxic odor

that was difficult to inhale. The scent weighed heavily on my heart because it reminded me of how fragile people can be. We placed flowers on the grave, burned candles, planted an avocado tree, held hands as we prayed, sang, and then sang and prayed some more.

The afternoon was emotionally moving: We nurtured our body and soul as we sat on the terrace to witness the exact time of the anniversary of the earthquake, 4:47 P.M.. At this time, everyone stood in unison, vehicles stopped moving, and bicycles and motorbikes stood still on the roads. Everyone came out and put their hands up in the air and chanted "Jesus," then sang the Haitian anthem and continued with their marches, memorials, collective meals, and remembrance plans. The sun set very quickly, and people began dancing in the streets in the dark as candles were being lit everywhere. Driving to Jacmel, the beautiful mountains on the southeast side of Haiti, we could not believe the hundreds of thousands of people still in the streets singing, dancing, celebrating their survival, expressing gratitude to one another, and embracing one another.

The Association for Trauma Outreach & Prevention (ATOP) of Meaningfulworld is a charitable 501 c (3) organization founded in 1990, to address the psychosocial and eco-spiritual needs of surviving communities globally. Specifically, it aims to promote the advancement of knowledge about the immediate and long-term human consequences of traumatic events and promotes effective methods of prevention, relief and restoration to those traumatized and to those treating traumatized populations. This goal is accomplished through the recognition of achievement in the advancement of knowledge in the area and through dissemination of knowledge through discussion, education, training, networking, support of professionals, and collaboration with other trauma organizations, and the use of knowledge transfer media. ATOP has served in over 29 missions in 25 countries around the world post natural and human-made disasters, the recent ones being: Haiti, Kenya, Sierra Leone, Mexico, Lebanon, and Armenia. The next ATOP Humanitarian Missions are in Niger Delta in June, Congo in July, Romania in October, and Lebanon in December.

We, the ATOP Team, began our work immediately, surveying Haitians about their feelings and their continued challenges on the day of the earthquake anniversary. Haitians call one another "emotional" but at the same time, it is taboo to express one's emotions or discharge negative feelings, unless it is through reactive behaviors. The next day our ATOP team trained more than 30 students of social work and psychology from several universities, including the University of Notre Dame. Initially, an annual conference was organized to address the emotional and spiritual impact of the earthquake, but due to election upheaval as well as the cholera epidemic, the conference was cancelled. We decided to go on with our humanitarian mission and one-year follow-up evaluation as planned and were grateful for the local coordination of efforts by Fr. Wismick, Jean Yves Valcour, and Sister Lamercie. The training utilized the 7-step Biopsychosocial and Eco-Spiritual Model. This seven-step model has been utilized in over 25 countries and 30 calamities, both natural and human-made, with excellent response. Through this model various aspects of the disaster are assessed, identified, explored, processed, worked through, released, and a new meaning achieved. This innovative model incorporates various theories including: psychodynamic, interpersonal (Sullivanian), existential and humanistic (Viktor Franklian), electromagnetic (EMF), Learning theory, flower essences, essential oils, physical release (Bessel van der Kolk), mind-body-spirit continuum, chakra balancing, prayers and meditation.

Although the roads are still unpaved and rubble caused by the quake still blocks many streets, people have the determination to get to their destinations. Of course, some streets were unpaved and difficult to drive or walk through even before the earthquake, but more deterioration is taking place each day. The majority of the group expressed how the training made them feel better physically: headaches have gone away, body aches transformed, shoulders feel released of all stress; and emotionally: frustration is transformed; hope is strengthened, and plans for action solidified. Everyone prayed to have a smooth election without further violence. Haitians are a fun-loving, honest, sharing, and caring people who are tired of being used by opportunistic dictators. I then invited previous team members Junior Duplier and "Billy" Carl Prophet, who functioned as our interpreters and coordinators of transportation.

On day four we went to the elementary school in Petionville to teach on the subjects of love, nonviolent communication, assertiveness, and forgiveness. More than 200 students standing in rows in the courtyard listened attentively; it was extremely heartwarming to witness their hunger to hear, their curiosity to observe, and their commitment to the messages of love. They were asked to repeat each message after hearing it, and they did so loudly and with conviction. At the end the students surrounded me, asking me what my name was, where I live, and so on! They sang and took photos in groups. We then met with the teachers. I observed that the teachers were using physical punishment (hitting, pinching, slapping) for disciplining purposes. I then conducted a class on disciplining strategies, mindfulness, love, and forgiveness.

On day five we visited the Community Hospital that we worked in last year. We met with the directors and physicians, made an evaluation and comparison, and donated bags of medicine.

On day six we visited Complexe D'orchidee, another primary school, which is located in the heart of a debilitated neighborhood, Delmar 2—perhaps the second-poorest area in Port au Prince. This school is supported by Rose, a Haitian-American who now lives in Boston. Traveling through the neighborhood, one would never imagine there is a school in this area; in fact, the local driver insisted that we must have been given the wrong address, as there could be no school in this neighborhood. Then we turned right and went through an alley and heard the beautiful voices of the children. When we entered we were shocked to see how respectfully the students stood up in unison and began singing a "welcome to our school" song in Creole as well as in English, which brought tears to our eyes. We then visited each and every classroom, spoke with the teachers, hugged the children, and at the end, the team donated a bag of crayons, paper, and other goods to the school. The tuition for each student is $100 a year, therefore, ATOP is asking your help to support a child in Haiti by paying for one child's tuition, so they can be educated. I have attached a photo from this very school. Education is the key to the salvation of the next Haitian generation.

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The Practice of Psychology in Greece

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Psychology first appeared as an academic discipline in Greece in 1926, when a psychology course was first taught at the University of Athens by Theofilos Voreas. Since then, it has been developing slowly in Greece. It was not until recently that psychology received more attention.

Nine years ago, psychology was not a very popular field of study. If somebody were to see a psychologist to ask for help, he or she would have felt the need to hide this fact from other people. A common perception that people had was that seeking help from a psychologist meant that one must have psychological problems. It was commonly believed that one should have something very serious before seeking help from a psychologist. Even today, people harbor prejudice towards psychologists and those that seek their services. This may result from a lack of knowledge about both psychologists and psychological disorders.

Psychology is a relatively young discipline and profession in Greece. In 1979, a law was issued to acknowledge and establish the profession of the psychologist in Greece. Psychology has a 17-year "official" history as an applied professional practice. It was in 1993 when the first licenses in psychology were issued. In order for somebody to become a psychologist in Greece, he or she has to complete a four-year degree in psychology at an accredited university.

Now that licensure has been established, the question is how somebody in Greece can obtain a degree in psychology. While in the United States students usually get into a university first and then declare their majors as sophomores, in Greece, students have to decide what they want to do before entering the university. In other words, in Greece students have to know if they want to become a lawyer or a psychologist as soon as they graduate from high-school. In order to get admitted to a psychology program in a higher education institution, applicants have to take the National Level Examination. The exam typically takes place after students graduate from high-school, and performance on the National Level Examination determines if a student will be offered admission to a certain program in one of the accredited universities. If, for example, somebody fails the National Level Examination or gets a lower score than requirements for acceptance into one of the Psychology programs, he or she will have either to retake the examination or make another career choice. Since the final grade on the examination is the criterion for acceptance to the psychology programs or to any other program, there is a lot of competition. Basically, the idea is that as a future psychologist, one has to score above the average to make one's dream come true. The National Level Examination takes place only once a year and all applicants across the

country are tested on the same questions. This examination is difficult, and in order to prepare for that, applicants take private classes throughout their last year of high-school. There are even cases of students who begin preparing for the exam two years before the actual exam day. There is a lot of pressure on students to perform well on the examination because their future depends on their exam score.

Currently, there are four different universities in Greece that offer a recognized degree in psychology: the University of Crete, the Panteion University of Athens, the National and Kapodistrian University of Athens, and the Aristotelian University of Thessaloniki, which is the largest university in Greece. The duration of psychology courses of study without specialization is usually four years (approximately eight semesters). For successful completion of studies, it is important to complete 180 hours, including 160 hours (40 courses) attending classes, thesis (10 hours) and a practical training (10 hours). 75% of the classes are directly related to psychology, while the other 25% are related to other aspects, such as Philosophy and Education.

Although pursuing a Master's in psychology is not required to practice psychology in Greece, it is considered highly desirable these days. There are a few postgraduate courses in psychology offered in Greece right now. The duration of the programs is about two years, including one year of practice. Currently, there are postgraduate courses in exercise psychology, school psychology, clinical psychology, developmental-cognitive psychology, and organizational-industrial psychology. Doctoral programs in these fields of Psychology are available as well.

In case somebody has completed a psychology degree abroad and wants to work as a psychologist in Greece, he or she will have to make sure that the degree is recognized. There is an organization called the Hellenic National Academic Recognition Information Center (Hellenic NARIC). This organization works under the Hellenic Ministry of Education and is responsible for the recognition of university degrees that are awarded by accredited foreign Higher Education Institutions. The documents that are required for recognition of degrees from foreign institutions are listed on the official website: http://www.doatap.gr/en/dikaiolog.php. In the case of non-European applicants, a work permit is also necessary in order to practice psychology in Greece.

In Greece, anybody with a four-year degree in psychology can call himself or herself a psychologist. However, getting a Bachelor's in Psychology does not automatically mean that anyone can practice psychology. In order to practice psychology or use the title "psychologist", a person would have to hold a psychology license. The Greek professional license that allows practice of psychology is given to all individuals who have graduated from a psychology program with a bachelor's degree after the completion of some paperwork. It seems that this criterion is extremely low compared to what is required in the U.S. in order to become a licensed psychologist. In the United States, a Ph.D. from an APA-accredited psychology program is typically required.

According to the law, there are no official specializations in Greece. Therefore, somebody who has earned a Bachelor's in psychology and licensure along with a Master's in Sport Psychology is considered to be a psychologist with a Master's in Sport Psychology and not a Sport Psychologist. Usually, psychologists in Greece claim a specialty in some psychology area such as school or clinical psychology although the State has not yet issued an official specialty certificate. Greece is in the process of adopting the EuroPsy Certificate which is a European Certification program that was established across Europe. The purpose of EuroPsy is to define the standards in regards to the application of the profession of Psychologist in more than one setting. These standards define the requirements in order to practice the job of psychologists. The EuroPsy is not a license for the practice of psychology and is not intended to substitute for the laws in each nation for granting licensure. It is basically a set of criteria that defines the tasks of a psychologist. The EuroPsy is issued for a limited period of time and has to be renewed. In order to get the EuroPsy, one has to provide documentation of successful completion of an academic program in psychology. He or she also would have to demonstrate successful completion of supervised practical training. Last but not least, he or she would have to accept the European Code of Conduct for Psychologists.

Various associations have also been founded to represent psychologists of different disciplines in Greece, such as the Association of Greek Psychologists, the Panhellenic Psychological Association, the Greek Psychological Association (ELPSE), the Greek Association for Behavioral Modification (member of EABCT), and the Greek Psychoanalytic Association.

Although there has been a lot of progress in the field of psychology in Greece, it seems that there are many changes that need to occur in terms of the requirements for licensure and specializations for psychologists. The criteria to become a licensed psychologist have to be reviewed and should follow the standards that exist in the U.S. If the criteria were more uniform across nations, a person who is a psychologist in Greece could also be considered a psychologist in the USA.

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Family Influences on the Career Choices of International Undergraduate College Students

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Abstract

A literature review, consisting of books and peer-reviewed empirical research studies, was conducted on how families influence international college students' career choices. Due to the limited studies related to international students, parental influences related to other student groups were also examined to draw conclusions regarding international students. Results of the review indicated that parents play a major role in children's gender-role socialization and cultural socialization, which may affect adolescents' and subsequently college students' career choices. We discussed two cultures (individualistic and collectivistic) and how the degree of parental influence on international students' career choice may be different depending on to which culture the student might belong. Implications of our findings and suggestions for future research studies regarding international students are provided.

Family Influences on the Career Choices of International Undergraduate College Students

Despite the fact that there have been many literature reviews written over the years pertaining to college students and the career decision-making process, most of these literature reviews focus on U.S. students. There are very few literature reviews with an emphasis on international students. A majority of the U.S. colleges and universities, however, host international students; thus it is important to understand how international students choose a career in order for college career counselors and advisors to effectively provide these students with assistance. Previous research (e.g., Bright, Pryor, Wilkenfeld, & Earl, 2005; Lent et al., 2002) indicates that the student's family plays an influential role during the career decision-making process. The purpose of this review is to identify how the family may be affecting an international student's career choice, and to propose suggestions to researchers regarding future research studies that could be conducted. International students in this review refer to foreign undergraduate college students, with a particular emphasis on students from more collectivistic cultures, who were studying in the United States. Because studies were limited, it was necessary to also include research studies that looked at college students from the U.S. and in other foreign countries so that we could draw additional conclusions regarding international students. The definition of family in this review pertains to the students' parents or legal guardians, as well as to their extended family. In the following sections, gender-role socialization and cultural socialization will be discussed to determine how an international student's family may influence his or her career choice.

Family and Gender-Role Socialization

In order to understand how family might be influencing college students' career decisions, it is important to look at how these students might be socialized into their gender roles as children. Socialization is "the way in which individuals are assisted in the acquisition of skills necessary to function in their social group" (Grusec, 2002, p. 143). Gender socialization occurs when children and adolescents learn about and develop gender roles (Cobb, Walsh, & Priest, 2009). Wood and Eagly (2002) indicate that gender socialization begins in infancy and that as children grow up they develop gender schemas in which they discover the concept of being men and women. The most important gender socializing medium for children is family, especially parents. West and Zimmerman (1987) state that the conception of gender develops on a daily basis through "social interactions" in order to develop differences between men and women (p.136). Based on this premise, children learn and establish gender role identities through the constant interactions they have with their parents. Gelman, Taylor, and Nguyen (2004) also indicate that children learn gender roles by watching their parents and other adult family members. Leaper (2002) indicates that parents teach their children values and attitudes about gender, as well as what they consider being appropriate gender roles by mentioning or enforcing gender stereotypes.

Children's and adolescents' gender development may affect their career development, which begins during middle childhood and early adolescence. Parents are the most influential factor regarding children's career development because they pass on career information as well as their beliefs regarding certain careers in relation to gender to their children (Bryant, Zvonkovic, & Reynolds, 2006). One of the main ways parents influence career development is by influencing their children's academic development based on their attitudes toward gender and gender stereotypes, which may affect children's perception of their level of competence in different academic subjects (Wigfield, Battle, Keller, & Eccles, 2002).

Recent research in a western cultural context has examined how parents socialize their sons and daughters regarding math and science. Tenenbaum and Leaper (2003) discovered that sons and daughters are treated differently by parents. They found that fathers gave sons more explanations and used more scientific vocabulary than daughters during a physical science lesson. Lindberg et al. (2008) found gender differences in mother-child interactions they observed during a math assignment. Mothers who believed in gender equality gave equal support and teaching to both boys and girls, whereas mothers who believed in traditional gender roles and

who were more educated in math gave girls more coaching and help than they gave the boys. Thus, both mothers and fathers may encourage or inhibit their children's attitudes and future career interests in different subjects. Based on these research studies, female international students from a western culture may believe that they are not as good as male students in math and science careers and may become less likely to pursue these majors. In fact, UNESCO (2008) found that women worldwide are underrepresented in the field of science. Out of 121 countries surveyed, only 15% of the countries have reached gender equality in science; most are located in Central Asia.

Family and the Cultural Socialization

Like gender socialization, cultural socialization is a type of socialization children and adolescents are exposed to predominantly by their families. Rothbaum and Trommsdorff (2007) state that there are two different types of culture children and adolescents are socialized into: individualism and collectivism. More individualistic cultures emphasize autonomy and independent decision making, whereas more collectivistic cultures focus on interdependence and having close social relationships (Rothbaum & Trommsdorff, 2007; Triandis, 1995).

A family's involvement in a child's cultural socialization starts during infancy through the process of parental attachment (Bridges, 2003). According to several researchers (e.g. Harwood et al., 2002; Keller et al., 2004), more collectivistic parents spend more time together with their young children, such as holding them, which helps the children develop close relationships. More individualistic parents help their children develop autonomy by being more separated from their children and encouraging them to make their own decisions.

Parents also culturally socialize their children through their parenting styles. The authoritative parenting style is considered to be the best parenting style for more individualistic cultures because it encourages children to be independent, whereas the authoritarian parenting style is considered to be the best for more collectivistic cultures because it emphasizes discipline and the importance of having close social relationships (e.g. Baumrind, 1971; Chao & Tseng, 2002).

Mazzarol and Souter (2002) found that international students' families are a major factor in decisions to study abroad. Once international students arrive in the United States, Poyrazli, Kavanaugh, Baker, and Al-Timimi (2004) found that they begin going through the process of acculturation, which is the process of having to adjust to a new culture. Not only do international students have to adjust to American culture, they have to become fluent in English and adapt to the U.S. education system as well (2004). Yeh and Inose (2003) said that acculturation may be more difficult for international students who come from more collectivistic cultures because more differences exist between international students from more collectivistic cultures and international students from more individualistic cultures.

Yi, Lin, and Kishimoto (2003) stated that succeeding academically is the most important concern international students have. This could be due to the fact that, according to Popadiuk and Arthur (2004), international students feel considerable pressure from their families to do well. Even though international students want to achieve their academic goals, Prue (2004) indicated they may have a hard time adjusting to the U.S. education system due to different teaching styles. Zhang and Dixon (2003) indicated that how international students deal with their acculturative issues can affect whether or not they will academically succeed. Therefore, students who struggle with acculturation may not do well in college.

It is important to present a major recent research study by Singaravelu, White, and Bringaze (2005) that compared more individualistic cultures to more collectivistic cultures regarding college students' career choice. They compared U.S. students to international students in order to look at how satisfied these students were with their major/career choices. The international student group was divided into Asian and non-Asian groups. All of the students indicated that their family, particularly their fathers, was an important influencing factor when they were choosing a major/career. Family influence was considered to be a stronger factor for the non-Asian international students, whereas it was considered the lowest by the U.S. students. Constantine, Wallace, and Kindaichi (2005) state that particularly college students from more collectivistic cultures are socialized to consider how their decisions will affect other people, so they will choose careers that will satisfy their parents. Tang (2002) points out that college students from more collectivistic cultures are more willing to compromise with their parents regarding their career choice. Therefore, international students from more collectivistic cultures may defer their career choice to their parents or feel that they need to strongly consider their family's wishes regarding their career choice, whereas the ones from more individualistic cultures may feel that they have more control over their career choice.

Conclusions

Based on the research studies in this literature review, it appears that families influence international college students' career choices through gender-role socialization and cultural socialization. Families, especially parents, start giving their young children messages about gender roles and what each gender stereotypically might want to choose as a career. In addition, families in more individualistic cultures tend to encourage their children to make their own decisions with some guidance, while families in more collectivistic cultures may expect that the child gives more weight to his or her parents' wishes. Therefore, counselors, student advisors, and college faculty who work with international students may need to consider the influence of the family when helping these students to make the decision to declare, stay in, or change a major.

One limitation of this literature review is the fact that few research studies related to career choice have been conducted on undergraduate international students who are studying in the United States. Because there is a lack of research

regarding the career decision-making process of international students, there are several research studies that researchers should consider conducting. The first research study could be a longitudinal study that looks at undergraduate international students. Researchers could begin to follow the students from the time they enter college in the United States, and they could look to see what the international students' majors are when they begin their college education in the United States. The students could be followed throughout their undergraduate education in order for the researchers to explore their patterns of choosing a major. Researchers should also look at the frequency with which international students change their majors. A second research study researchers could conduct is a study that compares U.S. and international undergraduate students in order to see if there are any possible differences regarding how often the students change their majors while they are in college. If the researchers find any differences between the U.S. and international students they should explore the reasons why the differences exist.

Finally, there is still a lack of research regarding the specific ways in which international students' families influence their career decisions. Therefore, more research needs to focus on how the family influences international students' career choices. In order to do this, researchers should conduct a mixed method study. During the first part of the study the researchers could interview the international students to see how their families might be influencing their career choices. The researchers would then administer a career choice survey to the international students to answer questions about their major choice. Both the interview and career choice survey questions should be based on the Chope's Family Protocol, which provides ways of assessing how the family influences the career decision-making process of college students (Chope, 2005). Chope's Family Protocol has been used with many different cultures and ethnic groups, which makes it a good assessment to use with international students. Because Chope's Family Protocol is one of the few assessments that measures how the family influences college students' career choices, developing measures to explore how the family influences the career decision-making process of college students should be an important part of career development research. Due to the fact that more recent research has begun to focus on the career decision-making process of international students, this is likely to continue to become a popular research topic in future studies for years to come.

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Social Psychology and International Conflict Resolution

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New York Peace Institute

For almost 25 years, I sometimes tolerated, sometimes enjoyed, a typical academic career in social psychology, teaching at five universities, publishing a textbook and research papers, and even serving as a department chair. During those years, having arrived in academia mostly by chance (Gross, 1998), it occasionally occurred to me that ivory tower scholarship was not my natural calling. For one thing, I often found myself diverted off campus by forays into political campaigns, business deals, and social causes. For another, I was afflicted by writer's block and almost perished on the tenure track.

As a grad student at Stanford, during some very difficult years at the University of Wisconsin in the late 60s (where the three "colleagues" closest to my interests were unavailable and unsupportive), and even after becoming tenured, I continued to feel tension between relatively pure science shared only with interested colleagues, and applied work with potential to impact and benefit non-academics and the general society.

My first attempts to stray from the rigorous laboratory work that defined the experimental social psychology of the 1960s were ventures into field studies inspired by the work of Donald Campbell and others. Abandoning the Psychology 101 subject pool yielded results with increased external validity, created interesting work for my collaborators and me and provided fodder for some papers and talks (Gross & Doob, 1976; Doob & Gross, 1968; Gross, 1975). However, despite some interest by the media including a mention in Playboy, the impact of these field studies on society was hardly noticeable.

Prior to relatively recent involvement in international work, my most extensive attempt at applied research began during the painful years at Wisconsin in collaboration with social work colleague, Irving Piliavin. Based on earlier laboratory work demonstrating that people often do not ask for needed help (e.g. Broll, Gross, & Piliavin, 1974), we successfully applied for a federal grant to study the effects of different methods for delivering service to a population of welfare mothers in Minneapolis. An extensive three-year field study yielded results that clearly identified a means of service delivery that greatly benefited the recipients compared to the standard method in use at the time. Subsequently, we prepared the results for publication in a major social work journal, (Piliavin & Gross, 1977), and sent several copies to the U.S. Department of Health Education and Welfare.

We anticipated that it would be difficult to obtain the attention of busy policy makers, but surprisingly we found that our results were read and understood. Naïvely, however, we had failed to recognize that our interests and values differed from those with power to implement and act. We had inadvertently delivered a template that allowed bureaucrats to determine how they could conserve funds, mainly by retaining the programs *least* likely to result in more aid for the needy target group. Because this and other attempts at applied research failed to have a desirable impact on various social problems, I came to recognize that academic research without opportunity to implement results was inadequate to affect real world phenomena.

A fortuitous diversion into a lucrative business in the mid 80's provided an opportunity for me to finally resign my academic position and to dedicate more of my time to applied problems, especially in the international arena. This travel-related business also provided cheap or free airfare that allowed me to become familiar with cultures on several continents.

Although I had previously devoted some time to projects outside the USA including airline consulting in Ethiopia and teaching English in Mexico, I was formally introduced to international conflict scholarship and peacemaking applications during an intensive summer fellowship at the Solomon

Asch Center for Ethnopolitical Conflict at the University of Pennsylvania in the late 1990's (http://www.brynmawr.edu/aschcenter/about/index.htm). Visitors to the Asch workshops included many international scholars, including psychologists Paul Rozin and Clark MacCauley who co-directed the program, and Herbert Kelman, Ervin Staub, Michael Wessels, among many others. Roy Eidelson, past president of Psychologists for Social Responsibility, served as Executive Director of the Asch Center until it moved to its present location at Bryn Mawr College in 2008.

In addition to the excellent lectures, stimulating discussions and extensive readings, the Asch center experience led to a number of collegial connections, some of which resulted in interesting and challenging international work. For example, Shanee Stepakoff invited me to offer mediation training to her staff at the UN Special Court in Freetown, Sierra Leone; Charles Malcolm asked me to deliver a research colloquium on help-seeking in Cape Town; and Thomas Hill opened the door to my current adjunct professorship at New York University's Center for Global Affairs where I offer applied courses in mediation skills.

Having devoted much of my volunteer time after retirement from academia to conflict resolution work, especially mediation (Gross, 2007), I often attended professional ADR (Alternative Dispute Resolution) conferences. While attending one of these meetings a few years ago, I heard Kenneth Cloke, co-founder of Mediators Beyond Borders (MBB) (www.mediatorsbeyondborders.org), speak about his vision for the new organization. The opportunity to combine my international interests with the conflict resolution skills I had acquired from many trainings and volunteer work, mainly with the Safe Horizon Mediation Program in New York City[1] , became apparent immediately.

During the past few years, in collaboration with MBB teams, I have developed and worked on a number of projects designed to build conflict resolution capacity in locations around the world. My involvement with MBB as a project leader and as a board member, has included working with Liberian refugees and child soldiers, Hurricane Katrina victims, villagers in Colombia and members of the Iraqi Peace Network. In addition, I have advocated for the use of mediation to resolve conflicts with delegates and others attending UN climate change conferences, and with Ghanaian attorneys and land settlement officers.

At first, I viewed my ventures into peace making and conflict management as a separate career almost completely divorced from the many years endured within psychology departments. However, it soon became apparent that important principles derived from social psychological research could be applied during MBB and other interventions.

One of the most basic principles, and one often ignored when dealing with groups in conflict, is that all stakeholders must be invited to participate in facilitated discussions, meetings and other activities. Although sometimes impractical when dealing with very large populations, I consider it critical to ensure that those who are likely to affect decisions and actions be strongly encouraged to attend and participate in all meetings. Inclusion of relevant stakeholders has almost become a standard practice, but this was not always the case. My consciousness for this critical factor had been raised by one of the studies assigned in my first year of social psychology grad school!

Although some have criticized the interpretation of its results, the classic study at Harwood Mills (Coch & French 1948) indicates that decisions reached with full group participation were more likely to be accepted and implemented. The Coch and French results are not directly relevant to conflict situations, but there is a strong implication that people not present or even those represented by others are less likely to buy into whatever agreements or decisions are made during group meetings. As a consequence of the Harwood Mills research combined with much group work experience, I now delay, reschedule, move venues, and take whatever actions are necessary to encourage full attendance of all who are involved in a conflict. One of the first tasks in mapping a conflict, and planning for useful interventions, is to identify all of those involved or affected. The identification process often involves intense interviewing and networking to make sure that all of the critical players are invited to the table and strongly encouraged to attend.

Another important strategy borrowed from social psychological theory and research is closely related to the popular and widely tested "contact hypothesis" and the renowned Robber's Cave study (Allport, 1954, Sherif, M, Harvey, O.J., White, B.J. Hood, W.R. & Sherif, C.W., 1969/1988) that predict that when parties work on a common problem, they often develop more positive attitudes towards each other. Allport and others have proposed and demonstrated that properly managed contact between adversarial groups working on a common problem can lead to better interactions. Some necessary conditions for the effectiveness of intergroup contact include equal status between groups or parties; common superordinate goals for the task at hand; and an interdependent task structure that requires cooperation between groups to perform the task well.

Because of the potential benefits of such contact, we have recently introduced pre-mediation training as warm-up exercises in large multi-party conflicts. In addition to the usual advantages of trainings, especially those that include interactive skill exercises, these exercises also offer benefits derived from simply engaging disputants in a common task not directly related to the conflict that brought them to the table. This method has been employed successfully among groups involved in New York City community disputes and in a recent MBB intervention between two potentially violent student groups at a West African University.

In the West African sessions, we successfully risked including some content material in the training exercises that related to issues at conflict. After the training, which included tasty food, videos, handouts with major take-away points and certificates of completion, many of the participants recog-

[1] After July 1, 2011, this Program will become independent and be renamed "New York Peace Institute".

nized that they had survived, tolerated, and in many cases enjoyed mutual activities with others previously identified only as adversaries. In a sense we had successfully channeled the spirit of the camp boys at Robber's Cave (Sherif et al., 1948) who had first despised and shunned boys assigned to competing teams, but later learned to cooperate with them after collaborating on common tasks.

Although we have consciously borrowed major principles from social psychological research related to the Harwood Mills and Robber's Cave studies, many of our other international practices have benefited more subtly from social psychological theory and data. For example, when we are able to successfully engage adversaries in dialog or other peaceful mutual activities, their cognition that "I worked/ talked with them successfully" can be viewed as inconsistent with the cognition that "I hate them" or " I should shun them". When opposing parties engage in mutual activities, negative beliefs become inconsistent or dissonant (Festinger, 1957) with the positive behavior and are likely to change.

As another example, we often encourage disputing parties to understand the other side's point of view, and to empathize with their feelings when mediating or facilitating dialog among adversaries. And when asking our clients to consider an intervention or training, we usually include both potential benefits and costs or risks. These mediation and presentation practices are at least tenuously related to the finding that two-sided communications are usually more credible and often more persuasive than a one-sided sales pitch (Hovland, Lumsdaine, & Sheffield, 1949).

Our international work is certainly not the first or only application of psychological principles related to conflict, negotiation, and peacemaking (e.g. Pruitt 2011; Rubin 1981; Kelman, 2010). Many prominent social psychologists have produced excellent research and writing that is directly relevant to negotiation, conflict management and peacemaking. And a number of academic journals[2] regularly publish articles applying psychological data and theory to peacemaking and conflict resolution.

The empirical frame inculcated via a solid education and extensive experience in academic psychology does more than make it likely that we will apply concepts like inclusion and equal status contact. In addition, a scientific background leads to better understanding of the utility of systematic data collection that can be used effectively in evaluating projects to determine whether they should be continued, adjusted or abandoned. Lastly, experimental social psychology's focus on how situational variables frequently overwhelm individual differences leads us to consider the impact of various interventions and/or causes of problems in general (for more on this issue see Zimbardo, 2007).

[2] See for example *Peace and Conflict: Journal of Peace Psychology*, The Journal of the Society for the Study of Peace, Conflict, and Violence: Peace Psychology Division of the American Psychological Association; and *Conflict Resolution Quarterly*, a publication of the Association for Conflict Resolution http://www3.interscience.wiley.com/journal/97519532/home.

Looking back on my career change from academic to applied and international work, it seems less an abrupt break and more a fortunate transition. It has become increasingly clear that my peacemaking colleagues and I often build elements of our interventions and projects on the solid foundation of academic research.

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A Brief Experiment in China: A Western-Style Department of Psychology at Fu Jen Catholic University, 1929-1933

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In 1932 the *American Journal of Psychology* published a review of recently established psychology laboratories in China (Chou, 1932). As an update to this publication Gregory J. Schramm, a Benedictine monk and experimental psychologist, published a brief report in the journal *Child Development* describing the psychology laboratories that he helped establish at Fu Jen Catholic University in Beijing. Among the three laboratories at the university Schramm identified the child study laboratory as most distinguished, "… believed to be the first and only one in China, which was originally erected and completely controlled by a department of psychology without school system connections" (Schramm, 1933, p. 279).

Gregory J. Schramm was born in Newark, New Jersey on January 9, 1898. Schramm completed his AB degree in St. Vincent's College in Beatty, Pennsylvania (1920) and was ordained in the order of St. Benedict (O.S.B.) in 1925 after completing S.T.B. and S.T.L. degrees at St. Vincent's Seminary in Latrobe, Pennsylvania (Curtis & Elder, 1960). After earning an MA from Catholic University of America, Schramm continued his training in experimental psychology in two influential American departments of psychology. He attended Columbia University at a time when the "Columbia School of Psychology" under W. S. Woodworth had already established itself as one of the "Seven Psychologies" (Heidbreder, 1933). Schramm's (1927) thesis "The Relative Affectivity of Association and Personal Reference Stimuli as Measured by the Psycho-galvanic Reflex and Introspection" was within the framework of Woodworth's dynamic psychology which supported the use of introspective and objective response measures (Graham, 1967).

Figure 1 – Catholic University of Peking changed its name to Fu Jen Catholic University when the Chinese Ministry of Education officially approved the university in 1927. The Cassinese-Benedictines of St. Vincent Archabbey purchased the Beile Tao Palace in Beijing as its campus and constructed the main building in 1930. (Courtesy of St. John's Abby, Collegeville, Minnesota)

Schramm continued his training in experimental psychology at Johns Hopkins University but shifted his interest to child development, earning his Ph.D. in 1929. His dissertation, *Direction of movements of children in emotional responses,* was a systematic examination of children's approach and avoidance responses to animals. Schramm systematically exposed children 3 to 6 years of age to a rabbit, rat, frog and parakeet at successively varying distances as they were confined to a high chair or free to walk in the room. The high chair used in the confined condition contained four pneumatic sensors that measured gross body movements. Among his observations was one of the earliest descriptions of habituation in children. His dissertation work was not published immediately, however, appearing in the journal *Child Psychology* six years after earning his doctorate (Schramm, 1935). But there was good reason for the delay in publication. Shortly after earning his Ph.D. the Cassinese-Benedictines of St. Vincent Archabbey (Latrobe, Pennsylvania) appointed Schramm acting dean of the College of Education in a new university in China– Catholic University of Peking (Beijing).

Two Chinese Catholic scholars from Beijing petitioned Pope Pius X in Rome in 1912 to establish a Catholic university in China that would integrate Christian faith in its curriculum with Chinese intellectual and western scientific thought. At the request of the Holy See the Cassinese-Benedictines of St. Vincent Archabbey established the university in 1925 beginning with an affiliation with Fu Jen Academy (also named McManus Academy of Chinese studies). The university's duality as a western Catholic and Chinese university was achieved successfully by introducing western science

Figure 2. Gregory Schramm in the general psychology laboratory of the Psychology Department at Fu Jen Catholic University. (Courtesy of St. John's Abby, Collegeville, Minnesota)

while preserving an appreciation of Chinese culture (Chen, 2004).

In 1927 a reformed Ministry of Education under a new Chinese National Government forced expansion of the university from 1 to 3 schools and a name change to *Fu Jen Catholic University*. One of the added schools was the School of Education consisting of a Department of Pedagogy and a Department of Psychology. Schramm was acting dean of the School of Education the first year but served as the chair of the Department of Psychology his remaining years at the university (Chen, 2004; Wu, 1993). The department curriculum was described as offering "… all the important fields in the realm of Psychology at the collegiate level. The varieties of psychologies spread over the four-year course" (Fu Jen News Letter, April 1931, p. 7). In the early days of experimental psychology Catholic psychologists at Christian institutions had to come to terms with the new scientific psychology by defending its legitimacy while arguing against assertions that the new science demanded an atheistic or agnostic philosophy (Misiak & Staudt, 1954). With training in experimental laboratories at three different American psychology departments Schramm was in an excellent position to introduce the science of psychology to Chinese students within a Catholic context.

Schramm designed the child study laboratory primarily to observe and test preschool children under controlled laboratory conditions. The young American psychologist's efforts as director of a "pioneer child study laboratory" in an exotic land even made notice in the popular press (The Science News-Letter, 1932). However by 1933 as a result of the hardships of the Great American Depression the Cassinese Congregation of Benedectine Monasteries could no longer finance Fu Jen Catholic University, transferring operation to the care of the *Divine World Fathers* (Wu, 1993). When the Chinese Communist Government took power in 1949 the Ministry of Education dismantled Fu Jen Catholic University, annexing what remained to the Beijing Normal University in 1952. Fu Jen Catholic University would be re-established in Taiwan in 1961.

With St. Vincent Archabbey no longer involved in Fu Jen Catholic University Schramm returned to America. In 1937 he was hired as a lecturer of psychology in the urban division of Seton Hall College in New Jersey (Setonian, Feb 8, 1937). The urban division of the college was established in 1936 as an extension college to provide men and women unable to attend the program at the main South Orange campus (which at the time was exclusively male) an opportunity to attend college in Newark and Jersey City. By the next academic year Schramm was appointed professor of psychology on the South Orange campus in the newly named Department of Philosophy and Psychology. He would establish a laboratory and teach experimental psychology and child psychology. But by 1940 there was no longer a Department of Psychology on the South Orange campus and Schramm had left to teach for two years in the graduate program at Fordham University. He would eventually return as a faculty member in a newly formed Psychology Department at Seton Hall University and retire in the late 1960s. Schramm died September 15, 1972.

Figure 3. Gregory Schramm testing a child participant in the gardens of the Child Study Laboratory. (Fu Jen News Letter, April 1931, p. 14)

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The January 2011 issue of *Interpersonal Acceptance*

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Thoughts on the Status of the Mental Health Psychologies in Thailand

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Introduction

In an attempt to promote the development of Psychology in Thailand, and especially those disciplines dealing with mental health as Clinical Psychology, Counseling Psychology, Social Work and Marriage and Family Therapy, senior scholars from the US have been annually invited to lecture or teach mini-Psychology courses, consult on curricular development and promote the exchange of Thai students to the US for advanced doctoral training (Svare, 2011). Among the intended audience of these top-down efforts, it is presumed would be Thai administrative personnel who are in the position to initiate and establish the necessary structural organizations to implement new Psychology programs and Departments at various institutions of higher education in Thailand. Not only are advanced programs at the Master's and Doctoral levels needed, but a dynamic and flourishing undergraduate college level curricular is a sine qua non to provide a broad based feeder system into the yet-to-be established graduate programs. This is an important step in the revitalization of

the profession of Clinical/Counseling Psychology in the Thai Mental Health Care System without which jobs taken over by other mental health professionals would override and make superfluous the Thai Psychologist, or at least relegate them to technician status, similar to the first generation of Thai psychologists (Tapanya, 2004).

Impediments

However, there are at least five deterrents/impediments for the growth and development of Clinical/Counseling Psychology in Thailand. These may be broadly categorized into the following areas: cultural, religious, educational, economic, and the influence of the family.

The cultural area involves the attitude ingrained in young Thais from very early on to respect their elders, to treat them with deference and unquestioned obedience. These concepts are expressed in the Thai term *kao rop* meaning *respect*. In a much broader sense it is expressed in the relationship between *phuu yai* (big person) and *phuu nawy* (little person) along the lines of social rank defined by age (adults vs. children, elder vs. younger siblings), wealth (haves vs. have-nots), occupational status (employers vs. employees), education (highly educated vs. less educated), political power (elected vs. appointed), law enforcement (military/police vs. civilians), nationality (Thais vs. farangs or foreigners), etc.

In the religious arena, it is not uncommon for young Thai males to enter a Buddhist Wat (temple) for a short period (1week up to 3 mos.), and this brings great merit for the family. Here the novitiate is exposed to a set of monastic vows imposing disciplinary rules accompanied by meditation and religious (Dharma) study. During the day, barefoot robed monks may be seen receiving gifts (food or money) in their bowls, and through this process, much merit is accorded the donor. Monks are often brought into homes to bless and recite prayers for anniversaries as for a respected and departed member; into Universities to religiously celebrate auspicious occasions, into political (see Fig. 1) and monarchy-related events. The ever pervasive appearance of monks is a constant reminder of the role of Buddhism in the daily life of all Thais. Monks are sought out for counseling on a variety of psychological issues or emotional problems, and the donation can be much less than the cost of seeing a Clinical Psychologist or a Psychiatrist, depending on the generosity of the donor. There is still a strong stigma attached to seeking mental health services, so it is more socially acceptable for Thais to seek help from monks.

Fig.1 The interior of Wat Luang in the city of Phrae (Northern Thailand) where a wealthy merchant from Chonburi has made a large donation to the monks in the presence of local government officials, bringing together the religious, political and familial influences ever present in Thai society.

In addition, there is a famous Wat in Saraburi Province that has a reputation for helping people who are suffering from drug (heroin/opium) addiction by employing traditional Thai herbal medicine, psychological support and aspects of Dharma. Wat Tham Krabawk claims a success rate of 70 to 80% with treatment lasting up to 6 months, initially involving emetic herbs to detoxify the body. Upon completing the program, patients ingest a sacred paper inscribed with a vow to remain drug free, which if broken would incur the wrath of the spirit world. In 1975, after 57,000 addicts were treated, the respected head of this Temple was awarded the Magsaysay Prize. Thus, because of the manner, style, discipline and the respect accorded the Buddhist monks, the Thai people, in general, believe that Monks can help solve or ameliorate their everyday problems, more so than psychologists and/or psychiatrists.

Thai people have their own way of dealing with stress and emotional problems. They practice meditation as prescribed by Buddhism. It would be difficult to scientifically prove that this technique has validity but the incontrovertible fact is that the growth of people from all walks of life practicing meditation suggests the use of this technique is considered a practical way of dealing with emotional issues, perhaps by leading to an increase in self-awareness.

The current Thai system of higher education with its emphasis on not questioning or challenging the authority of the Professor directly, because it is improper or impolite, is well known. This stifles creativity and independent thinking, while simultaneously encouraging rote learning where, in many cases, the notes of the Professor become the notes of the student without passing through the brains/minds of either. It would be interesting to note if there are any seminar courses or independent research courses both on an undergraduate level as well as in those Psychology programs offering a Ph.D. degree (like Chulalongkorn Univ.). It would be interesting to specify the courses constituting a Psychology major in the undergraduate curriculum. For instance, are there courses in Abnormal Psychology, Tests and Measurements, Internships or Clerkships, Biological Bases of Behavior, Theories of Personality, Social Psychology, etc.? Is a Senior Research Project in the college curricula required before graduating? This offers an opportunity for the student to actually get involved in designing/ planning and carrying out his/her own research. If a senior Project is required, are

there opportunities for these studies to be presented? This could easily be accommodated at Mahidol University (See Fig. 2) where many such conferences are annually hosted. Alternatively, is there a national honor society serving as a venue for such an activity, similar to the US Psi Chi Society that is strictly for undergraduates? There are a number of advantages for such a formation, not the least of which is identification with the discipline, coupled with an increase in motivation to study further by working for an advanced degree. This bottom-up approach would further strengthen the development of Psychology.

Fig. 2 An aerial view of Siriraj Hospital and Mahidol University on the banks of the Chao Phraya River, Bangkok, Thailand

Another important element having a detrimental effect on the formation of new programs concerns the recent Thai economic situation. A change in the government's policy toward funding higher education programs occurred at and around 2004. Prior to that, public universities were under the jurisdiction of the Ministry of Education and received financial support from them. Since then, the economic recession in Thailand mandated a reduction in subsidies, thereby forcing all public universities to initiate fund-raising activities. In addition to curtailing new programs, all employees of public universities hired after 2004 were no longer considered civil servants, and therefore, were not entitled to health care or retirement benefits. Without money, it is impossible to hire the necessary faculty to staff new programs to meet the need of an expanding student enrollment. While recognizing the need for development in the direction of Psychology, its growth seems to be halted or at best, severely curtailed. Unless the Thai people are aware of the importance of Psychology in their everyday life, the chance for expansion is minimal, regardless of the money. Other programs focusing on public health issues (lymphatic filariasis, HIV-AIDS, mosquito allergies, malaria, parasitic infectivity, etc.) are considered more important, and therefore, are more likely recipients of the limited financial aid that is available.

Finally, the role of the family impacts the type of care received by the mentally ill. At the center of Thai society is the family unit consisting of all blood relatives and those who marry into the family. In the next strata, are friends, professional colleagues, and close acquaintances. Beyond this circle is everyone else. When anything goes awry within the family circle, the members close ranks and attempt to ameliorate or lessen the negative impact. The Thais have great respect for the family unit. Therefore, in many cases, when one member is stricken with a mental illness, instead of seeking long-term care in a mental hospital, home care is the preferred mode of treatment. This obviates, to a certain degree, the stigma associated with "losing face" by having a mentally ill family member, even though hospitalization and the treatments they offer are recommended. Also, since most Thai parents want their children to be well, seeking mental health services may bring shame and guilt to the family. Consequently, people with mental health concerns may exhibit reluctance in seeking parental advice/support, and would more likely seek out friends. Thus, the concept of peer counselors becomes critical in the advancement of Psychology in Thailand. China and Taiwan have already adopted this model under the supposition that it increases/improves mental health more effectively. It also may help in "planting seeds" to germinate interest in a new generation of students to pursue their education in this important field, reasoning that they also can make a difference.

Conclusions

These impediments are not written in stone. They can be overcome but the process is long and arduous. There is no quick easy fix. The establishment of new curricula in new programs is a combination of a top-down effort by administrators and a bottom-up approach by the undergraduate departments. This will strengthen a broad-based foundation for the implementation of graduate level training that is currently lacking. Marketing is needed to inform and educate the Thai people about Psychology. This may be realized through (a) advertizing and public relations efforts through local media outlets, (b) showcasing to the public at University/Collegiate events, the research efforts of Psychology majors, (c) highlighting specialized interests that characterize particular Psychology Departments. All of these activities would be aimed at explaining the technical aspects of Psychology in a jargon-free manner to the Thai public. At the same time, this is a two-way street. Scholars in the US can learn much from what has already existed in Thailand. It is more about collaboration and learning from one another, rather than "having them to be more like us."

Note: *John J. Boitano, PhD is a Distinguished Professor of Psychology and Neuroscience from Fairfield University (Retired) and Research Consultant to the Department of Parasitology, Mahidol University, Bangkok, Thailand. Patsharaporn Techasintana, MD from Mahidol University, is currently working for her PhD in Immunology at the University of Missouri, Columbia, Missouri. Pam Rasmidatta, a graduate of Chulalongkorn University, Bangkok, Thailand, has an MBA from the University of New Haven, West Haven, Connecticut*

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Internationalizing Your Psychology Course: Preliminary Survey Findings

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Colleges and universities across the country are internationalizing their campuses and curricula. Increasing numbers include the goal of developing global citizens in their mission statement. There are many compelling reasons why a growing number of instructors have tried to internationalize their courses in some way. These include the need to develop intercultural awareness, sensitivity, and knowledge among students, the lack of "Cross-national" knowledge, research, and perspectives about psychology, and that psychology is inherently an international or global field of study (Stevens & Gielen, 2007). There has been an increasingly urgent call by prominent psychologists in the U.S. to internationalize the U.S. psychology curriculum (e.g., Bartolini, Gharib, & Phillips, 2009, Grenwald-Mayes & Moore, 2002; Hogan, 1996; Marsella, 2007; Stevens & Gielen, 2007; Stevens & Wedding, 2004; Takooshian, 2004; Velayo, Oliva, & Blank, 2008).

In 2004, the American Psychological Association was one of the grant recipients from the American Council on Education (ACE) funded through the Carnegie Foundation. APA formed a small task force of psychologists with an international perspective and relevant expertise to determine ways to promote the internationalization of the teaching and learning of psychology at colleges and universities in the United States (APA Task Force on Internationalizing the Undergraduate Psychology Curriculum, 2005).

Internationalization of the psychology curriculum has been an important concern of Division 52, International Psychology, since its inception in 1997. The Division's Curriculum and Training Committee is charged with promoting and supporting internationalization of psychology across the educational span, including high schools, colleges and universities, graduate school, and specialized training programs. As part of this effort, several APA Convention panels have been offered along with hospitality suite conversations to promote internationalization of the curriculum. Lively discussions among panel audiences and hospitality suite attendees suggested a number of psychology faculty are very interested in finding ways to incorporate global perspectives into the courses they teach. We hoped that from a survey of faculty who are currently internationalizing their psychology courses we would learn something about the methods and approaches they use. The Curriculum and Training Committee conducted a survey to discover how psychology faculty members have attempted to internationalize the courses they teach.

Description of Survey Project

The online survey "Internationalizing the Psychology Curriculum" began early in 2009. The survey was sent to members of Division 52 and select non-members through the teaching of psychology listserv administrated by the Office of Teaching Resources. There were 128 respondents to the survey by the end of 2010. More than half of the survey respondents had begun to internationalize courses they teach. Survey responses in this article have been edited.

International and Internationalized Courses

Courses inherently international, such as cross-cultural, international, and peace psychology, were most frequently mentioned as courses taught with international content. Of courses not traditionally thought of as international, survey respondents had internationalized courses in developmental, research methods, abnormal, gender, history, introductory, organizational, educational, cognitive, neuro/physiological, and personality. The method used most often (91.7%) to revise courses to include global perspectives was infusion of international content throughout the course. Far fewer (16.7%) added international content in a module format. Several individuals had both infused and added modules to internationalize courses.

How Faculty Internationalized Courses

When survey respondents gave specific examples of how they had internationalized psychology courses, nearly all responses corresponded to one or more of the following categories: lectures, classroom activities, and student assignments. Many responses reflected a desire to expose students to greater diversity in areas such as cultural, economic, education systems, and gender relations.

How Faculty Internationalize Lectures:

- Use a comparative method, United States compared to another country, such as in teaching gender and educational systems
- Include contributions of non-United States psychologists
- Infuse cultural content into all examples
- Use case studies from other countries
- Include anthropology sources and concepts
- Use international data sets
- Draw from personal cultural and international experience
- Include indigenous psychologies

How Faculty Internationalize Classroom Activities:

- Show films that enhance an international perspective and critical thinking pertaining to psychological constructs
- Post a global map to point out world areas
- Invite guest speakers such as visiting scholars, international students, and study-abroad returnees
- Students discuss how given information applies internationally
- Discuss methodologies used in other countries
- Assign exercises using international data sets
- Discuss world events and current issues
- Fields trips such as to the United Nations

International Student Assignments:

- Research and papers on psychology in other countries
- Research on psychologists from other countries
- Readings in the field of international psychology
- Readings from other disciplines
- Read news from other countries
- Interview someone from another culture
- Collaborative project with students in another country

There also seems to be a growing number of psychology instructors who recognize the importance of using Internet-based technologies in the classroom as an efficient and convenient way to help internationalize their courses (Power & Velayo, 2006). Such technologies can be particularly relevant and effective pedagogical devices in internationalizing the psychology curriculum (Velayo, Oliva, & Blank, 2008). Blogs, wikis, Facebook, Google groups, LinkedIn, Twitter, YouTube videos, and Skype are among the more common web platforms used to enhance lectures, classroom activities, and student assignments. Given that many students are relatively familiar with many of these technologies, their use can facilitate readiness to seek international content to infuse in the course, and also to communicate and collaborate with others across geographical regions of the world.

Goals for Psychology Students with Respect to Internationalization

Stated goals for psychology students reflected four main areas; content knowledge, perceptual framework, skills, and experiences. Representative responses are included below:

Content Knowledge

Survey respondents want their students to know psychology is an international discipline and to understand what makes it so. Following are representative comments regarding what faculty want their students to know with respect to international content knowledge in psychology:

- Awareness of limitations of current state of psychological research, that the vast majority of research has been conducted by Western researchers with Western college students
- Understand the issues surrounding psychological universals and cultural specifics
- Understand that culture not only affects the subjects we study in textbooks, but it affects how researchers establish hypotheses and methods, and how clinicians try to reach people across cultures
- Help students understand the influence of growing up in other nations on peoples' thinking and behavior
- Help students understand things American psychology and psychology in other nations have in common and how they differ. Provide students information on the historical impact of other nations on American psychology
- Awareness of broader world of psychology and opportunities for teaching, research, and service in other countries
- Know how to do international research

Perceptual Framework

In addition to content knowledge, many faculty expressed a desire for students to develop an open, non-ethnocentric framework through which to view international content. They wanted students to appreciate how the lens through which differences are viewed impacts understanding. Several survey respondents suggested that students need to first examine their own life history and context in order to appreciate how an interpretive lens is formed and how it filters perceptions. While some respondents mentioned conceptual framework in a general manner, others specifically linked conceptual framework to psychology. Selected responses reflecting this theme include:

- Become aware that the United States' view is only one view

- To realize that culture and context affect behavior
- Diminish American ethnocentrism in the profession
- To gain non-U.S. perspectives and appreciate different outlooks on key psychological concepts
- Appreciation of similarities and differences. Respect for diversity reduces ethnocentricity
- A growing sense of cosmopolitanism, marked by increased tolerance and openness
- To adopt a comparative/anthropological perspective when traveling and studying psychology

Skills

Several survey respondents' goals for students included skills needed presently and in the future for international psychology practice and research. Competency in applying psychological principles to individuals in countries worldwide and the ability to work with individuals from other countries or cultures are representative of skill-related goals mentioned by survey respondents.

Experiences

A number of faculty recommended that their students participate in international and cultural experiences. These experiences were sometimes included in a course such as service learning or a field trip, but more often were extracurricular. Study abroad, participation in cultural events, attendance at international conferences, and service learning offered through other parts of the university were suggested as ways for students to gain international experience.

What It Means to be a Global Citizen in the Context of an Internationalized Psychology Curriculum

The American Council on Education, Center for Global Initiatives worked with a number of colleges and universities between 2002 and 2007 to develop strong international outcomes goals for their students in its Global Learning for All initiative (2006). Institutions developed goals and outcomes that addressed both framework and content for international education. Most of the institutions embodied the notion of global citizenship preparing students to be competent and compassionate individuals who participate in the world in a manner that betters life for people and the planet. Although a common definition of global citizenship has not been adopted for psychology students, Hobbs and Chernotsky (2007) propose a three-part definition for students in interdisciplinary international studies programs that may have some relevance to psychology. First, students need an awareness of complexity and interdependence in the world. Second, students need a perceptual framework that reflects openness and appreciation of difference. Finally, students must be able to effectively communicate across cultures. A number of survey responses included these and other ideas of global citizenship in the context of an internationalized psychology curriculum. This question elicited particularly rich answers. Following are several representative responses:

- I think to be a "global citizen" means to have some understanding of how the rest of world works; to be aware of other cultures and how those cultures influence behavior and cognition; and to be able to accept that differences do not mean inferiority. Global citizens should be able to communicate a sense of understanding and respect for each other even though they may speak different languages.
- It is important that psychology professors and students seek information on research, teaching, and practice internationally. We should reach out to like-minded colleagues abroad; seek the findings of research conducted in other cultures and countries; attend international conferences where possible; and teach our students how to acquire knowledge about psychology internationally.
- A Global Citizen/Psychologist is one who has the philosophy of psychology as a transformational discipline focusing on broad competencies rather than narrow skills or type of education. A Global Citizen/ Psychologist conducts her/himself in ways that are culturally sensitive, multimodal, and reflective of multiple ways of knowing, cognizant that behavior cannot be considered apart from specific contexts.
- The competent Global Citizen/Psychologist must have both a broad knowledge of the scientific and theoretical principles of psychology from a global perspective and the ability to apply that knowledge in culturally sensitive ways and in diverse settings. The Global Citizen/Psychologist is flexible and open to new developments in the field and in personal behavior exercises critical thinking, practices in ways sensitive to social justice and universal ethical principles, examines critically the role of personal values, and appreciates cultural diversity.
- Global Citizen: a World citizen. Somebody who belongs to several countries and cultures at the same time. Somebody who doesn't identify with one citizenship as their primary citizenship, but feels they belong to several places in the world. A psychology graduate who has the knowledge and the competence to be able to work and generate knowledge in more than two places, countries, cultures in the world.
- To have an openness to different perspectives, research orientations and varied understandings of psychology, depending on one's cultural background. To be able to impart in the classroom psychological research and practice that accounts for differences and similarities on an international landscape. To get away from the notion that Americanized psychology is somehow superior to alternate approaches around the world.

Faculty who Internationalized Courses

Survey respondents were varied with respect to institution type (figure 1), faculty rank (figure 2) and courses taught (table 1). The greatest number were from comprehensive universities. Next, were equal numbers from community

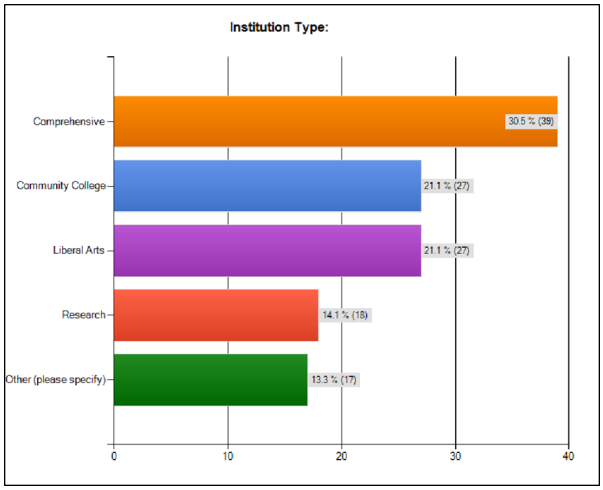

Figure 1. Bar graph showing institutional affiliation type of survey respondents

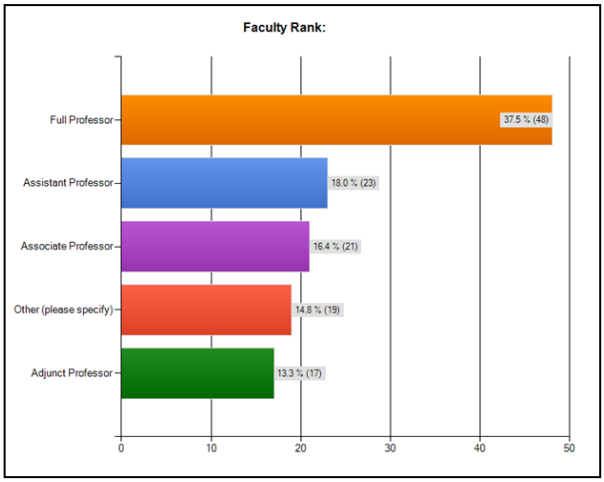

Figure 2. Bar graph showing faculty ranks among survey respondents

colleges and liberal arts institutions. Fewer respondents were from research institutions. Others were from more than one institution type, a high school, or other combination of research and private practice.

In terms of faculty rank, Full Professors were by far the largest groups of survey respondents. Assistant and Associate Professors were nearly equal in number. In addition, there were adjunct professors who responded to the survey.

Survey respondents have engaged in a broad range of international experiences and activities (table 2). However, it is interesting to note that only 25% had been involved with an interdisciplinary international committee or task force at their institution. Approximately three fourths had not been involved with such a group.

When asked the extent to which respondents' institutions encourage internationalism, approximately half identified a

"Internationalized" Course	Created	Revised
Cross-cultural/multicultural	29	14
Other (Psych)	13	21
Other (Non-psych)	7	9
Developmental	5	18
Research Methods/Statistics	5	8
Abnormal	4	16
Gender	3	9
History	3	6
Introductory/General	3	13
Social	3	15
Organizational	2	1
Educational	1	2
Cognitive	0	2
Neuro/Physiological	0	2
Personality	0	4

Table 1 List of "internationalized" courses that survey participants had created or revised

International Activities of Respondents	Frequency	Percentage
International Faculty Teaching Exchange	26	24.8
International Research	63	60
Leading Study Abroad Trip	20	19
Internationalize Courses Taught	61	58.1
Participation in Campus International Activities	51	48.6
International Service Learning as Part of Class	12	11.4
Other(s) (e.g., international conferences, U.N. involvement, studied abroad, Fulbright, international committees, international travel, lived abroad, course development in other countries, foreign national)	38	36.2

Table 2 List of international activities of survey respondents

high level of institutional commitment across the campus to internationalism. Twenty percent identified a more limited commitment to internationalism. Seventeen percent perceived no overt commitment to internationalism, and four percent reported their institutions to be antagonistic toward international efforts.

With respect to support from respondents' academic departments in internationalizing the curriculum, approximately 55% perceived no support or encouragement, 29% reported a high level of encouragement, 15% perceived some encouragement, and 2% perceived hostility toward efforts to internationalize the psychology curriculum. However, as some faculty who perceived high or moderate encouragement to internationalize were quick to point out, encouragement does not always mean monetary support or release time. The picture that emerges is that many psychology faculty members are making significant independent efforts to internationalize their teaching.

Despite challenges, internationalization of the psychology curriculum is solidly underway. The Curriculum and Training Committee has revised its survey and is in the process of collecting more data. Many survey respondents expressed a desire for resources to help with international

course creation and revision. Sample syllabi, curriculum guidelines, reading lists, model programs, recommended textbooks, release time and funding were most often mentioned as needed resources. A number of respondents suggested that internet based resources would be the most helpful.

The Curriculum and Training Committee encourages faculty who have internationalized teaching resources to share these by sending them to the chair of the Committee, Gloria Grenwald at grenwald@webster.edu or to Division 52 webmaster, Richard Velayo at rvelayo@gmail.com. The resource bank will eventually be posted on the APA Division 52 (International Psychology) website.

Recommended Resources to Internationalize the Teaching of Psychology

There are abundant resources that can be very useful in incorporating international content into a psychology course but these are not generally available through a single published resource. For those who wish to read more about internationalizing the psychology curriculum, Velayo (2011) lists recommended resources (listed alphabetically based on authorship) to help you gain more knowledge and develop your own unique approach to internationalizing your courses.

1. APA Task Force on Internationalizing the Undergraduate Psychology Curriculum. (2005). *Report and recommended learning outcomes for internationalizing the undergraduate curriculum.* Retrieved on July 11, 2010 from http://www.acenet.edu/Content/NavigationMenu/ProgramsServices/cii/ current/past/APAFinalACEReportjtp.doc [This document recommends five relevant goals and associated learning outcomes for internationalizing the undergraduate psychology curriculum in the United States.]
2. International Journal of Psychology (2006, Volume 41, Issue 1). [This special issue of the journal published on behalf of the International Union of Psychological Science (IUPsyS) features the topic on "International Practices in the Teaching of Psychology" with guest editors, Victor Karandashev and Sherri McCarthy.]
3. *International Psychology Information Clearinghouse.* Retrieved on July 11, 2010 from http://www.internationalpsychology.net/resources/ [This 100+ page comprehensive listing of relevant resources has been compiled by Michael Stevens, PhD (Professor of Psychology at Illinois State University) and made accessible on the website of APA's Division of International Psychology. It contains general resources - accessible via the web or in print form - including career information, international psychology organizations, work opportunities for academic, research, and clinical settings, potential funding sources for US and non-US instructors and students, books, articles, syllabi, conference presentations, and many other resources.]
4. McCarthy, S., Newstead, S., Karandashev, V., Prandini, C., Hutz, C., & Gomes, W. (Eds.) (2007). *Teaching psychology around the world, Volume 1.* Newcastle upon Tyne, UK: Cambridge Scholars Publishing. [This book provides an overview of teaching psychology internationally by incorporating research and perspectives from psychologists in more than 30 countries. It also includes relevant information for secondary, undergraduate, and post-graduate psychology programs.]
5. McCarthy, S., Karandashev, V., Stevens, M., Thatcher, A., Jaafar, J., Moore, K., Trapp, A., & Brewer, C. (Eds.) (2009). *Teaching psychology around the world, Volume 2.* Newcastle upon Tyne, UK: Cambridge Scholars Publishing. [This book includes current information on the teaching and practice of psychology collected by experts in the field throughout the world. It is highly recommended by prominent U.S. psychologists. One of the chapters from this book that you may find useful is by Meiners (2009) titled "Viewing films to build 'global competence': A case study."]
6. Woolf, L. M., Hulsizer, M. R., & McCarthy, T. (2002a). *International psychology: A compendium of textbooks for selected courses evaluated for international content.* Retrieved March 31, 2011 from http://teachpsych.org/otrp/resources/index.php?category=International%20Psychology [This electronic resource contains a compilation of information on textbooks in introductory, social, and lifespan developmental psychology, which have been evaluated for international content. It includes comparative tables (amount of international coverage per textbook and per chapter, total number of chapters, number and gender of authors, etc.), plus narrative reviews of each of the textbooks given these three content areas.]
7. Woolf, L. M., Hulsizer, M. R., & McCarthy, T. (2002b). *International psychology: Annotated bibliography, relevant organizations, and course suggestions.* Retrieved March 31, 2011 from http://teachpsych.org/otrp/resources/index.php?category=International%20Psychology [This contains a diverse set of resources including sample syllabi, annotated bibliographies, and video suggestions to help you incorporate international content into selected existing courses. It may also be useful to those who wish to develop a course on international psychology.]
8. Pawlik, K., & d'Ydewalle, G. (2006). *Psychological concepts: An international historical perspective.* Hove, UK: Psychology Press. [This book provides an international perspective on each of the core psychological concepts, describing and analyzing them from a historical point of view. Authors from 11 countries and 4 continents, all distinguished in their respective research areas, contributed the 14 chapters.]
9. Stevens, M. J., & Wedding, D. (Eds.). (2004). *Handbook of International Psychology.* New York: Brunner-Routledge. [This book chronicles the evolution of psychology in different world regions for the purpose of reducing the ethnocentric nature of the western

psychology. Each chapter follows a uniform outline, unifying the volume as a whole, but allowing for the cultural diversity and status of psychology in each country.]

10. Stevens, M. J., & Gielen, U. P. (Eds.). (2007). *Toward a global psychology: Theory, research, interventions, and pedagogy*. Mahwah, NJ: Erlbaum. [This book is a thorough review of the existing literature on international psychology from around the world and provides the knowledge needed to successfully engage in the science and practice of psychology in an increasingly globalized society. It provides an overview of conceptual models, research methodologies, interventions, and pedagogical approaches related to international psychology.]
11. Wedding, D., & Stevens, M. J. (2009). *Psychology: IUPsyS global resources.* [CD-ROM (8th ed.)]. Hove, UK: Psychology Press. [This resource contains a set of tools covering all aspects of psychology around the world. New material is added to this CD-ROM and existing sections are updated and/or expanded annually.]

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Velayo, R. (2011). Internationalizing your psychology course. *Excellence in Teaching*. Retrieved from http://teachpsych.org/resources/e-books/eit2010/eit10-05.pdf

Velayo, R. S., Oliva, J., & Blank, D. (2008). Using the internet: A call to internationalize the psychology curriculum. *International Psychology Bulletin, 12*(1), 22-26.

Request for Info: Department Study Abroad Opportunities

Hello Division 52 members:

The student committee of Division 52 is seeking to gather information on what types of study abroad and/or international immersion experiences are available across psychology programs. We hope to use this information to create a resource for students and/or faculty to find information on what types of study abroad experiences exist around the world. If you could take a few minutes and answer the below questions, we would greatly appreciate any information you can provide on what study abroad experiences exist around the globe! Responses can be sent back to me, at anhutchison@bsu.edu.

Please provide the following information, if available:

1. What types of study abroad or immersion experiences does your psychology department offer to your students (e.g. target student population, undergraduate or graduate focus, location, length of time, activities completed during experience, etc.)?
2. How do these opportunities further students' education?
3. How do these opportunities contribute to the study of psychology?
4. Any other information that you feel would contribute to this project.

Again, thank you so much for taking the time to provide this valuable information!

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Student Committee of Div. 52 - Member at Large
Second Year Doctoral Student
Counseling Psychology and Guidance Services
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Psychologists' Role in Advancing the Agenda and STEM Education for Girls and Women at the United Nations: A New Agency and Psychologists' Events at the Commission on the Status of Women

The following three articles describe psychologists' role in new developments at the United Nations regarding the women's agenda.

The New "UN Women" at the United Nations

Judy Kuriansky, Ph.D. (DrJudyK@aol.com)

Mary O'Neill Berry, Ph.D.

The global women's movement now has a rare opportunity to participate in building a new UN agency focused on leading the UN to improve the lives of girls and women worldwide. That hope lies in the creation of a new United Nations organization -- the United Nations Entity for Gender Equality and the Empowerment of Women, known as UN Women (www.unwomen.org) that was formed in July 2010, became operational January 1, 2011 and was formally launched in March 2011 in conjunction with the Commission on the Status of Women annual meeting at UN headquarters in New York.

Psychologists representing psychology-related NGOs at the United Nations were present at various ceremonies for the launch of UN Women, and are actively preparing to contribute psychological research and best practices relevant to the mission of the new agency.

At the launch luncheon for UN Women (seated from left to right) APA UN Representatives Janet Sigal and Susan Nolan; colleague Cecilia Marzabadi; and (standing) APA Main UN Representative Deanna Chitayat and APA Div 52 CIRP liaison and IAAP UN Main Representative Judy Kuriansky

One major event was a luncheon at UN headquarters, with the new head of UN Women, Michelle Bachelet, former President of Chile, as the main speaker. Women and men representing over 200 organizations worldwide were present, along with representatives of psychology associations accredited at the United Nations, and UN dignitaries. The Main UN Rep from the International Association of Applied Psychology and APA Division 52 liaison to CIRP, Judy Kuriansky, and the Main UN Rep from the American Psychological Association, Deanna Chitayat, spoke briefly with the President of the New York Chapter of UN Women and with Mrs. Ban Ki-Moon, wife of UN Secretary-General Ban Ki-Moon.

The UN Secretary-General's wife, Mrs. Ban Ki-Moon (left) with APA Div 52 CIRP liaison Judy Kuriansky (middle) and APA UN rep Deanne Chitayat (right)

UN Women is composed of four previously separate groups: UNIFEM (United Nations Development Fund for Women, founded in 1976), DAW (Division for the Advancement of Women, founded in 1946), OSAGI (Office of the Special Advisor on Gender Issues and Advancement of Women, founded in 1997) and INSTRAW (International Research and Training Institute for the Advancement of Women, founded in 1976). The new Executive Board consists of 41 elected people, headed by an Under Secretary General *Michelle Bachelet*. Four seats on the Executive Board are reserved for the highest donors, two from the developing world and two from the traditional major donor countries (one of the latter will be the United States).

The functions of UN Women are:

- to provide substantive support to UN bodies
- to support national efforts to promote/enhance gender equality through country-driven programs
- to undertake advocacy at regional and national levels
- to support Member States in implementing and monitoring the 12 areas of the Beijing Platform for Action and CEDAW (*Committee on the Elimination of Discrimination against Women*)

- to undertake research and analytical work and act as a knowledge hub on gender equality and women's empowerment
- to lead and coordinate the UN system's strategies, policies, and actions in this arena
- to strengthen the accountability of the UN system, including providing oversight/monitoring/ reporting on system-wide performance regarding gender equality and to monitor and report on system-wide compliance with intergovernmental mandates on gender balance, including at senior and decision-making levels

The budget was estimated to amount to USD 500 million annually.

Why UN Women came about: While many organizations had been active in women's issues at the UN and in civil society, and while NGOs had achieved some progress by putting forth statements, declarations, platforms, and conferences related to women's rights and issues, there was great frustration about lack of implementation due partly to lack of resources and the low level authority of women's voices in the UN. The new agency was formed with the promise to be a true "game-changer" -- a new way for women's issues to be talked about and acted upon at the United Nations in a both effective and efficient way. An added advantage is having a high level UN official put in place at the helm, with the high grade of "Under Secretary General."

The challenge is daunting. To help, the GEAR campaign (standing for Gender Equality Architecture Reform) was also launched (www.gearcampaign.org). This network of over 300 women's, human rights and social justice groups and NGOs has four mandates, to: (1) establish meaningful, systematic, and diverse civil society participation; (2) help shape UN Women to play a critical role in the 21st century global women's movement, by ensuring that UN Women becomes a coordinated, strong, and strategic organization that further advances the UN's work on gender equality and women's empowerment and improves the daily conditions of girls and women's lives; (3) pressure donors to aim for USD 1 billion in funding; and (4) seek powerful, capable and effective leadership at every regional and country level.

Enthusiasm about UN Women is high.

A Celebration of the Launch of UN Women and a Special Tribute to Women in Technology & Science

The luncheon celebrating UN Women on February 25, 2011, in the UN Delegates Dining Room, was hosted by the Metro New York Chapter of the US National Committee for UN Women. Many of the luncheon attendees were in New York attending the UN's annual Commission on the Status of Women, whose theme this year was increasing the participation of women and girls in technology and science.

In her welcome, the Chapter President, Cheryl Benton, called the luncheon "an historic occasion celebrating the launch of UN Women, and a significant step by the UN to improve and enhance the lives of women and girls everywhere." Expressing enthusiasm over the new organization, she noted that the theme of the chapter conference and of the luncheon is consistent with the theme of this year's conference on the Status of Women: "Access and Participation of Women and Girls in Science and Technology," by honoring women in technology and science.

In an unusual opening for the afternoon's presentations, Saranne Rothberg, Founder and CEO of The Comedy Cures Foundation, performed a comedy routine, noting that she has also performed at the launch in February 2008 of UN Secretary-General Ban Ki-Moon's Global Campaign to UNite To End The Violence Against Women, and was the first therapeutic humor consultant called to Ground Zero after September 11th. The audience was moved as she shared her story as a survivor of breast cancer, going on to create her foundation to bring joy, laughter, and therapeutic humor programs to kids and grown-ups living with illness, depression, trauma and disabilities. The recipient of several humanitarian awards, Saranne has been featured by media worldwide, including CNN, PBS, NPR and The New York Times, and as a "Hero" in Oprah's book, "Live Your Best Life."

The audience was awed when Saranne introduced the next performer, her 17 year old daughter, Lauriel Harte Marger, who is a partner in Comedy Cares as well as a United Nations Youth Advisor and a World Health Organization Health Champion who helped launch this year's UN International Year of Youth. With her two best friends, Lauriel launched a socially conscious singing group, "The Bonde", with their adaptation of an African chant, "Kamwanna" which protests the rape of young girls. At the luncheon they performed an original song, "Behind The Lies," which is a protest anthem to end Female Genital Mutilation.

The stage was set to introduce the keynote speaker, Michelle Bachelet, the new UN Under Secretary General and Executive Director of UN Women. The audience audibly gasped when it was announced that among Ms. Bachelet's many credits, she had an 82% approval rating when she recently stepped down as the President of Chile.

The head of UN Women, Michelle Bachelet, addresses the luncheon gathering at UN headquarters during the Commission on the Status of Women meetings

Bachelet noted in her speech that her training as a pediatrician made her sensitive to the importance of women in

STEM (science, technology, engineering and mathematics) – the theme of the CSW conference.

There is widespread agreement that Ms. Bachelet is the right woman for the job with a rich background to help her accomplish UN women's goals. A pediatrician, with graduate studies in Military Sciences, she speaks Spanish and English and has a command of German, French and Portuguese. A dynamic global leader with highly honed political skills, she served as the region's first female minister of defense and as the first women elected as President in the history of Chile, for a full four-year term from February 2006 to March 2010 -- with the greatest approval from people in the history of Chile – after which she founded Dialoga Foundation, to support new ideas, action, and leadership in Chile.

Bachelet pledged to involve all women at all levels in achieving UN women's goals and to do more than just "talk" but to accomplish action items and advance the empowerment of women at the UN and globally. She was pleased that the creation of UN Women gives women more political weight and voice and noted that "women all over the world are very powerful agents of development, agents of change, peacebuilders, and peacekeepers. They are also essential…because they have good ideas and proposals and they are hard workers in their communities."

Bachelet has been quoted as saying that women have said to her, "I can die now because I know that my daughter has a better future." She is also proud that holding the highest office in Chile as a woman made her sensitive to women's problems. As a result, she gave pensions for housewives to collect when they reached 65 years old so they would not need to depend on their husbands for everything; developed a network of nurseries and kindergartens to help working mothers; and presented bills to Parliament requiring equal salaries for women and men.

The last speaker was Susan Hassler, Editor-in-Chief of a monthly magazine, IEEE Spectrum, the publication for the IEEE (the world's largest technology association) read by over 385,000 technology professionals and senior executives worldwide in the high technology sectors of industry, government, and academia. With her more than 20 years of experience as a science editor and journalist dealing with a wide range of complex topics from developmental neurobiology to genetic and metabolic engineering, Hassler talked about the positive impact of women in the fields of technology and science.

Chapters of UN Women, such as the Metro New York Chapter, advocate, educate, and raise funds on behalf of UN Women. To join UN Women's chapters, go online at www.unwomen-usnc.org/chapters. Chapter members participate in educational and informational programs, fundraisers and other events, and receive notices about the progress of UN Women. National Committee Chapters are in New York, Atlanta, Georgia; Chicago, Illinois; East Florida; Gulf Coast, Florida; National Capital; New Haven, Connecticut; North Carolina; and the San Francisco Bay Area. New chapters can also be formed.

A Contribution of Psychology to UN Women: Women and Organizational Leadership

Walter Reichman Ed.D.
Mary O'Neill Berry Ph.D.
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Florence Denmark, Ph.D.
UN Representatives for the International Association of Applied Psychology

In response to the call by UN Women for contributions to help their mission, representatives to the United Nations from the International Association of Applied Psychology prepared the below document about the role of women in organizational leadership. The document represents an important example of how psychologists can impact the mission of UN agencies, by providing research and best practices in our area of expertise, in this case focused on organizational psychology.

This report was delivered to the office of the head of UN Women, Michelle Bachelet, which then sent a response email of appreciation for the submission, inviting IAAP to comment on their first strategic plan when it is published on their Website.

The report read as follows:

A major goal of the United Nations is to bring about gender equality; in fact, Millennium Development Goal # 3 is to "promote gender equality and empower women." Psychologists have long been researching the role of women in all aspects of life, including their role in organizations. Psychologists join other disciplines in asserting that the achievement of gender equality requires that women have the same opportunity as men to be leaders in organizations, both as entrepreneurs and also within existing organizations.

Presently the number of women leaders in organizations lags behind men in developed countries such as the United States and the United Kingdom, as well as in the developing countries. In the United States only 2% of the Fortune 1000 companies have chief operating officers who are female and of the top 280 companies listed on the London Stock Exchange less than 28% have female top executives. In China, women comprise less than 18% of heads of government departments (United Nations, 2009).

Despite these discouraging statistics there are still sufficient numbers of women in leadership positions for psychologists to be able to research their development into such positions as well as to examine their leadership style and effectiveness. The considerable body of psychological research on leadership has defined the activities and criteria of effective organizational leadership in the 21st century. These activities include: emphasizing task accomplishment, considerate behavior toward employees who carry out the required tasks,

and the ability to inspire and motivate employees to higher levels of effort and dedication. This model is known as *transformational* leadership in contrast to *transactional* leadership which emphasizes reward and punishment for following directions. Transformational leadership demands a relationship between leaders and followers directed at bringing about change that is in the best interest of both (Ayman and Korabik, 2010).

With regard to differences between men and women in leadership positions, a review of research indicates that some studies find that males and females do not differ on the degree to which they focus on task completion or the degree of consideration they show their employees, while other studies have found that women are higher in both skills, e.g. that women focus more on tasks and are more considerate of employees. These studies also show that women tend to be more transformational in their leadership than men. A key component of transformational leadership is better communication and more positive negotiations among leaders and subordinates (Ayman and Korabik, 2010). Research also indicates the benefits of female leadership for company success in that there is a statistically significant relationship between the number of women in top management and the financial performance of the company (Bowers, 2009).

The leadership style of women, which promotes organizational success, is in keeping with the cultural changes of the 21st century. In our ever-changing world, flexibility in thinking and performing and an emphasis on consultation are necessary ingredients for success. In addition, under globalization the business leader must have an ability to confront and appreciate increasing diversity and negotiate with and understand those who differ from us. This too, is a component of transformational leadership.

Despite these leadership advantages, there are many blocks to women gaining leadership positions in organizations. Although women in organizations demonstrate all the appropriate attitudes and skills, they are still disadvantaged in both securing and maintaining leadership positions (Kent and Moss, 1994). Even though women demonstrate their leadership ability, they are not perceived as having or being credited with that ability. Psychologists believe that this is due to stereotyping in that leadership is more often associated with male roles and behavior than with female behavior (Ayman and Korabik, 2010). A study by Catalyst on women executives at the vice president level and above in Fortune 1000 companies cited stereotyping and pre-conceptions of women as one of the most significant barriers to women advancing in the workplace (cited in Sanchez-Hulces and Davis, 2010). Even more troublesome is that when women gain positions of leadership, they almost always encounter resistance to carrying it out (Eagly and Chin, 2010). It is uncomfortable for people to see a stereotype broken and will require steps to be taken to promote favorable stereotypes.

Women who achieved leadership positions described their careers as progressing through a labyrinth of hurdles, discrimination, stereotyping and challenges. Those who make it past the proverbial "glass ceiling" often find themselves on what has been termed the "glass cliff." A female leader is on a glass cliff when she is promoted to a leadership position to deal with a problem that was not of her making and has a low probability of a positive solution. Those who survive the glass cliff say they did so by working hard and working smart (Sanchez-Hulces and Davis, 2010). Working smart usually involves seeking allies, negotiating and collaborating to reach a solution.

In further research on successful female leaders, these women attribute their success to parental encouragement during their childhood, which fostered a sense of self-worth and a belief they could accomplish their goals. In the business world, they report learning from role models and mentors, networking and developing relationships and partnering with accomplished associates. In life in general, they report having developed life skills and guidelines for melding their personal and professional lives. Their experiences drew them to develop a transformational way of dealing with people that evolved into a transformational leadership style (Cheung and Halpern, 2010).

The barriers to women's success in top levels of organizations also have roots in childhood, since that is when stereotypes begin to form. For example, the stereotype that leadership is associated with men and masculinity begins as early as age five. Also, this stereotype seems to be held more strongly by boys than girls, making it more difficult for women to overcome since men in most cultures are given higher status and greater privilege than women and their prejudices carry more weight (Ayman and Korabik, 2010).

From this overview of the psychological research on women and organizational leadership, we can conclude that the skills and attributes of women are invaluable for the success of organizations in the global world economy of the 21st century.

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The Contributions of Psychology to the Commission on the Status of Women 2011 Conference Focusing on Education of Women and Girls in STEM (science, technology, engineering and mathematics): Two Parallel Events by Psychologists

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Event #1: Workshop and Demonstration of STEM Education: Best Practices and Products

A parallel event organized by psychologists for the 2011 conference of the Commission on the Status of Women was entitled "Workshop and Demonstration of STEM Education: Best Practices and Products." Held on February 24, the presentation focused on techniques and teaching strategies to encourage women and girls to get involved with careers in STEM (science, technology, engineering, and mathematics). Sponsored by the International Association of Applied Psychology at the request of APA, other psychological association co-sponsors included APA, IUPsyS (the International Union of Psychological Science) and ICP (the International Council of Psychology).

APA Main United Nations representative Deanna Chitayat opened the event at the Salvation Army auditorium (a United Nations satellite venue), mentioning how we must question why not as many women as men are involved in STEM careers and introducing that in this program, teachers and students will present best practices and programs involving females in these pursuits.

Glen Schuster, a representative from the NASA Endeavor Science Teaching Certificate Project developed by NASA through a US Satellite partnered with Columbia University Teachers College, reported that this day marked the last scheduled launch of the Discovery Shuttle and then proceeded to describe the Endeavor fellowship and recent graduates' successes. The Endeavor program is a fellowship for K-12 formal educators whereby fellows take five courses online, earn graduate credit, and receive a certificate in STEM education upon completion (see www.us-satellite.net/endeavor).

The next speaker, Sharika Castronovo, a teacher from the Environmental Science Manhattan School for Children, presented how she has adjusted her curriculum to motivate female students in her classroom to get actively involved in STEM activities. These include to:

- make science fun (e.g. making baking soda rockets)
- help girls develop personal connections to show them that they have the skills
- have students write about science though journaling
- have students discuss their ideas to explore successes as well as mistakes
- make it "cool" to participate
- include families by providing worksheets with projects to do at home (e.g. a night at the observatory)
- create school-wide projects to help to get more girls involved

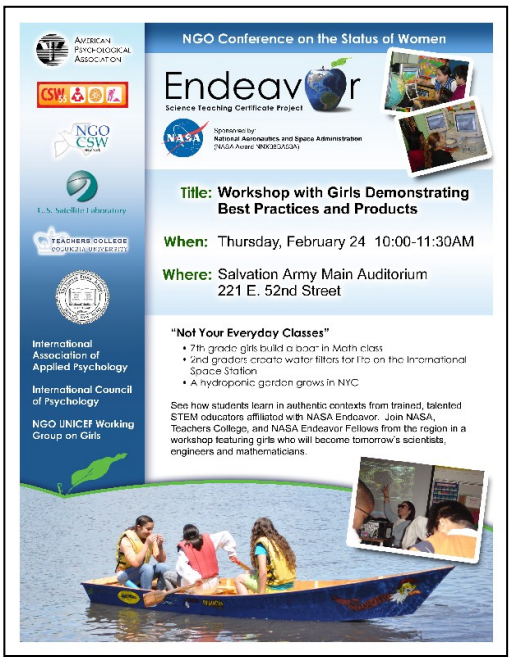

Two girls from her class described their experiences making an energy bike by connecting a bike to water and then to a battery, as well as their greenhouse projects (e.g. developing a hydroponic greenhouse for the classroom, allowing students to develop experiments). In other projects using technology in the classroom, a conference call was made with a female marine biologist and the students made a newscast about endangered animals. Such projects motivate the students to learn science and to use technology.

Louise McMinn, a math and science coach in Stamford, Connecticut at the Scofield Magnet Middle School, then described the after-school STEM programs she developed. She reported that (1) recently the number of women in STEM programs has started to decrease; (2) it is hard to find women actively engaged in science since they often get in administrative positions; and (3) there is a need to get more girls interested in STEM careers. Since after-school programs allow

more freedom to get girls interested in STEM skills and careers – compared to in-class programs which not only need to engage students but have to meet specific educational standards -- McMinn created an after-school program in astrobiology, for girls only. This program was developed after she noticed that even though girls in her class admit that they like to do experiments, they tend to take less active roles in the project.

The astrobiology after-school program for girls utilizes NASA programs found online for content. Recently, her students tested soil samples to decide if there was life present which allowed the girls to reconsider the question, "What is the meaning of life?" The curriculum also includes: extremophiles (examining microorganisms that live in extreme environments); AstroVenture (a simulator to determine what conditions are required to sustain life); rocketry, specifically a design challenge to land a rocket (e.g. make a shock-absorbing container to protect an item such as an egg from breaking); and a waste limitation management and recycling design challenge. Her students studied the water quality in five sites in their town of Stamford, Connecticut and then developed a digital presentation about their study. McMinn reiterated that the NASA website offers design challenges and is a great resource for classroom activities.

The next speaker, Marylin Ortiz is a 5th grade inclusion teacher in Newark (i.e., her class has special education students in addition to general education students). She emphasized the need to encourage girls to become involved with STEM activities and to consider STEM careers. She developed a course, called "Inspiring Girls in Engineering," which provides female role models in the field of engineering, and teaches about how men and women are built differently; for example, engineers have been involved in modifying snowboarding equipment for women. Although STEM activities promote the genders working together, Ms. Ortiz separates girls from boys during science projects, creating classroom competition in order to get more students involved, especially since girls usually take a less active role in science projects. She concluded with a quote from Hillary Clinton: "The future of women and girls are tied together. Girls cannot advance without the advancement of women and no improvement in the lives of women will be sustained unless girls are given the tools and opportunity to reach their potential. For they are the women of tomorrow."

The fifth presenter, Linda Richardson, is the Principal of Ann Street School in Newark, New Jersey, a school that has received the National Blue Ribbon of Excellence by the United States Department of Education (the highest award an American school can receive). She shared personal reflections about being a product of the women's movement and her challenge of becoming a principal in a male-dominated field. Emphasizing the need to have women in STEM programs and how to foster this goal, she reported that her district has provided opportunities for girls to set up and participate in math and science fair projects, such as building model boats, that require developing drafts, making models, and taking measurements to build a 15-foot skiff boat.

Four of her students in this project shared their experience in making a full-size functional boat within the time period of 12 weeks. In a dramatic moment, two of the male teachers brought the boat down the aisle and placed it in the front of the auditorium. The students reported that although they were not initially enthused about the project, they quickly became motivated once they realized that they would be building a real boat. Also, the girls were more excited and involved in this project than the boys, and enthusiastically described their experience in working with power tools (e.g. a belt sander and drills) for the first time, their struggles with using math to obtain the correct measurements, and the decision-making process and teamwork required to successfully build the boat. In addition, their class took a field trip to a yacht company in New Jersey and learned how the father who owned the company designed the boats, however, his daughter utilized the computer to implement her father's designs. The girls concluded by describing how their class launched the boat, amusing the audience by noting that the male teachers who assisted overturned the boat and needed to be rescued while the girls successfully rowed the boat and kept it afloat.

Female students who built a boat (pictured against the wall)

Dr. Felicia Moore Mensah from Columbia University Teachers College, in concluding the program, described how she used to dream about becoming an astronaut and shared her experiences of incorporating science into her life. She emphasized the importance of bringing STEM experiences to females, whether they live in a rural or urban environment. Telling girls and women that they are already scientists, she said, can help them expand their career options. Given that there are a number of STEM-focused scholarships, the opportunities for young women are plentiful.

All involved agreed that the event was not only successful but inspirational, especially given the related experiences of the young girls themselves.

In the question and answer session, a representative from the World Association of Girl Guides and Scouts said that the

girls inspired her and that she was looking forward to sharing what she learned. A representative from the World Federation of Mental Health noted that the program helps young women develop dignity and inquired about how the programs relate to psychological wellbeing. Principal Richardson responded that the projects also develop moral character and acknowledged that affective as well as academic aspects need to be recognized. She said that while the girls building the boat were stressed (as well as challenged), they (and the teachers) managed the stress well. In addition, the project won first place at the Algebra Olympics (beating out high school students). One of the male faculty members supervising the boat building described that he managed his stress during the process by considering the benefits the students were deriving from the project and remembering that while the girls might not remember how they did in 8th grade, they would undoubtedly remember the experience and pride in building a boat. Dr. Chitayat commented on how upbeat the students were in discussing their experience and how this relates to increasing self-esteem and self-efficacy.

Regarding funding, Ms. Ortiz reported that a grant funded the water filtration system but in the past she paid for the projects out of her own pocket. Ms. Castronovo said she received donations from her students' parents as well as outside contributions to fund the $800,000 greenhouse she now uses as an interactive classroom. Ms. McMinn suggested that education programs include grant writing to secure necessary finding for such projects. The boat project was funded partly by community resources, with networking being crucial to establish relationships to make companies with products and services related to the project aware of the project and how they can contribute.

In response to Dr. Kuriansky's query about future plans to promote the projects digitally, a faculty member reported that he has been working with NASA to post all their projects online to share with educators.

Regarding how the projects are eco-friendly, Ms. Castronovo reported that she teaches in an eco-friendly greenhouse, and a faculty member described how the students engaged in the boat building were encouraged to use natural lighting and to recycle, and were required to take care of their own garbage.

In describing how they are ambassadors of science education, one student said her girl scout troop does science projects with the brownies and juniors, including showing them what they can do with science. Another student described her involvement with a science contest outside of school and her participation in an event about how crime scene investigators work on forensic cases.

It was suggested in conclusion that in-school as well as broad after-school, programs as well as an interdisciplinary approach, are crucial in getting female students interested in STEM skills and careers.

Parallel Event #2: What Psychology Offers to the Education of Women and Girls

Another psychology-related event at the CSW was a caucus on "What Psychology Offers to the Education of Women and Girls." A panel of three psychologists included two representatives from the American Psychological Association team at the United Nations, Deborah L. Vietze, Ph.D., Professor of Psychology at the City University of New York and a member of the Ph.D. faculty in Social Psychology, Developmental Psychology and Urban Education and Beatrice J. Krauss, Ph.D., a Professor of Urban Public Health and Executive Director at Hunter College Office of Faculty Research and Project Development and the Center for Community and Urban Health, as well as Judy Kuriansky, Ph.D., the United Nations representative for the International Association of Applied Psychology and Division 52 liaison to the APA Committee on International Relations.

The aim of the Caucus was to indicate what psychology has done and can do for STEM education, and to create discussion and action steps. Dr. Krauss focused on education and health; Dr. Vietze addressed education in general and access to vocations; and Dr. Kuriansky described the interrelationship between health and financial empowerment of girls, giving examples of field projects. Intended as a workshop, the event evoked lively discussion from the attendees, who represented a wide range of ages, gender and countries. Several CSW delegates from Africa were particularly keen about how to encourage more women to be involved in STEM education and careers and their desire to collaborate on projects.

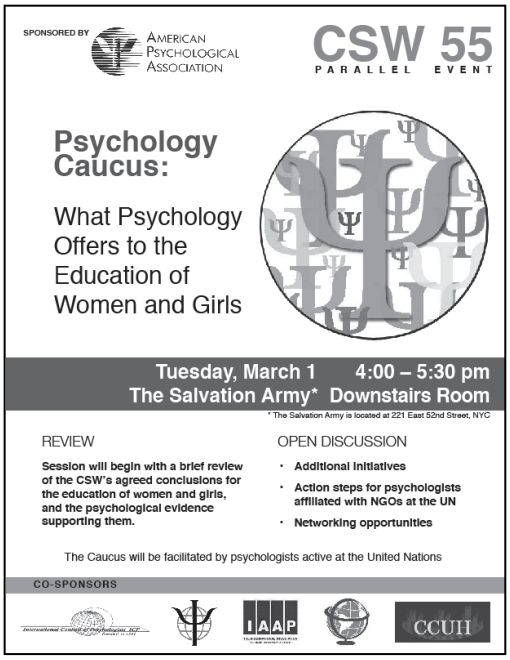

Presenters from APA and IAAP with attendees at the Commission on the Status of Women parallel event on the role of Psychology in the Education of Girls

Young women in the audience of the parallel event

Youth from European Lawyers Youth Group describing their intention to further include women

APA Division 52 CIRP liaison Judy Kuriansky presenting about female entrepreneurship at the APA-sponsored CSW Parallel event on "The Role of Psychology in the Education of Women and Girls"

Aftermath of the Japanese Earthquake and Tsunami: Immediate Response and Impact of Events as Healing Efforts

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From a psychological point of view, when a crisis strikes one part of the world, global solidarity and support – both heartfelt as well as financial – are important in healing. These have been extended to Japan in the wake of the 9.0 magnitude earthquake and subsequent devastating tsunami.

Immediately after the environmental tragedies hit Japan, health professionals and the interfaith community throughout the world started mobilizing special events to help and international psychologists like myself began contacting local mental health professionals and organizations. This report summarizes immediate efforts in New York City to express solidarity and support through fundraising concerts and vigil ceremonies.

Exactly one week after the tragedy, a Prayer Service and Candlelight Vigil for Japan was held at the Church Center for the United Nations at UN Plaza in New York City. An overflowing audience of the interfaith community, UN officials and concerned citizens came to "mark the first week anniversary" showing their solidarity.

Sitting in a row of Buddhist monks and next to my friend Jean-Pierre Amisi Ramazani who had just interviewed me about my IAAP project in Lesotho Africa for UN radio, I was moved to tears not only at the tragedy, but at the cruel irony of this nuclear disaster happening in a country where so much anti-nuclear war effort is being put forth. For example, Mayor Tadatishi Akiba of Hiroshima has been the head of Mayors for Peace for years, and spoke eloquently against nuclear armament at the 2009 Department of Public Information/NGO Conference about disarmament, where my own "Stand Up for Peace Project' has performed as well as participated in annual peace and anti-nuclear concerts and symposia throughout Japan including for the Dalai Lama and Reverend Desmond Tutu.

This solemn event opened with an incense offering and welcome by co-organizers Reverend T. Kenjitsu Nakagaki, Buddhist priest and Vice President of the Interfaith Center for New York, and Reverend Kathleen Stone from the UN Church Center. Meditations and prayers were then offered by Japanese Religious Leaders from different sects, including Reverend Nakagaki representing Jodoshinshu Buddhism, Reverend Masafumi Nakanishi from Shintoism, Reverend Shogun Kumakura from Nichirenshu Buddhism, Reverend Yugo Suzuki from Christianity, and Reverend Masamichi Kamiya from Rissho Kosei-kai Buddhism.

Welcome by Reverend Nakagaki and incense lighting by Reverend Shogun Kamakura at prayer service at the United Nations Church Center one week after the 3/11 tragedy in Japan.

Messages were delivered from leaders of the Japanese community, including Riki Ito, President of the Japanese Lions Club and Gary Moriwaki, President of the Japanese American Association of New York. In a statement on behalf of the Consulate General of Japan, Fumiho Suzawa explained that 6,500 lives were lost, 10,000 people were still missing and hundreds of thousands of people had been evacuated. Tears have been shed, she said, but the government expresses "gratitude for the outpouring of kindness and support towards all the people."

A message was read on behalf of the Sri Lankan community in New York, expressing sadness since they "know the suffering caused by this event first-hand since we also experienced a similar event…[thus] sending sincere and heartfelt sympathy towards the Japanese community worldwide."

Pianist Taka Kigawa performed J.S. Bach's Prelude in C major from "Well Tempered Clavier Book I" and Chopin's Prelude in C-sharp minor, Op 45; and Maurice Ravel's "Pavane pour une infante défunte."

A silent prayer and mediation, and traditional incense offering, was followed by a candlelight vigil. Holding lights and paper Japanese flags, we walked in silence from the church to Dag Hammarskjöld Plaza a few blocks away, to share testimonials and to network. There, I connected with many people from the health sector to determine the best way to help. Emiko Nagano, volunteer community organizer of the Humanist Movement, said that if we send love to the people of Japan they will feel our love.

Starting the prayer vigil at the UN Church Center in support of Japan: from left, Russell Daisey, international composer; UN Radio reporter Jean-Pierre Amisi Ramazani; Russ Jennings, owner of Common Soul Productions; Dr. Judy Kuriansky, IAAP UN rep and APA Division 52 member; Universal Peace Initiative founder SuZen.

Candlelight ceremony and testimonials at UN Dag Hammarskjöld park in honor of Japan

As a psychologist who has been at many disaster sites around the world, I know that people in crisis appreciate knowing that others care.

The strong message that resonated throughout was that "Japan will overcome" and that the "people of Japan are facing this tragedy with dignity" but that support is direly needed.

The next week, an "Interfaith Time of Reflection for Japan" was held at the majestic Riverside Church near Columbia University in New York City. The event was led by Reverend Nakagaki and co-sponsored by The Mission and Social Justice Ministry of The Riverside Church, the Universal Peace Initiative and its co-founder SuZen; and the Interfaith Center of New York. The large gathering was in part a result of networking through the Japanese community and through social media by volunteers trained by Columbia Journalism School Professor and social media expert Sree Sreenivasan. The solemn afternoon, in a perfectly respectful and moving tone, began with a processional, greetings from Reverend Nakagaki, a musical offering from pianist Masayo Ishigure playing "Yomigaeru-Rising Phoenix," and offerings to the altar with candlelight, incense, flowers and fruits by SuZen and mothers and children. Welcomes were offered by Reverend Robert Coleman of The Riverside Church and Reverend Chloe Breyer of the Interfaith Center of New York who said movingly that we "come together to pray in shared presence in sacred space, to give thanks [to all supporters and to honor the Japanese people who] through great suffering have an example of grace and dignity."

The theme of grace and dignity of the Japanese people in the face of such tragedy prevailed – an important testimony to psychological resilience.

Interfaith prayers were offered in many religious traditions, including Muslim (by Iman Shamsi Ali of the Islamic Cultural Center of New York); Jewish (by Rabbi Harlan Wechsler of the New York Board of Rabbis); Sikh (by Bhupinder Singh of UNITED SIKHS); Hindu (by Chan Jamoona of the United Hindu Cultural Center); Christianity (by Reverend Dr. Arnold Thomas of The Riverside Church); and Buddhism (by Reverend Shogen Kumakura of the Buddhist Council of New York).

Religious leaders offer prayers at The Riverside Church "Interfaith Time of Reflection for Japan"

Exceptionally moving reflections were offered by the Presidents of three Japanese Prefectures affected by the earthquake and tsunami, including Kenjjiro Sasaki from the Miyagi Perfecture in Sendai; Ypji Shikama from the Fukushima Perfecture; and Robert Iwasaki from the Iwate Perfecture. Their first-hand stories about the suffering of the people from the loss of loved ones, homes and livelihood, the threat from food shortage and radiation, and fears for the future, were heart-wrenching. As one ever-so-dignified gentleman cried, many others gasped empathically.

Several musical offerings including "Tamuke-Giving Hands" were performed, Candles of Hope were lit, and Japanese poet Popona Tsukino read two of her haiku poems about the tragedy, followed by silent prayer and mediation. Everyone was then invited to offer incense in the front of the church.

Division 52's Judy Kuriansky lighting incense at the "Interfaith Time of Reflection for Japan" at Riverside Church

It is significant to note psychologically that the prayer services and invocations emphasized "gratitude" to those who are supporting Japan through this crisis. This emphasis on gratitude reminded me of the song my "Stand Up for Peace Project" co-founder Russell Daisey and I wrote and have performed in Japan many times that is called "Appreciation." When we perform it, I explain that it was inspired from my years in Japan – teaching, doing TV shows, and live broadcasts of my New-York based advice radio show – where I learned about Japanese Naikan therapy which is based on expressing thanks to people and things in your life. It is consistent with Buddhist tradition to offer gratitude rather than make requests.

That same evening, I attended a concert held at Columbia University Miller Theatre headlined by Yoko Ono. The noted performance artist opened her set with a song written about the loss of John Lennon with lyrics like "He is Gone," accompanied by her son with Lennon (Sean Lennon) on guitar. The other acts were eclectic, including grunge band Sonic Youth.

At the end of the concert, Yoko announced, "Give, and you will get back." As a psychologist, I note that unconditional giving without concern for return is more powerful.

Ironically a fire alarm cleared the hall immediately after the performance, causing some mayhem outside as many fire trucks arrived, which some equated to the emotionality of the disaster. Fortunately most people had already exited.

Two days later, another concert was held to raise funds particularly for the children who have been affected by the catastrophe. Everyone was invited to "Stand With Japan in its hour of crisis" and "Let's remind everyone in despair that they are not alone in their time of need."

The evening opened with the national anthems of Japan and the United States of America, and featured twenty diverse musical acts, including traditional Japanese drums, opera arias, jazz piano and vocals, a four-person cello recital, duets and solos of classical music (e.g. Chopin, Bach and Rachmaninoff) and modern styles as well as original compositions (e.g. "Stand With Japan" and "I Do What I Can" songs). In the finale performance, jazz pianist Davell Crawford, hailed as the "Prince of New Orleans," noted the solidarity he feels for Japan given his hometown's devastation after Hurricane Katrina. Having led "Wellness Workshops" in Louisiana after Hurricane Katrina, with APA member and Louisiana psychologist Darlyne Nemeth, I was powerfully reminded of the connection not only between these two experiences involving such destructive floods, but the universality of so many natural disasters suffered by so many people in so many countries throughout the world in recent years.

One guitarist made a particularly moving dedication in my estimation, noting that while we are far away from Japan at this moment geographically, the energy of the message of support and love, and offerings from the heart, can still be felt by the people who are suffering.

Performances at the Concert for Japan Earthquake and Tsunami Victims in New York City at First Church of Christ, Scientist

The concert was organized by Nozomi Terao, who had two months earlier founded a non-profit organization called "Happy Dolls" linking children with dolls as messengers of hope. A similar concept evolved after 9/11 where young children sent toys and cards to children who had suffered losses of loved ones from the World Trade Tower attacks. My colleagues and I at the International Association of Applied Psychology had done a similar project for children in post-earthquake Haiti, where we had second graders in a New York City public school make cards, and youth in Japan send cranes (a traditional peace symbol), to children in Haiti.

Concerts are useful at these times of crisis since psychologically music is a universal language that reaches across cultures.

Upcoming concerts in New York include a series of 5 "Save Japan Benefits" throughout April; and the Japan-US Chorus Charity Concert to be held at Carnegie Hall on May 20th featuring men's glee clubs, with free admission and donations going to the Sendai Relief Fund.

Funds are of course direly needed for recovery in Japan as in all disasters. Tickets for the Yoko Ono concert were $50 and $100. While the concerts at the UN Church Center and The Riverside Church were free, offerings were made at the latter. Proceeds went to several organizations: the New York Japanese-American Lions Club Japan Earthquake Fund (as there are already many clubs in the affected area), with the promise that all donations would go directly to the affected area; the Religious NGO Network on Humanitarian Support (a cooperative system of NGOs); the United Church of Christ and American Baptist Church (that is on the ground and affiliated with the interdenominational Riverside Church); and the Humane Society International (organizing to shelter affected animas). About $30,000 was raised at the March 29th concert at the First Church of Christ with all the proceeds promised to be sent to SAVE THE CHILDREN Japan Earthquake Tsunami Relief. Other donation organizations recommended were the Japanese American Association and others listed on www.jaany.org.

The heartfelt expressions and actions of these events greatly affected all those involved, and serve as an example of immediate responses and outpourings of support and solidarity that are healing for individuals, communities and the world in these times when we are all so inter-connected globally.

Special Issue on Psychological Consequences of 2010 Chile Earthquake

Dear Colleagues,

For those of you interested on this subject, let me bring your attention to the following:

Vogel and Vera-Villarroel, the invited editors of a special issue of *Terapia Psicologica* write, "this special issue is an attempt to organize preliminary information collected by researchers on the psychological consequences of the natural disaster that occurred in Chile's south central area on February 27, 2010. This issue focuses on the types of psychological interventions that have been conducted in the affected areas, while emphasizing the need to define intervention strategies for middle- and long-term effects. Finally, some intervention strategies applied in other countries are reviewed." To see the website of the *Journal* and the special issue on Chile's earthquake and disasters please visit http://teps.cl/en/ (*Terapia Psicologica* 2010, Vol. 28, #2).

Most cordially,

Andres Consoli and Wilson Lopez

Presidente Saliente/Past President (2009-2011) SIP
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Interamerican Society of Psychology
Sociedade Interamericana de Psicologia
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American Psychological Association 2011 APA Convention Travel Awards for Early Career Professionals

The Board of Convention Affairs along with the Board of Scientific Affairs and the Committee on Early Career Psychologists are pleased to announce a travel award program for early career members from all areas of psychology (education, practice, public interest and science) to attend the 2011 APA Annual Convention in Washington, D.C., August 4-7, at the Washington Convention Center.

Thirteen award recipients will receive $750 to be applied toward their 2011 APA convention expenses. The program is designed to encourage attendance and increase representation of early career members at this year's APA convention.

All early career APA members (within seven years receipt of their doctorate) are encouraged to apply. Preference will be given to applicants who are first-time attendees, or whose primary work is in basic psychological science or those who will be presenting at the 2011 convention. The submission package must include the following information:

1. Brief statement (maximum one page) about your interest in attending the convention and how you will use this award to support your attendance. Please highlight any significant achievements in your career as well as any leadership positions you have held as an early career psychologists (within APA, other related scholarly or professional organizations such as state and local psychological associations) and indicate how you believe you would benefit from attending the convention. Also, please include in your statement if the 2011 convention will be your first APA convention and if you will be receiving other funding to help cover your expenses.
2. If you are presenting at the 2011 APA convention, please include an abstract of your presentation along with the title and the names of co-presenters. Please note that you do not need to be a presenter to be eligible for this travel award.
3. Include your Curriculum Vitae (the year you were awarded a doctorate in psychology should be clearly stated).

Electronic submission instructions: Please submit all materials in a single Word document. Put your name and the name of the award in the subject line (e.g. Jane Smith, Early Career Travel Award).

The deadline for submission of materials is April 25, 2011, midnight (EST). Email or fax all materials to Kraig Scott (kscott@apa.org); fax # 202-216-7628. Award winners will be notified in May 2011 and will be acknowledged during the Early Career Social Hour sponsored by the Committee on Early Career Psychologists at the APA convention on Friday, August 5, 2011 at 6PM.

Janet Hyde Graduate Student Research Grant

Proposals are being sought for Hyde Graduate Student Research Grants. These grants, each up to $500, are awarded to doctoral psychology students to support feminist research. The grants are made possible through the generosity of Janet Shibley Hyde, Ph.D., who donates the royalties from her book, *Half the Human Experience*, to this fund. Past recipients of Hyde Graduate Student Research Grants are not eligible to apply. Because the purpose of this award is to facilitate research that otherwise might not be possible, projects that are beyond the data analysis stage are not eligible.

Please send all application materials attached to a single e-mail message to both of the Hyde Award Co-chairs at the following addresses by March 15, 2011 (or September 15th for the fall deadline):

Dr. Mindy J. Erchull, merchull@umw.edu and Dr. Olivia Moorehead-Slaughter, oms@parkschool.org

Requirements:

1. Cover page with project title, investigator's name, address, phone, fax, and e-mail address
2. A 100-word abstract
3. A proposal (5-pages maximum, double-spaced) addressing the project's purpose, theoretical rationale, and procedures, including how the method and data analysis stem from the proposed theory and purpose.
4. A one-page statement articulating the study's relevance to feminist goals and importance to feminist research.
5. The expected timeline for progress and completion of the project (including the date of the research proposal committee meeting). The project timeline should not exceed two years.
6. A faculty sponsor's recommendation, which includes why the research cannot be funded by other sources. This letter should be attached to the e-mail with the application materials. Please do not send it separately.
7. Status of IRB review process, including expected date of IRB submission and approval. Preference will be given to proposals that have received approval.
8. An itemized budget (if additional funds are needed to ensure completion of the project, please specify sources)
9. The applicant's curriculum vitae
10. All sections of the proposal should be typed and prepared according to APA style (e.g., please use 12-point font)

Proposals that fail to meet the guidelines described above will not be reviewed.

Review Process

A panel of psychologists will evaluate the proposals for theoretical and methodological soundness, relevance to feminist goals, applicant's training and qualifications to conduct the research, and feasibility of completing the project.

Other Requirements

Only one application will be accepted per student, for each application deadline. Applicants who are involved in multiple projects that meet the submission requirements should choose the project that best fits the evaluation criteria (see "Review Process").

Within 24 months of receipt of the grant, recipients are expected to submit to the Hyde committee co-chairs a complete and final copy of the research document (e.g., a copy of the thesis, dissertation or journal manuscript based on the sponsored research), along with a 500-word abstract for publication in Division 35 newsletter. In addition, grant recipients shall acknowledge the funding source in the author's notes in all publications. Hyde award winners will be announced at the APA convention during Division 35 Social Hour. The names of the Hyde award winners may also be posted in Division 35 newsletter as well as on Division 35 web page and listserv.

Questions and other communications may be sent to the committee co-chair:

Mindy J. Erchull, Ph.D.
Co-Chair, Hyde Research Award Committee
Department of Psychology
University of Mary Washington
1301 College Avenue
Fredericksburg, VA 22401-5300
Phone: (540) 654-1557
E-mail: merchull@umw.edu

Congratulations to Division 52 Fellow Judy Kuriansky

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Friends of the UN Announces 2011 Tolerance Awardees: Honors Dr. Judy Kuriansky with 2011 Lifetime Achievement in Global Peace and Tolerance, Nejeed Kassam as first Youth Ambassador, and Launches Tolerance Awareness Campaign, "Wear My Hat" with Awards

New York, NY 1/21/11 – Dr. Noel Brown, President of 'Friends of the UN' (FOTUN) announces that as Friends of the UN grows to become the world's largest and most connected community of global citizens working to support the achievement of the Millennium Development Goals and the ideals of the United Nations, the association has named its two new honorees for 2011's Global Peace and Tolerance Awards.

"To help people see that fundamentally all people are the same, though we wear different hats, have different lives and grow up culturally different, then we might begin to realize we can take deeper steps of global engagement towards a more peaceful, tolerant world. Further, we can get things done to overcome dire global circumstances, and achieve these goals together," says Dr. Brown.

The first hat to symbolize the worldwide campaign will be awarded to Dr. Judy Kuriansky, the 'Friends of the UN' 2011 Awardee for a Lifetime Achievement in Global Peace and Tolerance at a ceremony at the 8th Annual United Nations Youth Assembly, taking place at UN headquarters in New York January 20-21, hosted by the Friendship Ambassador Foundation. Kuriansky, an internationally acclaimed clinical psychologist, humanitarian, journalist and Main United Nations NGO representative for the International Association of Applied Psychology and the World Council of Psychotherapy, will address the youth participants about field models in Haiti and Africa that advance the MDGs, as well as the role of youth and the importance of tolerance in such efforts.

"Dr. Judy Kuriansky is the epitome of the global, responsible citizen we want all people on the planet to strive to be. For years she has tirelessly given her talent and time to causes of peace which make the world a better and more tolerant place for many," said Dr. Brown.

In receiving the prestigious honor, Judy Kuriansky joins luminaries such as Dr. Michael E. DeBakey, the Honorable Mikhail Gorbachev, Melba Moore, Maestro Zubin Metha, Arnold Schwarzenegger, Alanis Morissette, Kyai Haji Abdurrahman Wahid and Sergio Vieira de Mello (Posthumous) who signify what being a 'Friend of the UN' means, and becomes an Ambassador for its ideals and goals.

A well know radio call-in advice host for decades, Kuriansky is on the adjunct faculty of Columbia University Teachers College and Columbia College of Physicians and Surgeons and a Visiting Professor at Beijing Health Science Center, and has done disaster relief worldwide including after the Asian tsunami and earthquakes in Haiti and China. She also serves on the Boards of the Peace Division of the American Psychological Association and U.S. Doctors for Africa.

"My first event with my 'new hat' of Tolerance as a 'Friends of the UN' Ambassador," says Dr. Kuriansky, *"will be to announce a 'call to action' at the upcoming Youth Assembly at the United Nations, inviting young people to join me in becoming a Friend of the UN, to work together to foster mutual understanding and appreciation of diversity,"* says Kuriansky whose recent book "Beyond Bullets and Bombs" about grassroots peacebuilding chronicles youth efforts towards mutual understanding, tolerance and cooperation. *"Youth have an important role to play in promoting and em-*

bodying the ideals which the UN charter set out 60 years ago." The United Nations International Year of Youth began in August 2010.

Additionally, in her new role, Dr. Kuriansky will 'Share Her Hat' with 'Friends of the UN' 2011 Youth Ambassador Nejeed Kassam who, at 24 embodies the hope and acceptance that we want to see in the future world.

Dr. Kuriansky says, *"Nejeed is an aspiring change-maker devoted to helping other youth to appreciate diversity. At a young age he is the creator and director of the High on Life campaign and the editor of the book, 'High on Life: Stories of Hope, Change, and Leadership'. He is the founder of the international NGO 'End Poverty Now' where he continues to work as the organization's Executive Director, as well as Networks for Change".*

Adds Dr. Brown, *"Nejeed Kassam IS the change we want to see in the world. As a young person who will inherit the world we are proud to name him as a Youth Friend of the United Nations and believe his own future actions will benefit the whole world, as his current initiatives at such an early age have shown".*

As an Ambassador for Friends of the UN, Dr. Kuriansky will wear her Tolerance hat at many events and invite others to 'Wear My Hat' as a symbol of their commitment to tolerance. For example, models, designers and attendees at the upcoming February Fashion Week in New York City will be invited by Dr. Judy to 'Wear My Hat'.

"I want to show that tolerance and peace is chic," says Kuriansky, whose Stand Up for Peace Project plays at peace concerts and has done seminars about peace and conflict resolution worldwide.

Friends of the United Nations will further its mission with events, media campaigns and dialogue conferences related to important issues world peoples must face together, asking individuals, corporations, NGOs and governments alike to become a member and partner in its goals for the future.

"We have only one world in this life, and for now, only one planet on which to live together," says Dr. Brown. "For the foreseeable future, we must find new ways to create, collaborate and move forward – in tolerance and peace – or, I fear we won't."

Founded in 1985, Friends of the United Nation (FOTUN) is an independent, non-partisan organization dedicated to increasing awareness of the United Nations' activities through partnerships with educational institutions, corporations, media, international governments and NGOs to bridge the gap between ideas necessary to achieve global progress and collaboration of people worldwide in actual work on issues of peace, human rights, the environment, children and responsible social and economic development.

For more information and to join Friends of the UN, visit www.fotun.org or Facebook at http://on.fb.me/g8JaSu.

Correspondence related to this article should be sent to:
Donnetta Campbell, donnettacc@yahoo.com

The Florence L. Denmark and Mary E. Reuder Award for Outstanding International Contributions to the Psychology of Women and Gender

Purpose

The award is named for two charter members of Division 52 who are known for their scholarly contributions, international outlook, and outstanding mentoring. The award's purpose is to recognize and encourage other outstanding psychologists who have made similar international contributions to further the understanding of women and/or gender. The outstanding contributions can be cross-cultural studies of women and gender, the mentoring of young colleagues across borders, the training of psychologists to do international work, or other areas deemed important by the Award Committee.

Criteria for Eligibility

The recipient must be a psychologist with a demonstrated interest in international or cross-cultural psychology. Current membership in Division 52 is not a requirement. The Committee will make up to one award per year.

The Award

The award shall consist of a plaque. The winner will be announced during the Division's annual business meeting at the APA convention.

Submission Requirements and Procedure

Submission requirements are a copy of the candidate's c.v. and a letter of nomination setting forth the most outstanding contributions of the candidate.

Six copies of the materials should be sent to:
Joan C. Chrisler, Ph.D.
Department of Psychology
Connecticut College
New London, CT 06320
USA

Deadline: All materials must be received by May 1, 2011.

E-mail questions to Dr. Chrisler at jcchr@conncoll.edu.

Fourth Annual Psychology Day at the United Nations

Reach Them, Teach Them:
The Role of Psychology in Achieving Universal Access to Education

United Nations Headquarters and Surrounding Venues
New York, New York

Thursday, 14 April 2011
10:00am – 5:00pm

Morning DPI Briefing
Reach Them, Teach Them

Afternoon Concurrent Workshops
Innovative Ideas
Innovative Technologies
Challenging Places and Situations

To register, go to http://sites.google.com/site/unpsychday/

Nominations for International Union of Psychological Science Awards

Nominations are invited for the following International Union of Psychological Science sponsored awards to be given at the 2012 International Congress of Psychology in Capetown, South Africa. Deadline for nominations is only 6 months away. More details at http://www.iupsys.net/index.php/prog-awards or by following the hotlinks below.

Mattei Dogan Prize: Recognizes a contribution that represents a major advancement in psychology by a scholar or team of scholars of high international reputation.
Young Investigator Awards: Recognize young post-doctoral scientists who have already made a significant contribution to psychological science.
Achievement Against the Odds Award: Honors a researcher or team of researchers who succeeded in conducting research under extremely difficult circumstances.

Lifetime Career Award: Honors distinguished and enduring lifetime contributions to international cooperation and advancement of knowledge in the field of psychological science.

The deadline for receipt of nominations for the 2012 Awards is 30 September 2011.

Call for Student Research Manuscripts on Women and Gender

Deadline April 1, 2012

The Society for the Psychology of Women (SPW) of the American Psychological Association and the Association for Women in Psychology (AWP) seek research manuscripts for the 2012 Annual Student Prize for Psychological Research on Women and Gender.

Research Topics

The student research manuscript should focus on women's lives and issues, or more generally, on gender ideologies and behavior, from a feminist perspective.

Eligibility

Jointly-authored papers are eligible, but the first author must have been a student at the time the research was conducted, as indicated by a statement by the first author, in a cover letter accompanying the submission, specifying when and from what institution the first author obtained the degree, the name of the faculty who supervised the research, and the department of the supervising faculty. Entries should be of journal length and in *APA* style. Eligible papers include unpublished manuscripts as well as papers that have been submitted or accepted for publication. Published or presented papers are also eligible as long as they have a date of 2011 or 2012. All papers should be submitted in manuscript form, not as pre-prints or prints with information about submission and publication status provided in the cover letter.

Evaluation

Entries will be judged on theoretical creativity, methodology, clarity and style, and social importance of the research questions and findings for the psychology of women and gender.

Awards

A $250.00 prize will be awarded to the best paper. First and alternate winners will be announced at the 2012 meeting of the American Psychological Association.

Submission Procedure

Please attach a copy of your paper to an e-mail sent to the address below. Also, please send four (4) copies of the paper, a self-addressed, stamped postcard, and a self-addressed stamped business size envelope by April 1, 2012 to: Silvia Sara Canetto, Ph.D., Department of Psychology, Colorado State University, Fort Collins, CO 80523-1876 (silvia.canetto@colostate.edu)

The Submission Deadline for the 2011 AWP/SPW Student Research Manuscript Prize is April 1, 2012

Call for Papers: Journal of Asia Pacific Counseling (JAPC)

www.kcajournal.org

Deadline: April 30, 2011

The Journal of Asia Pacific Counseling (JAPC) is an official publication of the Korean Counseling Association (KCA) that has more than 8,000 South Korean counselors and counseling psychologists as its members. Korean Counseling Association has long recognized the need for having an outlet for scholarly work that gives special attention to the applications of counseling with diverse populations in the Asia Pacific region. In setting up the Journal of Asia Pacific Counseling, many internationally renowned scholars have provided invaluable input regarding the title of the journal, potential editors, and the target audience.

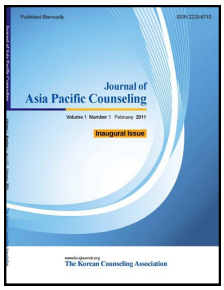

JAPC is intended for both researchers and practitioners, and includes theoretical, empirical, and methodological articles in the areas of counseling interventions, prevention, career development and vocational psychology, supervision and training, assessment, multicultural aspects of counseling, and consultation.

All articles are published in English, and JAPC is issued twice a year in February and August. The inaugural issue has just been released in the past month. Please visit the homepage of the Journal of Asia Pacific Counseling (www.kcajournal.org) for full details on aims and scope, editorial policy, and article submission.

The next due date for manuscript submission is on April 30, 2011. Please submit manuscripts via e-mail (japc@snu.ac.kr), following the guidelines described on the homepage of the journal.

We hope you will seriously consider JAPC for your scholarship.

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Graduate Student Scholarships To Be Offered for Teaching the Psychology of Men Continuing Education Program at the APA Washington D.C. Convention

Teaching the Psychology of Men will be a Continuing Education Program during the APA Convention in Washington, D.C. Eleven scholarships will be awarded to graduate students who want to attend the workshop free of charge.

The purpose of this introductory workshop will be to assist psychologists in developing course work on the psychology of men using the theoretical and empirical literature on men and masculinity. Participants will learn basic knowledge on how to create a psychology of men course or how to infuse this content into existing courses on gender or the psychology of women. Each presenter will share their syllabi, reading materials, class manuals, evaluation processes, and other resources. The workshop will discuss pedagogical processes such as traditional lecturing, psychoeducational techniques, group discussion approaches, use of video media, student assessment techniques, managing classroom problems, and the infusion of diversity and multiculturalism as critical content.

The goals of the workshop are to help psychologists:

1) Design a psychology of men course or incorporate the psychology of men into existing courses;
2) Locate syllabi, core concepts, readings, media, self assessments, and other resources to teach the psychology of men;
3) Utilize multiple teaching methods when teaching the psychology of men including psychoeducational and multicultural approaches; and
4) Enumerate the critical problems/dilemmas and solutions when teaching the psychology of men.

The teaching faculty for the workshop include: James M. O'Neil, Ph.D., University of Connecticut, Storrs, CT; Christopher Kilmartin, Ph.D., Mary Washington University, Fredericksburg, VA; James Mahalik, Boston College, Chestnut Hill, MA.

Information about the graduate student scholarships, how to apply, criteria for selections, and the deadline date can be obtained by emailing Jim O'Neil, Chair, Committee on Teaching the Psychology of Men, Society for the Psychological Study of Men and Masculinity (SPSMM), Division 51 of APA, at jimoneil1@aol.com.

Registration For APA Continuing Education Programs Begins April 15, 2011: Call 1-800-374-2721, ext. 5991 or register online at apa.org/ce.

The Institute for the Study and Promotion of Race and Culture 2011 Diversity Challenge: Intersections of Race or Culture and Gender or Sexual Orientation October 28-29, 2011

Each year the Institute for the Study and Promotion of Race and Culture addresses a racial or cultural issue that could benefit from a pragmatic, scholarly, or grassroots focus through its Diversity Challenge conference. The theme of the 2011 conference is the examination of intersecting identities from multiple frameworks. The two-day conference held at Boston College includes panel discussion/symposia, workshops, structured discussions, a poster session, and individual presentations by invited experts and selected guests including educators, administrators, researchers, mental health professionals, and community organizations. Individuals interested in presenting should check the ISPRC website where the Call for Proposals is posted, http://www.bc.edu/schools/lsoe/isprc/dc2011.html. The proposal deadline is May 2, 2011.

General information about the conference including pre-registration will also available on the website. For all inquiries feel free to email isprc@bc.edu.

International Employment Opportunities

Michael J. Stevens, PhD, DHC
Illinois State University
mjsteven@ilstu.edu

Murdoch University, School of Psychology: The School of Psychology at Murdoch University seeks applications for a senior lectureship in clinical psychology. The appointee will have a primary responsibility for teaching and supervising in the postgraduate clinical psychology program. The appointee will also be expected to conduct research and supervise student research. Applicants should hold relevant postgraduate qualifications in psychology, be registered or registrable as psychologists within Australia, and be eligible for membership of the College of Clinical Psychologists in the Australian Psychological Society. They should have experience in providing clinical supervision and teaching in an academic environment. Knowledge and expertise in the area of psychological assessment would be an advantage. The School has a tradition of excellence in research and teaching, particularly in areas of applied psychology and offers a range of accredited courses in psychology (including specializations in clinical and organizational psychology at the postgraduate level). Information about the School of Psychology can be found at http://www.psychology.murdoch.edu.au/. Information about this position and other upcoming positions in the School of Psychology can be obtained from Associate Professor Max Sully, Dean of the School of Psychology, at +08 9360 2253 or M.Sully@murdoch.edu.au. Application procedures and a position description with detailed selection criteria are available from the University's web site at http://jobs.murdoch.edu.au/. All applicants should address the selection criteria within their application. Please send applications to recruitment@murdoch.edu.au. Closing date: March 2011

University of New England, Clinical Psychology Program: Join the UNE Clinical Psychology Program to strengthen and expand the University's research and teaching capacity in this area and to serve the needs of education in clinical psychology in regional Australia. This Program is well-established and popular with students, particularly those wanting to live and work in rural and regional areas. The Clinical Program at UNE has five full-time staff, a part-time clinic receptionist, and contributions from the other fifteen psychology staff as well as from adjunct practitioner-educators. The Clinical Program staff work closely with the other academics in Psychology and the program is integrated with the general psychology program in regards to teaching and research collaboration. There are 12 Commonwealth supported student places per year. The program provides a key pathway for education and training in clinical psychology in a major rural and regional centre in Australia. The successful applicant may have teaching and research interests in any area of clinical psychology including (but not limited to) child clinical psychology, adult mental health, clinical neuropsychology, and health psychology.

Further information about psychology at UNE, including the Clinical Program is available at www.une.edu.au/bcss/psychology/. Informal enquiries may be directed to Dr. Tanya Hanstock, Director of the Clinical Psychology Program, Tel: +61 2 6773 2871, E-mail: thansto2@une.edu.au

Salary: AUD$90,977 to $104,763 per annum (Senior Lecturer level); or AUD$74,438 to $88,222 per annum (Lecturer level) plus 17% employer superannuation and optional salary packaging. A 15% market loading currently applies to this position. This loading is subject to review from time to time.

Closing date: April 11, 2011

An application package, including selection criteria that must be addressed, may be obtained from www.une.edu.au/recruit/ or by phoning Human Resource Services, +61 2 6773 3972. Applications will be received up to 5 pm on the closing date.

Macquarie University, Department of Psychology: An outstanding opportunity exists for two clinical neuropsychologists and one organizational psychologist to join one of the leading psychology departments in Australia. The organizational position is Level B (Lecturer) and the Neuropsychology positions are at Level B or C (Lecturer/ Senior Lecturer) and Level D or E (Associate Professor/Professor). Located on the north shore of Sydney, the Psychology Department at Macquarie University is a research intensive department that is home to the Centre for Emotional Health, a newly planned Centre for Elite Performance, Expertise, and Training, and other highly productive research groups and laboratories. It is also closely affiliated with the Macquarie Centre for Cognitive Science (MACCS), the Centre of Excellence in Cognition and its Disorders (a national centre of excellence), the Macquarie University Hospital (which specializes in neurosurgical research and practice), and the Mild Traumatic Brain Injury Clinic at Westmead Hospital. The Psychology Department has outstanding undergraduate and post-graduate programs, and a large number of excellent higher-degree research students. The successful applicants will contribute to the undergraduate curriculum and to the postgraduate programs in clinical neuropsychology or organizational psychology. The successful applicants will be expected to teach and carry out research in a relevant area, supervise research students, and seek external research funding and will have the opportunity to maintain a neuropsychology or organizational psychology practice.

Neuropsychology positions:
For the Level B or C appointment available teaching areas include behavioral management and psychopathology, and

psychological assessment. The Level D or E will have the relevant professional expertise to provide academic leadership for the program. Candidates must have a PhD in psychology and be eligible for membership to the Australian Psychological Society's College of Clinical Neuropsychologists, and for endorsement as a clinical neuropsychologist with the Psychology Board of Australia.

Organizational Psychology position:
Candidates must have a PhD in psychology and be eligible for membership of the Australian Psychological Society's College of Organizational Psychologists, and for endorsement as an organizational psychologist with the Psychology Board of Australia.

For full details of the positions and selection criteria, please visit http://www.mq.edu.au/jobs/. Anticipated start date for these roles is from July 2011.

Appointment: Full-time, continuing (permanent)

Inquiries: Professor Bill Thompson on +61 2 9850 9949 or E-mail: bill.thompson@mq.edu.au

Package: Salary level dependent on level of appointment

Applications close: March 2011

University of British Colombia, School of Arts & Sciences: The Irving K. Barber School of Arts & Sciences invites applications for a tenured or tenure-track position in the area of clinical psychology at the rank of associate professor, to begin with a possible start date of January 1, 2012. The position will be held in Psychology (http://web.ubc.ca/okanagan/psyo/welcome.html) within the Barber School. The successful candidate will assume the role of clinical training director, and will provide leadership, guidance, direction, and coordination and inspiration to students/interns, members of the training committee, and other program staff on matters relating to training in professional psychology. Minimum Qualifications: A PhD in clinical psychology from an APA/CPA-accredited university; minimum 4 years of full-time university teaching at the rank of assistant professor (or equivalent) or higher; evidence of scholarly achievement comparable to peers at major research universities; a productive research program; experience and skills in teaching and mentoring within a university-based clinical psychology PhD program; and licensed or license eligible in clinical psychology in British Columbia. The Barber School (http://web.ubc.ca/okanagan/ikbarberschool/welcome.html) - the largest faculty in the University of British Columbia, Okanagan Campus - offers opportunities for world-class research that spans the sciences, social sciences, and humanities within an intimate teaching and learning environment. UBC is consistently ranked among the world's top 40 universities, and the UBC system comprises two distinct and autonomous campuses in the province of British Columbia - one in Vancouver and the other in Kelowna. Applicants should provide a cover letter, curriculum vitae, evidence of teaching ability (e.g., course evaluations), program of research, and the names and contact information of three referees. All documents must be submitted as E-mail attachments and sent to recruitment.bsas@ubc.ca. For additional information, go to http://web.ubc.ca/okanagan/facultystaff/prospective/recruitment/tenuretrack.html#bsas. Applications will be reviewed starting April 30, 2011.

Pine River Institute, Chief Executive Officer: Pine River Institute is a residential treatment center and outdoor leadership experience for youth 13 to 19 struggling with mental health issues, and specifically, substance abuse. Their campus is located on a 200-acre site 100 kilometers northwest of Toronto, Ontario, and includes a residential program for 36 adolescents, an eight-bed therapeutic wilderness program near Algonquin Park, an aftercare program, and a head office in Toronto. Its family-centered program is innovative and highly structured, and creates opportunities for troubled teens to engage in a focused transformation process through a fusion of education, therapy, recreation, and life skills. The majority of its students is from Ontario and funded by the Ministries of Health and Education. They also work with families from across Canada and internationally. The organization has been in operation for 4.5 years, and has achieved stable funding from the Ministries of Health and Education. The current CEO and the Board have developed a 10-year developmental trajectory (strategic plan). A collaborative, relational therapeutic milieu culture has been achieved, and the new CEO will implement the growth strategy within the context of ensuring the integrity of the Institute's integrated educational and therapeutic program (the Pine River Model - comprehensive developmental-systemic approach). Reporting to the Board of Directors, and working collaboratively with the Institute's Executive Director, Clinical Director, and staff, the new CEO will lead the organization through its next stage of growth and success. To meet the challenges of this position, candidates should meet the following criteria:

- Relevant graduate degree (psychology, social work, mental health, health sciences, Public policy, etc.).
- Professional affinity with the Pine River treatment model;
- Proven ability to build organizational capacity with clinical and service excellence, and ensure accountability for such; an excellent manager and coach for staff;
- Demonstrated ability to develop, foster and nurture strong working relationships with external stakeholders (local community, government(s), other leading clinical/professional organizations, relevant community organizations, business, key funders/donors) to advance an organization's mission, and plans. Proven ability to be an effective champion and advocate for an organization, its plans and its people; become a valued "go-to" thought leader;

- Proven senior leadership/management experience in a mental health, addiction treatment, adolescent health organization.

Please forward your resume, in confidence, to Heather Connelly, Managing Director, Kinley & Connelly, Stanton Chase International (Toronto), 220 King Street West, Toronto ON, M5H 1K4, (416)593-5550, hconnelly@kinleyconnelly.com or to Cheryl Lai, clai@kinleyconnelly.com.

***Science Applications International Corporation (Germany), Addictions Counselor*:** Develop and implement a community -based adolescent substance abuse prevention and treatment program on U.S. military base overseas (Netzaberg, Germany). The duties include intake, screening, assessment, case management, providing AOD training and specialized education on a variety of topics, treatment planning, discharge and continuing care planning, records management, and participation in quality assurance. The essential prevention and education role includes classroom education for adolescents, in-service training to community agencies, community education, screening for and facilitation of prevention support groups for youth from high risk environments, and participate in community awareness campaigns. Also, obtain and maintain written referral agreements with all community agencies, briefing referral agencies about the ASACS program and how to transfer adolescents for assessment and case record management and documentation, maintaining program statistics maintaining Continuous Quality Improvement Manual; maintain valid license. Required Education: Masters

NOTES: 4 openings. US Residents Only. Employer will assist with relocation costs. Two-part compensation package includes salary plus Living Quarters Allowance. Foreign-Earned income (U.S. Federal and State Tax Exempt).

Sterling Medical, Child Psychologist: Civilian opportunity for a child Psychologist to provide EDIS services to the U.S. Navy located in Okinawa, Japan. Sterling Medical offers excellent compensation, relocation, paid time off and holidays off, CEU allowance, health/dental/life/ADD and disability insurance, and tax advantages. For more information, please contact Rochelle Myers at (800)852-5678 x.323 EST, or E-mail rmyers@sterlingmedcorp.com. Fax number is (727)821-0711. Child psychologist must have a doctorate in clinical or counseling psychology from an APA-approved program, and completed an APA-approved internship, with a fellowship in child psychology. Must have 2 years experience in family-centered services to children with disabilities and/or behavioral disorders.

New Zealand, Clinical Psychologists: We have full-time clinical psychologist vacancies to fill for community mental health and other service organizations. You must have: Ph.D. in clinical psychology; current practicing license. A minimum of two-years post-supervisory experience. The ability to receive your New Zealand psychologist registration with clinical scope; the desire to commit two years or longer. E-mail: office@alignrecruitment.com; Phone: +64 3 366 8779: Fax: +64 3 377 6770; Web www.alignrecruitment.com. An expatriate American is available to assist with all enquiries.

University of Otago, Department of Psychological Medicine: Applications are invited for the part-time position of associate professor/senior lecturer in the Department of Psychological Medicine from graduates with relevant specialty qualifications in clinical psychology. Duties include contributing to: undergraduate medical school teaching, relevant specialist topic(s) in the postgraduate programs in cognitive behavior therapy and psychiatry, Departmental and Faculty examination duties, developing a personal research program and making applications for external funding support within 1 year of appointment. Those appointed at associate professor level will be expected to have already developed a substantive research program of at least national standing. The appointment will be for up to 0.8 FTE for a senior lecturer or up to 0.7 FTE for an Associate professor. This position offers an exciting academic opportunity to contribute to the development of undergraduate and postgraduate mental health education, and to mental health research, within the School of Medicine and Health Sciences, University of Otago, Wellington.

Specific enquiries may be directed to Professor Peter Ellis, Head, Department of Psychological Medicine, University of Otago, Wellington, P.O. Box 7343, Wellington South, New Zealand, Tel: +64 4 385 5656, Fax: +64 4 385 5877, E-mail: pete.ellis@otago.ac.nz

To see a full job description and to apply online go to: www.otago.ac.nz/jobs

Nanyang Technical University, Business School: The Nanyang Business School (NBS) invites applications for assistant professor/research scientist with the Culture Science Institute in the area of social neuroscience, in the Division of Strategy, Management and Organization. Applicants should hold a doctorate degree with expertise in social neuroscience (broadly defined) and research interests in culture, social cognition, behavioral economics, and other business related topics. The Culture Science Institute (CSI) is a newly developed research institute at NBS, Nanyang Technological University in Singapore. It aims at conducting cutting-edge transdisciplinary research on culture and business. The school has recently built a research laboratory equipped with state-of-the-art ERP/EEG system, bio-physiological system, eyetrackers, and other facilities for acquiring behavioral data. Functional MRI facility will also be available at a later stage. Successful candidates will be offered an internationally competitive salary commensurate. International faculty will enjoy subsidized housing in a 500-acre residential campus environment, on-campus childcare center, and children's educational allowances for Singapore's acclaimed international schools. Applicants should submit (1) a curriculum vitae with a full list of publications, (2) statements of teaching and research

interests, (3) representative publications, and (4) three references and letters of recommendation. Applications will be screened until positions are filled. Please send application package electronically (PDF documents) to HeadSMO@ntu.edu.sg, and addressed to:
Professor Soon ANG
Goh Tjoei Kok, Endowed Chair & Professor in Management
Head, Division of Strategy, Management & Organization
Nanyang Business School, Nanyang Technological University
Singapore 639798

Nanyang Technological University, School of Humanities and Social Sciences: The School of Humanities and Social Sciences at Nanyang Technological University (NTU), Singapore, invites qualified academics to apply for a faculty position as assistant professor. Applications are welcome from any area of academic psychology, though preference will be given to social psychology and/or areas that complement the research foci in Psychology at NTU. Successful candidates should possess strong research track records, including publications in international peer reviewed journals, and should demonstrate a commitment to effective teaching. The successful candidate is expected to have completed the requirements for the PhD degree in psychology, or a cognate discipline, and post-doctoral experience will be a significant advantage. A visiting appointment, particularly in social psychology, will also be considered. Salary will be competitive and will commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package. Further information about the University and the Division of Psychology can be viewed at the following websites: NTU: www.ntu.edu.sg. Division of Psychology: http://www.ntu.edu.sg/hss/psychology/Pages/default.aspx.

To apply, please refer to the Guidelines for Submitting an Application for Faculty Appointment (http://www.ntu.edu.sg/ohr/career/submitApplications/pages/faculty.aspx) and E-mail your application package [consisting of cover letter, curriculum vitae, personal particulars form, teaching and research statement, three selected reprints/preprints of publications, and the names and email addresses of three potential referees] to:
Head, Division of Psychology
School of Humanities and Social Sciences
Nanyang Technological University
14 Nanyang Drive
Singapore 637332
E-mail: H-DPSY@ntu.edu.sg

Review of applications begins on April 4, 2011 and we will continue until the position is filled. Only short-listed candidates will be notified.

Özyegin University, Department of Psychology: Özyegin University invites applications for an assistant professor position in psychology. A PhD degree is required. Applicants must have a strong commitment to teach at both the undergraduate and graduate levels, to conduct theoretical as well as applied research, and to provide community service. Özyegin University is a private, not-for-profit university located in Istanbul, at the crossroads of Europe and Asia. Founded in 2008, Özyegin University aims to be a "Third Generation University" that facilitates the transformation of knowledge to economic and societal value. Internationally competitive salaries and benefits are offered to qualified candidates. The language of education is English. Currently, Özyegin University has undergraduate and graduate programs in engineering, business, and hotel management. Plans are under way to start programs in law, economics, international business, entrepreneurship, finance, civil aviation management, as well as psychology. Following the successful launch of the undergraduate program in 2011, we plan to launch graduate programs within 3 years. Our intent is to have particular strengths in clinical psychology as industrial/organizational psychology, while serving all areas of the discipline. Candidates should submit a cover letter, together with their curriculum vitae, teaching and research statements, and complete contact information of three professional references. Please direct questions and submit applications by E-mail to Prof. Erhan Erkut, Rector (rector@ozyegin.edu.tr), +90 216 559 2300. Review of applications will continue until the position is filled.

Accredited Internship Training Programs – Canada:

Alberta Children's Hospital
1820 Richmond Road, SW
Calgary, Alberta
Canada T2T 5C7
Accredited: June 30, 1992
Next site visit scheduled 2008

British Columbia Children's Hospital
4480 Oak Street
Vancouver, British Columbia
Canada V6H 3V4
Accredited: May 19, 1995
Next site visit scheduled 2012

Center for Addiction and Mental Health, Clarke Division
(formerly listed as The Clarke Institute of Psychiatry)
250 College Street
Toronto, Ontario
Canada M5T 1R8
Accredited: May 23, 1991
Next site visit scheduled 2007

Children's Hospital of Eastern Ontario
401 Smyth Road
Ottawa, Ontario
Canada K1L 8L1
Accredited: May 4, 1990
Next site visit scheduled 2012

The Hospital for Sick Children
Department of Psychology
555 University Avenue
Toronto, Ontario
Canada M5G 1X8
Accredited: August 10, 2001
Next site visit scheduled 2011

IWK–Grace Health Center
(formerly listed as IWK Children's Hospital)
5850 University Avenue
P.O. Box 3070
Halifax, Nova Scotia
Canada B3J 3G9
Accredited: January 9, 1996
Next site visit scheduled 2006

London Health Sciences Center
339 Windermere Road
London, Ontario
Canada N6A 5A5
Accredited: May 13, 1999
Next site visit scheduled 2007

University of Manitoba Counseling Service
474 University Center
Winnipeg, Manitoba
Canada R3T 2N2
Accredited: June 30, 1992
Next site visit scheduled 2012

University of Manitoba Faculty of Medicine
Department of Clinical Health Psychology
PZ-350, 771 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 3N4
Accredited: May 1, 1979
Next site visit scheduled 2011

McGill University Psychology Internship Consortium
(This program is affiliated with the McGill University doctoral training program in clinical psychology)
Department of Psychology
1205 Dr. Penfield Avenue
Montreal, Quebec
Canada H3A 1B1
Accredited: September 1, 1972
Next site visit scheduled 2007

University of Ottawa
(This program is affiliated with the University of Ottawa doctoral training program in clinical psychology.)
Center for Psychological Services
School of Psychology
11 Marie Curie
Ottawa, Ontario
Canada K1N 6N5
Accredited: October 27, 1987
Next site visit scheduled 2007

Queen Elizabeth II Health Sciences Center
(formerly listed as Camp Hill Medical Center)
1763 Robie Street
Halifax, Nova Scotia
Canada B3H 3G2
Accredited: October 23, 1992
Next site visit scheduled 2006

Royal University Hospital
Department of Clinical Health Psychology
Saskatoon, Saskatchewan
Canada S7N OW8
Accredited: May 12, 1994
Next site visit scheduled 2011

St. Joseph's Healthcare
Anxiety Treatment and Research Center
6th Floor, Fontbonne Building
50 Charlton Avenue, East
Hamilton, Ontario
Canada L8N 4A6
Accredited: July 15, 2005
Next site visit scheduled 2010

Vancouver Hospital and Health Sciences Center—UBC Hospital (formerly listed as University Hospital—University of British Columbia Site)
Internship Training Program in Professional Psychology
2211 Wesbrook Mall
Vancouver, British Columbia
Canada V6T 2B5
Accredited: November 6, 1987
Next site visit scheduled 2006

CANADEM JPC International Internships: CANADEM is looking for qualified Lawyers, MAs and other university graduates interested in development, human rights and peace building to work overseas starting in June with the following international organizations:

- Sierra Leone Special Court
- UNDP (United Nations Development Programme) - Central Asia, Africa
- UNESCO (United Nations Educational, Scientific, and Cultural Organization) - Thailand
- OSCE (Organization for Security and Cooperation in Europe) - Balkans
- IOM (International Organization for Migration) - Washington DC, Ukraine
- UNHCR (United Nations High Commissioner for Refugees) - Geneva, Croatia
- IFES (International Foundation for Election Systems) - Congo (Kinshasa)

- UN ODC (United Nations Office on Drugs and Crime) - Uzbekistan

CANADEM is sponsoring up to 40 internship placements, pending funding notice from the Department of Foreign Affairs and International Trade (DFAIT) and the Canadian International Development Agency (CIDA). You must be under 30, underemployed and meet all other eligibility criteria (for more information please visit our website at www.canadem.ca).

Of the over 120 JPCs placed by CANADEM over the past four years, most found relevant employment after completing their internships. Many continued working as full-time staff members with their host organization.

On-Going Support: CANADEM interns are given assignments and responsibilities commensurate with their academic, working and volunteer experiences. Contracts include:

- An in-Canada pre-departure orientation (early summer);
- A six months overseas posting;
- On-going follow-up while an intern (including job leads); and
- A final in-Canada debriefing session.

Throughout the internships, the Program Coordinator remains in contact with the JPCs and, as the internships draw to a close, provides assistance in reworking and updating resumes.

Funding: This project is undertaken within the Government of Canada's Youth Employment Strategy (YES) with contributions from DFAIT and CIDA. CANADEM provides its interns with a $12,000 stipend out of which all direct expenses are paid (e.g. travel, health insurance, briefing sessions, accommodations, etc).

For Application, Eligibility and Additional Information Visit: www.canadem.ca

"A national roster of Canadian skilled in human rights, peace building, democratization, admin-logistics, security, reconstruction and other field expertise." tel: (613) 789-3328, fax: (613) 789-612, e-mail: neil.burron@canadem.ca , web: www.canadem.ca

Please send all completed applications to: jpc@CANADEM.ca.

The Seeds of Sustenance Fellowship Program: The Seeds of Sustenance (SOS) Fellowship Program is a unique cross-sectoral and sustainable training program providing skills and practical information in food production, nutrition, AIDS prevention, and income generation to rural African communities affected by HIV/AIDS. Through this program, Global Service Corps recruits, prepares, and trains pairs of Local and Visiting Fellows to become qualified instructors in HIV/AIDS prevention and care, nutrition, and sustainable agriculture methods. Visiting Fellows and Local Fellows receive a one-month initial training in Arusha, Tanzania. Following this training, Fellow pairs work with Participating Organizations (POs) for five to eleven months. Fellows assist POs with the development of community training and education programs, and facilitate in-depth field seminars for local communities. http://www.globalservicecorps.org/d/levelsofservice.html#internship

St. Francis College, Department of Psychology: The Department of Psychology at St. Francis College invites applicants for a tenure-track Assistant Professor position to begin September, 2011. The College seeks a highly motivated professional with a Ph.D. in Developmental, Social or Experimental Psychology. The successful applicant must be qualified by training and experience to teach both undergraduate and graduate level courses in general psychology, developmental psychology, social psychology, statistics, experimental psychology, and to provide supervision to students. The successful applicant will work with a diverse faculty and student body and is expected to teach 12 credit hours (or graduate equivalent) per semester, provide advising and research mentoring for undergraduate and graduate students and serve on departmental and college committees. Preference will be given to applicants who demonstrate a history of experience and proficiency in conducting research and have prior experience in teaching upper-division undergraduate courses.

St. Francis College is a Franciscan founded, coeducational, liberal arts institution of higher learning in which teaching, research, and service are central to its total learning environment. Located in Brooklyn Heights, and with Manhattan just one subway stop away, the entire spectrum of art, culture, and educational/research facilities is at your fingertips. St. Francis College has been recognized by U.S. News & World Report as one of the top Baccalaureate Colleges in the North and ranked on the Forbes.com list of America's Best Colleges. The psychology department has six full-time faculty members (five tenured), 250 undergraduate majors, and as of September 2011, will have students enrolled in a new five-year combined BA/MA program in General Psychology.

Candidates should submit a statement of teaching/research interest, curriculum vitae, and three letters of reference. All applications should be emailed to the address listed below to the attention of Dr. Michele Hirsch, Chair of the Search Committee.

Review of applications will continue until the position is filled. Apply for this position through My HigherEdJobs. Contact: Dr. Michele Hirsch, Chair of the Search Committee St. Francis College, e-mail hr@stfranciscollege.edu.

International Employment Opportunities

The **Graduate School of Professional Psychology (GSPP) at the University of Denver** is seeking 2 core faculty members specializing in international disaster psychology. The full-time position is tenure-track; the half-time position is a clinical appointment. Salary and rank will depend on academic and clinical or field experience. There are numerous practice opportunities in Denver. Duties include teaching in the Master's Program in International Disaster Psychology, advising, supervising local and/or overseas practica, and participating as a core member of the GSPP. The applicant should have sufficient academic background and field experience in international disaster psychology to be able to teach a variety of courses in the program. Preference will be given to license or license eligible applicants. A doctorate in clinical psychology is preferable. The University of Denver is an EEO/AA Employer. Minorities are strongly encouraged to apply. Please apply at: http://www.du.edu/hr/employment/jobs.html. Inquiries may be addressed to Dr. Judith Fox, Director, Master's Program in International Disaster Psychology, at jufox@du.edu. Applications will be reviewed beginning February 1, 2011. Subject to budget availability, preferred starting date is September 2011.

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Fax: 765-496-1228
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Studying Virtual Worlds: What's in It for Psychology?

A review of

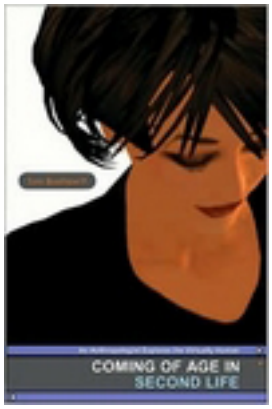

Coming of Age in Second Life: An Anthropologist Explores the Virtually Human

by Tom Boellstorff

Princeton, NJ: Princeton University Press, 2008. 316 pp. ISBN 978-0-691-13528-1. $29.95

Buy from amazon.com

Reviewed by
Richard Velayo

Imagine a world where you can transform your appearance, fly over places, teleport to another location at an instant, create objects at will, live in a house of your dreams, host and attend events in fantastical locations, communicate with others and make friends without the constraints of distance, and virtually do just about anything. Does such as world exist?

In a virtual world such as the Internet site Second Life (http://secondlife.com/), these are all made possible. Anthropologist Tom Boellstorff, from his avatar's point of view, takes us on a tour of Second Life during its formative years, describing his experiences of having immersed himself in this virtual world for years (since June 2004). He provides us with an

ethnographic portrait of the culture in Second Life by describing the features within the world and by presenting several fascinating vignettes that vividly illustrate various kinds of behaviors and social interactions of avatars (i.e., virtual representations of "actual" people who participate in this virtual environment). Interestingly, he considers virtual worlds as "places" (though virtual) where its users are able to live, explore, interact, form relationships, and build communities just as they would in real life.

Given the content and writing style of this academic book, many readers may conclude that it is geared primarily to anthropologists, other social scientists, and perhaps graduate students in these fields. However, *Coming of Age in Second Life: An Anthropologist Explores the Virtually Human* may also be suitable to those with a college degree and a serious interest in Second Life as a novel medium for social interaction. The writing style is educated but accessible, and the book is full of entertaining anecdotes and observations, though it may not appeal to those already familiar with the intricacies of social customs in Second Life. It is certainly not a book about how to use Second Life. Boellstorff clearly presents it as a study based on extensive ethnographic research that takes a thoughtful look at the way people behave in virtual worlds.

Personality and social psychologists will find Boellstorff's views interesting to say the least and perhaps may feel challenged in their views about psychological models of the self. Boellstorff invites his readers to reflect on the old and new meanings of the virtual and the human, claiming that we are all virtual humans anyway, viewing the world as we do through the prism of culture. He argues that being "virtually human" is what we have been all along.

An inquiry that psychologists will want to make about the function of this book and the knowledge it offers about Second Life is the extent to which social behaviors and norms in virtual environments are comparable with those in the physical world. One such study that attempted to answer such inquiry was that of Yee, Bailenson, Urbanek, Chang, and Merget (2007), in which data were collected from observing avatars that revealed that social norms of gender, interpersonal distance, and eye gaze transfer into virtual environments, even though the modality of movement is entirely different (i.e., via keyboard and mouse as opposed to eyes and legs). There are also some important insights in the book that may be of interest, especially to social psychologists. Two examples that come to mind are Boellstorff's points about the kindness that Second Life residents routinely extend to one another and the extent of multichannel communication.

Second Life: Implications for Psychological Research

Psychologists can learn much from the methodological approach that Boellstorff has taken in studying Second Life. This is the first book to take a sustained exploration of an environment like Second Life from a purely anthropological perspective and, presumably,

will become the basis for new approaches on how such spaces are studied. This book would be important reading for those considering using Second Life as a platform for social and psychological research. Boellstorff does an effective job of describing how his study was conducted and the ethical principles he employed while doing it.

Western psychologists tend to be partial toward a more quantitative approach to acquiring knowledge, but, in the case of this book, the qualitative approach in studying Second Life provides us with a rich understanding of the myriad characters and how they behave and interact. A reader will likely come away asking questions about how our lives are being transformed in very real ways by what is happening in the virtual world. Research psychologists will have a field day in studying psychological phenomena in such worlds.

The second part of the book, titled Culture in a Virtual World, comprises much of the content of this three-part book and is likely to be the most interesting to psychologists. It illustrates many familiar psychological constructs such as temporal and visual perception, the concept of self, self-agency, sexuality and love, language, creativity, addiction, altruism, antisocial behavior, and interpersonal communication and behaviors, to mention a few. An earlier example was Donath's (2007) exploration of how virtual world users may accurately communicate and understand the behaviors of other graphical avatars, as well as their physical characteristics and capabilities, given the graphical and multimodal limitations of virtual worlds.

Bainbridge (2007) pointed out that virtual worlds offer great potential as sites for research in the social and behavioral sciences. There are a number of research methodologies that may be used from within virtual worlds, including formal experimentation, observational ethnography, and quantitative analysis of social networks.

Second Life: Implications for the Practice and Teaching of Psychology

Virtual environments such as Second Life could potentially be unique platforms for psychological research; additionally, they also have profound implications for teaching and training methods, clinical interventions, advocacy, social support communities, and even collaboration between psychologists from around the world. Interestingly enough, a number of discussion groups and other places exist within Second Life that offer counseling and mental health support. You can find these virtual places simply by doing a search within the Second Life environment and teleporting directly to them. There are also several virtual classrooms available on Second Life scheduled during specific times in which avatars may gather in a virtual classroom environment with an “instructor” avatar leading the class or lecture. Both textual and audio modes of communication are available to supplement the graphical interface and on-screen presentations.

Psychologists have yet to extensively explore how Second Life may be used in ways that "extend" their work. The possibilities are endless, and the need to investigate and experiment in the use of virtual worlds as media for delivering psychological services, teaching and training, and forming support groups will become even more apparent as virtual worlds evolve into a more mainstream part of the Internet.

In general, this book has successfully planted seeds for psychological inquiry about virtual worlds, Second Life in particular. Some interesting inquiries may include the following: Are behaviors seen in inhabitants in virtual worlds opening new realms in observing and explaining human behavior? Do behaviors in such worlds provide valuable insights about being human and how we evolve in a world in which technology seems to permeate and change our lives and the ways we interact with others? As virtual worlds gain popularity, how will this affect our real-world lives? Will new pathologies emerge as a function of this? Obviously, there are more questions of possible interest to psychologists who realize the far-reaching impact on psychology.

Boellstorff, through his book, may have provided many psychologists with a powerful catalyst to test relevant psychological theories and phenomena in virtual worlds and to explore how the use of this Internet-based technology may transform the way we advocate policy, do research, present instructional material, and conduct therapeutic interventions.

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Exposure to Disability and Hearing Loss Narratives in Undergraduate Audiology Curriculum

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Purpose: To determine whether exposure to disability and hearing loss narratives increased undergraduate communication sciences and disorders (CSD) students' affective responses to scenarios of individuals with hearing impairment.
Method: Thirty-five CSD undergraduates responded to 8 scenarios (K. English, L. L. Mendel, T. Rojeski, & J. Hornak, 1999). Sixteen students completed a course in audiologic rehabilitation with no exposure to disability and hearing loss narratives; 19 students completed the same course with exposure. Two audiologists, independent and blind to group status, rated the 35 student responses for affective and technical content.
Results: Students exposed to the narratives incorporated more affective elements into their technical responses than students not exposed.
Conclusions: Narratives appear to be effective in increasing affective elements in students' technical/informational responses and may have a place and be of value in undergraduate CSD curriculum.

Key Words: narratives, undergraduate curriculum, audiology

Although the types of information presented to audiology students often include the most current technological advances in assessments and amplification devices, the impact of hearing loss on individuals and their families may not be adequately addressed. Students need to be trained on how to listen actively and attentively to the affective content as well as the technical/informational components of the message (English, Mendel, Rojeski, & Hornak, 1999), that is, the individual's and/or family's perceptions, cognitive understanding, and response to assessments, diagnosis, treatment, and habilitation/rehabilitation options. It is the individual and/or his or her family who must learn how best to cope with the hearing loss, its effect on siblings and social and work environments, and the potential sorrow of dealing with a dysfunctional system (English et al., 1999).

Counseling, if addressed at all at the undergraduate level (McCarthy, Culpepper, & Lucks, 1986), typically instructs audiology students to respond to the technical and informational aspects of hearing loss. Thus, they are taught to provide information in nontechnical terms and/or provide reassurance when the individual or parents of the child with hearing loss expresses grief or sadness. To train students to view hearing loss solely as a disorder fails to address the affective aspects needed to adequately serve the individual, profession, and public.

Charon (2001) argued that "narrative competence," in addition to technical and medical competence, is needed to treat patients successfully. Physician training that includes narratives enables physicians to listen with empathy to their patients' stories and better understand the impact of health loss, disease, and disability (Charon, 2001). The individual's and/or family's stories can help them find meaning in their suffering. Further, stories from practitioners increase reflection and professionalism, giving meaning to the practitioner

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about why they chose the profession and the direction their profession is taking, thus serving as a mechanism for improvement in care (Charon, 2001). Current medical models not only include but embrace biopsychosocial and patient-centered care as a means to treat and respect the patient as a whole, not just as an individual with a disease or disability (Charon, 2001; Kleinman, 1988; World Health Organization, 2001). Narrative knowledge is used in other professions, such as nursing, law, history, and philosophy, as a way to understand stories through cognitive and affective means (Mishler, 1986; Polkinghorne, 1988; Swenson & Sims, 2000). Thus, encouraging the individual to express his or her experiences in text, novels, or film can lead to greater understanding and appreciation of the disease/disorder by the practitioner. The individual's illness, disease, or disability is no longer the sole issue; another dimension and perspective is revealed (Charon, 2001; Engel, 1977; Erdman, Wark, & Montano, 1994; Kleinman, 1988; World Health Organization, 2001). The use of narratives is just beginning to emerge in our profession as evidenced by two recent articles in the *ASHA Leader* (Kuster, 2008; Silverman, 2008). This study examined whether the inclusion of narratives could be of benefit in audiology curriculum.

Exposure to disability and hearing loss narratives may serve to increase empathy, reflection, professionalism, and trust between the audiologist and individual with hearing loss. They may help to provide the student (and practicing audiologist) with the skills needed to merge the technical/informational aspects of audiology with the unique experiences of the individual with hearing impairment and the affected family. The individual and practitioner become partners, which is essential when dealing with chronic conditions such as hearing loss (Erdman, Wark, & Montano, 1994). Satisfactory habilitation/rehabilitation occurs by understanding the meaning and significance of hearing loss to the individual and their family. This is manifested by being able to differentiate a cognitive response from an affective one. Therefore, the specific aim of this study was to determine if undergraduate CSD majors showed increased affective responses to scenarios of individuals with hearing impairment when exposed to books, articles, and films from the perspective of the individual with disability and hearing loss and their family—in other words, narratives.

Method

Participants

Thirty-five undergraduate CSD majors completed a validated instrument by English et al. (1999) designed to measure students' abilities to recognize and respond suitably to eight scenarios. Group 1 included 16 students (all women; mean age: 21.3 years; range: 19–23 years) who completed an undergraduate course in audiologic rehabilitation with no exposure to disability and hearing loss narratives. Curriculum for this group included characteristics of, as well as primary and secondary consequences of, hearing loss; audiologic rehabilitation models of assessment and management for children, adults, and the geriatric population; hearing aids, cochlear implants, and assistive technologies; auditory and visual stimuli in communication; and basic psychosocial aspects of hearing impairment. See Appendix A for a list of assigned readings.

Group 2 included 19 students (1 man and 18 women; mean age: 21.5 years; range: 19–23 years) enrolled in the same course with the same instructor but in the following year. To control for consistency of teaching as much as possible, students in Group 2 received the same curriculum, syllabus, and readings as students in Group 1. In addition to the readings assigned to both groups, students in Group 2 were exposed to disability and hearing loss narratives via additional reading assignments focused on narratives (see Appendix A). The definition of narratives and their purpose were explained to students in Group 2. The narratives selected were chosen to illustrate the impact of the disability and/or hearing loss not only on the individual with the impairment or disability but on the family as well.

On the first day of class, students in each group were asked to respond in written form to questions that tapped their knowledge on the meaning of *disability, impairment,* and *handicap*; deafness as a culture and/or disability; and what they thought a rehabilitation audiologist does. These questions were asked to determine if students from both groups entered the course with the same levels of knowledge or understanding of audiologic rehabilitation. Of note, no student from either group mentioned counseling when asked what a rehabilitation audiologist does. Responses included variations of "fits hearing aids," "teaches lipreading," and "works in the schools with deaf children." No students were able to differentiate a *disability* from an *impairment* from a *handicap*. In addition, no student was enrolled in nor had completed a course in counseling, which is fairly typical at the undergraduate level. Students enrolled in the CSD program follow the same sequence of courses. Thus, responses were interpreted as suggesting equivalency among students on their entering knowledge base, as no qualitative differences were found between the students in Group 1 and Group 2.

Materials and Instrumentation

A list of readings assigned to students in both Groups 1 and 2 and the narratives assigned only to students in Group 2 can be found in Appendix A. Narratives assigned to students in Group 2 included books on the impact of hearing loss from the perspective of the individual with the impairment (Biderman, 1998; Chorost, 2005), and articles (Belkin, 2004; Kinsley, 1987; Rosner, 2004; Sacks, 1999) and films (Oberkotter Foundation, n.d.; Weisberg & Aronson, 2000) from the perspective of the parent, other family members (e.g., siblings), and others (e.g., journalists). To verify that readings were completed, students were required to post comments on the discussion board of BlackBoard, an online teaching tool. In addition, class discussion of these readings and a paper were assigned (see Appendix B for assigned paper).

Each student in each group provided written responses to eight scenarios (English et al., 1999). That is, all eight scenarios were used as the tool to assess if the narratives increased Group 2 students' affective responses (see Appendix C).

These scenarios were designed by English et al. (1999) to determine if doctor of audiology (AuD) graduate students' affective responses better matched or "mirrored" patients' concerns after completing an audiology counseling course. In their study, two cohorts of 14 students, 7 in each group, were administered this instrument the first day of class and again on the last day after completing a counseling course. The eight scenarios were rated for face validity by two audiologists and a counselor specialized in working with individuals with hearing loss. These three professionals rated scenarios in this measure as a request for information, an expression of concern, or a combination of both (English et al., 1999). Students' responses were rated as being *very technical, somewhat technical, both technical and affective, somewhat affective,* and *very affective*.

Procedure

This study was deemed exempt by the institutional review board at Pace University, as this was to be used for educational purposes, all student responses were confidential, and results would be reported in the aggregate.

To recap, each student in each group answered questions on the first day of class to ascertain their understanding of what a rehabilitation audiologist does and to determine if students in each group entered the class with an equivalent knowledge base. At the end of the course each student in each group was asked to respond in written form to each of the eight scenarios used by English et al. (1999) for their counseling course to AuD students.

Two audiologists, independent and blind to student group status, rated the undergraduate CSD majors' responses using the same 1-to-5 scale as that used in English et al. (1999), where 1 = very technical response, 2 = somewhat technical response, 3 = both technical and affective response, 4 = somewhat affective response, and 5 = very affective response.

Examples of student responses from both Groups 1 and 2 are shown below to illustrate the range of *very technical* to *very affective* responses for Scenario 6: "My family says our daughter was born with a hearing loss because I worked until the week she was born" (English et al., 1999; see Appendix C):

Very technical (1): "Working does not cause a hearing loss" (response from student in Group 1).

Somewhat technical (2): "I've never read anything like that. Where did you get that idea?" (response from student in Group 1).

Both technical and affective (3): "The hearing loss was caught early. I know you're worried but she'll be fine" (response from student in Group 2).

Somewhat affective (4): "It's awful your family blames you. You know that's not true. I'm sure she'll do just fine in school" (response from student in Group 2).

Very affective (5): "People want reasons for unexpected events, don't they? It must be upsetting to think someone blames you for this" (English et al., 1999).

To determine interrater reliability, an intraclass correlation coefficient (ICC) was calculated. An ICC of .93 was obtained, indicating excellent agreement by the two audiologists (McGraw & Wong, 1996).

Results

The results supported the hypothesis that exposure to disability and hearing loss narratives increases students' affective responses to scenarios of individuals with hearing impairment. Table 1 displays the means and standard deviations of the students' ratings of scenarios by group; that is, students not exposed to the narratives (Group 1) and students exposed to the narratives (Group 2). Scenarios 2 and 6 were excluded from the analyses because they demonstrated significant heterogeneity of variance between the two groups; Levene's tests were $F(1, 33) = 10.55$, $p < .01$, and $F(1, 33) = 28.96$, $p < .001$, respectively.

Differences between students not exposed to disability and hearing loss narratives (Group1) and students exposed to disability and hearing loss narratives (Group 2) were examined using a multivariate analysis of variance (MANOVA).

Table 1. Means, standard deviations, univariate *F* ratios, and effect sizes (η^2) for scenario ratings.

	Group 1 (not exposed to narratives) (n = 16)		Group 2 (exposed to narratives) (n = 19)			
Scenarios[a]	*M*	*SD*	*M*	*SD*	$F(1, 33)$	η^2
1	1.78	0.98	2.95	0.62	18.19*	.36
3	1.81	0.70	2.95	0.62	25.66*	.44
4	1.69	0.54	3.13	0.55	60.63*	.65
5	2.03	0.64	3.32	0.75	28.94*	.47
7	1.78	0.82	3.11	0.66	28.27*	.46
8	1.63	0.62	3.03	0.54	51.23*	.61

Note. $N = 35$. Ratings: 1 = very technical response, 2 = somewhat technical response, 3 = both technical and affective response, 4 = somewhat affective response, and 5 = very affective response.
[a]See Appendix C for the eight scenarios (English et al., 1999). Scenarios 2 and 6 violated the assumption of homogeneity of variance and were excluded from the analyses.

*$p < .001$.

The MANOVA assumptions of the multivariate normality and homogeneity of variance/covariance were met. A multivariate effect was found showing significant differences in ratings for students not exposed to narratives (Group 1) and students exposed to narratives (Group 2); $F(6, 28) = 11.92$, $\eta^2 = .72$. Univariate F tests revealed that the six scenarios differed significantly at the .001 level between the narrative conditions. Results of the univariate F tests and their corresponding effect sizes are reported in Table 1. Thus, scores for students exposed to narratives for each scenario were higher (having more affective components) than scores of students not exposed to the narratives.

Discussion

The purpose of this study was to determine if exposure to disability and hearing loss narratives increased undergraduate CSD majors' affective responses to scenarios of individuals with hearing loss.

Students exposed to these narratives (Group 2) incorporated more affective elements into their technical/informational responses (closer to a rating of 3) than students not exposed (Group 1; closer to a rating of 1 and 2). Very few students from either group gave *somewhat affective* (a rating of 4) or *very affective* responses (a rating of 5), but a shift between the two groups occurred. These narratives appeared to increase students' reflective listening skills. For many students the concept of developing reflective listening skills was introduced for the first time. This skill is important to develop, as audiologists are typically in the position to give advice as professionals. Audiologists must learn to listen, to *hear* what the individual or family is truly saying, as well as support, respond, and comment neutrally to highly charged postures often taken by individuals and their families. It must be remembered that the undergraduate students who participated in this study ranged in age from 19 to 23 years and had no experience with any "hands-on" counseling. Most students would need some counseling experience before spontaneously providing a *very affective* response.

Several limitations of this study must be considered. First, students in Groups 1 and 2 could have been inherently different, though this is unlikely. No differences in knowledge base of the students entering the audiologic rehabilitation course were found, based on the questions administered the first day of class. Second, it may not be possible to totally control for consistency of teaching across the years, as instructors often modify the curriculum and change as a result of their own growth and interests. To address this concern, the same instructor taught this course in consecutive years, and the same syllabus was used for each group except for the addition of the assigned narrative readings and films. Third, Group 1 was administered the scenarios at the end of the course (Week 14). Group 2 was administered the scenarios 2 weeks after the reading and discussion of the final assigned disability and hearing loss narrative (Week 12).

Finally, the English et al. (1999) measure was not originally designed and therefore not validated to determine if exposure to disability and hearing loss narratives was a potentially effective tool in increasing undergraduate CSD majors' affective responses to scenarios of individuals with hearing impairment. As English et al. (1999) noted, because there are no clear right and wrong answers to teach, the validity and reliability of their measure may be somewhat problematic. The scale used by English et al. (1999) may artificially reduce the complexity of a student's response, and also implies that an affective response is superior to a technical one. An ideal response is one that is congruent with the individual's message, and a combined technical and affective response (a rating of 3) may be the most appropriate. Still, even with this limitation, this scale was useful in showing that students exposed to the disability and hearing loss narratives provided more affective components to their responses than students not exposed. Further exploration on the value of narratives in audiology and in general CSD curricula is needed.

Conclusions

Instructors often feel they must provide technical and content information first, and if there is time, affective components are included. This study showed that technical content was still provided along with narratives. Exposure to disability and hearing loss narratives appears to help students listen to what is said behind the words, which is an important and necessary component to effective audiologic habilitation/rehabilitation. Narratives may also help students better appreciate the value and importance of listening for affective inquiries.

Undergraduate CSD students exposed to disability and hearing loss narratives incorporated more affective elements into their technical responses than did undergraduate CSD students not exposed. Thus, narratives appear to be an effective tool for increasing awareness of and broadening student perspective of the impact of hearing loss on the individual and family. Narratives may have a place and be of value in the undergraduate curriculum.

Acknowledgments

Portions of this article were presented at the New York State Speech-Language-Hearing Association Convention, Saratoga Springs, NY, April 29, 2006, where the second author of this article received the Undergraduate Research Award. The second author's work was conducted as an undergraduate in the Department of Biology & Health Sciences, Pace University.

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Appendix A

Readings

Readings assigned to both Groups 1 and 2:

1. Erdman, S. A., Wark, D. J., & Montano, J. J. (1994). Implications of service delivery models in audiology. *Journal of the Academy of Rehabilitative Audiology, 27*, 45–60.
2. National Association for the Deaf. (2000). *NAD position statement: Cochlear implants*. Retrieved February 18, 2008, from www.nad.org/ciposition.
3. Schow, R. L., & Nerbonne, M. A. (Eds.). (2004). *Introduction to audiologic rehabilitation* (4th ed.). Boston: Pearson/Allyn & Bacon.
4. World Health Organization. (2001). *International classification of functioning, disability, and health*. Retrieved February 15, 2008, from www.who.int/classifications/icf/en/.

List of narratives assigned only to students in Group 2 (exposed to narratives):

1. Belkin, L. (2004, September 12). The lessons of classroom 506. *The New York Times Magazine*. Retrieved February 18, 2008, from www.nytimes.com/2004/09/12/magazine/12MAINSTREAMING.html.
2. Biderman, B. (1998). *Wired for sound: A journey into hearing*. Toronto, Ontario, Canada: Trifolium Books.
3. Chorost, M. (2005). *Rebuilt: How becoming part computer made me more human*. New York: Houghton Mifflin.
4. Kinsley, E. P. (1987). *Welcome to Holland*. Retrieved February 15, 2008, from http://agingforall.com.
5. Oberkotter Foundation. (n.d.). *Dreams spoken here* [Motion picture]. (Available from www.oraldeafed.org).
6. Rosner, J. (2004). Lullabies for Sophia. *The Hastings Center Report*, *34*(6), 20–21.
7. Sacks, O. (1999). The revolution of the deaf. In B. R. Barber & R. M. Battisoni (Eds.), *Education for democracy* (pp. 315–330). Washington, DC: Kendall Hunt.
8. Weisberg, R. (Producer) & Aronson, J. (Director). (2000). *Sound and fury* [Motion picture]. United States: Aronson Film Associates.

Appendix B

Paper Assigned to Students in Group 2

The class has read and discussed several audiologic and disability models (Erdman, Wark, & Montano, 1994; Schow & Nerbonne, 2004; World Health Organization, 2001), disability narratives (Belkin, 2004; Kinsley, 1987), a position statement (National Association for the Deaf, 2000), and an article and two films on deafness as disability and culture (Oberkotter Foundation, n.d.; Sacks, 1999; Weisberg & Aronson, 2000), as well as hearing loss narratives (Biderman, 1998; Chorost, 2005; Rosner, 2004) from the perspective of the individual with the hearing impairment, family members, and a journalist. These readings, films, and class discussions have broadened your perspective of deafness specifically in terms of disability, culture, wellness, and medical models; activity limitations and participation; and environmental and social barriers. Include these citations and perspectives in your paper as to how the readings, films, and class discussions have influenced your beliefs/opinions regarding hearing loss/deafness as a disability, as a culture, and what effective audiologic rehabilitation models need to include.

Appendix C

Eight Scenarios (from English et al., 1999)

1. “I am so tired of trying to talk to my father with his hearing problem. I can’t understand why those hearing aids don’t work.”
2. “These new hearing aids seem to make me tired. I’m having a hard time adjusting to them – my old ones were easier to use.”
3. “Other kids are making fun of my child because she wears that FM device.”
4. “I think I can get by without hearing aids. I’m only 52, not some old lady.”
5. “My spouse is upset because you’ve told her she has a hearing loss. She acts like it’s my fault.”
6. “My family says our daughter was born with a hearing loss because I worked until the week she was born.”
7. “Your tests have got to be wrong. I’m sure my child hears much better than you say – he’s just being uncooperative. I think he doesn’t like you.”
8. “I can’t wear hearing aids – my boss will think I’m no longer a good worker.”

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Submission Guidelines for Research Articles *International Psychology Bulletin*

Research article submissions: The IPB publishes peer-review research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 1500 words and should be submitted to Dr. Senel Poyrazli at poyrazli@psu.edu. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association (5th ed., 2001). Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you don't have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

2007 and Beyond: Reflections on the 10th Anniversary of the Division of International Psychology

Michael J. Stevens, PhD, DHC
President
APA Division 52 International Psychology

I am honored to have served as President of the Division of International Psychology in 2007. I am deeply appreciative of the support and encouragement of colleagues and friends. I was very fortunate to have followed in the steps of outstanding past-presidents who guided Division 52 from its inception to the present and on whose legacy and vision I drew throughout the year. The Division has seen tremendous growth over its 10-year history. My mission, as President, was to consolidate our gains while enlarging the scope of our contributions to international psychology. Let me highlight some noteworthy accomplishments in 2007, the tenth anniversary of Division 52, and identify the directions we are taking in 2008 and beyond.

State of the Division

Division 52 is one of the few APA divisions not to have suffered a downturn in membership over the past several years. At present, the Division has slightly more than 900 members. Our international and student affiliates have increased appreciably, which is critical to the diversity and vitality of the Division. Our valuing of diversity can be seen in the appointments made to leadership positions on committees and task forces. Establishment of both a Student Committee and Early Career Professionals Committee, as well as Board approval of a needs assessment of early career professionals, demonstrates our commitment to mentoring future leaders of Division 52 and international psychology, generally. Our efforts to recruit new members will soon include a PowerPoint template that can be used by Division 52 members attending conferences to inform others of the opportunities available with membership in Division 52. As critical as it is to attract new members to the Division, we must work diligently to retain them by capturing their interest and energy.

Division 52 is stable financially because of income generated from dues and investments as well as thoughtful expenditures. However, due to rising costs, the Division has been increasingly constrained in financing worthy projects, such as producing an educational video with interviews of international psychologists and co-sponsoring conferences relevant to international psychologists. Consequently, the Board agreed to raise dues in 2008 by $5 across membership categories, except for international affiliates. Our decision will provide fiscal leverage in advancing the Division's expanding agenda. However, we must seek creative new ways of raising money for ambitious longer-term projects, such as corporate donations, estate planning, and grants.

Presidential Initiatives

2007 featured not only several important presidential initiatives, but also efforts to heighten the Division's visibility and expand networking opportunities.

With regard to visibility, Division 52 took an active role in supporting or offering input on important agenda items proposed within APA, such as the *Resolution Condemning Academic Boycotts*, *Resolution on Emancipating and Rehabilitating Enslaved Persons and Prevention of Future Slavery*, and *Resolution Against Genocide*. The Division reauthorized the continuation of APA's leadership of the International Network on Lesbian, Gay, and Bisexual Concerns and Transgender Issues in Psychology, and supports the formation of a task force to investigate the merits of an evidence-based practice policy for applied psychologists. In addition, two Division 52 projects were featured in the *Monitor on Psychology*: the Adopt-a-Psychologist Program and Mentoring Program, both designed to facilitate ongoing, bilateral collaboration with psychologists around the world. Articles published in the Division's newsletter, *International Psychology Bulletin*, are now indexed in PsycEXTRA. And, our student leaders co-authored a chapter on returning international students for an APA Books publication entitled, *Studying Psychology in the United States: Expert Guidance for International Students*.

As for networking, Division 52 is working closely with the International Section of Division 17 (Counseling Psychology) on joint programming at the March 2008 International Counseling Psychology Conference and at future APA conventions, as well as cooperating on projects of mutual concern, such as internationalizing the psychology curriculum. Similarly, the Division established ties with Division 2 (Teaching) via the joint Task Force on the Internationalization of the Teaching of Psychology, which is developing collaborative international networks and co-sponsored conference symposia and workshops in this area of growing interest. Our Curriculum and Training Committee is participating in a textbook-donation initiative under the auspices of the National Institute on the Teaching of Psychology. While we continue to collaborate with CIRP and the Office of International Affairs (OIA) on a number of ongoing and new projects (e.g., psychology at the UN, developing a Psychologists' Map of the World), we are taking unprecedented steps to establish ties with several APA directorates on matters that have an international focus (e.g., revision of the International Classification of Functioning). We also maintain a speaker exchange with the Society for Cross-Cultural Research and

are extending such exchanges to include national psychology associations. In August 2008, I will address the Asociacíon Guatemaleca de Psicología, inaugurating a promising and mutually beneficial avenue for scientific and applied collaboration.

Given their timeliness and the opportunities they afford, I would like to summarize several presidential initiatives launched in 2007:

Conference Co-sponsorship

Division 52 was a cooperating organization for the July 2007 *China-U.S. Conference: Youth At-Risk* in Beijing and Shanghai. The conference aimed to establish partnerships with the Chinese youth-at-risk network. The U.S. Steering Committee and Global Interactions, Inc. are planning a *China -U.S. Summit on Partnerships* in April 2008. The Division is invited to work with teams of Chinese from universities, organizations, and schools to arrange visits with U.S. partners and form new partnerships that address China's growing at-risk youth.

Support for the Social Psychology Network

Division 52 endorsed the Social Psychology Network (SPN), a scientific and educational organization that serves psychologists worldwide. The SPN has an interactive directory of psychologists from more than 35 countries, source material in 15 languages, and over 1,000 links to web sites outside the U.S. With representatives from eight other divisions, Division 52 moved at the February 2007 Council meeting that APA support this invaluable resource.

Extra-APA Connections

Division 52 supports an initiative to broaden its membership base and partner with state, regional, and international psychology associations. In August 2007, our Outreach Committee and Past-President networked with leaders of the International Council of Psychologists in San Diego to strengthen existing ties and explore future joint ventures, including ethical practice in international settings and internationalizing curriculum and training.

Promoting International Psychology

Division 52 received an interdivisional grant to establish a nationwide speakers bureau that will bring expert international psychologists to present at nearby high schools, colleges and universities, and community groups. In early 2008, the National Speakers Bureau will be publicized on the websites of Psi Beta, Psi Chi, and TOPPS as well as by email and written correspondence to psychology departments throughout the U.S. in order to promote and inform the public about international psychology.

Ethics in International Context

In consultation with the APA Ethics Office and OIA, the newly established Ethics Committee is addressing ethical challenges faced by U.S. psychologists engaged in international scientific and applied practice. Data will be gathered from colleagues on ethical dilemmas encountered while working in international contexts. These data will serve to clarify the needs for guidance in ethical decision making that arise as psychologists interpret ethical principles and standards of conduct in international settings.

Division 52 in San Francisco

The 2007 APA convention was a remarkable success for Division 52. The Division's convention and hospitality-suite programs were highly informative and very well attended, as were the awards ceremonies that honored those whose contributions to the Division and/or to international psychology were unusual and outstanding.

In addition to programming and awards ceremonies, highlights of our tenth anniversary celebration in San Francisco included Board approval of the Division's new mission statement:

Division 52 seeks to develop a psychological science and practice that is contextually informed, culturally inclusive, serves the public interest, and promotes global perspectives within and outside of APA.

2008 and Beyond

Looking ahead, there are three directions that Division 52 either has undertaken or is seriously contemplating: internationalizing the psychology curriculum, legislative and policy advocacy, and publication of a journal dedicated to international psychology. Each reflects the globalizing of psychology and the necessity of becoming proactively engaged in this juggernaut.

In addition to producing an educational video with interviews of international psychologists, the Division is committed to conference programming that advances the internationalization of the undergraduate and graduate psychology curricula. Perhaps the first conference of its kind convened at St. Francis College in New York City in November 2007. Follow-up conference proposals have been submitted to regional (Eastern Psychological Association), national (APA), and international (International Conference on the Teaching of Psychology in St. Petersburg, Russia) venues for 2008, and an edited book on internationalizing the psychology curriculum is in the planning stages.

Division 52 has attained a level of maturity commensurate with taking on an advocacy role. As socially responsible international psychologists, we should embrace advocacy as a means to further social justice. If the Division is to assume an advocacy role, we must first identify our international legislative and policy priorities in order to establish a clear focus for future advocacy efforts. Second, we must learn effective advocacy strategies that will empower us to influence federal legislative and international policy-making processes. I will continue to gather your thoughts about advocacy, specifically the content and process we would like this activity to take.

The Division 52 Board approved the formation of a task force to explore the merits of an online divisional or APA journal. Such a journal would fulfill the Division's mission to develop a psychological science and practice that promotes global perspectives. At present, there are surprisingly few journals devoted to international psychology, and the need for a multidisciplinary, transnational journal that publishes conceptual and empirical scholarship on a diverse array of global issues and concerns is compelling. Whether to launch such a journal, whether to produce it ourselves or in partnership with others, and whether its scope should be broad or narrow are matters the task force will consider and present to the Board in 2008.

In closing, Division 52's tenth anniversary year was highly productive and rewarding thanks to the creativity, energy, talents, and dedication of our membership. I cannot imagine a more auspicious time in which to be an international psychologist and member of Division 52 – to communicate and collaborate with colleagues at home and abroad on the myriad challenges we face in an ever more interconnected and hard-pressed world. Division 52 is indispensable in identifying, understanding, and meeting these global challenges and I am confident it will do so!

Psychology International
November-December 2007
Issue of Psychology International,
APA International Affairs'
official publication can be viewed at:
http://www.apa.org/international/pi/

Call for Announcements
to the Division 52
"Announce-only" Listserv

The Division 52 "Announce-only" listserv is available to its members and affiliates only and is distributed once a month. Submit announcements regarding international issues and topics of interest to the Division to rvelayo@pace.edu

For the latest announcements, notes, and news from the Division of International Psychology…

Go to…
Division 52's
ANNOUNCEMENTS WEBSITE
at
http://webpage.pace.edu/rvelayo/announcements.htm

A Message from Uwe P. Gielen
2008 President of APA Division 52

For Division 52, 2007 has been a very successful year thanks to the hard work of numerous people as well as the inspired leadership of our 2007 President, Michael J. Stevens. He did indeed set an example for what it means to be the president of a dynamic and forward looking division. Furthermore, all of us should be deeply grateful to Joy Rice who served as Past President in 2007. Her many contributions to Division 52 have helped to strengthen the division at a time when many of the other APA divisions are slowly shrinking while struggling to attract new and younger members. I also would like to thank Sandra Foster who worked very hard as the Division's Secretary. She was succeeded by Neal Rubin as her skillful successor.

I am indeed looking forward to working together with our 2008 President-Elect, Lynn Collins. One important goal she has set herself is to make Division 52 more visible and attractive to psychologists located around the country. At present, a disproportionate number of our members live on the East Coast. If you have any suggestions for how one might strengthen the division's presence all around the country, please send us an email (Lynn's email address is collins@lasalle.edu). Furthermore, we hope to gain additional international members in the new year.

It seems the time has arrived to broaden the international base of the psychology curriculum as it is presently offered at many US institutions as well as elsewhere. A successful conference on this topic was held at St. Francis College during November 9-10, 2007. (A brief report on this conference by Jennifer Lancaster can be found in this issue.) Moreover, the internationalization of the psychology curriculum naturally lends itself to cooperative endeavors with other APA divisions such as, for instance, Divisions 1, 2, and 17 among many others.

So, if you have suggestions and ideas about how Division 52 might contribute to the strengthening of international psychology both in the US and abroad, send us (e.g., Lynn Collins, Michael J. Stevens (mjsteven@ilstu.edu), Uwe P. Gielen (ugielen@hotmail.com)) a note.

In 2006, Division 52 came to an agreement with Erlbaum Associates to publish a new book series entitled Global and Cross-Cultural Psychology. In the meantime, Erlbaum Associates has become a part of Psychology Press, Taylor & Francis Group. I am glad to report that Psychology Press has agreed to continue the Global and Cross-Cultural Psychology series, with Division 52 acting as a sponsor. A brief report about a meeting on this matter between Paul Dukes as a representative of Psychology Press and Harold Takooshian and Uwe P. Gielen as representatives of Division 52 can be found in this issue.

I would like to invite all of you to the March 13-16, 2008, EPA meeting in Boston, which will include a rich general convention program as well as an exciting, internationally oriented program sponsored by Division 52. You can find a preview of the international part of the EPA program in this issue. I am looking forward to seeing many of you in Boston.

With my best wishes to all of you for a prosperous and happy 2008,

Uwe P. Gielen

Election Results
Div52 Student Committee for 2009

Lillian Flores Stevens
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Amanda C. Kracen
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Dear Division 52 Members,

After an election that generated a lot of interest, we are delighted to announce that Manijeh Badiee and Sherry Wang of the University of Nebraska-Lincoln have been elected as Co-Chairs of the Division 52 Student Committee for 2009. Congratulations to them! We think they will contribute greatly to Division 52.

Manijeh and Sherry are currently working toward doctoral degrees in the counseling psychology program at the University of Nebraska-Lincoln. Their initial exposure to and interest in international issues began when they immigrated to the U.S., both at age 6. Sherry and Manijeh love to travel, and have collectively visited or studied abroad in countries such as Morocco, France, Germany, Burkina Faso, Senegal, Mali, Hong Kong, England, Spain, France, Italy and the Czech Republic, while maintaining strong ties to their native countries of Taiwan and Iran, respectively. They share similar research interests, particularly in developing culturally sensitive approaches for working with immigrants and refugees. Recently, Sherry designed her first study examining the cultural experiences of Chinese international students in their adjustment and adaptation to the Midwest. Meanwhile, Manijeh is co-planning a student programming hour at the International Counseling Psychology Conference entitled Transitioning Issues for International Students.

Division of International Psychology, American Psychological Association Annual Meeting

(Unapproved Minutes)

Thursday, August 16, 2007
6:00 - 10:00pm
San Francisco Marriott Hotel –
Sierra Conference Suite K
San Francisco

Present: Norman Abeles, Ayse Ciftci, Lynn Collins, Florence Denmark, Eros DeSouza, Sandra Foster, Uwe Gielen, Gloria Gottsegen, Gloria Grenwald, John Hogan, Ani Kalayjian Amanda Kracen, John Lewis, Paul Lloyd, Mercedes McCormick, Rivka Meir, Ann O'Roark, Robert Ostermann, Wade Pickren, Senel Poyrazli, Joy Rice, Kate Richmond, Neal Rubin, Nancy Filipe Russo, Mathilde Salmberg, Lillian Stevens, Michael Stevens, Chalmer Thompson, Richard Velayo, Danny Wedding.

Absent: Fred Bemak, Thema Bryant-Davis, Joan Chrisler, John Davis, Carol Enns, René Goodstein, Sharon Horne, Tonya Jonson, Shay Mann, Roberta Nutt, Charles Spielberger, Harold Takooshian, Oksana Yakusko.

Members and Guests: Anne Bettesworth (Public Interest Directoate), Steven Breckler (Science Directorate), Lynn Bufka (Practice Directorate), Merry Bullock (Office of International Affairs), Maryanne Ernesto (Science Directorate), Gwendolyn Keita (Public Interest Office), Virginia Mullin, Hagop Pambookian, Artemis Pipinelli, Clare Porac (Education Directorate).

1. President Stevens called the meeting to order at 6:00 pm, with a round-robin of Board members and chairs/co-chairs and introduction of guests.

2. A motion was made and passed unanimously to approve the minutes from the 2007 Philadelphia Midwinter Meeting.

3. A motion was made and passed unanimously to approve the minutes from the 2007 Philadelphia Midwinter Meeting Strategic Planning Session.

4. Past-President's Report. Rice invited everyone to the Division's awards session. She summarized progress on her strategic initiatives, including establishing the mentoring committee and membership recruitment. She described her visit to the Hill as the Federal Advocacy representative this past spring and reported on international networking and partnership projects with the International Council of Psychologists, the International Committee for Women and the Society for the Psychology of Women. Rice also participated in a year-long online discussion concerning women, leadership and national and international collaboration, resulting in a co-edited book.

5. President's report. M. Stevens summarized his report and noted the July 2007 China-U.S. Conference: Youth at Risk, and that the Division has endorsed the Social Psychology Network (SPN), but noted that the forces may be against APA's support of SPN financially. He also commented on connections with ICP, the Eastern Psychological Association, and the New York State Psychological Association. There is also exploration of closer connection with the International Section of Division 17. He discussed the CODAPAR grant, saying that the database had been completed. Under current discussion is how this database can be disseminated and housed so that people can be contacted to volunteer and share their expertise. All the Fellows of the Division are listed in the database as potential speakers. M. Stevens hopes that all will be active by 2008. Kalayjian suggested that the Division's Speakers Bureau be coordinated with the APA's Speakers Bureau. Heightening the visibility of the Division has been aided by new business items raised with COR and through a major article featuring Kalayjian and Meir in the *Monitor on Psychology*. M. Stevens is working with other professionals for bi-directional mentoring and speaker exchange and other bi-directional relationships with U.S. and non-U.S. professional organizations. He also notes greater opportunities to partner more closely with CIRP and with the Office of International Affairs to work on mutual goals and to reduce any overlapping efforts.

6. President-Elect's Report. President-elect Gielen summarized his initiatives for the coming year. He wants to focus on the internationalizing of the psychology curriculum and will promote this at the International Conference on Teaching Psychology in St. Petersburg, Russia (July 12-16, 2008, concurrent with the ICP conference). Work is continuing on the Ursula Gielen Global Psychology Book Award and the video project: *International Psychologists at Work: A Video*. Gielen has also been serving as the Book Review Editor of the *International Psychology Bulletin* and he has submitted (along with Jessica Verderame) an entry entitled "International Psychology" to Wikipedia. He also noted the November 9-10, 2007 conference on "Internationalizing the Psychology Curriculum" at St. Francis College, New York City, and the February 20-23, 2008 conference in New Orleans by the Society for Cross-Cultural Research. Members of Division 52 will be among the presenters at both conferences.

7. Council Representative's Report. Wedding presented a verbal report and commented that his written report would be

issued within two weeks, following the COR meeting on Sunday, August 19. He noted the International Affairs Office's Psychologists' Map of the World project and the interviews planned with Fulbrighters who have served in various countries. APA President Brehm has invited a number of international representatives and many are attending. Russ Newman has resigned, along with two other senior APA leaders. Among the priorities of CEO Norm Anderson is to appoint a diversity officer to enhance diversity within APA, and to upgrade the website as one effort to attract new, younger members. There will be a public and a membership portal and more access to electronic publications, a crucial source of revenue. There will be a slight increase in dues to $279. There was almost unanimous support for four additional seats on Council, to include four groups. The Association of Black Psychologists, among them, has been invited to take one of these four seats. Division 52 is one of the divisions supporting the SPN; however, the Board of Scientific Affairs has recommended that it not be approved. Wedding also commented on a meeting with Susan Harris from the Publications and Communications Board to discuss a journal on international psychology that could eventually become the journal of Division 52. The working title is *Global Mental Health*. Kalayjian noted that IAAP has decided to expand the focus of its journal beyond I/O Psychology. She suggested talking to Ray Fowler about this issue to make certain there is no duplication between IAAP and Division journal efforts. M. Stevens said he is in favor of the Division being involved in some way with the journal if it comes to fruition.

8. Member-at-Large Reports. Russo and Spielberger were not present at the time for reports, so M. Stevens noted Russo's report. Velayo discussed his report noting that he has been appointed Chair of a Internationalizing the Teaching of Psychology Task Force for Division 2 (Teaching of Psychology). He also commented on the Text Book Donation Initiative of the National Institute on the Teaching of Psychology (NITOP). He noted concerns that have been raised about this effort, including shipping issues as well as the accessibility of electronic versions of publications. There will be another meeting to further explore this initiative. Kalayjian suggested that aid containers going overseas had room for materials including textbooks. Velayo suggested that certain countries would be the focus of this textbook donation effort. Ostermann suggested that Rotary Club has found a means for sending books overseas.

9. Federal Advocacy Report. Rice said she will issue a detailed report after the next APA State Leadership Conference in Washington March 8 to 11, 2008.

10. Treasurer's Report. Kalayjian described the outcomes of the Finance Committee (Rice, M. Stevens, Gielen, Kalayjian) meeting that occurred prior to the Board meeting. She noted that expenses were reduced for the Hospitality Suite and noted an increase for Communication/Publications. She commented that the financial position of the Division was quite good. She then presented her 2008 Budget versus figures for 2007 income and expenses. There has been an increase for *IPB* of $200. A motion was made and passed unanimously to approve the budget.

Action Items

11. Dues increase. M. Stevens proposed increases in Division dues to fund new projects and new committees and, perhaps, to better support those attending the Midwinter meeting. The motion for the increase passed unanimously.

- Dues will be increased by five dollars for APA Fellows, Members, and Associates (both dues paying and dues exempt), and Professional Affiliates and Students
- Dues will not be increased for International Affiliates, thereby remaining at $23

12. Mission Statement Revision. The draft of the statement developed at the Midwinter Strategic Planning Session was presented to the Board for its approval. There was discussion about the phrase "for the common good," with suggestions for substituting, "in the public interest" instead. A motion to finalize the amended wording was passed unanimously. It now reads, "Division 52 seeks to develop a psychological science and practice that is contextually informed, culturally inclusive, serves the public interest, and promotes global perspectives within and outside of APA."

13. Ursula Gielen Global Psychology Book Award (Funding). A motion was made and passed unanimously that a $500 stipend be given to help pay the awardee's expenses to the convention and that the Division pay the registration fee. Gielen will be funding the former expense for two years and the Division will be paying the APA registration convention fee for the winner. Wedding suggested that the publisher of the winner's book be approached for additional funding. It was also proposed that the award be contingent on the winner's commitment to present at the convention.

14. ECP Committee (Survey; Funding). A discussion ensued regarding the Early Career Psychologist Questionnaire. Discussed were changes in wording, for example, noting collaboration with other psychological organizations besides EPA, and adding a reference to race as well as ethnicity. The group expressed continuing support for the survey of the needs of the Division's Early Career Professionals. M. Stevens thanked Richmond, Kracen and Salmberg for all their hard work on the ECP Committee.

15. Committee on Living Abroad (Restoration). M. Stevens asked that this committee be restored to help support Division 52 members living abroad and returning to the US. Russo commented that the International Affairs Office was already funded to assist such people, and expressed concern about

funding the committee in light of the vote just taken to increase dues. M. Stevens acknowledged her point and suggested that the committee chair work with the International Affairs Office. The motion to restore this committee, without any budget allocation, was passed unanimously.

Standing Committee Reports

16. Awards. Rice announced that the awardees would be acknowledged in a ceremony in the Hospitality Suite. Written reports were noted for Denmark-Reuder, Mentoring, and the Student International Research (including an addendum report) awards.

17. Fellows. O'Roark introduced one of the new Fellows, Virginia Mullin, who was attending as a guest. O'Roark then invited everyone to the presentation by Division Fellows on Friday morning of the convention and other relevant programming involving Fellows.

18. History/Archives. Hogan noted that he was missing minutes for 2001 and suggested that they may not have been written at that time.

19. International Committee for Women. Enns was not present, but Rice noted her report. The new Committee Chair is Joan Chrisler and the annual meeting is Saturday at 9:00 am. She commented on the noteworthy programming coming up at the convention, ICFW advocacy projects, and the collaboration with the Global Issues Committee of the Society for the Psychology of Women.

20. Membership. Lewis distributed the latest figures on membership and commented on the net loss of 67 members from the past year. Velayo wondered if the numbers reflected the membership of APA, and that is the case. Wedding expressed his disappointment at this loss, saying that the Division had come close to its goal of 1,000 members. Kalayjian commented that several new members will be joining as a result of convention activities, that several new members also signed up at the ICP conference, and that the final membership figure will actually be greater than the 2006 figure. Richmond suggested that a membership table be set up at the international conference in Berlin and Kalayjian recommended that some banners be purchased to make the table attractive. Kracen then described their ECP Committee's outreach effort this year: lollypops with "Join Division 52" printed on them.

21. Nominations. Rice noted the outcome of the election and thanked all those who stood for office.

22. 2007 Program. Pickren spoke on behalf of Horne who was unable to attend the convention. He thanked her for all her efforts in organizing the program. He commented that the Hospitality Suite program had been challenging to organize in order to represent all the various interests. He introduced the new co-chair, Ayse Ciftci. M. Stevens thanked Pickren for all the work done by the Committee. Gielen noted that the Midwinter meeting will be held during the EPA meeting in Boston on March 13-16, 2008. He invited those present to contact him with program ideas.

23. Curriculum & Training. Grenwald discussed a web-based, best-practices resource that introduces instructors to international teaching materials that can be integrated into specific psychology courses. This is one step in moving forward on internationalizing the psychology curriculum.

24. Early Career Professionals. Salmberg noted it has been a very busy year for the Committee and invited everyone to review the report and give his/her feedback. M. Stevens commented on the separation of the Student and ECP committees.

25. Outreach/Networking. Co-Chair McCormick described her conversation hour presentation at the recent ICP conference in San Diego. In her report is a Power Point presentation that can be used to develop a conversation hour on collaboration with Division 52 at future conferences. Rice noted additional programming possibilities at future conferences, and suggested giving columns to the editors of other international publications, including the ICP newsletter. Rice noted the discussion of a joint task force with ICP on ethics and/or curriculum and training, and suggested that the respective Division 52 chairs, Rubin and Grenwald, contact their counterparts in ICP. The Division 52 and ICP websites are linked.

26. Ethics. Rubin described this initiative, established by President Stevens. He noted it took quite a while to 'open' the door of the APA Ethics Office as staff were busy managing issues pertaining to the resolution on torture. He noted that Behnke is open to hearing the ethics-related issues encountered by psychologists in the Division.

27. Establishing an International Task Force on Evidence-Based Practice in Applied Psychology. O'Roark noted this proposed initiative, one already enacted by the Canadian Psychological Association, is led by those involved in international psychology. They are also working on a statement of international ethics. O'Roark recommended that there be a statement of evidence-based practice for applied psychology. This would fall short of a mandate, but would list issues of interest to those in the Division. O'Roark asked for substantive input from the Board.

28. Office of International Psychology. Senior Director Bullock thanked the group for its responsiveness to issues discussed at the Midwinter Meeting. The presidents of 18 international psychological groups are present at APA as guests of APA President Brehm. The reception for international visitors will be at 5 pm on Sunday and M. Stevens asked all to

attend. She proposed a joint membership drive for new international affiliates. She concluded with some announcements: The Psychologists' Map of the World allows access to considerable information about psychology in various region (but no specific liaison from the Division was requested at this time); Diplomacy in Psychology would offer training for those going abroad, similar to training offered to diplomats; and APA will help sponsor Psychology Day at the UN. She invited everyone to stop by the International booth during the convention.

29. Representative from the Practice Directorate. Special Assistant Bufka discussed the development of the manual to facilitate the use of the International Classification of Functioning with its 1200 codes covering range of functioning from reading to driving to voting. The effort is to develop content to add value to each entry. The intention is that the manual be adapted for wide use. Information is available on the Internet. They are working with the World Health Organization to update the ICD, and she noted the efforts to harmonize the DSM with the ICD as it is being revised. Richmond suggested that their website be posted on the Division's site.

30. Representative from the Public Interest Directorate. Executive Director Gwendolyn Keita discussed the Violence Prevention Program that has recently been advertised on television. The Greek Psychological Association is the newest association to adopt the program. The AIDS Program will hopefully be extended to Kenya by the time of the 2008 APA convention. The LGB Oversight Group has been involved in networking. The Work, Stress, and Health Initiative is preparing for its seventh annual conference with about 40% of the participants coming from other countries. An effort has been made to work with the European group to synchronize their conferences on alternate years in November and the Directorate is working on sharing resources, such as journals. The first issue of their E-Newsletter is now available. Anne Bettesworth, also from the Public Interest Directorate, presented on global health issues. She noted efforts on immigration and requested the Division's input in the form of suggested policy statements.

31. Science Directorate. Stephen Breckler and Maryanne Ernesto (Testing & Assessment) presented on activities of the Directorate. Breckler noted the hiring of Howard Kurtzmann as the first Deputy Director. A proposal has been put forth by the German Psychological Association to create standards for personnel assessment. This is likely to be the first of several collaborations relating to international assessment standards. Ernesto invited the Division to appoint a liaison to the Directorate.

32. Education Directorate. Clare Porac, Associate Director for Graduate and Postgraduate Education and Training, distributed informational folders to those present. She was not able to remain in order to discuss the content.

Committee Reports

33. International Liaisons. Meir distributed her written report and thanked all of those who had "adopted" a psychologist, but noted that those who had should continue to correspond with that person in order to nurture the relationship and retain them as members. She encouraged the "adopters" to pay the $25 for their membership and stressed the importance of these new members receiving the publications. She asked those present to email her with details of those adopted so she can track these new members. Gielen suggested sending them the website address but for those who do not have Internet access, that a paper copy of the publication be mailed to them. Meir is going to add each member's area of interest on the website. She urged everyone to send their checks to her directly and she will forward them to APA.

34. Newsletter. Poyrazli suggested that a task force be organized to discuss an online journal (as a general international journal) as well as the involvement in any new international journal. Poyrazli asked Wedding to join the task force and M. Stevens suggested that he and Gielen serve on this task force.

By Consent - Informational Reports

35. Aging. Abeles commented that the Aging Committee had been communicating via email throughout the year and noted his election as President of IAAP Division 7 (Applied Gerontology). Abeles' written report was in the agenda booklet.

36. Denmark-Reuder Award. Chrisler's written report was in the agenda booklet.

37. Student International Research Awards. Ostermann and Thompson's written report was in the agenda booklet.

38. Newsletter. Poyrazli's written report was in the agenda booklet.

39. Webmaster. Velayo and Mann's written report was in the agenda booklet.

40. Information Clearinghouse. M. Stevens' written report was in the agenda booklet.

41. Curriculum & Training. Grenwald's written report was in the agenda booklet.

42. Early Career Professionals. Richmond and Salmberg's written report was in the agenda booklet.

43. Student. Kracen and L. Stevens' written report was in the agenda booklet.

44. Liaisons – International. (Meir's written report was in the agenda booklet.

45. Mentoring. Kalayjian summarized her written report, which was in the agenda booklet. A new report was distributed. The Mentoring committee met earlier before the EC meeting. There was no time to report.

46. Long-Range Planning. Lloyd's written report was in the agenda booklet.

47. Outreach. McCormick's written report was in the agenda booklet.

48. Ethics. Rubin's written report was in the agenda booklet.

49. Public Interest. Denmark's written report was in the agenda booklet.

50. Disaster-Trauma. Kalayjian's written report was in the agenda booklet.

51. International Lesbian, Gay, and Bisexual Concerns Oversight Group. Gottsegen presented a written report of her activities to Foster and M. Stevens for inclusion in the agenda booklet.

Adjournment. President Stevens adjourned the meeting at 10:00 pm.

Respectfully submitted,

Sandra Foster, Secretary

International Book Series to Expand

In 2004, our International Psychology Division joined Lawrence Erlbaum Associates to launch a bold new book series on "Global and cross-cultural psychology," with the two-fold purpose to encourage and disseminate new books in international psychology, while generating revenues for the division. The founding series editors were President-elect Uwe Gielen of St. Francis College and Past President Harold Takooshian of Fordham University. The first volume of the series in 2007 was the major release of *Toward a global psychology,* edited by Michael J. Stevens and Uwe P. Gielen.
After Erlbaum was acquired by Taylor & Francis Publishers in 2007, T&F Psychology Editor Paul Dukes confirmed the continuation of the series, and his pleasure to be its primary editor within Psychology Press--the unit of T&F most experienced with international books, such as the publications of IUPsyS, the International Union of Psychological Science. Dukes is enthusiastic to work with our Division, applying his 15 years of experience working with international psychology books in Psychology Press and its predecessor firm, Erlbaum Associates, Ltd, in London. Psychology Press hopes to add

PHOTO: Editors (left to right): Uwe Gielen, Paul Dukes, Harold Takooshian

international psychology among its new "arenas" at www.psypress.com. Those interested to propose a volume in the new Psychology Press series can contact the editors for an instruction sheet, at: ugielen@hotmail.com, or takoosh@aol.com.

Eastern Psychological Association, International Program 2008
[as of Jan. 2008]

March 14-15, 2008, Winthrop Room,
Boston Park Plaza Hotel, www.easternpsychological.org
For any details: Uwe at ugielen@hotmail.com, or
Harold at 212-636-6393

March 13-14: Mid-winter Board Meeting on THURSDAY (afternoon), FRIDAY (morning)

FRI, 11:00 – 12:20 pm, Symposium: International Perspectives on Governmental Violence and Peace
Chair: **Kathleen Malley-Morrison** (Boston University)
Participants: (1) **Mathilde Salmberg** (Georgetown University), Views on Fighting Terrorism from Sweden and the United States. (2) **Abram Trosky** (Boston University), Views on National Security from England and the United States. (3) **Rouba Youssef** (Butler Hospital, Providence, RI), Lebanese Perspectives on Protest and Patriotism. (4) **Nyryan Nolido** (Brigham and Women's Hospital, Boston): A Right to Peace? Views from the Philippines and the U.S.

FRI, 12:30- 1:50 pm, Symposium:
The Social Psychology of Comprehensive Political Change
Chair: **Gloria B. Gottsegen** (Lehman College, CUNY)
Participants: (1) **Ting Lei** (Borough of Manhattan Community College, CUNY), **Ching-Tse Lee** (Brooklyn College, CUNY), and **Ina Lei** (Borough of Manhattan Community College, CUNY), Turning Personal Pain into Group Gain: Changing Collective Consciousness from Adversity to Advantage. (2) **Kobi Skolnick** (Borough of Manhattan Community College, CUNY), The Making of a Terrorist: Applying Basic Psychological Concepts in Order to Understand Radicalization. (3) **Judy Kurianksy** (Columbia University, Teachers College), Post-Annapolis: What Real People Are Doing to Bring Peace in the Middle East.
Discussant: **Michael J. Stevens** (Illinois State & The Lucian Blaga University, Romania)

FRI, 2:00-3:20 pm, Symposium:
The Role of Research in Professional Development:
Early Career Professionals Present Academic, Clinical and Organizational Perspectives
Chair: **Mathilde Salmberg** (Georgetown)
Participants: **Mathilde Salmberg** (Georgetown University), **Kate A. Richmond** (Muhlenberg College), **Senel Poyrazli** (Penn State University - Harrisburg), **Gloria G. Grenwald** (Webster University), **Shay C. Mann** (Virginia Commonwealth University).

FRI, 3:30- 4:50 pm, Symposium:
Internationalizing the Curriculum in Psychology
Chair: **John D. Hogan**
(Saint John's University)
Participants: (1) **Richard S. Velayo** (Pace University) and **Gloria G. Grenwald** (Webster University), Goals and Learning Outcomes in an Internationalized Psychology Curriculum: Updates from APA. (2) **Wade Pickren** (Ryerson University), Indigenous Psychologies and the History of Psychology Curriculum. (3) **Florence L. Denmark** (Pace University), Internationalizing the Psychology of Women Curriculum. (4) **Michael J. Stevens** (Illinois State University & The Lucian Blaga University, Romania), Changing the Curriculum to Reflect a Worldview. (5) **Mercedes A. McCormick** (Pace University and Private Practice): The Practice of Psychology: Lessons Learned from Adopting an International Perspective.

FRI, 5:00-6:20 pm, Symposium:
Gems of Cross-Cultural Research
Chair: **Ann O'Roark** (Independent Practice)
Participants: (1) **Padmini Banerjee** (Delaware State University), Amalgamated Identities: New Phenomenon or New Paradigm? (2) **Kaye V. Cook** (Gordon College) and **Meghan Savina** (Boston College), A Hermeneutic Paradigm Reveals Cambodian-American Buddhist and Christian Understandings of the Virtues. (3) **Yoon A. Lee**, Perceptions of Child Maltreatment in European Americans, Korean Americans, and Koreans.
Discussant: **Senel Poyrazli** (Penn State University - Harrisburg).

SAT, 9:30- 11:00 am, Symposium:
Psychology at the United Nations: Past, Present, Future
Chair: **Harold Takooshian** (Fordham University)
Participants: (1) **Neal S. Rubin** (Argosy University): Stress Reduction Among U.N. Peace-Keepers. (2) **Janet Sigal** (Fairleigh Dickinson) and **Inka Weissbecker** (University of Louisville), The Disconnect Among UN Personnel in New York, Geneva, the Field, and Academe. (3) **Lynda J. Carpenter** (New York Organ Donor Network): Human Organ Donation: A Vital New NGO? (4) **Harold Takooshian** (Fordham University) & **Elaine C. Bow** (Iona College): Psychology NGOs Today. (5) **Edwin G. Hollander** (Baruch College, CUNY): Inclusive Leadership at the United Nations: Attention to the Needs of Civil Society.
Discussants: **Florence L. Denmark** (Pace University), **Ani Kalayjian** (Fordham University).

What are the growing roles of scientific and applied psychology in the United Nations today? Among the 3,000 nongovernmental organizations (NGOs) at the United Nations, the number representing psychology since year 2000 has grown

to about 60 psychologists, representing about 10 psychology NGOs. They are involved in highly diverse topics that have a behavioral component, including aging, children, families, mental health, peace, women, human rights, and human settlements. This symposium brings together several U.N. representatives to discuss the past, present, and future of psychology at the U.N.

SAT, 11 – 12:20 pm, Address:
The Rise of Global Psychology
Chair: **Florence L. Denmark** (Pace University). Presenter: **Uwe P. Gielen** (St. Francis College).

SAT, 12:30-1:50 pm, Address:
Negotiating a Historical Compromise: New Opportunities in the Israeli-Palestinian Peace Progress
Chair: **Uwe P. Gielen** (St. Francis College). Presenter: **Herbert C. Kelman** (Harvard University).

SAT, 2-3:20 pm, Holistic Interventions in International Psychology: Mind, body, and spirit
Chair: **Ani Kalayjian** (Fordham University)
Participants: (1) **Ani Kalayjian** (Fordham University): The Mind-Body-Spirit Continuum. (2) Rivka Bertisch Meir (Fort Lee, NJ): The Power of the Mind. (3) **Artemis Pipinelli** (Lehman College, CUNY): Obesity: Challenges for the Mind-Body and Spirit. (5**) Ann M. O'Roark** (St. Augustine, FL): Evidence-based Practice in International Psychology

SAT, 3:30- 4:50 pm, Workshop: Becoming More Involved in International Psychology: Why and How?
Chair: **Michael J. Stevens**
(Illinois State & The Lucian Blaga University, Romania)
Should students and professionals become more involved in international psychology? If so, how best to do this? Michael Stevens is the co-editor of *Global Psychology* (Erlbaum, 2006) and past President of the APA Division International Psychology. In this unusual three-part workshop: (1) Stevens begins with a handout and brief message on the question, Why become more involved in global psychology? (2) Then in a series of 12 three-minute "flash presentations," 12 veteran international psychology professionals and students will each offer a helpful factsheet accompanied by very brief remarks on a specific avenue to become more involved. (3) This is followed by 30 minutes of moderated discussion of the topic. These practical factsheets are intended to advise on specific topics for diverse groups: students (such as overseas internships, cross-national research), faculty (teaching overseas, cross-national testing), practitioners (consulting overseas), researchers (publishing cross-cultural articles and books), and others (joining international groups, working with the U.N.). The workshop will include excerpts from a new video by J. Kuriansky & U. P. Gielen on "Distinguished Psychologists Around the World: A Video in the Making."

International activities in New York, 2007-2008

Harold Takooshian
Fordham University

Since 2002, our International Division's New York group has hosted dozens of local gatherings for our growing number of members (280 in 2007). In Fall 2007, members participated in six gatherings: (1) On September 7, a dozen psychologists working with the United Nations joined 40 colleagues and students for an international reception hosted by Dean Elaine Congress at Fordham University. (2) On October 1, over 100 joined World Habitat Day at the United Nations. (3) On October 10-11, over 100 visited the first Psychology Day in the United Nations, chaired by Florence Denmark. (4) On November 9, 80 participated in the 19th

PHOTO: On January 3, four of the 12 psychologist-photographers on exhibit at SoHo Photo Gallery, (l to r): Iris Fodor, Uwe Gielen, Michele Hirsch, Joel Morgovsky.

Greater New York Conference on Behavioral Research at Hofstra University, chaired by Professor Lola Nouryan. (5) On Nov 9-10, a dozen Division officers were among 100 who converged on Saint Francis College for a two-day conference on "Internationalizing the psychology curriculum," chaired by Division 52 President-elect Uwe Gielen. (6) On November 30, 75 participated in the 7th annual interfaith Holiday Healing Circle, chaired by Anie Kalayjian at Fordham University.

On January 3, 2008, over 100 visited the SoHo Photo Gallery for the opening of "Psychologists in Focus," organized by Joel Morgovsky--an international exhibition of photos by 12 psychologist photographers: Iris Fodor (NYU), Margery Franklin (Sarah Lawrence), Ruth Formanek (Hofstra), Judith L. Gibbons (St. Louis), Uwe P. Gielen (St. Francis), William R. Herkelrath (Northwest), Michele Hirsch (St. Francis), Gisa Indenbaum, Anie Kalayjian (Fordham), Ching-tse Lee (Brooklyn), Joel Morgovsky (Brookdale), Lynn Passy.

For spring, 2008 in New York City, early plans are currently being formed for international activities:

1. February 29-March 1, the international conference on "The violence of everyday life," organized by C. Edward Robins at Fordham University. (Details: cerobinsny@aol.com)
2. March 24-28, the 2008 meetings of the American Educational Research Association (AERA) feature a symposium and reception saluting the 100th anniversary of the birth of Anne Anastasi. (Details: tpatelis@collegeboard.org)
3. March 27, Carol Bellamy, former Director of UNICEF, lectures on women at St. Francis College. (Details: ugielen@hotmail.com)
4. March 28, Reception for the 10th anniversary of the Institute for International and Cross-Cultural Psychology, hosted by St. Francis College. (Details: ugielen@hotmail.com)
5. April 12, the 36th Hunter Psychology Conference, featuring presentations on international and cross-cultural psychology. (Details: takoosh@aol.com)
6. April 13, the 11th Community Day at St. Francis College—an international festival of prayer, music, dance, poetry, art, and cuisine. (Details: ugielen@hotmail.com)
7. May 10, the 16th Pace University Psychology Conference, featuring sessions on international psychology. (Details: mampsyyoga@aol.com)

For any specific details, or to participate, contact Harold Takooshian at takoosh@aol.com. The International Division seeks to form local groups in other cities besides New York. To form a group in your area, just contact takoosh@aol.com for a free checklist on forming a local group.

2nd International Congress on Interpersonal Acceptance and Rejection in Crete, Greece

Ronald P. Rohner, President
International Society for Interpersonal Acceptance and Rejection
r.rohner@uconn.edu

The deadline for receipt of Abstracts for the forthcoming 2nd International Congress on Interpersonal Acceptance and Rejection in Crete, Greece has been extended to March 3, 2008. I would like to extend a personal invitation to you to prepare a paper, poster, symposium, or workshop at the Congress, if you haven't done it already. You can get information about the Congress from its website at www.isipar08.org.

Can Governmental Aggression be Acceptable? Views from the United States and Spain.

Kathleen Malley-Morrison
Helena Castanheira
Boston University

Levels of tolerance for two forms of governmental aggression (invasion and torture of prisoners) were investigated in samples of 58 Spanish adults (27 female, 28 male, 3 unspecified) and 57 American adults (28 female, 29 male). Qualitative explanations for rating scale scores were coded based on a system derived from Bandura's theory of moral disengagement. On the quantitative rating scale scores, although tolerance was low in general, multivariate analyses of variance revealed that the American sample showed significantly greater tolerance for both invasion and torture than did the Spanish sample. Moreover, tolerance for invasion was greater than tolerance for torture. Content analyses of the qualitative explanations of the rating scale scores revealed that the most common forms of moral disengagement for both invasion and torture were forms of moral and utilitarian justification. There were few statistically significant gender differences; however, females were significantly more likely to have engaged in war protests, and marginally more likely to provide some rationale for their quantitative ratings.

The terrorist attacks of September 11, 2001, the United States' invasion of Afghanistan and Iraq, disclosures of torture at Abu Ghraib and Guantanamo Bay, and other intra- and international conflicts have generated considerable controversy around the world concerning not just terrorism but also state aggression (e.g., Annas, 2005; Jervis, 2003; Nardin, 2005). Moreover, the stories in the media concerning events such as the invasion of Iraq vary considerably cross-nationally (Schpiro, 2002). In an era when various forms of governmentally-sanctioned violence are being reprised, what are the views of ordinary citizens in regard to invasions of one country by another and the use of torture during times of war? The purpose of the current study was to compare perspectives on state violence in two countries (the United States and Spain) with very different histories regarding conflict and violence in the 20th century. Of particular interest was the extent to which the Americans and Spaniards varied in their reliance on different forms of moral disengagement to justify their judgments concerning invasion and torture.

During the last century, Spain's political history was marked by internal and external violence and the regular collapse of the state in its attempts to establish democracy. The violent civil war from 1936-39, and the 36 year long *pax armata* of the Franco dictatorship that followed, made the armed forces central to a political stability based on repression until Franco's death in 1975. With the transition to democracy, pressure from regional groups seeking territorial autonomy and in some cases independence has resulted in the emergence of radical nationalist groups. The most radical of these groups is ETA (Basque for "Basque Homeland and Freedom"), which is listed by both the European Union and the United States as a terrorist group. The oldest terrorist organization in the Western world, ETA has attempted to achieve the independence of the Basque Country by violent means, including the bombing and killing of politicians, police, soldiers, civilians, and tourists (Moreno, 2005).

In 2003, Spain sided with the countries (identified by the U. S. government as "The Coalition") that supported the invasion of Iraq, with the intention of obtaining support from those countries in the fight against ETA's terrorism, while giving the impression of social improvement and control (Moreno, 2005). However, opinion polls revealed that more than 80% of the Spanish population were against the presence of the Spanish troops in Iraq, and 67% of the population expressed the view that there was no real motive to initiate the Iraq war (Moreno, 2005). On March 11, 2004, Spain suffered the worst European terrorist attack ever. Over 200 people, mostly students and workers, were killed in railway bombings. The government tried to connect the attack with ETA; however, the bulk of the evidence indicated that the attack had been perpetrated by opponents to Spain's involvement in the Iraq war. The government's attempt to confuse the public over ETA's responsibility for the attacks and its continuing efforts to prove this link caused a backlash reaction against the government, which in turn caused the government to lose the elections on March 14, only three days after the attack.

Despite the fact that many Americans view their country as the epitome of democracy, peace, and international

assistance, there is in the U.S. considerable social acceptance of both military aggression and torture (Arlin, 2006; Chomsky, 2004). Although US presidents used military force more than 200 times between 1948 and 1998, and have kept the nation involved in war since 2003 (Tago, 2005), Americans display a kind of cultural myopia ("American exceptionalism") whereby they view America's treatment of developing nations as based on noble intentions (Churchill, 2003, cited in Arlin, 2006). Within this context, human rights abuses that become public are considered to be isolated exceptions to the country's characteristically "benign" policies and practices (Chomsky, 2004; Churchill, 2003, cited in Arlin, 2006).

According to Bandura's socio-cognitive model of moral disengagement (e.g., Bandura, 1999; 2002; McAlister, Bandura, & Owen, 2006), during the course of development, people construct moral standards that guide conduct and are regulated by self-sanctions. These self-sanctions are mutable and can be disengaged, leading to inconsistencies between moral principles and actions, which, in turn, generate rationalizations whereby individuals try to justify behaviors that clash with their moral standards. Bandura labels this process as *moral disengagement*. Among the forms of moral disengagement described by Bandura are: 1) cognitive reconstructions of harmful behavior and moral or utilitarian justifications of the behavior (legitimizing actions conflicting with moral principles by appealing to socially worthy or moral purposes, making advantageous comparisons, and euphemistic labeling); 2) removing or obscuring personal accountability (for example, through displacement and diffusion of responsibility); and 3) devaluing (e.g., dehumanizing) or placing blame on the enemy.

In Bandura's view, the media have become a strategic tool for producing disengagement, and played a role in the finding that the terrorist attack on the World Trade Center was accompanied by a significant rise in moral disengagement and public support for military action (Bandura, 2004, cited in McAlister, Bandura, & Owen, 2006). Moreover, Bandura views the minimizing and obscuring of civilian casualties, which has characterized much of media reporting on the Iraq war in the United States, as an important contributor to public support of military force--it minimizes moral self -sanctions and thus public opposition to war (Kelman, 1995).

Media portrayals of events since September 11, 2001, have varied internationally. For example, in a study analyzing the framing of the war in Iraq, European newspapers provided a "bigger and more balanced picture," covering more sides and quoting diverse sources, while American media covered the war from the perspective of the Coalition, quoting Coalition sources in almost all of their stories (Pastelardo, 2006, p. 2). Perhaps these differences in media reporting, plus historical and political differences between the countries, contributed to the fact that studies on the influences of media on opinions found Spanish people to have high opposition to the invasion of Iraq (Willnat et al., 2006).

In the current cross-national study, we examined not only rating scale indices of tolerance for governmental aggression (invasion and torture) but also the participants' justifications for their scale scores. In particular, we analyzed explanations for the types of moral disengagement and engagement displayed. We hypothesized that Americans would show greater tolerance of both invasion and torture than Spaniards, and that explanations for ratings would show greater use of moral disengagement by American than Spanish participants. Also, based on previous research (e.g., Ashy & Malley-Morrison, 2007; Caprioli & Boyer, 2001; Fite, Genest, & Wilcox, 1990, Hashim & Malley-Morrison, 2007; Malley-Morrison, Daskalopoulos, & You, 2006; Malley-Morrison, et al., 2006) revealing lower levels of tolerance for governmental aggression in females than in

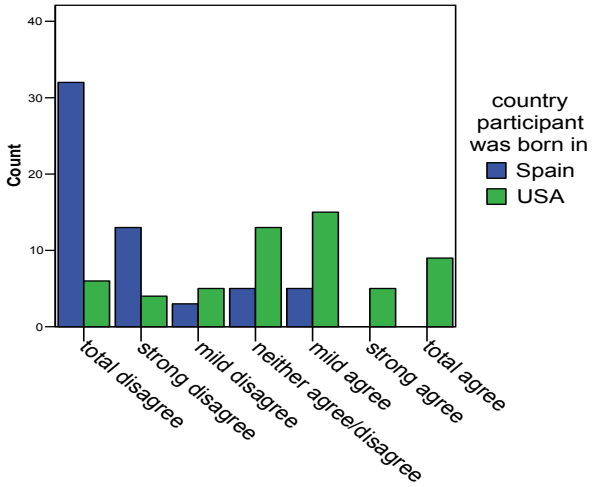

Figure 1. Distribution of Rating Scales Responses Regarding Invasion

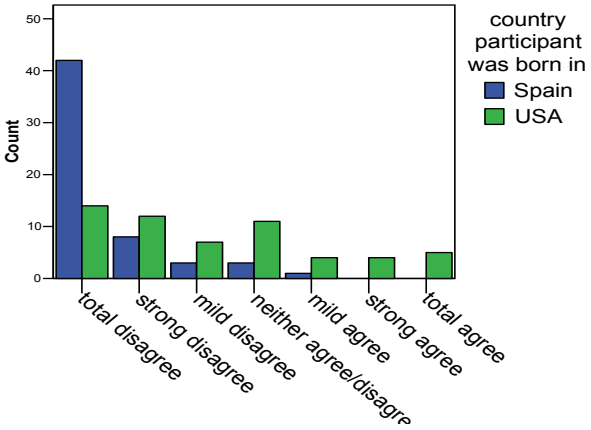

Figure 2. Distribution of Rating Scale Responses Regarding Torture

Table 1: Descriptive statistics for rating scale scores for invasion and torture items, separated by gender

		Spain		United States	
		Mean	SD	Mean	SD
Invasion	Females	1.85	1.13	4.25	1.58
	Males	2.00	1.53	4.48	2.03
Torture	Females	1.44	1.01	2.96	1.73
	Males	1.51	0.94	3.41	2.11

*p<0.001

males, we predicted that men would show greater tolerance for both invasion and torture than women. Finally, given what we saw as greater outrage in the media regarding the depiction of the degrading practices used by US troops at Abu Ghraid than outrage at the wars in Iraq and Afghanistan, we hypothesized that there would be significantly less tolerance for torture than for invasion in both the US and Spanish samples.

Methods

The sample consisted of 58 Spanish adults age 17 to 70 (27 female, 28 male, 3 unspecified) and 57 American adults age 17 to 75 (28 female, 29 male) who were participating in an international study of perspectives on governmental aggression and peace. Participants in both samples were largely middle class and responded to a survey posted on the internet. The American adults were selected from a large sample of internet respondents in order to be roughly matched with the Spanish sample on age, gender, and religion. All participants were recruited through the peer networks of research team members and completed the Personal and Institutional Rights to Aggression Scale (PAIRTAS; Malley-Morrison, et al., 2006). There were three independent translations of the PAIRTAS into Spanish and the final merged translation was done by the second author of this paper. The Spanish sample was 60% Christian, 26% Agnostic, Atheist or none, and 14% other or did not report, and the American sample was 60% Christian, 28% Agnostic, Atheist or none, and 12% other or did not report. The Spanish sample was 45% Caucasian, 5% other and 50% did not report (but were likely because of the recruitment strategies to be primarily Caucasian), while the American sample was 86% Caucasian and 14% other. For the purposes of this study, two items from the PAIRTAS were analyzed: 1) "Sometimes one country has the right to invade another country"; and 2) "The government has the right to order the torture of prisoners in time of war." Participants were asked to rate each item on a scale of 1 to 7 (from totally disagree to totally agree) to indicate the extent to which they agreed with it and then to provide, in their own words, the reasoning behind their rating scale score. Evidence for the construct validity of the PAIRTAS comes from previous studies confirming hypotheses being tested by the measure (e.g., Ashy & Malley-Morrison, 2007; Daskalopoulos, Zaveri, & Malley-Morrison, 2006; Malley-Morrison et al., 2006). The demographic questionnaire included an item asking whether respondents had ever participated in any form of protest against war. A chi square contingency test indicated that significantly more of the women than of the men had engaged in some sort of protest against war, $\chi^2 = 3.91$, $p < .05$.

Table 2: Principle US and Spanish themes re: Invasion

	Spain		U.S.	
	N	%	N	%
Support for Invasion				
Moral or Utilitarian justification	15	26	7	12
Attribution of blame	0	0	18	31
Unspecified support	3	5	0	0
Against Invasion	25	43	5	9
Self Defense	6	11	11	20
No Answer	9	15	16	28

*p<0.001

Table 3: Principal US and Spanish themes re: Torture

	Spain		U.S.	
	N	%	N	%
Support for torture				
Moral justification	1	2	4	9
Advantageous comparison	1	2	12	21
Removing personal agency			2	4
Devaluing the victim	1	2	1	2
Unspecified Support			3	5
Against Torture				
Moral engagement	5	9	5	9
Utilitarian engagement	6	10	3	5
Humanizing the victim	7	12	2	4
Violates Genebra treaty	1	2	2	4
Unspecified disagreement	13	23	5	9
No answer	23	40	17	30

*p<0.001

Results

Figures 1 and 2 show the distribution of responses across the seven points of the rating scale for the invasion and torture items respectively. Table 1 provides the means and standard deviations, separately by gender and country, for the rating scale scores on the invasion and torture items. In support of our first hypothesis, a two way analysis of variance (with gender and nationality as the predictors) revealed that, overall, participants from the United States scored higher than participants from Spain on a country's right to invade another country, $F(1,3)=64.31$, $p=.001$. A second two way analysis of variance revealed that U.S. participants scored higher than Spanish participants on the right of governments to torture prisoners of war, $F(1,3)=33.87$, $p=.001$.

Table 2 summarizes the major themes identified in the qualitative responses provided by participants in support of their quantitative ratings. In support of our second hypothesis, overall, there were more examples of moral disengagement in the U.S. than in the Spanish sample, t (1,100), =3.75, $p<.001$.

More discrete analyses of the qualitative responses showed that in both samples the most commonly used mechanisms of moral disengagement to support invasion were: 1) moral or utilitarian justifications, including stopping the other government from murdering people or committing acts of genocide, helping people, and providing humanitarian help, and 2) attribution of blame to the invaded country—e.g., arguments concerning the need for self-defense or response to threat. In regard to torture, as can be seen in Table 3, the most commonly used mechanism of moral disengagement was again moral or utilitarian justification, with Americans particularly likely to use the mechanism of advantageous comparison. Pearson chi square and Fisher's exact test analyses revealed that significantly more Americans than Spaniards used advantageous comparisons in indicating some support for torture of prisoners of war, $\chi^2=10.71$, $p<.001$, and marginally more Americans than Spaniards gave arguments concerning the moral justifiability of torture, Fisher's exact $p<.10$. Marginally more Spaniards than Americans gave arguments against torture that emphasized its dehumanizing effects, Fisher's exact $p=.08$. There were no statistically significant gender differences at the alpha=.05 level; however, in the Spanish sample, significantly more women than men provided at least some rationale for their ratings concerning the acceptability of torturing prisoners of war, $\chi^2=4.38$, $p<.04$.

Finally, paired samples t tests were run to determine whether there were significant differences in tolerance for invasion as compared with tolerance for torture. Consistent with our hypothesis, there was greater tolerance for invasion than for torture in both Spain, $t=2.52$, $p=.015$, and the United States, $t=4.10$, $p<.001$.

Discussion

Although the full range of scores on the rating scale was used for both items, support for both invasion and torture of prisoners was, in general, relatively low. However, as predicted, there were statistically significant differences between the countries, with respondents from the United States showing more tolerance for the two forms of governmentally-sanctioned violence than the respondents from Spain did—a finding that is consistent with earlier research with the PAIR-TAS. For example, Malley-Morrison, Daskalopoulos, and You (2006) found that domestic participants (adults born in the United States to two parents also born in the United States) were more tolerant of several different forms of

States) were more tolerant of several different forms of governmental aggression than international participants (adults born outside the US to parents also born outside the US).

Contrary to expectation, there were few gender differences on either of the governmental aggression items, either across the sample as a whole or within countries. This lack of gender differences in tolerance for aggression is quite different from findings in other studies of attitudes toward violence (e.g., Ashy & Malley-Morrison, 2007, Caprioli & Boyer, 2001; Fite, Genest, & Wilcox, 1990, Hashim & Malley-Morrison, 2007, Malley-Morrison, Daskalopoulos, & You, 2006; Malley-Morrison et al., 2006), which typically show greater tolerance in men than in women. We believe that at least in the U.S. sample, the general lack of gender differences may be related to random noise occurring in the process of matching European Americans to Spanish participants. In the larger European American sample from which the current European Americans were drawn, there were differences in the predicted direction on both items that were both arithmetically larger and statistically significant. We think it is also relevant to our original expectations that the women were significantly more likely than the men to have engaged in anti-war protest activities and were at least marginally more likely to try to give some rationale for any level of support for torturing prisoners of war.

As predicted, respondents in both Spain and the United States were more intolerant of torture than of invasion. Although this finding may be related to media coverage of the different forms of governmentally-sanctioned aggression, with more lurid details concerning the Abu Ghraib mistreatment of prisoners than of the horrors of war, it is also possible that there is something more immediate and personal about torture than about war contributing to these findings. For example, individuals may have more difficulty psychologically distancing themselves from explicit scenes of torture than from scenes of war because the scenes of war are more routinized and perhaps often more sanitized.

The general tendency of Americans to be more tolerant of government aggression than people from many other countries is probably due to many factors, including their lack of exposure to armed aggression in their own country, the consistency with which their leaders have themselves invoked moral disengagement, and the complicity of the media with the government in conveying themes of moral disengagement. Practitioners of peace in both countries may want to focus on strategies to increase moral engagement in regard to issues of governmental violence—for example, through the kinds of peace promotion programs described in Howard et al (2007), which specifically addresses moral disengagement and ways to work with the theory. Moreover, both the American and the Spanish findings are a good reminder, we hope, that although wars are declared by leaders, it is ordinary people who not only fight the wars but also either support or resist their leaders' agendas. Factors that promote peace, like those that promote war, can be found at the level of individuals as well as at the level of society. Efforts to invoke moral disengagement within individual citizens may be worthy of significant attention along with the political, social, and economic factors more commonly considered.

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International Association for Group Psychotherapy and Group Processes

Francis Bonds-White, Ed.D, President of the International Association for Group Psychotherapy and Group Processes (IAGP) and a member of Division 52, is pleased to announce that the IAGP Congress 2009 will be held in Rome, Italy, August 24-29, 2009.

The theme of the Congress: Groups in a Time of Conflict. For further information please check the IAGP web page, www.iagp.com or contact the Co-Chairs of the Congress at 2009congress@iagp.com

Membership in the International Association of Applied Psychology's Division of Psychological Assessment and Evaluation

Psychologists, assessment specialists, researchers, and practitioners are encouraged to become members of the International Association of Applied Psychology (IAAP), and specifically the Division of Psychological Assessment and Evaluation (Division 2). The Division is committed to researching topics important to applied psychology around the world, including testing and statistical methods and practices. Division members receive the quarterly newsletter, the journal Applied Psychology: An International Review, and reduced registration fees for IAAP's international conference held every four years (the next one is scheduled for Melbourne, Australia in 2010). Most importantly, Division members become connected to hundreds of scholars around the world who share similar goals and interests in applied psychology and test theory, test applications, and testing practices. An application for membership can be obtained at the IAAP website <www.IAAPSY.org>. Individual membership dues are $60 (£40) and student dues are $10 (£7).

Using the Internet: A Call to Internationalize the Psychology Curriculum

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The psychology curriculum continues to become more international with the help of the growing number of users (educators, trainers, researchers, students) of Internet-based technologies (IBTs) from all over the world, thereby making us increasingly interconnected and interdependent. The paper makes the case that the use of IBTs can effectively help internationalize the psychology curriculum. Some examples are presented describing how these technologies may be used in the teaching and training of psychology students, and in the promotion of a more international perspective in psychological research.

The Internet is virtually making the world a smaller place and that includes the world of psychology. It used to be based on a paradigm in which an individual user accesses content, but has now transformed itself to one in which communities create and share ideas. Millions of Americans now use the Internet regularly (through electronic mail, online chats, file transfers, websites, distance learning technologies, virtual worlds, social networking sites, and other forms of electronic data exchange) and the number of Internet users around the world is growing at a tremendous rate. With the growth of the Internet worldwide, it is apparent that nations are becoming increasingly interconnected and interdependent (Power & Velayo, 2006; Velayo, 2000). Its influence is certainly far-reaching and is changing the way psychology instructors teach and the way students are educated, trained, and do research. In many ways, our students probably utilize much more of what the Internet has to offer than we think they do. As such, the Internet allows us to network more efficiently and effectively, circumventing the constraints imposed by distance and time. The new generation of students tends to be relatively comfortable with new technologies and instructors ought to experiment on how these technologies may allow them to better teach and for students to better learn. There is no doubt that Internet-based technologies (IBTs), those that are currently used and innovations that we have yet to develop, will continue to contribute significantly to the globalization of psychology, in general, and the psychology curriculum in particular.

In an article that recently appeared in *The Educator: Newsletter of the Education Directorate of the American Psychological Association,* Dr. Anthony Marsella, one of the prominent figures in international psychology, provided valuable insights on how education and training in psychology need to adapt in order to influence and shape global changes (Boenau, 2007). He pointed out that the challenge of a global psychology is to educate and train psychologists to be ethnically, culturally, and racially sensitive and to prepare our students to honor and value global diversity rather than uniformity. Given such position, psychology as a field will need to adjust its curricula, practica, research, and training contexts. How may we best achieve this given the resources available? IBTs may best achieve this goal of promoting the internationalization of the psychology curriculum and in developing greater appreciation for diversity through curricular changes.

Internet-based Technologies (IBTs)

There are now several IBTs in place, some are more popular than others, and there are those that continue to grow in popularity as the information age continues to unfold. The most common uses of the Internet include email, interlinked webpages of the World Wide Web, remote access, online chats or instant messaging (IMs), collaboration, videoconferencing, file sharing, streaming media, and voice telephony (VoIP). There are also those gaining popularity such as social networking websites (e.g., MySpace, Facebook, Friendster), virtual worlds (e.g., Second Life, The Sims Online, There), video and audio-sharing websites (e.g., YouTube, podcasting), browser-based collaborative tools (e.g., blogs, wikis, online documents, spreadsheets, and calendars) and even multi-player online role-playing games (e.g., EverQuest, World of Warcraft, Ultima Online). Interestingly enough, many anticipate that PC-based software will eventually cease to exist as Internet-based software and technologies become

more accessible and even free, as evident in the growing movement towards "open source" software, that in which software is created collaboratively and distributed freely to anyone and everyone.

There are a growing number of instructors using a number of these technologies, some more than others, in their psychology courses. Extending the use of such technologies beyond one's national borders, to reach out and to include those from other nations, has become more feasible. The education and training of future psychologists, both local and international, will involve a widespread dialogue between nations and cultures. Innovative ways to utilize these Internet -based technologies as pedagogical, training, and research tools need to be further explored and studied. Not only do these technologies allow for greater and faster communication between psychologists and students residing in different nations (as well as geographical regions within a country), but these also provide a venue for greater understanding between peoples, greater curricular and scholarly collaborations, and an enhanced level of experience the goes beyond just reading about another culture beyond one's own. Such transformation necessitates curricular changes.

The Case for Using the Internet to Help Internationalize the Psychology Curriculum

The psychology curriculum in many institutions is still generally dominated by print publications that, for the most part, were written by western psychologists. Most psychology courses, even those in other countries, use textbooks that contain insufficient international content and minimally discuss relevant international issues (Velayo, 2000). Students of today's psychology may need to further understand the differences (and similarities) between cultures, such as how psychology differs in an individualistic culture compared to psychology in a collectivistic culture. Because of the relative lack of multi-national education in the psychology curriculum, psychologists tend to be unprepared to deal with the needs of those within the broader global community facing various types of conflicts (Woolf, 2001).

It is important to note that the population of the world has reached about 6.6 billion people and more than 85% of the population is from non-western ethnic and cultural traditions. As the number of psychologists continues to multiply all over the globe, psychology is more international than ever before (Rosenzweig, 1999). Adair, Coelho, and Luna (2002) found that psychology has a "significant presence" in 47 countries and a "minimal presence" in at least 41 others. These authors also point out that 45% of articles indexed in PsycINFO, a major psychology electronic database, were written by authors from outside the U.S. even though PsycINFO excludes numerous psychology journals written in a language other than English. Thus, psychology's knowledge base in science and practice is steadily becoming more international.

Using the Internet to educate and train students can put us in touch with nations that we would otherwise know little about or have limited access to. Given that the Internet has revolutionized the exchange and management of knowledge, we, like others abroad, will need to be responsive to the demands of a growing multi-racial, multi-ethnic, and multinational network of people within the field. Emerging social, cultural, political, and environmental problems around the globe are imposing intense and complex demands on our discipline, challenging our sense of identity as psychologists and as a professional collective. We can assist in addressing and resolving these concerns if we are willing to reconsider some of psychology's fundamental premises, methods, and practices that are largely rooted within Western cultural traditions and to expand our appreciation and understanding of psychologies from abroad.

For example, one of the burning issues currently related to international human rights is that American psychologists have been employed by the Department of Defense to assist in the mental torture of POWs to obtain information deemed necessary for "national security." In response to the critique of misusing psychology in dealing with international affairs, APA just issued a strong warning against this type of practice. An overview of APA's latest position on torture and other cruel, inhuman, and degrading treatment or punishment appears in the November 2007 issue of the Monitor (Okorodudu, Strickland, Van Hoorn, & Wiggins, 2007). Perhaps IBTs could enable us to make such issues more transparent and available. For example, given the aid of video-sharing technologies (e.g., YouTube), audio or video interviews of relevant people (policymakers, lawyers, national leaders, and even prison guards, and/or their prisoners) posted on websites may provide a venue to share various sides of the story from the first-person perspective. Online participants may go to that website and share their own opinions for discussion, even share files, develop links, and conduct video-conferencing with others in real time. This is one way to demonstrate the clear advantage of IBTs in internationalizing the psychology curriculum which may not be available with other pedagogical approaches. Students can have direct, and sometimes real-time access to the subject matter without being confined by spatio-temporal factors or geographical barriers. Consequently, students can be on the site where things happen and could conduct observation via the Internet on ongoing events. The convenient access to first-hand information through multi-directional communications can be solely provided by IBTs.

Other relevant international issues for psychologists include adjustment syndromes such as alienation, culture shock, acculturation, identity conflict and confusion, and migration stress are now emerging as major problems for counselors in schools, colleges, industry, clinics and private practice (Marsella & Pedersen, 2004). There are also societal and group disorders such as cultural disintegration, cultural dislocation, ethnic cleansing, social disillusionment, sick societies, urban blight and decay, social fragmentation, cults,

endemic crime and violence, and cultural abuse and collapse. These issues may all be presented and discussed through IBTs. With all of these emerging disorders, it is as important as ever to internationalize the psychology curriculum through the education and training of mental health professionals in dealing with various peoples of different countries. Greater effort must be made in order to recognize that there are many non-western psychologies that reflect the cultural experiences and contexts of other people than those presented in western psychology textbooks (Marsella, 2001). Using IBTs in ways that may serve to supplement a more global curricular experience of students is worth exploring.

The American Psychological Association, recognizing the need to internationalize psychology, formed a task force in 2003 to report and to provide recommendations on ways to internationalize the undergraduate psychology curriculum. The task force proposed relevant learning outcomes for undergraduate psychology majors, recommended that psychology programs and instructors of psychology take a leadership role in promoting the internationalization of student learning, and enumerated plans that may help faculty incorporate an international dimension into their teaching. The report also provided action plans to help internationalize the curriculum and make these approaches available to a wider group of disciplinary associations besides the APA (Lutsky, Torney-Purta, Velayo, Whittlesey, Woolf, & McCarthy, 2005). We now have the Internet as a readily available and relatively inexpensive medium by which we may carry out these action plans. This includes (but not limited to) expanding the existing clearinghouse of materials available from the websites of APA Division 2 (Teaching of Psychology) and Division 52 (International Psychology) that faculty could immediately use for course development and creating discussion boards and blogs to allow for psychologists and students from around the world to exchange ideas and network.

On Teaching and Training

Access to the Internet has revolutionized how we are able to efficiently access information and exchange ideas. The opportunities that IBTs provide make it even easier to help internationalize the educational and training experiences of our students. In order for colleges and psychology departments to internationalize their curricula, faculty members in the social/behavioral sciences need to find effective and creative ways to incorporate new material into their lesson plans (Grenwald-Mayes & Moore, 2000). There are many other different ways that instructors can incorporate a more global perspective into their current psychology curriculum through the use of the Internet.

Instructors may have students think more globally by having them utilize the Internet to correspond with psychologists and/or other students from other nations as an integral part of a course – to consider the viewpoints of other cultures when learning psychological constructs, perhaps by interviewing those from abroad and/or conducting collaborative projects. Such cross-national correspondences may even be part of a cross-cultural training and cultural sensitivity training program in which students assess their own multicultural competence through self-evaluation and through more systematic assessment methods. The rising use of distance-learning platforms such as Blackboard and other internet-based technologies is opening new avenues for teaching international materials (Takooshian & Velayo, 2004; Velayo, 2004).

Another useful IBT for teaching and training is videoconferencing or teleconferencing. Guest lecturers from other countries may be invited to speak on their area/s of expertise through the use of recorded footage on streaming video or through webcasts. The presentation may be done live to allow students the opportunity to interact with the guest.

An example of using IBTs would be to have students (or even professionals and scholars in psychology) from different cultures or nations discuss whether a particular behavior or belief is *emic* (culture-specific) or *etic* (culture-neutral). Instead of lecturing about the distinction or providing notes, wouldn't it be more effective if this material were gathered together in a blog for them to discuss? There would not be much more work for the instructor and students could read a variety of what others think about the topic; and there would even be a greater possibility for discussion between all those involved.

Another good example of using IBTs is to have students, as part of a course, review research written by non-western authors on a topic that is being taught in class. For example, if students are being taught the attachment theory, students should first be encouraged to invite interested participants from different parts of the world to identify the critical issues involved in attachment, and to tackle the issues from a cross-cultural rather than a mono-cultural angle. One possible issue related to attachment may be stated as follows: Provided the significance of infant-parent relationship in western psychological theory and given the close distance between American parents and their young children, why do so many American adults detach themselves from the parents at nursing homes? In contrast, given some hierarchically organized Asian families in which parent have much greater distance with their children and spend much less time with them, they develop long lasting relationship with their children who would never send their parents to a nursing home. Rather, they strongly feel obligated and delighted to support their parents financially, socially, physically, as well as emotionally. As revealed in Gielen and Lei's (2007) study on Chinese American youth in New York City, almost every one of the hundred interviewees responded that they are going to support their parents one way or another. A cross-cultural comparative study would require students in the class using IBTs to virtually observe the family dynamics in different cultures and directly inquire about the participants points of view through video conferences or even video clips posted on YouTube. Subsequently, students would then pool all

information collected in an organized manner and share it with interested parties where online discussions or blogs may be formed with others sharing information from a variety of perspectives. By doing so, the learning process is not passive or unidirectional, but rather interactive in which students can share and reflect on their own views.

One other valuable way to help build on the growing number of resources that instructors may use to internationalize the curriculum is to have them contribute to the expanding clearinghouse of materials that faculty from all over the globe could immediately use for course development. Examples of such clearinghouse may be accessed through the APA Division of International Psychology website at http://internationalpsychology.net/resources/ (Stevens, 2007) and another from APA's Society for the Teaching of Psychology Office of Teaching Resources in Psychology (OTRP) at http://teachpsych.org/otrp/resources/resources.php?category=International Psychology (Woolf, Hulsizer, & McCarthy, 2002).

On Research

An international perspective in psychological research is especially relevant in understanding ourselves and others and how this translates to the content material learned by our students. The inclusion of indigenous psychologies in the knowledge base of all psychology is also an important emerging issue to tackle. Sampson (1995) describes the post-modern era characterized by "postindustrial, information-based and globally linked social environment" in which current Western views of the self – as free, independent, and self-contained – will become inadequate in providing a basis for understanding the individual. It is anticipated that it will become essential for a person, to view themselves as parts of a global system in which people's identities are inextricably linked with where they are socially located in that system. Thus, many personality and social psychologists may have to recalibrate their views to reinforce the central importance of culture in shaping the way people construe the self. For example, Ono (1996), examined how users reveal a reflexive projection of the self in Internet "speech," and how Internet communication encourages users to internalize globalization in their self-identity. This study further describes the Internet as a global networked society.

The Internet has also greatly influenced how people work and learn, manage themselves in the workplace, and manage knowledge in their lives. Organizational psychologists should further their research on how technology can help people and organizations achieve the level of competence necessary to survive and succeed in the global marketplace (Marquardt & Kearsley, 1998).

Students should learn to access research literature from outside the United States (e.g., the ability to search databases, and the ability to read in a language other than their native language). In addition, data collection via the Internet is also becoming a popular way to conduct research, which is central to the education and training of psychologists, by collecting data that is internationally diverse. There are interactive questionnaires and experiments now on the web, the most common of which are associated with experiments on perception and cognition. There are also Internet-based surveys and data-collection websites (e.g., SurveyMonkey, Zoomerang, CreateSurvey) that may be used to collect data from various parts of the world as long as they have access to the Internet. One such site is surveymonkey.com (a website that allows you to create psychological testing surveys). Psychological surveys may even be translated into other available languages and be posted on the site for easy access.

Conclusion

The Internet is a relatively inexpensive yet fairly reliable tool that can efficiently promote a more global psychology by building connections among psychologists and students of psychology from various parts of the world. The educational use of Internet, through websites, distance learning technologies, and Internet-based research technologies can be used in the internationalization of the psychology curriculum (Brown & Kesselring, 2000).

As the world we live in becomes more complex and more connected with the use of Internet, the value of international and intercultural education has become more important than ever (Schwarz, 2001). For psychology to grow as a profession and academic discipline, the psychology curriculum as a whole needs to focus on international and global trends (Marsella, 2001). The Internet can serve as an effective educational, training, and research tool to help internationalize the psychology curriculum. The use of IBTs will need to be encouraged and be made an integral part of the psychology curriculum, keeping in mind that the primary goals are to promote a more global, less ethnocentric approach to psychology, and to prepare ourselves and our students towards further globalization.

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This is the fifth article in a series developed by Division 52's Student and Early Career Committee (SECC). Inspired by the recent Mentoring initiatives, these articles are intended to introduce readers to leaders on a professional and personal level. Also, as food is often a shared delight, we ask each leader to share a favorite recipe! So continue to watch this space in the International Psychology Bulletin for insight, wisdom, reflections on Div 52, and lip-smacking recipes!

The Vibrancy of International Research: An Interview with Oksana Yakushko, Ph.D.

As shared with Jennifer R. Arm
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Oksana Yakushko, Ph.D. is an Assistant Professor of Counseling Psychology in the department of Educational Psychology at the University of Nebraska, Lincoln. She received her doctorate in Counseling Psychology from the University of Missouri, Columbia in 2004. Dr. Yakushko is a member of Divisions 17, 35 and 52. In 2003, Dr. Yakushko received the Student International Research of the Year Award from Division 52. She is also Co-Chair of the Task Force on Immigration and Refugee Issues within the division.

What internationally-related work have you done? How did you become interested in this work?

I am an international person, which means I naturally bring this perspective to my work. I came to the United States from the Ukraine as an undergraduate student and have continued to nurture my international interests throughout my professional development. My own experiences have taught me that the United States is not the only country that is contributing to the field of Psychology; the rest of the world also has a lot to offer the field.

I have conducted most of my international work in the Ukraine, Russia and the former Soviet Union. This work has involved projects related to gender roles, career development of immigrants, the impact of persecution during Stalin's leadership upon later generations, and human trafficking. A recent project involved considering the rise of capitalism in Ukraine since the fall of the Soviet Union in 1991 and changes in sexist ideology. While many people assume capitalism brings positive change and benefits, through my work, I learned that Ukrainian women in this study were found to have stronger benevolent sexist attitudes about their gender and more hostile attitudes towards men compared to Ukrainian men. These findings reflect remasuclinization of the former Soviet Republics, which has consequences for women and may contribute to difficulties in intimate relationships between men and women. Division 52 has recognized my efforts in this area as I received the Student International Research of the Year Award in 2003.

In terms of my work on human trafficking, I have primarily served as a consultant on this topic. I would like to study human trafficking through empirical methods in the future. Since trafficking practices are well hidden from the public, it is a difficult topic to study. Therefore, I am currently working to establish local contacts that would facilitate future research. I am also working with Dr. Sharon Horne from The University of Memphis on an international multi-site project studying gender violence in the former Soviet Union and Eastern Europe. My work with this project has involved instrument translation. My work on xenophobia also involved instrument development as I constructed a scale to measure this construct.

Is there anything that surprised you/you had not expected about being involved in international work when you began?

I have found my work in the Ukraine to be a kind of tug-of-war. On the one hand it is easy to conduct research in the Ukraine as this is my home country. However, at the same

time, many Ukrainians perceive me as different from them since I live in the United States. As I negotiate this dilemma, I try to honor my own struggle in this meanwhile I respect the people with whom I work.

I have also been pleasantly surprised that I have received so much support within my department for my international work. Both when I was initially offered my faculty position and since my arrival, the College of Education and Human Sciences at the University of Nebraska, has provided support. This verbal encouragement has been reiterated and demonstrated as my department has provided funding for international research projects.

What do you think is the most important thing you have learned from your international / multicultural work? How has your work shaped your personal growth as a psychologist?

Be humble. The more I learn, the more I realize there is more I don't know than I do know. This is a continuing lesson for me. Sometimes I think I know a lot about a particular topic, like for example the Ukraine, but then as I continue with my research and consulting, I realize how much more there is beyond what I know.

I have also come to recognize that I am an international person. I bring this perspective to my professional work. For example, my international viewpoint is infused into my teaching, writing, mentoring and research, and is part of who I am as a professional. And as I continue to connect with people in other countries, I learn how they see things. This only opens me up and brings fullness to my professional and personal life. For me, this is a way to live.

How do you see yourself as a leader in this area?

I see myself as a leader in the field because I do research on topics and in regions that tend to be less commonly studied. For example, my work on human trafficking is especially unknown and is a new area within the field of Psychology.

I am currently one of three finalists for a position as an early career professional on APA's Committee on International Relations. If I receive this award, I see this position as an opportunity to continue to contribute as a leader in the international arena. Further, I hope I would bring my experiences on the Committee to working with students. Mentoring students is another important part of what I do, and I strive to help students to get involved in international research.

What led you to Division 52?

When I was a graduate student, I learned there was a division for international topics, Division 52. When I joined Division 52, I was excited to meet professionals in the field and become involved. Currently, there are two divisions in APA which I consider to be my home- Division 52 and Division 17, The Society of Counseling Psychology. The Society of Counseling Psychology is also forging important international studies and partnerships. I tend to split my time and energies between these two divisions, contributing to international projects in both.

What do you think are the most important benefits of being a Division 52 member? How has being a member shaped or influenced your career path?

The connections and collaborations that develop through being in Division 52 are reasons why this division is so strong and vibrant. I have found the division to be a place that creates opportunities. For example, I was looking for an instrument in another language, and I was able to find this through my connections in the Division. Listserves and websites are also helpful resources that facilitate Division events, opportunities, and partnerships. Participating in the division has encouraged me throughout in my international work and professional development. Currently, I am Co-Chair for the Task Force on Immigration and Refugee Issues within the division.

What advice can you give to new members of Division 52 who are just beginning their careers?

I encourage new members to get more involved, find opportunities to contribute. Getting involved will help you get know people. Get in, get dirty and get to know people. This is what makes the division a vibrant one.

What was your favorite holiday or vacation?

I love traveling internationally so my favorite kind of vacation is when I travel overseas with my husband and son. Also, I enjoy any vacation which includes hiking. My most recent trip was to Norway, so I was able to get in some hiking during my travel abroad.

Please share a favorite international/ethnic recipe with us.

There are two Ukrainian salads that I particularly enjoy. One salad is made with Beets and the other with Carrots.

Beet Salad
- Boil beets
- Grate the beets finely
- Add chopped prunes, walnuts, salt and pepper and mayonnaise
- Stir and Serve

Carrot Salad
- Grate carrots
- Add vinegar and oil
- Add raisins and almond slivers
- Stir and Serve

SUBMISSION DEADLINES
International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 1500 words and should be submitted to Dr. Senel Poyrazli at Poyrazli@psu.edu. Submission Deadlines: Spring issue March 31, Summer issue June 30, Fall issue September 15, and Winter issue December 15.

This is the sixth article in a series developed by Division 52's Student Committee (SC). Inspired by the recent Mentoring initiatives, these articles are intended to introduce readers to leaders on a professional and personal level. Also, as food is often a shared delight, we ask each leader to share a favorite recipe! So continue to watch this space in the International Psychology Bulletin for insight, wisdom, reflections on Div 52, and lip-smacking recipes!

Getting to Know: Sharon G. Horne, PhD

As shared with Güler Boyraz
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Sharon G. Horne is an Associate Professor of Counseling Psychology at The University of Memphis. She received her doctorate in Counseling Psychology from the University of Georgia. Her current interests are international issues of psychology; gay, lesbian, and bisexual health; and gender issues.

What internationally-related work have you done? How did you become interested in this work?

I was fortunate to have two very early inspiring international experiences—the first was when I was in junior high school, my Granddad was a visiting scholar at Cambridge in England, and my Mom and I took advantage of the occasion and visited him and toured around Scotland and the English countryside. Second, I spent my sophomore year of college in Germany and traveled throughout Western Europe and many parts of what was then Eastern Europe. I was always interested in Russian literature, and at Indiana University I declared Russian language and literature as well as journalism as majors. I was drawn to Slavic and Eastern European history and culture. My travels at 19 broadened my perspective on the world and my own country and spurred on interests in the Soviet Union and other regions of the world. When I finished my undergraduate degree, I was clear that I wanted to contribute to service in social justice and was determined to join the Peace Corps, which I did and served in Niger, West Africa. Africa really exposed me to a diversity of cultures and languages and gave me a wonderful first experience at teaching. Since my early twenties, I have worked and lived in many areas of the world and continue to do cross-cultural research with local colleagues and conduct trainings on psychological issues including GLBT, domestic violence, and gender concerns in those settings.

What do you think is the most important thing you have learned from your international / multicultural work? How has your work shaped your personal growth as a psychologist?

I think the learning process is accelerated in international work because the challenges and the rewards are both so abundant. For me, international work brings to the forefront areas that need growth since there is nothing like cross-cultural international work that exposes your flaws and limitations. For example, learning that your way of communicating is not working or misunderstanding cultural cues can really challenge your sense of effectiveness. This work also allows you to develop a stronger sense of purpose as you realize the importance and the benefits of engaging in cross-cultural collaboration. And of course, I have had re-affirmed over and over that there is connection and understanding across vast differences in culture and experience and that it is important to find these communalities and learn from one another. Values such as respect, trust, integrity and justice appear to be universal.

I feel that I became a psychologist *through* my international work and being able to integrate the two. Even as a graduate student, I had a supportive faculty at the University of Georgia who encouraged me to continue my international

work through the program. I try to bring a global perspective to whatever I am teaching whether it is theories of psychotherapy or supervision, and I mentor doctoral students who are international or who are interested in international issues.

How do you see yourself as a leader in this area?

I feel that I have contributed to the understanding of social justice in international psychology and have conducted research in the areas of ambivalent sexism and domestic violence, as well as international GLBT issues. Along with Dr. Susan Mathews, I developed an approach to international consultation that was built upon our experiences working collaboratively in international contexts. It draws from multicultural and feminist principles like respect for cultural differences and equality and encourages consultants to move beyond the expert Western tradition of consultation. I would like to continue to work in the areas of social justice in international contexts and to educate students on how to become internationally aware psychologists.

What led you to Division 52?

It seems like it was a natural fit given my interests and the mission of Division 52. It is always great to be part of a group that shares similar vision and interests, and I have been fortunate to meet many members whose international interests overlap with mine and who are invested in bringing an international perspective to U.S. psychology.

What do you think are the most important benefits of being a Division 52 member? How has being a member shaped or influenced your career path?

Engaging in international work can be pretty isolating within U.S. psychology, and being a part of 52 brings you together with others doing similar work—sometimes in the same region or if not, then methodologically. It gives you an opportunity to learn more about the important work being done in psychology around the world by our international colleagues, and it centralizes international psychology within APA. As this year's program chair I was inspired and impressed with the range of work submitted to 52 and the diversity of projects and research that was represented. Being exposed to new ideas challenges how I approach my work and which directions I take.

What advice can you give to new members of Division 52 who are just beginning their careers?

Just find a way to be active within the division—there are many leadership and networking opportunities. If you have a chance, go to the hospitality suite during APA and meet other members and learn more about the workings of the division. Our Student and Early Career Committees are really active and welcoming and go above and beyond to make new members feel at home. As well, The International Psychology Bulletin and 52 website are great ways to stay informed with 52 activities. I'm a relatively new member of 52 and I have found everyone to be inviting and friendly. If you have an idea for a project or an initiative, the members of 52 are very open to fresh ideas and new member input.

What was your favorite holiday or vacation?

Wow, I love holidays and vacation so choosing just one would be a challenge! I enjoy beaches and snorkeling so trips to Mexico, Thailand, and Kenya were enjoyable for those reasons. However, just spending time with family and friends over good food is my favorite type of holiday. My partner, Heidi Levitt, and I have a daughter who is four months old and who just received her passport and there are many adventures ahead of us.

Please share a favorite international/ethnic recipe with us.

This is a favorite recipe from Africa that Heidi and I have named our "Healing Heart Coconut Shrimp." We serve it whenever someone we know is having a hard time of it, especially when they are so down they "can't eat a thing." Miraculously after we ask them to just try a little bit, they are soon asking for seconds and thirds and are startled to find themselves smiling, and occasionally laughing along! We think it has something to do with the sweet coconut combined with the spicy pepper. Try it as a special cure for the blues!

HEALING HEART COCONUT SHRIMP

2-3 lbs. shrimp, peeled and deveined
¼ cub butter
3-4 cloves garlic, minced
1 small onion, finely chopped
2-3 sprigs parsley, finely chopped
2 chili peppers, or 1 tsp. cayenne pepper
1 tsp. salt
2 tsp. cumin
2 large tomatoes, chopped
2-3 cups coconut milk—depends on how much shrimp is used

Heat butter in a heavy skillet over moderate heat, and quickly cook the shrimp until they are a rich golden pine. Remove them for the pan with a slotted spoon. In the same butter, sauté the garlic, onion, parsley and chilies for 2-3 minutes. Add the salt, cumin and tomatoes and cook until the mixture thickens slightly, stirring constantly to avoid burning. Reduce heat to low, return shrimp to the pan and add the coconut milk. Stir until shrimp is heated through. Serve over sticky rice.

The International Society for Interpersonal Acceptance and Rejection and the School of Primary Education, University of Crete, Greece

have the pleasure to officially announce that **the 2nd International Congress on Interpersonal Acceptance and Rejection** will be held in Rethymno town on the island of Crete (at the University of Crete), from July 3rd – 6th, 2008.

For more information, please visit the Congress website: www.isipar08.org or contact Prof. Elias Kourkoutas, President of the Organizing Committee, at hkourk@edc.uoc.gr.

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Book Review: Swords into Plowshares, Spears into Pruning Hooks: Innovations in Contact between Warring Groups

Kuriansky, J. (Ed.). (2007). *Beyond bullets and bombs: Grassroots peacebuilding between Israelis and Palestinians.* Westport, CT: Praeger.

Reviewed by:
Michael J. Stevens, PhD, DHC

> Everyone is entitled to his own faith. No one should violate the intimate spiritual life of another. That is how I think now, that is how I have thought in the past, and if I live any longer, that is how I will think then.
>
> Bishop Boris Kharalampiev of Pazardjick,
> WWII rescuer of Bulgarian Jews

Peace in the Middle East requires a systematic and comprehensive approach that includes top-down approaches, that is, the negotiation of treaties and policies at the highest levels of government. Effective peace building simultaneously requires both middle-out and bottom-up approaches. Middle-out strategies involve efforts to influence community leaders, who then influence those above them along with their local constituencies. Bottom-up strategies are designed to influence large numbers of people directly. These middle-out and bottom up approaches are featured in Dr. Judy Kuriansky's most recent edited book, *Beyond Bullets and Bombs: Grassroots Peace Building Between Israelis and Palestinians*, which makes a singular contribution to the literature on the Middle East conflict and its resolution. It will inform concerned citizens, researchers and practitioners in the humanities and social sciences, as well as leaders in the public and private sector.

Kuriansky is distinctly qualified to edit such a benchmark volume, part of the Praeger series on contemporary psychology spearheaded by Dr. Chris Stout. A renowned clinical, international, and media psychologist, Kuriansky represents the International Association of Applied Psychology and World Council of Psychotherapy at the UN and serves on the UN NGO Committee on Mental Health. She has written extensively on peace building and has delivered lectures, programs, and workshops worldwide on this topic, receiving numerous awards for her contributions to advancing peace. As a follow-up to her earlier book, *Terror in the Holy Land: Inside the Anguish of the Israeli-Palestinian Conflict*, Kuriansky has assembled a new international set of authors, although most are Israelis and Palestinian. Their experiential, intellectual, and work backgrounds are quite varied, resulting in a panoply of multicultural, multidisciplinary, and multisectoral viewpoints. The chapters are similarly diverse in their emphasis on underlying conceptual models, supportive empirical data, innovative applied practices, and heroic personal narratives. Unlike *Terror in the Holy Land*, the richly diverse material and voices of *Beyond Bullets and Bombs* are linked to the potential peace dividend of Allport's (1954) contact hypothesis.

The 40 chapters of *Beyond Bullets and Bombs* are divided into four parts, each introduced by Kuriansky. Although the organization of chapters into their respective parts is thoughtful, the diverse aims and methods presented in several applied chapters could justify their placement into different parts. A few of these chapters could have been pruned from the book, as they do not offer much beyond similar interventions that are described more articulately elsewhere. In addition, it would have been beneficial to include at least one chapter on understanding and preventing terrorism from a psychosocial and/or sociocultural perspective, as this central topic is virtually neglected (see Stevens, 2005). For the most part, the chapters are evenhanded in tone. One, however, is thoroughly jingoist notwithstanding the use of balmy academic prose to render questionable positions more palatable.

Part One is a cornucopia of psychosocial and sociocultural perspectives with which to frame the Israeli-Palestinian conflict. Of particular value are models which identify individual and collective processes that either exacerbate or modulate the dynamics of intergroup conflict. From these models, authors fashion a broad spectrum of transformative methods, essentially dialogic, intended to humanize the other and promote reconciliation and healing. These social-reconstructive efforts underscore the paradox of incumbents of adversarial groups engaging in sensitive interpersonal listening, a topic also addressed in later chapters. The chapter by Karen Doubilet offers a cogent analysis of how status asymmetries in the Israeli-Palestinian conflict limit the applicability of the contact hypothesis (see Dixon, Durrheim, & Tredoux, 2005) and, thus, necessitate rethinking the goals and strategies of contact-oriented programs. Another by Yaron Prywes applies Kurt Lewin's $B = f(P \times E)$ equation to the reversal of intergroup violence; brilliantly integrating micro- and macro-level perspectives, Prywes calls for a consultative approach to establish optimal boundaries between groups with competing identities while ensuring each group's security.

Part Two offers compelling bottom-up examples of how rapport and respect between enemies can be enhanced via dialogue, specifically by sharing personal narratives. The

Parent Circle – Families Forum is a program for Israeli and Palestinian families that have lost relatives through violence, yet remain strongly committed to reconciliation and peace. Such bottom-up strategies are complemented by middle-out interventions, such as Nonviolent (Compassionate) Communication, which train peace activists on both sides. Other programs are apolitical and limited to interfaith encounters geared toward nurturing a fragile civil society. Still others are informal, such as Open Space Technology, in which group discussions take place without facilitators, and Living Room Dialogues, in which conflicting parties challenge their assumptions over a meal en route to mutual understanding. The chapter by Steinberg and Bar-On presents evidence of qualitative change in the discourse of workshop participants, noting that shifts in communication, though uneven, offer hope that intransigent perceptions of self, the other, and relationships can evolve.

Part Three extends the concept of contact via dialogue to creative new formats. Middle East Education through Technology is a bottom-up educational program for Israeli and Palestinian youth designed to enhance leadership and teamwork skills. Just Vision is a middle-out media approach consisting of online interviews with civic leaders whose personal narratives and peace-building activities express the values of equality and respect. Music is employed to repair relationships and strengthen cooperation between adversarial groups. Theater is used to promote dialogue on sensitive themes, such as stereotypes and violence. A promising grassroots approach to peace involves summer camps for Israeli and Palestinian youth. The Seeds of Peace Program offers integrated accommodations and activities plus facilitated dialogue; SeedsNet is a secure listserv that permits ongoing contact once campers return home. Because of real-world asymmetries, Israelis and Palestinians have divergent communication needs, with Israelis preferring to discover similarities and relate as individuals versus Palestinians, who stress collective identity and raise conflict-related issues. Consequently, camp encounters often have a mix-model approach to contact, grounded in social identity theory and realistic conflict theory. Thus, opportunities to dialogue as individuals, which promote understanding, must be complemented by opportunities to relate as representatives of conflicting groups, which promote negotiation.

Part Four speaks to peace building in schools, in therapy, and in the media. Because the chapters on mental health lean toward outreach and training, details on psychotherapeutic interventions for clients impaired by intergroup conflict are lacking. Public schools have been opened where Israeli and Palestinian children receive a bilingual, multicultural education. Textbooks have been written that expose children to the historical narratives of both groups, a welcome alternative to materials that maintain enmity. Teachers have been trained to implement lesson plans that foster cognitive and experiential growth; preliminary findings show that students better understand the views of the other and desire a more harmonious coexistence. Multisectoral training is available for clergy, diplomats, journalists, and NGO representatives to learn how they may unwittingly perpetuate trauma, can coordinate efforts at healing, and can instill moderation in national leaders and the general public. Television and radio series have been aired that depict pressing social issues and constructive solutions within the context of daily living; the Common Ground News Service publishes balanced and solution-oriented articles about the Middle East crisis that encourage rapproachment.

Israelis and Palestinians have tried to settle their longstanding conflict many times before, but to no avail. Will the 2007 gathering at Annapolis of 40-plus nations and organizations fulfill the agreed upon goal of a final peace treaty by the end of 2008? In addition to top-down treaty making, *Beyond Bullets and Bombs* showcases the necessity of bottom-up and middle-out approaches in establishing genuine peace in the Middle East. Interpersonal understanding and intergroup negotiation are the goals of interventions designed to bring enemies into contact in order to humanize the other and demythologize collective narratives. Dr. Judy Kuriansky has triumphed in informing us of the many paths to peace; we must now walk those paths.

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Stevens, M. J. (2005). What is terrorism and can psychology do anything to prevent it? *Behavioral Sciences and the Law, 23,* 507-526.

Call for Papers
International Psychology Bulletin
(APA Division 52)

We are accepting research manuscripts to be published in 2008 and 2009. Submitted papers will be subjected to a peer-review process. Please e-mail your manuscripts to the editor Dr. Senel Poyrazli at poyrazli@psu.edu. To review a copy of the Bulletin, please visit http://www.internationalpsychology.net

Book Review: Giving Peace a Chance: An Up-close and Personal Look at the "Forever War"

Kuriansky, J. (Ed.). (2006). *Terror in the holy land: Inside the anguish of the Israeli-Palestinian conflict.* Westport, CT: Praeger.

Reviewed by:
Michael J. Sevens, PhD, DHC

Terror in the Holy Land: Inside the Anguish of the Israeli-Palestinian Conflict (2006), edited by Judy Kuriansky, is at times an uncomfortable read, yet is altogether worthwhile. It is part of the contemporary psychology series edited by Chris Stout and published by Praeger. Kuriansky is uniquely qualified to bring this book of diverse voices together. A renowned media psychologist, she is a licensed clinical psychologist and adjunct professor at Columbia University Teachers College and College of Physicians and Surgeons. She represents the International Association of Applied Psychology and World Council for Psychology at the UN. She has lectured, conducted research, designed and led workshops and programs, and been honored throughout the world. She is an eminent international psychologist.

The book was conceived in 2002 at the World Congress of Psychotherapy as a vehicle through which representatives of both sides of the Israeli-Palestinian conflict could describe their suffering, articulate the psychosocial issues contributing to that conflict, and propose grassroots interventions intended to promote peace. The diversity of the volume is reflected in the ethnic and national identity of chapter authors, their training backgrounds, and their views of the Israeli-Palestinian conflict. The chapters are also diverse in their length, narrative and empirical content, conceptual and applied foci, descriptive and explanatory emphases, and academic and personal style of writing. Most importantly, virtually every chapter speaks to the complex, multi-determined causes of the current conflict, which is essential to a full appreciation of the suffering of individuals and families on both sides and to crafting innovative solutions for peace.

Terror in the Holy Land has four parts: Times of Terror, Psychosocial Issues in the Conflict, Women and Children Caught in the Conflict, and Therapeutic and Educational Efforts for Understanding, Coping, and Reconciliation. Although nested within each part according to similarity in content, chapters often have multiple foci or are integrative and, hence, could have been organized into an alternative configuration.

The first part, Times of Terror, establishes the context for the Israeli-Palestinian conflict and the psychosocial approaches for understanding it, including the individual and collective needs for social identity, heroes and myths, and national narratives. Other chapters describe the personal evolution of female homicide bombers as well as women who reject violence in favor of unity, macro-social conditions that contribute to the physical and psychological deterioration of individuals and families, and efforts to strengthen resilience and personal meaning notwithstanding chronically elevated fear and distress. One touching passage describes a woman who purchased lace undergarments as a symbol for her determination to exert personal control in the face of the unpredictable. It is comforting to learn, at the end of part one, that surveys show growing bilateral support for compromise and peace.

The second part addresses several psychosocial issues that permeate the Israeli-Palestinian conflict, namely revenge, humiliation, power asymmetry, and the search for identity, all of which are interlaced. A few chapters offer frameworks for peace, such as the process-oriented approach through which compassion, forgiveness, and community with adversarial groups can be forged out of a pre-existing thirst for retribution. One chapter provides an intriguing extension of terror-management theory, called Collective Identity Terror Management, in which collective self-efficacy and agency buffer groups against the fear of collective identity annihilation. The unique identity conflicts and approaches to conflict resolution of Israeli Bedouins are also examined. The chapters in Part Two, as in part one, are replete with interventions for individuals and small groups, including humor, aimed at overcoming obstacles to reconciliation. Narratives of transformed human lives are compelling, especially that of a Palestinian human rights activist whose personal journey illustrates the process by which suffering and hatred can evolve into empathy and social responsibility.

The third part centers on two at-risk populations: women and children. Chapters in this part of the book attempt to show how violence and the conditions that follow therefrom adversely impact Israeli and Palestinian women's lives (e.g., stress, domestic abuse, maternal illness). Some authors frame their analyses and interventions in feminist theory. Others present disturbing findings from research studies. For example, Palestinian teens who reported feeling oppressed and treated unjustly were more likely to experience higher anxiety and depression, which themselves were associated with greater sympathy for terrorism. The question that this study poses for Israeli policy makers is whether economic, military, and political strategies intended to ensure the safety of its citizen are paradoxically laying the groundwork for more violence. Part Three also features holistic prevention programs that are compatible with classroom curricula and designed to foster resilience in children as well as methods and materials to enhance coping skills and prevent or reverse children's demonization of the enemy.

Finally, in the fourth part, educators, mental health professionals, and physicians offer an array of procedures to improve understanding, coping, and reconciliation, some of which have been culturally adapted. Several chapters contain

narratives of working in a trauma center, integrating a Western perspective of human functioning and psychotherapy with a Palestinian cultural worldview, and training health professionals to integrate mind-body practices into their ongoing treatments. Particularly informative is a chapter that describes how ethnocultural views of identity, family, gender roles, politics, religion, and time influence the mental representations of psychological dysfunction and treatment among Israeli Palestinians. Issues such as stigma and shame at the individual, family, and community levels, preferences for indigenous healing, suspicion of Western-trained providers regardless of their ethnicity, and the need for flexible clinical and ethical decision making to incorporate cultural values are also presented. Other chapters describe an adult-education class that challenges rigidly held beliefs, which maintain distrust and a false sense of security, and nurtures the capacity to embrace alternative realities about the enemy and conflict. The concluding chapter articulates immediate and enduring factors that contribute to intractable conflict along with guidelines for reducing such conflict that obtain from these factors, including non-violent protest and moral appeals for peace.

Terror in the Holy Land accomplishes what no other book has achieved: to convey the personal suffering of Israelis and Palestinians as well as instill hope through wise and courageous voices for reconciliation and peace. The book is informative and engaging; it broadens and deepens our understanding of this tragic conflict and "local" strategies for its resolution. A statement by one author, however, belies a source of disappointment with the book: "…I cannot help feeling frustrated that dialogue with both suffering parties has had less influence in the dynamics of the conflict than I would hope" (Mendelsohn, 2006, p. 118). Regrettably, the bottom-up approaches for building peace that are presented are seldom integrated with either top-down or middle-out strategies. Top-down approaches to peace building include efforts to influence national and/or international authorities to craft laws and develop policies that are informed by psychological science. Middle-out approaches involve efforts to influence community leaders, who in turn influence leaders above them along with their constituencies. Any resolution to the Israeli-Palestinian conflict will require a multi-level, multi-sectoral approach that blends bottom-up with top-down and middle-out strategies. Keeping this in mind, the book might have offered more insight into how such a grand synthesis could be conceived and implemented. A second disappointment lies in the fact that many proposed interventions are not clearly tied to a conceptual framework and are not adequately supported by data or documentation of their effectiveness, especially the maintenance and generalization of any benefits they may bring about. Although this was not the aim of the book, a sophisticated reader will be left wondering about the theoretical rationale for selecting certain interventions over others and the empirical evidence that justifies their application. A final question concerns human nature itself: notwithstanding impressionistic reports suggesting that awareness, understanding, reconciliation, and peace are possible, are there limits to the possibilities for peace that are set by the degree to which humans are hard-wired for tribalism and conflict? A sobering thought, indeed.

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ANNOUNCING THE PUBLICATION OF…

Jimerson, S., Oakland, T., & Farrell, P. (Ed).
The handbook of international school psychology.
Thousand Oaks, CA: Sage.

The status of school psychology in 43 countries is discussed. Each country-related chapter includes a discussion of the context for services (e.g., a country's prominent demographic, geographic, economic, political, educational qualities); the origins, history, and current status of school psychology; its infrastructure; preparation of school psychologists; current issues; and print and electronic references. Additional chapters discuss the history of school psychology and the impact of the International School Psychology Association and provide a synthesis of information from the 43 countries. Although national differences exist, values and practices are common across countries and thus link the specialty of school psychology, given its common goals to help educate and in other ways promote the development of healthy children and youth. School psychology constitutes psychology's porthole to children and youth from all backgrounds. Thus, knowledge of its status in the reporting countries and others informs us as to the nature and level of services provided to children and youth.

Pilisuk, M. & Achord Rountree, J. (2007)
Who benefits from global violence and war: Uncovering a destructive system. **Westport, CT: Greenwood/Praeger**

Military, economic, and environmental violence in the era of globalization cause immense suffering and may ultimately threaten the existence of life as we know it, but the author, Pilisuk, explains that the future can change if we understand and act upon the roots of violence. A professor emeritus of psychology and human and community development, Pilisuk explains how most violence is the product of a human-built social order in which some people and institutions control most of the resources, make the decisions that necessitate violence, and operate with minimal accountability. […] This text includes scholarship hailing from across disciplines, combined with information from investigative journalism, and insights from nonprofit watchdog groups, all shedding light on centralized power and its effects. Pilisuk presents material including the range of tactics used to manipulate and destroy adversaries, the human capacity to kill as a challenge, and how media is used by powerful groups to manipulate fear and maintain their power. Here readers find solid social science to support what whistleblowers and social critics are observing about a system that needs change.

ALSO ANNOUNCING THE PUBLICATION OF…..

Hays, P. A. (2008). *Addressing cultural complexities in practice: Assessment, diagnosis, and therapy (2nd Edition).* Washington D.C.: American Psychological Association.

Hays, P. A., & Iwamasa, G. Y. (2006). *Culturally responsive cognitive-behavioral therapy: Assessment, practice, and supervision*. Washington D.C.: American Psychological Association.

*If you would like to include a book in a future issue of IPB, please email information to Jennifer Lancaster at jlancaster@stfranciscollege.edu *

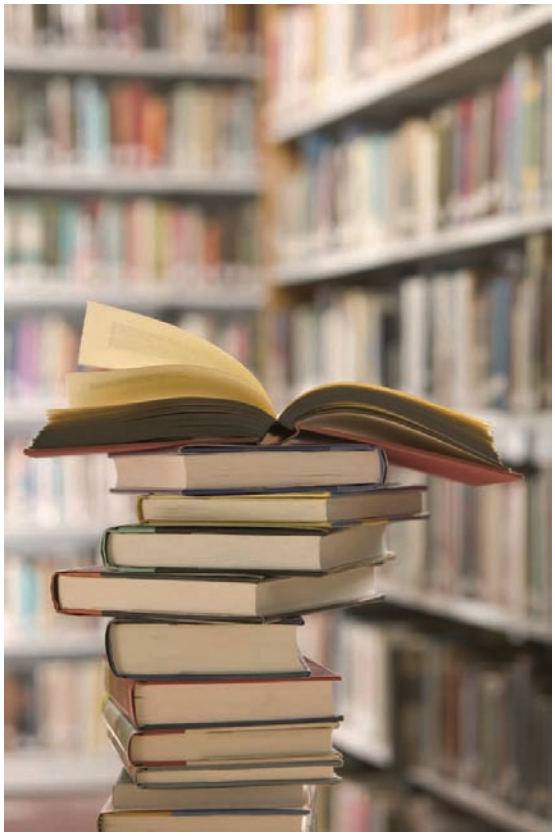

Recent Initiatives Impacting International Policy: An update from the Public Interest Government Relations Office

Day Al-Mohamed
Senior Legislative and Federal Affairs Officer
Public Interest Directorate
American Psychological Association

The Public Interest Government Relations Office (PI-GRO) of the American Psychological Association actively engages in shaping federal policy to promote psychology for the advancement of health, education, and human welfare. PI-GRO's policy initiatives include a range of activities impacting older adults; children, youth, and families; individuals with disabilities; ethnic minorities; individuals with HIV/AIDS; lesbian, gay, bisexual, and transgender persons; women; and socioeconomic status issues.

PI-GRO activities include the preparation of legislative background materials, statutory provisions, language recommendations and formal comments on proposed national and international policy statements, legislation, and regulations, as well as training and mobilizing the APA membership for grassroots advocacy efforts. The office also identifies and secures the participation of psychologists to testify at congressional hearings and briefings, and to represent the association on federal agency advisory councils and executive branch meetings.

The information below outlines some of PI-GRO's key recent activities impacting international issues.

Immigration and Immigrants

With the congressional interest and activities that have evolved around immigration policy, PI-GRO has focused its efforts on issues involving health care, education, and language access.

Health Care Access

Since 1996, documented immigrants have been barred for five years from access to health care and other important services available under federal programs. To address this, PI-GRO staff has been actively working on the issue of immigrant access to services and supports such as the following legislative proposals:

The Immigrant Children's Health Improvement Act would provide states the increased flexibility to provide federally-funded Medicaid and *State Children's Health Insurance Program* (SCHIP) to meet the public health needs of low-income documented immigrant children and pregnant women. While legislation for the provision of health care access for immigrant children has not passed, the strong support for immigrant access to health care has lead to commitments by several legislators to bring forward future legislation to address this important issue.

The Supplemental Security Income (SSI) Extension for Elderly and Disabled Refugees Act would provide SSI benefits for refugees, asylees and other humanitarian immigrants such as victims of trafficking, Amerasian immigrants, and immigrants granted withholding of deportation/removal for an additional two years. In most states, SSI beneficiaries also receive Medicaid (medical assistance) to pay for hospital stays, doctor bills, prescription drugs, and other critical health costs.

Language Access and English Language Learners

PI-GRO staff has been working to ensure the provision of native language access, and funding and services for English Language Learners in a range of legislative and regulatory initiatives such as:

The Individuals with Disabilities Education Improvement Act (IDEA) to provide linguistically-appropriate services to infants and toddlers with disabilities and children who may have been victims of abuse.

The State Children's Health Insurance Program (SCHIP) to include an enhanced federal matching rate to states for translation and interpretation services in the continuing versions of the legislation.

The Health Equity and Accountability Act of 2007 to require each Federal agency to develop and implement a system by which individuals with limited English proficiency will have meaningful access, setting minimum standards for these services.

The No Child Left Behind Act (NCLB) reauthorization advocating for increased flexibility and appropriate funding for services that support English language learners.

The Development, Relief, and Education for Alien Minors (DREAM) Act to allow undocumented immigrants under age 30 to remain in the United States and alter their status if they attend college or join the military.

Collaborative Activities with the APA Office on International Relations

PI-GRO works collaboratively with APA's Office on International Relations on an array of issues. These activities have included the provision of comments and recommendations on United Nations NGO coalition documents and statements to encourage more inclusive language that fully encompasses APA's comprehensive perspective including:

Official Statement of the NGO Committee on UNICEF - *Emerging Themes from NGOs on the World Fit for Children (+5) Commemoration based on the Report of the Secretary General:* Follow-up to the Special Session of the General

Assembly on Children regarding themes identified as needing significantly greater attention by Member States as they reaffirm their commitments of 2002.

Statement from the Society for Women and AIDS in Africa to the U.N. Economic and Social Council Commission on the Status of Women regarding the discrimination and inequitable distribution of funding for HIV/AIDS treatment, counseling and supports for women and girls.

Statement from NGOs to the U.N. Economic and Social Council Commission for Social Development on the theme - *Promotion of Full Employment and Decent Work for All* to advance the goal of full employment as a basic priority of economic and social policies, and to eliminate barriers to financial and employment security for all individuals.

Language recommendations proposed by the PI-GRO and the Office on International Relations throughout the various statements included:

- additional supports for adolescent health;
- culturally and linguistically appropriate initiatives for racial and ethnic minorities and indigenous populations;
- the incorporation of pediatric treatment, and psychosocial and behavioral interventions for individuals with HIV/AIDS;
- efforts to combat discrimination and stigma in education and employment for individuals with disabilities; and
- supports and services for child-soldiers and victims of trafficking.

Getting Involved

PI-GRO will continue to advocate for inclusive national and international policy that addresses the comprehensive stance of APA. We invite all APA members to participate in this vital process. Expertise in all areas of psychology are necessary and instrumental to ensure that international issues are effectively integrated into APA's overall advocacy strategies.

We encourage you to sign up for the APA's Public Policy Action Network at http://www.apa.org/ppo/ppan/aboutppan.html to receive legislative updates and participate in coordinated outreach to your federal legislators.

For a comprehensive overview of all Public Interest Government Relations issues, visit APA's Government Relations Web site at www.apa.org/ppo/pi.

For more information on these policy issues, please contact Day Al-Mohamed, J.D. in APA's Public Interest Government Relations Office at DWilliamsAl-Mohamed@apa.org or 202-336-6061.

Special Issue
American Journal of Media Psychology "Media Psychology and International Public Diplomacy"

Michael Elasmar, Ph.D, Editor
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There was a time when much of international public diplomacy took place among diplomats and opinion leaders of various countries. Today, international public diplomacy entails explicit and implicit messages sent by a government in one country to members of a general public in another country for the purpose of shaping their attitudes toward some aspect of the sending country. What processes can best describe attitude formation and/or attitude change as it relates to international public diplomacy in a global media environment? What role, if any, do the international media networks (news and entertainment, traditional and Web-based) play in this context?

Researchers with interests in such areas as attitude formation and change, media psychology, social psychology, cross-cultural communication, political communication, public opinion, international communication, news exposure, international relations, media effects and related topics are invited to submit papers to the American Journal of Media Psychology for a special issue that focuses on explaining attitude formation and attitude change as related to international public diplomacy within a global media environment.

Submissions sought are ones that tackle this topic by either focusing exclusively on applying psychology and/or communication theories to this topic area, and/or conducting comprehensive literature reviews of studies that have findings that are applicable to this topic area, and/or carrying out theory-driven empirical investigations that focus on this topic.

Currently, we are still accepting manuscripts.

The American Journal of Media Psychology is a peer-reviewed scientific journal that publishes theoretical and empirical papers and essays and book reviews that advance an understanding of media effects and processes on individuals in society. Submissions should have a psychological focus, which means the level of analysis should focus on individuals and their interaction with or relationship to mass media content and institutions. All theoretical and methodological perspectives are welcomed. For instructions on submitting a manuscript, please point your browser to http://www.marquettejournals.org/mediapsychology.html

Questions about this call for manuscripts can be directed to Dr. Michael Elasmar, Editor, American Journal of Media Psychology at elasmar@bu.edu.

Human Trafficking: Challenges for International Psychology

Dr. Ani Kalayjian
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From Himalayan villages to Eastern European cities, people—especially women and girls—are attracted by the prospect of a well-paying job as a domestic servant, waitress, factory worker or prostitute. Traffickers recruit victims through fake advertisements, mail-order bride catalogs, and casual acquaintances.

Upon arrival at their destination, victims are placed in conditions controlled by traffickers and are exploited to generate illicit revenues. Many are physically confined, their travel or identity documents are confiscated, and they or their families are threatened if they do not cooperate. Traffickers blackmail the women and girls forced to work as prostitutes with the threat that they will tell the girls' families of their activities. Trafficked children are dependent on their traffickers for food, shelter, and other basic necessities. Even in New York, on December 18, it was announced that a couple in Long Island had been keeping two Asian young girls as slaves, deprived of their human rights.

Another tactic of traffickers that helps them maintain control over the women is to play on the victims' fears that authorities in a strange country will prosecute or deport them if they ask for help, or if they ask for their human rights.

Trafficking in human beings is a global issue and needs a global response. There is a need to strengthen the criminal justice response to trafficking through legislative reform, raising awareness, and training, as well as through national and international cooperation.

The following are current statistics that pertain to the issue of trafficking.

- Europol estimates that the sex-trafficking industry is now worth several billion dollars a year.
- A recent CIA report estimated that between 45,000 and 50,000 women and children are brought to the United States every year under false pretenses and are forced to work as prostitutes, abused laborers, or servants.
- UNICEF estimates that more than 200,000 children are enslaved via cross-border smuggling in West and Central Africa.

A report from 2000 by the Congressional Research Service gives the following figures.

- More than 225,000 victims arrive in US annually from Southeast Asia and more than 150,000 come from South Asia.
- The former Soviet Union has become the largest new source of forced prostitution, with 100,000 individuals trafficked each year from the New Independent States, including Armenian women sent to neighboring countries such as Turkey.

Reported profile of victims and the purpose of human trafficking at the global level

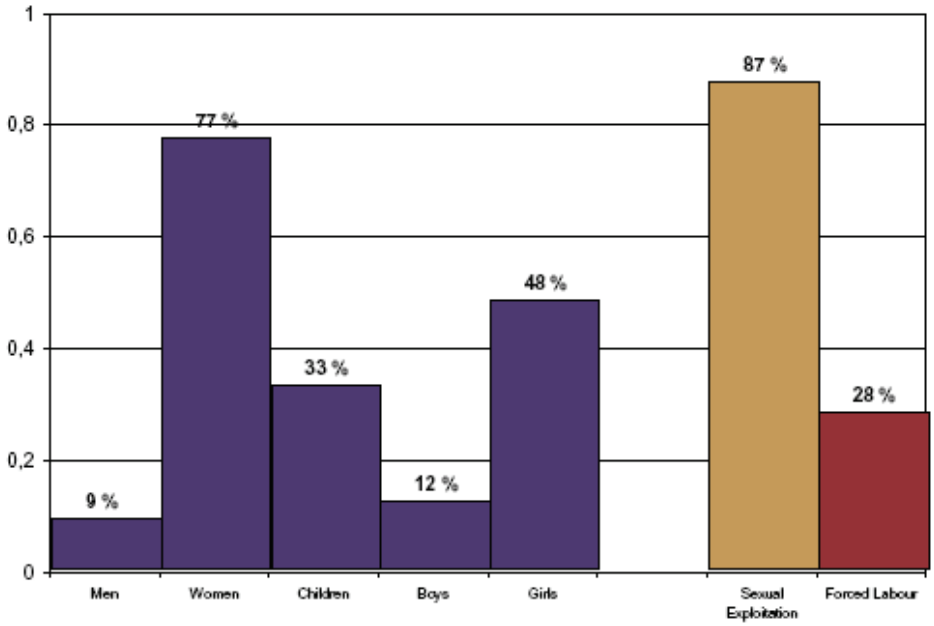

*Source: Report on Human Trafficking, United Nations (April, 2006)

- More than 75,000 are trafficked from Eastern Europe, 100,000 from Latin America and the Caribbean, and more than 50,000 from Africa.

"Trafficking in persons" shall mean the recruitment, transportation, transfer, harboring, or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labor or services, slavery or practices similar to slavery, servitude, or the removal of organs."

—Article 3, paragraph (a) of the Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention Against Transnational Organized Crime

The three aspects of human trafficking:

1) The act
2) The means
3) The motive

Who is most vulnerable?

- Traffickers target women and children in particular.
- Poverty, unemployment, and lack of education and access to resources are the driving forces behind people taking risks to improve their living conditions.
- South Asia, Southeast Asia and the nations of the former Soviet Union are the largest current sources of people for the trafficking business.
- Conflict zones, in which combatants create a market for the illegal trade and where the governmental and local law enforcement systems have eroded, make abduction, transportation, and forced service easier for traffickers to perpetrate.
- Conflict zones such as Sri Lanka, Cambodia, and Argentina, where young boys are abducted to be used for suicide bombers and other terrorist acts.

What is the UN doing?

The UN has put in place a Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children. Its purpose is to prevent and combat trafficking, to protect and assist victims, and to promote international cooperation.

Summary and key points of the Protocol:

- The Protocol sets forth a functioning definition of "human trafficking," as developed and agreed upon by the international community.
- While setting out strict legal guidelines for dealing with traffickers, the protocol also address the need to protect victims of trafficking in their home countries and abroad.
- Law-enforcement agencies of countries that ratify the Protocol are required to cooperate in such matters as assisting with the identification of offenders and trafficked persons, sharing information about the methods of offenders, and supporting the training of investigators and law-enforcement and victim-support personnel.

UN Global Program against Trafficking Human Beings

The key components of the Program are data collection, assessment and technical cooperation.

Assessment

– The assessment component of the Program, performed in cooperation with United Nations Interregional Crime and Justice Research Institute (UNICRI), includes data collection on various smuggling routes and the methods used by organized criminal groups in trafficking.

– The UN is also collecting "best practices" used in combating trafficking and the involvement of organized crime. A database containing trafficking trends and routes, as well as information about victims and traffickers has been established so that policy makers, practitioners, researchers, and the NGO community can use the collected data.

Technical cooperation

– Based on the assessment, seven countries are now involved in technical cooperation projects. Specific intervention measures are being introduced that are designed to strengthen the capacity to combat forms of trafficking at the national and international levels.

– These measures will assist countries of origin, transit, and destination to develop joint strategies and practical actions.

What are the obstacles?

- Lack of an incorporative, universal database
- Difficulty in collecting reliable data due to the international and illicit nature of human trafficking
- Varying political stances on prostitution between states
- Lack of international attention
- Demonization of victims by international press and the public

What are NGOs doing?

Support and assistance:

Organizing social support and practical assistance for the victim-survivors (safe shelter, legal aid, finances for basic needs, medical services, counseling)

Advocacy and campaigning:

Performed in the fields of domestic legislation and litigation, social policies, migrant women's' rights, (migrant) prostitutes' rights, assistance program and strengthen political commitment to combating trafficking of women

Information and training
Documentation and information services, tailored to inform specific relevant groups in the society, are aimed at increasing public awareness of the issue
Publications/collaboration/data collection
Developing and delivering innovative child-protection programs

What can you do?

- Educate yourself about the nature and scope of the problem.
- Disseminate information about human trafficking to the public.
- Participate in seminars and workshops aimed at victim advocacy.
- Form a meaningful and loving relationship and DO NOT buy sex, which reinforces the need to have women and children trafficked.

For more information related to this topic, please refer to http://www.meaningfulworld.com

Human Organs Save Lives: An Emerging Opportunity f or Psychologists World-Wide

Lynda J. Carpenter & Harold Takooshian

As the number of psychologists grows world-wide (Stevens & Gielen, 2007), so also do bold new opportunities for these psychologists. One of the most overlooked yet important of these emerging opportunities is in the fast-growing field of human organ donation and transplantation (Sanz et al., 2007). This brief report offers an overview of the good and bad news about organ donation world-wide, and how indigenous psychologists in each nation might participate in this life-saving specialty.

First the good news: Organs save lives. Since the first transplantations of a human kidney between identical twins in 1954 in Boston, and a human heart between strangers in Capetown, South Africa in 1967, organ transplantation has grown into an immense and life-saving field in the USA (WHO, 2004). In 1988, the discovery of cyclosporine, a medicine to reduce organ rejection, greatly increased the feasibility of all sorts of transplants. Today patients receiving organs live longer than ever before, thanks to these anti-rejection drugs and new follow–up protocols. Each year in the USA, life-saving surgeons transplant 12,000 kidneys, 2,100 hearts, 850 lungs, and 4,500 livers. In 2006, 11,000 organ donors saved an estimated 22,000 lives with transplanted organs, and such transplantation is similarly increasing in other nations (Olbrisch et al., 2002).

But the bad news: There is a world-wide shortage of human organs. More than 500,000 are waiting worldwide. In the USA, an ever-growing waiting list has more than 98,000 severely ill patients registered to receive a donated organ, and an average of 18 die each day while waiting (Carpenter, 2007). These people of all ages and backgrounds compete for scarce organs, and many are told they have virtually no chance of success because the demand so far outnumbers the supply (Batson & Oster, 2007). Though nearly 100% of Americans favor the use of donated organs, barely 50% are registered donors—a gap apparently related to misinformation about donation. In 2003 Tommy Thompson (then U.S. Secretary of Health and Human Service) initiated the Organ Donation Breakthrough Collaborative, to raise donation rates in the top 200 U.S. hospitals to 75%; with great success. Yet until the supply of life-saving organs increases, many will continue to die while waiting. One patient requiring a kidney transplant purchased his organ on eBay, but U.S. law prevented this kidney from being transplanted. Recipients desperately waiting for a transplant may go to many extremes, but the WHO (2004) guidelines prohibit the sale of human body parts. Today a patient waiting for an organ can check www.matchingdonors.com, to receive an organ from an altruistic stranger, or other sites for detailed information—such as www.donatelifeny.org, or www.unos.org.

How can indigenous psychologists help? Consider these two points: (1) in each nation, there are wide variations in beliefs, values, policies about organ donation. (2) Like the USA, each nation seems to have its inaccurate information about organ donation, that likely prevent more people from registering as organ donors, or being organ donors upon death. It is simple for a local psychologist to cooperate with their local organ procurement organization (OPO) to study this process, and thus help increase the donation of life-saving

organs. For example, in one of several U.S. studies, a team of four Fordham University researchers used an anonymous 20-item public opinion survey to test for a link between one's beliefs and behavior (Nickols, Stark, Viviano, & Whitney, 2007). Based on responses of 135 New Yorkers, they found, as hypothesized, that: (1) On a 0-40 point scale, the accuracy of people's knowledge varied greatly, from 16 to 37, with a mean of 25.0. Of the 10 items listed in table 1, the two least accurate beliefs--about religion (1.7), and about wealth (1.8)--could well deter donations. (2) The more accurate one's beliefs, the more they intended to donate organs ($r = +.23$, $p<.05$).

Table 1: Ten common myths, and the mean U.S. accuracy score on each, from 0 (inaccurate) to 4 (very accurate)

1.7 Virtually every major religion supports the donation of our organs and tissues to others. (T)
1.8 Given equal need, a wealthy American will get an organ before a poor American.
2.1 A person who survived cancer 10 years ago can *not* donate any of his/her organs.
2.3 Today, fewer than 50% of organ transplants succeed.
2.6 A person's next of kin must give permission before one can become an organ donor.
2.7 Hospital staff may be more likely to let an accident victim die if they see "organ donor" printed on their driver's license.
2.8 Most people who need an organ transplant receive it.
2.8 When a deceased person donates organs, their family has to incur additional medical costs as a result.
3.0 Today, people receiving a donated organ (e.g., heart, lungs, liver, kidneys, pancreas, intestine) can lead completely full and vital lives. (T)
3.3 A person's organs can only go to someone within their own racial group.
Note: (T) = two true statements, among 8 myths.

It is quite simple for indigenous psychologists to translate and replicate this or a similar checklist, to gauge public beliefs in their region, then identify and correct any local misconceptions. An ideal design would be a pre-post design, in which students or others are surveyed before and after a brief presentation on the often-misunderstood process of organ transplantation. Indeed, such a recent effort within the Chinese-American community by the NY Organ Donor Network reported success in raising donation rates once cultural concerns had been correctly identified (Rivera & Hebert, 2007). A similar effort by psychologists in other nations could prove to be international "psychology at its best" (Miller, 1969), in which the skills of local psychologists directly impact, if not save human lives. Anyone interested in this opportunity can contact the first author at jmlynda@gmail.com for U.S. surveys and additional details.

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Conference on Internationalizing the Psychology Curriculum

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On November 9-10, 2007, premier faculty from various institutions gathered at St. Francis College in Brooklyn (New York City) for a conference on *Internationalizing the Psychology Curriculum*. The event was sponsored by the Institute for International and Cross-Cultural Psychology and hosted by Uwe P. Gielen and Jennifer Lancaster of St. Francis College.

The conference welcomed leaders in the field of international psychology to present their research findings and ideas to the body of participants who included fellow psychologists as well as undergraduate students. Division 52 President **Michael J. Stevens** (Illinois State University-Normal) began the conference with a challenge to "kick it up a notch" in

internationalizing the psychology curriculum. **Richard Velayo** (Pace University) provided an update from the APA Task Force charged to examine this issue. Also among the presenters was **Senel Poyrazli** of Pennsylvania State University who presented "*Contributing to the Internationalization of Psychology Curriculum: Challenges Faced by Psychology Instructors.*" Providing the technology piece were **Ting Lei** (City University of New York), **Quiao Yun Li** (Cooper Union College), and **Ina Lei** (City University of New York) who presented "… *Distance is a Click Away in Internationalizing the Curriculum*." This was followed by a round table discussion involving both the presenters and the audience. **Judy Kuriansky** from Teachers College, Columbia University videotaped the discussion for possible future use in a Division 52-sponsored video on international psychology.

Day Two of the Conference continued to examine the issue of internationalizing the curriculum from more varied angles. **Wade Pickren** (Ryerson University) began the day discussing how indigenous psychologies might help to revitalize the history of psychology course. **Juris G. Draguns** (Pennsylvania State University) followed with a discussion from the field of abnormal psychology which highlighted the need for research papers to be available world-wide. Psychologists outside the US are doing great research, but only a limited number of people have access to that literature, an issue which is problematic, said Draguns. Long-time international psychology supporter and scholar, **Florence L. Denmark** (Pace University) spoke to the issue of internationalizing the psychology of women curriculum. Undergraduate students from St. Francis College (**John Angerami, Brendan Gorman, Laura Donodeo**, and **George Gundy**) then provided a student perspective on the topic which included their views as to how international topics could be introduced in the curriculum and how such an internationalization might impact their academic and professional careers. **Uwe P. Gielen** (St. Francis College) then presented "*A Global View of Childhood*" which emphasized some of the issues related to children who reside outside the US. **Harold Takooshian** (Fordham University) and **Uwe P. Gielen** presented details as to their experiences in Kuwait and how we might be able to measure outcomes in psychology from an international perspective.

The conference closed with summaries and remarks from both **Michael J. Stevens** and **Juris G. Draguns**. The information exchange and dialogue of the two-day affair will likely lead to a book edited by **Michael J. Stevens** and **Uwe P. Gielen** and include chapters from some of the conference speakers as well as others. Details of the publication are still being solidified.

International Genocide Scholars Association Officially Recognizes Assyrian, Greek Genocides

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In a groundbreaking move, the International Association of Genocide Scholars (IAGS) has voted overwhelmingly to recognize the genocides inflicted on Assyrian and Greek populations of the Ottoman Empire between 1914 and 1923.

The resolution passed with the support of fully 83 percent of IAGS members who voted. The resolution (text below) declares that "it is the conviction of the International Association of Genocide Scholars that the Ottoman campaign against Christian minorities of the Empire between 1914 and 1923 constituted a genocide against Armenians, Assyrians, and Pontian and Anatolian Greeks." It "calls upon the government of Turkey to acknowledge the genocides against these populations, to issue a formal apology, and to take prompt and meaningful steps toward restitution."

In 1997, the IAGS officially recognized the Armenian genocide. The current resolution notes that while activist and scholarly efforts have resulted in widespread acceptance of the Armenian genocide, there has been "little recognition of the qualitatively similar genocides against other Christian minorities of the Ottoman Empire." Assyrians, along with Pontian and Anatolian Greeks, were killed on a scale equivalent in per capita terms to the catastrophe inflicted on the Armenian population of the empire -- and by much the same methods, including mass executions, death marches, and starvation.

IAGS member Adam Jones drafted the resolution, and lobbied for it along with fellow member Thea Halo, whose mother Sano survived the Pontian Greek genocide. In an address to the membership at the IAGS conference in Sarajevo, Bosnia, in July 2007, Jones paid tribute to the efforts of "representatives of the Greek and Assyrian communities ... to publicize and call on the present Turkish government to acknowledge the genocides inflicted on their populations," which had made Asia Minor their home for millennia. The umbrella term "Assyrians" includes Chaldeans, Nestorians, Syriacs, Aramaens, Eastern Orthodox Syrians, and Jacobites.

"The overwhelming backing given to this resolution by the world's leading genocide scholars organization will help to raise consciousness about the Assyrian and Greek genocides," Jones said on December 15. "It will also act as a powerful counter to those, especially in present-day Turkey, who still ignore or deny outright the genocides of the Ottoman

Christian minorities."

The resolution stated that "the denial of genocide is widely recognized as the final stage of genocide, enshrining impunity for the perpetrators of genocide, and demonstrably paving the way for future genocides." The Assyrian population of Iraq, for example, remains highly vulnerable to genocidal attack. Since 2003, Iraqi Assyrians have been exposed to severe persecution and "ethnic cleansing"; it is believed that up to half the Assyrian population has fled the country.

Extensive supporting documentation for the Assyrian and Greek genocides was circulated to IAGS members in the months prior to the vote, and is available at http://www.genocidetext.net/iags_resolution_supporting_documentation.htm. IAGS President Gregory Stanton may be contacted at iagspresident@aol.com.

FULL TEXT OF THE IAGS RESOLUTION:

WHEREAS the denial of genocide is widely recognized as the final stage of genocide, enshrining impunity for the perpetrators of genocide, and demonstrably paving the way for future genocides;

WHEREAS the Ottoman genocide against minority populations during and following the First World War is usually depicted as a genocide against Armenians alone, with little recognition of the qualitatively similar genocides against other Christian minorities of the Ottoman Empire;

BE IT RESOLVED that it is the conviction of the International Association of Genocide Scholars that the Ottoman campaign against Christian minorities of the Empire between 1914 and 1923 constituted a genocide against Armenians, Assyrians, and Pontian and Anatolian Greeks.

BE IT FURTHER RESOLVED that the Association calls upon the government of Turkey to acknowledge the genocides against these populations, to issue a formal apology, and to take prompt and meaningful steps toward restitution.

International Employment Opportunities

Michael J. Stevens, PhD, DHC
President
APA Division 52 International Psychology

American University of Antigua, Behavioral Science Department— The American University of Antigua (AUA) is seeking applications for full-time faculty for the Behavioral Science Department. AUA is a young and fast growing medical university located on the beautiful Caribbean island of Antigua. Our hospital-based curriculum follows the U.S. model of medical education with emphasis on integration of the basic sciences. A high degree of clinical correlations, case studies, and problem-solving is incorporated in all courses throughout the basic science segment. The basic science segment is taught in Antigua and the clinical segment is conducted in various hospitals in the United States. AUA is ECFMG recognized and approved by the New York State Medical Board. Our students are eligible for taking the U.S. medical licensure examinations. AUA is a teaching institution and our focus is on excellence in teaching and student support. However, research activities in various areas of medicine and biomedical sciences are encouraged and supported.

Responsibilities: The successful candidates will participate in teaching both the premed and medical school behavioral science courses and will provide individual, couple, and group counseling and outreach activities for students.

Qualifications: PhD or EdD in psychology or a counseling-related field. All applicants must have experience in teaching and counseling.

Salary: Tax-free, commensurate with experience. Financial assistance for relocation to Antigua will be provided.

Initial Employment: 12 months, full-time

Application Deadline: The position is available immediately and the application deadline will be kept open until the position is filled.

Application Procedure: Please send cover letter, CV, transcripts, statement of teaching philosophy, and three letters of reference with contact information to:
Dr. Deborah Gerrity
Associate Professor of Behavioral Sciences and University Counselor
E-mail: dgerrity@auamed.net
Web: www.auamed.org

Queensland Government, Center of Excellence— The Center of Excellence is seeking leading experts in disability and mental health research and practice for the new Center of Excellence for Behavior Support. The Center will lead and participate in local and international research in behavior support to assist adults with a disability who exhibit severely challenging behaviors to participate in every day life. The Center will draw on expertise from across the disability, health and mental health sectors to guide policy and practice, and deliver workforce training.

Director, Learning and Development— You will lead the development and delivery of statewide learning and development activities for clinicians and direct support workers who support adults with intellectual or cognitive disabilities and challenging behaviors. Learning programs will focus on evidence-based practice and positive behavior support. (Total package value AU$98 621 – $104 306)

Director, Research in Behavior Support— You will lead research in behavior support and practice, providing valuable evidence to inform the development of disability and mental health services. Your research outcomes will help shape the future of behavior support and practice for adults with intellectual or cognitive disabilities and challenging behaviors. (Total package value AU$120 077 – $125 637)

Director, Policy Research— You will lead policy research in prevention, early intervention, and positive lifestyle behavior support for adults with intellectual or cognitive disabilities and challenging behaviors. The results of this policy research will guide practice to reduce or eliminate the use of restrictive practices. (Total package value AU$120 077 – $125 637)

Individual Response Leader (five positions)— You will provide strong leadership skills in clinical practice across the disability and mental health sectors. While working toward reducing the use of restrictive practices to manage challenging behaviors, you will provide expert guidance for clinicians and service providers who deliver positive and active support services to adults with intellectual or cognitive disabilities and challenging behaviors. (Total package value AU$109 886 – $114 520)

Principal Clinician (six positions)— You will lead a multidisciplinary team that will conduct assessments, develop plans and coach direct support workers to provide positive behavior support to adults with intellectual or cognitive disabilities and challenging behaviors. You will work closely with disability service providers to support adults with a disability to participate in community living. (Total package value AU$98 621 – $104 306)

Successful applicants will be offered an excellent remuneration and benefits package.

Disability Services Queensland can offer visa sponsorship to non-residents of Australia through a Temporary Business Long Stay Visa (Sub-class 457) and assistance to relocate to Brisbane, Australia.

For an information pack e-mail careers@disability.qld.gov.au or call +61 7 3224 2813.
To apply, visit www.disability.qld.gov.au/positive-futures.

Simon Fraser University, Interdisciplinary Chair— Simon Fraser University seeks to fill a junior university chair effective September 1, 2008, subject to budgetary authorization and approval by the Board of Governors. This is a tenure-track appointment at the senior assistant or junior associate level. The position is funded by and associated with the SFU Community Trust Endowment Fund (CTEF) project "Education organization and outcomes in diverse communities", an interdisciplinary research project involving faculty from the Department of Psychology, Department of Economics, Graduate Public Policy Program, and Faculty of Education. The position can be located in any of these four units (a cross-appointment is also possible).

Social or developmental psychologists with interests in intergroup relations, identity, diversity, culture, and/or prejudice and discrimination (all broadly defined), who have demonstrated excellence in research and teaching, will be given serious consideration for an ap-

pointment to the Department of Psychology. The successful candidate will be expected to take an active role in training graduate students as well as providing undergraduate teaching, and will have the opportunity to connect with a multi-disciplinary group of researchers. Candidates should have completed their Ph.D. within the last 10 years.

Applicants should send a letter of application, curriculum vitae, and copies of research papers to: Ms. Linda Sheldon, West Mall Complex Room 4657, Simon Fraser University, 8888 University Drive, Burnaby British Columbia, V5A 1S6. Applicants should also arrange for three letters of reference to be sent directly to the same address. E-mail inquiries should be directed to kowallis@sfu.ca.

Cape Breton District Health Authority— Cape Breton District Health Authority, Sydney, Nova Scotia, has immediate openings for clinical psychologists. The successful candidates will have a doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology. He/she must be registered or eligible for registration with the Nova Scotia Board of Examiners in Psychology.

The Adult Mental Health Outpatient Clinic position requires the candidate to work in a multidisciplinary team to provide assessment, individual and group treatment to adult patients aged 19 years and older with a variety of mental health disorders. Expertise in the treatment of anxiety and mood disorders is required. Development of group treatment programs for adult services is a key component of the position.

The Mental Health – Child and Adolescent Services positions require the candidates to provide assessment and treatment to patients up to age 19, including those with neurodevelopmental disorders, and their families.

For the full job posting and list of requirements, visit our web page at www.cbdha.nshealth.ca, go to job postings and click on Continuing Vacancies Job Posting number 2486 for the Adult Mental Health Outpatient Clinic position and Job Posting number 2447 or 1621 for the Mental Health – Child and Adolescent Services positions. Apply with cover letter and resume to:
Janine Gillis Manager, Recruitment & Selection Human Resources Department, Cape Breton District Health Authority, 1482 George Street, Sydney, NS B1P 1P3. Fax: (902) 567-7224
E-mail: gillisj@cbdha.nshealth.ca

University of Victoria, Department of Psychology— The University of Victoria invites applications for a senior-level endowed research chair in human adult development and aging. The appointment will be in the Department of Psychology with affiliation to the University's multidisciplinary Center on Aging. Starting date is negotiable but may commence as early as July 2008. Applicants should have established an international reputation for a program of research addressing cutting edge issues in the field. Quality of the work is more important than a specific topic of investigation. Interest and expertise in longitudinal methods and experience in collaborative research are desirable. Evidence of teaching excellence is a selection criterion.

The successful candidate will be expected to bring and maintain a superior program of research (as evidenced by publications and external grant support), and to play a leadership role in facilitating world-class research within the Department and Center. Although a reduced teaching load accompanies the chair, the appointee also will be expected to contribute to the University's teaching mission at the senior undergraduate and graduate levels.

The University of Victoria is a rich setting for the study of Adult Development and Aging. This exceptional position offers the opportunity for an outstanding individual to join a Psychology department (www.uvic.ca/psyc) that has a history of strength in life-span developmental research. The Department also has strong research clusters in cognition and brain sciences, social psychology, and clinical psychology. In addition, the Center on Aging (www.coag.uvic.ca) is one of the premier multidisciplinary research centers in Canada with participation from multiple departments (e.g., anthropology, geography, nursing, physical education, psychology, sociology). The context affords the individual unique opportunities to further their research through collaborations both within (e.g., Island Medical Program) and outside (e.g., seniors' organizations, hospitals, service agencies) of the university.

The University of Victoria is located in Victoria, British Columbia, Canada. Victoria has an ideal demographic for aging research with a substantially higher proportion of older persons than the national average. Greater Victoria has a population of approximately 350,000 and is the capital of the province. It is a "destination" city boasting a mild Pacific Northwest climate, beautiful mountain and ocean views, year-round outdoor activities, and a wide range of cultural opportunities.

To apply, send (1) a letter of application, including a statement of research interests, accomplishments, and plans, specifically documenting how these fit with the strengths of the Department of Psychology and the Center on Aging. In addition, the letter should note your teaching interests, experience, and objectives, (2) a curriculum vitae (including citizenship status), and (3) copies of selected and relevant scholarly publications, and available evidence of teaching effectiveness. Letters of reference will be requested at a subsequent date. Send materials to:
Peter Keller, PhD, Dean of Social Sciences, University of Victoria
PO Box 3050 STN CSC, Victoria BC V8W 3P5 Canada
Phone: 250-721-5058
E-mail: soscoff@uvic.ca
Web: www.uvic.ca/psyc and www.coag.uvic.ca

University of Victoria, Department of Psychology— The Department of Psychology, University of Victoria, invites applications for a Tier 2 Canada research chair (CRC) in cognitive neuroscience to begin July 1st, 2008, at the level of assistant or associate professor. Tier 2 chairs were created for excellent emerging scholars acknowledged by their peers as having the potential to lead their fields of study. Each CRC appointment is accompanied by funds to support the chair holder's research. Tier 2 CRC appointments are normally made at the tenure-track assistant professor level. Exceptional candidates may be appointed at a more senior level but normally candidates must have received a doctorate within the past 10 years. Any successful applicant will hold a regular position within the Department of Psychology with eligibility for tenure. In accordance with the regulations governing Canada Research Chairs, the best-qualified candidate will be appointed, regardless of citizenship or immigration status. Chair nominations are adjudicated by a peer review administered by the CRC secretariat and appointments are conditional upon approval by the secretariat. General information

about CRCs may be found at www.chairs.gov.ca.

The Department of Psychology seeks candidates who have a strong background and training in cognitive applications of electrophysiological methods and event-related potentials (ERPs) and demonstrated experience with computational modeling and functional magnetic resonance imaging (fMRI). The successful candidate will play a key role in the continued development of the department's brain and cognition laboratory. The candidate's research interests will add to the existing strengths of the department, which include the study of visual cognition, learning, memory, language, and aging. Duties include the maintenance of a successful program of research (as evidenced by publications and external grant support), teaching at the undergraduate and graduate levels, and contributing to the collegiality, reputation, and day-to-day operation of the department and the university (e.g., collaborative research, curriculum development, and committee service). Applicants must have a Ph.D. in cognitive psychology, cognitive neuroscience, or neuroscience and be eligible for an appointment as a Tier 2 Canada Research Chair (visit www.chairs.gc.ca/web/program/nominate_e.asp for details).

To apply, send a letter of application, a curriculum vitae, a statement of research interests and accomplishments, a statement of teaching philosophy, copies of publications, evidence of teaching experience, and three confidential letters of recommendation to:
Michael Masson, CRC Search Committee, Department of Psychology
University of Victoria, PO Box 3050 STN CSC,
Victoria BC V8W 3P5 Canada
Phone: 250-721-753, E-mail: mmasson@uvic.ca
Web: www.chairs.gc.ca/web/program/nominate_e.asp

York University, Department of Psychology— There are two tenure-track appointments (1) Clinical Psychology (2) Clinical Developmental Psychology

(1) CLINICAL - The Department of Psychology, Faculty of Health, York University, invites applications for a tenure-track appointment at the assistant professor level in (adult) clinical psychology - one of six graduate areas of specialization. York's psychology department is one of the largest in North America, and is housed in the new Faculty of Health. Our program in clinical psychology subscribes to the scientist-practitioner model and is both CPA- and APA-accredited. Candidates must have a promising research program and publication record. Preference will be given to candidates with expertise in: qualitative research methods, health psychology or addictions.

A Ph.D. in clinical psychology, preferably from an accredited clinical program that includes an accredited internship, is required. Applicants must be registered, or eligible for registration, with the College of Psychologists of Ontario. The successful candidate will be expected to teach both undergraduate and graduate courses, to provide clinical supervision of graduate students, and to conduct a major program of research.

(2) CLINICAL/DEVELOPMENTAL - Applications are invited for a tenure-track appointment in clinical-developmental psychology at the assistant professor level. Our clinical-developmental program, one of six areas of graduate specialization, is CPA- and APA-accredited, and its faculty are a diverse, dynamic group of scientist-practitioners.

Candidates should have a promising program of research and publication record and with a specialization in one of the following three areas of health or mental health: (1) mental health (particularly internalizing disorders), (2) pediatric neuropsychology/neuropathology, and (3) developmental and/or physical disabilities. Excellent candidates with specific interests in other areas, such as intervention, prevention, program evaluation, or other areas of child and adolescent psychology, will be considered.

Graduate and undergraduate teaching and supervision in these areas will be expected. A Ph.D. in clinical psychology, preferably from an accredited clinical program that includes an accredited internship, is required, and applicants must be registered, or eligible for registration, with the College of Psychologists of Ontario.

The positions commence July 1, 2008, and are subject to budgetary approval. Applicants are requested to submit a curriculum vitae, a statement of research and teaching interests, and relevant reprints; and arrange to have three letters of reference sent, by January 15, 2008, to:
Professor Laurence Harris, Chair, Department of Psychology
Faculty of Health, York University, 296 BSB
4700 Keele Street, Toronto, Ontario, Canada, M3J 1P3
Phone: (416) 736.5116, Fax: (416) 736.5814
E-mail: psychair@yorku.ca

University of Toronto, Department of Psychology— The University of Toronto invites applications for a full-time position at the rank of lecturer, effective on or after July 1, 2008. Applicants should possess a Ph.D. in psychology and possess an outstanding record in teaching and related scholarly activities. Applicants must be prepared to teach Introductory psychology as well as other courses in the social, personality, and/or abnormal streams. The successful candidate will be expected to assume a full lecturer teaching load at the undergraduate level (normally the equivalent of six one-semester courses), supervise undergraduate research projects, engage in teaching-related scholarly activities, and perform related professional and administrative activities within the department. This three-year teaching contract may lead to a continuing teaching position in the department, subject to a favorable review of performance. Salary will be commensurate with qualifications and experience.

Applications will be accepted until January 31, 2008 or until the position is filled. Applicants should provide a curriculum vitae, statement of teaching philosophy and interests, and should arrange to have three confidential letters of recommendation sent on their behalf to:
Chair, Department of Psychology, Room 4020, Sidney Smith Hall
100 St. George Street, Toronto Ontario M5S 3G3
Fax: 416-978-4811
E-mail: chair@psych.utoronto.ca

Chinese University of Hong Kong, Department of Educational Psychology— The Chinese University of Hong Kong invites applications for associate professor(s)/assistant professor(s) (Ref. 07/160(075)/2) (Closing date: February 5, 2008). The Department plans to further develop its strength in psychological assessment and interventions of children and adolescents with special behavior, education and learning needs. Applicants should have (1) excellent academic qualifications including a doctoral degree in school psychology or related disciplines, (2) a strong research and practice background in psychological/cognitive assessment and intervention of school children with special needs, 3) a strong commitment to excellence in teaching and research, and 4) a track record of program-

matic research and publication, or sound indicators of promise as a productive researcher. The appointees will (1) teach postgraduate/undergraduate courses (both English and Chinese are used as media of instruction) (2) supervise postgraduate students, and (3) assist in administrative matters. Appointments will normally be made on contract basis for two years initially commencing August 2008, leading to longer-term appointment or substantiation later subject to mutual agreement. Applications will be considered until the posts are filled. Salary will be highly competitive, commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package, including medical care, plus a contract-end gratuity for appointments of two years, and housing benefits for eligible appointees. Further information about the University and the general terms of service for appointments is available at http://www.cuhk.edu.hk/personnel. For application, send full resume, copies of academic credentials, a publication list and/or abstracts of selected published papers, together with names, addresses and fax numbers/e-mail addresses of three referees to whom the applicants' consent has been given for their providing references to:
Personnel Office
The Chinese University of Hong Kong
Shatin, N.T., Hong Kong
Fax: (852) 2603 6852)

University of Hong Kong, Department of Social Work and Social Administration— Founded in 1911, the University of Hong Kong is committed to the highest international standards of excellence in teaching and research, and has been at the international forefront of academic scholarship for many years. Of a number of recent indicators of the University's performance, one is its ranking at 18 among the top 200 universities in the world by the UK's Times Higher Education Supplement. The University has a comprehensive range of study programs and research disciplines, with 20,000 undergraduate and postgraduate students from 50 countries, and a complement of 1,200 academic members of staff, many of whom are internationally renowned.

Applications are invited for appointment as Associate Professor/Assistant Professor (4 posts) in the Department of Social Work and Social Administration, from July 1, 2008, on a three-year fixed-term basis, with the possibility of renewal.

The Department of Social Work and Social Administration is the leading social work training and social policy research institution in Hong Kong. It is committed to achieving international standards and status in both teaching and research. Further information about the Department can be found at http://www.hku.hk/socwork/.

Applicants must have outstanding records of teaching, research and publications, and with expertise in social work professional practice. Specialization in the fields of either clinical work with family, children and youth, or substance abuse and other mental health concerns, clinical psychology or gerontology will be an advantage. The appointees will be responsible for teaching at both undergraduate and postgraduate levels, and are expected to be active in research and educational innovations.

Annual salaries will be in the following ranges (subject to review from time to time at the entire discretion of the University):
Associate Professor: HK$622,740 - 963,060
Assistant Professor: HK$474,600 - 733,440
(approximately US$1 = HK$7.8)

The appointments will attract a contract-end gratuity and University contribution to a retirement benefits scheme, totaling up to 15% of basic salary, as well as leave, and medical/dental benefits. Housing benefits will also be provided as applicable. At current rates, salaries tax does not exceed 16% of gross income. Further particulars and application forms (272/302 amended) can be obtained at https://www.hku.hk/apptunit/; or from the Appointments Unit (Senior), Human Resource Section, Registry, The University of Hong Kong, Hong Kong (Fax: 852 2540 6735 or 2559 2058; E-mail: senrappt@hkucc.hku.hk).

University of Macau, Faculty of Social Sciences and Humanities— The University of Macau invites applications for the position of associate/assistant professor in clinical psychology. Applicants must hold a doctoral degree (Ph.D, DClinPsy, Psy.D.) in clinical psychology. Applicants should have (1) strong commitment to teaching and research, (2) a track record of publication, and (3) clinical experiences. Preference will be given to registered/licensed psychologists. Teaching experience with good student evaluations will be an asset. The appointee will be expected to teach a variety of undergraduate courses and postgraduate courses, to supervise student theses and practicum and to take an active role in curriculum development. Applicants should visit http://www.umac.mo/vacancy for more details and apply on or before 30/01/2008, preferably ONLINE at Jobs@UM (https://isw.umac.mo/recruitment/). For enquiry, contact vacancy@umac.mo.

Bremen International Graduate School of Social Sciences— The BIGSSS--www.bigsss-bremen.de) invites applications for the following academic positions:

Assistant Professorship in Social Science Research Methods--For the Methods Center of BIGSSS we are seeking candidates with a strong record in the methods of social research and a focus on large-n and small-n comparative research designs, especially case-study designs and methodology. The successful candidate should be willing to assume coordinator functions in the Methods Center. Scholars with a substantive research focus on topics in political science or sociology, in particular on topics which align with one of BIGSSS' research themes, are particularly encouraged to apply. The initial contract runs for 5 years.

University Lecturer (Post-Doc) in "Socio-Cultural Change and the Individual"— Applicants preferably have a disciplinary background in social or developmental psychology, communication, sociology or political science, and experience in the management of graduate programs. The holder of the position will have responsibilities in teaching and in coordinating BIGSSS' thematic field "Attitude Formation, Value Change, and Intercultural Communication." The initial contract runs for 3 years.

Applicants for both positions should demonstrate accomplishment in both teaching and research, and the ability to obtain research funding. They are expected to have a strong record of scholarly productivity (including an outstanding dissertation), and a commitment to institutional excellence and inter-institutional cooperation. Any experience in interdisciplinary settings will be considered a strong point.

BIGSSS' language of instruction is English. Preferably, work at the Graduate School should begin in July 2008.

For both positions, please send your applications by January 31, 2008 to the following address
Bremen International Graduate School of Social Sciences
Prof. Dr. Steffen Mau, Founding Dean
Universität Bremen
PO Box 330440 28334
Bremen, Germany

More information on the Graduate School can be found at www.bigsss-bremen.de.

International candidates will be considered. Employer will assist with relocation costs. The salary will be commensurate with qualifications and experience.

CRAssociates, Germany— CRAssociates, a U.S.-based healthcare-management company, is recruiting for the following position:
• Psychologist • Child Psychologist • Neuropsychologist

The position will be located in the following regions:

Landstuhl: Surrounded by beautiful mountains, valleys and vineyards, a perfect location for a local excursions and visit to France Belgium.

Bavaria: Enjoy the region best known for its quaint towns, cobblestone streets, and winding rivers-only a short train ride to Austria and Switzerland.

Heidelberg: Reside in one of the most beautiful locations in Germany. Explore history and culture in this picturesque city-spend weekends in Switzerland or France.

CRAssociates offers competitive salaries, housing, dependent schooling allowances, paid holidays, vacations, and continuing education. Generous benefit package including paid medical insurance and paid relocation (air travel, household goods), a privately owned vehicle, access to military installations including commissary and base, exchange privileged 401(k), and much more.

U.S. Military and Civilian Behavioral Health Services, Germany—Founded in 1963, Sterling Medical is one of the largest providers of healthcare services to government agencies, HMO's, hospitals, and clinics nationwide and overseas. As such, we extend social and psychological services to our clients, including care for psychological and developmental needs of families. We currently seek adult and child psychologists for an array of behavioral health services to support families of the U.S. military and civilian service providers who are living and serving abroad in Europe. Current opportunities are in Germany with anticipated opportunities in England and Italy.

Primary Requirements: accredited APA doctorate in clinical or counseling psychology, completed APA approved internship, updated and current state license, minimum of 2 years clinical psychology experience accrued within past 5 years.
Program Specific Requirements for two service programs:
Early Intervention Services: experience providing family-centered services in a natural setting, home-based environment to a population of young children (ages 0-3) with disabilities and their families, including diagnosis and treatment of sleeping, feeding, attachment, and other behavior disorders using behavior management and other techniques; skilled in providing evaluation, consultation, and direct care psychological services for infants/toddlers (and their families) who have significant behavioral disorders (may occasionally include children/adolescents up to age 21 who are receiving special education services).

Behavioral/Mental Health Services: knowledge and experience with combat/deployment issues, medically unexplained symptoms, and PTSD and/or disasters are highly desired; skilled in providing evaluation, consultation and direct care psychological services for either children/adolescents or adults; proficiency in administration and interpretation of basic psychological test measures to include intelligence testing, personality testing with objective and projective instruments and basic neuropsychological screening techniques.
Benefits: 2-year service agreement with renewable options, excellent compensation package (includes tax advantages), considerable paid time-off and 10 federal holidays roundtrip airfare and lodging, potential furnishing and auto/vehicle allowance, relocation costs.
For details, please contact: Tom Thaman during standard EST business hours at 1-800/852-5678. x158, or e-mail: tthaman@sterlingmedcorp.com

University of Guam, Department of Psychology— The University of Guam is seeking applicants for a tenure-track position in clinical psychology at the assistant or associate professor level, to begin August 18, 2008. Applicants should have a Ph.D. or Psy.D. in clinical psychology from an accredited clinical program and internship. The successful candidate will (1) teach undergraduate and graduate courses in clinical and other areas of psychology, (2) work with other faculty to establish a master's program in clinical psychology, (3) conduct an active research program, (4) perform university and community service, including clinical supervision in UOG's Isa Psychological Services Center, and (5) seek external funding for research and/or service activities. Review of applications will begin immediately and continue until the position is filled. For further details and application information, see the full job announcement www.uoghro.com/career.php or e-mail dfernand@uog9.uog.edu

Employer will assist with relocation costs. Assistant Prof. - $34,993-$71,084 per academic year; Associate Prof. - $40,086-$80,936 per academic year. Travel and a relocation allowance will be paid for a tenure-track appointment.

University of Groningen, Department of Psychology— The University of Groningen, the Netherlands, anticipates four tenure-track assistant professor positions for a new, English-language Bachelor of Science in Psychology program. Preference will be given to applicants in social psychology (in particular, cross-cultural psychology), cognitive neuroscience (must be able to teach biopsychology), quantitative methods and clinical psychology. Excellent applicants from other areas with broad teaching interests are also welcome. The Bachelor of Science in Psychology consists of five semesters of psychology courses and a one-semester minor. Approximately 50% of the appointment is for teaching and administration and 50% for research. Research facilities include EEG, fMRI, a driving simulator and a simulated ambulance call center. Opportunities for supervising Master's and Ph.D. theses in the existing psychology program are available.

Requirements: • Motivated researcher and teacher • Ph.D. in Psychology • Publications in international journals • Excellent command of English • Ability to attract funding.

Excellent career prospects! The faculty's career development policy is characterized by flexible personnel management with a focus on the individual. Ample opportunities for professional development of teaching and other skills are available.

Conditions of employment: The University of Groningen offers a salary dependent on qualifications and work experience up to a maximum of € 4868 gross per month for a full-time appointment (12 monthly payments), an 8% holiday allowance, and participation in a pension scheme for government employees.

The appointment will be on a temporary basis for a maximum of six years. Prior to the completion of the sixth year performance will be assessed. A positive assessment will lead to promotion to the rank of associate professor with tenure. After an additional six years, promotion to the rank of full professor is possible.

For more information about these positions contact:
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E-mail: a.johnson@rug.nl
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Phone: +31 (0)50 363 6778
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Applicants should send a curriculum vita, letter of interest, statement of research interests and names of three references to vmp@rug.nl

The closing date for applications is February 20, 2008. Candidates must be able to start no later than September 1, 2008. Interview and moving expenses will be fully covered.

Employer will assist with relocation costs. An additional 8% will be paid each year as vacation money.

Singapore Management University, School Social Science— The Singapore Management University is looking for its Founding Dean of the School of Social Sciences. We are looking for a sociable, creative person who will energetically develop our interdisciplinarity, especially in research, and who will also foster cutting-edge teaching. The Dean must be a distinguished international scholar in any of our existing disciplines mentioned below or in social science broadly conceived, must be sensitive to the diversity of methods of different disciplines in the social sciences, and must be keen on expanding the school in exciting ways that help and inform the other schools. The successful candidate will play a large role in mentoring the research of the young, multi-national faculty, in recruiting new faculty and developing new curricula, should have excellent collaborative leadership skills and will delegate tasks, with our excellent administrative support.

The School of Social Sciences started in April 2007, after being part of the School of Economics and Social Sciences for several years. It is one of six schools within the Singapore Management University, which was founded in 2000. The 25 members of faculty include psychologists, political scientists, sociologists, philosophers, historians and literature and theater scholars. We will expand to about 40 members of faculty. We now have about 450 students, which will increase to about 800. We offer the Bachelor of Social Sciences and courses in the humanities and provide compulsory core courses in critical thinking for all SMU students.

The Singapore Management University is an expanding, new institution that emphasizes giving students a broad-based education. Its state-of-the-art campus lies in the heart of one the world's most vibrant and cosmopolitan cities. SMU, an equal opportunity employer, offers very competitive salaries and relocation packages.

To apply, send your CV, plus a covering letter by January 20, 2008 to:
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7 Temasek Boulevard #20-01
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Singapore 038987
Fax: +65 6338 1260
E-mail: sossdean@heidrick.com

American University of Sharjah, Department of International Studies— The American University of Sharjah in the United Arab Emirates invites applications for a faculty position in psychology within the Department of International Studies. Our department continues to expand its social science faculty and recently established a psychology laboratory, with an eyetracker and other equipment.

AUS has emerged as a dynamic international university, growing from 250 to 5,000 students since its foundation in 1997. Located in the Sharjah/Dubai area, perhaps the most dynamic cosmopolitan areas in the Middle East, AUS is fully accredited with the North American system and offers a generous compensation package, free housing, support for research, and other benefits. There is no income tax in the UAE.

We are interested in applicants (Ph.Dd or ABD) with expertise in any major field of psychology. We value teaching and research achievement and seek colleagues with experience in both. Appointments will generally be made at the rank of assistant professor with a 3/3 yearly teaching load. Initial contracts are normally for a period of three years and are renewable.

Send letter of interest, CV, and contact information (including email addresses) for three references. Materials should be addressed to:
Dr. William Heidcamp, Dean
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and should be emailed to: cashr@aus.edu. Faculty who are appointed starting with the Fall 2008 semester must be in Sharjah by August 19, 2008.

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The effects of experienced childhood maternal abuse on adult attachment styles

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Joseph Oliva, Richard Velayo, Ph.D, and Katherine Erwin

Pace University

The Effects of Experienced Childhood Maternal Abuse on Adult Attachment Styles

The relationship between experienced maternal abuse and the development of an insecure attachment style was examined. Data was collected via self-report questionnaires in a large, urban college campus. The questionnaires used were the Revised Conflict Tactics Scales (CTS-2, Straus, Hamby, Boney-McCoy, & Sugarman, 1996) and Attachment Questionnaire (AQ, Bartholomew & Horowitz, 1991). The sample included 81 females and 86 males, ranging in age from 18-57 years old. No significant correlation was found between the experience of maternal abuse and the development of a fearful attachment style. The results did support a significant correlation between maternal abuse and the development of an insecure-dismissive attachment style. Future research is needed with more diverse samples that consist of more variability in abuse.

The US Department of Health and Human Services (2003, April 1) has estimated that 903,000 children in the United States were victims of abuse or neglect in 2001. With such a strikingly large number of victims, it is important that we fully understand the long-term impacts of abuse, including how experiencing abuse will affect these children in all aspects of their adult lives, including attachment style (Levendowsky & Shapiro, 1999). Insufficient psychological and emotional development is often the result of one of two experiences: trauma inflicted by another individual or abuse by a caregiver. Abuse perpetrated by a caregiver often results in childhood psychopathology and insecure attachment styles later in life (Levendowsky & Shapiro, 1999). There has been research conducted on maternal abuse and maltreatment, as well as on insecure attachment, but little has been done to link the two topics together (Morton & Browne, 1998). The purpose of this study is to examine the relationship between experienced maternal abuse and insecure attachment.

The theoretical foundation for attachment theory is largely based on the work of John Bowlby and the empirical work of Mary Ainsworth (Ainsworth & Bowlby, 1991). Bowlby was interested in the effects of early separation from parents on child development. Bowlby's clinical observations led him to create a theory on the attachment behavioral system (as cited in Pervin, 2002). According to this theory, an infant goes through a series of innate phases

in the development of an attachment to a maternal caregiver. Interactions between the infant and primary caregiver provides the basis for the development of expectations of future relationships (Pervin, 2002).

Mary Ainsworth is a psychologist who conducted a study in which she observed the interaction between infants and their mothers, which is known as the Strange Situation. The Strange Situation is an observable measurement that places an infant in a series of introductions, separations, and reunions with their mother and an adult stranger (Ainsworth, Bell, & Stanton, 1971; Ainsworth, Blehar, Waters, & Wall, 1978). Ainsworth observed the interaction between infant and mother in different situations and placed the infant in one of four attachment categories: secure attachment, insecure-avoidant attachment, insecure-ambivalent attachment, and insecure-disorganized attachment. Ainsworth concluded that a securely attached infant has a healthy relationship with their mother (Ainsworth et el., 1971). Insecure-avoidant infants show insecurity by avoiding the caregiver (Ainsworth, 1979). Insecure-ambivalent infants first cling to their caregiver and then push them aside with anger (Ainsworth et el., 1971). Insecure-disorganized infants show patterns of avoidance and fearfulness from their caregiver (Ainsworth, 1979).

It is important to look at the findings of Ainsworth because researchers have found that early attachments in children seem to foreshadow later functioning and social behavior (Schneider, Atkinson, & Tardif, 2001; Sroufe, 2002). It has been shown that male children with an insecure-attachment style display both more attention-seeking and more disruptive and aggressive behavior when interacting with peers than do securely-attached boys (David & Lyons-Ruth, 2005). Research also shows that attachment security provides a foundation for care-oriented feelings and caregiving behaviors, whereas attachment insecurity suppresses or interferes with compassionate caregiving (Mikulincer, Shaver, & Gillath, 2005).

Abuse is defined as any action by an individual that may result in the physical or emotional harm of another individual (Lowenthal, 1996; Yanowitz, Monte, & Tribble, 2003). An individual's attachment style can be either secure or insecure. A child can have a secure, an avoidant (sometimes called detached), or a preoccupied attachment style (George, 1996). An avoidant/detached child views themselves positively and others negatively (George, 1996). A child with a preoccupied attachment style has a negative self-image and either a negative or positive image of others (Berk, 2000).

Attachment styles for adults are similar to that of children, only they are labeled differently. There are three categories of adult insecure attachment: dismissive (also called avoidant), anxious/ambivalent (also called preoccupied), and fearful. Adults who develop insecure attachment styles are thought to have experienced insensitive or inconsistent care from their parents during childhood (Volling, Notaro, & Larsen 1998). Children that have an avoidant/detached attachment style will have a dismissive attachment style as an adult (Berk, 2000). An adult with a dismissive attachment style has a positive self-image and a negative image of others (Muller & Lemieux, 2000). An adult with an anxious/ambivalent attachment style views himself negatively and others positively (Muller & Lemieux, 2000). An adult, who has an anxious/ambivalent attachment style, had a preoccupied attachment style in childhood (Berk, 2000). Finally, fearful adults, who were labeled as having a preoccupied attachment style as children (Berk, 2000), have a negative self-image and a negative image of others as well (Muller & Lemieux, 2000).

Parenting styles are shown to have a great effect on the behaviors of a child, especially if that child has been abused. Maltreated children are at risk for developing a wide range of problems and disorders (Maughan & Cicchetti, 2002). Individuals that experience abuse as a child have been shown to have poor emotion regulation, attachment problems, and problems in peer relations (Azar, 2002). Being physically

abused has been linked with children's anxiety, personality problems, depression, conduct disorder, and delinquency (Maughan & Cicchetti, 2002). Later, during the adult years, maltreated children show increased violence toward other adults, dating partners, and marital partners, as well as increased substance abuse, anxiety, and depression (Malinowsky-Rummell & Hansen, 1993).

There are several mediating factors thought to link childhood abuse to adult attachment styles. Several studies established a link between poor social skills in children and previous history of abuse (Rowe & Eckenrode, 1999; Solomon & Serres, 1999; Yanowitz et al., 2003). DiTommaso, Brannen-McNulty, Ross, and Burgess (2003) observed that in a measure of social skills, those whose scores reflected good social skills also self-reported a secure attachment style. Conversely, those whose scores indicated poor social skills self-reported an insecure attachment style—primarily fearful attachment. These attachment styles reportedly carried over into adulthood (DiTommaso et al., 2003).

One negative repercussion of childhood abuse is the inability of the child to form effective coping strategies (Levendowsky & Shapiro, 1999). According to Crittenden (1992), a child forms their internal representational models through their experiences. If a child is abused they will form a model reflective of the way in which they dealt with these experiences (Crittenden, 1992). This model will most likely lead to future use of maladaptive coping strategies, resulting in poor interpersonal relationships later in life (Levendowsky & Shapiro, 1999).

A child can be the victim of witnessed or experienced abuse, both contributing to the child's development of a specific type of attachment style when older (Foshee, Bauman, & Linder, 1999). Maternal abuse plays a significant role in the disintegration of a secure attachment between mothers and children. Rapoza and Malley (1996) examined the impact of maternal violence on adult attachment styles. The researchers concluded that maternal abuse is significantly correlated with dismissive and preoccupied attachment styles. The participants labeled as such reported difficulties in their present interpersonal relationships (Rapoza & Malley, 1996). In addition, a proceeding study found that maltreatment from a maternal figure to a child significantly damages any chance of a secure attachment between mother and child, consequently interfering with future emotional relationship attachments and conflict resolutions (Morton & Browne, 1998).

There have been few studies on the differences of how males and females internalize abuse. Research conducted by Rapoza and Malley (1996) found that there is a significant difference in male and female attachment styles due to maternal abuse. The female participants reported having dismissive and fearful attachment styles whereas the male participants reported no significant relationship between their attachment styles and experiences of maternal maltreatment. This is one isolated study with no other explicit research to support it, so it is important to be wary of its implications.

In this study, we hypothesize that:

1. Experiencing maternal abuse will be positively correlated with insecure-fearful attachment in both males and females.
2. Experiencing maternal abuse will be positively correlated with insecure-dismissive attachment in both males and females.
3. Abused females will score higher than abused males on scales of insecure attachment.

Methods

Participants

Participants in this study were 81 females and 86 males ranging in age from 18 to 57 years old, with an average age of 23.18 years old. Approximately one-third of the sample was college students completing a psychology research methods course at a large urban

university in the Northeast. In order to generate a data set for class research projects, these students completed a set of self-report measures assessing information on attachment style and frequency of experienced maternal abuse. In addition, each student was expected to recruit three male and three female volunteers to contribute to the class data set. APA ethical guidelines were followed throughout this process. The average respondent was single, 23 years old, Caucasian, and a student who self-reported to be from a middle to upper middle socioeconomic class.

Measures

For the purposes of the present study, the measures used were the Revised Conflict Tactics Scales and the Attachment Questionnaire. Experienced maternal abuse was measured. The Revised Conflict Tactics Scales (CTS-2), adapted from Straus, Hamby, Boney-McCoy, and Sugarman (1996), has six 24-item scales, each of which has subscales for measuring the frequency with which particular conflict tactics have been used or experienced. These subscales include: a) tactics observed during childhood (negotiation, psychological aggression, and physical aggression in the mother to father and father to mother relationship), b) tactics experienced during childhood (negotiation, psychological aggression, and physical aggression in the mother to you and father to you relationship), and c) tactics experienced and perpetrated in the dating relationship (negotiation, psychological aggression, and physical aggression from you to partner and partner to you). Response scales for each item range from 0 (never) to 25 (more than 20 times). Alpha reliability coefficients for the internal consistency reliability of this questionnaire are relatively high, between 0.79 and 0.95 (Straus et al., 1996). High correlations between the test and abuse variables support its construct validity (Straus et al., 1996).

Adult attachment style was measured by the Attachment Questionnaire (AQ, Bartholomew & Horowitz, 1991). This questionnaire consists of four short paragraphs with 7-point response scales (ranging from 1 "Not at all characteristic of you" to 7 "extremely characteristic of you") yielding ordinal (continuous) scores for four attachment types (secure, dismissive, anxious-ambivalent, and fearful); these scores are useful for calculating correlations between endorsement of particular attachment styles and other variables. In a fifth item, participants indicate which of the four types is most like themselves; this response yields a categorical score, which might be used as an independent variable in an analysis of variance – although except with a very large sample, this approach is often not very useful. Alpha reliability coefficients of these attachment ratings were computed in its first use by Bartholomew and Horowitz (1991) and found to be high—they ranged from 0.87 to 0.95. Other questionnaires designed to determine attachment styles have confirmed the AQ's convergent validity (Bartholomew & Horowitz, 1991).

Data Analysis

In order to address the hypotheses for the current study, the following data analyses were conducted: Pearson *r* correlations were calculated among the two study variables and a *t* test was conducted to determine gender differences with experienced maternal abuse as the independent variable and adult attachment style as the dependent variable.

Results

Table 1 provides the descriptive statistics for all the major study variables, separately by gender. As can be seen, the mean for experienced abuse is higher for males than females. When the four different attachment styles (secure, dismissive, preoccupied, and fearful) were divided by gender, it can be seen that females scored higher on scales of both secure and fearful attachment, while males scored higher on scales of dismissive and preoccupied attachment.

Table 2 provides the correlation matrix for the correlations between the Attachment Styles scores and the Conflict Tactics Scales scores for experienced psychological and physical maternal abuse in males and females. As can be seen,

Table 1. *Descriptive statistics by gender.*

	N	*M*	*SD*
Experienced Maternal Psychological Abuse			
Females	85	21.61	8.51
Males	81	17.90	7.17
Experienced Maternal Physical Abuse			
Females	81	4.86	7.06
Males	85	8.28	9.49
MALL			
Females	81	22.77	12.5
Males	85	29.90	15.11
Secure Attachment			
Females	80	4.46	1.53
Males	86	4.27	1.62
Dismissive Attach.			
Females	80	3.36	1.77
Males	86	3.87	1.69
Preoccupied Attach.			
Females	80	2.63	1.66
Males	86	3.10	1.81
Fearful Attach.			
Females	80	3.21	2.07
Males	86	2.93	1.80

there is no significant correlation between experienced maternal abuse and fearful attachment style in males or females. However, there is a significant correlation between dismissive attachment style in both males and females to experienced maternal physical abuse.

Table 3 presents the results of a *t* test, with gender as the independent variable and the scores on each of the four attachment styles as the dependent variables. These analyses revealed that gender did not contribute significantly to the development of any of the attachment styles.

Discussion

The findings did not support the hypothesis that there is a correlation between experienced maternal abuse and the development of an insecure-fearful attachment. The findings did not support the hypothesis that abused females would score higher than abused males on scales of insecure attachment, as well. The results did support the hypothesis that there is a correlation between dismissive attachment style in both males and females and experienced maternal physical abuse. The results also support another study in which maternal abuse was significantly correlated with dismissive and preoccupied attachment styles (Rapoza & Malley, 1996).

Compared to the work of Ainsworth (1979), the results did show that maltreatment in some form at childhood would lead to an insecure attachment style later in life. The results of this study also correlate with the results of other studies in which a link was established between poor social skills in children and previous history of abuse (Rowe & Eckenrode, 1999; Solomon & Serres, 1999; Yanowitz et al., 2003). Current research has shown that developing an insecure attachment type as a child will cause negative effects on attachment and interpersonal relationships later in life (Malinowsky-Rummell & Hansen, 1993).

There are a few different reasons for why this study did not work. One such reason is that there was not enough variability in reported abuse. The reason for this variability could be that

Table 2. *Correlation between experienced maternal abuse and attachment styles.*

Variables	5. experienced maternal psychological abuse	6. experienced maternal physical abuse
1. secure attachment style	-.076	-.053
males	-.121	-.055
females	.015	-.021
2. dismissive attachment style	.111	.316**
males	.115	.355**
females	.040	.223*
3. preoccupied attachment style	.060	-.043
males	-.043	-.079
females	.129	-.062
4. fearful attachment style	.046	-.039
males	.028	-.101
females	.104	.066

** - Correlation is significant at the 0.01 level (2-tailed).
* - Correlation is significant at the 0.05 level (2-tailed).

Table 3. *t-test for gender and attachment style*

Variables	Females		Males			
	X	*SD*	*X*	*SD*	*t*	*p*
Secure	4.460	1.530	4.270	1.620	0.799	0.425
Dismissive	3.360	1.770	3.870	1.690	-1.895	0.060
Preoccupied	2.630	1.660	3.100	1.810	-1.783	0.076
Fearful	3.210	2.070	2.930	1.800	0.935	0.351

participants were not willing to report abuse or that their interpretations of abuse differ from that of this study's definition of abuse. While responding to the questionnaires, participants might not have reported abuse for a number of reasons, such as protecting their parents, not wanting others to know about their abuse, or to remember being abused would be too hurtful for them to bring up past memories.

Another possibility of why this study didn't work is that the average participant was a college student who reported to be from middle to upper socioeconomic class. This shows that the sample was drawn from a homogeneous population and therefore, not enough variability in the responses of the participant. What was not taken into consideration from these participants is that their definition of abuse could vary because of religious beliefs, cultural differences, or parenting styles. What can be considered abuse to one person might not be considered abuse to another.

One last possible reason why this study did not prove to work is that the scaling techniques for measuring the variables of abuse and attachment were inadequate. The format of the questionnaires that were used forced a broad response of being abused or not. Forms of abuse, such as neglect or sexual abuse, were also unable to be measured with these questionnaires. There are also errors that come along with questionnaires of self-report. Self-report limits the interpretation to perceptions of abuse. This problem could have been avoided if the methods

of obtaining data were by using interviews because the respondent might have answered more thoroughly if they were talking to an actual person.

Suggestions for future research could be that using a more diverse sample would lead to different data obtained. Using a population that has previously reported abuse, such as Child Services, would be better in finding correlations between abuse and attachment styles. If abused populations, such as violent environments, were targeted for data, there might have been a positive correlation found between experienced maternal abuse and insecure-fearful attachment styles.

Future research can also include longitudinal studies, following infant-parent relations from birth until adolescence. Parenting style and attachment style can be looked at and recorded from these studies and can be compared to the child's adult attachment style and relationships to other people when they grow up. Future research related to the topic of maternal abuse and attachment style can also be done by conducting twin studies, in which the attachment style of each twin would observed and then compared to how they were raised. Observations of different attachment styles in infancy could explain the different factors that effect attachment style as an adult. Again, more diverse samples compared to this study would be needed in order to get a better picture of how maternal abuse effects attachment style in adults and children.

The findings of this study can be applied in different clinical settings. The findings can be used by community psychologists to form parenting programs. These programs can help teach parents how to better raise their children and how to form a healthy attachment style with them at a young age, since it has been shown that early attachments as a child foreshadow behavior and social functioning as an adult (Schneider et al., 2001). Another type of program to help parents is to train them before they become a parent. This type of program would allow parents to be counseled on different parenting methods and learn how the attachment process works in an infant. Other types of programs can teach psychologists to better understand patients of different attachment style backgrounds. Understanding a person's attachment style in adulthood and childhood could help the psychologist better asses the present problems a patient is trying to cope with.

Although some of the findings in this study did not correlate with the present research, the finding that experiencing maternal abuse is positively correlated with dismissive and preoccupied attachment styles in both males and females did support the present research (Rapoza & Malley, 1996). The present study shows a correlation between developing an unhealthy attachment style as an adult and undergoing abuse or maltreatment as a child. According to current research and the research done by Ainsworth on attachment theory, proper measures should be taken when raising a child in order for that child to develop a secure attachment style in childhood and to develop a secure attachment style later in life (Ainsworth, 1979; Pervin, 2002).

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A Profile of the Efficient Email User: Cognitive-Motivational Factors Related to Email Use

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Abstract

This study provides an exploratory investigation of the relationship between email management style (specifically regarding preference for and responsiveness towards email) and cognitive-motivational factors among its users. Another purpose is to develop a broad range of strategies that help users effectively manage their electronic mail. Preliminary findings show that strategies relating to extrinsic motivation, self-efficacy, help-seeking, peer learning, organization, and rehearsal may point to greater efficiency in email usage. Suggestions on ways to become more efficient at handing electronic mail are presented.

One of the most popular Internet-based technologies used today is electronic mail (i.e., email) which, over the years, has provided us with the ability to effectively and efficiently communicate with one another despite our physical distance. For many, managing email has become a routine as a function of their work, as well as their social and personal lives. Given that email is one of the most popular Internet-based technologies used today, it is, therefore, important that email users find effective ways of sorting and organizing their emails. Moreover, email technology continues to significantly affect how we live our lives – the way we communicate with each other, when and where we choose to correspond with people, and how we view others and ourselves given the kind of "virtual" interactions we carry out through this medium. Surely, there are salient factors that determine our ability and efficacy to use this technology. As such, psychologists across various subfields may find it interesting to investigate how email has contributed to our interpersonal skills, how it has affected the way we thinking about ourselves and interact with others. Email technology appears to have permeated the lives of many people to the point that we often rely on it in the way we interact with others.

We were motivated to investigate ways to be more efficient at handling email because of the flurry of work-related emails that we receive every single day. We are very much aware that we are not alone in this experience. Today's professionals are constantly bombarded with emails from various sources. What we thought would be most interesting to do is to see how people manage their emails – focusing on how email is perceived compared to other forms of communication, and how responsive they are at handling work emails based on the source of such email – in relation to the general strategies they use to deal with relevant tasks. This preliminary study also generated a list of strategies that help enhance efficiency in handling electronic mail.

The next section describes how email came to be and how it has been studies in recent past.

About Email and Some Studies of Interest

In 1971, the first electronic mail message ever was sent by Ray Tomlinson (recognized as the "inventor of email"), born in Amsterdam, New York in 1941 (Garwood, 2006). Tomlinson had obtained a degree in Electrical Engineering, and, at the time of his historic message, he was an engineer for Bolt, Beranek and Newman, which had won the contract to create ARPANET, a communication network that would allow scientists and researchers to share each other's computer facilities. The first email was simply a test message sent by Tomlinson to himself.

Today, Tomlinson's innovation is the most used Internet application. In 2003, Veritas Software Corporation conducted a study which concluded that organizations are relying predominantly on email when it comes to communication and even other aspects of organizational activities. In 2004, the average corporate user received 94 emails per day. Because of the anonymity of the communication transactions, however, Constant, Sproull, and Kiesler *(1997)* have argued that the use of electronic technology, such as email, doesn't necessarily compare to face-to-face communication.

Researchers in the past decade have been actively investigating technology use and disuse among conventional and communications technologies (Workman, 2005). In a study of email users, Lantz (1998) found that the ability to effectively handle email is inversely correlated with the number of messages stored in the inbox.

Psychology-related studies on email correlate its use with shyness and locus of control (Chak, 2004; Yuen, 2004), helping behavior (Lewis, 2004), self-esteem and interpersonal risk (Joinson, 2004), stress and coping (Hoke, 2004), cyberpsychology (Emond, 2003), depression (Morgan & Cotten, 2003), socialization and personality attributes (Bonebrake, 2002), organizational psychology (Krishnamurthi, 1996; Thach & Woodman, 1994), and social development (Heitner, 2003).

Email technology has therefore been investigated by psychologists in a variety of ways in the recent past. Some studies have investigated the different ways people manage their email messages, however, there has not been a study that have looked at the relationship between user learning characteristics and the behaviors associated with email usage.

Our research provides, for the first time, an exploratory investigation of the relationship between cognitive-motivational strategies and patterns of email use (preferences and degree of responsiveness). Our ultimate purpose is to discover a broad range of strategies that may help users effectively manage their electronic mail. We hypothesized relationships between certain email management practices and cognitive-motivational variables, as measured by the Motivated Strategies for Learning Questionnaire (MSLQ), which assesses a learner's strengths and weaknesses in terms of academic motivations and learning strategies.

Richard Velayo

Method

This study involved 143 participants (57 males, 85 females, 1 unspecified), ranging from 14yo to 60yo (Mean age = 27, SD = 8.3). They comprised working professionals, as well as graduate, undergraduate students in the New York City Metropolitan area.

Participants were asked to respond to two instruments:

(1) *"Handling of Electronic Mail" Survey* (Velayo, 2006) - contains 33 items that assess email usage, organization, and perceptions

towards email. Items are in the form of multiple-choice items, 5-point scales, and open-ended questions based on hypothetical scenarios). The survey's scales include: Patterns of Use, Preferences, Speed of Responsiveness, Scenario-based Decisions, and Perceived Advantages and Disadvantages of Email Usage. For the purpose of this study, only Preferences and Speed of Responsiveness were used. *Preferences* refer to the cluster of items pertaining to one's preference and value for email over other forms of communication (e.g., phone call, face-to-face, meetings, instant messaging) whereas *speed of responsiveness* is measured based on the cluster of items pertaining to the level of responsiveness or speed in which one may answer an email received given a particular context/source.

David Blank

(2) *Motivated Strategies for Learning Questionnaire* (Garcia & Pintrich, 1996) – contains fifteen scales that assess strategies for learning including: (a) Cognitive strategies (rehearsal, elaboration, organization, critical thinking, and metacognition); (b) Motivational strategies (intrinsic motivation, extrinsic motivation, task value, control beliefs, self-efficacy, and test anxiety; and (c) Resource Management strategies (time/study environment, effort regulation, peer learning, and help-seeking)

Summary of Findings

Of the 15 cognitive-motivational variables of the MSLQ, there were six factors that were found to be consistently and most highly correlated (predictive) with (1) email preferences and/or (2) responsiveness.

With respect to *motivation,* efficient email users (those whose average preference and responsiveness ratings is 4 or more on the five-point scale items in the Handling of Electronic Mail Survey (Velayo 2006) tend to have higher *extrinsic motivation* for learning than those with low preference and responsiveness ratings (those whose average responsiveness ratings is 2 or lower) ($t = 3.671$, $p < .05$). This finding suggests that those who tend to perceive themselves as efficient users of email may also have the ability to use and appreciate external rewards that go along with dealing with email tasks. It is interesting to note that intrinsic motivation does not appear to be a significant factor in determining efficiency or responsiveness to email. It appears that the extrinsic motivators, possibly in the form of self-imposed rewards or just the feeling of "relief" for having dealt with email can be powerful factors in becoming an efficient email user. The use of extrinsic motivators is also more effective than relying on factors that enhance intrinsic motivation because of one has greater control of extrinsic factors that enhance motivation. It is more difficult to intrinsically motivate oneself in dealing with email. In addition, the same group of efficient email users also had a significantly higher *level of efficacy* and belief about being able to do well on learning tasks ($t = 2.417$, $p < .05$) than those with low responsiveness ratings. This finding suggests that those with high levels of confidence in dealing with email tasks have greater responsiveness to email.

As for *resource management skills,* efficient email users (those whose average preference ratings is 4 or more on the five-point scale items in the Handling of Electronic Mail Survey (Velayo 2006) tend to have significantly higher scores on *help-seeking behaviors* ($t = 2.95$, $p < .05$) and tend to use of *peer learning strategies* ($t = 2.671$, $p < .05$) than those with low preference/responsiveness ratings (those whose average responsiveness ratings is 2 or lower). Help-seeking involves the use of resources of more competent people. Peer learning involves the ability to effectively work in groups to obtain input/feedback from others. This suggests that efficient users of email tend to seek the assistance of others as a resource when responding to certain emails and also tend to collaborate with others to derive feedback or help make decisions. Moreover, they tend to view email as preferable to most other forms of communication (e.g., phone, in-person meeting) and generally respond faster to email inquiries from various sources. In addition, those with faster responsiveness to emails are better able to manage and regulate how much of their time and effort need to be allocated to accomplish a specified work task.

Though it is evident that motivational and resource management strategy factors seem to be more salient in predicting email usage patterns (preferences and responsiveness), the *cognitive strategies* – organization and rehearsal – help explain why more efficient users (those with high responsiveness ratings toward email) have good organizational strategies and focus on relatively frequent systematic/routine behaviors to undertake email tasks (i.e., rehearsal strategies).

There were ancillary findings that are interesting to note. *Intrinsic motivation* ($r = .223$, $p < .05$) *and peer learning* ($r = .17$, $p < .05$) are most predictive of the *number of email accounts one may have*. This suggests that effective email users tend to "like" using email and see high value in it use. They also tend to use it beyond work or school - as a way to keep in touch and socialize with friends and family. Thus, one likely explanation is that each email account has a particular purpose related to the group of people one corresponds with. In addition, *help-seeking* ($r = .154$, $p < .05$) is also highly indicative of the *number of times one checks email*. A likely explanation is that email users who rely on others tend to correspond with a multitude of people via email to help them accomplish their tasks. Email allows them the ability to efficiently use their time and undertake some tasks without having to be with others within the same physical space.

Practical Tips for Email Management

The tips listed below provide ways by which a user may better manage and cope with the voluminous number of emails they receive. These tips were derived from participant's responses to open-ended questions on the *Handling of Electronic Mail Survey* (Velayo, 2006). These are not meant to provide a comprehensive listing of how a user or an organization may be able to limit or prevent unnecessary emails, nor do these account for existing technologies that filter email. Rather, such tips allow one to better categorize and prioritize one's emails and to become cognizant of the behaviors that get in the way of handling e-mail efficiently.

Cognitive strategies/tips:

- Create folders to archive and sort incoming messages based on "source" of the email (e.g., research, teaching, service). You may also create an "archive folder" and just save your files in it. Your computer operating system is able to sort your files based on name and date and you can also do a file search within your archive folder.
- Create a manageable number of separate email accounts for each email source (e.g., work, personal) to help prioritize and organize email.
- Generate folders to sort email based on "level of importance" to prioritize messages (e.g., "To Do Today" folder, "Due by" folder).
- Delete obsolete or irrelevant email messages (as soon as you receive them) to help reduce clutter and organize your inbox.
- Determine and follow a system of dealing with emails after accumulating a certain amount or after certain intervals, instead of leaving them in your inbox for long periods of time.

Motivational strategies/tips:

- Try giving yourself a daily or weekly email checking quota, and once you hit it, you can't check your email any more until the next day/week when your quota resets. Offer yourself a reward like going to see a movie or going out to dinner the first week you come in under quota.
- You should not expect complete efficiency all the time; keeping up with email can be hard work. Reward yourself at the end of the day after dealing with relevant emails after Withhold the

reward until you have dealt with those emails. Rewards should be contingent on a specific designated goal of how you wish to deal with your emails.

- Don't feel pressured to respond to each and every email. Those who need to contact you will try to reach you in other ways or send you 'reminder emails'. For those who do not, their email message may not be that important or they may no longer need your response.

Resource Management strategies/tips:

- Experiment with how often you really need to check email. Then, decide in advance exactly when you'll check email. Don't check email haphazardly. You can easily waste 30-60 minutes per day checking email too often. In most cases you should be fine checking your email 3 times per day maximum. See how infrequently you can push it without causing problems. For many people once a day or even once every two days will work just fine.
- Respond to as many emails as you could when you check/read them. Having too many "unresponded" emails will only clutter your inbox and will only make you feel more anxious and overwhelmed.
- Write email messages in a more direct and succinct manner.
- Explore alternative ways to have others contact you (e.g., telephone/voicemail, leave messages with secretary) if these alternatives are more manageable.
- Avoid belonging to 'listservs' unless you are serious at reading the postings that are sent to your inbox.
- In certain instances, you may ask others to help you respond to select emails you receive, especially those you think may be better answered by another person or persons.

Other suggestions:

- Save or archive selected emails - those you think you may need to refer to later on. Organize them into folders that would make it easier for you to search for them later on.
- You may want to impose limits on email correspondences. If you think that speaking on the phone of meeting in person would make better use of your time, let the other person know. There are times when things get accomplished much faster without having to email each other back-and-forth relentlessly.
- Use email vacation messages to let others know that you will not be checking your email over a certain period of time and who they may contact during the period in which you may not be reached by email.
- Organization is key to becoming an efficient email user. You may want to explore a system of organizing your e-mail files that is easy to manage and/or one that is similar to how you already organize your other electronic files (assuming you have one) so that the method by which you organize your email is easy to get accustomed to.

Websites that provide information on better email management practices:

- 30 seconds to an empty email Inbox (August 22, 2006 by Chanpory) (http://www.lifeclever.com/2006/08/22/30-seconds-to-an-empty-email-inbox/)
- Efficient email (March 11, 2006, by Steve Pavlina) http:/ www.stevepavlina.com/blog/2005/03/efficient-email/
- Tips for More Efficient Use of Email (June 2005, RGI News) http://www.rgilearning.com/newletters/rgi_news_june05.htm

Future Research

The next phase of our research on email usage will look into other scales/items of the *"Handling of Electronic Mail" Survey* in relation to the MSLQ and other measures of cognitive styles and learning patterns. Behavioral and cognitive effects of email use as a function of instructional tasks and scenario manipulation will also be investigated. It will also be crucial to analyze the actual content of email text and how one respond to them, and to examine demographic and cultural variables that influence email use.

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Transactions

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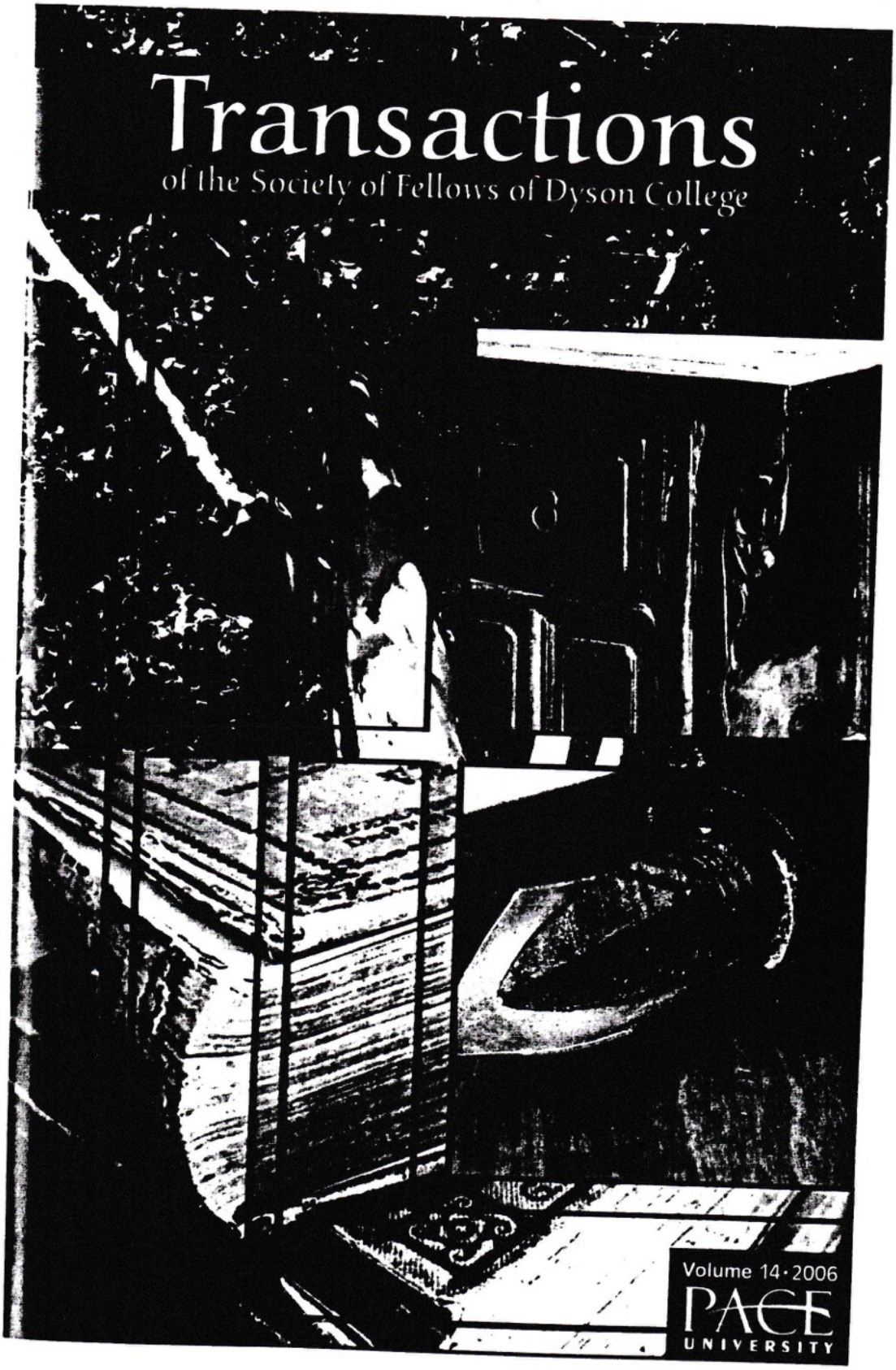

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Effect of Presentation Modality and Color Congruency on Reaction Time in a Modified Stroop Task

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Abstract

This study examined the relationship between presentation modality and color congruency on reaction time in a modified Stroop task. Previous studies involving the Stroop effect have observed differences in reaction time between congruent and incongruent stimuli through the manipulation of color, semantic meaning, or presentation modality. To our knowledge, none have involved concrete semantically related objects, with the task of naming the prototypical colors of stimuli when presented in either a textual or visual modality. In this study, 88 participants were randomly assigned to one of four groups—congruent-colored text, incongruent-colored text, congruent-colored picture, or incongruent-colored picture. Results indicate that textual stimuli were processed significantly faster than their image counterparts, with congruent colored conditions having faster RT's than incongruent colored conditions.

Effect of Presentation Modality and Color Congruency on Reaction Time in a Modified Stroop Task

There is an abundance of research that details how words and images are processed in the brain. Researchers have explored questions relating to how a word is processed for meaning, how images are perceived and interpreted for meaning, and how these two modalities interact. Also of note is to what extent different modalities are automatically processed or require a conscious allocation of attentional resources for interpreting meaning. The Stroop task and its many variations have proven to be successful measures in examining competition between automatic and non-automatic attentional processes. Studies on word versus image processing have also examined differences between these modalities, most of them inquiries on the extent to which each can be identified, categorized, encoded, and retrieved.

The Stroop color-word interference task examines the speed at which the ink color, a surface characteristic, of color words can be identified. Incongruent colored words (e.g., the word BLUE presented in red ink) have repeatedly shown delays in reaction time compared to controls in numerous studies and variants of the Stroop task (MacLeod, 1991). This delay in reaction time, referred to as interference, is thought to occur due to the incongruent color word acting as a distractor as participants attempt to name the presented ink color. Although many believe that what is now called the Stroop effect first originated with John Ridley Stroop (1935), it is often overlooked that James Cattell (1886) first explored the surface-level speed at which color patches could be identified, compared to the naming of color words printed in black ink. Cattell observed that participants could identify the words of colors significantly faster than their respective color patches. It was not until Stroop's classic study that color patches and color words were presented simultaneously, in order to examine the interaction effects of each (MacLeod 1991).

Since that time, many variations of the Stroop task have been conducted to measure interference using text, colors, and other manipulations of stimuli including the use of images. According to MacLeod (1991), the overall reaction time for processing textual stimuli has been consistently faster than that of visual stimuli (i.e., color) in variations of the Stroop task. Other studies, not related to the Stroop effect, have explored in greater detail cognitive processes behind image versus word processing.

Dual Coding Theory

In response to research questions relating to modality strength for knowledge representations, Paivio (1986) proposed the Dual-Coding Theory, which states that sensory input is both verbal and nonverbal. Nonverbal or analogue representations mainly refer to mental imagery, including prototypical features of concrete objects. Verbal and nonverbal information are processed separately in different cognitive systems, and the relative strength of encoding and recalling information depends on whether or not each system is involved in processing stimuli. For example, an image of a cat activates verbal and nonverbal pathways during the identification process, compared to reading the word 'cat' which activates only verbal pathways. This theory is related to phenomena found in the Stroop effect, namely involving the relative processing speeds of two types of stimuli words and image characteristics (i.e., colors) of words.

Potter, Kroll, Yachzel, Carpenter, and Sherman (1986) found that pictures were always named more slowly than words when used in surface-level identification tasks. These experiments attempted to examine different models of cognitive processing, particularly the lexical, conceptual, and dual-coding models According to Potter et al. (1986), pictures activate conceptual information across imaginal and verbal representations in the lexicon. Meaning, taken from this acti-

vation, is two steps removed for images while only one step removed for words. This process occurs because objects are labeled by category names; thus, images and their corresponding words are connected in the lexicon to make the encoding and retrieval of information stronger.

Though this account reasons that image representations are more strongly processed due to parallel activation of verbal and nonverbal systems, images are not necessarily processed faster than text. Words are consistently identified faster than images as shown in studies on surface-level naming tasks. According to a study by Arieh and Algom (2002), words are processed faster than images in naming tasks, while pictures assume superiority over words in timed categorization tasks. If words are identified faster than images, more interference is likely to result in textual stimuli over their image counterparts in a modified Stroop procedure. This assumption parallels the classic Stroop study, where words are named faster than the color of the words.

Instance Theory of Logan

The instance theory of Logan (1988) is another model that attempts to examine differences in processing between verbal and nonverbal stimuli. Logan (1980) stated that stimulus recognition involved a decision making process built upon the residual collection of "evidence" or individual instances taken from the real world. Sensory information from a subject's environment accumulates until a response is "forced" beyond a certain threshold. The process has two distinct types of responses, one involuntary or automatic (e.g., reading text) and the other relating to the voluntary allocation of attention (e.g., seeing images). Drawing from this theory, the strength of information from textual stimuli breaks through the threshold of evidence, thus providing a response more often than the attentional weight of visual stimuli. This theory can be applied to reaction times in cognitive tasks involving words versus images since the more attention required to recognize a stimulus, the longer it will take to produce a response.

Automatization

A primary factor involved in explaining the working mechanisms of the Stroop Effect is the distinction between voluntary and involuntary attentional processes. According to Sternberg (2006), automatization is the process by which a procedure changes from being highly conscious to being relatively automatic. A prime example of this is reading, which MacLeod (1991) declares to be almost "obligatory." The automatic process of reading directly relates to interference in Stroop tasks involving incongruent colored words. The identification of images or image characteristics (i.e., color) however, is not as automatic compared to the reading of text. Naming a word's ink color is a controlled surface-level process, where participants must suppress textual information in order to focus their attention on each item's image characteristic. The result is more interference, evidenced by a delay in reaction time in naming the target dimension (color) and ignoring the distractor dimension (text).

Studies in Stroop Testing

Color-Word Interference Test

In Experiment 2 of Stroop's (1935b) classic study, color patches and color words were combined for the first time to investigate the effects of words on color identification. Previous studies had used color words in black ink, comparing those stimuli to their respective color patches. Stroop was interested in the interaction effects of each, when compounded and presented together (MacLeod, 1991). Also known as the Serial Color-Word Test, the task of the experiment was to name the color while ignoring the presented word. Stroop presented multiple items on a single card, instructing participants to read aloud each item's ink color as quickly as possible. The formula used to measure reaction time was to take the total time per card divided by the number of stimuli to get an approximate time per stimulus. In Experiment 3, the task was reversed—participants were instructed to name the word while ignoring the presented ink color. Interference, marked by a significant delay in reaction time, was high in the color-naming experiment but not vice versa, due to participants being unable to ignore distractor words. The presence of interference in the color-naming task, not the word-naming task, is referred to as asymmetry and has led researchers to affirm theories involving the automaticity of reading text. Because of the ease of administering the original color-word interference test, many variations have been used to further investigate these results.

Picture-Word Interference Task

Since the original Stroop interference task, many variations have been generated as new questions involving automaticity, interference, attentional bias, and asymmetry arose. One such variation, the picture-word interference task, was created to investigate how semantic words and pictures interacted with each other. Developed by Hentschel (1973), the task was to name the target image (e.g., a line drawing of an APPLE) while ignoring the distractor word (e.g., the word BANANA placed inside the drawing). The words were either exactly the same as the image, semantically related to the image (i.e., from a similar semantic category such as TABLE and CHAIR), or were not related to the image at all. Incongruent words caused the most interference when naming the drawing. Again, the results are asymmetrical when the task is reversed; naming incongruent images did not have the same effect as naming words. This variation further added to evidence that verbal representations are processed automatically while visual representations are not. The study also stimulated interest in measuring subtle differences in interference, such as how words with semantic associations cause longer delays than other "unrelated" verbal stimuli.

Semantic Testing

A Stroop color-naming task administrated by Lupker (1982) found that

non-words, as well as words that were difficult to pronounce caused less interference than words that were well known. Higher word familiarity results in easier activation of verbal pathways linked to specific semantic areas of the lexicon. The more frequent these pathways are activated, the faster the overall processing of words. Faster processing of highly familiar words resulted in greater interference than less familiar/non-words. Klein (1964) performed an experiment that measured reaction times to color naming and investigated interference of semantic words having specific color associations. Like other variations of the Stroop task, a set of colors were used, but instead of the words representing colors, the words represented concrete objects typically associated with colors used in the stimulus set. For example, Klein used the colors red, green, yellow, and blue, with the associated words fire, grass, lemon, and sky. Interference was highest with the color-associated words when presented in an inappropriate ink color. This effect decreased dramatically with the presentation of non-associated, rare, or nonsense words. It appeared that the more meaningful the word to a specific color, the higher the chance of interference in color identification. Though interference rates were not as strong as found with actual color words, there were still significant differences in reaction times between semantic congruent and incongruent-colored conditions. This suggests a degree of automaticity in the activation of semantic word associations, where the use of lexical knowledge (i.e., the item's associated color) causes interference when trying to name the presented color of the word.

Statement of Purpose

Klein's study showed that even words with semantic color associations result in interference when presented in incongruent colors. These semantic stimuli activated specific regions of the lexicon, where information such as meaning and descriptive characteristics (e.g., color) is stored. Participants had to suppress this lexical information and instead allocate attention to the presented ink color of each item, in order to elicit a correct response. This study is essentially an extension of Klein's by involving the use of semantic stimuli, which allowed the use of concrete items in their verbal and corresponding visual modalities. This study was conducted to assess participant response times to semantic stimuli when presented in two different modalities, words and images, in order to examine differences in the allocation of attentional resources required for each.

Studies investigating picture versus word superiority have found that words are processed faster in naming studies, while pictures are faster than words in categorization studies, suggesting a degree of asymmetry depending on the task. In addition, various analogues of the Stroop task are relevant in investigating competition between attentional resources, namely, the response competition between target (ink color) and distractor (word) dimensions (MacLeod, 1991). The current study involved textual and pictorial items and incorporated a task requiring deeper processing than other Stroop studies, which typically ask participants to name the presented ink colors of stimuli. Instead, the task was to name the prototypical color of concrete, semantic objects that have strong color associations. Here, the target dimension (prototypical color) and distractor dimension (presented color) are of special interest, given the novelty of this task in Stroop research. Identifying the prototypical color now required participants to embrace information activated in the lexicon, rather than suppress it, and instead had to suppress the presented ink color in order to arrive at a correct response. The reversal of the task marks a change in where attention is to be prioritized—to the lexical properties of stimuli rather than their surface level characteristics.

Experimental Hypotheses

Clark (1987) found that text is always faster in any type of Stroop testing because of automatization in processing. However, non-directional hypotheses were chosen for this study due to the difference in the task from other Stroop studies, as well as the use of images in congruent and incongruent-colored conditions. In general, the experimenters expected participants to experience the following process during the experiment: They would first identify and focus attention on the meaning of the word or image, while "ignoring" the presented color, initially. The observance of the color is involuntary; however, attention must be "shifted" to it in order to become consciously aware of identifying it. Second, the object's lexical and semantic characteristics would be compared to the presented color information for accuracy. Any discrepancy would cause interference, whereas matching colors would lead to faster processing. Competing input of presented color versus color typicality cause a delay, since the inaccurate information must be suppressed in order for the other to receive prioritized attention and elicit a response. With this process in mind, the following hypotheses were made:

H1 There will be a significant difference in reaction time between the text and the image modalities (either text or picture), regardless of color congruency (congruent or incongruent colored items).

H2 There will be a significant difference in reaction time between con gruent and incongruent colored stimuli, regardless of presentatios modality.

H3 There will be a significant interaction effect between color congru ency and presentation modality on reaction time.

Method

Participants

Ninety-four participants, mostly undergraduate students, were invited to participate in this study. Participants were drawn from psychology courses, computer science courses, and at random, either voluntarily or for extra credit. Six participants were excluded from analysis due to their scoring less than 80% accuracy on the computer-based test during the experiment. Of the remaining 88 par-

ticipants, 40 were male (45.5%) and 48 female (54.5%). The age range varied from 18 to 43 years old, with the mean being 21.64 years. The median age was 21.

Experimental Design

The study used a 2 x 2 between groups factorial design, with a total of four conditions (Figure 1). The first independent variable was item-presentation modality, of which concrete items were presented as either text or images. The second independent variable was the presented color of items, being either congruent or incongruent with their actual prototypical color.

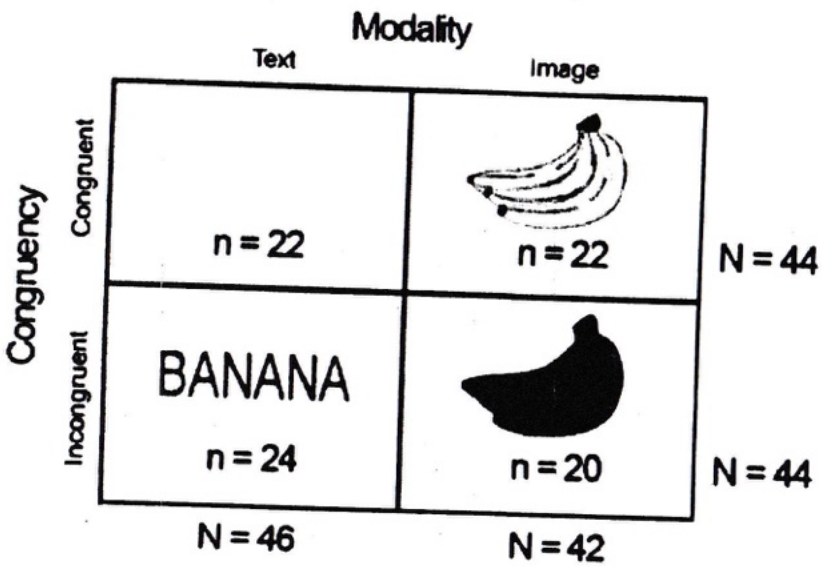

Figure 1. Experimental design conditions and distribution of sample sizes

Prototypical colors of concrete items (Appendix A) were assessed and determined through pilot testing administered to a small sample of subjects prior to the implementation of this experiment, in order to ensure a relative degree of validity concerning the prototypical color of proposed test items. The primary dependent variable measured was reaction time (RT), recorded in milliseconds (ms), to responses for stimuli presented in a computer-based modified Stroop task. Percentages of correct responses were recorded as a secondary dependent variable to ensure that participants understood directions to the experiment and that resulting RTs could be considered valid. Respondents whose scores resulted in more than 3 incorrect responses were excluded from data analyses.

Materials

To accurately measure individual reaction times of stimuli in milliseconds, a computer program was implemented into the design. This program allowed image files to be organized and shown in a slide show format. Image files were altered in accordance to the four different conditions, with all conditions having the same concepts, only in different modalities and colors. For example, the concept CHERRY was presented as a congruent-colored image, congruent-colored text, incongruent-colored image, and incongruent-colored text. Participants responded to each stimulus by pressing pre-assigned keys on a standard keyboard to indicate which prototypical color best fit the stimulus. The answer choices were red, yellow, or green, of which participants were instructed to categorize each stimulus as belonging to one of those options in terms of prototypical color. The V, B, and N keys represented red, yellow, and green, respectively. These keys, to minimize typing and categorization error, were color-coded with stickers (See Appendix B for a schematic layout of the keyboard design).

The computer software used was able to measure, in milliseconds, the latency of response from the initial onset of the presented stimulus to the keying of a participant's response. At the end of each test, a log file was generated, containing the list of presented image files along with their respective RTs for each item shown. In addition to the RT for each item, the log file also indicated the keyed response of each participant compared to the correct response, in order to calculate the percentage correct for an entire set of trials. The colors of image items that were presented (see example shown in Appendix C) were manipulated to create the incongruent-colored conditions. All prototypically red items were changed to blue, yellow items were changed to purple, and green items were changed to orange. All colors were manipulated using a RGB color scheme through Adobe Photoshop CS2 software.

Procedure

Participants were randomly placed into one of the four conditions prior to the administration of the computer-based test. Participants were instructed to name the most common, prototypical color by pressing one of the corresponding color-coded keys for each item presented. They were reminded to respond as quickly and accurately as they could in determining each item's prototypical color. There were a total of six practice trials and 18 test trials presented to each participant.

Results and Discussion

A total of 94 participants were initially invited to take part in this study. Of this sample, six participants were excluded from data analysis due to their responding to more than 3 of the 18 stimulus items by their incorrect color. The remaining participants (N = 88) resulted in the following sample distribution by condition (see Figure 1, above): congruent-colored text (n = 22), incongruent-colored text (n = 24), congruent-colored picture (n = 22), and incongruent-colored picture (n = 20).

Participants' mean RTs were computed for each of the four conditions.

shown in Figure 2. A 2 (Modality: Text or Image) x 2 (Color Congruency: Congruent or Incongruent) between-subjects analysis of variance (ANOVA) was performed on mean RTs in each condition (see Appendix I). Confirming our first hypothesis, significant differences in RT were found between text and image presentation modalities, $F(1, 84) = 6.66$, $p < .05$. Particularly, RTs were faster for textual conditions (M = 855 ms) than image conditions (M = 984 ms), with the average difference being approximately 130 ms. Confirming our second hypothesis, overall differences in RT were significant as a function of color congruency, $F(1,84) = 4.29$, $p < .05$. Congruent colored conditions (M = 867 ms) were significantly faster than incongruent colored conditions (M = 966 ms), by nearly 100 ms. No significant interaction effects were observed between modality and congruency, $F(1,84) = .588$, $p = .445$.

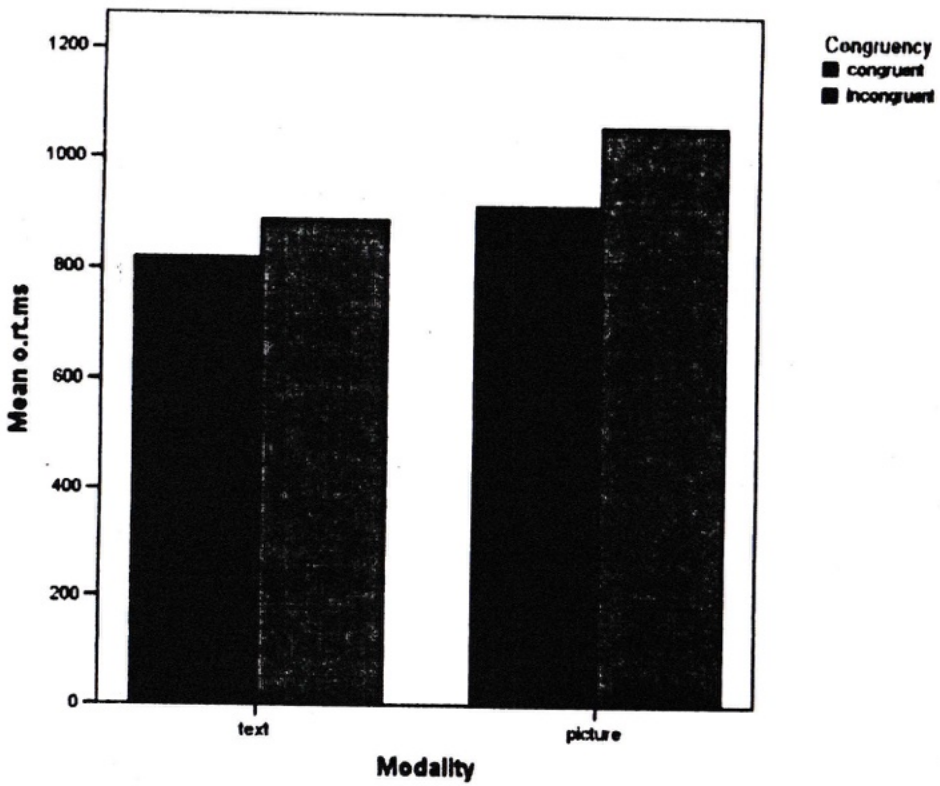

Figure 2. Mean RTs of participants, listed by modality and color-congruency.

Looking at the mean RTs between the textual conditions, a delay of 68 ms was found in the incongruent group, suggesting that manipulation of font color for textual stimuli caused interference as subjects responded to them by indicating their prototypical color. This delay in reaction time is likely to have occurred due to the automatic processing of text. As the words were read, the surface characteristic (color) of the words was also observed as sensory input. The reading of the words activated semantic pathways in the lexicon, where prototypical features of each concept were stored. An assessment of incoming sensory information provided by the presented font color was invariably compared to concept features stored in the lexicon, in this case, an item's prototypical color. This relates to the Instance Theory of Logan (1988), in that the information had to be compared to a concept taken from the lexicon, built upon instances from previous experiences with the stimuli. Any discrepancy between sensory input and lexical information caused longer delays in response latencies. The congruent colored text, absent of this discrepancy, aided in facilitating participants' responses as incoming sensory information and the reading of text simultaneously activated pathways during processing. Sensory information was parallel to object color characteristics stored in the lexicon.

Compared to the textual conditions, the two image conditions were observed to have taken an average of 130 ms longer. This is consistent with the literature, that the identification of words is faster than that of images, due to the automaticity of reading. Images take longer to be processed due to the features of the image (lines, shapes, colors, contours, etc.) not being recognized as quickly compared to the combined letters that compose words. Within the image modality conditions, an average delay of 147 ms was observed in the incongruent-colored images group compared to the congruent-colored image group. A similar explanation is offered, with the exception that images activate conceptual pathways leading to a categorical area within the lexicon. When images are processed they are essentially two-steps removed from an answer due to the extra step involved of both verbal and non-verbal systems being activated. The comparison of sensory input with information stored in the lexicon may still have occurred—thus the delay observed when presented images were incongruent-colored. This comparison involuntarily causes interference, since the participant had to ignore the presented color in order to proceed with a correct response.

Another possible explanation behind the delay in the incongruent-picture condition is that of the sensory input of color being a prime feature used to identify objects at first glance. The color of items, in addition to other characteristics such as size, shape, and so on, all serve as mental clues that facilitate the identification of an image. This is not the case with words. In the incongruent-picture condition, participants could not rely on the incoming color information to serve as a clue in properly identifying each stimulus, compared to the congruent-image condition. The correct color information of the congruent-image condition served as a facilitating feature in the object's identification. Color is crucial in identifying images compared to identifying words, explaining why the differences in RT were stronger between color congruency for images than words. This suggests that the semantic meaning attached to the stimuli was largely responsible for certain delays in RT's. According to Klein (1964), the more meaningful the word, the

higher the interference and in this case, the semantic meaning of the images also caused interference.

It is also interesting to note the similar results to other Stroop studies that were found, given the change in task. Where participants usually must ignore the meaning of a word in traditional Stroop tasks, here, they had to integrate the meaning of the word or image in order to respond. Even though target and distractor dimensions were changed, interference still occurred. Our experiment was able to show how incoming sensory information and lexical representations, when different, cause a discrepancy in where attentional resources are to be allocated. This results in a delay of reaction time, as observed in the incongruent colored conditions of both word and picture modalities.

Limitations & Directions For Future Research

There are some notable limitations in this study, mostly being associated with the experimental design and availability of participants. As noted by MacLeod (1991), many Stroop studies do not incorporate a proper control condition for color congruency, resulting in a combined measurement of interference and facilitation. The two phenomena can be separated by introducing a proper control condition, such as words printed in black ink. Using a proper control, results can show how much faster participant response times were to the congruent condition, and how much of a delay was observed under the incongruent condition. Unfortunately, the difference in the RT's combined interference and facilitation effects. Proper congruency controls for this study might have included black words and black and white images. An additional independent variable could also have been added, being the task itself. If this study had a control task of naming the presented color, a better examination of the effects of changing the task to naming the prototypical color would have been possible. While the addition of independent variables seems to enhance the overall quality of a study, it must be noted that the addition of variables also increases the complexity—and necessary resources needed to complete the experiment—at an exponential level.

The computer software used was an excellent tool in measuring individual trial reaction times in milliseconds; however, voice-activated response testing software is even more precise and may have detected more subtle differences between groups. Another limitation in this study was the limited number of stimuli. This was because while some concepts with strong prototypical color associations could be presented as text, they could not necessarily be presented as easily identifiable pictures (e.g., SKY). Future directions for research might include the use of voice-activated response software, increasing the number of trials by presenting each stimulus more than once, using proper color congruency controls, and expanding the design to incorporate the additional independent variable of task manipulation in order to better relate to previous Stroop studies.

Appendix A

List of Stimuli for Text and Image Conditions

Items associated with RED

APPLE	LOBSTER	FIRETRUCK
CHERRY	STRAWBERRY	HEART

Items associated with YELLOW

BANANA	CORN	TAXI
BUTTER	SUN	CHEESE

Items associated with GREEN

DOLLAR	BROCCOLI	FROG
CELERY	TURTLE	PEAS

Appendix B

Color-coding scheme of keyboard for computer test.

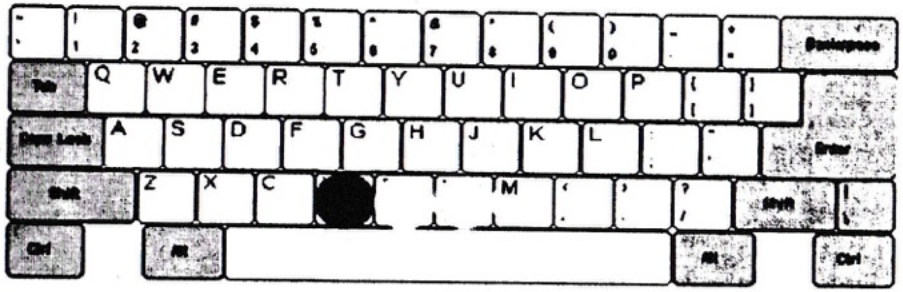

Appendix C

Stimulus items shown in their congruent image form.

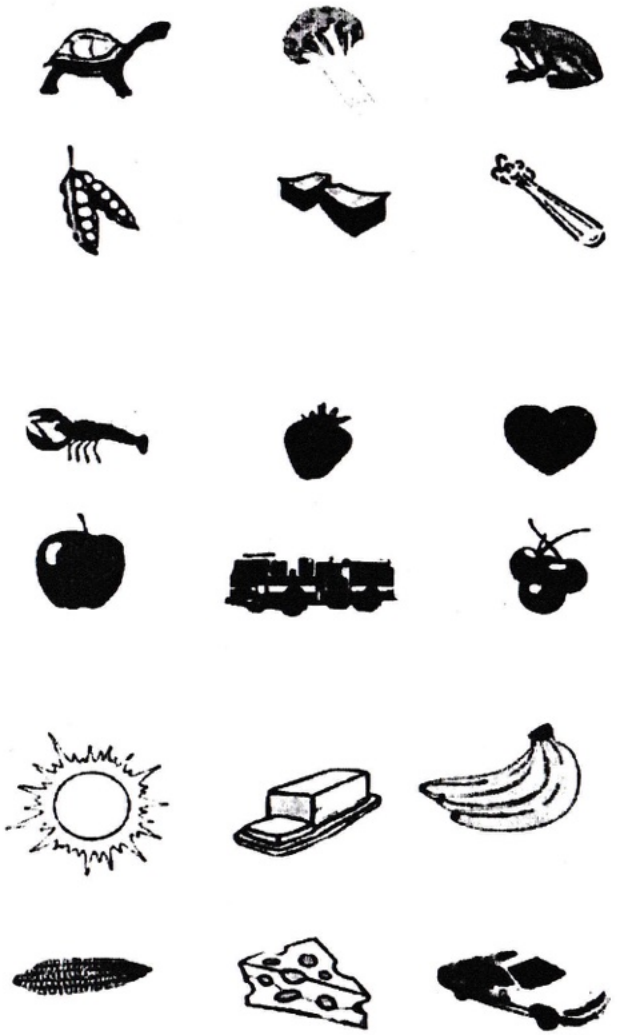

Appendix D

Informed Consent Form

You are invited to participate in a study on reaction time involving pictures and words of common, everyday items. The entire experiment will take approximately 30 minutes to complete

As a participant, you will be asked to fill out a Demographic Information Sheet. You are not required to provide your name or other personal contact information, in order to maintain anonymity.

Following the Demographic Information sheet, you will be asked to participate in the following:

- A computer based test: A test on reaction time involving common, everyday objects presented in either a picture or word format. There are 36 items in the test.
- A post-test survey: To be administered after the computer based test.
- Debriefing: At the completion of the experiment, you will be informed of the purpose of the study and the rationale behind it. Once the study is complete, you will be informed, at your request, of the study's findings.

You, as a participant, will not be subjected to any situations deemed stressful in this experiment. There are no risks, emotional or physical, involved in being part of this study. Your personal information will remain confidential and data will only be used for research purposes. If at any time you no longer wish to participate in this study, you are free to stop the experiment without prejudice.

The experimenters intend to present the summarized findings of this study at collegiate/professional conferences and may publish these findings in an academic journal.

I have read and understand the above information presented, and have been given answers to any questions concerning this study.

_____ _____

Participant's signature Date

Appendix E

Demographic Information Sheet

Participant ID (*for identification purposes only*): ___ ___ ___ ___

Gender: Male _____ Female _____

Age (in years): _____ Date of Birth (*mm/dd/yy*) _____ / _____ / _____

Race / Ethnicity (*Optional*):

_____Asian or Pacific Islander

_____Black or African American

_____Hispanic or Latino (of any race)

_____White (Non Hispanic or Latino)

_____Other (Please specify): _____

Year in School: Freshman ___ Sophomore ___ Junior ___ Senior ___

Major: _____

Handedness: Right ___ Left ___ Ambidextrous ___

Is English your primary language? Yes: ___ No: ___

If No, what other language(s) do you speak? _____

If No, is English considered your primary language? Yes ___ No ___

How long have you lived in the United States? _____

Thank you for completing this demographics survey.

Appendix F

Post-Test Survey

Thank you for Participating in our research study. Please answer the following questions to the best of your ability:

1. Please try to write the names of all of the objects, or as many as you can, that you saw o the test:

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

2. At anytime were you confused while taking the test? Which concepts did you find confusing?

3. Were there any items that you couldn't or had trouble identifying? If so, which ones?

4. Did you have any technical issues while using the computer? If so what problems did you have?

5. Any other considerations to let us know about? (ex: distracted, blurry vision, etc.)

Appendix G

Debriefing Form

Participant ID _____

You just completed an experiment that involved naming the prototypical color of different objects shown to you by a computer program, which measured your reaction time. There were four groups in this experiment, to which one of them you were randomly assigned.

Two groups were shown objects in their picture form (e.g., a picture of a LEMON), and were either accurately colored (e.g., yellow) or inaccurately colored (e.g., blue). The other two groups were shown objects as text, where the words were colored in two different ways as well. The words were either represented in their prototypical color (e.g., LEMON in yellow font) or in an incongruent color (e.g., LEMON in blue font). All participants were to name the *prototypical color* of each object, despite what the actual color of the object was.

The reaction times from these four groups, *congruent colored text, congruent colored images, incongruent colored text, and incongruent colored images* will be compared to one another once the experimenters have tested all participants and analyzed the data. We suspect that there will be a difference in reaction time between the text and picture conditions, as well as between congruent and incongruent colored items.

If you would like a detailed follow-up report informing you of the results of this experiment, please leave your email address at the bottom of this form. Individual results will not be made available (only group averages for each condition).

Thank you for participating in this study.

I have read and understand the above information regarding this study.

Signature: _____ Date: _____

Any questions, contact Study Coordinators:

Shawn McGinniss Mac734@gmail.com

Jamie Clark BlueBarettes@gmail.com

Tiffany Allaway TinyTiffi@myself.com

Appendix H

Participant Procedure Instructions

Directions:

You are about to be shown a series of items that have very common color associations. For example, lemons are usually yellow, grass is green, and so on.

Please answer as quickly (and accurately) as you can for each item.

If you have any questions, ask an experimenter for help before beginning.

Press one of the color-coded keys to begin!

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INTERNATIONAL PSYCHOLOGY REPORTER

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http://www.internationalpsychology.net

Volume 10, No.1 **Winter 2006**

MESSAGE FROM THE 2005 PRESIDENT OF DIVISION 52

Norm Abeles, Ph.D
2005 President

Good News and Not-So-Good News from the White House Conference on Aging

For the next issue of the International Psychology Reporter, Division 52 President, Joy Rice, PhD will take over and write you a message. In the meantime let me tell you of some interesting happenings. I returned the other day from the White House Conference on Aging which was held at a hotel (not the White House) in Washington, DC. I was also at the last Conference in 1995, as the WHCoA is held once every ten years. The 1200 delegates were selected by their congressional representatives (one each) and the 50 Governors (several based on state population). There were also 400 at large delegates and some delegates from specific organizations. Among the 1200 delegates there were 7 psychologists, including our 2005 APA President, Ronald Levant.

We were presented with 73 resolutions and asked to reduce those to 50, after which the top ten resolutions were selected (mostly to satisfy the media because they wanted a short list of resolutions).Each delegate had an opportunity to select 50 resolutions. These resolutions were grouped into 7 general headings: *Planning Along the Lifespan; Workplace of the Future; Our Community: Health and Long Term Living; Civic and Social engagement; Technology and Innovation in the Marketplace*, and finally, *Cross-cutting items*. So what about the items with international implications? Well, there were two of them. First, there was a resolution which covered global aging insights and was titled "Identify Best Practices derived from experiences of other industrial countries facing an aging population". There was another cross-cutting item dealing with elders who have limited English proficiency. Unfortunately, neither of these resolutions made the Top 50. However, in the exhibit area there was a 2004 report by the International Longevity Center headed by Robert Butler, MD., who first used the word "ageism". This report included an article on growing older in the world's major cities. The longevity center publication cites research dealing with coronary artery disease among older persons in London, Paris and New York. The study was designed to assess differences in mortality, morbidity and treatment patterns as well as gender disparities in the invasive treatment of coronary artery disease for persons over the age of 65. The study concluded that even after accounting for disease prevalence, rates of revascularization (coronary bypass surgery and angioplasty) are lower in Manhattan than in Paris not only for those over 65 but for those in the 45-65 year old age group as well. This is interesting because we usually assume that high tech procedures are used more often in the United States.

Another report noted that there is gender disparity in treatment of heart disease across three national health systems with known differences in patterns of medical practice. The article points out those gender disparities are a function of underdiagnosis of heart disease in women. Finally, another study compared hospital conditions in London, Paris and New York. The study found that not providing universal access to primary care results in more costly hospitalizations that could be avoided (p17). In New York, 28% of the population is uninsured, while in London and Paris there are no financial barriers for those who legally reside there. In New York City the costs of avoidable hospital conditions are three times higher than in London and Paris among Medicare participants and the uninsured even after controlling for race, gender, age and socioeconomic status (International Longevity Center, 2004).

So much for this international detour. Which resolutions made the list of the top 10? Here is a listing:

1. Reauthorize the older American Act
2. Develop a coordinated, comprehensive long term care strategy
3. Insure that Older Americans have transportation options
4. Strengthen and improve Medicaid

Continued on p. 3….

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JOIN US
as a Member of DIVISION 52!
Membership Application may be accessed at:
http://www.internationalpsychology.net/membership/

SUBMISSION INSTRUCTIONS

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (Division reports, academic articles, etc.) can be up to 1500 words and should be submitted by email to Dr. Senel Poyrazli at poyrazli@psu.edu. For research article submissions, authors are asked to follow guidelines presented in the Publication Manual of the American Psychological Association (5th edition, 2001).

Submission deadlines:

Spring issues – March 31
Summer issues – June 30
Fall issues – September 1
Winter issue – December 31

International Psychology Reporter is the publication of Division 52 of the American Psychological Association

All Division 52 members are invited to report on their scholarly activities related to their books. Interested members should contact Dr. Jennifer Lancaster at jlancaster@stfranciscollege.edu.

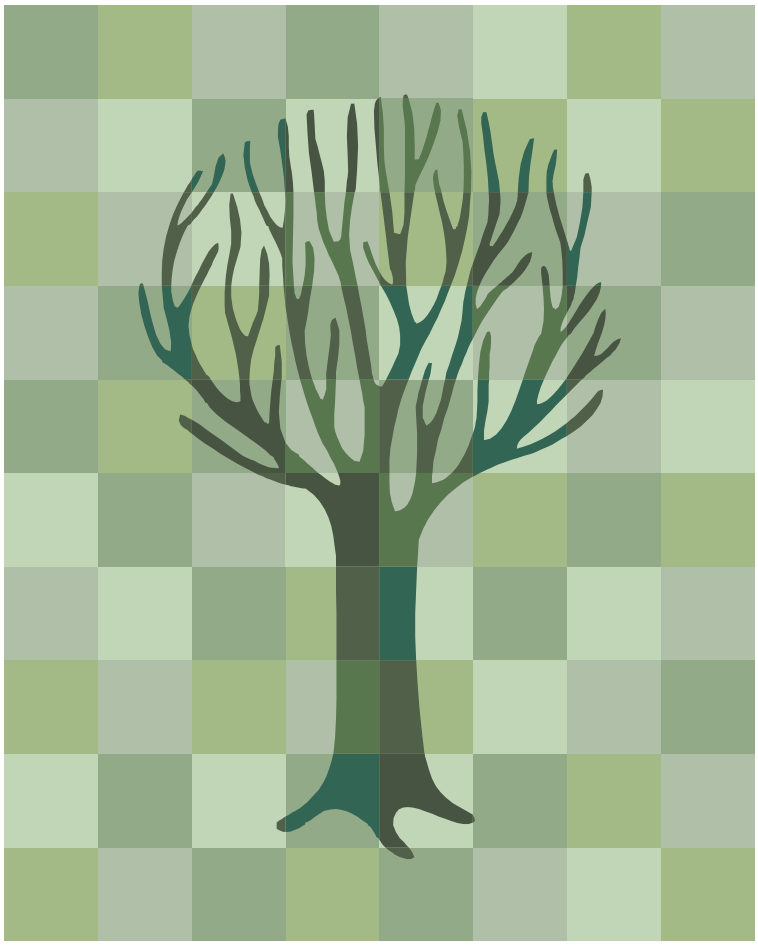

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5. Strengthen and improve Medicare
6. Support geriatric education and training for all Health care professionals, paraprofessionals, students and direct care workers
7. Promote innovative models of non-institutional long-term care
8. Improve recognition, assessment and treatment of mental illness and depression among older Americans
9. Attain adequate numbers of health care personnel in all professions who are skilled and specialized in geriatrics
10. Improve state and local based integrated delivery systems to meet 21st century needs.

So the good news is that important resolutions were forwarded for considerations by policy makers in the public and private sectors. I hope that some of these resolutions will be enacted by federal or state laws or will receive significant support from the private sector. With that I wish all of you a very happy, healthy and successful 2006!
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DIVISION 52 NEWS and UPDATES

APA EXPERT SUMMIT on Immigration and Joint Midwinter Conference & Division 52 MidWinter Meeting 2006

Lynn Collins, Ph.D.
LaSalle University
Email: collins@lasalle.edu

Joy K. Rice, President, Division 52
University of Wisconsin
E-mail: jkrice@wisc.edu

APA Division 52 will be holding its Midwinter Board Meeting on February 2-3, 2006 in San Antonio Texas in conjunction with APA's Expert Summit on Immigration. The organizing firm is Reisman-White. Their website address is http://www.reisman-white.com/. Follow the "Conference Registrations" link. The website contains an overview of the conference, some information on the plenary keynote speakers, a conference registration page as well as a link to the host hotel.. Many other APA Divisions will be holding their midwinter meetings immediately following the Summit including Division 52. We are pleased to have a good turnout for the meeting and will update you on our proceedings in the next newsletter.

The special Division 52 conference programming includes posters and a symposium on "Immigration: Focus on Women, Children and Families." (Give the details in the acrobat file).

Division 52 Symposium for the Breakout Session: "Focus on Women, Children, and Families"

Co-Chairs: Lynn H. Collins, Ph.D. & Joy K. Rice, Ph.D.
Participants:
Jean Lau Chin, Ed.D., ABPP, *California School of Professional Psychology, Alliant International University*, *San Francisco*.
Oliva M. Espin, Ph.D., *San Diego State University.*
Fred Bemak, Ed.D., *George Mason University*
Rita Chi-Ying Chung, Ph.D., *George Mason University*

The first presentation is entitled, "Creating Immigration Legend." Dr. Chin will discuss the immigrant experience and the importance of creating family and immigration legend to bond and to heal from the trauma of immigration. Drawing on her book, "Learning from My Mother's Voice", the Dr. Chin examines perennial and pervasive themes of separation, loss, guilt, and bicultural identity in the lives of immigrant families. She will compare Asian and Western myths, symbols and legends and how powerful such stories and images can be to both sustain and oppress as immigrant families struggle to build new lives in a different culture. Dr. Chin is also the author of The Psychology of Prejudice and Discrimination (Praeger Press).

The second presentation is, "Gender Roles and Sexuality in Women's Experience of Migration." Dr. Espin will focus on the impact of the experience of migration on women's gender roles and their sexuality. Based on the voices of women from different regions of the world, this paper will present and analyze the transformations and resistances expressed through women's sexuality and their roles in the course of the migration experience and subsequent acculturation.

The third presentation will be, "Perspectives on Mental Health Interventions with Immigrant and Refugee Women, Children, and Families: Cross-Cultural Issues and Practice." Dr. Bemak will examine how although 11% of the U.S. population is now comprised of refugees and immigrants, mental health professionals have not adequately addressed the significant and unique needs of this population. Many refugees come from war-torn countries, have faced persecution and torture, and a loss of human rights, while both refugees and immigrants find themselves having to adapt to a new culture that is oftentimes dramatically different than their home countries. It is important for mental health professionals to clearly understand pre-migration trauma, transitional migration experiences, and the effects of pre-migration and transition on post-migration and mental health in order to effectively work with these populations. This presentation will explore cross-cultural issues that are consistent with culturally responsive mental health interventions that impact women, children, and families and discuss an innovative model of cross-cultural psychotherapy that is specifically geared towards working with migrant populations that takes into account migration, adaptation, and acculturation, human rights, and social justice.

The fourth presentation is entitled, "Psychosocial Challenges of Immigrant and Refugee Women and Families: Implications for Practice and Research." Dr. Chung will focus on the psychosocial challenges encountered by immigrant and refugee women and their families. Women face unique challenges in adjustment and adaptation. Since women are the primary caretakers of the family they are in a significant position of maintaining traditional culture within the family system and simultaneously balancing and integrating the adaptation to the new culture. They therefore play a key role in redefining family structure, boundaries, dynamics, and relationships for themselves and family members. The presentation discusses implications for practice and research.

Division 52 Posters

Each division was only allotted space for two posters, however, Division 43 accommodated one of our posters and other divisions provided other slots. The following posters will be displayed at the conference:

Migration, Loss, and Family Process. Peter Chang, Ph.D., *The Wright Institute.*

Cape Verdean Women in America: Acculturation and Gender Roles. Maria Coutinho, M.A., *Boston College.* Elizabeth Sparks, Ph.D., *Boston College*

Black Caribbeans in the U.S.: Structural Conditions, Family Contact and Emotional Support. Ishtar Govia, M.T.S., M.A., *University of Michigan;* James S. Jackson, Ph.D., *Institute for Social Research;* Daniel Katz, Ph.D., *University of Michigan.*

Continuum in Asian Indian Immigration Experience: A Grounded Theory Initiative. Shruti Poulsen, Ph.D., *Purdue University;* Nithyakala Karuppaswamy, Ph.D., *University of Illinois at Springfield;* Rajeswari Natrajan, Ph.D., *Alliant International University.* (accepted by Division 43)

[Many thanks to Michael J. Stevens, Ph.D., D.H.C. (Illinois State University), Sunita M. Stewart, Ph.D. (Children's Medical Center of Dallas & UT Southwestern

Medical Center at Dallas), and Richard S. Velayo, Ph.D. (Pace University) for their help with poster review, and George K. Hong, Ph.D. (California State University - Los Angeles) of Division 43 for his interest in our poster.]

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Rita Chi-Ying Chung, Ph.D., *George Mason University*

Abstract:

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Many thanks to Michael J. Stevens, Ph.D., D.H.C. (Illinois State University), Sunita M. Stewart, Ph.D. (Children's Medical Center of Dallas & UT Southwestern Medical Center at Dallas), and Richard S. Velayo, Ph.D. (Pace University) for their help with poster review, and George K. Hong, Ph.D. (California State University – Los Angeles) of Division 43 for his interest in our poster.

International Fellowship Research Opportunities

The Mentoring Committee of Division 52 has added a page to our webpages, listing international research and teaching opportunities. Comments or suggestions for this page should be sent to the chair, Irene Hanson Frieze, at frieze@pitt.edu or at (412)624-4336. She is seeking additional volunteers for the committee. The Mentoring Committee is working on creating a way of linking researchers in different countries so that people outside of the U.S. can find sponsors if they want to come to the U.S. or if they want help in preparing papers for publication in U.S. journals. We would also like to have volunteers to host U.S. scholars who want to work in other countries.

Book Reviewing Opportunity

Danny Wedding, PhD, MPH
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I welcome D52 members as reviewers for *PsycCRITIQUES: Contemporary Psychology—APA Review of Books.* Many of our members have already written reviews of books relevant to international psychology; anyone interested in reviewing for the journal should sign up at www.jbo.com/cpreview/, mentioning in the "Notes" section that they are members of D52.

EPA International Program: March 2006 in Baltimore

Uwe Gielen, Ph.D.
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Since its founding in 1997, our APA International Division has steadily promoted international psychology in the USA. Year 2006 promises to be another banner year under our dynamic President Joy Rice, with our exciting midwinter Board meeting on Feb 2-6 in San Antonio linked with the first-ever APA Summit on Immigration, and our annual APA meeting on August 10-13 in New Orleans.

Meanwhile, our D52 has outreached to the 7 regional associations to increase their international sessions. Thanks to the EPA Board, Executive Officer Arnold Glass, and Program Chair Rachel Barr, EPA includes "international" as one of the nine official tracks for its 2006 meeting--a "first" for EPA or any regional group. The March 17-18 EPA program at the Baltimore Wyndham Inner Harbor Hotel includes two invited speakers, and eight back-to-back symposia featuring folks from at least ten international or cross-cultural psychology groups. EPA has long enjoyed a reputation as an unusually friendly, lively, low-cost meeting, with details available at www.easternpsychological.org.

EPA International Program
Friday-Saturday, 17-18 March 2006, Baltimore
Schaefer Room, Wyndham Inner Harbor Hotel,
www.easternpsychological.org

FRI 8:30-9:50: INVITED ADDRESS: Merry Bullock, Director, APA *Office of International Affairs.* Going International: Challenges and Opportunities.

FRI 10-11:20: INTERNATIONAL PSYCHOLOGY ORGANIZATIONS TODAY
Chair: Thomas Blass, *University of Maryland Baltimore County*
Participants:
Florence L. Denmark, *Pace University*. International Association for Applied Psychology
Edith Grotberg, *Alexandria VA*. International Council of Psychologists
Anie Kalayjian, *Fordham University.* World Federation for Mental Health
Uwe P. Gielen, *St. Francis College.* Society for Cross-Cultural Research
Merry Bullock, *APA*. International Union of Psychological Sciences
John C. Norcross*, University of Scranton,* & Gerald P. Koocher*, Simmons College*. International Society for Clinical Psychology
John D. Hogan, *St. John's University.* APA International Division

As psychology now grows apace outside the USA, the field is served by a variety of independent organizations, with specific missions very different from one another. This includes IAAP (formed in 1920), ICP (1941), WFMH (1948), IUPsyS (1951), SCCR (1971), ISCP (1997), and APA Division of International Psychology (1997). In the first half of this two-part session, an officer of each organization briefly describes its role within international psychology--including its origin, mission, current size, publications, conferences, special projects, and membership details. Part two is an open discussion of the growing interaction of these organizations in strengthening psychology on the world scene.

FRI 11:30-12:50: OPPORTUNITIES TODAY IN INTERNATIONAL PSYCHOLOGY
Chair: Harold Takooshian, *Fordham University*
Participants:
Uwe P. Gielen, *St. Francis College,* & Michael Stevens*, Illinois State University.* Publishing international and cross-cultural psychology books.
Senel Poyrazli & Elizabeth M. Colechio, *Pennsylvania State University*. Publishing international and cross-cultural psychology articles
Merry Bullock, *APA*. International Affairs and the Committee on International Relations in Psychology
Rivka Bertisch Meir, *Hunter College,* & Michael Meir*, Touro College*. Involving overseas colleagues
Elaine Bow, *Nyack College*, & Harold Takooshian, *Fordham University*. Psychologists at the United Nations
Fiorella Paradisi, *UMDNJ*. Early-career psychologists' involvement in international psychology.
Anica C. Mulzac, *St. Francis College*. Student involvement in international psychology.

How can individual U.S. psychologists and students become more involved in the growing fields of cross-cultural and international psychology--with research, practice, education, and advocacy? This discussion session offers information on new opportunities--including publication of books and articles, sources of information and funding, new developments at the United Nations, and resources for students.

FRI 1-2:20: GLOBALIZATION, CULTURE, AND THE PERSON
Chair: Fathali M. Moghaddam, *Georgetown University*
Participants:
Rom Harre*, Oxford University and Georgetown University*
Fathali M. Moghaddam, *Georgetown University*
Gerrod W. Parrott, *Georgetown University*
Steven R. Sabat, *Georgetown University*

Terrorism, mass migration of refugees, ethnic cleansing, global warming and natural disasters... Globalization is associated with major challenges for humankind, reviving debates about human nature and what constitutes a person. Participants in this symposium discuss topics ranging from terrorism, to emotions, to stereotyping, to explore the idea of a person, and how conceptions of personhood are dependent and independent of cultural context. It is proposed that positioning theory can serve as a useful framework for such discussions.

FRI 2:30-3:50: CROSS-CULTURAL PSYCHOLOGY: METHODS AND FINDINGS
Chair: Oraine Ramoo, *Lehigh University*
Discussant: Lynn H. Collins, *LaSalle University*
Participants:
Naomi Lee, *Georgetown University.* Beauty.
Lynn H. Collins, *LaSalle University.* Sex roles.
Joseph R. Ferrari, *DePaul University,* Juan Diaz-Morales, *University of Madrid,* Spain, Jean O'Callaghan, *Roehampton University, UK,* Karem Diaz & Doris Argumendo, *Catholic University of Peru.* Procrastination.
Florence L. Denmark, *Pace University.* Ageing.
Senel Poyrazli, *Pennsylvania State University.* International students.

The recent rise in psychological research across cultures adds diversity to our findings, as it reveals subtle yet powerful impacts of culture on human behavior. This symposium discusses methods and findings of cross-cultural research across a variety of topics--attraction, ageing, procrastination, sex-roles, and adjustment of international students at U.S. universities.

SAT 8:30-9:50: INVITED ADDRESS: Haroutune K. Armenian, *President, American University of Armenia.* Wartime to earthquakes: Psychological determinants of physical illness.

SAT 10-11:20: ARMENIAN BEHAVIORAL SCIENCES
Chair: Shakeh J. Kaftarian, National Institutes of Health
Participants:
Samvel S. Jeshmaridian, *Kennan Institute.* Collaboration between Armenian and US behavioral scientists.
Diane L. Kupelian, *Bethesda MD.* Stress and mental health.
Alice Kassabian, *Fairfax Psychotherapy Center.* Helping women survivors of genocide.
Harold Takooshian, *Fordham University.* Ethnic identification of Armenian-ancestry behavioral scientists
Anie Kalayjian, *Fordham University.* 1988 Post-earthquake relief: Impacts on the Armenian Republic

A growing number of ethnic psychology associations now apply behavioral research and practice to issues specific to their ethnic group--Jews, Arabs, Blacks, Asians, Italians, Native Americans. Since the U.S. Armenian Behavioral Science Association was formed in 1987 by members from six disciplines, ABSA has brought together researchers, practitioners, and students to focus attention on current issues facing this ancient national group--genocide, stress, migration, ethnic identification. Since 1991, new issues have arisen when the collapse of the Soviet Union created the first fully independent Armenian Republic in over 500 years, and the founding of a bold new American University of Armenia in Yerevan, Armenia.

SAT 11:30-12:50: NATURAL DISASTERS: MENTAL HEALTH INTERVENTIONS
Chair: Anie Kalayjian, *Fordham University*
Participants:
Nicole Moore, *Fordham University.* Immediate impacts of the 2004 tsunami
Jena Binder, *Fordham University.* Six-month follow-up after the 2004 tsunami
Fiorella Paradisi, *UMDNJ.* Impacts of tsunami relief efforts on the care-givers
Anie Kalayjian, *Fordham University.* Hurricane relief following Katrina and Rita

Psychologists are increasingly involved in relief efforts addressing mental health needs following natural disasters, in several roles--research, direct service, advocacy. This symposium brings together disaster experts who responded to the 2004 tsunami in Southeast Asia, and Hurricanes Katrina and Rita in the southeastern USA. They focus on the immediate and longer-term needs of the local survivors, as well as the care-givers themselves, and effective research-based interventions.

SAT 1-2:20: HISTORICAL PERSPECTIVES ON PSYCHOLOGY IN NYC: AN OVERVIEW AND 3 SNAPSHOTS
Chair: John D. Hogan, *St. John's University*
Discussant: Wade Pickren, *American Psychological Association.*
Participants:
John D. Hogan, *St. John's University.* Psychology in NYC: An Overview
Mark E. Mattson, *Fordham University.* Rev. William C. Bier, SJ: Defender of the faith and defender of psychology.
Elizabeth Messina, *Lenox Hill Hospital.* Confronting racist ideologies behind "intelligence" testing and the impact on Italian Americans.
Kurt Salzinger, *Hofstra University.* Psychology at the New York Academy of Sciences.

SAT 2:30-3:50: HISTORY OF PSYCHOLOGY ORGANIZATIONS IN NEW YORK CITY.
Chair: John D. Hogan, *St. Johns University*
Discussant: Wade E. Pickren, *American Psychological Association*
Participants:
Ted Rice, *George Washington University.* Psychology Department histories.
Edwin P. Hollander, *Baruch College & CUNY Graduate School.* The U.N. and international activities.
Evan Stark, *John Jay College,* & Harold Takooshian, *Fordham University.* SPSSI-NY and social issues.

Two panels offer overviews of significant people and events in the history of psychology in New York City, and their interaction with various social and cultural forces. Though NYC has been the source of many key figures, concepts, and developments in our field since the origin of psychology in the 1800s, there is little systematic research on the history of psychology in NYC. A team of local historians is now examining this rich and fascinating history--including the City's psychology departments, United Nations, Ellis Island, NY Academy of Sciences, and local groups like the Society for the Psychological Study of Social Issues (SPSSI-NY).

Division 52 Welcomes Editorial Assistant

Division 52 welcomes one of its members, Elizabeth M. Colechio, as the editorial assistant for *International Psychology Reporter*. Elizabeth currently is in the master's Applied Research Psychology program at Penn State's Harrisburg campus. She graduated *magna cum laude* from Alma College (MI), from which she earned her B.A. in psychology and in history, in April 2005; she hopes to continue her education in the Neuroscience doctoral program at the Penn State Hershey Medical Center/College of Medicine in Hershey, PA, after completing her master's degree.

U.S. News

"Responsible for What History Will Make of It": The Significance of the End of World War II*

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[This lecture was presented on November 18th, 2005 at the Institute for International and Cross-Cultural Psychology, St. Francis College, New York City.]

Die Jungen sind nicht verantwortlich für das,
was damals geschah. Aber sie sind verantwortlich für das,
was in der Geschichte daraus wird.
Wir Älteren schulden der Jugend nicht
die Erfüllung von Träumen,
sondern Aufrichtigkeit. Wir müssen
den Jüngeren helfen zu verstehen,
warum es lebenswichtig ist,
die Erinnerung wachzuhalten.

Richard von Weizsäcker, May 8, 1985

Holger Henke, Ph.D.

The first part of this paper's title refers to a speech made in 1985 by the then German President Richard von Weizsäcker in which he basically said that the younger generations cannot be held responsible for what happened in Germany during the Nazi regime, but that they will be responsible for how History will think about this time. I found this quote appropriate, not just because I agree with the content, but more so because it points to a central concern of mine in this paper, namely the question how the commemoration of this most significant period of the 20th century will

change, is already in the process of changing. My motivation is the simple idea that – as already expressed in late 1945 by the philosopher Karl Jaspers – we are what we commemorate.[i] In the following, I wish to comment on a number of issues pertaining to Germany 60 years after the war, the question of how different generations appropriate history in distinct and different ways, why WWII was such a defining moment in German, European and world history, and what are some of the lessons of this time we ought to keep in mind in our day and age.

Whose significance?

The question this title immediately raises is: "significance for whom"? No doubt, this watershed event in world history has quite different meanings for different people. Nonetheless, I believe that these particular perspectives can be transcended and that there are some general comments which can be made with regard to the significance of WWII. In other words, there are likely to be lessons and meanings that will survive the test of time and the particular perspectives of different generations or people. Still, we need to attend to the nuances as well. Although many historians will tell us differently, History is not just the recording of factual events as they happened. In fact, more importantly, it is about how we explain and interpret what happened, particularly when it involves contentious issues relating to events such as conquest, genocide, forced resettlement, and similar questions including deep moral and ethical dimensions. And so, I agree with the well-known cultural studies scholar Stuart Hall who recently said: "... writing a national history is not only to tell yourselves the stories that flatter you; it's to tell yourself some difficult stories."[ii]

It is from this position that I look at the gaps that exist between the grammar and the rhetoric of the nation – and I am doing this fully aware of the thin line that often separates a moralistic interpretation of world history from the danger of falling into revisionism.

Having been born in Germany, I am an immigrant, not for the first time, but I am also a citizen of the United States. As such, I am concerned with the extent to which WWII still seems to influence the American imagination and public morality of war and warfare. While you can count the amount of American films that deal with the Vietnam War – deal with it critically, I mean – on the fingers of one or two hands, films that deal with Hitler's Germany are dime a dozen. Nothing is wrong with that *per se* – in fact, this fascination is certainly a global phenomenon. I also do not necessarily have any problem with the fact that it renders a rather one-sided view of Germany and Germans. Nazi films just make good entertainment, I suppose. After all, they allow the outside spectator to take a close look at evil without feeling guilty about it. However, I believe it is also possible to take a more critical look at this prominence of WWII lore in popular American culture.[iii] The question could be raised, for example, whether this WWII fascination does not conveniently deflect attention from much more difficult interrogations of our own military and political engagements abroad? I will return to this line of reasoning in a little while.

What we should state at this point already, is that the Shoah – otherwise known as the Holocaust – is not just German history, but also world history. To the extent, therefore, that it has in some way become a part of everybody's history, we have to be aware that it is heavily imbued with an element of voyeurism – at least at the level of the popular imagination and mass culture.[iv] For Jewish people, on the other hand, it will always remain a symbolic marker of their historic victimization, which nowadays, of course, has been turned into a source of nation- and peoplehood. For Germans, finally, the Shoah will always – whether they like it or not – remain the reference point of their role as history's ultimate perpetrators. And, let me repeat, from this role flows an obligation to be vigilant against – no, critical of – political ideologies and any and all violations of human rights at the individual level, but more importantly where it involves the power of the state, any state, not just the German state.

On the Uniqueness of World War II

Two characteristics stand out that make this war different from others. After all, some people may argue that it was just one of many, too many, wars in the long history of humankind – and to some extent they are right to make this observation. However, what makes WWII different is: First, that it was a war on truly global scale, fought throughout Europe, but also in Africa, Asia, the Atlantic Ocean, the Pacific Ocean, and even in the Caribbean. The numbers alone are staggering: when Japan surrendered on 15 August 1945, thereby officially ending this global conflict, some 55 million people had been killed – most of them civilians. Secondly, and even more importantly, the history of WWII is of course inextricably linked to the odious years of the Hitler regime in Germany and more particularly the Shoah. This industrial, assembly belt-like, slaughtering of about 6 million European Jews, and we should add other groups such as Sinti, Roma, Slavic peoples, gays, Catholics and political dissidents, some total 11 million so-called "undesirables," based on no other motive than a totally lunatic ideology of racial superiority and a primordial quest for *Lebensraum* (space), unquestionably marks the absolute low-point in human history.

The singularity of the Shoah is, of course, not a claim that denies other peoples' sufferings or genocides such as in Rwanda or during the Middle Passage and slavery. Genocide is a universal phenomenon. Nor is this claim a contest that would somewhat perversely hold that Germans are the "baddest" soldiers or killers of all, or that one group's suffering was worse than another group's. Abuse, human suffering and death is in each case unique and must not to be compared or ranked against any other individual's or group's tribulations. And yet, we have to be clear why we need to say "unique" and "incomparable" when we consider Auschwitz.[v] No matter which example we cite in order to attempt an assessment, there is one clear difference with the Shoah. For the first time in history the world witnessed the systematic, unconstrained, bureaucratically administered, and industrially organized annihilation of an entire people found "guilty" only because they were inaccurately viewed as belonging to particular "race." The "Final Solution" of the so-called Jewish Question, as the Nazis termed it, did not leave any room for doubt or escape, but provided a purely ideological motive for the state-organized erasure from history of an entire people. Herein lies the different nature, the uniqueness of the Shoah: "It was the only time in recorded history that a state tried to destroy an entire people, regardless of an individual's age, sex, location, profession, or belief. And it is the only instance in which the perpetrators conducted this genocide for no ostensible material, territorial, or political gain."[vi]

There is yet another important aspect which survivors such as Elie Wiesel or Primo Levi have explained and that needs to be mentioned here: thus, many descriptions of the Nazi death camps make the point that the prisoners there did not really die a death that could under any circumstances be called what we usually understand when we speak of death.[vii] Rather, they explain, death camp prisoners became part of an assembly belt system that fabricated corpses. Significantly, the SS guards spoke of "figures" (*Figuren*) rather than of "bodies" or "corpses." Even if still alive, many of the death camp prisoners appeared to have in spirit already passed the threshold of death and all that was left was their body to die as well. Thus, Auschwitz stands for a kind of machine that stripped the prisoners of all aspects of their human dignity and did not just take their life, but even deprived them of their death as well. Auschwitz therefore became the perverted ultimate fulfillment and cipher of Nazi politics, which propaganda minister Goebbels once described as "the art of making the seemingly impossible possible."[viii]

Germany and the End of World War II

Where does Germany as a country stand today and what do younger generations there make of the responsibility that flows from the historical heritage? I would like to suggest that, collectively, (West) German society since the end of WWII has gone through distinct phases that are not entirely dissimilar from the five emotional phases distinguished by psychiatrists: *Denial* 1945-ca.1960; *Anger & Bargaining* ca.1960-ca.1975; *Depression* ca.1975-85; and *Acceptance* since 1985.

On 8 May 1945 the power of the factual established what had been clear in the mind of most Germans in the weeks and months before the war ended – that a time of great hardship would now begin during which foreign powers would occupy and define the parameters of everyday life. Ten or twenty years later Germany was back on its feet, however, despite some original plans to dismantle its industrial capabilities. This was in no small measure due to the visionary plans of politicians such as Jean Monnet and Robert Schuman, as well as the generous Marshall Plan from which Germany received some $1.4 billion (1948-52). The *Wirtschaftswunder*, the economic boom of the post-war years, of chancellors Adenauer and Erhardt allowed many Germans to simply forget that many little and quite a few big Nazis continued to wield

considerable power at various levels, up into the highest echelons of government. There was hardly any public discourse about what had happened during the Nazi years and how it could have happened. "We didn't know what was going on" became the convenient standard answer to questions about the Shoah.

Following the change of political climate in the late 1960s and 1970s, new generations of Germans began to increasingly question their parents' or grandparents' generation's role in and involvement with Nazi Germany. This was one of the factors that led in the 1970s to significant terrorist activities by a small group of leftist urban guerillas. Previously repressed questions thus festered into painful open debates and political violence. Some of the catalysts in this change of collective attitude were the Eichmann trial in Jerusalem (1961), the Auschwitz trials in Frankfurt (1963-65), and a speech by President Heinrich Lübke in which he spoke against the tendency to be silent in the face of the German crimes during the Third Reich. However, it was not until the late 1970s and into the 1980s that Germany and Germans came to finally accept that they were not, certainly not in the first place, the victims of Hitler, but that in many instances they were Hitler's willing executioners – as the American scholar Daniel Jonah Goldhagen has poignantly formulated it. In December 1970 Chancellor Willy Brandt visited the former Jewish ghetto in Warsaw and famously – and controversially – went on his knees in a spontaneous symbolic gesture of asking for forgiveness; in 1975 – the US had just withdrawn from Vietnam – German President Scheel introduced the term "liberation" in connection with the allied victory. But it really took ten more years – until 1985 – when the German public with President von Weizsäcker's stellar speech fully acknowledged in a well-nuanced commemoration all victims of the dictatorship and the War. In the two decades since then, Germans have tried to symbolically meet their responsibility. The German government, Social Democratic and Christian Democratic administrations alike, has played a central role in rebuilding the societies of the former Soviet bloc. German industry and the state have paid hundreds of million of dollars in compensation to former slave laborers. In Berlin, prime commercial real estate has been blotted out for an impressive memorial to the Shoah. The official acknowledgment and historical research of the extent of German society's entanglement with the Nazis has reached the highest levels of forthrightness.

To this neat schema, however, I would want to add something we have been seeing in the past 10 or so years taking shape increasingly in the German public's attitude towards Hitler, the Shoah and WWII – growing levels of "guilt fatigue."[ix] There is often a palpable discomfort about being reminded of the collective historical responsibility growing out of Germany's crimes against humanity accumulated in the Nazi years. Reading some of the newspaper headlines or articles on this topic one sometimes has the impression that Germany is a society waiting to exhale – but unable to. Increasingly, again, right-wing nationalists and fringe parties are trying to push the envelope with regard to what is commonly considered the consensus about the Nazi crimes, and increasingly they are finding resonance – particularly in parts of Germany with high unemployment and infrastructural weaknesses.

Still, the public debate about the Nazi years lingers on to this very day. Thus, Nuremburg, Auschwitz, and Stalingrad are permanent points of reference in political debates in Germany, particularly in debates that involve moral and ethical questions – e.g., discrimination against foreigners, abortion rights, the right to die for the terminally ill or incapacitated, political asylum, questions of war and peace … and the list goes on. Earlier this year an observer even spoke of a "shrill circus of commemoration."[x]

The continuing attention is understandable, even welcome. As the last surviving eyewitnesses are dying and new generations face themselves confronted with this painful history, the need arises to somehow describe – in an attempt to explain – the horrors of these years. It is also understandable because those who we often call eyewitnesses have testified that Auschwitz is an unspeakable crime – a crime for which there are no words. Indeed, surviving witnesses also sometimes confessed that as survivors they often feel complicit to the crimes perpetrated in Auschwitz, complicit in order to survive and report, and that the real witnesses never had a chance to testify.[xi] Still, the lessons of Nazi Germany, the WWII, and the Shoah, have to be learned again and again, because as nuanced and refined as any historian's interpretation may be, there will always be political forces influenced by leftist or rightist ideologies, who will feel compelled to use these interpretations in one way or another in order to boost their particular views. The German philosopher Jürgen Habermas has called this the "public use of history."[xii]

The lessons of the Shoah do not only, should not only, lead to an automatic condemnation of any Neonazi activities, but they can also sharpen our eye for current forms of anti-semitism prevalent among some parts of Muslim immigrant youth in Germany, in the rest of Europe, and elsewhere in the world. They also focus our view on those in the media and the intelligentsia who are using the Israeli-Palestinian conflict to not just criticize Israel's policies – this would be tolerable – but who are actually using the conflict to question Israel's right to exist as an independent state, which is simply not an acceptable proposition and reveals an "implicitly genocidal attitude."[xiii] Finally, the lessons of the Shoah should heighten our concerns with currently ongoing genocides, such as the one committed in Darfur, Sudan, by Arab Janjaweed militia against the African ethnic population.

Transatlantic Relations following the End of World War II

The consensus in today's Germany is that one is grateful for the role of the United States in liberating Europe from Nazism. Germany and Germans are also grateful to Britain and France, as well as extremely mindful of the huge blood sacrifice the Soviet Union paid as a consequence of being attacked by Hitler. In a very real sense, WWII would have lasted much longer and perhaps not ended in a defeat of Hitler had the Soviet Union never become involved. Finally, there is an acute awareness in Germany and Europe that the Cold War was to a large extent the consequence of WWII and a determination to avoid the downward spiral that led into two world wars fought in Western Europe.

In the U.S., this basic disposition in Europe is often misread in a simplistic and somewhat self-gratifying way as anti-Americanism. The most recent instance this hyperbolic claim was publicly made was prior to the Iraq War, which was allegedly aimed at weapons of mass destruction, but really in pursuit of the fall of Saddam Hussein. Rather than to be seen as anti-Americanism, French and German public reaction and foreign policy are much better explained as opposition to this particular war and as a pervasive mistrust of the general directions of the Bush Administration.[xiv] The active military and diplomatic support of Germany and France for the war against the Taliban in Afghanistan should speak loudly to this. As one observer puts it: "The Federal Republic has ended its post-war stance dominated by a civilian logic and has become a 'normal' state prepared to intervene."[xv] Few, if any, governments in Europe and the rest of the world seem to have any serious problem with this, and this too speaks volumes about the role of the end of WWII in public memory and discourse in Germany and elsewhere. In the words of British historian Norman Stone: "Today we have the Germany which we want to have."[xvi]

The current state of transatlantic affairs is best considered under different aspects – political, economic, and military. Politically, Europe is reluctant to accept its status as an international player of major proportions. On the other hand, the United States has not demonstrated that it accepts Europe in this role. Economically, Europe is – despite continuing hiccups – on its way to pose serious competition to US capital. The growing value and importance of the Euro as a global currency speaks loudly to this. Militarily, the balance of power, as well as the military threat potential has dramatically changed in Europe, as it has elsewhere in the world. In the case of Germany, the military doctrine has changed from a focus on national defense to what is called the "realization of interests." The maintenance of a strong U.S. presence in Europe is not considered vital anymore on either side of the Atlantic. The Pentagon is currently considering withdrawal of between 35-48,000 GIs from Germany – with this decision it is neither reacting to German requests, nor faced with widespread German protests against this withdrawal. Sporadic protest against the presence of U.S. military still exists at the local level, but for the most part communities are concerned about the expected economic consequences of the withdrawal. On the other hand, the recent closure of a military base in Frankfurt will facilitate the expansion of the Frankfurt Airport.

Lessons to be Learned

The catastrophe in Germany did not begin in 1945; it started in 1933, and probably even earlier than that. Perhaps the most important lesson to be learned from the end of WWII is, therefore, that a malfunctioning democracy in a powerful and influential country can lead to far-reaching,

devastating consequences. To the extent that the end of WWII was a triumph of freedom in Europe and because of this historical experience, we need to always allow the posing of difficult and painful questions. These questions are not the usual lore we are fed by the media and by representatives of the state for the purpose of feel-good speeches. Legitimacy should not flow from constant repetition of the same ideas. And so, for example, the question needs to be asked, if we freed Europe and helped democracy take root there, don't we have to accept it if our transatlantic partners come to dramatically different conclusions about important issues such as the Iraq War? I am not sure that our diplomatic reaction to this opposition reflected the level of diplomatic maturity one would have expected. Although this is not a comparison to the final days of the Weimar Republic, concerned citizens should not allow themselves to be outfoxed by Yellow Journalism and the anti-democratic posture which is evident in the denunciation of those who question the reach for increased executive power.[xvii] I am in particular referring here to attempts to curtail the power of the judiciary and elements of the U.S. Patriot Act, which by its very name already appears to be inoculated against such interrogation.

The lesson of post-war Germany also shows that the historical dust under our carpets may give us political asthma today. In the face of the incomprehensible it is not enough to be morally outraged; we also need to guard actively against violations of human rights and basic tolerance wherever they occur and accumulate. Thus, other painful historical questions need to be revisited simply because they have been considered for too long a historical taboo, have therefore not sufficiently become part of public knowledge, and because they put, for example, the recent Abu Ghraib prisoner abuse scandal into a yet different light. I want to highlight three critical issues:

- Certainly, it was the Nazis who started attacks on civilians with their V6 rocket attacks on London and there is no excuse for this or any other deliberate violence against civilians. Since it is established by international law that deliberately targeting civilians is an odious practice, we also need to ask if it is not necessary to revisit the questionable and documented involvement of our military in Korea, where in 1948 (i.e., before the Korea War started) on the island of Cheju within a year as many as 60,000 of its 300,000 residents were accused of being communists and killed or executed with the full knowledge and sometimes assistance of U.S. military. U.S. military officers also oversaw executions of civilians "suspected of collaborating" with the "communists" in South Korea itself.[xviii]
- Usually, and perhaps understandably, the decision to bomb Hiroshima and Nagasaki is depicted in the United States as the attempt to quickly cause surrender of the Japanese and thereby minimize further losses of American lives.[xix] I do not dispute that this was indeed an important motive. However, I think that we would have to revisit the critical voices of individuals who opposed the drop of the nuclear bomb, in order to get a fuller picture. Thus, for example, Ralph A. Bard, Undersecretary of the Navy, wrote in a top-secret memorandum to Secretary of War Stimson five weeks before the drop that the use of the atomic bomb without any warning runs against "the position of the United States as a great humanitarian nation," particularly as he acknowledged attempts by the Japanese to negotiate a surrender – a view supported by President Eisenhower in 1963.[xx] There is also the muted voice of nuclear scientists such as Dr. Leo Szilard, who helped develop the bomb, but opposed its use on both moral and political grounds and in a revealing interview in 1960 spoke of the "fake alternatives of either having to invade Japan or of having to use the bomb against her cities."[xxi] Let us remember that President Roosevelt himself had warned in 1939 against using bombs against inhabited cities. However, a factor usually not mentioned is that apparently Stalin himself had intentions to extend the Soviet grip in Asia following Japan's defeat. His official entry into the war on August 8, 1945, and the attack against Japanese army in Chinese Manchuria are a case in point. Truman and his Secretary of State James Byrnes were immensely concerned about the role of the Soviet Union, and certainly the use of the atomic bomb served two purposes in this regard: 1) it would end the war in Asia without Stalin's help and 2) it would send a powerful message to the Soviet Union that the United States had these weapons and would use them. To my mind these two factors may have been of even greater importance than the now usually cited concern about minimizing U.S. casualties in Asia. These are central questions still to be answered, because Hiroshima and Nagasaki gave us the nuclear arms race during the Cold War, and have contributed to the nuclear proliferation we are seeing today. And because nuclear weapons have been used in the past, they may unfortunately yet again be used in the future.[xxii]

  In announcing the drop to the American public, Truman on the other hand misrepresented Hiroshima as – in his words – a "military base" chosen "to avoid, insofar as possible, the killing of civilians."[xxiii] Thus, WWII, which had begun with the lie of Poland's aggression against Germany, also ended with deception. Following our experience with the horrible events of 9/11, the 60 year anniversary of the end of WWII should also make it possible to consider the following question: How, in which way, were the unsuspecting citizens of Hiroshima and Nagasaki different from those people working in the Twin Towers?
- Finally, difficult questions are to be asked with regard to the ways in which during war we have treated enemy combatants as well as civilians. It disturbs me a great deal that at the beginning of the 21st century we are still having prisoner camps such as Guantanamo Bay and – allegedly – secret CIA prisons abroad, to which the public has very limited access and which are operating below the radar of normal civil and international law.[xxiv] The Abu Ghraib experience does frankly not augur well for the current practices possibly in place in such camps and with regard to what we consider terrorists. Like others, I want people of the ilk of Bin Laden face justice, but I would also like to know that we achieve this not by means that put us morally into their league. This is simply a call for a transparency that is now lacking and that allows the specter of the dastardly Lubyanka Prison to hover over our interrogations of suspected terrorists. Recently, the question of Gitmo has come under greater public scrutiny and criticism.[xxv] It is gratifying to see that we're living in a system that eventually may be able to correct such aberrations, but in these camps it becomes obvious how vulnerable the democratic and humanitarian impulse is even in our country, once we are faced with a stressful politically and militarily situation.

I think that many of our contemporary concerns, including terrorism, would be more productively addressed, if together with a military strategy, tangible socio-economic care became once again a focus concern of the West. The fact that the EU recently doubled its development expenditures is a good start. That President Bush recently announced an acceleration of aid for Africa is also a welcome development. But the question is indeed: Why are we not in Darfour? I would like to cite Jeffrey Sachs in his recent book "The End of Poverty":

> *"Currently, more than 8 million people around the world die each year because they are too poor to stay alive. Every morning our newspapers could report, 'More than 20,000 people perished yesterday of extreme poverty.' [...] The nearly $500 billion that the U.S. will spend this year on the military will never buy lasting peace if the U.S. continues to spend only one-thirtieth of that, around 16 billion, to address the plight of the poorest of the poor, whose societies are destabilized by extreme poverty."*[xxvi]

Development is certainly not just a question of economic resources and justice and peaceful coexistence are not achieved by markets or warfare alone. However, new priorities in the industrialized world could help us a lot in leaving a better world for our children and our neighbor's children. This is not simply a moral argument, but also a conclusion pragmatic thought can lead us to.

Endnotes:

[*] This lecture is dedicated to the memory of Simon Wiesenthal.

[i] "Was und wie wir erinnern, und was wir darin als Anspruch gelten lassen, das wird mit entscheiden über das, was aus uns wird" ("What and how we remember, and what in the process we pass off as a truthful claim, will contribute to what we will become" – my translation) – quoted in Ullrich, S. (2005, April). Wir sind, was wir erinnern, Die Zeit Geschichte, 27.

[ii] Paul, A. (2004). The Ironies of History: An Interview with Stuart Hall. *Ideaz: An interdisciplinary social science and humanities journal creating alternative space for alternative expression, 3* (1-2), 70.

[iii] Indeed, the fascination has long transcended the popular media and is now expressing itself on the internet, where an increasingly active online trade with WWII memorabilia and reproductions (such as SS uniforms) is taking place.

[iv] The etymology of the term "holocaust" is historically tied to an often polemic interpretation and antisemitic usage, which suggested that pogroms and other acts of violence against Jews were of a sacrificial nature and involved divine will. Thus, the implication is that one may find in Auschwitz a certain "sense." Elie Wiesel, who introduced the term, later regretted his choice and would have liked to take it back. The Italian philosopher Giorgio Agamben concluded that whoever continues to use the term "shows ignorance or lack of sensitivity or both" – Agamben, G. (2003). *Was von Auschwitz übrig bleibt. Das Archiv und der Zeuge.* Frankfurt a.M.: Suhrkamp, 28 (my translation).

[v] See e.g., Grobman, A. (2000). The Uniqueness of the Holocaust. [Online]. Retrieved April 28, 2005 from the World Wide Web: http://www.holocaust-trc.org/uniqueness.htm

[vii] Deborah Lipstadt, quoted in Blech, B. (2005). "The Uniqueness of the Holocaust." [Online]. Retrieved April 28, 2005 from the World Wide Web: http://www.aish.com/holocaust/issues/ The_Uniqueness_of_the_Holocaust.asp

[vii] See Agamben, op.cit., 54-67.

[viii] iIbid., 67.

[ix] Note, for example, the remarks by the well-known German novelist Martin Walser, who in 1998 provocatively complained about the moral weight (*Moralkeule*) of Auschwitz, which is constantly invoked in discussions about nationalism.

[x] Jessen, J. (2005, March 23). Im grellen Zirkus des Gedenkens. *Die Zeit,* p.45.

[xi] Agamben, op.cit., 14-19.

[xii] Habermas, J. (1998).Űber den őffentlichen Gebrauch der Historie. In Jürgen Habermas, *Die postnationale Konstellation. Politische Essays* (pp.47-61). Frankfurt: Suhrkamp.

[xiii] Bauer, Y. (2005, March 23). Die Schande bleibt. Die Zeit, p.46; Bauer's phrase echoes Goldhagen's questions regarding the tacit agreement of many elites in Nazi Germany (see Habermas, op.cit., 59).

[xiv] See e.g., Vaisse, J. (2003). The Future of Transatlantic Relations: A View from Europe. (Testimony to the U.S. House Committee on International Relations, subcommittee on Europe). [Online]. Retrieved June 17, 2005 from the World Wide Web: http://www.brookings.org/dybdocroot/ views/testimony/vaisse20030617.pdf

[xv] Becker, J.M. (n.d.). Standortschließungen: Unglück oder Chance? [Online]. Retrieved May 13, 2005 from the World Wide Web: http://www.uni-kassel.de/fb5/frieden/themen/Standorte/becker.html

[xvi] Stone, N. (2005, May 4). Genau so wollten wir sie doch. Die Zeit, p.3.

[xvii] See also Hersh, S.M. (2003, October 27). The Stovepipe. *The New Yorker* [Online]. Retrieved November 17, 2005 from World Wide Web: http://www.cs.umass.edu/~immerman/play/ TheStovepipe.html

[xviii] See, for example, University of Chicago professor Bruce Cumings' research on the massacre – Cumings, B. (1997). American Involvement in "April 3 Cheju Massacre" [Online]. Retrieved November 27, 2005 from the World Wide Web: http://www1.korea-np.co.jp/pk/036th_issue/98040102.htm

[xix] See, for example, Kennedy, D.M. (2005, August 1). Crossing the Moral Threshold. *Time,* p.50; Kennedy appears quite uninformed or at least disingenuous when he suggests that "dropping the Bomb … was among history's most notorious foregone conclusions."

[xx] See the so-called Bard Memorandum – Bard, R.A. (1945, June 27). Memorandum on the Use of S-1 Bomb [Online]. Retrieved May 15, 2005 from the World Wide Web: http://www.dannen.com/decision/bardmemo.html, and, for Eisenhower's comments, Long, D. (n.d.). Hiroshima. Who Disagreed With The Atomic Bombing? [Online]. Retrieved August 6, 2005 from the World Wide Web: http://www.doug-long.com/quotes.htm

[xxi] Szilard, L. (1960, August 15). President Truman Did Not Understand. *U.S. News & World Report*, pp.68-71; also available at Dannen, G. (1996). Leo Szilard, Interview: President Truman Did Not Understand [Online]. Retrieved November 17, 2005 from the World Wide Web: http://www.peak.org/~danneng/decision/usnews.html. In this context, also consider Szilard's hypothetical consideration: "Let me say only this much to the moral issue involved: Suppose Germany had developed two bombs before we had any bombs. And suppose Germany had dropped one bomb, say, on Rochester and the other on Buffalo, and then having run out of bombs she would have lost the war. Can anyone doubt that we would then have defined the dropping of atomic bombs on cities as a war crime, and that we would have sentenced the Germans who were guilty of this crime to death at Nuremberg and hanged them?"

[xxii] In this regard we have to be aware that the 2002 Nuclear Posture Review of the Bush Administration does not only regard nuclear weapons as a deterrence, but also considers their pre-emptive and tactical use (e.g., mini-nukes to bust bunkers). Without doubt, this application of nuclear devices would seriously blur the distinction between conventional and nuclear warfare.

[xxiii] It is true that Hiroshima would have played a defensive role in the case of an Allied invasion of Japan. Nevertheless, it is important to keep in mind that it had be chosen as a target precisely because until then the U.S. military had not yet bombarded it. On the day of the explosion, Hiroshima was in fact full with refugees from other cities that had been firebombed previously.

[xxiv] This assessment has been corroborated in Amnesty International's 2005 Annual Report "The State of the World's Human Rights" [Online]. Retrieved November 17, 2005 from the World Wide Web: http://web.amnesty.org/ report2005/usa-summary-eng. To cite just one of many examples mentioned in the report:

> *During the year, the authorities initiated various criminal investigations and prosecutions against individual soldiers as well as investigations and reviews into interrogation and detention policies and practices. The investigations found that there had been 'approximately 300 recorded cases of alleged abuse in Afghanistan, Guantánamo and Iraq.' On 9 September, Major Paul Kern, who oversaw one of the military investigations, told the Senate Armed Services Committee that there may have been as many as 100 cases of 'ghost detainees' in US custody in Iraq. Secretary of Defense Rumsfeld admitted to having authorized the Central Intelligence Agency (CIA) to keep at least one detainee off any prison register.*

[xxv] See e.g. Zagorin, A. and Duffy, M. (2005, June 20). Inside the Interrogators of Detainee 063. Time, pp.26-33.

[xxvi] Here quoted from Sachs, J. (2005, March 14). The End of Poverty. Time, p.46.

35th Annual Meeting of the Society for Cross-Cultural Research (SCCR)

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The 35th Annual Meeting of the Society for Cross-Cultural Research (SCCR) will be held on February 22-26, 2006 at the Mulberry Inn in Savannah, GA . SCCR is a unique interdisciplinary organization in which cultural anthropologists, cross-cultural psychologists, and members of several other social science disciplines interact and present their findings and formulations. For further information and for registration forms contact Juris Draguns, Ph.D., President Elect, SCCR, at jgd1@psu.edu, (814) 863-1735 (Phone) or (814) 863-7002 (fax). Early registration is accepted before February 5, 2006.

Hello World!: The Case for the Internationalization of Introductory Psychology Textbooks

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With the continued expansion and greater use of the Internet, more accessible air travel, continuing immigration of world citizens, and increasing globalization of business, it is apparent that once-separate societies are becoming increasingly interconnected and interdependent. In many ways the world is internationalizing at a much faster pace than psychology. Everyday we look at television news or read a newspaper; international events are making headlines that affect American society. If

psychology is to advance significantly as a science, students will need to understand human development and mental health of a far broader population than is currently presented in the introductory psychology textbooks. For the purpose of this paper, internationalization is defined as countries and societies outside of the United States.

Marsella (1998) pointed out the need for a new psychology and that it is no longer sufficient to train our students in isolation of other disciplines from students across the world, from contact with other cultures. He further added that this new psychology should be attuned to the changing times, a psychology that is alert to ethnocentric biases inherent in the Western academia psychology and one that values the diverse psychologies of the world.

Without leaving our shores, according to the United States Census Bureau (2003), 33.5 million foreign-born people live in the United States. Foreign born residents in the U.S. are currently made up of 53% Latin American, 35% from Asia and 13% from Europe. Demographic changes are also occurring within the U. S. population that demand changes in psychology textbooks. The United States Bureau of Census (1995) predicted that by the year 2050, approximately 50% of the U. S. population will be people of color. With this in mind it is becoming imperative that the psychology curriculum embraces international perspectives. It is also worth noting that 95% of the world's 6.5 billion people live outside the U.S. Estimates provide as of July 2005 are shown in Table 1.

At least 1.5 million students take an introductory psychology class every year in the United States (Cush & Buskist, 1997; Griggs, Jackson, Christopher, & Marek, 1999) and 97% of colleges and universities offered an introductory psychology course in 1997 (Pearlman & McCann, 1999). Students who enroll in an introductory psychology course are not necessarily psychology majors. For most students, introductory psychology is the only course in the field of psychology they will take. Since this is their only exposure to the field, the comprehensiveness of the topics covered is of particular importance.

Given that psychology as a science deals with the mental processes and behavior of society, how may psychology as a discipline be more inclusive of non-American societies in our undergraduate curriculum and textbooks? Unfortunately in most instances it has seemingly ignored most non-American societies. Research performed for the Office of Teaching Resources in Psychology (OTRP) by Woolf, Hulsizer and McCarthy (2002) revealed the following statistics on international content of introductory psychology textbooks (see Table 2).

The main barrier restricting international content to textbooks is language.

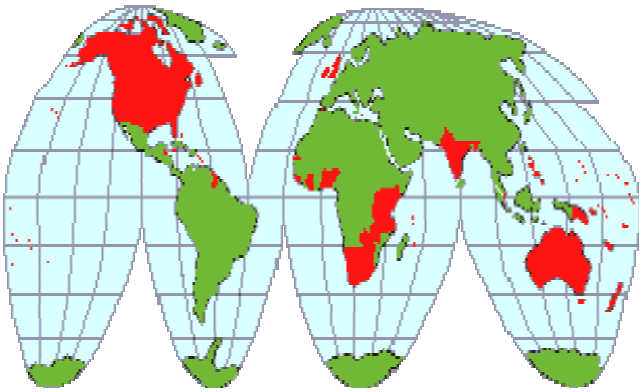

On this world map, you can see English speaking nations in red and non-English speaking nations in green. Research is rarely published in the U.S. from non-English speaking countries. National geographic estimates 9% of the world's population grow up with English as their first language. Mandarin Chinese is well established at the world's largest language in terms of native speakers. There are roughly 6,000 languages existing in the world today, so it is clearly a difficult task to translate many relevant research topics.

Until recently, the majority of the world's psychologists lived in the U.S. This is changing rapidly with psychology growing at a much faster pace outside the U.S. It is now estimated 60 percent (or more) of the world's psychologists live outside the U.S. (Hogan, 1995). With better funding becoming available for research outside the U.S., more published research is being performed. This may lead to the professional field of psychology in the U.S. being left behind should the profession not take notice of international research.

Even though the textbooks exclude the majority of research performed worldwide, US methods of clinical diagnosis and intervention and US psychology has exported these research results based on US norms and values to other countries, resulting in an inappropriate generalization. US assessment procedures, tests and normative data have been used extensively in other countries, sometimes without consideration of cultural differences that affect reliability and validity (Dana, 2000).

An example of this is when Anthony J. Marsella, Ph.D. was working on a research project in the jungles of Borneo. He was using the most sophisticated diagnostic instruments developed at Harvard and Yale to measure the mental health of the natives. Results indicated that those who were tested were diagnosed with schizophrenia.

One of the suggestions by Takooshian and Velayo (2004) to help infuse a more "international perspective" in our psychology courses through distance learning technology is to pick a textbook that clearly incorporates an international perspective and that which has supplemental materials (e.g., instructor's manual, CD-ROMs) that provide activities that foster a multicultural approach to psychology. They further pointed out that the Internet is one significant piece of technology that will continue to pave the way towards a more "international" approach to the psychology curriculum.

There have been attempts at internationalizing the psychology curriculum by incorporating a more international perspective in introductory psychology textbooks. A recent study suggests that there is a lack of consistency in the "international" content of many of these textbooks (e.g., citation of foreign-born authors and of studies in non-U.S.countries) (Wolff, Hulsizer, & McCarthy, 2002). In addition, there are supplementary Internet-based ancillary materials that help foster a multicultural approach to teaching psychology (Bronstein & Quina, 2003).

Although it has been a few years since the last published report of the Curriculum Committee (Marsella, 2000) of APA's Division of International Psychology, its members are often provided with international materials in the quarterly *International Psychology Reporter* (IPR). IPR contains materials that may be integrated or used as a supplement to classroom textbooks, at least a dozen original articles per issue by leaders in their specialty, which are available nowhere else, and offer useful information on global trends, indigenous psychologies of other nations, suggestions on internationalizing the curriculum (Fowler, 2000), and Internet resources (Velayo, 2000). These materials will hopefully find its way, at least as citations, in many of our introductory psychology textbooks.

Textbook publishers tend to operate from an ethnocentric perspective and that theories based on the U.S. population are applicable to all groups. Yet with the increase of an international and diverse population within the U.S., the current textbooks have lost much of their relevancy for the student audience. Certainly, psychology textbooks should aim to reflect a psychology appropriate and relevant in a world context.

If psychology textbooks and psychology in general do not change, it is inevitable it will loose it relevancy for much of its audience. Demographics and economics will probably be the driving force behind these changes.

Table 1
Country or world region rankings based on population.

	Country	Population
1	World	6,446,131,400
2	China	1,306,313,812
3	India	1,080,264,388
4	European Union	456,953,258
5	United States	295,734,134

*Table 2
Introductory Psychology Textbook Characteristics (Sorted by Overall Percentage of Paragraphs Reflecting International Content)

Textbook[a]	Edition	International Content	# of Authors	# of Female Authors	Number of Chapters	Number of Text Pages	Mean Pages per Chapter	Total Pages
Weston	2	4.6	1	0	18	861	47.8	991
Hockenbury	2	3.8	2	1	15	642	42.8	786
Uba	1	3.7	2	2	16	696	43.5	778
Wade	6	3.4	2	2	17	649	38.2	750
Kassin	3	2.9	1	0	18	740	41.1	822
Myers	6	2.7	1	0	19	689	36.3	830
Plotnik	5	2.7	1	0	25	609	24.4	724
Huffman	5	2.6	3	2	17	617	36.3	722
Feldman	5	2.4	1	0	18	646	35.9	774
Halonen	3	2.4	2	1	16	612	38.3	692
Morris	10	2.4	2	0	15	611	40.7	724
Baron	5	2.3	1	0	16	658	41.1	736
Zimbardo (1999)	15	2.3	2	0	18	808	44.9	884
Weiten	5	2.3	1	0	16	697	43.6	841
Gray	3	2.1	1	0	17	681	40.1	782
Wood	3	2.0	2	1	17	606	35.6	726
Santrock	6	1.8	1	0	16	592	37.0	664
Atkinson	13	1.7	5	2	18	676	37.6	768
Lefton	7	1.6	1	0	17	637	37.5	728
Zimbardo (2000)	3	1.6	3	1	14	575	41.1	666
Coon	9	1.4	1	0	20	694	34.7	821
Lahey	7	1.4	1	0	17	641	37.7	701
Matlin	3	1.4	1	1	18	599	33.3	737
Nairne	2	1.1	1	0	16	651	40.7	750
Rathus	6	1.0	1	0	15	732	48.8	837
Kalat	5	0.9	1	0	16	638	39.9	720
Gerow	6	0.7	2	0	15	639	42.6	727
Sdorow	4	0.6	1	0	17	635	37.4	765
Wortman	5	0.2	3	2	18	632	35.1	755

Note. There were no international authors.
[a]Textbooks are listed by the first author's surname.

**derived from Woolf, Hulsizer, and Tracy, 2002*

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International News

Yu HaiXia Learns Communication Skills

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Yu HaiXia, our Chinese Little Sister sponsored by Division 52 members at the Half the Sky orphanage just celebrated her fifth birthday on November 10. Her nanny gives the following report on HaiXia. "Because of her health problems, Haixia didn't come to school so often. We are also trying to help Haixia with problems in relating to other children. We found that Haixia couldn't do well to control herself or maybe because other children are much smaller in the class, Haixia didn't have the patience to be with them. When they were playing, Haixia was a bit self-centered. It was hard for her to talk and discuss with other children and she fully depended on teachers to solve the problem. For example, If she wanted a toy, she told teachers,' Teacher, I want to play that piano.' She was afraid of being refused by other children and to avoid embarrassment, she asked teachers' help. Little Haixia needs help with psychological preparation on being refused by other children. So once others refused, she dropped her tear. Take for an example, in the dance rehearsal, after practising for several times, she would cry sadly and said,' teachers, I'm not dancing.' Yet, she desires to be in our group so after encouragement and explanation by teachers, her ability of self-control enhances and she is able to speak more words now. She is also learning to understand and appreciate the feelings of the other children which will help her make friends.

Annual Convention: ASIAN PSYCHOLOGICAL ASSOCIATION

The Asian Psychological Association (APsyA), which has been founded in Jakarta, August 16, 2005, will have its 1st convention, in Bali, Indonesia, on August 18-20, 2006. The conference is sponsored by prominent universities in Indonesia and co-sponsored by International Association of Applied Psychology (IAAP). For more information, please visit www.apsya.org or contact Dr. Sarlito W. Sarwono, interim chairman, at sarwono@ui.edu.

Research Articles

A Study on Child-Rearing Support in the Slum of Urban Areas in the Philippines

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Introduction

The project reported on here is being carried out in a Catholic parish in Cebu City, Philippines. In this parish, church and community social-workers work together, with financial aid from non-governmental organizations (NGOs) from foreign countries, to improve the situations of slum-dwelling children and their families who are very poor.

For about 10 years a Feeding Center set up within the parish with support of a Japanese volunteer group has provided free food to supplement the nutrition of disadvantaged children and their families. The Feeding Center helps children survive at some level; their nutritional status has improved. However, regional staffs and NGO personnel realize that food supplements alone do not come close to giving them the help they need to develop normally. Their rate of school attendance remains low and other educational resources - pre-school programs, for example - for encouraging their psychological and social development are also lacking (see Figure 1).

The aim of the project of concern here is to provide appropriate psychological and educational supports to young children and their families who already receive nutritional aid that allows them to live at sustenance level. A significant feature of the project is that it seeks to provide parenting education for children's care-givers as well as new educational opportunities for the children themselves.

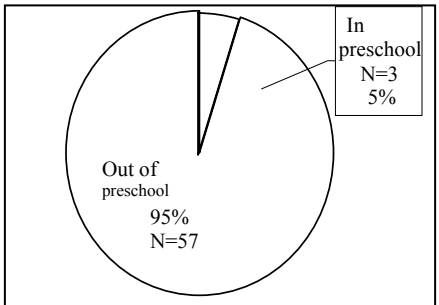

Figure 1. Children out of preschool in the Feeding Center

Objectives of the study reported here

The results of study selected for report here are relevant to answering several questions that need answering in connection with attempts to create an educational project that is aimed both at educating children outside the home and at optimizing the parenting activities of their caregivers. These include:

1. The developmental status, both physical and psychological, of children whose families rely on the Feeding Center for nutritional supplements.
2. The relationship between these children's developmental statuses and the kind of family systems in which they are growing up.
3. The relationships between parents' perceptions of their parent-child relationships and the number of their children and between parents' perceptions of their parent-child relationships and the availability of family members and neighbors to support them in their child-rearing activities.
4. Caregivers' perceptions of the value of Feeding Center project for their children.

Methods

The participants were 57 caregivers from 57 families who had 91 children in total. The structured interviews were conducted by 6 to 8 local interviewers. Before the interview sessions, local interviewers were trained with the help of Japanese psychologists. The questions used for these interviews were written in both English, and a regional language, Bisayan. The contents of questionnaires were fully examined by multiple translators. The duration of interviews ranged from 30 minutes to 90 minutes. The total duration for all the interviews was 7,170 minutes (119.5 hours). The gross monitoring was also performed for 83 children under six years old. The number of children in age and gender is summarized in Table 1.

Table 1
The number of children in age and gender

		Age		Total
		Under 3	3 and up and under 6	
Gender	Male	13	18	31
	female	30	22	52
Total		43	40	83

The detailed contents of the interviews were as follows.

1. The research for children …
   - ***The developmental test***: Irton's (1994) Child Development Chart was utilized as interview questions. Some items of the chart were revised in accordance with the actual condition of the local area. This research includes the following five areas: 1) social, 2) self-help, 3) gross motor, 4) fine motor, and 5) language areas.
2. The research for child rearing environments …
   - ***Parental Mental Health***: Rodroff's (1977) CES-D20 was utilized as interview questions. Some items were revised in accordance of the actual condition of the local area.
   - ***Parents' evaluation of parent-child relationship***: Parent Stress Index Short Form (PSI/SF, Abidin, 1995) was utilized for interviews. One of sub-measurements, Parent-Child Dysfunctional Interaction was revised in accordance with the local conditions.
   - ***The questionnaires on child rearing support systems as environmental conditions***: 6 sub-measurements were founded based on the regional information by interview with local staffs.
3. The research on the Feeding Center…
   - ***The caregivers' perceptions about the meanings of the Feeding Center***: Caregivers were asked to answer the question, "What does the Feeding Program mean to you?" and to write down their perceptions.

Main Results

1. Results of research on the children's development…
   - ***Physical Growth:*** The degree of nourishment among children was estimated by each child's weight for age. The ratio of children with average nutrition was less than 10% (See Table 2).

Table 2
Physical Growth

Nutrition	N	%
Severe Malnutrition	14	16.87
Moderate Malnutrition	40	48.19
Mild Malnutrition	22	26.51
Normal Nutrition	7	8.43

   - ***Child Development:*** The results of the child development examination were summarized in Table 3. It appeared that the development of fine-motor and language areas was prominently delayed.

2. Effects on developmental status of different child-rearing environments…
   - ***A state of development in children and family systems***(Figure 2): Children who were raised in an extended family showed better states of both physical and mental development than children in a nuclear family (t=-1.68, df=72.48, p<.10, N=76; t=-2.75, df=51.03, p<.01, N=75). 3. How parents perceive parent-child relationships. Correlation between the state of parents' mental distress and the number of their children: r=-.30, (p<.05, N=56). The parents with a larger number of children seemed to have a better state of mental health.

Table 3
Child Development

Development	Social	Self-Help	Gross-Motor	Fine-Motor	Language
Typical (%)	46 (63.89)	36 (50.00)	47 (65.28)	34 (47.22)	26 (36.11)
Border (%)	13 (18.06)	16 (22.22)	12 (16.22)	18 (25.00)	25 (34.72)
Delay (%)	13 (18.06)	20 (27.78)	13 (18.06)	20 (27.78)	21 (29.17)
Total	72	72	72	72	72

3. Correlation between availability of parents' environmental supports in their parenting (e.g. caregivers, family, and neighbors) and parents' evaluations of parent-child relationships: Parents with higher supports for child rearing are likely to perceive better relationships with children (t=2.07, df=76, p<.05, N=44).

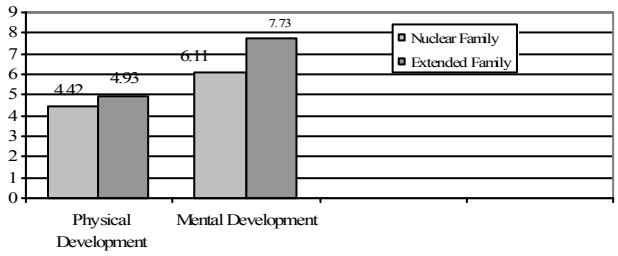

4. *The psychological effects on caregivers by participating in the Feeding Program.* The duration of participation in the Feeding Program showed significantly negative correlation with the caregivers' mental distress. The caregivers with a longer period of participation in this program are likely to have better mental health conditions (r_s=-.36, p<.05, N=47). Free descriptions by caregivers about the meanings of participating in the Feeding Program were categorized into several subgroups by the K-J method (See Table 4).

Conclusions

The research results reported here provide evidence that a program of the kind now being introduced, one that combines nutritional and educational supports, is needed. Less than 20% of these slum children give evidence of severe malnutrition. However, 90% of them show some delay in physical development even though their families have presumably had access to nutritional supplements throughout the children's lifetimes. Nutritional supplements seem to have worked both by supporting the physical development of children and by allaying their parents' anxieties and continue to be needed. The psychological testing indicates that the children also suffer delays in all of the areas of psychological / behavioral development assessed and that delay is especially apparent in the area of language development. There is clearly much room for the psychological and educational interventions that the project is introducing to have positive effects.

The results suggesting that children developed better both physically and mentally in extended than in nuclear families, that parents attitudes toward parenting were not adversely affected by larger numbers of children, and that parents attitudes toward parenting were improved when parents had greater family and neighborhood supports for their parenting activities provide important clues about the kinds of parenting and parental support practices that should be advocated in order to be effective educators of parents in this particular population.

The program now being introduced is compatible with the research results reported. It provides early childhood education and a psycho-educational program for caregivers (see photographs).

Finally, the program also provides an example of successful collaboration between academic researchers and members of an NGO that has allowed both parties to benefit form their collaboration. In this case, members of the NGO, which had nurtured a good, long-term, down-to-earth relationship with members of a target population in order to help them, provided researchers with an initial understanding of the target population which researchers were then able to improve on in a way that allowed researchers to advise members of the NGO how to better help those whom they wanted to help.

Table 4
Parents' evaluation of the meanings participating in the Feeding Program

Category	Subcategory	Examples of descriptions by parents	Number of count	Subtotal (%)
Foods	Foods	Can get foods, can get something to eat,	3	36 (25%)
	Nutrition Supplement	Can give nutritious meals to my undernourished children, Can get appropriate nutrition	33	
Betterment of children's development	Children's development and growth	Improve child development, Children can walk better, Help children develop	13	46 (32%)
	Health	Good for health, Make children healthier	24	
	Gain Weight	Gain weight Help children gain weight	9	
Support for poor people	Aids for poor people	Receive services to reach out to poor children Help poor families	6	10 (7%)
	Helping out with the family budget	Help out with the family budget , Help family survive	4	
Education, Leaning	Learning	A place to learn , Give us education and advice	7	22 (15%)
	Eating	Learn how to cook , Learn manners to how to eat	4	
	Religion, Spiritual life	Can teach my family what I learned regarding spiritual life, Can learn about a religion	8	
	Child Rearing	Learn how to take care of children, Teach us how to raise children	3	
Mental Support	Support for children	Empower children , Good for children's future	2	22 (15%)
	Support for family members	Tremendous supports for family members , Help me have a better relationship with my children , Make marital relationship	10	
	Change in perspectives and have self-growth	Change my perspective on child development , Have mental self-growth , Open to change	7	
	Significant place	A part of our daily life , Significant place	3	
Good		Good , Helpful for me	7	7 (5%)
Unidentifiable		can eat several kinds of mushrooms	1	1 (1%)
		Total	144	144

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Parenting educational program – Lecture

A class of the play-age group

Changing Content Language from English to Arabic in the United Arab Emirates: Psychological and Educational Implications

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In 1993, the Ministry of Education in the United Arab Emirates (UAE) decreed that English should become mandatory in the schools. A decade later, in this fast-growing nation, the language of instruction at the university level is changing from Arabic to English. Female university students aspiring to become future teachers of the nation, experiencing the change, are exhibiting a certain reluctance to continue their education and simultaneously keeping pace with this contemporary development. This fact seems to refocus attention on the restructuring of classroom teaching techniques to help students overcome this fundamental change, regulate their psychological reactions, and keep them actively involved and motivated. The instructor's roles as a counselor, a catalyst and agent of change are once more reactivated in motivating students to stay in the academic field to obtain their final degrees.

For a better understanding of the cultural background of the female student body in Abu Dhabi, it is pertinent to look at the dominant social and psychological factors in the society. The culture of the UAE requires that female students strictly abide by the cultural demands and follow societal rules. Such rules dictate that females should only hold certain jobs or pursue certain careers. More pertinent to this reflection is that most female students in this midland city are not to leave their homes except for specific reasons, namely education. Based on inquiries, interviews, and student surveys, one of the few careers that most parents will allow their daughters to work in and be part of are careers pertaining to the educational field. Parents seem to hold a great esteem for this profession and thus motivate their daughters to follow this path as it is a "noble" and "highly respected" career. With such a background, and the shift of languages in content courses, female students are experiencing learning difficulties which in turn seem to affect their motivation in general and their daily classroom performance in particular. Covington (1997) suggests that "arranging exciting learning opportunities is a necessary first step in shifting the reasons for learning in more positive directions [...]" (p.86). In an early study conducted by the researcher, results indicated support for such a thesis as students' attitudes changed when students were more exposed to practical experiences in the classroom than towards lectures focusing on the language involved in the instruction.

In two language methods courses, the researcher who had been teaching for one year in this area of the United Arab Emirates reportedly touched upon the fact that students were not motivated to learn as their level of English was incompatible with the course demands at the College of Education. However, in instances when students were involved with projects and practical applications of theory, students seemed motivated and eager to learn. Activities focusing on performance-based assessment seemed to enhance their motivation and regulate their consistent involvement throughout the academic semester.

In some instances, students discussing language development agreed with the instructor to go and observe children in schools and record children's discourse for further analysis. Language being the tool as well as the target was then addressed by the students as well as by the instructor. As students paid attention to children's discourse, they in turn started paying attention to their own language. In other instances, where parts of speech were discussed, the students created games and worksheets for assessment as well as evaluation. These were either group efforts or were carried out individually. Worksheets were then shared in class among students and distributed after final amendments and corrections were made. Corrections were also carried out in class with the help of the instructor and the students' feedback. Though errors and mistakes were quite prevalent, such tasks created a context for improving language away from the stress of pure evaluation on by the instructor. Students reported feeling more at ease and regaining confidence in their linguistic skills as they gradually acquired the language pertinent to the course. Petty errors and mistakes were also depicted by students as they became aware of each others' errors and mistakes and were able to use methods of self correction and constructive criticism as well as a discussion of ways of remediation for such errors. It also kept the students motivated and interactive. Amneh wrote:

> *"At the beginning of the semester I felt very bad and it was hard to continue. But I was encouraged to continue. Trips to schools and doing something helped me. After this course and the projects, this helped me trust in my skills and in my language."*

Others expressed feelings of empowerment and confidence in their own capabilities of creating tasks and taking control of their own language development.

Lecturing, which seems to be highly practiced in these parts of the world, needs to be reconsidered. In lecturing while emphasis is on language, a shift in the instructional language, in this case from Arabic to English, is bound to cause obstacles for students. As this nation is thriving and striving to educate their young ones and particularly the females, it is of extreme importance to bring attention to the utility of practical techniques in the classroom to avoid stressful linguistic situations. "Nearly 80% of all US college classrooms in the late 1970s are reportedly using some form of the lecturing method…" (Cashin, 1990). This practice seems to have been widely used in universities and more so in the authentic situations where instructors' control is predominant.

This study seems to imply that in situations where students are trying to learn English within a content course, less emphasis on language and more emphasis on activities is required. As the world moves to the English language and universities seem to implement English as content

language, it is pertinent to choose appropriate tasks that would actively involve students to bring more focus onto content and enhance students' motivation to complete their coursework and reach their desired diplomas, while helping them regulate their psychological reactions to this change. Students' reflections revealed that tasks that implied practical work ranging from the simple group projects to group research and school visits seemed to promote positive feelings, confidence, and perseverance to accomplish desirable outcomes.

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Next Priorities for Intervention in Kenya: Results from a Cohort Study of Drug Use, HIV and HCV Patterns in Five Urban Areas

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Abstract

In Kenya, alcohol, cigarettes, Khat (miraa) and cannabis sativa, have remained the most popular abused substance and have been linked to increasing rates of HIV/HCV . This study's objective was to identify the types, frequency, and methods of substances used and their relationship to HIV and HCV seroprevalence among substance abusers in five representative Kenyan cities. *Methods:* Purposive and snow-ball sampling was used. Among 1420 substance abusers, psychosocial and substance use factors were assessed, with a subset of 120 tested for HIV and Hepatitis C Viral (HCV) infection.–*Results*: In five Kenya cities, the highest oral daily consumption of the drugs was recorded in Malindi (83.3%) and Mombasa (56.6%). Snorting and sniffing was used on a daily basis mainly in Mombasa (85.0%) followed by Nakuru (72.7%) and Nairobi (70.6%). Malindi exclusively practiced injection of drugs on a daily basis with a one-day prevalence rate of 100.0%, followed by Mombasa (86.5 %) and Nairobi (67.9%). Across the five cities, the most prevalently substance abused was Alcohol (36.3%) followed by nicotine (17.5%), Cannabis sativa (9.9%), Heroin (8.0%), Khat whose active ingredient is Catha edulis (2.8%), and cocaine (2.2%) and the most popular route of intake was oral (45.7%), nasal (38.7%) and injection (10.4%). Of the 120 tested for HIV and HCV, approximately 61% were seropositive for Hepatitis C and 42% for HIV and 85% were Injection Drug Users (IDUs). Interestingly, of these IDUs, 49.5% tested positive for HIV and 70.29% tested positive for Hepatitis C (HepC). These results support a relationship between IDU behavior and HIV/HepC and the need for an IDU-focused prevention effort that would 1) integrate sexual and injection behavior risk reduction, 2) identify and complement local cultural strengths, and 3) link Kenya's nascent democratic governance initiatives with building the necessary IDU prevention infrastructure.

Introduction

In Kenya, alcohol, cigarettes, Khat(miraa) and cannabis sativa, have remained the most important drugs abused followed by solutes and prescribed drugs with fast emerging trends of injecting drug use, especially the narcotics. Nearly all the studies done in Kenya on drug and substance use, however, have been school or community based general populations (Ndetei, Ongecha, Mutiso (2005), Dhadphale, et al.,(1982), Yambo, Acuda,(1983), Kuria, (1993), Ndetei, et al. (1997). The Trend data indicate a near doubling of the rates of drug use among adolescents in the early 1990s (Bravender, Knight, 1998). Alcohol and substance abuse is further associated with increased dropout from school, poor scholastic attainment, drunk-driving, delinquency, early pregnancy and family difficulties (Friedman, et al.(1996), Kokotailo, et al.(1992). The study that we report on here is cohort-based and specific to abusers identified from rehabilitation and treatment centers, hospitals, streets and drug dens, within five urban areas. Our aim is to provide a basis for more finely tuned priorities and measures of prevention interventions related to the destabilizing risk triangle of drug use, HIV and HCV.

Specifically, the use of drugs of injection is associated with risk of contracting HIV/AIDS, hepatitis B and C infections, tuberculosis and sexually transmitted diseases. In South Africa an epidemiological study (Parry et al. (2002) revealed alcohol, cannabis and mandrax (methaqualone) as the most frequently reported abused drugs. They comprised the largest proportions of drug-related arrests, psychiatric diagnoses and drug-positive trauma patients. A significant increase in indicators for cocaine/crack and heroin occurred in two sites in the same period. They also noted that the use and burden of illicit drugs appeared to be increasing (Parry, et al 2002, 2005) However a prospective study to monitor heroin nature and extent of heroin user identified the users to be white males, aged 21-24 years who smoked rather than injected (Parry, et al., 2002, 2005). A number of other studies within the continent have focused on the sexually transmitted infections (STIs) as a major risk factor for HIV transmission with HIV/STI co-infection rates as high as 30% and HIV prevalence rate of 21.9%. Yet the authors could not fully explain the higher HIV prevalence from the STIs and behavior change among this low risk group. Though, we may suspect based on other data and studies reviewed by O'Leary (2000), that even if women are proactive in their general health care, they may not have the means to negotiate their sexual health with their male partners.

HIV infection associated with injecting drug use exists in all regions and is a growing problem (UNODCP, 2002). More and more countries are reporting cases of injecting drug use from 80 countries in 1992 to 136 in 1998. Of these 136, 114 of them have reported HIV cases as a result of injecting drug use. At the global level, some 22% of the world's HIV/AIDS population injects drugs. The joint United Nations Program on HIV/AIDS estimates that the global proportion of HIV infections due to contaminated injection equipment was 5-10% in 1996 (UNAIDS 2002). .

Reasons for this IDU increase include, migration of indigenous drug users; involvement of locals in the cultivation or manufacture of drugs; living along a drug trans-shipment route; change in the form of drug to make it more easily injectable; geographical proximity to a country or region where injecting is commonplace and availability of other forms of drugs (UNODCP. 1997).

The largest international comparative study on injecting drug use and HIV infection (The WHO Drug Injecting Study Phase I) was undertaken in 12 cities (Athens, Bangkok, Berlin, Glasgow, London, Madrid, New York, Rome, Rio de Janeiro, Santos, Sydney and Toronto). It comprised 6390 drug injectors mainly outside drug treatment settings. The results indicated that IDUs were mainly males, predominantly 20-34 years of age (80-90%); single, never married, widowed, separated, divorced (88-90%); childless or, at most with one child. Over 50% had less than ten years of full-time education and majority were unemployed. Between 0-40% were living with a current sexual partner, while 4-35% were homeless. In each

center more than 50% of IDUs had been in prison or jail overnight at least once. The study also identified the proportion of IDUs having blood (or saliva) tests, showing laboratory signs of HIV infection in which low seroprevalence (<5%) was seen in Glasgow, Toronto, and Sydney; medium (5-20%) in London, and high (>20%) in New York, and Bangkok (WHO, 1994). Similar findings were reported among 282 regular young drug users (using heroin, cocaine, methadone and/or amphetamines at least 3 days/week) in Amsterdam where HIV prevalence among those who had injected drugs was 16.2% and only 1.8% for those who had never injected (Welp, et al. 2002) .

However, this contrasted with the Vancouver Injection Drug Users Study (VIDUS), found that the young (13-24 years of age) injectors (N=232) were more likely to be female; work in the sex trade; report condom use; inject heroin daily; smoke crack cocaine daily; and need help injecting unlike in the WHO studies that majority were males. HIV prevalence at baseline among the youth was 10% (Miller, et al 2002).

In Kenya, a rapid assessment on IDUs was carried out in 2001, which estimated a total of 5000 heroin injectors in Nairobi but did not ascertain their HIV serostatus (Odek-Ogunde, 2001). This study aims to fill that gap by identifying the types, frequency, and methods of substance used and the relationships of these factors to HIV and HCV seroprevalence among cohorts of substance abusers in five representative Kenyan cities.

Methods

Study Sites

The study sites selected were the main commercial and urban centers consistent with other worldwide findings in which the highest levels of drug abuse were found in the major urban centers (World Health Organization). Some of the common characteristics of the urban centers included being well connected to each other by air, road and partly sea, their cosmopolitan nature and their high level contacts with other continents through tourism among others. Mombasa and Malindi are coastal towns, Nairobi the capital city and Nakuru and Kisumu are much more inland.

Methodology

This was a descriptive, cross-sectional study of identified abusers (N=1420) in five major urban centers in Kenya, namely Mombasa (n=350), Malindi (n=183), Nairobi (n =364), Nakuru (n=246) and Kisumu (n=277). The study population included active and former substance abusers, either HIV positive or negative, found in rehabilitation and treatment centers, streets, and hospitals and in substance use dens within the five geographical areas. The sampling procedure included purposive sampling and snow balling.

Those identified were approached for informed consent after consent explanation by a researcher or trained research assistant. Structured questionnaires on social-demographic inferential, types of drugs abused, the time pattern and methods of use were used for face to face interview. Confidentiality was observed and assured.

A subset --120 drug users from Mombasa -- underwent serological testing for HIV and Hepatitis C status. The investigative team comprised of a research coordinator, 5 addiction & HIV/AIDS counselors and two ex-drug abusers who helped in approaching and identification of the drug dens or abusers. The five counselors worked with drug abusers for at least two years in the city. Serological testing was done at Al-Farooq hospital, a reputable Medical Centre located in a central area of Mombasa. The city was divided into well-defined catchment areas, for outreach workers to get in touch with the drug abusers who were approached in their own hang-outs, work places and homes. This was done to inform them about the study, and enlist their participation. Those recruited into the study were provided with fare to the Al-Farooq Hospital.

At Al-Farooq Hospital, prospective participants were received in the waiting room where each was allocated a number (e.g. 1,2,3,4,5 up to 120) by the counselors. The latter explained the concept and purpose of the study again and reminded them that their blood would be sampled for HIV & Hepatitis C individually. Each participant signed a consent form and completed a pre-test counseling session lasting about 30 minutes. The bio-data of the subject was recorded (e.g. Name, Sex, Age, drug and mode of use and area of abode, etc).

The participant then had blood sample collected by a Laboratory technician in presence of counselor to ensure that the number allocated to the client corresponded with the number labeled on the sample bottle. The blood was tested for HIV and Hepatitis C using the standard procedure in place in Kenya in all VCT Centers. For Hepatitis C the BioRapid – HCV kit was used. This is a rapid binding immunoassay in-vitro diagnostic test procedure, with four high sensitivity recombinant antigens. The results were read visually. Each received their results the next day whereby a post-test counseling session lasting 20-30 minutes was provided. The Data was entered and analyzed using the SPSS version 11.

Results

The majority (74.3%) in this study were aged 20-29 years in Nigeria (Kehinde, Lawoyin, (2005). In Harare, Zimbabwe and Moshi, Tanzania the HIV prevalence among women attending primary care clinics was found at 29.3% and 11.5% respectively (Mbizvo, et al, 2005).

Most Frequently Used Drug (%)

Alcohol was the most abused drug in Kenya with a national abuser rate of 36.3% followed by nicotine (17.5%), Cannabis sativa (9.9%), heroin (8.0%), Khat (2.8%) and cocaine (2.2%) (Table 1).

Ever Used Drugs (%)

With the exception of Malindi, the majority of whom did not respond to this question, over 90.0% of the people had a history of ever using drugs of abuse and the majority were active users on a daily basis (average daily prevalence rate of 46.0%).(table 2).

Methods of Use (%)

Oral (45.7% on average) and nasal (38.7%) were by far the most common modes of consumption of drugs, followed by intravenous administration (injection) at 10.4% (table 3).

Method of use over time (%) (Table 4)

These varied by region as can be seen in table 4 though there is a high current consumption through all modes in all towns except Malindi that users don't sniff nor snort, but has a 100% one-day prevalence for injection use.

HIV and HCV status

Among the 120 tested for HIV (not necessarily AIDS) and HCV, 111 (92.5%) were males and 9 (7.5%) females with 54.2% aged 30 or less. Of the males 94 (84.7%) were IDUs and 17(15.3%) were non-IDUs whereas 7(77.8%) and 2(22.2%) of the females were IDUs and non-IDUs respectively (tables 5, 6).

Of the IDUs 46/94 (48.9%) males and 6/7 females (85.7%) tested positive for HIV (Table 7) with the respective results for a positive Hepatitis C being 66/94 (70.2%) for males and 5/7 (71.4%) for females. Of the total tested 60.8% were positive for Hepatitis C and 41.7% were positive for HIV.

Discussion

The types of abused drugs found in this study reflect the same pattern observed in schools (Kuria, 1993) with the exception of intravenous use, which is an emerging factor. It is important to note that the 1995 rapid assessment did not report any hard drugs. The 1997 epidemiological school survey (Ndetei, 1997), showed only 0.3% heroin use, 0.3% Mandrax/amphetamines use and 0.3% cocaine and Mandrax use, but there was no intravenous drug use. Alcohol remains the most common and is highly consumed in Nakuru and Kisumu, reflecting the traditional pattern of lifestyle whereby consumption of alcohol was acceptable and even used in several festivities consistent with their location. The majority of the users were young (76.2%), below age 30 years.

In this study cocaine was found in 8.2% of the study cohorts in Nairobi, Mombasa (1.4%), Nakuru (1.2%), Kisumu (0.4%) and none in Malindi. Heroin was highest in Mombasa (22.3%), followed by Malindi (9.8%), Nairobi (6.0%), Nakuru (1.2%) and Kisumu (0.7%) and used intravenously. Most of the cohorts were active and current drug users. This pattern of drug use, especially the IDU, was highest in the Coastal towns of Mombasa and Malindi, mainly among the Swahili is largely a reflection of the fact that these were active cohorts and not those undergoing rehabilitation after detoxification. Some authors have established links between increased heroin abuse, growth of the tourist industry and the rise of Muslim revivalist groups, created partly as a response to the spread of heroin abuse (13). The Mombasa harbor had been used as a significant transit points for cocaine and heroin destined for Europe, America, Southeast and Southwest Asia with 'Spillover effects,' in which drugs destined for other countries are sold to local consumers.

IDU is a new phenomenon compared with previous published school surveys. There is sharing of needles even in people who know that they

are HIV positive. HIV status and IDU use are a significant association in Kenya; as an emerging new trend for spread of HIV.

The subset that was tested for HIV and HCV was relatively younger, with 54.2% aged 30 or less. This age pattern is consistent with findings from other studies. The sex ratio is inconsistent with other findings like the Amsterdam study where an emerging increase female ratio was found. The low turnout of females in the tested subset can be attributed to the following:-their low number in general, their fear of being tested as many of them were also commercial sex workers, the way the sample was achieved through snowballing and the fact that little attention had been paid to them as an affected group up to now.

The younger the age group, the higher the HIV and HCV positive results. This has the implication in that the most affected group is the youngest one. The rates were even higher for HCV for the respective age groups. The trend of the results is the same when the age group is compared with the cohort sample. There is higher HIV/HCV co-infection rate among the females than the males for which the authors have no explanation. The figure (49.5%) found in this study was 2.5%, which is 2 to 3 times as high.

Whereas research indicates that IDUs can and do change their needle-sharing and cleaning practices, HIV prevention efforts have not been successful in the realm of sexual behavior, particularly with regard to condom use. IDUs still report low rates of condom use with their partners. IDUs act as a bridging group for HIV transmission to the general population through sexual risk behavior, thus policies and interventions must focus on this aspect of behavior change and, should target, at a minimum, the steady sexual partners of IDUs as well as the IDUs themselves and their injecting risk behavior

Conclusion

There is an upward trend in injecting drug use among the drug users. These results also confirm a linkage between IDU behavior and HIV. There is a need for further research to determine the effects of co-infection of HIV, HCV and other diseases like STIs or tuberculosis and other opportunistic infections. Distinct regional variations within Kenya will require interventions that are context-specific.

However, maximizing the goodness of contextual or cultural fit is a major line of research investigation in HIV/AIDS prevention (Devieux et al., 2004) and must be linked with the urgency of syndemic patterns (co-occurring epidemics) in African countries. Castro and Farmer (2005) have underscored that intervention design depends on integrating context with what works—that populations respond and change their behavior accordingly, to health care infrastructures and interventions that work. The U.N. Commission on HIV/AIDS and Governance in Africa [http://www.uneca.org/chga/about.htm] is an acknowledgement of the relationship between HIV prevention, health care infrastructure and institutions of law and governance. A recent study by Menon-Johansson (2005) found higher HIV prevalence among countries with poor governance, confirming the Nobel Laureate Amartya Sen's work linking public health with democratic institutions.

Countries like Kenya have the advantage of beginning with this knowledge that individual, behavioral-only interventions—even when evidence-based and effective—are not enough by themselves. They require ecological structures of support, as the U.S. has begun to realize in the last five years in its funded research initiatives through the National Institutes of Health. IDU-focused prevention in Kenya must combine knowledge about effective behavioral interventions with what is now known about cultural adaptation, and do so in such a way that adds to and links the prevention infrastructure with the country's efforts at building democratic institutions and economic freedom, particularly for women.

Table 1
Most Frequently Used Drugs by Region (%)

	Mombasa n=350	**Malindi n=183**	**Nairobi n=364**	**Nakuru n=246**	**Kisumu n=277**
Alcohol	29.4	6.6	36.8	54.1	54.5
Nicotine	21.4	21.9	16.5	16.7	10.8
Cannabis Sativa	10.6	3.3	12.1	15.0	7.9
Catha Edulis	5.4	0.0	4.9	3.3	0.4
Cocaine	1.4	0.0	8.2	1.2	0.4
Heroin	22.3	9.8	6.0	1.2	0.7
Sedatives	0.6		1.6	0.4	0.7
Pethidine	0.0		0.5	2.0	0.4
Kuber	0.0		0.0		0.4
Morphine	0.0		5.5		0.4
Inhalants (Glue)	0.0		0.3		1.4
Phencyclidine	0.6		0.5		
Pills / Piriton	0.0		0.5		
Amphetamines	0.0		1.6		

Table 2
Ever Used Drugs (%)

	Mombasa n=350	**Malindi n=183**	**Nairobi n=364**	**Nakuru n=246**	**Kisumu n=277**
Ever used drugs	92.0	49.2	95.3	93.1	76.2
Today	68.9	37.7	53.6	37.4	31.0
Past 30 days	10.0	2.2	21.2	25.2	19.5
More than 30 days	0.9	0.5	8.8	6.9	5.1
Less than 12 months	5.1	1.1	4.9	8.5	7.6
More than 12 months	7.7	4.9	8.5	14.0	14.1
Not specified	7.4	53.6	3.0	7.3	22.7

Table 3
Methods of Use (%)

	Mombasa n=314	**Malindi n=75**	**Nairobi n=340**	**Nakuru N=222**	**Kisumu n=209**
Swallow	33.4	16.0	47.4	59.5	72.2
Smoke	43.9	62.7	30.6	32.4	23.9
Snort/Sniff	5.7	0.0	5.0	5.0	1.4
Inject	12.1	21.3	15.9	0.9	1.9

Table 4
Method of Use Over Time (%)

SWALLOW	**Mombasa**	**Malindi**	**Nairobi**	**Nakuru**	**Kisumu**
Today	56.6	83.3	47.0	30.8	41.1
Past week	17.9	0.0	26.2	28.6	23.5
Past 30 days	0.9	0.0	9.1	9.8	5.9
More than 30 days	2.8	0.0	6.1	12.8	11.8
More than 12 months	12.3	16.7	11.6	18.0	17.6

SMOKE	Mombasa	Malindi	Nairobi	Nakuru	kisumu
Today	86.1	85.1	56.7	54.9	40.0
Past week	5.8	4.3	17.3	25.4	24.0
Past 30 days	0.7	0.0	10.6	2.8	8.0
More than 30 days	0.7	4.3	6.7	2.8	6.0
More than 12 months	6.6	6.4	8.7	14.1	22.0

SNORT/ SNIFF	Mombasa	Malindi	Nairobi	Nakuru	Kisumu
Today	85.0	0.0	70.6	72.7	33.3
Past weeks	5.0	0.0	11.8	9.1	66.7
Past 30 days	5.0	0.0	5.9	9.1	0.0
More than 30 days	0.0	0.0	5.9	9.1	0.0
More than 12 months	5.0	0.0	5.9	0.0	0.0

INJECTION	Mombasa	Malindi	Nairobi	Nakuru	Kisumu
Today	86.5	100.0	67.9	0.0	25.0
Past week	27.0	0.0	23.2	50.0	25.0
Past 30 days	0.0	0.0	8.9	0.0	25.0
More than 30 days	5.4	0.0	0.0	0.0	0.0
More than 12 months	5.4	0.0	0.0	50.0	25.0

Table 5
Gender Vs Status

	Gender	
HCV Status	**Male**	**Female**
Positive	66 (65.3)	5 (5.0)
Negative	28 (27.7)	2 (2.0)
X= 0.92.11	df= 1	
HIV Status		
Positive	46? (45.5)	4? (3.9)
Negative	48 (47.5)	3 (3.0)
Total	94 (93.1)	7 (6.9)

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International Perspectives on Governmental Aggression

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Researchers interested in international perspectives on a range of social issues have fertile grounds for pilot testing of procedures and obtaining preliminary data right within the rich, multi-cultural United States. As pointed out by Rice (2005), the foreign-born population, which currently composes 11.1% of the nation's population, increased by 57% from 19.8 million in 1990 to 31.1 million in 2000; the native born population increased by only 9.3% during the same decade. According to recent figures, more than 50 percent of these immigrants were born in Latin America, over 25 percent were born in Asia, 14 percent were born

in Europe, and the rest were born in other regions of the world (Schmidley, 2003). Data from immigrant and international student/visitor samples are valuable in their own rights (Rice, 2005) as well as being a source of international data on a range of current issues.

For several years, our research group has been deeply involved in collecting data from over 25 countries (including Australia and at least two countries from every other continent) on international perspectives on family violence and abuse (see Malley-Morrison, 2004; Arai et al., 2005). Recently we have extended our work to investigate international perspectives on institutional violence, particularly violence by governments. We have developed a scale, the Personal and Institutional Rights to Aggression Scale (PAIRTAS), to assess the extent to which individuals believe that family members sometimes have the right to hit other family members, and that governments sometimes have the right to perform such acts of aggression as invading another country. Respondents indicate on a scale from 1 (total disagreement) to 7 (total agreement) the extent to which they agree with statements concerning the potential right to use aggression. Then, in their own words, they provide an explanation of the reasoning behind their rating on the item.

In this paper, we present some of the provocative findings we have obtained from analyses comparing the quantitative responses of two groups—an "international group" (they and their parents were all born in some country other than the US), and a domestic group (they and their parents were born in the United States). In addition, a United Nations (2005) categorization of countries as "developed" (e.g., the United States, France Japan, Australia), "developing" (e.g., Mexico, Brazil, India), and "least developed" (e.g., Laos, Afghanistan, Uganda) was used to classify participants into groups based on the level of development of the country from which they and their parents came. We predicted that respondents from the domestic group, and from the developed nation group, would show greater tolerance of governmental aggression than individuals from the international group and from developing/underdeveloped countries. Moreover, based on previous research indicating stronger support for aggression in men than in women, we predicted that the men would show greater tolerance than women for governmental aggression. Our measure of tolerance for governmental aggression was level of agreement with five PAIRTAS items: "Sometimes the police or military have the right to use violence against their own citizens"; Sometimes a government has the right to execute one of its citizens"; Sometimes one country has the right to invade another country"; "Sometimes a country has the right to ignore international treaties or international human rights agreements"; and "Sometimes the heads of a government have the right to kill innocent civilians in order to fight international terrorism."

The sample for this study included both students taking research methods courses at a large northeastern urban university and friends and family members recruited by those students to ensure as diverse a sample as possible for their studies. The rights survey was just one of many measures administered by the students, who were exploring a variety of research problems and hypotheses for their semester projects. APA ethical procedures were followed throughout the process. The complete sample of 1065 participants, which included 578 women and 485 men, ranged in age from 15 to 72, with a mean of 24. The international sample for most analyses was 168 or 107, with some variation because not every participant responded to every item in the survey packets, and some of the PAIRTAS items were added only to later versions of the scale.

We began by running t tests comparing the international (n=167) with the domestic participants (n=599), and the developed nation participants with the developing nation participants on the five PAIRAS items. The results were as follows: The domestic sample scored significantly higher than the international sample on all five of the aggression variables, indicating stronger support for the right of governments to use these forms of aggression. Moreover, the participants from the developed nations scored significantly higher than those from the developing nations on tolerance for police/military violence, invasion, ignoring treaties, and killing civilians (but not on tolerance for capital punishment). Finally, there were gender differences in the expected direction (men showing more tolerance for aggression than women) on police/military violence, capital punishment, invasion, and ignoring treaties (but not on killing civilians). In order to assess the extent to which the predictor variables contributed independently and additively to the tolerance variables, a series of linear multiple regressions were run, with gender entered on Step 1, international/domestic status at Step 2, and developed/developing nation at Step 3. For the police/military violence against citizens, and capital punishment variables, gender contributed significantly to the equation at Step 1, and international/domestic status contributed significantly and additively at Step 2, with national developmental status not adding significantly at Step 3. In regard to tolerance for invasion of another country and for ignoring international treaties, each predictor added significantly to the amount of variable explained. Finally, in regard to tolerance for killing civilians in a fight against terrorism, it was only the international/domestic status variable that contributed significantly to the outcome. When a new variable was computed by summing the scores on the five items concerning presumed government right to use aggression, each of the predictors contributed independently and additively to the final predictive equation, which explained about 11% of the variance in tolerance for governmental aggression.

Thus, our findings were generally consistent with our hypotheses. As in prior studies with different but related measures, males showed greater tolerance for the use of aggression (in this case by government) than females. Participants in the international group showed significantly less tolerance for governmental aggression than the domestic group. In the regression analyses, international status generally contributed to the prediction of tolerance for aggression over and above the contribution made by gender. Finally, participants from developing countries showed significantly less tolerance for governmental aggression than did participants from developed countries, on the overall tolerance scale as well as several of the individual items.

Our next major goals are to analyze the qualitative data, and to recruit participants in other countries. We welcome the participation of researchers from other countries who would like to collaborate with us in this project.

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The Forgotten Centennial of the "Binet-Simon Intelligence Scale" in 2005

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It is an accepted fact that French psychologist Alfred Binet and psychiatrist Théodore Simon designed, 101 years ago, the first practical measurement of intelligence, *Échelle Métrique de l'Intelligence*, known as the "Binet-Simon Intelligence Scale." Initially, Henri Beaunis read their paper, "Méthodes Nouvelle Pour Diagnostiquer l'Idiotie, l'Imbecitité et la Débilité Mentale," on April 28, 1905, at the 5th International Congress of Psychology in Rome (see Binet & Simon, 1905a). It was then published, in the *l'Année Psychologique* (Binet & Simon, 1905b) in Paris. The authors discussed their diagnostic psychological, pedagogical, and medical methods, emphasizing the importance of psychological method (i.e., measurement) in identifying low ability schoolchildren in order to help them in special schools.

Binet and Simon (1905b) stated that their purpose was "to be able to measure the intellectual capacity of a child who is brought to us in order to know whether he is normal or retarded. …" (p. 191). But with the

measured children's general intelligence to determine their intellectual level ("niveau," in French), they would compare it "with that of normal children of the same age or of an analogous level" (p. 193). However, the authors cautioned about the measurability of "intelligence."

The Binet-Simon Scale "Took American psychologists by storm" (Epstein, 1998, p. 13) and became "The prototype of all of today's tests for the measurement of intelligence" (Matarazzo, 1992, p. 1007) providing, also, the foundation for new tests around the world (e.g., Freeman, 1934; Viens, Chen, & Gardner, 1997). And since 1905, the scale was translated, revised, and adapted for use in various countries, including Belgium, Germany, England, Italy, and Switzerland. In the U.S., Lewis M. Terman's (1916) *Measurement of Intelligence* was widely accepted and became popular. With the appearance of Terman and Merrrill's (1937)

Measuring Intelligence, and in subsequent editions, the test became known as the "Stanford-Binet Intelligence Scale" (e.g., Roid, 2003; Thorndike, Hagen, & Sattler, 1986). Siegler (1992) considered the Binet-Simon Scale a "remarkable achievement" (p. 185). Earlier, appreciating its value and enormous influence, Jenkins and Paterson (1961) stated: "Probably no psychological innovation has had more impact on the societies of the Western world than the development of the Binet-Simon scales" (p. 81).

Psychology publications are rife with laudatory statements about the scale and, also, about Alfred Binet. Young (1924) wrote Binet's contribution "Stands supreme for its general originality and the fact that he synthesized the growing movement into his now well-known scale" (p. 11). While for Raymond Cattell (1941), Binet with "his inventive, subtle mind" was "One of those knight-errant of science for whom the most untrodden path has the greater lure" (p. 33).

No wonder, then, Terman, the 1923 American Psychological Association (APA) President, considered Binet his favorite psychologist (Terman, 1930), while Henri Piéron (1930) and Freeman (1934) regarded Binet *a great* psychologist. Others marveled at Binet's many novel ideas, pioneering research in diverse disciplines, and praised his contributions.

In 1939, the French scientific community formally commemorated in Paris (a) the Centennial of Théodule Ribot's birth, and the 50th anniversary of (b) the establishment of the Chair of Experimental Psychology at the Collège de France and (c) the founding of the first French Laboratory of Physiological Psychology at the Sorbonne. On this historic occasion and cognizant of contributions of Ribot, Pierre Janet and, especially, of Alfred Binet's great achievement and influence on U.S. psychology, Gordon W. Allport, the 1939 APA President, expressed the U.S. genuine appreciation of Binet and his diverse "prodigious contributions" adding that "To him American psychology must acknowledge a particular indebtedness" (p. 96).

The American Association for the Advancement of Science (AAAS), in 1984, chose and ranked the Binet-Simon Scale (see Miller, 1984) as one of the 20 discoveries "among this [20th] century's most significant historical developments in any field," having had, Hammond (1984) continued, "a significant impact on the way we live or the way we think about ourselves and the world" (p. 9). Similarly, years later, *Time Magazine* considered Binet one of the 20th "century's 20 most influential scientists, thinkers and inventors" whose invention was "a great theoretical breakthrough" (Isaacson, 1999, p. 6; Lemann, 1999).

Incredibly though, the APA, "the world's greatest organization of psychologists" (Cattell, M.C., 1929, p. 339), did not remember to celebrate the centennial of the revolutionary discovery by Binet and Simon at its 113th annual convention in Washington, D.C. It is certainly ironic that U.S. psychologists, especially, the intelligence "experts," simply ignored this earliest landmark contribution to psychology, neglected to appropriately mark the momentous occasion and also pay homage to Binet and Simon.

The "Binet-Simon" scale and its originators, however, were not forgotten at the 2005 APA convention. Pambookian had organized two programs: (a) a Division 1 (Society of General Psychology) symposium on the "Binet-Simon Intelligence Scale: A Century of Contributions Worldwide" (Pambookian, 2005a) and (b) a Division 2 (Society for the Teaching of Psychology) Hospitality Suite conversation hour on the "Centennial of the Binet-Simon Intelligence Scale: A Grateful Observance" (Pambookian, 2005b). Also participating in the programs were Andrew D. Carson, Jacqueline Cunningham, Thomas D. Oakland, Peter Merenda, and Ruben Ardila from Colombia (but he could not be present for unexpected reasons).

How could APA "forget" the centennial of such a monumental invention that transformed and revolutionized the world societies? Are psychologists today so self-absorbed that they are indifferent to psychology's past and its rich heritage? Or, is such an oversight simply due to selective memory, hence non-acknowledgement of Psychology's worthy predecessors and noteworthy achievements?

Many psychologists (including, e.g., Brody, 2000; Daniel, 1997; Sternberg, 1988, 2000) are rather erratic in their citations and, while discussing psychometric tests, standard IQ tests, individual differences so relevant to Binet tradition, do not even mention Binet, the father of intelligence testing! Yet, Sternberg (1992), elsewhere, acknowledges that Binet "had a profound impact on our thinking about intelligence, an impact that carries down to the present day" (p. 2).

Psychologists are still grappling with the nature and definition of intelligence. That is the reason authors, in their books and articles, around the world, keep referring (a) to Boring's (1923) famous article defining "Intelligence as the Tests Test It" (e.g., Deary, 2000; Matthews, Zeidner, & Roberts, 2002; Sternberg, 2000a, 2004; Sternberg & Grigorenko, 2001; Sternberg & Kaufman, J.C., 1998; Sternberg, Lautrey, & Lubart, 2002); and (b) to the *Journal of Educational Psychology's* "Intelligence and Its Measurement: A Symposium" (1921) (e.g., Sternberg 2004; Sternberg & Grigorenko, 2001; Sternberg & Kaufman, J.C., 1998). In both instances, none of the authors refers to Binet's "definition" of intelligence or realizes the fact that Binet, in 1911 or earlier, may have said, in jest, to Simon (1939), a long-time collaborator, that intelligence was "C'est ce que nous mesuront par notre échelle métrique …" [It is what we measure by our metric scale] (p. 551). Jean Bourjade (1937), of the Université de Lyon, had, also, affirmed Binet having said, "J'appelle intelligence ce que mesure mon échelle" [I call intelligence what my scale measures] (p. 139).

Despite substantial improvements, technical advancement, and enormity of "psychology brain power," little has changed since 1905. That is what today's prominent psychologists (e.g., Kamphaus & Kroncke, 2004; Kaufman, A.S., 1979; Naglieri, 2000, 2001; Nagliei & Das, 2002; Sternberg, 2000b; Sternberg & Grigorenko, 1999; Sternberg & Kaufman, J.M., 1996) state and appear to be frustrated for lack of progress! Because, Detterman (1979) stated vehemently, "We have ignored Binet's insight much to our detriment" (p. 249). Needed, undoubtedly, is Binet-caliber psychologists! But Binet may still be helpful. To reiterate Pambookian (2003), I must stress that "Ahead of his time, Binet is still relevant and can help us if we just 'rediscover' him"! (p. 4).

Truly, not clinging to Psychology's past, we should acquaint ourselves with earlier research, accomplishments, and pioneers that enriched psychology and made it what it is today. While Boring (1929) had in mind the experimental psychologist, I believe, though, any psychologist "needs historical sophistication within his own sphere of expertness. Without such knowledge he sees the present in distorted perspective, he mistakes old facts and old views for new, and he remains unable to evaluate the significance of new movements and methods" (p. vii). But besides learning about psychological developments and earlier contributions, psychologists must also accept and appreciate their enduring legacy. Moreover, acknowledging past achievements and honoring the pioneers, in no way, diminish one's scientific worth, research, and significant innovation!

As APA presidents, leaders and renowned psychologists have their own "agendas," and research and scholarly endeavors to pursue, I suggest that the association establish a "Special Events Committee" to identify, ahead of time, noteworthy anniversaries of events and individuals, publicize them and plan celebrations at appropriate times throughout the year. And mobilizing "expert" members and through "Psychology Moment" on public radio, specific-focus columns in newspapers, television documentaries, special conferences where psychology's best minds would "Meet the Psychology Press" and "Face the Psychologists," that Committee would educate the public, promote psychology and help fulfill the APA 2005 President Levant's (2005) initiative by making psychology a household word.

As scientists, our responsibility is to psychology and its advancement. We must, therefore, follow the AAAS and Time Magazine as good models, and start acknowledging and celebrating psychology's influential

accomplishments and its giants –irrespective of their scholarly interests and national origin.

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Book and Film Reviews

The Middle East: A Cultural Psychology

by Gary S. Gregg
With a Foreword by David Matsumoto
New York: Oxford University Press, 2005. 458pp.
ISBN: 13 978-0-19-517199-0

Reviewed by Ahmed Abdel-Khalek
Kuwait University

Although Dr. Gregg has been trained in the American psychology discipline and tradition, and is neither an Arab citizen nor of Arab ancestry, he has written a fascinating and thorough book about a turbulent part of the world, i.e., the Middle East and North Africa (MENA). It is particularly noteworthy that Dr. Gregg has spent five years in the Arab country of Morocco, where he conducted ethnographic research. I second Uwe P. Gielen's comment on the volume's backcover that "this is an original and timely book." Moreover, it is interesting to an Arab psychologist such as the present reviewer to read this engaging book written by a psychologist outside the MENA countries. It sometimes happens that persons and societies do not fully grasp their inner life, and

that an outsider can add observations helpful to those persons and societies. This is true for this volume. It is also worth noting that Dr. Gregg has provided an exhaustive review of literature written by psychologists, anthropologists, and sociologists in English, Arabic, and French.

The book consists of two parts. Part one introduces the cultural context of psychological development in the MENA countries. It begins with a discussion of the various existing stereotypes about the Arab world, and examines some common misunderstandings of the MENA societies that have been mistakenly offered as "explanations" for the region's current problems. Afterwards, the author provides a social ecological background for psychological development, social organization and cultural values in this region under the title: *Honor and Islam: Shaping emotions, traits, and selves.*

Part two of this important book is entitled *Periods of psychological development*. It introduces a model of cultural influences on personality development in which Dr. Gregg adopts a framework based on six developmental periods and three levels of psychological organization. Subsequently, he reviews the pertinent MENA-oriented writings on psychological development by life-stage, i.e., infancy, early childhood, late childhood, adolescence, early adulthood, and mature adulthood. A closing coda appears under the title: *A research agenda for MENA specialists in cultural psychology*. Here the author suggests several future research priorities for each developmental period. Foremost among them are three areas: individualism versus collectivism, the cultural shaping of emotions, and acculturation and biculturalism.

A critic might argue that Gregg treats MENA as if they were a single country. However, the author is aware of this objection and addresses it as follows, "My review includes research on Muslim groups from Morocco to Pakistan and Turkey to Sudan - a huge and complex area whose cultures have been formed by millennia of mixing peoples, languages, ways of life, and religions. No homogenous shared culture - and certainly no shared "personality" or "mentality" - has resulted from this mixing. Nonetheless, I will discuss it as a *culture area*" (p. 4).

However, the present reviewer begs to differ with this approach inasmuch as a vast diversity of peoples resides in this large geographic region. Moreover, while Pakistan and Turkey are mainly Muslim countries, they are not Arabic. In addition, there exists a growing subculture in the rich countries in the Arabic Gulf; their economies are based mainly on oil, and they are enjoying a very high per capita income when compared to the other Arab countries. Regarding Morocco, where the author spent five years: it is not a typical country of the MENA area, but it is certainly an ideal example of NA. I would like to add that some Arabic sources and references are neither accurate nor do they represent an objective perspective. The spelling of some of the Arabic names and titles in Latin letters also needs revision.

By and large, however, this interesting, notable, and thoughtful book deserves reading, and I recommend it to a wide range of potential readers in different disciplines including psychology, anthropology, sociology, and politics, especially since no other book representing a similar, wide ranging lifespan and cultural psychology approach to psychological development in the MENA countries is currently available in the English language.

Shake Hands With the Devil: The Journey of Romeo Dallaire
A Review of the Film

VHS, DVD and 35mm
91 minutes, 2005
Directed by Peter Raymont
Produced by Peter Raymont and Lindalee Tracey
Written by Roméo Dallaire, based on his book.

Reviewed by
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This documentary film presents the story of the highest-ranking military official who was hospitalized for Post Traumatic Stress Disorder (PTSD) as a result of witnessing the Rwandan genocide. The film is based on Romeo Dallaire's book about his experiences during the Rwandan genocide and his subsequent struggles dealing with his depression and trauma. Dallaire was a Canadian General heading the United Nations (UN) peacekeeping mission in Rwanda. The documentary follows Dallaire's visit to Rwanda during the 10th anniversary of the genocide, including footage of the 1994 massacres.

Dallaire was aware of the tensions developing between Hutus and Tutsis, two ethnic groups in Rwanda. He witnessed government propaganda against the Tutsis and encouragement of ethnic cleansing by the Hutus. He felt he had a personal responsibility to prevent the genocide, but was denied assistance by the UN. First, the Belgians withdrew all of its forces after the Hutus killed ten of their soldiers. They were more concerned about keeping their troops safe than preventing a genocide. Then, the UN during their meeting in New York made the decision not to use force to protect Rwandans. Dallaire was left with only 300 soldiers to protect the UN headquarters, while watching the genocide take place. Dallaire was told that "Rwanda was Black and didn't have any strategic value". At the same time he saw the international community reacting to what was happening in Yugoslavia by sending troops for peacekeeping efforts to stop the genocide there. As a result, the Yugoslavians were protected by UN intervention and Rwandans were not.

Dallaire hoped that the Catholic Church in Rwanda might be able to help. But, they refused to say that killing Tutsis was against God's will. Even though Dallaire was able to provide a safe haven to some Tutsis within the UN compound, he felt helpless and frustrated with the global indifference of the international community. When he went outside of the compound to assess the magnitude of killings, he witnessed tens of thousands of people murdered on the streets…he witnessed atrocities…he couldn't understand how a human being would harm another human being in such a brutal way…he couldn't understand why the international community focused on O. J. Simpson case, while 800,000 people were being killed in Rwanda. When a news reporter asked him why he stayed, he answered that he wanted to see what was happening so he could serve as a witness and speak about the genocide.

In the film, Dallaire also talks about his psychological struggles after his return to Canada. He attempted suicide twice due to PTSD and depression; he was hospitalized for his suicidal thoughts. He couldn't live with the pain, sounds, and smell he remembered. He couldn't stand the "loudness of silence". He states that he became suicidal when he realized he couldn't erase Rwanda from his memory and he couldn't see the future. Currently he continues to experience survival guilt and uses medication to deal with his psychological reactions to what happened in Rwanda.

In the documentary Dallaire also states why he entitled his book "Shake Hands With the Devil". During peace negotiations, he twice met with the leaders of the Hutu militia groups who engaged in killings of the Tutsis. When he shook hands with them, their hands were cold and evil like.

The documentary raises the consciousness about individual and global responsibility for those who are in danger and helps viewers develop empathy towards oppressed groups. The film also helps break the common belief about military generals being cold and heartless by showing Dellaire as somebody who is caring and full of compassion. The

film could easily be incorporated into psychology undergraduate and graduate courses. For example, psychology students could be asked to have a discussion about who was really to blame for the genocide and how internalized blame could push someone into depression. When teaching trauma related courses, the film could be used as a tool to illustrate how anger and feelings of hopelessness could lead to the development of suicidal feelings and PTDS. The film could be used in conjunction with the movie Hotel Rwanda where Nick Nolte plays the role of a UN peacekeeper similar to Dellaire's. I highly recommend this film especially for students and professionals in counseling, clinical, social, and community psychology.

The documentary received the World Documentary Audience Award at the Sundance Film Festival. The film is available at California Newsreel, www.newsreel.org, in the form of DVD or VHS. California Newsreel is a company that has produced film and video for social change since 1968.

Books by Members

ANNOUNCING THE PUBLICATION OF…

Social Change and Psychosocial Adaptation in the Pacific Islands: Cultures in Transition

ISBN: 0-387-23292-3

Marsella, A.J., Austin, A., & Grant, B. (Eds.) (2005) NY: Springer Publications

This volume is the product of an international gathering of scholars and health professionals for the specific purpose of understanding and documenting the wide-ranging psychosocial consequences of rapid social change among people of Pacific Island nations. Westernization can now be found throughout the Pacific Islands with the exception of a few isolated regions in Melanesia and Micronesia. From clothing, to food, to religions, to the presence of new economies, the changes are many and profound. The result from the social upheaval – both directly and indirectly – has been the onset of numerous psychosocial problems ranging from substance abuse to suicide – the social pathologies. These problems are found at serious levels among youth and young adults. This volume offers an overview of these conditions across a sample of Pacific Islands nations and cultural groups that include aboriginals areas of Northern Australia, various groups in Guam, and Fiji, Micronesians from Chuuk, Pohnpei, and the Marshall Islands, Native Hawaiians, and Solomon Islanders. The chapters capture the complexity of the past and present forces that have shaped the Pacific Nations and the consequences that often arise as cultures encounter one another and become cultures in transition.

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Amelia M. Arria & James C. Anthony

Chapter 12: Conclusions
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ALSO ANNOUNCING THE PUBLICATION OF…

Stevens, M. J., & Gielen, U. P. (2006). *Toward a global psychology: Theory, research, interventions, and pedagogy.* Mahwah, NJ: Erlbaum.

Toward a Global Psychology defines the emerging field of international psychology. It provides an overview of the conceptual models, research methodologies, interventions, and pedagogical approaches that are most appropriate to transnational settings. In so doing, the book provides readers with a rich appreciation of how to approach a global psychology as researchers, practitioners, and students. The book's thorough review of the existing literature on international psychology from around the world provides the knowledge needed to successfully engage in the science and practice of psychology in an increasingly globalized society.

Stevens, M., & Wedding, D. (2004) (Eds.). *The handbook of international psychology.* NY: Brunner-Routledge.

This book overviews the science, training and practice of psychology in 27 countries scattered across 9 regions of the world.

Stevens, M., & Wedding, D. (2005) (Eds.). *PSYCHOLOGY: IUPsyS Global Resource* (CD-ROM). East Sussex, United Kingdom: Psychology Press.

This CD-ROM attempts to capture relevant information on psychology and psychologists around the globe. It is distributed to everyone who subscribes to the *International Journal of Psychiatry*, and it is available for individual purchase through Psychology Press.

Takooshian, H. (2005, Jan.). (Ed.). *Social psychology of city life.* (Special issue). *Journal of Social Distress and the Homeless, 14* (12).

Wedding, D. (Series Editor), Butler, L., Freedland, K.E., Sobell, L. C., & Wolfe, D.A. (2005). *Advances in psychotherapy: Evidence-based practice.* Gottingen, Germany: Hogrefe & Huber.

This series of 20 -25 books presents clinically relevant evidence based practice information in a compact, user-friendly manner. The first four books in the series address bipolar disorder, heart disease, obsessive compulsive disorder and pathological gambling.

Wedding, D., Boyd, M.A., & Niemiec, R.M. (2005). *Movies and mental illness: Using films to understand psychopathology.* Gottingen, Germany: Hogrefe & Huber.
(Danny Wedding directs the Missouri Institute of Mental Health, part of the medical school at the University of Missouri-Columbia.)

This book explores the portrayal of mental illness in contemporary films.

All Division 52 members are invited to report on their scholarly activities related to their books. Interested members should contact:
Dr. Jennifer Lancaster at jlancaster@stfranciscollege.edu

Miscellaneous

The Dual Role of Multinational NGOs in the Globalizing World

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Research on this paper was supported in part by a Short-Term Grant from the Kennan Institute of the Woodrow Wilson International Center for Scholars, Washington, D.C. The author is very thankful for this support.

A very general picture of any society's structure is a Triangle consisting of Government, Business, and NGO-Sector. When saying Government, all the branches of Government as well as all the levels of political power from Parliament to Local Authorities are understood. Business includes industry, agriculture, roads, and different types of transportation. NGO Sector is something that takes the place of traditional Trade Unions. It is a sort of civil rights movement worldwide and one of the crucial and most influential factors in the contemporary world. The emergence and development of Inter-national, Multi-national and Trans-national NGOs is the landmark for the real existence of **globalization** processes worldwide. Governments, World Business, and NGO Sector worldwide represent a triangle symbolizing power/authorities, money/finance, and morality/ethics respectively. At the same time, the developments of the last decades show that NGOs are not really equal partners to Industry and Government: Governments decide the Terms and Conditions for the activity and behavior of any Local NGO; An NGO should not enter into collaboration with a for-profit corporation if the main motivation of the corporation is to gain a market advantage over competitors (cf., Anderson & Kaplan; Jeshmaridian, 2000). For the developed societies, NGOs are considered partners to Government because of the fact that they can address social and environmental problems with greater efficiency and cost effectiveness than government agencies. In developing societies, NGOs are more often partners to Business. This situation gives the Local and Professional NGOs an opportunity to earn money by their mostly kind but sometimes unkind activities.

From the viewpoint of ethics and morality, Inter-/Multi-/Trans-national NGOs play a dual role in the globalization processes. On the one hand, NGOs help to foster an ethical culture in governmental and corporate realms. They make both government and business act responsibly and become more transparent, honest and accountable before society (cf., Kittrie, 1997; Ward, 2004). In that way, NGOs have the internal responsibility to follow the highest code of ethical conduct in their own activities. From that point of view, they have a comparative advantage, namely moral advantage. Psychologically, they have the aptness to be transparent and honest themselves and to give out accurate information to the whole society or to any social structure or to any citizen. NGOs promote governmental and corporate ethics in different ways. They point out transgressions, such as governmental corruption, corporate pollution, human rights abuses. They often address political, social, economic inequities and advocate various remedies.

Parallel to many positive and promoting factors, we can also see unethical behaviors of various NGOs, independent of their size and type: whether they are miser, macro, huge or quasi/huge, ultra-violet or infra-red, professional, worldwide or local. The motivation of various behaviors of individuals as well as of social groups, the interactions between them are highly difficult to understand, moreover, to predict. It is more difficult to understand society's works in globalization processes. Multilateral institutions such as the United Nations and the World Bank, in fact, are GO-NGOs: NGOs created by governments. GO-NGOs' motivation is too difficult to understand. They have a national government as a roof. Moreover, they are Government-owned NGOs. Such GONGOS are some sort of tools in the hands of national governments to fulfill their goals and purposes.

If an NGO, e.g., in Armenia is not a Gongo, it is viewed or can potentially be viewed as a political threat to the Government as far as it is considered a PANGO – a Party NGO, better to say a Party-owned NGO. As a result, these NGOs are marginalized by legal constraints and bureaucracies, which make their survival impossible. And how about if the roof of a certain NGO is not a government or a party but is a Mafia: What can we expect from MA-NGOs? The social values of Mafias are severe and far more inflexible than those of governments. Can such principles and social situations promote the reduction of international terrorism? Can the local poverty be alleviated in the atmosphere of mafia organizations? (cf. Jeshmaridian, 1999; Rubenstein, 1983).

Besides Mangos, Gongos, and Pangos the world knows other aberrational NGOs, such as: BRI-NGOs – Briefcase NGOs, CRI-NGOs – Criminal NGOs, CO-NGOs – Commercial NGOs, COR-NGOs – Corrupted and/or corrupting NGOs, TA-NGOs – Dancing NGOs, CASI-NGOs or BI-NGOs – Playing NGOs, SINGOs and SRI-NGOs – Singing NGOs (Sring is an Armenian word meaning Flute, a musical instrument). All these types of NGOs have some special aberration of human morality and ethics and denote a definite destruction of a certain society. SOROS Foundations and Open Society Institutes (OSI) in the post-Soviet and post-socialist societies have the traits of several types of NGOs as follows: Sringo – they first play their sring-flutes to attract the scientific and educational structures by their fame, money and promises; then they become a Tango: they dance a tango with a Bingo, a local or national game-playing NGO and as a result of that game corrupted and bribed NGOs – Congos, Cringos, and Corngos are born. The more SOROS Foundations and OS Institutes become corrupted, the better they fulfill their missions, though the human, social, political collapse becomes real and the collapse of human conscience becomes easier.

Today, we are in need of two very important actions: 1) Investigating and understanding NGOs and 2) Developing Morality Code for contemporary NGOs.

1) All the types of NGOs need both national and cross-national research. The methodology of such investigation can play a crucial role in understanding the social psychology of NGOs in our world undergoing

globalization: We ought to understand what the subject and object of our research are. NGOs are very often grouped according to their activity and/or professional orientation and they have names of definitely symbolic colors – Greens, Blues, Browns. We ought to understand the process how these NGOs grow into global structures and which are the mechanisms that make them globally worldwide. These social and psychological mechanisms should be investigated in the process of their acquisition. In interactive relations NGOs are the ones that depend on others: Government and Business. NGOs act in real social psychological situations, and their motivation, decision making processes, and the whole behavior very much depend on the actions and social values of power/Government and finance/Business. We also ought to understand what NGOs bring to advance human security. One day (and that day, I believe, is very near) Morality will play the crucial role in the world and Morality will act and behave and influence the social world mostly through NGOs in the Triangle of Power-Finance-Morality.

2) The next most important action that should be taken is that any democratic society, today, has to get involved in the search for a meaningful working ethic for contemporary NGOs. These societies will go toward a working ethical paradigm for NGOs. Today's societies require and demand a Code of Ethics for both governmental and non-governmental organizations as well as for public figures. Many great thinkers of today suggest develop an overall **CODE System** for Inter-, Trans- and Multi- national NGOs (cf. Soros, 1990). A globally important issue arises: what kind of principles should the human ethical code adhere. It is definitely concluded that a sort of International Code should be adopted for all Inter-, Trans, and Multi-national NGOs. Moreover, in the process of globalization one code for all types of NGOs should exist – local and international, multinational and transnational, large, small, and miser.

Chung Hwan Kwak, the chairperson of WANGO – World Association of NGOs – views the human Family as the foundation of Ethics (Ward, 2004). The World Association of NGOs has proposed Code of Ethics and Conduct for NGOs. The Futuristic Vision of/for NGOs is highly complicated and conflicting: NGOs that challenge existing political arrangements and challenge those government policies, which pose a threat to human security, can face serious repercussions from the implicated governments that are unwilling to hear public criticism of their actions (Walsh, 2000; Ward, 2004). Some governments have sought to restrict the power of NGOs by creating legislation, which limits their sanctioned activity to the non-political arena. I believe the future belongs to World NGOs and one day, the World Government won't ask the NGOs what they did to protect their own rights, but will ask what they did to protect the rights of others.

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International Roving Reporter: Cruising the Danube from Bucharest to Budapest August-September, 2005

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Recently we took a Riverboat cruise on the Danube from Romania to Hungary. This turned out to be a wonderful, convenient way to travel in order to explore small towns and villages and engage in close cultural contacts with the local people. We talked with fine local guides, walked through villages ravaged by war in the early 1990s, made home visits for lunch with local host families, and had professors and other knowledgeable people from the various locales visited come to deliver lectures and answer questions aboard ship – all as part of familiarizing us with the five countries we toured: Romania, Bulgaria, Serbia, Croatia, and Hungary.

After a day or two, I recognized I needed a framework around which to absorb, organize, and comprehend what I was hearing, observing, sensing, and reading. What flashed back into memory was a paradigm learned many years ago in a basic sociology course, used periodically since – and elaborated slightly below (the portions after the slash marks represent the additions).

Each society is made up of five basic interlocking and independent institutions:

1. Family
2. Political/Government/Military
3. Economic/Financial
4. Religious
5. Educational/Cultural

As one institution changes, all of the others change reactively – just as happens in family systems. For example, when communism became the dominant political ideology and system in Eastern Europe in the first half of the 20th century, free enterprise all but disappeared and the state controlled all business and agricultural ventures. The USSR and its politburo decided who could study what and where, what they would be paid, and demanded that everyone's primary loyalty be to the Communist Party, not to one's family, one's God or religion. Since religion provided a system of beliefs and guideposts for living that offered different and conflicting meaning and values to life than communism did, going to church (or synagogue) was strongly discouraged. Church attendance diminished sharply, churches fell into disrepair, and clergy could no longer exert much influence over non-existing congregants nor speak out publicly on behalf of humanitarian values without fear of imprisonment. Values were instilled by "the party"; the family and its influence were submerged to a low second place. If need be, one would turn against a family member for the good of "the party".

Now that the Communist stronghold has been broken, a new and more multifaceted political infrastructure is arising in each of the break-away countries. Each country has turned westward toward the European Union and each has recently joined NATO. Hungary, the most prosperous, advanced and westernized of these five countries, is already a member of the EU. The other four countries are preparing for entry, and have tentative acceptance dates ranging from 2007 to 2010. Various criteria have been set for their admission; these ostensibly are the same for all countries, and include the cessation of graft and corruption, bribery and the black market in money exchange.

Given my continuing special interest in International Adoption (Schwartz & Kaslow, 2003), I used the opportunity I had in Bucharest to query several knowledgeable lecturers and guides about the changing picture regarding Romanian orphans and orphanages. The EU has told Romania unequivocally that it must be able to take care of its own children and not permit them to be adopted by families from overseas who sometimes pay exorbitant fees to a variety of people, like facilitators, for them (i.e., no more "selling" of children), a picture everyone is reluctant to acknowledge actually transpired. When I asked what has happened to the children, I was given two explanations: 1) The women are no longer having as many children; and 2) Romanian families are coming forward to adopt them. I could not get an explanation as to how the birth rate dropped so substantially so rapidly, nor where all of these

Romanian families were coming from now when they had been non-existent or unavailable formerly. But this is a definite qualification the EU has set for admission, and one the Romanian government and people are determined to meet. This was one of the few questions I raised which evoked resistance to answering, so obviously it is a raw and sensitive issue.

Generally, most perceive many benefits will accrue from joining the EU. However, on the local level, families engaged in cottage industries are frankly worried that they will not be able compete economically and will lose more of their small incomes. Unemployment rates are already high. As malls and super markets a la Wal-Mart enter their local economies, they realize they will have difficulty marketing their wares. Those in Croatia who returned to their decimated homes after what they called *The Homeland War* of 1991-1995 have been rebuilding their bombed-out, shrapnel-pierced homes on the small parcels of land given back to them, as close to the road as possible so that they can maximize the amount of ground used to grow fruits and vegetables – for their own consumption, and to sell whatever extra they can produce at the local market. They fear the *encroachment of supermarket giants* and already are suffering from competition with imports from Western Europe, even though they like the new products.

We passed through some gigantic locks that connect Romania, Bulgaria and Croatia. Most of us got up very early to see this magnificent, complex feat of engineering that works so well to allow freight, cruise ships, and other traffic to navigate the Danube.

In Croatia our group was subdivided into small groups so we could go to private homes for lunch. Families there who had responded to an advertisement had then been being selected for this program after careful inspection of their homes for cleanliness, culinary skill, gracious hospitality, and some English-speaking ability. They considered it an honor. They are all given the same basic menu to prepare, and then can embellish it as they choose. They are licensed and compensated, and this has become an enjoyable way of supplementing their meager incomes as well as of reconnecting with the outer world and telling their stories. Some have become licensed Bed and Breakfast Inns, new to their country, and part of the vanguard of what should become a fine tourist industry in this lovely Croatian countryside. Our hostess, Eva, cooked a delicious lunch and had made her own slivovitz, an Eastern European brandy imbibed before meals, and a light cherry wine to go with the chicken cordon bleu. She also had wine and other cooked goodies for sale, which we purchased happily. What she exemplified to us was the resilience and courage we saw and heard from everyone we spoke to. Eva commented repeatedly about how her family had clung together during the long years of war and deprivation—hiding out together, sharing whatever they had in their 4-generation extended family. Now they still live close to one another, and together when need be, as her mother and grandmother had done with her and her husband until they died. It truly is an all-for-one and one-for-all family mind set, and from this they draw strength. Any thought of labeling this "enmeshment" would be erroneous; it is about love, caring, and survival.

In Serbia there is another version of the war of the 1990s. Much sadness lingers about the horrible conflagration. Within many families, the ethnic strife was as much an internal as an external one. For instance, our guide relayed her own story that was fairly typical of the ones we heard. Her mom was Catholic and born in Belgrade (then Yugoslavia). Her father was Eastern Orthodox, and born in what is now Croatia. One grandparent was Jewish and came from Hungary. Those with such ethnic diversity mixes had coexisted within families without problems for decades. During the war everyone had to choose sides, and the turmoil and inner struggles were intolerable. No matter the choice, some loyalty was violated, some hearts were broken. These wounds are still healing, as are the bullet and shrapnel wounds still seen in many places.

In Hungary, horse farms, called *Putsa*s, are still scattered about, and they do put on some wonderful shows having horses display various skills, under the excellent leads of *chicos*, or horsemen. Our tour group spent an enjoyable half day at a horse farm taking an old-fashioned horse-drawn carriage ride, drinking local slivovitz while eating a pita-like bread dipped in a creamy garlic dip (real comfort food, and delicious) – and then watching a typical novelty show. It was great fun and provided good local color.

There is so much more to say, but space allotted is limited. In closing, I return to the original paradigm as it is generically applicable to the five countries today. The family seems to be cherished as the cornerstone of each society. The political systems are becoming increasingly democratic, and the corresponding economic systems are thus more entrepreneurial and engaged in free market_enterprise. Churches are being refurbished, and a variety of denominations are active; people are not afraid to go to church and practice their religion. Conversely, those who are agnostics and atheists are free to pursue their own beliefs. Education is highly valued and everyone we met is pursuing the best possible education they can access for themselves and their children. They study hard and long hours, and see education as the way to be upwardly mobile financially and socially. Many hope to be able to go to Western Europe or the United States to get a college education. They have many wonderful dreams and are doing all they can to fulfill them. Families help each member to get their turn to reach that elusive goal. Cultural life abounds with theatres, opera houses, concert houses and schools for the arts in almost every city and town and many excellent companies rendering myriad performances.

If you have not been to these countries ever or recently, try to go, for, indeed, they have much to offer that is informative, provocative, and affirms one's belief in the resilience of humanity.

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2007 APA SCIENTIFIC AWARDS PROGRAM: CALL FOR NOMINATIONS

The APA Board of Scientific Affairs (BSA) invites nominations for its 2007 scientific awards program. The **Distinguished Scientific Contribution Award** honors psychologists who have made distinguished theoretical or empirical contributions to basic research in psychology. The **Distinguished Scientific Award for the Applications of Psychology** honors psychologists who have made distinguished theoretical or empirical advances in psychology leading to the understanding or amelioration of important practical problems.

To submit a nomination for the Distinguished Scientific Contribution Award and the Distinguished Scientific Contribution Award for the Applications of Psychology, you should provide a letter of nomination; the nominee's current vita with list of publications; the names and addresses of several scientists who are familiar with the nominee's work; and a list of ten most significant and representative publications, and at least five reprints representative of the nominee's contribution (preferably in electronic form).

The **Distinguished Scientific Award for Early Career Contribution to Psychology** recognizes excellent young psychologists. For the 2007 program, nominations of persons who received doctoral degrees during and since 1997 are being sought in the areas of:

- applied research (e.g., treatment and prevention research, industrial/organizational research, educational research)
- behavioral and cognitive neuroscience
- individual differences (e.g., personality, psychometrics, mental ability, behavioral genetics)
- perception, motor performance
- social

To submit a nomination for the Distinguished Scientific Award for Early Career Contribution to Psychology, you should provide a letter of nomination, the nominee's current vita with list of publications, and up to five representative reprints (preferably in electronic form).

To obtain nomination forms and more information, you can go to the Science Directorate web page (www.apa.org/science/sciaward.html) or you can contact Jennifer Webb, Science Directorate, American Psychological Association, 750 First Street, NE, Washington, DC 20002-4242; by phone, (202) 336-6000; by fax, (202) 336-5953; or by E-mail, jwebb@apa.org.

The deadline for all award nominations is June 1, 2006.

Call for Announcements
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The Division 52 "Announce-only" listserv is available to its members and affiliates only and is distributed once a month. Submit announcements regarding international issues and topics of interest to the Division to rvelayo@pace.edu

For the latest announcements, notes, and news from the Division of International Psychology…

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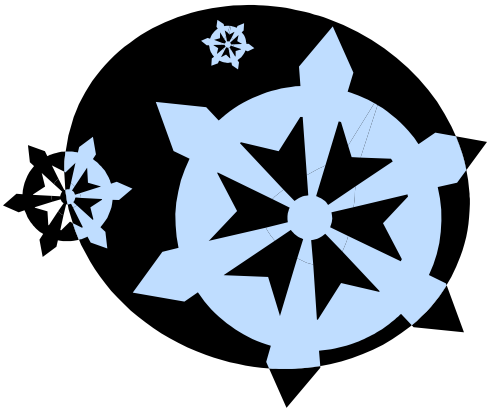

To access the current issue of ***Psychology International***: ***Newsletter of the APA Office of International Affairs***, please visit http://www.apa.org/international/picurrent.html. The newsletter is edited by Merry Bullock.

To download the multilingual poster for "CIRP: 60 years of international psychology" as a WORD file, please go to http://webpage.pace.edu/rvelayo/CIRPposter.doc. The CIRP, Committee on International Relations in Psychology of the American Psychological Association was formed in 1944. The poster states the word "psychology" in 60 different languages.

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Forming a local group of international psychologists: Why and how?

Harold Takooshian, Fordham University
and Richard S. Velayo, Pace University

The past 10 years has seen a clear rise in the number of US psychologists involved in diverse international activities—teaching, research, practice, and advocacy. Two examples of this within the APA are the formation of APA Division 52 (International Psychology) in 1997 (which now tops 1,000 members), and the designation of APA as a nongovernmental organization (NGO) at the United Nations in 2000.

How can international psychology be promoted at the local level? This article briefly describes a group of active international psychologists in the New York City area—its origins, current activities, why and how other localities may form such a local group.

March 2002 participants in the SPSSI-NY symposium on *Psychologists at the UN* launch "NY52." Left to right: Nora Pharaon, Joseph DeMeyer, Anie Kalaygian, (back row) Harold Takooshian, Kay Deaux, Karen Wyche, Peter Walker.

Origins

Since 1984, New York City has had an active group of local members APA Division 9, the Society for Psychological Study of Social Issues. This SPSSI-NY group hosts gatherings each year for its 400 local SPSSI members. When SPSSI-NY hosted a symposium at Fordham University on "Psychologists at the United Nations," in 2002, it sparked the formation of a new group—"NY52," made up local members of APA Division 52–International Psychology. At the time, fully 25% of the 800-plus members of the division lived in Greater New York.

Activities

Since 2002, NY52 has hosted a few gatherings each year, adapted to the interests of its local members, and now including some yearly "traditions." The financial cost is close to zero–local institutions graciously donate their facilities without charge—meeting rooms, refreshments, publicity—while NY52 provides the expert speakers for these lively local activities.

(1) **Travelers:** One typical activity is to host a gathering for international colleagues traveling through New York, who can address issues in their homeland, for example, Garen Harutyunian from Armenia and James Georgas from Greece.

(2) **United Nations:** After hosting in 2003 a session with APA's UN representatives, NY52 organized a historic gathering on April 1, 2004, at Pace University where 110 people met with 20 psychologists from six psychology NGOs at the UN. Since then, NY52 has hosted such UN-related gatherings twice each year.

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(3) **Collaborations:** Besides UN psychologists, NY52 has collaborated with other local groups. For example, on September 3, 2004, NY52 collaborated with Psi Chi, when 75 people gathered in the Presidents' Room of Yale University to celebrate the 75th anniversary of the Ninth International Congress of Psychology where Psi Chi was founded in 1929.

(4) **Film presentations:** NY52 has presented two feature films, the multi-national "Stolen Childhoods" in 2004, and in 2005 "Out of Silence," about sexual abuse in Kenya.

(5) **Community outreach:** After the 9-11-2001 terrorist attack on New York City, NY52 has co-hosted an annual "Holiday Healing Circle" each December, where disaster expert Anie Kalayjian assembles psychologists and healers of many faiths for an interfaith holiday celebration.

(6) **Conferences:** Each year in May, NY52 hosts a meet-and-greet during the annual Pace University Psychology Conference, where students and others can hear NY52 members present cutting-edge symposia on international psychology. There have also been other local NYC-based conferences that have hosted a gathering of international psychologists including the Greater NY Conference on Behavioral Research, and the Hunter College Psychology Conference. In spring 2007, the Psychology Section of the New York Academy of Sciences will sponsor a talk by Dr. Michael Stevens, the 2007 president of Division 52, on "The Coming of Age of International Psychology: Advances in Theory, Research, and Practice." These events/conferences provide a venue for psychologists with similar interests to meet and share their work, and to possibly recruit other psychologists and students to become members of Division 52 and APA.

Recently, on September 5, 2006, NY52 with the cooperation of APA's Office of International Affairs, organized a meeting of international psychologists on "Psychology and Social Issues at the United Nations," held at Fordham University in New York City. It was attended by 80 psychologists and students, and featured 18 panel presentations grouped into themes: HIV and AIDS, The Role of I-O Psychology in Improving the UN, Innovations at the UN, Forgiveness, Getting Involved in Global Work, and Working Effectively with the UN. These presentations highlighted the diverse roles of psychology in global issues, including the 8 UN Millennium Development Goals. This was the third annual gathering of psychologists working with the UN, and was held the day before the annual NGO Conference at UN headquarters that was attended by over 2,000 NGO representatives worldwide (http://ungodpiconference.org).

Why and How?

Psychology continues to establish itself as a global discipline and its relevance in the international arena is becoming more apparent and valued. The benefits of forming a local group of international psychologists are numerous. NY52 members have a chance to meet with each other in a collegial atmosphere and keep up to date on international topics. Many nonmembers, both students and professionals who attend local NY52 activities, have gone on to join Division 52, so the number of members in NYC has risen steadily from 210 to over 250 in the past four years.

Moreover, it is estimated that within the NYC area alone, there are about 60 psychologists actively involved in the United Nations. A good proportion of these

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psychologists are designated Non-Government Organization representatives of the organizations they are affiliated with (e.g., American Psychological Association, International Association of Applied Psychologists, International Council of Psychologists, Society for the Psychological Study of Social Issues, International Society for Traumatic Stress Studies, Association for Women in Psychology, International Union of Psychological Sciences, International Orthopsychiatric Association, and World Federation for Mental Health). This has also contributed to the success of NY52.

Though New York is currently the only US city with a thriving international group, there is likely any number of other cities with the necessary ingredients to sustain such a group: a nucleus of 20+ international psychologists, and a few local host institutions. Such cities surely include San Francisco, Boston, and the Washington-Baltimore metropolitan area. The missing key ingredient is a person or two willing to organize a gathering in their city. Division 52 can provide the e-mails for local division members and guidance on hosting the first event.

Ideally, by the time Division 52 marks its 20th anniversary in 2017, it will have several NY-style regional groups across the US and overseas. Interested readers are most welcome to contact us with any specific questions or comments. ψ

September 2006: 15 UN psychologists were among 80 participants in the forum on *Psychology and Social Issues at the United Nations* at Fordham University in New York City.

UN Focus: the Human Settlements Committee

Harold Takooshian, Richard S. Velayo, Peter R. Walker

One key role of the six-person APA team at the United Nations is to be active in the wide array of U.N. working committees, to disseminate useful psychological concepts into the work of the U.N. and its 3,000 allied nongovernmental organizations (NGOs). Some NGO committees include Ageing, Children, Families, Health, Indigenous peoples, Mental Health, and Peace. Because psychologists have been so few at the UN compared with other disciplines, psychological science and practice concepts have been surprisingly absent from UN committees.

The NGO Committee on Human Settlements (CHS) works closely with UN Habitat to monitor environmental trends that impact humans. To do so, NGO representatives on the CHS represent an array of organizations and disciplines—realty, engineering, architecture, law, ecology, sociology, and urban planning. In past years, the CHS has focused heavily on issues in the physical environment that relate to the UN's 8 Millennium Development Goals (MDGs)–such as water, housing, energy, sanitation, arable land, slums, poverty, sustainable development, population, conservation (Walker, 2005). For over 30 years, the CHS has been unusually active under several able leaders like urban planners Narelle Townsend and Richard May, businessman Rene Frank, and activist Sandra Hernandez-Colon. CHS holds a monthly meeting at the UN in New York City, to help Habitat prepare global and regional conferences, workshops, reports, and other activities. The CHS is now planning for the World Urban Forum-3 in Vancouver, British Columbia.

Since 2004, three psychologists have been members of the CHS—educational psychologist Richard S. Velayo of Pace University represents the International Council of Psychologists (ICP), environmental psychologist Peter R. Walker of Westport CT represents SPSSI–the Society for the Psychological Study of Social Issues, and applied psychologist Harold Takooshian of Fordham University represents APA. Velayo was appointed the managing editor of the new CHS Newsletter, and Takooshian was elected vice-chair of the CHS in 2005, charged by CHS to develop speaker series for its monthly meetings—one that balances behavioral sciences among its more traditional CHS foci (Takooshian, 2005).

To become involved or get details on Habitat or CHS, contact ngochs@yahoo.com, 212-636-6393, or check http://www.unhabitat.org.

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Walker, P.R. (2005, January). Human settlements and urban life: A United Nations perspective. *Journal of Social Distress and the Homeless, 14,* 55-61. Ψ

SHELTER FOR ALL
United Nations Human Settlements Programme
UN HABITAT

INTERNATIONAL PSYCHOLOGY REPORTER

A Publication of the Division of International Psychology [Division 52 of the American Psychological Association]
http://www.internationalpsychology.net

Volume 9, No. 1 **Fall 2004 / Winter 2005**

MESSAGE FROM THE PRESIDENT

Norman Abeles, Ph.D.
President

Before very long we will be in Boston for the Eastern Psychological Association Meeting and we will have our Board Meeting there. Our own Dr. Anie Kalayjian will report on the Southeast Asian Tsunami Disaster and the post Tsunami Mental Health Outreach Project (MHOP) to Sri Lanka which she is spearheading. This is in collaboration with United Sikhs, an NGO based in the UK and the project is also collaborating with Columbia University's School of Public Health, Center for Disaster Preparedness. The first team left for Colombo, Sri Lanka on February 9 after which they plan to go out into the fields and into refugee camps.

Meanwhile at the American Psychological Association level, the APA Board of Directors on January 6 donated $100,000 to the American Red Cross to assist in the relief efforts. This is an unprecedented effort by APA and current APA President Ron Levant pointed out that this was such a major catastrophe that it was essential that APA participate. CEO Norman Anderson also noted that the degree of human suffering needed to be addressed in a way that is unique to psychology. It is hoped that the expertise of psychologists can be useful by making Information available and providing assistance with the grief, and accompanying trauma and depression to the Tsunami survivors and their families. The Eastern Psychological Association Meeting will include a number of Div 52 Program activities. These include a paper session in cross-cultural psychology chaired by Oraine Ramoo, a symposium on psychology around the world chaired by Michael Stevens, a discussion on psychology organizations and the global agenda chaired by Anie Kalayjian, and a discussion on student involvement in International Psychology chaired by Gloria Gottsegen. Gloria is also the Council Representative for our Division. Paul Lloyd will Chair a workshop on positive psychology and international perspectives in management while a symposium on international and cross-cultural materials in psychology courses will be chaired by Uwe Gielen.

Of special interest to our Division members is the Resolution on Culture and Gender Awareness in International Psychology adopted by the APA Council of Representatives at their July 28, 2004 meeting. This resolution in part pointed out that more than 60% of the world's psychologists live outside the United States and noted that most individuals including psychologists are not likely to access journals or books in languages other than English. Further, it was noted that there is a need for greater awareness and commitment to gender, cultural, social, economic, and religious justice so we can more fully understand the Values and mores of other nations and cultures. The resolution in part advocates for more research on the role played by cultural ideologies and encourages psychologists to advocate for cross-national research that helps to eliminate discrimination in all arenas. The resolution also charged the Committee on International Relations in Psychology to collaborate with appropriate Boards and Committees and to implement any directives from the Council of Representatives resulting from the adoption of this resolution. Be sure to read the entire Resolution which can be found on the APA web page .It is particularly relevant to our Division.

In other activities of potential interest to our Division I should note that I recently served on our current APA President's (Dr. Ron Levant) Task Force on enhancing diversity. APA President Ron Levant noted in the introduction that APA needs to be made more welcoming to marginalized minorities. The task force was composed of APA leaders with expertise in a number of dimensions of diversity Including ethnicity, race, disability status, sexual orientation, aging, religion and Gender. The Task Force's report will be available at the Consolidated Meetings in March and will eventually be acted upon by the governing body of APA, the Council of Representatives.

I look forward to meeting many of our members at the Eastern Psychological Association Meeting in Boston this March and at the APA Convention in Washington DC in August. For those of you who travel abroad we could also meet at the European Congress of Psychology in Granada Spain later this year. If you have questions or comments feel free to contact me at the following e mail address: abeles@msu.edu. ◄

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JOIN US
as a Member of DIVISION 52!
Membership Application may be accessed at:
http://www.internationalpsychology.net/membership/

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This issue of International Psychology Reporter may be accessed from the Division 52 website at: http://www.internationalpsychology.net

SUBMISSION INSTRUCTIONS

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (Division reports, academic articles, etc.) can be up to 1500 words and should be submitted by email to Dr. Harold Takooshian at takoosh@aol.com.

Submission deadlines:
Spring issues -- March 31
Summer issues – June 30
Fall/Winter issues -- December 31

International Psychology Reporter is the publication of Division 52 of the American Psychological Association

EDITOR SEARCH: International Psychology Reporter

Uwe Gielen, Ph.D.
Communications Committee Chair

Harold Takooshian, Ph.D.
Interim Co-editor, International Psychology Reporter

Nominations are now sought for the Editorship of The International Psychology Reporter, the official newsletter of APA Division 52. Based on bylaw 4.1.D, this is an unpaid position to serve for three years (August 2005-August 2008), with the Editor responsible for all aspects of production of 4 issues per year.

The Board of Directors takes this opportunity also to invite members' feedback in this brief survey about the Reporter, to share with the incoming Editor. Please take a moment to submit your frank suggestions on the 6 items below no later than April 1, 2005 to ugielen@hotmail.com, or fax to 718-522-1274. All responses are held in strict confidence, and cumulated for a report to the Board of Directors for action at its March 12, 2005 meeting in Boston. Any inquiries can be directed to Dr. Gielen at ugielen@hotmail.com.

1. Nomination for the Editor, including a brief statement of support

2. Suggestions for Assistant Editors, including a brief statement of support

3. Any specific things you like MOST about the *International Psychology Reporter* to date.

4. Any specific things you like LEAST about the Reporter to date.

5. Any specific columns or other sections you would like to see regularly in the *International Psychology Reporter*:
   __students
   __ book reviews
   __ personal news
   __ photos
   __ United Nations
   __ other: _____

6. Would you like to see advertisements in the *International Psychology Reporter*?
   __no __yes

7. Would you need a hardcopy of the electronic issue/s of the *International Psychology Reporter*?
   __no __yes

DIVISION 52 NEWS and UPDATES

Division 52 Elections Update

Richard Velayo, Ph.D.
Chair, Nominations Committee

This coming April, all members of the Division of International Psychology will receive the official APA ballot to elect two officers: President-elect (2006) and Treasurer (2006-2008). We are indeed very fortunate to have excellent candidates running for these positions. Their names and candidacy statements are as follows:

For PRESIDENT-ELECT (2006) / PRESIDENT (2007):

Elaine C. Bow, Ph.D.

Elaine C. Bow, PhD, holds a doctoral degree in Industrial and Organizational Psychology. Elaine has served on the psychology faculty of The MBA Program, Nyack College since 2003, and is an adjunct Associate Professor at Fordham University. Before joining Nyack College, Elaine was an adjunct Associate Professor at John Jay College of Criminal Justice where she taught undergraduate and graduate courses. Elaine also has extensive corporate experience, having worked for both Fortune 100 and 500 companies, and as a private consultant to various corporate entities. RESEARCH: Areas of research include workplace diversity, specifically with respect to goal setting and expectancy, cross-cultural psychology with an emphasis on group interactions, psychosocial affiliation, and gender. SERVICE: Elected Secretary/Treasure of the Academic Division of the New York State Psychological Association (2003-2006); co-chair of The Membership Committee for Division 52 of the American Psychological Association; co-chair of the Membership Committee of New York State Psychological Association, and member of Division 52's Public Interest Committee. PROFESSIONAL ASSOCIATIONS: Academy of Management, American Psychological Association, American Psychological Foundation, Eastern Psychological Association, patron, New York Academy of Sciences, New York State Psychological Association, lifetime member, Psi Chi, The Society for the Psychological Studies of Social Issues.

STATEMENT: As an active member of NYSPA and the APA, I am committed to serving the international community. In this challenging time fought with natural disaster, intentional disaster and cruelty to others, psychologists have the unique training to make significant positive contributions. It would be a privilege to contribute to the already outstanding efforts of Division 52 to further the cause of all people throughout the world community.

Michael J. Stevens, PhD, DHC

I am a professor at Illinois State University and at the University of Sibiu, Romania, where I completed a Fulbright grant and received a Doctor Honoris Causa. I teach a course in international psychology and have lectured in China, Finland, and Uruguay. My recent scholarship on international psychology includes the *Handbook of International Psychology* and *Psychology: IUPsyS Global Resource* with Danny Wedding, and *Toward a Global Psychology* with Uwe Gielen. I also consult with SOBIS Consult in Romania.

I have been a member of our Division since its formation. I chaired the International Liaisons Committee, recruiting psychologists from 77 countries to help network our Division to the world. I created the Information Clearinghouse, which contains resources that support international teaching, research, practice, and service. For these contributions, I received the Division's Recognition Award and Outstanding Mentor Award. I now co-chair the 2005 Program.

I am enthusiastic about serving as your president. First, I will nurture the accomplishments and vision of our past presidents. Second, having built links to psychologists and psychological institutions worldwide, I feel well positioned to advance our Division's international presence and impact. I offer the following goals for your consideration:

- Increasing, diversifying, and internationalizing membership;
- Mentoring minority and international members for leadership positions;
- Enhancing international communication and collaboration via web-based technologies;
- Establishing international research and practice ties to psychological associations abroad; and
- Forming interdivisional consultancies, based on members' specialty training and international experience, and marketing them to governments and NGOs.

For TREASURER (2006-2008):

Anie Kalayjian, Ed.D., RN

Anie Kalayjian, RN, EdD, BCETS, DrSc (Hon), the International Division's 2004 Program Chair and Acting Treasurer, was awarded an Honorary Doctor of Science from Long Island University in 2001 recognizing her 25 years as a pioneering clinical researcher, professor, and administrator at the United Nations. She is the author/editor of the landmark book, *Disaster and Mass Trauma* (1995), and 40+ articles/chapters on clinical methods, human rights, trauma, and women's issues. Since 1990, Anie is an officer or chair &Vice Chair of several U.N. units -- its Human Rights Committee, NGO annual conferences, and NGO Executive Committee. Anie is a Fellow of APA and our International Division 52. In 52, Anie has served on several committees, including Acting Treasurer and 2004 Program Chair for the APA Convention Hawaii this past year.

STATEMENT: I will be honored to continue serving as the Treasurer of our Division, as I have enjoyed working closely with other officers of 52 the past 3 years. In Hawaii last year I coordinated our outreach with APA President Diane Halpern & my co-chair Uwe Gielen. As a result, our 2004 international program at APA in Hawaii was the largest, with over 400 presenters from 40+ nations. My election as the Treasurer would permit me to continue applying my energies and talents to our wonderful international division, to increase our membership and find other ways to make our division financially prosperous. Like my mentor Victor Frankl, my motto is: "When one helps another, both are strengthened."

Jason Young, Ph.D.

Jason Young, Ph.D. has been a faculty member of the Department of Psychology at Hunter College since 1990. His teaching and research interests focus on attitudes and persuasion, including the influence of media on personal and social attitudes, and the development of more effective public service messages encouraging safer sex. He has published on such topics as the agenda-setting effect of the

news media, evolutionary perspectives on attitudes and social cognition, and the impact of emotion and arousal on risky decision-making. In all of these areas, he has integrated cross-cultural approaches, working with students who have collected research data in Japan, Israel, Greece, and Trinidad. Most recently, he has an ongoing series of collaborative projects with a colleague at the University of the West Indies in Trinidad on the impact of news media on fear of crime. He has been very active as advisor of the Hunter College Chapter of Psi Chi, the U.S. Honors Society in Psychology, as well as been a member and reviewer for the International Society for Political Psychology.

STATEMENT: The growth of Psychology as a discipline requires that it expand its traditional boundaries and work to integrate the perspectives of the international community. Not only is this good science, but several new theoretical approaches, such as evolutionary psychology, demand a much broader consideration of attitudes and behaviors that cross national lines. This approach promises a much richer and fruitful discipline, and I am proud to work with Division 52 as it promotes this work. ◄

Student International Research Awards for 2005

Robert Ostermann, Ph.D.
Chair, Student Awards Committee

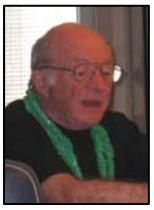

The Board of Directors of International Psychology, Div. 52 of the American Psychological Association, announced that awards will be given for student international research - a part of the Div. 52's ongoing program to encourage and recognize the global research contributions made by students in colleges and universities around the world. Norman Abeles, President of Div. 52, points out, "As we move toward global psychology, students are the ones who quickly recognize that the body of psychological knowledge needs to reflect the distinct characteristics of human behavior of various cultures and circumstances in different countries – even the smallest and most remote."

Accordingly, Norman Abeles has appointed Robert F. Ostermann, Ph.D., Distinguished Professor Emeritus of Fairleigh Dickinson University, as chairman for this project.

Awards to be made at the APA 2005 Convention in Washington, D.C. in each of these categories:

A. International experimental/ experiential research
B. International comparative study
C. Descriptive study of large samples of mixed nationalities/cultures
D. Study of a trans-national sample
E. Descriptive research or correlation study in a developing country
F. International theoretical/historical analysis
G. Case study of representative international or cross-cultural significance.

Each research award will be given to a student affiliate of APA or to undergraduate or graduate student affiliates of APA Division 52, as principal researcher, whose theoretical or empirical study explores psychological issues in an international context or employs global collaboration and resources beyond the student's own country. **The paper must be based on the student's independent project, thesis or dissertation completed after June, 2004.** Separate awards will be given for graduate and undergraduate submissions.

Submission Requirements:

1. A paper (or summary) not exceeding ten pages including references, figures and tables in APA publication format along with a one page abstract describing the study and its relationship to international interests and concerns. **Include a separate Cover Page with title, student's name, address, phone, e-mail address and academic institution.**
2. Faculty endorsement attesting that the student is the author and principal investigator and a student affiliate of APA or Division 52. (See below.)
3. **E-mail submissions as a Microsoft Word attachment to rfostermann@adelphia.net**

Review will be by an international committee, members of Division 52, considering the following: originality, clarity of expression, complexity of analysis, sample difficulty (size, remoteness and complexity), insightfulness of findings and discussion, scope and timeliness of international references, significance and relationship to current international issues.

Application forms, submission requirements and membership procedure are posted on the APA Div. 52 web site: http://www.internationalpsychology.net/awards/. Read the requirements carefully.

E-mail submissions to: Robert F. Ostermann, Ph.D. at rfostermann@adelphia.net.

[Note: **DEADLINE is JUNE 1, 2005**. Late submissions will not be read.]
◄

Division Awards for 2005

Florence Denmark, Ph.D.
Chair, Division Awards Committee

Recommendations are requested for the following 2005 awards to be presented at the APA Convention in Washington, DC:

There are two Distinguished International Psychologist Awards to be presented. One award is given to a psychologist from the United States and the second award is for a psychologist outside the United States. Both awards give recognition to individuals who have made outstanding contributions to international psychology either through significant research and/or contributions to international organizations.

In addition, Division 52 presents recognition to an APA staff member who has been of assistance to our division. We will also recognize the contributions of our 2004 President, Richard Velayo.

Please submit your award nominations by May 1 to me at fdenmark@pace.edu ◄

Information Clearinghouse Committee Update

Michael J. Stevens, Ph.D.
Chair, Information Clearinghouse Committee

The International Psychology Information Clearinghouse contains general resources, career resources, opportunities in academic and research settings, opportunities in clinical and service settings, funding for research, support for conferences, support for travel, awards, resources for American psychology students, and resources for foreign psychologists and psychology students.

The Clearinghouse continues to be expanded and updated. The Clearinghouse now contains 227 sources of information on various opportunities in international psychology.

The Clearinghouse can be downloaded from the APA52 website (http://orgs.tamu-commerce.edu/div52/Clearinghouse.doc) and is available through the CD-ROM, *Psychology: IUPsyS Global Resource*, published by Psychology Press (http://www.psypress.co.uk/iupsys/). New additions of the *Global Resource* appear annually as CDs. ◄

Outreach Committee
Seeks Digital Photos with Captions

Mercedes McCormick, Ph.D. and Harold Takooshian, Ph.D.
Chairs, Outreach Committee

Div. 52's Outreach Committee invites all members- ***new and current*** - to have a virtual presence in the Division. Send a digital photo with a caption and email address that describes your work in psychological activities. These photos are to be sources of information to inspire members and to be vehicles to stimulate connection and collaboration among the membership. The photos will appear periodically on the Division's new Web site soon after if debuts under the link ***Global Gallery***. Kindly remember to follow ethical guidelines especially in regard to informed consent that are necessary by such an activity. Thank you for your interest and participation in this initiative.

For inquiries, contact Mercedes A. McCormick, Ph.D., Chair (mmccormick2@pace.edu) or Harold Takooshian, Ph.D., Co-chair (takoosh@aol.com). ◄

International Psychology Program
at the Eastern Psychological Association

Harold Takooshian, Ph.D.
Past President, APA Division 52

At the 2005 meeting of the Eastern Psychological Association in Boston this March 11-12, 2005, our international division officers will offer a series of 7 symposia on cross-cultural and international students, organizations, research, teaching, positive psychology, families. This event is immediately followed by the Midwinter Board Meeting of the Division (March 12-13).

Date: March 11-12, 2005
Place: Kent Room, Sheraton Boston Hotel
EPA Website: http://www.eaternpsychological.org
For inquiries, contact Dr. Harold Takooshian at takoosh@aol.com

Program Schedule

March 11, 2005 (Friday)

8:30 - 10 am: SYMPOSIUM: INTERNATIONAL PERSPECTIVES ON SIBLING ABUSE: A COGNITIVE-ECOLOGICAL APPROACH Chairs: **Mizuho Arai**, (Massachusetts -Boston), **John Kim** (Boston University).

10:15 - 11:45 am: PAPER SESSION: CROSS-CULTURAL PSYCHOLOGY. Chair: **Oraine Ramoo** (Saint Francis). **Maxentia M. Bozian** & **Alin A. Gavreliuc** (West University, Romania), **Paul Finn** (Saint Anselm). Identity dynamics and the acculturation process: An intercultural study of USA and Romania. **Birgit Bryant** & **Leigh Sexton** (LeMoyne), Olympic swimming and individualism: Can culture influence performance in the Olympic arena? **Elizabeth A. Donovan** et al. (Boston U), Cross-cultural attitudes regarding child abuse. **Senel Poyrazli** & **Marcos Lopez** (Pennsylvania State). Perceived discrimination and homesickness: A comparison of international students to American students.

Fri 12 - 1:30 pm: SYMPOSIUM: PSYCHOLOGY AROUND THE WORLD--CURRENT DIRECTIONS. Chair: **Michael J. Stevens** (Illinois State). **Michael J. Stevens** (Illinois State), Ongoing and emerging international trends in psychology. **Danny Wedding** (Director, Missouri Mental Health Institute), Psychologists influence public policy around the globe. **Peter F. Merenda** (Rhode Island). The future of psychology world-wide: Psychometrics and psychometricians **Charles D. Spielberger** (South Florida). Discussant: **Nancy Felipe Russo** (Arizona State). How is the science and practice of psychology developing differently in nations and regions around the world today? How do "indigenous" psychologies compare with North American psychology? In this symposium, the two co-Editors of the new *Handbook of International Psychology* (Brunner & Routledge, 2004) join with other prolific authors on international psychology to look at international psychology today--its history, current trends, and likely future in the 21st century.

Fri 1:45 - 3:15 pm: DISCUSSION: PSYCHOLOGY ORGANIZATIONS AND THE GLOBAL AGENDA. Chair: **Anie Kalayjian** (United Nations). **Joy K. Rice** (Wisconsin Medical School). **Frances M. Culbertson** (Capitol Associates LLC, Madison, WI). **Joan C. Chrisler** (Connecticut College), **Lynn H. Collins** (LaSalle), **Mercedes A. McCormick** (Pace), **Elaine C. Bow** (Nyack). What are some of the international organizations today within psychology, how do they differ from one another? In this discussion, officers of several international organizations discuss the history and current activities of some of these groups, and why and how individuals can become more involved in them. A fact sheet will be prepared and distributed at the start of this session, profiling ten of these international organizations. Discussion of post-tsunami disaster relief in South Asia in spring 2005 will also be included.

3:30- 5:00 pm: DISCUSSION: STUDENT INVOLVEMENT IN INTERNATIONAL PSYCHOLOGY. Chair: **Gloria B. Gottsegen** (Lehman). **Kate A. Richmond** (Pennsylvania), Student participation. **Senel Poyrazli** (Penn State), International students on US campuses. **Philip J. Spencer** (Fordham), Applying for international student grants. **Marcus Patterson** (Boston University), APAGS and student involvement. **Robert F. Ostermann** (Fairleigh Dickinson), Student research awards. How can undergraduate and graduate students get more involved in the growing trend towards international psychology? In this discussion section, several students and faculty involved in international psychology present helpful techniques and materials for students who seek to become more involved.

March 12, 2005 (Saturday)

8:30 - 10:00 am: WORKSHOP: POSITIVE PSYCHOLOGY AND INTERNATIONAL PERSPECTIVES ON MANAGEMENT. Chair: **Paul J. Lloyd** (Southeast Missouri State). **Sandra Foster** (London, UK), **Ann Marie O'Roark** (Saint Petersburg, FL). Within psychology today, there is a growing global movement towards "positive psychology" research, theory, practice. How can positive psychology be integrated into cross-national work consulting with organizations? In this workshop, experienced consulting psychologists present their own experiences as a platform for interactive discussion.

10:15 - 11:45 am: SYMPOSIUM: INTERNATIONAL AND CROSS-CULTURAL MATERIALS IN PSYCHOLOGY COURSES. Chair: **Uwe P. Gielen** (Saint Francis). **Florence L. Denmark** (Pace), Gender. **Richard S. Velayo** (Pace), Distance learning technology. **John D. Hogan** (Saint John's), History. **Norman Abeles** (Michigan State), Aging. **Uwe P. Gielen** (Saint Francis), Development. **Harold Takooshian** (Fordham) Teaching materials. How can we integrate more cross-cultural and international content into our psychology curriculum at different level--with our introductory, undergraduate, and graduate students? In this symposium, several experienced teachers, authors, officers of the APA Division of International Psychology review materials currently available to help internationalize our courses.

SAT, NOON - 5 PM, SUNDAY 9 AM - NOON: APA52 MIDWINTER BOARD MEETING
◄

Council Representative's Report
February 17-20, 2005

Gloria B. Gottsegen, Ph.D.
Division 52 Council Representative

I attended the Council of Representatives annual meeting in Washington, DC on February 17-20, 2005 as the Division 52 representative. The Council's agenda was lengthy and there are many items to report. I shall try to highlight projects that are particularly relevant to our Division 52 members.

President Ron Levant presided and described his three initiatives: Making Psychology a Household Word, Health Care for the Whole Person (a biopsychosocial model) and Enhancing Diversity in APA.

He named several Task Forces for the current year – Evidence Based Practice; Ethical Aspects of Investigations Related to National Security; Gender Identity, Gender Variance and Intersex Conditions; and Sexualization of Girls. He announced that APA had donated $100,000 to the Red Cross for Tsunami Disaster relief efforts and that an additional $150,000 was earmarked for mental health efforts for survivors. These funds are to be used for training purposes in the various countries through the auspices of the International Union of Psychological Sciences.

Council passed the Guidelines for Education and Training at the Doctoral and Post-doctoral Level in Consulting Psychology/Organizational Consulting Psychology, funded two meetings of a Working Group on Psychoactive Medications for Children and Adolescents, funded a two year Task Force on Socio Economic Status within the Public Interest Directorate and renewed Clinical Geropsychology as a Proficiency in Professional Psychology.

Council passed several resolutions: The Psychological Needs of our Troops, Veterans and Their Families which are the Consequences of the Current War; Against Imposing the Death Penalty for Certain Groups of People – e.g., Persistent Mental Disability, Mental Disorder or Disability at the Time of the Offense or Mental Disorder or Disability after Imposition of Death Sentence; In Favor of Empirically Supported Sex Education and HIV Prevention Programs for Adolescents.

Council received the Report of the Task Force on the World Conference Against Racism and passed a resolution condemning anti-Semitic and anti-Jewish and other religious, religion-related, and/or religion-derived prejudice and discrimination. Council also passed a resolution condemning prejudice and discrimination in all its forms.

Council defeated a petition for the establishment of a new Division – The Society for Human-Animal Studies.

Finally, Council passed a $539,800 budget for 2005. ◄

U.S. News

New York Regional Group in Fall 2004

Harold Takooshian, Ph.D.
Fordham University

About 230 of the 800+ members of our APA International Division live in Greater New York--spanning from Connecticut to New Jersey. This is up from 180 members when the NY Regional Group formed in 2002, to offer a few local activities each season to promote international psychology and fellowship among members. In Fall 2004, our NY International group offered five free gatherings, kindly hosted by local institutions.

1. On Sept. 1, 25 students and colleagues attended a lecture on "Treating trauma in children," with Garen Harutyunian (Republic of Armenia) at Fordham University.
2. On September 3, 75 students and faculty convened at Yale University for "75 years of excellence," the public Convocation hosted by Dean Peter Salovey to celebrate the 1929 International Congress of Psychology, and the founding of Psi Chi Honor Society at Yale on September 4, 1929.
3. On Sept 8, 20 psychologists and others working at the United Nation convened at the U.N. Church Center, for a "Conversation hour with psychologists @ the United Nations."
4. On Oct 13, 60 people attended a lecture and reception, "Cultural and biological perspectives on race," with Jefferson M. Fish (St. John's), hosted by Uwe Gielen and Saint Francis College in Brooklyn NY.
5. On Dec 10, 75 people joined the joyous music and dancing at the 4th Interfaith Holiday Healing Circle at Fordham University, which was hosted by Anie Kalayjian, and featured healers from six faith traditions.

In addition, several members of Division 52 joined United Nations staff at two international gatherings at the villa of psychologist Anthony DeLuca in Staten Island NY in August and December 2004. Looking ahead to Spring 2005, the NY International group foresees several more diverse gatherings including sessions on "publishing international books," "genocide and human rights" (Drew University), "scientific psychology and global issues" (Fordham), and members' presentations of their research or other international work at the 33rd Hunter Psychology Conference on April 16 (150-word abstracts due by March 1 to psychcollective@yahoo.com).

For any details, or to help plan events for 2005, contact Harold Takooshian at takoosh@aol.com.

The Fall 2004 NY International Committee kindly helped organize these gatherings: Sue and Daniel Bockert (Georgia), Paul Echandia (Pace), Anthony DeLuca (Sofia), Florence Denmark (Pace), Uwe Gielen (St. Francis), John D. Hogan (St. John's), Anie Kalayjian (Fordham), Artemis Pipinelli (Walden), Vincent Prohaska (Lehman), Oraine Ramoo (St. Francis), Robert W. Rieber (John Jay), Anne Garrett Robinson (Gateway CC), Steve Salbod (Pace), Peter Salovey (Yale), Laurie Santo (Yale), Narrelle Townsend (UN), Richard Velayo (Pace).

Garen Harutyunian (2d from left) lectured at Fordham on Sept 1, 2004.

Conversation hour with psychologists@ United Nations on Sept. 8, 2004

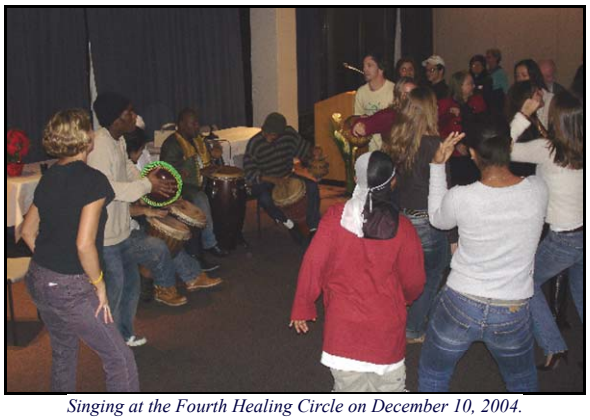

Singing at the Fourth Healing Circle on December 10, 2004.

Out of Tragedy: Work Towards Resilient Communities

Leo F. Flanagan, Jr., PhD*, and Lisa Orloff
World Cares Center, Inc.

More than three years after the terrorist attacks of September 11th, 2001, we initiated a new support group specifically for rescue and recovery workers. By chance all members of this group were volunteers fulfilling these roles in the aftermath of the attacks on New York City. Remarkable as it may seem, to a person these individuals still experience frank symptoms of PTSD and came to us with one common question: Am I the only one? Indeed, many members of this and other groups here in New York, in Oklahoma City (about to observe the 10th anniversary of the bombing of the Murrah Building) and in Madrid ask themselves this question.

An estimated 100,000 volunteers, many unaffiliated with any formal voluntary organization, responded to the needs of their fellow human-beings. One individual working construction at the WTC immediately began to act as the trained EMT he is at his local volunteer fire department. Another led an ambulance crew in from Long Island. Both would be caught in the collapse of the first tower – left to puzzle why they survived when so many others did not. These are just two of the individuals who continue to experience difficult challenges in virtually every sphere of their lives – work, relationships, and health. So it is clear that those who rise to meet the needs created by devastating attacks often pay the price on a long-term basis.

Further complicating the challenges they face is the reality that volunteers are often not the focus of healing and supportive programs. Volunteers after all are here to provide assistance – not to seek it (as is true for full-time rescue and recovery workers such as police, fire and emergency health). And so having risen to the occasion of meeting our most serious challenges, these people are left to their own devices – often excluded from programs and services because they are neither "survivors" nor credentialed respondents.

In recognition of this situation, World Cares Center, Inc. was founded. WCC's mission is to prevent or minimize the devastating impact of responding to disasters from both natural and human causes on the people and their communities. The two core services provided to accomplish this mission are:

- September Space
- PERCS Trauma Prevention and Disaster Preparedness Program

September Space is a permanent community center in New York City open to all those impacted by the attacks of September 11th, 2001 and subsequent tragedies. It may be the only community center that is both permanent and welcoming of all those impacted by September 11th: survivors; family members; volunteers; full-time first responders. It offers a wide and diverse range of supportive services including:

- Interpersonal communications training
- Massage therapy
- Art therapy
- Career counseling
- Social activities (dance lessons, holiday gatherings)
- Support groups

It also conducts an on-going exchange program with its companion organizations in Oklahoma City. Under this program, a group of September Space participants travel to Oklahoma City each year on the anniversary of the bombing of the Murrah Building. In kind, Oklahoma citizens come to New York City each September. And so a lasting bridge is built between these two communities. Currently, we are seeking to build similar relationships with those impacted by the slaughter of innocents in a Russian school, the citizens of Madrid recovering from the train bombings of 2004 and the people of the Indian Ocean devastated by the tsunami of December 2004.

PERCS Trauma Prevention and Disaster Preparedness Program is based on the key principles of community psychology[i]. It assumes that with effective preparation, skill-building and support that the human spirit will prove to be resilient even in the aftermath of devastation.

PERCS is a suite of programs offered by *World Cares Center, Inc.* PERCS stands for Prepare, Educate, Respond, Collaborate & Support; a lengthy title but one designed to communicate the need to support disaster responders prior to through well-after the occurrence of a disaster.

PERCS offers support to assist communities in preparing, responding to and recovering from disasters at three levels:

- *Primary Prevention:* Educating people as to the experience, rewards and stressors of volunteering in a disaster environment.
  - The goal is to reduce the incidence of stress related physical, emotional, mental and social dysfunctions in response to a disaster.
  - Modules focus on self-assessment, selecting an appropriate volunteer assignment, self-care behaviors, building personal resilience and engaging social support.
- *Secondary Prevention:* Responding in the immediate aftermath of a disaster by assessing the use of volunteers, briefing spontaneous volunteers in self-care and advising local organizations in leading & using volunteers
  - The goal is to reduce the severity of stress related physical, emotional and mental dysfunctions in response to a disaster.
  - This short module provided immediately before the volunteer accepts an assignment focuses on the immediate needs of self-assessment, warning signs of impaired functioning while working the disaster, accessing support services and communicating and accepting the support of significant others.
- *Tertiary Prevention:* Providing communities with a model, protocols and on-going advice to establish a long-term community center to support the needs of those impacted by a disaster.
  - The goal is to support people in long-term adaptation to stress related physical, emotional, mental and social dysfunctions arising from exposure to a disaster.
  - Comprehensive training, protocols, process maps and on-going consulting provide the impacted community with the ability to establish a permanent community center to support those impacted over the long-term.

World Cares Center is committed to defining and developing strategies, tactics and tools that define the standard of care for disaster response volunteers at all three of the above levels. To achieve this we collaborate with researchers in the social and health sciences. This coming August we will launch a joint action research project with our companion organizations in Oklahoma City.

For further information contact Leo F. Flanagan, Jr., PhD, Director of PERCS Trauma Prevention and Disaster Preparedness, Leo@FlanaganConsultants.com, 203-321-8423; or Lisa Orloff, Executive Director & Founder, World Cares Center, Inc., lorloff@septemberspace.org, 212-563-1432.

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*The first author wishes to acknowledge that he owes a debt of gratitude to Professor Morton Bard, friend and mentor, who shared with him: "It's not that people succumb to stress that is amazing. It's how they preserver and thrive even under the most terrible circumstances that is really remarkable." ◄

75 Years of International Psychology Celebrated at Yale

Harold Takooshian, Ph.D.
Fordham University

Florence Denmark, Ph.D., Paul Echandia, Ph.D.,
and Richard S. Velayo, Ph.D.
Pace University

The President's Room of Yale University is an elegant rotunda lined with stately portraits of many past presidents since Yale was founded in 1701. Under their watchful gaze, 75 people from several states convened in the President's Room of Yale to participate in "75 years of excellence" on September 3, 2004. This historic convocation saluted two landmark events: the Ninth International Congress of Psychology hosted by Yale on September 1-7, 1929, and the founding of Psi Chi, the national honor society for psychology, on September 4, 1929.

On September 3, the first of 12 speakers was host Peter Salovey, the Dean of Yale College, who welcomed participants to Yale and the convocation. Harold Takooshian of Fordham University joined Salovey to moderate the convocation, and introduce ten speakers who noted its three-fold significance--for international psychology, for Psi Chi and Psi Beta, and for Yale.

The 1929 Congress was the first international congress held on American soil, over 16 years in the planning. It has been called "the most impressive gathering of psychologists in the history of the field," with 826 participants from 21 nations -- including three-quarters of all APA members that year. Among such luminaries as Ivan Pavlov (Russia), Francis Galton (England), Jean Piaget (Switzerland), and Kurt Lewin (Germany), two graduate students from Kansas almost went unnoticed. But not quite. With courage, Edwin B. Newman and Frederick "Bud" Lewis followed their dream to create a national honor society in psychology, undaunted by an ardent objection from distinguished Harvard Professor Edwin G. Boring. And so they did, when students representing 11 schools signed the charter. Psi Chi is now a unique organization at several turns: the world's largest psychology organization with 467,000 life members, the largest honor society with chapters at 1,010 campuses, and the founder of its partner society Psi Beta in 1981 to offer recognition to the growing number of students in two-year schools.

Yale University was the natural venue for these two watershed events, since the Yale faculty are known internationally, and have long emphasized their mission of students' education alongside research excellence. Current psychology faculty at Yale continue to undertake undergraduate teaching with their research.

Two keynote speakers shared their rich historical insights. John Hogan of St. John's University spoke as the official historian of Psi Chi, Psi Beta, and the APA Division of International Psychology. With trademark wit, Hogan detailed how the determination of students Newman and Lewis led Professor Boring to become one of the Society's many admirers. Hogan noted his history of Psi Chi would be incomplete without describing Ruth Cousins, its legendary Executive Officer for 33 years (1958-1991), and quoting Edwin Newman: "Psi Chi is not so much what we founded as it is what Ruth made it."

The second keynote speaker was Dan Bockert from Lookout Mountain, Georgia, the past Director of Publications for Psi Chi from 1989 till 2003, and the "unofficial" historian of Psi Chi, with an insider's knowledge of the organization. With aplomb, Bockert focused on the precarious first five years of the Society, and the oft-overlooked role of "the other Ruth," Ruth Guilford, whose able and selfless devotion led Psi Chi to flourish rather than wither during 1930-1935. As New York's Yankee Stadium is known as "the house that Ruth built," Dan described Psi Chi as "the house the two Ruths built."

Yale University was represented by Dean Salovey, Department Chair Kelly Brownell, Psi Chi faculty advisor Laurie Santos, five student officers of the highly active Yale chapter of Psi Chi, and Professors John Bargh, Linda Bartoshuk, William McGuire, Jerome Singer, and Edward Ziegler.

International psychology was represented by APA past-President Florence L. Denmark, Richard Velayo of Pace University, and Robert W. Rieber of CUNY. Rieber slowly walked across the room as he delivered his message, noting that Lev Vygotsky of Russia was listed in the 1929 program "but actually never made it to Yale... until today," as Rieber presented a signed copy of his new biography of Vygotsky to Yale and Dean Salovey.

Psi Chi was represented by its dynamic Eastern Vice President Vincent Prohaska of Lehman College. Prohaska reported that Psi Chi is now the number-one sponsor of student research, with awards exceeding $160,000 per annum, and the able five-person staff and ten-person Council who head Psi Chi today are committed to expanding this sum by recycling revenues from the 22,000 members who join each year. Prohaska presented Yale with an embossed volume of the oral history of Psi Chi, co-edited by Stephen F. Davis and Michael Wertheimer. This volume included original letters from the Psi Beta and Psi Chi offices.

Psi Beta, the partner society for two-year colleges, was represented by past-President Ann E. Garrett Robinson of Gateway Community College. With panache, Robinson described the tight bond linking Psi Chi and Psi Beta, which were headed for years by Ruth Cousins and her daughter Carol Tracy. She noted "how pleased Newman and Lewis would be to know their "child" Psi Chi spawned yet another wonderful child in Psi Beta." On behalf of the Hon. John W. DeStefano, Jr., the Mayor of New Haven, Robinson presented Yale with a parchment proclaiming September 3 as "Psi Chi day in the City of New Haven."

The convocation ended with a group photo and sharing of a 75th anniversary cake. More information on the groups is available at http://www.psichi.org, http://www.psibeta.org, http://www.yale.edu, and http://www.internationalpsychology.net. Those interested to obtain a 90-minute videotape of the entire convocation by videographer Steven Salbod of Pace University can contact takoosh@aol.com for details.

Yale conferees in front of (seated) John Hogan, Florence Denmark, Daniel Bockert.

..."until today," Robert Rieber presents his biography of Lev Vygotsky To Yale Dean Salovey.

Under a portrait of Yale President Noah Porter, Convocation speakers (l to r): Ann Garrett Robinson, Florence Denmark, Rachel Stanton, Peter Salovey, Laurie Santos, Harold Takooshian, John Hogan, Daniel Bockert, Kelly Brownell.

[Photo credits, Dr. Paul Echandia, Pace University, NY]

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What Works in Treatment for Latino Men? Results of a Qualitative Analysis of Cultural Treatment Components for Partner Abusive Latino Men in the United States

Christauria Welland, Psy.D. and Neil Ribner, Ph.D.
Alliant International University

Intimate partner violence is defined by the World Health Organization as "acts of physical aggression, psychological abuse, forced intercourse and other forms of sexual coercion, and various controlling behaviors such as isolating a person from family and friends or restricting access to information and assistance." Intimate partner violence is increasingly seen as an important public health problem. In 48 population-based surveys from around the world, 10-69% of women reported being physically assaulted by an intimate male partner at some point in their lives. In the United States, the American Psychological Association (*Guidelines on Multicultural Education, Training, Research, Practice and Organizational Change for Psychologists*) has expressed the growing need for culturally-sensitive approaches to research and practice for different ethnic groups. The *Task Force Report on Violence and the Family* cited the need for culturally-sensitive approaches for different ethnic groups in the treatment of domestic violence offenders. The research presented briefly in this article was an attempt to discover specific treatment components that should be incorporated into domestic violence treatment for monolingual Spanish-speaking Latino men residing in California.

The population of California is currently 31% Latino; this percentage is projected to reach 39% by 2020. In San Diego County, where the research study was conducted, the Latino population stands at 28% and is projected to rise to 33% by 2020. There are over 400 Latino men in treatment for domestic violence in the San Diego area, and of these, 89% are first or second generation Mexican immigrants. Therapists in California need to be prepared to treat increasing numbers of Latino, specifically Mexican, partner abusive men, in a culturally competent manner.

The study was conducted in two parts. First, the authors completed a demographic and risk factor survey of 159 Latino men in domestic violence treatment at four different agencies, and secondly, individual, in-depth qualitative interviews with twelve survey respondents were conducted. The anonymous, paper-and-pencil survey was conducted because descriptive statistics for the Latino domestic violence population were unavailable from the treating agencies and the Department of Probation.

The following major results of the survey were selected based on their importance as demographic and risk factor findings: Sixty-five percent of the total sample was 35 years old or younger. Only 18% of the men had completed high school or more, with 37% of respondents reporting a 6th grade education or less, and 49% of respondents having had an 8th grade education or less. Moderate to severe domestic violence in their family of origin had been witnessed by 45% of respondents. Fifty-one percent of respondents reported having been moderately to severely physically abused by their parents. Calculating annual family income for 5 family members (average number of children, 2.6), 70% of respondents lived under the poverty line. Fifty-three percent of respondents had committed domestic violence before, without being arrested. Regarding alcohol use, 44% reported being intoxicated during the incident. Finally, at the time of the incident, 57% of the men's children were either present in the same room or in the home.

Several risk factors are related to domestic violence in the general population, with three factors being consistently found across the population of assaultive men: 1) a history of childhood violence; 2) low socioeconomic status with low educational achievement; and 3) alcohol use and abuse. The population of Latino men surveyed clearly fit these parameters.

The process of qualitative or discourse analysis was used for the second part of the study. Twelve interview participants were chosen. All were Mexican immigrants who had completed forty or more weeks of their 52-week court-ordered treatment.

Support was found for four major ecosystemic strengths of Mexican culture that reject domestic violence, and that might be expected to act as protective factors: 1) Positive aspects of the male gender role, such as providing for and protecting the family; 2) *Familismo,* strong attachment to family; 3) *Respeto*, deferential behavior towards others based on social position; and 4) the importance of spiritual values, offering a framework for respectful family life. However, for these abusive men, these accepted cultural strengths did not deter them from violence.

The interviewees offered the following justifications for their violence, with corresponding theories of domestic violence in the general population mentioned under each heading: 1) Normalization of Violence. They had learned to be violent by being frequently exposed to violence in their families and communities. This explanation corresponds to the social learning theory of the intergenerational transmission of violence. 2) Negative Aspects of Male Gender Roles, comprising both a) generally negative male gender roles, which presuppose the superiority of men and the duty of women to serve them; and b) *machismo,* which the men identified as a further, consistently negative distortion of the male role. The influence of patriarchal gender socialization in fostering a climate where domestic violence is tolerated and even supported was a prominent theme for all the men. The emphasis on the effects of gender socialization supports the sociocultural or feminist theory of domestic violence. 3) Psychological Dysfunction related to Early Trauma. Most had suffered physical and emotional abuse as children, and had witnessed domestic violence. Five of the twelve men had symptoms of Posttraumatic Stress Disorder; others had problems with impulse control or depression. This finding relates to the clinical model and to self-psychology theory. 4) Maladaptive coping skills, including a lack of relationship skills, uncontrolled anger, and a high incidence of alcohol abuse. A lack of coping skills and distorted thinking form the basic premise of the cognitive-behavioral theory of domestic violence. 5) Environmental Stressors, such as financial stress and difficulties with immigration and discrimination. This finding lends support to the ecosystemic theory of domestic violence.

As regards their treatment experience, the interviewees described the usefulness of clear and structured teaching methods. As for the clinical style of the therapist, they appreciated such qualities as self-confidence, *respeto, simpatía,* and understanding. The strategy the men most disliked was therapists' unwillingness to validate their concerns, and a tendency to blame clients for all the problems in their relationship. Their comments lend support to research demonstrating the greater efficacy of an empathic approach towards domestic violence offenders.

The interviewees reported that therapist ethnicity was unimportant, as long as the therapists were fluent in Spanish, possessed a good grasp of the material, and profound knowledge of Mexican culture. This knowledge increased the clients' trust in their therapist's ability, consistent with findings that ethnicity is a distal variable in therapy, while credibility is the proximal variable.

The interviewees were proud of the changes in attitude and behavior that had resulted from treatment, such as better communication skills, and the ability to manage their anger. They also identified becoming more flexible in gender roles as a vital element of their new approach to their family. Gender equality, although an innovative idea, was eventually accepted, and they were integrating it into their current relationships. Overcoming alcohol addiction, usually through simultaneous court-ordered programs, was another major accomplishment. Finally, the men spoke gratefully of the parenting skills some had acquired in treatment. Being able to break the cycle of violence for their children and grandchildren was intensely motivating.

The following culturally specific topics were identified by the interviewees as essential in treatment for Latino men: 1) Emphasis on discussion of rigid male gender roles, especially *machismo;* 2) An emphasis on parenting education; 3) Acknowledgment of discrimination against immigrants and women; 4) Discussion of changing gender roles after immigration; 5) Open discussion of sexual abuse in relationships; 6) Inclusion of spirituality as related to prevention of domestic violence.

These components were subsequently added to the translation of a respected domestic violence treatment program (Wexler, 1999), and a new program specifically for Latino men was piloted for two years. It was then published, initially in the United States as *Violencia Doméstica 2000.* It is currently in press in Mexico City for distribution to the Spanish-speaking world under the title *Sin Golpes: Como Transformar la Respuesta Violenta de los Hombres en la Pareja y la Familia* (Welland & Wexler, 2005). A further quantitative research study into psychological factors of Latino partner abusive men is nearing completion, to be presented at the California Psychological Association's next meeting in Pasadena.

The authors are grateful to the men who shared their experiences in this study. Their courage in discussing their personal journey through pain and darkness into light paves the way for other men like them to create a new life for themselves and their families. As one participant said so simply, "I like that my therapist taught me another way to be a man."

References are available from the authors upon request.

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China Revisited

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The 28th International Congress of Psychology, convened August 8 -13, 2004 in Beijing, provided a welcome opportunity to revisit China after 22 years. Our first visit, in 1982, had been as members of a group of psychologists led by Ray Fowler. On this trip we were primarily in Beijing and Shanghai with a visit to Guilin and a Yangtze river cruise in between. In this essay we will recount some personal observations on the many changes we noted.

In 1982, China was (as it still is) the world's most populous nation with over one billion people (David, 1982). At that time, we were engulfed by men and women wearing shapeless blue grey unisex Mao suits; in 2004 we saw none. In 1982 the never-ending flow of bicycles was interspersed by an occasional black government car; today cars clog congested streets with drivers often ignoring the "zebra" crossings and endangering pedestrians. We were told that in Shanghai alone there are more than one million cars, including 48,000 taxis, all contributing to pervasive smog. Twenty-two years ago the shops were mostly government owned and operated, selling primarily Chinese produced goods; in 2004 they are largely individually owned enterprises. High rise glitzy shopping malls feature prestigious European boutiques with foreign made clothes and other luxury goods. The old "Friendship" stores still exist but offer no bargains. The red banner propaganda posters of earlier years have been replaced by outdoor bill boards displaying western models with advertisements using English subtitles to increase marketing appeal. The only portrait of Mao we saw was the familiar one in Tiananmen Square. There were no portraits of government or party officials in the hotels, offices, or shops we visited. Starbucks and McDonalds are everywhere. The dynamic economic growth is reflected in the towering cranes, the new glass and marble office buildings, and the super modern hotels and new or remodeled cultural centers such as the Shanghai Museum. All this is in stark contrast to life in the countryside. But even there, some farmers have turned their simple homes into accredited (by local authorities) rentable accommodations for weekend guests. Along the banks of the Yangtze river, in areas flooded as part of the gigantic Three Gorges Dam development, villagers have been moved into apartment buildings with elevators installed only if the building rises eight floors or higher.

The physical and political changes we observed were dramatic. Since Deng Xiaoping's famous statement of a quarter century ago, "To get rich is glorious," China has seen the greatest burst of wealth creation in human history (The Economist, 2004a). Per capita income has increased significantly while income inequality between urban rich and rural poor has widened to a worrisome degree. Urban residents earn on average three or more times as much as migrant workers or farmers (The Economist, 2003). The relentless "march to capitalism" has greatly influenced Communist Party policies. A socialist market economy is replacing the centrally planned economy. There is a widespread belief that economic growth will solve all problems. This is unsettling for a government that likes to identify itself as "socialist" though many Chinese joke privately that presently the United States has a better claim to that description (The Economist, 2004b). Millions of migrants, largely unemployed peasants displaced by development projects or workers dismissed from state-owned enterprises, are pouring into urban centers, providing cheap labor. Of Shanghai's 16.4 million inhabitants, three million are migrant workers. Most are unregistered as city dwellers and ineligible for many social services. Prostitution, officially illegal, is tolerated. Aggressive beggars and scam artists prey on visitors. Air pollution has become an acknowledged urban environmental problem. Water pollution exists primarily in rural areas where some of the dirtiest polluting industries have been relocated (Kurlantzick, 2004; Yardley, 2004a, 2004b;). In a new book on China's environment, Economy (2004) documents how the air quality in two-thirds of Chinese cities is below Word Health Organization standards. Some public health observations: cigarette smoking was banned in the Congress halls and in our hotels. We saw little on the streets of Beijing and Shanghai. We also noted very few obese Chinese.

One of the purposes of our 1982 visit was to learn about the dramatic social action program designed to curb population growth. In 1979 China became the first country in history to restrict the right to procreate, a policy enforced through state- and party-guided incentives and disincentives (David, 1982b). The psychologists we met at that time endorsed the rationale for the one-child family policy but wondered about longer term effects, emphasizing the need for research on physical and intellectual development as well as on the personality of only children (Ching, 1982).

Professor Ching (now Jing) was the President of the very well organized 2004 International Congress. He welcomed suggestions for symposia on reproductive health and sexuality topics. Two symposia and a Conversation Hour, organized under the auspices of the World Federation for Mental Health Committee on Responsible Parenthood, attracted participants from several countries and a culturally diverse audience. We were impressed by the many English-speaking Chinese students at the Congress. English is the second language of the educated (many trained in the U.S.) and of international commerce. In Shanghai, English instruction begins in the third grade.

At the Conversation Hour a Chinese psychologist reported on her research, noting that well educated young Beijing couples seldom want more than one child because the cost of education has become a burden. Families have to pay rising school related fees from kindergarten through college. In Shanghai, tuition is free up to the 9th grade but parents must pay for books, uniforms, and food. Several psychologists in urban areas are focusing their studies on parental stress and coping behavior (Shi, 2004)

Another problem is that previously free public health services have deteriorated. For example, China is currently the only country in the Western Pacific Region which relies on parents to finance childhood immunizations. The underfunding of health services has led to "red packets" (bribes) to assure good treatment from physicians and nurses (The Economist, 2004a). Underfunding is not, however, the sole reason for public health service problems. A Beijing-based economist (Van der Tak, 2004) told us that it was a combination of a choice for market-based funding and price regulations. Some health services and products can be offered at prices that allow hospitals and physicians to earn a profit. Other services and products can only be provided at a loss – for which hospitals and physicians may then request additional compensation.

We wondered about urban university-educated only children now in their mid-twenties. They belong to the first cohort of Chinese youth whose formative years were spent amid rapid economic growth and an explosion of commercialism. The privations and turmoil of the Maoist years and the Cultural Revolution are often merely a part of family lore (Yardley, 2003). Parental resources do not have to be shared with siblings. Often they still live at home, even when married, postpone having a baby, and are not afraid to borrow money. Keenly aware of fashion, brands, and quality, they crowd the boutiques on Nanjing Road in Shanghai (The Economist, 2004c).

Hardee, Xie, and Gu (2004) reported some of the effects of the one-child family policy (modified over the years) on women's lives in rural areas. They used survey and focus group data collected in 1996 and 1998 with three generations of women. The oldest women had more children than they wanted and regretted not having access to modern contraceptives. Middle age women had desired fewer children but would have preferred making their own fertility decisions. The youngest women had grown-up with and were largely resigned to the restrictions on family size. Across generations, the majority of women believed family planning had a positive effect on women's lives, citing better health, less household work, and more educational and career opportunities for their children. All women, regardless of age, felt strong pressure to have a son. Currently, rural families are permitted to have two children if the first is a girl or if the first child has a disability or died. Moreover, if couples themselves are only children, they may have a second child. Members of minorities may also have two children and Tibetans are allowed three.

During one day of the Congress, Dr. Baochang Gu, Deputy Executive Director of the Chinese Family Planning Association (with a Ph.D. in sociology and demography from the University of Texas in Austin) and co-author of the rural inquiry, drove us to a regional family planning center located about one hour north of Beijing. The three story air-conditioned facility dispenses contraceptives free of charge to all who request them without inquiring about age or marital status. (An attractively packaged box of condoms included the word "condom" printed in big English capital letters). Additional services include free once-a-year health checks, ultrasound screening, and abortion via vacuum aspiration. In the Conference Room a very large wooden plaque proclaimed in huge gold colored Chinese characters "Control Population Quantity; Improve Population Quality." Great efforts are devoted to strengthen reproductive health services and HIV/AIDS prevention programs in the surrounding countryside but sexuality education continues to be a very sensitive topic. It is embarrassing for teachers and parents. Abortion of unwanted pregnancies among unmarried adolescents has increased and premarital sex has become the norm.

Over the years the Chinese Family Planning Association (CFPA), affiliated with the International Planned Parenthood Federation, has become one of the largest nongovernmental organizations in the country. It works in close cooperation with the government and receives major funding from the state. In Shanghai, local CFPA leaders told us about devoting considerable resources to improving sexuality education, reinforcing the fight against HIV/AIDS, and developing specialized counseling services for unmarried adolescent migrant women (among other activities).

While the one-child family policy resulted in an estimated 300 million fewer births over the last 10 years, one of the unintended consequences has been a growing gender imbalance. Chinese census figures for 2000 show 117 boys born for every 100 girls, described as "the largest, highest, and longest" gender imbalance in the world (Gu, 2004). Many couples abort female fetuses, hoping to try again for a boy (China Daily, 2004a). Nearly all babies placed for adoptions abroad are girls (Xinhua, 2003). The gender gap has led to warnings by social scientists that in coming years some 40 million men might not find wives, fueling social tensions. The Chinese call such men "bare branches" of the family tree that will never bear fruit. There have already been press reports of kidnappings as bachelors try "purchasing" wives (China Daily, 2004a).

To reduce the imbalance in the next 10 years, the government has banned the use of ultrasound for sex determination and sex-selective abortion. Such a policy is difficult to enforce when physicians are increasingly dependent on private income. Programs are being launched in more than a dozen of China's poorest provinces to foster more respect and concern for women and girls, teaching rural families to value their daughters more. Financial aid is being expanded to farmers 60 years of age and older, living in poor areas, who have no children, no son, or just one child, or two daughters, or whose children are deceased or disabled (Hoo, 2004). There is a shift in policy from using disincentives, punishing families who have too many children, to rewarding those who had fewer children and abided by the one-child policy. Still looming ahead, however, is the "demographic time bomb" created by rising longevity and falling fertility (Kahn, 2004). Some cities are relaxing the one-child family policy to permit the birth of a second child under certain conditions (China Daily, 2004b). As Gu indicates "there is no road map yet on how to achieve the goal of a normal sex ratio" in China (Gu, 2004).

When discussing China, the sensitive question of free access to information inevitably arises. Newspapers are censored, some books and movies are banned. Satellite TV is available in 4 and 5 star hotels but requires special permission for home installation. Controversial web sites and internet servers are blocked.

Sexual mores can only be pushed so far: homosexual bars remain officially taboo, magazine sex columnists are shut down when they become too prominent, and a museum on ancient Chinese sex culture was moved from Shanghai to a town a two-hour drive away. Political activists risk imprisonment. However, there seems to be a greater governmental and party willingness to accept criticism when related, for example, to environmental disasters, long term governmental planning, or corruption. Many people believe that, over time, economic growth will inevitably bring greater freedom and democratic reforms. A new generation is emerging adept in accessing the Internet. Their capacity to disseminate once "secret" information was proven during the SARS epidemic. As one consequence, governmental actions on health policy and HIV/AIDS prevention improved significantly.

One amusing personal note. We were surprised by how many people approached us to inquire about our ages. Most Chinese women and men of a certain age dye their hair black. We have never changed our hair color. When one woman stared at Tema's white hair and asked her age, she replied "75 and my husband standing over there is 81." The woman looked surprised and blurted out in English "Oh, an antique!"

Two weeks of revisiting Beijing and Shanghai and seeing a bit of the countryside do not make us China specialists. We found our Chinese hosts most hospitable, invariably courteous, and very willing to answer our many questions, even when we inquired about their personal

contraceptive preferences (mostly IUDs and condoms). We came away with an appreciation of an ancient people, whose culture has evolved over more than 40 centuries. China is an awakening giant whose economic, political, and military influence in the region and in world affairs will grow steadily in the foreseeable future.

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Promoting International Awareness of Psychological Research and Updating Course Material Through Conference Summaries

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Conferences are excellent avenues for disseminating the latest psychological research. Unfortunately, the amount of information available at conferences is often overwhelming. One of the questions my advisor in graduate school would always ask me after a conference is "what is the take home message from this conference?" After posing the question we would spend some time discussing what each of us felt were the key findings and what some of the research trends were in the conference. This kind of discussion helped to summarize the vast amount of information gained through conference attendance into a manageable amount of information that could be readily applied in our own research. It also helped provide breadth since we did not always go to the same sessions. As a result, I have always tried to summarize the key points and research trends of conferences I attend into several short statements.

I have found that the conference summary not only benefits my own understanding and research, but it directly impacts my students as well. When I return from a conference, I present the summary to my students and we discuss the latest research methods and results while drawing connections between the material we covered in class and the current trends in research.

Organizations will sometimes publish conference summaries. The American Psychological Association, for example, publishes summaries and highlights of different sessions of the annual APA convention in the *Monitor*. Similarly, highlights of the APS convention are presented in the *Observer*. Conference summaries are helpful for several reasons. First, these conferences are large enough that it is not possible to attend every session. Therefore, attendees who cannot attend one session because it conflicted with another session they attended, for example, can read a summary of the missed session and be aware of the important points addressed in it. The summaries are also valuable to people who could not attend the conference (e.g., students). However, there are numerous conferences of interest to psychologists that are not summarized in this way although a conference summary is occasionally published in a journal (e.g., Arnold, 1996; Bruhn & Parcel, 1982).

Fortunately, there are a few journals that designate space for conference summaries. One of these journals is *Voprosy Psychologii*. This journal is one of the leading psychological journals in Russia (it is also one of two Russian journals indexed in PsychInfo). Summarizing a conference for an international journal such as this has at least two potential benefits. First, the conference summary can facilitate personal research and teaching as already discussed. Second, the summary allows researchers from another country to understand the current trends in psychological research conducted in the United States and to see how their own research can either add to or be benefited from that described in the summary. This type of cross-cultural-pollination of ideas can help enhance research and potential international collaboration. Thus, writing something as simple as a conference summary can have a significant impact on personal research, teaching, and international relations and research. We should continually search for opportunities such as this to move closer to a global research community in which international exchanges of research ideas and psychological theory emphasizing different perspectives facilitates understanding of psychological principles worldwide.

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International Status of Testing: A Brief Summary

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Test use is universal. Tests are used in virtually every country, with new-borns through the elderly, and most commonly with students. Tests are used to describe academic attainment, estimate future behaviors, assist in guidance and counseling services, plan interventions and evaluate progress, screen for special needs, diagnose disabling disorders, help place persons in jobs or programs, and assist in determining whether persons should be credentialed, admitted/employed, retained, or promoted. Tests also are used widely in research and for various administrative and institutional planning purposes. Testing resources include group and individually administered measures of aptitudes,

achievement, intelligence, personality, social, language, perception, and motor skills.

Availability of Locally Developed Tests is Uneven

Although test use is universal, the availability of locally developed tests is uneven. Locally developed tests generally are available in Australia, Western Europe, and the United States. Few locally developed tests are found in Asia, Central and South America, the Middle East, Mexico, sub-Sahara Africa, and the countries that comprised the former Soviet Union.

International and Regional Efforts to Promote Test Development and Use

Important developments impacting test development and use are occurring internationally and regionally. These efforts, in part, mirror the growing global interest in psychology. Its scholarship, once dependent mainly on contributions from scholars in Western Europe and North America, is broadening to include research and other forms of scholarship from many countries in Africa, Asia-Pacific, Eastern Europe, and South America. Furthermore, its practices and technology are growing in popularity in countries that recognize psychology's potential contributions to important social goals (e.g., higher educational attainment, more effective and efficient industrial and managerial practices) and resolving vexing social issues (e.g., mental illness, violence prevention, racial-ethnic understanding, population control).

The globalization of psychology is seen in the international use of tests and other forms of data collection instruments. Their use helps address various needs: to facilitate research, describe behavior, identify talent, certify attainment of knowledge and other abilities and skills, improve educational and vocational selection, diagnose disorders, and monitor change. These needs are universal and prompt decisions by many countries to develop or in other ways acquire testing technology to help address these needs.

International Test Commission

The International Test Commission (ITC) has been addressing global issues important to test development and use for more than 25 years. The ITC has sponsored three international conferences and developed guidelines that address broad and important international issues. These include test adaptations, test use, and computer-based and internet delivered testing. Most guidelines have been translated into languages other than English. These guidelines and the ITC's newsletter, *Testing International*, are accessible through its web site (http://www.intestcom.org). The ITC also publishes a scholarly journal, *International Journal of Testing*. An ITC-sponsored international conference in 2004 at William and Mary University will address issues important to test development and use with diverse populations in ways that help support fairness and equity.

International Association for Evaluation of Student Achievement

The work of the International Association for Evaluation of Student Achievement (IEA) often has a profound impact on education. IEA has co-sponsored and directed three international surveys of achievement. The Third International Mathematics and Science Survey (TIMMS) represents a watershed in international assessment due to the participation of 41 countries and the importance of its results. TIMMS measured, compared, and discussed acquisition of knowledge in science and mathematics in grades 4, 8, and 12. A prior study examined reading. The results of IEA's Civic Education Study of 90,000 14-year olds in 28 countries together with their teachers and school principles provided one of the first international studies on social and political knowledge and views of those involved in education.

Forthcoming Issue of Applied Psychology: International Review

Various efforts hold promise for test development and use. A forthcoming issue of *Applied Psychology: International Review* addresses the following issues: uses and abuses of psychological and educational tests internationally; assessment in developing countries; advances in psychometric theory, models, and method; personality assessment; assessment in organizations; and large scale assessment and educational policy.

For example, Laurence Wolff identifies issues and problems associated with educational assessments in several countries of Latin America and suggests ways assessment programs in this region can be used more effectively to improve educational quality. Fanny Cheung discusses the use of Western- and indigenously-developed personality tests in Asia. She and others have developed models of personality that better reflect Asian traits, some of which typically are not included on personality tests developed in the West.

Iberian-Latin American Association on Psychological Assessment

The Iberian-Latin American Association on Psychological Assessment is assuming leadership for the development and use of psychological tests in Spanish- and Portuguese-speaking countries.

The Brazilian Institute on Psychological Assessment

Brazil, similar to many countries, had few locally developed standardized tests. Psychologists and others typically relied on translated tests or informal measures, often qualitative assessment measures. However, recognizing the need for additional test instruments, psychologists in Brazil were instrumental in creating of six regional university-based laboratories devoted to psychological assessment: University of Brasilia, University of Sao Paulo, Pontifical Catholic University of Campinas, University of Sao Francisco, Federal University of Brasilia, University of Unisinos. Each laboratory is responsible for constructing/adapting, developing, and norming tests on the Brazilian population. The model developed in Brazil could assist other countries in their test development activities.

The Brazilian Institute on Psychological Assessment (IBAP) was found in 1997 to lend support and to the help coordinate the work of these laboratories. IBAP initiated a scientific journal devoted to psychological assessment, *Psychological Assessment*, in 2002.

In August 2003, Brazil's First National Conference on Psychological Assessment and the IX International Conference on Psychological Assessment were held concurrently in Campinas, Brazil. More than 900 delegates from Brazil, Portugal, Spain, and the United States attended.

Protecting Copyright

The failure to protect copyright constitutes one of the major impediments to test development. The critical work of authors and testing companies leading to the development and distribution of tests is disrespected when record forms and test manuals are photocopied—a common practice in most counties. These practices extinguish interest in engaging in these critical endeavors.

The Russian government seemingly is taking steps to institute government-imposed rules and regulations governing testing policies and practices, including the protection of copyright for both foreign and locally developed tests. This effort could have a major impact on promoting test development and use in Russia.

The Futures of Testing

Conditions external to the specialization of testing strongly impact its activities. Tests typically have been developed and used to meet the needs of a country's institutions (e.g., governmental, educational, industrial, military, professional). A country's social, political, linguistic, religious, industrial, and economic conditions and values, together with its needs and resources strongly determine the degree to which tests will be developed and used.

Test use is stronger in countries that value science, technology, and individual differences; utilize resources based on notions of meritocracy instead of egalitarianism; have well-established universal education systems and well-developed undergraduate and graduate programs in psychology and other social sciences; have well-established systems supporting commerce and industry; have technology and commercial resources needed to develop and distribute tests; and, as noted above,

have and enforce legal protection of copyright (e.g., the photocopying of test materials is illegal and punished). Countries lacking these qualities generally develop and use fewer tests.

Various conditions internal to the specialty, conditions over which it has some control, also impact test development and use. International advances in test development and use are likely to benefit from efforts that increase the number and quality of graduate preparation programs for those who develop and use tests, increase the number and effectiveness of national test associations, facilitate communication among those interested in test development and use, promote a broader base of theory and research, develop and promote standards for test development and use, and develop assessment methods that respond to important social needs. ◄

School Psychology Internationally*

Thomas Oakland**
University of Florida

School psychology services exist in approximately 30 countries, including most Western European and some Eastern European countries, Australia, Canada, Brazil, Hong Kong, Israel, New Zealand, Turkey, and the United States. School psychology services in these countries are authorized by state or national legislation and/or are represented by a professional association. The presence of a strong national association is the single most important quality that determines the presence and strength of school psychology within a country.

Signs of growth in school psychology are seen in some large countries that have few school psychologists (e.g., the People's Republic of China, the Russian Federation), whereas growth in others is not apparent (e.g., Africa, Arab countries, India, Indonesia, Pakistan, and most of Central and South America).

How Many and Where They Work

Approximately 100,000 to 110,000 school psychologists work internationally, an increase of about 20% 1990s. The plurality, about 25,000, work in the United States . Most are women and are in their 30s to 40s. Those providing school psychology services may hold the title of school psychologist, educational psychologist (e.g., in countries associated with the British Commonwealth), psychologist, or counselor (e.g., in Australia). Employment numbers are closely associated with a country's gross national product (GNP). On average, 2,000 school psychologists are employed in countries with a high GNP and about 300 in those countries with a low GNP. Some countries employ fewer than 10 school psychologists.

School Psychologist and Student Ratio

On average, one school psychologist serves a population of 11,000 students. The ratio of school psychologists to students averaged 1:3,500 in countries with a high GNP, and 1:26,000 in those with a low GNP. Few work in rural areas. Annual salaries, based on 1990 data, also varied considerably by GNP, with an average of $17,000 for those working in high-GNP countries and $3,000 for those working in low-GNP countries.

School Psychology Faculty

Among faculty who teach in school psychology programs, 35% had a doctoral degree and 50% had a master's degree. Faculty typically worked 21 hours weekly at a university. Most had two or more jobs. Faculty salaries varied considerably. Those who had taught between 5 to 10 years averaged $33, 000 in high-GNP countries and $4,000 in low-GNP countries.

International School Psychology Association

The International School Psychology Association (ISPA) was formed about 25 years ago to help address international issues important to the practice of school psychology. ISPA's membership approximates 550 from 48 countries. The ISPA holds conferences yearly, often to help stimulate the development of school psychology within the host country. The ISPA publishes a newsletter and sponsors a peer-reviewed journal, *School Psychology International*. It is a member of the UNESCO Nongovernmental Organization Liaison Committee, provides international leadership on children's rights, offers crisis-intervention response services, and sponsors receptions during the annual meetings of the National Association of School Psychologists as well as cross-national member exchanges. The Special Collections Library at the University of Memphis houses its archives, and Thomas Fagan serves at its archivist.

Future of School Psychology Internationally

The future of school psychology internationally will be influenced by many conditions, including four that are external (i.e., the degree services are institutionalized through legislation, as well as economic, language, and cultural conditions) and five that are internal (i.e., professionalism, the scope and functions of service, expansion of professional services, improved interface with education, and promotion of test development and use. Each is briefly discussed below.

External Qualities That Affect School Psychology Internationally

Institutionalization of services through legislation

The future of school psychology is bright in countries that institutionalize school psychology services through legislation. Lacking such legislation, school psychology services are likely to be nonexistent or marginal at best. Thus, efforts are needed to work outside the profession to secure needed legislative endorsement and associated financial support.

A country's GNP.

Economic realities strongly influence psychology. Psychology is stronger in industrial countries with a high GNP and, within countries, in prosperous urban areas. Thus, growth of school psychology will occur in countries as they become more prosperous; within them, growth will occur first in larger cities and nearby suburbs. Little growth can be expected in low-GNP countries.

English language use

English has become the most prominent language of science and the professions. Psychology and school psychology are strong in all English-speaking countries except Belize. The growth of school psychology is likely to be stronger in countries that use English as their second language and require its psychology students to be fluent in English.

Scholarship in psychology that reflects research and theory from more countries

Cultural views have a decisive influence on the emergence of and support for psychology, including school psychology. Psychology and its professional specialties emerge and remain strong when they are viewed as providing technically sophisticated and relevant services within a context that respects cultural values and beliefs. Psychology's decided Western emphasis limits its effect in many regions (e.g., Africa, Asia, the Asian subcontinent, the Middle East). The future acceptance of the discipline and practices of psychology depends, in part, on the extent to which psychology expands to embrace conditions that are important to child growth and development, as well as other educational, social, and cultural issues, in non-Western countries. Thus, the growth of school psychology will be stronger to the extent that its scholarship incorporates more perspectives from countries other than the United States and those in Western Europe.

Internal Qualities That Affect School Psychology Internationally

Development of strong national associations

The growth of school psychology requires the presence of national professional associations representing school psychologists in all countries. About 10% of countries have them. The attainment of the remaining four conditions discussed below depends, in part, on the formation of strong and viable national associations of school psychology.

Establishment of parameters for school psychology practice

Statements that establish the nature of service, prepared and endorsed by a national professional association, are needed. They help establish the nature of practice, conditions for academic and professional preparation, and interprofessional understanding and respect. Statements defining practice also aid lobbying efforts to mandate school psychology services and to certify and license practitioners.

Expansion of practices

School psychology services in many countries are restricted to caring for the needs of the mentally retarded and conducting assessments . Although important, these services constitute a limited range of possible services that the profession is able to provide and that clients need. Emphasis on primary prevention, interventions, consultation, organizational and program development, and supervision is needed in many countries to expand the nature of school psychology practices and demonstrate the profession's ability to meet national priorities through these services.

Response to critical educational needs

School psychology has two important affiliations: psychology and education. School psychology services emerge when specialists in public policy and education see value in funding these services. These specialists, not school psychologists, typically determine whether school psychology services are provided and the nature of these services. Thus, school psychologists must demonstrate to these specialists the value that school psychology services add to education.

The presence of school psychology generally follows a discernible pattern. General education services for students in elementary schools are established first, followed by those for students in secondary schools. Special education services may follow. Thereafter, school psychology services may be added. When federal or state laws governing school psychology services are vague or absent, the views of leaders in special education may be especially important in determining whether these services will be used.

Development of national test resources

Test use often constitutes one of school psychology's most important and unique contributions to education. Nationally developed educational and psychological tests are often needed for improving professional services. However, testing resources are frequently are inadequate.

Most countries use tests developed elsewhere, principally the United States. National norms and information on a test's psychometric features are often unavailable. The availability of nationally developed tests to assess children's achievement, intelligence, personality, temperament, and other qualities would advance research and practice.

**Many of the data reported below are derived from the most recent international survey of school psychology (Oakland, T., & Cunningham, J. (1992). A survey of school psychology in developed and developing countries. School Psychology International, 13, 99–130). Except when otherwise noted, the data reflect conditions in 54 countries not including the United States. Portions of the current article appear in the November 2003 issues of the American Psychologist.*

***Dr. Oakland is Past President of the International School Psychology Association and the 2003 recipient of APA's Award for Distinguished Contributions to the International Advancement of Psychology.*

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Psychology in Armenia

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October 7-10, 2004, Yerevan, Armenia

The International Psychiatric Conference on Mental Health Perspectives in Public Health, devoted to the 100th anniversary of Academician A. H. Mehrabyan, was organized by World Psychiatric Association, Armenian Association of Psychiatrists and Narcologists, Armenian Medical Association, Yerevan, Armenia, October 7-10, 2004. Among the lectures, Armenian Professor Ada S. Tadevosyan's "The Psychiatrist in the World of Suffering," Russian Professor Valery N. Krasnov's "Structural-dynamic Analysis as a Method in Psychopathology" and US Professor Haigaz M. Grigorian's "Mental Health Perspectives and Public Health" were listened to with profound interest. Among Psychiatry presentations, the most impressive reports were those of Marietta Melik-Pashyan, Armen Melik-Pashayan Armenia), Samvel Margaryan (Armenia), Hrachia Tatevian (Armenia), Narine Manasyan (Armenia) Samvel Sukiasyan (Armenia), N. Khodakarami J. Maghsoudi (Iran), Samuel Tyano (Israel), Jeannette Lely, Erik Romme (The Netherlands).

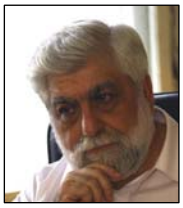

Among Psychology presentations, "PSYCHOLOGICAL ASPECTS OF QUALITY OF LIFE ASSESSMENT IN PATIENTS WITH PSYCHOSOMATIC DISORDERS" presented by ***Professor Sergey N. Enikolopov*** (Mental Health Research Centre of Russian Academy of Medical Science, Moscow, Russia) was recognized as the best. It is an investigation, conducted in Moscow, on assessment among patients with psychosomatic disorders. From the discussion one could come to know that a definite and concrete cognitive dissonance exists in the value systems of the subjects and that the patients employ quite different value approaches and life positions when assessing their own and other's behaviors, actions and activities. It could also be concluded that persons' motives have a key impact on their understanding of life assessment.

Sixty-eight Abstracts are included in the Proceedings Booklet of the Conference. [ISBN 99930-78-55-7]

October 21, 2004, Yerevan State University

Information Day of the European Union "TEMPUS" Educational Program in Armenia

Under the auspices of the EU Tempus Program, Ministry of Education and Science of Armenia, Yerevan Office of the Delegation of the European Commission to Georgia and Armenia, Directorate General for Education and Culture of the European Commission, and National Tempus Office organized a TEMPUS INFORMATION DAY. It took place on Thursday, 21 October, 2004 at Yerevan State University.

The goals of the full day program were the following:

- To underline integration of the Armenian High Education system in the Bologna process;
- To deliver information on latest Tempus program developments and innovations;
- To present cooperation opportunities for Armenian Universities with European Union countries;
- To make practical recommendations to potential applicants;
- To elaborate the selection procedure.

TEMPUS is the Trans European cooperation/mobility scheme for higher education which supports projects aiming to reconstruct and develop curricula and teaching materials, upgrade teaching facilities, and/or improve university administration in higher education institutions.

The TEMPUS program started in 1990. Armenia has been participating in the TEMPUS program since 1995.

November 11-23, 2004

US Psychology Professor Addresses Armenian Students and Professionals

Hagop Pambookian, Professor of Psychology, Shawnee University, Portsmouth, Ohio was the guest of The Armenian Philosophical Academy, Armenian Pedagogical University, Yerevan Ajarian University. The Armenian psychology students, lecturers, and scholars had the chance to talk and share useful information with the prominent US Professor. Hagop Pambookian's schedule was well planned, so the Professor was able to address different groups and meet with various individuals, in a comparatively short period of time. He lectured for the students and had professional talks at about a dozen institutions of higher education. Besides his host institutions, Prof. Pambookian was also kindly received by the Armenian Linguistic University "Interlingua," Yerevan State University, Yerevan Rotary Club, Mental Health Rehabilitation Centre "Stress", TV Channel "Gendron" ("Center"). Hagop Pambookian was elected Honor Member of the Armenian Pedagogical Academy.

Though there was so much to talk about and the time was short, the US Professor was able to sensitize the Armenian professors and students alike. "There is so much to be done!" he used to exclaim, during his visit. The prominent Armenian American Professor, whose visit was hosted by Academician Georg Brutian, Professor Sergey Arzumanyan, and Docent Samuel Jeshmaridian, is the Founder of the Pambookian Book Foundation (over 5000 Psychology top books in English) at the Armenian National Academy's Library.

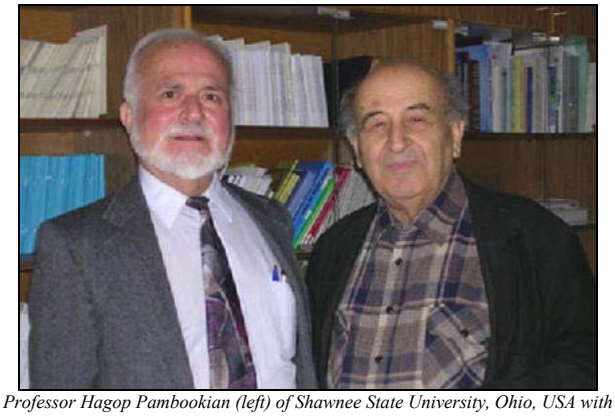

Professor Hagop Pambookian (left) of Shawnee State University, Ohio, USA with Professor Georg Brutian, Academician of National Academy of Sciences of Armenia.

Professor Hagop Pambookian (right) of Shawnee State University, Ohio, USA with Professor Ghukasyan, Rector of the Yerevan Pedagogical State University, Armenia

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Psychological Phases of Disasters and Stages of Emotional Response After a Mass Disaster

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Psychological Phases of Disasters

According to experts in disaster fields, five psychological phases are likely to occur after a disaster (American Red Cross Manual on Disaster Health Services). According to this author's research in many disaster ridden countries around the world, these phases vary in length and intensity depending upon vulnerability, kind of disaster, extent of physical damage, and resources available.

1. *Initial impact phase*: characterized by increased shock, disbelief, anxiety and fears.
2. *Heroic phase:* characterized by survivors helping each other in efforts to deal with the catastrophe.
3. *Honeymoon phase:* characterized by experiences of joy at having survived and feeling important and special for receiving aid from various private and governmental organizations.
4. *Disillusionment phase:* characterized by increased frustration and resentment at officials and agencies for failing to provide assistance in a more timely fashion.
5. *Reconstitution phase:* characterized by thoughts and plans for reconstruction and acceptance of the need to assume responsibility for personal problems.

Stages of Emotional Response After a Mass Disaster

Although disasters differ in their intensity and magnitude, according to this author's research, the following are universal reactions to disasters:

1. *Shock and disbelief:* During the first stage, survivors are in shock, emotionally numb, and in some cases in denial, because the pain is too severe for any human being to bear.

2. *Strong emotional response:* In this second stage, the survivor is emotionally aware of the problem and feels overwhelmed and unable to cope with it.

Common Reactions in Children:

1. Separation anxiety
2. Refusing to sleep or be left alone
3. Conduct disorder
4. Regressive behaviors: thumb-sucking, enuresis, or clinging behavior
5. Hyperactivity
6. Withdrawal
7. Somatic complaints: stomach ache, headache, joint aches, etc
8. Sleep disturbances

Common Reactions in Adolescents:

1. Withdrawal
2. Anger
3. Increased aggression
4. Regression
5. Sleep disturbances
6. Nightmares
7. Increased daydreaming
8. Inability to concentrate 9. Irritability

Common Reactions in Adults:

a. Uncertainty and fear
b. Anger expressed towards terrorists
c. Feeling tense, edgy and jumpy
d. Loss of appetite
e. Sleep disturbances and nightmares
f. Withdrawal
g. Loss of concentration
h. Inability to make decisions
i. Aggression: domestic violence, increased alcohol/drug use, etc.

3. *Acceptance:* In this stage, the survivor begins to accept the magnitude of the disaster and makes an appropriate effort to address it. Survivors feel more hopeful and goal-oriented. At this time, survivors may take more specific actions to help themselves and their families.

4. *Recovery:* Last but not least is the recovery stage, during which survivors feel that they have returned to their pre-disaster level of functioning. A sense of well being and adjustment is restored and realistic memories of the traumatic experience are developed.

In these chaotic and catastrophic times it is important to do the following:

1. Continue your pre-disaster routine (as much as possible): work, school, housework, and other activities. Since there is a lot of uncertainty, it is best to focus on things that you have control, or can be certain about. Try to reduce the time you spend worrying about the things you cannot change; ask yourself "What can I do now?" rather then "Why did this tragedy happen to me, to us, to New Yorkers?"

2. Use your resources and support systems fully: Stay with family, friends, neighbors, and co-workers;

3. Don't hide your feelings -- talk it out: Talk, cry, express, and share your feelings: grief, sadness, anger, helplessness, or whatever else you may be feeling. You're not in this alone. It is normal to have those feelings after such a disaster, and it is healthy to get them out of your system. If you don't, they may be locked in your body, psyche, or soul, and become poisonous. Help your children to tell their stories, express their feelings, role model for them;

4. Reach out to your spiritual support system: Go to your church, temple, mosque, or wherever else you may receive spiritual support. According to my research, spiritual support has helped survivors;

5. Know your limits – and make time to rest, and relax;

6. Avoid self-medication: Drugs and alcohol may seem to remove stress temporarily, but in the long run they generally create additional problems or behavior that compound the stress you were feeling initially. Even caffeine and nicotine can have a negative effect on your ability to control the sources of anxiety in your life.

7. Find a positive lesson that you learned through this catastrophic experience: Every experience and disaster can have a positive meaning which is individually unique. The sooner you find that meaning the sooner you can gain control and heal. That does not mean that you avoid the grief and the expression of sadness. Take your time to cry, feel sad, and grief, and then go on to discovering a meaning.

8. Find love and express love: Caring and loving produces positive feelings in us all, and helps us cope with the worst situation. Be generous with your hugs and physical expression of love, caring and compassion.

If the above steps do not help you with your stress after this catastrophic tragedy you may contact me, Dr. Anie Kalayjian, Fordham University, 201, or E-mail: kalayjiana@aol.com.

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The Importance of a Psychological Crisis Management Plan for the Athens Olympic Games

Elizabeth K. Carll, PhD, Chair
Committee on Violence and Disaster

The mission of the Committee on Violence and Disaster is to collaborate with international psychologists to develop a best practices protocol with regard to disaster and crisis intervention. As part of this effort, in 2003, Elizabeth Carll had the opportunity to meet with a group of European disaster and trauma psychologists and the head of the Disaster and Crisis Task Force of European Federation of Psychologists' Associations (EFPA) in Vienna. As a result, EFPA agreed to be a collaborator and participant in this project with APA Division 52's Committee on Violence and Disaster.

Most recently as part of this collaboration, the chair of the EFPA Task Force on Disaster and Crisis Psychology, and Secretary General of the Association of Greek Psychologists had expressed concerns that there should be a crisis management plan in place for the 2004 Olympics in Athens to deal with the emotional aftermath of possible terrorism or large scale accidents. There had been a number of terrorist alerts in Europe, in addition to the unfortunate disaster in Madrid earlier in the year.

Although the Secretary General of the Association of Greek Psychologists, had several meetings with officials and the Organizing Committee of the Olympic Games, an official response as to the status of psychological contingency plans had not been received. EFPA sent a letter, in May 2004, requesting information about the crisis management plan in place and offered assistance to the Olympic Organizing Committee. As the Games were drawing closer, both the Secretary General of the Association of Greek Psychologists and the chair of the EFPA Task Force on Disaster and Crisis Psychology asked Elizabeth Carll to facilitate the possibility of APA also sending a similar letter, emphasizing the importance of such a plan.

The above request was discussed with APA president Diane Halpern and Division 52 president, Richard Velayo. As a result, it was requested that Elizabeth Carll draft a letter which was reviewed and signed by Diane Halpern, Richard Velayo, and Elizabeth Carll, and was sent to the president of the Organizing Committee of the Athens Olympic Games in June.

The letter emphasized that since the goal of terrorism is to create fear and panic, the psychological component is integral to an effective crisis management plan. Given this possibility, it is important that a comprehensive crisis management plan, which includes dealing with the immediate emotional shock and trauma, be in place should such an unfortunate event occur.

Since the terrorist attack at the 1972 Munich Olympic Games, contingency plans for crisis management have been developed. More recently these crisis management plans have included training and dealing with the psychological aftermath at Olympic Game venues, such as in Lilliehammer, Atlanta, and Sydney. Given the current international climate today, the potential for a terrorist incident and disaster is even more of a concern than in the past.

In collaboration with EFPA, the APA urged that the Olympic Committee contact the Association of Greek Psychologists to discuss the plans that were in place and possibly provide any volunteer assistance that may needed to help insure the well-being of all who participate and attend the Olympic Games.

In follow-up to this action, Vassiliki Boukouvala, Secretary General of the Association of Greek Psychologists, subsequently met again with Olympic officials. It was determined that psychologists with expertise in trauma and disaster intervention, serving in the armed forces as part of NATO, would be available to respond to any crises at the Olympic venue, should such an unfortunate event occur. It was positive to learn that intervention plans for the psychological aftermath of any potential

terrorist attack or disaster would also be included in the crisis contingency plans of the Athens Olympic Games.

Psychologists can provide important assistance in preparation for and in the aftermath of violence and crises and need to be proactive in supporting the psychological welfare of the international community.

2005 APA Convention Program

The Committee on Violence and Disaster is also cosponsoring, a symposium, with Division 46 at the 2005 APA Convention in Washington DC. Check the convention brochure for *Innovations and Best Practices in Violence and Disaster Intervention*.
Chair: Elizabeth Carll; *Participants:* Rony Berger, Yael Danieli, Anthony Marsella, and Elizabeth Carll.
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Multimedia Technology and the Internationalization of Psychology*

Richard Velayo, Ph.D.
Past-President, Division 52
Pace University, New York

At the current rate of technological growth that we all experience in our everyday lives, it is not surprising that its impact on the field of Psychology has been tremendous and continues to be so. Few would dispute that technology is significantly changing the face of higher education, bringing about a host of new tools and choices. The same forces that directly influence pedagogy are also causing changes in areas of research, practice, policy-making, and international relations. Internet and interactive technologies are changing the way we communicate with the people we deal with and among ourselves as psychologists. Although technologies have provided us with more efficient and effective ways to do many tasks, I am particularly interested in designing multimedia technology to produce effective presentation and pedagogical tools, examining combinations of modalities (such as textual, visual, and audio elements) that enhance the quality and impact of information. The impact of technological innovations is very much evident in many aspects of a psychologist's professional life, not to mention its impact on bringing psychologists from various cultures and nations together.

The Psychology of Technology

A study by Mitchell Weil and Larry Rosen in 1994 suggested that we may not be ready for eventual changes brought about by the rapid growth of technologies. In their work with practicing psychologists, they found at that time that less than 1% have what they referred to as an "Information Age" Office (an office in which all business operations are performed on computer by a highly computer-literate staff. Information is routinely communicated to and from other computers through electronic transmission. All insurance billing is transmitted via fax or modem by direct linkages with major insurance carriers. The fax machine is on a dedicated phone line. The office also has a sophisticated voice mail system that has distribution groups and preprogrammed messaging for emergency paging.) Times have certainly changed from 10 years ago.

How many of you think that you have leaped into this "Information Age" kind of office? Although a significant proportion have embraced this change, there are those in our field who find the transition difficult or even resist it? In Weil and Rosen's 1994 study, there are several clear reasons why these Psychologists will find it difficult to assimilate. These are:

- Too Many Choices /Lack of Information
- Too Much Jargon
- Technophobia
- Bad Early Experiences and/or Poor Introduction to Technology

Transformations

Computer technology has changed the way we teach, do research, and practice…

Teaching

Teaching with technology is undoubtedly here to stay. There are many instances in which students even expect their courses (…yes, even psychology courses) to have some technology component to it, be it the use of e-mail, computer conferencing, research using electronic databases, or a dedicated website for the course.

Pedagogical strategies are also evolving because of technology. For example, the use of web boards (a computer conferencing tool) and distance learning tools allow courses to be conducted without the constraints of time and place. Of course, there are proponents and opponents of these new pedagogical trends.

Electronic and computer-based technologies increase the speed of communication between psychologists of different nations (as well as geographical regions within a country), therefore allow the training and the education of psychologists to be conducted anywhere and any time. Such transformation imposes changes in the role of trainers and educators of psychologists. The Internet also allows for the management of knowledge and provides just-in-time information and skill-sharing among psychologists through electronic support systems and networks (Marquardt & Kearsley, 1998).

Many new technologies, the Internet in particular, have already had a strong application in training and education (Kincaide, Ferracutti, & Santiago, 1997). The role of psychology on the education and training of future psychologists, both local and international, would be to start a universal dialogue between nations and cultures of the world. Computer-based distance education and training in developing countries ought to fulfill the same goals as the whole educational system to prepare people for the oncoming globalization. A virtual college is one expression of a growing virtual society.

Research

The continual progress of computer technology and the increase in Internet usage by the general public provide intriguing opportunities for researchers in all areas of psychology.

Many psychologists are now taking advantage of these innovative media to conduct a number of research projects, from social psychological surveys to experiments on cognitive processes. The Web certainly offers many advantages over traditional means of data collection. I have begun preparing for the future by converting two of my research projects into what I call "Internet-accessible" media in which participants could fill out questionnaires via the Internet and e-mail their responses to me. The number of experiments and surveys available online has increased dramatically in the past five years and will continue to offer research opportunities for researchers to advance their theoretical ideas and experimental designs.

New information about various subfields in psychology and the Internet critically influences the way we work, live, communicate, and/or behave. Research opportunities for social scientists exploring the social norms issues of human behavior as well as interesting outcomes published by Western researchers of computer-mediated communication and virtual communities are evidently growing (Bajan, 1998). For example, Ono (1996), examines how users reveal a reflexive projection of the self in Internet "speech," and how Internet communication encourages users to internalize globalization in their self-identity. This study further describes the Internet as a global networked society. Data collection via the Internet is also becoming a popular way to do research. Many interactive questionnaires are now on the web, the most common of which are associated with experiments on perception and cognition.

The inclusion of indigenous psychologies in the knowledge base of all psychology is also an important emerging issue to tackle. Sampson (1995) describes the postmodern era characterized by "postindustrial, information-based and globally linked social environment" in which current Western views of the self – as free, independent, and self-contained – will become inadequate in providing a basis for understanding the individual. It is anticipated that it will become essential

for a person, to view themselves as parts of a global system in which people's identities are inextricably linked with where they are socially located in that system. Thus, many personality and social psychologists may have to recalibrate their views to reinforce the central importance of culture in shaping the way people construe the self.

The Internet has also greatly influenced how people work and learn, manage themselves in the workplace, and manage knowledge in their lives. Industrial / Organizational psychologists should further their research on how technology can help people and organizations achieve the level of competence necessary to survive and succeed in the global marketplace of the next century (Marquardt & Kearsley, 1998).

Practice

Many practicing psychologists have tapped the Internet market not just to advertise, but to deliver their services… provide interventions and consultations. Then again, many of us have doubts about the clinical effectiveness of such practices.

Nonetheless, many are also using listservs and other forms of asynchronous communications to share or consult one another on issues of common interest.

The internationalization of our field through sophisticated communication technologies put us in touch with countries known previously to only a few. We, like others abroad, will need to be responsive to the demands of a multi-racial, multi-ethnic, and multinational group of psychologists. According to Mays, Rubin, Sabourin, and Walker (1996), the challenges that new technologies bring can and will range from such issues as ethical decisions of who can and will have access to expensive technology that saves and prolongs life; to the development of conflict management strategies for peaceful coexistence with neighbors whose behaviors, beliefs, and values are strongly shaped by their cultural, religious, and ethnic backgrounds and socioeconomic circumstances. Thus, inclusion of and sensitivity to various socio-cultural perspectives are all the more necessary.

Given the changes in telecommunications, transportation, and economic ties, we are probably linking our careers to events and forces in distant lands. Emerging social, cultural, political, and environmental problems around the globe are imposing intense and complex demands on our discipline, challenging our sense of identity as psychologists and as a professional collective. We can assist in addressing and resolving these concerns, especially if we are willing to reconsider some of Psychology's fundamental premises, methods, and practices that are rooted within Western cultural traditions and to expand its appreciation and use of psychologies from abroad. Marsella (1998), suggested that there may even be a need to advocate the development of a meta-discipline of psychology – global community psychology – defined as a set of premises, methods and practices for psychology based on multicultural, multidisciplinary, multisectoral, and multinational foundations that are global in interest, scope, relevance, and applicability. The characteristics of global-community psychology as a disciplinary specialty are important to discuss, are as various issues supporting its development and need.

So What's the Lesson Here?

As psychologists, it may be wise to begin, if we have not yet done so, to anticipate and prepare for changes brought about by the globalization of psychology facilitated by the Internet if we are to successfully and effectively promote our discipline to the world. Some of the transformations in the field of psychology as a function of this multi-modal approach that technologies afford us to do. I look at the role of technology as essential to the growth of psychology. Many of us have been caught off guard, have procrastinated in using effective technologies that are available to us, or have found it difficult to train ourselves with the more "standard" technological tools of the times. In order to remain competitive and to provide what our students, clients, participants, and customers, may expect of us, it may be a strategic to begin investing in our technological knowledge and skills… in our discipline's future.

The Internet's influence on psychology and how cultures are viewed will also have a profound impact on the world's various cultures themselves. Though cultural and language barriers exist in bring psychologists together, telecommunications technology has begun to thin out these barriers such as through sophisticated language translation software programs, and Internet-based platforms (e.g., Internet 2, distance education). Although psychology may be largely assumed to be a value-free, universal, and relatively objective branch of science, in actuality, it is deeply enmeshed with Euro-American cultural values that champion rational, liberal, and individualistic ideals (Kim, 1996). In North America for example, free exchange of ideas is valued, and ideas are purportedly evaluated through public and competitive avenues. This belief certainly affects how conferences are organized, research collaborations developed, research is funded, and publications are accepted. In East Asia, human relationships characterized as being virtue-based rather than rights-based is more evident. Individuals are considered to be linked in a web of interrelatedness and ideas are exchanged through established social networks. The dissemination of research findings does take a different form. Thus, there is value in becoming cognizant and sensitive to these differences.

Moreover, the generalizability of findings in psychological literature may now be assessed given its particular cultural perspective. Kim (1996) even proposed the need for the development of universal psychological science. Empirical research and the development of psychological models that relate to technology use is needed to determine ways in which psychologists may effectively use technologies in their profession, particularly those that focus on information-sharing and presentations, as well as the interaction among psychologists.

A Growing "Cyberpsychology"

There are many other related questions asked about this growing "cyberpsychology," some of which are as follows:

- Should society guarantee universal access to the Internet?,
- Should there be restrictions on the content of the Internet?,
- What are the long-term effects of interacting in a virtual environment?,
- Will advanced multimedia systems and Internet connectivity replace the traditional classroom experience?,
- Can psychological services be effectively delivered over the Internet? How so?, and
- Can interactive technologies reduce mental health care delivery costs?

In the near future, we can expect to provide clearer answers to some, if not most, of these questions. One thing seems to be certain … that the Internet and multimedia technologies has opened the gates for a more efficient and effective communication among many members of the psychology community around the world. . As Dr. Florence Denmark, who was then President of Division 52, mentioned in her Presidential Address at the 1999 Annual Convention held in Boston, "The Internet is one major factor that contributes to making our small world smaller."

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**Division 52 Presidential Address delivered on July 28, 2004 a the 112th Annual Convention of the American Psychological Association*

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BOOK REVIEW

Where Is East Asian Social Psychology Going?

Review by

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PROGRESS IN ASIAN PSYCHOLOGY. CONCEPTUAL AND EMPIRICAL CONTRIBUTIONS, edited by Kuo-Shu Yang, Kwang-Kuo Hwang, Paul B. Pedersen, and Ikou Daibo. Westport, CT: Praeger, 2003, xi+333pp. ISBN: 0-313-32463-8, ISSN: 0736-2714 [hardcover], US$64.95.

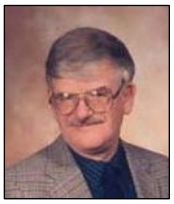

Of all the specialties in the realm of psychology one would expect social psychology to be most cognizant of the pervasive influence of cultural meaning systems and practices on human behavior. Surprisingly this is not the case for American psychology as, for instance, a review of the authoritative *Handbook of Social Psychology* (Gilbert, Fiske, & Lindzey, 1997) demonstrates. By and large, American social psychologists have attempted to construct a "universal" social psychology while conveniently ignoring the fact that both their theoretical constructions and their data are overwhelmingly western in origin.

In recent years, however, a group of mostly East Asian psychologists, with the sympathetic support of some western cross-cultural and cultural psychologists such as Harry C. Triandis, John W. Berry, and Patricia M. Greenfield, have attempted to create a distinctive Asian social psychology. As a part of this effort, the Asian Association of Social Psychology (AASP) was founded in 1995 and held its first conference that year in Hong-Kong. Under the leadership of the Hong Kong based psychologist Kwok Leung, a book series was established under the title of *Progress in Asian Social Psychology*. The volume under review is the third one in the series. It mostly contains papers presented at the 1999 Taipei biannual AASP conference, which was attended by more than 300 scholars from thirteen Asian countries and eight non-Asian countries. Together with the two earlier volumes in the series (Leung, Kim, Yamaguchi, & Kashima, 1997; Sugiman, Karasawa, Liu, & Ward, 1999), the book can help us gain an overview of recent efforts in Asian social psychology as presented by some of its most influential practitioners.

Let us first take a look at the editors and contributors of the volume. They are mostly associated with institutions located in East Asian countries such as Japan (9 contributors), Taiwan (7), South Korea (6), Hong Kong (5), and Singapore (2 plus 1 Singaporean now living in England), United Sates (2), India (1), and New Zealand (1, a self defined "Chinese-American New Zealander"). The book's senior editor, Kuo-Shu Yang, is a research fellow at the Academia Sinica in Taipei and arguably the foremost living Chinese psychologist. Perhaps for political reasons, psychologists from the People's Republic of China are not represented in the volume, except for the five contributors living in the special enclave of Hong Kong.

The book is divided into five parts focusing, respectively, on conceptual perspectives, socialization in family and school, achievement and achievement motivation, group and intergroup dynamics, and deviant behavior and rehabilitation. The contributions in Part I explore different trends toward the indigenization of psychology in India (Jai B. P. Sinha), Korean self concepts in contrast to western concepts (Sang-Chin Choi and Kibum Kim), and "benevolent" (paternalistic) authority structures in Confucian-heritage societies (James H. Liu and Shu-Hsien Liu).

Part II contains a chapter on the beneficial and harmful effects of filial piety (Kuang-Hui Yeh), a cross-cultural comparison of parental beliefs about shame and moral socialization (Heidi Fung, Eli Lieber, and Patrick W. L. Leung) and a discussion of Chinese views of education (Wen-ying Lin). The three chapters in Part III continue the heavy emphasis of many of the earlier chapters on such Confucian themes as educational achievement, early socialization toward moral responsibility, "benevolent authority," interdependent self-constructions, and the linkage between generations through the moral glue of filial piety. Eli Lieber and An-Bang Yu compare achievement motivation in Taiwan and the United States, Weining C. Chang and Lilian Quan analyze the impact of collectivism on the motivation to achieve in Singapore, and Uichol Kim and Young-Shin Park disect success attributions among Korean students and adults.

The four contributions to Part IV trace the dynamics of behavior within and between groups. Asako Miura analyzes communication styles and performance in face-to-face and computer-mediated group brainstorming, Fumio Murakami discusses the themes of equity and interpersonal harmony in the context of reward allocation as an instrument for group management, Tomoko Oe and Takashi Oka report an experiment on effective and ineffective strategies to suppress stereotypes, and Anna Lim and Colleen Ward's experimental study indicates that Singaporean Chinese working in the private sector had more favorable perceptions of a (fictional) American employee than a matched employee from the People's Republic of China.

The remaining three chapters in Part V focus on problem behavior and conceptions of rehabilitation. Kye-Min Yang, Hyun-hee Chung, and Uichol Kim analyze the negative effects of school violence and social exclusion on South Korean adolescents and report that bullying is a serious and rapidly increasing problem in Korean schools. Akira Sakamoto, Kiyoko Sekiguchi, Aya Shinkyu, and Yuko Okada report Japanese time-series data from 1959-1990 and conclude that media coverage of capital punishment appears to augment rather than decrease homicide rates, whereas coverage of life sentences does not appear to have this augmentative effect. Finally, Sing-fai Tam, Wai-kwong Man, and Jenny Yuen-yee Ng compare Eastern and Western perspectives on rehabilitation and discuss social psychology theories relevant to the rehabilitation process.

Asian social psychology, at least as presented in this volume, refers predominantly to the social behavior of men, women, and children living in Confucian-heritage societies, and it is often based on the responses of university and high school students in short-term experiments or on questionnaires. When cross-cultural comparisons are made they most often involve the United States or some East Asian societies rather than societies located in Africa, Latin America, Europe or the western parts of Asia. In this context, one may doubt whether this social psychology is any more representative of the lives of semi-literate peasants from Turkmenistan, polyandrous women from Nepal, Pashto tribesmen from

Afghanistan, former head hunters from New Guinea, Siberian pastoralists, Russian engineers, or temple dancers from Bali than can be said to hold true for mainstream western social psychology. East Asian social psychologists, like their societies in general, appear to be preoccupied with catching up with the United States rather than with comparing themselves with their neighbors in West and Central Asia.

How distinct and original is (East) Asian social psychology as seen through the eyes of the contributors to this volume? Methodologically speaking, not very much. There is nothing in the book that would surprise a mainstream American, Scandinavian or German social psychologist. Similarly, the postmodern emphasis on qualitative interviews and interpretation, ethnographic detail, reflection on one's subjectivity and role in the research process, and steady emphasis on within-group diversity is largely missing from the chapters nor do they contain much emphasis on the advantages of interdisciplinary cooperation and multiplicity of perspectives.

Conceptually speaking, however, Asian social psychologists are beginning to break new ground. Confucian dynamism, benevolent authority structures, nurturant group leaders, filial piety, shame oriented moral socialization practices, the arts of *guangxi* (a special kind of Chinese networking skill), *renquing* (interpersonal sensitivity to social favor), interconnected and permeable indigenous self-conceptions, Indian conceptions of liberation (*moksha*), socially rather than individually oriented achievement motives, deprecating rather enhancing self-presentation strategies, and quite a few other ideas have recently been advanced by Asian and some western psychologists. When taken together, they may be used to analyze societies that are integrated by different sociocultural forces than those prevailing in African, Latin American, North American, or Islamic societies. We may add in this context that many Asian cultural practices, ideas, and family structures can nevertheless be successfully adapted to western sociocultural systems, as has become manifest in the striking educational and economic success of East Asian and Indian immigrants in the US, Canada, and increasingly, Australia. Their success suggests that the West has much to learn from the East about cultural flexibility, successful socialization practices, stable family systems, and social control of deviance.

East Asian social psychology, in spite of its tender age, has entered a successful quantitative and qualitative growth phase. Consequently, the highly selected contributions to the volume are of good quality and introduce some interesting concepts and findings. They suggest that for the first time in the history of social psychology, a critical mass of nonwestern researchers and theoreticians has coalesced and is ready to lead social psychology in new and exciting directions. Given the relentless drive of East Asian societies toward economic success together with their superior educational systems, we should not be surprised about the recent rise of psychology there. After all, psychology tends to prosper in those societies that are well-to-do, reasonably open and modern.

One may ask, however, whether the contents of this book are not pervaded by an implicit, yet powerful, form of East Asian ethnocentrism. Homo Asiaticus, as s/he appears in this volume, tends to live in an efficient and modern society located on the Pacific Rim, has grown up in a fairly small though moderately collectivistic family, speaks an East or Southeast Asian language and increasingly some English, is thoroughly literate, spends much of his/her time thinking about achievement and educational success rather than sex and aggression, is a child of the information age, and possesses a mind filled with both modern and Neo-Confucian ideas. This Homo Asiaticus, however, is unlikely to bow toward Mecca, to be veiled, or to hate the West. S/he does not speak Russian, Persian, or any number of other Asian languages, and does not live in a pre-modern or poor society.

Whereas East Asian social psychologists are thoroughly aware of scientific developments in the United States, they mostly ignore European or Latin American achievements. In this context it is hard to avoid the impression that "the dominance of psychological models internationally is determined by military and economic clout" (Moghaddam, 2003, p. 1) rather than merely by their scientific merits. Although the United States are likely to remain the only psychology superpower for some time to come, we may interpret the efforts of East Asians social scientists toward the creation of an indigenous social psychology as a bid to match the economic and political rise of their respective countries in the realm of cultural creation. Given that East Asian social psychologists are frequently aware of the political underpinnings and implications of their work, it is not exaggerated to say that *Progress in Asian Social Psychology* represents not only a scientific but also a politically significant effort. We can be certain that similar efforts will follow.

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In Memory of . . .
DR. CARMI HARARI

Carmi Harari, EdD (1920-2003)

Carmi Harari was born in New York City on December 4, 1920, the son of Dina and Ezra Harari, an actor in the Yiddish theatre. The Harari family spent some years in the Holy Land in the 1920s, then returned to New York State, where Carmi became a union organizer in the 1930s. Carmi entered the City College of New York and, after serving in the U.S. Air Force (1943-1946), completed his BSS at CCNY (1946), his MA at New York University (1947), and his doctorate in psychology at Teachers College of Columbia University (1968).

For over 30 years Carmi served as Executive Director of the Humanistic Psychology Center of New York, while also teaching at several colleges. He was a noted psychoanalyst, clinical and forensic psychologist, disability examiner, and a prolific author who lectured world-wide on peacemaking and political psychology. Carmi was an officer or active member of a dozen international psychology groups including the American Psychological Association, where he served on the APA Council of Representatives (1974-94), Committee on International Relations in Psychology, and was an APA Fellow in eight divisions: clinical, psychotherapy, independent practice, social issues, humanistic, peace, group, international.

As a family man, Carmi married Clara Shoshen in 1942, and they had two daughters. After divorce, Carmi wed psychologist Zaraleya Kurzweil in 1979. Carmi's two daughters, Karen Tarnofsky and Michelle Kelly, remember him warmly: "He was a wonderful father, very giving and caring to us. He had high standards and helped us achieve our potential with loving guidance. He wanted us to be the very best we could be. As children, we spent many summers traveling, and shared some unforgettable adventures. We visited Israel several times to Carmi's

family and mother Dina, and also Mexico to Carmi's father Ezra. When his two daughters married and moved west, Carmi often visited us and his four grandchildren--Alyssa, Emily, Phillip and Jacob." Carmi passed away peacefully on July 19, 2003 at age 82. A memorial service was held at his home with Zaraleya in New City NY.

At the August 2003 APA meetings in Toronto, officers of the International Division expressed their admiration for Carmi's distinguished work in psychology, and sympathy with his family on his passing.

Submitted by:
Karen H. Tarnofsky, Michelle Chino Kelly
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SIGHTINGS

2004 Midwinter Meeting of Division 52
Eastern Psychological Association
April 18, 2004
Washington, DC

Arthur Freedman (standing), Ann O'Roark and Paul Lloyd, facilitating the Visioning/Organizational Renewal Session

Division 52 Board members hard at work

The Division 52 Board taking a break from the meeting to pose for the camera

International Psychology Symposia
At the 2004 Eastern Psychological Assertion
April 17, 2004
Washington, DC

Photo 1: Division 52 Officers, Chairs, and Guests soon at the International Psychology symposia at the 2004 Eastern Psychological Association

Photo 2: Division 52 Officers, Chairs, and Guests soon at the International Psychology symposia at the 2004 Eastern Psychological Association

112th Annual Convention of the American Psychological Association

July 27 – August 1, 2004
Honolulu, Hawaii

Division 52 Board Meeting on July 27, 2004

Past-Presidents of Psi Chi at Florence Denmark's Reception

Photo 1: Slide presentation at the Division 52 Hospitality Suite, Honolulu Hawaii (July 2004)

(From left to right): Richard Velayo, Uwe Gielen, Paul Dukes, Anthony Marsella, and Weihua Niu.

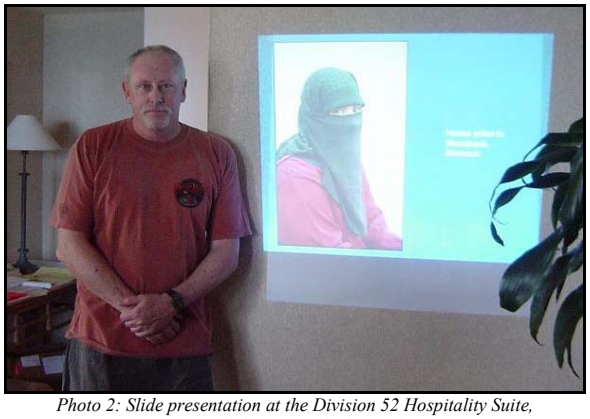

Photo 2: Slide presentation at the Division 52 Hospitality Suite, Honolulu Hawaii (July 2004)

Dr. J. Groebel presenting at the Division 52 Hospitality Suite.

(From left to right): Ana Laura Comunian, Juris Draguns, Anthony Marsella, and Uwe Gielen

Dinner with the staff of Lawrence Earlbaum and Associates

Student Committee Group meeting with Richard Velayo (2004 Division 52 President)

(From left to right): Noel Quintero, Florence Denmark, William Masten, Anie Kalayjian, Giuseppe Sottile, Harold Takooshian, and Mei Jiang

International Congress of Psychology Convention

August 2004

Beijing, China

Henry David, Ph.D. at dinner at the International Congress of Psychology in Beijing. Dr. David I organized this event on behalf of the World Federation for Mental Health Committee on Responsible Parenthood.

Some attendees of the International Congress of Psychology in Beijing (including Nancy Russo and Susan Pick, and Henry David)

MISCELLANEOUS

4th ITC International Conference Equitable Assessment Practices: Building Guidelines for Best Practices

The International Test Commission (ITC) held its fourth international conference, *Equitable Assessment Practices*: *Building Guidelines for Best Practices*, October 7-10, 2004, at the College of William and Mary.

The purpose of this conference was to highlight advancements for developing and using tests and assessment data in a manner that helps ensure fairness for all individuals, regardless of age, gender, race/ethnicity, and exceptionality. The conference participants discussed issues related to equitable assessment practices and fairness in testing and offered skill-building training in assessment and psychometric practice. Pre-conference assessment and measurement workshops and conference presentations highlighted recent advances in theory, research, and practice that promote equity to those who take tests, those who use test results, and those engaged in the business of test development and distribution.

More than 150 participants came from five continents and 15 countries. The conference was co-chaired by Drs. Bruce A. Bracken and Thomas Oakland, and hosted by the Center for Gifted Education.

International conference keynote speakers included David Bartram (SHL Group, United Kingdom), Fanny Cheung (The Chinese University of Hong Kong), Elias Mpofu (formerly of Zimbabwe, now Pennsylvania State University, USA), and Robert Sternberg (Yale University, USA)

Invited conference workshops included such topics as adaptive behavior, intelligence, differential item functioning, personality assessment, and neuropsychology, executive functioning, and structural equation modeling. Workshop presenters included Barbara Byrne, Peter Isquith, Elizabeth Lichtenberger, Thomas Oakland, Hector Ochoa, Gale Roid, Robert Stern, Lawrence Weiss, and Bruno Zumbo.

Submitted by:
Harold Takooshian, Ph.D.
Past President, Division 52
Fordham University

5th Conference of the International Test Commission "Psychological and Educational Test Adaptation Across Languages and Cultures

The 5th Conference of the International Test Commission "Psychological and Educational Test Adaptation Across Languages and Cultures: Building Bridges Among People" will be held in Brussels, Belgium from July 6 to 8, 2006. The main goal of the conference is to bring together experts on the topic of test translation and adaptation theory and practices with researchers, educators, psychologists, policy experts, and testing specialists for the purpose of sharing insights, guidelines, and research findings. The conference program will consist of invited lectures, workshops, symposia, paper sessions, and posters. Topics that will be on the program include presentation of the 2nd edition of the ITC guidelines for test adaptation, advances in test adaptation methodology, approaches to testing validity invariance over language groups and cultures, test ownership and adaptation, and international comparative studies of educational achievement. Applications of test adaptation advances will be broad to include the educational, industrial, and clinical fields. More information about the conference can be obtained by writing itc2006@psp.ucl.ac.be or by going to the conference website at http://www.psed.ucl.ac.be/itc2006.

Submitted by:
Thomas Oakland and Bruce Bracken

U.N. Psychology Graduates

Psychologist Anthony DeLuca is the Rector of Ignatius University, Dean of the International School of Mental Health Practitioners (ISMHP) and, since 2004, Ambassador for the Republic of Kyrghyzstan to the United Nations. In 2004, five United Nations personnel completed a series of psychology courses that ISMPH offered at the United Nations: Robert Afriyie, Adonia Ayebare, Ha Chan-Ho, Margardida R. Izata, Cyril N. Thomas. In August of 2004, officers of Division 52 joined several United Nations personnel in a ceremony at Rev. DeLuca's villa in Staten Island, NY, where the five U.N. graduates were presented with diplomas and certificates of recognition. For details on psychology course offerings at the United Nations in 2005, contact Rev. DeLuca at ignatiusu@aol.com

Rev. DeLuca (far left) with U.N. graduates and officers of Division 52 [Richard Velayo (in far right), Harold Takooshian, Anie Kalayjian, Elizabeth Messina]

UN graduates and other attendees

Submitted by:
Harold Takooshian, Ph.D.
Past President, Division 52
Fordham University

Application for Mental Health Professionals to Volunteer in the South/Southeast Asia Disaster

[This form may be downloaded as a WORD file at http://webpage.pace.edu/rvelayo/DisasterApplicationforMentalHealthProfessionals.doc]

December 31, 2004

Dear Colleagues:

We were all deeply affected by the news of the terrible disaster that struck 11 countries, from Indonesia to Somalia. Certainly, our thoughts and prayers are with all the victims as well as the survivors of the disaster and their loved ones. May our positive energies, thoughts and consolation be with them and us all at this time.

With this letter we are seeking donations to help fund our disaster relief efforts. Kindly send your checks to: Association for Disaster & Mass Trauma Studies, which is a not-for-profit NGO, with 501c3 status. All your donations are tax deductible.

In addition, if you are a professional who has done any disaster outreach addressing mental health and Psychosocial aspects of disasters, kindly complete the application and send it back to me at E-mail: kalayjiana@aol.com.

Much gratitude and appreciation,

R. Anie Kalayjian
Chair, Committee on Trauma and Disaster
APA Division 52

Name: _____

Address: _____

City: _____ **State:** _____ **Zip code:** _____

Contact Information: **Home:**_____ **Fax:** _____ **Mobile:** _____ **Office:** _____ **E-mail:** _____

Degree: _____ **Year granted:** _____ **License:** _____

Specialty: Child: _____ **Adolescence:** _____ **Adult:** _____ **Older adult:** _____

Affiliation: _____

Past disaster experience: **Year(s):** _____ **Countries:** _____

Types of disaster:_____

I am a: ___**Female** ___**Male**

My age is: ___**a. under 30** ___**b. 30-39** ___**c. 40-49** ___**d. 50-59** ___**e. 60-69**

1. I need to be notified:
- **A. At least 2 weeks before my departure:**_____
- **B. One month before my departure:**_____
- **C. Two months before my departure:** _____

2. I can volunteer for: ___**a. Two weeks** ___**b. Three weeks** ___**c. One month**

3. I speak the following languages (kindly specify languages used in the 11 countries impacted by this disaster):
_____

4. I am available the following weeks: _____

5. Do you have considered yourself experienced in group therapy? Yes ___ **No** ___

6. Kindly describe in two sentences the reason you wish to volunteer:
_____
_____
_____

7. What was your initial feeling when you heard about this disaster, and what did you do to alleviate your feelings?
_____
_____

Kindly complete and E-mail to Dr. Kalayjian: kalayjiana@aol.com, fax: 201 941-5110

[This poster may be downloaded as a WORD file at http://webpage.pace.edu/rvelayo/CIRPposter.doc]

CIRP: 60 years of international psychology **

Sielkunde [1] PSIKOLOGJI [2] የሥነ ፡ ልቡና ፡ ትምህርት [3] علم النفس [4]

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Call for Announcements to the Division 52 "Announce-only" Listserv

The Division 52 "Announce-only" listserv is available to its members and affiliates only and is distributed once a month. Submit announcements regarding international issues and topics of interest to the Division to rvelayo@pace.edu

For the latest announcements, notes, and news from the Division of International Psychology…

Go to …
Division 52's
ANNOUNCEMENTS WEBPAGE
at
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SUBMISSION INSTRUCTIONS

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (Division reports, academic articles, etc.) can be up to 1500 words and should be submitted by email to Dr. Harold Takooshian at takoosh@aol.com.

Submission deadlines:
Spring issues -- March 31
Summer issues – June 30
Fall/Winter issues -- December 31

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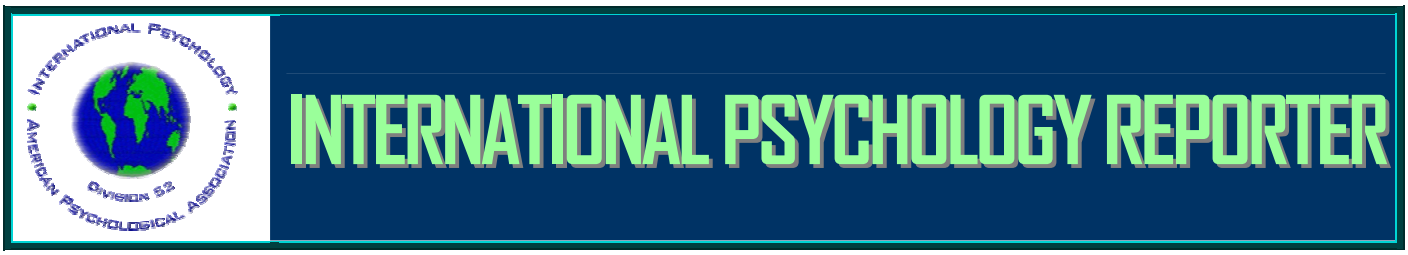

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International Students at American Universities: Fostering Sensitivity

Richard S. Velayo
Pace University

Given the increasing number of foreign-born students in American universities, it is important for instructors to take into account the variety of cultures and varying motivations of international students. Instructors must become more skilled and cognizant of the obstacles that international students face that go beyond language differences. In this article three important areas are presented to help foster instructor sensitivity and enhance the multicultural and multinational classroom experience: interpersonal interactions, approach to assignments, and response to hierarchy. Teaching tips are presented within each of these areas.

Key Words: classroom, teaching tips, pedagogy, multicultural, international, diversity

Introduction

As an academic psychologist, originally native to the Philippines, I have found the number of international students in American universities and colleges astonishing. Over the years, I have observed the deep commitment on the part of universities and individual professors to diversity in the student body. Yet, it is important that pedagogues understand that, within a multicultural classroom setting, multiple assumptions about academic conventions are operating on the part of both faculty and students. Without the awareness and sensitivity to these assumptions, they can become obstacles to productive class participation and learning (e.g., Wulff, 1987; Lee, 1997; Collingridge, 1999, De Vita, 2000). I believe that it is incumbent on us, as teachers in a multicultural classroom setting, to understand these difficulties in order to help all students become fully engaged in learning.

When taking into account the obstacles faced by international students, instructors tend to focus primarily on language differences. However, there are other salient factors that deserve equal attention. In this article I shall discuss three important areas where our sensitivity to cultural difference can enhance the classroom experience: interpersonal interactions, response to hierarchy, and approach to assignments. Although these considerations tend to apply to cultural diversity in the broad sense, my focus here is on the international student.

Interpersonal Interactions

Outside of the U.S., the general pedagogic model in university and college is one in which students primarily attend formal lectures given in large lecture halls and in which there tends to be very minimal interaction between instructors and students in or out of class. In Japan, for example, oral class participation is not a significant part of one's course grade. Understandably, a new Japanese student may feel alienated in a large management class, where a significant percent of the grade is determined by participation. Similarly, a Korean student may feel trepidation in a class where students are expected to make oral presentations. In other countries, such as France, students in the most highly esteemed engineering schools graduate with an extensive theoretical background but may be lacking in experimental or practical work. As a result, international students can find it difficult to adapt to the interactive dynamic that has become a key component in many institutions of higher education in the United States (US).

To implement inclusive approaches to communication and to foster active participation on the part of all students in a culturally diverse class, it is important to identify key issues concerning the learning experience of international students (De Vita, 2000). International students often need time to learn customs associated with classroom discourse. For example, there are evident differences in the exchange patterns in oral discourse between international and US-born students (Tapper, 1996). In most other countries, it is inappropriate for students to state their opinions to their professor. In contradistinction, in the US we generally expect students to readily express their opinions. At the same time, however, we also expect them to know how to soften disagreements by using cushioning remarks like "I see your point, but,..." These are subtle forms of communication that are not

Richard S. Velayo, Ph.D is an associate professor of psychology at Pace University. Dr. Velayo is past president and fellow of the American Psychological Association's Division of International Psychology, past president of NYSPA's Academic Division, vice-chair of the New York Academy of Sciences' Psychology Steering Committee, the fellows chair of the Society for General Psychology (APA), and a non-government organization representative (NGO) of the International Council of Psychologists to the United Nations. His scholarly interest is in the multicultural approach to the classroom and the pedagogical use of multimedia and internet technology.

readily apparent and can take time for a foreign student to recognize and master. In addition, it is common for international students to feel self-consciousness about their accent and their lack of verbal fluency, or to have a fear of being wrong or of making a mistake.

Here are some suggestions on what instructors can do to address these issues and provide encouragement to their foreign students:

- *If the classroom context allows, use different kinds of questions to stimulate interaction.* For example, asking students "What in your opinion might work here?" or "Can you guess how we can find out the answer to this?" Such solicitations may be less intimidating than the more direct approach of asking "What is the answer to this question?" In a way, you are providing an opportunity for inquiry or dialogue without the pressure of having the student necessarily provide the "right" answer.
- *Try to wait up to a few seconds (10 at the most) after asking a question before moving on.* Americans tend to become uncomfortable with long pauses. We often rush in to fill in such pauses. However, when international students are willing to make contributions, they may need extra time, so giving them a few seconds can be immensely helpful.
- *Clarify what the student means.* Expressions like "So, do you think that..." and "If I understand you, you're suggesting that..." provides the opportunity to check for mutual understanding, not to mention enhanced participation.
- *Instead of waiting for volunteers to respond to each question, "cold call" on international students who are conspicuous for their lack of participation.* This applies to situations in which certain students may welcome an invitation into the discussion but lack the confidence to initiate it. This approach should be done carefully so that students can feel that they can "pass" penalty-free when they have nothing to contribute.

Approach to Assignments

While subject matters that focus on quantitative problems or data manipulation are relatively self-explanatory in approach, the content and format of many other assignments may not be. It is particularly important that guidelines for oral and written assignments be made explicit, if they are to be helpful for international students.

Many international students may not know how to structure and deliver an effective oral presentation that conforms to our expectations. Unless explicit guidelines are provided international students are left to wonder what kind of information effective American speakers typically include in an introduction to a 20-minute research presentation; or what constitutes an effective visual presentation. We need to provide them answers that are clear and to the point. We should especially make great efforts to explain the importance of body language, sincerity, and enthusiasm in making effective presentations.

Similarly, instructors should demonstrate in their handouts the precise, organized, and thorough approach that we expect to see in students' written assignments. Many foreign students may not fully understand how to structure an argument memo or a research paper for an academic audience in the U.S. For example, Americans highly favor placing the author's main point or opinion in the introductory portion of a document and using the succeeding pages to support that opinion. This is, however, not a universal approach to writing. In fact, it is contrary to what many well-educated European students have been taught which is to "save the best for last." Therefore, our expectations must be explicit regarding the format as well as the content of written work and oral presentations. Where appropriate, we should provide tangible models which students can use, such as journal articles and videos of past presentations. This will help in exhibiting the characteristics we seek in their work.

Another area that must be addressed explicitly is the role of academic honesty in assignments. English language cultures have a particularly rigorous approach to protecting intellectual property. In many other cultures, however, individual and independent expression of ideas is not greatly valued; instead, students are expected to honor respected authorities by repeating their contributions verbatim. In addition, standard documentation conventions are not widely used in all intellectual communities. Students from other cultures may have difficulty understanding or accepting our concept of plagiarism and the intricacies of documenting sources of information. Letting our students know that we are aware of such differences and working with them to understand these expectations can help prevent such academic problems from occurring.

Response to Hierarchy

International students, especially those whose cultures possess strict linguistic and behavioral codes, often express concern about how to operate within the hierarchical system typical of many U.S. educational institutions. These difficulties stem, in part, from the grammatical differences that exist between English and other languages. Thus, one of the difficulties that arise is that the English language is unusual in that it does not have explicit grammatical forms for indicating hierarchy. Whereas most other languages have specific pronouns and forms of address for people of different status and ages, in English the word "you" is used to refer to virtually everyone — peers, parents, professors, strangers, employers, to name a few. On the other hand, to indicate

formality English speakers use complex sentence structures, such as, "I was curious if it would be at all possible...," instead of "Can I..." In addition, when speaking English rising intonation on one word may indicate an acknowledgment of hierarchy in one context but not in another (Pickering, 2001). These different modes for expressing formality are certainly a challenge for new international students, and can result in difficulties in navigating the hierarchical structure of the typical American classroom.

I have also noticed in American universities, there is much more subtle negotiation of hierarchy in formal classroom settings, than international students are likely to have encountered in their home countries. Imagine a class in which the professor tolerates consumption of food and beverages in the classroom, or informal attire (e.g. tank tops and shorts.) This level of informality can be startling, even offensive, to new students from countries such as Mexico and Thailand. It may seem highly disrespectful of the instructor and, as a result, may affect the newcomers' attitudes towards their peers and their instructors. In trying to adjust, international students may exhibit inappropriately passive or inappropriately bold demeanor.

To further confuse the situation, instructors vary in their levels and expressions of familiarity. Some conduct themselves, their classes, and their interactions with a degree of formality that may be comfortingly familiar to some international students. Other instructors regularly sit on desks, swinging their legs as they talk or listen. They may be on a first-name basis with students, and many are available for help, or enjoy friendly conversations outside of class. The level of comfort is such that the better teachers can admit their lack of knowledge in class, not a common occurrence in many countries.

Again, many problems can be avoided by anticipating potential difficulties, by explicitly acknowledging differences in ones own styles and motivation, and by stating expectations explicitly in matters such as terms of address and classroom behavior.

Realizing the Potential of the Multicultural Classroom

The cultural diversity on many college campuses is an exciting resource, which, if fostered sensitively, can enrich the intellectual lives of us all. As teachers, we can be instrumental in creating a multicultural environment that truly benefits everyone. International students who feel their differences are understood will be more likely to engage fully in their classroom experience; they will feel more comfortable pursuing questions about other aspects of their environment. In addition, explicit discussion of these issues in and out of class will have the added benefit of heightening the awareness of American students to different cultural assumptions in academic life.

The psychological status of international students — how they perceive and feel about themselves and how they are viewed by their hosts — is an essential step in developing effective pedagogical strategies for enhanced interpersonal interactions, coping with class requirements, and dealing with behaviors deemed appropriate in the classroom. It is therefore important that we learn to spend some time in the first week of classes discussing with our students our motivation for structuring classroom dynamics the way we do. Throughout the term, we should provide explicit guidelines for any area in which a different cultural assumption may affect the international student's performance. These guidelines allow international students to "play the game" with the same rules as the American students.

If those of us, who teach, make a concerted effort to converse occasionally with international students before or after class and express our curiosity about, or awareness of, some of the differences between our educational culture and that of other countries, we will go a long way toward increasing their comfort levels and improving the international student's overall educational experience.

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Visual and Auditory Elaborative Imagery: Modality Effects on Paired-Associate Learning

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This study examined the effects of imposed elaborative imagery (visual and auditory) on the learning of paired-associate concepts presented in two different modalities. Participants assigned to conditions with imposed visual elaborations yielded significantly higher scores on a Concept Pairs Memory Test than participants assigned to conditions with auditory elaborations, or no elaborations. Findings are consistent with the dual-coding theory, which recognizes superiority for high-imagery items in memory tasks. Furthermore, the findings suggest that visual elaborative imagery is more salient than auditory imagery in depicting an identical relationship between the two items of a concept pair and, therefore, higher in imaginal value. The application of the dual-coding theory to elaborative learning, and the educational implications of imposed elaborative learning are discussed.

In an effort to improve the comprehension of material learned in classrooms, educators often use elaboration strategies to illustrate and reinforce material. Previous findings suggest that when new information is presented in conjunction with relatable concepts (verbal or visual), the information becomes more salient (e.g., Willoughby, Wood, Desmarais, Sims, & Kalra, 1997; Wood, Pressley, & Winne, 1990). An example of such a strategy is elaborative imagery. Imagery is frequently incorporated in educational instruction to illustrate the studied material more effectively. Visualizing described information is often helpful, especially when the material is unfamiliar to the learner (Wood et al., 1990). Therefore, concrete, or visually-oriented, descriptions are useful when introducing new material.

The *concreteness* of an idea, or the ease with which it may be visualized, is believed to affect its salience. This represents the underlying assumption of the *dual-coding theory* (Paivio, 1976), which states that concrete ideas have both visual and verbal meaning (e.g., tree), and are therefore more easily remembered than abstract ideas, which are only processed verbally (e.g. ,loyalty). This theory has been supported in many studies, and it has been applied to a variety of learning tasks (e.g., Paivio, Walsh, & Bons, 1994; Mayer & Anderson, 1991; Sadoski, Goetz, & Fritz, 1993). The dual-coding theory suggests that there are different memory systems regulating incoming verbal and nonverbal stimuli (Heil, Rosler, Hennighausen, 1994). Verbal information is encoded in *logogens*, which are single characteristics of verbal information, and each must be processed individually. Likewise, visual information is encoded in *imagens*, which are comprised of visual traits. These may be processed many units at a time. Johnson, Paivio, and Clark (1996) found that stimulus presentation modality (visual and verbal) are most appropriately applied to the corresponding internal systems. It is suggested that this distinction between verbal and visual stimuli influences memory retention differences.

The dual-coding theory suggests that the concreteness of an idea alone may affect its salience. However, Marschark and Hunt (1989) found that in tasks of paired-associate learning, concrete items were only better associated when imagery was used to relate the pair in a meaningful way. Participants were presented with concrete and abstract pairs, and were then

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asked to write down a short phrase, or a *mediator*, associating the two items. During a recall test, participants were either provided with the mediator or one of the items of the pair, and were then asked to write down the corresponding item(s). A concreteness effect was only observed if the mediator was provided, suggesting that when elaboration is prevented, differences between concrete and abstract pairs are not present. For example, the concrete word, "tree" will only be more salient than the abstract word, "loyalty" if the learner is able to visualize certain characteristics of a tree (e.g., type of tree, dimensions of the tree, color of the leaves, etc.) While this finding threatens the dual-memory construct, it provides evidence for the influence of elaborative imagery on memory.

It has also been suggested that the vividness of imagery influences its effectiveness. A study by Dewhurst and Conway (1994) found that concrete items are better remembered when presented pictorially, rather than textually. Participants viewed pictures and text in succession. After a one-hour delay, they viewed a presentation containing both familiar and unfamiliar items, and were instructed to indicate whether they had seen each item during the original presentation. Pictorially-presented items were more accurately recalled. Similarly, McDermott and Roediger (1994) found that pictorial representation of concrete items produced greater priming effects than textual representation of identical items. Though verbal communication allows for general representation of concrete ideas, visual representation supplies the learner with specific traits, such as color and size, in order to create a more significant memory (Willoughby et al., 1997). For example, while relaying similar information, a description of a tree may not provide as much information as a photograph. Likewise, a direct experience with an actual tree may provide more information than a photograph. It is therefore conceivable that stimuli differing in imaginal value will have varying significance to the learner.

Imagery is found to be effective in elaborating on presented information. Elaboration strategies give meaning, salience, and interest to information in order to properly store, and easily recall the material. Different memory tasks are facilitated by different elaboration strategies (Willoughby, Wood & Khan, 1994). Strategies using imagery tend to be most beneficial when applied to unfamiliar material. A study by Willoughby et al. (1997) tested elaborative imagery against elaborative interrogation. While the use of imagery merely requires participants to perceive the elaboration, elaborative interrogation requires participants to answer questions about the new material. The success of elaborative interrogation when applied to familiar material is attributed to a large base of preexisting knowledge and new associations made with existing networks. However, imagery is believed to be more effective when elaborating on new information because attention is drawn to the item itself, rather than information related to the item (Wood et al., 1990).

Hypothesis

The effectiveness of imagery as an elaboration strategy has found support in previous studies, and has been found to be most influential when applied to unfamiliar material. Conceivably, concrete ideas may be communicated either visually or verbally; a picture of a scene may provide comparable information to a detailed description of that picture. It may not, however, be as salient. While previous research has focused mainly on the appropriateness of elaborative imagery when applied to various learning tasks, the focus of the current study is to determine whether the modality in which imposed elaborative imagery is introduced influences its effectiveness as a learning strategy in a test of paired-associate learning. It is hypothesized that participants who receive imposed visual elaborative imagery during the study phase of the presentation will correctly recall more pairs than participants who receive imposed auditory elaborative imagery of identical information. No specific predictions are made based on the concept pairs' presentation modality.

Method

Participants

Thirty-seven participants were recruited for this study. Participants included undergraduate students from two Northeastern urban universities, and those who have either finished college or are currently not attending school. Ages ranged from 18 to 60, and with the exception of participants under 18 years (for simplification of authorization), no willing participant was excluded due to age. Ninety percent of participants were between 20 and 56 years of age, with a mean of 29 years, and the majority of participants were female (67.6%). Eight percent of participants had obtained only a high school diploma. Forty-one percent of participants had acquired some college credit. Twenty-four percent had obtained a college degree. Eleven percent had some graduate school experience, and 16% had obtained a graduate degree.

Design

This study comprised a 2 X 3 between-subjects factorial design. Independent variables included modality of concept pairs (visual and auditory) and modality of elaborative imagery (visual, auditory, and no

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elaborative imagery). The dependent variable was the number of correct responses on a test of paired-associate learning. Participants were assigned to one of six conditions.

Materials

As a test of paired-associate learning, the Concept Pairs Memory Test (Velayo & Quirk, 2000) was altered, and used with permission from the author. The original version of this test consists of 40 concept pairs presented in timed succession (10 second duration per slide) using PowerPoint. The pairs are presented in one, or any combination of two modalities (pictorial, textual, auditory). During the testing phase, thirty single items are presented in the modality(s) of the original presentation, and participants are asked to recall the corresponding item.

The version of the Concept Pairs Memory Test used for this study consists of 20 concept pairs presented in either visual or auditory form. Figure 1 provides an example of a concept pair included in a condition featuring a visual presentation. The corresponding verbal narration (included in a condition containing auditory presentation of concept pairs) is heard as "teddy bear" and "teapot." Following each concept pair, an elaboration on a possible relationship between the pair is provided through the use of *imposed elaborative imagery*. This provides the viewer with information regarding a potential relationship between the two items of the concept pair, and is presented in either visual or auditory form. For conditions containing imposed visual elaborative imagery these slides contain photographs of the items of the concepts pairs interacting, as can be seen in Figure 2. For conditions containing auditory elaborations, these slides feature blank screens and auditory narrations describing the interactions (e.g., "The teddy bear is being served tea from a teapot.") Control conditions present the concept pairs, followed by blank slides, containing no elaborative imagery. Including blank slides, all conditions view 40 slides during the presentation, and each is displayed for 10 seconds. Following this presentation, a testing phase presents one item of each concept pair (in the modality of the original presentation) with instruction to recall the corresponding item. Each testing slide is also viewed for 10 seconds. This version of the Concept Pairs Memory Test was organized specifically for this study.

FIGURE 1.

An example of a concept pair viewed by participants assigned to a condition with visual presentation of pairs

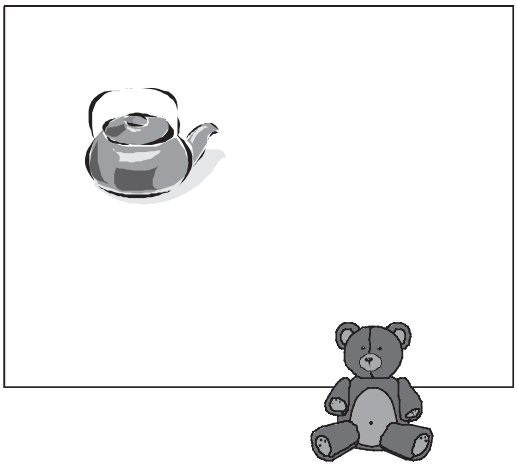

FIGURE 2.

An elaboration of a potential relationship between the two items of the pair, viewed by participants assigned to a condition with visual elaborative imagery

Procedure

Participants were recruited individually on campus, or participation was arranged based on individual availability. Participants read and signed detailed informed consent forms; no deception was used in this study. They were then randomly assigned to conditions for the Concept Pairs Memory Test. Each participant was placed at a computer containing PowerPoint software. Headphones were attached to computers, and given to participants who were assigned to conditions containing auditory stimuli. The Concept Pairs Memory Test was then administered. During the testing phase participants viewed/heard one item of each pair and reported the corresponding item to the

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experimenter. Responses were recorded by the experimenter, and later scored. Following the test, participants read and signed a debriefing form, explicitly describing the purpose of the study.

Results

Performance on the Concept Pairs Memory Test was analyzed using a 2 X 3 analysis of variance (ANOVA) with presentation modality (visual and auditory) and elaboration modality (visual, auditory, and no elaboration) as the independent variables, and scores on the concept pairs test as the dependent variable. The mean and standard deviation for each condition are organized in Table 1. Results of this analysis indicated a significant main effect for modality of imposed elaborative imagery, $F(2, 68) = 8.16$, $p = .001$, $h^2 = .35$. No significant main effect was found for modality of concept pairs presentation, $F(1, 35) = .27$, $p > .05$, and no interaction effect was found, $F(2, 68) = .48$, $p > .05$. Post hoc analyses (Scheffe) revealed a significant difference between conditions containing imposed visual elaborative imagery ($M = 18$, $SD = 2.38$) and those containing either imposed auditory elaborative imagery ($M = 10.77$, $SD = 5.16$; $p = .002$) or no imposed elaborative imagery ($M = 12.8$, $SD = 5.4$; $p = .03$). No significant difference was found between conditions containing imposed auditory elaborative imagery and conditions with no elaborative imagery imposed, $p > .05$.

TABLE 1

Descriptive Statistics for Performance on the Concept Pairs Memory Test With Respect to Experimental Condition

Conditions	*M*	*SD*	*n*
Individual conditions			
Visual Presentation			
Visual Elaboration	18.43	2.07	7
Auditory Elaboration	9.57	5.83	7
No Elaboration	12.50	7.06	6
Auditory Presentation			
Visual Elaboration	17.50	2.81	6
Auditory Elaboration	12.17	4.36	6
No Elaboration	13.20	3.19	5
Across conditions			
Visual Elaborations	18.00	2.38	13
Auditory Elaborations	10.77	5.17	13
No Elaborations	12.82	5.37	11

Discussion

The results of this experiment yielded significant findings with respect to the modality of imposed elaborative imagery. Consistent with the hypothesis, participants in conditions containing visual elaborative imagery consistently recalled more concept pairs than participants in conditions containing auditory elaborations, or no elaborations. This finding suggests that imposed elaborative imagery is more effective when using a visual rather than an auditory representation of the elaboration. No prediction was made concerning modality of concept pair presentation, and no significant difference was observed.

The results of this study expand on previous findings concerning the role of imagery in learning processes. According to the dual-coding theory, ideas of a concrete nature are more easily remembered than abstract concepts due to the availability of imaginal cues (Paivio et al., 1994). This theory suggests a strong influence of imagery on processes of perception and memory. Higher rates of concreteness have been found to increase performance on verbal tasks. Sadoski, Kealy, Goetz, and Paivio (1997) suggested that information enhanced by imagery is better encoded, and retrieved faster, than information with less imaginal value. Findings of the current study support the dual-coding theory, and suggest that imagery may vary in quality with respect to modality. While verbal narration of elaborative imagery conveyed identical information to visual depictions, and both modalities featured concrete ideas, elaborative imagery was most salient when presented visually. This suggests that different modalities encode concrete ideas with differing levels of imaginal value.

Concrete material is also viewed as easier to understand and remember (Sadoski et al., 1993). This idea is also supported by the findings of the current study. Conditions with visual elaborative imagery provided visual stimuli, which allowed participants to better recognize the proposed relationship between the two items of each pair. It is, therefore, conceivable that visually-presented elaborative imagery is more salient and more interesting than verbally-presented elaborative imagery. Likewise, Mayer, Bove, Bryman, Mars, and Tapangco (1996) found that images paired with concise, rather than lengthy text was most effective in communicating information. The authors suggested that while visual stimuli often require verbal narration, excessive verbal stimuli can be overwhelming, or distracting. This is one potential explanation for the results obtained in this study.

Current findings support and elaborate on certain beliefs about effective teaching. While the bene-

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fits of elaborative imagery have been consistently reported (Willoughby et al., 1997), the current study suggests a relevance of modality in this process as well. Effective use of elaborative imagery in an educational setting involves visual presentation, and is not comparably supported by verbal representation. Practical implications include the use of visually-presented elaborative imagery (e.g., videos) in place of verbal description of imagery when discussing concrete ideas in an educational setting. It is also suggested that pictures may supplement verbal information in textbooks, allowing for the development of more permanent memories.

The results obtained bring forth questions concerning what factors contribute to successful encoding of elaborative imagery, as well as how this may affect educational instruction. A relevant issue, though not directly explored in this study, is the influence of imposed elaborative learning on the learner's motivation. While the use of elaborative imagery seemed to provide certain advantages, it is conceivable that the utilization of passive (or imposed) learning may discourage creative processing. Future research should also examine whether the effects observed in this study would be amplified if elaborative imagery included stimuli with varying levels of imaginal value (e.g., drawings vs. photographs vs. tangible objects). Further investigation would provide greater insight into these matters.

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MESSAGE FROM THE PRESIDENT

Extending our Reach: Focal Points That Help Internationalize Psychology

Richard S. Velayo, PhD, President, Division 52

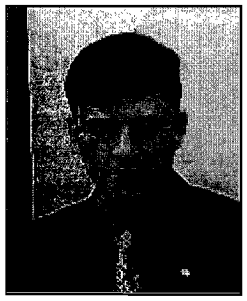

The means by which we reach out to others around the world are important factors towards our goal of making psychology a more international discipline. More importantly, our Division hopes to further develop a global community of psychologists and students with the potential to share knowledge, resources, and to help make the world a better place to live through greater understanding of our differences and commonalities.

My involvement in the Division of International Psychology during the past few years has allowed me to reflect on ways our Division can extend our reach to other psychologists (and those interested in the field) to help make psychology a more recognized and valued academic and professional field. My reflection has led me to look at four areas or focal points that may help assist us in reaching this goal: scholarship, curriculum, advocacy, networking and collaboration. Certainly, these areas are not mutually exclusive of each other and the strategies intended for one area may significantly benefit another area. These focal points are by no means meant to be comprehensive, but I believe it provides a preliminary set of plans/ideas that will likely lead to developing a more strategic approach to reaching out to our colleagues and others abroad and from within the U.S.

Scholarship

- Encourage collaborative research between colleagues from different nations. More specifically, research that take into account cross-national and cross-cultural comparisons are essential. Research studies may be especially recognized and presented at the APA conferences and other division-sponsored events.
- Provide greater access to scholarly publications and resources in psychology and affiliated fields. Many of our colleagues from abroad may have very limited access to psychological information that will allow them to be up-to-date and current in the field. In addition, many may find themselves unable to afford access to these materials. Psychological literature in many countries may be scarce, and may not be readily obtained either as a function

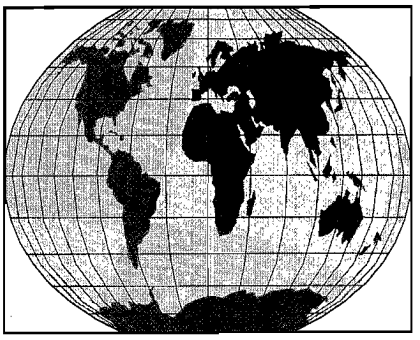

of lack of funding, inadequate facilities, and/or of logistical shortcomings. With increasing access to psychology databases via the Internet, one hopes that this will become less of a problem in the near future. Nonetheless, the inequities in hardware resources and technological expertise between countries may put those more resource-challenged countries slower at catching up with the others. Donating and/or investing in basic level resources to countries that need these most will help alleviate the disparities.
- Consider the extent in which some research findings may be generalized or even relevant in other cultures. A less ethnocentric view of psychological research may have quite a profoundly positive experience. Replication of studies in a variety of cultures and/or the impact of certain psychological models could be highly beneficial in providing for better understanding of other cultures, not to mention our own.

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(Pres. Message cont from page 1)

- Encourage meta-analytic studies that look at commonalities (etic) among nations, rather than largely focusing on differences (emic), may be a research perspective with great implications toward better cross-national and cross-cultural understanding.

Curriculum – Pedagogy and Training

- Encourage collaborative teaching among colleagues from different nations through faculty exchange programs. Institutions, departments of psychology, and granting agencies may encourage faculty to spend their sabbatical leaves and/or even short trips to other countries as opportunities to teach and give talks in institutions abroad. Explore ways in which these trips may be funded.
- Consider teaching online courses in which a good proportion of the class are comprised of students from abroad or even international students studying in the U.S. Distance learning technologies continue to become more intuitive and easy to learn and use. There is also an increasing demand for online courses from the growing population of adult learners and other non-traditional students. As a result, there is mounting interest in and demand for instructors to teach online.
- Enhance the psychology curriculum by emphasizing a more multicultural/international approach by incorporating more citations of international authors, research, and examples in the courses taught. One way to help internationalize the curriculum is to choose textbooks that have greater amount of international content and to make sure that students read these parts of the text. Another strategy would be to carry out activities or have course requirements that allow, or even require students to reflect on the multicultural perspective or application of the learned material, such as interviewing peoples about their views of psychological concepts, conducting a literature search, and comparing belief systems and practices. This approach to teaching helps emphasize the need to build understanding, empathy, and respect for cultural diversity, and thereby helping build the foundation for peace and furthering the exchange of ideas. In a world in which access to information has become faster and easier, the need to encourage international dialogue about how psychologists can contribute to the quality of life and cultures is long overdue.
- Develop a system that encourages early career psychologists, graduate and undergraduate psychology students, to become involved in international psychology, or issues of international interest. One of the best investments we as international psychologists can make is to nurture and help motivate our best students to pursue psychology as a career and to inculcate in them the value of a multicultural / international perspective. Unfortunately, psychologists tend to label themselves based on their content area of subspecialty, and as a consequence, inadvertently resulting in a

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APA Division 52 Newsletter

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Submission deadlines for:
Spring issue –March 31, 2005
Summer issue - May 30, 2005
Fall/Winter issue - October 31, 2004

International Psychology Reporter is the publication of Division 52 of the American Psychological Association

(Pres. Message cont. from page 2)
more "ethnocentric" view of the discipline and of world cultures.

Advocacy

- Get involved or at least be aware of other international psychology organizations from within the U.S. (e.g., International Association of Applied Psychology (IAAP), International Council of Psychologists (ICP), International Association for Cross-Cultural Psychology (IACCP), the International Union of Psychological Sciences (IUPsyS), International Psychology Student Organization (IPSO), and of course APA's Council of International Relations in Psychology (CIRP)].and those from abroad. The APA Office of International Affairs has a comprehensive list of all international and domestic psychological organizations.
- Psychology organizations that share a common cause may consider pooling their resources and energies towards helping make important policies that help promote greater understanding and unity among nations and cultures. In addition, psychologists can help assist in helping people in other nations at times of difficulty and turmoil.
- Affiliate with other international organizations in which psychology can contribute significantly. For example, the U.N has offices in almost every country in the world and have several committees in which psychologists may join. There is also the Red Cross, Save the Children Foundation, Amnesty International, and many more.

Networking and Collaboration

- Capitalize on the use of technologies that foster dialogue and promote collaborative endeavors. Technologies that currently exist include distance learning software, language translation devices, interactive Internet-based survey forms, databases, downloadable files, real-time chat, videoconferencing, webcasts, streaming video and other multimedia formats, etc. I encourage you to check our new Division 52 homepage at http://www.internationalpsychology.org for our Division will be incorporating many of these technologies in the near future and will continue to explore ways in which technology may help internationalize psychology. From this site, one may access http://www.psychat.org which contains language translation features that allow our users to convert e-mail, short documents, and chats to 14 different languages by far. [Thank you to our Website Technology Task Force and Mr. Giuseppe Sottile for spearheading our efforts to enhance the design and features of our homepage.]
- Develop programs and small grants that encourage psychologists of various nations to travel and share their expertise with one another in person. Division 52 currently boasts a total of 74 liaisons, each representing their own country. Seeking resources that allow us the opportunity to travel and establish closer professional relationships with colleagues abroad will not only strengthen our relationships with them but will also pave the way towards greater inclusion of international psychologists in psychological events, literature and the news, propel a multicultural approach in our understanding of the human psyche, and an enhanced appreciation for diversity.
- Develop programs for the APA convention and in other international and regional conferences (psychology and affiliated fields) that will draw attendance and interest. Our Division 52 program in Hawaii features a diversity of topics and formats that help promote the Division and its mission. [Refer to the Division 52 Announcements Page for program updates at http://webpage.pace.edu/rvelayo/announcements.htm]. International psychology organizations may extend its reach by becoming involved in many regional, national, and international events that help promote the discipline worldwide. In addition, the frequency and variety of events that we become involved in provide more opportunities for psychologists to become involved in the outreach efforts.
- Provide incentives for potential

(Continued on page 4)

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(Pres. Message cont. from page 3)
members. Make membership fees in organizations be reasonably affordable for individuals and institutions. One of the concerns many psychologists, especially many from abroad, have expressed is the financial limitations that prevent them from joining psychological organizations. Exploring ways to help increase membership is essential. One idea is by having institutional memberships or memberships based on affiliation with country-based organizations. Membership may potentially be increased by providing discounted membership dues, discounts, and/or benefits, to those who are already members of other international organizations (CIRP, IUPsyS, IAAP, ICP, etc.). One other strategy would be to look into the feasibility of having different categories and rates for membership based on a set of clear and fair set of criteria. Another strategy would be to have international organizations sponsor the memberships of certain psychologists based on established criteria.

The Division continues to explore ways to meet the challenge of internationalizing psychology. At the 2004 APA Convention in Hawaii, our Division showcases an excellent program highlighting a diversity of topics in International Psychology at its best! Moreover, this will be the first APA Convention in which Division 52 sponsors a hospitality suite for three days. [Note: Go to http://internationalpsychology.org, then click on "Announcements" for updates on the Division's APA and Suite programs]. The suite will be utilized for a number of events (e.g., receptions, conversation hours, book displays/exhibits) and as an informal gathering place for members and other APA attendees to meet and chat. Take advantage of opportunities to meet and establish connections with many international psychologists and students, and to help our Division recruit potential members.

By the way, if you just learn two words in Hawaiian, let these be "aloha" and "mahalo"! To learn more about these words, go to http://www.geocities.com/~olelo/shelties/mahalo-aloha.html

◆ **NEWS FROM DIVISION 52** ◆

2004 Convention Program for the

INTERNATIONAL PSYCHOLOGY DIVISION APA DIVISION 52

July 28 – August 1, 2004

WEDNESDAY, JULY 28

8:00-8:50 am
Symposium: *From Cambodian Killing Fields to the Streets of Lowell* Divisions: 9, 45, 48, 52 **Hilton** Hawaiian Village Beach Resort and Spa, Sixth Floor—Mid-Pacific Conference Center, Nautilus Suite 1 *Chair:* Linda Silka *Participants:* Khan Chao, Brenda Bond, Robin Toof *Discussant:* Joyce Gibson

Symposium: ***Women's Issues in International Psychology*** Divisions: 52, 9, 35, 45, Psi Chi **HCC 321B** *Cochairs:* Mei Jiang, William Masten *Participants:* Euna Oh, Thema Bryant-Davis, Anvita Madan-Bahel, Yu-Wei Wang *Discussant:* Florence Denmark

9:00-9:50 am
Invited Address—Morton Deutsch Conflict Resolution Award: ***Assessing Psychology's Contribution to Understanding and Ameliorating Violent Ethnopolitical Conflict*** Divisions: 48, 9, 35, 39, 45 **HCC 301A** *Participant:* Ronald Fisher

Symposium: ***Psicologia en Las Americas—The TIES That Bind*** Divisions: 52, 35, 45 **HCC 316B** *Cochairs:* Thomas Collins, Antonio Suck *Participants:* Barbara Collins, Antonio Suck, Elizabeth Jacob, Laura Sendra, Thomas Collins

10:00-10:50 am
Workshop: ***Group Therapy with African Survivors of Torture and Refugee Trauma*** Divisions: 49, 12, 29, 52 **HCC 308A** *Cochairs:* Adeyinka Akinsulure-Smith, Hawthorne Smith *Participants:* Adeyinka Akinsulure-Smith, Hawthorne Smith

Symposium: ***Psychological Research and Practice in Service of International Human Rights*** Divisions: 52, 9, 12, 19, 45, 48 **HCC 304B** *Cochairs:* Anie Kalayjian, Marcus Patterson *Participants:* Florence Denmark, Anie Kalayjian, Elizabeth Donovan, Marcus Patterson, Mikyung Jang

11:00-11:50 am
SYMPOSIUM: ***MULTICULTURAL ISSUES WITH JAPANESE CLIENTS---LOOKING FOR EFFECTIVE PSYCHOTHERAPUETIC INTERVENTION*** **DIVISION: 52 HCC – MEETING ROOM 304B** ***CHAIRS:*** **MASAKO MORI, TAKUYA SAITO** ***PARTICIPANTS:*** **MASAKO MORI, TAKUYA SAITO, JUNKO TANAKA-MATSUMI, AKIRA KIDO**

12:00-12:50 pm
Presidential Address and Presentation of Division 52 Awards: Divisions 52, 45, 46 **HCC Room 313B** *Participant:* Richard Velayo

1:00-1:50 pm
Symposium: ***Caring for Humanitarian Workers and Peacekeepers—How Can Psychologists Help*** Divisions: 52, 9, 18, 19, 35, 45, 48 **HCC Room 319B** *Chair:* Neal Rubin *Participants:* Joseph DeMeyer, Nora Pharoan, Neal

(Continued on page 5)

(Convention program cont. from page 4)
Rubin Astrid Stenkelberger

3:00-3:50 pm
Invited Address: ***Maori and Indigenous Education—Voice of Vision*** **Divisions: 45, 48, 52 Hilton Hawaiian Village Beach Resort and Spa, Sixth Floor—Mid-Pacific Conference Center, Nautilus Suite 1** *Participant:* **Adreanne Ormand** ***Chair:*** **Steven James** ***Discussant:*** **Ethel Tobach**

THURSDAY, JULY 29

8:00-8:50 am
Symposium: ***International Classification of Functioning, Disability, and Health—Rehabilitation Psychology Implications*** Divisions: 22, 20, 38, 40, 52 **HCC 319B** *Chair:* Susanne Bruyere *Participants:* David Peterson, Geoffrey Reed, Marcia Scherer *Discussant:* Daniel Rohe

8:00-9:50 am
Symposium: ***Emotions—Why So Similar, and Why So Different Across Cultures?*** Divisions: 8, 12, 23, 35, 39, 45 **HCC 323A** *Chair:* Louise Sundararajan, Phillip Shaver, Joseph Campos, Joseph de Rivera, Louise Sundararajan *Discussant:* David Matsumoto

9:00-9:50 am
Symposium: ***Learning from International Psychologists About Feminist and Social Justice Issues*** Divisions: 52, 9, 17, 35, 45, 48 **HCC 306A** *Chair:* Carolyn Enns *Participants:* Makiko Kasai, Kiyomi Sawano, Famima Al-Darmaki, Natacha Marie Foo Kune, Mohammed Sayed, and Sayaka Machizawa *Discussants:* Mary Heppner, Thema Bryant-Davis

Social Hour: ***Breakfast Reception for International Visitors*** Sponsors: APA Committee on International Relations in Psychology, 52, Psi Chi, International Association of Applied Psychology, International Council of Psychologists **Hilton Hawaiian Village Beach Resort and Spa, Seventh Floor–Mid-Pacific Conference Center, South Pacific Ballroom 1**

10:00-10:50 am
Poster Session: ***Women, Children, and Families—International Perspectives*** Divisions: 52, 45 **HCC, Level 1-Exhibit Hall, Kamehameha Exhibit Hall** *Cochairs:* Joy Rice, Lynn Collins

10:00-11:50 am
Symposium: ***Challenges of Being the Psychologist-Advisor to Heads-of-State in Europe*** Divisions: 13, 46 **HCC 302A** *Chair:* Ann O'Roark, *Co-chair:* Florence Denmark *Participant*: Jo Groebel *Interviewers:* Randall White, Virginia Mullin, Paul Lloyd, Uwe Gielen, Florence Kaslow *Discussants:* H. Skipton Leonard Sandra Shullman

Symposium: ***Pacific Rim Nations' Indigenous Psychologists—Peace, Conflict, and Nonviolence Issues*** Divisions: 48, 9, 18, 19, 35, 39, 45, 52 **HCC 306A** *Chair:* Ethel Tobach *Participants:* Debora Upegui-Hernandez, Juan Rapadas, Jasook Koo *Discussants:* Albert Valencia, Julie Levitt, Judith Van Hoorn

11:00-11:50 am
Poster Session: ***Psychological Issues Pertaining to Asian Populations*** Divisions: 52, 45 **HCC, Level 1-Exhibit Hall, Kamehameha Exhibit Hall** *Cochairs:* Peter Merenda, Sandra Foster

4:00 pm
Social Hour: ***Welcome Reception and International Conversation Hour*** Division: 38 **Hilton Hawaiian Village Beach Resort and Spa, Sixth Floor—Mid-Pacific Conference Center, Coral Ballroom V**

FRIDAY, JULY 30

8:00-8:30 am
Film Program: ***After Silence—Civil Rights and the Japanese Experience*** APA ad hoc Committee on Films, **HCC Room 314**

8:00-8:50 am
Symposium: ***Ka Po'e O Hawai'I—Implications for Racial, Ethnic, and Cultural Identity Research*** Divisions: 45, 8, 9, 12, 44, 52, APAGS **HCC 319B** *Cochairs:* SooJean Choi-Misailidis, Joseph Ponterotto *Participants:* SooJean Choi-Misailidis, 'Iwalani Else, Robert Bidwell *Discussant:* Joseph Ponterotto

Symposium: ***From the Chinese to Cross-Cultural Personality Assessment Inventory (CPAI)*** Divisions: 52, 8, 12, 35, 45 **HCC 327** *Cochairs:* Fanny Cheung, Frederick Leong *Participants:* Sayrui Wada, Fanny Cheung, Ellen Lin, Frederick Leong, Shu Fai Cheung *Discussant:* Junko Tanaka-Matsumi **ADD PARTICIPANT: TIMOTHY CHURCH**

9:00-9:50 am
Symposium: ***Globalization of Psychology—Travel, Research, and Professional Opportunities for You*** Divisions: 1, 52 **HCC 304B** *Chair:* Frances Culbertson *Participants:* Merry Bullock, Raymond Fowler, Florence Denmark ***Discussant:*** Charles Spielberger

Symposium: ***Psychology Around the World*** Divisions: 52, 9, 35, 45, Psi Chi **HCC 313C** *Cochairs:* Harold Takooshian, Uwe Gielen *Participants:* Juris Draguns, Karen Harutyunyan, Richard Velayo, Shahe S. Kazarian *Discussant:* Danny Wedding

10:00-10:50 am
Invited Address—Presidential Program: ***Making Public Spaces Intimate, Health Trauma-Tic Wounds: Psychology, Forgiveness, and Confronting the Present Past*** Sponsor: APA Board of Directors **HCC 312** *Participant:* Pumla Gobodo-Madikezela *Chair:* Eileen Borris

Invited Address: ***Kupa 'a I ke hahua o Hawai'I—Stand Firmly Behind the***
(Continued on page 6)

(Convention program cont. from page 5)
Foundation of Hawai'I Sponsors: Committee on International Relations in Psychology, Division 48 **HCC 305B** *Participant:* Kamana'opono M. Crabbe *Chair:* Ethel Tobach *Discussant:* Joseph Kaholokula

11:00-11:50 am
Poster Session: ***International Psychology—Cross-Cultural Perspectives*** Divisions: 52, 45 **HCC, Level 1-Exhibit Hall, Kamehameha Exhibit Hall**
Cochairs: John Hogan, Neal S. Rubin

Invited Address—2004 International Contributions to Psychology Award: ***Parental Acceptance-Rejection Syndrome: Universal Correlates of Perceived Rejection*** Sponsor: APA **HCC 308B** *Participant:* Ronald Rohner *Chair:* Abdul Khaleque

Invited Address: ***Carrying APA's Commitment Against Racism Forward Into National and International Contexts—Perspectives of Indigenous Peoples*** Sponsors: Committee on International Relations in Psychology, 9, 45, 48, Committee on Ethnic Minority Affairs **HCC 305B** *Participant:* Mililani Trask *Cochairs:* Tawa Witko, Corann Okorodudu *Discussant:* James Jackson

12:00-12:50 pm
Symposium: ***Psychological Response to the Threat of Severe Acute Respiratory Syndrome (SARS)*** Divisions: 38, 52 14 **HCC 312** *Cochairs:* Anita DeLongis, Cecilia Cheng *Participants:* Cecilia Cheng, Anita DeLongis, Weining Chang *Discussant:* Fanny Cheung

1:00-1:50 pm
Poster Session: ***Clinical and Practice Issues in International Psychology*** Divisions: 52, 45 **HCC, Level 1-Exhibit Hall, Kamehamaha Exhibit Hall** *Cochairs:* Michael Stevens, Gloria Gottsegen

3:00-3:50 pm
Conversation Hour: ***Facilitating Global Participation in Cross-Cultural Training*** Division: 14 **Hilton Hawaiian Village Beach Resort and Spa, Sixth Floor—Mid-Pacific Conference Center, Nautilus Suite II** *Chair:* Kurt Kraiger *Participants:* Richard Brislin, Dharm Bhawuk

SATURDAY, JULY 31

8:00-8:50 pm
Symposium: ***Early Intervention in Disaster Mental Health and Trauma Treatment*** Divisions: 31, 12, 48, 52, 55 **HCC 323A** *Chair:* Kathryn Dardek *Participants:* Rony Berger, Kenneth Larsen, Hayden Duggan, Bruce Lackie *Discussant:* Kathryn Dardek

8:00-9:50 am
Symposium: ***Suicidal Behavior in Adolescent, Elderly, and Asian and Pacific Islander Populations*** Divisions: 9, 12, 31, 35, 45, 52, 53 **HCC 323C** *Chair:* Caroline Sakai *Participants:* Danelle Gerona, Mavis Maiava Alaimalo, Lynn Goya, Danielle Hall, Efland Amerson *Discussant:* Caroline Sakai

Symposium: ***Violence Prevention for Children—United States and New Zealand*** Divisions: 16, 7, 9, 12, 31, 35, 37, 38, 41, 52, 53 **HCC 308B** *Chair:* Stephen Rollin *Participants:* John Kerbs, Jeffrey Sprague, Rick Lovell, Stephen A Rollin

9:00-9:50 am
Poster Session: ***Internationalization of Counseling Psychology*** Division: 17 **HCC, Level 1-Exhibit Hall, Kamahameha Exhibit Hall** *Chair:* Stewart Cooper

Symposium: ***Forgotten Natives—Identity Development of Multiracial Native Hawaiians and Psychological Functioning*** Divisions: 45, 9, 35, 52 **HCC 306B** *Chair:* Linda McCubbin *Participants:* Stephen Quintana, Kamana'opono M. Crabbe

10:00-11:50 am
Symposium: ***CIRP / APA International Initiatives*** Sponsors: Committee on International Relations in Psychology, 26, 52 **HCC 303B** *Chair:* Judith Torney-Purta *Participants:* Judith Torney-Purta, Joan Buchanan, Henry David *Discussants:* Norman Abeles, Frances Culbertson, Florence Denmark, Raymond Fowler, Wayne Holtzman, Wilbert McKeachie, Joseph Matarazzo, Charles Spielberger

11:00-11:50 am
Invited Address—2004 APA International Humanitarian Award: ***Global Variations on a Psychological Theme*** Sponsor: APA **HCC 305B** *Participant:* Chris Stout *Chair:* Lisa Grossman

Film Program: ***The Boys of Buchenwald*** Sponsor: APA ad hoc Committee on Film and Other Media **HCC 314**

12:00-12:50 pm
Symposium: ***Positive Perspectives in International Consulting*** Divisions: 13, 52 **HCC 304A** *Cochairs:* Ann O'Roark, Sandra Foster *Participants:* Virginia Mullin, Pittu Launganai, Paul Stevenson, David Dunning, Kerry Cronan *Discussant:* Ann O'Roark

12:00-1:50 pm
Roundtable Discussion: ***Feminist Perspectives in International Psychology—Building Partnerships and Creative Collaboration*** Divisions: 17, 35, 39 **Hilton Hawaiian Village Beach Resort and Spa, Second Floor—Tapa Conference Center, Tapa Ballroom 1**

3:00-3:50 pm
Conversation Hour: ***Carrying APA's Commitment Against Racism Forward in National and International Contexts—Perspectives of Indigenous Peoples*** Divisions: 9, 45, 48, Committee on International Relations in Psychology **Hilton Hawaiian Village Beach Resort and Spa, Sixth Floor—Mid-Pacific Conference Center, Nautilus Suite I**

(Continued on page 7)

(Convention program Cont. from page 6)

SUNDAY, AUGUST 1

8:00-9:15 am
Film Program: ***Senorita Extraviada—Missing Young Woman*** Sponsor: APA ad hoc Committee on Films **HCC 314**

9:00-9:50 am
Symposium: ***International Perspectives on Same-Sex Marriage*** Divisions: 44, 9, 35, 42, 52 **HCC 323B** *Chair:* Joseph Gillis *Participants:* Joseph Gillis, Michael Stevens, David Whitcomb *Discussant:* Robert-Jay Green

Symposium: ***Responsible and Ethical Conduct of Research With Ethnocultural Populations*** Divisions: 45, 8, 9, 35, 38, 48, 52 **HCC 309** *Chair:* Joseph Trimble *Participants:* Jeffery Mio, Felipe Castro, Dina Birman, J. Douglas McDonald *Discussant:* Yee

Symposium: ***Trauma, Resiliency, and Forgiveness—Cross-Cultural Perspectives*** Divisions: 52, 9, 12, 18, 19, 35, 45, 48 **HCC 306B** *Chair:* Jan Fite *Participants:* Diana Motyl, Daniela Schreier, Kenneth Larson, Takuay Saito, Roni Berger *Discussant:* Diane F. Halpern

10:00-10:50 am
Symposium: ***Training Experiences, Outcomes, and Transitions of International Students*** Division: 17 **HCC 308A** *Chair:* P. Paul Heppner *Participants:* Pius Nyutu, Hyun-Joo Park, Chia-Chih Wang, Oksana Yakushko *Discussant:* P. Paul Heppner

Symposium: ***Does Freedom Matter? Toward Its Systematic Study as a Psychological Variable*** Divisions: 52, 19, 35, 45, 48 **HCC, 316C** *Chair:* Juris Draguns *Participants:* Richard Brislin, Dharm Bhawuk, Herbert Barry III, Michael Salzman, Juris Draguns

11:00-11:50 am
Symposium: ***Occupational Health Psychology in Japan—Educational, Research, and Professional Initiatives*** Divisions: 17, 2, 14 **HCC 306A** *Cochairs:* Heather Fox, Lorraine Eyde *Participants:* Takashi Haratani, Akihito Shimazu, Noritio Kawakami, Satoru Shima, Shotaro Kosugi *Discussant:* Steven Sauter

Symposium: ***Psychologists in the 21st Century—Culturally Responsive Work with Immigrants and Refugees*** Divisions: 52, 9, 27, 45, 48, Psi Chi, APA Task Force on Immigrant Children, Youth, and Families **HCC 318A** *Chair:* Fred Bemak *Participants:* Luis Vargas, Rita Chi-Ying Chung, Joan Koss-Chioino, Mary Clare, Fred Bemak *Discussant:* Anthony Marsella

12:05-1:00 pm
Film Program: ***Anna Freud—Under Analysis*** Sponsor: APA ad hoc Committee on Films and Other Media **HCC 304A**

COUNCIL REPRESENTATIVE'S REPORT
February, 2004

Gloria B. Gottsegen, PhD

I attended the Council of Representatives midwinter meeting in Washington on February 19-22, 2004 as the Division 52 representative.

APA President Diane Halpern presented her report and outlined her three initiatives for the year. They are Work and Family Interactions, a Retiring Psychologists initiative and Prejudice in Any Language.

CEO Norman Anderson then discussed the innovations he is making in his new position. He has started some reorganization of the APA Central Office. His immediate interests are to increase non dues revenue, to increase the influence of psychology world wide and to increase our international cooperation with other psychology associations.

Steven Breckler was introduced as the new head of the Science Directorate. He comes to us from the National Science Foundation and formerly from Johns Hopkins.

The Council accepted the report of the Task Force on Advertising and Children :entitled Psychological Issues in the Increasing Commercialization of Childhood and Psychological Implications of Commercialization in Schools.

A Presidential citation was presented to the federal commission: Achieving the Promise: Transforming Mental Health Care in America.

A resolution on HIV Prevention Strategies Involving Legal Access to Sterile Injection Equipment was passed as well as a Resolution on Children's Mental Health.

Much time was appropriately spent on the financial worth of APA and the two buildings owned. The APA staff now numbers 518 and only 16% of our income comes from Member dues. An additional 60% comes from sale of publications. In 2003-2004 our electronic revenue exceeded that of our print products. However we were again warned that our members are getting older and the number of dues exempt members is steadily rising.

Council went into Executive Session to discuss the retirement package given to former CEO Ray Fowler. It consisted of a base salary and benefits for 2002, deferred compensation, end of contract leave and a 21/2 year payout of the remaining contract term. After much discussion Council agreed to ratify the package with the stricture that Council be notified more fully about such terms in the future and in a more timely fashion.

The next meeting of the Council will be July 27, 28 and 30, 2004 in Hawaii.

NATIONAL NEWS - ON A PERSONAL NOTE

Reflections on my Initial Start Toward Becoming a Psychometrician

Peter F. Merenda, PhD
University of Rhode Island

In January 2004, I was greatly surprised and elated to learn that APA Division 5 (Evaluation, Measurement, and Statistics) had just selected me as the 10th Samuel J. Messick Awardee for 2005. The award is endowed by the Educational Testing Service, Princeton, New Jersey, where I could have become a staff member in 1949, just after it became a chartered national testing agency in 1948. Later, between 1954 to 1961, I served under a subcontract with ETS as an item writer for the U.S. Coast Guard Officers Promotion Examinations. This year in April, I was attending with my wife, Rose, the Annual Convention in New Orleans of the Association of Childhood Education International. At one of the book booths, I came across a book that caught my attention (Lemann, 2000). The book primarily features the career of Henry Chauncey, the first President of ETS, 1948-1970. In 1970, William Turnbull, Chauncey's number two man at ETS from its very beginning succeeded him as president, 1970-79. (Incidentally, during his tenure as President of ETS and until he died in 1986, Bill Turnbull was actively involved in international psychology, especially as a contributing member of the International Council of Psychologists (ICP). We were close friends and colleagues).

Upon being notified by Roger Kirk, Division 5 chair of the Awards Committee, of my selection of the Messick Award, I wrote to both of them to share the good news. They were the ones who got me started on the path to become a psychometrician

Early Training in Measurement and Psychometrics

In 1948, I became a student at the Harvard Graduate School of Education. My first two instructors in courses in these two areas were Julian Stanley and David Tiedeman, who was to become my major professor. Upon being notified by Roger Kirk, Division 5 chair of the Awards Committee, of my selection of the Messick Award, I wrote to both of them to share the good news. They were the ones who got me started on the path to become a psychometrician. Later, when I transferred to the University of Wisconsin — Madison, Chester Harris, Julian Stanley, and Avril Barr completed my training. And among them only Stanley is still alive. During the 1948-49 academic year, I had intended to begin my advanced statistics courses with Truman Lee Kelley, but he was on terminal sabbatical leave before retiring. So I began my instruction in statistics with Kenneth Vaughn, and I spent a semester tutoring as a mathematician, some of my fellow students, the fundamentals of probability and mathematical statistics.

The Possibility of Becoming Affiliated with Henry Chauncey

Henry Chauncey, became an assistant dean at Harvard College in 1929. He still held that position in the 1930s when James Bryant Conant became President of Harvard University. During the 1933-34 academic year, Conant called upon Henry Chauncey and another assistant dean, Wilbur Bender, to develop a program to select deserving high school students for scholarship grants to Harvard College. The program was to include tests beyond or equivalent to the traditional College Board Essay exams. This began the Conant-Chauncey interest and career in national objective testing. In January, 1948, the Educational Testing Service received its charter in Princeton, New Jersey, as the first national testing agency in the USA. Conant became the first Chairman of the Board of Directors, and then Board appointed Chauncey as its first president.

The rest is history — I became the first Director of the Research Department and Research Director of the U.S. Naval Examining Center, 1950-57, first in Norfolk, VA and then permanent headquarters at Great lakes, Illinois.

In the Spring of 1949, Chauncey notified Dana Cotton, Harvard's Director of the Employment Bureau, that he wanted him to recommend a Harvard person to come to Princeton to serve as Assistant-to-the-President. Dana selected me and I traveled to 20 Nausau Street to be interviewed by Chauncey. Although I was just completing my first year beyond my master's studying psychometrics, I was married with two young daughters at the time. Also, my position at the University of Massachusetts for returning veterans of WWII as Instructor of Psychology and Head of the Counseling and Testing Center was coming to an end.

However, when I arrived at ETS I learned that someone who was already on the initial staff had become interested in the position and Chauncey had accepted him. But,

(Continued on page 9)

(cont. from page 8)
the ETS invitation to come for an interview had not been rescinded. What had happened was that Warren Findley had received the dossier that Dana Cotton had submitted on me. He noted that my bachelor's degree from Tufts was in mathematics. Warren had just come to ETS from Montgomery, Alabama, to become its first Director of the Test Development Department. He had told Chauncey that he would like to interview me for the position of item writer in the mathematics division. What transpired during the interview later served to be responsible for really getting me started on my way to becoming a professional psychometrician. Findley, in Montgomery, had been the top psychometrician at the Air University, Maxwell Field. During the interview he could sense that I was interested more in becoming a research psychologist in testing and test development than an item writer. But, he told me that while ETS was still not ready to organize its Research Department, there was a new possible opportunity being opened for me. He had just learned that the U.S. Secretary of the Navy had recently signed the order to create and establish its first service — wide center for developing competitive examinations for the advancement of enlisted personnel and the promotion of commissioned officers through the grade of commander. He gave me the name of the psychologist at the Bureau of Naval Personnel in Washington, DC to contact if I were still interested in the U.S. Civil Service. The rest is history — I became the first Director of the Research Department and Research Director of the U.S. Naval Examining Center, 1950-57, first in Norfolk, VA and then permanent headquarters at Great lakes, Illinois.

Reference

Lemann, N. (2000). The Big Test: The Secret History of the American Meritocracy. New York: Farrar, Straus and Giroux.

MORE NEWS

Membership Fee Reduction

for the International Council of Psychologists—ICP

Joy K. Rice, Secretary, ICP

Here's a opportunity to join another great international organization at a special rate.

Current members of Division 52 can now receive a one time greater than 25 % membership fee reduction as a new member of the International Council of Psychologists (ICP). Instead of $85, Division 52 members in good standing who would like to join ICP will pay only $60 for their first year of full benefits as new ICP members.

Many members of APA already enjoy membership in ICP as the two organizations have common goals and interests, but ICP offers collaborative and friendship opportunities with psychologists from more than 60 countries around the world.

To become a member of ICP, please email the Secretary General, Dr. Matti Gersenfeld at <matti@nni.com>.

The 2004 annual convention will be in Jinan in the People's Republic of China August 2 to 6, 2004. The ICP Board of Directors Meetings, CE Workshops, and the Scientific Program Sessions will be held at the beautiful Crowne Plaza Jinan where delegates are staying. For more information on the conference, contact Dr. Chok Hiew at <hiew@unb.ca>.

NOTE
APPLICATION FOR MEMBERSHIP NOW INCLUDES:
Check if interested in receiving listserv announcements:_____

Student Representatives

Kate Richmond
Mei Chang

The student committee of Division 52 is looking for a few motivated students to join an already growing network of international students interested in becoming involved in Division 52. At the most recent Board Meeting, several student objectives were enthusiastically discussed, and we are now in the process of implementing the new initiatives.

FOR QUALITY PSYCHOLOGICAL PUBLICATIONS VISIT:

WWW.APA.ORG/BOOKS

These initiatives include creating a Division Student Board, providing student programming in the Division Suite to promote student involvement, and designing a brochure for undergraduate and graduate students regarding the benefits of supporting Division 52. We are also interested in creating a formal mentoring program within the Division as a means to increase networking opportunities for students and international professionals. This mentorship program may include a "shadowing day" at the United Nations. If you are interested in becoming involved within the student committees, please email Kate Richmond at richmond-kate@hotmail.com.

INTERNATIONAL NEWS

Symposium on International Psychology

By Judy Kuriansky, PhD
International Association of Applied Psychology

Abstracted from speech given at the Pace College May 8 Symposium on International psychology, on "Cross-cultural models of collaborations between China and America in therapy and research: Clinical, epidemiological, and technological approaches" By r. Judy Kuriansky on behalf of the International Association of Applied Psychology.

Chinese health professionals are increasingly interested in learning about the western models of therapy, and Americans are becoming increasingly aware of how eastern therapeutic techniques can help patients treated by western methods.

The course material covers a vast variety of topics relevant to service Chinese couples and improve their marriages and family relationship as well as their sexual lives and reproductive health care.

Over the years I have become more aware of how these can be integrated, and have taught western techniques in the East and eastern techniques in the West, as well as developed techniques crossing both cultures.

In the past five years I have been applying my decades of radio call-in talk show hosting to training staff from the China Center for Reproductive Health Technical Instruction in Shanghai in their hotline service and in evaluating calls to their hotline.

I have also been training Chinese health professionals in American marital counseling techniques. These have been conducted over five days, or two days, or in one day, in cities from Beijing to Shanghai, Chengdu in the west, Kunming and Shenzhen in the south, to Shenyang in the north. The groups have included physicians from all disciplines, including gynecology, urology, reproductive health, and psychiatry who wanted to learn about how to treat patients' sexual problems and create more harmony in their patients' relationships.

The courses have been consistent with the Chinese government's mandate to provide "high quality of care" to every Chinese person by the year 2010. The course material covers a vast variety of topics relevant to service Chinese couples and improve their marriages and family relationship as well as their sexual lives and reproductive health care. The specific topics include information about relationship problems, ways to facilitate better communication, diagnosis and treatment of male and female sexual dysfunction, ethics, medical aspects of sexuality, how to resolve relationships problems, emotional concomitants of sexually transmitted diseases, and interview techniques. Participants learned techniques they could immediately apply to their patients to encourage marital harmony, and physician skills in eliciting information from patients and developing healthy doctor-patient interactions.

Research on the trainings showed significant improvement in participants' knowledge of treatment techniques and comfort in dealing with the issues presented by patients, as well as a high degree of satisfaction with the courses. The participants were highly attentive and interested in the information and much useful information was shared that can have a great impact on medical care of Chinese people through the expert commitment and talent of the Chinese doctors who participated in the course.

Xu Feng is a gynecologist who attended a training in Chengdu from Qing in Sichuan province, and plans to open a women's clinic. "I

Deng Xuyang, Vice-director of Southeast University Psychological Counseling Center in Nanjing, wants to include treatment for men and women's sexual problems in his clinic, and found great value in the information presented in order to institute new services in his clinics and therefore offer unique services to the clientele

came because I wanted to learn how to treat women's problems, including not having orgasm." Deng Xuyang, Vice-director of Southeast University Psychological Counseling Center in Nanjing, wants to include treatment for men and women's sexual problems in his clinic, and found great value in the information presented in order to institute new services in his clinics and therefore offer unique services to the clientele.

Professor Hu Peicheng, Secretary General of the CAS and Professor of Medical Psychology at the Health Science Center of Peking University in Beijing, said, "This training makes history in China, as the first training of medical doctors sponsored by the China Sexology Association and given by American experts." Some of the participants subsequently made a trip to the US, which I arranged and hosted.

The China Association of

(Continued on page 11)

(Symposium on...cont. from page 10)
Sexology, founded in 1994, is an organization of more than 3,200 health professionals from all around the country, dedicated to promote sex research and education of Chinese professionals as well as the public.Liu Changmou, a highly accomplished physician from Maoming municipality, who travels several times to the U.S., recommended that the highly valuable training information should be disseminated to many Chinese doctors. He also wisely advised, "Sex science in America is more advanced than in other countries, making it valuable for China to learn from Americans about how to treat male and female sexual dysfunctions especially in medical practice." Liu advises that "all Chinese doctors should have such information," but also urged reasonable caution that "we must pay attention to the traditions of China." Chi Weidong and Li Lizhen are both urologists and a husband and wife team who run a clinic in Da Tong in Shan Xi province. Chi said the training had a positive effect on their marriage as well as their professional work. "Before we came to the training program, we paid little attention to our relationship," said Chi. " All we thought about was our career. We learned many things from the training program. We have to help the patients to relax before we try to treat the disease. We must pay attention to the psychological aspect of the problem besides how to treat patients, we learned something about our relationship. We must make time for ourselves." Chinese mental health professionals now want to set up training programs with similar credentials and requirements as American graduate schools. Contact me about this if you are interested.

"Before we came to the training program, we paid little attention to our relationship," said Chi. " All we thought about was our career. We learned many things from the training program. We have to help the patients to relax before we try to treat the disease.

DIVISION 52 AT THE UN

Florence Denmark, PhD

Division 52 members have been quite active at the UN and in sharing information about their UN activities with each other and with other interested individuals.

Past President Harold Takooshian and current President Richard Velayo organized a United Nations panel that was held at Pace University. Twenty-two psychologists from 8 psychology organizations described their groups' efforts and activities at the United Nations. Most, if not all of the 22 are members of Division 52 and some of us met each other for the first time.

A few of the specific activities by individual members include the following in alphabetical order:

Harold Cook serves on the Executive Committees of both the Family and the Mental Health Committees. He has just been selected to be part of the steering committee for the North American regional consultation on the UN global study on children and violence.

Florence Denmark is Chair of the Committee on Ageing (COA) and presides over their monthly general meetings as well as monthly Executive Committee meetings. The latter, of course, involves a great del of preparation and organization. She is also active on the Ageing Committee's Development Committee (fundraising) and the International Day of Older Persons Committee (IDOP). She spoke at the Global Population Forum in Washington, DC at the request of Mr. Mohammed Nizamuddin. Her talk, which was psychologically focused, was very well received among a group largely composed of demographers. In addition, she is a member of the Committee on Mental Health and the Committee on the Status of Women. She attended some of the meetings on the Commission on the Status of Women (CSW) and the latter's sub-committee on older women (SCOW).

Maram Hallak has been elected to the NGO Executive Committee of the Department of Public Information.

Margot B. Nadien has attended all the *U.N. Committee on Aging* meetings, and almost all of the meetings of the *Executive Committee of the UN Aging Committee.* As the co-chair with Pat Brownell of the *Subcommittee on Elder Abuse*, she planned and participated in several meetings of the Elder Abuse Subcommittee; and with Pat, also planned and co-chaired the program, "Older Women and Abuse: A Global Research Perspective," which was presented on March 4,2004 as the program of the *NGO Committee on Ageing*.

Corann Okorodudu continues to serve as the Main Representative for the APA NGO representatives. She is active on several UNICEF committees.

Harold Takooshian organized UN panels at Fordham University, Hunter College and Pace University.

Richard Velayo attended the UN DPI-NGO Orientation held on February 25-26. As an NGO newcomer, he was particularly overwhelmed at the extent and complexity of UN activities in which NGO's may participate in. One of the Committees he is looking forward to participate in has to do with the design and development of the U.N. website (http://www.un.org/). In addition, he recently joined the Ageing Committee in which he plans to take an active part.

Pete Walker is treasurer of the NY NGO Committee in Ageing and has

(continue on page 16)

◆ **STUDENTS' PAGE** ◆

Motivating Unmotivated Students

by
Rosalie Favuzza

When choosing a topic to conduct my action research on I wanted to choose a topic that will always be of use to me. I decided to focus on one particular student whom seemed unmotivated in everything. Therefore I decided to conduct my action research on motivating unmotivated students through literacy and cooperative learning groups. I wanted to be sure to choose a topic that wouldn't be limited to my class, I wanted to be sure and pick something that I could learn from and use in the future.

As a child, I was exceptionally shy and never fully felt comfortable in any of my classrooms. Since I received excellent grades and was exceptionally well behaved none of my teachers made the effort to make me feel confident.

One of the most challenging problems that educators face is motivating unmotivated students. This is a problem that exists in all grades and classes. Trying to reach these students can sometimes be frustrating for teachers and it is very easy to forget about them and label them lazy or unintelligent. I decided that I wouldn't fall into that trap and instead I would be the teacher who changes their attitude towards learning.

It's not difficult to identify unmotivated students. They are usually the students whose attitude toward school is indifferent. They focus on avoiding you instead of getting your attention. The student I am focusing on is Jonathon. He was born in Mexico and moved to this country in September. When he entered my classroom he seemed terrified and wouldn't even acknowledge me. When I spoke to him he wouldn't look at me. He spent most of the time avoiding me and hiding from me. He never causes any problems and tends to stay to himself all the time. I decided that I would concentrate on him and not forget about him. I volunteered to accept all the low-level ELL(English Language Learner) students because I felt it would be beneficial for them to be together. I have 5 ELL students (Zhao, Daniel, Liba, Qingxia and Jonathon) Therefore I plan separately for them and they never get forgotten. Not only do they all sit at the same table but also they work together in cooperative groups all day. Since they all entered at the same level I feel that this will help them feel more comfortable and eliminate any fear of failure they might face.

When he entered in September he didn't speak, write or read in English. Presently he is reading up to level K books, writing responses and participating in book talks with his reading group. He is well aware of his progress. In addition he is always smiling and raising his hand to try to answer a question.

My goal in completing this action research is to take Jonathon out of his shell and make him feel confident and comfortable in the classroom. As a child, I was exceptionally shy and never fully felt comfortable in any of my classrooms. Since I received excellent grades and was exceptionally well behaved none of my teachers made the effort to make me feel confident. I decided I would do that for Jonathon and in return it would turn him on to learning. I want to be the teacher that changes his life and that he will never forget.

Final Reflection

Now that I have reached the end of my action research I am pleased to state that I have been successful in reaching an unmotivated student. Jonathon has made a total transformation from a terrified recluse to confident boy who stands up for himself and always wants to participate in class discussions. In September he wouldn't even look at me and if I approached him and asked a question he would give me a distressed stare. Furthermore his ESL teacher wanted to have him referred for special education. His reading and writing have also improved astonishingly.

When he entered in September he didn't speak, write or read in English. Presently he is reading up to level K books, writing responses and participating in book talks with his reading group. He is well aware of his progress. In addition he is always smiling and raising his hand to try to answer a question. The progress he has made went far beyond any of my expectations. I am confident that I have made a difference in this child's life and in return he has taught me a valuable lesson. As an educator I touch so many lives, however when you are able to reach a student like Jonathon the reward is phenomenal.

My recommendations for future team members are to choose a focus question that you are truly interested in and more importantly choose a focus that will make a difference. As educators it is our obligation to make a difference and when we do, it makes all our hard work well worth it.

Participating in this team has been a remarkable experience. Professionally it has helped me overcome one of the most challenging problems that educators face,

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◆ **BOOK REVIEW** ◆

Battle of Symbols: Global Dynamics of Advertising, Entertainment and Media

Reviewed by
Melba N. Mathurin
Institute for International and Cross-Cultural Psychology
St. Francis College, USA

John Fraim
Battle of the Symbols: Global Dynamics of Advertising, Entertainment and Media (2003).
Einsiedeln, Switzerland: Daimon Verlag.
ISBN: 3-85630-621-8

Symbols permeate our everyday existence and have been a part of all societies throughout time. They convey information that represents both tangible and abstract ideas. Symbols have multiple meanings around the world but are similarly used as a form of communication to represent ideas, beliefs and objects. Symbols that are shared may generate psychological emotions based on common experience. In this way, they have the ability to involve people in a shared reality that they both create and participate in. However, the meanings of symbols obtain its power from the significance and emphasis that it is given in a particular time and place. Therefore, a community participates in creating its overall meaning. In this way, Fraim presents the major thesis and strength of his work in *Battle of Symbols*. He invites his readers to collectively contemplate and examine the symbols that are manufactured in America. Furthermore, what do these symbols mean to Americans, how do they influence their thoughts and ultimately their behavior, and what is their global impact?

> Whereas in the past, the West represented the novel and the East the conventional, Fraim notes that in the disagreement between symbols, the West is now presented in the United States as signifying the "civilized" sphere and parts of the East the "uncivilized" territories (p .132).

Battle of Symbols aims to provide a comprehensive analysis of the growth of traditional symbols, the pervasive influence of symbols in modern-day American advertising, and the influence that symbols have in the global sociocultural, economic, and political arenas. In this context, the events of September 11th, 2001 together with matters leading up to this event are examined symbolically. For instance, Fraim employs Jung's symbolic approach to examine how the introverted tendencies of the East and the extroversion of the West present a psychological duality; and how these differences are frequently the cause of misunderstandings and conflict. Whereas in the past, the West represented the novel and the East the conventional, Fraim notes that in the disagreement between symbols, the West is now presented in the United States as signifying the "civilized" sphere and parts of the East the "uncivilized" territories (p .132). Seen in this way, America and more generally, the West are depicted as restoring law, order and civilization to parts of the "barbaric" East.

> In this context, Americans experienced an increased sense of unity and community. The tragic event brought them together through participation in the common symbolic language of patriotism. This idea was not lost on the American advertising industry who found a new way to market sympathetically products and profit while exploiting the emotional patriotic needs of Americans.

Today, symbols continue to maintain the power to influence emotions and therefore behavior. As seen after September 11th, they united those people who shared a common domestic and international interest but separated and ostracized others who had a different point of view. In this context, Americans experienced an increased sense of unity and community. The tragic event brought them together through participation in the common symbolic language of patriotism. This idea was not lost on the American advertising industry who found a new way to market sympathetically products and profit while exploiting the emotional patriotic needs of Americans. Patriotism, so it was implied, meant liberal spending to support the United States economy. However, as Fraim notes, symbols that are exploited or over used ma-

> These same symbols, when not properly understood may produce feelings of tension and disharmony in people around the world and eventually evoke deep resentment as seen in the events of September 11th. In this context, Fraim explores the ways in which American symbolic brands are viewed by other countries.

generate disinterest among consumers. America has become a worldwide leader in the creation of symbols that take the form of brands in the world of advertising and entertainment. Fraim examines Madison Avenue and Hollywood as the leading producers of these "brand symbols". In this context, advertising and entertainment, together with communication systems such as the Internet are seen as the main

(Continued on page 14)

(Battle of symbols cont from page 13)
mediums by which symbols are transmitted to various countries. Symbolic brands are packaged and repackaged to fit the American consumers' growing and changing needs. Brands compete to keep up with the "what's next" syndrome that seems to permeate the over consumption of American consumers.

These same symbols, when

Fraim's examination of symbolism in postmodern America and its influence on global dynamics presents a thought-provoking and insightful read. It challenges the reader to consider, from a fresh perspective, the barrage of "symbolic brands" that he or she is experiencing on a daily basis

not properly understood may produce feelings of tension and disharmony in people around the world and eventually evoke deep resentment as seen in the events of September 11th. In this context, Fraim explores the ways in which American symbolic brands are viewed by other countries. For instance, what did the World Trade Center represent to the terrorists? The World Trade Center, a symbol of financial power and capitalism dominated the skyline of Manhattan's financial district. To Americans, the World Trade Center symbolized commerce and industriousness, in contrast, the terrorists viewed this imposing landmark as the ominous tower of Babylon. There was no doubt that the World Trade Center symbolically represented a different reality to its attackers than to Americans.

Fraim convincingly demonstrates that symbolic brands will continue to infiltrate American culture and this is metaphorically represented in the idea that image is everything. The question now becomes: What is that image that is being represented? And are Americans prepared to ask and perhaps most importantly answer that question? Should that goal be accomplished, they can then assess how others, around the world, may view their symbols. This is an important

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SOME RECENT AND FORTHCOMING PUBLICATIONS IN CROSS-CULTURAL AND INTERNATIONAL PSYCHOLOGY

Uwe P. Gielen, pHd
Institute for International and Cross-Cultural Psychology,
St. Francis College

This brief bibliography contains volumes on international and cross-cultural psychology that have been published since 2002 or will be published in the foreseeable future. The list does not include volumes dealing with specific ethnic groups in the United States.

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(cont. from page 14)

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(Continue on page 20)

◆ ANNOUNCMENT ◆

I am pleased to inform you that the English version of the Family System Test (FAST) is now available for US researchers and clinicians. For more details, please, contact the FAST web site (www.fast-test.com).

If you have any questions, please, do not hesitate to contact me.

Thank you very much for your time and attention!

Thomas M. Gehring, PhD, PsyD
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VISIT THE APA ONLINE
www.apa.org
Links to all divisions

DIVISION 52 WEB SITE

www.internationalpsychology.org

(Div. 52 at the UN cont from page 11)
organized a panel for the September NGO Conference of the Department of Public Information. He is also active on the UN Committee for Sustainable Development.

Al Weiss's work at the United Nations is primarily with Committee on Ageing, the Education Committee, and the UNICEF working group on education. He has also worked with the Committee on the Family. His main propositions have been to preserve the health and welfare of children, particularly young children, by focusing on the elements necessary to make their lives more reasonable in the long run. His work with the family group is centered on providing basic elements needed to educate the children, a concept which is damaged throughout the world.

The Handbook of International Psychology at APA!

The Handbook of International Psychology chronicles the discipline and profession of psychology as it is evolving in different regions of the world. *The Handbook* surveys the history, methodology, education and training, and future of psychology in twenty-seven countries across sic continents. Some of these counties have rich histories in psychology, such as Argentina and Germany. Some have emerging psychologies, such as Indonesia and Kenya. Some are lesser-known, such as China and India. Still others are marked by massive social change, such as Iran and Poland. Michael Stevens and Danny Wedding, the editors, have carefully selected all contributors, as well as an advisory board created especially for this book. Each chapter follows a standard outline, unifying the volume as a whole, yet allowing for the _expression cultural diversity and the distinctive nature of psychology in each country.

Brunner-Routledge, publisher of *The Handbook* is offering a 20% discount on the purchase price to anyone registered for the 2004 APA Convention; an additional 25%-30% discount is available to Division 52 members who attend one of the social hours where *The Handbook* will be displayed. To find out more about *The Handbook*, visit www.brunner-routledge.com or www.psychology.ilstu.edu/mjsteven /Research/HIP.html

Break the communication barrier

Log on to www.psychat.org for real time translated chat rooms, e-mails, and text.
A link for this site can also be found on Division 52 web site:

www.internationalpsychology.org

WHAT IS PSYCEXTRA?

PsycINFO is launching a new database-PsycEXTRA- to bring together gray literature resources specific to the field of psychology and make them available for research, training, self-help, and general information. PsycEXTRA will include the following document types:

- White Papers
- Policy Papers or Standards
- Consumer Brochures or Pamphlets
- Newsletters, Newspapers, or Magazines
- Fact Sheets
- Reports, such as Annual, Progress, Research, or Technical

As part of the PsycEXTRA content, we would like to include full text content, particularly research reports, briefs, fact sheets, and newsletters. Having your content as part of our coverage will help link librarians and information professionals, as well as clinicians, consumers, policy-makers, and researchers, to the content you produce. We will bring your content to the attention of a very wide audience, many of whom may not yet be aware that your material exists. To bring even more attention to you, we will link the users of PsycEXTRA directly to your URL.

We are hoping to launch PsycEXTRA in mid-second quarter 2004. The database will be updated on a bi-weekly basis and available on an annual site license from APA and one vendor partner. For the first year, we project more than 400 institutional subscribers in addition to nearly 10,000 individual subscribers through APA membership.

To start coverage, we would like to have you review our coverage agreement, which I am attaching. For more information on

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(PsychExtra cont. from page 16)

PsycEXTRA please go to http://psycextra.apa.org. Once you've completed and signed the coverage agreement, just fax it back to us. Then you all you'll need to do is let us know how you will supply the content, and we'll take care of the details of the precise classification and indexing that will make your content easy to identify in PsycEXTRA.

We look forward to working with you on this exciting new venture. If you have questions, please feel free to e-mail me or contact our Product Development manager Alvin Walker at awalker@apa.org at 202-336-5663

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(Motivating... Students cont. from page 12)

which is motivating the unmotivated. I strongly feel that no child is lazy or apathetic towards school. If they appear in this manner then it is our responsibility to help these students. As educators we need to vary our teaching styles to ensure that no child is forgotten. In addition we need to build self-confidence in our students, make learning fun and allow students some control over what they learn. Although at times it might seem arduous the greatest reward anyone can receive is to know they have changed a person's life. Therefore I would say the most beneficial part of this experience was watching Jonathon's success. My recommendations for future team members are to choose a focus question that you are truly interested in and more importantly choose a focus that will make a difference. As educators it is our obligation to make a difference and when we do, it makes all our hard work well worth it.

(Battle of Symbols cont. from page 14)

consideration because ultimately, it will help Americans understand better the global battle between symbols. Finally, Fraim tells us that this symbolic battle is not a recent phenomenon but one that has been germinating for some time. Exactly how this battle will continue to play out is uncertain.

Fraim's examination of symbolism in postmodern America and its influence on global dynamics presents a thought-provoking and insightful read. It challenges the reader to consider, from a fresh perspective, the barrage of "symbolic brands" that he or she is experiencing on a daily basis. In this instance, the reader becomes an active consumer and consciously begins to engage in understanding better the world of symbols that surrounds him/her. On the other hand, the strength of the main idea, considering the meaning of modern symbols as guides to an understanding of crucial factors in world dynamics, is sometimes diluted with over quoted citations from a wide variety of sources. In this way, Fraim's voice seems to be lost and the reader is eager to be brought back to the main line of reasoning. Lastly, *Battle of Symbols,* although interesting, would have more impact if it developed fewer themes with greater consistency and in more depth. Too often, the reader must make an effort to integrate the presented information into a meaningful whole something, which should really be the author's task.

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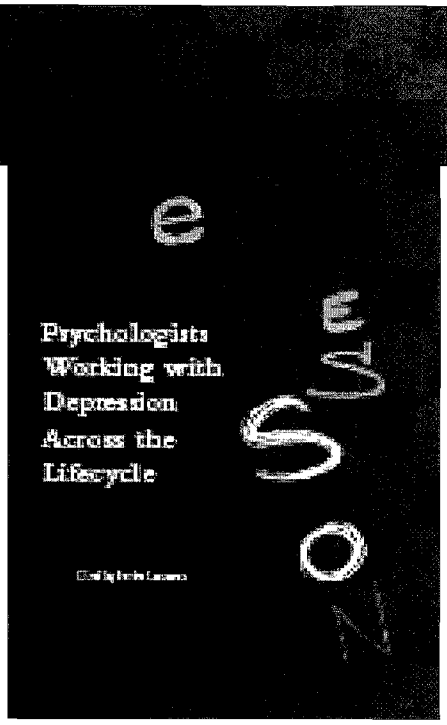

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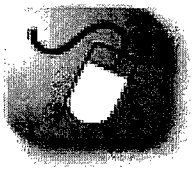

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The Division of International Psychology promotes and advances international practice, research, and communication between psychologists around the world through yearly meetings where symposia, papers, poster sessions, business meetings and social hours are scheduled. The Division newsletter will be published three times a year to keep members informed. All areas of the discipline are welcomed as participants in the Division.

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International Psychology Reporter

Volume 7, No. 2 | APA Division 52 Newsletter | Summer 2003

MESSAGE FROM THE PRESIDENT

Our mission: Reaching out

Harold Takooshian, PhD
President

How well is our APA Division of International Psychology reaching out to fulfill its mission to promote international psychology? In context, our Division is best seen as one of a network of seven international psychology efforts, each with its own unique emphases (Davis, 2000; Merenda, 1995, Overmier & Overmier, 2003):

1. IAAP (formed in 1920) is the International Association of Applied Psychology. It currently numbers 2,000 members world-wide, publishes a quarterly journal (*Applied Psychology: An International Review*), and hosts a quadrennial congress. (www.iaapsy.org)

2. ICP (1941) is the International Council of Psychologists. It currently numbers 1,500 members world-wide, publishes a quarterly newsletter (*International Psychologist*), and hosts an annual convention.

3. IACCP (1972) is the International Association for Cross-Cultural Psychology. It currently numbers 800 members, publishes a bimonthly *Journal of Cross-Cultural Psychology*, and hosts a biennial meeting.

4. IUPsyS (1951) is the International Union of Psychological Sciences. It is a union of 64 member nations (no individual members), publishes the *International Journal of Psychology*, and hosts a quadrennial International Congress of Psychology. (www.iupsys.org)

5. IPSO (1999) is the International Psychology Student Organization, an emerging new group composed of students across many nations. (www.psychologystudents.org)

6. CIRP (1944) is the APA Committee on International Relations in Psychology. It is an elected committee of nine psychologists, which oversees the many programs of the APA Office of International Affairs, including its quarterly Newsletter, *Psychology International*. (www.apa.org/international)

7. Our Division 52 fits well as the seventh and (except for IPSO) newest kid on this friendly international block. Formed in 1997, it now numbers 896 members, publishes this quarterly, *The International Reporter*, and hosts a lively annual program at the APA conventions. According to section 1.2 of our bylaws, "The purposes of this Division are to further the development and advancement of international relations among psychologists..." As a membership group within APA, the Division's unique aim is to "add feet" to the APA's CIRP and International Affairs office.

Yet those of us involved in the formation of the APA Division of International Psychology in 1997 can attest to a few clear points: (1) Long-awaited: the approval of the new division by the APA Council "had been the culmination of years of planning" (Hogan, 2001), after earlier petitions failed. (2) Small: though the concept of an international division within APA now enjoys wide favor among its 84,000 members (who seem to recog-

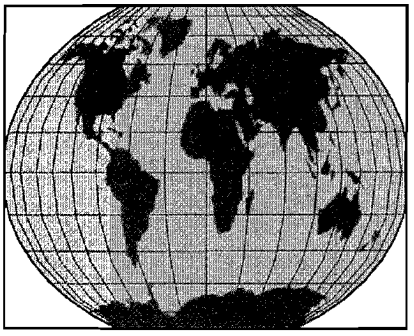

nize this was truly overdue), the division just barely met the minimum number of members for Council approval in 1997. (3) Flat: despite valiant efforts, the Division's size remained quite flat at about 725 members during its first five years.

Consider a number of advantages that should foster our Division's rapid growth. The number of psychologists outside North America virtually doubles per decade (Rosenzweig, 1992). The Division offers unique member benefits, including the excellent Reporter, annual meeting, awards, website. Thanks to APA, people can join the Division for an annual fee of only $20 (for professionals) and $10 (for students), with no need to spend over $180 to first become an APA member.

Sadly, a number of factors seem to inhibit our Division's growth. Many folks are still unaware of it, even those involved in global activities. Many overseas psychologists falsely assume they must first spend $180 to join APA before they can join its International Division. Still others have never seen Editor Ivan Kos' superb Reporter, and

(Continued on page 2)

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(continued from page 1)
simply do not know what they are missing by failing to join.

Happily, since 2002, our Division has now grown from 725 up to 896, following several new initiatives. I am pleased to report a sample of these here. For one, an active new regional group was formed in New York City (the highest concentration of Division members), and has grown from 160 to 205 members since the regional group began its activities in 2002. Our webmasters Bill Masten and Mustafa Baloglu regularly update our website and, in 2003, uploaded PsyChat translation software and the entire Fall 2002 issue of the International Reporter for nonmembers to see what they are missing. Our 2003 Program Chair Lynn Collins planned another highly inclusive Toronto program, and inserted applications with her acceptance letters to over 100 nonmember presenters.

In 2003, the new position of Outreach Chair was created, and Dennis Carmody designed proactive efforts to reach out to overseas and U.S. nonmembers. When our ever-helpful friends at APA, Donna Wighington and Keith Cooke, kindly provided a storable database of our membership, Dennis carefully analyzed the data, with these results: Of our 896 members, 810 are in the USA, 21 in Canada, and only 65 (or 7 percent) in 35 nations outside North America. Of these 65, 8 are in Israel, 7 Japan, 5 Korea, 3 in 3 nations (Hong Kong, Mexico, Singapore), 2 in 7 nations (Argentina, Bermuda, Brazil, Egypt, Italy, Sweden, Switzerland), only 1 in 22 nations. Imagine only 1 member in all of India, and a flat zero in China, Russia, France, UK. The room for growth is clear. As Outreach Chair, Dennis has now e-mailed a first-ever personal announcements to 75 national associations and other global groups and, with some effort, he obtained the e-mails of 100 authors in the Journal of Cross-Cultural Psychology who were not members of our division. Thanks to a generous donation from Carole Rayburn, the Division may establish a Rayburn Fund to allow free memberships to qualified nonmembers in poor nations which now have no member of our Division.

Since Spring 2003, APA President-elect Diane Halpern has been quietly working with our 2004 Program Chair, Anie Kalayjian, to make the Honolulu meeting truly unforgettable. The office of APA Membership Chair Pat Miyamoto has designed and printed a stunning call-for-papers for Hawaii, featuring details on both APA and Division 52, which cannot help
(continued on page 6)

LETTERS TO EDITOR

Hello,

I am writing to comment on the brief article titled "Go Boldly Forth! Making Psychology a Household Word" written by Ronald F. Levant in the Spring 2003 (Vol 7, No.1) issue of International Psychology Reporter.

While reading this brief column I was struck by the optimism and general enthusiasm the writer both holds and encourages for the growth of the field. I have read other comments by Dr. Levant in the past through other sources, and I find that he offers much through his vision of what psychologists and psychology in generally can offer for the future of improved healthcare.

Thank You,

Irene Katsamanis, MA, MS
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International Psychology Reporter
APA Division 52 Newsletter

Volume 7, No.1 Spring 2003

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International Psychology Reporter is the publication of Division 52 of the American Psychological Association

◆ NEWS FROM DIVISION 52 ◆

Division of International Psychology: A Brief History

John D. Hogan, PhD, St. John's University, NY

Introduction

On February 21, 1997, the APA Council of Representatives approved a petition to create a new division: APA Division 52, the Division of International Psychology. The successful effort had been the culmination of years of planning and work by a small group of people dedicated to fostering an international outlook within the APA. The focus on an international viewpoint by the APA was not an entirely new undertaking for the organization. In fact, the APA had been involved in international activities at some level for years before the approval of the Division 52 petition.

In 1944, the APA established a Committee on International Relations in Psychology (CIRP) whose initial mission was to advise the organization on the recovery and restoration efforts concerning the laboratories and libraries destroyed in Europe during World War II (Fowler, 1998). Later, the role of the committee was expanded to consult with the APA on a wider range of international issues. In 1974, a full time Office of International Affairs was created to coordinate several international programs, including a book/journal donation program, a travel grant program, and a quarterly newsletter. Despite these efforts by the APA, a group of individuals felt that certain goals could be achieved only through the creation of a separate APA international division.

The effort to form a new division resulted in friction with individuals who felt that the division might duplicate activities and generate unnecessary tension with the Office of International Affairs. Even some later champions of the division were initially opposed to its formation. As a result of this opposition, the goal of creating a new division was difficult. For example, an earlier proposal presented to the APA Council of Representatives was rejected. As with other new divisions, the APA required that petitioners collect a specified number of signatures supporting the division – the number based on a percentage of the APA membership. However, each time the required number of signatures was gathered, it would turn out to be insufficient. In the interim, the APA had grown larger, and a greater number of signatures were required to meet the appropriate percentage.

Substantial "behind the scenes" work was necessary to promote the new division.

(N.B.: Several oral histories of the division are currently being conducted, in part to clarify various aspects of the "pre-history" of the division. Material from them will be incorporated into a later history.) Ernst Beier, PhD, a clinical psychologist with both a university and a private practice background, was one of the prime movers in getting the division started. Several people described him as the "initiator" and "banner carrier" for the new division. He and Frances Culbertson, PhD, worked with various APA boards and committees, gathering support. Other individuals were recruited and immediately immersed themselves in the effort. Among them were Leonore Loeb Adler, PhD, Henry David, PhD, Florence Denmark, PhD, and Gloria Gottsegen, PhD. Ivan Kos, PhD, a clinical psychologist and international consultant, lent his considerable expertise in the initial stages. Sarah Jordan and Joan Buchanan, both of APA, were also very important in offering early support for the division. One of the first hurdles for the group was to collect the required number of signatures for presentation to the APA Council. In the end, 788 signatures were collected. (The complete list of petitioners appeared in Vol. 1, Issue 1, of the *International Psychology Reporter*. All are identified as "charter members" of the division.)

Ernst Beier, PhD, Florence Denmark, PhD, and Frances Culbertson, PhD, acted as the initial Executive Committee and recruited additional members for the Board of Directors. In all, fifteen individuals who had been active in forming the division assumed various offices on a "pro tem" basis and the membership was asked to confirm their status by mail vote. Regular elections were scheduled for May, 1998. Those serving on a "pro tem" basis on the Board of Directors were: Ernst G. Beier, PhD, President; Florence Denmark, PhD, President Elect; Sheila Joshi, PhD, Secretary; and Leonore Loeb Adler, PhD, Treasurer. Members-at-large on the Board were Frances Culbertson, PhD; Henry David, PhD; Gloria Behar Gottsegen, PhD; and Carl N. Zimet, PhD. Other "pro tem" offices were filled by: Frances Culbertson, PhD, Liai-

(Continued on page 4)

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(Continued from page 3)
son/Observer to the APA Council of Representatives; Ivan Kos, PhD, Newsletter Editor; Mary E. Reuder, PhD, Fellows Chair; Joan Chrisler, PhD, Membership Chair; Harold Takooshian, PhD, Program Chair; Joy Rice, PhD, Program Co-Chair; and Robert Morgan, PhD, Awards Committee Chair.

The first formal meeting of the division took place at the 105th annual APA Convention, held in Chicago, from August 15-19, 1997. Because Div. 52 was approved the previous February, there had been no opportunity to develop a program in time to meet the customary convention deadlines. However, the division was able to share some convention time with the APA Committee of International Relations in Psychology (CIRP) and, in that way, to present an abbreviated program. The first formal Board Meeting of the division was held on Saturday, August 16. A tee-shirt was created celebrating the new division, funded by APA, with a logo by Mirella Kos.

Sarah Jordan, the Director of Divisional Services for APA, continued to provide guidance to the division during its formative period, particularly as a "go-between" for the division and APA. Initial dues were set at $12/ year, beginning in 1998. The Board requested donations from the charter members to support the operation of the division during the remainder of 1997. The first issue of the newsletter, the *International Psychology Reporter*, consisting of 10 pages, appeared in June, 1997, and a second issue appeared in October, 1997. The publication of the early issues was possible through the financial assistance of Raymond D. Fowler, PhD, Chief Executive Officer of the APA. Ivan Kos, PhD was the founding editor of the newsletter and continued in that role. He had many contacts in the international community and was able to call on them for articles. From the beginning, he envisioned the newsletter as being multifaceted, consisting of a variety of features, but always available as a vehicle to "provide all members with the opportunity to express themselves equally."

Early growth and change (1997-1998)

By the Fall of 1997, several new initiatives were underway. A set of proposed bylaws for the division, developed under the leadership of Gloria Gottsegen, PhD, appeared in the *Reporter* (10/97). James McHugh, the APA general counsel provided assistance on legal issues as the bylaws were being developed. Members were asked to indicate their approval or disapproval of the bylaws by mail ballot, due January 1, 1998. The bylaws included a mission statement: "The purpose of this division is to further the development and advancement of international relations among psychologists in the areas of sharing knowledge, encouraging visitation, and encouraging intercultural research and development in clinical practice, and to promote the general objectives of the APA."

Student membership in Division 52 became a reality in the fall of 1997. Co-chairs of the Student Membership Committee were Shannon E. McCaslin, a 2nd year doctoral student in clinical psychology at the University of North Dakota, and Kristin Lang, a 4th year doctoral candidate at Loyola University in Chicago. William G. Masten, PhD, was appointed to the position of web-page chair. The official web site became available in January, 1998: http://www.TAMU-Commerce.edu/orgs/div52.

During this period, Mary Reuder, PhD and her fellows committee were at work preparing criteria for fellow status in Division 52. Since APA requirements state that no one can become a fellow of a division until they have been a member for at least one year, no Division 52 Fellows were eligible until February, 1998, a year after the official establishment of the division. (In August, 1998, 72 charter fellows of the division were approved.) While the first newsletter was devoted almost entirely to issues reflecting the establishment of the division, the second issue began to include other substantive articles, reflecting both international and domestic concerns. By early 1998, Division 52 was represented on the APA Council of Representatives by a single seat.

Division site:

http://www.apa.org/about/division/div52.html

Harold Takooshian, PhD, and Joy K. Rice, PhD, as Program Committee chair and co-chair respectively, began preparing for the division's first full APA program, to be presented during the annual convention that was held in San Francisco, August 14-18, 1998. It was a particularly auspicious beginning for the division's programs since the APA convention immediately followed the 24th Congress of the International Association of Applied Psychology (IAAP) held on August 9-14, also in San Francisco. Harold and Joy sent e-mails to the heads of twenty international behavior science groups to ensure that there would be international representation on the program. They were rewarded with submissions from six continents -- the first arriving in September from Australia. In all, 39 countries were represented in the inaugural program.

Permanent status and further initiatives: (1999)

At the APA Council of Representatives (COR) meeting, held from February 19-21, 1999, in Washington, DC, Division 52 was granted permanent status. Florence Denmark, PhD, became division president in 1999, with Frank Farley, PhD, as president-elect, Lenore Walker, EdD, treasurer, Harold Takooshian, PhD, the new "member-at-large" of the board, and John D. Hogan, PhD, the new program chair. Budget constraints limited the *Reporter* to only two issues in 1999 (the fall/winter issue was a "double" issue), but efforts were made to ensure that three separate issues would be published each year in the future. According to Joan Chrisler, PhD, membership chair, the division had 952 members as of July 21, 1999. Of those, 130 were students, and 866 were from the U.S. Not all were dues-paying members. (According to Lenore Walker, EdD, treasurer, as of June 30, 1999, the division had 549 dues-paying members.)

Two special interest groups within the division were approved by President Denmark. An "International Committee for Women" was begun, with Joy K. Rice, PhD, as chair. It held its first meeting on Friday, August 20, 1999, at the Annual APA Convention, held in Boston, MA. A "Committee on Aging" was also begun, with Margaret M. Hastings, PhD, as chair. Evana Hsiao became the new student membership co-chair, replacing Kristin Lang who left to pursue a clinical internship. Student membership continued to be strong. Toward the end of 1999, Sheila Joshi, PhD, had to resign as secretary due to a serious illness in her family. She had done an extraordinary job in helping to organize the division in its earliest days. William Masten, PhD, the division webmaster, volunteered to serve as acting-secretary until a new secretary could be elected.

Amendments were proposed to the division bylaws and approved by the division Board of Directors in August, 1999. Many of the proposed changes were stylistic or grammatical, and were suggested by the APA legal counsel. Other changes included the establishment of a webmaster position and, as a new standing committee, the "International Committee for Women." It was also proposed that the term of the treasurer be lengthened from

(Continued on page 5)

(Nominations 2000 cont. from page 4)
for Women." It was also proposed that the term of the treasurer be lengthened from two to three years. The proposed amendments appeared in the *International Psychology Reporter* (fall/winter, 1999, pp. 11-13) with the request for a member vote by January 15, 2000. At the Board of Directors meeting held on August 19, 1999, Irene Deitch, EdD, was appointed chair of the Public Relations Committee and Richard Velayo, PhD, was appointed chair of the 2000 Program Committee. Michael Stevens, PhD, agreed to continue as chair of the International Liaisons Committee and Harold Takooshian, PhD, agreed to continue as chair of the Fellows Committee.

The division enters a new century: 2000-

At the February 2000 Board Meeting, division president Frank Farley, PhD, proposed changing the name of the division to "The Society for International Psychology: A Division of the American Psychological Association." He felt that the name change would promote greater visibility and a stronger identity for the division. His proposal was approved by the Board of Directors. However, the Board of Directors that followed reversed the decision, and permission for the change of name was not sought from the membership. The number of fellows of the division continued to grow so that by August, 2000, the division had 126 fellows (72 charter fellows in 1998, 18 fellows in 1999, and 36 fellows in 2000).

The division newsletter, International Psychology Reporter attracted a sparkling array of distinguished authors. The fall/winter 2000 double-issue was particularly impressive, and included articles by then current APA President, Patrick DeLeon, PhD; APA President-elect, Norine Johnson, PhD; APA CEO and Past President, Raymond Fowler, PhD; several other APA Past Presidents, Florence Denmark, PhD, Frank Farley, PhD, and Jack Wiggins, PhD; a future APA President, Philip Zimbardo, PhD; APA Recording Secretary, Ronald Levant, EdD; the Secretary-General of the International Council of Psychologists, Kay Greene, PhD; and the Chair of CIRP, Anthony Marsella, PhD. And these were just some of the contributors! The ability of editor Ivan Kos, PhD, to attract such high level authors to the newsletter was astonishing.

Bill Masten, PhD, who had taken over as acting-secretary, was elected secretary with his term beginning January 1, 2002. Frances Culbertson, PhD, was reelected as the APA Council Representative. Membership issues continued to be of concern. Between 2000 and 2001, the total paid membership decreased from 923 to 783. During the same period, unpaid membership was up slightly, from 118 to 133. It was noteworthy that several other divisions within the APA were adding international interest groups to their organizational structure. It was beginning to appear as if a "new" international psychology was coming of age.

References

Fowler, R. D. (1998). International activities in the American Psychological Association. *International Psychology Reporter, 2* (1), 6-7.

Appendix A

Division Presidents

Ernst G. Beier 1997-98
Florence L. Denmark 1999
Frank H. Farley 2000
Gloria Behar Gottsegen 2001
Charles D. Spielberger 2002
Harold Takooshian 2003
Richard Velayo 2004
Norman P. Abeles 2005

Division Awards 1999

Career Awards for Outstanding Contributions to International Psychology:
Frances Culbertson
Charles D. Spielberger

Distinguished International Psychologist:
Florence L. Denmark
Edwin Fleishman

Certificates of Recognition for Service to Division 52
Leonore Loeb Adler
Gloria Behar Gottsegen
Sheila Joshi
William Masten
Harold Takooshian

Division Awards 2000

Distinguished Career Awards in International Psychology:
Henry P. David
Peter F. Merenda

Distinguished International Psychologist Award:
Raymond D. Fowler
Bernhard Wilpert

Special Recognition Award:
Joan Buchanan

Certificate of Recognition for Outstanding Service to the Division:
Ivan Kos
Joy K. Rice
Michael J. Stevens
Richard S. Velayo
Carl N. Zimet

Division Awards: 2001

Distinguished International Psychologist Award:
Robert F. Morgan
Elizabeth Nair

The Past President's Gavel
Frank H. Farley

Certificates of Recognition for Outstanding Service to the Division
Joan C. Chrisler
Florence L. Denmark
Joy K. Rice
Harold Takooshian

Student Awards:
Shannon McCaslin
Evana Hsaio

Division Awards: 2002

Distinguished International Psychologist Award:
Susan Pick
Harry Triandis

Past President's Award:
Gloria Behar Gottsegen

Special Service Award:
L. Keith Cooke

Special Recognition Awards:
Ruth Behar
Louise Evans

Outstanding Mentor Award:
Michael J. Stevens

Outstanding Dissertation Award:
Lawrence Hsin Yang, Boston University

Certificates of Recognition for Outstanding Service to the Division:
Henry P. David
Susan E. Dutch
Mirella Kos

(Nominations 2000 cont. from page 2)
but draw Pacific Rim and other nonmembers to Hawaii--a conference that "cannot be missed." There, our Division hopes to cooperate with CIRP on the celebration of its sixtieth anniversary.

As our division looks to the future, it is vibrant, financially stable, growing in membership, and poised within a supportive APA to cooperate more closely with the older international groups that bless our field of psychology, to implement our mission to reach out more effectively to our international colleagues.

References:

Davis, J.M. (2000, Spring). Four international organizations in psychology: An overview. *Eye on Psi Chi, 4,* 33-37.

Hogan, J.D. (2002, August). APA Division 52: A brief history. Unpublished report.

Merenda, P.F. (1995). International movements in psychology: The major international associations of psychology. *World Psychology, 1,* 27-48.

Overmier, J.B., & Overmier, J. (2003). *Psychology: IUPsyS Global Resource CD 2003.* East Sussex: Psychology Press. (www.psycpress.co.uk)

Rosenzweig, M.R. (1992). (Ed.). *International psychological science.*

CALL TO MEMBERS:

to submit short academic articles up to 1500 words, viewpoints of approximately 200 words, relevant news regarding research in intercultural and/or international psychology, as well as a news regarding upcoming programs, courses, or job opportunities.

You are also invited to submit your expressions of interest to participate in particular research, or your desire to join specific programs. You may also share your knowledge of international positions available, and/or your wishes to engage in or announce any other pertinent international contact.

The next issue of *The International Psychology Reporter* is scheduled for Fall/Winter, 2003. Please send your contributions by Oct 31, 2003 to:

Ivan Kos, PhD
Editor
International Psychotherapy Associates
625 Main Street, # 625
New York, NY 10044
fax: 212-486-0174
e-mail: IKosIpa@aol.com

Division of International Psychology

Committee for International Liaisons: Annual Report

Michael J. Stevens, PhD, Chair

LIAISON PROGRAM

At this time last year, 69 psychologists served as country liaisons to APA52. Since August 2002, four new liaisons were added to the APA52 web-based liaison list (http://orgs.tamu-commerce.edu/div52/flags.html) and listserv (div52affiliates@listserver.tamu-commerce.edu). New liaisons are from Ethiopia, Guatemala, Namibia, and New Zealand. The total number of liaisons is now 73. Efforts were already made to encourage liaisons to apply for APA52 membership; this pas year, liaisons from Afghanistan, Guatemala, Romania, and Yemen joined APA52.

Contact information for 12 liaisons was updated, and the web-based liaison list and listserv were updated twice. One liaison was replaced (Pakistan) and one can no longer be reliably contacted (Ethiopia).

The Liaison Program was publicized in the Fall issue of *Eye on Psi Chi* (Stevens, 2002).

Since August,2002, activities related to the Liaison Program have included disseminating the liaison list and specific contact information, forwarding conference announcements and advising on conference participation, soliciting authors for special journal issues and participants for symposia, advising on the submission of articles to the *Reporter*, consulting on grant proposals, making arrangements for editorial mentoring, forwarding requests for faculty and student exchanges and job and post-doctoral vacancies, and providing information on psychology in other countries.

Discussions were undertaken with the Indonesian liaison to explore possible ties between APA52 and a national research and service center on human resources located in Indonesia. The center is conceived of as a data archive and collection base for APA52 members interested in conducting research or consulting in Indonesia or in neighboring countries. It would have facilities to accommodate fellows staying in Jakarta for extended periods of time.

GOALS FOR THE LIAISON PROGRAM

Expand the number of liaisons in underrepresented regions and arrange for multiple liaisons in psychological specialties. The Liaison Program will work more closely with Uwe Gielen and the Communications Committee to increase exchange of information and collaboration. With Judith Torney-Purta and the Divisional Liaisons Committee, the Liaisons Program will attempt to share resources and coordinate international efforts with other APA divisions. In cooperation with Dennis Carmody and the Outreach Committee, the Liaison Program will work to increase international membership in APA52, particularly from the Pacific rim; we have already posted an invitation for liaisons to join APA52 as members or affiliates through the liaison listerv with personal invitations to follow.

CLEARINGHOUSE PROGRAM

The International Psychology Information Clearinghouse has been expanded, updated, reorganized; all Internet addresses are now functional.

The Clearinghouse now contains 178 source of information on various opportunities in international psychology, an increase of 47 sources since August 2002.

Information has been reclassified from 7 into 10 descriptively concise categories, which include general resources, career information and resources, opportunities in academic and research settings, opportunities in clinical and service agencies, funding for research, support for conferences, support for travel, awards, resources for American psychology students, and resources for foreign psychologists and psychology students.

The Clearinghouse is available via the APA52 web site (http://orgs.tamu-commerce.edu/div52/Clearinghouse.doc) and as an email attachment. The Clearinghouse has also been published in *Psychology: IUPsyS Global Resource* (http://www.psypress.co.uk/iupsys/cd.html), with new editions appearing annually.

The Clearinghouse was featured in the Fall issue of *Eye on Psi Chi* (Stevens, 2002).

Since August 2002, activities related to the Clearinghouse Program have included disseminating the clearinghouse and providing information on training in international psychology, joining international societies, seeking employment

(Continued on page 7)

(Cont. from page 6)
abroad, applying for research grants, participating on disaster response teams, obtaining travel support, and seeking access to electronic journals through the International Affairs Office's Journal Donations Program.

The Clearinghouse Program encouraged an initiative to translate John Hogan's brief history of APA52 into Spanish for posting on the APA52 web site.

GOALS FOR THE CLEARINGHOUSE PROGRAM

Identify psychology programs with courses and research opportunities in international psychology, distance-learning in psychological specialties, and organizations that offer international internships; and in collaboration with Judith other Divisional Liaisons to APA52, the Clearinghouse Program will seek to expand the list of governmental agencies, private agencies, and professional organizations that fund international teaching, research, and consultation.

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MORE NEWS FROM DIVISION 52

NEW C.D. ON INTERNATIONAL PSYCHOLOGY

Psychology Press is pleased to announce the release of the new *IUPsyS Global Resource CD 2003,* edited by Bruce and Judith Overmier. This CD is the most complete guide to date on all aspects of psychology around the world--organizations, programs, conventions, people, addresses, articles, books, indigenous psychologies. The 2003 list price for this CD is U$37.50. Details are available at www.psypress.co.uk .

NOTE: The publisher kindly offers a 20% discount to members of Division 52 who order the CD directly from Psychology Press in 2003. For any details, contact kate.moysen@psypress.co.uk.

NEW SELF-HELP DIRECTORY

"Although the world is full of suffering ... it is also full of overcoming it." --Helen Keller

The seventh edition of *The self-help sourcebook* has just been published, as an invaluable new 448-page Directory for psychology practitioners and teachers who are often asked for help on non-psychological problems. Such problems may be common or rare, and include many different types of Abuse, Addictions, Disabilities, Employment, Family, Grief, Medical/Health, Terrorism/Trauma. The *Sourcebook* thoroughly indexes the invisible world-wide network of thousands of local self-help groups across the USA and the world, which offer help to literally millions of people with all sorts of personal problems. Such self-help groups can be a wonderful complement to traditional therapy, especially for clients will multiple problems. The *Sourcebook* is published by the American Self-Help Group Clearinghouse, at a list price of U$18 postpaid. Details on the *Sourcebook* and its self-help groups are available at www.selfhelpgroups.org.

NOTE: A deep discount on the *Sourcebook* is available to members of 52. For details, contact Co-Editor Edward J. Madara, at 973-326-6789.

Members of APA Division 52 are now invited to nominate others

CALL FOR FELLOW NOMINATIONS

Members of APA Division 52 are now invited to nominate others (or themselves) for election as a fellow of Division 52, based on their "unusual and outstanding contributions" to international psychology. Write soon for a packet of forms.* This year all completed materials must be submitted by 5 pm Friday, December 12, 2003 -- including the nominee's vita, personal statement, and endorsements from 3 current APA fellows. As of 1999, at least 2 of the 3 endorsers must be a fellow of division 52. The list of 15 criteria for fellow of division 52 is available on William Masten's website, along with the complete list of 100+ current fellows of division 52 -- www.TAMU-Commerce.edu/orgs/div52 .

* NOTE: Those currently a fellow of another APA division can ask about a streamlined nomination procedure. -- Paul J. Lloyd, Fellows Committee Chair, Southeast Missouri State University, Cape Girardeau MO 63701, USA. Phone: 573-651-2437. E-mail: plloyd@sbcglobal.net

EARLY CALL FOR HAWAII - 2004

Aloha! It is not too early to plan to participate in the International Program at the magnificent 2004 APA convention in Honolulu, July 28 - August 1. Details are in the Monitor in September 2003. We welcome posters, papers, and symposia on any aspect of international or cross-cultural research, theory, practice, education, advocacy. Posters are especially encouraged on specific themes: cross-cultural therapy, assessment, teaching & learning, women & gender, Asian psychology, ethnic prejudice and tolerance. Innovative formats welcome. No fax submissions. For details contact Chairperson Anie Kalayjian at kalayjianAPA@aol.com, or Co-chair Uwe P. Gielen at ugielen@hotmail.com.

INQUIRY

Psychology in the USA is based on specific training models, such as the Boulder Science-Practitioner model for doctoral programs, or the 1993 St. Mary's model for undergraduate education. What are some training models used in Europe, Asia, or other nations besides the USA? Dr. Wade E. Pickren in the APA Library/Archive in Washington DC welcomes any information you may have to share on this question, for an upcoming project he is now planning. Please contact him soon at wpickren@apa.org.

NEW STUDENT GROUP

For information on the new and growing International Student Psychology Organization, check www.psychologystudents.org, or contact President Edward Van Rossen at the University of Leuven in Belgium, edward@ipso.intranets.com .

FREE NEWSLETTER

The International Union for Psychological Sciences is pleased to announce its new online Newsletter in 2003. Members of 52 are invited to receive a free subscription, by signing on at www.iupsys.org. For any details, contact IUPsyS Deputy Secretary-General Merry Bullock, at mbullock@apa.org.

Sharing My Current Perspectives With You

Norman Abeles, PhD, former APA President
Division 52 President Elect Designate

Next year, I will be President-Elect of Division 52 and I was pleased to be asked by your Editor, Ivan Kos to introduce myself to the membership of the Division. By the time you read this, I will have returned from a symposium presentation on prescription privileges (as discussant) at the 8th European Congress of Psychology in Vienna, Austria. The other three participants were John Norcross, Bob Resnick and Gerry Koocher.

My other involvements with international psychology include membership on the USNC/IUPsyS. That is short for the United States National Committee for the International Union of Psychological Sciences. This committee represents psychology as a profession and as a science and aims to provide for an exchange of information between psychologists from different countries. It also helps to organize International Congresses (e.g., International Congress of Applied Psychology; International Congress of Scientific Psychology). The next International Congress of Psychology will occur in Beijing China on August 9-13, 2004 and the next International Congress of Applied Psychology will occur in Athens Greece July 16-21, 2006. There will also be a regional Conference of Psychology on December 13-18, 2003. This conference, the Middle East and North Africa Conference on Psychology (MENA) will take place in Dubai, United Arab Emirates and is cosponsored by the International Association of Cross Cultural Psychology as well as by IUPsyS and IAAP. One bit of breaking news from the International Association of Applied Psychology: The Supreme Court of Spain has decreed that a formal certificate will now be required for positions in private and public institutions for specialists in clinical psychology. The certificate requires a specialized training program designed for University graduates in psychology and will require competitive examinations and interviews for admission to this program of study.

Some of the other functions of the International Unions of Psychological Sciences include providing aid to scholars in different countries and to assist in the exchange of students and young research workers. The issue of international visitors has become a significant problem since 9/11 as many potential visiting scholars find it more difficult to obtain visas to enter the United States. I may discuss this further in future presentations.

One of the current projects of IUPsyS is to have a work group to design a universal declaration of ethical principles for psychologists which hopefully will be submitted at the 2004 meeting in Beijing. In the development stage is an International Student Organization which may seek affiliation with the International Union.

I am also a member of APA's Committee on International Relations in Psychology. At its last meeting of CIRP there was discussion of APA President-Elect Diane Halpern's Presidential Project to include a multicultural website on prejudice. One of Dr. Halpern's goals with regard to the project is an effort to obtain multiple language translations on prejudice and related topics. The Committee on International Relations in Psychology is in the process of discussing how suitable materials can be identified and the committee is in the process of discussing aspects of this Presidential Project and how CIRP can be of assistance to President-Elect Halpern. Among other matters of business CIRP discussed next year's APA convention in Honolulu and CIRP will provide ideas on how to make next year's convention a success. Other activities of CIRP include responsibility for overseeing the development of occasional Special Sections on International Perspectives in the American Psychologist. CIRP reviews proposals for these Special Sections. Another item under discussion by CIRP concerns UNESCO (United Nations Educational, Scientific and

(Continued on page 9)

Correction to the Division 52 Program at 2003 APA Convention

Please note that it is a correction to the Division 52 Program at 2003 APA Annual Convention. An omission of a contributor had occurred.

Symposium: "The Contributions of Internationalization to the Psychology of Women

Co-Chairs: Dr. Esther Halpern, Israel
Dr. Frances Culbertson, USA

Participants in order of presentation:

Rice, J.K., USA
"Internationalizing the Psychology of Women within the American Psychological Association"

Roth, R. Austria
"Cross-Cultural Issues in Women's Reproductive Health"

Margaona, E., Mexico
"Psychology and women in Latin America: Its Contribution Toward Their Development"

Ebanga, T., Cameroon
"The Influence of the Beijing Conference on the Perception of a Cameroon Woman"

Halpern,E., and Wasserzug, H., Israel
"Issues in Internationalization of Psychology and Women's Studies in an Israeli Perspective" (Please note that this contribution was omitted from the listing of participants)

Discussants:
Denmark, F., USA
Culbertson, F., USA

The main goal of APA at the United Nations is to help contribute to the development and implementation of policies that respect human rights and contribute to human well-being utilizing psychologically informed means.

(cont. from page 8)

Cultural Organization). You may recall that the United States withdrew from that organization in 1984. The United States has rejoined UNESCO according to an announcement by President Bush in September 2002. One of the questions being discussed now is whether or not APA will apply to join as an organizational member of the US National Commission for UNESCO. Currently, APA is a non-governmental organization (NGO) accredited with the UN economic and Social Council and we have a Main Representative working on behalf of APA at UN headquarters. This representative oversees the work of the other five NGO representatives who work on behalf of APA. The current representative is Dr. Okorodudu and she is a current member of CIRP. In her April 2003 report to CIRP, Dr. Okorodudu noted that APA has completed two full years as a non-governmental organization at the United Nations. The main goal of APA at the United Nations is to help contribute to the development and implementation of policies that respect human rights and contribute to human well-being utilizing psychologically informed means. One example of the work of the APA delegation was to develop a working relationship between South African and US researchers who were interested in reducing the spread of HIV/AIDS in both countries. Other efforts included work by Florence Denmark, PhD from Pace University in New York and Deborah Ragin, PhD from Mt Sinai School of Medicine. Their work on this delegation focused on gender issues in the NGO committee on the Status of women. Dr. Denmark has been especially active in the area of aging and serves on the subcommittee on Older Women. She also served as the co-chair of the 12th Annual commemoration of the International Day of the Older Person, which was held at UN Headquarters in New York in October 2002.

As a member of APA's governing body, the Council of Representatives, I was pleased to vote for the adoption of Guidelines on Multicultural Education, Training, Research, Practice and Organizational Change for Psychologists which was passed in August 2002. Let me focus briefly on Guideline #5 which deals with the use of culturally-appropriate skills in clinical practice. The Guideline notes that while US society is becoming more culturally diverse as well as becoming more linguistically diverse, psychological services tend to be less utilized by minority groups. It is suggested that psychologists become more familiar with cultural, sociopolitical and related factors which may affect psychological concerns of clients. In particular, psychologists need to be familiar with the limitations of assessment instruments especially those that are used for employment screening and personality assessments in work settings (p48). The Guidelines also encourage practitioners to learn about helping practices used in non-Western cultures and encourages becoming familiar with non-traditional interventions (p49). It may be that our Division can continue to be helpful in offering ways for practitioners to become more familiar with helping practices which will be effective with non traditional clients. In a workshop given by Peter Marsella and Paul Pederson at the APA meeting in Chicago in 2002, the authors listed 50 ways to internationalize the curriculum of "Western" Psychology. Among them they include the need to understand cultural and international variations in psychopathology and the need to develop skills for teaching and learning about peace keeping, terrorism, acculturation and conflict resolution among others. They also encourage that we internationalize our curriculum to include a psychological science which is multicultural and multidisplinary. These are clearly not simple tasks nor is it likely that every psychologist will be involved in modifying curricula which are now part of Western culture. However, I believe that in this 21st century we need to make progress on working on internationalizing our curriculum. In this regard, the Society for Teaching of Psychology (APA Division 2) last year issued a call for proposals which aim to internationalize the psychology curriculum. Two grants were made available through the APA Education Directorate in collaboration with the APA Committee on International Relations (CIRP).

I have tried to share some of my perspectives with you. Feel free to contact me at abeles@pilot.msu.edu with comments or questions.

References

1. American Psychological Association (2002). Guidelines on Multicultural Education, Training, Research, Practice, and Organizational change for Psychologists. Author: Washington, D.C.

Graduate Commencement

Saturday, May 17

Peter F. Merenda

Honorary Doctor of Humane Letters

Retired University of Rhode Island Professor, Peter F. Merenda, co-founded the Department of Psychology more than 40 years ago with Kenneth Carpenter. He also established the graduate programs in psychology, the College of Continuing Education psychology degree program and served two terms as department chair and was the first associate dean of the Graduate School and the University Coordinator of Research. In 1968, he also co-founded the Department of Computer Science and Statistics.

Merenda has distinguished himself with a career as a noted researcher and leader in his field and has served as president of several national and international psychologi-cal associations. He has been invited to lecture throughout the Americas, Europe and Asia and has published more than 250 articles, two books and presented more than 100 symposia. He has received notable honors including two Fulbright Awards, the American Psychological Association Karl R Heiser Presidential Award and the American Psychological Association Award for Outstanding Contributions to International Psy-chology. He is a named fellow with several national professional societies.

While this record of achievement and hard work is itself quite remarkable, it is Merenda's dedication to the University continuing years into his retirement, that most distinguishes his life. He advocated tirelessly for psychology and excellence in undergraduate and graduate training. He promoted and supported the careers of many students and colleagues throughout the years. He served in advisory capacities on many committees enabling the successful completion of theses and dissertations.

NATIONAL NEWS

A TIME FOR PSYCHOLOGY'S PROACTIVE INVOLVEMENT

Pat DeLeon, former APA President

It was just two years ago that I was last invited to share my thoughts with the Division. At that time, I reflected that: "(I)t has been my observation that over the years, psychology's international agenda has been individual, rather than systems, oriented." Admittedly, a number of outstanding individuals – including many former and serving APA Presidents – have personally contributed countless hours representing psychology and APA extraordinarily well at international conferences and events. And, Danny Wedding, Bob Frank, Kris Hagglund, and now Dan Crimmins have all had the honor of serving as Robert Wood Johnson (RWJ) Health Policy Fellows. For those of us intimately interested in the evolution of our nation's health policy, this is perhaps the highest tribute one of our colleagues can be accorded. Over the years, the RWJ program has carefully explored the lessons to be learned from international successes and less fortunate efforts. However, I would again rhetorically ask: "How is the Division systematically utilizing their unique expertise?"

Former APA CEO Ray Fowler has noted that: "We [in the U.S.] are a very small piece of the world's population and only 20 percent of the world's psychologists [100,000 of the estimated 500,000]. Psychology around the world is experiencing the kind of explosive growth we had post-WWII. In another decade or so, there will probably be a million psychologists in the world." In my judgment, collectively, as both a science and as a profession, psychology has yet to develop a highly visual and proactive international agenda. Judith Albino, President of Alliant University, reports that her educational institution has campuses in Mexico and Nairobi, Kenya; with programs in Japan, Thailand, and several other nations in the planning stages. Where are our other training institutions? Where will future generations of psychologists obtain first-hand exposure during their formative years in international health? How many psychology programs have developed collaborative agreements with Schools of Public Health or Health Administration, where international health courses are traditionally taught?

The Fiscal Year 2004 budget justification for the John E. Fogarty International Center for Advanced Studies in the Health Sciences (FIC) at the National Institutes of Health (NIH) requested $64.2 million. The Senate Appropriation Committee recommended an additional $1.6+ million and noted that: "Adapting research advances in biomedicine to populations at home and abroad requires a continuing commitment to basic science as well as rigorous clinical and applied (epidemiological) studies. Examples are vaccines, anti-infective agents, drugs, and more efficient diagnostic tools, combinations of interventions, and health policies to reduce the risk of disease and its associated human, social, and economic consequences. These challenges will benefit from a more coordinated and multi-disciplinary approach to global health needs. It is the mission of the FIC to address these challenges by forging collaborations with a range of domestic and global partners in international research and training to pursue three core objectives: first, to accelerate the pace of discovery and its application by special projects enabling scientists worldwide to share conceptual insights, analytic methods, data sets, patient cohorts, or special environments; second, to engage and assist young as well as more established U.S. investigators to address scientific challenges related to global health; and third, to help develop a cadre of highly capable young foreign investigators positioned to cooperate with U.S. scientists in areas of the world that, due to geography, genetics, or disease burdens, provide unique opportunities to understand disease pathogenesis, anticipate disease trends, or develop interventions of relevance and priority for both the United States and the collaborating country."

The FIC budget justification proffers: "Never have global health and disparities in health care, including access to and affordability of the products of medical research, been more prominent on the world's agenda.... In this, the 35th year since the establishment of the John E. Fogarty International Center (FIC), its work has never been as relevant to these issues nor has the Center been recognized as much as it is today for its leadership in supporting cutting-edge research collaborations with U.S. academic institutions and research capacity building in the most affected countries. These efforts are critical to the Center's mission, succinctly expressed as 'Science for Global Health,' and to advancing the leadership role of the United States in this endeavor. Nations around the world have expressed firm commitment toward meeting the eight goals outlined in the United Nations Millennium Declaration. FIC is addressing the five health-related Millennium Development Goals.... To assist this process FIC's research program in International Studies on Health and Economic Development will clarify the relationship between improvements in health; i.e., nutritional status and economic productivity.... Medicine has been called 'the last, and certainly the finest, untapped resource of international diplomacy.' As the Global Forum on Health Research notes, 'good health is central for (a) the promotion of development; (b) the fight against poverty; and (c) global security. In turn, health research is central for the efficient and effective promotion of health.'"

In reviewing the Administration's plans for the Fogarty Center it is important to reflect upon (and appreciate) the timeliness of former APA President Norine Johnson's vision. Under Norine's progressive leadership, the APA membership voted overwhelmingly to expressly include "health" in our Association's underlying mission statement. Today the Congress is in the midst of determining the specifics of its Medicare Prescription Drug Benefit proposals and at the same time, the White House budget office has criticized the expansion of payments to teaching hospitals that train clinical psychologists as an example of "provisions that would increase the cost of the program and that are unrelated to strengthening and improving Medicare." We know better. We should applaud the hard work of Russ Newman and the Practice Directorate staff, especially Marilyn Richmond. Psychology is one of our nation's (and the world's) premier health professions and we can contribute significantly to the Fogarty Center's health agenda.

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Hawaii Convention Promises Special International Programming

Diane F. Halpern, PhD, President-elect, APA 2003
Director, Berger Institute for Work, Family, and Children
Claremont McKenna College, Claremont, CA

Aloha-every tourist to the magnificent state of Hawaii has heard this word of greeting, often shouted by tour group leaders as a way of getting groups into a jovial mood or by shopkeepers in the hope of attracting customers. Division 52 members who have studied psychology in multiple cultures and locations around the world won't be surprised to learn that the commercial and casual use of this beautiful word belies its deeper significance in the Hawaiian culture. According to one historic source, this is the intended meaning of "Aloha," in the words of Queen Lili'uokalani: "Aloha was the recognition of the life in another. If there was life there was manna, goodness and wisdom, and if there was goodness and wisdom there was a god-quality. . . . Aloha could not be thoughtlessly or indiscriminately spoken, for it carried its own power. No Hawaiian could greet one another with Aloha unless he felt it in his heart. If he felt anger or hate in his heart he had to cleanse himself before he said, 'Aloha.' " Thus, one interpretation is that Aloha signifies the presence of the divine breath, and when we meet in Hawaii it is to share our breath. It is in this spirit-the original meaning of Aloha-that I invite you to attend to 2004 Convention of the American Psychological Association in Honolulu, Hawaii, July 28th to August 1st, 2004.

The 2004 Convention is being planned to take advantage of the incredible beauty of our 50th state, especially its Hawaiian and Asian heritage, diverse peoples, and its easy access to Asian and other Pacific Rim countries. Although the convention program is still in its early planning stages, I wanted to be sure that Division 52 members plan now, so you can contact colleagues in other countries to arrange programs and international events that might not be possible with mainland meetings. As American Psychological Association president in 2004, I am working closely with Division 52 leadership to attract more international members. I am sending invitations to psychologists in Pacific Rim countries to join the American Psychological Association and to submit poster presentations for the 2004 convention directly to Division 52. After a careful consideration of convention programming, it was decided that poster sessions would not count toward any division's programming hours for the convention. (I'll spare readers the details about how and who makes these decisions, but if you guessed that there are lots of committees that have to agree, you understand how large membership organizations function.) This arrangement makes it easy for Division 52 to sponsor submissions from international psychologists and to make valuable connections with psychologists around the world. As a loyal member of Division 52, I am pleased that we could work out this win-win arrangement. If all goes well, there will be a wealth of new international members at the 2004 Convention in Hawaii and a great opportunity to extend the work of the Division, which I consider to be a critical imperative for psychology.

As you plan your programming for 2004, there will be several changes from the usual convention format that you'll want to consider. Perhaps the first change that you will notice is that the convention is earlier in 2004 than in previous years. With most of the convention falling at the end of July, we will need to have submissions for the program earlier than ever, so plan now! The early start date for the convention is in response to complaints that some semester schools start back-to-school events in mid-August and to the range of dates available for a convention as large as American Psychological Association's. Another important departure from our usual schedule is that the official convention program will run from 8 am to 2 pm. There will be some special events in the afternoon and social events in the evening, but the program is planned so that you can spend time with family and friends on the many magnificent beaches and other attractions. (Did you know that the only royal palace in the United States is the 'Iloni Palace in Oahu or that there are several beaches in Oahu that are considered by the beach connoisseurs as the best in the world?) We are planning to make this a vacation that you will want to share with your family and friends, so bring the whole family because there will be plenty to do for all ages and interests.

It will be my great honor to present the President's Lifetime Contribution to Psychology Award to Albert Bandura at the 2004 Convention in Hawaii. You won't want to miss the presentation by this great psychologist. Although the program is still in its early stages, a few of the many outstanding programs have been confirmed. I have arranged to have Lou Hermann, Director of the Dolphin Institute and professor of psychology at University of Hawaii describe his work on communicating with dolphins. If you are interested in seeing his work first hand, you can visit the Dolphin Institute where Dr. Herman will demonstrate how he literally "speaks with the animals." Developmental psychologists surely know the ground-breaking longitudinal studies by Emmy Werner and her colleagues on the development of resilience in children during the first ten years of life. Her classic book, "The Children of Kauai," was required reading in many psychology departments. The study began when Hawaii was still a territory and ended soon after the islands became our 50th state in 1959. She will be returning to Hawaii and will have some of the original participants from her famous studies participate in the presentation with her. She plans to show early videos of the children who are now grown adults, so that we can see the developmental projectories of these children and how her original work on resilience has "held up" over the intervening decades. This promises to be another special event for attendees of the 2004 convention.

For members who attend the convention for Continuing Education credits, we are also offering some unique opportunities. Although at the time I am writing this article, it is too early for me to know everything that will be offered, I know that the Division on Aging will be offering credits on board an inter-island cruise and other CE Sponsors are considering other new ways to blend the Hawaiian experience with educational opportunities. The Asian-American Psychological Association will be holding their Annual Meeting just prior to the start of the convention and will be offering special programs on Asian psychologies that should be of particular interest to Division 52 members. There will be several anniversaries celebrated in Hawaii-the 25th anniversary of the National Latino/a Psychological Association and the 30th Anniversary of APA's Committee on Women. The Committee on Women will reenact the "storming of the Council of Representatives meeting" that was marked the beginning of the Committee

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INTERNATIONAL NEWS

INTERNATIONAL ROVING REPORTER:

A Sojourn in Slovenia

Florence W Kaslow, PhD, ABPP

Early May 2003 took us to Slovenia for the 2003 IFTA Conference. This fascinating conference, entitled "Resisting Abuse", was sponsored by the Slovene Society of Family Therapy and the University Psychiatric Hospital of Ljubljana. IFTA was pleased to be a co-sponsor. Many of the almost 200 participants were from Eastern Europe, particularly Slovenia and other parts of the former Yugoslavia. Slovenia, which is in the northern portion of what used to be Yugoslavia, seceded in 1991 and is now a proud and independent country. Nestled in the foothills of the Austrian Alps, this is a beautiful and serene area. The Congress was held at the Conference Center in Lake Bled and our residence for the five days of the conference (and a few extra for just vacationing) was at Grand Hotel Toplice, which fronts on Lake Bled. From the balcony of our room we could see the Castle that sits atop the hill on the other side of the Lake, and an Island, to which we took a large gondola-type boat to see the famous Church. It was all very picturesque and is an idyllic locale for such a conference.

Most of the IFTA Board were present, which brought participants from Argentina, Iceland, Israel, Hungary, Canada, South Africa, Finland, Sweden, the United States, United Kingdom, etc. There were also attendees from Belgrade and Croatia, as well as the other aforementioned countries. As always, it was fascinating to be part of panels and dialogues with people from other lands whose life experiences and traditions have been markedly different. This was particularly evident when engaging in conversations over dinner with an Arab woman who resides in Israel and who teaches in an Arabic studies program in northern Israel. It was heartening that she was willing and able to attend, invited and encouraged by IFTA President, Dr. Chana Winer. At this micro-level, I certainly see efforts at understanding, and that some collaboration is possible. This is most heartening.

Other APA members who were present included David McGill, Robert and Sharon Massey, and Terry Trepper.

However, no matter how lovely the setting and how fine the facilities at Lake Bled, it was distressing to hear how prevalent abuse is, and it seems to be all over the world! Our Arab participant spoke of her research with abused Arab girls and women – and how difficult it is to reach and help these women, given the traditional patriarchal family structure and community mores. Under Israeli law, as in the U.S.A. and other Western societies, reporting of child abuse by professionals is mandatory. However, such reporting violates the strong family prohibition against dishonoring the family by making its private travails public. If the situation is reported, the girl may be removed from her home, causing further shame to the family. It seems no one supports her and they may not visit her. Often she remains in institutional care until age 18 years, and then has no where to go, as everyone in the extended family has shared in the humiliation and there seems to be no forgiveness. As a single woman with no active family ties, she has no status in the community and is left to make it on her own, which is very hard to do.

The alternative method of dealing with this noxious situation that the Arab professor and her colleagues are recommending is for the therapist to whom the abuse is reported to determine with the girl, and perhaps her mother, who the most powerful and respected man, other than the father, is. The situation is explained to him and he is asked if he will become involved so that the family can deal with the crisis itself, protect the girl from further abuse, and avoid shame and loss of family "honor". He is coached to convene a group, usually of the important men in the family system, and together they confront the perpetrator, hold him responsible for his behavior, and warn him against repeating the actions and bringing shame on the family. They set up a system for monitoring his behavior. This approach clearly has advantages if it protects the girl from further harm, assures her the family will take care of her instead of blaming and isolating her, and strengthens the family (as the bulwark of society). However, one needs a way to reconcile this kind of family resolution of its errant member's misbehavior, with guidance from a professional, with the legal requirements of reporting.

This more benign approach seems to me to have much merit and perhaps could be tried in other places where a network of key extended family members can be convened and activated. Perhaps we could report and ask that a period of time be granted for the family to take action, if an appropriate leader, who is willing to intervene, can be located. The family can report through him to the therapist, and if the situation seems to be remedied, nothing further will need to be done. However, if the family's efforts prove inadequate or ineffective, then the Protective Service Agency can be notified and get involved. This approach bears similarities to the Network Therapy of Ross Speck and Caroline Attneave (1972), and Uri Rueveni (1975), and the link therapy of Landau (1990). Going back to the future may provide a valuable approach to helping families marred by abuse to find (and perhaps re-engage with) the resources within the extended family to strengthen their coping abilities and increase their sense of security and competence. This strategy curtails blaming the victim, by squarely placing the responsibility on the perpetrator, and offers the family a secure and more private holding environment in which to resolve its problems. Clearly this approach, like all others, would not be the treatment of choice for all families in which abuse occurs, but should be tried with families whose structure, dynamics and members would be receptive to it

There were many other excellent and informative presentations, and it was interesting to learn about family therapy in Slovenia. In addition, I particularly enjoyed hearing Drs. Jill and David Scharff talk about their psychodynamic model of couple therapy, using a pleasing tandem dialogue format of presentation.

However, the highlight for me occurred at the Saturday night banquet. The IFTA Board used this as the opportunity to make a very elaborate and moving testimonial to my having been founding President of IFTA (1987-1990) and my having served diligently for 16 years on the IFTA Executive Board. As this seems long enough to occupy such a position on any Board, I had tendered my resignation in Slovenia. That Chana Winer and all of the other assembled Board members made this such a special occasion with a beautiful gift and individual tributes made it an event I will long remember.

The next IFTA Conference will be in Istanbul, Turkey in March 2004, and is open to non-members. For further information, contact:

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Adios para ahora!

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Two Voices from International Psychology

Katherine Richmond, PhD
Lenore Walker, PhD

This article is written from the perspective of a mentor and mentee who have explored international psychology opportunities to enrich our psychological knowledge and practice. The motivation for this article stems from our desire to share our experiences in international psychology, as it has become an integral part of our relationship.

Lenore: When Kate came to me for some mentoring in international psychology, I had to figure out exactly what a student needed from a mentor. Was it practical understanding about diversity issues? Was it advice about traveling in a different country with emphasis on learning the similar and different customs to ours? Was it providing introductions to well known international psychologists who I knew well enough to feel comfortable to make such connections? Was it hanging out together with my friends and sharing the fun times at international meetings? I decided to start where Kate was at, always a good point to begin when you don't have all the answers!

Kate: Understanding and respecting diversity, as defined by my Sue, Sue & Sue textbook seemed to me to be a useful clinical skill to add to my already growing list of conceptualizations of the human experience. Similar to many of my peers, I spoke the diversity psychological lingo and naively believed that I incorporated ideas of diversity into my practice of clinical psychology. Of course, this is the politically correct clinical mentality! But, I believe it was John Lewis's class on "The Assessment and Intervention on Diverse Populations" that shifted my ideas about issues of cultural and history as they apply to clinical practice. Instead of glancing at the clock for a minute by minute count of lunch hour, I found myself immersed in the lectures and heated discussions that ensued. It quickly became apparent that many of my classmates (including myself) had never travelled abroad. Sure, some of us had a week visit to Europe or even somewhere more exotic, but those trips were confined to tourist attractions and fancy hotels if we went with family. So, we relied on our textbooks to explain the nuances and customs of diverse groups of people. According to my grade, I am culturally competent. But, was I really?

This question began the beginning of my journey into international psychology. Equipped with curiosity and a small graduate budget, I planned a six-week stay in Cuernavaca, Mexico with a native family. I remember when I arrived to the Miami International Airport the check-in clerk said, "are you sure you are going to Mexico by yourself?" Somewhat taken aback, I realized that the check-in clerk did have a legitimate point. I was a young, (very) White, female, American woman in a country where I barely knew the language or customs.

Lenore: When Kate emailed from Mexico wanting to know if she could work on the battered woman research project when she returned from Mexico, I sensed a real change in her. She was leaving the textbooks behind and focused on applying her clinical and research skills with real people ... all of a sudden the Mexican people with whom she was interacting were exhibiting all the contradictions we know happen with our relationships in our own country. In one of our first discussions, Kate told me she was reading Laura Brown's book, Subversive Dialogues, an important feminist treatise that questions the social milieu's impact on women and subsequent clinical psychology issues raised in therapy. I began to supplement Kate's knowledge from Brown's book by adding some of my own dialogues with Brown, based on our 20-year friendship and collegial relationship. Within a short period of time, I overcame my hesitation about mixing my friendships with mentoring and suggested Kate call Brown and invite her to be a discussant on a panel presentation Kate wanted to submit to A.P.A. I knew that was the right decision to make when Brown quickly agreed, finding Kate's ideas refreshing and interesting.

Kate: My time spent in Mexico was the first time I truly felt as a "minority." I did not know the language well enough to effectively communicate, and I often became sick from the food. For issues of safety, my family warned that I not take taxies by myself or walk alone at night. Many days, I felt isolated and completely dependent upon my Mexican family members. The first two weeks were filled with many episodes of charades and quick trips to the bathroom. From these first few weeks, however, emerged a friendly (an incredibly patient) culture, where I was welcomed and encouraged to participate in daily living rituals. As I became more comfortable with my surroundings (and with the language), my anxieties and fears dissipated. I was no longer simply an observer but an active participant in the culture, where I felt included and capable of deciphering aspects of my surroundings that I enjoyed (and did not particularly enjoy). As those in the diversity world would say, I was "assimilating."

Although I was in Mexico for only six weeks, my experience profoundly shaped my world-view. So often in our formal education we are taught from a perspective based on logical positivism, which emphasizes linear and reductionistic forms of science. Issues of spirituality, intuitions, and connection are devalued; yet, in Mexico, therapists (and shamans) often relied on these constructs to inform treatment. More importantly, these diverse ways of approaching therapy worked to improve the lives of those seeking treatment! If we are to fully understand and appreciate the socio-political economical concerns our clients bring into session, we need to embrace these facets of the human experience.

Lenore: Discussions about how to integrate Kate's cultural experiences into her therapy and research continued when she returned back to Ft. Lauderdale continued the informal mentoring.

Kate: Upon returning from Mexico, I sought the mentorship from two professors who also shared my enthusiasm for

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international travel and research. They encouraged me to join Division 52 and to attend an international conference. During that year, the International Association of Applied Psychology (IAAP) announced their call for papers for the 25th Annual IAAP conference in Singapore. With the support and guidance of my mentors, we submitted an abstract for review.

Lenore: One of the most exciting parts of participating in international conferences is to meet other psychologists from different countries and cultures who are interested in the same areas of psychology as I am. Can students have as much fun?

Kate: The 25th Annual IAAP conference in Singapore provided a unique forum for intellectual debates and discussions regarding international psychology. Surrounded by world-renowned psychologists and a culturally rich environment, we sipped Singapore Slings and spoke toward the tension between respecting diverse people and encouraging unity. While at the conference, I met several students from other countries with similar visions and interests as my own. After a few exciting and energizing meetings, an international student executive board was formed and a list service for all student members was created by the student president to continue the spirit of the conference through email. The list serv network , composed of students from all over the world, allows for international dialogue and the potential for future research collaborations.

Lenore: Kate got to meet Patricia Villavicencio, a psychologist who I met at an international conference ten years before in Amsterdam when she was still a student at the University of Madrid. We have kept in

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ON THE PERSONAL NOTE:

Ancient History of Wines in Sicily'

Peter F. Merenda, PhD

As my international psychology colleagues and friends know, practically every year since 1961, my wife, Rose, and I spend some time in Italy, mainly in Sicily, and especially in Palermo where we have had a condo apartment since 1971. This year, in June in Palermo, Rose presented to me on the American "Father's Day" (June 15) the very informative book on wines in Sicily referenced in the footnote below. Much of what is in the book and which I have experienced within the past 42 years, in well-known to me. However, much of the history of wines in Sicily, going as far back as nearly 18 centuries ago, was a great revelation to me. I am taking this opportunity to share this interesting history with the international psychology community.

Many wine makers and wine connoisseurs in the United States are aware of Sicilian wines, but I doubt that any, like myself, are cognizant of its extensive history. Also, unless they have spent much time in Sicily, they have not enjoyed the great bouquets of their most outstanding wines, which are hardly exported to the USA.

The major portions of this paper have been taken from Vinando: In Viaggio con il vino in Sicilia (On the wine trails in Sicily). August, 2001, Palermo: Officine-Grafiche

Archaeologists have reported that their findings reveal that wine was introduced in Sicily as early as the 16xx century B.C. by sailors and settlers from Mycene. These shipments of wine were followed by those by the Phoenicians who were the first in times of recorded history to establish permanent settlements on the Island. Phonecian ruins are still visible in Sicily in places like the island of Mozia off the shore of Marsala, and in Solonto, along the coast of Porticello, a few miles east of Palermo.

Beginning in the 8th century B.C. when the Greeks ruled Sicily, and the great Greek settlements in Selinunte, Agrigento, and Siracusa were being established, the growing of vineyards on the island, itself, flourished and has continued to this day. As the first Millennium, AD.. approached, and the Romans were now the rulers of Sicily, the making of the sweet *wine, Malvasia,* in the Aeolian islands off the northern coast, the Syracuse *Pollio,* and the Messina *Mamertino,* were heavily exported from Sicily throughout the entire Roman Empire. But, when the Romans were defeated by the Byzantines in the 2nd Century AD., grape-growing and wine-making in Sicily began to decline steadily.

By the 9th Century AD. (early 800s), when the Arabs took control of the whole island, all wine production ceased. Under Islamic rule, keeping in conformity with the teachings of the Koran, the drinking of all alcoholic beverages was banned. The Islamic rule continued in Sicily until the 11th Century AD. (late 1000s) when the Arabs were defeated by the Normans.

With the Christian Norman conquest of Sicily came a return to `viticulture" (the growing of grapevines) and the production of wine. However, it was not as widespread as it was before the Arabs became the rulers. It was not until the middle ages (14th century) after the Angevins (French) were replaced by the Aragonese (Spaniards) that the glorious days of wine making returned to Sicily. Sicilian wine was once more extensively exported from the island to all parts of Italy and beyond. In the 1500s Sicilian wines such as the Etna reds, as well as those from Noto, Palermo, and Cammarata were among the Mediterranean wines in greatest demand. At the turn of the Century, the Alcamo white wine, which even today is one of Sicily's prize wines, became noted by foreign wine connoisseurs.

From the Middle Ages to the Present Day

During the Bourbon dynasty in Sicily in the 1800s, after the Napoleanic regimes, the production of wine flourished - but not outstandly so- in the regions around Alcamo, Vittoria, and Castelvetrano. And the much sought-after moscato wine from Marsala continued to be extensively exported. But, near the end of the 19th century (1880-8 1), the Sicilian grapevines were destroyed by an epidemic disease. This disaster temporarily halted wine production. It did, however, lead to new and improved methods of viticulture, which resulted in the harvesting of grapes of much higher quality. Also, by that time the Bourbons had been ousted by Garibaldi and his troops (1860-61) and the entire nation of Italy, including Sicily and Sardinia had been unified. Much improved agricultural systems were introduced throughout all of Italy, including better means of irrigation. All of these new developments led to the production of the present day high quality Sicilian wines. To name a few of the best, including location of the vineyards: Alcamo *(Bianco D'Alcamo/Chardonnay);* Avola *(Nero d'Avola* reds/ *Regaleali* reds & whites), Casteldaccia *(Corvo* reads & whites), Catania *(Etna* reds), Licata (Nero *d'Avola* reds); Lipari *(Malvasia),* Marsala *(Marsala* wines); Menfi *(Settesoli* reds); Messina *(Polari* reds); Noto *(Moscato);* Pantelleria *(Moscato Passito);* Ragusa *(Pachino);* Siracusa *(Pollio* yellow gold wine); Vittorio *(Cerasuolo* reds).

◆ STUDENTS' PAGE ◆

Internships Abroad: How we can facilitate new sites

Lauren Arbolino

Graduate students in psychology programs face a difficult decision upon completing their coursework. They must apply and interview for a yearlong internship. Depending on their program and degree, some students apply for APPIC approved internships while others search for appropriate internships commensurate with their interests or experience. Internships occur in clinical, hospital, school, institutional, or private practice settings. The decision of where to intern for one year is a temperate one. Students must evaluate goals, interests, previous training, and determine their priorities for the future. For some, location and funding are critical in making internship choices.

Opportunities exist in almost every sector of the United States. However, what opportunities are there for those graduate students who wish to pursue internships abroad? Internships abroad could address an intern's needs. Experience working abroad could be salient to an intern's training if their interests are aligned with international work issues. Few opportunities exist for graduate students interested in an internship abroad.

Students may be interested in interning abroad but may be deterred due to difficulties finding suitable placements. There may be placements abroad that exist as potential internship sites. However, there is no vehicle for interested students to find these potential placements. Psychology displays considerable interest in cross-cultural development, appropriate service delivery for children from multicultural backgrounds, effective intervention for trauma victims and environmental affects on cognition and aging. An internship abroad may allow students to examine these and other issues. We can better confront psychological issues that transcend national boundaries by providing opportunities to train abroad. This can encourage future research in areas of international concern and facilitate research opportunities with the cooperation of professionals, training programs and internship settings.

Since few APPIC approved sites abroad are currently in place, students may be deterred from seeking out an internship abroad. Those who are interested in APPIC approved internships may be daunted by the prospect of having to compensate for a non-accredited internship. Students may see compensatory value if the internship is structured, reputable and encompasses similar experiences to those available through an accredited internship. Therefore, many students are not deterred by non-accredited internships given any one of the following constraints: the internship is new and is in the process of applying for accreditation, it is recognized as a good internship despite its non-accreditation, the experience the student desires is highly specified and can be attained through an alternative placement and reasons for non-accreditation do not negatively impact the benefits offered by the placement. Students may be willing to forgo APPIC approved internships if the internship is established and offers effective training and supervision. Consequently, the fact that internships abroad may not be accredited is not a legitimate reason to avoid establishing them. Finally, APPIC approved internships exist in Canada. This is certainly an impetus for us to create APPIC approved internships in other countries as well. Another aspect of internship opportunities abroad is short-term placement. Graduate students are fulfilling practica and field-work experience in their own programs. Short-term placements could attend to these needs. The intern could the benefit from placement abroad and training, yet the settings themselves could benefit from the assistance of a psychologist-in-training.

I propose that professionals interested in international work and research create an outlet for graduate students interested in interning and/or working abroad. We should encourage supervisors and trainers to support a broader array for interning opportunities. We are living in a time where collaborative work has been facilitated by internet capabilities and other mass media outlets that foster communication. This makes the sharing of ideas and practices realistic. In a recent article in APA's division 16 "The School Psychologist", Tracey G. Scherr highlighted her experiences abroad. She states, "My understanding of the importance of an international perspective of school psychology is a strength that I will bring to the field. I strongly believe we must learn from other countries in order to best implement practices." I believe there are students seeking specific training, unique experiences, a chance to collaborate with professionals who work abroad and the opportunity to invest in international pursuits. Let's find a vehicle that enables students to meet these goals.

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touch via email and other international conferences and she and I and Christina Antonopoulou, a Greek psychologist put together a symposium for the Singapore conference. One thing led to another and Kate began to collaborate with Patricia and me. A month in Spain collecting research data from battered women has been added to our cross-cultural research program. Kate's interest helped encourage another research student's desire to go to Russia to collect research data from a population there. The SIP meetings in Lima, Peru will provide a third international research site and several others are in the plans.

Kate: My enthusiasm of the student division of IAAP continues to grow, specifically because this venue allows for students to develop professional international connections, where research endeavors can expand past the confines of country boundaries and research findings can be more readily disseminated to diverse populations. With the simple ease of writing an email, students can now connect to other interested and motivated students to support and further their research visions. Information regarding the student division of IAAP can be located on the IAAP website at www.iaapsy.org. In the current academic year, students can join IAAP for 50% less than the usual price required for annual dues.

Without my international experiences, I doubt that I would have acquired unique ways in understanding human development and resiliency. My trip to Mexico was only three years ago, and yet I have grown so much both personally and professionally in that short period of time. I am thankful for the mentorship that I received, and I know this support was crucial in understanding how best to network within the international framework. I encourage other students to seek this type of mentorship, and I welcome the opportunity to discuss international psychology with other interested students.

Students Quote of the Summer:

I respect faith, but doubt is what gets you an education.

Wilson Mizner (1876 - 1933)

CROSS-CULTURAL PERSPECTIVES

Philippine Psychology: A Glimpse at Its History and Recent Developments

Richard S. Velayo, Ph.D.
Division 52 President-elect

As a Filipino national, I am naturally curious about how the field of psychology in the Philippines has progressed since having graduated from college in Manila almost 18 years ago. In my perusal of the various websites related to Philippine Psychology, including those of various psychology programs offered in major universities, I discovered how much psychology has evolved into a highly regarded discipline as indicated by the continued growth in the number majors and graduate degree recipients, the various activities of the Psychological Association of the Philippines (PAP), including its hosting of international conferences, and the rise in the number and quality of scholarly work authored by Filipino psychologists, not to mention the wide range of psychology-related topics published in Philippine national academic journals and periodicals. A summary of the chronology of key events in Philippine psychology can be accessed at http://www.philippinepsychology.net/chronology.html

What I find most noticeably interesting is the greater emphasis on the "Filipino psyche" in the various national publications, as well as in the training of psychologists as reflected in the psychology curricula of the country's major undergraduate and graduate institutions. Certainly, when I was an undergraduate student at De La Salle University in Manila, I never noticed such a proliferation of courses that extensively takes into account the Filipino culture and its people. There is also a growing number of graduate-level research and training programs in psychology, one in particular, even offers a concentration in Philippine Psychology.

Philippine psychology has a fairly rich history dating back to the 1920's. What is most impressive is how its evolution has paved the way for greater cultural focus in psychological research and training.

A Historical Glimpse of Psychology in the Philippines

Psychology as a science and a profession has had a long and colorful history in the Philippines. The first departments of Psychology were established in the late 1920's and early 1930's at the University of the Philippines and the University of Santo Tomas. The Psychological Association of the Philippines (PAP) was founded in 1962, and the first annual convention of psychologists was held the year after. In 1968, the PAP published the first volume of the Philippine Journal of Psychology. During the same year, the first corporation that offers psychological services and retailer of psychological tests was established.

The "formal" inception of Psychology as a field in the Philippines is considered 40 years old when the Psychological Association of the Philippines was established. Nonetheless, the evolution of Philippine Psychology can be traced since 1926. The selected landmark events are as follows:

1926	The University of the Philippines Department of Psychology is established within the School of Education. Agustin Alonzo is chairman.
1930s	The Department of Psychology at the University of Santo Tomas is established.
1932	Sinforoso Padilla organizes the Psychological Clinic at the University of the Philippines.
1933	Jesus Perpinan sets up the Far Eastern University Psychological Clinic.
1938	Angel de Blas, OP, sets up the Experimental Psychology Laboratory in the University of Santo Tomas.
1948	Estefania Aldaba-Lim sets up the Institute of Human Relations at Philippine Women's University.
1954	Joseph Goertz establishes the Psychology Department at the University of San Carlos.
1961	Fr. Jaime Bulatao establishes the Department of Psychology and the Central Guidance Bureau at the Ateneo de Manila University.
1962	The Philippine Psychological Corporation is founded. The corporation offers psychological services and is the main retailer of psychological tests. The Psychological Association of the Philippines (PAP) is founded.
1963	The PAP holds its first annual convention, leading to its first publication, Symposium on the Filipino Personality.
1968	The Philippine Journal of Psychology, the official journal of the PAP makes its first appearance. The PAP, together with the Philippine Association of Social Workers, Philippine Economics Society, Philippine National Historical Association, Philippine Sociological Society, and Philippine Statistical Association form the Philippine Social Science Council.
1970s	Psychology becomes the most popular undergraduate major in many colleges and universities. Psychological testing flourishes as the overseas contract workers boom begins.
1975	The *Pambansang Samahan ng Sikolohiyang Pilipino* (National Association of Filipino Psychologists) is founded by Virgilio Enriquez
1975+	Several universities in the Visayas and Mindanao regions of the Philippines establish psychology departments.
1982	The PAP decides the time has come for quality control in the practice of psychology. It introduces a bill in the *Batasan Pambansa* (National Legislative Council) that would require practicing psychologists to be licensed.
1986	Philippine revolution overthrows the Marcos dictatorship. Psychologists play a key role in the new government's Moral Recovery Program.
1990	The PAP is among the founding members of the Afro-Asian Psychological Association.
1992	The PAP and nine other national psychological associations establish the Asia-Oceania Psychological Association.

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1995 The PAP hosts a regional conference of the International Council of Psychologists with the theme "Psychological Issues in a Growing Global Community". The proceedings are later published in a book, Understanding Behavior, Bridging Cultures.

1998 The PAP hosts the 4th biannual Afro-Asian Psychological Association.

Cristina J. Montiel receives the Distinguished Contribution Award from the Psychologists for Social Responsibility of the American Psychological Association "For her unwavering commitment to social justice in her personal and professional life." Her work is a model for those who aspire to do peace activism and scholarship, to combine passion with analytical rigor, and to speak with both their heart and mind. The APA Division of Peace Psychology also confers on her the Outstanding Service Award.

The Philippine Journal of Psychology

The Philippine Journal of Psychology, published semi-annually, is the official journal of the PAP. It prints original studies and research work by psychologists and other social scientists in fields related to psychology, with the assistance of the Philippine Social Science Council. The journal website may be accessed at http://www.philippinepsychology.net/pjp/index.html

The June-December 2002, Vol. 35 (nos. 1 & 2) issue featured several topics that range from issues in theory and research, developmental, personality, measurement, clinical, and social/cultural psychology. Interestingly, many of the topics focus on indigenous psychology, drawing its themes and ideas on psychological principles based on the Filipino cultural experience. To get a better idea of this, below are selected titles from this issue which, I may add, comprise over 80% of the journal topics.

I. ISSUES IN THEORY AND RESEARCH

- The Filipino Psychologist and the World of Psychology (Abraham I. Felipe)
- Filipino Psychology in the Third World (Virgilio G. Enriquez)
- The Case for an Indigenous Psychology (Rita H. Mataragnon)
- Oh, That Terrible Task of Teachers to Teach Psychology in the Philippines (Jaime C. Bulatao, S.J.)
- A Probe into the Philippines' Potential for Cross-Cultural Psychological Research: The View from Early Socialization Findings (Gregorio H. del Pilar III)
- Gender Imagery in Philippine Psychology: A Critique of the Literature (Amaryllis T. Torres)
- Methods, Mind or Meaning: Shifting Paradigms in Philippine Psychology (Amaryllis T. Torres)

Psychology Research in the Philippines: Observations and Prospects (Allan B. I. Bernardo)

II. DEVELOPMENTAL PSYCHOLOGY

- Nutritional Status and Intellectual Performance in a Rural Philippine Community (Helen A. Guthrie, George M. Guthrie and Amanda Tayag)
- The Development of Moral Judgment in Filipino Urban Children (Ma. Carmen C. Jimenez)

How We Raise our Daughters and Sons: Child-Rearing and Gender Socialization in the Philippines (Ma. Emma Concepcion D. Liwag, Alma S. de la Cruz and Ma. Elizabeth J. Macapagal)

III. PERSONALITY, MEASUREMENT, AND CLINICAL PSYCHOLOGY

- Personal Preferences of Filipino Students (Jaime C. Bulatao, S. J.)
- Conceptions of Good Psychological Health and Personality Functioning of Filipino College Students: A Multi-Method Investigation (Timothy Church, Marcia S. Katigbak and Imelda Castañeda)
- Symptoms of Mental Disorder in the Philippines (Lee Sechrest)
- De-Westernization of a Dementia Screening Scale: The Philippine Experience (L. K. Ledesma, B. V. Diputado, G. O. Orteza and C. E. Santillan)

Ambiguity Values of Philippine Thematic Apperception Test (Elizabeth R. Ventura)

IV. SOCIAL AND CULTURAL PSYCHOLOGY

- The 'Kristo' of the Cockpit: An Unsung Phenomenon (Mary Ann Alabanza, Ma. Alma Bella Gonzaga and Freddie R. Obligacion)

Demographic and Socio-Psychological Determinants of High-Level Migration from the Philippines to the United States (Josefina B. Jayme)

Psychology Programs in Colleges and Universities

Today, psychology is one of the most popular undergraduate majors in the country, and enrollment in master's and doctoral degree programs in psychology is very strong. The most active areas of research and scholarship in colleges and universities include applied social psychology, psychological measurement, child and family psychology, and indigenous psychological concepts. Many trained psychologists practice in the applied areas of psychology including, industrial-organizational psychology, counseling and therapy, testing and evaluation, and community development.

All the major universities in the Philippines offer psychology as an undergraduate major as well as various traditional areas of concentration at the masters and doctoral levels. At the undergraduate level, some programs most likely offer elective courses such as "Filipino Personality" and "Filipino Child Psychology." At the graduate level, the curriculum may include seminars or core courses that are indigenous such as "Filipino Personality," "Psychopathology Among Filipinos," and "Psychological Testing in the Philippines" to name a few. Similar types of courses are also evident in other programs in the arts and sciences.

One doctoral program that caught my attention is the Ph.D. in Psychology Program with a concentration on Philippine Psychology offered at the University of the Philippines. (See http://www.upd.edu.ph/~kssp/psych/filpsych.htm). This program spearheads a key transformation in the training of Filipino psychologists. The program describes Philippine Psychology as... "the study of Psychol-

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We must provide assertive leadership and not accept any lesser status. And perhaps most importantly in the long run, our educational institutions must ensure that their students are active participants in these collaborative efforts – that is psychology's challenge for the next decade. The behavioral sciences are the key to quality health care.

For the coming fiscal year the FIC has proposed several new initiatives. "Strengthening the Global Culture of Science. For scientists to work as equals in collaboration with colleagues around the world, there must exist a shared culture of scientific ethos and values. FIC will continue to enhance the scientific capabilities of investigators in partner institutions in the developing world to promote a global culture of science and to establish a firm framework upon which equal collaborations can be built. Such efforts benefit both the U.S. partner and the foreign scientist and ultimately the global community through dissemination of research results generated through scientific rigor and the use of a common set of guiding principles. To accomplish this broad objective of strengthening the global culture of science, FIC will expand existing programs in information technology, genetics, and bioethics and will establish new activities in FY 2004 that contribute to the objective through the establishment of:

Pilot International 'Glue' Grants. Biomedical science [and we would add, behavioral science] has entered an era in which new approaches to solving problems is required. Individual laboratories working alone are no longer the only means to move scientific fields forward; at times, new approaches effectively linked together, involving a consortia of laboratories, may lead to success more quickly and efficiently. This model has been demonstrated to work, exemplified by the recent triumph of an international consortium of scientists in the public arena in sequencing the human genome....

Focus on Global Health through the Gender Lens. Issues of gender are receiving increasing attention in all areas of health research. Risk factors in heart disease prevalence, progression and response to drug treatment or surgery for example, differ dramatically between the sexes. FIC, working closely with the Office of Research on Women's Health, will utilize existing programs to further support research and research training on gender issues in priority global health areas in the developing world..... FIC will enhance its efforts to bring women scientists from the developing world into medical research, from early professional training to the senior scientist level....

Addressing the Growing Burden of Ill Health due to Trauma and Injuries. Every day, almost 16,000 people die worldwide from injuries. Many more survive with permanent severe disabilities. In low- and middle-income countries in the Western Pacific, for example, the leading injury-related causes of death are road traffic injuries, drowning, and suicide, while in Africa they include in addition to traffic injuries, war and civil disorders, and crime and interpersonal violence. In the Americans, the leading injury-related cause of death among people ages 15 to 44 years in the higher-income countries is traffic injuries, while in the low- and middle-income countries of the Americas it is interpersonal violence. With the continuing increase in the numbers of youth, who are typically uninformed risk-takers, the burden of ill health due to injuries is expected to rise dramatically in the coming decades.... Conclusion. A classic Arab proverb says 'He who has health, has hope; and he who has hope, has everything.'... health and disease are universal concerns – they transcend national boundaries...." Aloha.

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on Women 30 years ago.

And, who can travel to Hawaii without a luau? American Psychological Association is holding an optional luau on Thursday night of the convention, so be sure to sign up early as places are limited. It should be a spectacular event. Our closing session on Sunday will leave everyone humming Hawaiian music and dancing the hula.

I look forward to seeing you in Hawaii in 2004. And for those of you who love challenging tongue twisters, practice saying the name of the Hawaiian state fish ten times fast. What you don't know it? It's "humuhumunukunukuapua" which roughly translates as "fish put together like a jig saw puzzle with a face like a pig" or "fish who comes out of the water and sounds like a pig." This will be a great convention.

(Continued from page 17)

ogy born out of the Filipino experience and world view. Philippine Psychology draws its ideas from the culture, thought, perspectives, society, and history of the Filipino people. Philippine Psychology is also a systematic and scientific approach to knowledge using methods that are appropriate to the Filipino experience. The goal of the program is to provide the student with knowledge and competence in developing the theory, method and application of Philippine Psychology."

Hosting of International Conferences

International Psychology conventions have also been held in the Philippines. In July of 2002, the International Council of Psychologists (ICP) held their annual Convention in Mandaluyong City, Manila. A regional conference of the ICP was also hosted by the PAP in 1995. The PAP also hosted the 4th biannual Afro-Asian Psychological Association in 1998. Another conference that will be held in Manila is the 5th Annual Convention of the Asian Association of Social Psychology (AASP), an organization formed in 1995 whose goals are to (1) promote the development of social psychological research and its application in Asia-Pacific, (2) provide opportunities for students to pursue education and careers in social psychology, and (3) serve as an academic forum for social psychologists in Asia-Pacific.

There have been a few other Asian regional conferences in psychology and the social sciences held in the Philippines, but almost all have been held in Manila, rather than in other metropolitan areas in the Philippines.

Informational Sources on Philippine Psychology

Books

Below is a list of recommended readings for those interested in learning more about Philippine Psychology. These may be ordered by e-mail via the Psychological Association of the Philippines at pap2@edsamail.com.ph

Forty Years of Philippine Psychology (Edited by Allan B.I. Bernardo, Madelene

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Division 52, the Division of International Psychology, is a new Division of the American Psychology Association. This Division welcomes all individuals who are interested in interacting with international colleagues in the practice, research, training, and communication of psychological knowledge, particularly knowledge that enhances the understanding and positive interactions of people around the world. It works closely with the APA Committee of International Relations in Psychology (CIRP).

The Division of International Psychology promotes and advances international practice, research, and communication between psychologists around the world through yearly meetings where symposia, papers, poster sessions, business meetings and social hours are scheduled. The Division newsletter will be published three times a year to keep members informed. All areas of the discipline are welcomed as participants in the Division.

The Division focuses on international issues in the field of psychology. It is particularly interested in nurturing students' engagement with national and international students and psychologists. During the Convention, at its yearly social hour, students will be able to communicate with psychologists from other countries, and possibly develop research and training contacts that will contribute positively to their developing theoretical orientations as well as professional carreers and goals. Students interested in the international arena will be able to present their research at symposia as well as at paper and poster sessions. In the future, there will be a students research award(s). Student members enjoy reduced dues and may obtain a special discount on rooms at the conventions.

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750 First Street, NE
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(Continued from page 18)

A. Sta. Maria, and Allen L. Tan)

Published by the Psychological Association of the Philippines in commemoration of its 40th anniversary. It contains 30 of the best articles that have been published over the past 40 years in the Philippine Journal of Psychology. There are literature reviews, conceptualizations, experiments, case studies, surveys, and field studies.

Understanding Behavior, Bridging Cultures: Readings on an emerging global psychology (Edited by Allan B.I. Bernardo, Natividad A. Dayan, and Allen L. Tan)

This book contains papers from a regional conference of the International Council of Psychologists hosted by the Psychological Association of the Philippines in August 1995. The conference theme was "Psychological Issues In a Growing Global Community." The papers in this volume are organized into three parts: (1) Behavior, personality and development in cultural context; (2) When cultures meet: migrants, refugees and the multi-cultural experience; (3) The cultural dimensions of mental health. The epilogue features the keynote address of then-ICP president Emily Miao who makes a strong case for the importance of international psychology organizations and of collaborative activities among international psychologists.

Phenomena and Their Interpretation: Landmark Essays, 1957–1989 (By Jaime C. Bulatao, S.J.

Drawn from keen, rigorous, and empathic observation of the Filipino psyche. Descriptions of phenomena of religion, consciousness, and culture. Second printing 1998.

Group Process and the Inductive Method: Theory and Practice in the Philippines (By Carmela D. Ortigas)

An ideal basic reading text and reference for group-centered leadership. Aims at guiding the leader to motivate learners to involve themselves in issues affecting their personal, professional, community and organizational lives. Revised edition, fourth printing 1999.

Human Resource Development—The Philippine Experience: Readings for the Practitioner (Edited by Carmela D. Ortigas)

Brings together writings of Philippine practitioners in human resource development. Has three main parts: (1) HRD in organizations, (2) the HRD client system, and (3) HRD interventions, strategies, and issues. Revised edition, second printing 1997. 7 x 10 inches. 184 pages.

Philippine Psychology Network Forum (This is an Internet-based forum to discuss the history and development of Philippine psychology.) See http://pub16.ezboard.com/fphilpsychphilippinepsychology

Philippine Psychology website (This site is intended to serve as a resource and departure point for persons interested in aspects of Philippine psychology.) See http://www.philippinepsychology.net/.

Conclusion

Philippine psychology has a rich history. Since 1926, the psychology has developed into a thriving academic and professional discipline. Similar to many colleges and universities in the United States, psychology is the most popular major in the arts and sciences. The discipline continues to evolve and many of the changes that have recently occurred are in the graduate and undergraduate psychology curricula, the growing number of publications. The hosting of and continued affiliation with international organizations in psychology and related fields is expected to continue. The developmental trend in Philippine Psychology is reflected in the incorporation of a cultural persona of the "Filipino psyche" evident in scholarly publications and in the training of Filipino psychologists. Though Filipino psychologists have contributed significantly during times of crisis and political unrest, the extent in which Philippine Psychology will play a greater role in the country's political arena remains to be seen. I think that given the volume of psychology graduates and growing national concerns regarding mental health and education, Filipino psychologists will soon see greater opportunities as major players in national politics. In any case, I certainly look forward to seeing more Filipino psychologists extending themselves towards greater involvement in the arena of international psychology.

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Effects of Racial Background and Sex on Identifying Facial Expressions and Person Perception

SHANN E. SAGLES
SHARON COLEY
GERMILINA ESPIRITU
PATRICIA ZAHREGIAN
RICHARD VELAYO*
Pace University

This study investigated the ability to accurately identify facial expressions of emotions of people of varying racial background: Asian, Black, Hispanic, and White. Through the use of a Person Perception Questionnaire and a Pictorial Test, 151 participants identified facial expressions of anger, disgust, fear, and sadness based as a function of the target individual's racial background and sex. Results indicated that for the emotions of anger, disgust, and sadness, there were significant interactions based on the individual's target race and sex. In addition, there were significant findings for the emotions of anger and fear identified in the White target individuals compared to the target individual typifying other races. We also found significant differences in the way women were perceived, compared to men, in social, intellectual, and favorability trait scores. These results may be applied in the areas of marketing and multicultural education to educate others concerning the differences in emotional expression across cultures.

EMOTIONAL EXPRESSION IS A PROCESS THAT HAS often intrigued and aroused curiosity. At the same time, researchers have focused for many years on culture as a factor in the identification of emotions. Researchers in psychology and other behavioral sciences have pondered whether some emotional expressions are culturally specific or if they are universal among all people. What cultural factors dictate the manner in which emotions are expressed? Do age and sex influence emotional expression and its identification in others? Recent research has shown that emotions such as anger, fear, disgust, or sadness may, in fact, be influenced by one's sex and racial background.

Research on gender roles has examined how society places expectations on the way men and women express themselves. For example, studies by Brody (1997) and Timmers, Fischer, and Manstead (1998) indicated that men tended to display emotions that demonstrated their authority whereas women were more inclined to show emotions that reflected their "femininity." These studies also found that participants who did not conform to society's stereotypes of gender-related emotional expression were often subject to risking their personal and even professional relationships.

Research has also shown how the origins of gender stereotypes of emotional expression can be traced to early childhood. Fritz (1997) explored how boys in Western society are influenced to act in ways in which they displayed emotions "typical" of a man from anger to disgust.

In cross-cultural studies of emotion, the focus has centered on the cultural determinants of emotional expression and its identification across different societies. Results of studies by Markus, Kitayama, and VandenBos (1996) and Rubin (1998) indicate that some emotions are predetermined by what a person's culture dictates as appropriate. A comparison example used by both studies was the difference be-

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tween Western culture, which emphasizes the outward expression of emotions, and Asian societies, which may discourage such expression.

The two experiments that were the models for the present study involved how people in different cultures express emotions and how they identified emotional states in other cultures. Pittam, Gallois, Iwawaki, and Kroonenberg (1995) investigated the differences in the concepts of emotional expression by Australian and Japanese persons of themselves and each other. The results showed that with the use of pictures of fixed expressions, participants rated Australians as more expressive and Japanese as less demonstrative. Markham and Wang (1996) focused on the recognition of emotion by Chinese and Australian children. In the same way, the participants identified the emotional states of each other. Using pictures from Ekman and Friesen's book, *Pictures of Facial Affect* (1976), the research concluded there was some evidence of an ethnic bias in emotion recognition. The ethnic bias consisted of participants being able to correctly identify emotional expressions of people from their own cultures but not those of people from other cultures. Another factor that influenced the results in both experiments was the knowledge or lack thereof that each group had of the other (Markham & Wang, 1996).

Significance of the Study

A study involving cross-racial identification of emotions has many implications for racially heterogeneous societies like the United States. One of those implications involves minimizing misinterpretations of how an individual perceives someone's emotional state. This misinterpretation can occur, for example, when people ride public transportation where certain individuals might mistake facial expressions of persons from another race or culture as being hostile, when in fact, they may be sad. Connections can also be made in the education of culturally diverse children with emotional and behavioral disorders where instructors may misinterpret emotional outbursts that are culturally specific (Jackson & Bynum, 1997). This awareness can pave the way for modification of certain teaching techniques in order to accommodate the students' needs. In clinical settings, therapists can also learn more about how certain patients of varied backgrounds may have emotional outbursts that correlate with their symptoms and allow for the possibility of misdiagnoses. The present study, although having to do with emotional expression recognition, can provide some valuable information for further research in this area. As for theoretical implications, researchers could find out how people of certain cultural backgrounds express themselves differently in the same or similar situations. These considerations are just some of the major theoretical and practical implications of this research project. This research intended to establish if facial expressions demonstrated by people, varying in racial background and sex, affected person perception among people of different racial backgrounds.

Hypotheses

To examine how facial expressions as a function of racial background and sex were identified by participants, we tested the following experimental hypotheses:

1. There would be significant differences in the identification of facial expressions among participants as a function of the target individual's racial background.
2. There would be significant differences in the identification of facial expressions among participants as a function of the target individual's sex.
3. There would be significant interaction effects between the racial background and sex of the target individual in the identification of facial expressions among participants.
4. The participants' performance on the Pictorial Test would significantly influence their scores on the social and intellectual trait section of the Person Perception Questionnaire.

Method

Participants

The participants consisted of 151 individuals (ages 18–49) who identified the facial expressions. These individuals (69 women, 82 men) were classified by their racial backgrounds as Asian (18 women, 20 men), Black (18 women, 22 men), Hispanic (16 women, 21 men), or White (17 women, 19 men). The targets for the photographs likewise represented the same age demographic and the four racial criteria needed for the experiment. Individuals who served as targets were comprised mostly of the experimenters' friends and coworkers.

Experimental Design

The experimental design involved randomly assigning participants to groups in which they viewed one of four photographs, and in which the target in the photos were either of the same or different race. The purpose behind this method was to test one of the hypotheses that assumed that participants were not likely to correctly identify specific emotions because of the target individual's racial background. In this case, the independent variable was the race of the target individual (Asian, Black, Hispanic, and

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White) in the photographs. Because we randomly assigned the photographs to participants of the same and opposite sex, this factor served as a classification variable; thus, we used a 4 (race target) × 2 (sex target) factorial design.

Materials

The 35-mm photos of the target individuals, taken from the base of the chin to the top of the forehead, excluded their attire and body type. The rationale for this procedure was to eliminate extraneous variables that may have influenced the participants' responses. The subjects of the photographs elicited, under normal conditions, their facial expression for each of the specific test emotions: sadness, disgust, fear, and anger. The pictures used for the study were chosen through pilot tests conducted among the experimenters' classmates. The pilot participants viewed the pictures and recommended which target individuals best exhibited the emotional expressions being elicited; we made the final selections according to their suggestions.

A Pictorial Test and a Person Perception Questionnaire were constructed for use in this experiment. The Pictorial Test used a Likert-type scale format that included four color photographs featuring the four corresponding emotions. The participant rated the degree to which each photograph displayed each of the four emotions on a scale of 1 to 5 (1 = *least likely* to 5 = *very likely)*. The participants' chosen rating for each picture was used for data analysis regardless of whether the participant chose the correct one.

The Person Perception Questionnaire consisted of 20 Likert-type items that were based on findings reported by Rosenberg, Nelson, and Vivekananthan (1968). That investigation found that people evaluated others in terms of their social and intellectual traits. These main trait categories were divided into two subcategories: 10 favorable and 10 unfavorable traits. The favorable and unfavorable traits each consisted of 5 social and intellectual traits (see Table 1). Participants were asked to rate the individual in each photograph on a scale of 1 to 5 (1 = *very true* to 5 = *hardly true at all)*. In terms of scoring, assigned values were given for each trait. For favorable traits, the ranking *mostly true* received a score of –4, whereas *partly true* received a score of –2. On the other hand, for unfavorable traits, a ranking of *mostly true* received a score of –4, whereas *partly true* received a score of –2. The participants' impression score consisted of the average of the rankings for all 20 items. The questionnaire's authors reported no reliability coefficients, but studies have indicated that it was pretested and designed for the purpose of research (Rosenberg et al., 1968). A sample question appears below:

> Helpful — tending to aid or assist a person in want, trouble, or distress. _____

TABLE 1

The Person Perception Traits Scale

	Social traits	Intellectual traits
Favorable traits	Helpful	Scientific
	Sincere	Determined
	Tolerant	Skillful
	Sociable	Intelligent
	Humorous	Persistent
Unfavorable traits	Unhappy	Foolish
	Vain	Frivolous
	Irritable	Wavering
	Boring	Unreliable
	Unpopular	Clumsy

Procedure

Prior to the experiment, we administered informed consent forms to the participants; then they filled out a demographic sheet consisting of information regarding their racial and educational backgrounds, age, and occupation. Afterwards, the participants rated the photographs in the Pictorial Test. The measure of the second dependent variable, the 20-item Person Perception Questionnaire, was then administered. After the completion of the experiment, we distributed explanatory debriefing forms.

Results

Using a two-way between-subjects analysis of variance (ANOVA) for a 4 × 2 factorial design, the first main effect hypothesis, which stated that participants would significantly differ in the identification of facial expressions because of the target person's racial background, was confirmed at the 0.05 alpha level for the emotions of anger, $F(3, 143) = 4.96$, $p = .003$, $\eta^2 = .094$, and fear, $F(3, 143) = 5.92$, $p = .001$, $\eta^2 = .111$. Post hoc analyses using a Scheffé test revealed that anger expression in the Black and White individuals' pictures was significantly easier to identify than in the Hispanic individuals' photographs (see Figure 1). In the same way, fear expression was significantly easier to identify in the White individuals' pictures than in the Black and Hispanic pictures, regardless of sex of target (see Figure 2). There were no significant findings corresponding to the second hypothesis, which stated that participants would significantly differ in identifying facial expressions because of the target individual's sex.

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FIGURE 1

Mean interaction scores of correctly identifying anger facial expressions between the four target individuals varying in racial background and sex.

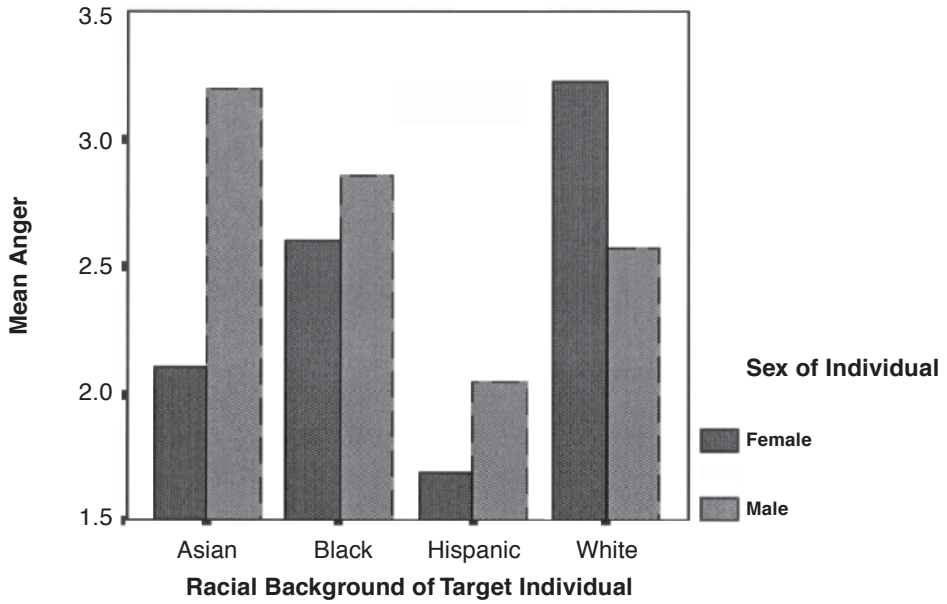

There were no main effects for disgust and sadness, but there were significant interaction effects between target racial background and sex in both facial expressions. Results confirmed the third (interaction effect) hypothesis for the racial background and sex factor in the identification of facial expressions for anger, $F(3, 143) = 3.00$, $p < .05$, disgust, $F(3, 143) = 9.06$, $p < .001$, and sadness, $F(3, 143) = 2.72$, $p < .05$. Using a Scheffé post hoc analysis test, results showed that race influenced the accuracy of judgments of anger, as that emotion was less readily identified in the Hispanic picture ($M = 1.87$, $SD = .21$) than in the White ($M = 2.91$, $SD = .21$), Black ($M = 2.74$, $SD = .20$), and Asian pictures ($M = 2.66$, $SD = .20$). In the facial expression for fear, as in the Asian picture ($M = 3.32$, $SD = .22$) and Black picture ($M = 2.87$, $SD = .22$), fear tended to be more identifiable in the White picture compared to the pictures of the other three races. In the facial expression for sadness, where the findings approached statistical significance, as in the Asian picture ($M = 2.94$, $p = .23$), Black picture ($M = 3.67$, $p = .22$), White picture ($M = 2.95$, $p = .23$), and Hispanic picture ($M = 3.47$, $p = .24$), sadness seemed to be more identifiable in the Black picture compared to the Asian and White pictures.

The two-way between-subjects ANOVA also revealed a significant interaction between racial background and sex on both anger and disgust. Through the use of multiple t-test comparisons, significant target sex and racial background differences were found regarding how the anger and disgust facial expressions were identified. As seen in Figure 1, anger expression was significantly easier to identify in the Asian male picture when compared to the Asian female, $t(36) = 2.87$, $p < .005$, and Hispanic female, $t(34) = 4.23$, $p < .001$, pictured. Similarly, the Black male's picture of anger expression was relatively easier to recognize than in the Hispanic male's, $t(41) = 2.15$, $p < .05$, and the Hispanic female's, $t(36) = 3.1$, $p < .005$, photograph. The White female's expression of anger was also easier to identify than the Hispanic female's, $t(31) = 4.34$, $p < .001$, and male's, $t(36) = 3.15$, $p < .005$, pictures. Anger expression in the Black female picture was substantially more identifiable than in the Hispanic female picture, $t(32) = 2.16$, $p < .05$.

In the disgust facial expression, Figure 3 shows greater variance in scores than did the anger facial expression as a comparison in the interaction between the target racial background and target sex. We found that disgust expression on the Pictorial Test was significantly easier to identify in the Asian male picture than in the Asian female picture, $t(36) = 2.62$, $p < .02$, and Hispanic female picture, $t(34) = 2.69$, $p < .02$. In the same way, the Hispanic male's picture of disgust was easier to identify than in both the Asian female picture, $t(37) = 3.09$, $p = .004$, and Hispanic female picture, $t(35) = 3.14$, $p = .003$. The Black male picture of disgust was more identifiable than in the

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FIGURE 2

Mean scores of correctly identifying the fear facial expressions between the four target individuals varying in racial background.

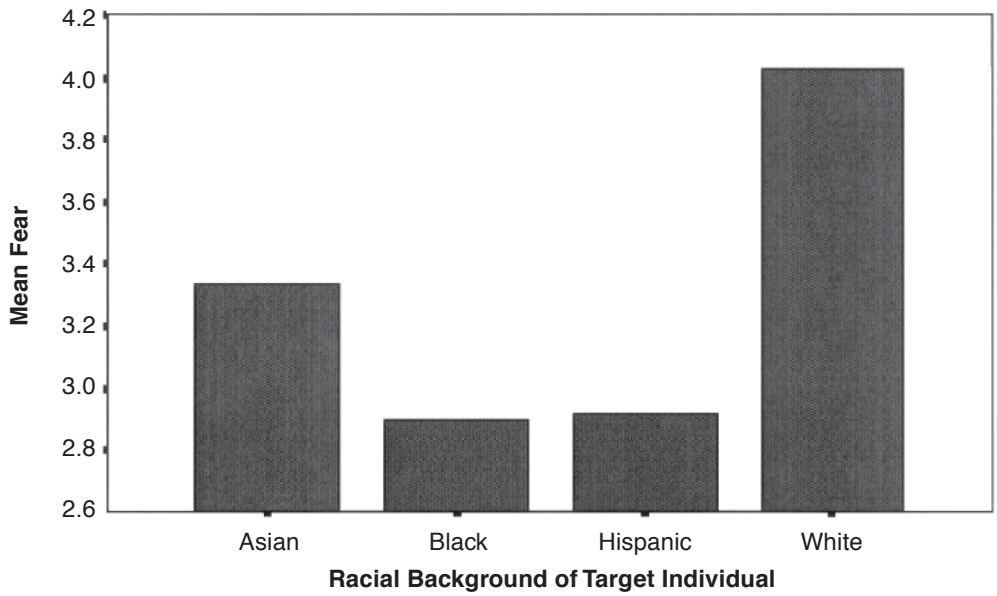

Asian female picture, $t(34) = 2.48$, $p < .02$, and the Hispanic female picture, $t(32) = 2.55$, $p < .02$. The same was true with the White female picture, as disgust was more easily identified than in the Asian female picture, $t(33) = 3.77$, $p = .001$, and the Hispanic female picture, $t(31) = 3.77$, $p = .001$.

There were also significant main effects on how both sex and target race influenced social and intellectual trait judgments of the people as measured by the Person Perception Scale, where a higher rating in terms of the favorable social and intellectual traits produced a higher score. On the other hand, a higher rating in unfavorable social and intellectual traits resulted in a lower score. Using a between-subjects ANOVA, women were perceived as more favorable when compared to men, $F(1, 143) = 5.97$, $p = .02$ (see Figure 4). ANOVA also revealed a main effect of target sex, as the female photographs were seen as more socially positive than were the male pictures, regardless of race, $F(1, 143) = 11.41$, $p = .001$. However, no significant differences were found in the target racial background with the social, intellectual, and favorability trait scores, as well as in the intellectual trait scores according to the target sexes.

ANOVA also revealed interaction effects between target racial background and sex in the social trait scores, $F(3, 143) = 4.81$, $p < .005$, and the intellectual trait scores, $F(3, 143) = 3.04$, $p < .05$. The Black female picture was rated significantly higher on social traits than the White individuals' photograph, regardless of sex. The results also showed that the Black male picture was rated significantly higher on intellectual traits than the Hispanic individuals' pictures, regardless of sex.

Discussion

This study yielded many interesting and significant findings both in the identification of emotions and in person perception. Although sex of the target individual did not influence participants' identification of the target individuals' facial expression, race played an important role throughout the study.

We found that anger was relatively easier to identify in White and Black individuals than in Hispanic individuals. In addition, fear was also easier to identify in White individuals compared to the other three races. Individual differences, like the target individual's facial structure (e.g., shape of nose, natural facial maturity, etc.), may explain this difference. For example, perhaps the target individual's eyebrows were shaped in a way that made him or her look angry even when they are not asked to elicit an anger expression. Participants may have rated the person's other emotional expressions lower because they predetermined that he or she was solely presenting a "naturally angry" demeanor. Another explanation could be the lack of information some participants had regarding people of other races. This "stranger

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FIGURE 3

Mean interaction scores of correctly identifying the disgust facial expressions between the four target individuals varying in racial background.

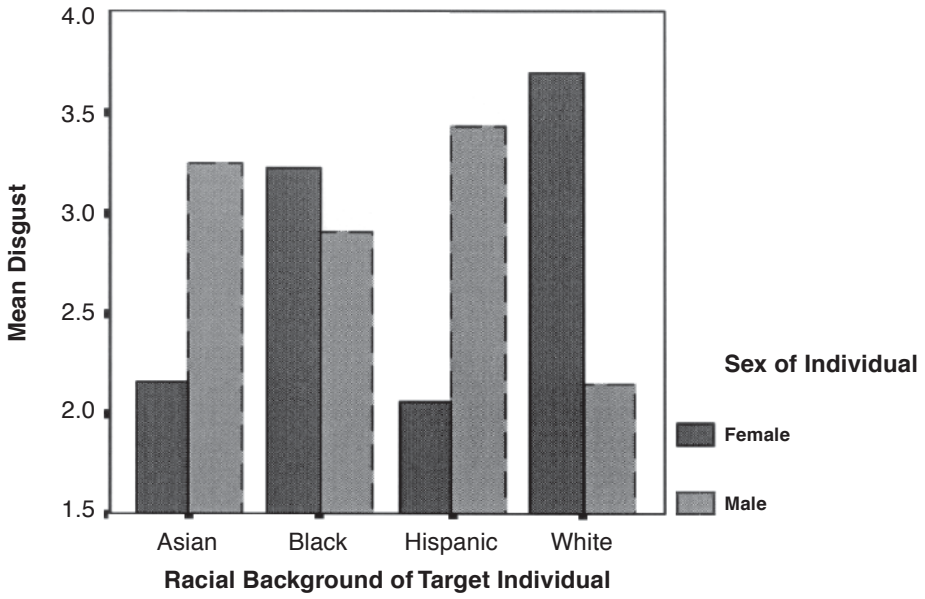

effect" was evident in the Pittam et al. (1995) and Markham and Wang (1996) research where they concluded that the lack of knowledge the participants had of the target race pictured contributed to the way the participants identified the emotions presented. In this case, perhaps frequent interactions with the particular races would help people make accurate judgments of other people's facial expressions.

In terms of the way people were perceived on the Person Perception Scale, there were a number of interesting findings. Participants generally rated Black women as more highly sociable than White individuals, and Black men were seen as having more intellectual traits than Hispanics. Perhaps these results reflect a generalized finding, or they may be unique to this study. Again, the critic has to take into account peripheral factors and the way they may have influenced some participants, from the frequency of their interactions with people representing the target individuals' race to incorrectly identifying expressions because of facial structure.

Unlike previous cross-cultural studies on emotion identification, which tested people of different racial backgrounds in their native lands, the participants of this study consisted of people of varying cultures living in the New York metropolitan area. In this case, the close proximity of the different cultures may have influenced the way participants identified facial expressions and perceived target individuals' intellectual and social traits. Hence, living in such a culturally heterogeneous population enables people to better interact with and understand people from other countries. People in a culturally homogeneous population are less likely to accurately depict the emotional expressions of others from foreign countries because they have had less exposure to these people.

Men and women were perceived differently along social and intellectual favorability trait scales. Regardless of race, women scored higher in total traits (combination of social and intellectual) and were perceived as both more sociable and intellectual than their male counterparts. For the most part, women may be considered to be reliant on their intellectual qualities, whereas men are thought of as depending more on their physical strength. This finding can be argued when considering that women typically outnumber men in most college classes. Similarly, women are thought to be more sociable than men because of their ability to function better in group situations. Men, on the other hand, tend to be more aloof and operate better in circumstances where they have to work alone (Timmers et al., 1998).

Some suggestions for future studies would be controlling the degree to which the target individuals in the pictures posed particular target emotions. Perhaps vignettes of certain situations would aid tar-

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FIGURE 4

Mean of total trait scores between the target individuals varying in sex.

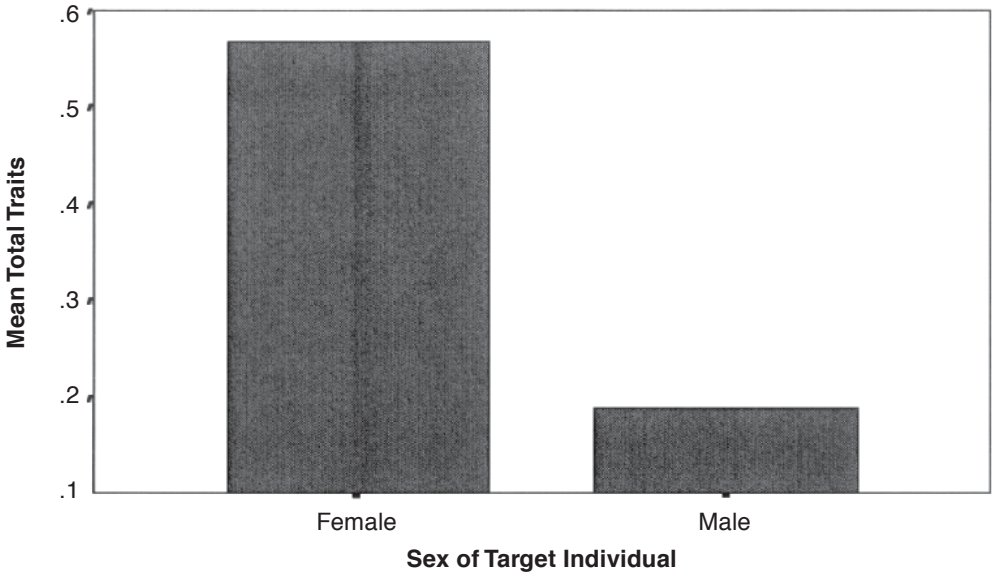

gets in making the appropriate pose. At the same time, future researchers should take note of ethical issues concerning the potential distress such procedures may cause in the subjects of the pictures. For example, if disgust were the emotion being elicited, the vignette would have to contain something potentially disturbing that could evoke a "genuine" emotion in the target individual. Taking pictures of people in public settings could be an option, but doing so without people's consent would not only be unfeasible but also unethical. Unfortunately, past research has not addressed the issue of acquiring photographs because most of the pictures were acquired from previously published sources. For future studies, researchers should look for better ways of acquiring photographs that accurately depict the emotions studied without having them look "artificial."

Past research on cross-cultural emotions has focused on participants in one country identifying emotions of people from other parts of the world. There should be more emphasis on studying the emotions of people of different cultures who live in the same city or country. The basis for such studies is to help educate others in the way some cultures may use certain facial expressions to convey an emotion, which may be different from the norm and may be subject to misinterpretation. Future research should also investigate other factors that may influence a person's ability to identify facial expressions (e.g., organismic or person variables, specific facial features, and cultural biases). This kind of research may be applied in the areas of marketing, community outreach, and multicultural education. This study may help educate people in the way some cultures may use certain facial expressions to convey an emotion differently than what they expect or the "norm."

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ABSTRACT

There is evidence of the pedagogical effectiveness of online teaching and the teaching styles that work best with it. However, few studies have looked at the specific pedagogical approaches in relation to specific learning variables such as cognitive components, motivational components, and social components, and the online teaching features that make distance education so useful and preferred by many students. The present study was designed to help establish policies and guide strategies to prepare both students and instructors for distance education. Students (N=189) in a course using Blackboard, a distance learning software package that allows for teaching of courses asynchronously, participated in a study to determine the usefulness of using the various features of the software either as an online course or as a supplement to face-to-face instruction. Preliminary findings indicated that given the format in which the course is taught as well as the academic area, pedagogical use of certain online teaching features varied. Both formats, either completely or partially online, are conducive to learning, but most importantly, students' writing skills seemed to improve more when completing online courses. Several suggestions are given for teachers of psychology on how to enhance a partial or complete online class. (Contains 10 figures and 29 references.) (JDM)

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Asynchronous Approaches to Teaching Psychology Courses Online

Richard Velayo

Pace University, New York

Presented at

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Asynchronous Approaches to Teaching Psychology Courses Online

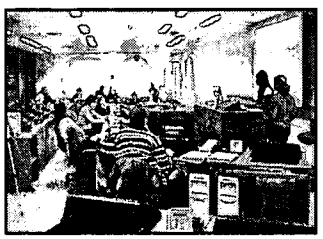

There is research evidence that point to the pedagogical effectiveness of online teaching and the teaching styles that work best with it, but there have been few studies that have looked at how specific pedagogical approaches used in teaching online in relation to specific learning variables such as cognitive components (e.g., student comprehension, note-taking skills), motivational components (e.g., student interest), social components (e.g., classroom interaction), and the online teaching features used (e.g., discussion board, virtual chat, access on online lectures, etc.) that make distance education so useful and preferred by many students.

Emerging technologies have forced a redefinition of distance education. At the same time, the distance education research agenda has also evolved. The focus has shifted to a more learner-centered approach. Researchers are not merely looking at achievement but are examining learner attributes and perceptions as well as interaction patterns and how these contribute to the overall learning environment. While there is continued interest in distance learning technologies, the focus is not on which medium is best, but on what attributes of the medium can contribute to a positive, equivalent learning experience.

While it is often risky to summarize research in a few sentences, it is also the obligation of those who have studied the literature extensively to provide others with their best estimates of what has been reported. The distance education literature has several characteristics that make summarization difficult. The largely anecdotal nature of distance education literature makes it difficult to generalize. Widely criticized comparison studies continue to be popular. Comparing the achievements of distance learners with those of traditional learners or between distance learners using different technologies appear to continue to show "no significant difference." Subjects tend to be highly motivated, with adult learners providing little help in generalizing to other populations. In spite of these limitations, it is possible to draw the following tentative conclusions from the research literature. Although these summary statements should be interpreted skeptically, they are supported by the literature.

- Distance education is just as effective as traditional education in regard to learner outcomes (e.g., Bramble & Martin, 1995; Bruning, Landis, Hoffman, & Grosskopf, 1993; Cheng, Lehman, & Armstrong, 1991; Clark, 1983, 1984; Martin & Rainey, 1993).
- Distance education learners generally have more favorable attitude toward distance education than do traditional learners, and distance learners feel they learn as well as if they were in a regular classroom (e.g., Biner, Dean, & Mellinger, 1994; Fast, 1995; Jegede & Kirkwood, 1994; Ross, Morrison, Smith, & Cleveland, 1991; and Sorensen, 1995).
- Successful distance education learners tend traditionally to be abstract learners whoa re intrinsically motivated and possess internal locus of control (e.g., Bernt & Bugbee, 1993; Biner, Bink, Huffman, & Dean, 1995; Dille & Mezack, 1991;

Coggins, 1988; Fjortoft, 1995; Garland, 1993; Laube, 1992; Ross & Powell, 1990; and Stone, 1992).

- While interaction seems intuitively important to the learning experience, interaction should not be added without real purpose. Focusing on building collaboration and group interaction may be more important than focusing on individual participation (e.g., Baker, 1995; Bauer & Rezabeck, 1992; May, 1993; Fulford & Zhang, 1993; Schoenfelder, 1995; Souder, 1993; and Zhang & Fulford, 1994)
- Each form of distance education technology has its own advantages and disadvantages in contributing to the overall quality of the learning experience (Ahern & Repman, 1994; Egan, Welch, Page, & Sebastian, 1992; Garrison, 1990; and Tuckey, 1993).

The assessment tool administered to students and their instructors at the end of the course determined the effectiveness of using the various features of a distance learning (DL) software called **Blackboard** (version 5.5) either as a completely online course or a supplement to face-to-face instruction. Psycho-educational variables such as student motivation, comprehension of the material, specific "behaviors" in an online environment (e.g., discussion board postings and responses), outcome measures of learning (e.g., critical thinking, writing skills, comprehension), usage frequency and patterns of specific features of Blackboard, and others were incorporate in the questionnaire.

The assessment tool and protocol procedures generated from this project will be used to establish policies and guide strategies to prepare both students and instructors for distance education. Furthermore, this project will hopefully contribute to the growing trend in instructional psychology and educational technology research. By looking at how students are affected by different pedagogical styles in which online courses are taught and the media attributes provided by distance education technologies, effective teaching strategies might be proposed that will most likely enhance student learning and motivation.

METHOD

Students (N = 189) in courses offered at Pace University during the Fall 2001 semester that use Blackboard, a full-featured distance education software package that allows for the teaching of courses asynchronously, participated in the study. These students belonged to one of 21 courses in various disciplines from four schools.

Sample demographics:

Age:	Mean = 22.57	SD = 5.95	[min. score = 17; max. score = 54]
Gender:	Males = 54	Females = 132	No response: 3
Ethnicity:	Asian:	24	
	Black/African American:	23	
	Hispanic/Latin:	17	
	White/Caucasian:	106	
	Other:	4	
	Choose not to indicate:	11	
	No response:	4	
Year Level:	Freshpersons:	23	
	Sophomores:	39	
	Juniors:	41	
	Seniors:	74	
	Graduate:	8	
	Other:	1	
	No response:	3	
Computer Use per week:	Mean = 21.91	SD = 18.8	
Computer Proficiency:	Mean = 4.49	SD = 1.102	
Use of BlackBoard in previous courses:	Mean = 1.35	SD = 1.45	

How BlackBoard was used in current course:

124 Supplemental/Hybrid (i.e., some aspect/proportion of the course involves face-to-face instruction with students in addition to using Blackboard)

64 Completely Online (i.e., the course involves NO face-to-face instruction with students, course instruction is totally online/asynchronous using Blackboard)

Students completed the survey, which was made available to them online during the last two weeks of the semester. The survey contained questions regarding demographic information, how the various features of Blackboard are used in the course, measures of perceptions of learning (student comprehension, student interest and motivation, classroom interaction, and presentation of course material), and learning outcomes (course content, class participation, critical thinking, and writing skills). [Note: A copy of the questionnaire may be obtained upon request.]

Figure 1. A sample "Announcements Page" in BlackBoard.

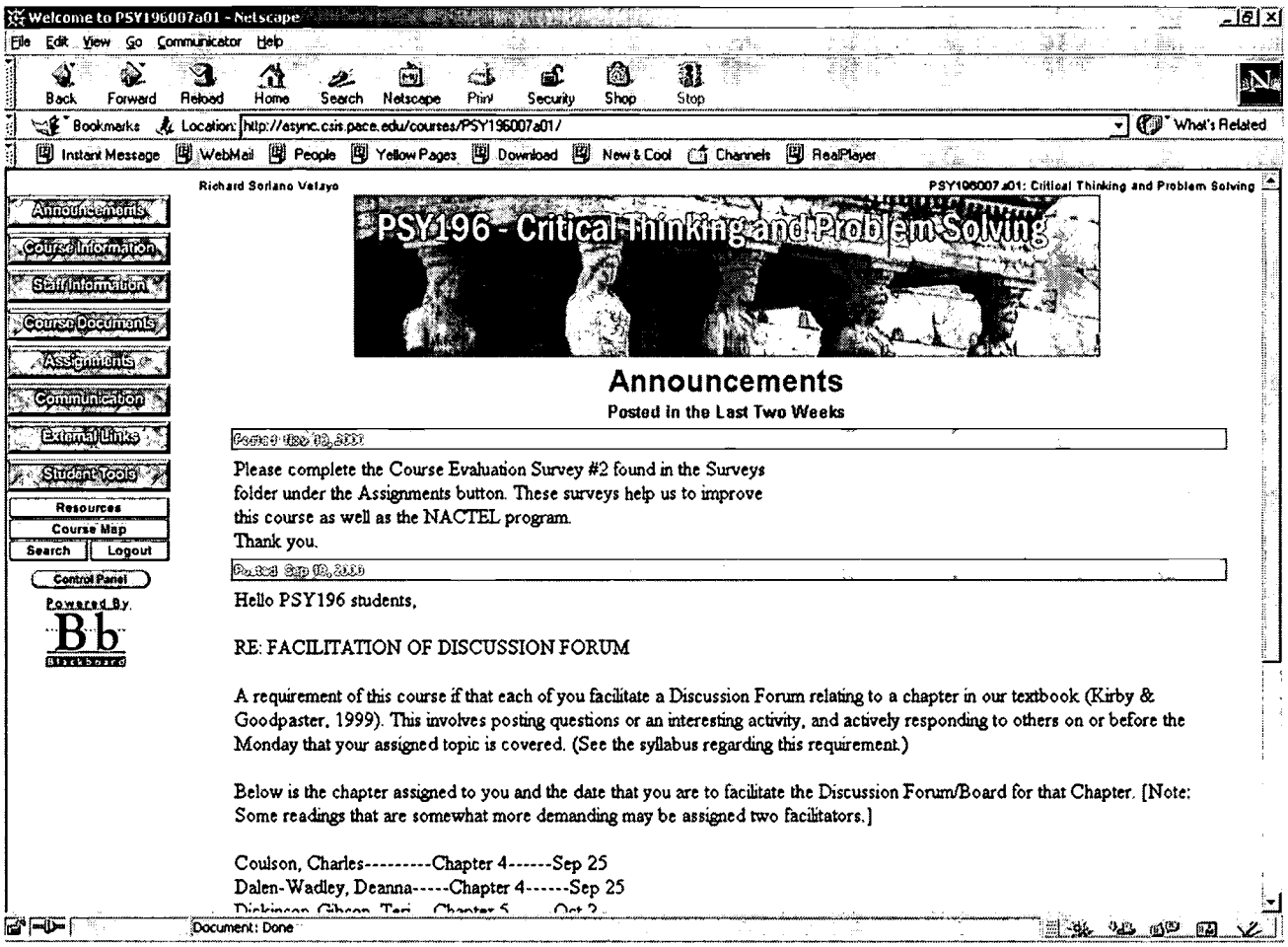

RESULTS

Preliminary findings indicate that given the format in which the course is taught (either completely online or partially online) as well as the academic area (e.g., arts, sciences, business, etc.) pedagogical use of certain features of online teaching varies and that student evaluation of these courses reflects students perceived them. Essentially, both formats are conducive to learning, but the most interesting finding is that writing skills seem to have been enhanced more among students in completely online courses. students look for a "match" in terms of the course requirements and the distance education features that allow them to function effectively in an online learning environment. In addition, given the findings of this study, a list of suggestions will be provided on how to enhance the distance education experience for both student and instructor.

Figure 2. Bar graph showing percentage of student ratings of **most useful feature** of Blackboard.

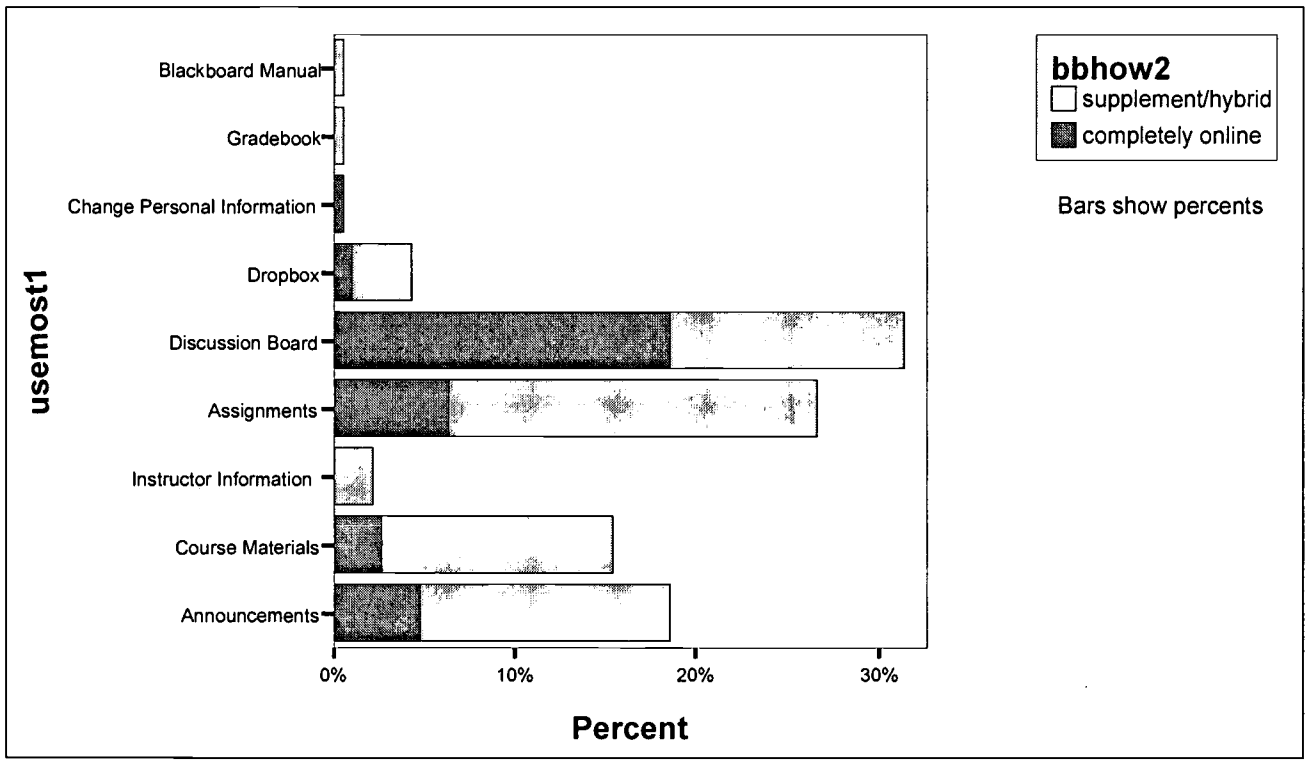

Figure 3. Bar graph showing percentage of student ratings of **second most useful** feature of Blackboard.

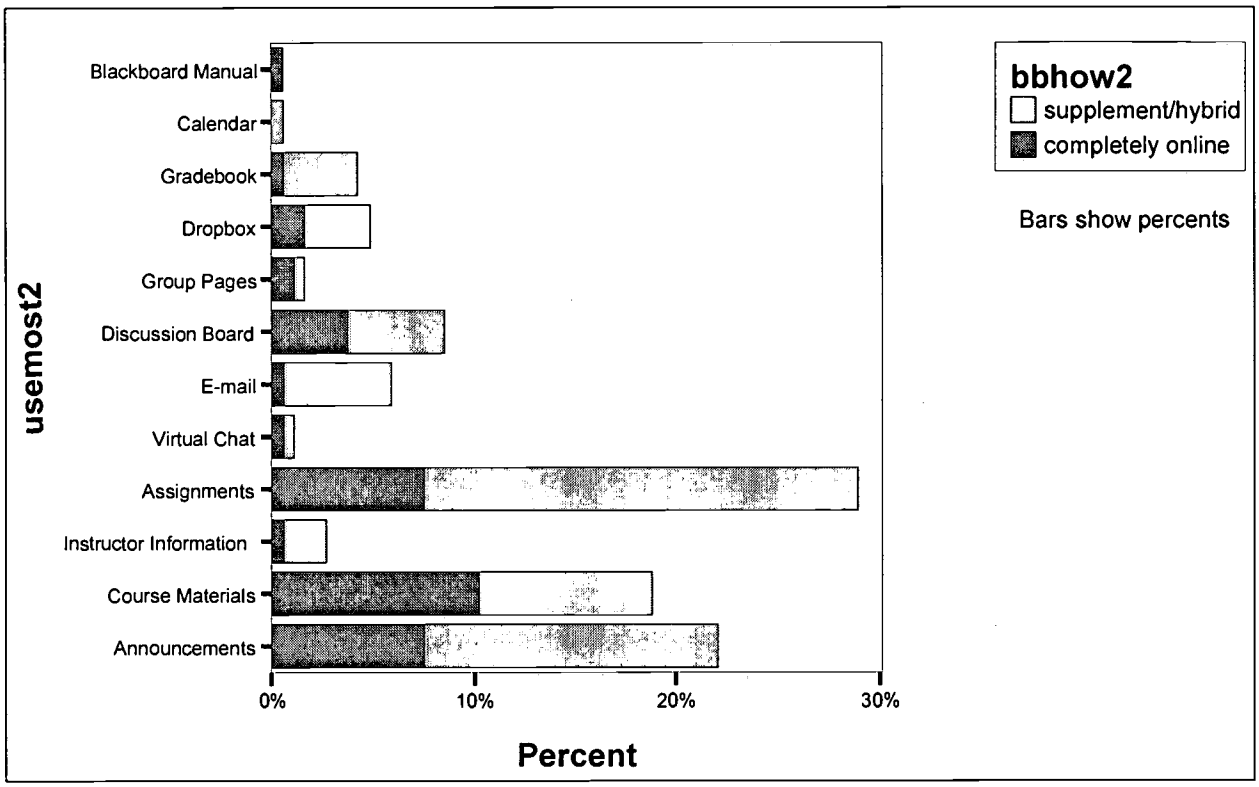

Figure 4. Bar graph showing percentage of student ratings of **least useful** feature of Blackboard.

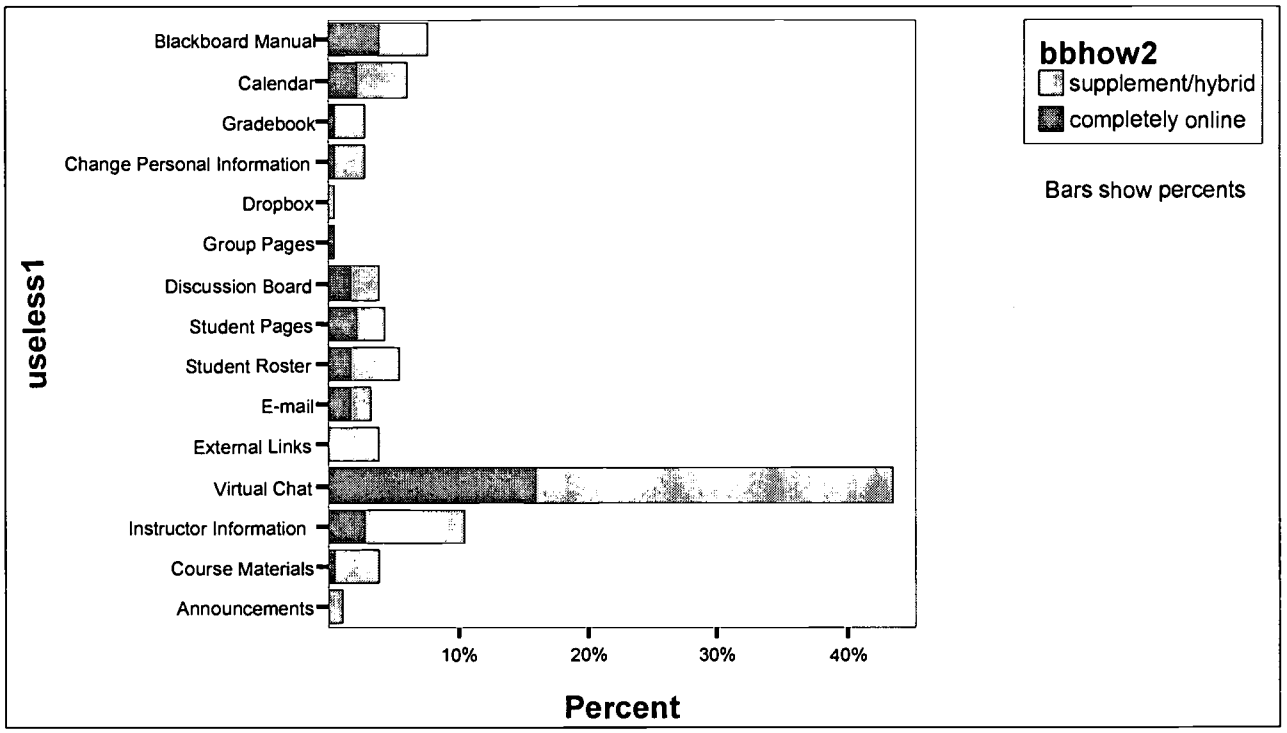

Figure 5. Bar graph showing percentage of student ratings of **second least useful** feature of Blackboard.

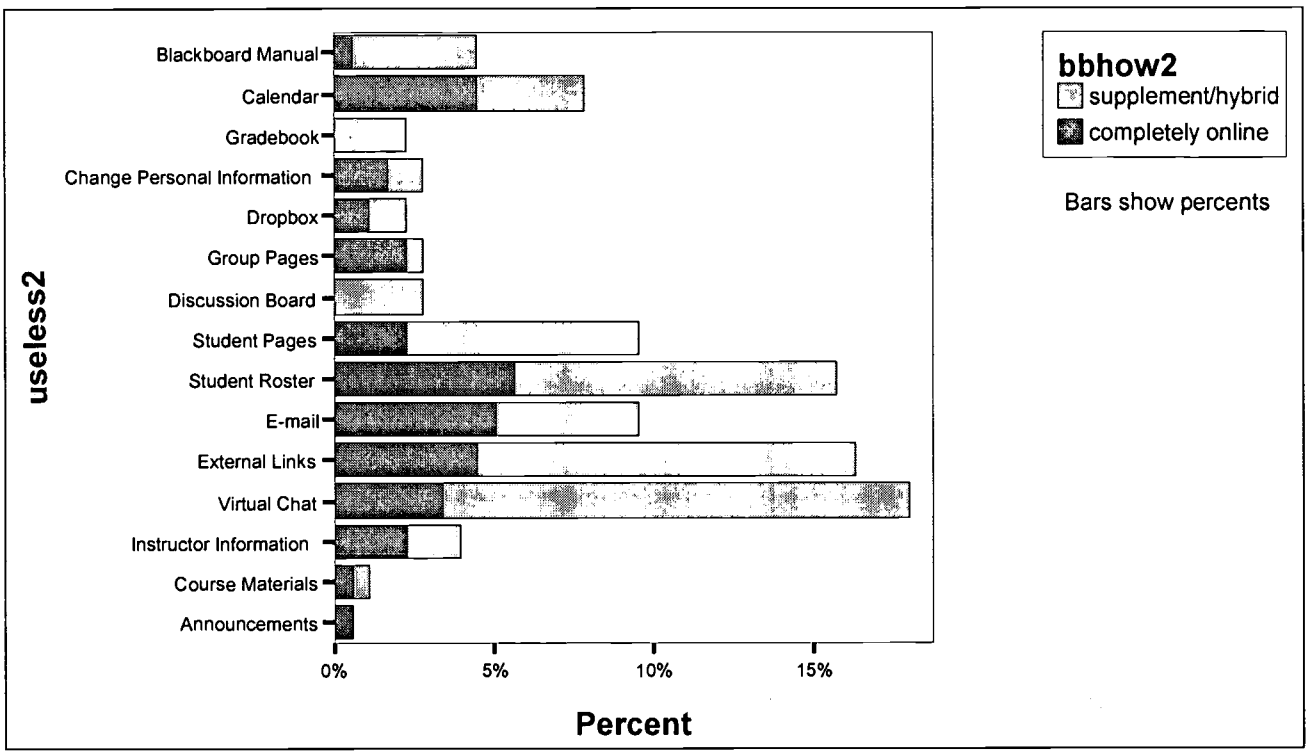

Figure 6. Bar graph showing percentage of student ratings of **most beneficial** feature of Blackboard.

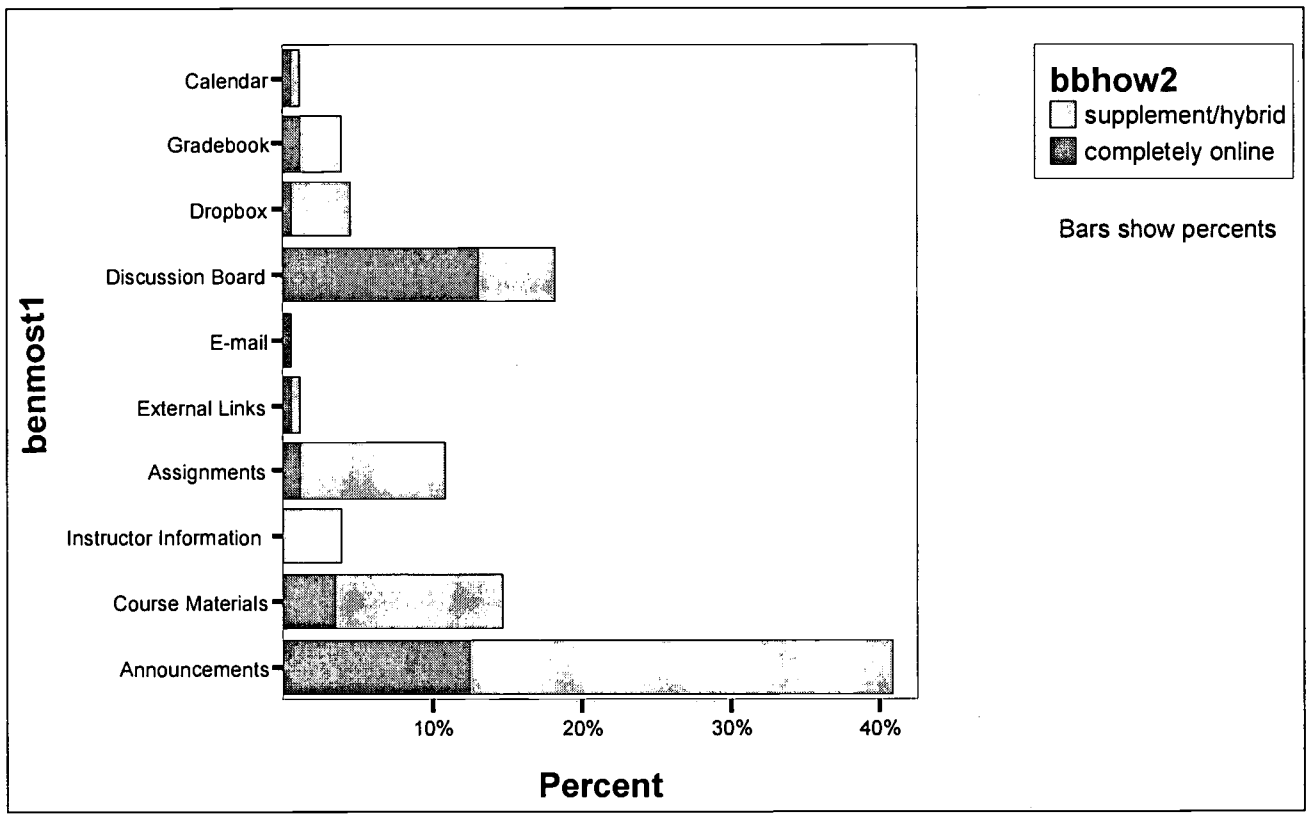

Figure 7. Bar graph showing percentage of student ratings of **second most beneficial** feature of Blackboard.

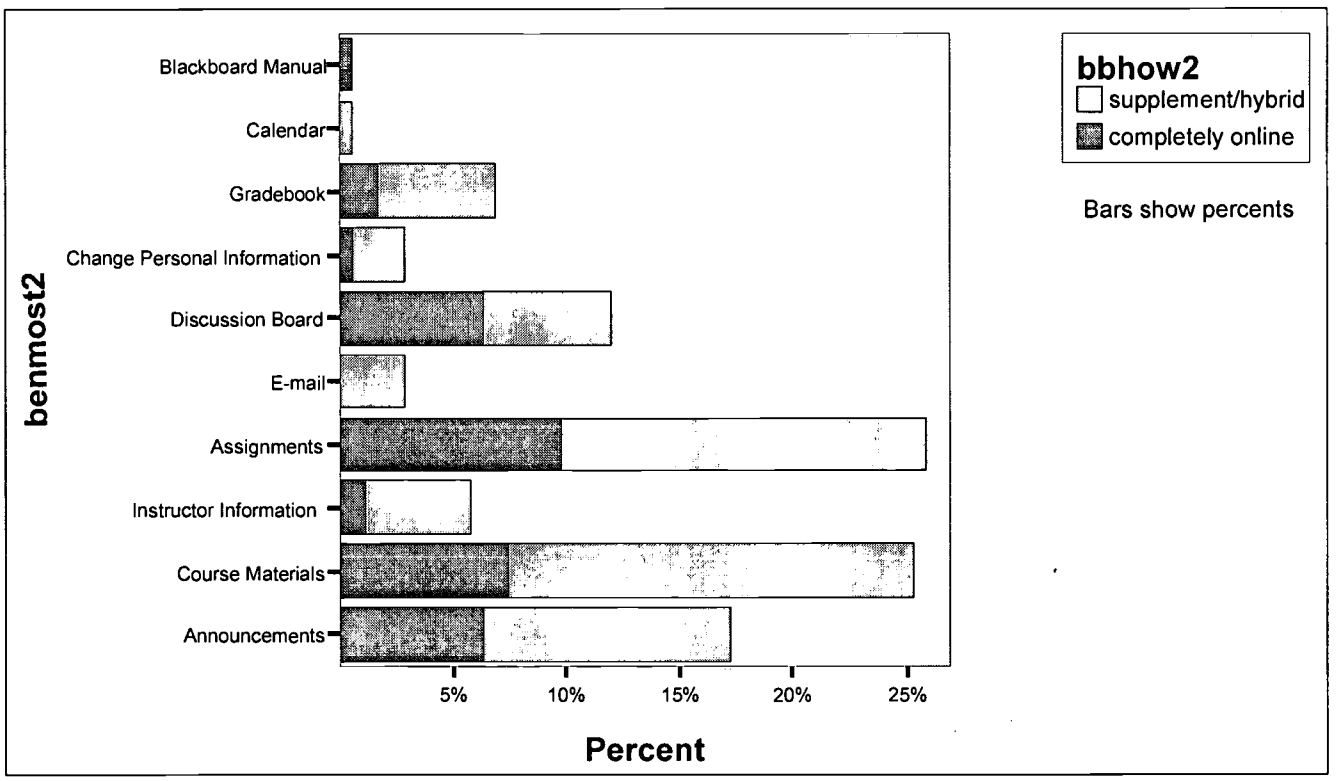

Figure 8. Bar graph showing percentage of student ratings of **least beneficial** feature of Blackboard.

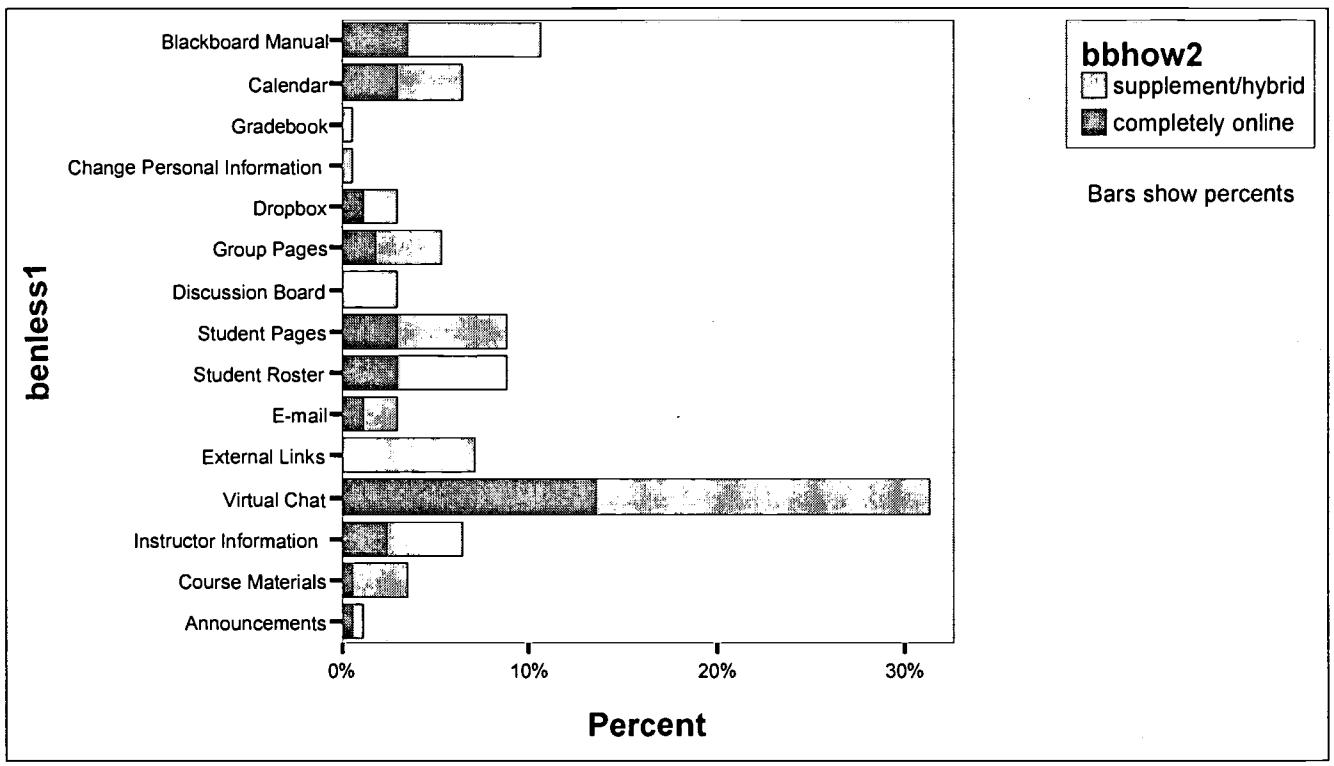

Figure 9. Bar graph showing percentage of student ratings of **second least beneficial** feature of Blackboard.

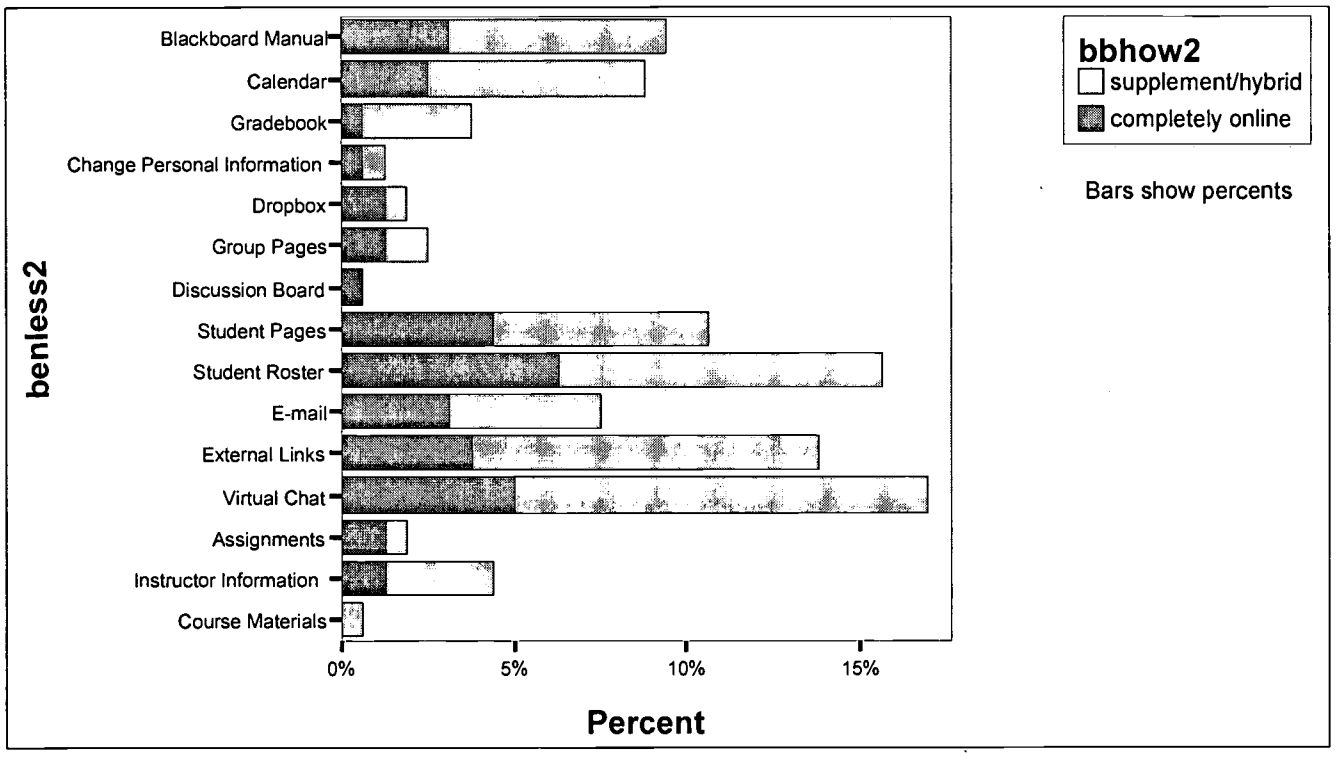

Figure 10. Box plots showing significantly higher development of writing skills for students in completely online courses than those in supplemental/hybrid courses.

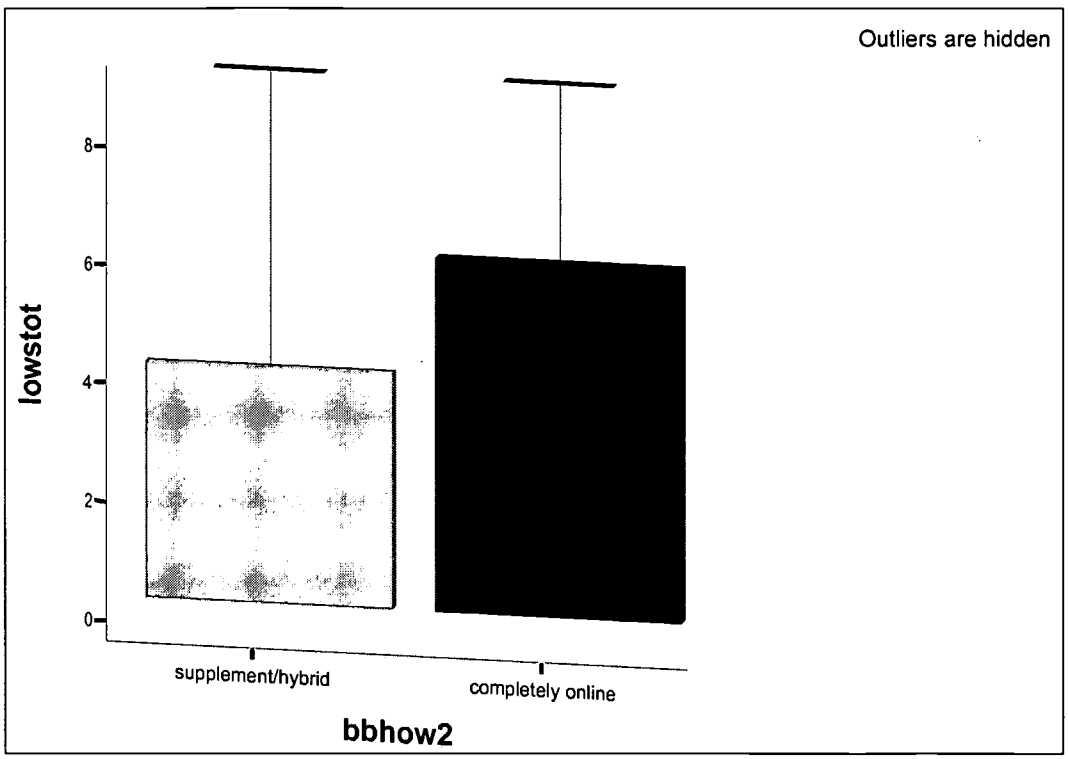

TIPS FOR TEACHERS OF PSYCHOLOGY

Given the growing number of psychology instructors using distance learning technologies in their courses, either as a supplement to face-to-face instruction or as a completely online format, it is important that instructors look at the impact of these technologies on student learning and motivation. Instructors of psychology, as with other disciplines, should assess how the various attributes that a distance learning technology can afford to do for the student (and even the teacher) to enhance the learning experience, especially as it relates to learning outcomes. There is no doubt that future research on the educational efficacy of these media attributes, their pedagogical use or applications, and the psychological and demographic characteristics of learners will be major variables that will be investigated further.

Based on my own experience teaching both online and hybrid psychology courses, and on the results of this study, I attempt to provide a few basic useful recommendations to teachers of psychology, from those courses that are more content-laded to skill-based and research-oriented courses. This list is by no means meant to be exhaustive. I believe that these recommendations apply to high school, undergraduate, and graduate level DL courses.

For completely online and supplemental/hybrid courses:

- The Discussion Board, Assignments, Course Materials, and Announcements are the most useful and beneficial features of a DL course. Incorporate their use in the accomplishment of course requirements. Use these features wisely and extensively.
- Other less useful features may be used as needed. If a feature is perceived to complicate how students function in the course, minimize its use, or not to require its use at all.
- Given that learning outcomes relating to Course Content, Class Participation, and Critical Thinking, show no significant differences between Completely Online and Supplemental/Hybrid courses, strategies that may enhance these learning outcomes in the context of a DL environment should be explored.
- Know as much about your students regarding their characteristics that may contribute to how they may adapt to the distance learning (DL) format. (e.g., Internet knowledge and access, previous DL courses taken,)
- Be familiar with the most essential features or media attributes of the DL technology. Early during the course, demonstrate clearly to your students the most useful attributes they will be using to succeed and learn most effectively in the course.
- As an instructor, post assignment, update lecture materials, regularly respond to the Discussion Board postings, and update the online gradebook regularly. This practice models the appropriate expectations you have of your students.
- Have student written projects/papers be made available online so that other students may provide direct feedback to each other about their work. The instructor could facilitate this process. Be an active participant to questions/topics posted.
- Technical support for students is important. Make sure that this is readily and conveniently available to them.

For completely online courses:

- Use the Discussion Board more extensively to foster discussion. Facilitate the online discussion only for the first and/or second course topics. Have students or teams of students post their own questions or topics of interest to them (upon your approval) and have them facilitate the discussion.
- The use of Virtual Chat for office hours or for meetings may prove to be unnecessary. Students often e-mail you if they need to communicate with you about their individual concerns or questions.
- A initial training program on this is crucial to familiarize students with how to use the DL technology to be able to function at a certain basic level.
- Students should be aware of what to expect from your use of the DL technology. Post lecture notes on a weekly basis promptly.
- Create a sense of classroom community early during the course. Encourage students to complete their student pages (homepage), have a discussion on topics that allow them to introduce themselves to each other (including you), and/or have an informal Discussion Board set up for matters that are not specifically course-related.

For supplemental/hybrid courses:

- Make writing a more integral part of the course requirements. Focus on ways to improve student writing skills by making use of the making use of the Discussion Board as a way to continue classroom discussion beyond the classroom.
- Given that you also meet students face-to-face, many DL features may not be used. Thus, do not make course requirements contingent on these features that may be unnecessary.

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Funding Undergraduate Research

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HOW CAN COLLEGE STUDENTS fund their research, internships, and other psychology projects? This question often arises on college campuses across the USA today, for a number of reasons. First, psychology has emerged as the number one undergraduate major (Chamberlin, 2000), with over 67,000 baccalaureates awarded yearly in the USA (Murray, 1996). Second, the curriculum for this major increasingly requires empirical research (Brewer et al., 1993), to the point where "every psychology student should do research as part of their undergraduate experience" (Nodine, 2001). Third, many undergraduates know the importance of empirical research for acceptance into competitive graduate schools in psychology (Takooshian, 1993). Fourth, undergraduates are encouraged to do hands-on research for increased career success (Landrum, 2002), self-confidence (Sadowski, Flagler, Dowd, Ball & Collins, 2002), and personal growth (Carmody, 1998). It is no surprise that each year literally hundreds of Psi Chi and other undergraduates go well beyond their course work, to present their research at conferences, or publish it in the *Psi Chi Journal of Undergraduate Research* or other journals (Thomas, Rewey, & Davis, 2002).

Yet research can be expensive. Not many students have much money left to cover research expenses (supplies, equipment, conference travel, etc.) after stretching to pay for tuition, books, and living expenses. So where can students most easily find funding to do high-quality research? Sadly, this funding question is hardly addressed even in some of the finest guidebooks for students, such as Appleby (1997) or Landrum, Davis, and Landrum (2000).

One exceptional resource appeared in the *Psi Chi Newsletter* of Fall 1993—a single page that cumulated 52 good (and otherwise hard to find) sources of funding for student researchers (Bockert, 1993). Yet this unique list is limited in a few ways: (a) it is simply unavailable to all but a few who have back issues from 1993; (b) it is dated, and (c) it focused only on APA divisions and state associations—to the exclusion of foundations, corporations, and other groups.

Here, a 2001 Psi Chi/Thelma Hunt Grant let us three collaborate on an updated and expanded listing of sources for students (particularly undergraduates) to fund their research, internships, travel, and related projects. This is in two parts: (a) This article gives a capsule overview of available funding. (b) A separate, Web-based roster names specific sources and contact information *(www.psichi.org/content/awards/list.asp)*. This overview is based on our interviews with funding specialists of diverse expertise, as well as perusal of websites, books, and unpublished reports.

Types of Funding

From the outset, it is useful to distinguish different types of funding. Susan Sharoma of the Foundations Center notes that unlike a *general scholarship* or *fellowship,* a *grant* is money given for a specific project. A grant is given before the research, unlike a *prize, honor,* or *award* given after the research is completed. Unlike a grant, a *loan* requires payback, and an *internship* requires some form of service. (Our review excludes information on traditional scholarships and fellowships, which is already amply available in bookstores, in libraries, and on the Internet. But along with grants, we also include awards and prizes, since these are closely related to grants, and can give the financial and spiritual impetus for follow-up research.) Some grants are also "targeted" to specific recipients or projects—such as minorities (Minority Undergraduates of Excellence [MUSE]), or research in Los Angeles (Haynes Foundation) or New York (Astor Foundation).

It is also useful to distinguish *indirect* from *direct* grants. Student researchers often receive funds indirectly, through a grant given to their school or professor for this purpose. For example, dozens of students each year receive $2,500 to do summer research through National Science Foundation (NSF) grants given to selected schools. In contrast, *direct* grants go right to the student. Indirect grants are far more common today, since grant-makers are more inclined to give grants to faculty or schools than directly to the individual students, so student researchers are wise to seek out faculty with indirect grants as an alternative to applying directly for their own. (Our focus here is only on direct grants to students, not indirect grants through faculty or schools.)

Types of Sources

Grants to students and others come from three very different sources—government, nonprofit, and private.

Government. "The U.S. government is by far the single largest source of financial aid to students" (Sharoma, 2001). Several federal agancies offer extramural research grants for psychology—NSF, the National Institutes of Health (NIH), the National Research Council (NRC), and the National Institute for Drug Abuse (NIDA). Luis Zayas, an expert on government funding, notes that only a small percentage of these funds is open to students—such as the NRC minority dissertation grants, NIH predoctoral fellowships, NSF predoctoral grants, or Fulbright student grants. Students can conveniently access these through *www.nsf.gov,* or *www.iie.gov* (for Fulbrights) and similar websites, but virtually all government grants given directly to students are limited to the graduate or even doctoral level, not to undergraduates.

Nonprofits. The USA is blessed with a variety of generous nonprofit organizations—foundations, professional associations, and community groups. Of 57,000 foundations in the USA, only 4,200 award funds directly to individuals, but these funds to individual scientists and artists total a hefty $468 million annually. For-

Acknowledgments. We gratefully thank several folks who kindly shared their expertise with us: Susan Sharoma, librarian for the Foundations Center; Jennifer M. Horvath, APAGS Program Coordinator; Sarah Jordan and Keith Cook of APA Division Services; Scott Horton of Fordham's Development Office; Professor Luis Zayas of Fordham; Professor Chris Koch of George Fox University; Patricia Zahregian of Pace University; and Elizabeth Cartier of Fordham. Not least of all, we thank Psi Chi for its dedicated promotion of student research, and its Thelma Hunt Grant that made this project possible.

tunately, foundations are highly organized, so it easy to consult one source—the Foundations Center—for quick access to the wide array of funds. In fact, the New York-based Foundations Center has libraries in many U.S. cities, its superbly indexed database is online *(www.fdncenter.org),* and many schools own its book and CD-ROM, "Foundation Grants to Individuals." Several professional groups also fund psychology student research. The more visible ones are Psi Chi *(www.psichi.org),* the American Psychological Association *(www.apa.org)* and its student group, the American Psychological Association of Graduate Students (APAGS), about half of APA's 53 divisions and state psychological associations, and the American Psychological Society's Student Caucus (APSSC). Less obvious are the countless related associations, such as the American Association for Marital and Family Therapy (AAMFT), the American Educational Research Association (AERA), Sigma Xi, the Association of Black Psychologists (ABPsi), and the Council on Undergraduate Research (CUR). These too are geared mainly to graduate students, but undergrads are sometimes eligible, and one group, Teachers of Psychology in Secondary Schools (TOPSS), is now extending awards to high school psychology researchers. APAGS used to print a useful booklet listing APA-related grants in conjunction with APA's Melton Library (APAGS, 1999).

Private. Each year corporations and other profit-making organizations such as Microsoft and Pfizer give millions in research grants, typically through their community relations, research and development, or marketing departments. One expert in this area, Scott Horton, notes this source is far too large to be ignored. Private grants may be large, available with little red tape, and quite open to student researchers, but they are especially challenging in a few other ways. There is no central registry or uniform guidelines, so individuals are "on their own" in approaching each organization and its contact person one at a time. Corporations' prime motive is usually proprietary and value-added rather than philanthropic ("How can your research benefit us?"), so their goal is typically bottom line, especially during times of recession.

Local funds. While using the Internet to find student research funds, we were surprised to uncover a fourth major source: local funds. There were 11,000 local student grants and awards, most of them given internally by schools. Upon reflection this made sense to us, and is a source not to be overlooked. Most colleges seem to have research institutes, small-grant programs, or awards named for distinguished alumni, and many psychology departments have a budget for mini-grants, "best paper" competitions, and/or "top student" awards. Though these local funds are too limited in eligibility to be fully included in our roster, the alert student or faculty advisor should not forget to check within their department and school, including the school's grants office.

In sum, our review of direct funding of undergraduate research can be summarized in these points: (a) It is much needed, given the acceleration of undergrad research today. (b) Sadly, funding that is scarce for faculty research, is more scarce for graduate students, and most scarce for undergraduates—based on the mistaken assumption that undergraduates are not involved in publishable research. (c) Happily, there are scores of good (if scattered) sources for direct funding for undergraduate research, if students or their mentors know where to look—within APA, other groups, foundations, and the private sector. (d) The group that is number one by far in the direct funding of undergraduate research today is Psi Chi, in both the number and total volume of its programs—with research grants, prizes, and travel awards topping $130,000 per annum—not to mention its conferences and two publications serving student researchers. (e) Since APA divisions and other groups like Psi Chi routinely limit their funding to student members, it is wise for students to join in advance a group or two that may fund their work. Fortunately, such organizations invite students to join at sharply discounted rates, and offer generous funding to these few savvy undergraduates.

A complete list of funding sources derived from this report is available at *www.psichi.org/content/awards/list.asp*

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The three authors are known as mentors of student researchers on their campus, and for developing regional and national programs to encourage student research.

Harold Takooshian earned his PhD at City University of New York with Stanley Milgram. He has taught at Fordham University since 1975, where he received Psi Chi's Denmark National Faculty Advisor Award (1988) and Cousins National Chapter Award (1993). Since 1997 he is also the director of the Fordham Institute, dedicated to involving undergraduates in behavioral research—through mentoring, internships, and small grants.

Richard S. Velayo earned his PhD at the University of Michigan with Wilbert McKeachie and Carl Berger. He has taught at Pace University since 1994, where he chairs the Pace University Undergraduate Psychology Conference each spring, and advises the chapter that received Psi Chi's Cousins National Chapter Award (1999).

Vincent Prohaska earned his PhD at the University of Chicago. He has taught at Lehman College, CUNY since 1990, where he is the Psi Chi faculty advisor and, since 1995, chair of its Psychology Department. He was the recipient of Lehman's 1997 "Teacher of the Year" Award, and the Psi Chi Denmark National Faculty Advisor Award (2001) and Cousins National Chapter Award (2001).

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Different Bimodal Multimedia Presentations Affect Students' Multiple-Choice Test Scores

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RICHARD S. VELAYO*

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This study investigated the effect of different types of bimodal presentations on learning. We randomly assigned participants to 1 of 3 presentation modalities: audiovisual, audio-textual, or visual-textual. Each participant completed a computer tutorial about the midbrain and the hindbrain. Subsequently, we administered a 42-item memory test to the participants. The multiple-choice test consisted of 28 verbal questions derived from the textual information and 14 visual questions derived from the pictorial information. There was a significant mean difference among the total visual test scores of participants assigned to the visual-textual modality and those assigned to the audiovisual or audio-textual modalities. However, there was no significant difference among the 3 bimodalities on total score in the verbal section of the memory test. Continued study is needed to examine further the effect of each bimodality as a predictor of actual test performance.

MULTIMEDIA INSTRUCTION, THE PRESENTATION of information using combinations of visual, audio, and textual modalities is becoming a popular tool in educational settings. Many educators and educational researchers are eagerly exploring the use of computer multimedia in the classroom to optimize learner acquisition of knowledge and thinking skills. Therefore, from a pedagogical point of view, studies concerned with the integration of more than one modality in presenting instructional information seem to highlight a very important aspect.

Previous research has emphasized the importance of the visual modality in learning. For example, Westman (1990) reported that students rely predominantly on visual-based learning techniques. Waddill, McDaniel, and Einstein (1988) found that students were able to remember new information better when pictures were presented along with textual content. Hong and O'Neil (1992) showed that participants who received diagrammatic (visual) presentations scored higher on a memory test than participants who received descriptive (verbal) instruction. Frieske and Park (1999) indicated that presentation of visual information and audio (TV format) led to higher performance compared with participants who received only auditory information. In addition, Patra and Rath (1999) indicated that students performed better when exposed to an audiovisual modality versus a visual-only format.

Animated visual displays can have a profound effect on learning. Rieber (1990, 1991) reported that students learned more information from animated graphics than from static graphics. For example, when teaching concepts of time, *continuous presentations,* such as animations that tell a story or present events chronologically, have been helpful. Park and Hopkins (1993) concluded that the dynamic visual display is generally more effective than a static display for enhancing student learning.

Less research exists concerning the effect of audio and textual presentation of material on test taking. Hue, Fang, and Hsu (1990) found that, contrary to Hong and O'Neil (1992), the auditory modality is an effective means to facilitate learning compared to textual presentation. These researchers demonstrated that when testing the short-term memory processing of auditory and visual modalities, students who received auditory presentations produced higher recall scores. Interestingly, Hong and O'Neil tested long-

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term memory, and this difference may be a reason for the contradictory findings.

Most studies of classroom learning include bimodal presentations in which the different kinds of modalities involved were given concurrently. Hodes (1994) indicated that the processing of both verbal and nonverbal stimuli is crucial for remembering factual information. In support, Mayer and Sims (1994) expanded Paivio's dual coding theory of learning, which states that the building of visual and verbal representations together result in the construction of a third referential connection that takes place in working memory (Clark & Paivio, 1991). The formation of this referential connection will lead to better learning. Several studies indicated that when the experimenter simultaneously presented visual and verbal materials, students performed better at remembering content material than students who received successive (asynchronous) presentations (Borras & Lafayette, 1994; Mayer & Anderson, 1992; Mayer & Sims, 1994).

Multimedia technology may be a powerful tool used to educate not only more traditional students but also students with biological or emotional handicaps. For example, Heimann, Nelson, Tjus, and Gillberg (1995) reported that multimedia instruction increased reading and communication skills in autistic children.

The present study attempted to elucidate further the effect that different kinds of bimodal presentations have on students' performance on multiple-choice tests. We hypothesized that participants assigned to the visual-textual condition should have significantly higher visual and verbal written test scores than the participants presented with the audio-visual or audio-textual conditions.

Method

Participants

The study included 144 participants (64 men, 80 women), 98% of whom were 102 undergraduate and 39 graduate students ranging in age from 16 to 85 years ($M = 28.22$, $SD = 11.11$). Most participants were students who received extra credit for the course they attended.

Materials

We utilized a computer-assisted tutorial on the "human brain" created using Microsoft PowerPoint software. The instructional material covered two major subdivisions of the human brain, the midbrain and the hindbrain. Six slides pertained to the midbrain and seven were related to the hindbrain. The textual (T) material consisted of a 1,500-word document derived from a college-level physiological psychology textbook (Carlson, 1994). The visual (V) component entailed different diagrams of the brain (pictorial elements), which were always accompanied by either text or audio material. The audio (A) material was a digitally recorded version of the textual component. Each slide always delivered information through a PowerPoint presentation in a bimodal format: either A-V, A-T, or V-T.

We developed a 42-item objective written test that included 28 verbal questions in a textual format (factual), subdivided into 12 for the midbrain and 16 for the hindbrain, and 14 visual questions (diagrams), subdivided into 6 for the midbrain and 8 for the hindbrain. In this test, we assessed the understanding of the main functions of the midbrain and hindbrain, the familiarity with major terms, and the ability to pinpoint the main parts of the brain. Two sample test items are presented in Figures 1 and 2.

Design and Procedure

Testing occurred individually in a quiet setting, such as the library. Participants first signed an informed consent form and were instructed that the testing session would take approximately 40 min. Next, participants filled out a demographic information sheet that also included a question that asked how familiar the participants were with the human

FIGURE 1

Sample verbal item.

The red nucleus and substantia nigra are important components of what system?

a) Visual
b) Auditory
c) Motor
d) All of the above

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FIGURE 2

Sample visual item.

From the diagram below, which displays a cross-section of the tegmentum, name the correct parts of the brain to which each arrow is pointing.

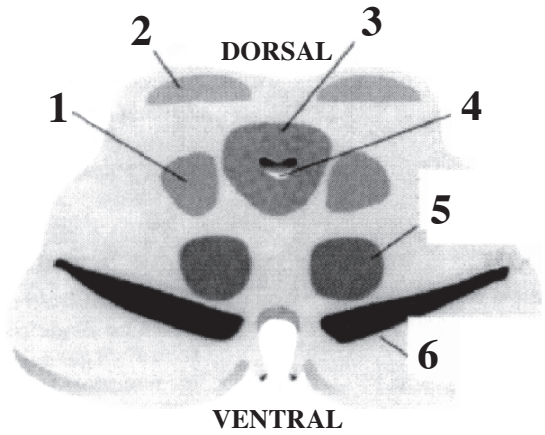

Arrow number 1 points to _____.

a) Superior colliculus
b) Inferior colliculus
c) Cerebral aqueduct
d) Red nucleus
e) Periaqueductal gray matter
f) Reticular formation

brain on a scale from 1 (*not familiar at all*) to 9 (*very familiar*). Participants were randomly assigned to one of three bimodal presentation conditions: A-T, A-V, or V-T. As a result, 36 participants were in the A-V group, 74 were in the V-T group, and 34 were in the A-T group. Despite the unequal number of participants in each group, the variances of the groups were comparable.

The administrator monitored the instructional courseware. Each slide, starting with the entire lesson on the midbrain (six slides), followed by the hindbrain (seven slides), was shown for 1 min. The presentation of the slide content was the same for all participants, that is, it was not counterbalanced primarily to establish consistency in the sequence of content presentation. The audio element was presented more than once for each slide, but without exceeding the specified time limit of 1 min. After all of the slides were shown, the participants completed the multiple-choice test. The time limit for the completion of the test was about 15 min. Finally, we administered a participant debriefing form.

Results

Based on the total visual score, there was a significant mean difference among the three bimodal presentations, $F(2, 142)$, 14.238, $p < .001$, $\eta^2 = .164$. Scheffé tests indicated that the participants assigned to the V-T modality ($M = 9.038$, $SD = .369$) scored significantly higher than the participants assigned to the A-V ($M = 7.111$, $SD = .544$) or A-T ($M = 5.588$, $SD = .559$) modalities, which did not differ reliably (see Figure 3).

Data related to the score of the verbal section showed no significant difference among the three bimodalities. Nevertheless, participants assigned to the V-T modality ($M = 15.633$, $SD = .650$) scored the highest relative to participants assigned to the A-T ($M = 14.330$, $SD = .948$) or the A-V ($M = 13.006$, $SD = .920$) modalities. A similar result was found for the total visual score in relation to the V-T modality. However, on the total verbal section, participants assigned to the A-V modality held the lowest score, whereas in the total visual test, the participants in the A-T modality had the lowest mean.

FIGURE 3

Bar graph of the means for each bimodality condition as a function of the total visual score.

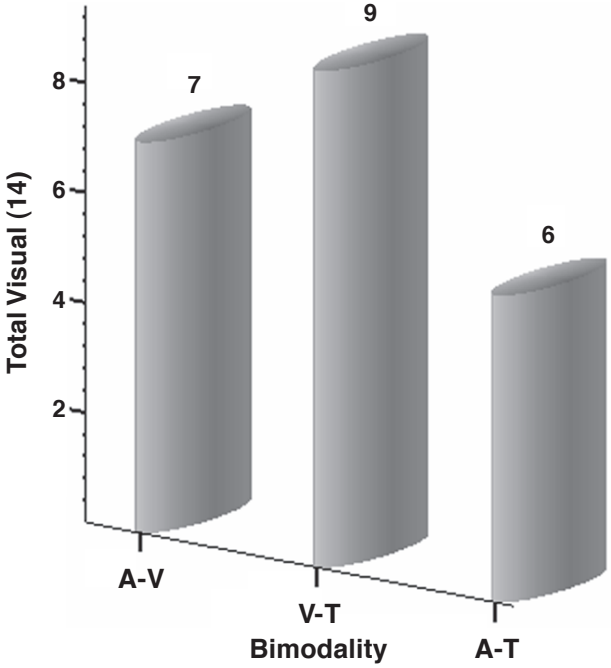

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Discussion

Overall, the present results indicate that including a visual component in multimedia presentations enhances learning of material related to physiological psychology. As predicted, the V-T participants scored significantly higher in the test pertaining to the total visual section than the A-V and A-T participants. Thus, evidence supports the relevance of the visual modality as being an important factor for effective learning (Hong & O'Neil, 1992; Westman, 1990).

These findings also have important implications for teaching. For instance, when an instructor lectures in a physiological psychology course, it is important that students are not only taught the functions of a specific organ. They also need to connect their understanding of the organ's function with pictorial illustrations, so that certain difficult concepts will appear more comprehensible. There definitely must be some truth in the old saying "a picture is worth a thousand words!"

Unexpectedly, no significant difference was found among V-T, A-V, and A-V participants in relation to the total verbal test, although the V-T participants still had the highest mean. This finding has major implications for the traditional assessment adopted in educational settings. In fact, most of the multiple-choice exams utilized in schools are of verbal (written text) and not visual (pictorial diagrams) nature. This finding may suggest that multimedia presentations are only effective given certain types of testing. Further research is needed to investigate whether there is a significant relation between the means of testing students (essay questions, oral exams, etc.) and the types of bimodality presentation instructors adopt.

Future studies may also investigate whether there is a predictive relation between the bimodality to which participants are assigned and the type of material they have to learn (e.g., abstract vs. concrete material, numbers vs. words, or stories vs. lists of concepts). Moreover, it could be pertinent to examine whether the time elapsed between the material presentation and the test administration influenced bimodality type. For example, will administering the test immediately after the presentation, 1 hr later, or 1 day later make any difference in the participants' score by presenting information to them in a different bimodality?

Limitations of this research include the fact that a larger number of participants, due to randomization, were assigned to the V-T component as compared to the A-V and A-T bimodalities; therefore, there was no proportionate sampling group. Another limitation was that participants had different expertise levels regarding the human brain (based on a question asked in the demographic sheet). Although the difference was not statistically significant, it is difficult to ensure whether the participants objectively evaluated themselves with regard to this item. As a result, this difference may have been a confounding variable as to how participants performed on the 42-item test.

Although the visual component seems to be the most dominant element of all modalities, it is important to integrate at least two modalities in a presentation or lecture in order to enhance and consolidate the learning process. Test performance is significantly higher when participants are exposed simultaneously to audio, textual, and visual diagrams rather than being exposed only to a visual element (Tindall-Ford, Chandler, & Sweller, 1997). Also, Waddill et al. (1988) and Frieske and Park (1999) indicated that participants remembered new information better when they were exposed to two types of modality rather than one.

In addition, although this study did not find a significant difference pertaining to the A-V and the A-T bimodalities when participants were tested, more research is required to determine the influence of these bimodalities on learning. For example, it may be that the equal distribution of A and T information in the current study was not effective. In other words, instructional material derived from 50% of A and 50% of T information may not be as effective as instructional material derived from 20% of A and 80% of T information. Perhaps it is not only a matter of what types of bimodalities instructors utilize, but also the proportion of each modality in an instructional bimodal presentation.

Instructional technology gives instructors the opportunity for flexibility in terms of how to structure a class presentation. They are better able to organize, tailor, and update a lecture according to the subject matter and the students' abilities. Moreover, instructional technology could be beneficial for students who thus may be able to learn more effectively and better recall certain kinds of information (e.g., statistical graphs, conceptual tables, or diagrams). Integrating the appropriate use of multimedia technology should also encourage students to utilize it in their own presentations in classrooms as well as in other contexts.

Using multimedia technology in classroom settings may greatly facilitate the development of our complex cognitive and learning processes. Therefore, understanding and mastering this type of technology as college and university instructors would seem warranted.

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How do Presentation Modality and Strategy Use Influence Memory for Paired Concepts?

Richard S. Velayo and Christopher Quirk

This experiment attempted to determine how modality (i.e., visual, auditory, textual, visual-textual, visual-auditory, and auditory-textual) influenced learners recall ability on a paired-associate learning task. The experimental procedure required subjects to observe paired-concepts either by visually observing pictorial representations of the concepts, by observing the words themselves, by listening to the concept pairs, or through some combination of modalities. Subjects were then tested as to their recall of the concept pairs. Additionally, subjects were asked to describe the recall strategy they used to remember the pairs. Results indicated that significant differences in recall performance related to both presentation modality and recall strategy.

Determining the ideal way to instruct students has been a research question among educators since formal education began. It has been suggested that many instructional techniques are inadequate because they require too heavy of a cognitive load-the amount of cognitive activity required for a student to learn a task (Sweller, 1994). Current research in educational psychology has attempted to realize the most efficient ways to reduce cognitive load among students and maximize their working memory. More specifically, the combining of various presentation modes (e.g., visual and auditory) has been investigated (Mousani, Low & Sweller, 1995) and there is a growing trend towards the pedagogical use of multimedia presentations in the classroom (Velayo & Smith, 1997). Paired-associate learning paradigms are useful experimental designs when investigating the learning and memory functioning (Houston, 1991).

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Paired-associate learning strategies have been shown to be effective in improving subjects' recall ability (Bulgren, Hock, Schumaker, & Deshler, 1995). In addition, research has examined qualities that lead to improved recall of paired-associates. Similarity of pairs has been evidenced to lead to improved cued-recall performance (Guttentag, 1995) and direct oppositionality of pairs has also been linked with improved recall (Ulasevich & Rychlak, 1994).

Previous studies have noted the impact of presentation modality on recall. Audiovisual presentations made to 2nd and 5th graders led to improved recall of paired-associates (Godley, Estes, & Fournet, 1984). Audiovisual presentations also led to greater recall of a political broadcast shown to 18-25 year old undergraduates (Gunter, Furnham, & Leese, 1986). Thompson and Paivio (1994) found recall of picture-sound stimuli was consistently greater than that of picture-only or sound-only stimuli. The results of these studies are consistent with Paivio's dual coding theory (Clark & Paivio, 1991). This theory states that the building of visual and verbal representations together result in the construction of a third referential connection in working memory, which will lead to improved learning.

Other studies have found that the com-

bined visual-textual modality has improved recall. Text presented with visual stimuli has been shown to lead to better recall than text presented with sentences (Zoller, Workman, & Kroll, 1989). One study found the visual-textual modality to be related to better recall than the textual-only modality even when the visual-textual modality presented summarized information and the textual-only modality provided either full text or full text with summaries (Mayer, Bove, Bryman, Mars, & Tapangco, 1996).

A study comparing two different bi-modal presentations also found differences in subjects' recall. In this study subjects shown an audiovisual presentation outperformed subjects shown a visual-textual presentation on retention tests (Mayer & Moreno, 1998).

The visual modality alone has also been shown to improve recall. In one study, paired-associates presented visually were remembered more successfully than those presented in the auditory modality (Dwivedi & Pandey, 1983). In another study, visual presentations were also shown to be more effective than olfactory presentations (Bowers, Trina, Philip, & May, 1994).

Research has also been done to examine the impact of encoding strategy on recall. Studies have found that use of specific encoding strategies can improve recall. For example, Straub & Granaas (1992) found that subjects given specific instructions to use imagery techniques recalled more items correctly than subjects given general memory instructions did. Bethene-Ervin and Smicklas-Wright (1998) found that instructions as to the use of encoding strategy aided older adults with their recall. Another study found that sixth and seventh graders shown reading material and told to use their prior knowledge to integrate what they read showed improved recall over students who were instructed to read for understanding alone (Woloshyn, Paivio, & Pressley, 1994). Therefore, another important element of recall ability appears to be the encoding strategy that a given individual uses.

This experiment attempted to determine how modality (i.e., visual, auditory, textual, visual-textual, visual-auditory, and auditory-textual) influence learners recall ability on a paired-associate learning task. It was hypothesized that: 1) the recall of concept pairs in the visual modality would be significantly higher than the recall of concept pairs in the textual and auditory conditions, and 2) the recall of concept pairs in the bi-modal conditions with a visual element (e.g., audio-visual) would be significantly higher than the recall of concept pairs in the textual-audio condition. Additionally, subjects were asked to describe the recall strategy they used to remember the pairs. These different strategies were explored with regard to how they related to recall performance.

Method

Participants

There were 324 participants (179 females and 145 males) in the study ranging in age from 14 to 85 years old. A majority of them were Pace University students varying in academic majors. The rest varied in occupation and educational level.

Materials

The presentation stimuli were three-ring binders containing pages, each showing a pair of concepts, for example "seashell" and "ear" (See Figure 1). The participant was shown a total of 40 different paired concepts. Each item in the pair was either represented visually (through a picture of the item), textually (through the written word corresponding to the item), and/or aurally (through hearing the words from a standard audio cassette player). The six modality type conditions are shown in Table 1 each with the corresponding number of participants.

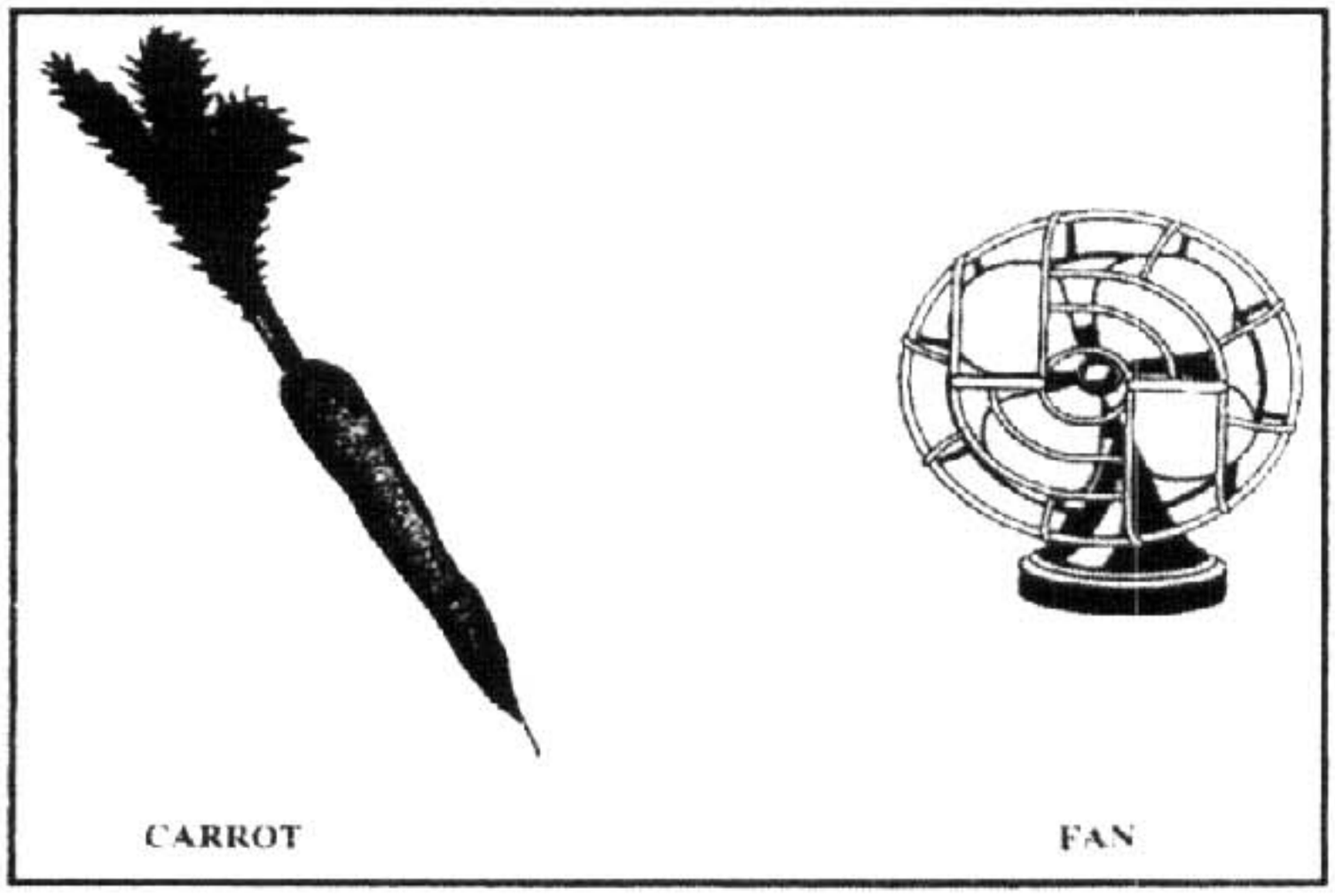

Figure 1. Sample concept pair (Visual-Textual Modality).

Table 1
Visual Representation of Number of Subjects per Modality Presentation

Modality Type	Number of Participants
Visual	n = 56
Audio	n = 56
Textual	n = 97
Audio-Visual	n = 52
Visual-Textual	n = 30
Audio-Textual	n = 32
	N = 324

Procedure

The experimental procedure required subjects to observe paired-concepts either by visually observing pictorial representations of the concepts (e.g., a picture of a tree with a picture of a leaf), observing the words themselves (e.g., viewing the words "tree" and "leaf"), by listening to the concept pairs (e.g., hearing the words "tree" and "leaf"), or through some combination of modalities (e.g., hearing "tree" and "leaf" while observing pictures of the objects). Participatns were then tested as to their recall of the concept pairs. One item of the pair would be presented, and the participants would then be asked to indicate the concept it was paired with. The total number of correct pairs was considered the subject's memory score. Each participant was presented the concept pairs through only one of the experimental modalities (i.e., visual, auditory, textual, visual-textual, visual-auditory, and auditory-textual), therefore creating an independent 6-group design. After being tested, participants were asked to identify the recall strategy they used. Recall strategies were then broken down into five categories. The five recall strategies are shown in Table 2, each with the corresponding number of participants.

Results

A single-factor between subjects ANOVA revealed significant differences in memory scores across the various modalities, $F = 5.291, p < .0001$. (See Tables 3 and 4). [Eta squared as a measure of effect size is .08]

Table 2
Recall Strategies Used by Corresponding Number of Participants

Recall Strategy	Number of Participants Using Strategy
Rehearsal/repetition/ memorization/listening/ looking/reciting	n = 71
Word association/ made sentences	n = 93
Visualization/imagery	n = 79
Similarities between words/ common attributes	n = 48
Others	n = 26

Table 3
ANOVA Table for Number of Concept Pairs Correctly Recalled as a function of Modality Type

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1658.804	5	331.761	5.291	.000
Within Groups	19875.419	317	62.698		
Total	21534.223	322			

Table 4
Significant Mean Differences Related to Presentation Modality (Bonferroni)

Dependent Variable: # of concepts correctly recalled

modality (I)	modality (J)	Mean Difference (I-J)	Std. Errorr	Sig.
audio	textual	-4.48	1.329	.013
	visual	-5.36	1.496	.006
	audio-visual	-5.96	1.525	.002
textual-audio	visual	-5.22	1.755	.047
	audio-visual	-5.82	1.779	.018

The audio-only modality condition (M = 7.77, sd = 6) showed significantly lower recall scores than the visual-only modality condition (M = 13.13, sd = 9.27), the textual-only modality condition (M = 12.25, sd = 8.20), and the audio-visual modality condition (M = 13.73, sd = 8.03). In addition, the textual-audio modality condition (M = 7.91, sd = 8.17) showed significantly lower recall scores than both the audio-visual modality condition (M = 13.73, sd = 8.03) and the visual-only modality condition (M = 13.13, sd = 9.27). See Figure 2 for a graph of mean recall scores for each presentation modality condition.

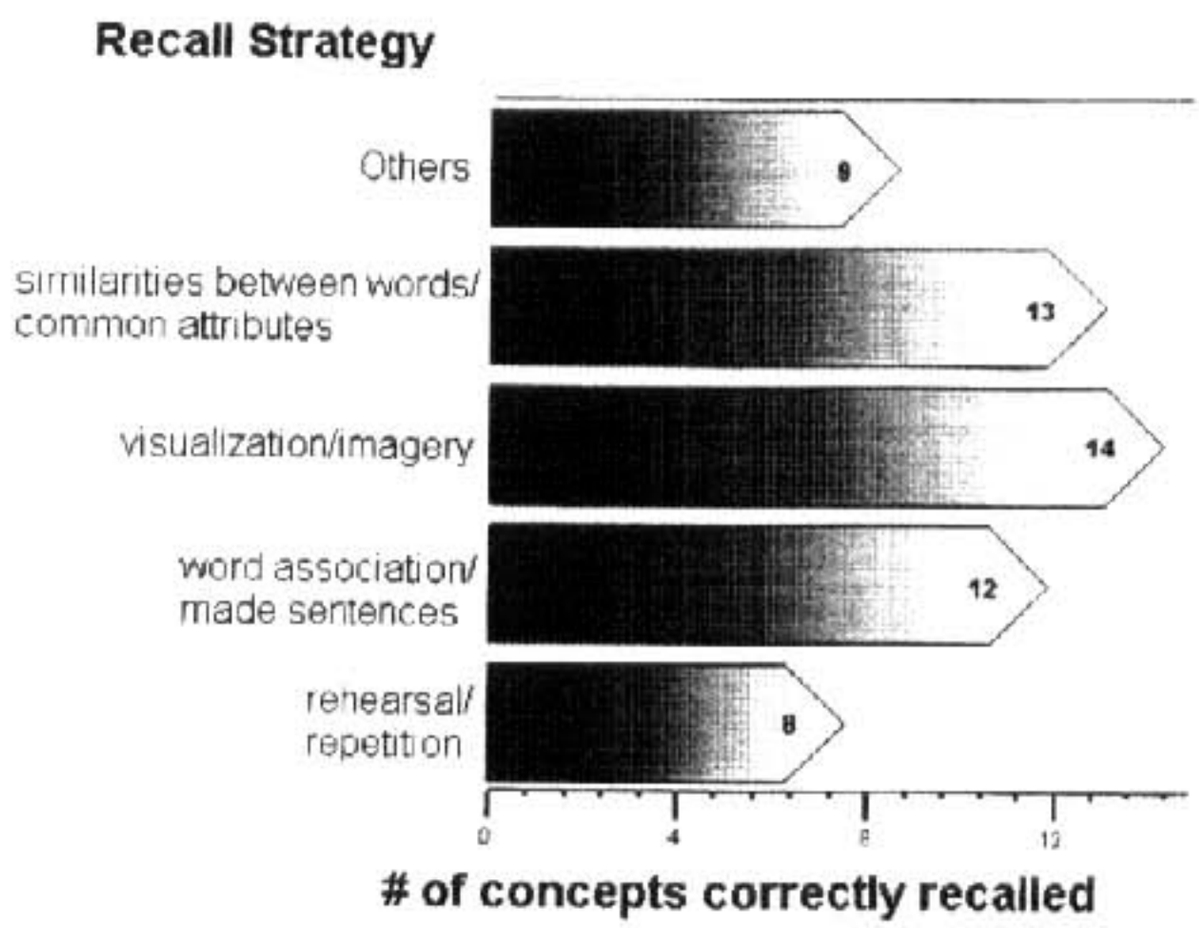

Figure 2. Mean recall score for each presentation modality

In addition, analysis of the different recall strategies used revealed a significant difference between groups, F = 8.651, p = <.0001. (See Tables 5 and 6). [Eta squared as a measure of effect size is .09.]

Table 5
ANOVA Table for Number of Concept Pairs Correctly Recalled as a Function of Recall Strategy.

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	2102.713	4	525.678	8.651	.000
Within Groups	18958.485	312	60.764		
Total	21061.199	316			

Table 6
Significant Mean Differences Related to Recall Strategy (Bonferroni)

(I) code for recall description	(J) Code for recall description	Mean Difference (I-J)	Std. Error	Sig
rehearsal/repetition/ memorization/ listening/looking/ reciting	word association/ made sentences	-4.31	1.229	.005
	visualization/ imagery	-6.81	1.275	.000
	similarities between words/common attributes	-5.53	1.457	.002
others	visualization/ imagery	-5.76	1.762	.012

Results of post-hoc (Bonferroni) comparisons showed a trend towards improved recall among those participants employing elaborative strategies (e.g., word association, visualizing, finding similarities). The findings showed significantly better performance for subjects using visualization (M = 14.34, sd = 7.80), identifying similarities in the pairs (M = 13.06, sd = 7.97), and using word association (M = 11.85, sd = 8.01) over subjects using rehearsal (M = 7.54, sd = 7.62). Also, participants using visualization strategies had significantly better recall scores than those who either could not identify the strategy they used or were inconsistent in their use of strategy-categorized as "others" with regard to recall strategy (M = 8.58, sd = 7.09). See Figure 3 for a graph of mean recall scores for each recall strategy.

Discussion

The use of the visual modality and the audio-visual combination has been demonstrated to facilitate learning on a paired-associate memory task. This result might be explained by the common belief that people in general prefer to acquire knowledge using visual cues.

The facilitative effects of learning through the visual modality have been well documented. Hong and O'Neil (1992) found that subjects who received instruction through visual presentation performed better on a task than those that received descriptive instructions. Likewise, Waddill, McDaniel and Einstein (1988) found that subjects remembered information better when presented with pictures in addition to textual content.

Learning through the visual modality has been shown to have an impact with children (Godley et al., 1984) as well as young adults (Gunter et al., 1986). Students at various levels could benefit from greater emphasis on visual and audio-visual presentations. The increasing use of computers in the classroom presents an opportunity to make more use of both visual and audio-visual presentations.

Presentation of material through the

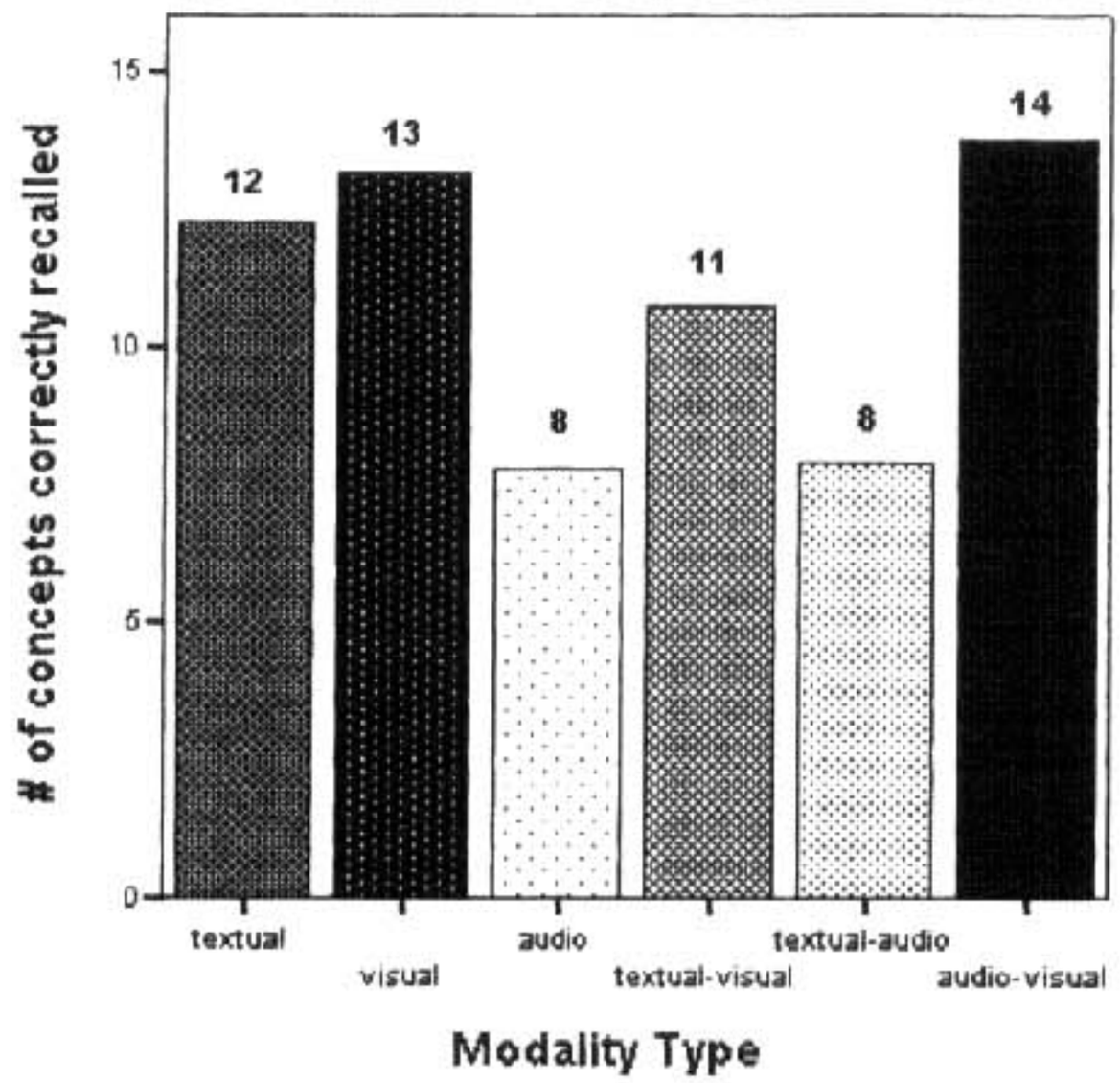

Figure 3. Mean recall score for each recall strategy.

visual modality is not emphasized enough in traditional teaching approaches (Westman, 1990). Therefore, given the context of this study, it is concluded that instructional material should focus on presenting material to students using both the visual and combined audio-visual modalities instead of many traditional approaches that concentrate on audio-textual presentation.

Additionally, learning strategies emphasizing elaborative skills should be related to students. As noted above, the increasing use of computers within classrooms and the relative ease of use of many modern multimedia authoring programs will allow instructors to more easily incorporate visual learning within the classroom. Encouraging such skills would be potentially valuable with a number of different populations and age groups.

This study found significant differences in recall ability related to participants encoding strategy use. Specifically, rehearsal/repetition strategies were related to poorer recall performance. This result is especially important given previous research findings that suggest it may be possible to instruct individuals on the use of elaborative encoding strategies (Straub & Granaas, 1992; Bethene-Ervin and Smicklas-Wright, 1998).

Future research should address the role computers and multimedia presentation can play in the classrooms. Different individuals are very likely to use different encoding strategies even when exposed to the same presentation modality. Therefore, future research could also examine whether there is a relationship between presentation modality used and encoding strategy, and how this relationship contributes to recall. In addition, further research into the effectiveness of instruction of specific encoding strategies is also warranted. Further exploration of bimodal versus unimodal presentations and their impact on recall in other learning contexts is also warranted.

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International Psychology Reporter

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A MESSAGE FROM THE PRESIDENT

The Society for International Psychology, The International Psychology Summit, Honoring New Fellows, Division Awards, and other Division 52 Goodies

Frank Farley, PhD
Division 52 President, Former APA President

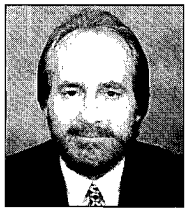

In my President's column in the last issue of the International Psychology Reporter I outlined the idea of Div. 52 as a conceptual division, a creator and mover of ideas about international psychology, providing inspiration and leadership for this expanding field. I railed against the notion of Div. 52 being just another APA division, embroiled in APA politics, consumed by committee busywork, doing its work with a short horizon. I argued for the seeking of common ground across the vast archipelago of specialties, sub-disciplines, and international variations we have in psychology. Our Division is new and unfettered by the past with a reason d'être set in the increasing inter-connectedness of nations and globalization of contemporary life. We are the freshest face in international psychology and opportunities abound for us to take initiative in building the kind of global discipline of psychology that many have dreamed of. That global discipline hasn't been achieved yet, and there is much work to be done. To this end, I have proposed the convening of an International Psychology Summit that would bring together leaders from the major international psychology associations to begin the discussion of placing psychology more firmly in an international framework, and outlining what professional structures and efforts (e.g. coordinating structure, educational efforts) will be needed. The idea is to plan for a Summit in 2001 or 2002 under the primary imprimatur of Division 52, but perhaps with co-sponsorship of some or all of the other major extant international organizations who would hopefully be participating (e.g. International Union of Psychological Sciences, International Association of Applied Psychology, International Council of Psychologists, etc.). At the February, 2000, meeting of the Division 52 Board of Directors, this idea of an International Psychology Summit was approved. Clearly, many details need to be worked out and I solicit your suggestions and input. My address is below.

Another major development at that February Board meeting was the approval of my proposal to change the name of Division 52 to the "Society for International Psychology - A Division of the American Psychological Association." There are still some steps to go through with this name change. If accomplished, such a name will give us a stronger identity in the international arena, being more than simply a sub-unit of a much larger entity (i.e., APA). It will also enhance our distinctiveness inside APA and among the 50+ other divisions. Please stay tuned on the fate of the name change!

At the February Board meeting noted above we took a dramatic step in the election of Division members to Fellow status. The Board voted almost 40 Division members to Fellow status in the Division! These were already Fellows of APA who were distinguished international psychologists. This recognition is a very important part of our division activities, and recognizes these highly accomplished members.

Concerning recognition of distinguished members, we also at the February Board meeting extended our award categories, so that the Division now has the following awards: Lifetime Achievement in International Psychology Award; Distinguished Contributions to International Psychology Award; Certificate of Recognition for Outstanding Service to the Division; Presidential Citations; and Past-Presidents Recognition Award.

I hope you will join in the exciting ventures of Division 52 or propose important things we should be doing. I hope you will attend our outstanding program (thank you Richard Velayo!) in Washington next August at the APA Convention, and come not only to our substantive sessions but to the Business Meeting, and the Social Hour. We need the widest possible support and input as the Division continues to forge a future. Please give some thought to becoming active in the life of Division 52. My address is: 213 Ritter Addition, Temple University, Philadelphia, PA 19122. Phone (215) 204-6024. FAX (215) 204-6013. Email: ffarley@astro.temple.edu ■

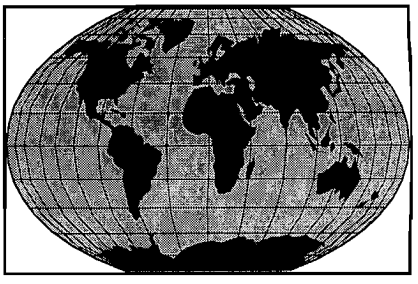

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LETTERS TO EDITOR

Dear Dr. Kos:

My name is Margaret Hogan. Currently, I am a senior at Philadelphia University. I am researching the state of psychology in Nigeria. Unfortunately, I am experiencing a great deal of difficulty finding information about this topic. I was hoping you could provide me with some help or refer me to someone who could help. My e-mail address is: hogan3@philau.edu. My home address is:302 Church Road, Jenkintown, PA 19046

I would truly appreciate any information that you or Division 52 members could supply me. Thank you for your time.

Sincerely,

Margaret Hogan

To Whom it May Concern:

I am researching doctoral programs in psychology with a focus on cross - cultural issues. Do you or anyother Division 52 member have a resource list of schools who have this type of focus. I already have a MA in International & Intercultural Managment.

Thank you for your assistance.

Diana F. Petrakos
dpetra@sover.net

ANNOUNCEMENT

Middle Eastern Psychological Association

Dr. S. Muhammad M. Jalali-Tehrani

It is with great pleasure that we announce the formation of the Middle Eastern Psychological Association. This association is currently in its initial phases and is accepting applications for charter members of the organization. Division 52 (International) of the American Psychological Association, is advising and supporting us through these formative stages.

The purpose of the organization is currently understood to include the following: 1. Increasing communication among psychologists in the region; 2. Developing a body of ongoing research and discourse, to be expressed in a professional journal, pertinent to psychological issues in this unique cultural, religious, and regional background; 3. Developing standards of education and practice which would give credibility to psychologists in the area and increase their status and standing internationally; 4. Provide continuing education for individuals who already hold degrees in psychology to help improve skills and knowledge; to support and develop education in psychology departments in the area through accessing material and expertise worldwide.

It is our purpose to form an organization which will INCLUDE rather than EXCLUDE psychologists who are currently practicing and teaching in the region. We seek to support, enrich, and build the practice and teaching of psychology

(Continued on page 3)

International Psychology Reporter
APA Division 52 Newsletter

Volume 4, No.1 Spring 2000

Ivan Kos, PhD	Editor
Robert R. Clark, PhD	Assistant Editor
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Eric C. Theiner, PhD	Assistant Editor
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ARTICLE SUBMISSION: For smaller articles (op-ed, comments, sugestions, etc.) submit up to 200 words by fax or e-mail. Longer articles (Division reports, academic articles, etc.) can run up to 1500 words and should be submitted on diskette, 3.5", IBM formatted. Time limitation in production requires all material to be submitted electronically.

Submit all materials to: Ivan Kos, PhD, Editor, International Psychotherapy Associates, 625 Main Street, suite 625, New York, NY 10044, Fax: 212-486-0174, E-mail: IKosIpa@aol.com

Submission deadlines for:
Spring issue -February 30, 2000
Summer issue - May 30, 2000
Fall/Winter issue - October 30, 2000

International Psychology Reporter is the publication of Division 52 of the American Psychological Association

◆ NEWS FROM DIVISION 52 ◆

HERE AND THERE

Irene Deitch, PhD

HAPPY NEW CENTURY - HAPPY YEAR OF THE DRAGON!!!!

THIS COLUMN IS WRITTEN FOR AND ABOUT OUR MEMBERSHIP AND GLOBAL FAMILY AND FRIENDS. IF YOU HAVE INFORMATION WHY NOT SHARE IT WITH US?

KUDOS TO:

DR. FLORENCE DENMARK - HAS CO-AUTHORED (V. RABINOWITZ AND J. SECHZER.) A BASIC TEXT FOR PSYCHOLOGY OF WOMEN & GENDER STUDENTS, ENGENDERING PSYCHOLOGY. SHE WAS DESIGNATED A DISTINGUISHED MEMBER OF PSI CHI, ALONG WITH **DRS. RAY FOWLER AND ALBERT BANDURA. DR. DENMARK** WILL BE LISTED WITH A BIOGRAPHICAL SKETCH, IN THE FORTHCOMING, NCYCLOPEDIA OF PSYCHOLOGY, EDITED BY DR. R. CORSINI

DR. HENRY DAVID - DIVISION 52, MEMBER-AT-LARGE, IS ORGANIZER OF PANEL ON, "REPRODUCTIVE BEHAVIOR RIGHTS AND RESPONSIBLE PARENTING," ADEN UNIVERSITY, MEDICAL FACULTY, IN HONOR OF 10TH YEAR OF THE YEMEN PSYCHOLOGICAL ASSOCIATION.

DR. HAROLD TAKOOSHIAN - DIVISION 52, CHAIR OF FELLOWS COMMITTEE, IS CANDIDATE FOR PRES-ELECT OF THE EASTERN PSYCHOLOGICAL ASSOCIATION. HE IS ALSO THE OUTGOING PRES. OF PSI CHI.

DR. FLORENCE KASLOW - PRESIDENT OF THE INTERNATIONAL ACADEMY OF FAMILY PSYCHOLOGISTS, WAS RECIPIENT OF THE 2000 APA AWARD FOR DISTINGUISHED CONTRIBUTION TO THE INTERNATIONAL ADVANCEMENT OF PSYCHOLOGY.

DR. DIANE WILLIS - PRESIDENT - ELECT OF APA DIVISION OF PSYCHOTHERAPY, WILL OFFER "INTERNATIONAL YEAR OF THE CHILD" AS HER PRESIDENTIAL THEME.

DR. TONI ANTINUCCI - PRESIDENT OF DIVISION OF ADULT DEVELOPMENT AND AGING, WILL WORK COLLABORATIVELY WITH US. "GLOBAL AGING ISSUES."

DR. DOROTHY LITWIN - DIVISION 52 MEMBERSHIP CHAIR, IS RESEARCHER FOR THE COMMITTEE ON AGING RECENTLY CO-AUTHORED FOR APA, "OLDER WOMEN PSYCHOLOGISTS."

DRS. FRAN CULBERTSON & DR. IRENE DEITCH WERE ELECTED TO SERVE ON APA'S MEMBERSHIP COMMITTEE.

DR. ANTHONY MARSELLA IS CHAIR OF APA'S COMMITTEE ON INTERNATIONAL RELATIONS IN PSYCHOLOGY.

DR. FRANK FARLEY IS PRESIDENT OF THE INTERNATIONAL COUNCIL OF PSYCHOLOGISTS. HE IS REGULARLY INTERVIEWED IN THE MEDIA.

DR. FRED LEONG - ELECTED TO FELLOW, WAS ALSO ELECTED TO SERVE ON APA'S COMMITTEE FOR INTERNATIONAL RELATIONS IN PSYCHOLOGY.

DR. BILL MASTEN - DIVISION 52 SECRETARY AND WEBMASTER, WAS ELECTED EDITOR OF THE NEWLY-FORMED INTERNATIONAL JOURNAL OF SCHOOL PSYCHOLOGY AND SPECIAL EDUCATION.

DR. RICHARD VELAYO - DIVISION 52 PROGRAM CHAIR, ON HIS TENURE AND PROMOTION TO ASSOCIATE PROFESSORSHIP, AT PACE UNIVERSITY IN NEW YORK CITY. HE IS CURRENTLY SERVING AS PRESIDENT OF THE ACADEMIC DIVISION OF THE NEW YORK STATE PSYCHOLOGICAL ASSOCIATION.

DR. LENORE WALKER - DIVISION 52 TREASURER, IS PRESIDENT ELECT OF DIVISION 46 (MEDIA PSYCHOLOGY), AND CANDIDATE FOR PRESIDENT OF DIVISION 42 (INDEPENDENT PRACTICE), SHE HAS ESTABLISHED 13 AFFILIATE CENTERS - (GLOBALLY) OF DOMESTIC VIOLENCE INSTITUTE.

DR. IRENE DEITCH - COLUMN EDITOR, CANDIDATE FOR DELEGATE-AT-LARGE, INTERNATIONAL COUNCIL OF PSYCHOLOGISTS. SHE IS ALSO VICE-PRESIDENT FOR PRACTICE FOR APA'S DIVISION OF FAMILY PSYCHOLOGY, AND MEMBER-AT-LARGE FOR APA'S DIVISION OF PSYCHOTHERAPY. ■

(Announcment cont. from page 2)

through strengthening existing programs and practitioners.

As a first step in this process, we are circulating questionnaires among universities and health services in the region to assess:

a. The level of education, areas of specialty, and experience of psychologists currently practicing and teaching in the area.

b. The types of psychology degrees currently being offered in the facility, a description of the course offerings and requirements related to these degrees; we also ask for a listing of psychology courses offered in those colleges and universities which do not offer psychology as a degree major.

c. The needs of psychology departments and clinics: especially what types of support the association could offer--developing a program, finding qualified teaching or clinical staff, increasing skills in your current personnel, accessing electronic sources of knowledge, continuing education, internet sites and clearinghouses, journals.

To join the steering committee, serve in an advisory capacity, become a charter member, or simply find out more about this important and timely organization please email: tehrani@emamreza.net or post a notice on our bulletin board http://www.casualforums.com/globe/Middle_East_Psych_Assoc ■

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Continues

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44 West 300 South, # 607
Salt Lake City, UT 84101

Division 52 Council of Representatives' Report

February 24 - 27, 2000, Capitol Hilton, Washington, D.C.

Frances M. Culbertson PhD, ABPP

The Council of Representatives meeting was called to order by Dr. Pat DeLeon, incoming president of the American Psychological Association. He received an enthusiastic welcome.

The opening half-day of the meeting was devoted to Technology and Psychology. A presentation was made to members of Council on the trends in technology, especially electronic communication, that will be relevant for us as an organization. Council members then broke into small groups, geared to discussing and coming up with recommendations or topics to be considered in the future Council meetings, in the areas of education, research, public interest issues, and practice. Discussion outcomes were reported and at a later date, they will be collated and distributed to Council members for their considerations.

One of the most significant actions of this Council was to create a 501(c) (6) organization, which is a companion organization to our Section 501 (c) (3), in order to engage in activities that will not be limited in the amount of lobbying it can undertake, nor in the ability to address professional issues. Having this companion organization will enable the combined organizations to have substantially more ability to meet future challenges without subjecting APA to the future risk of being out of compliance with applicable laws. The companion organization will not change the fundamental purpose or nature of APA. The Executive Director of the Practice Directorate
will also be the Executive Director of the companion organization. APA dues cannot be used to fund the compnanion organization. However, the existing mechanism of the special assessment of APA's licensed healthcare practitioners can be used to fund the new organization. It is to be noted that the creation of this organization will not change the fundamental purpose or nature of APA. The Committee for the Advancement of Practice (CAPP) will still govern the area of the Practice Directorate advocacy activities that will be moved into the companion organization. The APA borad will regularly report to the APA Council of Representatives on the activiites, decsiosions, etc., of the companion organization. Council will be free to advise the Board on any matter that it deems necessary. The new organization will at present directly benefit the practice community through its advocacy work but other APA's constituencies will possibly benefit as well. There is no limit on the number of companion organizations that could be created in the future to address other member constituencies. If you desire further information, please contact Theresa McGregor, Legal Assistant, American Psychological Association, email: tmcgregor@apa.org

Council discussed and returned to the Policy and Planning Board, its report on possible reorganizational changes of APA Boards and Committee, as there was some resistance to deactivating committees. The recommendations from the board were to, at this time, deactivate all continuing committees reporting to standing boards, and allow Council to allocate an annual budget for each standing board to fund its projects and goals. In essence, this would allow boards to reconsider their committee structure, possibly continuing current committees, possibly changing them. This reorganization would be important for Division 52 as CIRP would be one of the committees affected by this ruling.

Other Actions: APA approved "Guidelines for psychotherapy with lesbian, gay and bi-sexual clients." These are not mandatory standards but were designed to provide the highest levels of psychotherapy practice. Also, funding was continued for the Five Year Plan on the Commission on Ethnic Minority Recruitment, Retention anmd Training in Psychology.

Council approved a final meeting for the Test User Qualifications Task Force for completion of the final report on "Test User Qualifications."

Reauthorization of the Annual Division Leadership Conference was approved.

A new division, The American Society for the Advancemnet of Pharmacotherapy was approved.

The opportunity for APA to invest in the purchase of a warehouse building appears to be no longer viable.

Report on membership continues to be rather dismal: growth is slow; retention of new members is down; aging membership is increasing; divisional membership is down, but the bright note is the APAGS organization which is vibrant and active.

A final bright note: Division 31, (state organizations), provided flags at the desks of its state members, adding to the color of the Council meeting. ■

Division 52 International Committee for Women

Joy K. Rice, PhD, Chair

The International Committee for Women has organized a symposium for APA entitled, "Internationalizing the Psychology of Women: Avoiding Neo-Colonialism," and it will be on Friday, August 4, 2000 at 11AM. We would like to invite the attendance of all Division 52 members and interested people. The participants in the symposium are:

Dr. Mary Ballou, Chair and opening remarks

Dr. Joan Chrisler, "Internationalizing the Psychology of Women's Health"

Dr. Joy Rice, "Feminist Therapy, A Western Phenomenon?"

Dr. Lynn Collins, "The Study and Treatment of Women Addicts from an International Perspective"

Dr. Donna Goetz, " The Study of Women's Spirituality Internationally"

Dr. Janet Sigal, "Methodological Issues in Cross-cultural Research"

Dr. Florence Denmark and Dr. Hyun Sub Yun, Discussants

The Committee for Women has also taken on an international advocacy project pertaining to Fatima Jinnah Women University in Pakistan. We are working with Dr. Najma Najam who is a member of Division 52 and Vice Chancellor of Women University. The University is only a year old and has gone from 350 students to 1200 students in one year. They would be grateful for support in any form; book donations, endowment contributions, research collaborations, visiting scholars or publicity about the new university are all welcomed. Please contact Joan Chrisler <jcchr@conncoll.edu> if you would like to help and join our effort. Members of the Committee on Women are also working on a position paper and beginning some collaborative research together. ICFW will meet again at APA and we welcome new members; contact Joy Rice jkrice@facstaff.wisc.edu

COMMITTEE FOR WOMEN OF DIV. 52
Annual Report

A dozen members of The Committee for Women of Divison 52, International Psychology, had two productive meetings at APA in Boston. The results of our meetings follow.

1. NAME. The name of Committee shall be Committee for Women, Division of

(Continued on page 5)

(Continued from page 4)
International Psychology (CFW). CFW will be a Standing Committee of Division 52.

2. COMMUNICATION. We will update our members through annual meetings at APA, announcements in the 52 newsletter, information on the 52 website and through liaisons with many other divisions and organizations. Currently we have 10 liaisons who will publicize CFW activities, recruit membership and promote cooperative efforts in their division newsletters or other venues. We also plan to publish addresses for other list servs of international organizations with women's concerns in our newsletter.

3. DIVISIONAL VOICE. CFW will become an active voice for women with the Division through newsletter announcements, meetings, APA symposia, and the development and dissemination of a position statement. Members of CFW have submitted a symposium proposal for APA 2000.

4. COLLABORATIVE RESEARCH. The first project of CFW will be a book proposed by Irene Frieze. It is conceived as a supplemental diversity text in women's studies classes about the lives of young women in different cultures. Several CFW members will contribute chapters and we are looking for more participants. We will also attempt to summarize new research by CFW members in the newsletter.

5. ADVOCACY. CFW members are working collaboratively with members of the Beijing Platform Follow-up Committee from Division 46 and PsySR.

We welcome new membership and the participation of students and professionals from related disciplines around the world. ■

Preliminary Report of the Division 52 Program Committee

Chair: Richard Velayo, PhD
Co-chair: Frank Farley, PhD

1. The Division received 110 proposal submissions for APA 200 annual program. The submissions were from six continents, 27 countries, and consisted of a variety of session types - symposia, conversation hours, a workshop, papers, posters, addresses, and even a show. It is clear that the division has been successful in generating enough interest for its annual convention.

2. The deadlines were even tighter this year compared to last year's. All submissions must have been received by November 15, 1999. The program chair and co-chair, in consultation with Past President Denmark, decided to have a number of proposal submissions accepted without going through the formal review process. The vast majority of the submissions were sent to a Review Committee that consisted of six reviewers. The Committee wanted to accommodate all completed proposal submissions. In order to accommodate this goal, two poster sessions (with an APA imposed limit of 40 each) were planned and dozens of submitters were asked to consider accepting a spot on the program in a poster session. All but one author who submitted two proposals agreed. Hence, the Committee was able to include a total of 18 symposia, 2 paper sessions (consisting of four papers each), 2 conversation hours, 2 poster sessions, 1 workshop, 1 Comedy Jam, 1 Social Hour and Show, as well as the Presidential Address, the Invited Presidential Dialogue, the Business Meeting, and the Executive Board Meeting. In all, 108 submissions were accepted, with most (77) in the poster sessions.

3. Division 52 was allotted 24 hours for programming, the lowest number available. Invited addresses (in our case, this refers to the Presidential Address and the Invited Presidential Dialogue) are not counted in this total, nor are executive committee meetings scheduled on the Thursday before the official beginning of the Convention. The division also has the option of using non-transferable 8am hours. (Division 52 was allowed a maximum of four 8am hours.) The Program Committee took advantage of all the available options and scheduled a program of 31 hours including the Thursday Board Meeting. This year the divisions were told by the APA Convention Planning Office on what days they could schedule regular programs and for how many hours. Division 52 was not allowed to schedule any programs on Tuesday, August 8.

4. As with last year, Bill Masten graciously arranged for programs to be submitted online. This seems convenient for many of the international submissions. In practice, however, the process remained cumbersome. Although submitters could be notified immediately that their submissions were received - an important advantage -- the submissions needed to be printed out and at times having to make additional copies for review. In some cases, vital information was missing. In a few cases, submitters sent multiple copies of the same paper. Online submissions to the division may require some fine tuning, perhaps making instructions more clear and insisting that they be followed by submitters.

5. All programs had to be submitted to APA's online database. This year the process was not as cumbersome because of design features implemented in entering program information in the database. The APA Convention office included last year's database so that if a presenter was involved in last year's convention and there was no change in their biographical information, one would not have to enter the entire information about that person in the database. Three graduate students and the Program Chair were involved in data-entry. Inputting time alone took somewhere between 25 and 30 hours (probably closer to the latter). APA also made use of a listserve for all program chairs which was very helpful when it came time to co-listing programs.

6. The program submissions came from all branches of psychology. Similar to last year, many of the U.S. submissions had an international theme but a number of the submissions from other countries could easily have been sent to other divisions. Presumably, they were submitted to Div. 52 simply because of their international origination. Poster sessions can accommodate this variety in submission fairly easily although the authors may not be reaching the best audience. The division may want to give further thought to the types of programs it wishes to accept for the Convention. The division may wish to limit its submissions to those genuinely focusing on international or cross-national issues. ■

Announcement for Psychology International Call for Papers

The Journal of Clinical Psychology in Medical Settings will devote a forthcoming special issue to the topic of "Medical Psychology around the World." Dr. Danny Wedding will serve as guest editor for this special issue, and he is currently soliciting manuscripts from international psychologists working in medical schools and other medical settings.

All authors will be asked to follow a detailed, structured outline, and they must be able to submit the final draft of their manuscript no later than July 1, 2000. A model paper describing the state of medical psychology in Thailand will be available for review and guidance.

Questions and nominations of potential authors should be sent (via email if possible) to:

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◆ NATIONAL NEWS ◆

US Psychologists Partner with Rotary to Assist Mentally Ill in Jamaica

Jack G. Wiggins, PhD
Former APA President

Dr. Donald Moss, psychologist in Grand Haven, MI and a Michigan Rotarian has established a pilot psychosocial training program to diagnose, treat and rehabilitate the mentally ill in Trelawny and St. James Parishes in Jamaica. This project will begin on January 17, 2000 by training "primary care health workers in the identification, understanding, and treatment of mental illness as medical conditions, requiring pharmacological and psychosocial rehabilitation."

This pilot program is an extension of the Trelawny Outreach Project (TOP) which began in 1991 as a humanitarian effort to provide general medical care supported by Rotary Clubs in Rotary District 6290 (MI and ONT) and Rotary Clubs of Montego Bay and Montego Bay East. Dental care was added in 1995 and eye care in 1996. In 1998 the project was broadened to address educational and community needs for mental health care following site visits by Dr. Moss and other Rotarians.

Dr. Martin Gittelman, a psychologist who is Executive Secretary of Mental Health Workers Without Borders (MHWWB), located in New York City was contacted. He has agreed to oversee the training using his highly successful community-based rehabilitation model which combines psychosocial training with conventional antipsychotic medications.

In coordinating this project with Jamaican Health Authorities and Montego Bay area officials, Dr. Moss enlisted the aid of Dr. Darell Schregardus, of Holland Michigan, a clinical and community psychologist, with expertise in community support for mental health projects, to assist in the February 1999 site visit. Dr. Schregardus will join Drs.Moss, Gittelman and myself to comprise the mental health training team for TOP. The week long training will provide the community and family based specialized psychosocial rehabilitation training for the 25-30 most senior mental health workers in the area. These professional resources include: Family Nurse Practitioners, Mental Health Officers, Medical Officers, Psychologists, Psychiatric Unit Personnel, Pastors and other community leaders.

Dr. Gittelman and the MHWWB have established other community based psychosocial treatment programs around the world. China and the Philippine Islands each have several therapeutic community sites. Pakistan has a treatment center and an outreach program in Lahore operated by psychologists there. Plans are underway to establish similar programs in Africa and South America. The Jamaica project is the first joint Rotarian-MHWWB project in this hemisphere.

The success of these MHWWB community-based programs comes from educating the family and the community in how to deal with the mentally ill. One of the cardinal features of the training is how to keep the individual functioning at meaningful work in the community. To achieve maintenance at work and other socially related goals of independence, self-management, family and community support are provided when the individual is unable to maintain his/her usual level of functioning. Conventional neuroleptic medications, such as chlorpromazine, are used to maintain the person in the community. Community and family expectations of the individual are modified to allow for both the periods of reduced functioning and return to performance standards for that person.

Dr. Gittelman reports MHWWB outcome research data shows a 25%-50% reduction in relapse rates by using the combined psychosocial rehabilitation and medication over using conventional antipsychotic medications alone. The results of this combination model compares favorably with the relapse rates for the newer atypical antipsychotic medications. These findings are consistent with recent studies reporting a 50% increase in effectiveness in the treatment of depression using a combined psychotherapy-psychopharmacology treatment over monotherapy of using antidepressants alone. Similar findings have also been reported in the rehabilitation of ADHD when the family is involved in the treatment process over using methylphenidate as the sole intervention. Outcome evaluation of the TOP mental health program is built into the Jamaica community based training.

The Jamaica mental health project is especially timely in view of their depressed economy. The Kingston, Jamaica Gleaner wrote on February 24,1999, that a confidential study carried out for the Jamaican government recommended draconian reductions in health care spending amounting to $1.7 Billion in Jamaican dollars. Also in February 1999, the Public Health Service announced its "de-institutionization" plan to release 500 patients from Belleview Hospital in Kingston, its largest mental hospital. In this economic climate funds for the additional personnel to support the re-integration of these patients back into their families and the communities. The Western Regional Public Health system, under the leadership of Alex Kostantinov, M.D. and Wendell, Psychiatric Director of the Western Region, has committed to cooperate with the Rotary TOP mental health project.

Jamaica, like the rest of the world has an identified base of mentally ill who are stigmatized and denied employment. They are often pushed out of their families as troublesome non-contributors and then abandoned by their communities. In many cases they end up abusing drugs, homeless, and begging in the streets of larger cities of Kingston and Montego Bay. Periodic police roundups of the mentally ill that detract from "tourism" income attempt to relocate these people back into their communities. WHO statistics indicate a population prevalence of 0.50% for Schizophrenia, 1.17% Major Depression, 0.60% Bipolar Disorder, 1.15% Post-Traumatic Stress Disorder, 1.02% Obsessive-Compulsive Disorder and 2.70% Generalized Anxiety Disorder. Although Anxiety Disorders are 5 times more prevalent than Schizophrenia, Schizophrenia consumes a disproportionate amount of economic and community resources. Diagnosis, treatment and management of Schizophrenia can cost up to 25% of the mental health budget plus uncalculated amounts of community resources.

The TOP pilot program will initially focus on 100 seriously mentally ill (SMI) individuals. With the training provided to families with SMI members and mental health workers, it is hoped this number can be expanded exponentially over a 3 to 5 year period when we will be measuring outcomes. One of the positive aspects of these MHWWB demonstration programs is they tend to be self-maintaining since to cost of the low dosages of medication is only about 10 cents a day. It is affordable to the poor with minimal public assistance since their is no black market for these medications.

The December 1999 US Surgeon

(Continued on page 8)

Psychology Must Be "There"

Stanley Moldawsky, PhD

There Is Changing

There are many developments swirling around us as we go about the business of being professional psychologists. But, let us think: Where we want to be and how to get there?

Long Term Therapy

There are attempts by managed care to force us into a short term model of treatment that never allows for any intensity in the relationship in fact, it has taken the relationship out of therapy. But this is an important part of who we are and we should never give it up. As business interests attempt to change the way we practice, we must not succumb. We must be there to protect our patients and our profession. Long term therapy has been shown to be effective and has been shown to be better than short term therapy. The Consumer Reports research documents this as well as other research. However, more research is necessary and we must be there to encourage its use. We must resist falling into the managed care trap and continue to work in a way that makes the utmost use of ourselves as the instrument of change. We must be there and protect the relationship in therapy from being marginalized by managed care. In our training programs we must continue to teach long term therapy methods as well as short term methods. People will demand our expertise as they find the band aid approaches don't work.

Where Is "There"?

Telehealth: Modern communication in the electronic age has revolutionized the providing of professional help. The internet is being used to diagnose, refer, consult, treat, and Telehealth has erupted in our midst. Psychology must be there as we explore this new medium. Our expertise is very much needed and we must adapt. Rural folks can sometimes get to a computer sooner than they can get to a city and a psychologists. There is room for us to become consultants using this medium. We can call on experts who will listen to the overt signs of a person's pain and distress and be able to make some preliminary recommendations before actually seeing the person. There is a natural resistance to changing the way we do things. In spite of the fact that people are becoming used to responding on the internet, we are hard pressed to see it as a medium for use with our patients. But we are in the "internet age" and we need to position ourselves to be fully there. Some psychologists are already experts in dealing with long distance patients.

There are many cautions to be noted. We are in a gray area in regard to the ethics and legalities but we must be there to help resolve the ethical dilemmas posed by the new ways of working. We can't sit in our offices and let the other professions tell us how to be. We must be there and fashion our own destinies while providing psychological services in this new medium.

Prescription privileges: Prescription privileges has become a rapidly evolving movement and psychologists must be there to prepare themselves academically and professionally. We must create the legal avenues to lead us into the new millennium. As the APA has moved into a stronger position of support for the movement, a national examination has been created by the College of Professional Psychology. APA awarded $200,000 towards the building of this national exam and set up APA guidelines which set out a model curriculum for training in this modality. Psychologists are getting the training in many places and if they meet criteria spelled out in the APA guidelines they will be eligible to take examination. Meanwhile, many states are planing legislation to obtain the privilege and Guam is the first place that actually has a law permitting qualified psychologists to prescribe. The ten psychologist, graduates of the Department of Defense Program in Psychopharmacology, have been very busy touring the country demonstrating their knowledge and encouraging others to get the training if they are interested. We must be there to see that the training is respectable and do the political work to help the states enact enabling legislation. CAPP has an ambitious program of furthering all these efforts and APA Council of Representatives has given its support by financing site visits of trained psychologist prescribers.

Interdisciplinary collaboration: The role of psychology in serious mental illness as well as in heart disease, cancer, immune system diseases is becoming more and more recognized. We are working with physicians, nurses, and others in the treatment and diagnosis of those diseases. Psychologists are publishing books on the methods of working with cancer patients to help them deal with devastating effects of serious illness. Response to treatment has been clearly shown to be influenced by psychological factors. These are not just "feel good" reactions to enhance health. Being willing to listen (this is one of the things we do best) and allow for feelings to emerge (we're good here too) is conductive to more rapid recovery from serious illness. But this area of collaboration is relatively new and deserves our fullest attention. It calls for capacity to be truly able to engage in group process and join a professional "family" and give up some autonomy. It calls for willingness on the part of the other professionals to do the same. We are entering a field that is crying out for our participation and expertise. Psychology must be there as the area expands.

How to get "there"?

Advocacy: In all of the above mentioned areas advocacy is implied. In order to work towards inclusion in Telehealth, psychologists will have to be advocates. Laws will have to be written covering the ethics, the standards of care, what is and what is not acceptable. Psychology must be there in the world of advocacy. Nothing happens unless we make it happen. We must be there, politically sophisticated, on the cutting edge, and not behind the curve. We must be in the halls of Congress educating our legislators to the new developments and not be in the wings waiting. Regarding prescription privileges, we must be advocates and politically vigilant. No one is going to give us anything. "Who gave you the black eye?" asked one fellow of another. "No one gave it to me. I had to fight for it." State associations are the key in this regard. They will be working with the Practice Directorate to strategize about obtaining enabling legislation and political action in necessary. As so often happens only a few psychologists work in the political trenches. We will have to become advocates of ourselves and bring more troops into the political world to accomplish these goals.

Education: Our educational

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General's report has called public attention to the widespread problem of untreated mental illness in the United States. The same problem exists worldwide. Mental illness is a universal scourge in all human communities. "Mental illness accounts for a significant proportion of disability due to disease and imposes a heavy burden in terms of human suffering, stigmatization of the mentally ill and their families, and direct and indirect costs. ..." (World Health Organization Fact Sheet N 130, August 1996) Perhaps the heaviest burden of mental illness is in underdeveloped countries or areas with large rural populations or in the poor inter-city. In nations without an effective public mental health program, the MHWWB psychosocial therapeutic family-community model can be of significant value. The same model was introduced into Chaina is currently being used more extensively in China today. It also offers a significant opportunity for psychologists in those countries to apply their expertise in rehabilitating those with mental conditions. It many of these countries medications, including neuroleptics, antidepressants and anti-anxiety drugs, can be purchased "over-the-counter", without a prescription. Also herbal medicaments with demonstrated effectiveness, such as St. John's Wort, are readily available and affordable.

Dr. Alan Hopewell in private communications has called to my attention to the lack of mental health services along our Mexican border from McAllen to El Paso Texas. Although there are more psychological services on the US side there are in effect "mental health ghettos" on the South side even though psychotropic medications can be purchased without prescription in Mexico. Correspondents in Argentina and Brazil also lament the lack of mental health services in the rural areas of their nations. Dr. Stephen Touyz of the University of Sydney has expressed a need for a MHWWB type program in "the outback" of Australia. South Africa has authorized psychologists with approved training to prescribe. Implementation of this effort to meet public mental health needs has been hampered by delaying tactics of the South African psychiatric interests.

As we enter the new millennium, we are aware of the new economy and a global economy. Psychology is part of this new economy and hopefully will have a positive influence upon it. The 1950-1975 period has been described as the era of public policy to increase public access to health care. It resulted in what some have described as the "golden age" of private practice. The corporate downsizing of the last few years and the concomitant deregulation of health care by "managed care" has resulted in a new era of the "expansion of scope of practice" by all health professions. Psychology and mental health is actively involved in this evolutionary process of incorporating psychotropic medications in treatment protocols.

The Association for the Advancement of Pharmacotherapy (APAP) has had its petition approved by the APA Board of Directors to form a division, The American Society for the Advancement of Pharmacotherapy (ASAP). This petition will be considered at the February meeting of Council. The APA Commission for the Recognition of Specialties and Proficiencies in Professional Psychology (CRSPPP) has not met yet to consider the Petition for a Proficiency in Psychopharmacology. At least 10 states will have legislation to consider prescriptive authority for appropriately trained psychologists. Nurses, Optometrists, Pharmacists and Physician Assistants are also successfully pressing to expand their scope of practice in prescriptive authority. It latest count, 165,000 of the 2.5 million nurses in the US have some form of prescriptive authority.

Our congratulations to Dr. Moss and Rotary International for putting together this exciting psychosocial training program which supplements the psychotropic medications used as part of TOP. Perhaps it can be a model for psychologists in the rural US, as well as, in other nations to use in the new century before us. ■

◆ INTERNATIONAL NEWS ◆

Cultural and International Issues

Richard M. Suinn, PhD, Former APA President
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International Experiences

Over the years, I have been fortunate to have various international experiences. Previously, I was a visiting faculty in Mexico (Universidad de Veracruz), and on conference programs in Canada and Norway. I spent my sabbatical visiting and giving presentations at various universities in Japan. Recently, I have presented invited addresses in Japan and Portugal, met with psychologists in Venezuela and the Virgin Islands, and arranged our APA Board of Directors retreat meeting to be in Puerto Rico in recognition of our colleagues there. Some of the tests I developed to measure test or mathematics anxiety have been translated nto Chinese, Hebrew, Indonesian, Spanish & Turkish. Some of my articles on behavior therapy have been translated into Spanish, and my manual on sport psychology has been translated into German and Japanese.

It is my observation that other countries have unique strengths in the development or application of psychology in various ways. For instance, I was impressed on a visit to an elementary school in Japan, that autistic children were mainlined into a regular classrooom, so that the other children could help their autistic classmate. In attending the international congress in Venezuela, it appeared to me that community psychology was a strong focus for South American psychologists. In my role as external examiner for the Chinese University of Hong Kong, I have noted their making students aware of cross-cultural concepts. So there is good reason for psychology's progress and development to retain an international perspective.

My Presidential Year

My 1999 presidential year highlighted two initiatives: ethnic minority issues, and cancer. Let me briefly summarize some of the activities regarding ethnic minority and cultural issues.

The year 1999 began my year as APA president, as only the third person of color to be elected. It is noteworthy that this same year also saw five ethnic persons taking office as elected presidents of APA Divisions: Dr. Rosie P. Bingham, an African American, as president of the Division of Counseling Psychology; Dr. Steven James, a Native American, as president of the Psychology of Religion; Dr. Derald Wing Sue, an Asian American, as president of the Society for the Psychological Study of Ethnic Minority Issues; Dr. Siang-Yang Tan

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an Asian American as president of the Society for the Psychological Study of Gay, Lesbian and Bisexual Issues; and Dr. Melba Vasquez, a Latina, as president of the Division of the Psychology of Women. Hence APA leadership with cultural ties was the strongest ever during this year!

In recognition of this unique circumstance, some of these minority Divisional presidents organized the National Multicultural Conference and Summit as the kickoff event in January, 1999 for my own presidential year. This Conference represented a unique gathering of over 500 psychologists and students to discuss state-of-the-art issues in ethnic minority psychology, and societal issues such as ethnocentric monoculturalism, strategies for multicultural organizational change, social justice, and educational reform.

In addition to the election of five persons of color to presidencies of APA Divisions, ethnic minority psychologists have also achieved more visibility in recent years in other ways. Within the last three years, several minority psychologist received awards from APA: in 1997, Samuel Turner was awarded the APA Award for Distinguished Professional Contribution, Maria Root the AP Award for Distinguished Contribution to Psychology in the Public Interest, and Ruby Takanishi the APA Award for Distinguished Contribution to Research in Public Policy. In 1999, the American Psychologist published a number of articles on international topics and ethnic issues. A special issue of the American Psychologist appeared in January with ten articles on the theme of International Perspectives on Domestic Violence. Countries represented included Chile, Greece, Israel, Japan, Latin America, Mexico, Nicaragua, and Russia.

The 1999 Boston APA Convention. For me, the most rewarding event was the year's culmination in the Annual Convention in August, 1999 in Boston. Some of my presidential values involved the principles of inclusiveness, and the celebration of diversity. These were the foundation for my emphasis on celebrating and sharing of cultural experiences at this convention. Although the APA convention is an American experience for American psychologists, our Boston activities made clear that culture exists in the U.S. through ethnic minorities.

Let me describe the Opening Ceremonies held at the convention since it had such an impact on attendees. A primary goal was to share with the audience, significant cultural experiences represented by US ethnic minorities. Hence we opened with an American Indian Purification ceremony, which called blessings on the gathering of psychologists and their families. The four American Indians who participated are all psychologists from a variety of tribes.

Following this were two Hawaiian women chanting the traditional "E Hou Mai" which solemnly requested that wisdom and learning be achieved throughout our convention. This chant was chosen as appropriate to the goals of APA conventions - the sharing of knowledge. This experience was also my way of sharing my Island birth-heritage.

A unique "Ohana" ceremony then followed replete with several meanings. Members of specific cultures declared their commitment through the following words: "I am here as a member of my group; we are called (African-Americans, Asian-Americans, Latino/as, Native-Americans, Euro-Americans, students). We may have gone separate ways but today we come together...I join my voice with your voices, so we become many voices into one!"

The participants in the ceremony were not only from different ethnic groups, but also all were serving APA in official elected positions. In addition to Drs. Bingham, James, Sue, and Vasquez, Dr. Patrick De Leon, president-elect of APA spoke for Euro-Americans and Ms. Marcia Moody - an African-American and president of the APA Graduate Student Association-spoke on behalf of students.

The first intent of this ceremony was to demonstrate the ability of diverse cultural groups to join together in a common recognition of mutual humanity. The second was to recognize that such commonality and mutual joining can exist while still respecting group differences. Finally, the message emblazoned in the sign above the stage, proclaiming "Many Voices into One" offered the statement that psychologists who are diversity in other ways - science versus practice interests, educators versus community interests, applied versus theoretical interests, urban versus rural interests - should all be capable of coming together...at least starting with our convention. The Hawaiian term "Ohana" also had special significance, since in translation it means "Family".

In common with programs at some international congresses, a musical note was provided by the Boston Community Choir, a multiethnic group of gospel singers. This blend of multicultural voices was another way of confirming the ability of peoples to come together, and to be better for it. It was also a fitting prelude to our keynote speaker, the Reverend Jesse Jackson, Jr., who gave a dynamic address on the topics of cancer and ethnicity. The drama of his keynote was increased when he revealed the startling news that he had just buried his brother that morning, a victim of cancer. When he encouraged people in the audience with personal experiences with cancer to stand, and many stood including myself, there were few able to keep tears from flowing at this

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RxP In Argentina

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Compared with the US, psychology in Argentina has a very particular and different beginning, thereby acquiring a special orientation: the profession was founded by pedagogues, philosophers, and psychoanalytic psychiatrist members of the Argentine Psychoanalytic Association (APA). The source of growth led to at least three main consequences: a) psychology developed in the clinical area, mainly applied to health over others orientations; b) clinical care became mainly psychoanalytic in nature, and remains so today; and c) the medical establishment always maintained a more powerful hierarchy over psychologists.

Nevertheless, from 1985 the Psychologist Professional Law has given psychologists an important degree of autonomy. In the meantime, psychology has evolved into a profession respected by the community, with more power and cooperative organization. Regarding RxP, psychoanalytic education, along with medical organizations, act as obstacles, due to their non-biological orientation in Argentina and their opposition to a change in the psychologist's course of study. Notwithstanding these pressures, in Argentina, particularly in the nation's universities, we are working on this theme, by providing information to colleagues and students on the work being carried out by our colleagues from the US, and by incorporating some psychopharmacological issues in the contents of seminars.

We also welcome in our country several courses on psycho-neuro-inmune-endochrinology, where psychologists are accepted and trained on this speciality's concepts. ■

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moving revelation of just how many of us are touched by cancer.

International Health

Another goal of mine has been to further publicize the role psychologists have in primary health care, such as in cardiovascular disease and cancer. Despite the documented proof that psychological interventions are relevant for these diseases, psychologists continue to be underutilized.

Cardiovascular disease

Cardiovascular disease is the first ranked cause of death in several countries, for example, in Argentina, Chile, Cuba, Korea, Singapore, Sri Lanka, Trinidad, Tobago, and Uruguay. Current studies support the premise that anger and stress are relevant factors in increasing the risk of heart disease to such a degree that they might be called the 'toxic twins'. Anxiety or stress has long been identified as a contributor to essential hypertension. There is also evidence that anger can be associated with hypertension and that hostility may be the fundamental risk factor in the Type A behavioral pattern.

The professional psychologist now has available the means for assessing both anxiety and anger levels, and for intervening with such emotional conditions. The Spielberger State-Trait Anxiety Inventory and the Spielberger State-Trait Anger Scale are standardized assessment tools. In addition, interview and behavioral observations can aid in evaluating the dimensions of frequency, intensity and duration of either anxiety or anger states. We have developed a brief intervention program for self-management of anxiety or anger arousal, relying upon relaxation methods to de-activate the arousal. This approach called Anxiety/Anger Management Training (AMT) is a brief 6-8 session training program that has proven useful for both anxiety and anger states. After a heart attack, if psychological interventions are added to standard medical treatment, data suggest that mortality can be reduced by about 41% and morbidity by about 61% compared to the reliance of medical treatment and exercise alone.

Cancer

Cancer has also become an international health issue. Across various countries we find the following occurrences: France 204.7 cases per 100,000, Scotland 200.9/100,000, Netherlands 200.6/100,000, England 181.9/100,000, Hong Kong 181.6/100,000, Germany 181.2/100,000, and Spain 157.9/100,000.

Psychoeducational group programs have now been found to reduce the emotional distress which accompanies cancer, help with the side effects of chemotherapy, aid in controlling pain, and improve the quality of support systems and overall quality of life. The emotional distresses are brought under regulation through the two stage approach of recognizing and confronting the reality of the emotions, followed by identifying ways of keeping them under reasonable control. The nausea of chemotherapy can often be controlled through relaxation, positive imagery, hypnosis techniques. Pain can be regulated through such pain management techniques as attentional control, stress management, and distraction methods. Other psychological issues, such as conflict over self-image or loss of control, are addressed through traditional counseling approaches.

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Concluding Comment

To the degree that U.S. ethnic minority psychologists reflect cultures of certain other countries of origin, my presidential year might be viewed as highlighting internationalism. Ethnic minority issues and ethnic minority psychologists were the focus, or organizing force of conferences, APA leadership, awards, and publications during recent years.

Physical health and recovery from physical disease is a world-wide concern. Cardiovascular disease and cancer are two major health problems affecting the international world. Psychologists have devised approaches that are directly relevant and for which outcomes have been documented through research. It is important that the international community of psychologists continue to be aware of these applications, and share knowledge about their value across different cultures and countries.

FN1 Parts of this article appeared in publications in Professional Psychology: Rsearch and Practice, and in Cultural Diversity and Ethnic Minority Psychology. ■

Gender Equality Flies on Two Wings: Girls and Boys, Women and Men

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International Council of Psychologists

Gender equality is the fundamental principle underlying the 1995 Beijing Declaration and Platform for Action. The UN Division for the Advancement of Women, as part of the 2000 Beijing +5 process, analyzed status reports from 135 of the 189 nations that originally agreed to, and signed the Beijing Platform of Action. Almost without exception, these implementation reports state that the number one obstacle or challenge that prevents gender equality is cultural norms and beliefs regarding gender roles. Examples in the reports range from continued devaluation of women's labor as belonging solely in the home, to the still prevalent belief that women are the responsibility, or even the property of the husband or male relative. These two beliefs continue to keep women ignorant of their rights, and impede the transformation of legal rights into practical reality for women. The beliefs perpetuate long-standing practices and customs prejudicial to women, such as violence, polygamy, forced marriage, son preference, and honor killings. The United Nations, NGOs, and educators are looking to youth to make progress in changing unproductive cultural norms and stereotyped, prejudiced bleiefs.

In March, meetings of the 2000 Commission on the Status of Women (CSW) culminated in a celebration of international Women's Day, which included an international briefing sponsored by the United Nations Department of Public Information (DPI). The DPI briefing focused on the role of girls and boys, women and men working as partners to achieve gender equality. Yakin Erturk, Director of the Division for the Advancement of Women in the UN Department of Economic and Social Affairs, and faculty member at Middle East Technical University in Ankara, Turkey, presented the UN perspective on this partnership. Ms. Erturk addressed the concept of "deconstructing masculinity," which she said had met with strong resistance when she first introduced the subject at the UN. People, mainly women's groups, questioned her preoccupation with men and masculinity, when people still live

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in poverty, and have urgent basic needs that must be met, and when women's situation is still far from satisfactory. She responds to skeptics by pointing out that the very facts of widespread poverty and unmet basic needs make achieving gender equality a top priority, because, in environments of gender inequality, it is women who suffer most from conditions of poverty and unmet needs. She defends the focus on boys and men by pointing out that women are only one side of the equation for gender inequality, and that an answer to gender equality cannot be derived by ignoring the other side of the equation. "Can we establish gender equality if we do not focus on boys and men, and the ways in which current forms of masculinity are constructed?"

One of the gaps for boys in many parts of the world is that they have no place to talk to each other to obtain information about what boys and men should be, other than what they can get from each other, which is often wrong. Ms. Erturk described several men's movements, which are questioning traditional patriarchal masculinity, and exploring the development of alternative masculinities. The United Nations Development Program (UNDP) has an informal group of young men who get together to discuss and question the issues, without advocating a specific model of masculinity. The United Nations Educational, Scientific, and Cultural Organization (UNESCO) has a program devoted to masculinities and a culture of peace. Several Member States have programs on masculinities that address how boys can be socialized in school with regard to gender equality.

Numerous paragraphs of the Beijing Platform for Action stress the role of boys and men as partners with girls and women in achieving gender equality. The education of boys and girls is a centerpiece of that effort. One young man, a delegate to the CSW, relayed an experience he'd had while standing in line to get his photo ID made at the Commission meetings. The women in front of him talked at length about her public school program to empower young women, for which she had been honored by her community. After listening for some time, he finally asked, "Where are the boys while you do this? What are they doing? Who's working with them? Do the boys and girls ever do things together?" He reported that his questions were met with a blank stare, and that she never did respond.

Antigone Karali Dimitriadi, head of the Greek Delegation to the CSW, is President of the Research Center for Gender Equality, which is part of the Greek government. The center conducts research and implements programs to achieve gender equality in the areas of health, labor and education. One of the programs is focused on sensitizing teachers and eliminating gender discrimination, biased beliefs and stereotypical role models in the educational community. Originally designed as a voluntary consciousness-raising training for more than 1,000 teachers in three phases over a long period, the program soon attracted students, parents, anbd other members of the communities involved. The "Teacher Sensitization on Gender Equality" programs have been conducted through five different universities in all regional areas of Greece, for large school systems, as well as small village schools with very few students, where teachers often feel isolated. The goals of the prgrams are to: 1) make teachers conscious of the importance of their personal involvement and behavior, and their role as mentors in promoting gender equality within the educational process; 2) include school counselors and advisors; 3) help students understand gender equality within the context of human rights and values in a democratic society, as citizens and individuals, family and public life; 4) involve parents and the community in the gender equality sensitization process, through parent-teacher or cultural associations, and athletic or recreation clubs; and, 5) expand this program to neighborhood activities.

Ms. Karali Dimitriadi claims a statistically significant difference in reported attitudes and observed behaviors and actions in teachers, students, parents, and communities in many cases. One kindergarten teacher, after her third seminar, reported feeling proud that she was becoming conscious of the way she treated and reacted to the students. One day, preoccupied, she absent-mindedly gave instructions to two students, and suddenly heard herself saying, "Maria, go wipe the blackboard. John, go move the desks." She turned to see Maria and other girls run to the blackboard to use the cloths, and John and other boys pushing around the desks and tables. She was surprised at the unconscious ease with which she had elicited stereotyped behavior from compliant, unquestioning young boys and girls. After the crisis in Kosovo, which is next to Greece, a class of seven and eight-year old students expressed worries about war. The teacher said, "Instead of talking about it, let's draw pictures about what this crisis means to you." All 16 boys drew pictures of war, tanks, guns, and death scenes. Showing off their pictures, the boys announced, "This is war." All 14 girls drew pictures of beautiful women, some dressed in white, olive branch trees, or shining suns. Displaying their pictures, the girls said, "This is peace." The boys laughingly labeled the girls' pictures as "girl stuff." Ms. Karali Dimitriadi told the UN NGO audience that it is not fair to let boys grow up believing that the limited proper channel for expressing their feelings, particularly those of fear and uncertainty, is aggression, force, or violence.

Susanne Tamas, child educator, social worker, and Director of Governmental Relations for the Baha'i Community of Canada, told the assembly that the abandonment of stereotyping and prejudice requires a transformation in patterns of thought, practices and social structures that have prevailed for centuries. In the 1970s, Ms. Tamas and her fellow students in a school of social work were amazed to discover that children in difficulty could not be helped by removing them from their families, and then sticking them back into their families, and expecting things to be automatically better. She believes that any family has to be looked at as a system of relationships between the different parties, and suggests that, therefore, the transformation of girls and women cannot be the sole method when working to achieve gender equality, since girls and women interact regularly with boys and men on individual, family and collective levels.

The most provocative presentation, which drew frequent laughter of appreciation from assembled NGOs, came from Mufti Ziauddin, a human rights lawyer from Pakistan, whose causes include child labor and women's rights issues. He specializes in "going after" perpetrators of honor killings. "Honor killing" refers to a murder, in which the killing of a woman by her husband or male member of her husband's family is justified and goes unquestioned, on the basis of "protecting family honor." The interests, inspiration and motivation that led Mr. Ziauddin to become an advocate for women's rights were born in his experiences while growing up in a middle class Pakistani family, with five sisters, eight brothers, and three generations living in the same home. Early on, he perceived his father to be "head of the depqrtment," or in charge of the home. Mr. Ziauddin described his family relationships as "similar to those between Pakistan and India--always fighting." One of his brothers relentlessly bullied young Mufti because Mufti was small, and his brother more powerful due to his larger size. Unwilling to put up with the relentless bullying, and wanting to get even, Mufti tried to become friends with his father, hoping to gain

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protection. He soon realized that his father was "tribal," and thought that a boy should defend himself.

Young Mufti deliberately changed his perception of the family structure, and began to view and treat his mother as "head of the department." He describes discovering that "becoming the friend of my mother" soon enabled him to give his bullying brother "a very hard time," but not in any way he'd ever envisioned. Whereas Mufti had hoped to gain physical relief by engaging his father to intervene and physically restrain the older brother, he found that his mother provided emotional relief by giving him a lot of attention, the best food, and the best garments. When his brother continued to beat him, he decided to make friends with his five sisters to build up "an emotional army."

He came to believe that "it was better to be the brother of one sister than a brother of two brothers." With his brother, he had to be subordinate. With his sister, he felt elevated and inspired. After studying social work, he became a criminal defense attorney, and witnessed "unbelievable discrimination against women." Guided by the conviction that, "In my home, I was a brother of five sisters; let me now become the brother of 5,000 sisters," he began helping women in jail without charging them. He soon inspired friends to follow in his footsteps, and they founded a human rights organization, even though they couldn't use the words "human rights," "women's rights," or even directly address the condition of women. He said that learning to "do, not talk" served him well.

Mr. Ziauddin's recent reserach on violence against women has been published by UNICEF. In 1997, he saw that, within a seven-month period, 27 women were murdered, 22 of whom were married. Nineteen of the 27 murders were committed in the home, 17 of the 19 committed in the home of in-laws. Fourteen were murdered at the hands of their husbands, three at the hands of the father-in-law, and one by the brother-in-law. Mr. Ziauddin emphasized that the violence as coming from the in-laws, and that the solution was to declare the in-laws "outlaws," referring to the fact that "honor killings," up to that point in time, were never questioned.

Young CSW delegates in the audience reported their own experiences. A young man from Kenya, and representative of an organization called True Love Waits Kenya, said that in Africa, the family is central, and that young people are told that the man and woman, husband and wife, complement each other. He said that men respected women, and that there were songs praising women, motherhood, and cooking. He said, "It's very Africa. It's something so beautiful." A young delegate next to him jumped up, and said, "I'm from Nigeria. I'm an African, too. I know that we believe in, and respect family in our culture. But you should get it right! If a woman chooses to stay at home to be a homemaker and take care of the children, that is beautiful. The CHOICE is beautiful. But if another women wants to do something else, that woman should have the same opportunities as her brother to choose just that!" A young female delegate from the Czech Republic stated that in her country, there was a long tradition of higher and university education for women, and that even before World War II, a capable woman had no problem becoming a doctor or lawyer. After the communist coupe d'etat, the ideology was promoted that there is no difference between a man and woman, and that all women are able and obliged to do the same manual work as men. Some women were even directed to become miners. The actuality was that the hardest, most routine, and worst paid employments were always reserved for women, and all management positions reserved for men.

Susanne Tamas ended the session with a story about her own children, which provided a parting image of inspiration. Sophie, Peter, and their mother (Susanne) were visiting her dad and mom in the grandparents' home by the bay. Sophie and Peter wanted to go out in the rowboat, saying that Grandpa would watch out for them. It wasn't too long after they left that Susanne heard her dad shouting instructions to the children from the shore, and going outside, saw him pacing up and down the shoreline. Susanne went down to see what was happening. She saw that her son Peter, 9 years old and strong, was digging deep with the oar, and pulling it with his full weight. Sophie, only 7, and somewhat smaller and lighter, was doing her best, but couldn't dig as deep, and couldn't pull as hard. And the rowboat was going round and round in a circle. Susanne said to her still shouting father, "Dad, cool down. This is a self-correcting problem. So they sat down on the beach, and watched the two children go round and round.

After awhile, Peter became discouraged, and dropped his oar. Sophie kept right on paddling. Peter later told his mother that he was just sitting there, staring at the shoreline, when he felt the rowboat stop, noticed it start to turn, and then saw it circling, round and round in tbe opposite direction, with Sophie, only Sophie, still rowing. Susanne and her father caught the instant when the two children looked at each other, and realized what was going on. After a long pause, and pacing themselves to each other, they both started rowing. It wasn't long before the mother and grandfather had a new problem. They had to run and get the small motorboat, so they could race out to catch Sophie and Peter as they headed smoothly and quickly out of the bay, and down to the open water.

Susanne sees humanity as possessed of two wings--women and men, girls and boys, female and male. Unless both wings are strong, that bird is not going to get off the ground. If by luck or machination, it finds itself in the air, it's going to fly in circles, not in a directed line...and humankind will not be able to reach the heights to which it is capable. Gender equality flies on two wings. ■

The Role of Freedom in Psychology: A Phenomenon in Need of Conceptualization and Investigation

Juris G. Draguns, PhD
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At the height of the political upheavals of the last decade, Brislin (1993) wrote: "One of the driving forces behind societal changes is the desire for freedom in making choices about one's own life. In recent years, this desire has been part of political movements all over the world as people have expressed their demands for elected governments that will replace traditional and authoritarian ruling bodies. These demands have been seen in the former USSR. republics, South Africa, East Germany before reunification with the West, Nepal, Romania, China, the Philippines, Cuba, and other countries... The desire for freedom is extremely strong, and I believe that we will continue to see its impact in various parts of the world." (p. 369) If so, psychologists so far have not accorded sufficient importance to it conceptually nor have they systematically investigated the role of freedom in human behavior and experience. According to Westcott (1984), three theories have dominated the field: attribution, reactance, and existential. The former two approaches are for the most part relevant to the behavior in specific situations, and the existential approach is focused upon conditions that promote the subjective realization of being and feeling free.

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(Gender Equality cont. from page 12)

What happens, however, when human beings suddenly realize that the external restrictions upon them have been removed? What difference, if any, does such a change make upon the experience of self and environment and upon individual and social action? And is the striving for freedom really as strong and universal as Brislin implies? If so, under what conditions is it manifested in collective behavior, despite danger to life and limb?

Like everybody else, psychologists were caught by surprise by the cataclysmic changes in the former Soviet Union, Easter and Central Europe, South Africa, Indonesia, Nepal, and other countries. Bergquist and Weiss (1994) managed to conduct a number of intensive interviews with articulate and sophisticated informants in Hungary and Estonia shortly after the collapse of Communist rule. Their interviews were focused upon the following three questions: (1) What does freedom mean to you? (2) What does freedom look like for you? (3) What does freedom feel like for you? The concluded that the meaning of freedom involves "being able to (1) acknowledge and grieve for, yet ultimately forgive and free oneself from, the injustices suffered under oppression or tyranny, (2) reclaim projections with which one has endowed leaders and perceived enemies and basic elements of the existing society and culture, and (3) tolerate ambiguity and be courageous enough to make commitments" (pp. 275-276). Bergquist's and Weiss' findings constitute a plausible point of departure for a concerted, multimethod, interdisciplinary program of investigations focused on the experience of freedom, especially in those countries where it has recently been regained. As proposed elsewhere (Draguns, 1996, 1999) such research approaches may include: methods of biographical psychology; multinational comparative investigations on the cultural constancies and variations in the relationship of freedom to other values and objects of experience; procedures rooted in the investigations of subjective culture (Triandis, 1972); studies of personal decision making and intrapsychic conflict resolution; and replications of social psychology experiments relevant to freedom within the attribution and reactance frameworks. Other kinds of observational, correlational, and experimental studies could be added to this provisional and tentative list. As such a program is implemented, it behooves the psychological community to steer clear of the idealization of freedom. To be sure, freedom is a sublime and exhilerating experience for many people, but it may also be, as Fromm (1941) has reminded us, a burden from which many human beings may wish to escape. Freedom then may be the object of an approach-avoidance conflict and may be experienced in an ambivalent manner. Moreover, the Slovenian social psychologist, Pecjak (1990), has proposed some thought provoking formulations concerning the role of individualism-collectivism in mediating the quest for freedom and in determining the way in which freedom is experienced. All of these notions cry out to be tested by a variety of techniques in several countries and regions, prospectively and retrospectively, a task which the membership of this Division is uniquely equipped to undertake.

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(Psychology must cont. from page 7)

institutions will need to train to the cutting edge without giving up our heritage in long term methods. This can be done as long as we maintain respect for the breadth and depth of psychology and not just respond to the latest fads. However, adapting our methods to the new areas such as telehealth, Psychopharmacology, and the seriously ill is a task that is challenging but doable. Continuing education for practicing psychologists where these new techniques can be taught will have to be part of our responsibility.

Public education: APA has developed a remarkably successful public education campaign. With an initial endowment of $1.5 million and $1 million a year earmarked for 5 years, the campaign has changed coordinators in every state who have been putting on programs to educate the public about violence, stress in the workplace, marital distress, children at risk, and so forth. These programs need to continue and be expanded. The MTV "warning signs" program (the collaboration between APA's Practice Directorate and MTV) has been shown in thousands of schools and been part of a nationwide educational effort to deal with the shootings and fear aroused in Americans. Psychology must be there. We don't have the resources to do national TV ads to promote psychology, but we have shown creativity with a limited budget and this should continue.

In closing, psychology is not yet a household word. Give it time. But stay hopeful and optimistic. We will be there. ■

The United Nations Recomendations for Action

Selma G. Sapir, PhD

The International Plan of Action on Aging is the first international instrument on aging, guiding thinking and the formulation of policies and programs on aging. It aims to strengthen the capacities of governments and civil society to deal effectively with the aging populations and to address the developmental potential and dependency needs of older persons. It promotes regional and international cooperation. It includes 62 recommendations for action addressing research, data collection, and analysis, training and education. The recommendations address the following issues based on the above principles: 1) health and nutrition, 2) protection of elderly consumers, 3) housing and environment, 4) family, 5) social welfare, 6) income security and employment, and 7) education.

The plan should be considered in relation to agreed standards and strategies in the areas of human rights, advancement of women, families, population, youth, disabled persons, sustainable development, welfare, heath, housing, income security and employment, and, education. ■

STUDENTS' PAGE

What is EFPSA?

Tanja Kajtna
President, European Federation of Psychology Students' Association

European Federation of Psychology Students' Associations (EFPSA) was established in 1987 in Portugal, at the first international congress of psychology students. Any national or local association of psychology students, which aims are compatible with those of EFPSA, can join the Federation. The highest authority and decision making body of EFPSA is a General Assembly, which is composed of all representatives from full member countries. Each member country has a representative also in the Executive Board, which has the power to administer and represent EFPSA. The Federation meets once a year at the EFPSA congress, and once in October, at the Executive Board meeting.

EFPSA is politically independent, but is willing to support students' movements defending psychology students' interests.

Today, EFPSA has a more than ten years of working behind it, many full member countries all over Europe and we are still doing our best to achieve the aims of EFPSA, which are:

-to promote exchanges of social and ethical ideas among European psychology students in connection to their profession

-to improve the educational conditions for psychology students in Europe in order to enable them to become professionals

-to promote exchanges of psychology students from different European countries

-to promote scientific co-operation among European psychology students

Full member countries in EFPSA at this moment are Bulgaria, Croatia, Denmark, Estonia, Fuiinland, Germany, Hungary, Iceland, Norway, Poland, Portugal, Romania, Slovenia, and we are looking forward to accepting some new countries as members, some of them are Belgium, Bosnia, France and United Kingdom.

During the year (between congresses), the EFPSA work is kept up through different Task Forces. Currently working Task Forces are *Psychology students abroad* (its goal is finding information on how to study psychology in other countries and thus create a database for everyone, who is interested in studying abroad), *Travel network* (it's about creating a network of people, that would be willing to host a psychology student from another country, if he or she was traveling in their country and needed a place to stay), *Research network* (it has two purposes - one is enabling someone to do a cross - cultural study on something - helping that person to get results from other countries, and secondly, again, creating a database of final thesis' titles, that could be useful to European students of psychology).

We also have *exchanges,* this year there will be a Slovene - German exchange taking place in Slovenia. We also have a *mailing list* and a *web page,* which say practically all about EFPSA, but in a funny and amusing way.

The last two projects of EFPSA were an Executive Board meeting in Warszaw, which took place in November, and a winter school in Croatia, handling the subject of addiction and it s meaning. The outcome of this winter school will be a cross - cultural research on how much people, that will once work with youngsters (e.g. psychologists, teachers,...) know about drugs. It is a two year project - this year we composed a questionnaire, and the final work will be done next year, thus giving us time to gather results till then.

SEE YOU AT THE APA CONVENTION AUGUST 4-8, 2000 WASHINGTON, DC

Our next yearly congress will be held in Estonia in April, however, "we're always open" at <http://members.xoom.com/efpsa>

We will be very glad if you visit us on the web page or through e-mail. Some of them are published on the web page, but just in case:
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The Canadian Psychological Association, Section for Students

We are alive and well! Students across Canada engaged in the study of psychology are becoming much more involved in the psychological community. As a member of the Section for Students, a part of the Canadian Psychological Association (CPA), students are engaged in the largest network of psychology students in the country. The Section for Students crosses all CPA section boundaries and provides a forum in which students may learn from each other and begin to prepare for their careers in psychology. This goal is repeatedly met as greater representation and communication channels continue to open. As a young Section of only four years, we have been striving to become a greater voice in the Canadian psychological community and our persistent efforts have not been in vain.

The focus of this year's Executive Committee has been the increase of the number of Campus Representatives. Each University has the need to possess a link from their students to the Section Executive as well as the Association as a whole. We are quickly reaching this aspiration, as numerous students have shown interest in playing active roles. Additionnally, our communication strategies have been a target of expansion. Thus, the existing website was developed more fully and a listserve created so that information pertinent to students is attainable and as comprehensive as possible. Also, in order to recognize the academic excellence of students from this broad land, the creation of student awards for Excellence in Research in Honours, Masters and PhD theses was recently approved.

Currently we are in the midst of preparation for the Annual Convention to be held in the Nation`s Capital of Ottawa Ontario from June 28th to July1st. This year`s Section program is the largest yet, with symposia and posters discussing issues such as tips to obtaining financial assistance and academic funding, how to survive the graduate school experience, the publication process from start to finish, and the trials and tribulations of being involved in the political arena. As well, the social event is expected to live up to those of previous year`s if not be surmounted in attendance and enjoyment. To be noted is the fact that the 1st of July is an annual celebration across the country - Canada Day - with the millenium celebreation preparations abound. This will prove to make this year`s conference both exciting and unforgettable.

As we continue to work towards greater student participation and advancement, we encourage international students to engage themselves in communication with others. We look forward to hearing from you. ■

◆ CROSS-CULTURAL PERSPECTIVES ◆

Empowering Quake Survivors in Turkey: The Mental Health Outreach Program

Anie Kalayjian, PhD

"Before the earthquake I used to get upset about mundane things being broken. Now I collect the pieces of my house with joy."

"I did not feel a part of this country before the earthquake. Now I feel Turkey in my bones. The earthquake has taught me to love life more because death can happen at any moment."

These positive statements were given as part of an empowerment session conducted by natural disaster expert Dr. Anie Kalayjian, who organized and delivered the Mental Health Outreach Program for post earthquake community in Turkey. Dr. Kalayjian's team comprised of Research Psychologist Dr. Kathleen Kowalski and breath therapist Tara Forbreg in the aftermath of the 7.4 magnitude earthquake that devastated the towns of Izmir, Golcuk, and Yalova, Turkey on August 17, 1999.

Dr. Anie Kalayjian, author of the book "Disaster and Mass Trauma: Global Perspectives on Post Disaster Mental Health Management,' organized and conducted mental health intervention programs in Armenia, Northridge, CA, Kobe, Japan, after their earthquakes as well as with survivors and mental health/rescue professionals of Hurricane Andrew in Southern Florida. Dr. Kalayjian met His Beatitude Patriarch Mesrob II, the Patriarch of all Armenians in Turkey, when she was invited to present a lecture at the 6th International Conference on Psychotraumatology and Human Rights in June of 1999, which took place in Istanbul, Turkey. After the earthquake, Dr. Kalayjian received a call from the Patriarchate inviting her and her team to Turkey to respond to the post psychosocial needs of the earthquake survivors. The funding was then provided by the Armenian Patriarchate.

The Turkish Psychological Association, psychologists from Israel and Germany, Turkish and Armenian psychologist from Turkey, student psychologists as well as a group of 50 psychologists from the American Psychological Association conducted intervention programs soon after this earthquake. However, ongoing interventions are still needed as the more than 50,000 homeless survivors prepare for winter.

The team remained in the earthquake zone for two weeks where it conducted empowerment groups with over 600 people ages 5-60. They also conducted training sessions with psychologists, teachers, nurses, psychology students, school principles, social workers, and psychiatrists in the application of their Mental Health Outreach Program.

The Mental Health Outreach Program comprises a series of consecutive six steps through which various aspects of traumatic exposure are assessed, identified, explored, and worked through. The following are the 6 steps of the Bio-PsychoSocial, & Spiritual Model:

1.Assess Levels of Post Traumatic Stress: Participants were given a written questionnaire, the Reaction Index Scale, used by Dr. Kalayjian in previous disasters to determine the level of Posttraumatic stress disorder symptomatology. These findings, although not yet conclusive, were congruent with majority of post-trauma responses by survivors of other earthquakes.

2.Encourage Expression of Feelings: One at a time, each member in the group expressed what they were feeling in the 'here and now,' in relationship to the earthquake. The predominant feelings expressed were that of fear-of more earthquakes as well as uncertainty of the future. Flashbacks, hearing the sounds of the earth rip apart and buildings Mental Health Outreach to Turkey topple, avoidance behaviors, anger at the slow response of the government and of the corruption, and sleep disturbances were also expressed. Since these groups were conducted about 60 days after the earthquake, this was the first time that many of the survivors were able to express their grief for their loved ones.

3. Provide Empathy and Validation: Survivors' feelings were validated by the group leaders using statements such as "I can understand...," or that "It makes sense to me...." and sharing information about how other survivors from around the world have coped. Also used were intentional therapeutic touch, such as holding a survivor's hand. Here it was reinforced that the survivor's feelings of grief, fear, anger, as well as joy of surviving are all natural responses to the earthquake, and need to be expressed. When trauma ruptures the individual's links with the group, an intolerable sense of isolation, disarray and helplessness may occur (Dasberg, 1976). Providing validation and empathy in such a group will correct these effects by reestablishing the mutual exchange between the individual and the group.

4.Encourage Discovery & Expression of Meaning: Survivors were asked "What lessons, meaning or positive associations did you discover as a result of the earthquake?" This question is based on Viktor Frankl psy-

(Continued on page 16)

Some notes on the contributions of the Turkish psychological community to the healing work after the earthquake(s) in Turkey

Hale Bolak Boratav, PhD
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On August 17, a major earthquake in the magnitude of 7.1 on the Richter scale hit the Marmara region of Turkey. Before we even began to heal from this disaster, another major quake based in Düzce hit the the same region on November 12. Although Turkey has had major earthquakes in the past, as a nation, we were not prepared to cope with a disaster of this scale. A discussion of the official response, both civil and military, remains outside the scope of this brief report. In fact, I am going to limit myself to the efforts of the psychological community. But, to begin with, I think it is important to emphasize the following: At the individual level, most of us who wanted to do something felt helpless and did not necessarily seek out the means to get mobilized. Others either went to the disaster area and had the experience of not feeling useful or having heard from others who recounted similar experiences, felt pessimistic about opportunities to get involved in a meaningful way. Initially, organized efforts that individuals could connect with were quite few. This is precisely why the psychological community in Turkey deserves a special recognition.

The Turkish Psychological Association (TPD), the only official professional organi

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chotherapeutic principles: That there could be a positive meaning discovered in the worst catastrophe. Again, each member of the group was invited to focus on the strengths and meanings that naturally arise out of any disaster situation. Some of the positive lessons learned were: Interpersonal relationships are more important than material goods; to release resentment and show forgiveness; to not rely on the government but to take charge of one's own life; the coming together of nations, specially those with historic animosity as Armenia and Greece.

5.Provide Didactic Information: For those survivors who were still living at home or were planning on moving back into their own home, practical tools and information were given on how to gradually move back utilizing the systematic desensitization process. The importance of preparation was reinforced and how to prepare was elaborated. Camp members were given instructions to continue the 6 Step Mental Health Outreach Program on a weekly basis. Handouts were given to teachers and prospective group leaders on how to conduct earthquake drills an create safe and accessible exits. . Booklets were given to parents and teachers on how to relate to their children's nightmares, fears and disruptive behaviors. Assessment tools were given to psychologists and psychiatrists. Handouts were provided on grief as well as how to take care of oneself as a caregiver.

6.Provide Breathing Exercises: Breath was used as a natural medicine, and a healing tool. Since no one can control nature, and what happens outside of one's self, survivors were assisted in controlling how they respond to the trauma. This was an experiential section of the program; it provided survivors with instruction show to use breath to empower as well as engender gratitude, compassion, faith and strength, and forgiveness in response to stress and trauma.

Survivors stated that they benefited tremendously from this program. They reiterated statements such as: "This group has helped me a lot, now I have some tools, I have some information, I know what to do," "Your presence has helped us by giving us courage and encouragement, we are changed positively forever," and "Your group has been so warm, caring and compassionate, we will remember you always."

The need for mental health interventions in response to natural disaster is not widely accommodated due to the fact that this trauma is 'natural' rather than human-made. The need for mental health intervention after a war for example is self-evident. Yet, as the world becomes Mental Health Outreach Program for Turkey more heavily populated around major fault lines and along hurricane coastlines around the planet, massive human trauma derived from natural disasters will become more prevalent. The team strongly recommends the establishment of permanent natural disaster response teams to be formed in countries and cities affected by natural disasters.

Dr. Kalayjian is an officer on the UN NGO Human Rights Committee as well as the Chairperson of the World Federation For Mental Health Human Rights Committee, president of the International Society for Traumatic Stress Studies, NY Chapter, and she has over eleven years of disaster outreach management experience. She is Board Certified Expert in Traumatic Stress, and Board Certified in Emergency Crisis Response, Diplomate, American Academy of Experts in Traumatic Stress, Professor of Psychology at Fordham University and at John Jay College of Criminal Justice, and in private practice in New York & New Jersey.

Dr. Kowalski is on the board of The International Emergency Management Society, she has been with the former US Bureau of Mines, now the Office of Mine Safety and Health Research, NIOSH, Department of Health and Human Service. Since 1991, she has been serving as a Research Psychologist and PI on the Hazard Recognition Project and as Chief of the Surveillance, Statistics and Research Support Activity, she is also in private psychotherapy practice. Ms. Forbreg, is a survivor of many natural disaster, and for the past ten years she has utilized breath, voice, movement and writing as a complimentary healing modalities for trauma survivors. Ms. Forbreg co-researched and developed a multidisciplinary research to accelerate human learning potential, presented at the UNESCO conference on Life Science and Education in Paris, France. She has conducted workshops and lectures around the country in yoga, breathing and relaxation. She is the author of the forthcoming book Rage into Compassion, by Shambhala Publication and Random House. For further information and photos kindly contact the Program Director: Dr. Anie Kalayjian at (212)362-4018, E-mail: kalayjiana@aol.com or the team members: Dr. Kathleen Kowalski in Pittsburgh, PA (412)386-4531, and Ms. Tara Forbreg in Kansas City, MO (913)829-0298. ■

(Some Notes cont. from page 15)

zation of psychologists in Turkey with more than 1500 members, is an internationally recognized association and a member of EFPPA and IUPsyS. Established in 1976, the association plays an important role in the institutionalization of ethics in the profession, advocates for client rights, and sponsors academic and professional publications as well as continuing education courses for its members. TPD put out a special earthquake issue of its official publicationTürk Psikoloji Bülteni (Turkish Psychological Bulletin) this fall which I used as a primary resource in preparing this report.

After the disaster, TPD formed a special work group which identified three major goals: 1. The education of the public on the psychological effects of the earthquake; 2. Providing psychological support services to earthquake survivors, and 3. Developing plans towards prevention and/or mitigation of the psychological problems that the quake may cause in the long run particularly in children and young people. Towards the first goal, TPD issued a number of educational pamphlets the first of which was titled 'Recognizing and mitigating the psychological effects of the earthquake' with separate suggestions for adults and children. This pamphlet was quickly delivered to the public via the internet as well as major TV channels and newspapers, and subsequently, at least 100 000 copies were printed. Other pamphlets followed with titles such as 'The psychological difficulties that may be experienced by the rescue teams in disaster areas and some helpful suggestions', 'How to help your students cope with the psychological effects of the quake', 'How to help your children who have been affected by the quake', 'Some helpful suggestions for effective communication with survivors experiencing rage', 'Marriages in the aftermath of the quake', and 'Disasters and friendships.' TPD was also quick to take the initiative in the organization of psychological relief services after the earthquake. It was efficient in organizing its membership whose overwhelming response was unprecedented in the history of the association. Other volunteers responded to TPD's call as well. In coordinating these efforts, TPD provided a successful example of crisis management. Teams of 12 to 15 psychologists and human service volunteers working 4 to 7 day shifts provided psychological first-aid to the inhabitants of more than 70 tent cities in the disaster area. The teams received mandatory special training in psychological first aid with regular updates based on incoming reports and observations of the returning teams. Special care was taken to orient the volunteers to the constantly changing conditions of the area, and debriefing sessions were carried out upon their return. These services have been greatly appreciated both by the disaster victims and local authorities. The trainers, in turn, re-

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cieved advanced training from international trauma experts from various countries including US, Norway, and Israel. When the Düzce quake hit, the teams were able to use their experience from the first quake and intervened more efficiently to deliver emergency psychological services to the survivors. At the end of December, TPD organized a press conference and a series of panels to inform the public about their activities and what has been learned about the role of psychology and psychologists during disasters. TPD would welcome future collaborations with the international psychological community, and can be contacted via e-mail: bilgi@psikolog.org.tr

With so many people so deeply affected by the quake, there has been a growing realization that psychological relief services will be needed for a long time to come. Communities, families, homes, jobs and businesses have been torn apart; some people have been forced by necessity to relocate; in addition to losing their loved ones and material posessions, many people will live with physical disabilities and/or develop serious psychological problems that may affect their general well being and interpersonal relationships as well as work productivity and satisfaction in the long run. For many involved, losses have been multiple.

As a nation, we are also finally waking up to come to terms with what it means to live with earthquakes in this major earthquake zone. There is an urgency about developing long range plans towards being more proactive in the future. For example, an active trauma center has been in place in the Istanbul Çapa Medical School for several years now, but the larger psychological community is only now realizing the need to be more equipped with the necessary knowledge and skills in the area of trauma and the importance of educating the larger public about the psychological effects of trauma, risk and protective factors. TPD is considering starting a 'trauma psychology' certificate program that has international recognition. It will be important that such programs offer a diversified curriculum and do not limit themselves to training people to use techniques such as EMDR. Similarly, educational programs are underway that train both a wide range of service providers as well as the general public on the long range effects of the quake. Children and young people constitute the primary target population for these projects. Psychologists are currently working to establish long range collaborative projects with the government, particularly the Ministries of Education and Health, as well as international organizations such as UNICEF which has been particularly supportive of educational projects servicing the children and parents in the disaster area. The goal is to see these ministries institute more permanent psychological and educational services in the area.

Psychiatrists have also been working against the odds, both in terms of working conditions and bureaucratic hassles, to provide mental health services. Psychiatry Association of Turkey has been very actively involved in the psychological relief efforts after the quake. Specialized psychiatric services have been made available in the various medical schools as well as in the mental health stations established in the disaster area. Soon after the disaster, a group of members did a needs assessment in the area and reported back their suggestions for more effective delivery of direct services and education of health personnel by psychiatrists. They noted the importance of working collaboratively with the TPD and The Turkish Physicians Association (TTB). In addition to the ongoing work corrdinated the 'Disaster Psychiatry Scientific Work Unit', groups of psychiatrists have been working on various projects in the disaster area where they are doing close follow-ups with severely affected individuals.

Psychologists and psychiatrists have been very vocal about the difficulties that resulted from not being prepared as a nation for a disaster of this magnitude: The Ministry of Health was not able to mobilize its resources in a timely and efficient manner; lack of organization meant that individual psychiatrists went to the disaster area on their own initiative which sometimes meant less than an efficient use of expertise; the psychiatric needs of people doing rescue work and of those delivering psychological services were not adequately attended to. Psychologists and psychiatrists acknowledge the need to develop more professional readiness to intervene efficiently in the event of a similar disaster, to be in ongoing collaboration with governmental and non-governmental organizations involved in rescue efforts, and to be ready to take mental health services to the members of these organizations in the event of a disaster. In the future, they hope to work more closely with each other and with organized physicians, and aim to provide psychological relief services to health personnel involved in care and service delivery in the aftermath of a disaster.

With the end of the acute phase of disaster management, various ethical questions have also been raised and discussed, regarding the work of social science researchers and the media in the area. TPD has issued a set of ethical guidelines to be followed in psychological research in the disaster area, encouraging action research that is undertaken with the goal to improve the quality of life of people in the area through possible intervention projects. Psychologist have also appealed to the media as a force that has the potential and responsibility to direct people, asking for more sensitivity in general to refrain from the kind of sensational coverage that re-traumatizes the victims. Social psychologists have appeared on the media to discuss why certain psychological phenomena, such as the spread of rumors anticipating worse disasters, is common after a major disaster. They have made suggestions for the kinds of programming that might be helpful, such as programs that can make people more perceptive to psychological problems like loss or even everyday stresses and able to cope, and educational and supportive programs that can foster individual and institutional responsibility towards earthquake preparedness such as becoming knowledgable about safety of buildings and educating their children.

Maybe the most important lesson to be learned from this earthquake concerns the importance of coordination. Disaster management is a multi faceted project which requires effective cooperation and communication between different organizations of the government, municipal authorities, NGOs and the private sector. The psychological community has been finally recognized as playing an important role in this endeavor. It is a bittersweet experience to see that for many people in Turkey, psychology as a discipline, and psychologists as professionals have gained more respectability in the aftermath of this unfortunate disaster. ■

July 17-21, 2000, Padua, Italy

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The Globalization of Psychology via the Internet: Anticipating the Not-too-distant future

Richard S. Velayo, PhD
Pace University, New York

The Internet is virtually making the world a smaller place, even the world of psychology. Millions of Americans now use the Internet regularly and the number of Internet users around the world is growing at a tremendous rate. Its influence is certainly far-reaching, with its impact already felt in the areas of teaching, research, practice, policy-making, international relations, and more. Most of all, the Internet and interactive technologies are changing the way we relate to others and to ourselves as psychologists. The field of psychology is not particularly immune to this. In fact, such technology has and will continue to contribute significantly to the globalization of psychology as a discipline.

Division 52 is one of the divisions in APA that pioneers the use of the Internet in corresponding with its constituents. We have our own website which can be accessed at http://www.tamu-commerce.edu/orgs/div52/. In fact, many of the paper and poster proposals submitted for our program at the recently held APA conference in Boston were sent via e-mail. The submissions were from six continents comprised of 30 countries. In addition, information regarding the division and proposal submission procedures was submitted by accessing our website. We also have a "listserv" in which members may join by contacting Dr. Bill Masten, Webmaster for the Division 52 website, at William_Masten@tamu-commerce.edu Thus, these are indications that our division has begun to prepare for what is to come and what may well be the mainstream form of communication among our constituents.

We, as psychologists, should begin to anticipate changes brought about by this globalization via the Internet if we are to successfully and effectively promote our discipline to the world. Below are some of the challenging transformations in the field of psychology that I see as crucial given our use of the Internet.

On the Practice of Psychology

The internationalization of our field through sophisticated communication technologies put us in touch with countries known previously to only a few. We, like others abroad, will need to be responsive to the demands of a multi-racial, multi-ethnic, and multinational group of psychologists. According to Mays, Rubin, Sabourin, and Walker (1996), the challenges that new technologies bring can and will range from such issues as ethical decisions of who can and will have access to expensive technology that saves and prolongs life; to the development of conflict management strategies for peaceful coexistence with neighbors whose behaviors, beliefs, and values are strongly shaped by their cultural, religious, and ethnic backgrounds and socioeconomic circumstances. Thus, inclusion of and sensitivity to various socio-cultural perspectives is all the more necessary.

Given the changes in telecommunications, transportation, and economic ties, we are probably linking our careers to events and forces in distant lands. Emerging social, cultural, political, and environmental problems around the globe are imposing intense and complex demands on our discipline, challenging our sense of identity as psychologists and as a professional collective. We can assist in addressing and resolving these concerns, especially if we are willing to reconsider some of Psychology's fundamental premises, methods, and practices that are rooted within Western cultural traditions and to expand its appreciation and use of psychologies from abroad. Marsella (1998), suggested that there may even be a need to advocate the development of a meta-discipline of psychology - global community psychology - defined as a set of premises, methods and practices for psychology based on multicultural, multidisciplinary, multisectoral, and multinational foundations that are global in interest, scope, relevance, and applicability. The characteristics of global-community psychology as a disciplinary specialty are important to discuss, are as various issues supporting its development and need.

On Training and Education

Electronic and computer-based technologies increase the speed of communication be-

(Continued on page 19)

BOOKS HIGHLY RECOMMENDED FOR INTERNATIONAL PSYCHOLOGISTS

Book Reviewer: Robert F. Morgan, PhD

BUDDHA IN REDFACE by Eduardo Duran
On http://www.amberliterary.com/ as oof 2/2000.

The future is here. My first recommended book is an 'on-line' text available prior to paper publication. You may remember Edurado Duran's last book NATIVE AMERICAN POSTCOLONIAL PSYCHOLOGY (published by SUNY Press), with wife Bonnie Duran, was hailed by IAAP President Berhard Wilpert at the last World Congress of Psychology (San Francisco, 1998) as a significant leader for psychology in the new millenium. Wilpert's presidential address highlighted Duran's concept of cultural PTSD and its treatment. This book continues to be useful in university classes, including mine here in Guam. It was even transformed into a feature movie ("FOLLOW ME HOME") which won at the San Francisco Film Festival and was shown at the IAAP World Congress in the "Nations Within Nations" seminars.

Duran's new book is more personal, even more forceful. This can be effectively used in class as well (eg. Prevention, Multicultural). Here Eduardo honors his most powerful teacher in an unexpected role reversal with a dying American Indian client. On the way he reframes our most cherished applied theories with realtime and dreamtime adventures ranging from wrenching ceremony to nuclear halocaust. Eduardo's mentor will inevitably be compared to Castenada's Don Juan and other historic notraditional mentors practicing medicine without a paycheck.

As we move into this new century, we need to decide what is worth bringing with us from the last one: pack the suticases, leave the baggage. Duran's two books are a formidable beginning. There is more. BUDDHA IN A RED FACE goes beyond its multicultural insights, Native American spirituality, and therapist-client role reversal, to give us early warning of the most significant baggage the human species brought into this century, continues to face, and must resolve to survive. Read the book. ■

(The Globalization cont. from page 18)

tween psychologists of different nations (as well as geographical regions within a country), therefore allow the training and the education of psychologists to be conducted anywhere and any time. Such transformation imposes changes in the role of trainers and educators of psychologists. The Internet also allows for the management of knowledge and provides just-in-time information and skill-sharing among psychologists through electronic support systems and networks (Marquardt & Kearsley, 1998)

Many new technologies, the Internet in particular, have already had a strong application in education (Kincaide, Ferracutti, & Santiago, 1997). The role of psychology on the education and training of future psychologists, both local and international, would be to start a universal dialogue between nations and cultures of the world. Computer-based distance education and training in developing countries ought to fulfill the same goals as the whole educational system to prepare people for the oncoming globalization. A virtual college is one expression of a growing virtual society that also includes virtual corporations, telework, telemedicine, and teledemocracy. Interestingly enough, many of the more traditional colleges and universities have expanded their accessibility to peoples of other nations through various forms of distance learning platforms.

On Psychological Research

New information about various subfields in psychology and the Internet critically influences the way we work, live, communicate, and/or behave. Research opportunities for social scientists exploring the social norms issues of human behavior as well as interesting outcomes published by Western researchers of computer-mediated communication and virtual communities are evidently growing (Bajan, 1998). For example, Ono (1996), examines how users reveal a reflexive projection of the self in Internet "speech," and how Internet communication encourages users to internalize globalization in their self-identity. This study further describes the Internet as a global networked society.

The inclusion of indigenous psychologies in the knowledge base of all psychology is also an important emerging issue to tackle. Sampson (1995) describes the postmodern era characterized by "postindustrial, information-based and globally linked social environment" in which current Western views of the self - as free, independent, and self-contained - will become inadequate in providing a basis for understanding the individual. It is anticipated that it will become essential for a person, to view themselves as parts of a global system in which people's identities are inextricably linked with where they are socially located in that system. Thus, many personality and social psychologists may have to recalibrate their views to reinforce the central importance of culture in shaping the way people construe the self.

The Internet has also greatly influenced how people work and learn, manage themselves in the workplace, and manage knowledge in their lives. Industrial / Organizational psychologists should further their research on how technology can help people and organizations achieve the level of competence necessary to survive and succeed in the global marketplace of the next century (Marquardt & Kearsley, 1998).

Data collection via the Internet is also becoming a popular way to do research. Many interactive questionnaires are now on the web, the most common of which are associated with experiments on perception and cognition.

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The Internet's influence on psychology and how cultures are viewed will also have a profound impact on the world's various cultures themselves. Although psychology may be largely assumed to be a value-free, universal, and relatively objective branch of science, in actuality, it is deeply enmeshed with Euro-American cultural values that champion rational, liberal, and individualistic ideals (Kim, 1996). In North America, free exchange of ideas is valued, and ideas are purportedly evaluated through public and competitive avenues. This belief certainly affects how conferences are organized, research collaborations developed, research is funded, and publications are accepted. In East Asia, human relationships characterized as being virtue-based rather than rights-based is more evident. Individuals are considered to be linked in a web of interrelatedness and ideas are exchanged through established social networks. The dissemination of research findings does take a different form. Thus, our cognizance and sensitivity to these differences are needed. Moreover, the generalizability of findings in psychological literature may now often be assessed given its particular cultural perspective. Kim (1996) even proposed the need for the development of universal psychological science.

There are many other related questions being asked about this growing "cyberpsychology," some of which are as follows: Should society guarantee universal access to the Internet?, Should there be restrictions on the content of the Internet?, What are the long-term effects of interacting in a virtual environment?, Will advanced multimedia systems and Internet connectivity replace the traditional classroom experience?, Can psychological services be effectively delivered over the Internet?, and Can interactive technologies reduce mental health care delivery costs? Perhaps as we reach the new millennium, we can expect to achieve answers to some, if not most, of these questions. One thing seems to be certain and that Internet technology has opened the gates to a more efficient and effective communication among many members of the psychology community around the world. As Dr. Florence Denmark, current President of Division 52, mentioned in her Presidential Address at the recently held APA Convention in Boston, "The Internet is one major factor that contributes to making our small world smaller."

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◆ PSYCHO-POLITICAL PERSPECTIVES ◆

Roots of Antisemitism and the Successful Metamorphosis of Political Racism in Europe

Jos D. Meloen, PhD, University of Leiden, The Netherlands

At the turn of the millennium great expectations of progress in technology, human and political world affairs were voiced. Not long ago Francis Fukuyama predicted that most of the world would soon turn democratic. The internet would produce peaceful 'world burgers', and ex-dictators, like Augusto Pinochet, would never escape justice again.

Within a month return to reality was inevitable with a crashed Mars Polar Lander and the controversial landing of Jörg Haider's extreme right wing FPÖ in the Austrian government. He was congratulated by leaders of comparable far right parties, Serbia and Russia while European, US, and Israelian politicians condemned his coalition with the Christian Democrats. For the first time since the defeat of Nazism in 1945 in Germany and Austria, a new extreme right wing party rose to power through the electoral process, in the heart of Europe.

Many have started to wonder whether this new 'authoritarian specter', to cite Bob Altemeyer (1996), has returned, or whether this development is genuinely new. Those who point to the past argue that once again an extremist party entered government employing racist and xenophobic sentiments. Haider was quoted to have said in 1986: 'The FPÖ is not the successor of the National-Socialist Party. If that was true, we would now have the absolute majority'. He also praised Hitler's unemployment policies, after which he had to withdraw as governor in 1994.

But others point at changed circumstances. Austria is not a major European power. Also, there is no economic crisis in Austria and unemployment is low. The country became democratic and prosperous after the war. By contrast, in the 1930s half of Europe was covered with authoritarian and totalitarian governments, leaving democracies in the minority. This changed dramatically after World War II and again after the end of the Cold War. There is now hardly an European country left that has not adopted some kind of democratic system. Neither totalitarian nor authoritarian governments are very popular anymore. At the same time there is evidence that attitudes of Europeans have changed into a democratic direction and away from authoritarian ones.

Yet, there remains a uncomfortable feeling that the past may return. Democracy is most vulnerable where it grants political rights to those who threaten its very central values and eventually corrode or destroy democracy from within. It is easy to be tolerant when anti-democratic tendencies are marginal. But where should the line be drawn when it gains strongly in popularity?

Indeed, most remarkable is Haider's popularity, that gained the FPÖ 27 per cent in the parliamentary elections, leading Europe's far right in this respect: 25 per cent for Italy's Aleanza Nazionale and xenophobic Lega Norte together, 23 per cent for the Swiss Volkspartei, 15 per cent for the Belgian Vlaams Blok and Front National, 15 per cent for the Norwegian Fremskrittspartiet, 15 per cent for the French Front National and the break away Mouvement National together, 8 per cent for the Danish Folkeparti, and less than 4 per cent in Germany. Their common denominator is anti-immigrant, xenophobic and anti-asylum seeker sentiment, together with more or less hidden right wing extremist issues and nationalism. Although the historical events of the Holocaust have made the extreme right careful not to express antisemitism in public, it is generally assumed that this a 'silent partner' of generalized political racism. In a 1996 Austrian poll analyzed by Hilde Weiss 34 per cent agreed with the statement 'The Jews are too influential in Austria'. 26 per cent agreed with 'A lot has been exaggerated in regard to concentration camps and Jewish persecution'. 49 per cent agreed that 'Jews dominate world affairs'. 14 per cent did not accept Jews as neighbors in another Austrian survey. While only a few thousand Jews still live in Austria, negative stereotypes about Jews apparently still persist and were held more often among authoritarians (Enyedi and Erös, 1999). Relations between antisemitism and authoritarianism were reported in the 1990s in the Netherlands, Belgium, Hungary, Yugoslavia, and Germany, and in the past also in the US and other European countries. Unfortunately, studies are lacking for a more complete international picture. Many investigations have concentrated instead on the relation between authoritarianism and generalized prejudice against migrant workers and various ethnic, religious or other minorities, usually called ethnocentrism, or its opposite, multiculturalism. This relationship was demonstrated in a 44-country study conducted recently (Farnen and Meloen, 2000, in press). But it would be rather naive to believe that the authoritarians of the extreme right have abandoned their prejudices about Jews, as was suggested recently in the US (for more accurate information on right wing extremism and antisemitism, one may visit the Simon Wiesenthal website and the country reports of the Institute of Jewish Policy Research).

Jörg Haider - both his parents were early members of Nazi organizations - was called in the press a 'nazi-yuppie', but he denies to be a neo-nazi himself. Those who have called him so, were sued by him in court. Others called him a right wing populist. But there is one coincidental similarity between him and The Authoritarian Personality that he cannot deny: both turn 50 this year.

It was the American Jewish Committee in the 1940s that initiated five studies in prejudice that aimed to uncover the ideological roots of antisemitism, prejudice and what now is called right wing extremism, at the time usually called Fascism or Nazism. The most influential and most cited was the study by Theodore Adorno, Else Frenkel-Brunswik, Daniel Levinson and R. Nevitt Sanford, published as 'The Authoritarian Personality' (1950). The study was called 'an instant classic' and Wayne Hogan later suggested that the authors should have been nominated for the Nobel prize. At the same time the study was criticized for facing the wrong enemy (Fascism, instead of Communism) and for presumed methodological shortcomings (although most recognized the original and extensive methods used), or simply not taken seriously by suggesting the whole syndrome was merely a matter of 'yea-saying', and not of potential fascism. However, studies found very high authoritarianism scores among groups such as former German SS, US superpatriots, English fascists and racists, Dutch and Belgian right wing extremists, Afrikaner Apartheid supporters in South Africa, Italian neofascist MSI-supporters, and, more recently, Russian communists, supporters of the Polish communist Jaruzelski and Serbia's Milosevic. But even when such evidence of its validity was reported, many critics and reviewers kept ignoring these results, sometimes for decades. When Bob Altemeyer showed that alternative methods yielded mainly similar results, he complained that he was almost

(Continued on page 22)

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(Roots of antisemitisam cont. from page 20)
unable to get his results published, seeking refuge in a trilogy of books, now widely recognized as one of the most substantial contributions to the field of authoritarianism since Adorno et al. But he is not the only one active. I counted over 3300 studies, scientific articles and books, on authoritarianism and the related dogmatism of Milton Rokeach until this year. If the concept was as irrelevant or biased as some critics have suggested, than this does not explain the many contributions of well respected social scientists and why so many contributions showed positive results. Instead, the concept seems to have been reduced to a petty stereotype by some critics, who seem to claim that extemist ideologies are dead forever and democracy now is the future. But this does not explain the political racism and extremism that slowly has been growing in the past decades in European Union countries. Indeed, authoritarianism seems to have survived in the political margins.

What has changed since Adorno et al. is that the Jews as public target of extremist propaganda largely have been replaced by new outgroups, immigrants, Asians, Africans, Islamic groups, asylum seekers and refugees or any other unfortunate minority group. The new minority targets seem to serve the same functions for authoritarians as the Jewish groups did for the nazis. They are believed to be different, strange and internationally present, a possible threat to the nation and culture and, therefore, 'ideal' targets for fearful, suspicious people, who long for times gone, when all those immigrants had not yet entered the country and made them uncomfortable in their 'own' streets. Xenophobia and ethnocentrism are ever present undercurrents, even in democracies. However, these fearful, submissive and anomic people do not organize themselves usually. But in certain circumstances they are easy prey for the extreme right, as ever organized around a strong leader and within a strict hierarchy of discipline and obedience. When such a party ascends to power, populist ethnocentrism is tied to ideological and party line authoritarianism, where less committed supporters will eventually have to conform to. This is a threatening combination for any democracy and its many minority groups, Jews included.

Whether Haider and his FPÖ will undermine or - paradoxically - strengthen democracy, by feeding resistance against himself, the problem of tolerating political racism has become a major political issue now and a test for democracy in Europe. Histoire se repète, or so it seems, although probably not exactly in the same way.

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(Call for papers cont. from page 5)

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Performance and Completion time on a Memory Test as a Function of Academic Level

Richard S. Velayo, Ph.D.
Pace University

This study examined memory performance and completion time for each of three memory tests as a function of academic level (i.e., first-year students, college seniors, and graduate students). Participants were required to learn a computer-based instructional tutorial on the parts and functions of the human heart. Findings revealed that college seniors and graduate students performed significantly better than college first-years on the terminology test but not on the identification and comprehension tests. Moreover, seniors and graduate students finished the terminology test faster than the first-years.

The use of computers in schools and academic institutions is growing at a phenomenal rate. Computer-based tutorials provide a novel way for students to learn new information. The novelty in using computer-based tutorials as a means to enhance student learning is an important aspect of the technological future of teaching. Thus, the use of computers as tools for learning is an educational resource that needs to be developed.

Likewise, effective means of evaluating students using computer-based tutorials need to be created. Previous research has examined the role motivational factors play in students' performance on evaluative materials. Students are generally considered to adopt either a performance (extrinsically motivated) orientation or a mastery (intrinsically motivated) orientation. Within the traditional classroom, findings from experimental studies suggest students adopt a performance goal orientation (Elliott & Dweck, 1988; Thomas & Rohwer, 1986). However, students with a mastery orientation in a task consistently perform the task better both in terms of quality and quantity, than students with a performance orientation (Maehr & Nicholls, 1980). Recent research has demonstrated motivational factors play a significant part in how students will perform on memory tests based on a computer-based tutorial. Congruent with research in the traditional classroom, Velayo and Gersten (1996) found students with a mastery orientation scored consistently higher on memory tests than those students with a performance orientation.

Although the effect of motivational factors on memory test performance has been established in computer-based tutorial learning (Velayo & Gersten, 1996), other variables may contribute to the observed variance between test scores. One such variable might be the academic year level of subjects. As one progresses from high school through college and graduate school, it may be postulated one will acquire learning strategies such as mnemonics and associative schemas.

Using the same computer-based tutorial and memory tests implemented by Velayo and Gersten (1996), it was hypothesized academic year level would affect performance on three different memory tests. Specifically, college seniors and graduate students were expected to perform better than underclassmen. Upperclass college students and graduate students were expected to have developed specific cognitive strategies throughout the college years that would result in superior performance over freshmen college students on such tests.

Method

Participants

Participants in the study were 82 undergraduate and graduate psychology majors at Pace University. Undergraduates spanned all grade levels, ranging from first-year students to seniors.

Materials

The present study allowed students to utilize a computer-based multimedia tutorial to learn about the parts and functions of the human heart. The basis for the tutorial was adapted from Dwyer (1978). The tutorial consisted of three lessons. The first lesson, *The Heart and Its Functions*, provided a basic introduction to the parts of the heart through text and graphics. The second lesson, *The Circulation of the Blood*, described how blood flows in and out of the heart. The final lesson, *Cycle of the Heartbeat Consists of Two Parts*, outlined the systolic and diastolic phases of the heartbeat.

Three memory tests were developed to assess knowledge gained from the tutorial: an identification test in which

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the student selects the correct answer using a mouse, a teminology test in which the student types in the correct answer, and a comprehension test in which the student either selects or types in the correct answer.

Procedure

Upon beginning the experiment, participants were screened for previous knowledge on the subject of the human heart. They were then allowed to begin the tutorial, and shortly after took the three memory tests. The memory tests were taken using pencil and paper. After the test administration, participants were asked to complete a comprehensive evaluation of the courseware to assist in further revisions.

Results

An ANOVA on total scores and academic level revealed significant differences exist between various academic levels and total scores on the memory tests, $F(5,75) = 2.595$, $p < .04$. Paired-comparisons showed that college seniors and graduate students performed better overall than college first-years on total scores of the three tests. Further analysis revealed scores did not vary significantly by academic level on Tests 1 (Identification test) and 3 (Comprehension test). However, on Test 2 (Terminology test), scores did vary significantly, $F(5,75) = 3.105$, $p < .02$, again with college seniors and graduate students performing significantly better than college first-years (see Figure 1).

Figure 1

Column graph of Means for Score among First-years, Seniors, and Graduate students pertaining to Test 2 (Terminology)

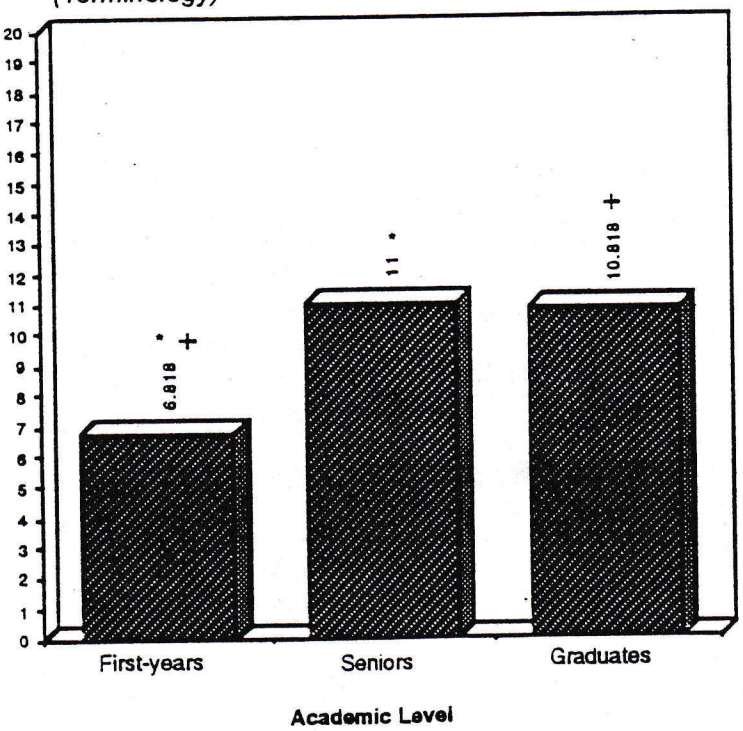

* = Significant differences between First-years and Seniors
+ = Significant differences between First-years and Graduates

Likewise, the amount of time it took to complete Test 2 varied significantly among academic levels, $F(5,75) = 3.86$, $p < .005$. Paired-comparisons revealed seniors and graduate students completed Test 2 significantly faster than first-years (see Figure 2). Significant differences between academic levels in both score and time on Tests 1 and 3 were not found.

Figure 2

Column graph of Means for Time among First-years, Seniors, and Graduate students pertaining to Test 2 (Terminology)

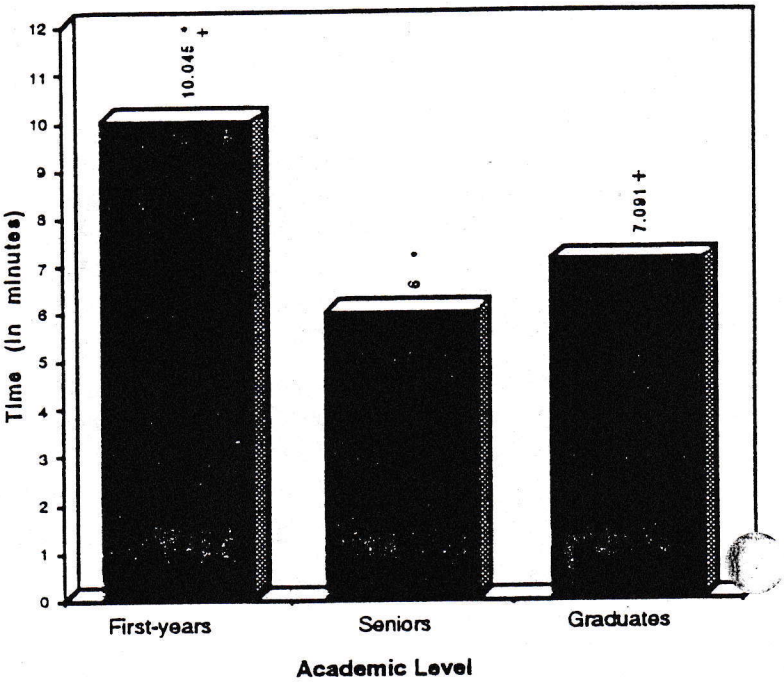

* = Significant differences between First-years and Seniors
+ = Significant differences between First-years and Graduates

Discussion

The results suggest Test 2 (Terminology test) requires a certain degree of cognitive organization and maturity that might occur as one progresses through the academic levels and gains more experience with such tests. As one progresses through college and onward to graduate school, one's vocabulary broadens and expands. Learning new terminology is facilitated by maintaining a lexicon broad enough to build new terminology from. That is, the stronger one's vocabulary, the easier it will be to learn new words. It is likely since the participants majored in psychology, a major often requiring a basic background in natural science, some familiarity with anatomical terms should be expected. Therefore, the terminology would be easier to learn as one's vocabulary and exposure to science-related concepts broadened. Graduate students and seniors scored better and completed Test 2 faster given that they may have a more complex and organized schema about the "human heart" which allowed them to accommodate or assimilate new informa-

tion on this topic. Formal college education may have contributed significantly to the development and organization of such schema.

As a by-product of one's vocabulary expanding throughout college, it follows one's self-efficacy for acquiring new terminology should increase. It is therefore possible, the first-year students experienced a decrease in efficacy as they completed the terminology test.

Further research should address issues of how best to evaluate students after being presented with a computer-based tutorial. Specifically, how students of different academic levels will perform on various types of tests.

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THE GENERALIST'S CORNER

Psychology in the Design of Multimedia Presentations in the Classroom: An Interview With Richard S. Velayo

Paul C. Smith
Alverno College

Paul Smith (PS), an Assistant Professor of Psychology at Alverno College (Milwaukee, WI) conducted this issue's interview for The Generalist's Corner. He chose multimedia instructional techniques as his focus and interviewed Richard Velayo (RV) as our expert. Velayo is an Assistant Professor at Pace University (New York, NY) and has made presentations on the topic of multimedia instruction at regional and national psychology conferences.

PS: Why would faculty choose to use multimedia presentations rather than more traditional methods?

RV: For teachers, multimedia offers ease and flexibility of use, ease in modification to instructional materials, organization, and the ease of providing handouts or packaged presentations on disk to students. Of course, multimedia presentations are also fun to make and use.

PS: One challenge in multimedia design is helping the user to understand the interface. In your work, you use the concept of affordances. Can you explain the idea?

RV: Donald Norman (1988, 1993) has pointed out some useful guidelines for those who design multimedia instruction materials. The term *affordance* refers to the possible functions of an object (Norman, 1993). An important aspect of designing an interface is to try to create icons that will afford appropriate actions, and not afford inappropriate actions. For example, an icon that appears as an arrow pointing to the left affords a particular function that is different from an icon that appears as an ear. When an object affords a particular action, then no instruction to the user may be necessary.

PS: I've seen some icons that don't provide much help to the user.

RV: Ideally, the correct action will be directly perceptible. People do not need instruction in how to use such things as cups, pens, and hammers in part because the actions appropriate to them are given by their salient properties. However, what if one of the icons on the computer screen looks like a pair of binoculars? As it happens, this icon searches for specified text. In retrospect, that seems like a reasonable meaning, but a user is not likely to recognize the purpose of this icon simply by looking at the icon's symbol. Green (1982) gave several other instances in which a symbol that is supposed to be instructive does not convey the intended meaning to the user.

PS: Your example emphasizes how important it is to understand the expectations of the user.

RV: The concept of affordances does go beyond the design of appropriate icons to the general design structure of the multimedia presentation itself. The structural design of a presentation should cater primarily to its intended consumers—in my case, my students. I have to be concerned with how to get them to attend to messages presented on screen; how the information flows across the display; what key words to use in order not to clutter the presentation; how many graphical elements, animations, and videos to use in a screen; what color is most appropriate to highlight certain information; what beginning and concluding displays should look like; and other factors. A good multimedia author will consider how these elements afford appropriate actions and ease of understanding by the learner.

PS: Directing attention to important material in multimedia presentations may require methods different from those used with printed text. What are some techniques for directing student attention in multimedia presentations?

RV: Many suggestions for directing student attention may seem like common sense. However, such common sense is not displayed in an unbelievable proportion of multimedia presentations. I think this may largely be due to the designer's limited ability to take the learner's perspective when designing presentations.

My experience in using multimedia presentations in class suggests that if a message is presented, the students will notice it. However, most people cannot attend to more than one thing at a time. For instance, if a fair amount of text is immediately followed by an animation, students may still be reading the text while the animation is going on.

PS: What are some effective means of making information stand out on a display?

RV: To get students to pay attention to a particular part of the display, present that part differently from the rest. For example, use a different color for the starting point than for the rest of the display, or use color for the starting point and white for the rest. Enclose the special material in a box, or underline it, or highlight it somehow. The idea is to attract attention by making a visually obvious distinction between the part to be emphasized and the rest of the display.

Flashing is another method of drawing attention to some part of a display. The main problem with flashing is deciding how long the flashing should last. If it stops too quickly, the student might not even notice it. If it continues over too long a period of time, the student will get bored. Furthermore, some people find flashing to be physically disturbing.

PS: Is it possible to overdo attention-getting techniques?

RV: Yes. For example, if several parts of the display are in color, none of them will be distinctive. If many sections are framed with boxes or are underlined, none will seem more important than the others.

PS: When students read printed text, they often have difficulty identifying the main points (Surber, 1994). Are there some techniques for helping students find the main points in multimedia displays?

RV: State the purpose of the lesson before presenting it. A short statement of purpose helps orient the students and tells them what to expect and focus on. Stating objectives snares attention and directs students to the material to be learned and away from other material. Be brief and precise. Students like to get on with the lesson and become impatient with lengthy statements at the beginning. The tasks and goals in some multimedia instructional tasks involve many objectives. Students are not likely to remember a long list of, say, more than five objectives. This is particularly true if they are not familiar with the subject matter. One way of getting around this dilemma is to present just a few objectives at a time, followed by appropriate instruction, and then repeat this pattern.

You can also show students a screen of questions that they should be able to answer by the end of the session. Provide them some time to think about these questions before proceeding to present the topic in greater detail.

PS: Authors of multimedia presentations face a number of issues concerning the flow of information. For example, it seems likely that a learner's scan of information projected from a computer screen will be quite different from that learner's scan of a page of printed text. How can multimedia presentations best control the flow of information?

RV: The design of the interface can dramatically affect the sequence in which students scan it. Design visual displays to indicate where a student should look first and how one's eyes should move across the display screen.

First, guide the student's eyes to the starting point. This can be accomplished in two ways: (a) Present only the material that must be noticed first, and nothing more, until the students have had a chance to comprehend the material; or (b) present all of the material at one time but make the starting point special in some way. Apply attention-getting techniques to draw the student's eye to the starting point.

Second, the display should flow smoothly. The visual design can also control the rhythm of the flow across the page (Nichols & Wilson, 1977; Salomon, 1994). Present the material in the order you want learners to notice it. The usual way of reading displays in English is from top to bottom and from left to right, so once the learners' eyes are at the bottom of a display, they are not likely to look back up to the top or to the middle unless cued to do so (Winn & Holliday, 1982).

Third, avoid unexpected minor changes. When learners finish a display, they expect you to continue on to the next one. The designer who wants learners to look at the upper part of the display again, rather than continue to a new display, is violating the learners' expectation. Therefore, the designer is obliged to apprise the learners explicitly of this change. Write a message to "Look above," or draw a line to direct attention. A small change in just part of the text is also apt to go unobserved by the learners, particularly if it occurs in an unexpected place. For instance, a minute change from one textually loaded display to the next textually loaded display may go unnoticed because most of the materials are the same.

Appropriate pacing of the presentation is also very important. Allow learners enough time to comprehend the material before changing the display. There is nothing more frustrating to learners than to have something wiped off the screen before they are finished studying it. The frustration is intensified when part of the text is overwritten by different text. Overwriting of this sort leaves students with the feeling that they do not know what is going on.

PS: Multimedia presentations can make especially effective use of graphics and animation to demonstrate key concepts. However, it is easy to forget the needs of the student when designing these features.

RV: Timing is especially important in the use of animation. The animation should be fast enough to get the idea across without taking an excessive amount of time to be displayed. On the other hand, it should not go so fast that the student does not see what is happening. Animation is exciting for the author to program, but before you decide on animation, consider whether it is really needed to demonstrate the content being presented.

Keep your graphics simple. Keep diagrams (e.g., graphs and tables) free of irrelevant details. Students should be able to see what is critical to the concept being taught. Cluttered diagrams do not make for effective teaching presentations. Overkill, such as using elaborate tables of data, is a common flaw in some computer-generated presentations. Some authors generate elaborate tables but make little use of them. The instructor may ask one question and then move on to an entirely new display. It is not necessary to generate and display a large amount of data just because the computer is capable of doing so. Generate tables only if the student is supposed to learn how to use a table of data or needs the data to make appropriate inferences.

PS: After you generate the individual display screens, are there any other steps you should take to help the materials come together as a unit?

RV: Adding introductory and concluding displays will help the materials become a cohesive whole. The

introductory display should include the name of the lesson as well as the name of the author(s), institutional affiliation, date of the presentation's most recent revision, and, of course, copyright information. Animation or fancy artwork on the title page is attractive the first time the student enters the lesson. You can enhance the title page with appropriate music and with the adaptation of visual techniques from film and television. However, these motivational features require appropriate computer hardware and software, including considerable computer memory.

Concluding displays tell students when they have reached the end of the lesson. Such a display should contain a very brief point-by-point synopsis of what has been covered in the lesson, what the next lesson will be, and a "what to do list" for the next class meeting.

PS: Some researchers, such as Thorndyke (1977), have suggested that design consistency can help learners to develop schemata that promote understanding of material. How important is design consistency in multimedia presentations?

RV: Design consistency is very important. The interface used should be the same or very similar for all presentations. The sequence in which screens are presented should also be consistent in every presentation. Given this consistency, students can quickly and easily understand how the class sessions are structured.

Even though the order of presentation is controlled primarily by the instructor, students should be encouraged to ask questions or have the professor activate certain icons on the screen. This makes it easier for students to learn what certain icons do. Each icon should have a consistent function so that students can learn what each icon does. Font type and size should be readable and consistent on all modules.

PS: What kind of classroom interactions best support multimedia presentations?

RV: I believe that the use of multimedia technology as a teaching-learning tool will be greatly enhanced by allowing students to have a high level of interactivity with the instructor. Variations in the sequence of presentation occur given student questions or demonstrated understanding or lack of understanding of the material. This points to a need to monitor student understanding during presentation. Thus, students should become active participants during each session by asking questions, clarifying and summarizing concepts, and exploring some of the icons on screen. Classroom discussions and small-group activities should be extensive and frequent.

PS: Many technology-oriented teachers complain about the amount of time required to write presentations. Can you comment on the trade-off between time invested and results?

RV: A teacher need not invest a tremendous amount of time to learn this. Certainly, some amount of time and effort is required to convert existing classroom material to multimedia format, but the investment will eventually make you a more efficient teacher and make your life easier. Once you've set up a multimedia presentation, future modifications become much easier. In addition, you can find other teachers who write multimedia presentations and have them show you how they do it.

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LEARNER COGNITIVE-MOTIVATIONAL CHARACTERISTICS AND PERCEPTIONS OF COMPUTER CONFERENCING USE

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ABSTRACT

This study examined the correlations between student cognitive-motivational characteristic s and their perceptions of computer conferencing use as a supplement to classroom instruction. 209 students in eight introductory psychology classes were given a pretest and a posttest questionnaire of their perception of computer conferencing use in the course. The Motivated Strategies for Learning Questionnaire (MSLQ) was administered to determine their cognitive-motivational characteristics for learning. Pretest perceptions were found to be positively related to intrinsic motivation, thinking skills, and task value, and negatively related to extrinsic motivation. Posttest results were similar and, in addition, time/study management, elaboration strategies, and self-efficacy were also highly correlated with several posttest perception items. Suggestions presented may enhance favorable student perceptions of computer conferencing.

The use of computer conferencing (CC) as an instructional device to supplement classroom instruction is gaining popularity in many institutions of higher learning (Velayo, 1993, 1994). As Hiltz (1986), Tooey and Wester (1989), and Velayo (1993, 1994) pointed out, CC provides the potential for communication that allows users to relay information and interact with one another regardless of time and distance between them. Thus, CC is a technological innovation that allows both teachers and learners to be able to interact with each other beyond the confines of the classroom.

The relationship between CC as an instructional method and learner characteristics deserve scientific exploration in order to provide some insight into which learner characteristics may influence the acceptance and use of CC. This study provides an initial attempt to determine correlational patterns between student perceptions of CC as a learning tool and student cognitive and motivational skills for learning.

A number of descriptive studies (e.g., Budin, 1991; Danowski, 1982, Fergu-

son, 1977; Hiltz, 1986; hiltz, Turoff, & Johnson, 1985; Phillips, 1983; Rice, 1982; Saunders & Heyl, 1988; Tooey & Wester, 1989) suggest that CC is a satisfactory alternative to face-to-face communication for a variety of communication activities (e.g., collaborative learning projects, extended discussion of course topics, relaying messages to students and/or instructor). In particular, CC is regarded as a useful device for the classroom because of the convenience and efficiency it offers to its users (Hiltz, 1986; Saunders & Heyl, 1988; Smilowitz, Compton & Flint, 1988; Waggoner, 1992a).

Other studies have examined the applications of CC. Johansen (1977) provided an organized and succinct comparisons of teleconferencing media. Waggoner (1992a) discussed some of the unique applications that have been developed in education. Waggoner (1992b) provided a comprehensive discussion, as well as suggestions, on CC use in collaborative learning situations. A comprehensive and influential review of research on the effects of noncomputer based teleconferencing media was written by Short, Williams, and Christie (1976). Although many of these studies report student evaluation and use of CC in an instructional context, none has particularly addressed the issue of determining learner psychoeducational or learning characteristics in relation to learner perceptions of CC.

This study examined ways to maximize CC's potentials by gaining a better understanding of the interaction of CC and student characteristics, especially in psychology and similar courses.

METHOD

Participants

209 undergraduate students (181 females, 106 males) enrolled in Introductory Psychology courses at a large Midwestern University participated in the study. Each student belonged to one of eight Introductory Psychology classes that used Cc as an instructional method to supplement instruction. Six were sections taught by teaching assistants and two were taught by professors. Although there were some between group differences in the implementation and use of CC, all courses used it to supplement classroom discussion and as an alternative way for instructor and students to communicate with one another.

The vast of majority of students did not have any prior experience with the use of CC. On a scale of 1 to 5 (1 being no experience at all and 5 being very experienced), the overall mean of student's previous experience with CC was 1.46 (SD=0.96). Amount of CC experience between groups was not significantly different.

Materials

A computer conferencing program called CONFER II (a registered trademark of Advertel Communications Systems, Inc.) enabled students to discuss con-

cepts presented in the course via a computer. This system is used widely at the University of Michigan to support classes, to hold "electronic meetings" among faculty and staff, to allow better communication among members of special interest groups, and to supplement classroom instruction (Tainter, 1990)

Pretest and posttest perception questionnaires were constructed to measure student perceptions of CC. There were nine perception items for both pretest and posttest versions, each in the form of a 5-point Likert-type scale. The nine perception items relating to CC use were "worthwhile to learn," "valuable in learning course", "freedom from anxiety", "motivational to learn material", "motivation to participate in CC", "help understand material", "encouraging in-class participation", "student responses useful", and "fun way to learn."

The Motivated Strategies for Learning Questionnaire (MSLQ) is a self-report instrument designed to assess college students' motivational orientations and their use of different learning strategies for a college course (McKeachie, Pintrich, Lin & Smith, 1986; Pintrich, Smith, Garcia, & McKeachie, 1991). The MSLQ was used to provide information about student cognitive and motivational characteristics for learning and to determine how these correlated with student perceptions of CC use. There is a total of nineteen subscales that measure student learning/cognitive strategies (e.g., time and study management, thinking skills) and motivation of course work (e.g., intrinsic and extrinsic motivation).

Research Design and Procedure

The research design involved a pretest-posttest analyses of student perceptions regarding CC use in their class. These questionnaires were given either by the course instructor or the experimenter. The pretest questionnaire was administered to all participants within the first three weeks of classes and after the participants were exposed to using CC (i.e., students had signed on at least once or had registered for the class conference). In addition, they completed the MSLQ immediately after the administration of the pretest perception questionnaire. The posttest version of the perception questionnaire was administered within the last week of classes.

RESULTS

Pretest perceptions were found to be positively related to intrinsic motivation, thinking skills, and task value, and negatively related to extrinsic motivation. Analyses of posttest perception items showed similar patterns of correlations and, in addition, time/study management, elaboration strategies, and self-efficacy had relatively high positive correlations with several posttest items.

Table 1 shows significant correlations for all groups combined between student perception items of CC use and student cognitive-motivational characteristics in both pretest and posttest measures of student perception. Nonetheless, in order to minimize the complexity of this analyses, only the most significant correlations ($p<.01$) are reported.

TABLE 1
SIGNIFICANT CORRELATIONS BETWEEN STUDENT PERCEPTION ITEMS AND THE MSLQ

Perception Item	Pretest		Posttest	
	MSLQ subscale (N=209)	r*	MSLQ subscale (N=164)	r*
Worthwhile to Learn	RTT	0.21	TA	0.22
	TH	0.21	TH	0.26
	IM	0.33	IM	0.26
	EM	-0.30	EM	-0.24
	TV	0.20	TV	0.24
			SE	0.22
Valuable in Learning Course	TH	0.24	TSM	0.31
	IM	0.35	ES	0.20
	EM	-0.21	TA	-0.21
			TH	0.26
			IM	0.30
			EM	-0.28
			TX	0.24
			SE	0.22
Freedom from Anxiety	TA	-0.30	TA	-0.24
	EM	-0.21		
	SE	0.22		
Motivation to Learn Material	TH	0.21	TSM	0.30
	IM	0.21	ES	0.25
	TV	0.22	TA	-0.23
			TH	0.30
			IM	0.30
			EM	-0.30
			TV	0.25
			SE	0.20
Motivation to Participate in CC	TSM	0.22	TSM	0.27
	TH	0.25	ES	0.25
	IM	0.29	TA	-0.23
	EM	-0.21	TH	0.30
	TV	0.20	IM	0.30
			EM	-0.26
Help Understand Material	IM	0.20	TSM	0.26
	TV	0.22	ES	0.29
			TH	0.31
			IM	0.27
			EM	-0.29
			TV	0.23
			SE	0.23

*$p<.01$

TABLE 1
SIGNIFICANT CORRELATIONS BETWEEN STUDENT PERCEPTION ITEMS AND THE MSLQ

Perception Item	Pretest: MSLQ subscale (N=209)	Pretest: r*	Posttest: MSLQ subscale (N=164)	Posttest: r*
Encourage In-Class Participation	ES	0.22	TSM	0.24
	RTT	0.21	TH	0.24
	TH	0.23	IM	0.31
	IM	0.21	EM	-0.27
	TV	0.21	TV	0.23
			SE	0.21
Student Responses Useful	PL	0.21	TSM	0.26
	TH	0.20	ES	0.24
			TH	0.23
			IM	0.25
			EM	-0.27
Fun Way to Learn	TH	0.21	ES	0.22
	IM	0.27	TH	0.25
	EM	-0.20	IM	0.31
			EM	-0.27

*$p<.01$

Abbreviations:

TSM - Time/Study Management
IM - Intrinsic Motivation
TA - Test Anxiety
PL - Peer Learning
TV - Task Value (utility)
RTT - Retrieval/test taking
ES - Elaboration Strategies
EM - Extrinsic Motivation
TH - Thinking
SE - Self-efficacy

Figure 1 shows a bar graph comparing the pretest and posttest means for the perception items (standard errors between pretest-posttest items were comparable). T-tests revealed no significant differences between pretest and posttest perception scores for all groups combines ($p>.05$).

Determining patterns of significant correlations between student perceptions of CC and cognitive-motivational characteristics provide important information on which student characteristics are more salient in the perceptions students form relating to the instructional use of CC. Pretest correlations pertain to which characteristics are most important in developing ways to introduce CC, while posttest correlations supplement the pretest findings in determining which characteristics contribute most to student perceptions of CC after they have used it over a period of time.

FIGURE 1
BAR GRAPH SHOWING MEANS FOR PRETEST AND POSTTEST PERCEPTION ITEMS

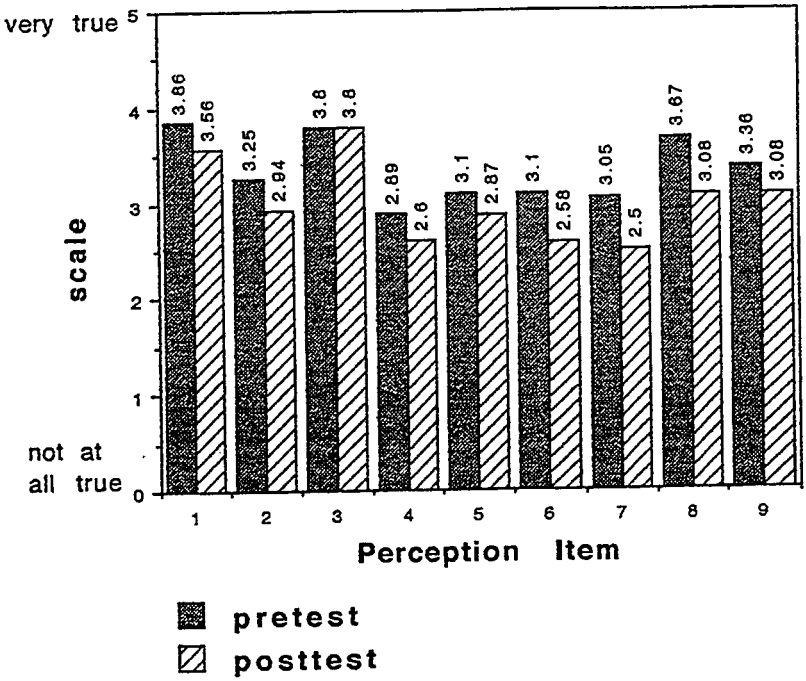

1 = Worthwhile
2 = Valuable in learning course
3 = Freedom from anxiety
4.= Motivation to learn material
5 = Motivation to participate
6 = Help understand material
7 = Encourage class participation
8 = Student responses useful
9 = Fun way to learn

Pretest Student Perceptions and the MSLQ

The correlational findings between the pretest perception measures and the MSLQ suggest that the important student variables that may greatly influence acceptance and positive perceptions towards CC use are intrinsic motivation, extrinsic motivation, and task value for the motivational domain, and thinking skills for the cognitive domain. Instructional strategies that complement the introduction and use of CC should consider these variables as most crucial predictors, not only of student perceptions, but of the successful implementation of CC.

Motivational Characteristics

For all groups combined, intrinsic motivation (IM) was significantly correlated with all perception items, with the exception of "freedom from anxiety" and "student responses useful." IM, from a goal-orientation perspective, refers to the degree in which a student perceives himself or herself to be participating in a task for reasons such as challenge, mastery, or curiosity. It indicates that a student's participation in CC is rewarding in itself, rather than looking at participation as a means to an end (e.g., to get a good grade, a student had to learn and use CC). Students who are highly intrinsically motivated in the learning of the course are more readily accepting of novel methods of instruction than those who are highly extrinsically motivated.

Extrinsic motivation (EM) was found to be inversely correlated with most perception items. EM refers to the degree to which a student participates in CC for reasons such as rewards, grades, competition, and evaluation by others, engaging in a learning task is viewed as a means to an end. Thus, students with high extrinsic motivation tend to perceive CC use more negatively, perhaps because these students perceive the learning and use of this technology as additional work.

Task value (TV) was found to be positively correlated with "worthwhile to learn," "motivation to learn material," "motivation to participate in CC," "help understand material," and "encourage in-class participation." Task value refers to the student's evaluation or perception of the level of interest, importance, and usefulness of the learning task. It relates to what the student thinks of the task, as opposed to goal orientation (e.g., IM, EM) which refers to the reasons why a student is participating in the task. High task value leads to more involvement in learning. The high correlation suggests that what students think of the value of the course is an important characteristic in their perception of the use of CC as an instructional tool. The recognition that the tasks associated with a course are useful and important lends itself to the perception that CC is a potentially useful tool in the learning of the material.

Cognitive Characteristics

Thinking skills (TH) was the major cognitive variable found to be most highly correlated with many of the perception items. TH refers to the degree to which a student applies previous knowledge to relatively new learning situations in order to reach decisions, solve problems, or make critical evaluations. The use of CC as an instructional method may have been evaluated more favorably by students scoring high in TH because they critically recognize and acknowledge the educational potential of such media. This cognitive characteristic appears to be a salient factor in developing more positive perceptions of CC.

Other cognitive characteristics that were highly correlated with only some pretest perception items were retrieval and test taking strategies (RTT), which was highly correlated with "worthwhile to learn"; self-efficacy (SE), which was found to be highly correlated with "freedom from anxiety"; time and study management (TSM), which was determined to be positively correlated with "motiva-

tion to participate in CC"; elaboration strategies (ES), which was found to be highly correlated with "encourage in-class participation"; and peer learning (PL), which was positively correlated with "student responses useful." These characteristics were not consistently highly correlated with all the perception items and are therefore assumed to be influential in the development of more specific perceptions towards CC use as an instructional device for the introductory psychology course (see Table 1). Nonetheless, further research should explore these specific correlations to determine the extent and reliability of the relationships.

Posttest Student Perceptions and the MSLQ

For the posttest analyses with all groups combined, several patterns were also observed. Similar to the results for the pretest, the MSLQ items that show significant positive correlations with the perception items were IM,TH and TV.

Motivational Characteristics

In addition to IM, self-efficacy (SE) was also determined to be highly correlated with all perception items except "freedom from anxiety", "motivation to participate in CC", "student responses useful", and "fun way to learn." Self-efficacy refers to one's self-appraisal of the ability to master a learning task, which includes one's ability and confidence towards such task. It is presumed that students with high confidence in their ability to accomplish a learning task tend to be less anxious in using CC. EM was again found to have a significant inverse relationship with several of the perception items.

Cognitive Characteristics

Similar to the pretest findings, TH and TV were found to have a significant positive relationship with several posttest perception items. Significant correlations were determined for TA, TSM, and ES. First, test anxiety (TA) was found to be negatively correlated with "worthwhile to learn", "value in learning course", "freedom from anxiety", "motivation to learn material", and "motivation to participate in CC." TA, viewed as a form of cognitive interference, refers to negative thoughts that disrupt the performance of a learning task. It appears that students with high test anxiety may have viewed the use of CC as a requirement that added to their anxiety and therefore contributing to their negative perception of its use. Second, time and study management (TSM), which was found to be correlated with "motivation to participate in CC" in the pretest results, was found to be in direct proportional relationship to all perception items except, "worthwhile to learn", "freedom from anxiety", and "fun way to learn." High ratings in TSM pertain to the ability to effectively schedule, plan, manage, and use study time. In addition, it also suggests the ability to set realistic goals, organize the study environment, relatively free of visual and auditory distractions, in order to provide a setting most conducive to learning. It is presumed that students who are better able to manage their study time are more likely to see CC as a beneficial tool to their learning in general. Elaboration strategies (ES) were

also determined to be highly correlated with several of the perception items except "worthwhile to learn", "freedom from anxiety", and encourage in-class participation." ES involve the ability to store information into long-term memory by building internal connections among items learned which include paraphrasing, creating analogies, summarizing, and generative note-taking. These strategies help the learner integrate the material to be learned with prior knowledge. CC use may have been viewed by student with high ES as an efficient and effective medium to learn new material. EM was again shown to be inversely related to all perception items except "freedom from anxiety."

Summary of Results

Intrinsic motivation, thinking skills, and task value were consistently found to be positively correlated with several perception measures for all groups combined. However, extrinsic motivation was consistently found to be inversely correlated with the perception items for all groups combined. Thus, the motivational component seems more salient in the formation of student perceptions. Time and study management, elaboration strategies, intrinsic motivation, and task value appear to be highly correlated with most of the posttest perception items while extrinsic motivation was again found to be significantly inversely correlated. Significant correlations between perception items and cognitive-motivational characteristics also show some variations between groups (Velayo, 1993).

CONCLUSION

Considerable emphasis is placed on the mediating role of student perceptions in instructional activities that parallels a number of general cognitive psychological theories (e.g., Anderson, 1985, 1985; Ausubel, 1968; Brown, Bransford, Ferrara, & Campione, 1983; Bruner, 1964, 1965; Piaget, 1971) and research on teaching (e.g., Shulman, 1986). Given that favorable initial perceptions toward CC is highly linked to a student's intrinsic and extrinsic characteristics, task value, thinking skills and others, it is important that CC be introduced and implemented in a manner that addresses these characteristics.

This study acknowledges the importance of the motivational characteristics involved in developing positive perceptions toward CC use as an effective learning tool. Teacher need to be cognizant of such concerns as early in the course as possible, and would have to find ways to alleviate them in order to plan for a more effective use of CC. Student motivation, learning skills, and prior knowledge about computers in general and the course content, will vary from student to student and from class to class. Thus, the early identification of incentives and the establishment of mutual expectations will set the tone for the participants in the conference. Individual differences such as personal communication skills, previous experience with computer use, technique, or topic, and physical and intellectual abilities may require careful individual attention on the part of the teacher to ensure full participation.

Cronbach (1957) encouraged educators to consider combining knowledge from correlational research on individual differences with the search for meaningful teaching methods to accommodate a broad spectrum of learners. The present study suggests the importance of student motivational characteristics (e.g., intrinsic and extrinsic motivation), and the value that students place on the learning tasks, as important constructs towards a favorable perception and effective use of CC. Some suggestions to make the conference more motivating to a wider variety of students are to provide them with some internal control as a means by which they have some influence over learning events by utilizing features embedded into instruction by the designer (Hannafin, 1984). For example, allowing students to take part in developing the structure of the conference and developing a system permits them to organize items and responses that would suit their individual preferences. Hopefully, these motivational strategies would enhance student motivation in the use of CC as a learning tool.

Similarly, it is important to develop strategies that cater to the cognitive component in student learning, most specifically on developing thinking skills, elaboration strategies, and time/study management. As Tennyson and Park (1986) recommend, intelligent systems need to be holistic and inferential to improve individual learning. Learning tasks should therefore cater to developing there higher-order cognitive characteristics. Developing a conferencing system that encourages the free flow of ideas, energetic discussion of a wide variety of issues of interest to students, and differing viewpoints may stimulate active use of this technology.

The following suggestions have indirect relationships with the results of this correlational study. Nonetheless, these may have considerable merit for instructors looking for ways to enhance CC use as a learning tool. Thus, these suggestions are aimed at providing the instructor with some techniques that may encourage student acceptance and participation in the conference. Since motivational and thinking components appear to be strong predictors of student perceptions of CC, the goals of these recommendations are: (a) to make students aware of the potential benefits of CC in their learning of the course, (b) to present to students an easy to learn, user-friendly system that they can use without much struggling in figuring out how to use it, and (c) to allow student to develop thinking skills in learning the course material by making conferencing activities fun and exciting. Several of these suggestions including a conceptual framework on the classroom application of CC were cited in Velayo (1994).

1. In the course of training students to use CC, it is suggested that students work in paris and/or groups of three. This will allow them to learn collaboratively from each other and will even encourage team work. The kind of activity assigned should clearly stipulate the task each student is to accomplish towards the accomplishment of the group's goals. Furthermore, students should take turn in varying their tasks when undertaking different projects.

2. It is imperative that the purpose and utility of the conference be made explicit to students. Make them aware of the potential benefits of using this technology in their learning and as an important way to communicate with one

another in class. Also, make sure that your expectations with regard to the CC use is communicated to the students. Be cognizant of student expectations.

3. It is important to convey to the students, early in the course, that you are available to guide, supervise, and support their learning of the system. It may be prudent to allow students with alternative ways to communicate or do the requirements, at least initially, as they are still learning how to use the conferencing system.

4. Encourage students to ask questions, conduct their preparations for a class project, share their ideas, and the like, using the conferencing medium. Student feedback is very important. Be receptive to student comments, suggestions, and questions about CC use in class. Their input must be given attention and consideration in the design and implementation of the system.

5. Regularly monitor the conference, respond to student inquiries and comments, paraphrase responses, and provide feedback to students. Ask students to exchange ideas, no matter how outrageous, and to critique each other's responses or work. However, it is important to set rules with regard to courtesy and the use of noninflammatory language.

6. Respond promptly to student questions, comments, and suggestions in the conference. This will encourage students to use CC as a means to obtain instructor response quickly and efficiently. Also, regularly enter questions, create items or topics that stimulate discussion, and the like to challenge the student's ability to think about issues and concepts presented in the course. Hopefully, this will not only encourage them to participate but also to think and elaborate about the things they learn.

7. Allow students sufficient time to explore and practice using CC and initially provide them with simple tasks to do (e.g., sign on, register as a participant to the conference, respond to an item, etc.)

8. Allow flexibility on the part of the students in their participation in the conference. It may be prudent to provide students, at least during the first few weeks of classes, with alternative options in undertaking class requirements that would eventually be made via CC. For example, during the first few weeks of classes, allow student to submit assignments in typewritten form instead of using the conference to submit their work. As mentioned earlier, it is important that students understand the utility of CC use in class in order to encourage acceptance and efficacy.

9. One way to motivate student acceptance and use of technology is to develop a conference that students find interesting. It should combine play and learning by embedding motivational features into the material. It should allow learners easy and flexible control of the learning environment and easy access from obtaining help or consultation regarding the use of the system. Thus, system considerations must therefore take into account both the motivational and task components in order to enhance the potentials of CC as a learning tool. A play or game-like CC environment may be an effective way of motivating students not only to participate but to learn how to use the system. Malone (1981) recognize the value of games in activating motivation to learn. Designing a sys-

tem that encourages team work among groups of students might be enticing for many students. For example, divide the class into groups and form teams that debate certain issues.

10. A practical suggestion is for teachers to administer some form of formal or informal survey at the beginning of the course to have an idea of the what the students are like in terms of their motivational and cognitive characteristics, as well as their expectations about the course and toward CC. This information is crucial because it allows the teacher to develop and structure the conference that would accommodate student sin the class in terms of their use of the conference. If students know that they played an important role in the design and implementation of the system, they are more apt to view the use of CC more favorably and probable give more credibility to the conference as an instructional tool.

Many teachers become quite preoccupied with establishing learning objectives for students without enough regard for student motivation (e.g., intrinsic motivation) for the course. Teachers should develop their use of CC technology that motivates students and clearly provides learning tasks that encourages CC use. The proper implementation of these features may, in turn, allow students to recognize and likely use CC in more effective ways.

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USING A SELF-REFERENCE STRATEGY TO ENHANCE MEMORY FOR COMPUTER-ASSISTED INSTRUCTION

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ABSTRACT

This experiment examined how well students remember information presented through computer-assisted instruction (CAI) as a function of a self-reference strategy. Students were randomly assigned to either the self-reference (SR) group [i.e., tutorial presented using the first person point of view in its text description and the inclusion of a "happy face" as a figure from which the learner identified with] or the control group [i.e., tutorial presented using the third person point of view in its text description without the "happy face"]. Memory test scores and student confidence levels were significantly higher for the SR group. Confidence level also had a relatively high correlation with the total memory test score. Amount of time spent on each tutorial lesson did not significantly differ between groups.

The objective of this research was to find out the effects of "self-referencing" on memory for computer-assisted instruction (CAI). The major tenet in the development of the courseware tutorial used is that it may be a more effective method to enhance students' ability to remember information if presented in a 'self-reference" context. According to Matlin (1989), self-reference occurs when a learner relates information to oneself to enhance involvement in the learning situation.

In the classic demonstration of the self-reference effect, Rogers, Kuiper, and Kirker (1977) asked participants to process lists of words according to the kinds of instructions usually studied in levels-of-processing research, that is, in terms of their physical features (letters), their acoustic (sound) features, or their semantic (meaning) features. However, other words were processed through a "self-reference" strategy (i.e., people were asked to decide whether a particular word could be applied to themselves). The results revealed that the self-reference task produced the best recall.

Apparently, when we think about a word in connection with ourselves, we develop a particularly effective coding for that word. For example, suppose you are trying to decide whether the word "helpful" applies to you yourself. You

might remember how you helped a classmate study for a math test or assisted an old lady cross the street. In these instances, the word "helpful" does apply.

Self-reference has repeatedly been shown to be effective in memory, for example, with instructions to create mental images (Brown, Keenan, & Potte, 1986), with words related to creativity (Katz, 1987), with children as young as ten years old (Haplin, PUff, Mason, & Marston, 1984), and with elderly adults (Rogers, 1983). Other studies have investigated whether "other -reference" instructions can be effective, that is, remembering information that has been related to those you know (e.g., Is it helpful to ask yourself whether the word helpful applies to your friend. In general, however, the findings indicate that it is more helpful to process a word in terms of whether it applies to you, to someone very familiar, or to a significant other rather than to someone unfamiliar (Bower & Gilligan, 1979:Ferguson, Rule & Carlson, 1983; Keenan & Baillet, 1980).

What produces the self-reference effect? So far, we know this self-reference phenomenon exist, but have no comprehensive psychological explanation for it. Genellan and Carver (1985) proposed that it is not so much the desirability of a word or concept but rather, its "relative importance" to the individual. For example, the participants in Ganellan and Carver's study recalled 42% of words that applied to themselves, in contrast to 32% of words that did not apply. Belleza (1984), however, suggest that the "self" is treated as an organized set of internal cues to which information can be associated that allows increased learner's involvement in the memory process. (Presumably, a person's mother or other highly familiar people are also associated with a rich, organized, set of internal cues.) Similarly, Klein and Kihlstrom (1986) focused especially on organization as an explanation for the self-reference effect. They suggest that the "organizing" of new information into one's already developed self-schema (i.e., interconnected set of knowledge about oneself) is much easier to do and therefore much easier to remember.

This research proposed a practical application of the self-reference effect in a particular learning context—learning by CAI. In this age of increased use of technological devices in education, the use of computer tutorials, interactive CD-ROM, and laser disk technology for student learning is of particular concern. Thus, in the development of these tutorials, it is important to be concerned with how to best "fit" them for the learner's use. This study determined the effects of self-referencing as a learning strategy to enhance memory by incorporating a self-referencing instructional feature in CAI.

EMPIRICAL QUESTIONS

The main purpose of this research was to determine how well college students remembered information presented through CAI (i.e., a tutorial courseware) because of self-referencing. The major interest was whether or not the self-reference strategy enhanced a learner's ability to remember information from computer-assisted instruction. Additional questions were: (a) Does a learner's level of "confidence" influence memory for instructional material?, and (b) Is there

greater involvement in learning the instructional material when employing a self-referencing strategy as indicated by the amount of time spent studying?

METHOD

Participants

The participants were 34 undergraduate students enrolled in an undergraduate psychology course at a large midwestern American university. They were encouraged to participate in the experiment by offering them extra-credit points toward their final grade and by explicitly pointing out to them the benefits of participating in this research (e.g., contribution to psychological and educational research, personal enrichment). There were 18 participants (14 males, 4 females) in the self-reference group and 16 participants (10 males, 6 females) in the control group, each of whom were randomly assigned. From this sample, there were 8 freshmen, 18 sophomores, 4 juniors, and 4 seniors.

Experimental Design

The experiment was an independent two-group design with the type of tutorial (i.e., self-reference versus control) as the between-group variable. The primary dependent variables were: (a) test scores for each of three memory tests (i.e., the identification, terminology, and comprehension tests); (b) the combined total score of all three memory tests; (c) level of "confidence" after completing all three lessons but prior to taking the tests; and (d) amount of study time it took to complete each tutorial lesson.

The two types of tutorial conditions were as follows:

1. Self-reference (SR) group - The courseware tutorial involved the use of the first person point of view in its text description and the inclusion of a "happy face" as a figure from which the learner can identify oneself with in the learning situation and to enhance involvement in going through the lessons. Verbal and computer instruction were provided to enhance self-referencing. More specifically, participants were told by the experimenter the following: "The computer tutorial sessions will teach you the parts and functions of the human heart. I am interested in how much you can remember of what will be taught to you. As the information is presented to you, imagine that you are studying the parts and functions of your own heart. Imagine how your heart beats and how blood goes in and out of it. More instructions on how to use this strategy will also be explained to you at the start of the tutorial. After you go through the tutorial, you will be given a series of tests on how much you remember."

The rest of the lesson content and the tests were basically the same as the control group but without the instructions pertaining to the self-reference strategy.

2. Control group - the tutorial involved the use of the third person point of view in its text description excluding the "happy face." No verbal or computer instructions were given to the participants relating to the self-referencing strategy.

Materials

Two software tutorials (a self-reference version and a control version) were developed to teach and test students the parts and function of the human heart. Both tutorials were developed from a questionnaire version (Velayo, 1993) containing basically the same information reported in a study by Dwyer (1978). Both tutorials contained three lessons: the heart and its functions, the circulation of the blood, and the systolic and diastolic cycles of the heartbeat, and three types of memory tests (i.e., an identification test, a terminology test, and a comprehension test) that were administered to the participant after studying all three lessons. Memory tests administered to the participants were incorporated within the tutorial software. The tutorial also automatically scored each test, the results of which were then shown to the participant after he or she finished all three tests.

Description of Courseware Tutorials

The content material in both types of tutorials, adopted from Dwyer (1978), is a 2,000-word instructional courseware that described the human heart, its parts, and the internal processes that occur during the systolic and diastolic phases.

According to Dwyer (1978), some of the favorable characteristics of this instructional courseware are: specific types of educational objectives (i.e., identification, terminology, and comprehension) to be achieved were identified; a specific content area that permitted meaningful learning to occur was selected (i.e., parts and functions of the human heart); three criterion tests measuring student learning and retention of the different types of educational objectives were constructed; and visualization was systematically integrated into the verbal content material. Other favorable features were also added in the development of the courseware to help enhance the learning of such material such as the use of arrows to point at certain parts of the heart to focus the student's attention; the use of animation to show the direction of blood flow to an from the heart; and the more interactive nature of the tutorial in view of the student being able to learn the lessons and take the tests in whatever sequence preferred. The student was also able to review the lessons and retake the tests if so desired. Each student was also permitted to take as much time as needed to complete one test before preceding to the next.

The following is a description of each test in terms of what each measures and the kind of educational objectives each test assesses.

Identification Test.

This 20-item multiple-choice (i.e., a student is required to point and select the correct answer using the mouse) test requires the learner to identify the different parts on a detailed drawing of the human heart. Learners are required to look at the picture of the heart and select the correct answer for each multiple-choice item based on what part of the heart the arrow points to. This test measures the student's ability to recognize, identify, and associate specific parts of the heart

with their correct labels.

Sample item: The arrow point to the...

aorta
mitral valve
superior vena cava
inferior vena cava
septum

(picture of a human heart)

Terminology Test.

This 20-item multiple-choice and fill-in test (i.e., a student is required to type the correct answer) is designed to measure the student's knowledge and ability to recall and recognize specific facts, definitions, and terms regarding the human heart.

Sample item: Multiple choice

Blood from the right ventricle leaves the heart through the_____.

veins
aortic artery
pulmonary artery
superior vena cava

Sample item: Fill-in

_____(are) the thick-walled chamber(s) of the heart.

Comprehension Test.

In this 20-item multiple-choice and fill-in test, the learner is given the location of certain parts of the human heart at a particular moment of its functioning and is asked to identify the position that other specified parts of the heart would be occupying at the same point in time. This test requires that the student have a thorough understanding of the heart, its parts, its internal processes, and processes occurring during the systolic and diastolic phases. This test is designed to measure the type of learning that occurs when the student comprehends what is being communicated and can use the information being received to explain some other phenomenon occurring simultaneously.

Sample item: Multiple choice

The contraction impulse in the heart starts in...

the septum
both ventricles simultaneously
both auricles simultaneously
the arteries

Sample item: Fill-in

Which valve is most like the tricuspid in function?

The scores obtained on the three tests used were also added up into a total score.

Procedure for Data-Gathering

The participants were first briefed as to purpose and the procedures they will undertake. They were instructed how to use the tutorial hands-on. When ready, students went on to study the tutorial lessons while the experimenter recorded the amount of time spent on studying each lesson.

Prior to test-taking, students were asked to fill out a 10-point confidence rating scale that asked how confident they were in being able to correctly remember what they had just studied. A rating of 1 was indicative of "not confident at all" while a rating of 10 indicates "very confident."

Students were then asked to take the memory tests in the same sequence—identification test first, terminology test next, and comprehension test last. After all three tests were completed, the computer tutorial automatically computed the scores for each and a total score equivalent to the sum of the three separate tests. Students were then debriefed regarding the objectives of the experiment.

RESULTS AND DISCUSSION

Results indicate that the self-reference (SR) group scored significantly higher than the control group for the terminology test ($t = 2.34$, $p < .05$) and the comprehension test ($t = 2.24$, $p < .05$). The total score for the SR group was also significantly higher than the control group ($t = 2.64$, $p < .05$). Table 1 shows the means and standard deviations on memory test scores for the self-reference group and the control group (see Figure 1 for a graphical representation.).

Students in the SR group were generally better at recalling and recognizing specific facts, definitions, and terms. They also had a better understanding of the human heart, its parts, and the internal processes during the systolic and diastolic phases. Their scores on the identification test did not significantly differ from the control group although their average score was higher. This may indicate that the self-referencing procedure had only a small impact on a student's ability to recognize, and identify the specific parts of the heart. It therefore appears that the self-referencing strategy is more influential in recall tasks that were measured primarily by the terminology and comprehension tests.

Thus, overall findings relating to the memory tests indicate greater means in the direction favoring the self-reference group and a higher variability of scores in the control group for the memory tests.

TABLE 1
MEAN AND STANDARD DEVIATIONS ON MEMORY TEST SCORES FOR THE SELF-REFERENCE GROUP AND THE CONTROL GROUP

	Self-reference Mean (SD) (N=18)		Control Mean (SD) (N=16)	
Memory Test Score				
identification test	16.5	(2.7)	15.1	(3.1)
terminology test*	13.7	(3.3)	10.0	(3.8)
comprehension test*	11.6	(3.0)	10.7	(2.9)
Total*	**41.8**	**(6.9)**	**35.8**	**(8.7)**

*$p < .05$

FIGURE 1
BAR GRAPH SHOWING MEAN SCORES FOR EACH MEMORY TEST AND THE TOTAL SCORE FOR THE SELF-REFERENCE GROUP (N=18) AND THE CONTROL GROUP (N=16)

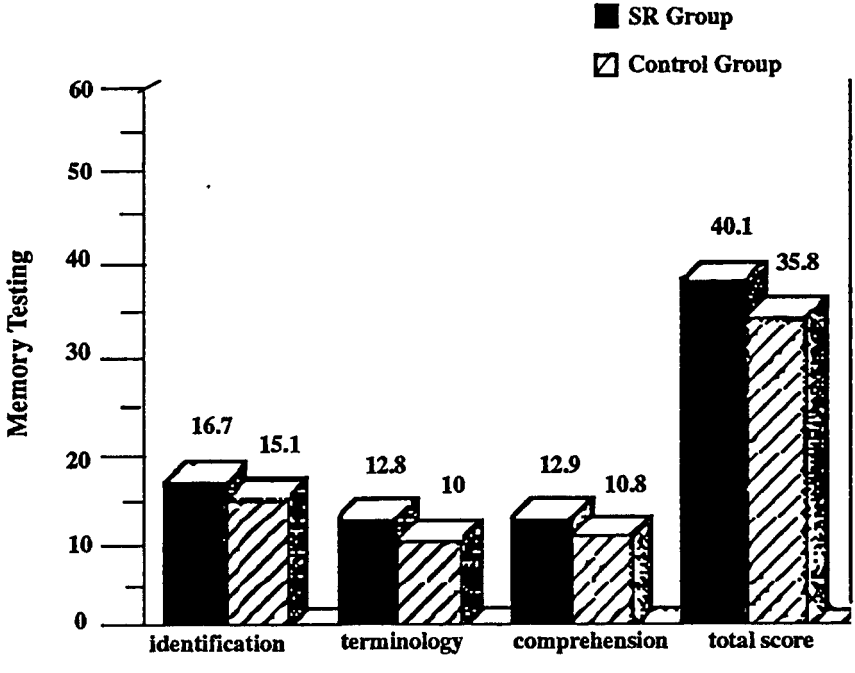

Students in the SR group had a higher confidence level with regard to doing well on the memory tests than the control group did, $t = 2.31$, $p < .05$ (See figure 2). It would appear that the self-reference group's higher expectation on their performance had a positive influence on their actual performance on the memory tests. Cognitive-motivational theories on learning (e.g., Eccles, 1983; McKeachie, Pintrich, Lin, Smith, & Sharma, 1986) anticipate this finding.

FIGURE 2
BAR GRAPH SHOWING MEAN CONFIDENCE RATINGS FOR THE SELF-REFERENCE (SR) GROUP (N=18) AND THE CONTROL GROUP (N=16)

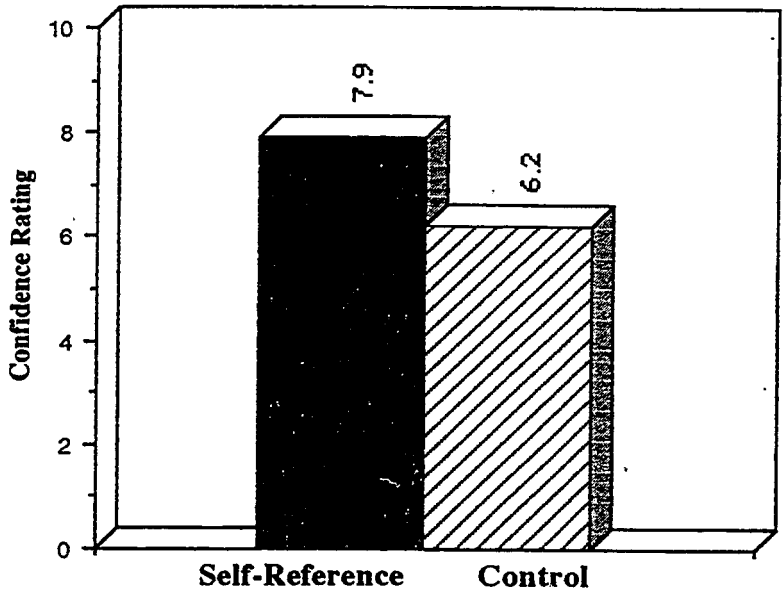

Confidence level also had a relatively high correlation with total score for the memory tests ($r = .601$, $p < .001$). This predictive relationship is supported by several models of motivation that look at similar concepts of self-efficacy and outcome expectancy (e.g., Bandura, 1977; Eccles, 1983, McKeachie et al., 1986).

There was no significant difference between groups in the amount of time spent on the lesson sequence.

The use of CAI as a means to enhance student learning is an important aspect of the technological future of instruction. The effective use of technology in teaching and learning is based on the development of education materials that would enhance learning. Given the findings of this study, the self-reference strategy has been shown to have a positive influence on the memory process and confidence level for learning through CAI. As Matlin (1989) pointed out, the self-reference effect enhances one's involvement in the learning context, and in

turn, improves one's ability to recall information. Such strategy may allow the learner to use the self-schema, in which new information becomes easier to "fit" or incorporate given that under normal circumstances, one's schema is highly organized and established. This makes it easier to encode new material. It is also possible that the self-reference strategy more easily lends itself to some visualization strategy in which learners imagine themselves in the context of the what they are learning.

Future studies on the instructional potentials of self-referencing may focus on determining its motivational properties for learning and memory. In addition, analyzing learner cognitive characteristics in relation to the effectiveness of the self-reference strategy may provide a better understanding on individual differences in the ability to encode, retain, and retrieve information. Different instructional contexts and subject matters would certainly be important components that influence the effectiveness of CAI and...in developing effective learning and memory strategies. Thus, the educational implications of this research are not limited to computer-assisted instruction but other instructional contexts as well.

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Supplementary Classroom Instruction via Computer Conferencing

Richard S. Velayo

Computer conferencing (CC) is a computer-mediated communications medium in which individuals or groups are able to interact with each other primarily through electronic text, without the relative constraints of having to meet at a specific place and time. This technology has found its way into many academic settings, especially at the postsecondary level of education, primarily as an instructional method used to enhance and supplement teaching and learning.

There have been a number of studies that suggest that CC is a satisfactory alternative to face-to-face communication for a variety of communication activities (e.g., Budin, 1991; Danowski, 1982; Ferguson, 1977; Hiltz, 1986; Hiltz, Turoff, & Johnson, 1985; Phillips, 1983; Rice, 1982; Tooey & Wester, 1989). It is regarded as a technological innovation that allows both teachers and learners the ability to interact with each other beyond the confines of the classroom (Hiltz, 1986; Saunders & Heyl, 1988; Smilowitz, Compton, & Flint, 1988; Waggoner, 1992a). Thus, CC may encourage learning and further interaction among students by allowing their responses, questions, and opinions to be made public. From such deliberations and interactions, participants in the conference learn from each other. Given the educational implications of CC, the proposed theoretical framework is helpful in providing educators with a useful guide in the instructional application of this technology. This may also be of interest to researchers in educational technology in discovering the potentials of this medium to educate. General considerations and recommendations that may enhance the effectiveness of CC as an instructional tool are also presented.

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Note, however, the portrayal of CC in this framework does not generally extend to a kind of distance learning application that some refer to as a "virtual classroom," but rather, students do meet as a class in which the use of CC complements and extends classroom learning.

A Conceptual Framework

Incorporating CC as a supplement to teaching and learning requires a conceptual framework from which to develop instruction that would be most appropriate for a particular learning context. There have been other models presenting various constructs of the learning process (e.g., Biggs, 1987, Chirwa, 1992; Dunkin & Biddle, 1974; Entwistle, 1981; McKeachie, Pintrich, Lin, Smith, & Sharma, 1986). Although there are some similarities among these models, the proposed framework (Figure 1) presents a more social-cognitive view of learning in a conferencing environment that is more "classroom-specific" and "student-centered." Its unique aspects are that it incorporates not only CC technology as a major instructional method of instruction, but also considers the teacher (a major component of the model) as an active agent in the conference who monitors student learning and motivation and (re)structures the conference to enhance its use as a learning tool.

This conceptual framework is derived largely from learner-centered models of learning developed by McKeachie, Pintrich, Lin, Smith, and Sharma (1986) and that of Chirwa's (1992) ILTE (Incorporating the Learner into the Technology Environment) model. An important aspect of the model presented is the assumption that the effects of instruction are mediated by students' cognitive and motivational characteristics. The model looks at CC as one important mediating factor that influences student cognition and motivation. It focuses primarily on how teaching, as supplemented by the use of CC, affects student thinking and motivation and, in turn, how it affects academic performance or achievement.

The theoretical framework of this study operates on the premise that the outcome of a student's academic performance is influenced more by the direction and degree of the student's self-regulated learning (i.e., student engagement and commitment to the learning task) than by any other single factor. CC may be one way to positively influence such engagement. CC is viewed not as a replacement for the instructor nor live discussions in class but rather as a unique medium that provides a complementary way of interacting which has useful educational applications.

Relationships Among Components

The dynamic interrelationships of the model's components are depicted using arrows. The direction of

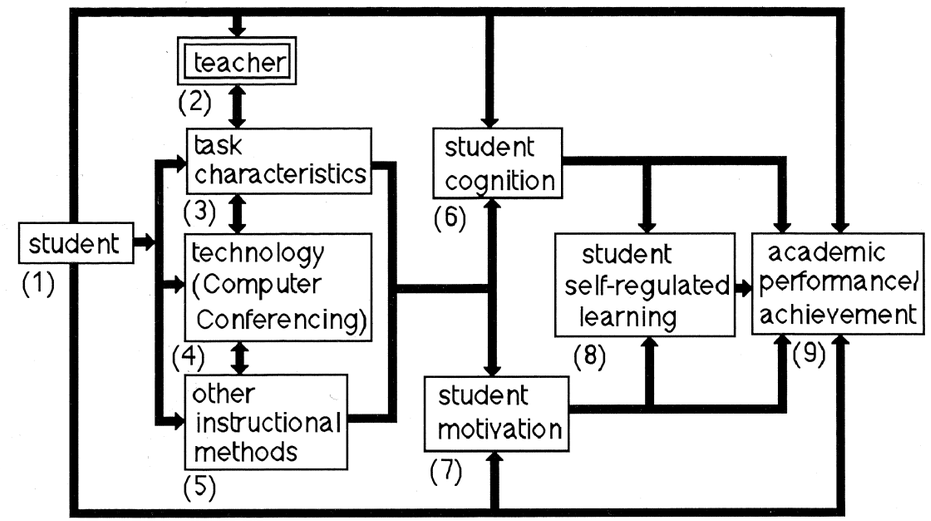

Figure 1. Model of computer conferencing used as a supplement to classroom instruction (Velayo, 1993).

the arrows show the relative influence of one construct on another. Analyses of the relative strengths and directions of these interrelationships may be found in Pintrich, Smith, Garcia, and McKeachie (1991), but with the absence of the teacher and the CC technology components. This proposed framework provides a perspective in looking at certain key components that may affect classroom learning from a learner-centered perspective with the inclusion of two other important components—CC technology and the teacher. In recognizing the powerful influence of these two constructs, teachers should develop their use of CC technology that motivates students and clearly provides learning tasks that encourages CC use.

Task characteristics, instructional methods, and the use of CC as an instructional tool must be developed in view of student entry characteristics. Teachers, therefore, must be able to obtain some knowledge about the students in order to provide a better match between learning and instruction. Flexibility in the implementation of CC must be integrated into the course, taking into account student needs, abilities, attitudes, and perceptions about its use, and the class in general. These factors continually influence student motivation and cognition about their learning of the course. The teacher regularly monitors, evaluates, and structures learning tasks and the use of instructional methods, primarily CC use, to maximize student learning in the course of the learning period. Teachers are able to obtain student comments on the effectiveness of the learning environment from evaluating student motivation and cognition by either formal methods (e.g., survey student on attitudes and perceptions) or informal methods (e.g., asking selected students their general impressions of the course).

The successful implementation and effective use of CC depends critically on the teacher's ability to teach and motivate the students regarding its use, purpose, and to convey to students the advantages of having the conference as an integral part of the learning. The following section offers some practical guidelines.

Preparing the College Classroom: Recommendations for CC Use

The influx of computers on campuses is inevitable and their value will be determined not by how many computers there are, but by how they are used. Computers are obviously not a panacea for the many problems affecting the quality of higher education, but they can offer ways to help improve learning in the classroom. One of these ways may be through CC. As Hiltz (1986) pointed out, there is enormous potential in the use of CC for teaching and learning.

This section presents important general recom-

mendations and considerations for instructors who use CC to supplement classroom instruction. These recommendations may also be of use to researchers exploring variables that enhance the educational potentials of this technology. The implementation of these recommendations, however, may be modified to suit the instructional context involved.

General Recommendations for CC Use

When planning to expose the student to the use of CC as a learning tool, the teacher must be aware of many factors that may influence student learning as well as the interrelationships among these factors. The general guidelines that have motivated these recommendations stem from a learner-centered approach to education. In order to incorporate the student into the conferencing environment, it is important for teachers, as well as students, to know their initial strengths and weaknesses, their wants and needs, and other entry characteristics that may influence learning.

These recommendations are categorized into three parts: (1) CC structure and training, (2) student acceptance and efficacy, and (3) implementing tasks through CC.

CC Structure and Training

1. The conference should be structured or organized prior to the beginning of the course. Students will want and need to have an idea of what the conference "looks" like, how it works, and what its intended purpose is, in order to provide a schema to better understand how the conference relates to learning in the course. This will also make the transition to the CC environment much easier to adjust to on the part of the student.

2. Certainly, training on the use of CC is important, but teach only the basic knowledge and skills to enable the student to function successfully in the CC environment in view of the instructional tasks of the course. It should not be surprising that teachers may have to show some students how to turn the computer on and explain what a floppy disk and a hard disk are. Students have varying levels of computer literacy. Initially, it may be best not to go over the details regarding the more complicated and technical aspects or capabilities of the system (e.g., uploading and downloading files). If these complex tasks are necessary in the use of CC in the course, these may be taught later. As they get more sophisticated in their use of the system, they will likely seek to learn more complex features and capabilities of the CC system.

3. Provide students with an easy-to-follow, step-by-step tutorial on how to successfully sign on and function effectively in the CC environment. During the initial stages of training, go through the steps together to see if students are able to follow directions. This will also provide feedback on how to improve the tutorial handout.

4. It may be best to initially do practice sessions in a computer lab for the first couple of weeks or so, where the instructor is readily available to respond to student inquiries.

5. In the course of training, it is suggested that students work in pairs or groups of three. This will allow them to learn collaboratively from each other and will encourage teamwork.

6. Have students register for the conference (i.e., sign up to participate in CC) by sending demographic registration information (e.g., year level, age, hobbies, and interests). This will allow students to get to know one another and hopefully establish a sense of community as a class.

Student Acceptance and Efficacy

1. Make CC use a graded requirement for the course. Students must use this technology on a regular basis as part of accomplishing learning tasks for the course. Otherwise, students may not use the technology, if other, more traditional options are explicitly made available to them.

2. It is imperative that the purpose and utility of the conference be made explicit to students. Make them aware of the potential benefits of using this technology in their learning and as an important way to communicate with one another in class. Also, make sure that expectations with regard to the use of CC are clearly communicated to all students. Be cognizant of student expectations.

3. It is important to convey to the students, early in the course, that the teacher is available to guide, supervise, and support their learning of the system. It may be prudent to allow students with alternative ways to communicate or do the requirements, at least initially, as they are still learning how to use the conferencing system.

4. Student feedback is very important. Be receptive to student comments, suggestions, and questions about CC use in class. Their input must be given attention and consideration in the design and implementation of the system.

5. Regularly monitor the conference, respond to student inquiries and comments, paraphrase responses, and provide feedback to students. Ask students to exchange ideas, no matter how outrageous, and to evaluate or review each other's responses or work. However, it is important to set rules with regard to courtesy and the use of noninflammatory language.

6. Respond promptly to student questions, comments, and suggestions in the conference. This will encourage students to use CC as a way to obtain instructor response quickly and efficiently.

7. Allow students sufficient time to explore and practice using CC and initially provide them with simple tasks to do (e.g., sign on, register as a participant to the conference, respond to an item, etc.).

8. Allow flexibility on the part of the students in view of their participation in the conference. It may be prudent to provide students, at least during the first few weeks of classes, with alternative options in undertaking class requirements that would eventually be made by using CC. For example, during the first few weeks of classes, allow students to submit assignments in a typewritten form instead of using the conference to submit their work.

9. Explore other ways to motivate students to participate in the conference. A play or game-like CC environment may be an effective way of motivating students not only to participate, but to learn how to use the system. Banet (1979) and Malone (1981) recognize the value of games in activating one's motivation to learn. Designing a system that is more "game-like" and that encourages teamwork among groups of students might be enticing for many students.

10. Finally, encourage students to ask questions, conduct their preparations for a class project, share their ideas, and the like, using the conferencing medium.

Implementing Tasks Through CC

1. Make sure that class requirements are clearly linked to the use of CC (e.g., use the conference as a way to obtain announcements, respond to graded open-ended questions, discuss group topics, etc.).

2. As an ongoing task for students, regularly ask them for a formative evaluation of CC use, during and even at the end of the course, on how the use of CC in class may be improved as a tool for learning.

3. CC may assist in reviewing for exams and tests.

4. Use the conference as a means to convey announcements and to disseminate other information about class matters.

In adopting CC technology, the recommendations mentioned above may prove to be crucial to the successful implementation of CC in instructional contexts. Nonetheless, what may be the most important initial step in enhancing student motivation is to help them become more "metacognitive" of their use of CC. That is, teachers may want to explain to the students early in the course: (a) why this technology is relevant, and (b) how it will help them in their learning.

Additional Considerations

Given the literature on the educational applications of conferencing technology, the following sections present some additional considerations with regard to the instructional use of CC. These sections are categorized as follows: (1) CC structure and system considerations, (2) student characteristics, and (3) class characteristics.

CC Structure and System Considerations

CC system software has become more sophisticated and user friendly over the years. Despite the increasingly sophisticated software design options available, there seems to be some limit to what a user will undertake and a time within which it must demonstrate a utility or payoff. This is an additional element to be considered in the design of a CC environment. Katter (1970) introduced the concept of a user's "line of credit" relating to a learner's introduction to a new system or task involving interactive computing. It suggests that during an allotted time period, the system used or learned must deliver the expected benefits before the user's "patience" is exhausted. Otherwise, the learner may not perceive the use of the system as beneficial for the specific purpose intended. The novelty inherent in the use of a CC system during this "line of credit" period must be used to engage the motivation of the learner to continue using the system and to undertake the academic task. Thus, instructors may need to develop innovative uses for CC by creating a variety of topics of interest to students and developing a variety of learning tasks associated with these topics.

Another important issue to consider are some of the apparent limitations of CC as a communication device (Waggoner, 1992b). For example, CC is limited to the transmission of typewritten text (at least at this point in its development and implementation) and nonverbal cues, which may be an important source of learning, and therefore information exchange is not always efficiently transmitted. This phenomenon has been widely studied (Feenberg, 1989; Kerr & Hiltz, 1982; Kiesler, Siegel, & McGuire, 1984). These studies suggest that mechanisms need to be developed and employed to compensate for the absence of the nonverbal element that is so integral to classroom learning. The consideration of this issue is particularly important in a teaching-learning situation where learner progress is assessed by observing nonverbal behavior and where some teacher feedback may be given nonverbally.

There are other major factors in a CC system that are of primary concern to students. These are the accessibility of computer resources able to utilize the CC system, use of an on-line "help" system for both instructors and students, methods of instruction to teach CC, limitations in the use of verbal typewritten communication, and the delay in communication inherent to asynchronous systems. At the present time, these seem to be inherent problems in many educational settings, but it is expected that the increased use and development of this technology will eventually minimize these concerns. Nonetheless, it is important for teachers to be intuitive as to the feasibility of CC for teaching and learning given the resources

available and the constraints that impinge on the tasks, methods, and goals involved.

Student acceptance of CC technology is certainly also a key component in its success as a learning tool. One way to motivate student acceptance and use of technology is to develop CC systems that are relatively easy to teach and learn. It is a good idea to combine play and learning by embedding motivational features into the design or structure of the conference. It should allow learners easy and flexible control of the learning environment and easy access from obtaining help or consultation regarding the use of the system. Thus, system considerations must take into account both the motivational and task components in order to enhance the potential of CC as a learning tool.

In addition, Tennyson and Park (1986) recommend that intelligent systems be holistic and inferential to improve individual learning. Learning tasks should therefore cater to developing student cognitive skills. Developing a conferencing system that encourages the free flow of ideas, energetic discussion of a wide variety of issues of interest to students, and differing viewpoints may stimulate active use of this technology.

Student Characteristics

Student preparation, training, and monitoring by the teacher are important concerns in the successful implementation and use of CC. Similarly, demographic, environmental, and other student characteristics should provide important information in the design and implementation of the conference and the tasks involved.

Cronbach (1957) encourages educators to consider combining knowledge from correlational research on individual differences with the search for meaningful teaching methods to accommodate a broad spectrum of learners. Some suggestions to make the conference more motivating to a wider variety of students is to provide them with some internal sense of control in influencing learning events by using features embedded into instruction by the designer (Hannafin, 1984). For example, allow students to take part in developing the structure of the conference and a system that permits students to organize items and responses that would suit their individual preferences. Compromises may have to be reached to satisfy most students.

It is probable that many students have to contend with two debilitating forces in their use of telecomputing technology namely, computer anxiety (Cambre & Cook, 1987; Harris & Grandgenett, 1992; Lambert & Lenthall, 1989; Oetting, 1983; Rosen & Maguire, 1990) and writing apprehension (Harris & Grandgenett, 1992). If CC is to be successfully implemented as a supplement to classroom learning, participants may need assistance in overcoming the crippling effects of these two forces. These may be minimized by having a relatively informal, free-flowing discussion of the issues within the conference. Conveying to students that their ideas and opinions within the conference are more important than their correct use of grammar and coherence in their writing, at least in the first few weeks of learning the system, may be helpful. In addition, the sharing of each other's "critical thinking" of the issues discussed in the conference is what really matters. Providing each student with sufficient training in getting used to the system for some period of time would also allow students to get acquainted with each other, and with the CC system itself. Hopefully, this will help alleviate much of the anxiety and writing apprehension they experience.

A practical suggestion for teachers is for them to administer some form of survey at the beginning of the course to have an idea of what the students are like in terms of their motivational and cognitive characteristics, as well as their expectations about the course and toward CC. This information is quite useful because it allows the teacher to develop and structure the conference that would accommodate the diversity among students. As shown in the proposed model, teaching takes on a facilitating role and restructures the conference based on student comments, student cognitive and motivational characteristics, and learning outcomes.

Class Characteristics

Because of the complexity of the learning environment, other "class" variables must be accorded some attention in developing a conducive CC environment. Though individuals in a class possess distinctive characteristics, they also develop characteristics as they become part of that class. Kerr and Hiltz (1982) pointed out three factors that may effect communication and learning through CC. These major factors are as follows:

(1) *Structural factors.* These refer to the size of the group or class, the extent to whether leadership in a group or class is centralized or decentralized, degree of geographical dispersion among participants, and the level of pre-existing ties among the participants in the class.

(2) *Leadership.* This is an important quality in the effective functioning of groups in a computer-mediated environment (Kerr, 1986). It may be important that the teacher, whether explicitly expressed or not, initially take the leader role. This would allow a more organized and structured introduction to the CC system. Leadership has been cited as a crucial element in collaborative learning activities in conventional face-to-face settings (Johnson & Johnson, 1975; Johnson, Johnson, Holubec, & Roy, 1984) and in the successful functioning of computer-mediated communication systems (Kerr, 1986). Since a major purpose of CC is to be able to share and discover knowledge using all participants as potential resources in a collaborative learning style, leadership is clearly a critical issue.

(3) *Group cohesiveness.* It is worthwhile to have some knowledge of the students' academic competitiveness, ability to work in groups, and willingness to express opinions and feelings. According to Waggoner (1992b), bringing a group together in an on-line communications activity, especially when the members of such a group do not initially know each other, may be assisted by beginning with more traditional communication methods, such as using the telephone, conventional mail, and written text. This may be important in providing the students with some skills on how to correspond, relate, and collaborate.

These additional considerations may be important factors in influencing student perceptions, use, and acceptance of CC. It is imperative that teachers be cognizant of the relative influence of these factors on the instructional potentials of CC.

Conclusion

Further research on the application of CC in various instructional contexts is necessary. The eventual use of CC as a supplement to classroom learning may well be imminent in the classroom of the future. Therefore instructors, as well as researchers, must now concentrate on how to develop effective and efficient use of this technology in view of realizing its potential contributions to learning and teaching. □

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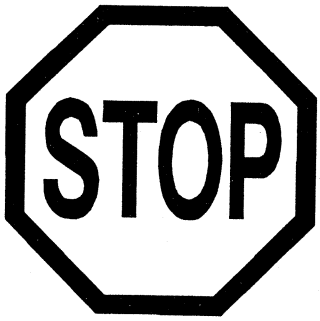

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RETENTION OF VISUAL AND VERBAL CONTENT AND PERCEIVED SELF-COMPETENCE IN AUDIOVISUAL INSTRUCTION

An experiment examined the effects of students' perceived self-competence on the retention of visual and verbal components in audiovisual instruction (i.e., film). The design was a 2 x 2 factorial with two between-groups variables namely, perceived self-competence (high and low) and time of testing (immediate and one week after film presentation). Recall and recognition questions on a film about plants were constructed as retention measures. In contrast to motivation models relating to academic achievement, perceived self-competence was not shown to significantly influence retention. Furthermore, verbal material was retained significantly better over a period of one week than the visual material presented in the film. Results also show a significant decrease in retention scores (from immediate to delayed) with the difference more apparent in recall than in recognition.

This study addresses two issues. The first is that perceived self-competence may be an important variable in understanding a student's ability to retain information. The second is that there may be a difference in the retention of verbal and visual elements in audiovisual instruction over a period of time.

It is important to explore how students retain information in learning situations because instructional procedures alone cannot fully account for students' diverse achievement patterns. One of several problems manifested by average students is low confidence in their own ability to learn or perform a

task which may be caused by lack of strategic knowledge to learn the material or because of motivational reasons. In this context, the search for improved instruction should focus on learner cognition and motivation, both of which are components that influence student involvement and achievement (McKeachie, , Pintrich, Lin, Smith, and Sharma, 1986).

Perceived Competence

Several researchers (e.g., Eccles, 1983; Weiner, 1985, 1986) have pointed out that it is not the actual task difficulty that determines students' expectancy for success but the student's perceived probability of success, given their perception of the task difficulty and their perceived ability. Accordingly, students' perceptions about themselves and the task are the most important components of motivation. In McKeachie et at's (1986) model of motivation, an important component that plays a direct role in expectancy formation and student achievement is "perceived self-competence." This is defined as "students' perceptions of their ability to accomplish a particular task." (McKeachie et al., 1986). It differs from expectancy for success in that a student can have a high perceived competence for a task, but under certain conditions (i.e., stress, boring task), not have a high expectancy for success. It is the interaction of the student's perception of task difficulty and perceived competence that is assumed to produce the student's expectancy (Dweck & Elliott, 1983; Eccles, 1983). In addition, perceived competence can vary along the specific to global dimensions as does expectancy; however, it is generally assumed to be more stable than expectancy (Harter, 1983).

The construct of perceived self-competence is related to the self-concept literature (Harter, 1983; Marsh, Cairns, Relich, & Debus, 1984; Shavelson & Bolus, 1982) as well as the self-efficacy literature (e.g., Bandura, 1982). A long history of research demonstrates that self-concept is correlated with achievement, with positive self-concepts related to higher achievement (see reviews by Harter, 1983; Purkey, 1970; Rosenberg, 1979; Wylie, 1979).

With an emphasis on the active learner and the dynamic relationships among students' self-perceptions, the term "perceived self-competence" is used rather than the static term "self-concept" to refer to students' self-perceptions of their ability for academic tasks. In addition, given the results in both the motivational (e.g., Eccles, 1983) and cognitive domains (e.g., Stevenson & Newman, 1986) that domain specific perceptions and cognitions are better predictors of academic achievement than global self-perceptions, this study focuses on a relatively specific self-perception towards a specified task (i.e, recall and recognition of the visual and verbal components of an educational film. The central idea in this study is that perceived self-competence may be an important variable in understanding cognitive processes, particularly with regard to a person's ability to remember and retain information over a period of time. Thus, this study dealt with the impact of this variable on one kind of cognitive task - memorization.

Instructional Medium: Visual and Verbal Components

The term "medium" is best used to describe ways of delivering instruction, yet it is common to describe or distinguish various forms of media by the superficial differences related to their physical appearance - their hardware devices. Salomon (1974,1979) points out that one way that media

differ, according to Salomon (1979), is in the symbol systems they are capable of employing. Symbol systems are the forms in which information is communicated. A symbol system is a set of elements, or symbols, relating to each other by syntactic rules or conventions, and correlated in specifiable ways to fields of reference (Gardner, Howard, & Perkins, 1974; Goodman, 1976; Salomon, 1979). Certain media can employ some symbol systems and not others. Radio, for example, can present audio-linguisticsymbolsystems (i.e., spoken words), while film may present pictorial symbol systems as well as both audio and visual linguistic codes. Salomon contends that knowledge presented in different symbol systems may be represented differently in memory and may require different mental skills to process. The use of a particular symbol system is presumed to be effective to the extent that it corresponds to the mental representation of a particular/ask for a particular learner and to the extent that it facilitates information processing related to a.

A particularly useful and straightforward criterion for distinguishing among symbol systems is by the sensory system or systems which they stimulate. Most symbol systems used in instruction stimulate the visual or auditory sensory systems. Thus, studying an instructional medium should consider the symbol systems associated with it that are most likely to influence learning (Kozma & Bangert-Drowns, 1987).

In view of reaming and memory, retention refers to the storage and organization of reamed information and to what happens to that stored information over time, regardless of how it was encoded or how it will be retrieved (Houston, 1981). There is a long tradition of intuitive, empirical and theoretical support for the superiority of audiovisual communication. Munsterberg (1894, p. 37) concludes a series of experiments by saying: "A series of presentations offered to two senses at the same time is much more easily reproduced than if given only to sight or to hearing." Communication practitioners have also emphasized the power of the audiovisual combination.

Two theories in the audiovisual literature support these conclusions. The first is the cue summation theory, which suggests that the stimulus cues in each channel are additive in their effect. It is stated somewhat more formally by Miller: "When the cues elicit the same responses simultaneously, or different responses in proper succession, they would summate to yield increased effectiveness" (Miller, 1957, p. 78).

A second theoretical position attributes a reinforcement effect to related stimuli presented simultaneously in two channels. When the audio and visual channels are closely related, each presents cues which elicits responses that are confirmed (reinformed) almost immediately in the other channel. Skinner, in particular, has demonstrated that immediate confirmatory reinforcement enhances learning (Holland & Skinner, 1961). Phrased in another way by May and Lumsdaine (1958), the theory states that "nonverbal stimuli when combined with the verbal explanations form a total pattern which has more power than words alone to evoke the desired responses. The nonverbal stimuli serve as reinforcers in the Pavlovian sense of reinforcement" (p.166).

Unfortunately, audio and visual cues do not always summate or reinforce each other to provide the desired effect in terms of the various reaming criteria (e.g., retention, comprehension). Both the cue summation and reinforcement theories acknowledge that the visual and verbal cues in each of the two channels may interfere with each other.

Research in the past two decades suggests that audiovisual presentations, ones in which there are visual supplements for the verbal information, will generally be learned and remembered significantly better than presentations without such visual tags (Carey & Hannafin, 1981; Fleet, 1980; Friedlander, Wetstone, & Scott, 1974; Hannafin, 1983; Hannafin & Carey, 1981; Nugent, 1982; Pezdek, Lehrer, & Simon, 1984). These generally points to the superiority of dual mode presentations over single-mode presentations. In other words, there is improved recall and recognition of information if the mode of instructional presentation incorporates both the visual and verbal components. There are, however, conflicting results about the saliency of visual versus verbal content. Some studies point to the visual content as generally more salient (e.g., Field & Anderson, 1985; Peeck, 1974; Rusted & Hodgson, 1985; Welch, 1982) while others did not find any significant difference between the saliency of visuals and verbals (e.g., Friedlander et al., 1974; Nugent, 1982). It is interesting to note that, in general, those studies reviewed which focused on recognition as the measure of retention did not find a significant difference in visual versus verbal content saliency (e.g., Friedlander et al., 1974; Nugent, 1982) and those which focused on recall as the measure of retention did find visual content to be more salient over verbal content (e.g., Field & Anderson, 1985; Rusted & Coltheart, 1979; Welch, 1982).

Thus, in addition to examining retention as a function of perceived self-competence, this study will also focus on the possible differences in the retention of verbal and visual elements in audiovisual instruction (i.e., educational film) over a period of time (i.e., one week).

This study examined reamer retention of the major components of audiovisual instruction--the audio and the visual elements--and the possible influence of the viewer's perceived self-competence on the retention of these components. The following questions were the focus of investigation. First, how well college students watching an educational movie encode and retain the visual and verbal information presented in synchrony (i.e., as an intact movie with soundtrack) as a function of the viewer's perceived self-competence? Second, is there a significant difference that may exist in the retention of visual and verbal content of an educational movie over a period of one week.

It was hypothesized that (1) reamers with high perceived self-competence towards remembering the contents presented in the film will perform significantly better on both recall and recognition measures than learners in the low perceived self-competence group, and that (2) in the delayed condition (i.e., testing for recall and recognition one week after the film presentation), there will be a significant difference between the retention of visual and verbal content in audiovisual instruction as measured by recall and recognition; that is, the visual content will be retained significantly better than the verbal content over a period of one week. [The immediate testing condition (i.e., testing for recall and recognition immediately after the film presentation) would serve as a comparison group for the delayed testing condition.]

Other inquiries were: (a) What are the differences in the retention of the instructional material between the recall and recognition measures? (b) Are there changes in the level of perceived self-competence as a participant undergoes the experiment (i.e., prior to the presentation of the film and after the presentation of the film?).

Method

Participants

The sample was composed of 86 undergraduate students (44 females, 42 males) from a Midwestern University selected from an initial pool of 126 students. Each participant was randomly assigned to either the immediate testing or the delayed testing group. Based on an initial 9-point perceived self-competence assessment scale, 126 students were grouped into high (7-9), medium (4-6), or low (1-3) perceived self-competence in retaining information about the film. Those categorized as high (n = 34) or low (n = 52) were included in the analyses which totalled 86 students.

Experimental Design

The design was a 2 x 2 factorial design with two between-groups variables as follows: (a) level of perceived self-competence (high perceived self-competence and low perceived self-competence) and (b) time of testing (immediate and delayed). The primary dependent variables were the student's retention scores for the verbal content material and the visual content material. The tests were composed of recall (short answer) and recognition questions (true-false and multiple choice) for each of the verbal and visual material.

Procedure

Participants were asked their perceived ability to remember the contents of a film prior to and after its presentation. The perceived self-competence assessment questions each took the form of a 9-point scale item ranging from "not confident at all' to "very confident." Students were first required to respond to the first self-competence scale just prior to the film presentation which asked, "How confident are you in remembering information presented in the film about to be shown? Please rate yourself on this confidence scale." The assessment scale administered after film presentation (either immediately or one week after) asked, "How confident are you in remembering information about the film shown? There is no right or wrong answer to this question. Your honesty will tee very much appreciated and your response to this scale will be held in the strictest confidence." The second self-competence assessment was administered after the presentation of the film to see what effect the film had on their perceived competence.

Experiment. Subjects were tested in groups to approximate a classroom setting and also as a convenient way to enforce the experimental procedures.

In screening those who may have watched the film before, each participant was asked about their knowledge of the film topic (i.e., various ways of how plants reproduce and adapt to the environment) prior to the presentation of the movie. Students who stated high prior knowledge of the film topic (i.e., those who had watched the film before) were allowed to participate in the experiment; however, their tests were not used in the data analysis. Those who stated (during or after the film presentation) that they had seen the film before were deals with in the same way. (Only one person among the entire sample stated this.)

Participants in all groups were then told to watch the movie and to pay careful attention to all verbal and visual elements of the film. They were told before the film presentation that their task, after

having viewed the movie, was to answer 48 questions about various ways plants reproduce and adapt to the environment. The immediate testing group was required to answer the questions immediately after having viewed the film, while the delayed testing group was required to answer the questions one week after having viewed the film. Each participant was given a deck of 48 numbered questions, each on a 5" x 8" card. The order of the questions was the same for each participant. The order of the tests for all groups were short answer recall questions first, true-false questions second, and multiple-choice questions third.

Because some of the answers to earlier questions were given in the phrasing of later questions, the cards containing the questions were placed in an envelope, and the participants were specifically instructed to take out the inverted deck, turn over the top card (question 1) and answer it on the answer sheet provided or leave it blank, and not to return to that question. They then fumed to question 2, etc. They-were told that once they had finished answering a question, they could not return to it and change their answer. They were informed that there is no penally for guessing. The same tests, as well as the sequence in which they were presented, were administered the same way to the delay groups one week later. The entire testing procedure took approximately one hour and fifteen minutes to complete. Debriefing of the subjects was done after all the participants in a session had finished answering the memory tests.

Audiovisual Content Material

The educational film used was entitled "Secrets of the Plant World." This sound and color film was 15 min in duration. This movie was chosen because of its interesting topic (i.e., various ways of reproduction and adaptation of plants), with information that was relatively new for most people. Thus, the film topic was assumed to be relatively unfamiliar to the participants to help minimize the confounding effects of prior knowledge of the instructional material. It was also visually exciting with time-lapse and close-up pictures and was most appropriate, according to its distributor, for junior high school through college-age viewers. It also contained material that was explicit and concrete so as to develop a more objective measure of retention.

Measures (Recall and Recognition)

Forty-eight questions about the film was used to measure retention of the audiovisual material. The measures of retention were in the form of a written recall and recognition of the material. There were 24 recognition questions (i.e., 12 true-false, 12 multiple choice) and 24 short answer recall questions. To achieve a balance of the retention measures, there were an equal number of questions that pertained to the verbal content alone and to the visual content alone for each of the recognition and recall questions.

Questions on the visual content and verbal content of the film were constructed and validated by having 20 randomly selected subjects from the pilot study either listen only to the verbal component (i.e., soundtrack only) and another group of subjects view only the visual component (i.e., film without the soundtrack) of the film. These subjects were then given the questionnaire (containing questions that pertain only either to the visual or verbal content) that tested how much they remembered of the contents of the film.

Results and Discussion

Perceived self-competence was not found to be an influential variable affecting retention of the visual or verbal components of the film. It is important to note that the specific task involved in this study is memorization and retention of instructional material and not academic achievement as many studies have looked at (e.g., Eccles, 1983; Stevenson & Newman, 1986). It is possible that this variable may not be as influential as other motivational components like task difficulty, expectancy for success, goal-orientation, or task value (See McKeachie et al., 1986). Different models of motivation may need to incorporate more explicitly the role of instructional context and reevaluate to what extent different motivational components affect reaming.

Thus, it is probable that these other components of the participants' attitudes and motivation affected their retention of the instructional material. In this study, most participants (i.e., undergraduate students enrolled in a psychology class) may not have considered the content material meaningful. The majority of the subjects participated in the experiment for the purpose of having to complete the class requirement of research participation, and such requirement was fulfilled regardless of how they performed on the retention tests. Thus, the possible lack of motivation to learn the instructional material (i.e., film) may have confounded the results. This could be controlled by blocking the participants on these "motivational factors" (e.g., evaluation of the subjects' efficacy levels towards the content material prior to the presentation of the instructional material).

It was also found that verbal material was retained significantly better over a period of one week, F= 1 .21, p>.O5, than the visual material presented in the film $F = 11.052$, $p < .01$. This finding went against the hypothesis (H2) posed that visual material will be retained significantly better than the verbal content over a period of one week. This result also did not support studies pointing to the saliency of the visual content over verbal content (e.g., Field & Anderson, Rusted & Hodgson, 1985; Welch, 1982). Figure 1 shows the mean comparisons of the immediate and delayed total scores for the visual and verbal components.

This result may have been caused by the enormous amount d visual material pre- sensed in the film compared to that of the verbal or narrative material. This may have resulted in the subjects having to face the more difficult task of trying to acquire more of the visual content presented than that of the verbal content. It is also possible that the retention questions, which were in the form of verbal (i.e., written) prompts, may be biased for the retrieval of verbal component of the film.

The difference between the immediate recall of the audiovisual material and the one-week delayed recall was 18%. Thus, there was a 78% retention of the audiovisual material for the immediate recall and 64% retention of the material after a one-week delay.

In view of the other inquiries of this study, the results were as follows:

(a) The major differences in the retention of the instructional material was also apparent in both the recall (i.e., short answer) measures, $F = 4.832$, $p < .05$, and the recognition (Le., true-false and multiple choice) measures, $F= 5.382$, $p < .05$. Thus, for both of these retention measures, there was a significant decrease in the retention test scores over a period of one week (See Figure 2). This suggests that there seems to be no significantly noticeable difference between ability to recall and

ability to recognize learned material in view of retaining information over a period of one week. Both types of retrieval tests show that the rate of forgetting is about the same over time.

Retention test scores for multiple choice questions, however, between the immediate and delayed testing were not significant at the .05 alpha level. Nonetheless, both the short answer, $F= 4.4$, $p < .05$, and true-false items, $F= 4.832$, $p < .05$, did yield significant differences in view of immediate and delayed testing (See Figure 3). This suggests that subjects generally do not retain information for both the short-answer and true-false items as they do for multiple-choice items. However, since much of the low retention scores for the delayed testing is attributable to the recall measure (i.e., short answer), this experiment supports the notion that recall requires a more complex retrieval strategy than that of recognition. As pointed out by Kail and Hagen (1982), recognition is relatively free of strategy use while the ability to recall is indicative of effective use of memory strategies. Despite the notion that multiple choice questions provide more cues than short answer questions, the true false items may have been relatively more difficult than the multiple choice items. This warrants further investigation as to the differences between these different forms of memory tests as it relates to visual and verbal retention. (b) There were no significant changes in the level of perceived self-competence as participants underwent the experiment prior to and after the presentation of the film. As mentioned earlier, the perceived self competence manipulation may either have been weak or quite ineffective. Other factors affecting self-competence may have to be consider to strengthen the effect of the manipulation. It is also probable that this variable may not have played a salient role in retention given the instructional context.

As part of the continuing search to understand how the human memory functions, further research should be made on varying the kind of instructional material presented (e.g., historical documentaries, popular film, textbooks, articles) and to look at more closely the unique blend of audio and visual elements that characterizes audiovisual instruction within particular instructional contexts. This may give insight as to the differences in the way we retain various types of information presented in different learning situations.

Methods to enhance learner perceived self-competence should also be examined. Some of these ways are through vicarious experience (ie., observing others perform a task successfully or unsuccessfully), enactive attainments (i.e., judging one's capabilities based on physiological arousal in taxing situations) to be able to compare their effectiveness in the retention of instructional material. Longitudinal studies on these different ways in influencing perceived self-competence may be explored further.

Studies on different populations (e.g., children at varying grade levels, college students in varying fields, learning disabled individuals) on the issue of how perceived self-competence affects memory may also provide important information on how organismic variables such as age, gender, and intellectual ability affect efficacy for a memory task and retention of instructional material. Other studies may focus more on looking at how different mnemonic strategies affect perceived self-competence of strategy use and how such efficacy is enhanced over a period of time. Analyzing various memorization tasks such as paired-associate tasks, list memorization, narrative materials, and lecture materials are also very much conducive to educational research. Educational Significance of the Study for Future Research

A criticism of educational practices involves the lack of effective instructional methods to facilitate memory improvement (Klatzky, 1975). Fundamental to this problem is the universal assumption that students will learn simply because they are asked, or told, to learn or because we supply them with one of the increasing number of technological devices or supports available. Moreover, learners who have failed frequently presumably not only have cognitive skill deficits but also motivational deficits, which further impair possibilities of improving their cognitive skills.

Peterson, Swing, Braverman, and Buss (1982) showed that an important part of student's cognitive processing during instruction involved attempts at understanding content. If instructional events interact with cognitive and motivational processes, then we might ask how the cues (e.g., attributions) that students derive from attempts at understanding content influence preexisting perceived self-competence and, in turn, how perceived self-competence reappraisals affect cognitive processes (e.g., attending, rehearsing, memorization) and different instructional tasks.

Educational practices differ in how they influence students' efficacy judgments (Bandura, 1982; Schunk, 1981, 1984, 1985a, 1985b). For example, in the context of developing student competency, students should begin to develop a sense of competence as they work at a task and experience some success. Some educational practices may validate this sense of efficacy by clearly conveying that students are becoming more capable, which should sustain task motivation and lead to further increases in perceived self-competence and, in turn, cognitive skills (e.g., memorization, comprehension). Other practices may offer ambiguous information about students' capabilities, or even convey information to the effect that students are not particularly skillful. In short, educational practices constitute an important contextual influence on students' percepts of efficacy.

It is important that educators become more aware of how students' perceptions of classroom instructional and materials affect their ability to learn and may help teachers find ways to influence such perceptions. Moreover, it may provide teachers with the knowledge of how to effectively communicate classroom material through audiovisual instruction (similar to the one that will be used in this study) and possibly how to maximize the saliency of its verbal and/or visual content. Thus, further research on this topic is essential to understanding classroom dynamics and how audiovisual instruction may be enhanced given the reaming task and the instructional context involved.

Future developmental research may also provide a better understanding of the way college students are able to retain information in comparison to children. According to Kail and Hagen (1982), not all components of memory (e.g., encoding, retrieval) develop at the same rate. Some processes seem to function in essentially the same manner in children and adults while others continue to develop throughout childhood, adolescence and adulthood (e.g., Bach & Underwood, 1970; Felzen & Anisfeld,1970; Means & Rohwer, 1976; Underwood, 1969).

GRAPH: Figure 1. Bar graph of visual and verbal test scope means for immediate and delayed testing groups.

GRAPH: Figure 2. Bar graph of recall and recognition test score means for immediate and delayed testiong groups.

GRAPH: Figure 3. Bar graph of short answer, true-false, and multiple choice test score means for immediate and delayed testing groups.

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RETENTION OF CONTENT AS A FUNCTION OF PRESENTATION MODE AND PERCEIVED DIFFICULTY

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This experiment measured the effects of presentation mode and the perceived difficulty on one's retention of academic content material. The six presentation modes were print, pictorial-plus-print, audio, pictorial-plus-audio, print-plus-audio, and pictorial-plus-print-plus-audio. Four memory tests were administered to 112 undergraduate students randomly assigned to the different presentation mode conditions. The main effects of presentation mode and perceived difficulty were found to be significant. Pairwise comparisons of means for mode, however, did not show any significant differences. Nonetheless, the means for pictorial-plus-audio and pictorial-plus-print-plus-audio mode condition are noticeably greater than the other modes. None of the pairwise comparisons of perceived difficulty means were significant but if an a priori trend had been predicted, the data would have supported the prediction that the greater the perceived difficulty of the content material, the lesser the retention.

Two important components in the learning process involve what the learner brings into the instructional context and the instructional method by which material is to be learned. The emphasis on student perceptions as mediators in learning is presented in a variety of general cognitive psychological theories and models (e.g., Anderson, 1985; Ausubel, 1968; Brown, Bransford, Ferrara, & Campione, 1983; Bruner, 1964, 1965; McKeachie, Pintrich, Lin, Smith, & Sharma, 1986; Piaget, 1971) and in research on teaching (e.g., Shulman, 1986). Instructional tasks and methods (e.g., tutorials, lectures) that learners engage in have also been a major focus of various cognitive psychological models (e.g., Brown et al., 1983; Doyle, 1983; Mosenthal, 1983). This study assessed how these two important variables affect the retention of instructional material. More specifically, the experiment examined the immediate and delayed retention of academic content material as a function of two variables, the presentation mode of instructional material and the student's perceived level of difficulty of the material to be memorized.

The available research evidence on modes of presentation generally depicts that pictorial-plus-audio and pictorial-plus-print presentations, ones in which there are visual supplements for the verbal information, will be learned and remembered significantly better than presentations without such visual tags (e.g., Carey & Hannafin, 1981; Field & Anderson, 1985; Hannafin & Carey, 1981; Dwyer, 1978; Dwyer & De Melo, 1984; Haring & Fry, 1979, Joseph & Dwyer, 1984; Peeck, 1974; Rusted & Coltheart, 1979; Rusted & Hodgson, 1985). However, the combination of two verbal sources (e.g., print-plus-audio) does not follow this pattern (e.g., Fleet, 1980; Nasser & McEwan, 1976; Nugent, 1982; Pezdek, Lehrer, & Simon, 1984; Young, 1973). Moreover, the pictorial-plus-print-plus-audio mode does not

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seem to differ significantly from the dual-mode presentations (e.g., Nugent, 1982; Pezdek et al., 1984; Rohwer & Harris, 1975). In examining single comparisons, or learning from either audio or visuals (e.g., drawings, pictures), the research presents conflicting results. Those studies supporting the superiority of visual information tend to rely on the literature regarding the iconic quality of children's cognitions (e.g., Hannafin, 1984; Pezdek et al., 1984). Furthermore, those supporting the superiority of the verbal (print or audio) mode of presentation tend to refer to the same literature but from the perspective that young children do not remember things verbally, and do not spontaneously associate remembered images with their verbal labels and therefore, when the learning measures involve verbal recall, are most helped when the verbal labels are provided for them (e.g., Rohwer & Harris, 1975; Welch, 1982).

In general, however, the literature on mode of presentation generally points to the superiority of bimodal modes, which do not significantly differ from the trimodal presentation (pictorial-plus-print-plus-audio), over single-mode presentations. Moreover, studies have shown that materials using pictorial-plus-audio and/or pictorial-plus-print are superior to those involving print-plus-audio.

Another important variable of concern to this study is perceived difficulty of the instructional material. The cognitive reformulations of the expectancy-value model derived from Atkinson's (1964) model of achievement motivation, have made the role of students' perceptions or cognitions central to learning and achievement (e.g., Dweck & Elliott, 1983; Eccles, 1983; Nicholls, 1984; Weiner, 1985a, 1986). Several researchers (e.g., Eccles, 1983; Weiner, 1985a, 1986) have pointed out that it is not the actual task difficulty that determines the students' expectancy for success but the student's perceived probability of success, given their perception of the task difficulty and their perceived ability. Accordingly, in these newer cognitive models of motivation, students' perceptions about themselves and the task are the most important components of motivation.

McKeachie et al.'s (1986) model of motivation discusses perceptions of task difficulty as playing a direct role in expectancy formation. Perceived difficulty is not the same as expectancy for success or actual ability. The model assumes that students' perceptions of task difficulty are important mediators of achievement behavior as contrasted with "objective" task difficulty. This is not to say that objective task difficulty is not important, but rather, this model suggests that student perceptions of task difficulty may modulate and change the relationship of task difficulty to students' expectancy for success and their subsequent achievement behavior. Perceived difficulty, in this study, is defined as a learner's efficacy and belief in the level of difficulty of a specified task (i.e., memorization) prior to the actual undertaking of such task.

The closely related concept of self-efficacyis also relevant in the development of perceptions of task difficulty. According to Bandura (1982a, 1982b), self-efficacy is a major factor which influences effort expended, persistence, and task accomplishments. A learner's beliefs about the learning situation may have a profound influence on one's ability to learn. Although Bandura's concept of self-efficacy was originally used to help explain coping behaviors in fearful situations, its use has been extended to other situations, including cognitive-skill learning (e.g., problem-solving) (Schunk, 1985). From the social-learning viewpoint, judgments of self-effi-

cacy, whether accurate or faulty, are based on information we receive about ourselves and the tasks we undertake. Verbal persuasion is one of the widely used methods to get people to believe they possess capabilities that will enable them to achieve what they seek (Bandura, 1982b). Although verbal persuasion alone may be limited in its power to create enduring increases in self-efficacy, it can contribute to successful performance if the self-appraisal is within realistic bounds.

The purpose of the study was to answer two major questions:

First, does the mode of presentation significantly affect retention of information as measured by recall and recognition? It was predicted that bimodal presentation involving pictures (i.e., pictorial-plus-print and pictorial-plus-audio) would yield higher scores than any of the single modes. Moreover, it was expected that the trimodal mode (i.e., pictorial-plus-print-plus-audio) would not yield significantly higher scores than the two bimodal modes mentioned.

These expectations yielded the following five specific hypotheses for mode: (H1) Pictorial-plus-print condition would be significantly superior to print-only mode condition; (H2) Pictorial-plus-print mode condition would be significantly superior to audio-only mode condition; (H3) Pictorial-plus-audio mode condition would be significantly superior to print-only mode condition; (H4) Pictorial-plus-audio mode condition would be significantly superior to audio-only mode condition; and (H5) Pictorial-plus-print-plus-audio mode condition would be significantly superior to print-only, audio-only, and print-plus-audio mode conditions.

Second, does the level of perceived difficulty of the content material influence the retention of content material?

Third, is there an interaction between the mode of presentation and perceived difficulty in their effect on retention of content material?

Method

Participants

The sample was composed of 112 undergraduate students (24 males, 88 females) in selected undergraduate psychology classes from a small comprehensive college. The total number of participants was composed of 93% students who received course credit and 7% undergraduate volunteers. Each participant was randomly assigned (with replacement) to the experimental conditions varying in presentation mode and perceived difficulty.

Experimental Design

The design was a 6 x 3 x 2 split-plot factorial design (SPF-63.2, Kirk, 1982) with two between-groups variables and one within-groups variable as follows: (a) mode of presentation (print-only, pictorial-plus-print, audio-only, pictorial-plus-audio, print-plus-audio, and pictorial-plus-print-plus-audio); (b) perceived difficulty (very easy, neutral, and very difficult); and (c) the within-group variable of retention tests (immediate and delayed). The primary dependent variable was the student's total score on the four tests designed to measure retention of the information presented. The experimental design and the number of students in each condition is shown in Figure 1.

Content Material

Pictorial and print versions. The content material was a 2,000-word instructional booklet which described the human heart, its parts, and the internal processes that occur during the systolic and diastolic phases (Dwyer, 1978). The instructional material for the print-only and pictorial-plus-print groups was presented in the form of a booklet. Each booklet consisted

Figure 1
Diagrammatic representation of the research design and distribution of the participants.

		Perceived difficulty		
		easy	neutral	difficult
Mode	PRI	6	5	6
	PIC + PRI	8	5	6
	AUD	7	5	7
	PIC + AUD	9	5	5
	PRI + AUD	6	7	7
	PIC + PRI + AUD	7	5	6

of approximately 2,000 words of instruction that were arranged into 37 paragraph-type frames on 8 1/2 x 11 in. (21.59 x 28.49 cm) sheets. For students who participated in the pictorial-plus-print, pictorial-plus-audio, and pictorial-plus-print-plus-audio groups, each frame included a 3 x 5 in. (7.62 x 12.7 cm) illustration showing a black and white picture of the human heart specifically designed to visually depict the verbal information. Thus, a total of 37 of these visual illustrations of the heart appeared in the instructional booklet.

To control for the frequency of presenting the instructional material, the students receiving the print-only mode were instructed to read the 2,000-word instructional booklet once and not to reread or go back to pages they had already read. Students in the pictorial-plus-print group received the same verbal content as the students who received the print-only mode and were instructed to read the material the same way.

Audio version. The audio version of the content material contained the same information as the print-only version but in audio form. Each participant was provided a headphone to hear a tape recording of the instructional material from a tape player instead of reading an instructional booklet. To control for the frequency of the presentation of the material, the audio tape was only played once and the students were instructed not to play back the tape. The audio version was presented to the audio-only, print-plus-audio, pictorial-plus-audio, and pictorial-plus-print-plus-audio groups.

Presentation Mode Conditions (Mode)

The different modes in which instruction was presented were as follows:

1. Print-only (PRI). The instruction booklet was presented without any audio or pictorial illustrations.
2. Pictorial-plus-print (PIC+PRI). The instruction booklet with pictorial illustrations was presented without any audio.
3. Audio-only (AUD). The audio version of the content material was presented without the instructional booklet which contains the verbal content and pictorial illustrations. Each student was provided a headphone plugged to a cassette player to listen to the audio version of the content material.
4. Pictorial-plus-audio (PIC+AUD).

The instruction booklet with pictorial illustrations but without the verbal content was presented together with the audio version of the content material.

5. Print-plus-audio (PRI+AUD). The instruction booklet without any pictorial illustrations and the audio version of the content material was presented together with the audio version.

6. Pictorial-plus-print-plus-audio (PIC+PRI+AUD) (triple-mode). The instructional booklet which contained both verbal content and pictorial illustrations was presented together with the audio version.

Perceived Difficulty

The instructional material for all presentation modes began with an introductory statement concerning the supposed degree of difficulty of the content material the student needs to study. Three different types of introductory statements were presented. These are as follows:

1. Very Easy: "The material you are about to read is classified as VERY EASY for COLLEGE FRESHMEN. This means that this material can easily be understood and remembered."

2. Neutral: "The material you are about to read is classified as AVERAGE in Difficulty for TYPICAL COLLEGE STUDENTS. The means that this material is neither too easy nor too difficult to be understood or remembered."

3. Very Difficult: "The material you are about to read is classified as VERY DIFFICULT for COLLEGE SENIORS. This means that this material cannot be easily understood or remembered. Careful attention and concentration is extremely necessary."

To strengthen the impact of perceived difficulty, each category for this variable (e.g., very easy) was supplemented by verbal persuasion by having the experimenter read a script pertinent to the perceived difficulty level for that group. The participants were also given a copy of the appropriate script and it was read to them prior to the presentation of the instructional material.

As a validity assessment, participants were asked their perceived difficulty of the instructional material before and after the immediate test by using a 5-point Likert scale item ranging form very easy to very difficult. They were required to respond to the scale prior to the reading or listening of the material and immediately after finishing all the immediate tests. From this validity assessment, it was found that the variable of perceived difficulty (i.e., easy, neutral, difficult) was highly correlated with the students' rating of their own perception of the content material's difficulty level prior to the presentation of the material ($r = .75$).

Procedure

Each student in each experimental condition participated in one of the six modes of instructional presentations and one level of the perceived difficulty. Then, they each took four separate tests. Answer sheets were provided to all participants. The same tests were administered one week later, without presenting the instructional booklet again, as a measure of delayed retention of the content material.

The following is a description of each test measured and the kind of educational objectives it assessed.

Drawing test. The 18-item drawing test (recall measure) presented the students with a list of terms which corresponds to the parts of the human heart discussed in the instructional booklet. The student was required to draw a diagram representing the heart and place the numbers of the listed parts in the proper positions or locations. This test evaluated student learning

of specific locations of the parts of the heart, not the quality of the drawing.

Identification test. This 20-item multiple-choice test (recognition measure) required the students to identify the numbered parts on a detailed drawing of the human heart. Each part of the heart is discussed in the instructional booklet was numbered on the drawing and appeared in a list on the answer sheet. Students were required to look at the detailed drawing and select the correct answer for each multiple-choice item. This test measured the student's ability to recognize, identify, and associate specific parts of the heart without their correct labels.

Terminology test. This 20-item test (recall and recognition) was designed to measure the student's knowledge and ability to recall and recognize specific facts, definitions, and terms regarding the human heart.

Comprehension test. In this 20-item test (recall and recognition measure), the students were given the location of certain parts of the human heart at a particular moment of its functioning and were asked to identify the position that other specified parts of the heart would be occupying at the same point in time. This test required that the students have a thorough understanding of the heart, its parts, its internal processes occurring during the systolic and diastolic phases. This test was designed to measure the type of learning that occurs when the individual comprehends what is being communicated and can use the information being received to explain some other phenomenon occurring simultaneously.

Total test. The scores on the four individual tests used were combined into a 78-item total test. This yielded a global score designed to measure the student's total understanding and ability to retain content material.

The students received the drawing test first, then the identification and terminology tests and lastly, the comprehension

Table 1
Summary Table for Split-Plot ANOVA of Total Scores

Source of Variation	SS	df	MS	F
Mode	6720.88	5	1344.18	3.93*
PD	2544.98	2	1272.49	3.72*
Mode x PD	4613.26	10	461.33	1.35
Subjects w. Mode x PD	32166.90	94	342.20	
Time	67.45	1	67.45	3.63
Mode x Time	33.97	5	6.97	--
PD x Time	35.15	2	17.58	--
Mode x PD x Time	65.60	10	6.56	--
Time x Subjects w. Mode x PD	1746.55	94	18.58	

*$p < .05$

Figure 2
Bar graph of means for mode of presentation
(total scores averaged across immediate and delayed test times).

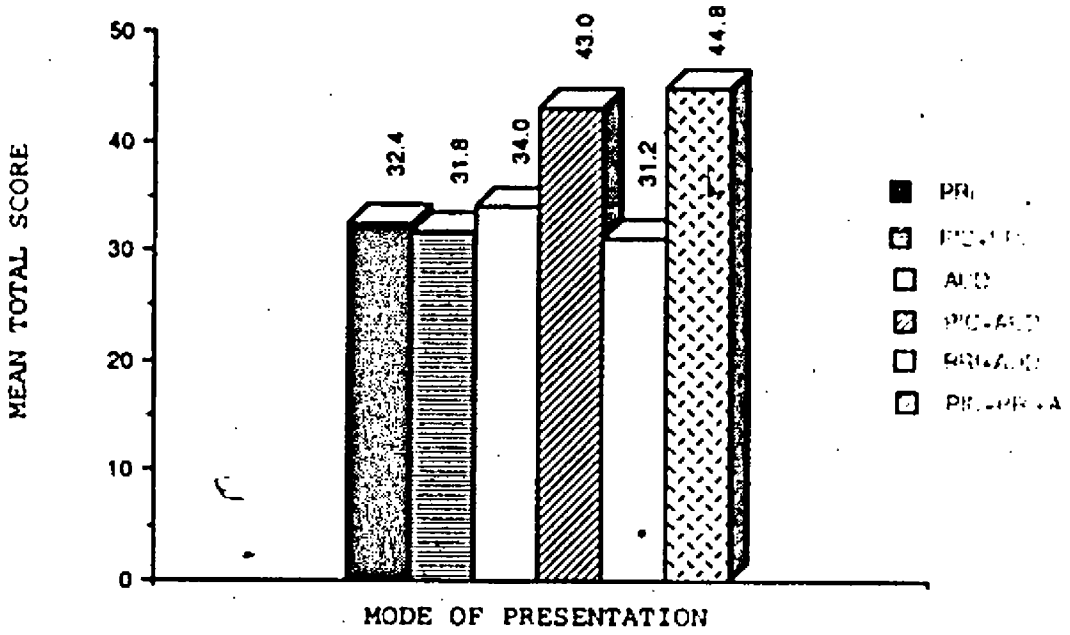

test. The answering of the tests was self-paced with no time limits. The students underwent the same test twice to measure immediate and delayed (i.e., one week after presentation of the material) retention of information.

Results and Discussion

Univariate Split-Plot Analysis of the Total Score

Table 1 shows that the main effects of presentation mode and perceived difficulty were both significant. There were no significant interaction effects and no significant repeated measures effects.

Averaged means of the different presentation modes using total scores are visually compared in Figure 2.

The Tukey-Kramer a posteriori multiple comparison test using a .05 level of significance showed that none of the pairwise comparisons of means for presentation mode were significant.

The mode of presentation means for the total score showed very little mean difference between the print-only, audio-only, pictorial-plus-print, and print-plus-audio modes. In contrast, the pictorial-plus-audio mode condition and the triple-mode condition both showed higher mean scores than the single modes and the two other bimodal modes, although they were not significantly higher.

The major procedural difference between a study done by Dwyer and De Melo (1984) and this study was that the former did not control for frequency of presentation among the participants. Their results showed that the bimodal version (printed prose supplemented by simple line draw-

ings) of the instructional unit significantly improved the students' retention of the material as measured by the identification, terminology, and comprehension tests as well as the total of these three tests. All the three tests showed that the pictorial-plus-print version of the content material was significantly superior to the print-only version. Contrary to this finding, the present study found no significant difference between the pictorial-plus-print mode and the print-only mode. The presence of the print mode seemed to worsen one's ability to retain information when the frequency of presenting the material is controlled for. It was possible that the procedural aspect of having instructed the participants not to reread the material in the present study put more pressure on them and may have increased the difficulty in the encoding of the printed material. The point in controlling for frequency of presentation was to see which mode was more effective regardless of time on task. The absence of the drawing test in the computation of Dwyer and De Melo's (1984) analysis of the total score may have also contributed to the differing results. Furthermore, it was possible that the difference in population studied (i.e., tenth graders versus undergraduate students) may also account for the difference in the results.

Exceptions to the hypothesized superiority of a bimodal presentation of iconic and/or linguistic codes were that the pictorial-plus-print, pictorial-plus-audio, and print-plus-audio means were not significantly superior to the print-only and audio-only means. These results not only contradict the theoretical framework, but also existing research demonstrating the effectiveness of pictorial augmentation of print (Dwyer & De Melo, 1984; Goldberg, 1974; Haring & Fry, 1979; Joseph & Dwyer, 1984; Peeck, 1974).

Perceived difficulty was found to be significant in the univariate split-plot ANOVA of the total score. The means for perceived difficulty were ordered such that the greater the perceived difficulty of the content material, the lesser the ability to retain such material. However, the Tukey-Kramer a posteriori multiple comparison test of all mean differences at the .05 protection level indicated no significant mean difference between the easy, neutral, and difficult conditions. Nonetheless, if an a priori linear trend had been predicted, the data would have supported such prediction. Total score means for perceived difficulty were 40.0 for the easy condition, 36.4 for the neutral condition, and 31.5 for the difficult condition. This suggests that perceived difficulty of the content material is an important cognitive variable

Table 2
Summary Table for 6 x 3 MANOVA for Immediate Tests

Source	Wilks' lambda	Approx. F	Hyp. df	Error df
Mode	0.56	2.87*	20	303
PD	0.87	1.69	8	182
Mode x PD	0.70	--	40	347

*$p < .001$

that can have considerable influence on encoding, but the method of verbal persuasion used in this study did not make enough impact.

This trend indicates that the more difficult the content material was perceived, the lesser the material is retained over time. It is probable that if the delayed measure was extended beyond one week from the time of encoding of the material, retention would have further decreased. In addition, increasing the number of participants in each perceived difficulty condition would have strengthened the outcome for this variable. The influence of perceived difficulty on the memory process certainly warrants further investigation to determine the extent of its influence on retention given different instructional contexts.

Multivariate Analysis of the Immediate and Delayed tests

Immediate tests. The combined dependent variables were significantly affected by the mode of presentation, but not by perceived difficulty, and not by their interaction (See Table 2). The major factors contributing to the significant effect of mode were the immediate drawing test, $F(5, 94) = 3.67$, $p < .01$, and the immediate identification test, $F(5, 94) = 8.78$, $p < .001$.

Delayed tests. The combined dependent variables were also significantly affected by the main effect of mode, but not by their interaction (Table 3). Similar to the univariate findings of the MANOVA for the immediate tests, the delayed drawing test, $F(5, 94) = 5.00$, $p < .001$, and the delayed identification test, univariate mode, $F(5, 94) = 5.47$, $p < .01$, were determined to be the major independent contributors to the significant effect of mode of presentation on the retention of content material for delayed testing.

Thus, these results show that for the immediate and delayed measures, the tests mostly contributing to the significant effect of mode on the retention of content material were the drawing tests (recall measure) and identification tests (recognition measure). These tests require a relatively basic understanding of the content material compared to the termonology and comprehension tests. Simple memorization of the material presented is sufficient for a student to be able to answer the items correctly since the questions focused more on the identification and location of the parts of the human heart. On the other hand, the terminology and comprehension tests required a more thorough understanding of both the heart's parts and functions. Simple memorization of the

Table 3
Summary Table for 6 x 3 MANOVA for Delayed Tests

Source	Wilks' lambda	Approx. F	Hyp. df	Error df
Mode	0.64	2.21*	20	303
PD	0.90	1.24	8	182
Mode x PD	0.64	1.09	40	347

*$p < .001$

heart's parts and their locations is necessary but not sufficient to be able to answer the items correctly since the questions dealt more with the roles of the various parts of the heart in the systolic and diastolic functions.

The presence of a significant main effect in the analysis of the drawing and identification tests suggests that these two tests might be structured more appropriately for the content material than the terminology and comprehension tests. The content material (i.e., the heart and its functions) has a highly visual character for most people and the drawing and identification tests both dealt with locating parts within a visual depiction of the human heart. The other two tests were more abstract in character. This approach to understanding the results suggests that if the objective of instruction had been carefully specified at the outset with a coordinate selection of content material and memory tests to match the instructional objectives, then instructional modes that most closely match the instructional objective and memory tests would have more clearly and reliably facilitated retention and retrieval (recall and recognition) of the material.

Recommendations for Future Research

Further investigation should be made of possible effects of controlling for time on task versus controlling for frequency of presentation of the material. Controlling for frequency of presentation limits the number of times the participants were allowed to encode or review the instructional material in the encoding process. On the other hand, controlling for time on task (e.g., Carey & Hannafin, 1981; Goldberg, 1974; Hannafin, 1983; Hannafin, 1984) limits the amount of time in which a participant is able to encode the material regardless of the number of times the subject is able to encode or review the material. The possible effect of controlling frequency of presentations is that some learners are not able to effectively encode material for the first presentation. In other words, the number of times the content material need to be presented for effective encoding in memory varies greatly from person to person. Nonetheless, in order to objectively compare the encoding properties of each mode, frequency of presentation was controlled by presenting the material only once for all modes of presentation. Time on task for all print conditions (without audio) was controlled by the participants in this study. Controlling for time on task takes into account how efficiently a learner is able to encode the material given that the learner has more control over the number of times the material is reviewed over a period of time. In the typical studying situation, most students study by encoding material given a specified time period; that is, they control for time on task, not frequency of presentation. Therefore, controlling for time on task may be more representative of a student's studying process.

Future related studies may increase the number of participants per cell. Although the current study had a total of 112 participants, the number of participants in each condition ranged only from 5 to 9 subjects.

It is highly probable that the participants' attitudes and motivation affected their retention of the instructional material. Most may not have considered the content material meaningful or serving a purpose to them. Thus, the possible lack of motivation is a potentially potent variable that may influence retention. This could be controlled by blocking the participants on these "motivational factors."

Further research is needed to define more closely the unique blend of symbol systems (i.e., iconic and linguistic) that characterizes various media and to determine how each symbol system can be used most effectively, singly and/or in combination, to promote learning. There are many different types of

pictorial aids possible, the various kinds of pictures and their functions within particular instructional contexts should be examined, as well as the types of information, objectives, and content conducive to pictorial presentation. Pictorial-realism continuums have received considerable research attention, but other areas of pictorial characteristics need to be explored to help give educators useful tools in enhancing the learner's memory abilities. With the popularity of computer graphics, the value of this type of research is obvious. Picture, size, color, and position, especially as used with print, are potential research variables.

Other ways to induce perceived difficulty as an independent variable may be studied such as vicarious experience (i.e., observing others perform a task successfully or unsuccessfully), enactive attainments (i.e., being affected by one's own past successes or failures), and physiological state (i.e., judging one's capabilities based on physiological arousal in taking situations) to be able to compare their efficiency and effectiveness in the retention of content material.

Summary of Significant Results

In summary, results for the univariate split-plot analysis of variance of the total score showed that the main effects of mode and perceived difficulty were found to be significant. There were no significant interaction effects and no significant repeated measures effects. None of the specific predictions for presentation mode was supported, but the means of the total scores for pictorial-plus-print and pictorial-plus-print-plus-audio mode condition are noticably greater than the other modes. None of the pairwise comparisons of mean differences between the easy, neutral, and difficult conditions were found to be significant, but if an a priori linear trend had been predicted, the data would have shown that the greater the perceived difficulty of the content, the lesser the ability to retain the material. Multivariate analyses showed that the drawing and identification tests, for both the immediate and delayed testing, were the major independent contributors to the significant effect of mode of presentation on the retention of content material. In addition, the results did not provide a refinement of the idea that "the more media channels used, the better." The data suggests the tendency of the print mode to worsen one's ability to retain information when the frequency of presenting the material is controlled.

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Internationalizing Postsecondary Education in Psychology: a global endeavor

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ABSTRACT The twenty-first century has witnessed a widespread call for internationalizing postsecondary psychology education. The authors discuss the rationale for recent efforts to enrich psychological contents, methods, and practices by internationalizing the teaching of psychology. They present aims and results of an online survey on how psychology instructors, primarily in the United States, can make psychology education more international. They also discuss strategies to incorporate international psychology perspectives in such aspects of teaching as lectures, classroom activities, assignments, and the use of Internet-based technologies. They describe the aims of a second online survey that compares European and US faculty perspectives on internationalization in psychology. Future research should empirically explore the effectiveness of instructional strategies and assess specifically defined learning outcomes of an internationalized psychology education.

Many psychologists in the United States are calling for the internationalization of the psychology curriculum to better prepare students for practice, research, and service in the twenty-first century (Leong, Leach, Marsella, & Pickren, 2012; Lutsky et al., 2005). Faculty face challenges that include the changing political, economic, social, and environmental forces, which cause them to re-think their teaching goals and methods so as to make psychology more relevant to global problems (Hogan & Vaccaro, 2007; Marsella, 2007). In this article, we present (a) a rationale for expanding the way psychology is typically taught in the United States; (b) a description of a survey administered to members of the American Psychological Association's (APA) International Psychology Division (52) and other APA members on international listservs (nearly all respondents were psychology instructors) and of another survey currently under way for psychology instructors in the United States and Europe; and (c) specific teaching strategies to help faculty incorporate a deliberately international perspective in their psychology courses.

Rationale for Internationalizing Psychology Education in the United States

Western, including US, psychology is often presented as universal to students in classrooms across the country. In reality, it is a psychology that reflects values and norms of the dominant social culture in its accumulated knowledge, methods used to acquire knowledge, and the perceptual frameworks through which content and process are understood. Although it is reasonable to expect psychology to reflect the normative culture of those by whom it is developed and for whom it is practiced, it typically is taught in a manner that divorces it from the cultural context in which it was created (Grenwald & Velayo, 2011).

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Through their learning experiences, students of psychology are enculturated into a psychological perspective, just as they are enculturated into a language community. Students and their professors rarely examine cultural influences on the epistemology of psychological knowledge. Thus, the social-cultural framework is rendered invisible by its familiarity. Only when one steps outside one's culture of origin by being exposed to other cultural milieus does the previously invisible framework begin to take shape. For example, when students learn about indigenous psychologies in other parts of the world, they begin to understand the peculiar cultural configurations of psychology in the United States.

In recent years, many voices (Marsella, 2007; Marsella & Pedersen, 2004; Stevens & Wedding, 2004) have called for psychologists in the United States to acknowledge the hegemonic position of US psychology, and of western psychology more generally, and to enrich its content, methods, and practice by incorporating diverse cultural perspectives and values so that a 'universal' psychology might be more fully realized. On this view, universals in psychology, should they emerge, will be taught side by side with culturally specific theories, methods, and practices. Students of international psychology will learn to appreciate the cultural specificity of psychology as well as its universality, and will have the appropriate skills to determine which is which.

Psychologists of tomorrow must be ready to understand and intervene in societal problems that impact individuals, families, and communities, such as war and conflict, terrorism, global climate change, disease, and the needs of the global poor, refugees, and immigrants (Marsella, 2007). Students who successfully complete an internationalized psychology program should have not only an increased knowledge base and expanded skills but also the motivation and ability to continue professional development that is internationalized (Yershova, DeJaeghere, & Mesterhauser, 2000).

Surveying Psychology Instructors about Making Psychology Education More International

Early in 2009, we developed and administered an online survey to learn more about how psychology faculty are internationalizing their courses. We sent the survey to the International Psychology Division members of the APA's Division 52 and to other APA members on international listservs. More than half of our 128 respondents had begun to internationalize how they teach psychology. Of those respondents, full professors were the largest group (nearly half). Associate and assistant professors followed, with just under 20 percent for each group. Adjunct and other instructors, some in secondary education settings, made up the remainder of respondents who were internationalizing their teaching. In descending order, faculty at comprehensive institutions, community colleges and liberal arts institutions (tie), research institutions, and other types of institutions reported that they had begun to internationalize the courses they teach (see also Grenwald & Velayo, 2011).

Our current online survey (Grenwald, Oberlechner, & Velayo, 2012) allows us to compare and contrast perspectives on an internationalized curriculum from psychology faculty in the United States and in various European countries. Among the questions we hope to answer are: Is the concept of 'internationalizing the psychology curriculum' familiar in Europe? How interested are psychology faculty in more broadly preparing their students to participate in an increasingly interconnected world? In which ways are they already doing it? What geographic differences exist in views and practices regarding a more international psychology education? With provisions of the Bologna Accord under way, there will be increasing conformity to an agreed-upon model for European higher education, and for both undergraduate and graduate degrees (European Commission: Education & Training, 2011). What are the implications for internationalizing psychology education under the Bologna Accord?

Recommendations for Psychology Instructors

Internationalization is more than the inclusion of international content into courses. It also involves the development of internationalized instructional strategies (Fraser & Bosanquet, 2006). The major goal of internationalizing psychology education is to increase student competence to do

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research and to practice psychology in a global setting. This goal can be achieved through lectures, classroom activities, out-of-class assignments, and Internet-based technologies. Accordingly, student-learning outcomes and their assessment should also reflect such competence. What follows reflects findings from the first survey of APA Division 52 members and selected others described above (Grenwald & Velayo, 2011).

Lectures

Lectures are a straightforward way to integrate international content into psychology courses. Cultural and ethnic references may be woven into lectures to illustrate the international diversity in psychology (Marsella & Pedersen, 2004). Some instructors compare and contrast issues related to gender and education in the United States with those in other countries or examine child-rearing practices across cultures. Other instructors use case examples from other countries, international data sets, or personal international experiences. Including contributions of non-US psychologists is another way to internationalize lectures. Guest lectures by individuals with international expertise or who represent another culture also internationalize course content. International students may be invited to provide guest lectures in which they share personal experience and background related specifically to course content (Gurung & Prieto, 2009; Ho, Bulman-Fleming, & Mitchell, 2003).

Classroom Activities

Classroom activities can serve as an important adjunct to lectures in promoting international perspectives. Faculty may employ activities that require the integration of cultural information, such as applying selected concepts and research findings to individuals in a different country. For example, the discussion of attachment theory may include differences in child-rearing practices that vary in terms of the extent to which parents teach autonomy to their children.

Discussion of world events helps students understand how those events impact psychological well-being and development in diverse communities. Such activities may draw from international data sets and from international news. For example, how do natural disasters or political unrest affect a population's mental health and attitudes toward life? Incorporating films into courses can enhance an international perspective on psychology (Meiners, 2009). Activities such as autoethnography (the cultural analysis of one's own culture) might be beneficial at the outset of a course, because first knowing one's own culture is an important part of understanding and appreciating others' (Marsella & Pedersen, 2004). Asking students at the beginning of the course about the culture(s) with which they identify and the countries they have visited can provide useful information for the instructor's inclusion of student cultural experiences during the course.

Student Assignments

Our survey results indicated that instructors often assign research papers about psychology and psychologists in other countries in order to broaden students' exposure to alternative views. Requiring students to read international news, interview someone from another culture, or conduct collaborative projects with students from other countries (either in person or via the Internet) may also be valuable.

Internet-based Technologies

Internet-based technologies are becoming increasingly popular as a means to incorporate international content into psychology courses (Velayo, 2011; Wankel, 2010). These resources enable many of the teaching strategies mentioned earlier, and are accessible and cost-effective (Guerin, 2009). Not all students are able to travel or study abroad due to the cost involved or to personal circumstances. Internet access allows psychology students a wide range of opportunities for cross-cultural collaboration without having to leave the country. It provides access to the international literature and to multimedia materials created by individuals in other countries.

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Videoconferencing (e.g., Skype) allows instructors in different countries to lecture jointly and students to participate in discussions with peers from other countries. Because many textbooks used for psychology courses include little, if any, international content (Woolf, Hulsizer, & McCarthy, 2002), international electronic databases, e-books, and e-articles can be useful supplements.

Recommendations for Future Research on Internationalizing Psychology Education

We offer two recommendations for internationalizing psychology education: (a) exploring the effectiveness of instructional strategies; and (b) assessing student-learning outcomes.

Exploring the Effectiveness of Instructional Strategies

It is important to determine the effectiveness of instructional strategies used to bring international content into the psychology classroom. Students who have completed a psychology course with an international component could be surveyed about their learning and, specifically, their classroom experience. Possible questions to be addressed are: does student interest increase when lectures include international content? What types of assignments do students find most effective for developing an international perspective? What can instructors do to increase student involvement in meaningful discussions about issues from an international perspective?

Similarly, instructors who incorporate international content in their courses could be surveyed by researchers to identify specific effective strategies. Empirical research on the use of specific instructional strategies could examine the context of specific courses, demographic characteristics of the students, pre-post levels of international psychological knowledge, and resources available to the instructor.

Assessing Student-learning Outcomes

Instructors need to specify student-learning outcomes that will help them determine whether students meet the international goals for a course. Such outcomes alert students to the fact that international content is not merely an add-on to the course but in fact is central to it (Bartolini, Gharib, & Phillips, 2009). The APA asserts 'international awareness' as one of its official goals for the undergraduate psychology major. In a 2004 collaboration with the American Council on Education, the APA formed a task force to help suggest ways to internationalize the undergraduate psychology curriculum (see Lutsky et al., 2005). The final report delineated goals and student-learning outcomes in five domains of psychology instruction: knowledge; methodology; discipline of psychology; interpersonal understanding; and global issues (Belar, 2008; Lutsky et al., 2005).

The future of psychology will be realized by today's students. Internationalizing the curriculum will prepare them to competently understand and potentially intervene in global problems. Many faculty members already are heeding the call to incorporate international content and themes in the courses they teach (e.g., Belar, 2008; Grenwald & Velayo, 2011; Guerin, 2009; Leong et al., 2012). We hope this brief review of models for curricular internationalization and available resources will encourage others to follow suit in the best interests of the psychologists of tomorrow.

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CHAPTER 18

Internationalizing the Curriculum

RICHARD S. VELAYO

As the world becomes more complex and interconnected, it is critical that universities and colleges internationalize their curricula. There is an increasing need to pursue strategic ways to prepare students to become more knowledgeable and respectful of different cultures, to be more informed about international and global matters, and to become effective citizens able to function well in our increasingly interconnected world. The effort to internationalize the curriculum should focus on affecting the spectrum of fundamental activities at the institutional, departmental, and faculty levels, each contributing distinctive and significant ways toward curricular reform. Although higher education recognizes the need to internationalize, particularly at the undergraduate level, there is a considerable gap between the rhetoric of internationalizing education and the reality of institutional activities and priorities.

An Internationalized Curriculum: Definition and Relevance

Various academic disciplines and professional schools have begun efforts to internationalize their curricula. Janet Knight (2004) proposed a working definition of "internationalization" as "the process of integrating an international, intercultural or global dimension into the purpose, functions or delivery of post-secondary education" (p. 7). In contrast, the term *multicultural* generally refers to domestic racial or racial diversity, and the term

intercultural describes an encounter with cultures of other nation states or diasporas (Green & Olson, 2003). Internationalization of the curriculum involves varied internationalization activities including foreign language courses, study abroad programs, interdisciplinary programs, and the development of courses or programs with an international, intercultural, or comparative focus (Bremer & van der Wende, 1995). The primary goal of internationalizing the curriculum is to transform students' national perspectives into a broader and more informed view of the world in which students understand and appreciate the interdependence among nations and among world cultures. Thus, an internationalized curriculum is critical to prepare students to work, live, and interact in a global society.

Knight (2000) pointed out that the curriculum is the most important element of internationalization in higher education. Josef Mestenhauser (1998) also noted that universities are required to reform their curricula if students are to have an international education. Persuasive arguments are made within the literature why internationalized curricula are integral to any process of internationalization in higher education (Bond, 2003a; Burn, 2002; Ellingboe, 1998; Harari, 1992). Ideally, an internationalized learning environment, whether it be in a classroom or the broader academic environment within an institution, should recognize, value, and accommodate students' cultural differences and worldviews and reflect the diverse cultures, perspectives, and experiences of students.

Suggestions for Internationalizing the Curriculum

Methods to internationalize curricula vary among institutions. Research has stressed that an effective implementation to curricular transformation requires a dedicated involvement of various constituencies within an institution (Bonfiglio, 1999; Edwards & Tonkin, 1990; Ellingboe, 1998; Green & Olson, 2003; Harari, 1992; Schoorman, 1999, 2000a, 2000b; Schuerholz-Lehr & van Gyn, 2006; Taylor, 2000). Deciding how best to internationalize and the extent of the internationalization process may be based on an institution's resources, mission, goals, context, and unique history. Curricular reform needs to occur at the institutional level, the departmental level, and at the faculty level for students' experiences with an internationalized curriculum to be effective.

Institutional Initiatives

When reform initiatives originate from top-level administrators, initiatives can focus on modifying college missions and policy documents, diversifying language requirements and internationally related courses for

students, establishing study abroad programs, and implementing intercultural competence training and incentives for curriculum planning and development for faculty. In creating collegewide reforms, it is essential to ensure that support for international education does not remain in the hands of a select few (e.g., institutional administrators) but, rather, be distributed throughout the college. To ensure programmatic continuity, colleges must constantly mentor new generations of leaders and educators with respect to efforts to continue and refine efforts to internationalize.

To develop meaningful international initiatives, a clearly stated institutional mission statement must develop globally engaged students and be supported by the institution's leadership (Wood, 2007). Faculty will be obliged, or perhaps encouraged, to think thoughtfully about their personal global perspectives and how they will expose their students to different worldviews. They may effectively redesign courses that entice students' interest in world events and inspire them to think about solutions to global problems. There have been strategic efforts by many U.S. colleges and universities to produce mission statements and international programs that focus on developing citizens who possess the language and cultural skills necessary to help sustain U.S. leadership in the world and be competitive in a global society (e.g., Byers-Pevitts, 2008; Griffiths & Chieffo, 2007; Rubin, 2009). Implementing a strong mission statement sets the tone for all subsequent international initiatives.

Another institution-based approach to internationalization is to diversify language requirements and internationally related courses. Although this step is in the right direction, developing and sustaining global educational goals is not easily accomplished by merely offering a few introductory courses. Many institutions require students to take a minimum number of internationally related courses as part of their undergraduate experience (Siaya & Hayward, 2003). An example is to link language acquisition to graduation requirements by requiring students to minor in at least one foreign language.

Arcadia University is one of several forward-thinking institutions that offer creative ways to increase the number of globally educated students, requiring them to enroll in two "global connections" courses, an international experience at home or abroad, and a reflection course (Rubin, 2009). Examples of such experiences include working with Latino immigrants and then traveling abroad to better understand the work of nongovernmental organizations (NGOs) in an international context. The university also offers stipends to faculty to become involved in internationalizing its curriculum.

Institutions can also aggressively promote education abroad programs by establishing partnerships with foreign government, industry, and other academic institutions to increase the number of graduates who demonstrate global awareness and competency. Only 108 institutions (of more than 4,200 U.S. colleges and universities) account for 50 percent of all the students abroad (Commission of the Abraham Lincoln Study Abroad Fellowship

Program [CALSAP], 2005). With almost 18 million students in higher education, only 1 percent study abroad every year (Goodman, 2009). CALSAP suggested that the profile of students studying abroad does not match the demographic profile of the U.S. undergraduate population. An approach to minimize this gap is for institutions to create programs that seek and financially support underrepresented students, nontraditional students, students with disabilities, community college students, and others. Daniel Obst, Rajika Bhandari, and Sharon Witherell (2007) noted efforts to provide and promote education abroad opportunities in less traditional locations such as the Middle East, China, and India. Notably, the availability of financial aid and timing of education abroad programs are relevant factors in determining whether students have the resources to study overseas. Lois DeFleur (2008) pointed out two institutions as examples. The State University of New York at Binghamton places a priority on creating programs during winter and summer breaks when students are not generally enrolled in classes. Michigan State University's (MSU) Freshman Seminars Abroad provides travel abroad opportunities for students through a 2-week summer program by taking students, led by MSU professors, to destinations such as Canada, Ireland, Japan, and South Africa.

Institutions can also implement intercultural competence training and incentives for curriculum planning and faculty development. Educators who have the necessary knowledge, skills, and experience can better design and conduct programs or teach courses that will result in positive intercultural learning outcomes. A helpful approach is to offer workshops for faculty to help them determine ways to internationalize their courses. These workshops may be led by other faculty members who have internationalized their courses or by departments committed to this objective. Faculty may also be provided with incentives (through grants, stipends, release time, sabbatical leaves, and awards) to help them contribute to internationalizing efforts. McGill University is a successful example of a flexible model for curriculum redesign that facilitates faculty efforts to integrate newly developed intercultural and interdisciplinary perspectives into the curriculum by offering workshops for faculty to help them redesign their course curricula and instructional approaches (Saroyan & Amundsen, 2004).

Departmental Initiatives

Academic departments can play a crucial role in internationalizing discipline-specific curricula. Course offerings and departmental initiatives can highlight the relevance of an international perspective as a goal within the major. For example, there is growing recognition of the importance of exploring ways to internationalize the psychology curriculum (Power & Velayo, 2006; Stevens & Gielen, 2007; Stevens & Wedding, 2004; Velayo, 2000). Departmental initiatives to help internationalize the curriculum

include using the experiences of international students in the major to secure international literacy, sponsoring talks and collaborative projects with those abroad, introducing new course content, and partnering with student affairs professionals.

Departments can use the experiences of international students to bring cross-border perspectives to the major and contribute to the diversity of a department, and indeed, the institution. Specific programs can be developed to take advantage of the learning opportunities that these students bring with them to the classroom. Departments can involve international students to help the departments become more internationalized through international students' interactions with faculty, staff, and other students. For example, international students, along with other students, can be invited to become actively involved in departmental committees and student-led committees. They may also be encouraged to participate in meetings in which faculty and students meet to discuss research and to join research teams. Departments can ask international students to participate in panel discussions and other public venues to offer their perspectives on issues relevant to the particular discipline represented by the department. Thus, international students can become key resources for on-campus internationalization efforts, although it is important to note that not all international students possess the necessary skills to teach others, and international students' worldviews may not always represent their country's mainstream culture (Raby, 2007).

Departments can also sponsor talks and collaborative projects with those from abroad. One way is to invite visiting foreign scholars to give talks, presentations, and perhaps even teach courses to provide the faculty and students with an international perspective. Additionally, using Internet-based technologies (e.g., e-mails, websites, podcasts, YouTube videos, videoconferencing, blogs, and wikis) and social media sites (e.g., Facebook) allows opportunities for scholars and students from different countries to collaborate on course projects and discussions on course topics. Such technologies can be relevant and effective pedagogical devices in internationalizing the psychology curriculum, or for that matter, just about any curriculum (Takooshian & Velayo, 2004; Velayo, Oliva, & Blank, 2008). Departments can also facilitate collaborative work between their faculty and faculty from other countries on projects that are beneficial for faculty scholarship for students' projects such as presentations in international or domestic conferences as well as publications in foreign journals and other forms of media.

Academic departments may also propose introducing new, specifically designed international courses in the major. The addition of new courses sets a context for in-depth internationalization that the infusion approach (incorporating international content within existing courses) lacks. Rosalind Raby (2007) pointed out that new classes can be general (world literature or introduction to global studies), specific (films of Latin America or global

environmental agriculture), or thematic (Spanish for nursing or Chinese in business). Some examples of new classes are Culture and International Business: Kiss, Bow, or Shake Hands (Santa Ana College); Introduction to Global Studies (Mission College); International Trade, Marketing, and Management (Long Beach City College); and International Politics (Santa Barbara City College). Although there are several benefits to adding new international courses, the process of doing so can be expensive and potentially time-consuming, especially if it requires curriculum committee approval. Generally, courses with a comparative focus (e.g., religion, literature, political science) or those that address cross-border issues (e.g., cultural anthropology, cross-cultural psychology, ethnic studies, intercultural communications) can be easily internationalized. Both faculty and administrators often attempt to internationalize their campuses through these types of courses (King & Fersh, 1992). However, any discipline can be easily internationalized by asking faculty to reconceptualize the curriculum. For example, if a biology course includes a section on infectious diseases, a discussion of pandemics will help infuse international considerations into class discussion.

Academic departments may also consider establishing partnerships with the student affairs professionals in the college to provide practical learning experiences that increase college students' level of global awareness. Examples of such partnership goals include creating language learning opportunities, international programs in campus housing, overseas internships and work experiences through career services, and campuswide programs that support internalization efforts. In addition, advising student majors by departments in conjunction with student affairs office can include information regarding education abroad opportunities. New student orientation programs, with the help of departmental representatives, may provide breakout sessions to help students learn about other cultures, as well as study aboard travel and internship possibilities abroad.

Faculty Initiatives

Faculty are ultimately responsible for internationalizing the curriculum. Sheryl Bond (2003b) noted that most faculty believe that the curriculum falls into their domain of responsibility. Faculty tend to incorporate both new content and pedagogy in their attempt to internationalize the courses they teach.

Infusing international content into a course is viable and cost-efficient and requires little more than faculty initiative and commitment to add international content, ideas, and themes in their class presentations. To infuse the curriculum, faculty can rely on life experiences, such as international travels, participation in internationally themed seminars, and even discussion of internationalized components of the textbooks used in the course. Although Mestenhauser (1998) suggested that merely adding pieces of international

content to courses may not be sufficient to internationalize curriculum, it may be an appropriate way for some instructors to begin the process of slowly adding international content and themes to their courses.

Relative to pedagogy, some useful strategies that instructors can use to internationalize their courses include the following:

- Having visiting scholars, international students, and study-abroad returnees (and those who have simply traveled and stayed in another country) as guest speakers
- Discussing faculty international experiences during class and informally during advising sessions or office hours
- Facilitating interaction between domestic and international students by providing more opportunities for collaborative student projects and structured activities
- Including contributions of non-U.S. authors on course reading lists and in class lectures (e.g., discussion of the history of a subfield or content area)
- Showing videos that enhance an international perspective and critical thinking pertaining to course concepts
- Adopting critical questioning and cross-national comparisons of course content as a means of helping students examine and challenge their own assumptions, beliefs, values, and practices regarding international perspectives (e.g., students learn that the perspectives common in their country are not the only possible perspectives from which to view life and that basic assumptions about the essential nature of course material may be questioned by others in some parts of the world)
- Encouraging students to attend international events and conferences on and off campus (providing extra credit when relevant)
- Discussing world events and current issues whenever possible and recommending good international news outlets
- Using Internet-based technologies (e.g., Facebook and other social media sites, blogs, wikis, virtual worlds, videoconferencing) while integrating international issues and ideas in teaching, training, and research

Individual faculty members, instead of working in isolation to internationalize their courses, can also collaborate with and use the services of study abroad programs, the international student office, and student international organizations on campus. They may also collaborate with other faculty members who have internationalized their courses to gain knowledge and share strategies with each other. Whatever teaching strategies are used, it is best to outline explicitly the expectations in an internationalized course and to guide students in understanding the reasons and goals for using particular teaching strategies in the classroom.

Conclusion: A Perspective on the Challenges to Internationalizing Curriculum

Joan Stark and Lisa Lattuca (1996) noted that the critical major barriers to internationalization include the lack of background knowledge by faculty in the international aspects of their discipline, the lack of institutional incentives that entice faculty to be involved in international work on curriculum development, and a narrow view of education by the university. Although these comments were made 15 years ago, they still apply to faculty and institutions that have not made a concerted effort to include international and global issues in their curriculum.

An institution's task is not to impose curriculum change but to provide ways for its constituents to acknowledge the need for change, value it, and agree to move toward a more comprehensive approach to internationalization. Sociopolitical forces within the institution may also prevent internationalization of the curriculum (Hill, 2001). Development, refinement, and maintenance of the curriculum operate within institutional sociopolitical constraints (e.g., departments competing for space and other resources). Thus, the crucial task is for faculty committed to internationalization of the curriculum to negotiate for the changes to the curriculum that would benefit all the key players: students, faculty, administrators, and in some cases, perhaps even boards of trustees. A useful faculty tactic along these lines is for faculty to seek membership on institutional committees that directly shape the nature of the curriculum (Ross, 2005). Similarly, in those cases in which the administration is primarily involved in making curricular decisions, faculty committed to internationalizing the curriculum should offer their support to administrators seeking faculty support for internationalization.

Faculty often play a critical role in curriculum design and reform, although some faculty may be uninterested, or worse, resistant to internationalizing the curriculum. Faculty interest, motivation, and lack of involvement are three likely key factors in limiting faculty contributions to internationalizing the curriculum (Labi, 2009). A key method to begin acculturating the institution toward internationalization is to hire new faculty who demonstrate interdisciplinary competence and who show international and global interest in their teaching and research.

Internationalization of the curriculum must be an institution-wide effort. Leadership for internationalization must be demonstrated at the highest levels of the institution, and mission statements must be global and inclusive. Academic departments must engage in curriculum reform to achieve international education objectives. Faculty participation must be inherent in recommendations for the future of global education. Faculty who are supported and encouraged by administrators to explore new internationally focused courses, or provide global perspectives in existing courses, will contribute significantly to curriculum reform. One hopes that

a more international perspective will eventually permeate curricula in institutions worldwide and that the day will come when students will be able to acquire relevant knowledge and perspectives about cultures other than their own. This goal is certainly one we can all strive to achieve.

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A Global Perspective

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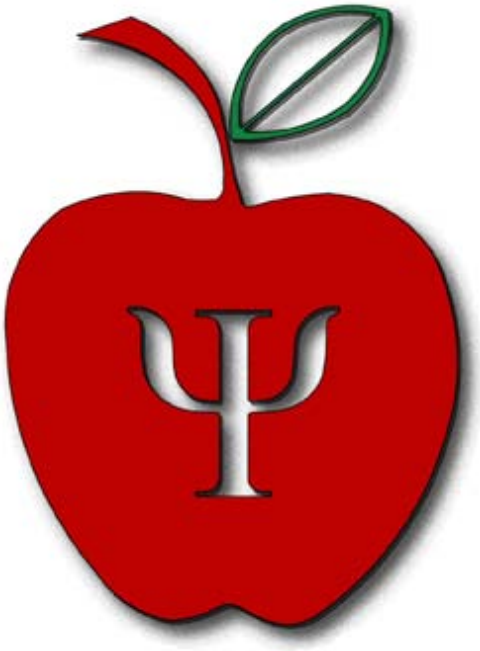

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Introduction

The Society for the Teaching of Psychology's PsychTeacher listserv, launched in 1998, provides a forum for psychology teachers at all levels to share ideas, seek advice, and discuss issues related to the teaching of psychology. Since the spring of 2000, the essay series *E-xcellence in Teaching* has been a feature of the listserv. Authors were invited to contribute essays related to various aspects of teaching psychology. This year's essays range from advice on internationalizing psychology courses, to thoughts on dealing with millennial students, to an introduction to the latest in technological tools.

In Chapter 1, Carnegie award-winning professor Richard Miller reflects on the joy and heart that distinguish great teachers. Miller maintains that scholarship and teaching are intimately connected, as good teachers always challenge students to think, to pose questions, and to seek answers to those questions.

Christy Price shares tips for dealing with so-called "Millennial" learners in Chapter 2. These students are sometimes characterized asmulti-taskers with short attention spans and an apparent lack of respect for learning. Price presents practical tips for understanding these students' needs and preventing or minimizing incivility in the classroom and in student-faculty interactions.

In Chapter 3, Karen Brakke and Barney Beins summarize the recommendations of the 2008 National Conference on Undergraduate Education in Psychology. Participants at the NCUEP worked to create a blueprint for the future of undergraduate psychology. Brakke and Beins highlight several themes that came out of the conference, including the central role of science in the discipline of psychology, the importance of psychological literacy, and the "changing landscape" of students and technology.

Sue Franz's contribution in Chapter 4 highlights several new technological tools that can streamline the work of teachers. These include tools for sharing files across multiple computers (Dropbox), managing your e-mail (Xobni), keeping up with new information (Google Reader), and even writing that same comment over and over again on student papers (PhraseExpress).

In Chapter 5, Richard Velayo introduces readers to International Psychology, and provides advice for bringing an international perspective to psychology classes. Velayo presents a range of options for introducing content such as lecture , class activities, and targeted writing assignments.

Most college faculty serve as advisors as well as instructors. In Chapter 6, Daniel Rogers and Monica Reis-Bergan discuss advising "dilemmas" that come with the multi-faceted role of advising. How do we deal with students whose skill levels do not match their goals? What about that less-than-stellar student who is expecting a recommendation letter? Rogers and Reis-Bergan provide advice on asking ourselves the tough questions about how to deliver less-than-welcome news to students.

"Pop psychology" is ubiquitous in our culture. In Chapter 7, Luis Cordon examines the history of some of these ideas. Although the purveyors of pop

psychology often present their theories as the latest "big idea," Cordon demonstrates that simplistic ideas about achieving wealth and happiness have been with us for a while.

In Chapter 8, Teresa Davis and Mary Ellen Fromuth provide a practical discussion of the costs and benefits of producing a customized textbook. Custom textbooks can be tailored to the specific needs of a course, and can often be less costly for students. On the other hand, creating a custom textbook can take an extensive amount of faculty effort. Davis and Fromuth's essay can help faculty answer the question of "Should we or shouldn't we?" In addition, they provide a helpful outline of the process involved in creating a customized text.

In our final essay in this volume (Chapter 9), Dana Dunn tells the tale of how he went from "reluctant" blogger to an enthusiastic blogger on the teaching of psychology for *Psychology Today.* Dunn provides advice for potential bloggers about the rewards and challenges of this form of writing for the general public.

Together, these essays make up Volume X of *E-xcellence in Teaching.* We thank all our contributors for sharing their thoughts and experiences with the readers of PsychTeacher, and with the rest of the psychology teaching community.

Chapter 1

Reflections on a Lifetime of Teaching and Learning

Richard L. Miller
University of Nebraska at Kearney

I would be willing to bet that most of us can think of at least one or two teachers whose influence led us to where we are today. In fact, I would be surprised if most college graduates didn't have at least one professor who made a difference in the direction their lives took. What makes one teacher more influential than another? What qualities do highly effective and influential teachers possess? I find this question interesting and to answer it I have done what academics always do - consulted the literature. I have also observed other teachers, and most importantly, I have listened to my students. Many of our more thoughtful colleagues have addressed this issue of what makes a good teacher (see Buskist, in press). I make no claim that mine is any better or more universal than anyone else's. I do claim that it is based on what works for me.

For one thing, good teachers require students to think, to solve problems, to pose questions, and to wonder about the why behind what we know. In his 1901 book "American Traits," Hugo Munsterberg contrasted the education received in high school with that received at university. He pointed out that the high school distributes knowledge that has been collected, whereas the university strives to teach students to take a critical attitude toward all collected knowledge. The high school teaches facts while the university should teach students the methods whereby they can uncover the facts for themselves.

Now there are those who say, "this is scholarship, not teaching" and some folks are pretty convinced that the two are different things. I am not. To me, they are different words for a very similar process that is at the heart of teaching and learning - the process by which we come to understand that which we didn't understand before.

D. W. Hamlyn (1996) in his commentary entitled "The Concept of a University," proposed that one of the enduring achievements of universities, dating back to the Middle Ages, was the scholarship of discovery: "If learning is to be pursued and if knowledge is to be enlarged there have to be institutions like universities, which have the double role of pushing back the frontiers of knowledge and of enabling future generations to carry on that process" (p. 216).

At today's university the commitment to both scholarship and teaching seems incontrovertible. It is enshrined in mission statements, strategic plans, and promotion and tenure guidelines. This recognition of the university's dual purpose has led to an unfortunate division between teaching and research - a division recognized by the meta-analysis of 58 studies conducted by Hattie and Marsh (1996) that found no relationship between research productivity and teaching effectiveness. Their

recommendation was that universities should aim to increase the circumstances where teaching and research meet. How can this be done?

Harry Kirke Wolfe is arguably one of the most important psychologists and educators of the early 1900s. His impact on the education of a vast number of students is probably matched only by his unfortunate obscurity. Because he did not train graduate students, his legacy has been more indirect than that of some more famous psychologists. Throughout his professional career, he labored diligently at the University of Nebraska to enhance the education of his students, working with them individually in the laboratory. His undergraduate lab ranked third in the nation in producing students who would later attain doctorates. Three of his students who became presidents of APA commented that Wolfe had influenced them more than any other mentor (Benjamin, 1987, p.69). Wolfe received no teaching credit for his lab work and neither did his students. Yet enrollments in his courses continued to mushroom. A student of his once remarked that they were willing to "venture the work for the sake of the zest" (Benjamin, 1999, p. 52).

Like Harry Kirke Wolfe, the greatest joy I have in teaching is the process of mentoring undergraduate research. My earliest experience with undergraduate research took place in 1966. I was the undergraduate student and my topic was leadership and conformity. My motivation was to seek a way to actually resolve a long-standing late night dispute within my circle of friends using something like evidence instead of opinion. The thrill was to create new knowledge and to be the first to know it, not to mention sharing it with others (see Miller, 1967), a thrill I try to encourage with my own students.

For me, wisdom begins with wonder. As one of my students noted some time ago: Professors teach in class, but teachers teach in and out of class. During my time at UNK, I have mentored over 200 undergraduate research projects that have been presented at regional or national conferences. My students and I have very similar goals - to discover that which we did not know before. We tend to avoid replications and extensions and often take risks in examining little known or at least little written about phenomena. As a result, we have published over 20 articles together in professional journals and they have published 27 articles as sole author, which brings us back to the relationship between scholarship and teaching. At this point there are very few topics that I teach about, but about which I can't bring in the results of a student research project to expand my students' knowledge. And don't think that this doesn't get their attention – it's pretty cool to realize that fellow students can contribute to the knowledge base.

I would like to share some feedback from my students that captured some things about good teaching that apply to many of us and certainly help illuminate what it means to be a good teacher. Marci Rust, one of my students, once wrote: "I must confess, having such a close relationship with an instructor and advisor as caring and involved as you are has been demanding, and at times more than I thought I could handle. I realize now that it was during those particularly demanding times that you had more faith in my abilities than I did. You have never ceased to encourage and drive me to excel beyond what I thought was possible." I think communicating to

students that they can be more than they thought possible is an important characteristic of good teaching.

Good teachers share their joy in being teachers. They are enthusiastic about their subject matter, about teaching, and about their students. They make their passion for teaching obvious to their students by taking an interest in the students themselves. Good teachers develop positive rapport with their students, which makes it more likely that students will attend class and participate in learning activities. One of my students once wrote: "I was a disinterested, unmotivated sophomore, lacking direction in my academic pursuits. You can probably imagine what a rude awakening to my indifference you were. I had never experienced an instructor with such a passion for teaching and knowledge; a passion you have never ceased to express over the past three years." Another student, Emily Balcetis, wrote, "it is not enough to just want to teach others. The others have to want to be taught. You have the gift of encouraging others to want to be taught. And you can see your influence throughout the department in both the faculty and the students. That, to me, is what makes you a good teacher."

Wilfreed Grenfell once said: "Real joy comes not from ease or riches or from the praise of men, but from doing something worthwhile." James Barrie suggested that, "Nothing is really work unless you would rather be doing something else." Good teachers teach because that is what we would 'rather' be doing. We in the academy are incredibly privileged to have the opportunity to do what we love, with students who are ready and eager to share our enthusiasm.

One of my favorite quotes that I think also captures what it means to be a good teacher is by Charlene Szumilas [Principal, Holy Trinity High School, Chicago] who said: "We hope that during their time with us, our students gain an understanding of what it takes to live a worthy life. That they understand what injustice is and will work to correct it. That when they see those less fortunate, they assist them. That they reach out to others in need even when they themselves are struggling. That they give generously of themselves and their talents. Above all, we hope that they help those with whom they come into contact to see the value of an educated heart."

Good teachers are those that assist their students in seeing the value of an educated heart – a heart that doesn't shy away from encouraging students to thoughtfully grapple with life's real challenges and controversies. It is perhaps the most satisfying of the many rewards of being a good teacher.

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Chapter 2

Incivility, Inattention, and Multitasking! Oh My! Creating Effective Learning Environments for Millennial Learners

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Recently, I have been traveling quite a bit, presenting conference keynotes and faculty development workshops sharing my research on engaging Millennial learners (i.e., students born between 1981 and 1999). What has surprised me most is how frequently faculty interest turns to the discussion of student incivility. One colleague relayed a story in which a visiting professor came to her class as part of a series on diversity issues. At some point during the discussion, the focus turned to the conflict in the Middle East. One student who disagreed with the speaker's views jumped up from his chair, pointed his finger (thankfully his forefinger) at the visitor and yelled, "You are full of ____!" The student then tore up his notes and stormed out of the classroom, slamming the door behind him! A second colleague told of how she met with a student regarding a paper the student had written. A good professor, she was providing constructive feedback but the student rejected all criticism and demanded a grade change. He left and promptly posted an angry diatribe on ratemyprofessor.com which concluded with a very unproductive statement about the professor's backside, specifically describing his professor as "a fat ___." Finally, in gathering comments from official student evaluations of professors, I was surprised when a third colleague shared the narrative section of his evaluation in which a student simply wrote, "OMG! WTF!" If you are not familiar with these acronyms, you'll need to consult Wikipedia as I am sure my editors would not appreciate an explanation here. The bottom line is if you ask colleagues, I am confident you will get a consensus on this: Student incivility seems to be on the rise.

Let's Be Frank

When my child began his formal educational training a couple of years ago, I was told, "Pre-K is the new kindergarten, and kindergarten is definitely the new first grade." Let's be frank: college is the new high school; everyone's going! In the must-see PBS documentary *Declining by Degrees,* the filmmakers suggest that in order to achieve a middle-class lifestyle in our society, college is no longer an option - it is a necessity. This means the more elite and prepared student body of 15 years ago has given way to a much broader mix of students who vary widely in their level of preparedness, ability, and capacity for imbibing. As a result, we may see more

students exhibit the overtly uncivil behaviors described above. Some of these extreme behaviors may result from an increase in the number of students with mental health issues, while others may be a by-product of more open enrollment combined with the well-known characteristics of Millennial generation culture such as

- helicopter parenting that has extended adolescence and delayed development of independence;
- multimedia exposure that has shortened attention spans and heightened the need for engagement;
- being fully raised within the technological age such that information and everything else is available at the click of a mouse, resulting in a low tolerance for delay;
- and a decline in adherence to social rules (Howe & Strauss, 2007; Twenge, 2006).

Add a dollop of educational consumerism, and we have the perfect recipe for student incivility!

The Million Dollar Question

Now that I have won the award for stating the blatantly obvious, the million dollar question is, in the eloquent verbiage of our Millennial students: WTF do we do about it? Before I go any further, it is important to note this essay is not a personal rant about students behaving badly. On the contrary, I have an extremely connected and positive relationship with my students and I don't mean that in a creepy, unprofessional way! In any given semester, I have approximately 200 students and I find the vast majority of them to be extremely cooperative, conscientious, and excited about their learning. In my 18 years of teaching, I have experienced what I would describe as uncivil student behavior in class on only two occasions. On both occasions we were discussing research cited in David Myers' *Exploring Psychology* text, which describes the role of prenatal sex hormones in the development of sexual orientation. Typically, I am not an uber-Freudophile who attributes behaviors to rigid toilet training, but both of these self-proclaimed heterosexuals seemed to be exhibiting reaction-formation or what is commonly known as "thou dost protest too much" syndrome. The point of sharing this is perhaps in my many years of teaching I have simply been lucky, but perhaps not? What if there were a formula for preventing or at least minimizing student incivility? Well put away your Ouija board and pull out your highlighter because, in gathering my research on Millennial learners, I think I may have stumbled upon some answers.

Step 1: Shift your paradigm to prevention

The first tip for dealing with and responding to these behaviors is to not take them personally. One of my colleagues has suggested the word incivility implies a specific choice or intention on behalf of the student to be uncivil. Perhaps it would behoove us to describe these behaviors as "unproductive to the learning environment,"

since students often cluelessly exhibit them without realizing how their behavior is perceived and the negative impact they might have on the learning environment. In addition, many faculty seem to have concerns about very specific student types such as the belligerent student, the Neanderthal who makes offensive comments, the know-it-all, the verbal dominator, the class-skipper, the perpetually late, the early leaver, the talker, the texter, the sleeper, the newspaper reader, the web-surfer, the unprepared, the student who demands special treatment, and the list goes on. We may find ways to successfully respond to and alter each specific behavior, but if we really wish to create an ideal learning environment, we need to focus on holistic measures of prevention as opposed to fragmented reactions to specific infractions.

Step 2: Practice verbal judo - producing closeness, as opposed to distance

Recently a colleague relayed a story in which she asked her students to define Multicultural Education. One student replied, "*It is a Marxist plot to undermine public education.*" Many of us might be quick to attack this perspective; however, as professors interacting with students, we need to practice what is known as "verbal judo" in which we use our body language, tone, and words as tools to send a message that deescalates conflict. In conducting interviews with Millennial learners I have come across countless students who have described antagonistic professorial responses to what students perceive as accidental or minor infractions. One student described a professor who angrily locked the door when class began such that those who were late could not attend. Another relayed that his professor became irate when the battery ran low on his criminal offender monitoring ankle bracelet and it began to beep. The lesson to be learned here is, *it is never productive to be defensive, to be reactionary, or to express a strongly negative emotional tone with a student.* Yet I frequently hear professors describe with bravado interactions in which they criticize, humiliate, deride, and belittle the very people they are charged to teach, develop, and inspire. It is imperative to acknowledge that every interaction we have will typically produce either closeness or distance. There is little neutrality in our dealings with students. The more we engage in distance-producing interactions with students, the more we can expect noncompliance and unproductive student behaviors in return. When we choose to fight and even feel that we have won these small battles with students, we set ourselves up for losing the war as we lessen our overall ability to assist them in achieving the learning outcomes of the courses we teach. Conversely, each closeness-producing interaction we have with students builds rapport, shows them we care, and prevents the likelihood of resistance and incivility. Sadly, over the years, I have known many professors whose typical mode of interaction with students comes from a place of power and control, yet these professors are often the ones most frustrated with the uncivil responses they are responsible for creating.

Step 3: Clearly communicate course policies and assignments with rationales and consistently administer consequences

I regularly hear colleagues lament that their syllabi have gone from a few short pages to massive tomes in which they attempt to anticipate every foreseeable student excuse and infraction. Yet an ounce of prevention will avert a ton of student angst when we provide rationales and consequences for assignments and policies. If we don't want students to challenge our grading procedures, a detailed rubric along with a rationale for each assignment will assist students in achieving learning outcomes and go a long way toward preventing student grade challenges after the fact. For example, if we have a policy that students will receive a reduction in points for late assignments, we should provide a policy rationale such as the following: "In order to be fair to students who work to turn in assignments on time, all late papers will lose 5% for each class day they are late." This statement should be prominently displayed on both the course syllabus and the rubric for the assignment. Still, we need to be prepared for students who will approach us with extenuating circumstances and/or excuses. So far this semester my students' hardships have ranged from, "*my husband rejected his kidney transplant*" to "*I had to do my taxes*," and it is only February! Some professors may prefer to make accommodations and exceptions on course policies for certain students. However, no matter the situation and the accompanying level of student angst, we should respond without negative emotion. We can extend sympathy and concern without escalating conflict or compromising course policies.

Step 4: Design courses and utilize methods with the prevention of incivility in mind

I have encountered professors who exhibit a wide range of attitudes and responses regarding specific student behaviors such as texting in class. On one end of the spectrum are professors who don't care if students text in class and who ignore such behaviors; on the other end are those who are so disturbed by student texting that they respond with extremely punitive methods such as having an immediate closed note quiz if they so much as see a cell phone in their classroom. That said, I fear hundreds of you are simultaneously saying to yourselves, "A closed note quiz ... what a great idea!" I want to reiterate: if we are troubled by student behaviors, we need to create and clearly state a policy along with the rationale for the policy and follow through with consequences for those who violate it. However, it has become painfully apparent to me that our methods play a powerful role in contributing to or averting unproductive student behaviors in the classroom. For example, I recently used my *i-clicker* classroom response system to gather a bit of feedback from students regarding their attitudes and texting behaviors. Of the 77 students polled, 18% said they never text in their classes. This was a shockingly low number from my perspective because of my approximately 200 students, I had seen fewer than 5 texting during class and had only two "textaholic" students texting so regularly that I thought it might be disruptive to their learning and those around them. If so many of my students were texting, why weren't they texting in my classes? I found the answer among the remaining 63

students who did report that they texted in their classes. Of these 63 texters, 87% strongly agreed or agreed with the following statement: "I text more in classes in which the professor's main method is lecture and less in those classes in which the professor uses a variety of methods such as discussion, group work, cases, and video or multimedia." Based on our discussions after the survey, it was very clear to me these students were at risk for all types of inattentive behaviors such as texting, surfing, talking, etc. when they were not engaged. In short, if we want to diminish behaviors associated with inattention, our course design and methods matter.

Conclusion

If you peruse the literature on student incivility in the college classroom, you will find a great deal of evidence in support of the recommendations provided here (Boice, 2000; McKeachie, 2006; Meyers, 2003; Weimer, 2002). Communicating clearly and providing a rationale for class policies, creating closeness as opposed to distance when interacting with students, and using engaging methods will not only lessen student incivility, but will help us work toward our ultimate goal of assisting students in achieving learning outcomes as well.

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Chapter 3

A Blueprint for the Future: From Puget Sound to Your Campus

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The Puget Sound Conference

Teaching and learning are difficult and complex tasks. Psychology exists in overlapping social, cultural, political, and educational contexts that shape and perhaps dictate its application. Outside of colleges and universities, life has never been more complex, the foundation of society has never been more seriously questioned, and the tension and conflict between people and between industrial, religious, and racial groups have never been more intense than they are today.

Furthermore, there are now several trends emerging in American higher education such as lower enrollments in many 4-year institutions, students with a wider range of backgrounds and preparations who are demanding more relevant academic curricula and more vocationally oriented training, and increased pressures for monitoring teaching productivity in a time of budgetary restraint.

Wide individual differences can be found among members of a class in general psychology, and it seems that many students have to be taught to read intelligently. Important as the differences in intelligence may be, they are overshadowed by much more important differences in maturity, preparation, interests, and religious, social, and cultural backgrounds. Similarities among students were more common when a college education was limited to a select few, and doubtless the standardized methods of teaching are a relic of those days. There has been pressure in the classroom to depart from standardized lecture formats, to keep the students doing things instead of merely listening, reading, or seeing them done.

These issues complicate the teaching of psychology, but ours is not the first generation to face them. In fact, the first three paragraphs of this essay comprise a set of nearly direct quotations of psychologist teachers between 1910 and 1960 (Beins, 1992). The important issues from the past remain important. What must change is the way we respond to them.

For the past two decades, the 1991 Saint Mary's Conference has influenced the teaching of psychology. The seminal *Handbook for Enhancing Undergraduate Education in Psychology* (McGovern, 1993) from that conference has provided

guidance on a host of pedagogical issues. However, the landscape of higher education has undergone a vast transformation since then.

So, after nearly 20 years and a lifetime of technological and pedagogical evolution, the next generation of educators has charted a course for the 21st century. The National Conference on Undergraduate Education in Psychology took place in June 2008 at University of Puget Sound in Tacoma, Washington. Funded by APA, NSF, and other sponsors, a star-studded steering committee of educators led by Diane Halpern issued a competitive call for conference participants. Of more than 200 applicants, the steering committee chose approximately 70 participants who represented different subdisciplines and institution types. The participants formed nine groups, each tasked with writing a book chapter addressing one of the following questions:

- Why do we need to rethink undergraduate education?
- Who is teaching Psychology? (including Quality of Instruction, Staffing Patterns, Rewards, and Training)
- What is being taught and learned in Psychology courses?
- Who are the students in undergraduate Psychology?
- When and where are students taking Psychology courses?
- What are the modes of instruction?
- How can we promote learning with new technologies?
- How are we using new knowledge about teaching and learning?
- What are the desired outcomes of undergraduate education in Psychology?

The final versions of the chapters, along with introductory and closing chapters and associated Quality Principles, appeared in a volume edited by Diane Halpern and published in 2010 by APA, entitled *Undergraduate Education in Psychology: A Blueprint for the Future of the Discipline*. This volume is a guide for educators, programs, departments, and institutions in addressing undergraduate education in psychology in the 21st century. Because the conference and the book are so closely tied, with the ideas discussed in the former put to paper in the latter, we will refer to them jointly here as the *Blueprint* as we discuss some of its themes and context.

Educational Context in the 21st Century

The *Blueprint* was conceived and produced in the midst of a veritable sea change in higher education. Recent and continuing technological developments have not only opened up new options for pedagogies and information gathering, but have, many claim, changed the nature of student learning in the current generation of 'digital natives' (Prensky, 2001) - college students who have grown up with computers and related technologies. At the same time, calls for accountability (e.g. U.S. Department of Education, 2006) and integrated learning (e.g., Bok, 2006) have forced colleges to re-examine their general education and major programs. The last decade has also been fraught with economic, environmental, and political concerns that affect the very

core of our functioning as a society, highlighting the need for psychology as a discipline to engage in broader participation in addressing these critical global issues.

Themes of the *Blueprint*

As the week of the Puget Sound conference progressed, it became apparent that there were several points of contact between the discussions of the different groups. As with any dynamic system, the *Blueprint* began to self-organize and develop some emergent properties, or themes, that wove throughout multiple chapters of the book and are reflected in the Quality Principles. What follows is our interpretation of some of these themes.

Facilitating psychological literacy is critical to our educational mission

The term *psychological literacy* represents a multifaceted skill set that allows individuals to use their knowledge of psychology to function well in their personal, professional, and civic lives. Such a skill set can benefit everyone, even those who are not psychology majors. We must remember that many, if not most, of the students we see in our classes will take only one or a few psychology courses while in college. If these students are to become psychologically literate and able to apply the content of psychology to the conduct of their own lives, we need to redouble our efforts to ensure that introductory psychology courses prepare students for the relevant contexts and decisions that they will face throughout their lives.

Science remains the core of psychology

Despite increasing popularity of applied and allied approaches to psychology, our discipline remains firmly grounded in scientific methods and values. An undergraduate degree in psychology should reflect this foundation, and should moreover, according to the *Blueprint*, include training in research methods supported by key areas of the discipline including biological bases, learning and cognition, developmental, and sociocultural domains.

Furthermore, it is critical that students who encounter psychology in only one or two courses recognize that what we know about behavior and mental processes is empirically based. The importance of identifying our discipline as a science is considered so important that the *Blueprint* includes a call for departments to adopt the moniker of Psychological Science.

There is no such thing as one size fits all

Institutions of higher learning vary in their missions and in their structures. As such, the curriculum of psychology can take diverse forms while remaining true to the scientific grounding of the discipline. Programs can put their stamp on the psychology curriculum to reflect the needs and interests of their students. In addition,

rather than advocating for particular pedagogical techniques, the *Blueprint* acknowledges that a myriad approaches can be efficacious and that educators should use instructional techniques that best match the learning goals, student characteristics, and content that apply to the learning context.

We are experiencing a changing landscape of students and technology

Our job in considering how best to engage our students is constantly changing. With the ongoing demographic changes and the rapid technological developments of the 21st century, the nature of our students and their expectations has undergone a revolution. It has become especially important, then, that we adopt a scientist-educator model within our profession.

As scientist-educators who engage in pedagogical scholarship, we can share best practices with each other, reduce the 'lag time' in adopting new and effective approaches, and improve student outcomes by finding effective matches between teaching and learning. As teachers, we can use our own psychological literacy to generate and evaluate pedagogical techniques.

Successful education in psychology requires commitment of stakeholders at multiple levels

Although we clearly play a critical role in transforming education in psychology, we cannot transform it on our own. But we can provide an overarching set of principles that guide educators. Consequently, the *Blueprint* ends with a set of Quality Principles that task students, faculty, programs, institutional administrators, and policymakers with taking responsibility for their role in fostering optimal learning outcomes. These Quality Principles further delineate steps that each of these stakeholder groups can (and should) take in working together to achieve the goal of excellence in undergraduate psychology education.

Putting the *Blueprint* to Work

The promise of the *Blueprint* is wasted if we do not heed its call. The conference has concluded, the book is published, and now we must follow up with action. Already, colleagues have reported that the *Blueprint* has been used to inform curriculum development, support departmental advocacy for resources, prompt at least one departmental name change, and develop policy-oriented assignments. Undoubtedly, the *Blueprint* will continue to leave its mark as it supports creative teaching professionals in a wide range of initiatives. We call on each of our colleagues to use the *Blueprint* as a guide in developing best practices and improving student learning in psychology during the coming years.

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Chapter 4

Technology for Educators

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Technology changes very quickly, and the signal to noise ratio is very high. As faculty, we don't have a lot of time to seek new ways of interacting with our computer-based information, let alone learn how to use those new tools. This essay introduces a few easy-to-use tools that can help teachers work more efficiently.

Dropbox:
Windows, Linux, Mac, iPhone/Droid apps with an app for Blackberry coming soon

Are you using a flashdrive to tote your files from your office to your classroom and then home? Do you back up your flashdrive or send files to yourself via email? Do you ever worry about losing your flash drive or losing track of which version of a file is most current? Consider Dropbox (http://dropbox.com). Imagine having access to your files wherever you are: At home, at work, on your laptop, at the public library, on your smartphone, on a boat, with a goat, in the rain, on a train. You get the idea.

Dropbox adds a folder in the 'My Documents' folder called 'My Dropbox.' Treat it like you would any other folder. Whatever you put in that folder will automatically be uploaded to Dropbox.com and then downloaded to any other computer where you have installed Dropbox. For example, I have it installed on my work computer and my personal laptop. I can also access it on my Droid using the Dropbox app or my phone's web browser. In my classroom, I can visit Dropbox.com and log in to my account to access my files. Dropbox serves as a handy backup. Not only are my files saved in three places (work, home, and on the Dropbox server), Dropbox retains previous versions of files for 30 days.

Another advantage of Dropbox is that I can share individual folders with other people. I have several folders inside my Dropbox folder. By right-clicking on the folder and mousing over 'Dropbox,' I can select 'Share this folder.' This will open my browser to the appropriate page on the Dropbox website. All I need to do is type in the addresses of the people with whom I want to share the folder, and Dropbox will send them invitations. A shared folder acts like a shared drive. Any change I make to a file will automatically be updated on the computers of everyone with whom I'm sharing that folder. When that person makes a change, the file is updated on my computer.

A minor disadvantage of this resource is that only those who install Dropbox are able to share files. While Dropbox makes it easy for others to join and set up Dropbox, some users may resist being 'forced' to use a new program.

Xobni (Inbox spelled backwards):
Windows XP, Vista, or 7; Outlook 2003, 2007, or 2010

Xobni is an add-in for Outlook (http://xobni.com) that makes managing the onslaught of email much easier. It can help you quickly find email messages, attachments, and contact information for anyone with whom you have ever exchanged emails (Figure 1).

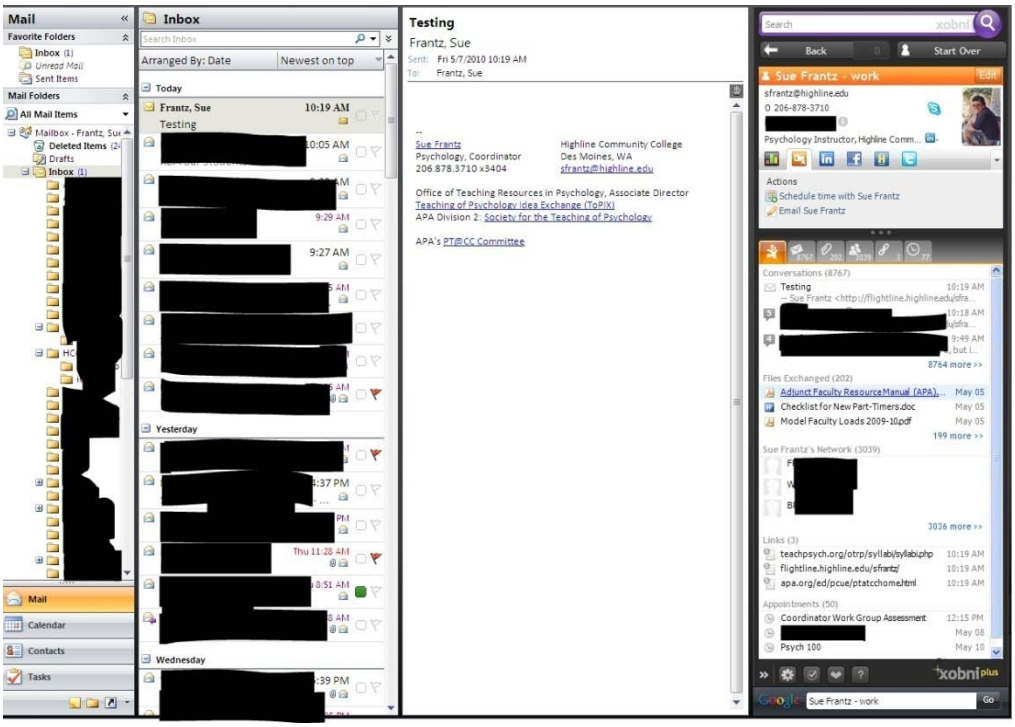

Figure 1: Xobni occupies the fourth column on the screen.

To illustrate how it works, I sent a blank email to myself. When I click on that email, I see the message in the reading pane (third column), and Xobni automatically pulls in whatever information it has collected about me. If I were looking at an email from you, I would see whatever information Xobni has collected about you. At the top you see my work email address. Next are my work and mobile numbers. I can even Skype directly from Xobni. I didn't have to enter any of this information; Xobni pulled it from emails that were sent to and from my Outlook. Where did the photo come from? Facebook. Xobni will show photos for people who use this email for their Facebook account and who have their Facebook photo set as publicly available.

Xobni's true power lies in its indexing of email. If I'm looking at an email you just sent me, I can also see the most recent email conversations we've had, the files we've exchanged, and website URLs we've shared, all of which I can open directly from Xobni. Xobni is also searchable. Typing "Jack" in the search box will locate everyone I've corresponded with who has "Jack" as part of their name. I will also get all the email messages that had "Jack" in the subject line or body of the message, all files exchanged that contain "Jack" in the name of the file, and any appointment that included someone named Jack. If 'Jack' is on the webpage of a URL that I and another person exchanged in an email, Xobni will give me the URL.

When Xobni was first released, it was criticized for slowing down Outlook. Xobni has largely resolved that issue. Outlook may initially take slightly longer to open but then there is no difference in how the program performs and the benefits of Xobni's search capabilities can quickly outweigh this slight delay.

Other Outlook Add-ins

If you live in Outlook, you might also be interested in Simply File (http://www.techhit.com/SimplyFile) for quickly filing email messages into folders, EZDetach (http://www.techhit.com/ezdetach) for quickly pulling attachments off email messages and saving them to your computer, and Bcc (http://www.bccthis.com) which allows you to send one message to one or more people while letting you send an additional comment to one or more additional people. Use bcc to keep someone in the loop while adding additional information for context. It works with Outlook, Gmail, and Blackberry.

Google Reader

How many websites do you visit each day? When do you find time to go into your college library's database to look at what's new in your professional journals? Do you keep checking in with your favorite bloggers to see if they have posted something new? Wouldn't it be nice if someone would just contact you to let you know when there is new content on a web page? RSS feed readers do just that. When you use a feed reader to 'subscribe' to a website, the reader periodically checks that website for new content.

In fact, you probably already have a feed reader. Outlook and Firefox, for instance, both can read RSS feeds. In Outlook, you can find "RSS Feeds" in your "Mail Folders" pane, just above your "Sent Items" folder. In Firefox, they're called "live bookmarks." Many web pages produce RSS feeds - content that is readily readable by RSS feed readers. Many post a sporty little orange icon. Your browser may also display this icon in the address bar to tell you an RSS feed is available. Click the icon to subscribe to the feed.

Figure 2. RSS feed icon.

Google Reader (http://www.google.com/reader) is popular because it's web-based rather than residing on your

computer; you can access your personal news feeds on any device that has internet access. I'll discuss how to use Google Reader, but all readers work basically the same way: Subscribe to a news feed. Read the news feed. Here's a one-minute overview courtesy of Google Reader: http://www.youtube.com/watch?v=VSPZ2Uu_X3Y.

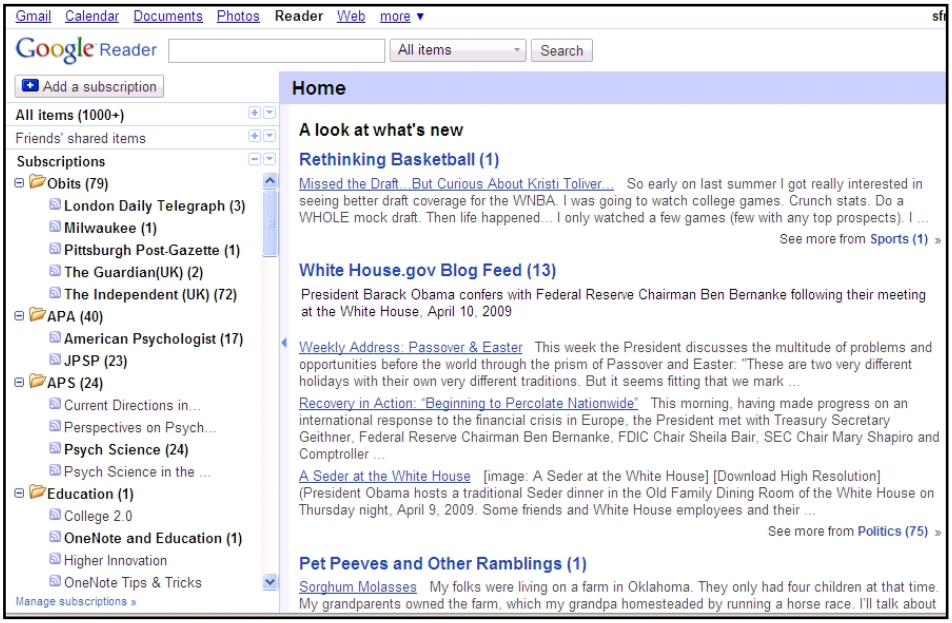

Figure 3. My Google Reader.

In the screenshot, on the left you can see some of the feeds to which I'm subscribed. The ones in bold are the ones with unread content; the number in parentheses tells me how many unread items are in that feed. On the right is content from some of my unread feeds.

Did you know that your library's database has RSS feeds? For instance in Figure 4, I have an "APA" folder that has two APA journals in it. Google Reader retrieves each journal's table of contents giving the title, author, and journal information. Some journals even provide the abstract. Clicking the article title takes me directly to the article in my library's database. A database search can also be an RSS feed. Whenever new content arrives in the database that matches your search criteria, the articles will

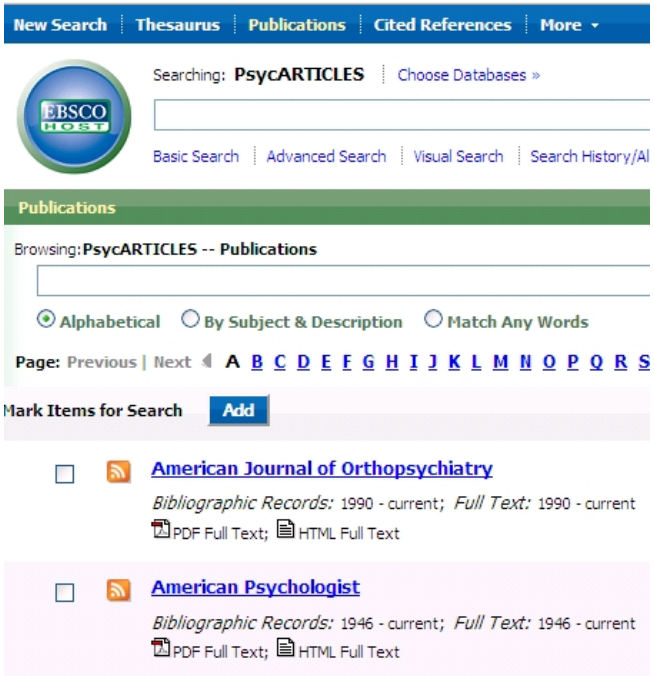

Figure 4. Library databases provide RSS feeds.

appear in your feed reader. To subscribe, visit your library's website, and open your favorite database. Locate the journals, magazines, or newspapers you are interested in and look for the orange RSS icon

In short, an RSS feed reader produces a personalized newspaper. Some people feel compelled to read everything in their news feed and if they don't, they feel guilty. Truly, your RSS feed reader doesn't care if you read it or not. Skim the headlines like you would a newspaper, and read only what you'd like.

Phrase Express: Windows 2000, XP, Vista, or 7

I spend a lot of time typing the same phrases over and over again. When students send me an assignment via email, I reply with a 'got it' message. When I send them their graded assignments, I write a 'your assignment is attached' message. When I grade papers electronically, I find myself typing the same sorts of comments over and over again such as, "Write out numbers that begin sentences." Phrase Express (http://www.phraseexpress.com) allows me to use keyboard shortcuts to make such comments.

PhraseExpress works wherever you type text – in email, in Word, in Excel, in your browser's search box. Using whatever combination of key strokes you designate, Phrase Express will automatically enter text, run a program, open a folder or file, do a web search, access your clipboard cache, open a calendar, or enter today's date. If you can do it on your computer, Phrase Express can do it with a shortcut. One downside of this application is that Phrase Express will sometimes behave strangely, such as performing an action with just part of a keyboard shortcut. For example, CTRL-ALT-V will produce a window that lists the last 20 copies I made. In Windows, CTRL-V pastes just the last copy. Sometimes CTRL-V will be enough to cause Phrase Express to show the last 20 copies. Closing and reopening Phrase Express usually resolves the issue.

Conclusion

This essay introduced several computing resources that can help you more easily manage files, email, and information, and can also provide you with shortcuts for common tasks. Resources such as these can enhance your ability to collaborate with colleagues, improve your access to information, and increase your efficiency as you juggle professional responsibilities.

Chapter 5

Internationalizing Your Psychology Course

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International Psychology: What It Is and Its Relevance in Teaching Psychology

There are two definitions that I think adequately capture the most relevant aspects of international psychology. First, international psychology is referred to as "an emerging branch of psychology that focuses on the worldwide enterprise of psychology in terms of communication and networking, cross-cultural comparison, scholarship, practice, and pedagogy" (International psychology, 2010). This definition suggests that it can be a distinct area within psychology that one can specialize in, and that it promotes a more global orientation to understanding the human psyche. The second definition describes international psychology as "a science-informed domain that cuts across traditional fields and subsumes an array of pressing global concerns and challenges, including but not limited to intergroup conflict and peace building, environmental degradation and preservation, and risks for and the prevention of physical, and mental illness" (Stevens, 2009, p. 42). This definition illustrates the interdisciplinary and empirically-based nature of international psychology and demonstrates that there are current topics relevant to understanding human behavior and thinking from a global perspective.

Though there are a number of articles that offer ways to internationalize the psychology curriculum (e.g., Bartolini, Gharib, & Phillips, 2009, Boenau, 2007; Hogan, 1996; Marsella, 2007; Stevens & Wedding, 2004; Takooshian, 2004); this essay has a more specific purpose: to offer simple ways for psychology instructors to internationalize the courses they teach.

There are compelling reasons why a growing number of instructors have tried to internationalize their courses in some way. Many aspects of human life continue to become more globally influenced and there is increasing realization in the field that the differences and commonalities in human behavior between cultures around the world can be explained as a function of the contextual and historical variations between nations as cultures evolve. Thus, psychologists have come to value the pursuit of a more global perspective in understanding how individuals behave and think.

Internationalization is also reflected in the mission of many colleges and universities. An international perspective, both in psychology and other disciplines, has increased in recent years because people from all over the world have greater connections with each other. This is the result of factors such as increased travel, telecommunications, geopolitical collaborations and conflicts, cross-national business dealings, environmental concerns, and humanitarian efforts that cross national

boundaries. Internationalization strategies within colleges and universities help students become globally and culturally competent citizens, and provide them with the kind of education that prepares them to function and compete in a more global society. Since most students will likely not have the opportunity to study or work abroad, internationalizing the curriculum through pedagogical strategies employed by course instructors is a viable and potentially cost-effective alternative.

Unfortunately, there is evidence that the existing psychology curriculum in the United States includes little on internationalization (Woolf, Hulsizer, & McCarthy, 2002a, 2002b). There is also an apparent lack of cross-national knowledge, research, and awareness of perspectives about psychology among many of our majors. Instructors tend to encounter roadblocks when they consider incorporating an international perspective in terms of what and how they teach. These roadblocks include but may not be limited to instructors' lack of familiarity with the international literature, lack of institutional financial support for internationalization, and instructors' other work-related obligations. Thus, psychology instructors need specific guidance concerning what they can do to add a more international perspective to their courses.

Before considering strategies, it is wise to know the relevant objectives for internationalizing a psychology course. I suggest reading the report from the APA Working Group on Internationalizing the Psychology Curriculum (APA Task Force on Internationalization the Undergraduate Psychology Curriculum, 2005) as a useful beginning framework. The authors of the report recommended five goals and associated learning outcomes. The five goals address psychological knowledge in international perspective, methodological issues in international research, the discipline of psychology in the international perspective (i.e., awareness of how the discipline of psychology is developed, studied, and applied in and across cultures), psychology and interpersonal understanding, and psychology and global issues. The report also provides suggested student learning outcomes for each goal to assist with course design and for use as a checklist to assess the effectiveness of the strategies at the end of the course.

Simple Strategies Instructors Can Use to Internationalize a Psychology Course

How may a psychology course be internationalized? There are a variety of different ways to go about this, so I offer the following pedagogical strategies that you may employ. Most of these strategies are based on a preliminary analysis of a recent survey that APA Division 52's Curriculum and Training Committee conducted asking its members who teach psychology what have they done to internationalize their courses.

Class Presentations and Lectures

- Have visiting scholars, international students, and study-abroad returnees (and those who have simply traveled and stayed in another country) as classroom resources.

- Show films/videos that enhance an international perspective and critical thinking pertaining to psychological constructs (see Meiners, 2009).
- Adopt critical questioning and cross-national comparisons of psychology as a means of helping students examine and challenge their own assumptions, beliefs, values, and practices from international perspectives (e.g., Students learn that the model they see in the U.S. is not the only possible model and that basic assumptions about the scientific nature of psychology are questioned in some parts of the world).
- Discuss world events and current issues whenever possible; recommend good international news outlets.

Student Activities

- Emphasize active learning activities (e.g., small group discussion, debate, role play, etc.) in teaching about global issues from a psychological perspective.
- Discuss faculty international experiences during class and informally during advising sessions or office hours.
- Facilitate interaction between domestic and international students by providing more opportunities for collaborative student projects and structured activities.
- Encourage students to attend international events (especially psychology conferences) on and off campus. Provide extra credit to students who do attend.

Writing Requirements

- Include contributions of non-U.S. authors on course reading lists and in-class lectures. (e.g., in presenting and discussing the history of a subfield or content area).
- Require students to include and cite international literature in the papers they write. If you prefer this to be optional, give them extra credit but make sure all students are informed of the opportunity.

Utilize the Internet

- Use social networking sites (e.g., Facebook, blogs, wikis, virtual worlds, Blackboard, videoconferencing, etc.) in teaching/training and research work.
- Use internet-based technologies (e.g., e-mails, Websites, podcasts, YouTube videos, videoconferencing, blogs, internet-based research technologies) that promise to be particularly relevant and effective pedagogical devices in internationalizing psychology curriculum (Velayo, Oliva, & Blank, 2008). Presuming that your students are already very familiar with such technology and may find it motivating if these resources are utilized in the course, this may facilitate their readiness to communicate and collaborate with others across geographical regions of the world. For example, a class of students from one institution could "meet" a class of students from an institution in another country via videoconferencing. Blackboard technology could be used to set up

a web-enhanced course that allows for discussions among students from different institutions around the world.

You may even be interested in developing a course on International Psychology. There have only been a handful of university-affiliated instructors that I know of who have done so. I would recommend looking over the syllabus developed by Dr. Michael Stevens of Illinois State University, which is available online at http://www.psychology.ilstu.edu/mjsteven/PSY326.html. You will find certain topics he covers to be useful to integrate into your own course. You will also notice that he has a required textbook (Stevens & Gielen, 2007), as well as a set of reproduced book chapters and journal articles drawn from various social science disciplines (e.g., political science, sociology).

Additional Resources

There are abundant resources that can be very useful in incorporating international content into a psychology course but these are not generally available through a single published resource. For those who wish to read more about internationalizing the psychology curriculum, I offer my top 12 recommended resources (listed alphabetically based on authorship) to help you gain more knowledge and develop your own unique approach to internationalizing your courses.

1. APA Task Force on Internationalizing the Undergraduate Psychology Curriculum. (2005). *Report and recommended learning outcomes for internationalizing the undergraduate curriculum.* Retrieved on July 11, 2010 from http://www.acenet.edu/Content/NavigationMenu/ProgramsServices/cii/current/past/APAFinalACEReportjtp.doc
[This document recommends five relevant goals and associated learning outcomes for internationalizing the undergraduate psychology curriculum in the United States.]

2. *International Journal of Psychology* (2006, Volume 41, Issue 1).
This special issue of the journal published on behalf of the International Union of Psychological Science (IUPsyS) features the topic on "International Practices in the Teaching of Psychology" with guest editors, Victor Karandashev and Sherri McCarthy.

3. *International Psychology Information Clearinghouse.* Retrieved on July 11, 2010 from http://www.internationalpsychology.net/resources/
[This 100+ page comprehensive listing of relevant resources has been compiled by Michael Stevens, PhD (Professor of Psychology at Illinois State University) and made accessible on the website of APA's Division of International Psychology. It contains general resources - accessible via the web or in print form - including career information, international psychology organizations, work opportunities for academic, research, and clinical settings, potential funding sources for US and non-US instructors

and students, books, articles, syllabi, conference presentations, and many other resources.]

4. McCarthy, S., Newstead, S., Karandashev, V., Prandini, C., Hutz, C., & Gomes, W. (Eds.) (2007). *Teaching psychology around the world, Volume 1.* Newcastle upon Tyne, UK: Cambridge Scholars Publishing.
[This book provides an overview of teaching psychology internationally by incorporating research and perspectives from psychologists in more than 30 countries. It also includes relevant information for secondary, undergraduate, and post-graduate psychology programs.]

5. McCarthy, S., Karandashev, V., Stevens, M., Thatcher, A., Jaafar, J., Moore, K., Trapp, A., & Brewer, C. (Eds.) (2009). *Teaching psychology around the world, Volume 2.* Newcastle upon Tyne, UK: Cambridge Scholars Publishing.
[This book includes current information on the teaching and practice of psychology collected by experts in the field throughout the world. It is highly recommended by prominent U.S. psychologists. One of the chapters from this book that you may find useful is by Meiners (2009) titled "Viewing films to build 'global competence': A case study."]

6. Woolf, L. M., Hulsizer, M. R., & McCarthy, T. (2002a). *International psychology: A compendium of textbooks for selected courses evaluated for international content.* Retrieved July 15, 2010 from http://www.teachpsych.org/otrp/resources/resources.php?category=International%20Psychology
[This electronic resource contains a compilation of information on textbooks in introductory, social, and lifespan developmental psychology which have been evaluated for international content. It includes comparative tables (amount of international coverage per textbook and per chapter, total number of chapters, number and gender of authors, etc.), plus narrative reviews of each of the textbooks given these three content areas.]

7. Woolf, L. M., Hulsizer, M. R., & McCarthy, T. (2002b). *International psychology: Annotated bibliography, relevant organizations, and course suggestions.* Retrieved July 15, 2010 from http://www.teachpsych.org/otrp/resources/resources.php?category=International%20Psychology
[This contains a diverse set of resources including sample syllabi, annotated bibliographies, and video suggestions to help you incorporate international content into selected existing courses. It may also be useful to those who wish to develop a course on international psychology.]

8. Pawlik, K., & d'Ydewalle, G. (2006). *Psychological concepts: An international historical perspective.* Hove, UK: Psychology Press.

[This book provides an international perspective on each of the core psychological concepts, describing and analyzing them from a historical point of view. Authors from 11 countries and 4 continents, all distinguished in their respective research areas, contributed to the 14 chapters.

9. Stevens, M. J., & Wedding, D. (Eds.). (2004). *Handbook of International Psychology*. New York: Brunner-Routledge.
[This book chronicles the evolution of psychology in different world regions for the purpose of reducing the ethnocentric nature of the western psychology. Each chapter follows a uniform outline, unifying the volume as a whole, but allowing for the cultural diversity and status of psychology in each country.]

10. Stevens, M. J., & Gielen, U. P. (Eds.). (2007). *Toward a global psychology: Theory, research, interventions, and pedagogy.* Mahwah, NJ: Erlbaum.
[This book is a thorough review of the existing literature on international psychology from around the world and provides the knowledge needed to successfully engage in the science and practice of psychology in an increasingly globalized society. It provides an overview of conceptual models, research methodologies, interventions, and pedagogical approaches related to international psychology

11. Wedding, D. & Stevens, M. J. (2009). *Psychology: IUPsyS global resources.* [CD-ROM (8th ed.)]. Hove, UK: Psychology Press.
[This resource contains a set of tools covering all aspects of psychology around the world. New material is added to this CD-ROM and existing sections are updated and/or expanded annually.]

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Chapter 6

Advising Dilemmas: Difficult Messages and Strategies for Delivering Them

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Advising interactions provide opportune teaching moments. Advisees arrive with questions, goals, and uncertainties in hand. Although their investment in the advice received will vary, there is great potential for advisees to receive new information and to correct misinformation. Faculty interest in these teaching moments also varies. Ware (1993) observed that "although theory, research, and practical applications permeate the advising literature, most academic psychologists appear relatively uninterested in advising-related activities and outcomes" (p. 47). This stems in part from advising taking time away from classroom teaching, research endeavors, and service activities. But we believe that advising dilemmas also impact such attitudes. By "advising dilemmas," we mean those moments when an advisee's question or situation requires a response that both parties are likely to experience as undesirable or unpleasant. Often the advisor feels a pull to deliver bad news, provide a reality check, or confront problematic behavior or thinking.

Our goal in this essay is to shed light on common advising dilemmas in an attempt to normalize the difficulty faculty experience in confronting them and provide action steps for advisors seeking to improve the outcomes. To accomplish this, we first consider the culture of advising and several contextual factors for advising interactions. We then examine three common advising dilemmas and offer practical strategies for successfully addressing them. We conclude by attending to several broad, department level issues that impact the specific advising dilemmas faculty encounter.

Advising Culture and Context

Several elements of the advising culture parallel that of patients and providers in the medical community. Prominent among these is advisees' tendency to consult multiple sources of information (e.g., websites, institution catalog, instructors, peers) prior to meeting with an advisor. Although informed advisees are desirable, problems emerge when they are more invested in the advisor confirming their self-assessments and plans than offering expert, objective guidance.

Because faculty react to the advising situation in diverse ways, second opinions are of value. Faculty differ in terms of their knowledge of issues critical to student success (e.g., university policies, trends in a subfield) and approaches to advising. For example, prescriptive advisors address the specific tasks and questions at hand whereas developmental advisors are concerned with students' broader growth (Crookston, 1972, reprinted 1994; Appleby 2001). The former "treats" the primary symptom while the later "treats" the entire student.

Like physicians who avoid discussing diet, substance use, and exercise, some faculty are so uncomfortable addressing students' grades, study habits, and classroom behavior that they simply fail to do it. Still others proceed by conceptualizing the task as difficult in the moment but ultimately in the student's best interest. Like patients fearful of receiving bad news from a physician, many advisees avoid advising altogether or skirt difficult topics. Others attempt to negotiate things beyond the advisor's control. They may argue that a particular course requirement in the major is unjustified or that a graduate program of interest is being unfair in using its minimum GRE requirement. Still other advisees deny the realities advisors present, such as the impossibility of raising an established GPA beyond a certain point.

It is important that advisors also recognize key contextual factors in advising dilemmas such as the dramatic changes to the employment situation for young college graduates. In his article *The Lost Generation*, Coy (2009) identifies several troubling trends. For example, in September of 2009 only 46% of 16-24 year olds had jobs – the lowest percentage on record since WWII. Advisees' fears related to unemployment, lack of insurance, and homelessness are likely increasing. The tight job market may also increase the number of alumni requesting advising. Students whose employment or graduate school plans were thwarted may contact a previous advisor for assistance.

Another contextual factor is highlighted by the attention recently given to the for-profit education industry. Media coverage of some students' negative experiences and the profit margins of some institutions has helped spur congressional inquiries into potential wastes of federal student aid (Field, 2010). As the number of graduate degrees offered by such institutions grows, advisors will face the issue of how to best help students evaluate the quality and costs of these programs independent from their likelihood of acceptance and the program's claims.

Common Dilemmas and Strategies for Responding

Faculty members face a variety of dilemmas when working with advisees. One common advising dilemma arises when students' math and writing skills are inadequate. These advisees often express strong dislike for fundamental aspects of the major. For example, Advisee X says he is taking the research methods course a third time despite his disdain for numbers and writing. His transcript reflects poor grades in related courses and low SAT scores. Despite his anguish, he repeatedly asserts that he will pass the course this time. In this situation, it is incumbent upon the advisor to not collude with the student in ignoring his skill deficits and instead commit to questioning

his past performance. Advisees often avoid this conversation by attributing previous struggles to external factors, and too often advisors accept this in order to avoid direct confrontation. This dilemma also demands a frank discussion about the nature of the major and field. Such skills deficits have immediate relevance to success in courses and long-term relevance to success in graduate school and careers (Appleby, 2001). This dilemma is a proverbial fork in the road. Many advisees in this position would be well served by an advisor who engages in an honest conversation about what other majors might be better suited to the students' skills and interests.

A second advising dilemma involves students who overestimate their chances of getting into graduate school. For example, Advisee X says, "I know I have a 480 Verbal GRE score and a 3.2 GPA, but I'm positive I will get into X clinical Ph.D. program." In this situation, it is important that the advisor first question her reasons for applying and the logic behind her confidence. Such advisees often need assistance to separate desire, or motivation, to attend graduate school from the ability to successfully complete it. Advisors are best equipped to address this dilemma when they understand: 1) the different types of programs that exist (e.g., clinical scientist vs. scientist practitioner), 2) the relative importance of application components, and 3) recent admissions statistics (for example resources, see Lawson, 1995; Norcross, Kohout, & Wicherski, 2005). Being armed with this information moves the advice and guidance advisors provide outside of opinion or personal experience and into the realm of empirical evidence. Advisors can also direct students to resources available for navigating the application process (e.g., American Psychological Association, 2009; Keith-Spiegel & Wiederman, 2000; Norcross, Sayette, & Mayne, 2008).

A third advising dilemma occurs when weak students request letters of recommendation. These advisees often begin their request by acknowledging some deficit they assume might normally prohibit a letter, such as inadequate qualifications for graduate school, limited interactions with the advisor, and/or needing the letter on short notice. Unlike other advising activities, this dilemma involves a request for the advisor's formal evaluation of the advisee. As a result, faculty should explore the costs and rewards of their decision. The advisee's welfare must be considered (e.g., Will he or she be well served by attending the program?). The welfare of the graduate program should also be considered (e.g., Would the advisee be an asset or liability to the program when working with mentors, serving clients, or teaching students?). After considering these issues, advisors should recognize they have multiple options for responding to a student's request. They can say "yes" knowing that the letter will be strong, or they can say "yes" but explain to the advisee what limits them from writing a strong letter. Advisors also can say "no" knowing the letter would not be strong enough, or they can say "no" and talk with the student about how this situation can be addressed to ensure a strong letter in the future.

Conclusion

Advising dilemmas like those discussed above may recur in part due to the persistence and prevalence of certain advising cultural and contextual factors.

Individual advisors can do much to enhance their effectiveness at and comfort in dealing with these dilemmas. Yet in addition to the expansion of advisors' knowledge and skills, it is important to attend to departmental-level concerns and decisions that impact advisors and advisees. For example, as advisors and departments consider advising dilemmas, decisions must be made regarding who is best equipped to address these challenges and where the limited resources are best applied. Some departments utilize advising specialists (faculty or staff) who have expertise and interest in working with larger numbers of advisees. If faculty alone carry the responsibility for advising, the time required must be evaluated in light of other responsibilities. How advising resources are prioritized among prospective, current, and former students should also be determined.

Some advising dilemmas can be reduced by clearly communicating to students the identity of the major and expectations for those pursuing it. Departments could offer a pre-major orientation or require a course on the psychology major and related careers. Standards for entering and remaining in the major can also be established and enforced. Struggling students can be more proactively engaged through intervention advising designed to directly address their problems and devise remedies. Advanced students can be assisted by offering workshops on preparing for post-degree plans or having departmental policies on situations that are often handled inconsistently across advisors (e.g., letters of recommendation, qualifications for research assistants).

Dilemmas contribute to perceptions that advising can be one of the most challenging of a faculty members' responsibilities. By developing an appreciation for the normalcy of such impasses and utilizing strategies for addressing them, advisors can begin to transform more of these dilemmas into teaching moments.

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Chapter 7

The Vacuity of Positive Thinking: A Century of Pop Psychology

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In many of our classes we leave out entirely much of the stuff that students, prior to arriving in our classrooms, thought was part of the field of psychology. However, teaching students enough about the history of pop psychology to understand why we don't devote much attention to it is quite worth the effort. Perhaps it would be best to begin with a definition: While books from actual psychological scientists frequently do well in the marketplace, the term "pop psychology" is generally reserved for works by academic outsiders submitting their ideas and advice directly to the public rather than undergoing the peer-review process of academic journals. While the science of psychology emphasizes replicable empirical evidence, much of pop psychology is devoted to simplistic advice and the uncritical repetition of already widely-held beliefs, common sense, and religious advice, retooled with psychological jargon to sound contemporary and scientific.

Just as I structure my History and Systems course around a set of themes, recurring ideas, and conflicts (free will vs. determinism, nativism vs. empiricism, mental phenomena vs. behavior), I have also found a unifying theme for pop psychology. The theme is that pop psychology has only ever really had one idea – an idea best described, to borrow from Norman Vincent Peale, as *The Power of Positive Thinking* (more on him later). There have been many variations on this theme but like any good musical composition, pop psychology (and pop theology too, for that matter) keeps restating the original theme.

The first successful and influential implementation of this idea in the modern era occurred at the hands of Mary Baker Eddy, who established the Church of Christ, Scientist in 1879 - the same year as the founding of Wundt's laboratory. Eddy was a pioneer of the approach of providing unsupported health advice and religious guidance wrapped in the trappings of the new science of psychology. A foundational principle of Christian Science is Eddy's notion that all illness is ultimately an illusion. The appearance of illness is actually caused by faulty beliefs, and the sick can therefore be healed via prayer which works by replacing bad thoughts with good ones (which *almost* sounds like cognitive behavior therapy).

Baker's basic text, *Science and Health: With a Key to the Scriptures*, was first published in 1875. Based on Eddy's writings, Christian Science practitioners work by essentially arguing the patient out of being sick. In the modern version, these

consultations don't always occur in person: Healing can ostensibly be accomplished over the telephone, by mail, and possibly even via e-mail. Consultation with a practitioner is not always necessary, as the sick person may also be able to self-heal through prayer and concentration.

In a history and systems course, Eddy's story can be integrated with a discussion of the early days of hypnosis, as her central insight can be traced to an 1862 visit to a doctor who used Mesmer's ideas—he claimed to manipulate the flow of magnetic fluid in her body using actual magnets along with his own animal magnetism. Eddy decided, correctly, that the magnets had nothing to do with her recovery. She instead credited Jesus Christ with the healing and decided that all illness could and should be treated in this way.

Eddy's book was so successful that she founded a church to promote her ideas, which grew to a membership of nearly 270,000 by World War II. Over the years, the church's membership has declined precipitously (the most recent estimate I could find places membership at around 30,000 as of 1991), probably due in part to the difficulty of sustaining its basic teachings in the face of modern medicine. Ms. Eddy did have one insight that modern psychology largely confirms: A patient's mental status and beliefs can influence the effectiveness of a treatment, though it isn't the actual cause of most illness.

In 1952, Norman Vincent Peale, a Protestant minister who oversaw a 5000-member congregation in Manhattan, published one of pop psychology's perennial bestsellers: *The Power of Positive Thinking* – a book that remains in print today having sold more than seven million copies. Though it remains his best-known book, it was actually the culminating event of a career in which he had already devoted considerable attention to blending his ministry with psychological ideas. Peale's basic technique for overcoming any adversity in life involves repeating positive affirmations over and over again until they sink into the unconscious mind and are internally repeated automatically. The central idea is that if you repeat positive things about yourself, you will come to believe them. The repetition is necessary in order to defeat the conscious will, which Peale asserts is unreliable and troublesome. Peale teaches that by giving up control to the unconscious, the individual gains access to the power of God - a portion of which has been placed in all of us. The person who believes that he or she possesses this power can proceed to do great things. In other words, thinking positive things will cause positive things to happen, and negative thoughts will cause negative things to happen. This remarkably durable idea sustained Peale through a long list of additional books, including:

- *The Power of Positive Thinking for Young People* (1954)
- *The Art of Real Happiness* (1956)
- *The Amazing Results of Positive Thinking* (1959)
- And (inevitably, given the publishing business) *Sin, Sex, and Self-Control* (1965).

The central idea of these books has cast a long shadow, with many (most?) other pop psychology authors freely borrowing from Peale.

A similar philosophy, presented from a non-religious, business-friendly perspective, was popularized by Dale Carnegie (1888-1955), author of the huge-selling *How to Win Friends and Influence People* (1936) which remains in print and is quite popular today. He is best-known for teaching people to overcome their fear of public speaking and other anxiety-provoking situations, along with (self-evidently) how to win friends and influence people. Carnegie's central principle is simply that it is possible to change other people's behavior by changing how we think about and react to them. If that sounds familiar it's because like those before him, he focused on the notion that thinking positively will produce desired results. By the time of Carnegie's death, *How to Win Friends...* had sold a remarkable 5 million copies in at least 31 languages and it continues to sell briskly today. This almost certainly makes him the all-time sales champion among pop psychology authors.

To self-help guru Tony Robbins, sales like Dale Carnegie's are unimpressive given the other ways Robbins has found to influence world events. Robbins has become so widely-respected that he was actually invited to a secret meeting at Camp David by U.S. President Bill Clinton in 1994. In his book *Awaken the Giant Within*, Robbins recounts meetings with Mikhail Gorbachev, Margaret Thatcher, François Miterrand, and Nelson Mandela. Given the prominence of those who have listened, the actual message is depressingly familiar: Think more positively about what you do, and you will accomplish all your goals.

Tony Robbins has a gift for titles: He promises to help seminar attendees/readers achieve *Unlimited Power* (1986). He also promises to *Awaken the Giant Within* (1992), presumably in preparation for taking *Giant Steps* (1994). In his *Unleash the Power Within* seminar, participants learn to overcome their fears by walking across hot coals after which they are presumably less afraid to try things they previously believed impossible. Firewalking doesn't actually require any special training or preparation as long as it is done properly, but most participants do not believe at first that they will be able to do it. The seminar focuses on learning to overcome internal resistance to trying new things. In learning to expect that they will accomplish more, via a process Robbins terms neuroassociative conditioning, participants are assimilating a message that once again sounds remarkably like Peale's power of positive thinking.

The latest author to borrow and expand on Peale's central idea is Rhonda Byrne, Australian reality-TV producer and author of the 2006 pop-culture phenomenon known as *The Secret*. *The Secret* is no mere book: It is actually intended as a companion piece to the popular DVD by the same title. The book presents nothing new. Once again, positive thoughts cause positive things to happen and negative thoughts cause negative things to happen. Byrne does have a new name for this, however: The Law of Attraction. Essentially the universe wants us to be happy and if we think hard about the things we want, we attract them to ourselves. Given that this is the central idea of a book published by Peale in 1952, Byrne's title is somewhat baffling—the strategy has hardly been a secret. Thanks to massive television exposure however, more than half a million copies of the DVD had been sold as of late 2007 and the book topped the *New York Times* bestseller list.

In both the movie and the book, the presentation of the law of attraction is simplistic and sensational. In one segment a child who really wants a new bicycle cuts out a picture of it, concentrates hard, and is subsequently rewarded for his efforts by receiving a bicycle. Of course his attainment of his goal is presented as having nothing to do with generous adults who are aware of his desire – he obtained it purely as a result of his own positive thinking which is now labeled with new, improved jargon. Positive thinking has now become "creative visualization."

The book and film focus largely on the positive idea that people have control over their own lives and can have whatever they want. There is a dark side to this philosophy, however—some portions of the book appear to suggest, among other things, that the only reason people are made ill by communicable diseases is that they believe germs can make them sick and that only those who believe in cancer can be harmed by it. This recycles old ideas in another way, sounding remarkably like Christian Science with a twist: Maybe people (including children) who are dying of terrible diseases have nobody to blame but themselves.

The history of scientific psychology has run in parallel with the far better-publicized, bigger-selling world of pop psychology. Ironically, some of the central ideas of pop psychology sound like stripped-down versions of well-established scientific concepts. Central to cognitive-behavioral therapy, an effective evidence-based treatment for such conditions as depression, is changing the patient's negative thoughts to positive ones. There's more to the process than mere positive thinking however, and effective treatment is usually attributed to the power of reinforcement schedules rather than deities. Where genuine psychology offers explanations that as products of science are complicated, tentative, and constantly subject to revision, pop psychology has given people what they want: A simplistic, one-size-fits-all solution to all of life's problems. The universe wants you to be happy and wealthy, and achieving those ends requires only believing that you will. Small wonder that they sell many more books than we do.

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Chapter 8

To Customize or Not to Customize? Benefits and Disadvantages

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Instructors are frequently solicited through e-mails or sales representatives to custom edit a textbook. There is little information available to instructors, however, about this process. Based on our experiences custom editing a general psychology textbook on three separate occasions, this essay discusses advantages and disadvantages to custom editing, as well as factors to consider in making the decision. Included are some practical suggestions for the process.

Benefits of a Custom Textbook

There are a number of major advantages to a custom text. First, there is the potential to lower the cost to the student. In some cases, the cost of a custom text can be less than half of a traditional book. Second, a custom text allows for the inclusion of university and department specific material. A custom text also allows the instructor to create a streamlined book more suitable for a one semester course without sacrificing depth. (Frequently shorter books tend to sacrifice depth for breath.) For our department, one of the most beneficial aspects of the custom text has been the ability to add handouts and worksheets for the students. These handouts and worksheets allow students to apply and practice concepts, and have been edited to include local examples. The handouts also can include review sheets and material not covered in the text, and can be incorporated into classes as either homework or in-class activities. Having this information included in the text not only saves considerable time in passing out material for large sections, but it also ensures that students have the material whether they are in class or not.

Disadvantages of a Custom Textbook

Although there are significant advantages to a custom text, a major disadvantage is the extensive time required in selecting and editing the book. The first version of our custom text was done over an almost 2 year period. The actual editing of the book is time consuming and done within a rigid timeline. The editing process includes making many decisions about the custom text. The initial consideration is to determine how much customizing is desired. Custom textbooks vary from those which differ little from the original to those that are extensively edited and include new

material. At our university, general psychology is a "general education" requirement, so that was one of the guiding principles in determining what information to include. There also were decisions regarding the format of the book that had to be made. We found having a price point for the cost of the book (e.g., keeping the book less than $50) was helpful in making the decisions.

In addition to the time requirements, there are some practical disadvantages to a custom text. Some of the university or department material can become dated. To handle this problem, in the text, our students are directed to a website that can frequently update links and instructions. Also, our custom book is meant to be a "one time" use book, which results in the students not being able to sell their books back at the university bookstore (this is one reason for our lower selected price point). Students do buy second hand books, but the books are frequently missing required material. Having a book on reserve at the library, however, and encouraging students to copy the material they are missing has helped with this problem.

Factors to Consider

In deciding to do a custom text, there are a number of factors to consider. First, it is important to determine your goals and your purposes for custom editing. For example, is your goal to improve an existing text by including additional material? Is your primary goal to edit an existing text to be more compatible with course and university goals, or is your primary goal to reduce cost to students (if this is a goal, what is the price point?). Having clear goals and purposes will help in making many of the decisions that will follow.

A second factor to consider is whether you have the time and commitment to work on a custom text. Depending upon how much editing is done, and how much original material is added, custom editing can be a time consuming process. It is important to consider whether you can meet the stated deadlines and whether you will be available when the book needs to be proofed (final proofing may be in the summer).

Third, it is important to take into account whether there is support for this project. Is there going to be support from the department chair and the university (e.g., release time, secretarial or graduate assistant support)? Are there university policies and legal issues that need to be considered? Legal issues need to be addressed at various stages of the process. Indeed, it is advisable to consider legal issues before even beginning the process. It also is important to assess whether other faculty members are willing to work on the book and use the book for the length of the adoption.

A fourth factor to think about concerns royalty. Will there be a royalty associated with the custom text (if yes, how much per book)? Once that decision is made, the next set of decisions concerns who will receive the royalty (e.g., individuals, department, or university). If the royalties go to the department, it is important to consider how the funds will be used. In our department, a committee makes the

decision. Finally, it is important to explore whether there are relevant legal and university policies concerning royalties.

A fifth factor to address involves how much customizing you want to do to the book. Custom editing can range from very little change to almost rewriting a book. A primary issue to consider is how much you want to change the basic text (e.g., keep all chapters or delete some; edit the individual chapters themselves; add content material). You next need to consider whether you want to add original/department specific material. There are at least four different types of material that can be added. First, there is material that is specific to your university and its policies. Second, there is departmental material (e.g., information about the department, research pool, faculty) that can be added. Third, there is discipline specific material (e.g., information about careers in psychology). Finally, there is course specific material (e.g., homework assignments, handouts to be used in class).

A final factor to consider is how you want to format the book. For example, do you want an E-book or a traditional book? If it is a traditional book, do you want a hard or soft cover, bound or loose-leaf, one time or multiple use? If material is removed from the original text, do you want it repaginated? Do you want the book in black or white or in color? Having a clear goal for your custom text will help in making these decisions. For example, if keeping cost down for the student is a goal, you can explore the cost of these options.

Outline of Process

1. Initial exploratory meetings and work
   a) Meet with other course instructors to discuss interest and concerns
   b) Meet with department chair to gauge university support
   c) Identify publishers with appropriate products and experience
   d) Examine other custom textbooks
   e) Establish a clear purpose and goals for the custom text
   f) Decide how much and what to do with any royalty
   g) Contact university legal department about issues and university policy regarding a custom textbook

2. Selection of book to be customized
   a) Narrow down books based on content and quality
   b) Develop a list of questions for publishers to answer in written form (please contact the authors for a list of questions)
   c) Have publishers submit formal proposals
   d) Set up presentations by publishers and their technology staff.
   e) Check references (Contact other professors/departments who customized with the potential editors)
   f) Select the final book

3. Working on the custom text
   a) Establish a timeline with editor
   b) Meet with other instructors to decide what to include in the textbook and who will do the work
   c) If desired, develop original material for the book
   d) If needed, publisher will have to obtain permission to include copyrighted material
   e) Edit the book to be consistent (e.g., if parts of a chapter were removed, the introduction to chapter and end of the chapter material may need to be revised)
   f) Make final decisions about the book
   g) Address legal issues: review of contract by university lawyers

4. Submit all edited material to custom editor
5. Proof copy and answer questions from editor
6. Monitor distribution and delivery dates

Lessons Learned

In going through this process, we learned a number of lessons. It is important to allow plenty of time, especially for the initial custom project. We also learned that it works best for this to be a collaborative effort, not only because of the amount of work involved, but also because of the proofing, attention to detail and organizational skills required. It is difficult for one person to "catch" everything and keep up with all the details. We also learned important lessons on the "business" side of custom editing. Get **everything** in writing ahead of time such as the cost of book, date of delivery, and date of next revision. This will help prevent any later misunderstandings. Related to this, it is important to be prepared with questions for publishers and book reps and to request written answers to these questions. Because of the amount of time you will be spending with the person, it is extremely important to select a custom editor who is easy to work with as well as competent. On the positive side, we learned that some of our initial fears about the custom text did not materialize. For example, we learned that loose-leaf books work well. Students don't usually lose the pages, and the format works well for the use of handouts. Overall, despite the time and effort required, we found the development of a custom text to be a worthwhile project.

Author Note

This essay was adapted from a poster presented at the annual convention of the American Psychological Association, San Diego, CA (2010, August).

Chapter 9

On Blogging about Teaching Psychology

Dana S. Dunn
Moravian College

I write a blog. This essay, which is written like most of my blogs (only longer--sorry), is a short history of how and why I blog, as well as a bit of a user's manual for interested readers who might want to take to the 'net to share their passion for psychology with the world (wide web). I asked the editors to sanction the writing style here, which is different than the other writing I do and distinct from the typical essays that appear in the E-xcellence series. But we are talking about blogging here, so the usual niceties don't apply (as much).

I was a reluctant blogger. I never subscribed to a blog (and still don't). I never followed a blogger. I am old fashioned, content to read a daily newspaper at sunrise rather than to prowl the Internet's avenues for news. To be truthful, aside from being amused by the blog-as-plot device in the book *Julie & Julia* (Powell, 2009), I never gave blogs much thought. And when I did so, my reflections were probably accompanied by an appropriate dose of doubt or derision because I am convinced our contemporary culture (including the academic culture of psychology) is already rife with a bit too much narcissism. Why encourage more, especially my own?

But, as we all know, life can be strange as well as complex. So perhaps it comes as little surprise that a gentle slide into hypocrisy is inevitable when loosely formed attitudes (mine) confront the opportunity to give a maligned thing a whirl (an invitation to blog). Here's how it all started: In early August 2009 a *Psychology Today* (PT) magazine editor asked me if I would be willing to write a blog on teaching psychology. I demurred and suggested others who might be better qualified as I was (truthfully and always) overcommitted on several fronts. And anyway, I was also about to begin a daunting year as President of the Society for the Teaching of Psychology. Where and when would I find the time to blog when I was already stressing about working my way through a now-even-longer than usual to-do list? "Exactly why you will be perfect," the wily and hip young editor replied. "Just write a draft blog entry of 700 words or so and see if you like doing it--it won't take any time at all--you'll see."

And here we are. I've been writing a blog on the teaching of psychology (listed as "*Head of the Class: How to Teach Psychology Well*") for PT since late August 2009 (go to: http://www.psychologytoday.com/blog/head-the-class to view recent and archived entries). I am one of PT's many bloggers, and I submit a new entry every 3 weeks or so. I view my blogging as a way to bring teaching issues, new pedagogies, and other related matters to the attention of people who probably have not been in a classroom, let alone a psychology course, for quite some time. I write about topics that occur to me when I am teaching, issues (often angst-ridden) my students raise in class

or their written work, select current events from the newspaper that cry out for psychological comment, the occasional pedagogical triumph or insight (both all too rare in my teaching life, alas), and, naturally, the occasional frustration associated with some aspect of teaching or higher education more generally. In short, I get to write about whatever I feel like writing about in my blog.

So, in spite of my initial trepidation, I do enjoy writing my teaching blog. Besides pointing out the benefits, however, I need to be equally candid about the accompanying challenges. I thought that I might spend the rest of this article outlining both sets of issues so that would-be bloggers (i.e., you) can decide whether blogging on teaching, psychology, or other matters has any appeal. Let's begin with an obvious challenge:

Time. There is never enough and doing a blog on a regular schedule (I could never commit to writing daily or even sporadic entries) takes time away from other duties. So, unless you are currently under committed in your career, realize that this is one more responsibility requiring attention. Certainly, a lone blogger in the wilds of the web can register opinions when the spirit moves her, but where there is some editorial oversight involved (however freewheeling it may be), entries should (must) arrive on a reasonable schedule. I am routinely surprised at how quickly three weeks passes and I need to produce an entry once more.

But on the up-side, it is a writing exercise. I like to stretch my writing muscles all the time, which is why I try to do different sorts of writing--everything from books and articles to book reviews and, well, blogs. In my experience, trying different types of writing allows you to be comfortable expressing your thoughts on a keyboard. Learning to "write on demand" also means that you can learn to write quickly. Speed is a good thing for doing a blog. I usually write a draft of my entry on a Tuesday morning and then post it later the same day or early the next one. I was not quick when I began, but experience led to comfort. I like to hope this form of writing will have a positive impact on some of my other writing ventures.

You still need to edit what you say. The spontaneity of blogging aside, I always edit my blog for spelling and punctuation, as well as style and clarity. If you are writing about teaching or other educational issues, you want to be taken seriously. If you are not already a compulsive editor of your own work, developing this quality is a good idea before you decide to post your wares (i.e., your ideas) on the Internet. Blogging is not like regular publishing in psychology where an editor, peers, and usually a copyeditor go over (let's be honest—improve) your prose before it appears in print. When blogging, you work without such safety nets so that any typos or other errors loom larger than those you might make in, say, an entry on your *Facebook* page (as a clumsy typist, I know whereof I speak).

What about writer's block? The blog must go on--at least that's how I approach my blogging. I stick to my three week schedule, which means that even if inspiration does not strike I still have to log an entry on something. So, I ask my wife to suggest possible topics, I ask friends and colleagues for leads, and I consult the running list of ideas I keep for such emergencies (although what seemed like a good idea when originally feverishly jotted down rarely seems interesting to me later). Eventually, I hit

on something I can write about and my worry about having nothing to say recedes until the next entry has to be done.

Who are you writing for, anyway? Ah, we're back to narcissism: Ultimately, you are writing for you (and possibly about you, too). By that I mean that the topic of a blog entry is something that spurred you to reflection and commentary. Of course, you are also writing for some other audience--in my case, I hope to speak to people who are interested in teaching issues in psychology and psychology more generally--but you never know who is going to read your entry. So, in a way, you are writing to please yourself: Your message must be one that resonates with your interests, concerns, and passions. Otherwise, why blog when there are other venues for sharing your ideas and often in much greater detail?

The great unknowns. One thing I really do like about writing a blog is that you never who is going to read your work and respond to it. Sometimes entries that I slaved over garner no reaction at all, while a few of those that I wrote quickly to meet my deadline so that I could move on to some other pressing task triggered genuine and friendly intellectual give and take. You just never know. And, in the interests of candor, sometimes you receive less-than-friendly responses to what you share, a not surprising reality that goes with territory of blogging.

Be brief and be gone. Words to live and write by. My friend, the teacher and sage, Charles Brewer, urges this adage on public speakers introducing others or simply sharing their thoughts aloud in front of an audience. With a little adjustment it applies beautifully to blogging; one big message per entry is ideal. Any more than that and you have an essay, which is a more carefully crafted and less spontaneous message, not what readers of blogs want. So, brevity is highly desirable trait of the blogger, one I have violated a bit in this piece. I hope you will forgive me, just as I hope that my observations on web logs (aka blogs) will be helpful to you.

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Sue Frantz has taught psychology for 17 years, the last 9 of those at Highline Community College, which is located in the Seattle area. Since early in her teaching career, she has been an early adopter of new technologies in which she saw pedagogical potential. She has had a web page with resources for her students since 1995. By the mid '90s she was giving presentations on (then) cutting edge technologies such as using email discussion groups to foster student engagement and interaction. She is currently exploring the teaching applications of Web 2.0 (primarily the use of wikis), interactive video conferencing, and audience response systems ("clickers").

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Chapter 10

A Perspective on Child Abuse in the Philippines

Looking at Institutional Factors

Richard Velayo

In many Third World countries, violence against children continues to be a pressing problem. Such violence is often manifested in the form of abuse. The Philippines is similar to many other Asian countries in the way Western culture has greatly influenced its development and way of life. The Philippines' historical roots began with Spanish colonization four centuries ago. This colonization contributed to the development of a culture in which the church and the school usually emerge as the most influential institutions influencing the way children are brought up. Cases of physical and sexual abuse, as well as those considered "abuses of neglect," continue to be of major societal concern. Thus, violence in schools as well as other institutional sectors of society that play a role in a child's development is a problem of global proportions faced by most developed and developing countries.

Despite the increasing global awareness of children's rights, there continues to be numerous documented cases of child abuse in many countries. In the Philippines, there are approximately 33 million children under the age of eighteen and authorities estimate that in 1999 alone, there were roughly 12,000 cases of child abuse (Yacat & Ong, 2002). The Department of Social Welfare and Development (DSWD) documented an increase in cases of child abuse and neglect from 1991 to 1997 (Yacat & Ong, 2002). Of

these cases 44.5% were classified as sexual abuse, 21.67% as physical abuse, and 15.07% as neglect. The Philippine General Hospital Child Protection Unit (PGH-CPU) (1998) also reported a similar trend during the same year in which 67.7% of the cases they handled were documented as child abuse cases. Physical abuse constituted only 10% of these cases. While the statistics suggest that the majority of alleged perpetrators of abuse are familiar to the victims of child abuse, 66% of abusers are family members, the statistics fail to reflect the abuse occurring in the Philippine institutions of the school and the church. Abuse in these institutions is difficult to measure for many reasons. Because of the esteem schools and the church hold in Philippine society, cultural factors prevent child abuse authorities from recognizing and addressing abuse occurring in the schools and church. This paper will illustrate a perspective on the problem of child abuse in Philippine society and will analyze institutional influences that have contributed to this problem.

The view of the child in Philippine society causes institutions and authorities to overlook and oftentimes encourage child abuse. Philippine authorities and institutions lack a clearly defined definition of abuse, especially in regards to verbal and psychological abuse. In conjunction with the Filipino view of the child, institutions remain focused on violence committed by children, as opposed to the violence committed by educators and clergy members. Much attention has been paid to child abuse occurring in families; however, with the considerable power and trust afforded to schools and the church, abuse often remains overlooked or under-examined. Research indicates that physical abuse cases may be underreported, and, therefore, the statistics fail to depict the actual incidences of abuse in communities. This underreporting may reflect a belief that only the most extreme forms of abuse necessitate intervention by the authorities. Thus, the home becomes overemphasized as the location where most abuse occurs. Numerous studies, articles, and books explore and validate the dominance of the family situation in the experience of abuse. A study conducted by the Psychosocial Trauma and Human Rights Program of the University of the Philippines Center for Integrative and Development Studies (UP-CIDS) stated that while both parent and child groups generally situated abuse in the context of parental discipline, some important differences existed. First, parents held more normative views of abuse and described it as a deviation from appropriate discipline. These parents perceived abuse as a manifestation of the abuse of parental authority and the taking advantage of the child's relatively inferior position in the family. Children viewed abuse less in terms of power, but rather as a betrayal of trust (Yacat & Ong, 2002). Children believed disciplinary measures became abusive when the discipline became excessive, intentional, and unreasonable. The characteristics of child abuse, the misuse of trust and power, are

not exclusive to the family and can occur in any adult-child relationship which is based on trust and power.

Brief History of Education in the Philippines

Education in the Philippines originates from the merging of the secular with the spiritual realms (Yacat & Ong, 2002). The school's primary task remains education; however, the church also retains the right and responsibility to look after children's moral and spiritual needs, creating a school-like atmosphere. The high number of private sectarian schools in the country demonstrate the church's continuing mandate to teach children religion and morality.

Prior to the Spanish colonization period (1521–1898), child socialization and instruction occurred mainly in the home rather than as part of any single institution. The colonization of the Philippines by Spain transferred the responsibility of the administration of education to the Catholic Church. The Spanish sought to indoctrinate the children with religion as a means to reach parents (Bennagen, Villones, & Eco, 1994). Along with the introduction of religion, Spanish culture, and formal schooling into Filipino society, the Spanish colonizers also introduced a separate curriculum for men and women (Vernon, 1962). Education for women rested on the assumption that women remained intellectually inferior; therefore, their curriculum focused less on academic subjects and more on domestic and social skills. In addition, education remained a benefit for only the *penisulares* (Spain-born Spaniards), *insulares* (Spaniards born in the Philippines) and the *mestizos* (half Spanish/Filipino) (Valeriano, 2003). The purpose of the church-administered education remained to keep the Philippine people subservient to the reigning Spanish colonists.

The Revolutionary government, established in 1898, attempted to sever the relationship between church and state by removing religion from the curriculum of government-supported schools while bringing education to the masses. However, the separation only commenced during the American period, in particular during the 1940s. During this period, American teachers used English as the medium of instruction as they focused on industrial skills (Tiongson, 1986). The separation of church and state created two institutions focused on the instruction of children. Despite their separation, the educational principles of each institution remain along with the adult-child relationship based on trust, power, and reliance.

The historical impact of the formation of a formal school system and the introduction of the Catholic Church developed trusted and culturally important institutions in which close adult-child relationships were

important. Formal institutions such as the church and school define adult-child relationships very clearly as authoritative and hierarchical (Yacat & Ong, 2002). The adult holds the power over the child in both institutions. In the classroom, the students are expected to follow the teacher's instruction. The church retains the same power structure, in which young boys serve as assistants and alter boys. In fact, communities often gain spiritual guidance through apprenticing their young people to the parish priest. In the home, school, and church, the adult holds the position of authority. Children lack the position to ask questions or challenge adult authority; rather, they recognize the need to succumb to authority.

The beliefs and attitudes held by parents, students, teachers, and the clergy toward discipline contribute to the under-reporting of abuse in the churches and schools. Parents, teachers, and the clergy believe that children deserve appropriate discipline. In accordance with the view of children as "tabula rasa," discipline plays a large role in shaping unruly children into model citizens. With teachers and clergy entrusted with shaping the behavior and knowledge of children, child abuse often is overlooked or is perceived as necessary in shaping the child.

Teachers perceive discipline as necessary in imparting knowledge to young people (Nepomuceno, 1981). Schoolteachers often believe that punishment (as a form of discipline) maintains a quiet and orderly learning environment, promotes self-discipline, serves as a deterrent to potential offenders, and prevents offenders from becoming repeat offenders. During the period when the church took responsibility for education, two types of teaching styles became prevalent: the dogmatic and the liberal.

The dogmatic teaching style is authoritarian and reflects the values of the feudalistic system. This type of teaching became prominent in disciplining students in elementary schools, secondary schools, and universities, and the discipline took the form of corporal punishment. The liberal teaching style, on the other hand, is based on the principles of science and competition, and it consists of subtracting time from desirable activities or adding additional academic work. The American period (1889–1941) marked a change from the dogmatic teaching style to a consistently liberal style of teaching.

The change to liberalism brought with it more insidious styles of disciple. Under this liberal style, teachers use strategies such as hitting, slapping, and verbally abusing students in order to embarrass them. While there exist an order in the Teacher Service Manual which prohibits the use of physical, emotional, and verbal punishment at present, the above forms of embarrassment comprise the most frequent used forms of reprimand (Tan, 1982; Yacat & Ong, 2002). Despite the role of the school in protecting children from abuse at home, children suffer from all kinds of abuses in school, including the shouting invectives at them, embarrassing them,

requiring them to complete work unrelated to school, and physically and even sexually abusing them. Teachers have become trained to identify and report failings of the home, to nurture children, and to care for them. The church remains the primary provider of assistance to abuse victims, but suffers the same pitfalls as the school.

School and Church: Institutional Powers in the Philippines

The perceived legitimacy of authority allows the school and church to obtain and exert power over their respective domains. Therefore, the representatives of these two institutions have been considered experts in their respective fields. Church representatives preside over matters that are considered divine, moral, or supernatural, while schoolteachers are the authority in secular matters such as knowledge acquisition. These functions earn educators and church workers high regard in Philippine society which regards these careers as very noble professions (Yacat & Ong, 2002).

The school and the church maintain significant importance in Philippine society in affording children education, morality, and future opportunities in society, thereby affording the school and the church the primary antecedents of abuse: trust and power. Schools maintain high-esteem in Philippine society due to the view that education is necessary for a successful and meaningful future. Filipino families regard education as the highest priority and a lasting legacy to their children. The primary role of the school is to provide a place for learning, for gathering information and skills that are essential to a child's integration into the adult world. In elementary and high school, students learn basic proficiency for living and the background needed for higher education (the latter perceived to be the ticket to a well-paying job and a stable career). In this regard, the school is greatly valued as a valid means of social mobility, especially when education is seen largely as a privilege, rather than a right, in a poverty-stricken country.

The School and the Filipino Child

Those children whose families fail to secure a proper education face bleak prospects. Filipino children who experience conflicts with the law tend to represent the most disadvantaged and marginalized sectors of society. Many of the children who are raised in poverty and who receive little or no education become suspected of committing minor crimes (Amnesty International, 2003). Those children who lack education, family, or community support are most likely to become delinquent or join gangs. A joint study

conducted by non-governmental organizations (NGOs) in the Philippines in 2000 reported that 90 percent of children in conflict with the law experienced abuse at home. Many of these children who flee their homes join the Philippines' large population of street children, estimated to number at least 200,000 (Amnesty International, 2003). Despite the introduction of laws and safeguards designed to protect children in custody, grave defects in the juvenile justice system still exist and has led to widespread abuses within the law enforcement establishment. Nevertheless, the Philippine government and has ratified the UN Convention on the Rights of the Child (CRC). Amnesty International has identified many serious problems in the treatment of children in detention, including: 1) torture or ill-treatment following arrest and in detention: including beatings, sexual assault, electric shock, being threatened with death; 2) detention with adults in overcrowded facilities which fail to meet minimum international standards for treatment of prisoners; 3) denial of prompt access to social workers, lawyers, and relatives following arrest; 4) lengthy delays in being brought before a judge, and delays of many months before trial which sometimes result in children serving longer than the maximum sentence for their alleged offence; and 5) inappropriate sentencing and treatment due to the absence of any requirement to establish the age of the child on arrest. At least eight juveniles are under sentence of death (Amnesty International, 2003). Therefore, those children unable to secure the proper education face poverty, street life, and the possibility of abuse in other institutional systems.

As a result of the view of education as a privilege, and in light of the terrible possibilities occurring without education, parents inadvertently transfer the responsibility of teaching almost entirely to the school, while also entrusting to it their children's future as flourishing members of society. Families, therefore, spend large amounts of effort, time, and money in securing their children's education. Due to the transfer of power from families to educators, the school becomes an extension of the home where socialization occurs, in which children imbibe the culture, learn the norms of society, and explore the limits of proper behavior through their interactions with their teachers and peers. What children learn regarding right, wrong, and justice comes from both the school and the home. Metaphorically, teachers become referred to as "second parents" of the child.

The school's view of the child also contributes to the style of teaching espoused by the Philippine school. Filipino adults view children as born "tabula rasa;" therefore, adults must constantly correct and instruct children regarding appropriate behavior. This in turn creates a learning environment that encourages children to act and think in a passive manner, making them vulnerable to disciplinary actions designed to shape them into model citizens. Thus, the same pattern emerges in both the school and

the home: the adults maintain absolute power over children. This imposing power becomes hypothetically justified by the noble responsibility of molding ignorant, passive, amoral, disorderly children into smart, active, compassionate, and obedient adults (Yacat & Ong, 2002).

The Church and the Filipino Child

The population of the Philippines is approximately 83% Roman Catholic, 9% Protestant, 5% Muslim, 3% Buddhist or other. The Catholic Church in the country draws its power from the historical and traditional role religion plays in the history of the Philippines and in Filipino life. Mabunga (1997) outlined two functions of the church: as a *buttress,* providing support, reconciliation, and consolation to individuals experiencing personal and social crisis while addressing their spiritual and emotional needs. The church also plays the role of the *prophetic,* a social critic answering the need for direction and vocalizing opinions regarding certain "secular" issues such as family planning, abortion, divorce and capital punishment (Yacat & Ong, 2002).

Church and School as Culturally Intertwined Institutions of Power

With the power bestowed on teachers and clergy members, the adult-child relationships within the institutions of the school and church closely mirror the Filipino family structure in regard to power and trust. The power and trust involved in these relationships remain primarily hierarchical in nature, where the individual holding the power maintains authority over a group or a unit of society. In the Filipino family, members become classified and ordered according to the power hierarchy. The father, the family's foundation, claims the upper-most rank in the hierarchy (this attitude originated during the Spanish occupation, due to the patriarchal nature of Spanish society); the mother occupies the next rank, followed by the eldest son or daughter, and continuing with children occupying ranks according to their birth order. The individual possessing the power retains complete control over all the subordinates and the subordinates surrender unconditionally. Therefore, the individual holding the power by virtue of the authority attributed to them in the dynamic of the power-trust relationship maintains the ability to manipulate, control and maneuver those beneath him (Valeriano, 2003). In turn, the child or subordinate remains obligated to submit to the power holder's commands and manipulation, while trusting that the powerful individual will protect his or her well-being.

With the power afforded to schoolteachers and clergy as the "second parents" of children, this power hierarchy exists outside the bounds of the family.

While abuse occurs within the adult-child dynamic in both the church and the school, abuse remains a largely invisible and silenced phenomenon. A preliminary survey conducted by Yacat and Ong (2002) of newspaper articles, interviews with staff and disclosure reports from the Center for the Prevention and Treatment of Child Sexual Abuse (CPTCSA), and disclosures from the roundtable discussion revealed that among reported abuse cases regarding the church and schools only the extreme forms of abuse merited attention and that the perpetrators rarely faced punishment. The extreme forms of abuse meriting attention include rape, molestation, sexual harassment, and extreme physical violence. CPTCSA received forty five disclosures of abuse in the years of 1997 and 1998. Teachers represented the perpetrators in six of these cases. The demographics of the cases consisted of five male victims, 10–13 years of age, and a lone female victim of 16 years of age. These cases involved fondling, the touching of private parts, and molestation. Another example involved a teacher who banged the heads of two boisterous students together, resulting to the death of one.

While these examples demonstrate the most drastic forms of abuse, the authorities consider some behaviors or circumstances less serious and therefore not abusive. For example, a mother who filed a complaint against a teacher for allegedly slapping her daughter in the face was instructed by the school principle to forget about the whole thing. However, she brought it to the attention of the Parent and Teacher Association and rather than receiving sympathy, she faced reprimand from the PTA for blowing the situation out of proportion. In frustration, she transferred her daughter to another school halfway though the school year (Yacat & Ong, 2002). This case illustrates the difficulties faced in accurately assessing the extent of abuse in the school. Only the most egregious forms of abuse become reported, and parents and children become discouraged from reporting less severe forms of abuse due to the threat of public embarrassment.

In addition to the under-reporting of lesser forms of abuse, teachers and clergy reported to engage in the more extreme forms of abuse are rarely punished. The church remains inclined to conceal incidents of abuse in order to protect its gracious image instead opting to settle cases, violating Republic act 7610 (Child Abuse Law) through extra-legal means. For example:

> The very first case handled by CPTCSA involved a priest who had a sexual relationship with his 15-year-old niece. It was found that, at age 12, the girl had come to live with her uncle to escape her father who had sexually abused her since she was eight years old. A neighbor who belonged to a non-governmental

> organization occasionally saw the girl crying outside her uncle's house, and was convinced that she had been exhibiting symptoms of sexual abuse. The neighbor sought assistance from CPTCSA. After an investigation, it was determined that the girl should be separated from the priest and her parents needed to be informed. After her parents were found, a series of negotiations took place. The parents succeeded in covincing their daughter to drop the charges against the priest. He was never prosecuted in any judicial court. CPTCSA filed a report regarding the incident to the church authorities. They later learned that the priest, who was up for candidacy as bishop, was neither promoted nor given any pastoral assignment after the abuse complaint was known (Yacat & Ong, 2002)

Another case reported to the CPTCSA concerned a priest from a prestigious and exclusive school accused of molesting several high school boys during the students' spiritual retreat. From among a batch of 40 students, only one boy revealed his painful story. However, no legal action against the priest was taken and the school authorities transferred the priest to another school under their order (Yacat & Ong, 2002). The scarcity of reports regarding abuses within the church and school does not demonstrate that such abuses remain isolated cases. Rather, the lack of reports signifies the problems regarding identifying and reporting abuse. The two predominant reasons for the lack of reporting and documentation of abuses cases remains the difficulty in identifying abuse and the problems inherent in the system for reporting abuse.

Cultural Vagueness in Defining Abuse

The varying definitions of abuse cause difficulties in delineating abuse and discipline (de la Cruz, Protacio, Balanon, Yacat, & Francisco, 2000). Teachers' belief in the necessity of discipline in molding young students often obscures the line between abuse and discipline. For example, many parents feel that if a teacher uses inadvertently embarrassing tactics in order to encourage the child to behave more appropriately, then those tactics do not reflect abuse. Due to the parental stamp of approval of these tactics teachers use hitting, humiliation, slapping, and throwing things in the name of discipline. Therefore, many children experience these types of abuses every day of their school lives. Some parents accept this behavior as occurring for their child's own good; however, other parents view this abuse as a failure to respect children's rights. For those parents who object to this sort of discipline, abuse occurs anytime an individual hurts a child in any way, regardless of intention or consciousness, which consequently affects the child's development as a human being. One parent key-informant in the study conducted by Yacat and Ong (2002) explained why teachers' actions towards children sometimes lead to abuse: "We may know children's

rights, but then the reality is that teachers are tasked to discipline children, and they are overloaded and underpaid. How does one keep from hurting a child (whether verbally, emotionally or physically) when he or she is under chronic stress?" Schoolteachers gain considerable attention for their lower pay. One Filipino politician stated that, "The overworked but underpaid teachers have always been extolled as the unsung heroes of our generation, and rightly so. On the hands of the teachers who mold young minds lies the future of the nation. Such being the case, the state I believe owes it to our educators to provide for their health and physical well-being" (Drilon, 1998). Teachers receive a great deal of understanding despite their treatment of children, due to their status as heroes and as builders of the future.

Of all the various definitions of abuse, only one response given in the Yacat and Ong (2002) study adhered strictly to all of the principles of the UN-CRC. The definition specified by the children, the teachers, and one parent reflects the Filipino cultural reality: Our children have grown up and are growing up accepting the fact that discipline and punishment (whether corporal, verbal, or any other type) go hand in hand. Children understand the necessity of these kinds of punishment and are willing to bear them as long as they are given love and justice. Due to the prevalence of abuse, it becomes difficult for people, especially children, to discern whether abuse is occurring or has occurred. The line, therefore, becomes blurred regardless of any experience of abuse. Parents may dismiss abusive actions committed by teachers because they either practice this kind of discipline at home or they may justify the teacher's behavior by deducing that the child's misbehavior merits the treatment.

Several issues create barriers to the reporting of abuse. First, children become afraid of ridicule or questions regarding their credibility by family, friends, and authorities. The close relationship between abuse and discipline also contributes to children's confusion in that some children begin to believe that they deserve the abuse. Therefore, victimized children hesitate to reveal abuse due to the fear that the community will side with the highly respected individual. This reluctance could also stem from the powerful role these institutions play in the community, which considers the church and school sacred institutions whose sanctity might become tainted by allegations of abuse. Due to these institutional roles in the community, the community would also face the blame for the abuse. Any abuse committed by an agent of a school or church is perceived as disrespectful to the community in which it exists. Due to the conjoined nature of the church, school and community, child victims and their families face a lack of support in reporting abuse. These institutions assume a protective stance regarding the perpetrators' welfare, rather than providing assistance and services to the victim, often to an extant that "victim blaming" occurs.

As the school and the church play an important and noble function in Philippine society, the possibility that some of the members of these institutions are abusers violates the general schema. Therefore, reports of abuse face a violent reception from members of the church, school and parent organizations in an attempt to preserve the righteous image of these institutions. In fact, the lack of support for any reports of abuse and the opposition against the very idea that abusive practices occur within the confines of the school or church, serves this purpose. In the case of the church, people find incredible difficulty in imagining, let alone accepting, that God's representatives would commit such atrocities. Due to the denial or opposition of the community regarding abuse, cases many go unnoticed, unreported, stagnate once reported, or become silenced.

The definition of abuse as occurring within the context of interpersonal encounters between children and adult authority figures limits the focus of abuse as an extreme infraction on interpersonal relationships. This limited view allows certain abuses to masquerade as disciplining practices and directly affect the developing child's view of the world and acceptance of abuse. Even organizations designed to develop policies, regulations, and sanctions remain ineffective when confronted with disciplining practices that border on abuse and become unsupportive or simply exist to pay lip-service to children's rights. As one youth participant shared:

> When it comes to participation in schools, yes, there is a student government but it is a token structure because it doesn't have any real power. And even if it were told to hold meetings, what would it organize? The president of the student government might be asked to speak in the program, or the students might be asked to prepare a song or dance number, but that's about the only participation that they get from children. (Yacat & Ong, 2002, p. 12)

Other examples include implementation of student fees, forced attendance at parties, mandatory sale of tickets in school-sponsored projects and programs, and the repression of sexual knowledge both in school and in the church. Schools fail to empower students to improve their quality of their lives when the authorities exert power and manipulation over student created organizations. In effect, these practices reflect the prevailing notions of children perpetuated by these institutions. As Philippine society widely accepts the need for discipline and the role of authority figures empowered by institutions to administer and instill such discipline, the roles that this view produces lend themselves to abuses.

Lack of a common definition contributes to difficulties in maintaining an accurate estimate of the problem and the creation of viable solutions. The examination of the perpetrators in the context of a network, not as an error confined to a single person, helps refine the analysis of the phenomenon of child abuse. This perspective suggests that a vast, complex,

and organized network of abusers exists with each one reinforcing each other's interests, thus perpetuating the cycle of abuse. In an effort to better understand child abuse as a distinct social phenomenon and thus determine the parameters of further intervention design, Protacio-Marcelino, de la Cruz, Balanon, Camacho, & Yacat (1998) identify six elements that constitute child abuse. They present the six elements as, 1) the type of abuse, 2) circumstance of abuse, 3) degree and duration of the abuse, 4) age, 5) gender, and 6) the perpetrator. The theories, methods, and approaches used in interventions are primarily based on western models with a distinct dearth of local theorizing from the Philippine perspective. Existing interventions directed towards child abuse cases remains basically eclectic. These intervention initiatives remain in an experimental stage in which the most effective method remains unidentified and largely unexplored. For intervention work on child abuse in the Philippines to elevate to the next level, what's needed is proper documentation and impact evaluation, as well as the development of localized theories and methodologies for assisting the victims and survivors of child abuse (Protacio-Marcelino, de la Cruz, Balanon, Camacho, & Yacat, 2002).

Prevention Efforts and Other Recommendations

Many programs designed to prevent violence in schools focus on the children as the source of violence. This may occur in response to concerns in the United States regarding childhood aggression. One Philippine preschool quoted the Children's Hospital of Pittsburgh with a list of adult tasks to reduce childhood aggression (School Violence: What Parents Can Do). Other community-oriented programs attempt to decrease youth violence through the integration of community, school, and church initiatives. For example, following his appointment, the Philippine National Police (PNP) Chief, Police Director General Leandro R. Mendoza, established two community-based initiatives aimed at creating lasting deterrents to crime. The first program involved schools in partnership with the PNP in which teachers organized school community coordinating councils. These councils planned, implemented, supervised, and monitored crimes occurring on school campuses and in the surrounding vicinities. The councils were charged with increasing student awareness of the dangers of illegal drugs, criminality, campus violence, and similar potentials for crime in schools. In addition, the councils established networks with local officials, civic leaders, and other non-government organizations. Part of their program initiative involved sports activities and other physical education programs. A majority of the crime prevention activities fell under the council's jurisdiction while the police maintained a visible presence on the campuses to ward

off criminal elements. The second program sought the involvement of the church in the prevention of the sale and use of illegal drugs at the community level. This program remained similar to the school-based councils, but it maintained a wider area of coverage. The newly formed church community coordinating councils conducted forums, seminars, conferences, and other public gatherings with the goal of enlightening members against the use of illicit drugs and to warn against the effects of public apathy. The twin programs aimed to empower the community to play active roles in crime prevention, especially in preventing the proliferation of drugs within the areas that are producing positive effects (anti-crime programs as effective antidotes to violence and crime). The programs initiated by Philippine authorities and institutions support the view that crime and violence in schools and communities originates from children's misbehavior and serves to reinforce the view of children as being in need of discipline. These programs fail to address the aggressive actions children in schools and churches experience on a daily basis and the aggression and acceptance of aggression they learn through the experience.

Due to the lack of information regarding child abuse in school and church, there exists a need for refining the identification and documentation process for abuse cases. Future strategies and initiatives should encompass the nature of both institutions (hierarchical, authoritative) and incorporate these features into any proposed action. First, students, teachers, and the clergy are in need of better education regarding the United Nations Convention on the Rights of the Child (UN-CRC) in order to appreciate and develop positive attitudes toward the importance of children's rights and to understand the respect and protection children deserve. Second, the increased involvement of parents in their children's education would lead to an increase in the detection, reporting, and documentation of abuse. Third, the institutionalization of abuse reporting to authorities along with educational campaigns regarding children's rights and abuse would lead to an increase in the number of reported child abuse events. Fourth, research on the various contexts of discipline, its different definitions, practices, and reasons would help solidify the definition of appropriate discipline. Fifth, venues for the facilitation of discussion regarding moral and ethical issues arising from the support of children's rights should be provided. Sixth, the policies regarding children's complaints regarding teacher- or administrator-inflicted abuse need review. In order to help protect children's rights schools should be encouraged to develop school policies which allow children to report complaints against their teachers, school staff, and administrators, create mechanisms for investigating the complaints, and penalize the offenders if investigation reveals the complaints to have merit. Seventh, a review of the notions regarding childhood and children as reflected in the school curriculum thereby necessitating

revision of administrative policies. The perspective towards children and childhood requires investigation in regard to church doctrines, teachings, and practices in order to discern the extent to which the church promotes and accommodates abuses by the clergy. In summary, prevention efforts aimed at reducing the incidence of child abuse in Philippine institutions must encompass the systemic factors leading to abuse, namely, identification and reporting practices, as well as the general attitudes held by the institutions which contribute to the abuse.

While child abuse in the home remains widely studied and reported in the Philippines, child abuse in the church and school receive drastically less attention. The same adult-child relationship dynamic in regards to trust and power occurs in these institutions as it does in the home. The lack of a solid and universal definition of abuse, as well as a system for reporting abuse, necessitates initiating programs that prevent abuse. In addition, situations of child abuse within the church and school require that authorities examine the systemic issues inherent in these institutions that encourage and produce abuse instead of merely directing their attention toward childhood aggression and violence. While current prevention programs aimed at decreasing youth violence remain impressive, the concern originates from western attention to the issue of school violence. In order to confront the problem of abuse in church and school, policy makers must design intervention programs directed at the sources of abuse. By creating a more open atmosphere for reporting abuse and improving the documentation system, the dimensions underlying abuse in the church and the school might come to light and more effective programs for confronting the problem can then be developed.

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ABSTRACT

This study analyzed college students' use of motivational strategies in academic contexts. Participants included 11 male and 26 female undergraduate students enrolled in psychology courses at an urban university, who completed the Motivated Strategies for Learning Questionnaire. Analysis focused primarily on responses to the following sample items: "How well I do in this course will depend on how hard I try," and "It is my own fault if I do not do well in this course." Results showed a significant difference between males and females concerning their attributions of success with female students more likely than males to attribute academic success to their own efforts. There were no significant gender differences concerning their attributions of failure. Results suggest that increased use of male/female/student/mentor programs might enable one gender to acquire benefits from the other in academic endeavors. (CH)

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Gender Differences in the Attribution of Internal Success among College Students

Elizabeth Grollino and Richard S. Velayo, Ph.D.

Pace University, New York

Presented at

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Abstract

This study involved the analyses of control beliefs between male and female undergraduate students in an urban university using the Motivated Strategies for Learning Questionnaire (MSLQ). The responses to items on the attribution of their internal success turned out to be bearing of a notable gender difference. The implications summon scholastic attention and give way to certain achievement promoting suggestions.

Introduction

This study focuses on the attribution of college students' control beliefs (i.e., internal success and internal failure) pertaining to their use of motivational strategies in academic contexts. Literature points out that control beliefs (i.e., locus of control) is a salient factor influencing academic achievement and, in turn, personal academic achievement is largely perceived as a key factor affecting the causal attribution of a learner's successes and failures. The suggestions this study provides may be a stepping stone for developing ways of improving classroom teaching strategies and enhancing students' use of motivational strategies for learning.

Methodology

Participants were 37 undergraduate students (11 males, 26 females) enrolled in psychology courses. They were given bonus points towards their final grades for the course upon their completion of the experiment which involved the administration of the Motivated Strategies for Learning Questionnaire (MSLQ).

The MSLQ is a self-report instrument designed to assess college students' motivational orientations and their use of different learning strategies (McKeachie, Pintrich, Lin, & Smith, 1986). It is a 6-page questionnaire containing 20 different subscales pertaining to cognitive and motivational strategies in academic learning. The items were in Likert-form scale of 1 to 5, (1 = not at all true of me, and 5 = very true of me). The questions analyzed primarily focused on the participants' responses to the following sample items: (See next page.)

Internal: Success

How well I do in this course will depend on how hard I try.

1 2 3 4 5 6 7 8 9

definitely no definitely yes

Internal: Failure

It is my own fault if I do not do well in this course.

1 2 3 4 5 6 7 8 9

definitely no definitely yes

Results

Of the several motivational subscales of the MSLQ, gender differences in the means for the internal success subscale was most apparent (See Figure 1). A significant difference between male internal success and female internal success was found but interestingly, there was no significant gender difference in internal failure.

internal success:

	MeanDiff.	df	T-Value	p-value*
M, F	-.44	35	-2.245	.0312

internal failure:

	MeanDiff.	df	T-Value	p-value
M, F	-.154	35	-0.393	.6964

Table 1. T-test analysis of mean differences between male and female learners on internal success and internal failure.

Figure 1. Bar graph of gender differences for internal success and internal failure measures

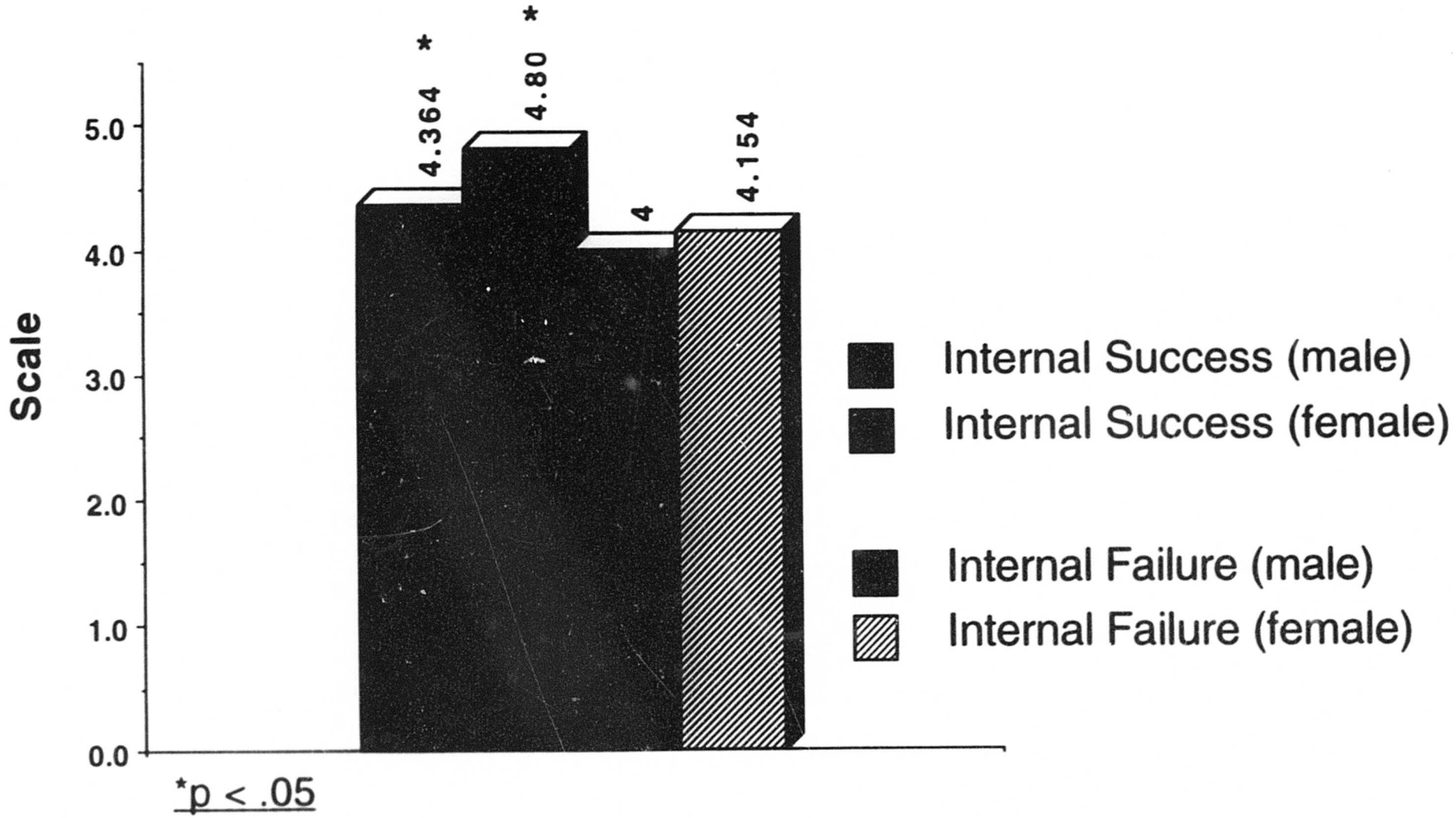

*p < .05

Implications

As you can see from Table 1 and Figure 1 there is a significant difference between the male and female students in terms of their internal success pertaining to causal attribution of academic achievement in academic contexts. Male students, in general, have a lesser tendency to attribute their academic achievements to internal causes (i.e., own ability to succeed or excel). Female students, however, have a greater tendency to attribute their academic success to their own efforts. It is speculated that differences in social expectations may play a significant role in this difference. Academic expectations may be greater for males than females in that when males succeed academically, the attribution they make to such success may be perceived to be less likely a function of one's own ability or efforts compared to female students. Female students who succeed academically may perceive their achievements largely as a function of their own efforts because there may be less social expectations for them to do so compared to males.

This may also indicate that the male students may be reaching their full academic potential more easily than the female students, who in contrast attributed their success primarily to their own efforts. This outcome appears to be an indication that female students today may be more introspective than males, which may possibly detrimental because this may allow more room for self-criticism and reduced effort to succeed if encountering failure in the classroom.

The findings of this study certainly needs further investigation. Cultural, geographical, and institutional variations may exist. Future investigation may consider increasing sample size, using other assessment tools for control beliefs, and looking at other academic contexts. In addition, the substantial use of male/female/student/ mentor programs should be stressed to minimize the gender gap in academe and in classroom learning in general. Another way to enhance academic success is to encourage professors to gather the data on students' use of motivational strategies in their classes.

[END]

Summary and Implications

This study focuses on the attribution of college students' internal success. It presents data that shows the difference between male and female genders; it points out a significant difference in the perception of their internal success. The feedback it provides can turn out to be a stepping stone for both teachers' and students' scholastic success. Moreover, "researchers who have addressed the situational specificity of attributions have consistently found that standard comparisons elicit attributional tendencies that are characteristic of maladaptive motivation patterns" (e.g., Ames, 1984a: Ames & Ames, 1981).

As you can see from the data there is a substantial difference between the male and female students. This indicates that male subjects have an externally oriented nature attributing their success primarily on whether or not the teaching ability of the program was adequate enough. In this study they did not look to themselves for their success as much as the female students. This also indicates that male students may be reaching their full academic potential more easily than female students. This outcome appears to be an indication that female students today may be more introspective than males, which in turn can hinder them academically since it can allow more room for self-criticism and depression from failure in the classroom. It could also turn out to be a hindrance for them in their personal lives if it

continues on and becomes a pattern. On the other hand it also makes for a catch-22; their self-attribution when succeeding surely becoming part of the reason for their continued success. And since self-attribution would certainly increase their confidence in their ability to succeed, it can also most definitely become the major reason for their scholastic suicide when failing. Moreover, due to the advancement of females over the generations, past female conditions are still being looked at today, this may provoke more of a scholastic emphasis to be placed upon them. This emphasis may very well make for the creation of a female success ideal in our society. It can make success and failure more of a personal issue for them because it inflicts the impression that they must still continue to prove themselves to society as an equal, adequate gender. In 1994 Dr. Gene N. Landrum stated in his book "Profiles of Female Genius, Thirteen Creative Women Who Changed the World" that men and women are different, even if they are great creative geniuses. One of the most obvious differences is based on the way men and women view the world. I am convinced that Anita Hill/Judge Thomas debacle had more to do with gender differences in relational values and attitudes than it had to do with any overt discrimination. Each of these adversaries saw the same issues from his or her own unique perspective based on <u>years of conditioning and gender differences</u>". Gender appears to have little bearing on creative achievement. <u>Hypomania</u>,

competitiveness, risk-taking propensity, and a keen intuitive vision have been found to be the critical variables in both men and women who have achieved great success. Both genders demonstrate these particular traits although to different degrees. Women are more methodical than men and are more prone to analyzing the ramifications of their decisions (pp.403 & 407).

In retrospect an appropriate suggestion, would seem to be that there be substantial use of Male/Female/Student/Mentor programs in schools. These programs should enable one gender to acquire benefits from the qualities of the other, each gender together in a scholastic situation, sharing their goals, experiences, and ways of dealing with things. This would naturally bring about the acquiring of each other's personal tendencies as well as their influence. "Research on creative genius has shown that men need to look important while woman need to look good. To men success is power, and to women success is a strong relationship. Women prefer to communicate; men prefer to intimidate. Women seek interpersonal approval; men seek interpersonal dominance. Women are sensitive to others' feelings; men are sensitive to their egos. Women give sex to get romance; men give romance to get sex. Women will discuss controversy; men will avoid controversy. These differences indicate that men and women approach life from far different perspectives" (Landrum, 1994, p. 407).

Furthermore, another way to enhance academic success would

be to encourage professors to gather the same type of data as gathered in this study from their individual classes. Afterwards, according to the overview of the data, they might encourage students by placing an emphasis on scholastic success as being an overall success attaining process rather than an individual short-term achievement. And as someone once said you can't win them all therefore with students, especially females who have internal attributing tendencies, I believe that more guidance should be given in accepting success modestly and in dealing with failure more positively. I would also encourage them to look to external reasons for success and failure as well as internal ones. These characteristics should be reinforced from time to time, and encouraged as much as possible. After all, this may eventually balance out the tables leaving us with a neatly shaven countertop.

END

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NYSPA's History: A Lens for Viewing the Future of Social Action, Women's Issues, and Clinical Practice in Psychology

Presenters: John D. Hogan. PhD, Florence L. Denmark, PhD, Gwendolyn L. Gerber, PhD, Mercedes McCormick, PhD, and Richard S. Velayo, PhD

The New York State Psychological Association (NYSPA) occupies a special place in the history of applied psychology in the United States. Not only was NYSPA the first state psychology association to achieve permanent status, it was also the first to develop a code of ethics and the first to pursue legislation for licensing. That last goal took a long time to achieve, but NYSPA's work did not go unnoticed and it became an inspiration for many other associations.

Despite its unique contributions, NYSPA was also very much a product of its times. Applied psychology in the early part of the 20th century was noticeably different from what it is today. During that period, most psychologists worked in academic institutions. The main role of "clinical" psychology was testing, not psychotherapy, although some psychologists did conduct psychotherapy. A large segment of the applied psychology community was made up of industrial/organizational psychologists. There was no legal protection for psychologists and many charlatans called themselves psychologists. Of course, there were physicians who viewed legitimate psychologists as charlatans. For them, psychotherapy was a medical procedure to be practiced only by physicians.

The role of women in psychology was an ambivalent one. Although the first doctorate in psychology earned by a woman was in 1894 (Margaret Floy Washburn at Cornell), women-in-general were not welcome in many doctoral programs. Since the doctoral degree was the entry level degree for teaching at universities, women were effectively shut out. Black psychologists, and other minorities, were almost totally absent from psychology. (In 1920, Francis C. Sumner became the first Black to receive a PhD in psychology.)

NYSPA's Early History

Unlike many organizations, NYSPA has never had a formal historian or archivist, and many of its important documents have been discarded through the years. Fortunately, in the late 1940s, a past president of NYSPA, Dorothea McCarthy, a professor at Fordham, was asked to compile a history of the organization. Much of what we know of its early history is due to her efforts. The rest is based on other records that have survived.

The NYS Association of Consulting Psychologists (NYSACP), the ancestral organization of NYSPA, was founded in 1921. (The phrase "consulting psychologist" was commonly used at the time to describe the work of an applied psychologist.) The founding of the association was directly related to an earlier founding, in 1917, of the American Association of Clinical Psychologists (AACP). Many applied psychologists were dissatisfied with the attitude of the American Psychological Association (APA) toward applied psychology - APA after all had been founded to promote the "science" of psychology. Hence, AACP was born. But the APA was concerned about having a competing organization of psychologists and, in 1919, it established a clinical section within APA to bring in the applied group. At that point, the AACP was dissolved.

Despite this recognition by APA, the discontent continued. Several of the people who had been active in both AACP and the clinical section of APA began efforts to establish a new organization in New York. One of the leaders in this effort was Leta Hollingworth, a professor at Columbia Teachers College. (Hollingworth was important in several pioneer efforts in applied psychology, including, in 1918, a proposal for a PsyD degree.) Another early promoter was David Mitchell who would become the founding president of NYSACP. He was a graduate of the University of Pennsylvania and, in 1921, a professor at Rutgers University.

Mitchell had been a student of Lightner Witmer, the founder of the first psychological clinic (1896). After he graduated with his doctorate in 1913, Mitchell remained at the University of Pennsylvania for several years to work in the clinic.

Eventually, he moved to Manhattan and the early meetings of NYSACP were held at his home at 225 W. 86th St. According the McCarthy, they were mostly informal dinner meetings. No minutes were kept. In its first year, the honorary president of NYSACP was Margaret Washburn, a native New Yorker, and at the time president of the APA, the second woman to serve in that office.

The entire NYSACP organization consisted of 50 to 60 people, including several recognizable names, such as Harry and Leta Hollingworth (he would later become a president of APA), and Harold and Mary Cover Jones (she is considered a founder of behavior therapy). One of the surprising things was how many women were part of the organization - approximately half. Most of these women had master's degrees and worked in the school system. They were effectively school psychologists before they held the formal title. But some of the women had more unusual jobs for the time. Elsie Bregman, for instance, worked for Macy's department store where she helped select the best candidates for various sales jobs.

No other permanent state psychological association was formed in that period. In fact, few were organized until after World War II, when modern clinical psychology began to grow. By then, NYSACP had already been working toward securing legal recognition for psychologists for years. As early as the 1920s, some members of the association remembered David Mitchell traveling to Albany to seek help from legislators regarding the practice of psychology.

Professional Development

After ten years of leadership under David Mitchell, some members of the association grew restless. They wanted change, particularly a larger national presence for applied psychology. Douglas Fryer, an I/O psychologist from New York University (NYU), became a pivotal player in the next step of NYSPA's development. He helped to organize the transformation of NYSACP into a new group, the Association of Consulting Psychologists (ACP). Although the new association professed to have an international reach, in fact its members were drawn from a 100 mile radius of New York City. There were other organizational changes as well.

Members of NYSACP had been meeting annually and presenting papers with the New York Branch of the APA. Fryer arranged it so that the new organization of consulting psychologists would have its own annual meeting, beginning in 1931. Its first meeting was held at NYU on Fryer's home turf. No papers related to applied psychology were presented at the meeting of APA's New York Branch that year. The separation of academic and applied psychology had taken a decisive turn.

The membership of ACP grew and it began publishing a newsletter. Perhaps most important, it began to move in several important directions for professional growth. The first was the development of a code of ethics. All the evidence suggests that no other psychology organization had developed a code of ethics before ACP did in 1933. The APA did not publish its first code of ethics until 1953. The two and a half page code from ACP drew some of its material from other codes, including those of accountants and attorneys, but not from any psychological organization, presumably because there was none to draw from.

The other major professional advance was the pursuit of licensing, also begun in the 1930s. This effort was less successful. New York psychologists did not achieve certification until 1956. A genuine licensing bill was not passed until 2004. But from the 1930s, NYSPA became a voice for the pursuit of licensing, and other states took up the challenge. Incidentally, NYSPA did not begin using its current name - the New York State Psychological Association - until 1948. The name change was an attempt to bring all New York psychologists together to work toward licensing, not only applied psychologists.

Social Action

NYSPA should be given credit for pursuing a code of ethics and licensure not only for its own professional enhancement, but also as a protection for the public. And although the association was more supportive of women than many professional organizations of the time, it was much less successful in bringing underrepresented groups into the association. Two of the most prominent early Black psychologists in New York, Kenneth and Mamie Phipps Clark, were apparently never members of NYSPA. This is surprising since Kenneth Clark worked so closely with NYSPA members Stuart Cook and Isidore Chein on the "social science statement" that was attached to the legal briefs in the famous Supreme Court case "Brown vs. the Board of Education." The "Brown" ruling declared that segregation in the schools was unconstitutional. The case was the first time that social science research was used in a Supreme Court decision.

Closing Remarks

NYSPA has been a leader in applied psychology from its inception. It has had some of the most

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prominent psychologists in the U.S. among its ranks, including several past APA presidents. (Three of the founders of the humanistic psychology movement - Carl Rogers, Abraham Maslow and Rollo May were all members of NYSPA at one time.) Today NYSPA is a vibrant organization of almost 3,000 members, with strong leadership, and a permanent staff of seven. Its history has been a microcosm of the history of applied psychology. In a similar way, its current concerns are a sensitive indicator of national concerns in applied psychology. Ψ

Important Dates

Executive Committee & Council Meetings

Cornell Club, NYC

September 19, 2008
November 14, 2008
January 9, 2009
March 13, 2009
June 12, 2009
November 20, 2009

Internship Fair

September 14, 2008

Lobby Day

April 21, 2009
Meeting Room 5, Concourse
Albany, NY

2009 Annual Convention

May 1-3, 2009
Gideon Putnam Resort
Saratoga Springs

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APA Division of International Psychology: Isang Maikling Pangkalahatang-ideya **

ni Richard S. Velayo, Ph.D., USA/Philippines, rvelayo@gmail.com

Noong Pebrero 21, 1997, inaprubahan ng mga pinuno ng American Psychological Association ang bagong division 52, "International Psychology," pagkatapos ng maraming taon ng pagpaplano. Ang misyon nito ay “pasulong ang pag-unlad at pagsulong ng mga internasyonal na relasyon sa mga psychologist sa mga lugar ng pagbabahagi kaalaman, paghikayat sa pagbisita, paghikayat sa intercultural na pananaliksik at pag-unlad sa klinikal na kasanayan, at upang itaguyod ang mga pangkalahatang layunin ng APA.”

Sa unang 25 taon nito, napatunayan ng 52 ang isang hindi pangkaraniwang aktibong dibisyon sa loob ng APA sa maraming paraan. (1) Ito naglalathala ng napakahusay na bulletin, *International Psychology Bulletin*, na may mga orihinal na artikulo tungkol sa sikolohiya sa buong mundo, na isinulat ng mga nangungunang psychologist, pati na rin ng mga mag-aaral at iba pa. 52 ay naglunsad din ng isang journal sa 2011, *International Perspectives in Psychology: Research, Practice, & Konsultasyon*. (2) Ito ay bumuo ng listserv at ng website, ngayon sa www.div52.net, na may napapanahong balita para sa mga miyembro. (3) Nag-aalok ito ng isang masiglang programa sa APA meeting tuwing Agosto, kung saan maaaring ipakita ng mga miyembro at iba pa ang kanilang gawain. Ang unang APA nito ang programa noong 1998 ay nagtampok ng 120 nagtatanghal mula sa 39 na bansa. (4) Tumatanggap ito ng mga nominasyon para sa taunang mga parangal nito para sa kahusayan: internasyonal na psychologist, tagapagturo, pananaliksik ng mag-aaral, pananaliksik sa kababaihan/kasarian, namumukod-tangi aklat, ECP. (5) Nag-aalok ito sa mga miyembro nito ng aktibong pakikilahok sa mahahalagang proyekto, isang bagong internasyonal na libro serye ng IAP Publishers, isang speaker network, at mga diskwento sa mga aklat o iba pang produkto.

Sa simula, nasiyahan ang 52 sa aktibong suporta ng mga pinuno ng APA, kabilang ang Chief Executive Officer na si Raymond D. Fowler. Apat sa unang 12 Pangulo ng 52 ang mga Pangulo ng buong APA: Florence Denmark, Frank Farley, Charles Spielberger, at Norman Abeles. Ang Dibisyong ito ay nagpapahintulot sa mga psychologist at mga mag-aaral mula sa USA at sa buong mundo na sumali sa International Division at maging aktibo para sa isang maliit na taunang bayad.

Noong 2022, ipinagdiwang ng 52 ang ika-25 anibersaryo ng pagdadala ng internasyonal na pananaw sa sikolohikal teorya, pananaliksik, edukasyon, at aplikasyon. Para sa anumang mga detalye, tingnan ang website nito, www.div52.net

Ngayon, ang 52 ay namumukod-tangi bilang isa sa hindi bababa sa limang internasyonal na organisasyon, bawat isa ay may sariling kakaibang misyon:

2. Ang IAAP (nabuo noong 1920) ay ang International Association of Applied Psychology. Sa kasalukuyan, merong 2,000 miyembro sa buong mundo, nag-aalok ng quarterly journal (Applied Psychology: An International Review), at isang quadrennial congress. (www.iaapsy.org).
3. Ang ICP (1941) ay ang International Council of Psychologists. Sa kasalukuyan, may bilang ng higit sa 100 miyembro sa buong mundo, nag-aalok ng isang quarterly newsletter (International Psychologist), at isang taunang convention. (https://icpweb.org/).
4. Ang IACCP (1972) ay ang International Association for Cross-Cultural Psychology. Sa kasalukuyan, merong 800 miyembro, nag-aalok ng dalawang buwanang Journal ng Cross-Cultural Psychology, at isang biennial meeting. (www.iaccp.org).
5. Ang IUPsyS (1951) ay ang International Union of Psychological Sciences. Ito ay isang unyon ng 75 miyembro mga bansa (walang indibidwal na miyembro), naglalathala ng International Journal of Psychology, at nagho-host ng quadrennial International Congress of Psychology. (www.iupsys.org).

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(Thinkfinity Cornerstone 3 Interdisciplinary Informatics)

Principal investigators

Dr. Vishal Lala, Associate Professor, Department of Marketing, Lubin School of Business
Dr. Richard Velayo, Professor, Department of Psychology, Dyson College of Arts and Sciences
Mr. Stephen Salbod, Data Analyst, Department of Psychology, Dyson College of Arts and Sciences
Dr. Weihua Niu, Associate Professor, Department of Psychology, Dyson College of Arts and Sciences

May 25, 2012

A) Please outline your original goals.

1) Setup Behavioral Lab: Set up a Behavioral lab to conduct consumer behavior and psychology experiments
2) Research: Conduct experimental research
3) Pedagogy: Conduct experiments to train students in causal research

B) What progress have you made towards your original goals on your project to date?

Setup Behavioral Lab

Behavioral Lab 1: A space has been reserved in W404, One Pace Plaza in the New York downtown campus to serve as a behavioral lab. The lab will be used on a time-sharing basis along with classes scheduled and the needs of the Finance department. Twenty five licenses of two experimental software, MediaLab and DirectRT, have been purchased and installed on 25 computers in behavioral lab 1.

Behavioral Lab 2: We are still working on identifying a suitable lab for installing the software. The constraints are the availability of 25 computers with acceptable software and hardware, and accessibility of the lab for use. We have narrowed it down to two labs, Y22 and W202B, both in One Pace Plaza in the New York downtown campus. We have purchased 25 licenses of MediaLab and DirectRT, the experimental software to be used, and will install these on the machines as soon as we decide on the space to be used.

Research

With the software installation having only concluded in April, there was little time left to run an experiment which requires student participants. The first experiment is slated to be run either in one of the summer sessions or in the Fall semester.

Pedagogy

The software will be incorporated into classes involving experimental research in the Fall semester.

C) Has your project impacted students? If so, how many?

None, so far. Students will not enjoy the benefits of the software until the Fall semester when we expect to integrate the software into our courses.

D) Has your project impacted other faculty members? If so, how many?

None, so far. Faculty will start reaping benefits of the software in the Fall when sufficient number of student participants are available to participate in studies.

E) What are your next steps?

Over the summer, the software installation will be complete. A few pretest will be run during the summer with small groups of students. In the fall semester, data collection for a couple of research projects will begin. With the integration of the software into courses in Fall, students will enjoy the benefits of the software too.

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Cornerstone 3 Reports : Interdisciplinary Informatics

The Thinkfinity Center for Innovative Teaching, Technology and Research

4-1-2010

Exploring Web 2.0 Technologies to Internationalize the Teaching of Psychology

Richard Velayo
Dyson College of Arts and Sciences

Recommended Citation
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PACE UNIVERSITY

FINAL Project Status Report

PROJECT TITLE: Exploring Web 2.0 Technologies to Internationalize the Teaching of Psychology

THINKFINITY PROGRAM: Cornerstone III: Interdisciplinary Programs

PRINCIPAL INVESTIGATOR: Richard Velayo, Ph.D., Psychology Department, Dyson, NYC Campus

DATE: April 30, 2010

A. Please outline your original goals

This project aims to explore effective ways in which instructors in psychology through the use Web 2.0 technologies in teaching to help with this "internationalization" initiative. Though the focus of this pilot project is the psychology curriculum, an investigation of the ways in which Internet-based technologies are used to internationalize curriculum in other disciplines will also be explored.

The original goals were as follows:

- Create a web portal (www.itopwebsite.com) to help instructors of psychology to internationalize the psychology curriculum, which contains clearinghouse of resources and web 2.0 technologies to facilitate collaboration among students and instructors.
- The development of an online survey to obtain feedback from psychology instructors from various parts of the globe to produce a list of "best practices" that will be valuable in setting up a more international curriculum using collaborative Internet-based technologies. This will be useful for students who seek resources related to the globalization of psychology as a field and for instructors to obtain resources to incorporate in their courses.
- Article/manuscript(s) will be submitted to select peer-reviewed journals in the area/s of psychology (e.g., Teaching of Psychology, International Psychology Bulletin, and The General Psychologist)
- Presentations in national and regional conferences (e.g., Upcoming conventions of the American Psychological Association, New York State Psychological Association). A workshop will be developed for psychology instructors (though instructors in other disciplines interested in internationalizing their courses) pertaining to how the Web 2.0 technologies may be applied and assessed in various undergraduate and graduate courses.

The anticipated outcomes of this study clearly apply to other disciplines and the interdisciplinary nature of this project is reflected in the relevant resources collected that are from various disciplines. Internationalization of the curriculum involves multidisciplinary and interdisciplinary efforts that many institutions and fields of study now consider as one of their major academic and professional initiatives.

Clearly, many empirical and qualitative studies in the field of computer science, business, education, languages, and cross-cultural anthropology have contributed in our understanding of how internet-based education may facilitate a more global perspective of one's discipline and a better understanding between peoples of various nations. Thus, the long-range objective of this project extends to other disciplines as well (especially the social and behavioral sciences) in terms of strategies in which the Internet may be utilized to enhance collaboration, infuse global content, and promote a more international perspective in the curriculum through an integrated portal.

In addition, given Pace's initiatives to have its faculty be more tech-savvy by incorporating web-based tools to enhance student engagement and learning especially in web-based environments, this study will provide a model portal that exemplifies how wikis, blogs, social networking websites, videoconferencing, virtual worlds, and other Internet-based technologies may be incorporated in their teaching, share resources that help internationalize the content, and infuse a more global perspective in these courses.

B and C. What progress have you made towards your original goals on your project to date?
What activities have been completed to contribute to meeting/progressing toward these goals?

The equipment and materials related to this project have been purchases and set up. In addition, the project investigator has gathered several related literature in psychology and from various other disciplines that demonstrate how instructors utilize Web 2.0 tools as a means to internationalize their courses.

The web portal (www.itopwebsite.com) has been created and houses various resources (e.g., articles, weblinks, contact information of key individuals with expertise and interest in this topic). We are also in the process of incorporating and testing Web 2.0 technologies (e.g., blogs, wikis, a Facebook page, webinars, video conferencing) to facilitate interaction among instructors on ways to internationalize their courses, that is, to explore and share ideas and strategies to effectively incorporate international content and collaboration between and among educators, students, and others.

A clearinghouse of electronic resources in psychology (e.g., syllabi, books, articles, weblinks, contacts) has been put together that may be of interest to those who seek to internationalize their courses. We envision that by the beginning of the fall 2009 semester, we will be able to put together a website that will house these resources as well as include Web 2.0 tools within the website to facilitate collaboration between educators, researchers, students, and curriculum managers in psychology who share the common vision of a more internationalized discipline.

The online survey has been developed to obtain feedback from psychology instructors from various parts of the globe to produce a list of "best practices" that will be valuable in setting up a more international curriculum using collaborative Internet-based technologies.

A workshop will be held at the 2010 Convention of the American Psychological Association, which will be held in August 2010 in San Diego, CA. This workshop is geared towards psychology instructors (though instructors in other disciplines interested in internationalizing their courses) pertaining to how the Web 2.0 technologies may be applied and assessed in various undergraduate and graduate courses.

D. What activities have not been completed? Please indicate why they have not been completed.

We have yet to test the WEB 2.0 technologies (Dimdim videoconferencing, Facebook, Twitter, YouTube, Blogger, PBwiki and Wikipedia) linked to the main portal site using a select group of individuals who are affiliated with the Division of International Psychology of the American Psychological Association. These individuals are board members of the Division and also a select group of Early Career Psychologists, as well as graduate and undergraduate students.

We have yet to gather enough people (a total of 10) to help test the site, but it is anticipated that we will be able to accomplish this in the middle of the summer. Many of these individuals who volunteered have

been busy with their academic work but have given their commitment to participate at the beginning of the summer.

We also have yet to analyze the data collected from the online survey form regarding internationalizing the teaching of psychology.

Another feature that we have yet to include in the site is a language translation feature. We are exploring a number of alternatives on how this may be done across the various web 2.0 tools built within the portal. This project will soon generate a specific lists of suggestions will need to be generated on how an instructor may best incorporate Web 2.0 technologies to facilitate the internationalization of the course. One of my primary objective is to be able to share the findings to the Pace community, specifically to our faculty. The results from this study may provide valuable information for administration and faculty to implement useful policies given Pace's distance learning as well as international education initiatives. Such findings will also be shared through conference presentations and publications in peer-reviewed journals. As mentioned previously, this project will yield of list of best practices in the use of Web 2.0 technologies, and generate learning goals and outcomes to assess if a course objective of incorporating international content and perspective has been achieved. I hope to be able to share the findings associated with this project with fellow psychologists as well as faculty in related disciplines so that they may be able to utilize Web 2.0 tools in their teaching through collaboration with those from other countries or even utilize content materials from non-U.S. sources. More importantly, I perceive the direct beneficiaries to be psychology students who will have the kind of international perspective about the psychology, especially how such perspective is manifested in their chosen career within (or even outside of) the field.

An article/manuscript has yet to be submitted to select peer-reviewed journals in the area/s of psychology (e.g., Teaching of Psychology, International Psychology Bulletin, and The General Psychologist)

E. Please outline the outcomes you have received as a result.

The web portal (www.itopwebsite.com) has now been put together and is almost ready for testing so that we may determine how it may be best used and possible how it may be tweaked.
The outcomes that have been accomplished are as follows:

The development of an online survey to obtain feedback from psychology instructors from various parts of the globe to produce a list of "best practices" that will be valuable in setting up a more international curriculum using collaborative Internet-based technologies. This will be useful for students who seek resources related to the globalization of psychology as a field and for instructors to obtain resources to incorporate in their courses.

A workshop will be held at the 2010 Convention of the American Psychological Association, which will be held in August 2010 in San Diego, CA. This workshop is geared towards psychology instructors (though instructors in other disciplines interested in

internationalizing their courses) pertaining to how the Web 2.0 technologies may be applied and assessed in various undergraduate and graduate courses.

F. Has your project impacted students? If so, how many?

Students in one of my graduate courses (PSY634 – Instructional Psychology: Multimedia Applications) which will be taught during the Summer 1 2010 semester) will be involved in the testing of the web portal. They will also be required to critique the site and to suggest ways in which it could be enhanced. In addition, one of their projects in the course is to provide content resources (e.g., weblinks, articles, samples syllabi, videos) to include in the site related to internationalizing the curriculum. Eventually, this site will serve to help students find resources that will help them incorporate international content in the psychology course that they are taking, perhaps include material relevant to final projects or research work that they are involved in.

G. Has your project impacted other faculty members? If so, how many?

One of my colleagues in the Psychology Department at Pace U., Dr. Mercedes McCormick, is involved in helping incorporate relevant content into this portal. There is also another colleague from Illinois State University, Dr. Michael Stevens, is also doing the same. Eventually, this site will serve to help instructors find resources that will help them incorporate international content in the psychology course/s they teach, perhaps infusing material relevant to making students more global in their perspective about psychology as well as to be able to communicate with psychologists and other students worldwide as part of their learning in the course.

H. Were there any unintended outcomes achieved?

Yes. In fact, the Division of International Psychology is interested in linking this web portal to make it an integral part of their own website (www.internationalpsychology.net). I am currently negotiating how this may happen and to make sure that I maintain some level of autonomy to this site. In addition, there is a possibility that this Division may be able to contribute some funds to the continuance of this project.

Another unintended outcome is the development of virtual lab on Second Life, which will be used as a way to conduct research through this new medium, a venue that has not been fully explored, especially in terms of conducting experiments.

H. Do your outcomes reflect the change or benefit you were hoping to receive?

Yes. The value of this project is foreseeable and expected, especially given that "internationalization" is now an explicit goal explicitly stated in the mission statement of various colleges and universities, as well as in numerous disciplines. Providing a venue through a web portal allows for a low-cost, efficient, and easy access to communicate

and collaborate, which is especially relevant in the field of psychology as we venture into a more globalized world/society.

J. How has your project furthered the Thinkfinity Cornerstone you selected?

This project will provide an opportunity to determine ways to enhance communication and collaboration between and among faculty, students, and professionals in the field.

K. Describe your future plans for sustaining the program or project.

This study is primarily an initial attempt at building a portal, so now that it is built, it needs to be tested so that we may be able to determine ways to enhance it for use by various constituents from with the U.S. as well as those from abroad. Its pedagogical value will be determined and hopefully, instructors of psychology and other fields interested in internationalizing their discipline/s will utilize this portal. Thus, this will be an ongoing project that will test and possibly incorporate technologies that will be helpful in internationalizing the teaching and training of psychology, and to promote collaboration from those involved.

-End-

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Awards Coordinator's Report

Division 1 had a very successful 2013 awards year. Many outstanding nominations were received for our various awards. A list of the award winners can be found in this issue of *The General Psychologist* below on page 9.

The Awards Ceremony at APA on was held on Saturday, August 3. It was very well attended, and the event was fun and very lively. Some well-known guests were easily recognizable, such as Dr. Florence Denmark and Dr. Phil Zimbardo. Some members of the Italian American Psychology Assembly (IAPA), including Dr. Bernard Carducci, who is the IAPA President, were present for a very special announcement: Division 1 will be renaming its poster award to the *Raymond Corsini Student Poster award* effective 2014 in honor of Dr. Corsini's centenary. An invitation to the Awards Ceremony was extended to Mrs. Kleo Corsini, but unfortunately, she was not able to make it.

Dr. Eric Charles deserves a special thank you – he did a superb job of looking after the suite programming for Division 1. Special thanks are also extended to all the Division 1 Award Chairs and their committee members for doing such a fine job and for getting back to me with their decisions on a timely basis. Their efforts enable us to celebrate on an annual basis the outstanding work and contributions from our colleagues and students and to encourage the next generation of psychologists in their path to excellence.

The call for award nominations for the 2014 year will be coming out shortly. We invite you to nominate someone or yourself. Information on the awards program can be found at http://www.apadivisions.org/division-1/awards/index.aspx. We also put out calls from time to time inviting individuals to join our awards process as award committee members. If you are interested, please respond to these calls or else feel free to contact me.

Josephine Tan, Ph.D., C. Psych.
Awards Coordinator
Email: jtan@lakeheadu.ca
Tel: 807-346-7751

Society for General Psychology:

APA Division One Awards

By Josephine Tan, Awards Coordinator

2013 APA Poster Session for Division 1

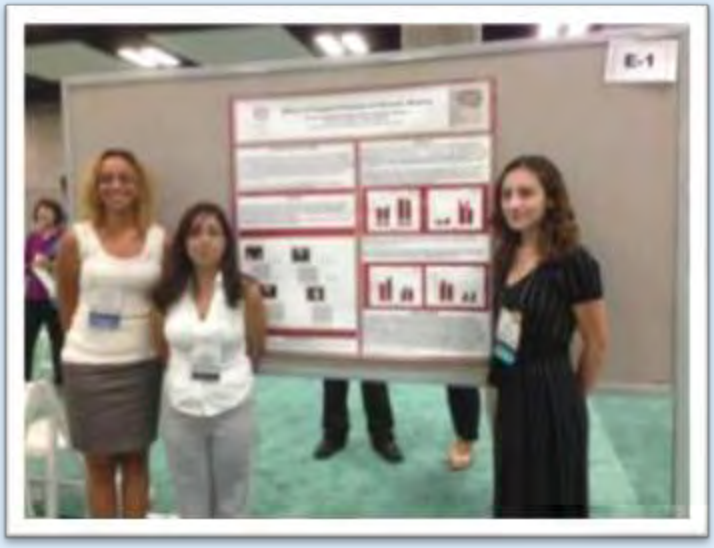

Above is the winning poster in the **2013 Anne Anastasi Student Poster Award** competition. The title of poster was "Effects of temporal pressure on episodic memory," and the authors were Audrey E. Martinez, M.A., Seda Terzyan, M.A., Angelyna M. Hinkle, M.A., David Rosenblatt, M.A., and Paul E. Haerich, Ph.D.

Standing beside the winning poster are (from left to right): Angelyna M. Hinkle, Audrey E. Martinez, and Seda Terzyan.

Above is a photo of one the three finalist posters, “Measuring student schema: Structural analysis of the Young Schema Questionnaire” by Matthew E. Kahler, B.S., John A. Blue Star, B.S., and Sean C. Woodland, B.S.

Standing beside the poster are Sean C. Woodland (left) and Matthew E. Kahler (right).

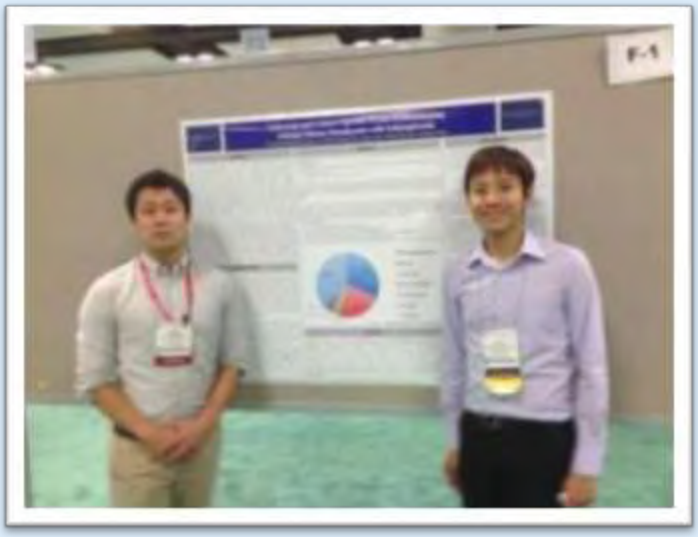

Pictured above is another of the three finalist posters, “Universal and culture-specific forms of stereotyping among Chinese immigrants with schizophrenia” by Tae Hyuk Keum, B.S., Yu Chak Ho, B.S., Jennifer Kim, B.A., Robin Hardin, B.S., and Seohyun Kim, B.A.

Standing beside the poster are Tae Hyuk Keum (left) and Yu Chak Ho (right).

Note: The remaining finalist poster was entitled “Examining meaning in life as a predictor of automatic stereotyping” by Ivorine Andrea Florez, B.A., Seamus P. Walsh, B.S., Margaret Bowden, Tracie L. Stewart, Ph.D.., and Stefan E. Schulenberg, Ph.D. The student authors were not there to present; Dr. Stewart presented alone.

2013 APA Division 1 Awards Ceremony

Jennifer M. Gómez, M.S., receiving her 2013 Anne Anastasi General Psychology Graduate Student Award (under 2 years of graduate work category) from Vincent Hevern, S.J., co-Chair of the award committee. Her project was entitled "Examining the effects of individual and cultural differences in trauma victimization". At extreme left in the foreground is Dean Keith Simonton, Ph.D., 2012-2013 past-President of Division 1. At extreme right in the foreground is Harold Takooshian, Ph.D., co-Chair of the 2013 award committee.

Lisa Osbeck, Ph.D. (left) with Nancy J. Nersessian, Ph.D.., (middle) and Wade Pickren, Ph.D. (right). Lisa and Nancy are co-authors of one of the two books that won the 2012 William James Book Award. The full reference for their book is *Science as Psychology: Sense-making and Identity in Science Practice* by Lisa Osbeck, Ph.D., Nancy Nersessian, Ph.D., Kareen Malone, Ph.D., & Wendy Newstetter, Ph.D. New York, NY: Cambridge University Press, 2010. Wade (2012-2013 Division 1 President) chaired the 2012 award committee.

Division 1 Awards Ceremony attendees.

Jennifer M. Gómez (left) talking with Nancy J. Nersessian (2nd from left). Lisa Osbeck (3rd from left) with Douglas Candland (far right).

Division 1 thanks the following individuals for their assistance in the 2013 award process!

Award Committee Chairs:

GEORGE A. MILLER AWARD: Wade Pickren, Ph.D., Ithaca College
WILLIAM JAMES BOOK AWARD: Janet A. Sigal, Ph.D., Fairleigh Dickinson University
ERNEST R. HILGARD AWARD: Dean Keith Simonton, Ph.D., University of California, Davis
ARTHUR W. STAATS LECTURE: Nancy Felipe Russo, Ph.D., Arizona State University
ANNE ANASTASI GENERAL PSYCHOLOGY GRADUATE STUDENT RESEARCH AWARDS: Harold Takooshian, Ph.D., Fordham University & Vincent W. Hevern, S.J., Le Moyne College
ANNE ANASTASI STUDENT POSTER AWARD: Nicholas Noviello, Ph.D. & Terece S. Bell, Ph.D., California School of Professional Psychology at Alliant International University, Los Angeles

Award Committee Members (in alphabetical order):

Bernard Beins, Ph.D., Ithaca College
G. Andrew H. Benjamin, Ph.D. University of Washington
Gordon M. Burghardt, Ph.D., University of Tennessee
Janet F. Carlson, Ph.D., University of Nebraska-Lincoln
Florence L. Denmark, Ph.D., Pace University
Emanuel Donchin, Ph.D., University of South Florida
Monroe Friedman, Ph.D., Eastern Michigan University
Gerald Gamache, Ph.D., University of St. Augustine, Florida
Uwe Gielen, Ph.D., St. Francis College
John Hogan, Ph.D., St. John's University
Jean P. Kirnan, Ph.D., College of New Jersey
Wilma Koutstaal, Ph.D., University of Minnesota
Ralph Kuechle, Ph.D., South Coast Children's Society
Robert V. Levine, Ph.D., California State University – Fresno
Jeffrey S. Mio, Ph.D., California State Polytechnic University – Pomona
Slater E. Newman, Ph.D., North California State University –Raleigh
Joseph J. Palladino, Ph.D., Miami University
Scott Plunkett, Ph.D., California State University, Northridge
Cecil R. Reynolds, Ph.D., Texas A&M University
Miguel Roig, Ph.D., Saint John's University
Ronald G. Shapiro, Ph.D., Providence RI
Susan Siaw, Ph.D., California State Polytechnic University, Pomona
Brian H. Stagner, Ph.D., Texas A&M University
Peter Suedfeld, Ph.D., University of British Columbia
Elizabeth V. Swenson, Ph.D., John Carroll University
Peter Theodore, Ph.D., California School of Professional Psychology at Alliant International University, Los Angeles

2013 Divisional Service Awards

The ***2013 Recognition Awards for Dedicated Service to Division 1*** were given out to
Nicholas Noviello, Ph.D., and
Terece S. Bell, Ph.D.

The following individuals received the *2**013 Division 1 Presidential Citations for Outstanding Service/Achievement***:
Gina Brelsford, Ph.D.,
Douglas K. Candland, Ph.D.,
Joan Chrisler, Ph.D.,
Marissa Harrison, Ph.D.,
Vincent Hevern, SJ.,
Lisa Osbeck, Ph.D.,
Brian Stagner, Ph.D.,
Harold Takooshian, Ph.D., and
osephine Tan, Ph.D.

Congratulations are extended to all the recipients!

Division 1, The Society for General Psychology
2013 Awards Announcement

Division 1 is pleased to announce its 2013 award recipients who were recognized at the 2013 APA meeting that was held in Honolulu, Hawaii. For more details on awards, please go to http://www.apadivisions.org/division-1/awards/index.aspx .

William James Book Award

Born Together-Reared Apart: The Landmark Minnesota Twin Study by Nancy L. Segal, Ph.D., California State University at Fullerton, published by Harvard University Press, Cambridge, MA, 2012.

Ernest R. Hilgard Award for Career Contributions to General Psychology

Morton Ann Gernsbacher, Ph.D.
University of Wisconsin-Madison

George A. Miller Award for the Outstanding Journal Article in General Psychology

Julianne Holt-Lundstad *Timothy B. Smith* *J. Bradley Layton*

Social Relationships and Mortality Risk: A Meta-analytic Review by Julianne Holt-Lunstad (Brigham Young University), Timothy B. Smith (Brigham Young University), and J. Bradley Layton (University of North Carolina at Chapel Hill), *PLoS Med 7*(7): e1000316.

2013 Arthur W. Staats Lecture for Unifying Psychology

Diane Halpern*, *Ph.D.
Claremont McKenna College

2014 Arthur W. Staats Lecture for Unifying Psychology

(Staats Lecture to be presented at 2014 APA)

Peter Salovey*, *Ph.D.
Yale University

Anne Anastasi Graduate Student Research Awards

Two or more years of graduate work

David I. Miller, M.A.
Northwestern University

Two or more years of graduate work

Reuben Ng, M.A., M.Phil.
Yale University

Under two years of graduate work

Jennifer M. Gómez, M.S.
University of Oregon

Finalists (in alphabetical order)

Marc Coutanche, M.A.
University of Pennsylvania

Emily D. Hooker
University of California, Irvine

Philip Sayegh, M.A.
University of Southern California

Anne Anastasi Graduate Student Poster Awards

Winning Poster:

Audrey E. Martinez, M.A., SedaTerzyan, M.A., Angelyna M. Hinkle, M.A., David Rosenblatt, M.A., & Paul E. Haerich, Ph.D.
Loma Linda University

Recognition Awards (in alphabetical order):

Ivonne A. Florez, B.A., Seamus P. Walsh, B.S., Margaret Bowden, *(University of Mississippi)*, ***Tracie L. Stewart, Ph.D.*** *(Kennesaw State University)*, ***& Stefan E. Schulenberg, Ph.D.*** *(University of Mississippi).*

Te Hyuk Keum, B.S., Yu Chak Ho, B.S., Jennifer Kim, B.A., Robin Hardin, B.S., & Seohyun Kim, B.A., *(Teachers College, Columbia University)*

Matthew E. Kahler, B.S., John A. Blue Star, B.S., & Sean C. Woodland, B.S. *(Brigham Young University).*

Division One Business

Business Meeting Minutes

August 2, 2013

Call to order by Dr. Pickren.

Dr. Tan and Dr. Stagner motioned to approve the business meeting meetings from 2012. This was unanimously approved.

1. President report: Wade reported that he was happy to pass the presidential gavel to Dr. Janet Sigal. He also chaired the committee for the George A. Miller award and the recipient is the article, "Social Relationships and Mortality Risk: A Meta-analytic Review," by Julianne Holt-Lunstad (Brigham Young University), Timothy B. Smith (Brigham Young University), and J. Bradley Layton (University of North Carolina at Chapel Hill).

2. Past-president report: Dean indicated he is chair of the Hilgard award and they chose Morton Ann Gernsbacher as the recipient. She will be giving an awards talk next year. Chair of nominations and elections committee, Emilio Ulloa, will be taking over as treasurer, and as member at large, Richard Velayo was elected. Joan Chrisler was elected as president-elect.

3. President-elect report-Janet indicated that her main task was sitting on the committee for the WJB award, which was awarded to Nancy Segal for her book,
"Born Together-Reared Apart: The Landmark Minnesota Twin Study".

4. Council of Representatives Report-Rosie indicated that the PENS report was appealed. There was a vote on the GG project. See more about this issue in the newsletter.

5. Secretary-Gina indicated that there will need to be replacement selected for position next year.

6. Treasurer-Joan was not present, but our monetary supplies are in good standing.

7. Member-at-large-Brian indicated that he was on the search committee for editor of *RGP* and he reviewed research awards for Harold.

8. Program Chair-Lisa was not present, but the program this year was well-attended.

9. Hospitality Suite Chair-Eric indicated the suite was well-attended so far to date. We have had post symposium discussions with approximately 50 people in attendance. We may want to increase the size of our hospitality suite at future conventions.

10. Historian-Don was not present, but he reminded us to send him to any reports or information from D1 for archives.

11. Journal Editor-Doug reported that his last edition of the journal will be the December edition. The journal is doing well. Submissions this year are around 100-110 and the acceptance rate is 21% during the last 3-4 years. RGP published 480 pages this year. June issue was a special issue, edited by Eric Charles. Doug was thanked for his work. Wade indicated that the new editor of the journal will be Dr. Gerianne Alexander of Texas A & M.

12. Newsletter editor-Marissa was not present. Wade remarked that she has done a great job.

13. Awards coordinator-Jo indicated that the awards handbook has been updated. The awards committee reports will be in the handbook. The call for next year's cycle of award nominations will occur very soon. Needs reviewers to help with the Anastasi poster and student research award chairs. Two MAL members are currently involved, but we need more people.

14. Webmaster-Grant not present, but indicated that the listserve has good traffic.

15. Membership-Mark was not present, but our membership continues to decline slightly.

16. Fellows-Richard was not present, but we have 7 new fellows this year.

17. Awards ceremony is at 4pm today. Poster award is tomorrow at 10 am.

18. Wade indicated he enjoyed being president and will enjoy being past president. He passed the gavel to Janet Sigal as the new president. She talked about how our division is inclusive of all disciplines and will celebrate next year the 66th anniversary of Division 1.

19. The meeting was adjourned at 12:40pm.

Respectfully submitted,
Gina M. Brelsford, Ph.D.
Secretary Division 1 of APA

Executive Committee Meeting Minutes

American Psychological Association
Division 1
Honolulu, Hawaii
July 31, 2013

Attendees: Richard O'Brien; Richard Velayo; Wade Pickren, Janet Sigal, Joan Chrisler, Eric Charles, Gina Brelsford, Lisa Osbeck, Rosie Phillips-Bingham, Brian Stagner, Zoeann Finzi-Smith, Doug Candland, Dean Simonton, Josephine Tan, Mark Terjensen

1. Meeting was called to order at 6:15pm.
2. Introductions were provided.
3. Meeting minutes from 2012 were approved with a small change to the theme of the 2013 convention.
4. Wade provided his report related to his term as president. The George A. Miler award was selected to be "Social Relationships and Mortality Risk: A Meta-analytic Review," by Julianne Holt-Lunstad (Brigham Young University), Timothy B. Smith (Brigham Young University), and J. Bradley Layton (University of North Carolina at Chapel Hill).
5. Janet (president-elect) provided her report on the WJBA. There were 11 submissions. It was a unanimous decision. Nancy Segal was the winner for her book "Born Together-Reared Apart: The Landmark Minnesota Twin Study". Program chair for next year is Grant Rich, "Integration of science and practice applied to global issues" is the possible theme for 2014. We may work with 4 other divisions for an interdivision grant on domestic violence (D. 42, 51, 17, 52); will work with them on this program due to our division hours being cut next year. It might be nice to have an anniversary celebration related to 66 years of Division 1.
6. Dean provided his past president report. The Hilgard Committee (outstanding career in general psychology) selected Morton Ann Gernsbacher for the award. Dean, as Chair of nominations and elections committee, indicated that Emilio Ulloa will be taking over as treasurer and Richard Velayo was elected as member at large. Joan Chrisler was elected as president-elect.
7. Lisa provided the program report. The theme of "Situating General Psychology in the 21st Century: Integration, unification, pluralism, or…?" We filled all of the program hours-37 hours including meetings. Wade's presidential address is a symposium this year. We are starting a coalition effort, "Big Questions, Essential Conversations" and we have two symposia coming out of this effort (D-1, 24, 26, 32, & 39).
8. Eric presented on the hospitality suite: 34 hours of suite programming in collaboration with D24 and D26.
9. Joan presented the treasurer's report: Financial report from last year and the budget for this year. We have made a substantial sum of money on the journal again this year. The duty of the treasurer is to advise on financial matters and be aware of and part of all financial decisions in addition to other duties that are typical of treasurers such as creating a budget or paying bills. The treasurer should also have a copy of the new journal editor's contract. The treasurer will need to collaborate with the awards chair and the hospitality suite chair on the financial needs of those positions. Rosie inquired about monetary support for council representatives. Zoeann also asked about student support for student representatives. Joan indicated that the budget is a living document, which can be changed.
10. Gina discussed only having one year left as secretary and a new secretary will need to be appointed.
11. Rosie presented on council. Telecounseling guidelines have been passed and internship accreditation guidelines have been passed. A discussion of the Good Governance Project ensued. This project has been ongoing for three years related to a strategic plan for APA. Structure of council was discussed. The PENS report was rescinded. APA affirmed the position against torture, particularly in national security centers.

12. Doug provided a report on his last term as journal editor of *RGP*. *RGP* was founded in 1996. Doug provided a history of *RGP*. Acceptance rate remains around 21%. The Division owns the journal as of 2010. The increased impact factor is notable. Revenue continues to be generated by electronic downloads.
13. Wade discussed the search for a new editor of *RGP*. We had 17 serious nominations or self-nominations. Four finalists and then the finalist was chosen to be Dr. Gerianne Alexander. She is currently at Texas A&M in the position of Associate Dean for Research in the College of Liberal Arts and a Professor of Psychology. A new system to review manuscripts has been adopted for *RGP*.
14. Marissa was not present, but she provided a brief report as Newsletter Editor. Her term is also ending and Wade would determine if she was going to continue after next year.
15. Member at Large (MAL)-Brian talked about not understanding his obligations or duties. This needs to be clearer for these positions. Wade indicated the member-at-large could take on leading a defunct committee that needs to be chaired or the MAL could take on the roles of chairing committees for the student poster award and the student research award.
16. Don provided an electronic report. He requests materials for D1 so they can be archived.
17. Grant provided an electronic report. We have a fairly active website.
18. Zoeann provided the student representative report. Zoeann is active on the student rep. listserve and she created a Facebook page for D1 to recruit students. A new student representative will need to be appointed after next year.
19. Jo presented her awards coordinator report. She indicated that the awards chair has to think in a 3-year epoch. Jo indicated that after winners for all major awards are selected-the work of the awards coordinator is to make sure all of the previous award winners present at the following year. Certificates, medals, checks are also to be acquired by the awards coordinator and distributed to the program chairs for delivery to the award winners. For this year's program, we selected the winners, so at the business meeting we are going to announce the 2013 winners. Anastasi student research award winners will be presented with their awards at the awards ceremony on Saturday evening. We will not know who the winners for the 2013 student poster winners will be until Sunday when they are judged. The cycle for 2014 has to be considered immediately upon return from APA. Hilgard, Miller, and James are all $1500, student research is $300, and the student poster is $100. We are changing the student poster award to the Raymond Corsini Student Poster Award. We have to have in place the Anastasi student research award chair and the Corsini Student Poster chair for 2014. We also will need an awards coordinator following august of 2014.
20. Nancy was not present to provide her oral report.
21. Mark provided his membership report. Division membership is down as is in most divisions. Slight upswing in student members and ECPs. Everyone who publishes in the journal is invited to join D1. There is a discussion between all division membership chairs related to how to use technology to engage students and ECPs. We will also need to find a new membership chair after 2014.
22. Rich presented on the fellows committee. He indicated there were 346 Fellows of D1. Not all Fellows have maintained their Fellow status. We have 7 new Fellows this year. These Fellows were named and *TGP* will present these names in the newsletter. Fellows include: Barney Beins, Frederick Wertz, Peter Hancock, Linda Sobell, Mark Sobell, Lisa Harlow, Ronald Shapiro. There is a Fellows workshop during convention if you wish to apply for fellow status.
23. Richard O'Brien presented on the IRB issue and scientific integrity. There appears to be an attempt to get rid of regulations for some research related to OHSRB. There are talks about trying to change the exempt status to excused status for research. Richard will continue in this position next year.

Discussion Items:

1. We need to identify chairs for the Corsini Student Poster Award and the Anastasi Student Research Award-there was discussion of passing these duties to the members-at-large. The presidential trio may have to decide on the Boneau Award and Presidential Citations for exceptional service.
2. Discussion related to providing honorarium to members of the Anastasi Award Committee, but it was decided that public acknowledgement is the best method.
3. Eric talked about the need to be reappointed as chair of the ECP committee. We need to find what is a benefit to ECPs for joining D1.
4. Mid-year meetings can be discussed at a future meeting, possibly during Joan's term as president.
5. There is a fee of $288 to run the division listserve from the DSO. The EC decided to continue use of DSO for our listserve.
6. D1 could use the Summit as a natural link for our Mid-Year meeting.
7. D1 could use the business meeting as an awards meeting at future conventions. This is a future agenda item.

Meeting was adjourned at 8:05pm.

Respectfully submitted,
Gina M. Brelsford, Ph.D.
Secretary D1

Click here for tips on APA-style writing.

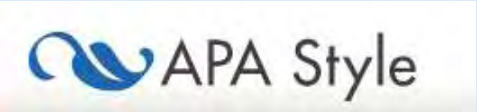

More D1 scenes from the...

Thumbs up from then-President, Wade Pickren

Dean Keith Simonton

Janet Sigal

L to R: Douglas Candland, Scott Churchill, Frederick Wertz, Christopher Ramey, Kolja Lehmann, James Lamiell, and Lisa Osbeck.

Philip Zimbardo

Vinny Hevern &
Wade Pickren

Congratulations to the New Fellows of Division 1!

According to the American Psychological Association, *"Fellow status is an honor bestowed upon APA Members who have shown evidence of unusual and outstanding contributions or performance in the field of psychology. Fellow status requires that a person's work has had a national impact on the field of psychology beyond a local, state, or regional level. A high level of competence or steady and continuing contribution are not sufficient to warrant Fellow status. National impact must be demonstrated."* Of 84,000+ APA members, about 6 percent are Fellows.

The Fellows Committee of the Society for General Psychology (APA Division 1) is proud to announce that eight psychologists were elected as Fellows of the Division based on their "outstanding and unusual" contributions to general psychology. One of them was elected as a new Fellow of APA, and seven current APA fellows were elected by the Division.

- **Bernard Beins, Ph.D.** *(Ithaca College)*
- **Peter Hancock, Ph.D., D.Sc.** *(University of Central Florida)*
- **Lisa Harlow, Ph.D.** *(University of Rhode Island)*
- **Susan Nolan, Ph.D.** *(Seton Hall University)*
- **Linda Sobell, Ph.D.** (*Nova Southeastern University)*
- **Mark Sobell, Ph.D.** *(Nova Southeastern University)*
- **Ronald Shapiro, Ph.D.** *(Independent Consultant, Providence, RI)*
- **Frederick Wertz, Ph.D.** (Fordham University)

For those who may be interested in applying for Fellow status in Division 1, contact Richard Velayo, Ph.D., by email at rvelayo@gmail.com. Criteria for qualifications as Division 1 Fellow may be found at http://www.apadivisions.org/division-1/membership/fellows/index.aspx .

My sincerest thanks to Drs. Florence Denmark, Antonio Puente, Janet Sigal, and Harold Takooshian who served as members of the Committee this past year!

Congratulations and best wishes to our new Fellows!

Sincerely,

Richard S. Velayo, Ph.D.
Chair, Fellows Committee

Who admires Raymond Corsini?

Help Division 1 Celebrate Dr. Corsini's Centennial Birth!

The late, great psychologist Raymond J. Corsini (1914-2008) of Hawai'i was a brilliant author, teacher, and mentor. Ray's career is described in the *American Psychologist* (January, 2010, on page 54).

Many of Ray's friends gathered in 2013 at the APA Convention in Honolulu where Division One Awards Chair Josephine Tan announced the launch of a new Corsini Student Research Award to mark the centenary of Ray's birth in 2014.

For a tribute to Ray in 2014, *The General Psychologist* seeks brief remembrances from Ray's students, colleagues, and friends. Did Ray's life touch yours somehow? If so, please send us this information by December 1, 2013: your name, current affiliation, your photo, and 1-3 paragraphs on how Ray's life touched yours. If you have a good photo or two of Ray, please add these, along with photo captions. These edited remembrances will appear in a tribute to Ray in *TGP* in 2014.

Please direct any questions to Corsini Committee chair **Bernardo Carducci**: bcarducc@ius.edu.

PHOTO: In Hawaii, Dr. Vernon Thompson's family joins the salute to their friend, Ray.

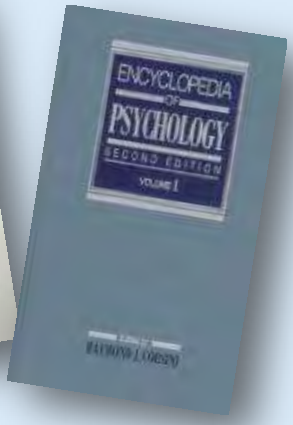

Review of General Psychology Welcomes a New Editor

By Wade Pickren, Past President of D1

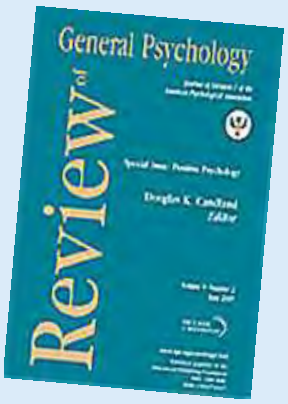

In the summer of 2012, Division One's leadership formed a committee to search for the new editor of our journal, *Review of General Psychology*. After many years as editor, Doug Candland had decided to step down and we all knew it would be hard for anyone to follow him. Under Doug's editorship the journal had grown in reputation and influence. Our members and the Division leadership wish to express our profound thanks to Doug for the excellence he brought to the journal.

The search committee members were Nancy Russo, Ph.D., Hortensia Amaro, Ph.D., Brian Stagner, Ph.D., and Thomas Teo, Ph.D. I served as Chair of the Committee. We worked with APA Journals and their web-based Editor Quest system to manage the process.

We received 17 high-quality nominations. After much deliberation, we were able to narrow the list to four finalists, each of them eminently qualified to serve as editor. The Committee carefully considered the merits of each finalist and unanimously decided that **Dr. Gerianne Alexander of Texas A & M University** was our first choice. Dr. Alexander agreed to serve as our editor for the next six years. She brings to the position a high-profile research reputation. Her research interests include the development of human sex differences in social and cognitive behavior; hormonal influences on typical and atypical behavior across the lifespan; and reproductive endocrinology and behavior. Her research has been well-funded by a variety of federal and private agencies.

Dr. Gerianne Alexander

Dr. Alexander brings to her editorship remarkable breadth as a researcher. Just as importantly, she brings a great intellectual curiosity about human behavior. While she is solidly based in psychology, she also sees the connections among psychological science, the biological sciences, as well as the profound insights about human beings that are found in our best fiction, art, and music. She is truly well-situated to continue to develop general psychology through the pages of *Review of General Psychology*.

Editor's Note: Read one of Dr. Alexander and Dr. Hines's landmark articles:
Alexander, G.M., & Hines, M. (2002). Sex differences in response to children's toys in nonhuman primates (*Cercopithecusaethiops sabaeus*). *Evolution and Human Behavior, 23*(6), 467-479.

Become a Fellow of Division 1

Fellows Committee Call for Nominations

The Division 1 Fellows Committee is seeking nominations and applications for Fellow status in the Division.

Fellows Committee Chair: Richard Velayo, Ph.D.
Email: rvelayo@gmail.com

There are two paths to Fellow status in the Division:

First, members of Division 1 who are APA members, but are not Fellows of APA, may apply for Fellow status in Division 1. They are known as "New Fellow" applicants and must meet both APA criteria and Division 1 criteria for Fellow status.

Second, any member of Division 1 who is already a current Fellow of APA may apply to become a Fellow of the Division. These applicants are known as "Current Fellows." Current Fellows are only evaluated by the Division Fellows Committee. Current Fellows are a good resource for information about being and becoming a Fellow. Letters from Current Fellows are also required for those applying for New Fellow status.

APA Fellow Criteria include:
1. Five (5) years of acceptable professional experience beyond receipt of the doctoral degree
2. Membership in APA for at least one year
3. Unusual and outstanding contributions that have had a national or international impact in general psychology

Division 1 Fellow Criteria are listed here:
http://www.apadivisions.org/division-1/membership/fellows/index.aspx

Process for New Fellows:

The process to apply to be an APA Fellow is now done via the **APA Fellows Online Application Platform**. This new system will allow nominees, endorsers, and Division Fellows Chairs to submit all required documents online.

The online system will replace the previous, paper-based process and all Fellows applications must be added to the system to be considered by the Fellows Committee.

Applications for New Fellow status require letters from three current Division 1 Fellows and completion of other materials described in the APA Fellows Online Application Platform. Please visit the Fellows webpage for more information and to access the new online system: http://www.apa.org/membership/fellows/index.aspx

All materials, including letters of reference, must be completed by November 18, 2013. The candidates' applications are reviewed by the Division Fellows Committee. Those receiving a positive recommendation will be forwarded to the APA Fellows Committee for their review. Fellow status is granted by the **APA Fellows Committee**. Please remember that there can be **only one nominating Division**.

Process for Current Fellows:

Current Fellows of the APA from other APA Divisions may apply for Division 1 Fellow status by sending a current vita and a letter highlighting the reasons that one has met the criteria for Fellow status in the Division. These candidates' applications must be emailed to Richard Velayo (rvelayo@gmail.com). **The due date for Current Fellows applications is April 15, 2014.** Current Fellows applications are evaluated by the Division Fellows Committee only.

AMERICAN PSYCHOLOGICAL ASSOCIATION

Taken from: http://www.apa.org/about/division/index.aspx

Divisions

APA's 54 divisions *are interest groups organized by members. Some represent subdisciplines of psychology (e.g., experimental, social or clinical) while others focus on topical areas such as aging, ethnic minorities or trauma. APA members and even nonmembers can apply to join one or more divisions which have their own eligibility criteria and dues. In addition, each division has its own officers, website, publications, email list, awards, convention activities and meetings.*

Spotlight from the 2013 APA Convention

Anne Anastasi

Graduate Student Poster Award Winner

Effects of Temporal Pressure on Episodic Memory

Audrey Martinez, M.A., Seda Terzyan, M.A., Angelyna Hinkle, M.A., David Rosenblatt, M.A., and Paul Haerich, Ph.D.

Loma Linda University

Introduction

This study examined the predictions of Priority Binding theory by manipulating temporal pressure across lists of emotional visual images. Priority Binding theory (MacKay et al., 2004) proposes that under temporal pressure, arousing negative stimuli delay binding of neutral items presented in close temporal proximity (as in lists with mixed neutral and negative stimuli). With fast presentation rates, a subsequent negative item may interrupt the binding process for the preceding neutral stimulus. This results in more accurate memory for negative images presented in mixed lists. However, in slow presentation rates, binding occurs equally for all items. Therefore, no such advantage is predicted comparing images presented in lists of the same valence.

Method

Participants (N = 42; recruited from subject pools at two private Southern California universities) were shown eight lists of 14 images selected from the International Affective Picture System. One pure negative, one pure neutral, and two mixed valence lists were presented at 0.5 Hz and at 4 Hz. using *E-Prime 2.0 Professional* to randomize this list order and list composition. Following each list, participants completed old-new recognition tests and rated their confidence using a remember/know paradigm.

Results

Accuracy: A three-way interaction resulted from performance differences between rates, and among lists at the fast rate, $p = .006$. In fast, pure lists, neutral valence images displayed an accuracy advantage over negative, $p < .001$, while in fast, mixed lists the difference was non-significant. Accuracy was better for slow than fast lists suggesting that processing benefited from the extra encoding time, $p < .001$. No differences among lists were observed at the slow rate. Sensitivity: Sensitivity (d'_e) paralleled accuracy; however the differences among lists were greater. d'_e was better at slow than fast presentation rates, $p < .001$, and for negative images at slow rates, $p < .03$. A two-way (Rate X List Type) interaction, $p < .03$, resulted from a non-significant trend for better sensitivity.

Discussion

The present study examined the effects of temporal pressure on recognition of emotional pictures. Manipulating presentation rate produced the largest effect and strongly influenced recognition accuracy, sensitivity and bias. The predictions of binding theory were

partially supported with a trend for negative images to exhibit a memory advantage over neutral images in the mixed, fast lists; there was also an unexpected memory advantage for neutral images in pure lists. A ceiling effect was found for recognition memory of lists at the slow rate, suggesting that extra viewing time allowed participants to better process and encode images. Slow-rate negative images produced higher d'_e and more liberal bias than neutral. Though image recognition appears to be influenced by emotional valence and arousal, it is still possible that image stimuli are differentially processed and remembered compared to word stimuli.

Reference

MacKay, D. G., Shafto, M., Taylor, J. K., Marian, D. E., Abrams, L., & Dyer, J.R. (2004). Relations between emotion, memory and attention: Evidence from taboo Stroop, lexical decision, and immediate memory tasks. *Memory & Cognition, 32*, 474-488.

Audrey E. Martinez, M.A., is a doctoral student at Loma Linda University in Loma Linda, CA. Her research focuses on emotion and human neurocognition.

"Ma Vie En Graduate School"

Advice for Future Students and for Student Futures

By Lavina Y. Ho
Applied Clinical Psychology, Penn State Harrisburg

Graduate school marks a time for academic and personal growth, as graduate students are given greater responsibility and autonomy in deciding their future plans in addition to ultimately determining their unique career path. My greatest advice to future graduate student applicants is to keep an open mind and to take advantage of all the opportunities around them.

Future graduate applicants usually have a set of plans laid out, and in instances where these plans may not work out, students may often lose faith in themselves and ultimately, their aspirations. However, the most important lesson that I have learned thus far is that hard work will yield results, but only after continued determination.

While it may seem as if the delayed gratification of graduate education is often overwhelming, careers take unexpected turns and often result in a deeper understanding of the self and an individual's capabilities. What's important to remember is that the unexpected nature of life creates opportunities for personal and academic growth.

Graduate life simply never ends. Knowledge begets greater knowledge, and an understanding that graduate students never cease learning in multiple facets of their lives. I highly recommend that graduate students get involved in their campus life, especially within their academic program. As graduate students, we have the ability to facilitate positive change on campus as well as promote the mental welfare of underserved communities in psychology. Acting as role models on campus also inspires greater community change, promotes undergraduate students to perform at their optimum abilities, and ultimately, to pursue graduate education.

Lavina Y. Ho *is an advanced student on scholarship in Penn State Harrisburg's Applied Clinical Psychology Master's Program. She is a Teaching Assistant, a Research Assistant, and an officer and community leader in Psi Chi and the Applied Psychology Association of PSH.*

Future APA Convention Dates

2014 Washington, D.C.
August 7-10 (Thursday through Sunday)

2015 Toronto, Ontario, Canada
August 6-9 (Thursday through Sunday)

2016 Denver, Colorado
August 4-7 (Thursday through Sunday)

2017 Washington, D.C.
August 3-6 (Thursday through Sunday)

2018 San Francisco, California
August 9-12 (Thursday through Sunday)

2019 Chicago, Illinois
August 8-11 (Thursday through Sunday)

2020 Washington, D.C.
August 6-9 (Thursday through Sunday)

2021 San Diego, California
August 12-15 (Thursday through Sunday)

Division One: Society for General Psychology

Book review

By J. Scott Lewis, Ph.D., Penn State Harrisburg

The Human Spark:
The Science of Human Development
By Jerome Kagan

Basic Books, 2013. 333 pages. ISBN: 978-0-465-02982-2

In this book, pioneer of developmental psychology Jerome Kagan updates his previous book *The Nature of the Child*. Kagan focuses on three questions of import in which new evidence brings up to date old ideas. What is the expected developmental course for cognition, emotional development, physical development and moral development in children? How does variation in experience affect the rates at which these traits develop? And, finally, what are the factors that influence variation in experience?

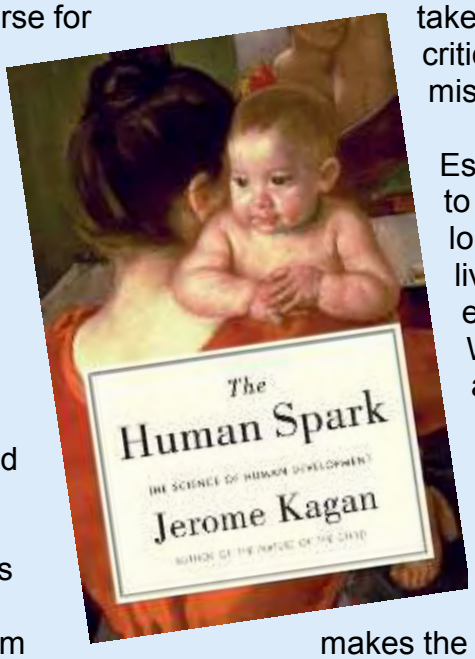

Of course, these are not new questions. They have been asked before in a variety of contexts, including through epigenetic and sociological frameworks. Kagan's contribution to the questions, however, deviates somewhat from the more mainstream approaches to the problem. Kagan questions many of the conventions currently in vogue in developmental psychology. For example, he questions the notion that past behavior in one setting is a good predictor of future behavior in a different setting.

Kagan sees such conceptions as part of a larger problem in developmental psychology; this problem is the lack of triangulation of evidence. Kagan sees this as providing a grossly incomplete picture of human behavior. He uses these weaknesses to offer a critique of some of the most popular theories in developmental psychology. Most notably, he takes aim at attachment theory, which he criticizes as an egregious misinterpretation of research.

Essentially, Kagan relies on sociology to make his case. Sociologists have long argued that culture shapes the lives of individuals within their experiential and historic context. C. Wright Mills made this same argument in 1959, and most sociologists accept it as axiomatic. Kagan discusses how culture shapes the choice that individuals make to influence their development. Offering a thorough review of the literature, the author makes the case not only for socialization, but also for epigenetics. He presents a wealth of evidence on the ways in which environment and experience influence the expression of genes.

A positive aspect of *Spark* is that Kagan takes a strongly interdisciplinary approach to his topic. The book provides an excellent overview of literature in a variety of areas of developmental psychology.

However, the book is so laden with information and thick with studies that it is often dry and sometimes a little hard to follow. The careful reader will, however, find it a rich source of information and a valuable compendium of information. The comprehensive coverage that it provides makes it an ideal companion to a textbook for those seeking a deeper understanding of many of the issues at the forefront of developmental psychology.

Dr. J. Scott Lewis *is Assistant Professor of Sociology and the program coordinator for Penn State Harrisburg's Bachelor of Social Science in Secondary Education Social Studies program. His interdisciplinary research interests include evolution and human behavior, the philosophy of social science, and pedagogy. He is the author of* Learn Sociology.

If you have a book you would like to see reviewed in *The General Psychologist*, or you would like to review a book for us, please contact the Editor.

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http://www.apa.org/

AMERICAN PSYCHOLOGICAL ASSOCIATION

DID YOU KNOW?

The APA provides valuable information about research in psychology. The APA website features a database for research funding sources, advice for research methodology and training opportunities, resources about publishing your research, and resources and readings to ensure the responsible conduct of research. Click here.

Division 1's ***Portraits of Pioneers in Developmental Psychology***
Edited by Wade Pickren, Donald A. Dewsbury, and Michael Wertheimer

Published October 26th, 2011 by Psychology Press – 351 pages

Click here for more information and purchasing options.

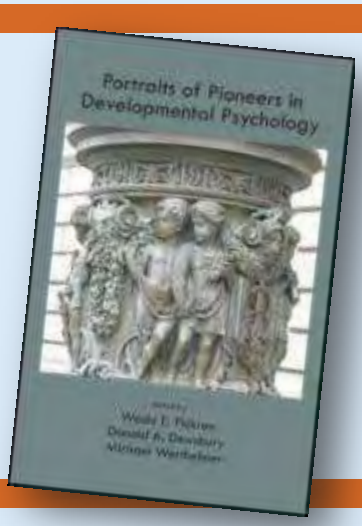

Is *Introductory Psychology* Asexual?

Marissa A. Harrison, Ph.D., Jennifer E. Zobler, M.A.,

Gina M. Brelsford, Ph.D., and Melanie S. Koser, B.A.

Penn State Harrisburg

Since psychology as a discipline aims to understand human behavior and mental processes, what could be a more fundamental behavior to understand than that which ultimately serves to perpetuate the species—**sex**? Indeed, sex is very important to most people, and for some, sexuality is a dominant force in their lives (Bancroft, 2009). Although some may be uncomfortable with sexuality and feel that discussing sex reflects evil or immorality, and some may backlash against any form of sexual progressiveness (Hyde & DeLamater, 2011), the fact is that sex is here to stay.

In their textbook *Understanding Human Sexuality*, Hyde and DeLamater (2011) eloquently underscored the importance of the study of sexuality for college students. Exposure to human sexuality research can facilitate self-understanding, minimize embarrassment about a fundamentally important topic, influence judgment and decision-making with respect to physical and emotional well-being, and foster tolerance of sexuality regardless of age, gender, ethnicity, sexual orientation, and culture. Further advantages of human sexuality education include arming students with the skills to maximize their own sexual health and minimize sexual exploitation of one's self and others (Baber & Murray, 2001). Thus, a college course in the psychology of human sexuality can be of tremendous developmental value with respect to promoting well-being and self and societal understanding. Given such importance, however, it seems logically indefensible that the dissemination of such essential information should be limited to students enrolled only in sexuality-specific courses. While it is likely impossible to infuse sexuality into every college course, the discipline of psychology offers a viable outlet tailored to disseminating such information to a widespread audience—Introductory or General Psychology. In the present work we make the argument that Introductory Psychology should *not* be asexual—that is, as behavioral scientists we should endeavor to include human sexuality in our most basic college psychology course.

The majority of college students are typically 18 to 25 years old (National Center for Educational Statistics, 2002). Referred to as emerging adults (Arnett, 2007), this age group is coming into their own, exploring various identities,

taking strides in developing world views separate than that of their parents and caregivers, and focusing on their own lives without yet committing to adult roles (Arnett, 2004; DeHaan, Yonker, & Affholter, 2011). Since both men and women engage in a myriad of partnered and solo sexual behaviors from early adolescence to late adulthood, emerging adults and society as a whole can benefit from programs that seek to improve upon sexual knowledge and healthy choices (Herbenick, Reece, Schick, Sanders, Dodge, & Fortenberry, 2010). Further, as Rutledge, Siebert, Chonody, and Killian (2011) pointed out, many US adolescents do not receive sufficient sex education in high schools and therefore come to college in need of information at this precarious juncture of development. During this crucial period of role exploration, one can argue the dire need for sexuality education.

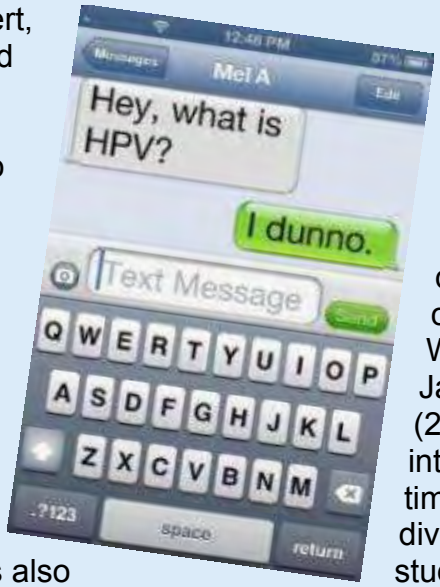

Introductory Psychology is a core requirement in the Psychology major, Psychology minor, and in many other majors and minors; it is also an elective sought by numerous college students. The American Psychological Association (2013) endorses Cush and Buskist's (1997) estimate that 1.5 million students complete an introductory psychology course each year. To wit, Bowker PubTrack (personal communication) documented that 413,464 students were enrolled in Introductory Psychology in the United States in the spring of 2011. As such, the material contained in Introductory Psychology textbooks reaches a vast audience. Indeed, the information in college textbooks can also impact others besides college students. For example, Advanced Placement Psychology is a college-level course taught to high school students, and current college-level textbooks are used in its instruction (College Board, 2010). Herein, then, lies the opportunity to deliver sexuality content to an even younger audience in their developmental prime. Even non-student individuals seeking knowledge or understanding of human behavior and mental processes may turn to an introductory psychology textbook online, from a friend, etc. Thus, Introductory Psychology offers a valuable opportunity to promote the understanding of human sexual behavior, and the presentation thereof can inform sexual decision-making and tolerance of self and others.

As such, the present study sought to document coverage of human sexuality topics in Introductory Psychology textbooks. We had no *a priori* prediction of degree of representation; rather, we aimed to document the presence and extent of coverage of various sexuality topics. Well over a decade ago, Griggs, Jackson, Christopher, and Marek (2000) noted that less than a third of all introductory books on the market at the time devoted full-chapter coverage to diversity and sex/gender. The present study parses this effort focusing on sexuality (and diversity therein), extends this effort by elaborating on specific themes for analyses, and offers a more recent glimpse of representation to determine whether contemporary introductory psychology is, indeed, asexual.

Method

Two long-time instructors (combined 20 plus years of experience) of college-level Psychology of Human Sexuality courses consulted several human sexuality textbooks (e.g., Hyde & DeLamater, 2011; Kelly, 2010; Rathus, Nevid, & Fichner-Rathus, 2010) and generated a list of 81 concepts typically covered in the class. This list of concepts appears in Table 1. Whereas it was not expected that every topic from a subdiscipline-specific course

would be covered in an introductory-level course, we used themes typically covered in sexuality courses as a basis to gauge representation.

A major textbook publisher kindly provided us with lists of the most required (i.e., the total number of students enrolled in courses requiring each book) introductory-level psychology textbooks in the United States from Spring 2011. The list was not publisher-specific (i.e., it did not solely list the publisher's own books).

We aimed to analyze the 15 most required introductory psychology texts. We obtained hard copies of 14 of the 15 books on the list for review. These 14 texts were published between the years of 2006 and 2009 by Pearson (*n* = 6), Worth (*n* = 6), Cengage (*n* = 1), and Wiley & Sons (*n* = 1) Publishers. We were unable to secure a copy of the 12th most required book on the list and therefore could not analyze it. Of note, we first attempted our analysis with online/e-book copies of the target textbooks but we found search features did not function with high accuracy. We thus conducted all analyses with hard copies.

In a departure from previous introductory textbook content analyses (cf. Habarth, Hansell, & Grove, 2011), we included full, brief, and modular editions of textbooks in our analysis. Our rationale is that the data show that these titles contain the information being disseminated to the most students, and therefore the sexuality information they include or exclude is essential to our analyses. For example, the *third* most required book (*n* = 25,919 students) was written by the author of the *second* most required book, and this number represented >30% more students than the *fourth* most required book. We would be remiss if we excluded the impact simply because the same person wrote more than one title. These 14 titles together accounted for 244, 038 enrolled students' required texts (Bowker PubTrack, personal communication), or 59% of the total introductory psychology books required in the United States during that semester. Stated another way, the majority of introductory psychology students in the United States were required to be consumers of these 14 book titles in Spring 2011.

Because our goal was to present evidence of systemic trends of sexuality coverage and not to comment upon or "call out" individual text authors, we opt not to list book titles; this follows the presentation method of Harbath et al. (2011) in their content analysis of psychoanalytic themes in introductory textbooks.

We read first the Index of each book searching for terms, and if the terms were not found, we read through each chapter of each book, paying close attention to areas in which sexuality might be mentioned but perhaps not indexed (e.g., *puberty* in Developmental Psychology chapters; *sexual attraction* in Social Psychology chapters). We noted whether each term or concept was *identified* (named only), *defined* (meaning was conveyed), or *discussed* (author provided context in two or more sentences).

Results

Results are presented in Table 1; 86% of terms and concepts were mentioned, 84% were defined, and 67% were discussed in at least one book. Of the 14 books reviewed, 5 (36%) featured a chapter devoted to human sexuality and gender.

Table 1

Percentage of Most Required (N = 14) Introductory Psychology Textbooks Mentioning, Defining, and Discussing Selected Sexuality-related Concepts

Concept/Term	% Mentioning	% Defining	% Discussing
Sexual Acts			
Masturbation/ one-person sex	36	7	0
Extramarital sex/ cheating/ adultery/infidelity	21	14	14
Premarital sex	57	50	43
Sexual intercourse	100	100	100
Oral sex	29	0	0
Sexual techniques	0	0	0
Sexual Cognitions			
Sexual desire	57	50	29
Sexual curiosity	14	14	0
Sexual decisions	0	0	0
Sexual fantasies	50	43	36
Physical attractiveness/ sexual attractiveness	100	100	86
Theories of Sexuality			
Biological	100	100	100
Evolutionary	100	100	100
Freudian	100	100	93
Sociological	86	86	86
Feminist	0	0	0
Researchers			
Masters and Johnson	100	93	79
Alfred Kinsey (Kinsey Report)	79	71	64
Physiology of Sexual Response			
Sexual response cycle	100	100	100
Penile erection	100	43	0
External sex organs	100	79	43
Internal sex organs	100	79	43
Sex hormones	100	100	50
Pheromones	21	14	0
Erogenous zones	43	21	0
Brain and sex	79	79	71

Sexual Development			
Sexual differentiation	93	86	64
Menstruation/ menarche	100	93	14
Puberty	100	100	64
Menopause	100	79	14
Sexuality during childhood	93	86	64
Sexuality during adolescence	100	100	100
Sexuality during adulthood	93	93	71
Sexual Orientation			
Heterosexual	100	100	86
Homosexuality	100	100	100
Gay	100	79	7
Lesbian	93	71	7
Transgender	57	57	21
LGBTQ	0	0	0
Intersex	36	36	7
Same-sex marriage	14	7	0
Gay prejudice	43	36	29
Gender Roles			
Gender stereotypes	64	64	36
Sexual scripts	64	64	43
Sex differences in personality	100	100	86
Sex differences in cognition	100	100	93
Sex differences in behavior	100	100	86
Reproduction			
Conception	93	86	29
Pregnancy	93	86	79
Childbirth	79	57	14
Infertility	0	0	0
Reproductive technology	0	0	0
Contraception/ pregnancy prevention	36	36	7
Abortion	21	7	0
Condoms	79	43	14
Diaphragm	7	7	0
Withdrawal	0	0	0
IUD	0	0	0
Rhythm method	0	0	0
Sexual Relationships			

Love	100	100	93
Sexual communication	14	7	14
Multicultural sexuality	57	57	57
Sexual Variation			
Paraphilias	36	57	7
Hypersexuality and asexuality	0	0	0
Cybersex	21	7	0
Sexual Coercion			
Rape	43	43	36
Incest	7	7	7
Sexual abuse	36	29	0
Sexual harassment	7	7	0
Sex Laws			
Sex-related laws	0	0	0
Selling Sex			
Prostitution	14	0	0
Pornography	14	14	7
Sexual Disorders (any type)			
Sex therapy	21	14	7
Sexually transmitted infections or diseases			
HIV/AIDS	93	93	79
HPV	36	29	14
Herpes	57	43	7
Gonorrhea	21	21	0
Syphilis	36	36	7
Pubic Lice	7	7	0
Hepatitis	7	7	0
Safe sex	71	50	43

Discussion

The question at hand is, "Is Introductory Psychology asexual?" Almost all the human sexuality terms and concepts for which we searched (nearly 9 out of 10) were at least mentioned, and two-thirds did receive discussion in at least one of the most required introductory textbooks. Further, over a third of books featured a human sexuality chapter. We thus interpret this as a cautiously positive **"no"** to our question and commend the efforts of our textbook-writing colleagues to infuse this important topic into the psychology curriculum. We would like to note for our esteemed text

author colleagues, however, some areas in which a discussion of such might promote sexually wise choices and inclusion.

Most books had some coverage of the usual suspects—*sexual development* (e.g., *menarche*, *puberty*), *love*, *physical attraction*, *sexual intercourse*, *conception*, *pregnancy*, and *childbirth*—with various discussion thereof. Curiously, however, no books mentioned the related topics *infertility* and *reproductive technology*. With about one out of six couples affected by infertility issues world-wide (World Health Organization, 2002), and with artificial reproductive technology evolving over the past 30 years affecting individuals, families, and societies around the world with social, cultural, and ethical implications (Inhorn & Birenbaum-Carmeli, 2008), this topic may warrant inclusion in future editions of introductory psychology textbooks.

A majority of textbooks we analyzed mentioned *safe sex*; however, less than half discussed it. Only two of the books discussed *condoms*, two discussed *human papillomavirus* (HPV; a virus that causes genital warts) and one discussed *herpes*. Although we understand textbook space is a premium, we implore our textbook author colleagues to introduce and elaborate upon safe sexual practices, even if this means a mere page of discussion. According to the Centers for Disease Control and Prevention (CDC) of the United States, people between the ages of 15 and 24 account for almost half of the 19 million new sexually transmitted infections reported each year, (CDC, 2012a), making this the highest rate of any age group (CDC, 2012b). Moreover, about 43% of women aged 14 to 59 years have HPV (CDC, 2010), and 16% of people in the US between age 14 to 49 have genital herpes (CDC, 2012c). Although one might rationalize that a safe sex discussion is better reserved for a biology or health class, the counterargument is that with its cognitive, social, and developmental correlates and consequences, this topic is inherently linked to the science of behavior and mental processes. Some coverage in an Introductory Psychology textbook—even one chart of diseases and risks—may help the college student population, typically emerging adults in the aforementioned at-risk age groups, make educated decisions about their and health and psychological well-being, and arguably, the health and well-being of others.

Further, only about a quarter of the most required Introductory Psychology texts discussed rape, and none discussed sexual harassment. The U.S. Department of Justice National Crime Victimization Survey (2012) showed that nearly a quarter of a million people in the US were raped or sexually assaulted in 2011. That is, as underscored by the Rape, Abuse, and Incest National Network (2013), every two minutes someone in the United States is sexually assaulted. Perhaps even two to three sentences describing the how, why, when, and who of such in a developmental or social chapter could promote awareness and decrease risk, providing an immeasurable service to textbook readers. Similarly, sexual harassment may appear to be a topic that should be dealt with in the workforce, but again, a few lines regarding the inappropriateness of sexual commentary, jokes, and advances in the workforce can promote awareness and responsibility.

Whereas 100% of the books analyzed discussed homosexuality, interestingly, none discussed gay marriage—a hot topic in the United States at the present time. A discussion of such in an Introductory Psychology course would make steps toward cultural literacy and social tolerance, promoting students' ability to recognize and respect diversity—a goal supported by the American Psychological Association (2007).
Given that Goal 8 of the *APA Guidelines for the Undergraduate Psychology Major* (2007) is to

promote student understanding of sociocultural and international diversity (p. 10), and the APA stresses the learning outcome of recognizing and respecting diversity (p.17), we found it surprising that only about half of the books we examined touched upon multicultural sexuality. If textbooks are to mention sexuality at all, we stress the necessity for textbooks to elaborate upon sexuality in this regard.

Of note, the word "sex" is *not* mentioned in the *APA Guidelines for the Undergraduate Psychology Major*, nor is the topic of sexual orientation, even though the Guidelines were reviewed by the APA Committee on Lesbian, Gay, and Bisexual Concerns (p. 6). We respectfully urge our colleagues to include this information in future iterations of the *Guidelines*.

Again, one cannot expect all material from a subdiscipline course to be represented in an introductory course; however, we were interested in learning the extent to which human sexuality is represented in introductory textbooks. Introductory texts aim to impart knowledge of nomoethetic and idiographic findings about the causes, correlates, and consequences of human behavior, but in doing so they can also promote skills and values that, per the aim of the Psychology major curriculum, aid students, particularly emerging adults, in the development of lifelong learning skills and competencies (APA, 2007, p. 3). We therefore argue strongly that knowledge of human sexuality is essential to include therein.

To summarize our analyses, we found that Introductory Psychology textbooks did indeed provide a commendable breadth and depth of human sexuality coverage. However, although the long length of textbooks is a concern to professors (Griggs, Proctor, & Cook, 2004; Griggs et al., 2000), we do offer the above suggestions for additional topics that merit inclusion in future iterations of texts.

Controversy!

The fact remains that some people, even college professors, are just not comfortable discussing human sexuality (see Hyde & DeLamater, 2011, for discussion). As an example, fairly recently, a colleague at a large college in a major city in the northeast US offered to teach a course on the psychology of human sexuality and was met with great resistance—one faculty member actually asked, "Where are you going to teach that, in the gym?" Although Introductory Psychology by definition and purpose is not a Human Sexuality course, by infusing sexual themes into Introductory Psychology courses, we can eliminate some of the embarrassment over human sexuality—a repertoire of behavior and mental processes fundamental to human existence. That is, we are likely making students more comfortable with the causes, correlates, and consequences of human sexuality through direct education or perhaps even via the mechanisms of mere exposure (Zajonc, 1968).

Limitations and Future Directions.

Our analyses focused on books required in Spring 2011. It is possible that some material analyzed above has been or will be added, changed, or subtracted in subsequent editions of the textbooks. It would be interesting to compare coverage of specific sexuality themes in newer iterations of the most required introductory psychology textbooks with the present findings. Further, we could not ascertain how much coverage has grown or changed from previous editions to our targeted books because of a lack of access to these older books. Moreover, it would be prudent to follow the approach of Harbath and colleagues (2011) and check for accuracy of sexual content in introductory psychology texts. Misinformation in this regard can lead to life-altering or even deadly consequences.

Of course, we note that even when information is included in a textbook, this does not guarantee an instructor will cover the material or require its reading for class. We thus urge our teaching colleagues to present at least some of the basics of human sexuality to our Introductory Psychology students to promote the self-understanding, diversity inclusion, and healthy choices that can be informed from exposure to this most fundamental of human behaviors.

There are definitive reasons the 14 books analyzed herein are the most frequently required in the United States. Reviewers have noted their clarity, thoroughness, thoughtfulness of presentation, and insightful applications of psychology to the real world, as well as the texts' self-study tools and vivid imagery that help keep students engaged (see College Board, 2013, for various reviews). The purpose of the present work was not to critique these invaluable resources, but rather, to note existing textbook coverage, and to urge our respected textbook authors, teachers of psychology, and other APA authors (e.g., *Guideline* developers) to promote an even deeper understanding of sexuality within our curriculum, beginning with the introductory course.

Some psychology instructors may argue that it is not our job to teach students "everything." In fact, one textbook author told us quite emphatically that if Introductory Psychology instructors *wanted* more human sexuality coverage in textbooks, it would be there. That being said, but for sexual behavior, humanity would not exist. As long as people are here and wish to remain here, sexuality will be here. Sexual behavior serves not only to propagate the species, but also as a prominent social force. If psychology aims to encourage an understanding of the human psyche, the psychology of sexuality must be a core curricular feature. Most people *are* curious about sexual behavior (Hyde & DeLamater, 2011), and with Introductory Psychology, we have a golden opportunity to impart knowledge of human sexual behavior and mental processes to arm students with the knowledge and power to be compassionate, understanding, safe, inclusive, and themselves.

Acknowledgements

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Please send your questions or comments to Marissa Harrison at mah52@psu.edu.

Book review

By Wandajune Bishop-Towle, Ph.D.

The Myth of Race

By Jefferson Fish

Argo-Navis, 2012. 154 pages. ISBN: 978-0786754366

One of several books by the author on this subject, The Myth of Race looks at the lack of biological evidence for race, as well as the manifestations and impact of the concept of race in a changing culture. With sharp analysis and engaging style, Fish draws on the disciplines of psychology, anthropology, and evolutionary biology, also sharing his own experiences as "white psychologist from the Bronx" married to, and raising a daughter with, an "African-American anthropologist from Brooklyn."

Fish describes how, as humans evolved, our outward appearance (hair texture, skin color, etc.) came to vary gradually as we spread out over the globe, resulting in spectra of traits with different frequencies and combinations depending on location—anthropologist refer to such a process of gradual change as a cline. In contrast to genetic traits, race as a concept varies by language and culture. In Brazil, for example, a person's *tipo* (tr: race), is based on appearance, not ancestry. A woman who might be described as a white brunette in the U.S. might be called *branca* (tr: white), or *morena* (a person with dark, straight-hair, and a deep complexion). There are many more tipos in Brazil than races here; members of the same family (that might be described as simply "mixed race" in the U.S.) can all represent different tipos. In our own language and culture, too, racial categories have been highly mutable, as Fish points out in an incisive (and witty) discussion of racial categories used by the U.S. census from 1790 to the present. Later in the book, Fish criticizes the research on race and IQ in terms of its omission of key environmental variables, apart from the fact that no empirical basis exists for classifying subjects according to "race."

In the chapter "Racial Myths and the Author's Family," Fish reflects on his own experiences in a "mixed race" marriage, using well-chosen anecdotes of family life. In another chapter, entitled "Dreams from My Daughter: Mixed Race Myths," he considers his daughter's "both/and" adaptation to growing up bicultural, alongside that of the better-known of Barack Obama, and discusses other possible outcomes for "third culture kids." The last chapter examines the idea of race as a meme (the term refers to an entity that is culturally transmitted, including such things as popular songs). Fish explores the roots of the race meme in European colonialism, as a justification for slavery, the persistence of the race meme, despite its lack of biological underpinnings, and

the role that the race meme plays in self-concept.

In summary, The Myth of Race rigorously debunks the false notion of biological race, and offers profound insight into the ways that the cultural concept of race effects us all. With its personal reflections and artful prose, it is a pleasure to read. The Myth of Race would make an excellent supplemental text for graduate or undergraduate courses in cross-cultural psychology—one sure to stimulate discussion.

***Wandajune Bishop-Towle, Ph.D.**, is a licensed psychologist, and co-owner of* Seasons of Peace Yoga *in Andover, Massachusetts, where she provides body-oriented psychotherapy. She is a graduate of the clinical psychology program at St. John's University and has a post-doctoral certificate in applied behavior analysis from North Texas University. Her ancestors of recent generations include indigenous Americans, as well as people from Europe and Africa.*

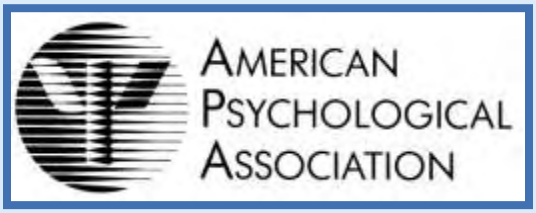

Greetings from the AP® Psychology Reading!

Elizabeth Yost Hammer, Ph.D.,
Xavier University of Louisiana
AP® Psychology Chief Reader

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If you are interested in applying to be an AP Psychology Reader, you can access an online application at the following Educational Testing Service site:

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Dr. Elizabeth Y. Hammer *is a Kellogg Professor in Teaching and the Director of the Center for the Advancement of Teaching at Xavier University in NOLA. She is an APA Division 2 Fellow.*

Editor's Note: College Board's Advanced Placement® (AP®) Program allows students to take a college-level course while still in high school, typically offered by one of their own teachers. AP teachers receive training to increase their expertise, and university faculty and other, veteran AP teachers develop curricular standards for the Program that ensure a college-level experience (College Board, 2013). It is important to note that for the AP Psychology Program these standards recapitulate those of the American Psychological Association's Guidelines for the Undergraduate Psychology Major.

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Thank you to all our contributors!

Submission Deadline for Spring 2014 *TGP* Articles is March 1.

We encourage articles from students and early career psychologists!

Send ideas and submissions to the NEW Editor of *TGP.*

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Thank you to Biggie Takooshian, most definitely a "good luck" cat!

American Psychological Association Working Group on Internationalizing the Undergraduate Psychology Curriculum: Report and Recommended Learning Outcomes for Internationalizing the Undergraduate Curriculum (November 2005)

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With special thanks to the Carnegie Corporation and the American Council on Education for their generous support of this project.

This document represents the work of the APA Working Group on Internationalizing the Undergraduate Psychology Curriculum. The document does not represent policy of the American Psychological Association.

Foreword

In 2004 the Carnegie Corporation awarded a grant to the American Council on Education (ACE) to coordinate a multidisciplinary effort to promote the internationalization of teaching and learning at colleges and universities in the United States. The American Psychological Association was one of four organizations (i.e., Association of American Geographers, American Historical Association, American Political Science Association and American Psychological Association) selected to participate in this initiative. Specific goals set forth for the project included:

- To articulate global learning outcomes relevant to specific disciplines and to communicate these outcomes to the membership of the participating associations;
- To take a leadership role in promoting the internationalization of student learning and to provide concrete strategies that other disciplinary associations can adapt;
- To help faculty incorporate an international dimension into their teaching and the learning experiences of their students;
- To develop action plans for each association to promote internationalization in its discipline; and,
- To disseminate these approaches to a wider group of disciplinary associations.

To address this charge, the American Psychological Association formed a small working group of psychologists with an international perspective and relevant expertise. The members of this working group were nominated by APA boards and committees, including APA Division 2 (Society for the Teaching of Psychology), APA Division 52 (International) and the Committee on International Relations in Psychology (CIRP). The working group met twice during the 2004-2005 academic year and produced a draft statement of learning outcomes along with an action plan.

The working group then solicited feedback on its draft report and recommendations via email from members of the APA Committee on International Relations in Psychology (CIRP), board members of the Division of International Psychology, and individuals (both international and within the U.S.) identified by members of the working group as having particular interest or expertise in this matter. Attendees at a conversation hour held by the working group during the 2005 APA convention provided additional feedback. We are grateful for the suggestions we received, which addressed the following questions posed by the working group:

(1) Do you have suggestions for the justification of this document? Are there omissions?
(2) Do you have suggestions for the wording and organization of the stated goals?
(3) Do you have suggestions for the promotion/dissemination of these goals?

Results of this project will be submitted to the American Council on Education in order to complete the multidisciplinary requirements of the grant to APA. This final report and recommendations for learning outcomes will be submitted to the APA Board of

Educational Affairs for approval. The recommendations will then be disseminated to undergraduate psychology programs.

Introduction

The mission of psychology, as embodied in the Mission Statement of the American Psychological Association, is "to advance scientific interests and inquiry [on psychology], and the application of [psychological] research findings to the promotion of health, education, and the public welfare" (American Psychological Association, 2005). Quite appropriately, neither of these charges is limited to a particular geographic area. In fact it is fundamental to basic science to assess the specificity or universality of findings across diverse populations, geographic and otherwise, and to applications to promote human welfare worldwide and to be adjusted as appropriate to particular conditions. In sum, the mission of psychology is inherently international in its scope and sensitivities.

Attention to the international character and responsibilities of psychology's mission has increased recently due to factors that have strengthened connections between once physically distant peoples. These factors include travel and migration, global communication and culture, contemporary geopolitical events and conflicts, international business and commerce, global environmental concerns, and international human rights. Moreover, the consumers psychology serves (e.g., in classrooms and applied settings) are increasingly aware of the potential impact of these internationalizing forces in light of their own backgrounds, experiences, and knowledge. Thus, psychology in the twenty-first century is becoming more appreciative than ever of the importance of pursuing its mission globally.

Doing so would build upon psychology's history as an international discipline. Early psychologists opened laboratories, engaged in practice, and began teaching in such diverse countries as Japan, Mexico, India, Argentina, New Zealand, and Russia. Indeed, the First International Congress of Psychology took place in 1887. Today, as the number of psychologists burgeons around the globe, psychology is more international than ever before (Rosenzweig, 1999). Adair, Coelho, and Luna (2002) found that psychology has a "significant presence" in 47 countries and a "minimal presence" in at least 41 additional countries. Adair, et al. also report that 45% of articles indexed in PyscINFO©, a major psychology electronic database, were written by authors from outside the United States. Psychology's knowledge base in science and practice is, then, international as well.

The American Psychological Association has played a prominent role in recognizing and promoting this internationalization of the discipline. In 1944, APA established the Committee on International Relations in Psychology (CIRP), and in 1961 it opened an Office of International Affairs (OIA). APA is also home to Division 52: International Psychology. Moreover, APA's Policy and Planning Board (2005) recently identified "Developing a Global Perspective" in the discipline as a primary APA goal for the next 15 years.

These trends and efforts raise a key question: how ought the undergraduate psychology curriculum address the internationalization of psychology? We believe internationalization ought to be an important priority in the undergraduate psychology curriculum. What we mean by "internationalization" in this context is elaborated in the learning outcomes we later specify but can be summarized as follows: an understanding of how psychologists pursue psychological science and apply psychology around the world and of how scientists and practitioners address psychological phenomena that potentially vary internationally.

We see support for our view concerning the importance of internationalization in a recent report by the working group on Undergraduate Psychology Major Competencies (2002), endorsed by APA's Board of Educational Affairs. The report specified "Sociocultural and International Awareness" as one of 10 primary undergraduate psychology learning goals and associated five learning outcomes with this goal. These learning outcomes are:

(a) Interact effectively and sensitively with people from diverse backgrounds and cultural perspectives.
(b) Examine sociocultural and international contexts that influence individual differences.
(c) Explain how individual differences influence beliefs, values, and interactions with others and vice versa.
(d) Understand how privilege, power, and oppression may affect prejudice, discrimination, and inequity.
(e) Recognize prejudicial attitudes and discriminatory behaviors that might exist in themselves and others.

These student learning outcomes constitute an important first step when thinking about how undergraduate education might incorporate a global perspective on psychology, but they are neither focused on nor specific about internationalization.

Unfortunately, evidence suggests the existing psychology curriculum in the United States pays little attention to internationalization (Woolf, Hulsizer, & McCarthy, 2002).This may be due to obstacles faculty face when they consider incorporating an international perspective into their teaching, including a lack of familiarity with the international literature, the absence of institutional support for internationalization, and competing priorities. What this suggests is that a reassertion of the need for internationalization of the psychology curriculum is in order and that psychology faculty might value more specific guidance on what internationalization entails and on how to manage professional challenges to internationalization.

Why is it important to recognize internationalization in the teaching of psychology? First, it is scientifically unsound to ignore a significant portion of the research literature from which students might learn simply because that research is conducted outside the boundaries of the United States. Second, work in international psychology raises fundamental questions for psychological understanding and practice. For example, international research may help students appreciate how universally applicable particular findings or practices might or might not be. This may help students recognize demographic, socio-cultural, economic, political, religious, ethnic, and other potential sources of variability in psychological phenomena. Familiarity with approaches and practices internationally may also enrich students' understanding of psychology and help them become more thoughtful about the as-

sumptions they bring to psychology. Third, internationalization itself warrants particular attention as an important phenomenon in the world in which today's students live. Fourth, there are compelling reasons for attention to this issue to be found in the *Resolution on Culture and Gender Awareness in International Psychology*, adopted by the APA Board of Directors and Council of Representatives in August of 2004. How, for example, will increased communication, interaction, movement, and influence affect psychological processes, practices, and outcomes? Finally, an internationally-informed psychology will help meet the needs, interests, and appreciations of the increasing numbers of international students at North American institutions.

What follows specifies goals and associated learning outcomes for the undergraduate psychology curriculum to address the current conditions, challenges, and responsibilities of internationalization. We believe these goals and learning outcomes should be addressed throughout the psychology curriculum and not merely in isolated cross-cultural or multi-cultural psychology courses. And we believe that internationalization represents one of the most important priorities we face as undergraduate educators seeking to prepare students for twenty-first century life in psychology and in the world.

Learning Goals and Outcomes to Internationalize Undergraduate Psychology

Goal 1: Psychological knowledge in international perspective. Students should recognize, acknowledge, and describe sociocultural differences and commonalities between people, and consider how the diversity of human behavior around the world contributes to the study and practice of psychology.

Outcome1.1: Students will demonstrate the ability to articulate the psychological implications of demographic, sociocultural and socioeconomic characteristics and variability in the world, and assess the extent to which the phenomena studied in contemporary psychology reflect and are influenced by that variability.

Outcome 1.2: Students will be knowledgeable about the contributions of important figures from other countries and about the work of international organizations in the development of psychology as a field. Students will make efforts to integrate knowledge about these contributions into their own work, study, and academic endeavors as appropriate.

Outcome 1.3: Students will study a region of the world other than their own and be able to point out the differences and commonalities between aspects of their cultural background and those of the people in that region in light of one or more psychological theories.

Outcome 1.4: Students will be able to recognize the historical and current state of psychology as a discipline in another region of the world of particular relevance to them.

Outcome 1.5: Students will be able to analyze models of how culture influences behavior (e.g., cognitive, social, interpersonal).

Goal 2: Methodological issues in international research. Students should be aware of research methods and skills necessary for international research competence.

Outcome 2.1: Students will have the skills to access research literature from journals outside the United States (e.g., the ability to search databases, and the ability to read in a language other than their native language).

Outcome 2.2: Students will identify and appreciate the contribution to psychology of research methodologies conducted throughout the world and of methods used in that research, including observations, interviews, ethnographies, and mixed-method studies.

Outcome 2.3: Students will be aware of ethical concerns in research in other countries, (e.g., the rights of participants, their protection from harm, and credit to researchers from those countries).

Outcome 2.4: Students will understand that constructs developed in one cultural setting do not have identical meanings in other settings, resulting in the need to adapt measures and check with expert informants (as well as translating and back-translating questions).

Outcome 2.5: Students will guard against making sweeping generalizations about a culture that are based on small unrepresentative samples (and will recognize other problems with external validity).

Goal 3: Discipline of psychology in the international perspective. Students should be aware of how the discipline of psychology is developed, studied, and applied in and across cultures.

Outcome 3.1. Students will recognize that theories and concepts may be influenced by the cultural, social and political systems existing at the time of their development.

Outcome 3.2. Students will understand psychological theories and concepts developed in other countries.

Outcome 3.3. Students will understand ways in which psychology is studied, applied, and practiced in other countries.

Outcome 3.4: Students will understand that psychological education, training, and processes for reviewing ethical issues in research differ according to the structure of university systems and routes to obtaining credentials or academic qualifications in different countries.

Goal 4: Psychology and interpersonal understanding. Students should be able to use their psychological knowledge and understanding of cultural differences and behavior to demonstrate skills and values that will help them function effectively in a complex multicultural global world.

Outcome 4.1: Students will examine their cultural biases and values and how these may influence interactions/relationships with others from different backgrounds in light of psychological theories and findings.

Outcome 4.2: Students will be able to use psychological concepts to facilitate effective interactions with people whose beliefs, philosophies, and values differ from their own.

Outcome 4.3: Students will recognize the role of language in understanding individuals and cultures.

Outcome 4.4: Students will show awareness and sensitivity to perspectives that are different from their own.

Goal 5: Psychology and global issues. Students should be able to recognize, appreciate, and describe the role that psychological knowledge plays in addressing issues related to the human condition from a global perspective.

Outcome 5.1. Students will be able to apply their knowledge of psychology to issues of global concern and human welfare (e.g., poverty, health, migration, the status of women and children, human rights, international conflict, and the natural environment).

Outcome 5.2. Students will have an appreciation of the value of psychology in the pursuit of social justice in ways that are sensitive to the cultural context.

Outcome 5.3. Students will be able to recognize the role of national and cultural identity in their understanding and treatment of other people.

Outcome 5.4. Students will understand how privilege, power hierarchies, and oppression affect prejudice, discrimination, and inequity. Students will recognize prejudicial attitudes and discriminatory behavior in themselves and others.

Outcome 5.5: Students will understand that the processes of internationalization and globalization (e.g., migration, international commerce and communication, international cooperation and conflict) influence both individual and group psychological processes.

Action Plan

In addition to establishing goals for internationalizing the undergraduate curriculum, the working group developed a plan for implementation and dissemination. The first step was to distribute the document to a wider audience of scholars with expertise in internationalizing the discipline for the purpose of obtaining additional feedback and cross validation. The working group received feedback and made adjustments to the goals and student learning outcomes that reflected the collective wisdom of the experts.

Clear implementation of the goals and learning outcomes will require widespread dissemination. The learning goals and outcomes for internationalizing the curriculum will be submitted to the APA Board of Educational Affairs for approval. Endorsement of the document will allow for dissemination as a resource to the undergraduate education community. This document will be distributed by the Education Directorate through the website and relevant publications and conferences of the APA. Finally, the working group will continue to work toward development of a manuscript to be submitted to the *American Psychologist*, the organization's flagship professional journal.

Several unfunded recommendations were also put forth by the working group. Key among them were suggestions to expand the clearinghouse of materials that faculty could immediately use for course development. The working group identified several resources that already exist through the Society for the Teaching of Psychology Office of Teaching Resources in Psychology (OTRP). Unfortunately, faculty members are often unaware of these resources. One possible outcome from this project will be an increased awareness of internationalizing the curriculum, encouraging an increased utilization of existing resources. Ultimately, the actions taken thus far by the working group will result in an increased attention to internationalizing the undergraduate curriculum.

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International Council of Psychologists ICP
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AN INTERDISCIPLINARY ASSOCIATION

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September 10-14

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TREASURER GERALD GAMACHE

PRESIDENTS' COLUMN MAY

Ludwig Frederick Lowenstein, Ph.D

When I was a teenager I played American football in New York with a team that was not particularly strong. Whenever we met up with a tough challenge I remember my fellow players saying "Give the ball to crazy Ludwig. He doesn't mind the hard tackles." This reminded me a little bit about my election as President of ICP Inc. Perhaps you thought ICP Inc. needed someone a bit mad during our time of difficulties in being able to recruit members, and generally having problems, which in the past was not so much the case.

I think one reason why I was elected was that few wanted such a job in midst of economic and social unrest. My life has been one of looking challenges in the eye and I remain optimistic about outcomes of a fresh membership drive, even with international associations springing up all around us – something for every specialization.

Since becoming President I am so pleased to have a wonderful family of fellow players on my team working hard for the future of ICP Inc., seeking new members in a variety of ways. Ideas seem to be flashing around like lightning!

I must say I am extremely blessed in having people around me who are taking the task of seeking new members very seriously and I want very much for this to continue. I welcome the ideas presented by others like Tara Pir, President Elect and Joy Rice, International Association Liaison Chair and the ready acceptance of these ideas by many others. Liaison with other organisations may be the way forward and I welcome any other ideas you may have. Please keep them coming. This can take us towards new horizons for ICP Inc.

I commend Dr. Ana Guil, Board Director at Large, for her hard work to put the conference venue together. On behalf of the ICP, Inc. Board of Directors, I express great appreciation to the Dean of the Faculty for Jesús Garcia Martínez, Decano de la Facultad de Psicología de la Universidad de Sevilla, (Dean of the School of Psychology. University of Seville) for his very generous offer of meeting spaces and resources gratis for the conference and board meetings in honor of Dr. Guil's faculty status there. I hope he and many others in his faculty, staff and students, will become members of ICP Inc.

Hasta la vista. Adios hasta South Africa y Espãna.

[continued on page 2]

[President, con't.]

I particularly extend appreciation to Dr Jerry Gamache, ICP, Inc. Treasurer, who is just recovered from an operation. I would like to praise him for his courage in being ready to work almost immediately. We had a good meeting in New York recently and managed to agree on some future policies as well as present awards for two members, Margot Nadien and Alfred Weiss, retiring from UN work for ICP Inc .

We had a wonderful lunch at a local restaurant arranged by Florence Denmark, Chair of ICP Inc. UN Delegation, and each retiree was presented with a plaque for their many years of service and dedicated work. Florence Denmark, as modest as usual, asked me to present these well-deserved plaques.

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ALL SUBMISSIONS FOR THE FALL NEWSLETTER MUST BE TO DR. ANN O'ROARK BY **SEPTEMBER 15, 2012.**

EMAIL: ANNOROARK@BELLSOUTH.NET

We should never forget all the people that have been supporting ICP Inc. through good and bad times who still work behind the scenes such as Florence Denmark, Ann Marie O'Roark, Anna Laura Comunian and many others. We have been very lucky to find a wonderful web master in Beverly Stevens, who along with Ann Marie O'Roark have helped to forge ahead with our website and put our ideas into practice. Long may they work with us. I could not do without them!

Our Finance Committee Chair, Dr Michael Stevens, unfortunately is retiring from the position this year and we wholeheartedly thank him for his diligence and dedicated work. This means however, that there is a vacancy for this position. If any of you would like to apply please let me know.

I am sure that you are looking forward to the Symposium in South Africa and the conference in Seville with the same anticipation that I feel. It will mean the renewal of our togetherness and our working together, most especially for the purpose of ICP Inc. becoming a truly magnificent organisation.

The arrangements for the ICP Inc. conference in Seville are well on their way. The theme of the 70th annual scientific program is: Celebrating 70 years of Working Towards Health, Peace and Social Justice. We especially invite contributions for papers on "Women" and / or "Immigration," our highlight topics for this year's conference. Please submit your papers to Tara Pir as soon as possible in order that she can get the programme together. [email: tarapirimces@msn.com]

Our Membership Secretary and Dr Jerry Gamache I know are working hard to find our past members and help to renew their interest in ICP.

Top: Pres. Lowenstein, right, presents plaque to retiring UN Rep. Margot Nadien, left.

[continued on next page]

[President, con't.]

Each one of us must be an Ambassador of ICP Inc., singing its praises because we are unique – a family. We need to encourage others to join our family members. I am certain our World Area Chair Dr Sandra Neil is doing all she can to recruit more members and to continue to encourage the Area Chairs to gather as many members as possible and also to arrange local area meetings. Send your recommendations or volunteer: drneil@satiraustralia.com.

Despite the terrible weather we are having in the UK, Spring is truly on the way. We still have too much rain and not enough sunshine. I have been blessed by the fact that I have had eleven lambs born this year on my little farm. This very much heartens me as the cycle of rebirth is happening once again and I am hopeful that this will be the same for ICP Inc. in the coming months.

My best wishes to you all,

Ludwig Lowenstein

The ICP Inc, UN representatives luncheon. Treas. Gamache, 2nd right, Kathleen Lowenstein, 2nd left, Ludwig Lowenstein, 3rd left.

International Council of Psychologists

ICP Responds to Globalization

Dr. Tara Pir. Ph.D
President-Elect

In the 21st Century we live in a globalized world. Our current social, political, and economic landscape as well as personal lives are impacted by not only local but global changes. One common sense and immediate reaction by business and service providers is to adjust and transform their expectations, views, goals and objectives to meet new and emerging needs of our citizens.

Health and Mental health/psychological services should be among if not on top of the list of businesses expected to change their strategic plan to be responsive to the changes of our time. ICP is one of the oldest international organizations which create the ideal forum for this transformation. ICP invites not only individual membership, but organizations from around the world to develop liaison relationships to promote the shared mission and be responsive to the global changes. Also the American Psychological Association (APA) has been one of the organizations that demonstrate this responsibility and responsiveness to the need of international engagement as a professional organization.

This year I was part of the delegates to Cuba sponsored by APA as its first international delegation for professional exchange with Cuban Psychologist. The agenda was designed to visit research facilities/ academic organizations and the health and mental health system of care. The outcome was extremely productive and mutually beneficial. A memorandum of understanding was developed for future collaboration, research/ publications, journals, articles and book chapters of special interest. The APA delegate members benefited from continuing education credits for all the meetings attended. They described their experience visiting Cuba as "transformative" and "powerful". I believe this is a natural reaction to a very meaningful and worthy initiation. Although the electronic advances of our time removed the barriers of countries/continent and facilitated connections among people, psychologists in Cuba have been Deprived from the rest of the world for nearly half a century.

[continued on next page]

[President Elect, con't.]

I hope we can use our people-to-people power to remove some of the political barriers to connect with each other and exchange information, for this is how humanity is designed.

This year's ICP annual convention in Seville will be a response to the globalization need of our profession. This is an invitation for collaborative partnership among health and mental health professionals to participate in sharing research and knowledge opportunities.

This year the theme for our scientific convention is "Women and Immigration". I'm inviting our professionals to submit their abstract for presentation. Attached please find the guidelines for submission. We've extended the deadline to June 30, 2012.

Looking forward to an exciting convention in Seville.

Dr. Tara Pir, Ph.D.

PHOTOS OF SEVILLA, SPAIN

St. Augustine, Florida. May 2012. The local newspaper carried an article about a man who at 104 years old was actively traveling the country and globe to continue his education. I first heard about the continuing education opportunities offered by "OLLI" from a colleague who is going to Cuba on a guided experience sponsored by OLLI, the Osher Lifelong Learning Institute. Cuba , a long forbidden and forbidding island south of Florida in the Caribbean, is the "hot" place for professionals to explore this year. Both President Elect Tara Pir and Director at Large Ana Guil [see her report in Spanish in this newsletter] have made professional learning trips to that exotic place in halcion blue waters. OLLI may currently lead the way in enticing older professionals and curious senior-agers to maintain their enthusiasm for the wonders of the world and of knowledge sources yet untapped, but it is something ICP, Inc. pioneered.

Professional Development. One of the most appealing aspects of membership in ICP, Inc. is the opportunity for continuing education and professional development in such an ever expanding global context. John Dewey, the 20th century educational psychology learning icon (Democracy and Education, 1933), insisted that the first and most important part of education is geography. Little did he know how relevant that would become in the 21st century. It is so very easy to understand what Daniel Kahneman, the psychologist who received the 2003 Nobel Prize in Economics, meant by his acronym **WYSIATI** (Thinking, Fast and Slow, 2011). **What You See Is All There Is.** Kahneman demonstrated how this self-limited, parochial way of thinking about situations and problems is one of the several major causes of humans' flawed thinking.

Each year a group of ICP, Inc. colleagues schooled in diverse specializations arrives in a different place for face to face conversation, for extending their continuing education in professional issues, and for seeing first hand venues of common interest that keep us alert to the reality that **W**hat **W**e **H**ave **S**een **B**efore **I**s **N**ot **A**ll **T**here **I**s [**WWHSBINATI**]. How different it was to actually see Pavlov's laboratory and walk on the floor built to float above the hard flooring so the dogs could be more comfortable and not feel the vibrations that might interfere with his research. How amazing to stand with friends of 20 years in the garden of Confucius home place and see the lasting impact of one strong thinker.

The ICP, Inc. Professional Development is not only academic and research sharing, but includes **Lessons of Experience** that become more meaningful and powerful over time because they were shared with colleagues with many different perspectives, perceptual fields, and places of origin. It is because of the accumulated **Lessons of Experience,** and each annual meeting is a completely different experience, that those who are members of ICP, Inc. are able to continue to be ever

[continued on next page]

[Past-President, con't.]

more inclusive [allied disciplines are welcomed into full membership] and to remain anchored in strong value for individual differences, peace, social justice and well-being.

Leadership Opportunities. The person to person, pioneering new concepts, innovating and creative solution seeking climate of ICP, Inc. is unique. The opportunities for initiative within the association are easily accessible. For those who are willing to attend to the uniqueness of this association and to give time to taking care of their responsibilities, there will be great professional development, many lessons of experience, and ongoing leadership opportunities. Many of the ICP, Inc., members are looking forward to Lifelong Learning even past 104 years of age, especially as that age is not too distant in the future for us.

BOARD OF DIRECTORS 2012 ELECTION

An immediate leadership opportunity is the annual election to the Board of Directors. The ballot will be sent out in late June, or early July. Members in good standing can be nominated [by others or self-nominated]. Those who are currently accepting this call to leadership are:

TREASURER. Gerald Gamache and Dennis Trent

DIRECTOR AT LARGE. Cecilia Chang, Ana Guil, Elisa Margaona, Sarlito Sarwono, and John Tivendell

Send other nominations to me at annoroark@bellsouth.net

Other leadership opportunities are noted on the new membership application form that appears in the last section of the newsletter. Everyone who wishes to become active is encouraged to sign up for a committee and to make a contribution to the life and the future of ICP, Inc.

Warm good wishes and come to Sevilla.

ICP representatives (from left to right) Eva Sandis, Pete Walker, Florence Denmark, and Richard Velayo

BOARD SECRETARY REPORT

Dr. Donna Goetz
Lombard, IL, USA
May 15, 2012

Many good things are happening in our organization. Dr. Lowenstein requested that ICP send a letter to the Executive Officers of International Union of Psychological Science to formally tell them we will be having our 2012 meeting at the University of Seville, Spain. The Board of ICP made this decision last August, when it became clear that the costs to travel to the conference in South Africa would be prohibitive for most of our members. We did express hope that the Congress of International Psychology would have a productive meeting. Dr. Nick Hammond, Executive Officer of the IUPSyS responded "In particular, I note that you raise the possibility of exploring the feasibility of linking our two Congresses in 2016, in Yokohama."

ICP is deeply grateful to Ana Guil who generously offered to undertake planning and holding the conference at her University with only a year's notice. We invite you all to come and participate in what promises to be a lovely and productive conference. We set the conference fees for the Seville at a modest rate of $25 for students. So please invite and encourage students to attend.

Ani Kalayjian volunteered to process the necessary paperwork for ICP that APA requires for us to offer CEUs. Although, many of our participants do not require CEUs, the Board thinks that it is important to offer CEUs for those who attend our meetings.

Tara Pir, our incoming president is the chair of Long Term Planning for future conferences. Tara presented several possible venues for future meetings at the Chicago, 2010 annual meeting. She has recruited new members and initiated an invitation to the California Psychological Association to liaison with ICP.

We will be having important discussions at the Seville conference. We need to decide on what future ICP wants. Ludwig Lowenstein pondered whether we should return to the principles of the founder members which was a group of psychologists helping other psychologists to solve a problem. This will be an engaging topic for the upcoming

[continued on next page]

[Secretary, con't.]

meeting in Seville.

Correspondence

President Lowenstein to Lapsed Members
President Lowenstein to Dean Universidad de Sevilla in appreciation for contributing use of classrooms and AV equipment for 2012 ICP, Inc. conference and board meetings, Sept. 10-14.
President Elect Pir to California Psychological Association for establishment of formal Liaison relations.
President Lowenstein and UN Main Representative Denmark: Certificates of Appreciation to Retiring ICP, Inc. Representatives.

Executive Committee Decisions

Finance Committee Clarification of dues structure and required dues from all members. Unanimous.
Review and Acceptance of Minutes of Outgoing and Incoming Board Meeting Minutes 2011.No changes presented to Secretary Goetz.
Addition of special access link for Board members on ICP-WEB.ORG Unanimous

Appointments
Acceptance of resignation of Merima Isakovic from Research Interest Groups Coordinator role.

REPORT FROM THE TREASURER

Gerald L. Gamache, PhD
USA

Dear ICP Membership,

At ICP last convention, the ICP Board made recruitment a top priority. However, almost a year later, ICP has gained six members and none confirmed in 2012. Our current paid membership is a little more than 100.

To simplify the membership application process our President has suggested all new applications be sent to the Treasurer with the application fee. They are forwarded electronically to Membership chair Dr. Rose whose committee will validate and welcome each applicant.

[Treasurer, con't.]

A new application form is provided in this IP.

A new recruitment campaign will be announced in Seville by our President, with a cash prize of $1000 USD!

I remind those of you who have not paid their 2012 dues, you can still pay dues by PayPal or check to me. Note: You do not have to join PayPal to use their service. To pay your 2012 dues by credit card using PayPal go to our website www.icpweb.org and on the left side of the main screen, you click on "Pay 2012 Dues".

The 2012 election ballot will be emailed to all eligible members in July. To be eligible to be placed in nomination or to vote, your dues must be current.

Seville Conference Registration and Payment for Articles submitted for publication in the 69th Proceedings Book [DC 2011] are now on the website.

Dr. Gamache
ICP Treasurer

TREASURER MEETS WITH UN REPRESENTATIVES IN NYC

Seated: Director at Large Velayo; Treasurer Gamache; Retiring Representative Nadien

Co-chairs of Psychology Day at the UN: ICP representative Martin Butler and ICP board member Janet Sigal.

ICP 70th CONFERENCE
Sevilla, 10-14 September 2012

CELEBRATING 70 YEARS OF WORKING TOWARDS HEALTH, PEACE AND SOCIAL JUSTICE

Women & Immigration

The next International Council of Psychologists' Annual Meeting will be celebrated in the University of *Sevilla* (Spain), from 10 to 14 September in 2012.

Situated on the shores of river Guadalquivir, its capital -*Sevilla*- has the fame of being one of the most beautiful cities in Spain, with approximately 700.000 habitants. Its climate is very pleasant in the spring and autumn; and beer, wine and *tapas* (appetizer) are of reasonable prize, variety and exquisite.

Sevilla is located in the South of Europe, near Africa. You can arrive by plane (0:50h from Madrid) or by train "Ave" (2:30h from Madrid).

Its University, founded in 1551 is the oldest in Europe and in actuality one of the biggest in size and excellence in Spain, with 70.000 students and over 4.000 teachers and investigators.

Its more emblematic building -the rectory- is located in the Old Tobacco Factory, where it assumes that the mythical Carmen worked (the protagonist of the novel of Prosper Mérimée, which used Georges Bizet in its famous Opera).

Psychology studies started at the University of Sevilla 36 years ago. Today, its teaching personnel are divided into four departments: Personality, Evaluation and Psychological Treatments; Developmental and Educational Psychology and Experimental Psychology; and Social Psychology.

And it also bestows the Grade of Psychology, seven different Masters: Educational Psychology; Health Psychology; Social Intervention and Community Psychology; International Migrations, Health and Wellbeing: Models and Strategies of Interventions; Organizational and Work Psychology; Advanced Studies in Brain and Behaviour; and Family Mediation Intervention.

Address: Faculty of Psychology, Campus de Ramón y Cajal, Calle Camilo José Cela s/n, Sevilla 41018

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International Council of Psychologist

10 - 14 Septiembre 2012
Sevilla

Call For Proposals

This year ICP annual convention in Seville will include members and organizations from around the world especially Europe and the United States. This year's convention is being held in one of the world's most attractive historical places, Universidad de Seville, the oldest European University. The theme for the 2012 scientific convention is:

Celebrating 70 Years of Working Towards Health, Peace, and Social Justice.

"Women" and "Immigration" are two special interest tracks being highlighted in the conference. Professionals from different disciplines in the health and mental health domains are especially encouraged to submit their research/ study projects in the areas of "women" and/or "immigration". Spanish language presentations will be conducted in a separate room for Spanish speaking audiences. Below please find the guidelines for submission. In addition we've extended the deadline to June 30, 2012. Send to: Dr. Tara Pir, Program Coordinator. tarapirimces@msn.com

70th Annual ICP Convention Abstract Submission Guidelines: DUE JUNE 30, 2012

1. Select Theme: ☐ Women ☐ Immigration ☐ General Scientific Program

2. Select One Format:

☐ **Symposium**: 90 minutes. 1 Moderator/Chair, 2-3 Presenters. 5 minutes for introduction, 15 minutes for each presenter, 5 minutes for questions, 5 minutes for discussant.

☐ **Paper**: 10-15 minutes. To be included in a Paper Session.

☐ **Social / Conversation Hour**: 1 Hour

☐ **Poster Presentation**: ☐ Program Participant
☐ InAbsentia Student Exhibit

3. Presenter: ☐ Student/Intern ☐ Early Career ☐ Professional

4. Abstract Requirements: Language: Abstract will be considered **ONLY** in English. **Presentation Language:** ☐English ☐ Spanish.

Computer Software: Word, Word Perfect or Plain Text. Font: Times New Roman, 12 point size. Word Count: 10 words or less for title; 250 words for the body

5. Request for Technical Support

☐ Slide Projector

☐ SVGA Projector/Computer/Multimedia

☐ DVD Player [Note that Spain is PAL/Region 2]

Please bring your own Computer/Laptop/Tablet and/or Flash Drive

CALL FOR WORKSHOP PROPOSALS

Celebrating 70 Years of Working Towards Health, Peace and Social Justice

Highlighted Tracks: Women and / or Immigration

70th International Council of Psychologists, Inc. Annual Scientific Conference
Seville, SPAIN
September 10-14, 2012
www.icpweb.org

Dr. Kalayjian

The ICP Continuing Education Program Committee invites proposals for full day or half day seminars as part of the Workshop Program of the 70th International Council of Psychologists. Workshops will focus on key themes and interventions in Scientific Psychology internationally. These workshops are offered in a supportive learning environment wherein the leader and participants will have the opportunity to exchange knowledge and skills about the workshop theme.

All participants will have the opportunity to earn continuing education units established by ICP, Inc.: World Continuing Education Credits. APA SPONSOR CEUs are not yet confirmed, but are in-process.

Workshop Proposal Content

Proposals are to 2-3 pages and contain the following information:

- Proposed Title of the Workshop
- A brief description of the Workshop, specifying the workshop goals and the international Scientific Psychology theme and/or intervention that will be the focus.
- A brief description why the workshop is of particular interest.
- An indication as to whether the workshop is to be considered for a half or full day meeting.
- A list of the presenters and their roles and their curriculum vita showing credentials and experience in the workshop topic.
- Supply contact information, including the names, postal addresses, phone numbers and email addresses of the workshop presenter.
- If a similar was presented in the past include information on where, when, and attendance.
- ICP will advertise your workshop through the conference program and other media publications.

Proposal Submission

Workshop proposals need to be submitted by August 1, 2012
Presenters will be notified of the committee's decision by August 15, 2012.
Inquiries concerning workshop submissions need to be sent to Dr. Ani Kalayjian, email: drkalayjian@meaningfulworld.com Copy to Scientific Program Chair, President Elect Dr. Tara Pir: tarapirimces@msn.com

Call for 2012 In Absentia Poster Proposals

ICP 70th CONFERENCE Sevilla, Spain - September, 10-14

InAbsentia Poster Chair: Anna Laura Comunian,PhD, Italy.
annalaura.comunian@unipd.it

Scientific Program Theme:

Celebrating Seventy Years of Working Towards Health, Peace, and Social Justice. Theme Tracks: 1. Women. 2. Immigrants

InAbsentia Posters Are Invited On All Topics in

International Psychology

1 . ICP's INABSENTIA EXHIBIT of posters is a continuous display.

In-Absentia graduate student poster authors do not need to be in attendance or register to submit a poster proposal. Proposals ASAP. No later than August 15

Send to: annalaura.comunian@unipd.it

2. OPTIONS FOR EXHIBIT DISPLAY

Power point slides via email to:

annalaura.comunian@unipd.it

STANDARD DISPLAY & LAMINATE Completed Posters of accepted proposals are to be surface-mail to:

DR. ANA GUIL, UNIVERSIDAD DE SEVILLE
Facultad de Psicologia Dpto. de Psicologia Social
C/Camilo Jose Cela s/n 41018-Sevilla (SPAIN)
ATTN: A. Comunian. International Council of Psychologists

3. AWARDS

Awards for students: first first prize is $100. Second place prize is $50.

Authors are requested to send cover letter with proposal and include:

- PROOF OF GRADUATE STUDENT IN PSYCHOLOGY STATUS **OR** POSTER BASED ON GRADUATE & EARLY CAREER RESEARCH
- CONTACT INFORMATION
- PHOTOGRAPH

ICP is a person-to-person association. As a mentor / incubator association, ICP welcomes psychology students & encourages studies in International Psychology.

Above: Mexico City Poster Exhibit

Below: St. Petersburg Russia Poster

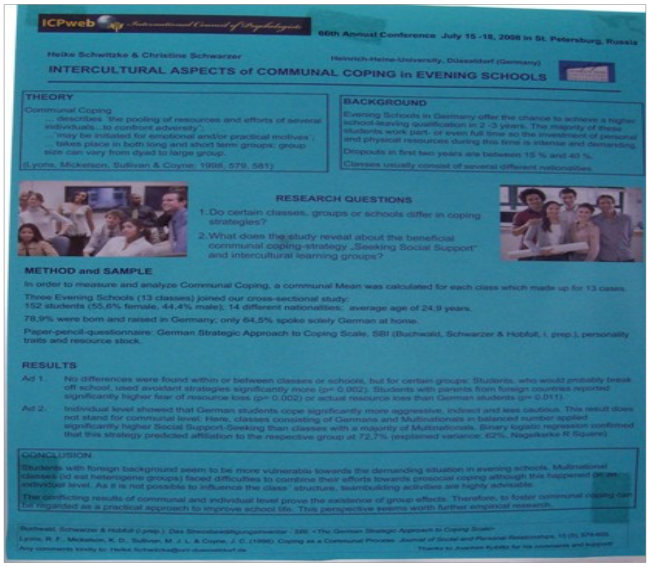

ICP, Inc. 70th ANNUAL CONVENTION
Seville, Spain
September 10-14, 2012

THEME: Celebrating 70 years of Working Towards Health, {Peace. And Social Justice: Women and Immigration

Conference Coordinator: President Elect Tara Pir
Scientific Program Assistants: Donna Goetz and Julia Rose
Local Arrangements Committee: Chair: Ana Guil
Local Host Committee: Sara Vera Gil; Rocio Guil; Silva Gonzalez, Concha Garrido Conzales de Riancho, Translator: Ana DeCicco,
Awards Chairs: Joan Chrisler, Cecilia Cheng, Anna Laura Comunian, Sherri McCarthy, Gerald Gamache
InAbsentia Graduate Student Posters: Anna Laura Comunian
ExOfficio: President Lowenstein, Treasurer Gamache, and Past Presidents O'Roark and Barreda-Hanson

REGISTRATION FORM

Complete all of the following information

When complete:

- E-mail or send by post to: Dr. Jerry Gamache, ICP Treasurer, 8 Althea Street, St. Augustine, FL 32084-2181 USA with payment in US dollars, or,
- Send Registration Form to the address above AND Pay Registration fee via PayPal on ICP website: www.ICPweb.org

Dr. _____ Prof. _____ Ms. _____ Mr. _____ Mrs. _____ Guest _____

Last Name (Family Name): _____

Given Name (First and Middle Name or Initial): _____

Work: Department/Organization: _____

Preferred address for correspondence: Office Address _____ Home Address ____

Address Street: _____

City: _____

State: _____ Zip Code: _____

Country: _____

Office Phone/Fax: _____ Home Phone: _____

Please provide your country code for phone and Fax

Email: _____

Preferred Name on Badge: _____

Special dietary/disability requirements: (Please specify): _____

Registration Fee is payable at ICPweb.org via PayPal using Master Card or Visa. Checks on USA banks should be made payable to ICP and marked "70th Conference Registration Fee Country (A, B, C, Student, Professional, or Other)
Mailed to the ICP Treasurer, Dr. Jerry Gamache. 8 Althea Street, St. Augustine, FL 32084-2181 along with this form**.**
Those who choose to pay on-line please send completed form to the address above to complete your registration.

Registration Fees

Member Category	Registration until August 1st	Registration After August 1st	On-site Registration
Member Country*			
Category A	$350.00	$375.00	$400.00
Category B	$250.00	$275.00	$300.00
Category C	$200.00	$200.00	$200.00
Students:			
ICP Student Member	$75.00	$75.00	$75.00
Non-member Student	$100.00	$100.00	$100.00
Non-member Professional	$400.00	$425.00	$450.00
Accommodating Individual	$100.00	$100.00	$100.00

Country of RESIDENCE will determine the registration fees above

Category "A" Countries or Areas:
Andorra, Australia, Austria, Belgium, Brunei, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Kuwait, Liechtenstein, Luxembourg, Netherlands, Norway, Qatar, Sweden, Switzerland, UAE, UK, USA

Category "B" Countries or Areas:
Bahamas, Bahrain, Barbados, Czech Republic, Greece, Hong Kong, Iran, Israel, Italy, Japan, Korea, Malta, New Zealand, Oman, Portugal, Singapore, Slovenia, Spain

Category "C" Countries or Areas: Any country or area not listed above

Student status for non-members are required from the university or department.

Registration for Members and Guests includes:

- Full access to all scientific sessions
- Convention Badge
- Book of Programs/Abstracts

SCIENTIFIC PROGRAM REGISTRATION	ICP MEMBERSHIP COUNTRY OR STATUS (CIRCLE ONE) *A B C STUDENT* *NON-MEM STUDENT NON-MEM PROF* *ACCOMADATING IND*	US Dollars
ACCOMPANYING PERSON NAME: _____		
BANQUET $50.00 PER PERSON NUMBER _____		
CONTINUING EDUCATION Descriptions and Fees to be announced later. See website ICPWEB.ORG AND NEWSLETTERS.		
Paypal (Receipt Date): _____ Check Number: _____ Credit Card: _____ Expiration: _____		Total $_____

- **REMEMBER: You are responsible for making your own hotel reservations in Seville, Spain, transportation to Seville and sightseeing.**

GRAPHIC ART BY University of Seville GRADUATE STUDENTS

ANNUAL ICP, INC. AWARDS

CALL FOR NOMINATIONS FOR 2012

Distinguished Contributions and Outstanding Service Award. The **Frances Mullen Award** is given to an association member who has contributed to ICP, Inc. and the development of international psychology. The Committee Chair receives nominations for inclusion in an ICP, Inc. Hall of Distinction for members who are deceased and for a current active member. Recognitions are made during the annual conference, in the newsletter, and on the website. Active Member recipient is invited to give an address at the annual conference. First Award Given to Frances Mullen 1986.

Send nominations with a letter of recommendation to:
Dr. Anna Laura Comunian **annalaura.comunian@unipd.it**

Gender Research and Service Award. The **Denmark-Gunvald Award** consists of 1) a certificate, 2) a check for $200 US, and 3) an invited address at the conference (one-hour time slot). The Committee Chair makes a certificate for the award or arranges for one to be made. The second award established by ICP, Inc.
Send nominations with documentations to Dr. Joan Chrisler **jcchr@conncoll.edu**

Early Career—The **Seisoh Sukemune/Bruce Bain Encouragement of Early Career Research Award.** The recipient must be a psychologist or of comparable status in an allied discipline (or student) and receives a prize of 1) a plaque, 2) $200 US, 3) an invitation to present the research at the next Scientific Convention, and 4) admission fee is waived at the next ICP Scientific Convention.
Send nominations with documentations to. Dr. Cecilia Cheng ceci-cheng@hku.hk

International Research and Service— The Fukuhara Excellence in Advanced International Research and Service Award. This award is given to a midcareer or senior level psychologist with distinguished contributions to international psychology in research and service and is funded through an ICP, Inc. Award Fund established by Dr. Machiko Fukuhara. Dr. Fukuhara The award is accompanied by a check, a certificate, conference registration for participation and presentation at the annual conference, and the next year's dues for ICP membership.
Send nominations with letter of recommendation to:
Dr. Gerald Gamache **drjerrygamache@bellsouth.net**

In Abstentia—. **InAbstentia Graduate Student Posters** are invited from graduate students who are unable to attend the annual conference. Submissions are displayed throughout the conference and reviewed by an evaluation panel of ICP members. ICP senior members are enlisted at the annual convention and asked to send mentoring comments to authors of the posters. The **Dayan/O'Roark/Barreda-Hanson Award** are based on international content and poster composition. First prize is $100.00 US; Second prize is $50.00 US.
See CALL for **InAbsentia Posters with Conference Call for Proposals and Workshops**. **annalaura.comunian@unipd.it**

Latin Student Conference Paper—The **Alvarez Memorial Award** is funded by "long-time ICP leaders". The prize consists of: 1) $200 US,2) admission fee is waived at the next ICP Scientific Convention, and is presented at the annual membership meeting of the Convention (where the paper is presented). **A panel of ICP, Inc. members selects the paper during the conference. Register papers with Dr. Sherri McCarthy, Sponsor. Sherri.McCarthy@nau.edu**

President's Appreciations Awards are an acknowledgment of service and / or outstanding contribution to ICP during the previous year. As per **advice /recommendations of Committee Chairs and Past Presidents**, typically the following are or may be recognized: a) Board and Chair Term Endings; b) Long Term Service Awards; c) Conference Keynoters; d) President's Appreciations and Ambassadors Appointments.
Send suggestions to the Current President. ludwig.lowenstein@btinternet.com

Dr. Ani Kalayjian accepts award at 2011 ICP, Inc. conference in Washington, D.C.

ICP INC, UN NGO/DPI 1981

Dr. Denmark (front), with ICP interns (l-r): Monica Manfred, Laura Corona, Huiyan Ye, Jennifer Kelly and Kristin Segovich

In my last article for the newsletter I mentioned that I would write about the Psychology Coalition at the United Nations rather than focus on activities of our UN team. However, let me point out we are a great team, well organized and keeping very active in the United Nations.

The Psychology Coalition at the United Nations is composed of psychologists who represent Non-Governmental Organizations (NGOs) accredited at the United Nations (UN) and psychologists affiliated with United Nations departments, agencies and missions. Members of the Coalition collaborate in the application of psychological principles, science, and practice to global challenges of the UN agenda, including those outlined in the Millennium Development Goals. The Coalition seeks to accomplish this overarching aim through advocacy, research, education and policy and program development guided by psychological knowledge and perspectives to promote human dignity, human rights, psychosocial well-being and positive mental health.

In addition to the International Council of Psychologists the organizations include the American Psychological Association, the Association for Trauma Outreach and Prevention, the International Association of Applied Psychology, the International Council of Psychologists, the International Society for Traumatic Stress Studies, the International Union of Psychological Science, the Society for Industrial/ Organizational Psychology, and the Society for the Psychological Study of Social Issues. There has been a significant increase in the number of psychologists representing these organizations. Psychologists are also to be found in other organizations and they can also be part of the Coalition as individual members.

In the Fall, during the planning of the Fifth Annual Psychology Day at the UN, APA and SPSSI took the lead in calling for the formation of a coalition and worked with representatives of other psychology organizations in developing a mission statement for the Coalition and an advocacy statement for the 2012 Commission on the Status of Women. In February and March 2012, APA, SPSSI, ICP and IAAP professionals and interns, with the support of other psychology organizations, formed a team that launched very successful advocacy interventions at the Commission on Social Development, the Commission on the Status of Women, the Informal Negotiations for the Rio+20 Summit on Sustainable Development, and the Commission on Population and Development. The volume of this work and the number of contacts made directly with representatives of government missions at the UN has been truly remarkable.

An Ad Hoc Task Force (including Florence Denmark) drafted By-Laws which identifies a structure that will enable the members of the Coalition to work together effectively to accomplish our mission. The By-Laws went through four readings and revisions before being approved at the March 22, 2012 meeting of the Coalition, contingent on a review by and feedback from the headquarters of each organization. However, some fine tuning is still needed. I will share the By-Laws with you once they are finalized.

An important point stressed early in the By-Laws is that "Membership in the Coalition is not intended to diminish or take away from the responsibilities that psychologists have to the missions of their respective Non-Governmental Organizations or to service on NGO Committees at the UN. Instead, organizational membership in the Coalition should provide opportunities to enhance and broaden the contributions of the representatives of each psychology organization to implementing their mission on NGO committees and in other areas of functioning at the UN."

Although the members of the Coalition represent organizations that are accredited at the UN, the Coalition as an entity does not have accreditation status at the UN at this time.

ICP, Inc. UN representative Norma Simon

(Courtesy F. Denmark)

UNITED NATIONS: VIENNA

Dr. Roswith Roth

The NGO Committee on the Family met May 14,2012. Drs. Sandra Neil and Bob Silverberg gave a very interesting talk with the title "Strengthening Couples and Families. The Satir Model". The talk and the discussion were a big success and highly acclaimed by the participants. They were invited to give a workshop in Graz/Austria and Zagreb/ Croatia next year.

At the same time Peter Crowley our secretary in the Committee on the Family in Vienna was invited to an Expert Meeting at the UN in New York to present a project of the Committee on the Family in Vienna preparing for the 20th Anniversary of the International Year of the Family in 2014.

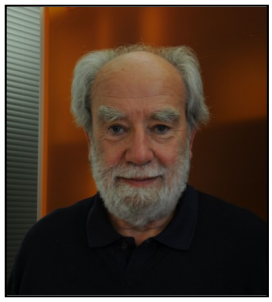

We will give more details in the next IP.

Best regards,

Roswith

Dr. Florence Denmark, center, receives highest APA award 2011, Washington, D.C. Surrounded by ICP, Inc. friends.

UNITED NATIONS NEWS

UN Women Civil Society Announces Advisory Groups: Global, Regional and National

United Nations, New York — UN Women Executive Director Michelle Bachelet today announced the members of her Global Civil Society Advisory Group that will facilitate regular consultations and dialogue between civil society and UN Women.

"I am delighted that a group of outstanding international women's rights advocates and experts on gender issues have agreed to serve on my Global Civil Society Advisory Group. They will play an important consulting role, and provide strategic perspectives on advocacy on gender equality and women's empowerment and on UN Women's thematic priorities," said Ms. Bachelet.

The establishment of UN Women Civil Society Advisory Groups at the global, regional, and national levels was announced this year at the 56th session of the Commission on the Status of Women. All members have proven track records of work in areas related to gender equality and women's empowerment, and bring diverse experience and expertise to the group. Members include grassroots, rural and community-based leaders, leaders of indigenous people's groups, feminist scholars, human rights lawyers, and male leaders working on gender and women's rights issues.

The main objective of this Group is dialogue and engagement to advance global goals of gender equality and women's empowerment. The membership of the Group will be rotational, and the current members will be serving for a period of two years.

The current members of the Group are: Marling Haydee Rodriguez, President of the Union of Cooperatives Las Brumas, Nicaragua; Teresa Fernández de la Vega Sanz, Former Vice-President of Spain, Eminent Jurist and Founder, Women for Africa Foundation, Spain; Tarcila Rivera Zea, Founder, Center of Indigenous Cultures of Peru, Peru; Rawwida Baksh, Former Head of the Women's Rights Programme, International Research and Development Centre, Trinidad and Tobago; Patricia Perez, Global Chair of International Community of

[continued on next page]

UNITED NATIONS NEWS, CON'T.

[Denmark, con't.]
Women Living with HIV/AIDS (ICW), Argentina; Charlotte Bunch, Founder of GEAR Campaign, United States; Todd Minerson, Executive Director, White Ribbon Campaign, Canada; Hibaaq Othman, Strategist for Dignity Fund, the Think Tank for Arab Women and Karama, Somalia; Nehad Abol Komsan, Founder and Chairperson of the Egyptian Center for Women's Rights, Egypt; Rabea Naciri, President of the Democratic Association of Moroccan Women, Morocco; Violet Shivutse, Leader, GROOTS, Kenya; Bineta Diop, Executive Director and Founder, Femmes Africa Solidarité, Senegal; Kumi Naidoo, Executive Director of Greenpeace International, South Africa; Josephine Castillo, Organizer-Trainer, Damayan Ng Maralitang, Pilipinong Api (DAMPA), Philippines; Hina Jilani, Founder, Human Rights Commission of Pakistan, Pakistan; Bandana Rana, Executive President of Saathi and Regional Coordinator, South Asian Campaign for Gender Equality, Nepal; Sharon Bhagwan Rolls, Founder, FemLINKPACIFIC, Fiji; Drude Dahlerup, Professor of Political Science at Stockholm University, Denmark; Selma Acuner, Professor, Ankara University, Turkey; Cecile Gebroval, Programme Director, European Women's Lobby, France; and Joanne Sandler, retired Deputy Director, UNIFEM, USA.

The first meeting of the Global Civil Society Advisory Group will be convened at the time of the 67th session of the General Assembly in September.

United Nations Peacekeepers Appreciated on May 29

On 11 December 2002, the United Nations General Assembly adopted resolution 57/129 designating 29 May as the International Day of United Nations Peacekeepers. The Day serves as an occasion to "pay tribute to all the men and women who have served and continue to serve in United Nations peacekeeping operations for their high level of professionalism, dedication and courage and honours the memory of those who have lost their lives in the cause of peace."

The United Nations has no standing army or police force of its own but relies on its Member States to contribute military and police personnel required for peacekeeping operations. The men and women who serve in these operations are first and foremost members of their own national services and then seconded to work with the United Nations; they wear their own countries' uniforms and are identified as UN peacekeepers only by a UN blue helmet or beret and a badge.

United Nations Peacekeepers come from countries large and small, rich and poor and bring with them their own unique experiences and cultural backgrounds. They provide security as well as political and peace-building support to help countries torn by conflict make the difficult transition to peace. Over the years, UN Peacekeeping has evolved to meet the demands of different conflicts and a changing global political landscape. There are currently 17 UN peace operations deployed on four continents.

Since the first United Nations peacekeeping mission was established in 1948, more than 2990 UN peacekeepers have lost their lives in the service of peace. This briefing will look at the complex role of UN peacekeepers in the context of today's multidimensional peacekeeping operations. It will also examine the global partnership between the Security Council, UN Secretariat and the UN's Agencies, Funds and Programmes on the one hand and Member States who generously provide troops, police and financial contributions as well as countries which host peacekeeping missions on the other. It also will look at the critical role of partners such as NGOs in the process of peacekeeping.

ICP, Inc. UN intern Laura Corona with an APA intern.

(F. Denmark photo)

MEMBERSHIP CHAIR REPORT

Membership Report

Dr Julia Rose Membership Chair

March 2012

Committee and Area Chairs Meeting

'Buzz' and ' Energy ' were the key words to sum up the membership committee and Area Chairs' meeting at the conference in Washington DC in August 2011. Some new members joined the team and contributed with enthusiasm to new ideas for membership recruitment and retainment. One of the key suggestions was the dissemination of information, for example, keeping the membership informed of all changes, dates of meetings and conferences including changes of dates as they happen, this is vital for those booking time off work and booking flights. Another suggestion was for Area Chairs to chase up membership fees to members in their areas. A further suggestion was to have a membership page on the website for membership and for important information to be published such as date changes noted above. Some of the time during the meeting was spent updating the wonderful membership directory that Anne Marie and Gerry Gamache had put together. As with any directory Personal details change so quickly.

In addition we had two new members join ICP whilst they were present at the conference. Also new area chairs came forward, and have been passed on to our World Area Chair Dr Sandra Neil.

Poster Presentations

Part of my role in Washington DC was to take part in judging the Student/Trainee (Judges Dr Tara Pir, Dr Donna Goetez and Dr Julia Rose). The outcomes are as follows:

Overall the quality of the posters was excellent. During the judging we considered the following criteria: contribution to international/cross cultural research, presentation of poster, content, accuracy, references, directions for future research and the authors were trainees/students. Extra comments were sent separately to the authors of the posters.

First Place was awarded to *"Cross Culture Analysis on Padua Moral Judgment Scale". Diana Mabelia and Lucie Ronconi, University of Padua.*

This poster was considered to be a high standard, with a strong contribution to international / cross cultural research. The overall presentation was good with clear content and illustrations, worthwhile research and future directions for further research.

Second Place was awarded to *"Gender and Discursive Positioning Doing Transgender in Highly Normative Contexts".* Alexander Hochdan, Paulo Francesco Cottone and Dania Vallini. Department of Sociology University of Padua, Department of Applied Psychology, University of Padua.

This poster was a good piece of research, with a good contribution to international/ cross-cultural research. The content was clear, however perhaps a little too busy for a poster.

Third Place was awarded to *"The Quality of Life in Pedriatric Oncology: A Project of Psychological Support for Children & Adults".* Elsa Cavagna and Marialvisa Dotii, Spelia Civili Brescia, International Network of Health Promoting Hospital & Health Service.

This was considered a good and worthwhile piece of research. Good clear content and tables, and excellent presentation with a strong contribution to international research.

New Members

The last two months I have been active in trying to recruit new members, I have written to the Universities in the UK, inviting qualified psychology staff and students to join ICP. Through our World Area Chair Dr Sandra Neil, our Area Chairs will be doing the same. Dr Sandra Neil and I continue to work closely together to address recruitment and retention. We will be having another face-to-face meeting in May in London UK and Dr Robert Silverberg will be joining us.

Ludwig, our current President has also been active and has written a small article for the British Psychological Society (BPS) at his own expense. We will keep you informed of progress. Through the article, Ludwig has raised the awareness of ICP in the UK, so we are hoping more new members will join in the near future.

This year, we have had **8 new members from a variety of Countries:** 1 Germany, 1 UK, 2 India, 1 Indonesia, 1 Romainia, 1 Sri Lanka, 1 USA.

There are four additional new members from the UK that are due to join within the next few weeks.

[continued on next page]

[Membership Report, cont.]

Membership Committee

Membership Chair: Dr Julia Rose, England, UK

Dr Justina Aire – Caribbean and S Africa
Dr Cheng-Chein Chen – Taiwan
Dr Chizuko Sugita- Japan
Dr Maria Rosa Mazzoli- Italy
Dr Ani Kalayjian- USA East
Dr Maria Thompson- UK
Dr Neal Rubin- USA
Professor Janet Sigal- USA
Erica Green-USA Central and Graduate School
Lisa Gray: Student Representative UK
Jennifer DeMucci: Student Representative USA

Ex-Officio Members
President: Dr Ludwig Lowenstein UK
President Elect &
Long Range Planning Chair: Dr Tara Pir USA
World Area Chair: Dr Sandra Neil Austrailia

The membership committee will be finalizing the new membership campaign within the next few weeks.

Report Respectfully Submitted

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Intern Kristin Segovich, registering people for Psychology Day at the UN

MEMBER NEWS . . .

Richard S. Velayo, Ph.D.

I am honored to have been invited to write this article about my professional activities and scholarship by my dear colleague and friend, Dr. Ann O'Roark (ICP Past-President and Newsletter Editor of the International Psychologist).

Professional Biography

I am a professor of psychology at Pace University in New York City. I received my PhD in Education and Psychology (Combined Program) from the University of Michigan (Ann Arbor), M.A. in Applied Behavior Analysis from the University of the Pacific (Stockton, California), and B.A. in Psychology / B.A. in Sociology-Anthropology degrees from De La Salle University (Manila, Philippines). At the University of Michigan, I was mentored by Wilbert (Bill) McKeachie, Ph.D. (well-renowned and revered scholar and educator in the area of Teaching of Psychology), who has been influential in my career and continues to be an inspiration to me. I taught at De La Salle University and Montana State University before coming to Pace University in 1994 as a full-time faculty member of its Psychology Department.

Since I started my academic life at Pace University, I have been very much involved in teaching, research and service work within and outside of the University. The courses that I teach regularly are Experimental Psychology, Cognitive Psychology, Introductory Psychology, and a unique online course that I developed called Instructional Psychology: Multimedia Applications. I am also a consultant for various doctoral dissertations and supervise various Masters-level theses projects. Some of my service-related departmental activities include Technology Coordinator (1994 - present), Chair/Coordinator of the Pace Psychology Annual Conference (1995 - 2004, 2012), Editor of the "Psych Eye" newsletter (the official newsletter of Pace's Psychology Department, NYC) (1996 - present), Masters Program Coordinator (2000-2005), and Co-Advisor to its Psi Chi chapter (2010 - present). Some of service work at Pace has extended to various college and university-wide committees having served as Chair of the Academic Resources Committee and Fellow of the Dyson College Arts and Sciences (1999 – 2001), Chair of the Communication Studies Department (NYC campus)

[Velayo, con't.]

Chair of the Academic Resources Committee and Fellow of the Dyson College Arts and Sciences (1999 – 2001), Chair of the Communication Studies Department (NYC campus) (2000 - 2002), and Secretary and Webmaster (2000 - 2005) for Pace's New York Faculty Council (NYC campus).

I am also actively involved in various psychology organizations outside of Pace University. For APA's Division of International Psychology (Division 52), I had served as President (2004), Member-at-Large (2008 - 2009), and continue to be its Webmaster and Chair of its Website Technology Committee (2005 - present). I was President (2001 and 2008) of the New York State Psychological Association's Academic Division, Fellows Chair (2005-2007, 2012) for The Society for General Psychology (APA, Division 1), Chair (2006-2008) of the Psychology Section of the New York Academy of Sciences, Chair (2006) and Program Publisher (2006 - 2012) for the NGO Committee on Ageing's Annual International Day of Older Persons, and Planning Committee Member and Program Publisher for the United Nations Psychology Day since its inception (2007 - 2012), and Co-Chair (2009) of APA's Committee on Divisions/APA Relations (CODAPAR). Since 2009, I have taken on the role of Treasurer of the NGO Committee on Ageing, and a Member of the Executive Steering Committee of the Eastern Region for Psi Chi (The International Honors Society in Psychology).

For ICP, I currently serve as a Member-at-Large of ICP (- 2014). Since having been a member of ICP since 2000, I have been involved in the organization in a number of ways, including Chair of the Communications and Publications Committee (2006 - 2009), Member of the Continuing Education Committee (2008 - 2009), a Representative to the United Nation's Non-Government Organizations (since 2007) and ICP Liaison to the Division of International Psychology of the American Psychological Association (since 2007). I continue to promote ICP in various capacities through my involvement in UN-NGO Committees and in various regional and national psychology organizations in the U.S. At the 2010 ICP Convention, I was humbled and pleasantly surprised to be recognized with the ICP President's Award (presented to me by Dr. Ann O'Roark on behalf of ICP) for Outstanding Association Support.

My current scholarly work in international psychology focuses on the internationalization of the psychology curriculum. More specifically, my three research interests involve: (1) exploring teaching and course-based strategies that help psychology instructors infuse international content and perspective in their courses, (2) using social media and other internet-based technologies as a tool help internationalize the education and training of psychology students, and (3) developing ways to assess the extent to which a psychology course is "internationalized". Below is a list of most recent publications associated with this research on this topic.

Velayo, R. (2012). Internationalizing the Curriculum. In J. Groccia, M. Alsudiary, & W. Buskist (Eds.), *Handbook of College and University Teaching: A Global Perspective* (pp. 268-278). Thousand Oaks, CA: Sage.

Grenwald, G., Oberlechner, T., & Velayo, R., (in press). Internationalizing Postsecondary Education in Psychology: A Global Endeavor. *Psychology Learning and Teaching, 11*(3).

Grenwald, G. & Velayo, R. (2011). Internationalizing Your Psychology Course: Preliminary Survey Findings. *International Psychology Bulletin, 15*(2), 53-58.

Velayo, R. (2011). Internationalizing the Teaching of Psychology By Using Emerging Social Media. *Eye on PsiChi, 15*(2), 6-7.

Velayo, R. (2010). Internationalizing Your Psychology Course. Essays from *E-xcellence in Teaching*, 10, 25 -31. Retrieved from http://teachpsych.org/resources/e-books/eit2010/index.php

A Call to Internationalize the Teaching of Psychology

Why is there a need to internationalize the teaching of psychology? How may ICP be a contributing force towards helping achieve this goal?

There are compelling reasons why a growing number of instructors have tried to internationalize their courses in some way. The study of psychology is inherently global and the field continues to become more globally influenced with the increasing realization that the differences and commonalities in human behavior between cultures around the world can be explained as a function of the contextual and historical variations between nations. Psychologists, therefore, have come to value the pursuit of a more global perspective in understanding how individuals behave and think. As a result, there are many psychologists in the United States who are calling for the internationalization of the psychology curriculum to better prepare students for practice, research, and service in the twenty-first century (Leong, Leach, Marsella, & Pickren, 2012; Lutsky, Torney-Purta, Velayo, Whittlesey, Woolf, & McCarthy, 2005, Marsella, 2007; Marsella & Pederson, 2004; Stevens & Wedding, 2004, Velayo, 2004). Psychol-

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[Velayo, con't.]

ogy in the U.S., and of Western psychology more generally, needs to enrich its content, methods, and practice by incorporating diverse cultural perspectives and values so that a more cross-national perspective in psychology might be realized.

I grapple with the notion of how psychology organizations may best promote a more international perspective in the teaching of psychology, despite knowing that many such organizations have various other relevant issues and concerns to deal with. I think that international psychology organizations would be particularly effective in advocating and encouraging this goal. ICP is one of the organizations, with its international membership and reach, that can effectively foster such internationalization efforts.

Teaching and Course-based strategies

We are very much cognizant of the increasing need to pursue strategic ways to prepare our students to become more appreciative and knowledgeable of different cultures, to be better informed about global issues, and to become effective citizens able to effectively function in an increasingly interconnected world. Generally, there is an apparent lack of cross-national knowledge, awareness, and research of perspectives about psychology among psychology students. Despite the growing awareness of the importance of internationalizing the psychology curriculum, many instructors are unclear on how they may be able to internationalize the courses they teach. Thus, it is essential to provide them with simple pedagogical strategies that can be effectively implemented to infuse an international perspective in their courses, given the context in which they teach.

The major goal of internationalizing psychology education is to increase student competence in the research and practice of psychology in a global setting. This goal can be achieved through lectures, classroom activities, out-of-class assignments, and Internet-based technologies. Examples of teaching strategies may are provided in Grenwald, Oberlechner, & Velayo (in press) and in Grenwald and Velayo (2011).

Internet-based Strategies

As psychologists, we experience how technology, specifically the Internet, has changed our lives and how we are able to learn about and connect with people from far away places with relative ease and efficiency. The use of the Internet can be an efficient and cost-effective tool to help internationalize psychology education. A growing number of psychology instructors recognize the importance of incorporating a more global perspective in the courses they teach, especially as people become increasingly interconnected and interdependent through Internet-based technologies (Power & Velayo, 2006; Velayo, 2000). Internet-based technologies allow for greater and faster communication between psychologists and students residing in different nations and different regions within a country, they also provide for greater cross-national understanding, increased curricular and scholarly collaborations, and enhanced level of experience that goes beyond just reading about another culture.

Social media technologies provide opportunities that help internationalize the education and training experience of students (Velayo, 2011). Blogs, wikis, Facebook, Google groups, LinkedIn, Twitter, YouTube, and Skype are among the more common web platforms used to enhance collaboration and sharing among learners. These technologies promise to be particularly relevant and effective pedagogical devices provide an effective mechanism to internationalize a course (Velayo, Oliva, & Blank, 2008). Nonetheless, innovative ways to utilize social media technologies as pedagogical and training tools need to be further explored. Psychology instructors may not use all of these technologies, but knowing what the technologies can do is important in determining which ones are useful for integrating a more international perspective in teaching. The use of the Internet in teaching may not only help infuse international content in a course, but it also helps facilitate collaboration and engagement among students and instructors.

Undoubtedly, currently used and emerging internet-based technologies shall continue to contribute significantly to the globalization of psychology, in general, and the psychology curriculum in particular.

Assessing an Internationalized course

Students who successfully complete an internationalized psychology program are expected to not only increase their knowledge base and expand their skills but also have enhanced motivation and ability to pursue professional development that is internationalized (Yeshova, DeJaeghere, & Mesterhauser, 2000). The changes that occur in the attempt to the broader psychology curriculum in general, and psychology courses in particular, necessitates assessment on a regular basis to determine whether students have sufficiently obtained a level of international perspective and knowledge base. In other words, an important part of internationalization efforts is to determine the effectiveness of the pedagogical strategies used to bring international content into the psychology classroom. One method is to survey students who have completed a psychology course with an international component about

 [continued on next page]

[Velayo, con't.]
their learning and, specifically, their classroom experience. Instructors who incorporate international content in their courses may also be surveyed to identify specific strategies that are the most effective. Empirical research on the use of specific instructional strategies could examine the context of specific courses, demographic characteristics of the students, pre-post levels of international psychological knowledge, and resources available to the instructor (Grenwald, Oberlechner, & Velayo, in press).

I think it is imperative that instructors identify what student learning outcomes they expect from their students in the psychology course/s that they have attempted to internationalize. Such outcome measures alert students that international content is not merely an add-on to the course but in fact is central to it (Bartolini, Gharib, & Phillips, 2009). The APA asserts "international awareness" as one of its official goals for the undergraduate psychology major.

In a 2004 collaboration with the American Council on Education, the APA formed a task force to help suggest ways to internationalize the undergraduate psychology curriculum (See Lutsky, Torney-Purta, Velayo, Whittlesey, Woolf, & McCarthy, 2005). The final report delineated five goals and associated learning outcomes: psychological knowledge in international perspective; methodological issues in international research; the discipline of psychology in the international perspective (i.e., awareness of how the discipline of psychology is developed, studied, and applied in and across cultures); psychology and interpersonal understanding; and psychology and global issues. The report also provides suggested more specific student learning outcomes for each goal to assist with course design, which may be used as a checklist or as ratings scale to assess how certain internationalization strategies impacted student learning.

ICP and Promoting the Internationalization of the Psychology Curriculum

Internationalization is undoubtedly one of the "buzzwords" that continues to pervade psychology, as well as many other disciplines. ICP, as one of a number of international organizations in psychology, has an important role to play in taking a influential role in promoting internationalization efforts through teaching, research, and advocacy through its members, and the programs and events that it sponsors, including its annual convention, as well as its affiliations with various other psychology organizations and institutions.

One of the key missions of ICP is the educational - *to advance the science and practice of psychology and to support the use of psychological knowledge to promote social health and justice.* An important component towards achieving this mission is to promote and support efforts towards a more internationalized curriculum. The future of psychology will be realized by today's students. They will eventually be the ones who shape the field. Preparing them for a increasingly globalize world is crucial and their role as psychologists will become increasingly more important as peoples around the world become more interconnected and interdependent. An internationalized psychology curriculum will prepare them to competently understand and potentially intervene in global problems. By doing so, students will be better able to understand and intervene in societal problems that impact individuals, families, and communities (e.g., war and conflict, global climate change, disease, terrorism, , and the needs of the global poor, immigrants, and refugees (Marsella, 2007).

I therefore call on ICP to take on the challenge of actively promoting research on and implementation of an internationalized psychology curriculum.

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[Velayo, con't.]

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ICP, INC. FINANCE COMMITTEE CHAIR ANNOUNCES NEW PUBLICATION

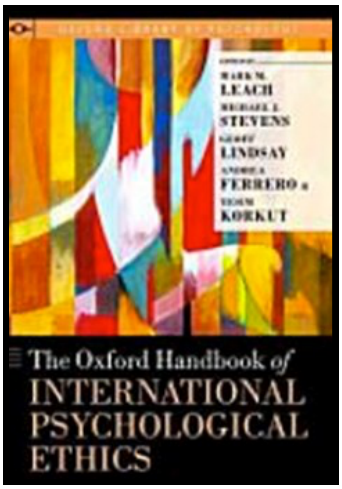

Leach, M. M., Stevens, M. J., Lindsay, G., Ferrero, A., & Korkut, Y. (Eds.). (2012). *The Oxford i nternational handbook of psychological ethics.* New York: Oxford University Press.

ICP BOARD DIRECTOR AT LARGE SARLITO SARWONO PUBLISHES BOOK ABOUT THERAPY WITH TERRORISTS

"Deradicalisation de la personnalite d'ex-terroristes, a l'aide du Davido-CHaD: 10 cas d'ex-terrorises indonesiens" (2012, Paris: Edilivre).

This book is about my project on deradicalization of ex-terrorists in Indonesia. I have been working with around 50 ex-terrorists since 2009. Some were still in jail, some have been freed. My theory is that these people are not insane, they are normal people with normal lives. The difference between them and other people is only in their ideology. Ideology is an opinion, an attitude that was learned, not birth given. Since it is learned, it can be changed by relearning/ reeducation. My team has successfully changed their attitude (not their political ideology) to become less violent. Today they participate in my program to preach Islam as a peaceful, non-violent religion.

The Davido-CHaD projective test is used with 10 of the ex-terrorists to examine childhood trauma, which leads to current violence. One of the subjects is described in detail, to reveal the psychodynamics of an individual who becomes a terrorist. This particular person is not involved in any violent-religious activities anymore. He is currently working as a guard in a private security company (this last part is not written in the book).

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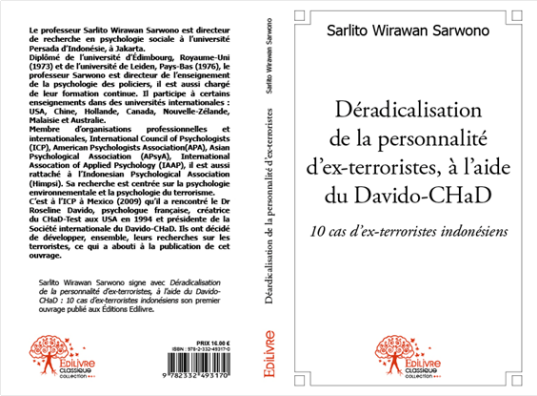

[Member News, con't.]

Dr. Beverly Stevens ICP, Inc. Web Manager, and Dr. Michael Stevens, Board of Directors Member at Large attending Mexico City Conference Banquet.

NEW MEMBERS

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RENEWAL MEMBERS

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[continued on next page]

[New Members, con't.]

NEW STUDENT MEMBERS

2011-2012

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In Absentia Student Poster Exhibit

INTERNATIONAL NEWS

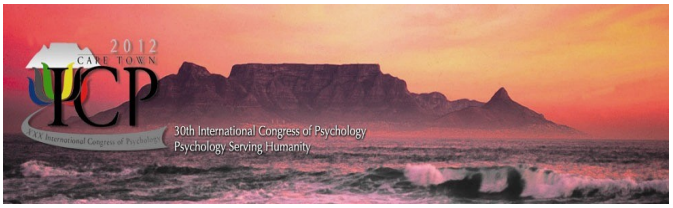

Welcome to South Africa and ICP 2012 - Cape Town 22-27 July 2012

To pay, please log in to the registration system. 22 July 2012: ICP Opening Ceremony.

CONGRATULATIONS: Marousa Kalagkona, Elizabeth Gil Vieira, Larisa Abelite and Lindiwe Shange our lucky draw winners.

www.icp2012.com/ICP/register.jsp

The International Congress of Psychology, held every four years under the auspices of the International Union of Psychological Science, is the flagship event in international psychology. The previous 29th ICP was held in Berlin in July 2008 and attracted some 11,000 abstract submissions and over 10,000 delegates. The 30th International Congress of Psychology is the first to be held in Africa, and is organised by the National Research Foundation of South Africa and the Psychological Society of South Africa, in partnership with key South African universities and national government departments.

Organised around the theme *Psychology Serving Humanity*, the congress will highlight how psychology translates its science and practice into the knowledge, skills and tools that are able to underpin the human condition. Besides Invited Addresses and Symposia by global leaders in their fields, there will be scintillating State of the Science Lectures and Controversial Debates on topics of current interest, and exhibitions by leading publishing houses, technological innovators and international psychology organisations. Special activities will include an exciting Emerging Psychologists' Programme, Advanced Research Training Seminars for psychologists from the developing world, various pre and post congress satellite conferences and a variety of tours (including famous World Heritage sites like Robben Island and Table Mountain) and breathtaking wildlife safaris for delegates and accompanying persons.

INTERNATIONAL NEWS, con't.

Nice opportunity for clinicians...

I wanted to give you a heads up on a new website that cannot only help you build your business but also help patients find the help they need – Therapists.com. I just joined the Advisory Board of this new mental health portal because it allows clinical professionals to provide the breadth and depth of information needed to increase the chance of a good fit with prospective patients.

Subscribing therapists are provided the opportunity to answer in their profile the questions most frequently asked by patients. And since seeing and hearing another person is often necessary to gauge chemistry, Therapists.com profiles include the opportunity to record first-person videos. I will be taking advantage of the publishing feature that allows subscribers to write articles or participate in online communities.

The site was created by C.J. Newton who has the rare combination of mental health knowledge and Internet expertise needed to develop the trusted online resource that both therapists and consumers need.
http://www.Therapists.com

PS you can get $99 off an annual subscription by entering CHRISSTOUT in the coupon field, yes, kind of embarrassing for me, but good for you….

Cheers,
Chris

Dr. Chris E. Stout drchrisstout@gmail.com>
Founding Director, http://CenterForGlobalInitiatives.org

News from the International Social Science Council (ISSC)

Katsuya Kodama, of the International Peace Research Association and an ISSC Executive Committee Member, has won the Ahimsa (non-violence) Award for International Peace. For details, see:
www.worldsocialscience.org/?p=2770

APS and EAPP (European Association of Personality Psychology) Joint Symposium

APS and EAPP are running a preconference symposium, The Cognitive Neuroscience of Personality Dynamics, on July 10, 2012, the day before the 16th European Conference on Personality in Trieste, Italy. The event is free but registration is required. For details see:
www.psychologicalscience.org/index.php/convention/

News from the International Science Council (ICSU)

ICSU was a sponsor of Planet Under Pressure, a four-day conference which brought together more than 3,000 experts to assess the state of the planet and explore solutions to impending social and environmental crises. A final declaration was issued, with a view to informing the United Nations Conference on Sustainable Development in Rio de Janeiro in June, 2012, focussing particularly on how many Earth-system processes are dominated by human activities. For details, see:
www.icsu.org/news-centre/news/top-news/highlights-of-the-state-of-the-planet-declaration

The 23rd International CODATA (Committee on Data for Science and Technology) Conference, Open Data and Information for a Changing Planet, takes place in Taipei on 28-31 October 2012. This event will bring together scientists and policy makers from all over the world to discuss scientific data issues and challenges which impact on our planet and our society. For details, see:
www.icsu.org/news-centre/news/23rd-international-codata-conference-call-for-abstracts-sessions-and-nominations

Introducing the Second Edition-"Magazine SOLEPSI" of the Latin American Society of Psychology Students, which details the history of PSICOTOUR that has taken place in our 5 years of existence as an organization.

During the consolidation process SOLEPSI have considered the performance of Latin American conference of Psychology Students, in order to enhance and improve academic reflection, exchange, production and transmission of knowledge. These sessions were to host inaugural Faculty of Humanities of the Universidad Nacional de San Luis, Argentina. Later (in the second half of the year) Venezuela will host the conference, and will continue with those countries that wish to carry out the proposed SOLEPSI.

Finally, we appreciate the comments following the First Edition-"SOLEPSI Magazine", this motivates us to keep improving. We listen to your suggestions, questions, comments and notes.

Continue sharing your SOLEPSI Magazine, which can be read on the following link: http://issuu.com/solepsiorganizacion/docs/solepsi_magazine2?mode=window&backgroundColor=%23222222

Regards.
Jorge Quispe
Editor.

ICP PROCEEDINGS 2011

All delegates of the ICP 2011 Convention Proceedings are cordially invited to submit a paper.

We will publish the Proceedings of the 69th Annual Convention in Washington 2011.

To meet publisher costs, we have to charge for each contribution

First author	Coauthor
A – Country submission US$ 30,00	US$ 60,00
B – Country submission US$ 20,00	US$ 40,00
C – Country submission US$ 15,00	US$ 30,00

Specifications:

- Submission on disc, CD or by email (as attachment) using MS Word. **Submission must be accompanied by the above mentioned fee (where to send the money s. below)**, without payment the contribution cannot be included into the proceedings
- **English language manuscript only**
- No paper can exceed **10 pages**, including references, 1 ½ spaces between lines, #12 Times Roman
- Figures and Tables submit in camera ready form or on disc, CD (or by email as attachment)
- **References in APA style** (please check!)
- **Indicate the affiliations, the email-addresses and postal addresses of you and your co-authors**
- Write your **family name in capital letters** (we often cannot distinguish the given name from the family name)

Please submit your manuscript to Dr. Anna Laura Comunian annalaura.comunian@unipd.it and Ludwig Lowenstein ludwig.lowenstein@btinternet.com as soon as possible.

Submission Deadline: SEPT 30, 2012

Name & address of the First Author (please print):

_____

Names, affiliations, and addresses of co-authors (please print):

_____

_____

_____

_____

Payment on the website: ICPWEB.ORG

or send to: **Dr. Gerald L. Gamache, Ph.D**
ICP Treasurer
c/o KGA International
8 Althea St
Saint Augustine , FL 32084

email: geraldgamache@bellsouth.net

Please indicate: 2011 ICP Proceedings

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Category C Countries: All other countries

ICP PUBLICATIONS

ICP SILVER ANNIVERSARY BOOK. ***The First Quarter Century. 1942-1967.*** Ed. Lillian G. Portenier.
Note: Publishing information needed.

ICP GOLDEN ANNIVERSARY BOOK. ***Psychology in International Perspective. Fifty Years of the International Council of Psychologists.*** *(1992). Eds. U. P.*Gielen, L.L.Adler, N. A. Milgram. Amsterdam/ Lisse: Swets & Zeitlinger

East Meets West. (reference needed) Eds. David Y.F. Ho & H. Vanderploeg.

Note: Proceedings from the 1988 ICP Singapore Conference.

Psychology and Education in the 21stCentury Proceedings. Proceedings of the 54th Annual Convention. International Council of Psychologists. Banff, Canada. July 24-28, 1996. Eds. B. Bain, H. Janzen, J. Paterson,L.Stewin, A.Yu. Edmonton, Canada: ICPress. February, 1997.

It's All About Relationships. (2002) . Eds. Anna Laura Comunian & Uwe Peter Gielen. **Berlin: Pabst Science Publishers.** ISBN 3-89967-014-0 (Europe). ISBN 1-59326-062-8(USA)

Note. Contains papers from the 2000 ICP Conference in Padua, Italy, and from the University of Padua, Department of Psychology, and the Institute for International Cross Cultural Psychology at St. Francis University, NYC. .

Iguacu Brazil Conference Proceedings Book. Sherri McCarthy. *Proceeds of the 1st Joint Meeting of the International Conference of Psychologists and the International Conference on Psychology Education.* Nwecastle,UK: Cambridge Scholars Press

INTERNATIONAL COUNCIL OF PSYCHOLOGISTS, INC. PROCEEDINGS PUBLICATIONS. MANAGED BY ROSWITH ROTH, PhD., Graz, AUSTRIA

Milgram, N., Roth, R., & O'Roark, A.M. (Eds.) (2010). 67th Conference Proceedings. In-Process.

Roth, R., Hiew, C. & Comunian A.L. (Eds.) (2009). 66th Conference. ***Peace, Hope and Well-Being across the Cultures.***

Proceedings of the 65th Annual Convention International Council of Psychologists in San Diego CA, USA,August 11-14, 2007. **Aachen: Shaker Verlag.**

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Dayan, N, Grotberg, E. Roth, R., Hiew, C. & Bernardo, A.B. (Eds.). (2006). ***Making a Difference in the Life of Others Proceedings of the 62nd Annual Convention International Council of Psychologists. August 3-6,2004, Jinan, China.*** **Aachen: Shaker Verlag.**

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Roth, R. & Farley, F. (Eds.) (2002). The ***Spiritual Side of Psychology at Century's End.*** **Proceedings of the 57th**

Annual Convention, International Council of Psychologists, August 1999, Salem, MA USA. Lengerich: Pabst Publishers.

Roth, R. & Neill, S. (Eds.) (2001). ***A Matter of Life: Psychological Theory, Research and Practice. Proceedings of the 56th Annual Convention, International Council of Psychologists, August 1998,Melbourne, Australia.*** **Lengerich: Pabst Publishers**

Roth, R. (Ed.) (1999). ***Psychologists Facing the Challenge of a Global Culture with Human Rights and Mental Health. Proceedings of the 55th Annual Convention, International Council of Psychologists, July1997, Graz, Austria.*** **Lengerich: Pabst Publishers.**

ICP, Inc. Publications are Digitized for Electronic Access by PsychEXTRA

PsychEXTRA is a companion database to the American Psychological Association's PsychINFO which links clinicians, librarians, consumers, policy-makers and researchers to a variety of credible information sources. Their database covers psychology, behavioral science, and health.

During the agreement negotiated between ICP, Inc. and PsychEXTRA by Past President Ann Marie O'Roark, ICP, Inc agrees to allow PsychEXTRA staff to retrieve certain data from the website to be included in the PsychEXTRA database at http://psycextra.apa.org

Articles published in the Conference Proceedings Books, the newsletter, and the conference program that are not prohibited by copyright by an agent other than ICP, Inc. will be made available to researchers and colleagues in several languages and around the world. The contract is for three years and is renewable.

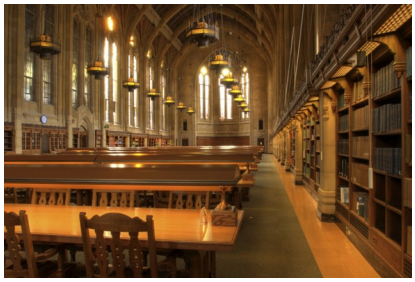

INTERNATIONAL COUNCIL OF PSYCHOLOGISTS, INC.

2012 MEMBERSHIP DUES STATEMENT

CATEGORY "A" COUNTRIES: $100
(Australia, Austria, Bahrain, Belgium, Brunei, Canada, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong, Iceland, Ireland, Israel, Italy, Japan, Kuwait, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Qatar, Saudi Arabia, Singapore, Spain, Sweden, Switzerland, Taiwan, United Arab Emirates, USA)

CATEGORY "B" COUNTRIES: $60
(Antigua & Barbuda, Argentina, Bahamas, Barbados, Brazil, Croatia, Cyprus, Czech Republic, Iran, Korea, Malaysia, Malta, Mexico, Oman, Phillippines, Poland, Seychelles, Slovakia, Slovenia, South Africa, Suriname, Turkey, Venezuela, Yemen)

CATEGORY "C" COUNTRIES: $40 **(All other countries)**

STUDENT AFFILIATE: ALL: $25
(Send with this form: name, address, phone number of college, Major Professor, and expected date of graduation)

Charitable Donation

The following are deductible as charitable contributions in money or property (but not the value of your time or services) to domestic organizations operated exclusively for religious, charitable, scientific, literary, or educational purposes or the prevention of cruelty to children or animals; domestic fraternal organizations if the gifts are to be used exclusively for religious, charitable, scientific, etc., purposes; veterans' posts and organization; federal, state, or local governments if the gift is made exclusively for public purposes; qualified private organizations engaged in fostering natural beauty; or nonprofit cemetery and burial companies. ICP, when approached by a contributor contemplating a gift or donation, should request a specific purpose for that gift or donation, which could be either a gift or donation to the general fund or a specific project. When accepted, a letter acknowledging the gift or donation shall be written by the President, or at the Presidents' discretion, the Treasurer.

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Email: drjerrygamache@bellsouth.net Telephone (904) 824-5668

PAYMENTS MAY ALSO BE MADE VIA PAYPAL AT ICPWEB.ORG

Gifts to 501(c) 3 Organizations

From: Dr. Jerry Gamache, ICP Treasurer
To: ICP Board of Directors

Subj: Gifts to 501(c)3

Background: ICP operates as a IRS designated 501(c)3 tax exempt organization which means ICP does not pay federal income on revenue earned. Such designation allows dues or registration at ICP conventions to be tax deductible for the membership. However, ICP has no guidelines for accepting contributions or donations.

IRS Guidelines: The IRS guidelines are contained in the 2010 Individual Tax Return Form 1040 Instructions, paragraph 615, lines 16 – 19.

"The following are deductible as charitable contributions in money or property (but not the value of your time or services) to domestic organizations operated exclusively for religious, charitable, scientific, literary, or educational purposes or the prevention of cruelty to children or animals; domestic fraternal organizations if the gifts are to be used exclusively for religious, charitable, scientific, etc., purposes; veterans' posts and organization; federal, state, or local governments if the gift is made exclusively for public purposes; qualified private organizations engaged in fostering natural beauty; or nonprofit cemetery and burial companies.

For the taxpayer seeking deductions:

Unreimbursed expenses incurred in performing services for a charitable or governmental organization may also be deductible. This includes the cost of special uniforms, auto, travel expenses, and other actual expenses in doing volunteer work for a qualified organization. A taxpayer who uses his auto in performing services for a charity can deduct either his actual out-of-pocket expenses for oil, gas, etc., or a flat 14 cents a mile. Add parking and tolls to the amount you claim under either method. But do not deduct and amount that were repaid to the taxpayer.

Travel expenses, such as for transportation, meals, and lodging, incurred when a taxpayer is away from home performing services for a charitable organization are deductible, provided that there is no significant element of personal pleasure, recreation, or vacation in the travel. However, the fact that the taxpayer enjoys the service to the charitable organization, such as where a troop leader takes a youth group on a camping trip, will not cause the deduction to be denied. "

Discussion: ICP should adapt a policy regarding gifts or donation.

Suggestion: ICP, when approached by a contributor contemplating a gift or donation, should request a specific purpose for that gift or donation, which could be either a gift or donation to the general fund or a specific project. When accepted, a letter acknowledging the gift or donation shall be written by the President, or at the Presidents' discretion, the Treasurer.

FOR CONTRIBUTIONS TO SPONSOR THE ICP ANNUAL CONFERENCE, SEND PROPOSALS TO THE PRESIDENT, TREASURER, AND COORDINATING CONFERENCE CHAIR. INCLUDE:

1. Name of the organization and officers. Address and contact information
2. What aspect of the conference is to be supported: reception, program book, agenda book, conference bags, breaks, etc.
3. The logo for the organization.

LONG RANGE PLANNING

Dr. Janet Sigal

The Long Range Planning Committee (LRPC) is pleased to announce that ICP will have two meetings in 2012.

The first is the quadrennial symposium that ICP organized in cooperation with the International Congress of Psychology and IUPsyS in Cape Town, South Africa from July 22-27.

The Annual Conference and Board Meetings for 2012 will be held in Seville, Spain from September 10-September 14. Guidelines for presentation submissions for the Seville ICP scientific program are included in this IP52.1,

Plans are being made for a possible conference in Singapore in 2013. An exploration of meeting in St. Augustine, Florida is in-process. Work has begun for an ICP conference in Paris, France in 2014.

If you are interested in hosting an ICP conference in the future, please send the following information to Janet Sigal, email, Janet 2822@aol.com and Martin Butler, email, butlerpsych@cs.com.

GUIDELINES FOR HOSTING AN INTERNATIONAL COUNCIL OF PSYCHOLOGY ANNUAL CONFERENCE AND BOARD MEETING

The International Council of Psychology, Inc holds an annual scientific program and Board meeting each year. The conference host (local arrangements committee, coalition or proposal agents) must be a member of ICP,Inc. To establish the feasibility of submitting an application, a potential applicant might begin with an overview of some logistical issues for proposing a Congress venue:

Is there a conference venue to host at least 100 participants?
Are there sufficient hotel rooms close to the conference venue
Is there a scientific community to develop or sponsor the program?

How are Countries Selected?

If you believe your country/city/university would be appropriate for hosting an International Council of Psychology annual meeting, you may wish to submit an application. It is the IICP, Inc. Board of Directors that votes for the selection. Although it is hard to predict just what features of a proposal define the voting outcome, the Board typically takes the following items into account (the order of the items which are listed here is not necessarily in the order of importance):

Geographical Rotation among continents and countries attempts to guarantee broad geographical coverage, proximity to other major professional conferences, or in regions where psychologists may not have presented a scientific program previously.

The scientific community in the conference country is especially invited to participate in the scientific program.

Communication: There is a requirement for intensive and frequent communication between the Board President, Scientific Program Chair, Local Arrangements Chair, Workshops Chair, InAbsentia Student Posters Chair, and Awards Chairs.

Costs for participating in the Congress are another factor. The Board will expect that the registration fee will be reasonable, that there is a range of good hotel rates (particularly including inexpensive ones), and that travel costs can be kept as low as possible.

Despite efforts to keep costs low, travel is expensive for **young psychologists**, and for psychologists from the **developing world and transition countries**. It is therefore important to provide a plan that will guarantee special fees, housing, and support for those colleagues. This plan should be clearly outlined in the budget, including special provisions for ARTS programmes (by agreement, at least 30 ARTS participants are provided registration waivers).

A **balanced budget** needs to be provided in outline. It is important to show realistically how the income (registration fees and other) will cover your costs. It may be helpful to consult the preceding organisers of Conferences in drafting the budget. The budget is reviewed by the President and the Treasurer, who can offer advice.

The International Congresses of Psychology adhere strictly to the **ICSU principles of free circulation of scientists**. Provide evidence that any scientist, from whatever country, will be allowed to enter your country without special requirements (except for the regular passport and visa). Based on former bids, it is a good idea to include an official letter from your country's government, stating explicitly that your country adheres to the ICSU principles of free circulation of scientists

Timing

Before the next International Council of Psychologists (in 2012 Seville, Spain, September 8-14)

Submit a letter of intent to the Long Range Conference Planning Chair.
The finalised application file should be forwarded to LRCP Chair, ICP,Inc. President and Treasurer **several months ahead of the Conference meeting date.**

Dr. Janet Sigal

ICP, Inc., PROPOSAL

INTERNATIONAL COUNCIL OF PSYCHOLOGISTS **LONG RANGE CONFERENCE PR** **INITIAL PROPOSAL**

SITE AND YEAR OF PROPOSAL

Invitation

Rationale for Holding the Annual Meeting at this Site

Type the name[s] and contact formation of the person[s] submitting the proposal

Hotel and Lodging Information

Travel Information

Allied Association Conferences

ANNUAL CONFERENCE PROPOSED SCHEDULE

• • •

photos

INTERNATIONAL COUNCIL OF PSYCHOLOGISTS
Membership Application

ICP Treasurer: Dr. Jerry Gamache
8 Althea Street, St. Augustine, FL 32084
drjerrygamache@bellsouth.net

PLEASE WRITE "YES" IN FRONT OF THE CLASS OF MEMBERSHIP
FOR WHICH YOU ARE APPLYING
MEMBERSHIP STATUS IS REVIEWED BY THE ICP MEMBERSHIP COMMITTEE AND BOARD CONFIRMED

_____ **A MEMBER** is a psychologist or professional in an allied discipline field who (a) holds or is eligible to hold membership in a national psychological association affiliated with the International Union of Psychological Science (IUPsyS), or (b) meets comparable requirements in their discipline or in a particular country, as determined by the application review agent, and (c) has been actively engaged for a period of not less than two years prior to application for membership in professional work or study that is primarily focused on quality of life, wellness, and is psychological in nature.

_____ **A STUDENT AFFILIATE** is a graduate student or full-time undergraduate student actively working toward a degree or certificate in psychology or in an area of study involving major emphasis on psychological aspects of a related field of study.

PREFERRED TITLE: Dr ___Prof ___ Mr ___ Mrs ___ Ms ___ Other_____

Languages spoken_____

FULL NAME (Print)_____

PREFERRED MAILING ADDRESS (Print) Street or Post Box_____

City _____ State _____

Zip/Mail Code_____ Country_____

TELE Home_____ TELE Work_____
CELL PHONE_____FAX_____

E-MAIL_____WEB PAGE_____

HIGHEST APPROPRIATE DEGREE OR CERTIFICATE (Degree, Date, Major Subject, Institution, Location)

_____

OTHER DEGREES

_____

_____

Student Affiliate applicant—you must provide (1) the name and address of your university, (2) name and address of your major professor, (3) your anticipated degree or certificate, and (4) your anticipated date of graduation.

ENDORSERS: all applicants
If you are a member of a national psychological association affiliated with the International Union of Psychological Science (IUPsyS), and are endorsed by at least one current ICP Board Member and/or Area Chair, you do not need to provide any other endorsement than the typed full name of that endorser or endorsers on the application.2. Other applicants: Please ask two professional persons to sign as endorsers on the other side of this application, or have them send a letter of endorsement directly to the ICP Secretariat (address at the top of this page). These endorsers should be familiar with your training and/or experience in psychology, and should either be members of ICP or be recognized professional persons who can be identified by the Membership Application Processing Committee. (one or two)—Names, addresses, and EMAIL addresses

If endorsers are not available, please submit a complete curriculum vitae or resume with your application.

[continued on next page]

EXPERIENCE (Applicant's last 2 positions or last 10 years)—(Dates, Titles, Institutions or Companies, and Locations) Send CV or Resume

_____

_____

If your interest in ICP was encouraged by someone other than an endorser, please give the name(s)

_____

MEMBERSHIP(S) IN PROFESSIONAL SOCIETIES (Society Name, Admission Date, and Membership Class)

_____

_____

_____

_____

Your signature: _____

Name_____ Date_____

PAYMENT: The ICP Membership year is January 1 – December 31.

Country of residence determines dues category. Please write "yes" in front of one category.

_____CATEGORY "A" COUNTRIES OR AREAS: $100 (U.S. DOLLARS)
(Australia, Austria, Bahrain, Belgium, Brunei, Canada, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong, Iceland, Ireland, Israel, Italy, Japan, Kuwait, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Qatar, Saudi Arabia, Singapore, Spain, Sweden, Switzerland, Taiwan, United Arab Emirates, USA)

_____CATEGORY "B" COUNTRIES: $60 (U.S. DOLLARS)
(Antigua & Barbuda, Argentina, Bahamas, Barbados, Brazil, China, Croatia, Cyprus, Czech Republic, Iran, Korea, Malaysia, Malta, Mexico, Oman, Poland, Seychelles, Slovakia, Slovenia, South Africa, Suriname, Turkey, Venezuela, Yemen)

_____CATEGORY "C" COUNTRIES: $25 (U.S. DOLLARS) (All other countries)

_____STUDENT AFFILIATE: _____Category A: $25 US _____Category B: $25 US _____Category C: $25 US

APPLICATION AMOUNT DUE $_____

PAYABLE TO: INTERNATIONAL COUNCIL OF PSYCHOLOGISTS
See HTTP://WWW.ICPWEB.ORG for Credit Card & PayPal plus Background Form http://www.ICPWEB.ORG

Send Application and Payment or Confirmation of Payment To:

Dr. Gamache via Street or Email Address Given At Top Of Application

SEND CC OF APPLICATION TO:

Dr. Julia Rose, Vancouver House, 111 Hagley Road, Edgbaston, Birmingham B16 8LB United Kingdom or e-mail: rosejulia6@aol.com
Send Dr. Rose your completed background information form.

APPLICANTS: If you volunteer for a committee assignment (recommended) fill out the Committee Assignment Worksheet and submit with application form.

See next page for committee volunteer opportunities

[continued on next page]

Applicant Committee Assignment Worksheet

_____ I volunteer for the Committee assignment shown.

_____ Please send more information on the Committee assignment shown.

____ **Archives Committee**:
Committee Chair is liaison to and communicates with the Archives of the History of American Psychology at the University of Akron, Ohio. Information about AHAP is provided in the newsletter several times a year along with instructions for how members are to ship ICP records, older than three years to the Archives
.

_____**Area Chair**:
Area Chairs represent ICP, Inc. in a specified geographic region. Country or State Area Chairs are coordinated by the World Area Chairs Coordinator and submit reports twice a year to the WACC for publication in the newsletter and for an annual report to the President and Board. Disseminating information about ICP, Inc. conferences, recruiting members, and organizing regional meetings are typical activities of Area Chairs.

____ **Awards:**
Committee members issue calls for nominations in relevant newsletters and websites, solicit several candidates, review documents submitted, arrange certificates and stipends if provided, arrange for appropriate time allocations in the annual conference scientific program, prepare newsletter and regiona l announcements of recipients. In order of establishment by ICP, Inc.

___ **Distinguished Contributions and utstanding Service to International Psychology**. Frances Mulen Award [1986]
___ **Gender Research and Service**: Denmark-Grunwald Award
____**Early Career Research**: Bain-Sukemune Award [1996]
____ **InAbsentia Student Poster Exhibit and Awards**: Dayan-O'Roark-BarredaHansen-Comunian [2005]
____ **Latin Student Research Paper** presentation at Annual conference: Ernesto Gonzalez Rosales Alvarez / McCarthy Award [2009]
____ **Advanced International Research and Service**: Fukuhara Award [2011]

____ **Membership Committee**:
Committee Chair provides recruitment literature, records application information, updates contact data and membership details for newsletter Publication , and welcomes new members, Contacts non-continuing members and Provides statistics on membership constituencies to the President and Board. Committee members assist the Chair with recruiting and maintenance activities in their regions.

____ **Continuing Education:**
Committee members meet via telephone and e-mail to develop call for proposals for workshops for the annual scientific conferences. CE administers the necessary documentations for awarding continuing education credits. In addition to developing the ICP, Inc. World CE program, the American Psychological Association CE sponsor authorization is maintained or arranged with allied organizations..

____ **Finance Committee**:
Committee members review the annual budget and assist the Treasurer as requested. FC oversees and makes recommendations for ICP, Inc.'s financial investments and award programs. The FC audits the tasks of the Treasurer annually.

____ **Interest Groups:**
Interest Groups are formed to enable collaborations On topics of professional concern or research. Groups plan joint research and/ or program events for the annual scientific conference. Papers are presented in the International Understanding section of the newsletter.
Currently active groups are:

____ Creativity & Education [Milgram]
____ Forensic [Lowenstein]
____ Health (Pir)
____Peace and Human Rights[Neil]
____Religion & Spirituality[Rayburn]
____Women's Issues [Muhlbauer]

____ **Liaison Representatives**
Individuals who are members of professional associations other than ICP, Inc. submit articles to the Liaison Coordinator for presentation of information about that organization in the newsletter and submit ICP, Inc. information to the association in which they hold membership/represent.

____ **Long Range Conference Planning:**
Committee members solicit and review proposals for ICP, Inc. annual conferences 3 to 5 years in advance. Timing and sites are coordinated with major Professional congresses. LRCP presents completed proposals from the proposal submitters. Once a Local Arrangement Committee (LAC) is established, LRCP provides information and assistance. The LAC makes arrangements for meeting site, hotel information, tours, banquet, and promotional materials.

International Psychology Bulletin

Volume 15 No. 3 Summer 2011

Editor
Grant Rich

Associate Editors
Harold Takooshian
Richard Velayo

Official Bulletin of the Division of International Psychology [Division 52 of the American Psychological Association]
http://www.internationalpsychology.net

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Submission Guidelines for
Research Articles
International Psychology Bulletin

Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.

Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

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SUBMISSION DEADLINES
International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

Submission Deadlines: Spring issue March 31st

Summer issue June 30th

Fall issue October 15th

Winter issue December 15th

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Presidential Column

John D. Hogan, PhD
President, Division 52

I'm writing this column a day after returning from the annual APA Convention which was held this year in Washington, DC. I had the pleasure of meeting many of our members there, but I realize that other members could not attend. I want to take this opportunity to review some of the highlights of the meeting for everyone.

Board Meeting. We began with a four hour Board meeting on Wednesday, August 3, a day before the official opening of the Convention. Our officers and committee chairs had a chance to bring us up to date on all of their activities. Michael Stevens, our Treasurer, reported on our financial status. While our approach to division investments has been somewhat conservative, the volatile stock market has demonstrated that our approach is likely the wise one. Michael has been doing a wonderful job of overseeing our finances during his term as treasurer, and we are very grateful for his service. He will be succeeded in 2012 by Susan Nolan.

At the recommendation of Janet Sigal, the Board voted on and unanimously approved the creation of a new award for Early Career Psychologists (ECPs). We still need to work out the details but we hope the award will not only recognize the fine work of some of our younger members but also encourage other young members to join the division. Neal Rubin, our president-elect, has proposed a "heritage mentoring project" through which younger members will be paired with more senior members and encouraged to prepare biographical articles on outstanding international psychologists, both living and dead, for publication in the *International Psychology Bulletin.*

Joy Rice, a member-at-large of the division, handled all of the details regarding our recent member-approved change in the bylaws. The revision created a voting position on the Board for a student representative and designates one of the member-at-large positions for ECPs. During the Board meeting Joy was presented with the Denmark/Reuder Award which recognizes her great contributions to the division, particularly her work with mentoring and women's issues. Joy is a former president of the division and a former chair of CIRP. She co-authored the 2004 APA Resolution on Cultural and Gender Awareness in International Psychology.

Judith Gibbons, the founding editor of our new journal *International Perspectives in Psychology: Research, Consultation, Practice* brought us up-to-date on the journal which will publish its first issue in Spring, 2012. Judy has received more than 70 manuscripts, most of which are in the process of being reviewed. The board for the journal consists of 43 scholars with primary affiliations in 32 countries. Judy scheduled several sessions during the convention to advertise the journal and encouraged us all to get the word out.

Opening Ceremonies. The opening ceremonies for the convention were a particular treat because they honored one of the founding members of the division, Florence L. Denmark. Melba Vasquez, the current APA president, presented Florence with an award for "Lifetime Contributions to Psychology," APA's highest honor. Florence has been involved in all aspects of the division since its founding, including serving a term as president. In 1980, she was also president of APA. We recognized Florence during the award ceremonies in our suite and thanked her for all that she has done for the division and for many of us individually.

Division Programs. Senel Poyrazli and Mark Terjesen were co-chairs of the program for this year, with Senel focusing primarily on the "regular" APA program and Mark focusing on the suite programs. By all accounts, the programs were successful in every way, with scholarly and provocative presentations, lively conversation, and good attendance. The management of the program is often the hardest part of any convention and we are very grateful for Senel and Mark for their good work. It seems likely that next year, we will be allotted even fewer program hours by APA as there will be an across-the-board revision in division hours. All the more reason, it seems to me, for us to focus on the excellent suite programs that we have developed in the past. They often provide a greater opportunity for presenters and fellow psychologists to share information. This year we also used our suite to present many of our division awards -- which are listed elsewhere in the International Psychology Bulletin -- and to sponsor a breakfast for our new fellows.

Business Meeting. As usual, we held our business meeting on Saturday morning of the convention. It was a good opportunity to meet many of our members and to hear brief reports from our officers and committee chairs. Neal Rubin, our president-elect, had the last word at the business meeting. He outlined some of his plans for next year, including the

strong possibility of our having a joint mid-winter meeting in February, 2012, with the Society for Cross-Cultural Research in Las Vegas. Toward the end of the meeting, I presented presidential certificates to Lynette Bikos, Senel Poyrazli, Mark Terjesen, and Michael Stevens for their many and varied contributions to the division.

I can't end a discussion of the meeting without thanking Ayse Ciftci for her wonderful efforts to keep us organized and on track, Harold Takooshian for all of the invaluable "behind the scenes" work that he does, Rivka and Michael Meir for their sumptuous "catering service," and Rivka (again!) and Artemis Pipinelli for making such an effort to recruit new members during the meeting.

As you can see, it was a wonderful convention! In my effort to be brief, I've left many important contributors off this list. But I send my great thanks to all the officers and committee chairs for their contributions to the continued success of our division. I'm grateful to you all!

John D. Hogan, PhD
Professor, Dept. of Psychology
St. John's University
Queens, NY 11439

Forthcoming in the Fall Issue of International Psychology Bulletin Scenes from the APA Convention

If you would like to take a sneak peak at APA photos, they appear at www.picasaweb.com/takoosh courtesy of Harold Takooshian.

D52@WPA 2011

Amongst the 2200 attendees, 35 major addresses, and 21 poster sessions, *International Psychology* was well-represented at the 91st Annual Convention of the Western Psychological Association (April 28 – May 1, 2011). In addition to a poster session with 50 posters having international content, there were 17.5 hours of symposia and papers.

Among the major addresses, Gaithri Fernando, Ph.D., of California State University, Los Angeles spoke on intimate partner violence as a global mental health priority. Additionally, Michael Harris Bond, Ph.D., of Hong Kong Polytechnic University gave an address titled, *Unweaving the Rainbow of Culture for Psychology.*

D52 was actively promoted at the convention. Division members and student affiliates distributed business cards, promotional stickers, and membership applications, encouraging internationally focused presenters and attendees to visit the division's website and join. The promotional stickers were designed by clinical psychology doctoral student Kim Huynh, M.A., Seattle Pacific University.

After Saturday's programming, D52 members joined the International Council of Psychologists at the Bonaventure Brewing Company in downtown Los Angeles for dinner and conversation. The event was arranged by Tara Pir, Ph.D.

The 92nd Annual Convention of the Western Psychological Association will be held in San Francisco-Burlingame, April 26 – 29, 2012. If you are interested in presenting as part of the international program, please use the WPA Call-for-Paper submission process and select *International Psychology* from one of the "topic" areas listed within the on-line submission process. Instructions for on-line submission can be found at the WPA website (http://www.westernpsych.org/convention/index.cfm).

Respectfully submitted,

Lynette H. Bikos, Ph.D.
D52 Western Region Outreach Chair
Associate Professor of Clinical Psychology & Director of Research
Seattle Pacific University

Steven R. Lopez, from the University of Southern California chaired the symposium, Four Research Reports from a Summer Research Training Program on Latino Mental Health in Puebla, Mexico.

Doctoral students from Seattle Pacific University present results of their longitudinal assessment of international immersion learning experiences during the international poster session.

Faculty and graduate students from the International Immersion learning Experiences in Higher Education symposium discussed research results and best practices.

Jason Platt, Ph.D., Linna Wang, Ph.D., and Tatiana Glebova, Ph.D., challenged participants to think about concepts such as patriotism, liberation, and the validity of psychologies.

Members of the International Council of Psychologists congregate before the ICP/D52 joint dinner.

The symposium, Threats to Family Wellness in Immigrant Communities: Hopes and Challenges, was chaired by Marcel Soriano, Ph.D., from California State University, Los Angeles.

Tara Pir, Ph.D., and Lynette Bikos, Ph.D., preside over the ICP/D52 joint dinner at Bonaventure Brewing Company in downtown Los Angeles.

Graduate students converse about international interests at the ICP/D52 joint dinner.

Sherri McCarthy, Ph.D., Tara Pir, Ph.D., and Lynette Bikos, Ph.D., converse before the ICP/D52 gathering.

Attendees at the ICP/D52 dinner place their orders.

ICP and WPA members, graduate psychology students, and their guests gather for a picture at the ICP/WPA conversation and dinner.

APA Division 52 'Ursula Gielen Global Psychology Book Award' (2012)

The mission of Division 52 is to advance psychology internationally as a science and profession, and through education and advocacy. In support of this mission, the Ursula Gielen Global Psychology Book Award is presented to the author(s) or editor(s) of a recent book that makes the greatest contribution to psychology as an international discipline and profession, or more specifically, the degree to which the book adds to our understanding of global phenomena and problems from a psychological point of view. Examples include psychological interventions at the micro- and macro- levels, multinational organizations, questions of mental health, pedagogy, peace and war, gender roles, contributions of indigenous psychologies to global psychology, textbooks that integrate theory, research and practice from around the globe, edited volumes integrating contributions from scholars around the world, and overviews of international and global psychology.

Inclusions and Exclusions

Nominations may include authored or edited volumes in any language. All submissions must be accompanied by a 2-page letter in English making a case for the book's potential contribution to global psychology. Copyright must be 2010. Nominations may not include fiction and biographies.

Specifics of the Award

Winners will be announced in early 2012, presented with a certificate, and invited to give an address at the August APA 2012 Convention in Orlando, FL. They will receive one full payment of the convention fee and a stipend of $500 to help fund their attendance at the convention.

Criteria

In judging the contribution of each book, the following set of guidelines will be used:

1. How creative and novel are the ideas expressed in the book?
2. How large and significant a contribution does the book make to psychology as a global discipline and profession?
3. Are the book's contents international or global in nature?
4. Is the book scientifically rigorous and logically sound? Are its theoretical bases well supported and translatable into sound and ethical practice?
5. What is the literary quality of the work? Is it interestingly and well written? Is the audience for whom it is written explicitly stated and does it reach that audience?
6. Does the book maintain a clear focus on psychology as a science and practice?

Procedures

All nominations, accompanied by the 2-page letter, and three copies of the book, must be made by October 1, 2011, and sent to:

Renée Goodstein, Ph.D.
Chair, Ursula Gielen Global Psychology Book Award
Psychology Department
St. Francis College
180 Remsen Street
Brooklyn, NY 11201
USA
(718) 489-5437
e-mail: rgoodstein@stfranciscollege.edu

About Ursula Gielen:

Ursula Gielen (1916-1997, Germany) was vitally interested in the well-being of indigenous, persecuted, and poor people around the world, with a special emphasis on women and children. Her legacy and commitment to international concerns and human welfare continues through her children: Ute Seibold, a former foreign language secretary in Switzerland; Uwe Gielen, an international psychologist in the United States; Odina Diephaus, a former interpreter with the European Parliament in Belgium and France; and Anka Gielen, a counseling psychologist in Germany.

Committee Members:

Renée Goodstein, Ph.D., Chair
Florence L. Denmark, Ph.D.
Juris G. Draguns, Ph.D.
Michael J. Stevens, Ph.D.
Harold Takooshian, Ph.D.
Uwe P. Gielen, Ph.D. (ex officio)

Ursula Gielen Book Award Winners

2008: *Families Across Cultures: A 30-Nation Psychological Study*. Editors: James Georgas (University of Athens, Greece), John W. Berry (Queen's University, Canada), Fons J. R. van de Vijver (Katholieke Universiteit Brabant, The Netherlands), Cigdem Kagitcibasi (Koc University, Turkey), and Ype H. Poortinga (Katholieke Universiteit Brabant, The Netherlands).

2009: *Culture and Leadership Across the World: The GLOBE Book of In-Depth Studies of 25 Societies*. Editors: Jagdeep S. Chhokar (Indian Institute of Management, India), Felix C. Brodbeck (Aston University, UK) and Robert J. House (University of Pennsylvania, USA).

2011: *International Handbook of Cross-Cultural Counseling: Cultural Assumptions and Practices Worldwide*. Editors: Lawrence H. Gerstein (Ball State University, USA), P. Paul Heppner (University of Missouri, USA), Stefanía Ægisdóttir (Ball State University, USA), Seung-Ming Alvin Leung (The Chinese University of Hong Kong), and Kathryn L. Norsworthy (Rollins College, USA).

LEAVING A LEGACY

TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

New Fellows in International Psychology: The Class of 2011

In 2011, eleven psychologists were elected as Fellows of the Division of International Psychology, based on their "unusual and outstanding contributions to international psychology." Six of these were elected as new Fellows of APA, and five current APA fellows were elected by the Division. APA fellows represent about 5% of all APA members. According to APA, "Fellow status requires that a person's work has had a national impact on the field of psychology beyond a local, state, or regional level. A high level of competence or steady and continuing contributions are not sufficient to warrant Fellow status. National impact must be demonstrated." The three-person D52 fellows committee for 2011 is **Kurt F. Geisinger, Senel Poyrazli, Harold Takooshian** (Chair).

William Roberts Herkelrath, PhD,
Dean (ret.), College of Social and Behavioral Sciences, Northwest University, Kirkland, WA

Samvel Sergei Jeshmaridian, PhD,
Professor and Chair, Department of Human Services, Technical Careers Institute, New York City

Tahereh Pirhekayaty, PhD, (Tara Pir, PhD),
Founder and CEO of the Institute for Multicultural Counseling & Education Services, Inc., Los Angeles CA

Grant Jewell Martinez Rich, PhD,
Assistant Professor, University of Alaska Southeast, Juneau, and the Editor of the APA *International Psychology Bulletin*

Mihaela Robila, PhD,
Associate Professor of Family Studies, CUNY Queens College

Nancy Marie Sidun, PsyD, ABPP, ATR,
Chief/ Supervising Clinical Psychologist and Director of Clinical Training, Kaiser Permanente-Hawaii

Armand R. Cerbone, PhD, ABPP,
Private Practice, Chicago, Illinois

Itamar Gati, PhD,
Samuel and Esther Melton Professor, Departments of Education and Psychology, Hebrew University of Jerusalem

Lawrence H. Gerstein, PhD,
Professor of psychology, and Director of the doctoral program in counseling psychology, and Center for Peace and Conflict Studies at Ball State University

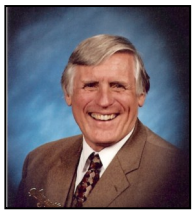

J. Jeffries McWhirter, PhD, ABPP,
Professor Emeritus of Psychology in Education, Arizona State University

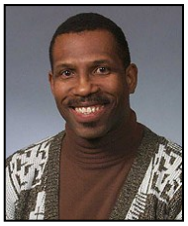

Frank C. Worrell, PhD,
Professor and Associate Dean, Academic Affairs, Graduate School of Education, UC Berkeley

Additional Biographies for the Six "Initial" APA Fellows in 2011

By Harold Takooshian

Samvel S. Jeshmaridian, PhD

Samvel Jeshmaridian's outstanding contribution to international psychology is as a multilingual scholar, teacher and researcher who has emerged as a go-to expert within APA and its International Division--to bridge U.S. psychology with the indigenous psychologies of Europe and Asia. Since his first psychology degree in 1974 in the USSR, his career has transitioned thrice: (1) first as a unit chief within the prestigious USSR Academy of Sciences during the Soviet era of the 1980s; (2) after 1991, in the post-Soviet era, he segued to consulting work in the beleaguered Republic of Armenia; (3) since 2005, he made the challenging transition to psychology in the USA, where he is now Professor and Department Chair at Technical Careers Institute (TCI) in New York City.

Dr. Jeshmaridian is long regarded as an authority in cross-cultural psychology, whose cross-national research has been supported by a series of competitive awards—an IREX Scholar (1993-4), Open Society Scholar (1994), Senior Fulbright to the USA (1996-97), and George Kennan Scholar (2005). As a researcher, he authored 90 publications in 5 languages, and offered 65 presentations at international and other conferences—about half of these on cross-cultural and international themes. As a teacher, he is a popular lecturer who has taught at 7 institutions in the USA and overseas, using his multilingual skills to develop syllabi that are noted for their cross-national concepts and research. As our APA International Division works to internationalize psychology, Dr. Jeshmaridian has been invaluable—as a generous consultant and reviewer.

William R. Herkelrath, EdD

William Herkelrath completed his MA in pastoral counseling in 1977 at Gordon Conwell Seminary, and his EdD in counseling psychology in 1982 at Boston University, with later certification from Harvard (2006). Over the past 25 years, his two outstanding international contributions have been his (1) skilled cross-national work to design culturally relevant programs for health care for the poor, and (2) innovative blend of photography with psychology to promote social justice.

From 1978-now, Dr. Herkelrath has held a variety of positions in six institutions as a therapist, professor, department chair and, since 2007, Dean of Social and Behavioral Sciences at Northwest University in Kirkland, WA. The 15 college and graduate courses he has developed are known as a model for integrating two strong themes of culture and social justice. Since 1999, he has organized outreaches to meet the needs of the poor in Brazil (with Evangemed Ministries, Project Brazil), then in India since 2008 (with Mercy Hospital, Darjeeling University)—training counselors and designing delivery systems to aid abused children and adolescents in urban Calcutta and rural villages in India.

In 2002 Dr. Herkelrath founded the Bainbridge Institute, with the innovative mission to promote social justice through photography and multi-media. In his travels across six continents, he has taken powerful documentary photographs of diverse communities, and used these to promote social justice themes, through conferences and exhibitions with the APA, schools, and museums world-wide. With other like-minded psychologist-photographers, he recently formed "Psychologists in Focus" to advance this unusual approach to psychology advocacy, to promote social justice cross-nationally.

Tahereh Pirhekayaty, PhD

After completing her BA (1970) and MA (1977) in Tehran, Dr. Tara Pir completed her PhD in clinical psychology in 1985 at Alliant International University, with later certifications in psychology, CBT, behavioral medicine. Since 1985, she has developed a stellar career as a multilingual teacher, researcher, administrator, and award-winning expert in the areas of multicultural counseling (within a nation) and cross-cultural counseling (across nations).

Since 1989, Dr. Pir has been the founder and CEO of IMCES—the Institute for Multicultural Counseling and Education Services--her pioneering international center based in Los Angeles. With government and private funding, IMCES has emerged as a model for many other organizations, on how to apply her PEI (Prevention and Early Intervention) approach to the multiple needs of ethnic communities that eschew counseling—working with courts, police, health care and family centers. Dr. Pir has become a "go-to" expert on this, with over 20 elected or appointed leadership roles in government (Los Angeles Dept. of Mental Health) and psychology (international Council of Psychologists). Her IMCES is now a registered NGO with the United Nations, and offers APA-approved internships. Dr. Pir has been an organizer and keynote speaker at global conferences in eight nations, and recently published her approach to multi-cultural counseling in the *Counseling Psychology Quarterly* (2009). She has been President of the Iranian-American Psychological Association (2005-2007), a regular contributor on mental health topics for the Farsi magazine Janavan, and producer of a federally-funded PSA on this topic. One of Dr. Pir's colleagues noted that he has followed her work for 25 years, and "can think of few people who qualify as clearly" for APA fellow status.

Grant Rich, PhD, NCTMB

Grant Rich completed his interdisciplinary PhD in psychology: human development in 2001 at the University of Chicago, combining anthropology and psychology. Since then he quickly immersed in pioneering work in cross-cultural psychology--as an innovative teacher, prolific author and editor, crossing the fields of psychology, anthropology, and regional studies.

Among his diverse array of 120 publications from 2001-2009--articles, chapters, book reviews, and essays--five publications stand out: (1,2) His much-cited special issues on "positive psychology" in the *Journal of Humanistic Psychology* (2001) and *Journal of Youth and Adolescence* (2003); (3,4) his two special issues for the American Anthropological Association, on "Consciousness and the body" (2000), and "Altered states of consciousness" (2001); and most of all, (5) his volume on "*Massage therapy – The evidence for practice*" (Elsevier, 2002), which received high praise from reviewers, including Harvard Medical School, as a unique data-based review of the field of massage. Given the unusual breadth of his expertise in cross-cultural psychology, he is a much-sought reviewer for over 20 journals, book publishers, and professional associations.

As a teacher, Dr. Rich has taught at several institutions, from Maine to Alaska. He has used his cross-cultural work in many nations (including NEH-funded work on the "Tropical Atlantic" and on "Maya Worlds" in Central America), to develop syllabi for five new cross-cultural courses that meld psychology with anthropology and cultural studies.

In his service, Dr. Rich has been generous as a volunteer to his community in the USA and overseas, and to his profession. Based on this fine work in D52, he was unanimously selected for a three-year term for the key post as the incoming Editor of the Division's International Psychology Bulletin in 2010, a role he has performed with distinction.

Mihaela Robila, PhD, CFLE

Mihaela Robila completed her BA in Bucharest in 1997, PhD in Syracuse in 2002, and two postdocs in 2002-2003 at Tufts University and Tulane Medical School. In fewer than 10 years, she has emerged with an award-winning career as a multilingual teacher, researcher, and international authority on the increasingly important topic of immigrant families.

Her work with immigrant families is outstanding at several turns: (a) her two pioneering volumes on "Families in Eastern Europe" (2004) and "Eastern European Immigrant Families" (2009); (b) 22 oft-cited publications on this topic, 15 of these in refereed journals; (c) 60+ research presentations, many of these at global conferences; (d) service as a reviewer for 12 journals and on the editorial board of three others; (e) grant reviewer for several groups, including NSF and NIH; (f) 12 research/teaching grants, including major funding from the U.S. State Department and the Spencer Foundation.

Dr. Robila is now sought out as a consultant on immigration at the highest level, by United Nations and U.S. government policy-makers. Her rare combination of clinical training and expertise on the psychology of immigration promises to have an increasing and positive impact on data-based immigration policies.

Nancy M. Sidun, PsyD, ABPP, ATR

Nancy Sidun's contributions to international psychology are impressively diverse. Since completing her doctorate in 1986 at Argosy-Illinois, she served at six institutions as a researcher, teacher, practitioner, consultant, department head, and even interim President (of Argosy University-Honolulu in 2003). Her 24 years as a clinical director of multicultural programs in Chicago, then Hawaii, led her to develop leadership roles as a go-to expert on a few related and pressing cross-cultural issues: increasing diversity in clinical training, international adoptions, child sexual abuse, and now human trafficking.

Dr. Sidun effectively combines multiple leadership roles to address these cultural issues above: (a) As a researcher, she offered 51 conference presentations (2001-2010), and 9 publications (1997-2010), 8 of these as first author. (b) As a teacher who headed 4 graduate programs, she pioneered innovative curricula to increase cultural diversity and address emerging issues in sexual abuse and human trafficking. (c) As an administrator, her many roles include Chair of the APA Committee on Women in Psychology (2009-2012), co-founder of the D52 Task Force on Human Trafficking. (d) As an expert consultant on cultural issues, she worked with several policy groups in Illinois, Samoa, China (the Half the Sky Foundation, since 2001), Hawaii (for Governor Linda Lingle in 2007-08), and chaired 4 APA site visits (2006-07).

Congratulations Fellows!

International Psychology Awards for 2011

Since its origin in 1997, the APA Division of International Psychology has presented a growing number of awards for outstanding cross-cultural and international work. A list of past awardees appears at www.internationalpsychology.net. For 2011, five committees of independent reviewers carefully selected honorees, who received their awards at the 119th APA meetings in Washington DC in August of 2011. **

Outstanding International Psychologist (in USA)

Michael J. Stevens, PhD, DHC,
Illinois State University, & The Lucian Blaga University of Sibiu

Outstanding International Psychologist (outside USA)

Narasappa Kumaraswamy, PhD,
University Malaysia Sabah

Florence L. Denmark/Mary E. Reuder Gender Award

Joy K. Rice, PhD,
University of Wisconsin-Madison

Henry P. David International Mentor Award

Lawrence H. Gerstein, PhD,
Ball State University

Tahereh Pirhekayaty, PhD, (Tara Pir, PhD),
IMCES Institute, Los Angeles CA

Harold Takooshian, PhD,
Fordham University

Ursula Gielen International Book Award

Lawrence H. Gerstein, PhD,
Ball State University,

P. Puncky Heppner, PhD,
University of Missouri-Columbia,

Stefanía Ægisdóttir, PhD,
Ball State University,

Seung-Ming Alvin Leung, PhD,
Chinese University of Hong Kong

Kathryn L. Norsworthy, PhD,
Rollins College

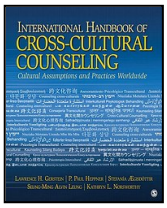

International Student Research Award

Elena S. Yakunina, MA,
University of Akron

R. Eric Lewandowski, MS
Teachers College, Columbia University,

Joseph C.S. Siu, MCS, MSW,
California School of Professional Psychology, Alliant International University-Hong Kong

*** The Division is grateful to all of the many independent judges who shared their expertise, and the chairs of these five international award committees: **Danny Wedding** (outstanding psychologists), **Joan C. Chrisler** (gender), **Renee Goodstein** (book), **Mercedes A. McCormick** (mentors), **Sheila J. Henderson** (student research).*

Psychology in 70 Languages

Sielkunde 1 PSIKOLOGJI 2 የሥነ ፡ ልቡና ፡ ትምህርት 3 علم النفس 4

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Psychologie 17 Psychology 18 Psikolog 19 Psühholoogia 20

Sikolohiya 21 Psykologi 22 Psychologie 23 Psychologie 24

Ψυχολογία 25 ფსიქოლოგია 26 ,ન૦મનો 27 Ka ike e pili ana i ka uhane o kanaka 28

פסיכולוגיה 29 साइकोलोजी 30 Psikologia 31 Sálarfræði 32

Psikologi 33 Síceolaíocht 34 Psicologia 35 心理學 36

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KEY: 1. Afrikaans 2. Albanian 3. Amharic 4. Arabic 5. Armenian 6. Belarusan 7. Bengali 8. Breton 9. Bosnian 10. Bulgarian 11. Burmese 12. Catalan 13. Chinese 14. Croatian 15. Czech 16. Danish 17. Dutch 18. English 19. Esperanto 20. Estonian 21. Filipino (Tagalog) 22. Finnish 23. French 24. Georgian 25. German 26. Greek 27. Gujarati 28. Hawaiian 29. Hebrew 30. Hindi 31. Hungarian 32. Icelandic 33. Indonesian 34. Irish 35. Italian 36. Japanese 37. Khmer 38. Korean 39. Loa 40. Latin 41. Latvian 42. Lithuanian 43. Macedonian 44. Malay 45. Maltese 46. Mongolian 47. Norwegian 48. Pharsee (Farsi) 49. Polish 50. Portuguese 51. Romanian 52. Russian 53. Sanskrit 54. Serbian 55. Slovenian 56. Somali 57. Spanish 58. Swahili 59. Swedish 60. Tagalog 61. Thai 62. Tibetan 63. Turkish 64. Ukrainian 65. Urdu 66. Vietnamese 67. Welsh 68. Yiddish 69. Zulu 70. Galician

The International Division of the American Psychological Association salutes the International Council of Psychologists on its 70 years of service to psychology, 1941-2011.

Credits to: *Carolyn Bauer, Rivka Bertisch Meir, Samvel Jeshmaridian, Ann O'Roark, Grant Rich, Harold Takooshian, and Richard Velayo*

International Liaison Column

This debuts a new column that highlights the Division's liaisons. The purpose is to encourage professionals and students to belong as a liaison without the need to become a full APA member, receive our bulletin, and have the possibility to interact with psychologists from all over the world. It is anticipated that three new liaisons will be featured in each issue of the International Psychology Bulletin.

International psychology liaisons now link our Division 52 with psychology representatives in 87 nations. A complete PDF roster appears at www.itopwebsite.com/moreIP/International_Liaisons.html. Contact me for any details or revisions, **Rivka Bertisch Meir, Ph.D., M.P.H.,** Chairperson, International Liaison, winsuccess@aol.com.

1. **AFGHANISTAN**, Said Hashemi, Said_Hahsemi@yahoo.com
2. **ANGOLA**, Vera Matos, Ph.D., vermatos@gmail.com
3. **ARMENIA**, Vladimir Mikaelyan, v_mikaelyan@mail.ru
   Khachatur Gasparyan, gasparyk@childpsych.columbia.edu
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Peer-Reviewed Research Article

Trust in Social Institutions: Comparisons between the Chinese, American, and Canadian Populations

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This research explored predictions derived from cross-cultural research regarding the amount of trust citizens of one country have in other countries. Participants from Canada, China, and the United States were asked the degree to which they trusted institutions from their home country and other countries. Results were largely consistent with cross-cultural research, such that the Chinese trusted their own country but did not trust the Western countries; and Canadians trusted Americans, and such trust was reciprocated to Canadians from Americans. Findings are discussed relative to cross-cultural theories and social identity theory.

Key Words: Trust, Chinese, Canadian, American, institutions, cross-cultural

Given the importance of trust to international diplomacy, travel, and commerce, whether citizens of one country are trusted by others is an important issue--trust was a central issue during the Cold War (Kydd, 2005), and it still plays a critical role today in nearly every aspect of international relations (e.g., Li, 2007). However, because individual countries differ in their values and philosophy, the manner in which citizens of different countries build trusting relationships on a national or international basis may heavily depend on each country's specific psychology (Doney, Cannon, & Mullen, 1998).

Trust is defined as the "assurance of not being exploited" during a social interaction (Kelley & Thibaut, 1978, p. 232). Trust is critical for the fulfillment of obligations of a social exchange, and as such, as critical for the development of successful social relations (Blau, 1964). In international relations, trust in other nations is vital to successful international relations (Larson, 1997), particularly given the interdependence of the modern world (Doney et al., 1998). Trust in other nations reduces conflicts (Anderson & Narus, 1990) and cultivates successful strategic alliances (Browning, Beyer, & Shetler, 1995). At home, trust in other nations affects opinion about international relations: trust in other nations affects opinions regarding the presence of military forces in other nations (Brewer, Gross, Aday, & Willnat, 2004), voting behavior (Aldrich, Sullivan, & Borgida, 1989), and even overall foreign policy (Page & Shapiro, 1992). Conversely, trust in one's own nation similarly affects international relations (e.g., Lühiste, 2006).

The presence or absence of trust for another nation not only manifests itself in trust between governments (Larson, 1997), but also between the people and institutions. Numerous theorists have posited that it is the nation's culture that defines the peoples' propensity to trust other countries or peoples. Fukuyama (1995), for example, argued that the trust within a society is shaped by that society's culture, whereas Doney et al. (1998) similarly argued that a nation's culture influences how trust is developed in one country versus another (see also, Newton, 2001).

The nationality of the truster is one of the factors that affect trust in others, just like other demographic and socioeconomic variables, including gender, age, socioeconomic status (Niu & Rosenthal, 2009). One variable important for understanding whether citizens of one country will trust another is individualism versus collectivism (Hofstede, 1991; Triandis, 1995). According to Hofstede (1991), individualism is defined as a society's orientation that the individual is a unique entity with loose connections to the group. Individualistic cultures tend to be found in Western cultures (e.g., United Kingdom, United States, Canada; Hofstede, 2001). Alternatively, collectivism stresses an individual's place in a structured relational network and the interpersonal bonds within the network. Collectivistic cultures tend to be found in Eastern culture (e.g., Japan, China, South Korea; Hofstede,

2001). In support of this distinction, research indicates that collectivistic cultures depict ingroups as a complex network of interrelated individual members (Ho, 1993; Hwang, 1999; Lebra, 1976), but individualistic cultures emphasize the group's categorical, depersonalized nature (Prentice, Miller, & Lightdale, 1994; Seeley, Gardner, Pennington, & Gabriel, 2003).

Such cultural orientations indicate different foundations for trusting others. Yuki and colleagues (Yuki, 2003; Yuki, Maddux, Brewer, & Takemura, 2005) posit that for individualistic cultures, trust is heavily grounded in extant distinctions between categories between the ingroup and outgroup, in which trust is given to ingroup members but not outgroup members. For collectivistic cultures, however, trust is affected strongly by relationship networks. In this way, trust is greatest toward those with whom one shares a direct or indirect personal connection, independent of group categorization. There is considerable evidence to support such distinctions. First, ingroup bias based on categorical distinctions is stronger in individualistic societies than in collectivistic societies (Bond & Hewstone, 1988; Bond, Hewstone, Wan, & Chiu, 1985; Heine & Lehman, 1997). Second, in individualistic cultures, people who share one's group membership are perceived to be trustworthy (Yamagishi & Kiyonari, 2000), and trusting behavior is directed toward members of one's group more than the outgroup (Tanis & Postmes, 2005). Third, Yuki et al. (2005) found that in collectivistic cultures, trust was influenced by the presence of a relational connection with an outgroup target, but not by perceived categorical information. Fourth, Hu (2007) found that in collectivistic cultures, trust in business settings is grounded in adherence to social norms and obligations, whereas in individualistic cultures, trust is more heavily dependent on individuals' competence and overall performance (see also McAllister, 1995).

Present Study

To test cultural differences in trust propensity in different countries, trust data were collected from three countries: the United States (an individualistic country; Hofstede, 2001), Canada (an individualistic country), and China (a collectivistic country). To measure trust across different cultures-- but to maintain the same definition of trust-- Hardin's conceptualization of social trust was utilized (Hardin, 2001, 2002), which defined trust as the public's belief that institution will do what is "right." Four social subsystems (academic institutions, businesses and companies, the law and legal system, and mass media institutions) were selected as the focus of trust, and participants in the three countries were asked their degree of trust for the three nations of interest.

Predictions

With respect to trust for Canadians and Americans, trust was expected to follow categorical information regarding participants' own country relative to other countries. Interestingly, Americans see a strong differentiation between themselves and Canadians (e.g., Davies, Steele, & Markus, 2008); but for Canadians, such strong categorical differentiation does not always hold. The permeation of American media, culture, arts, and history has led to a minimization and attenuation of categorical differentiation for Canadians, such that strong differentiation occurs primarily under conditions of threat (e.g., Lalonde, 2002). As such, it was hypothesized that Americans will not trust Canadian institutions, but it was expected Canadians would trust American institutions.

With respect to China, the degree of trust was hypothesized to be dependent on the degree and presence of a relational network. An era of isolationism has left the Chinese people's personal connectedness with Western cultures at a minimum; and as a consequence, it has reduced international travel, contact, and engagement with Western cultures, in particular (Brown, 1976; Levine, 1989; Yahuda, 1984). Despite growing interconnectedness with the West over the past 20 years, there are still substantial hurdles to leap before increased interdependence and strong interpersonal bonds are pervasive (Peng, 2003; Yeung, 2006). As a result, it was expected trust in China would be high for their own nation (where personal connections are present), but would be lower for the United States and Canada, in which relational networks are at a minimum.

Method

Participants

There were 369 individuals (185 men, 184 women) recruited to participate in the study. Participants' ages ranged from 18 years to 75 years old, with an average age of 33.44 (SD = 5.32). Participants were recruited in Canada (greater Ottawa area, Province of Ontario), China (Kunming city in Yunnan province) and the United States (greater Boston area, State of Massachusetts). Only those participants who stated that they were born in the Canada, China, or United States, respectively, were used in the analyses. The sample was nearly equally divided between three countries: 127 were recruited in the United States (M_{age} = 34.46), 122 from Canada (M_{age} = 32.05), and 120 from China (M_{age} = 33.54).

Procedure

As part of a larger study on individuals' attitudes toward international relations, researchers approached potential participants in one of several public places (e.g., cafeteria, café, tea-shop, public library). To assess participants' trust in various social institutions, participants were asked to estimate their belief that different social institutions (academic institution, business/company, law and legal institution, and mass media) would "do what is right regarding an international issue." Participants indicated their response on a 1 (*strongly distrust*) to 7 (*strongly trust*) scale. Participants completed these questions for three target countries: the United States, China, and Canada. To avoid order effects, the order in which the different target countries were presented to participants was counterbalanced. After completing these questionnaires, participants were thanked and dismissed.

Results

Given the high correlation among the four social institu-

tions (r's ≥ .80), the analysis began by averaging the scores to generate one score for each target nation. Next, to ensure that trust scores could be compared across countries, responses within each country were standardized (van de Vijver & Leung, 1997; Leung & Bond, 1989). T scores were computed using the equation, T = (X − M) / S, in which X was the score to be standardized, and M and S were the mean and standard deviation of the corresponding country. Standardization of the scores eliminated cross-country differences in grand means and standard deviations eliminated unwanted sources of error, such as methodological artifacts (i.e., response sets; van de Vijver & Leung, 1997).

Reliability

The reliability of the trust assessments using standardized scores across the three host countries was acceptable: Beside one value (American's trust in American institutions, α = .62) all alphas ranged between .71 and .84.

International Trust

The data for trust were subjected to a 3 (host nation) × 3 (target nation) ANOVA. Figure 1 illustrates the means for trust for host nation by target nation. Higher standardized scores indicate a greater level of trust. The main effect for host nation was significant, $F(2, 366) = 38.57$, $p < .05$; but the main effect for target nation was not, $F(2, 732) = 0.01$, $p = .99$. The expected Host Nation × Target Nation interaction was significant, $F(4, 732) = 40.11$, $p < .05$, and was explored using contrasts by host nation.

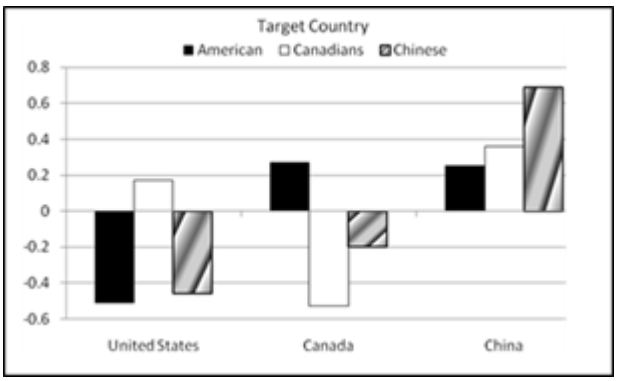

Figure 1. Patterns of within-nation standardized trust in social institutions as a function of target and host country.

China. The simple effect for target nation was significant, $F(2, 238) = 11.42$, $p < .05$. Orthogonal contrasts revealed that Chinese participants trusted Chinese institutions ($M = 0.69$, $SD = 0.69$) more than the combination of American and Canadian institutions, $F(1, 119) = 46.64$, $p < .05$. Chinese participants did not differ in their trust level between American ($M = 0.25$, $SD = 0.96$) and Canadian ($M = 0.36$, $SD = 0.94$) institutions, $F(1, 119) = 1.71$, $p = .19$.

United States. The simple effect for target nation was significant, $F(2, 250) = 35.19$, $p < .05$. Orthogonal contrasts revealed that Americans trusted Canadian institutions ($M = 0.17$, $SD = 0.79$) more than the combination of Chinese and American institutions, $F(1, 125) = 65.19$, $p < .05$. The second orthogonal contrast revealed that Americans did not differ in their level of trust for American institutions ($M = -0.51$, $SD = 0.90$) and Chinese institutions ($M = -0.46$, $SD = 0.85$), $F(1, 125) = 0.27$, $p = .60$.

Canada. The simple effect for target nation was significant, $F(2, 244) = 33.41$, $p < .05$. The first orthogonal contrast indicated that Canadians trusted American institutions ($M = 0.27$, $SD = 0.92$) more than a combination of Canadian and Chinese institutions, $F(1, 122) = 58.16$, $p < .05$. The second contrast revealed that Canadians trusted Chinese institutions ($M = -0.20$, $SD = 1.02$) more than Canadian institutions ($M = -0.53$, $SD = 1.02$), $F(2, 122) = 10.62$, $p < .05$.

Discussion

In this research, models of cross-cultural relations were tested to predict patterns of international trust. Trust from the Western countries was consistent with expectations, such that Canadians trusted Americans and Americans trusted Canadians. Alternatively, trust in collectivistic countries also matched expectations, such that the Chinese did not trust either Americans or Canadians, but trusted their home country.

One unexpected finding was that Canadians did not place a great deal of trust in their own country's institutions. Although assessment of trust was not directed toward the state government, evaluations of trust may have had an effect on trust in the non-government circles that were assessed. Polls indicate that a majority of Canadians (59%), more than Americans, felt that central government was not doing enough to address the concerns of the Canadian people (Gallup, 2006). When asked whether the national government could be trusted to deal with domestic problems, Canadian citizens reported a lower belief than did Americans (China was not part of the survey). Although speculative (because China was not part of the Gallup poll), it appears that the lowered trust in Canada by Canadians may have resulted from their own distrust for their national government.

Whereas results were interpreted using cross-cultural models, it is possible to interpret the results using social identity theory. Social identity theory (SIT; Tajfel & Turner, 1979; Turner, 1982) argues that individuals' social identities are derived primarily from their membership in groups. In order to maintain and enhance individual self-esteem, group members are generally motivated to maintain a positive social identity. Tajfel and Turner (1986) proposed that one important technique for maintaining a positive social identity is to favorably compare one's group to relevant outgroups (i.e., positive distinctiveness). Research has indicated that the desire for positive distinctiveness helps limit trust to only those who share a social identity (e.g., Hogg, Abrams, Otten, & Hinkle, 2004, Rotenberg & Cerda, 1994). This motivation for positive distinctiveness indicates that it may be difficult to develop positive relations even during times of cooperation

(Hertel & Kerr, 2001). Whereas it might be tempting to conclude that social identity theory provides a plausible explanation for the findings; the results are mixed. Specifically, whereas Canadians did not trust Canadians and Americans did not trust Americans (which would be predicted from their model), the rest of the predictions were entirely consistent with expectations: Canadian and American trust patterns matched onto social categories (i.e., shared a social identity), and for the Chinese, for whom there is no social identity overlap, they did not trust either the Americans or Canadians.

A final point of interest is the significant interaction between the host nation and target nation. This interaction indicates that the international trust relationships were not necessarily symmetrical and reciprocal as might be expected. Whereas the Chinese do not trust Americans, such distrust was not reciprocated to the same degree by Americans (see also Niu, Xin, & Martins, 2010). Whereas relationships between individuals are commonly reciprocal, the same cannot be said for interactional trust (e.g., Kiyonari, Yamagishi, Cook, & Cheshire, 2006). The most likely explanation for the lowered likelihood of reciprocation between individuals, versus groups, is the perception of groups as inherently untrustworthy (Cohen, Montoya, & Insko, 2006; Wolf et al., 2009).

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From Who Cares to We Care: A review of *Diversity in Mind and in Action*

Chin, J. L. (Ed.). (2009). Diversity in Mind and in Action (Vols. 1-3). Westport, CT: Praeger. ISBN-10:0313347077; ISBN-13:978-0313347078.

Reviewed by Ting Lei, Ph.D.
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Diversity in Mind and in Action is a book in the series of *Praeger Perspectives: Race and Ethnicity in Psychology* published by ABC-CLIO in 2009 and edited by Jean Lau Chin. This book includes three volumes: Volume 1 is titled *Multiple Faces of Identity* and includes ten chapters; Volume 2 is titled *Disparity and Competence*: *Service delivery, education, and employment contexts*, and it includes twelve chapters; and the title for Volume 3 is *Social Justice Matters!: Social, psychological, and political challenges;* it includes eleven chapters.

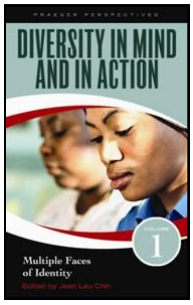

While Volume 1 is mostly focused on what is going on in the individual's mind in terms of identity issues, Volume 2 is more concerned with how our social systems have been treating or mistreating minority people as members of groups, and Volume 3 emphasizes how our systems should, but have not, treated persons of non-normative backgrounds. Philosophically speaking, the transition from Volume 2 to Volume 3 is from an ontological *is* to a deontological *ought.*

After the editor's introduction, Volume 1 starts with a chapter on the multiracial movement in this country. Granted that the authors are a counseling psychologist and a clinical psychologist, they fairly present a sociopolitical background to account for the genesis of the discrepancy between American minorities' self and racial identities. The authors successfully create an impression that American history is short though it is certainly not sweet in terms of racial relations. Another chapter on the topic of identity is written by two Vietnamese-American social and personality psychologists under the auspices of their dissertation advisor, who is of Hispanic descent. Their focus is on bicultural identity integration in a diverse world. Chapters 3, 4, and 5 are more about identification than identity processes, and all three chapters interface with both sex/gender and race/ethnicity issues. Specifically, Chapter 3 discusses how LGBT Asian Americans identify themselves and their ways of coming out in context. Chapter 4 lists current perspectives on interracial marriage and poses challenging questions as well. Chapter 5 addresses some issues confronting women of color in higher education. Chapters 6 and 7 are related to Asian Americans' mental health, with Chapter 6 being contributed by the editor (Jean Chin) herself on the topic of healing narratives. Notwithstanding this fascinating topic, Chin did not conduct an in-depth or thick analysis from the natives' point of view (cf. Geertz, 1973, 1983) or stand on giant Arthur Kleinman's (1989) shoulders to follow the well-established approach of illness narrative analysis that was derived from the same cultural context as the author's. The last three chapters in Volume 1 center on the social and personality psychology of Hispanic and African Americans, such as personal and social selves in the context of migration, with a focus on resilience and protective factors. It should be noted that given the volume's focus on identity, a topic pertaining to the personality and social developmental areas, only two (Chapters 2 and 10) out of ten chapters are authored by personality/social psychologists. All the other contributors are either clinical or counseling psychologists, who come from the editor's close circle of colleagues. A similar circle of close colleagues is going stretch the limit of their scholarship to cover issues discussed in Volumes 2 and 3, as can be seen in the following.

Seven out of the twelve chapters in Volume 2 are on the topic of education and five out of these chapters are authored or co-authored by clinical or counseling psychologists, while the other two chapters have been contributed by a university president (Mildred García) and a sociologist (Melanie Bush). In her chapter García talks about her role as an education administrative leader in navigating diversity, whereas Bush discusses her research findings from a project centered on diversity curriculum reform at the nation's largest urban university (i.e. the City University of New York, which happens to be García's alma mater). Issues of cultural competence in high school are discussed in Chapter 6, empowerment through education and employment is introduced in Chapter 1, and diversity training in educational institutions is a common theme running through chapters 7, 8, and 11. The five chapters that are not directly related to diversity development in schools can be considered as a forum for clinical/counseling psychologists to chat about diversity issues in the workplace or in healthcare settings.

Given the title's emphasis on issues of social justice as well as social, psychological, and political changes, Volume 3 has all the leading authors in the related disciplines of clinical and counseling psychology, with a few social psychologists as secondary or tertiary authors. The present reviewer wishes not to commit himself to any "credentialistic fallacy", but he checked the authors' credentials after reading the chapters and felt that in quite a few of them what and how the authors write seems to go beyond the scope of their expertise. In any

event, in this volume the first chapter includes a concern with social justice theory and research in relation to social changes. In the same terms of social justice, Chapter 4 discusses Latinos' immigration while Chapter 5 is mainly about gerodiversity and Chapter 6 presents a comprehensive review of "ableism." In line with Chapter 5, Chapter 6 also talks about aging but focuses on women while postulating a biopsychosocial-cultural perspective. After minority elders' voices are revealed in Chapter 5, minority women's experiences of trauma recovery are documented in Chapter 8. In a similar vein to the dialogue on trauma recovery just mentioned, Chapter 7 talks about the treatment of disabilities stemming from interpersonal violence whereas Chapter 3 addresses the cost of being a person of LGBT background in America's health care system. Chapter 2 is entitled *Aversive racism*, which makes readers wonder whether there is any non-aversive racism. Chapter 11 concludes Volume 3 by arguing that multicultural counseling and psychotherapy frequently contribute to the promotion of psychological emancipation.

Across the three volumes the term *diversity* is defined and delimited differently. For example, it is broadly defined in Volume 1 to include cultural, racial/ethnic, sex/gender, and sexual orientation, but in Volume 2 diversity is mainly limited to discussions of cultural and racial/ethnic types, whereas in Volume 3 diversity as a term has been expanded to include (mental/physical) disability, seniority, poverty*, inter alia*. Overall, more than 80% of the book's diversity discourse focuses on issues related to race, ethnicity and culture. In this context, race refers mainly to people of color who collectively constitute the minority or "non-normative group" in this country. In contrast to the minority or non-normative group, the majority or normative group should be called "people of no color", which in reality refers to white people. However, white is a color in itself rather than a term referring to no color, and this poses a semantic problem that throws the polarization of black and white into doubt. To what extent this doubt may delegitimize the debate between black and white is an issue left unresolved by any of the more than 40 authors represented in these three volumes.

One may also ask whether this 3-volume book could really serve its intended purpose which is to convince the targeted readers that diversity does matter. The readers whose minds the authors presumably wish to change come especially from the mainstream or normative part of the society who historically have been privileged and therefore might experience difficulties in sympathizing with the suffering of the non-normative people. Even though such people may not be opposed to diversity, they might not think that they should be especially concerned with this issue either. To articulate this point, Melanie Bush in Volume 2 cites an article from *The Chronicle of Higher Education* in which the author states: "The opposite of being pro-diversity is not being anti-diversity. It's being diversity-indifferent, and that's me. My T-shirt would not say "Diversity sucks." It would say, "Diversity--Who Cares?" (Clegg, 2000, p. B8). Indeed, why should Clegg and people like him change their minds and share their protected privileges with "people of a lesser God"? Furthermore, would they be persuaded to do so after reading this 3-volume book on diversity? Some of them might perhaps be induced to wear a T-shirt with a new imprint like "Diversity---We care," after selectively reading a few solid chapters that could so-to-speak act as scholarly stars shining through the clouds in a dark sky. This, in turn, leads to the question of, who spread the clouds that cover the other stars and is there any way to remove those clouds so that more viewers can be enlightened?

Ironically, an answer to the first question just raised is being advanced by the editor herself, who applies a top-down approach across the three volumes. As a case in point, the editor inappropriately uses exclamation marks in order to raise her tone of voice when referring to the title (viz., *Social justice matters!*) of Volume 2 as well as in each of her chapters contained in the three volumes. As an author, Chin overuses "demand words" such as "must" and "should" while offering too few sound arguments on the basis of logical reasoning. To be sure, most of the targeted readers are those coming from the privileged rather than the underprivileged class, and they therefore do not have to subject themselves to the commands uttered by a double-underprivileged (i.e. a minority female) author. In order to move the readers or to open their hearts as well as inducing them to nod their heads, a bottom-up approach would appear to be more adequate (cf. Lei & Gielen, 2008). Rather than superimposing her own beliefs or dogmas, an author adopting a bottom-up approach would attempt to initiate the readers' self-discovery journey while keeping their best interest in mind as well. Then throughout the journey together, via a rear-view mirror the readers may be enabled to look into their past and the historical background of the "de-diversity" movement from which some light may be shed into the direction of the future and thereby necessary changes could be highlighted. To illustrate this suggestion, one example from a reviewed chapter is introduced below.

The authors (Derald Wing Sue, Annie Lin, & David P. Rivera) of the chapter, *Racial microaggressions in the workplace: Manifestation and impact,* cogently quote historical facts demonstrating that subtle assaults on minorities, who are most likely under-represented at the higher levels of management, have become part of the traditional American workplace. One solution would be to diversify by increasing the representation of minorities in upper-middle management positions. To that end, it would be necessary to prepare minorities for the more challenging jobs through higher education. But then one might ask how white Americans could be induced to raise their own taxes or give up some of their own vested benefits in order to help enrich the education of the oppressed black people? To this question, Sue et al. responded as follows:

"These figures are disturbing for two reasons. First, it is projected that within several short decades, people of color will become a numerical majority in the United States (U.S. Census Bureau, 2004). Already, approximately 75 percent of those entering the labor force are persons of color or women, and by the time the so-called baby boomers begin to retire,

those contributing to social security and pension funds will be predominantly visible racial/ethnic minorities (Sue & Sue, 2008). If persons of color continue to occupy the lower rung of the employment ladder of the most undereducated, underemployed, unemployed, and underpaid, it bodes poorly for the economic health of the future retirees, business and the nation. Second, a society that continues to allow unfair disparities to exist between certain groups compromises its moral integrity, failing to provide equal access and opportunity to all …." (Volume 2, p. 158).

As can be seen in the quotation above, Sue et al. appeal not only to the reader's head by citing powerful trends predicting the country's future but they also echo Adam Smith's (1759/2010) theory of moral sentiments thereby appealing to the reader's heart. In light of this illuminating approach, even oppressors might realize that they have to chart a course of diversity so that they can move together with the traditionally oppressed into a brave new future world. Choosing to ignore this issue may lead both to financial bankruptcy and to moral corruption, which few would consider to be the best way to live one's life. The key of this approach is to make people feel connected on the high ground where they all can mutually benefit each other. For the same purpose but to restructure the three volumes as a whole, an orthogenetic framework of reference operating like a multidimensional web of meaning construction (à la Heinz Werner, 1940/2010) is proposed in the following.

First, diversity shouldn't be seen as skin-deep, as too many authors do in their respective chapters. After scratching the surface, we need to take a *phylogenetic* perspective to dig down deep into the genetic constitution and evolutionary epigenes (trigger factors that turn on or turn off genes thereby helping to change genotypes into phenotypes) that help shape the contents of character as well as the colors of skins. From the investigation of the *phylogenesis*, which may be located on the first dimension of *orthogenesis*, of Homo sapiens we would come to realize that the *sine qua non* of different subspecies of human being is so close to each other in spite of the visible differences. Then, we can examine the issue of diversity in relation to ethnic, social, cultural, and historical variables on the *ethnogenetic* dimension. After the ethnogenetic examination, we can study individual developmental processes in the light of diversity on the *ontogenetic* dimension. The microaggression discussed earlier would be examples to be situated on the *microgenetic* dimension, which focuses on temporary or local changes as a result of situational or contextual factors. Last but not least, under the orthogenetic framework *pathogenesis* refers to the etiology of disease or illness. To be sure, these five orthogenetic dimensions can be cross-referenced with each other. For instance, in one of her chapters Chin outlines how Chinese people explain the genesis of some diseases in the context of health beliefs which originate from traditional Chinese medicine.

Throughout the three volumes, most chapters are ethnogenetically-oriented, and of those many are cross-referenced to the ontogenetic dimension with a focus on education while a few others also refer to the pathogenetic dimension. On the other hand, no chapter addresses fundamental questions of diversity from a phylogenetic perspective and only a few chapters can be located on the microgenetic dimension.

This book would be worth reading if you are a clinical/counseling, developmental, social psychologist or mental health professional who needs to draw upon some materials suitable for multicultural curricula appealing to college freshmen. It would also make you feel good if you are a minority psychologist (full disclosure: the present reviewer is one of them) because the indignities of social injustice are denounced in many of the chapters. However, in order to act as an engine for social change the first and foremost step must be to convince the majority that diversity really matters since we all are reciprocally related to each other. Without adopting a bottom-up approach and addressing issues with reference to a comprehensive framework, this feel-good book may not lead to enough good consequences. Consequently, diversity will remain a dream that minorities have but may never be able to realize.

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ANNOUNCING THE PUBLICATION OF ...

La relazione al centro. [*Relationship at the centre: Healing in a troubled world*]
G. T. Barrett-Lennard
Publisher: London and Chichester: Whurr Edition/Wiley (2010)
ISBN: 978-8861531383

This book offers a new perspective on the working and potential healing of relations between persons and between peoples, relevant to our desperate times. Humans are born into relationships and personal selves emerge through experiences of relationship, which broaden and evolve through life. Inquiry into diversity and 'relations' within the self opens the way to other primary spheres: interpersonal and family relations, community process as relationship, the nature and far-reaching phenomena of loneliness and alienation, and organizational and big-system relations.

One chapter maps the wide spectrum of inter-connected human systems, and another presents a view of helping theory and practice development extended through this spectrum. Over the whole range, the processes, healing and development of relationship are in central focus. In a final review of the span of critical need and challenge, the book confronts alternatives and proposes steps toward recovery.

Why noise matters: A worldwide perspective on the problems, policies and solutions
John Stewart with Arline Bronzaft, Francis McManus, Nigel Rodgers & Val Weedon
Publisher: Earthscan (October, 2011)
ISBN: 978-1849712576

Is noise the most neglected green issue of our age? This book argues compellingly that it is, and tells you all you need to know about noise as a social, cultural, environmental and health issue.

Across the world, more people are disturbed by noise in their day-today lives than by any other pollutant on Earth. From the shanty towns of Mumbai to the smart boulevards of Paris, noise is a problem. It is damaging people's health, costing billions, and threatening the world's natural sound systems in the same way that climate change is altering its eco-systems. Drawing on evidence from all over the world, this book showcases policies and strategies that have worked to decrease noise pollution, and offers lessons for policymakers and environmental health professionals, campaigners and any individual affected by noise. Written by a renowned noise campaigner and experts in law and health, this book tells you all you need to know about noise as a social, cultural and environmental issue and how we can act to build a more peaceful world.

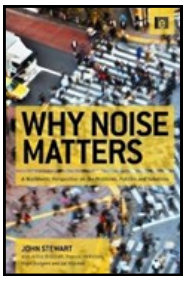

Eastern European immigrant families
Mihaela Robila
Publisher: New York, NY: Routledge (2009)
ISBN: 978-0-415-99406-4

After the fall of communism in Eastern Europe in early 1990s, international migration from this region has grown significantly. However, the literature on Eastern European immigrant families has been very limited. This book presents key issues related to immigration from Eastern Europe, such as a historical background, the factors determining contemporary migration, its benefits and challenges. There is also a focus on children and families, addressing child-rearing beliefs and practices, cultural beliefs, marital interactions and gender roles. The challenges faced by Eastern Europeans as they immigrate around the world are also explored.

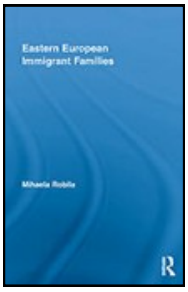

Migration, technology & transculturation: A global perspective
Myna German & Padmini Banerjee (Eds.)
Publisher: CIGS Lindenwood University Press (2011)
ISBN: 978-0984630745

Based on exhaustive reporting and academic studies from authors across the world, this volume shows how the changing face of technology is shaping the lives of global migrants. While once a painful goodbye sent immigrants packing to the different areas of the world in the 19th and 20th centuries, the global millennium, replete with Skype, Facebook, email, and chat has made global nomads a reality, but they are also very connected to their home port. This volume offers a convergence of perspectives on these new developments, combining conceptual and empirical work

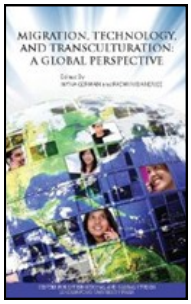

from the different continents throughout the world. Chapters by psychologists, sociologists, anthropologists, geographers, historians, media specialists and literary studies writers reflect on these new international social networks and technologies and their impact on these new forms of communication and identity formation among global migrants. The global reach of the authors span the countries of Italy, Germany, the UK, Brazil, Australia, the US, India, and in between. This is a substantial pioneering effort in this field of research on this global topic.

Return migration and identity: A global phenomenon, a Hong Kong case
Nan Sussman
Publisher: Hong Kong University Press (2011)
ISBN: 978-9888028849

The global trend for immigrants to return home has unique relevance for Hong Kong. This work of cross-cultural psychology explores many personal stories of return migration.

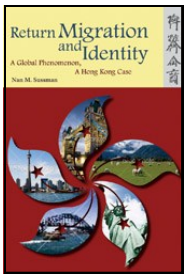

The author captures in dozens of interviews the anxieties, anticipations, hardships, and flexible world perspectives of migrants and their families, as well as friends and co-workers. The book examines cultural identity shifts and population flows during a critical juncture in Hong Kong history between the Sino-British Joint Declaration in 1984 and the early years of Hong Kong's new status as a special administrative region after 1997. Nearly a million residents of Hong Kong migrated to North America, Europe, and Australia in the 1990s. These interviews and analyses help illustrate individual choices and identity profiles during this period of unusual cultural flexibility and behavioral adjustment.

Interpersonal acceptance and rejection: Social, emotional, and educational contexts
Elias Kourkoutas & Fatos Erkman (Eds.)
Publisher: BrownWalker Press (2011)
ISBN: 978-1599425696

This volume draws on research to offer a global perspective on issues of fundamental importance to family functioning, childhood development, and adult intimate relationships, as well as to policy and practice for children, adolescents, couples, and families at risk. It draws on the perspectives of major social science disciplines such as clinical and educational psychology, anthropology, psychology, special education, and sociology, thus ensuring topics are discussed within broad theoretical frameworks. The authors cover a wide spectrum of questions and topics in relation to perceived acceptance and rejection by significant others.

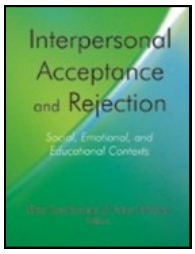

Chapters are set in the context of worldwide trends in the area of interpersonal acceptance-rejection. They considerably advance our knowledge of interpersonal acceptance-rejection theory and practice by tackling issues in major life contexts such as family, education, intimate relationships, and clinical-therapeutic practice.
The book presents these important issues within the context of up-to-date research on interpersonal relationships that helps strengthen family and couple relationships and enhance the quality of attachment relationships in families. Contributors to this edited book come from many parts of the world, including the Americas, Asia, Australia, Europe, and the Middle East.

ALSO ANNOUNCING THE PUBLICATION OF...

Psychology in Ukraine: A historical perspective
Ivan Holowinsky
Publisher: University Press of America (2009)
ISBN: 978-0761840466

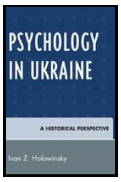

This book was conceptualized as an effort to provide for a Western reader, not familiar with psychology in the East, a broad outline of Ukrainian Psychology within the socio-historical context.

Grief therapy with Latinos: Integrating culture for clinicians
Carmen Vazquez & Dinelia Rosa
Publisher: Springer Publishing Company (2011)
ISBN: 978-0826106599

This book serves as both a graduate textbook and clinical reference that helps in the understanding of relevant cultural values and their effect on the grieving process. This book also addresses the application of specific interventions in a culturally relevant manner, including the relevance of language in grief therapy, psychology and counseling with a Latino population.

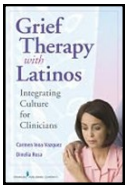

*If you would like to include a book in a future issue of IPB and have not already done so, please email information to Jennifer Lancaster at jlancaster@stfranciscollege.edu

** Please note that at least one author/editor must be member of Division 52 and the work must have been published in the last three years.

Notes from the Underlings: What Supervisees Report About their Cultural Matches with Supervisors

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California School of Professional Psychology
Alliant International University, San Francisco

Trainees in clinical psychology learn many of their clinical skills in supervision, thus I began reflecting on my supervision experiences and wondering how the cultural match between my supervisors and myself affected my learning. As a female Russian immigrant trainee who has been paired with male and female Russian-speaking and non-Russian supervisors, I am familiar with the nuances that these matches bring out in my training. These nuances have included language-bound phenomena, worldviews based on national and immigration history, gender roles, and age-related and social status hierarchies. I have noticed that all of these facilitate or impede the relatedness, openness, and comfort level that I feel with my supervisors. With this in mind I wondered about the experiences of other students from different cultures and countries. Specifically, I wanted to know what types of issues came up overtly or covertly in the relationships with their supervisors, what they found difficult to discuss or what was ultimately helpful, and whether they found that these particular supervision matches increased their clinical expertise and improved client care.

Falender and Shafrenske (2004) suggest that cultural competence in training should include a certain awareness, knowledge, and appreciation of various cultural variables between the supervisor and supervisee. Generally, it seems that two people work best together when they have a thorough understanding of, or at least an open curiosity for, each other's cultures, national history, immigration experience, and status in the United States. Texts that focus on cultural competence in supervision usually encourage trainers to become aware of their own cultural expectancies or biases, and to help their supervisees do the same. For example, Vargas, Porter, and Falender (2008) call for supervisors to continue to explore variables of cultural diversity affecting the supervision relationship and to openly dialogue with their supervisees. Further, Wedding, McCartney, and Currey (2009) instruct teachers (whether professors, advisors, or supervisors) to understand the factors that may be unique to international students studying in the U.S. and to remain sensitive to their students' levels of acculturation and functioning within an American academic system. However, these texts are written about supervision and training in general and do not always describe the experiences of students specifically.

For this project, I interviewed two female clinical psychology students, both currently training at practicum sites in the San Francisco Bay Area. I asked them to describe first their own cultural identities and then those of their supervisors. I was interested to see how they perceived their supervisors' cultures and what particular variables came up in supervision. I also asked the interviewees to think of a clinical case and to describe their experiences of discussing the case within their particular supervisory pairings.

My first interviewee, Sofia (both interviewees chose their pseudonyms to protect their privacy), identified herself as Mexicana, fully Mexican-American, born in the U.S. and raised in both countries. Thus, she labelled herself as bicultural, binational, and bilingual in English and Spanish. She described her current supervisor as a Latino man from a Peruvian background. She knew that he was born in Peru and immigrated to the U.S. in his late teens. English was his second language, and thus, they switched between Spanish and English in supervision. The issue of language became an area of effort and growth in her training. Sofia described that their conversations usually began in Spanish, the more familiar and familial language, as well as the language of the clients at the agency. However, because the academic training for both has been largely in English, it became inevitable to intersperse English for theoretical terms. Sofia mentioned that she hated mixing the languages at first because her community looked down on this and considered it "Whitewashing". But having a supervisor who was able and willing to engage with her in both languages taught her to code-switch more effectively and ultimately gave her a sense of pride in her ability to quickly translate experiences for herself and her clients. Thus she stated that this increased her linguistic fluency and improved her therapeutic skills by helping her to translate theoretical formulations in English into interventions in Spanish.

Sofia also described a greater sense of comfort in discussing how to work with clients "not by the book" when she knew that she was talking with another member of her community. Rapport in supervision was easier to establish because both shared a passion for serving the community, were connected to their native countries and were intimately familiar with the struggles of their immigrant clients. In addition, Sofia valued an unspoken understanding of cultural rules. For example, their culture allowed her to call her supervisor by his title rather than his first name, as would be appropriate in many American academic and clinical settings. In other instances, Sofia appreciated that they covertly agreed on the less rigid guidelines around physical boundaries and touch. She explained that ultimately her supervisor successfully modelled a relationship that maintained culturally appropriate norms while pushing her to develop in her identity as a Mexican-American clinician, which has been a crucial part of her professional training.

Similar themes came up in my second interview with Katy, who described herself as Indonesian nationally and Chinese ethnically. Katy explained that she grew up as a minority both in her ethnicity and her religion as she was Chinese and Christian in a predominantly Muslim Indonesia. She moved to the U.S. at 18 years of age to attend university and graduate school. Katy first described the prevalence of her feeling like an outsider in a White academic culture, where the teaching of psychology came from an exclusively

Western perspective that did not always agree with her understanding of normal human behavior and health. In addition, she often felt unheard and irrelevant at her institution when raising questions and concerns about clients to which other students did not relate. By contrast, Katy's supervisor at a predominately White institution was a Korean-American woman, born in the U.S. to parents from Korea. It was refreshing for Katy to be matched with a supervisor who on some level personally understood her struggle of having to adjust to a dominant culture and thus often encouraged her to brainstorm interventions that agreed with her worldview. This allowed Katy to develop professionally by not simply acculturating to a Western model of health, but by integrating various nuanced cultural considerations.

Despite the comfort and bond between Katy and her supervisor, some cultural dynamics presented challenges in the supervisory relationship. Katy felt uneasy when her supervisor insisted that Katy call her by her first name rather than her title. This situation presented a dilemma of whether Katy should disregard her own values or those of an authority figure. Furthermore, voicing this difference in norms felt difficult to Katy because it also went against her cultural rule against questioning authority. As such, she looked for her supervisor to be tuned in and curious about Katy's experience in supervision, rather than assume that Katy would voice her own concerns. As Katy's supervisor established an atmosphere of understanding and open communication, Katy felt more comfortable to discuss and resolve any challenges in their dynamic. Ultimately, Katy found supervision most effective when both parties capitalized on shared experiences and found a common ground in values while respectfully exploring each other's perspectives as they pertained to client care.

Overall, the stories of both interviewees supported the idea that regardless of the accuracy of the cultural match between the student and the supervisor, it was the supervisor's openness, curiosity, humbleness, and lack of imposition of viewpoints that helped the students explore themselves and develop professionally. The students also encouraged supervisors to understand their positions of power and explore the cultural values that may be placed on figures of authority. It was also striking that although both dyads represented people from different countries of origin, supervisees felt connected to their supervisors based on otherness within the dominant culture and community membership. The reports of these students also match my experiences in that I have been most comfortable and open to learning in pairings where supervisors were unassuming and willing to think with me outside the academic box. Having supervision in my native language has also helped me to integrate those worldviews that I derived as part of my upbringing in Russia with those I learned in academic settings in the U.S. Thus, it seems essential that supervisors learn ways to explore cultural variables in supervision. It also seems imperative that the field train more clinicians from diverse backgrounds and speaking different languages who could serve as professional role models to students seeking to become culturally competent.

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Daria Diakonova-Curtis by email at ddiakonova@alliant.edu.

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Editor's Note: *This column is geared towards our student committee members and all students of international psychology. All Div52 student members are invited to submit ideas or drafts for future articles, as well as questions they would like to see addressed in future columns – such as overseas internship opportunities, study abroad availability, cross-cultural research, etc.*

Contact the Editor at optimalex@aol.com to submit an idea or a question.

Psychology Students Travel to Nepal

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Eastern Connecticut State University

Study abroad programs are becoming prioritized by colleges due to their being identified as part of the trend toward globalization. However, American students have been found to not participate in study abroad programs as much as students from other Western countries (Lewin, 2009). Study abroad courses have also been identified as a best practice for engaged learning for college students. In response to these data, Eastern Connecticut State University (ECSU) has committed to increasing student engagement through the use of study abroad and global field courses. The psychology department has been searching for a way to integrate this practice into training for our students, not only to meet the goals of ECSU but also the goals of psychology as a field. Diversity and culture are integral parts of the field of psychology . The American Psychological Association (2007) has suggested that one of the 10 goals for undergraduate psychology education should be "sociocultural and international awareness." The process of creating a global field course focusing on psychology was a learning process that resulted in what was without question the most rewarding experience I have had in my 16 years of teaching.

Reception at Little Angels College

As with many universities there is a wealth of faculty from diverse cultures at ECSU. I made contact with Geeta Pfau, Ph.D. a nurse in the health service center at ECSU during a talk we gave on HIV on college campuses for the Latino Leadership Conference. We began to talk about taking students to Nepal. Dr. Pfau had many contacts in Nepal as she was born in and studied in Kathmandu. The key was to find a course to link to the travel to Nepal. I had been teaching health psychology for many years and the textbook I use focuses on the impact of culture on health. During a sabbatical we began putting together the course with a host college in Kathmandu. We also began contacting possible sites we wanted to visit with students. After 4 months of planning and marketing the course was proposed for Summer 2011.

Eight psychology students, 1 sociology major and IT staff person, Barbara Williams, participated in the global field course. The course was designed to examine health in Nepal versus the United States from cultural, educational, sociological and psychological perspectives. One week of course work was followed by travel to Nepal between June 1st and 11th. In Nepal, students traveled to Dhulikhel and Pokhara and visited 2 hospitals, a free medical clinic, Kathmandu University, Maiti Nepal, an orphanage, 2 psychiatric facilities and an Ayurvedic clinic. Students also did sightseeing which included several Buddhist and Hindu temples and ancient royal palaces. During the trip, our host, Little Angels College, coordinated our ground transportation and provided us with a guide throughout our stay. None of the eight students who participated in the course had ever left the country before. This, coupled with our destination being a collectivistic developing nation nearly around the world, promised to be an eye opening experience.

Our flight itinerary took us from New York to New Delhi, where we had an overnight stay. While we did not have time to travel into Delhi, students were amazed at the sights, sounds, smells and food of India. The next morning we left for Kathmandu where we were greeted by our host school and welcomed with a reception. Following the reception we presented our itinerary for the week ahead.

At each location students were given a presentation overview followed by questions and answers and a tour of each facility. What was clear throughout our trip was the need for psychologists to help the Nepali people deal with many aspects of poverty, health, education and a patriarchal society. Psychological treatment in Nepal is a complex and challenging issue. According to Dr. Dhruba Man Shrestha, there are a total of 418 psychiatric beds and a total of 107 mental health care workers for population of over 25 million in Nepal. Of those 5 are clinical psychologists and 1 child psychologist. This is complicated by Nepal having many rural areas that rely on local healers for treatment of psychological and physiological disorders. This coupled with a 40% literacy rate makes treatment for the mentally ill challenging. Interestingly, there were some consistencies in the public's view of psychology. In many places students were asked why they were in Nepal and when they explained that they were psychology students, they were asked if they could read their minds.

Eastern students were most affected by our visit to Maryknoll Nepal, the first non-government organization providing psychiatric services throughout the country. Video was shown of 2 men with schizophrenia, one who was leashed and the other caged for many years. Family members do not have the knowledge or ability to care for the men and felt this was their only solution. However, Maryknoll took in both of these cases, and they are being taught self-care behav-

Lecture at Maryknoll

iors and how to farm. We were able to meet 1 of the 2 men in the videos and to see him functional and interacting with us and other patients was a moving experience. Maryknoll relies on volunteers to provide psychological services and donations to fund its community outreach, day care and residential programs. Recently, a key donor to Maryknoll passed away. Students saw the opportunity to make a difference and made a donation of cash and clothing as well as a second donation in the name of our host school coordinator Shristi Limbu. The gift donation was sufficient to cover the medication costs for 10 patients for one month.

Students were also able to go to Maiti Nepal, an organization that was created to rescue and rehabilitate women sold into sex trafficking and their children. The founder of Maiti Nepal was awarded 100,000 dollars by CNN as hero of the year for her efforts. Students were presented with the economic and social pressures such as the need for dowries for marriage of female children, which maintain the practice of sex trafficking and were shown pictures of women who had survived torture and in some cases having organs taken from them for sale on the black market. The grounds of Maiti Nepal house a school for children of the women and an orphanage. A key component of Maiti Nepal is psychological services for the women and families of the victims of sex trafficking.

An interesting theme throughout our trip was the lack of technology. There were no computer systems to track patient histories. Likewise, hospital rooms were missing the sounds of monitors and IV pumps. The people of Nepal were warm and friendly throughout our trip and were eager to have their pictures taken, with their only reward being the ability to see themselves in their pictures. Nepal is an amazing country with the incredible beauty of the Himalayas contrasted with the poverty. However, this did not appear to affect most people. We were told that the focus on family and spirituality were more important than things and this was evident by the abundance of temples (both Buddhist and Hindu) nearly everywhere both in the city and in rural areas. Students were surprised to learn that all religious holidays are celebrated by all people.

There were many other experiences which deeply affected the students on the trip. Students completed a final projecting linking their readings to their experiences in Nepal. Also, all of the students participated in a course blog and uploaded photos and their impression of what they experienced (http://statectuniversity.wordpress.com). As an instructor, the trip to Nepal was eye opening and the most rewarding experience of my teaching career. To see students being affected by the new world around them was an incredible experience. Relationships were established with all sites and plans are moving forward for another trip to Nepal in May 2012.

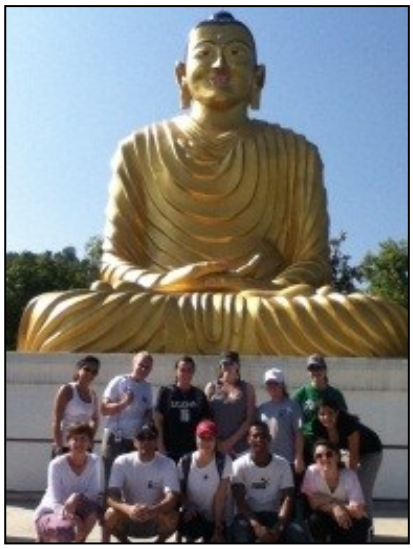

Buddha hike group

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A Division 52 Success at the European Congress in Istanbul, Turkey

Neal S. Rubin, Ph.D., ABPP
Argosy University, Chicago

The theme of the 12th European Congress of Psychology in Istanbul, Turkey, 7/4 – 7/8 July, 2011, was "Understanding and Embracing Diversity." As a part of the Europlat program at the Congress, Division 52 members presented a symposium, "Integrating Human Rights and Social Justice with Diversity in Psychology Education and Training: Multiculturalism, Immigration, Trafficking and the United Nations." The aim of the symposium was to contribute to the conversation generated by the Europlat Initiative, a movement of European academics and professionals to standardize psychology education and the certification of psychologists across European Union countries.

Our symposium originated with the assumption that today, we are interconnected as never before in human history. Advances in technology, climate change, the world financial crisis and the world response to natural disasters have unified diverse populations. Our concern with how we are similar and how we are different as humans both intrigues and troubles us, generating compelling empathy as well as destructive fearfulness in the world today. In this context the place of the education and training of psychologists, across countries and educational systems, to understand and embrace diversity, has become all the more compelling.

Therefore, the purpose of our symposium was to illustrate how the teaching and training of 21st century psychologists can blend an appreciation of human diversity with universality, by integrating multiculturalism with human rights and social justice education. Our symposium presenters originated from three countries (New Zealand, Turkey and the United States) and are currently on faculty at three universities in the United States. In short, we presented models for teaching diversity based on our research and field experience on topics such as immigration, multiculturalism, human trafficking and developments at the United Nations. What follows is a synopsis of each presentation and the response by our European colleagues.

Diversity and Human Rights in Psychology: A View from the United Nations

Neal Rubin, Ph.D., ABPP, a Professor at the Illinois School of Professional Psychology at Argosy University, Chicago, initiated the presentation by describing some of his experiences as an APA/NGO representative at the United Nations. He detailed how in 1999 the American Psychological Association was granted special consultative status as a non-governmental organization (NGO) by the Economic and Social Council (ECOSOC) of the United Nations. Since that time a team of APA psychologists have endeavored to contribute psychologically informed perspectives to the behavioral dimensions of 21st century human rights issues. Their work, along with the efforts of psychologists representing other psychological organizations (for ex., ICP, IAAP, IUPsyS, SPSSI), involves deliberations with U.N. staff and its agencies, representatives of member states and members of the NGO community. These psychologists have also sought to educate fellow professionals regarding the potential roles of psychologists in addressing social justice issues worldwide. For example, he described the success of the fourth "Annual Psychology Day at the United Nations" in April of this year. He outlined how psychologists are informing the dialogue at this world body regarding the way in which psychological science can inform progress on pressing human rights issues and reciprocally, how psychologists are educating colleagues regarding diversity and social justice issues. He concluded by emphasizing that diversity and global awareness should be viewed as essential components of teaching ethical principles to psychologists.

Cultural and Individual Differences and Diversity in Professional Psychology Training

Ayse Ciftci, Ph.D., an Assistant Professor of Counseling Psychology in the Department of Educational Studies at Purdue University, presented her views and pedagogic model for teaching human diversity. She articulated how cultural and individual differences and diversity are significant components of professional psychology training and constitute one of the accreditation domains of the American Psychological Association (APA). However, she acknowledged that the educational techniques and depth of training of tomorrow's psychologists to work effectively in diverse environments vary among psychology training programs. For this symposium, Dr. Ciftci presented the ways in which she and her colleagues incorporate diversity training in their APA accredited counseling psychology program through coursework, program-related activities, prelims, practicum experiences, and student evaluations. Employing her own professional and personal experiences as a Turkish professor teaching Advanced Multicultural Counseling courses in the U.S., she described how she has learned to use her cultural background and research expertise on cross-cultural adaptation as educational tools. Additionally, she outlined how she integrates social justice and international issues in her classes through multiple assignments (such as development and delivery of social justice interventions). Last, she discussed the specifics of some of her experiential learning processes by presenting case examples from some of the "difficult dialogues" activities she has integrated into her classroom teaching.

Trafficking Girls into the Sex Industry: International Cross-Cultural Psychosocial Perspectives

Rita Chi-Ying Chung, a Professor of Counseling and Development in the College of Education and Human Development at George Mason University, described an insidious form of migration: forced migration through human trafficking. She described that although human trafficking has been

in existence for centuries, globalization, enhanced technology, and increased international travel have resulted in growing demands in the sex trade and a steady increase in human trafficking worldwide. She observed that though human trafficking for commercial sex has been addressed in various disciplines, the psychosocial issues are oftentimes ignored. As a consequence, in her presentation she discussed the long and short term ramifications of trafficking girls from a cross-cultural, psychosocial perspective. She asserted that for psychology training to remain in the forefront of social issues, it is important to include human trafficking in psychological training. Accordingly, to be effective in working with this population, in both training and practice psychologists must emphasize multicultural, social justice and interdisciplinary issues as these concerns relate to trafficking for commercial sex. In order to illustrate this perspective on education and training, she presented examples of the linkage between psychosocial and diversity issues with the violation of fundamental human rights that human trafficking represents.

Immigrant and Refugee Mental Health: Global and Cross-Cultural Perspectives in Psychological Training and Practice

Fred Bemak, Ph.D., Professor and Director of the Diversity Action and Research Center, College of Education and Human Development of George Mason University, informed us that migrants continue to grow in numbers and comprise over 3% of the world's population, an estimated 214 million people. He emphasized that psychology has a pivotal role in addressing the movement of people that accompanies rapid social, familial, cultural, economic, and political changes. Given wars, conflicts, natural disasters, famine, drought, poverty, climate change, and disease, millions of refugees and immigrants are fleeing their homes, villages, and countries. Dr. Bemak's presentation discussed the psychological effect of migration on individuals, families, host communities, and societies. He engaged the audience to consider the subsequent role of psychologists in addressing the related psychosocial issues of migrant populations. Following this introduction, he explored the increasing mental health needs of these populations from a cross-cultural perspective, presented a culturally responsive social justice model of intervention for addressing trauma, acculturation, adaptation, loss, and separation, and then in summary, examined the educational and training implications for psychologists.

Response

We were very gratified by the response we received at the European Congress. First, following our symposium papers, our audience was energetically engaged in a discussion of salient questions and concerns. This cross national, multi-lingual and multi-cultural group of colleagues were genuinely responsive and appreciative, while also intensely interested in getting more details from the panel on issues of their particular interests. For example, our European colleagues explored the details of our and their educational processes, focusing on methods to establish an evidence base for determining cultural competence in students within and across nations. Ideas as well as frustrations were shared in an illuminating exchange. It was clear that, with respect to embracing diversity, we shared many challenges and potential solutions as 21st century educators and professionals. Discussion spilled into the convention center hallway with a shared desire to communicate beyond the moment.

Second, following our symposium, discussion with representatives of the International Congress of Psychology (ICP) led to an invitation for our panel to present a symposium at next summer's meeting. The theme of the 30th International Congress of Psychology is "Psychology Serving Humanity" and will be held in Cape Town, South Africa, 22 – 27 July, 2012. Join us at ICP 2012 and watch for our symposium, "Enriching Our Shared Humanity: Imperatives for a Human Rights Framework for Psychologists."

Nominations for International Union of Psychological Science Awards

Nominations are invited for the following International Union of Psychological Science sponsored awards to be given at the 2012 International Congress of Psychology in Capetown, South Africa. Deadline for nominations is less than two months away. More details at http://www.iupsys.net/index.php/prog-awards or by following the hotlinks below.

Mattei Dogan Prize: Recognizes a contribution that represents a major advancement in psychology by a scholar or team of scholars of high international reputation.

Young Investigator Awards: Recognize young post-doctoral scientists who have already made a significant contribution to psychological science.

Achievement Against the Odds Award: Honors a researcher or team of researchers who succeeded in conducting research under extremely difficult circumstances.

Lifetime Career Award: Honors distinguished and enduring lifetime contributions to international cooperation and advancement of knowledge in the field of psychological science.

The deadline for receipt of nominations for the 2012 Awards is 30 September 2011.

A Brief History of Psychology in Argentina

Michael Tamburino
St. John's University

The history of psychology in Argentina is complicated and, in many ways, interconnected with the political development of the country. This essay will serve as a general introduction and background to psychology in Argentina. First, the article addresses the development of the psychiatry movement and its early focus on somatic causes to pathology. Second, the essay outlines the transition from a biological emphasis to psychoanalytic psychology, by all accounts the primary psychological orientation to this day in Argentina (Bass, 2006; Plotkin, 2001). Third, the development of psychology as a separate field is discussed, including the rise of psychology as a profession and subsequent implications for training and service distribution. Finally, an analysis of the impact of the collapse of the Argentine economy in December, 2001, on the course of psychological study and practice is addressed.

The Beginnings of Psychiatry

In late 19th century Argentina, there was increasing interest in understanding the rationale behind criminal behavior (Ruggiero, 2003). This interest became a public outcry following a string of cold-blooded murders committed by a Luis Castruccio in July of 1888. Questions about why and how someone could commit such heinous crimes led to an emphasis on asylums for study and treatment of these "more disturbed" individuals. Subsequently, the role of medical professionals (i.e., psychiatrists) in providing this treatment and study became integral.

Lucio Melendez, founder of the asylum Hospicia de las Mercedes, is considered to be the first Argentine psychiatrist. He was the first to hold the chair of mental diseases in the School of Medicine at the University of Buenos Aires, as well as being the first chair of psychiatry in Cordoba in 1888 (Plotkin, 2001). Melendez, like many of his peers, was heavily influenced by French and Italian views of psychology and mental pathology. Indeed, within the medical community as a whole, Italian and French were mandatory languages and only those physicians who had demonstrated a degree of success in Europe were recognized in Argentina. The French influence on Argentine psychology placed a particular emphasis on psychopathology. This emphasis was also popular because of its utility in understanding criminal behavior.

In this context, Melendez imported the ideas of prominent French physicians to answer these questions, including the concept of positivism. Positivism dictates that the only true knowledge is that which is based on sense experience and positive verification. This led to the popularity of somatic theories of mental illness which looked to the body, as opposed to the mind, for the etiology of mental illnesses (Plotkin, 2003). According to Nathan Hale, a prominent North American psychoanalytic historian, the "somatic style" gave almost no credence to the role of environment in mental illness; the origin and treatment of mental illness was to be found in the brain and peripheral nervous system (Plotkin, 2001).

Between 1880 and 1940, the theory of degeneracy was the most popular of these "somatic theories" (Caimari, 2003; Plotkin, 2001). Originally introduced by the French physician Benedicto-August Morel, it held that psychopathology was transmitted from generation to generation within families and that, with every subsequent generation, the pathogen would grow stronger. This became a particularly fashionable argument against the admittance of immigrants to the country from southern Europe in the beginning of the 20th century.

Psychology in Academia

As discussed previously, Argentine psychology, heavily influenced by France and Italy, had a clinical-psychopathological approach from the outset. However, unlike the experimental emphasis placed on psychology in the United States, psychology in Argentina was spread throughout the disciplines of sociology, biology, and philosophy without a clear-cut focus or direction. This failure to delineate an explicit field and role for psychology, however, did not stop Argentina from distinguishing itself among other Latin American countries in psychological teaching and research (Plotkin, 2001).

Beginning in 1896, Felix Kruger, a former student of Wundt's and his eventual successor in Leipzig, spent two years in Argentina (Vezzetti, 2007). During that period, he held the second chair of psychology at the University of Buenos Aires in the School of Philosophy and Literature. Contrary to the emphasis on the Wundt's empirical methods of studying psychology emphasized in North America, Kruger emphasized the non-experimental aspects. In this vein, he began to introduce the works of anti-positivist writers emphasizing the importance of the mind in psychological phenomena (Plotkin, 2001). As will be discussed later, this laid the groundwork for an anti-positivist sentiment in Argentine psychology and psychiatry in the early 20th century.

For the moment, however, this movement would have to wait; when Kruger left for Germany in 1898, so did his interpretation of Wundt's work. That same year, Horacio Pinero established the first psychology laboratory in Argentina, also at the University of Buenos Aires. Pinero, like many of his fellow Argentine colleagues, was familiar with Wundt primarily through positivist biased French translations of his work (Plotkin, 2001). While the lab was patterned after Wundt's in Leipzig, it had a decidedly positivist flavor, focusing almost exclusively on the physiological aspects of Wundt's work.

A physician by the name of Jose Ingenieros typified this positivist approach, viewing psychology as a subcategory of biology. However, Ingenieros also believed in the efficacy of psychotherapy, including the merits of hypnotism and dream interpretation. Further, in this era of increased emphasis on

understanding the behavior of mentally ill criminals, he was the first psychiatrist in Argentina to advocate for actually *listening* to these patients (Ruggiero, 2003). He brought this approach into the classroom as well, and between 1904 and 1919, he taught psychology courses with an applied, clinical focus in the School of Philosophy and Literature at the University of Buenos Aires.

Ingenieros exemplified the flexibility in psychology to that point. He was the first director of the Institute of Criminology in 1907, as well as being the founder of the *Revista de Filosofia* in 1915. He used this publication to disseminate important scientific and philosophical ideas of the day. Ingenieros often included his own writing in the areas of criminology, hysteria, and sexual pathology (Rodriguez, 2003). This included a discourse on love, *Tratado del amor*, in which he discussed the adaptive quality of erotic sexuality.

Ironically, Ingenieros, a positivist and somatist to his death in 1925, had a profound impact on Jorge Thenon and Celes Carcamo, two primary figures in the rise of psychoanalysis in Argentina (Bass, 2006). Indeed, Carcamo would go on to be the first president of the Argentine Psychoanalytic Association (APA). It was Ingenieros' belief in the efficacy of psychotherapy that helped lead to a more open stance on psychoanalysis, the popular "talking cure."

The Rise of Psychoanalysis

In contrast to the more dogmatic interpretations of psychological approaches witnessed in other countries, there was less polarization and pressure to "choose a side" in Argentina in the early 20th century (Plotkin, 2001). This allowed for the appropriation of psychological approaches/orientations from France, Germany, Spain, etc., without concern for ideological consistency. The result was an initially broader range of psychological ideas without a clear "Argentine psychology." As the political landscape changed, however, this ideological freedom would not last.

Beginning in the 1920's, there was growing anti-positivist sentiment culminating in a "positivist" crisis (Plotkin, 2001; Plotkin, 2003). This can be traced to the work of individual's such as Kruger and Ingenieros, as well as the increasing popularity of psychoanalysis in Europe, particularly France.

Psychoanalysis became even more popular in the 1930's with the beginning of both the Spanish Civil War and World War II. At that time, many leftist members of the psychological community, a significant proportion of whom were affiliated with the Communist Party, advocated for a more anti-experimentalist view of psychology. While there was no evidence of a formal Freudian-Marxist movement in Argentina as was observed in France and Germany, many psychiatrists saw the potential of (psychoanalytic) psychotherapy in facilitating the construction of a new modern society (Plotkin, 2001).

Psychoanalysis As Orthodoxy

In 1942, the Argentine Psychoanalytic Association (APA) was established by Angel Garma, a classically trained analyst from Spain (Vezzetti, 2003); later that same year, it was recognized by Ernest Jones, one of Freud's most important disciples. During the next meeting of the International Psychoanalytic Association (IPA) in 1949 following WWII, the APA became an official member. Unlike other members of the IPA, no psychoanalysts with established careers emigrated to Argentina; the APA consisted almost entirely of Argentine born professionals. Because of the absence of European trained psychoanalytic professionals, when the APA was established there was no pre-existing psychoanalytic orthodoxy (Plotkin, 2001). However, with the APA came the delineation of "rules" for the practice of psychoanalytic psychology. Argentine psychology now had its own dogmatism.

The final piece to eliminating ideological freedom in Argentine psychology was the emergence of the Peronist movement in 1945 (Plotkin, 2001). The political and ideological radicalization of Peron forced intellectuals to take sides; you were either a liberal-progressive against the Peron government or a nationalist-Catholic supporter. Peron's administration further demanded adherence from all academic institutions to its political doctrine, which it often achieved through appointing its own deans and faculty. The result was that many of the progressive psychology faculty were dismissed or resigned, including 1,250 professors at the University of Buenos Aires between 1943 and 1946.

In response to the state dictated uniformity of ideology among public institutions, private universities (termed CLES; Colegio Libre de Estudios Superiores) began to appear (Plotkin, 2001). The curriculum included Psychoanalytic psychology courses, and the APA became a counterculture.

Psychoanalysis and Psychology

Whether in politically harsh or advantageous times, psychoanalysis was consistently held in high esteem by intellectuals and medical professionals (Bass, 2006). Indeed, the merit of psychology as a science in Argentina was based on its association with psychoanalysis. With the exception of the developmental psychology of Jean Piaget, all other psychological theories were simply techniques (Plotkin, 2003). With the addition of CLES's, the number of universities and, subsequently, training settings, grew exponentially. As a result, by the 1960's psychoanalysis and psychology was beginning to separate from the field of medicine as a greater number of psychologists became trained in psychoanalytic principles (Knobel, 1975).

Courses in psychology were typically offered within the departments of philosophy or humanities although the emphasis was on psychotherapy, particularly psychoanalytic psychotherapy (Knobel, 1975). However, while many psychologists in training were receiving instruction on approaches to psychoanalytic psychotherapy, they were not formally recognized by the APA which dictated that, except for extreme circumstances, analysts must by medical doctors. The APA's own experience of having its professional scope artificially restricted did not appear to make it more sympathetic to the needs of psychologists. Further, they now enjoyed the sup-

port of the Peronist government including a Ministry of Public Health law which did not allow for the practice of psychotherapy by non-medical professionals (Ablard, 2003).

Several universities responded by expanding the scope of specialization among doctoral level psychology degrees, including clinical, educational, and industrial specialties, in an effort to secure professional legitimacy. However, initially there was a lack of agreement on uniform standards for training (Knobel, 1975). Indeed, while certain attempts at uniformity have been taken, there is still concern over the breath and overall quality of training at the doctoral level, specifically with regard to testing and knowledge of newer interventions (Solano, 2004).

Psychology in the University

The first formal Ph.D. level psychology programs in Argentina were not established until 1956, following the fall of the Peron administration (Plotkin, 2001). That year witnessed a psychometry program in Rosario and a three year psychology program in Buenos Aires. The program in Buenos Aires was taught mainly by psychoanalysts (M.D.'s) and was headed by a medical doctor, Marcos Victoria. By 1964, there were no fewer than 11 mandatory courses in psychoanalysis as part of the curriculum. However, psychology programs were still located primarily in the School of Philosophy as opposed to the School of Medicine and the Ph.D. awarded following successful completion did not allow the psychologist to practice psychotherapy legally (Knobel, 1975; Plotkin, 2001).

Given the barriers put up by the APA and the Argentine government, it is fair to ask the question, "Why would psychology students still want psychoanalytic training and from the very same professionals who put up these barriers to practice?" Plotkin (2001) outlines two primary reasons. First, many young Argentines viewed psychoanalysis as a "modern psychology" with the potential to catalyze social change. Students particularly preferred, and often demanded, faculty with leftist leanings such as Jose Bleger, a member of the Argentine Communist Party until 1961 (Vezzetti, 2003). Bleger's professional profile included theorizing on the compatibility of Freud and Marx which was very popular among students in the 1950's and 1960's.

Second, when psychology programs began forming in the 1950's, the only psychological paradigm in place in Argentina was psychoanalytic. Anti-positivism and the Peron administration had eliminated any imported psychology involving more empirical or research based methods and Argentina did not have a "home grown" alternative. Studying psychology meant studying psychoanalysis.

Psychiatry v. Psychology (i.e., M.D. v. Ph.D.)

Similar to other parts of the world, there was conflict in Argentina between psychiatrists and psychologists. In Argentina, doctoral level psychologists were often viewed as intellectuals but not doctors able to diagnose and "heal" (Knobel, 1975; Plotkin, 2001). However, with the advent of psychology programs, Ph.D. level psychologists were now the recipients of five years of psychoanalytic and psychotherapeutic study, training that most M.D.'s lacked. The response of psychiatrists was simple, "only those with a medical degree can perform the 'art of healing.'" Indeed, Marcos Victoria, the first director of the psychology Ph.D. program at Buenos Aires University was one of the most outspoken supporters of this belief.

At the same time, psychiatrists believed that psychologists could play in useful role in mental health (Knobel, 1975). According to Bleger and other members of the APA, the role of psychologists should be as "mental health agents" advocating for the importance of mental health services among the greater population. Of course, those deemed in need of mental health services should be attended to by a psychiatrist. For the APA, this provided the rationale for the training in psychoanalytic techniques and interventions psychologists would receive as well as the continued restriction on the actual practice of these techniques. While there were some psychiatrists who believed that there were "certain circumstances" in which a psychologist could provide interventions if supervised by a psychiatrist (Plotkin, 2001), there was consensus in the APA that psychologists could never understand enough of the biological and anatomical complexities of human pathology to heal on their own.

Although the main battle happened along lines of degree (i.e., Ph.D. v. M.D.) gender also played a part. Initially the majority of psychologists had been women and the profession was often seen as similar to the profession of teaching, a "female" and subordinate career. It is only with the election of Osvaldo Devries, the first male president of the APBA (Association of Psychologists of Buenos Aires) in 1968, and the consequent "masculinization" of the field that the subordinate role of psychologists was successfully challenged (Plotkin, 2003).

In this context, the greatest effort centered on liberating psychology from the APA model of training. The APBA passed regulations stipulating that only psychologists could teach courses offered within the organization. This proved successful as the aggregate number of psychologists increased allowing more university faculty positions to be held by Ph.D.'s relative to M.D.'s.

Psychologists also had to deal with a hostile government. Although the APA was usually untouched, the APBA was often the subject of propaganda campaigns and raids by government officials who branded members as Marxists and intellectual criminals. The conflict went so far as to result in the disappearance of Beatriz Perossio, then president of the APBA, in 1977, who was tortured and executed. In response to a hostile APA and Argentine government, the APBA became an advocate for the rights of psychologists in political and professional terms, performing as a pseudo-union.

In this context, the APBA cultivated strong relationships with universities. The APBA was also generally more open to different treatment modalities, an approach of great importance in treating middle and lower class Argentine citizens. This flexibility gave psychologists greater access to community and institution based mental health settings and

jobs than their APA peers. However, even though psychologists now began working as therapists, it was still technically illegal!

The ban on the legal practice of psychotherapy by psychologists lasted until the 1980's when, following intense lobbying and chants of "make legal what is legitimate," the APA and Argentine government finally removed its sanctions (Plotkin, 2003). The psychiatrists' "monopoly on mental health" was no more. Psychoanalytic training has since been offered to psychologists both through the APA, sanctioned by the IPA (International Psychoanalytic Association), and by institutions supported solely by the APBA. The latter are predominantly Lacanian, an indication of the still powerful influence of French psychoanalytic psychology in Argentina.

Psychology Following Economic Collapse

Since the late 1990's, the Argentine economy had been in a state of decline, culminating with a catastrophic political and financial collapse in December, 2001 (Plotkin, 2003). In a span of ten days there were five heads of state and, within the next year, the economy shrank by 15%. The peso was so devalued that the trade of goods and services, including mental health services, began to happen at "clubs of exchange" under a bartering system. Both psychiatrists and psychologists began to offer therapy sessions for free or in exchange for food or crafts.

In a larger sense, this also began to shift the focus to briefer therapy alternatives. Previously, Argentine mental health services had down-played the importance of medication in mental illness, viewing it simply as a means of getting the patient to a place where they could be analyzed (Vezzetti, 2003). However, with the economic crisis, this approach, as well as the utility of long analyses, has been questioned. Increasingly, quicker therapeutic methods have been employed as an influx of acutely distressed patients are treated.

At present, psychoanalysis continues to be the preferred theoretical, scientific, and applied psychology in Argentina (Bass, 2006). However, both psychiatrists and psychologists are working to develop more cost-effective, efficient methods of administration. Following the turmoil of the last ten years, Argentina is developing a more flexible, responsive mental health services system incorporating a more diverse range of theoretical approaches and interventions.

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Clinical Psychology to Join Efforts in Addressing the Mental Health Crisis in Ethiopia

Beyenech Tsegaye, Ph.D.

Introduction

I applaud the leadership of the Addis Ababa University for supporting the decision to train clinical psychologists at a graduate level in Ethiopia. This is indeed a visionary move and long overdue.

The field of psychology in the Ethiopian educational system can finally play a significant and much needed role in the mental health arena in Ethiopia. This ground work lays the foundation for psychologists to play a critical role in addressing the mental health crisis in the country. Such a move would also mean that psychiatrists and psychiatric nurses who have been carrying the sole burden will no longer be alone in addressing the mental health needs of Ethiopian citizens.

The establishment of graduate level education in clinical psychology, not only responds to the need for trained clinicians, but it also opens the opportunity for research to be done which will better serve the mental health community and the Ethiopian society in general. Clinical psychology will have the opportunity to make its way in Ethiopian society in the midst of the mental health crisis which confronts the nation.

It is with enthusiasm and excitement that I write this paper as I think about the future of psychology in the homeland that I left almost four decades ago. In this capacity I will offer a brief preliminary analysis of the position of psychological services in Ethiopia and its future role in the area of mental health.

For far too long, psychology was given a back seat in the health care delivery system in Ethiopia. Ethiopia as a nation and a society as a whole have not realized the contribution psychology makes in improving peoples' lives and its capacity in empowering people to reach their potential. In attempting to briefly discuss the reasons for the absence of psychology in Ethiopian society, I will offer some tentative perspectives on the issue.

If you are wondering why psychology is absent in the area of health care services throughout Ethiopia, you are not alone. Attempting to answer the question of why psychology failed to play a role in mainstream Ethiopia is a complex matter in light of the fact that there is no documented body of knowledge addressing this concern. An accurate and comprehensive response to this question requires additional study and research. Perhaps, with the help of the future researchers in the clinical psychology program at Addis Ababa University, we will come closer to finding an answer to this question.

The purpose of this paper is to offer the reader the good news about the developing opportunity for clinical psychology to impact the delivery of mental health services in Ethiopia. Although it is regrettable that it took the Ethiopian educational and public health systems this long to realize the vital role clinical psychology plays in the area of mental health, the change is highly welcomed!

Unlike the public view of psychology in western societies, psychology is not a household word in Ethiopia. The absence of psychological/psychiatric terminologies would have to be conceptualized in linguistically accurate and culturally relevant terms. Such an endeavor could no doubt be undertaken now that the path to further the development of clinical psychology is underway. Fekadu, Desta, Alem, and Price (2007) reported the difficulties they encountered in conducting research in the absence of effective translation of psychiatric and psychological constructs. Alem and Dereje (2003) attribute some of the problems of conducting research in the developing world to the deficiencies in assessment tools for cognitive and personality disorders. These psychiatrists' tireless work in advocacy and calling attention to the mental health service crisis seems to have finally paid-off through the establishment of the Institute of Psychology. The energized clinical psychology students will soon be challenged to develop theoretical models that are appropriate to the culture utilizing the large and rich body of knowledge in psychology to conduct research. To the faculty and the soon to become scholar practitioners and researchers, the work seems to be cut out for them to change the course of the impoverished mental health care delivery system of Ethiopia.

Brief Historical Perspective for the Absence of Psychology

In offering a brief perspective on the issue of why psychology took a back seat in the mental health system within the country, it would be helpful to consider at least a couple of perspectives. The first is the role of spirituality as it relates to healing and the second is the omission, until now, of clinical psychology from the educational system.

The role of the spiritual approach to healing for all kinds of ailments is basic for Ethiopians. The spirituality of the peoples of Ethiopia and their various belief systems are deeply rooted in ancient heritage and have a strong spiritual component in the ways they conceptualize illnesses, with a strong tendency to blame oneself when one becomes ill. There is a perception that both illness and symptoms are a manifestation of God's unhappiness with oneself and/or the work of the devil. Such views usually promote a readiness to pray in an effort to seek forgiveness and be healed. At times many bargain with God (*Silet*) to fulfill their wishes, seeking healing in exchange for doing some deeds in the name of a particular church.

The numbers of mentally ill in the nation have dramatically increased over time. Evidence of this increase can easily be witnessed by those visiting Addis Ababa regularly, as they see increasingly more and more individuals walking the streets aimlessly, lacking any purpose or direction. This drastic increase may have resulted from a combination of factors, such as the progressive disintegration of family and extended family units for various reasons. No doubt the unfavorable economic conditions coupled with the effects of long wars

have contributed to the displacement and separation of families to the cities in search of improved living conditions. Uprooted from their self-sustaining and harmonious farming communities individuals end up in impersonal and uncaring cities where there is no safety net available. This can no doubt set the stage for serious psychological turmoil within one's existence. Such groups of individuals become marginalized in their own country. While debate about these matters undoubtedly will take place amongst the students of the Psychology Institute, the fact remains that the increasing number of mentally ill persons is becoming visible and acknowledged by the average Ethiopian at this time. Working to understand the extent of the relationships between/among contributing factors will remain an objective to be addressed at the Psychology Institute.

In an effort to understand the issue of mental health in Ethiopia, the lack of help seeking behaviors of individuals with mental illness is seen by many to relate to the issue of stigma, although no supporting factual evidence for this was uncovered by this writer. Similarly, in the absence of research, one could easily assume that the tendency of Ethiopians' help seeking behaviors for any kind of illness (mental or medical) would be to be secretive for as long as was feasible. This could largely be due to the strong tendency for Ethiopians to blame themselves for any kind of illness. It also makes sense that the desired preference for healing in many cases consists of praying for divine intervention. Their deep religious beliefs stand strong and they exhaust the interventions from the spiritual healers through the church if they are of the Ethiopian Orthodox Christian Church, and from other types of indigenous healing practitioners. It is often the case that only after other interventions don't work, that the patient is willing to try modern medicine, as a last resort.

Since the patient wants to exhaust all of the other options for healing, (i.e. traditional medicine and /or spiritual intervention such as prayer and the use of Holy water for divine intervention and forgiveness from God) before resorting to modern medicine, their condition may have worsened and deteriorated. On the other hand, one could also assume that it is because of the absence of modern intervention (both medical and mental health) in the rural areas where the majority of the population lives that the patients' arrival at the clinic site is often only after the condition has deteriorated. My sense is that given the option to make independent decisions along with the availability of a clinic in close proximity, and the availability of funds, many patients most likely would still prefer a spiritual intervention. This is of course speculation and needs to be further investigated in a systematic manner.

I pose these questions to simply illustrate the need for research to better understand the motivating factors in the patients' decision making behaviors concerning types of interventions. Without research, one cannot be certain but can only speculate as my statements above suggest. This is why I am so delighted about the graduate level training in clinical psychology. Since the discipline has a strong tradition in research, coupled with the program producing highly skilled scholar practitioners as it evolves, I am confident that these questions and others will be investigated. These recent developments in Addis Ababa University brought vivid memories to mind involving a set of events contributing to my going so far away from my comfort zone to study psychology four decades ago. I always had a passion for working with people and in understanding human behavior and individual differences. My motivation to go abroad for higher education was mostly precipitated by the fact that the AAU administration made a decision regarding my field of study which was not my choice or my particular area of interest. This was done in an effort to deal with the overcrowding conditions of classrooms and to balance the heavy loads for some instructors. As a result I was assigned to major in Semitic Languages with a minor in Linguistics and French, which were not my choice at that time. Retrospectively, the study in Linguistics gave me a very good foundation and complementary knowledge to my then emerging interest in psychology. Feeling disillusioned, I considered the situation as a challenge, explored my options and focused on pursuing my education abroad. My interest in psychology became even stronger after the unfortunate experience of others imposing life changing decisions in the realm of my education.

Why Not Then?

Due to the strong presence of religious faith and power of the church in the lives of the average Ethiopian, philosophical discussions on the mind, body, and spirit were left to the clergy and religious leaders. It did not appear that the educational system recognized the importance of such discussions and investigations in the understanding of human behaviors. Therefore, one could speculate that the role of the Ethiopian Church played a major factor in the absence of the field of psychology and its applications in clinical settings in Ethiopia. On the other hand, some suggest that mental illness was not common. This reminds me of my Ethiopian friends in my undergraduate college years who were questioning why I would come this far to a different country to study psychology, expressing their belief that the church and the priests deal with such matters. Some argue that it is because the condition is considered a stigma and thus kept as a family secret or denied by the affected individual or family members, meaning the mentally ill are sheltered and protected by the family. However, there is another argument which involves the fact that there is no meaningful mental health delivery system in Ethiopia. There is only one mental hospital in the entire country that cares for the chronically mentally ill, leaving citizens outside of the nation's capital with no viable placements to take their loved ones for services.

Why Now?

There are many reasons why clinical psychology is being realized by the current educational leadership of the country. First and for most, credit should be given where it is due; to the psychiatry department staff of Addis Ababa University who played a critical role by calling attention to the mental health crisis of the nation. Not only did they carry the burden of providing mental health services under the most difficult

conditions, they also brought attention to the seriousness of the problem through published research conducted under very restrictive and limited conditions. Their tireless efforts in communicating the dire needs to the world I believe paved the way for the realization of the need for a clinical psychology training program in the country.

After facing the untenable task of providing mental health in Ethiopia, the psychiatry staff of Addis Ababa University continued to call for multi sector collaboration. Reporting the escalating need and demand for mental health services, Hanlon, et al. (2010) also outlined the lack of collaboration among the multi-sector groups such as the traditional healers, among others. Many blame the poor mental health conditions in Ethiopia on the brain drain issue the country is facing for many reasons. However, it is worthy of note, that the issue of brain drain with respect to health services is for the most part limited to those who are medically trained in Ethiopia and does not really include psychologists. The field of psychology was never given the opportunity to get the necessary attention and funding to train psychologists to be critical players in the mental health arena. It is in the area of medical education in which the government invested most. It is the medical doctors that Ethiopia used its limited resources to train who ended up fulfilling the health care service needs of the rich nations like the United States. Though one cannot blame those who left Ethiopia after receiving their medical degrees for wanting a better life, their choice to leave the country after being trained for free, certainly places Ethiopia at a great disadvantage, especially when these individuals did not contribute to their own educations. In their continued effort to bring attention to the mental health crisis in Ethiopia, Alem et al. (2010) accurately characterized the "globalization of medical education" to mean the supply of health care providers by poor nations like Ethiopia to rich nations like the United States without investing in their education. From my perspective, it is very disheartening to think about the nation that placed almost all its eggs in one basket by investing its very limited resources disproportionately on medical training while neglecting the areas of psychology and its specialty in mental health, with its potential impact in the welfare of individuals and the betterment of society in general, until now. A review of the WHO-AIMS (2006) on the mental health report on Ethiopia, offers a detailed account of the state of mental health in Ethiopia, basically confirming the absence of a basic infrastructure needed to provide services.

The Mental Health Crisis

One can easily assume that the mental health crisis in Ethiopia at this time is really a cumulative effect of the multitude of problems the population had to endure for a long time. This is a population that has been traumatized repeatedly as a result of wars and natural disasters. The cumulative effects of these man-made as well as natural disasters are difficult to effectively manage even for wealthy nations with good mental health delivery systems. Those who survived frequently were displaced as they relocated to different places, which often meant the dismantlement of families and support systems. Such individuals have a high probability of being traumatized. Most in the nation have experienced trauma of various types and many who survived had no meaningful intervention or support services to assist them in coping. In my opinion, it is no wonder that the prevalence rate of mental illness continues to grow.

The mental health program in Ethiopia is characterized by WHO as "one of the most disadvantaged" in the country and the prevalence rate of mental illness has exceeded 15% for adults and 11% for children. Ethiopia, like many other developing nations has been identified as neglecting the mental health needs of the people. Though the presence of NGOs is ever increasing, they have no involvement with mental health in the country. Despite the awareness of the WHO and the UN's recognition of the growing prevalence rate of mental illness, these entities presence and involvement so far does not seem to have made any meaningful impact with respect to mental health services. In a descriptive analysis of the admissions to the only psychiatric hospital in the nation, Fekadu et al. (2007) report how the lack of community based residential psychiatric services as well as the absence of effective rehabilitation centers are resulting in flooding the sole mental hospital in the country.

Ethiopia's decision to train psychologists in the country offers a wonderful opportunity. It is also hopeful that with the Institute of Psychology in place, these well trained psychologists will be in a position to impact not only the mental health service system but also become the change agents in various governmental agencies to effect and promote progress thereby establishing an effective and progressive mental health system at a national and community level. These change agents would have the capacity to meaningfully impact the government systems in much needed areas such as in early intervention programs, the elementary and secondary schools, in the universities, local hospitals and community centers.

Moving Forward to a Sustainable and a Stronger Mental Health System

During the past 3-4 years, I had the opportunity to visit Ethiopia and had the privilege of meeting the leading mental health professionals who are confronting the challenges of the mental health crisis in the country. I have talked with many of them and reviewed their publications, where they made their pleadings to health care professionals and leaders to make a difference and where they discussed their tirelessly efforts to bring much deserved attention to the nation's mental health crisis. Their energy and dedication inspired me and my desire to give back to the community grew and struck a light within me to start the steps in preparation to join their efforts to improve the delivery of mental health services in Ethiopia. Having been a mental health professional for over three decades providing my clinical services both in private and public settings in the United States, I feel blessed to be in a position to be able to continue my professional services to those in need. However, this time it is to my Ethiopian people I left close to four decades ago. As I finalized my deci-

sions and started to take the necessary steps to make my contribution possible (e.g., taking early retirement from my employment), the news about the establishment of the Psychology Institute at Addis Ababa University, simply topped the cake!

With the opening of the Institute, and the positive developments in the recently established psychiatry residency program within Ethiopia along with the plan to establish a masters level clinical psychology training program within the Psychiatry Department of Addis Ababa University, I see a big green light for a promising future of clinical psychology and the important role it will finally play in the development of a more effective mental health delivery system in Ethiopia.

To move forward in making the mental health service delivery effective, strong collaboration and team work is necessary. One of the ways of accomplishing this is through a strong professional association. I believe it is time to strengthen the Ethiopian Psychological Association (EPA). All efforts must be made to strengthen the association. EPA's strength will be instrumental in multiple ways; in the areas of training and education, setting the standards of practice, advocating, consulting, and research, among others. With the training of clinicians comes the need for a Mental Health Policy and a regulatory body at the Regional and/or National level. A stronger professional association could play a critical role in different areas. To this end, I would be delighted to hear from anyone interested in collaborating with me in organizing, establishing, strengthening, and/or mobilizing the Ethiopian Psychological Association. Please use my contact information below to reach me.

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References

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First Class of PsyD Students Graduates from California School of Professional Psychology Hong Kong Program

On May 14, 2011, the California School of Professional Psychology (CSPP) at Alliant International University awarded the PsyD degree in clinical psychology to a dozen students from the CSPP Hong Kong program's inaugural class. This program is the first US-based doctorate in clinical psychology to be offered in Asia. CSPP collaborates with the City University of Hong Kong to offer the program, and all classes are taught in English. These graduates will become leaders in applying clinical psychology in Hong Kong, Macau, China and Taiwan. Dr. Danny Wedding, Associate Dean for Management and International Programs at CSPP, commented, "We are especially proud of our first graduating class, and we are confident these students are among the best trained clinical psychologists in Asia." Dr. Wedding is pictured below with one of the graduates, Dr. Rose Kwok Wo Oi, and all of the graduating students, their faculty, and Alliant administrators are shown in the photo below.

Request for Info: Department Study Abroad Opportunities

Hello Division 52 Members:

The student committee of Division 52 is seeking to gather information on what types of study abroad and/or international immersion experiences are available across psychology programs. We hope to use this information to create a resource for students and/or faculty to find information on what types of study abroad experiences exist around the world. If you could take a few minutes and answer the below questions, we would greatly appreciate any information you can provide on what study abroad experiences exist around the globe! Responses can be sent back to me, at anhutchison@bsu.edu.

Please provide the following information, if available:

1. What types of study abroad or immersion experiences does your psychology department offer to your students (e.g. target student population, undergraduate or graduate focus, location, length of time, activities completed during experience, etc.)?
2. How do these opportunities further students' education?
3. How do these opportunities contribute to the study of psychology?
4. Any other information that you feel would contribute to this project.

Again, thank you so much for taking the time to provide this valuable information!

Ashley Hutchison, M.S.
Student Committee of Div. 52 - Member at Large
Second Year Doctoral Student
Counseling Psychology and Guidance Services
Ball State University

Addendum: Psychology in Russia Today

Alex Voronov, Harold Takooshian, Henry Solomon

As the International Psychology Bulletin (IPB) approaches its 15th anniversary in 2012, IPB continues to experiment with effective, new formats to extend psychology across national borders. Under its three editors Ivan Kos (1997-2004), Senel Poyrazli (2004-2009) and now Grant Rich, IPB has progressed far beyond simple APA news, to fill clear needs in the global psychology literature--offering regional reports, feature articles, book reviews, and peer-reviewed cross-cultural research.

One special challenge is to report the "indigenous psychologies" that naturally flourish within each region of the globe. Indigenous psychology has been defined as "the scientific study of human behavior or mind that is native, that is not transported from other regions and that is designed for its people" (Stevens & Gielen, 2007, p. 151). The largest index of indigenous psychologies has been compiled by the International Union of Psychological Sciences, IUPsyS (Stevens & Wedding, 2006).

In this first-ever addendum, IPB reports on indigenous psychology in Russia. In 2010, Russia celebrated its 125th anniversary of the birth of experimental psychology in 1885, with a major all-Russia conference hosted by the Institute of Psychology of the Russian Academy of Sciences, and resulting in an 888-page volume of Russian-language proceedings (Barabanshikova, 2010). Russian psychology has certainly seen many remarkable twists and turns during its 125 years—from the brilliant research by early giants (Vladimir Bekhterev, Ivan Pavlov, Alexander Luria) to the infamous murder of Bekhterev in 1927, and the outlawing of psychological testing ("testy") in 1936 by the Communist Party of the Soviet Union (Takooshian & Trusov, 1992). Today, some universities publish multidisciplinary journals which include a section of behavioral/psychological research.*

Professor Alexander Voronov of the State Academic University of Humanities in Russia was one of the key architects of the 2010 all-Russia conference. With the help of Professor Henry Solomon in New York City, they arranged a Skype teleconference in November of 2010 to provide a live "bridge" between Russian and American researchers. In this addendum, Voronov enlisted ten bilingual Russian colleagues and students to provide summaries of their current research, to give a snapshot of Russian psychology today. These summaries were minimally edited for uniformity of format, to retain their original tone as well as content.

Based on readers' comments, and the availability of future contributors, this addendum may serve as a model for future sections of IPB, offering English-language readers a window to indigenous psychologies in other regions—China, India, Africa, Latin America. Editor Grant Rich appreciates reader feedback, suggestions, and proposals at optimalex@aol.com. These summary abstracts are available on the Division 52 website.

References

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*One example is the Bulletin of the People's Friendship University—Psychology and pedagogy, which includes English-language summaries, and is accessible to those who know where to find this on the internet (http://193.232.218.57/?pagec=572).

Psychology International

Volume 22, Number 1, April 2011

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A Little Bit Can Go A Long Way:
A Reflection on Global Health Disparities

The latest issue of *Psychology International* can be accessed on the web at: http://apa.org/international/pi

Call for Student Research Manuscripts on Women and Gender

Deadline April 1, 2012

The Society for the Psychology of Women (SPW) of the American Psychological Association and the Association for Women in Psychology (AWP) seek research manuscripts for the 2012 Annual Student Prize for Psychological Research on Women and Gender.

Research Topics

The student research manuscript should focus on women's lives and issues, or more generally, on gender ideologies and behavior, from a feminist perspective.

Eligibility

Jointly-authored papers are eligible, but the first author must have been a student at the time the research was conducted, as indicated by a statement by the first author, in a cover letter accompanying the submission, specifying when and from what institution the first author obtained the degree, the name of the faculty who supervised the research, and the department of the supervising faculty. Entries should be of journal length and in *APA* style. Eligible papers include unpublished manuscripts as well as papers that have been submitted or accepted for publication. Published or presented papers are also eligible as long as they have a date of 2011 or 2012. All papers should be submitted in manuscript form, not as pre-prints or prints with information about submission and publication status provided in the cover letter.

Evaluation

Entries will be judged on theoretical creativity, methodology, clarity and style, and social importance of the research questions and findings for the psychology of women and gender.

Awards

A $250.00 prize will be awarded to the best paper. First and alternate winners will be announced at the 2012 meeting of the American Psychological Association.

Submission Procedure

Please attach a copy of your paper to an e-mail sent to the address below. Also, please send four (4) copies of the paper, a self-addressed, stamped postcard, and a self-addressed stamped business size envelope by April 1, 2012 to: Silvia Sara Canetto, Ph.D., Department of Psychology, Colorado State University, Fort Collins, CO 80523-1876 (silvia.canetto@colostate.edu)

The Submission Deadline for the 2011 AWP/SPW Student Research Manuscript Prize is April 1, 2012

Janet Hyde Graduate Student Research Grant

Proposals are being sought for Hyde Graduate Student Research Grants. These grants, each up to $500, are awarded to doctoral psychology students to support feminist research. The grants are made possible through the generosity of Janet Shibley Hyde, Ph.D., who donates the royalties from her book, *Half the Human Experience*, to this fund. Past recipients of Hyde Graduate Student Research Grants are not eligible to apply. Because the purpose of this award is to facilitate research that otherwise might not be possible, projects that are beyond the data analysis stage are not eligible.

Please send all application materials attached to a single e-mail message to both of the Hyde Award Co-chairs at the following addresses by September 15, 2011 (or March 15th for the spring deadline):

Dr. Mindy J. Erchull, merchull@umw.edu and Dr. Olivia Moorehead-Slaughter, oms@parkschool.org

Requirements:

1. Cover page with project title, investigator's name, address, phone, fax, and e-mail address
2. A 100-word abstract
3. A proposal (5-pages maximum, double-spaced) addressing the project's purpose, theoretical rationale, and procedures, including how the method and data analysis stem from the proposed theory and purpose.
4. A one-page statement articulating the study's relevance to feminist goals and importance to feminist research.
5. The expected timeline for progress and completion of the project (including the date of the research proposal committee meeting). The project timeline should not exceed two years.
6. A faculty sponsor's recommendation, which includes why the research cannot be funded by other sources. This letter should be attached to the e-mail with the application materials. Please do not send it separately.
7. Status of IRB review process, including expected date of IRB submission and approval. Preference will be given to proposals that have received approval.
8. An itemized budget (if additional funds are needed to ensure completion of the project, please specify sources)
9. The applicant's curriculum vitae
10. All sections of the proposal should be typed and prepared according to APA style (e.g., please use 12-point font)

Proposals that fail to meet the guidelines described above will not be reviewed.

Review Process

A panel of psychologists will evaluate the proposals for theoretical and methodological soundness, relevance to feminist goals, applicant's training and qualifications to conduct the research, and feasibility of completing the project.

Other Requirements

Only one application will be accepted per student, for each application deadline. Applicants who are involved in multiple projects that meet the submission requirements should choose the project that best fits the evaluation criteria (see "Review Process").

Within 24 months of receipt of the grant, recipients are expected to submit to the Hyde committee co-chairs a complete and final copy of the research document (e.g., a copy of the thesis, dissertation or journal manuscript based on the sponsored research), along with a 500-word abstract for publication in Division 35 newsletter. In addition, grant recipients shall acknowledge the funding source in the author's notes in all publications. Hyde award winners will be announced at the APA convention during Division 35 Social Hour. The names of the Hyde award winners may also be posted in Division 35 newsletter as well as on Division 35 web page and listserv.

Questions and other communications may be sent to the committee co-chair:

Mindy J. Erchull, Ph.D.
Co-Chair, Hyde Research Award Committee
Department of Psychology
University of Mary Washington
1301 College Avenue
Fredericksburg, VA 22401-5300
Phone: (540) 654-1557
E-mail: merchull@umw.edu

Call for Papers: Journal of Asia Pacific Counseling (JAPC)

www.kcajournal.org

Deadline: October 31, 2011

The Journal of Asia Pacific Counseling (JAPC) is an official publication of the Korean Counseling Association (KCA) that has more than 8,000 South Korean counselors and counseling psychologists as its members. Korean Counseling Association has long recognized the need for having an outlet for scholarly work that gives special attention to the applications of counseling with diverse populations in the Asia Pacific region. In setting up the Journal of Asia Pacific Counseling, many internationally renowned scholars have provided invaluable input regarding the title of the journal, potential editors, and the target audience.

JAPC is intended for both researchers and practitioners, and includes theoretical, empirical, and methodological articles in the areas of counseling interventions, prevention, career development and vocational psychology, supervision and training, assessment, multicultural aspects of counseling, and consultation.

All articles are published in English, and JAPC is issued twice a year in February and August. Please visit the homepage of the Journal of Asia Pacific Counseling (www.kcajournal.org) for full details on aims and scope, editorial policy, and article submission.

The next due date for manuscript submission is on October 31, 2011. Please submit manuscripts via e-mail (japc@snu.ac.kr), following the guidelines described on the homepage of the journal.

We hope you will seriously consider JAPC for your scholarship.

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International Employment Opportunities

Michael J. Stevens, PhD, DHC
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Cypress Health Region ECP (Canada), Clinical/ Developmental Psychologist: The Cypress Health Region is dedicated to excellence in its provision of quality health care services and is home to some of Saskatchewan's healthiest people. The Cypress Health Region s staff complement of 1m700 employees provide a variety of facility and community based services for the 46,000 residents living in 80 rural and urban communities in southwest Saskatchewan. With regional amalgamation successfully achieved, an annual operating budget in excess of $90M, and a new regional hospital. The ECP will provide both clinical and preventative psychological services to children from birth to school age and to their families and caregivers and to other agencies involved with these children. Clinical services will include assessment and diagnosis of developmental delays and other psychopathology, provisions of individualized programs for preschool children who are experiencing difficulties, and provisions of information and counseling to families, caregiver, and other agencies.

Qualifications:

- Masters degree or PhD in psychology, with preference to a doctoral specializing in clinical or developmental psychology, focusing on preschool population
- Eligible for registration with the Saskatchewan College of Psychologists and the Authorized Practice Endorsement with the Saskatchewan College of Psychologists
- Knowledge and ability to apply, empirically validated theories and interventions in the areas of clinical and developmental psychology. Ability to intervene at the individual and system level, and develop, implement, and evaluate preventative programs. Ability to apply the methods of assessment in the domains of development, psychopathology, intellect, and achievement for early childhood population.
- Knowledge of ethical and legal issues in practice with preschool children and families. Interpersonal skills to interact with clients, parents, health professionals, other agencies, and community groups.
- Valid driver's license

Private Practice (Canada), Clinical Psychologist: Step into a fully fee-for-service practice in Canada, the fourth best country in the world to live in according to the 2008 UN Human Development Report. If you're looking for an invigorating career change or have ever considered moving to Nelson, British Columbia - "Berkeley North" - for its great outdoor lifestyle and vibrant community feel, click on the videos and pictures at: http://web.me.com/toddkettner/Nelson_BC_Psychology_Practice_for_Sale/Home.html. You'd be joining two highly qualified and personable psychologists along with a great staff including a receptionist and psychometrist. We may also consider hiring an experienced psychologist as an employee. Feel free to contact Todd Kettner, PhD, RPsych at 250/352-6600 or e-mail kettner@summitpsychology.org for more information or just to chat about the possibilities.

Mobley Group Pacific Limited (China), I/O or Clinical Counseling Psychologist: Mobley Group Pacific Limited is a management consulting firm focusing on supporting organizations, management teams and business leaders in enhancing their effectiveness and organizational performance, with particular geographic focus in greater China and the Asia Pacific region. We are a rapidly growing firm making continuous efforts to source high caliber-talented professionals to become part of our quality consulting team to meet our growing business and client demands.

Qualifications:
PhD or advanced degree in psychology (I/O, clinical or counseling) or behavioral sciences, or MBA; business knowledge Fluent in both English and Mandarin is the prerequisite.

Responsibilities:

- Provide high quality professional services to clients in the areas of executive assessment, coaching, development planning, team development, management due diligence, organizational culture and 360-degree feedback; cross-cultural consulting services; leadership development program design; research, validation and publication; Hogan and other psychometric testing platforms; facilitation of strategy, planning and development events; and other related areas
- Contribute to business development, client management, consulting tool and process development
- Contribute to team learning
- Contribute to the client-focused, high professional standards, supportive team, learning and balanced work-life culture of MGP
- Coordinate and collaborate with the professional staff in the Shanghai and Hong Kong offices
- Continue your personal and professional development

Location:
Will be based in MGP Shanghai or Hong Kong office, with periodic travel to clients mostly located in the greater China and Asia-Pacific regions; some travel in Europe and the US is also expected.

Compensation and Benefits:

- Competitive base salary and performance-based bonus structure
- Health Insurance or Social Benefits required by the local Government
- Holidays and Professional Learning/Training Opportunities

Contact:
Stella Wang, Consultant
stellaw@MobleyGroupPacific.com

Please make sure to send a cover letter and curriculum vitae along with your application.

Serco (Germany), Clinical Social Worker: Serco is a leading provider of professional, technology and management solutions to the federal government in the areas of national security and intelligence, human capital management, IT and professional services, and engineering and logistics. We advise, design, integrate and deliver solutions that transform how clients achieve their missions. Headquartered in Reston, VA, Serco North America has approximately 11,000 employees who have helped transform government and public services around the world.

We have an immediate need for a licensed clinical social worker to provide clinical social work services in Bamberg, Germany as part of a multi-disciplinary US Army health care team to patients who are eligible beneficiaries of the Military Health Care System. The LCSW will utilize short-term and long-term care models, patient and provider consultation models, and education to address behavioral health concerns and medical conditions related to behavioral health needs of service members and their families. This individual works primarily with service members and their families in behavioral health settings to address issues related to deployments to conflict areas. Services will include screenings, clinical assessments, treatment, case management, consultation, referral, and education that are IAW professional standards of the National Association of Social Workers, Army Medical Departments' standards, and DOD-directed Clinical Practice Guidelines.

Individuals hired for these positions are awarded status to work in Germany under the Status of Forces Agreement. This exempts the employees from German taxes on salaries received for work under this contract. Additionally, individuals will be eligible to use the military commissary, base exchange, gas station, bank, clubs, and recreation facilities. Tuition reimbursement for full tuition for grades K-12 at Department of Defense Dependent Schools is available; this is on a space-available basis (reimbursement of tuition for International Schools is considered on a case-by-case basis). Reimbursement for relocation (up to $20,000 total for the trip there and back plus cost of family member plane tickets) is available. Use of the military medical treatment facility is available on a space-available, for fee basis; an international health care plan is available.

Serco also offers a comprehensive benefit package including group medical coverage, paid vacation and sick leave, 10 paid federal holidays, life insurance, 401K with match, and tuition reimbursement for college courses.

The duties of this job opportunity include:

- Assess and resolve complex social, economic, and psychosocial problems that may impact on the service members' and their families' medical treatment while an outpatient, an inpatient, or under evaluation for medical discharge from the service
- Conduct psychosocial evaluations and provides therapeutic interventions, including crisis intervention, to individuals, groups, and families
- Serve as a behavioral health referral resource and subject matter expert in behavioral health-related programs to medical staff in various medical settings
- Evaluate individual and family systems; assess patient functioning within work, family, and routines of daily living; identify areas needing continued support, resources, and treatment
- Provide services for high-risk populations (e.g., service members pending discharge due to physical and/or behavioral health injuries and illnesses, service members wounded as a result of military duties, and families of services members killed in action)
- Support local and remote soldier readiness processing events that prepare large numbers of service members for mobilization, deployment, demobilization, and redeployment. This includes behavioral health services, screening, evaluation, management, and referral for those with deployment-related symptoms, and providing service members with assistance with administrative requirements
- Develop comprehensive treatment care plans IAW behavioral healthcare standards
- Coordinate services for soldiers/patients who move out of local area to ensure continuity of care
- Assist soldiers and patients with navigating healthcare systems
- Coordinate and assist installation community agencies and the MTF in the referral process; provide reintegration training and services for those returning from deployment
- Educate patients, their families, commanders, and healthcare staff on community resources
- Maintain complete and accurate records and documents all patient contacts and services; maintain inpatient and outpatient medical records IAW AR 40-66
- Participate in departmental quality assurance programs

- Present patient cases in case staffing meetings
- Conduct crisis intervention services/on-call duties as assigned
- Participate in and/or directs research and conducts clinical investigations in behavioral health or social work

US International University (Kenya), Clinical Psychologist: USIU is a private, not-for-profit, chartered university located on the outskirts of Nairobi, Kenya, accredited by the Western Association of Schools and Colleges and The Commission for Higher Education in Kenya. USIU boasts a diversified faculty and student body from over 40 nations, with a vibrant history of growth and development.

We are expanding our psychology programs to offer our first doctorate degree in clinical psychology (PsyD), and we are also expanding our master of arts in psychology to include an MA in clinical psychology and an MA in marriage and family therapy.

We have four openings for full-time faculty who are licensed psychologists with an earned PhD or PsyD to start with us in September 2011 or early 2012, preferably with a two-year renewable contract. We seek faculty who meet three or more of the following criteria:

- Licensed clinical psychologists, who hold an earned doctorate in psychology.
- Direct clinical expertise to include assessment, diagnoses, psychotherapeutic treatment, and general scope of practice in individual and group therapy.
- Direct family therapy expertise with families, couples, and children.
- Academia/faculty experience in clinical psychology, preferably at the doctorate level.
- Clinical supervision experience and continuing education preferably with pre-doctorate or post-doctorate students, or with private practice consultation and supervision expertise.
- Psychometric expertise in application of objective, cognitive, and projective testing.
- Direct research experience and expertise in clinical psychology.

Applicants are requested to email a letter of interest and resume/curriculum vitae to Dr. Carol J. Watson, USIU Coordinator of Psychology Programs, E-mail: cwatson@usiu.ac.ke, Website: www.usiu.ac.ke

Applications will be accepted until positions are filled.

New Zealand, Clinical Psychologists: We have full-time clinical psychologist vacancies to fill for community mental health and other service organizations. You must have: Ph.D. in clinical psychology; current practicing license. A minimum of two-years post-supervisory experience. The ability to receive your New Zealand psychologist registration with clinical scope; the desire to commit two years or longer. E-mail: office@alignrecruitment.com; Phone: +64 3 366 8779: Fax: +64 3 377 6770; Web www.alignrecruitment.com. An expatriate American is available to assist with all enquiries.

LaSalle College of the Arts (Singapore), Art Therapist: Contemporary in focus and innovative in approach, LaSalle College of the Arts has been nurturing generations of creative practitioners. As a leading specialist tertiary institution for contemporary arts education, LaSalle offers the most comprehensive range of degrees and diplomas. Here is an opportunity for you to contribute to the creative arts and play a role in establishing Singapore as a global arts hub.

Art therapy in Southeast Asia is a new and developing field. At LaSalle, the Art Therapy Programme is multi-culturally driven and includes the integration of eastern and other international behavioral norms.

LaSalle is seeking a dynamic, appropriately qualified and trained individual to lead the Masters in Art Therapy Programme in Singapore. This position will report to the head of school.

Responsibilities:

- To teach and develop students to become practicing art therapists while also promoting the profession and its standards of practice in Singapore
- To conduct and coordinate seminars and workshops on art therapy practice at hospitals, schools and other organizations in Singapore and abroad
- To be responsible for administering the Art Therapy Programme in its entirety and managing part-time lecturers and placement providers
- To undertake clinical work in the field and to include students in this placement activity whilst conducting relevant clinical research
- To initiate workshops that promotes art therapy in Singapore and abroad
- To be actively involved in own creative process/ research

For more information, contact: hr_4@lasalle.edu.sg.

NYU (Abu Dhabi), Clinical Psychologist: NYU Abu Dhabi has an exciting opportunity for a full-time clinical psychologist located in Abu Dhabi, UAE. At NYU Abu Dhabi, wellness counselors play a critical and multifaceted role as mental health professionals, mentors, advisors, and administrative colleagues. The wellness counselor (Clinical Psychologist II) provides clinical assessment, psychotherapy, group therapy, and crisis intervention and management for an internationally diverse student body, and oversees a multidisciplinary team of counselors trained in a variety of different psychological

disciplines.

To qualify, you must have a PhD in clinical psychology, US state license, the ability to obtain license in Abu Dhabi and three years' post-doctoral clinical experience. Experience supervising postdoctoral and doctoral clinicians and/or other counseling staff members preferred. Experience as a college or university counselor is highly preferred, with a preference for candidates with experience in the UAE or other gulf country. Experience with a diverse adolescent or college population required. Experience with alcohol and other drug issues, and/or eating disorders preferred. The ideal candidate must understand the wider perspective of the institution and how student life supports and fits into the broader educational mission. He/she understands and appreciates the intellectual, emotional, social, psychological, and political development of undergraduate students in a diverse international community committed to intellectual rigor and ethical values, and thinks creatively and critically about programs, services, and resources in order to provide the best possible environment to support students. The selected candidate will adapt to new work situations, people, ideas, procedures, and organizational structures in order to accommodate an evolving work environment; exhibit maturity, reliability, composure, and stability under pressure in order to handle on-the-job challenges; has excellent communication, mediation, and consultative skills and is able to work with students, faculty and staff from many backgrounds; and possesses the ability to build successful relationships with faculty, students, parents, and co-workers.

NYU offers a superior benefits package, which includes NYU tuition for self and eligible family members, generous vacation, medical, dental, and pension plans. For more information and to apply for this position online), visit our web site at: www.nyucareers.com.

University of Western Australia (Australia), School of Psychology: The University of Western Australia is seeking to appoint a senior academic in psychology to a newly created tenurable position in the School of Psychology. The appointed person will be a leader in the field with an international reputation for research, a track record in attracting significant research funds, and the capacity to develop a team of world-class researchers and educators of clinical psychologists. The appointee will play a key role in the integration of clinical research and teaching with the existing research clusters in the school. Applications from those with specialist expertise in pediatric clinical psychology, clinical neuropsychology, or clinical health psychology are particularly encouraged to apply. Although a higher-level Winthrop Professorial appointment is preferred, applicants may be considered for a slightly more junior professorial position depending on their level of experience. In the recent (January 2011) Excellence in Research for Australia (ERA) assessment, psychology at UWA achieved the highest ERA rating of 5 and was one of only three psychology schools in Australia to achieve this level. The school hosts research programs in Australian Research Council funded centers, including the Centre of Excellence in cognition and its disorders and the Bushfire Co-operative Research Centre. Additionally, the school has a number of staff funded by the Australian Research Council on prestigious professorial or future fellowships. The school has research and teaching strengths in cognitive science and cognitive neuroscience (including developmental psychology, developmental disorders, neuropsychology, and perception), abnormal cognition and clinical psychology, and social psychology and organizational psychology.

For further information regarding the positions contact: Winthrop Professor David Morrison, Head of the School of Psychology on Tel: +61 8 6488 3240, or e-mail david.morrison@uwa.edu.au. Closing date: August 26, 2011.

The University offers an attractive salary with benefits including 17% employer superannuation, generous leave provisions, fares to Perth (if applicable) for the appointee and dependants, together with a substantial relocation allowance. The information for candidates' brochure which includes details to lodge your application may be found via a link at http://www.jobs.uwa.edu.au/; or at https://www.his.admin.uwa.edu.au/Advertising/3541CandidateInformation.pdf; or by contacting Ms. Toni Pilgrim, Human Resources, e-mail toni.pilgrim@uwa.edu.au.

Carleton University (Canada), Department of Psychology: The Department Of Psychology at Carleton University invites applications from qualified candidates for a preliminary (tenure-track) appointment in quantitative methods at the rank of assistant professor beginning January 1, 2012. Applicants must have a PhD., demonstrated excellence in teaching statistics and methodology, and must possess a strong commitment to research and scholarship, as reflected in publications, with preference to publications in health, environment, or digital media. The successful candidate will have the ability to develop an externally-funded, high quality research program; will be committed to effective teaching at the undergraduate and graduate level; and will contribute effectively to the academic life of the Department. The Department is interested in candidates who are able to teach advanced statistics at the graduate level including ANOVA, regression, multivariate statistics, and other advanced statistical techniques (e.g., HLM, SEM), and basic and advanced statistics at the undergraduate level. The successful candidate will have a program of research applying their methodological skills to areas of psychological research that contribute to Carleton's strategic research direction in health, environment, or new digital media.

The Department of Psychology offers opportunities to explore psychology's major fields including health, developmental, cognitive, applied, forensic, and personality/social. We also have intellectual ties with academic units offering degrees in

cognitive science, child studies, human-computer interaction, and neuroscience. Carleton has offered undergraduate degrees in psychology since 1953 and graduate degrees in psychology since 1961. The Department of Psychology currently offers undergraduate programs in the Faculty of Arts and Social Sciences as well as the Faculty of Science. Graduate programs in psychology are offered at the master's and doctoral levels. Further information on the department is available at http://www2.carleton.ca/psychology/.

Please send applications to Chair, Department of Psychology, Carleton University, 1125 Colonel By Drive, Ottawa, ON. K1S 5B6. Fax: (613)520-3667. Applications and reference letters can be sent by email to psychchair@carleton.ca. Applicants should include a curriculum vitae, a statement outlining statistical expertise, a statement describing current and future research interests, examples of publications, and materials relevant to teaching experiences. Interviews will include both a research talk and a lecture on an advanced statistical method. Applicants should ask three referees to write letters directly to the Chair. Applications will be considered after July 31, 2011, or until the position is filled.

Located in Ottawa, Ontario, Carleton University is a dynamic research and teaching institution with a tradition of leading change. Its internationally recognized faculty, staff, and researchers provide more than 24,000 full- and part-time students from every province and more than 100 countries around the world with academic opportunities in more than 65 programs of study. Carleton's creative, interdisciplinary, and international approach to research has led to many significant discoveries and creative work in science and technology, business, governance, public policy, and the arts. As an innovative institution, Carleton is uniquely committed to developing solutions to real world problems by pushing the boundaries of knowledge and understanding daily.

British Columbia Mental Health and Addiction Services (Canada), Licensed Psychologist: As part of the provincial mental health services continuum, BC Mental Health & Addiction Services provides a diverse range of specialized, "one-of-a-kind" tertiary level mental health services to residents across all geographic areas in British Columbia. These include adult/geriatric and neuropsychiatry services located at Riverview Hospital, Adult Forensic Psychiatric Services located at the Forensic Psychiatric Hospital, plus six regional clinics, and Child and Youth Mental Health Services located at BC Children's Hospital. In addition to direct services, BC Mental Health & Addiction Services acts as a support and resource to service providers across the province, and contributes to research and education. BC Mental Health & Addiction Services is an agency of the Provincial Health Services Authority (PHSA), which plans, manages and evaluates selected specialty and province-wide health care services across BC. The Provincial Health Services Authority (PHSA) embodies values that reflect a commitment to excellence. These include:

- Patients first
- Best value
- Results matter
- Excellence through knowledge
- Open to possibilities

These dynamic roles are ideal for accomplished psychologists who exude both professionalism and compassion.

- Licensed Psychologist
- Forensic Psychiatric Services
- Port Coquitlam, Nanaimo and Prince George, BC
- *Regular and Temporary Full Time Opportunities*
- Monday to Friday 0830-1630
- Salary: $40.39-$52.66/hour

Ongoing opportunities are available at the Forensic Psychiatric Hospital in Port Coquitlam, the flagship inpatient Forensic Hospital for the province of BC and an accredited site for APIC internship programs as well as our six forensic regional outpatient clinics across BC (Nanaimo, Kamloops, Surrey, Vancouver, Prince George, and Victoria). The secure, 190-bed hospital is an internationally acclaimed, state-of- the-art facility and serves individuals referred by the courts for treatment and assessment. Under the general direction of the Provincial Director, FPSC (Forensic Psychiatric Services Commission), and the Director, Clinical Services, consistent with the ethics and standards of the College of the Psychologists of BC, and Forensic Psychiatric Services, this position requires an in-depth knowledge of psychology including developmental theories, family and social dynamics, treatment and behavior management modalities, and psychological testing and interpretation. The ability to prepare comprehensive written assessment for the courts and referral agencies and in-depth knowledge of the justice system, complex legal issues, and other forensic matters is necessary. Our team of psychologists has an in-depth knowledge of relevant legislation, sound knowledge of the service delivery system for offenders and their families at the local and regional and provincial level, and the ability to testify in the court as an expert witness. Opportunities are available to become a key member of a team providing forensic assessment and multidisciplinary treatment plans. This role will also provide supervision to practicum students and the opportunity for research.

You must possess or be eligible for current registration with the College of Psychologists of BC as a clinical psychologist, with a doctorate in psychology, and specific training in the field of clinical psychology. Post-graduate training in the field of forensic psychology is also desirable. The knowledge, skills and ability required for this position are consistent with a licensed clinical psychologist and three years experience in clinical psychology, with experience in forensic psychology preferred.

Criminal record check required. Travel required, need own

vehicle.

Applications will be accepted until position filled. For further information about these opportunities contact Linda Hand at 875-7216 or lhand@phsa.ca.

For more information on all that the PHSA has to offer, visit: http://careers.phsa.ca.

For more information about the agency that you are interested in, please visit the website at www.bcmhas.ca.

Cape Breton District Health Authority (Canada), Clinical Psychologists: The Cape Breton District Health Authority, Sydney, Nova Scotia, has immediate openings for permanent full-time clinical psychologists. The successful candidates will have doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology. They must be registered or eligible for registration with the Nova Scotia Board of Examiners in Psychology.

The positions in Child & Adolescent Mental Health Services require the candidates to work in a multidisciplinary team to provide assessment, individual and group treatment to children and adolescents patients aged 0-19 years with a variety of mental health disorders. Our multi-disciplinary approach involves services within our district as well as within the community, including consultation to schools, daycares, children's aid services, and group homes.

The Autism Intervention Program again involves a multidisciplinary team approach including in-home behavioral interventionists, psychiatry, social work, psychology, and occupational therapy. The program requires a candidate that can provide clinical leadership in the areas autism assessment and diagnosis, pre-school assessment, behavioral intervention, and the provincial EIBI program, as well as help facilitate the transition to schools for children with autism both in an outpatient and home setting. The Autism Program is part of a province wide initiative and utilizes the pivotal response therapy (PRT) model for early intervention. There are also opportunities to be part of larger, multi-site research projects within this program.

Child and Adolescent Services is an outpatient service involving a multidisciplinary team approach including in-home behavioral interventionists, psychiatry, psychology, and social work. The service requires a candidate that can provide mental health assessment, psycho-educational assessment, and treatment to patients up to age 19, including those with neuro-developmental disorders, and their families. Customized training opportunities are available to further develop skills in these specialty areas for interested and motivated candidates.

The position in the Adult Mental Health Clinics requires that the candidate work in two separate clinics to provide assessment, individual and group treatment to adults aged 19 years and older with a variety of mental health disorders. Our multidisciplinary approach involves services within our district as well as the community including consultation to primary care physicians, family services, addiction services and other community agencies.

The Eating Disorders Clinic involves a multi-disciplinary team approach including diagnostic assessment, consultation and direct treatment services for individuals with eating disorders across the lifespan. Consultation service is also provided to pediatrics, inpatient psychiatry, and primary care physicians for patients requiring inpatient admission and treatment. Clinical supervision is provided to the dietitian assigned to the Eating Disorders Clinic.

The Adult Outpatient Mental Health Clinics are an outpatient service involving a multidisciplinary team approach, individual and group treatment, consultation, and education. The team may involve psychiatry, psychology, social work, nursing, and occupational therapy. For further information, or to apply with cover letter and resume please contact:
Janine Hussey Manager, Recruitment & Retention Cape Breton District Health Authority, 1482 George Street Sydney, NS B1P 1P3; Fax: (902)567-7224; E-mail: husseyjan@cbdha.nshealth.ca.

University of Hong Kong (China), Department of Psychology: Founded in 1911, The University of Hong Kong is committed to the highest international standards of excellence in teaching and research, and has been at the international forefront of academic scholarship for many years. Ranked 21st among the top 200 universities in the world by the UK's *Times Higher Education*, the University has a comprehensive range of study programs and research disciplines spread across 10 faculties and about 100 sub-divisions of studies and learning. There are over 23,400 undergraduate and postgraduate students coming from 50 countries, and more than 1,200 members of academic and academic-related staff, many of whom are internationally renowned.

Applications are invited for the appointments as assistant professor in clinical psychology in the Department of Psychology, from January 1, 2012, or as soon as possible thereafter, on a 3-year fixed-term basis, with the possibility of renewal, or with consideration for tenure after satisfactory completion of a second fixed-term contract. Applicants should possess a PhD degree in clinical psychology, with a good record of research, together with a track record of teaching, or sound indicators of promise as a teacher, in clinical psychology. The appointees are expected to maintain an active research program, be responsible for teaching courses at both graduate and undergraduate levels, and supervise research students. Information about the Department can be obtained at http://www.hku.hk/psychology.

Annual salary for an Assistant Professorship will be in the range of HK$484,980- 749,520 (approximately US$ =HK$7.8) (subject to review from time to time at the entire discretion of the University). The appointments will attract a contract-end gratuity and University contribution to a retirement benefits scheme, totaling up to 15% of basic salary, as well as leave, and medical/dental benefits. Housing benefits will be provided as applicable. At current rates, salaries tax does not exceed 15% of gross income.

Further particulars and application forms (152/708) can be obtained at http://www.hku.hk/apptunit/ or from the Appointments Unit (Senior), Human Resource Section, Registry, The University of Hong Kong, Hong Kong (Fax: +852 2540 6735 or 2559 2058; E-mail: senrappt@hku.hk). Review of applications will begin on July 15, 2011, and will continue until the posts are filled. Candidates who are not contacted within 3 months of the date of their applications may consider their applications unsuccessful.

University of Hong Kong (China), Department of Educational Psychology: The Department invites applications for several positions with prospect for substantive appointments in counseling psychology, including school guidance, school/educational psychology, special needs and learning difficulties, and other areas of psychology. Ranks are open with preference given to assistant professor/associate professor levels. Applicants should have (1) excellent academic qualifications including a doctoral degree in psychology or education, (2) a strong research background in areas that will contribute or add to the existing strengths of the department, (3) strong commitment to excellence in teaching and scholarship, and (4) a track record of programmatic research and publications. The appointees will (a) teach postgraduate and undergraduate courses (including theory and applied courses for postgraduate degree programs), (b) supervise postgraduate students, and (c) assist in administrative matters. Both English and Chinese are used as the medium of instruction. Salary will be highly competitive, commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package, including medical care, plus a contract-end gratuity for appointments of 2 years, and housing benefits for eligible appointees. Further information about the University and the general terms of service for appointments is available at http://www.cuhk.edu.hk/personnel. The terms mentioned herein are for reference only and are subject to revision by the university. Application procedure send full resume, copies of academic credentials, a publication list and/or abstracts of selected published papers, together with names, addresses and fax numbers/e-mail addresses of three referees to whom the applicants' consent has been given for their providing references (unless otherwise specified), to the Personnel Office, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong. Closing date: November 30, 2011. Fax: +852 269 6 1462 by the closing date.

Danish Institute for Study Abroad (Denmark), Psychology Program Director: DIS seeks an accomplished administrator and excellent teacher in the field of psychology to lead its growing undergraduate psychology program and the child diversity and development program in cooperation with the Associate Program Director and two additional fulltime administrative employees. The Program Director will expand the curriculum, hire and mentor psychology faculty, teach one course per semester (courses are taught in English), and participate in other projects and academic leadership tasks at DIS. The successful candidate will work directly with U.S. students and Danish faculty and administrators as well as faculty from U.S. partner universities. The Director will be part of an energetic and innovative program team and report to the Associate Director of DIS.

Primary responsibilities:

- Manage and develop the DIS psychology program and child diversity and development program
- Expand the psychology curriculum, with emphasis on experiential learning elements such as practicum and academically integrated study tours
- Mentor faculty and ensure high academic quality of psychology offerings
- Teach undergraduate psychology course(s)
- Cooperate with U.S. universities on curriculum development

Experience and skills:

- PhD in psychology
- Demonstrated organizational and leadership skills; providing vision and competent leadership in development of academic programs
- Minimum of 3 years successful teaching experience from the U.S. at college/university level
- Demonstrated administrative and interpersonal skills in leading and motivating faculty and staff in an intercultural setting

Personal qualifications:

- Self-motivated, proactive, and determined to reach goals
- Well organized, strategic, creative, analytical
- Flexible, service-minded and team-focused
- Study abroad experience preferred

Submit a curriculum vitae and an application letter. Also, submit a one-page essay describing your philosophy of intercultural teaching and learning for undergraduate psychology students. Include references and teaching evaluations. Salary and start date negotiable.

For more information please contact Malene Torp, Associate Director, DIS, Copenhagen mto@dis.dk or (+45) 3376 5491. Submit to job@dis.dk. Title the E-mail "Psychology Pro-

gram Director".

For more information about DIS: www.dis.dk.

American Hospital Services Group (Guam), Licensed Psychologist: American Hospital Services Group LLC currently seeks a licensed psychologist who has completed a pediatric fellowship in psychology to work as a civilian contractor at U.S. Naval Hospital Guam. Malpractice Insurance is covered by under the Federal Tort Claims Act.

http://www.med.navy.mil/sites/usnhguam/information/Pages/default.aspx

Schedule:
Monday - Friday 7:30am - 4:30pm

Housing allowance, retention bonus, relocation reimbursement and 8 hours of PTO every 2 weeks.
Job description:
Responsible for and applies psychological procedures and techniques, including interviewing, behavioral assessment, cognitive-behavioral therapy, and psychological testing/ psychodiagnostic testing, in the evaluation, diagnosis, and treatment of psychological and neuropsychological disorders. The following are desirable skills:

- Individual, family, and group psychotherapy, and couples therapy, alcohol and drug treatment evaluations
- Consults with medical personnel, legal authorities, military commanders, and school districts, as required
- Maintain accurate and current notes in both the Department of Psychology records and patient medical records of all patients seen, as appropriate, and produces reports of evaluation and/or treatment, as required
- Participate in military specific training (for example, training to perform Command Directed Evaluations, security clearances, Military Training Instructor clearances, pre-post deployment screening, PTSD, combat stress)
- Conduct applied research and clinical investigations in clinical/behavioral health psychology

Requirements:

- Have a Doctor of Philosophy (PhD) or (PsyD) degree in clinical or counseling psychology from an APA-accredited psychology program
- Completion of pediatric fellowship in psychology
- Have and maintain a current license to practice psychology in any one of the 50 states, the District of Columbia, Puerto Rico, or the U.S. Virgin Islands. Valid BCLS Card is required to start
- 24 months of experience in the last 36 months

For more information contact Patrick Hoffman at 1-800-872-8626, ext, 235 or email a copy of your curriculum vitae to phoffman@ahsg.us.

Koya University (Iraq), Applied Psychology Program: This position primarily provides co-leadership with national faculty at Koya University for the establishment, operations, and ongoing development of the first graduate program in applied psychology in Iraqi Kurdistan, as a major initiative for capacity building in the Iraqi mental health field. The position entails oversight of all aspects of the program to ensure that it meets appropriate educational standards in the preparation of versatile, competent, and professionally responsible clinical professionals who can then contribute to further growth of the discipline. It additionally calls for a knowledge of contemporary psychological science, theory, and models of practice with individuals and systems, and the ability to culturally adapt them to the clinical needs of Kurdish and Arab populations. These needs include but are not limited to trauma recovery, treatment strategies for depression and anxiety, prevention of gender-based violence and suicide, and elimination of stigma and promotion of human rights for those with psychological problems.

The position secondarily entails responsibility for close collaboration in program planning, implementation, and evaluation with the leadership of the Trauma Rehabilitation and Training Center and clinical supervision of the center staff and additional mental health workers in the Burn Hospital and other sites as needed. It also calls for consultation regarding services at the Qalawa Camp, the Duhok Mental Health Center, and other related mental health projects as needed, including the integration of psychosocial approaches and psychoeducation into the delivery of primary care treatments. The majority of beneficiaries will be victims of human rights abuses, and the position requires both academic and work-related experience in trauma-informed mental health care.

The individual will report to the Country Director and be based generally three days a week on the campus of Koya University and the rest of the week in Sulaimaniya or on field visits in Iraqi Kurdistan. The position also may involve national and international travel.

Education and/or Experience**:**
The position requires a doctorate in clinical or counseling psychology with successful completion of a 1-year internship accredited by the American Psychological Association. It also requires graduate level psychology teaching experience; and an academic appointment as assistant, associate, or full professor at a university is preferred. State licensure and diplomate certification in clinical or counseling psychology by the American Board of Professional Psychology or other advanced training certification are also preferred. Significant experience in cross-cultural psychology, trauma-related assessment and therapies, clinical supervision, and international educational and training programs is strongly recommended as well.

Competencies:
The position requires a well-informed general background and interest in academic and professional psychology and in international mental health research, practice, and education. In addition, the following qualities are of particular value:

- Sensitivity to and respect for cultural diversity and alternative values and understandings of the world
- Adaptability to new and unfamiliar circumstances; willingness to listen to and learn from others, and to examine one's own assumptions and interactions
- Self-awareness; appropriate balance between professional authority and personal humility; and comprehensive openness to new perspectives and challenges
- Primary commitment to local capacity- building and inclusive style of decision-making and power-sharing
- Initiative, creativity, and flexibility in problem-solving and program development
- Integration of overall conceptual vision with careful attention to practical detail, as needed
- Ability to work both in close collaboration with colleagues and independently
- Leadership skills in administering projects, supporting and motivating staff, modeling dedication and healthy work ethic, setting effective short- and long-term objectives and plans, and monitoring and evaluation of programs
- Organizational skill in data analysis, report and grant-writing, budget management, and staff development
- Ability to accept and to delegate responsibilities and to exercise oversight, as needed
- Familiarity with educational and teaching modalities, design of syllabus and lecture formats, facilitation of classroom discussion, construction of testing and assessment, and use of computer-based learning
- Experience in mentoring graduate students regarding academic and professional issues; sensitivity to students' needs; and ability to work with students with a wide range of backgrounds, experience, skill levels, and language proficiency
- Expertise with psychotherapy and psychosocial theories and techniques with different populations
- Knowledge of preventative and systemic strategies for mental health promotion
- Excellent communication skills with students, colleagues, and representatives of other programs; capacity to provide direct, timely, and constructive feedback, and to establish clear policies and procedures
- Ability to manage stress and meet all work demands while maintaining positive self-care
- Demonstrated concern for broad-based issues of human rights and social justice
- Strong understanding of and adherence to professional standards of conduct
- Support of all values, policies, and goals of Heartland Alliance and Koya University

Victoria University (New Zealand), School of Psychology: Victoria University of Wellington, from its location in Wellington, the capital city, undertakes teaching and research to maintain, disseminate and advance knowledge. Victoria provides worldwide opportunities for its staff as members of the international network of scholars, scholarship, and research, providing diversity and depth to our perspectives. Internationally Victoria is recognized as a leading University in New Zealand and Australia, and as a world leader in a number of areas of scholarship and enquiry. The appointee will contribute to teaching at the undergraduate level, teach adult clinical psychology at the graduate level, supervise postgraduate research, and assist with the administration of the clinical program. Qualifications required include a PhD, a postgraduate qualification in clinical psychology and recent clinical practice experience, as well as evidence of successful teaching and research. Eligibility for registration as a psychologist under the Psychologists' Act (1981) is also required.

We are particularly interested in appointing someone with expertise in the following areas: adult mental health and psychological assessment. Applications close August 30, 2011. For more information and to apply online visit http://vacancies.vuw.ac.nz.

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International Psychology Bulletin

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Associate Editors
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Harold Takooshian

Incoming Editor
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Submission Guidelines for
Research Articles
International Psychology Bulletin

Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 1500 words and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.
Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

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SUBMISSION DEADLINES
International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 1,500 words and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

Submission Deadlines: Spring issue March 31st

Summer issue June 30th

Fall issue September 15th

Winter issue December 15th

A new journal…Cancún…Brooklyn…a new task force… What's next? A new President!

Lynn Collins, Ph.D.
President, Division 52

This is my last Presidential Column. I have enjoyed my Presidential year's highlights and challenges. As I leave the position, there are many exciting continuing and new initiatives within Division 52. Nancy Sidun has created a task force on human trafficking that is growing in membership. Please contact her if this is an area of interest to you (n.sidun@hawaiiantel.net). Grant Rich of Alaska joins us as the new Editor of the International Psychology Bulletin. We are grateful to Senel Poyrazli for her vision and energy that lead to the development of this excellent scholarly newsletter. It was Senel's and Wade Pickren's exceptional perseverance in the process of taking Division to the next level that led to the development of a division journal. Joy Rice, Federal Advocacy Coordinator reports that there are important discussions underway with the new administration regarding healthcare, including mental health care. Ani Kalayjian has developed an active global mentoring program. We have an impressive group of new Fellows again this year, thanks to more hard work from Harold Takooshian. And, of course, thanks to Michael Stevens' ever watchful eye on the budget, the Division is financial healthy. Of course, there are many others who continually contribute enormous amounts of their time and energy to this division that deserve our gratitude. Moving forward, I would like to draw attention to a few upcoming events.

Division 52 journal is slated to be launched at APA!

The Division's first journal, *International Perspectives in Psychology: Research, Practice, & Consultation,* will soon be launched! The journal will publish conceptual models, methodologies, and research findings to help study and understand human behavior and experiences around the globe from a psychological perspective. We are currently in the midst of working with APA to select an editor for the journal. We hope that Division members will spread the word about this journal to help us generate a wealth of energetic and talented authors, editorial board members, and reviewers, as well as an avid, international readership. This is an exciting development with unlimited potential to advance Division 52's mission. If think that you or someone you know would make an excellent editor, please be sure to nominate her or him by emailing Gary Vanderbos (Gary@APA.org) or me (Collins@LaSalle.edu).

Get Ready for Cancún in April 2010

It has been an exciting year, and some of its momentum led to the Division 52 mini-convention at Western Psychological Association's meeting in Cancún, Mexico. The 2010 WPA Convention will be in Cancún from April 22 to April 25, 2010 at the Fiesta Americana Condesa Cancún. Many thanks to Stanley Sue, current WPA President, and Chris Cozby, WPA Executive Director, for their generosity in giving us time within their program.

Under the leadership of Lynette Bikos of Seattle Pacific University, the Division 52/WPA mini-convention will feature three keynote speakers and four symposia covering international research in these four areas: Early Childhood Education Research, The Globalization of Higher Education, Adolescence/Young Adulthood, and Around the World. The speakers and topics are:

- John Thoburn, Ph.D., ABPP, Zeba Ahmad M.A., Jake Bentley M.A., & Kendra Jones M.A. (Seattle Pacific University) "International Disaster Psychology Ethics: A Social Justice Model Imbedded in a Family Systems Paradigm."
- Dr. María del Pilar Grazioso (Universidad del Valle de Guatemala) "Cultural Incidents Present during the Establishment of the Therapeutic Alliance."
- Henry C. Ellis, Ph.D. (University of New Mexico, USA) "Educational Consulting Experiences in Kuwait and the United Arab Emirates."

In addition to an excellent line up of speakers presenting on other topics, including Phil Zimbardo (see the WPA convention for details), many of WPA's invited speakers will also be addressing international issues:

- Stanley Sue (University of California, Davis). "10th Year Anniversary of the Surgeon General's Report on Mental Health: Culture, Race and Ethnicity"
- Mary E. Kite (Ball State University) "The More Things Change…: Teaching About Stereotyping and Prejudice" American Psychological Association G. Stanley Hall Lecture
- Hector Betancourt (Loma Linda University, USA, and Universidad de La Frontera, Chile) "Psychological Perspectives on Social Inequities: Culture, Behavior, and Health Disparities"
- Chi-Ah Chun (California State University, Long Beach) "East Is East, and West Is West. What Happens When The Twain Shall Meet? Studying Stress and Coping in Asian Immigrants"
- Terry A. Cronan (San Diego State University) "Ethnic and International Disparities in Cancer: Incidence, Diagnosis, and Treatment"
- Jo Ann Farver (University of Southern California) "Acculturation and the Well-Being of American Immi-

grant Families and Children: Factors that Produce Differences in Adaption"

- Mirta Margarita Flores Galaz (Autonomous University of Yucatan) "Mexican Ethnopsychology: Assertiveness"
- James M. Jones (University of Delaware) "The TRIOS Factor: A Psychocultural Theory of Surviving and Thriving in the African Diaspora"
- Rolando Diaz-Loving (National Autonomous University of Mexico) "Values, Beliefs and Norms of the Mexican Family: 50 Years of Socio-Cultural Premises"
- V. Nelly Salgado de Snyder (National Institute of Public Health, Mexico) "Psychological and Social Determinants of Health among Mexican Immigrants in the U.S."
- Invited Symposium. Steven Lopez (University of Southern California). "Remembering Dr. Rogelio Díaz-Guerrero: A Pioneer in Cultural Psychology"
- Daniel L. DeNeui (Southern Oregon University) and Leticia Chacón Gutiérrez (Universidad de Guanajuato, Campus León) "Construyendo Puentes: The Value of Research and Teaching Collaborations Between Mexican and U.S. Scholars"

I mention this conference first because attending requires some planning. You will need a passport to fly to Cancún. Information on passports is available from this State Department website: http://travel.state.gov/passport/passport_1738.html. The current time to process new passport applications is approximately six weeks. The WPA Hotel and Transportation page will soon have a link to a travel service that has developed tours for WPA attendees. In addition, you can reserve airport transportation with them. You can find more information about WPA and the convention at http://www.westernpsych.org/convention/index.cfm.

Join the board at the 2010 Division 52 Mid-Winter Meeting in Brooklyn, NY!

The Division 52 Board is having its Mid-Winter Meeting in Brooklyn, NY in conjunction with Eastern Psychological Association, March 4th through 7th. The Executive Committee meeting will take place the afternoon of Saturday March 6 and on the morning of Sunday, March 7. You are welcome to join us. For the sixth year, EPA offers a two-day international program, consisting of 10 sessions from 9:00 am till 4:20 pm on Friday and Saturday. Our Division 52 invited speaker Philip Zimbardo of Stanford speaks on Thursday night. The Division 52 program will be posted at our Division website, http://www.internationalpsychology.net, shortly.

There are, of course, many other developments taking shape within the division. If you really want to be "in the know," please feel free to join us at our board meeting at EPA in Brooklyn, NY, or our sessions and informal dinner out in Cancún, Mexico! With that said, I turn the Division over to the very able Danny Wedding.

Lynn H. Collins, Ph.D.
La Salle University
Philadelphia, PA, USA

LEAVING A LEGACY TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

Grant Rich appointed IPB Editor for 2010-2012

The APA Division of International Psychology is pleased to announce the appointment of Grant J.M. Rich, PhD as the new Editor of the *International Psychology Bulletin* for a three-year term, from March 1, 2010 through December 31, 2012.

Rich has an unusually broad background in many ways. He is a licensed social worker and massage therapist, who received the Bernice Neugarten Award for his doctoral research in developmental psychology at University of Chicago in 2001. He has a decade of experience as a researcher, author, editor, and professor at several institutions from Maine to Alaska, before joining the psychology faculty of the University of Alaska Southeast in Juneau, AK. His colleagues describe Rich as an ideal editor for IPB—an able, friendly, conscientious, tech-savvy professional with a heart for service, who does well at whatever he undertakes.

Outgoing Editor
Senel Poyrazli, Ph.D.
Pennsylvania State University - Harrisburg

Incoming Editor
Grant J. Rich, Ph.D.
University of Alaska Southeast - Juneau

Rich is the third Editor of IPB. The founding Editor was Ivan Kos, PhD of New York City (1997-2004) whose dedicated efforts established the *International Psychology Reporter* (IPR) as a premier newsletter for international psychology. The second editor was Senel Poyrazli, PhD of Penn State-Harrisburg (2005-2010), whose talents brought IPB to new heights--as a re-named and much-expanded on-line resource, which became indexed by APA Psyc-EXTRA, and also developed a peer-review section to publish high-quality original research. Rich hopes to build on Poyrazli's work, as the division also plans to launch its new APA journal in 2011: *International Perspectives in Psychology: Research, Practice, Consultation*.

The three-person IPB search committee was chaired by Editor Senel Poyrazli, with Associate Editors Harold Takooshian and Richard Velayo. After President Lynn H. Collins reviewed their unanimous recommendation and supporting materials, she offered Rich the position, which he accepted. The committee was impressed by the excellence of all three candidates for Editor, and encouraged the other two to become more involved in division publications.

Rich expects to participate in the division's midwinter meetings in Brooklyn, NY on March 5-7, 2010. He welcomes comments and inquiries by email, optimalex@aol.com.

Division 52 Membership Survey

Click here to access survey
(Web link)

Dear 52 Member:
We have developed a survey to measure your opinions of your membership in Division 52. The purpose of the survey is to determine how we can improve the services that the Division provides to enhance your membership in the division. Please send any comments or questions to Janet2822@aol.com and susan.nolan@shu.edu

We welcome your input.

We appreciate your participation in this survey.

Division 52
at Western Psychological Association
Cancún, Mexico
Saturday, April 24, 2010

8:00 – 9:20 Peninsula III, Symposium: **Early Childhood Education Research.** Henry C. Ellis, University of New Mexico, Chair and Discussant. Our panel of research presentations regarding early childhood education research provides showcases a diversity of methods, topics, and international teams. The first presentation, researchers investigated the transferability of both psychometric qualities and the utility of the Response-to-Intervention Model as a pre-kindergarten screen to children in Ecuador. In the second presentation, researchers compared the way that U.S. and Korean teachers used concrete manipulatives to teach fractions to third graders. In our third presentation, researchers evaluate the effectiveness of an after-school Learning Center model for elementary students with limited English proficiency. Our Discussant will summarize themes, contradictions, and limitations across the three research projects and, following the presentations, will moderate a short discussion with those in the audience.

(1) PRE-KINDERGARTEN SCREENER: IMPLEMENTING THE RESPONSE-TO-INTERVENTION MODEL IN ECUADOR. Arlene Ortiz, Fordham University; Manuela Guimarães, New York City Department of Education; Patricio Romero, Mineola School District; Tara C. Raines, Gwinnett County Public Schools. (2) U.S. AND KOREAN TEACHERS USE CONCRETE MANIPULATIVES TO TEACH FRACTIONS. Kammy K. Kwok, Jae H. Paik, Susan Courey, & April Won, San Francisco State University. (3) EFFECTIVENESS OF LEARNING CENTER ON LIMITED-ENGLISH-PROFICIENT STUDENTS IN 1ST-4TH GRADES. Tomas E. Martinez, Ellen F. Sugar, Elizabeth Ramirez, & Candace Siegmund, Pepperdine University.

9:30 – 10:20 Peninsula III, Paper: **Neurophenomenology: The Mind and the Brain.** Susan Gordon, Southbury Clinic for Traditional Medicines. Lynn H. Collins, past President Division 52/ International Psychology, La Salle University, Chair.

10:30 – 11:20 Peninsula III, Invited Speaker: **Educational Consulting Experiences in Kuwait and the United Arab Emirates.** Henry C. Ellis, University of New Mexico. Division 52/ International Psychology Program Chair and Host: Lynette H. Bikos, Seattle Pacific University.

11:30 – 12:50 Peninsula III, Symposium: **The Globalization of Higher Education.** Maria del Pilar Grazioso, Universidad del Valle de Guatemala, Chair and Discussant. International travel, such as study abroad, is not new to colleges and universities. While the topic has been of interest to researchers for a number of years, researchers are revisiting this topic with more sophisticated questions. Specifically, they are attempting to identify predictors that enhance the sojourn experience as well as delineate the factors that sustain the gains that are made. This symposium assembles four presentations that discuss research and issues related to internationalizing the curricula at the undergraduate and graduate levels. Our Discussant will summarize themes, contradictions, and limitations across the four research projects and, following the presentations, will moderate a short discussion with those in the audience.

(1) PROFESSIONAL DEVELOPMENT OUTCOMES ASSOCIATED WITH INTERNATIONAL INTERNSHIPS. Kari A. Knutson Miller, California State University, Fullerton; Amber M. Gonzalez, University of California Santa Barbara; Monique E. Arteaga, Amy P. Chaikittirattana, & Scott W. Ramirez, California State University, Fullerton. (2) INTERNATIONALIZING THE PSYCHOLOGY CURRICULUM. Rashmi Jaipal, Bloomfield College NJ. (3) GLOBE-TREKKING: PRELIMINARY RESULTS FROM A LONGITUDINAL, MIXED METHODS INVESTIGATION. Lynette H. Bikos, Julia Kocheleva, Rebekah L. Forman, & Nicole Myr, Seattle Pacific University.

1:00 – 2:20 Peninsula III, Symposium: **Adolescence/Young Adulthood.** Lynn H. Collins, past President Division 52/ International Psychology, La Salle University, Chair and Discussant. Adolescence is a developmental period that is generally recognized in most modern societies. This panel of presentations provides insight into the similarities and differences among samples of Brazilian, Japanese, and Iranian-American adolescents and young adults. Across the three presentations, the researchers used qualitative and quantitative strategies to tease out the complexities and nuances of the experience of adolescence for these participants. Our Discussant will summarize themes, contradictions, and limitations across the three research projects and, following the presentations, will moderate a short discussion with those in the audience.

(1) RITES OF PASSAGE: AGE AND GENDER DIFFERENCES IN A BRAZILIAN SAMPLE. Sherri McCarthy,

Northern Arizona University-Yuma; Luciana Karine de Souza, Universidade Federal de Minas Gerais. (2) JAPANESE EMERGING ADULTS' PERCEPTIONS OF ADULTHOOD: A QUALTIATIVE STUDY. Kayoko Furusawa, Izumi Kamioka, & Teru Toyokawa, Pacific Lutheran University; Reiko Kogo, Kinki University. (3) PERCEIVED PARENTING, SELF-ESTEEM, AND GENERAL SELF-EFFICACY OF IRANIAN AMERICAN ADOLESCENTS. Gila Frank, Ronita Saeed, Mark P. Otten, & Scott W. Plunkett, California State University, Northridge.

2:30 – 3:20 Condesa III, Invited Speaker: **Cultural Incidents Present During the Establishment of the Therapeutic Alliance.** Maria del Pilar Grazioso, Universidad del Valle de Guatemala. Division 52/International Psychology Program Chair and Host: Lynette H. Bikos, Seattle Pacific University.

3:30 – 4:20 Peninsula III, Invited Speaker. **International Disaster Psychology Ethics: A Social Justice Model Imbedded in a Family Systems Paradigm.** John Thoburn with Zeba Ahmad, Jake Bentley, & Kendra Jones, Seattle Pacific University. Lynn H. Collins, past President Division 52/ International Psychology, La Salle University, Chair.

4:30 – 6:00 Peninsula III, Symposium: **Around the World.** John Thoburn, Ph.D., Seattle Pacific University, Chair and Discussant. Around the world, psychologists are creating multi-disciplinary teams and using clever diverse research techniques to study a variety of phenomena. This symposium showcases some of the best. The first presentation takes us to Belize. Our presenter will review survey data concerning psychological disorders and treatments and discuss practitioner types and access to practitioners. For example, did you know that the 2008 Belize telephone directory lists zero psychologists and zero psychiatrists, but does include massage therapists and pages of physicians? Our second presentation takes us to Thailand, where the presenter will discuss the results of research regarding the ongoing recovery efforts following the devastating Indian Ocean Tsunami. We will also be treated to a peek at the International Tsunami Museum (and examine evidence regarding its effectiveness) which has been open for three years. In our third presentation, researchers provide a comparison of positive psychological dispositions and mental health among college students from the U.S., Japan, Thailand, and Australia. The researchers will discuss how these attitudes (e.g., optimism, zest, gratitude, and grit) serve as protective factors and promote mental health. In our final presentation our presenter will describe how his team used the "lost letter technique" (dropping addressed/stamped envelopes near mailboxes) as used to measure attitudes toward people of Middle-Eastern descent in various cities in the US and Europe. Our Discussant will comment on the methods, results, and findings of these presentations as well as facilitate a short discussion with the audience.

(1) HEALING MODALITIES IN BELIZE. Grant J. Rich, University of Alaska Southeast. (2) NATURAL DISASTERS: MENTAL HEALTH, RESILIENCE, AND EDUCATIONAL INTERVENTIONS. David N. Sattler, Western Washington University. (3) A CROSS-NATIONAL COMPARISON OF POSITIVE PSYCHOLOGICAL DISPOSITIONS AND MENTAL HEALTH. Douglas C. Smith, Southern Oregon University; Michael Furlong, University of California, Santa Barbara; Richard Langford, University of Hawaii, West Oahu; Edward Krishnan, Assumption University; Megan Zurawski, & Gloria Herrera, Southern Oregon University. (4) AN INTERNATIONAL LOST LETTER STUDY: MEASURING ATTITUDES TOWARDS MIDDLE-EASTERNERS. Afshin Gharib, William Phillips, Matthew Davis, Stephanie Lemp, & Janie Kuhlman, Dominican University of California.

For more information, contact the Division 52/International Psychology at WPA/ Cancun Program Chair, Lynette H. Bikos, Ph.D., lhbikos@spu.edu

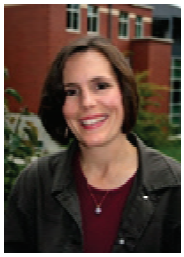

Are You a Psychologist who was a Peace Corps Volunteer?

Merry Bullock at the APA International Directorate and several members of Div. 17 - Society of Counseling Psychology are looking for psychologists who were Peace Corps Volunteers. If you are one, please contact Mary at mbullock@apa.org.

International Program
EASTERN PSYCHOLOGICAL ASSOCIATION

www.easternpsychological.org

4-7 March 2010, **Boardroom**, Brooklyn New York Marriott Hotel,
For any details: www.internationalpsychology.net, or Harold at 212-636-6393

Mid-winter Board Meeting on SATURDAY (noon) till SUNDAY (noon), March 6-7
International supper, 7-9 pm Saturday. RSVP to Uwe: ugielen@hotmail.com

FRI, 9 – 10:20 am, **Symposium: Dragon Seed: A photographic journey through New York Chinatown**
Chair: **Weihua Niu** (Confucius Institute, Dyson College, Pace University)
Presenter: **Uwe P. Gielen** (St. Francis College) Discussants: **Ting Lei** (CUNY), **Jonathan Palumbo** (St Francis College), **Chris LaSalle** (St. Francis College)

Migration has now made New York City the home of the largest Chinese community in the Western Hemisphere, with 500,000 persons of Chinese descent. This slide presentation combines a visual tour of New York's Chinatown, with social psychological and demographic data on this community. It also describes on-going research on the psychosocial adaptations of Chinese youth.

FRI, 10:30 – 11:50 am **Symposium: Ethnic psychology today**
Chair: **Michael Meir** (Technical Career Institutes)
Counseling and Psychotherapy in Turkey. **Şenel Poyrazlı** (Penn State University), **Süleyman Doğan** (Ege University-Turkey), & **Mehmet Eskin** (Adnan Menderes University-Turkey).
Psychology and Italian-Americans. **Elizabeth G. Messina** (Lenox Hill Hospital)
Greek psychology. **Artemis Pipinelli** (Lehman College) & **Thomas Mallios** (New York City)
Armenian psychology. **Samvel Jeshmaridian** (Borough of Manhattan Community College) & **Ani Kalayjian** (www.meaningfulworld.com).
Hispanic psychology. **Rafael Art Javier** (Saint Johns University).
Feminist attitudes: Does culture make a difference? **Christine Graham**, **Delilah Opal Hutson-Ellenberg, Mahfuz F. Ahmed** (Fordham University)
Discussant: **Rivka Bertisch Meir** (www.DoctorRivka.com), **Ayse Çiftçi** (Purdue University)

How has psychology developed differently among diverse ethnic and nationality groups? This symposium brings together leading psychologists from diverse backgrounds to review indigenous or ethnic psychologies today in the USA and overseas.

FRI, 12 – 1:20 pm, **Psychologists at the United Nations**
Chair: **Ani Kalayjian** (www.meaningfulworld.com)
A brief history of psychology organizations at the United Nations. **Siroon P. Shahinian** (Great Neck, NY).
Psychology organizations today. **Susan A. Nolan** (Seton Hall University).
Teaching psychology to United Nations personnel. **Anthony J. DeLuca** (Rector, Ignatius University) & **Harold Takooshian** (Fordham University).
Stress reduction among U.N. peace-keepers. **Neal S. Rubin** (Argosy University- Chicago).
Student internships at the United Nations. **Wismick Jean-Charles** (International Assoc. of Applied Psychology).
Discussants: **Deanna Chitayat** (Chair, APA team at the United Nations), **Florence L. Denmark** (Pace University), **Sherry Dingman** (Marist College), **Janet A. Sigal** (Fairleigh Dickinson), **Cidna Valentin** (CUNY Graduate Center)

How have psychologists become increasingly involved in United Nations activities in recent years? This symposium describes past activities, current roles, and future opportunities.

FRI, 1:30 – 2:50 pm, **International psychology: A fascinating history**
Chair: **Lynn H. Collins** (LaSalle University)
Paris 1889, Yale 1929: Comments on the First and Ninth International Congress of Psychology. **John D. Hogan, PhD** (St. John's University)
New York in 1912: Carl Jung's lectures. **Sylvester Wojkowski** (Jungian Psychoanalytic Association)
Margaret Mead in New York City. **Mark E. Mattson** & **Robert W. Rieber** (Fordham University)
The International Council of Psychologists, past and future. **Ann M. O'Roark** (President, International Council of Psychologists)
Psychologists at the United Nations: The early years. **Edwin P. Hollander** (Baruch College & CUNY Graduate Center).
Discussant: **Neal S. Rubin** (Argosy University- Chicago)

Though it was only in 1997 that the American Psychological Association welcomed International Psychology as its

Division 52, international psychology can trace a very colorful history, starting with the odd meeting that was the first International Congress at the new Eiffel Tower in 1889.

FRI, 3 – 4:20 pm, **International Psychology poster session** (in the Exhibit Hall, posters 1-7, plus others)

FRI, 3 – 4:20 pm, Workshop: Becoming More Involved in International Psychology: Why and How?
Chair: **Harold Takooshian** (Fordham University)

How can students and professionals become more involved in international psychology? In this unusual three-part workshop: (1) Takooshian begins with a handout and brief message on the question, Why become more involved in global psychology? (2) Then in a series of 12 three-minute "flash presentations," 12 speakers each offer a helpful fact-sheet accompanied by a brief message on their specific avenue to become more involved. (3) This is followed by 30 minutes of moderated discussion of the topic. These practical factsheets are intended to advise on specific topics for diverse groups: students (such as overseas internships, cross-national research), faculty (teaching overseas, cross-national testing), practitioners (consulting overseas), researchers (publishing cross-cultural articles and books), and others (joining international groups, working with the U.N.).

SAT, 9 – 10:20 am, **Symposium: Internationalizing the Curriculum in Psychology**
Chair: **Richard S. Velayo** (Pace University)
Implications of Web 2.0 technologies on the internationalization of teaching, research, and practice of psychology. **Richard S. Velayo, Mercedes McCormick, Sara Pollack, Smith Kidkarndee** (Pace University)
Students' views on internationalizing the curriculum. **Jennifer M. Lancaster** (Saint Francis College).
The contribution of economic and political freedom to disciplinary vitality. **Michael J. Stevens** (Illinois State University & The Lucian Blaga University, Romania).
Internationalizing the Psychology of Women curriculum. **Florence L. Denmark & Maria Klara** (Pace University).
Discussants: **Joan C. Chrisler** (Connecticut College), **Jason R. Young** (Hunter College), **Gloria G. Grenwald** (Webster University), **Kate A. Richmond** (Muhlenberg College).

What can teachers and others do increase the internationalization of the field of psychology? This symposium brings together several experienced teachers and researchers to discuss the importance of technology, the political context, student involvement, and other important factors.

SAT, 10:30 – 11:50 am, **Symposium: Publishing cross-cultural and international work: Why and how?**
Chair: **Danny Wedding** (Missouri Institute of Mental Health).
Books. **Uwe P. Gielen** (Saint Francis College), & **Robert Dimbleby** (Hogrefe & Huber Publishers).
Book Reviews. **Danny Wedding** (Editor, APA PsycCritiques).
Bulletins. **Senel Poyrazli** (Penn State University), & **Grant J. Rich** (University of Alaska Southeast).
Journals. **Lynn H. Collins** (LaSalle University).
Students. **Jennifer Doran** (New School for Social Research), & **Jason R. Young** (Hunter College).
Discussants: **Parviz Morewedge** (Global Scholarly Publications), **Uwe P. Gielen** (Saint Francis College)

As international psychology continues to expand, how can individuals publish their work in cross-cultural and international psychology? This symposium assembles several experienced editors to review the growing number of options open to researchers, teachers, practitioners, and students of psychology.

SAT, 12 – 1:20 pm, **Paper session: Cross-cultural psychology: Research and applications**
Chair: **Renée Goodstein** (Saint Francis College)
A comparison of the teachings of Buddhism and clinical psychology. **Marvin Levine** (Stony Brook University)
Anxiety, appraisal, and coping: A cross-cultural comparison of American and Nigerian undergraduates. **Comfort B. Asanbe** (College of Staten Island/CUNY), **Sarah Iyabode Aiyedogbon** (Kogi State Polytechnic, Nigeria), **Krista Supino** (College of Staten Island CUNY)
Child trafficking and commercial sexual exploitation: Promising prevention and reintegration programs. **Yvonne Rafferty**, **Ilisa Naukam** (Pace University)
Seeking continuity beyond discontinuities: Sense of coherence and psychological well-being in refugees. **Padmini Banerjee** (Delaware State University)
A mother's progressive voice: How Ann Dunham shaped Barack Obama's values and world-view. **Dinesh Sharma** (St. Francis College)

SAT, 1:30 – 2:50 pm, **Symposium: Applied Photo-Psychology**
Chair: **Joel Morgovsky** (Brookdale Community College)
Presenters: **Joel Morgovsky** (Brookdale Community College), **Iris E. Fodor** (New York University), **Rod Golden** (Santa Clara University) [This is in tandem with the D52 international photo exhibit at nearby St. Francis College]

SAT, 3 – 4:20 pm, **Symposium: Increasing life-saving human organ donations: A global challenge for psychology**
Chair: **Samvel S. Jeshmaridian** (Borough of Manhattan Community College)
How much is life-saving organ donation a global human rights issue? **Heather M. Wynne**, **Nolia Hill**, **Isolene Roberts**, **Iveta N. Stephanopoulos**, **Nicole R. Tomlinson**, **Carolyn Volpe** (Fordham University)
Can a DVD reduce misconceptions of potential organ donors? **Peggy Ann Barnett** & **Christine Hoskins** (Fordham), **Katherine Stavrianopoulos** (John Jay), **Samvel**

Jeshmaridian (Borough of Manhattan Community College) Social behavior and peer-to-peer campaigns on college campuses. **Bobbie Watkins** (New York Organ Donor Network) The experience of receiving a life-saving organ. **Ted Lawson** & **Glenda Daggert** (New York Organ Donor Network)

Since 1988, human organ transplantation has saved tens of thousands of lives worldwide. How can we best remedy the increasing global shortage of life-saving human organs? This panel brings together several experts of diverse backgrounds to focus on the question, "What new methods are behavioral scientists developing, to increase the supply of life-saving human organs?"

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A Role for Psychology in the Shadow of the UN Conference on Climate Change

Susan A. Nolan, PhD,
APA-NGO Representative to the United Nations

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Psychology International can be accessed at: http://www.apa.org/international/pi

Investigating International Immersion Learning in Doctoral Psychology Training Programs

If you are a faculty member or doctoral student who has interest, experiences, or special knowledge of *international immersion learning* in doctoral programs in Counseling and Clinical Psychology programs, you are invited take part in a qualitative research study investigating this phenomenon. Specifically, we are interested in learning (a) how programs integrate international immersion learning experiences, (b) what faculty and students anticipate as intended outcomes of such experiences, (c) what successes and obstacles are being faced (and tackled), and (d) what are future possibilities for this element of globalization.

Your participation would involve a 50 minute (or so) telephone or internet-based interview about the phenomenon. To learn more about participation, please contact Lynette H. Bikos, Associate Professor of Clinical Psychology, Seattle Pacific University, lhbikos@spu.edu, 206.281.2017.

The project has been approved by SPU's Institutional Review Board (IRB #091002014; valid through 1/10/2011).

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Measuring Intercultural Attitudes of Undergraduates Who Study Abroad: Scale Development and Validity

Julia Shaftel and Timothy L. Shaftel
University of Kansas

The Intercultural Student Attitude Survey was created to assess changes in the attitudes and future plans of undergraduate college students who study internationally. The scale measures 6 constructs: cross-cultural open-mindedness, ability to manage stress, adventurousness, self-confidence, and disposition toward an international career and foreign language study. Existing scales do not cover these areas and do not focus on topics and settings pertinent to undergraduate students. Concurrent validity of the ISAS was assessed with the Cross-Cultural Adaptability Inventory (CCAI, Kelley & Meyers, 1995) and the Six Factor Personality Questionnaire (SFPQ, Jackson, Paunonen, & Tremblay, 2000). Subjects were American undergraduates surveyed while studying abroad in Italy and control students at three universities in the US. Results supported hypotheses about correlations in open-mindedness, flexibility, self-confidence, and managing stress across scales. Future applications include assessment of students' attitudes toward international education and cross-cultural environments as well as college study abroad outcomes.

Included within intercultural competence are the ability to behave and communicate effectively and appropriately in another culture; adaptability to new and different environments; cognitive flexibility; and openness, respect, and curiosity for cultural differences (Deardorff, 2006). These skills and attributes are similar to those defined as cultural intelligence or CQ, which encompasses cognitive, metacognitive, motivational, and behavioral aspects that enable one to adapt to a new culture (Ward, Fischer, Lam, & Hall, 2009). Cognitive CQ refers to specific cultural knowledge; metacognitive CQ is cultural awareness and thoughtfulness during cross-cultural interactions; motivational CQ encompasses the desire to learn about and function effectively in intercultural situations; and behavioral CQ refers to flexibility within the repertoire of actions available to an individual.

Several scales have been developed to assess intercultural competence, such as the Intercultural Sensitivity Scale (Chen & Starosta, 2000), focusing on confidence and openness in cross-cultural communication, and the Intercultural Development Inventory, measuring progress on dimensions of Bennett's Developmental Model of Intercultural Sensitivity (Hammer, Bennett, & Wiseman, 2003). The Cross-Cultural Adaptability Inventory (CCAI, Kelley & Meyers, 1995) is used in industry to assess cross-cultural training needs as well as in research on outcomes of study abroad and international sojourns.

Based on anecdotal evidence from returning students, the attitudes that seem to be affected by study abroad include open-mindedness, adventurousness, self-confidence, and resilience, along with heightened interest in learning a foreign language and choosing an international career. The Intercultural Student Attitude Survey (ISAS) was devised to assess these changes. No other instrument reflects the student context or outcomes of international education or is intended to measure the effects of study abroad rather than other types of international experience. Because the ISAS focuses on attitudes rather than specific cultural knowledge or skills, it reflects primarily the motivational aspect of cultural intelligence. While some of the content of the ISAS is similar to the Intercultural Sensitivity Scale, the changes that are observed as a result of international study extend beyond intercultural communication. We wanted to assess interest in foreign language study and future international careers, both of which are relevant for undergraduate students. Of the other attributes or characteristics related to attitude change with international educational experience that we wanted to measure, open-mindedness and resilience are included on the CCAI. The CCAI assesses four factors: Flexibility-Openness, Emotional Resilience, Perceptual Acuity, and Personal Autonomy. Intercultural competence is likely to be correlated with personality factors, as Brackett et al. (2006) found for self-report measures of emotional intelligence. Therefore, a personality measure, the Six Factor Personality Questionnaire (SFPQ, Jackson, Paunonen, & Tremblay, 2000) was used to assess personality characteristics that might differentially affect response to study abroad experience or mediate outcomes. The SFPQ measures three personality factors that we were interested in, Openness to Experience, Extraversion, and Independence, which is the SFPQ interpretation of the Big Five factor of Emotional Stability. The other Big Five personality factors of Conscientiousness and Agreeableness are also assessed by the SFPQ, with Conscientiousness subdivided into two component parts.

ISAS items were initially written by the authors and faculty at the campus in Italy and field tested with study abroad students during the summer of 2003. The most promising items were assembled into a 50-item scale on which data were collected from fall 2003 through summer 2004,

with the expectation that not all of the items would prove valuable and the scale would ultimately be revised and shortened. Of the 568 students in this dataset, 301 were surveyed in Italy and 267 in the US. Though the reliability (alpha coefficient) for the 50-item scale was .91, item analyses resulted in the deletion of items with low point-biserial correlations, or those that did not correlate well with total scores. Exploratory factor analysis using maximum likelihood estimation and direct oblimin rotation resulted in twelve factors with eigenvalues greater than 1 accounting for 58% of scale variance. Items that did not load on any factor or loaded only weakly on their intended factors were removed. For example, three items involving eating unfamiliar food formed a factor that was not central to the purpose of the scale. Questions about starting one's own company did not enrich any of the desired factors and were deleted. The result was a 35-item scale measuring six desired constructs of open-mindedness or cultural curiosity, adventurousness or risk-taking, resilience or ability to manage stress, self-confidence, and interest in foreign language study and international careers. Items were written in both positive and negative directions and included both cognitive (value) and affective (enjoyment) aspects of these topics.

This version of the ISAS was used over eight semester and summer terms, from fall 2007 through fall 2009, with 1105 controls (40% female) and 578 students studying in Italy (61% female). Factor loadings may change from dataset to dataset, particularly for cross-loading items when factors are correlated, as are the ISAS factors. Therefore, exploratory factor analysis with maximum likelihood and direct oblimin rotation was used with the large recent dataset to identify the factor structure for further analyses. Six factors were specified, accounting for 56% of the total variance. This factor structure was used for the current analysis of a subset of these data that included students who had also completed the CCAI and SFPQ. The six factors were named New Experiences (for adventurousness and risk-taking), International Careers, Open-Mindedness, Stress Management (for resilience in dealing with difficult situations), Self-Confidence, and Foreign Language.

A crucial step in evaluating the validity of any scale is to demonstrate that it measures the intended constructs. Therefore, during spring 2008 and spring and summer 2009, data were collected with the CCAI and SFPQ along with the ISAS in order to evaluate the concurrent validity of the ISAS. Our hypotheses were that the ISAS factors would correlate meaningfully with their intended counterparts on the CCAI and the SFPQ:

1. ISAS Open-Mindedness will correlate with CCAI Flexibility-Openness and SFPQ Openness to Experience.
2. ISAS Stress Management will correlate with CCAI Emotional Resilience.
3. ISAS New Experiences will correlate with SFPQ Independence.
4. ISAS Self-Confidence will correlate with SFPQ Extraversion.
5. ISAS International Careers and Foreign Language will not correlate with CCAI or SFPQ factors because these topics are not included on either scale.

Method

The dataset consisted of 396 undergraduates surveyed in the US and at a study abroad program in Italy during the spring of 2008 and the spring and summer of 2009. The program features business, journalism, and communications studies courses in English and is sponsored by a consortium of 30 American universities. Participants were students from these universities attending either a four-month semester (n = 128) or a one-month summer session (n = 66). Subjects in Italy were surveyed both at the beginning and end of their terms, though only pretest data were used for this validity study. Subjects studying in the US attended three consortium universities in the South and Midwest and were surveyed once during a semester term (n = 161) or a summer session (n = 41). Of students surveyed in Italy, 61% were female while 48% of students surveyed in the US were female. Thirty-four percent of control students and 37% of study abroad students indicated that they were considering a career involving international travel. Sixty-eight percent of control students and 74% of study abroad students responded that they had previously traveled internationally for one week or more. Students were not asked to report on previous study abroad experiences, and our hypothesis is that the majority of students had not studied abroad prior to this experience due to the fact that most were college sophomores and juniors. Preliminary studies had shown that the length of time abroad or the number of prior trips were not strongly related to attitude differences whereas the contrast was marked between students who had traveled internationally for even one week versus those who had not.

The ISAS factors showed significant intercorrelations, ranging from .18 for Foreign Language and Self-Confidence to .37 for Foreign Language and Open-Mindedness. The CCAI has also been shown to have high factor intercorrelations (Davis & Finney, 2006). In a preliminary test of bivariate (Pearson) correlations, all factors of the CCAI and the ISAS showed significant positive correlations. The SFPQ factors of Extraversion and Openness to Experience showed significant positive correlations with all ISAS factors, Independence and Conscientiousness had no correlations with ISAS factors, and Agreeableness was correlated only with Open-Mindedness. Therefore, in order to isolate tests of the desired correlations, partial correlations were computed for each factor of the ISAS with each factor of the CCAI and SFPQ in turn. In this manner the influence of the other factors in each scale and any potential suppression effects would be eliminated. Fifty-four partial correlations were computed, 24 for the 6 ISAS factors with the 4 CCAI factors and 30 for the 6 ISAS factors with the 5 SFPQ factors. Because multiple correlations were computed with the same dataset, Type I error was controlled with the Bonferroni method, which had the effect of restricting significance to p values of less than .001. The number of students whose complete data al-

lowed partial correlations to be computed ranged from 338 to 387 for each pair of factors.

Results

Reliability (alpha coefficient) for the ISAS was .92. The results partially confirmed our hypotheses about factor correlations across scales. There were 11 significant partial correlations (*pr*) ranging in strength from *pr* = .21 to *pr* = .52 with five correlations of strength greater than *pr* = .30. These correlations are shown in Table 1.

Supporting Hypothesis 1, Open-Mindedness was correlated with CCAI Flexibility-Openness (*pr* = .42) and SFPQ Openness to Experience (*pr* = .25). Hypothesis 2 was confirmed with the correlation of Stress Management with CCAI Emotional Resilience (*pr* = .42), and Hypothesis 4 with the correlation of Self-Confidence with SFPQ Extraversion (*pr* = .52). Self-Confidence was also correlated with CCAI Emotional Resilience (*pr* = .32), and International Careers was correlated with SFPQ Openness to Experience (*pr* = .43), neither of which were hypothesized. Additional unanticipated significant correlations included Stress Management with SFPQ Extraversion (*pr* = .21), and Open-Mindedness with CCAI Perceptual Acuity (*pr* = .29) and SFPQ Agreeableness (*pr* = .23).

Hypothesis 3 was not supported as there was actually a small negative relation between New Experiences and SFPQ Independence that did not quite reach significance. Independence is the SFPQ interpretation of the Big Five Personality Factor of Emotional Stability and reflects independence from and even disregard for the opinions of others. This construct is not consistent with the idea of New Experiences, which assesses taking advantage of opportunities and a desire for new experiences. However, SFPQ Independence was significantly related to Stress Management (*pr* = .23), which suggests that these two scales share concepts related to self-reliance in the face of difficulty. Finally, there was a negative correlation between Open-Mindedness and CCAI Emotional Resilience (*pr* = -.22). To investigate this correlation, we ran a linear regression of the four CCAI factors entered as a block with Open-Mindedness as the dependent variable. Only Flexibility-Openness (β = .49) and Perceptual Acuity (β = .37) showed significant effects; Emotional Resilience was not a significant predictor of Open-Mindedness. This alternate evaluation of the relation suggests that it is spurious.

Conclusions

The purpose of this study was to investigate the concurrent validity of a measure of student intercultural attitudes with validated instruments. Four correlations with large effect size according to Cohen (1992) were found: Stress Management with CCAI Emotional Resilience, Open-Mindedness with CCAI Flexibility-Openness, International Careers with the personality factor of Openness to Experience, and Self-Confidence with the personality attribute of Extraversion. Moderate effects included the anticipated relation of Self-Confidence with CCAI Emotional Resilience. These results demonstrate that these characteristics are measured by the ISAS and that attitudes about international educational experiences are clearly related to Big Five personality characteristics. Open-Mindedness was also moderately related to CCAI Perceptual Acuity and to the personality factors of Openness to Experience and Agreeableness. That Open-Mindedness showed significant partial correlations with two subscales on each of the CCAI and SFPQ is reassuring as this is perhaps the central characteristic of students who choose to go abroad for an educational experience and one of the most

	ISAS Factors					
	Open-Mindedness	Stress Management	Self-Confidence	New Experiences	International Careers	Foreign Language
CCAI Factors						
Flexibility-Openness	.42**	-.01	-.04	-.04	.12	-.07
Emotional Resilience	-.22*	.42**	.32**	.11	.11	.08
Perceptual Acuity	.29**	-.06	-.09	.01	-.05	.05
Personal Autonomy	-.02	-.02	-.03	.13	-.18	.07
SFPQ Factors						
Openness to Experience	.25**	.00	.08	-.02	.43**	.04
Extraversion	-.05	.21*	.52**	.12	.11	-.08
Independence	-.09	.23*	.07	-.18	.17	.01
Agreeableness	.23*	.09	-.09	-.05	.05	-.09
Conscientiousness	.05	.07	-.13	-.03	-.10	.11

*p<.005 after Bonferroni control of Type 1 error
**p<.001 after Bonferroni control of Type 1 error

Table 1: Significant partial correlations between ISAS factors and CCAI and SFPQ factors

desired outcomes.

One of the most interesting findings for study abroad programs is their attractiveness to women. The majority of study abroad participants on the Italy campus are women, as is evidenced by the makeup of the current dataset. Goldstein and Kim (2006) found that women had significantly lower levels of ethnocentrism or prejudice and greater foreign language interest than men and that both of those characteristics were predictive of studying abroad, leading to a higher proportion of women participating in study abroad experiences. This helps explain why women find study abroad attractive, and it also reveals that men who study abroad are less ethnocentric than those who stay home. The ISAS Open-Mindedness scale is intended to capture attitudes similar to ethnorelativism that are also denoted by the Big Five personality factor of Openness to Experience and Flexibility-Openness on the CCAI.

No factor on the CCAI or SFPQ was related to New Experiences, which was intended to measure adventurousness and a certain degree of risk taking, and which is not assessed by any other scale known to us. Based on our interactions with students who study abroad, we believe that adventurousness is a characteristic of many of the undergraduates who are willing to test themselves in an unfamiliar environment. Foreign language study, which was also unrelated to either the CCAI or the SFPQ, is an important dimension for college and university study abroad programs. Interest in learning a foreign language is higher in students who plan to study internationally (Goldstein & Kim, 2006) and foreign language proficiency is an outcome of study abroad (Parsons, 2009). We are interested in measuring both the value of foreign language competence and the desire to learn a foreign language in students who choose to study abroad.

Our current research includes investigation of the sensitivity of the ISAS to study abroad experiences using pre- and post-tests with both control and travel groups. Our prior research with the CCAI and SFPQ has shown changes in attitudes as a result of studying internationally. If the ISAS proves to be sensitive to change in students' attitudes about cultural differences or future international careers, it may be a useful tool for demonstrating the value of investment in student participation in study abroad programs. The ISAS may also be helpful for assessing the preparatory needs of students who plan to study abroad in order to offer appropriate pre-travel training, for program selection, and for support throughout the experience.

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The ISAS is available from the authors upon request.

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Violence Against Women: Recognizing the Problem and Offering Solutions

Kristof, N. D., & WuDunn, S. (2009). Half the sky: Turning oppression into opportunity for women worldwide. New York, NY: Knopf. ISBN-10:0307267148. ISBN-13: 978-0307267146; Price: $15.00

Reviewed by Florence L. Denmark, Ph.D.
Pace University, New York, U.S.A.

Half the Sky, written by Nicholas D. Kristof and Sheryl WuDunn, is a critical and comprehensive analysis of the lives of women across the globe, their oppression and their stories of opportunity. It is a superbly written, accessible, and informative piece of work. Unlike many books which attempt to address this massive and somewhat overwhelming topic, Mr. Kristof and Ms. WuDunn approach it from a personal, authoritative, and knowledgeable position, garnered from years of reporting throughout the world. It is evident that this book is the product of not only what they witnessed while on past assignments for the *New York Times*, but also is a product of something more personal. As a reader, you believe that they care, that they want better for the world's women, and that they have a personal stake into ensuring that others see what they have seen.

In reading *Half the Sky*, I am reminded how this is not the case in the majority of the world. Not only is this not the case in terms of equality, but, rather, women are oppressed, beaten and abused. The book systematically tackles issues such as: sex trafficking and sex slaves, prostitution, mass rape, honor killings, fatality in childbirth, misogyny in religion, and the lack of health care and education for women. What is evident is that the lives of women across the globe are starkly different than the experiences of many of us. Instead of looking away, this book steers us towards the problem, shines a light on it and asks "What can we do?"

All of the cases and stories are presented in an informative and yet culturally sensitive manner. To do this, the authors pair personal stories with each problem that is presented. The readers meet Long Pross who was 13 years old when she was taken and sold to a brothel in Cambodia where the owner punished her and gouged out her eye with a metal rod. They meet Woineshet, an Ethiopian girl, who was kidnapped and raped by a man and three others for days. The man subsequently wanted to marry her, and it is common for a woman to be forced to marry a man who raped her, since by Ethiopian law, he cannot be prosecuted for violating a woman he later married. Readers also meet Mahabouba, a woman who did not have access to any medical care during birth. The baby died in childbirth and she suffered a fistula and crawled for a day to a missionary where she was brought to the Addis Ababa Fistula Hospital in Ethiopia, one of the only hospitals of its kind.

What is critical is that the stories are presented in an honest manner. This is how women are living today and this honesty is invaluable. What is also important is the manner in which the authors link women's issues to world issues. For instance, women who are encouraged to enter the workforce in developing countries will undoubtedly foster stronger economic gains for those countries. Women who have access to education, stay in school longer, can provide and contribute more for their families, become a more prominent figure in the family, are economically stronger, and have fewer children. Therefore, by educating women, issues such as population, poverty and abuse of women begin to be improved. The message is clear: women's issues should be addressed not only based on it being a humanitarian cause, but only because it makes sense for the countries due to the host of benefits it can cause. In other words, helping women not only is a good, moral move, but a smart one as well. There are many ways that are outlined in the book which helps readers determine how they can help. Organizations are mentioned throughout the volume and the Appendix lists groups that specialize in supporting women.

The stories presented, although realistic and sometimes painful to read, are ones chosen because they also inspire hope. Many women written about in this book find a way, despite the most abhorrent conditions, to improve their lives through their own determination or by the help of someone else. Therefore, the book inspires more than anything else. These simple human stories of women striving for something better makes reading the book a personal experience. The reader imagines, "What if this was me? Or, what if this was my sister, my aunt, my girlfriend, my mother?" It unifies the female experience and destroys an insulated, Western world view in which many of us live day to day. This volume is truly a remarkable read, and one which I would recommend to anyone who wants to improve the world today for us all.

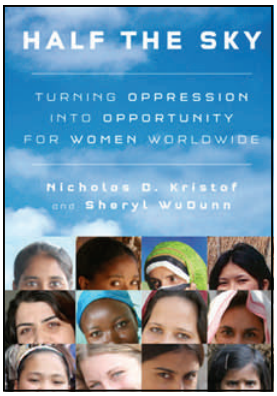

Situated Cognition in Tech-Transfer: The Globalization of Indian Firms

Surie, Gita (2008). Knowledge, Organizational Evolution and Market Creation: The Globalization of Indian Firms from Steel to Software. Northampton, MA: Edward Elgar Publishing. ISBN-10: 1847204562. ISBN-13: 978-1847204561; Price: $115.00

Reviewed by Dinesh Sharma
The Institute for International and Cross-Cultural Psychology, St. Francis College

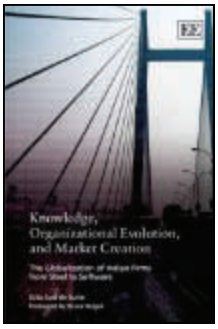

A collection of books has recently been published celebrating India's economy on the global stage. None of the books, however, attempts to describe the behavioral, organizational and developmental process involved in transforming the world's second largest population into the workforce for the information and biotech age. Gita Surie, a senior fellow at the Wharton School and Assistant Professor at the Adelphi University School of Business, makes a bold attempt to fill this knowledge gap. Her book, titled *Knowledge, Organizational Evolution, and Market Creation*, based on a decade long research project conducted coincidentally in parallel with the recent wave of globalization to engulf the South Asian subcontinent, traces the evolution and internalization of Indian firms.

The book presents an integrative framework for understanding organizational change in emerging economies. The central claim of the book is that the international expansion of Indian firms follows an evolutionary process building on the acquisition of new-found capabilities. Knowledge creation is central to building new capabilities, which are acquired and accelerated through cross-border replication of knowledge.

In Stage 1, the capabilities are scarce in the domestic environment, where modernization consists of investments in industrial technology, skilled labor, and an overall shift from agriculture to technology and infrastructure. Given the domestic economy may lack both the knowledge and the capital investment the early emphasis on growing business must be on knowledge transfer from exogenous sources. Stage 2 consists of diffusion of knowledge and capabilities followed by a large scale adoption of the new learning within the institutional framework. Stage 3 is marked by the cross-border innovation, where local firms participate in knowledge creation and compete in the global economy.

The book attempts to link the microeconomic change with the macroeconomic forces, using Lave and Wenger's cognitive theory of "situated cognition". In a unique melding of concrete with the abstract, the concept of technology transfer is contextualized within the psychological concepts of praxis and apprenticeship, something psychologists might find interesting. This is undoubtedly one way to understand organizational change. What the apprenticeship model may underestimate, however, is the emotional and cultural transition involved in the complex process of technology transfer in transforming a society such as India from "a knowledge borrower" to "a knowledge creator."

The sociocultural change driven by the influx of "new money" and technological innovation has undoubtedly created new communities of learners and experts. The new symbolic experts work on shared tasks across national borders, who are directly or indirectly employed by international firms. In satellite offices including "human body shops" that dot the globe, teams of developers and managers run the back offices that are the backbone of international business and global markets. In this new business environment, "the sun never sets" on the business lifecycle. The rotating shifts logging-in at different local times are coordinated with a centralized global research and operations team. There truly is no downtime in the 24/7 global economy. Surie's book analyzes India's entry into the global economy from the vantage point of the traditional Indian manufacturing firms as well as software and biotechnology firms.

The globalization of the steel industry exemplifies the process of knowledge transfer at the outset of the modernization of India. Founded almost one hundred years ago in pre-independence India, the steel industry relied heavily on European technology for mining its natural wealth. However, as we fast-forward to the 1980's, the major steel manufacturer decided to invest in upgrading its blast furnace equipment and increase its capacity to stay competitive and acquired new equipment from Germany. In November 1992, eight months behind schedule the steel manufacturer produced almost 3,000 tons of steel, which matched the sophistication and production of the best furnaces in the world. Today, the Indian steel manufacturer has acquired several multinational steel manufacturers and ranks 5th in the world in steel production.

In the mid-1980's Bangalore was not even on the global map. However, a handful of software companies were founded by IIT and computer science graduates thrilled by the possibility that computers could revolutionize the world. Supported by technological developments that promised "to flatten the world", these companies quickly gained recognition with the Fortune 500 companies while some of them went on to list on the New York Stock Exchange. Leapfrogging the pitfalls and growing pains of the traditional manufacturing sector, the IT companies entered the global marketplace by providing what the author calls the "knowledge assembly line." The precondition for the success of the Indian software industry may have existed in the Indian subpopulation given the educational system is thoroughly westernized and English is the language of commerce. The emphasis of Surie's book, however, is on the business processes and mechanisms and less on the cultural, linguistic and human capital reserves that have fueled the rise of the software in-

dustry.

In summary, this book is important for its contribution to the literature on the rise of Indian business and economy. The book has a wide reaching theoretical scope and makes significant linkages with cognitive, behavioral and cultural theories. The internationalization of Indian firms is rapidly changing Indian society and culture. Hence, there is a growing need for systematic organizational research that examines Indian business practices from an integrative perspective. Travel and journalistic books chronicling the rise of India as "the elephant economy" lumbering to stay on a growth trajectory compared to the East Asian tigers and the Chinese dragon are interesting to read. However, these travel books only skim the surface of the changes that are sweeping Indian business. Therefore, Surie's research on Indian firms presents a rare glimpse of the organizational and economic forces that are globalizing Indian industry from steel to software.

History of Psychology on a Global Scale

Adrian C. Brock (2009). Internationalizing the history of psychology. New York: New York University Press, 2009. 260 pages. ISBN: 13–978–0–8147–9136–3.

Reviewed by Samvel Jeshmaridian
City University of New York

New York University Press has published a highly readable new book on international psychology. The book contains 11 chapters developed by 13 authors, including Adrian C. Brock, the editor. An international group of authors discusses various ways of making Western psychological thought more understandable to members of all cultures as well as helping the reader to gain a better understanding of the psychologies of other cultural "worlds." By this volume, the understanding of today's psychology and its historical evolution has been made intellectually deeper, scientifically broader, and culturally more comprehensive.

The authors trace the development of psychological thought as if flying at various heights above the beautiful yet far from unitary landscape of psychological thought. Like space-pilots, they guide the reader toward a better comprehension of what various psychologies are accomplishing in this world. They describe psychology as inhabiting a multi-hued space created by psycho-historical patterns and socio-psychological perspectives. These, in turn, are engraved in human history and more specifically, in the history of the scientific study of human emotions, perceptions, memory, and behavior.

In his brief yet broadly conceived "Introduction," Adrian C. Brock outlines the structure of the volume and its methodology.

Johann Louw, in his essay, "Constructing Subjectivity in Unexpected Places," discusses "the history of the present" (Michel Foucault, 1975), in the sense of tracing principles at "the periphery" of psychological thought and making them meaningful for those psychologists whose perceptions and understanding remain at the center of psychological thought.

Cecilia Taiana is the author of the next chapter, "Transatlantic Migration of the Disciplines of the Mind: Examination of the Reception of Wundt's and Freud's Theories in Argentina." Using as an example the reception and prevailing usage of Wundt's and Freud's theories and methods in Argentina, Cecilia Taiana discusses the more general fate of scientific theories that have migrated from one continent (Europe) to another (South America). She also describes how the ideas of the French psychologists Theodule Ribot and Pierre Janet have been altered in the course of their trans-Atlantic journey.

In his contribution entitled "From Tradition through Colonialism to Globalization,"Anand C. Paranjpe presents a brief history of Indian psychological thought from ancient times to the modern globalization period. He describes various approaches to the understanding of human beings and human nature in Indian philosophy and psychology and compares them to the European psychological principles that were first developed in the Greco-Roman period but continue to serve as the foundations of modern scientific psychology.

Aydan Gulerce is the author of a chapter entitled "History of Psychology in Turkey as a Sign of Diverse Modernization and Global Psychologization." Given that Turkey has no indigenous traditions in philosophical or psychological thought, the author skillfully describes the evolution of Turkish social thought as a modernization process and a consequence of the globalization tendencies prevailing in contemporary scientific psychology in Turkey.

In his essay entitled, "Origins of Scientific Psychology in China, 1899-1949," Geoffrey Blowers discusses a few key concepts of Chinese psychology and how they are perceived by various 20th-century Chinese psychologists. He then compares them to the (more or less) equivalent terms in the English language that have been developed by Western psychologists.

In his chapter on "Behavior Analysis in an International Context," Rubén Ardila describes the principles and methodologies psychologists use in different countries and "worlds" such as Europe, Latin America, the socialist world, Japan, Africa, India, Australia, and New Zealand.

John D. Hogan and Thomas P. Vaccaro are the authors of a chapter discussing the "Internationalizing the History of U.S. Developmental Psychology." In a clear and scientifically structured way, they outline how developmental psychologies in various countries (e.g., U.S.A., France, Switzerland, Ger-

many, and Russia) have mutually influenced each other over the years.

Adrian Brock, in his essay entitled, "Psychology and Liberal Democracy," traces the sources of ideological affinities and their internal linkages to psychology in the context of a variety of social structures and political systems.

In their discussion of, "Double Reification: The Process of Universalizing Psychology in the Three Worlds," Fathali M. Moghaddam and Naomi Lee state that U.S. psychological thought has been and remains dominant all over the world. In this context, they present rich historical data demonstrating that U.S. psychology has been the driving force in the global spread of psychology.

In her chapter, "Psychology in Eurocentric Order of the Social Sciences: Colonial Constitution, Cultural Imperialist Expansion, Postcolonial Critique," Irmingart Staeuble discusses the organization of psychological science in various settings and historical situations, while attempting to trace causal linkages.

Kurt Danziger is the author of "Universalism and Indigenization in the History of Modern Psychology." His chapter traces the problems of coherence and intellectualization in the history of contemporary psychological thought.

Finally, editor Adrian Brock has contributed a postscript that summarizes a few typical social psychological questions that can be asked about the linkage of culture and modernity, such as, Interdisciplinarity, globalization, and the psychologization of socio-cultural perception and thinking.

In summary it can be stated that the editor as well as all the authors have done an excellent job tracing the dialectics of contemporary psychology all over the world. Moreover, all the chapters contain one important positive ingredient: whether their focus is more universal or more culture-specific in nature, they are "dipped" in culture.

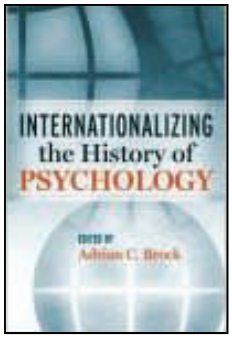

The January 2010 issue of

Interpersonal Acceptance

(Newsletter of the International Society for Interpersonal Acceptance and Rejection) is now available for viewing at http://www.isipar.org/Newsletter.html

It contains: Information about the nominees for the forthcoming ISIPAR elections; an article by Charles H. Heller, entitled "Applications of Parental Acceptance-Rejection Theory and Evidence to Forensic Psychology"; information about the 3rd International Congress on Interpersonal Acceptance and Rejection to be held in Padua Italy in July, 2010, including possible funding sources; and details about the University of Connecticut Rohner Center Awards for Distinguished Contributions to Theory, Research, and Practice on Interpersonal Acceptance and Rejection. Please share the newsletter with anyone you know who might like to know about it or about the Society.

You can read all prior issues of *Interpersonal Acceptance* by going to www.isipar.org

Yale convocation celebrated "80 years of excellence"

Harold Takooshian, Richard S. Velayo,
& Florence L. Denmark

On September 4, 2009, over 50 faculty and students from as far as North Carolina converged on the stately Presidents Room of Yale University in New Haven CT for a convocation to mark "80 years of excellence." This was the anniversary of the Ninth International Congress of Psychology at Yale on 1-7 September 1929—"the most impressive gathering of psychologists in the history of the field"—with 826 participants from 21 nations, including such notables as Ivan Pavlov, Jean Piaget, Kurt Lewin, and Franz Kofka.

The keynote message was delivered by Division 52 President-Elect John D. Hogan, who went beyond the 1929 meeting to share scenes of the near-forgotten First International Congress in 1889, at the then-new Eiffel Tower in Paris. Barely 10 years after Wundt's first laboratory, this Congress also brought together such diverse notables as Francis Galton of the UK, Alfred Binet of France, William James of the USA, Cesar Lombroso of Italy, and Ivan Sechenov of Russia.

Hogan also detailed the founding of Psi Chi on September 4, 1929 at the Yale Congress, by two University of Kansas students, Edwin Newman and Frederick "Bud" Lewis, which has now grown into the world's largest honor society in any field--touching the lives of over 500,000 life members at 1,100 campuses.

The convocation was hosted by Yale professors Peter Salovey, Laurie Santos, and Woo-Kyoung Ahn. The International Division of the American Psychological Association was represented by its past-Presidents Florence Denmark, Uwe Gielen, and Richard Velayo, who detailed the remarkable growth of "international psychology" since their group formed in 1997. Psi Chi was represented by Eastern Vice President Jason Young and past-President Vincent Prohaska, who announced the recent vote in 2009 to re-name Psi Chi "the International Honor Society in Psychology"--with new chapters now forming outside of North America.

PROCLAMATION
Of The City Of New Haven
DECLARING
SEPTEMBER 4, 2009
PSYCHOLOGY DAY

WHEREAS, Yale University hosted the Ninth (9th) International Congress of Psychology in September of 1929 in New Haven, which is widely regarded as "the greatest gathering of Psychologists in the history of the field" & Yale Faculty and students today continue to make pre-eminent contributions to the science & practice of Psychology to "bring out the best" in individuals and society; and

WHEREAS, Psi Chi was founded at Yale University on September 4, 1929 by two students, Edwin B. Newman and Frederick Howell Lewis to "encourage, stimulate and maintain excellence in all fields, including Psychology", and Psi Chi is now the world's largest honor society, with 500,000 life members and a federation of chapters at 1,100 campuses; and

WHEREAS, Psi Chi in 1981 helped to form Psi Beta – the first Psychology Honor Society to serve the unique needs of students at two-year colleges and Psi Beta has now grown into a pre-eminent honor society with chapters at 150 campuses across this nation; and

WHEREAS, The American Psychological Association (APA) and the Association for Psychological Sciences (APS) have also grown into International Organizations with vigorous programs to advance Psychology globally; and

WHEREAS, On this day when students, professors and the community gather in New Haven to celebrate the progress of International Psychology and the 80th Birthday of Psi Chi, the City of New Haven is pleased to join in this celebration.

NOW, THEREFORE, do I, as Mayor of the City of New Haven, proclaim the 4th Day of September 2009 as Psychology Day and to celebrate Psi Chi and 80 years of excellence, I hereby proclaim:

PSYCHOLOGY DAY
SEPTEMBER 4, 2009

Dated at New Haven, Connecticut, this 4TH day of September 2009.

John DeStefano, Jr. Mayor

conferees, Psi Chi presented to Yale a commemoration plaque, to salute "80 years of excellence." In addition, Dr. Jane Levine presented a Proclamation signed by Mayor John DeStefano, proclaiming September 4, 2009 as "PSYCHOLOGY DAY" in the City of New Haven. The Proclamation saluted Yale, Psi Chi, Psi Beta and, in part, saluted APA at the American Psychological Society for growing "into international organizations, with vigorous programs to advance psychology globally." This convocation was taped by Richard Velayo and Steven Salbod, and a DVD is available from takoosh@aol.com

On behalf of the

Preparation of Faculty for a School Psychology Program in Vietnam

Kimberly S. Kassay and Mark D. Terjesen
St. John's University

Son Nguyen, Hong Nguyen, Long Phan, Phuoc Hoang, and Binh Pham
Hanoi National University of Education

This article will describe the most recent steps towards the development of the first formal school psychology training program at Hanoi National University of Education (HNUE) in Vietnam. A brief history of the efforts to date will be provided followed by a presentation and evaluation of a summer-long training program geared towards preparing the faculty of HNUE for instruction in, management of, and evaluation of the success of the training program. Future directions in the program development will be discussed with consideration of the profession itself, and the international and cultural context in which this profession will exist.

With a population of over 86 million, Vietnam is the thirteenth most populous country in the world (U.S. Census Bureau, 2008). Vietnam is considered a low-income developing country, but it is expected to attain middle-income country status by 2010 (World Bank, 2007). It would stand to reason that economic change may in turn have an impact upon education. These economic changes combined with recent advances in the education system (Ministry of Education and Training [MOET], 2003) have created a need for school psychological services and an economy that is able to support these needs (World Bank, 2007). Educational change would seem to be a logical objective in a country where approximately 33.5% of the population is under 15 years of age (Bonderant, Henderson, & Nguyen, 2003). Five years of primary education is now compulsory, new schools have been built, and standards have been set for teachers and textbooks (World Bank, 2007). Support for education reform is demonstrated by an increasing state budget for education in Vietnam; as it has risen from 8% in 1990 to 15% in 2000 and is expected to reach 18% by 2010 (MOET, 2003).

With mandated change in primary education, change in University-based education has also occurred, with the objective of developing modern Universities who will train graduates to be leaders in their respective areas (MOET, 2003). The Hanoi National University of Education (HNUE) was the first university to train teachers in Vietnam and has recently added a specialty area: the Applied Psychology Section (APS) within the Department of Psychology and Education (DPE) (APS, 2007).

While no formal school psychology training programs presently exist in Vietnam, approximately 50 individuals who perform many of the functions of school psychologists do throughout the country (APS, 2007; Jimerson, Stewart, Skokut, Cardenas, & Malone, 2009). Given the needs of the 22 million school-aged children in Vietnam (Embassy of Vietnam, n.d.) it would be difficult to imagine that this number is sufficient. To this end, the DPE of HNUE began a collaborative relationship with the administration and faculty of St. John's University (STJ) in 2006 to develop a school psychology training program (Terjesen & Kassay, 2007). It is hoped that such a program would adequately meet the educational and mental health needs of students in Vietnam.

Preparation for a Training Program

Upon deciding to develop a school psychology training program at HNUE, the administration and faculty of the APS sought professional assistance from STJ to begin planning the program. The objectives identified were to provide on-going professional development for the future lecturers and supervisors of the HNUE school psychology program. This would be accomplished through continued education opportunities, access to professional literature, and consultation with international colleagues through a mentoring program.

Initially, two faculty members from STJ, Drs. Mark Terjesen and Kate Walton, and two STJ doctoral candidates, Kimberly Kassay and Maria Bolger, traveled to Vietnam for a series of 10 full-day consultation meetings during January of 2008 at HNUE. These meetings were held to determine how to best build the school psychology training program at HNUE considering the prior determined needs, available resources, managing the pragmatic component of training, along with what is considered "Best Practices" in development of a training program (Terjesen, Kassay, & Bolger, 2008).

The next step involved training the APS faculty members to be lecturers and supervisors in the school psychology program. This was accomplished through a series of six 20-hour training courses, divided into three 2-course sessions, during the summer of 2008 and were taught by professors from STJ and other American universities (Terjesen et al., 2009). The content for these trainings was determined by results of a needs assessment of the subject areas that the faculty members reported being deficient in and those that were identified as integral to the future profession of school psychology in Vietnam.

Specialized and Experiential Training in School Psychology

Building upon the prior training, it was determined that the next important step in the professional development of APS faculty members would be for them to receive more specialized training in school psychology in the form of short workshops given by STJ faculty, supervisors, advanced-doctoral level students, and colleagues in the New York area during the summer of 2009. In addition to this training, scheduled visits to a number of schools, educational facilities, and hospitals/mental health clinics were conducted to assist HNUE faculty in seeing and understanding the current manner in which these services are provided in the U.S. The goal

of this visit was to provide the HNUE faculty with knowledge of specialized subjects in school psychology and first-hand experience of the field as it currently exists in the U.S. so they can use their knowledge and experience as they prepare a training program that will be able to train professional school psychologists to meet the mental health and educational needs of children and adolescents in school settings in Vietnam.

Prior to initiation of the specialized and experiential training, HNUE and STJ faculty reviewed the content of prior trainings, results of surveys of knowledge and perceived efficacy, and a needs assessment survey based on the core training domains outlined by ISPA (ISPA, n.d.) was administered to determine content and sites to visit. This needs assessment asked APS faculty members to rate their current understanding and interest in each of the ISPA training domains. The results of this assessment were used in the planning of the site visits and lectures and were given to the site visit coordinators and lecturers to guide the focus of their presentations.

Training Participants

Four members of the APS faculty stayed for three weeks, four stayed for three months, and one faculty member will stay in the United States for six months. In addition to the concentrated lectures and site visits, the faculty members of HNUE also attended graduate level courses offered in the STJ psychology department while they were visiting. The criteria to form this group of participants were determined by HNUE. The aim was to have the group combine faculties from related domains to school psychology. Participants included HNUE administrators, along with faculty whose area of specializations were in developmental, counseling, and personality psychology, curriculum development and teaching methodologies. The aim of the visit was to receive both an overall view of the field as well as specific, concrete examples of application. Upon their return, this group will offer recommendations to the DPE and APS on varied aspects of the training program, training process and faculty development to assist in the development of the training program in school psychology.

Lecture Content

Based on results from the needs assessment survey as well as consideration for what would be "Best Practices" in school psychology, content area was identified and speakers were invited to present lectures to the faculty of HNUE. The content areas were somewhat broad but specific enough to assist in their preparation for the training program in Vietnam. Content areas included content that was broad-based in nature (History of Psychology), that focused on school psychology as a field (History of School Psychology; Special Education Process), that were targeted towards very specialized populations (e.g., Autism, ADHD/CD; PTSD; Anxiety; Depression), treatment approaches (PCIT; REBT/CBT), consultative (work with teachers; work with parents) and assessment (cognitive; personality; functional behavior analysis). The lectures were a combination of both didactic and demonstrative methodologies and all presenters integrated technology in their presentations. Each lecturer also provided their lecture and additional readings to the HNUE faculty ahead of time to assist in preparation and understanding. These lectures were designed to be both practical in nature (i.e., what do you do if X happens) as well as instructional (i.e., what are effective ways to teach this area).

Site Visits

In providing the HNUE faculty with the opportunity to observe the practice of school psychology and how practitioners are formally trained in the profession, consideration was given as to how to integrate these visits with the training lectures as well as how to educate the HNUE faculty in terms of how these sites serve as externship and internship placements for the graduate students at STJ. Included in these visits were nine public schools, one private special-education preschool, two publicly funded clinics that primarily serve children and adolescents, two private mental health facilities that serve adults and children, two University counseling centers, a University based clinic, and a publically funded clinic within a hospital setting. These diverse experiences provided a varied exposure to the manner in which educational and mental health needs of children are served within the U.S.

Summary

Building upon the prior program development and training this experience provided an opportunity for the future trainers of school psychologists within HNUE an opportunity to further develop their knowledge and skills as well as see models of how services are provided. The challenges going forward are many and there will in all likelihood be economic, cultural, and practical barriers that will impact upon the programs development and progress at varied points. However, the knowledge gained and experiences provided in the visit were beneficial in a number of ways: helping more clearly define the goal of school psychology in Vietnam, offering new methodologies (e.g., cross-cultural; school-based approaches) of scientific research that are essential for the trainers in school psychology, and finally re-invigorating and motivating the pioneer in the face of the challenges that lie ahead. The trainers at HNUE report that this intense summer training program helped better prepare them to meet the educational and mental health needs of children and their families going forward. Future steps to continue to build their professional knowledge and skills are currently in development.

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The Third International Congress on Interpersonal Acceptance and Rejection will be held in Padua, Italy from July 28 through July 31, 2010.

You can get information about the Congress at its website, http://isipar2010.psy.unipd.it.

You can also get information about the sponsoring organization—the International Society for Interpersonal Acceptance and Rejection—at www.isipar.org.

The Congress is interdisciplinary and will address research and practice on all aspects of interpersonal acceptance and rejection.

Internationalizing the curriculum: Lessons from a student service-learning project in Kigali, Rwanda

Amy Paderta, B.A. and Sandra G. Zakowski, Ph.D.
Clinical Psychology, Argosy University, Chicago

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Abstract

This article portrays the preparation and implementation of a service-learning project in Rwanda for doctoral clinical psychology students from Argosy University, Chicago. The project was developed in collaboration with Women's Equity in Access to Care and Treatment (WE-ACTx), a Rwandan NGO. The purpose of the service-learning project was to help provide needed services to Rwandan mental health staff and to provide an opportunity for graduate students in psychology to receive ethical, culturally-informed, international clinical experience. The work plan developed by the Argosy team and Rwandan counselors is described, with an emphasis on conducting cross-cultural focus groups and training and facilitating a self-care and secondary trauma retreat. Students' experiences regarding personal and professional development and learning are discussed.

Introduction

Upon arrival in Rwanda, one is struck by the country's remarkable beauty and serenity in the aftermath of atrocity. In 1994, close to one million Rwandans were massacred in the genocide against the Tutsi minority group, leaving millions more Rwandans displaced and without family (Straus, 2006; Gourevitch, 1998). Now, fifteen years later, many Rwandans suffer from poverty, complex traumatic symptoms, HIV/AIDS, grief, loneliness, depression, and anxiety (Kaberra & Sewpaul, 2008). There is also tremendous strength and resilience among the population, as is so often the case in the aftermath of human disaster.

In fall 2008, faculty and students of Argosy University, Chicago began to develop a service-learning program for graduate students in clinical psychology. The project was a collaboration between the University, Heartland Alliance International Programs, EDMC Foundation, and Women's Equity in Access to Care and Treatment (WE-ACTx) in

Rwanda. This article focuses on project development, preparation, structure, tasks, and lessons learned.

Planning

WE-ACTx is an NGO located in Kigali, Rwanda founded by US physicians in 2004 to respond to the growing service needs of HIV-positive women. In addition to medical services, the need for mental health, income generation, and legal services quickly became apparent, and professionals were recruited to provide training and consultation. As a result of one of the authors' (SGZ) affiliation with Heartland Alliance Marjorie Kovler Center and her prior consultation work with WE-ACTx, the idea of developing a service-learning program for psychology graduate students was presented to Argosy University, Chicago.

Literature on service-learning projects (Hagan, 2004; McClam, et al., 2008; Melland, 2004) highlights the importance of ensuring mutually beneficial and collaborative experiences for both students and the community served; additionally, proper preparation, culturally-appropriate action, and debriefing/reflections must be embedded into program development. Following such models, the rationale behind the Rwanda service-learning project was: (a.) to help provide needed services to WE-ACTx mental health staff including training and support, and, (b.) to provide an opportunity for graduate students in psychology to receive ethical (Sommers-Flanagan, 2007), culturally-informed, international clinical experience.

A committee of faculty and students was formed in October 2008 to plan and raise $12,000 needed for the project. Fundraising was challenging; the committee researched foundations and sent proposals to the 15 foundations whose mission most closely matched that of the project, without success. A fundraising letter was sent to corporate and private donors and fundraising events commenced.

While fundraising efforts continued, several initiatives were implemented to educate the campus community on the project. Faculty and students began an international psychology journal club to discuss scholarly articles, initiated campus activities including viewing and discussion of a Rwandan genocide film, and hosted a colloquium by a Rwandan counselor. A course sequence was also developed; the first was a didactic course to introduce students to the fundamental principles and ethical considerations of international humanitarian work, the psychological consequences of genocide and HIV/AIDS, and the sociopolitical context of Rwanda. Students learned via case studies provided by WE-ACTx counselors, self-reflection exercises, discussion, and presentations emphasizing the importance of conducting well-informed, culturally sensitive, and collaborative humanitarian work. The course was essential in preparing students intellectually and emotionally for their experience in Rwanda. The second course included the service-learning trip. The service plan was developed in collaboration with WE-ACTx staff, supervisors, and consultants in Chicago. The goal was to provide needed assistance to WE-ACTx during the fifteenth anniversary of the genocide and to provide students with developmentally appropriate learning experiences. It was emphasized throughout the planning that flexibility would be essential to successful international work, and that while a relatively detailed plan was established, it would be likely to change depending on the situation and needs once in Rwanda.

Project Work Plan and Execution

The plan included: (a.) assessing the applicability of the Child Depression Inventory, (b.) conducting focus groups, (c.) evaluating HIV-positive children enrolled in a nutritional program, (d.) assisting in children's support groups, (e.) leading secondary trauma processing groups for counselors, (f.) providing collaborative professional development trainings to counselors, (g.) touring local mental health care facilities, and (h.) engaging in a student exchange at Rwanda National University. Following will be examples of service-learning experiences.

Counselor trainings

Based on a list of training topics generated by WE-ACTx staff, students prepared several training modules from which counselors chose *Psychodrama* and *Couples Therapy*. Before each training, the Argosy team discussed ways to provide collaborative trainings, respecting local healing practices while enhancing expertise. The treatment team learned about Rwandan culture and treatment models, WE-ACTx's client population, and the nature of the counselors' work; thus, cultural learning was a continual process that happened in discussion between the visiting team and the local staff. For example, during training on couple's therapy, Gottman's Strong House Theory (2007) was collaboratively modified to suit the specific needs of WE-ACTx clients. Throughout the training, students invited discussions about Rwandan beliefs around marital life, gender roles, child rearing practices, and conflict management. This gave students a sense of how couples engage with one another and provided a starting point for working with local staff on adapting Gottman's model to WE-ACTx clients.

Focus groups with WE-ACTx clients and staff

The Argosy team was asked to conduct focus groups around Intimate Partner Violence (IPV) and HIV/AIDS to examine the needs of women and couples experiencing IPV and to provide ideas for additional services. Preparation consisted of readings (e.g., Nabors, 2001; Morgan, 1996; Munodawafa, et al., 2005) and planning meetings where the Argosy team discussed possible client perceptions/attitudes towards outside facilitators, building rapport, and reviewing informed consent, including facilitator roles, purpose, and outcomes. To avoid excessive agreeableness from cultural beliefs around welcoming outsiders, clients were informed by their counselors prior to the focus group and were given the choice to attend. During facilitation, co-leaders recognized cultural stigmas surrounding IPV and HIV/AIDS in Rwandan society and invited participants to share what felt comfortable/safe for them. Through the experience, graduate students witnessed the challenges WE-ACTx clients face, potential solutions to such

issues, and client strengths.

Secondary trauma processing group for counselors

Secondary trauma is defined as the therapist's internalization of the client's traumatic transferences, interfering with the therapist's feelings, memories, sense of self/other, and notions of safety (McCann & Pearlman,1993). Most WE-ACTx mental health counselors are survivors of the genocide working with survivors. Consequently, there is unremitting interplay between workers' primary trauma and secondary trauma, where their own trauma can be triggered by their clients' stories.

The Argosy team was asked to facilitate an afternoon retreat and attend to the counselors' needs through discussing and participating in activities on secondary trauma and resilience. Students prepared exercises proposed by Pearlman and Saakvitne (1996). In one activity, titled *Silent Witness* (p. 93), students asked workers to write down three ways in which they were affected by their work. Together, participants silently read each others' experiences and a discussion followed. Counselors reported sleep disturbances, restlessness, fatigue, loss of motivation, sadness, isolation, irritability, anger, helplessness, and feeling overwhelmed by clients' needs. Following this exercise, counselors spontaneously and symbolically threw their worries into the lake, then transitioned to a Rwandan song and dance activity. This activity exemplified the integration of a planned intervention based on Western models of trauma with local ways of healing.

Lessons Learned

Students gained invaluable lessons from the service-learning project, enhancing their personal and professional development. Essentially, students learned to appropriately, sensitively, and ethically work cross-culturally. For example, students made the trainings collaborative rather than establishing the Western-as-expert paradigm (van Ommeren & Wessells, 2007). Students asked questions, continually solicited feedback, and focused on the strengths of mental health care workers and their clients.

Facilitating focus groups gave students a better sense of issues many WE-ACTx clients face, including domestic violence, stigma/isolation of women with HIV/AIDS, and discrimination and dating challenges of HIV-positive adolescents. Additionally, students were trained to effectively work with an interpreter, learning to succinctly convey their message and to work together to understand cultural nuances. In the process, students attended to the cultural, emotional, and interpersonal needs of clients.

The retreat on secondary trauma gave students insight into the vitality of creating a space for consultation, supervision, and self-care. Additionally, students gained awareness to the complex issues plaguing a nation recovering from genocide, including establishing a just nation, restoring trust, forgiving perpetrators, reconciling differences, and establishing peace. Students also understood the impact of rape and genocide on one's individual and cultural identity.

Students appreciated the importance of knowing the country's history to truly understand the personal, interpersonal, and societal factors that construct the social fabric of Rwanda. It was equally important to understand students' own racial identity and the transference evoked by skin color; students engaged in difficult dialogues around race, processing their racial development and addressing assumptions, projections, transferences, and feelings.

The group found this work to be essential in debunking the Western-as-expert paradigm. Overall, the development of this program speaks to the ever-growing need for graduate students to receive supervised experiences internationally in order to competently and ethically work cross-culturally. Furthermore, it is important for students to develop an awareness of the role of psychology in the international arena.

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How can we "go global?"

Harold Takooshian and Elaine Congress,
Fordham University

"How can we become more involved in international activities?" On September 14, 2009, this question was the focus of a three-hour convocation at Fordham University in New York City. After a welcome, the 110 participants split into three 75-minute workshops, then later re-gathered at a gala reception to speak one-on-one with the 22 presenters.

Welcome. Participants were welcomed by messages from four organizers of international activities: Dean **Elaine P. Congress** and Professor **Harold Takooshian** of Fordham University, past-President **Florence L. Denmark** of the American Psychological Association (APA), and past-President **Susan Opotow** of the Society for Psychological Study of Social Issues (SPSSI). About half of the 110 participants were students, and half were professionals from the United Nations or other local universities.

Workshops. The convocation then divided into three simultaneous 75-minute workshops, each with a rapporteur to report the information for later publication: (1) **United Nations**: four UN reps updated others on the 62nd UN conference in Mexico City on 9-11 September 2009, on the theme "For peace and development, disarm now!" (2) **Human Rights**: five experts described how individuals and groups are promoting global human rights. (3) **Students**: seven experts advised students on how to be more involved in the UN and other international activities. The 55 participants included 30 students from the new International Studies course taught by Fordham Professor **Chris Toulouse**.

Reception. After these workshops, participants re-gathered for a gala reception, and one-to-one chats with the 22 presenters and each other. Professor **Robert Chazin** of Fordham Graduate School of Social Service was presented with an award to recognize his two decades of international work, including his recent design of a new graduate curriculum on human rights. On behalf of the United Nations and its Conference of Non-Governmental Organizations (CoNGO), President **Liberato Bautista** and NYC Director **Anita Thomas** described the important role of CoNGO since 1948, to coordinate the UN activities of its 560 member NGOs. They referred participants to their web list of 50 active CoNGO committees in New York, Geneva, and Vienna: www.ngocongo.org.

Film. **Mahroo Moshari** (mahroon@yahoo.com) kindly arranged the post-reception screening of Jeremy Gilley's bold new DVD, "The day after peace," www.peaceoneday.org , which tells the true story of one man who successfully created an annual global day of non-violence.

Since 2004, this was the sixth annual NYC international convocation in September, hosted this year by Fordham University and its International Studies Program, in collaboration with CoNGO, SPSSI, and the APA Division of International Psychology. This year proved unusually lively, by bringing together three diverse groups—UN reps, international faculty and students from many schools, including Fordham. Once again the convocation was free to participants, thanks to the 22 presenters who volunteered their expertise. For any details, check the UN conference at www.unngodpiconference.org , or www.internationalpsychology.net/ny, or contact takoosh@aol.com, or congress@fordham.edu.

(1) United Nations: Mexico City update

Wismick Jean-Charles, *Fordham University*
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On 9-11 September 2009, hundreds of UN representatives converged on Mexico City for the 62nd annual DPI/ NGO conference on the theme: "Peace and Development, Disarm Now." Here at Fordham, four UN representatives reported the outcomes of this conference. The workshop chair, Fordham Dean **Elaine Congress**, began with a brief background on the 2008 Conference in Paris, focused on "Reaffirming Human Rights for all," to honor 60 years of the Universal Declaration of Human Rights. She then introduced the three panelists to the 25 workshop participants.

Juanita Carrillo of Fordham (drjpcarrillo@gmail.com), an NGO representative to the United Nations for the International Association of Gerontology and Geriatrics (IAGG), reviewed the extensive process to organize the DPI/ NGO conference--from selecting the topic nearly a year ago to the presentation of the Conference Declaration at the closing ceremony in Mexico City. She explained the role of the planning committee, the mission of the executive committee, the duty of the committee of experts, and the meaning of the visual identity of the conference (a plant emerging out of a grenade) symbolizing disarmament evolving into peace.

Martha Bial of Fordham (bial@fordham.edu) just returned from the Mexico City conference. She outlined the format of the three-day conference that included opening and closing ceremonies with keynote addresses, roundtables (plenary sessions), afternoon workshops, exhibits of peace work, and receptions. She noted that the 1,300 attendees were representatives of non-governmental organizations (NGOS) from around the globe. She also reported about the workshop entitled "Impact of Armed Violence on Vulnerable Generations" sponsored by IAGG, that focused on the effects of armed conflicts on older people. She offered guidelines and some recommendations to reduce armed conflicts while recognizing that advocacy on social issues takes a long time to effect change.

Florence L. Denmark of Pace (fdenmark@pace.edu), the main APA representative to the United Nations, described the upcoming "Psychology Day at the UN." She presented the theme for this third annual psychology day conference: "Psychology and Diplomacy: Negotiating Peace and Human Rights." The day will include two panels, one on "Negotiating for Humanitarian Access," the other on "Organizational Diplomacy: Internal Negotiating". She encouraged students and others to get involved in international

activities though NGOs at the UN, emphasizing how grassroots civil society can work with agencies and governments to advocate for peace and to effect change for a better world.

The discussion following these presentations was exceptionally lively, including questions from faculty and eager students seeking opportunities to participate in United Nations-related activities. The enthusiastic attendees have left the room happily exchanging business cards and sharing comments about how the workshop was both informative and captivating.

Professor Chris Toulouse addressed a SRO room of students interested in international issues.

Dr. Bobbi Nassar of the UN moderated the roundtable workshop on human rights.

CoNGO President Liberato Bautista addressed the international reception.

Reception participants shared a huge international cake.

(2) Human rights

Samvel Jeshmaridian, *City University of New York*
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This workshop was chaired by **Bobbi Nassar**, Chair of the NGO Committee on Human Rights, who introduced panelists Robert Chazin and Ani Kalayjian.

Professor **Robert Chazin** of Fordham Graduate School of Social Service (chazin@fordham.edu) differentiated four domains for social work. They are the World domain as reflection of Globalization; State domain referring to Governments; Community as the arena for practice; and the personal

domain, involving work with individuals, families and small groups. Social work with individual problems includes issues of sexuality, spirituality, bereavement, anger, alienation, depression, while families struggle with unemployment, poverty, schooling and housing. Professor Chazin discussed these domains in the light of human rights and social justice making accents on the importance of reaccreditation of human rights curricula.

Since Professor Chazin's is a social work educator, he stressed the principle of human rights for social work perspectives. He explained, "Today's national conflict regarding a public option for health care vs. those who want to maintain a private health care system is a good example of this conflict. Human rights advocates argue for inclusion of a public option to ensure medical care for all our citizens." Use of a human rights framework is an important shift from the profession's longstanding concern with human needs. He concluded that social work is and has always been a human rights profession.

Professor **Ani Kalayjian** of Fordham University (drkalayjian@gmail.com) talked on outreach activities and disaster intervention in different countries. All her illustrations were part of her own personal experience: hurricanes Katrina and Rita, various disasters in Armenia, Pakistan, Sri Lanka, and Sierra Leone. She explained the principles of the Biopsychosocial Approach in organizing the outreach and supporting people under disaster. Though these people have variety in their culture, language, religion, and human rights perception, the Biopsychosocial way of working with them is effective and helpful. Professor Kalayjian stressed The United Nation's positive role in the field of helping professions.

At the end of the panel, Dr. Nassar explained the peculiarities and differences between UN Resolution, Declaration, and Convention, their authoritative powers and moral orientations.

(3) Involving Students in International Activities: Why and How?

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A full room of 60 students and faculty heard this panel of seven experts, chaired by **Harold Takooshian** of Fordham.

Patrick Sciaratta, of the Friendship Ambassador's Association (www.faf.org) stressed the importance of students' early involvement in international work. He noted the strong desire of today's students for hands-on experience and involvement—not just reading or hearing about international work. In August, 1,000 young people from the Pacific area, including 100 Chinese youth leaders, came together to work on international issues. Many students were only 15 to 16 years of age. A video of the U.N. Youth Assembly may be found on YouTube. Students may attend an upcoming three-day U.N. event, a great networking opportunity, that would normally cost $1,000 to $1,500 to attend, but which students may attend for a registration fee of $45. Those in attendance will include the son of Mahatma Gandhi, Jesse Jackson, Kathy Ireland, Angelina Jolie, and other key individuals and NGOs which are working on international issues.

Fred Campano of Fordham University (compano@fordham.edu), discussed two different paths that can lead to obtaining professional employment at the U.N, or an U.N. Internship. Typically the U.N. seeks only graduate student interns, or individuals who hold a master's degree or doctorate. Countries must have an available post before you may apply. The UN developed strict hiring procedures to depoliticize the hiring process. Country posts are now allotted based upon the percentage of the total U.N. dues that each country pays. For example, the U.S. pays 25% of the total U.N. dues, so the U.S. receives 25% of the U.N. posts. It may take two years to gain professional-level employment at the U.N. The process involves taking a competitive examination. Approximately six months after the exam, interview candidates are selected. Only a small percentage of applicants are hired. A popular, alternate path to obtaining a professional position at the U.N. is to begin one's career as a clerical employee. The downside to this approach is that you will not be involved in any professional work. However, the U.N. is a wonderful place to work: the salaries are excellent, the benefits are great, and you receive six weeks of vacation and sick leave in your first year of employment. After working in a clerical capacity for two to three years, the U.N. allows clerical employees to take the GSP exam, and those who earn a passing score may apply for positions within the U.N. professional ranks.

Jo Anne Murphy, the U.N. Program Coordinator at *Fairleigh Dickinson* University (joanne_murphy@fdu.edu), discussed the numerous international and U.N.-related opportunities that FDU creates for its students. When the U.N. General Secretary recently spoke at FDU, he referred to "the well-worn path between FDU and the U.N., that goes both ways." Dr. Murphy emphasized that, "students who are interested in receiving international experience and U.N. involvement must demand such programs and opportunities from their university." FDU has begun an exciting global learning initiative, a global virtual faculty program with 75 professors participating from all over the world. Recently, a nursing class at FDU participated in a virtual meeting with a world expert regarding global health who was located in Geneva. Students and professionals from all over the world may access this online resource library, and view teaching sessions and meetings at: www.gig.org. FDU's U.N. Pathways program provides students with a variety of opportunities to interact with U.N. ambassadors. There are also opportunities for students to attend U.N. briefings; interact with NGOs associated with the U.N., and participate in virtual meetings such as the recent Nuclear Non-Proliferation video conference. Obtaining an U.N. internship can be difficult and complicated, but FDU creates unpaid internships for students that allow them to establish person-to-person relationships with U.N. personnel.

Kelly Roberts, Assistant Director of the Fordham Office of International Service (keroberts@fordham.edu) spoke

about international opportunities for Fordham students who wish to study abroad, through NAFSA; opportunities for students to attend U.N. briefings; and the assistance that Fordham provides to students interested to obtain internships with NGOs and the positions within the State Department. Ms. Roberts recently escorted two Fordham students and U.N. interns, Azizi Siexas and Sandra Choi, to Cuba's permanent mission to the United Nations. This enabled them to learn more about Cuba's new projects and policies and the kind of work they have been doing towards the Millennium Development Goals (MDGs).

Christopher Toulouse (Toulouse@fordham.edu) of Fordham University's Center for Teaching Excellence and International Studies Program, brought his class of 30 Fordham students. Dr. Toulouse stressed that the time for students to start thinking about becoming involved in international work is their first year of college. This strategy allows students to focus on where they wish to go internationally during their 3rd year, and collect international data for their thesis in their 4th year. Dr. Toulouse gave practical advice about the use of technology and international work: 1) Rely only upon authoritative sources of information found on the Internet, publications such as the New York Times, the Economist, the Atlantic Monthly, and the New Yorker. 2) Ask hard questions about what is going on in the world, and why. Be cautious, and ask hard questions especially when reading information on the internet. 3) When posting information to Facebook and blogs, use discretion rather than telling the world exactly how you feel. You never know when a host family, or unintended others, might read your post—feelings can be hurt and relationships permanently damaged. 4) Be aware that international work is not for the faint of heart or those who desire a quiet life.

Rivka B. Meir of CUNY and Fordham University (winsuccess@aol.com), Director of the APA International Liaison program, discussed the importance of joining international groups such as APA Division 52, International Psychology. The $15 annual membership fee gives students information on new developments in international psychology, a connection with other students and psychologists from 89 countries abroad, and opportunities to collaborate on global data collection. She also encouraged attendees to "Adopt a Psychologist" from abroad who may lack the resources to pay annual APA membership dues.

Uwe P. Gielen, Director of the Saint Francis College Institute for International & Cross-Cultural Psychology (ugielen@hotmail.com) spoke about his research regarding Asians and Asian-Americans living in New York City. He also announced that the 21st Greater New York Conference on Behavioral Research will be hosted by St. Francis College in Brooklyn NY on November 6, with a deadline of October 13 for students and faculty to submit their research findings for presentation, at gnyc@fordham.edu.

Remembering Henry P. David (1923-2009)

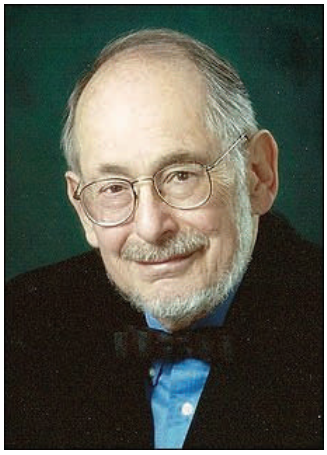

Meaningfulworld Mission to Armenia: Empowerment, forgiveness, and transforming learning disabilities into challenges

Dr. Ani Kalayjian and Jennifer De Mucci

The Association for Trauma Outreach and Prevention (ATOP) of Meaningfulworld organized the third team of the Meaningfulworld Mission to Armenia from 18th to 27th of November 2009. The mission was a successful endeavor not only in the work conducted within the trainings, but the impact the soul of the country and the people had upon our team. From the first day in Armenia, the team noticed the unsurpassed hospitality of the people and their respectful, kind and gentle demeanor. It is not often that one is made to feel so comfortable and at home within a foreign land. We were immediately welcomed by our colleagues in Armenia and treated as family. Perhaps one of the most memorable experiences for the entire team came before the week of training, having been invited to a dinner in the home of Dr. Kalayjian's cousin. In addition to delicious homemade "yogurt soup" and hospitality, it was here that we first experienced the true heart and soul of the Armenians. At dinner we were educated on the country's rich history, and could sense the pride within our historian while he recounted these details. In his own words he was "An Armenian, whose dream is to see Historic Great Armenia, including Van, Tvin, Tigranakert, all Kilikia (Cilicia), and Greater and Lesser Armenia; to live and die in the Holy Armenian land." It was clear to feel the essence of what it means to be Armenian, having lost and suffered so much through history, yet retaining a historical pride, resilience and sense of hope. It was at this time that the importance of our mission was made clear as we came to understand the heart of the country that would be our home for ten unforgettable days.

Dr. Ani Kalayjian and Jennifer De Mucci, President and Research Coordinator for ATOP, respectively, delivered the Empowerment portion of the mission to Armenia. Dr. Kathy Tiner and Kathryn Mendoza conducted the overcoming learning disability training programs. On the first day, Monday, 23rd November, we conducted the empowerment training project, and on the second day the Special Education Workshop. The team also delivered lectures, visited orphanages/children's centers, and set agendas for collaborative research and future trainings. This Meaningfulworld team conducted trainings at the Mental Health Foundation Center, and the FAR Children's Center. They also trained the personnel, social workers, and psychologists in preventative and restoration methods for treating children with trauma. Dr. Kalayjian's *Biopsychosocial & Eco-Spiritual Model* was utilized throughout the mission.

The team presented their work to the US Embassy office of Development and Reintegration programs in Yerevan. Follow up collaboration plan was set forth with local NGO's. The team visited various children's centers (previously called orphanages) as part of the third phase of a 10-year follow-up mission to observe progress and development. Donations of clothing and school supplies from several generous individuals were given out at these centers.

The trip to Armenia was one which provided many rewards and challenges to the Meaningfulworld team. Throughout the trainings, the team was introduced to individuals in varying levels of empowerment, thus providing each day of training to be unique. At the first empowerment training at the Mental Health Foundation, the group consisted of young women eager to learn conflict resolution skills through the power of forgiveness. The first training was a success for all involved, and resulted in several participants planning to create a Chapter of Meaningfulworld in Yerevan, Armenia.

A special education workshop conducted by Dr. Kathy Tiner and Kathryn Mendoza was held on the second day of trainings at Bridge of Hope in Yerevan. The workshop was attended by psychologists, teachers and mothers of children with special needs. Dr. Tiner and Ms. Mendoza (translated by Dr. Kalayjian) instructed participants on various learning tools which are aimed to be helpful in working with children with Attention Deficit and Learning Disabilities. Emphasis was also placed upon integrating special needs children within the public schools.

The Meaningfulworld team traveled outside of Yerevan to conduct trainings in Apovian and Vanatzor. Perhaps one of the most enriching experiences of the mission was traveling to the city of Vanatzor, which provided the team with beautiful views of the country. In Vanatzor the team was greeted by Gevork Manoukian and his team at the Armenian Constitutional Rights -Protective Centre. In addition to Dr. Kalayjian's empowerment training, Dr. Tiner also presented on the future of integrating schools. ATOP's work in Vanatzor was much appreciated and the team received a very warm hospitality which will always be cherished.

At all trainings, the team was introduced to many individuals whose varied experience further enriched the meaning of our work in Armenia. Both the Meaningfulworld team as well as participants were able to learn and grow from one another in the trainings. Many individuals stated that they had never before experienced trainings such as the ones presented by Dr. Kalayjian emphasizing the *Biopsychosocial and Eco-Spiritual Model* and the power of forgiveness. The empowerment training included ancestral mediation followed by a healing circle in which participants were encouraged to share their feelings and experiences. The current protocols between Armenians and Turks resurfaced the generational impact of the Genocide, and many expressed difficulty to forgive the perpetrators' decedents who are engaged in denial. One woman stated that she was not ready to forgive as she still recalls stories of her grandmother's "nails being torn out by Ottoman soldiers." Although difficult emotions were conjured at the training, many participants reported feeling a sense of peace by the end of the day and gratitude for having been a part of this new kind of experience of transformation and forgiveness. One young woman stated that at the beginning of the day she was "in a bad mood with a headache and not wanting to be bothered by anyone;" however, by the end of the training she reported feeling uplifted and felt the benefits of forgiveness on her spirit.

She also spoke of her own experiences and feelings regarding the pain of Genocide memories of her grandparents and how her anger stemmed not simply from stories of what happened but the literature and songs taught throughout her childhood which addressed the Genocide. But after the training she reported learning the true value of forgiveness. Here it is seen that hope for finding empowerment through forgiveness and healing the scars of the Genocide may begin with the young generation.

In addition to trainings, the ATOP mission also visited several Children's Centers providing donations of toys, clothes, and school supplies. The children at these centers were filled with love and affection and left a lasting impression upon the hearts and minds of the Meaningfulworld team. Additionally, the gratitude expressed by the facilitators at these centers left the team with a feeling of contentment that we were able to make a difference, however small in the lives of these beautiful children.

As Dr. Tiner stated: "I was especially impressed with the kind and gentle nature of Armenian people. I am also very pleased at the progress of integration of children with special needs into the public school systems. All educators we met were very informed, thoughtful, conscientious, and knowledgeable of the special needs of the children."

While in Armenia, the team also disseminated questionnaires created by Dr. Kalayjian assessing the psychological impact of the recent Armenian-Turkish Protocols. Many Armenians reported feelings of disappointment and anger regarding the conditions placed within the protocols regarding the issue of Genocide recognition and the status of Karabagh. Clearly there is still much that needs to be changed before a fair agreement can be made between the two countries. The finding of this current research was presented by Dr. Kalayjian on 17 December at Fordham University.

The entire team was positively impacted by the mission to Armenia. Except for Dr. Kalayjian, for most of us it was the first time visiting the country and it proved to be more than we ever could have expected. The richness of the culture and the depths of its history can be felt on every corner and within every individual we met from Echmiadzin to Vanatzor from Bangladesh to Apovian. The warmth and genuine humanity and humility of the people are as beautiful as the country itself. The Meaningfulworld Team expresses sincere gratitude to the World Wide Network for Gender Empowerment of Fielding Graduate University, the Mental Health Foundation, Fund for Armenia Relief, Armenian Constitutional Protective Rights Centre, and all those who shared donations and toys for the children.

WNGE presents a workshop in Saudi Arabia

Dr. Ani Kalayjian

World Wide Network for Gender Empowerment of Fielding Graduate University was invited to take part in the International Nursing Symposium 'Building Connections for Global Nursing: Engage, Empower and Transform' which was held at the King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia, 27-28 October 2009.

The profession of nursing is vital to the delivery of quality health care. Organizations depend on the education, experience and the caring nature of nurses to improve the quality of life for individuals, families and communities in our global society. The symposium focused on nursing leadership, practice, education, research, informatics and quality. Each area of interest was covered by presentations, workshops and poster sessions.

WNGE organized and presented a workshop entitled: "Education and Empowerment within the health care system." Workshop faculty were Dr. Anna DiStefano, Provost of Fielding Graduate University as well as the Chair of WNGE and who gave a summary of the goals and mission of WNGE; Dr. Andrea Zielke-Nadkarni, Professor of Nursing Science at Munster University, Germany, who presented on her research helping developing countries have easy access to cooking tools; Dr. Patricia Hinchberger, Professor at University of California, who discussed her research on work place violence, especially in hospitals; Dr. Elham Al Ateeq, Associate Dean for Clinical Affairs and Associate Dean for Academic Affairs, College of Nursing Alhasa, Saudi Arabia, who discussed her own dissertation based on her work on leadership in nursing, and Dr. Ani Kalayjian who presented her 7-step model, addressing how to prevent violence through the Biopsychosocial and Eco-Spiritual Model and through the practice of forgiveness. The workshop was very moving as stated by many participants. Participants asked thought provoking questions as to how to continue being in peace.

Dr. Al-Barnawi, the Chairperson of the symposium, stated that the symposium provided an opportunity for nurses, physicians, students and other health care professionals to learn innovative and creative ideas from national and international speakers. She specially thanked the WNGE panelists who created a wonderful space for people to hear about a spiritually moving method for caring, compassion, transformation, and meaning-making.

WNGE Core Members were also invited to a conference at Alhasa College of Nursing, which proved to be another productive and meaningful conference where participants disseminated valuable research based studies, and set forth plans for future international collaboration.

Geis Memorial Scholarship Award for Dissertation Research

Division 35 Society for the Psychology of Women
Natalie Porter, PhD, Chair

Application Deadline April 1, 2010

The annual Geis Memorial Scholarship Award for Dissertation Research offers $15,000 for the 2010-2011 academic year to fund dissertation research in the Psychology of Women by an advanced doctoral candidate. Eligible research will:

- be feminist
- address a feminist/womanist issue
- use social psychology research methods to make a significant contribution to social psychology theory and research

Dr. Florence L. (Lindy) Geis was a social psychologist with a strong commitment to research on the Psychology of Women and to the mentoring of women graduate students. In her will, she left an endowment to fund doctoral students conducting dissertation research in feminist psychology.

Proposals will be judged on suitability, feasibility, and merit of research. Funding need not be used solely to fund the research project. More information can be found online at http://www.apa.org/divisions/div35 under Awards and Grants.

For an application, e-mail nporter@alliant.edu

Natalie Porter, PhD
Professor
California School of Professional Psychology-Alliant International University
Phone: (415) 955-2137

The Fourth International Conference on Psychology Education (ICOPE2010)

Following the tradition of ICTP2008 held in St. Petersburg, Russia, the conference will convene in Sydney, Australia from July 8-11, 2010, and be organized by the Australian Psychology Educators Network (APEN).

More information on the conference is available at http://icope2010.psy.unsw.edu.au

The Institute for the Study and Promotion of Race and Culture 2010 Diversity Challenge: Race and Culture in Teaching, Training, and Supervision

Each year the Institute for the Study and Promotion of Race and Culture addresses a racial or cultural issue that could benefit from a pragmatic, scholarly, or grassroots focus through its Diversity Challenge conference. The theme of the 2010 conference is the examination of race and culture in teaching, training, and supervision. The two-day conference held at Boston College includes panel discussion/symposia, workshops, structured discussions, a poster session, and individual presentations by invited experts and selected guests including educators, administrators, researchers, mental health professionals, and community organizations. Individuals interested in presenting should check the ISPRC website in January 2010 when the Call for Proposals will be posted, www.bc.edu/isprc. General information about the conference including pre-registration will also available on the website.

I Congress of Psychology and Behavior Analysis

The congress will be held at the State University of Londrina, UEL - Londrina, Parana, Brazil from May 13th to 15th, 2010. Themes include behavior analysis, clinics, forensics, education, health, institutional and others.

Deadline for paper submission:
March 21st, 2010

Deadline for symposium submission:
February 5th, 2010

More information on the congress is available at http://www.uel.br/eventos/cpac/USicpacprinc.php

Registration orders or further questioning should be directed to the Central Organizing Committee at CPAC_uel@yahoo.com.br c/o Celso Socorro Oliveira.

International Employment Opportunities

Michael J. Stevens, PhD, DHC
Illinois State University
mjsteven@ilstu.edu

University of Victoria, Department of Psychology: The Department of Psychology at the University of Victoria invites applications for a tenure-track appointment in cognitive neuroscience at the level of assistant professor to begin July 1, 2010. The ideal candidate will have a strong background and training in functional magnetic resonance imaging and in computational cognitive neuroscience techniques, but applications demonstrating competence in either of these methods will be considered. The candidate's research interests will add to the existing strengths of the department that include the study of cognitive control, attention, learning, memory, eyewitness testimony, visual cognition, motor control, development and aging. The successful candidate will play a key role in the development of a 1.5 T General Electric MRI system, presently being upgraded to be capable of acquiring functional data, at the Royal Jubilee Hospital located approximately 1 mile from campus. The candidate will also have access to Westgrid, a high-performance computing network that encompasses 14 partner institutions across four provinces. Duties include the maintenance of a successful program of research (as evidenced by publications and external grant support), teaching at the undergraduate and graduate levels, and contributions to the collegiality, reputation, and day-to-day operation of the Department and the University (e.g., collaborative research, curriculum development and committee service). Applicants must have a PhD in cognitive psychology, cognitive neuroscience, neuroscience, computer science, or a related discipline. The deadline is December 7, 2009, but applications will be reviewed until the position is filled. To apply, submit a letter of application (including a statement of research interests and accomplishments and a statement of teaching interests and experience), a curriculum vitae, copies of publications, evidence of teaching experience, and arrange for three confidential letters of reference to be sent to: Cognitive and Brain Sciences Search Committee Department of Psychology University of Victoria PO Box 3050 STN CSC Victoria, British Columbia V8W 3P5 Canada.

Children and Youth in the Cypress Health Region, Child and Adolescent Clinical Psychologist: As a member of the Community Health Services Child & Youth Mental Health team, the psychologist provides treatment, consultation and referral services for Children and Youth in the Cypress Health Region. Other duties include consultation to community agencies, public seminars and lectures. Must possess a master's degree or a PhD in psychology (master's = $31.756 -$38.842 per hour; PhD = $40.005 - $48.928 per hour). Must be registered with the Saskatchewan College of Psychologists, extensive clinical experience in child and youth mental health services, good working knowledge of relevant legislation, extensive knowledge in psychotherapeutic techniques and the administration, scoring and interpretation of a wide range of psychological tests, knowledge of concepts of mental illness and proven ability to formulate diagnoses based on the DSM IV, and ability to design and deliver prevention and promotion programs to professionals and public. Valid driver's license required. In addition to an excellent benefit plan and strong community advantages, the Cypress Health Region also offers assistance in locating spousal employment opportunities. Our incentive package includes relocation funding of $5,000. Successful applicants may also be eligible for up to $10,000 in grant funding from Saskatchewan Health. Employer will assist with relocation costs.

IWK Health Centre, Provincial Child and Youth Forensic Services: The Provincial Child and Youth Forensic Services team, a service operated under the Mental Health and Addictions Program at the IWK Health Centre, has a position for a clinical psychologist. The mission of Provincial Child and Youth Forensic Services is to provide evidence-based best practice Health and Mental Health Services to children, youth, and families involved with Justice Services. The clinical psychologist will work with the expanding and dynamic Youth Justice Assessment Services Team which provides specialized, comprehensive, interdisciplinary assessments for the judicial system, specifically in the relation to matters before the Youth Justice Court. The Clinical Psychologist conducts court ordered assessments under section 34 of the Youth Criminal Justice Act as well as risk assessments for the Criminal Code Review Board. The assessment report provides the court with rehabilitative recommendations for sentencing purposes and recommendations around risk management. These assessments require the ability to work within deadlines and to work effectively with other members of the assessment team to meet standards for quality control. This position will require some travel to other parts of the province which is compensated. The clinical psychologist works collaboratively with social work to conduct interdisciplinary assessments. The clinical psychologist also consults with other teams within the Mental Health and Addictions Program around Forensic case management and risk assessments. The Residency Program in Pediatric and Child-Adolescent psychology at the IWK Health Centre is both APA- and CPA- approved. The successful candidate will be expected to actively participate in training residents. Candidates with appropriate credentials may be considered for academic adjunct appointment in an appropriate university department at Dalhousie University. Further information about this position can be obtained from Vicky Veitch Wolfe, PhD, Psychology Professional Practice Chief, at 902-470-8458 or vicky.wolfe@iwk.nshealth.ca. Applicants must specify the

competition number and include a copy of his/her curriculum vitae, pertinent scientific publications and three letters of recommendations from professionals attesting to the applicant's clinical training, clinical skills and character. For individuals with less than 3 years of experience, an additional letter must be provided, from the Director of Clinical Training, at the institution where the applicant completed his/her clinical internship.

Qualifications:

- PhD / PsyD in clinical psychology from an accredited university program
- Registered, or eligible to be registered, with the Nova Scotia Board of Examiners in Psychology
- Minimum 5 years of formal training and clinical experience in child/adolescent mental health
- Demonstrated ability to consult with professional and paraprofessional staff
- Demonstrated ability to diagnose and formulate treatment protocols for a wide range of adolescent mental health problems
- Demonstrated ability to effectively consult with other health, social service and education agencies
- Demonstrated knowledge in the area of ecological intervention preferred
- Demonstrated ability to work well as part of an interdisciplinary team required
- Demonstrated excellent verbal and written communication skills required
- Ability to participate in the clinical training activities of the psychology discipline
- Education, experience, or training in the related subspecialty area preferred
- Competencies in other languages an asset; French preferred

Interested parties are asked to submit a current resume including month and year of employment in past positions and a cover letter outlining their qualifications for the role. Please include the competition number, and if you are an employee of the IWK Health Centre, in the subject line of your email or within your cover letter and send to:
Email: Human.Resources@IWK.nshealth.ca (preferred method)
IWK Health Center, Human Resources, 5850/5980 University Avenue, PO Box 9700, Halifax, NS B3K 6R8, Canada; Tel: (902) 470-8012, Fax: (902) 470-6612

International Max Planck Institute for Human Cognitive and Brain Sciences; 15 positions: The Max Planck Institute for Human Cognitive and Brain Sciences in Leipzig, Germany, Department of Social Neuroscience (Director: Prof. Tania Singer), invites applications for group leader, senior researcher, postdoctoral, and PhD student positions in the following fields:
A. Social Neuroscience (social cognition, decision making, neuroplasticity, development)
B. Psychopathology (social cognition in individuals with autism, alexithymia, psychopathy)
C. Psychobiology (stress physiology, biomarkers)
D. Psychology (subjective affect, motivation)
The positions are part of a new interdisciplinary department (to be opened in 2010) that will investigate the foundations of human social behavior and, more specifically, the developmental, neural, and hormonal mechanisms underlying social cognition and social emotions. Most of these positions will be involved in a longitudinal study on the effects of cognitive and affective training on the brain, health, subjective well-being, and behavior. These positions are primarily devoted to research, with no teaching and minimal administrative duties, and will begin no later than September 1, 2010.
Successful candidates for the group leader and the senior researcher positions have research experience as a postdoctoral fellow in one of the above-mentioned fields and show evidence of scholarly promise in the form of publications and other achievements.
- Positions in fields A and B require a background in structural and functional MRI (preferably with SPM, Matlab) and behavioral analyses. Knowledge of other neuroscientific methods (e.g., TMS/tDCS, EEG) would be advantageous.
- Positions in field C require experience in using biological markers (e.g., cortisol assays, stress physiology, genetic markers) in conjunction with neuroimaging paradigms.
- Positions in field D require experience with motivational and social psychological paradigms, and preferably with structural equation modeling (or latent growth modeling of longitudinal data) and event-sampling methods.
The Max Planck Institute in Leipzig (http://www.cbs.mpg.de) offers an international research environment, with English being the language spoken in the laboratory. It brings together a large number of researchers with diverse backgrounds, who are united by their interest in the human brain and methods for its exploration. Moreover, it offers a friendly and generous environment with an excellent infrastructure (e.g., three human 3T and one 7T MRI, rt-fMRI, EEG, TMS/tDCS, MEG, pharmacology laboratory, behavioral laboratory). The Department also has additional laboratory space in Berlin, which is located just an hour by train to the north of Leipzig. For further details, see http://www.cbs.mpg.de/singer or contact Tania Singer (singer@iew.uzh.ch). Applications (including a CV, list of publications, statement of research interests, and contact information of 3 referees) should be sent as a single PDF file, with your name as the file name, to Tania Singer (singer@iew.uzh.ch) and Tamara Herz (therz@access.uzh.ch). Review of applications will begin immediately and continue until the positions are filled. Shortlisted candidates will be invited to meet Tania Singer in Zurich or at the CNS Meeting in Montreal (April 2010) or the HBM Meeting in Barcelona (June 2010).

Germany, Clinical Psychologists: Adult psychologists needed to work with active duty military members and their families in Landstuhl, Germany, on a contract basis. Minimum 1-year commitment, paid relocation, tax incentives, and

paid malpractice insurance. Position includes on-base privileges such as commissary and exchange, gasoline, officers clubs, recreational facilities, etc. Must be licensed in any state, and have completed an APA-accredited internship in clinical or counseling psychology. For more details, send curriculum vitae to Mary Holland at mholland@neshold.com. Fax is (757) 420-6616.

Ben-Guiron University, Department of Psychology: The Psychology Department, Ben-Gurion University, Israel (www.bgu.ac.il/psychology) offers tenure-track positions in clinical, clinical-neuropsychology, and clinical child/infant psychology. Please send description of research agenda, CV, pdfs of representative publications, and email addresses of references to Prof. Nachshon Meiran, nmeiran@bgu.ac.il.

Align Recruitment, Forensic Clinical Psychologist: We have full-time clinical psychologist vacancies to fill for community mental health and other service organizations. You must have a PhD in clinical psychology, current practicing license, minimum of 2 years post-supervisory experience, the ability to receive your New Zealand psychologist registration with clinical scope, and the desire to commit 2 years or longer. E-mail office@alignrecruitment.com; Tel: +64 3 366 8779: Fax: +64 3 377 6770; Web www.alignrecruitment.com. An expatriate American is available to assist with all enquiries.

King Fahd University, Department of General Studies: The Department of General Studies at King Fahd University of Petroleum & Minerals (KFUPM) in Dhahran, Saudi Arabia, invites applications for full-time faculty positions at the rank of assistant/associate professor in psychology. Applicants are expected to hold a PhD degree with a strong commitment to research and teaching as well as serving the university. Applicants are also expected to have superior ability to teach in English (as the language of instruction at KFUPM is English). Candidates with Middle Eastern expertise are strongly encouraged to apply.

Salary and Benefits:

These positions are full-time, 2-year renewable contracts with competitive tax-free salary based on qualifications and experience, free furnished air-conditioned on-campus housing unit with free essential utilities and maintenance. Subject to University policy, the appointment includes the following additional benefits: air ticket/s to Dammam on appointment; annual repatriation air tickets to Dammam for the faculty and up to three of his dependents; tuition fees for school-age dependent children enrolled in local schools; local transportation allowance; 2 months' paid summer vacation, end-of service benefits, and free access to recreation facilities. KFUPM campus has a range of facilities including medical and dental clinic, and teaching and research support facilities, such as extensive library acquisitions and library databases, computing facilities, smart classrooms, and research and teaching laboratories. The campus is within a very short distance from the cities of Dammam and Al-Khobar.

Review of applications will continue until the positions are filled. To apply, send (preferably by e-mail) cover letter, detailed resume, completed KFUPM application form with copies of credentials (academic degrees and transcript/s) and three referees to the following address:

Dean of Faculty & Personnel Affairs, Dept. Ref. No. DGS-PSY-010, KFUPM Box 5005, Dhahran 31261, Saudi Arabia; E-mail: faculty@kfupm.edu.sa or c-gsd@kfupm.edu.sa; Fax: +966-3-860-2429 or 860-2442

To download the KFUPM Application Form, click on the link http://www.kfupm.edu.sa/fpa/serv/InfApplicFacPosi.mht

For more information, please visit the KFUPM web site: http://www.kfupm.edu.sa

Institute of Mental Health, Research Officer: You will be part of a multidisciplinary team conducting translational research in psychiatry. You will be trained in relevant assessments and assess research participants on clinical and neuropsychological scales. You will also be tasked to undertake recruitment and collect data from case-records/patient interviews. You will have opportunities to attend courses and conferences as well as to co-author papers for publications and make presentations at local and overseas scientific meetings.

Duties and Responsibilities:

- Psychological testing and diagnostic assessments
- Subject recruitment
- Data collection and management
- Analyses and reporting of study data
- Completion of appropriate research clinical trainings and engaging in general activities pertaining to the planning and execution of research studies.

Requirements:

- Master's degree in psychology
- Training and experience in conducting psychological testing (neuropsychological testing an asset)
- Strong communication and presentation skills

To apply, email your detailed resume, stating your current and expected salary to:

The Human Resource Department, Institute of Mental Health / Woodbridge Hospital, 10 Buangkok View Singapore 539747; E-mail: careers@imh.com.sg, www.imhresearch.com.sg

Singapore Management University, School of Social Sciences: The School of Social Sciences (SOSS), Singapore Management University, invites applications for tenure-track positions in psychology at the assistant, associate, or full professor rank, to begin in July 2010. Positions are available in cognitive psychology (with focus on judgment and decision making) and industrial/organizational psychology. The positions require a doctorate in psychology by the date of appointment. We are seeking candidates with a demonstrated record of, or high potential of, scholarly research commensurate with the rank and a strong ability or aptitude to teach a wide range of undergraduate and postgraduate courses. The SOSS,

which has a strong record of attracting the best students in Singapore and the region, is committed to an interdisciplinary and integrated undergraduate curriculum. The ideal candidate will have a strong commitment to excellence in research and teaching at both undergraduate and postgraduate levels (the PhD in psychology program will begin with its first student intake in August 2010). A research interest in Singapore and the Asian region will be an advantage. The teaching load is light compared to many research universities. The research support is excellent and salary and benefits are highly competitive.

Full evaluation of applications will start December 1, 2009 and on-campus interviews will typically be conducted in the period from January to March 2010. However, submission of applications is open and evaluation will continue until the positions are filled. Applicants must submit, in electronic form (Word or PDF file), a detailed curriculum vitae, a description of research interest and philosophy, and a statement of teaching interests and philosophy to the following address: socialsciencescv@smu.edu.sg. Applicants should also send hardcopies (if not available in electronic form) of selected publications and teaching evaluations. Applicants should arrange for three confidential letters of recommendation to be sent directly to: The Dean's Office, School of Social Sciences, Singapore Management University, 90 Stamford Road, Level 4, Singapore 178903. Information about the University and the School can be found at www.socsc.smu.edu.sg.

University of Exeter, Department of Psychology: The Department of Psychology at the University of Exeter in the UK is seeking to fill a permanent (equivalent to tenure track) faculty position in clinical psychology, starting in September 2010. The position provides 80-100% dedicated research time for the first 3 years to support the appointee in generating a sustainable externally funded research program. We particularly welcome applications from people who can build on existing strengths in the Mood Disorders Center http://centres.exeter.ac.uk/mood/, and ideally bridging with work on health behavior, primary prevention, health services research, public health, and/or chronic disease (e.g., diabetes, obesity, cardiovascular disease). The Department includes an accredited doctoral clinical psychology program, master's-degree programs in cognitive behavioral therapy and mindfulness-based cognitive therapy, and a clinic that is fully integrated with out research and teaching. The starting salary for Lecturer will be circa £32,000 [US $50,718] per annum on University pay scale Grade F, with progression possible to £38,757 [US $61,427] and for Senior Lecturer will be circa £39,000 [US $61,812] per annum Grade G, progression possible to £52,086 [US $82,552]. For a clinically qualified person a market supplement of currently £11,139 [US $17,655] per annum will also be paid (subject to annual review) in accordance with the University's agreed policy on market supplements. This allowance is pensionable and will be reviewed in August each year. These figures will vary depending upon the exchange rate. The University can offer an excellent range of staff benefits and facilities including final pension salary scheme. Contact Professor Willem Kuyken by e-mail at w.kuyken@exeter.ac.uk or any member of the Mood Disorders Center Faculty. Applicants interested in applying can download an application pack from http://www.admin.ex.ac.uk/personnel/jobs/H80N1931.pdf. The closing date for completed applications is 12 noon February 12, 2010.

Bermuda Hospitals, Child and Adolescent Services: The Bermuda Hospitals Board is an innovative multidisciplinary healthcare system, dedicated to excellence, and committed to patient-centered care. Our supportive environment celebrates diversity in the workplace and places great emphasis on professional and personal development of all our staff. We invite applications for clinical psychologist child and adolescent services. You will be responsible to provide psychological services to individuals and/or groups, evaluate and improve current services and programs, conduct research projects, and consult with other child friendly organizations. An effective communicator, able to work harmoniously in a demanding and diverse environment, you will provide clinical supervision to junior staff and assist with in-service training programs. You have a terminal degree in clinical psychology recognized by country of training as a requirement for independent practice (e.g., master's in UK, doctorate in US), a minimum 4 years post-qualification experience with at least 2 years specializing in child and adolescent services, and the appropriate professional affiliations. Eligible for registration as an independent psychologist under the Bermuda Psychologists Practitioners Act 1998, you have sound knowledge of other local agencies providing services to children and adolescents. Able to work collaboratively with interdisciplinary and multidisciplinary teams, you have excellent interpersonal, organizational, written, and verbal skills. Apply directly online, quoting posting to: www.bermudahospitals.bm. Pre-employment substance abuse screening is mandatory for all successful applicants. Web site: www.bermudahospitals.bm

McGill University, Department of Educational and Counseling Psychology: The Department of Educational and Counseling Psychology (http://www.mcgill.ca/edu-ecp) invites applications for a tenure track position at the assistant, associate or full Professor rank, effective August 1, 2010. Our counseling psychology program offers three degrees: two MA non-thesis programs (internship and research) and a PhD program accredited by the CPA, the APA, and the OPQ (licensing body of psychologists in Quebec). The programs operate from a scientist-practitioner model. Current faculty have expertise in health and wellness; feminism, multiculturalism, and career psychology; and psychotherapy processes and outcomes. We are searching for a candidate with a strong counseling psychology identity whose research and teaching interests are in the areas of career counseling and/or multiculturalism. The successful candidate will have an earned doctorate in counseling psychology or related discipline at the time of appointment, be a licensed or license-eligible psychologist (in Quebec), demonstrate evidence of scholarly

productivity and publication commensurate with rank at a research-intensive university, have demonstrated competence in counseling and teaching, and be able to supervise master's and doctoral students. The ability to liaise with the Quebec licensing body of career counselors (OCCOPPQ) would be an asset. The application deadline is January 15, 2010, or until the position is filled. Persons wishing to be considered for this position should forward a statement of research interests, a statement of teaching philosophy and interests, a curriculum vitae, and samples of research, and arrange to have three letters of recommendation submitted directly to: Professor Alenoush Saroyan, Chair, Department of Educational and Counseling Psychology, McGill University, 3700 McTavish Street, Montreal, Quebec, Canada H3A 1Y2. Electronic submissions are accepted and should be forwarded to: ecp@mcgill.ca. Please enter "Counseling Search" and your name in the subject field.

McGill University, Department of Educational and Counseling Psychology: The Department of Educational Counseling and Psychology (http://www.mcgill.ca/edu-ecp) invites applications for a tenure track position in the learning sciences program at the assistant or associate professor rank, effective August 1, 2010. The successful candidate will have an active program of interdisciplinary research, investigating learning as it happens in real-world settings (schools, workplace and informal settings). Research interests can include, medicine, mathematics and science, computer science, anthropology, sociology, information sciences, neurosciences, and design studies. Applicants should have an earned doctorate in the cognate fields of the learning sciences at the time of appointment, demonstrate evidence of scholarly productivity and publication commensurate with rank at a research-intensive university, and demonstrate competence in teaching and graduate supervision. The successful candidate will be expected to teach at graduate and undergraduate levels and supervise master's and doctoral students. The application deadline is January 15, 2010, or until the position is filled. Persons wishing to be considered for this position should forward a statement of research interests, a statement of teaching philosophy and interests, a curriculum vitae, and samples of research, and arrange to have three letters of recommendation submitted directly to: Professor Alenoush Saroyan, Chair, Department of Educational and Counseling Psychology, McGill University, 3700 McTavish Street, Montreal, Quebec, Canada H3A 1Y2. Electronic submissions are accepted and should be forwarded to: ecp@mcgill.ca. Enter "Learning Sciences Search" and your name in the subject field.

Redeemer University College, Department of Psychology: Redeemer University College invites applications for a tenure-track position (any rank) in any area of experimental psychology, beginning July 1, 2010. We prefer candidates who can teach courses in personality, principles of learning, and social psychology, although applications from candidates with expertise in any area of experimental psychology will be seriously considered. As a liberal arts and sciences university college rooted in the Reformed tradition of Christianity, we seek candidates who are committed to teaching and pursuing scholarship from this perspective. Applicants should possess, or be near completion of, a PhD. Interested applicants should submit a curriculum vitae, three letters of reference, evidence of teaching quality, and a one-page or two-page statement describing their own faith commitment and how it shapes their academic work. The deadline for applications is January 31, 2010, or until the position is filled. Direct general inquiries and applications to: Dr. Jacob P. Ellens, Vice President, Academic, Redeemer University College, 777 Garner Road East, Ancaster, ON L9K 1J4 Canada.
E-mail: jelens@redeemer.ca

Cape Breton District Health Authority, Eating Disorder Clinic: Reporting to the Manager of Emergency & Acute Outpatient Mental Health Services, the psychologist provides assessment and treatment to adult patients aged 19 yrs and older with a variety of mental health disorders. The psychologist will function as a primary therapist within a multidisciplinary team and will be involved in the planning, development and evaluation of treatment for patients utilizing both individual therapy and group treatment models. Development of group treatment programs for adult services is a key component of the position. The successful candidate will have a doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology. He/she must be registered or eligible for registration with the Nova Scotia Board of Examiners in Psychology.

Requirements

- Doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology
- Registered, or eligible for registration with the Nova Scotia Board of Examiners in Psychology
- 5 years clinical experience in an inpatient/outpatient mental health setting, providing independent assessment and treatment of adult mental health disorders
- Specialized expertise in the treatment of eating disorders involving independent assessment, consultation, diagnosis and treatment
- Experience in the development of effective linkages with other health, social service and community agencies as appropriate
- Training or experience in crisis intervention and suicide risk assessment
- Willing to participate in clinical training activities
- Valid driver's license and access to reliable transportation
- Physical ability to perform the duties of the position
- Good attendance and work record

Please send your resume and cover letter to: Kim Dilney, Employment Coordinator, Human Resources Department, Cape Breton District Health Authority, 1482 George Street, Sydney, NS B1P 1P3, Canada; Fax: (902)567-7224

Bremen International Graduate School, Social Sciences: The Bremen International Graduate School of Social Sciences (BIGSSS) invites applications to its PhD and postdoctoral programs. BIGSSS is an inter-university institute of the University of Bremen and Jacobs University, and is funded by the German Excellence Initiative. The program provides close supervision of dissertation work within a demand-tailored education and research framework. BIGSSS is part of an international network of highly acknowledged graduate programs. It supports its doctoral and postdoctoral fellows in achieving early scientific independence and provides funds for the conduct, presentation, and publishing of their research. The language of instruction is English. Successful applicants for the PhD and postdoctoral fellowships will pursue a topic in one or more of BIGSSS' five thematic fields: global integration; integration and diversity in the new Europe; social integration and the welfare state; attitude formation, value change, and intercultural communication; and life-course and lifespan dynamics.

20 PhD stipends/fellowships - BIGSSS seeks candidates with strong academic abilities and a master's degree (or equivalent) in political science, sociology, or psychology. Applicants with a degree in law, economics, or other social science disciplines are also welcome. We offer PhD stipends of € 1250/month for 36 months, contingent on successful completion of each year.

4-6 postdoctoral stipends/fellowships - We seek candidates pursuing English-language publication projects based either on their dissertations (by making findings available to an international audience through a book or journal article) or new research. Postdoctoral stipends of € 1750/month may run for between 6 and 24 months. The competition is open to candidates who have received a doctorate in political science, sociology, psychology, law, economics or other social science disciplines within the last 3 years and to those who can be expected to finish prior to commencing their postdoctoral stay.

PhD fellowships will start September 1, 2010. Postdoctoral fellows may plan their stays to begin later. Non-German students are strongly encouraged to apply. Applications must be submitted online under "Admissions" at www.bigsss-bremen.de until March 15, 2010. More information as well as lists of required application materials can be found at www.bigsss-bremen.de. For additional inquiries, please check the online FAQ and feel free to contact our admissions officer at admissions-officer@bigsss-bremen.de

University of Hong Kong, Department of Psychology: Applications are invited for the appointment as assistant professor in school / educational psychology in the Department of Psychology, from September 1, 2010, or as soon as possible thereafter, on a 3-year fixed-term basis, with the possibility of renewal. Applicants should possess a doctoral degree in school / educational psychology or an equivalent qualification, with relevant work experience, and be eligible for professional practice in school / educational psychology. Knowledge of Chinese community and familiarity with the local community are preferred. Applicants should also have a strong record of research and teaching. The appointee is required to contribute to the teaching and administration of a professional graduate program in school / educational psychology. He/she is also expected to maintain an active research program and will be responsible for teaching both graduate and undergraduate courses, and supervising research. Information about the Department can be obtained at http://www3.hku.hk/psychodp/

Annual salary for an assistant professorship will be in the range of HK$504,480–779,640 (approximately US$1=HK$7.8) (subject to review from time to time at the entire discretion of the University). The appointment will attract a contract-end gratuity and University contribution to a retirement benefits scheme, totaling up to 15% of basic salary, as well as leave, and medical/dental benefits. Housing benefits will also be provided as applicable. At current rates, salaries tax does not exceed 15% of gross income. Further particulars and application forms (152/708) can be obtained at http://www.hku.hk/apptunit/ or from the Appointments Unit (Senior), Human Resource Section, Registry, University of Hong Kong, Hong Kong; Fax: (852) 2540-6735 or 2559 2058; E-mail: senrappt@hku.hk). Review of applications will begin immediately until the post is filled. Candidates who are not contacted within 3 months of the date of their application may consider their application unsuccessful.

Lingnan University, Department of Sociology and Social Policy: Lignan University, a distinctive liberal arts institution in the Hong Kong Special Administrative Region, is committed to the provision of quality education distinguished by the best liberal arts traditions. Adopting a whole-person approach to education, it offers a wide range of honors bachelor's degrees and postgraduate programs up to the doctoral level in the disciplines of arts, business, and social sciences. Lingnan University is fully committed to the pursuit of excellence in both teaching and research. Applications are invited for the following position, which will be tenable from mid-August 2010 or by mutual agreement thereafter:

Assistant Professor:

The Department of Sociology and Social Policy (http://www.LN.edu.hk/socsp/) combines teaching and research in sociology, social policy, and behavioral sciences. It contributes with the Department of Economics and the Department of Political Science to the integrated Social Sciences Program in the University. Applicants are recommended to visit the

departmental web site and program web site (http://www.LN.edu.hk/progs/ssprog/) for more information. The appointee should have a PhD degree in psychology, with particular experience in behavioral science and social psychology. Areas of teaching specialization are open, but willingness to teach in at least two of the following is preferred: Introduction to Behavioral Science, Human Development and Psychology of Adulthood, Exploring Psychology in Western and Chinese Cultures, Positive Psychology, Abnormal Psychology, Stress Management & Life Balance, Environmental Psychology, and Social Psychology. The ability to contribute to introductory courses in research methods and statistics in social sciences will also be an advantage.

Applicants are required to provide information on their research records and evidence of quality teaching. Excellent communication and presentation skills are essential. Administrative experience will be a distinct advantage. The successful appointee is expected to have a strong commitment to teaching excellence and services to the Department and the University community, and to engage actively in quality research and publication. The monthly salary will be around HK$45,300 - HK$71,400 (approximate exchange rate: US$1 = HK$7.8). The remuneration will be commensurate with qualifications and experience. Fringe benefits include annual leave, medical and dental benefits, mandatory provident fund, gratuity, and, if applicable, housing benefits and incoming passage and baggage allowance for the eligible appointee. Appointment will normally be made on an initial fixed-term contract of 3 years, renewable subject to mutual agreement. Applicants are invited to forward their dossier together with a personal data sheet (Form R1), which is obtainable from the University's web site at http://www.ln.edu.hk/hr/application-forms, to the Human Resources Office, Lingnan University, Tuen Mun, Hong Kong by post, by Fax at (852) 2891-5782, or by Email to recruit@LN.edu.hk (as attachment in MS Word format). Applicants should supply at least three names and contact information of referees having the applicant's prior consent to provide reference. Applications will continue to be received until the position is filled, but review of applications will begin in mid-December 2009. The University reserves the right not to fill the post or to fill the post by invitation or by search. Further information on the University and its programs and activities can be found on the University's web site: http://www.LN.edu.hk. Enquiries can be directed to recruit@LN.edu.hk.

Sabanc University, School of Arts and Social Science: Sabanc University, invites applications and/or nominations for a faculty position in social cognitive psychology. The position is open as of September 2010, to mid-career candidates as well as candidates who have recently completed their PhD or are near completion. We seek a scholar with a PhD in psychology, with strong specialization in social cognitive psychology, applied cognitive science, applied decision making with a solid theoretical background. Further specialization in one or more of the following areas is preferred: conflict analysis and resolution, social psychology, political psychology, self and identity, social cognition, naturalistic decision-making, and psychology of education and learning. The successful candidate must have a strong record and potential for top quality scholarly publication, as well as promise of outstanding teaching at both the undergraduate and graduate levels.

Sabanc University is a private, department-free, innovative academic institution. It is strongly committed to interdisciplinary research and teaching both at the undergraduate and graduate levels. To meet this challenge, the School of Arts and Social Sciences is organized around multidisciplinary degree programs including conflict analysis and resolution (MA), cultural studies (BA, MA), economics (BA, MA, PhD), European studies (MA), history (MA, PhD), management (BA), political science (MA, PhD), social and political sciences (BA), Turkish studies (MA), visual arts & communication design (BA, MA), and the Faculty of Management offers degree programs in management (BA), finance (MA), MBA, executive MBA, leaders for industry (a dual degree offered with the Faculty of Engineering and Natural Sciences) and PhD in management and organizations, operations management, and finance. The university admits top-ranking students for its undergraduate programs through a centralized university entrance examination. Faculty members are provided with excellent support, including housing facilities on its modern campus if available or a housing stipend.

Applicants are asked to complete an online application form through the university website (Applicant Tracking System): http://www.sabanciuniv.edu/eng/?aday_calisanlar/akademik_is_basvurulari.html

Additionally, a curriculum vitae, a clear statement of current and planned research and teaching activities, and at least three letters of reference should be sent via email to: Mehmet Bac, Dean, Faculty of Arts and Social Sciences, bac@sabanciuniv.edu with Cc: Inci Ceydeli, Faculty Administrative Manager, inci@sabanciuniv.edu

New York University at Abu Dhabi, Interactive Media and Technology: New York University has established a campus in Abu Dhabi with the ambition to become the leading institution of global higher education in the 21st century. NYU Abu Dhabi invites applications and nominations for one or more tenured or tenure-track positions in digital media design for the Arts and Humanities. We are seeking experienced individuals with an interdisciplinary interest in technology, digital media, and science, i.e., in the theoretical and practical aspects of their interrelation, and a completed doctorate in one of these fields. Specific research interests may range from cinema and film studies and visual culture to the learning sciences and memory and cognition. Preferred candidates will have an active agenda and proven track record of research, publication, and undergraduate teaching.

NYU Abu Dhabi is recruiting faculty of international distinction committed to active research and the finest teaching, to building a pioneering global institution of the highest quality, and to forging an international community of scholars and students. To accomplish these goals, NYU Abu Dhabi is committed to providing outstanding resources and facilities for faculty research and teaching. Alongside its highly selective liberal arts college, NYU Abu Dhabi will create distinctive graduate programs and a world-class institute for advanced research that fosters creative work across the Arts, Humanities, Social Sciences, Sciences, and Engineering. Situated at a new global crossroads, NYU Abu Dhabi has the resources and resolve to become a preeminent center of collaborative intellectual pursuit and impact. NYU New York and NYU Abu Dhabi are integrally connected. The faculties work together, and the campuses form the foundation of a unique global network university, linked to NYU's other study and research sites on five continents. Major research projects and public programs are underway. We have recruited our first cohort of faculty across many disciplines and the first class of students of remarkable potential from across the world will arrive in Fall 2010. The international character of NYUAD is reflected in the global composition of the faculty and the student body as well as the research agenda and curriculum, which have been designed to promote inventiveness, intellectual curiosity, multidisciplinary interest, and intercultural understanding.

The terms of employment are competitive compared to U.S. benchmarks and include housing and educational subsidies for children. Faculty may spend time at NYU in New York and at its other global campuses. The appointment might begin as soon as September 1, 2010, or could be delayed until September 1, 2011.

Review of applications for the positions listed above will begin immediately, with a final deadline of January 31, 2010, for receipt of applications. Applicants need to submit the following documents in PDF format to be considered: curriculum vitae, statement of research and teaching interests, representative publications, and three letters of reference. For more information on the Arts and Humanities searches and for instructions on how to apply, please visit our web site at http://nyuad.nyu.edu/human.resources/open.positions.html. If you have any questions, please Email: nyuad.itp@nyu.edu

Department Chair, International Psychology
The Chicago School of Professional Psychology – Chicago Campus: The Chicago School of Professional Psychology (www.thechicagoschool.edu) is an independent, regionally accredited not-for profit graduate school providing education for careers in psychology and related behavioral and health sciences. The Chairperson of the International Psychology Department is responsible for providing visionary leadership for the academic direction of the department. The Department Chair must be an optimistic, action-oriented leader who will motivate faculty to embrace these values in the classroom and within the institution. Responsibilities include curriculum quality and development, scheduling, preparation for programmatic accreditation, assessment of student learning and program improvement, and supervision of faculty and department administrators.

The International Psychology PhD was launched on line in 2009. The Department Chair is being brought in to lead and grow the campus-based version of the program.

Position Qualifications:

- A doctoral degree in psychology, concentration open, with a license or license eligibility desired.
- Teaching and academic administration at the post-secondary level as well as professional experience is required.
- Extensive international experience in at least one of the following areas is essential: international field work (e.g., Fulbright Scholar; visiting professor); international research including partnering with international scholars and/or collaborating on-site in data design, collection, and publication; international professional association work (e.g., officer with one of the international associations such as International Council of Psychologists).
- Solid people development skills with a focus on providing opportunities for faculty and staff to excel.

Why consider the opportunity?

- Healthy institution in growth mode. It is an exciting time to be a part of the institution. Opportunities are unlimited.
- The International Psychology program is the first of its kind in the US. You will help build and grow the campus-based program.
- Culture. The Chicago School offers a culture of innovation and excellence. It is a fast-paced, fun place to work. Bright, hardworking, ambitious employees are valued and rewarded. TCS was named one of the "best colleges to work for" by The Chronicle of Higher Ed in 2009.

For more information or to apply, contact:
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Computer conferencing as an instructional tool: Exploring student perceptions of use, cognitive and motivational characteristics, and frequency of interaction

Velayo, Richard Soriano, Ph.D.

The University of Michigan, 1993

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by

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"Understanding the human aspects of technological change helps us appreciate how individuals might be affected by the change and how they might react to the change. It also helps us understand the larger social consequences of the change we are attempting. . . it helps to keep us focused on the important aspects of the change -- not the technology itself, but the social inventions we create around the technologies."

- Thomas J. Switzer (1992, p.228)

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To all students and teachers who need not fear technology

... it is actually one of our most helpful allies to learning.

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I hope that my efforts will encourage other instructors to pursue effective and innovative ways to use computer conferencing as a educational tool and provide an impetus for researchers toward the further exploration of the academic potentials of this technology.

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CHAPTER I

INTRODUCTION

Computer-mediated communication, specifically computer conferencing (CC), is an area of particular interest because of the rapid rate at which educational institutions are using it to enhance student learning. CC is a form of computer-mediated communications that allows users to relay information and interact with one another regardless of time and distance between them. A number of descriptive studies (e.g., Budin, 1991; Danowski, 1982; Ferguson, 1977; Hiltz, 1986; Hiltz, Turoff & Johnson, 1985; Phillips, 1983; Rice, 1982; Saunders & Heyl, 1988; Tooey & Wester, 1989) suggest that CC is a satisfactory alternative to face-to-face communication for a variety of communication activities. In particular, CC is regarded as a useful device for the classroom (Hiltz, 1986; Saunders & Heyl, 1988; Smilowitz, Compton, & Flint, 1988; Waggoner, 1992a).

Given the educational implications of CC, the overall purpose of this study was to explore the relationship between the implementation and use of CC technology as an instructional tool and the social-psychological characteristics of the learner (i.e., student) relating to the use of this technology. More specifically, this exploratory research examined students' perceptions of CC use and how these perceptions change over time, analyzed what student cognitive and motivational characteristics are related to perceptions of CC, described the frequency of student interaction based on how CC was introduced and used, and determined student comments and suggestions regarding the academic application of this technology.

CC may encourage further "out-of-classroom" interaction among students and teachers. This technology provides students the ability to communicate beyond the classroom walls and learn from each other. From this perspective, much of the learning in CC is likely to involve some form of collaboration, in which the major objective of the class is to learn from one another -- whether the means of attaining educational goals take the form of an informal class discussion, conducting a class project, or similar means.

Classroom learning, therefore, becomes highly collaborative in that learning occurs as students or groups work together toward a common goal. Collaborative learning as a teaching and learning strategy has gained increasing popularity during the last 20 years. It has been described, used, studied, evaluated, in various classroom settings (e.g., Budin, 1991; Harasim, 1987; Johnson, D. and Johnson, R., 1975, 1986; Slavin, 1985; Waggoner, 1992b).

Nonetheless, there are different ways in which CC may be used as an educational tool. However, this study examined eight classes in Introductory Psychology in which CC was used to supplement classroom instruction. It hopes to add to the growing research on improving the educational applications of technology, CC in particular, by offering recommendations on ways to effectively implement CC as an instructional tool to supplement classroom learning.

What exactly is Computer Conferencing?

Computer conferencing (CC) is a computer-mediated communications medium in which individuals or groups are able to interact with each other, primarily via electronic text, without the relative constraints of having to meet at a specific place and time. Tooey and Wester (1989), described CC as an on-line communications medium which allows participants to exchange ideas and information with other users, regardless of the time of day or the distance between the users. Thus, it is a technological innovation that allows both teachers and learners to be able to interact with each other beyond the confines of the classroom. This technology is rapidly finding its way in many college courses, especially at the postsecondary level of education, as an instructional method used to enhance teaching and learning.

CC systems are quite similar to electronic mail (e-mail) and bulletin board systems (bbs). At the present time, they are all text-based and allow users to communicate with one another, regardless of time and place. However, there are some important distinctions

among these three media. E-mail communication is one-to-one, one-to-a list of users, and possibly responses of participants sent to one. E-mail messages are not normally separated or organized by topic. Readers must sort through their messages. Bulletin boards, however, store notes under topics but do not let users respond and know what is new in each area. Some of the more advanced bulletin board systems, however, have sophisticated built-in CC features.

A CC system is designed from software which resides in a host computer that is accessed by users either with a direct connection, or more often, via a terminal or microcomputer and a modem. The host computer stores the "text" for the conference in a sequence that is relatively similar to a live discussion. Each conference is structured around a specific topic or agenda and appends participants' comments to topics. New participants joining an existing conference for the first time can read other participants' comments and add their own comments to the discussion. The next time they enter the conference, they will be informed of any new discussion and, if so, can go directly to the point where they left off. At any time during the session, the users may go back and review earlier discussions. Users also have the ability to comment on earlier entries or messages, thereby bringing the group's attention to an earlier point in the conversation. The system keeps a record of all messages, such that users can review what has been written. Everything discussed is saved and available for future reference.

Most conferencing systems permit conferences to be one of three types: open, closed, or private. An open conference is one that is open to any participant who wishes to join in the discussion. A closed conference is one in which a user must ask the conference moderator's permission to join. A private conference is the most exclusive of the three because only invited participants are even aware of the conference's existence. This study may apply to any of these three types.

Computer Conferencing: Brief History and Popular Systems

This section aims to provide a brief historical overview of CC and other popular conferencing systems.

In the early 1970s, President Richard Nixon put the United States economy under wage and price controls in an attempt to stem inflation. In deciding which wage or price increases to allow, the government needed to collect and transmit huge amounts of economic information. Thus, the U.S. Office of Emergency Preparedness (OEP) hired a computer scientist to design a computerized communication system that would link the ten OEP regional offices. Called the Emergency Management Information System and Reference Index (EMISARI), it permitted nearly instant dissemination of guidelines, rulings, and official policy statements on wage and price controls (Meeks, 1987). EMISARI eliminated the necessity for most face-to-face meetings or phone calls as well as the delays caused while waiting for data to arrive by mail. Instead, people at any OEP site typed messages on computer terminals which everyone else could read. Questions, replies, and back-up information remained in the system, creating constantly updated economic and policy archives. These abilities --- "many-to-many" communications and message storage ---comprise the essential features of early computer-based conference systems. Many computer conference programs have been written since then, such as COM, EIES, PARTI, NOTEPAD and other systems.

COM was developed by the Swedish National Defense Research Institute in 1977 and has undergone several revisions since then (Meeks, 1987). It operates a gigantic international electronic mailbox and CC system. It has the ability to route electronic messages through a complicated maze of networked computer system around the world and allows participants at different sites to contribute to the conferences without logging on to a remote computer. It operates mostly in academic and research environments.

EIES (Electronic Information Exchange System) is a system with many commands, options, and modifiers developed by Murray Turoff (Meeks, 1985). It allows participants

to create commands which can be renamed to one's liking. It is a curious mix of technical, academic, and "nonsense" conferences with an extremely wide range of topics.

PARTI (Participate Conferencing system), offered by Participation Systems Incorporated, is primarily a conferencing system for the masses and was developed by C. H. Stevens (Meeks, 1985). Conferences within the system are organized into branches or subtopics, and conferences are relatively easy to organize. It also allows users to help in the system's ongoing development by offering suggestions. It lets a user operate a flexible range of on-line tools such as a private, person-to-person message system, searching a conference by keyword or phrase, on-line balloting, and a person-to-person real-time messaging capability. It also has the ability to create open or closed conferences which gives the conference organizer the ability to tailor the membership of any conference to his or her specifications. However, PARTI has so many features that they may remain unknown to a user unless a manual is available.

NOTEPAD is a stripped down, easy-to-use, no-nonsense business tool that feels less powerful than other conferencing systems because of its simple features and commands (Meeks, 1985). It provides a combination of real-time and stored message conferencing to build the contents of a message base. It allows a user to create a survey, compile the results, and send them to the rest of the conference members. Conference contents can be searched by keywords or phrases, time, dates, or person. It is considered very user-friendly.

Other popular conferencing systems are eForum (basically a user-friendly system for business-related issues), CoSy (focuses on academic issues), and GENIE (largely for the scientific and engineering field).

CONFER II (also called "CONFER"), the conferencing system examined in this study, was developed by Robert Parnes (Meeks, 1985) and is used largely by students, faculty, and staff at the University of Michigan. Its conferences are organized into major topics of discussion called "items." Each item relates to the general conference theme and

comments on particular items are logged as "responses" which are short, concise points of view or pieces of additional information relating to an item. Zinn (1977) investigated the use of CONFER (term used to refer to "computer conferencing" at the University of Michigan, Ann Arbor). His paper described hardware and software for information systems at the University of Michigan, the development of CONFER, and a rationale for computer-aided communication within professional communities. He proposed that computer-based communications would extend the benefits of a face-to-face conference in quite interesting and useful ways. CONFER has been used in a number of advanced seminars and shows promise in a wide variety of teaching situations. At the present time, there is widespread educational uses of CONFER in a variety of courses at the University of Michigan.

Although CONFER was the conferencing system used by the participants of this study, it will nonetheless be referred to as CC (i.e., computer conferencing). Furthermore, this study is less concerned with the differences between CC systems than it is in their use as an instructional tool given their general common features.

A brief description of the general capabilities and uses of CONFER is presented later in this chapter.

Review of Related Literature on Computer Conferencing

There are a number of studies on the use of CC. Some of the most accessible primary works in this area are articles by Hiltz (1978a, 1978b), Hiltz and Turoff (1978, 1980), Turoff (1978), all of which provided the first major text on all aspects of CC, and by Johansen (1977), which has provided an organized and succinct review of teleconferencing media comparisons, and Waggoner (1992a) which discusses some of the unique applications that have been developed in education. Waggoner (1992b) also provides a comprehensive discussion, as well as suggestions, on CC use in educational settings. A comprehensive and influential review on research about the effects of

noncomputer-based teleconferencing media was written by Short, Williams, and Christie. (1976). Other useful studies are those by Ferguson (1977), Hiltz, Turoff, and Johnson, (1985), Kiesler, Siegel, and McGuire (1984), Rice (1980), and Saunders and Heyl (1988).

The literature reviewed in this paper focused on CC in general without reference to a specific type of CC system. The findings provide an overview of the relevant aspects that have motivated this study. They are categorized in terms of attitudes and use, medium of communication, and group decision-making. These categories are also deemed important in providing a survey of several measures that describe and evaluate CC use, as well as the benefits and drawbacks experienced by its users.

Computer Conferencing: Attitudes and Use.

In view of the use and acceptance of CC, not all potential "users" actually use a computer-based conferencing system much. Difficult access to a terminal, lack of basic computer knowledge, or other professional activities with higher priority can be very significant reasons for limited use (Hiltz, 1978b; Johansen, Vallee, Spangler, & Shirts, 1977; Rice, 1980). A common objection, the necessity of typing skills, does not seem to be a major factor (Chapanis, 1975; Johansen et al., 1977), at least after the beginning period of learning conferencing. Apparently most of the user's time is spent on non-typing activities and combines slow typing with mental composition. The concern for cost of use and difficulties relating to typing skills do not seem to be very important factors in acceptance. Social and work relationships, and other contextual factors such as conflict resolution and authority in an organizational usage setting, are the major factors that impact acceptance and use (Hiltz, Turoff, & Johnson, 1985; Shulman and Steinman, 1978).

With regard to pattern of use, there seems to be stages in acquiring computer conferencing facility: (1) culture shock, learning the commands, loss of interpersonal cues, new social dynamics, (2) ability to use basic commands, (3) push toward sociability, introduction of new cues and group norms, (4) serious use, perhaps dependence/addiction (Hiltz, 1978b, 1986; Hiltz & Turoff, 1978; Rice, 1980; Turoff, 1978). In the beginning,

entries are generally longer (Johansen et al., 1977) and in the form of private messages. At the second learning level, a preference for group conferencing develops; at very high usage levels, users tend to return to messaging and to using private messages (Hiltz & Turoff, 1980; Turoff, 1978). Irving (1978) reported initial rises to high activity followed by a decrease and then leveling off to the end of a 9-month pilot use. It was also found that experienced users evaluate asynchronous conferencing (i.e., nonreal time communication) more favorably than do new users. Moreover, communication links among users tend to become more dense with use (Hiltz & Turoff, 1978). In general, with increased hours of CC use, items per session increase (from four to six), session length increases (from 15 to 40 minutes), the number of conference comments rises, then falls (Hiltz & Turoff, 1980), and the number of words per session may increase (Infomedia, 1979).

Although there is a high correlation between the number of private and group messages one sends (Johansen, DeGrasse, & Wilson, 1978), these modes appear to be distinct, being preferred differentially as users gain experience. On average, group or public messages are 150 percent longer and have four times the received/sent ratio than private messages. Even several conference types have distinct received/sent ratios (Hiltz, 1986; Hiltz & Turoff, 1978; Johansen et al., 1978). The amount of conversation or conferencing increases in a CC environment, and increased amount of conversation is generated by messages directed to individuals (Hiltz, 1986; Hiltz & Turoff, 1978, 1980). Direct messages seem to receive slightly more responses.

Not surprisingly, but importantly, users' attitude to such systems change with use. Satisfaction increases, sense of tediousness decreases, and impersonality of work environment decreases with increasing usage (Conrath & Bair, 1974; Hiltz, 1978b, 1982, 1986; Irving, 1978; Johansen et al., 1978; Rice, 1980). It may be that the users view computer-mediated conferences as simple substitutes for familiar messaging media (such as a letter or a meeting), but develop an understanding that CC has its own advantages, uses, and constraints (Hiltz, 1978b, 1986). With increased usage, perceived usefulness of

features that facilitate long-term group communication, active control, tailoring of the system, and composition also increase (Hiltz, 1986; Hiltz & Turoff, 1980). In addition, users seem to need a "real" task to motivate use and favorable perception (Hiltz, 1978b, 1986). Hiltz and Turoff (1980) suggested that those who implement the use of CC should allow longitudinal development of system design because user behavior evolves and simple message systems become insufficient for regular, experienced users (Hiltz and Turoff, 1980). Regular application should see CC as a different but complementary medium.

Saunders and Heyl (1988) conducted a study involving a nontraditional, graduate level, professional health care program. Six faculty members and 25 students geographically dispersed throughout the United States and Canada, who are full-time clinicians or managers of health care facilities, responded to questionnaires after the first year and a half of classes. Results showed that CC was evaluated as most appropriate for giving and receiving directions, exchanging and requesting information, showing (dis)agreement, exchanging opinions, and requesting suggestions. The courses rated as most appropriate for CC included comments based on course content oriented toward exchange of ideas, rapid feedback, instructor's summary, and overview of material. The study also pointed out the importance of noting individual student comments and expanding on the points they made. Student concerns were difficulty in following course discussions, time commitments in using CC, and anxiety about using the computer. Some suggestions for future use of CC were to solicit background in computer use, tailor training to fit level of experience, anticipate extensive training requirements, test students on basic knowledge about signing on and off and using various components of system on-site, and stress time requirements in recruitment literature.

There have also been studies done on computer anxiety as it relates to frequency of use. Although computer experience alone may not necessarily be a solution to computer anxiety (Rosen & Maguire, 1990), some evidence suggest that computer anxiety could decrease with more structured computer use (Cambre & Cook, 1987; Lambert & Lenthall,

1989). In a study of traditional versus electronic mode of communication among undergraduate students and their teachers in a writing course, computer anxiety was found to be a negative predictor of the frequency of electronic teacher-student interaction. Computer anxiety was also negatively related to frequency of more traditional type of interaction like writing (Hartman, Neuwirth, Kiesler, Sproull, Cochran, Palmquist, & Zubrow, 1991). In contrast, Harris et al. (1992) found no significant relationship between a student's initial level of computer anxiety and the frequency of using telecomputing resources. Nonetheless, it is wise to be cognizant of the possible negative effects of computer anxiety. Further research, therefore, is needed to determine whether the use of computer-mediated communication generally cause significant change in computer anxiety and/or writing apprehension. Such research should specify the methods and contexts in which these changes may occur. Nonetheless, the application of CC should take these into consideration in view of preparing students for CC use and system implementation.

Moreover, Hartman et al. (1991), in a study of the effects of computer network technologies on student-student and teacher-student interactions in a composition course, showed that writing apprehension was inversely correlated to frequency of teacher-student interaction in both the electronic communication and the traditional instruction modes, although the relationship was weaker for electronic communications. Mabrito (1991), in a study of low-apprehensive and high-apprehensive freshmen writers, found that students who were highly apprehensive exhibited different strategies than those students who have low apprehension both face-to-face and e-mail sessions. Those with high levels of writing apprehension also participated more frequently in electronic writing revision sessions than in face-to-face sessions. Thus, in view of CC learning contexts, much more can be learned about the relationship between level of writing apprehension and the acceptance and participation of electronic tools for which writing is a necessary form of communication.

In summary, the factors concerning the lack of acceptance and use of CC as a learning tool include accessibility of computers, a user's level of basic CC knowledge,

absence of social cues, time commitment, the relative novelty of the technology, writing apprehension, and possibly computer anxiety. With increased use however, the participants' sense of satisfaction increased, and the feeling of tediousness and impersonality initially perceived about the CC environment eventually decreased. Participants deemed that CC is most appropriate in courses that foster efficient exchange of ideas and rapid feedback, and those that provide instructor summary and overview of material.

Computer Conferencing as a Medium of Communication.

As far as user participation is concerned, studies show that communication through CC can be about twice the level of face-to-face interaction (for a group of about 12 people) (Hiltz & Turoff, 1977, 1982, 1986). Because of the multiplicative effect of using a messaging system with a number of users, the number of characters passing through a user's account may be several times greater than possible through continuous typing to separate individuals (Irving, 1978; Vallee, 1976).

CC also reduces the inequality of participation usually presented in other forms of group interaction (Hiltz, 1978b; Hiltz & Turoff, 1978; Johansen, 1977). Thus, more reserved group members may finally gain access to discussions and decision-making, while any one individual may have a harder time monopolizing the group's attention. In fact, the emergence of group leaders is different, and simply less likely, in CC.

There are interactions which do not demand high interpersonal involvement and may be typified as cooperative in nature. CC is not nearly as satisfactory as face-to-face or video for bargaining, resolving disagreements, getting to know someone, and tasks requiring constant focused discussion (Hiltz, Johnson, & Turoff, 1986; Williams, 1977). However, for very embarrassing or conflicting interactions, CC may be the medium of choice precisely because it minimizes the interpersonal dimension. The earlier point regarding changing attitudes with increasing use holds here as well. New users generally rate face-to-face higher on all group processes or tasks, while experienced users develop

the ability to discriminate the appropriate uses listed above. Also intriguing is that users feel more confident in their perceptions gained from face-to-face meetings than by CC, but these face-to-face meetings are in fact not more accurate (and sometimes less so) (Short et al., 1976). Nonetheless, the precise ways in which CC can be expected to differ from face-to-face interaction remain inconclusive primarily because research in the area is still sparse. The form of CC communication is (presently) written text, whether by CRT or printer. Written material in CC can be more effective for the communication of factual information than face-to-face, perhaps because of its preciseness and the greater comprehension gained from rereading text without pressure to overcome response latency.

Many opponents of CC emphasize its loss of nonverbal communication and social presence (Rice, 1980). Certainly, CC does not typically allow cues for nonverbal feelings, intentions, physical relationships, and the like. Immediate feedback is usually missing, and public or rhetorical questions often go unanswered. However, synchronous conferencing does allow immediate response, and personal cues often appear in new forms, while direct questions are almost always answered --- even when addressed to strangers (Johansen, 1977; Kiesler et al., 1984). The absence of visual and nonverbal cues may be an advantage to some users --- those with visual or speech handicaps and those usually intimidated by turn-taking conventions or rapid cross-fire. However, there are cases where the loss of such cues, mixed with rapid responses in synchronous mode, led to escalated misunderstanding (Uhlig, 1977). For those who object to delayed response, there are those who appreciate the break from eye contact so they can compose a thoughtful response (Hiltz & Turoff, 1978). The face-to-face channel, when compared to CC (Hiltz, 1986; Johansen, 1977), does allow or provide increased bandwidth and information types, more variance in message length, more questions, interruptions, ability to digress and lose thread, and quicker adjustment to changes in interaction.

In a study by Ferguson (1977), 20 people engaged in a wide variety of research projects on higher education and found that more private messages than public messages

were sent via CC. It was also found that the total number of messages sent increased at a relatively proportional rate from the beginning of the conference to the end, with a slight lag in public messages in the middle of the conference which was accounted for by the fact that the participants were precluded from activity at that time. No one person dominated the discussions, participation was fairly evenly distributed throughout the conference, and 36% of all messages were sent after normal work hours (i.e., 9 a.m. to 5 p.m.). The results of the questionnaire administered to the participants showed that most participants were sometimes frustrated with the conference but seldom bored and confused. They perceived high ability to express ideas completely but felt overloaded with information. They felt that CC encouraged imagination, creative thinking, and cooperation but had little effect on consensus. CC provided them the opportunity for information exchange, development of alternatives, identification of important areas of discussion and specific information. Much discontent with the conference was with subject matter and not the conference logistics. Where participation was highest, there was least frustration and discontent. Participants with the highest number of private messages were least likely to claim that there was little personal contact. In comparison to face-to-face conferences, conference users were glad that the conference took place in addition to normal work activities, without "travel" expenses. They found it to be an enjoyably unique experience and enjoyed the added opportunity for information exchange. The paper concluded that CC can be an effective tool to share ideas independent of time and space, more training time would ease apprehensions, more real time or synchronous conferencing would help keep discussions in focus, and finally, it can be extremely precise for information exchange. As participants become more comfortable with the medium, discontent diminishes remarkably.

Using a typology of group activities developed by Short et al. (1976), several researchers have arrived at very similar conclusions about the appropriate communicative uses for CC. In general, CC is at least as good as, and sometime better than, face-to-face (in some experiments, video) for the following tasks: (1) exchanging information

(especially technical), (2) asking questions, (3) exchanging opinions or orders, (4) staying in touch, (5) generating ideas (Hiltz, 1986; Hiltz & Turoff, 1978; Infomedia, 1979; Johansen et al., 1978; Rice, 1980; Short et al., 1976; Williams, 1977).

In summary, the strengths of CC pointed out were as follows --- (1) It may be an efficient way of communicating factual information to many people; (2) It reduces inequality of participation; (3) As a written text, it renders greater precision and comprehension among users; (4) It is especially good for embarassing or conflicting interactions because of its less interpersonal nature than face-to-face interaction; (5) In CC, direct questions, even from strangers, often get answered; (6) The lack of verbal and social cues can be an advantage to those with speech, visual, or mental handicaps and those intimidated by turn-taking conventions and rapid crossfire; and (7) The use of CC generally increases from beginning to the end of the conferencing period.

Computer Conferencing: Group Decision Making.

A considerable amount of research examined group decision processes through the use of CC. Using small groups given simple or complex group decisions tasks, researchers have attempted to compare the effects of different communication media (usually face-to-face versus CC). In general, CC groups take longer to reach agreement (Hiltz, 1978b; Hiltz, Johnson, & Turoff, 1986; Johansen, 1977). Perhaps because fewer items are exchanged, group problems are injected into the task, or a leader is less likely to emerge quickly, if at all. There may be less consensus in CC groups for complex problems or human-relations-oriented problems (Hiltz, 1978b, 1986). For reasons of group coordination, mentioned earlier, it seems that unstructured problems require a stronger leader, which CC suppresses somewhat.

Moreover, a body of literature on the effects of CC on individuals' judgments is also beginning to accumulate. A consistent claim in the literature is that since the physical presence of others is excluded, individuals may be expected to be less inhibited and more task-oriented in face to face situations (Hiltz, Johnson, & Turoff, 1986).

One of the expected consequences of the task orientation of CC is that participants feel less group belongingness. The reasoning behind this proposition is that the impersonal nature of CC group processes results in participants identifying less with the group than they would in face-to-face situations. The assumption is supported by the literature that suggests that CC is less friendly or less socially oriented than face-to-face interaction (Chapanis, 1975; Danowski, 1982; Hiemstra, 1982; Hiltz, 1975; Hiltz, Johnson, & Turoff, 1986; Phillips, 1983).

The literature also point out that it is much easier for a group member to hold out against the other members of the group. There is less certain evidence for this claim because the research has only tangentially examined the social pressures of CC. Hiltz, Johnson, and Mathews (1978) allude to the absence of nonverbal behaviors as a basis for expecting positions to be held more strongly. Kiesler, Siegel, and McGuire (1984) argue for less social pressure in CC because of the increased occurrences of uninhibited behaviors. For Kiesler et al. (1984), uninhibited behavior is defined as the frequency of flaming comments (i.e., utterances in which there is swearing, insults, name calling, or other statements that appear hostile). Kiesler et al. concluded that the increases in uninhibited comments indicate decreases in social pressure and thus individual members can be expected to make more independent judgments. Flaming comments, however, are not a direct nor adequate measure of the willingness of group members to succumb to group pressures. Hiltz, Turoff, and Johnson (1985) also examined flaming comments. Their research reported a very low level of uninhibited behaviors in computer conferences of middle-managers, but nevertheless a high degree of independence.

The difference between the findings of Kiesler et al. (1984) and those of Hiltz et al. (1985) suggests that "flaming comments" have different consequences for different groups. The differences result from each group's own normative structure. The subjects of the Kiesler et al. (1985) study may have had cultural norms that sanctioned flaming comments when communicating via computers, whereas Hiltz et al. (1984) studied individuals who

may have had cultural norms against such behaviors in any context. Different groups develop their own different rules by which hostile comments and deviant behaviors are used and understood by the members (Fisher, 1980). If the group has norms which approve the presence of such comments, then their presence does little to affect their selection of solutions. If group norms disapprove of such behaviors, then their occurrence can be expected to be minimal. Individuals who persist with their flaming comments may be regarded as deviant and excluded from the discussion. Both conditions, therefore, result in flaming comments having little impact on the group's decision processes.

The presence of a group exerting social influence affect an individual's critical judgments. If, as Chapanis (1975) claimed, CC is more egalitarian than face-to-face interaction, it follows that in CC, there would be less pressure to conform since participation is more equalized among all group members.

Further reason to anticipate less pressure to conform comes from Hiltz's (1975) hypothesis that the remoteness and impersonality of CC would allow participants to feel free to express disagreement or suggest potentially unpopular ideas. Hiltz's position may account for Ferguson's (1977) observation that group members are able to express their ideas more completely. Both positions indicate the role of social influence on making individual judgments.

Smilowitz (1988) conducted a study of college freshmen and sophomores which demonstrated that subjects tend to be explicit about their own opinions regarding a certain topic/issue. They are more critical of the information they receive because they can read the textual message and take as much time as they need. The critical evaluation of messages which are too discrepant may result in attributions of a failure in the CC network, or mistyped information, rather than the messages being perceived as actually representing the intent of the sender. It was also indicated that removing the physical presence of others diminishes the influence that a unanimous majority has on the opinions of an individual.

The results further imply that in the conferencing environment, subjects may be more critical and more willing to evaluate the information they are receiving.

The most obvious implication for CC group communication echoes Hiltz's (1975) position: It is easier for a deviant to persist in the conferencing environment. Since the effect of the majority opinion is diminished, individuals with deviant opinions are more likely to hold out rather than succumb. As pointed out by Fisher (1980), the deviant is important to group functioning in a number of ways, and therefore fewer constraints on deviants might be a positive outcome in some situations of using CC groups.

It may be premature to think that these features of CC necessarily improve group decision making without further study. Because of the limited capacity of CC to effectively incorporate the richness of traditional group processes, CC may be minimally useful to group decision making and perhaps a potential interference. Factors such as social validation, commitment to the choices made by the group, communication styles among the participants and substantive conflict may depend upon the quality of interaction possible only in more immediate contexts. The mode of communication in CC is, after all, primarily writing.

In summary, groups in CC usually take longer to reach agreement, do not observe the emergence of one leader, are more task-oriented and more egalitarian. In these groups, individuals are likely to be less inhibited. Individuals are also less likely to conform if their views differ from that of the group. Although most users have less sense of group belongingness, they rated CC as an effective tool to share ideas regardless of time or space in view of exchange of information, exchange of opinions, asking questions, staying in touch, generating ideas, and showing (dis)agreement.

The literature on CC relays its potential not only as an alternative means of communication, but as an instructional tool to supplement classroom learning. The studies reviewed provide teachers with relevant knowledge of important factors and issues to

consider in setting up a conferencing system to supplement instruction. This study, however, took a more "learner-focused" perspective by determining student perceptions toward CC use and what cognitive and motivational factors are correlated in the shaping of these perceptions. It also examined the various characteristics by which CC was implemented in eight Introductory Psychology classes in view of frequency of interaction among students, and student comments and suggestions on improving CC use. Thus, the findings of this study hopes to add to the growing literature on computer-mediated learning.

Moreover, as shown later on in this chapter, a conceptual framework was developed in order to provide a theoretical base for this study.

The Development of CONFER at the University of Michigan

CONFER II was constructed in March of 1975 for experiments with computer-based conferencing on the University of Michigan computer system (i.e., Michigan Terminal System). The two motivating forces were (1) research on University governance, for example, a need for computer assistance with communication among members of a committee and with their constituents, and (2) research on information systems in teaching and learning, for example, a need for more effective communication, organization, and reporting of information in seminars, students projects, and curriculum planning (Zinn, Parnes, & Hench, 1976).

Robert Parnes, a research scientist at the University of Michigan, created CONFER II in the mid-1970s that runs on the University of Michigan mainframe computer. Today, CONFER is used widely at the university to support many classes, to hold "electronic meetings" among faculty and staff, and for communication among members of special interest groups (Tainter, 1990). The Center for Research on Learning and Teaching (CRLT) at the University of Michigan was one of the first places to promote the use of computer conferences for academic communication. CRLT's efforts date back more than

17 years. Today, the University of Michigan continues to be a center of computer activity, where software called CONFER II (a registered trademark of Advertel Communications Systems, Inc.) makes electronic discussions possible. (Tainter, 1990).

CONFER, programmed in FORTRAN, relies heavily on the system subroutines of MTS (Michigan Terminal System) in a way which greatly reduces the cost and raises the reliability of operation. CONFER is available to users whenever MTS is available. Improvements to the system are continuously being done and the University supports projects to enhance its presentation and use.

CONFERencing at the University of Michigan

CC, often referred to as CONFER among students, faculty, and staff at the University of Michigan, has been put to many different uses. Some are restricted to the members of a college or a university committee, while others are open to anyone in the campus community. CONFER has been used in various courses including literature and composition classes in which students use their conference to test ideas for essays, describe proposals, and receive comments from other class members. It may be used as an organizational tool, providing a way to distribute information about the class to students. It also gives small groups of students a way to communicate with one another on a class project they must complete during the semester. It may also be used for polling, and participants may be able to offer explanations for their choices. The conference also helps elicit discussions related to course readings that might not otherwise get started, such as topics about racism, anti-semitism, and homophobia. CONFER may also be used for role-playing simulations and other computer-based exercises. CONFER also opens the instructor to all sorts of opportunities that he or she might not otherwise get because it increases the amount of contact with students. Also, everyone sees what everyone says, unless the student and instructor choose to keep their exchange private. Participants can all "talk" at once, removing the boundaries of time and space.

A CONFER session begins with the user signing on to the mainframe from a personal computer linked in one of several ways to the campus network and giving the appropriate command to start the conferencing program. The first information CONFER shows each time a user enters a conference is tell the user about any new entries registered since the last time that user entered that same conference. These new entries may be in the form of "items" and/or "responses". An item puts forth an idea or question for all conference participants to consider, usually in a sentence or two, although these opening statements are sometimes much longer. Any participant can initiate a discussion by entering an item. In the responses, conference participants continue the discussion. As in face-to-face discussions, responses may include questions asking for clarification and other comments. But the computer conference differs in several ways from face-to-face meeting. For example, there is no "waiting your turn." Any participant/user can respond immediately without needing a moderator's acknowledgment and without interruptions. One can take as much time to compose a response, go over it once finished, and edit it before submitting it for other participants to see. Also, many discussions can take place at the same time through different items and their responses.

Conference participants are not forced to enter a response to each discussion, however. They can simply pass over the discussion, perhaps to respond some other time. If the topic is no longer of interest, a user can even give a command to "forget" the discussion, and CONFER will stop showing the item or any of its responses.

CONFER can also broadcast notices which are called "bulletins." Bulletins can be sent to all members of a certain conference, informing them of activities or pieces of information. Similarly, a user can send himself/herself personal bulletins called "notes" to remember important dates or activities scheduled in advance. Private correspondence is handled through the sending of messages which functions like a standard e-mail system.

CONFER is a fairly sophisticated conferencing program with several more features but only the more frequently used and important ones pertinent to typical classroom conferences were mentioned in this section.

Evaluation of the Literature: Educational Potential of Computer Conferencing

This study has so far provided a review of relevant literature on computer conferencing (CC) and some empirical research on its use and impacts. There are certainly pros and cons to the use of CC. Nonetheless, the growing use of this technology warrants considerable attention. Indeed, it can be used to educate. The educational potentials of CC is rapidly being realized because of its many features. Looking for ways to maximize its potential must therefore be explored.

CC primarily facilitates communication from one person to many others. It loosens the time constraints placed on face-to-face conversation and keeps a record of all participants' comments, so users can join a "conversation" when convenient. A computer conference allows users to take part in many conversations at the same time or just eavesdrop. Some users regularly initiate new discussions and others poll participants for their opinions (Tainter, 1990). Nonetheless, the use of CC as a communication tool is still evolving and an important promising application focuses on how it can be used for instruction.

CC offers revolutionary capabilities not available in traditional educational approaches. Students who live or work in remote locations can participate in classes using CC, and experts at different locations can be available to instruct. Overall, participation among students can be increased, since it becomes more difficult for a strong personality to dominate the discussion. More rational and better developed discussions, increased interaction among students (Welsh, 1982), and willingness to request assistance via CC than face-to-face encounters have all been reported by organizers of CC systems (e.g.,

Saunders & Heyl, 1988). In addition, CC may also have the enormous potential for exposing the classroom to many points of view. It may be a valuable tool for extending the classroom and promoting meaningful communication for other groups of people with common interests.

These advantages, however, may be offset by disadvantages inherent in limitations of the media and/or unfavorable attitudinal or psychological responses. CC allows limited visual and audio communication. Feedback may be delayed or never provided. Its use may prove frustrating if an inquiry remains unanswered because the instructor or student is sick, traveling, or otherwise unable or unwilling to respond. There may also be psychological drawbacks to using CC. Participants may fear using unfamiliar technology, feel isolated from other conference participants, or feel driven by the system. For instance, they may often feel the need to respond to questions from others or find an overwhelming number of entries after several days absence from the system. There is also the probable occurrence of insensitive or harassing language in conferences, and the absence of non-verbal signals such as body language or tone of voice that reveal a participant's intentions. Furthermore, CC discussions oftentimes express counter-cultural, anti-establishment views (Tainter, 1990). The language used is very often glib, joking, and sarcastic. Nonetheless, the effects of these possible limitations may be minimized with careful implementation in the classroom. The numerous and valuable advantages of CC warrant further exploration as a tool for learning and teaching.

Because of the unique features and capabilities inherent in CC, this technology allows learning activities that often take place inside the classroom, particularly class discussions, to go beyond the confines of the classroom walls. It offers the opportunity for "out-of-classroom" learning and provides an extension of interactive communication among students and teacher. Thus, the application of this technology may benefit from a conceptual framework of instruction that include important constructs of the teaching-learning process.

A Conceptual Framework Incorporating Technology of CC in the Teaching-Learning Process

In order to provide a theoretical base for this study, a conceptual framework that incorporates the learner into the CC environment has been developed. Though it is not the purpose of the study to specifically analyze the strength and direction of the relationships among the components in such framework, it did allow the author to focus on certain constructs (e.g., student cognitive and motivational characteristics, instructional tasks and methods) deemed important in characterizing the social-cognitive nature of academic learning. Furthermore, it also served as a useful guide in developing suggestions for instruction given the characteristics of the students, the tasks, and the instructional methods involved with particular emphasis on the use of technology (i.e., CC). In addition, it may provide teachers with a theory of instruction to assist them in the implementation and use of technology (e.g., CC).

This integrated framework, derived from two learning models by McKeachie, Pintrich, Lin, Smith, and Sharma (1986) and by Chirwa (1992) (See Figures 1 and 2, respectively), aims to provide instructors and organizers of CC with a foundation for structuring instruction, create a more effective CC environment, develop a philosophy of learning, and develop instructional theory. In addition, it is hoped that this proposed framework can serve as an impetus from which the use of CC as an instructional tool may be further developed.

McKeachie, Pintrich, Lin, Smith, and Sharma (1986) proposed a cognitive model, with a social-cognitive approach to college teaching and learning (Figure 1). It focuses on the process-product relationships between teaching behavior and student learning. This model heavily focuses on students' thinking, motivation, and feelings. Furthermore, the model is also concerned with how teaching affects student thinking and motivation and, in turn, how it affects academic performance / achievement. McKeachie et al. (1986) pointed out that this framework or approach to looking at the dynamics of college classroom

learning allows us to examine various patterns of student motivation and cognition that mediate instructional activities in the classroom. The instructional method component provides a theoretical perspective on how CC may effect student cognition, motivation, and perceptions of its use. McKeachie et al. (1986) provided a detailed description of each component of the model.

In addition, Chirwa (1992) proposed a conceptual model for incorporating the learner into the technology environment (ILTE) (Figure 2) . The major constructs of the model are the student, the teacher, human wants and needs as influenced by society, and technology. The stability of the relations within the technology environment are maintained by these structural components. Although there are descriptions of Chirwa's model that explain its dynamics, these were not considered in developing the proposed framework for CC use primarily because of its more macro level approach in depicting the transfer of information and the dynamics among the various components of the technology environment.

The proposed framework for CC use offers a more "classroom-specific", student-centered, social-cognitive look at the relationships among the constructs presented (Figure 3). Nonetheless, it takes into account important constructs of the models presented by Chirwa (1992) and McKeachie et al. (1986), although it specifically addresses CC as an instructional tool for learning. However, in contrast to Chirwa's (1992) model which focused on incorporating the learner into the technology environment, the model shown in Figure 1 incorporates technology to suit classroom instruction and the student. In addition, there is particular emphasis placed on the "teacher" constuct, which is viewed as possessing the ability to instigate changes in the classroom by restructuring and redesigning instructional tasks, methods, and the use of CC to enhance student learning and motivation.

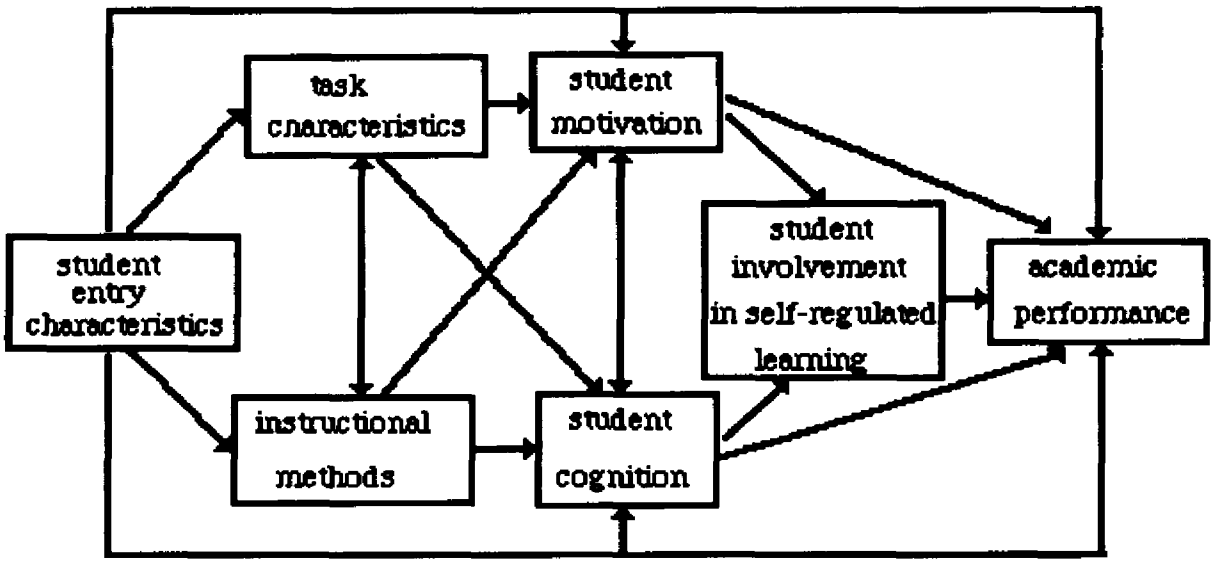

Figure 1. General Model of College Teaching and Learning (General Model of College Teaching and Learning (McKeachie, Pintrich, Lin, Smith, and Sharma, 1986, p. 3)

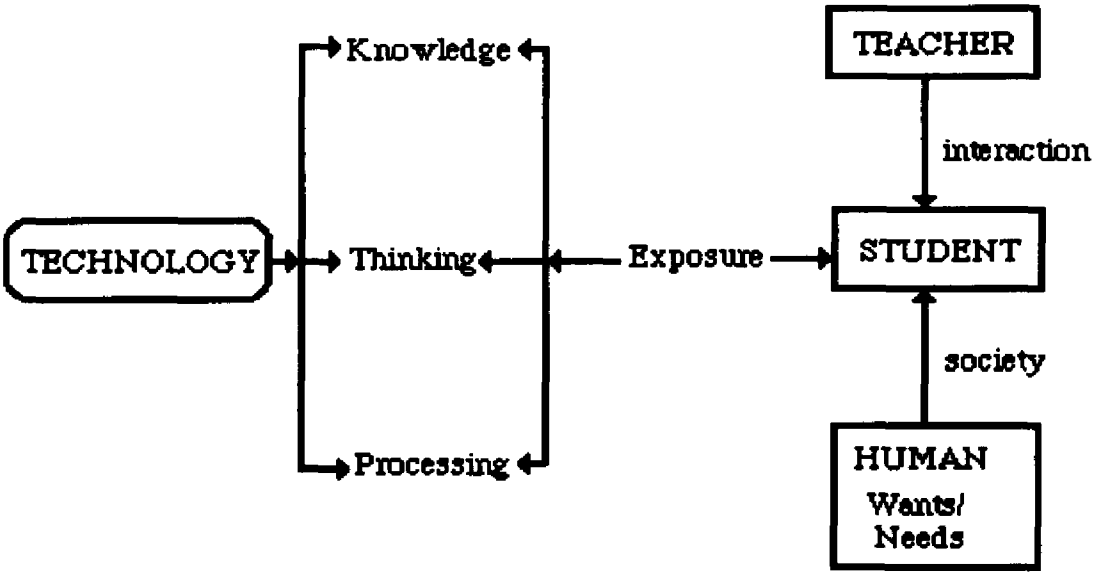

Figure 2. Conceptual Framework for Incorporating Learner into the Technology Environment (ILTE) (Chirwa, 1992, p. 584)

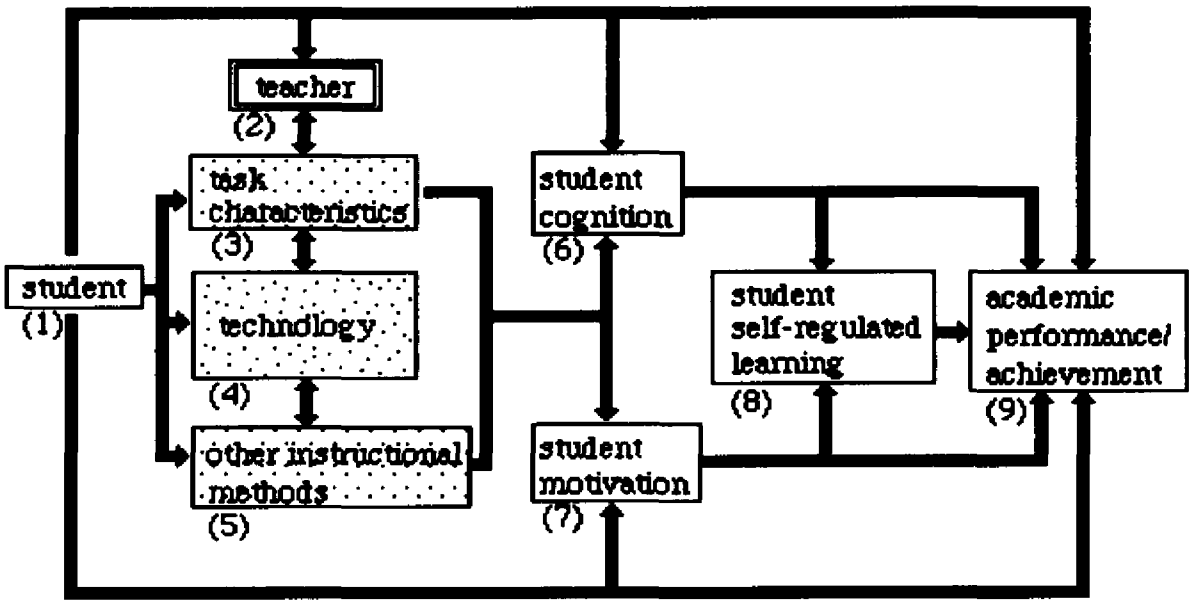

Figure 3. Model Incorporating Technology (Computer Conferencing) as a Supplement to Classroom Instruction.

Figure 3 shows the conceptual framework that motivated this study. The framework operates on the premise that the outcome of a student's academic performance is influenced more by the direction and degree of the student's engagement in learning than by any other single factor. CC may be one way to positively influence such engagement. CC will be viewed not as a replacement of the instructor nor live discussions in class but rather as a medium that provides a unique, but complementary, way of interacting which has useful educational applications. Thus, in view of the use of CC in the classroom, student engagement may be enhanced when teachers are able to: (a) focus the curriculum on developing skills, insight, and judgment that students bring to the discussion; (b) give students meaningful learning tasks that are incorporated or linked with the instructional method or technology used; (c) provide an atmosphere of rich interaction with other

students and teacher/s that encourages inquiries, feedback, problem-posing and problem-solving; and (d) recognize, and take advantage of, the variety of characteristics, competencies, and problems that students bring to the class.

Similar to McKeachie et al.'s (1986) model, the proposed framework assumes that students are active processors of what they learn. There is considerable emphasis placed on the mediating role of student perceptions in instructional activities which parallels a number of general cognitive psychological theories (e.g., Anderson, 1985, Ausubel, 1968; Brown, Bransford, Ferrara, & Campione, 1983; Bruner, 1964, 1965; Piaget, 1971) and more recent research on teaching (e.g., Shulman, 1986).

A brief description of each of the major constructs of this model (see Figure 1) are as follows:

Student/s (1)

Student entry characteristics represent the motivational and cognitive characteristics students have from previous educational experience, student wants and needs, as well as other demographic characteristics of the student. These entry characteristics influence and interact with instructional tasks/activities and the use of instructional methods and technology to enhance learning. Student initial perceptions of the tasks, instructional methods, and the use of technology, are also considered part of this construct.

In order to incorporate the student into the conferencing environment, it is important for teachers, as well as students, to know their initial strengths and weaknesses, their wants and needs, and other entry characteristics that may influence learning. The "student" construct is valuable in restructuring the learning environment which can be achieved by: a) determining student entry characteristics and potentials in view of their learning needs, b) encouraging students to learn by exposing them to various different social values and opinions, c) providing students with resources and strategies to enhance their motivation and efficacy for learning, and d) providing an environment that enhances self-esteem and develop a sense of community among students in the class.

Teacher (2)

It is important that the teacher possesses the knowledge and skills to competently impart knowledge to students, motivate students, and facilitate further learning. In addition, the ability to effectively teach, convey to students the purpose and benefits, and be receptive to student feedback about CC figure importantly. The teacher has the ability to monitor student cognition and motivation through their performance and feedback from them.

The teacher should be capable of stimulating learning which can be achieved through the following: a) the teacher should be able determine and be sensitive to the intellectual and social skills of students, b) the teacher needs to explore student prior knowledge and react accordingly in terms of restructuring the course, c) the teacher should also be relatively flexible in adapting learning material to the needs of individual students, d) the teacher should be able to construct strategies that challenge and enhance student cognitive abilities, and e) the teacher should develop strategies to motivate students to learn and use CC.

Task Characteristics (3)

Task characteristics, achieved through CC, refer to the activities students are required to do in class (e.g., class participation, papers, exams, presentations, and so on). Effective ways to incorporate the learner into the learning environment may be achieved by: a) defining the CC learning environment with respect to the feasibility of the tasks given the constraints of time and resources, b) considering student strengths and weaknesses in establishing these tasks, and c) selecting materials that match student learning and motivational needs.

Technology (Computer Conferencing) (4)

Technology is seen in this context as an instructional method to enhance learning. In view of this study, CC is seen as a primary instructional method used as a supplement to classroom discussion in which students extend interaction with their instructor and with

each other. This component provides a theoretical perspective on how CC may influence student cognition, motivation, perceptions, and attitudes regarding its use. CC, as with the influence of other instructional methods applied in a learning context, acts on the students' cognitive and motivational processes to stimulate thinking and processing capabilities. This kind of learning environment must provide the learner with the resources and strategies to learn and acquire knowledge.

Other Instructional Methods (5)

Other instructional methods refer to other teaching and learning strategies used inside the classroom to assist in learning and teaching. This may include teaching students the appropriate use of these strategies, and the effective use of lectures, discussions, exams, review sessions, collaborative learning activities, and the like.

Student Cognition (6) and Student Motivation (7)

Student motivation and student cognition are two broad categories of student characteristics that influence student involvement. Similar to McKeachie et al.'s (1986) description, the conceptualization of student motivation is viewed from a general expectancy-value model of motivation that is mostly cognitive in nature. Student cognition includes the students' use of learning strategies, their content knowledge about issues presented in the course, and their general problem-solving and thinking skills.

Student Self-Regulated Learning (8)

Student involvement in self-regulated learning concerns student engagement and commitment to the academic task. It is assumed that the student is actively and meaningfully engaged in the task. In other words, it involves self-regulated learning which is a combination of cognitive and metacognitive involvement as well as motivated involvement with a task.

Academic Performance/Achievement (9)

Academic performance/achievement refers to student learning outcomes (e.g., grades, instructor evaluation of student). It is viewed as primarily a function of student

involvement in self-regulated learning. This may also reflect how the other components of the model contribute to the potential outcomes due to instructional tasks and methods.

Relationship among the Constructs of the Model

The dynamic interrelationships of the constructs are depicted using arrows. The direction of the arrows show the relative influence of one construct on another. Pintrich, Smith, Garcia, & McKeachie (1991) have analyzed the relative strengths and directions of these interrelationships but with the absence of the teacher and the CC technology component. It is important to note that it is not the objective of this study to further analyze what Pintrich et al. (1991) have done but it does provide a perspective for looking at the key components that may affect classroom learning from a learner-centered perspective. In view of the present study, student cognitive and motivational characteristics were analyzed in view of how these relate to their perceptions and attitudes regarding CC use. Furthermore, the components of the model allow the teacher to design and structure classroom tasks and instructional methods given the CC environment and knowledge about student cognitive and motivational characteristics.

As a learner-centered model, the interaction among these classroom variables depict the learning and teaching process over a period of time. Task characteristics and instructional methods, and the use of CC as an instructional tool must be developed in view of student entry characteristics. Teachers, therefore, must be able to obtain some knowledge about the students in order to provide a better match between learning and instruction. Flexibility in the implementation of CC must be integrated in the course taking into account student needs, abilities, attitudes and perceptions about its use, and the class in general. These factors, then continually influence student motivation and cognition in their learning of the course. The "teacher" regularly monitors, evaluates, and structures learning tasks and the use of instructional methods, primarily CC use, to maximize student learning in the course of the learning period. Teachers are able to obtain feedback on the effectiveness of the learning environment from evaluating student motivation and cognition

by either formal methods (e.g., survey student on attitudes and perceptions) or informal methods (e.g., asking selected students their general impressions of the course).

Student cognition and motivation mediates their involvement in self-regulated learning which, in turn, is observed in their academic performance. However, academic performance is also partly influenced by student entry characteristics which may not necessarily have been a function of learning from the course. Thus, the teacher's tasks are to: a) obtain relevant knowledge about the students, and b) determine the appropriate task characteristics, implementation of CC, and other instructional variables and methods to maximize effective learning given the resources available.

The successful implementation and effective use of CC critically depends on the teachers ability to effectively implement, teach, and motivate the students on its use, purpose, and to convey to students the advantages of having the conference as an integral part of the learning.

As mentioned earlier, the purpose of this study is not to examine all the constructs of the proposed model, nor does it analyze the strengths, magnitudes, and directions of the interrelationships of these constructs. However, this model does provide a conceptual base for the study. More specifically, it suggests the importance of student perceptions toward CC and student characteristics (i.e., cognitive and motivational characteristics) in relation to the actual use of CC technology. Various instructional features of the classes (Table 1) that use CC were also examined in looking at variations in measures of frequency of CC interaction, as well as comments and suggestions on its use.

Problem Statements

The general purpose of this study was to explore the relationship between the implementation and use of CC technology as a supplement to classroom instruction and the social-psychological characteristics of the student. This study explored CC as an instructional tool in view of student perceptions and evaluations of this technology, the

relationships that exist between such perceptions and student cognitive-motivational characteristics for learning, the frequency of student CC interaction, and student comments and suggestions in different instructional groups. Student perceptions regarding CC use are important not only because they may be shaped by their cognitive and motivational characteristics but also because they are likely motivated by characteristics of the learning tasks and instructional methods involved. The findings may provide teachers with valuable information on how to structure and design CC use to motivate learning.

More specifically, the important questions are as follows:

1) Are there significant changes in student perceptions regarding the use of CC as a learning and motivational tool in the course of the semester, given the method in which it was used? As a supplement to this question and to determine initial differences in student perceptions towards CC, are there significant pretest perception mean differences between groups?

2) How do student cognitive and motivational characteristics correlate with student perception of computer conferencing use?

3) How do students belonging to different instructional groups of computer conferencing use differ in terms of frequency of interactive communication?

4) What comments (i.e., benefits, drawbacks, attitudes) and suggestions do students have regarding the use of CC in the course?

In addition, brief descriptions of each instructor's perceptions and evaluations regarding CC use in their class are presented.

Based on the pretest-posttest evaluations of CC use, student cognition and motivational characteristics, and the descriptive analyses of the frequency of conferencing interactions among students, some suggestions for enhancing the effectiveness of educational computer conferencing are provided.

CHAPTER II

METHOD

Participants

The sample was composed of 287 undergraduate students (181 females, 106 males) enrolled in Introductory Psychology courses at the University of Michigan in Ann Arbor during the Fall 1991 or the Winter 1992 semester. There were 79% freshpersons, 11% sophomores, 7% juniors, and 3% seniors (and over) at the time of their participation. Each participating student belongs to one of eight classes that used CC to supplement instruction. Of these classes, six were sections in an Introductory Psychology course taught by teaching assistants and two were basic level courses, equivalent to Introductory Psychology, taught by professors.

The vast majority of students did not have any experience with the use of CC. On a scale of 1 to 5 (1 pertaining to no experience at all and 5 pertaining to very experienced with CC), the overall mean of student's previous experience with CC was 1.46 with a standard deviation of 0.96. Previous CC experience between classes or sections were not found to be significantly different.

Descriptions of the Instructional Methods for CC

The manner in which CC was designed and implemented in individual classes was largely dependent on the discretion of the participating instructor. Therefore, each class varied in how conferencing was implemented and used. Each class, which is referred to as a "group," is described in terms of how computer conferencing was taught (i.e., CC training), how items were set up for the course (i.e., CC structure), what tasks were asked of students in using CC (i.e., CC use/tasks), the objectives/goals set for CC use by the instructor (i.e., CC goals), the instructor's perceived CC knowledge and experience,

whether or not CC was a required part of the course, the percentage to which CC contributed to student final grade. The descriptive variables used to characterize each class conference are summarized in Table 1.

Group	training	structure	use/ tasks	goals	instructor's perceived cc knowledge	CC required	% of grade based on CC use
1	-extensive handout -lab session (1) -practice item (1)	-syllabus/topical -all items set up at start of course -all academic items	-occasional in-class discussion -respond to half of all items by first 2 wks. -respond to assigned items/wk.	-express own views on issues -sense of community -learn from each other -learn to interact via CC -reflect on opinions	- (5) - highly knowledgeable	Yes	40%
2	-handout -lab sessions (3) -practice item (1)	-based on course components -first 10 items set up at start of course -items created each week based on topics to be read or discussed (2-4) -mostly academic items, 1 social, 1 CC item	-regular in-class discussion -selected few responses to read in class	-allow all student to participate -awareness of others' views -disseminate information -reply to questions -determine ways to improve CC use	- (5) - highly knowledgeable	Yes	25%

Table 1. Tabular summary describing the instructional methods of CC use for each group.

(continued next page)

Group	training	structure	use/ tasks	goals	instructor's perceived cc knowledge	CC required	% of grade based on CC use
3	-handout -no lab session -briefly discussed CC in class -wrote commands on board and answered questions	-based on student questions and interesting topics -items created by instructor or student as needed	-alternative way to ask and respond to questions -receive fast replies from instructor or peers	-improve comm. -to save time	- (4) - average to very knowledgeable	No	0%
4	-handout -no lab session -discussed how to sign on and basic commands in class	-based on exams and assignments -items created by instructor or student as needed	-questions and issues about exams or assigns. -few items on readings -review for exams	-get students to talk more with each other about the material -easy way to communicate about "business" matters	- (4) - average to very knowledgeable	No	0%
5	-handout -no lab session -little explanation of handout	-based on exams -some nonacademic items -items created by instructor or student as needed	-questions about exams -social interaction -disseminate information	-supplement discussion -easy way to access the instructor -get involved in discussion	- (4) - average to very knowledgeable	No	0%

(continued next page)

Group	training	structure	use/ tasks	goals	instructor's perceived cc knowledge	CC required	% of grade based on CC use
6	-handout of basic commands -lab session (2) -explained how to sign on, reviewed commands	-based on weekly topics (syllabus) -items mostly created by the instructor (students may also do so) -mostly academic items	-continuous discussion of issues -encourage informal discussion of issues	-daily contact with students -enrich and supplement discussion	- (5) - highly knowledgeable	Yes	not specified
7	-no handout -one class session teaching how to use CC (not a lab session) -provided consultation to students who need help	-items created as needed by instructor or student -items that are of interest to students -no particular format	-submit assign. via CC as an option -questions on exams and assignments -nonacademic matters	-enhance comm. with instructor and each other	- (3) - moderately knowledgeable	No	0%
8	-handout -no lab session -no discussion of handout but encouraged to ask questions on CC use	-items created by instructor or students as needed -items mostly based on weekly topics and readings -several nonacademic responses	-responses are optional -few specific topics of common interest	-disseminate information -reply to questions -alternative way to communicate	- (5) highly knowledgeable	No	0%

In order to provide a more thorough understanding of each group and to supplement Table 1, the succeeding narrative descriptions include additional information about each group. Instructors in each class are referred to by their group number. For example, Group 2's instructor is referred to as Instructor 2.

Group 1.

(a) CC training - Instructor 1 provided the students with a handout on how to learn CC showing all the basic commands students needed to know. A class meeting was set aside so that students are able to do actual hands-on practice in a computer laboratory. Students learned how to sign on and register for the conference by sending one another demographic information. An item on tips and hints was created by the instructor for students to access and to serve as a guide to their learning of the system. Students also used this item to ask help and pose questions regarding CC. The instructor explained to them the purpose of CC in class and how it will benefit their learning in the course.

(b) CC structure - The conference items was structured by course topic, similar to the way the syllabus was set up for this class. All 107 items were created even before the start of classes, and all were related to the content of the course, that is, they were all academic. The items were all related to course content and were in the form of controversial questions or statements designed to entice students to express their opinions on different topics in psychology and encourage exchange of ideas among students. The instructor served as the sole creator of items. Nonetheless, the items were set up in that any student response fit into any of these items created, as long as they were course-related.

(c) CC use/tasks - Students were required to respond or comment to at least half the items/topics created by the first two weeks of classes which is intended to provide the student with a better understanding of the structure of the conference and to serve as a tool for intensive practice in getting used to the conferencing system. Thereafter, they were

required to respond to designated items each week. In-class discussion of student responses was sometimes done. The instructor further encouraged students to go ahead or go back to items they had already responded to. On average, students signed on to the conference about 3 times per week. Feedback was given to students quite often and student questions and concerns are normally responded to by the instructor, sometimes by other students.

(d) CC goals - Instructor objectives for CC use were to allow students to conveniently and comfortably express their views on controversial issues covered in the course, to establish a sense of community as a class, to learn from each others' viewpoints, to think and reflect about their own views on certain topics, and to learn how to interact with each other through this new technology.

(e) Additional information - There were a total of 56 students in this group. CC use was required of students and contributed 40% to a student's final grade. The instructor, also a professor, rated himself as very knowledgeable and experienced with regard to the use of CC. In fact, among all the other instructors in the study, Instructor 1 is most experienced in the using CC as an instructional tool in an Introductory Psychology course.

Group 2.

(a) CC training - A 3-page handout showing the basic commands on CC was provided for the students. In the presence of Instructor 2, three computer lab sessions were dedicated for training students on the use of CC. The first session focused on explaining the purpose of using CC in class and how this may help in their learning of the course, and how to sign on and register for the conference. The second session dealt with practicing different commands (e.g., responding to an item), while the last session provided an additional practice session for the class. Students were asked to work in pairs so both students in the dyad can assist each other's learning of the conferencing system. One practice item was created so that students were able to test the use different commands,

send each other messages, and to ask questions and provide comments with regard CC. Instructor 2 often emphasized the benefits of using CC in class.

(b) CC structure - Of the 37 items created, the first 10 items were set up based on the structural components of the course (e.g., lecture, class projects, and exams) and the subsequent items in terms of controversial topics based on weekly coursepack readings assigned for the week (e.g., Do you agree with the author's ideas on the role of Psychology as a discipline? Why or why not?). In addition, though the items created were mostly academic, there were nonacademic items (i.e., items not related to the content of the course) such as inquiries about CC use and a social/nonacademic item. According to Instructor 2, items on coursepack readings were meant to stimulate discussion both in the conference and in class. On average, there were about 2 to 4 items created each week for students to respond to.

(c) CC use/tasks - Students were required to respond to items assigned for the week before a designated deadline. Each week, Instructor 2 regularly summarized the student responses in class and selected some to read aloud for the purpose of encouraging interesting ideas/responses from students. Classes devoted about 10 to 15 minutes of the time talking about their responses and encouraging further discussion of the topic. The instructor only occasionally provided feedback through CC because most of the feedback is given during in-class discussions.

(d) CC goals - The objectives of Instructor 2 for the use of CC were to allow all students to participate in discussions, to be aware and learn from other's opinions, to disseminate information and reply to questions, to provide feedback from students on how to improve the use of CC as a tool to help student learning, and to make the management of the class more efficient.

(e) Additional information - There were a total of 50 participating students in this group. CC was required and accounts for 25% of a student's final grade. Instructor 2, a

teaching assistant, rated himself to be very knowledgeable with regard to CC use and has used CC in one other course before.

Group 3.

(a) CC training. In one session, Instructor 3 briefly went over the handout provided for the students without any hands-on demonstration, although important commands were written on the board and briefly explained to the students. Students were then told to learn CC by themselves by going to any of the campus computing sites and following the instructions provided for by the handout of commands given to them.

(b) CC structure - Only seven items were created based on what the instructor or students thought were interesting questions or topics related to the course content. Students may also create items. There were no predetermined items created at the start of classes, but rather, they were created as the semester went along.

(c) CC use/tasks - Students used CC as an alternative and voluntary way to ask class-related questions and receive fast replies from the instructor as well as their peers.

(d) CC goals - Instructor objectives were to make communication among member of the class more efficient, that is, as a time-saving device.

(e) Additional information - There were a total of 9 participating students in this group. CC was not a requirement of the course and was therefore not graded. It was, nonetheless, encouraged for use. Few students, however, did use it in the course. Instructors 3, a teaching assistant, rated himself as average to very knowledgeable in the use of CC.

Group 4.

(a) CC training - The instructor briefly set aside two discussion sessions explaining to students how to sign on, how CC may be able to benefit them as a way to extend discussion outside the classroom. Instructor 4 also provided them with a tutorial handout describing how to sign on and the basic commands they need to know in order to function

successfully in their use of the CC system. Instructor 4 briefly discussed the basic CC commands in class but no lab session was provided for hands on practice.

(b) CC structure - CC was primarily used to review and discuss exams or assignments. Each of the 18 items were created as needed. Most of the items were about student concerns about exams and assignments. Items were created by either the instructor or student as needed.

(c) CC use/tasks - Most items had to do with upcoming assignments or exams. Students did ask questions and instructor responded to them. There were few items designed to stimulate discussion about assigned article readings because it was deemed more appropriate by the instructor to talk about them in class. Therefore, the conference primarily became a venue for reviewing for and reacting to exams and other class requirements.

(d) CC goals - The instructor's initial goals set for the use of CC were to get students to converse more to each other about the class material, and to provide an easy way to communicate about class-related or "business" matters.

(e) Additional information - There were 15 participating students in this group. CC was not required although it positively contributed to the "class participation" grades of those who preferred to use it in addition to or in place of participation in in-class discussions. Instructor 4, a teaching assistant, rated herself as average to very knowledgeable in CC use.

Group 5.

(a) CC training - There was very little demonstration provided for the students on the use of CC and the reasons for using it in class. Nevertheless, handouts were given to students to review on their own if they would wanted to avail of its use.

(b) CC structure - Similar to Group 4, the 6 items created were primarily related to exam reviews and discussion of exam results. There were some non-academic items created by students. The items were created either by the instructor or students as needed.

(c) CC use/tasks - CC was used primarily to ask question about exams. Although there were two items that were more of a more social nature, CC was primarily used as a on-line review session for an exam and to convey student attitudes and perceptions about the exam results. It was also used to make some class-related announcements such as deadlines for papers.

(d) CC goals - The goals set by the instructor were to supplement in-class discussion of course content, to provide the instructor quick and easy access to students, to provide students with a convenient way to get in touch with the instructor, and to encourage some students to get involved in class discussion.

(e) Additional information - A total of 12 participating students were in this group. Similar to Group 4, CC was not required of students although it positively contributed to their grade for class participation for those students who used it. Instructor 5, a teaching assistant, rated herself as average to very knowledgeable in CC use.

Group 6.

(a) CC training - Students were provided with a summary sheet of commands. A whole session (2 hours) was provided in which students went through training on how to sign on and use some of the basic CC commands. The first two weeks after the student's initial exposure to CC was considered a training period. They were even encouraged to create their own items which they did. Instructor 6 particularly stressed the importance of using CC to enhance class discussion and obtain announcements relating to the course.

(b) CC structure - The 41 items created were based on weekly discussion topics, that was in accordance with the course syllabus. These items were usually created by the instructor a week or two before the topical item is actually taught or discussed in class. Students may also create items for discussion. Most of the items were course-related but responses became very informal as the discussion went along. Several items were presented in a debate-like format to encourage student responses and interaction.

(c) CC use/tasks - CC is a continual discussion of topics that students and or instructor thought were not sufficiently discussed in class. Instructor 6 encouraged informal discussion of issues and allowed for the virtual free flow of ideas. Students must have at least sign on and registered as a participant in the conference early in the semester. Nonetheless, since the primary teaching method centers around an informal discussion of the course content, CC was the major way of keeping up with the discussion of the material. In that sense, students felt that without utilizing CC, they will not be learning "with" the class. The instructor regularly monitors the conference and responds to student comments and questions.

(d) CC goals - The goals set by the instructor 6 for CC use were to provide a venue for daily contact with students, and to enrich and supplement the class discussion.

(e) Additional information - There were a total of 15 participating students in this group. CC use was required. No specific grading system was provided and interestingly enough, all students in this group got a final grade of A by the end of the semester. Of course, the students were not aware of this in the course of the semester. Instructor 6, a professor, rated himself as highly knowledgeable in CC use.

Group 7.

(a) CC training - There were no tutorial handouts given to the students nor any hands on lab sessions to practice CC use. In one class session, Instructor 7 wrote and explained the basic commands on the board and entertained questions from students. The instructor particularly emphasized that if they needed help with CC, they may see him during his office hours.

(b) CC structure - The total number of items created was 19. Although items were created either by the instructor or by students as needed, most of the items related to topics of interest to students. There was no particular format or structure for the conference.

(c) CC use/tasks - Students, in addition to responding to items, have the option to enter and send their written assignments through CC. CC was primarily used to ask

questions and receive information regarding exams and assignments, and discuss nonacademic matters.

(d) CC goals - Instructor 7 mentioned that the goal for CC use in class was simply to enhance communication among students and between students and instructor.

(e) Additional information - A total of 77 participating students were in this group. CC was not required and was not part of the student's final grade. Instructor 7, a teaching assistant, rated himself as moderately knowledgeable in CC use.

Group 8.

(a) CC training - A tutorial handout was given but no actual hands on training was provided. There was no discussion of the handout but students were encouraged to approach the instructor for questions on CC use. Students were asked to learn the use of CC on their own.

(b) CC structure - Fourteen items were structured based on the topics presented in lecture, discussion, or assigned readings. It is very much like the setup for Group 2, however, the items were more general and students may create items, though they seldom did.

(c) CC use/tasks - Student responses to items were optional, but students, nonetheless, were encouraged to created their own items. Generally, the items were class-related although there were few specific topics of interest to the students that did not conform to the specific issues presented in the course.

(d) CC goals - The goals set by the instructor for CC were to disseminate information, reply to student questions, and to serve as an alternative means for some students to participate in class discussion.

(e) Additional information - 53 students participated in this group. CC was not a requirement and did not contribute to student final grade. Instructor 8, a teaching assistant, rated himself as highly knowledgeable in CC use.

ANOVA findings indicate that there were no significant differences in students' previous experience with CC between groups at the start of the semester. Therefore, groups were comparable in terms of CC prior knowledge and skills prior to their actual use of CC in class.

Instruments

The major sources of data are the pretest and posttest questionnaires on student perceptions towards CC use, the Motivated Strategies for Learning Questionnaire (MSLQ), an end-of-semester instructor questionnaire on the use of CC, and transcripts of randomly selected students depicting the items and responses that transpired in each group conference. Each instrument used is briefly described.

(1) A pretest and a posttest student perception questionnaire (See Appendix A and B, respectively) were constructed to measure student perceptions towards CC. There were 9 perception items for both pretest and posttest versions, each in the form of a 5-point Likert-type scale, appearing in both the pretest and posttest versions. The nine perception items relating to CC use were "worthwhile to learn," "valuable in learning course," "freedom from anxiety," "motivation to learn material," "motivation to participate in CC," "help understand material," "encourage in-class participation," "student responses useful," and "fun way to learn."

The posttest version, however, also allowed students to give their comments, attitudes, and suggestions on CC use as a integral part of the course. These were open-ended questions that were eventually coded to determine whether their answers focused more on student cognition or learning of the course, student motivation or efficacy for learning, or the instructional tasks relating to their use of CC. Appendix C shows the student data code sheet for transforming these qualitative data into meaningful nominal codes.

(2) The Motivated Strategies for Learning Questionnaire (MSLQ) is a self-report instrument designed to assess college students' motivational orientations and their use of different learning strategies for a college course (McKeachie, Pintrich, Lin, & Smith, 1986) (See Appendix D). The MSLQ was used to provide information about student cognitive and motivational characteristics and to determine how these correlated with student perceptions of CC use. There are a total of nineteen subscales that measure student learning and study habits (e.g., time and study management, thinking skills) and motivation for course work (e.g., intrinsic and extrinsic motivation). More information on the MSLQ may be found in the Manual for the Use of the Motivated Strategies for Learning Questionnaire by Pintrich, Smith, Garcia, and McKeachie (1991).

(3) Transcript data (i.e., conference items and responses) relating to the conference was also analyzed. Transcript data from randomly selected students, five from each of the eight groups (for a sample size of 40 students) was examined to obtain a representative description of the frequency of interaction for each class conference. The qualitative transcript variables examined were as follows: (1) Citing (i.e., number of times lecture or professor, teaching assistant, another student, text or reading, and personal experience were cited); (2) Agreeing/Disagreeing (i.e., number of times a student agreed or disagreed with another's opinion; (3) Questioning/Commenting(i.e., number of times a student asked a class-related or CC question or comment; (4) number of Nonacademic responses given; and (5) Other responses that do not fall under any of these variables mentioned. Appendix F shows the transcript data code sheet for transforming these qualitative variables into meaningful codes. In addition, the quantitative transcript variables examined were (1) the number of times a student responded in the entire conference, (2) number of student responses per item, (3) number of items a student created, and (4) number of lines per student response.

(4) All instructors completed an instructor questionnaire during the last week of the semester to determine instructor perception and evaluation of the effectiveness of CC use in

their particular class, how students were trained in using this technology, how they and their students actually used CC, whether it was a required part of the course, and other questions necessary in providing a comprehensive description of each of the classes (See Appendix E). Information relating to instructor perceptions and evaluations was not a major part of this research, but was nonetheless presented to complement the descriptions of the different classes and the findings.

Research Design and Procedure

Prior to the actual undertaking of the study, the instructor's permission was obtained to conduct the study in their respective classes. The students in participating classes were asked to read, sign, and date an Informed Consent Form (See Appendix G). All participating instructors were briefed regarding the goals and procedures of the study prior to the administration of the Informed Consent Forms or any of the questionnaires.

The research design involved a pretest-posttest analysis of student perceptions regarding CC use in their class (See Appendix A, Part 1 and B, Part 1). These questionnaires were given either by the course instructor or the experimenter. The student pretest perception questionnaire was administered to all participants within the first three weeks of classes and after the participants have had exposure to using CC (i.e., those students who have signed on at least once or have registered for the class conference). In addition, information was obtained regarding student cognitive and motivational characteristics by having them complete the Motivated Strategies for Learning Questionnaire (See Appendix D) immediately after the administration of the student pretest perception questionnaire.

For the next several weeks, the conferencing activities in each class took place. The posttest version of the student perception questionnaire was then administered within the last week of classes. After the students have completed the posttest perception

questionnaire, a Student Feedback Form was handed to each participating students in order to debrief them about the purpose and nature of the study (See Appendix H).

During the last week of classes and after having collected most of the pretest and posttest perception questionnaires from the students, the eight participating instructors were asked to complete the instructor questionnaire (Appendix E) that described their perceptions, suggestions, and use of CC (e.g., Do you think CC has been an effective teaching tool for you as an instructor?, Briefly describe how you taught CONFER to your students?, What do you think are the benefits of using CONFER in this class?).

Data Analyses

Due to the diversity of instructional methods in the use of CC, and varying grading criteria among the participating classes, group differences in student perceptions of CC use were primarily analyzed based on the differences and similarities of the major descriptions of each group (Table 1). Analyses of significant changes in pretest to posttest perception scores focused on changes within groups, although a separate comparison of group means for the pretest perception items between groups were reported to determine variations in initial students perceptions and infer possible explanations based on differences in the way CC was implemented and used by each group. Correlational analyses of the perception items and the students' cognitive-motivational characteristics focused on all groups combined, although differences between groups were briefly discussed. Descriptive analyses addressed variations in instructional methods that may have contributed to differences in the frequency of interactive communication between groups. The descriptive analyses on student comments and suggestions on CC use focused on all groups combined, although comparisons on intergroup differences were briefly discussed. Lastly, descriptive accounts of each instructor's perceptions and evaluations of CC use in their classes are presented.

CHAPTER III

RESULTS AND DISCUSSION

Significant Changes in Student Perceptions toward the Use of Computer Conferencing

Tests for the normality of the distributions for all of the perception measures were done. It was determined that several of the measures typified a normal distribution. For the pretest measures of perception, these were "valuable in learning course," "motivation to learn material," "motivation to participate in CC," and "help understand material," "encourage to participate," and "fun way to learn." For the posttest measures of perception, these were "valuable in learning course," "motivation to learn material," "motivation to participate in CC," "student responses useful," and "fun way to learn." Despite this initial screening, both parametric (i.e., t-tests) and nonparametric analysis (i.e., Wilcoxon signed rank test) were nonetheless used to analyze the student perception data.

Table 2 presents a comparison of student pretest and posttest perception means for all groups combined, for each of the eight groups, and for all group combined less those found with significant within-group differences.

	Group									
Perception Item	ALL	1	2	3	4	5	6	7	8	ALL but significant
sample size	(287)	(56)	(50)	(9)	(15)	(12)	(15)	(77)	(53)	
worthwhile to learn										
Pretest	*3.86*	4.15	4.04	3.78	3.93	3.8	4.4	*3.57*	3.64	3.97
Posttest	*3.56*	4.33	4.17	2.4	3.78	2.8	4.64	*2.72*	3.08	3.9
valuable in learning course										
Pretest	*3.25*	3.9	3.38	2.11	2.7	3.0	4.0	*2.96*	3.1	3.36
Posttest	*2.94*	4.02	3.71	1.8	2.78	1.5	4.1	*1.79*	2.5	2.39
freedom from anxiety										
Pretest	3.8	3.4	3.9	4.67	3.86	3.9	4.23	3.75	3.8	- -
Posttest	3.8	3.62	3.4	4.4	3.78	4.0	4.5	3.73	4.2	- -
motivation to learn material										
Pretest	*2.9*	3.62	3.26	2.0	2.79	2.67	2.9	*2.4*	2.73	3.1
Posttest	*2.6*	3.33	3.45	2.0	2.56	1.9	3.64	*1.6*	2.44	3.06
motivation to participate in CC										
Pretest	*3.1*	3.58	3.5	2.44	3.2	2.5	4.15	*2.67*	2.62	3.23
Posttest	*2.87*	3.83	3.33	2.4	3.11	2.33	3.6	*1.98*	2.42	3.23
help understand material										
Pretest	*3.1*	3.44	3.28	2.56	3.36	3.0	3.46	*2.76*	*3.02*	3.29
Posttest	*2.58*	3.33	3.48	1.8	2.67	1.33	3.64	*1.54*	*2.14*	3.25
encourage in-class participation										
Pretest	*3.05*	3.68	*3.4*	2.67	3.2	2.78	3.09	*2.51*	*2.96*	3.29
Posttest	*2.5*	3.37	*2.95*	1.8	2.5	1.7	3.93	*1.49*	*2.14*	3.2
student responses useful										
Pretest	*3.67*	4.06	3.96	3.6	3.7	3.56	4.25	*3.19*	3.51	3.85
Posttest	*3.08*	3.91	3.93	2.8	3.3	3.0	4.3	*1.73*	2.81	3.59
fun way to learn										
Pretest	*3.36*	3.75	3.34	3.44	3.8	3.11	4.1	*3.19*	2.96	3.43
Posttest	*3.08*	3.8	3.55	2.6	3.56	2.33	4.2	*2.07*	2.89	3.47

Italicized numbers indicate significant pretest to posttest mean differences

Table 2. Student pretest and posttest mean perception scores for each group and for all groups combined.

Tables 2a to 2i shows the significant results for the paired t-test analyses, along with the corresponding Wilcoxon signed rank test results, on the perception measures for

all groups (i.e., total) and for each of the eight groups. Note that the values presented for both the t-test and the Wilcoxon rank test of analyses are relatively similar. The Bonferroni-Dunn test was done as a post-hoc analyses of the perception data for each group to guard against spurious predictions between pretest and posttest student perception measures. In using this procedure, the overall protection level of pairwise comparisons of pretest and posttest student perception means for each group was determined to be significant at $p < .0064$.

Figures 4a to 4h present line graphs showing those groups, as well as all groups combined, with significant differences between pretest and posttest means for each of the student perception items. Appendix I and Appendix J show the descriptive statistics (i.e., means, standard deviations, medians, and modes) for the pretest and the posttest student perception items.

Note that the nine perception items were measured on a scale of 1 to 5, with 1 being least characteristic and 5 being most characteristic of a student. Therefore, the higher the rating on the scale (i.e., the closer to 5), the more it is indicative of a more favorable perception towards CC as an instructional tool.

Perception Item: worthwhile to learn

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.30	183	-4.828***	-4.62***
By group:				
Group 7	-0.85	50	-5.423***	-4.291***

***p<.0001

Table 2a. Significant differences between pretest and posttest student perception scores for "worthwhile to learn."

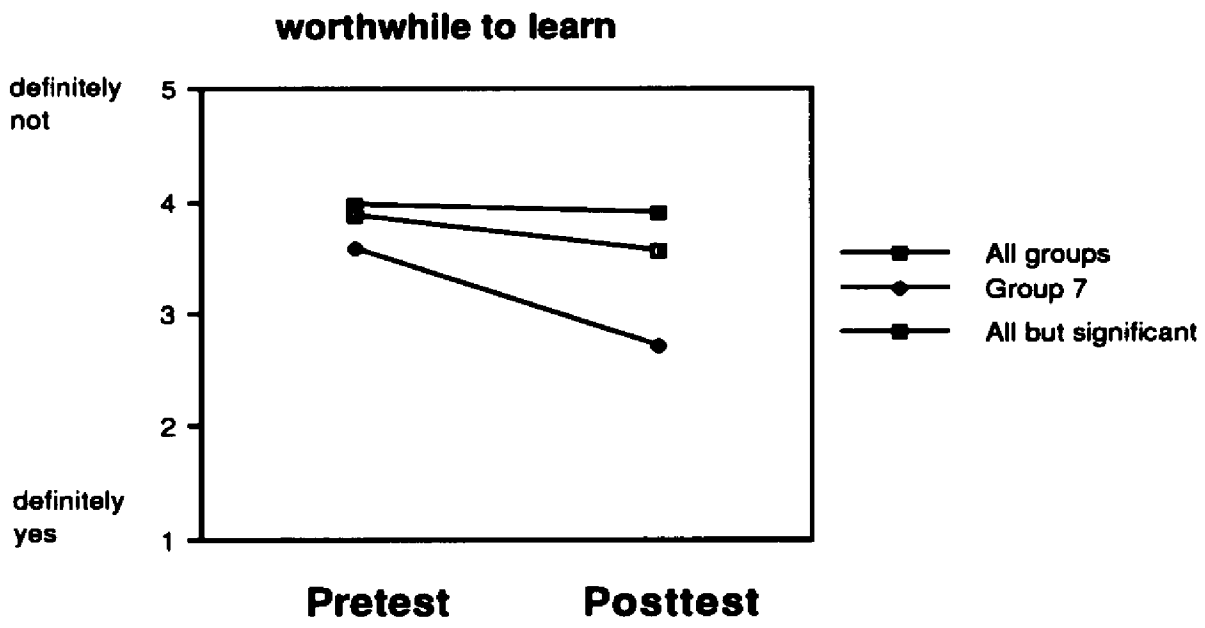

Figure 4a. Line graph for groups showing significant differences between pretest and posttest means for "worthwhile to learn"

It is also important to note that despite their low sample sizes, there were also noticeable mean decreases from pretest to posttest student perception for "worthwhile to learn" that approached the 0.05 alpha level for Group 3 (mean difference = -1.38) and Group 5 (mean difference = -1.0). Similarly, Group 8 also showed a noticeable decrease in pretest to posttest perception mean (mean difference = -0.56).

Over the course of the semester, student perception means of whether CC was worthwhile to learn generally declined, with the exception of groups 1, 2, and 6. Group 7 significantly contributed to this decrease. Similar to the other groups that showed a large decline in "worthwhile to learn", this group, especially, primarily left much of the CC training up to the students, did not consider CC use as part of the student final grade, presented CC as an alternative and optional method to communicate with the instructor or other students, and generally did not fully integrate CC as part of the course, but rather, as an option for students who may be interested in using it. Moreover, CC use did not

emphasize discussion of class content but rather as a way to respond to and answer "quick and simple" questions addressed to the instructor by individual students, although such questions may have been irrelevant to other students. Social, nonacademic matters also seem to be prevalent as a topic of communication. Thus, it is presumable that these factors mentioned may not cater to the development of positive student perception towards CC.

Perception Item: valuable in learning course

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.31	184	-4.717***	-4.434***
By group:				
Group 7	-1.17	51	-10.147***	-5.810***

***p<.0001

Table 2b. Significant differences between pretest and posttest student perception scores for "valuable in learning course."

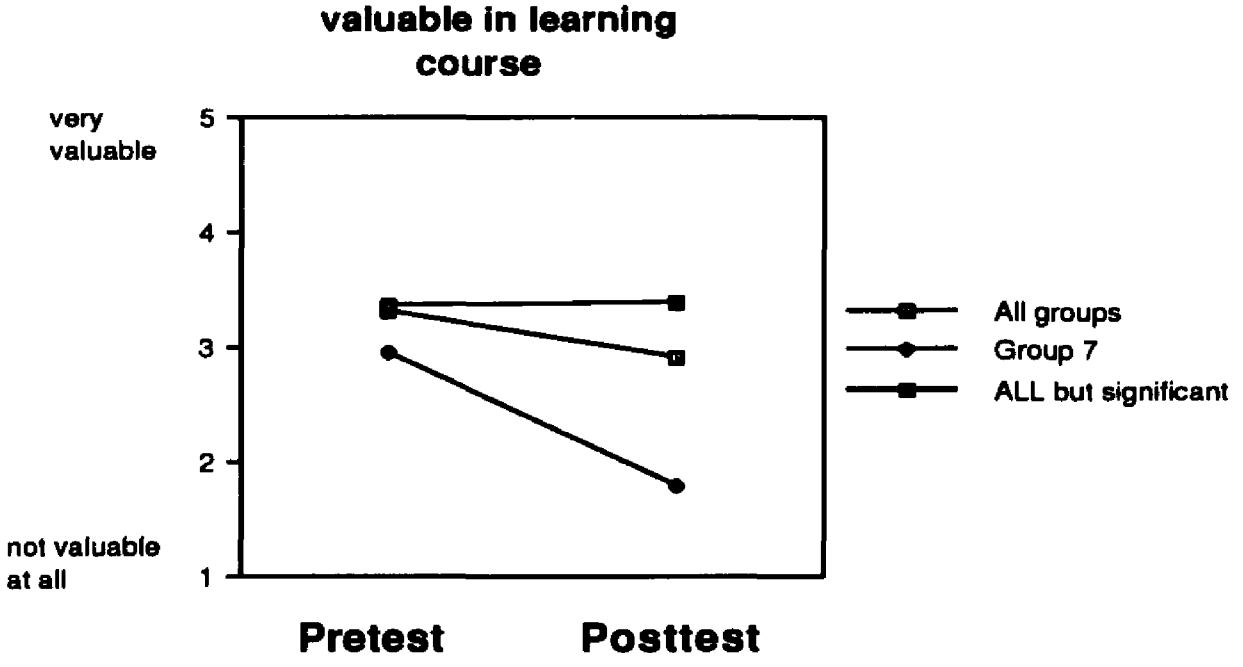

Figure 4b. Line graph for groups showing significant differences between pretest and posttest means for "valuable in learning course"

Group 5 (mean difference = -1.5) also shows a noticeable mean decrease for "valuable in learning course" despite not having reached a 0.05 level of significance. Similarly, Group 8 showed a noticeable decrease in pretest to posttest perception mean (mean difference = -0.60).

Student perception of the value of CC in their learning of the course also generally decreased with the exception of Groups 1, 4, and 6. Overall, there was a significant mean difference between pretest and posttest scores, with Group 7 as the major contributor to this decline. Since the use of CC was not accorded much relevance to the objectives of the course, students tended not to use, or even explore this option because of the other more seemingly convenient and more traditional method that were available in which students may ask questions and hold discussions. There was no particular format or agenda set for the conference. In addition, there appeared to be greater disparity between the CC goals set by the instructor and the actual use of CC by students in class. In other words, CC did not enhance interaction among the members of the class.

Perception Item: freedom from anxiety

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	0.01	183	0.286	0.275

Table 2c. Significant differences between pretest and posttest student perception scores for "freedom from anxiety."

No significant mean changes in perception scores were found for "freedom from anxiety." However, noticeable mean decreases were apparent for Group 2 (mean difference = -0.50) and a mean increase for Group 8 (mean difference = 0.40), although

these approached but did not reach significance levels. These two groups are nonetheless discussed.

Groups 2 and 8 had noticeable changes in pretest to posttest scores for " freedom from anxiety" but in differing directions. In Group 2, students became more anxious by the end of the semester. This may be due to the fact that a good part of their grade was based on responding to items by the set deadline as posed by the instructor. Most of the responses seemed well thought out and highly "academic." It appears that most of them responded for the purpose of "satisfying the requirement" and to meet the instructor expectations, rather than to further deliberate on the topic discussed. After the deadline to respond to items, students did not go back to those items in order to continue discussion. Students seemed to have been extrinsically motivated to concur with the requirement of having to respond. In addition, there were many students in Group 2 who may have felt intimidated with having CC as a required and graded part of the course, and they may have perceived CC as additional work for them. Nonetheless, the students did participate regularly in the conferencing. In contrast, students in Group 8 generally did not perceive CC as anxiety-provoking as they did at the beginning of the semester. The optional use of CC may have contributed to this finding in which students realized that meeting the requirements of the course was not dependent on their use of this technology. In addition, the lack of training and topics of common interest to many students may have contributed to the students' lack of interest in its use.

Perception Item: motivation to learn material

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.30	183	-2.529*	-2.730*
By group:				
Group 7	-0.80	50	-6.214***	-6.271***

***p<.0001
*Although this statistic was determined to be significant at $p < .05$, the Bonferroni method does not require its overall significant value to determine significance for each paired comparison.

Table 2d. Significant differences between pretest and posttest student perception scores for "motivation to learn material."

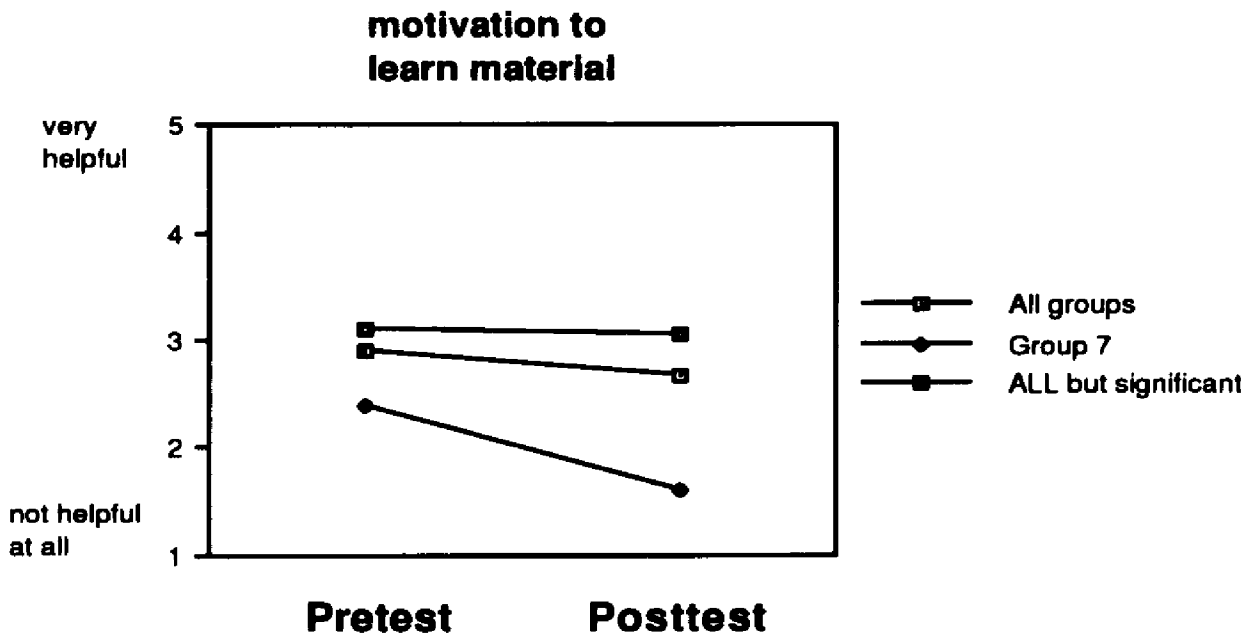

Figure 4c. Line graph for groups showing significant differences between pretest and posttest means for "motivation to learn material"

A noticeable increase in pretest to posttest perception mean is evident in Group 6 (mean difference = 0.74). Nonetheless, this did not reach the significance level set forth by the Bonferroni-Dunn test.

There was a significant decrease in student perception of CC as a motivator to their learning of the material presented in class. It was Group 7 that contributed significantly to this decrease. A probable reason for this was that students in Group 7 were not provided with much incentive to use the technology and it was not made clear to them how its use would enhance interest in their learning of the course. CC was seldom used by the students, even as a communication tool, and nonacademic responses were proportionally abundant. In contrast, students in Group 6 generally perceived CC as a motivating factor in their learning of the material. It is this group that used CC as a primary means of holding discussion of course topics and is clearly linked with classroom discussion. Students discussed class-related issues, although many of the responses often digressed or overlapped with other topics. Students were clearly motivated in its use and there seems to be a real sense of purpose for having the conference as an extension of classroom learning. The instructor regularly encourages the students to share their ideas, and conduct informal discussions of the issues. It is possible that the relatively social atmosphere in the conference provided a form of intrinsic motivation. There was a free exchange of ideas and much of these discussion seemed informal.

Perception Item: motivation to participate in CC

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.23	185	-2.906**	-2.832**
By group:				
Group 7	-0.69	52	-4.334***	-3.699***

***p<.0001
**Although this statistic was determined to be significant at $p < .01$, the Bonferroni method does not require its overall significant value to determine significance for each paired comparison.

Table 2e. Significant differences between pretest and posttest student perception scores for "motivation to participate in CC."

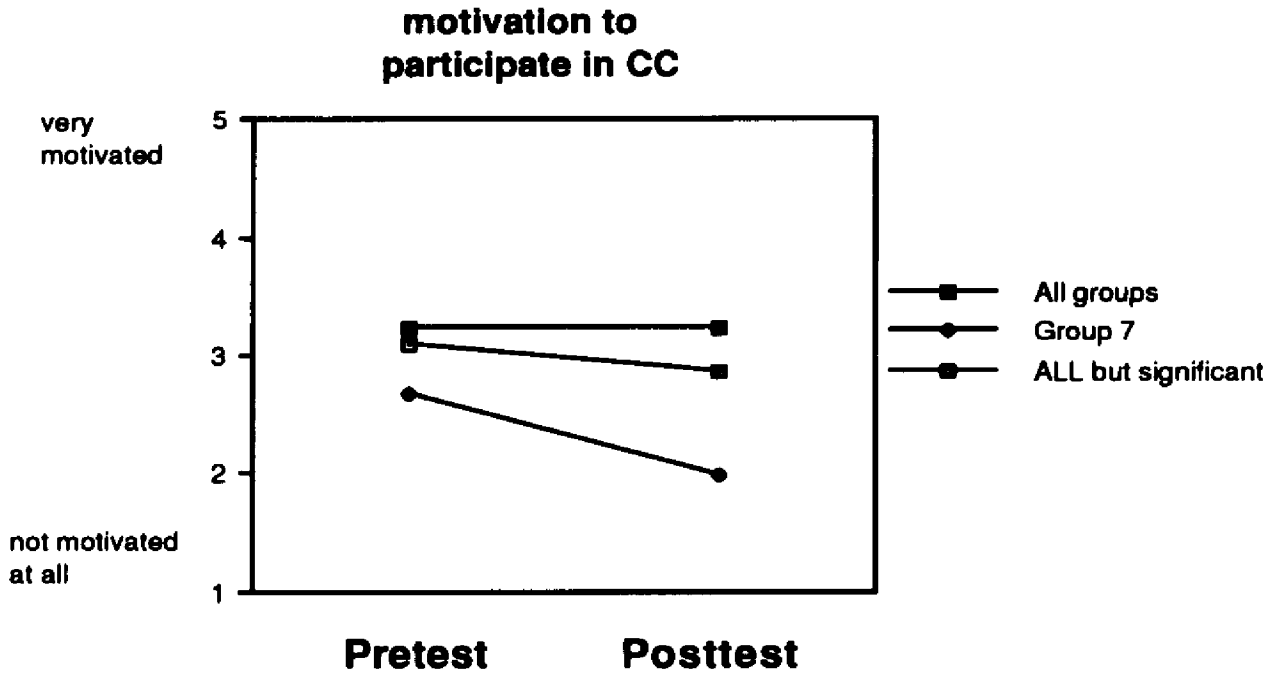

Figure 4d. Line graph for group/s showing significant differences between pretest and posttest means for "motivation to participate in CC"

With all groups combined, there was a significant decline in student perception of their "motivation to participate in CC" in the course of the semester. CC in Group 7, being optional and providing practically no guidance nor any form of training, not to mention that CC did not contribute to the student's final grade, students were likely to be unmotivated to participate in the conference. Students were relatively uncommitted to learning the technology for "purposeful" application in the course possibly because CC's potential as a learning tool was not effectively conveyed to them, other than it was an "alternative way to communicate with each other." Nonetheless, CC did not really enhance communication among students. Other common problems pointed out by students in this group were access to computer facilities and the lack of familiarity with the use of CC. Also, much of the discussion was done in class, which resulted in making conferencing activities to extend classroom discussion dormant.

Perception Item: help understand material

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.52	184	-5.583***	-5.006***
By group:				
Group 7	-1.22	51	-8.962***	-5.373***
Group 8	-0.88	27	-4.759***	-4.756***

***p<.0001

Table 2f. Significant differences between pretest and posttest student perception scores for "help understand material."

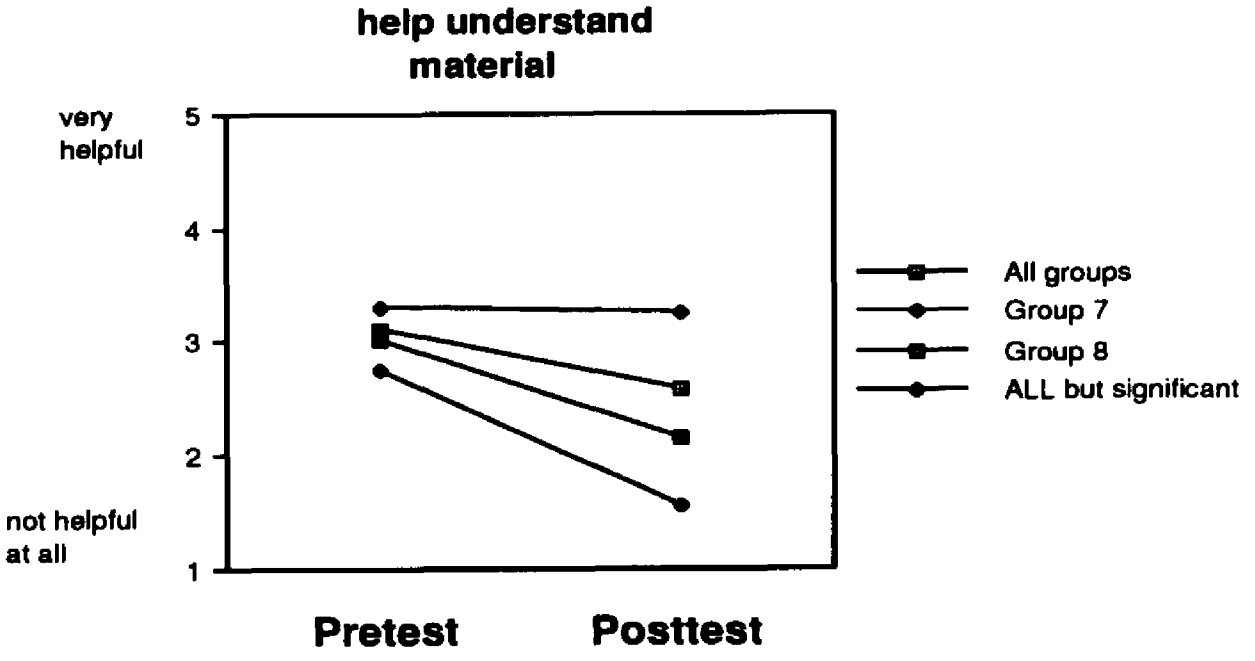

Figure 4e. Line graph for groups showing significant differences between pretest and posttest means for "help understand material"

Group 5 (mean difference = -1.67) also had a noticeable mean decrease for "help understand material", but a there were not enough participants in this group to obtain a meaningful t-value nor a Wilcoxon tied z-value.

There was a significant decrease in student perception that CC was helpful in their understanding of the course material. Contributing to this significance were Groups 7 and 8. In Group 7, the decline may have been a result primarily of their lack of student motivation to use CC due to its lack of integration with the course, absence of CC training, ambivalence with regard to its purpose, and the lack of interesting topics that would have encourage further discussion. In addition, many of the topical issues presented in the conference were not directly related to the topics presented in the course syllabus. Lastly, students in Group 8 tended to use CC to discuss non-class related topics. Only a handful of students brought up class-related topics and these responses were oftentimes directed to the instructor, not to the other students. In both groups mentioned above, neither one required the use of CC nor did CC use contribute to the students' final grade.

Perception Item: encourage in-class participation

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.55	165	-5.235***	-4.862***
By group:				
Group 2	-0.45	38	-3.957***	-3.986***
Group 7	-1.02	44	-5.174***	-4.067***
Group 8	-0.82	26	-3.732***	-3.558***

***p<.0001

Table 2g. Significant differences between pretest and posttest student perception scores for "encourage in-class participation."

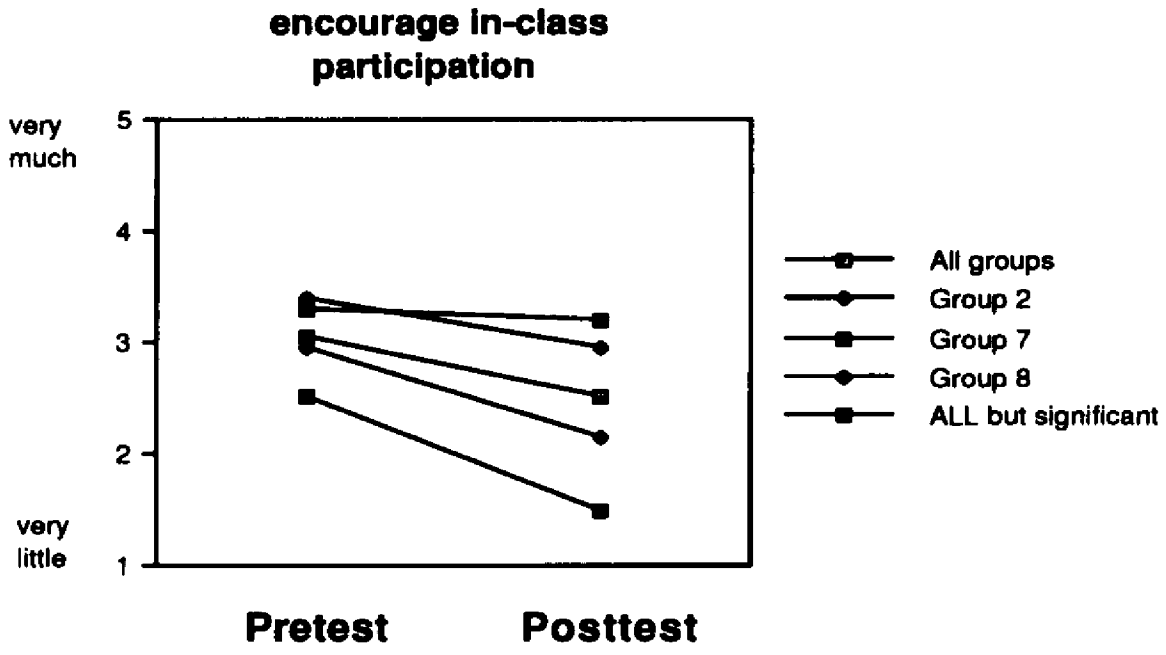

Figure 4f. Line graph for groups showing significant differences between pretest and posttest means for "encourage in-class participation"

Despite these groups' low sample sizes, group 3 (mean difference = -0.87) and group 5 (mean difference = -1.08) also had relatively large mean decreases for "encourage in-class participation" but both did not reach the 0.05 significance level. Similarly, Group 4 had a noticeable mean decrease that did not reach significance (mean difference = -0.70).

Significant mean decreases in student perception of CC's ability to encourage in-class participation were evident in Groups 2, 7, and 8. For Group 2, a possible explanation is that "in-class" participation was not graded and student did not have an incentive to participate within the actual classroom setting. Students' responses to the conference was constantly monitored by the instructor, graded, and therefore made students focus their energies into responding diligently to the conference. For Groups 7 and 8, CC use was an option and, in addition, students were not provided with any hands

on training on how to use CC. Thus, many students simply did not use CC. Furthermore, the many conference items for Groups 7 and 8 were not class-related and therefore were not covered in in-class discussion.

Perception Item: student responses useful

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-0.59	182	-5.790***	-5.366***
By group:				
Group 7	-1.46	49	-7.648***	-5.189***

***p<.0001

Table 2h. Significant differences between pretest and posttest student perception scores for "student responses useful."

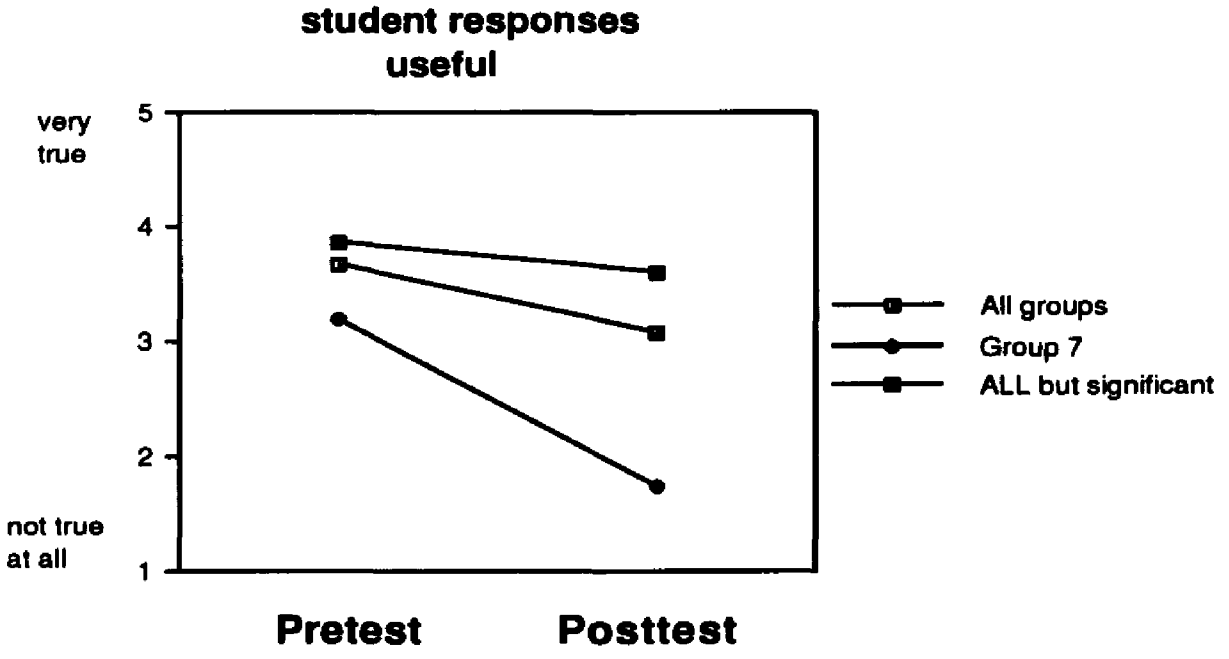

Figure 4g. Line graph for groups showing significant differences between pretest and posttest means for "student responses useful"

Group 3 (mean difference = -0.08) and Group 5 (mean difference = -0.56) also had relatively large mean decreases from pretest to posttest that did not achieve the 0.05 alpha level. Similarly, Group 8 had a noticeable mean decrease (mean difference = -0.70).

Overall, students found other students' responses to be less useful by the end of the semester. Group 7 was determined as the major contributor to this decrease. In this group, few students regularly used CC and many who did use it found the lack of participation not only disappointing and limiting in terms of learning from others. Many of the student responses involved non-class related topics. Thus, conference content was generally not geared toward the discussion and sharing of class material and students may not have found student responses to be helpful to their learning. CC discussion rarely focused upon ideas introduced in class, and student responses were not seen as especially helpful by other students.

Perception Item: fun way to learn

	Mean Difference	df	t-value	Wilcoxon Tied z-value
All groups (total)	-.0.28	182	-2.953**	-2.944**
By group:				
Group 7	-1.12	50	-7.074***	-4.864***

***p<.0001
**Although this statistic was determined to be significant at $p < .01$, the Bonferroni method does not require its overall significant value to determine significance for each paired comparison.

Table 2i. Significant differences between pretest and posttest student perception scores for "fun way to learn."

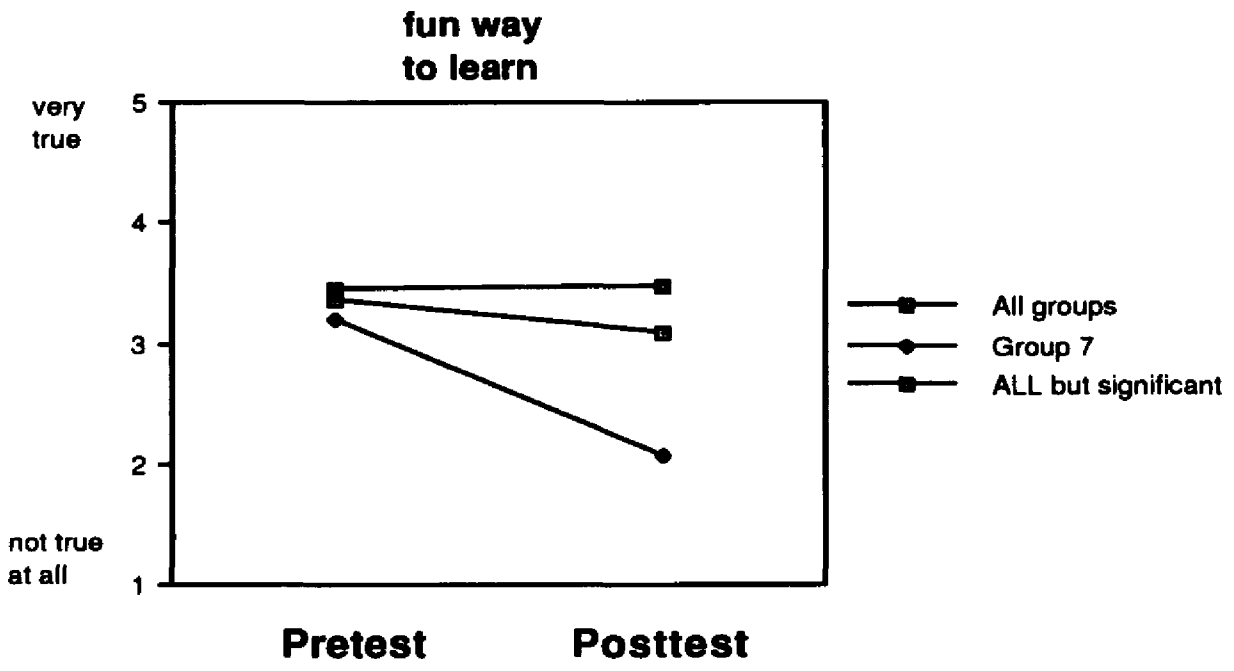

Figure 4h. Line graph for groups showing significant differences between pretest and posttest means for "fun way to learn"

Decreases in mean scores were also apparent for Group 3 (mean difference = -0.84) and Group 5 (mean difference = -0.78) for "fun to learn."

Perceptions of students in Group 7 significantly declined for "fun way to learn" in the course of the semester. Many of the students in this group, in fact, did not regularly use this technology and most likely had reservations in using it for obvious reasons. First, it was not required and students may have considered CC use as additional work with no incentive. Second, they were not taught how to use it and the potential benefits of its use were not even pointed out to them. Third, it was seldom used by both instructor and students. Fourth, CC was not integrated part of the course but rather considered as an alternative tool to communicate with the instructor. Thus, it may be a mistake on the part of the instructor to assume a "fingertip effect" in the successful use of CC, that is, providing

students with the technology will not automatically make them learn and use of it. There was a great deal of ambivalence and uncertainty involved with using CC if students had no prior experience with CC. The apparent lack of utility and importance of this technology for this group apparently did not contribute favorably to students' perception of CC as a "fun way to learn."

Summary

The brief discussions of the significant results for each perception item mainly focused on what seemed to be important group characteristics pertinent to the implementation and of CC. That is, the explanations of the results were primarily based on group differences in CC training, structure, use/tasks, goals, instructor's perceived CC knowledge, whether CC was a required part of the course, and the percentage to which CC use contributed to the students' final grade.

Overall, t-test and Wilcoxon signed rank test results for within group differences indicate that for all groups combined, there were significant decreases in all perception means, with the exception of "freedom from anxiety." Thus, Group 7 contributed most to these significant declines. Group 7 had significant declines in eight out of the nine perception measures namely, "worthwhile to learn," "valuable in learning course," "motivation to learn material," "motivation to participate in CC," "help understand material," "encourage in-class participation," and "student responses useful." Group 2 showed a significant decrease only in "encourage in-class participation." In addition, Group 8 also had significant decreases in perception scores for "help understand material," "encourage in-class participation." Several noticeable, though not significant, decreases in perception means were also noticed among several groups (e.g., Groups 3, 5, and 8) that did not reach significance level based on the Bonferroni-Dunn post hoc analyses.

In looking at the perception means of all groups for both the pretest and the posttest, some patterns were noticed. Groups 1, 2, and 6 exhibited relatively higher means

for the various perception items in both pretest and posttest. Some common features between these groups were their more structured, purposeful use of the technology, the contribution of student use of CC towards their final grade, the manner in which CC was introduced and taught, the structure of the conference items. In contrast, groups 7 and 8 illustrated significantly low means for the various items. These groups, Group 7 in particular, also showed higher frequency of significant mean decreases on the perception items. This pattern suggests that differences in both CC use and the method by which it was introduced that exist within and between these groups contributed to the significant differences in means. Students who found CC use to be an enjoyable experience were more likely to find it more beneficial and gain more from its use than those who either did not use it or did not find it to be a worthwhile experience. Although the findings did not support those of Conrath and Bair (1974), Hiltz (1978b, 1982), Hiltz and Turoff (1980), Johansen et al. (1978), and Rice (1980), who concluded increased user satisfaction with increased usage, it did however, complemented their finding that those users who find CC to be an enjoyable experience are more likely to find it to be more beneficial and gain more from its use than those who either did not use it or did not find it to be a worthwhile experience.

As mentioned earlier, Groups 3, 5, and 8 also experienced several noticeable mean decreases in the perception items, but such decreases did not achieve significance which may have been largely due to insufficient data or sample size. Nonetheless, several common features between these groups which may have contributed to the decrease in student perception scores were that CC was considered to be "optional," CC use did not contribute to student final grade, no lab sessions were provided for hands on training of CC, there was lack of integration between CC use and the learning tasks, and there was lack of focus in conveying the idea of CC as a beneficial learning tool rather than simply an alternative way of communicating with one another.

Significant mean differences in pretest perception scores between groups

Although the following correlational analyses was not a major question posed in this study, it may serve to supplement and explain the significant pretest-posttest differences within groups by looking at initial differences in student perceptions between groups. This analyses was deemed necessary to account for between group mean differences in student pretest perception scores. Therefore, ANOVA and Bonferroni-Dunn tests were used to determine intergroup mean differences among the pretest perception items. The significance level of the group comparisons was determined to be significant at $p < .0064$.

Significant pretest perception differences between groups may be indicative of the influence of the variations in the way CC was introduced to each group, how students were taught or trained, the structure of the conference, initial tasks and goals conveyed by the instructor to the students, instructor's perceived CC knowledge and experience, and the extent to which CC contributed to a student's final grade. These results could provide important insight on effective ways to introduce and encourage the use of CC, and to enhance student acceptance of this technology as an instructional tool.

Perception item (pretest) (df=7, residual=245)	Sum of Squares	Mean Square	F-value
worthwhile to learn	16.87	2.41	3.12*
valuable in learning course	52.78	7.54	8.51**
freedom from anxiety	18.09	2.58	1.88
motivation to learn material	58.58	8.37	7.82**
motivation to participate in CC	60.98	8.71	8.63**
help understand material	20.28	2.90	3.17*
encourage in-class participation	40.21	5.75	4.46*
student responses useful	32.34	4.62	4.34*
fun way to learn	25.71	3.67	3.23*

*significant at $p < .01$
**significant at $p < .0001$

Table 3. ANOVA results determining significant mean differences between groups for pretest perception items

The ANOVA results shown in Table 3 are supportive of the t-test and Wilcoxon signed rank test findings for all groups combined. Thus, there were significant mean differences in perception scores between groups for both the pretest and the posttest, with the exception of "freedom from anxiety."

For post hoc testing, separate ANOVA procedures for unpaired group comparisons were done to test for significant differences in student perception means for the pretest. Significant differences in pretest perception means between groups using the Bonferroni-Dunn test (significance level of $p < .0064$) was only found between Groups 1 and 7 for "motivation to learn material," with a mean difference of 1.24 in favor of Group 1. This suggests that the differences in implementation and use of CC between these two groups had a considerable impact in shaping student perception towards CC. The descriptions shown in Table 1 reflect several major differences between Group 1 and Group 7 which somewhat typifies opposite sides of a continuum. As mentioned, Group 1 provided effective training to students in which the structure and use of the conference adhered to the goals set for the use of CC. Important factors that may have contributed to the highly significant difference may also be attributed to the contribution that CC use played in determining student final grade and whether it was considered a requirement for the course. Thus, favorable initial perceptions towards CC is largely shaped by these factors.

Nonetheless, because there were several significant group mean comparisons for the pretest perception items at $p < .01$ which may be meaningful, a tabular summary of these comparisons is shown in Appendix K. Note that these comparisons were not statistically significant based on the conservative alpha level of $p < .0064$ determined by the Bonferroni-Dunn test. However, providing this visual summary is helpful in determining noticeable patterns that exist in comparing relatively large group mean differences across the various pretest perception items. These pretest perception mean comparisons show that Group 1 had significantly higher perception means than Group 7 for "valuable in learning course," "motivation to learn material," "motivation to participate in CC," "encourage in-class participation," and "student responses useful." Group 1 had significantly higher mean scores than Group 8 for "valuable in learning course" and "motivation to participate in CC." Moreover, Group 1's means were significantly greater than Group 3's for "valuable in learning course" and "motivation to learn material." Group 2 had significantly

higher perception means than Group 7 for "motivation to learn material," "motivation to participate in CC," and "encourage in-class participation." Group 6's mean for "motivation to participate in CC" was significantly higher than those of Groups 7 and 8.

In brief, looking at both the pretest perception means (Appendix I) and the large pretest mean differences in certain group comparisons (Appendix K), some patterns were noticed. Groups 1, 2, and 6 generally have higher pretest perception means. Again, these differences my be attributed to the way CC was initially introduced to the students and in terms of student knowledge of the extent to which CC use contributed to their final grades. Interestingly, Groups 1, 2, and 6 not only provided students with handouts and lab sessions to supplement student training of CC, but these groups also required CC use, provided a conference structure that was integrated to the learning tasks of the course, and student participation in the conference contributed significantly to their final grade. In addition, the predominance of academic or class-related items in these conferences seems likely to make students perceive the conference as a relevant component in their learning of the course. Instructor's perceived CC knowledge and experience also seemed to have a great influence in student perception. Thus, this indicates that student perception of CC, and its actual use by students, were greatly influenced by these factors.

Correlation between Student Perception Measures and the MSLQ

This section presents the results and briefly discusses the significant correlations between the student perception measures and student cognitive-motivational characteristics. Pretest and posttest correlations for each group are discussed separately, although this was not a major question of the study. Thus, the discussion focused on deriving noticeable patterns of correlations for all groups combined.

Table 4 shows significant correlations for all groups combined between student perception items of CC use and student cognitive-motivational characteristics in both pretest and posttest measures of student perception. There were several significant correlations found. Nonetheless, in order to minimize the complexity of this analyses, only the most significant correlations are reported in Table 4, that is, those having a Pearson r value greater than +0.2 or lower than -0.2, $p < .01$.

Means and standard deviations of the MSLQ subscales for each group and all groups combined are shown in Appendix L.

	Pretest		Posttest	
Perception Item	MSLQ subscale (N=209)	r*	MSLQ subscale (N=164)	r*
worthwhile to learn	RTT	0.21	TA	-0.22
	TH	0.21	TH	0.26
	IM	0.33	IM	0.26
	EM	-0.30	EM	-0.24
	TV	0.20	TV	0.24
			SE	0.22
valuable in learning course	TH	0.24	TSM	0.31
	IM	0.35	ES	0.20
	EM	-0.21	TA	-0.21
			TH	0.26
			IM	0.30
			EM	-0.28
			TV	0.24
			SE	0.22
freedom from anxiety	TA	-0.30	TA	-0.24
	EM	-0.21		
	SE	0.22		
motivation to learn material	TH	0.21	TSM	0.30
	IM	0.21	ES	0.25
	TV	0.22	TA	-0.23
			TH	0.30
			IM	0.30
			EM	-0.30
			TV	0.25
			SE	0.20
motivation to participate in CC	TSM	0.22	TSM	0.27
	TH	0.25	ES	0.25
	IM	0.29	TA	-0.23
	EM	-0.21	TH	0.30
	TV	0.20	IM	0.30
			EM	-0.26
help understand material	IM	0.20	TSM	0.26
	TV	0.22	ES	0.29
			TH	0.31
			IM	0.27
			EM	-0.29
			TV	0.23
			SE	0.23

*$p < .01$

(continued next page)

	Pretest		Posttest	
Perception Item	MSLQ subscale (N=209)	r*	MSLQ subscale (N=164)	r*
encourage in-class participation	ES	0.22	TSM	0.24
	RTT	0.21	TH	0.24
	TH	0.23	IM	0.31
	IM	0.21	EM	-0.27
	TV	0.21	TV	0.23
			SE	0.21
student responses useful	PL	0.21	TSM	0.26
	TH	0.2	ES	0.24
			TH	0.23
			IM	0.25
			EM	-0.27
fun way to learn	TH	0.21	ES	0.22
	IM	0.27	TH	0.25
	EM	-0.2	IM	0.31
			EM	-0.27

*p < .01

Abbreviations:
TSM - Time/Study Management
ES - elaboration strategies
PL - peer learning
RTT - retrieval/test taking
TA - test anxiety
TH - thinking
IM - intrinsic motivation
EM - extrinsic motivation
TV - task value (utility)
SE - self-efficacy

Table 4. Significant Correlations (Pearson r) between Student Perception Items (pretest and posttest) and the MSLQ for all groups combined. (Criteria: -0.2 > r >0.2, p < .01).

The main purpose of determining significant correlations between student perceptions and cognitive-motivational characteristics was to determine general patterns of correlations across the various perception measures that show what student characteristics are more salient in the kind of perception students form regarding the instructional use of CC. Pretest correlations pertain to which variables are important to consider in developing ways to introduce CC, while posttest correlations supplements the pretest findings in

determining variables that may contribute to student perceptions of CC after actual use over a period of time.

As mentioned, although beyond the scope of this study, results comparing intergroup correlations is shown but with the absence of an in-depth discussion on the matter.

Pretest student perceptions and the MSLQ

Motivational characteristics.

For all groups combined, intrinsic motivation (IM) was determined to be significantly correlated with all perception items, with the exception of "freedom from anxiety" and "student responses useful." IM, from a goal-orientation perspective, refers to the degree in which a student perceives himself or herself to be participating in a task for reasons such as challenge, mastery, or curiosity. It indicates that the student participation in the task is rewarding in itself, rather than looking at participation being a means to an end. Students who are highly intrinsically motivated in the learning of the course are readily more accepting of a novel method of instruction (i.e., CC) than those who are highly extrinsically motivated.

Extrinsic motivation (EM) was found to be inversely correlated with most perception items. This refers to the degree to which a student perceives oneself to be participating in a task for reasons such as rewards, grades, competition, and evaluation by others. Engaging in a learning task is viewed as a means to an end. Thus, students with high extrinsic motivation tend to perceive CC use more negatively, perhaps because these students perceive the learning and use of this technology as additional work for them.

Task value (TV) was found to be positively correlated with "worthwhile to learn," "motivation to learn material," "motivation to participate in CC," "help understand material," "encourage in-class participation." Task value refers to the student's evaluation or perception of the level of interest, importance, and usefulness of the learning task. It relates to what the student thinks of the task as opposed to goal orientation (e.g., IM, EM)

which refers to the reasons why a student is participating in the task. High task value leads to more involvement in learning. The high correlation suggests that what students think of the value of the course is an important characteristic in their perception of the use of CC as an instructional tool. The recognition that the tasks associated with a course are useful and important lends itself to the perception that CC is a potentially useful tool in the learning of the material.

One seemingly important motivational characteristic that was highly correlated with "freedom from anxiety" was self-efficacy (SE). It is presumed that students that have high confidence in one's ability to accomplish a learning task tend to be less anxious in using CC. Further research, nonetheless, should explore these correlation.

Cognitive characteristics.

Thinking skills (TH) was the major cognitive variable found to be highly correlated with many of the perception items. TH refers to the degree to which a student applies previous knowledge to relatively new learning situations in order to reach decisions, solve problems, or make critical evaluations. The use of CC as an instructional method may have been evaluated more favorably by students scoring high in TH because they critically recognize and acknowledge the educational potential of such medium. Thus, this cognitive characteristic appears to be a salient factor in developing more positive perceptions towards CC.

Other important cognitive characteristics that were highly correlated with some perception items were retrieval and test taking strategies (RTT) which was highly correlated with "worthwhile to learn"; self-efficacy (SE) which was found to be highly correlated with "freedom from anxiety"; time and study management (TSM) which was determined to be positively correlated with "motivation to participate in CC"; elaboration strategies (ES) which was found to be highly correlated with "encourage in-class participation"; and peer learning (PL) which was positively correlated with "student responses useful." Further research should explore these correlations.

In brief, the correlational findings between the pretest perception measures and the MSLQ suggest that the important student variables that may influence acceptance and positive perceptions towards CC use are IM, EM, and TV for the motivational domain, and TH for the cognitive domain. Instructional strategies that complement the introduction and use of CC should consider these variables as most crucial predictors, not only of student perceptions, but of the successful implementation of CC.

Posttest student perceptions and the MSLQ.

Interestingly, for the posttest analyses with all groups combined, several interesting patterns were also observed. Similar to the results for the pretest, the MSLQ items that show significant positive correlations with the perception items were IM, TH, and TV. Other variables found to be significantly proportional to several perception items were time and study management (TSM), elaboration strategies (ES), and self-efficacy (SE), while test anxiety (TA) was negatively correlated. In addition, EM was again shown to be inversely related to all perception items except "freedom from anxiety."

Motivational characteristics.

In addition to IM, self-efficacy (SE) was also determined to be highly correlated with all perception items except "freedom from anxiety," " motivation to participate in CC," "student responses useful," and "fun way to learn." Self-efficacy refers to one's self-appraisal of the ability to master a learning task, which includes one's ability and confidence towards such task.

As mentioned, EM was again found to have a significant inverse relationship with several of the perception items.

Cognitive characteristics.

Similar to the pretest findings, TH and TV were found to have a significant proportional relationship with several posttest perception items. In addition, similar results were determined for TA, TSM, and ES. First, test anxiety (TA) was found to be negatively correlated with "worthwhile to learn," "value in learning course," "freedom from

anxiety," "motivation to learn material," and "motivation to participate in CC." TA, viewed as a form of cognitive interference, refers to negative thoughts that disrupt the performance of a learning task. Second, time and study management (TSM), which was found to be correlated with "motivation to participate in CC" in the pretest results, was found to be in direct proportional relationship to all perception items except, "worthwhile to learn," "freedom from anxiety," and "fun way to learn." High ratings in TSM pertain to the ability to effectively schedule, plan, manage, and use their study time. In addition, it also suggests the ability to set realistic goals, organize their study environment, relatively free of visual and auditory distractions, in order to provide a setting most conducive to their learning. Fourth and last, elaboration strategies (ES) were also determined to be highly correlated with several of the perception items except "worthwhile to learn," "freedom from anxiety," and "encourage in-class participation." Elaboration strategies involve the ability to store information into long-term memory by building internal connections among items learned which include paraphrasing, creating analogies, summarizing, and generative note-taking. These help the learner integrate the material to be learned with prior knowledge.

In summary, the cognitive and motivational characteristics mentioned above were determined to be most salient to student perceptions toward CC. For the pretest, these were IM, EM, and TV as the motivational variables, and TV as the cognitive variable. In the posttest correlations, in which students have actually used CC over a period of time, the important characteristics, in addition to the four mentioned for the pretest, were TA, SE, ES, and TSM. Thus, instructors need to be cognizant of these student characteristics in implementing CC as an instructional tool. Nevertheless, further research is needed to determine the strengths and possible causal links between these variables.

Correlation between perception items and MSLQ: Intergroup comparisons

Although the major focus of this analyses was to determine significant correlations between student cognitive-motivational characteristics and student perception of CC use for all groups combined, supplementary tables showing significant correlations for each group

between the pretest and posttest perception measures, respectively, and the MSLQ subscales is shown in Appendix M (pretest) and Appendix N (posttest). The most significant correlations have a Pearson r value greater than +0.3 or lower than -0.3, and a significance level of $p < .05$ (due to the lower sample size of each group compared to all groups combined).

The purpose of presenting these data on intergroup differences was only to supplement the analyses of all groups taken together to see if the correlations seen applies to each of the different groups. An in-depth analyses of such data, however, was not conducted in this study. Nonetheless, upon looking at the pretest and posttest analyses of the groups separately, there were some patterns noticed.

In the pretest analyses (Appendix M) for instance, there were more perception items that were significantly correlated with IM in Group 1, RTT in Group 2, EM in Group 6, and TV for Group 7. There were no consistent patterns of significant correlations across the different groups. However, there were correlational patterns observed within groups. The posttest analyses (Appendix N), similarly, showed no consistent pattern or correlations across groups. However, within group variations were again apparent. Some examples are as follows. Organizational strategies (OS) appeared to be positively correlated with many of the perception items in Group 2, and elaboration strategies (ES) in Group 3. Retrieval/test taking (RTT) strategies appeared to be negatively correlated with many of the perceptions items in group 4. Thus, the separate correlations for each group did not concur with the correlational results when all groups are combined. It is presumed that the different methods by which CC was introduced and used by the students contributed to the kind of results obtained. More research comparing correlational differences between and within groups may provide useful insight to explaining this phenomenon.

As mentioned, the correlational findings comparing the different groups is beyond the scope of the present study.

Descriptive Analyses of the Frequency of CC Interaction by Students

Analyses of the frequency of interaction (FOI) by students in the different groups were analyzed to provide insight on ways to enhance interactive discourse within the CC environment. Unlike the measures used in studies by Hiltz and Turoff (1978, 1980), Irving (1978), Johansen et al. (1977), this study is not an analysis of conferencing activities over time but rather focused on transcript data at the end of the conferencing period to determine conferencing interactions by students. Moreover, it is not a comparison of face-to-face versus teleconferencing communication such as those by Hiltz and Turoff (1977, 1982, 1986), Hiltz, Turoff, and Johnson (1986), and Williams (1977).

The measures that have been analyzed are indicative of the frequency of "interactive" communication/discourse by students, and not the content of their communication. Some of the measures are similar to those used by Saunders and Heyl (1988).

There were two sets of FOI measures -- qualitative and quantitative. The qualitative measures were categorized in terms of (1) citing, (2) agreeing/disagreeing, (3) questioning/commenting, (4) nonacademic matters, and (5) unclassified responses (i.e., others, not applicable). The code sheet for these qualitative transcript data is shown in Appendix F. The quantitative measures were (1) number of responses, (2) number of responses per item, (3) number of items created by student, and (4) number of lines per response.

The descriptive analyses is based on data from 40 randomly selected students, five from each group, from the total pool of 287. The responses of these students are assumed to be representative of the group to which they belong. In interpreting the results, however, it is important to be cognizant of the large differences among the number of items created in each group, which may greatly influence student FOI. For example, there were a

total of 107 item for the conference in group 1 which resulted in the greater frequency counts in the FOI measures.

Since textual communication (i.e., communication through writing) is an encouraged and necessary prerequisite to learning, especially in the context of CC, a descriptive analyses of these variables are presented comparing the different groups, given the variations in which CC was used in each group. The analyses of the results for this section may provide insight on ways to increase the frequency of interaction among students in their use of CC.

Qualitative measures of student frequency of interaction

Table 5a shows a frequency count of the categories of each of the FOI measures for all the sampled students and for sampled students within each group. Table 5b shows the mean frequencies of the FOI measures for all sampled students and for sampled students for each group.

Measure of FOI	ALL (n=40)	1 (n=5)	2 (n=5)	3 (n=5)	4 (n=5)	5 (n=5)	6 (n=5)	7 (n=5)	8 (n=5)
		Group							
total number of items created		(107)	(37)	(7)	(18)	(6)	(41)	(19)	(14)
Citing									
citing lecture/Prof.	195	172	12	0	4	2	0	2	3
citing TA	148	0	40	0	18	0	40	14	36
citing student	1024	667	64	0	77	1	247	6	62
citing text/reading	281	112	142	0	8	3	14	0	2
citing personal exp.	306	111	47	4	14	0	119	0	11
Agreeing/Disagreeing									
agree w. opinion	370	173	99	0	19	3	48	1	27
disagree w. opinion	151	65	70	1	1	1	9	1	3
Questionning/Commenting									
question about class	577	510	23	6	14	6	9	2	7
confer question	274	255	11	1	0	3	1	1	2
class comments	487	150	172	0	62	1	43	10	49
Nonacademic matters									
	628	215	46	6	72	8	210	12	59
Unclassified responses									
other	6	4	2	0	0	0	0	0	0
n/a	22	14	7	0	0	0	1	0	0

Table 5a. Frequency count of the categories of each of the FOI measures for all the sampled students and for sampled students for each group.

Measure of FOI	ALL (n=40)	1 (n=5)	2 (n=5)	3 (n=5)	4 (n=5)	5 (n=5)	6 (n=5)	7 (n=5)	8 (n=5)
		Group							
total no. of items created		(107)	(37)	(7)	(18)	(6)	(41)	(19)	(14)
Citing									
citing lect/prof	4.88	34.4	2.4	0	0.8	0.4	8	0.4	0.6
citing TA	3.7	0	8	0	3.6	0	0	2.8	7.2
citing student	25.6	133.4	12.8	0	15.4	0.2	49.4	1.2	12.4
citing text/reading	7.0	22.4	28.4	0	1.6	0.6	2.8	0	0.4
citing personal exp.	7.65	2.78	9.4	0.8	2.8	0	23.8	0	2.2
Agreeing/Disagreeing									
agree w. opinion	9.25	34.6	19.8	0	3.8	0.6	9.6	0.2	5.4
disagree w. opinion	3.78	13	14	0.2	0.2	0.2	1.8	0.2	0.6
Questionning/Commenting									
question about class	14.4	102	4.6	1.2	2.8	1.2	1.8	0.4	1.4
confer question	6.8	51	1.38	0.2	0	0.6	0.12	0.14	0.29
class comments	12.18	30	34.4	0	12.4	0.2	8.6	2	9.8
Nonacademic matters									
	15.7	43	9.2	1.2	14.4	1.6	42	2.4	11.8
Unclassified responses									
other	0.15	0.8	0.4	0	0	0	0	0	0
n/a	0.55	2.8	1.4	0	0	0	0.2	0	0

Table 5b. Mean frequencies of the FOI measures for all sampled students and for sampled students for each group.

(1) Citing

Overall, student interaction was characterized by the high frequency of citations of students by other students (e.g., In response to Jennifer's comments regarding extrasensory perception,. . .). However, these kinds of responses were more prevalent in

Group 1, followed by Groups 6, and then Groups 4, 2, and 8. In a conferencing environment, this finding is indicative of the importance of integrating learning tasks with the instructional use of CC. In addition, the frequency of citing personal experience (e.g., I had a friend who suffered an eating disorder. . .) and textual material (e.g., I thought that the article by Freud was interesting. . .) were also relatively common, although these activities were much more prevalent in Groups 1, 2, and 6. The incidence of citing the instructor (e.g., As the professor pointed out during lecture. . .) also varied between groups.

Groups 1, 2, and 6 had the highest incidence of citing various sources in the conference. The highest incidence of text/reading citations was in Groups 2 in which students used CC primarily to respond to items presented by the instructor which involved the use of course readings to back up arguments and statements that they made within their responses. Students primarily provided responses to items presented without much interaction among students. Thus, there was less interaction among students. In contrast, Groups 1 and 6 placed more emphasis on interactive communication among students. Responses that cited other students were thus more prevalent in these two groups. Students in most groups had the tendency to cite the instructor they interact with more closely in class. Thus, Groups 1 and 6, which were supervised by professors had students citing lecture and professors more often than those headed by teaching assistants (TAs). Groups 1 and 2 had the highest incidence of citing textual or reading materials, while Groups 1 and 6 had the highest incidence of sharing of personal experiences which may be attributed to the higher degree of rapport among students in these classes. Students in groups 3, 5, and 7, in contrast, cited infrequently. Students may not have found it necessary to respond to one another, to the instructor, nor to their readings and personal experiences. Based on the instructional tasks involved in CC use in these groups, citations may not have been a crucial and encouraged part of their conference. There were high proportions of nonacademic communication by students. Many of the class-related

responses, as well as items, for these groups were exam- or assignment-related questions (e.g., grading, test format), and therefore did not require students to cite course material or to respond to one another unless there was a specific question posed to them. The presence of well-constructed academic items, required use of CC, and CC tasks that are well-integrated into the course, all appear to be contributing factors to the frequency of CC interaction among students.

On average, a student in Group 1 made more citations, followed by Group 6, 2, 8, and 4.

(2) Agreeing/Disagreeing

Overall, there was a greater frequency of agreement with another's opinion than disagreement within the conferencing environment (e.g., I definitely agree with Chris' idea on Behaviorism. . .). Despite the greater sense of "anonymity" in a conferencing environment compared to in-class discussion, students more often agree with issues they discussed.

Again the highest incidence of interaction in terms of agreeing or disagreeing another's opinion was observed in groups 1, 2, and 6. Students in these sections frequently commented on one another's responses and often expressed their own opinions. In groups 3, 5, and 7 there was a much lower frequency of agreement and disagreement noted among participants indicating that these students did not see this activity as a part of CC communication in the course. CC use in these groups developed into exam reviews, questions regarding assignments in class or other nonacademic issues. Thus, students may not have been encouraged to express differences or similarities of opinion with one another.

On average, a student in Group 1 made more responses that agreed/disagreed with another's opinion, followed by Groups 2, 6, 8, and 4.

(3) Questioning/Commenting

Student questions about class-related issues (e.g., Does anyone really think that eyewitness testimony should "always" be a credible source of information in court?) and about CC (e.g., How can I delete previous lines of text I typed?) was proportionally high in Group 1 compared to the other groups. Class comments was proportionally higher, however, in Group 2, followed by Groups 4, 8, and 6. In terms of frequency, Group had the second most number of course-related comments, next to Group 2.

Class-related and CC questions were most frequently observed in Group a, while general comments about the class were highest for Groups 1 and 2. The highest incidence occurred in groups 1 and 2, of which discussion on CC mostly pertained to class related items weekly which was in accordance with class readings and lecture topics. Students in Group 1 were more likely to ask for assistance with the use of CC because of the expertise of their instructor in CC. Furthermore, the students had more items that they had to respond to, which may have encouraged them to initially ask more questions regarding CC use in their class.

Groups 3, 5, and 7 again demonstrated the lowest incidence of questioning or comments. These groups showed a lack of participation in the conference resulting in minimal interaction by students. It was probable that students found CC was not the most appropriate venue to address questions and to receive immediate feedback or clarification from the instructor or from other students.

On average, a student in Group 1 had comparably more class-related and CC questions than any of the other groups. However, the average student in Groups 1 and 2 had more class-related comments followed by Groups 4, 8, and 6.

(4) Nonacademic Responses

Overall, nonacademic responses (e.g., Everyone is invited at the "club" tonight. It's Friday, so have some fun.) from students were quite frequent, considering that the major objectives of these classes were to use CC to supplement class discussion. Apparently, a CC environment should provide students with the capability of

communicating social or nonacademic topics. It is probable that this medium may be intrinsically motivating many students in using the technology. If this is the case, CC instructors should look into integrating a non-academic item within their conferences.

Groups 1 and 6 had the highest frequency of nonacademic responses among all groups. Therefore, the average student in these classes made more nonacademic responses than any of the other groups. These two sections represented students who used CC the most, and exhibited the highest degree of interaction among students. Proportionally, group 2 scored very high in degree of citing among participants rather than nonacademic issues because CC was designed primarily to encourage class-related discussion. Group 4 and 8 also had a proportionally fair number of nonacademic responses. The lack of a definite agenda of topics to discuss among these groups may have contributed to such finding. Many items were not related to class concepts and thus a higher degree of nonacademic or social material was observed within their group conferences. Groups 1, 5, and 7 represented the lowest scores in degree of nonacademic discussion. This can most likely be understood in terms of the general pattern of CC use found within these sections. There was little participation among these groups in general.

(5) Other responses

Groups 3, 4, 5, 7, and 8 demonstrated no incidence of CC interaction that were nonclassifiable (i.e., other, not applicable). Most of the students' responses were categorized in one of the other measures of frequency of interaction. The other groups, nonetheless, had a very low frequency of nonclassifiable responses, with the highest being Group 1 which, for the most part, may simply be a result of the high degree of CC use among its students. Therefore, there are no further discussion of this measure.

Quantitative measures of student frequency of interaction

Quantitative data was also obtained to provide the frequency of communication that transpired within the conferencing period for each of the different groups. Table 5c shows

the means and standard deviations of the quantitative FOI measures for all sampled students and for sampled students within each group.

	Group								
Measure of FOI	ALL (n=40)	1 (n=5)	2 (n=5)	3 (n=5)	4 (n=5)	5 (n=5)	6 (n=5)	7 (n=5)	8 (n=5)
Total no. of items in conference		(107)	(37)	(7)	(18)	(6)	(41)	(19)	(14)
no. of responses									
Mean	65	302	38	3	35	5	47	3	17
SD	(105)	(39)	(15)	(2.5)	(22)	(3.6)	(46)	(3)	(12)
no. of responses per item									
Mean	1.24	2.82	1.03	0.38	1.92	0.77	1.15	0.18	1.33
SD	(1.1)	(.34)	(.41)	(.26)	(1.25)	(.6)	(1.1)	(.16)	(.95)
no. of items created by student									
Mean	0.58	0	0	0.4	0.2	0.2	3.25	0.14	0
SD	(1.5)	(0)	(0)	(.8)	(.45)	(.45)	(2.4)	(.38)	(0)
no. of lines per response									
Mean	7.3	20.4	10.4	2.2	6.1	3.5	6.0	2.64	5.7
SD	(7)	(5.2)	(3.1)	(1.1)	(2.2)	(2.1)	(4.5)	(.73)	(4.7)

Table 5c. Means and standard deviations of the quantitative FOI measures for all sampled students and for sampled students for each group.

(1) Average number of responses.

The average student in Group 1 made the most number of responses, followed by Group 6, 2, 4, and 8. Due to the enormous number of items created in Group 1 (N=107) that students had to respond to, the finding was not surprising. Thus, the findings on student number of responses were primarily a function of the number items created for the conference and the whether CC use was a required part of the course.

(2) Average number of responses per item.

An average Group 1 student had the greatest number of responses per item of the conference, followed by Groups 4, 8, 6, and 2. This suggests that the required use of CC and the integrated use of this technology in the course may influence student frequency of response to the conference. Note that 4 and 8 did not require its use but there were relatively few items that students may have responded to in comparison to Groups 1, 2, and 6.

(3) Average number of items created by student.

Only Groups 1 and 2 did not allow students to be able to create items. Students in all groups, with the exception of Group 6, generally did not take advantage of this option. Group 6 students, however, were encouraged to create items they thought would generate interesting discussion for the class.

(4) Average number of lines per response

Group 1 students, followed by those in Group 2, seem to type longer responses to items. This is generally because of the nature of the items created. For these groups, items posed were generally presented in the form of a question or series of questions that a student is required to respond to. Items created in the other groups primarily required quick answers to inquiries or general comments about class-related, or academic issues. Students in these groups, did not have to fully elaborate on their responses but relied on quick and speedy exchange of ideas.

Summary

Groups 1, 2, and 6 all demonstrated a relatively higher frequency of CC use of CC which may be attributed to higher levels of intrinsic interest, the manner in which CC was presented to students, and interest in the items presented on CC. The descriptive analyses of the student transcript data generally suggests that the frequency of interaction (FOI) among students may be increased by requiring the use of CC, incorporating CC use in learning tasks, develop ways to encourage and motivate students to use the conference as a

major source of learning in the course. Otherwise, students may be inclined to rely more on face-to-face communication instead of realizing the benefits of this technology. But if CC is to be effectively used by students as an extension of classroom learning and discussion, it is important that students perceive this technology as important to their learning in the course. Moreover, similar to the findings of Saunders and Heyl (1988), the study indicated that CC is most appropriate for courses (e.g., Introductory Psychology) that particularly encourage exchange of ideas/opinions, discussion of (dis)agreements, and requesting suggestions. This is evident for Groups 1, 2, and 6 in which there were relatively high frequency of student interaction.

Student Comments and Suggestions on CC Use as an Instructional Tool

This section focuses on the presentation of the "proportional comparisons" of student comments and suggestions among the different CC groups due to large differences in the number of student comments and suggestions between the groups. Based on the conceptual framework presented in Figure 3, these responses were categorized or coded as either relating to cognition/learning, motivation/efficacy, instructional task/use, or other (unclassified responses). The specific responses of the students, though important, were not discussed in detail. The discussion of results focused on the categories (i.e., cognitive, motivational, instructional components) in which these specific student responses fall in order to determine and compare the saliency of these constructs in view of the proposed model. These results also provide supplementary information in designing the structure and use of the conference that would encourage positive perceptions for students and enhance CC use as an instructional tool.

Appendix C presents the code sheet for categorizing student comments and suggestions, and provides examples of responses belonging to each category. In addition, discussions of intergroup comparisons were limited to the proportional contributions of each of these categories. The analyses of the results in this section is deemed important in determining ways by which CC may be effectively introduced to students and used as an instructional method to supplement the course.

Table 6 shows the frequency count of these student comments and suggestions for each group and for all groups combined. These student comments and suggestions, obtained in the students posttest perception questionnaire (see Appendix B, Part 2), pertain to the following: (1) benefits of CC use, (2) drawbacks of CC use, (3) how CC can best be taught, (4) what the student like most about CC use in class, (5) what the student like least about CC use in class, and (6) suggestions on how to improve CC use to benefit their learning of and motivation for the course.

Item - code	ALL (n=40)	1 (n=5)	2 (n=5)	3 (n=5)	4 (n=5)	5 (n=5)	6 (n=5)	7 (n=5)	8 (n=5)
	Group								
CC benefits									
1	44	25	8	0	2	1	1	4	3
2	94	15	28	2	7	2	13	15	12
3	55	13	17	2	0	0	0	11	12
9	16	0	1	2	0	1	0	8	4
CC drawbacks									
1	5	3	0	0	0	0	0	0	2
2	65	8	11	1	3	2	6	24	10
3	108	32	31	2	6	1	3	12	21
9	18	2	4	2	0	0	3	4	3
Teaching/training									
1	6	2	1	0	3	0	0	0	0
2	45	7	19	2	1	1	4	5	6
3	82	21	13	3	3	1	1	32	8
9	24	4	9	2	0	1	1	5	2
Attitude-like most									
1	11	6	5	0	0	0	0	0	0
2	129	32	33	3	5	1	12	23	20
3	18	1	6	0	3	2	0	5	1
9	12	0	0	2	0	0	0	6	4
Attitude-like least									
1	0	0	0	0	0	0	0	0	0
2	80	17	18	3	5	1	5	21	10
3	68	22	21	1	2	2	2	7	11
9	10	1	2	1	0	0	0	3	3
Suggestions									
1	1	1	0	0	0	0	0	0	0
2	48	12	22	0	3	1	2	4	4
3	69	12	15	4	4	1	1	25	7
9	17	1	5	0	0	1	1	3	6

codes: 1-cognition/learning
2-motivation/efficacy
3-instructional task/CC
9-other

Table 6. Frequency distribution of coded qualitative student data pertaining to computer conferencing benefits, drawbacks, attitudes, and suggestions.

Perceived benefits of CC.

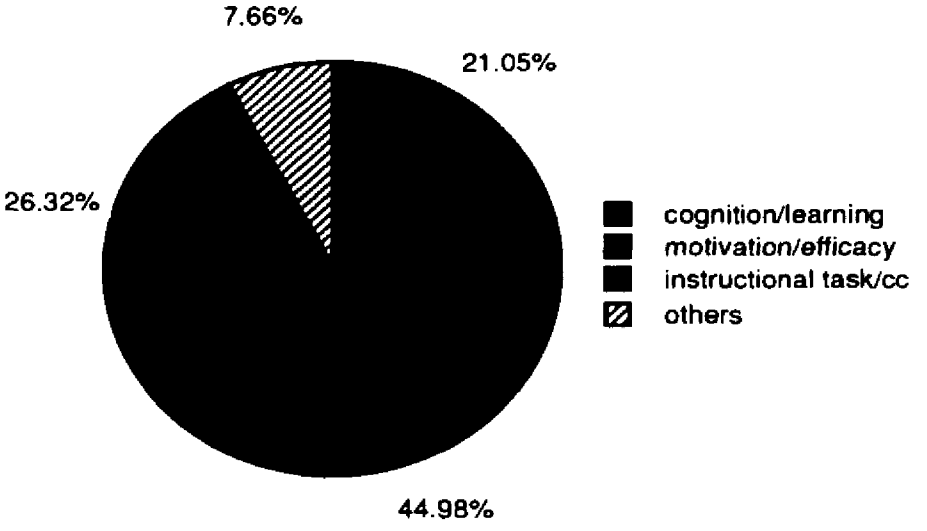

Figure 5a. Pie chart on the benefits of CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for all sampled students.

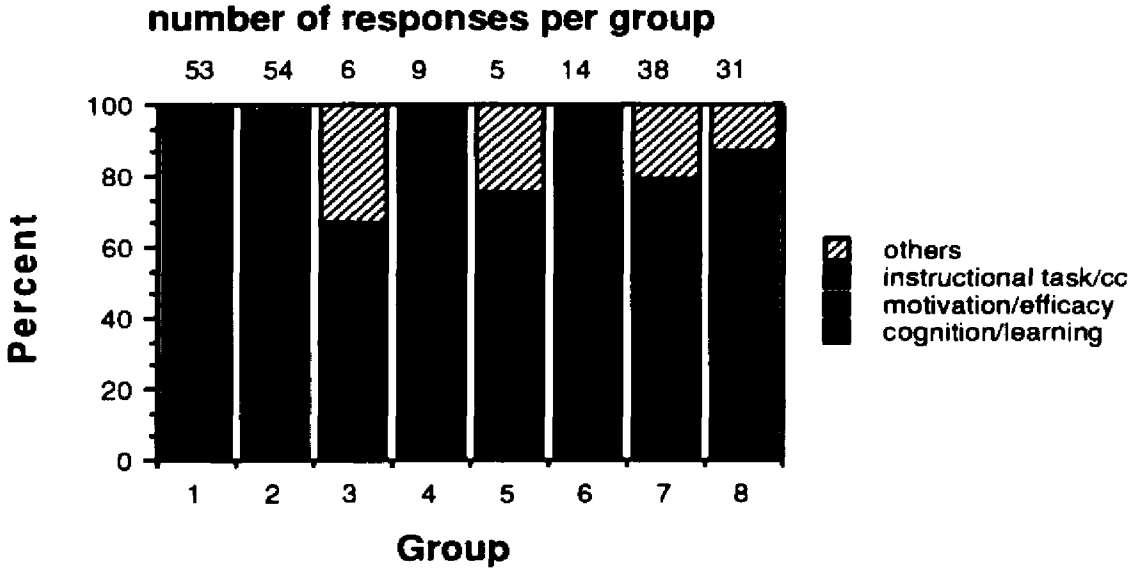

Figure 5b. Stacked bar graph on the benefits of CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for sampled students in each group.

Interestingly, majority of the students who responded to this question found the motivational aspects of CC use to be most beneficial to them (e.g., I really enjoyed being able to interact and get to know others in class.). They often mentioned that it was a convenient and efficient way of meeting and getting to know people in class, while others thought that it was the novelty of it all that was motivating. A fair number of students mentioned benefits relating to cognition/learning in which many of them pointed out that it allowed them to learn from other students' responses, and made them think about issues presented in class more. Similarly, a number of students thought that it was most beneficial because of the instructional tasks involved in their use of CC (e.g., learning CC). They mostly mentioned that this would be beneficial to their learning of computers in general, and the Michigan Terminal System. In addition, many of them thought that this was an efficient way to communicate with the instructor if they have class-related questions.

Students in Group 1 had more responses related to cognitive/learning benefits of CC than of instructional or motivational benefits, although a fair number of responses were found to relate to these categories as well. Group 2, 4, 5, 6 and 7, in contrast, demonstrated a higher proportion of responses relating to motivation/efficacy. Groups 1, 2, 3, 7, and 8 had relatively large proportions of student perceived benefits relating to instructional tasks.

Perceived drawbacks of CC.

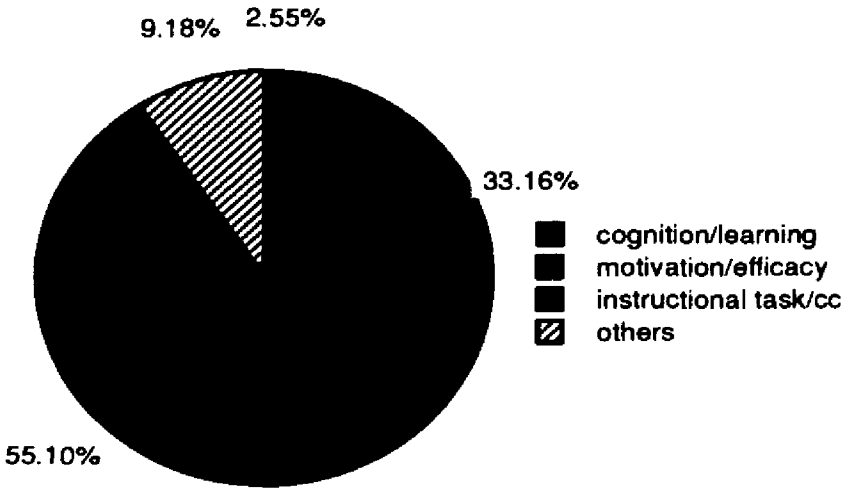

Figure 6a. Pie chart on the drawbacks of CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for all sampled students.

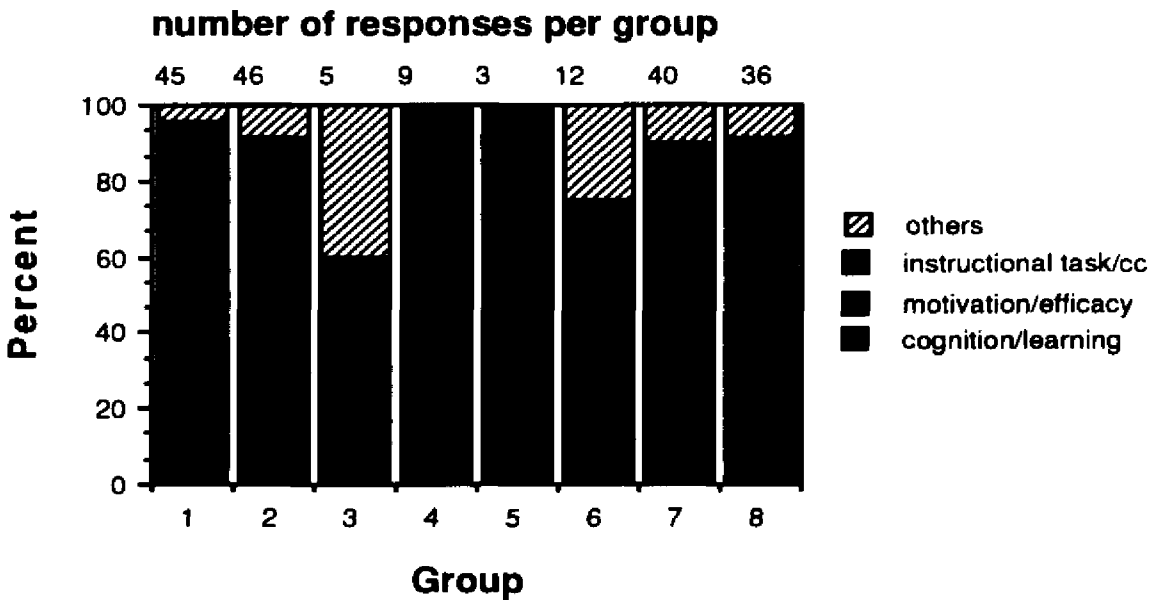

Figure 6b. Stacked bar graph on the drawbacks of CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for sampled students in each group.

Overall, many students also found that the drawbacks of CC use pertained largely to the instructional tasks that they have to do through this technology. For example, many of them thought that learning CC was simply additional work to them that could do without in their learning of the course. Initially, many of them experienced difficulty and frustration in learning how to function in the CC environment, finding time to sign-on and respond to items, and accessing available computers to use on campus. The next largest proportion of responses related to motivation/efficacy suggesting that many students found CC use to be unmotivating and impersonal.

Perceived drawbacks relating to instructional tasks were proportionally greater in Groups 1, 2, 4, and 8. Many responses pointed to the difficulty experienced in learning to use the conferencing system, accessing available computers on campus, and finding time to sign on and respond to items. It is especially noticeable in Groups 1, 2, and 8. Students were required to respond in Groups 1 and 2, and were therefore subjected to the pressures of meeting deadlines and requirements.

Groups 5, 6, and 7 showed a higher proportion of perceived CC drawbacks relating to motivation. This indicates that many students in these sections found CC to be unmotivating, and did not contribute much to their learning of the course and their participation in class.

Teaching/training suggestions on CC use.

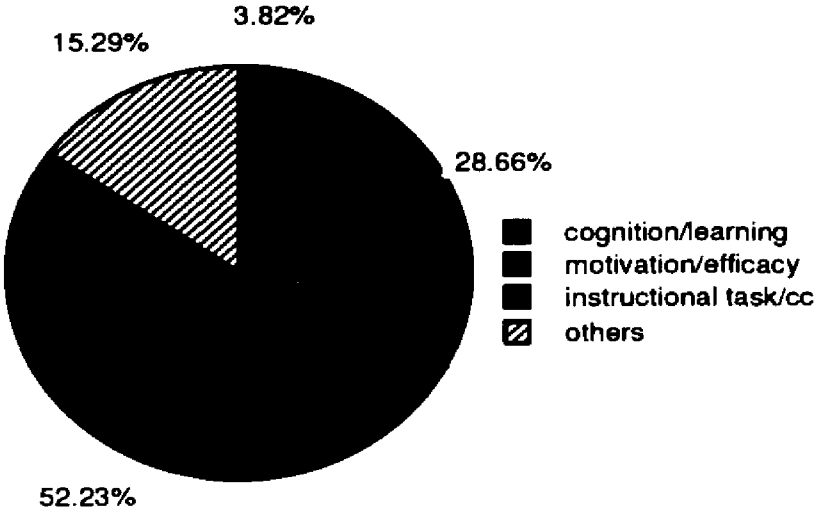

Figure 7a. Pie chart on teaching/training suggestions on CC use comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for all sampled students.

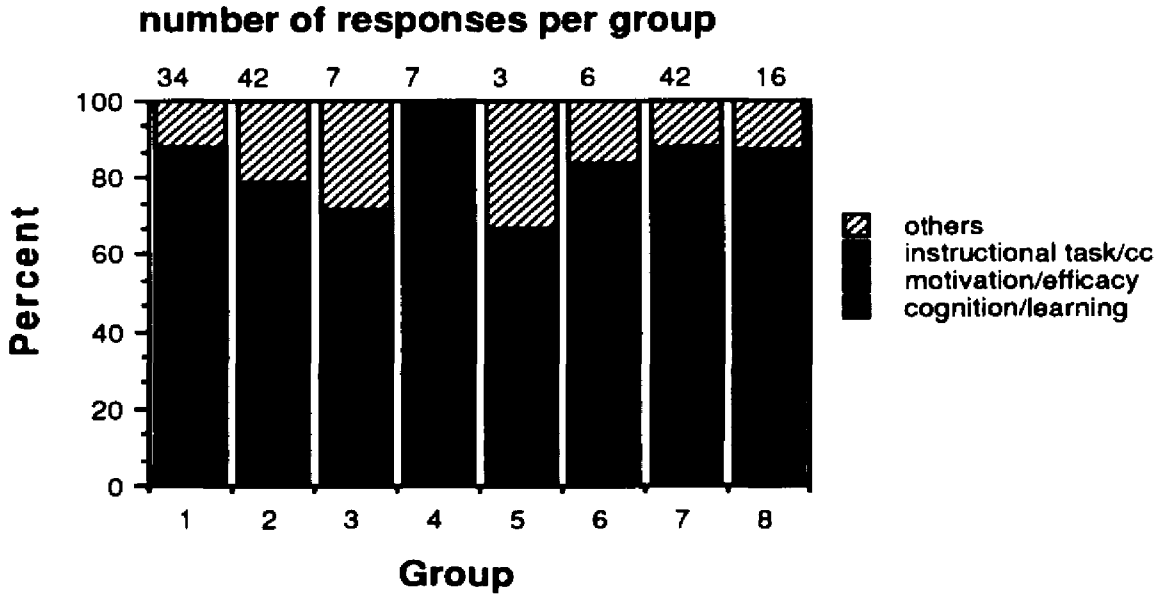

Figure 7b. Stacked bar graph on teaching/training suggestions for CC use comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for sampled students in each group.

There were proportionally greater suggestions relating to instructional tasks associated with CC use (e.g., lack of sufficient training, difficulty in learning CC), followed by motivation/efficacy (e.g., communicating via CC was not enjoyable, impersonal, felt pressured to participate). Groups 1, 3, 7, and 8 typified this finding. Suggestions relating to motivational aspect of CC use followed for students in many groups. Only sections 1, 2, and 4 offered suggestions relating to cognition or learning.

What Students like most about CC.

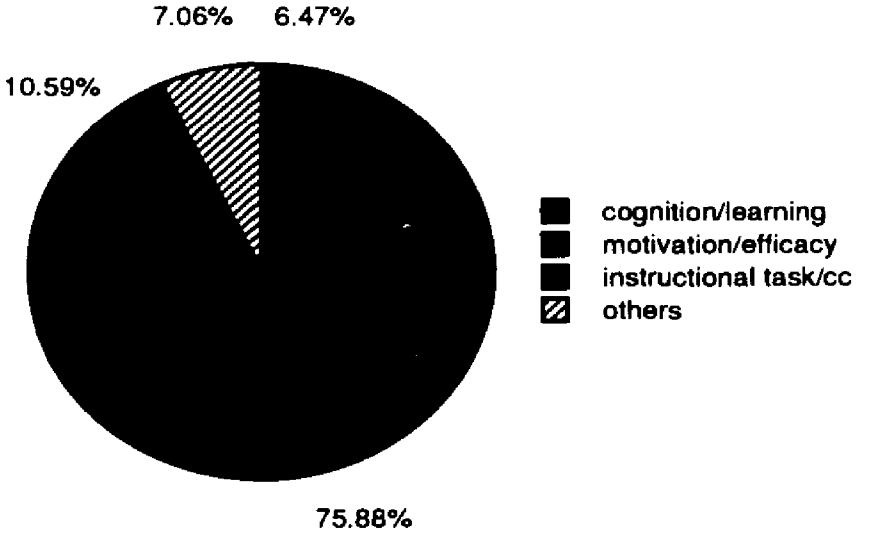

Figure 8a. Pie chart on what students like most about CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for all sampled students.

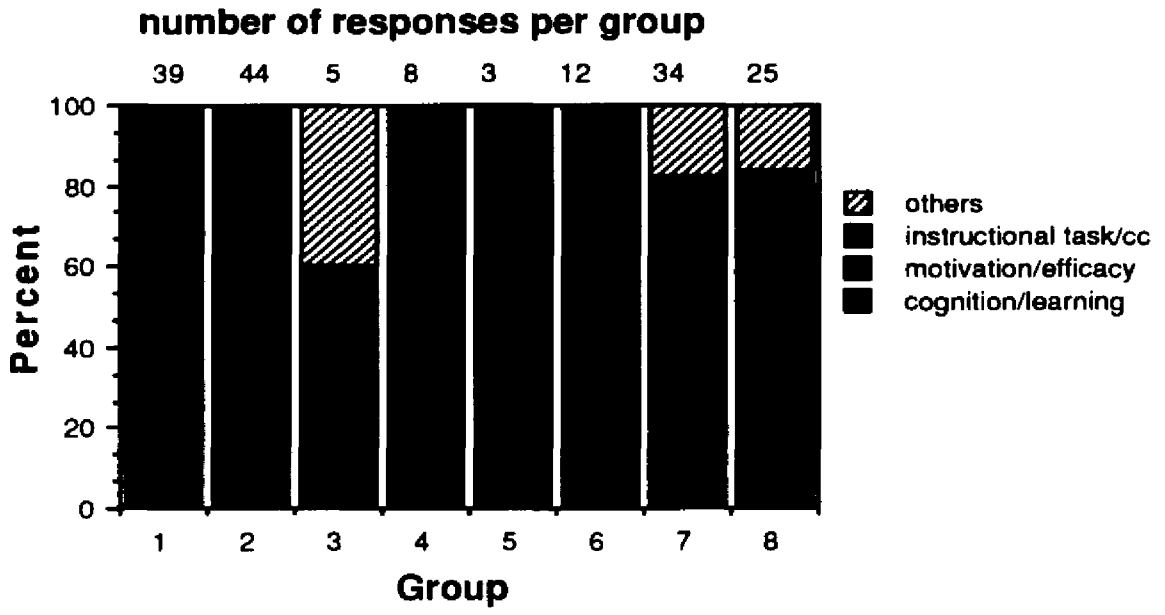

Figure 8b. Stacked bar graph on what students like most about CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for sampled students in each group.

Motivational factors were most prevalent in the responses that students offered in view of what they liked about CC. It is apparent for nearly all groups that the motivational qualities of CC were what many students liked, such as interaction between students, exchange of ideas, fun using computers, etc. Responses of this nature were especially prevalent in all groups, except in Group 5. Students who had participated in these groups enjoyed their use of CC having described their likes as motivational in nature, and these section all represented a high degree of CC usage. In Group, 6 only motivational responses were offered.

Groups 1 and 2 were the only two groups that pointed to CC use a contributing to their learning of the material, that is, learning/cognition. This may be because CC was emphasized most as a learning tool in these sections, with students having to respond to class-related items. The other groups did not have as much strong emphasis placed upon

using CC as a tool to enhance learning of the material, at least explicitly, than these two groups.

What Students like least about CC.

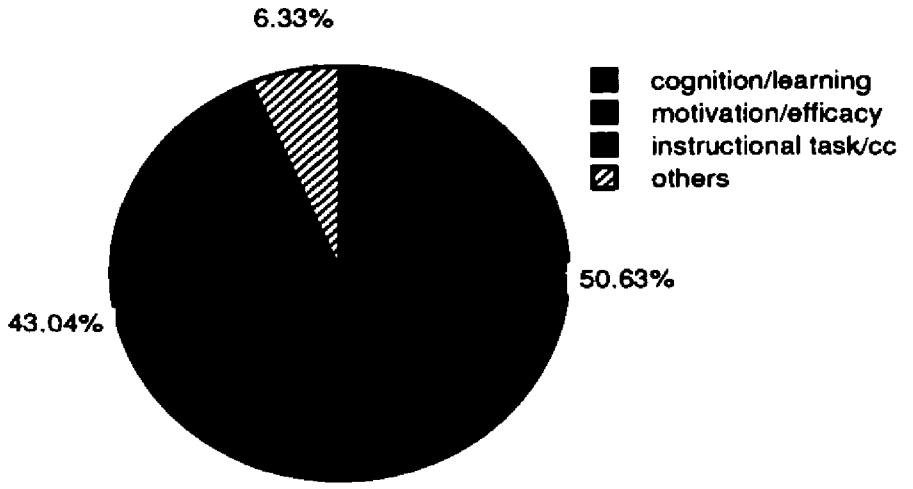

Figure 9a. Pie chart on what students like least about CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for all sampled students.

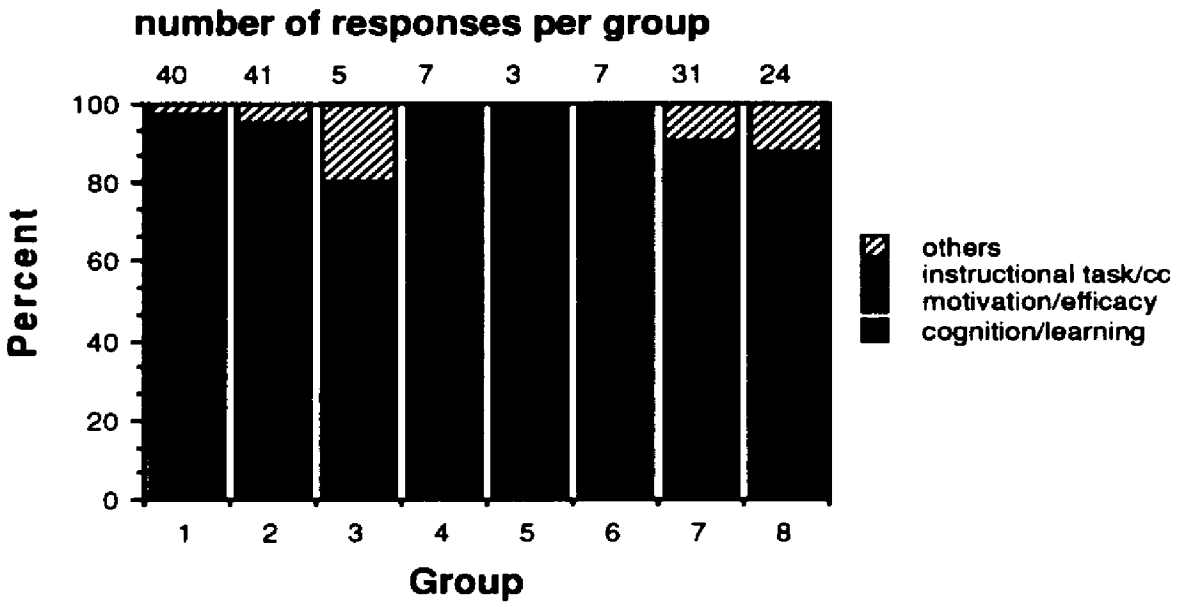

Figure 9b. Stacked bar graph on what students like least about CC comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for sampled students in each group.

Many students did not like the motivational deficits of CC (e.g., impersonal, felt pressured to participate, did not enjoy using it), followed by instructional tasks (e.g., CC participation, learning CC, access to computers). This finding indicates that motivating students to use CC and making the instructional tasks more enjoyable are areas that require improvement.

Additional Suggestions on CC Use.

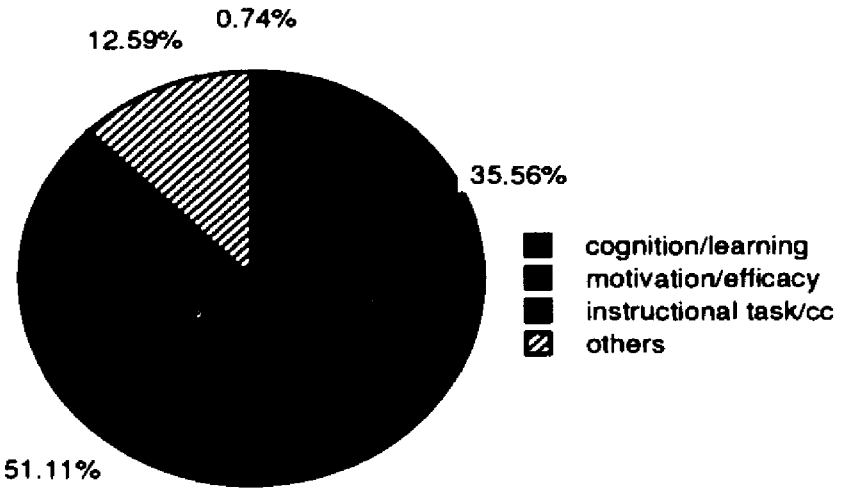

Figure 10a. Pie chart on students' additional suggestions on CC use comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for all sampled students.

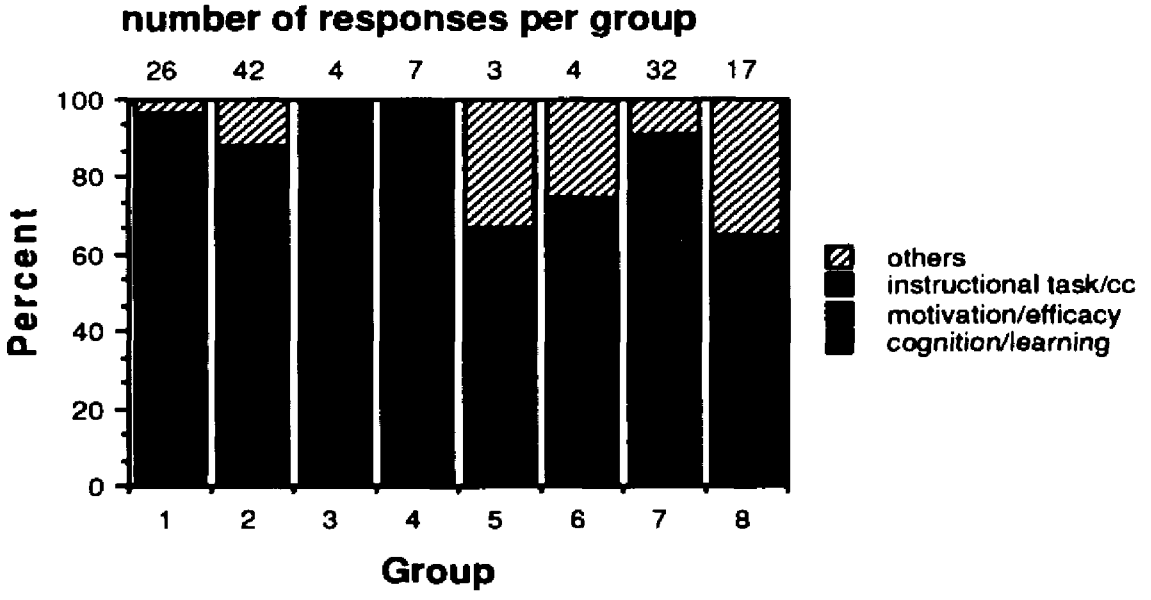

Figure 10b. Stacked bar graph on students' additional suggestions on CC use comparing frequency of coded responses relating to cognition/learning, motivation efficacy, instructional task/CC, and others for sampled students in each group.

About half of the sampled students' general suggestions for CC use were categorized as instructional task. Some of the more frequently mentioned suggestions were to make campus computers more accessible for student use, more time devoted to the training of students on how to use CC, creating items that would encourage responses, and better integration of CC use with the course.

Summary

Interestingly, most students perceived CC benefits in terms of it's motivational qualities to enhance learning, but perceived CC drawbacks pointed to the instructional tasks in which CC is used. Many students acknowledged that they liked the motivating qualities of CC, but many others, in contrast, did not like it for the opposite reason. This suggests that many students do indeed recognize the potential of CC to motivate student learning but may be critical of the method by which it was used in their class. Regarding student suggestions on CC teaching and training, majority of students pointed to ways in which the learning tasks for the course may be best linked with the use of CC. Most of the suggestions were to find ways to better learn CC, access computers, find time to sign on, improve items on the conference, and the like. These findings complement those by Ferguson (1977), Saunders and Heyl (198), Hiltz (1978b), Johansen et al. (1977), and Rice (1980). In view of the proposed model of this study, these findings point to the saliency of motivational and the instructional task components in view of their influence on student perceptions and use of CC.

Instructor Perceptions and Evaluations of CC Use

The following section is presented primarily to provide supplementary descriptive information on CC use among the different groups. Presenting this data may provide greater insight into the dynamics of CC use among the different groups in the study.

Using the data from the instructor questionnaire (see Appendix D), the following section summarizes the instructor's perceptions and evaluations regarding the use of CC in their class. Although the data presented in this section is not the major focus of this study, it may nonetheless provide useful insight and explanation regarding the effectiveness of CC use within the different groups. As mentioned, the instructor questionnaire was completed during the last week of classes. Table 7 shows a tabular summary of each instructor's perceptions of computer conferencing use in their class. Supplementary narrative descriptions of each instructor's evaluation of CC use follows.

	Instructor							
Item	1	2	3	4	5	6	7	8
teaching tool for instructor	5	4	1	2	2	4	4	4
motivational tool for instructor	5	3	2	4	2	4	4	3
learning tool for students	4	4	2	3	2	4	4	4
motivational tool for students	5	3	2	3	2	4	2	3
freedom from anxiety	4	3	3	3	2	5	2	2
teaching/managing the class	5	5	1	5	2	4	3	2
student participation (in-class)	5	4	1	2	1	2	1	2
student responses reflect learning	4	5	1	3	1	4	2	2
fun way to teach	5	4	1	4	2	4	4	4
worthwhile for students to learn	5	5	2	4	4	5	2	4
computer knowledge	5	5	4	3	4	5	2	5
cc knowledge	5	5	4	4	4	5	3	5

Table 7. Summary of responses by Instructors regarding their perceptions on computer conferencing use in class (5-point Likert scale).

Instructor 1 (Group 1).

CC use in Group 1 contributed the largest percentage towards student final grade (40%) of all the sections sampled. Instructor 1 felt that CC allowed students to develop many skills and enhance their learning of the course content. CC provided an opportunity to use and apply the material learned in class through conferencing, which forced students

to form opinions on psychological issues and to learn from each other. Because of the ease of accessibility, CC was a way to handle the routine business of the course as well. In addition, Instructor 1 hoped to create a sense of community among students and the instructor while also mastering the skills necessary to use a CC system.

Because CC appeared more time-consuming than it is in reality, Instructor 1 found that many students lacked the self-discipline necessary to initiate and maintain steady CC participation. Overall, he found the use of CC to be a successful teaching method, useful for any psychology course. He stated that CC would be most beneficial to student learning in courses which involved the exploration and debate of complex and subjective topics. Future recommendations include creating more interesting item topics, decreasing the number of topics to which students are required to respond, and to grade only the first few weeks of conferencing over the semester.

Instructor 2 (Group 2).

Instructor 2 described student responses as reflecting deeper thinking and elaboration of course material. CC also increased student interaction and allowed students the opportunity to master the material by learning from one another. He found CC contributed to an efficient use of time allowing students quick access to the instructor. Furthermore, because students were required to respond to 2 to 4 items per week, students completed readings and attended class regularly.

However, because students were required to sign on to the conference so often, it was a drawback for those who had less access to a computer and the time to complete the assignments. He saw a need to motivate students to enjoy using CC rather than viewing its use as simply more work.

Instructor 2 found the use of CC to be worthwhile and would recommend its use in any psychology course as well as other humanities and social science courses. He recommended obtaining student input on setting up the conference thus allowing students a sense of ownership of the conference environment. Additionally, encouraging students to

review and respond to past CC items may illicit higher quality responses and discussion. Finally, providing students with better access to computers was seen as a way to enhance student motivation for using CC.

Instructor 3 (Group 3).

The goal of CC use in this section was as a time saving device for students to ask questions of the instructor and their classmates, thus also improving communication among class members.

However, students from this class did not make much use of CC, apparently lacking an interest in its use. It was difficult for this instructor to set up and run the conference. Instructor 3 felt that although the computer skills necessary to use CC were worthwhile to have it was not worth the time that it took to teach these skills to students. He stated that he would not use CC again in teaching the course, although he did acknowledge its utility in teaching other upper level psychology courses such as abnormal psychology.

Instructor 4 (Group 4).

Increasing communication among students was the basic goal of CC use in this class. Instructor 4 found the greatest benefits of CC to be the ease with which students could access her, the enjoyment students received in talking to each other through CC, and the ability for quieter students to share ideas in a less threatening environment. She found that getting more students involved in conferencing and sparking interest in items pertaining directly to course content were the challenges of using CC as a teaching tool. She stated that she would use CC again to teach any psychology course. She recommended providing a lab session in which CC use is demonstrated and that a required CC exercise be assigned.

Instructor 5 (Group 5).

In this class, CC was not a mandatory requirement and was not used a great deal. CC was used primarily for students to access the instructor with specific questions for test preparation and included a few items of a social nature.

The ease of accessibility to others and the instructor was the greatest benefit of CC use in this section. However, because CC was not required students made little attempt to read the material and reflect upon the content with other students. What resulted was short and simple "question and answer" dialogues between the students and the instructor. Instructor 5 stated the greatest drawback to use of CC was the lack of meaningful discussion between participants.

Instructor 5 did state that she would use CC in teaching any other psychology course. Similarly she felt that CC would be beneficial for student learning in any course which involved discussion and the sharing of ideas.

Instructor 6 (Group 6).

Instructor 6 used CC in teaching this psychology course as another vehicle for class contact and discussion. He found CC especially valuable for those students who participated regularly and for whom the CC format was more congenial to their style.

Instructor 6 was a great advocate for CC use in teaching this and other psychology courses. Additionally, he felt that CC would benefit student learning in any course as long as students have access to the computing system, as he found that difficulty in accessing CC led to low participation. Furthermore, he stated that there was a need to increase the availability of computer resources to all students to lend to increased use of CC university wide.

Instructor 7 (Group 7).

Instructor 7 used CC in teaching this course to enhance communication between students and the instructor regarding course material and assignments. He found that most of his students were reluctant to use the conference unless there was a particular assignment involving CC, especially those students with limited computer experience.

He felt that CC was an effective learning tool and worthwhile for those students who did choose to utilize the conference. He also stated that he would use CC again in

teaching this and other psychology courses in the future with a few changes in conference use.

Instructor 7 suggested the use of deadlines for signing on and the use of more structured CC assignments. Additionally, he indicated that providing a session in the computer lab for demonstration would help students learn to log onto the system. Lastly, he suggested providing separate conferences for each class section in a high-enrollment course, so that students have their own conference separate from other sections of the course.

Instructor 8 (Group 8).

This instructor hoped to provide students with another avenue for participation by using CC in this course. Accordingly he found the potential for shy students to participate in discussion to be one of the greatest benefits of CC. He also valued the possibility that CC offered students to further pursue interesting questions and issues related to psychology.

Having a strong background in computer science, Instructor 8 recognized that many students exhibited "technophobia" and had difficulty getting onto the conferencing system. He admitted that CC can be difficult to access because it is a "character-oriented system" versus a "graphic-oriented program" with which most students are most accustomed. Regardless, he reported that CC would be of value to student learning in this and other psychology courses as well as computer science classes.

Limitations of the Study

This study described the different groups in a relatively qualitative way. The differences in instructional methods may require a more comprehensive and extensive investigation of group differences beyond the variables that were examined in this study (e.g., how CC was taught to students, CC structure). In addition, a more quantitative approach may allow for more sophisticated statistical analysis between instructional

variables and student variables (e.g., perception of use, cognitive and motivation characteristics).

There are also intergroup differences that may have confounded some of the findings of this study. First, there are big differences in the number of conference items between certain groups. For example, there were 107 conference items created in Group 1 while there were only 6 conference items for Group 5. This may have contributed to big differences in the frequency of interaction between these two groups which provided students in the conference the variety of topics to respond to. In addition, the specific item topics and how they were presented to the students may have been an influential factor in their perception about CC, their frequency of interaction, or the kind of responses they provide. Second, differences in sample sizes should also be taken into consideration in interpreting the results. More specifically, Group 3 only had nine students, while Group 5 had only twelve. Third, the composition of students between groups may also be a confound. For instance, Group 1 was an Introductory Honors class composed of "brighter-than-average" students, and Group 6 consisted of relatively small, closely knit students from the Residential College. There are other variables that could potentially influence student perception and use of CC and these should be investigated.

The sample population was also limited to introductory psychology classes. Other courses may have yielded differing results because of differences in course content. Instructor teaching skills, knowledge of the subject matter, student perception of the credibility of the instructor, other instructional methods used in the course, other student characteristics, and teacher variables may be important factors in affecting student perception and use of CC.

Significant mean differences between pretest and posttest student perception among the groups may not have been totally a function of actual use of CC in a particular class, given the structure, goals, requirements, and the other descriptive variables examined in the study. Because of the exploratory, non-experimental nature of the study, several

variables may not be controlled to maximize homogeneity in the general composition between the different groups (e.g., sex composition, intellectual ability).

Experimental manipulations of instructional variables may provide a causal explanations regarding how to effectively introduce CC in a course. The exploratory nature of this study did not allow for much control over several potentially confounding variables that may have affected the way students perceived and used CC.

As suggested by Hiltz and Turoff (1980), those who implement CC should allow the longitudinal development of the system due to the evolution in learner behavior. Longitudinal studies that track learner patterns of use, perceptions and attitudes regarding CC would provide a better understanding of conferencing dynamics.

Summary of Results

Significant within group decreases in student perception measures towards CC were most evident in Group 7. A significant pretest mean difference for "motivation to learn material" was determined between Groups 1 and 7. In addition, an overview of group perception means show that Groups 1, 2, and 6 had relatively higher student pretest perception means. Thus, favorable perceptions by students were characterized by those groups that provided extensive CC training, required its use, and clearly integrated CC in the curriculum through learning tasks.

Some cognitive-motivational student characteristics were found to be highly correlated with student perception towards CC. Intrinsic motivation, thinking skills, and task value were consistently found to be positively correlated with several perception measures for all groups combined. However, extrinsic motivation was consistently found to be inversely correlated with the perception items for all groups combined. Thus, the motivational component seems more salient in the formation of student perceptions. Similar findings were obtained for the posttest analyses. In addition, time and study management, elaboration strategies, and self efficacy appear to be highly correlated with

most of the posttest perception items while test anxiety was found to be significantly inversely correlated. Significant correlations between perception items and cognitive-motivational characteristics also show variations between groups. No noticeable patterns, however, were observed across groups.

Descriptive analyses on frequency of interaction (FOI) showed noticeable intergroup differences. The measures of FOI were apparently higher for groups which required CC use and contributed to student final grade, the structure and learning tasks of the conference were clearly related to the course material, and CC was used as an integral part of the course.

Comparisons of student comments and suggestions, as well as instructor perceptions and evaluations, suggest intergroup similarities and differences. Results revealed that the perceived benefits of CC focused on its ability to motivate student learning; the drawbacks of CC largely pertain to the instructional tasks to which CC was used; and comments regarding how CC was taught pointed to the inadequacies in which it was introduced and taught to the students. In addition, depending on the class, many students liked how CC was able to motivate them to learn. Nonetheless, it was also what many students liked least due to CC's inability to do so. Finally, many student suggestions on improving the use of CC in class centered on the instructional tasks in which CC was used. Similarly, instructor comments related quite comparatively to the findings. Therefore, student comments and suggestions largely focused on the motivational and instructional aspects of CC use. This suggests that instructors need to particularly focus on these two aspects for the effective implementation and use of CC as an instructional tool.

In conclusion, CC works best if it is integrated into the course curriculum in which students are required to use it to accomplish the learning tasks and goals associated with the course. Students need to perceive CC as an important tool for their learning and not just as a means of communicating with others in class. Thus, it is the teacher's objective to clearly convey the educational benefits that students may derive from CC and to actually have

students realize these benefits through their use of the conferencing system. In addition, the conceptual model that provided a theoretical base for this study may best be implemented and used in an instructional context by incorporating CC technology not just as a supplement to classroom instruction but more importantly, as an integral part of classroom learning. As mentioned, learning tasks and activities must be clearly integrated with CC use.

CHAPTER IV

RECOMMENDATIONS FOR THE INSTRUCTIONAL USE OF COMPUTER CONFERENCING

Given the findings of this study, the literature on the applications of computer technology in instructional contexts, and the proposed theoretical framework, this section presents important general recommendations and considerations for instructors who use CC to supplement classroom instruction. These recommendations may also be of use to researchers exploring variables that enhance the educational potential of this technology. The implementation of these recommendations may be modified to suit the particular instructional context involved.

The first part of this section presents recommendations based largely on the findings of this study given the features of the conferencing groups analyzed, student perceptions, suggestions, use, and cognitive-motivational characteristics. The second part involves additional considerations based largely on related literature on the educational applications of computer-mediated communication applied more specifically to a CC context.

In addition to these instructional recommendations, ways of evaluating the effectiveness of CC use and suggestions on how to encourage its use in educational settings are offered.

Preparing the College Classroom: Recommendations for CC Use

The influx of computers on campuses is inevitable and their value will be determined not by how many computers there are, but by how they are used. Computers are obviously not a panacea for the many problems affecting the quality of higher education, but they can certainly offer ways to help improve learning in the classroom. One of these ways may be through CC. As Hiltz (1986) pointed out, there is enormous potential in the use of CC for university teaching and learning.

When planning to expose the student to the use of CC as a learning tool, the teacher must be aware of the many factors that influence student learning as well as the interrelationships among these constructs (See Figure 3). It seems that many teachers become quite preoccupied with establishing learning objectives for students without enough regard for student motivation (e.g., intrinsic motivation) for the course as well as how learning tasks (e.g., learning how to use CC, participating in CC) pave the way towards the accomplishment of these objectives. Interestingly, the results of this study convey the importance of two constructs in the successful implementation, acceptance, and use of CC by students namely, student motivation and instructional tasks.

In recognizing the powerful influence of these two constructs, teachers should develop their use of CC technology in ways that motivate students and clearly provide learning tasks that encourage CC use. Given the instructional use of CC in those groups studied in which the conference was perceived more favorably (i.e., Groups 1, 2, and 6), the recommendations offered were derived from the instructional characteristics evident in these groups. Their characteristic features (See Table 1) are believed to enhance student acceptance and use of CC, as well as encourage the development of instructional tasks suited for CC use. The proper implementation of these features may, in turn, allow students to recognize and likely use CC in more effective ways.

These recommendations are categorized into three parts namely: 1) CC structure and training, 2) student acceptance and efficacy, and 3) implementing tasks via CC.

1) <u>CC structure and training.</u>

- The conference should be structured or organized prior to the beginning of the course. Students will want and need to have an idea of what the conference "looks" like, how it works, and what it's intended purpose is, in order to provide them with a schema to better understand how the conference relates to their learning in the course. This will also make the transition to the CC environment much easier to adjust to on the part of the student.

- Certainly, training on the use of CC is important, but teach only the necessary basic knowledge and enough skills to enable the student to function successfully in the CC environment in view of the instructional tasks of the course. It should not be surprising that teachers may have to show students how to turn the computer on and explain what a floppy disk and a hard disk are. Students in class may have varying levels of computer literacy. Initially, it may be best not to go over the details regarding the more complicated and technical aspects or capabilities of the system (e.g., uploading and downloading files). If these complex tasks are necessary in the use of CC in the course, they may be taught later on after the more basic knowledge have been learned by the students. As they become more sophisticated in their use of the system, they will likely seek to learn more complex features and capabilities of the CC system.

- Provide students with an easy-to-follow, step-by-step tutorial on how to successfully sign on and function effectively in the CC environment. During the initial stages of training, go through the steps together to see if students are able to follow the directions. This will also provide you with some feedback on how to improve the tutorial handout .

- It may be best to initially do practice sessions in a computer lab for the first couple of weeks or so, where the instructor is readily available to respond to student inquiries. This will allow you and your students to bring up and deliberate about questions, suggestions, and comments they may have about the conference. It is best to do the training as early in the course as possible. Everyone may be able to sign on and practice using it at the same time, and this may be the best time for students to ask questions about the system. As Ferguson (1977) pointed out, more training time would likely ease student apprehensions.

- In the course of training, it is suggested that students work in pairs and groups of three. This will allow them to learn collaboratively from each other and will even encourage team work.

- Have students register for the conference (i.e., sign up to participate in CC) by sending demographic registration information (e.g., year level, age, hobbies and interests). This will allow students to get to know one another and establish a sense of community as a class. This information may also serve as the class database from which they become acquainted with one another.

2) Student Acceptance and Efficacy.

- Make CC use a graded requirement for the course. Students must use this technology on a regular basis as part of accomplishing learning tasks for the course. Otherwise, students may just not avail of using this technology if other, more traditional options are explicitly made available to them.

- It is imperative that the purpose and utility of the conference be made explicit to students. Make them aware of the potential benefits of using this technology in their learning and as an important way to communicate with one another in class. Also, make sure that your expectations with regard to the CC use is clearly communicated to the students. Be cognizant of student expectations.

- It is important to convey to the students, early in the course, that you are available to guide, supervise, and support their learning of the system.

- Student feedback is very important. Be receptive to student comments, suggestions, and questions about CC use in class. Their input must be given attention and consideration in the design and implementation of the system.

- Regularly monitor the conference, respond to student inquiries and comments, paraphrase responses, and provide feedback to students. Ask students to exchange ideas, no matter how outrageous, and to critique each other's responses or work. However, it is important to set rules with regard to courtesy and the use of noninflammatory language.

- Respond promptly to student questions, comments, and suggestions in the conference. This will encourage students to use CC as a means to obtain instructor response quickly and efficiently. Also, regularly enter questions, create items or topics that

stimulate discussion, and the like to challenge the student's ability to think about issues and concepts presented in the course. Hopefully, this will not only encourage them to participate but also to think and elaborate about the things they learn.

- Allow students sufficient time to explore and practice using CC and initially provide them with simple tasks to do (e.g., sign on, register as a participant to the conference, respond to an item, etc.).

- Allow flexibility on the part of the students in view of their participation in the conference. It may be prudent to provide students, at least during the first few weeks of classes, with alternative options in undertaking class requirements that would eventually be made via CC. For example, during the first few weeks of classes, allow student to submit assignments in a typewritten form instead of using the conference to submit their work. As mentioned earlier, it is important that students understand the utility of CC use in class in order to encourage acceptance and efficacy.

- Explore other ways to motivate students to participate in the conference. A play or game-like CC environment may be an effective way of motivating students not only to participate but to learn how to use the system. Banet (1979) and Malone (1981) recognize the value of games in activating motivation to learn. Designing a system that is more "game-like" and that encourages team work among groups of students might be enticing for many students.

- Also encourage students to ask questions, conduct their preparations for a class project, share their ideas, and the like, using the conferencing medium.

3) Implementing Tasks via CC.

- An important finding in the study is the high correlation between student perception and some cognitive characteristics, particularly thinking skills, elaboration strategies, and time/study management. As Tennyson and Park (1986) recommended, intelligent systems should be holistic and inferential to improve individual learning. Learning tasks should therefore cater to developing these higher-order cognitive

characteristics. Developing a conferencing system that encourages the free flow of ideas, energetic discussion of a wide variety of issues of interest to students, and differing viewpoints may stimulate active use of this technology.

- Make sure that class requirements are clearly linked to the use of CC (e.g., use the conference as a way to obtain announcements, respond to graded open-ended questions via CC, discussing group topics, submit homework and exercises, and conduct preparation for class projects and papers via CC).

- As an ongoing task for students, regularly ask them for a formative evaluation of CC use, during and even at the end of the course, on how the use of CC in class may be improved as a tool for learning and motivating them to participate.

- Reviews for exams and tests may be supplemented with the use of CC. This way, other students may also respond to questions of other students which may possibly encourage more discussion. However, it may not be such a good idea to have exam reviews as the primary use of the conference because students may only find time to use CC just prior to an exam or to simply ask exam-related questions, as opposed to having an ongoing intellectual discussion of class-related material to develop critical thinking and collegial relationships among them.

- Use the conference as a means to convey announcements and to disseminate other information about class matters. For example, handouts may be entered into the conference for the students to access and possibly respond to. This will also provide an incentive for students to utilize CC and to enhance learning of this technology.

In adopting CC technology, the recommendations mentioned above may prove to be crucial to the successful implementation of CC in instructional contexts. Nonetheless, what may be the most important initial step in enhancing student motivation is to help them become more "metacognitive" of their use of CC. That is, teachers may want to explain to the students early on in the course: a) why this technology is relevant, and b) how it will help them in their learning. Because of the transition from the more traditional face-to-face

classroom communication to a computer-mediated communication environment to supplement classroom instruction adds to the complexity of the instructional milieu, students would certainly find it helpful not only to know how CC is used in class but also to understand the importance of learning CC and how it would benefit their learning of the course.

These suggestions are by no means exhaustive and definitive. Further application and research as to the effective use of CC as an instructional tool is necessary to support, modify, or reevaluate some of these suggestions. In addition, the use of CC must be tested in other instructional settings to determine its feasibility.

Additional Considerations

The complex interactions among the numerous constructs presented in the proposed model requires an encompassing approach to the multifaceted phenomenon that occurs when the communication among students and teacher is mediated by a nontraditional, and probably unfamiliar medium like CC. It is important to be cognizant of several other constructs that may have a profound influence of CC use among students. The following sections presents some additional considerations not found in this study but are nonetheless reflected in the related literature.

Some CC Structure and System Considerations

One way to motivate student acceptance and use of technology is to develop CC systems that are relatively easy to teach and learn. It should combine play and learning by embedding motivational features into the material. It should allow learners easy and flexible control of the learning environment and easy access from obtaining help or consultation regarding the use of the system. Thus, system considerations must therefore take into account both the motivational and task components in order to enhance the potentials of CC as a learning tool.

CC system softwares have become more sophisticated and user friendly over the years. Despite the increasingly sophisticated software design options available, there seems to be some limit to what a user will undertake and a time within which it must demonstrate a utility or payoff. This is an additional element to be considered in the design of a CC environment. Katter (1970) introduced the concept of a user's "line of credit" relating to a learner's introduction to a new system or task involving interactive computing. It suggests that during an allotted time period, the system used or learned must deliver the expected benefits before the user's "patience" is exhausted. Otherwise, the learner may not perceive the use of the system as beneficial for the specific purpose intended. The novelty inherent in the use of a CC system during this "line of credit" period must be used to engage the motivation of the learner to proceed with use of the system and the undertaking of the academic task. Thus, instructors may need to develop innovative uses for CC by creating a variety of topics of interest to students and developing a variety of learning tasks associated with these topics.

Another important issue to consider are some of the apparent limitations of CC as a communication device. For example, CC is limited to the transmission of typewritten text (at least at this point in its development and implementation) and nonverbal cues, which may be an important source of learning, and therefore information exchange is not always efficiently transmitted. This phenomenon has been widely studied (Feenberg, 1989; Kerr and Hiltz, 1982; Kiesler, Siegel, & McGuire, 1984; Rice, 1980; Uhlig, 1977). These studies suggest that mechanisms need to be developed and employed to compensate for the absence of the nonverbal element that is so integral to classroom learning. The consideration of this issue is particularly important in a teaching-learning situation where learner progress is assessed by observing nonverbal behavior and where some teacher feedback may be given nonverbally. The delayed communication inherent in most asynchronous systems also requires intervention strategies to compensate for the advantages ensuing from immediate feedback experienced in face-to-face communication.

There are other major factors in a CC system that are of primary concern to students. These are the accessibility of computer resources able to utilize the CC system, use of an on-line "help" system for both instructors and students, methods of instruction to teach CC, limitations in the use of verbal typewritten communication, and delay in communication inherent to asynchronous systems. At the present time, these seem to be an inherent problem in many educational settings but it is expected that the increased use of this technology will eventually minimize these concerns. Nonetheless, it is important for teachers to be intuitive as to the feasibility of CC use for teaching and learning given the resources available and the constraints that impinge on the tasks, methods, and goals involved.

Student Characteristics

Since student participation in a CC environment is a main concern with regard to the use of CC as an instructional tool, student preparation, training, and monitoring by the teacher is an important concern. Similarly, demographic, environmental, and other student characteristics should provide important information in the design and implementation of the structure of the conference and the tasks involved.

This study acknowledges the importance of the motivational characteristics and the instructional tasks involved in developing positive perceptions of CC as an effective learning tool. Having determined that many students pointed out concerns regarding these issues, the teacher needs to be cognizant of such concerns as early in the course as possible, and would have to find ways to alleviate them in order to plan for a more effective use of CC. Student motivation, learning skills, and prior knowledge about computers in general and the course content, will vary from student to student and from class to class. Thus, the early identification of incentives and the establishment of mutual expectations will set the tone for the participants in the conference. Individual differences such as personal communication skills, previous experience with computer use, technique, or topic, as well

as physical or intellectual conditions may require careful individual attention on the part of the teacher to ensure full participation.

Moreover, Cronbach (1957) encourages educators to consider combining knowledge from correlational research on individual differences with the search for meaningful teaching methods to accommodate a broad spectrum of learners. Again, the present study suggests the importance of student motivational characteristics (e.g., intrinsic and extrinsic motivation), and the value students place on the learning tasks, as important constructs towards a favorable perception and effective use of CC. Some suggestions to make the conference more motivating to a wider variety of students is to provide them with some internal control as a means by which they have some influence over learning events by utilizing features embedded into instruction by the designer (Hannafin, 1984). For example, allow students to take part in developing the structure of the conference and developing a system that permits students to organize items and responses that would suit their individual preferences. Compromises may have to be reached regarding this issue to satisfy most students.

Other concerns relating to the motivational aspects of CC use among students may not only be largely based on the introduction of a relatively new technology. It is probable that many students have to contend with two debilitating factors namely, computer anxiety (Cambre & Cook, 1987; Lambert & Lenthall, 1989; Rosen & Maguire, 1990) and writing apprehension (Harris and Grandgenett, 1992; Hartman et al., 1991). If CC is to be successfully implemented as a supplement to classroom learning, participants may need assistance in overcoming their crippling effects. These two problems may be minimized by having a relatively informal, free-flowing discussion of the issues. Convey to students that their ideas and opinions regarding the conference are more important, at least initially, than their grammar and coherence in writing. In addition, the sharing of each other's "critical thinking" of the issues discussed in the conference is what really matters. Providing each student with sufficient training in getting used to the system for some period of time would

allow students to get acquainted not only with each other, but with the CC system itself. Hopefully, these will help alleviate much of the anxiety and writing apprehension they experience.

A practical suggestion for teachers is for them to administer a formal or informal survey at the beginning of the course to have an idea of the what the students are like in terms of their motivational and cognitive characteristics, as well as their expectations about the course and toward CC. This information is crucial because it allows the teacher to develop and structure the conference that would accommodate students in the class in terms of their use of the conference. As shown in the proposed model (Figure 3), the teacher takes on a facilitating role and restructures the conference based on student feedback, student cognitive and motivational characteristics, and learning outcomes. Furthermore, if students know that they played an important role in the design and implementation of the system, they are more apt to view the use of CC more favorably and probably give more credibility to the conference as an instructional tool.

Class Characteristics

Because of the complexity of the classroom environment, other "class" variables must be accorded some attention in developing a conducive CC environment. Though individuals in a class possess distinctive characteristics, they also develop characteristics as they become part of that class. Kerr and Hiltz (1982) pointed out three factors that may effect communication and learning through CC. These major factors are as follows:

1) Structural factors. These refer to the size of the group or class, the extent to which leadership in a group or class is centralized or decentralized, degree of geographical dispersion among participants, and the level of pre-existing ties among the participants in class. Similar to obtaining relevant information from individual students and taking it into consideration in developing and structuring the conference, information about the class or the groups that compose the class is also important.

2) Leadership. This is an important quality in the effective functioning of groups in a computer-mediated environment (Kerr, 1986). It may be important that the teacher, whether explicitly expressed or not, initially take the leader role. This would allow a more organized and structured introduction to the CC system. Leadership has been cited as a crucial element in collaborative learning activities in conventional face-to-face settings (Johnson, & Johnson, 1975; Johnson, Johnson, Holubec, & Roy, 1984). It has also been cited as important in the successful functioning of the computer-mediated communication systems (Kerr, 1986). Since a major purpose of CC is to be able to share and discover knowledge using all participants as potential resources in a collaborative learning style, leadership is clearly critical issue. Oftentimes, the teacher initially takes the role of a leader and eventually diffuses his/her leadership responsibilities when students are ready and prepared for a more collaborative interaction with others, yet at the same time perceives himself or herself as an important functioning member of the class. However, it is the teacher who leads in terms of managing the conference and knows more about the conference's technical system, knowledge and assumptions about the group members, and assumptions about the relative utility of given teaching strategies within the instructional context. The ability of the teacher-leader to intervene appropriately and to guide the overall activity may be the single most important planning consideration. As the semester goes along, however, leadership roles may be accorded to some of the students in class (e.g., facilitate discussion sessions, conduct projects). Leadership by the teacher, nonetheless, is a key factor in the effectiveness of that teaching and learning strategy.

3) Group cohesiveness. This can also play a role in the effectiveness of the group. It is worthwhile to have some knowledge of the students' academic competitiveness, ability to work in groups, willingness to express opinions and feelings. According to Waggoner (1992b), bringing a group together in an on-line communications activity, especially when the members of such group do not initially know each other, may be assisted by beginning with more traditional communication methods such as using the telephone, conventional

mail, and written text. This may be important in providing the students some skills on how to correspond, relate, and collaborate.

These additional considerations may be important factors in influencing student perceptions, use, and acceptance of CC. It is imperative that teachers be particularly cognizant of the relative influence of these factors towards the instructional potentials of CC.

Measures for Evaluating the Effectiveness of CC Use

Since a learner-centered approach is deemed most effective in the integration of CC technology in the curriculum, it is important to obtain formative feedback and evaluation from students who have used CC as an instructional tool in the course. Such evaluation is a potentially rich source of information for developing teaching strategies and in research with regard to the application of computer-mediated communication in teaching and learning.

Waggoner (1992b) pointed to two main sources of relevant data. The first includes information on observed participation (i.e., data collected in the CC system that can be saved on tape or disk for research purposes). An advantage of on-line class discussion is that a record or transcript of the communications may be saved and later reviewed for research which may reflect the quality of learning exhibited by participants. Some variables that may be of use for research purposes are frequency and duration of participation, content analysis of the text , and discourse analysis of the interaction among the conference participants. In this study, frequency of student interaction was analyzed using various measures of discourse. The second is self-reported information which involves comments from the conference participants about the utility of the system, student perceptions and attitudes about its use, and their suggestions on how it may be improve. Instruments that measure self-reported data may be used or may be developed to ascertain attitudes towards use of various kinds of communication media. Other measures may aim to determine user

learning styles that may suggest important information to the teacher regarding strategies to employ in implementing CC. There are some instruments that were developed to solicit perceptions about efficacy of group function within the computer-mediated process (e.g., Waggoner, 1987). Taken together, both these sources of information can contribute to a better understanding of the processes and outcomes involved in CC use in learning in view of the actual communication that takes place in the computer-mediated learning environment and the effectiveness of such medium as perceived by the participants involved.

In addition, there are also ways to obtain outcome measures on learning. These are designed and tested primarily to determine its effectiveness in learning contexts. Student learning can be measured though usual classroom learning or achievement measures such as exams or quizzes, level of participation, papers, and the like. In a learning activity using CC, measures of knowledge, efficacy and soundness of the structure/design of the conference, and the level at which learning and teaching goals that have been met may be constructed and taken. All this information would provide much needed feedback in redesigning and refinement of CC use for future applications.

Feedback on CC use should be systematically incorporated into the classroom and the course curriculum. Student and instructor feedback are necessary in order to determine useful suggestions for CC's future classroom use. For instance, students may want additional hands-on practice in learning the system, more instructor involvement in the conference, increase accessibility to computer facilities, more interesting topical discussions by providing better incentives, and others. Positive feedback on the use of CC may also encourage and extend CC use in other content domains in which instructors may be motivated to become involved in integrating computing in their own classrooms.

Measures related to the structure/design of the conference (e.g., the way it was taught to students, the manner by and purpose for which it is used) may be quite idiosyncratic because of the differences among CC systems and the variety in which CC is implemented for use in a particular course and the composition of participants.

Nonetheless, these learning measures are important in that an evaluation should be made with regard to the extent to which intended goals have been achieved in the course of the learning process.

Encouraging the Transition towards CC Use

This section is directed to teachers who use or intend to use CC to supplement their teaching of a course, and who would like to encourage other teacher to do the same. These teachers can become proactive and begin the transition toward classrooms that are not bound by time and place. Johnson, Harlow, and Maddux (1992) have suggested ways that teacher educators working with technology, in general, can take a proactive role and provide an impetus for change in the classroom. In adapting their suggestions, believers of the potentials of CC as an instructional tool to supplement classroom learning are offered the following suggestions:

First, model the use of this technology in your own courses. We have a tendency to teach as we were taught or maybe we, at times, fail to explore innovative means by which to teach. Thus, we may be hesitant in trying new ideas and taking risks in applying new ways of teaching. It is therefore important to remember that change occurs with the introduction of something new. Trying new and creative ideas in utilizing technological innovations to improve teaching and learning, we can model change among educators, and hopefully the successful implementation of CC in their own classes.

Second, invite educators who specialize in curriculum design into a discussion about the application of CC to skills and subject areas. They may just be curious enough that they may just take the time to visit and observe your use of CC in classrooms which, in turn, may encourage them to use it in their own teaching. The purpose will be to infuse technology into the entire curriculum. These colleagues of yours will share with you their specialties, and thus be able to work together on increasing educational options and achieving educational goals.

Third, take your ideas out to schools and institutions, classrooms, and teachers in order to share your knowledge of this technology, subject it to their scrutiny where they can be shared with and tested. Be cognizant though that these teachers are quite busy, may work under limited resources, and may be very skeptical of our ideas. It is imperative that you show them how to make it work.

Once permission is granted and resources are available for the instructional use of CC in an academic setting, teachers need to prepare their students for this relatively new technology. Toffler (1991), Keyes (1991) and others have pointed out that computer knowledge is relatively commonplace among the children entering our schools today. Most students have been involved with playing video games, and many have some experience with using a computer. Nonetheless, the proper introduction and presentation of CC as a tool for classroom learning is crucial. Therefore, the primary goal in mind should not only be to teach the technology, but also to encourage its use as a tool that will enhance student learning.

Further research and application of CC in various instructional contexts is necessary. The eventual use of CC as a supplement to classroom learning may well be imminent in the classroom of the future. Therefore instructors, as well as researchers, must now concentrate on how to develop effective and efficient use of this technology in view of realizing its potential contributions to learning and teaching.

CHAPTER V

SUMMARY AND CONCLUSIONS

The innovative use of computer conferencing (CC) in academic settings is gaining popularity in many classroom settings and offers new possibilities for purposeful "out-of-classroom" learning. Direct, face-to-face communication (i.e., in-class instruction), in combination with asynchronous computer-mediated communication, may enhance the learning experience among students, enrich the college experience, and improve teaching in a significant way. As relationships build between college students and teachers, it is now possible that they can be nurtured and sustained using such technology. Thus, interaction among students and instructor may grow into a more integral and intensive on-going experience.

This study examined eight different classes that used CC as an instructional tool to supplement Introductory Psychology courses (N=287) by looking at significant changes in student perceptions toward CC, determining correlational patterns between student perceptions on CC use and their cognitive-motivational characteristics, describing variations in frequency of CC interaction between groups that are relatively different in the way CC was introduced and used, and presenting student comments and suggestions regarding CC use among these groups. The implementation and use of CC varied among the groups studied. Conferencing in each group was described in terms of training, structure, use/task, instructor goals, instructor's perceived CC knowledge, CC requirement, and the percentage in which CC contributed to student final grade.

With regard to the design and procedural aspects of the study, students were given a pretest and a posttest questionnaire that measured their perception towards CC, including their comments and suggestions on CC use for the posttest version, and a self-report questionnaire that determined their cognitive and motivational characteristics for learning. Similarly, instructors in each group responded to a questionnaire regarding their perceptions and evaluations of CC use.

The findings of this study serves as an impetus for further research on CC. First, significant mean differences in student perceptions within groups were more evident in Group 7. Students' initial perception for "motivation to learn material" was found to be significantly different between Group 1 and Group 7. More favorable student perceptions were characteristic of those groups (i.e., Groups 1, 2, and 6) that provided extensive CC training, required its use, and clearly integrated CC in the curriculum through learning tasks, and those that did not. Generally, there were significant decreases in mean perception scores from pretest to posttest for those groups (e.g., Group 7) in which CC had minimal contribution to student learning and was seldom used by students. Second, several of the perception items were found to be significantly correlated with certain student cognitive and motivational characteristics for all groups combined. Intrinsic motivation, thinking skills, and task value were factors consistently found to have a significant positive correlation with several perception scores. However, extrinsic motivation was consistently found to have a significantly inverse relationship with the perception items for all groups combined. Similar results were obtained for the posttest analyses. In addition, time and study management, elaboration strategies, and self-efficacy were highly correlated with many of the posttest perception items while test anxiety was significantly inversely correlated. Significant correlations between perception items and cognitive-motivational characteristics show variations between groups and no noticeable patterns across groups were observed. Third, the measures for frequency of interaction (FOI) were apparently higher for groups in which CC use was required, the structure and learning tasks of the conference were clearly related to the course material, and CC was used as an integral part of the course. Fourth, student comments and suggestions revealed that (a) the benefits of CC in class focused on its ability to motivate student learning (e.g., I enjoyed interacting with other members of the class via CC), (b) the drawbacks of CC pertain largely to the instructional tasks to which CC was meant to be used (e.g., I found it difficult to learn CC), (c) suggestions on how CC may be effectively taught pointed to the inadequacies in

which it was presented and taught to the students (e.g., provide more hands-on training sessions), (d) depending on the class, many students liked how CC was able to motivate them to learn, yet interestingly, it was also what many other students liked least due to what they claim as CC's inability to motivate them, and (e) most student suggestions on improving the use of CC in class centered on the instructional tasks in which it was used (e.g., convenient access to computers on campus). Instructor suggestions echoed similar suggestions.

These findings suggest that the use of CC as a supplement to classroom learning must consider some important factors for its successful implementation and effective use. The motivational potentials of CC and the instructional tasks involved in its use were determined to be the most important factors that influence student acceptance and use of this technology. Nonetheless, further research on these and other constructs that influence student learning through CC should be undertaken.

A conceptual framework was developed to provide a theoretical base for this study. Although the framework shows the relative "links" between important constructs in student learning, it was not the purpose of the study to test the relative strengths and magnitudes of these relationships. However, the results of the study do point out the relative importance of "student motivation" and "instructional tasks" in view of the implementation and use of CC among students. In addition, given the results of this study, CC works best if implemented and used as an integral part of the course, that is, require students to use it in accomplishing learning tasks and goals associated with the course. It is important that students perceive the benefits CC has to offer, not just as a tool for communicating with others in class. Therefore, the teacher's objective is to clearly convey and realize the educational benefits of using the conference. Favorable student perceptions and effective use of CC is not simply a function of incorporating CC technology as a supplement to classroom instruction as originally conceived but, more importantly, as an integral part of classroom learning.

A portion of this paper was also devoted to pointing out some recommendations and considerations in the implementation of CC, providing ways to evaluate its effectiveness, and offering suggestions to encourage the transition towards its use.

CC itself will not improve education but it can, however, offer opportunities for instructional innovations in accomplishing learning and teaching goals. CC is one technology that is available to help attain these goals. The issue, therefore, is how to best use this relatively new method of instruction to serve educational purposes. As such, CC has the potential to allow teachers and students to reach out to each other in more efficient ways for them to be able to discuss, share, challenge, and learn!

APPENDICES

APPENDIX A

STUDENT SURVEY ON CONFER USE
(Pretest version)

This survey deals with your perceptions and evaluations of the use of CONFER (i.e., computer conferencing) in your class. The purpose for having set up a computer conference in this class is to provide a convenient way to be able to communicate and hold discussions about certain issues without having to meet face-to-face or coordinate schedules. More importantly, the use of CONFER may provide a way to enhance student learning and motivation for the course. Thus, we need your input on how CONFER can benefit you in class and how its use may be improved.

The second part of this survey is called the Motivated Strategies for Learning Questionnaire (MSLQ). It is intended to help you be more cognizant of your study habits and skills, and to determine how these relate to your use of CONFER in class.

Your individual answers will be kept confidential. Completing the questionnaire is voluntary. Your cooperation in responding to this survey will be helpful in developing CONFER as an integral part of this course/discussion in the most effective way to motivate students and enhance the learning of the course material.

Your participation is greatly appreciated. Thank you very much.

* *

Student ID. # _____

Course and Section number: _____

Name of Instructor: _____ Name of T.A.: _____

Today's date: _____

Sex: M or F

Year level (Circle One): Fr So Jr Sr Grad Other (please specify) _____

Major or Intended Major: _____ School/College:_____

* *

Circle the appropriate number on the scale presented after each item.

Part 1: Perceptions toward CONFER (Include a brief explanation to your answer)

1. Do you think it is (will be) worthwhile to learn CONFER?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

2. To what extent do you think CONFER will be valuable in your learning of this course?

1	2	3	4	5
not valuable at all				very valuable

Briefly explain:

3. Does the use of CONFER in class make you feel anxious and concerned?

1	2	3	4	5
definitely yes				definitely not

Briefly explain:

4. To what extent do you think CONFER helps (will help) in motivating you to learn the material in class (i.e., enhancing your interest)?

1	2	3	4	5
not helpful at all				very helpful

Briefly explain:

5. How motivated are you in participating in CONFER?

1	2	3	4	5
not motivated at all				very motivated

Briefly explain:

6. To what extent do you think the use of CONFER will help you understand what you learn in class?

1	2	3	4	5
not helpful at all				very helpful

Briefly explain:

7. To what extent do you think the use of CONFER (will) encourage you to participate in in-class discussion of the issues/topics in the course?

1	2	3	4	5
very little				very much

Briefly explain:

8. Do you think you would find other students' responses to CONFER useful in your own learning?

1	2	3	4	5
not true at all				very true

Briefly explain:

9. Do you think CONFER is (will be) a fun way to learn the material in class?

1	2	3	4	5
not true at all				very true

Part 2: Learning CONFER

1. How much previous experience do you have with the use of CONFER?

1	2	3	4	5
no experience at all				very experienced

-END-

Thank you for responding to this questionnaire!

APPENDIX B

STUDENT SURVEY ON CONFER USE
(Posttest version)

In the beginning of the semester, you were asked to respond to a survey regarding the use of CONFER in your class. This survey you are about to fill out is the second of two surveys intended to help evaluate the use of CONFER in this course. The purpose of these surveys is to be able to track changes in your perceptions and evaluations of CONFER use in the course of the semester. Your participation is intended to determine ways in which CONFER can benefit students in similar classes and how its use may be improved.

Responding to this survey is voluntary. As with the past survey, your responses will be kept confidential. Your cooperation in responding to this survey will be helpful in developing CONFER as an integral part of this course in the most effective way to motivate students and enhance the learning of the course material. Moreover, responding to this survey will be useful to you in thinking about your learning.

If you have any comments regarding this questionnaire or issues on CONFER use, you may write them at the back of the last page of this survey.

Your participation is greatly appreciated. Thank you very much.

* *

Student ID. # _____

Course and Section number: _____

Name of Instructor: _____ Name of T.A.: _____

Today's date: _____

Sex: M or F

Year level (Circle One): Fr So Jr Sr Grad Other (please specify) _____

Major or Intended Major: _____ School/College: _____

* *

Circle the appropriate number on the scale presented after each item.

Part 1: Perceptions toward CONFER (Include a brief explanation to your answer for each item)

After a semester of using CONFER in the psychology class you are in,

1. do you think it was worthwhile learning CONFER?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

2. do you think CONFER has been valuable in your learning in this course?

1	2	3	4	5
not valuable at all				very valuable

Briefly explain:

3. has the use of CONFER in class made you feel anxious and concerned?

1	2	3	4	5
definitely yes				definitely not

Briefly explain:

4. to what extent do you think CONFER has helped in motivating you to learn the material in class (i.e., enhancing your interest)?

1	2	3	4	5
not helpful at all				very helpful

Briefly explain:

5. how motivated were you in participating in CONFER?

1	2	3	4	5
not motivated at all				very motivated

Briefly explain:

6. to what extent did the use of CONFER help you understand what you learned in class?

1	2	3	4	5
not helpful at all				very helpful

Briefly explain:

7. to what extent did the use of CONFER encourage you to participate in in-class discussion of the issues/topics in the course?

1	2	3	4	5
very little				very much

Briefly explain:

8. did you find other students' responses to CONFER useful in your own learning?

1	2	3	4	5
not true at all				very true

Briefly explain:

9. do you think CONFER was a fun way to learn the material in class?

1	2	3	4	5
not true at all				very true

Briefly explain:

Part 2: Briefly answer ALL questions presented below.

A. CONFER Use

After a semester of using CONFER in the psychology class you are in,

1. what do you think were the benefits of using CONFER in this class?

2. what do you think were the difficulties or drawbacks of using CONFER in this class?

3. what suggestions do you have on how CONFER can be better taught to you?

B. Attitude on CONFER use

After a semester of using CONFER in the psychology class you are in,

1. what did you like most about CONFER use in this class?

2. what did you like least about CONFER use in this class?

C. **After a semester of using CONFER,** what other suggestions do you have on how CONFER may be used to enhance or help your learning and/or motivation in this course? (You may write on the back side of this page.)

If you have any comments regarding this questionnaire or issues on CONFER use, you may write them at the back of the last page of this survey.

-END-

APPENDIX C

CODE SHEET FOR STUDENT QUALITATIVE DATA
(Posttest only)

Qualitative data for Part 2 in the posttest questionnaire are coded as follows:

Qualitative Items to be Coded

CODES	Categories (with examples)
1	**Learning/Cognition** reflection/elaboration of material learned, increase understanding accuracy of information
2	**Motivation/Efficacy** enjoy interaction/communication with others anxiety (emotional arousal) related to participation getting to know others in class motivation to learn, fun impersonal felt pressured to participate
3	**Instructional Tasks/Computers/CONFER Use** learn about computers/CONFER/MTS participate in CONFER difficult to learn CONFER pertaining to items, its structure or content pertaining to responses (e.g., length, content) finding time to sign on access to computer
9	**Unclassifiable responses**

-END-

APPENDIX D

MOTIVATED STRATEGIES FOR LEARNING QUESTIONNAIRE (MSLQ)

National Center for Research to Improve Postsecondary Teaching and Learning, School of Education, The University of Michigan

This attached questionnaire is intended to help you analyze your study habits, learning skills, and motivation for course work. Items are intended to see how they relate to your use of CONFER in class.

Circle the number that best applies to you. **THERE ARE NO RIGHT OR WRONG ANSWERS TO THIS QUESTIONNAIRE.**

* *

Student ID Number _____

Instructor's Name_____ T.A.'s Name _____

Course and Section number _____

Today's Date_____

* *

	not at all true of me				very true of me
<u>Metacognition - Planning</u>					
Before I study new material thoroughly, I often skim it to see how it is organized.	1	2	3	4	5
When I study, I set goals for myself in order to direct my activities in each study period.	1	2	3	4	5
I try to think through a topic and decide what I am supposed to learn from it rather than just reading it over.	1	2	3	4	5
Before I start on an assignment, I usually try to figure out what is the best way to do it.	1	2	3	4	5
When reading for a course I make up questions to help focus my reading.	1	2	3	4	5
In preparing for a test, I use different approaches depending on whether it will be an essay test or true/false/multiple choice.	1	2	3	4	5
I study differently for science courses than I do for social science courses.	1	2	3	4	5

	not at all true of me				very true of me
Metacognition - Monitoring					
When I read I think, "Do I understand everything?"	1	2	3	4	5
I try to adapt my studying and learning style to the instructor's requirements and teaching style.	1	2	3	4	5
If I get confused taking notes in lecture, I make sure I sort it out after class.	1	2	3	4	5
If course readings are difficult to understand, I change the way I read the material.	1	2	3	4	5
Time and Study Management					
I find it hard to stick to a study schedule.	5	4	3	2	1 R
I usually keep up with the weekly reading or work for this class.	1	2	3	4	5
I make good use of my study time.	1	2	3	4	5
I'm slow getting started if I need to work on an assignment in the evening.	5	4	3	2	1 R
I attend class regularly.	1	2	3	4	5
I often find that I don't spend very much time on class because of other activities.	5	4	3	2	1 R
Study Environment					
I usually study in a place where I can concentrate on my course work.	1	2	3	4	5
I make sure that my primary place for studying is set up to help me study effectively.	1	2	3	4	5

	not at all true of me				very true of me
Attention					
When I find that my mind is wandering while studying, I get up and move around before continuing.	1	2	3	4	5
In any easy lecture, I take more notes.	1	2	3	4	5
In a lecture that is very difficult, I take fewer notes.	1	2	3	4	5
I daydream a lot during lectures.	5	4	3	2	1 R
Elaboration Strategies					
When reading assignments, I try to relate the material to what I already know.	1	2	3	4	5
I write brief summaries of the main ideas in my notes.	1	2	3	4	5
I try to relate ideas in this subject to those in other courses whenever possible.	1	2	3	4	5
I sometimes stop reading to think about what the author is really saying.	1	2	3	4	5
Organization Strategies					
When I study for an exam, I pull together information from different sources such as lectures, readings, and discussions.	1	2	3	4	5
When I study, I look for the main points.	1	2	3	4	5
I try to fit what I learn into an overall framework.	1	2	3	4	5
I work out a diagram or outline to help me organize.	1	2	3	4	5

	not at all true of me				very true of me
Rehearsal Strategies					
When I study for a test, I spend most of my time memorizing definitions and facts.	1	2	3	4	5
When I study, I go over and over the assignments.	1	2	3	4	5
When I study, I try to remember as much detailed information as possible.	1	2	3	4	5
Peer Learning					
When I get ready for a test, I usually try to study with a Group.	1	2	3	4	5
When I study with other students, we bring questions to ask each other.	1	2	3	4	5
I work on course assignments with other people whenever possible.	1	2	3	4	5
When I run into something I don't understand, I try to get a classmate to explain it.	1	2	3	4	5
I like to study with other students.	1	2	3	4	5
Retrieval and Test Taking					
When I can't remember something, I try to remember something else that might be related.	1	2	3	4	5
When I am blocked in answering an essay question, I start by writing an outline of an answer even if I'm not sure what the content of the answer will be.	1	2	3	4	5
When I can't decide which of two multiple choice alternatives is right, I write down the pro's and con's of each.	1	2	3	4	5

	not at all true of me				very true of me
Text Anxiety (Cognitive Interference)					
While taking a test, I worry a lot about items I can't answer.	1	2	3	4	5
When I take tests, I worry a lot about the consequences of failing.	1	2	3	4	5
When I take a test, I think a lot about how poorly I am doing,	1	2	3	4	5
During tests, I think about how other students are doing.	1	2	3	4	5
Thinking					
When a theory, interpretation, or conclusion is presented in class or readings, I try to decide if there is good supporting evidence.	1	2	3	4	5
When I read an assertion or conclusion, I think about possible alternatives.	1	2	3	4	5
I often find myself questioning things I hear or read.	1	2	3	4	5
I treat the course material as a starting point and try to develop my own ideas about it.	1	2	3	4	5
I try to play around with ideas of my own related to what I am studying in this course.	1	2	3	4	5
Thinking is fun.	1	2	3	4	5

Motivation Scale: Value Components

Intrinsic Motivation: Challenge					
I prefer work that is challenging.	1	2	3	4	5
I prefer coursework that arouses my curiosity, even if it is difficult.	1	2	3	4	5
I am interested in this course.	1	2	3	4	5

	not at all true of me				very true of me
Extrinsic Motivation: Grade Orientation					
Getting a good grade is my main goal for this class.	1	2	3	4	5
A good grade in this course is more important to me than what I learn from the course.	1	2	3	4	5
Task Value - Utility					
What I learn in this course will be useful in my vocation.	1	2	3	4	5
I think the course material in this class is useful for me to learn.	1	2	3	4	5
Control Beliefs (Reasons for Success and Failure)					
Internal: Success					
How well I do in this course will depend on how hard I try.	1	2	3	4	5
Internal: Failure					
It is my own fault if I do not do well in this course.	1	2	3	4	5
Motivation Strategies					
I think about how this course relates to my goals.	1	2	3	4	5
I set goals for each week or day.	1	2	3	4	5
Effort Management					
I work hard to get a good grade even when I don't like a course.	1	2	3	4	5
Even when course materials are dull and uninteresting, I manage to keep working until I finish.	1	2	3	4	5

	not at all true of me				very true of me
Self-Efficacy					
I feel confident that I can do well on the assignments for this course.	1	2	3	4	5
I am an effective learner.	1	2	3	4	5

* * * *

APPENDIX E

INSTRUCTOR QUESTIONNAIRE ON CONFER USE

This questionnaire deals with how you used CONFER as a teaching/communication tool in your class. The purpose for having set up a computer conference in class was to provide a convenient way for you and your students to be able to communicate and possibly hold discussions without having to meet face-to-face or coordinate schedules. More importantly, the use of CONFER may provide "teachers" a way to enhance student learning and motivation for the course. Thus, your input is needed in order to provide information on how CONFER can benefit you and your students.

Your cooperation in responding to this survey will be helpful in possibly developing CONFER as an integral part of this course in the most effective way to motivate students and enhance the learning of the course material.

Your participation is greatly appreciated. Thank you very much.

* *

Instructor's Name or Social Security #: _____

Course and Section Number: _____

Today's date: _____

* *

Part 1: Circle the appropriate number on the scale presented after each item.

1. Do you think CONFER has been an effective teaching tool for you as a teacher/T.A.?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

2. Do you think CONFER has been an effective motivational tool for you as a teacher/T.A.?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

3. Do you think CONFER has been an effective learning tool for your students?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

4. Do you think CONFER has been an effective motivational tool for your students?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

5. Do you think the use of CONFER in class made your students feel anxious and concerned?

1	2	3	4	5
definitely yes				definitely not

Briefly explain:

6. To what extent did the use of CONFER help you in the teaching and managing of your class?

1	2	3	4	5
not helpful at all				very helpful

Briefly explain:

7. To what extent do you think the use of CONFER encouraged your students to participate in in-class discussion of the issues/topics in the course?

1	2	3	4	5
very little				very much

Briefly explain:

8. Did you find your students' responses in CONFER a reflection of better learning of the material presented in the course?

1	2	3	4	5
not true at all				very true

Briefly explain:

9. Do you think CONFER was a fun way to teach the material in class?

1	2	3	4	5
not true at all				very true

Briefly explain:

10. Do you think it was worthwhile for your students to learn CONFER?

1	2	3	4	5
definitely not				definitely yes

Briefly explain:

11. How knowledgeable are you about computers in general?

1	2	3	4	5
not knowledgeable at all				very knowledgeable

12. How knowledgeable are you about computer conferencing?

1	2	3	4	5
not knowledgeable at all				very knowledgeable

Part 2: Teaching CONFER

1. Briefly describe how you taught CONFER to your students?

2. Briefly describe how you used CONFER in discussion and/or lecture as an aid to student learning and/or motivation?

3. a) Did you require students to respond/sign on to CONFER? (Circle one.)

   YES NO

   If yes, how often each week?

   If yes, what percentage did CONFER participation contribute to student final grade?

Part 3: Attitude on CONFER use

1. What do you think are the benefits of using CONFER in this class?

2. What do you think are the difficulties or drawbacks of using CONFER in this class?

3. a) Would you use CONFER again in teaching this course?

   YES NO

   b) other Psychology courses?

   YES NO

   Which ones?

Part 4: What suggestions do you have on how CONFER may be used to enhance or help your students in their learning and motivation for this course? Specify what changes you would make, if any, in using CONFER for your class. (You may use the back of the last page of this questionnaire for your response.)

-END-

Thank you very much for responding to this survey.

APPENDIX F

CODE SHEET FOR TRANSCRIPT DATA

The transcripts of the conferences will be analyzed in terms of its quantitative and qualitative content from a sample of students that will be randomly selected from each class. In addition, a brief description of the structure of the conference (e.g., types of items), and how conference participation was implemented will be discussed.

Quantitative Variables (Student)

total number of responses

average number of responses per item

items created

total number of lines per response (based on a Macintosh computer screen, portrait format)

Qualitative Variables (Student)

Code	Variable CONTENT (Category)	Variable FREQUENCY (Integer)
1	citing lecture or professor	#
2	citing TA	
3	citing another student	
4	citing text/article/readings	
5	citing personal experience/s	
6	agreement with another's opinion	
7	disagreement with another's opinion (arguments)	
8	inquiry/asking questions about a class-related topic	
9	CC inquiries/problems	
10	comments about the class (lecture or discussion)	
11	non-academic/social matters	
12	other	
13	N/A (response not applicable to item)	

APPENDIX G

Informed Consent Form

Survey on the Use of CONFER in Introductory Psychology

The use of computer conferencing (i.e., CONFER) in your Introductory Psychology class may be a convenient and efficient way in which you can communicate and hold discussions with your instructor/TA as well as with your other classmates without having to meet face-to-face or coordinate schedules. Moreover, learning conferencing may benefit you by adding to your knowledge about computers and how they can be used to exchange ideas or information with one another. Thus, we need your input on how CONFER can benefit you in class and how its use may be improved.

The title for this research is "Exploring the Use of Computer Conferencing in Introductory Psychology". Two surveys will be conducted. The first one will be given sometime at the beginning of the semester and second one at the end of the semester. These surveys will ask you about your perceptions, evaluations, and suggestions on your use of CONFER in your class. Each survey will approximately take about 20-30 minutes to complete. Completing the survey is voluntary and your answers will be held confidential. Transcripts of the conferencing and final grades may also be looked at as part of the study. As a potential participant in this survey, you may withdraw your participation at any time. Your cooperation in responding to this survey will be helpful in the development and improvement of CONFER as an integral party of this course. It may also help students and instructors use CONFER to enhance classroom interaction and learning in and outside of the classroom. Thus, your participation is valuable in this study.

If you want to participate in this survey, please fill out the blank spaces below. Your participation is greatly appreciated. Thank you very much.

Richard Velayo
Research Coordinator
(313) 477-3326

Carl Berger, Ph.D.
Research Advisor

Signature: _____

Name (please print): _____

Student no. or SS #: _____

Date: _____

Course Name and Section number: _____

Name of Instructor/T.A.: _____

APPENDIX H

STUDENT FEEDBACK FORM

Exploring the Use of Computer Conferencing in Introductory Psychology

Richard S. Velayo
L-215 West Quad
Department of Psychology
580 Union Drive
University of Michigan, Ann Arbor
(313) 747-3721

The purposes of this study are (1) to explore your perceptions and evaluations the use of computer conferencing (i.e., CONFER) over the course of the semester, (2) determine what your suggestions are on ways to improve conferencing use as a supplement to classroom instruction, (3) analyze whether your perceptions relate to your study habits, thinking, and motivation, and (4) observe the kind of communication that transpires in the conferencing environment among students and between instructor and students. From these objectives, this study aims to develop recommendations in how the use of computer conferencing may be improved to help students learn, especially students in Introductory Psychology classes.

As a relatively new technological application in teaching, one potential use of computer conferencing in education is to link teacher with students, as well as students with other students in carrying on discussions about class-related issues on-line regardless of day, time, or location. In this study, computer conferencing provides an extension of the classroom and a complementary way for the students and the instructor to relay information to one another and/or discuss various topics covered in an undergraduate psychology course.

You may or may not have been provided with some training to learn how to use the computer conferencing system (i.e., CONFER). Nonetheless, you were asked to respond to a pretest perception questionnaire on CONFER use. A similar questionnaire (posttest version) was then administered during the last week of classes. The items on both of these questionnaires focused on your perceptions, evaluations, and suggestions on computer conferencing use in your Introductory Psychology course.

In addition, the transcripts of all CONFER items and responses will be examined to yield a quantitative and qualitative account of student-student and student-instructor interaction. Other data include the Motivated Strategies for Learning Questionnaire (MSLQ) and student final grades.

Since the instructional use of computer conferencing is steadily growing, research on this topic is imperative. This technology may become a more effective and efficient learning-teaching tool if your input and concerns are taken into consideration in its design and implementation of the course.

Your participation is greatly appreciated. You have been a valuable source of information to improve the use and understanding of computer conferencing in the classroom. Thank you very much.

APPENDIX I

DESCRIPTIVE STATISTICS FOR STUDENT PERCEPTION ITEMS (PRETEST)

		Group								
Perception Item		ALL	1	2	3	4	5	6	7	8
sample size		(287)	(56)	(50)	(9)	(15)	(12)	(15)	(77)	(53)
worthwhile to learn	Mean	*3.86*	4.15	4.04	3.78	3.93	3.8	4.4	*3.57*	3.64
	SD	(.90)	(.8)	(1.04)	(1.09)	(.83)	(.6)	(.77)	(.9)	(.77)
	Median	4	4	4	4	4	4	5	4	4
	Mode	4	4	4	3	4	4	4	4	4
valuable in learning course	Mean	*3.25*	3.9	3.38	2.11	2.7	3.0	4.0	*2.96*	3.1
	SD	(1.04)	(.85)	(1.03)	(1.05)	(.99)	(1.0)	(1.08)	(.94)	(.85)
	Median	3	4	3	2	3	3	4	3	3
	Mode	4	4	4	2	3	3	4	3	3
anxiety	Mean	3.8	3.4	3.9	4.67	3.86	3.9	4.23	3.75	3.8
	SD	(1.19)	(1.25)	(1.2)	(.71)	(1.2)	(1.54)	(1.17)	(1.16)	(1.1)
	Median	4	3.5	4	5	4	5	5	4	4
	Mode	4	2	4	5	4	5	5	4	4
motivation to learn material	Mean	*2.89*	3.62	3.26	2.0	2.79	2.67	2.9	*2.4*	2.73
	SD	(1.13)	(1.1)	(1.19)	(.71)	(.89)	(1.0)	(1.1)	(.96)	(.99)
	Median	3	4	3	2	3	3	3	2	3
	Mode	3	4	4	2	3	3	3	2	3
motivation to participate in CC	Mean	*3.1*	3.58	3.5	2.44	3.2	2.5	4.15	*2.67*	2.62
	SD	(1.11)	(.94)	(.93)	(1.51)	(1.19)	(.71)	(1.2)	(.97)	(1.0)
	Median	3	4	4	3	3.5	3	5	3	3
	Mode	3	3	4	1	4	3	4	3	3
help understand material	Mean	*3.1*	3.44	3.28	2.56	3.36	3.0	3.46	*2.76*	*3.02*
	SD	(.99)	(.99)	(.85)	(1.51)	(.63)	(.71)	(1.33)	(.96)	(.89)
	Median	3	3	4	2	3	3	3	3	3
	Mode	3	3	3	2	3	3	3	2	3
encourage in-class participation	Mean	*3.05*	3.68	*3.4*	2.67	3.2	2.78	3.09	*2.51*	*2.96*
	SD	(1.19)	(1.1)	(1.12)	(1.8)	(.86)	(1.09)	(1.7)	(1.07)	(1.03)
	Median	3	4	4	2	3	3	4	2	3
	Mode	4	4	4	1	3	2	3	2	3

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		Group								
Perception Item		ALL	1	2	3	4	5	6	7	8
sample size		(287)	(56)	(50)	(9)	(15)	(12)	(15)	(77)	(53)
student responses useful	Mean	*3.67*	4.06	3.96	3.6	3.7	3.56	4.25	*3.19*	3.51
	SD	(1.08)	(.96)	(1.08)	(1.4)	(.89)	(.73)	(.87)	(1.16)	(.87)
	Median	4	4	4	4	4	4	4.5	3	4
	Mode	4	4	4	4	4	3	4	4	4
fun way to learn	Mean	*3.36*	3.75	3.34	3.44	3.8	3.11	4.1	*3.19*	2.96
	SD	(1.1)	(1.15)	(1.24)	(.88)	(.89)	(.93)	(.79)	(1.1)	(.9)
	Median	3	4	4	3	4	3	4	3	3
	Mode	4	3	4	3	4	3	4	3	3

Italicized numbers indicate significant pretest to posttest mean difference (based on Bonferroni-Dunn post hoc analyses)

APPENDIX J

DESCRIPTIVE STATISTICS FOR STUDENT PERCEPTION ITEMS (POSTTEST)

		Group								
Perception Item		ALL	1	2	3	4	5	6	7	8
sample size		(287)	(56)	(50)	(9)	(15)	(12)	(15)	(77)	(53)
worthwhile to learn	Mean	*3.56*	4.33	4.17	2.4	3.78	2.8	4.64	*2.72*	3.08
	SD	(1.23)	(.97)	(.82)	(1.5)	(.67)	(1.1)	(.63)	(1.1)	(1.1)
	Median	4	5	4	2	4	3	5	3	3
	Mode	4	4	4	1	4	3	4	3	3
valuable in learning course	Mean	*2.94*	4.02	3.71	1.8	2.78	1.5	4.1	*1.79*	2.5
	SD	(1.33)	(1.02)	(.94)	(1.3)	(.97)	(.58)	(.83)	(.8)	(1.03)
	Median	3	4	4	1	3	1.5	4	2	2.5
	Mode	3	4	4	1	3	1	4	1	2
anxiety	Mean	3.8	3.62	3.4	4.4	3.78	4.0	4.5	3.73	4.2
	SD	(1.16)	(1.05)	(1.2)	(1.34)	(1.2)	(1.4)	(.76)	(1.22)	(1.03)
	Median	4	4	3.5	5	4	4.5	5	4	4.5
	Mode	4	3	4	3	4	4	4	4	4
motivation to learn material	Mean	*2.6*	3.33	3.45	2.0	2.56	1.9	3.64	*1.6*	2.44
	SD	(1.25)	(1.03)	(1.04)	(1.4)	(.88)	(.96)	(1.1)	(.86)	(1.05)
	Median	3	3	3	1	3	1.5	4	1	2.5
	Mode	3	3	3	1	3	1	4	1	3
motivation to participate in CC	Mean	*2.87*	3.83	3.33	2.4	3.11	2.33	3.6	*1.98*	2.42
	SD	(1.31)	(1.04)	(.95)	(1.95)	(1.27)	(1.2)	(1.3)	(1.08)	(1.13)
	Median	3	4	3	1	3	3	4	2	2
	Mode	3	4	3	1	4	1	4	1	2
help understand material	Mean	*2.58*	3.33	3.48	1.8	2.67	1.33	3.64	*1.54*	*2.14*
	SD	(1.26)	(.99)	(1.02)	(1.1)	(.87)	(.58)	(1.08)	(.77)	(1.05)
	Median	2	3	4	1	3	1	4	1	2
	Mode	1	3	4	1	3	1	4	1	1
encourage in-class participation	Mean	*2.5*	3.37	*2.95*	1.8	2.5	1.7	3.93	*1.49*	*2.14*
	SD	(1.32)	(1.22)	(1.23)	(1.1)	(.88)	(1.16)	(.92)	(.75)	(1.13)
	Median	3	4	3	1	3	1	4	1	2
	Mode	4	4	4	1	3	1	4	1	1

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		Group								
Perception Item		ALL	1	2	3	4	5	6	7	8
sample size		(287)	(56)	(50)	(9)	(15)	(12)	(15)	(77)	(53)
student responses useful	Mean	*3.08*	3.91	3.93	2.8	3.3	3.0	4.3	*1.73*	2.81
	SD	(1.38)	(.92)	(1.09)	(1.67)	(1.2)	(1.7)	(.73)	(.85)	(1.2)
	Median	3	4	4	2	3	4	4	2	3
	Mode	4	4	4	1	3	1	4	1	3
fun way to learn	Mean	*3.08*	3.8	3.55	2.6	3.56	2.33	4.2	*2.07*	2.89
	SD	(1.33)	(1.13)	(1.02)	(1.5)	(.73)	(1.2)	(.98)	(1.15)	(1.2)
	Median	3	4	4	2	4	3	4.5	2	3
	Mode	4	4	4	1	3	1	4	1	3

Italicized numbers indicate significant pretest to posttest mean difference (based on Bonferroni-Dunn post hoc analyses)

APPENDIX K

SIGNIFICANT DIFFERENCES AT $p < .01$ IN PRETEST PERCEPTION MEANS BETWEEN GROUPS

Perception item (pretest)	Groups	Mean Difference	Critical Difference
valuable in learning course	1, 3	1.81**	1.30
	1, 7	0.96**	0.67
	1, 8	0.83**	0.74
motivation to learn material	1, 3	1.63**	1.42
	1, 7	1.24***	0.74
	2, 7	0.87**	0.74
motivation to participate in CC	1,7	0.92**	0.72
	1, 8	0.96**	0.79
	2, 7	0.81**	0.72
	6, 7	1.49**	1.15
	6, 8	1.53**	1.20
encourage in-class participation	1, 7	1.17**	0.90
student responses useful	1, 7	0.87**	0.74

***$p<.001$
**$p<.01$

APPENDIX L

MEANS AND STANDARD DEVIATIONS FOR MSLQ SUBSCALES

MSLQ Subscale sample size		ALL (287)	Group 1 (56)	2 (50)	3 (9)	4 (15)	5 (12)	6 (15)	7 (77)	8 (53)
MP	Mean	3.36	3.38	3.33	3.46	3.37	3.46	3.19	3.41	3.31
	SD	(.53)	(.54)	(.52)	(.48)	(.39)	(.77)	(.4)	(.53)	(.57)
MM	Mean	3.37	3.48	3.5	3.25	3.52	3.31	3.04	3.36	3.2
	SD	(.61)	(.59)	(.59)	(.92)	(.56)	(.4)	(.64)	(.61)	(.55)
TSM	Mean	3.5	3.55	3.68	3.93	3.46	3.19	3.65	3.37	3.4
	SD	(.67)	(.74)	(.61)	(.7)	(.39)	(.68)	(.72)	(.66)	(.68)
STE	Mean	3.82	3.6	4.01	4.17	3.54	3.75	3.81	3.83	3.88
	SD	(.91)	(1.05)	(.86)	(.66)	(1.13)	(1.0)	(.92)	(.92)	(.67)
ATT	Mean	3.0	2.95	3.03	3.06	3.28	3.06	2.88	2.93	3.04
	SD	(.59)	(.6)	(.57)	(.45)	(.97)	(.46)	(.54)	(.61)	(.5)
ES	Mean	3.31	3.3	3.42	3.64	3.32	3.31	3.33	3.19	3.31
	SD	(.78)	(.82)	(.8)	(.92)	(.94)	(.56)	(.7)	(.81)	(.63)
OS	Mean	3.88	3.73	4.04	4.11	3.98	3.47	3.83	3.93	3.78
	SD	(.66)	(.63)	(.65)	(.91)	(.69)	(.72)	(.77)	(.66)	(.59)
RS	Mean	3.46	3.29	3.43	3.67	3.52	3.42	3.17	3.61	3.46
	SD	(.77)	(.85)	(.76)	(.82)	(.94)	(.43)	(.82)	(.68)	(.77)
PL	Mean	2.77	2.77	2.7	2.33	2.76	2.72	2.66	2.92	2.72
	SD	(.93)	(1.11)	(.85)	(.91)	(1.05)	(1.28)	(.78)	(.91)	(.77)
RTT	Mean	3.18	3.3	3.04	3.52	3.67	3.29	2.97	3.02	3.26
	SD	(.79)	(.67)	(.8)	(.78)	(.92)	(.7)	(.92)	(.81)	(.74)
TA	Mean	2.85	2.59	2.81	2.61	2.7	3.0	2.62	3.15	2.85
	SD	(1.01)	(.99)	(1.03)	(.75)	(1.16)	(.95)	(.93)	(1.06)	(.9)
TH	Mean	3.49	3.81	3.45	3.56	3.61	3.27	3.4	3.4	3.36
	SD	(.72)	(.72)	(.76)	(.91)	(.8)	(.69)	(.77)	(.67)	(.59)
IM	Mean	3.93	4.14	3.87	3.93	3.93	3.79	4.26	3.83	3.86
	SD	(.64)	(.68)	(.53)	(.8)	(.71)	(.4)	(.45)	(.68)	(.64)

(continued next page)

MSLQ Subscale sample size		ALL (287)	1 (56)	2 (50)	3 (9)	4 (15)	5 (12)	6 (15)	7 (77)	8 (53)
						Group				
EM	Mean	3.37	3.17	3.35	3.17	3.43	3.12	2.0	3.68	3.58
	SD	(.99)	(1.12)	(.94)	(.71)	(.92)	(.79)	(1.17)	(.91)	(.68)
TV	Mean	3.91	4.02	3.99	3.94	3.75	4.31	4.5	3.67	3.9
	SD	(.88)	(.87)	(.79)	(.77)	(.83)	(.7)	(.61)	(.96)	(.89)
CB	Mean	4.26	4.33	4.27	4.33	4.18	4.31	4.0	4.21	4.33
	SD	(.74)	(.76)	(.73)	(.5)	(.61)	(.53)	(1.17)	(.74)	(.74)
MS	Mean	3.44	3.43	3.45	3.72	3.54	3.31	3.69	3.36	3.44
	SD	(.93)	(.96)	(.96)	(.91)	(.97)	(1.07)	(.81)	(.97)	(.82)
EFF	Mean	3.81	3.81	3.77	3.89	3.25	3.88	3.81	3.91	3.86
	SD	(.95)	(1.07)	(1.01)	(.86)	(.92)	(.74)	(.9)	(.86)	(.93)
SE	Mean	4.2	4.36	4.27	4.5	3.96	3.69	4.38	4.07	4.23
	SD	(.69)	(.68)	(.71)	(.61)	(.57)	(.88)	(.77)	(.65)	(.68)

Abbreviations:
MC - metacognition - planning
MM - metacognition - monitoring
TSM - Time/Study Management
STE - Study environment
AT - attention
ES - elaboration strategies
OS - Organizational Strategies
RS - rehearsal strategies
PL - peer learning
RTT - retrieval/test taking
TA - test anxiety
TH - thinking
IM - intrinsic motivation
EM - extrinsic motivation
TV - task value (utility)
CB - control belief
MS - motivational strategies
EF - effort management
SE - self-efficacy

APPENDIX M

TABLE OF SIGNIFICANT CORRELATIONS (PEARSON r) BETWEEN STUDENT PRETEST PERCEPTION SCORES AND THE MSLQ FOR EACH GROUP (Criteria: -0.3 > r > 0.3, p < .05).

	Group							
Perception Item	1 (n=38)	2 (n=46)	3 (n=9)	4 (n=14)	5 (n=7)	6 (n=10)	7 (n=49)	8 (n=37)
worthwhile to learn	IM(0.46) TV(0.32)	RTT(0.35)				PL(-.075) TA(-0.68) IM(0.71) EM(-0.72)	TH(0.31) IM(0.41) EM(-0.3)	CB(0.37)
valuable in learning course	IM(0.41)	PL(0.39) EF(-0.35)	MM(0.71) ES(0.85) TH(0.8) EF(0.71)			MM(-0.84)		IM(0.41)
anxiety	MP(0.33) MM(0.37) ES(0.38) TA(-0.46) TH(0.44) EM(-0.5) SE(0.62)	TA(-0.39)	TA(-0.92)		TA(-0.87) SE(0.81)	TA(-0.79)	MS(-0.34) EF(-0.37)	
motivation to learn material	IM(0.34) MS(0.34)	RTT(0.32)					TV(0.42)	OS(0.38)
motivation to participate in CC	TH(0.44)	RTT(0.31)	TSM(0.79) IM(0.69) EM(-0.72) EF(0.82)	MM(0.59) RTT(-0.71) MS(-0.54)		PL(-0.72) TA(-0.67) EM(-0.87)	TV(0.31)	OS(0.34)
help understand material	PL(0.44) TH(0.33)	-EF(0.3)	RTT(0.82) TV(0.79) EF(0.73)	ES(0.57) OS(0.72) RS(0.61) TA(0.58)	IM(0.76) CB(-0.85)	STE(0.64) EM(0.-0.82)		
encourage in-class participation	STE(0.33) ES(0.35) PL(0.39)	STE(0.33) RTT(0.47)	ES(0.92) TH(0.7)	PL(0.58) MS(-0.65)	TA(-0.76)		IM(0.35) TV(0.3)	TH(0.38)

(continued next page)

Group

Perception Item	1 (n=38)	2 (n=46)	3 (n=9)	4 (n=14)	5 (n=7)	6 (n=10)	7 (n=49)	8 (n=37)
student responses useful		TSM(0.41) STE(0.45)		MP(0.75) MM(0.63) RTT(-0.63)	CB(-0.81) TH(0.67)	PL(-0.8) TV(0.34) IM(0.77) EM(-0.81)	PL(0.3)	
fun way to learn	ES(0.4) IM(0.51) TV(0.39)		TSM(0.67)			ES(0.78) RS(-0.69)		ES(-0.35)

Abbreviations:

MC - metacognition - planning
MM - metacognition - monitoring
TSM - Time/Study Management
STE - Study environment
AT - attention
ES - elaboration strategies
OS - Organizational Strategies
RS - rehearsal strategies
PL - peer learning
RTT - retrieval/test taking
TA - test anxiety
TH - thinking
IM - intrinsic motivation
EM - extrinsic motivation
TV - task value (utility)
CB - control belief
MS - motivational strategies
EF - effort management
SE - self-efficacy

APPENDIX N

TABLE OF SIGNIFICANT CORRELATIONS (PEARSON r) BETWEEN STUDENT POSTTEST PERCEPTION SCORES AND THE MSLQ FOR EACH GROUP (Criteria: -0.3 > r > 0.3, p < .05).

Group

Perception Item	1 (n=37)	2 (n=39)	3 (n=5)	4 (n=8)	5* (n=3)	6 (n=10)	7 (n=41)	8 (n=21)
worthwhile to learn	IM(0.41) EM(-0.33) TV(0.34)	OS(0.37)	ES(0.92) IM(0.88) EM(-0.88) TV(0.94)	RTT(-0.73) TA(0.76)		TV(0.63) SE(0.63)		PL(0.45)
valuable in learning course	IM(0.4) EM(-0.38) TV(0.45)	RTT(0.94)	ES(0.85) MS(-0.79)	RTT(-0.73)		TA(-0.64)	TSM(0.39)	TSM(0.53)
anxiety		RTT(0.43) TA(-0.3)	TA(-0.96)			TSM(0.64) AT(-0.81) RTT(0.65) TH(-0.72)	MS(0.41)	
motivation to learn material	TH(0.41) IM(0.36) EM(-0.36)	OS(0.35)	ES(0.97) RTT(0.94) IM(0.89) TV(0.89) EF(0.89)			EM(-0.75)	TA(0.34)	
motivation to participate in CC	PL(0.34) TH(0.43) EM(-0.34)	OS(0.32) RTT(0.31) EM(-0.98)	ES(0.86) IM(0.9) EF(0.9)	RTT(-0.85)		TH(0.68) EM(-0.85) EF(-0.67)		MM(0.51) RS(0.7) EM(0.46)
help understand material	PL(0.44) TH(0.33) IM(0.33)	ES(0.33) PL(0.41) TH(0.44)	ES(0.94) IM(0.92) EM(-0.92) EF(0.92)	RTT(-0.8)		STE(0.74) EM(-0.75)		RS(0.53)
encourage in-class participation			ES(0.94) IM(0.92) EM(-0.92) EF(0.92)	OS(0.79) RS(0.79))				TH(-0.45)

(continued next page)

Group

Perception Item	1 (n=37)	2 (n=39)	3 (n=5)	4 (n=8)	5* (n=3)	6 (n=10)	7 (n=41)	8 (n=21)
student responses useful	TSM(0.34) PL(0.34) TV(0.43)	STE(0.39) ES(0.34) PL(0.41)	RTT(-0.76)		EM(-0.68)		MM(0.46)	TSM(0.44) RS(0.51)
fun way to learn	ES(0.42) TH(0.48) IM(0.41)		ES(0.92) IM(0.89) EM(-0.89) TV(0.94)			CB(0.72)	MS(-0.31)	RS(0.48)

Abbreviations:

MP - metacognition - planning
MM - metacognition - monitoring
TSM - Time/Study Management
STE - Study environment
AT - attention
ES - elaboration strategies
OS - Organizational Strategies
RS - rehearsal strategies
PL - peer learning
RTT - retrieval/test taking
TA - test anxiety
TH - thinking
IM - intrinsic motivation
EM - extrinsic motivation
TV - task value (utility)
CB - control belief
MS - motivational strategies
EF - effort management
SE - self-efficacy

*Note that there were no meaningful significant posttest correlations computed for Group 5 because of insufficient sample size.

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Retention of Content Material as a Function of Mode of Presentation and Preconceived Degree of Difficulty

A Thesis Presented to
the Faculty of the Graduate School
University of the Pacific

In Partial Fulfillment
of the Requirements for the Degree
Master of Arts

by
Richard S. Velayo

December 1988

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Richard S. Velayo

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Abstract

The effects of the mode of presentation and the preconceived degree of difficulty on the retention of academic content material were measured. The design of the experiment was a 6 x 3 x 2 split-plot factorial. The levels for the mode of presentation were: (a) print-only, (b) pictorial-plus-print, (c) audio-only, (d) pictorial-plus-audio, (e) print-plus-audio, and (f) pictorial-plus-print-plus-audio. The levels for the preconceived degree of difficulty were: (a) very easy, (b) neutral, and (c) very difficult. The participants were 112 undergraduate students (24 males, 88 females) randomly assigned to the experimental conditions. The dependent variables were the immediate and delayed retention of content material measured through the use of four criterion tests: a drawing test, an identification test, a terminology test, and a comprehension test. Results for the univariate split-plot ANOVA of the total scores showed that the main effects of mode and preconceived degree of difficulty were found to be significant. All four predicted differences between means were not statistically significant. Only one of the three

hypotheses of no significant difference was supported--the hypothesis of no significant difference between the pictorial-plus-print-plus-audio condition and the pictorial-plus-audio condition. No significant mean differences between the easy, neutral, and difficult conditions were found, although there was a significant main effect and the means for these conditions were ordered such that the more difficult the content material was perceived, the lesser was the ability to retain such material. Multivariate analysis of the immediate and delayed tests showed that the major factors contributing to the significant effect of mode were the drawing and identification tests, but subsequent multiple comparison tests did not show significant support for any predictions. For the identification test, a significant main effect for mode showed that the pictorial-plus-audio and pictorial-plus-print-plus-audio means were significantly superior to the audio-only mean.

Retention of Content Material as a Function of Mode of Presentation and Preconceived Degree of Difficulty

Central to all intellectual functions is our capacity for memory. Memory plays a very important part in the way we function and, more specifically, the way we learn. In the present study, I measured the effects of the mode of presentation of information and the preconceived degree of difficulty on the immediate and delayed retention of content material.

When psychologists study memory, they first examine all of its three major components (i.e., encoding, storage, and retrieval) and then focus more on the storage component which is also referred to in this study as "retention." For instance, if we examine the studying behavior of college students and the rate at which they learn and store information, then we are concerned primarily with acquisition or learning. However, if we focus on what happens to that stored information after the students have studied, then we are concerned primarily with retention or memory. To study learning means to study retention

as well. In fact, the only way we can test to see if learning has occurred is to test for retention of the material in question (Houston, Bee, Hatfield, & Rimm, 1981). This study, though dealing with both learning and retention, focused on the retention of information.

A common criticism of current educational practices involves the lack of effective instructional methods to facilitate memory improvement (Klatzky, 1975). Fundamental to this problem is the universal assumption that students will learn simply because they are asked, or told, to learn or because we supply them with one of the increasing number of technological devices or supports available. We instead need to learn more about how to facilitate a person's ability to develop and use effective and efficient memory strategies. Although it is true that many of us acquire effective memorization skills as a function of our individual experiences, there still is a need to study and systematize these skills.

The present study dealt with the immediate and delayed retention of content material as a function

of two variables, the mode of presentation of instructional material and the student's preconception of the degree of difficulty of the material to be memorized. In the following sections, research on each of these variables has been reviewed. However, since I could find no research study that specifically took into account both variables, the following discussion of the literature is divided into three main sections: (1) studies on learning and memory as a function of the mode of presentation of content material, (2) self-efficacy and verbal persuasion, and (3) purpose of the present study.

Mode of Presentation of Instructional Material

Pictorial versus print modes. In a research study conducted by Goldberg (1974), 216 fifth-grade children (113 boys, 103 girls) were presented with illustrated or nonillustrated incidental information (i.e., information which subjects were not aware they needed to remember). The primary purpose of the study was to determine whether illustrations facilitate incidental learning. The subjects within each class were paired according to

reading scores obtained on the Metropolitan Achievement Test. Each member of the matched pair was then randomly assigned to the imagery or nonimagery group. The imagery and nonimagery groups differed by the presence or absence of illustrations for their incidental-learning materials. The incidental learning materials consisted of prose material relating to social studies or science facts. A fixed amount of time was alloted for text comprehension and the tests. One recall (fill-in) and one recognition (multiple choice) test were administered to all children. The main effect of imagery was significant; the higher scores obtained by the imagery group in both curricular areas clearly demonstrate that illustrated incidental material was better retained than nonillustrated incidental material. Most children also scored higher on incidental-learning recognition questions than on recall questions.

In a study by Peeck (1974), 71 fourth graders read an adapted version of a "Rupert Bear" story. Subjects were given either an illustrated or a nonillustrated text while the retention test

contained questions on elements exclusively present either in the pictures, or in the text, or present in both pictures and text. In order to secure as natural a reading process as possible, the children were not given any learning instructions (i.e., the children were not instructed to remember the material) nor were they prepared for a retention test. Testing for retention took place (a) immediately after completion of the story, (b) after 1 day, and (c) after a week. The subjects were allowed to read the material at their own pace. Results showed that retention of the text contents was higher in the illustrated than in the nonillustrated condition. Participants in the illustrated condition retained significantly more picture-plus-text contents than children in the nonillustrated condition for the immediate and delayed measures.

In a study by Haring and Fry (1979), participants were 75 fourth graders and 75 sixth graders from a middle-class school. A 360-word version of "Mercury and the Woodcutter" from Aesop's Fables was adapted for this study. A

system of prose analysis was used to analyze the story into 350 idea units (i.e., words used in the passage, terms specifying the roles or relationships between those words, and terms specifying the relationships of ideas in the narrative). Two sets of pictures were drawn to be completely redundant with the text they illustrated. The children were assigned to one of three conditions. The first condition consisted of a text with a set of 10 pictures depicting only 179 idea units. The second condition consisted of a text with 13 pictures that were more detailed and depicted all 350 idea units. Children in the third condition received the text with no pictures. Thus, each student received a copy of the story in a booklet with one of the two sets of pictures interspersed or with no pictures. The students were instructed to read the story once at their own pace after which they were asked to write everything they remembered about the story. Unannounced, 5 days later, all participants were again asked by the experimenters to write all they could remember of the story. Results revealed that

children in the two picture conditions recalled significantly more idea units both immediately and 5 days later than did children in the no-pictures condition. The more detailed pictures did not facilitate significantly more recall. The interaction of grade and time of recall was not significant. However, main effects were found for grade and for time of recall.

In a study by Rusted and Coltheart (1979), 72 children (9-year-olds) were required to read descriptive passages presented with line drawings (pictorial) or without line drawings (nonpictorial) of the subjects of those passages. The 36 poor readers had a mean chronological age of 8.3 years. Six short factual passages were contructed, each having as its subject a highly unusual plant or creature. Each passage was constructed both with and without a black outline drawing of the subject. The six passages were randomly divided into two sets of three. Each student received both sets, one set with pictures and the other set without. Each passage was read twice to familiarize the children with the words in the passages. About 5

to 7 min following the second reading, participants were required to verbally recall (immediate recall) all they could of the passages. Students were then instructed to write down the list of names of the six creatures from the passages (delayed recall). Results show that in the immediate recall, the children recalled significantly more features from the passages presented with pictures than from those presented without. This pattern of results was repeated in delayed recall where children still recalled more from passages presented with pictures. Further analyses also showed that in immediate recall, a significantly greater proportion of nonpictorial features were remembered compared to delayed recall. There was no significant overall conditions difference in the proportion of pictorial and nonpictorial features recalled in delayed recall. However, in the picture condition, a higher proportion of pictorial features was recalled, while the reverse was true in the no-picture condition. The effect of presentation condition was significant with more of both pictorial and nonpictorial features recalled

in the picture condition than in the nonpictorial condition.

In a study by Rusted and Hodgson (1985), 9-year-old children (40) were required to read either factual or fictitious passages, presented with or without a relevant picture. Two passages, one factual and one fictitious, were written about each of six unusual creatures. For each creature, the factual passage presented a short description, while the fictitious text provided a short story, relating an incident involving that creature. The two texts contained the same eight critical facts about the creatures, four physical features which could be portrayed pictorially and four nonpictorial features concerning living/eating habits. Type of passage (factual/fictitious) was a between subjects variable, with 20 children randomly assigned to each condition. Students were told that the study was about remembering and that they would be asked to read some short passages and afterwards to recall all they could about each. Results revealed no significant difference in critical feature recall between the factual and the

fictitious passages. The presence of a relevant picture significantly improved recall. There was also a main effect for type of features recalled, with more nonpictorial features being recalled than pictorial ones. There were two significant interactions in the analysis. In the interaction of type of passage and presence/absence of illustrations, the illustrations had a greater effect on recall when presented with the factual texts. Test of simple main effects indicated that the advantage of illustrated over unillustrated texts was significant for factual passages only. The other significant interaction occurred between presence/absence of illustrations and pictorial/nonpictorial feature recall. Tests of simple main effects indicated that the presence of illustrations significantly improved recall of pictorial facts but not of nonpictorial facts (i.e., descriptions that were not shown in an illustration). Although the three-way interaction between passage type, illustrations, and feature type was not significant, planned comparisons indicated that, for factual passages, illustrations

significantly improved recall of both pictorial and nonpictorial facts. For fictitious passages, illustrations significantly improved recall for pictorial facts but not for nonpictorial facts which tended to be recalled better in the absence of illustrations.

Dwyer and De Melo (1984) conducted an experiment with 151 undergraduate students which was designed to investigate the effect of several different variables on information acquisition: (a) mode of instruction [verbal (printed) instruction alone versus verbal instruction complemented by simple line drawings], (b) mode of achievement test [visual testing (presence of pictorial cues to supplement test material) versus nonvisual testing (absence of pictorial cues to supplement test material)], (c) mode of drawing test [verbally cued (i.e., names of parts of the heart were given) versus free recall (i.e., names of parts of the heart were not given)], and (d) order of drawing test (before or after taking the identity, terminology, and comprehension tests). The material used in this

study was a 2,000-word instructional booklet describing the human heart, its parts, and the internal processes that occur during the systolic and diastolic phases. Results showed that the visual version (printed prose complemented by simple line drawings) of the instructional unit significantly improved students' information acquisition on both the immediate and delayed retention tests as compared to printed prose alone. Students who received the nonvisual test format (printed prose only) achieved higher mean test scores than those who received the visual version of the same tests. However, these differences disappeared on the 2-week delayed retention tests. The criterion tests were constructed to measure recall and recognition of the instructional material. The nonvisual testing mode was found to be more effective for the comprehension scores and total scores on tests of immediate and delayed retention. The order of drawing test and mode of drawing test had no significant main effects on the students' performance on the tests.

Summary: Pictorial versus print. Researchers have generally found that pictures are effective supplements to the retention of prose material when such pictures are well-designed and congruent with prose content and sequence. Nevertheless, the relative information carrying value of verbal and visual presentations is not clear. Some researchers who have compared the effectiveness of verbal and pictorial presentations of the same information have concluded that verbal presentations are equally effective as pictorial presentations, noting that during delayed recall, there was no significant difference between pictorial and nonpictorial features. However, conflicting results have been reported. Consequently, definitive findings about the effectiveness of different presentation modes for transmitting information are not readily derived from existing research. Combined pictorial-print modes, on the other hand seem to be more effective than single mode presentations in the retention of content material.

Pictorial versus audio. A study done by Friedlander, Wetstone, & Scott (1974), measured preschool children's comprehension of visual and verbal elements in a 3 min age-appropriate informational television program. Thirty-one children with ages ranging from 4- to 6-years-old participated. Recall performance was measured through questions for which the information available was presented both visually and auditorily, visually only, or auditorily only. More than half of the children demonstrated comprehension of less than half of the tested information. Analysis of the data indicated that the children did comprehend the general flow of ongoing activity but demonstrated poor comprehension of statements of fact related to the central theme, and of elements presented either in visual or auditory modality alone. Recall performance was significantly higher on the audio-plus-visual questions. In general, the study found that the verbal-visual form of presentation was better recalled than single-mode presentations.

In an experiment (Experiment 1) conducted by

Levin and Berry (1980), 50 fourth-grade children were randomly assigned in equal numbers to picture and control conditions. In the picture condition, the children were shown text material with accompanying illustrations while they listened to a series of newspaper stories. In the control condition, the children simply listened to the stories and saw no pictures. Five human interest and novelty stories were gleaned from local newspapers and each article was condensed to approximately 100 words. All resulting stories were ascertained to be at a fourth-grade reading level. For each passage, a single 8 1/2 x 11 in. (21.59 x 28.49 cm) colored line drawing was constructed to illustrate the main idea of the passage. Six short-answer paraphrase questions were composed for each passage. The child's task was to remember the content of the newspaper articles. Results indicate that for pictured information, the average recall of picture subjects surpassed that of the controls. Moreover, for nonpictured information, the recall means were quite similar. Thus, it was concluded that text-

relevant pictures facilitated recall of information.

The second experiment by Levin and Berry (1980) was conducted to determine whether the effects observed in Experiment 1 would be the same when the interval between presentation and testing was longer. The subjects in this second experiment were 37 fourth-graders. Nineteen children were randomly assigned to the picture condition, and 18 to the control condition. A sixth newspaper passage was developed and added to the previous five. The number of questions per passage was reduced from six to four, with two relating to pictured and two to nonpictured information. After presenting the material to the children, recall of the passage's content was assessed 3 days later in the same manner as in Experiment 1. Even though the overall level of recall was lower than that of Experiment 1, the pattern of recall differences between the experimental and control groups in the two experiments was similar. The average recall of pictured information by picture subjects was significantly higher than that of control subjects.

Picture and control students also did not differ significantly with regard to recall of nonpictured information. Thus, the picture effect was replicated using the present newspaper passages, even with a 3-day interval between the initial presentation and subsequent test.

A study by Carey and Hannafin (1981) examined the relationships among presentational stimuli (oral, visual, oral-plus-visual), types of content (concrete, abstract), and learner ability (high verbal, low verbal). A total of 248 third grade students either heard a short story, watched pictures showing the same short story, or heard and watched a combination of the oral and picture presentations. All presentations lasted 15 min to control time on task. Student recall of concrete and abstract information was measured by a recall test immediately after and 2 weeks after the presentations. A second dependent variable was a measure of mislearning (i.e., information that was not "correct," but was learned and remembered). This score was derived by counting the number of items for which a subject had made the same

incorrect response on both the immediate and delayed tests. Students learned as much or more concrete and abstract information from pictures as from oral prose, and learned the most information from the combination of oral prose with pictures. Mislearning of concrete and abstract information, such as repeating the same incorrect response on both immediate and delayed tests, was higher from the picture presentation than from the oral presentation, and lowest from the combination of oral prose with pictures. Significant interactions were not found among types of presentational stimuli, types of content, and levels of learner ability.

In a similar study by Hannafin and Carey (1981), a total of 152 fourth grade students participated in a study examining the effects of visual-only, verbal-only, and combined audiovisual (or visual-verbal) prose presentations and different elaboration strategy conditions on learning of abstract and concrete prose. The students saw and/or heard a short animated story, during which they were instructed to think of

pictures, think of words, draw pictures, write sentences, or use their own personal strategy to help them remember the material. A test measured recall of concrete and abstract prose immediately after and 1 week after the presentations. The audiovisual group recalled significantly more concrete and abstract information than students in the other groups, while the visual-only group had higher recall of concrete prose than did the verbal only group. Repeated errors (making the same incorrect response in both the immediate and the delayed tests) were lowest in the combined audiovisual group. The visual-only group made more repeated errors for abstract prose than did the verbal-only group, but this pattern was reversed for repeated errors in concrete prose recall. Students using pictorial elaboration strategies made fewer repeated errors than did students using other elaboration strategies.

A study by Welch (1982) investigated the learning impact of audio, visual, and audiovisual information channels in televised messages among 50 4- to 6-year old preschool children. The messages

were contained in a videotape which consisted of a half-hour "Mister Roger's Neighborhood" program and a program of 12 selected segments of "Sesame Street." A second videotape was prepared containing the same programs but the position of segments of the programs was reversed to control for the order effects on learning. Each child viewed one of the videotapes once. Immediately after the tape ended, the experimenter administered a recall test which was broken down in terms of the mode by which the information necessary to answer the question was presented (audio track, the visual track, and both tracks congruently). Results of the study indicated that audiovisual messages and visual messages were recollected significantly better than audio ones. There was no significant difference between audiovisual and visual messages.

Hannafin (1983) examined the effects of different presentation modes and verbal ability on the recall of abstract and concrete prose. The subjects were 180 third graders. Five different versions of a children's short story were developed. All were adapted from "Wump World"

which dealt with fictitious invaders of a fictitious world. The five presentation conditions were: ORAL, an audiotape presentation of the story; SIMPLE, a slide presentation of the illustrations used in the text of the short story; CLOSE-UP, the same sequence of slides used in the SIMPLE condition, with additional close-up pictures of criterion information distributed throughout the story; ORAL + SIMPLE, a combination of the audiotape and the SIMPLE slides; and ORAL + CLOSE-UP, a combination of the audiotape and CLOSE-UP slides. Time on task was controlled within the rates and segments of the story (i.e., the pace of the presentation for the ORAL and SIMPLE conditions was congruent with the pace of the ORAL presentation), permitting an exact equalization of the pacing of the presented information. The two dependent variables were abstract recall and concrete recall which were measured through a short answer essay test. The test was administered orally by audiotape. The subjects saw and/or heard the presentation in accordance with treatment and group assignment. The test was given immediately

after presentation and repeated 2 weeks later for a measure of delayed recall. The group receiving the ORAL + CLOSE-UP picture presentation obtained the highest mean performance on both immediate and delayed tests, followed by the groups presented ORAL + SIMPLE picture, CLOSE-UP picture, SIMPLE picture, and finally ORAL only prose presentation. The performance yielded by bimodal presentations not only resulted in a predictable improvement overall, but also in a predictable improvement of each progressively loaded level of presentation. A significant main effect was found for test scale with students recalling more concrete than abstract information. The findings in this study supported the hypothesis that combined oral-picture presentations resulted in superior learning of both concrete and abstract content.

In a follow-up study by Hannafin (1984), a total of 121 third and fourth graders were randomly assigned to instructional treatment groups, each of which featured a short children's story. The purpose of this study was to investigate the relative effectiveness of different verbal versus

pictorial versus verbal-pictorial presentations on student recall of concrete and abstract prose. Three treatment presentations, each depicting an adapted children's text, "The Wump World," were used. The three presentations included: ORAL, an audiotape verbal presentation of the story; PICS, a slide presentation of the text pictures used to depict the story; and ORAL + PICS, a combination of the audiotape and slides. Each version was 18 min in duration and paced identically to control student time on task. The criterion measure was a short-answer test, measuring recall of abstract and concrete information. All test directions and questions were presented once and paced through audiotape. The criterion test was administered immediately after the presentation and 1 week later as a measure of delayed recall and retention. Recall of concrete information was significantly greater than abstract recall. The ORAL + PICS presentation was consistently the most effective for both abstract and concrete recall. The mean scores obtained by the ORAL and PICS presentation groups for abstract recall were comparable but the

PICS presentation was significantly more effective than the ORAL presentation for recall of concrete content. In effect, picture presentations were relatively more effective overall than oral-only.

A study by Pezdek and Stevens (1984) examined the relationship between children's cognitive processing of video (visual) and audio information on television. Ninety-six 5-year-old children viewed a videotape segment of "Sesame Street" followed by a comprehension test and a recognition test. Equal numbers of subjects viewed an experimental segment in which (a) the audio and video tracks were from the same segment (audiovisual match), (b) the audio and video tracks were not from the same segment (audiovisual mismatch), (c) the video track was presented alone, or (d) the audio track was presented alone. The design allowed unconfounded comparisons of modality-specific processing. In the audiovisual mismatch condition, memory for audio information was reduced more than memory for video information. However, comprehension and recognition of audio information was similar in the audio-only and

audiovisual match conditions. These results suggest that in regular television programs, the video information does not interfere with processing the audio information, rather, the video material simply appears to be more salient and more memorable than the audio material.

Field and Anderson (1985) examined 5- and 9-year-old's television viewing and program recall in response to learning instructions. The television program consisted of segments that emphasized visual information, auditory information, or information presented redundantly in both auditory and visual modalities. The 80 children were shown a 35 min color videotape containing six short segments. The program included the three types of modality emphasis. Two of the segments were primarily visual, most of the informative content was communicated visually, with very little information provided by the auditory modality. These segments were animated stories with musical accompaniment. Two other segments contained mainly auditory content, with little or no informative support from the visual modality. Puppet skits

composed of dialogue among characters who moved very little around a fixed background were used. The third type of story emphasized audiovisual content, in which the central material was presented on both the auditory and the visual channel. The same information could be learned by either listening or viewing. Recall questions were designed to examine learning of auditory, visual, and audiovisual content. Recall of information was significantly better for audiovisual emphasis than for visual or auditory among the younger children. Among the older children, auditory and audiovisual material were recalled much better than among younger children. The general finding, however, was that audiovisual information increased attention as well as recall.

Summary: Pictorial versus audio. Again, the bimodal mode (pictorial-plus-audio) was generally found to be more effective than single mode presentations. Support for the effectiveness of the visual mode is evident in some studies. In other studies, however, comparison of recall between pictorial versus audio features of an

instructional material showed varying results. Some studies pointed to the superiority of the visual mode while others did not find any significant difference between the pictorial and audio modes of presentation whether the information was concrete or abstract.

Print versus audio. In a study by Van Mondfrans and Travers (1964), students were given a series of learning trials with stimulus materials of differing degrees of meaningfulness and redundancy using three modes of presentation. The first experiment tested the hypothesis that when redundant information is transmitted simultaneously through two sense modalities, more information is retained than when only one modality is involved. The modalities used were those of vision and hearing. Participants were 72 undergraduate students randomly assigned to the experimental conditions. The stimulus materials were nonsense syllables in one learning condition, words in a second learning condition, and words with constraint (i.e., words arranged to form a sentence) in the third learning condition. Each

list of nonsense syllables was presented with each mode of presentation so that the effects of inter- and intralist similarity were counterbalanced. Half of the students participated under a 4 s stimulus presentation and for the rest of the subjects stimuli were exposed at a 2 s rate. Each student was assigned to a learning condition (nonsense syllables, words, or words with constraint), to an order of lists (there were three different lists in each learning condition), and to a sequence of treatments (auditory, visual in the form of printed material on film, and both). The auditory presentation was tape recorded. The visual presentation was presented using a film strip, and the combined audio-visual presentation was presented using a synchronized combination of the tape recording and the film strip. In the auditory presentation, each nonsense syllable or word was pronounced only once, otherwise frequency of information presentation was not controlled. After each complete presentation of a list, using one of the three different presentation modes, subjects were allowed 1 1/2 min in which to write

down as many of the nonsense syllables or words remembered. Student's scores were the number of errors made in learning the lists. The effects of time, material meaningfulness, modality, order, and the interaction between modality and the stimulus material were all significant. More was learned at the 4 s exposure rate than the 2 s rate, but there was no interaction between exposure time and the mode of presentation. The nonsense syllables tended to be more difficult to learn than the words. Words were not significantly more difficult to learn than the words with constraint. The first list presented was more difficult to learn than the second, and the second was more difficult to learn than the third. The auditory presentation was significantly less efficient than the other two, and there was no significant difference between the visual presentation and the audio-visual presentation. The only significant interaction was meaningfulness of material and mode of presentation. When the stimulus material was nonsense syllables, the auditory mode of presentation produced learning inferior to the

other two, which were similar.

Young (1973) compared reading and listening comprehension and retention. Ninety undergraduates were randomly assigned to each of the two experimental groups, and 31 students participated in a control group. The stimulus material consisted of 14 informative messages; each message was about 1 1/2 min in length and covered a variety of topics. The test consisted of six multiple-choice items for each of the messages. For the listening group, an audiotape of the 14 messages was prepared. For the reading group, the messages were prepared on 16 mm silent motion picture film in a manner that presented each message one line at a time. Each line was shown for a length of time which would give an overall time for each message corresponding to the time taken to record the message on the audiotape. This was done to control for the rate of presentation. The tests were administered immediately after the presentation of each of the messages. One week later, as a measure of retention, students took the test again without hearing or reading the messages. Control subjects

were permitted to read at their own speed and to respond to the test items (immediate test). No retention measure (delayed test) was obtained for their group. The analysis revealed a significant main effect for time of testing, the scores on the delayed test were significantly lower than the scores on the immediate test. No other comparisons were significant.

Summary: Print versus audio. Van Mondfrans and Travers (1964) indicated that the auditory presentation was significantly less efficient than print-only and auditory-plus-print modes and that there was no significant difference between print-only and auditory-plus-print modes. In contrast, Young (1973) found no significant difference between readers and listeners of the same content material on either the immediate or delayed tests. Certain factors may have accounted for the difference in findings of these two studies. In the study by Van Mondfrans and Travers (1964), the frequency of presentation of the visual and audiovisual material was not controlled, although the audio material was only presented once. The

content to be learned was relatively simple material. Young's (1973) study, on the other hand, focused on the retention of content material in which frequency of presentation was controlled for and the material was comparatively complex.

Pictorial versus print versus audio. In a study by Rohwer and Harris (1975), prose learning in high socioeconomic status (SES) white and low SES black fourth-grade children was assessed as a function of presentation media, test-item structure, and response methods. The seven presentation conditions included both single media (oral, print, and pictures) and combined media. The study materials were prose passages in which two related concepts (two types of monkeys, two tribes of people, two cars) were contrasted. A passage consisted of two paragraphs, each devoted to a description of one of the concepts. Three single-medium versions of the passages were constructed: oral, print, and pictorial. Oral presentation was accomplished by the playback of audiotape recordings of each passage. Printed versions of the passages were presented in slides.

All three of the passages were presented successively to each of the 168 children by means of one of the seven combinations of media. The presentation rate was constant across media conditions, that is, for the visual media, slides appeared at the rate of one every 20 s and for the oral materials, 20 s elapsed between the onset of one group of two sentences and the onset of the subsequent group. This rate was selected as the time required to register all of the material offered in the oral-plus-print-plus-pictures condition. The learning of the material was tested by means of short answer and free recall methods. The free recall method disclosed a significant advantage for print over oral presentation mode. There was also a significant advantage of oral over picture presentation, however, the beneficial effect of oral presentation was apparent in the high SES white children but not among the low SES black children. There was a significant main effect favoring print over pictures; the interaction with SES was not significant. Thus, when considered by itself, the pictorial medium

appears inferior to each of the verbal media, oral and print. Regarding combined-media comparisons for high SES white childen, the oral-plus-print condition was, for the most part, inferior to the other two conditions which did not differ significantly, while for low SES black children, the oral-plus-pictures condition was regularly superior to the remaining conditions which were largely equivalent in their effects. Finally, performance in the three-media condition (oral-plus-pictures-plus-print) did not differ significantly, in either SES group, from performance in the dual media conditions. For the low SES black children, performance in the combined media conditions, especially in oral-plus-pictures, was superior to that in single-media conditions, whereas among high SES white subjects combinations of media were of little benefit.

Nasser and McEwen (1976) hypothesized that when the same verbal content is delivered across media (television, audio, print, print-plus-audio), bimodal media will elicit higher recall. The 100 college students, in this study were randomly

assigned to one of four treatment conditions: audio alone, print alone, print-plus-audio, and videotape. After exposure to the experimental broadcast message through the assigned media channel condition, subjects were given a recall test. The message used was a broadcast on trade possibilities with China; all four versions of this broadcast were taken from the same manuscript. The audio version was taped directly from the videotape version. The print-plus-audio version was a combination of the audiotape recording and a slide presentation of the written transcript. Slides were arranged so that they would correspond to natural pauses in the audio version to aid in sychronization of tape and slides. The print version was the same slide projection employed in the print-plus-audio condition, with the exception that each student, through a hand control, could operate the speed of the projector. Recall was measured by a multiple-choice exam. Results indicated that print-plus-audio elicited higher recall than audio alone. The other comparisons were not significant, that is, there were no

significant differences between videotape and print-only, videotape and audio-only, and print-plus-audio and print-only.

Browne (1978) compared factual recall from film and print stimuli. The primary hypothesis in this study was that reading the written version would lead to better recall than watching the film documentary. The documentary that was selected described the legislative process in Oklahoma. To measure recall, true or false and multiple-choice questions were used. Participants were volunteers from two jury pools at the Oklahoma County Courthouse. A total of 31 participants read the written feature and 32 watched the film. There was no significant difference between the reading and film groups on the pretest. The comparison between the reading and the film group after the media presentation indicated the reading group did better than the film group.

Peng and Levin (1979) found that story-relevant pictures significantly improved 64 second graders' recall of stories, both immediately after hearing the stories, as well as 3 days later. The

learning materials were two 10-sentence narrative stories recorded on tape. Children in the control conditions listened to the stories while viewing a typewritten version presented sentence by sentence on index cards. Children in the picture conditions heard the stories while viewing a series of colored line drawings, each picture capturing the content of each sentence. The recall questions were recorded on tape, and the subjects were allowed as much time as necessary to respond to each question. It was found that over a 3-day period, story-relevant pictures helped children recall stories. Although they had more to forget, children aided by pictures did not forget more than those in the control groups.

Fleet (1980) studied the effectiveness of four types of presentation modalities for facilitating retention. Subjects consisted of 100 black undergraduate students. There were four experimental treatment groups of 25. These groups varied in terms of mode of presentation (live, video-audio, audio, and manuscript). The retention measure was a multiple-choice test. The

presentation involved a speech delivered by a person who was not known to any of the subjects. For the live presentation, students reported to a studio where the speech was delivered. For the video-audio presentation, a video-audio tape of the live presentation was used. For the audio presentation, the audio portion of the video-audio tape was presented. For the manuscript presentation, each subject silently read a printed copy of the presentation. The audio-video and the audio presentations were presented only once, while the reading of the manuscript was self-paced. There were no significant differences between the groups in the amount of content retained.

Nugent's (1982) research studied whether presentations by an iconic system (pictures) or a linguistic system (print or audio) aided the learning of 201 fourth-to-sixth graders. The instructional materials were prepared from a nonverbal film that presented factual information about the life of a cheetah. The seven instructional treatments to which each student was randomly assigned were: visuals-plus-print

(videotape of film with subtitles), visuals-plus-print-plus-audio (videotape of film which contained the audiotrack and subtitles), visuals-plus-audio (videotape of film with audiotrack), print-plus-audio (videotape of subtitles only with audiotrack), visuals alone (videotape of film alone), print alone (videotape of subtitles alone), and audio only (audiotrack alone). A multiple choice comprehension test was given after the presentation of the material. The students learned equally well from print, visuals, and auditory presentations. The audio-plus-print presentation, in which information was presented through a linguistic or verbal symbol system, did not have an advantage over single presentations in either mode. On the other hand, presentation of information by both pictorial and linguistic modes was generally more powerful than single presentations. It was pointed out that the iconic system is presumably more specialized in processing concrete objects and events, and the linguistic system provides semantic orientation, and the two can interact and work jointly in facilitating

learning.

In a study done by Joseph and Dwyer (1984) the same prose material from Dwyer and De Melo (1984) was used as the instructional unit. The sample consisted of 414 tenth grade public school students enrolled in mandatory health classes. Three factors were examined. First, the question of whether all types of visuals [i.e., line drawings, realistic photographs, hybrid (a picture of the heart, half of which was in the form of a line drawing and half in the form of a realistic photograph), and a combination of line drawings and realistic photographs] are equally effective in facilitating student achievement was examined. Second, they tested whether students' prior knowledge of the content affects their ability to profit from visualization as reflected in performance on criterion tests. Third, the effectiveness of externally-paced method (i.e., audio version of content material presented by means of a tape recording) and self-paced method (i.e., print version of content material) of presenting visualized instruction on immediate and

delayed retention of the content was assessed. The modes of presentation were print-only (self-paced), pictorial-plus-print (self-paced), audio-only (externally-paced), and pictorial-plus-audio (externally-paced). The dependent measures were a drawing test, an identification test, a terminology test, and a comprehension test. Each test was administered twice--immediate testing and 2 weeks later for delayed testing. Findings indicated that for the drawing test, the students receiving the externally-paced instruction (print-plus-audio) scored significantly higher than students receiving the self-paced instruction (print-only). There were no significant differences among means of the types of visuals for those with low prior knowledge. For those with medium prior knowledge, receiving the combination of line drawing and realistic photograph was significantly more effective than the nonpictorial condition (i.e., print-only or print-plus-audio) in facilitating student achievement. For students with high prior knowledge, the realistic photograph and hybrid picture conditions were significantly more

effective than the nonpictorial condition. For the identification test, there were no significant differences among the types of visuals means for the low prior knowledge group. However, for the medium prior knowledge group, the externally-paced combination of line drawing and realistic photograph condition (pictorial-plus-print-plus-audio) and self-paced combination (pictorial-plus-print) condition were significantly more effective than the nonpictorial condition. For the high prior knowledge group, the externally-paced combination picture condition (print-plus-audio-plus-combination pictorial) was significantly less effective than all the other types of visuals including the no visual condition. For the high prior knowledge groups that were self-paced (i.e., print-only, pictorial-plus-print), the realistic photograph condition was significantly more effective than the nonpictorial condition. The results on the total score (i.e., sum total of scores for all four tests) analysis were similar to the results on the identification test except that for the self-paced, medium prior knowledge

subgroup, there were no significant differences. No significant findings for mode and pacing method were found for the terminology and comprehension tests. It was also found out that students with high levels of prior knowledge achieved equivalent or significantly higher scores on the criterion measures than students with low and medium prior knowledge regardless of the type of visual or mode of instruction received. The main effect for the type of visual did not yield any significant results. No relevant findings were found in the delayed testing data.

Pezdek, Lehrer, and Simon (1984) compared the relationship between comprehension and memory for text and television, and comprehension and memory for text and radio. The subjects were 48 third graders and 48 sixth graders. The primary independent variables in the experiment were age and media condition. Half of the subjects participated in a reading and television condition, and half participated in a reading and radio condition. Two folk tales were edited such that there were three matched versions for each story:

(1) a storybook with colored pictures, (2) a radio version, and (3) a color television version. The audio tracks in the television and radio conditions were identical, and these were the same as the transcript of the book. The same material was thus included in each condition, with the addition of still pictures in the storybook version and animation in the television version. Each child read one story and was presented either the radio or television version of the other story, with the assignment of story to media condition counterbalanced across participants. Children read the stories aloud to ensure that they read the complete story and decoded words correctly. Immediately following each task, participants were presented the appropriate memory and comprehension tests. Television was superior to radio on the comprehension and sentence recognition tests. Within subjects comparisons of performance in the television and reading conditions revealed similar levels of performance on most measures. Within subjects comparisons of performance in the radio and reading conditions revealed a superiority of

the reading condition over the radio condition on the comprehension and sentence recognition measures. Thus, children generally performed at similar levels in the television and reading conditions, and better in both of these conditions than in the radio conditions.

Summary: Pictorial versus print versus audio. In comparing combined modes of presentation, studies have generally shown that materials using pictures and audio produce learning superior to that involving audio and print, pointing out the advantage of pictorial versus printed modes or orally presented information. Pictorial-plus-print was also found to be more effective than print alone. Moreover, these studies have indicated that recall performance in three-media conditions does not differ significantly from performance in dual-media conditions. The presence of illustrations to supplement print or audio seems generally sufficient to elicit the best recall. Transmission of redundant information (i.e., information presented more than once) through more than one channel generally improved retention superior to

that of a single channel. This is the case for pictorial-plus-print, pictorial-plus-audio, and pictorial-plus-print-plus-audio, but not print-plus-audio. In comparing narratives presented in print versus audio form, no differences were found in the learning of younger children and college students. With college-level prose material, print-plus-audio was superior to audio alone, but print-plus-audio presentation had no advantage over print-only materials.

Summary

The available research evidence leads to the conclusion that pictorial-plus-audio and pictorial-plus-print presentations, ones in which there are visual supplements for the verbal information, will be learned and remembered significantly better than presentations without such visual tags. In other words, there is improved recall and recognition of information if the mode of instructional presentation is pictorial-plus-audio or pictorial-plus-print. Most of the research points to the superiority of joint or combined modes of presentation, however, the combination of two

verbal sources does not follow this pattern. The pictorial-plus-print-plus-audio mode do not seem to differ significantly from the dual-mode presentations. In examining single comparisons, or learning from either print, audio, or visuals (e.g., drawings, pictures), the research presents conflicting results. Most of the literature reviewed focused on the verbal (print or audio) as the primary source of information using visuals as supplementary device to possibly improve retention of content material. This is probably so because, generally, communication among humans is verbally transmitted through language. With regard to the relative merits of visual-only versus audio-only presentations, the evidence is conflicting. Those studies supporting the superiority of visual information tend to rely on the literature regarding the iconic quality of children's cognitions. On the other hand, those supporting the superiority of the verbal (print or audio) mode of presentation tend to refer to the same literature but from the perspective that young children do not remember things verbally, and do

not spontaneously associate remembered images with their verbal labels and therefore, when the learning measures involve verbal recall, are most helped when the verbal labels are provided for them (Welch, 1982). In sum, the review of the literature on mode of presentation generally points to the superiority of bimodal modes, which do not significantly differ from the trimodal presentation (pictorial-plus-print-plus-audio), over single-mode presentations. Moreover, studies have shown that materials using pictures-plus-audio and/or pictures-plus-print are superior to that involving print-plus-audio.

Self-Efficacy and Verbal Persuasion

Since no study from the literature gathered has specifically addressed the variable of preconceived degree of difficulty in relation to memory, the closely related concept of self-efficacy was reviewed. I have defined preconceived degree of difficulty as a person's belief in the level of difficulty of a specified task prior to the actual undertaking of such task. Based on this definition, the concept of self-efficacy, in my

opinion, is closest in meaning to preconceived degree of difficulty and will thus be discussed in this section.

According to Bandura (1982a, 1982b), self-efficacy is a major factor which influences one's choice of activities, effort expended, persistence, and task accomplishments. Although self-efficacy was originally used to help explain coping behaviors in fearful situations, its use has been extended to other situations, including cognitive-skill learning (Schunk, 1985).

Bandura (1982b) pointed out that "self-percepts of efficacy influence thought patterns, actions, and emotional arousal. The higher the level of induced self-efficacy, the higher the performance accomplishments. Perceived self-efficacy helps to account for such diverse phenomena as changes in coping behavior produced by varied conditions, resignation and despondency to failure experiences, and achievement strivings." (Bandura, 1982a, p. 122). People often do not perform optimally, even though they know fully well what to do. This is because self-referent thought

also mediates the relationship between knowledge and performance. Acting on misjudgments of personal efficacy or the belief that a task is too difficult for one's capabilities can produce adverse consequences. People tend to avoid activities that they believe exceed their coping capabilities, but they undertake and perform assuredly those that they judge themselves capable of managing (Bandura, 1977). Judgments of self-efficacy also determine how much effort people will expend and how long they will persist in the face of obstacles or aversive experiences. From the social-learning viewpoint, judgments of self-efficacy, whether accurate or faulty, are based on information we receive about ourselves and the tasks we undertake. Verbal persuasion is one of the widely used methods to get people to believe they possess capabilities that will enable them to achieve what they seek (Bandura, 1982b). Although social persuasion alone may be limited in its power to create enduring increases in self-efficacy, it can contribute to successful performance if the self-appraisal is within realistic bounds.

Persuasive efficacy influences, therefore, have their greatest impact on people who have some reason to believe that they can do a task (Chambliss & Murray, 1979a, 1979b). Perceptions of self-efficacy affect emotional reactions as well as behavior. This is especially true of anxiety and stress reactions to unfamiliar or potentially aversive events. Self-efficacy theory suggests an alternative way of looking at human anxiety (e.g., test-taking conditions).

In attempts to influence human behavior, verbal persuasion is widely used because of its ease and ready availability. People are led, through suggestion or instruction, into believing they can cope successfully with what may have overwhelmed them in the past. As Bandura stated, "efficacy expectations included in this manner are also likely to be weaker than those arising from one's own accomplishments because they do not provide an authentic experiential base for them" (Bandura, 1977, p. 198). Since these studies do not deal with the issue of memory and learning, the results will not be discussed.

In the study by Schunk and Cox (1986), the self-efficacy model was tested with 90 learning disabled students who performed below their measured abilities but did not possess intellectual deficits. This experiment investigated how verbalization in solving math problems (as a method to increase feelings of self-efficacy) influences performance and also explored how effort-attributional feedback affected such performance. The students (Grades 6 through 8) received training and solved problems over sessions. Students in the first condition verbalized aloud while solving problems (continuous verbalization), those in the second condition verbalized only during the first half of training (discontinued verbalization), and those in the third condition did not verbalize (no verbalization). All the students were periodically monitored and received effort feedback during the first half of training, effort feedback during the second half of training, or no effort feedback. Continuous verbalization led to better performance than did discontinued and no verbalization. Providing effort feedback promoted these

achievement behaviors more than not providing feedback.

The present study investigated the effects of preconceived degree of difficulty through the use of verbal persuasion on the student's ability to remember prose material. Another aspect of the study was to determine how preconceived degree of difficulty interacts with various modes of presentation on the retention of content material.

Purpose of the Present Study

In the literature reviewed, the focus has either been on the effects of mode of presentation on learning and memory, or the concept of self-efficacy induced through verbal persuasion. However, the effects of preconceived degree of difficulty, as I have defined it, on learning and memory and its interaction with mode of presentation have not been researched based on my review of the literature from 1964 to 1986. My study focused on the interaction between these two variables which may reveal ways by which learning and teaching strategies may be improved. In the world of formal education, teaching should not only

focus on "external" teaching devices (e.g., visual aids) to help students but also on the "internal" cognitive factors affecting the learner during the learning process itself. The primary target of my study, thus, was to help find ways to improve formal education particularly at the secondary and collegiate levels since the material used to measure retention in this study has been used primarily with these populations.

This study analyzed the effects of the mode of presentation and the student's preconceived degree of difficulty of a memory task on the immediate and delayed retention of information. The modes of presentation that were studied were print-only, pictorial-plus-print, audio-only, pictorial-plus-audio, print-plus-audio, and pictorial-plus-print-plus-audio. The categories for the preconceived degree of difficulty were easy, neutral, and difficult. The purpose of the study was to empirically answer the following:

(1) Do the mode of presentation and preconceived degree of difficulty, each taken independently of each other, significantly affect

retention of information as measured by recall and recognition? Based on the literature reviewed on mode of presentation, I predicted that bimodal presentations involving pictures (i.e., pictorial-plus-print and pictorial-plus-audio) would yield higher scores than any of the single modes. Moreover, I expected the trimodal mode (i.e, pictorial-plus-print-plus-audio) would not yield significantly higher scores than the two bimodal modes I mentioned. These expectations yielded the following seven specific hypotheses for mode:

H1: Pictorial-plus-print mode condition would be significantly superior to print-only mode condition.

H2: Pictorial-plus-print mode condition would be significantly superior to audio-only mode condition.

H3: Pictorial-plus-audio mode condition would be significantly superior to print-only mode condition.

H4: Pictorial-plus-audio mode condition would be significantly superior to audio-only mode condition.

H5: There would be no significant difference between pictorial-plus-print-plus-audio mode condition and pictorial-plus-print mode condition.

H6: There would be no significant difference between pictorial-plus-print-plus-audio mode condition and pictorial-plus-audio mode condition.

H7: There would be no signficant difference between pictorial-plus-print-plus-audio mode condition and print-plus-audio mode condition.

(2) Is there an interaction between the mode of presentation and preconceived degree of difficulty in their effect on retention of information as measured by recall and recognition?

Method

Participants

The sample was composed of 112 undergraduate students (24 males, 88 females) from the University of the Pacific. They were chosen from selected psychology classes (Child Development, Behavior Change I, Abnormal Psychology, and Business, Engineering and Psychology) offered during the spring semester of 1987-1988. They were encouraged

to participate in the experiment by having their professor give them extra credit points for the class they were recruited from or by simply pointing out to them the benefits of participating in the research (e.g., contribution to psychological and educational research, personal enrichment). The total number of participants was composed of 93% students who received course credit and 7% undergraduate volunteers. Each participant was randomly assigned (with replacement) using the table of random numbers to the 18 different experimental conditions of the design. A limit of at least 5 participants for each experimental condition was imposed.

Experimental Design

The design was a 6 x 3 x 2 split-plot factorial design (SPF-63.2, Kirk, 1982) with two between-groups variables and one within-groups variable as follows: (a) mode of presentation (print-only, pictorial-plus-print, audio-only, pictorial-plus-audio, print-plus-audio, and pictorial-plus-print-plus-audio); (b) preconceived degree of difficulty (very easy, neutral, and very

difficult); and (c) the within variable of retention tests (immediate and delayed). The primary dependent variable was the student's total score on the four tests designed to measure retention of the information presented. The experimental design and the number of students in each condition is shown in Figure 1.

		Preconceived Degree of Difficulty		
		Easy	Neutral	Difficult
Mode of Presentation	print-only	6	5	6
	pictorial+print	8	5	6
	audio-only	7	5	7
	pictorial+audio	9	5	5
	print+audio	6	7	7
	pictorial+print +audio	7	5	6

Figure 1. Diagrammatic representation of the research design and distribution of the participants.

Content Material

Pictorial and print versions. The content material was a 2,000-word instructional booklet which described the human heart, its parts, and the

internal processes that occur during the systolic and diastolic phases (Dwyer, 1978) (see Appendix A). According to Dwyer (1978), the instructional content of this material was designed to reduce and control, as well as possible, deficiencies in past media research such as the incongruence between content material of different modes of presentation. He also cited some favorable characteristics of this material: specific types of educational objectives (e.g., terminology, comprehension) to be achieved were identified; a specific content area that permitted meaningful learning to occur was selected; four criterion tests measuring student achievement of the different types of educational objectives were constructed; and visualization was systematically integrated into the verbal content material (Dwyer, 1978).

The instructional material for the print-only and pictorial-plus-print groups was presented in the form of a booklet. Each booklet consisted of approximately 2,000 words of instruction that were arranged into 37 paragraph-type frames on 8 1/2 x

11 in. (21.59 x 28.49 cm) sheets. For students who participated in the pictorial-plus-print, pictorial-plus-audio, and pictorial-plus-print-plus-audio groups, each frame included a 3 x 5 in. (7.62 x 12.7 cm) illustration showing a black and white picture of the human heart specifically designed to visually depict the verbal information (see Appendix B). Thus, a total of 37 of these visual illustrations of the heart appeared in the instructional booklet. Words were printed in each illustration to facilitate the proper spelling of the term presented and to enable students to distinguish between those parts of the heart for which spelling and pronunciation are almost identical. These printed words were used in the instructional materials requiring a pictorial presentation mode and were located in about the same place on each page of an instructional booklet. Arrows were used in the illustrations to focus the students' attention on a specified part of the human heart being discussed. Figure 2a shows a sample page from the print-only instructional booklet, and Figure 2b shows a sample

page from the pictorial-plus-print version.

PRINT-ONLY INSTRUCTIONAL BOOKLET

Superior
Vena Cava

As you would view a cross-sectional diagram of the heart, blood enters the right auricle through veins. Only veins carry blood to the heart. The superior vena cava is one of the two veins which deposits blood in the right auricle. There are no valves at the openings of these veins into the right auricle. The superior vena cava drains blood into the right auricle from all body parts above heart level; i.e., head and arms.

Figure 2a. Sample frame from the print-only instructional booklet.

PICTORIAL-PLUS-PRINT INSTRUCTIONAL BOOKLET

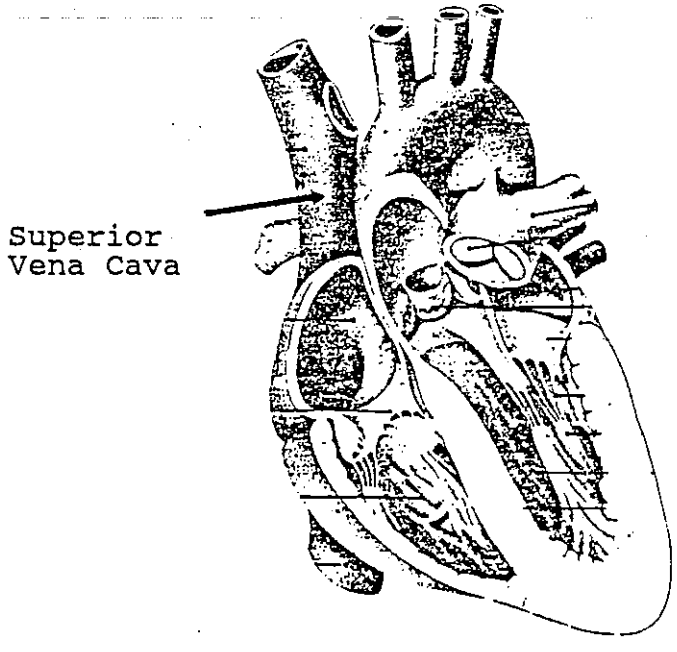

As you would view a cross-sectional diagram of the heart, blood enters the right auricle through veins. Only veins carry blood to the heart. The superior vena cava is one of the two veins which deposits blood in the right auricle. There are no valves at the openings of these veins into the right auricle. The superior vena cava drains blood into the right auricle from all body parts above heart level; i.e., head and arms.

Figure 2b. Sample frame from the pictorial-plus-print instructional booklet.

To control for the frequency of presenting the instructional material, the students receiving the print-only mode were instructed to read the 2,000-word instructional booklet once and not to reread or go back to pages they had already read. This was monitored by at least two experimenters present during the experimental sessions. The purpose of controlling for frequency of presentation was to see which mode was more effective when frequency of presentation was constant across modes. The experimenters were an undergraduate psychology major, a psychology graduate student, and me. Students in the pictorial-plus-print group received the same verbal content as the students who received the print-only mode and were instructed to read the material the same way.

Audio version. The audio version of the content material, which was narrated by a female graduate student, contained the same information as the print-only version but in audio form. Thus, each participant was provided a headphone to hear a tape recording of the instructional material from a tape player instead of reading an instructional

booklet. The use of headphones minimized possible confounding effects of outside noises. Each student was also allowed to set the audio volume to the level they preferred. To control for the frequency of the presentation of the material, the audio tape was only played once and students were instructed not to play back the tape. The audio version was presented to the audio-only, print-plus-audio, pictorial-plus-audio, and pictorial-plus-print-plus-audio groups.

Preconceived Degree of Difficulty (PDD)

The instructional material for all presentation modes began with an introductory statement concerning the supposed degree of difficulty of the content material the student needs to study. Three different types of introductory statements on preconceived degree of difficulty were presented. These were as follows:

1. Very Easy: "The material you are about to read is classified as VERY EASY for COLLEGE FRESHMEN. This means that this material can easily be understood and remembered."

2. Neutral: "The material you are about to read is classified as AVERAGE in Difficulty for TYPICAL COLLEGE STUDENTS. This means that this material is neither too easy nor too difficult to be understood or remembered."

3. Very Difficult: "The material you are about to read is classified as VERY DIFFICULT for COLLEGE SENIORS. This means that this material cannot be easily understood or remembered. Careful attention, and concentration is extremely necessary."

To strengthen the impact of preconceived degree of difficulty, each category for this variable (e.g., very easy) was supplemented by verbal persuasion by having the experimenter read a script pertinent to the preconceived degree of difficulty level for that group (see Appendix C). The participants were also given a copy of the appropriate script and it was read to them prior to the presentation of the instructional material.

As a validity assessment, participants were asked their preconception of the difficulty level of the instructional material before and after the

immediate test by using a 5-point Likert scale item ranging from very easy to very difficult (see Appendix D). They were required to respond to the scale just prior to the reading or listening of the material and immediately after finishing all the immediate tests. From this validity assessment, it was found that the variable of preconceived degree of difficulty prior to the immediate testing was highly correlated with the students' ratings of their own preconception of the content material's difficulty level (r = .75).

Mode Conditions (Mode)

The different modes in which instruction was presented were as follows:

1. Print-only (PRI). The instruction booklet was presented without any audio or pictorial illustrations.

2. Pictorial-plus-print (PIC+PRI). The instruction booklet with pictorial illustrations was presented without any audio.

3. Audio-only (AUD). The audio version of the content material was presented without the instructional booklet which contains the verbal

content and pictorial illustrations. Each student was provided a headphone plugged to a cassette player to listen to the audio version of the content material.

4. Pictorial-plus-audio (PIC+AUD). The instructional booklet with pictorial illustrations but without the verbal content was presented together with the audio version of the content material.

5. Print-plus-audio (PRI+AUD). The instructional booklet without any pictorial illustrations and the audio version of the content material was presented.

6. Pictorial-plus-print-plus-audio (PIC+PRI+AUD). The instructional booklet which contained both verbal content and pictorial illustrations was presented together with the audio version.

Procedure

Each student in each experimental condition participated in one of the six modes of instructional presentations and one level of the preconceived degree of difficulty. Then, they each

took four separate tests. Answer sheets were provided to all participants (see Appendix E). The same tests were administered 1 week later, without presenting the instructional booklet again, as a measure of delayed retention of the content material.

The following is a description of each test, as well as the total test, in terms of what each measured and the kind of educational objectives it assessed. These tests are shown in Appendix F.

Drawing test. The 18-item drawing test (recall measure) presented the students with a list of terms which corresponded to the parts of the human heart discussed in the instructional booklet. The student was required to draw a diagram representing the heart and place the numbers of the listed parts in the proper positions or locations. This test evaluated student learning of specific locations of the parts of the heart, not the quality of the drawing.

Identification test. This 20-item multiple-choice test (recognition measure) required the students to identify the numbered parts on a

detailed drawing of the human heart. Each part of the heart discussed in the instructional booklet was numbered on the drawing and appeared in a list on the answer sheet. Students were required to look at the detailed drawing and select the correct answer for each multiple-choice item. This test measured the student's ability to recognize, identify, and associate specific parts of the heart with their correct labels.

Terminology test. This 20-item multiple choice test (recall and recognition measure) was designed to measure the student's knowledge and ability to recall and recognize specific facts, definitions, and terms regarding the human heart. This test was slightly modified from Dwyer's original by making the number of recall and recognition questions equal. The modification involved converting 10 of the 20 items to fill-in questions and keeping the other 10 items as multiple-choice items. The selection of the 10 items modified was random.

Comprehension test. In this 20-item multiple-choice (recall and recognition measure),

the students were given the location of certain parts of the human heart at a particular moment of its functioning and were asked to identify the position that other specified parts of the heart would be occupying at the same point in time. This test required that the student have a thorough understanding of the heart, its parts, its internal processes, and processes occurring during the systolic and diastolic phases. This test was designed to measure the type of learning that occurs when the individual comprehends what is being communicated and can use the information being received to explain some other phenomenon occurring simultaneously. This test was modified from Dwyer's original by making the number of recall and recognition questions equal in the same way as the terminology test.

Total test. The scores obtained on the four individual tests used were combined into a 78-item total test. This yielded a global score designed to measure the student's total understanding and ability to retain content material.

The students received the drawing test first,

then the identification and terminology tests, and lastly, the comprehension test. Each of them was permitted to take as much time as needed to complete one test before proceeding to the next.

According to Dwyer (1978), the validity of these individual criterion tests was based on the correspondence between the content material in the instructional booklet and the content measured by the different test items. The verbal versions of the criterion tests have been used with more than 40,000 university and high school students. Furthermore, the Kuder-Richardson Formula 20 Reliability coefficient for each test was computed by Dwyer to determine reliability. The average reliability coefficients for each test were .83 for the terminology test, .81 for the identification test, .83 for the drawing test, .77 for the comprehension test, and .92 for the total test. Each of these four tests were also found to be highly correlated with the total test (r = .86 for the drawing test, r = .80 for the identification test, r = .83 for the terminology test, and r = .75 for the comprehension test).

All phases in the experimental procedure with the participant were done in one setting (Psychology building Room 118) in order to control for setting effects on memory. Exposure to each experimental condition was done in a group for each experimental condition. Each participant was also screened regarding their knowledge of anatomy, particularly that of the human heart, by asking them whether they had taken college courses in anatomy or physiology or were very knowledgeable about the parts and functions of the human heart. A total of 16 students with prior knowledge were allowed to participate in the experiment, however, their tests were not used in the data analysis of this study to maximize homogeneity of subjects across groups.

Completion of the reading of the instructional material involved instructing the participants not to reread or relisten to the material. Each participant was only allowed to interact with the material once. The answering of the tests, however, was self-paced with no time limits. The students underwent the same test twice to measure

immediate and delayed retention of information. The delayed testing was administered 1 week after the immediate testing.

The specific procedural steps in the data collection phase of this study were as follows:

1. Permission was asked from the psychology faculty to recruit participants from their classes. A letter of permission was sent to the professors concerned (See Appendix G). Potential participants were encouraged to join the study by pointing out the benefits that this research offers for them (e.g., extra credit points in class, personal enrichment, being able to contribute to psychological and educational research).

2. The list of participants was finalized and each student was randomly assigned (with replacement) to the treatment groups. The process of randomly assigning (with replacement) each participant was done by first assigning 5 students regardless of sex to each condition. Participants whose schedule conflicted with that of other participants as well as the experimenter's schedule were replaced and reassigned to another group. At

least 7 participants were scheduled for each experimental group to control for experimental mortality and for anatomy/physiology preknowledge.

3. A schedule was set up to administer the experiment to the students belonging to each of the 18 experimental groups. Treatment and testing were done by experimental group. The schedules for administering the tests was based on the availability of both the students and the administrating experimenter.

4. The students were informed by verbally reminding them and giving them a written notice of the time and place of the experiment for which they were scheduled. To get them to arrive on time, I asked them to come 10 min before the start of the scheduled testing.

5. Before starting the experimental treatment, rapport was established with the participants, by making them feel comfortable and briefly explaining the things the participants needed to know about the experiment. I used an appropriate instructional script which contained information to persuade students in a particular experimental

group regarding the assigned level of preconceived difficulty of the material (see Appendix H).

6. Administration of the experimental condition:

(a) All materials needed for that experimental condition were presented upon their arrival (e.g., instructional booklets, audio tapes, other audio equipment).

(b) They were handed the appropriate instructional booklet and/or audio tape to read and/or listen to. The experimenter reiterated the presupposed degree of difficulty of the particular instructional booklet depending on the specified experimental condition through the use of the corresponding instructional script.

(c) When a participant finished reading or listening to the material, the individual tests were given separately in the following sequence: drawing test, identification test, terminology test, and lastly, the comprehension test. A test must have been completed and returned to the experimenter before the next test was given. This was done for each participant in all the

experimental conditions.

(d) Upon completion of all the tests, the participants were reminded of their next schedule for testing which was 1 week from the date of the first testing session. They were cautioned not to discuss the experiment with anyone. The participants were also informed that their test scores would be privately revealed to them after completing both the first testing (immediate measure) and the second testing (delayed measure). Moreover, they were reminded that they would only receive their extra credit points in class upon completion of both testing sessions and that a list of those students who have fully complied with the requirements of the experiment would be supplied to their professor.

(e) The experimenter thanked the students for participating.

Results

This chapter is divided into three main parts: (1) a univariate split-plot analysis of the total scores across the four tests, (2) two multivariate

analyses of the four immediate tests and four delayed tests, and (3) four univariate split-plot analyses of each of the four memory tests (drawing, identification, terminology, and comprehension). The independent variables considered for each analysis were mode of presentation (print-only, pictorial-plus-print, audio-only, pictorial-plus-audio, print-plus-audio, and pictorial-plus-print-plus-audio) and preconceived degree of difficulty (easy, neutral, and difficult). The dependent variables were the student's total score (the sum of scores on the four memory tests) as well as the scores on each memory test. An alpha level of .05 was used for each analysis.

Data Screening

Split-plot ANOVA. Data screening was done by running the CONDESCRIPTIVE and MANOVA procedures for analyzing data using the SPSS-X system. The dependent variable was the total scores across all four tests. The repeated measures (within-group) variable was the immediate and delayed test times. Total N = 112 and the results of evaluations of the assumptions of normality (skew with criterion of z

$\geqslant \pm 3.0$), and homogeneity of variance (Bartlett-Box F with criterion of .01 level of significance) were satisfactory. There were no univariate outliers (criterion = $z \geqslant \pm 3.0$). Initial evaluation of the data indicated lack of support for the multisample circularity (sphericity) assumption (Bartlett's test of sphericity with the criterion of .01, SPSS-X MANOVA of the total immediate and of total delayed scores) but since the number of levels of the repeated measures variable was only two, the apparent failure of multisample circularity has no effect on the F test. These same procedures were used to evaluate the assumptions for the split-plot analyses of each of the four memory tests (i.e., drawing, identification, terminology, and comprehension). Total N = 112 and the results of evaluation of all assumptions for each test were found to be satisfactory. There were no univariate outliers.

MANOVA for immediate and delayed tests. The SPSS-X system was also used in evaluating the data used for the separate immediate and delayed MANOVA runs in which the dependent variables were the

separate scores on the drawing, identification, terminology, and comprehension tests. Additional runs for data screening were the REGRESSION and PLOT procedures. For the univariate tests of assumptions done separately on the immediate and delayed tests, total N = 112 and the results of evaluating the univariate assumptions of normality (skew with criterion of $z \geqslant \pm 3.0$), and homogeneity (Bartlett-Box F with criterion of .01) were found to be satisfactory. There were no univariate outliers (criterion = $z \geqslant \pm 3.0$). Multivariate normality was assumed to be satisfied given the nature of the dependent measures of memory. Tests of the multivariate assumptions of linearity (visual inspection of bivariate scatterplots of all pairs of dependent variables using SPSS-X PLOT procedure) and multicollinearity/singularity ($R^2 > .98$) of the immediate and delayed tests were satisfactory. Using the SPSS-X REGRESSION analysis procedure with each dependent measure in turn serving as the predicted variable, multivariate outliers were located and deleted before a MANOVA with all multivariate assumptions satisfied was

done. A total of 12 outliers were detected during five runs of the Regression analysis leaving a total N = 100 for the two MANOVAs with the screened data.

Univariate Split-Plot Analysis of The Total Score

A 6 x 3 x 2 split-plot analysis of variance (SPF-63.2, Kirk, 1982) was performed on the immediate and delayed total scores across all four tests. SPSS-X MANOVA procedure was used for the analysis.

Table 1 shows that the main effects of mode of presentation and preconceived degree of difficulty were both significant. There were no significant interaction effects and no significant repeated measures effects.

Table 1

Summary Table For Split-Plot ANOVA of Total Scores

Source of Variation	SS	df	MS	F
Mode	6720.88	5	1344.18	3.93*
PDD	2544.98	2	1272.49	3.72*
Mode x PDD	4613.26	10	461.33	1.35
Subjects w. Mode x PDD	32166.90	94	342.20	
Time	67.45	1	67.45	3.63
Mode x Time	33.97	5	6.97	--
PDD x Time	35.15	2	17.58	--
Mode x PDD x Time	65.60	10	6.56	--
Time x Subjects w. Mode x PDD	1746.55	94	18.58	

*$p < .05$

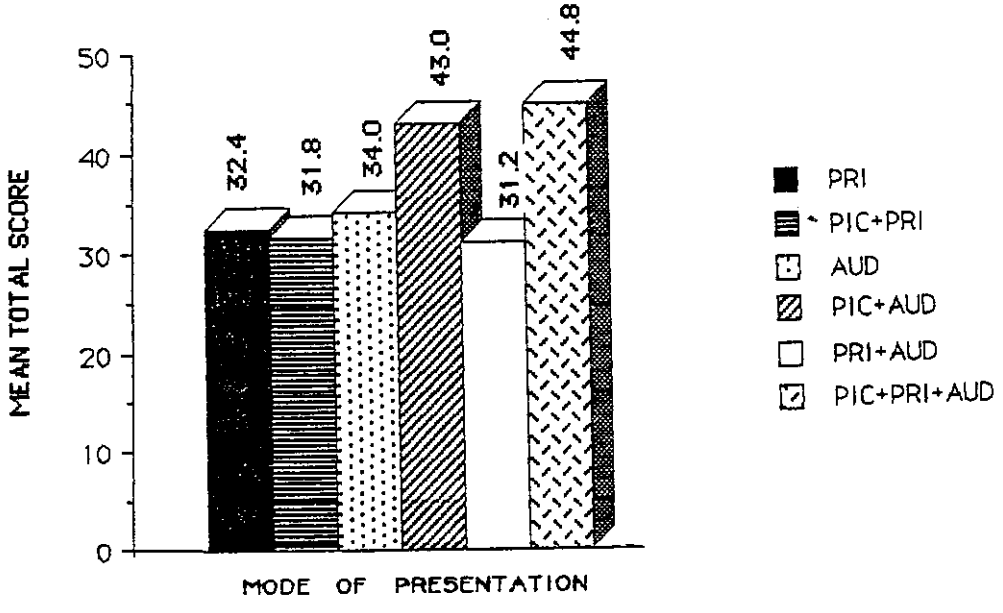

Figure 3. Bar graph of means for mode of presentation (total scores averaged across immediate and delayed test times).

The Dunn-Sidak (a priori nonorthogonal contrast) multiple comparison procedure was used to test each of the predictions. A .05 level of significance was used for the group of four one-tailed predictions (i.e., that bimodal presentations that involved pictures would be significantly superior to any of the single mode presentations). None were significant. For the three two-tailed predictions (i.e., that any of the bimodal presentation means would not significantly differ from the triple-mode mean) equivalent to predicting a null hypothesis, the probability of a Type I error was increased to .25 to increase the power for each test. Contrary to the prediction, the pictorial-plus-print-plus-audio mode mean was significantly superior (at alpha = .25) to the pictorial-plus-print mode mean and the print-plus-audio mode mean. The one other comparison was not significant (pictorial-plus-print-plus-audio mean = pictorial-plus-audio mean). The Tukey-Kramer (a posteriori) multiple comparison test using a .05 level of significance showed that none of the pairwise comparisons of means for mode of

presentation were significant.

The Tukey-Kramer a posteriori multiple comparison test of all mean differences at the .05 protection level indicated no significant mean difference between the easy, neutral, and difficult conditions. The total score means for preconceived degree of difficulty were 40.0 for the easy condition, 36.4 for the neutral condition, and 31.5 for the difficult condition.

Multivariate Analysis of The Immediate And Delayed tests

Separate 6 x 3 MANOVAs (SPSS-X MANOVA procedure) were performed for the immediate tests and the delayed tests using the drawing, identification, terminology, and comprehension tests as the dependent variables. The data sets with multivariate outliers (N = 112) and without multivariate outliers (N = 100) were both analyzed and the results are presented in this section for the immediate and delayed tests.

Immediate tests. For both data with and without outliers, the combined dependent variables were significantly affected by the mode of

presentation, but not by preconceived degree of difficulty, and not by their interaction (Tables 2 and 3). The major factors contributing to the significant effect of mode were the immediate drawing test, univariate $F(5, 94) = 3.67$ (with outliers), $F(5, 82) = 3.54$ (without outliers), $p < .01$, and the immediate identification test, univariate $F(5, 94) = 8.78$ (with outliers), $F(5, 82) = 6.94$ (without outliers), $p < .001$. According to the univariate analyses, the immediate tests of terminology and comprehension each did not make a significant independent contribution to the significant main effect of the mode of presentation for immediate testing on retention.

Table 2

Summary Table For 6 x 3 MANOVA For Immediate Tests (with outliers, $N = 112$)

Source	Wilks' lambda	Approx. F	Hyp. df	Error df
Mode	0.56	2.87*	20	303
PDD	0.87	1.69	8	182
Mode x PDD	0.70	--	40	347

*$p < .001$

Table 3

Summary Table For 6 x 3 MANOVA For Immediate Tests

(without outliers, N = 100)

Source	Wilks' lambda	Approx. F	Hyp. df	Error df
Mode	0.56	2.48*	20	263
PDD	0.83	1.94	8	158
Mode x PDD	0.61	1.03	40	301

*p < .001

Delayed tests. For both data with and without outliers, the combined dependent variables were also significantly affected by the main effect of mode, but not by preconceived degree of difficulty, and not by their interaction (Tables 4 and 5). Similar to the univariate findings of the MANOVA for the immediate tests, the delayed drawing test, univariate mode $F(5, 94) = 5.0$ (with outliers), $F(5, 82) = 4.48$ (without outliers), $p < .001$, and the delayed identification test, univariate mode $F(5, 94) = 5.47$ (with outliers), $F(5, 82) = 4.11$ (without outliers), $p < .01$, were determined to be the major independent contributors to the significant effect of mode of presentation

on the retention of content material for delayed testing.

Table 4

Summary Table For 6 x 3 MANOVA For Delayed Tests (with outliers, N = 112)

Source	Wilks' lambda	Approx. F	Hyp. df	Error df
Mode	0.64	2.21*	20	303
PDD	0.90	1.24	8	182
Mode x PDD	0.64	1.09	40	347

*p < .01

Table 5

Summary Table For 6 x 3 MANOVA For Delayed Tests (without outliers, N = 100)

Source	Wilks' Lambda	Approx. F	Hyp. df	Error df
Mode	0.62	2.01*	20	263
PDD	0.84	1.75	8	158
Mode x PDD	0.63	--	40	301

*p < .01

Univariate Split-Plot Analysis Of Each Memory Test.

A 6 x 3 x 2 split-plot ANOVA was performed on the scores for each of the four tests used. The SPSS-X MANOVA procedure was used for each analysis.

Drawing test. Table 6 shows a significant main effect for mode of presentation but no significant main effect of preconceived degree of difficulty. There was no significant interaction effect between mode of presentation and preconceived degree of difficulty. Moreover, the repeated measures effect (immediate and delayed test time) was found to be significant. The immediate and delayed score means were 7.7 and 8.1, respectively. The interactions between preconceived degree of difficulty and time, and between mode, preconceived degree of difficulty, and time, were both determined to be significant. All other interactions with time were nonsignificant.

Table 6

Summary Table For 6 x 3 x 2 Split-Plot ANOVA For Drawing Test

Source of Variation	SS	df	MS	F
Mode	857.42	5	171.48	4.75*
PDD	214.98	2	107.49	2.98
Mode x PDD	348.71	10	34.87	--
Subjects w. groups	3393.33	94	36.10	
Time	22.96	1	22.96	5.83*
Mode x Time	13.61	5	2.72	--
PDD x Time	35.11	2	17.56	4.46*
Mode x PDD x Time	91.39	10	9.14	2.32*
Time x Subject w. Mode x PDD	369.90	94	3.94	

*$p < .05$

The Tukey-Kramer a posteriori multiple comparison procedure, using a .05 protection level, showed that none of the pairwise comparisons for mode of presentation means were significant. The mode of presentation means across immediate and delayed tests were 6.3 for the print-only mode, 6.6 for the pictorial-plus-print mode, 7.0 for the audio-only mode, 10.4 for the pictorial-plus-audio

mode, 6.2 for the print-plus-audio mode, and 11.0 for the pictorial-plus-print-plus-audio mode.

The Gabriel's simultaneous test procedure was used in the a posteriori contrast-contrast analysis of the significant omnibus PDD x Time interaction (See Figure 4). A visual inspection of the slopes suggested separate comparisons of the mean difference of the easy condition (-0.4) and the difficult condition (0.4) with the neutral condition (1.6). It was determined that there were significant differences (protection level = .05) between the easy condition mean difference and neutral condition mean difference, and between the neutral condition mean difference and the difficult condition mean difference. Figure 5 is a graph of the immediate and delayed mean scores of the 18 groups of the significant Mode x PDD X Time interaction. This graph does not show any clear meaningful trends so no further analysis was done of the significant interaction effect.

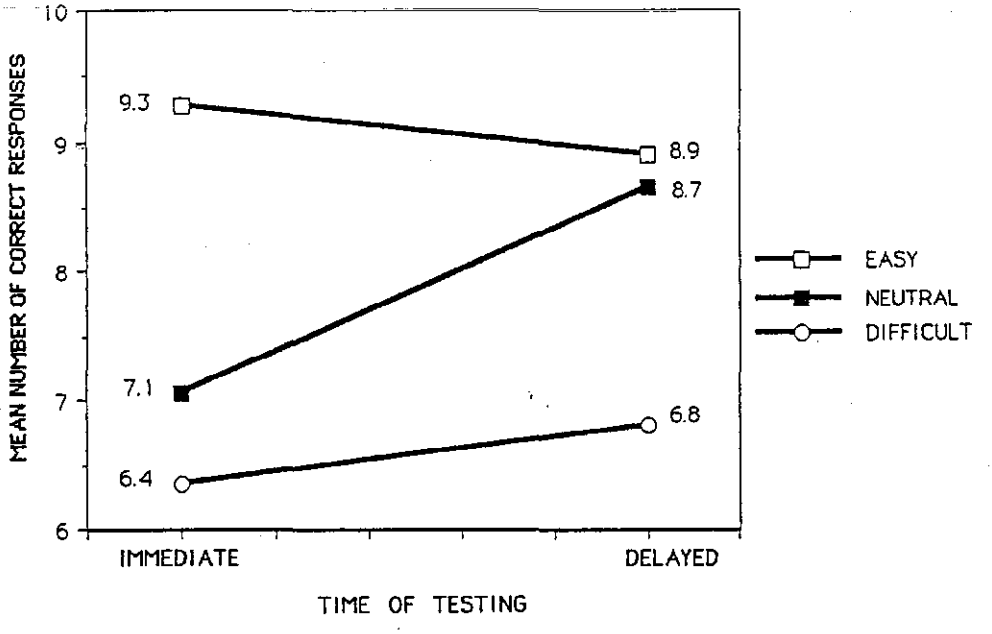

Figure 4. Line graph of means for PDD x Time Interaction (Drawing Test).

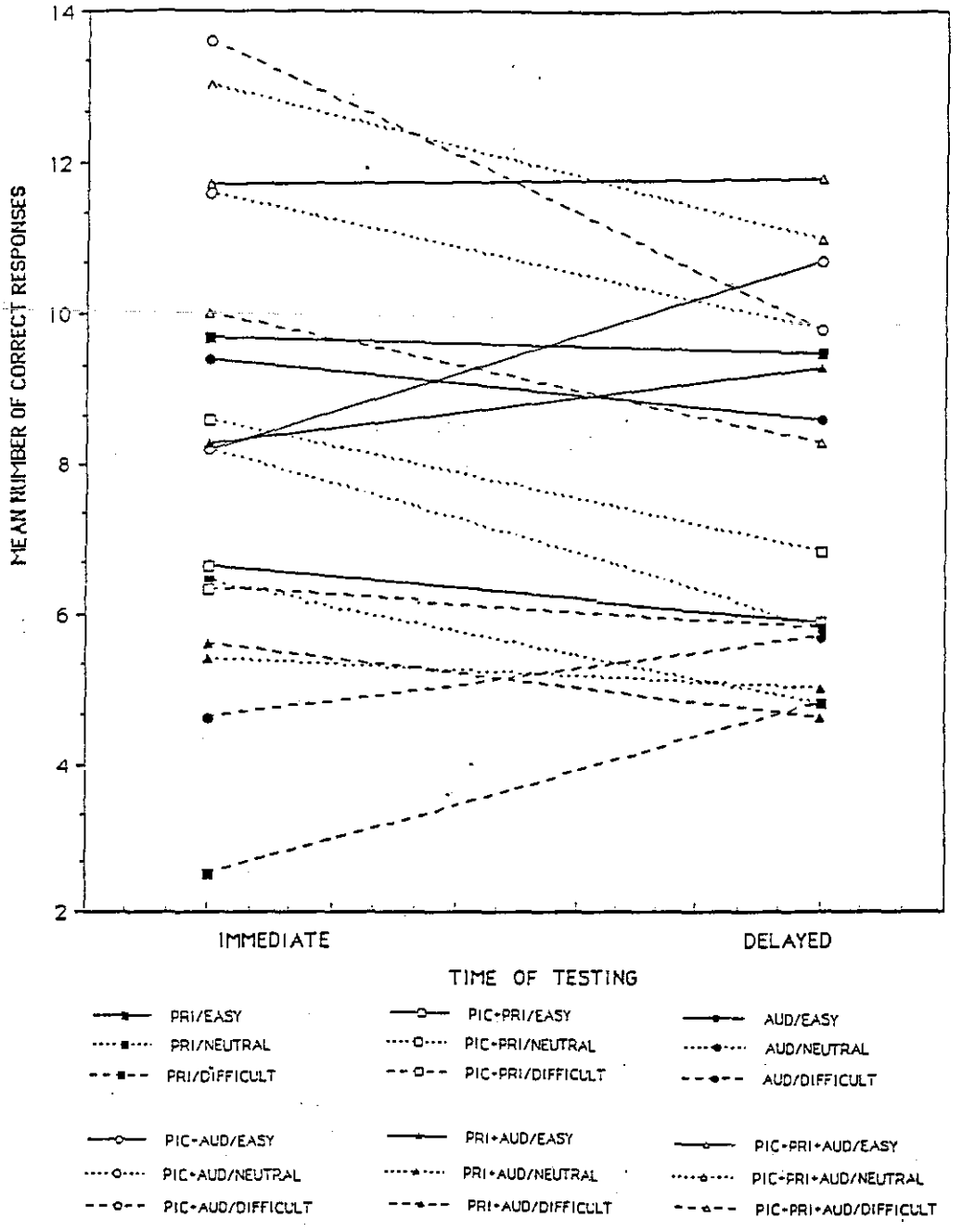

Figure 5. Line graph of drawing test score means for Mode x PDD x Time Interaction (18 groups).

Identification test. Table 7 shows that there were significant main effects for mode of presentation and preconceived degree of difficulty. The interaction between mode and time was also significant. All other effects were not significant.

Table 7

Summary Table For 6 x 3 x 2 Split-Plot ANOVA For Identification Test

Source of Variation	SS	df	MS	F
Mode	1053.83	5	210.77	7.73*
PDD	210.09	2	100.54	3.69*
Mode x PDD	321.97	10	32.20	1.18
Subjects w. groups	2562.75	94	27.26	
Time	10.03	1	10.03	2.57
Mode x Time	52.04	5	10.41	2.66*
PDD x Time	5.99	2	2.99	--
Mode x PDD x Time	35.18	10	3.52	--
Time x Subject w. Mode x PDD	367.32	94	3.91	

*$p < .05$

The Tukey-Kramer a posteriori multiple comparison procedure showed that the pictorial-plus-audio and the pictorial-plus-print-plus-audio means were significantly superior to the audio-only mean at the .05 protection level (See Figure 6). No other comparisons for mode were found to be significant. The Tukey-Kramer procedure yielded no significant differences in the pairwise comparisons of means for the easy, neutral, and difficult conditions. The identification test score means for preconceived degree of difficulty were 11.8, 10.5, and 9.2 for the easy, neutral, and difficult conditions, respectively.

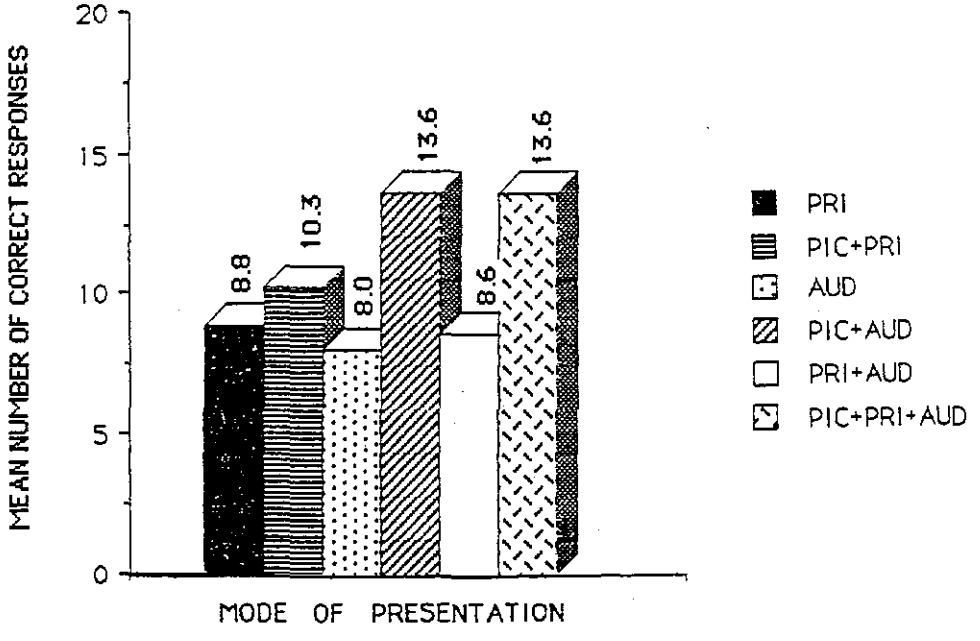

Figure 6. Bar graph of means for mode of presentation (Identification Test means across immediate and delayed tests).

The Gabriel's simultaneous test procedure was used with a posteriori contrast-contrast comparisons to analyze the significant Mode x Time interaction (See Figure 7). A visual inspection of the slopes suggested a comparison of the mean difference of print-only (2.5) with the mean differences of the other modes (i.e., 0.1 for pictorial-plus-print, 0.6 for audio-only, 0.6 for pictorial-plus-audio, 0.9 for print-plus-audio, and 0.4 for pictorial-plus-print-plus-audio). Results indicated that there was no significant difference (protection level = .05) between the print-only mode mean difference and the other mode mean differences with respect to the Mode x Time interaction.

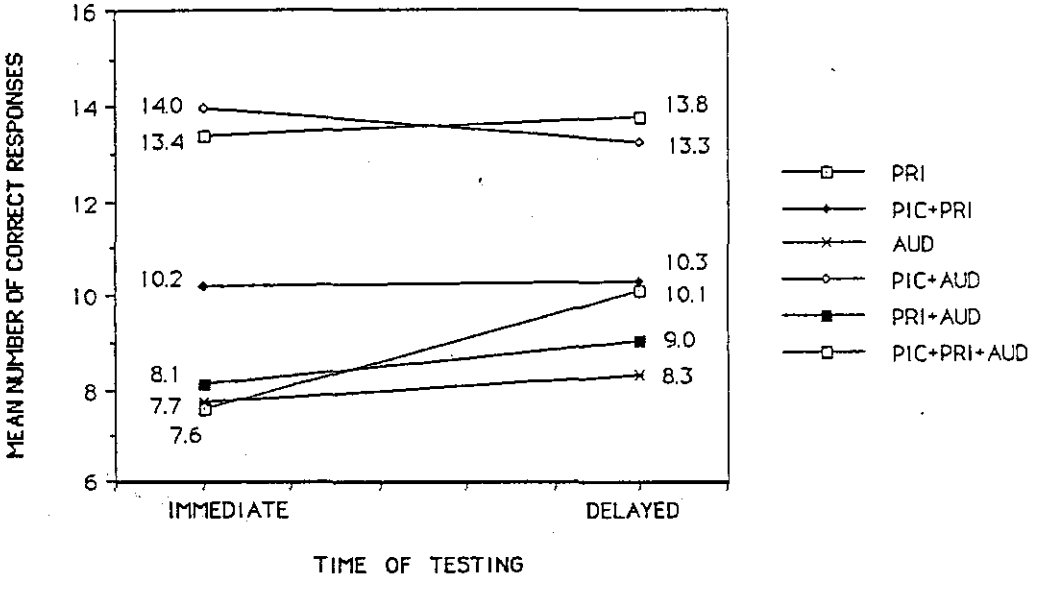

Figure 7. Line graph of means for Mode x Time (Identification Test).

Terminology test. A 6 x 3 x 2 split-plot ANOVA was performed on the immediate and delayed terminology test scores. There were no significant main or interaction effects (Table 8).

Table 8

Summary Table For 6 x 3 x 2 Split-Plot ANOVA For Terminology Test

Source of Variation	SS	df	MS	F
Mode	284.28	5	56.86	1.6
PDD	149.21	2	74.60	2.1
Mode x PDD	441.88	10	44.19	1.24
Subjects w. groups	3347.35	94	35.61	
Time	7.54	1	7.54	2.26
Mode x Time	7.19	5	1.44	--
PDD x Time	3.72	2	1.86	--
Mode x PDD x Time	51.74	10	5.17	1.55
Time x Subject w. Mode x PDD	313.81	94	3.34	

Comprehension test. A 6 x 3 x 2 split-plot ANOVA was performed on the immediate and delayed comprehension test scores. There were no significant main or interaction effects (Table 9).

Table 9

Summary Table For 6 x 3 x 2 Split-Plot ANOVA For Comprehension Test

Source of Variation	SS	df	MS	F
Mode	135.65	5	27.13	1.46
PDD	101.81	2	50.91	2.74
Mode x PDD	186.48	10	18.65	1.00
Subjects w. groups	1747.22	94	18.59	
Time	6.48	1	6.48	2.47
Mode x Time	13.42	5	2.68	1.02
PDD x Time	7.44	2	3.72	1.42
Mode x PDD x Time	34.79	10	3.48	1.32
Time x Subject w. Mode x PDD	246.96	94	2.63	

Discussion

Univariate Split-Plot ANOVA of Total Score

Overall, the results differed from what was originally hypothesized. Regarding the effect of mode of presentation, there was a significant effect but it was not in the direction expected based on the literature reviewed. All one-tailed predictions (i.e., that the bimodal presentations

involving pictures would be significantly superior to any of the single mode presentations) and two of the three two-tailed predictions (i.e., that any of the bimodal presentations would not significantly differ from the pictorial-plus-print-plus-audio mode) were not supported. The only prediction that was supported by the data was the two-tailed prediction of no significant difference between the pictorial-plus-print-plus-audio mean and the pictorial-plus-audio mean.

The mode of presentation means for the total score showed very little mean difference between the print-only, audio-only, pictorial-plus-print, and print-plus-audio modes (see Figure 3). In contrast, the pictorial-plus-audio mode condition and the triple-mode condition both showed higher mean scores than the single modes and the two other bimodal modes, although they were not significantly higher.

The major procedural difference between Dwyer and De Melo's (1984) study and my study was that the former did not control for frequency of presentation for the 151 undergraduate

participants. The results of their study showed that the bimodal version (printed prose complemented by simple line drawings) of the instructional unit significantly improved the students' retention of the material as measured by the identification, terminology, and comprehension tests as well as the total of these three tests. All the three tests showed that the pictorial-plus-print version of the content material was significantly superior to the print-only version. Contrary to this finding, the present study found no significant difference between the pictorial-plus-print mode and the print-only mode. It was possible that the procedural aspect of having instructed the participants not to reread the material in the present study put more pressure on them and may have increased the difficulty in the encoding of the printed material. The point in controlling for frequency of presentation was to see which mode was more effective regardless of time on task. The absence of the drawing test in the computation of Dwyer and De Melo's total score may have also contributed to the differing results.

In a similar study by Joseph and Dwyer (1984) the same instructional unit (i.e., the heart and its functions) was used for 414 tenth grade public school students enrolled in mandatory health classes. It was found that for the total score analysis of the data from those with medium prior knowledge, externally-paced presentations (i.e., one form of pictorial-plus-print-plus-audio) was significantly superior to the print-plus-audio condition, however, the three other modes of pictorial presentation were not superior to the no-picture condition. Moreover, there were no significant differences for any of the low prior knowledge conditions. The present study found no significant differences between any mode means in the total score analysis. It was possible that the difference in population studied (i.e., tenth graders versus undergraduates) may account for the difference in the results or that the one significant finding in Joseph and Dwyer's study is not replicable.

Exceptions to the hypothesized superiority of a bimodal presentation of iconic and/or linguistic

codes were that the pictorial-plus-print, pictorial-plus-audio, and print-plus-audio means were not significantly superior to the print-only and audio-only means. These results not only contradict the theoretical framework, but also existing research demonstrating the effectiveness of pictorial augmentation of print (Dwyer & De Melo, 1984; Goldberg, 1974; Haring & Fry, 1979; Joseph & Dwyer, 1984; Peeck, 1974).

Preconceived degree of difficulty was found to be significant in the univariate split-plot ANOVA of the total score. The means for preconceived degree of difficulty were ordered such that the more difficult the content material was perceived, the lesser the ability to retain such material. None of the pairwise comparisons of means were found to be significant, however, if an a priori linear trend had been predicted, the data would have supported such a prediction. It is possible that preconceived degree of difficulty is an important cognitive variable that can have considerable influence on encoding, but the method of verbal persuasion used in this study did not

make enough impact. Verbal persuasion is a flexible and readily available method to induce the variable of preconceived degree of difficulty, although better ways of enhancing its impact should be explored along with different methods of inducing motivational state as well (e.g., vicarious experience or physiological state).

Multivariate Analysis of Immediate and Delayed Tests

Results showed that for both the immediate and delayed tests, the tests mostly contributing to the significant effect of mode on the retention of content material were the drawing and identification tests. This finding was true for the MANOVA analyses with the outliers and without the outliers. The drawing test (fill-in questions) evaluated student learning of specific locations of the parts of the heart, while the identification test (multiple-choice questions) measured the student's ability to recognize, identify, and associate specific parts of the heart with their correct labels. The terminology test (fill-in and multiple-choice questions) was designed to measure

the student's knowledge and ability to recall and recognize specific facts, definitions, and terms regarding the human heart while the comprehension test (fill-in and multiple-choice questions) was designed to measure the type of learning that occurs when the student comprehends the material and can use the information being received to explain some other phenomenon occuring simultaneously (e.g., systolic and diastolic processes). The drawing (recall measure) and identification (recognition measure) tests require a more basic understanding of the content material. Simple memorization of the material presented is sufficient for a student to be able to answer the items correctly since the questions focused more on the identification and location of the parts of the human heart. On the other hand, the terminology and comprehension tests required a more thorough understanding of both the parts and functions of the human heart. Simple memorization of the parts of the human heart and their locations is necessary but not sufficient to be able to answer the items correctly since the questions dealt more on the

roles of the various parts of the heart in the systolic and diastolic functions.

For both the immediate and delayed tests, the terminology and comprehension tests, both of which were the tests modified from Dwyer's original to make the number of recall and recognition items more equal, did not show a significant effect of the mode of presentation. For each of these tests, the modification involved the conversion of 10 randomly selected items of the 20 items to fill-in questions while keeping the rest as multiple-choice items. However, the mean scores for the four tests were similar, 7.9 for the drawing test (44% correct), 10.6 for the identification test (53% correct), 8.5 for the terminology test (42% correct), and 9.2 for the comprehension test (46% correct).

Since the students were unfamiliar with this type of material (i.e., parts and functions of the human heart), most of them performed poorly. Out of a possible perfect total score of 78 points, the grand total mean was 36.2 (46% correct).

The presence of a significant main effect in the analysis of the drawing and identification tests suggests that these two tests might be structured more appropriately for the content material than the terminology and comprehension tests. The content material (i.e., the heart and its functions) has a highly visual character for most people and the drawing and identification tests both dealt with locating parts within a visual depiction of the human heart. The other two tests were more abstract in character. This approach to understanding the results suggests that if the objective of instruction had been carefully specified at the outset with a coordinate selection of content material and memory tests to match the instructional objectives, then instructional modes that most closely matched the instructional objective and memory tests would have more clearly and reliably facilitated retention and recall of the material.

Univariate Split-Plot Analysis of Each Memory Test

Among the four tests used to measure retention of content material, only the drawing test and the

identification test yielded significant results.

For the drawing test, the mode of presentation had a significant main effect on retention but no significant pairwise comparisons of means were found. In the study by Joseph and Dwyer (1984), the main effect of pacing was significant such that externally-paced modes (i.e., four forms of pictorial-plus-print-plus-audio; print-plus-audio) were generally superior to the self-paced modes (i.e., four forms of pictorial-plus-print; print-only) in the drawing test. The analysis of the interaction of time and preconceived degree of difficulty for my data showed that both the easy and difficult conditions were significantly different from the neutral condition. There was a tendency for people who perceived the instructional material as neutral to improve their drawing score from the immediate to delayed tests while those who perceived it to be easy or difficult showed little change. No explanation to this phenomenon can be inferred from previous studies or developed by rational analysis.

For the identification test, both the mode of

presentation and preconceived degree of difficulty were found to be significant although there were no significant mean differences for preconceived degree of difficulty. The students' ability to recognize, identify, and specify parts of the heart with their correct labels, was enhanced by the pictorial-plus-audio and pictorial-plus-print-plus-audio modes relative to the audio-only mode. This is consistent with Joseph and Dwyer's (1984) study which found that bimodal presentations that involved pictures were generally better than nonpictorial presentations for the drawing and identification tests.

Similar to my study, no significant results for presentation mode were found for both the terminology and comprehension tests in the study by Joseph and Dwyer (1984).

Summary of Significant Results

In summary, results for the univariate split-plot ANOVA of the total score showed that the main effects of mode and preconceived degree of difficulty were found to be significant. However, only one prediction was supported--the hypothesis

of no difference between the triple-mode condition and the pictorial-plus-audio mode condition. No significant mean differences between the easy, neutral, and difficult conditions were found. For the multivariate analyses of the immediate and delayed tests, univariate analyses showed that the drawing and identification tests, for both the immediate and delayed testing, were the major independent contributors to the significant effect of mode of presentation on the retention of content material. In the univariate split-plot analysis of the drawing test, none of the pairwise comparisons for mode of presentation means were significant. The univariate split-plot analysis of the identification test showed that the pictorial-plus-audio mode and the triple-mode means were significantly superior to the audio-only mode and not significantly different from each other. In summary, with this one exception, results of this study did not provide a refinement of the idea that "the more media channels used, the better."

Recommendations

This section suggests some recommendations to

improve the present study and possible issues to consider for future related research topics.

Further investigation should be made on possible effects of controlling for time on task versus controlling for frequency of presentation of the material. Controlling for frequency of presentation limits the number of times the participants were allowed to encode or review the instructional material in the encoding process. On the other hand, controlling for time on task (e.g., Carey & Hannafin, 1981; Goldberg, 1974; Hannafin, 1983; Hannafin, 1984) limits the amount of time in which a participant is able to encode the material regardless of the number of times the subject is able to encode or review the material. The possible effect of controlling frequency of presentation is that some learners are not able to effectively encode material for the first presentation. In other words, the number of times the content material need to be presented for effective encoding in memory varies greatly from person to person. Nonetheless, in order to objectively compare the encoding properties of each

mode, frequency of presentation was controlled by presenting the material only once for all modes of presentation. Time on task for all print conditions (without audio) was controlled by the participants in the present study. Controlling for time on task takes into account how efficiently a learner is able to encode the material given that the learner has more control over the number of times the material is reviewed over a period of time. In the typical studying situation, most students study by encoding material given a specified period of time; that is, they control for time on task, not frequency of presentation. Therefore, controlling for time on task may be more representative of a student's studying process.

Future related studies may increase the number of participants to at least 20 subjects per cell to improve the reliability of the study. Although the current study had N = 112, the number of participants in each experimental condition ranged only from 5 to 9 subjects.

It is highly probable that the participants' attitudes and motivation affected their retention

of the instructional material. In this study, most participants (i.e., psychology students) may not have considered the content material meaningful. The majority of the subjects participated in the experiment for the purpose of receiving extra credit points from their psychology classes; credit was earned regardless of how they performed on the memory tests. Thus, the possible lack of motivation to learn the content material may have confounded the results. This could be controlled by blocking the participants on these "motivational factors" (i.e., evaluation of the subjects' motivational level towards the content material prior to the presentation of the instructional material).

As part of the continuing search to understand how the human memory functions, there is a need for further research to define more closely the unique blend of symbol systems (i.e., iconic and linguistic) that characterizes various media and to determine how each symbol system can be used most effectively--singly and/or in combination--to promote learning. There are many different types

of pictorial aids possible, the various kinds of pictures and their functions within particular instructional contexts should be examined, as well as the types of information, objectives, and content conducive to pictorial presentation. Pictorial realism continuums have received considerable research attention (Dwyer, 1978), but other areas of pictorial characteristics need to be explored to help give educators useful tools in enhancing the learner's memory abilities. Picture size, color, and position, especially as used with print, are potential research variables.

Other ways to induce preconceived degree of difficulty as an independent variable may be researched such as vicarious experience (i.e., observing others perform a task sucessfully or unsuccessfully), enactive attainments (i.e., being affected by one's own past successes or failures), and physiological state (i.e., judging one's capabilities based on physiological arousal in taxing situations) to be able to compare their efficiency and effectiveness in the retention of content material. This could provide crucial

information on how preconceived degree of difficulty can be more effectively manipulated as an independent variable.

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Appendix A

Instructional Script

The Heart and Its Functions

The human heart is a hollow, bluntly conical, conical, muscular organ. Its pumping action provides the force that circulates the blood through the body. In the average adult, the heart is about five inches long and about two and one half inches thick. A man's heart weighs about eleven ounces and a woman's heart weighs about nine ounces. The heart lies toward the front of the body and is in a slanting position between the lungs, immediately below the breastbone. The wide end points toward the right shoulder. The small end of the heart points downward to the front of the chest and toward the left. The lower portion of the heart is called the apex and is the part that you feel beating.

In order to better comprehend the following instruction, it will be helpful to visualize a cross-section view of a human heart in a position such that you are facing the person. As you visualize it, the right side of the heart will be

on the left side.

To understand the functioning of the heart, you will be able to identify the parts of the heart. The heart is enclosed in a thin double-walled sac. The layer which forms the outer wall of the sac is called the pericardium. It is composed of a tough, transparent, elastic tissue. It protects the heart from rubbing against the lungs and the walls of the chest. The inner portion of the double walled sac is called the epicardium. It is attached to the heart muscle.

The heart muscle is called the myocardium; it controls the contraction and relaxation of the heart. The myocardium constitutes by far the greatest volume of the heart and its contraction is responsible for the propulsion of the blood throughout the body. The myocardium varies in thickness. For example, the myocardium forming the auricle walls is thin when compared to the thickness of the myocardium forming the ventricle walls.

The endocardium is the name given to the inside lining of the heart wall.

The human heart is really two pumps combined into a single organ which circulates blood to all parts of the body. The heart is divided longitudinally into two halves by the septum. The two halves may be compared to a block of two houses, which are independent of each other but have a common wall, the septum, between them.

Each half of the heart is divided into an upper chamber and a lower chamber; the upper chambers are called auricles and the lower chambers are called ventricles. Although there is no direct communication between the right and left sides of the heart, both sides function simultaneously. As was stated previously, the upper chambers on each side of the septum are auricles, and lower chambers are called ventricles. Auricles have thin walls and act as receiving rooms for the blood while the ventricles below act as pumps, moving the blood away from the heart.

As you would view a cross-sectional diagram of the heart, blood enters the right auricle through veins. Only veins carry blood to the heart. The superior and inferior vena cavas are the two veins

which deposit blood in the right auricle. There are no valves at the openings of these veins into the right auricle from all body parts above heart level, for example, the head and the arms.

The other vein, the inferior vena cava, deposits blood into the right auricle from the trunk and legs, that is, from regions below the heart level. As blood from the body fills the right auricle, some of it begins to drip into the right ventricle immediately.

The auricles and ventricles on each side of the heart communicate with each other through openings. The opening between the right auricle and right ventricle is called the tricuspid valve. This valve consists of three triangular flaps of thin, strong, fibrous tissue. These flaps permit the flow of blood into the right ventricle, but prevent it from flowing backward into the right auricle because the ends of the flaps are anchored to the floor of the right ventricle by slender tendons.

The three flaps act like swinging doors which open only in one direction. Thus, blood passes

from the right auricle through the tricuspid valve into the right ventricle. As soon as the right ventricle is filled with blood, both ventricles begin to contract.

The first effect of the pressure produced in the right ventricle is to force blood behind the flaps of the tricuspid valve.

While the blood pressure behind the flaps brings the flaps together and prevents the flow of blood, the contraction of the right ventricle continues until the blood presses hard enough to open the pulmonary valve and to force the blood into the pulmonary artery. The pulmonary valve is located between the right ventricle and the pulmonary artery.

The pulmonary valve, like the tricuspid valve, consists of three flaps which fill with blood backing up in the pulmonary artery. As soon as the right ventricle begins to relax from its contraction, the pulmonary valve prevents blood from flowing back into the right ventricle from the pulmonary artery. The pulmonary valve opens only when the pressure in the right ventricle is greater

than the pressure in the pulmonary artery, forcing the blood into the pulmonary artery.

The pulmonary valve is composed of flaps or pockets, which the swollen pulmonary artery quickly fill with blood as soon as the right ventricles begins to relax from its contraction. The flaps or pockets of the valve are thus passed together, and no blood flows back into the right ventricle.

After the blood passes through the pulmonary valve, it enters the pulmonary artery from which it is carried up through the heart to both the left and right lungs where it is cleansed and oxygenated.

Returning from the lungs, the blood enters the heart through four pulmonary veins and collects in the left auricle.

Like the right auricle, the left auricle also contracts when it is full, squeezing blood through the mitral valve into the left ventricle. The mitral valve is located between the left auricle and the left ventricle.

The mitral valve is similar in contruction to the tricuspid valve. As the left ventricle

contracts simultaneously with its mate, the right ventricle, it forces blood behind the flaps of the mitral valve, thereby closing the path back to the left auricle.

The contraction of the left ventricle pumps the blood through the entire body. For this reason, it is the largest, strongest, and most muscular section of the heart. When the left ventricle which is filled with blood contracts, the resulting pressure in the ventricle opens the aortic valve located in the mouth of the aorta.

The aorta is the large artery which carries the blood from the left ventricle.

The Circulation of the Blood

The directional flow of the blood in the heart is determined by valves which allow the blood to flow in only one direction.

Both auricles receive blood simulataneously through unguarded openings in the veins. The right auricle receives its blood through the superior and inferior vena cavas while the left auricle receives its blood through the pulmonary veins.

A wave of muscular contraction starts at the top of the heart and passes downward, simultaneously, over both sides of the heart; that is, both auricles contract at the same time and then relax as the contraction passes down to the ventricles. When the auricles are caused to contract, they become small and pale, and in doing so the blood in their chambers is subjected to increased pressure which forces blood through both the tricuspid and mitral valves.

As the ventricles fill, eddies of the blood float the flaps on both the tricuspid and the mitral valves out to a partially closed position.

As the ventricle pressure becomes greater than that in the auricles, the valves are tightly closed and so prevent blood from being forced backward into the auricles.

While the auricles are relaxing from the contraction, blood flows into them from the veins as the contraction of the ventricles is initiated.

The instant that the contraction of the auricles has been completed, the ventricles are stimulated to contract; this contraction increases

the pressure in the chambers forcing the valves, both the tricuspid and mitral, completely shut.

The pulmonary valve and the aortic valve, also called the semi-lunar valves, that guard the entrances to the pulmonary artery on the right and the aortic artery on the left are closed by the back pressure provided by blood already in these vessels. When the ventricle pressure becomes greater than that in the exit vessels, the pulmonary and aortic valves open.

Blood flows from the right ventricles into the pulmonary artery en route to the lungs and from the left ventricle into the aorta for distribution through the entire body.

Immediately following ejection of blood into the arteries, the ventricles begin to relax; this lowers the pressure within their chambers, and the greater pressure in the arteries closes the semi-lunar valves. Pressure within the ventricles is sufficient, however, to maintain closure of the tricuspid and mitral valves against the already increasing auricle pressure.

As the ventricles relax further, pressure

within them decreases correspondingly, and the tricuspid and mitral valves are forced open by increased auricle pressure caused by blood flowing into them from the veins. Therefore, before the next auricle contraction, blood is already flowing from the auricles into the ventricles because a greater blood pressure exists in the auricles than in the ventricles.

The Cycle of the Heartbeat Consists of Two Parts

The relaxation of the ventricles, during which they are filled with blood, is called the diastolic phase.

The heart relaxes between beats in the diastolic phase. Blood flows into the heart filling both auricles. While blood is flowing into the auricles, the recoil of the artery wall still maintains part of the pressure developed by the contraction of the ventricles. This is the time of lowest pressure in the arteries or what is called the diastolic pressure.

The contraction phase or systolic phase begins when the auricles contract. The blood forces its way through the mitral and tricuspid valves into

the ventricles.

The ventricles contract and force the blood through the semi-lunar valves, that is, the pulmonary and aortic valves.

After passing through the pulmonary and aortic valves, the blood enters the pulmonary and aortic arteries. The blood leaves the ventricles under terrific pressure and surges through the arteries with a force so great that it bulges their elastic walls. At this point, arterial blood pressure is greatest; this pressure is called the systolic pressure. The heart relaxes again and the tricuspid and mitral valves close. Blood flows into the auricles; the mitral and tricuspid valves are forced open, and the cycle begins again.

Appendix B

Pictures of the Human Heart

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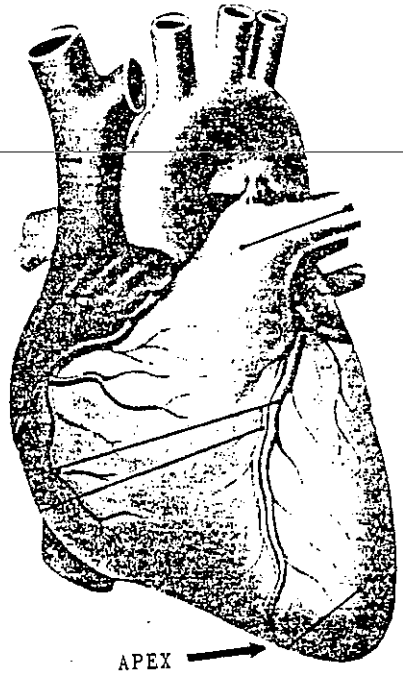

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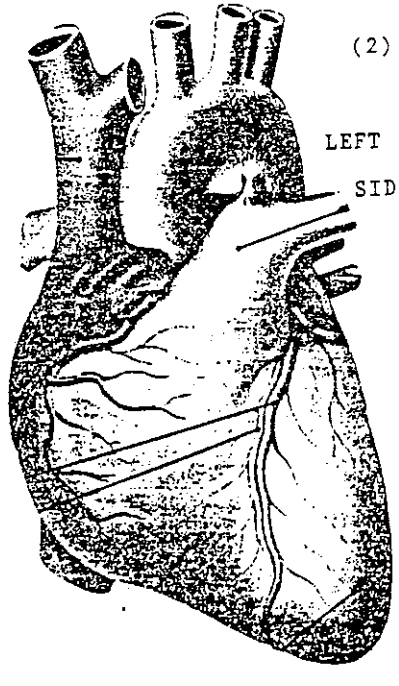

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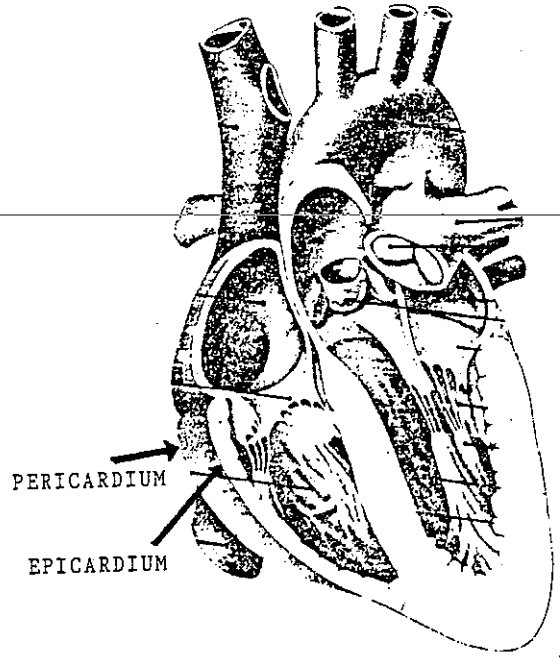

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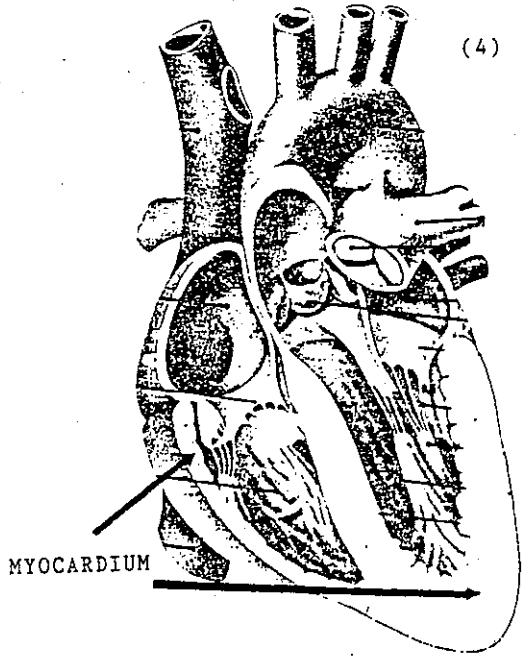

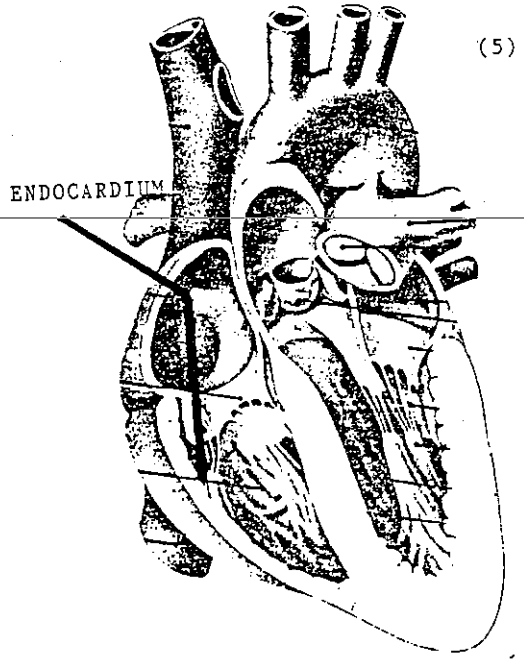

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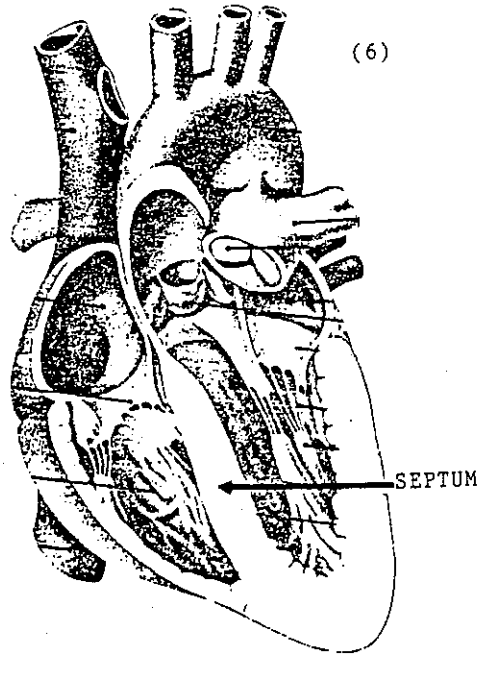

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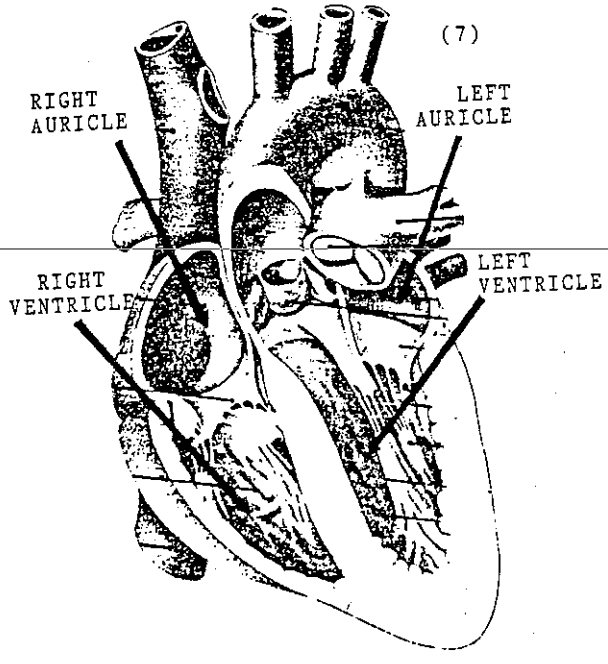
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LEFT AURICLE
RIGHT VENTRICLE
LEFT VENTRICLE

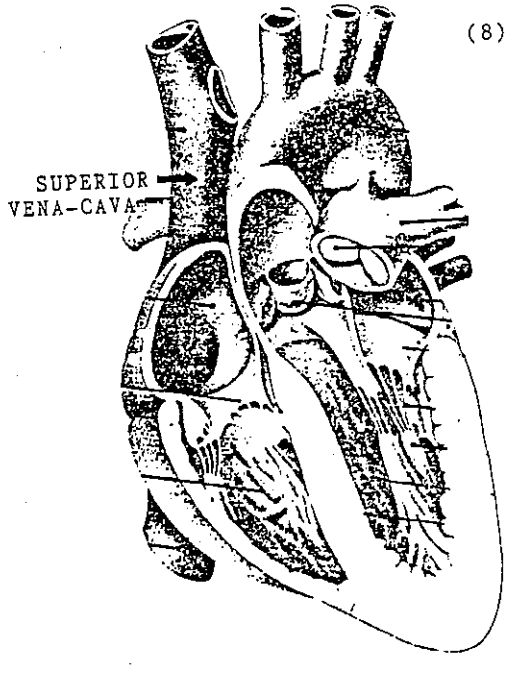
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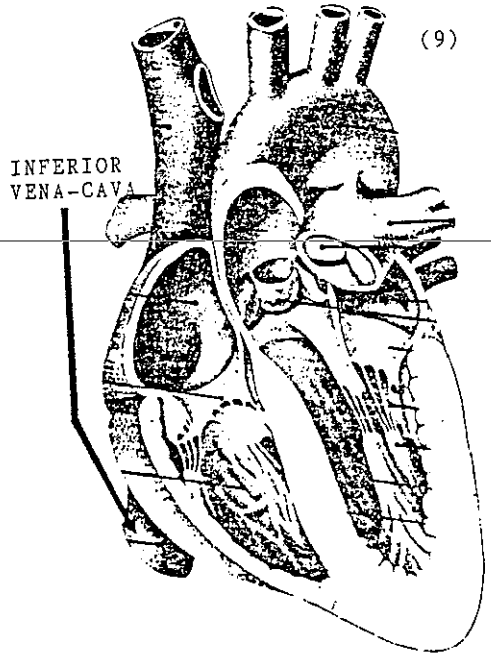
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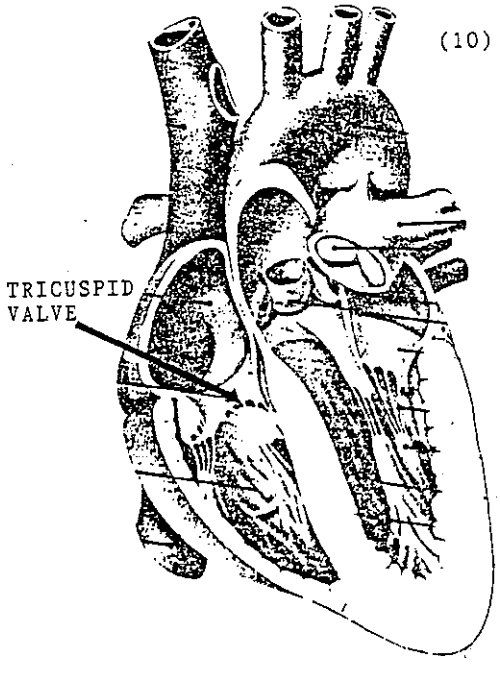
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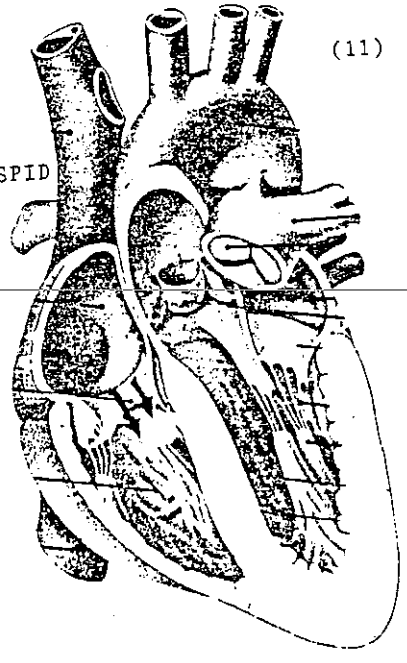
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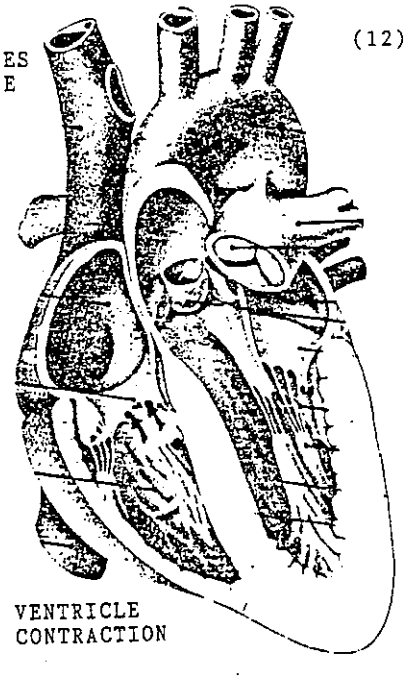
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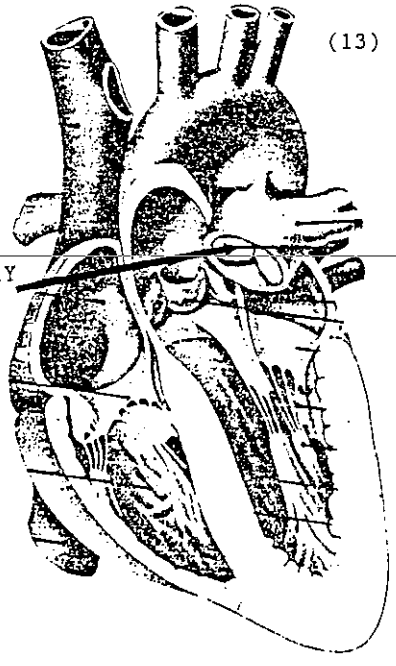

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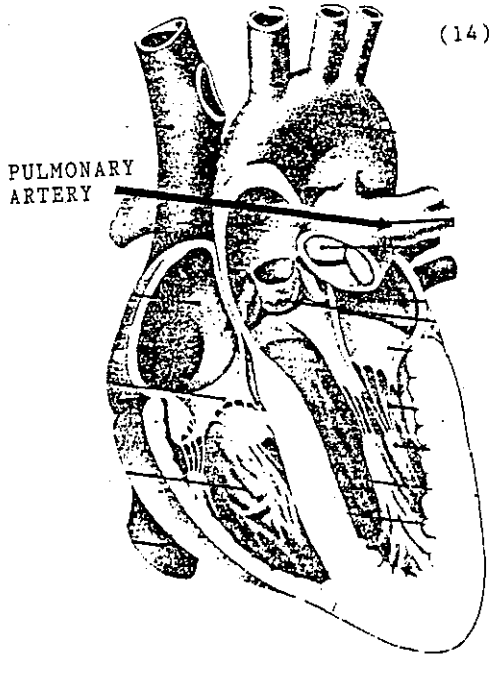

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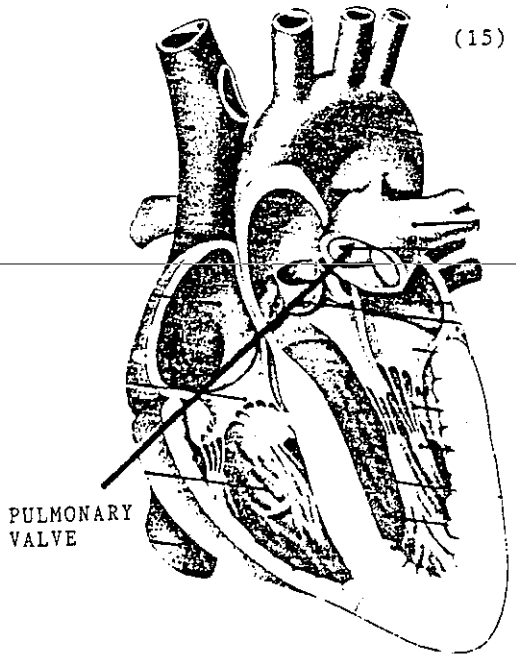

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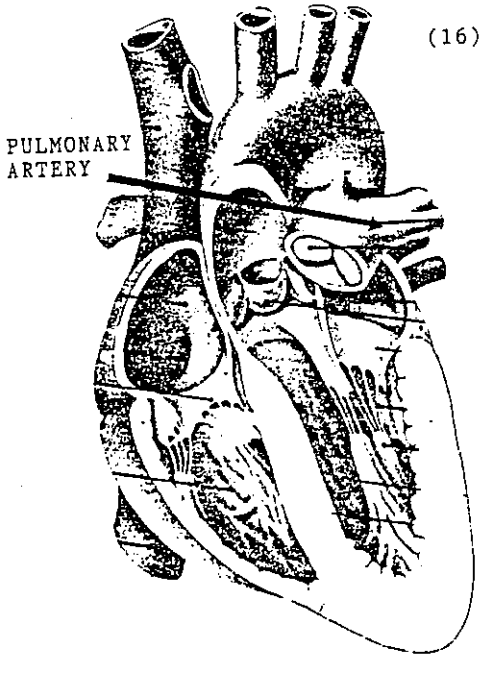

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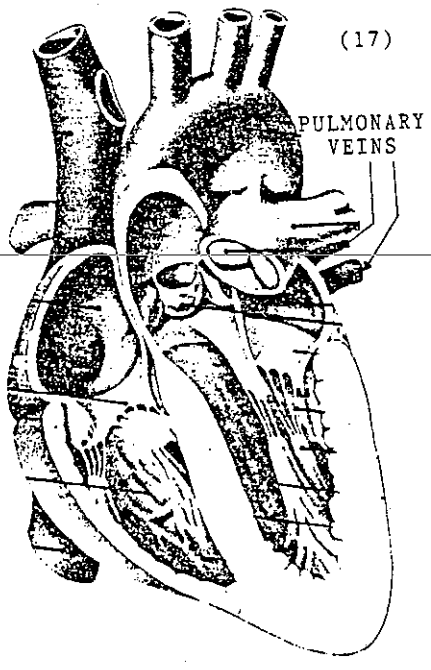
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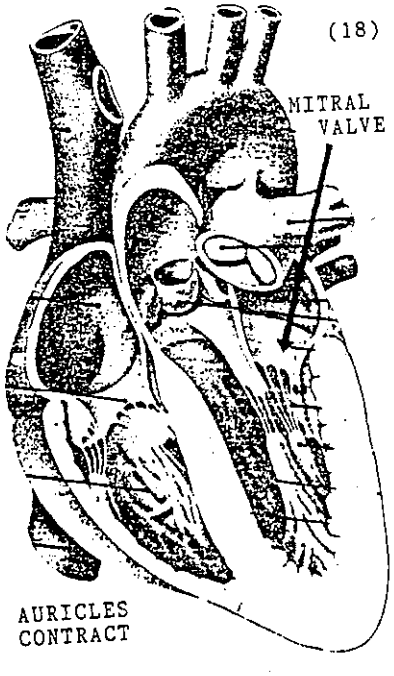
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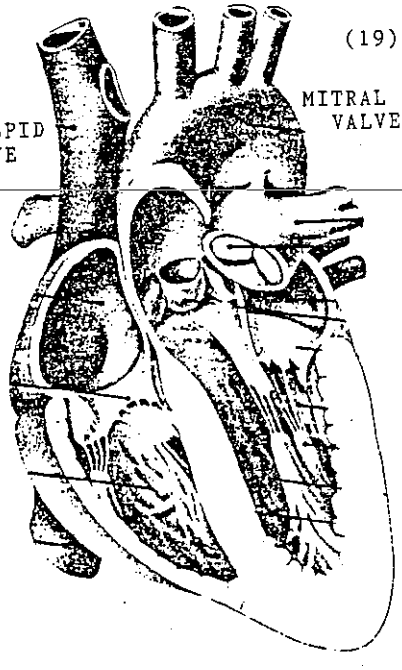
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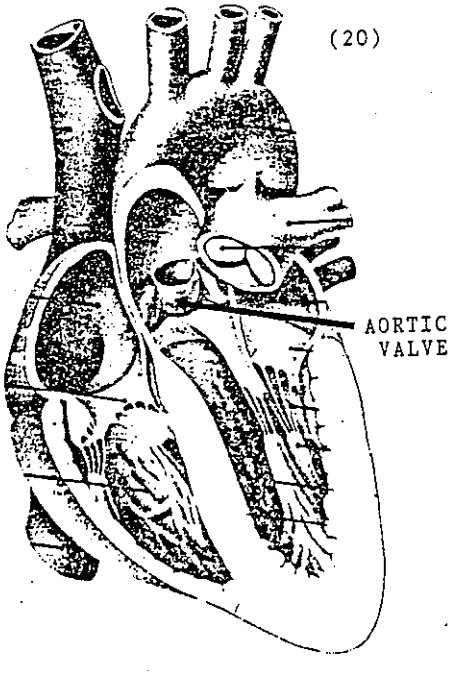
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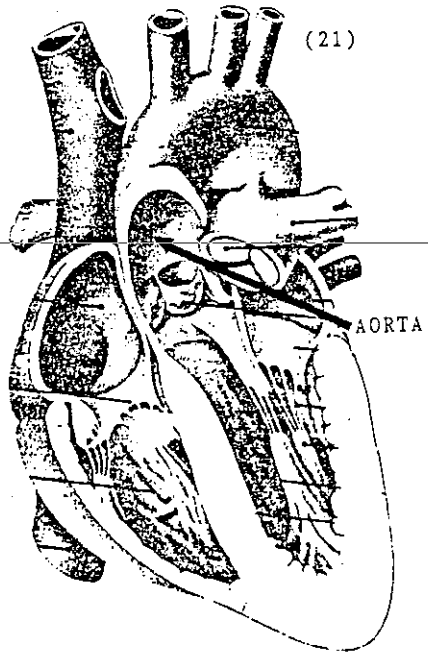
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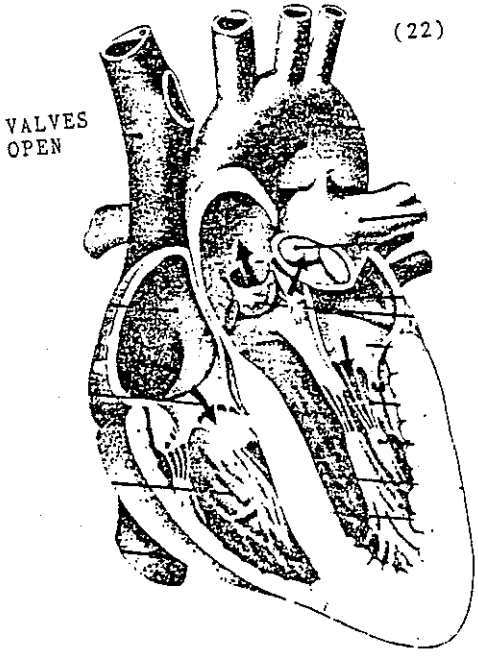
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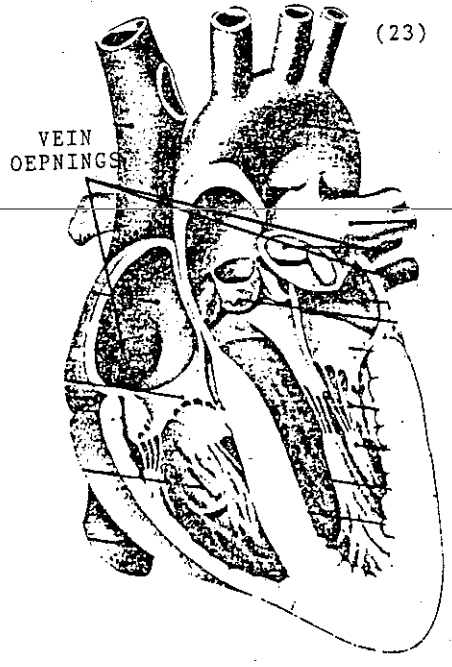
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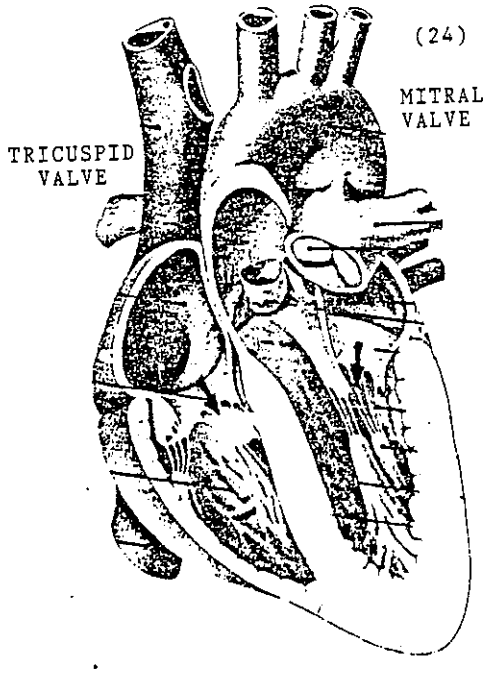
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VALVE
TRICUSPID
VALVE

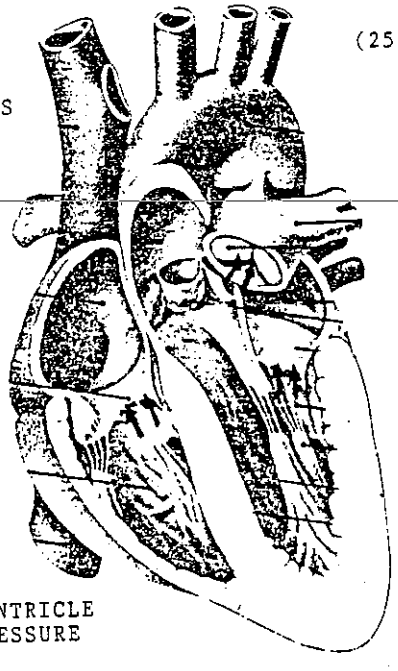
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CLOSE
VENTRICLE
PRESSURE

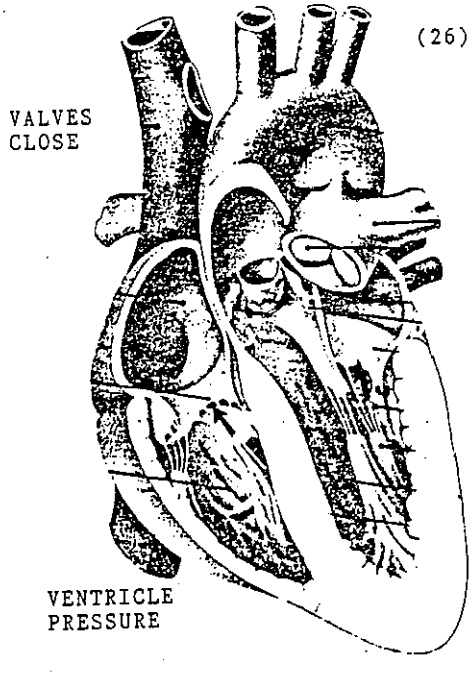
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PRESSURE

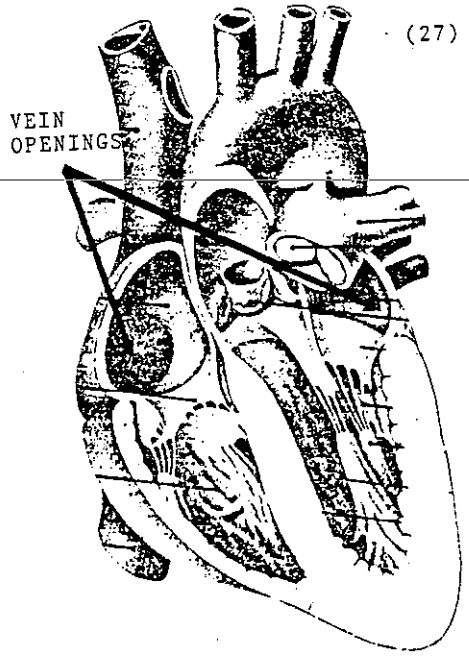

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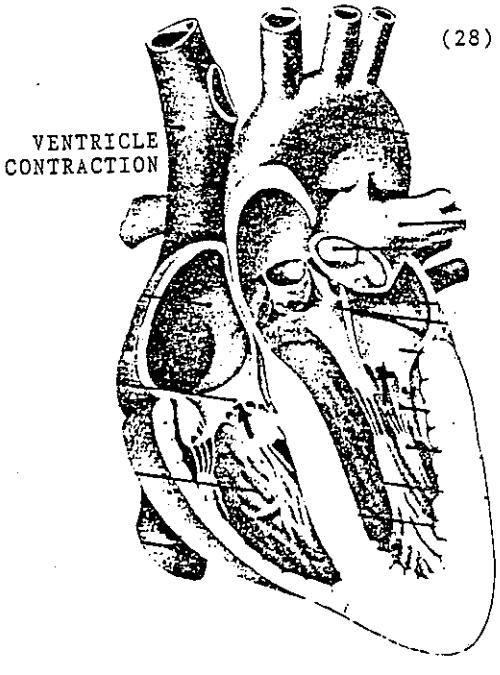

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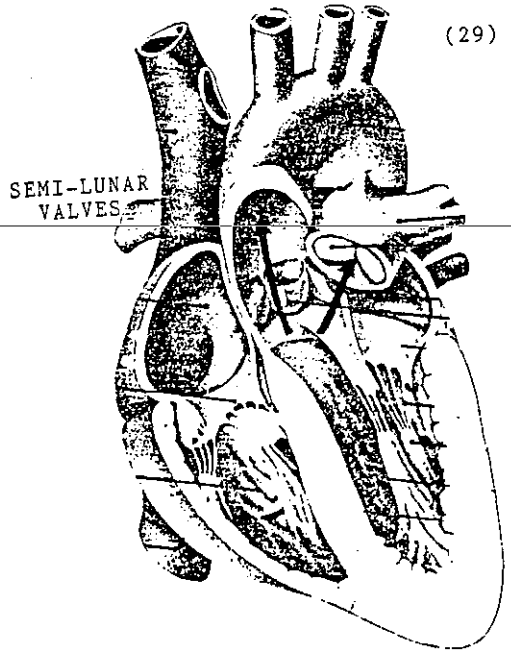

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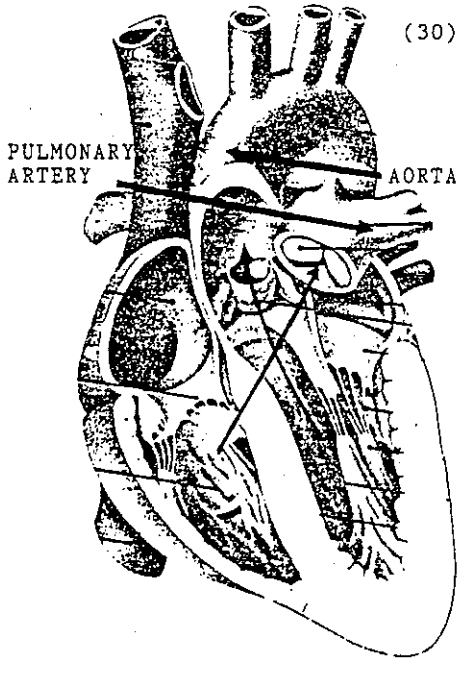

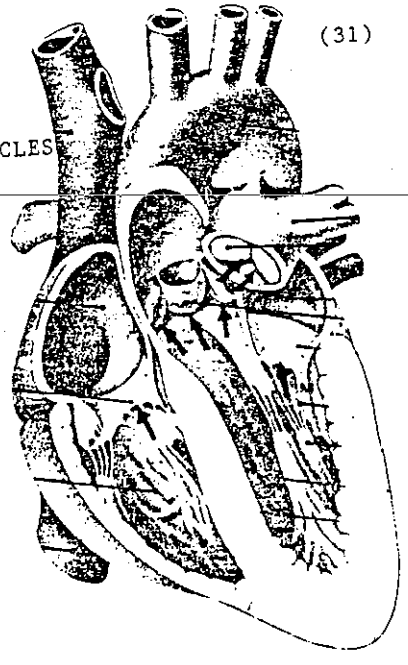
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RELAX

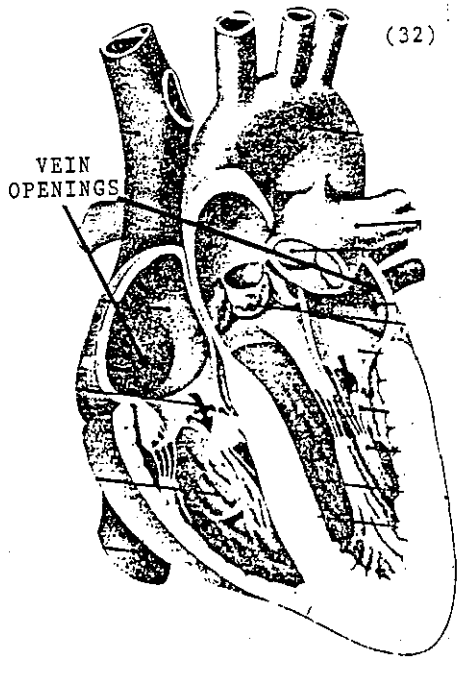
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OPENINGS

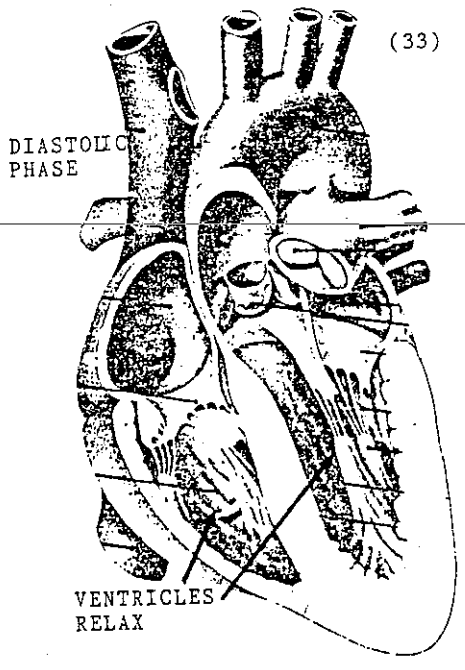
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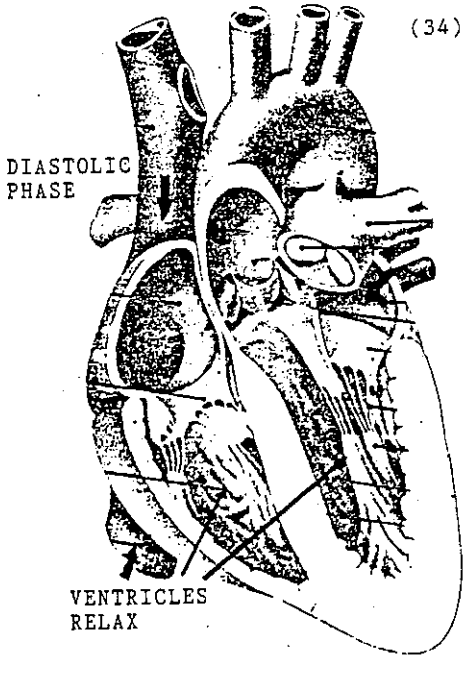
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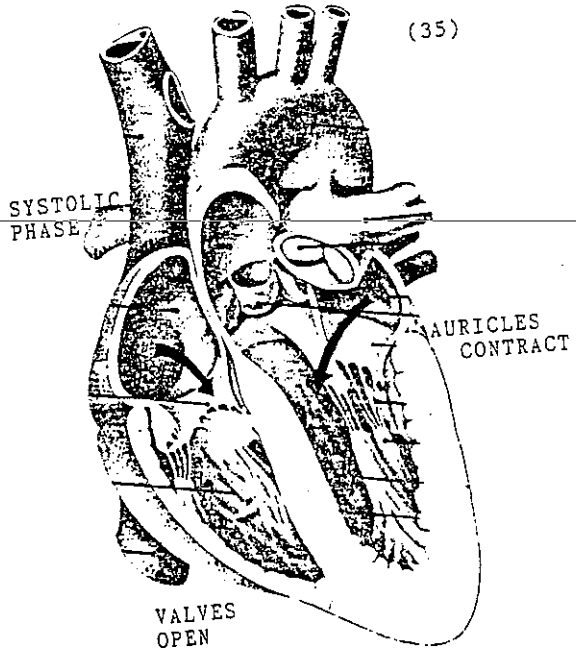
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PHASE
AURICLES
CONTRACT
VALVES
OPEN

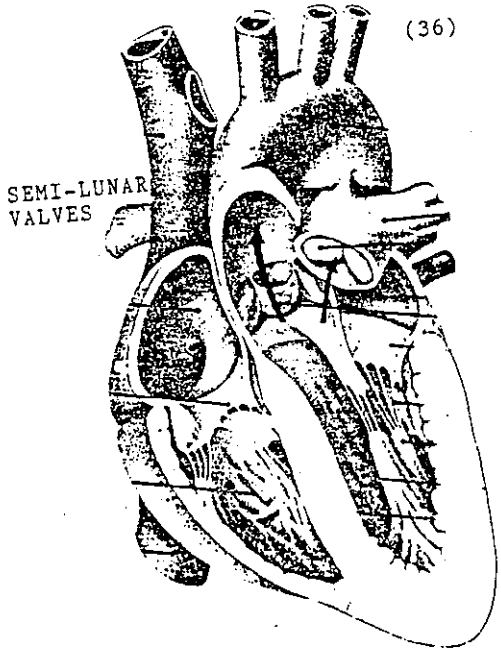
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SEMI-LUNAR
VALVES

(37)

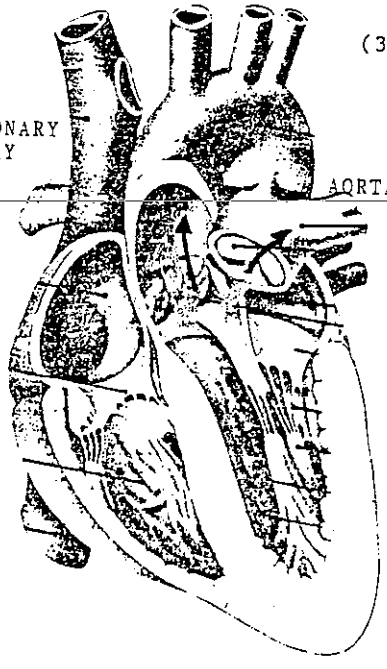

Appendix C

Introductory Statements on Preconceived Degree of Difficulty

Instructional Material

Directions: This instructional booklet describes the parts of the human heart and its internal processes. Do not turn to the next page unless you are told to do so. Read the material carefully. Remember, you may read the material only ONCE. DO NOT REREAD A PAGE AND DO NOT GO BACK TO PAGES YOU HAVE ALREADY READ.

NOTE: This material you are about to read is classified as VERY EASY for COLLEGE FRESHMEN. This means that this material can easily be understood and remembered.

* * * *

Instructional Material

Directions: This instructional booklet describes the parts of the human heart and its internal processes. Do not turn to the next page unless you are told to do so. Read the material carefully. Remember, you may read the material only ONCE. DO NOT REREAD A PAGE AND DO NOT GO BACK TO PAGES YOU HAVE ALREADY READ.

NOTE: This material you are about to read is classified as AVERAGE in difficulty for TYPICAL COLLEGE STUDENTS. This means that this material can easily be understood or remembered.

* * * *

Instructional Material

Directions: This instructional booklet describes the parts of the human heart and its internal processes. Do not turn to the next page unless you are told to do so. Read the material carefully. Remember, you may read the material only ONCE. DO NOT REREAD A PAGE AND DO NOT GO BACK TO PAGES YOU HAVE ALREADY READ.

NOTE: This material you are about to read is classified as VERY DIFFICULT for COLLEGE SENIORS. This means that this material can easily be understood or remembered. Careful attention and concentration is extremely necessary.

* * * *

Appendix D

Validity Assessment Scale for Preconceived Degree of Difficulty

Immediate Assessment

Name: _____ Date: _____

Sex: M F

Please answer the following question:

Before proceeding with the session, how difficult do you think the instructional material will be?

1	2	3	4	5
Very Easy	Easy	Average	Difficult	Very Difficult

Delayed Assessment

Name: _____ Date: _____

Sex: M F

Please answer the following question:

Now that you have been presented the instructional material and have taken the tests, how would you rate the level of difficulty of the instructional material?

1	2	3	4	5
Very Easy	Easy	Average	Difficult	Very Difficult

Appendix E

Answer Sheets

Name:_____
Date:_____
Sex: M F

ANSWER SHEET NO. 1

Part One

Drawing Test

Name: _____
Date: _____
Sex: M F

ANSWER SHEET NO. 2

Part Two

Identification Test

1.	a	b	c	d	e	11.	a	b	c	d	e
2.	a	b	c	d	e	12.	a	b	c	d	e
3.	a	b	c	d	e	13.	a	b	c	d	e
4.	a	b	c	d	e	14.	a	b	c	d	e
5.	a	b	c	d	e	15.	a	b	c	d	e
6.	a	b	c	d	e	16.	a	b	c	d	e
7.	a	b	c	d	e	17.	a	b	c	d	e
8.	a	b	c	d	e	18.	a	b	c	d	e
9.	a	b	c	d	e	19.	a	b	c	d	e
10.	a	b	c	d	e	20.	a	b	c	d	e

Name: _____
Date: _____
Sex: M F

ANSWER SHEET NO. 3

Part Three

Terminology Test

1.	a	b	c	d	e	11.
2.	a	b	c	d	e	12.
3.	a	b	c	d	e	13.
4.	a	b	c	d	e	14.
5.	a	b	c	d	e	15.
6.	a	b	c	d	e	16.
7.	a	b	c	d	e	17.
8.	a	b	c	d	e	18.
9.	a	b	c	d	e	19.
10.	a	b	c	d	e	20.

Name: _____
Date: _____
Sex: M F

ANSWER SHEET NO. 4

Part Four

Comprehension Test

1.	a	b	c	d	e	11.
2.	a	b	c	d	e	12.
3.	a	b	c	d	e	13.
4.	a	b	c	d	e	14.
5.	a	b	c	d	e	15.
6.	a	b	c	d	e	16.
7.	a	b	c	d	e	17.
8.	a	b	c	d	e	18.
9.	a	b	c	d	e	19.
10.	a	b	c	d	e	20.

Appendix F

Part One

Drawing Test

Draw a picture of a heart and place the number of the identified parts where they would be located on the heart. Use the answer sheet provided.

1. superior vena cava
2. aorta
3. tricuspid valve
4. pulmonary vein
5. septum
6. epicardium
7. aortic valve
8. pulmonary valve
9. inferior vena cava
10. pulmonary artery
11. myocardium
12. endocardium
13. mitral valve
14. right auricle
15. right ventricle
16. left auricle
17. left ventricle
18. apex

Part Two

Identification Test

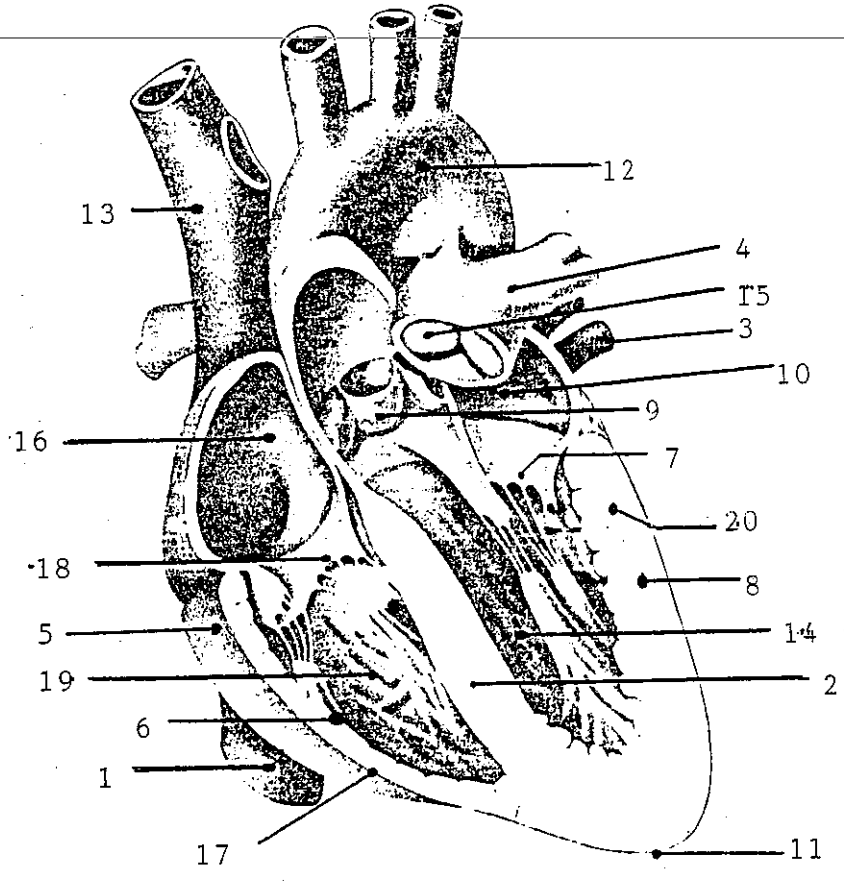

Identification test

Select the answer you feel best identifies the part of the heart indicated by the numbered arrows and mark the corresponding letter on the provided answer sheet.

1. Arrow number one (1) points to the
   a. aorta
   b. mitral valve
   c. superior vena cava opening
   d. inferior vena cava opening
   e. septum

2. Arrow number two (2) points to the
   a. pericardium
   b. endocardium
   c. septum
   d. myocardium
   e. pulmonary artery

3. Arrow number three (3) points to the
   a. inferior vena cava openings
   b. superior vena cava openings
   c. aortas
   d. pulmonary veins
   e. pulmonary arteries

4. Arrow number four (4) points to the
   a. pulmonary vein
   b. pulmonary artery
   c. aorta
   d. tricuspid valve
   e. mitral valve

5 Arrow number five (5) points to the
   a. myocardium
   b. ectoderm
   c. pericardium
   d. endocardium
   e. aortic base

6. Arrow number six (6) points to the
   a. endocardium
   b. myocardium
   c. pericardium
   d. muscle
   e. septum

Identification test

7. Arrow number seven (7) points to the
   a. venic valve
   b. pulmonary valve
   c. tricuspid valve
   d. mitral valve
   e. aortic valve

8. Arrow number eight (8) points to the
   a. pericardium
   b. endocardium
   c. ectrocardium
   d. ectodern
   e. myocardium

9. Arrow number nine (9) points to the
   a. superior vena cava opening
   b. inferior vena cava opening
   c. aortic valve
   d. pulmonary valve
   e. mitral valve

10. Arrow number ten (10) points to the
    a. right auricle
    b. right ventricle
    c. left auricle
    d. left ventricle
    e. pulmonary artery

11. Arrow number eleven (11) points to the
    a. pericardium
    b. myocardium
    c. endocardium
    d. endoderm
    e. apex

12. Arrow number twelve (12) points to the
    a. septum
    b. aorta
    c. pulmonary artery
    d. pulmonary veins
    e. none of these

13. Arrow number thirteen (13) points to the
    a. superior vena cava opening
    b. right auricle
    c. mitral valve
    d. tricuspid valve
    e. none of these

Identification test

14. Arrow number fourteen (14) points to the
    a. right ventricle
    b. left ventricle
    c. left auricle
    d. right auricle
    e. pericardium

15. Arrow number fifteen (15) points to the
    a. pulmonary vein
    b. aorta
    c. pulmonary valve
    d. right auricle
    e. aortic valve

16. Arrow number sixteen (16) points to the
    a. right ventricle
    b. right auricle
    c. left ventricle
    d. left auricle
    e. epicardium

17. Arrow number seventeen (17) points to the
    a. epicardium
    b. pericardium
    c. endocardium
    d. myocardium
    e. none of these

18. Arrow number eighteen (18) points to the
    a. aortic valve
    b. pulmonary valve
    c. mitral valve
    d. tricuspid valve
    e. septic valve

19. Arrow number nineteen (19) points to the
    a. left ventricle
    b. right ventricle
    c. right auricle
    d. left auricle
    e. vascular space

20. Arrow number twenty (20) points to the
    a. myocardium
    b. endocardium
    c. ectocardium
    d. epicardium
    e. none of these

Part Three

Terminology test

1. Blood from the right ventricle leaves the heart through the _____.
   a. veins
   b. aortic artery
   c. pulmonary artery
   d. pulmonary veins
   e. superior vena cava

2. The _____ is (are) the strongest section(s) of the heart.
   a. left ventricle
   b. aorta
   c. septum
   d. pulmonary veins
   e. tendons

3. When blood returns to the heart from the lungs, it enters the _____.
   a. right auricle
   b. pulmonary veins
   c. left auricle
   d. right ventricle
   e. pulmonary artery

4. Vessels that allow the blood to flow from the heart are called _____.
   a. veins
   b. arteries
   c. apex
   d. tendons
   e. flaps

5. Blood passes from the left ventricle out the aortic valve to the _____.
   a. lungs
   b. body
   c. aorta
   d. pulmonary artery
   e. left auricle

6. Deoxygenated blood enters the heart through the _____.
   a. aortic artery
   b. pulmonary veins
   c. pulmonary artery
   d. superior and inferior vena cavas
   e. superior vena cava only

Terminology test

7. The _____ allow(s) blood to travel in one direction only.
   a. septum
   b. valves
   c. arteries
   d. veins
   e. tendons

8. The _____ is located between the left auricle and the left ventricle.
   a. aortic valve
   b. pulmonary valve
   c. septum
   d. tricuspid valve
   e. mitral valve

9. The semi-lunar valves are the valves having triangular flaps and are located on the _____.
   a. pulmonary veins
   b. superior and inferior vena cavas
   c. pulmonary and aortic arteries
   d. mitral and tricuspid structures
   e. pulmonary artery and veins

10. Immediately before entering the aorta, blood must pass through the _____.
    a. left ventricle
    b. mitral valve
    c. lungs
    d. superior vena cava
    e. aortic valve

11. _____ (are) the thick walled chamber(s) of the heart.

12. The heartbeat consists of two parts; the contraction of the ventricles is called the _____ phase.

13. The relaxation of the ventricles is called the _____ phase.

14. The chamber of the heart which pumps oxygenated blood to all parts of the body is the _____.

15. The _____ is another name for the part of the heart called the heart muscle.

Terminology test

16. _____ is (are) the part of the heart which controls its contraction and relaxation.

17. The _____ is the name given to the inside lining of the heart wall.

18. The tissue which protects the inside lining of the pericardium is called the _____.

19. The _____ is the passage between the right auricle and the right ventricle.

20. The outside covering of the heart is called the _____.

Part Four

Comprehension test

1. The contraction impulse in the heart starts in
   a. the septum
   b. both ventricles simultaneously
   c. both auricles simultaneously
   d. the arteries

2. In the diastolic phase, the ventricles are
   a. fully contracted
   b. partially contracted
   c. fully relaxed
   d. partially relaxed

3. During the systolic phase, blood is being forced through the
   a. pulmonary and aortic arteries
   b. superior and inferior vena cavas
   c. tricuspid and mitral valves
   d. pulmonary veins

4. When the heart contracts, the
   a. auricles and ventricles contract simultaneously
   b. ventricles contract first, then the auricles
   c. right side contracts first, then the left side
   d. auricles contract first, then the ventricles

5. Which one of the following statements is false? When the auricles contract, blood is forced out of the
   a. superior and inferior vena cavas
   b. pulmonary veins
   c. tricuspid and mitral valves
   d. aortic and pulmonary valves

6. When the mitral and tricuspid valves are forced shut, in what position is the pulmonary valve?
   a. closed
   b. partially open
   c. open
   d. partially closed

7. During the systolic phase, in what position is the aortic valve?
   a. fully open
   b. partially open
   c. partially closed
   d. fully closed

Comprehension Test

8. Blood is being forced out the pulmonary veins simultaneously as blood is
   a. entering the vena cavas
   b. being forced out of the aortic and pulmonary valves
   c. passing through the mitral and tricuspid valves
   d. being forced through the pulmonary artery

9. If the aortic valve is completely closed, which of the following statements is correct?
   a. the systolic phase of the heart is occuring
   b. the diastolic phase of the heart is occuring
   c. the mitral and tricuspid valves are completely shut
   d. the blood is rushing into the right and left auricles

10. When the heart relaxes, the
    a. auricles relax first, then the ventricles
    b. right side relaxes first, then the left side
    b. left side relaxes first, then the right side
    d. ventricles relax first, then the auricles

11. Which valve is most like the tricuspid in function?

12. When blood is being forced out the right ventricle, in what position is the tricuspid valve?

13. When the blood is being forced out of the aorta, it is also being forced out of the _____.

14. During the systolic phase, in what position will the mitral valve be?

15. When blood is entering through the vena cavas, it is also entering through the _____.

16. While impure blood is entering the superior vena cava, it is also entering the _____.

17. When blood leaves the heart through the aorta, it is also simultaneously leaving the heart through the _____.

18. When the pressure in the right ventricle is superior to that in the pulmonary artery, in what position is the tricuspid valve?

19. Blood leaving the heart through the aorta had left the heart previously through the _____.

20. When the blood in the aorta is exerting a superior pressure on the aortic valve, what is the position of the mitral valve?

Appendix G

Letter of Permission to Concerned Faculty

January 18, 1988

To Dr. Esther Cohen,

I am presently in the process of looking for participants for my Master's Thesis focusing on the effect of instructional mode of presentation and preconceived degree of difficulty on memory. Instructional mode will be in the form of written passages, diagrams, and audio recordings. Preconceived degree of difficulty, on the other hand, will vary according to each student's preconception of the relative difficulty of the memory task.

In order to complete my research, a minimum of 90 students are needed. The students will be expected to participate in two 1-hour groupsessions. I am thereby asking for your cooperation in recruiting participants from your Behavior Change I class this semester. My assistant or I will be in touch with you as to a convenient time in which we could speak to your class during the month of February about this opportunity for your students to participate in an actual research project. As an incentive for your students to participate, you might consider some type of class credit for them.

Thank you very much.

Sincerely,

Richard Velayo

Noted:

Ken Beauchamp
Thesis Chair

Appendix H

Script for Experimenter

Audio-only Condition.

Hi, my name is Richard. I want to thank all of you for coming. Before I proceed, I would like to remind you that we will also be meeting next week at this same time and place for additional testing (give them a written memo for next week's meeting). If this is a problem, talk to me after you are done with today's testing.

The research I am doing concerns memory. Research studies have been done regarding how effective instructions are in the form of audio recordings. The findings in these studies indicate that. . .

(1) VERY EASY condition: for college freshmen, the material you are about to listen to has been classified as VERY EASY.

(2) NEUTRAL condition: for the typical college student, the material you are about to listen to has been classified as AVERAGE IN DIFFICULTY.

(3) VERY DIFFICULT condition: for college seniors, the material you are about to listen to has been classified as EXTREMELY DIFFICULT.

When the testing begins, you will be listening to the audio tape using the tape recorder and headphones you are provided with. Once you have started, you are not allowed to rewind the tape for any reason, so please listen to the tape very carefully and try to remember everything you can from what you have heard. When you have finished listening to the tape once, raise your hand so I can give you the first of four tests. Each test will be given separately, so you need to finish a test before I give you the next one. The purpose of the tests is to evaluate how much you remember of the material you heard. Do your best in answering the test questions and you may take your time in answering them. All of your test scores will be held confidential and will only be revealed to you, if you wish, approximately 4 weeks from today. Remember, you are allowed to listen to the tape once. Do not rewind or listen again to the tape.

Before we begin, has anyone taken college courses in anatomy or physiology or believes himself to be very knowledgeable about the parts and functions of the human heart? (Mark an "X" on the answer sheets of participants have.)

Do you have any questions before we proceed?

(Distribute and collect introductory statement.)

(Distribute instructional material and explain directions.)

(Proceed with presentation of material; then administer each tect separately.)

(Remind students of their next session.)

Pictorial + audio, print + audio, pictorial + print + audio Conditions.

Hi, my name is Richard. I want to thank all of you for coming. Before I proceed, I would like to remind you that we will also be meeting next week at this same time and place for additional testing (give them a written memo for next week's meeting). If this is a problem, talk to me after you are done with today's testing.

The research I am doing concerns memory. Research studies have been done regarding this material and the tests that will follow. The findings in these studies indicate that. . .

(1) VERY EASY condition: for college freshmen, this material has been classified as VERY EASY.

(2) NEUTRAL condition: for the typical college student, this material has been classified as AVERAGE IN DIFFICULTY.

(3) VERY DIFFICULT condition: for college seniors, this material has been classified as EXTREMELY DIFFICULT.

When the testing begins, you will be listening to the audio tape using the tape recorder and headphones you are provided with. Please keep pace with the tape in looking at your instructional booklets. Once you have started, you are not allowed to rewind the tape for any reason, so please listen to the tape very carefully and try to remember everything you can from what you have heard. When you have finished listening to the tape once, raise your hand so I can give you the first of four tests. Each test will be given separately, so you need to finish a test before I give you the next one. The purpose of the tests is to evaluate how much you remember of the material. Do your best in answering the test questions and you may take your time in answering them. All of your test scores will be held confidential and will only be revealed to you, if you wish, approximately 4 weeks from today. Remember, you are allowed to listen to the tape once. Do not rewind or listen again to the tape.

Before we begin, has anyone taken college courses in anatomy or physiology or believes himself to be very knowledgeable about the parts and functions of the

human heart? (Mark an "X" on the answer sheets of participants have.)

Do you have any questions before we proceed?

(Distribute and collect introductory statement.)

(Distribute instructional material and explain directions.)

(Proceed with presentation of material; then administer each test separately.)

(Remind students of their next session.)

Pictorial + print and print-only Condition.

Hi, my name is Richard. I want to thank all of you for coming. Before I proceed, I would like to remind you that we will also be meeting next week at this same time and place for additional testing (give them a written memo for next week's meeting). If this is a problem, talk to me after you are done with today's testing.

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VERY EASY.

(2) NEUTRAL condition: for the typical college student, the material you are about to read has been classified as AVERAGE IN DIFFICULTY.

(3) VERY DIFFICULT condition: for college seniors, the material you are about to read has been classified as EXTREMELY DIFFICULT.

Start reading the material only when I signal you to do so. Once you have started, you are not allowed to reread or go back to pages you have already read, so please read the material very carefully and try to remember everything you can from what you have read. When you have finished reading the material once, raise your hand so I can give you the first of four tests. Each test will be given separately, so you need to finish a test before I give you the next one. The purpose of the tests is to evaluate how much you remember of the material you read. Do your best in answering the test questions and you may take your time in answering them. All of your test scores will be held confidential and will only be revealed to you, if you wish, approximately 4 weeks from today. Remember, you are allowed to read the material only once. Do not reread or go back to those pages you have already read.

Before we begin, has anyone taken college courses in anatomy or physiology or believes himself to be very knowledgeable about the parts and functions of the human heart? (Mark an "X" on the answer sheets of participants have.)

Do you have any questions before we proceed?

(Distribute and collect introductory statement.)

(Distribute instructional material and explain directions.)

(Proceed with presenation of material; then administer each test separately.)

(Remind students of their next session.)

APA Division of International Psychology: Isang Maikling Pangkalahatang-ideya **

ni Richard S. Velayo, Ph.D., USA/Philippines, rvelayo@gmail.com

Noong Pebrero 21, 1997, inaprubahan ng mga pinuno ng American Psychological Association ang bagong division 52, "International Psychology," pagkatapos ng maraming taon ng pagpaplano. Ang misyon nito ay “pasulong ang pag-unlad at pagsulong ng mga internasyonal na relasyon sa mga psychologist sa mga lugar ng pagbabahagi kaalaman, paghikayat sa pagbisita, paghikayat sa intercultural na pananaliksik at pag-unlad sa klinikal na kasanayan, at upang itaguyod ang mga pangkalahatang layunin ng APA.”

Sa unang 25 taon nito, napatunayan ng 52 ang isang hindi pangkaraniwang aktibong dibisyon sa loob ng APA sa maraming paraan. (1) Ito naglalathala ng napakahusay na bulletin, *International Psychology Bulletin*, na may mga orihinal na artikulo tungkol sa sikolohiya sa buong mundo, na isinulat ng mga nangungunang psychologist, pati na rin ng mga mag-aaral at iba pa. 52 ay naglunsad din ng isang journal sa 2011, *International Perspectives in Psychology: Research, Practice, & Konsultasyon*. (2) Ito ay bumuo ng listserv at ng website, ngayon sa www.div52.net, na may napapanahong balita para sa mga miyembro. (3) Nag-aalok ito ng isang masiglang programa sa APA meeting tuwing Agosto, kung saan maaaring ipakita ng mga miyembro at iba pa ang kanilang gawain. Ang unang APA nito ang programa noong 1998 ay nagtampok ng 120 nagtatanghal mula sa 39 na bansa. (4) Tumatanggap ito ng mga nominasyon para sa taunang mga parangal nito para sa kahusayan: internasyonal na psychologist, tagapagturo, pananaliksik ng mag-aaral, pananaliksik sa kababaihan/kasarian, namumukod-tangi aklat, ECP. (5) Nag-aalok ito sa mga miyembro nito ng aktibong pakikilahok sa mahahalagang proyekto, isang bagong internasyonal na libro serye ng IAP Publishers, isang speaker network, at mga diskwento sa mga aklat o iba pang produkto.

Sa simula, nasiyahan ang 52 sa aktibong suporta ng mga pinuno ng APA, kabilang ang Chief Executive Officer na si Raymond D. Fowler. Apat sa unang 12 Pangulo ng 52 ang mga Pangulo ng buong APA: Florence Denmark, Frank Farley, Charles Spielberger, at Norman Abeles. Ang Dibisyong ito ay nagpapahintulot sa mga psychologist at mga mag-aaral mula sa USA at sa buong mundo na sumali sa International Division at maging aktibo para sa isang maliit na taunang bayad.

Noong 2022, ipinagdiwang ng 52 ang ika-25 anibersaryo ng pagdadala ng internasyonal na pananaw sa sikolohikal teorya, pananaliksik, edukasyon, at aplikasyon. Para sa anumang mga detalye, tingnan ang website nito, www.div52.net

Ngayon, ang 52 ay namumukod-tangi bilang isa sa hindi bababa sa limang internasyonal na organisasyon, bawat isa ay may sariling kakaibang misyon:

2. Ang IAAP (nabuo noong 1920) ay ang International Association of Applied Psychology. Sa kasalukuyan, merong 2,000 miyembro sa buong mundo, nag-aalok ng quarterly journal (Applied Psychology: An International Review), at isang quadrennial congress. (www.iaapsy.org).
3. Ang ICP (1941) ay ang International Council of Psychologists. Sa kasalukuyan, may bilang ng higit sa 100 miyembro sa buong mundo, nag-aalok ng isang quarterly newsletter (International Psychologist), at isang taunang convention. (https://icpweb.org/).
4. Ang IACCP (1972) ay ang International Association for Cross-Cultural Psychology. Sa kasalukuyan, merong 800 miyembro, nag-aalok ng dalawang buwanang Journal ng Cross-Cultural Psychology, at isang biennial meeting. (www.iaccp.org).
5. Ang IUPsyS (1951) ay ang International Union of Psychological Sciences. Ito ay isang unyon ng 75 miyembro mga bansa (walang indibidwal na miyembro), naglalathala ng International Journal of Psychology, at nagho-host ng quadrennial International Congress of Psychology. (www.iupsys.org).

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Awards Coordinator's Report

Division 1 had a very successful 2013 awards year. Many outstanding nominations were received for our various awards. A list of the award winners can be found in this issue of *The General Psychologist* below on page 9.

The Awards Ceremony at APA on was held on Saturday, August 3. It was very well attended, and the event was fun and very lively. Some well-known guests were easily recognizable, such as Dr. Florence Denmark and Dr. Phil Zimbardo. Some members of the Italian American Psychology Assembly (IAPA), including Dr. Bernard Carducci, who is the IAPA President, were present for a very special announcement: Division 1 will be renaming its poster award to the *Raymond Corsini Student Poster award* effective 2014 in honor of Dr. Corsini's centenary. An invitation to the Awards Ceremony was extended to Mrs. Kleo Corsini, but unfortunately, she was not able to make it.

Dr. Eric Charles deserves a special thank you – he did a superb job of looking after the suite programming for Division 1. Special thanks are also extended to all the Division 1 Award Chairs and their committee members for doing such a fine job and for getting back to me with their decisions on a timely basis. Their efforts enable us to celebrate on an annual basis the outstanding work and contributions from our colleagues and students and to encourage the next generation of psychologists in their path to excellence.

The call for award nominations for the 2014 year will be coming out shortly. We invite you to nominate someone or yourself. Information on the awards program can be found at http://www.apadivisions.org/division-1/awards/index.aspx. We also put out calls from time to time inviting individuals to join our awards process as award committee members. If you are interested, please respond to these calls or else feel free to contact me.

Josephine Tan, Ph.D., C. Psych.
Awards Coordinator
Email: jtan@lakeheadu.ca
Tel: 807-346-7751

Society for General Psychology:

APA Division One Awards

By Josephine Tan, Awards Coordinator

2013 APA Poster Session for Division 1

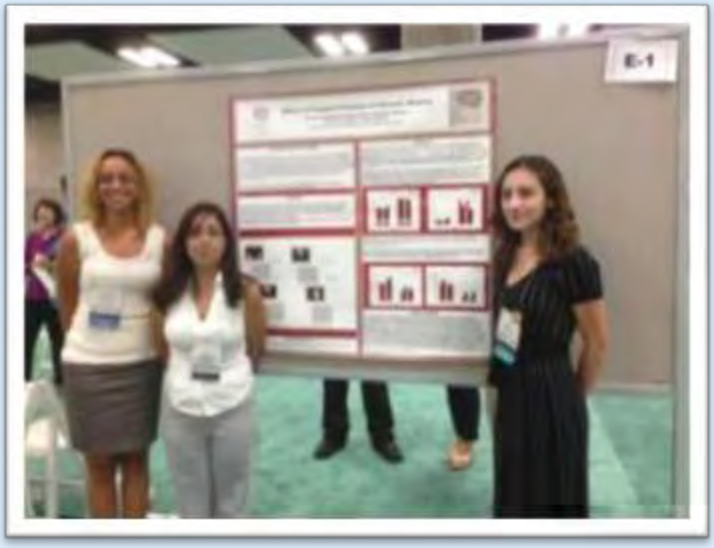

Above is the winning poster in the **2013 Anne Anastasi Student Poster Award** competition. The title of poster was "Effects of temporal pressure on episodic memory," and the authors were Audrey E. Martinez, M.A., Seda Terzyan, M.A., Angelyna M. Hinkle, M.A., David Rosenblatt, M.A., and Paul E. Haerich, Ph.D.

Standing beside the winning poster are (from left to right): Angelyna M. Hinkle, Audrey E. Martinez, and Seda Terzyan.

Above is a photo of one the three finalist posters, “Measuring student schema: Structural analysis of the Young Schema Questionnaire” by Matthew E. Kahler, B.S., John A. Blue Star, B.S., and Sean C. Woodland, B.S.

Standing beside the poster are Sean C. Woodland (left) and Matthew E. Kahler (right).

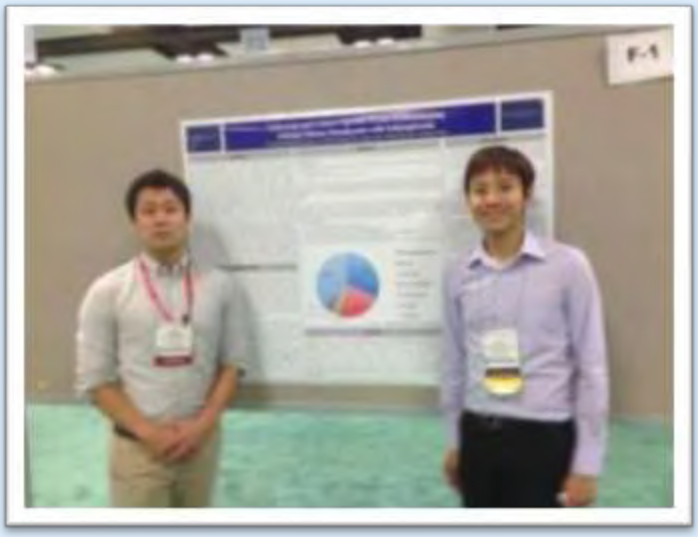

Pictured above is another of the three finalist posters, “Universal and culture-specific forms of stereotyping among Chinese immigrants with schizophrenia” by Tae Hyuk Keum, B.S., Yu Chak Ho, B.S., Jennifer Kim, B.A., Robin Hardin, B.S., and Seohyun Kim, B.A.

Standing beside the poster are Tae Hyuk Keum (left) and Yu Chak Ho (right).

Note: The remaining finalist poster was entitled “Examining meaning in life as a predictor of automatic stereotyping” by Ivorine Andrea Florez, B.A., Seamus P. Walsh, B.S., Margaret Bowden, Tracie L. Stewart, Ph.D.., and Stefan E. Schulenberg, Ph.D. The student authors were not there to present; Dr. Stewart presented alone.

2013 APA Division 1 Awards Ceremony

Jennifer M. Gómez, M.S., receiving her 2013 Anne Anastasi General Psychology Graduate Student Award (under 2 years of graduate work category) from Vincent Hevern, S.J., co-Chair of the award committee. Her project was entitled "Examining the effects of individual and cultural differences in trauma victimization". At extreme left in the foreground is Dean Keith Simonton, Ph.D., 2012-2013 past-President of Division 1. At extreme right in the foreground is Harold Takooshian, Ph.D., co-Chair of the 2013 award committee.

Lisa Osbeck, Ph.D. (left) with Nancy J. Nersessian, Ph.D.., (middle) and Wade Pickren, Ph.D. (right). Lisa and Nancy are co-authors of one of the two books that won the 2012 William James Book Award. The full reference for their book is *Science as Psychology: Sense-making and Identity in Science Practice* by Lisa Osbeck, Ph.D., Nancy Nersessian, Ph.D., Kareen Malone, Ph.D., & Wendy Newstetter, Ph.D. New York, NY: Cambridge University Press, 2010. Wade (2012-2013 Division 1 President) chaired the 2012 award committee.

Division 1 Awards Ceremony attendees.

Jennifer M. Gómez (left) talking with Nancy J. Nersessian (2nd from left). Lisa Osbeck (3rd from left) with Douglas Candland (far right).

Division 1 thanks the following individuals for their assistance in the 2013 award process!

Award Committee Chairs:

GEORGE A. MILLER AWARD: Wade Pickren, Ph.D., Ithaca College
WILLIAM JAMES BOOK AWARD: Janet A. Sigal, Ph.D., Fairleigh Dickinson University
ERNEST R. HILGARD AWARD: Dean Keith Simonton, Ph.D., University of California, Davis
ARTHUR W. STAATS LECTURE: Nancy Felipe Russo, Ph.D., Arizona State University
ANNE ANASTASI GENERAL PSYCHOLOGY GRADUATE STUDENT RESEARCH AWARDS: Harold Takooshian, Ph.D., Fordham University & Vincent W. Hevern, S.J., Le Moyne College
ANNE ANASTASI STUDENT POSTER AWARD: Nicholas Noviello, Ph.D. & Terece S. Bell, Ph.D., California School of Professional Psychology at Alliant International University, Los Angeles

Award Committee Members (in alphabetical order):

Bernard Beins, Ph.D., Ithaca College
G. Andrew H. Benjamin, Ph.D. University of Washington
Gordon M. Burghardt, Ph.D., University of Tennessee
Janet F. Carlson, Ph.D., University of Nebraska-Lincoln
Florence L. Denmark, Ph.D., Pace University
Emanuel Donchin, Ph.D., University of South Florida
Monroe Friedman, Ph.D., Eastern Michigan University
Gerald Gamache, Ph.D., University of St. Augustine, Florida
Uwe Gielen, Ph.D., St. Francis College
John Hogan, Ph.D., St. John's University
Jean P. Kirnan, Ph.D., College of New Jersey
Wilma Koutstaal, Ph.D., University of Minnesota
Ralph Kuechle, Ph.D., South Coast Children's Society
Robert V. Levine, Ph.D., California State University – Fresno
Jeffrey S. Mio, Ph.D., California State Polytechnic University – Pomona
Slater E. Newman, Ph.D., North California State University –Raleigh
Joseph J. Palladino, Ph.D., Miami University
Scott Plunkett, Ph.D., California State University, Northridge
Cecil R. Reynolds, Ph.D., Texas A&M University
Miguel Roig, Ph.D., Saint John's University
Ronald G. Shapiro, Ph.D., Providence RI
Susan Siaw, Ph.D., California State Polytechnic University, Pomona
Brian H. Stagner, Ph.D., Texas A&M University
Peter Suedfeld, Ph.D., University of British Columbia
Elizabeth V. Swenson, Ph.D., John Carroll University
Peter Theodore, Ph.D., California School of Professional Psychology at Alliant International University, Los Angeles

2013 Divisional Service Awards

The ***2013 Recognition Awards for Dedicated Service to Division 1*** were given out to
Nicholas Noviello, Ph.D., and
Terece S. Bell, Ph.D.

The following individuals received the *2**013 Division 1 Presidential Citations for Outstanding Service/Achievement***:
Gina Brelsford, Ph.D.,
Douglas K. Candland, Ph.D.,
Joan Chrisler, Ph.D.,
Marissa Harrison, Ph.D.,
Vincent Hevern, SJ.,
Lisa Osbeck, Ph.D.,
Brian Stagner, Ph.D.,
Harold Takooshian, Ph.D., and
osephine Tan, Ph.D.

Congratulations are extended to all the recipients!

Division 1, The Society for General Psychology
2013 Awards Announcement

Division 1 is pleased to announce its 2013 award recipients who were recognized at the 2013 APA meeting that was held in Honolulu, Hawaii. For more details on awards, please go to http://www.apadivisions.org/division-1/awards/index.aspx .

William James Book Award

Born Together-Reared Apart: The Landmark Minnesota Twin Study by Nancy L. Segal, Ph.D., California State University at Fullerton, published by Harvard University Press, Cambridge, MA, 2012.

Ernest R. Hilgard Award for Career Contributions to General Psychology

Morton Ann Gernsbacher, Ph.D.
University of Wisconsin-Madison

George A. Miller Award for the Outstanding Journal Article in General Psychology

Julianne Holt-Lundstad *Timothy B. Smith* *J. Bradley Layton*

Social Relationships and Mortality Risk: A Meta-analytic Review by Julianne Holt-Lunstad (Brigham Young University), Timothy B. Smith (Brigham Young University), and J. Bradley Layton (University of North Carolina at Chapel Hill), *PLoS Med 7*(7): e1000316.

2013 Arthur W. Staats Lecture for Unifying Psychology

Diane Halpern*, *Ph.D.
Claremont McKenna College

2014 Arthur W. Staats Lecture for Unifying Psychology

(Staats Lecture to be presented at 2014 APA)

Peter Salovey*, *Ph.D.
Yale University

Anne Anastasi Graduate Student Research Awards

Two or more years of graduate work

David I. Miller, M.A.
Northwestern University

Two or more years of graduate work

Reuben Ng, M.A., M.Phil.
Yale University

Under two years of graduate work

Jennifer M. Gómez, M.S.
University of Oregon

Finalists (in alphabetical order)

Marc Coutanche, M.A.
University of Pennsylvania

Emily D. Hooker
University of California, Irvine

Philip Sayegh, M.A.
University of Southern California

Anne Anastasi Graduate Student Poster Awards

Winning Poster:

Audrey E. Martinez, M.A., SedaTerzyan, M.A., Angelyna M. Hinkle, M.A., David Rosenblatt, M.A., & Paul E. Haerich, Ph.D.
Loma Linda University

Recognition Awards (in alphabetical order):

Ivonne A. Florez, B.A., Seamus P. Walsh, B.S., Margaret Bowden, *(University of Mississippi)*, ***Tracie L. Stewart, Ph.D.*** *(Kennesaw State University)*, ***& Stefan E. Schulenberg, Ph.D.*** *(University of Mississippi).*

Te Hyuk Keum, B.S., Yu Chak Ho, B.S., Jennifer Kim, B.A., Robin Hardin, B.S., & Seohyun Kim, B.A., *(Teachers College, Columbia University)*

Matthew E. Kahler, B.S., John A. Blue Star, B.S., & Sean C. Woodland, B.S. *(Brigham Young University).*

Division One Business

Business Meeting Minutes

August 2, 2013

Call to order by Dr. Pickren.

Dr. Tan and Dr. Stagner motioned to approve the business meeting meetings from 2012. This was unanimously approved.

1. President report: Wade reported that he was happy to pass the presidential gavel to Dr. Janet Sigal. He also chaired the committee for the George A. Miller award and the recipient is the article, "Social Relationships and Mortality Risk: A Meta-analytic Review," by Julianne Holt-Lunstad (Brigham Young University), Timothy B. Smith (Brigham Young University), and J. Bradley Layton (University of North Carolina at Chapel Hill).

2. Past-president report: Dean indicated he is chair of the Hilgard award and they chose Morton Ann Gernsbacher as the recipient. She will be giving an awards talk next year. Chair of nominations and elections committee, Emilio Ulloa, will be taking over as treasurer, and as member at large, Richard Velayo was elected. Joan Chrisler was elected as president-elect.

3. President-elect report-Janet indicated that her main task was sitting on the committee for the WJB award, which was awarded to Nancy Segal for her book,
"Born Together-Reared Apart: The Landmark Minnesota Twin Study".

4. Council of Representatives Report-Rosie indicated that the PENS report was appealed. There was a vote on the GG project. See more about this issue in the newsletter.

5. Secretary-Gina indicated that there will need to be replacement selected for position next year.

6. Treasurer-Joan was not present, but our monetary supplies are in good standing.

7. Member-at-large-Brian indicated that he was on the search committee for editor of *RGP* and he reviewed research awards for Harold.

8. Program Chair-Lisa was not present, but the program this year was well-attended.

9. Hospitality Suite Chair-Eric indicated the suite was well-attended so far to date. We have had post symposium discussions with approximately 50 people in attendance. We may want to increase the size of our hospitality suite at future conventions.

10. Historian-Don was not present, but he reminded us to send him to any reports or information from D1 for archives.

11. Journal Editor-Doug reported that his last edition of the journal will be the December edition. The journal is doing well. Submissions this year are around 100-110 and the acceptance rate is 21% during the last 3-4 years. RGP published 480 pages this year. June issue was a special issue, edited by Eric Charles. Doug was thanked for his work. Wade indicated that the new editor of the journal will be Dr. Gerianne Alexander of Texas A & M.

12. Newsletter editor-Marissa was not present. Wade remarked that she has done a great job.

13. Awards coordinator-Jo indicated that the awards handbook has been updated. The awards committee reports will be in the handbook. The call for next year's cycle of award nominations will occur very soon. Needs reviewers to help with the Anastasi poster and student research award chairs. Two MAL members are currently involved, but we need more people.

14. Webmaster-Grant not present, but indicated that the listserve has good traffic.

15. Membership-Mark was not present, but our membership continues to decline slightly.

16. Fellows-Richard was not present, but we have 7 new fellows this year.

17. Awards ceremony is at 4pm today. Poster award is tomorrow at 10 am.

18. Wade indicated he enjoyed being president and will enjoy being past president. He passed the gavel to Janet Sigal as the new president. She talked about how our division is inclusive of all disciplines and will celebrate next year the 66th anniversary of Division 1.

19. The meeting was adjourned at 12:40pm.

Respectfully submitted,
Gina M. Brelsford, Ph.D.
Secretary Division 1 of APA

Executive Committee Meeting Minutes

American Psychological Association
Division 1
Honolulu, Hawaii
July 31, 2013

Attendees: Richard O'Brien; Richard Velayo; Wade Pickren, Janet Sigal, Joan Chrisler, Eric Charles, Gina Brelsford, Lisa Osbeck, Rosie Phillips-Bingham, Brian Stagner, Zoeann Finzi-Smith, Doug Candland, Dean Simonton, Josephine Tan, Mark Terjensen

1. Meeting was called to order at 6:15pm.
2. Introductions were provided.
3. Meeting minutes from 2012 were approved with a small change to the theme of the 2013 convention.
4. Wade provided his report related to his term as president. The George A. Miler award was selected to be "Social Relationships and Mortality Risk: A Meta-analytic Review," by Julianne Holt-Lunstad (Brigham Young University), Timothy B. Smith (Brigham Young University), and J. Bradley Layton (University of North Carolina at Chapel Hill).
5. Janet (president-elect) provided her report on the WJBA. There were 11 submissions. It was a unanimous decision. Nancy Segal was the winner for her book "Born Together-Reared Apart: The Landmark Minnesota Twin Study". Program chair for next year is Grant Rich, "Integration of science and practice applied to global issues" is the possible theme for 2014. We may work with 4 other divisions for an interdivision grant on domestic violence (D. 42, 51, 17, 52); will work with them on this program due to our division hours being cut next year. It might be nice to have an anniversary celebration related to 66 years of Division 1.
6. Dean provided his past president report. The Hilgard Committee (outstanding career in general psychology) selected Morton Ann Gernsbacher for the award. Dean, as Chair of nominations and elections committee, indicated that Emilio Ulloa will be taking over as treasurer and Richard Velayo was elected as member at large. Joan Chrisler was elected as president-elect.
7. Lisa provided the program report. The theme of "Situating General Psychology in the 21st Century: Integration, unification, pluralism, or…?" We filled all of the program hours-37 hours including meetings. Wade's presidential address is a symposium this year. We are starting a coalition effort, "Big Questions, Essential Conversations" and we have two symposia coming out of this effort (D-1, 24, 26, 32, & 39).
8. Eric presented on the hospitality suite: 34 hours of suite programming in collaboration with D24 and D26.
9. Joan presented the treasurer's report: Financial report from last year and the budget for this year. We have made a substantial sum of money on the journal again this year. The duty of the treasurer is to advise on financial matters and be aware of and part of all financial decisions in addition to other duties that are typical of treasurers such as creating a budget or paying bills. The treasurer should also have a copy of the new journal editor's contract. The treasurer will need to collaborate with the awards chair and the hospitality suite chair on the financial needs of those positions. Rosie inquired about monetary support for council representatives. Zoeann also asked about student support for student representatives. Joan indicated that the budget is a living document, which can be changed.
10. Gina discussed only having one year left as secretary and a new secretary will need to be appointed.
11. Rosie presented on council. Telecounseling guidelines have been passed and internship accreditation guidelines have been passed. A discussion of the Good Governance Project ensued. This project has been ongoing for three years related to a strategic plan for APA. Structure of council was discussed. The PENS report was rescinded. APA affirmed the position against torture, particularly in national security centers.

12. Doug provided a report on his last term as journal editor of *RGP*. *RGP* was founded in 1996. Doug provided a history of *RGP*. Acceptance rate remains around 21%. The Division owns the journal as of 2010. The increased impact factor is notable. Revenue continues to be generated by electronic downloads.
13. Wade discussed the search for a new editor of *RGP*. We had 17 serious nominations or self-nominations. Four finalists and then the finalist was chosen to be Dr. Gerianne Alexander. She is currently at Texas A&M in the position of Associate Dean for Research in the College of Liberal Arts and a Professor of Psychology. A new system to review manuscripts has been adopted for *RGP*.
14. Marissa was not present, but she provided a brief report as Newsletter Editor. Her term is also ending and Wade would determine if she was going to continue after next year.
15. Member at Large (MAL)-Brian talked about not understanding his obligations or duties. This needs to be clearer for these positions. Wade indicated the member-at-large could take on leading a defunct committee that needs to be chaired or the MAL could take on the roles of chairing committees for the student poster award and the student research award.
16. Don provided an electronic report. He requests materials for D1 so they can be archived.
17. Grant provided an electronic report. We have a fairly active website.
18. Zoeann provided the student representative report. Zoeann is active on the student rep. listserve and she created a Facebook page for D1 to recruit students. A new student representative will need to be appointed after next year.
19. Jo presented her awards coordinator report. She indicated that the awards chair has to think in a 3-year epoch. Jo indicated that after winners for all major awards are selected-the work of the awards coordinator is to make sure all of the previous award winners present at the following year. Certificates, medals, checks are also to be acquired by the awards coordinator and distributed to the program chairs for delivery to the award winners. For this year's program, we selected the winners, so at the business meeting we are going to announce the 2013 winners. Anastasi student research award winners will be presented with their awards at the awards ceremony on Saturday evening. We will not know who the winners for the 2013 student poster winners will be until Sunday when they are judged. The cycle for 2014 has to be considered immediately upon return from APA. Hilgard, Miller, and James are all $1500, student research is $300, and the student poster is $100. We are changing the student poster award to the Raymond Corsini Student Poster Award. We have to have in place the Anastasi student research award chair and the Corsini Student Poster chair for 2014. We also will need an awards coordinator following august of 2014.
20. Nancy was not present to provide her oral report.
21. Mark provided his membership report. Division membership is down as is in most divisions. Slight upswing in student members and ECPs. Everyone who publishes in the journal is invited to join D1. There is a discussion between all division membership chairs related to how to use technology to engage students and ECPs. We will also need to find a new membership chair after 2014.
22. Rich presented on the fellows committee. He indicated there were 346 Fellows of D1. Not all Fellows have maintained their Fellow status. We have 7 new Fellows this year. These Fellows were named and *TGP* will present these names in the newsletter. Fellows include: Barney Beins, Frederick Wertz, Peter Hancock, Linda Sobell, Mark Sobell, Lisa Harlow, Ronald Shapiro. There is a Fellows workshop during convention if you wish to apply for fellow status.
23. Richard O'Brien presented on the IRB issue and scientific integrity. There appears to be an attempt to get rid of regulations for some research related to OHSRB. There are talks about trying to change the exempt status to excused status for research. Richard will continue in this position next year.

Discussion Items:

1. We need to identify chairs for the Corsini Student Poster Award and the Anastasi Student Research Award-there was discussion of passing these duties to the members-at-large. The presidential trio may have to decide on the Boneau Award and Presidential Citations for exceptional service.
2. Discussion related to providing honorarium to members of the Anastasi Award Committee, but it was decided that public acknowledgement is the best method.
3. Eric talked about the need to be reappointed as chair of the ECP committee. We need to find what is a benefit to ECPs for joining D1.
4. Mid-year meetings can be discussed at a future meeting, possibly during Joan's term as president.
5. There is a fee of $288 to run the division listserve from the DSO. The EC decided to continue use of DSO for our listserve.
6. D1 could use the Summit as a natural link for our Mid-Year meeting.
7. D1 could use the business meeting as an awards meeting at future conventions. This is a future agenda item.

Meeting was adjourned at 8:05pm.

Respectfully submitted,
Gina M. Brelsford, Ph.D.
Secretary D1

Click here for tips on APA-style writing.

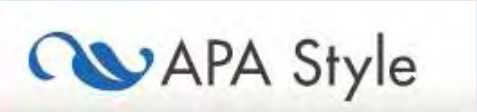

More D1 scenes from the...

Thumbs up from then-President, Wade Pickren

Dean Keith Simonton

Janet Sigal

L to R: Douglas Candland, Scott Churchill, Frederick Wertz, Christopher Ramey, Kolja Lehmann, James Lamiell, and Lisa Osbeck.

Philip Zimbardo

Vinny Hevern &
Wade Pickren

Congratulations to the New Fellows of Division 1!

According to the American Psychological Association, *"Fellow status is an honor bestowed upon APA Members who have shown evidence of unusual and outstanding contributions or performance in the field of psychology. Fellow status requires that a person's work has had a national impact on the field of psychology beyond a local, state, or regional level. A high level of competence or steady and continuing contribution are not sufficient to warrant Fellow status. National impact must be demonstrated."* Of 84,000+ APA members, about 6 percent are Fellows.

The Fellows Committee of the Society for General Psychology (APA Division 1) is proud to announce that eight psychologists were elected as Fellows of the Division based on their "outstanding and unusual" contributions to general psychology. One of them was elected as a new Fellow of APA, and seven current APA fellows were elected by the Division.

- **Bernard Beins, Ph.D.** *(Ithaca College)*
- **Peter Hancock, Ph.D., D.Sc.** *(University of Central Florida)*
- **Lisa Harlow, Ph.D.** *(University of Rhode Island)*
- **Susan Nolan, Ph.D.** *(Seton Hall University)*
- **Linda Sobell, Ph.D.** (*Nova Southeastern University)*
- **Mark Sobell, Ph.D.** *(Nova Southeastern University)*
- **Ronald Shapiro, Ph.D.** *(Independent Consultant, Providence, RI)*
- **Frederick Wertz, Ph.D.** (Fordham University)

For those who may be interested in applying for Fellow status in Division 1, contact Richard Velayo, Ph.D., by email at rvelayo@gmail.com. Criteria for qualifications as Division 1 Fellow may be found at http://www.apadivisions.org/division-1/membership/fellows/index.aspx .

My sincerest thanks to Drs. Florence Denmark, Antonio Puente, Janet Sigal, and Harold Takooshian who served as members of the Committee this past year!

Congratulations and best wishes to our new Fellows!

Sincerely,

Richard S. Velayo, Ph.D.
Chair, Fellows Committee

Who admires Raymond Corsini?

Help Division 1 Celebrate Dr. Corsini's Centennial Birth!

The late, great psychologist Raymond J. Corsini (1914-2008) of Hawai'i was a brilliant author, teacher, and mentor. Ray's career is described in the *American Psychologist* (January, 2010, on page 54).

Many of Ray's friends gathered in 2013 at the APA Convention in Honolulu where Division One Awards Chair Josephine Tan announced the launch of a new Corsini Student Research Award to mark the centenary of Ray's birth in 2014.

For a tribute to Ray in 2014, *The General Psychologist* seeks brief remembrances from Ray's students, colleagues, and friends. Did Ray's life touch yours somehow? If so, please send us this information by December 1, 2013: your name, current affiliation, your photo, and 1-3 paragraphs on how Ray's life touched yours. If you have a good photo or two of Ray, please add these, along with photo captions. These edited remembrances will appear in a tribute to Ray in *TGP* in 2014.

Please direct any questions to Corsini Committee chair **Bernardo Carducci**: bcarducc@ius.edu.

PHOTO: In Hawaii, Dr. Vernon Thompson's family joins the salute to their friend, Ray.

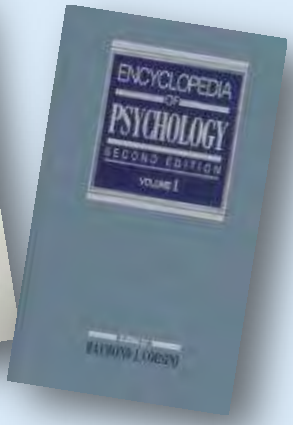

Review of General Psychology Welcomes a New Editor

By Wade Pickren, Past President of D1

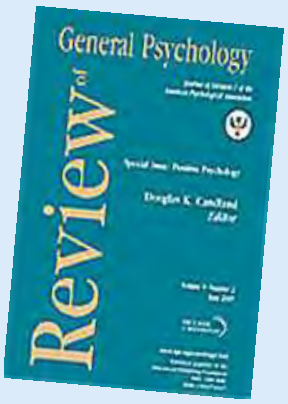

In the summer of 2012, Division One's leadership formed a committee to search for the new editor of our journal, *Review of General Psychology*. After many years as editor, Doug Candland had decided to step down and we all knew it would be hard for anyone to follow him. Under Doug's editorship the journal had grown in reputation and influence. Our members and the Division leadership wish to express our profound thanks to Doug for the excellence he brought to the journal.

The search committee members were Nancy Russo, Ph.D., Hortensia Amaro, Ph.D., Brian Stagner, Ph.D., and Thomas Teo, Ph.D. I served as Chair of the Committee. We worked with APA Journals and their web-based Editor Quest system to manage the process.

We received 17 high-quality nominations. After much deliberation, we were able to narrow the list to four finalists, each of them eminently qualified to serve as editor. The Committee carefully considered the merits of each finalist and unanimously decided that **Dr. Gerianne Alexander of Texas A & M University** was our first choice. Dr. Alexander agreed to serve as our editor for the next six years. She brings to the position a high-profile research reputation. Her research interests include the development of human sex differences in social and cognitive behavior; hormonal influences on typical and atypical behavior across the lifespan; and reproductive endocrinology and behavior. Her research has been well-funded by a variety of federal and private agencies.

Dr. Gerianne Alexander

Dr. Alexander brings to her editorship remarkable breadth as a researcher. Just as importantly, she brings a great intellectual curiosity about human behavior. While she is solidly based in psychology, she also sees the connections among psychological science, the biological sciences, as well as the profound insights about human beings that are found in our best fiction, art, and music. She is truly well-situated to continue to develop general psychology through the pages of *Review of General Psychology*.

Editor's Note: Read one of Dr. Alexander and Dr. Hines's landmark articles:
Alexander, G.M., & Hines, M. (2002). Sex differences in response to children's toys in nonhuman primates (*Cercopithecusaethiops sabaeus*). *Evolution and Human Behavior, 23*(6), 467-479.

Become a Fellow of Division 1

Fellows Committee Call for Nominations

The Division 1 Fellows Committee is seeking nominations and applications for Fellow status in the Division.

Fellows Committee Chair: Richard Velayo, Ph.D.
Email: rvelayo@gmail.com

There are two paths to Fellow status in the Division:

First, members of Division 1 who are APA members, but are not Fellows of APA, may apply for Fellow status in Division 1. They are known as "New Fellow" applicants and must meet both APA criteria and Division 1 criteria for Fellow status.

Second, any member of Division 1 who is already a current Fellow of APA may apply to become a Fellow of the Division. These applicants are known as "Current Fellows." Current Fellows are only evaluated by the Division Fellows Committee. Current Fellows are a good resource for information about being and becoming a Fellow. Letters from Current Fellows are also required for those applying for New Fellow status.

APA Fellow Criteria include:
1. Five (5) years of acceptable professional experience beyond receipt of the doctoral degree
2. Membership in APA for at least one year
3. Unusual and outstanding contributions that have had a national or international impact in general psychology

Division 1 Fellow Criteria are listed here:
http://www.apadivisions.org/division-1/membership/fellows/index.aspx

Process for New Fellows:

The process to apply to be an APA Fellow is now done via the **APA Fellows Online Application Platform**. This new system will allow nominees, endorsers, and Division Fellows Chairs to submit all required documents online.

The online system will replace the previous, paper-based process and all Fellows applications must be added to the system to be considered by the Fellows Committee.

Applications for New Fellow status require letters from three current Division 1 Fellows and completion of other materials described in the APA Fellows Online Application Platform. Please visit the Fellows webpage for more information and to access the new online system: http://www.apa.org/membership/fellows/index.aspx

All materials, including letters of reference, must be completed by November 18, 2013. The candidates' applications are reviewed by the Division Fellows Committee. Those receiving a positive recommendation will be forwarded to the APA Fellows Committee for their review. Fellow status is granted by the **APA Fellows Committee**. Please remember that there can be **only one nominating Division**.

Process for Current Fellows:

Current Fellows of the APA from other APA Divisions may apply for Division 1 Fellow status by sending a current vita and a letter highlighting the reasons that one has met the criteria for Fellow status in the Division. These candidates' applications must be emailed to Richard Velayo (rvelayo@gmail.com). **The due date for Current Fellows applications is April 15, 2014.** Current Fellows applications are evaluated by the Division Fellows Committee only.

AMERICAN PSYCHOLOGICAL ASSOCIATION

Taken from: http://www.apa.org/about/division/index.aspx

Divisions

APA's 54 divisions *are interest groups organized by members. Some represent subdisciplines of psychology (e.g., experimental, social or clinical) while others focus on topical areas such as aging, ethnic minorities or trauma. APA members and even nonmembers can apply to join one or more divisions which have their own eligibility criteria and dues. In addition, each division has its own officers, website, publications, email list, awards, convention activities and meetings.*

Spotlight from the 2013 APA Convention

Anne Anastasi

Graduate Student Poster Award Winner

Effects of Temporal Pressure on Episodic Memory

Audrey Martinez, M.A., Seda Terzyan, M.A., Angelyna Hinkle, M.A., David Rosenblatt, M.A., and Paul Haerich, Ph.D.

Loma Linda University

Introduction

This study examined the predictions of Priority Binding theory by manipulating temporal pressure across lists of emotional visual images. Priority Binding theory (MacKay et al., 2004) proposes that under temporal pressure, arousing negative stimuli delay binding of neutral items presented in close temporal proximity (as in lists with mixed neutral and negative stimuli). With fast presentation rates, a subsequent negative item may interrupt the binding process for the preceding neutral stimulus. This results in more accurate memory for negative images presented in mixed lists. However, in slow presentation rates, binding occurs equally for all items. Therefore, no such advantage is predicted comparing images presented in lists of the same valence.

Method

Participants (N = 42; recruited from subject pools at two private Southern California universities) were shown eight lists of 14 images selected from the International Affective Picture System. One pure negative, one pure neutral, and two mixed valence lists were presented at 0.5 Hz and at 4 Hz. using *E-Prime 2.0 Professional* to randomize this list order and list composition. Following each list, participants completed old-new recognition tests and rated their confidence using a remember/know paradigm.

Results

Accuracy: A three-way interaction resulted from performance differences between rates, and among lists at the fast rate, $p = .006$. In fast, pure lists, neutral valence images displayed an accuracy advantage over negative, $p < .001$, while in fast, mixed lists the difference was non-significant. Accuracy was better for slow than fast lists suggesting that processing benefited from the extra encoding time, $p < .001$. No differences among lists were observed at the slow rate. Sensitivity: Sensitivity (d'_e) paralleled accuracy; however the differences among lists were greater. d'_e was better at slow than fast presentation rates, $p < .001$, and for negative images at slow rates, $p < .03$. A two-way (Rate X List Type) interaction, $p < .03$, resulted from a non-significant trend for better sensitivity.

Discussion

The present study examined the effects of temporal pressure on recognition of emotional pictures. Manipulating presentation rate produced the largest effect and strongly influenced recognition accuracy, sensitivity and bias. The predictions of binding theory were

partially supported with a trend for negative images to exhibit a memory advantage over neutral images in the mixed, fast lists; there was also an unexpected memory advantage for neutral images in pure lists. A ceiling effect was found for recognition memory of lists at the slow rate, suggesting that extra viewing time allowed participants to better process and encode images. Slow-rate negative images produced higher d'_e and more liberal bias than neutral. Though image recognition appears to be influenced by emotional valence and arousal, it is still possible that image stimuli are differentially processed and remembered compared to word stimuli.

Reference

MacKay, D. G., Shafto, M., Taylor, J. K., Marian, D. E., Abrams, L., & Dyer, J.R. (2004). Relations between emotion, memory and attention: Evidence from taboo Stroop, lexical decision, and immediate memory tasks. *Memory & Cognition, 32*, 474-488.

Audrey E. Martinez, M.A., is a doctoral student at Loma Linda University in Loma Linda, CA. Her research focuses on emotion and human neurocognition.

"Ma Vie En Graduate School"

Advice for Future Students and for Student Futures

By Lavina Y. Ho
Applied Clinical Psychology, Penn State Harrisburg

Graduate school marks a time for academic and personal growth, as graduate students are given greater responsibility and autonomy in deciding their future plans in addition to ultimately determining their unique career path. My greatest advice to future graduate student applicants is to keep an open mind and to take advantage of all the opportunities around them.

Future graduate applicants usually have a set of plans laid out, and in instances where these plans may not work out, students may often lose faith in themselves and ultimately, their aspirations. However, the most important lesson that I have learned thus far is that hard work will yield results, but only after continued determination.

While it may seem as if the delayed gratification of graduate education is often overwhelming, careers take unexpected turns and often result in a deeper understanding of the self and an individual's capabilities. What's important to remember is that the unexpected nature of life creates opportunities for personal and academic growth.

Graduate life simply never ends. Knowledge begets greater knowledge, and an understanding that graduate students never cease learning in multiple facets of their lives. I highly recommend that graduate students get involved in their campus life, especially within their academic program. As graduate students, we have the ability to facilitate positive change on campus as well as promote the mental welfare of underserved communities in psychology. Acting as role models on campus also inspires greater community change, promotes undergraduate students to perform at their optimum abilities, and ultimately, to pursue graduate education.

Lavina Y. Ho *is an advanced student on scholarship in Penn State Harrisburg's Applied Clinical Psychology Master's Program. She is a Teaching Assistant, a Research Assistant, and an officer and community leader in Psi Chi and the Applied Psychology Association of PSH.*

Future APA Convention Dates

2014 Washington, D.C.
August 7-10 (Thursday through Sunday)

2015 Toronto, Ontario, Canada
August 6-9 (Thursday through Sunday)

2016 Denver, Colorado
August 4-7 (Thursday through Sunday)

2017 Washington, D.C.
August 3-6 (Thursday through Sunday)

2018 San Francisco, California
August 9-12 (Thursday through Sunday)

2019 Chicago, Illinois
August 8-11 (Thursday through Sunday)

2020 Washington, D.C.
August 6-9 (Thursday through Sunday)

2021 San Diego, California
August 12-15 (Thursday through Sunday)

Division One: Society for General Psychology

Book review

By J. Scott Lewis, Ph.D., Penn State Harrisburg

The Human Spark:
The Science of Human Development
By Jerome Kagan

Basic Books, 2013. 333 pages. ISBN: 978-0-465-02982-2

In this book, pioneer of developmental psychology Jerome Kagan updates his previous book *The Nature of the Child*. Kagan focuses on three questions of import in which new evidence brings up to date old ideas. What is the expected developmental course for cognition, emotional development, physical development and moral development in children? How does variation in experience affect the rates at which these traits develop? And, finally, what are the factors that influence variation in experience?

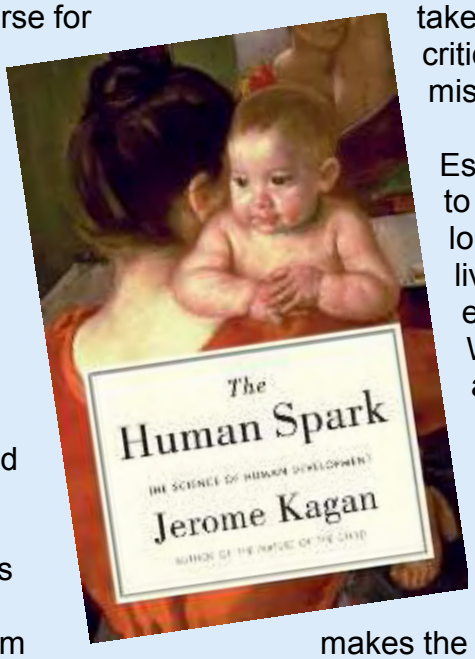

Of course, these are not new questions. They have been asked before in a variety of contexts, including through epigenetic and sociological frameworks. Kagan's contribution to the questions, however, deviates somewhat from the more mainstream approaches to the problem. Kagan questions many of the conventions currently in vogue in developmental psychology. For example, he questions the notion that past behavior in one setting is a good predictor of future behavior in a different setting.

Kagan sees such conceptions as part of a larger problem in developmental psychology; this problem is the lack of triangulation of evidence. Kagan sees this as providing a grossly incomplete picture of human behavior. He uses these weaknesses to offer a critique of some of the most popular theories in developmental psychology. Most notably, he takes aim at attachment theory, which he criticizes as an egregious misinterpretation of research.

Essentially, Kagan relies on sociology to make his case. Sociologists have long argued that culture shapes the lives of individuals within their experiential and historic context. C. Wright Mills made this same argument in 1959, and most sociologists accept it as axiomatic. Kagan discusses how culture shapes the choice that individuals make to influence their development. Offering a thorough review of the literature, the author makes the case not only for socialization, but also for epigenetics. He presents a wealth of evidence on the ways in which environment and experience influence the expression of genes.

A positive aspect of *Spark* is that Kagan takes a strongly interdisciplinary approach to his topic. The book provides an excellent overview of literature in a variety of areas of developmental psychology.

However, the book is so laden with information and thick with studies that it is often dry and sometimes a little hard to follow. The careful reader will, however, find it a rich source of information and a valuable compendium of information. The comprehensive coverage that it provides makes it an ideal companion to a textbook for those seeking a deeper understanding of many of the issues at the forefront of developmental psychology.

Dr. J. Scott Lewis *is Assistant Professor of Sociology and the program coordinator for Penn State Harrisburg's Bachelor of Social Science in Secondary Education Social Studies program. His interdisciplinary research interests include evolution and human behavior, the philosophy of social science, and pedagogy. He is the author of* Learn Sociology.

If you have a book you would like to see reviewed in *The General Psychologist*, or you would like to review a book for us, please contact the Editor.

Please visit the APA Homepage at:

http://www.apa.org/

AMERICAN PSYCHOLOGICAL ASSOCIATION

DID YOU KNOW?

The APA provides valuable information about research in psychology. The APA website features a database for research funding sources, advice for research methodology and training opportunities, resources about publishing your research, and resources and readings to ensure the responsible conduct of research. Click here.

Division 1's ***Portraits of Pioneers in Developmental Psychology***
Edited by Wade Pickren, Donald A. Dewsbury, and Michael Wertheimer

Published October 26th, 2011 by Psychology Press – 351 pages

Click here for more information and purchasing options.

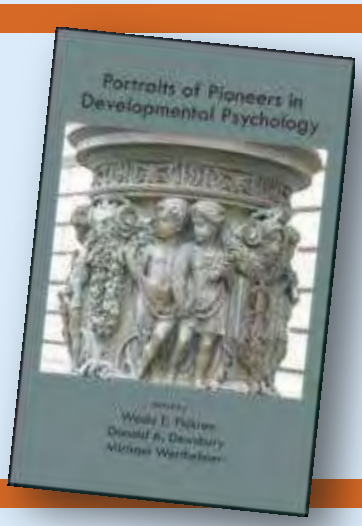

Is *Introductory Psychology* Asexual?

Marissa A. Harrison, Ph.D., Jennifer E. Zobler, M.A.,

Gina M. Brelsford, Ph.D., and Melanie S. Koser, B.A.

Penn State Harrisburg

Since psychology as a discipline aims to understand human behavior and mental processes, what could be a more fundamental behavior to understand than that which ultimately serves to perpetuate the species—**sex**? Indeed, sex is very important to most people, and for some, sexuality is a dominant force in their lives (Bancroft, 2009). Although some may be uncomfortable with sexuality and feel that discussing sex reflects evil or immorality, and some may backlash against any form of sexual progressiveness (Hyde & DeLamater, 2011), the fact is that sex is here to stay.

In their textbook *Understanding Human Sexuality*, Hyde and DeLamater (2011) eloquently underscored the importance of the study of sexuality for college students. Exposure to human sexuality research can facilitate self-understanding, minimize embarrassment about a fundamentally important topic, influence judgment and decision-making with respect to physical and emotional well-being, and foster tolerance of sexuality regardless of age, gender, ethnicity, sexual orientation, and culture. Further advantages of human sexuality education include arming students with the skills to maximize their own sexual health and minimize sexual exploitation of one's self and others (Baber & Murray, 2001). Thus, a college course in the psychology of human sexuality can be of tremendous developmental value with respect to promoting well-being and self and societal understanding. Given such importance, however, it seems logically indefensible that the dissemination of such essential information should be limited to students enrolled only in sexuality-specific courses. While it is likely impossible to infuse sexuality into every college course, the discipline of psychology offers a viable outlet tailored to disseminating such information to a widespread audience—Introductory or General Psychology. In the present work we make the argument that Introductory Psychology should *not* be asexual—that is, as behavioral scientists we should endeavor to include human sexuality in our most basic college psychology course.

The majority of college students are typically 18 to 25 years old (National Center for Educational Statistics, 2002). Referred to as emerging adults (Arnett, 2007), this age group is coming into their own, exploring various identities,

taking strides in developing world views separate than that of their parents and caregivers, and focusing on their own lives without yet committing to adult roles (Arnett, 2004; DeHaan, Yonker, & Affholter, 2011). Since both men and women engage in a myriad of partnered and solo sexual behaviors from early adolescence to late adulthood, emerging adults and society as a whole can benefit from programs that seek to improve upon sexual knowledge and healthy choices (Herbenick, Reece, Schick, Sanders, Dodge, & Fortenberry, 2010). Further, as Rutledge, Siebert, Chonody, and Killian (2011) pointed out, many US adolescents do not receive sufficient sex education in high schools and therefore come to college in need of information at this precarious juncture of development. During this crucial period of role exploration, one can argue the dire need for sexuality education.

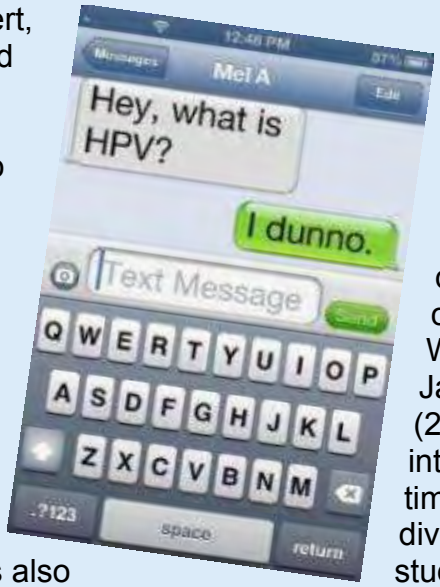

Introductory Psychology is a core requirement in the Psychology major, Psychology minor, and in many other majors and minors; it is also an elective sought by numerous college students. The American Psychological Association (2013) endorses Cush and Buskist's (1997) estimate that 1.5 million students complete an introductory psychology course each year. To wit, Bowker PubTrack (personal communication) documented that 413,464 students were enrolled in Introductory Psychology in the United States in the spring of 2011. As such, the material contained in Introductory Psychology textbooks reaches a vast audience. Indeed, the information in college textbooks can also impact others besides college students. For example, Advanced Placement Psychology is a college-level course taught to high school students, and current college-level textbooks are used in its instruction (College Board, 2010). Herein, then, lies the opportunity to deliver sexuality content to an even younger audience in their developmental prime. Even non-student individuals seeking knowledge or understanding of human behavior and mental processes may turn to an introductory psychology textbook online, from a friend, etc. Thus, Introductory Psychology offers a valuable opportunity to promote the understanding of human sexual behavior, and the presentation thereof can inform sexual decision-making and tolerance of self and others.

As such, the present study sought to document coverage of human sexuality topics in Introductory Psychology textbooks. We had no *a priori* prediction of degree of representation; rather, we aimed to document the presence and extent of coverage of various sexuality topics. Well over a decade ago, Griggs, Jackson, Christopher, and Marek (2000) noted that less than a third of all introductory books on the market at the time devoted full-chapter coverage to diversity and sex/gender. The present study parses this effort focusing on sexuality (and diversity therein), extends this effort by elaborating on specific themes for analyses, and offers a more recent glimpse of representation to determine whether contemporary introductory psychology is, indeed, asexual.

Method

Two long-time instructors (combined 20 plus years of experience) of college-level Psychology of Human Sexuality courses consulted several human sexuality textbooks (e.g., Hyde & DeLamater, 2011; Kelly, 2010; Rathus, Nevid, & Fichner-Rathus, 2010) and generated a list of 81 concepts typically covered in the class. This list of concepts appears in Table 1. Whereas it was not expected that every topic from a subdiscipline-specific course

would be covered in an introductory-level course, we used themes typically covered in sexuality courses as a basis to gauge representation.

A major textbook publisher kindly provided us with lists of the most required (i.e., the total number of students enrolled in courses requiring each book) introductory-level psychology textbooks in the United States from Spring 2011. The list was not publisher-specific (i.e., it did not solely list the publisher's own books).

We aimed to analyze the 15 most required introductory psychology texts. We obtained hard copies of 14 of the 15 books on the list for review. These 14 texts were published between the years of 2006 and 2009 by Pearson (*n* = 6), Worth (*n* = 6), Cengage (*n* = 1), and Wiley & Sons (*n* = 1) Publishers. We were unable to secure a copy of the 12th most required book on the list and therefore could not analyze it. Of note, we first attempted our analysis with online/e-book copies of the target textbooks but we found search features did not function with high accuracy. We thus conducted all analyses with hard copies.

In a departure from previous introductory textbook content analyses (cf. Habarth, Hansell, & Grove, 2011), we included full, brief, and modular editions of textbooks in our analysis. Our rationale is that the data show that these titles contain the information being disseminated to the most students, and therefore the sexuality information they include or exclude is essential to our analyses. For example, the *third* most required book (*n* = 25,919 students) was written by the author of the *second* most required book, and this number represented >30% more students than the *fourth* most required book. We would be remiss if we excluded the impact simply because the same person wrote more than one title. These 14 titles together accounted for 244, 038 enrolled students' required texts (Bowker PubTrack, personal communication), or 59% of the total introductory psychology books required in the United States during that semester. Stated another way, the majority of introductory psychology students in the United States were required to be consumers of these 14 book titles in Spring 2011.

Because our goal was to present evidence of systemic trends of sexuality coverage and not to comment upon or "call out" individual text authors, we opt not to list book titles; this follows the presentation method of Harbath et al. (2011) in their content analysis of psychoanalytic themes in introductory textbooks.

We read first the Index of each book searching for terms, and if the terms were not found, we read through each chapter of each book, paying close attention to areas in which sexuality might be mentioned but perhaps not indexed (e.g., *puberty* in Developmental Psychology chapters; *sexual attraction* in Social Psychology chapters). We noted whether each term or concept was *identified* (named only), *defined* (meaning was conveyed), or *discussed* (author provided context in two or more sentences).

Results

Results are presented in Table 1; 86% of terms and concepts were mentioned, 84% were defined, and 67% were discussed in at least one book. Of the 14 books reviewed, 5 (36%) featured a chapter devoted to human sexuality and gender.

Table 1

Percentage of Most Required (N = 14) Introductory Psychology Textbooks Mentioning, Defining, and Discussing Selected Sexuality-related Concepts

Concept/Term	% Mentioning	% Defining	% Discussing
Sexual Acts			
Masturbation/ one-person sex	36	7	0
Extramarital sex/ cheating/ adultery/infidelity	21	14	14
Premarital sex	57	50	43
Sexual intercourse	100	100	100
Oral sex	29	0	0
Sexual techniques	0	0	0
Sexual Cognitions			
Sexual desire	57	50	29
Sexual curiosity	14	14	0
Sexual decisions	0	0	0
Sexual fantasies	50	43	36
Physical attractiveness/ sexual attractiveness	100	100	86
Theories of Sexuality			
Biological	100	100	100
Evolutionary	100	100	100
Freudian	100	100	93
Sociological	86	86	86
Feminist	0	0	0
Researchers			
Masters and Johnson	100	93	79
Alfred Kinsey (Kinsey Report)	79	71	64
Physiology of Sexual Response			
Sexual response cycle	100	100	100
Penile erection	100	43	0
External sex organs	100	79	43
Internal sex organs	100	79	43
Sex hormones	100	100	50
Pheromones	21	14	0
Erogenous zones	43	21	0
Brain and sex	79	79	71

Sexual Development			
Sexual differentiation	93	86	64
Menstruation/ menarche	100	93	14
Puberty	100	100	64
Menopause	100	79	14
Sexuality during childhood	93	86	64
Sexuality during adolescence	100	100	100
Sexuality during adulthood	93	93	71
Sexual Orientation			
Heterosexual	100	100	86
Homosexuality	100	100	100
Gay	100	79	7
Lesbian	93	71	7
Transgender	57	57	21
LGBTQ	0	0	0
Intersex	36	36	7
Same-sex marriage	14	7	0
Gay prejudice	43	36	29
Gender Roles			
Gender stereotypes	64	64	36
Sexual scripts	64	64	43
Sex differences in personality	100	100	86
Sex differences in cognition	100	100	93
Sex differences in behavior	100	100	86
Reproduction			
Conception	93	86	29
Pregnancy	93	86	79
Childbirth	79	57	14
Infertility	0	0	0
Reproductive technology	0	0	0
Contraception/ pregnancy prevention	36	36	7
Abortion	21	7	0
Condoms	79	43	14
Diaphragm	7	7	0
Withdrawal	0	0	0
IUD	0	0	0
Rhythm method	0	0	0
Sexual Relationships			

Love	100	100	93
Sexual communication	14	7	14
Multicultural sexuality	57	57	57
Sexual Variation			
Paraphilias	36	57	7
Hypersexuality and asexuality	0	0	0
Cybersex	21	7	0
Sexual Coercion			
Rape	43	43	36
Incest	7	7	7
Sexual abuse	36	29	0
Sexual harassment	7	7	0
Sex Laws			
Sex-related laws	0	0	0
Selling Sex			
Prostitution	14	0	0
Pornography	14	14	7
Sexual Disorders (any type)			
Sex therapy	21	14	7
Sexually transmitted infections or diseases			
HIV/AIDS	93	93	79
HPV	36	29	14
Herpes	57	43	7
Gonorrhea	21	21	0
Syphilis	36	36	7
Pubic Lice	7	7	0
Hepatitis	7	7	0
Safe sex	71	50	43

Discussion

The question at hand is, "Is Introductory Psychology asexual?" Almost all the human sexuality terms and concepts for which we searched (nearly 9 out of 10) were at least mentioned, and two-thirds did receive discussion in at least one of the most required introductory textbooks. Further, over a third of books featured a human sexuality chapter. We thus interpret this as a cautiously positive **"no"** to our question and commend the efforts of our textbook-writing colleagues to infuse this important topic into the psychology curriculum. We would like to note for our esteemed text

author colleagues, however, some areas in which a discussion of such might promote sexually wise choices and inclusion.

Most books had some coverage of the usual suspects—*sexual development* (e.g., *menarche*, *puberty*), *love*, *physical attraction*, *sexual intercourse*, *conception*, *pregnancy*, and *childbirth*—with various discussion thereof. Curiously, however, no books mentioned the related topics *infertility* and *reproductive technology*. With about one out of six couples affected by infertility issues world-wide (World Health Organization, 2002), and with artificial reproductive technology evolving over the past 30 years affecting individuals, families, and societies around the world with social, cultural, and ethical implications (Inhorn & Birenbaum-Carmeli, 2008), this topic may warrant inclusion in future editions of introductory psychology textbooks.

A majority of textbooks we analyzed mentioned *safe sex*; however, less than half discussed it. Only two of the books discussed *condoms*, two discussed *human papillomavirus* (HPV; a virus that causes genital warts) and one discussed *herpes*. Although we understand textbook space is a premium, we implore our textbook author colleagues to introduce and elaborate upon safe sexual practices, even if this means a mere page of discussion. According to the Centers for Disease Control and Prevention (CDC) of the United States, people between the ages of 15 and 24 account for almost half of the 19 million new sexually transmitted infections reported each year, (CDC, 2012a), making this the highest rate of any age group (CDC, 2012b). Moreover, about 43% of women aged 14 to 59 years have HPV (CDC, 2010), and 16% of people in the US between age 14 to 49 have genital herpes (CDC, 2012c). Although one might rationalize that a safe sex discussion is better reserved for a biology or health class, the counterargument is that with its cognitive, social, and developmental correlates and consequences, this topic is inherently linked to the science of behavior and mental processes. Some coverage in an Introductory Psychology textbook—even one chart of diseases and risks—may help the college student population, typically emerging adults in the aforementioned at-risk age groups, make educated decisions about their and health and psychological well-being, and arguably, the health and well-being of others.

Further, only about a quarter of the most required Introductory Psychology texts discussed rape, and none discussed sexual harassment. The U.S. Department of Justice National Crime Victimization Survey (2012) showed that nearly a quarter of a million people in the US were raped or sexually assaulted in 2011. That is, as underscored by the Rape, Abuse, and Incest National Network (2013), every two minutes someone in the United States is sexually assaulted. Perhaps even two to three sentences describing the how, why, when, and who of such in a developmental or social chapter could promote awareness and decrease risk, providing an immeasurable service to textbook readers. Similarly, sexual harassment may appear to be a topic that should be dealt with in the workforce, but again, a few lines regarding the inappropriateness of sexual commentary, jokes, and advances in the workforce can promote awareness and responsibility.

Whereas 100% of the books analyzed discussed homosexuality, interestingly, none discussed gay marriage—a hot topic in the United States at the present time. A discussion of such in an Introductory Psychology course would make steps toward cultural literacy and social tolerance, promoting students' ability to recognize and respect diversity—a goal supported by the American Psychological Association (2007).
Given that Goal 8 of the *APA Guidelines for the Undergraduate Psychology Major* (2007) is to

promote student understanding of sociocultural and international diversity (p. 10), and the APA stresses the learning outcome of recognizing and respecting diversity (p.17), we found it surprising that only about half of the books we examined touched upon multicultural sexuality. If textbooks are to mention sexuality at all, we stress the necessity for textbooks to elaborate upon sexuality in this regard.

Of note, the word "sex" is *not* mentioned in the *APA Guidelines for the Undergraduate Psychology Major*, nor is the topic of sexual orientation, even though the Guidelines were reviewed by the APA Committee on Lesbian, Gay, and Bisexual Concerns (p. 6). We respectfully urge our colleagues to include this information in future iterations of the *Guidelines*.

Again, one cannot expect all material from a subdiscipline course to be represented in an introductory course; however, we were interested in learning the extent to which human sexuality is represented in introductory textbooks. Introductory texts aim to impart knowledge of nomoethetic and idiographic findings about the causes, correlates, and consequences of human behavior, but in doing so they can also promote skills and values that, per the aim of the Psychology major curriculum, aid students, particularly emerging adults, in the development of lifelong learning skills and competencies (APA, 2007, p. 3). We therefore argue strongly that knowledge of human sexuality is essential to include therein.

To summarize our analyses, we found that Introductory Psychology textbooks did indeed provide a commendable breadth and depth of human sexuality coverage. However, although the long length of textbooks is a concern to professors (Griggs, Proctor, & Cook, 2004; Griggs et al., 2000), we do offer the above suggestions for additional topics that merit inclusion in future iterations of texts.

Controversy!

The fact remains that some people, even college professors, are just not comfortable discussing human sexuality (see Hyde & DeLamater, 2011, for discussion). As an example, fairly recently, a colleague at a large college in a major city in the northeast US offered to teach a course on the psychology of human sexuality and was met with great resistance—one faculty member actually asked, "Where are you going to teach that, in the gym?" Although Introductory Psychology by definition and purpose is not a Human Sexuality course, by infusing sexual themes into Introductory Psychology courses, we can eliminate some of the embarrassment over human sexuality—a repertoire of behavior and mental processes fundamental to human existence. That is, we are likely making students more comfortable with the causes, correlates, and consequences of human sexuality through direct education or perhaps even via the mechanisms of mere exposure (Zajonc, 1968).

Limitations and Future Directions.

Our analyses focused on books required in Spring 2011. It is possible that some material analyzed above has been or will be added, changed, or subtracted in subsequent editions of the textbooks. It would be interesting to compare coverage of specific sexuality themes in newer iterations of the most required introductory psychology textbooks with the present findings. Further, we could not ascertain how much coverage has grown or changed from previous editions to our targeted books because of a lack of access to these older books. Moreover, it would be prudent to follow the approach of Harbath and colleagues (2011) and check for accuracy of sexual content in introductory psychology texts. Misinformation in this regard can lead to life-altering or even deadly consequences.

Of course, we note that even when information is included in a textbook, this does not guarantee an instructor will cover the material or require its reading for class. We thus urge our teaching colleagues to present at least some of the basics of human sexuality to our Introductory Psychology students to promote the self-understanding, diversity inclusion, and healthy choices that can be informed from exposure to this most fundamental of human behaviors.

There are definitive reasons the 14 books analyzed herein are the most frequently required in the United States. Reviewers have noted their clarity, thoroughness, thoughtfulness of presentation, and insightful applications of psychology to the real world, as well as the texts' self-study tools and vivid imagery that help keep students engaged (see College Board, 2013, for various reviews). The purpose of the present work was not to critique these invaluable resources, but rather, to note existing textbook coverage, and to urge our respected textbook authors, teachers of psychology, and other APA authors (e.g., *Guideline* developers) to promote an even deeper understanding of sexuality within our curriculum, beginning with the introductory course.

Some psychology instructors may argue that it is not our job to teach students "everything." In fact, one textbook author told us quite emphatically that if Introductory Psychology instructors *wanted* more human sexuality coverage in textbooks, it would be there. That being said, but for sexual behavior, humanity would not exist. As long as people are here and wish to remain here, sexuality will be here. Sexual behavior serves not only to propagate the species, but also as a prominent social force. If psychology aims to encourage an understanding of the human psyche, the psychology of sexuality must be a core curricular feature. Most people *are* curious about sexual behavior (Hyde & DeLamater, 2011), and with Introductory Psychology, we have a golden opportunity to impart knowledge of human sexual behavior and mental processes to arm students with the knowledge and power to be compassionate, understanding, safe, inclusive, and themselves.

Acknowledgements

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Please send your questions or comments to Marissa Harrison at mah52@psu.edu.

Book review

By Wandajune Bishop-Towle, Ph.D.

The Myth of Race

By Jefferson Fish

Argo-Navis, 2012. 154 pages. ISBN: 978-0786754366

One of several books by the author on this subject, The Myth of Race looks at the lack of biological evidence for race, as well as the manifestations and impact of the concept of race in a changing culture. With sharp analysis and engaging style, Fish draws on the disciplines of psychology, anthropology, and evolutionary biology, also sharing his own experiences as "white psychologist from the Bronx" married to, and raising a daughter with, an "African-American anthropologist from Brooklyn."

Fish describes how, as humans evolved, our outward appearance (hair texture, skin color, etc.) came to vary gradually as we spread out over the globe, resulting in spectra of traits with different frequencies and combinations depending on location—anthropologist refer to such a process of gradual change as a cline. In contrast to genetic traits, race as a concept varies by language and culture. In Brazil, for example, a person's *tipo* (tr: race), is based on appearance, not ancestry. A woman who might be described as a white brunette in the U.S. might be called *branca* (tr: white), or *morena* (a person with dark, straight-hair, and a deep complexion). There are many more tipos in Brazil than races here; members of the same family (that might be described as simply "mixed race" in the U.S.) can all represent different tipos. In our own language and culture, too, racial categories have been highly mutable, as Fish points out in an incisive (and witty) discussion of racial categories used by the U.S. census from 1790 to the present. Later in the book, Fish criticizes the research on race and IQ in terms of its omission of key environmental variables, apart from the fact that no empirical basis exists for classifying subjects according to "race."

In the chapter "Racial Myths and the Author's Family," Fish reflects on his own experiences in a "mixed race" marriage, using well-chosen anecdotes of family life. In another chapter, entitled "Dreams from My Daughter: Mixed Race Myths," he considers his daughter's "both/and" adaptation to growing up bicultural, alongside that of the better-known of Barack Obama, and discusses other possible outcomes for "third culture kids." The last chapter examines the idea of race as a meme (the term refers to an entity that is culturally transmitted, including such things as popular songs). Fish explores the roots of the race meme in European colonialism, as a justification for slavery, the persistence of the race meme, despite its lack of biological underpinnings, and

the role that the race meme plays in self-concept.

In summary, The Myth of Race rigorously debunks the false notion of biological race, and offers profound insight into the ways that the cultural concept of race effects us all. With its personal reflections and artful prose, it is a pleasure to read. The Myth of Race would make an excellent supplemental text for graduate or undergraduate courses in cross-cultural psychology—one sure to stimulate discussion.

***Wandajune Bishop-Towle, Ph.D.**, is a licensed psychologist, and co-owner of* Seasons of Peace Yoga *in Andover, Massachusetts, where she provides body-oriented psychotherapy. She is a graduate of the clinical psychology program at St. John's University and has a post-doctoral certificate in applied behavior analysis from North Texas University. Her ancestors of recent generations include indigenous Americans, as well as people from Europe and Africa.*

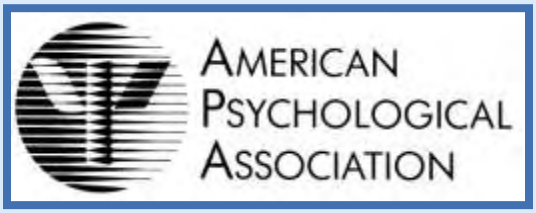

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Elizabeth Yost Hammer, Ph.D.,
Xavier University of Louisiana
AP® Psychology Chief Reader

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Dr. Elizabeth Y. Hammer *is a Kellogg Professor in Teaching and the Director of the Center for the Advancement of Teaching at Xavier University in NOLA. She is an APA Division 2 Fellow.*

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Students who master the material can take a specialized **AP Exam** to earn college credits. Each college/university sets its own guidelines for credit acceptance. The AP Psychology Exam consists of a multiple-choice section and a free-response (essay) section. (Above, Dr. Liz Hammer explains how the free-response section is scored.) Each subject's AP Exam is developed by content experts, including college and high school Development Committee members, the Chief Reader, and Educational Testing Service (ETS) assessment specialists.

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Thank you to Biggie Takooshian, most definitely a "good luck" cat!

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Research Articles
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Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.

Specifically, please pay attention to the following:

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- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

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SUBMISSION DEADLINES
International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 3,000 words (negotiable) and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

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Presidential Column

John D. Hogan, PhD
President, Division 52

I'm writing this column a day after returning from the annual APA Convention which was held this year in Washington, DC. I had the pleasure of meeting many of our members there, but I realize that other members could not attend. I want to take this opportunity to review some of the highlights of the meeting for everyone.

Board Meeting. We began with a four hour Board meeting on Wednesday, August 3, a day before the official opening of the Convention. Our officers and committee chairs had a chance to bring us up to date on all of their activities. Michael Stevens, our Treasurer, reported on our financial status. While our approach to division investments has been somewhat conservative, the volatile stock market has demonstrated that our approach is likely the wise one. Michael has been doing a wonderful job of overseeing our finances during his term as treasurer, and we are very grateful for his service. He will be succeeded in 2012 by Susan Nolan.

At the recommendation of Janet Sigal, the Board voted on and unanimously approved the creation of a new award for Early Career Psychologists (ECPs). We still need to work out the details but we hope the award will not only recognize the fine work of some of our younger members but also encourage other young members to join the division. Neal Rubin, our president-elect, has proposed a "heritage mentoring project" through which younger members will be paired with more senior members and encouraged to prepare biographical articles on outstanding international psychologists, both living and dead, for publication in the *International Psychology Bulletin.*

Joy Rice, a member-at-large of the division, handled all of the details regarding our recent member-approved change in the bylaws. The revision created a voting position on the Board for a student representative and designates one of the member-at-large positions for ECPs. During the Board meeting Joy was presented with the Denmark/Reuder Award which recognizes her great contributions to the division, particularly her work with mentoring and women's issues. Joy is a former president of the division and a former chair of CIRP. She co-authored the 2004 APA Resolution on Cultural and Gender Awareness in International Psychology.

Judith Gibbons, the founding editor of our new journal *International Perspectives in Psychology: Research, Consultation, Practice* brought us up-to-date on the journal which will publish its first issue in Spring, 2012. Judy has received more than 70 manuscripts, most of which are in the process of being reviewed. The board for the journal consists of 43 scholars with primary affiliations in 32 countries. Judy scheduled several sessions during the convention to advertise the journal and encouraged us all to get the word out.

Opening Ceremonies. The opening ceremonies for the convention were a particular treat because they honored one of the founding members of the division, Florence L. Denmark. Melba Vasquez, the current APA president, presented Florence with an award for "Lifetime Contributions to Psychology," APA's highest honor. Florence has been involved in all aspects of the division since its founding, including serving a term as president. In 1980, she was also president of APA. We recognized Florence during the award ceremonies in our suite and thanked her for all that she has done for the division and for many of us individually.

Division Programs. Senel Poyrazli and Mark Terjesen were co-chairs of the program for this year, with Senel focusing primarily on the "regular" APA program and Mark focusing on the suite programs. By all accounts, the programs were successful in every way, with scholarly and provocative presentations, lively conversation, and good attendance. The management of the program is often the hardest part of any convention and we are very grateful for Senel and Mark for their good work. It seems likely that next year, we will be allotted even fewer program hours by APA as there will be an across-the-board revision in division hours. All the more reason, it seems to me, for us to focus on the excellent suite programs that we have developed in the past. They often provide a greater opportunity for presenters and fellow psychologists to share information. This year we also used our suite to present many of our division awards -- which are listed elsewhere in the International Psychology Bulletin -- and to sponsor a breakfast for our new fellows.

Business Meeting. As usual, we held our business meeting on Saturday morning of the convention. It was a good opportunity to meet many of our members and to hear brief reports from our officers and committee chairs. Neal Rubin, our president-elect, had the last word at the business meeting. He outlined some of his plans for next year, including the

strong possibility of our having a joint mid-winter meeting in February, 2012, with the Society for Cross-Cultural Research in Las Vegas. Toward the end of the meeting, I presented presidential certificates to Lynette Bikos, Senel Poyrazli, Mark Terjesen, and Michael Stevens for their many and varied contributions to the division.

I can't end a discussion of the meeting without thanking Ayse Ciftci for her wonderful efforts to keep us organized and on track, Harold Takooshian for all of the invaluable "behind the scenes" work that he does, Rivka and Michael Meir for their sumptuous "catering service," and Rivka (again!) and Artemis Pipinelli for making such an effort to recruit new members during the meeting.

As you can see, it was a wonderful convention! In my effort to be brief, I've left many important contributors off this list. But I send my great thanks to all the officers and committee chairs for their contributions to the continued success of our division. I'm grateful to you all!

John D. Hogan, PhD
Professor, Dept. of Psychology
St. John's University
Queens, NY 11439

Forthcoming in the Fall Issue of International Psychology Bulletin Scenes from the APA Convention

If you would like to take a sneak peak at APA photos, they appear at www.picasaweb.com/takoosh courtesy of Harold Takooshian.

D52@WPA 2011

Amongst the 2200 attendees, 35 major addresses, and 21 poster sessions, *International Psychology* was well-represented at the 91st Annual Convention of the Western Psychological Association (April 28 – May 1, 2011). In addition to a poster session with 50 posters having international content, there were 17.5 hours of symposia and papers.

Among the major addresses, Gaithri Fernando, Ph.D., of California State University, Los Angeles spoke on intimate partner violence as a global mental health priority. Additionally, Michael Harris Bond, Ph.D., of Hong Kong Polytechnic University gave an address titled, *Unweaving the Rainbow of Culture for Psychology.*

D52 was actively promoted at the convention. Division members and student affiliates distributed business cards, promotional stickers, and membership applications, encouraging internationally focused presenters and attendees to visit the division's website and join. The promotional stickers were designed by clinical psychology doctoral student Kim Huynh, M.A., Seattle Pacific University.

After Saturday's programming, D52 members joined the International Council of Psychologists at the Bonaventure Brewing Company in downtown Los Angeles for dinner and conversation. The event was arranged by Tara Pir, Ph.D.

The 92nd Annual Convention of the Western Psychological Association will be held in San Francisco-Burlingame, April 26 – 29, 2012. If you are interested in presenting as part of the international program, please use the WPA Call-for-Paper submission process and select *International Psychology* from one of the "topic" areas listed within the on-line submission process. Instructions for on-line submission can be found at the WPA website (http://www.westernpsych.org/convention/index.cfm).

Respectfully submitted,

Lynette H. Bikos, Ph.D.
D52 Western Region Outreach Chair
Associate Professor of Clinical Psychology & Director of Research
Seattle Pacific University

Steven R. Lopez, from the University of Southern California chaired the symposium, Four Research Reports from a Summer Research Training Program on Latino Mental Health in Puebla, Mexico.

Doctoral students from Seattle Pacific University present results of their longitudinal assessment of international immersion learning experiences during the international poster session.

Faculty and graduate students from the International Immersion learning Experiences in Higher Education symposium discussed research results and best practices.

Jason Platt, Ph.D., Linna Wang, Ph.D., and Tatiana Glebova, Ph.D., challenged participants to think about concepts such as patriotism, liberation, and the validity of psychologies.

Members of the International Council of Psychologists congregate before the ICP/D52 joint dinner.

The symposium, Threats to Family Wellness in Immigrant Communities: Hopes and Challenges, was chaired by Marcel Soriano, Ph.D., from California State University, Los Angeles.

Tara Pir, Ph.D., and Lynette Bikos, Ph.D., preside over the ICP/D52 joint dinner at Bonaventure Brewing Company in downtown Los Angeles.

Graduate students converse about international interests at the ICP/D52 joint dinner.

Sherri McCarthy, Ph.D., Tara Pir, Ph.D., and Lynette Bikos, Ph.D., converse before the ICP/D52 gathering.

Attendees at the ICP/D52 dinner place their orders.

ICP and WPA members, graduate psychology students, and their guests gather for a picture at the ICP/WPA conversation and dinner.

APA Division 52 'Ursula Gielen Global Psychology Book Award' (2012)

The mission of Division 52 is to advance psychology internationally as a science and profession, and through education and advocacy. In support of this mission, the Ursula Gielen Global Psychology Book Award is presented to the author(s) or editor(s) of a recent book that makes the greatest contribution to psychology as an international discipline and profession, or more specifically, the degree to which the book adds to our understanding of global phenomena and problems from a psychological point of view. Examples include psychological interventions at the micro- and macro- levels, multinational organizations, questions of mental health, pedagogy, peace and war, gender roles, contributions of indigenous psychologies to global psychology, textbooks that integrate theory, research and practice from around the globe, edited volumes integrating contributions from scholars around the world, and overviews of international and global psychology.

Inclusions and Exclusions

Nominations may include authored or edited volumes in any language. All submissions must be accompanied by a 2-page letter in English making a case for the book's potential contribution to global psychology. Copyright must be 2010. Nominations may not include fiction and biographies.

Specifics of the Award

Winners will be announced in early 2012, presented with a certificate, and invited to give an address at the August APA 2012 Convention in Orlando, FL. They will receive one full payment of the convention fee and a stipend of $500 to help fund their attendance at the convention.

Criteria

In judging the contribution of each book, the following set of guidelines will be used:

1. How creative and novel are the ideas expressed in the book?
2. How large and significant a contribution does the book make to psychology as a global discipline and profession?
3. Are the book's contents international or global in nature?
4. Is the book scientifically rigorous and logically sound? Are its theoretical bases well supported and translatable into sound and ethical practice?
5. What is the literary quality of the work? Is it interestingly and well written? Is the audience for whom it is written explicitly stated and does it reach that audience?
6. Does the book maintain a clear focus on psychology as a science and practice?

Procedures

All nominations, accompanied by the 2-page letter, and three copies of the book, must be made by October 1, 2011, and sent to:

Renée Goodstein, Ph.D.
Chair, Ursula Gielen Global Psychology Book Award
Psychology Department
St. Francis College
180 Remsen Street
Brooklyn, NY 11201
USA
(718) 489-5437
e-mail: rgoodstein@stfranciscollege.edu

About Ursula Gielen:

Ursula Gielen (1916-1997, Germany) was vitally interested in the well-being of indigenous, persecuted, and poor people around the world, with a special emphasis on women and children. Her legacy and commitment to international concerns and human welfare continues through her children: Ute Seibold, a former foreign language secretary in Switzerland; Uwe Gielen, an international psychologist in the United States; Odina Diephaus, a former interpreter with the European Parliament in Belgium and France; and Anka Gielen, a counseling psychologist in Germany.

Committee Members:

Renée Goodstein, Ph.D., Chair
Florence L. Denmark, Ph.D.
Juris G. Draguns, Ph.D.
Michael J. Stevens, Ph.D.
Harold Takooshian, Ph.D.
Uwe P. Gielen, Ph.D. (ex officio)

Ursula Gielen Book Award Winners

2008: *Families Across Cultures: A 30-Nation Psychological Study*. Editors: James Georgas (University of Athens, Greece), John W. Berry (Queen's University, Canada), Fons J. R. van de Vijver (Katholieke Universiteit Brabant, The Netherlands), Cigdem Kagitcibasi (Koc University, Turkey), and Ype H. Poortinga (Katholieke Universiteit Brabant, The Netherlands).

2009: *Culture and Leadership Across the World: The GLOBE Book of In-Depth Studies of 25 Societies*. Editors: Jagdeep S. Chhokar (Indian Institute of Management, India), Felix C. Brodbeck (Aston University, UK) and Robert J. House (University of Pennsylvania, USA).

2011: *International Handbook of Cross-Cultural Counseling: Cultural Assumptions and Practices Worldwide*. Editors: Lawrence H. Gerstein (Ball State University, USA), P. Paul Heppner (University of Missouri, USA), Stefanía Ægisdóttir (Ball State University, USA), Seung-Ming Alvin Leung (The Chinese University of Hong Kong), and Kathryn L. Norsworthy (Rollins College, USA).

LEAVING A LEGACY

TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

New Fellows in International Psychology: The Class of 2011

In 2011, eleven psychologists were elected as Fellows of the Division of International Psychology, based on their "unusual and outstanding contributions to international psychology." Six of these were elected as new Fellows of APA, and five current APA fellows were elected by the Division. APA fellows represent about 5% of all APA members. According to APA, "Fellow status requires that a person's work has had a national impact on the field of psychology beyond a local, state, or regional level. A high level of competence or steady and continuing contributions are not sufficient to warrant Fellow status. National impact must be demonstrated." The three-person D52 fellows committee for 2011 is **Kurt F. Geisinger, Senel Poyrazli, Harold Takooshian** (Chair).

William Roberts Herkelrath, PhD,
Dean (ret.), College of Social and Behavioral Sciences, Northwest University, Kirkland, WA

Samvel Sergei Jeshmaridian, PhD,
Professor and Chair, Department of Human Services, Technical Careers Institute, New York City

Tahereh Pirhekayaty, PhD, (Tara Pir, PhD),
Founder and CEO of the Institute for Multicultural Counseling & Education Services, Inc., Los Angeles CA

Grant Jewell Martinez Rich, PhD,
Assistant Professor, University of Alaska Southeast, Juneau, and the Editor of the APA *International Psychology Bulletin*

Mihaela Robila, PhD,
Associate Professor of Family Studies, CUNY Queens College

Nancy Marie Sidun, PsyD, ABPP, ATR,
Chief/ Supervising Clinical Psychologist and Director of Clinical Training, Kaiser Permanente-Hawaii

Armand R. Cerbone, PhD, ABPP,
Private Practice, Chicago, Illinois

Itamar Gati, PhD,
Samuel and Esther Melton Professor, Departments of Education and Psychology, Hebrew University of Jerusalem

Lawrence H. Gerstein, PhD,
Professor of psychology, and Director of the doctoral program in counseling psychology, and Center for Peace and Conflict Studies at Ball State University

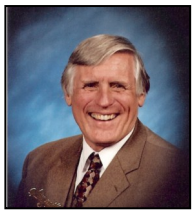

J. Jeffries McWhirter, PhD, ABPP,
Professor Emeritus of Psychology in Education, Arizona State University

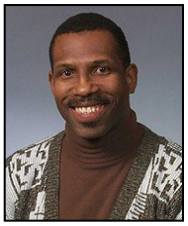

Frank C. Worrell, PhD,
Professor and Associate Dean, Academic Affairs, Graduate School of Education, UC Berkeley

Additional Biographies for the Six "Initial" APA Fellows in 2011

By Harold Takooshian

Samvel S. Jeshmaridian, PhD

Samvel Jeshmaridian's outstanding contribution to international psychology is as a multilingual scholar, teacher and researcher who has emerged as a go-to expert within APA and its International Division--to bridge U.S. psychology with the indigenous psychologies of Europe and Asia. Since his first psychology degree in 1974 in the USSR, his career has transitioned thrice: (1) first as a unit chief within the prestigious USSR Academy of Sciences during the Soviet era of the 1980s; (2) after 1991, in the post-Soviet era, he segued to consulting work in the beleaguered Republic of Armenia; (3) since 2005, he made the challenging transition to psychology in the USA, where he is now Professor and Department Chair at Technical Careers Institute (TCI) in New York City.

Dr. Jeshmaridian is long regarded as an authority in cross-cultural psychology, whose cross-national research has been supported by a series of competitive awards—an IREX Scholar (1993-4), Open Society Scholar (1994), Senior Fulbright to the USA (1996-97), and George Kennan Scholar (2005). As a researcher, he authored 90 publications in 5 languages, and offered 65 presentations at international and other conferences—about half of these on cross-cultural and international themes. As a teacher, he is a popular lecturer who has taught at 7 institutions in the USA and overseas, using his multilingual skills to develop syllabi that are noted for their cross-national concepts and research. As our APA International Division works to internationalize psychology, Dr. Jeshmaridian has been invaluable—as a generous consultant and reviewer.

William R. Herkelrath, EdD

William Herkelrath completed his MA in pastoral counseling in 1977 at Gordon Conwell Seminary, and his EdD in counseling psychology in 1982 at Boston University, with later certification from Harvard (2006). Over the past 25 years, his two outstanding international contributions have been his (1) skilled cross-national work to design culturally relevant programs for health care for the poor, and (2) innovative blend of photography with psychology to promote social justice.

From 1978-now, Dr. Herkelrath has held a variety of positions in six institutions as a therapist, professor, department chair and, since 2007, Dean of Social and Behavioral Sciences at Northwest University in Kirkland, WA. The 15 college and graduate courses he has developed are known as a model for integrating two strong themes of culture and social justice. Since 1999, he has organized outreaches to meet the needs of the poor in Brazil (with Evangemed Ministries, Project Brazil), then in India since 2008 (with Mercy Hospital, Darjeeling University)—training counselors and designing delivery systems to aid abused children and adolescents in urban Calcutta and rural villages in India.

In 2002 Dr. Herkelrath founded the Bainbridge Institute, with the innovative mission to promote social justice through photography and multi-media. In his travels across six continents, he has taken powerful documentary photographs of diverse communities, and used these to promote social justice themes, through conferences and exhibitions with the APA, schools, and museums world-wide. With other like-minded psychologist-photographers, he recently formed "Psychologists in Focus" to advance this unusual approach to psychology advocacy, to promote social justice cross-nationally.

Tahereh Pirhekayaty, PhD

After completing her BA (1970) and MA (1977) in Tehran, Dr. Tara Pir completed her PhD in clinical psychology in 1985 at Alliant International University, with later certifications in psychology, CBT, behavioral medicine. Since 1985, she has developed a stellar career as a multilingual teacher, researcher, administrator, and award-winning expert in the areas of multicultural counseling (within a nation) and cross-cultural counseling (across nations).

Since 1989, Dr. Pir has been the founder and CEO of IMCES—the Institute for Multicultural Counseling and Education Services--her pioneering international center based in Los Angeles. With government and private funding, IMCES has emerged as a model for many other organizations, on how to apply her PEI (Prevention and Early Intervention) approach to the multiple needs of ethnic communities that eschew counseling—working with courts, police, health care and family centers. Dr. Pir has become a "go-to" expert on this, with over 20 elected or appointed leadership roles in government (Los Angeles Dept. of Mental Health) and psychology (international Council of Psychologists). Her IMCES is now a registered NGO with the United Nations, and offers APA-approved internships. Dr. Pir has been an organizer and keynote speaker at global conferences in eight nations, and recently published her approach to multi-cultural counseling in the *Counseling Psychology Quarterly* (2009). She has been President of the Iranian-American Psychological Association (2005-2007), a regular contributor on mental health topics for the Farsi magazine Janavan, and producer of a federally-funded PSA on this topic. One of Dr. Pir's colleagues noted that he has followed her work for 25 years, and "can think of few people who qualify as clearly" for APA fellow status.

Grant Rich, PhD, NCTMB

Grant Rich completed his interdisciplinary PhD in psychology: human development in 2001 at the University of Chicago, combining anthropology and psychology. Since then he quickly immersed in pioneering work in cross-cultural psychology--as an innovative teacher, prolific author and editor, crossing the fields of psychology, anthropology, and regional studies.

Among his diverse array of 120 publications from 2001-2009--articles, chapters, book reviews, and essays--five publications stand out: (1,2) His much-cited special issues on "positive psychology" in the *Journal of Humanistic Psychology* (2001) and *Journal of Youth and Adolescence* (2003); (3,4) his two special issues for the American Anthropological Association, on "Consciousness and the body" (2000), and "Altered states of consciousness" (2001); and most of all, (5) his volume on "*Massage therapy – The evidence for practice*" (Elsevier, 2002), which received high praise from reviewers, including Harvard Medical School, as a unique data-based review of the field of massage. Given the unusual breadth of his expertise in cross-cultural psychology, he is a much-sought reviewer for over 20 journals, book publishers, and professional associations.

As a teacher, Dr. Rich has taught at several institutions, from Maine to Alaska. He has used his cross-cultural work in many nations (including NEH-funded work on the "Tropical Atlantic" and on "Maya Worlds" in Central America), to develop syllabi for five new cross-cultural courses that meld psychology with anthropology and cultural studies.

In his service, Dr. Rich has been generous as a volunteer to his community in the USA and overseas, and to his profession. Based on this fine work in D52, he was unanimously selected for a three-year term for the key post as the incoming Editor of the Division's International Psychology Bulletin in 2010, a role he has performed with distinction.

Mihaela Robila, PhD, CFLE

Mihaela Robila completed her BA in Bucharest in 1997, PhD in Syracuse in 2002, and two postdocs in 2002-2003 at Tufts University and Tulane Medical School. In fewer than 10 years, she has emerged with an award-winning career as a multilingual teacher, researcher, and international authority on the increasingly important topic of immigrant families.

Her work with immigrant families is outstanding at several turns: (a) her two pioneering volumes on "Families in Eastern Europe" (2004) and "Eastern European Immigrant Families" (2009); (b) 22 oft-cited publications on this topic, 15 of these in refereed journals; (c) 60+ research presentations, many of these at global conferences; (d) service as a reviewer for 12 journals and on the editorial board of three others; (e) grant reviewer for several groups, including NSF and NIH; (f) 12 research/teaching grants, including major funding from the U.S. State Department and the Spencer Foundation.

Dr. Robila is now sought out as a consultant on immigration at the highest level, by United Nations and U.S. government policy-makers. Her rare combination of clinical training and expertise on the psychology of immigration promises to have an increasing and positive impact on data-based immigration policies.

Nancy M. Sidun, PsyD, ABPP, ATR

Nancy Sidun's contributions to international psychology are impressively diverse. Since completing her doctorate in 1986 at Argosy-Illinois, she served at six institutions as a researcher, teacher, practitioner, consultant, department head, and even interim President (of Argosy University-Honolulu in 2003). Her 24 years as a clinical director of multicultural programs in Chicago, then Hawaii, led her to develop leadership roles as a go-to expert on a few related and pressing cross-cultural issues: increasing diversity in clinical training, international adoptions, child sexual abuse, and now human trafficking.

Dr. Sidun effectively combines multiple leadership roles to address these cultural issues above: (a) As a researcher, she offered 51 conference presentations (2001-2010), and 9 publications (1997-2010), 8 of these as first author. (b) As a teacher who headed 4 graduate programs, she pioneered innovative curricula to increase cultural diversity and address emerging issues in sexual abuse and human trafficking. (c) As an administrator, her many roles include Chair of the APA Committee on Women in Psychology (2009-2012), co-founder of the D52 Task Force on Human Trafficking. (d) As an expert consultant on cultural issues, she worked with several policy groups in Illinois, Samoa, China (the Half the Sky Foundation, since 2001), Hawaii (for Governor Linda Lingle in 2007-08), and chaired 4 APA site visits (2006-07).

Congratulations Fellows!

International Psychology Awards for 2011

Since its origin in 1997, the APA Division of International Psychology has presented a growing number of awards for outstanding cross-cultural and international work. A list of past awardees appears at www.internationalpsychology.net. For 2011, five committees of independent reviewers carefully selected honorees, who received their awards at the 119th APA meetings in Washington DC in August of 2011. **

Outstanding International Psychologist (in USA)

Michael J. Stevens, PhD, DHC,
Illinois State University, & The Lucian Blaga University of Sibiu

Outstanding International Psychologist (outside USA)

Narasappa Kumaraswamy, PhD,
University Malaysia Sabah

Florence L. Denmark/Mary E. Reuder Gender Award

Joy K. Rice, PhD,
University of Wisconsin-Madison

Henry P. David International Mentor Award

Lawrence H. Gerstein, PhD,
Ball State University

Tahereh Pirhekayaty, PhD, (Tara Pir, PhD),
IMCES Institute, Los Angeles CA

Harold Takooshian, PhD,
Fordham University

Ursula Gielen International Book Award

Lawrence H. Gerstein, PhD,
Ball State University,

P. Puncky Heppner, PhD,
University of Missouri-Columbia,

Stefanía Ægisdóttir, PhD,
Ball State University,

Seung-Ming Alvin Leung, PhD,
Chinese University of Hong Kong

Kathryn L. Norsworthy, PhD,
Rollins College

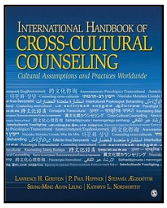

International Student Research Award

Elena S. Yakunina, MA,
University of Akron

R. Eric Lewandowski, MS
Teachers College, Columbia University,

Joseph C.S. Siu, MCS, MSW,
California School of Professional Psychology, Alliant International University-Hong Kong

*** The Division is grateful to all of the many independent judges who shared their expertise, and the chairs of these five international award committees: **Danny Wedding** (outstanding psychologists), **Joan C. Chrisler** (gender), **Renee Goodstein** (book), **Mercedes A. McCormick** (mentors), **Sheila J. Henderson** (student research).*

Psychology in 70 Languages

Sielkunde 1 PSIKOLOGJI 2 የሥነ ፡ ልቡና ፡ ትምህርት 3 علم النفس 4

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Sikolohiya 21 Psykologi 22 Psychologie 23 Psychologie 24

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Psikologi 33 Síceolaíocht 34 Psicologia 35 心理學 36

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The International Division of the American Psychological Association salutes the International Council of Psychologists on its 70 years of service to psychology, 1941-2011.

Credits to: *Carolyn Bauer, Rivka Bertisch Meir, Samvel Jeshmaridian, Ann O'Roark, Grant Rich, Harold Takooshian, and Richard Velayo*

International Liaison Column

This debuts a new column that highlights the Division's liaisons. The purpose is to encourage professionals and students to belong as a liaison without the need to become a full APA member, receive our bulletin, and have the possibility to interact with psychologists from all over the world. It is anticipated that three new liaisons will be featured in each issue of the International Psychology Bulletin.

International psychology liaisons now link our Division 52 with psychology representatives in 87 nations. A complete PDF roster appears at www.itopwebsite.com/moreIP/International_Liaisons.html. Contact me for any details or revisions, **Rivka Bertisch Meir, Ph.D., M.P.H.,** Chairperson, International Liaison, winsuccess@aol.com.

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2. **ANGOLA**, Vera Matos, Ph.D., vermatos@gmail.com
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   Khachatur Gasparyan, gasparyk@childpsych.columbia.edu
4. **ARGENTINA**, Lic. Cristina V. Rauch, cvrauch@fibertel.com.ar
   Lic. Melina Konfederak, lic.melina.konfederak@hotmail.com
   Celia Hehn, celihehn@msn.com
   Dr. Hugo Klappenbach, hklappen@unsl.edu.ar
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   Lillian Nejad, lnejad@yahoo.com
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Peer-Reviewed Research Article

Trust in Social Institutions: Comparisons between the Chinese, American, and Canadian Populations

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This research explored predictions derived from cross-cultural research regarding the amount of trust citizens of one country have in other countries. Participants from Canada, China, and the United States were asked the degree to which they trusted institutions from their home country and other countries. Results were largely consistent with cross-cultural research, such that the Chinese trusted their own country but did not trust the Western countries; and Canadians trusted Americans, and such trust was reciprocated to Canadians from Americans. Findings are discussed relative to cross-cultural theories and social identity theory.

Key Words: Trust, Chinese, Canadian, American, institutions, cross-cultural

Given the importance of trust to international diplomacy, travel, and commerce, whether citizens of one country are trusted by others is an important issue--trust was a central issue during the Cold War (Kydd, 2005), and it still plays a critical role today in nearly every aspect of international relations (e.g., Li, 2007). However, because individual countries differ in their values and philosophy, the manner in which citizens of different countries build trusting relationships on a national or international basis may heavily depend on each country's specific psychology (Doney, Cannon, & Mullen, 1998).

Trust is defined as the "assurance of not being exploited" during a social interaction (Kelley & Thibaut, 1978, p. 232). Trust is critical for the fulfillment of obligations of a social exchange, and as such, as critical for the development of successful social relations (Blau, 1964). In international relations, trust in other nations is vital to successful international relations (Larson, 1997), particularly given the interdependence of the modern world (Doney et al., 1998). Trust in other nations reduces conflicts (Anderson & Narus, 1990) and cultivates successful strategic alliances (Browning, Beyer, & Shetler, 1995). At home, trust in other nations affects opinion about international relations: trust in other nations affects opinions regarding the presence of military forces in other nations (Brewer, Gross, Aday, & Willnat, 2004), voting behavior (Aldrich, Sullivan, & Borgida, 1989), and even overall foreign policy (Page & Shapiro, 1992). Conversely, trust in one's own nation similarly affects international relations (e.g., Lühiste, 2006).

The presence or absence of trust for another nation not only manifests itself in trust between governments (Larson, 1997), but also between the people and institutions. Numerous theorists have posited that it is the nation's culture that defines the peoples' propensity to trust other countries or peoples. Fukuyama (1995), for example, argued that the trust within a society is shaped by that society's culture, whereas Doney et al. (1998) similarly argued that a nation's culture influences how trust is developed in one country versus another (see also, Newton, 2001).

The nationality of the truster is one of the factors that affect trust in others, just like other demographic and socioeconomic variables, including gender, age, socioeconomic status (Niu & Rosenthal, 2009). One variable important for understanding whether citizens of one country will trust another is individualism versus collectivism (Hofstede, 1991; Triandis, 1995). According to Hofstede (1991), individualism is defined as a society's orientation that the individual is a unique entity with loose connections to the group. Individualistic cultures tend to be found in Western cultures (e.g., United Kingdom, United States, Canada; Hofstede, 2001). Alternatively, collectivism stresses an individual's place in a structured relational network and the interpersonal bonds within the network. Collectivistic cultures tend to be found in Eastern culture (e.g., Japan, China, South Korea; Hofstede,

2001). In support of this distinction, research indicates that collectivistic cultures depict ingroups as a complex network of interrelated individual members (Ho, 1993; Hwang, 1999; Lebra, 1976), but individualistic cultures emphasize the group's categorical, depersonalized nature (Prentice, Miller, & Lightdale, 1994; Seeley, Gardner, Pennington, & Gabriel, 2003).

Such cultural orientations indicate different foundations for trusting others. Yuki and colleagues (Yuki, 2003; Yuki, Maddux, Brewer, & Takemura, 2005) posit that for individualistic cultures, trust is heavily grounded in extant distinctions between categories between the ingroup and outgroup, in which trust is given to ingroup members but not outgroup members. For collectivistic cultures, however, trust is affected strongly by relationship networks. In this way, trust is greatest toward those with whom one shares a direct or indirect personal connection, independent of group categorization. There is considerable evidence to support such distinctions. First, ingroup bias based on categorical distinctions is stronger in individualistic societies than in collectivistic societies (Bond & Hewstone, 1988; Bond, Hewstone, Wan, & Chiu, 1985; Heine & Lehman, 1997). Second, in individualistic cultures, people who share one's group membership are perceived to be trustworthy (Yamagishi & Kiyonari, 2000), and trusting behavior is directed toward members of one's group more than the outgroup (Tanis & Postmes, 2005). Third, Yuki et al. (2005) found that in collectivistic cultures, trust was influenced by the presence of a relational connection with an outgroup target, but not by perceived categorical information. Fourth, Hu (2007) found that in collectivistic cultures, trust in business settings is grounded in adherence to social norms and obligations, whereas in individualistic cultures, trust is more heavily dependent on individuals' competence and overall performance (see also McAllister, 1995).

Present Study

To test cultural differences in trust propensity in different countries, trust data were collected from three countries: the United States (an individualistic country; Hofstede, 2001), Canada (an individualistic country), and China (a collectivistic country). To measure trust across different cultures-- but to maintain the same definition of trust-- Hardin's conceptualization of social trust was utilized (Hardin, 2001, 2002), which defined trust as the public's belief that institution will do what is "right." Four social subsystems (academic institutions, businesses and companies, the law and legal system, and mass media institutions) were selected as the focus of trust, and participants in the three countries were asked their degree of trust for the three nations of interest.

Predictions

With respect to trust for Canadians and Americans, trust was expected to follow categorical information regarding participants' own country relative to other countries. Interestingly, Americans see a strong differentiation between themselves and Canadians (e.g., Davies, Steele, & Markus, 2008); but for Canadians, such strong categorical differentiation does not always hold. The permeation of American media, culture, arts, and history has led to a minimization and attenuation of categorical differentiation for Canadians, such that strong differentiation occurs primarily under conditions of threat (e.g., Lalonde, 2002). As such, it was hypothesized that Americans will not trust Canadian institutions, but it was expected Canadians would trust American institutions.

With respect to China, the degree of trust was hypothesized to be dependent on the degree and presence of a relational network. An era of isolationism has left the Chinese people's personal connectedness with Western cultures at a minimum; and as a consequence, it has reduced international travel, contact, and engagement with Western cultures, in particular (Brown, 1976; Levine, 1989; Yahuda, 1984). Despite growing interconnectedness with the West over the past 20 years, there are still substantial hurdles to leap before increased interdependence and strong interpersonal bonds are pervasive (Peng, 2003; Yeung, 2006). As a result, it was expected trust in China would be high for their own nation (where personal connections are present), but would be lower for the United States and Canada, in which relational networks are at a minimum.

Method

Participants

There were 369 individuals (185 men, 184 women) recruited to participate in the study. Participants' ages ranged from 18 years to 75 years old, with an average age of 33.44 (SD = 5.32). Participants were recruited in Canada (greater Ottawa area, Province of Ontario), China (Kunming city in Yunnan province) and the United States (greater Boston area, State of Massachusetts). Only those participants who stated that they were born in the Canada, China, or United States, respectively, were used in the analyses. The sample was nearly equally divided between three countries: 127 were recruited in the United States (M_{age} = 34.46), 122 from Canada (M_{age} = 32.05), and 120 from China (M_{age} = 33.54).

Procedure

As part of a larger study on individuals' attitudes toward international relations, researchers approached potential participants in one of several public places (e.g., cafeteria, café, tea-shop, public library). To assess participants' trust in various social institutions, participants were asked to estimate their belief that different social institutions (academic institution, business/company, law and legal institution, and mass media) would "do what is right regarding an international issue." Participants indicated their response on a 1 (*strongly distrust*) to 7 (*strongly trust*) scale. Participants completed these questions for three target countries: the United States, China, and Canada. To avoid order effects, the order in which the different target countries were presented to participants was counterbalanced. After completing these questionnaires, participants were thanked and dismissed.

Results

Given the high correlation among the four social institu-

tions (r's ≥ .80), the analysis began by averaging the scores to generate one score for each target nation. Next, to ensure that trust scores could be compared across countries, responses within each country were standardized (van de Vijver & Leung, 1997; Leung & Bond, 1989). T scores were computed using the equation, T = (X − M) / S, in which X was the score to be standardized, and M and S were the mean and standard deviation of the corresponding country. Standardization of the scores eliminated cross-country differences in grand means and standard deviations eliminated unwanted sources of error, such as methodological artifacts (i.e., response sets; van de Vijver & Leung, 1997).

Reliability

The reliability of the trust assessments using standardized scores across the three host countries was acceptable: Beside one value (American's trust in American institutions, α = .62) all alphas ranged between .71 and .84.

International Trust

The data for trust were subjected to a 3 (host nation) × 3 (target nation) ANOVA. Figure 1 illustrates the means for trust for host nation by target nation. Higher standardized scores indicate a greater level of trust. The main effect for host nation was significant, $F(2, 366) = 38.57$, $p < .05$; but the main effect for target nation was not, $F(2, 732) = 0.01$, $p = .99$. The expected Host Nation × Target Nation interaction was significant, $F(4, 732) = 40.11$, $p < .05$, and was explored using contrasts by host nation.

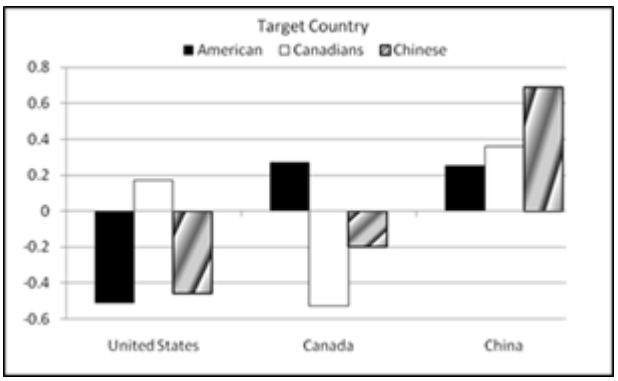

Figure 1. Patterns of within-nation standardized trust in social institutions as a function of target and host country.

China. The simple effect for target nation was significant, $F(2, 238) = 11.42$, $p < .05$. Orthogonal contrasts revealed that Chinese participants trusted Chinese institutions ($M = 0.69$, $SD = 0.69$) more than the combination of American and Canadian institutions, $F(1, 119) = 46.64$, $p < .05$. Chinese participants did not differ in their trust level between American ($M = 0.25$, $SD = 0.96$) and Canadian ($M = 0.36$, $SD = 0.94$) institutions, $F(1, 119) = 1.71$, $p = .19$.

United States. The simple effect for target nation was significant, $F(2, 250) = 35.19$, $p < .05$. Orthogonal contrasts revealed that Americans trusted Canadian institutions ($M = 0.17$, $SD = 0.79$) more than the combination of Chinese and American institutions, $F(1, 125) = 65.19$, $p < .05$. The second orthogonal contrast revealed that Americans did not differ in their level of trust for American institutions ($M = -0.51$, $SD = 0.90$) and Chinese institutions ($M = -0.46$, $SD = 0.85$), $F(1, 125) = 0.27$, $p = .60$.

Canada. The simple effect for target nation was significant, $F(2, 244) = 33.41$, $p < .05$. The first orthogonal contrast indicated that Canadians trusted American institutions ($M = 0.27$, $SD = 0.92$) more than a combination of Canadian and Chinese institutions, $F(1, 122) = 58.16$, $p < .05$. The second contrast revealed that Canadians trusted Chinese institutions ($M = -0.20$, $SD = 1.02$) more than Canadian institutions ($M = -0.53$, $SD = 1.02$), $F(2, 122) = 10.62$, $p < .05$.

Discussion

In this research, models of cross-cultural relations were tested to predict patterns of international trust. Trust from the Western countries was consistent with expectations, such that Canadians trusted Americans and Americans trusted Canadians. Alternatively, trust in collectivistic countries also matched expectations, such that the Chinese did not trust either Americans or Canadians, but trusted their home country.

One unexpected finding was that Canadians did not place a great deal of trust in their own country's institutions. Although assessment of trust was not directed toward the state government, evaluations of trust may have had an effect on trust in the non-government circles that were assessed. Polls indicate that a majority of Canadians (59%), more than Americans, felt that central government was not doing enough to address the concerns of the Canadian people (Gallup, 2006). When asked whether the national government could be trusted to deal with domestic problems, Canadian citizens reported a lower belief than did Americans (China was not part of the survey). Although speculative (because China was not part of the Gallup poll), it appears that the lowered trust in Canada by Canadians may have resulted from their own distrust for their national government.

Whereas results were interpreted using cross-cultural models, it is possible to interpret the results using social identity theory. Social identity theory (SIT; Tajfel & Turner, 1979; Turner, 1982) argues that individuals' social identities are derived primarily from their membership in groups. In order to maintain and enhance individual self-esteem, group members are generally motivated to maintain a positive social identity. Tajfel and Turner (1986) proposed that one important technique for maintaining a positive social identity is to favorably compare one's group to relevant outgroups (i.e., positive distinctiveness). Research has indicated that the desire for positive distinctiveness helps limit trust to only those who share a social identity (e.g., Hogg, Abrams, Otten, & Hinkle, 2004, Rotenberg & Cerda, 1994). This motivation for positive distinctiveness indicates that it may be difficult to develop positive relations even during times of cooperation

(Hertel & Kerr, 2001). Whereas it might be tempting to conclude that social identity theory provides a plausible explanation for the findings; the results are mixed. Specifically, whereas Canadians did not trust Canadians and Americans did not trust Americans (which would be predicted from their model), the rest of the predictions were entirely consistent with expectations: Canadian and American trust patterns matched onto social categories (i.e., shared a social identity), and for the Chinese, for whom there is no social identity overlap, they did not trust either the Americans or Canadians.

A final point of interest is the significant interaction between the host nation and target nation. This interaction indicates that the international trust relationships were not necessarily symmetrical and reciprocal as might be expected. Whereas the Chinese do not trust Americans, such distrust was not reciprocated to the same degree by Americans (see also Niu, Xin, & Martins, 2010). Whereas relationships between individuals are commonly reciprocal, the same cannot be said for interactional trust (e.g., Kiyonari, Yamagishi, Cook, & Cheshire, 2006). The most likely explanation for the lowered likelihood of reciprocation between individuals, versus groups, is the perception of groups as inherently untrustworthy (Cohen, Montoya, & Insko, 2006; Wolf et al., 2009).

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From Who Cares to We Care: A review of *Diversity in Mind and in Action*

Chin, J. L. (Ed.). (2009). Diversity in Mind and in Action (Vols. 1-3). Westport, CT: Praeger. ISBN-10:0313347077; ISBN-13:978-0313347078.

Reviewed by Ting Lei, Ph.D.
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Diversity in Mind and in Action is a book in the series of *Praeger Perspectives: Race and Ethnicity in Psychology* published by ABC-CLIO in 2009 and edited by Jean Lau Chin. This book includes three volumes: Volume 1 is titled *Multiple Faces of Identity* and includes ten chapters; Volume 2 is titled *Disparity and Competence*: *Service delivery, education, and employment contexts*, and it includes twelve chapters; and the title for Volume 3 is *Social Justice Matters!: Social, psychological, and political challenges;* it includes eleven chapters.

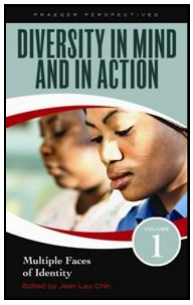

While Volume 1 is mostly focused on what is going on in the individual's mind in terms of identity issues, Volume 2 is more concerned with how our social systems have been treating or mistreating minority people as members of groups, and Volume 3 emphasizes how our systems should, but have not, treated persons of non-normative backgrounds. Philosophically speaking, the transition from Volume 2 to Volume 3 is from an ontological *is* to a deontological *ought.*

After the editor's introduction, Volume 1 starts with a chapter on the multiracial movement in this country. Granted that the authors are a counseling psychologist and a clinical psychologist, they fairly present a sociopolitical background to account for the genesis of the discrepancy between American minorities' self and racial identities. The authors successfully create an impression that American history is short though it is certainly not sweet in terms of racial relations. Another chapter on the topic of identity is written by two Vietnamese-American social and personality psychologists under the auspices of their dissertation advisor, who is of Hispanic descent. Their focus is on bicultural identity integration in a diverse world. Chapters 3, 4, and 5 are more about identification than identity processes, and all three chapters interface with both sex/gender and race/ethnicity issues. Specifically, Chapter 3 discusses how LGBT Asian Americans identify themselves and their ways of coming out in context. Chapter 4 lists current perspectives on interracial marriage and poses challenging questions as well. Chapter 5 addresses some issues confronting women of color in higher education. Chapters 6 and 7 are related to Asian Americans' mental health, with Chapter 6 being contributed by the editor (Jean Chin) herself on the topic of healing narratives. Notwithstanding this fascinating topic, Chin did not conduct an in-depth or thick analysis from the natives' point of view (cf. Geertz, 1973, 1983) or stand on giant Arthur Kleinman's (1989) shoulders to follow the well-established approach of illness narrative analysis that was derived from the same cultural context as the author's. The last three chapters in Volume 1 center on the social and personality psychology of Hispanic and African Americans, such as personal and social selves in the context of migration, with a focus on resilience and protective factors. It should be noted that given the volume's focus on identity, a topic pertaining to the personality and social developmental areas, only two (Chapters 2 and 10) out of ten chapters are authored by personality/social psychologists. All the other contributors are either clinical or counseling psychologists, who come from the editor's close circle of colleagues. A similar circle of close colleagues is going stretch the limit of their scholarship to cover issues discussed in Volumes 2 and 3, as can be seen in the following.

Seven out of the twelve chapters in Volume 2 are on the topic of education and five out of these chapters are authored or co-authored by clinical or counseling psychologists, while the other two chapters have been contributed by a university president (Mildred García) and a sociologist (Melanie Bush). In her chapter García talks about her role as an education administrative leader in navigating diversity, whereas Bush discusses her research findings from a project centered on diversity curriculum reform at the nation's largest urban university (i.e. the City University of New York, which happens to be García's alma mater). Issues of cultural competence in high school are discussed in Chapter 6, empowerment through education and employment is introduced in Chapter 1, and diversity training in educational institutions is a common theme running through chapters 7, 8, and 11. The five chapters that are not directly related to diversity development in schools can be considered as a forum for clinical/counseling psychologists to chat about diversity issues in the workplace or in healthcare settings.

Given the title's emphasis on issues of social justice as well as social, psychological, and political changes, Volume 3 has all the leading authors in the related disciplines of clinical and counseling psychology, with a few social psychologists as secondary or tertiary authors. The present reviewer wishes not to commit himself to any "credentialistic fallacy", but he checked the authors' credentials after reading the chapters and felt that in quite a few of them what and how the authors write seems to go beyond the scope of their expertise. In any

event, in this volume the first chapter includes a concern with social justice theory and research in relation to social changes. In the same terms of social justice, Chapter 4 discusses Latinos' immigration while Chapter 5 is mainly about gerodiversity and Chapter 6 presents a comprehensive review of "ableism." In line with Chapter 5, Chapter 6 also talks about aging but focuses on women while postulating a biopsychosocial-cultural perspective. After minority elders' voices are revealed in Chapter 5, minority women's experiences of trauma recovery are documented in Chapter 8. In a similar vein to the dialogue on trauma recovery just mentioned, Chapter 7 talks about the treatment of disabilities stemming from interpersonal violence whereas Chapter 3 addresses the cost of being a person of LGBT background in America's health care system. Chapter 2 is entitled *Aversive racism*, which makes readers wonder whether there is any non-aversive racism. Chapter 11 concludes Volume 3 by arguing that multicultural counseling and psychotherapy frequently contribute to the promotion of psychological emancipation.

Across the three volumes the term *diversity* is defined and delimited differently. For example, it is broadly defined in Volume 1 to include cultural, racial/ethnic, sex/gender, and sexual orientation, but in Volume 2 diversity is mainly limited to discussions of cultural and racial/ethnic types, whereas in Volume 3 diversity as a term has been expanded to include (mental/physical) disability, seniority, poverty*, inter alia*. Overall, more than 80% of the book's diversity discourse focuses on issues related to race, ethnicity and culture. In this context, race refers mainly to people of color who collectively constitute the minority or "non-normative group" in this country. In contrast to the minority or non-normative group, the majority or normative group should be called "people of no color", which in reality refers to white people. However, white is a color in itself rather than a term referring to no color, and this poses a semantic problem that throws the polarization of black and white into doubt. To what extent this doubt may delegitimize the debate between black and white is an issue left unresolved by any of the more than 40 authors represented in these three volumes.

One may also ask whether this 3-volume book could really serve its intended purpose which is to convince the targeted readers that diversity does matter. The readers whose minds the authors presumably wish to change come especially from the mainstream or normative part of the society who historically have been privileged and therefore might experience difficulties in sympathizing with the suffering of the non-normative people. Even though such people may not be opposed to diversity, they might not think that they should be especially concerned with this issue either. To articulate this point, Melanie Bush in Volume 2 cites an article from *The Chronicle of Higher Education* in which the author states: "The opposite of being pro-diversity is not being anti-diversity. It's being diversity-indifferent, and that's me. My T-shirt would not say "Diversity sucks." It would say, "Diversity--Who Cares?" (Clegg, 2000, p. B8). Indeed, why should Clegg and people like him change their minds and share their protected privileges with "people of a lesser God"? Furthermore, would they be persuaded to do so after reading this 3-volume book on diversity? Some of them might perhaps be induced to wear a T-shirt with a new imprint like "Diversity---We care," after selectively reading a few solid chapters that could so-to-speak act as scholarly stars shining through the clouds in a dark sky. This, in turn, leads to the question of, who spread the clouds that cover the other stars and is there any way to remove those clouds so that more viewers can be enlightened?

Ironically, an answer to the first question just raised is being advanced by the editor herself, who applies a top-down approach across the three volumes. As a case in point, the editor inappropriately uses exclamation marks in order to raise her tone of voice when referring to the title (viz., *Social justice matters!*) of Volume 2 as well as in each of her chapters contained in the three volumes. As an author, Chin overuses "demand words" such as "must" and "should" while offering too few sound arguments on the basis of logical reasoning. To be sure, most of the targeted readers are those coming from the privileged rather than the underprivileged class, and they therefore do not have to subject themselves to the commands uttered by a double-underprivileged (i.e. a minority female) author. In order to move the readers or to open their hearts as well as inducing them to nod their heads, a bottom-up approach would appear to be more adequate (cf. Lei & Gielen, 2008). Rather than superimposing her own beliefs or dogmas, an author adopting a bottom-up approach would attempt to initiate the readers' self-discovery journey while keeping their best interest in mind as well. Then throughout the journey together, via a rear-view mirror the readers may be enabled to look into their past and the historical background of the "de-diversity" movement from which some light may be shed into the direction of the future and thereby necessary changes could be highlighted. To illustrate this suggestion, one example from a reviewed chapter is introduced below.

The authors (Derald Wing Sue, Annie Lin, & David P. Rivera) of the chapter, *Racial microaggressions in the workplace: Manifestation and impact,* cogently quote historical facts demonstrating that subtle assaults on minorities, who are most likely under-represented at the higher levels of management, have become part of the traditional American workplace. One solution would be to diversify by increasing the representation of minorities in upper-middle management positions. To that end, it would be necessary to prepare minorities for the more challenging jobs through higher education. But then one might ask how white Americans could be induced to raise their own taxes or give up some of their own vested benefits in order to help enrich the education of the oppressed black people? To this question, Sue et al. responded as follows:

"These figures are disturbing for two reasons. First, it is projected that within several short decades, people of color will become a numerical majority in the United States (U.S. Census Bureau, 2004). Already, approximately 75 percent of those entering the labor force are persons of color or women, and by the time the so-called baby boomers begin to retire,

those contributing to social security and pension funds will be predominantly visible racial/ethnic minorities (Sue & Sue, 2008). If persons of color continue to occupy the lower rung of the employment ladder of the most undereducated, underemployed, unemployed, and underpaid, it bodes poorly for the economic health of the future retirees, business and the nation. Second, a society that continues to allow unfair disparities to exist between certain groups compromises its moral integrity, failing to provide equal access and opportunity to all …." (Volume 2, p. 158).

As can be seen in the quotation above, Sue et al. appeal not only to the reader's head by citing powerful trends predicting the country's future but they also echo Adam Smith's (1759/2010) theory of moral sentiments thereby appealing to the reader's heart. In light of this illuminating approach, even oppressors might realize that they have to chart a course of diversity so that they can move together with the traditionally oppressed into a brave new future world. Choosing to ignore this issue may lead both to financial bankruptcy and to moral corruption, which few would consider to be the best way to live one's life. The key of this approach is to make people feel connected on the high ground where they all can mutually benefit each other. For the same purpose but to restructure the three volumes as a whole, an orthogenetic framework of reference operating like a multidimensional web of meaning construction (à la Heinz Werner, 1940/2010) is proposed in the following.

First, diversity shouldn't be seen as skin-deep, as too many authors do in their respective chapters. After scratching the surface, we need to take a *phylogenetic* perspective to dig down deep into the genetic constitution and evolutionary epigenes (trigger factors that turn on or turn off genes thereby helping to change genotypes into phenotypes) that help shape the contents of character as well as the colors of skins. From the investigation of the *phylogenesis*, which may be located on the first dimension of *orthogenesis*, of Homo sapiens we would come to realize that the *sine qua non* of different subspecies of human being is so close to each other in spite of the visible differences. Then, we can examine the issue of diversity in relation to ethnic, social, cultural, and historical variables on the *ethnogenetic* dimension. After the ethnogenetic examination, we can study individual developmental processes in the light of diversity on the *ontogenetic* dimension. The microaggression discussed earlier would be examples to be situated on the *microgenetic* dimension, which focuses on temporary or local changes as a result of situational or contextual factors. Last but not least, under the orthogenetic framework *pathogenesis* refers to the etiology of disease or illness. To be sure, these five orthogenetic dimensions can be cross-referenced with each other. For instance, in one of her chapters Chin outlines how Chinese people explain the genesis of some diseases in the context of health beliefs which originate from traditional Chinese medicine.

Throughout the three volumes, most chapters are ethnogenetically-oriented, and of those many are cross-referenced to the ontogenetic dimension with a focus on education while a few others also refer to the pathogenetic dimension. On the other hand, no chapter addresses fundamental questions of diversity from a phylogenetic perspective and only a few chapters can be located on the microgenetic dimension.

This book would be worth reading if you are a clinical/counseling, developmental, social psychologist or mental health professional who needs to draw upon some materials suitable for multicultural curricula appealing to college freshmen. It would also make you feel good if you are a minority psychologist (full disclosure: the present reviewer is one of them) because the indignities of social injustice are denounced in many of the chapters. However, in order to act as an engine for social change the first and foremost step must be to convince the majority that diversity really matters since we all are reciprocally related to each other. Without adopting a bottom-up approach and addressing issues with reference to a comprehensive framework, this feel-good book may not lead to enough good consequences. Consequently, diversity will remain a dream that minorities have but may never be able to realize.

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ANNOUNCING THE PUBLICATION OF ...

La relazione al centro. [*Relationship at the centre: Healing in a troubled world*]
G. T. Barrett-Lennard
Publisher: London and Chichester: Whurr Edition/Wiley (2010)
ISBN: 978-8861531383

This book offers a new perspective on the working and potential healing of relations between persons and between peoples, relevant to our desperate times. Humans are born into relationships and personal selves emerge through experiences of relationship, which broaden and evolve through life. Inquiry into diversity and 'relations' within the self opens the way to other primary spheres: interpersonal and family relations, community process as relationship, the nature and far-reaching phenomena of loneliness and alienation, and organizational and big-system relations.

One chapter maps the wide spectrum of inter-connected human systems, and another presents a view of helping theory and practice development extended through this spectrum. Over the whole range, the processes, healing and development of relationship are in central focus. In a final review of the span of critical need and challenge, the book confronts alternatives and proposes steps toward recovery.

Why noise matters: A worldwide perspective on the problems, policies and solutions
John Stewart with Arline Bronzaft, Francis McManus, Nigel Rodgers & Val Weedon
Publisher: Earthscan (October, 2011)
ISBN: 978-1849712576

Is noise the most neglected green issue of our age? This book argues compellingly that it is, and tells you all you need to know about noise as a social, cultural, environmental and health issue.

Across the world, more people are disturbed by noise in their day-today lives than by any other pollutant on Earth. From the shanty towns of Mumbai to the smart boulevards of Paris, noise is a problem. It is damaging people's health, costing billions, and threatening the world's natural sound systems in the same way that climate change is altering its eco-systems. Drawing on evidence from all over the world, this book showcases policies and strategies that have worked to decrease noise pollution, and offers lessons for policymakers and environmental health professionals, campaigners and any individual affected by noise. Written by a renowned noise campaigner and experts in law and health, this book tells you all you need to know about noise as a social, cultural and environmental issue and how we can act to build a more peaceful world.

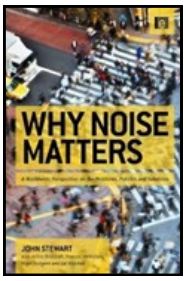

Eastern European immigrant families
Mihaela Robila
Publisher: New York, NY: Routledge (2009)
ISBN: 978-0-415-99406-4

After the fall of communism in Eastern Europe in early 1990s, international migration from this region has grown significantly. However, the literature on Eastern European immigrant families has been very limited. This book presents key issues related to immigration from Eastern Europe, such as a historical background, the factors determining contemporary migration, its benefits and challenges. There is also a focus on children and families, addressing child-rearing beliefs and practices, cultural beliefs, marital interactions and gender roles. The challenges faced by Eastern Europeans as they immigrate around the world are also explored.

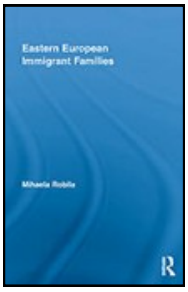

Migration, technology & transculturation: A global perspective
Myna German & Padmini Banerjee (Eds.)
Publisher: CIGS Lindenwood University Press (2011)
ISBN: 978-0984630745

Based on exhaustive reporting and academic studies from authors across the world, this volume shows how the changing face of technology is shaping the lives of global migrants. While once a painful goodbye sent immigrants packing to the different areas of the world in the 19th and 20th centuries, the global millennium, replete with Skype, Facebook, email, and chat has made global nomads a reality, but they are also very connected to their home port. This volume offers a convergence of perspectives on these new developments, combining conceptual and empirical work

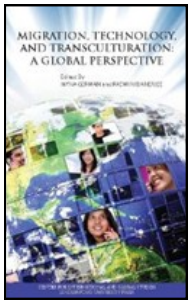

from the different continents throughout the world. Chapters by psychologists, sociologists, anthropologists, geographers, historians, media specialists and literary studies writers reflect on these new international social networks and technologies and their impact on these new forms of communication and identity formation among global migrants. The global reach of the authors span the countries of Italy, Germany, the UK, Brazil, Australia, the US, India, and in between. This is a substantial pioneering effort in this field of research on this global topic.

Return migration and identity: A global phenomenon, a Hong Kong case
Nan Sussman
Publisher: Hong Kong University Press (2011)
ISBN: 978-9888028849

The global trend for immigrants to return home has unique relevance for Hong Kong. This work of cross-cultural psychology explores many personal stories of return migration.

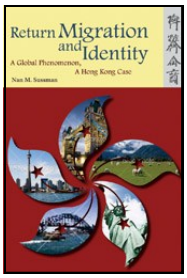

The author captures in dozens of interviews the anxieties, anticipations, hardships, and flexible world perspectives of migrants and their families, as well as friends and co-workers. The book examines cultural identity shifts and population flows during a critical juncture in Hong Kong history between the Sino-British Joint Declaration in 1984 and the early years of Hong Kong's new status as a special administrative region after 1997. Nearly a million residents of Hong Kong migrated to North America, Europe, and Australia in the 1990s. These interviews and analyses help illustrate individual choices and identity profiles during this period of unusual cultural flexibility and behavioral adjustment.

Interpersonal acceptance and rejection: Social, emotional, and educational contexts
Elias Kourkoutas & Fatos Erkman (Eds.)
Publisher: BrownWalker Press (2011)
ISBN: 978-1599425696

This volume draws on research to offer a global perspective on issues of fundamental importance to family functioning, childhood development, and adult intimate relationships, as well as to policy and practice for children, adolescents, couples, and families at risk. It draws on the perspectives of major social science disciplines such as clinical and educational psychology, anthropology, psychology, special education, and sociology, thus ensuring topics are discussed within broad theoretical frameworks. The authors cover a wide spectrum of questions and topics in relation to perceived acceptance and rejection by significant others.

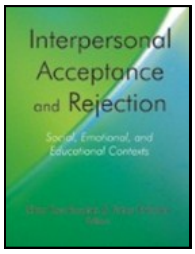

Chapters are set in the context of worldwide trends in the area of interpersonal acceptance-rejection. They considerably advance our knowledge of interpersonal acceptance-rejection theory and practice by tackling issues in major life contexts such as family, education, intimate relationships, and clinical-therapeutic practice.
The book presents these important issues within the context of up-to-date research on interpersonal relationships that helps strengthen family and couple relationships and enhance the quality of attachment relationships in families. Contributors to this edited book come from many parts of the world, including the Americas, Asia, Australia, Europe, and the Middle East.

ALSO ANNOUNCING THE PUBLICATION OF...

Psychology in Ukraine: A historical perspective
Ivan Holowinsky
Publisher: University Press of America (2009)
ISBN: 978-0761840466

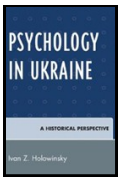

This book was conceptualized as an effort to provide for a Western reader, not familiar with psychology in the East, a broad outline of Ukrainian Psychology within the socio-historical context.

Grief therapy with Latinos: Integrating culture for clinicians
Carmen Vazquez & Dinelia Rosa
Publisher: Springer Publishing Company (2011)
ISBN: 978-0826106599

This book serves as both a graduate textbook and clinical reference that helps in the understanding of relevant cultural values and their effect on the grieving process. This book also addresses the application of specific interventions in a culturally relevant manner, including the relevance of language in grief therapy, psychology and counseling with a Latino population.

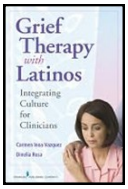

*If you would like to include a book in a future issue of IPB and have not already done so, please email information to Jennifer Lancaster at jlancaster@stfranciscollege.edu

** Please note that at least one author/editor must be member of Division 52 and the work must have been published in the last three years.

Notes from the Underlings: What Supervisees Report About their Cultural Matches with Supervisors

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Trainees in clinical psychology learn many of their clinical skills in supervision, thus I began reflecting on my supervision experiences and wondering how the cultural match between my supervisors and myself affected my learning. As a female Russian immigrant trainee who has been paired with male and female Russian-speaking and non-Russian supervisors, I am familiar with the nuances that these matches bring out in my training. These nuances have included language-bound phenomena, worldviews based on national and immigration history, gender roles, and age-related and social status hierarchies. I have noticed that all of these facilitate or impede the relatedness, openness, and comfort level that I feel with my supervisors. With this in mind I wondered about the experiences of other students from different cultures and countries. Specifically, I wanted to know what types of issues came up overtly or covertly in the relationships with their supervisors, what they found difficult to discuss or what was ultimately helpful, and whether they found that these particular supervision matches increased their clinical expertise and improved client care.

Falender and Shafrenske (2004) suggest that cultural competence in training should include a certain awareness, knowledge, and appreciation of various cultural variables between the supervisor and supervisee. Generally, it seems that two people work best together when they have a thorough understanding of, or at least an open curiosity for, each other's cultures, national history, immigration experience, and status in the United States. Texts that focus on cultural competence in supervision usually encourage trainers to become aware of their own cultural expectancies or biases, and to help their supervisees do the same. For example, Vargas, Porter, and Falender (2008) call for supervisors to continue to explore variables of cultural diversity affecting the supervision relationship and to openly dialogue with their supervisees. Further, Wedding, McCartney, and Currey (2009) instruct teachers (whether professors, advisors, or supervisors) to understand the factors that may be unique to international students studying in the U.S. and to remain sensitive to their students' levels of acculturation and functioning within an American academic system. However, these texts are written about supervision and training in general and do not always describe the experiences of students specifically.

For this project, I interviewed two female clinical psychology students, both currently training at practicum sites in the San Francisco Bay Area. I asked them to describe first their own cultural identities and then those of their supervisors. I was interested to see how they perceived their supervisors' cultures and what particular variables came up in supervision. I also asked the interviewees to think of a clinical case and to describe their experiences of discussing the case within their particular supervisory pairings.

My first interviewee, Sofia (both interviewees chose their pseudonyms to protect their privacy), identified herself as Mexicana, fully Mexican-American, born in the U.S. and raised in both countries. Thus, she labelled herself as bicultural, binational, and bilingual in English and Spanish. She described her current supervisor as a Latino man from a Peruvian background. She knew that he was born in Peru and immigrated to the U.S. in his late teens. English was his second language, and thus, they switched between Spanish and English in supervision. The issue of language became an area of effort and growth in her training. Sofia described that their conversations usually began in Spanish, the more familiar and familial language, as well as the language of the clients at the agency. However, because the academic training for both has been largely in English, it became inevitable to intersperse English for theoretical terms. Sofia mentioned that she hated mixing the languages at first because her community looked down on this and considered it "Whitewashing". But having a supervisor who was able and willing to engage with her in both languages taught her to code-switch more effectively and ultimately gave her a sense of pride in her ability to quickly translate experiences for herself and her clients. Thus she stated that this increased her linguistic fluency and improved her therapeutic skills by helping her to translate theoretical formulations in English into interventions in Spanish.

Sofia also described a greater sense of comfort in discussing how to work with clients "not by the book" when she knew that she was talking with another member of her community. Rapport in supervision was easier to establish because both shared a passion for serving the community, were connected to their native countries and were intimately familiar with the struggles of their immigrant clients. In addition, Sofia valued an unspoken understanding of cultural rules. For example, their culture allowed her to call her supervisor by his title rather than his first name, as would be appropriate in many American academic and clinical settings. In other instances, Sofia appreciated that they covertly agreed on the less rigid guidelines around physical boundaries and touch. She explained that ultimately her supervisor successfully modelled a relationship that maintained culturally appropriate norms while pushing her to develop in her identity as a Mexican-American clinician, which has been a crucial part of her professional training.

Similar themes came up in my second interview with Katy, who described herself as Indonesian nationally and Chinese ethnically. Katy explained that she grew up as a minority both in her ethnicity and her religion as she was Chinese and Christian in a predominantly Muslim Indonesia. She moved to the U.S. at 18 years of age to attend university and graduate school. Katy first described the prevalence of her feeling like an outsider in a White academic culture, where the teaching of psychology came from an exclusively

Western perspective that did not always agree with her understanding of normal human behavior and health. In addition, she often felt unheard and irrelevant at her institution when raising questions and concerns about clients to which other students did not relate. By contrast, Katy's supervisor at a predominately White institution was a Korean-American woman, born in the U.S. to parents from Korea. It was refreshing for Katy to be matched with a supervisor who on some level personally understood her struggle of having to adjust to a dominant culture and thus often encouraged her to brainstorm interventions that agreed with her worldview. This allowed Katy to develop professionally by not simply acculturating to a Western model of health, but by integrating various nuanced cultural considerations.

Despite the comfort and bond between Katy and her supervisor, some cultural dynamics presented challenges in the supervisory relationship. Katy felt uneasy when her supervisor insisted that Katy call her by her first name rather than her title. This situation presented a dilemma of whether Katy should disregard her own values or those of an authority figure. Furthermore, voicing this difference in norms felt difficult to Katy because it also went against her cultural rule against questioning authority. As such, she looked for her supervisor to be tuned in and curious about Katy's experience in supervision, rather than assume that Katy would voice her own concerns. As Katy's supervisor established an atmosphere of understanding and open communication, Katy felt more comfortable to discuss and resolve any challenges in their dynamic. Ultimately, Katy found supervision most effective when both parties capitalized on shared experiences and found a common ground in values while respectfully exploring each other's perspectives as they pertained to client care.

Overall, the stories of both interviewees supported the idea that regardless of the accuracy of the cultural match between the student and the supervisor, it was the supervisor's openness, curiosity, humbleness, and lack of imposition of viewpoints that helped the students explore themselves and develop professionally. The students also encouraged supervisors to understand their positions of power and explore the cultural values that may be placed on figures of authority. It was also striking that although both dyads represented people from different countries of origin, supervisees felt connected to their supervisors based on otherness within the dominant culture and community membership. The reports of these students also match my experiences in that I have been most comfortable and open to learning in pairings where supervisors were unassuming and willing to think with me outside the academic box. Having supervision in my native language has also helped me to integrate those worldviews that I derived as part of my upbringing in Russia with those I learned in academic settings in the U.S. Thus, it seems essential that supervisors learn ways to explore cultural variables in supervision. It also seems imperative that the field train more clinicians from diverse backgrounds and speaking different languages who could serve as professional role models to students seeking to become culturally competent.

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Daria Diakonova-Curtis by email at ddiakonova@alliant.edu.

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Editor's Note: *This column is geared towards our student committee members and all students of international psychology. All Div52 student members are invited to submit ideas or drafts for future articles, as well as questions they would like to see addressed in future columns – such as overseas internship opportunities, study abroad availability, cross-cultural research, etc.*

Contact the Editor at optimalex@aol.com to submit an idea or a question.

Psychology Students Travel to Nepal

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Eastern Connecticut State University

Study abroad programs are becoming prioritized by colleges due to their being identified as part of the trend toward globalization. However, American students have been found to not participate in study abroad programs as much as students from other Western countries (Lewin, 2009). Study abroad courses have also been identified as a best practice for engaged learning for college students. In response to these data, Eastern Connecticut State University (ECSU) has committed to increasing student engagement through the use of study abroad and global field courses. The psychology department has been searching for a way to integrate this practice into training for our students, not only to meet the goals of ECSU but also the goals of psychology as a field. Diversity and culture are integral parts of the field of psychology . The American Psychological Association (2007) has suggested that one of the 10 goals for undergraduate psychology education should be "sociocultural and international awareness." The process of creating a global field course focusing on psychology was a learning process that resulted in what was without question the most rewarding experience I have had in my 16 years of teaching.

Reception at Little Angels College

As with many universities there is a wealth of faculty from diverse cultures at ECSU. I made contact with Geeta Pfau, Ph.D. a nurse in the health service center at ECSU during a talk we gave on HIV on college campuses for the Latino Leadership Conference. We began to talk about taking students to Nepal. Dr. Pfau had many contacts in Nepal as she was born in and studied in Kathmandu. The key was to find a course to link to the travel to Nepal. I had been teaching health psychology for many years and the textbook I use focuses on the impact of culture on health. During a sabbatical we began putting together the course with a host college in Kathmandu. We also began contacting possible sites we wanted to visit with students. After 4 months of planning and marketing the course was proposed for Summer 2011.

Eight psychology students, 1 sociology major and IT staff person, Barbara Williams, participated in the global field course. The course was designed to examine health in Nepal versus the United States from cultural, educational, sociological and psychological perspectives. One week of course work was followed by travel to Nepal between June 1st and 11th. In Nepal, students traveled to Dhulikhel and Pokhara and visited 2 hospitals, a free medical clinic, Kathmandu University, Maiti Nepal, an orphanage, 2 psychiatric facilities and an Ayurvedic clinic. Students also did sightseeing which included several Buddhist and Hindu temples and ancient royal palaces. During the trip, our host, Little Angels College, coordinated our ground transportation and provided us with a guide throughout our stay. None of the eight students who participated in the course had ever left the country before. This, coupled with our destination being a collectivistic developing nation nearly around the world, promised to be an eye opening experience.

Our flight itinerary took us from New York to New Delhi, where we had an overnight stay. While we did not have time to travel into Delhi, students were amazed at the sights, sounds, smells and food of India. The next morning we left for Kathmandu where we were greeted by our host school and welcomed with a reception. Following the reception we presented our itinerary for the week ahead.

At each location students were given a presentation overview followed by questions and answers and a tour of each facility. What was clear throughout our trip was the need for psychologists to help the Nepali people deal with many aspects of poverty, health, education and a patriarchal society. Psychological treatment in Nepal is a complex and challenging issue. According to Dr. Dhruba Man Shrestha, there are a total of 418 psychiatric beds and a total of 107 mental health care workers for population of over 25 million in Nepal. Of those 5 are clinical psychologists and 1 child psychologist. This is complicated by Nepal having many rural areas that rely on local healers for treatment of psychological and physiological disorders. This coupled with a 40% literacy rate makes treatment for the mentally ill challenging. Interestingly, there were some consistencies in the public's view of psychology. In many places students were asked why they were in Nepal and when they explained that they were psychology students, they were asked if they could read their minds.

Eastern students were most affected by our visit to Maryknoll Nepal, the first non-government organization providing psychiatric services throughout the country. Video was shown of 2 men with schizophrenia, one who was leashed and the other caged for many years. Family members do not have the knowledge or ability to care for the men and felt this was their only solution. However, Maryknoll took in both of these cases, and they are being taught self-care behav-

Lecture at Maryknoll

iors and how to farm. We were able to meet 1 of the 2 men in the videos and to see him functional and interacting with us and other patients was a moving experience. Maryknoll relies on volunteers to provide psychological services and donations to fund its community outreach, day care and residential programs. Recently, a key donor to Maryknoll passed away. Students saw the opportunity to make a difference and made a donation of cash and clothing as well as a second donation in the name of our host school coordinator Shristi Limbu. The gift donation was sufficient to cover the medication costs for 10 patients for one month.

Students were also able to go to Maiti Nepal, an organization that was created to rescue and rehabilitate women sold into sex trafficking and their children. The founder of Maiti Nepal was awarded 100,000 dollars by CNN as hero of the year for her efforts. Students were presented with the economic and social pressures such as the need for dowries for marriage of female children, which maintain the practice of sex trafficking and were shown pictures of women who had survived torture and in some cases having organs taken from them for sale on the black market. The grounds of Maiti Nepal house a school for children of the women and an orphanage. A key component of Maiti Nepal is psychological services for the women and families of the victims of sex trafficking.

An interesting theme throughout our trip was the lack of technology. There were no computer systems to track patient histories. Likewise, hospital rooms were missing the sounds of monitors and IV pumps. The people of Nepal were warm and friendly throughout our trip and were eager to have their pictures taken, with their only reward being the ability to see themselves in their pictures. Nepal is an amazing country with the incredible beauty of the Himalayas contrasted with the poverty. However, this did not appear to affect most people. We were told that the focus on family and spirituality were more important than things and this was evident by the abundance of temples (both Buddhist and Hindu) nearly everywhere both in the city and in rural areas. Students were surprised to learn that all religious holidays are celebrated by all people.

There were many other experiences which deeply affected the students on the trip. Students completed a final projecting linking their readings to their experiences in Nepal. Also, all of the students participated in a course blog and uploaded photos and their impression of what they experienced (http://statectuniversity.wordpress.com). As an instructor, the trip to Nepal was eye opening and the most rewarding experience of my teaching career. To see students being affected by the new world around them was an incredible experience. Relationships were established with all sites and plans are moving forward for another trip to Nepal in May 2012.

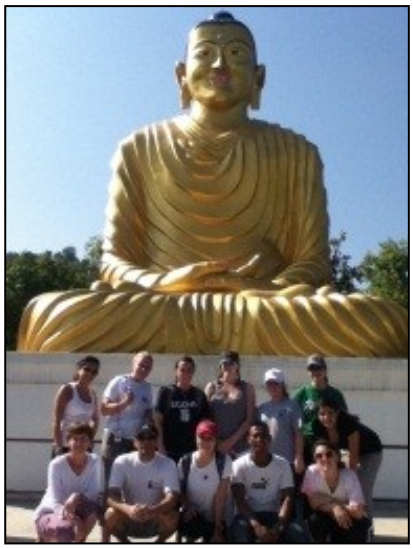

Buddha hike group

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A Division 52 Success at the European Congress in Istanbul, Turkey

Neal S. Rubin, Ph.D., ABPP
Argosy University, Chicago

The theme of the 12th European Congress of Psychology in Istanbul, Turkey, 7/4 – 7/8 July, 2011, was "Understanding and Embracing Diversity." As a part of the Europlat program at the Congress, Division 52 members presented a symposium, "Integrating Human Rights and Social Justice with Diversity in Psychology Education and Training: Multiculturalism, Immigration, Trafficking and the United Nations." The aim of the symposium was to contribute to the conversation generated by the Europlat Initiative, a movement of European academics and professionals to standardize psychology education and the certification of psychologists across European Union countries.

Our symposium originated with the assumption that today, we are interconnected as never before in human history. Advances in technology, climate change, the world financial crisis and the world response to natural disasters have unified diverse populations. Our concern with how we are similar and how we are different as humans both intrigues and troubles us, generating compelling empathy as well as destructive fearfulness in the world today. In this context the place of the education and training of psychologists, across countries and educational systems, to understand and embrace diversity, has become all the more compelling.

Therefore, the purpose of our symposium was to illustrate how the teaching and training of 21st century psychologists can blend an appreciation of human diversity with universality, by integrating multiculturalism with human rights and social justice education. Our symposium presenters originated from three countries (New Zealand, Turkey and the United States) and are currently on faculty at three universities in the United States. In short, we presented models for teaching diversity based on our research and field experience on topics such as immigration, multiculturalism, human trafficking and developments at the United Nations. What follows is a synopsis of each presentation and the response by our European colleagues.

Diversity and Human Rights in Psychology: A View from the United Nations

Neal Rubin, Ph.D., ABPP, a Professor at the Illinois School of Professional Psychology at Argosy University, Chicago, initiated the presentation by describing some of his experiences as an APA/NGO representative at the United Nations. He detailed how in 1999 the American Psychological Association was granted special consultative status as a non-governmental organization (NGO) by the Economic and Social Council (ECOSOC) of the United Nations. Since that time a team of APA psychologists have endeavored to contribute psychologically informed perspectives to the behavioral dimensions of 21st century human rights issues. Their work, along with the efforts of psychologists representing other psychological organizations (for ex., ICP, IAAP, IUPsyS, SPSSI), involves deliberations with U.N. staff and its agencies, representatives of member states and members of the NGO community. These psychologists have also sought to educate fellow professionals regarding the potential roles of psychologists in addressing social justice issues worldwide. For example, he described the success of the fourth "Annual Psychology Day at the United Nations" in April of this year. He outlined how psychologists are informing the dialogue at this world body regarding the way in which psychological science can inform progress on pressing human rights issues and reciprocally, how psychologists are educating colleagues regarding diversity and social justice issues. He concluded by emphasizing that diversity and global awareness should be viewed as essential components of teaching ethical principles to psychologists.

Cultural and Individual Differences and Diversity in Professional Psychology Training

Ayse Ciftci, Ph.D., an Assistant Professor of Counseling Psychology in the Department of Educational Studies at Purdue University, presented her views and pedagogic model for teaching human diversity. She articulated how cultural and individual differences and diversity are significant components of professional psychology training and constitute one of the accreditation domains of the American Psychological Association (APA). However, she acknowledged that the educational techniques and depth of training of tomorrow's psychologists to work effectively in diverse environments vary among psychology training programs. For this symposium, Dr. Ciftci presented the ways in which she and her colleagues incorporate diversity training in their APA accredited counseling psychology program through coursework, program-related activities, prelims, practicum experiences, and student evaluations. Employing her own professional and personal experiences as a Turkish professor teaching Advanced Multicultural Counseling courses in the U.S., she described how she has learned to use her cultural background and research expertise on cross-cultural adaptation as educational tools. Additionally, she outlined how she integrates social justice and international issues in her classes through multiple assignments (such as development and delivery of social justice interventions). Last, she discussed the specifics of some of her experiential learning processes by presenting case examples from some of the "difficult dialogues" activities she has integrated into her classroom teaching.

Trafficking Girls into the Sex Industry: International Cross-Cultural Psychosocial Perspectives

Rita Chi-Ying Chung, a Professor of Counseling and Development in the College of Education and Human Development at George Mason University, described an insidious form of migration: forced migration through human trafficking. She described that although human trafficking has been

in existence for centuries, globalization, enhanced technology, and increased international travel have resulted in growing demands in the sex trade and a steady increase in human trafficking worldwide. She observed that though human trafficking for commercial sex has been addressed in various disciplines, the psychosocial issues are oftentimes ignored. As a consequence, in her presentation she discussed the long and short term ramifications of trafficking girls from a cross-cultural, psychosocial perspective. She asserted that for psychology training to remain in the forefront of social issues, it is important to include human trafficking in psychological training. Accordingly, to be effective in working with this population, in both training and practice psychologists must emphasize multicultural, social justice and interdisciplinary issues as these concerns relate to trafficking for commercial sex. In order to illustrate this perspective on education and training, she presented examples of the linkage between psychosocial and diversity issues with the violation of fundamental human rights that human trafficking represents.

Immigrant and Refugee Mental Health: Global and Cross-Cultural Perspectives in Psychological Training and Practice

Fred Bemak, Ph.D., Professor and Director of the Diversity Action and Research Center, College of Education and Human Development of George Mason University, informed us that migrants continue to grow in numbers and comprise over 3% of the world's population, an estimated 214 million people. He emphasized that psychology has a pivotal role in addressing the movement of people that accompanies rapid social, familial, cultural, economic, and political changes. Given wars, conflicts, natural disasters, famine, drought, poverty, climate change, and disease, millions of refugees and immigrants are fleeing their homes, villages, and countries. Dr. Bemak's presentation discussed the psychological effect of migration on individuals, families, host communities, and societies. He engaged the audience to consider the subsequent role of psychologists in addressing the related psychosocial issues of migrant populations. Following this introduction, he explored the increasing mental health needs of these populations from a cross-cultural perspective, presented a culturally responsive social justice model of intervention for addressing trauma, acculturation, adaptation, loss, and separation, and then in summary, examined the educational and training implications for psychologists.

Response

We were very gratified by the response we received at the European Congress. First, following our symposium papers, our audience was energetically engaged in a discussion of salient questions and concerns. This cross national, multi-lingual and multi-cultural group of colleagues were genuinely responsive and appreciative, while also intensely interested in getting more details from the panel on issues of their particular interests. For example, our European colleagues explored the details of our and their educational processes, focusing on methods to establish an evidence base for determining cultural competence in students within and across nations. Ideas as well as frustrations were shared in an illuminating exchange. It was clear that, with respect to embracing diversity, we shared many challenges and potential solutions as 21st century educators and professionals. Discussion spilled into the convention center hallway with a shared desire to communicate beyond the moment.

Second, following our symposium, discussion with representatives of the International Congress of Psychology (ICP) led to an invitation for our panel to present a symposium at next summer's meeting. The theme of the 30th International Congress of Psychology is "Psychology Serving Humanity" and will be held in Cape Town, South Africa, 22 – 27 July, 2012. Join us at ICP 2012 and watch for our symposium, "Enriching Our Shared Humanity: Imperatives for a Human Rights Framework for Psychologists."

Nominations for International Union of Psychological Science Awards

Nominations are invited for the following International Union of Psychological Science sponsored awards to be given at the 2012 International Congress of Psychology in Capetown, South Africa. Deadline for nominations is less than two months away. More details at http://www.iupsys.net/index.php/prog-awards or by following the hotlinks below.

Mattei Dogan Prize: Recognizes a contribution that represents a major advancement in psychology by a scholar or team of scholars of high international reputation.

Young Investigator Awards: Recognize young post-doctoral scientists who have already made a significant contribution to psychological science.

Achievement Against the Odds Award: Honors a researcher or team of researchers who succeeded in conducting research under extremely difficult circumstances.

Lifetime Career Award: Honors distinguished and enduring lifetime contributions to international cooperation and advancement of knowledge in the field of psychological science.

The deadline for receipt of nominations for the 2012 Awards is 30 September 2011.

A Brief History of Psychology in Argentina

Michael Tamburino
St. John's University

The history of psychology in Argentina is complicated and, in many ways, interconnected with the political development of the country. This essay will serve as a general introduction and background to psychology in Argentina. First, the article addresses the development of the psychiatry movement and its early focus on somatic causes to pathology. Second, the essay outlines the transition from a biological emphasis to psychoanalytic psychology, by all accounts the primary psychological orientation to this day in Argentina (Bass, 2006; Plotkin, 2001). Third, the development of psychology as a separate field is discussed, including the rise of psychology as a profession and subsequent implications for training and service distribution. Finally, an analysis of the impact of the collapse of the Argentine economy in December, 2001, on the course of psychological study and practice is addressed.

The Beginnings of Psychiatry

In late 19th century Argentina, there was increasing interest in understanding the rationale behind criminal behavior (Ruggiero, 2003). This interest became a public outcry following a string of cold-blooded murders committed by a Luis Castruccio in July of 1888. Questions about why and how someone could commit such heinous crimes led to an emphasis on asylums for study and treatment of these "more disturbed" individuals. Subsequently, the role of medical professionals (i.e., psychiatrists) in providing this treatment and study became integral.

Lucio Melendez, founder of the asylum Hospicia de las Mercedes, is considered to be the first Argentine psychiatrist. He was the first to hold the chair of mental diseases in the School of Medicine at the University of Buenos Aires, as well as being the first chair of psychiatry in Cordoba in 1888 (Plotkin, 2001). Melendez, like many of his peers, was heavily influenced by French and Italian views of psychology and mental pathology. Indeed, within the medical community as a whole, Italian and French were mandatory languages and only those physicians who had demonstrated a degree of success in Europe were recognized in Argentina. The French influence on Argentine psychology placed a particular emphasis on psychopathology. This emphasis was also popular because of its utility in understanding criminal behavior.

In this context, Melendez imported the ideas of prominent French physicians to answer these questions, including the concept of positivism. Positivism dictates that the only true knowledge is that which is based on sense experience and positive verification. This led to the popularity of somatic theories of mental illness which looked to the body, as opposed to the mind, for the etiology of mental illnesses (Plotkin, 2003). According to Nathan Hale, a prominent North American psychoanalytic historian, the "somatic style" gave almost no credence to the role of environment in mental illness; the origin and treatment of mental illness was to be found in the brain and peripheral nervous system (Plotkin, 2001).

Between 1880 and 1940, the theory of degeneracy was the most popular of these "somatic theories" (Caimari, 2003; Plotkin, 2001). Originally introduced by the French physician Benedicto-August Morel, it held that psychopathology was transmitted from generation to generation within families and that, with every subsequent generation, the pathogen would grow stronger. This became a particularly fashionable argument against the admittance of immigrants to the country from southern Europe in the beginning of the 20th century.

Psychology in Academia

As discussed previously, Argentine psychology, heavily influenced by France and Italy, had a clinical-psychopathological approach from the outset. However, unlike the experimental emphasis placed on psychology in the United States, psychology in Argentina was spread throughout the disciplines of sociology, biology, and philosophy without a clear-cut focus or direction. This failure to delineate an explicit field and role for psychology, however, did not stop Argentina from distinguishing itself among other Latin American countries in psychological teaching and research (Plotkin, 2001).

Beginning in 1896, Felix Kruger, a former student of Wundt's and his eventual successor in Leipzig, spent two years in Argentina (Vezzetti, 2007). During that period, he held the second chair of psychology at the University of Buenos Aires in the School of Philosophy and Literature. Contrary to the emphasis on the Wundt's empirical methods of studying psychology emphasized in North America, Kruger emphasized the non-experimental aspects. In this vein, he began to introduce the works of anti-positivist writers emphasizing the importance of the mind in psychological phenomena (Plotkin, 2001). As will be discussed later, this laid the groundwork for an anti-positivist sentiment in Argentine psychology and psychiatry in the early 20th century.

For the moment, however, this movement would have to wait; when Kruger left for Germany in 1898, so did his interpretation of Wundt's work. That same year, Horacio Pinero established the first psychology laboratory in Argentina, also at the University of Buenos Aires. Pinero, like many of his fellow Argentine colleagues, was familiar with Wundt primarily through positivist biased French translations of his work (Plotkin, 2001). While the lab was patterned after Wundt's in Leipzig, it had a decidedly positivist flavor, focusing almost exclusively on the physiological aspects of Wundt's work.

A physician by the name of Jose Ingenieros typified this positivist approach, viewing psychology as a subcategory of biology. However, Ingenieros also believed in the efficacy of psychotherapy, including the merits of hypnotism and dream interpretation. Further, in this era of increased emphasis on

understanding the behavior of mentally ill criminals, he was the first psychiatrist in Argentina to advocate for actually *listening* to these patients (Ruggiero, 2003). He brought this approach into the classroom as well, and between 1904 and 1919, he taught psychology courses with an applied, clinical focus in the School of Philosophy and Literature at the University of Buenos Aires.

Ingenieros exemplified the flexibility in psychology to that point. He was the first director of the Institute of Criminology in 1907, as well as being the founder of the *Revista de Filosofia* in 1915. He used this publication to disseminate important scientific and philosophical ideas of the day. Ingenieros often included his own writing in the areas of criminology, hysteria, and sexual pathology (Rodriguez, 2003). This included a discourse on love, *Tratado del amor*, in which he discussed the adaptive quality of erotic sexuality.

Ironically, Ingenieros, a positivist and somatist to his death in 1925, had a profound impact on Jorge Thenon and Celes Carcamo, two primary figures in the rise of psychoanalysis in Argentina (Bass, 2006). Indeed, Carcamo would go on to be the first president of the Argentine Psychoanalytic Association (APA). It was Ingenieros' belief in the efficacy of psychotherapy that helped lead to a more open stance on psychoanalysis, the popular "talking cure."

The Rise of Psychoanalysis

In contrast to the more dogmatic interpretations of psychological approaches witnessed in other countries, there was less polarization and pressure to "choose a side" in Argentina in the early 20th century (Plotkin, 2001). This allowed for the appropriation of psychological approaches/orientations from France, Germany, Spain, etc., without concern for ideological consistency. The result was an initially broader range of psychological ideas without a clear "Argentine psychology." As the political landscape changed, however, this ideological freedom would not last.

Beginning in the 1920's, there was growing anti-positivist sentiment culminating in a "positivist" crisis (Plotkin, 2001; Plotkin, 2003). This can be traced to the work of individual's such as Kruger and Ingenieros, as well as the increasing popularity of psychoanalysis in Europe, particularly France.

Psychoanalysis became even more popular in the 1930's with the beginning of both the Spanish Civil War and World War II. At that time, many leftist members of the psychological community, a significant proportion of whom were affiliated with the Communist Party, advocated for a more anti-experimentalist view of psychology. While there was no evidence of a formal Freudian-Marxist movement in Argentina as was observed in France and Germany, many psychiatrists saw the potential of (psychoanalytic) psychotherapy in facilitating the construction of a new modern society (Plotkin, 2001).

Psychoanalysis As Orthodoxy

In 1942, the Argentine Psychoanalytic Association (APA) was established by Angel Garma, a classically trained analyst from Spain (Vezzetti, 2003); later that same year, it was recognized by Ernest Jones, one of Freud's most important disciples. During the next meeting of the International Psychoanalytic Association (IPA) in 1949 following WWII, the APA became an official member. Unlike other members of the IPA, no psychoanalysts with established careers emigrated to Argentina; the APA consisted almost entirely of Argentine born professionals. Because of the absence of European trained psychoanalytic professionals, when the APA was established there was no pre-existing psychoanalytic orthodoxy (Plotkin, 2001). However, with the APA came the delineation of "rules" for the practice of psychoanalytic psychology. Argentine psychology now had its own dogmatism.

The final piece to eliminating ideological freedom in Argentine psychology was the emergence of the Peronist movement in 1945 (Plotkin, 2001). The political and ideological radicalization of Peron forced intellectuals to take sides; you were either a liberal-progressive against the Peron government or a nationalist-Catholic supporter. Peron's administration further demanded adherence from all academic institutions to its political doctrine, which it often achieved through appointing its own deans and faculty. The result was that many of the progressive psychology faculty were dismissed or resigned, including 1,250 professors at the University of Buenos Aires between 1943 and 1946.

In response to the state dictated uniformity of ideology among public institutions, private universities (termed CLES; Colegio Libre de Estudios Superiores) began to appear (Plotkin, 2001). The curriculum included Psychoanalytic psychology courses, and the APA became a counterculture.

Psychoanalysis and Psychology

Whether in politically harsh or advantageous times, psychoanalysis was consistently held in high esteem by intellectuals and medical professionals (Bass, 2006). Indeed, the merit of psychology as a science in Argentina was based on its association with psychoanalysis. With the exception of the developmental psychology of Jean Piaget, all other psychological theories were simply techniques (Plotkin, 2003). With the addition of CLES's, the number of universities and, subsequently, training settings, grew exponentially. As a result, by the 1960's psychoanalysis and psychology was beginning to separate from the field of medicine as a greater number of psychologists became trained in psychoanalytic principles (Knobel, 1975).

Courses in psychology were typically offered within the departments of philosophy or humanities although the emphasis was on psychotherapy, particularly psychoanalytic psychotherapy (Knobel, 1975). However, while many psychologists in training were receiving instruction on approaches to psychoanalytic psychotherapy, they were not formally recognized by the APA which dictated that, except for extreme circumstances, analysts must by medical doctors. The APA's own experience of having its professional scope artificially restricted did not appear to make it more sympathetic to the needs of psychologists. Further, they now enjoyed the sup-

port of the Peronist government including a Ministry of Public Health law which did not allow for the practice of psychotherapy by non-medical professionals (Ablard, 2003).

Several universities responded by expanding the scope of specialization among doctoral level psychology degrees, including clinical, educational, and industrial specialties, in an effort to secure professional legitimacy. However, initially there was a lack of agreement on uniform standards for training (Knobel, 1975). Indeed, while certain attempts at uniformity have been taken, there is still concern over the breath and overall quality of training at the doctoral level, specifically with regard to testing and knowledge of newer interventions (Solano, 2004).

Psychology in the University

The first formal Ph.D. level psychology programs in Argentina were not established until 1956, following the fall of the Peron administration (Plotkin, 2001). That year witnessed a psychometry program in Rosario and a three year psychology program in Buenos Aires. The program in Buenos Aires was taught mainly by psychoanalysts (M.D.'s) and was headed by a medical doctor, Marcos Victoria. By 1964, there were no fewer than 11 mandatory courses in psychoanalysis as part of the curriculum. However, psychology programs were still located primarily in the School of Philosophy as opposed to the School of Medicine and the Ph.D. awarded following successful completion did not allow the psychologist to practice psychotherapy legally (Knobel, 1975; Plotkin, 2001).

Given the barriers put up by the APA and the Argentine government, it is fair to ask the question, "Why would psychology students still want psychoanalytic training and from the very same professionals who put up these barriers to practice?" Plotkin (2001) outlines two primary reasons. First, many young Argentines viewed psychoanalysis as a "modern psychology" with the potential to catalyze social change. Students particularly preferred, and often demanded, faculty with leftist leanings such as Jose Bleger, a member of the Argentine Communist Party until 1961 (Vezzetti, 2003). Bleger's professional profile included theorizing on the compatibility of Freud and Marx which was very popular among students in the 1950's and 1960's.

Second, when psychology programs began forming in the 1950's, the only psychological paradigm in place in Argentina was psychoanalytic. Anti-positivism and the Peron administration had eliminated any imported psychology involving more empirical or research based methods and Argentina did not have a "home grown" alternative. Studying psychology meant studying psychoanalysis.

Psychiatry v. Psychology (i.e., M.D. v. Ph.D.)

Similar to other parts of the world, there was conflict in Argentina between psychiatrists and psychologists. In Argentina, doctoral level psychologists were often viewed as intellectuals but not doctors able to diagnose and "heal" (Knobel, 1975; Plotkin, 2001). However, with the advent of psychology programs, Ph.D. level psychologists were now the recipients of five years of psychoanalytic and psychotherapeutic study, training that most M.D.'s lacked. The response of psychiatrists was simple, "only those with a medical degree can perform the 'art of healing.'" Indeed, Marcos Victoria, the first director of the psychology Ph.D. program at Buenos Aires University was one of the most outspoken supporters of this belief.

At the same time, psychiatrists believed that psychologists could play in useful role in mental health (Knobel, 1975). According to Bleger and other members of the APA, the role of psychologists should be as "mental health agents" advocating for the importance of mental health services among the greater population. Of course, those deemed in need of mental health services should be attended to by a psychiatrist. For the APA, this provided the rationale for the training in psychoanalytic techniques and interventions psychologists would receive as well as the continued restriction on the actual practice of these techniques. While there were some psychiatrists who believed that there were "certain circumstances" in which a psychologist could provide interventions if supervised by a psychiatrist (Plotkin, 2001), there was consensus in the APA that psychologists could never understand enough of the biological and anatomical complexities of human pathology to heal on their own.

Although the main battle happened along lines of degree (i.e., Ph.D. v. M.D.) gender also played a part. Initially the majority of psychologists had been women and the profession was often seen as similar to the profession of teaching, a "female" and subordinate career. It is only with the election of Osvaldo Devries, the first male president of the APBA (Association of Psychologists of Buenos Aires) in 1968, and the consequent "masculinization" of the field that the subordinate role of psychologists was successfully challenged (Plotkin, 2003).

In this context, the greatest effort centered on liberating psychology from the APA model of training. The APBA passed regulations stipulating that only psychologists could teach courses offered within the organization. This proved successful as the aggregate number of psychologists increased allowing more university faculty positions to be held by Ph.D.'s relative to M.D.'s.

Psychologists also had to deal with a hostile government. Although the APA was usually untouched, the APBA was often the subject of propaganda campaigns and raids by government officials who branded members as Marxists and intellectual criminals. The conflict went so far as to result in the disappearance of Beatriz Perossio, then president of the APBA, in 1977, who was tortured and executed. In response to a hostile APA and Argentine government, the APBA became an advocate for the rights of psychologists in political and professional terms, performing as a pseudo-union.

In this context, the APBA cultivated strong relationships with universities. The APBA was also generally more open to different treatment modalities, an approach of great importance in treating middle and lower class Argentine citizens. This flexibility gave psychologists greater access to community and institution based mental health settings and

jobs than their APA peers. However, even though psychologists now began working as therapists, it was still technically illegal!

The ban on the legal practice of psychotherapy by psychologists lasted until the 1980's when, following intense lobbying and chants of "make legal what is legitimate," the APA and Argentine government finally removed its sanctions (Plotkin, 2003). The psychiatrists' "monopoly on mental health" was no more. Psychoanalytic training has since been offered to psychologists both through the APA, sanctioned by the IPA (International Psychoanalytic Association), and by institutions supported solely by the APBA. The latter are predominantly Lacanian, an indication of the still powerful influence of French psychoanalytic psychology in Argentina.

Psychology Following Economic Collapse

Since the late 1990's, the Argentine economy had been in a state of decline, culminating with a catastrophic political and financial collapse in December, 2001 (Plotkin, 2003). In a span of ten days there were five heads of state and, within the next year, the economy shrank by 15%. The peso was so devalued that the trade of goods and services, including mental health services, began to happen at "clubs of exchange" under a bartering system. Both psychiatrists and psychologists began to offer therapy sessions for free or in exchange for food or crafts.

In a larger sense, this also began to shift the focus to briefer therapy alternatives. Previously, Argentine mental health services had down-played the importance of medication in mental illness, viewing it simply as a means of getting the patient to a place where they could be analyzed (Vezzetti, 2003). However, with the economic crisis, this approach, as well as the utility of long analyses, has been questioned. Increasingly, quicker therapeutic methods have been employed as an influx of acutely distressed patients are treated.

At present, psychoanalysis continues to be the preferred theoretical, scientific, and applied psychology in Argentina (Bass, 2006). However, both psychiatrists and psychologists are working to develop more cost-effective, efficient methods of administration. Following the turmoil of the last ten years, Argentina is developing a more flexible, responsive mental health services system incorporating a more diverse range of theoretical approaches and interventions.

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Clinical Psychology to Join Efforts in Addressing the Mental Health Crisis in Ethiopia

Beyenech Tsegaye, Ph.D.

Introduction

I applaud the leadership of the Addis Ababa University for supporting the decision to train clinical psychologists at a graduate level in Ethiopia. This is indeed a visionary move and long overdue.

The field of psychology in the Ethiopian educational system can finally play a significant and much needed role in the mental health arena in Ethiopia. This ground work lays the foundation for psychologists to play a critical role in addressing the mental health crisis in the country. Such a move would also mean that psychiatrists and psychiatric nurses who have been carrying the sole burden will no longer be alone in addressing the mental health needs of Ethiopian citizens.

The establishment of graduate level education in clinical psychology, not only responds to the need for trained clinicians, but it also opens the opportunity for research to be done which will better serve the mental health community and the Ethiopian society in general. Clinical psychology will have the opportunity to make its way in Ethiopian society in the midst of the mental health crisis which confronts the nation.

It is with enthusiasm and excitement that I write this paper as I think about the future of psychology in the homeland that I left almost four decades ago. In this capacity I will offer a brief preliminary analysis of the position of psychological services in Ethiopia and its future role in the area of mental health.

For far too long, psychology was given a back seat in the health care delivery system in Ethiopia. Ethiopia as a nation and a society as a whole have not realized the contribution psychology makes in improving peoples' lives and its capacity in empowering people to reach their potential. In attempting to briefly discuss the reasons for the absence of psychology in Ethiopian society, I will offer some tentative perspectives on the issue.

If you are wondering why psychology is absent in the area of health care services throughout Ethiopia, you are not alone. Attempting to answer the question of why psychology failed to play a role in mainstream Ethiopia is a complex matter in light of the fact that there is no documented body of knowledge addressing this concern. An accurate and comprehensive response to this question requires additional study and research. Perhaps, with the help of the future researchers in the clinical psychology program at Addis Ababa University, we will come closer to finding an answer to this question.

The purpose of this paper is to offer the reader the good news about the developing opportunity for clinical psychology to impact the delivery of mental health services in Ethiopia. Although it is regrettable that it took the Ethiopian educational and public health systems this long to realize the vital role clinical psychology plays in the area of mental health, the change is highly welcomed!

Unlike the public view of psychology in western societies, psychology is not a household word in Ethiopia. The absence of psychological/psychiatric terminologies would have to be conceptualized in linguistically accurate and culturally relevant terms. Such an endeavor could no doubt be undertaken now that the path to further the development of clinical psychology is underway. Fekadu, Desta, Alem, and Price (2007) reported the difficulties they encountered in conducting research in the absence of effective translation of psychiatric and psychological constructs. Alem and Dereje (2003) attribute some of the problems of conducting research in the developing world to the deficiencies in assessment tools for cognitive and personality disorders. These psychiatrists' tireless work in advocacy and calling attention to the mental health service crisis seems to have finally paid-off through the establishment of the Institute of Psychology. The energized clinical psychology students will soon be challenged to develop theoretical models that are appropriate to the culture utilizing the large and rich body of knowledge in psychology to conduct research. To the faculty and the soon to become scholar practitioners and researchers, the work seems to be cut out for them to change the course of the impoverished mental health care delivery system of Ethiopia.

Brief Historical Perspective for the Absence of Psychology

In offering a brief perspective on the issue of why psychology took a back seat in the mental health system within the country, it would be helpful to consider at least a couple of perspectives. The first is the role of spirituality as it relates to healing and the second is the omission, until now, of clinical psychology from the educational system.

The role of the spiritual approach to healing for all kinds of ailments is basic for Ethiopians. The spirituality of the peoples of Ethiopia and their various belief systems are deeply rooted in ancient heritage and have a strong spiritual component in the ways they conceptualize illnesses, with a strong tendency to blame oneself when one becomes ill. There is a perception that both illness and symptoms are a manifestation of God's unhappiness with oneself and/or the work of the devil. Such views usually promote a readiness to pray in an effort to seek forgiveness and be healed. At times many bargain with God (*Silet*) to fulfill their wishes, seeking healing in exchange for doing some deeds in the name of a particular church.

The numbers of mentally ill in the nation have dramatically increased over time. Evidence of this increase can easily be witnessed by those visiting Addis Ababa regularly, as they see increasingly more and more individuals walking the streets aimlessly, lacking any purpose or direction. This drastic increase may have resulted from a combination of factors, such as the progressive disintegration of family and extended family units for various reasons. No doubt the unfavorable economic conditions coupled with the effects of long wars

have contributed to the displacement and separation of families to the cities in search of improved living conditions. Uprooted from their self-sustaining and harmonious farming communities individuals end up in impersonal and uncaring cities where there is no safety net available. This can no doubt set the stage for serious psychological turmoil within one's existence. Such groups of individuals become marginalized in their own country. While debate about these matters undoubtedly will take place amongst the students of the Psychology Institute, the fact remains that the increasing number of mentally ill persons is becoming visible and acknowledged by the average Ethiopian at this time. Working to understand the extent of the relationships between/among contributing factors will remain an objective to be addressed at the Psychology Institute.

In an effort to understand the issue of mental health in Ethiopia, the lack of help seeking behaviors of individuals with mental illness is seen by many to relate to the issue of stigma, although no supporting factual evidence for this was uncovered by this writer. Similarly, in the absence of research, one could easily assume that the tendency of Ethiopians' help seeking behaviors for any kind of illness (mental or medical) would be to be secretive for as long as was feasible. This could largely be due to the strong tendency for Ethiopians to blame themselves for any kind of illness. It also makes sense that the desired preference for healing in many cases consists of praying for divine intervention. Their deep religious beliefs stand strong and they exhaust the interventions from the spiritual healers through the church if they are of the Ethiopian Orthodox Christian Church, and from other types of indigenous healing practitioners. It is often the case that only after other interventions don't work, that the patient is willing to try modern medicine, as a last resort.

Since the patient wants to exhaust all of the other options for healing, (i.e. traditional medicine and /or spiritual intervention such as prayer and the use of Holy water for divine intervention and forgiveness from God) before resorting to modern medicine, their condition may have worsened and deteriorated. On the other hand, one could also assume that it is because of the absence of modern intervention (both medical and mental health) in the rural areas where the majority of the population lives that the patients' arrival at the clinic site is often only after the condition has deteriorated. My sense is that given the option to make independent decisions along with the availability of a clinic in close proximity, and the availability of funds, many patients most likely would still prefer a spiritual intervention. This is of course speculation and needs to be further investigated in a systematic manner.

I pose these questions to simply illustrate the need for research to better understand the motivating factors in the patients' decision making behaviors concerning types of interventions. Without research, one cannot be certain but can only speculate as my statements above suggest. This is why I am so delighted about the graduate level training in clinical psychology. Since the discipline has a strong tradition in research, coupled with the program producing highly skilled scholar practitioners as it evolves, I am confident that these questions and others will be investigated. These recent developments in Addis Ababa University brought vivid memories to mind involving a set of events contributing to my going so far away from my comfort zone to study psychology four decades ago. I always had a passion for working with people and in understanding human behavior and individual differences. My motivation to go abroad for higher education was mostly precipitated by the fact that the AAU administration made a decision regarding my field of study which was not my choice or my particular area of interest. This was done in an effort to deal with the overcrowding conditions of classrooms and to balance the heavy loads for some instructors. As a result I was assigned to major in Semitic Languages with a minor in Linguistics and French, which were not my choice at that time. Retrospectively, the study in Linguistics gave me a very good foundation and complementary knowledge to my then emerging interest in psychology. Feeling disillusioned, I considered the situation as a challenge, explored my options and focused on pursuing my education abroad. My interest in psychology became even stronger after the unfortunate experience of others imposing life changing decisions in the realm of my education.

Why Not Then?

Due to the strong presence of religious faith and power of the church in the lives of the average Ethiopian, philosophical discussions on the mind, body, and spirit were left to the clergy and religious leaders. It did not appear that the educational system recognized the importance of such discussions and investigations in the understanding of human behaviors. Therefore, one could speculate that the role of the Ethiopian Church played a major factor in the absence of the field of psychology and its applications in clinical settings in Ethiopia. On the other hand, some suggest that mental illness was not common. This reminds me of my Ethiopian friends in my undergraduate college years who were questioning why I would come this far to a different country to study psychology, expressing their belief that the church and the priests deal with such matters. Some argue that it is because the condition is considered a stigma and thus kept as a family secret or denied by the affected individual or family members, meaning the mentally ill are sheltered and protected by the family. However, there is another argument which involves the fact that there is no meaningful mental health delivery system in Ethiopia. There is only one mental hospital in the entire country that cares for the chronically mentally ill, leaving citizens outside of the nation's capital with no viable placements to take their loved ones for services.

Why Now?

There are many reasons why clinical psychology is being realized by the current educational leadership of the country. First and for most, credit should be given where it is due; to the psychiatry department staff of Addis Ababa University who played a critical role by calling attention to the mental health crisis of the nation. Not only did they carry the burden of providing mental health services under the most difficult

conditions, they also brought attention to the seriousness of the problem through published research conducted under very restrictive and limited conditions. Their tireless efforts in communicating the dire needs to the world I believe paved the way for the realization of the need for a clinical psychology training program in the country.

After facing the untenable task of providing mental health in Ethiopia, the psychiatry staff of Addis Ababa University continued to call for multi sector collaboration. Reporting the escalating need and demand for mental health services, Hanlon, et al. (2010) also outlined the lack of collaboration among the multi-sector groups such as the traditional healers, among others. Many blame the poor mental health conditions in Ethiopia on the brain drain issue the country is facing for many reasons. However, it is worthy of note, that the issue of brain drain with respect to health services is for the most part limited to those who are medically trained in Ethiopia and does not really include psychologists. The field of psychology was never given the opportunity to get the necessary attention and funding to train psychologists to be critical players in the mental health arena. It is in the area of medical education in which the government invested most. It is the medical doctors that Ethiopia used its limited resources to train who ended up fulfilling the health care service needs of the rich nations like the United States. Though one cannot blame those who left Ethiopia after receiving their medical degrees for wanting a better life, their choice to leave the country after being trained for free, certainly places Ethiopia at a great disadvantage, especially when these individuals did not contribute to their own educations. In their continued effort to bring attention to the mental health crisis in Ethiopia, Alem et al. (2010) accurately characterized the "globalization of medical education" to mean the supply of health care providers by poor nations like Ethiopia to rich nations like the United States without investing in their education. From my perspective, it is very disheartening to think about the nation that placed almost all its eggs in one basket by investing its very limited resources disproportionately on medical training while neglecting the areas of psychology and its specialty in mental health, with its potential impact in the welfare of individuals and the betterment of society in general, until now. A review of the WHO-AIMS (2006) on the mental health report on Ethiopia, offers a detailed account of the state of mental health in Ethiopia, basically confirming the absence of a basic infrastructure needed to provide services.

The Mental Health Crisis

One can easily assume that the mental health crisis in Ethiopia at this time is really a cumulative effect of the multitude of problems the population had to endure for a long time. This is a population that has been traumatized repeatedly as a result of wars and natural disasters. The cumulative effects of these man-made as well as natural disasters are difficult to effectively manage even for wealthy nations with good mental health delivery systems. Those who survived frequently were displaced as they relocated to different places, which often meant the dismantlement of families and support systems. Such individuals have a high probability of being traumatized. Most in the nation have experienced trauma of various types and many who survived had no meaningful intervention or support services to assist them in coping. In my opinion, it is no wonder that the prevalence rate of mental illness continues to grow.

The mental health program in Ethiopia is characterized by WHO as "one of the most disadvantaged" in the country and the prevalence rate of mental illness has exceeded 15% for adults and 11% for children. Ethiopia, like many other developing nations has been identified as neglecting the mental health needs of the people. Though the presence of NGOs is ever increasing, they have no involvement with mental health in the country. Despite the awareness of the WHO and the UN's recognition of the growing prevalence rate of mental illness, these entities presence and involvement so far does not seem to have made any meaningful impact with respect to mental health services. In a descriptive analysis of the admissions to the only psychiatric hospital in the nation, Fekadu et al. (2007) report how the lack of community based residential psychiatric services as well as the absence of effective rehabilitation centers are resulting in flooding the sole mental hospital in the country.

Ethiopia's decision to train psychologists in the country offers a wonderful opportunity. It is also hopeful that with the Institute of Psychology in place, these well trained psychologists will be in a position to impact not only the mental health service system but also become the change agents in various governmental agencies to effect and promote progress thereby establishing an effective and progressive mental health system at a national and community level. These change agents would have the capacity to meaningfully impact the government systems in much needed areas such as in early intervention programs, the elementary and secondary schools, in the universities, local hospitals and community centers.

Moving Forward to a Sustainable and a Stronger Mental Health System

During the past 3-4 years, I had the opportunity to visit Ethiopia and had the privilege of meeting the leading mental health professionals who are confronting the challenges of the mental health crisis in the country. I have talked with many of them and reviewed their publications, where they made their pleadings to health care professionals and leaders to make a difference and where they discussed their tirelessly efforts to bring much deserved attention to the nation's mental health crisis. Their energy and dedication inspired me and my desire to give back to the community grew and struck a light within me to start the steps in preparation to join their efforts to improve the delivery of mental health services in Ethiopia. Having been a mental health professional for over three decades providing my clinical services both in private and public settings in the United States, I feel blessed to be in a position to be able to continue my professional services to those in need. However, this time it is to my Ethiopian people I left close to four decades ago. As I finalized my deci-

sions and started to take the necessary steps to make my contribution possible (e.g., taking early retirement from my employment), the news about the establishment of the Psychology Institute at Addis Ababa University, simply topped the cake!

With the opening of the Institute, and the positive developments in the recently established psychiatry residency program within Ethiopia along with the plan to establish a masters level clinical psychology training program within the Psychiatry Department of Addis Ababa University, I see a big green light for a promising future of clinical psychology and the important role it will finally play in the development of a more effective mental health delivery system in Ethiopia.

To move forward in making the mental health service delivery effective, strong collaboration and team work is necessary. One of the ways of accomplishing this is through a strong professional association. I believe it is time to strengthen the Ethiopian Psychological Association (EPA). All efforts must be made to strengthen the association. EPA's strength will be instrumental in multiple ways; in the areas of training and education, setting the standards of practice, advocating, consulting, and research, among others. With the training of clinicians comes the need for a Mental Health Policy and a regulatory body at the Regional and/or National level. A stronger professional association could play a critical role in different areas. To this end, I would be delighted to hear from anyone interested in collaborating with me in organizing, establishing, strengthening, and/or mobilizing the Ethiopian Psychological Association. Please use my contact information below to reach me.

Correspondence related to this article should be sent to:
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References

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First Class of PsyD Students Graduates from California School of Professional Psychology Hong Kong Program

On May 14, 2011, the California School of Professional Psychology (CSPP) at Alliant International University awarded the PsyD degree in clinical psychology to a dozen students from the CSPP Hong Kong program's inaugural class. This program is the first US-based doctorate in clinical psychology to be offered in Asia. CSPP collaborates with the City University of Hong Kong to offer the program, and all classes are taught in English. These graduates will become leaders in applying clinical psychology in Hong Kong, Macau, China and Taiwan. Dr. Danny Wedding, Associate Dean for Management and International Programs at CSPP, commented, "We are especially proud of our first graduating class, and we are confident these students are among the best trained clinical psychologists in Asia." Dr. Wedding is pictured below with one of the graduates, Dr. Rose Kwok Wo Oi, and all of the graduating students, their faculty, and Alliant administrators are shown in the photo below.

Request for Info: Department Study Abroad Opportunities

Hello Division 52 Members:

The student committee of Division 52 is seeking to gather information on what types of study abroad and/or international immersion experiences are available across psychology programs. We hope to use this information to create a resource for students and/or faculty to find information on what types of study abroad experiences exist around the world. If you could take a few minutes and answer the below questions, we would greatly appreciate any information you can provide on what study abroad experiences exist around the globe! Responses can be sent back to me, at anhutchison@bsu.edu.

Please provide the following information, if available:

1. What types of study abroad or immersion experiences does your psychology department offer to your students (e.g. target student population, undergraduate or graduate focus, location, length of time, activities completed during experience, etc.)?
2. How do these opportunities further students' education?
3. How do these opportunities contribute to the study of psychology?
4. Any other information that you feel would contribute to this project.

Again, thank you so much for taking the time to provide this valuable information!

Ashley Hutchison, M.S.
Student Committee of Div. 52 - Member at Large
Second Year Doctoral Student
Counseling Psychology and Guidance Services
Ball State University

Addendum: Psychology in Russia Today

Alex Voronov, Harold Takooshian, Henry Solomon

As the International Psychology Bulletin (IPB) approaches its 15th anniversary in 2012, IPB continues to experiment with effective, new formats to extend psychology across national borders. Under its three editors Ivan Kos (1997-2004), Senel Poyrazli (2004-2009) and now Grant Rich, IPB has progressed far beyond simple APA news, to fill clear needs in the global psychology literature--offering regional reports, feature articles, book reviews, and peer-reviewed cross-cultural research.

One special challenge is to report the "indigenous psychologies" that naturally flourish within each region of the globe. Indigenous psychology has been defined as "the scientific study of human behavior or mind that is native, that is not transported from other regions and that is designed for its people" (Stevens & Gielen, 2007, p. 151). The largest index of indigenous psychologies has been compiled by the International Union of Psychological Sciences, IUPsyS (Stevens & Wedding, 2006).

In this first-ever addendum, IPB reports on indigenous psychology in Russia. In 2010, Russia celebrated its 125th anniversary of the birth of experimental psychology in 1885, with a major all-Russia conference hosted by the Institute of Psychology of the Russian Academy of Sciences, and resulting in an 888-page volume of Russian-language proceedings (Barabanshikova, 2010). Russian psychology has certainly seen many remarkable twists and turns during its 125 years—from the brilliant research by early giants (Vladimir Bekhterev, Ivan Pavlov, Alexander Luria) to the infamous murder of Bekhterev in 1927, and the outlawing of psychological testing ("testy") in 1936 by the Communist Party of the Soviet Union (Takooshian & Trusov, 1992). Today, some universities publish multidisciplinary journals which include a section of behavioral/psychological research.*

Professor Alexander Voronov of the State Academic University of Humanities in Russia was one of the key architects of the 2010 all-Russia conference. With the help of Professor Henry Solomon in New York City, they arranged a Skype teleconference in November of 2010 to provide a live "bridge" between Russian and American researchers. In this addendum, Voronov enlisted ten bilingual Russian colleagues and students to provide summaries of their current research, to give a snapshot of Russian psychology today. These summaries were minimally edited for uniformity of format, to retain their original tone as well as content.

Based on readers' comments, and the availability of future contributors, this addendum may serve as a model for future sections of IPB, offering English-language readers a window to indigenous psychologies in other regions—China, India, Africa, Latin America. Editor Grant Rich appreciates reader feedback, suggestions, and proposals at optimalex@aol.com. These summary abstracts are available on the Division 52 website.

References

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*One example is the Bulletin of the People's Friendship University—Psychology and pedagogy, which includes English-language summaries, and is accessible to those who know where to find this on the internet (http://193.232.218.57/?pagec=572).

Psychology International

Volume 22, Number 1, April 2011

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A Little Bit Can Go A Long Way:
A Reflection on Global Health Disparities

The latest issue of *Psychology International* can be accessed on the web at: http://apa.org/international/pi

Call for Student Research Manuscripts on Women and Gender

Deadline April 1, 2012

The Society for the Psychology of Women (SPW) of the American Psychological Association and the Association for Women in Psychology (AWP) seek research manuscripts for the 2012 Annual Student Prize for Psychological Research on Women and Gender.

Research Topics

The student research manuscript should focus on women's lives and issues, or more generally, on gender ideologies and behavior, from a feminist perspective.

Eligibility

Jointly-authored papers are eligible, but the first author must have been a student at the time the research was conducted, as indicated by a statement by the first author, in a cover letter accompanying the submission, specifying when and from what institution the first author obtained the degree, the name of the faculty who supervised the research, and the department of the supervising faculty. Entries should be of journal length and in *APA* style. Eligible papers include unpublished manuscripts as well as papers that have been submitted or accepted for publication. Published or presented papers are also eligible as long as they have a date of 2011 or 2012. All papers should be submitted in manuscript form, not as pre-prints or prints with information about submission and publication status provided in the cover letter.

Evaluation

Entries will be judged on theoretical creativity, methodology, clarity and style, and social importance of the research questions and findings for the psychology of women and gender.

Awards

A $250.00 prize will be awarded to the best paper. First and alternate winners will be announced at the 2012 meeting of the American Psychological Association.

Submission Procedure

Please attach a copy of your paper to an e-mail sent to the address below. Also, please send four (4) copies of the paper, a self-addressed, stamped postcard, and a self-addressed stamped business size envelope by April 1, 2012 to: Silvia Sara Canetto, Ph.D., Department of Psychology, Colorado State University, Fort Collins, CO 80523-1876 (silvia.canetto@colostate.edu)

The Submission Deadline for the 2011 AWP/SPW Student Research Manuscript Prize is April 1, 2012

Janet Hyde Graduate Student Research Grant

Proposals are being sought for Hyde Graduate Student Research Grants. These grants, each up to $500, are awarded to doctoral psychology students to support feminist research. The grants are made possible through the generosity of Janet Shibley Hyde, Ph.D., who donates the royalties from her book, *Half the Human Experience*, to this fund. Past recipients of Hyde Graduate Student Research Grants are not eligible to apply. Because the purpose of this award is to facilitate research that otherwise might not be possible, projects that are beyond the data analysis stage are not eligible.

Please send all application materials attached to a single e-mail message to both of the Hyde Award Co-chairs at the following addresses by September 15, 2011 (or March 15th for the spring deadline):

Dr. Mindy J. Erchull, merchull@umw.edu and Dr. Olivia Moorehead-Slaughter, oms@parkschool.org

Requirements:

1. Cover page with project title, investigator's name, address, phone, fax, and e-mail address
2. A 100-word abstract
3. A proposal (5-pages maximum, double-spaced) addressing the project's purpose, theoretical rationale, and procedures, including how the method and data analysis stem from the proposed theory and purpose.
4. A one-page statement articulating the study's relevance to feminist goals and importance to feminist research.
5. The expected timeline for progress and completion of the project (including the date of the research proposal committee meeting). The project timeline should not exceed two years.
6. A faculty sponsor's recommendation, which includes why the research cannot be funded by other sources. This letter should be attached to the e-mail with the application materials. Please do not send it separately.
7. Status of IRB review process, including expected date of IRB submission and approval. Preference will be given to proposals that have received approval.
8. An itemized budget (if additional funds are needed to ensure completion of the project, please specify sources)
9. The applicant's curriculum vitae
10. All sections of the proposal should be typed and prepared according to APA style (e.g., please use 12-point font)

Proposals that fail to meet the guidelines described above will not be reviewed.

Review Process

A panel of psychologists will evaluate the proposals for theoretical and methodological soundness, relevance to feminist goals, applicant's training and qualifications to conduct the research, and feasibility of completing the project.

Other Requirements

Only one application will be accepted per student, for each application deadline. Applicants who are involved in multiple projects that meet the submission requirements should choose the project that best fits the evaluation criteria (see "Review Process").

Within 24 months of receipt of the grant, recipients are expected to submit to the Hyde committee co-chairs a complete and final copy of the research document (e.g., a copy of the thesis, dissertation or journal manuscript based on the sponsored research), along with a 500-word abstract for publication in Division 35 newsletter. In addition, grant recipients shall acknowledge the funding source in the author's notes in all publications. Hyde award winners will be announced at the APA convention during Division 35 Social Hour. The names of the Hyde award winners may also be posted in Division 35 newsletter as well as on Division 35 web page and listserv.

Questions and other communications may be sent to the committee co-chair:

Mindy J. Erchull, Ph.D.
Co-Chair, Hyde Research Award Committee
Department of Psychology
University of Mary Washington
1301 College Avenue
Fredericksburg, VA 22401-5300
Phone: (540) 654-1557
E-mail: merchull@umw.edu

Call for Papers: Journal of Asia Pacific Counseling (JAPC)

www.kcajournal.org

Deadline: October 31, 2011

The Journal of Asia Pacific Counseling (JAPC) is an official publication of the Korean Counseling Association (KCA) that has more than 8,000 South Korean counselors and counseling psychologists as its members. Korean Counseling Association has long recognized the need for having an outlet for scholarly work that gives special attention to the applications of counseling with diverse populations in the Asia Pacific region. In setting up the Journal of Asia Pacific Counseling, many internationally renowned scholars have provided invaluable input regarding the title of the journal, potential editors, and the target audience.

JAPC is intended for both researchers and practitioners, and includes theoretical, empirical, and methodological articles in the areas of counseling interventions, prevention, career development and vocational psychology, supervision and training, assessment, multicultural aspects of counseling, and consultation.

All articles are published in English, and JAPC is issued twice a year in February and August. Please visit the homepage of the Journal of Asia Pacific Counseling (www.kcajournal.org) for full details on aims and scope, editorial policy, and article submission.

The next due date for manuscript submission is on October 31, 2011. Please submit manuscripts via e-mail (japc@snu.ac.kr), following the guidelines described on the homepage of the journal.

We hope you will seriously consider JAPC for your scholarship.

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International Employment Opportunities

Michael J. Stevens, PhD, DHC
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Cypress Health Region ECP (Canada), Clinical/ Developmental Psychologist: The Cypress Health Region is dedicated to excellence in its provision of quality health care services and is home to some of Saskatchewan's healthiest people. The Cypress Health Region s staff complement of 1m700 employees provide a variety of facility and community based services for the 46,000 residents living in 80 rural and urban communities in southwest Saskatchewan. With regional amalgamation successfully achieved, an annual operating budget in excess of $90M, and a new regional hospital. The ECP will provide both clinical and preventative psychological services to children from birth to school age and to their families and caregivers and to other agencies involved with these children. Clinical services will include assessment and diagnosis of developmental delays and other psychopathology, provisions of individualized programs for preschool children who are experiencing difficulties, and provisions of information and counseling to families, caregiver, and other agencies.

Qualifications:

- Masters degree or PhD in psychology, with preference to a doctoral specializing in clinical or developmental psychology, focusing on preschool population
- Eligible for registration with the Saskatchewan College of Psychologists and the Authorized Practice Endorsement with the Saskatchewan College of Psychologists
- Knowledge and ability to apply, empirically validated theories and interventions in the areas of clinical and developmental psychology. Ability to intervene at the individual and system level, and develop, implement, and evaluate preventative programs. Ability to apply the methods of assessment in the domains of development, psychopathology, intellect, and achievement for early childhood population.
- Knowledge of ethical and legal issues in practice with preschool children and families. Interpersonal skills to interact with clients, parents, health professionals, other agencies, and community groups.
- Valid driver's license

Private Practice (Canada), Clinical Psychologist: Step into a fully fee-for-service practice in Canada, the fourth best country in the world to live in according to the 2008 UN Human Development Report. If you're looking for an invigorating career change or have ever considered moving to Nelson, British Columbia - "Berkeley North" - for its great outdoor lifestyle and vibrant community feel, click on the videos and pictures at: http://web.me.com/toddkettner/Nelson_BC_Psychology_Practice_for_Sale/Home.html. You'd be joining two highly qualified and personable psychologists along with a great staff including a receptionist and psychometrist. We may also consider hiring an experienced psychologist as an employee. Feel free to contact Todd Kettner, PhD, RPsych at 250/352-6600 or e-mail kettner@summitpsychology.org for more information or just to chat about the possibilities.

Mobley Group Pacific Limited (China), I/O or Clinical Counseling Psychologist: Mobley Group Pacific Limited is a management consulting firm focusing on supporting organizations, management teams and business leaders in enhancing their effectiveness and organizational performance, with particular geographic focus in greater China and the Asia Pacific region. We are a rapidly growing firm making continuous efforts to source high caliber-talented professionals to become part of our quality consulting team to meet our growing business and client demands.

Qualifications:
PhD or advanced degree in psychology (I/O, clinical or counseling) or behavioral sciences, or MBA; business knowledge Fluent in both English and Mandarin is the prerequisite.

Responsibilities:

- Provide high quality professional services to clients in the areas of executive assessment, coaching, development planning, team development, management due diligence, organizational culture and 360-degree feedback; cross-cultural consulting services; leadership development program design; research, validation and publication; Hogan and other psychometric testing platforms; facilitation of strategy, planning and development events; and other related areas
- Contribute to business development, client management, consulting tool and process development
- Contribute to team learning
- Contribute to the client-focused, high professional standards, supportive team, learning and balanced work-life culture of MGP
- Coordinate and collaborate with the professional staff in the Shanghai and Hong Kong offices
- Continue your personal and professional development

Location:
Will be based in MGP Shanghai or Hong Kong office, with periodic travel to clients mostly located in the greater China and Asia-Pacific regions; some travel in Europe and the US is also expected.

Compensation and Benefits:

- Competitive base salary and performance-based bonus structure
- Health Insurance or Social Benefits required by the local Government
- Holidays and Professional Learning/Training Opportunities

Contact:
Stella Wang, Consultant
stellaw@MobleyGroupPacific.com

Please make sure to send a cover letter and curriculum vitae along with your application.

Serco (Germany), Clinical Social Worker: Serco is a leading provider of professional, technology and management solutions to the federal government in the areas of national security and intelligence, human capital management, IT and professional services, and engineering and logistics. We advise, design, integrate and deliver solutions that transform how clients achieve their missions. Headquartered in Reston, VA, Serco North America has approximately 11,000 employees who have helped transform government and public services around the world.

We have an immediate need for a licensed clinical social worker to provide clinical social work services in Bamberg, Germany as part of a multi-disciplinary US Army health care team to patients who are eligible beneficiaries of the Military Health Care System. The LCSW will utilize short-term and long-term care models, patient and provider consultation models, and education to address behavioral health concerns and medical conditions related to behavioral health needs of service members and their families. This individual works primarily with service members and their families in behavioral health settings to address issues related to deployments to conflict areas. Services will include screenings, clinical assessments, treatment, case management, consultation, referral, and education that are IAW professional standards of the National Association of Social Workers, Army Medical Departments' standards, and DOD-directed Clinical Practice Guidelines.

Individuals hired for these positions are awarded status to work in Germany under the Status of Forces Agreement. This exempts the employees from German taxes on salaries received for work under this contract. Additionally, individuals will be eligible to use the military commissary, base exchange, gas station, bank, clubs, and recreation facilities. Tuition reimbursement for full tuition for grades K-12 at Department of Defense Dependent Schools is available; this is on a space-available basis (reimbursement of tuition for International Schools is considered on a case-by-case basis). Reimbursement for relocation (up to $20,000 total for the trip there and back plus cost of family member plane tickets) is available. Use of the military medical treatment facility is available on a space-available, for fee basis; an international health care plan is available.

Serco also offers a comprehensive benefit package including group medical coverage, paid vacation and sick leave, 10 paid federal holidays, life insurance, 401K with match, and tuition reimbursement for college courses.

The duties of this job opportunity include:

- Assess and resolve complex social, economic, and psychosocial problems that may impact on the service members' and their families' medical treatment while an outpatient, an inpatient, or under evaluation for medical discharge from the service
- Conduct psychosocial evaluations and provides therapeutic interventions, including crisis intervention, to individuals, groups, and families
- Serve as a behavioral health referral resource and subject matter expert in behavioral health-related programs to medical staff in various medical settings
- Evaluate individual and family systems; assess patient functioning within work, family, and routines of daily living; identify areas needing continued support, resources, and treatment
- Provide services for high-risk populations (e.g., service members pending discharge due to physical and/or behavioral health injuries and illnesses, service members wounded as a result of military duties, and families of services members killed in action)
- Support local and remote soldier readiness processing events that prepare large numbers of service members for mobilization, deployment, demobilization, and redeployment. This includes behavioral health services, screening, evaluation, management, and referral for those with deployment-related symptoms, and providing service members with assistance with administrative requirements
- Develop comprehensive treatment care plans IAW behavioral healthcare standards
- Coordinate services for soldiers/patients who move out of local area to ensure continuity of care
- Assist soldiers and patients with navigating healthcare systems
- Coordinate and assist installation community agencies and the MTF in the referral process; provide reintegration training and services for those returning from deployment
- Educate patients, their families, commanders, and healthcare staff on community resources
- Maintain complete and accurate records and documents all patient contacts and services; maintain inpatient and outpatient medical records IAW AR 40-66
- Participate in departmental quality assurance programs

- Present patient cases in case staffing meetings
- Conduct crisis intervention services/on-call duties as assigned
- Participate in and/or directs research and conducts clinical investigations in behavioral health or social work

US International University (Kenya), Clinical Psychologist: USIU is a private, not-for-profit, chartered university located on the outskirts of Nairobi, Kenya, accredited by the Western Association of Schools and Colleges and The Commission for Higher Education in Kenya. USIU boasts a diversified faculty and student body from over 40 nations, with a vibrant history of growth and development.

We are expanding our psychology programs to offer our first doctorate degree in clinical psychology (PsyD), and we are also expanding our master of arts in psychology to include an MA in clinical psychology and an MA in marriage and family therapy.

We have four openings for full-time faculty who are licensed psychologists with an earned PhD or PsyD to start with us in September 2011 or early 2012, preferably with a two-year renewable contract. We seek faculty who meet three or more of the following criteria:

- Licensed clinical psychologists, who hold an earned doctorate in psychology.
- Direct clinical expertise to include assessment, diagnoses, psychotherapeutic treatment, and general scope of practice in individual and group therapy.
- Direct family therapy expertise with families, couples, and children.
- Academia/faculty experience in clinical psychology, preferably at the doctorate level.
- Clinical supervision experience and continuing education preferably with pre-doctorate or post-doctorate students, or with private practice consultation and supervision expertise.
- Psychometric expertise in application of objective, cognitive, and projective testing.
- Direct research experience and expertise in clinical psychology.

Applicants are requested to email a letter of interest and resume/curriculum vitae to Dr. Carol J. Watson, USIU Coordinator of Psychology Programs, E-mail: cwatson@usiu.ac.ke, Website: www.usiu.ac.ke

Applications will be accepted until positions are filled.

New Zealand, Clinical Psychologists: We have full-time clinical psychologist vacancies to fill for community mental health and other service organizations. You must have: Ph.D. in clinical psychology; current practicing license. A minimum of two-years post-supervisory experience. The ability to receive your New Zealand psychologist registration with clinical scope; the desire to commit two years or longer. E-mail: office@alignrecruitment.com; Phone: +64 3 366 8779: Fax: +64 3 377 6770; Web www.alignrecruitment.com. An expatriate American is available to assist with all enquiries.

LaSalle College of the Arts (Singapore), Art Therapist: Contemporary in focus and innovative in approach, LaSalle College of the Arts has been nurturing generations of creative practitioners. As a leading specialist tertiary institution for contemporary arts education, LaSalle offers the most comprehensive range of degrees and diplomas. Here is an opportunity for you to contribute to the creative arts and play a role in establishing Singapore as a global arts hub.

Art therapy in Southeast Asia is a new and developing field. At LaSalle, the Art Therapy Programme is multi-culturally driven and includes the integration of eastern and other international behavioral norms.

LaSalle is seeking a dynamic, appropriately qualified and trained individual to lead the Masters in Art Therapy Programme in Singapore. This position will report to the head of school.

Responsibilities:

- To teach and develop students to become practicing art therapists while also promoting the profession and its standards of practice in Singapore
- To conduct and coordinate seminars and workshops on art therapy practice at hospitals, schools and other organizations in Singapore and abroad
- To be responsible for administering the Art Therapy Programme in its entirety and managing part-time lecturers and placement providers
- To undertake clinical work in the field and to include students in this placement activity whilst conducting relevant clinical research
- To initiate workshops that promotes art therapy in Singapore and abroad
- To be actively involved in own creative process/ research

For more information, contact: hr_4@lasalle.edu.sg.

NYU (Abu Dhabi), Clinical Psychologist: NYU Abu Dhabi has an exciting opportunity for a full-time clinical psychologist located in Abu Dhabi, UAE. At NYU Abu Dhabi, wellness counselors play a critical and multifaceted role as mental health professionals, mentors, advisors, and administrative colleagues. The wellness counselor (Clinical Psychologist II) provides clinical assessment, psychotherapy, group therapy, and crisis intervention and management for an internationally diverse student body, and oversees a multidisciplinary team of counselors trained in a variety of different psychological

disciplines.

To qualify, you must have a PhD in clinical psychology, US state license, the ability to obtain license in Abu Dhabi and three years' post-doctoral clinical experience. Experience supervising postdoctoral and doctoral clinicians and/or other counseling staff members preferred. Experience as a college or university counselor is highly preferred, with a preference for candidates with experience in the UAE or other gulf country. Experience with a diverse adolescent or college population required. Experience with alcohol and other drug issues, and/or eating disorders preferred. The ideal candidate must understand the wider perspective of the institution and how student life supports and fits into the broader educational mission. He/she understands and appreciates the intellectual, emotional, social, psychological, and political development of undergraduate students in a diverse international community committed to intellectual rigor and ethical values, and thinks creatively and critically about programs, services, and resources in order to provide the best possible environment to support students. The selected candidate will adapt to new work situations, people, ideas, procedures, and organizational structures in order to accommodate an evolving work environment; exhibit maturity, reliability, composure, and stability under pressure in order to handle on-the-job challenges; has excellent communication, mediation, and consultative skills and is able to work with students, faculty and staff from many backgrounds; and possesses the ability to build successful relationships with faculty, students, parents, and co-workers.

NYU offers a superior benefits package, which includes NYU tuition for self and eligible family members, generous vacation, medical, dental, and pension plans. For more information and to apply for this position online), visit our web site at: www.nyucareers.com.

University of Western Australia (Australia), School of Psychology: The University of Western Australia is seeking to appoint a senior academic in psychology to a newly created tenurable position in the School of Psychology. The appointed person will be a leader in the field with an international reputation for research, a track record in attracting significant research funds, and the capacity to develop a team of world-class researchers and educators of clinical psychologists. The appointee will play a key role in the integration of clinical research and teaching with the existing research clusters in the school. Applications from those with specialist expertise in pediatric clinical psychology, clinical neuropsychology, or clinical health psychology are particularly encouraged to apply. Although a higher-level Winthrop Professorial appointment is preferred, applicants may be considered for a slightly more junior professorial position depending on their level of experience. In the recent (January 2011) Excellence in Research for Australia (ERA) assessment, psychology at UWA achieved the highest ERA rating of 5 and was one of only three psychology schools in Australia to achieve this level. The school hosts research programs in Australian Research Council funded centers, including the Centre of Excellence in cognition and its disorders and the Bushfire Co-operative Research Centre. Additionally, the school has a number of staff funded by the Australian Research Council on prestigious professorial or future fellowships. The school has research and teaching strengths in cognitive science and cognitive neuroscience (including developmental psychology, developmental disorders, neuropsychology, and perception), abnormal cognition and clinical psychology, and social psychology and organizational psychology.

For further information regarding the positions contact: Winthrop Professor David Morrison, Head of the School of Psychology on Tel: +61 8 6488 3240, or e-mail david.morrison@uwa.edu.au. Closing date: August 26, 2011.

The University offers an attractive salary with benefits including 17% employer superannuation, generous leave provisions, fares to Perth (if applicable) for the appointee and dependants, together with a substantial relocation allowance. The information for candidates' brochure which includes details to lodge your application may be found via a link at http://www.jobs.uwa.edu.au/; or at https://www.his.admin.uwa.edu.au/Advertising/3541CandidateInformation.pdf; or by contacting Ms. Toni Pilgrim, Human Resources, e-mail toni.pilgrim@uwa.edu.au.

Carleton University (Canada), Department of Psychology: The Department Of Psychology at Carleton University invites applications from qualified candidates for a preliminary (tenure-track) appointment in quantitative methods at the rank of assistant professor beginning January 1, 2012. Applicants must have a PhD., demonstrated excellence in teaching statistics and methodology, and must possess a strong commitment to research and scholarship, as reflected in publications, with preference to publications in health, environment, or digital media. The successful candidate will have the ability to develop an externally-funded, high quality research program; will be committed to effective teaching at the undergraduate and graduate level; and will contribute effectively to the academic life of the Department. The Department is interested in candidates who are able to teach advanced statistics at the graduate level including ANOVA, regression, multivariate statistics, and other advanced statistical techniques (e.g., HLM, SEM), and basic and advanced statistics at the undergraduate level. The successful candidate will have a program of research applying their methodological skills to areas of psychological research that contribute to Carleton's strategic research direction in health, environment, or new digital media.

The Department of Psychology offers opportunities to explore psychology's major fields including health, developmental, cognitive, applied, forensic, and personality/social. We also have intellectual ties with academic units offering degrees in

cognitive science, child studies, human-computer interaction, and neuroscience. Carleton has offered undergraduate degrees in psychology since 1953 and graduate degrees in psychology since 1961. The Department of Psychology currently offers undergraduate programs in the Faculty of Arts and Social Sciences as well as the Faculty of Science. Graduate programs in psychology are offered at the master's and doctoral levels. Further information on the department is available at http://www2.carleton.ca/psychology/.

Please send applications to Chair, Department of Psychology, Carleton University, 1125 Colonel By Drive, Ottawa, ON. K1S 5B6. Fax: (613)520-3667. Applications and reference letters can be sent by email to psychchair@carleton.ca. Applicants should include a curriculum vitae, a statement outlining statistical expertise, a statement describing current and future research interests, examples of publications, and materials relevant to teaching experiences. Interviews will include both a research talk and a lecture on an advanced statistical method. Applicants should ask three referees to write letters directly to the Chair. Applications will be considered after July 31, 2011, or until the position is filled.

Located in Ottawa, Ontario, Carleton University is a dynamic research and teaching institution with a tradition of leading change. Its internationally recognized faculty, staff, and researchers provide more than 24,000 full- and part-time students from every province and more than 100 countries around the world with academic opportunities in more than 65 programs of study. Carleton's creative, interdisciplinary, and international approach to research has led to many significant discoveries and creative work in science and technology, business, governance, public policy, and the arts. As an innovative institution, Carleton is uniquely committed to developing solutions to real world problems by pushing the boundaries of knowledge and understanding daily.

British Columbia Mental Health and Addiction Services (Canada), Licensed Psychologist: As part of the provincial mental health services continuum, BC Mental Health & Addiction Services provides a diverse range of specialized, "one-of-a-kind" tertiary level mental health services to residents across all geographic areas in British Columbia. These include adult/geriatric and neuropsychiatry services located at Riverview Hospital, Adult Forensic Psychiatric Services located at the Forensic Psychiatric Hospital, plus six regional clinics, and Child and Youth Mental Health Services located at BC Children's Hospital. In addition to direct services, BC Mental Health & Addiction Services acts as a support and resource to service providers across the province, and contributes to research and education. BC Mental Health & Addiction Services is an agency of the Provincial Health Services Authority (PHSA), which plans, manages and evaluates selected specialty and province-wide health care services across BC. The Provincial Health Services Authority (PHSA) embodies values that reflect a commitment to excellence. These include:

- Patients first
- Best value
- Results matter
- Excellence through knowledge
- Open to possibilities

These dynamic roles are ideal for accomplished psychologists who exude both professionalism and compassion.

- Licensed Psychologist
- Forensic Psychiatric Services
- Port Coquitlam, Nanaimo and Prince George, BC
- *Regular and Temporary Full Time Opportunities*
- Monday to Friday 0830-1630
- Salary: $40.39-$52.66/hour

Ongoing opportunities are available at the Forensic Psychiatric Hospital in Port Coquitlam, the flagship inpatient Forensic Hospital for the province of BC and an accredited site for APIC internship programs as well as our six forensic regional outpatient clinics across BC (Nanaimo, Kamloops, Surrey, Vancouver, Prince George, and Victoria). The secure, 190-bed hospital is an internationally acclaimed, state-of- the-art facility and serves individuals referred by the courts for treatment and assessment. Under the general direction of the Provincial Director, FPSC (Forensic Psychiatric Services Commission), and the Director, Clinical Services, consistent with the ethics and standards of the College of the Psychologists of BC, and Forensic Psychiatric Services, this position requires an in-depth knowledge of psychology including developmental theories, family and social dynamics, treatment and behavior management modalities, and psychological testing and interpretation. The ability to prepare comprehensive written assessment for the courts and referral agencies and in-depth knowledge of the justice system, complex legal issues, and other forensic matters is necessary. Our team of psychologists has an in-depth knowledge of relevant legislation, sound knowledge of the service delivery system for offenders and their families at the local and regional and provincial level, and the ability to testify in the court as an expert witness. Opportunities are available to become a key member of a team providing forensic assessment and multidisciplinary treatment plans. This role will also provide supervision to practicum students and the opportunity for research.

You must possess or be eligible for current registration with the College of Psychologists of BC as a clinical psychologist, with a doctorate in psychology, and specific training in the field of clinical psychology. Post-graduate training in the field of forensic psychology is also desirable. The knowledge, skills and ability required for this position are consistent with a licensed clinical psychologist and three years experience in clinical psychology, with experience in forensic psychology preferred.

Criminal record check required. Travel required, need own

vehicle.

Applications will be accepted until position filled. For further information about these opportunities contact Linda Hand at 875-7216 or lhand@phsa.ca.

For more information on all that the PHSA has to offer, visit: http://careers.phsa.ca.

For more information about the agency that you are interested in, please visit the website at www.bcmhas.ca.

Cape Breton District Health Authority (Canada), Clinical Psychologists: The Cape Breton District Health Authority, Sydney, Nova Scotia, has immediate openings for permanent full-time clinical psychologists. The successful candidates will have doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology. They must be registered or eligible for registration with the Nova Scotia Board of Examiners in Psychology.

The positions in Child & Adolescent Mental Health Services require the candidates to work in a multidisciplinary team to provide assessment, individual and group treatment to children and adolescents patients aged 0-19 years with a variety of mental health disorders. Our multi-disciplinary approach involves services within our district as well as within the community, including consultation to schools, daycares, children's aid services, and group homes.

The Autism Intervention Program again involves a multidisciplinary team approach including in-home behavioral interventionists, psychiatry, social work, psychology, and occupational therapy. The program requires a candidate that can provide clinical leadership in the areas autism assessment and diagnosis, pre-school assessment, behavioral intervention, and the provincial EIBI program, as well as help facilitate the transition to schools for children with autism both in an outpatient and home setting. The Autism Program is part of a province wide initiative and utilizes the pivotal response therapy (PRT) model for early intervention. There are also opportunities to be part of larger, multi-site research projects within this program.

Child and Adolescent Services is an outpatient service involving a multidisciplinary team approach including in-home behavioral interventionists, psychiatry, psychology, and social work. The service requires a candidate that can provide mental health assessment, psycho-educational assessment, and treatment to patients up to age 19, including those with neuro-developmental disorders, and their families. Customized training opportunities are available to further develop skills in these specialty areas for interested and motivated candidates.

The position in the Adult Mental Health Clinics requires that the candidate work in two separate clinics to provide assessment, individual and group treatment to adults aged 19 years and older with a variety of mental health disorders. Our multidisciplinary approach involves services within our district as well as the community including consultation to primary care physicians, family services, addiction services and other community agencies.

The Eating Disorders Clinic involves a multi-disciplinary team approach including diagnostic assessment, consultation and direct treatment services for individuals with eating disorders across the lifespan. Consultation service is also provided to pediatrics, inpatient psychiatry, and primary care physicians for patients requiring inpatient admission and treatment. Clinical supervision is provided to the dietitian assigned to the Eating Disorders Clinic.

The Adult Outpatient Mental Health Clinics are an outpatient service involving a multidisciplinary team approach, individual and group treatment, consultation, and education. The team may involve psychiatry, psychology, social work, nursing, and occupational therapy. For further information, or to apply with cover letter and resume please contact:
Janine Hussey Manager, Recruitment & Retention Cape Breton District Health Authority, 1482 George Street Sydney, NS B1P 1P3; Fax: (902)567-7224; E-mail: husseyjan@cbdha.nshealth.ca.

University of Hong Kong (China), Department of Psychology: Founded in 1911, The University of Hong Kong is committed to the highest international standards of excellence in teaching and research, and has been at the international forefront of academic scholarship for many years. Ranked 21st among the top 200 universities in the world by the UK's *Times Higher Education*, the University has a comprehensive range of study programs and research disciplines spread across 10 faculties and about 100 sub-divisions of studies and learning. There are over 23,400 undergraduate and postgraduate students coming from 50 countries, and more than 1,200 members of academic and academic-related staff, many of whom are internationally renowned.

Applications are invited for the appointments as assistant professor in clinical psychology in the Department of Psychology, from January 1, 2012, or as soon as possible thereafter, on a 3-year fixed-term basis, with the possibility of renewal, or with consideration for tenure after satisfactory completion of a second fixed-term contract. Applicants should possess a PhD degree in clinical psychology, with a good record of research, together with a track record of teaching, or sound indicators of promise as a teacher, in clinical psychology. The appointees are expected to maintain an active research program, be responsible for teaching courses at both graduate and undergraduate levels, and supervise research students. Information about the Department can be obtained at http://www.hku.hk/psychology.

Annual salary for an Assistant Professorship will be in the range of HK$484,980- 749,520 (approximately US$ =HK$7.8) (subject to review from time to time at the entire discretion of the University). The appointments will attract a contract-end gratuity and University contribution to a retirement benefits scheme, totaling up to 15% of basic salary, as well as leave, and medical/dental benefits. Housing benefits will be provided as applicable. At current rates, salaries tax does not exceed 15% of gross income.

Further particulars and application forms (152/708) can be obtained at http://www.hku.hk/apptunit/ or from the Appointments Unit (Senior), Human Resource Section, Registry, The University of Hong Kong, Hong Kong (Fax: +852 2540 6735 or 2559 2058; E-mail: senrappt@hku.hk). Review of applications will begin on July 15, 2011, and will continue until the posts are filled. Candidates who are not contacted within 3 months of the date of their applications may consider their applications unsuccessful.

University of Hong Kong (China), Department of Educational Psychology: The Department invites applications for several positions with prospect for substantive appointments in counseling psychology, including school guidance, school/educational psychology, special needs and learning difficulties, and other areas of psychology. Ranks are open with preference given to assistant professor/associate professor levels. Applicants should have (1) excellent academic qualifications including a doctoral degree in psychology or education, (2) a strong research background in areas that will contribute or add to the existing strengths of the department, (3) strong commitment to excellence in teaching and scholarship, and (4) a track record of programmatic research and publications. The appointees will (a) teach postgraduate and undergraduate courses (including theory and applied courses for postgraduate degree programs), (b) supervise postgraduate students, and (c) assist in administrative matters. Both English and Chinese are used as the medium of instruction. Salary will be highly competitive, commensurate with qualifications and experience. The University offers a comprehensive fringe benefit package, including medical care, plus a contract-end gratuity for appointments of 2 years, and housing benefits for eligible appointees. Further information about the University and the general terms of service for appointments is available at http://www.cuhk.edu.hk/personnel. The terms mentioned herein are for reference only and are subject to revision by the university. Application procedure send full resume, copies of academic credentials, a publication list and/or abstracts of selected published papers, together with names, addresses and fax numbers/e-mail addresses of three referees to whom the applicants' consent has been given for their providing references (unless otherwise specified), to the Personnel Office, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong. Closing date: November 30, 2011. Fax: +852 269 6 1462 by the closing date.

Danish Institute for Study Abroad (Denmark), Psychology Program Director: DIS seeks an accomplished administrator and excellent teacher in the field of psychology to lead its growing undergraduate psychology program and the child diversity and development program in cooperation with the Associate Program Director and two additional fulltime administrative employees. The Program Director will expand the curriculum, hire and mentor psychology faculty, teach one course per semester (courses are taught in English), and participate in other projects and academic leadership tasks at DIS. The successful candidate will work directly with U.S. students and Danish faculty and administrators as well as faculty from U.S. partner universities. The Director will be part of an energetic and innovative program team and report to the Associate Director of DIS.

Primary responsibilities:

- Manage and develop the DIS psychology program and child diversity and development program
- Expand the psychology curriculum, with emphasis on experiential learning elements such as practicum and academically integrated study tours
- Mentor faculty and ensure high academic quality of psychology offerings
- Teach undergraduate psychology course(s)
- Cooperate with U.S. universities on curriculum development

Experience and skills:

- PhD in psychology
- Demonstrated organizational and leadership skills; providing vision and competent leadership in development of academic programs
- Minimum of 3 years successful teaching experience from the U.S. at college/university level
- Demonstrated administrative and interpersonal skills in leading and motivating faculty and staff in an intercultural setting

Personal qualifications:

- Self-motivated, proactive, and determined to reach goals
- Well organized, strategic, creative, analytical
- Flexible, service-minded and team-focused
- Study abroad experience preferred

Submit a curriculum vitae and an application letter. Also, submit a one-page essay describing your philosophy of intercultural teaching and learning for undergraduate psychology students. Include references and teaching evaluations. Salary and start date negotiable.

For more information please contact Malene Torp, Associate Director, DIS, Copenhagen mto@dis.dk or (+45) 3376 5491. Submit to job@dis.dk. Title the E-mail "Psychology Pro-

gram Director".

For more information about DIS: www.dis.dk.

American Hospital Services Group (Guam), Licensed Psychologist: American Hospital Services Group LLC currently seeks a licensed psychologist who has completed a pediatric fellowship in psychology to work as a civilian contractor at U.S. Naval Hospital Guam. Malpractice Insurance is covered by under the Federal Tort Claims Act.

http://www.med.navy.mil/sites/usnhguam/information/Pages/default.aspx

Schedule:
Monday - Friday 7:30am - 4:30pm

Housing allowance, retention bonus, relocation reimbursement and 8 hours of PTO every 2 weeks.
Job description:
Responsible for and applies psychological procedures and techniques, including interviewing, behavioral assessment, cognitive-behavioral therapy, and psychological testing/ psychodiagnostic testing, in the evaluation, diagnosis, and treatment of psychological and neuropsychological disorders. The following are desirable skills:

- Individual, family, and group psychotherapy, and couples therapy, alcohol and drug treatment evaluations
- Consults with medical personnel, legal authorities, military commanders, and school districts, as required
- Maintain accurate and current notes in both the Department of Psychology records and patient medical records of all patients seen, as appropriate, and produces reports of evaluation and/or treatment, as required
- Participate in military specific training (for example, training to perform Command Directed Evaluations, security clearances, Military Training Instructor clearances, pre-post deployment screening, PTSD, combat stress)
- Conduct applied research and clinical investigations in clinical/behavioral health psychology

Requirements:

- Have a Doctor of Philosophy (PhD) or (PsyD) degree in clinical or counseling psychology from an APA-accredited psychology program
- Completion of pediatric fellowship in psychology
- Have and maintain a current license to practice psychology in any one of the 50 states, the District of Columbia, Puerto Rico, or the U.S. Virgin Islands. Valid BCLS Card is required to start
- 24 months of experience in the last 36 months

For more information contact Patrick Hoffman at 1-800-872-8626, ext, 235 or email a copy of your curriculum vitae to phoffman@ahsg.us.

Koya University (Iraq), Applied Psychology Program: This position primarily provides co-leadership with national faculty at Koya University for the establishment, operations, and ongoing development of the first graduate program in applied psychology in Iraqi Kurdistan, as a major initiative for capacity building in the Iraqi mental health field. The position entails oversight of all aspects of the program to ensure that it meets appropriate educational standards in the preparation of versatile, competent, and professionally responsible clinical professionals who can then contribute to further growth of the discipline. It additionally calls for a knowledge of contemporary psychological science, theory, and models of practice with individuals and systems, and the ability to culturally adapt them to the clinical needs of Kurdish and Arab populations. These needs include but are not limited to trauma recovery, treatment strategies for depression and anxiety, prevention of gender-based violence and suicide, and elimination of stigma and promotion of human rights for those with psychological problems.

The position secondarily entails responsibility for close collaboration in program planning, implementation, and evaluation with the leadership of the Trauma Rehabilitation and Training Center and clinical supervision of the center staff and additional mental health workers in the Burn Hospital and other sites as needed. It also calls for consultation regarding services at the Qalawa Camp, the Duhok Mental Health Center, and other related mental health projects as needed, including the integration of psychosocial approaches and psychoeducation into the delivery of primary care treatments. The majority of beneficiaries will be victims of human rights abuses, and the position requires both academic and work-related experience in trauma-informed mental health care.

The individual will report to the Country Director and be based generally three days a week on the campus of Koya University and the rest of the week in Sulaimaniya or on field visits in Iraqi Kurdistan. The position also may involve national and international travel.

Education and/or Experience**:**
The position requires a doctorate in clinical or counseling psychology with successful completion of a 1-year internship accredited by the American Psychological Association. It also requires graduate level psychology teaching experience; and an academic appointment as assistant, associate, or full professor at a university is preferred. State licensure and diplomate certification in clinical or counseling psychology by the American Board of Professional Psychology or other advanced training certification are also preferred. Significant experience in cross-cultural psychology, trauma-related assessment and therapies, clinical supervision, and international educational and training programs is strongly recommended as well.

Competencies:
The position requires a well-informed general background and interest in academic and professional psychology and in international mental health research, practice, and education. In addition, the following qualities are of particular value:

- Sensitivity to and respect for cultural diversity and alternative values and understandings of the world
- Adaptability to new and unfamiliar circumstances; willingness to listen to and learn from others, and to examine one's own assumptions and interactions
- Self-awareness; appropriate balance between professional authority and personal humility; and comprehensive openness to new perspectives and challenges
- Primary commitment to local capacity- building and inclusive style of decision-making and power-sharing
- Initiative, creativity, and flexibility in problem-solving and program development
- Integration of overall conceptual vision with careful attention to practical detail, as needed
- Ability to work both in close collaboration with colleagues and independently
- Leadership skills in administering projects, supporting and motivating staff, modeling dedication and healthy work ethic, setting effective short- and long-term objectives and plans, and monitoring and evaluation of programs
- Organizational skill in data analysis, report and grant-writing, budget management, and staff development
- Ability to accept and to delegate responsibilities and to exercise oversight, as needed
- Familiarity with educational and teaching modalities, design of syllabus and lecture formats, facilitation of classroom discussion, construction of testing and assessment, and use of computer-based learning
- Experience in mentoring graduate students regarding academic and professional issues; sensitivity to students' needs; and ability to work with students with a wide range of backgrounds, experience, skill levels, and language proficiency
- Expertise with psychotherapy and psychosocial theories and techniques with different populations
- Knowledge of preventative and systemic strategies for mental health promotion
- Excellent communication skills with students, colleagues, and representatives of other programs; capacity to provide direct, timely, and constructive feedback, and to establish clear policies and procedures
- Ability to manage stress and meet all work demands while maintaining positive self-care
- Demonstrated concern for broad-based issues of human rights and social justice
- Strong understanding of and adherence to professional standards of conduct
- Support of all values, policies, and goals of Heartland Alliance and Koya University

Victoria University (New Zealand), School of Psychology: Victoria University of Wellington, from its location in Wellington, the capital city, undertakes teaching and research to maintain, disseminate and advance knowledge. Victoria provides worldwide opportunities for its staff as members of the international network of scholars, scholarship, and research, providing diversity and depth to our perspectives. Internationally Victoria is recognized as a leading University in New Zealand and Australia, and as a world leader in a number of areas of scholarship and enquiry. The appointee will contribute to teaching at the undergraduate level, teach adult clinical psychology at the graduate level, supervise postgraduate research, and assist with the administration of the clinical program. Qualifications required include a PhD, a postgraduate qualification in clinical psychology and recent clinical practice experience, as well as evidence of successful teaching and research. Eligibility for registration as a psychologist under the Psychologists' Act (1981) is also required.

We are particularly interested in appointing someone with expertise in the following areas: adult mental health and psychological assessment. Applications close August 30, 2011. For more information and to apply online visit http://vacancies.vuw.ac.nz.

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International Psychology Bulletin

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Editor
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Associate Editors
Richard Velayo
Harold Takooshian

Incoming Editor
Grant Rich

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http://www.internationalpsychology.net

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Submission Guidelines for
Research Articles
International Psychology Bulletin

Research article submissions: The IPB publishes peer-reviewed research articles that deal with issues related to international psychology. The review process takes approximately two months. The manuscripts can be up to 1500 words and should be submitted to Dr. Grant J. Rich at optimalex@aol.com. The manuscript must be written in APA style described in the Publication Manual of the American Psychological Association.
Specifically, please pay attention to the following:

- Use Times New Roman font if possible.
- Please do not use electronic style sheets, forced section breaks, or automatic footnotes.
- On the first page of the manuscript, include the title of the manuscript and names and affiliation of the authors.
- On this page, you should also indicate the contact person, their e-mail, and phone number.
- Please make sure that authors' names or any identifying information is not included in the manuscript, with the exception of the title page.
- Avoid figures if possible.
- Cite your sources within the manuscript based on the APA style.
- List your references at the end of the paper based on the APA style.
- Present tables at the end of the manuscript, after references, each on a separate page.

To learn more about the APA style, refer to http://apastyle.apa.org. If you do not have access to the APA publication manual, you may want to get a recent journal article published by one of the APA journals and try to familiarize yourself with the APA style through this method.

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SUBMISSION DEADLINES
International Psychology Bulletin

For smaller articles (op-ed, comments, suggestions, etc.), submit up to 200 words. Longer articles (e.g., Division reports) can be up to 1,500 words and should be submitted to Dr. Grant J. Rich at optimalex@aol.com.

Submission Deadlines: Spring issue March 31st

Summer issue June 30th

Fall issue September 15th

Winter issue December 15th

A new journal…Cancún…Brooklyn…a new task force… What's next? A new President!

Lynn Collins, Ph.D.
President, Division 52

This is my last Presidential Column. I have enjoyed my Presidential year's highlights and challenges. As I leave the position, there are many exciting continuing and new initiatives within Division 52. Nancy Sidun has created a task force on human trafficking that is growing in membership. Please contact her if this is an area of interest to you (n.sidun@hawaiiantel.net). Grant Rich of Alaska joins us as the new Editor of the International Psychology Bulletin. We are grateful to Senel Poyrazli for her vision and energy that lead to the development of this excellent scholarly newsletter. It was Senel's and Wade Pickren's exceptional perseverance in the process of taking Division to the next level that led to the development of a division journal. Joy Rice, Federal Advocacy Coordinator reports that there are important discussions underway with the new administration regarding healthcare, including mental health care. Ani Kalayjian has developed an active global mentoring program. We have an impressive group of new Fellows again this year, thanks to more hard work from Harold Takooshian. And, of course, thanks to Michael Stevens' ever watchful eye on the budget, the Division is financial healthy. Of course, there are many others who continually contribute enormous amounts of their time and energy to this division that deserve our gratitude. Moving forward, I would like to draw attention to a few upcoming events.

Division 52 journal is slated to be launched at APA!

The Division's first journal, *International Perspectives in Psychology: Research, Practice, & Consultation,* will soon be launched! The journal will publish conceptual models, methodologies, and research findings to help study and understand human behavior and experiences around the globe from a psychological perspective. We are currently in the midst of working with APA to select an editor for the journal. We hope that Division members will spread the word about this journal to help us generate a wealth of energetic and talented authors, editorial board members, and reviewers, as well as an avid, international readership. This is an exciting development with unlimited potential to advance Division 52's mission. If think that you or someone you know would make an excellent editor, please be sure to nominate her or him by emailing Gary Vanderbos (Gary@APA.org) or me (Collins@LaSalle.edu).

Get Ready for Cancún in April 2010

It has been an exciting year, and some of its momentum led to the Division 52 mini-convention at Western Psychological Association's meeting in Cancún, Mexico. The 2010 WPA Convention will be in Cancún from April 22 to April 25, 2010 at the Fiesta Americana Condesa Cancún. Many thanks to Stanley Sue, current WPA President, and Chris Cozby, WPA Executive Director, for their generosity in giving us time within their program.

Under the leadership of Lynette Bikos of Seattle Pacific University, the Division 52/WPA mini-convention will feature three keynote speakers and four symposia covering international research in these four areas: Early Childhood Education Research, The Globalization of Higher Education, Adolescence/Young Adulthood, and Around the World. The speakers and topics are:

- John Thoburn, Ph.D., ABPP, Zeba Ahmad M.A., Jake Bentley M.A., & Kendra Jones M.A. (Seattle Pacific University) "International Disaster Psychology Ethics: A Social Justice Model Imbedded in a Family Systems Paradigm."
- Dr. María del Pilar Grazioso (Universidad del Valle de Guatemala) "Cultural Incidents Present during the Establishment of the Therapeutic Alliance."
- Henry C. Ellis, Ph.D. (University of New Mexico, USA) "Educational Consulting Experiences in Kuwait and the United Arab Emirates."

In addition to an excellent line up of speakers presenting on other topics, including Phil Zimbardo (see the WPA convention for details), many of WPA's invited speakers will also be addressing international issues:

- Stanley Sue (University of California, Davis). "10th Year Anniversary of the Surgeon General's Report on Mental Health: Culture, Race and Ethnicity"
- Mary E. Kite (Ball State University) "The More Things Change…: Teaching About Stereotyping and Prejudice" American Psychological Association G. Stanley Hall Lecture
- Hector Betancourt (Loma Linda University, USA, and Universidad de La Frontera, Chile) "Psychological Perspectives on Social Inequities: Culture, Behavior, and Health Disparities"
- Chi-Ah Chun (California State University, Long Beach) "East Is East, and West Is West. What Happens When The Twain Shall Meet? Studying Stress and Coping in Asian Immigrants"
- Terry A. Cronan (San Diego State University) "Ethnic and International Disparities in Cancer: Incidence, Diagnosis, and Treatment"
- Jo Ann Farver (University of Southern California) "Acculturation and the Well-Being of American Immi-

grant Families and Children: Factors that Produce Differences in Adaption"

- Mirta Margarita Flores Galaz (Autonomous University of Yucatan) "Mexican Ethnopsychology: Assertiveness"
- James M. Jones (University of Delaware) "The TRIOS Factor: A Psychocultural Theory of Surviving and Thriving in the African Diaspora"
- Rolando Diaz-Loving (National Autonomous University of Mexico) "Values, Beliefs and Norms of the Mexican Family: 50 Years of Socio-Cultural Premises"
- V. Nelly Salgado de Snyder (National Institute of Public Health, Mexico) "Psychological and Social Determinants of Health among Mexican Immigrants in the U.S."
- Invited Symposium. Steven Lopez (University of Southern California). "Remembering Dr. Rogelio Díaz-Guerrero: A Pioneer in Cultural Psychology"
- Daniel L. DeNeui (Southern Oregon University) and Leticia Chacón Gutiérrez (Universidad de Guanajuato, Campus León) "Construyendo Puentes: The Value of Research and Teaching Collaborations Between Mexican and U.S. Scholars"

I mention this conference first because attending requires some planning. You will need a passport to fly to Cancún. Information on passports is available from this State Department website: http://travel.state.gov/passport/passport_1738.html. The current time to process new passport applications is approximately six weeks. The WPA Hotel and Transportation page will soon have a link to a travel service that has developed tours for WPA attendees. In addition, you can reserve airport transportation with them. You can find more information about WPA and the convention at http://www.westernpsych.org/convention/index.cfm.

Join the board at the 2010 Division 52 Mid-Winter Meeting in Brooklyn, NY!

The Division 52 Board is having its Mid-Winter Meeting in Brooklyn, NY in conjunction with Eastern Psychological Association, March 4th through 7th. The Executive Committee meeting will take place the afternoon of Saturday March 6 and on the morning of Sunday, March 7. You are welcome to join us. For the sixth year, EPA offers a two-day international program, consisting of 10 sessions from 9:00 am till 4:20 pm on Friday and Saturday. Our Division 52 invited speaker Philip Zimbardo of Stanford speaks on Thursday night. The Division 52 program will be posted at our Division website, http://www.internationalpsychology.net, shortly.

There are, of course, many other developments taking shape within the division. If you really want to be "in the know," please feel free to join us at our board meeting at EPA in Brooklyn, NY, or our sessions and informal dinner out in Cancún, Mexico! With that said, I turn the Division over to the very able Danny Wedding.

Lynn H. Collins, Ph.D.
La Salle University
Philadelphia, PA, USA

LEAVING A LEGACY TO DIVISION 52

A Call for a Charitable Bequest to APA Division 52

If you are interested in making a charitable bequest or other planned gift to the Division of International Psychology, contact Michael Stevens at (309) 438-5700 or at mjsteven@ilstu.edu or Lisa Straus at (202) 336-5843 or at estraus@apa.org.

Grant Rich appointed IPB Editor for 2010-2012

The APA Division of International Psychology is pleased to announce the appointment of Grant J.M. Rich, PhD as the new Editor of the *International Psychology Bulletin* for a three-year term, from March 1, 2010 through December 31, 2012.

Rich has an unusually broad background in many ways. He is a licensed social worker and massage therapist, who received the Bernice Neugarten Award for his doctoral research in developmental psychology at University of Chicago in 2001. He has a decade of experience as a researcher, author, editor, and professor at several institutions from Maine to Alaska, before joining the psychology faculty of the University of Alaska Southeast in Juneau, AK. His colleagues describe Rich as an ideal editor for IPB—an able, friendly, conscientious, tech-savvy professional with a heart for service, who does well at whatever he undertakes.

Outgoing Editor
Senel Poyrazli, Ph.D.
Pennsylvania State University - Harrisburg

Incoming Editor
Grant J. Rich, Ph.D.
University of Alaska Southeast - Juneau

Rich is the third Editor of IPB. The founding Editor was Ivan Kos, PhD of New York City (1997-2004) whose dedicated efforts established the *International Psychology Reporter* (IPR) as a premier newsletter for international psychology. The second editor was Senel Poyrazli, PhD of Penn State-Harrisburg (2005-2010), whose talents brought IPB to new heights--as a re-named and much-expanded on-line resource, which became indexed by APA Psyc-EXTRA, and also developed a peer-review section to publish high-quality original research. Rich hopes to build on Poyrazli's work, as the division also plans to launch its new APA journal in 2011: *International Perspectives in Psychology: Research, Practice, Consultation*.

The three-person IPB search committee was chaired by Editor Senel Poyrazli, with Associate Editors Harold Takooshian and Richard Velayo. After President Lynn H. Collins reviewed their unanimous recommendation and supporting materials, she offered Rich the position, which he accepted. The committee was impressed by the excellence of all three candidates for Editor, and encouraged the other two to become more involved in division publications.

Rich expects to participate in the division's midwinter meetings in Brooklyn, NY on March 5-7, 2010. He welcomes comments and inquiries by email, optimalex@aol.com.

Division 52 Membership Survey

Click here to access survey
(Web link)

Dear 52 Member:
We have developed a survey to measure your opinions of your membership in Division 52. The purpose of the survey is to determine how we can improve the services that the Division provides to enhance your membership in the division. Please send any comments or questions to Janet2822@aol.com and susan.nolan@shu.edu

We welcome your input.

We appreciate your participation in this survey.

Division 52
at Western Psychological Association
Cancún, Mexico
Saturday, April 24, 2010

8:00 – 9:20 Peninsula III, Symposium: **Early Childhood Education Research.** Henry C. Ellis, University of New Mexico, Chair and Discussant. Our panel of research presentations regarding early childhood education research provides showcases a diversity of methods, topics, and international teams. The first presentation, researchers investigated the transferability of both psychometric qualities and the utility of the Response-to-Intervention Model as a pre-kindergarten screen to children in Ecuador. In the second presentation, researchers compared the way that U.S. and Korean teachers used concrete manipulatives to teach fractions to third graders. In our third presentation, researchers evaluate the effectiveness of an after-school Learning Center model for elementary students with limited English proficiency. Our Discussant will summarize themes, contradictions, and limitations across the three research projects and, following the presentations, will moderate a short discussion with those in the audience.

(1) PRE-KINDERGARTEN SCREENER: IMPLEMENTING THE RESPONSE-TO-INTERVENTION MODEL IN ECUADOR. Arlene Ortiz, Fordham University; Manuela Guimarães, New York City Department of Education; Patricio Romero, Mineola School District; Tara C. Raines, Gwinnett County Public Schools. (2) U.S. AND KOREAN TEACHERS USE CONCRETE MANIPULATIVES TO TEACH FRACTIONS. Kammy K. Kwok, Jae H. Paik, Susan Courey, & April Won, San Francisco State University. (3) EFFECTIVENESS OF LEARNING CENTER ON LIMITED-ENGLISH-PROFICIENT STUDENTS IN 1ST-4TH GRADES. Tomas E. Martinez, Ellen F. Sugar, Elizabeth Ramirez, & Candace Siegmund, Pepperdine University.

9:30 – 10:20 Peninsula III, Paper: **Neurophenomenology: The Mind and the Brain.** Susan Gordon, Southbury Clinic for Traditional Medicines. Lynn H. Collins, past President Division 52/ International Psychology, La Salle University, Chair.

10:30 – 11:20 Peninsula III, Invited Speaker: **Educational Consulting Experiences in Kuwait and the United Arab Emirates.** Henry C. Ellis, University of New Mexico. Division 52/ International Psychology Program Chair and Host: Lynette H. Bikos, Seattle Pacific University.

11:30 – 12:50 Peninsula III, Symposium: **The Globalization of Higher Education.** Maria del Pilar Grazioso, Universidad del Valle de Guatemala, Chair and Discussant. International travel, such as study abroad, is not new to colleges and universities. While the topic has been of interest to researchers for a number of years, researchers are revisiting this topic with more sophisticated questions. Specifically, they are attempting to identify predictors that enhance the sojourn experience as well as delineate the factors that sustain the gains that are made. This symposium assembles four presentations that discuss research and issues related to internationalizing the curricula at the undergraduate and graduate levels. Our Discussant will summarize themes, contradictions, and limitations across the four research projects and, following the presentations, will moderate a short discussion with those in the audience.

(1) PROFESSIONAL DEVELOPMENT OUTCOMES ASSOCIATED WITH INTERNATIONAL INTERNSHIPS. Kari A. Knutson Miller, California State University, Fullerton; Amber M. Gonzalez, University of California Santa Barbara; Monique E. Arteaga, Amy P. Chaikittirattana, & Scott W. Ramirez, California State University, Fullerton. (2) INTERNATIONALIZING THE PSYCHOLOGY CURRICULUM. Rashmi Jaipal, Bloomfield College NJ. (3) GLOBE-TREKKING: PRELIMINARY RESULTS FROM A LONGITUDINAL, MIXED METHODS INVESTIGATION. Lynette H. Bikos, Julia Kocheleva, Rebekah L. Forman, & Nicole Myr, Seattle Pacific University.

1:00 – 2:20 Peninsula III, Symposium: **Adolescence/Young Adulthood.** Lynn H. Collins, past President Division 52/ International Psychology, La Salle University, Chair and Discussant. Adolescence is a developmental period that is generally recognized in most modern societies. This panel of presentations provides insight into the similarities and differences among samples of Brazilian, Japanese, and Iranian-American adolescents and young adults. Across the three presentations, the researchers used qualitative and quantitative strategies to tease out the complexities and nuances of the experience of adolescence for these participants. Our Discussant will summarize themes, contradictions, and limitations across the three research projects and, following the presentations, will moderate a short discussion with those in the audience.

(1) RITES OF PASSAGE: AGE AND GENDER DIFFERENCES IN A BRAZILIAN SAMPLE. Sherri McCarthy,

Northern Arizona University-Yuma; Luciana Karine de Souza, Universidade Federal de Minas Gerais. (2) JAPANESE EMERGING ADULTS' PERCEPTIONS OF ADULTHOOD: A QUALTIATIVE STUDY. Kayoko Furusawa, Izumi Kamioka, & Teru Toyokawa, Pacific Lutheran University; Reiko Kogo, Kinki University. (3) PERCEIVED PARENTING, SELF-ESTEEM, AND GENERAL SELF-EFFICACY OF IRANIAN AMERICAN ADOLESCENTS. Gila Frank, Ronita Saeed, Mark P. Otten, & Scott W. Plunkett, California State University, Northridge.

2:30 – 3:20 Condesa III, Invited Speaker: **Cultural Incidents Present During the Establishment of the Therapeutic Alliance.** Maria del Pilar Grazioso, Universidad del Valle de Guatemala. Division 52/International Psychology Program Chair and Host: Lynette H. Bikos, Seattle Pacific University.

3:30 – 4:20 Peninsula III, Invited Speaker. **International Disaster Psychology Ethics: A Social Justice Model Imbedded in a Family Systems Paradigm.** John Thoburn with Zeba Ahmad, Jake Bentley, & Kendra Jones, Seattle Pacific University. Lynn H. Collins, past President Division 52/ International Psychology, La Salle University, Chair.

4:30 – 6:00 Peninsula III, Symposium: **Around the World.** John Thoburn, Ph.D., Seattle Pacific University, Chair and Discussant. Around the world, psychologists are creating multi-disciplinary teams and using clever diverse research techniques to study a variety of phenomena. This symposium showcases some of the best. The first presentation takes us to Belize. Our presenter will review survey data concerning psychological disorders and treatments and discuss practitioner types and access to practitioners. For example, did you know that the 2008 Belize telephone directory lists zero psychologists and zero psychiatrists, but does include massage therapists and pages of physicians? Our second presentation takes us to Thailand, where the presenter will discuss the results of research regarding the ongoing recovery efforts following the devastating Indian Ocean Tsunami. We will also be treated to a peek at the International Tsunami Museum (and examine evidence regarding its effectiveness) which has been open for three years. In our third presentation, researchers provide a comparison of positive psychological dispositions and mental health among college students from the U.S., Japan, Thailand, and Australia. The researchers will discuss how these attitudes (e.g., optimism, zest, gratitude, and grit) serve as protective factors and promote mental health. In our final presentation our presenter will describe how his team used the "lost letter technique" (dropping addressed/stamped envelopes near mailboxes) as used to measure attitudes toward people of Middle-Eastern descent in various cities in the US and Europe. Our Discussant will comment on the methods, results, and findings of these presentations as well as facilitate a short discussion with the audience.

(1) HEALING MODALITIES IN BELIZE. Grant J. Rich, University of Alaska Southeast. (2) NATURAL DISASTERS: MENTAL HEALTH, RESILIENCE, AND EDUCATIONAL INTERVENTIONS. David N. Sattler, Western Washington University. (3) A CROSS-NATIONAL COMPARISON OF POSITIVE PSYCHOLOGICAL DISPOSITIONS AND MENTAL HEALTH. Douglas C. Smith, Southern Oregon University; Michael Furlong, University of California, Santa Barbara; Richard Langford, University of Hawaii, West Oahu; Edward Krishnan, Assumption University; Megan Zurawski, & Gloria Herrera, Southern Oregon University. (4) AN INTERNATIONAL LOST LETTER STUDY: MEASURING ATTITUDES TOWARDS MIDDLE-EASTERNERS. Afshin Gharib, William Phillips, Matthew Davis, Stephanie Lemp, & Janie Kuhlman, Dominican University of California.

For more information, contact the Division 52/International Psychology at WPA/ Cancun Program Chair, Lynette H. Bikos, Ph.D., lhbikos@spu.edu

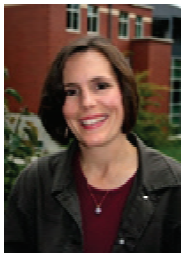

Are You a Psychologist who was a Peace Corps Volunteer?

Merry Bullock at the APA International Directorate and several members of Div. 17 - Society of Counseling Psychology are looking for psychologists who were Peace Corps Volunteers. If you are one, please contact Mary at mbullock@apa.org.

International Program
EASTERN PSYCHOLOGICAL ASSOCIATION

www.easternpsychological.org

4-7 March 2010, **Boardroom**, Brooklyn New York Marriott Hotel,
For any details: www.internationalpsychology.net, or Harold at 212-636-6393

Mid-winter Board Meeting on SATURDAY (noon) till SUNDAY (noon), March 6-7
International supper, 7-9 pm Saturday. RSVP to Uwe: ugielen@hotmail.com

FRI, 9 – 10:20 am, **Symposium: Dragon Seed: A photographic journey through New York Chinatown**
Chair: **Weihua Niu** (Confucius Institute, Dyson College, Pace University)
Presenter: **Uwe P. Gielen** (St. Francis College) Discussants: **Ting Lei** (CUNY), **Jonathan Palumbo** (St Francis College), **Chris LaSalle** (St. Francis College)

Migration has now made New York City the home of the largest Chinese community in the Western Hemisphere, with 500,000 persons of Chinese descent. This slide presentation combines a visual tour of New York's Chinatown, with social psychological and demographic data on this community. It also describes on-going research on the psychosocial adaptations of Chinese youth.

FRI, 10:30 – 11:50 am **Symposium: Ethnic psychology today**
Chair: **Michael Meir** (Technical Career Institutes)
Counseling and Psychotherapy in Turkey. **Şenel Poyrazlı** (Penn State University), **Süleyman Doğan** (Ege University-Turkey), & **Mehmet Eskin** (Adnan Menderes University-Turkey).
Psychology and Italian-Americans. **Elizabeth G. Messina** (Lenox Hill Hospital)
Greek psychology. **Artemis Pipinelli** (Lehman College) & **Thomas Mallios** (New York City)
Armenian psychology. **Samvel Jeshmaridian** (Borough of Manhattan Community College) & **Ani Kalayjian** (www.meaningfulworld.com).
Hispanic psychology. **Rafael Art Javier** (Saint Johns University).
Feminist attitudes: Does culture make a difference? **Christine Graham**, **Delilah Opal Hutson-Ellenberg, Mahfuz F. Ahmed** (Fordham University)
Discussant: **Rivka Bertisch Meir** (www.DoctorRivka.com), **Ayse Çiftçi** (Purdue University)

How has psychology developed differently among diverse ethnic and nationality groups? This symposium brings together leading psychologists from diverse backgrounds to review indigenous or ethnic psychologies today in the USA and overseas.

FRI, 12 – 1:20 pm, **Psychologists at the United Nations**
Chair: **Ani Kalayjian** (www.meaningfulworld.com)
A brief history of psychology organizations at the United Nations. **Siroon P. Shahinian** (Great Neck, NY).
Psychology organizations today. **Susan A. Nolan** (Seton Hall University).
Teaching psychology to United Nations personnel. **Anthony J. DeLuca** (Rector, Ignatius University) & **Harold Takooshian** (Fordham University).
Stress reduction among U.N. peace-keepers. **Neal S. Rubin** (Argosy University- Chicago).
Student internships at the United Nations. **Wismick Jean-Charles** (International Assoc. of Applied Psychology).
Discussants: **Deanna Chitayat** (Chair, APA team at the United Nations), **Florence L. Denmark** (Pace University), **Sherry Dingman** (Marist College), **Janet A. Sigal** (Fairleigh Dickinson), **Cidna Valentin** (CUNY Graduate Center)

How have psychologists become increasingly involved in United Nations activities in recent years? This symposium describes past activities, current roles, and future opportunities.

FRI, 1:30 – 2:50 pm, **International psychology: A fascinating history**
Chair: **Lynn H. Collins** (LaSalle University)
Paris 1889, Yale 1929: Comments on the First and Ninth International Congress of Psychology. **John D. Hogan, PhD** (St. John's University)
New York in 1912: Carl Jung's lectures. **Sylvester Wojkowski** (Jungian Psychoanalytic Association)
Margaret Mead in New York City. **Mark E. Mattson** & **Robert W. Rieber** (Fordham University)
The International Council of Psychologists, past and future. **Ann M. O'Roark** (President, International Council of Psychologists)
Psychologists at the United Nations: The early years. **Edwin P. Hollander** (Baruch College & CUNY Graduate Center).
Discussant: **Neal S. Rubin** (Argosy University- Chicago)

Though it was only in 1997 that the American Psychological Association welcomed International Psychology as its

Division 52, international psychology can trace a very colorful history, starting with the odd meeting that was the first International Congress at the new Eiffel Tower in 1889.

FRI, 3 – 4:20 pm, **International Psychology poster session** (in the Exhibit Hall, posters 1-7, plus others)

FRI, 3 – 4:20 pm, Workshop: Becoming More Involved in International Psychology: Why and How?
Chair: **Harold Takooshian** (Fordham University)

How can students and professionals become more involved in international psychology? In this unusual three-part workshop: (1) Takooshian begins with a handout and brief message on the question, Why become more involved in global psychology? (2) Then in a series of 12 three-minute "flash presentations," 12 speakers each offer a helpful fact-sheet accompanied by a brief message on their specific avenue to become more involved. (3) This is followed by 30 minutes of moderated discussion of the topic. These practical factsheets are intended to advise on specific topics for diverse groups: students (such as overseas internships, cross-national research), faculty (teaching overseas, cross-national testing), practitioners (consulting overseas), researchers (publishing cross-cultural articles and books), and others (joining international groups, working with the U.N.).

SAT, 9 – 10:20 am, **Symposium: Internationalizing the Curriculum in Psychology**
Chair: **Richard S. Velayo** (Pace University)
Implications of Web 2.0 technologies on the internationalization of teaching, research, and practice of psychology. **Richard S. Velayo, Mercedes McCormick, Sara Pollack, Smith Kidkarndee** (Pace University)
Students' views on internationalizing the curriculum. **Jennifer M. Lancaster** (Saint Francis College).
The contribution of economic and political freedom to disciplinary vitality. **Michael J. Stevens** (Illinois State University & The Lucian Blaga University, Romania).
Internationalizing the Psychology of Women curriculum. **Florence L. Denmark & Maria Klara** (Pace University).
Discussants: **Joan C. Chrisler** (Connecticut College), **Jason R. Young** (Hunter College), **Gloria G. Grenwald** (Webster University), **Kate A. Richmond** (Muhlenberg College).

What can teachers and others do increase the internationalization of the field of psychology? This symposium brings together several experienced teachers and researchers to discuss the importance of technology, the political context, student involvement, and other important factors.

SAT, 10:30 – 11:50 am, **Symposium: Publishing cross-cultural and international work: Why and how?**
Chair: **Danny Wedding** (Missouri Institute of Mental Health).
Books. **Uwe P. Gielen** (Saint Francis College), & **Robert Dimbleby** (Hogrefe & Huber Publishers).
Book Reviews. **Danny Wedding** (Editor, APA PsycCritiques).
Bulletins. **Senel Poyrazli** (Penn State University), & **Grant J. Rich** (University of Alaska Southeast).
Journals. **Lynn H. Collins** (LaSalle University).
Students. **Jennifer Doran** (New School for Social Research), & **Jason R. Young** (Hunter College).
Discussants: **Parviz Morewedge** (Global Scholarly Publications), **Uwe P. Gielen** (Saint Francis College)

As international psychology continues to expand, how can individuals publish their work in cross-cultural and international psychology? This symposium assembles several experienced editors to review the growing number of options open to researchers, teachers, practitioners, and students of psychology.

SAT, 12 – 1:20 pm, **Paper session: Cross-cultural psychology: Research and applications**
Chair: **Renée Goodstein** (Saint Francis College)
A comparison of the teachings of Buddhism and clinical psychology. **Marvin Levine** (Stony Brook University)
Anxiety, appraisal, and coping: A cross-cultural comparison of American and Nigerian undergraduates. **Comfort B. Asanbe** (College of Staten Island/CUNY), **Sarah Iyabode Aiyedogbon** (Kogi State Polytechnic, Nigeria), **Krista Supino** (College of Staten Island CUNY)
Child trafficking and commercial sexual exploitation: Promising prevention and reintegration programs. **Yvonne Rafferty**, **Ilisa Naukam** (Pace University)
Seeking continuity beyond discontinuities: Sense of coherence and psychological well-being in refugees. **Padmini Banerjee** (Delaware State University)
A mother's progressive voice: How Ann Dunham shaped Barack Obama's values and world-view. **Dinesh Sharma** (St. Francis College)

SAT, 1:30 – 2:50 pm, **Symposium: Applied Photo-Psychology**
Chair: **Joel Morgovsky** (Brookdale Community College)
Presenters: **Joel Morgovsky** (Brookdale Community College), **Iris E. Fodor** (New York University), **Rod Golden** (Santa Clara University) [This is in tandem with the D52 international photo exhibit at nearby St. Francis College]

SAT, 3 – 4:20 pm, **Symposium: Increasing life-saving human organ donations: A global challenge for psychology**
Chair: **Samvel S. Jeshmaridian** (Borough of Manhattan Community College)
How much is life-saving organ donation a global human rights issue? **Heather M. Wynne**, **Nolia Hill**, **Isolene Roberts**, **Iveta N. Stephanopoulos**, **Nicole R. Tomlinson**, **Carolyn Volpe** (Fordham University)
Can a DVD reduce misconceptions of potential organ donors? **Peggy Ann Barnett** & **Christine Hoskins** (Fordham), **Katherine Stavrianopoulos** (John Jay), **Samvel**

Jeshmaridian (Borough of Manhattan Community College) Social behavior and peer-to-peer campaigns on college campuses. **Bobbie Watkins** (New York Organ Donor Network) The experience of receiving a life-saving organ. **Ted Lawson** & **Glenda Daggert** (New York Organ Donor Network)

Since 1988, human organ transplantation has saved tens of thousands of lives worldwide. How can we best remedy the increasing global shortage of life-saving human organs? This panel brings together several experts of diverse backgrounds to focus on the question, "What new methods are behavioral scientists developing, to increase the supply of life-saving human organs?"

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A Role for Psychology in the Shadow of the UN Conference on Climate Change

Susan A. Nolan, PhD,
APA-NGO Representative to the United Nations

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Psychology International can be accessed at: http://www.apa.org/international/pi

Investigating International Immersion Learning in Doctoral Psychology Training Programs

If you are a faculty member or doctoral student who has interest, experiences, or special knowledge of *international immersion learning* in doctoral programs in Counseling and Clinical Psychology programs, you are invited take part in a qualitative research study investigating this phenomenon. Specifically, we are interested in learning (a) how programs integrate international immersion learning experiences, (b) what faculty and students anticipate as intended outcomes of such experiences, (c) what successes and obstacles are being faced (and tackled), and (d) what are future possibilities for this element of globalization.

Your participation would involve a 50 minute (or so) telephone or internet-based interview about the phenomenon. To learn more about participation, please contact Lynette H. Bikos, Associate Professor of Clinical Psychology, Seattle Pacific University, lhbikos@spu.edu, 206.281.2017.

The project has been approved by SPU's Institutional Review Board (IRB #091002014; valid through 1/10/2011).

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Measuring Intercultural Attitudes of Undergraduates Who Study Abroad: Scale Development and Validity

Julia Shaftel and Timothy L. Shaftel
University of Kansas

The Intercultural Student Attitude Survey was created to assess changes in the attitudes and future plans of undergraduate college students who study internationally. The scale measures 6 constructs: cross-cultural open-mindedness, ability to manage stress, adventurousness, self-confidence, and disposition toward an international career and foreign language study. Existing scales do not cover these areas and do not focus on topics and settings pertinent to undergraduate students. Concurrent validity of the ISAS was assessed with the Cross-Cultural Adaptability Inventory (CCAI, Kelley & Meyers, 1995) and the Six Factor Personality Questionnaire (SFPQ, Jackson, Paunonen, & Tremblay, 2000). Subjects were American undergraduates surveyed while studying abroad in Italy and control students at three universities in the US. Results supported hypotheses about correlations in open-mindedness, flexibility, self-confidence, and managing stress across scales. Future applications include assessment of students' attitudes toward international education and cross-cultural environments as well as college study abroad outcomes.

Included within intercultural competence are the ability to behave and communicate effectively and appropriately in another culture; adaptability to new and different environments; cognitive flexibility; and openness, respect, and curiosity for cultural differences (Deardorff, 2006). These skills and attributes are similar to those defined as cultural intelligence or CQ, which encompasses cognitive, metacognitive, motivational, and behavioral aspects that enable one to adapt to a new culture (Ward, Fischer, Lam, & Hall, 2009). Cognitive CQ refers to specific cultural knowledge; metacognitive CQ is cultural awareness and thoughtfulness during cross-cultural interactions; motivational CQ encompasses the desire to learn about and function effectively in intercultural situations; and behavioral CQ refers to flexibility within the repertoire of actions available to an individual.

Several scales have been developed to assess intercultural competence, such as the Intercultural Sensitivity Scale (Chen & Starosta, 2000), focusing on confidence and openness in cross-cultural communication, and the Intercultural Development Inventory, measuring progress on dimensions of Bennett's Developmental Model of Intercultural Sensitivity (Hammer, Bennett, & Wiseman, 2003). The Cross-Cultural Adaptability Inventory (CCAI, Kelley & Meyers, 1995) is used in industry to assess cross-cultural training needs as well as in research on outcomes of study abroad and international sojourns.

Based on anecdotal evidence from returning students, the attitudes that seem to be affected by study abroad include open-mindedness, adventurousness, self-confidence, and resilience, along with heightened interest in learning a foreign language and choosing an international career. The Intercultural Student Attitude Survey (ISAS) was devised to assess these changes. No other instrument reflects the student context or outcomes of international education or is intended to measure the effects of study abroad rather than other types of international experience. Because the ISAS focuses on attitudes rather than specific cultural knowledge or skills, it reflects primarily the motivational aspect of cultural intelligence. While some of the content of the ISAS is similar to the Intercultural Sensitivity Scale, the changes that are observed as a result of international study extend beyond intercultural communication. We wanted to assess interest in foreign language study and future international careers, both of which are relevant for undergraduate students. Of the other attributes or characteristics related to attitude change with international educational experience that we wanted to measure, open-mindedness and resilience are included on the CCAI. The CCAI assesses four factors: Flexibility-Openness, Emotional Resilience, Perceptual Acuity, and Personal Autonomy. Intercultural competence is likely to be correlated with personality factors, as Brackett et al. (2006) found for self-report measures of emotional intelligence. Therefore, a personality measure, the Six Factor Personality Questionnaire (SFPQ, Jackson, Paunonen, & Tremblay, 2000) was used to assess personality characteristics that might differentially affect response to study abroad experience or mediate outcomes. The SFPQ measures three personality factors that we were interested in, Openness to Experience, Extraversion, and Independence, which is the SFPQ interpretation of the Big Five factor of Emotional Stability. The other Big Five personality factors of Conscientiousness and Agreeableness are also assessed by the SFPQ, with Conscientiousness subdivided into two component parts.

ISAS items were initially written by the authors and faculty at the campus in Italy and field tested with study abroad students during the summer of 2003. The most promising items were assembled into a 50-item scale on which data were collected from fall 2003 through summer 2004,

with the expectation that not all of the items would prove valuable and the scale would ultimately be revised and shortened. Of the 568 students in this dataset, 301 were surveyed in Italy and 267 in the US. Though the reliability (alpha coefficient) for the 50-item scale was .91, item analyses resulted in the deletion of items with low point-biserial correlations, or those that did not correlate well with total scores. Exploratory factor analysis using maximum likelihood estimation and direct oblimin rotation resulted in twelve factors with eigenvalues greater than 1 accounting for 58% of scale variance. Items that did not load on any factor or loaded only weakly on their intended factors were removed. For example, three items involving eating unfamiliar food formed a factor that was not central to the purpose of the scale. Questions about starting one's own company did not enrich any of the desired factors and were deleted. The result was a 35-item scale measuring six desired constructs of open-mindedness or cultural curiosity, adventurousness or risk-taking, resilience or ability to manage stress, self-confidence, and interest in foreign language study and international careers. Items were written in both positive and negative directions and included both cognitive (value) and affective (enjoyment) aspects of these topics.

This version of the ISAS was used over eight semester and summer terms, from fall 2007 through fall 2009, with 1105 controls (40% female) and 578 students studying in Italy (61% female). Factor loadings may change from dataset to dataset, particularly for cross-loading items when factors are correlated, as are the ISAS factors. Therefore, exploratory factor analysis with maximum likelihood and direct oblimin rotation was used with the large recent dataset to identify the factor structure for further analyses. Six factors were specified, accounting for 56% of the total variance. This factor structure was used for the current analysis of a subset of these data that included students who had also completed the CCAI and SFPQ. The six factors were named New Experiences (for adventurousness and risk-taking), International Careers, Open-Mindedness, Stress Management (for resilience in dealing with difficult situations), Self-Confidence, and Foreign Language.

A crucial step in evaluating the validity of any scale is to demonstrate that it measures the intended constructs. Therefore, during spring 2008 and spring and summer 2009, data were collected with the CCAI and SFPQ along with the ISAS in order to evaluate the concurrent validity of the ISAS. Our hypotheses were that the ISAS factors would correlate meaningfully with their intended counterparts on the CCAI and the SFPQ:

1. ISAS Open-Mindedness will correlate with CCAI Flexibility-Openness and SFPQ Openness to Experience.
2. ISAS Stress Management will correlate with CCAI Emotional Resilience.
3. ISAS New Experiences will correlate with SFPQ Independence.
4. ISAS Self-Confidence will correlate with SFPQ Extraversion.
5. ISAS International Careers and Foreign Language will not correlate with CCAI or SFPQ factors because these topics are not included on either scale.

Method

The dataset consisted of 396 undergraduates surveyed in the US and at a study abroad program in Italy during the spring of 2008 and the spring and summer of 2009. The program features business, journalism, and communications studies courses in English and is sponsored by a consortium of 30 American universities. Participants were students from these universities attending either a four-month semester (n = 128) or a one-month summer session (n = 66). Subjects in Italy were surveyed both at the beginning and end of their terms, though only pretest data were used for this validity study. Subjects studying in the US attended three consortium universities in the South and Midwest and were surveyed once during a semester term (n = 161) or a summer session (n = 41). Of students surveyed in Italy, 61% were female while 48% of students surveyed in the US were female. Thirty-four percent of control students and 37% of study abroad students indicated that they were considering a career involving international travel. Sixty-eight percent of control students and 74% of study abroad students responded that they had previously traveled internationally for one week or more. Students were not asked to report on previous study abroad experiences, and our hypothesis is that the majority of students had not studied abroad prior to this experience due to the fact that most were college sophomores and juniors. Preliminary studies had shown that the length of time abroad or the number of prior trips were not strongly related to attitude differences whereas the contrast was marked between students who had traveled internationally for even one week versus those who had not.

The ISAS factors showed significant intercorrelations, ranging from .18 for Foreign Language and Self-Confidence to .37 for Foreign Language and Open-Mindedness. The CCAI has also been shown to have high factor intercorrelations (Davis & Finney, 2006). In a preliminary test of bivariate (Pearson) correlations, all factors of the CCAI and the ISAS showed significant positive correlations. The SFPQ factors of Extraversion and Openness to Experience showed significant positive correlations with all ISAS factors, Independence and Conscientiousness had no correlations with ISAS factors, and Agreeableness was correlated only with Open-Mindedness. Therefore, in order to isolate tests of the desired correlations, partial correlations were computed for each factor of the ISAS with each factor of the CCAI and SFPQ in turn. In this manner the influence of the other factors in each scale and any potential suppression effects would be eliminated. Fifty-four partial correlations were computed, 24 for the 6 ISAS factors with the 4 CCAI factors and 30 for the 6 ISAS factors with the 5 SFPQ factors. Because multiple correlations were computed with the same dataset, Type I error was controlled with the Bonferroni method, which had the effect of restricting significance to p values of less than .001. The number of students whose complete data al-

lowed partial correlations to be computed ranged from 338 to 387 for each pair of factors.

Results

Reliability (alpha coefficient) for the ISAS was .92. The results partially confirmed our hypotheses about factor correlations across scales. There were 11 significant partial correlations (*pr*) ranging in strength from *pr* = .21 to *pr* = .52 with five correlations of strength greater than *pr* = .30. These correlations are shown in Table 1.

Supporting Hypothesis 1, Open-Mindedness was correlated with CCAI Flexibility-Openness (*pr* = .42) and SFPQ Openness to Experience (*pr* = .25). Hypothesis 2 was confirmed with the correlation of Stress Management with CCAI Emotional Resilience (*pr* = .42), and Hypothesis 4 with the correlation of Self-Confidence with SFPQ Extraversion (*pr* = .52). Self-Confidence was also correlated with CCAI Emotional Resilience (*pr* = .32), and International Careers was correlated with SFPQ Openness to Experience (*pr* = .43), neither of which were hypothesized. Additional unanticipated significant correlations included Stress Management with SFPQ Extraversion (*pr* = .21), and Open-Mindedness with CCAI Perceptual Acuity (*pr* = .29) and SFPQ Agreeableness (*pr* = .23).

Hypothesis 3 was not supported as there was actually a small negative relation between New Experiences and SFPQ Independence that did not quite reach significance. Independence is the SFPQ interpretation of the Big Five Personality Factor of Emotional Stability and reflects independence from and even disregard for the opinions of others. This construct is not consistent with the idea of New Experiences, which assesses taking advantage of opportunities and a desire for new experiences. However, SFPQ Independence was significantly related to Stress Management (*pr* = .23), which suggests that these two scales share concepts related to self-reliance in the face of difficulty. Finally, there was a negative correlation between Open-Mindedness and CCAI Emotional Resilience (*pr* = -.22). To investigate this correlation, we ran a linear regression of the four CCAI factors entered as a block with Open-Mindedness as the dependent variable. Only Flexibility-Openness (β = .49) and Perceptual Acuity (β = .37) showed significant effects; Emotional Resilience was not a significant predictor of Open-Mindedness. This alternate evaluation of the relation suggests that it is spurious.

Conclusions

The purpose of this study was to investigate the concurrent validity of a measure of student intercultural attitudes with validated instruments. Four correlations with large effect size according to Cohen (1992) were found: Stress Management with CCAI Emotional Resilience, Open-Mindedness with CCAI Flexibility-Openness, International Careers with the personality factor of Openness to Experience, and Self-Confidence with the personality attribute of Extraversion. Moderate effects included the anticipated relation of Self-Confidence with CCAI Emotional Resilience. These results demonstrate that these characteristics are measured by the ISAS and that attitudes about international educational experiences are clearly related to Big Five personality characteristics. Open-Mindedness was also moderately related to CCAI Perceptual Acuity and to the personality factors of Openness to Experience and Agreeableness. That Open-Mindedness showed significant partial correlations with two subscales on each of the CCAI and SFPQ is reassuring as this is perhaps the central characteristic of students who choose to go abroad for an educational experience and one of the most

	ISAS Factors					
	Open-Mindedness	Stress Management	Self-Confidence	New Experiences	International Careers	Foreign Language
CCAI Factors						
Flexibility-Openness	.42**	-.01	-.04	-.04	.12	-.07
Emotional Resilience	-.22*	.42**	.32**	.11	.11	.08
Perceptual Acuity	.29**	-.06	-.09	.01	-.05	.05
Personal Autonomy	-.02	-.02	-.03	.13	-.18	.07
SFPQ Factors						
Openness to Experience	.25**	.00	.08	-.02	.43**	.04
Extraversion	-.05	.21*	.52**	.12	.11	-.08
Independence	-.09	.23*	.07	-.18	.17	.01
Agreeableness	.23*	.09	-.09	-.05	.05	-.09
Conscientiousness	.05	.07	-.13	-.03	-.10	.11

*p<.005 after Bonferroni control of Type 1 error
**p<.001 after Bonferroni control of Type 1 error

Table 1: Significant partial correlations between ISAS factors and CCAI and SFPQ factors

desired outcomes.

One of the most interesting findings for study abroad programs is their attractiveness to women. The majority of study abroad participants on the Italy campus are women, as is evidenced by the makeup of the current dataset. Goldstein and Kim (2006) found that women had significantly lower levels of ethnocentrism or prejudice and greater foreign language interest than men and that both of those characteristics were predictive of studying abroad, leading to a higher proportion of women participating in study abroad experiences. This helps explain why women find study abroad attractive, and it also reveals that men who study abroad are less ethnocentric than those who stay home. The ISAS Open-Mindedness scale is intended to capture attitudes similar to ethnorelativism that are also denoted by the Big Five personality factor of Openness to Experience and Flexibility-Openness on the CCAI.

No factor on the CCAI or SFPQ was related to New Experiences, which was intended to measure adventurousness and a certain degree of risk taking, and which is not assessed by any other scale known to us. Based on our interactions with students who study abroad, we believe that adventurousness is a characteristic of many of the undergraduates who are willing to test themselves in an unfamiliar environment. Foreign language study, which was also unrelated to either the CCAI or the SFPQ, is an important dimension for college and university study abroad programs. Interest in learning a foreign language is higher in students who plan to study internationally (Goldstein & Kim, 2006) and foreign language proficiency is an outcome of study abroad (Parsons, 2009). We are interested in measuring both the value of foreign language competence and the desire to learn a foreign language in students who choose to study abroad.

Our current research includes investigation of the sensitivity of the ISAS to study abroad experiences using pre- and post-tests with both control and travel groups. Our prior research with the CCAI and SFPQ has shown changes in attitudes as a result of studying internationally. If the ISAS proves to be sensitive to change in students' attitudes about cultural differences or future international careers, it may be a useful tool for demonstrating the value of investment in student participation in study abroad programs. The ISAS may also be helpful for assessing the preparatory needs of students who plan to study abroad in order to offer appropriate pre-travel training, for program selection, and for support throughout the experience.

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The ISAS is available from the authors upon request.

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Violence Against Women: Recognizing the Problem and Offering Solutions

Kristof, N. D., & WuDunn, S. (2009). Half the sky: Turning oppression into opportunity for women worldwide. New York, NY: Knopf. ISBN-10:0307267148. ISBN-13: 978-0307267146; Price: $15.00

Reviewed by Florence L. Denmark, Ph.D.
Pace University, New York, U.S.A.

Half the Sky, written by Nicholas D. Kristof and Sheryl WuDunn, is a critical and comprehensive analysis of the lives of women across the globe, their oppression and their stories of opportunity. It is a superbly written, accessible, and informative piece of work. Unlike many books which attempt to address this massive and somewhat overwhelming topic, Mr. Kristof and Ms. WuDunn approach it from a personal, authoritative, and knowledgeable position, garnered from years of reporting throughout the world. It is evident that this book is the product of not only what they witnessed while on past assignments for the *New York Times*, but also is a product of something more personal. As a reader, you believe that they care, that they want better for the world's women, and that they have a personal stake into ensuring that others see what they have seen.

In reading *Half the Sky*, I am reminded how this is not the case in the majority of the world. Not only is this not the case in terms of equality, but, rather, women are oppressed, beaten and abused. The book systematically tackles issues such as: sex trafficking and sex slaves, prostitution, mass rape, honor killings, fatality in childbirth, misogyny in religion, and the lack of health care and education for women. What is evident is that the lives of women across the globe are starkly different than the experiences of many of us. Instead of looking away, this book steers us towards the problem, shines a light on it and asks "What can we do?"

All of the cases and stories are presented in an informative and yet culturally sensitive manner. To do this, the authors pair personal stories with each problem that is presented. The readers meet Long Pross who was 13 years old when she was taken and sold to a brothel in Cambodia where the owner punished her and gouged out her eye with a metal rod. They meet Woineshet, an Ethiopian girl, who was kidnapped and raped by a man and three others for days. The man subsequently wanted to marry her, and it is common for a woman to be forced to marry a man who raped her, since by Ethiopian law, he cannot be prosecuted for violating a woman he later married. Readers also meet Mahabouba, a woman who did not have access to any medical care during birth. The baby died in childbirth and she suffered a fistula and crawled for a day to a missionary where she was brought to the Addis Ababa Fistula Hospital in Ethiopia, one of the only hospitals of its kind.

What is critical is that the stories are presented in an honest manner. This is how women are living today and this honesty is invaluable. What is also important is the manner in which the authors link women's issues to world issues. For instance, women who are encouraged to enter the workforce in developing countries will undoubtedly foster stronger economic gains for those countries. Women who have access to education, stay in school longer, can provide and contribute more for their families, become a more prominent figure in the family, are economically stronger, and have fewer children. Therefore, by educating women, issues such as population, poverty and abuse of women begin to be improved. The message is clear: women's issues should be addressed not only based on it being a humanitarian cause, but only because it makes sense for the countries due to the host of benefits it can cause. In other words, helping women not only is a good, moral move, but a smart one as well. There are many ways that are outlined in the book which helps readers determine how they can help. Organizations are mentioned throughout the volume and the Appendix lists groups that specialize in supporting women.

The stories presented, although realistic and sometimes painful to read, are ones chosen because they also inspire hope. Many women written about in this book find a way, despite the most abhorrent conditions, to improve their lives through their own determination or by the help of someone else. Therefore, the book inspires more than anything else. These simple human stories of women striving for something better makes reading the book a personal experience. The reader imagines, "What if this was me? Or, what if this was my sister, my aunt, my girlfriend, my mother?" It unifies the female experience and destroys an insulated, Western world view in which many of us live day to day. This volume is truly a remarkable read, and one which I would recommend to anyone who wants to improve the world today for us all.

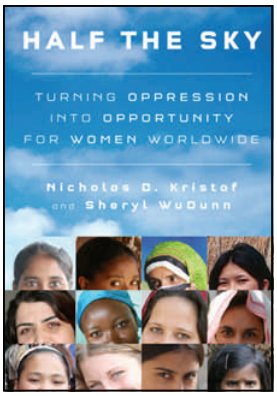

Situated Cognition in Tech-Transfer: The Globalization of Indian Firms

Surie, Gita (2008). Knowledge, Organizational Evolution and Market Creation: The Globalization of Indian Firms from Steel to Software. Northampton, MA: Edward Elgar Publishing. ISBN-10: 1847204562. ISBN-13: 978-1847204561; Price: $115.00

Reviewed by Dinesh Sharma
The Institute for International and Cross-Cultural Psychology, St. Francis College

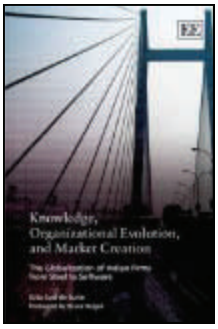

A collection of books has recently been published celebrating India's economy on the global stage. None of the books, however, attempts to describe the behavioral, organizational and developmental process involved in transforming the world's second largest population into the workforce for the information and biotech age. Gita Surie, a senior fellow at the Wharton School and Assistant Professor at the Adelphi University School of Business, makes a bold attempt to fill this knowledge gap. Her book, titled *Knowledge, Organizational Evolution, and Market Creation*, based on a decade long research project conducted coincidentally in parallel with the recent wave of globalization to engulf the South Asian subcontinent, traces the evolution and internalization of Indian firms.

The book presents an integrative framework for understanding organizational change in emerging economies. The central claim of the book is that the international expansion of Indian firms follows an evolutionary process building on the acquisition of new-found capabilities. Knowledge creation is central to building new capabilities, which are acquired and accelerated through cross-border replication of knowledge.

In Stage 1, the capabilities are scarce in the domestic environment, where modernization consists of investments in industrial technology, skilled labor, and an overall shift from agriculture to technology and infrastructure. Given the domestic economy may lack both the knowledge and the capital investment the early emphasis on growing business must be on knowledge transfer from exogenous sources. Stage 2 consists of diffusion of knowledge and capabilities followed by a large scale adoption of the new learning within the institutional framework. Stage 3 is marked by the cross-border innovation, where local firms participate in knowledge creation and compete in the global economy.

The book attempts to link the microeconomic change with the macroeconomic forces, using Lave and Wenger's cognitive theory of "situated cognition". In a unique melding of concrete with the abstract, the concept of technology transfer is contextualized within the psychological concepts of praxis and apprenticeship, something psychologists might find interesting. This is undoubtedly one way to understand organizational change. What the apprenticeship model may underestimate, however, is the emotional and cultural transition involved in the complex process of technology transfer in transforming a society such as India from "a knowledge borrower" to "a knowledge creator."

The sociocultural change driven by the influx of "new money" and technological innovation has undoubtedly created new communities of learners and experts. The new symbolic experts work on shared tasks across national borders, who are directly or indirectly employed by international firms. In satellite offices including "human body shops" that dot the globe, teams of developers and managers run the back offices that are the backbone of international business and global markets. In this new business environment, "the sun never sets" on the business lifecycle. The rotating shifts logging-in at different local times are coordinated with a centralized global research and operations team. There truly is no downtime in the 24/7 global economy. Surie's book analyzes India's entry into the global economy from the vantage point of the traditional Indian manufacturing firms as well as software and biotechnology firms.

The globalization of the steel industry exemplifies the process of knowledge transfer at the outset of the modernization of India. Founded almost one hundred years ago in pre-independence India, the steel industry relied heavily on European technology for mining its natural wealth. However, as we fast-forward to the 1980's, the major steel manufacturer decided to invest in upgrading its blast furnace equipment and increase its capacity to stay competitive and acquired new equipment from Germany. In November 1992, eight months behind schedule the steel manufacturer produced almost 3,000 tons of steel, which matched the sophistication and production of the best furnaces in the world. Today, the Indian steel manufacturer has acquired several multinational steel manufacturers and ranks 5th in the world in steel production.

In the mid-1980's Bangalore was not even on the global map. However, a handful of software companies were founded by IIT and computer science graduates thrilled by the possibility that computers could revolutionize the world. Supported by technological developments that promised "to flatten the world", these companies quickly gained recognition with the Fortune 500 companies while some of them went on to list on the New York Stock Exchange. Leapfrogging the pitfalls and growing pains of the traditional manufacturing sector, the IT companies entered the global marketplace by providing what the author calls the "knowledge assembly line." The precondition for the success of the Indian software industry may have existed in the Indian subpopulation given the educational system is thoroughly westernized and English is the language of commerce. The emphasis of Surie's book, however, is on the business processes and mechanisms and less on the cultural, linguistic and human capital reserves that have fueled the rise of the software in-

dustry.

In summary, this book is important for its contribution to the literature on the rise of Indian business and economy. The book has a wide reaching theoretical scope and makes significant linkages with cognitive, behavioral and cultural theories. The internationalization of Indian firms is rapidly changing Indian society and culture. Hence, there is a growing need for systematic organizational research that examines Indian business practices from an integrative perspective. Travel and journalistic books chronicling the rise of India as "the elephant economy" lumbering to stay on a growth trajectory compared to the East Asian tigers and the Chinese dragon are interesting to read. However, these travel books only skim the surface of the changes that are sweeping Indian business. Therefore, Surie's research on Indian firms presents a rare glimpse of the organizational and economic forces that are globalizing Indian industry from steel to software.

History of Psychology on a Global Scale

Adrian C. Brock (2009). Internationalizing the history of psychology. New York: New York University Press, 2009. 260 pages. ISBN: 13–978–0–8147–9136–3.

Reviewed by Samvel Jeshmaridian
City University of New York

New York University Press has published a highly readable new book on international psychology. The book contains 11 chapters developed by 13 authors, including Adrian C. Brock, the editor. An international group of authors discusses various ways of making Western psychological thought more understandable to members of all cultures as well as helping the reader to gain a better understanding of the psychologies of other cultural "worlds." By this volume, the understanding of today's psychology and its historical evolution has been made intellectually deeper, scientifically broader, and culturally more comprehensive.

The authors trace the development of psychological thought as if flying at various heights above the beautiful yet far from unitary landscape of psychological thought. Like space-pilots, they guide the reader toward a better comprehension of what various psychologies are accomplishing in this world. They describe psychology as inhabiting a multi-hued space created by psycho-historical patterns and socio-psychological perspectives. These, in turn, are engraved in human history and more specifically, in the history of the scientific study of human emotions, perceptions, memory, and behavior.

In his brief yet broadly conceived "Introduction," Adrian C. Brock outlines the structure of the volume and its methodology.

Johann Louw, in his essay, "Constructing Subjectivity in Unexpected Places," discusses "the history of the present" (Michel Foucault, 1975), in the sense of tracing principles at "the periphery" of psychological thought and making them meaningful for those psychologists whose perceptions and understanding remain at the center of psychological thought.

Cecilia Taiana is the author of the next chapter, "Transatlantic Migration of the Disciplines of the Mind: Examination of the Reception of Wundt's and Freud's Theories in Argentina." Using as an example the reception and prevailing usage of Wundt's and Freud's theories and methods in Argentina, Cecilia Taiana discusses the more general fate of scientific theories that have migrated from one continent (Europe) to another (South America). She also describes how the ideas of the French psychologists Theodule Ribot and Pierre Janet have been altered in the course of their trans-Atlantic journey.

In his contribution entitled "From Tradition through Colonialism to Globalization,"Anand C. Paranjpe presents a brief history of Indian psychological thought from ancient times to the modern globalization period. He describes various approaches to the understanding of human beings and human nature in Indian philosophy and psychology and compares them to the European psychological principles that were first developed in the Greco-Roman period but continue to serve as the foundations of modern scientific psychology.

Aydan Gulerce is the author of a chapter entitled "History of Psychology in Turkey as a Sign of Diverse Modernization and Global Psychologization." Given that Turkey has no indigenous traditions in philosophical or psychological thought, the author skillfully describes the evolution of Turkish social thought as a modernization process and a consequence of the globalization tendencies prevailing in contemporary scientific psychology in Turkey.

In his essay entitled, "Origins of Scientific Psychology in China, 1899-1949," Geoffrey Blowers discusses a few key concepts of Chinese psychology and how they are perceived by various 20th-century Chinese psychologists. He then compares them to the (more or less) equivalent terms in the English language that have been developed by Western psychologists.

In his chapter on "Behavior Analysis in an International Context," Rubén Ardila describes the principles and methodologies psychologists use in different countries and "worlds" such as Europe, Latin America, the socialist world, Japan, Africa, India, Australia, and New Zealand.

John D. Hogan and Thomas P. Vaccaro are the authors of a chapter discussing the "Internationalizing the History of U.S. Developmental Psychology." In a clear and scientifically structured way, they outline how developmental psychologies in various countries (e.g., U.S.A., France, Switzerland, Ger-

many, and Russia) have mutually influenced each other over the years.

Adrian Brock, in his essay entitled, "Psychology and Liberal Democracy," traces the sources of ideological affinities and their internal linkages to psychology in the context of a variety of social structures and political systems.

In their discussion of, "Double Reification: The Process of Universalizing Psychology in the Three Worlds," Fathali M. Moghaddam and Naomi Lee state that U.S. psychological thought has been and remains dominant all over the world. In this context, they present rich historical data demonstrating that U.S. psychology has been the driving force in the global spread of psychology.

In her chapter, "Psychology in Eurocentric Order of the Social Sciences: Colonial Constitution, Cultural Imperialist Expansion, Postcolonial Critique," Irmingart Staeuble discusses the organization of psychological science in various settings and historical situations, while attempting to trace causal linkages.

Kurt Danziger is the author of "Universalism and Indigenization in the History of Modern Psychology." His chapter traces the problems of coherence and intellectualization in the history of contemporary psychological thought.

Finally, editor Adrian Brock has contributed a postscript that summarizes a few typical social psychological questions that can be asked about the linkage of culture and modernity, such as, Interdisciplinarity, globalization, and the psychologization of socio-cultural perception and thinking.

In summary it can be stated that the editor as well as all the authors have done an excellent job tracing the dialectics of contemporary psychology all over the world. Moreover, all the chapters contain one important positive ingredient: whether their focus is more universal or more culture-specific in nature, they are "dipped" in culture.

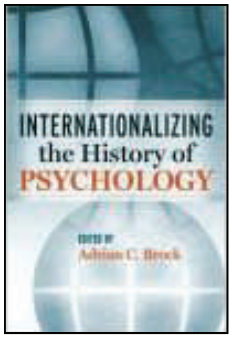

The January 2010 issue of

Interpersonal Acceptance

(Newsletter of the International Society for Interpersonal Acceptance and Rejection) is now available for viewing at http://www.isipar.org/Newsletter.html

It contains: Information about the nominees for the forthcoming ISIPAR elections; an article by Charles H. Heller, entitled "Applications of Parental Acceptance-Rejection Theory and Evidence to Forensic Psychology"; information about the 3rd International Congress on Interpersonal Acceptance and Rejection to be held in Padua Italy in July, 2010, including possible funding sources; and details about the University of Connecticut Rohner Center Awards for Distinguished Contributions to Theory, Research, and Practice on Interpersonal Acceptance and Rejection. Please share the newsletter with anyone you know who might like to know about it or about the Society.

You can read all prior issues of *Interpersonal Acceptance* by going to www.isipar.org

Yale convocation celebrated "80 years of excellence"

Harold Takooshian, Richard S. Velayo,
& Florence L. Denmark

On September 4, 2009, over 50 faculty and students from as far as North Carolina converged on the stately Presidents Room of Yale University in New Haven CT for a convocation to mark "80 years of excellence." This was the anniversary of the Ninth International Congress of Psychology at Yale on 1-7 September 1929—"the most impressive gathering of psychologists in the history of the field"—with 826 participants from 21 nations, including such notables as Ivan Pavlov, Jean Piaget, Kurt Lewin, and Franz Kofka.

The keynote message was delivered by Division 52 President-Elect John D. Hogan, who went beyond the 1929 meeting to share scenes of the near-forgotten First International Congress in 1889, at the then-new Eiffel Tower in Paris. Barely 10 years after Wundt's first laboratory, this Congress also brought together such diverse notables as Francis Galton of the UK, Alfred Binet of France, William James of the USA, Cesar Lombroso of Italy, and Ivan Sechenov of Russia.

Hogan also detailed the founding of Psi Chi on September 4, 1929 at the Yale Congress, by two University of Kansas students, Edwin Newman and Frederick "Bud" Lewis, which has now grown into the world's largest honor society in any field--touching the lives of over 500,000 life members at 1,100 campuses.

The convocation was hosted by Yale professors Peter Salovey, Laurie Santos, and Woo-Kyoung Ahn. The International Division of the American Psychological Association was represented by its past-Presidents Florence Denmark, Uwe Gielen, and Richard Velayo, who detailed the remarkable growth of "international psychology" since their group formed in 1997. Psi Chi was represented by Eastern Vice President Jason Young and past-President Vincent Prohaska, who announced the recent vote in 2009 to re-name Psi Chi "the International Honor Society in Psychology"--with new chapters now forming outside of North America.

PROCLAMATION
Of The City Of New Haven
DECLARING
SEPTEMBER 4, 2009
PSYCHOLOGY DAY

WHEREAS, Yale University hosted the Ninth (9th) International Congress of Psychology in September of 1929 in New Haven, which is widely regarded as "the greatest gathering of Psychologists in the history of the field" & Yale Faculty and students today continue to make pre-eminent contributions to the science & practice of Psychology to "bring out the best" in individuals and society; and

WHEREAS, Psi Chi was founded at Yale University on September 4, 1929 by two students, Edwin B. Newman and Frederick Howell Lewis to "encourage, stimulate and maintain excellence in all fields, including Psychology", and Psi Chi is now the world's largest honor society, with 500,000 life members and a federation of chapters at 1,100 campuses; and

WHEREAS, Psi Chi in 1981 helped to form Psi Beta – the first Psychology Honor Society to serve the unique needs of students at two-year colleges and Psi Beta has now grown into a pre-eminent honor society with chapters at 150 campuses across this nation; and

WHEREAS, The American Psychological Association (APA) and the Association for Psychological Sciences (APS) have also grown into International Organizations with vigorous programs to advance Psychology globally; and

WHEREAS, On this day when students, professors and the community gather in New Haven to celebrate the progress of International Psychology and the 80th Birthday of Psi Chi, the City of New Haven is pleased to join in this celebration.

NOW, THEREFORE, do I, as Mayor of the City of New Haven, proclaim the 4th Day of September 2009 as Psychology Day and to celebrate Psi Chi and 80 years of excellence, I hereby proclaim:

PSYCHOLOGY DAY
SEPTEMBER 4, 2009

Dated at New Haven, Connecticut, this 4TH day of September 2009.

John DeStefano, Jr. Mayor

conferees, Psi Chi presented to Yale a commemoration plaque, to salute "80 years of excellence." In addition, Dr. Jane Levine presented a Proclamation signed by Mayor John DeStefano, proclaiming September 4, 2009 as "PSYCHOLOGY DAY" in the City of New Haven. The Proclamation saluted Yale, Psi Chi, Psi Beta and, in part, saluted APA at the American Psychological Society for growing "into international organizations, with vigorous programs to advance psychology globally." This convocation was taped by Richard Velayo and Steven Salbod, and a DVD is available from takoosh@aol.com

On behalf of the

Preparation of Faculty for a School Psychology Program in Vietnam

Kimberly S. Kassay and Mark D. Terjesen
St. John's University

Son Nguyen, Hong Nguyen, Long Phan, Phuoc Hoang, and Binh Pham
Hanoi National University of Education

This article will describe the most recent steps towards the development of the first formal school psychology training program at Hanoi National University of Education (HNUE) in Vietnam. A brief history of the efforts to date will be provided followed by a presentation and evaluation of a summer-long training program geared towards preparing the faculty of HNUE for instruction in, management of, and evaluation of the success of the training program. Future directions in the program development will be discussed with consideration of the profession itself, and the international and cultural context in which this profession will exist.

With a population of over 86 million, Vietnam is the thirteenth most populous country in the world (U.S. Census Bureau, 2008). Vietnam is considered a low-income developing country, but it is expected to attain middle-income country status by 2010 (World Bank, 2007). It would stand to reason that economic change may in turn have an impact upon education. These economic changes combined with recent advances in the education system (Ministry of Education and Training [MOET], 2003) have created a need for school psychological services and an economy that is able to support these needs (World Bank, 2007). Educational change would seem to be a logical objective in a country where approximately 33.5% of the population is under 15 years of age (Bonderant, Henderson, & Nguyen, 2003). Five years of primary education is now compulsory, new schools have been built, and standards have been set for teachers and textbooks (World Bank, 2007). Support for education reform is demonstrated by an increasing state budget for education in Vietnam; as it has risen from 8% in 1990 to 15% in 2000 and is expected to reach 18% by 2010 (MOET, 2003).

With mandated change in primary education, change in University-based education has also occurred, with the objective of developing modern Universities who will train graduates to be leaders in their respective areas (MOET, 2003). The Hanoi National University of Education (HNUE) was the first university to train teachers in Vietnam and has recently added a specialty area: the Applied Psychology Section (APS) within the Department of Psychology and Education (DPE) (APS, 2007).

While no formal school psychology training programs presently exist in Vietnam, approximately 50 individuals who perform many of the functions of school psychologists do throughout the country (APS, 2007; Jimerson, Stewart, Skokut, Cardenas, & Malone, 2009). Given the needs of the 22 million school-aged children in Vietnam (Embassy of Vietnam, n.d.) it would be difficult to imagine that this number is sufficient. To this end, the DPE of HNUE began a collaborative relationship with the administration and faculty of St. John's University (STJ) in 2006 to develop a school psychology training program (Terjesen & Kassay, 2007). It is hoped that such a program would adequately meet the educational and mental health needs of students in Vietnam.

Preparation for a Training Program

Upon deciding to develop a school psychology training program at HNUE, the administration and faculty of the APS sought professional assistance from STJ to begin planning the program. The objectives identified were to provide on-going professional development for the future lecturers and supervisors of the HNUE school psychology program. This would be accomplished through continued education opportunities, access to professional literature, and consultation with international colleagues through a mentoring program.

Initially, two faculty members from STJ, Drs. Mark Terjesen and Kate Walton, and two STJ doctoral candidates, Kimberly Kassay and Maria Bolger, traveled to Vietnam for a series of 10 full-day consultation meetings during January of 2008 at HNUE. These meetings were held to determine how to best build the school psychology training program at HNUE considering the prior determined needs, available resources, managing the pragmatic component of training, along with what is considered "Best Practices" in development of a training program (Terjesen, Kassay, & Bolger, 2008).

The next step involved training the APS faculty members to be lecturers and supervisors in the school psychology program. This was accomplished through a series of six 20-hour training courses, divided into three 2-course sessions, during the summer of 2008 and were taught by professors from STJ and other American universities (Terjesen et al., 2009). The content for these trainings was determined by results of a needs assessment of the subject areas that the faculty members reported being deficient in and those that were identified as integral to the future profession of school psychology in Vietnam.

Specialized and Experiential Training in School Psychology

Building upon the prior training, it was determined that the next important step in the professional development of APS faculty members would be for them to receive more specialized training in school psychology in the form of short workshops given by STJ faculty, supervisors, advanced-doctoral level students, and colleagues in the New York area during the summer of 2009. In addition to this training, scheduled visits to a number of schools, educational facilities, and hospitals/mental health clinics were conducted to assist HNUE faculty in seeing and understanding the current manner in which these services are provided in the U.S. The goal

of this visit was to provide the HNUE faculty with knowledge of specialized subjects in school psychology and first-hand experience of the field as it currently exists in the U.S. so they can use their knowledge and experience as they prepare a training program that will be able to train professional school psychologists to meet the mental health and educational needs of children and adolescents in school settings in Vietnam.

Prior to initiation of the specialized and experiential training, HNUE and STJ faculty reviewed the content of prior trainings, results of surveys of knowledge and perceived efficacy, and a needs assessment survey based on the core training domains outlined by ISPA (ISPA, n.d.) was administered to determine content and sites to visit. This needs assessment asked APS faculty members to rate their current understanding and interest in each of the ISPA training domains. The results of this assessment were used in the planning of the site visits and lectures and were given to the site visit coordinators and lecturers to guide the focus of their presentations.

Training Participants

Four members of the APS faculty stayed for three weeks, four stayed for three months, and one faculty member will stay in the United States for six months. In addition to the concentrated lectures and site visits, the faculty members of HNUE also attended graduate level courses offered in the STJ psychology department while they were visiting. The criteria to form this group of participants were determined by HNUE. The aim was to have the group combine faculties from related domains to school psychology. Participants included HNUE administrators, along with faculty whose area of specializations were in developmental, counseling, and personality psychology, curriculum development and teaching methodologies. The aim of the visit was to receive both an overall view of the field as well as specific, concrete examples of application. Upon their return, this group will offer recommendations to the DPE and APS on varied aspects of the training program, training process and faculty development to assist in the development of the training program in school psychology.

Lecture Content

Based on results from the needs assessment survey as well as consideration for what would be "Best Practices" in school psychology, content area was identified and speakers were invited to present lectures to the faculty of HNUE. The content areas were somewhat broad but specific enough to assist in their preparation for the training program in Vietnam. Content areas included content that was broad-based in nature (History of Psychology), that focused on school psychology as a field (History of School Psychology; Special Education Process), that were targeted towards very specialized populations (e.g., Autism, ADHD/CD; PTSD; Anxiety; Depression), treatment approaches (PCIT; REBT/CBT), consultative (work with teachers; work with parents) and assessment (cognitive; personality; functional behavior analysis). The lectures were a combination of both didactic and demonstrative methodologies and all presenters integrated technology in their presentations. Each lecturer also provided their lecture and additional readings to the HNUE faculty ahead of time to assist in preparation and understanding. These lectures were designed to be both practical in nature (i.e., what do you do if X happens) as well as instructional (i.e., what are effective ways to teach this area).

Site Visits

In providing the HNUE faculty with the opportunity to observe the practice of school psychology and how practitioners are formally trained in the profession, consideration was given as to how to integrate these visits with the training lectures as well as how to educate the HNUE faculty in terms of how these sites serve as externship and internship placements for the graduate students at STJ. Included in these visits were nine public schools, one private special-education preschool, two publicly funded clinics that primarily serve children and adolescents, two private mental health facilities that serve adults and children, two University counseling centers, a University based clinic, and a publically funded clinic within a hospital setting. These diverse experiences provided a varied exposure to the manner in which educational and mental health needs of children are served within the U.S.

Summary

Building upon the prior program development and training this experience provided an opportunity for the future trainers of school psychologists within HNUE an opportunity to further develop their knowledge and skills as well as see models of how services are provided. The challenges going forward are many and there will in all likelihood be economic, cultural, and practical barriers that will impact upon the programs development and progress at varied points. However, the knowledge gained and experiences provided in the visit were beneficial in a number of ways: helping more clearly define the goal of school psychology in Vietnam, offering new methodologies (e.g., cross-cultural; school-based approaches) of scientific research that are essential for the trainers in school psychology, and finally re-invigorating and motivating the pioneer in the face of the challenges that lie ahead. The trainers at HNUE report that this intense summer training program helped better prepare them to meet the educational and mental health needs of children and their families going forward. Future steps to continue to build their professional knowledge and skills are currently in development.

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The Third International Congress on Interpersonal Acceptance and Rejection will be held in Padua, Italy from July 28 through July 31, 2010.

You can get information about the Congress at its website, http://isipar2010.psy.unipd.it.

You can also get information about the sponsoring organization—the International Society for Interpersonal Acceptance and Rejection—at www.isipar.org.

The Congress is interdisciplinary and will address research and practice on all aspects of interpersonal acceptance and rejection.

Internationalizing the curriculum: Lessons from a student service-learning project in Kigali, Rwanda

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Abstract

This article portrays the preparation and implementation of a service-learning project in Rwanda for doctoral clinical psychology students from Argosy University, Chicago. The project was developed in collaboration with Women's Equity in Access to Care and Treatment (WE-ACTx), a Rwandan NGO. The purpose of the service-learning project was to help provide needed services to Rwandan mental health staff and to provide an opportunity for graduate students in psychology to receive ethical, culturally-informed, international clinical experience. The work plan developed by the Argosy team and Rwandan counselors is described, with an emphasis on conducting cross-cultural focus groups and training and facilitating a self-care and secondary trauma retreat. Students' experiences regarding personal and professional development and learning are discussed.

Introduction

Upon arrival in Rwanda, one is struck by the country's remarkable beauty and serenity in the aftermath of atrocity. In 1994, close to one million Rwandans were massacred in the genocide against the Tutsi minority group, leaving millions more Rwandans displaced and without family (Straus, 2006; Gourevitch, 1998). Now, fifteen years later, many Rwandans suffer from poverty, complex traumatic symptoms, HIV/AIDS, grief, loneliness, depression, and anxiety (Kaberra & Sewpaul, 2008). There is also tremendous strength and resilience among the population, as is so often the case in the aftermath of human disaster.

In fall 2008, faculty and students of Argosy University, Chicago began to develop a service-learning program for graduate students in clinical psychology. The project was a collaboration between the University, Heartland Alliance International Programs, EDMC Foundation, and Women's Equity in Access to Care and Treatment (WE-ACTx) in

Rwanda. This article focuses on project development, preparation, structure, tasks, and lessons learned.

Planning

WE-ACTx is an NGO located in Kigali, Rwanda founded by US physicians in 2004 to respond to the growing service needs of HIV-positive women. In addition to medical services, the need for mental health, income generation, and legal services quickly became apparent, and professionals were recruited to provide training and consultation. As a result of one of the authors' (SGZ) affiliation with Heartland Alliance Marjorie Kovler Center and her prior consultation work with WE-ACTx, the idea of developing a service-learning program for psychology graduate students was presented to Argosy University, Chicago.

Literature on service-learning projects (Hagan, 2004; McClam, et al., 2008; Melland, 2004) highlights the importance of ensuring mutually beneficial and collaborative experiences for both students and the community served; additionally, proper preparation, culturally-appropriate action, and debriefing/reflections must be embedded into program development. Following such models, the rationale behind the Rwanda service-learning project was: (a.) to help provide needed services to WE-ACTx mental health staff including training and support, and, (b.) to provide an opportunity for graduate students in psychology to receive ethical (Sommers-Flanagan, 2007), culturally-informed, international clinical experience.

A committee of faculty and students was formed in October 2008 to plan and raise $12,000 needed for the project. Fundraising was challenging; the committee researched foundations and sent proposals to the 15 foundations whose mission most closely matched that of the project, without success. A fundraising letter was sent to corporate and private donors and fundraising events commenced.

While fundraising efforts continued, several initiatives were implemented to educate the campus community on the project. Faculty and students began an international psychology journal club to discuss scholarly articles, initiated campus activities including viewing and discussion of a Rwandan genocide film, and hosted a colloquium by a Rwandan counselor. A course sequence was also developed; the first was a didactic course to introduce students to the fundamental principles and ethical considerations of international humanitarian work, the psychological consequences of genocide and HIV/AIDS, and the sociopolitical context of Rwanda. Students learned via case studies provided by WE-ACTx counselors, self-reflection exercises, discussion, and presentations emphasizing the importance of conducting well-informed, culturally sensitive, and collaborative humanitarian work. The course was essential in preparing students intellectually and emotionally for their experience in Rwanda. The second course included the service-learning trip. The service plan was developed in collaboration with WE-ACTx staff, supervisors, and consultants in Chicago. The goal was to provide needed assistance to WE-ACTx during the fifteenth anniversary of the genocide and to provide students with developmentally appropriate learning experiences. It was emphasized throughout the planning that flexibility would be essential to successful international work, and that while a relatively detailed plan was established, it would be likely to change depending on the situation and needs once in Rwanda.

Project Work Plan and Execution

The plan included: (a.) assessing the applicability of the Child Depression Inventory, (b.) conducting focus groups, (c.) evaluating HIV-positive children enrolled in a nutritional program, (d.) assisting in children's support groups, (e.) leading secondary trauma processing groups for counselors, (f.) providing collaborative professional development trainings to counselors, (g.) touring local mental health care facilities, and (h.) engaging in a student exchange at Rwanda National University. Following will be examples of service-learning experiences.

Counselor trainings

Based on a list of training topics generated by WE-ACTx staff, students prepared several training modules from which counselors chose *Psychodrama* and *Couples Therapy*. Before each training, the Argosy team discussed ways to provide collaborative trainings, respecting local healing practices while enhancing expertise. The treatment team learned about Rwandan culture and treatment models, WE-ACTx's client population, and the nature of the counselors' work; thus, cultural learning was a continual process that happened in discussion between the visiting team and the local staff. For example, during training on couple's therapy, Gottman's Strong House Theory (2007) was collaboratively modified to suit the specific needs of WE-ACTx clients. Throughout the training, students invited discussions about Rwandan beliefs around marital life, gender roles, child rearing practices, and conflict management. This gave students a sense of how couples engage with one another and provided a starting point for working with local staff on adapting Gottman's model to WE-ACTx clients.

Focus groups with WE-ACTx clients and staff

The Argosy team was asked to conduct focus groups around Intimate Partner Violence (IPV) and HIV/AIDS to examine the needs of women and couples experiencing IPV and to provide ideas for additional services. Preparation consisted of readings (e.g., Nabors, 2001; Morgan, 1996; Munodawafa, et al., 2005) and planning meetings where the Argosy team discussed possible client perceptions/attitudes towards outside facilitators, building rapport, and reviewing informed consent, including facilitator roles, purpose, and outcomes. To avoid excessive agreeableness from cultural beliefs around welcoming outsiders, clients were informed by their counselors prior to the focus group and were given the choice to attend. During facilitation, co-leaders recognized cultural stigmas surrounding IPV and HIV/AIDS in Rwandan society and invited participants to share what felt comfortable/safe for them. Through the experience, graduate students witnessed the challenges WE-ACTx clients face, potential solutions to such

issues, and client strengths.

Secondary trauma processing group for counselors

Secondary trauma is defined as the therapist's internalization of the client's traumatic transferences, interfering with the therapist's feelings, memories, sense of self/other, and notions of safety (McCann & Pearlman,1993). Most WE-ACTx mental health counselors are survivors of the genocide working with survivors. Consequently, there is unremitting interplay between workers' primary trauma and secondary trauma, where their own trauma can be triggered by their clients' stories.

The Argosy team was asked to facilitate an afternoon retreat and attend to the counselors' needs through discussing and participating in activities on secondary trauma and resilience. Students prepared exercises proposed by Pearlman and Saakvitne (1996). In one activity, titled *Silent Witness* (p. 93), students asked workers to write down three ways in which they were affected by their work. Together, participants silently read each others' experiences and a discussion followed. Counselors reported sleep disturbances, restlessness, fatigue, loss of motivation, sadness, isolation, irritability, anger, helplessness, and feeling overwhelmed by clients' needs. Following this exercise, counselors spontaneously and symbolically threw their worries into the lake, then transitioned to a Rwandan song and dance activity. This activity exemplified the integration of a planned intervention based on Western models of trauma with local ways of healing.

Lessons Learned

Students gained invaluable lessons from the service-learning project, enhancing their personal and professional development. Essentially, students learned to appropriately, sensitively, and ethically work cross-culturally. For example, students made the trainings collaborative rather than establishing the Western-as-expert paradigm (van Ommeren & Wessells, 2007). Students asked questions, continually solicited feedback, and focused on the strengths of mental health care workers and their clients.

Facilitating focus groups gave students a better sense of issues many WE-ACTx clients face, including domestic violence, stigma/isolation of women with HIV/AIDS, and discrimination and dating challenges of HIV-positive adolescents. Additionally, students were trained to effectively work with an interpreter, learning to succinctly convey their message and to work together to understand cultural nuances. In the process, students attended to the cultural, emotional, and interpersonal needs of clients.

The retreat on secondary trauma gave students insight into the vitality of creating a space for consultation, supervision, and self-care. Additionally, students gained awareness to the complex issues plaguing a nation recovering from genocide, including establishing a just nation, restoring trust, forgiving perpetrators, reconciling differences, and establishing peace. Students also understood the impact of rape and genocide on one's individual and cultural identity.

Students appreciated the importance of knowing the country's history to truly understand the personal, interpersonal, and societal factors that construct the social fabric of Rwanda. It was equally important to understand students' own racial identity and the transference evoked by skin color; students engaged in difficult dialogues around race, processing their racial development and addressing assumptions, projections, transferences, and feelings.

The group found this work to be essential in debunking the Western-as-expert paradigm. Overall, the development of this program speaks to the ever-growing need for graduate students to receive supervised experiences internationally in order to competently and ethically work cross-culturally. Furthermore, it is important for students to develop an awareness of the role of psychology in the international arena.

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How can we "go global?"

Harold Takooshian and Elaine Congress,
Fordham University

"How can we become more involved in international activities?" On September 14, 2009, this question was the focus of a three-hour convocation at Fordham University in New York City. After a welcome, the 110 participants split into three 75-minute workshops, then later re-gathered at a gala reception to speak one-on-one with the 22 presenters.

Welcome. Participants were welcomed by messages from four organizers of international activities: Dean **Elaine P. Congress** and Professor **Harold Takooshian** of Fordham University, past-President **Florence L. Denmark** of the American Psychological Association (APA), and past-President **Susan Opotow** of the Society for Psychological Study of Social Issues (SPSSI). About half of the 110 participants were students, and half were professionals from the United Nations or other local universities.

Workshops. The convocation then divided into three simultaneous 75-minute workshops, each with a rapporteur to report the information for later publication: (1) **United Nations**: four UN reps updated others on the 62nd UN conference in Mexico City on 9-11 September 2009, on the theme "For peace and development, disarm now!" (2) **Human Rights**: five experts described how individuals and groups are promoting global human rights. (3) **Students**: seven experts advised students on how to be more involved in the UN and other international activities. The 55 participants included 30 students from the new International Studies course taught by Fordham Professor **Chris Toulouse**.

Reception. After these workshops, participants re-gathered for a gala reception, and one-to-one chats with the 22 presenters and each other. Professor **Robert Chazin** of Fordham Graduate School of Social Service was presented with an award to recognize his two decades of international work, including his recent design of a new graduate curriculum on human rights. On behalf of the United Nations and its Conference of Non-Governmental Organizations (CoNGO), President **Liberato Bautista** and NYC Director **Anita Thomas** described the important role of CoNGO since 1948, to coordinate the UN activities of its 560 member NGOs. They referred participants to their web list of 50 active CoNGO committees in New York, Geneva, and Vienna: www.ngocongo.org.

Film. **Mahroo Moshari** (mahroon@yahoo.com) kindly arranged the post-reception screening of Jeremy Gilley's bold new DVD, "The day after peace," www.peaceoneday.org , which tells the true story of one man who successfully created an annual global day of non-violence.

Since 2004, this was the sixth annual NYC international convocation in September, hosted this year by Fordham University and its International Studies Program, in collaboration with CoNGO, SPSSI, and the APA Division of International Psychology. This year proved unusually lively, by bringing together three diverse groups—UN reps, international faculty and students from many schools, including Fordham. Once again the convocation was free to participants, thanks to the 22 presenters who volunteered their expertise. For any details, check the UN conference at www.unngodpiconference.org , or www.internationalpsychology.net/ny, or contact takoosh@aol.com, or congress@fordham.edu.

(1) United Nations: Mexico City update

Wismick Jean-Charles, *Fordham University*
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On 9-11 September 2009, hundreds of UN representatives converged on Mexico City for the 62nd annual DPI/ NGO conference on the theme: "Peace and Development, Disarm Now." Here at Fordham, four UN representatives reported the outcomes of this conference. The workshop chair, Fordham Dean **Elaine Congress**, began with a brief background on the 2008 Conference in Paris, focused on "Reaffirming Human Rights for all," to honor 60 years of the Universal Declaration of Human Rights. She then introduced the three panelists to the 25 workshop participants.

Juanita Carrillo of Fordham (drjpcarrillo@gmail.com), an NGO representative to the United Nations for the International Association of Gerontology and Geriatrics (IAGG), reviewed the extensive process to organize the DPI/ NGO conference--from selecting the topic nearly a year ago to the presentation of the Conference Declaration at the closing ceremony in Mexico City. She explained the role of the planning committee, the mission of the executive committee, the duty of the committee of experts, and the meaning of the visual identity of the conference (a plant emerging out of a grenade) symbolizing disarmament evolving into peace.

Martha Bial of Fordham (bial@fordham.edu) just returned from the Mexico City conference. She outlined the format of the three-day conference that included opening and closing ceremonies with keynote addresses, roundtables (plenary sessions), afternoon workshops, exhibits of peace work, and receptions. She noted that the 1,300 attendees were representatives of non-governmental organizations (NGOS) from around the globe. She also reported about the workshop entitled "Impact of Armed Violence on Vulnerable Generations" sponsored by IAGG, that focused on the effects of armed conflicts on older people. She offered guidelines and some recommendations to reduce armed conflicts while recognizing that advocacy on social issues takes a long time to effect change.

Florence L. Denmark of Pace (fdenmark@pace.edu), the main APA representative to the United Nations, described the upcoming "Psychology Day at the UN." She presented the theme for this third annual psychology day conference: "Psychology and Diplomacy: Negotiating Peace and Human Rights." The day will include two panels, one on "Negotiating for Humanitarian Access," the other on "Organizational Diplomacy: Internal Negotiating". She encouraged students and others to get involved in international

activities though NGOs at the UN, emphasizing how grassroots civil society can work with agencies and governments to advocate for peace and to effect change for a better world.

The discussion following these presentations was exceptionally lively, including questions from faculty and eager students seeking opportunities to participate in United Nations-related activities. The enthusiastic attendees have left the room happily exchanging business cards and sharing comments about how the workshop was both informative and captivating.

Professor Chris Toulouse addressed a SRO room of students interested in international issues.

Dr. Bobbi Nassar of the UN moderated the roundtable workshop on human rights.

CoNGO President Liberato Bautista addressed the international reception.

Reception participants shared a huge international cake.

(2) Human rights

Samvel Jeshmaridian, *City University of New York*
(jeshmarid@yahoo.com)

This workshop was chaired by **Bobbi Nassar**, Chair of the NGO Committee on Human Rights, who introduced panelists Robert Chazin and Ani Kalayjian.

Professor **Robert Chazin** of Fordham Graduate School of Social Service (chazin@fordham.edu) differentiated four domains for social work. They are the World domain as reflection of Globalization; State domain referring to Governments; Community as the arena for practice; and the personal

domain, involving work with individuals, families and small groups. Social work with individual problems includes issues of sexuality, spirituality, bereavement, anger, alienation, depression, while families struggle with unemployment, poverty, schooling and housing. Professor Chazin discussed these domains in the light of human rights and social justice making accents on the importance of reaccreditation of human rights curricula.

Since Professor Chazin's is a social work educator, he stressed the principle of human rights for social work perspectives. He explained, "Today's national conflict regarding a public option for health care vs. those who want to maintain a private health care system is a good example of this conflict. Human rights advocates argue for inclusion of a public option to ensure medical care for all our citizens." Use of a human rights framework is an important shift from the profession's longstanding concern with human needs. He concluded that social work is and has always been a human rights profession.

Professor **Ani Kalayjian** of Fordham University (drkalayjian@gmail.com) talked on outreach activities and disaster intervention in different countries. All her illustrations were part of her own personal experience: hurricanes Katrina and Rita, various disasters in Armenia, Pakistan, Sri Lanka, and Sierra Leone. She explained the principles of the Biopsychosocial Approach in organizing the outreach and supporting people under disaster. Though these people have variety in their culture, language, religion, and human rights perception, the Biopsychosocial way of working with them is effective and helpful. Professor Kalayjian stressed The United Nation's positive role in the field of helping professions.

At the end of the panel, Dr. Nassar explained the peculiarities and differences between UN Resolution, Declaration, and Convention, their authoritative powers and moral orientations.

(3) Involving Students in International Activities: Why and How?

Kathleen S. Koltko-Rivera, *Fordham University*
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A full room of 60 students and faculty heard this panel of seven experts, chaired by **Harold Takooshian** of Fordham.

Patrick Sciaratta, of the Friendship Ambassador's Association (www.faf.org) stressed the importance of students' early involvement in international work. He noted the strong desire of today's students for hands-on experience and involvement—not just reading or hearing about international work. In August, 1,000 young people from the Pacific area, including 100 Chinese youth leaders, came together to work on international issues. Many students were only 15 to 16 years of age. A video of the U.N. Youth Assembly may be found on YouTube. Students may attend an upcoming three-day U.N. event, a great networking opportunity, that would normally cost $1,000 to $1,500 to attend, but which students may attend for a registration fee of $45. Those in attendance will include the son of Mahatma Gandhi, Jesse Jackson, Kathy Ireland, Angelina Jolie, and other key individuals and NGOs which are working on international issues.

Fred Campano of Fordham University (compano@fordham.edu), discussed two different paths that can lead to obtaining professional employment at the U.N, or an U.N. Internship. Typically the U.N. seeks only graduate student interns, or individuals who hold a master's degree or doctorate. Countries must have an available post before you may apply. The UN developed strict hiring procedures to depoliticize the hiring process. Country posts are now allotted based upon the percentage of the total U.N. dues that each country pays. For example, the U.S. pays 25% of the total U.N. dues, so the U.S. receives 25% of the U.N. posts. It may take two years to gain professional-level employment at the U.N. The process involves taking a competitive examination. Approximately six months after the exam, interview candidates are selected. Only a small percentage of applicants are hired. A popular, alternate path to obtaining a professional position at the U.N. is to begin one's career as a clerical employee. The downside to this approach is that you will not be involved in any professional work. However, the U.N. is a wonderful place to work: the salaries are excellent, the benefits are great, and you receive six weeks of vacation and sick leave in your first year of employment. After working in a clerical capacity for two to three years, the U.N. allows clerical employees to take the GSP exam, and those who earn a passing score may apply for positions within the U.N. professional ranks.

Jo Anne Murphy, the U.N. Program Coordinator at *Fairleigh Dickinson* University (joanne_murphy@fdu.edu), discussed the numerous international and U.N.-related opportunities that FDU creates for its students. When the U.N. General Secretary recently spoke at FDU, he referred to "the well-worn path between FDU and the U.N., that goes both ways." Dr. Murphy emphasized that, "students who are interested in receiving international experience and U.N. involvement must demand such programs and opportunities from their university." FDU has begun an exciting global learning initiative, a global virtual faculty program with 75 professors participating from all over the world. Recently, a nursing class at FDU participated in a virtual meeting with a world expert regarding global health who was located in Geneva. Students and professionals from all over the world may access this online resource library, and view teaching sessions and meetings at: www.gig.org. FDU's U.N. Pathways program provides students with a variety of opportunities to interact with U.N. ambassadors. There are also opportunities for students to attend U.N. briefings; interact with NGOs associated with the U.N., and participate in virtual meetings such as the recent Nuclear Non-Proliferation video conference. Obtaining an U.N. internship can be difficult and complicated, but FDU creates unpaid internships for students that allow them to establish person-to-person relationships with U.N. personnel.

Kelly Roberts, Assistant Director of the Fordham Office of International Service (keroberts@fordham.edu) spoke

about international opportunities for Fordham students who wish to study abroad, through NAFSA; opportunities for students to attend U.N. briefings; and the assistance that Fordham provides to students interested to obtain internships with NGOs and the positions within the State Department. Ms. Roberts recently escorted two Fordham students and U.N. interns, Azizi Siexas and Sandra Choi, to Cuba's permanent mission to the United Nations. This enabled them to learn more about Cuba's new projects and policies and the kind of work they have been doing towards the Millennium Development Goals (MDGs).

Christopher Toulouse (Toulouse@fordham.edu) of Fordham University's Center for Teaching Excellence and International Studies Program, brought his class of 30 Fordham students. Dr. Toulouse stressed that the time for students to start thinking about becoming involved in international work is their first year of college. This strategy allows students to focus on where they wish to go internationally during their 3rd year, and collect international data for their thesis in their 4th year. Dr. Toulouse gave practical advice about the use of technology and international work: 1) Rely only upon authoritative sources of information found on the Internet, publications such as the New York Times, the Economist, the Atlantic Monthly, and the New Yorker. 2) Ask hard questions about what is going on in the world, and why. Be cautious, and ask hard questions especially when reading information on the internet. 3) When posting information to Facebook and blogs, use discretion rather than telling the world exactly how you feel. You never know when a host family, or unintended others, might read your post—feelings can be hurt and relationships permanently damaged. 4) Be aware that international work is not for the faint of heart or those who desire a quiet life.

Rivka B. Meir of CUNY and Fordham University (winsuccess@aol.com), Director of the APA International Liaison program, discussed the importance of joining international groups such as APA Division 52, International Psychology. The $15 annual membership fee gives students information on new developments in international psychology, a connection with other students and psychologists from 89 countries abroad, and opportunities to collaborate on global data collection. She also encouraged attendees to "Adopt a Psychologist" from abroad who may lack the resources to pay annual APA membership dues.

Uwe P. Gielen, Director of the Saint Francis College Institute for International & Cross-Cultural Psychology (ugielen@hotmail.com) spoke about his research regarding Asians and Asian-Americans living in New York City. He also announced that the 21st Greater New York Conference on Behavioral Research will be hosted by St. Francis College in Brooklyn NY on November 6, with a deadline of October 13 for students and faculty to submit their research findings for presentation, at gnyc@fordham.edu.

Remembering Henry P. David (1923-2009)

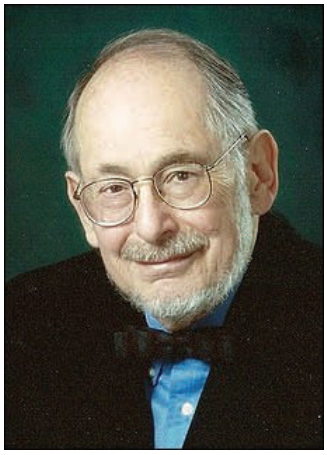

Meaningfulworld Mission to Armenia: Empowerment, forgiveness, and transforming learning disabilities into challenges

Dr. Ani Kalayjian and Jennifer De Mucci

The Association for Trauma Outreach and Prevention (ATOP) of Meaningfulworld organized the third team of the Meaningfulworld Mission to Armenia from 18th to 27th of November 2009. The mission was a successful endeavor not only in the work conducted within the trainings, but the impact the soul of the country and the people had upon our team. From the first day in Armenia, the team noticed the unsurpassed hospitality of the people and their respectful, kind and gentle demeanor. It is not often that one is made to feel so comfortable and at home within a foreign land. We were immediately welcomed by our colleagues in Armenia and treated as family. Perhaps one of the most memorable experiences for the entire team came before the week of training, having been invited to a dinner in the home of Dr. Kalayjian's cousin. In addition to delicious homemade "yogurt soup" and hospitality, it was here that we first experienced the true heart and soul of the Armenians. At dinner we were educated on the country's rich history, and could sense the pride within our historian while he recounted these details. In his own words he was "An Armenian, whose dream is to see Historic Great Armenia, including Van, Tvin, Tigranakert, all Kilikia (Cilicia), and Greater and Lesser Armenia; to live and die in the Holy Armenian land." It was clear to feel the essence of what it means to be Armenian, having lost and suffered so much through history, yet retaining a historical pride, resilience and sense of hope. It was at this time that the importance of our mission was made clear as we came to understand the heart of the country that would be our home for ten unforgettable days.

Dr. Ani Kalayjian and Jennifer De Mucci, President and Research Coordinator for ATOP, respectively, delivered the Empowerment portion of the mission to Armenia. Dr. Kathy Tiner and Kathryn Mendoza conducted the overcoming learning disability training programs. On the first day, Monday, 23rd November, we conducted the empowerment training project, and on the second day the Special Education Workshop. The team also delivered lectures, visited orphanages/children's centers, and set agendas for collaborative research and future trainings. This Meaningfulworld team conducted trainings at the Mental Health Foundation Center, and the FAR Children's Center. They also trained the personnel, social workers, and psychologists in preventative and restoration methods for treating children with trauma. Dr. Kalayjian's *Biopsychosocial & Eco-Spiritual Model* was utilized throughout the mission.

The team presented their work to the US Embassy office of Development and Reintegration programs in Yerevan. Follow up collaboration plan was set forth with local NGO's. The team visited various children's centers (previously called orphanages) as part of the third phase of a 10-year follow-up mission to observe progress and development. Donations of clothing and school supplies from several generous individuals were given out at these centers.

The trip to Armenia was one which provided many rewards and challenges to the Meaningfulworld team. Throughout the trainings, the team was introduced to individuals in varying levels of empowerment, thus providing each day of training to be unique. At the first empowerment training at the Mental Health Foundation, the group consisted of young women eager to learn conflict resolution skills through the power of forgiveness. The first training was a success for all involved, and resulted in several participants planning to create a Chapter of Meaningfulworld in Yerevan, Armenia.

A special education workshop conducted by Dr. Kathy Tiner and Kathryn Mendoza was held on the second day of trainings at Bridge of Hope in Yerevan. The workshop was attended by psychologists, teachers and mothers of children with special needs. Dr. Tiner and Ms. Mendoza (translated by Dr. Kalayjian) instructed participants on various learning tools which are aimed to be helpful in working with children with Attention Deficit and Learning Disabilities. Emphasis was also placed upon integrating special needs children within the public schools.

The Meaningfulworld team traveled outside of Yerevan to conduct trainings in Apovian and Vanatzor. Perhaps one of the most enriching experiences of the mission was traveling to the city of Vanatzor, which provided the team with beautiful views of the country. In Vanatzor the team was greeted by Gevork Manoukian and his team at the Armenian Constitutional Rights -Protective Centre. In addition to Dr. Kalayjian's empowerment training, Dr. Tiner also presented on the future of integrating schools. ATOP's work in Vanatzor was much appreciated and the team received a very warm hospitality which will always be cherished.

At all trainings, the team was introduced to many individuals whose varied experience further enriched the meaning of our work in Armenia. Both the Meaningfulworld team as well as participants were able to learn and grow from one another in the trainings. Many individuals stated that they had never before experienced trainings such as the ones presented by Dr. Kalayjian emphasizing the *Biopsychosocial and Eco-Spiritual Model* and the power of forgiveness. The empowerment training included ancestral mediation followed by a healing circle in which participants were encouraged to share their feelings and experiences. The current protocols between Armenians and Turks resurfaced the generational impact of the Genocide, and many expressed difficulty to forgive the perpetrators' decedents who are engaged in denial. One woman stated that she was not ready to forgive as she still recalls stories of her grandmother's "nails being torn out by Ottoman soldiers." Although difficult emotions were conjured at the training, many participants reported feeling a sense of peace by the end of the day and gratitude for having been a part of this new kind of experience of transformation and forgiveness. One young woman stated that at the beginning of the day she was "in a bad mood with a headache and not wanting to be bothered by anyone;" however, by the end of the training she reported feeling uplifted and felt the benefits of forgiveness on her spirit.

She also spoke of her own experiences and feelings regarding the pain of Genocide memories of her grandparents and how her anger stemmed not simply from stories of what happened but the literature and songs taught throughout her childhood which addressed the Genocide. But after the training she reported learning the true value of forgiveness. Here it is seen that hope for finding empowerment through forgiveness and healing the scars of the Genocide may begin with the young generation.

In addition to trainings, the ATOP mission also visited several Children's Centers providing donations of toys, clothes, and school supplies. The children at these centers were filled with love and affection and left a lasting impression upon the hearts and minds of the Meaningfulworld team. Additionally, the gratitude expressed by the facilitators at these centers left the team with a feeling of contentment that we were able to make a difference, however small in the lives of these beautiful children.

As Dr. Tiner stated: "I was especially impressed with the kind and gentle nature of Armenian people. I am also very pleased at the progress of integration of children with special needs into the public school systems. All educators we met were very informed, thoughtful, conscientious, and knowledgeable of the special needs of the children."

While in Armenia, the team also disseminated questionnaires created by Dr. Kalayjian assessing the psychological impact of the recent Armenian-Turkish Protocols. Many Armenians reported feelings of disappointment and anger regarding the conditions placed within the protocols regarding the issue of Genocide recognition and the status of Karabagh. Clearly there is still much that needs to be changed before a fair agreement can be made between the two countries. The finding of this current research was presented by Dr. Kalayjian on 17 December at Fordham University.

The entire team was positively impacted by the mission to Armenia. Except for Dr. Kalayjian, for most of us it was the first time visiting the country and it proved to be more than we ever could have expected. The richness of the culture and the depths of its history can be felt on every corner and within every individual we met from Echmiadzin to Vanatzor from Bangladesh to Apovian. The warmth and genuine humanity and humility of the people are as beautiful as the country itself. The Meaningfulworld Team expresses sincere gratitude to the World Wide Network for Gender Empowerment of Fielding Graduate University, the Mental Health Foundation, Fund for Armenia Relief, Armenian Constitutional Protective Rights Centre, and all those who shared donations and toys for the children.

WNGE presents a workshop in Saudi Arabia

Dr. Ani Kalayjian

World Wide Network for Gender Empowerment of Fielding Graduate University was invited to take part in the International Nursing Symposium 'Building Connections for Global Nursing: Engage, Empower and Transform' which was held at the King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia, 27-28 October 2009.

The profession of nursing is vital to the delivery of quality health care. Organizations depend on the education, experience and the caring nature of nurses to improve the quality of life for individuals, families and communities in our global society. The symposium focused on nursing leadership, practice, education, research, informatics and quality. Each area of interest was covered by presentations, workshops and poster sessions.

WNGE organized and presented a workshop entitled: "Education and Empowerment within the health care system." Workshop faculty were Dr. Anna DiStefano, Provost of Fielding Graduate University as well as the Chair of WNGE and who gave a summary of the goals and mission of WNGE; Dr. Andrea Zielke-Nadkarni, Professor of Nursing Science at Munster University, Germany, who presented on her research helping developing countries have easy access to cooking tools; Dr. Patricia Hinchberger, Professor at University of California, who discussed her research on work place violence, especially in hospitals; Dr. Elham Al Ateeq, Associate Dean for Clinical Affairs and Associate Dean for Academic Affairs, College of Nursing Alhasa, Saudi Arabia, who discussed her own dissertation based on her work on leadership in nursing, and Dr. Ani Kalayjian who presented her 7-step model, addressing how to prevent violence through the Biopsychosocial and Eco-Spiritual Model and through the practice of forgiveness. The workshop was very moving as stated by many participants. Participants asked thought provoking questions as to how to continue being in peace.

Dr. Al-Barnawi, the Chairperson of the symposium, stated that the symposium provided an opportunity for nurses, physicians, students and other health care professionals to learn innovative and creative ideas from national and international speakers. She specially thanked the WNGE panelists who created a wonderful space for people to hear about a spiritually moving method for caring, compassion, transformation, and meaning-making.

WNGE Core Members were also invited to a conference at Alhasa College of Nursing, which proved to be another productive and meaningful conference where participants disseminated valuable research based studies, and set forth plans for future international collaboration.

Geis Memorial Scholarship Award for Dissertation Research

Division 35 Society for the Psychology of Women
Natalie Porter, PhD, Chair

Application Deadline April 1, 2010

The annual Geis Memorial Scholarship Award for Dissertation Research offers $15,000 for the 2010-2011 academic year to fund dissertation research in the Psychology of Women by an advanced doctoral candidate. Eligible research will:

- be feminist
- address a feminist/womanist issue
- use social psychology research methods to make a significant contribution to social psychology theory and research

Dr. Florence L. (Lindy) Geis was a social psychologist with a strong commitment to research on the Psychology of Women and to the mentoring of women graduate students. In her will, she left an endowment to fund doctoral students conducting dissertation research in feminist psychology.

Proposals will be judged on suitability, feasibility, and merit of research. Funding need not be used solely to fund the research project. More information can be found online at http://www.apa.org/divisions/div35 under Awards and Grants.

For an application, e-mail nporter@alliant.edu

Natalie Porter, PhD
Professor
California School of Professional Psychology-Alliant International University
Phone: (415) 955-2137

The Fourth International Conference on Psychology Education (ICOPE2010)

Following the tradition of ICTP2008 held in St. Petersburg, Russia, the conference will convene in Sydney, Australia from July 8-11, 2010, and be organized by the Australian Psychology Educators Network (APEN).

More information on the conference is available at http://icope2010.psy.unsw.edu.au

The Institute for the Study and Promotion of Race and Culture 2010 Diversity Challenge: Race and Culture in Teaching, Training, and Supervision

Each year the Institute for the Study and Promotion of Race and Culture addresses a racial or cultural issue that could benefit from a pragmatic, scholarly, or grassroots focus through its Diversity Challenge conference. The theme of the 2010 conference is the examination of race and culture in teaching, training, and supervision. The two-day conference held at Boston College includes panel discussion/symposia, workshops, structured discussions, a poster session, and individual presentations by invited experts and selected guests including educators, administrators, researchers, mental health professionals, and community organizations. Individuals interested in presenting should check the ISPRC website in January 2010 when the Call for Proposals will be posted, www.bc.edu/isprc. General information about the conference including pre-registration will also available on the website.

I Congress of Psychology and Behavior Analysis

The congress will be held at the State University of Londrina, UEL - Londrina, Parana, Brazil from May 13th to 15th, 2010. Themes include behavior analysis, clinics, forensics, education, health, institutional and others.

Deadline for paper submission:
March 21st, 2010

Deadline for symposium submission:
February 5th, 2010

More information on the congress is available at http://www.uel.br/eventos/cpac/USicpacprinc.php

Registration orders or further questioning should be directed to the Central Organizing Committee at CPAC_uel@yahoo.com.br c/o Celso Socorro Oliveira.

International Employment Opportunities

Michael J. Stevens, PhD, DHC
Illinois State University
mjsteven@ilstu.edu

University of Victoria, Department of Psychology: The Department of Psychology at the University of Victoria invites applications for a tenure-track appointment in cognitive neuroscience at the level of assistant professor to begin July 1, 2010. The ideal candidate will have a strong background and training in functional magnetic resonance imaging and in computational cognitive neuroscience techniques, but applications demonstrating competence in either of these methods will be considered. The candidate's research interests will add to the existing strengths of the department that include the study of cognitive control, attention, learning, memory, eyewitness testimony, visual cognition, motor control, development and aging. The successful candidate will play a key role in the development of a 1.5 T General Electric MRI system, presently being upgraded to be capable of acquiring functional data, at the Royal Jubilee Hospital located approximately 1 mile from campus. The candidate will also have access to Westgrid, a high-performance computing network that encompasses 14 partner institutions across four provinces. Duties include the maintenance of a successful program of research (as evidenced by publications and external grant support), teaching at the undergraduate and graduate levels, and contributions to the collegiality, reputation, and day-to-day operation of the Department and the University (e.g., collaborative research, curriculum development and committee service). Applicants must have a PhD in cognitive psychology, cognitive neuroscience, neuroscience, computer science, or a related discipline. The deadline is December 7, 2009, but applications will be reviewed until the position is filled. To apply, submit a letter of application (including a statement of research interests and accomplishments and a statement of teaching interests and experience), a curriculum vitae, copies of publications, evidence of teaching experience, and arrange for three confidential letters of reference to be sent to: Cognitive and Brain Sciences Search Committee Department of Psychology University of Victoria PO Box 3050 STN CSC Victoria, British Columbia V8W 3P5 Canada.

Children and Youth in the Cypress Health Region, Child and Adolescent Clinical Psychologist: As a member of the Community Health Services Child & Youth Mental Health team, the psychologist provides treatment, consultation and referral services for Children and Youth in the Cypress Health Region. Other duties include consultation to community agencies, public seminars and lectures. Must possess a master's degree or a PhD in psychology (master's = $31.756 -$38.842 per hour; PhD = $40.005 - $48.928 per hour). Must be registered with the Saskatchewan College of Psychologists, extensive clinical experience in child and youth mental health services, good working knowledge of relevant legislation, extensive knowledge in psychotherapeutic techniques and the administration, scoring and interpretation of a wide range of psychological tests, knowledge of concepts of mental illness and proven ability to formulate diagnoses based on the DSM IV, and ability to design and deliver prevention and promotion programs to professionals and public. Valid driver's license required. In addition to an excellent benefit plan and strong community advantages, the Cypress Health Region also offers assistance in locating spousal employment opportunities. Our incentive package includes relocation funding of $5,000. Successful applicants may also be eligible for up to $10,000 in grant funding from Saskatchewan Health. Employer will assist with relocation costs.

IWK Health Centre, Provincial Child and Youth Forensic Services: The Provincial Child and Youth Forensic Services team, a service operated under the Mental Health and Addictions Program at the IWK Health Centre, has a position for a clinical psychologist. The mission of Provincial Child and Youth Forensic Services is to provide evidence-based best practice Health and Mental Health Services to children, youth, and families involved with Justice Services. The clinical psychologist will work with the expanding and dynamic Youth Justice Assessment Services Team which provides specialized, comprehensive, interdisciplinary assessments for the judicial system, specifically in the relation to matters before the Youth Justice Court. The Clinical Psychologist conducts court ordered assessments under section 34 of the Youth Criminal Justice Act as well as risk assessments for the Criminal Code Review Board. The assessment report provides the court with rehabilitative recommendations for sentencing purposes and recommendations around risk management. These assessments require the ability to work within deadlines and to work effectively with other members of the assessment team to meet standards for quality control. This position will require some travel to other parts of the province which is compensated. The clinical psychologist works collaboratively with social work to conduct interdisciplinary assessments. The clinical psychologist also consults with other teams within the Mental Health and Addictions Program around Forensic case management and risk assessments. The Residency Program in Pediatric and Child-Adolescent psychology at the IWK Health Centre is both APA- and CPA- approved. The successful candidate will be expected to actively participate in training residents. Candidates with appropriate credentials may be considered for academic adjunct appointment in an appropriate university department at Dalhousie University. Further information about this position can be obtained from Vicky Veitch Wolfe, PhD, Psychology Professional Practice Chief, at 902-470-8458 or vicky.wolfe@iwk.nshealth.ca. Applicants must specify the

competition number and include a copy of his/her curriculum vitae, pertinent scientific publications and three letters of recommendations from professionals attesting to the applicant's clinical training, clinical skills and character. For individuals with less than 3 years of experience, an additional letter must be provided, from the Director of Clinical Training, at the institution where the applicant completed his/her clinical internship.

Qualifications:

- PhD / PsyD in clinical psychology from an accredited university program
- Registered, or eligible to be registered, with the Nova Scotia Board of Examiners in Psychology
- Minimum 5 years of formal training and clinical experience in child/adolescent mental health
- Demonstrated ability to consult with professional and paraprofessional staff
- Demonstrated ability to diagnose and formulate treatment protocols for a wide range of adolescent mental health problems
- Demonstrated ability to effectively consult with other health, social service and education agencies
- Demonstrated knowledge in the area of ecological intervention preferred
- Demonstrated ability to work well as part of an interdisciplinary team required
- Demonstrated excellent verbal and written communication skills required
- Ability to participate in the clinical training activities of the psychology discipline
- Education, experience, or training in the related subspecialty area preferred
- Competencies in other languages an asset; French preferred

Interested parties are asked to submit a current resume including month and year of employment in past positions and a cover letter outlining their qualifications for the role. Please include the competition number, and if you are an employee of the IWK Health Centre, in the subject line of your email or within your cover letter and send to:
Email: Human.Resources@IWK.nshealth.ca (preferred method)
IWK Health Center, Human Resources, 5850/5980 University Avenue, PO Box 9700, Halifax, NS B3K 6R8, Canada; Tel: (902) 470-8012, Fax: (902) 470-6612

International Max Planck Institute for Human Cognitive and Brain Sciences; 15 positions: The Max Planck Institute for Human Cognitive and Brain Sciences in Leipzig, Germany, Department of Social Neuroscience (Director: Prof. Tania Singer), invites applications for group leader, senior researcher, postdoctoral, and PhD student positions in the following fields:
A. Social Neuroscience (social cognition, decision making, neuroplasticity, development)
B. Psychopathology (social cognition in individuals with autism, alexithymia, psychopathy)
C. Psychobiology (stress physiology, biomarkers)
D. Psychology (subjective affect, motivation)
The positions are part of a new interdisciplinary department (to be opened in 2010) that will investigate the foundations of human social behavior and, more specifically, the developmental, neural, and hormonal mechanisms underlying social cognition and social emotions. Most of these positions will be involved in a longitudinal study on the effects of cognitive and affective training on the brain, health, subjective well-being, and behavior. These positions are primarily devoted to research, with no teaching and minimal administrative duties, and will begin no later than September 1, 2010.
Successful candidates for the group leader and the senior researcher positions have research experience as a postdoctoral fellow in one of the above-mentioned fields and show evidence of scholarly promise in the form of publications and other achievements.
- Positions in fields A and B require a background in structural and functional MRI (preferably with SPM, Matlab) and behavioral analyses. Knowledge of other neuroscientific methods (e.g., TMS/tDCS, EEG) would be advantageous.
- Positions in field C require experience in using biological markers (e.g., cortisol assays, stress physiology, genetic markers) in conjunction with neuroimaging paradigms.
- Positions in field D require experience with motivational and social psychological paradigms, and preferably with structural equation modeling (or latent growth modeling of longitudinal data) and event-sampling methods.
The Max Planck Institute in Leipzig (http://www.cbs.mpg.de) offers an international research environment, with English being the language spoken in the laboratory. It brings together a large number of researchers with diverse backgrounds, who are united by their interest in the human brain and methods for its exploration. Moreover, it offers a friendly and generous environment with an excellent infrastructure (e.g., three human 3T and one 7T MRI, rt-fMRI, EEG, TMS/tDCS, MEG, pharmacology laboratory, behavioral laboratory). The Department also has additional laboratory space in Berlin, which is located just an hour by train to the north of Leipzig. For further details, see http://www.cbs.mpg.de/singer or contact Tania Singer (singer@iew.uzh.ch). Applications (including a CV, list of publications, statement of research interests, and contact information of 3 referees) should be sent as a single PDF file, with your name as the file name, to Tania Singer (singer@iew.uzh.ch) and Tamara Herz (therz@access.uzh.ch). Review of applications will begin immediately and continue until the positions are filled. Shortlisted candidates will be invited to meet Tania Singer in Zurich or at the CNS Meeting in Montreal (April 2010) or the HBM Meeting in Barcelona (June 2010).

Germany, Clinical Psychologists: Adult psychologists needed to work with active duty military members and their families in Landstuhl, Germany, on a contract basis. Minimum 1-year commitment, paid relocation, tax incentives, and

paid malpractice insurance. Position includes on-base privileges such as commissary and exchange, gasoline, officers clubs, recreational facilities, etc. Must be licensed in any state, and have completed an APA-accredited internship in clinical or counseling psychology. For more details, send curriculum vitae to Mary Holland at mholland@neshold.com. Fax is (757) 420-6616.

Ben-Guiron University, Department of Psychology: The Psychology Department, Ben-Gurion University, Israel (www.bgu.ac.il/psychology) offers tenure-track positions in clinical, clinical-neuropsychology, and clinical child/infant psychology. Please send description of research agenda, CV, pdfs of representative publications, and email addresses of references to Prof. Nachshon Meiran, nmeiran@bgu.ac.il.

Align Recruitment, Forensic Clinical Psychologist: We have full-time clinical psychologist vacancies to fill for community mental health and other service organizations. You must have a PhD in clinical psychology, current practicing license, minimum of 2 years post-supervisory experience, the ability to receive your New Zealand psychologist registration with clinical scope, and the desire to commit 2 years or longer. E-mail office@alignrecruitment.com; Tel: +64 3 366 8779: Fax: +64 3 377 6770; Web www.alignrecruitment.com. An expatriate American is available to assist with all enquiries.

King Fahd University, Department of General Studies: The Department of General Studies at King Fahd University of Petroleum & Minerals (KFUPM) in Dhahran, Saudi Arabia, invites applications for full-time faculty positions at the rank of assistant/associate professor in psychology. Applicants are expected to hold a PhD degree with a strong commitment to research and teaching as well as serving the university. Applicants are also expected to have superior ability to teach in English (as the language of instruction at KFUPM is English). Candidates with Middle Eastern expertise are strongly encouraged to apply.

Salary and Benefits:

These positions are full-time, 2-year renewable contracts with competitive tax-free salary based on qualifications and experience, free furnished air-conditioned on-campus housing unit with free essential utilities and maintenance. Subject to University policy, the appointment includes the following additional benefits: air ticket/s to Dammam on appointment; annual repatriation air tickets to Dammam for the faculty and up to three of his dependents; tuition fees for school-age dependent children enrolled in local schools; local transportation allowance; 2 months' paid summer vacation, end-of service benefits, and free access to recreation facilities. KFUPM campus has a range of facilities including medical and dental clinic, and teaching and research support facilities, such as extensive library acquisitions and library databases, computing facilities, smart classrooms, and research and teaching laboratories. The campus is within a very short distance from the cities of Dammam and Al-Khobar.

Review of applications will continue until the positions are filled. To apply, send (preferably by e-mail) cover letter, detailed resume, completed KFUPM application form with copies of credentials (academic degrees and transcript/s) and three referees to the following address:

Dean of Faculty & Personnel Affairs, Dept. Ref. No. DGS-PSY-010, KFUPM Box 5005, Dhahran 31261, Saudi Arabia; E-mail: faculty@kfupm.edu.sa or c-gsd@kfupm.edu.sa; Fax: +966-3-860-2429 or 860-2442

To download the KFUPM Application Form, click on the link http://www.kfupm.edu.sa/fpa/serv/InfApplicFacPosi.mht

For more information, please visit the KFUPM web site: http://www.kfupm.edu.sa

Institute of Mental Health, Research Officer: You will be part of a multidisciplinary team conducting translational research in psychiatry. You will be trained in relevant assessments and assess research participants on clinical and neuropsychological scales. You will also be tasked to undertake recruitment and collect data from case-records/patient interviews. You will have opportunities to attend courses and conferences as well as to co-author papers for publications and make presentations at local and overseas scientific meetings.

Duties and Responsibilities:

- Psychological testing and diagnostic assessments
- Subject recruitment
- Data collection and management
- Analyses and reporting of study data
- Completion of appropriate research clinical trainings and engaging in general activities pertaining to the planning and execution of research studies.

Requirements:

- Master's degree in psychology
- Training and experience in conducting psychological testing (neuropsychological testing an asset)
- Strong communication and presentation skills

To apply, email your detailed resume, stating your current and expected salary to:

The Human Resource Department, Institute of Mental Health / Woodbridge Hospital, 10 Buangkok View Singapore 539747; E-mail: careers@imh.com.sg, www.imhresearch.com.sg

Singapore Management University, School of Social Sciences: The School of Social Sciences (SOSS), Singapore Management University, invites applications for tenure-track positions in psychology at the assistant, associate, or full professor rank, to begin in July 2010. Positions are available in cognitive psychology (with focus on judgment and decision making) and industrial/organizational psychology. The positions require a doctorate in psychology by the date of appointment. We are seeking candidates with a demonstrated record of, or high potential of, scholarly research commensurate with the rank and a strong ability or aptitude to teach a wide range of undergraduate and postgraduate courses. The SOSS,

which has a strong record of attracting the best students in Singapore and the region, is committed to an interdisciplinary and integrated undergraduate curriculum. The ideal candidate will have a strong commitment to excellence in research and teaching at both undergraduate and postgraduate levels (the PhD in psychology program will begin with its first student intake in August 2010). A research interest in Singapore and the Asian region will be an advantage. The teaching load is light compared to many research universities. The research support is excellent and salary and benefits are highly competitive.

Full evaluation of applications will start December 1, 2009 and on-campus interviews will typically be conducted in the period from January to March 2010. However, submission of applications is open and evaluation will continue until the positions are filled. Applicants must submit, in electronic form (Word or PDF file), a detailed curriculum vitae, a description of research interest and philosophy, and a statement of teaching interests and philosophy to the following address: socialsciencescv@smu.edu.sg. Applicants should also send hardcopies (if not available in electronic form) of selected publications and teaching evaluations. Applicants should arrange for three confidential letters of recommendation to be sent directly to: The Dean's Office, School of Social Sciences, Singapore Management University, 90 Stamford Road, Level 4, Singapore 178903. Information about the University and the School can be found at www.socsc.smu.edu.sg.

University of Exeter, Department of Psychology: The Department of Psychology at the University of Exeter in the UK is seeking to fill a permanent (equivalent to tenure track) faculty position in clinical psychology, starting in September 2010. The position provides 80-100% dedicated research time for the first 3 years to support the appointee in generating a sustainable externally funded research program. We particularly welcome applications from people who can build on existing strengths in the Mood Disorders Center http://centres.exeter.ac.uk/mood/, and ideally bridging with work on health behavior, primary prevention, health services research, public health, and/or chronic disease (e.g., diabetes, obesity, cardiovascular disease). The Department includes an accredited doctoral clinical psychology program, master's-degree programs in cognitive behavioral therapy and mindfulness-based cognitive therapy, and a clinic that is fully integrated with out research and teaching. The starting salary for Lecturer will be circa £32,000 [US $50,718] per annum on University pay scale Grade F, with progression possible to £38,757 [US $61,427] and for Senior Lecturer will be circa £39,000 [US $61,812] per annum Grade G, progression possible to £52,086 [US $82,552]. For a clinically qualified person a market supplement of currently £11,139 [US $17,655] per annum will also be paid (subject to annual review) in accordance with the University's agreed policy on market supplements. This allowance is pensionable and will be reviewed in August each year. These figures will vary depending upon the exchange rate. The University can offer an excellent range of staff benefits and facilities including final pension salary scheme. Contact Professor Willem Kuyken by e-mail at w.kuyken@exeter.ac.uk or any member of the Mood Disorders Center Faculty. Applicants interested in applying can download an application pack from http://www.admin.ex.ac.uk/personnel/jobs/H80N1931.pdf. The closing date for completed applications is 12 noon February 12, 2010.

Bermuda Hospitals, Child and Adolescent Services: The Bermuda Hospitals Board is an innovative multidisciplinary healthcare system, dedicated to excellence, and committed to patient-centered care. Our supportive environment celebrates diversity in the workplace and places great emphasis on professional and personal development of all our staff. We invite applications for clinical psychologist child and adolescent services. You will be responsible to provide psychological services to individuals and/or groups, evaluate and improve current services and programs, conduct research projects, and consult with other child friendly organizations. An effective communicator, able to work harmoniously in a demanding and diverse environment, you will provide clinical supervision to junior staff and assist with in-service training programs. You have a terminal degree in clinical psychology recognized by country of training as a requirement for independent practice (e.g., master's in UK, doctorate in US), a minimum 4 years post-qualification experience with at least 2 years specializing in child and adolescent services, and the appropriate professional affiliations. Eligible for registration as an independent psychologist under the Bermuda Psychologists Practitioners Act 1998, you have sound knowledge of other local agencies providing services to children and adolescents. Able to work collaboratively with interdisciplinary and multidisciplinary teams, you have excellent interpersonal, organizational, written, and verbal skills. Apply directly online, quoting posting to: www.bermudahospitals.bm. Pre-employment substance abuse screening is mandatory for all successful applicants. Web site: www.bermudahospitals.bm

McGill University, Department of Educational and Counseling Psychology: The Department of Educational and Counseling Psychology (http://www.mcgill.ca/edu-ecp) invites applications for a tenure track position at the assistant, associate or full Professor rank, effective August 1, 2010. Our counseling psychology program offers three degrees: two MA non-thesis programs (internship and research) and a PhD program accredited by the CPA, the APA, and the OPQ (licensing body of psychologists in Quebec). The programs operate from a scientist-practitioner model. Current faculty have expertise in health and wellness; feminism, multiculturalism, and career psychology; and psychotherapy processes and outcomes. We are searching for a candidate with a strong counseling psychology identity whose research and teaching interests are in the areas of career counseling and/or multiculturalism. The successful candidate will have an earned doctorate in counseling psychology or related discipline at the time of appointment, be a licensed or license-eligible psychologist (in Quebec), demonstrate evidence of scholarly

productivity and publication commensurate with rank at a research-intensive university, have demonstrated competence in counseling and teaching, and be able to supervise master's and doctoral students. The ability to liaise with the Quebec licensing body of career counselors (OCCOPPQ) would be an asset. The application deadline is January 15, 2010, or until the position is filled. Persons wishing to be considered for this position should forward a statement of research interests, a statement of teaching philosophy and interests, a curriculum vitae, and samples of research, and arrange to have three letters of recommendation submitted directly to: Professor Alenoush Saroyan, Chair, Department of Educational and Counseling Psychology, McGill University, 3700 McTavish Street, Montreal, Quebec, Canada H3A 1Y2. Electronic submissions are accepted and should be forwarded to: ecp@mcgill.ca. Please enter "Counseling Search" and your name in the subject field.

McGill University, Department of Educational and Counseling Psychology: The Department of Educational Counseling and Psychology (http://www.mcgill.ca/edu-ecp) invites applications for a tenure track position in the learning sciences program at the assistant or associate professor rank, effective August 1, 2010. The successful candidate will have an active program of interdisciplinary research, investigating learning as it happens in real-world settings (schools, workplace and informal settings). Research interests can include, medicine, mathematics and science, computer science, anthropology, sociology, information sciences, neurosciences, and design studies. Applicants should have an earned doctorate in the cognate fields of the learning sciences at the time of appointment, demonstrate evidence of scholarly productivity and publication commensurate with rank at a research-intensive university, and demonstrate competence in teaching and graduate supervision. The successful candidate will be expected to teach at graduate and undergraduate levels and supervise master's and doctoral students. The application deadline is January 15, 2010, or until the position is filled. Persons wishing to be considered for this position should forward a statement of research interests, a statement of teaching philosophy and interests, a curriculum vitae, and samples of research, and arrange to have three letters of recommendation submitted directly to: Professor Alenoush Saroyan, Chair, Department of Educational and Counseling Psychology, McGill University, 3700 McTavish Street, Montreal, Quebec, Canada H3A 1Y2. Electronic submissions are accepted and should be forwarded to: ecp@mcgill.ca. Enter "Learning Sciences Search" and your name in the subject field.

Redeemer University College, Department of Psychology: Redeemer University College invites applications for a tenure-track position (any rank) in any area of experimental psychology, beginning July 1, 2010. We prefer candidates who can teach courses in personality, principles of learning, and social psychology, although applications from candidates with expertise in any area of experimental psychology will be seriously considered. As a liberal arts and sciences university college rooted in the Reformed tradition of Christianity, we seek candidates who are committed to teaching and pursuing scholarship from this perspective. Applicants should possess, or be near completion of, a PhD. Interested applicants should submit a curriculum vitae, three letters of reference, evidence of teaching quality, and a one-page or two-page statement describing their own faith commitment and how it shapes their academic work. The deadline for applications is January 31, 2010, or until the position is filled. Direct general inquiries and applications to: Dr. Jacob P. Ellens, Vice President, Academic, Redeemer University College, 777 Garner Road East, Ancaster, ON L9K 1J4 Canada.
E-mail: jelens@redeemer.ca

Cape Breton District Health Authority, Eating Disorder Clinic: Reporting to the Manager of Emergency & Acute Outpatient Mental Health Services, the psychologist provides assessment and treatment to adult patients aged 19 yrs and older with a variety of mental health disorders. The psychologist will function as a primary therapist within a multidisciplinary team and will be involved in the planning, development and evaluation of treatment for patients utilizing both individual therapy and group treatment models. Development of group treatment programs for adult services is a key component of the position. The successful candidate will have a doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology. He/she must be registered or eligible for registration with the Nova Scotia Board of Examiners in Psychology.

Requirements

- Doctoral degree in clinical psychology from an educational institution acceptable to the Nova Scotia Board of Examiners in Psychology
- Registered, or eligible for registration with the Nova Scotia Board of Examiners in Psychology
- 5 years clinical experience in an inpatient/outpatient mental health setting, providing independent assessment and treatment of adult mental health disorders
- Specialized expertise in the treatment of eating disorders involving independent assessment, consultation, diagnosis and treatment
- Experience in the development of effective linkages with other health, social service and community agencies as appropriate
- Training or experience in crisis intervention and suicide risk assessment
- Willing to participate in clinical training activities
- Valid driver's license and access to reliable transportation
- Physical ability to perform the duties of the position
- Good attendance and work record

Please send your resume and cover letter to: Kim Dilney, Employment Coordinator, Human Resources Department, Cape Breton District Health Authority, 1482 George Street, Sydney, NS B1P 1P3, Canada; Fax: (902)567-7224

Bremen International Graduate School, Social Sciences: The Bremen International Graduate School of Social Sciences (BIGSSS) invites applications to its PhD and postdoctoral programs. BIGSSS is an inter-university institute of the University of Bremen and Jacobs University, and is funded by the German Excellence Initiative. The program provides close supervision of dissertation work within a demand-tailored education and research framework. BIGSSS is part of an international network of highly acknowledged graduate programs. It supports its doctoral and postdoctoral fellows in achieving early scientific independence and provides funds for the conduct, presentation, and publishing of their research. The language of instruction is English. Successful applicants for the PhD and postdoctoral fellowships will pursue a topic in one or more of BIGSSS' five thematic fields: global integration; integration and diversity in the new Europe; social integration and the welfare state; attitude formation, value change, and intercultural communication; and life-course and lifespan dynamics.

20 PhD stipends/fellowships - BIGSSS seeks candidates with strong academic abilities and a master's degree (or equivalent) in political science, sociology, or psychology. Applicants with a degree in law, economics, or other social science disciplines are also welcome. We offer PhD stipends of € 1250/month for 36 months, contingent on successful completion of each year.

4-6 postdoctoral stipends/fellowships - We seek candidates pursuing English-language publication projects based either on their dissertations (by making findings available to an international audience through a book or journal article) or new research. Postdoctoral stipends of € 1750/month may run for between 6 and 24 months. The competition is open to candidates who have received a doctorate in political science, sociology, psychology, law, economics or other social science disciplines within the last 3 years and to those who can be expected to finish prior to commencing their postdoctoral stay.

PhD fellowships will start September 1, 2010. Postdoctoral fellows may plan their stays to begin later. Non-German students are strongly encouraged to apply. Applications must be submitted online under "Admissions" at www.bigsss-bremen.de until March 15, 2010. More information as well as lists of required application materials can be found at www.bigsss-bremen.de. For additional inquiries, please check the online FAQ and feel free to contact our admissions officer at admissions-officer@bigsss-bremen.de

University of Hong Kong, Department of Psychology: Applications are invited for the appointment as assistant professor in school / educational psychology in the Department of Psychology, from September 1, 2010, or as soon as possible thereafter, on a 3-year fixed-term basis, with the possibility of renewal. Applicants should possess a doctoral degree in school / educational psychology or an equivalent qualification, with relevant work experience, and be eligible for professional practice in school / educational psychology. Knowledge of Chinese community and familiarity with the local community are preferred. Applicants should also have a strong record of research and teaching. The appointee is required to contribute to the teaching and administration of a professional graduate program in school / educational psychology. He/she is also expected to maintain an active research program and will be responsible for teaching both graduate and undergraduate courses, and supervising research. Information about the Department can be obtained at http://www3.hku.hk/psychodp/

Annual salary for an assistant professorship will be in the range of HK$504,480–779,640 (approximately US$1=HK$7.8) (subject to review from time to time at the entire discretion of the University). The appointment will attract a contract-end gratuity and University contribution to a retirement benefits scheme, totaling up to 15% of basic salary, as well as leave, and medical/dental benefits. Housing benefits will also be provided as applicable. At current rates, salaries tax does not exceed 15% of gross income. Further particulars and application forms (152/708) can be obtained at http://www.hku.hk/apptunit/ or from the Appointments Unit (Senior), Human Resource Section, Registry, University of Hong Kong, Hong Kong; Fax: (852) 2540-6735 or 2559 2058; E-mail: senrappt@hku.hk). Review of applications will begin immediately until the post is filled. Candidates who are not contacted within 3 months of the date of their application may consider their application unsuccessful.

Lingnan University, Department of Sociology and Social Policy: Lignan University, a distinctive liberal arts institution in the Hong Kong Special Administrative Region, is committed to the provision of quality education distinguished by the best liberal arts traditions. Adopting a whole-person approach to education, it offers a wide range of honors bachelor's degrees and postgraduate programs up to the doctoral level in the disciplines of arts, business, and social sciences. Lingnan University is fully committed to the pursuit of excellence in both teaching and research. Applications are invited for the following position, which will be tenable from mid-August 2010 or by mutual agreement thereafter:

Assistant Professor:

The Department of Sociology and Social Policy (http://www.LN.edu.hk/socsp/) combines teaching and research in sociology, social policy, and behavioral sciences. It contributes with the Department of Economics and the Department of Political Science to the integrated Social Sciences Program in the University. Applicants are recommended to visit the

departmental web site and program web site (http://www.LN.edu.hk/progs/ssprog/) for more information. The appointee should have a PhD degree in psychology, with particular experience in behavioral science and social psychology. Areas of teaching specialization are open, but willingness to teach in at least two of the following is preferred: Introduction to Behavioral Science, Human Development and Psychology of Adulthood, Exploring Psychology in Western and Chinese Cultures, Positive Psychology, Abnormal Psychology, Stress Management & Life Balance, Environmental Psychology, and Social Psychology. The ability to contribute to introductory courses in research methods and statistics in social sciences will also be an advantage.

Applicants are required to provide information on their research records and evidence of quality teaching. Excellent communication and presentation skills are essential. Administrative experience will be a distinct advantage. The successful appointee is expected to have a strong commitment to teaching excellence and services to the Department and the University community, and to engage actively in quality research and publication. The monthly salary will be around HK$45,300 - HK$71,400 (approximate exchange rate: US$1 = HK$7.8). The remuneration will be commensurate with qualifications and experience. Fringe benefits include annual leave, medical and dental benefits, mandatory provident fund, gratuity, and, if applicable, housing benefits and incoming passage and baggage allowance for the eligible appointee. Appointment will normally be made on an initial fixed-term contract of 3 years, renewable subject to mutual agreement. Applicants are invited to forward their dossier together with a personal data sheet (Form R1), which is obtainable from the University's web site at http://www.ln.edu.hk/hr/application-forms, to the Human Resources Office, Lingnan University, Tuen Mun, Hong Kong by post, by Fax at (852) 2891-5782, or by Email to recruit@LN.edu.hk (as attachment in MS Word format). Applicants should supply at least three names and contact information of referees having the applicant's prior consent to provide reference. Applications will continue to be received until the position is filled, but review of applications will begin in mid-December 2009. The University reserves the right not to fill the post or to fill the post by invitation or by search. Further information on the University and its programs and activities can be found on the University's web site: http://www.LN.edu.hk. Enquiries can be directed to recruit@LN.edu.hk.

Sabanc University, School of Arts and Social Science: Sabanc University, invites applications and/or nominations for a faculty position in social cognitive psychology. The position is open as of September 2010, to mid-career candidates as well as candidates who have recently completed their PhD or are near completion. We seek a scholar with a PhD in psychology, with strong specialization in social cognitive psychology, applied cognitive science, applied decision making with a solid theoretical background. Further specialization in one or more of the following areas is preferred: conflict analysis and resolution, social psychology, political psychology, self and identity, social cognition, naturalistic decision-making, and psychology of education and learning. The successful candidate must have a strong record and potential for top quality scholarly publication, as well as promise of outstanding teaching at both the undergraduate and graduate levels.

Sabanc University is a private, department-free, innovative academic institution. It is strongly committed to interdisciplinary research and teaching both at the undergraduate and graduate levels. To meet this challenge, the School of Arts and Social Sciences is organized around multidisciplinary degree programs including conflict analysis and resolution (MA), cultural studies (BA, MA), economics (BA, MA, PhD), European studies (MA), history (MA, PhD), management (BA), political science (MA, PhD), social and political sciences (BA), Turkish studies (MA), visual arts & communication design (BA, MA), and the Faculty of Management offers degree programs in management (BA), finance (MA), MBA, executive MBA, leaders for industry (a dual degree offered with the Faculty of Engineering and Natural Sciences) and PhD in management and organizations, operations management, and finance. The university admits top-ranking students for its undergraduate programs through a centralized university entrance examination. Faculty members are provided with excellent support, including housing facilities on its modern campus if available or a housing stipend.

Applicants are asked to complete an online application form through the university website (Applicant Tracking System): http://www.sabanciuniv.edu/eng/?aday_calisanlar/akademik_is_basvurulari.html

Additionally, a curriculum vitae, a clear statement of current and planned research and teaching activities, and at least three letters of reference should be sent via email to: Mehmet Bac, Dean, Faculty of Arts and Social Sciences, bac@sabanciuniv.edu with Cc: Inci Ceydeli, Faculty Administrative Manager, inci@sabanciuniv.edu

New York University at Abu Dhabi, Interactive Media and Technology: New York University has established a campus in Abu Dhabi with the ambition to become the leading institution of global higher education in the 21st century. NYU Abu Dhabi invites applications and nominations for one or more tenured or tenure-track positions in digital media design for the Arts and Humanities. We are seeking experienced individuals with an interdisciplinary interest in technology, digital media, and science, i.e., in the theoretical and practical aspects of their interrelation, and a completed doctorate in one of these fields. Specific research interests may range from cinema and film studies and visual culture to the learning sciences and memory and cognition. Preferred candidates will have an active agenda and proven track record of research, publication, and undergraduate teaching.

NYU Abu Dhabi is recruiting faculty of international distinction committed to active research and the finest teaching, to building a pioneering global institution of the highest quality, and to forging an international community of scholars and students. To accomplish these goals, NYU Abu Dhabi is committed to providing outstanding resources and facilities for faculty research and teaching. Alongside its highly selective liberal arts college, NYU Abu Dhabi will create distinctive graduate programs and a world-class institute for advanced research that fosters creative work across the Arts, Humanities, Social Sciences, Sciences, and Engineering. Situated at a new global crossroads, NYU Abu Dhabi has the resources and resolve to become a preeminent center of collaborative intellectual pursuit and impact. NYU New York and NYU Abu Dhabi are integrally connected. The faculties work together, and the campuses form the foundation of a unique global network university, linked to NYU's other study and research sites on five continents. Major research projects and public programs are underway. We have recruited our first cohort of faculty across many disciplines and the first class of students of remarkable potential from across the world will arrive in Fall 2010. The international character of NYUAD is reflected in the global composition of the faculty and the student body as well as the research agenda and curriculum, which have been designed to promote inventiveness, intellectual curiosity, multidisciplinary interest, and intercultural understanding.

The terms of employment are competitive compared to U.S. benchmarks and include housing and educational subsidies for children. Faculty may spend time at NYU in New York and at its other global campuses. The appointment might begin as soon as September 1, 2010, or could be delayed until September 1, 2011.

Review of applications for the positions listed above will begin immediately, with a final deadline of January 31, 2010, for receipt of applications. Applicants need to submit the following documents in PDF format to be considered: curriculum vitae, statement of research and teaching interests, representative publications, and three letters of reference. For more information on the Arts and Humanities searches and for instructions on how to apply, please visit our web site at http://nyuad.nyu.edu/human.resources/open.positions.html. If you have any questions, please Email: nyuad.itp@nyu.edu

Department Chair, International Psychology
The Chicago School of Professional Psychology – Chicago Campus: The Chicago School of Professional Psychology (www.thechicagoschool.edu) is an independent, regionally accredited not-for profit graduate school providing education for careers in psychology and related behavioral and health sciences. The Chairperson of the International Psychology Department is responsible for providing visionary leadership for the academic direction of the department. The Department Chair must be an optimistic, action-oriented leader who will motivate faculty to embrace these values in the classroom and within the institution. Responsibilities include curriculum quality and development, scheduling, preparation for programmatic accreditation, assessment of student learning and program improvement, and supervision of faculty and department administrators.

The International Psychology PhD was launched on line in 2009. The Department Chair is being brought in to lead and grow the campus-based version of the program.

Position Qualifications:

- A doctoral degree in psychology, concentration open, with a license or license eligibility desired.
- Teaching and academic administration at the post-secondary level as well as professional experience is required.
- Extensive international experience in at least one of the following areas is essential: international field work (e.g., Fulbright Scholar; visiting professor); international research including partnering with international scholars and/or collaborating on-site in data design, collection, and publication; international professional association work (e.g., officer with one of the international associations such as International Council of Psychologists).
- Solid people development skills with a focus on providing opportunities for faculty and staff to excel.

Why consider the opportunity?

- Healthy institution in growth mode. It is an exciting time to be a part of the institution. Opportunities are unlimited.
- The International Psychology program is the first of its kind in the US. You will help build and grow the campus-based program.
- Culture. The Chicago School offers a culture of innovation and excellence. It is a fast-paced, fun place to work. Bright, hardworking, ambitious employees are valued and rewarded. TCS was named one of the "best colleges to work for" by The Chronicle of Higher Ed in 2009.

For more information or to apply, contact:
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Margaret E. Donnelly (1911–2006)

DOI: 10.1037/0003-066X.62.7.700a

Margaret Extitus Donnelly died on July 16, 2006, at the age of 95. A member of the American Psychological Association (APA) for 64 years, Margaret worked behind the scenes in several APA divisions and was probably best known for an edited book published when she was 81 years old, a tribute to her vitality and lifetime commitment to psychology.

Margaret was born in Brooklyn, New York, on June 7, 1911, and remained a Brooklyn resident her entire life. She received her bachelor's degree in philosophy (1937) and her master's degree in experimental psychology (1940), both from Fordham University. Her doctoral studies at Fordham were interrupted first by an uncooperative mentor and later by marriage and the birth of her daughter, Virginia Mary. She completed her doctorate in general theoretical psychology at Fordham in 1973.

Prior to completing her doctorate, Margaret taught at several colleges and universities, including Bard College, Seton Hall University, and Hunter College in the Bronx (later Herbert Lehman College of the City University of New York), but she spent most of her professional life as a faculty member at Pace University. A life-long scholar, Margaret pursued postdoctoral learning in such diverse subjects as Charles Darwin (Cambridge University), the Rorschach (with Bruno Klopfer), and Carl Jung (at the Jung Institute in Kusnacht, Switzerland). She continued teaching into her nineties.

Margaret played an important role in the establishment of APA Division 36 (originally called Psychologists Interested in Religious Issues, or PIRI, and now called Psychology of Religion). The division had grown out of the American Catholic Psychological Association (ACPA) in which Margaret had been an active member for many years. She was the founding secretary-treasurer of the division (1976) and continued in that position until 1982. In addition, she served the division as member-at-large and archivist.

She was also active in APA Division 1 (General Psychology) and Division 24 (Theoretical and Philosophical Psychology). She was probably best known for her 1992 edited book on William James (*Reinterpreting the Legacy of William James*), which was published by the APA and contained an extraordinary collection of scholars' comments on the work of James, particularly his *Principles of Psychology* (1890).

Margaret made many contributions to the New York State Psychological Association (NYSPA). She was president of the NYSPA Academic Division and a recipient of its Wilhelm Wundt Award for her research contributions to psychology. In recent years, she had been chronicling the history of the Pace University Department of Psychology. In her nineties, she joined a newly formed collective of psychology historians who are documenting the history of psychology in New York.

Margaret was predeceased by her husband, Joseph Donnelly. In addition to her daughter, Virginia Mary, she is survived by her granddaughter, Kate Phillips.

Florence L. Denmark and Richard S. Velayo
Pace University

Richard A. Pasewark (1927–2007)

DOI: 10.1037/0003-066X.62.7.700b

Richard A. Pasewark was born on October 21, 1927, and raised in the Bronx, New York. He died on February 2, 2007, at home in Oak Harbor, Washington, after a battle with pancreatic cancer. He is survived by his wife Karen, his sons Michael, Mark, and Kyle, his grandson Eric, and his brother William.

Richard received his bachelor's degree from City College of New York (1949) and his master's (1950) and doctoral (1957) degrees in psychology from New York University. He joined the Wyoming Division of Mental Health in 1957 and by 1959 became its director, the first psychologist in history to become a director of a state division of mental health. In 1961 he joined the faculty at the University of Wyoming (UW), where he remained for 33 years, giving tirelessly of himself to the department, students, faculty, university, and region.

Richard was the director of training at UW for 18 years, established the Psychology Clinic, and led the psychology program to American Psychological Association (APA) accreditation. He served as the psychology department chair as well as on many boards and professional associations. He was president of the Wyoming Psychological Association (three times) and a member of the Governor's Executive Committee on Criminal Administration (10 years), the Wyoming Association for Mental Health, the Mental Health Council for the Western Interstate Commission for Higher Education, the Governor's Planning Committee on Law Enforcement, the Southeast Mental Health Center, the Albany County Mental Health Services, and the Wyoming Board of Psychologist Examiners.

No one has had a greater impact on the face of psychology in Wyoming than Richard, who helped to develop licensing laws, commitment procedures, definitions of mental illness, and other legislation related to the practice of psychology. He was instrumental in obtaining grants and establishing community mental health centers and other service organizations throughout the state. In addition to being actively involved at the community, state, regional, and national levels, Richard was also a respected scholar and author of more than 125 publications, 15 grants, and numerous presentations. He was a pioneer in his main research interests, which included rural community psychology and the insanity defense. His work on the insanity defense was seminal and reached international audiences.

Among Richard's proudest honors and awards were the Humphrey Distinguished Faculty Award (1976), his nomination for the CASE (Council for Advancement and Support of Education) National Professor of the Year Award (1983), becoming a fellow in APA's Divisions 12 (Society of Clinical Psychology) and 41 (American Psychology–Law Society), and receiving the UW Outstanding Former Faculty Award (2004).

His UW colleagues, speaking of his accomplishments more than 10 years after he retired, may have summed up his legacy best: "Richard's contributions were so great and so far-reaching that it is still hard to imagine anyone who could fill his shoes."

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ICP Position on Responding to World Events
6 March 2024

The ICP board has been approached to make statements about current world events. Many of our members, in reading about world events, want to take action as a measure of their concern and care about dignity, justice, and human rights the world around.

In response to these requests, ICP formed a task group to consider the ICP mission, vision and values as expressed in the ICP bylaws, and to make recommendations for ICP actions going forward.

The following is an ICP position proposal developed by the task group.

The purpose of ICP is to advance psychology and the application of its findings throughout the world. The mission of ICP is to promote human rights, dignity, and justice and further international understanding and world peace by facilitating collaborative relationships around the world. The International Council of Psychologists values diversity in knowledge and methodological approaches, cultural humility, peer relations, mutual understanding, scientific approaches, critical thinking, and inclusion.

When there are world events, in support of its mission and values, the ICP will use its available educational and communication mechanisms (e.g. webinars, interest groups, newsletter articles, briefs, letters) to

- provide tools and resources,
- facilitate the dissemination and exchange of information,
- promote dialogue, and
- raise awareness of psychological aspects of historical, cultural, social and political contexts.

The ICP will not, as an organization, make organization-based statements about world events, as an expression of concern or as a demand for action. It will encourage its members to be informed and engaged as global citizens, and it will attempt to provide a platform for showcasing resources about psychological approaches, responses and interventions, as well as a platform for discussion about the role and power of psychology in support for dignity, justice and human rights.

To support this strategy the ICP will:

- Inform members of materials and tools relevant to the specific issues that currently exist on the ICP website or that ICP committees or groups collate (e.g. curated lists of webinars, blogs, and newsletter articles addressing issues)
- Invite members to engage with relevant interest groups
- Create opportunities for town halls, webinars or other discussion platforms for members to exchange information and opinion. These efforts will be organized by the ICP Board and/or committees and coordinated through the Secretariat.

International Research

Going International: A Practical Guide for Psychologists

Book 2:

Engaging in International Collaborative Research

American Psychological Association

This booklet is the second in a series of introductory guides developed by the APA Committee on International Relations in Psychology to foster international activities. The other booklets in this series are available online at http://www.apa.org/international/resources/publications/index.aspx

Engaging in International Collaborative Research
2nd in a series:
A practical guide for Psychologists

Developed by:
APA Committee on International Relations in Psychology, 2013-14

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Introduction

The goal of this booklet is to provide an introductory guide for U.S. based psychologists, graduate students and early career psychologists interested in pursuing international research opportunities. It is written to help span the gap between knowledge of sound research practices, knowledge of local ethical and regulatory processes, and the application of that knowledge in international collaborative research.

We have prepared the booklet to provide practical suggestions to psychologists interested in pursuing international research collaborations. Our expectation is that this booklet will help you develop a better understanding of what is involved in conducting international research. This, in turn, will help you decide whether you want to pursue this direction or not. Given our practical orientation, we will focus on essential steps, such as developing a strong knowledge base about the host country and its people, updating your knowledge regarding the status of psychological research in the host country, developing cross-cultural competence, forming relationships with international colleagues, and addressing issues related to IRB processes and ethics.

What are international research collaborations?

For purposes of this booklet *international research collaborations* refer to research projects that involve active participation of investigators whose primary institutional affiliations are in different countries. Although there may be substantial variability in the scope of these international projects, they are all characterized by the joint nature of the research process across national boundaries. In each case, cross-national teams jointly initiate, perform, and report empirical research in an area of common interest.

Why do international collaborative research?

Designing and conducting international collaborative research provides opportunities to generate knowledge, enhance the external validity of research completed elsewhere, extend the range of applicability of existing research, and develop mutually beneficial relationships that can contribute to solving global problems.

The underlying premise is that psychologists working with colleagues from other countries can accomplish

more than those same people working apart. When such collaboration works, it creates synergy and fosters ways of addressing research questions, extending existing research to other populations, constructing meaning, and drawing implications that would not have been otherwise possible. This also means that both partners optimize use of their resources and find solutions to intractable problems. At least this is the hope – and often the promise. Furthermore, the expectation is that the research would be mutually beneficial to stakeholders across national boundaries and facilitate sustainable solutions to world problems.

International Collaborations: Important Dimensions

Developing Relationships with International Colleagues

All collaborative activities begin by identifying potential partners with relevant expertise and established records of scholarship and publications. You also will need to decide the country or countries where you will seek a partner. In selecting the country and the partner, you need to answer questions such as the following: What is unique about the

country and the partner that will allow you to accomplish together what you cannot do separately? How can you ensure that the work is mutually beneficial? What will each of you contribute to the whole? In what ways do you complement each other? How will you work together? What difference will you make together? How will you ensure that the outcomes of the work can contribute to sustainable developments? Once you have answered these questions you are ready to identify researchers in the country of interest. You can identify potential partners from other countries through the Internet, national and international associations, conferences and conventions, international centers, organizations, and networks. We comment briefly on these resources.

Internet. Authors generally include their email addresses and institutional affiliation in their papers and publications; you may initiate contact with them by expressing interest in their work and exchanging articles or ideas. The Internet also allows you to join an interest group that focuses on your research interests. This can be a powerful means to initiate contact with others. Professional associations such as the American Psychological Association have made

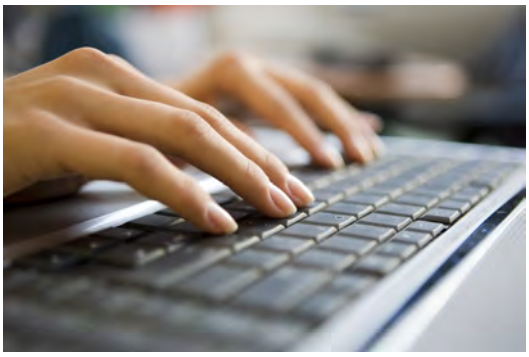

numerous listservs available through its specialty divisions. Such interest groups offer valuable opportunities to learn from others, express your ideas, and identify colleagues who work in your area of interest.

Professional Associations. National and international associations hold annual meetings where you can attend symposia and paper presentations, participate in interest group sessions, meet other researchers, and share information and ideas with them. You also may do follow-up with potential partners who have complementary expertise in substantive areas and research methodology. In identifying potential partners do not hesitate to consider seasoned researchers. They may be as eager to collaborate with you as you are interested in working with them. They value the fresh ideas, up-to-date methodological skills, and interdisciplinary perspectives you may bring to the proposed research. Thus, this is a win-win situation, in which partners learn from each other.

International centers, organizations, and networks. You also may identify potential collaborators through international centers and

organizations. For example, if you are interested in health-related research you may find it beneficial to review the activities supported by the National Institutes of Health, Fogarty International Center that focuses on fostering global health research and reducing health disparities (www.fic.nih.gov). These resources can be helpful in identifying potential partners outside of the U.S. Of course, colleagues from other countries might also contact you about working together.

Working with a Mentor

If you are an early career psychologist you may consider finding a mentor who can help you to link with relevant networks, identify potential partners, and learn how to create international relationships. The mentor also may help you in assessing the extent to which you are ready to undertake international research. It also will be useful to maintain contact with the mentor through different phases of your international venture.

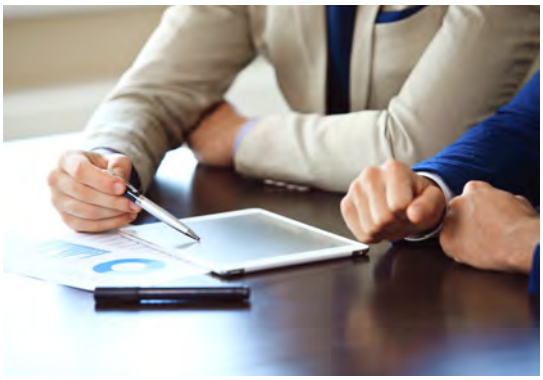

Conduct a SWOT Analysis

After you have identified a potential partner(s) from another country (countries) you may conduct a SWOT analysis (strengths,

weaknesses, opportunities, and threats) analysis (Stead & Harrington, 2000) to evaluate the skills you have and to determine whether and how the proposed partnership can assist you in achieving your research goals. Conducting such analysis entails assessing your own strengths and weaknesses as well as those of potential collaborator(s). To create an effective team it is important to find collaborators who can cover your weaknesses in exchange for your strengths. For example, if you plan to use mixed method design for the proposed research and have a strong background in quantitative methods you may find it beneficial to seek a person with strengths in qualitative methods. Once you have identified the strengths and weaknesses the next step is to conduct an analysis of needs in your research area that require urgent attention in the host country. This analysis may indicate the research direction that may foster meaningful collaboration and also may be of interest to funding agencies. Whereas the analysis of opportunities focuses on elements that the collaborative project could use to its advantage, analysis of threats (challenges) draws your attention to

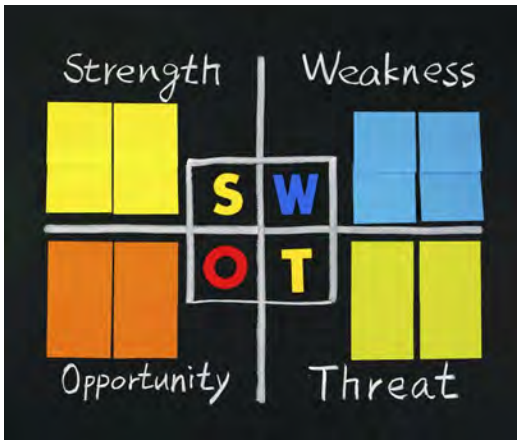

elements that could cause difficulties in achieving the goals and objectives you have proposed. In assessing these challenges, it is essential to focus on appreciation of research ethics by all members of the research team; problems regarding expertise and ethics can be a challenge not only to your reputation but also to the viability of the project itself. It is also critical that you attend to actual or perceived disparities in power and purpose and resolve discrepancies before you proceed.

Negotiating with International Partners

Once you have selected an international partner(s) and conducted a SWOT analysis, the next task is to negotiate with them a number of practical issues. Some key issues are outlined below.

How will the responsibilities be shared for research-related tasks?
It is important to develop an agreement regarding the allocation of specific tasks such as finalizing the research design, drawing the sample, collecting data in the field, conducting data analysis, interpreting the

results, reporting results to the host community, and preparing manuscripts for publication. It can be useful to construct a table outlining the key tasks, their timeline, and the person or persons responsible for each task. This information also will be helpful in preparing the project budget.

Who will obtain IRB approvals? If a U.S. researcher is planning to conduct research in another country, IRB approvals from both countries will be necessary. This means that you need to allocate adequate time to get the required approvals. Many funding agencies have specific requirements for IRB approvals and some of them have their own IRB as well. It is critical to decide in advance what approvals are needed and who will take the responsibility for obtaining approvals.

What will be the scope of the research you plan to conduct? Early in the planning with a colleague from another country, it is essential to discuss issues such as the depth of what you wish to study, the amount of time it will take, the extent to which it will require interaction with the study participants, the number of variables you plan to study, the number of sites you would use to collect data, and the methods of data collection and data analysis you would use. In conducting such conversations it may be useful to jointly use a checklist to determine

whether a proposed research project is realistic and feasible. See Leedy and Ormrod (2010) for an example of a checklist.

Who will be responsible for securing grant support? If the proposed research involves preparing a grant application for external funding, the partners from the host country need to be involved in this phase as well. Given their day-to-day contact with the potential study population, they can offer cultural components that a visiting researcher might otherwise miss.

If the proposed research will be conducted in a community setting, service providers should be involved in the grant writing phase. Full involvement of both the academics and community providers from the host country is vital for a successful partnership. Since many U.S. agencies, including NIH, support international research through a domestic grant with a foreign component, it is common for a principal investigator from a U.S. institution to work with a researcher and/or community providers from another country in preparing the application. It is, therefore, important to share the agency's guidelines with international partners and to

allocate the tasks associated with grant proposal preparation.

Who will own the data? It is important to agree how the outputs (e.g., measurement instruments, data files) of the proposed research will be shared. Agreement in this regard is particularly important because empirical research, whether qualitative or quantitative, often generates data that can be used for testing additional hypotheses. We, therefore, recommend that your negotiations with international partners include a discussion of not only who will own the data but also how the decisions will be made for using data to conduct additional analyses and to report the findings.

Who will publish the results? How will the order of authorship be determined? Negotiating this matter in advance prevents disagreements arising from academics whose tenure and/or promotion may be affected by the order of authorship. Once you come to an agreement in this regard it becomes easier to allocate who will perform various tasks associated with preparing manuscripts for each publication. It also is possible that the partners take turns in being listed as senior author for different publications thereby taking different responsibilities in preparing papers, presentations, monographs, and reports.

Who will share the findings with members of the participating community in the host country, with funding agencies, and with the academic communities in the U.S and host country? In community-based research it is essential to share the results with the participating community before publishing them in academic journals. This allows the researchers to hear the community's interpretation of the results and perhaps learn more from that interpretation. In conducting negotiations with the international partner you should, therefore, discuss who will be responsible for performing this task, when the task will be completed, and how the input will be used in data interpretation and reporting. In addition, negotiation also should include discussion about reporting the results to funding agencies and to the academic communities in the U.S. and host country. In sum, our recommendation is to negotiate in advance who will be responsible for sharing the results with different audiences in the U.S. and the host country, when these activities will be undertaken, and what resources will be needed. Moreover, we suggest that you consider together how participating communities

can experience sustainable benefits from the research and include relevant strategies in your research planning.

Who will deal with local politics? Local politics, administration structures, and regulatory processes vary across countries. Negotiations should therefore include a discussion of who will be responsible for dealing with local politics, bureaucracies, and administrative and regulatory structures. The timeline and budget for the project also should take these tasks into consideration. Note that the implementation of proposed activities will be delayed if the necessary approvals have not been received in a timely manner.

How will partners communicate on an ongoing basis? Engaging in international collaborations requires ongoing dialogue throughout the phases of the project. Face-to-face communication is ideal and researchers should include budgets for visits with each other. However, between visits, communication can be facilitated through phone calls, email, or electronic face-to-face modes such as Skype. Setting up a regular schedule for contact between visits will be critical to maintaining ongoing communication as well as joint oversight of the research project.

Preparing Yourself for International Research and Partnerships

In addition to developing partnerships with colleagues from other countries and negotiating the nature of those relationships, the

researcher needs to prepare him/herself for working in another country. This preparation involves several issues.

What do you need to know about the host country and its people? To work effectively in another country, it is critical to understand the history, culture, and social

context of the host country and its people. Achieving that understanding can happen in several ways. First, you can read literature on the social-cultural-historical background of the country and the people of interest. In addition to understanding the country as a whole, it is important to understand the particular members of the population you plan to study. For example, if you are focused on a minority ethnic group, you need to learn about them and their history in relationship to that of the country as a whole. Second, nothing surpasses direct experience in the culture. Although reading can be helpful, direct interaction with members of the local community is critical to developing an in-depth understanding of cultural norms, values, and beliefs; and to understanding key issues that affect the population of interest. It is advisable to visit the host country and local communities prior to planning your research. Such visits also provide an opportunity to meet face to face with your partners and make more informed decisions about working together and about the topic of your research. Conducting formative research using methods such as

ethnography also can inform your understanding of the culture, its members, and the critical psychological issues that warrant investigation.

What do you need to know about psychological research in the host country? In addition to understanding the country and its people, researchers also need to explore the nature of psychological research that has been conducted in or about the host country. Particularly important to explore are questions such as the following: What psychological theories have been applied to or developed for the population? Who has conducted research in the host country—indigenous psychologists or international researchers? What is the status of psychology and psychological research—what do we know about the 'psychology' of the population? What topics have been studied? What are gaps in knowledge? What methodologies have been used? Is there research that is accessible only in the local language? How can you access that? Finally, how will the existing research inform the project you develop? Certainly, your communication with psychologists or other researchers in the host country will be critical to accessing existing literature, especially if distribution is limited or language is not accessible.

How do you develop 'intercultural' competence?

We adopt the term 'intercultural' for our discussion. Intercultural refers to the interactions across cultures, consistent with the development of international research we have described in this booklet. For example, international research requires communication between research partners from different cultures. Intercultural competence involves broadening of your cognitive and behavioral repertoire (beyond that developed within your own culture) in order to engage in a range of interpretations and behaviors that can be applied across cultural experiences (Friedman & Antal, 2005). Such flexibility is dependent on perspective taking, attention to cultural nuances, interpersonal skills, and a broad repertoire of potential behaviors. So how does one develop such competence? Competence in 'negotiating reality' (Friedman & Antal, 2005) across cultural boundaries results from an iterative professional and personal development process of reflection, inquiry, and action (see Allan, 2003; Friedman & Antal, 2005; Koehn, 2004): (a) Examine your own cultural

background, worldview, identity, and behavioral repertoire. (b) Study other cultures and engage cognitively and behaviorally in challenging your worldview and identity and integrating divergent cultural thinking. (c) Engage in interactions across cultures (even within your own country initially) that require negotiating perspectives and norms. (d) Continue to reflect on your cultural experiences, beliefs and behavior to ensure flexibility of adaptation to culturally different settings. As this discussion suggests, intercultural competence does not just involve learning about the culture of another but requires a way of knowing and interacting that is adaptable to cultural variations and that is constantly evolving. Most important is your willingness to engage in negotiation across cultural boundaries with others.

Concluding Comments

Often international research requires working with others from other disciplines, particularly in settings where psychology is in the formative

stages. Increasingly, tackling issues of global importance is becoming an interdisciplinary endeavor, for example, requiring collaboration among psychologists, sociologists, health professionals, economists, and community experts. Thus, one should be prepared for working in interdisciplinary teams. This will require interpersonal skills for working in group settings such as facilitating group interactions, engaging in collaborative problem solving, negotiating different perspectives, resolving conflicts, and reaching consensus. Competencies necessary to work across disciplines are not unlike those for working across other 'cultural' boundaries. In addition, the process as described in the previous section on intercultural competence will need to be applied at a group level as well.

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Resources

American Psychological Association Office of International Affairs, http://www.apa.org/international/

The Office of International Affairs serves as APA's touch point for international information, activities, and initiatives within APA. It leads outreach and interaction with APA's international members and affiliates, coordinates APA's participation and representation in international venues, and facilitates the change with national psychology associations and global policy bodies.

Fulbright Program, http://www.cies.org/about-us/what-fulbright

The Fulbright Program, including the Fulbright-Hays Program, is a program of highly competitive merit-based grants for international exchange for students, scholars, teachers, professionals, scientists and artists. Under the Fulbright Program, competitively selected U.S. citizens may become eligible for scholarships to study, conduct research, or exercise their talents abroad; and citizens of other countries may qualify to do the same in the United States.

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations, http://www.researchintegrity.org/Statements/Montreal%20Statement%20English.pdf

This document outlines the responsibilities that are particularly relevant to collaborating partners at the individual and institutional levels and are fundamental to the integrity of collaborative research.

National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. (2014).*Culture matters*: *International research collaboration in a changing world*. Washington, D.C.: The National Academic Press

This summary of a workshop report highlights key challenges and strategies to address international collaborative research.

During the workshop, global representatives provided input on four areas that can affect international research and agreements within the context of culture.

National Institutes of Health Fogarty International Center, http://www.fic.nih.gov

The Fogarty Center is dedicated to advancing the mission of the National Institutes of Health (NIH) by supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad and training the next generations of scientists to address global health need.

National Research Council. (2014). *Building infrastructure for international collaborative research in the social and behavioral sciences: Summary of a workshop*. Washington, D.C.: The National Academic Press.

This report is summarizes the discussions from a workshop held in September 2013, that focuses on ways to overcome the challenges associated with conducting international collaborative research. The themes and issues identified during the proceedings are outlined in this report.

National Research Council. (2008). *International collaborations in behavioral and social sciences research: Report of a workshop*. Board on International Scientific Organizations. Washington, D.C.: The National Academic Press

This report provides the papers presented at an October 2006 workshop organized by the U.S. National Committee for Psychology and the National Research Council. Workshop participants included behavioral and social scientists who have collaborated internationally. They considered the results of a

survey of cross-national projects leaders and then brought their own experiences to hear in assessing barriers, challenges, and opportunities for international collaborative research in social and behavioral sciences.

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INTRODUCTION TO THE SPECIAL ISSUE ON INTERNATIONAL ORGANIZATIONAL CONSULTING: CONSULTING PSYCHOLOGY GOES GLOBAL

Stewart E. Cooper
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This Special Issue of the *Consulting Psychology Journal: Practice and Research* on "International Organizational Consulting: Consulting Psychology Goes Global" provides highlights of experienced practitioner consulting psychologists' work in a variety of multinational contexts. A brief description of the context for the Special Issue is provided, followed by an outline of the articles the special issue contains. Questions addressed by the articles include the following: how do the assumptions of organizational consulting psychology as taught and practiced in the United States need to be changed when applied to individual, group, and organizational consultation in other countries? Are there issues specific to international organizational consulting psychology different from those addressed by existing cross-cultural psychology findings? How do practicing consulting psychologists learn how to negotiate international consulting projects from start to finish? What kind of overarching templates are useful when entering a new country of international practice?

Keywords: international consulting, cross-national coaching, multinational consultation

This Special Issue of the *Consulting Psychologist: Practice and Research* (CPJ) focuses on individual, group, and/or organizational level consultations in international contexts using a wide range of organizational consultation methodologies. Several of the major conceptual frameworks that influence international consulting are presented in this introductory article. The five articles that describe the international organizational consulting work of seasoned and highly regarded consultants each refer to one or more of these models.

This introduction is divided into two parts. Starting with the need and focus of this Special Issue, the first part identifies the major literature and research-based themes to orient the reader to the framework of the experience-based articles. These themes also are sufficiently applied so that they can advise practitioners approaching international assignments. The second part of this introductory article outlines the structure of the special issue, including brief highlights of the articles in the issue.

Correspondence concerning this article should be addressed to Stewart E. Cooper, PhD, ABPP, VU Counseling Services, 1602 LaPorte Avenue, Valparaiso, IN 46383. E-mail: stewart.cooper@valpo.edu

The Need and Focus of This Special Issue

The most effective and successful corporations and organizations are more likely to emerge when the confluence of excellent leadership, highly effective teams, and organizational structure and processes match the internal and external organization contexts in which the individuals, teams, and organization function (Cummings & Worley, 2009). Although the themes and issues described in this special issue apply broadly to domestic U.S. organizations, the added context of working internationally makes such consultation much more complex and risky.

Three components often related to success in organizations are leadership development, team development, and organizational development (OD). Other components, such as selection of persons and teams, are also important depending on the specific needs of the consultee. Leadership development (Day, 2000; Pearce, Conger, & Locke, 2007) may include learning how to manage interpersonal relationships, the social influence process, and the team dynamics. It can focus on the contextual factors surrounding the team, such as the perception of the organizational climate and the social network linkages between the team and other groups in the organization. Team development (Heathfield, 2012) focuses on the team members and teams' skills, accountability, and commitment as oriented toward collective performance results, work products, and personal growth. OD (Bradford & Burke, 2005) focuses on the systems framework, goals, methods, and human capital, and is measured by the success in reaching clearly articulated and measurable outcomes.

Leadership development, team development, and OD are complicated many-fold when the organization is multinational or when its leaders and/or consultants are from different countries than the one which is home to the organization (see, e.g., Lowman, 2013). Issues of significant cross-cultural communications, interpersonal operating patterns, and individual behavior differences often emerge. "A very basic truth [is that] Western psychology is rooted in an ideology of individualism, rationality, and empiricism that has little resonance in many of the 5,000 cultures found in today's world. More than 85% of the world's six billion people are from nonwestern ethnic and cultural traditions." (Marsella, 2001, p.7). Of course, organizational consultants have not yet worked in all 5,000 cultures!

Emerging Themes in International Organizational Consultation

Four main thematic areas may exist for those consulting psychologists practicing in international contexts (Cummings & Worley, 2009). The first theme concerns the critical importance of the cultural context of the organizations. The second theme emphasizes worldwide organization development. The third theme centers on national and regional economic development. The fourth factor considers the role of consultation in facilitating global social change. The articles in this special issue emphasize cultural contexts and worldwide economic development as the principle influences on their respective consultation processes and interventions. Therefore, a brief presentation on each of these two areas follows. The factors of national and regional economic development and of social change may significantly affect consultations focused on these two domains, especially in subsistence and developing economies. [See Cummings & Worley, 2009 for additional information].

Cultural Contexts

A concentrated focus attending to the cultural contexts helps ensure the organizational consulting change processes are aligned with the values held by the members of a company, country, or region. Several models germane to understanding such cultural differences have been developed. These include the cultural dimensions theory by Geert Hofstede (Hofstede, 2001; Hofstede, Hofstede, & Minkov, 2010; Hofstede, & Peterson, 2000), Hampden-Turner and Trompenaars (2000), and more recently, Javidan, Dorfman, de Luque, and House (2006).

Hofstede's widely known research, used by several of the articles in the Special Issue, highlights five dimensions of culture: (1) context orientation; (2) power distance; (3) uncertainty avoidance; (4) achievement orientation; and (5) collectivism/individualism. Several of the authors reported using this model as a foundation for adjusting their interventions for cultural fit. Several also referred to

Trompennaars. His model describes seven cultural orientations that are important to understanding individual or group relationships. The seven are as follows: (1) universalism versus particularism; (2) individualism versus collectivism; (3) neutral versus emotional; (4) specific versus diffuse; (5) achievement versus ascription; (6) attitudes regarding time; and (7) attitudes toward the environment.

The Global Leadership and Organizational Behavior Effectiveness Research Project (GLOBE) study House, Hanges, Javidan, Dorfman, and Gupta, (2004) incorporated both the Implicit Leadership Theory (ILT) and Hofstede's dimensions into a single research study. The GLOBE study extended the ILT to include individuals of a common culture maintaining a relatively stable common belief about leaders, which varies from culture to culture. Javidan et al. (2006) labeled this the Culturally Endorsed Implicit Leadership Theory (CLT). The GLOBE study expanded Hofstede's dimensions to include Uncertainty Avoidance, Power Distance, Collectivism I: Societal Collectivism, Collectivism II: In-Group Collectivism, Gender Egalitarianism, Assertiveness, Future Orientation, Performance Orientation, and Humane Orientation (House, Javidan, & Dorfman, 2001). All three of the above perspectives are useful to the international organizational consultant.

Worldwide Organization Development

Few changes in the world have had a more profound influence than the emergence of the global marketplace. Many companies that have focused on globalizing have grown tremendously. Companies that do not address globalization have floundered or perished (Cummings & Worley, 2009). Organizations operating globally must manage significant assets in diverse countries. They must balance product and functional concerns with numerous geographic issues. They contend with the need to coordinate working across cultural and linguistic boundaries that can impact organization practices or customer preferences.

Consideration of the need for global integration versus the need for local responsiveness creates a four-cell model that can guide organizational consultation intervention selection. According to Cummings and Worley (2009), corporations high on the need for global integration and lower on the need for local responsiveness are thought to need a global integration approach. Employee involvement and senior management team building are interventions that may be particularly fitting. In contrast, organizations low on the need for global integration but high on the need for local responsiveness are considered to have an international orientation. Examples of consultation interventions more suitable for this organizational context include strategic planning and cross-cultural training. Organizations high on need for global integration and low on the need for local responsiveness benefit from a transnational orientation. Building a corporate vision and intergroup relationships are common interventions. Finally, adopting a multinational approach is best for organizations low on both need for global integration and need for local responsiveness. Building reward systems as well as strategic alliances may be more effective interventions for such organizations.

Articles in the Special Issue

The sections above have provided some context for this Special Issue. What follow is a description of both the structure of the special issue as well as a brief summary of each of the articles it includes. Each of the contributing authors was asked to consider several questions. This Special Issue features five articles by highly experienced organizational consulting psychologists who have engaged in substantial professional international consultancy work. These authors focus on the importance of attending to the international contextual element to successful consultations when consulting cross-culturally and cross-nationally. Questions addressed by the articles include the following: How do the assumptions of organizational consulting psychology as taught and practiced in the United States need to be changed when engaged in individual, group, and organizational consultation in other countries? Are there issues specific to international organizational consulting psychology different from those addressed by existing cross-cultural psychology findings? How do

practicing consulting psychologists learn how to negotiate international consulting projects from start to finish? What kind of overarching templates are useful when entering a new country of international practice?

Following the introduction to the Special Issue and the five main articles, an integrative article (Fulkerson, this issue, pp. 325–337) provides overarching perspectives of the authors' contributions. Fulkerson elaborates upon the common themes that emerged from the five articles. Subsequently, he will suggest areas for future applied and foundational scholarship to further advance the science, practice, and craft of consulting in international contexts.

The five main articles are intended to help the reader understand the essential importance of successfully integrating culture into international organizational consultation work. The articles will accomplish this by each telling a unique story of respective lessons learned by the authors in their work with clients and consultants who are developing leaders, teams, and organizations operating in international contexts. Both common themes and distinctions among the contributions will contribute to a mosaic. None of the principle articles will include an exhaustive literature review, but various contributors will cite resources that serve as a foundation for their work as well as their own scholarship. Further, these five articles will focus on real experiences and real practice—lessons learned along the way.

Article 1: Consulting in International Contexts: Examining and Testing Assumptions

Organizations that are called "global corporations" are generally U.S./Western European–based companies that have expanded their operations globally. Microsoft is a prime example. In these global corporations, U.S./Western European business culture is dominant and leadership focuses on how to manage and lead individuals from other cultures to change. Much of these authors' (Leonard, Freedman, Hill, Ng, Warrier, & Chu, this issue, pp. 250–267) earlier practice working with global business was done in this context. Leadership development models that work well in the global corporations, work poorly or not at all in local, particularly nonwestern, cultures. This article examines and explores the assumptions that consultants from the United States or Western European cultures use in their consulting practices and how these impact the success of their efforts.

Article 2: Thirty Years of Global Leadership Training: A Cross-Cultural Odyssey

White and Shullman (this issue, pp. 268–278) have spent much of their respective professional lives training leaders. This article presents a rich narrative description of their work as international organizational consultants operating and delivering services in the global environment. It is based on their experiences in the U.K., Germany, France, Italy, Spain, Sweden, Malaysia, Singapore, Australia, New Zealand, South Africa, Russia, Canada, the United Arab Emirates, Qatar, Israel, China and others countries.

The article describes factors that make the practice of global management and global consulting more complex than consulting domestically. White and Shullman (this issue), based on their work with dozens of international organizations and corporations, analyze the root cause of failures by global organizational management consultants and consider the difficulty of determining the right approach for all stakeholders within the broader global systems to audiences around the world. They argue that the common misperception of Eastern cultures and organizations by many Western managers and consultants who have not been properly prepared to anticipate the differences is a major source of failed international consultancies. The article provides examples of interventions that have been tried by consultants and managers, internationally, with varying degrees of success. It offers recommendations as to organizational strategies, guiding principles, and competencies that can help global consultants better navigate the ethical maze their clients face and that they themselves face as they work with diverse cultures and organizations.

Article 3: Dyad Team Development Across Cultures: A Case Study of Two High Potentials

Vandaveer (this issue, pp. 279–294) discusses the impact of differing cultures among top level organizational leaders; a Team member dyad in this case will be within the framework of a specific case involving (a) a male American expatriate leader, president of a large business unit for an American multi-national company, and based in the U.S. and, (b) one of his direct reports, a Pakistani woman who was the Director of Strategy and Planning for the business unit. The business unit President was a results-driven, high-performance-standards, perfectionist, yet caring leader, whose primary leadership style was "pace setting" (Goleman, "Leadership That Gets Results" – HBR 2000). The focal leader had joined the president's new leadership team from the planning role for the Africa-Mid-East region.

This case illustrates some of the complexities of cross-cultural leadership, particularly where there is as high a degree of variance in values, styles, and world-views driven largely as more and more people are educated outside their home countries and are increasingly experienced in and acculturated toward living and working in multiple countries. Literature and experientially based learning and conclusions drawn from this one consultant's experiences in working with leaders and their multicultural teams are outlined, and implications for development of both international leaders and international consultants are articulated.

Article 4: Selecting and Developing Organizational Leaders in Latin America: La Cultura Importa

The focus of this article is on work of developing organizational leaders in Central and South American contexts. International consulting psychologists in the modern global economy face a difficult task in trying to adapt leaders to operating in different cultural contexts, including the one of the country they are visiting, the region, and particularly that of the organization which is hiring them. Companies with huge operations all over the world have their own inside experts, from Latin America to Asian affairs, who travel constantly and study individual needs in each areas.

This article is grounded in the author's experiences consulting in Argentina, Brazil, Chile, Colombia, Mexico, and Peru. One of its primary purposes is to help consultants develop some understanding of the differences in contracting, diagnosis, and intervention that have to be met when attempting to do consulting work in those countries. Two issues are addressed to explain the six respective minicases. The first concerns the focus on the selection and development of leaders. The second focuses on enhancing the effectiveness of the particular business.

Article 5: Global Consulting in a Culturally Diverse World: Ethical and Legal Implications

Finkelman & Lopez (this issue, pp. 307–324) present an overview of the ethical and legal dilemmas faced by organizational consultants in global environments. They describe the critical factors that make the practice of global management and global consulting complex, ambiguous and challenging. In consideration of the common misperception of Eastern cultures and organizations by many Western managers and consultants who have not been properly prepared to anticipate the differences, the article offers recommendations as to organizational strategies, guiding principles, and competencies that can help global consultants better navigate the ethical maze they and their clients face in working with diverse cultures and organizations. Through the use of consultancy examples drawn from their professional experiences, the authors analyze typical causes of failures resulting from cross-culturally complex ethical or legal dilemmas.

Article 6: Consulting in International Contexts: An Integrative Perspective

The final article in this Special Issue on consulting in international contexts is authored by a highly seasoned consultant (Fulkerson, this issue, pp. 325–337) who has focused his consultancies in this area of organizational consulting psychology. This synthesis article highlights the

commonalities of the main articles in terms of themes and practices. In specific, Fulkerson discusses the contributions of the above articles from the framework of six foundations: (1) the practice of organizational consulting psychology, (2) understanding of the global context, (3) awareness of the specifics of different cultures, (4) recognition of when culture does not matter, (5) skills in the dynamics of cross-cultural facilitation and engagement, and (6) awareness of cross-national ethical challenges and considerations. He then discusses the competencies international organizational consultants need. Finally, he gives suggestions related to future practice development as informed by the needed applied research to further advance this field.

Contributions of the Special Issue

The field of international organizational consulting is, in many ways, still in its infancy. Practice far exceeds the science (Lowman, 2012) that will hopefully inform it (and vice versa) in the future. The articles in this special issue provide a rich narrative of the experiences of seasoned consultants working in international consulting contexts. As such, it contributes to an expanded understanding of the complexities of this very challenging and very stimulating OCP work. The use of case studies as a research method in several of the articles illustrates the potential of scholarship of this approach. The issues presented in the other articles are salient to international organizational consultation work.

It is hoped that this special issue will excite practitioners and applied researchers alike to further explore the development and expansion of effective and efficacious organizational consultation in international contexts. The world has become global, and this trend will continue to grow exponentially.

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- Reviewing a manuscript takes time (1–4 hours per manuscript reviewed). If you are selected to review a manuscript, be prepared to invest the necessary time to evaluate the manuscript thoroughly.

GUIDELINES FOR EDUCATION AND TRAINING

AT THE DOCTORAL AND POSTDOCTORAL LEVEL

IN CONSULTING PSYCHOLOGY (CP) /ORGANIZATIONAL CONSULTING

PSYCHOLOGY (OCP)

Approved by APA Council of Representatives in August 2017

Prepared for the

Society for Consulting Psychology (SCP)

Division 13 of the American Psychological Association (APA13)

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Tom Reynolds, Education & Training Guidelines Revision Committee

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Section A. Introduction

This document represents a revision to the Guidelines approved in 2005 and authored by Ann M. O'Roark, PhD, Paul J. Lloyd, PhD, and Stewart Cooper, PhD. Members of the original Division 13 Guidelines Development Committee, 1997–2001, were Rodney L. Lowman, PhD, Clayton Alderfer, PhD, Michael Atella, PhD, Stewart Cooper, PhD, Andrew Garman, PhD, David Hellkamp, PhD, Richard Kilburg, PhD, Paul Lloyd, PhD, and Ann M. O'Roark, PhD. The Education and Training Committee Chair (1994–1997) of the Preparations for Development was DeWayne Kurpius, PhD.

Members of the Education and Training Guidelines Revision Committee who have updated the guidelines include: Elizabeth C.D. Gullette, PhD (E&T Guidelines Revision Committee Chair, 2012-2016), John Fennig, PhD (SCP President, 2015), Tom Reynolds, PsyD, Carolyn Humphrey, PhD (SCP Secretary, 2014-2017 and Education Domain Leader, 2010-2013), and Melanie Kinser, PhD (SCP Education Domain Leader, 2014-2017).

The purpose of these revised "Guidelines for Education and Training at the Doctoral and Postdoctoral Levels in Consulting Psychology/Organizational Consulting Psychology," which update and replace the guidelines originally approved in 2005 and published in 2007 (APA, 2007), is to provide a common framework for use in the development, evaluation, and review of education and training in consulting psychology/organizational consulting psychology (CP/OCP). The intent of these guidelines is to improve the quality of teaching and learning in the area of the practice of CP, especially OCP, within the scientific discipline and profession of psychology. Towards these ends, this document is intended as guidance for psychologists who

teach or plan curricula for teaching CP/OCP at doctoral or postdoctoral levels of professional education and training in psychology.

These guidelines will be updated within ten years of the date initially approved by the American Psychological Association (APA) in accordance with provisions of Association Rule 30-8.3 and in alignment with the governance coordinating responsibilities and review managed by the Board of Educational Affairs (BEA) (2004, Developing and Evaluating Standards and Guidelines Related to Education and Training in Psychology: Context, Procedures, Criteria, and Format).

A.1. Terminology

A.1.(a). Use of terms standards and guidelines

Guidelines are defined as pronouncements, statements, or declarations that suggest or recommend specific professional behavior, endeavors, or conduct for psychologists (American Psychological Association, 1992). The guidelines set forth in this document are consistent in intent and content with this definition, serving as a framework for guiding principles and suggested learning goals referred to as competencies. The guidelines set forth in this document are voluntary, not mandatory; they are aspirational teaching and learning objectives, not required standards. As such, they are intended to afford broad latitude for curriculum and continuing education program development in the emerging field of CP/OCP practice.

A.1.(b). Rationale for use of term(s)

Guidelines is the appropriate term of choice for aspirational recommendations in regard to curriculum development, learning objectives, and teaching strategies to those responsible for graduate and postdoctoral education and training in psychology. Although ultimate responsibility for matters of curriculum development and pedagogy is that of the faculty in higher education

institutions and programs, the involvement of national regulatory and disciplinary associations in developing and promulgating guidelines related to professional development is recognized, especially for new or changing areas of practice. CP/OCP is such an area in the practice of psychology.

A.2. Scope of Application and need for proposed guidelines

A.2.(a). Scope of application

Although there are other applications of CP for which alternative or additional competencies may be relevant (e.g., health-related CP), the guidelines for education and training in this document relate to CP as it is applied to OCP. They are intended for use as suggestions or recommendations for psychology faculty responsible for teaching or planning curricula at doctoral or postdoctoral education and training levels in professional psychology. In that vein, however, they are not intended to take precedence over the judgment of faculty or others of academic authority responsible for specific education and training programs. Nor are these guidelines intended to replace, usurp, or conflict with training policies or guidelines that have been developed and approved for other areas of practice in psychology. Moreover, these guidelines are not meant to serve as guidelines for accreditation.

A.2.(b). Need for proposed guidelines

As stated in the original guidelines proposal, the premise on which the need for these guidelines is based is stated as follows: *Being an effective psychologist is not enough to be an effective consultant. There is a body of knowledge and skills unique to this particular application of psychology, and just graduating from a doctoral program in psychology does not [necessarily] prepare one to provide consultees with the best possible consulting services* (Robinson-Kurpius, Fuqua, Gibson, Kurpius, & Froehle, 1995, p.88).

This distinction and need was recognized in the earliest years of APA when the 1915 Whiple Resolution task group set up the Committee of Five to differentiate professionally qualified psychological experts from commercial consultants without scientific psychological knowledge or experience who were offering services and opinions for public consumption. SCP/APA Division 13 traces its roots to this Committee of Five and the work of that committee and its successors in defining consulting psychology (Rigby, 1996). Despite this long history, and a rapidly expanding body of CP knowledge and skill base literature (O'Roark, 1999), CP and OCP are underrepresented in doctoral and postdoctoral education and training programs (Blanton, 2014; Hellkamp, Zins, Ferguson, & Hodge, 1998; Garman, Zlatoper, & Whiston, 1998). Moreover, consulting is important to the effectiveness of many if not all practicing psychologists to greater-or-lesser degrees, many of whom may not yet be aware that organizational consulting psychologists typically do more assessments for determining appropriate interventions (action research / calibration consultation to understand client culture and climate) than they do interventions. The continued growth in consulting psychology, especially organizational consulting psychology, heightened the awareness within the division of a need to consolidate and disseminate education and training guidelines for CP useful for doctoral, postdoctoral, and continuing education (CE) programs in professional psychology (Hellkamp & Garmon, 1998; 151 O'Roark, 1999).

While there are doctoral and postdoctoral education and training courses on consultation in a few universities (Blanton, 2014; Hellkamp, Zins, Ferguson, & Hodge, 1998; Munz, 1977)), there exist no other guidelines that address the three-domain competency model considered central in CP/OCP guidelines. The domain infrastructure for OCP addresses competencies focused on individual, group, and organizational/systems (I-G-O) levels. The uniqueness of this

feature of the OCP guidelines was validated when SCP invited four closely aligned divisions to write articles providing comparative analysis, critiques, and feedback on the OCP guidelines for publication in a special issue of the Consulting Psychology Journal: Practice and Research (Cooper, 2002). These articles were invited by the journal's guest editor following completion of the formal call for comment on an earlier draft of the original guidelines, issued by BEA to APA governance groups, divisions, legal counsel, and other interested/affected parties. Since that time, this has become a common way of organizing the competencies required for consulting psychology (e.g., Lowman, 2016).

In summary, OCP guidelines were developed in response to perceived need based on three types of evidence: an increase of interest among psychologists in CP/OCP without a corresponding growth in education and training programs focused on that area of practice; an increase of literature in recent years distinctive to the practice of CP and, especially, OCP that needed to be synthesized; and, a growing consensus of professional support for the three-domain competency model for preparation to practice CP/OCP. It is anticipated that consulting competencies relevant, for example, for a mental health or school psychologist will include knowledge and skills pertinent to each I-G-O domain, but will not include all competencies named for OCP practitioners.

A.3. Process of developing proposed guidelines

The Society of Consulting Psychology (SCP) is responsible for developing these guidelines. Prompted by the increased interest in CP/OCP practice, SCP in 1997 called together an Education and Training (E&T) ad hoc work group of selected division members with recognized experience and expertise backgrounds to undertake the task of developing and writing guidelines for education and training at the doctoral and postdoctoral level in consulting

psychology/ organizational consulting psychology (CP/OCP). Towards that end, the original guidelines document was the result of iterative drafts [1999 – 2004] that had been periodically distributed for comment and feedback from SCP members, APA divisions and governance groups, and non-APA colleagues. The participants in that process and details of the process were detailed in the 2005 Guidelines.

This revision was undertaken, in accordance with guidance from the APA (2004a) in relation to Association Rule 30-8.3, to ensure currency of guidelines related to both their scholarly basis and their practical use. The current revision represents an update to the original guidelines that subsumes the substantive work done in that in-depth process and adds structural clarity, updated evidence and literature citations, and integration of recent developments in society that impact consulting psychology (e.g., use of technology, globalization, heightened awareness of identity group issues).

A.3.(a). Participants and processes in developing guidelines

The original 2005 CP/OCP Guidelines were the result of the substantive contributions of eight Education and Training (E&T) Committee members, including: Rodney L. Lowman (E&T Chair, 1998-2000), Clayton Alderfer, Michael Atella, Andrew Garman, David Hellkamp, Richard Kilburg, Paul Lloyd, Ann O'Roark, and Stewart Cooper (E&T Chair, 2000-2004). They represented different aspects of CP/OCP practice, a nation-wide distribution, and individuals recognized as having expertise and experience in substantive content components. The extensive process used to inform the original guidelines was detailed in that document (see E.1).

Members of the Education and Training Guidelines Revision Committee who have updated the guidelines include: Elizabeth C.D. Gullette (E&T Guidelines Revision Committee Chair, 2012-2016), John Fennig (SCP President, 2015), Tom Reynolds, Carolyn Humphrey (SCP

Secretary, 2014-2017 and Education Domain Leader, 2010-2013), and Melanie Kinser (SCP Education Domain Leader, 2014-2017).

The procedure for gathering input on needed revisions to these guidelines, which took place in 2015, included interviewing thought leaders in the field of consulting psychology from the following groups: authors of the 2007 guidelines, members of the Society of Consulting Psychology (SCP)/Division 13 Guidelines Development Committee, and the co-chairs of another competency-related project in SCP specific to coaching; as well as surveying members of SCP. The goal of both methods was to collect feedback on the strengths, weaknesses, and gaps that should be addressed in a revision of the 2007 guidelines. In addition, the revision committee reviewed other published guidelines that relate to other areas of psychology and to specific issues or competencies covered in this document to evaluate suitability to be referenced for a more in-depth treatment of a given issue.

The general consensus that emerged from this process was that the guidelines were largely solid and a revision should not aim to make substantial substantive changes but rather to update language and information, address contemporary issues that impact consulting work (such as increased diversity along multiple dimensions as well as the hypergrowth of technology and its permeation of all aspects of work), leverage other relevant guidelines and bodies of work that could add value to the discussion herein, enhance the section on organization-level competencies, tighten up the organization of the document, and provide a reading list of OCP resources to support the professional development of consulting psychologists. These changes are addressed in the document that follows (see Appendix A for an Organizational Consulting Psychology Bibliography).

Other issues raised, though not by a majority, included supervision, licensure, master's education and training, and adding a fourth "level" to the OCP competency framework that would address large system change beyond organizations (e.g., communities, industries, transnational systems). The importance of supervised experience is more explicitly emphasized in this revision, particularly in the section on what are now organized as the personal and procedural general competencies, but for a fuller discussion of best practices in supervision in OCP, see Blanton (2014), which also touches on the current status of the licensure discussion. Licensure is addressed as well in Appendix B of this document, *Ways to Learn About and Develop Skills in Consulting Psychology.* Regarding the issue of master's-level training, it was agreed that a common set of competencies to guide curriculum development is adequate at this point and does not preclude other curricular differences appropriate to the goals of the two different degrees. This is in keeping with the most recent guidelines published by the Society for Industrial and Organizational Psychology (SIOP), which conclude that "distinctions between master's-level and doctoral-level training might lead to substantial differences in the two levels of training. However, none…suggests that the basic content of the field changes as a function of the level of education. Thus, only one set of competencies is provided within these guidelines." (SIOP, 2016, p. 2). Addressing a fourth level for consulting psychology was determined to be important enough an issue not to be attempted within the scope of this current revision. From this process, a draft was produced that the SCP Executive Board reviewed and final edits were then incorporated into this final document, which then received final SCP Executive Board approval.

A.3.(b). Policy documents relevant to proposed guidelines

The following documents provided foundations, baseline, and substantive information for preparing the original SCP/OCP guidelines and remain germane to the updated document for the reasons originally cited: Association Rules of the American Psychological Association (APA, 2004b); Developing and Evaluating Standards and Guidelines Related to Education and Training in Psychology: Context, Procedures, Criteria, and Format (APA, 2004a); American Psychological Association ASME Guidelines, (APA, 1992); Ethical Principles of Psychologists and Code of Conduct (APA, 2002); Guidelines On Multicultural Education, Training, Research, Practice, and Organizational Change For Psychologists (APA, 2003); Guidelines for Psychotherapy with Lesbian, Gay, and Bisexual Clients (2000); Guidelines for Education and Training at the Doctoral Level in Industrial/Organizational Psychology (SIOP, 1998), which have since been updated as referenced in this revision (SIOP, 2016); and, Principles for the Validation and Use of Personnel Selection Procedures, 4th Edition (SIOP, 2003).

The original guidelines also relied on the 1999 Bylaws of the Society of Consulting Psychology (SCP) for the definition of consulting psychology (www.div13.org/bylaws.aspx) and, for the general definition of psychological practice, the APA "Model Act for State Licensure of Psychologists," which has since been updated (APA, 2011) and the Association of State and Provincial Psychology Boards (ASPPB) "Model Act for Licensure of Psychologists," also recently updated (ASPPB, 2010).

Additional information was provided for the revised guidelines by the Guidelines for the Practice of Telepsychology (APA, 2013), in response to the rise of technology and its demands on psychological practice, including consulting psychology. And, finally, given ongoing demographic and socio-political shifts that will continue to require evolution in the field of

psychology, these revised guidelines refer to the *Guidelines for Psychological Practice with Lesbian, Gay, and Bisexual Clients* (APA, 2012), and the *Resolution on Gender and Sexual Orientation Diversity in Children and Adolescents in Schools* (APA and National Association of School Psychologists [NASP]; 2015).

Section B: Implementation and Maintenance of Proposed Guidelines

Implementation and maintenance of the proposed guidelines is assigned to the Education and Training (E&T) Committee of the Society of Consulting Psychology (SCP)/APA Division 13.

B.1. Plan for promulgating proposed guidelines

Once approved, the SCP E&T Committee will post an updated announcement about the revised guidelines on the Division 13 website, and will publish an announcement in the Division 13 newsletter and journal. In addition, it will provide electronic dissemination of the guidelines to graduate departments and professional schools of psychology, the Council of Chairs of Training Councils, state psychological associations, and APA divisions for possible use in graduate or postdoctoral programs, conferences and workshops, distance learning CE events, and other appropriate education and training events.

B.2. Plan for maintaining currency of guidelines

The SCP E&T Committee will plan for the review and update the proposed guidelines on a regular basis. No later than five years after APA approval of the proposed guidelines, the SCP E&T chair will present a schedule for updating, including recommendations for an ad hoc review committee, a time-table for presenting an updated draft to the SCP Board for review, to the division APA Council Representative, and to the APA Board of Educational Affairs for APA

governance reviews prior to APA Council re-endorsement in time for the update required by Association Rule 80.3.

Section C: Content of Proposed Guidelines

The substance of the guidelines follows.

Guidelines for Education and Training at the Doctoral and Postdoctoral Level in Consulting Psychology (CP)/Organizational Consulting Psychology (OCP)

Purpose of the Guidelines

The purpose of these revised "Guidelines for Education and Training at the Doctoral and Postdoctoral Levels in Consulting Psychology/Organizational Consulting Psychology," which update and replace the guidelines originally approved in 2005 and published in the *American Psychologist* in 2007 (APA, 2007), is to provide a common framework for use in the development, evaluation, and review of education and training in consulting psychology/organizational consulting psychology (CP/OCP). The intent of these guidelines is to improve the quality of teaching and learning in the area of the practice of CP, especially OCP, within the scientific discipline and profession of psychology.

Towards these ends, this document is intended as guidance for psychologists who teach or plan curricula for teaching CP/OCP at doctoral or postdoctoral levels of professional education and training in psychology. The guidelines are structured in the form of *overarching principles*, *general competencies*, and *level-specific competencies* that are ideally obtained by persons receiving training at the doctoral or postdoctoral level in CP/OCP (see Figure 1).

Revision Process

This revision was undertaken, in accordance with guidance from the APA (2004a) in relation to Association Rule 30-8.3, to ensure currency of guidelines related to both their scholarly basis and their practical use.

The procedure for gathering input on needed revisions to these guidelines, which took place in 2015, included interviewing thought leaders in the field of consulting psychology from the following groups: authors of the 2005 guidelines, members of the Society of Consulting Psychology (SCP)/Division 13 E&T Guidelines Revision Committee, and the co-chairs of another competency-related project in SCP specific to coaching; as well as surveying members of SCP. The goal of both methods was to collect feedback on the strengths, weaknesses, and gaps that should be addressed in a revision of the 2005 guidelines. In addition, the revision committee reviewed other published guidelines that relate to other areas of psychology and to specific issues or competencies covered in this document to evaluate suitability to be referenced for a more in-depth treatment of a given issue.

The general consensus that emerged from this process was that the guidelines were largely solid and a revision should not aim to make substantial substantive changes but rather to update language and information, address contemporary issues that impact consulting work (such as increased diversity along multiple dimensions as well as the hypergrowth of technology and its permeation of all aspects of work), leverage other relevant guidelines and bodies of work that could add value to the discussion herein, enhance the section on organization-level competencies, tighten up the organization of the document, and provide a reading list of OCP resources to support the professional development of consulting psychologists. These changes are addressed in Appendix E.2. *Organizational Consulting Psychology Bibliography*.

Other issues raised, though not by a majority, included supervision, licensure, master's education and training, and adding a fourth "level" to the OCP competency framework that would address large system change beyond organizations (e.g., communities, industries, transnational systems). The importance of supervised experience is more explicitly emphasized in this revision, particularly in the section on what are now organized as the personal and procedural general competencies, but for a fuller discussion of best practices in supervision in OCP, see Blanton (2014), which also touches on the current status of the licensure discussion. Licensure is addressed as well in Appendix E.3. *Ways to Learn About and Develop Skills in Consulting Psychology.* Regarding the issue of master's-level training, it was agreed that a common set of competencies to guide curriculum development is adequate at this point and does not preclude other curricular differences appropriate to the goals of the two different degrees. This is in keeping with the most recent guidelines published by the Society for Industrial and Organizational Psychology (SIOP), which conclude that "distinctions between master's-level and doctoral-level training might lead to substantial differences in the two levels of training. However, none…suggests that the basic content of the field changes as a function of the level of education. Thus, only one set of competencies is provided within these guidelines" (SIOP, 2016, p. 2). Addressing a fourth level for consulting psychology was determined to be important enough an issue not to be attempted within the scope of this current revision.

From this process, a draft was produced that the SCP Executive Board reviewed and final edits were then incorporated into this final document.

Definitions

Consulting psychology, a practice that focuses on consultation to, with, or for individuals and organizations at individual, group, and organization/systems levels rooted in multiple areas

of substantive expertise, is used here as defined in the 1999 Bylaws of the Society of Consulting Psychology (SCP), Division 13 of the American Psychological Association (APA):

Consulting psychology, for the purposes of these By-Laws, shall be defined as the function of applying and extending the special knowledge of a psychologist, through the process of consultation, to problems involving human behavior in various areas. A consulting psychologist shall be defined as a psychologist who provides specialized technical assistance to individuals or organizations in regard to the psychological aspects of their work. Such assistance is advisory in nature and the consultant has no direct responsibility for its acceptance. Consulting psychologists may have as clients individuals, institutions, agencies, corporations or other kinds of organizations (www.div13.org/bylaws.aspx).

Also relevant to these guidelines is the general definition of psychological practice noted in the APA "Model Act for State Licensure of Psychologists" (APA, 2011) and the Association of State and Provincial Psychology Boards (ASPPB) "Model Act for Licensure of Psychologists" (ASPPB, 2010). Related to this revised guidelines document, it should be noted that the most recently adopted version of the Model Act states that "language has been revised throughout the document to make it more inclusive of non-health service psychology, most notably industrial-organizational psychology," which is reflected, for example, in references to "consultation" and "organizational effectiveness." Additionally, the latest Model Act recognizes that "new technology and increased mobility of psychologists has necessitated the development of new language to address interjurisdictional practice, and the delivery of psychological services by electronic or other means (i.e., telepsychology)." This latter point, which was also raised in the feedback gathered for this revision, as previously noted, is reflected in the addition of

"technology" to the "business operations" competency in these revised guidelines. *Practice of psychology* is defined (ASPPB, 2010, pp. 7-8) as follows:

> the observation, description, evaluation, interpretation, prediction and modification of human behavior by the application of psychological principles, methods, and procedures, for the purposes of preventing, eliminating, evaluating, assessing, or predicting symptomatic, maladaptive, or undesired behavior; evaluating, assessing and/or facilitating the enhancement of individual, group and/or organizational effectiveness – including personal effectiveness, adaptive behavior, interpersonal relationships, work and life adjustment, health, and individual, group and/or organizational performance; or assisting in legal decision-making. The practice of psychology includes, but is not limited to, psychological testing and the evaluation or assessment of personal characteristics, such as intelligence; personality; cognitive, physical, and/or emotional abilities; skills; interests; aptitudes; and neuropsychological functioning; counseling, consultation, psychoanalysis, psychotherapy, hypnosis, biofeedback, and behavior analysis and therapy; diagnosis, treatment, and management of mental and emotional disorder or disability, substance use disorders, disorders of habit or conduct, as well as of the psychological aspects of physical illness, accident, injury, or disability; psychoeducational evaluation, therapy, and remediation; consultation with other psychologists, physicians, other health care professionals and patients regarding all available treatment options, including medication, with respect to provision of care for a specific client or patient; provision of direct services to individuals and/or groups for the purpose of enhancing individual and

thereby organizational effectiveness, using psychological principles, methods and/or procedures to assess and evaluate individuals on personal characteristics for individual development and/or behavior change or for making decisions about the individual, such as selection; and the supervision of any of the above. Psychological services may be rendered to individuals, families, groups, systems, and/or organizations. The practice of psychology shall be construed within the meaning of this definition without regard to whether payment is received for services rendered or if the practice was conducted in person or via electronic means.

Finally, these guidelines are framed as a set of *competencies*, with competency having the commonly accepted definition of a capability that encompasses knowledge, skill and ability. Thus, the framework discussed herein lays out the capabilities that a doctoral-level consulting psychologist should learn and be able to apply.

Figure 1. Overview of Consulting Psychology/Organizational Consulting Psychology Guidelines

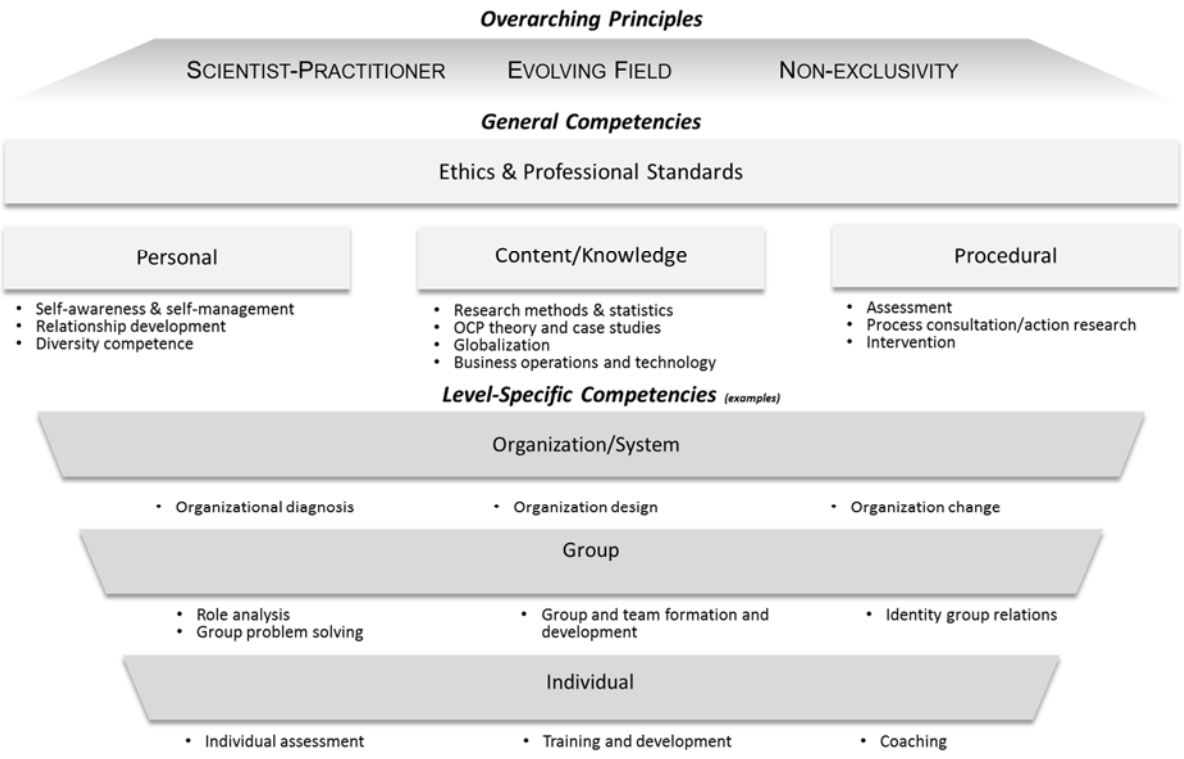

Overview of the OCP Competency Framework

Areas of Training Addressed

This document proceeds from three overarching principles and 11 general areas of learning competencies, culminating in competencies specific to three domains or levels of organizational consulting psychology: *individual*, *group*, and *organization/systems* (I-G-O). Although there are other applications of CP for which alternative or additional competencies may be relevant (e.g., health-, military-, or school-related CP), the specific areas of expertise addressed in this document relate to CP as it is applied to organizational consulting psychology (OCP). These guidelines are not intended to replace, usurp, or conflict with training policies or principles that have been developed and approved for other areas of practice such as those in industrial/organizational, clinical, counseling, or school psychology. In fact, these guidelines recognize the significant value that other standards and guidelines can provide in concert with these guidelines, which do not seek to recreate those in-depth resources but instead to focus in on

the set of individual, group, and organization/systems competencies uniquely relevant to organizational consulting psychology and to leverage other resources as appropriate by referencing them where relevant. Users of these guidelines are encouraged to refer to such references for a more thorough treatment of specific areas or topics (e.g., the use of technology in psychology practice, multicultural competence).

Figure 1 provides an overview of the CP/OCP guidelines in the form of a competency framework guided by, or premised by, the three overarching principles. The framework comprises 11 general competencies common to the effective practice of CP/OCP and a number of level-specific competencies. The 11 general competencies are organized into the personal, knowledge-based, and procedural domains with Ethics and Professional Standards as a foundational anchor. The specific competencies are organized by the level at which the consulting is *primarily* directed —individual, group, and organization/systems (I-G-O).

Overarching Principles

The overarching principles include: (1) recommended adherence to the *Scientist–Practitioner* model; (2) *Evolving Field* - recognition of the evolving nature of the field; and (3) *Nonexclusivity* - acknowledging the multiple avenues for preparation for various roles as a consulting psychologist (also referred to as equifinality). These are the acknowledged assumptions and psychological context within which the OCP competencies are framed.

General Competencies

The 11 general competencies as detailed and promulgated by APA specialists in those topics show the psychological context within which the OCP competencies function. In this revision, competence in (1) *Ethics and Professional Standards* is explicitly emphasized as a

foundational competency that permeates all other competencies, as illustrated in Figure 1. The remaining nine general competencies are grouped into personal, knowledge-based, and procedural types in acknowledgment of the relative - though not exclusive - emphasis in training approach or methodology for each. The development of personal competencies requires a greater emphasis on feedback, reflection, interpersonal exposure and personal growth/maturation, all augmented by supervision; these competencies include: (2) *Self-Awareness and Self-Management*; (3) *Relationship Development*; and (4) *Diversity Competence*. The development of the more knowledge-based competencies requires a relatively greater emphasis on exposure to concepts and content domains; these include: (5) *Research Methods and Statistics*; (6) *OCP Theory and Case Studies*; (7) *Globalization; and (8) Business Operations and Technology*. The development of the procedural competencies requires a relative emphasis on applied practice with supervision and is heavily influenced by the ethical, personal, and knowledge-based competencies; these procedural competencies include: (9) *Assessment*; (10) *Intervention*; and (11) *Process Consultation/Action Research.*

Level-Specific Competencies

These CP/OCP guidelines address attention to specific competencies pertinent to the work of consulting at each of three levels: (1) *Individual Level Competencies*, (2) *Group Level Competencies*, and (3) *Organization/Systems Level Competencies*.

These three elements of the OCP guidelines framework – overarching principles, general competencies, and level-specific competencies – are elaborated below.

Overarching Principles

Scientist–Practitioner Assumptions

Consistent with the orientation of the SCP/Division 13 of APA, these revised guidelines reaffirm the importance of CP/OCP being guided by the *science* of psychology in evaluating and assessing the effectiveness of interventions and assessment methodologies used in the *practice* of OCP. *This reaffirmation recognizes that the scientist-practitioner principle is too often inadequately enacted and that this requires "changed behavior on the part of both practitioners and of researchers" (Lowman, 2012, p. 151).* The use of the term *interventions* here is consistent with the work of Dougherty (2000), who defined *interventions* as activities both the consultant and the client agree have a high probability for solving the problem at hand.

It is recommended that the consulting psychologist be competent to conduct and/or to evaluate and to utilize scientific-based research in the practice of CP/OCP. The effective consulting psychologist, ideally, has in-depth knowledge of the major theoretical models in psychology and of their particular methodologies and intervention strategies as they apply to individual, group, and organizational consulting domains. CP/OCP embraces a scientist–practitioner model (Baker & Benjamin, 2000; Stricker, 2000) of training, including training in traditional research skills (e.g., statistics, research design, test construction).

No single model of empirical research, however, is assumed to have a monopoly on truth by the endorsement of the scientist–practitioner model of consultation. CP/OCP trainees learn, for example, not just about research methodologies but also about the role of the consultant as an active participant in the consulting process at hand (Lippitt & Lippitt, 1978). Action research, an assessment or study of the situation and problem undertaken by the consultant prior to the implementation of particular consultation services or interventions, is traced to Kurt Lewin

(1951). An example of such practice in OCP is the joint consultant– client determination of an organization's needs or critical problems and ideal outcomes, sometimes called *calibration consultation*, a process that is important when applying complex constructs to practical problems (Schein, 1985), especially in international or multicultural organizations (O'Roark, 2002).

Evolving Field

CP and OCP have evolved over time. The body of knowledge and methods of service delivery have continued to grow over the past few decades, stimulated by the writings and publications of former SCP president Thomas Backer (1982a, 1982b). DeWayne Kurpius, who was the 1991 winner of SCP/APA Division 13's award for lifetime achievement in consulting to organizations, prepared a consulting psychology reading list for a survey conducted while he was the Education and Training Committee chair for SCP (Robinson-Kurpius, Fuqua, Gibson, Kurpius, D., & Froehle, 1995). The list was similar to a 1999 SCP survey of "the best of the century" in consulting psychology, which reported the names of psychologists with the greatest influence on contemporary consulting psychologists, as well as listing 68 authors and 93 titles (O'Roark, 2007), e.g.: *Organizational Diagnosis* (Levinson, 1972); *Process Consultation* (Schein, 1969); *Intervention Theory and Methods* (Argyris, 1970); and *The Theory and Practice of Mental Health Consultation* (Caplan, 1970). Carl Rogers is cited six times. Three of these nominations are for his book *Freedom to Learn* (Rogers, 1969). Edgar Schein received four citations, two for his book *Organizational Culture* and *Leadership* (Schein, 1985, 1992) and two for *Process Consultation* (Schein, 1969). Other top-rated writings are those of Block (1981/1999), Caplan and Caplan (1993), Katz and Kahn (1978), Lippitt and Lippitt (1978), Senge (1990), and Tobias (1990).

More recently, Rodney Lowman, an eminent leader in consulting psychology and in SCP, has curated one of the most comprehensive and in-depth edited volumes on the field available in *The Handbook of Organizational Consulting Psychology* (Lowman, 2002), which features contributions from seasoned experts in the field, many from SCP/Division 13, on a wide range of issues germane to these training guidelines. Thought leaders in the field have also grappled with and responded to contemporary movements and issues, including the rise of coaching as a sub-discipline; the implications of technology for consulting psychology; the impact of social, political, and cultural change on consulting science and practice; and the issues of supervision and licensure in training and practice. Note the affiliation that SCP entered into with the International Society for Coaching Psychology (ISCP) in 2012 to advance the discipline of coaching psychology, and the partnership of these two bodies in a joint conference on the topic in 2015, the output of which was published in a special issue of SCP's Consulting Psychology Journal under the title *International Perspectives on Becoming a Master Coaching Psychologist.* The rise of technology and its demands on psychological practice are evidenced by the development of Guidelines for the Practice of Telepsychology (APA, 2013). And the field has responded to ongoing demographic and socio-political shifts, that will continue to require evolution, with guidelines related to a number of diversity variables (see the discussion of *diversity competence* below).

OCP will continue to evolve and sometimes to use techniques that have received limited research investigation, which creates some tension with the scientist-practitioner ideal. The concern is to do so in an ethical manner. Standard 2.01(e) of the *Ethical Principles of Psychologists and Code of Conduct* (APA, 2002) was specifically written to provide guidance. It states,

> (e) In those emerging areas in which generally recognized standards for preparatory training do not yet exist, psychologists nevertheless take reasonable steps to ensure the competence of their work and to protect clients/patients, students, supervisees, research participants, organizational clients, and others from harm. (p. 1064)

This standard is highlighted in regularly offered ethics workshops sponsored by SCP and is also attended to in articles published in the division's two official publications, *Consulting Psychology: Practice and Research*, a journal, and *The Consulting Psychologist*, the division newsletter.

Nonexclusivity

SCP/APA Division 13 recognizes the diverse nature of the field of CP/OCP. Its practitioners come from a variety of academic and professional backgrounds, and there are multiple paths of entry into the field. Many practitioners come from a background in clinical/counselling psychology or industrial-organizational psychology, both of which provide considerable training that is relevant for the practice of CP (see, for example, the SIOP [2016] training guidelines). In fact, some of the most innovative training models for CP/OCP practitioners are emerging in programs described as "business psychology," "social-organizational psychology," or that include multidisciplinary training in psychology and business administration. Additionally, practitioners of CP/OCP often ground their work in the research and scholarly work that evolves out of other fields. For example, applied research and practice in sports psychology, a field historically prominent in European psychology (Foster, 2002), and academic training applied in areas such as health psychology (Lloyd & Foster, 2006; Lloyd & Veneziano, 2002) have proved useful to the practice of CP. Some of the resources available to

complement any one specific training path include the *APA Handbooks in Psychology* series (www.apa.org) as well as, of course, the more targeted *APA Fundamentals of Consulting Psychology* series (e.g., Lowman, 2016) as well as a number of other handbooks and series, published for example by Sage and Jossey-Bass, (e.g., Lowman, 2002).

Beyond training, the demands of consulting as a discipline require flexibility and continual adaptation to meet the changing needs of clients who seek CP/OCP services. Therefore, by necessity, the field of CP/OCP must cultivate its own diversity, which is facilitated by a stance of nonexclusivity.

These guidelines are intended to assist in the specific development of doctoral programs, postdoctoral training, and continuing education institutes/workshops in CP/OCP. The guidelines and references have been prepared to reflect the current state and historical development of the OCP field, highlighting the contributions of SCP/APA Division 13 leaders, and to provide a conceptual framework for the development of training programs. It is expected that these CP/OCP guidelines will continue to change over time to keep pace with advances in research and practice.

General Competencies

These CP/OCP guidelines comprise sets of competencies needed for CP practice in work and organizational contexts. The document intentionally identifies *recommended competencies* (or "end states") rather than presenting "model curricula" or specific course work since there are multiple ways to obtain the desired competencies. Indeed, innovation in doctoral and postdoctoral training methodologies for helping students achieve these competencies is encouraged.

Foundational Competency: Ethics and Professional Standards

Professional ethics and standards compliance is considered as a pervasive, general competency in the CP/OCP guidelines model. Knowledge of the psychologists' code of ethics will permeate each of the three levels of interventions; it is also re-addressed in the concluding section of these CP/OCP guidelines. Particular references to the APA code of ethics are included in several sections of these guidelines, for example, Standard 2: Competence (General Competencies, *Assessment*, paragraph 3); Standard 4: Privacy and Confidentiality (I. Individual-Level Consulting Psychology Competencies, paragraph 7); and Standard 9: Assessment (I. Individual-Level Consulting Psychology Competencies, paragraphs 2 and 4).

The ethics code was written with general language, including modifiers such as "reasonably," "appropriate," and "potentially," which requires the application of judgment, which should be explicitly developed through training and supervision. Handelsman, Gottlieb, and Knapp (2005) note that "if ethics training is limited primarily to learning rules, then students may not appreciate the extent to which the need for sound ethical thinking will permeate their professional lives. The development of an identity as an ethical psychologist is a far more complex matter that deserves greater attention (p. 59)." Thus, in addition to familiarity with the code, it is important to be familiar with various models for and factors involved in ethical decision-making. Indeed, there is a growing literature regarding such models and factors. Examples include Handelsman, Gottlieb and Knapp's (2005) acculturation model; Pope and Vasquez's (2016) 17-step decision-making model; Vergés' (2010) approach to integrating contextual issues; and Rogerson, Gottlieb, Handelsman, Knapp and Younggren's (2011) discussion of nonrational processes that impact ethical decision making. Reflection on,

discussion of, and application of such models in the course of understanding and grappling with ethical issues can promote the development of ethical thinking and decision-making.

Personal Competencies: Self-Awareness and Self-Management; Relationship Development; Diversity Competence

The original guidelines rightly emphasized the role of *self-awareness/self-management* and *relationship development* as prerequisites for all areas of psychological practice. These revised guidelines reiterate the primacy of these and pull into that fundamental set what was previously referred to as multicultural and international awareness but which is herein referred to as *diversity competence* to address all types of individual and social difference, including multicultural, international, and identity group. This is a higher order competency in that it requires elements of the first two competencies (e.g., awareness of one's own social identity, awareness of one's biases, empathy for those who are "other," and the ability to build relationships across difference). All three of these personal competencies apply in each of the levels of consulting services – individual, group, and organization/systems.

The capacity for developing self-awareness and self-management can be strengthened and deepened in a wide variety of ways. Graduate-level and post-doctoral education, practicums, and internship work pertinent to these competencies ideally include close critiquing of personal value and belief systems as well as analysis of interpersonal exchanges with colleagues and clients. The development of this capacity for self-directed reflection is facilitated by one-on-one supervision.

Through practicums and internships, psychologists also learn how to build constructive, collaborative relationships with a variety of types of people and organizational representatives.

They learn how to maintain both objectivity and personal engagement as they work with clients to further specific consultative goals.

Given the diversifying effects of globalization, technology, demographic changes, generational shifts and increased public awareness of individual and social identity differences, consulting psychologists acquire appropriate understanding of and sensitivity to issues of diversity. This competency applies to consulting with multicultural clients in one's home country as well as in international settings and with clients from the full range of "identity groups" (defined to include but not be limited to national heritage, age, occupational field, educational experience, social class, gender, race, ethnicity, culture, gender identity and expression, sexual orientation, disability status, and geographic location [e.g., rural, remote]) (Dana, 2001; House et al., 1999; O'Roark, 2002; Sue, Arredondo, & McDavis, 1992; Triandis, 1987).

Moreover, attention should be paid to the "intersectionality" of multiple identity dimensions. As noted in the Guidelines for Psychological Practice with Lesbian, Gay, and Bisexual Clients (APA, 2012, citing Cole 2009), the "concept of intersectionality is used to characterize the variable, differential, and unique effects of constructs such as race, ethnicity, culture, gender, age, sexual orientation, class, and disability on the individual's life. Intersectionality is defined by multiple categories of identity, difference, and disadvantage (p. 20)." In keeping with attention to the complexity inherent in diversity, it is also important to understand the dynamics of a context, such as racial dynamics or social class dynamics within a setting or geographic region.

"Acknowledging the potential for the self to inadvertently cause harm to clients through acts of omission or commission, whether from ignorance or arrogant assumption, the

international [or 'diversity competent'] consultant takes time to hone the self-as-instrument" (O'Roark, 2002, p. 520). This involves an ability to receive appropriate critical feedback from clients and colleagues and a willingness to change behavior as needed (without violating essential ethics) to work effectively with individuals with diverse identity-group, organizational-culture, and social backgrounds in work-related contexts. It is recommended that organizational consulting psychologists have learning experiences that expose them to models and methods for accomplishing these tasks and demonstrate a reasonable ability to implement them. Such learning experiences should ideally include direct exposure to and supervised work with diverse contexts and audiences (e.g., international exchange programs or work assignments). Additionally, resources relevant to this competency include the *Guidelines on Multicultural Education, Training, Research, Practice,* and *Organizational Change for Psychologists (*APA, 2003), *Guidelines for Psychological Practice with Lesbian, Gay, and Bisexual Clients* (APA, 2012), *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* (APA, 2015), the *Resolution on Gender and Sexual Orientation Diversity in Children and Adolescents in Schools* (APA & NASP, 2015), and APA resources on working with older adults, including *Multicultural Competency in Geropsychology* (APA, 2009) and *Guidelines for psychological practice with older adults* (APA, 2013) (see also Glover & Friedman, 2015 and Lowman, 2013). Resources supporting the acquisition of a global perspective and an understanding of how work, organizational culture and leadership relate to national culture and political-economic context include both contemporary news sources (e.g., newspapers, business magazines) and empirically-based publications (see, for example, Hofstede, Hofstede, & Minkov, 2010 and Bhagat, Triandis, & Mcdevitt, 2014).

While genuine, appropriate behavior is considered germane to effectiveness in every consulting venture, working with international clients, multicultural workgroups, and members of different identity groups brings the consultant's credibility and relevance under intensified scrutiny. The challenge for the organizational consultant is to temper interventions with consideration of the client's perspective and context as well as awareness of one's own and how they relate to the client's. The total of such dynamics is referred to as becoming "culture-centered" in the APA Multicultural Guidelines (APA, 2003).

In the interest of articulating a way of proactively addressing the "anticipated impact of the proposed guidelines (applying skills, techniques, and models included in these guidelines) on diverse individuals and groups" (APA, 2004a, p.10) with respect to corporate culture, gender, individual, and role differences, the published model for an international organizational consulting process is a variation on the *calibration consultation* model used for working in the United States with multicultural work groups, unique structural configurations, and employee subgroupings such as gender, first-language groups, payroll groups, and union–nonunion employees. The process is adapted from the full-cycle "action research" process, which calls for the consultant to learn the organization's culture before imposing an intervention. Calibration and *guanxi* (Chinese for instrumental relationship development) are terms that call attention to the need for the consultant to calibrate cultural dimensions and build relationships in the client organization before recommending any type of psychological intervention or organizational improvement activity (see the section of this document labeled III. Organization/Systems-Level Consulting Psychology Competencies).

Finally, Consulting Psychologists have the duty and opportunity to work within the legal and behavioral frameworks of anti-discrimination and employment rights laws, including, among

others, Title VII of the Civil Rights Act of 1964, Americans with Disabilities Act (ADA) and others enforced by the Equal Employment Opportunity Commission (EEOC). Consulting Psychologists understand, advocate and implement in their work the legal rights, responsibilities and opportunities for employers, employees and prospective employees.

With regard to all three of these personal competencies, curricular descriptions and policies of postdoctoral programs are suggested as ways to inform learners how the faculty assists with the achievement of professional and psychological maturity necessary for effective practice in the field.

Content/Knowledge-based Competencies: Research Methods and Statistics; OCP Theory and Case Studies; Globalization; Business Operations and Technology

Research methods and statistics competencies are one important mechanism through which the scientist-practitioner principle is realized. Having knowledge of and experience with research enhances one's ability to bring empirically-based practice to bear in that it allows a consulting psychologist to understand, critically evaluate, and apply published research findings. These same skills allow a consulting psychologist to avoid applying practices that are not well-founded. Moreover, taking a rigorous action research approach to applied practice promotes the transfer of learning from practice back to research for those who take the time to write up their cases and experiences. Finally, facility with research methods and statistics is important in that these same skills are used in assessment and the analysis of data collected on individuals, groups, and organizations (e.g., conducting surveys, interpreting formal assessment data) as well as in designing effective interventions. An added benefit of facility with data analysis and statistics is that it provides a good beginning base for understanding business operating finances as well.

OCP consultants who do not develop comfort and competence in reading organizational financial reports and budgets will be at a distinct disadvantage when competing with business administration management consultants or when coaching high-level executives.

Knowledge of *OCP theory and case studies* serves as the substantive and applied scholarly foundation for engaging in OCP. Knowing the history, scope, and watershed applications of consulting psychology proves practically useful in preparing the consultant for designing interventions and for establishing credibility with organizational clients, who often read the management books that fill the airport shelves and enjoy telling their own versions of the good and the bad experiences with consultants.

An understanding of g*lobalization*, the removal of economic, movement, and communication barriers that promotes integration of markets, trade, and ideas, and its implications for OCP, has become a requirement for consultants. Knowledge of *globalization* interacts with the personal competency of *diversity competence*, as suggested in that section. Regardless of what type of organizational client a consultant is working with (e.g., business, non-profit, non-governmental organization, educational institution, military group), globalization has some degree of influence. The impact of globalization may be obvious when organizations already operate or expand their operations internationally, but it is also important for organizations based in one country, which still must function within a broader global environment characterized, for example, by interdependent economies (as evidenced by the financial crisis that began in the United States in 2008 and rippled through the world economy for years) and by an increasingly multicultural workforce and constituent base.

In the context of accelerating globalization, organizations and their leaders face an intensified need to lead people, manage stakeholder relationships, and build organizational

cultures across traditional national boundaries. As such, an understanding of cross-cultural dynamics has become increasingly important. This places a growing demand on CPs/OCPs to possess expertise in new areas. In particular, they need to understand how effective leadership styles differ from culture to culture (Hofstede, Hofstede, & Minkov, 2010), as well as how elements of national culture are likely to influence organizational dynamics (Bhagat, Triandis, & Mcdevitt, 2014). More and more, this expertise will serve as an important lens through which CPs/OCPs assess and intervene across individual, group, and organizational/systemic levels.

Understanding business operations and technology applies both to "business" generally (to understand the operations and interests of client organizations, whether for-profit or not) and to the consulting psychologist's business (i.e., being able to run or contribute to a viable consulting operation), including understanding basic issues of finance, governance, and value creation as well as more specific issues such as the legal constraints on competing for contracts, becoming familiar with industry-wide regulations, etc. Competence in this arena is important both substantively and in terms of the credibility of the consultant.

Similarly, being competent in relation to technology applies to both client organization and practitioner methods. Regarding the client organization, technology-related competence means having at least a basic understanding of technology in and around the client and the implications of that technology on the issues addressed in consulting (e.g., individual overload and stress from 24/7 connectivity; virtual, technology-enabled teams; digital transformation, including culture change, to support an evolving strategy). Regarding technology as used by the practitioner, it is now an expectation that all consulting professionals be competent in the use of technology in the delivery of their services and that they understand and can communicate the impact of technology on and to clients. As the APA Telepsychology Guidelines (2013) state

> two of the most salient issues that the Telepsychology Task Force members focused on when creating this document were the psychologist's own knowledge of and competence in the provision of telepsychology and the need to ensure that the client/patient has a full understanding of the potentially increased risks to loss of security and confidentiality when using technologies (p. 793).

Procedural Competencies: Assessment; Process Consultation/Action Research; Intervention

Assessment is considered to be not only a general competency but also a pivotal CP/OCP competency in all three I-G-O consulting levels. It is given special attention here as a general competency to begin to highlight the aspects distinctive to OCP. Ryan and Zeran (1972) usefully defined assessment as (a) disciplined analysis of (b) a present situation that requires (c) determining what pertinent elements combine to (d) generate the current situation. Ideally, interactions among the pertinent elements can be synthesized into a new alignment that provides means for optimizing system outcomes.

Assessment competencies for organizational consulting can be depicted on dual continua: scientist–practitioner and theory to practice. While assessment approaches, methods, and instruments vary dramatically according to the I-G-O level of focus and cultural context, skills to be developed in assessment, regardless of I-G-O focus, include identifying (observing, using logical deduction), integrating (classifying), and inferring (matching evidence to goals and assessment schemas) in order to assist in decision making, in implementing change, or in improving understanding (Barclay, 1991). Assessment, generically, is the systematic process of making inferences in order to arrive at a diagnosis for use in informed decision making regarding interventions. Special attention to and need for assessment in preparation to work with

multicultural groups and international organizations is highlighted and defined in the calibration consultation model (O'Roark, 1995, 2007).

The pervasive aspect of competence (Standard 2 of the *Ethical Principles of Psychologists and Code of Conduct*, APA, 2002) in systematic, formal assessment across the three interactive levels (I-G-O) is recognized by representing psychological assessment as a general competency in these CP/OCP guidelines (see Figure 1).

Similarly, *process consultation* (Schein, 1969, 1985, 1987, 1999) is an important general competency and OCP competency in each I-G-O level. Schein considered process consultation to be integral in a philosophy of helping that stands in contrast to medical (doctor/expert) consulting approaches. While he advocated never depriving a client (individual, group, or system) of one's expertise, Schein (1989) detailed the value of starting in a process consultation mode, which means working from several basic assumptions:

> clients . . . seek help when they do not know exactly what their problems are . . . the help they really need is in figuring out exactly what is wrong . . . most clients do not know what kinds of help are available and what kinds of help are relevant to their problems . . . many of the problems in human systems are such that clients . . . would benefit from participation in the process of making the diagnosis . . . only clients know what form of remedial intervention will really work because only they know what will fit their personalities and or group or organizational cultures. (p. 5)

Process consultation/action research is included in these CP/OCP guidelines as a general competency goal. Process skills contribute to a number of other competency areas and illustrate a

hallmark expertise in OCP. Process skills are integral to organizational assessment and in most forms of intervention.

Intervention, or activity that consultant and client agree will likely be effective in addressing the problem (Dougherty, 2000), refers to the psychological procedures and processes introduced into the organization. Standard, classical activities and innovations or variations fill volumes of "how to" books, such as the early University Associates publication of Pfeiffer and Jones's (1975) series called *Structured Experiences for Human Relations Training*, now published as handbooks by Jossey-Bass.

Level-Specific Competencies

Level-specific competencies are organized into three broad domains of psychological expertise that are considered important in becoming competent as an organizational consulting psychologist: individual, group, and organization/system~~s~~ (I-G-O). This I-G-O model is primarily intended for organizing and conceptualizing purposes when thinking about curriculum design issues and continuing education programs; it is assumed that, to some degree, competencies in each level will interact with one another and that the effective practice of CP/OCP draws simultaneously on competencies relevant at each of the levels.

Although specific competencies do not always neatly fit within a single domain, grouping by focal categories of the organization levels serves as a useful organizing metric in thinking through the issues of how best to train people to become consulting psychologists. Within each of the three levels, a series of specific competencies is identified as having primary, but not exclusive, relevance to that intervention domain. Illustrative competencies, elaborated in subsequent sections, are listed below.

Primarily Individual-Level Core Competencies

- Individual assessment for purposes of career and vocational assessment
- Individual assessment for purposes of employee selection
- Individual assessment for purposes of employee development
- Job or work analysis
- Individual coaching for performance or development
- Career counseling

Primarily Group-Level Core Competencies

- Assessment of group functioning, effectiveness, and/or processes
- Team development (e.g., team formation, team building, team alignment)
- Forming and coaching or advising group-level teams in organizations (e.g., cross-functional project teams, self-directed work groups)
- Intergroup assessment and intervention (e.g., work processes, information-sharing, conflict, boundaries)
- Facilitating group-level training and development interventions, such as action learning teams
- Helping groups navigate the dynamics of diversity and social identity

Primarily Organization/Systems-Level Core Competencies

- Understanding of organizational theory
- Facilitating the design of effective organizations, with attention to structures and processes
- Conducting organizational assessment and diagnosis (e.g., performance, culture, engagement, values, management practices)

- Designing and delivering organizational development initiatives
- Supporting organizational change work

In the following sections of this document, the core CP/OCP competencies are elaborated and illustrated. The competencies described here necessarily constitute an abbreviated listing of skills important in becoming a consulting psychologist.

I. Individual-Level Consulting Psychology Competencies

In the individual level, consulting psychologists learn the skills for performing assessments and interventions centered on persons as separate entities in organizational and work contexts. It is recommended that consulting psychologists learn the knowledge, skills, and abilities required to assess and intervene with individuals in nonclinical work- and career-related contexts and how to differentiate between situations requiring assessment or intervention with abnormal psychological conditions and those with the more normal range of behavior.

A. Individual-Level Assessment

Doctoral-level consulting psychologists understand and learn to competently employ individual-level assessment methods and techniques appropriate for the types of problems and issues confronted by individuals in work, career, and organizational contexts. They become competent in psychometric issues in individual assessment and in procedures for conducting valid individual-level assessments and evaluations for purposes of career assessment, personnel selection, personal development, and in the context of determining appropriateness for, and specific needs of, coaching and counseling of persons in the work and career context. Such assessments are based on relevant evaluations using, as appropriate, psychological tests and other assessment procedures and include understanding of the legal and regulatory context in which

individual assessments occur (*Ethical Principles of Psychologists and Code of Conduct*, Standard 9; APA, 2002).

The consulting psychologist learns to understand intrapsychic-level dynamics and socio-cultural dynamics affecting observed individual behavior and can integrate this information into decision making regarding interventions appropriate for the client's situational context. CP individual-level assessment skills do not normally include assessment of abnormal personality or mental dysfunction except to the extent that the consulting psychologist learns to recognize what impacts on work performance and, then, to differentiate persons whose individual needs may require a different type of intervention, such as a referral for a formal mental health evaluation or intervention.

Doctoral-level consulting psychologists learn individual-level assessment methodologies, including skills required for the administration and interpretation of a representative-level sample of relevant instruments and in providing feedback to individuals completing such measures (*Ethical Principles of Psychologists and Code of Conduct*, Standard 9; APA, 2002). These guidelines intentionally do not specify a list of assessment devices, procedures, or psychological tests (e.g., specific measures of occupational interests, abilities, and personality traits) in which consulting psychologists become competent, since any such list would quickly become outdated or irrelevant. It is advised that the consulting psychologist learn meta-skills in individual-level psychological test administration, interpretation, and feedback and experience administering, interpreting, and providing feedback with a sufficiently large number of scientifically sound instruments that new tests can quickly be mastered as they become available. As Cummings (2002) points out, it is also advised that the consulting psychologist gain experience assessing a diverse range of clients. Bringing diversity competence to assessment competence would mean

supervised experience with clients representing a variety of cultures, backgrounds and identity groups.

For competence in working at the individual level, the consulting psychologist learns to define relevant assessment questions, to choose appropriate instrumentation, to administer the relevant tests, and to provide feedback, both test results and pertinent behaviorally based feedback, to all relevant parties. Feedback includes helping the individual(s) assessed (and other relevant parties, such as third parties) understand the results and limitations of the assessment, helping to place the results in the appropriate organizational context, such as company culture and employee classifications and federal/state regulatory obligations (as represented in payroll categories, union membership, and safety requirements such as hard hats), addressing the affective aspects of such feedback, and helping identify relevant individual–situational (including, but not limited to interpersonal, identity groups, corporate purpose/values/ structure/management practices) implications of the results of the assessment. See *Using Feedback in Organizational Consulting* (Gregory & Levy, 2015), in the APA Fundamentals of Consulting Psychology series for more detailed guidance.

Thus, consulting psychologists learn to identify and put into a developmental and organizational context the strengths and limitations of each of several assessment methods: empirical methods (e.g., behavioral, content analysis), psychometric methods (cognition–learning, affect– behavior, conation–willing, i.e., integrative decision making), and more intuitive methods (projective and other). The history of the development of each methodology is supplemented with detailed exposure to preferred techniques, emphasizing the strengths and limitations that pertain to diagnostic outcomes specific to CP/OCP: classification for description,

evaluation, placement; classification for performance competency; classification for consultant intervention, therapeutic recommendations, or referral for clinical treatment.

At the individual level, the consulting psychologist learns to understand and integrate the various components of psychological assessment (e.g., test results, behavioral observational data, relevant background and life history information) and to synthesize these data into pragmatically relevant results. The consulting psychologist is skilled in a range of individual-level assessment procedures (e.g., objective, projective, structured observation, ethnographic field methods, interviews, ethical standards assuring privacy and confidentiality [*Ethical Principles of Psychologists and Code of Conduct*, Standard 4; APA, 2002]) and applies synthesis thinking to produce integrated results that are germane to the referral question(s) for which the assessment was undertaken.

B. Individual-Level Interventions

Consulting psychologists learn to implement a range of interventions that focus on the individual development level and are sensitive to life span perspectives and individual experiences. These interventions can be classified as educational, training, coaching, and counseling.

1. Educational. Consulting psychologists learn how to provide educational-based interventions for individuals. The goal of such activities would be to promote the acquisition and use of new knowledge by clients. The range and depth of such educational interventions will vary greatly and may incorporate various modalities including face-to-face and various telecommunications-based formats.
2. Training. Practitioners learn how to provide training interventions for individuals. The goals of such activities are to assist individuals in developing and

strengthening skills relevant to the workplace. The range and types of skills applicable to jobs are enormous, and it is not expected that organizational consulting psychologists be able to demonstrate competency in all of them. However, practitioners are able to assess problems and design skill-building interventions that will help clients manage the challenges that they face.

3. Coaching. Practitioners learn how to provide competent, assessment-anchored coaching and other individual-level interventions. The goals of such activities include helping clients to improve their abilities to diagnose problems that they are confronting in the workplace; to change problematic attitudes, values, beliefs, and behaviors that may interfere with their performance; and to improve their skills, self-awareness, and self-efficacy in their work-related roles. Coaching may include education and training interventions as part of a package of activities that are usually negotiated and delivered to a client in the context of a formal agreement. While every consulting psychologist should be capable of holding one-on-one conversations of a coaching nature – i.e., promoting reflection, insight, and/or new perspectives or abilities, typically through greater reliance on inquiry and listening than on directing –coaching in the context of longer-term engagements or developmental relationships that promote potentially deep change in an individual, as in executive coaching, is considered a more specialized and advanced competence. See Vandaveer, Lowman, Pearlman, & Brannick (2016) for a discussion of a professional practice analysis of executive coaching sponsored by SCP and SIOP that forms the foundation of a competency model for this more advanced type of coaching.

4. Counseling. Consulting psychologists learn to provide counseling interventions for individuals. The goal of such activities is to help individuals overcome internal psychological or behavioral barriers to the performance of their roles in the workplace. Although consulting psychologists are familiar with and able to apply an array of counseling theories and methods, they are not necessarily expected to be prepared to conduct long-term mental health treatment with clients for chronic or non-work-related conditions. Rather, consulting psychologists refer such clients to appropriately prepared colleagues when they believe that such care is necessary.

Foci for Individually Directed Interventions

CP/OCP training programs prepare practitioners to intervene with individuals in the workplace who may be encountering a wide variety of problems and issues. To be sure and inevitably, the academic and practice aspects of the programs will not be able to expose students to the full array of difficulties and challenges that clients may present to them once they leave school or when transitioning into CP/OCP. However, there are some foci for individual interventions that may be reasonable to include in curriculum and programs. These can include such specific applications as those named below.

Representative Individual-Oriented Consulting Competencies

- Career management
- Coaching on managerial roles and behaviors
- Fostering the development of leadership and followership behavior
- Technical roles in organizations

- Interpersonal relationships and psychosocial challenges, with analysis and accommodation of issues related to diversity (race, gender, gender identity and expression, values, sexual orientation, age, nationality) in organizations
- Intrapsychic aspects of work such as motivation, resistance to change, and emotional management
- Crisis management concerning individual behavior in organizations
- Individual performance in relationship to groups and organizations
- Role conflict management
- Assisting individuals to work effectively in globally oriented, culturally diverse organizations and within a multicultural work force
- Life span perspectives

Course work and practicum experiences in CP/OCP training programs integrate theory, research, technical skills and implementation methods, and approaches to evaluating individually based interventions. Consulting psychologists are, ideally, prepared to design, implement, and evaluate these approaches.

II. Group-Level Consulting Psychology Competencies

Group-level OCP competencies take the group as the primary unit of analysis. The group-level frame of reference pertains both to the interpersonal relations among members of task or cohort groups - including leader-follower behavior, authority dynamics, dealing with diversity/differences, cooperation, collaboration, conflict management, communication, labor-management relations, and interorganizational relations - as well as to the work-related variables such as role definition and alignment, workflow, planning and task coordination, and goal setting and performance tracking.

Crucial propositions are the following: (1) roles in organizations are shaped by group-level forces; (2) individuals in organizations function as representatives of their work group, whether or not they intend to do so; (3) dynamics of task groups cannot be adequately understood independently of the external relations/group-identifications of members of a work group; and (4) unconscious processes within individuals, within groups, and between groups affect individual roles, intragroup dynamics, intergroup relations, and interorganizational relations.

In doctoral and postdoctoral education programs in consulting psychology, psychologists learn how to carry out interventions with groups embedded in organizations. This education includes knowledge about (a) the self in relation to these phenomena, such as personal prejudice and bias, (b) relevant concepts and theories from social psychology, (c) specific and relevant case studies and statistical research results, and (d) social technologies appropriate to the work group. Effective intervention is associated with favorable confluence among all four of these elements. When knowledge and skills (competencies) related to any aspect are missing, or if all are not brought together in a congruous fashion, then additional OCP education is recommended.

The following sections elaborate specific types of group-level assessment and intervention approaches suggested as competencies for which an organizational consulting psychologist is trained: role analysis and renegotiation; group formation and development; group and intergroup problem solving; identity groups and intergoup relations; and group-level interventions.

A. Role Analysis and Renegotiation

The purpose of these activities is to enable individuals in roles within organizations to understand the forces that shape their roles and to take constructive initiatives to adjust those forces that cause dysfunctional consequences for themselves and/or the organization.

Consulting psychologists learn to establish their own roles in relation to their OCP work, know several versions of role theory (including those that take account of group- level processes), become familiar with the research on role dynamics in organizations, and gain competency in being able to diagnose barriers to effectiveness and then assist clients in analyzing and renegotiating their roles.

B. Group Formation and Development

Relevant OCP activities include facilitating group leaders and members to form a group, establishing productive relations between leader and members, developing constructive relations among peers within the group, and fashioning cooperative relations between the focal group and other groups, organizations, and stakeholders with whom the group must interact in order to perform effectively or achieve the group objective.

Note that a team is a particular type of group in which the team membership is relatively stable, the group has shared goals, and the members are interdependent in achieving their goals, at least to some extent. Teams have become an increasingly important focus of attention in both research and consulting practice. For a review of research important to applied work with teams, including both diagnosis and intervention, see Gullette (2015). Another specific type of group that a consulting psychologist may work with is an *action learning group*, whose purpose is the accomplishment of a project in the context of an explicit goal for members to learn and develop (Marquardt, Leonard, Freedman, and Hill, 2009).

Consulting psychologists who provide this service learn to understand their own predispositions toward authority and group dynamics, gain working knowledge of theories of group and intergroup dynamics, become familiar with the empirical research on groups in organizations and the multicultural literature, and learn methods for diagnosing problems of the team, designing interventions to address those problems, and preparing the leader, team members and/or others who may be involved in implementing interventions. The organizational consulting psychologist gains competency in identifying both optimal, positive models of functioning and those that are dysfunctional and/or pathology driven.

C. Work Groups and Intergroup Problem Solving

The organizational consulting psychologist learns intervention skills that assist two or more identified groups with improving their relationship in order to carry out *interdependent work assignments* more effectively. Activities may be developed for operational groups (such as engineering and production or production and sales) that have different functions along a flow of work, between different hierarchical-level groups (such as between field units and head-quarters), between entities attempting to merge, between labor and management groups, or between culturally diverse members of the work group. See, for example, Ernst and Chrobot-Mason (2011) for a discussion of "boundary spanning" informed by social psychology theory and applied practice.

Recommended competencies for organizational consulting psychologists who provide these services include learning to understand their own predispositions toward authority and intergroup relations (especially those that involve ethnocentric forms of conflict) in order to determine whether they can proceed to work alone or should invite one or more consultants

representing different perspectives to assist in delivering the service. In situations requiring a team of consultants, which may stem from self-insight, or simply the size of a project and the number of participating client-individuals, organizational consulting psychologists who work together are prepared to manage their relations with one another and in relation to the client in ways that enhance rather than diminish the quality of service.

D. Identity Groups and Intergroup Relations

Identity-group membership includes variables such as race, ethnicity, nationality, family, age, generation, gender, gender identity and expression, sexual orientation, disability, religion, educational status, and social stigma. The OCP goal of interventions is to eliminate group-level forces that result in members of some identity groups within organizations being treated unfairly by members of other identity groups on such matters as work assignments, salaries, and promotional opportunities. Interventions to alter unfairness among identity groups include educational activities that expand the knowledge and self-awareness of individuals and designing and recommending procedures that adjust distribution of authority and power among identity groups within organizations.

Competencies recommended for organizational consulting psychologists who provide these services include methods for assessing their own identities in relation to the client organizations where they provide services and learning strategies for working cooperatively with members of diverse identity groups to effect change (e.g., Whites with Blacks, women with men). They become knowledgeable about theory and research concerning the identity groups and cultures with which they interact, as well as of the intersectionality of multiple identity categories (APA, 2012).

They adapt interventions appropriate to the conditions found in organizations and the diagnosed problems facing work groups. Additionally, OCPs are aware of which groups are particularly susceptible to workplace bias in the absence of federal protections (e.g., groups that are diverse with respect to sexual orientation and gender identity) and develop skills not only to effectively work with those individuals and groups but to advocate for systemic change.

E. Group-Level Interventions

Consulting psychologists learn to apply what they have learned about groups to address specific issues and problems within the organizational/systems context. Relevant competency areas include, for example, managing group conflict, enhancing group functioning so that it is better aligned with organizational objectives, assisting groups in creating conditions of social support to ameliorate the effects of organizational and occupational stress, and helping organizations design work groups that effectively bridge individual and organizational needs.

III. Organization/Systems-Level Consulting Psychology Competencies

This level focuses either on interventions in which an entire organization is the targeted intervention level or in which the organization itself is integral in effecting changes to segments of the larger organization or system. In order for the organizational consulting psychologist to play a useful role in conducting organization-level interventions, recommended competencies include developing, administering, and interpreting surveys (such as organizational culture assessments and employee opinion/satisfaction polls); designing and participating in the leadership of organizational strategic planning and change management programs; conducting organization effectiveness interventions; delivering management development programs; and conducting research and evaluation activities. Competencies recommended in conjunction with this domain of intervention include those addressing organization theory and design;

organizational assessment competencies and organizational diagnosis; organizational change; and the consultation process.

A. Organization Theory and Design

Prior to practicing organization-level assessments and interventions, consulting psychologists learn about organizations, understand structures and systems for organizing work, and develop a solid theoretical foundation from which to make recommendations. Training in organizational theory, behavior, and design are the foundations from which interventions are designed. Capelle (2014) defines organization design as "the relationship of an organization to its environment and the interrelationships of its parts. This includes the alignment of positions, accountabilities and authorities, people, deliverables, and tasks." (p. 1) Thus organization design goes beyond "boxes and lines" on the organization chart and can be a powerful tool in alleviating problems and enhancing effectiveness in an organization (e.g., by removing "bottlenecks" or aligning incentives to desired goals).

Relevant topic areas to learn about include organizational theory, both modern and historical (e.g., scientific management, the human relations movement, open systems theory, and organizational diagnostic theory); organizational structure and design (e.g., legal structures, centralization/decentralization, matrix configurations); organizational ecology (e.g., the effects of size, growth, market, and life cycle); organizational effectiveness (business planning, financial indicators, industry benchmarking); globalization (economic, social, and legal challenges, multilingual and multicultural issues); organizational diagnosis; and organizational culture and ethics.

B. Organizational Assessment and Diagnosis

The goal of organizational diagnosis is to develop an understanding of a system (purpose, where things are going well, where things are not going well) by its members by using the methods of applied behavioral science. The phases of organizational diagnosis include entry, data collection, analysis, and feedback. The approach to assessing an organization is informed by theoretical perspective as well as by the presenting issue (as in research, the question one is trying to answer). This leads to a wide range of specific tools and methods, which will continue to evolve. Consulting psychologists learn and apply theoretical frameworks, as noted previously, and keep up with the literature (e.g., Alderfer, 2011) and advances in assessment methods, such as the emergence of organizational network analysis as a way to visualize the informal networks of power, influence, and communication that lie alongside the formal structures mapped out in organization charts. Fast-moving innovations in the use of technology with organizational research and practice (e.g., Westaby, 2012) present opportunities but also underscore the challenges of keeping pace from an ethical and competence perspective.

Consulting psychologists who provide this service learn to develop a sound and feasible contract for doing the diagnosis and then how to carry out structured and unstructured observation, individual and group interviews, organic and standard questionnaires, and archival searches. Having obtained data from multiple sources and in various forms, they learn how to conduct appropriate qualitative and statistical analyses and to integrate the results.

The organizational consulting psychologist learns to present the findings from the organizational diagnosis, both orally in appropriately designed meetings and in writing. A full blown organizational diagnosis potentially addresses all of the foregoing areas of group-level

inquiry (i.e., roles, teams, workflow, and identity groups) as well as organizational/systemic constructs. The requirements for proper preparation in each of those areas apply to organizational diagnosis as well. Conversely, methods used in organizational diagnosis are also, often, applied at the group and individual levels of interventions.

Developing expertise in organizational surveying and other assessment methodologies involves learning how to translate theory into applied practice. Skills to be mastered include systematic data collection efforts including survey and test design implementation and evaluation. In learning to design surveys and other measures, attention is paid to item design and evaluation. Practice in developing such measures, pilot testing them on representative samples, and evaluating these pilots can be covered through a combination of class projects and practicums. Expertise in general survey and test design topics might also be addressed, including the effects of factors such as length, methods of distribution (anonymity, paper-and-pencil vs. interactive voice response), and management (database theory and design, data security). In implementation of such assessment projects, skill in client definition (who is the key client, who comprises the client constituency to be assessed) and learning to develop and negotiate clear, realistic contracts remain critical.

Consulting psychologists also learn project skills, including managing a project from initial conceptualization to implementation and outcomes evaluation. As part of this process, consulting psychologists learn to consider such issues as incorporation of key stakeholders, development and execution of communication plans, formative and summative evaluations, and continuous quality and operational improvement of the process itself. Additionally, it is recommended that consideration and costing of alternative organizational assessment procedures

be covered, helping students learn how to compare and contrast the costs and benefits of alternative strategies.

Evaluating diagnostic techniques includes learning to use statistics to examine reliability (test–retest and internal consistency) and validity (content, construct, criterion-related) of assessment devices. It is recommended that classical test methods, and item-based methods such as item response theory, be covered in conjunction with this work. It is advisable for the organizational consulting psychologist to learn a variety of diagnostic assessment methodologies, including those associated with the use of the psychologist him- or herself as an instrument for accurate organizational diagnosis.

C. Organizational Development and Change

The organizational change domain focuses on working with organizations undergoing changes that are atypical for that organization in amount, quality, or both, whereas organizational development is about intentional change with a goal of enhancing the effectiveness of the people, and, thus the organization. A thorough understanding of client preferences concerning perceived change needs, organization design, and theories of organizational change (including drivers of both organizational inertia and organizational resilience) and an understanding of the characteristic psychological processes change evokes and of how to manage those reactions provide the foundation for effective intervention.

Organizational change approaches and theories of change necessarily incorporate knowledge and theories in the individual, group, and organizational domains, developmental theories, the organization's history, and change management theories and practice. Knowledge of work- place stressors and stress management techniques becomes particularly useful during change interventions. Positive approaches (e.g., those based on positive psychology

interventions, such as appreciative inquiry) are as important as those oriented to dysfunction. Organizational development interventions follow from organizational assessment or diagnosis and are designed in support of improving dysfunction or enhancing effectiveness. Halfhill et al. (2002) provide an instructive summary and examples of *Interventions that work (and some that don't*) in the organizational development and change domain.

Consultation Process Management

The OCP competencies listing will be an evolving set of recommendations that will likely continue to include knowledge and skill relevant for each consultation phase: contact and entry; contract formulation; problem identification and diagnostic analysis; goal setting and planning; action taking (intervention); and contract completion, continuity, and support. These service delivery and project management competencies are integral in brief as well as extended consultations. Additional education and training is important for those consulting psychologists who operate psychological consulting firms or departments within firms offering broader-range consulting services to businesses, industries, agencies, and organizations.

First and Last: Ethics

Ethical guidelines for consulting psychologists in general and organizational consulting psychologists in particular were introduced into the *Ethical Principles of Psychologists and Code of Conduct* in 2002 (APA, 2002). Further clarification came in 2010 when APA amended the Code's Introduction and Applicability section, as well as Ethical Standards 1.02 and 1.03 (APA, 2010). As noted previously, however, the Code's guidance is best applied with well-developed judgment and ethical decision-making. In OCP, a common challenge, for example, is clarifying how to proceed when personal values clash with perceived values of the individual or organizational client. This may come up initially in deciding whether to accept employment or

contract work with an organization. Or the question of what to do may arise in the course of providing service to a client, if one discovers a profound difference in values. Standard 1.03 deals with individual-organizational conflict and should be top of mind in such cases. It is suggested that, in addition to familiarity with the APA Code of Ethics, CPs/OCPs be familiar with models and processes for ethical decision-making (as referenced previously), engage in dialogue with a mentor consultant and/or regularly attend professional association gatherings to keep ethical competencies fresh and active.

CPs/OCPs also keep in mind that recommendations for ethical competencies associated with the practice of OCP are associated with eleven questions that permeate every consultation, and the answers infuse the services provided:

- Who is my primary client, and who encompass all stakeholder clients? The organization? The manager? The individual employee?
- What is my specific role? Am I and are other stakeholders clear on what my role includes and what it does not include?
- What are the parameters of confidentiality in the client's expectation? Are they acceptable to me?
- Are the goals of the organization and consulting contract congruent with my personal and professional values and ethics?
- What rights, power, and freedom does each individual participant in the consultation process have? Are these acceptable to me?
- How do I balance the task dimension and the human dimension of my work with this organization?

- What control do I have over the use and dissemination of information I gather as a consultant?
- What are the parameters of my accountability? Are they acceptable to me?
- Do I have the skills to be an effective and efficient consultant to this organization and for this concern?
- How do I integrate high professional and scientific standards with the need to operate cost effectively and profitably?
- How do I maintain objectivity and independence and avoid being used improperly by one faction of the organization?

Those engaged in organizational consulting psychology will face difficult and unexpected decisions, for example when they encounter behaviors and philosophies within an organization that are repugnant to them personally. Former SCP President Kenneth Bradt suggested that while all professions have codes of ethics and while heavy legal requirements speak to some issues, individual decisions often come down to very personal value judgments of right and wrong. Those in the behavioral sciences and especially the helping professions may confront them more often, perhaps in part because they are attuned to the broader social implications of their work.

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Section E: Appendices

E.1. 2005 SCP Guidelines for Education and Training at the Doctoral and Postdoctoral Level in Consulting Psychology (CP)/ Organizational Consulting Psychology (OCP) – *see attached*

E.2. Organizational Consulting Psychology Bibliography (includes but expands upon References in Section D)

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E.3. Ways to Learn About and Develop Skills in Consulting Psychology (See also the Society for Industrial and Organizational Psychology's (2016) *Guidelines for Education and Training in Industrial/Organizational Psychology:* siop.org/ETguidelines.aspx)

1. **Informational Interviewing/Exchanges:** A meeting in which a person seeks advice and information from an expert within their field or job of interest. These interviews are typically open-ended and driven by the person seeking the information, based on their personally developed questions, and expert input/guidance from the one interviewed. This method can be conducted via face-to-face contact or virtual mediums. Some examples include: Video chatting, phone chatting, and email. While General and Level-specific competency development does not occur this way, it can provide direction on where to go and how and what to learn.
2. **Independent Reading/Study:** Learning in which the person assumes basic responsibility for and commitment to the accomplishment of General and Level-specific competency development. It is a self-initiated effort is of central concern and for which such effort can successfully result in the development of competencies at least at the knowledge level. Skills are typically not developed this way, at least not to any level of proficiency. Examples would include individual efforts that target predetermined benchmarks through academic reading, proposals or technical reports, and designing and conducting research. This is a good method to stay current on profession and skill specific needs through

independent reading of Organizational Consulting Psychology, Industrial/Organizational Psychology and related professional publications.

3. **Formal Course Work:** Classroom instruction by a teacher on the Principles, General and Level-specific Competencies. Courses can be part of a degree program, stand-alone university course or official continuing education program. Courses can be taken in person, real time, or online – either real-time or ascychronously (at one's own time discretion relative to others in the course). Teaching methods can include lectures, case studies, projects, discussion, presentations, and other approaches. Learners can have the opportunity to work together with peers, taking advantage of the benefits of cooperative peer learning.
4. **Modeling/Observation/Job Shadowing:** Non-classroom implicit instruction that is obtained as a result of working with and paying attention to professionally qualified personnel in the daily conduct of their jobs or projects. This method implies that learning of important skills might well be achieved without explicit instructional intent on the part of the model being observed. Conversely, modeling may also be done in a purposeful and self-conscious manner. Modeling/ observation, because of its general nature, cuts across several of the above training methods. Observations can occur in person or by remote web camera or review of work done by professional others that is video recorded.
5. **On-the-Job-Training:** Field-based experience providing "hands-on" task learning under the direct guidance of a professionally qualified task expert. Such training is usually done simultaneously with one's job. Participation, unlike traineeships, involves compensation. Learners develop General and Level-specific Competencies "in vivo" – live in the context in which the tasks occur. From a social-learning perspective, mastery

of skills and knowledge can be best acquired this way, assuming a base level to perform the tasks.

6. **Project Work:** Individual or group-based work, either classroom or non-classroom based, in which the learner is actively engaged in assignments related to the field. These projects can vary in length and grant the learner real-world professional experience. Projects are designed to portray the knowledge, skills, and abilities that are being learned by the person through educational and other settings. Traditionally, these projects are supervised by teaching faculty, qualified mentors, and learning-minded bosses/supervisors at work. Professional associations often engage members in project work both as a method of getting work done and as a developmental opportunity for the volunteering or compensated member.
7. **Traineeships:** Organized and systematic program of learning provided by credentialed professionals in real world work settings. Supervised fieldwork as a trainee/intern should be a required and integral part of graduate training in Consulting Psychology in order to prepare them for practice in the field (Blanton, 2014). For example, Shoenfelt (2003) provides a checklist to facilitate successful experiences in applied projects that are incorporated into I-O psychology graduate training. Traineeships require meaningful professional supervision of the training experience (Byrne et al., 2014). Examples would include practicum and internship experiences, field-work teaching/training, thesis/dissertation research, etc. Participation is not motivated primarily by compensation. The training program should be responsive to the Graduate Program expectations of knowledge and skills taught to the student trainee. In order to assure a quality experience for students, faculty and administration should have clear criteria for vetting their supervision sites and for the qualifications of the direct supervision. A number of highly

effective programs have methods of linking the academic and fieldwork in a way that enriches both types of learning. Providing opportunities for collaborative work between program faculty and students and/or among students of various experience levels is seen as an effective practice.

8. **Supervision/Mentoring**: Individualized course of learning, guidance and support between and individual (sometimes a group) and a credentialed professional or team of professionals. This is an important element of a well-run traineeship. It is often done as a stand-alone method by students, early career and even experienced Consulting/Organizational psychologists – to achieve improvements in the General and Level-specific Competencies and to evolve personally and professionally in more holistic ways. Supervisors and mentors serve not only as skills coaches but also as career guides, professional references, and sometimes counselors to those they are working with.
9. **Licensing:** This is based on the State in which one works in the United States – where one officially "offices," and also takes into account where one delivers significant amounts of work. The licensing bodies in the United States are the state boards of psychology, which should be contacted for details regarding their specific licensing requirements. Many countries around the world also have their own licensing processes. This is a distinct way to demonstrate competency to the public, hold oneself accountable to that and commit to a life-long path of Continuing Education. There are limitations of current State-based and Country-based licensing. Significant efforts are underway toward state compacts, portability and interstate/multistate agreements in psychology and many other professions, to facilitate work across state lines. Ultimately, Consulting Psychology is in need of a licensing/credentialing tool that reflects the global nature of where Consulting

Psychologists base their practices and where they deliver services.

Pace University Academic Integrity Code

I. Philosophy of Academic Integrity and the Academic Integrity Code

The Academic Integrity Code supports Pace University's commitment to academic honesty and creates a culture at the University that emphasizes high standards of academic integrity, ethical behavior, and responsible conduct.[1] The purpose of the Code is to educate students about what constitutes academic misconduct, to deter cheating and plagiarism, and to create a fair process and a set of procedures to handle cases of academic misconduct including documentation and application of sanctions. Academic integrity is defined as honesty and ethical conduct in learning and the educational process. The educational environment is enhanced when students believe that their academic competence is being judged fairly and that they will not be at a disadvantage because of the dishonesty of another. All members of the University community are expected to uphold the highest standards of academic integrity.

The Academic Integrity Code applies to all undergraduate and graduate students at all campuses of Pace University (except the Law School). It supersedes the academic integrity policies of the different schools within Pace University. All students registered for classes in the University are subject to the terms of this Code, expected to be familiar with the Code, and to abide by the policies, procedures, and sanctions of this Code.

II. Academic Misconduct and Violations of this Code

Violations of the Academic Integrity Code are considered to be acts of academic misconduct and are serious offences to the Pace academic community. Academic misconduct may also violate the law and be the basis for criminal prosecution outside the University. A fundamental assumption underlying this Code is that faculty possess full authority and responsibility for the conduct of their classes of instruction in accordance with University policy. Faculty, students and all members of the University community who in good faith have reason to believe that a violation of this Code has occurred, have a moral obligation to report this information to a course instructor, proctor, or the Chair of the Academic Conduct Committee. All forms of academic dishonesty and misconduct violate this Code. It is not possible to list definitively every type of academic misconduct, hence, the following violations are set forth as examples of proscribed conduct and are not to be considered complete or exclusive:

A. Cheating. Intentionally using or attempting to use unauthorized materials, information, or study aids in any academic exercise. The term academic exercise includes all forms of work submitted for credit or hours.

B. Fabrication. Intentional and unauthorized falsification or invention of any information or citation in an academic exercise.

C. Facilitating academic dishonesty. Intentionally or knowingly helping or attempting to help another to violate any provision of this Code.

D. Plagiarism. The adoption or reproduction of ideas or words or statements of another person as one's own without acknowledgment. This would include, for example, copying the answers of another person or copying or substantially restating the published, unpublished, or on-line work of another person without appropriate attribution, or collaborating with another person on an academic endeavor without the prior knowledge of the instructor or without proper acknowledgment of the other person's contribution.

E. Misrepresentation. Any act or attempted act of knowingly presenting false information or data related to academic work as genuine information or data.

F. Unauthorized possession or use of academic materials. Wrongfully obtaining, possessing, using, or distributing to others, examination or other materials that have not been officially released by the instructor.

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[1] This Academic Integrity Code is modeled in part on the Code of the College of Arts and Sciences at Boston University, University of Maryland, College Park, and other academic institutions. It was adopted by Pace University on September 1, 2017.

G. Unauthorized communication. Any form of communication (except with the instructor or proctor) during an examination, or knowingly informing another of the content of an examination not officially released by the instructor.
H. Forgery or alteration. Placing any unauthorized signature on any school-related document or making any unauthorized change to an examination or other work product, grade, grade list, official University record or document (including but not limited to transcripts, letters of recommendation, degree certificates, or other school-related documents).
I. Theft or destruction of academic materials. Removing or destroying examinations, examination books or similar materials, or any work product before or after submission, including wrongfully altering evidence of possible poor performance.
J. Duplicative work. Submitting the same or substantially the same work product in response to a subsequent assignment. It is expected that students produce new coursework for each assignment; material produced for credit prior to a course may not be submitted for credit to another instructor without his or her prior knowledge and consent, nor may a student submit the same or substantially the same work product simultaneously to two different course instructors for credit.
K. Acts that are harmful or unfair to other students. Unauthorized removing, damaging, or altering materials from libraries, classrooms, or offices; altering or destroying another student's work or records; inappropriately permitting another student to use one's knowledge, information, or work product; or in any way interfering with the work of another so as to impede the other's academic performance or the fair judgment thereof.
L. Making or offering any false statements to the Academic Conduct Committee regarding any Academic Conduct Committee matter.
M. Other violations.[2] Violation of any other University rule, regulation, policy or sanction, relating to matters of academic integrity.

III. Procedures

It is the goal of this Code to establish procedures that are fair for both students and faculty, and that will be followed and applied in good faith by the University.

Course instructors and other school officials, who have knowledge of an act or acts which they deem constitute academic misconduct, hereafter shall follow the procedures set forth in this Code, to include the obligation to document and report such misconduct to the Chair of the Academic Conduct Committee. The Pace University community, its students, faculty, staff, and administration, encourages all course instructors to make full use of this Code and to use the procedures outlined below to help promote academic honesty and ethical conduct within the University. An examination proctor, if aware of an act or acts of academic misconduct, is obligated to report this information to the course instructor.

If a student or another member of the Pace community is aware of an act or acts of academic misconduct, he/she shall contact the course instructor and/or the Chair of the Academic Conduct Committee who shall thereafter consult with the course instructor.

In furtherance of the objectives of fair and expeditious resolution of matters of possible violations of this Code, two forms of resolution are available: Direct Resolution and Resolution by the Academic Conduct Committee. In cases involving issues of academic integrity, the following procedures shall be applied:

A. Direct Resolution

1. If:
   (a) the person initiating the charges (hereafter referred to as the complainant) is a

[2] If the matter concerns student academic integrity, it shall be reported by the instructor or complainant to the Chair of the Academic Conduct Committee. See the procedures outlined in Section III. If the matter concerns behavioral conduct, the matter shall be adjudicated under appropriate policies and procedures set forth in the Student Handbook. If the matter introduces multiple concerns (for example, academic integrity, behavioral conduct, discrimination, the Title IX Coordinator/Affirmative Action Officer and/or any other appropriate University Official, the Chair of the Academic Conduct Committee, and the Dean for Students, shall coordinate the procedures.

course instructor, and

(b) the alleged academic misconduct relates directly to a course taught or an examination monitored by the instructor or a proctor, and

(c) neither the student's official academic record or the file of the Academic Conduct Committee contains evidence of any instances of prior academic misconduct, then the complainant, in his or her sole discretion, shall have the option of attempting Direct Resolution of the matter. If the instructor as complainant has a legitimate educational interest in a student's educational records, he or she may consult either the student's official academic record or the file of the Academic Conduct Committee to determine whether there have been any previous violations of the Code by the student.[3] (If the complainant determines that the student has previously violated the Code, he or she must notify the Chair of the Academic Conduct Committee as described in Section III.B.)

2. As soon as practicable, the complainant shall inform the student suspected of academic misconduct of that person's observations, conclusions, and the proposed sanctions to be imposed.
3. The student will be given a reasonable time, but not less than twenty-four hours, to consider the accusations and proposed sanctions and can consult with anyone he or she wishes about these matters.
4. If the student accepts the proposed sanction, the matter may be resolved between the student and the complainant. All violations of the Code shall be documented and reported to the Chair of the Academic Conduct Committee. The complainant shall submit to the student the standard form entitled Documentation of Direct Resolution. The form shall be completed by the complainant and then signed by both parties. The complainant shall submit the form to the Chair of the Academic Conduct Committee, who will send/place the form in the Committee's file located in the Office of Provost on each campus. The Chair of the Academic Conduct Committee is also encouraged to send a copy to the student's academic advisor.
5. If, after discussion between the complainant and the student, the student does not contest the charges but is, for any reason, unavailable to sign the Documentation of Direct Resolution form, the complainant shall notify the Chair of the Academic Conduct Committee (as described in Section III.B.2).
6. If a student feels that he or she is unsatisfied with the outcome of the Direct Resolution process, or that he or she has been unjustly accused and/or penalized by an instructor for alleged academic misconduct, the student may follow the Student Grievance Procedure outlined in the Student Handbook. If the matter concerns a grade, the student may follow the Grade Appeal Procedure outlined in the University Catalog. If the Dean for Students, Assistant Dean for Community Standards and Compliance, or the Dean of the College in which the course was taught, determines that the matter is primarily an issue of student academic integrity, the Dean or Assistant Dean for Community Standards and Compliance may refer the matter to the Chair of the Academic Conduct Committee for consideration.
7. If the alleged violation of the Code takes place during the months of June, July, or August, the complainant may resolve the matter through Direct Resolution or may contact the Committee Chair by telephone or e-mail. If the matter can not be resolved through Direct Resolution, either through the complainant or the Committee Chair (as also described in Section III.B.3), the matter shall be postponed until the fall semester, when a Committee hearing may be convened, if necessary.

B. Resolution by the Academic Conduct Committee

If the complainant is a school official other than a course instructor, or the complainant elects not to attempt Direct Resolution, or the student and the complainant can not within a reasonable period of time reach an accord; or the matter is not subject to Direct Resolution by the

[3] The University and this Code adhere to the Family Educational Rights and Privacy Act of 1974 as Amended.

complainant (for example, if the student's official academic record or the file of the Academic Conduct Committee contains a record of a prior instance of academic misconduct), the following procedures shall apply.

1. The complainant shall notify the Chair of the Academic Conduct Committee in writing:
   (a) describing the alleged act of academic misconduct (including the date, time, witnesses if any, and other details);
   (b) enclosing and/or describing relevant evidence, if any;
   (c) describing any discussions between the complainant and the student;
   (d) requesting that the matter be addressed by the Academic Conduct Committee (hereafter referred to as the Committee).

Upon receipt of written notification from the complainant, the Committee Chair may, in his or her sole discretion, attempt to resolve the matter between the complainant and the student, within a reasonable period of time, before convening the Committee. The Committee Chair may only impose the sanctions described in Section V of this Code. If the Committee Chair successfully resolves the matter, the Documentation of Direct Resolution form shall be completed and signed by the complainant, the student, and the Committee Chair. If the matter is not so resolved by the intervention of the Committee Chair, he or she shall cause the Academic Conduct Committee to be convened.

C. The Academic Conduct Committee

1. Two Academic Conduct Committees shall report to the Provost. One Committee shall handle cases that occur in Westchester and the other shall handle cases that occur in New York City. Membership of each Committee shall consist of eleven persons including the Chair: six faculty members and five students. The six faculty members on each Committee will serve for terms of two years, which will be staggered so that each spring three faculty members shall be elected at large by each Location Council of the Joint Faculty Council to serve on the Committee. The students shall serve on the Committee for a term of one year. Each spring, five students shall be elected at large through the Student Government Associations on each campus, New York City and Westchester, to serve for the following academic year. Service on the Committee shall begin on the first day of the fall semester and continue through May of the spring semester. Each year, at the first meeting of the Committee, the Committee members shall elect a Chair who must be a faculty member. A faculty member may serve as Chair for more than one year if he or she is reelected by the Committee. The Committee Chair, in addition to serving on the Committee from September through May, shall make himself or herself accessible by telephone or e-mail during the summer months.
2. Members of the Committee shall notify the Committee Chair, and shall be excused, if they are unable to attend a hearing or if any particular matter involves an actual or potential conflict of interest between the member of the Committee and the complainant or the student.
3. The Committee Chair may, but shall not be required to, appoint pro tempore members to replace members of the Committee who have been excused because of their inability to attend or to participate.
4. The Committee Chair shall:
   (a) arrange for the Committee to be convened as soon as practicable, and
   (b) submit to the Office of the Provost the following information: the names of the complainant, the student, and the date, time, and location of the hearing.
5. The Committee Chair shall inform the accused student (by letter, sent by certified mail, return receipt requested, at least ten days prior to the hearing) of the following:
   (a) The alleged violation of the Code;
   (b) That the student is requested to attend the hearing and the date, time and location thereof;
   (c) That the student may request the Committee Chair to reschedule the hearing for a reason deemed justifiable in the sole discretion of the Committee Chair;

(d) That the student shall have the right to have access to and to obtain copies of any documents intended to be used as evidence at the hearing as well as the names of any witnesses who may testify at the hearing;
(e) That the student shall be allowed to address the Committee and to produce witnesses on his or her behalf;
(f) That the student shall have the right to question the complainant and the right to question any witnesses;
(g) That at the hearing, the student shall be permitted to be accompanied by one person of his or her choosing, for example, a faculty advisor or an attorney, whose participation is limited to advising the student. The University neither provides nor pays for such advisors or attorneys.
(h) University Counsel may attend the hearing and advise the Committee Chair and members of the Committee.

6. At least ten days prior to the hearing, the Committee Chair shall send a copy of the letter described in Section III.C.5 to the complainant.
7. The Committee Chair may submit a written request to the student asking him or her to provide any copies of relevant documents and a list of any potential witnesses that the student may present in his or her defense at the hearing. The student may be requested to submit such material to the Committee Chair at least three business days before the hearing.

D. The Hearing

1. A quorum shall consist of seven members of the Committee, at least four of whom must be faculty members.
2. The Chair shall preside at the hearing, shall determine the scope of the hearings, and shall control all procedural aspects of the hearing in order to maintain fairness and decorum.
3. A majority vote of the Committee members present shall be required to render a judgment and impose a sanction. Votes of the Committee shall be by secret ballot and the Chair shall vote only to break a tie.
4. The hearing may proceed in the absence of the accused student if the Chair is satisfied that proper notice of the hearing was given to the student and, in the sole discretion of the Chair, there is no legitimate reason for the student's absence.
5. The order of the hearing shall be as follows:
   (a) Statement of charges by the Chair;
   (b) Presentation of evidence and examination of witnesses by the Chair. At the discretion of the Chair, members of the Committee may directly question the complainant, the student (if he or she elects to testify), and witnesses;
   (c) Presentation of evidence and examination of witnesses by the student (may be waived by the student);
   (d) Statement by the accused student (may be waived by the student);
   (e) Deliberation shall take place only among Committee members;
   (f) As soon as possible but not more than fourteen days after the hearing, the Committee shall determine whether the charges have been sustained and, if so, the appropriate sanction.
6. The hearings (but not the deliberations) of the Committee shall be recorded and preserved in the Office of the Provost. A copy of the recording may be obtained by the student from the Office of the Provost.
7. The Committee shall not be bound by judicial rules of evidence.
8. The burden of proof is on the University to establish that the student has violated the Code; the burden is satisfied based on a preponderance of the evidence.
9. The burden of proof is on the student to establish that any mitigating circumstances may be partly responsible for his or her actions or may warrant leniency on the part of the Committee; the burden is satisfied based on a preponderance of the evidence.
10. The complainant shall make himself or herself available for appearance before the Committee.

11. The accused student, the complainant, and all witnesses appearing at the hearing, will be requested to make an oral affirmation that all testimony given at the hearing is truthful. This attestation will include an acknowledgment that any false statements made during the hearing may result in a charge of academic misconduct and a possible sanction for presenting false information to the Committee. If a witness testifies but is unwilling to make the oral affirmation, the Committee may draw adverse inferences from his or her refusal to do so. Witnesses to the alleged academic misconduct may be requested to provide a written report and, if requested, to make themselves available for appearance before the Committee.
12. The hearing shall be closed to the public. At the discretion of the Chair, witnesses may be excluded from attending parts of the hearing and any examination of other witnesses.
13. The hearing may be recessed and reconvened by the Chair if, in his or her sole discretion:
    (a) additional evidence or witnesses are necessary or appropriate, or
    (b) a fair hearing can not be held because of lack of decorum, disturbances, illness, or other causes.
14. A past incident of academic misconduct is not evidence of guilt on a pending charge, and previous violations may not be considered by the Committee to determine a possible subsequent violation of this Code. Such past incidents may only be considered to determine an appropriate sanction.
15. If, after a hearing, it is determined that a student did not violate this Code, all records of the Committee's proceedings shall be kept in a separate and closed file in the Office of the Provost. Only the Committee Chair, the Provost, and other authorized persons, shall have access to these closed files.
16. The University shall take all reasonable steps to insure the confidentiality of all proceedings and the records produced therefrom. However, should any matter developed during the course of the proceedings become public knowledge, the University reserves the right to issue appropriate statements.

E. The Report

1. A report of the Committee including statements of the charges, evidence, findings, and sanctions, shall be written by the Committee Chair and sent to the Provost as soon as practicable after the hearing.
2. The Office of the Provost shall notify the student (by letter sent by certified mail, return receipt requested) of the nature of the report, the sanction or sanctions, and the right of the student to, and the procedure for, an appeal. If the sanction is a File Notation (see Section V.A.4), the letter shall also notify the student of the procedure for removing the File Notation from the student's file.
3. The Office of the Provost shall send a copy of the letter described immediately above to the Committee Chair, the complainant, and the Dean of the school in which the student is enrolled.
4. The Office of the Provost shall retain the authority to instruct other offices of the University as required to administer the outcome of the hearing and any sanctions.

F. Self-Referral

Students who commit acts of academic misconduct may demonstrate their renewed commitment to academic integrity by reporting themselves in writing to the Chair of the Academic Conduct Committee. The student's admission and self-referral may be considered a mitigating circumstance for purposes of determining a sanction. If it is determined by the Committee Chair or the Academic Conduct Committee as a whole, through investigation, through direct resolution, or through resolution by the Academic Conduct Committee, that a suspicion of academic misconduct existed at the time the student admitted the act, then the matter will be resolved in accordance with the normal procedures specified in this Code for resolving allegations of academic misconduct.

IV. Appeal to the Provost

A. Time for Appeal. A student may appeal the findings and/or the sanction(s) within fourteen days of the sending of the letter (described in Section III.E.2) to the student by the Office of the Provost.

B. Nature of Appeal. An appeal to the Provost shall be in writing, setting forth the basis of the appeal and whether the student is appealing the findings, the sanction(s), or both. The Academic Conduct Committee is not an advisory Committee to the Provost. The judgment of the Committee is conclusive and definitive. The judgment of the Committee may be modified by the Provost only for causes related to substantial prejudicial error in the Committee procedure or abuse of discretion on the part of the Committee.

C. Scope of Review. The Provost shall review the Committee's report and may review the recordings and evidence presented at the hearing. If new evidence emerges at this time, the Provost may send the matter back to the Committee for reconsideration.

D. Decision of the Provost. The Provost shall render a decision by written notice to the student within a reasonable time but not more than thirty days. Copies of the decision shall be sent to the Committee Chair, the complainant, and to the Dean of the school in which the student is enrolled. If Provost modifies the Committee's judgment, the Provost shall communicate his or her reasons for doing so, in writing, to the Committee Chair with his or her decision.

V. Sanctions

If it is determined that a student violated this Code, the following sanctions may be imposed by the Chair of the Academic Conduct Committee, as appropriate, depending upon the circumstances and the gravity of the misconduct, including but not limited to any one or combination of the following:

A. File Notation

1. For a very minor or technical violation.
2. The violation shall be noted in the student's official academic record and the Committee's file but shall not be recorded on the student's permanent transcript.
3. The violation shall not be disclosed when transcripts or other records are requested, except to a Pace school official who has a legitimate educational interest in the student's education records. This would include an instructor who believes the student has violated the Code and who wishes to consult the student's official academic record to determine if the student has previously violated the Code.
4. The notice of violation shall be removed from the student's official academic record:
   (a) if no further violations of this Code are committed by the student for a period of two years after the end of the semester in which the violation occurred, and
   (b) thereafter, a letter is sent by the student to the Provost stating: the nature and date of the violation, that two years have passed since the end of the semester in which the violation occurred, that the student has not during that period violated the Code, and requesting that the notice of the violation be removed from the student's official academic record.
5. A File Notation shall place no restrictions on the student's participation in academic or non-academic activities.

B. Reprimand

1. For violations of a minor nature or mitigated by extenuating circumstances.
2. A copy of the Reprimand will remain in the student's official academic record and the Committee's file but shall not be recorded on the student's permanent transcript.

3. A Reprimand shall not be disclosed when transcripts or other records are requested, except to a Pace school official who has a legitimate educational interest in the student's education records. This would include an instructor who believes the student has violated the Code and who wishes to consult the student's official academic record to determine if the student has previously violated the Code.
4. A Reprimand shall place no restriction on the student's participation in academic or non-academic activities.

C. Academic Disciplinary Probation

1. For violations deemed serious enough to warrant modification or termination of the student's right and privileges.
2. Probation shall be imposed for a specified period of time.
3. Probation shall be noted in the student's official academic record, the Committee's file, and on the student's permanent transcript.
4. Probation shall bar the student from participation in any recognized extracurricular, co-curricular, or intercollegiate activities during the probation period.

D. Suspension

1. For violations deemed sufficiently serious to warrant separation of the student from the University community for a specified time, but not serious enough to warrant expulsion.
2. Suspension shall be recorded in the student's official academic record, the Committee's file, and on the student's permanent transcript.
3. Suspension shall bar the student from participation in any academic or non-academic activities.

E. Expulsion

1. For extremely serious academic misconduct.
2. Expulsion is the permanent separation of the student from the University. Expulsion shall be recorded in the student's official academic record, the Committee's file, and on the student's permanent transcript.

F. Additional Sanctions

In addition to the foregoing sanctions, other sanctions may be imposed including but not limited to the following: financial aid from the University may be withdrawn, a previously granted degree may be revoked, and the Committee Chair may submit a written recommendation to a course instructor regarding a student's grade. The course instructor has the sole authority to determine a student's grade subject to the University's Grade Appeal Procedure. The Committee Chair may only recommend to an instructor that a student's grade be changed, for example, on an assignment, examination, or for the final grade in a course.

VI. Time Periods

Any period of time set forth herein, except time periods for sanctions, may be extended by the Committee Chair for just cause or because the date for performance falls on a day upon which the University does not conduct regular classes.

VII. Amendments and Modifications

This Academic Integrity Code may be amended or modified according to the same procedure required for making a change in the Faculty Handbook. In addition to this process, the student body shall be informed through its Student Government Association representatives of proposed amendments or modifications to the Code and be given a reasonable amount of time to present its views. Any such amendments or modifications shall be deemed effective upon the first day of the semester following the semester in which the changes are approved. Students shall be informed of any changes made to the

Academic Integrity Code and all students are subject to the Academic Integrity Code that is current.

_____

Documentation of Direct Resolution Regarding the Violation of the Pace University Academic Integrity Code

Student's name _____
Student University Identification Number _____
Instructor or Complainant _____
Course name and number _____
If not a course, please describe _____
Date on which the violation occurred _____

Describe the nature of the student's violation of the Academic Integrity Code:

Describe the sanction, arrived at through Direct Resolution, between the student and the instructor or person initiating the charges:

Both parties, the student and the instructor or person initiating the charges, are required to sign below.

I, (student's name) _____, acknowledge that the above statements are true and agree to the proposed sanction.

Signature: _____ Date: _____

I, (Instructor's name) _____, acknowledge that the above statements are true and approve of the proposed sanction.
Signature of instructor or person initiating the charges:

_____ Date: _____

* If the charges described above have been discussed with the student and the student does not contest the charges, however, the student thereafter is not available to sign this form, this form may be filled out by the person initiating the charges and sent to the Chair of the Academic Conduct Committee. Please explain the circumstances below:
_____
_____
_____
_____

Academic Conduct Committee Chair signature, if required _____ Date:_____

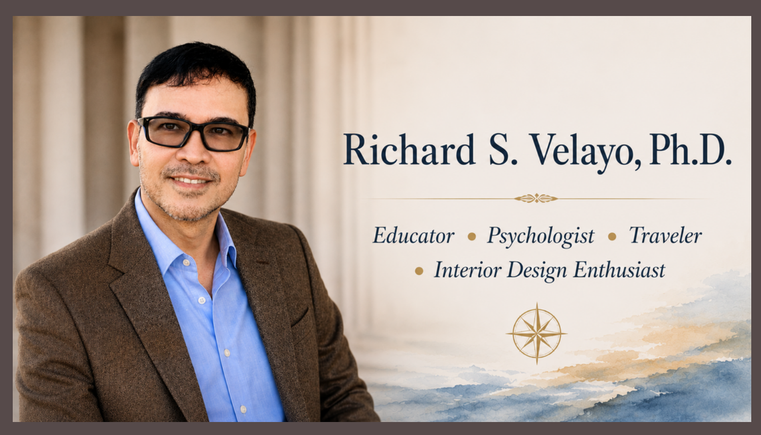

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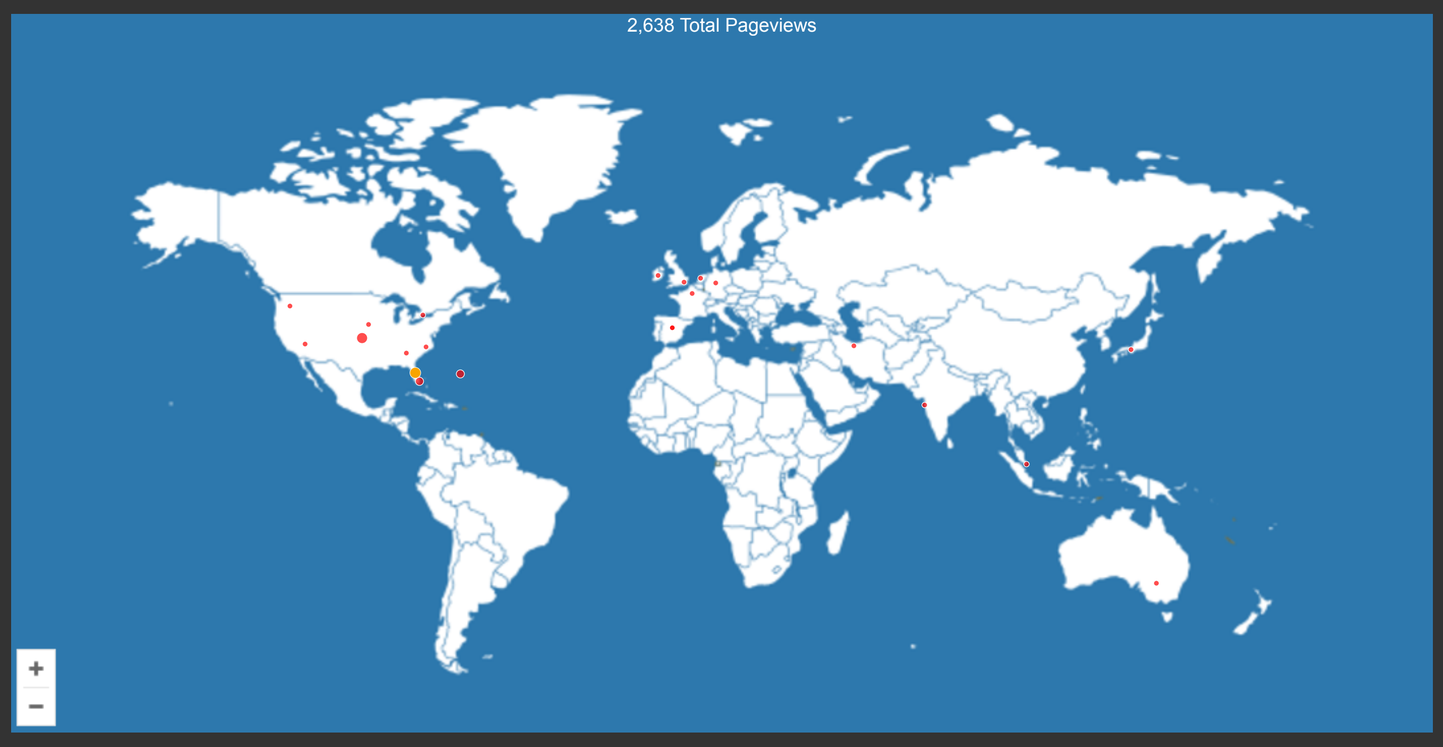

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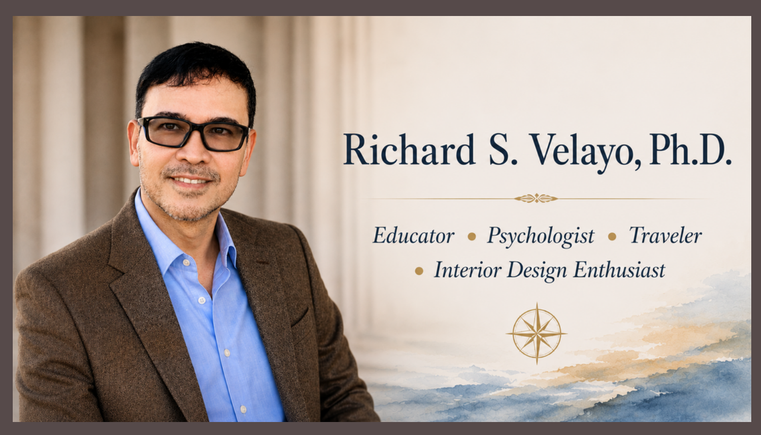

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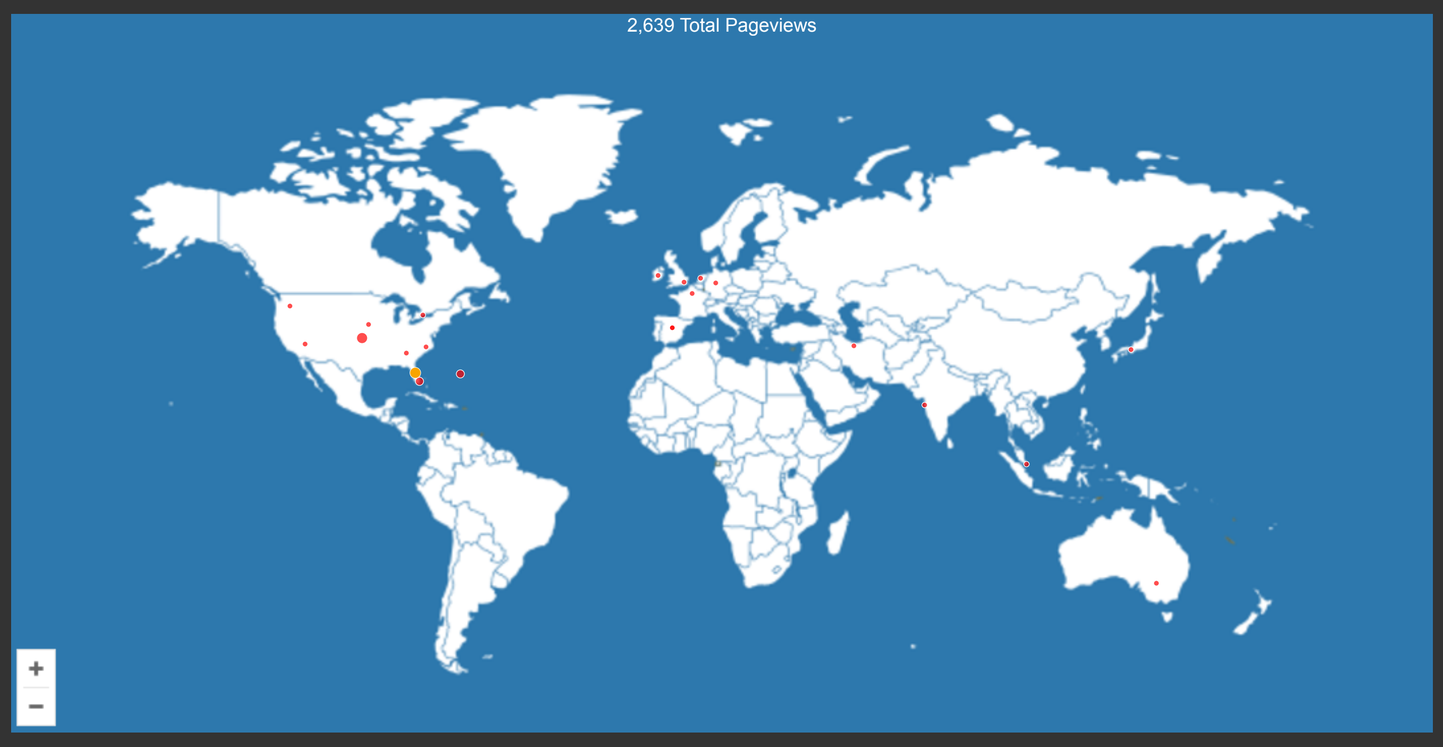

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Society for the Teaching of Psychology (APA Division 2)
OFFICE OF TEACHING RESOURCES IN PSYCHOLOGY (OTRP)

International Psychology: Annotated Bibliography, Relevant Organizations, and Course Suggestions

(2000 OTRP Instructional Research Award)

Linda M. Woolf, Michael R. Hulsizer, and Tracey McCarthy, Webster University (2002*)

* This manuscript was received in early 2001, but due to no fault of the authors, the editing process was not completed until 2002. Marky Lloyd, the OTRP Director responsible for this document, regrets the lengthy delay in distributing it.

Overview

This 29-page document** consists of resources for incorporating international content into selected existing courses as well as for developing whole courses in international psychology. The materials include an annotated bibliography of materials relevant to introductory, social, and life-span developmental psychology from an international perspective and a list of relevant international psychology organizations. In addition, sample syllabi, annotated bibliographies, and video suggestions are provided for developing whole courses in international psychology.

** See the companion document, International Psychology: A Compendium of Textbooks for Selected Courses Evaluated for International Content

Outline of Contents

I. Annotated Bibliography (pp. 2-12)
This section provides an annotated bibliography of the major books, articles, readers, and book chapters available for use in integrating international psychology into introductory, social, and life-span developmental psychology courses.

II. Relevant Organizations in International Psychology (pp. 13-14)
This section lists the major international psychology organizations with mailing addresses, phone numbers, and Web page information.

III. Course Suggestions (pp. 15-29)
This section includes course descriptions, objectives, annotated bibliographies, and video suggestions for courses that highlight international psychology research and theory. Five courses are included: (a) Aging in a Global Context, (b) Altruism and Aggression (c) Prejudice and Discrimination (d) Rethinking Child Welfare: A Global Perspective, and (e) Women and Global Human Rights.

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I. Annotated Bibliography

Aboud, F. (1998). *Health psychology in global perspective*. Thousand Oaks, CA: Sage.

Multidisciplinary text addressing international and cross-cultural issues relevant to the study and practice of health psychology. Addresses a variety of health concerns including AIDS/HIV, substance abuse, and mental illness. Also addresses family planning, community participation, and health education and promotion. Includes vignettes, case studies, and exercises for use in class.

Adamopoulos, J., & Kashima, Y. (Eds.). (1999). *Social psychology and cultural context*. Thousand Oaks, CA: Sage.

Excellent collection of articles examining various aspects of social psychology within the context of subjective culture. Topics covered range from cultural patterns of interpersonal behavior to applied cross-cultural psychology.

Adler, L. L., & Gielen, U. P. (2001). *Cross-cultural topics in psychology* (2nd ed.). Westport, CT: Praeger.

Articles examining a broad range of psychological topics such as development, personality, psychopathology, and treatment from a cross-cultural perspective. Includes topics of particular international concern such as multinational enterprises, immigration, and intercultural communication. Draws on authors from both inside and outside of the United States.

Al-Issa, I. (Ed.). (1995). *Handbook of culture and mental illness: An international perspective.* Madison, CT: International Universities Press.

Collection of essays examining the impact of culture on mental health concerns. Scholars and practitioners from various regions of the world discuss the classification, etiology, description, and treatment of mental disorders in various cultures and with various ethnic groups.

Al-Issa, I., & Tousignant, M. (Eds.). (1997). *Ethnicity, immigration, and psychopathology.* New York: Plenum.

Collection of essays examining the unique mental health stresses of ethnic minorities, immigrants, and refugees. Raises the importance of cultural understanding for clinical psychologists and other mental health professionals.

Anderson, A. (1999). Feminist psychology and global issues: An action agenda. *Women and Therapy, 22*, 7-21.

Interesting article arguing for greater involvement of feminist psychologists in global issues such as human rights and war.

Artiles, A. J., & Hallahan, D. P. (Eds.). (1995). *Special education in Latin America: Experiences and issues*. Westport, CT: Praeger.

Examines issues related to and programs focusing on special education in eight countries within South America, Central America, and the Caribbean. Particular emphasis is placed on discussing teacher education and service provision for children with mild and serious learning disabilities.

Bauserman, R. (1997). International representation in the psychological literature. *International Journal of Psychology, 32*, 107-112.

Study examining the representation of international research in psychology journals. Notes that publications from certain countries (e.g., Japan) and certain regions (Western Europe) have steadily increased while for some regions and developing nations, the representation remains low.

Bennett, J., & Grimley, L. K. (2000). Parenting in the global community: A cross-cultural/international perspective. In M. J. Fine & S. W. Lee (Eds.), *Handbook of diversity in parent education: The changing faces of parenting and parent education (*pp. 97-132). San Diego, CA: Academic Press.

Examines parenting within the context of culture and global environment. Includes a discussion of parenting programs in a variety of countries ranging from France to the Philippines.

Bond, M. H. (Ed.). (1996). *The handbook of Chinese psychology*. New York: Oxford University Press.

Excellent collection of essays concerning psychology as developed and applied in a variety of Chinese societies including the People's Republic of China and Taiwan. An extensive array of topics is covered ranging from psychotherapy to employee motivation. The text is particularly important for psychologists working or training individuals to work in the context of a Chinese culture or society.

Boukydis, C. F. Z. (2000). Support services and peer support for parents of at-risk infants: An international perspective. *Children's Health Care, 29*, 129-145.

Highlights an international survey of support services and peer self-help programs for families with infants in neonatal care. Examines the similarities and differences between these programs and impact on outcomes.

Carr, S. C., & Schumaker, J. F. (Eds.). (1996). *Psychology and the developing world*. Westport, CT: Praeger.

Important collection of articles concerning the application and development of psychological knowledge in developing nations. Raises important issues concerning the need for balance between Western psychological theory and application grounded solely in indigenous constructs. Various domains of psychology are included such as organizational, educational, health, developmental, social, and ecological psychology. Also included are discussions of social issues such as the impact of war on children and the psychosocial care of AIDS patients.

Comunian, A. C., & Gielen, U. P. (Eds.). (2000). *International perspectives on human development*. Lengerich, Germany: Pabst Science.

Important collection of theoretical and research articles by over 50 international scholars concerning the study of human development from a cross-cultural perspective. The text is divided into nine sections emphasizing historical and theoretical concerns, methodology, particular periods of the life span, and cognitive-developmental topics. This text is designed for a professional audience.

Culbertson, F. M. (1997). Depression and gender: An international review. *American Psychologist, 52*, 25-31.

Includes a discussion of the World Health Organization's assessment instrument for diagnosing depression. Argues for consideration of the interaction between culture and gender when seeking to understand and treat depression.

Denis, M. (1998). The place and role of psychology in cognitive science: An international survey. *International Journal of Psychology, 33*, 377-395.

Based on an international survey of psychological society members from 31 countries. Notes the reasons that psychology is uniquely poised to play a central role in cognitive science research around the world.

Denmark, F. L. (1998). Women and psychology: An international perspective. *American Psychologist, 53,* 465-473.

Discussion of the results of an international survey of women psychologists. Highlights that concerns such as sexism and antifeminism remain problems for some individuals around the world.

Diener, E., & Suh, M. E. (1998). Subjective well-being and age: An international analysis. In K. W. Schaie & M. P. Lawton (Eds.), *Annual review of gerontology and geriatrics: Vol. 17, Focus on emotion and adult development* (pp. 304-324). New York: Springer.

Interesting review of several large-scale international studies of subjective well-being and age.

Dovidio, J. F., Maruyama, G., & Alexander, M. G. (1998). A social psychology of national and international group relations. *Journal of Social Issues, 54*, 831-846.

Principally discusses a psychosocial approach to the analysis of intergroup conflict and conflict resolution. Includes a discussion of the application of this information to national and international issues.

d'Ydewalle, G., Bertelson, P., & Eelen, P. (1994). *International perspectives on psychological science: Vol. 2: The state of the art*. Howe, UK: Psychology Press.

Impressive articles by international psychologists on a broad spectrum of topics ranging from neuropsychology to organizational psychology.

Earley, P. C., & Erez, M. (Eds.). (1997). *New perspectives on international industrial/organizational psychology.* San Francisco: Jossey-Bass.

Collection of articles examining the role of culture and national context on a variety of organizational topics such as multinational teams, intercultural communication, and work motivation. Excellent resource for those wanting to internationalize an industrial/organization psychology course or lecture.

Enns, C. Z. (1994). On teaching about the cultural relativism of psychological constructs. *Teaching of Psychology, 21*, 205-211.

Examines a variety of psychological constructs impacted by cultural context highlighting the differences between Western individualistic and non-Western collectivist cultures. Provides techniques for teaching cultural relativism and diversity.

Fitzgerald, H. E., Johnson, R. B., Van Egeren, L. A., Castellino, D. R., & Johnson, C. B. (Eds.). (1999). *Infancy and culture: An international review and source book*. New York: Garland.

An annotated guide to the research literature concerning infants of color cataloged by geographic region and topic.

Gardiner, H., Mutter, J., & Kosmitzki, C. (1998). *Lives across cultures: Cross-cultural human development*. Needham Heights, MA: Allyn and Bacon.

Good companion text for use in developmental courses. Introduces students to a broad range of cross-cultural research both within the United States and internationally. Chapters are organized topically making correspondence to chronologically-organized life-span developmental texts a bit difficult. However within most chapters, the material is laid out chronologically.

Gergen, K. J., Gulerce, A., Lock, A., & Misra, G. (1996). Psychological science in cultural context. *American Psychologist, 51*, 496-503.

Argues for the development of a multicultural psychology that incorporates the diversity of cultural beliefs about self and ways of knowing and increased dialogue between psychologists internationally. Discusses and provides international examples concerning important issues and

problems inherent with the ethnocentric exportation of Western psychology to other global contexts.

Georgas, J., Manthouli, M., Besevegis, E., & Kokkevi, A. (Eds.). (1996). *Contemporary psychology in Europe: Theory, research, and applications*. Gottingen, Germany: Hogrefe and Huber.

A broad representation of psychological theory, practice, and research by European psychologists. Proceedings of the 1995 IVth European Congress of Psychology in Greece.

Gielen, U. P., & Comunian, A. C. (Eds.). (1998). *The family and family therapy in international perspective*. Trieste, Italy: Edizioni Lint Trieste.

Excellent collection of articles by authors from 13 countries concerning the practice of family therapy in an international context. The text is divided into seven sections including counseling and ethnic diversity, Chinese families, families and family therapy in Asia, families in traumatic situations (e.g., genocide, cults, natural disasters), attachment concerns, and exceptional children.

Gielen, U. P., & Comunian, A. C. (Eds.). (1994). *International approaches to the family and family therapy*. Padua, Italy: Unipress.

Essays examining the evolution and practice of family psychology and therapy in a variety of countries principally in Europe.

Gilbert, N. (1997). *Combating child abuse: International perspectives and trends*. New York: Oxford University Press.

A variety of programs in North America and Western Europe are described and discussed. These programs (and the book) are organized in terms of program orientation. Included are programs from the child protective, family service with mandatory reporting, and family service with nonmandatory reporting orientations.

Gilleard, C. J. (1997). Education and Alzheimer's disease: A review of recent international epidemiological studies. *Aging and Mental Health, 1*, 33-46.

Review of the international research on Alzheimer's disease. Implications for diagnosis are discussed in relation to education and income in both developing and developed nations.

Goldstein, S. (2000). *Cross-cultural explorations: Activities in culture and psychology*. Needham Heights, MA: Allyn and Bacon.

A great way to introduce cross-cultural and internationalism into introductory psychology. The demonstrations are clearly explained and organized around a typical introductory psychology course although they can be utilized in upper division classes as well.

Grigorenko, E., Ruzgis, P., & Sternberg, R. J. (1997). *Russian psychology: Past, present and future.* Huntington, NY: Nova Science.

Interesting collection of articles highlighting some of the prominent ideas and theories within Russian psychology. While some of the chapters have a narrow focus, others are broadly written making it easier to integrate the material into traditional undergraduate courses.

Grimley, L. K., & Bennett, J. (2000). Beginning school ready to learn: An international perspective. *School Psychology International, 21*, 322-325.

An examination of programs and issues related to early childhood education and parent education in a broad spectrum of world regions including both developing and developed nations.

Halpern, D. F., & Voiskounsky, A. E. (1997). *States of mind: American and post-Soviet perspectives on contemporary issues in psychology*. Oxford, England: Oxford University Press.

Excellent collection of essays and articles concerning the evolution and process of psychology in a sociopolitical context. Authors examine a variety of topics falling into four general areas. The first section of the text concerns politics and persuasion and includes articles related to political psychology, the psychology of truth and lies, as well as advertising and the media. The second section of the text concerns current crises in mental health such as alcoholism and trauma. The third section is particularly important as it addresses many of the concerns associated with interethnic conflict. The final section addresses research relevant to ecological and environmental psychology.

Hogan, J. D. (1996). International psychology and the undergraduate curriculum: A personal note. *Teaching of Psychology, 23*, 44-45.

Argues for the inclusion of international research within the psychology curriculum. Provides a rationale and strategies for inclusion.

Jackson, J. S., Brown, K. T., & Kirby, D. (1998). International perspectives on prejudice and racism. In J. L. Eberhardt & S. T. Fiske (Eds.), *Confronting racism: The problem and the response* (pp. 101-135). Thousand Oaks, CA: Sage.

Examines similarities between dominant group member's attitudes and out-group rejection in the United States and four Western European nations.

Kao, H. S. R., & Sinha, D. (Eds.). (1997). *Asian perspectives on psychology*. Thousand Oaks, CA: Sage.

Contrasts Asian psychology and Western psychology. Cognition, emotion, personality, social behavior, and health are examined by a number of international scholars from Eastern psychological perspectives. The importance of spiritual, transcendental, and social issues in Eastern psychology are included. Argues for the inclusion of Eastern perspectives into Western psychology.

Kaslow, F. W. (2000). Establishing linkages through international psychology: Dealing with universalities and uniquenesses. *American Psychologist, 55*, 1377-1388.

An interesting narrative describing one scholar's journey toward becoming an international psychologist.

Kennedy, G. J., & Tanenbaum, S. (2000). Suicide and aging: International perspectives. *Psychiatric Quarterly, 71*, 345-362.

Using data from the 1996 World Health Statistical Annual, the article examines suicide among older adults taking into account a variety of factors including national origin. Includes recommendations for reducing the suicide rate among older adults.

Killias, M., & Ribeaud, D. (1999). Drug use and crime among juveniles. An international perspective. *Studies on Crime and Crime Prevention, 8*, 189-209.

Interesting study examining the correlations between juvenile drug use (both soft and hard drugs), juvenile delinquency, and drug trafficking in 12 European countries and the United States. Substantial differences among these countries are noted and discussed.

Kirkcaldy, B. D., & Brown, J. M. (2000). Personality, socioeconomics and crime: An international comparison. *Psychology, Crime and Law, 6*, 113-125.

This article examines a variety of personality factors and individual as well as national socioeconomic indices in an attempt to correlate these with crime statistics. Although the results do

not indicate anything startling concerning the roots of crime, the study highlights how cross-cultural comparisons can raise issues regarding the impact of cultural variables on behavior.

Koltsova, V. A., Oleinik, Y. N., Gilgen, A. R., & Gilgen, C. K. (Eds.). (1996). *Post-Soviet perspectives on Russian psychology*. New York: Greenwood.

To understand Russian psychology, one must examine the history of Russia and the former Soviet Union. This text discusses the current state of psychological science in Russia against the backdrop of this history. Includes a broad range of topics that can be integrated into a number of psychology courses including developmental, personality, industrial, and social psychology.

Landis, D., & Bhagat, R. (Eds.). (1996). *Handbook of intercultural training* (2nd ed.). Thousand Oaks, CA: Sage.

Important handbook for psychologists involved in training individuals for work in an intercultural setting. The first section concerns the theory and methods of intercultural training including topics such as acculturation, international personnel selection, and program assessment. The second section highlights the contextual dimensions of intercultural training in such settings as the military and organizational contexts. The final section is of particular interest for those interested in international issues as it focuses on intercultural training for those who work in critical parts of the world.

Leach, M. M. (1997). Training global psychologists: An introduction. *International Journal of Intercultural Relations, 21*, 161-174.

An important article arguing that in the face of increasing global interconnections and dependencies, psychology may be ill-prepared to meet changing needs unless it addresses its underlying ethnocentrism. Provides suggestions for various training designs.

Lee, S. (1998). Global modernity and eating disorders in Asia. *European Eating Disorders Review, 6*, 151-153.

Discusses the impact of global modernity on the prevalence of eating disorders among Asian females. Raises additional issues relative to Asian cultural and governmental differences impacting the delivery of treatment.

Lee, Y-T., McCauley, C., & Draguns, J. (Eds.). (1999). *Personality and person perception across cultures.* Mahwah, NJ: Erlbaum.

Begins with the premise that personality and human nature are not independent of culture. Examines the impact of culture on personality and person perception in a variety of social and international contexts.

Lester, D. (1997). Suicide in an international perspective. *Suicide and Life-Threatening Behavior, 27,* 104-111.

This article examines suicide rates from various nations around the world examining similarities, differences, and trends. For example, male suicide rates are higher in all nations studied except for China where women have a higher suicide rate. Predictor variables for suicide in 17 industrialized nations are proposed.

Leung, K., Kim, U., Yamaguchi, S., & Kashima, Y. (Eds.). (1997). *Progress in Asian social psychology: Vol. 1*. New York: Wiley.

Proceedings of the 1995 Conference of the Asian Association of Social Psychology in Hong Kong. While most of these articles represent specialized research topics, a few may be of general use to

augment undergraduate and graduate lectures. Of particular interest may be a discussion of Hinduism, Islam, and Buddhism as a source of Asian values, a theoretical article concerning group dynamics, an article concerning the five-factor model of personality in China, research concerning psychological control, and articles regarding intergroup dynamics and conflict.

Lonner, W. J., Dinnel, D. L., Forgays, D. K., & Hayes, S. A. (1999). *Merging past, present, and future in cross-cultural psychology: Selected papers from the Fourteenth International Congress of the International Association for Cross-Cultural Psychology*. Lisse, Netherlands: Swets and Zeitlinger.

Excellent collection of 44 papers concerning a broad range of cross-cultural topics. A small number of articles concern cross-cultural concerns in the United States. However, most concern research, theoretical development, and issues from other regions of the world. Of particular interest is an article written by scholars from Africa challenging traditional American and European psychology.

Madge, N. (1999). Youth suicide in an international context. *European Child and Adolescent Psychiatry, 8*, 283-291.

Examines suicide rates and trends for adolescents in seven European countries.

Marsella, A. J. (1998). Toward a "global-community psychology": Meeting the needs of a changing world. *American Psychologist, 53*, 1282-1291.

Discussion of the need for the development of a specialty within psychology focusing on global-community concerns. Argues that this is needed in response to changes in technology, the development of multinational corporations, and increasing global interdependence.

Matsumoto, D. (2000). *Culture and psychology: People around the world* (2nd ed.). Belmont, CA: Wadsworth.

Introduces students to the world of psychology from a cross-cultural perspective. Includes recent international and cultural research in traditional areas of psychology as well as highlights topics of particular importance to the study of psychology and culture such as intercultural communication and ethnocentrism. It should be noted that the focus of this text is cultural diversity and is not exclusively international in focus.

Mays, V. M., Rubin, J., Sabourin, M., & Walker, L. (1996). Moving toward a global psychology: Changing theories and practice to meet the needs of a changing world. *American Psychologist, 51*, 485-487.

Discussion of the far-reaching changes in society bringing those in the U.S. closer to individuals of differing cultural and national backgrounds. Argues that psychologists in the U.S. can greatly facilitate the internationalization of America by addressing potential problem sources both domestically and abroad.

McDaniel, E., & Andersen, P. A. (1998). International patterns of interpersonal tactile communication: A field study. *Journal of Nonverbal Behavior, 22*, 59-75.

Interesting cross-cultural study examining the role of touch in interpersonal communication and the need for awareness of differences for effective intercultural communication.

Moghaddam, F. M., Taylor, D. M., & Wright, S. C. (1993). *Social psychology in cross-cultural perspective.* New York: W. H. Freeman.

Great supplementary text for a social psychology course. Many areas of inquiry within a typical social psychology course are discussed from a cross-cultural perspective. A very effective way to introduce these topics into course preparations with little detective work. Topics covered by the authors

encompass the major areas of research within social psychology. A large percentage of the material is based on research conducted outside the U.S.

Murphy-Berman, V., Levesque, H. L., & Berman, J. J. (1996). U.N. Convention on the Rights of the Child: A cross-cultural view. *American Psychologist, 51*, 1257-1261.

Examines cultural differences impacting the understanding and implementation of the United Nations Convention on the Rights of the Child. Includes discussions of cross-cultural variability in power distributions in families, degree of external control on individual behavior, accepted family responsibility levels, and collectivist vs. individualist cultural patterns.

Nader, K., Dubrow, N., & Stamm, B. H. (1999). *Honoring differences: Cultural issues in the treatment of trauma and loss*. Philadelphia: Brunner/Mazel.

Important collection of essays concerning the treatment of trauma and loss taking into account the importance of cultural understanding. The first part of the book examines cultural differences within the United States and the second part of the book examines these issues internationally. Raises the issue of the importance of cultural awareness and the impact of cultural concerns on trauma response and treatment considerations.

Pandey, J. (Ed.). (2001). *Psychology in India revisited - Developments in the discipline: Vol. 2: Personality and health psychology*. Thousand Oaks, CA: Sage.

Review of the recent psychological research in India related to personality and health psychology. Included are articles concerning consciousness studies, child and adolescent development, personality, self, gender, health, and therapy.

Pandey, J. (Ed.). (2000). *Psychology in India revisited - Developments in the discipline: Vol. 1: Physiological foundation and human cognition*. Thousand Oaks, CA: Sage.

Review of the recent psychological research in India related to animal behavior, physiological psychology, learning and memory, intelligence and cognition, and language.

Pandey, J., Sinha, D., & Bhawuk, D. P. S. (Eds.). (1996). *Asian contributions to cross-cultural psychology*. Thousand Oaks, CA: Sage.

Excellent collection of essays concerning the practice of and research concerning psychology in Asia. The first section of the text concerns theoretical issues including discussions of the problems associated with indigenous psychology. The second and third sections contain articles related to family, cognitive processes, self, and achievement. The final section addresses social values and problems of developing societies. A significant number of the chapters concern research and psychological issues in India and Nepal. Based on the fourth regional Asian Congress of International Association for Cross-Cultural Psychology held in Kathmandu, Nepal, in 1992.

Pawlik, K., & d'Ydewalle, G. (1996). Psychology and the global commons: Perspectives of international psychology. *American Psychologist, 51*, 488-495.

The majority of this article highlights the need for and process by which psychologists from varying national and regional backgrounds can engage in international cooperation and exchange. Also argues for the contributions that psychological science can make in a changing global context.

Pettigrew, T. F. (1998). Applying social psychology to international social issues. *Journal of Social Issues, 54*, 663-675.

Excellent article for use in a social psychology class. Demonstrates the applicability of social psychology to “real world” international social concerns by blending theoretical issues with a

discussion of Kelman's peace initiatives in the Middle East.

Price, W. F., & Crapo, R. H. (1998). *Cross-cultural perspectives in introductory psychology* (3rd ed.). Belmont, CA: Wadsworth.

A collection of 26 cross-cultural readings and vignettes organized topically for use in an introductory psychology course. Designed to augment students' knowledge of the material and raise issues of similarity and difference in relation to individuals in varying cultural contexts around the globe.

Redondo, S., Genoves, V. G., Perez, J., & Barberet, R. (Eds.). (1994). *Advances in psychology and law: International contributions*. Berlin, Germany: Walter De Greyter.

Based on contributions to the 1994 European Conference of Psychology and Law in Barcelona, Spain.

Retish, P., & Reiter, S. (Eds.). (1999). *Adults with disabilities: International perspectives in the community.* Mahwah, NJ: Erlbaum.

Examines a variety of concerns for adults with disabilities ranging from the transition from school to the workplace to parenting concerns. Includes articles focusing on specific issues, programs, or policies in a variety of industrialized countries around the globe as well as cross-cultural comparisons.

Roesch, R., & Carr, G. (2000). Psychology in the international community: Perspectives on peace and development. In J. Rappaport & E. Seidman (Eds.), *Handbook of community psychology* (pp. 811-831). New York: Plenum.

Examines the role that community psychologists can play in reframing and assisting with global peace and development concerns.

Rosenzweig, M. R. (1999). Continuity and change in the development of psychology around the world. *American Psychologist, 54*, 252-259.

Discusses the results of a survey conducted by the International Union of Psychological Science. Addresses the growth of psychology internationally and the challenges that will be faced as psychology takes its place in the global community

Rosenzweig, M. R. (Ed.). (1992). *International psychological science: Progress, problems, and prospects.* Washington, DC: American Psychological Association.

Survey of psychological research by scholars from six countries. Topics covered include learning and memory, visual perception, parenting and child development, health psychology, psychotherapy, and psychological assessment. Of particular interest is a chapter entitled, "Resources for Psychological Science Around the World."

Schmidt, L., & Room, R. (1999). Cross-cultural applicability in international classifications and research on alcohol dependence. *Journal of Studies on Alcohol, 60,* 448-462.

A good study for discussion of cross-cultural applicability of research and theory particularly in relation to psychological disorders. Data were gathered in nine counties concerning alcohol use and both psychological and physical dependence. Similarities and differences across cultures are discussed.

Scott, R. L. (1983). A course surveying the discipline of psychology from a Mexican perspective. *Teaching of Psychology, 10*, 171-172.

An interesting article describing an intercultural psychology seminar taught in Mexico.

Segall, M. H., Dasen, P. R., Berry, J. W., & Poortinga, Y. H. (1990). *Human behavior in global perspective: An introduction to cross-cultural psychology*. Needham Heights, MA: Allyn and Bacon.

General introduction to the influence of culture on human behavior. Includes research concerning the impact of culture on individuals in a multiethnic as well as international context.

Sexton, V. S., & Hogan, J. D. (Eds.). (1992). *International psychology: Views from around the world.* Lincoln, NE: University of Nebraska Press.

Provides a panoramic view of psychology from around the globe. Chapters are organized by country from Argentina to Zimbabwe. Each chapter describes the state of the profession, current research themes, and theoretical emphasis within that nation.

Singh, B., & Jenkins, R. (2000). Suicide prevention strategies--an international perspective. *International Review of Psychiatry,12*, 7-14.

Discusses and analyzes national suicide prevention strategies from an international public health perspective.

Smith, P. B., & Bond, M. H. (1999). *Social psychology across cultures.* Needham Heights, MA: Allyn and Bacon.

A natural supplement to any social psychology course. It examines the many areas of inquiry within a typical social psychology course from a cross-cultural perspective. A very effective way to introduce these topics into course preparations with little detective work. Topics covered by Smith and Bond touch on virtually every aspect of social psychological research.

Stead, G. B., & Harrington, T. F. (2000). A process perspective of international research collaboration. *Career Development Quarterly, 48*, 323-331.

Describes the benefits and pitfalls associated with international research collaboration.

Sugiman, T., Karasawa, M., Liu, J. H., & Ward, C. (Eds.). (2000). *Progress in Asian social psychology: Vol. 2.* Seoul, Korea: Kyoyook Kwahak Sa.

Interesting collection of theoretical and research articles based on the proceedings of the 1997 Conference of the Asian Association of Social Psychology in Kyoto. Text is divided into six parts including the methods of Asian social psychology, the Asian self, interpersonal, intrapersonal, and intergroup processes, social representations, and cultural development issues in Asia. Many of the articles in this volume could be easily integrated into a social psychology course.

Swadener, E. B., & Bloch, M. N. (Eds.). (1997). Children, families, and change: International perspectives [Special Issue]. *Early Education and Development, 8*(3).

Addresses the special concerns of children and family in relation to changing international trends and environments. Of particular importance to those who either work or are training individuals to work as researchers, educators, social policy coordinators, or advocates of children and their families.

United Nations (U.N.) (2001). *The state of the world's children 2001*. New York: United Nations.

This resource is a fountain of information. Provides discussion about and data on children around the world. Includes numerous invaluable charts and tables examining a variety of factors impacting childhood such as health, nutrition, and economics. It is available for free viewing on-line at <http://www.unicef.org/sowc01/>.

Weidner, G. (2000). Why do men get more heart disease than women? An international perspective. *Journal of American College Health, 48*, 291-294.

Cross-cultural study examining similarities and differences in factors associated with coronary heart disease among men principally from the West and from Eastern Europe.

Wingenfeld, S., & Newbrough, J. R. (2000). Community psychology in international perspective. In J. Rappaport & Seidman, E. (Eds.), *Handbook of community psychology (*pp. 779-810). New York: Plenum.

Discusses the history and status of community psychology training programs, practice, and research in a broad range of countries around the globe.

Worchel, S., & Simpson, J. A. (1993). *Conflict between people and groups: Causes, processes, and resolutions.* Chicago: Nelson-Hall.

This text has recently been reprinted and is now again in circulation. Text contains a set of four articles that address international conflict. Contributors to this section are, by and large, from universities outside of the U.S. Topics include the Yin-Yang Theory, Israeli-Palestine conflict, U.S.A.-U.S.S.R. relations, and negotiations in Poland.

Wosinska, W., Cialdini, R. B., Barrett, D. W., & Reykowski, J. (Eds.). (2001). *The practice of social influence in multiple cultures*. Mahwah, NJ: Erlbaum.

A welcome addition to the social psychology literature. This edited text addresses the many ways in which antecedents of social influence are shaped by culture. Draws on research conducted within the U.S. and around the globe. It's an excellent book.

Yates, M., & Youniss, J. (Eds.). (1999). *Roots of civic identity: International perspectives on community service and activism in youth*. New York: Cambridge University Press.

Essays examine the concept of civic identity in a variety of nations and political situations from Canada to Palestine.

The following resources contain many useful international references and course recommendations. They can be found on the Society for the Teaching of Psychology's Office of Teaching Resources in Psychology website - <http://www.lemoyne.edu/OTRP/index.html>.

Hill, G. W., IV. (1998). Informational Resources for Teaching Cross-Cultural Issues in Psychology (9 pages)

Hill, G. W., IV. (1998). Activities and Videos for Teaching Cross-Cultural Issues in Psychology (21 pages).

Woolf, L. M. (2000). Incorporating Genocide, Ethnopolitical Conflict, and Human Rights Issues into the Psychology Curriculum: Informational Resources (28 pages).

Woolf, L. M. (2000). Incorporating Genocide, Ethnopolitical Conflict, and Human Rights Issues into the Psychology Curriculum: Instructional Resources (31 pages).

II. Relevant Organizations in International Psychology

Interamerican Society of Psychology
(Sociedad Interamericana de Psicologia–SIP)
Dr. Wanda C. Rodriguez-Arocho, General Secretary
Universidad de Puerto Rico
P.O. Box 23345
San Juan, PR 00931-3345
Telephone: 787-764-0000 ext. 4184
Fax: 787-764-2615
E-Mail: wrodrig@rrpac.upr.clu.edu
Website: <http://www.sip-99.org.ve/>

International Association for Cross-Cultural Psychology (IACCP)
Dr. James Georgas
Department of Psychology
School of Philosophy
University of Athens
Panaepistemiopolis
Athens 15784
Greece
Telephone: 301 7277524
Fax: 3101 7277534
E-Mail: dgeorgas@dp.uoa.gr

International Association of Applied Psychology (IAAP)
Dr. Jose M. Prieto, Secretary General
Complutense University, Faculty of Psychology
Department of Individual Differences and Work Psychology
Suite 2218
Campus Somosaguas
Madrid 28223
Spain
Telephone: 34-91-3943236
Fax: 34-91-3510091
E-Mail: iaap@psi.ucm.es or jmprieto@psi.ucm.es
Website: <http://www.iaapsy.org>

International Council of Psychologists (ICP)
Dr. Kay C. Greene, Secretary General
30 Waterside Plaza, Suite 13E
New York, New York 10010-2630
USA
Telephone: 212-889-7956
Fax: 212-213-4032
E-Mail: Kaygreen@ix.netcom.com
Website: <http://members.tripod.com/icpsych/>

International Psychology
Division 52-Administration Office
American Psychological Association
750 First Street, NE
Washington, DC 20002-4242
USA
Website: <http://www.tamu-commerce.edu/orgs/div52/>

International Union of Psychological Science (IUPsyS)
Dr. Pierre L. J. Ritchie, Secretary General
School of Psychology
University of Ottawa
11 Marie Curie, Pavillon Vanier
Ottowa, Ontario KIN 6N5
Canada
Telephone: 613-562-5289
Fax: 613-562-5169
E-Mail: pritchie@uottawa.ca
Website: <http://www.iupsys.org>

Psychologists for Social Responsibility (PsySR)
2607 Connecticut Ave, NW
Washington, DC 20008
USA
Website: <http://www.rmc.edu/psysr/>

Society for the Psychological Study of Social Issues (SPSSI)
SPSSI Central Office
PO Box 1248
Ann Arbor Michigan 48106-1248
USA
Telephone: 734-662-9130
Fax: 734-662-5607
E-Mail: spssi@spssi.org
Website: <http://www.spssi.org>

A comprehensive listing of organizations can be found on the American Psychological Association's International Psychological Organizations and Related Organizations web site - <http://www.apa.org/international/intlorgs.html>

III. Course Suggestions

Aging in a Global Context

Over the next 30 years, we will see a dramatic increase in the number of older adults in the United States and around the world. Globally, the population of individuals 85 years of age and older are currently and will continue to be the fastest growing demographic group. These changes are occurring in almost all countries regardless of level of development or geographic location. This course will examine the impact of these changes on individuals and cultural systems. Additionally, this course will examine the similarities and differences experienced by individuals as they age in various countries around the world.

Sample Objectives

1. To learn about the changing demographic in the United States and around the world with respect to age and the impact of these changes on cultures internationally.

2. To develop an understanding of the various societal expectations of and attitudes towards older adults around the world.

3. To examine where and in what conditions older adults live in various parts of the world and the impact of these living arrangements on the older adult.

4. To explore the nature of intergenerational relationships internationally.

5. To develop an understanding of the social problems and public policies effecting the aged around the world. These will include policies related to political advocacy, economics, retirement, and health care.

6. To explore physiological, cognitive, personality, and social development and their interrelationships during later adulthood. Additionally, similarities and differences in development as experienced by older adults around the world will be explored.

Suggested International Readings

Bergener, M., Hasegawa, K., Finkel, S. I., & Nishimura, T. (1992). *Aging and mental disorders: International perspectives.* New York: Springer.

> Examines the similarities and differences in the etiology and treatment of mental disorders in older adults in both Eastern and Western cultures.

Counts, D. A. (1991). Aging, health and women in West New Britain. *Journal of Cross-Cultural Gerontology, 6,* 277-285.

> An interesting article discussing the negative impact of modernization on the older woman in Papua New Guinea.

Gist, Y. J. (1994). Aging trends - Southern Africa. *Journal of Cross-Cultural Gerontology, 9*, 255-276.

> An examination of demographic and social data as related to aging and the aged in Botswana, Lesotho, Namibia, South Africa, Swaziland, and Zimbabwe.

Keith, J., Fry, C. L., Glascock, A. P., Ikels, C., Dickerson-Putman, J., Harpending, H. C., & Draper, P. (1994). *The aging experience: Diversity and commonality across cultures.* Thousand Oaks, CA: Sage.

> This article highlights the findings of Project A.G.E. (Age, Generation, and Experience) that includes research on aging in Botswana, Hong Kong, Ireland, and the U.S.

Kol'tsova, V. A., Meshalkina, N. B., & Olegnik, Y. N. (1997). A life-span approach to the study of psychogerontology in Russia. In D. F. Halpern, & A. E. Voiskounsky (Eds.), *States of mind: American and post-Soviet perspectives on contemporary issues in psychology* (pp. 272-285). Oxford, England: Oxford University Press.

A review of psychogerontological research and the continued evolution of the field in post-Soviet Russia.

Lewis, M. (1982). Aging in the People's Republic of China. *International Journal of Aging and Human Development, 15,* 79-105.

A discussion of the lives of older adults in postrevolutionary China.

Maeda, D. (1992). Aging in Japan. In M. Bergener & K. Hawegawa (Eds.), *Aging and mental disorders: International perspectives* (pp. 3-22). New York: Springer.

Explores the unique factors impacting aging and the aged and describes services for the older adult in Japan.

Meeks, C. B., Nickols, S. Y., & Sweaney, A. L. (1999). Demographic comparisons of aging in five selected countries. *Journal of Family and Economic Issues, 20*, 223-250.

Examines a variety of issues such as economics, caregiving, long-term care, and housing related to aging and older adults in Brazil, India, Norway, Tanzania, and the United States.

Parthasarathy, N. R. (1980). On some aspects of aging in India. *The Indian Journal of Social Work, 40*, 381-388.

An examination of the demographics as well as social and health needs of older adults in India.

Sandis, E. (2000). The aging and their families: A cross-national review. In A. Comunian & U. P. Gielen (Eds.), *International perspectives on human development* (pp. 591-599). Lengerich, Germany: Pabst Science.

This chapter reviews a variety of trends impacting older adults and their families around the world.

Shimkin, D. B. (1989). Aging in the Soviet Union: A West Siberian perspective. *International Journal of Aging and Human Development, 28*, 185-189.

An ethnographic study of aging and the aged in the city of Kemerovo, Siberia.

Strom, R., & Heikkinen, R. L. (1992-93). Patterns of experienced aging with a Finnish cohort. *International Journal of Aging and Human Development, 36*, 269-277.

Interesting article discussing interviews with and narratives written by older adults in Finland concerning their experiences with aging.

Udvardy, M., & Cattell, M. G. (1992). Gender, aging and power in sub-Saharan Africa: Challenges and puzzles. *Journal of Cross-Cultural Gerontology, 7*, 275-288.

An examination of the impact of gender and age in seven sub-Saharan Africa countries.

Altruism and Aggression: A Global Perspective

We live in a violent time. Acts of unspeakable violence are being committed throughout the world. As a result, it is virtually impossible to pick up a newspaper, leaf through a magazine, or listen to the evening news without learning that somewhere, someplace, an act of violence has occurred. Yet, in the midst of this epidemic of violence, we still hear about instances of altruism – helping behavior. How is it that our species can be so destructive in one instant and so truly kind and helpful in another. This dual nature of humans is perplexing. Is our species inherently good or evil?

Sample Objectives

1. To become more knowledgeable about the various theories of altruism and aggression and how they apply within the United States and around the world.

2. To explore the many factors unique to human altruism and aggression from a variety of perspectives (e.g., instinctual, developmental, biological, social, and personality).

3. To become more knowledgeable about international human rights and how the United Nations Universal Declaration of Human Rights applies to acts of altruism and aggression.

4. To utilize knowledge about aggression to develop strategies to control or reduce aggressive behavior.

5. To utilize knowledge about altruism to increase the manifestation of this behavior throughout the world.

Suggested International Readings

Barash, D. P. (Ed.). (2001). *Understanding violence*. Needham Heights, MA: Allyn and Bacon.

A collection of classic articles on aggression. Articles are from a variety of disciplines including biology, psychology, sociology, anthropology, political science, and criminology.

Baron, R. A., & Richardson, D. R. (1994). *Human aggression* (2nd ed.). New York: Plenum Press.

A very in-depth collection of the psychological research addressing human aggression. An excellent starting point. Some research is from international scholars.

Batson, C. B. (1998). Altruism and prosocial behavior. In D. T. Gilbert, S. T. Fiske, & G. Lindzey (Eds.), *The handbook of social psychology: Vol. 2* (4th ed., pp. 282-316). Boston: McGraw-Hill.

Overview of helping behavior research. Some international research is cited. A brief discussion of collectivism is included.

Baumeister, R. F. (1999). *Evil: Inside human cruelty and violence*. New York: W.H. Freeman.

Provocative text that addresses the research surrounding the concept of evil. Global acts of aggression are discussed. Makes for an interesting discussion within an altruism and aggression course.

Berkowitz, L. (1993). *Aggression: Its causes, consequences, and control*. Boston: McGraw-Hill.

Text provides a general overview regarding the research surrounding human aggression. Some international research is cited.

Chomsky, N., Clark, R., & Said, E. W. (1999). *Acts of aggression: Policing "rogue" states.* New York: Seven Stories Press.

Examination of the U.S. conflict with Iraq. Authors discuss how U.S.-Arab relations conflict with U.N. resolutions and international law.

Clark, M. S. (Ed.). (1991). *Prosocial behavior*. Thousand Oaks, CA: Sage.

This book contains twelve articles that address helping behavior. Many include international research. One article approaches the topic of altruism in collectivistic and individualistic societies from an anthropological perspective.

Dobash, R. E., & Dobash, R. P. (Eds.). (1998). *Rethinking violence against women*. Thousand Oaks, CA: Sage.

Approaches the topic of violence against women from a variety of cross-disciplinary perspectives. Nice source of material from the U.S. as well as areas around the globe.

Donnelly, J. (1998). *International human rights* (2nd ed.). Boulder, CO: Westview Press.

A nice primer of international human rights. Much of the material can be easily integrated into an altruism and aggression course.

Geen, R. G. (1998). Aggression and antisocial behavior. In D. T. Gilbert, S. T. Fiske, & G. Lindzey (Eds.), *The handbook of social psychology: Vol. 2* (4th ed., pp. 317-356). Boston: McGraw-Hill.

Overview of aggression research. Some international research and cross-cultural research are discussed.

Geen, R. G., & Donnerstein, E. (Eds.). (1998). *Human aggression: Theories, research, and implications for social change*. San Diego, CA: Academic Press.

This edited book provides coverage in some of the most prominent antecedents of aggression. Although much of the coverage is based on research conducted in the U.S., many of the policy implications can be extended toward helping reduce violence around the globe.

Hall, H. V., & Whitaker, L. C. (Eds.). (1999). *Collective violence: Effective strategies for assessing and interviewing in fatal group and institutional aggression*. Boca Raton, FL: CRC Press.

An important collection of research examining violence committed by private groups and government institutions. International perspectives are presented.

Krahé, B. (2001). *The social psychology of aggression*. Philadelphia: Taylor & Francis Group.

Text is divided into chapters addressing various antecedents of aggression. Good textbook for use in an upper division undergraduate class. International content is integrated throughout the text.

Lauren, P. G. (1998). *The evolution of international human rights: Visions seen*. Philadelphia: University of Pennsylvania Press.

This text was written specifically for the fiftieth anniversary of the Universal Declaration of Human Rights. It provides a very thorough historical analysis of the evolution of this document.

Moghaddam, F. M., Taylor, D. M., & Wright, S. C. (1993). *Social psychology in cross-cultural perspective.* New York: W. H. Freeman.

Portions of the text address antecedents of altruism and aggression from a cross-cultural perspective. This is a very effective way to introduce these topics into course preparations with little detective work. A large percentage of the material is based on research conducted outside the U.S.

Schroeder, D. A., Penner, L. A., Dovidio, J. F., & Piliavin, J. A. (1995). *The psychology of helping and altruism: Problems and puzzles*. Boston: McGraw-Hill.

An overview of the research on helping behavior. Included are several examples of international research. A discussion of cross-cultural determinants of altruism is also included.

Shue, H. (1996). *Basic rights: Subsistence, affluence, and U.S. foreign policy* (2nd ed.). Princeton, NJ: Princeton Press.

A good look at U.S. foreign policy from the perspective of international human rights. Can be integrated into governmental manifestations of violence.

Steger, M. B., & Lind, N. S. (Eds.). (1999). *Violence and its alternatives: An interdisciplinary reader*. New York: St. Martin's Press.

A wide variety of classic articles about violence from authors around the globe are presented. Topical areas include: definitions and concepts, law, gender, race, nationalism, class, and nonviolent alternatives.

Worchel, S., & Simpson, J. A. (1993). *Conflict between people and groups: Causes, processes, and resolutions*. Chicago: Nelson-Hall.

This text has recently been reprinted and is now again in circulation. Text contains a set of four articles that address international conflict. Contributors to this section are, by and large, from Universities outside of the U.S. Topics include the Yin-Yang Theory, Israeli-Palestine conflict, U.S.A.-U.S.S.R. relations, and negotiations in Poland.

Prejudice and Discrimination: A Global Perspective

Us and Them. Why is there a tendency for humans to divide the social landscape in this fashion? This course will examine the essential features, principles, facts, and theories that surround stereotyping, prejudice, and discrimination. The theoretical approaches considered will include those from psychology, sociology, and international human rights. The class will examine inter-group relations as they pertain to different racial and ethnic groups throughout the world. We shall also discuss discrimination based on appearance, gender, age, ability, and sexual orientation.

The course also will give you the opportunity to debate current controversies related to the topics addressed during the course. There are no easy answers. Reality is not simply black or white, but rather infinite shades of gray. Therefore, it is necessary that you develop critical thinking skills, allowing you to make sense of the constant stream of information and misinformation that the world has to offer. These skills can have a profound impact on your life in terms of academic, professional, and personal success.

Sample Objectives

1. To introduce you to the many essential features, principles, facts, and theories that surround stereotyping, prejudice and discrimination.

2. To become familiar with prejudice and discrimination as it exists outside the United States.

3. To become more knowledgeable about international human rights and how the United Nations Universal Declaration of Human Rights applies to prejudice and discrimination.

4. To provide you with critical thinking skills that will enable you to analyze, evaluate, and make intelligent decisions concerning complex contemporary issues in psychology.

5. To help you improve your oral communication skills. This will allow you to enhance your effectiveness at expressing your view on various topics.

6. To encourage you to become more tolerant of ambiguity and diversity as it pertains to the human condition and to increase your ability to deal with multiple points of view.

Suggested International Readings

Back, L., & Solomos, J. (Eds.). (2000). *Theories of race and racism: A reader*. New York: Routledge.

This reader brings together some of the key works of authors from around the globe on issues related to race and racism. Readings also cut across disciplines.

Bonnett, A. (2000). *Anti-racism*. New York: Routledge.

The text provides a historical and international analysis of the development of anti-racism. The author draws on a host of Western and non-Western sources. This is a very good resource to internationalize a course on stereotyping, prejudice, and discrimination.

Brewer, M. B., & Miller, N. (1996). *Intergroup relations*. Pacific Grove, CA: Brooks/Cole.

A short very focused discussion of intergroup relations designed to meet the needs of students. International content in integrated throughout the text. Includes a chapter on international conflict.

Brown, R. (1995). *Prejudice*. Malden, MA: Blackwell.

A nice overview of prejudice and discrimination from a European perspective (the author is from the University of Kent). International examples and research are cited throughout the text.

Disch, E. (2000). *Reconstructing gender: A multicultural anthology*. Mountain View, CA: Mayfield.

This is a very good anthology dealing with the role of women in society. The readings are short and therefore attractive to students. Although much of the content addresses the situation in the U.S., there are some selections that address the role of women in the international arena.

Donnelly, J. (1998). *International human rights* (2nd ed.). Boulder, CO: Westview Press.

A nice primer of international human rights. Much of the material can be easily integrated into an prejudice and discrimination course.

Hall, H. V., & Whitaker, L. C. (Eds.). (1999). *Collective violence: Effective strategies for assessing and interviewing in fatal group and institutional aggression*. Boca Raton, FL: CRC Press.

An important collection of research examining violence committed by private groups and government institutions. International perspectives are presented. Includes a discussion of hate groups.

Hinton, P. R. (2000). *Stereotypes, cognition, and culture*. Philadelphia: Psychology Press.

Short text devoted to an overview of stereotyping. Contains a well-integrated chapter on stereotypes and culture. Text is written for students who have no prior knowledge of psychology.

Kelly, R. J., & Maghan, J. (Eds.). (1998). *Hate crimes: The global politics of polarization*. Carbondale, IL: Southern Illinois University Press.

A collection of previously unpublished essays examines hate crimes in a variety of international settings. Essays examine how local authorities cope with these issues and the means by which this problem can be controlled and contained.

Lauren, P. G. (1998). *The evolution of international human rights: Visions seen*. Philadelphia: University of Pennsylvania Press.

This text was written specifically for the fiftieth anniversary of the Universal Declaration of Human Rights. It provides a very thorough historical analysis of the evolution of this document.

Lewis, B. (1999). *Semites and anti-Semites: An inquiry into conflict and prejudice*. New York: W. W. Norton and Company.

Text examines the Arab-Israeli conflict in the Middle East. It begins by tracing the history of anti-Semitism and ends with how it manifests itself in today's global politics. Nice background material that can be incorporated into lecture.

Moghaddam, F. M., Taylor, D. M., & Wright, S. C. (1993). *Social psychology in cross-cultural perspective.* New York: W. H. Freeman.

Portions of the text address antecedents of prejudice and discrimination. This is a very effective way to introduce these topics into course preparations with little detective work. Some of the material is based on research conducted outside the U.S.

Shue, H. (1996). *Basic rights: Subsistence, affluence, and U.S. foreign policy* (2nd ed.). Princeton, NJ: Princeton Press.

A good look at U.S. foreign policy from the perspective of international human rights. Can be integrated into governmental manifestations of violence.

Steger, M. B., & Lind, N. S. (Eds.). (1999). *Violence and its alternatives: An interdisciplinary reader*. New York: St. Martin's Press.

A wide variety of classic articles about violence from authors around the globe are presented. Topical areas include: definitions and concepts, law, gender, race, nationalism, class, and nonviolent alternatives.

Stephan, W. C., & Stephan, C. W. (1996). *Intergroup relations*. Boulder, CO: Westview.

Nice overview of stereotyping, prejudice, and discrimination. International research is cited. Text contains a chapter on intercultural relations.

Worchel, S. (1999). *Written in blood: Ethnic identify and the struggle for human harmony*. New York: Worth.

Examines group and political processes that contribute to ethnic conflict. Current international material is very well integrated throughout the text. A nice addition to any course on stereotyping, prejudice, and discrimination.

Worchel, S., & Simpson, J. A. (1993). *Conflict between people and groups: Causes, processes, and resolutions.* Chicago: Nelson-Hall.

This text has recently been reprinted and is now again in circulation. Text contains a set of four articles that address international conflict. Contributors to this section are, by and large, from Universities outside of the U.S. Topics include the Yin-Yang Theory, Israeli-Palestine conflict, U.S.A.-U.S.S.R. relations, and negotiations in Poland.

Suggested International Videos

Roberts, S. (Ed.). (1999). *A guide to videos on prejudice and stereotyping.*

This guide provides descriptive information on videos that address stereotyping, prejudice, and discrimination. The compendium contains U.S. as well as international videos covering a wide range of topics pertinent to prejudice. Ordering information is also provided.

Can be obtained from:

Holocaust Resource Center and Archives
Queensborough Community College
The City University of New York
Bayside, New York
(718) 225-1617
hrcaho@worldnet.att.net

Rethinking Child Welfare: A Global Perspective

Every society is obligated to care for children in need of protection and to rehabilitate youth in need of redirection. There are both cross-cultural similarities and differences in the beliefs regarding the psychosocial antecedents and the sequelae of childhood challenges. Accordingly, the conceptualization of corrective tasks and actual child welfare practice also vary across social groups. The goal of this course is to provide students with a cross-cultural and multidisciplinary perspective on child welfare.

Sample Objectives

1. Students will define the concept of child welfare.

2. Student will explore similarities and differences between the concept of child welfare in the United States and other nations.

3. Students will be able to articulate pertinent and contemporary child welfare issues as delineated by various nations.

4. Students will identify universal child welfare concerns.

5. Students will explore cross-cultural understandings of the antecedents of identified child welfare concerns.

6. Students will explore global child welfare practices.

7. Students will explore the extent to which child welfare practices are either universal or are culturally bound.

8. Students will explore contextual factors related to child welfare philosophy and practice. For instance, students will identify the social, political, economic, and legal factors that inform child welfare research, theory, and attendant practice.

Sample Focus Areas

- Child Development
- Correlates of Poor Developmental Outcomes
- Child Mental Health
- Family Violence
- Child Physical Abuse
- Child Sexual Abuse
- Child Neglect
- Child Custody
- Female Genital Mutilation
- Female Infanticide
- Education
- Juvenile Delinquency
- Teen Pregnancy
- Parenting
- Poverty
- War and Armed Conflict

Suggested International Readings

Apfel, R. J., & Bennett, S. (Eds.). (1996). *Minefields in their hearts: The mental health of children in war and communal violence.* New Haven, CT: Yale University Press.

Health care professionals discuss their experiences of working with child survivors of war. Includes intervention, treatment, ethical concerns, refugee issues, and care for the caregiver.

Barker, G. (1994). Rebuilding nests of survival: A comparative analysis of the needs of at-risk adolescent women and adolescent mothers in the U.S., Latin America, Asia and Africa. *Childhood: A Global Journal of Child Research, 2*, 152-163.

Analyzes the factors that place adolescent females at risk for exploitation and identifies their learned psychological responses to harmful situations.

Boswell, G. (2000). *Violent children and adolescents: Asking the question why*. London, England: Whurr.

Explores the relationship between youth violence and the contextual correlates of violence among youth.

Briere, J., Berliner, L., Bulkley, J., Carole, J., & Reid, T. (1996). *The APSAC handbook on child maltreatment*. Thousand Oaks, CA: Sage.

Provides information on causes and consequences of child abuse and neglect.

Cohn, J. (1998). Violations of human rights in children and adolescents. *International Journal of Adolescent Medicine and Health, 10*, 185-192.

Discusses historically and currently the human rights violations against children that occur in almost all parts of the world. These violations range from neglect to the effects of war.

Cyril, G. (1987). *Preventing CAN deaths: An international study of deaths due to child abuse and neglect*. London, England: Tavistock/Routledge.

Provides a detailed analysis of over 170 CAN (child abuse and neglect) deaths in the UK and Canada. Addresses the issue of heightened risk and prevention.

Emilio, V. (1992). *Critical perspectives in victimology: International perspectives*. New York: Springer.

Presents contributions in research, prevention, treatment, and public policy in the field of victimology.

Geltman, P., & Stover, E. (1997). Genocide and the plight of children in Rwanda. *Journal of the American Medical Association, 277*, 289-294.

Study examining the long-term physical and psychological problems for children of Rwanda. Children studied were either internally displaced or refugees living in camps in Zaire.

Gilbert, N. (1997). *Combating child abuse: International perspectives and trends*. New York: Oxford University Press.

Provides a comparative overview of American and European approaches to addressing child maltreatment

Hoffman, A. (2001). *Teen violence: A global view*. Westport, CT: Greenwood.

Explores causes and solutions for the problem of youth violence around the globe.

Lutzker, J. (1998). *Handbook of child abuse research and treatment*. New York: Plenum.

Provides a contemporary compilation of research, theory, and practice related to child abuse and neglect.

Wessells, M. (Ed.). (1998). The Graca Machel/U.N. study on the effects of war on children [Special issue]. *Peace and Conflict: Journal of Peace Psychology, 4(*4).

A discussion of and response to the United Nation's Impact of Armed Conflict on Children study.

Suggested International Videos

The Africans: A Legacy of Lifestyles - Examines the importance of family life and compares traditional African societies with those that are more complex and centralized.

Broken Blossoms, or, The Yellow Man and the Girl - A Chinese man, living in London, befriends a young girl who was brutally mistreated by her father.

Cambodia/Vietnam - Profiles the cultures, politics, and economies of Cambodia and Vietnam. Includes an examination of topics such as family farming, disabled Cambodians, and education.

Children in Need - Examines people and programs working to change the lives of socially disadvantaged children.

China: Beyond the Clouds - Centers on the situation of children and youth in a changing world.

Future Risk: The Impact of Violence on Children - This program looks at the sources of violence impacting children.

Valentina's Nightmare (Frontline) - A documentary examining the Rwandan genocide by focusing on the experiences of a 13-year-old girl who hid among the corpses of her family and neighbors.

When the Bough Breaks - Illustrates behavioral manifestations of attachment problems.

Women and Global Human Rights

Discussions of human rights often fail to acknowledge the unique concerns of women around the globe particularly as they relate to the subordination of and injustices against women. Yet clearly, women's rights are human rights concerns. Violence against women and girls is the most pervasive violation of human rights in the world today. Discrimination against women and girls is an important basic cause of malnutrition. The very high rates of child malnutrition and low birth weight throughout much of South Asia are linked to such factors as women's poor access to education and their low levels of participation in paid employment compared with other regions. Women comprise 70% of the world's poor. Eighty percent of the world's refugees are women and children. And as stated by Her Excellency Mary Robinson, U.N. High Commissioner for Human Rights, "Bonded labour and the traffic in women and children have become our modern day versions of slavery." More than 1 million children, mostly girls, are forced into prostitution every year. Psychology is uniquely qualified to address the causes and consequences of these problems. Additionally, psychology has made substantial contributions in the assessment, intervention, and treatment of women who have experienced human rights violations.

Sample Objectives

1. To become more knowledgeable about global human rights and the United Nations Universal Declaration of Human Rights

2. To become more knowledgeable concerning the major human rights violations experienced by women across the globe including the United States.

3. To examine the unique concerns of women and why these concerns are often omitted from discussions of global human rights.

4. To examine the importance of understanding the psychosocial context including religious and national context when evaluating women's' human rights.

5. To become more knowledgeable concerning methods of intervention, assessment, and treatment in regards to women survivors of human rights violations.

6. To further develop library and cybrary research skills.

Suggested International Readings

Beyani, C. (1995). The needs of refugee women: A human-rights perspective. *Gender and Development, 3*, 29-35.

Discusses the special needs of refugee and displaced women including sexual exploitation and rape.

Bhavnani, K-K., & Davis, A. (1997). Fighting for her future: Reflections on human rights and women's prisons in the Netherlands. *Social Identities, 3*, 7-32.

Compares U.S. and Dutch prisons for women highlighting the progressive nature of women's prisons in the Netherlands due to their commitment to human rights principles.

Chapman, J. R. (1990). Violence against women as a violation of human rights. *Social Justice, 17*, 54-70.

Provides data on the severity and extent of violence against women around the world. Discusses the unique characteristics of violence against women as a human rights concern.

Cole, E., Espin, O. M., & Rothblum, E. D. (Eds.). (1992). *Refugee women and their mental health: Shattered societies, shattered lives.* Binghamton, NY: Harrington Park Press.

A collection of essays dealing with the special needs of women refugees. Written both by mental health care professionals and women refugees noting that these categories are not mutually exclusive. Includes information concerning the challenges and rewards of work with refugee women, psychological concerns and treatment, and the path to healing.

Cook, R. J. (1993). International human rights and women's reproductive health. *Studies in Family Planning, 24*, 73-86.

Argues for women's access to reproductive health services and that obstruction to such services is a form of systematic gender discrimination.

Cook, R. J. (Ed.). (1994). *Human rights of women: National and international perspectives.* Philadelphia: University of Pennsylvania Press.

Collection of essays concerning human rights of women including discussions of domestic violence and female genital mutilation.

El Dawla, A. S. (1999). The political and legal struggle over female genital mutilation in Egypt: Five years since the ICPD. *Reproductive Health Matters, 7*, 128-136.

This article evaluates the progress made towards the elimination of female genital mutilation after the International Conference on Population and Development in Cairo, Egypt.

Fraser, A. S. (1999). Becoming human: The origins and development of women's human rights. *Human Rights Quarterly, 21*, 853-906.

A historical analysis of the development of women's human rights. Includes a discussion of the current status of women under the Taliban.

Jeffreys, S. (1999). Globalizing sexual exploitation: Sex tourism and the traffic in women. *Leisure Studies,18*, 179-196.

Discussion of the sex tourism industry and its human rights ramifications.

Grewal, I. (1999). "Women's rights as human rights": Feminist practices, global feminism, and human rights regimes in transnationality. *Citizenship Studies, 3*, 337-354.

Argues that an examination of women's rights within the context of human rights must be examined on a local and cultural level, and perhaps more appropriately as issues of economic and social justice.

Human Rights in China (1996). Caught between tradition and the state: Violations of the human rights of Chinese women. *Women's Rights Law Reporter, 17*, 285-307.

Highlights the many factors impacting the rights of women in China. Provides an excellent example why the human rights of women must be examined within cultural and national contexts.

Lykes, M. B., Brabeck, M. M., Ferns, T., & Radan, A. (1993). Human rights and mental health among Latin American women in situations of state-sponsored violence. *Psychology of Women Quarterly, 17*, 525-544.

Important work that emerged from the efforts of the Division 35 (Psychology of Women) task force on human rights and the mental health of Latin American women living in situations of war or state-sponsored violence or both. Areas emphasized include refugee and internal displacement issues, the impact of torture, and methods of culturally appropriate intervention.

Meyer, M. K. (1998). Negotiating international norms: The Inter-American Commission of Women and the Convention on Violence Against Women. *Aggressive Behavior, 24*, 135-146.

Reports on the work of the Inter-American Commission of Women particularly in relation to the passing and implementation of the Convention on Violence Against Women.

Nichols-Casebolt, A., Krysik, J., & Hermann-Curie, R. (1994). The povertization of women: A global phenomenon. *Affilia, 9*, 9-29.

Examines the effect of poverty on women globally.

Oloka-Onyango, J. & Tamale, S. (1995). "The personal is political," or why women's rights are indeed human rights: An African perspective on international feminism. *Human Rights Quarterly, 17*, 691-731.

An interesting article that discusses the need for an examination of women's human rights within the context of nation and religion but also as a universal concern.

Peters, J., & Wolper, A. (1995). *Women's rights, human rights: International feminist perspectives.* New York: Routledge.

Wonderful collection of essays concerning women and global human rights. Includes sections focusing on regional reports, law, culture, violence and health, socioeconomic development, and unique victim groups.

Rasekh, Z., Bauer, H. M., Manos, M. M., & Iacopino, V. (1998). Women's health and human rights in Afghanistan. *JAMA: Journal of the American Medical Association, 280*, 449-455.

Research report discussing the health and human rights concerns of women under Taliban rule.

Reichert, E. (1998). Women's rights are human rights: Platform for action. *International Social Work, 41*, 371-284.

Discussion of the violence against women as a violation of human rights.

Stiglmayer, A. (Ed.). (1994). *Mass rape: The war against women in Bosnia-Herzegovina*. Lincoln, NE: University of Nebraska Press.

Essays confronting the causes, functions, and effect of mass rape in Bosnia-Herzegovina. Essays include historical information, challenges to traditional theories of rape, and the voices of victims and perpetrators.

Tang, K-L., & Cheung, J. T-Y. (2000). Guaranteeing women's rights: The U.N. Women's Convention. *International Social Work, 43*, 7-20.

A discussion of the United Nations Convention on the Elimination of All Forms of Discrimination Against Women (the Women's Convention) and the barriers to full implementation of this international agreement.

Tomasevski, K. (1998). Rights of women: From prohibition to elimination of discrimination. *International Social Science Journal, 50*, 545-558.

Interesting article discussing the barriers to attainment of equal human rights for woman globally.

Turshen, M., & Twagiramariya, C. (Eds.). (1998). *What women do in wartime: Gender and conflict in Africa.* London: Zed Books.

Excellent collection of essays concerning African women's experiences of war. Discusses the complexity of women's experiences as participants during wartime and as refugees escaping violence. Scholarly analysis of the cultural context is interwoven with the writings and words of African women. Includes the difficult topics of mass rape, sexual torture, and sexual slavery. The text goes beyond, however, the view of women solely as victims to include discussion of women as soldiers, guerilla fighters, as well as agents for positive change.

Whelan, D. (1994). Women, AIDS, and development. *Peace Review, 6,* 333-337.

An analysis of the relationship between women's economic dependence and risk for HIV infection.

Suggested International Videos

Annapurna Mahila Mandal: An Experiment in Grassroots Development for Women - Documentary featuring Annapurna Mahila Mandal efforts to organize a women's work cooperative. This cooperative began with 14 women involved in and now has over 10,000 members.

Approach of Dawn - Documents the human rights struggles of Mayan women of Guatemala.

Beyond the Veil: Are Iranian Women Rebelling? - Interesting undercover documentary examining Iranian women's feelings and perceptions concerning Islamic law.

Conversations with Women from the Third World - Interviews with women from Nigeria, Kenya, and India.

Kamala and Raji - Documentary exploring the lives of two working women in India.

Refugee Women: The Courage to Move Onward - This documentary concerns the plight of women refugees.

Regret to Inform - Documentary highlighting the experiences of American and Vietnamese women who lost their husbands during the war in Vietnam.

Sexual Harassment 9 to 5 - Examines the impact of sexual harassment in the workplace.

To Be a Mother in Latin America - This documentary examines reproductive rights and parenting in Latin America.

The Women's Bank of Bangladesh - Documentary focusing on the efforts of the Grameen bank to provide women with small-business loans and the impact of this effort on the lives of these women and their families.

You Can't Beat A Woman - This documentary consists of interviews with women survivors of violence from around the world as well as a range of professionals and scholars.

A Psicologia no Brasil: Um Ensaio Sobre suas Contradições

Psychology in Brazil:
An Essay on its Contradictions

La Psicología En El Brasil:
Un Ensayo Sobre Sus Contradicciones

Mitsuko Aparecida Makino Antunes

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Artigo

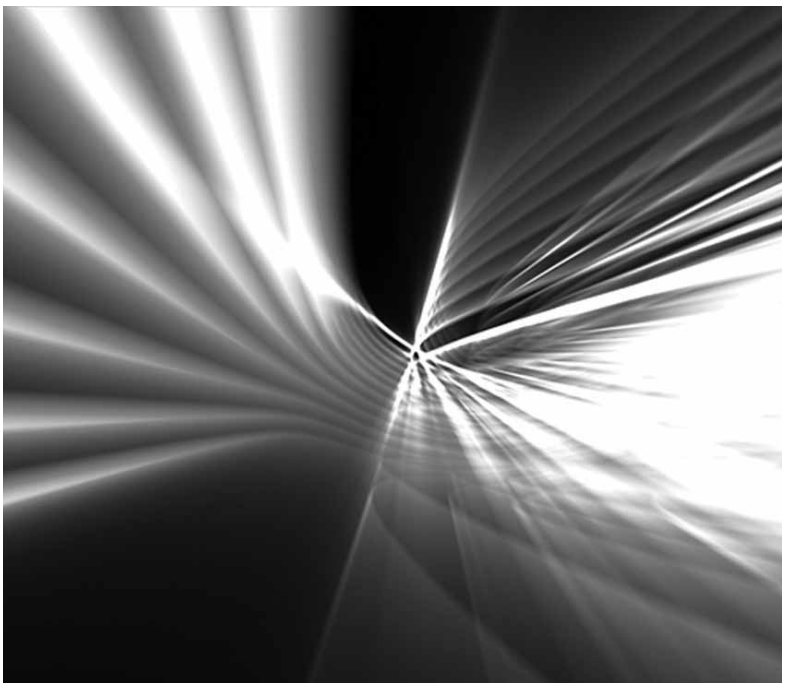

Resumo: Este artigo tem a finalidade de expor o percurso histórico da Psicologia no Brasil na perspectiva da tridimensionalidade do tempo, entendendo que a apreensão de sua concreticidade implica a compreensão do passado, que estrutura o presente e se projeta para o futuro. A compreensão da historicidade da Psicologia no Brasil como construção social, neste texto, tem como foco a análise das contradições que estiveram presentes nos diversos períodos, como condição para a compreensão das possibilidades de superação que permitiram saltos de qualidade no desenvolvimento da Psicologia, quer como conhecimento, quer como prática. Serão apresentadas, para cada período da história da Psicologia no Brasil, uma breve descrição de suas características e a análise de algumas produções, sejam elas teóricas, sejam práticas, que revelam suas contradições, sobretudo o confronto das concepções coexistentes em um mesmo tempo histórico, que demonstram o processo constitutivo dos saberes psicológicos e da Psicologia no Brasil a partir de distintos posicionamentos sociopolíticos e epistemológicos. Busca-se contribuir para a compreensão da constituição da Psicologia no Brasil a partir da dinâmica engendrada pelas e nas contradições históricas dessa área do saber, entendida como construção eminentemente social.
Palavras-chave: História da Psicologia- Brasil. Contradição. Construção do conhecimento. Memória

Abstract: This essay has the aim to explain the historical route of psychology in Brazil in the perspective of the tridimensionality of time, assuming that this aprehension implies the understanding of the past, that structures the present and projects itself into the future. The comprehension of psychology historicity in Brazil as a social construction has as focus the analysis of the contradictions that were present in the various periods, as a condition for the comprehension of the transcendence of the possibilities that permitted better quality in the development of psychology, be it knowledge, be it practice. A short description of the characteristics and the analysis of some productions, theoretical or practical, will be presented, revealing the contradictions of each period of the history of psychology in Brazil, mainly the confrontation of the conceptons present in the same historical time, that demonstrate the process that constitutes the psychological knowledge and psychology itself in Brazil from the dynamic generated by the historical contradictions of this area, which is seen as a social construction.
Keywords: History of psychology - Brazil. Contradiction. Knowledge construction. Memory.

Resumen : Este artículo tiene la finalidad de exponer el recorrido histórico de la psicología en el Brasil en la perspectiva de la tridimensionalidad del tiempo, entendiendo que la aprensión de su carácter de concreto implica la comprensión del pasado, que estructura el presente y se proyecta para el futuro. La comprensión de la historicidad de la psicología en el Brasil como construcción social, en este texto, tiene como foco el análisis de las contradicciones que estuvieron presentes en los diversos períodos, como condición para la comprensión de las posibilidades de superación que permitieron saltos de calidad en el desarrollo de la Psicología, ya sea como conocimiento, o como práctica. Serán presentadas, para cada período de la historia de la psicología en el Brasil, una breve descripción de sus características y el análisis de algunas producciones, sean ellas teóricas o prácticas, que revelan sus contradicciones, sobre todo el enfrentamiento de concepciones coexistentes en un mismo tiempo histórico, que demuestran el proceso constitutivo de los saberes psicológicos y de la psicología en el Brasil a partir de distintos posicionamientos sociopolíticos y epistemológicos. Se busca contribuir para la comprensión de la constitución de la psicología en el Brasil a partir de la dinámica engendrada por las y en las contradicciones históricas de esa área del saber, entendida como construcción eminentemente social.
Palabras clave: Historia de la psicología- Brasil. Historia de la contradicción. Construcción del conocimiento. Memória

Se as verdades científicas fossem definitivas, a ciência teria deixado de existir como tal, como investigação, como novas experiências, reduzindo-se a atividade científica à repetição do que já foi descoberto. O que não é verdade, para felicidade da ciência. Mas, se nem mesmo as verdades são definitivas e peremptórias, também a ciência é uma categoria histórica, um movimento em contínua evolução

(Antonio Gramsci).

Neste ano, comemoram-se 50 anos da regulamentação da profissão de psicólogo no Brasil. As datas expressas em números *redondos* são objetos especiais de comemoração. Comemorar significa lembrar, trazer à memória, recordar, o que remete à reflexão sobre a constituição da Psicologia: suas raízes, seu estado atual e seus anseios e projetos para o futuro. Parte-se, assim, da ideia de que "a tridimensionalidade do tempo se desenvolve em todas as épocas: agarra-se ao passado com seus pressupostos, tende para o futuro com suas consequências e está radicada no presente pela sua estrutura" (Kosik, 1978, p. 217). Assim, aos 50 anos da Lei 4119, de 27 de agosto de 1962, que regulamentou a profissão de psicólogo e estabeleceu os cursos para sua formação no Brasil, muitas têm sido as iniciativas para se refletir sobre a psicologia em seus múltiplos aspectos: produção de conhecimento, atuação profissional, ensino, organização, entre outros."

Se se entende o conhecimento como construção histórica e social, engendrado nas relações que se estabelecem entre os homens, determinadas nas sociedades de classe por interesses antagônicos, a compreensão da Psicologia em sua historicidade implica identificar e compreender as contradições inerentes à sua produção no fluxo da História. Assim, este artigo tem como finalidade apresentar um breve relato acerca do percurso histórico da Psicologia no Brasil, tendo como foco de análise algumas das muitas contradições presentes em seu processo de constituição. Como suporte a essa ideia, pode-se recorrer, por analogia, à afirmação de Gramsci, ao defender que não é possível um conhecimento crítico sobre a realidade que prescinda de sua compreensão histórica; diz ele:

> Não se pode separar a 'filosofia' da 'história da filosofia', nem a 'cultura' da 'história da cultura'. Não podemos ser filósofos (...) sem a consciência da nossa historicidade, da fase de desenvolvimento por ela representada e do fato de que ela está em contradição com outras concepções ou com elementos de outras concepções. A própria concepção do mundo responde a determinados problemas colocados pela realidade, que são bem determinadas e 'originais' em sua atualidade. (1984, p. 13)

Não se pretende, aqui, traçar um resumo da história da Psicologia no Brasil, mas expor algumas realizações, buscando mostrar como a contradição é inerente à realidade; conhecê-la é, portanto, um imperativo para aqueles que pretendem apreender a realidade concreta. No caso da Psicologia no Brasil, faz-se necessário compreendê-la como construção histórica e social, síntese de múltiplas determinações, orientada por determinadas concepções de homem e de sociedade e comprometida com posições de classe e, portanto, contraditória, sendo que o embate entre esses elementos que se opõem produz movimento e possibilita superação. Para isso, serão expostos alguns elementos da história da Psicologia no Brasil e suas contradições, como alternativa a uma narrativa cronológica construída de datas e nomes, na tradição da historiografia positivista, assim como uma leitura *presentista*, tal como criticada por Schaff (1978) e cujas consequências vão da negação da possibilidade de se conhecer o passado à sua banalização, que interpreta o passado a partir dos registros históricos e axiológicos do presente.

A produção de saberes psicológicos no período colonial e no século XIX

Deve-se entender que o período colonial no Brasil está articulado à expansão comercial europeia, uma das condições para o desenvolvimento do modo de produção capitalista. Mais especificamente, o Brasil, sob o domínio dos portugueses, constituiu-se como colônia de exploração. A espoliação das riquezas coloniais baseava-se no monopólio da metrópole, que determinava o que deveria ser produzido, a maneira de fazê-lo e a apropriação de seus produtos. A imensa riqueza obtida pela força de trabalho escrava na agricultura (baseada em latifúndios) ou na mineração garantiu às classes dominantes das metrópoles uma vida de luxo e opulência.

A organização da empresa colonial exigia, de um lado, um forte aparato repressivo (seja para a contenção de revoltas internas, seja para a defesa do território contra a invasão de outros países europeus) e, de outro lado, um sólido aparato de ordem ideológica, com a finalidade de transmitir, impor e manter ideologias que, em última instância, justificavam e legitimavam a exploração colonial.

No âmbito do aparato ideológico, a Companhia de Jesus assumiu importante função, mantendo sua influência mesmo após

sua expulsão de Portugal e de suas colônias no quadro das reformas pombalinas. Muitos jesuítas ocuparam-se de produzir e difundir conhecimentos que tinham como função organizar e manter a empresa colonial. A mais conhecida tarefa jesuítica no Brasil, porém, relaciona-se com a educação, mais precisamente, com a educação dos filhos dos colonos portugueses, com base em seu programa de estudos, o *Ratio Studiorum*, que tinha a finalidade de prepará-los para o seguimento dos estudos na metrópole, e a educação elementar e a catequese para os filhos dos nativos da terra.

O processo catequético e a educação das primeiras letras para os indígenas têm sido vistos como expressão de uma pedagogia repressiva, baseada em castigos, com vistas à disciplinarização e controle, com base na psicologia moral da época. Em seus estudos sobre a história da criança no Brasil, afirma Priore (1991, p. 13):

> Fortemente arraigada na psicologia de fundamento moral e religioso comum da época, e na capacidade impressionista que se desdobrou em autos sacramentais alegóricos, 'musicarias' e sermões recendendo a temor e estremecimento religioso, a fala dos jesuítas sobre educação e disciplina tinha gosto de sangue"

Em outras palavras, tratava-se, para a autora, de uma pedagogia do medo: (...) Junto à pedagogia do novo saber ocidental cristão, necessário era também impor-lhe uma pedagogia do medo que inspirasse desapreço pela carne e pelas necessidades físicas (...). A 'disciplina' tornou-se uma das cenas recorrentes do grande espetáculo que foi a catequese" (1991, pp. 21-22).

Estudos específicos sobre os saberes psicológicos no período colonial foram realizados por Massimi (1997, 1990, 2004), nos quais os jesuítas comparecem, na condição de educadores, como protagonistas de profícua produção de conhecimento. Segundo a autora,

> A educação é reconhecida pelos religiosos – imbuídos pelo espírito da pedagogia humanista – como instrumento privilegiado para criar um homem novo e uma nova sociedade no Novo Mundo. Por isso, a educação das crianças e a criação de escolas se constituíram os objetivos prioritários do plano missionário da Companhia no Brasil. Esse empreendimento acarretava a necessidade de formular conhecimentos e práticas de caráter pedagógico e psicológico (Massimi, 2004, p. 29)

Muitos jesuítas foram indubitavelmente ideólogos privilegiados da metrópole portuguesa. Destaca-se, nos estudos de Massimi (1997, 1990), a preocupação com a disposição para o trabalho e com a aculturação de indígenas, com o controle ou *cura* das emoções, que, em alguns casos, remetem à solução de problemas de ordem moral enfrentados pela colonização, assim como, em especial, a educação, pela difusão da ideologia dominante, pela catequese de indígenas ou pelo empenho na formação de quadros para a administração colonial.

Como ilustração, os dados de Berenchtein Netto (2012), obtidos em seu estudo sobre o suicídio na colônia, mostram que muitos escritos, dentre eles vários de autoria de jesuítas, tinham a finalidade de inibir o ato da morte voluntária, com base na danação eterna como punição ao pecado, sobretudo de indígenas, em um primeiro momento, mas principalmente de escravos africanos ou de seus descendentes, que encontravam na morte voluntária a possibilidade de fuga das condições desumanas de vida a eles impostas.

Entretanto, alguns jesuítas assumiram e defenderam concepções políticas e teóricas, muitas das quais podem ser consideradas saberes psicológicos, que entraram em confronto com esses mesmos interesses.

Massimi (1997, 1990) faz referência a várias obras produzidas no período colonial que contêm inegável caráter de originalidade, nas quais são encontrados elementos que se aproximam do que viria a ser a prática psicoterápica, estudos sobre a criança e sua educação, necessidade de se reconhecer a função do meio na aprendizagem e no desenvolvimento, reconhecimento da capacidade intelectual da mulher e consequente defesa de criação de escolas femininas e, inclusive, concepções que articulavam a prática médica e o conhecimento do psiquismo. Dentre os autores, encontram-se Alexandre de Gusmão (pedagogo, jesuíta) e Manoel de Andrade Figueiredo (calígrafo, de formação jesuítica), defensores da instrução feminina; Feliciano de Souza Nunes (filósofo), que nega a ideia corrente acerca da inferioridade mental da mulher; Azeredo Coutinho (bispo e economista), que propõe metodologia específica para a instrução feminina, nos Estatutos do Recolhimento de Nossa Senhora da Glória, primeiro colégio feminino brasileiro, fundado em 1802 (fechado em seguida), e que custou a seu idealizador a retirada compulsória para Portugal. A título de ilustração, seguem abaixo alguns trechos das obras desses autores:

> (...) Não só têm as mulheres a mesma aptidão e capacidade de entendimento e discurso, que nos homens se acham, senão também que sem comparação os excederiam se as aplicassem às artes e ciências a que eles ordinariamente se aplicam; e que 'ex-vi' disto, seriam tanto mais úteis e admiráveis, quanto nas operações do discurso melhor fossem instruídas (Feliciano de Souza Nunes, 1758 como citado em Massimi, 1997, pp. 109-110)

> "Com este (o menino rude) deve o prudente mestre usar de menos rigor no castigo, pois vemos que o demasiado mais lhe redunda em ruina, do que em proveito; porque afflicto de não poder perceber a lição e temeroso ao mesmo tempo do castigo, que o intimida, e mortifica, lhe confundem estas considerações, de tal sorte, o fragil entendimento, que confuso e aereo, muitas vezes succede, que abraçando o medo natural, se ausenta e foge da escola; e com estes melhor he que o mestre se mostre mais respectivo, que justiceiro, levando-os com castigo moderado, e ás vezes fingindo, applicando-lhes a grandeza da lição, segundo a capacidade dos talentos, até de lhes irem purificando os nervos da rudeza e alcançarem, com o exercício, mais clareza de engenho (Manoel de Andrade Figueiredo, 1722 como citado em Massimi, 1997, p. 105)

> (...) Assim como todos os acertos se atribuem aos mestres que ensinão, e não aos discipulos que aprendem, assim tambem os erros que se achão nos mininos, são nodoas, que se poem na fama dos mestres, que não ensinarão bem (Manoel de Andrade Figueiredo, 1722 como citado em Massimi, 1997, p.105)

As contradições podem ser verificadas de maneira mais clara nas posições políticas de alguns autores que entraram em confronto com a metrópole, ainda que alguns deles tivessem relações diretas e amigáveis com a coroa portuguesa, como foi o caso de Padre Vieira, que não apenas defendeu judeus convertidos e não convertidos (um dos motivos para sua intimação pelo Tribunal do Santo Ofício, o que lhe custou a detenção e, posteriormente, a prisão domiciliar) mas também se posicionou contra a escravização de indígenas e de africanos, denunciando a barbárie das condições de trabalho e de vida impostas a eles no Brasil, destacando as sevícias impostas sobretudo aos escravos negros.

No Sermão da Epifania, diz Padre Vieira, em defesa de suas ideias acerca do tratamento dado aos indígenas pelos colonos portugueses:

> Toda a causa de nos perseguirem aqueles chamados cristãos, é porque fazemos pelos gentios o que Cristo fez pelos Magos (...) querem que tragamos os gentios à fé e que os entreguemos à cobiça; querem que tragamos as ovelhas ao rebanho e que as entreguemos ao cutelo; querem que tragamos os Magos a Cristo e que os entreguemos a Herodes. E porque encontramos esta sem-razão, nós somos

> os desarrazoados; porque resistimos a esta injustiça, somos nós os injustos; porque contradizemos esta impiedade, nós somos os ímpios (...) (Vieira, citado por Pais, 2010, p. 67)

No Sermão Vigésimo Sétimo, diz Padre Vieira, em defesa dos negros escravos:

> Outra razão é serem também homens os que são escravos. Se a fortuna os fez escravos, a natureza fê-los homens; e por que há de poder mais a desigualdade de fortuna para o desprezo que a igualdade da natureza para estimação? Quando o desprezo a eles, mais me desprezo a mim; porque neles desprezo o que é por desgraça, e em mim o que sou por natureza.
>
> A esta razão forçosa em toda parte se acrescenta outra no Brasil, que convence a injustiça e exagera a ingratidão. Quem vos sustenta no Brasil, senão vossos escravos? Pois se eles são os que vos dão de comer, porque lhe haveis de negar a mesa, que é mais sua que vossa? Contudo a majestade, ou desumanidade da opinião contrária, é a que prevalece, e não só não são admitidos à mesa, mas nem às migalhas dela, sendo melhor a fortuna dos cães que a sua, posto que sejam tratados com o mesmo nome (...) (Vieira, citado por Pais, 2010, p. 63)

Essas são somente algumas ilustrações que mostram que os saberes psicológicos na colônia não são homogêneos, mas internamente contraditórios, e expressam as relações de exploração da metrópole sobre a colônia. Percebe-se que os saberes psicológicos compõem-se de ideias que dão sustentáculo à empresa colonial e de ideias a estas contrapostas, que também se manifestam em sua originalidade na perspectiva do conhecimento sobre o fenômeno psicológico.

Pode-se dizer que o entendimento dessas contradições do processo de colonização é fundamental para a compreensão das contradições dos saberes psicológicos – instâncias que constituem uma totalidade – e que estas são fundamentais para a apreensão da história da Psicologia no Brasil a partir de seus processos constituintes, isto é, do movimento que se produz a partir do embate de forças contrárias. Afirma Antunes:

> Essas ideias são faces de uma mesma realidade, pois refletem as contradições da formação social em questão. Assim, é possível compreender a originalidade de várias ideias psicológicas como tendo surgido do fato de que, em busca de soluções para alguns problemas, a criatividade tornou-se um imperativo; as necessidades impostas pela realidade exigiram soluções que, ao mesmo tempo que buscavam a manutenção da ordem estabelecida, também se constituíam em forças impulsionadoras do real em direção ao futuro, ou ainda, poderiam estar articuladas às forças que colocavam em questão o próprio *status quo*, no sentido da busca de uma nova ordem, o que pode ser confirmado pelo fato de que vários autores estudados por Massimi tiveram em uma ou outra ocasião problemas com o poder metropolitano ou com a Inquisição (2007, p.22)

Com o fim da condição colonial, o Brasil sofreu, a partir do início do século XIX, profundas transformações econômicas, políticas e sociais com a instalação da Corte no Rio de Janeiro, e, posteriormente, à guisa de independência em relação à coroa portuguesa, com a instauração da condição imperial. Com isso, houve a necessidade de formação de quadros para o aparato repressivo e administrativo, este último implicando maior preocupação com a educação e o ensino. A criação de cursos superiores, a impressão de livros e a instalação de várias instituições são exemplos das mudanças ocorridas no Brasil, pelo menos em seus núcleos urbanos.

O século XIX foi profícuo na produção de saberes psicológicos, mantendo muitas das preocupações do período colonial, porém, assumindo um caráter mais sistemático pela gradativa vinculação institucional e pela melhor elaboração dos conteúdos. As questões sociais tornaram-se o principal foco

de interesse médico ou pedagógico, fonte das preocupações com o fenômeno psicológico, o que não lhes conferiu um caráter de compromisso social com os interesses da maioria da população, mas não livres de contradições.

Há, nesse momento, um incremento do processo de urbanização, principalmente no Rio de Janeiro e em Salvador, caracterizado pela precariedade das condições de saneamento, o que produziu graves problemas de saúde, uma das manifestações dos profundos problemas de natureza social. As elites letradas referiam-se às *imundícies* físicas e morais, estas relacionadas às várias personagens urbanas, como "leprosos, loucos, prostitutas, mendigos, vadios, crianças abandonadas, alcoólatras". Foi nessa situação que surgiu, segundo Machado, Loureiro, Luz e Muricy (1978), a Medicina social, mais preocupada com a *saúde* do que com a *doença*, com a prevenção do que com a cura, pautando-se nos ideais de normalização e higienização social, com vistas à eliminação da desordem e dos desvios, sendo proposta, nesse sentido, a higienização de hospitais, cemitérios, quartéis, bordéis, prisões, fábricas e escolas.

Deve-se sublinhar que uma diferença em relação ao período anterior está no fato de que os indígenas, antes um dos mais importantes focos dos autores da época, deixam de certa forma o cenário das preocupações, dando lugar, no século XIX, à preocupação com os afrodescendentes. Uma das possíveis explicações para isso é o fato de que, no período colonial, o indígena constituía um problema para o colonizador, uma vez que aquele não se dobrava às condições necessárias impostas pela empresa colonial, particularmente a submissão ao trabalho escravo. Nativo desta terra, tendo sobre ela o domínio e não podendo ser apartado de sua cultura, o indígena podia resistir mais fortemente às investidas dos colonos portugueses. Diferente foi, porém, a condição dos africanos e afrodescendentes, que, apartados de sua terra, cultura, língua, tribo, estavam fragilizados não apenas pela força física mas, sobretudo, pela força do impedimento de suas expressões socioculturais. A solução do colonizador para o indígena foi sua eliminação física. A solução dos escravos africanos para a escravidão foi construir lenta e gradativamente uma forte base de resistência.

Em outras palavras, no século XIX, o indígena já não mais representava um problema para o colonizador. O problema era, então, o afrodescendente, que, livre ou sujeitado ainda à escravidão, já não mais correspondia às necessidades de força de trabalho para o novo ciclo econômico, agora deslocado para o sudeste do País, para a cafeicultura. A isso somam-se as ideias racistas, cada vez mais fortes e elaboradas, preocupadas em garantir não só a supremacia étnica de base europeia mas também em segregar ou eliminar a presença de outras origens étnicas e raciais na formação social brasileira. Coube ao pensamento científico, representado principalmente pelo poder médico, construir o discurso que sustentava tais ideias, dentre estas, muitas relacionadas ao fenômeno psicológico.

É preciso considerar que os problemas enfrentados pelo Império eram diversos e profundos. Leite, com base em memórias e livros de viagem, faz um estudo sobre as condições vistas e registradas nessas obras; afirma ela:

> Quanto às memórias, elas são fontes preciosas de conhecimento das relações interpessoais e das variedades de contatos étnicos e de camadas sociais. Três questões atravessavam essas relações: o sistema escravista de trabalho, a educação informal e a fragilidade da vida humana no período, ou seja, o alto índice de morbidade e mortalidade (2009, pp. 24-25)

Diz ainda a autora que "as memórias mostram aspectos internos e às vezes marcas psicológicas deixadas por essa presença de morte no cotidiano das famílias" (2009, p.25).

Percebe-se, pois, que o Brasil do século XIX, embora tivesse deixado a condição colonial, seguia imerso em profundos e graves problemas de diversas ordens, particularmente de caráter social. Por outro lado, nesse momento, o Brasil, agora nação formalmente considerada *autônoma*, adquiria maior facilidade de contato com outros países, o que facilitava a penetração de ideias correntes na Europa, especialmente na França, indiscutível centro intelectual da época. Por isso, o desenvolvimento do pensamento psicológico no Brasil, no século XIX, deve ser visto também a partir dos intercâmbios intelectuais com países estrangeiros.

Na Europa, no século XIX, os progressos da Filosofia e da Fisiologia começaram a caminhar em direção a uma possível síntese, conformando o que seria mais propriamente focado no fenômeno psicológico. Nesse momento, as mudanças ocorridas na Europa, decorrentes do avanço do modo de produção capitalista, criaram desafios e necessidades que precisavam ser respondidas. Necessitava-se de conhecimentos efetivos para melhor compreender tais problemas e sobre eles intervir, em busca de seu controle, especialmente sobre a conduta humana. Deve-se lembrar que a ideologia burguesa tinha no indivíduo o fundamento de uma sociedade baseada na propriedade privada, impondo a necessidade de se compreender o homem nessa perspectiva. Mais do que isso, as condições de exploração da classe trabalhadora precisavam ser justificadas e legitimadas por uma sociedade que afirmava a igualdade de direitos e a mobilidade social, que encontrava nas diferenças individuais a explicação para a desigualdade e para a exploração de uma classe por outra. Faz-se necessário também lembrar que uma sociedade alicerçada na divisão social do trabalho e no avanço técnico caminhava para a especialização do conhecimento. Estavam dadas, assim, as condições para que a Psicologia pudesse delimitar-se como área específica de conhecimento, conquistando, dessa forma, o estatuto de ciência autônoma.

Essas condições próprias da Psicologia, os problemas internos brasileiros e o acesso às ideias produzidas na Europa foram fundamentais para ampliar a produção dos saberes psicológicos no Brasil no século XIX, sustentados principalmente na Medicina e na educação.

As Faculdades de Medicina do Rio de Janeiro e da Bahia, criadas originalmente como cadeiras em 1808 e que passaram à condição de faculdades em 1832, foram algumas das muitas instituições que contribuíram para a produção dos saberes psicológicos no Brasil. A defesa de uma tese inaugural ao final do curso era obrigatória, e essas teses foram uma das mais profícuas fontes de estudo dos fenômenos psicológicos no interior da Medicina no século XIX.

Como já foi dito, muitos dos representantes da Medicina assumiram, nesse momento, uma função de controle social, com vistas à normalização e à higienização da sociedade, defendendo posições explícitas a favor da exclusão social, e até mesmo prescrevendo a reclusão daqueles considerados socialmente indesejáveis para as camadas dominantes e seus interesses. Assim foi também com muitas teses produzidas nesse período, das quais muitas relacionadas às questões psicológicas. Além das teses, encontram-se outros escritos produzidos por médicos, como livros, artigos em revistas e jornais e transcrição de conferências, nos quais é também recorrente a presença de temas de natureza psicológica, muitos dos quais apresentavam e defendiam

ideias semelhantes.

Fraga Filho, por exemplo, ao tratar das condições sociais na Bahia do século XIX, com foco nos "mendigos, moleques e vadios", salienta o discurso médico cujo caráter é moralizante, higienizador e normalizador. O autor faz referência à tese do médico Antônio Ribeiro Gonçalves, defendida em 1902 (mas relativa às condições próprias ainda do século XIX), sobre a qual afirma:

> Aqui o saber especializado e científico do médico apontava os aspectos nocivos da exposição desses menores à vida de rua. Foi o discurso médico que atribuiu a esses meninos maior grau de periculosidade. Inspirado em Lombroso, sustentava Ribeiro Gonçalves que eles eram de caráter 'profundamente viciado', familiarizados com as 'depravações mais baixas' e potencialmente inclinados para a criminalidade. Inquietava as autoridades e os bem pensantes o fato de que a rua os estivesse amestrando na vadiagem, o que não era nada alentador para quem se empenhava pela ordem pública e a moralização dos costumes (1996, p.115)

Entretanto, em meio a essas publicações que expressavam um posicionamento a favor de ideias e práticas excludentes, encontram-se, ainda que em expressa minoria e contraditoriamente, trabalhos que assumiram outras perspectivas.

Rocha faz referência à produção de alguns médicos baianos, dentre os quais Abílio Cesar Borges, o Barão de Macahubas, cujas ideias se contrapõem àquilo que era dominante na época, em particular, nos círculos médicos e, sobretudo, educacionais. Segundo a autora, esse médico destacou-se como um dos grandes educadores de sua época, "(...) tinha uma forma peculiar e diferenciada com relação à educação, advogando a abolição do castigo físico e a valorização dos corpos docente e discente" (2004, pp. 99-100). Como Diretor Geral da Instrução na Bahia, pretendia a valorização de professores e alunos e a eliminação dos castigos físicos na escola, mas, incompreendido, exonera-se e funda o Gymnasio Bahiano; foi um dos primeiros intelectuais a se preocupar com a educação de alunos com deficiência intelectual e a defender a instalação de uma cadeira de Linguagem Articulada para educandos surdos. Afirma a autora sobre o médico Abílio Cesar Borges:

> Dr. Abílio não somente remodelou os métodos e os processos de ensino e transformou o tirocínio escolar, mas também modificou os compêndios então adotados. Imaginou um processo de leitura que apelidou 'leitura universal', para demonstrar a eficiência e quanto merecia cuidados o problema do analfabetismo em sua pátria (2004, p. 101)

Outras produções certamente poderiam ilustrar as contradições desse período, mostrando que havia embate de ideias e práticas articuladas a interesses diversos e muitas vezes antagônicos, que provocavam movimentos que, certamente, concretizaram transformações no seio da sociedade em geral e dos saberes psicológicos em particular. Muitos movimentos sociais ocorreram no Brasil no século XIX, o que mostra movimento em busca de superação das condições sociopolíticas dadas e que certamente tiveram reflexos na produção intelectual; o estudo dessas ideias poderá contribuir para ampliar a compreensão dos saberes psicológicos no século XIX e suas condições de produção e afiliação ideológica.

O processo de autonomização da psicologia

Esse período, que vai do final do século XIX ao início dos anos 30, deve ser visto necessariamente como processo que vai gradativamente se engendrando ao longo do tempo, iniciando com ideias e práticas que se dão no interior de outras áreas do conhecimento

e que, aos poucos, vão se conformando como uma área autônoma, a Psicologia, tal como considerada na Europa e nos Estados Unidos. Antes disso, pode-se falar em saberes psicológicos, mas não se pode afirmar que se trate propriamente de Psicologia. Esta gradativamente conquista a condição de área específica de conhecimento e, mais tarde e como consequência, a de campo de intervenção prática. Esse processo foi determinado por fatores de ordem interna, como a necessidade de mais conhecimento acerca do fenômeno psicológico ainda no interior de outras áreas de saber ou campos de natureza prática (como a Medicina e a Educação) e, por outro lado, pela conquista do estatuto da Psicologia como ciência autônoma na Europa e nos Estados Unidos, assim como fatores de ordem externa, como as transformações da sociedade brasileira e seus velhos e novos problemas, que demandavam, por sua vez, o aprofundamento e a produção de novos conhecimentos, assim como novas modalidades e possibilidades de ação.

Nesse período, já era profícua a produção da ciência psicológica. França, Alemanha, Rússia e Estados Unidos, entre outros países, produziam relevantes pesquisas em Psicologia, assim como surgiam várias perspectivas teóricas e ampliavam-se as possibilidades de intervenção. Muitas dessas ideias foram trazidas para o Brasil por brasileiros que iam estudar e se aperfeiçoar principalmente na Europa ou por estrangeiros que vieram ministrar cursos, dar conferências ou prestar assessoria, alguns dos quais aqui se radicaram.

Nessa época, dominada política e economicamente pelos interesses dos produtores de café, movimentos sociais oriundos das camadas populares, de um lado, e das camadas médias, de outro, revelam o descontentamento e a necessidade de transformação da ordem social. Os movimentos populares foram enfrentados por forte esquema repressivo, o que não impediu a penetração de ideias como o anarquismo, o anarcossindicalismo e o socialismo, assim como a constituição de um significativo movimento organizado pelas classes trabalhadoras, do campo e das cidades. Entretanto, no âmbito das ideias que se articulam com o desenvolvimento da Psicologia, foram os movimentos dos setores intelectuais, portanto, das camadas médias, que formaram um substrato que permitiu a gradativa conformação da Psicologia como área específica de conhecimento, base necessária para as intervenções sociais articuladas a seus projetos.

A crítica ao Brasil agrário e ao atraso econômico formou a base para o projeto de um Brasil moderno e *à altura do século*, tendo a industrialização como meta. Almejava-se um novo país, o que demandaria a construção de um novo homem, adequado aos novos tempos. À educação caberia forjar esse novo homem, educação essa que deveria ser também moderna e à altura do século. É nessa condição que o escolanovismo ganhou maior sistematização e se tornou a proposta educacional alinhada ao projeto de um novo Brasil, do que decorre a adoção de uma nova Pedagogia, a Pedagogia nova, que se pretende fundamentalmente Pedagogia científica. Essa Pedagogia tem na Psicologia sua mais importante fundamentação científica. Foi nesse quadro que a área ganhou condições não apenas para se afirmar como ciência autônoma, não mais produzida no interior de outras disciplinas, mas, sobretudo, para se desenvolver e se ampliar, fundamentada no que se produzia na Europa e nos Estados Unidos. Essa condição se revela em várias instâncias, sobretudo nas Escolas Normais, que estabelecem a cátedra denominada Pedagogia e Psicologia, para a qual são criados laboratórios de Psicologia, produzidos compêndios e outras publicações, traduzidas

obras de autores estrangeiros e expandidos os conhecimentos da área como fundamentos para a prática pedagógica e a base teórica necessária a todo educador.
Muitas são as instituições que incorporaram a Psicologia como uma das áreas de estudo e de intervenção, entre elas, o *Pedagogium*, onde, em 1906, foi criado o primeiro laboratório de Psicologia no Brasil, planejado por Binet, em Paris, com a colaboração de Manoel Bomfim, que o dirigiu por cerca de quinze anos.

Os hospícios criados no século XIX se expandem no século seguinte, e muitos deles fundam laboratórios de Psicologia, que terão importante participação no desenvolvimento e no processo de autonomização da Psicologia.

Muitas foram as realizações desenvolvidas tanto no interior da Educação como da Medicina, que foram sustentáculos para que a Psicologia conquistasse o estatuto de ciência autônoma no Brasil. Demandas desses campos e possibilidades de respostas trazidas pela nova ciência foram fundamentais para esse processo.

Entretanto, é necessário compreender a que interesses serviam essas demandas e as respostas buscadas na Psicologia. No confronto com a ordem política estabelecida pelos interesses agrários, o ideário liberal constituiu a mais importante base teórica dos intelectuais e de outros membros das camadas médias descontentes com seu alijamento do poder e de suas benesses. Foi nessa condição e articulada a esses interesses que a Psicologia teve condições para se desenvolver. Ou ainda, pode-se dizer que a Psicologia que aqui se desenvolveu esteve articulada a esses interesses e a um projeto específico de modernização do País.

Jornais vinculados aos movimentos operários, de cunho anarcossindicalista ou socialista, trazem referências a questões da Psicologia e a obras na área. Estudos documentais são necessários para se conhecer melhor como a Psicologia era vista, que autores eram considerados e a que situações ela era chamada a contribuir como conhecimento específico. No entanto, a Psicologia que se estabeleceu e se institucionalizou foi a que teve origem em instituições educacionais e médicas, campos dominados por representantes das camadas médias, principalmente intelectuais.

Dessas instituições, as Escolas Normais foram os mais importantes substratos para o desenvolvimento da Psicologia. Nos anos 20, principalmente no bojo das reformas estaduais de ensino, essas escolas adotaram a Psicologia como uma das mais importantes bases científicas para reformar a educação. Nessa mesma época, são publicados os primeiros livros sobre testes, sendo que alguns desses autores estiveram ligados a essas reformas, como Isaías Alves e Lourenço Filho. De qualquer maneira, foi nessa época que se iniciou o movimento dos testes no Brasil, utilizados essencialmente como instrumentos de racionalização da prática educativa (a par com o movimento geral de racionalização, defendido principalmente como condição para a implementação e o desenvolvimento industrial), e que perdurou por décadas, apesar das críticas ao modo como foram utilizados.

Três obras[1] tratam especificamente dos testes de inteligência na terceira década do século passado. Embora o foco principal seja a aplicação desses testes à situação escolar, defende-se sua aplicação a outras situações da vida social, particularmente à indústria e ao comércio. Essa defesa ocorre em um momento em que a busca de racionalidade na gestão de escolas e de outras instituições encontra sua legitimação na objetividade e na superioridade dos produtos da ciência e das técnicas dela derivadas. Diz Alves:

> As vantagens práticas estão, entretanto, de tal modo reconhecidas, que o problema já passou, entre os povos de cultura adiantada, para o escriptorio do commerciante (...) para a direcção das fabricas (...) para o alistamento do exercito, que não pode levar às trincheiras de guerra homens apoucados de intelligencia, que se tornem peso morto, nessa terrível actividade onde o movimento intelligente é poderoso factor de Victoria, e até para a capacidade legal de cidadão, visto como no Estado de Nova York, os candidatos a eleitor são submettidos a teste de intelligencia, não podendo votar todo aquele que tenha idade mental inferior a 10, isto é, Q.I. inferior a 62 (1928, p. 122)

Medeiros e Albuquerque (1925) e Isaias Alves (1930), entre outras linhas de argumentação, recorrem à situação de guerra para demonstrar como foram desenvolvidos os testes de aplicação coletiva de inteligência, referindo-se à entrada dos EUA na Primeira Guerra Mundial como um dos marcos para a expansão da utilização dos testes. Alves também refere-se a esse episódio, citando a criação dos *Army Tests*, especialmente elaborados para a seleção de soldados para a Primeira Guerra Mundial, nos EUA. Ambos os autores consideram que a Primeira Guerra Mundial constituiu um fator impulsionador para o desenvolvimento da Psicologia e, particularmente, dos testes. Para Isaias Alves:

> A guerra foi sempre um grande impulsionador do progresso humano, por isso que, nesse terrível estado de necessidade, todas as forças da intelligencia cooperam na defeza dos grupos nacionaes, cada qual tentando superar o outro. Todas as sciencias progridem ao adejar da morte, como se o convalescer do povo devesse logo seguir às grandes chagas abertas pelos obuses, que a mechanica, a metallurgia, a geometria e a óptica, servindo-se de todas as outras, aliaram-se aos gazes, que a chimica elevou à mais culminante influencia na estratégia moderna.
> Por menos que pareça, não fugiu a sciencia psychologica a essa regra e assim é que se abriu um novo capitulo à psychologia pedagogica, ao estrugirem os clarins americanos do exercito que se mobilizou há onze annos (1930, p. 43)

Medeiros e Albuquerque explicita a função dos testes na seleção dos candidatos às Forças Armadas norte-americanas na Primeira Guerra Mundial, antecipando a maneira como os testes foram incorporados e utilizados no Brasil, principalmente no campo da educação; segundo ele,

> Precisava-se achar um criterio que descobrisse quaes os de intelligencia superior, para indical-os afim de occuparem postos de commando; descobrir tambem os que eram de intelligencia tão inferior, que só podiam servir a misteres inferiores; formar batalhões com uma certa uniformidade intellectual, onde isso fosse necessário; formar batalhões de intellectualidade superior, onde isso fosse exigido pela natureza dos serviços a executar; discriminar os que podiam servir para determinados misteres ou para receber ensino technico especial; indicar quaes os de intelligencia tão tarda, que, nas fileiras, pareceriam teimosos ou desobedientes, quando eram apenas estupidos, e finalmente excluir completamente os sub-normaes tão abaixo da normalidade que não tinham em que ser aproveitados (1925, p. 114)

No âmbito da Medicina, alguns hospícios também produziram conhecimentos em Psicologia, principalmente em seus laboratórios. Um deles foi o da Colônia de Psicopatas do Engenho de Dentro, criado em 1923, dirigido pelo psicólogo polonês Waclaw Radecki, que produziu pesquisas sobre várias questões psicológicas, como fadiga em crianças e jovens trabalhadores e seleção de aviadores e psicometria, entre outros assuntos. A Liga Brasileira de Higiene Mental, fundada em 1923, também criou um laboratório de Psicologia, considerando ser essa uma ciência afim à psiquiatria; mais tarde, essa liga articulou-se a um pensamento bastante reacionário, defendendo posições xenófobas e racistas.

1 Tests: *Introdução ao estudo dos meios scientificos de julgar a intelligencia e a applicação dos alumnos,* de 1925 (4a. ed.; não há referência à data da 1a. ed., embora o autor se refira ao ano anterior, 1924), de Medeiros e Albuquerque; *Teste individual de intelligencia*, 1928, e *Os testes e a reorganização escolar*, de 1930, ambas de Isaías Alves.

As ideias acima expostas são apenas uma pequena ilustração das articulações que se estabeleceram entre Psicologia e sociedade. Entretanto, houve produções cujo caráter divergia radicalmente da tendência hegemônica da época.

Manoel Bomfim, criador e diretor do primeiro laboratório de Psicologia no País, instalado no *Pedagogium*, e catedrático de Psicologia e pedagogia na Escola Normal do Rio de Janeiro, apresentava pensamento distinto. Além de ser crítico contundente da sociedade brasileira a partir de uma análise que identificava os problemas do Brasil na história de espoliação e exploração colonial, de combater as ideias do racismo científico e de posicionar-se politicamente contra o pensamento liberal vigente, produziu ele uma concepção psicológica original e avançada para a época. Bomfim criticava as pesquisas sobre os fenômenos psicológicos superiores realizadas em laboratório, pois, para ele, as condições restritas e artificiais deste não permitiam a apreensão da complexidade e das múltiplas determinações do psiquismo, especialmente do pensamento, por ele considerado função psíquica superior. O psiquismo era, para ele, um fenômeno de natureza histórico-social, e devia ser estudado a partir do *método interpretativo*, que deveria basear-se no estudo de suas múltiplas manifestações e apreendê-lo como parte da obra humana forjada ao longo da História. Bomfim deve ser considerado, por sua obra em geral, um intelectual que não se alinhava ao que era hegemônico na época e que antecipou muitas formulações – em Psicologia, Educação, Pedagogia, Sociologia, História, entre outras áreas de conhecimento – que só mais tarde viriam a ser desenvolvidas por outros autores e reconhecidas por intelectuais mais progressistas e críticos.

Sob a liderança de Ulysses Pernambucano, o Movimento Psiquiátrico de Recife antecipou as ideias da antipsiquiatria, que só se manifestariam décadas depois. Assumindo o cargo de diretor do Hospital de Doenças Nervosas e Mentais do Recife e participando da Assistência a Psicopatas de Pernambuco, aboliu as camisas de força e os calabouços e implantou ambulatórios e hospital aberto, dentre inúmeras outras realizações. Fundou a Liga de Higiene Mental de Recife, porém em uma direção bastante diferente das demais; aí criou ele a primeira Escola para Anormaes no Brasil, que deve ser entendida como uma iniciativa pioneira e progressista, uma vez que criança com deficiência passava a ser vista como sujeito da educação, e não mais como paciente de hospício a quem apenas restava a exclusão social pela reclusão. A prática de Ulysses Pernambucano revela que, para ele, não havia uma dicotomia entre Psicologia e psiquiatria, pois a atuação nesse campo, que hoje poderia ser denominado saúde mental, deveria ser fruto da colaboração de diferentes profissionais, o que também só muitas décadas depois viria a ser defendido. Concebia Pernambucano a doença mental como situação existencial, expressão da dinâmica psicológica do indivíduo, compreendido como sujeito ativo e constituído nas relações sociais.

Bomfim e Pernambucano representam o pensamento divergente, aquele que se contrapõe ao que é hegemônico em um dado momento. Ao se colocarem nessa perspectiva, não apenas mostram a natureza contraditória da realidade histórica e, por essa via, a dinâmica da constituição da Psicologia como ciência no Brasil, mas também oferecem concepções e possibilidades de compreensão do fenômeno psicológico que só mais tarde seriam consideradas pela Psicologia. Pode-se dizer que, no embate com forças sociais antagônicas, eles puderam superar o estado em que se encontrava a Psicologia naquele momento. Esse processo não é pontual e nem fruto de um feliz acaso, mas expressão de concepções de homem e de sociedade que determinam as formas de se conceber

a Psicologia. A coerência de suas ideias e a posição de embate com o pensamento hegemônico se confirmam no fato de que Bomfim foi alvo de duras críticas durante sua vida, pelas posições políticas e pelo combate às ideias do racismo científico então em voga entre a intelectualidade brasileira, tendo sua obra sido reconhecida só no final do século XX. Ulysses Pernambucano foi também um homem cuja coerência o levou à prisão mais de uma vez, ao tomar partido e defender trabalhadores canavieiros de Pernambuco.

Esse período é extremamente rico em produção e em contradições. Expressão do movimento da História, movido pelo embate de elementos que se contrapõem, mostra também que há um polo que vence o outro, mas como algumas contradições permanecem e outras são gestadas, o movimento persiste e transformações se processam. Não há dúvida de que houve uma visão hegemônica, mas não uma visão única. Também não há dúvida de que o pensamento contra-hegemônico foi profícuo e original, expressão também do momento histórico do qual fez parte.

O processo de consolidação da psicologia

Os movimentos gestados nas primeiras décadas do século XX culminaram com o golpe de outubro de 1930, constituindo-se em marco para uma série de mudanças de ordem econômica, política e social. A política econômica atrelada aos interesses dos setores agrários, sobretudo aqueles relacionados à produção e à exportação de café, geraram um amplo descontentamento na sociedade brasileira, culminando com a já referida Revolução de 30. Esse movimento que se sagrou vitorioso excluiu, de certa maneira, as camadas populares, já que foi conduzido por representantes das camadas médias, como intelectuais e militares, e por setores da classe dominante, como a burguesia industrial emergente, no interior da qual se encontravam aqueles que haviam acumulado capital com a produção de café. Esse período pautou-se pela implantação do processo de industrialização no Brasil. A construção de uma sociedade baseada em novas relações sociais de produção exigia novos conhecimentos e práticas, sendo a educação um dos instrumentos para a conformação do novo trabalhador, afeito às necessidades do processo industrial, e a Psicologia um de seus principais fundamentos científicos. Esse momento histórico, por suas necessidades, tornou-se terreno fértil para o desenvolvimento da área e para a consolidação de sua prática.

Esse período caracteriza-se pela expansão do ensino de Psicologia, das Escolas Normais para o ensino superior, especialmente nos cursos de Filosofia e pedagogia, pelo aumento da publicação de livros e periódicos, expansão das atividades de pesquisa, criação de associações de Psicologia, realização de congressos e, especialmente, pelo aumento dos campos de atuação da Psicologia que, da educação, estende-se para a organização do trabalho e para a prática clínica. Destaque deve ser dado ao fato de que muitas instâncias governamentais tiveram, na Psicologia, uma das bases científicas para a intervenção social, com especial ênfase nas questões relacionadas ao trabalho e a sua racionalização. Esses fatores condicionam o que se pode considerar como o processo de consolidação da Psicologia no Brasil, que, por sua vez, gerou as condições para que, em 1962, a profissão de psicólogo fosse reconhecida. Em outras palavras, foi nesse período que a Psicologia, respondendo a demandas impostas pelo modelo desenvolvimentista de economia e de uma política de intervenção do Estado no processo produtivo, se estabelece como ciência reconhecida e se consolidam as modalidades de atuação prática que, pode-se dizer, gestaram as condições para sua consolidação como ciência e profissão, sendo

essa última a que se oficializaria a partir da Lei nº 4119 (Lourenço Filho, 1971a,b).

Entre as instituições públicas que incorporaram a Psicologia e que contribuíram para seu desenvolvimento e difusão, encontra-se o Instituto Nacional de Estudos Pedagógicos – INEP, sediado na capital do País, Rio de Janeiro, e que estendeu sua ação para os demais Estados da Federação e até para países próximos. Sua atuação incluiu a oferta de estágios e de cursos de aperfeiçoamento para professores de Psicologia e chefes de serviços educacionais, incluindo serviços de Psicologia aplicada e de medidas educacionais, além da publicação da *Revista Brasileira de Estudos Pedagógicos*, profícua fonte de difusão de pesquisas e de estudos relacionados à Psicologia educacional.

O Instituto de Seleção e Orientação Profissional – ISOP, criado na década de 40 por Getúlio Vargas, foi outra importante instituição que, com a finalidade de formar técnicos para a indústria e o comércio, foi base para o desenvolvimento de pesquisas, de diversas modalidades de intervenção psicológica e de formação de profissionais especialistas nas questões psicológicas relacionadas à organização do trabalho.

Uma das mais importantes bases para o desenvolvimento da modalidade clínica de atuação deve-se aos Serviços de Orientação Infantil, criados no Rio de Janeiro e em São Paulo, na década de 40, nas Diretorias de Ensino, para atendimento de crianças com queixas escolares. A estas junta-se a Clínica do Instituto Sedes Sapientiae, fundada e dirigida por Madre Cristina Sodré Dória, com a mesma finalidade de atendimento a escolares.

É possível afirmar que estas, entre outras muitas realizações no campo da Psicologia, foram as condições fundamentais para que o trabalho realizado com base na ciência psicológica se consolidasse como modalidade específica de atuação profissional e que desse sustentação para a reivindicação de seu reconhecimento legal.

Houve, nessa época, um rápido desenvolvimento da Psicologia, relacionado, sobretudo, às demandas oriundas de uma sociedade que se transformava na direção da industrialização e cujas contradições exigiam ações que poderiam ter na ciência psicológica um poderoso substrato de natureza científica e técnica (representada especialmente pelos instrumentos de medidas psicológicas). Assim, a Psicologia se desenvolve, se fortalece e se consolida, como ciência e profissão, na medida de sua capacidade de responder às necessidades geradas por um projeto político, econômico e social dirigido pela nova classe dominante, a emergente burguesia industrial, que tem na modernização a base para suas realizações no campo das ideias e da gestão de seus negócios e da sociedade.

Entretanto, não se pode dizer que esse período tenha sido homogêneo e não tenha apresentado contradições; ideias e ações divergentes ou contrapostas ao que era corrente foram produzidas e difundidas.

Nesse momento em que os testes eram considerados a técnica por excelência da Psicologia, pois eram calcados na objetividade e, portanto, tidos como produtos inegáveis da ciência (de uma dada concepção de ciência), ocorreram também críticas e utilização distinta do que era corrente na época. Helena Antipoff realizou uma pesquisa em Belo Horizonte, no início dos anos 30, em que conclui que os testes mediam não apenas o que se supunha ser a inteligência mas também as condições materiais e sociais de existência da criança. Com isso, a ideia do teste como um instrumento absolutamente objetivo, como o consideravam seus defensores, é questionada. Antipoff, por outro lado, não

negou a importância dos testes, chegando mesmo a criar o teste Minhas Mãos, mas utilizou-os de maneira distinta, com a finalidade de melhor conhecer o educando e sobre ele poder intervir, oferecendo condições adequadas para a aprendizagem. Foi ela também pioneira, junto com Ulysses Pernambucano, na educação de crianças com deficiência intelectual, além da educação dos chamados superdotados e da educação rural.

Muitas outras ações empreendidas nesse período caracterizam-se pela contraposição às práticas hegemônicas. Além disso, vários personagens dessa época, como Mira y Lopez, diretor do referido ISOP, foram considerados adeptos do pensamento de esquerda, e, por esse motivo, perseguidos e limitados em suas possibilidades de ação e de expressão de ideias. Vale dizer que, na década de 40, Henri Wallon esteve no Brasil, a convite do Partido Comunista, fato esse não referido ou apenas pontualmente citado na historiografia da área no Brasil.

As realizações da Psicologia, nesse período, seja como área de saber, seja como campo de práticas, submetidas aos interesses dominantes ou a eles opostas, deram grande impulso a seu desenvolvimento, engendrando as condições para seu reconhecimento como profissão.

Segundo Lourenço Filho (1971a,b), em 1953, professores de Faculdades de Filosofia solicitaram uma seção especializada de Psicologia em Faculdades de Filosofia, Ciências e Letras. A Associação Brasileira de Psicotécnica encaminha, nesse mesmo ano, ao Ministério da Educação, um anteprojeto de lei para a regulamentação da profissão de psicologista e de sua formação, que recebe, em 1957, parecer favorável do Conselho Nacional de Educação. No ano seguinte, o Executivo envia ao Congresso mensagem sobre a referida lei. A Associação Brasileira de Psicologia Aplicada, a Sociedade de Psicologia de São Paulo e a Associação Brasileira de Psicólogos analisam, em 1961, o substitutivo do projeto em tramitação na Câmara dos Deputados. Em 27 de agosto de 1962, é aprovada a Lei nº 4119, que regulamenta a profissão de psicólogo e estabelece o currículo mínimo para sua formação. No ano seguinte, o Ministério da Educação publica uma portaria sobre a atuação da Comissão Especial de Registro de Psicólogos. Em 1964, o Decreto n° 53.464, de 21/01/64, regulamenta a Lei nº 4119/62 (Lourenço Filho, 1971a,b).

A psicologia como profissão regulamentada, ampliação dos campos de atuação e compromisso social

Há 50 anos, portanto, foi aprovada a Lei nº 4119, que reconheceu a profissão de psicólogo, com uma emenda sobre os cursos de formação desse profissional e de seu currículo mínimo. Esse foi o ponto de culminância de uma dura e longa luta, principalmente em relação à oposição de um grupo de médicos, que exigia o veto ao exercício da psicoterapia por profissionais que não tivessem formação em Medicina. Mais tarde, essa questão retornou nos projetos dos Deputados Kassab e Julianelli, sendo que atualmente está em cena de novo no projeto de lei do Ato Médico.

Menos de dois anos depois da regulamentação da profissão de psicólogo, um golpe militar instaura uma ditadura que perdurou até os anos 80. Nesse estado de exceção, entre tantas desventuras e retrocessos, foi promulgada a Lei n° 5540 (Saviani, 1987), mais conhecida como Reforma Universitária de 1968, produto dos acordos MEC-USAID. Essa lei, aprovada à revelia dos grupos diretamente interessados na questão da expansão de vagas no ensino superior, promoveu a abertura do ensino superior

para a iniciativa privada e estabeleceu mecanismos para reprimir e impedir os movimentos estudantis e docentes, que se constituíam, naquele momento, em um das mais organizados movimentos de oposição ao regime militar.

A proliferação de instituições privadas de ensino superior foi uma das consequências dessa reforma, muitas das quais criadas em condições acadêmicas precárias, e que ofereciam cursos de baixo custo e alta rentabilidade, sem garantia de formação adequada de seus alunos. A maioria dessas instituições foi criada com vocação meramente mercantilista. Muitos cursos particulares foram criados nos anos 70, respondendo a uma demanda cada vez maior pelo ensino superior e a um interesse crescente pela Psicologia.

Nessa época, foram criados muitos cursos de Psicologia que, para garantir a lucratividade, reduziam o número de disciplinas ao currículo mínimo, com docentes submetidos a baixos salários e com número elevado de alunos por sala de aula. Um grande contingente de alunos oriundos das camadas menos privilegiadas economicamente, que necessitavam estudar no período noturno para, com seu trabalho, pagar os custos de um curso superior muitas vezes de futuro incerto, formavam o corpo discente de muitas dessas instituições. A falta de docentes qualificados, a precariedade das suas condições de trabalho, as atividades restritas apenas ao ensino, desvinculadas da extensão e da pesquisa, contribuíram para uma crescente perda de qualidade do ensino da Psicologia. A isso deve-se acrescentar que o número de psicólogos formados era muito maior do que o mercado de trabalho demandava, em franco retraimento para a atuação do psicólogo se comparado ao período anterior ao da regulamentação da profissão.

O campo da clínica expandiu-se, sobretudo porque atraía maior número de alunos, tornando-se privilegiado nos currículos, mas não garantindo ao psicólogo meios de subsistência, pela demanda restrita e pelo número de profissionais disponíveis. Condição parecida verificou-se no campo do trabalho, que restringiu seu acesso aos psicólogos se comparado ao período anterior, ficando o profissional muitas vezes reduzido à condição de mero aplicador de testes em tarefas de seleção de pessoal. Críticas foram feitas ao caráter elitista e restrito da Psicologia clínica e ao comprometimento da Psicologia do trabalho muito mais com os interesses do capital do que com os do trabalhador.

Em relação à Psicologia na educação, as críticas foram muitas, e vieram tanto da Psicologia como da educação. De um lado, havia uma hipertrofia da Psicologia na educação, incorporada à Pedagogia e à prática educativa, e, por outro lado, a atuação do psicólogo na escola baseava-se em uma perspectiva clínica, no atendimento individual de crianças consideradas *portadoras de problemas* fora da sala de aula ou na realização de *psicodiagnósticos* para emitir laudos a fim de encaminhar alunos para classes especiais.

Entretanto, essa condição gerou muitas críticas, tanto de educadores como de psicólogos. Criticava-se o uso abusivo dos testes e apontavam-se as consequências para o aluno, pois os resultados eram interpretados como atribuições próprias do sujeito, responsabilizando-o pelos ditos *problemas de aprendizagem*, entre outros. As decorrências dessa prática foram nefastas para muitas crianças, condenando-as muitas vezes a uma *classe especial* que as relegava a um ensino incipiente, o que confirmava o diagnóstico e produzia de fato uma deficiência intelectual com todos os seus estigmas. Essa prática acabava por culpabilizar a criança e a família, e obscurecia os determinantes intraescolares da maioria dos problemas.

Outro conjunto de críticas referia-se à adoção do modelo médico, base da atuação de muitos psicólogos escolares, cuja ação era fundamentalmente clínica, em detrimento de ações mais propriamente pedagógicas e coletivas, como a contribuição para o processo de formação de professores. Foram poucos os trabalhos que assumiram um modelo mais educacional, procurando intervir na escola de maneira mais ampla. Foram esses os trabalhos que negaram a Psicologia escolar clínica e individualizante e a superaram, firmando-se, ainda que de forma minoritária, por longo tempo, e permitiram que se chegasse ao desenvolvimento atual desse campo de atuação.

Percebe-se, assim, que esse período constituiu um campo rico de contradições na Psicologia, expressão do momento vivido pela sociedade brasileira como um todo, que, sob o jugo de uma ditadura militar, enfrentava o estado de exceção criando formas de resistência que se expressavam por uma cada vez mais ampla luta pela democratização do País.

Foi nessa condição que a Psicologia logrou, nesse período, um desenvolvimento sem precedentes, ampliando gradativamente seu espectro de atuação e buscando respostas para os problemas sociais, inicialmente no interior dos campos tradicionais: educação, trabalho e clínica, e, posteriormente, ensaiando e implantando novas modalidades de intervenção, como a Psicologia comunitária, a Psicologia hospitalar (que mais tarde se expande para a saúde) e a Psicologia jurídica, entre outras, que se consolidariam e ampliariam sua capacidade de responder às demandas antes não atendidas e a outras acarretadas por problemas sociais então emergentes. Em outras palavras, a Psicologia passou a se preocupar com a maioria da população e seus problemas, com um claro compromisso social, tendo em vista a transformação da sociedade.

Também contraditória era a relação com o conhecimento produzido pela Psicologia, reproduzido nos cursos de formação e confrontados com a realidade. A formação do psicólogo nos primeiros tempos da Psicologia reconhecida como profissão era, em geral, baseada na reprodução de teorias e pesquisas estrangeiras, vindas principalmente dos Estados Unidos e da Europa e transplantadas mecanicamente para a nossa realidade, quando não aligeiradas e difundidas precariamente por obras de comentadores e não dos autores originais, obedecendo a uma lógica de mercado editorial precária e limitada. Assim, a crítica à prática profissional do psicólogo fez-se acompanhar também da crítica teórica e do questionamento da maneira como tais teorias eram aqui difundidas.

A produção de conhecimento em Psicologia expandiu-se e deu um salto de qualidade, em grande parte com a implantação de alguns cursos de pós-graduação que, embora com recursos escassos, conseguiram produzir críticas fundamentadas e articuladas aos problemas sociais, produzindo um significativo acervo de conhecimento original e criativo. A carência de investimentos em pesquisa no Brasil, associada à complexidade de nossa realidade e a seus múltiplos problemas, constituíram-se em condições relevantes para que a originalidade e a criatividade se tornassem marcas da produção de conhecimento psicológico, relacionadas à multiplicidade de aspectos de seu objeto de estudo e à adoção de diferentes perspectivas metodológicas.

A expansão da pós-graduação produziu melhorias na qualidade da formação do psicólogo, embora ainda de forma desigual, pois a articulação entre ensino e pesquisa não se efetivou para todos os cursos, ficando limitada às instituições que garantiam as condições de trabalho

necessárias para a concretização do princípio de indissociabilidade entre ensino, pesquisa e extensão.

A organização da categoria de psicólogos foi um fator de grande relevância para esse processo de transformação. Muitas das entidades representativas da Psicologia assumiram papéis de grande relevância na transformação da Psicologia no Brasil, fomentando a crítica e proporcionando condições para o debate e para a busca de soluções e possibilidades de superação daquela Psicologia limitada e elitista, em direção à constituição de uma ciência e de uma profissão radicada em sua realidade e com ela comprometida.

Pode-se afirmar, assim, que a Psicologia no Brasil passou por significativas transformações nesse período que se seguiu à regulamentação da profissão. Das limitações teóricas e da escassez de mercado de trabalho, da precariedade de formação de grande contingente de formandos, das limitações dos campos de atuação, do comprometimento com interesses dominantes à crítica que identificava as contradições e buscava a superação tanto de suas teorias como de suas modalidades práticas, buscando comprometer-se com os interesses e necessidades da maioria da população, a Psicologia caminhou para um novo patamar de produção e para um salto qualitativo em sua atuação profissional.

Esse processo é confirmado, entre muitas outras possibilidades, pela presença do psicólogo nos serviços públicos, assumindo cargos efetivos e desempenhando funções legalmente prescritas. Nessa condição, o mais relevante é que, em geral, a inserção desse profissional ocorre no âmbito da concretização de políticas públicas voltadas para as necessidades e para a promoção dos indivíduos das camadas populares, e muitas vezes atua em coletivos intersetoriais e contribui também para a elaboração, a construção e o acompanhamento dessas políticas.

Entretanto, há muitas oposições, muitas delas ainda não identificadas, outras pouco claras e algumas já antigas e em pleno processo de acirramento. Apenas a título de ilustração, destacar-se-á uma delas, que não apenas demonstra esse fato mas também o caráter contraditório da realidade histórica em geral. Trata-se da coexistência de uma Psicologia que avançou para uma ampliação em seu espectro de ação e que se consolidou como instância social comprometida com a construção de uma sociedade mais justa e igualitária e uma psicologia que ainda se submete a concepções tradicionais e ultrapassadas, que não se atualiza e que atua com base em modelos que já foram analisados, criticados e superados há décadas. O movimento histórico é, pois, heterogêneo, e há segmentos que tomam a dianteira do processo, outros que respondem mais tardiamente e outros que resistem.

Considerações finais

Ao passar pelos diferentes períodos da história da Psicologia no Brasil, este texto não pretendeu apresentar um quadro histórico da constituição dessa ciência em nosso país nem tampouco abordar todas as contradições nele presentes. Pretendeu-se tão somente mostrar, a partir de algumas situações ou produções, o movimento histórico produzido pela coexistência e pelo embate de elementos antagônicos que produzem as transformações, gerando o novo e superando as condições precedentes.

É possível perceber que ideias e práticas foram hegemônicas em determinados momentos históricos, mas nunca constituíram blocos monolíticos, estáticos e homogêneos. Posições e concepções diferentes, divergentes e opostas coexistiram e foram elas que, na

contraposição, provocaram mudanças e saltos de qualidade.

Esse processo, aqui pontualmente exemplificado por alguns fatos na história da Psicologia no Brasil, é inerente à realidade em geral. Por esse motivo, insiste-se na busca de estudos históricos que sejam capazes de identificar e de entender essas contradições como forma de aproximação com uma realidade que já não mais está disponível empiricamente em sua integralidade e cujo conhecimento é necessário para que se possa compreender a gênese e o movimento como processos constitutivos de nosso objeto de estudo, a Psicologia no Brasil, com a certeza de que muitos estudos e pesquisas são necessários para que essa compreensão se aprofunde e se amplie.

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Indian Cross-Cultural Counselling

- Implications of practicing counselling in urban Karnataka with Western counselling methods.

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Abstract

This study presents how Indian counsellors in urban India work with Western counselling methods with Indian clients. The study is categorised as part of the cross-cultural counselling research field where a major assumption is that counselling methods are part universal, part contextual. This study explores how counsellors in Bangalore culturally adapt Western methods. The method used is qualitative semi-structured interviews with seven counsellors at Parivarthan Counselling, Training and Research Centre in Bangalore. The theoretical framework in this study is based on New Institutional Theory, with constructs such as Glocalisation, Translation, and finally Cultural Preparedness to understand the context of the counselling profession in Bangalore. Results show that the Bangalore counsellors meet clients that are culturally prepared for short-term and advice-oriented counselling. The clients are part of a context where family and spirituality are of great importance. The counsellors use Western counselling methods only but adapt their approach and language with indigenous elements and emphasise the individuality of each client. They use a person-centred and an integrative approach, in which they are informed by several Western counselling methods, but do not use them dogmatically. The individuals' needs and the relationship between counsellor and client is emphasised. Parivarthan Counselling, Training and Research Centre is part of a complex organisational field with influences from India, the East as well as from the West.

Key words: cross-cultural counselling, counselling methods in India, mental health in India, Western counselling methods in India, cross-cultural psychology.

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1 Introduction

The connection between counselling methods and culture has been widely studied. Several scholars have directed focus to the Western bias that exists in science, and emphasised the need for cultural adaptation of methods and approaches in psychology and counselling. Professor Uwe P. Gielen in Laungani, (2009) writes that psychology, at its birth in 1879 was a two-sided enterprise. Wilhelm Wundt, known as the creator of psychology, made a division between "physiological-experimental psychology and *völkerpsychlogie* (psychology of people)" (p. x). He claims that the latter, the one that focused on cultural influence, was forgotten. Gielen writes that psychology has emerged as a stand alone science, but that it is biased and many times mistaken as universal. Gielen continues:

> (O)ur developmental, personality, social, clinical, and counselling psychologies, for instance, are suffused with individualistic assumptions and values that feel natural and right to most liberal Americans and Western Europeans but that would be experienced as odd, off-centre, and even immoral to the more collectivistic inhabitants of traditional sub- Saharan African villages (ibid., p. xi).

Sub-Sahara is given as an example by Gielen, illustrative of collectivistic inhabitants, which are also found in India[1]. What happens when methods, that are either posed as universal or simply produced in a Western context (not necessarily posed as universal) are used in non-Western countries? This question lies at the core of my essay.

I have chosen to explore cross-cultural counselling in India. Once a British colony with strong Western influences, India is a country with a rich indigenous culture and has a diversity of subcultures (Ranye & Cinarbas, 2005, p 155). In India there are over 400 different languages spoken. The country is a federation, with communist Kerala in the South and Tibetan influenced Dharamsala in the North, and within each state or region exists a multitude of expressions derived from these diverse influences. How are these cultural needs met in counselling with Western based methods?

Due to the lack of accreditation of counsellors in India and the lack of a governing body for the profession, counselling in one Indian region can suggest one thing and something else in another; practice and accessibility to counselling varies immensely.

I have chosen to do my field study in the state of Karnataka. Bangalore, it's capital, is one of India's biggest cities. It is known as a technological hub with a booming IT industry and a

[1] See section *previous research* and Laungani's theoretical model of East and West.

city under tremendous transition and modernization. Traditional Indian values meet with modernization and Western influences in a growing urban setting. More about why I chose this city can be found under the section *Selection.*

1.1 Definition

Counselling training in India can last from a two-week basic communication skills course, to a two-year Masters in clinical psychology, yet both of these educational backgrounds would qualify to practice under the title counsellor (Arulmani, 2009, p. 252). Therefore, *one single* established definition of what counselling is in Indian practice does not exist. On that note, one single definition of what counselling is, in an international context, does not exist either (Gerstein et al, 2009, pp. 5-6; 252). In Swedish social work, the term counselling has been introduced but is not widely known (Larrson & Trygged, 2010, p. 14). A broad definition of counselling is:

> A focus on using a broad array of psychological strategies and activities aimed at the process of helping others to reach individual, group, organisational and system goals." (Gerstein et al., 2009, p. 5)

In my essay I will focus on individual, couple and group counselling, with focus on psychosocial problems. The latter excludes themes such as medication, psychiatric help, diagnosis and severe mental illness. I have chosen this limitation partly because the scope of my Minor Field Study did not allow for more material. Partly because my interest in Western methods used in talking counselling is similar to the work that social workers do in Sweden. I therefore exclude the realm of psychologists that work with diagnosis and medication.

The centre in Bangalore that I have chosen to study does not offer help beyond counselling but they offer referrals to psychiatrists, programs for drug abuse, shelters, safe houses and so on. The counsellors do not diagnose, prescribe medication, they do not offer shelter at their centre. They are a stand alone non-governmental organisation (NGO) that offers an array of talk-based counselling. My empirical material therefore is focused on the type of counselling that is offered for psychosocial and emotional problems. A final definition is needed that includes the dimension of culture, I have chosen to use the term cross-cultural counselling:

> The pursuit and application of universal and indigenous theories, strategies (e.g., direct service, consultation, training, education, prevention), and research paradigms of counselling and mental health help seeking grounded and in-depth examination, understanding, and appreciation of the cultural and epistemological underpinnings of countries located worldwide. (Gerstein et al., 2009, p. 6)

When I write *cross-cultural counselling* the reader is referred to the definition above. How cross-cultural counselling is practiced specifically in Bangalore will be presented under the section *Results.* In conclusion, I am interested in how counsellors in the urban setting of Bangalore reason about the context for counselling and how they reason about their use of Western methods and approaches in the Indian context. I will from now on use the term *counselling* as description of talk-based counselling aimed at helping people with psychosocial mental health problems.

1.2 Problem

Within India there are several University level programs that offer degrees in counselling; the content made up of research and methods from U.S.A, Europe and India, though the Western methods dominate the field (Gerstein et al., 2009, p. 252). That research and methods are created in the West and put into use in a non-western countries is problematized by previous research. Scholars emphasise the need for *cultural sensitization*, meaning a practice that includes a cultural adaptation of counselling methods (Laungani, 2009; Gerstein et al. 2009). Further the lack of a governing body hinders a unified profession and therefore a range of diverse practices exits. Scholars claim that counselling methods should be culturally adapted and that the counsellor must be culturally sensitive in their practice. Lack of cultural sensitization risk ineffective methods. At worst it can cause psychological damage to individuals, and/or impose post-colonialism at a structural level.

1.3 Purpose

The purpose of my essay is to explore the use of Western mental health counselling methods through the perspective of counsellors at an Non-Governmental Organisation (NGO) in Bangalore. The focus lies on understanding the indigenous context for counselling at the chosen centre and analyse how the Western counselling methods are culturally sensitized.

1.4 Research questions

1. How is the context for the counselling profession at Parivarthan Counselling, Training and Research Centre in Bangalore described by the counsellors?
2. What methods or approaches do the counsellors use in their counselling?
3. How can the methods be understood in terms of cultural sensitization?

1.5 Outline

In the section *Background* the reader is introduced to the field of counselling in India and Bangalore. After that, in the section about *Method* follows a description of how the study was conducted from start to finish. I start of with describing the conceptualization process, followed by how I made my selection of the counselling centre in Bangalore. I then introduced the counselling centre to the reader. After that I present my intended plan and the actual outcome of the interviews; how I handle the interviews; alternatives to validity and reliability and finally my method of analysis. That is followed by *Ethical Considerations* in the study. The next section is a summary of the *Previous Research* within the field of cross-cultural counselling where I present Laungani's theoretical model of East and West; summarize three major research fields: cross-cultural counselling, cultural counselling and indigenous counselling. I also summarize several empirical studies about India and counselling/mental health. The section after that describes my *Theoretical Framework*; New Institutionalism, Glocalisation, Translation and finally Arulmani's construct of Cultural Preparedness. Finally I present my *Results, Analysis* and a *Summary and Discussion* of my conclusions.

2 Background

The section below offers the reader a short introduction to the meta-categories East and West. It is followed by a description about India and mental health services and about Bangalore and counselling services.

2.1 The East and the West

Reading about grand constructs such as the East and the West, inevitably lead to categorizations, which of course are based on generalizations. I have repeatedly come across labels such as the individualistic West and the collectivistic or communal East in previous research (Laungani, 2009, pp. 4-5). Of course there is something very problematic about generalizing entire continents in this manner, ignoring the heterogeneous world we live in. At this point in the essay I will use these categories to refer to methods that are produced within a Western culture, and how they are applied to ethnic minorities in the West or by counsellors in an Eastern country, like India. In the section *Previous Research* I present Laungani's theoretical model for these constructs. I find it necessary to categorise and do not necessarily

find the categorisation- as such, to be dangerous (mindlessly reproducing colonial discourse) what is dangerous is not discussing what a category means. With the help of Laungani's model I will discuss the categories East and West.

2.2 Brief history

India was a British colony from the year 1859 to 1947. The effects of colonization has influenced many areas in India. The British built mental hospitals during the colonial years, though primarily to treat Europeans residing in India. After India gained its independence in 1947 mental health services were expanded. Psychiatric services were instead incorporated into general hospitals rather than organized as stand alone mental institutions. This re-organisation led to somewhat of a decreased stigma for mental health patients. Around this time the government also formulated policies important for the advancement of the field, among them subsidized health care (Raney & Cinarbas, 2005, p. 154).

"In India, there are only 37 governmentally run mental hospitals, 3,500 psychiatrists, 1,000 psychiatric social workers, and 1,000 clinical psychologists to serve a population of more than one billion." (ibid., p. 154) There is great need for an expansion of mental health services. The lack of licensing and accreditation for professionals within the mental health field causes several problems, among them the lack of statistical information and the possibility of informed choices for patients and their families. Even though the services mentioned above are targeted at groups with severe mental illness, the mental health field affects the counselling profession and the stigma surrounding mental health problems.

Indigenous models of healing such as Ayurveda, Astrology, Yoga, Gurus, Priests and Shamans are prevalent in India and there is a development towards incorporating indigenous methods into counselling such as breathing exercises or holistic body-mind approaches from Yoga (Raney & Cinarbas, 2005, p. 157). Although to a large degree, the traditional methods mentioned above are separated from Western based counselling methods.

2.3 Bangalore and counselling services

In the urban city Bangalore, there are many different counselling services offered: career counselling within the corporate world, government funded counselling and non-governmental counselling centres (NGOs); secular and non-secular. There are counselling services offered as stand alone services or part of holistic interventions, such as combinations of long-term stay at institutions with rehabilitating programs (for example Medico-Pastoral

Association). Besides counselling, variations of training in psychotherapy, psychology and coaching are offered in short and long-term courses. Further various other methods such as hypnotherapy or Yoga Therapy exist. The problem of what is what, relates back to previous statement that titles are not accredited or protected and therefore a wide range of services are offered with various practices.

3 Method

In all research, empirical data is connected to ideas or concepts. "Measurement links the data to the concepts, yet the measurement process differs depending on whether our data and research approach are primarily quantitative or qualitative." (Neuman, 2011, p. 200) I have chosen to gather my empirical material through a minor field study in Bangalore, India. I have used semi-structured interviews, a qualitative method. Below follows a description of my methodological process.

3.1 Operationalization and Conceptualization

Qualitative studies are commonly approached through an inductive process, "where we are measuring and creating new concepts simultaneously with the process of gathering data" (Neuman, 2011, p. 200). Measuring can be done through quantitative and qualitative methods. While quantitative studies are commonly known for measurement in numbers and qualitative studies can do that also, the latter often includes measuring other units than numbers, such as words, observations, body language, tone in "non-standard shapes, sizes and forms" (ibid, p. 200). According to Neuman the measuring process includes two steps: operationalization and conceptualization. As mentioned above this process will look different depending on if it is a qualitative or quantitative study.

"Operationalization describes how we gather specific observations or data and how we struggle to understand the data as the data evolves into abstract constructs." (Neuman, 2011, p. 206) The operationalization of my study is made simultaneously with the gathering of data. Once I made the first interviews, I narrowed down the amount of questions I had in my initial interview guide. I also understood what topics I needed to ask in-depth and repeating questions about, to gain a fuller understanding of a certain topic. Through this process I found important concepts that further on where connected to theoretical constructs. As part of my operationalization I include a description of my intended plan for the interviews and the outcome, as well as my method of analysis.

I have chosen to gather my empirical material through qualitative interviews because they allow for open questions and instant follow-up questions. It has resulted in the type of in-depth empirical data that I intended to gather. This could also have been handled in a quantitative questionnaire with open questions, but I would loose the opportunity to ask spontaneously for clarifying answers and conduct in-depth interviews.

In my study I want to explore the counsellors subjective experience of cultural sensitivity. Previous research states that cultural sensitivity is needed. I do not want to prove to what *extent* it is practiced at Parivarthan. This study is based on a small number of practitioners, instead the focus is on understanding *how* the counsellors reason about cultural sensitivity.

In order to reach my goal I started of with abstract constructs such as counselling and culture. Through the help of previous research I came in contact with theoretical terminologies such as cultural sensitivity and various constructs concerning the relationship between counselling and culture such as: cross-cultural counselling; multicultural counselling; transnational counselling; indigenous counselling and so on. By reading about these research fields, visiting India, visiting the chosen centre and conducting interviews I have developed an understanding of the different constructs in an on-going process of finding boundaries. "In qualitative research, we also reflect on concepts before gathering data. However, many of the concepts we use are developed and refined during or after the process of data collection." (ibid., p. 200) This has influenced my choice of what to *finally* include in the sections: previous research, theory and results. By large the areas within previous research shaped my interview guide (see appendix 1 & 2).

As mentioned above in qualitative studies, measurement and conceptualization is produced parallel with collecting data. Through my stay in India and my recorded interviews I have gone through a process of placing further boundaries to the purpose, scope and core themes of my study (Neuman, 2011, pp. 202- 203). They are as follows: the unit that I study is a group: counsellors that work at Parivarthan. By studying the premise for the profession in India I have come to learn that the title counsellor means various things from organisation to organisation. I have therefore chosen the unit *one* organisation, and explore cultural sensitivity in counselling amongst counsellors within that organisation. All the interviewed counsellors are trained and work at the same centre. Some of them have also trained in the West, all of them have come in contact with counsellors or psychologists that are trained in Western countries by working together at Parivarthan. The respondents all have access to supervision, have gone to private counselling and abide by the same ethical guidelines.

3.2 Selection

Initially I wanted to establish contact with a counselling centre before arrival in India. I was open to visit one or several centres in any city in India. My criteria for the centre was that they conducted counselling face to face with clients, that they had several employed counsellors so that I could conduct several interviews, that they were trained counsellors[2] and that they used counselling methods (rather than pure therapy or coaching). I have therefore used purposive sampling (Neuman, 2011, pp. 267-268). My aim was not to find one case that would represent counselling in Bangalore. The practice of counselling, as stated previously, is different from case to case and finding cases that are representative would create demands beyond the scope of this essay.

Since I have no contact in the country I searched for counselling centres online. This limited my search a lot. I could only contact centres that first, have a website and second, that were in English. I googled the search words: counselling+ therapy+ social work+ mental health+ centre+ clinic+ organisation+ India in various combinations.

I found clinics and centres all over India and initially e-mailed them in short about my essay and asked if they would be interested in participating with interviews. I received few serious answers. Many answered that I could call them once I arrived, but I needed a contact that I could engage with before arrival. The counselling centre Parivarthan in Bangalore gave me a serious response, asked for my intentions, purpose and study plan and they matched my criteria.

3.2.1 Parivarthan Counselling, Training and Research Centre in Bangalore

All the counsellors that work at Parivarthan have gone through the preparatory course "Life Skills Training - Module I". After this course, counsellors can apply for the one year long "Training Program, Basic Skills in Counselling" which they all have completed to be able to work as counsellors at Parivarthan. They are taught several counselling methods and theories. Such as:

Theories of Counselling/ Psychotherapy:

- Humanistic Approaches: Person-Centred Counselling, Gestalt Counselling
- Transactional Analysis
- Cognitive Behavioural Therapy
- Psychodynamic Approaches

[2] Since there is no national governing Board supervising counselling I initially included centres that stated in their website that they have trained counsellors and asked for more details about the duration of training once someone from that centre answered my e-mail.

• Developmental theories under-pinning above approaches

Counselling Skills:
An integrative framework of training in micro skills of Counselling drawing from:
• G. Egan – 3 Stage Model of Helping Skills
• R. Carkhuff – Interpersonal skills
• A.E. & M.B. Ivey – Intentional Interviewing (Parivarthan, Training program) (www.parivarthan.org)

They also discuss a range of topics in the training such as ethics or spirituality. They work with children, adolescents, couples, families and individuals. The problems that the clients need help with vary immensely. The counsellors evaluate, from case to case, what the client needs. If the counsellors regard a problem as a serious mental health issue, they refer the client to a doctor or psychiatrist for evaluation. Thus, the counsellors that I have focused on do not work with medication or severe mental illnesses as previously mentioned.

3.2.2 Gatekeeper

Parivarthan's director is the one that answered my initial e-mail and kept contact with me before, during and after my stay. She answered several of my e-mails before arrival, she was clear about what was expected of me and helped me with practical things such as suggestions for housing.

She was also clear about the organisations ethical policy and that I was not allowed to interview clients or take part in counselling sessions. She made all my appointments for interviews with the counsellors and introduced me to NGOs' that work within the field of mental health. She was my so called "gate keeper" into the research field and made the circumstances for my empirical gathering very effective (Neuman, 2011, s. 429-430).

3.2.3 The respondents

One important aspect of the counsellors experience at Parivarthan is that some of them have educational experience from abroad (Germany, Netherlands, U.S.A) and that the clinic has had employees from the U.S.A. and the U.K., or they have offered work-shops with counsellors from a Western context. The counsellors have worked for several years in India, they are all born and raised in India. Some of the counsellors have not trained abroad and are schooled entirely in India. These experiences make the comparison between East and West, based on more than premonitions and speculations, which raises the validity of the study. Further the counsellors work part time at the centre and therefore also have other counselling jobs that contribute to the range of experiences. All the counsellors at the centre are female,

therefore no men are part of the study. This is a variable that will not be part of my analysis. Not because it is not important, on the contrary there could be a lot of interesting research done on how that affects the counselling. It is a boundary I have made due to the scope of the essay, I do not find - considering my purpose, research questions, and time in India, that it was possible for me to gather enough valid material to draw conclusions about gender as well.

All the counsellors have a Certificate in Counselling (BSIC), four counsellors have a Certificate in Couple and Family Counselling, five have a Certificate in Child and Adolescent Counselling, five also work as trainers at Parivarthan, one is in charge of out-reach work. One has training in Sand Therapy, two have studied NLP, one has a Masters in Integrative Psychotherapy, one is a Drama Therapist. I intentionally present the information about the respondents like this to maintain their anonymity. Since I am not examining the correlation between a counsellor's individual experiences with cultural sensitivity, I will not present the counsellors further. They will be presented as R1, R2 and so on in the section *Results* and each counsellor has been informed of what number substitutes their name.

3.2.4 Other respondents

I attended a work-shop at Parivarthan and through that came in contact with one more respondent that has started a counselling service at a school for children in Chennai. I also found a private counselling clinic in Bangalore through Google and conducted one interview with the founder of that counselling organisation. I have used the latter two as informative interviews, to better understand the context. As I found that I would need a lot more interviews from their specific background to be able to include them without a selection bias I have not used them in my analysis (Neuman, 2011, p. 294).

Since these respondents all work in urban settings I also looked for respondents that work with clients in a rural setting. I applied to visit an organisation in rural Karnataka but was declined with the motivation that I knew to little about the cultural context and that a bachelor essay would not contribute to their work.

Through my tutor I came in contact with an organisation in Trivandrum, Kerala. I conducted two interviews there with counsellors. Because of language barriers and perhaps my lack of knowledge about their specific context, I felt that my questions were not answered. I decided not to use these interviews. If I had had more time and came in contact with more counsellors in a similar context, and used translators the interviews could have been used as a comparison with the NGO in Bangalore. I did not find more counsellors in that setting and fore mostly at that time in my field study I felt limited by time.

Hence, I base my analysis on seven interviews and four follow-up interviews as well as complementary e-mail questions with the seven counsellors at the centre in Bangalore.

3.3.1 Interviews and observations – intended plan

I intended to ask each counsellor the same 15 questions and left room for individual follow-up questions. The interviews were planned to last about 45- 60 minutes and I was open to conduct follow- up interviews if necessary. I also planned to make interviews with NGOs' that work with mental health and counsellors from other clinics to widen the perspective. Before I travelled to India I asked the centre if I would also be able to interview clients. I was not able to interview them because of the centre's ethical policy.

Early on I also had a suggestion to leave a questionnaire for the clients to fill in anonymously but that suggestion was also declined due to ethical reasons. The reasons mentioned above are partly the explanation to why I have focused on the practitioners. Another important reason is that I wanted to extract conscious reflection about the use of Western methods in India and the use of Eastern methods in India. Practitioners have naturally access to a deeper understanding of this by putting their education into practice in relation to several clients.

3.2.2 Interviews – outcome

First I conducted an informative interview with the Director of the centre to learn more about how the centre works. I was then appointed interviews at the clinic with seven employed counsellors depending on when they had a slot open for me.

After the first two interviews (out of seven) I narrowed down my interview guide from fifteen to eight questions. I did not have enough time to ask all fifteen questions and also ask follow-up questions, also it became clear that some of the questions transcended each other and one question did not work in the context. With the eight questions I noticed that I still received the information I needed to achieve my purpose. The selected eight questions have been asked to all respondents (see appendix 1).

I intentionally left room for spontaneous follow-up questions as the counsellors have different specialties and interests.

The duration of the interviews vary from 49 minutes to 160 minutes. I chose to conduct four follow-up interviews. Two of them I interviewed first and needed to meet again with the selected eight questions, and two of them I chose because I needed further information about certain topics that were unclear to me.

A final selection was made in the analysis process where I choose to narrow down my empirical material further, and exclude questions about accessibility and obstacles (question 7 & 8 in the interview guide, as well as questions 1 & 5 in the follow-up interviews). Some of the answers from these questions transcend others. And other answers turned out to stretch beyond the purpose of the essay in the thematisation process.

3.3 Transcriptions

I recorded all of the interviews and transcribed them. Certain parts that I found irrelevant for my essay were deleted. Sounds like "ah"; "ehm" are deleted, as well as laughter or coughs. I have changed some words in the transcription to make it easier to read, such as missing verbs or repetitions. No changes have been made to alter the content of the interviews.

In total I had about 100 pages of transcriptions. I sent the transcription of each interview to the corresponding counsellor by e-mail to confirm that I could proceed and use the material. In these e-mails I asked the five follow-up questions mentioned above (See appendix 2). The purpose of these questions were to cross-check previous answers that I thought were unclear, and to ask more direct questions about the consequences of using Western counselling methods in Bangalore. The decision to include further material was done last, after the decision of not including other respondents from other counselling institutions.

Six out of seven counsellors answered the additional five questions, one counsellor was not able to answer them, nor confirm the transcription. I decided to use the interview anyway since she had signed the letter of consent and I was informed by the director that it should be alright.

3.4 Method of analysis

I have organized the transcriptions into themes. I did this by organizing the interviews in accordance to the interview guide. I created a file for each question and copied all the answers to the same question in each file. Secondly I organized the rest of the material (based on spontaneous follow-up questions) by opening a new document in Word for each new subject that arose and started an open coding, which is "the first coding of qualitative data that examines the data to condense them into preliminary analytic categories or codes" (Neuman, 2011, p. 510). When the entire material had been processed in this manner, I went over the content in my new themes. This was a first process of selecting of what I should continue to break down into themes, and select that which did not belong according to the purpose of the

essay. I repeated this process a few times: copying and pasting so that similar content would not end up in different themes. Some themes overlap, in these cases I have chosen the "home" of the theme by identifying a hierarchy in what is being said. For example a respondent might be asked about the urban context and says something about urbanization but is really describing a family system. In that case the content was sorted under the theme family. This second stage of coding is called axial coding. "…during which the researcher organizes the codes, links them, and discovers key analytical categories." (ibid., p. 512)

When I had a clear overview of the titles of the themes, I read each one in detail and made an overview of each "theme within the theme" which helped me make the final adjustments or selecting my analytical themes, called "selective coding" (ibid., p. 514). This process has resulted in the central themes: Profession in context; Context and family; Advice and Premature Endings; Eastern and Westerns Methods and Approaches.

3.5 Alternatives to validity and reliability

Some scholars suggest that qualitative studies should be valued by other criteria than validity and reliability. Qualitative studies do not arrive at *one* objective conclusion about the world and therefore it is difficult to generalise the findings to other contexts (external validity). It is also difficult to generalise the results to other cases because the empirical material is often based on a in-depth perspective rather than on quantity. One advantage of qualitative studies is that scholars are often present in the research environment for a long time and therefore strengthen the process of reaching conclusiveness between observations and theoretical selection (internal validity). Good reliability is measured by the possibility of replicating the study. Since qualitative studies are conducted in dynamic and social environments that are difficult to isolate, the setting of the study will inevitably have changed and parts in the attempt of a replication will be lost (external reliability) (Bryman, 2009, pp. 257-258). When members in a research team decide over which data should turn into categories and why, it is important that this process is made in a similar way (internal reliability).

In order to measure the value of a qualitative study despite some of the problems mentioned above, Bryman introduces scholars Lincoln's & Guba's model of alternative criterias. They are: *Credibility* instead of internal validity; *transferability* instead of external reliability, *dependability* instead of reliability and *confirmation* instead of objectivity (Neuman, 2009, p. 258).

3.5.1 Credibility

Credibility is attained by making sure that the results are credible. I have used the method of *respondent validation* meaning I have conducted follow-up interviews, I have transcribed my interviews and send them to each respondent for validation. I have asked follow-up questions after the transcriptions and received confirmation from six out of seven respondents.

3.5.2 Transferability

Transferability accounts for the possibility of transferring the empirical data and results to another context. Since qualitative studies are conducted in a dynamic context a transferring process can be difficult. What is suggested is "to produce what Gertz (1973a) calls 'thick descriptions, meaning rich accounts of the details that constitute a culture" (Bryman, 2009, p. 260, my translation). This provides other scholars with the possibility of analysing the context in which the study was conducted and determine which aspects are transferrable. I have written a thorough presentation of the Indian context and chosen to include a comprising part of my empirical data under the section results. Also I have clearly separated the results from analysis so the reader can easily separate my interpretations from the counsellors' words (ibid., p. 206).

3.5.3 Dependability

Dependability of the study is made by accounting for each step in the research process and if possible receive continuous feed-back from external perspectives, for example from a colleague or tutor. I have described my process from construct to operationalization to reach dependability and also received some feed-back from my tutor during the process of writing this essay.

3.5.4 Confirmation

Confirmation means that the researcher conducts the study without intentionally steering it to a theoretical bias or personal conviction. I conclude that I have done my outermost to be open to this study, to the centre I visited and the perspectives of my respondents by continuously being close to the empirical material and cross-checking my assumptions with what has been said. This has proven to be more important and difficult than when I wrote a Bachelor Essay in Sweden, my home country. I have tried to achieve confirmation by respondent validity, to make sure that my assumptions about India, counselling in India and ways of working there

have not clouded my ability to take in what is really been said rather than what I think is being said. For a cross-cultural study like this, I would in the future, have tried to stay much longer in the vicinity of the centre and in the urban Indian context. I would also have wanted to conduct a first set of interviews, transcribed them, asked for respondent validity and first then conducted follow-up interviews with all the respondents to cross-check my interpretations and the respondent's answers and world view. I found during the interviews that many things were difficult for me to understand, as I was not culturally prepared even though I had read about the context before hand. Inevitably descriptions of what I saw, experienced and valued as characteristics for the context are based on my individual choices of what is relevant to present in this essay.

I could never have described the entire setting and all dimensions involved, not even in Sweden. But as I state repeatedly, culture is contextual and culture prepares us for certain ways of communicating. Therefore a big part that shapes this essay is the fact that I am a Swedish woman entering an Indian context that is new to me. I would not have felt as assertive of my results had I skipped the follow-up interviews or the respondent validity. These were necessary steps to make sure I understood the counsellors as well as I could under the circumstances.

4 Ethical considerations

I have followed the ethical guidelines posed by the Swedish Board of Ethics, *Vetenskapsrådet,* (2002) and adhered to the *four ethical principals*. According to the *principle of consent*, I have given each respondent a letter of consent stating that their participation is optional and that they can withdraw their contribution after seeing the transcription of their interview (See appendix 3).

Second, is the *principle of information* which is partly fulfilled by the letter of consent. The purpose of the essay and how it will be spread is described in the letter of consent. Each respondent has been given the opportunity to read the essay before publication.

Third, the *principle of confidentiality* is fulfilled by making each respondent anonymous. Fourth principle is the *use of the material*, in the letter of consent I have stated that I will record all interviews, not spread them to anyone else and after the essay is done all recordings will be erased.

4.1 Risks

Participants who feel that they regret their contribution can withdraw after seeing the transcription of the interview but not after that. To minimize the risk of regret or uncertainty over the respondent's contribution I have sent the transcription of each interview to the respective respondent and offered them several weeks to consider any changes before confirming their participation. I have also, as mentioned, sent the essay to each respondent before digital publication.

I have written the name of the organisation in the essay and a background to the organisation to give a context to the interviews. There is a risk that the respondents at the clinic will recognize their colleagues due to this, also certain aspects of their life such as educational background is an important variable to the essay and might reveal the persons identity. I have informed them about this and they have given their consent despite this risk.

4.2 Contributions

I hope to contribute to the understanding of the use of Western methods in an urban, Indian context and therefore also to the understanding of the use of cross-cultural counselling. I think this essay will be of interest both in India and in Sweden and perhaps inspire further research.

4.3 Handling of the interviews

I have recorded all interviews and transcribed them personally. I have kept the recorded interviews in a safe manner and not spread them to others, once I was done with the final thematisation and written my results I deleted the recordings. I have offered my e-mail address to the respondents so they could contact me if they had any questions.

5 Previous research

I agree with many scholars that an understanding of the cultural context in which counselling methods are used is imperative (Langugani 2005; Arulmani 2009; Gerstein et al 2009). This is a general statement within the research field of counselling and culture. When I first started reviewing previous research I was overwhelmed. I had to deal with several problems. One is the inconsistency in terms, some definitions of cross-cultural counselling would not fit my study while others would.

I found a table of terminology in Gerstein et al. (2009) confirming that these terminological inconsistencies exist. After more reading I decided to use their definition of cross-cultural counselling and aim at include research that was in line with that content.

Another problem is that psychology and counselling as subjects are interlinked on some levels yet on others not at all. The same methods can be found in both disciplines, some voices do not make clear distinctions between the professions and others do. Therefore I have used literature about cross-cultural counselling and cross-cultural psychology.

A third problem was the sheer amount of articles found in Academic Search premier, Google Scholar, PsychInfo, Libris and DIVA. I initially made a table of my search words, hits and selection by abstract and by reading the articles with the search words: mental health counselling in India + cross-cultural counselling + multicultural counselling + transcultural counselling + internalization + cultural psychology to narrow down the relevance of the studies but still ended up with studies that had a very wide range. I found it very hard to make a consistent summary of my findings. Many of the articles were theoretical and not empirical; many were based on analysing counselling methods on ethnic minorities in the West, rather than how Indian counsellors use Western methods or hybrids of Western and Eastern methods. I therefore finally decided to fore mostly identify research fields rather than specific findings to capture the essence of existing perspectives on counselling and culture.

I have identified three re-occurring research fields that I think are relevant for my study: cross-cultural counselling; multicultural counselling; indigenous counselling. They are presented below. Further I wanted to include empirical studies from India and chose a study about indigenous methods in India; a study about evidence-based practice in rural India; and a study about shifting values from collectivistic to individualistic behaviour in India.

I have also included *Laungani's theoretical model or East and West*. One of many aspects that affects the transaction of methods and approaches[3] between countries or continents are culture; norms; values. By culture I mean not only the aesthetics in a society but the deeply rooted structures of everyday living, culture in the sense of expectations, norms for behaviour and discourse. Laungani (2009) has made several studies that lay the foundation of his theoretical model of East and West, and it is meant to introduce the reader to what values and discourses are prevalent in shaping the counselling context. Languani's model is pivotal in my essay because it enables me to generalize about grand constructs such as The East and The West.

[3] Not all ways of working in counselling are methods. The counsellors describe both methods, like Cognitive behavioural therapy (CBT) and approaches, such as a person-centred approach.

I also present research about the importance of the *alliance* between counsellor in relation to the importance of *methods* in counselling.

5.1 Culture and counselling: research fields

Applying cultural sensitivity to counselling methods can be traced back as far as the 1960's where Gilbert Wrenn (1962) "…raised concerns about counsellors' cross-cultural insensitivities" (Gerstein et al, 2009, p. 57). Still today scholars identify *ethnocentrism* as an obstacle to the internalization of the profession (ibid., p. 58). For example Arnett (2008) analysed the content in six *American Psychology Association* journals and found that they mainly focused on Americans, and Gerstein and AEgisdottir (2007) found the same results concerning research about *counselling* (ibid., p. 58).

Despite this, research about cross-cultural and multicultural counselling (and psychology) has had an international expansion helped by national and international organisations (ibid p. 54). The counselling profession is evolving in non-western countries but at various paces. They offer a diversity of services. Therefore defining counselling as an international phenomenon is difficult. "The definitions for counselling, counsellor and counselling psychologist are not consistent throughout the world. Neither is there consistency in current uses of these terms nor the required credentials to use one of these professional titles." (ibid., p. 59)

The handbook by Gerstein et. al "International handbook of cross-cultural counselling. Assumptions and Practices worldwide" (2009) is a thorough account of how internalization and globalisation has made its mark on the counselling profession in a global perspective and what demands the profession therefore is facing.

Collaborations across borders are part of our global world and lead to exchange of important knowledge. The same collaboration also puts great responsibilities on counsellors to culturally sensitize the use of Western counselling methods on ethnic minorities in the West or the use of them in non-western countries. "…we are faced with the sobering reality that Western, and particularly U.S., corporations, governments and even organized counselling and psychology exert tremendous influence and power globally." (Gerstein et. Al, 2009, p. 69) Research within the field of Western counselling methods used in Eastern countries is disparate. The terminology within the relevant research field is inconsistent. Key terms that are re-occurring are cross-cultural counselling, multicultural counselling,

indigenous counselling, transnational counselling, transnational psychology, internalization and cultural psychology (Gerstein et al., 2009, pp. 5-6).

What is consistent is that the research and production of methods used in counselling today are mainly produced in the U.S.A. Therefore most studies analyse counselling IN Western countries and study ethnic minorities IN Western countries but not all. There is a need for research to be conducted outside the West.

In the literature within this field, the term multicultural counselling has grown from analysing how specifically ethnic minorities have underused mental health services - to include how other categories of diversity in human beings such as age, gender, class, sexuality and so on is connected to the use of mental health services. Criticism towards traditional counselling include the following points: 1) it is too individualistic. 2) it is based on a language that can be excluding to those who do not master that language or the beliefs that the language is build on; the discourse can be excluding. 3) socio-political analysis of the counsellors context has not been addressed enough. They, as everybody else, are not immune to bias (Choudhuri, Santaigo-Rivera & Garett, 2012, p. 10).

Indigenous counselling is a third field that is not as established as cross-cultural or multicultural counselling but equally relevant. Gerstein et al. (2009) define it as "Psychological knowledge that is native, not transported from another location, and constructed for its people (Kim 1990) by scholars from the culture in consideration (Adamopoulos & Lonner, 2011)" (p. 6). What is considered psychological knowledge is debatable. If astrology is used to help people's mental health problems is it psychological knowledge? Hwang (2007) writes that indigenous psychology comes from the resistance towards western psychology and western paradigms and solutions. Research about indigenous psychology is therefore a reaction towards the Western hegemony and a solution towards finding contextual methods or adaptations (pp. 577-578). Indian psychology is on the rise. "It is suggested that Indian Psychology offers a counterpoint on consciousness, self, mind-control and self-realization to that of the Western psychology." (Paranjpe, 2011, pg. 1) Although the subject is not part of the curriculums in Indian Universities and it is often, mistakenly, labelled as Indian philosophy and a theoretical enterprise rather than practical. (ibid. pg. 13)

> Contrary to the common misunderstanding, Indian Psychology is not simply an aspect of philosophy and idle speculation, but a matter of practice in real life. It is recognized that traditional methods of healing and counselling, often manifest in the relationship between guru and chela, are effective forms of psychotherapy (Kakar, 1982; Neki, 1973). Moreover, the great variety of spiritual practices in Hindu, Buddhist, Jain and other traditions involve therapeutic elements along with rigorous methods of meditation and self-discipline leading

to the highest forms of personal transformation and edification. (Ibid., pg. 13)

I use the term cross-cultural counselling in my essay, it is the term that I have found most relevant as I explore western counselling methods in an Indian context.

5.2 Studies made in India

Below follows examples of empirical studies made in India that identify key aspects of mechanisms that effect the counselling context.

5.2.1 Incorporating indigenous methods

Raney & Çinarba¸s, (2005) question the universality of Western counselling methods and state that is imperative to assess if they are transferable to non-western cultures. They question if theories, approaches and strategies can be assessed without a cultural contextualization; if human beings psychological needs are similar regardless of culture. They explore these statements by analysing the situation for mental health counselling in India and Turkey, two developing countries that are influenced by Western phenomenon and where counselling is still a young service.

Mental health services in India are not accessible to everyone. The profession of counselling is young, a governing body does not exist and the ratio between educated counsellors and people in need of mental health services is strongly unbalanced (Raney & Çinarba¸s, 2005, p. 154). The authors argue that it is therefore crucial that counsellors also use indigenous models of healing to increase accessibility. Examples of these are the medical system of Ayurveda[4], astrologists, shamans and gurus (ibid., p. 154).

Raney & Çinarba¸s describe India as a society with many subcultures. They stress that diversity needs to be considered in counselling approaches, and further that this diversity results in different needs in different regions. Cultural sensitivity involves not only an analysis of the country India, but also of its' regions or its' communities. "Cultural sensitivity requires the mental health counsellor to be aware of clients' worldview and to use clients' perspective in interpreting the world." (ibid., p. 155)

[4] "Ayurveda is divided into eight different specialties, one being Bhuta Vidya, which deals with psychiatry (Das, 1987; Rajkumar, 1991; Sethi, Gupta, & Lal, 1977). The importance of mental health can be seen in the classification of Ayurveda into three categories: exogenous, endogenous, and psychic. Traditional systems of medicine such as Ayurveda make up 70% of overall health care as compared to that which is provided by physicians and general practitioners (Taylor, 1976). These traditional systems existed before, during, and after the British rule." (ibid p. 154)

Stigmatization of mental health problems is a factor that decreases the use of mental health services. In addition, the authors add that some mental health counsellors express an apathy towards long term involvement with individuals that suffer from severe mental illness, which leads to underuse of counselling services (ibid., p. 155).

Raney & Cinarba refer to Chowdhury et al (2001) study in West Bengal, India, about mental illness and found that most of the respondents made little distinction between emotional distress and severe mental illness. Suffering from anything on this scale led to teasing and categorization of being pagal or pagla i.e. mad. Raney & Çinarba¸s discuss Chowdhurys study as an example of the importance of cultural understanding of perceptions of mental illness (ibid., pp. 155- 156). Shamans and alternative medicine are examples of alternative treatment, and out casting as results of individuals being untreated or illnesses unresolved. The authors indirectly state that the indigenous treatment is not enough and suggest that practitioners should be involved in the primary care, raise awareness about cultural sensitivity, involve the community and various stakeholders, and establish preventive measures through various networks (Raney& Çinarba¸s p. 156). Accessibility will increase by integration of mental health services to primary care and including indigenous components in the counselling so that it will not only be available to a wealthy population.

5.2.2 Evidence-based psychological treatment

Patel,' Chowdhary,' Rahman & Verdeli' (2011) explore two, out of many, challenges in implementing evidence-based psychological treatment (PT) in developing countries. One is the lack of skilled practitioners and two "…the cultural acceptability and appropriateness of PTs (all of which have been developed in high-income countries (HIC) in different cultural contexts)" (Ibid, unnumbered).

The study is based on randomized controlled trails in India, Pakistan and Uganda. Results show that in all three cases the practitioners lack long-term training and had no mental health background but "…with relatively short training and continuing supervision (they) could deliver the PT effectively." (ibid.) The authors suggest that anyone from the local community can be involved in improving access to PT. In terms of the methods used and their applicability the results show that they were mostly cross-culturally applicable but with modifications such as changing jargon, using pictures, avoiding psychiatric labels, using religious idioms and involving family members.

This and other similar studies contextualises the obstacles that counsellors are facing today in reaching out to more clients. The authors indicate that there is some amount of universality

in what cross-cultural counselling must address in order to be effective. Other notable barriers were detected such as:

> …the low acceptability of PTs in contexts where local communities were unfamiliar with the use of 'talking' treatments for health problems; the stigma associated with accessing health care for 'mental' health problems; the competing work pressures and low motivation for health care workers; and the low adherence often due to the opportunity costs due to time taken to attend sessions and the direct costs of transport to health facilities. (ibid, unnumbered)

5.2.3 From collectivistic to both collectivistic and individualistic

Although the Indian culture traditionally has been considered collectivistic, research has indicated that the Indian society is rapidly transforming into a coexistence of both collectivism and individualism (Sinha, Sinha, & Sinha, 2001). Each one of the many cultural groups in India may differ significantly on a number of areas that range from acceptance of mental illness to help-seeking behaviours.

The authors discuss a range of possible behaviour patterns depending on whether the individual has collectivist intentions and or behaviour, individualistic intentions and or behaviour and a combination of both. Which one is evoked is context sensitive (Sinha, Sinha & Sinha, 2001, pp. 134- 135). In the urban context they propose the following: "People in a relatively large urban place, compared to a smaller urban place, will be more individualistic in their behaviour and intentions" (ibid., p.136).

Reasons for this could be, that urban places have greater economic wealth and better infrastructure which in turn lessens the need for collectivist behaviour such as interdependence and sharing of limited resources. Instead, the urban setting encourages individualism and leaves more room for anonymity (ibid., p. 135). The authors test this proposition, amongst other, on a sample of three locations in Eastern India, mostly on males, but with a variety of rural and urban backgrounds. The results show that Indians consider "…desh (place), kaal (time) and paatra (person) in deciding on how to respond" (ibid., p. 143). They further state that the appraisal of the situation at hand is more complex than Westerners' "context-free" norms. Which I find confusing, I find the term context absolute, one can not be without context, instead perhaps the Western context has norms that appear as free, but it is still a context that affects the individual's behaviour. Nonetheless, one of the interesting results in this study shows that Indians predominantly have a familial self, meaning the collective interests of the family come first, but that compelling individual possibilities, such as a new job, can combine collective with individual actions. Mind that

individual behaviour can still have collective intentions; a pattern that dominated the results in the study.

5.3 Laungani's theoretical model of East and West

"…not all events one experiences in another culture is unique and therefore difficult to interpret correctly." (Laungani, 2009, p. 55) A primary postulation in my essay is that even though certain human characteristics are universal, the expression of that behaviour is in some cases culturally specific. Certain behaviour in a foreign country might seem strange to a tourist but make perfect sense to people that reside within that cultural context. Such assumptions, of what is culturally-specific, must be handled with care to avoid reproducing prejudice, discrimination and shallow ethnic attributes. Laungani's model provides me with a conceptualization of the categories East and West.

He presents a theoretical model "…which attempts to explain similarities and differences between Eastern cultures and Western cultures in terms of their major value systems, which guide and influence their behaviours" (ibid., p. 56). He stresses that this is a model and not a fact, and that the set of constructs that he thinks relates to East or West should be interpreted as extending a long a continuum. They should not be interpreted as either/or categories, they are dimensional with several other norms and values attached to them and they are not "…orthogonal. They are correlated" (ibid., pp. 57-58). He uses Britain and India as specific examples as they are both multicultural countries and can be representative of the East and the West. The proposed core values are:

West	East
Individualism	Communalism
Cognitivism	Emotionalism
Free Will	Determinism
Materialism	Spiritualism

The theoretical model is quite extensive, below follows a summary of the aspects that he has found can be connected to the concepts above.

5.3.1 Individualism – Communalism

Laungani writes that he prefers the term Communalism over Collectivism as the latter does not include a communal way of life. He writes that individualism is a core value in Western society. He discusses several scholar's definition of what individualism is, one that I find useful is: "…individualism is concerned with giving priority to one's personal goals over the goals of one's in-group, or of one's family members" (ibid., p. 59). By prioritizing in this manner, self-achievement becomes important as does personal responsibility. Family life is hence organised on a horizontal level. The family unit is often confined to a nuclear family and is not necessarily involved in all stages of an individual's life. Many families also live in one-parent households. While in the East, family life is organized in a hierarchical way and each member in that family has a role that is subordinated to the family as an entity. They often live and communicate in extended family networks. One has collective responsibility for the family, for example money can often be shared and given away to those most in need in the family (ibid., pp. 61-63).

Identity in the West is often understood as something one grows into through developmental stages while in the East, identity is ascribed. Therefore in the West anxiety can be connected to achieving the expected identity. In the East, anxiety may be related to family-achievement - whether one pulls one's own weight and does not create an imposition.

Social behaviours in the West are class-related while Laungani means that they are fore mostly caste-related in India. The caste system is a hierarchical order in four categories: The Brahmins (learned, the priests); the Kshatriyas (warriors); the Vaishyas: businessmen and farmers and the Sudras (they serve the needs of the three other castes). One is born into a caste and can not climb up the hierarchical ladder but if one is unclean or polluted: touched by a lower caste, or marries a person from another caste: one breaks the principle of endogamy, of separating the castes (ibid., p. 64). Laungani writes that the caste system is still prevalent within the minds of many Hindus, although it is questioned, it has not escaped the discourse of hierarchies and norms (ibid., p. 68).

5.3.2 Cognitivism - Emotionalism

Rationality, logic and control are dominant in the West because it is organized as a *work-and-activity-centred society.* Part of this extends to public display of emotions, which thus are also controlled in public places (Ibid., p. 70). In a *relationship-centred society* like India, emotions are expressed more openly. Families live together with little privacy, sharing everyday life with the family can take its toll. Outbursts are common and serve as a release.

Yet Laungani points out that there is restraint in relation to the hierarchy in the family, or in knowing ones place and role: the young rarely display negative emotions towards the elder.

Relationships are earned and worked on in *work-and-activity-based* societies while in *relationship-centred* societies they are forced through family, arranged marriages in India, separation of castes.

Finally perceptions and attitudes towards time differ, in Western societies much time is spend on work and schedules can be quite rigid. While in Eastern societies relationships are given more time than work, and attitudes towards time are flexible (ibid., pp. 70 – 72).

5.3.3 Free Will - Determinism

Concepts of free will - if one chooses the things that occur in life or whether it is determined, exist in both the East and the West but in various degrees. Laungani points out that they are logical paradoxes, both can exist at the same time or tilt more to one conviction than the other. Historically, the West dominated by Christian theology thought that man hade free will yet that God knew the future of humans and therefore their lives were determined. A contradiction in terms. Science has been occupied with these matters for a long time but have not solved the contradiction. On the one hand we reason in terms or causality, a is an effect of b. While in other areas the same person that believes in a deterministic framework within psychology, medicine or biology believes in free choices concerning individual actions (ibid., pp. 73-74). Freud for example was a strong advocate of *psychic determinism*: even our unconscious associations are determined by what has previously occurred in our lives.

The same contradictions exist in Eastern cultures, Hindus and Buddhist believe in the law of karma and Muslims in the determining will of Allah.

There are several differences between determinism and karma. One is that karma applies to moral consequences and that those consequences can be results of actions conducted in previous lives. Consequences of actions can not be avoided, hence it is seen as a just system that effects everyone, with either good consequences/good karma or bad consequences/bad karma (ibid, p. 75). The logic of karma allows for acceptance of for example the caste system, unfavourable positions are (sometimes passively) accepted as part of the cycle. Karma does not rule out free will, quite the opposite it is believed that one has the freedom of (moral) choice and responsibility. With the law of karma follows a belief of life after death. The spiritual cycle helps Hindus in accepting their caste position, tragedies and other negative experiences as there is a comfort in reincarnation and the possibility of a better life.

5.3.4 Materialism - Spiritualism

During the history of Western philosophy the idea that there is an external reality than can be understood and "touched" has always been present (Laungani, 2009, p. 78). This leads to the belief in a solid world that can be measured and understood in an objective way, in itself. Of course there are problems with this, as non-material explanations to phenomenon are regarded with scepticism. The few, within Western science that explore the non-material are questioned. "Non-material explanations fall within the purview of the pre-scientific communities, or in other words, superstitious and backward societies, to be found mainly in underdeveloped countries and, by implication, in collectivist societies." (Laungani, 2009, p. 78)

Yogis in India have claimed for over 2000 years that they can alter their state of consciousness "…thereby bringing their autonomic nervous system under voluntary control" (ibid., p. 79). For a long time this was disregarded by Western scientists as unsubstantiated claims until a Western scientist[5] proved that this could be done on rats. Soon the subject of Yoga was introduced in American universities but Laungani claims it has been done without consideration to the philosophical, spiritual, teleological aspect of it. "Commercialism has replaced spiritualism." (ibid., p. 79)

Hindus believe that the world is in constant change, and therefore studying it is not useful, the world is illusory. What should be studied is what lies within a person. Therefore the study of self, beyond the material, is emphasised. The goal is to attain spiritual awareness and break the cycle of birth and re-birth (samsara), finally reaching moksha[6]. "The main object of Indian philosophy is to bring about a radical change in human nature, a change that eventually leads to human perfection, a divine God-like state. This… tends to make Indians more *inward* looking and Westerners more *outward* looking." (ibid., p. 80)

There are several rituals performed in Hindu life where the secular and the sacred are connected such as washing ones hand or offering food to others, many rituals concerning purity and pollution are connected to Hinduism and caste rather than only hygiene. While the distinction between secular and religious behaviour is more clear in Western society (ibid., p. 65).

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[5] Neal Miller (1969) trained rats to lower and raise their blood-pressure, he also trained his students to control over their autonomic responses.

[6] Moksha is the final liberation of the birth/rebirth cycle.

5.4 The alliance between counsellor and client

There is a lot of research within psychology, and psychotherapy and some in counselling about the importance of the relationship or alliance between counsellor and client (Larsson & Tryggved, 2010, p. 253). The authors write that within the research field of evidence based practice, the field of psychotherapy is relevant, as there are many similarities between counselling and psychotherapy. One of the issues that have been studied is whether the counselling methods or the client-counsellor relationship make the counselling or therapy the most successful.

> An important result has emerged in psychotherapy research and that is that the therapists ability to create a working alliance with the client so that the meeting is merged in empathy, warmth and support is of decisive importance to the treatment outcome… This means that counselling, that emphasises the importance of empathetic communication and active listening to the client becomes particularly relevant to bring attention to, concerning social workers in treatment-settings with clients. (ibid., p. 254, my translation)

At the same time research shows that some methods are better than others, for example when treating depression, psychotherapy is better than non-psychotherapeutical treatments (ibid., p. 254). Also there are examples of how certain treatment methods even harm the clients. Mullen, Shuluk & Soydan (2011) write that there is support for the claim that methods help in various ways and that it is not only the alliance that should be considered. Bringing attention to implications of methods is important in terms of avoiding potential damage (ibid., p.12). If merely the alliance was of importance it would be of no use to develop and implement new methods or interventions (ibid., p. 24). A combination is the most effective.

6 Theoretical framework

Social constructionism lays the foundation for the section about theories. Social constructionism is an ontology based on the stipulation that knowledge, constructs and practices are created contextually in relation to its surroundings. Constructs are products of social processes (Larsson, Lilja & Mannheimer, 2005, p. 314). Take the word depression as an example. When doctors use the word, they refer to a serious mental condition, while in every day discourse - the same word can mean a simple change in mood. The context defines the construct *depression* (ibid.) Social constructions are not exclusive or absolute, they co-exist with other constructs, for example with mentally ill or crazy, and because they are the products of its context, and context changes: certain knowledge changes. But social constructions are shaped by dominant discourse, by paradigms: such as Western counselling

dominates the research field of counselling and therefore shapes constructs of for example what is considered successful or unsuccessful counselling (ibid., p.16).

The main point with this theoretical framework is that counselling- in the widest sense of word including practice (how it is used and manifested) is contextual. When counselling knowledge is produced in one context, and is transported, imported or moved to another context, it changes. To understand the process of how information travels and changes in context I will use the theoretical constructs of *Translation* and *Glocalisation*. I will contextualize the organisational framework of Parivarthan through theories derived from *New Institutionalism* with constructs such as *institutional organisation, decoupling, rationalised myth* and *organisational field*. I use Arulmani's construct *cultural preparedness* to analyse the cultural context in India.

6.1 New Institutionalism

Larsson, S., Lilja, J., Mannheimer, K (2005) writes that social work most often is structured and practiced in organisations, therefore the study of organisations is vital to understanding the profession. Since organisations are dynamical they can be studied from several perspectives. Research about organisations have changed a lot during the last decades. A traditional analysis has been that organisations act like rational entities run by goals, therefore it has been assumed that organisations were structured in a intentional way. A theoretical shift has occurred (Lindqvist, 2000, p. 82). The rationality of a organisation is questioned. Instead focus has moved to the importance of the organisations surrounding to understand its' functionality. There are many different kinds of organisations. I will focus on the *institutional organisation* that is steered by "…social constructionist patterns that exist in its surroundings" (Larsson, Lilja & Mannheimer, 2005, p. 326, my translation).

> To become successful, an institutional organisation has to meet the demands of its surroundings. The demands are not made up of specific demands like they could be on a product, in market oriented organisations. In a institutional organisations surroundings, discourses place demands on the establishment. (ibid. p. 326, my translation)

Hence, for an institutional organisation to be successful it needs to adapt to the demands of its context, such as to laws, norms, the structure of similar organisations, demands and influences from research (ibid., p. 327). Since the demands are created contextually they do not always have a clear transmitter and these demands or norms, can be conflicting with the goals of the organisation. One way to solve this is to separate "…the formal structure from the practical

work" (ibid., p. 328). This is called *decoupling* (Lindqvist, 2000, p. 84). A social worker is for example guided and restrained by laws, guidelines of how social service should be run, but in the meeting with the client there is freedom for the social worker to steer how that meeting could go about. This is an example of decoupling as a strategy to steer away from institutionalism: separating the formal structure from the practical (Larsson, Lilja & Mannheimer, 2005, p. 328).

Further, an organisation can be in congruence or competition with its surrounding (Lindqvist, 2000, p. 82).

> Therefore one can also say that the surroundings creates- rather than effects- organisations. The provisions, work principles and game rules that apply to organisations thus become to a higher degree, decided. When one observes organisations in this manner – as part of a institutional field – one can say that even the 'surroundings" act according to determined approaches, behavioural patterns and cultural interpretive models. (ibid., p. 83, my translation)

Simply because an organisation adapts to the norms of its surroundings more than another organisation, does not mean that it is effective or better qualified. Instead the adaptation to norms creates a sense of legitimacy and the organisation gains control over more resources as a result of this. This is called *rationalised myths*, "…meaning the notion that certain activities are simply better suited to be conducted by a certain organisation in a certain way" (Lindqvist, 2000, p. 83).

I am not comparing several, specific organisations in my empirical material and therefore I will not be analysing institutionalising processes. I am looking at one organisation and to understand it I will include institutional surroundings as the respondents describe it. Institutional surroundings have to be understood in multiples, there is not one that can be generalised, there are several "alternative institutional environments" that may be in competition or in conflict (Lindqvist, 2000, p. 85).

The construct *organisational field* is used to describe "…organisations that, within a field of service or business, have similar tasks and therefore can be subject to the same process of change" (Lindqvist, 2000, p. 87, my translation). For example counselling belongs to an organisational field of mental health support and will be effected by similar institutional organisations within that field.

Within an organisational field there can be several *domains.* A domain is "…the claim an organisation has on delivering products and services to people" (Lindqvist, 2000, p. 88). Domains can be in harmony or in competition with each other. Either organisations agree on which organisation belongs to which domain or not. If there is *domain consensus* the

organisations work in agreement of who does what and co-operation works well, or they disagree and are in conflict of *domain claims* (ibid., pp. 88-89).

When several organisations evolve that belong to the same branch, a process of standardisation occurs. The strongest actors in this standardisation process is the government and the professions connected to that line of work (ibid., pg. 87).

> (This)… lessen(s) the diversity of the field which reduces the possibility to take subjective initiatives for change. When organisations thus have to consider each other in this conforming way, they are forced to what DiMaggio & Powell call *institutional isformism" (*ibid., pp. 87).

Meaning if several counselling organisations are standardized it is of interest to analyse how organisations react to these forces.

6.2 Glocalisation and translation

Giddens explains how ideas, objects and acts behave when they change context. He introduces the constructs *disembedding* and *embedding* (in Czarniawska, 2005, p. 112). Ideas and practices are embedded in a context with its own set of values and understandings. Once an idea is moved to another context, "…it can be as short as the distance between the office and the factory" the idea has changed (ibid., p.112, my translation). It is pulled, *disembedded* from its context, which means that ideas that move are never the same. They embed into something new, into a local translation. Czarniawska explains how this behaviour is connected to institutional organisations: "When an idea is transformed into an act and that act is repeated till it has a normative explanation ("that's how it should be done"), an institution is created" (ibid., p. 112).

Another prevalent word in this theoretical framework is *Translation.* When ideas move and change context they must be translated, adapted to the new context to survive. Similar to being embedded. In order to avoid analysing the shift of ideas as pure relocation and imitation, the receivers of ideas can be seen as active agents and both movers and transformers. The term translation was introduced by Bruno Latour to capture the active component in this transmission (Johansson, 2002, p. 145). Central to this construct is that ideas do not simply move from one place to another and are imitated by the receiver. For ideas to survive the change of context, they must land in the hands of active agents. The degree of engagement is affected by several variables. If the idea is moved from an organisational field to another that resemble each other, the institutional norms might be

strong, with clear norms of implementation, content and use. If not, there is more room for the receivers of the idea to adapt it to the local context (ibid., p.146). By viewing transportation as translation, this construct is focused on the process of change and focus amongst other things, on how the receivers interpret the idea and how they work with it (ibid., p. 146).

With globalisation and modern technology ideas can move fast over the Internet and into several directions across the world, at the same time.

The local and the global co-exist in a cause and effect spiral, one constantly affecting the other. Czarniawska explains that *globalisation* means that one practice travels from one part of the world to another or that a concrete act transforms into an abstract idea and can be spread. *Localisation* means that a local identity is created, that when an abstract construct becomes an act/practice- it becomes concrete in a local setting. This process between local and global ideas is called *glocalisation* (ibid., p.113).). Glocalisation captures how one idea moves into several different locations at the same time, rather than how one idea moves from one place to another (Czarniawska, 2005, p. 112- 113).

6.3 Cultural preparedness

The fundamental assumption in this theoretical construct is that the success of a counselling method or approach depends on if "…creators and consumers of the counselling service have been culturally prepared in a similar way" (Arulmani, 2009, p.254). This means that certain phenomenon within a culture prepares its inhabitants to think, feel, behave in certain culturally bound ways, share similar vocabulary, life orientation, values and so on. If counselling methods are produced outside the context in which they will be used, cultural preparedness must be considered.

Therefore, for counselling services to be effective in a global context, they can not be categorised as a Western specialty. "If these critiques are to be addressed, it would be necessary to examine subjective versus objective epistemologies with a view to building bridges that would allow counsellors from different persuasions to function in tandem." (ibid., p. 254) This allows for elements in Western methods to be directly incorporated in Indian counselling as long as they adhere to an objective epistemology, meaning that they should contain elements that are universal or objective. Parts of these methods should then be adapted to what its inhabitants are culturally prepared for. This theoretical construct will be used in the analysis to understand if a distinction between universal and contextual methods or elements in the methods are made by the counsellors and if so how.

Arulmani lists three key characteristics that Indians are culturally prepared for: 1) to Abide Contradiction; 2) Individualism and Collectivism; 3) The Centrality of Religion and Spirituality (ibid., pp.254- 256).

1) India's has a history of serving as home for different populations. For 2000 years people have travelled there for trade, migration and invasions. This has resulted in a population that consists of diverse groups. What is striking is that these groups have learnt to "coexist rather than merge" which in turn has resulted in an cultural context that invites relationships to be shaped despite disagreements and an atmosphere filled with contradictions (ibid., pp. 254-255).

2) Indian culture is identified as collectivistic. A theme already raised in previous research. Though studies (Sinah & Tripati 2001; Arulmani & Nag, 2006) have shown that Indians are collectivistic *and* individualistic. "The primacy of the family and caste and kinship bonds could be examples of collectivistic orientations. Beyond this, individualism seems to dominate." (Arulmani, 2009, pp. 255)

3) 80 % of Indians are practicing Hindus and India is a religiously diverse country. Each religion has it own set of beliefs, celebrations and norms and therefore effects "common cultural practice". Arulmani stresses that this theme is not about understanding the boundary between religion and counselling but to "…derive principles that could be integrated into a counselling approach…" (ibid., pp. 255).

Further Arulmani gives example of how a *Holistic Conception of Life* is founded in traditional healing methods such as Ayurveda that connects body and mind, individual health with one's social interactions. Hence disconnecting body and mind or the individual from his/her family in counselling "…will most likely fail to address the felt need" (of the client) (Arulmani, 2009, pp. 260).

> A counselling approach that is empirical and individualistic in its orientation, for example, may not find resonance amongst Indians, whose culture has prepared them over the ages to approach their existence in an intuitive, experiential, and community-oriented manner (Gerstein et al. 2009, pp. 254).

What Arlumani's construct adds, in comparison to Laungani's theoretical model of East and West (in previous research) is the *demand* of identifying what clients are culturally prepared for. Laungani's model is rather a categorization tool, based on several studies, to be able to operationalize the meta-constructs East and West.

7 Results

I have structured the presentation of my results by the central themes: *Profession in context; Context and family; Advice and Premature Endings; Eastern and Westerns Methods and Approaches*. Each central theme has sub-themes, together they form a unit which is analysed before the next unit is presented. These units are further summarized in the section: *Summary and Discussions.*

7.1 Profession in context

In this section I present the counsellors reflections about how they define counselling, how they reason about the conditions for counselling in terms of inconsistent training demands and the lack of a regulatory body for the counselling profession. The counsellors emphasise the client- counsellor alliance as a core value in their work. I end the section with an analysis using theoretical constructs from New Institutional Theory and drawing connections to previous research about alliance.

I asked all the counsellors to define what counselling is to them. None of them included descriptions of methods initially in their definition. One referred to theoretical frameworks. This does not mean that they do not use methods, but it gives an indication that methods are secondary to other elements at first hand. Rather they emphasised what counselling is for the client, a: ”safe space; sacred place; reflective space; a process” and they return to the importance of the relationship between the counsellor and the client. “…it is through the relationship through which the counsellors work, and it is a process of change which is facilitated by the counsellors but the client plays equally, or as an important role in it.” (R4) R7 describes the counsellor- client relationship as circular, that she learns as much from them as they from her. She continues that counselling is more than a profession, it is a way of life to embody empathy, non-judgment and authenticity. Also all counsellors emphasise the importance of following the client’s will and wishes.

> …it is a journey that I travel with the other person. Always mindful never to allow them to, never allow myself to become them… to achieve results they might want... So for me it is a journey, journey with somebody, I need to have expertise, skill and understanding but a lot of me is involved. (R3)

As mentioned previously the demands on training for counsellors is very varied in India, one counsellor compares the situation in India with the West. She says it has become very specialised in the West and that demands for evidence based practice is increasing.

> …to me it seems that therapist's who work in a more humanistic way, in a free flowing way find it very difficult to give evidence based thing so, I do not know how helpful it is. My hope is that it does not come to that point (In India)… I mean to know that there is a certain expertise with a title, I can only do so much. Knowing your limitations is helpful but also to not be to confined, like you say in rural areas you are not as trained but you are willing to help. You have the basics, and I think that all evidence shows, that it is the relationship that finally matters the most between counsellors. The techniques of it is really, you know, important, but not the main thing. (R7)

Several of the counsellors stress that it is the relational aspect that is the most important. To evolve a rapport, trust and relate to the client is central. To apply a specific training is not the most important, even if the latter is relevant. The quote above is an expression of association with specialisation, training and evidence-based practice and a fear that it would confine the counsellor. A combination of training and good rapport would be preferable.

> …it is a treatment in itself to be able to relate to the person and have that connection. If you have a person who can do that, then they perhaps can help a lot more than a person who has many qualifications but that aspect is not there. So I think personally at this point, that we will get there and I hope by then it will be a lot more understanding of the best way we can get there, we need a combination. (R7)

R7 thinks that the relationship is a treatment in itself, and that a trained person without the ability to evolve that rapport can not help as much. The counsellors at Parivarthan highly value the rapport and reason that it effects their work a lot.

7.1.1 The conditions of the profession

One theme that arose in the interviews early on was about the lack of unified training for counsellors and the lack of a national regulatory body. In India counselling is not systematised. I asked about how this affects the counselling situation and how the profession can be understood in comparison to the West.

> I think if the training is standardised and the institutes are recognized, then diplomas will be more widely accepted as professional qualifications. There could be a formal award of license to practice. This would promote excellence of counselling in India and counsellors would welcome it. It would also positively affect the perception of counselling among the population. I think it is inevitable that this will happen. (R6)

R4 also talks about the importance of a regulatory body providing guidelines for counselling. She thinks that a counsellor should have access to supervision, go to counselling themselves and abide to ethical guidelines. These requirements, and services do not exist today on a national level as a demand within the profession, but are practiced at Parivarthan.

R1 further adds to the diverse practice of counselling and says that a division of specialties between clinical psychologists and counsellors exists, but that they do similar work. "There is not much difference between psychotherapy and counselling." Further the title is not important, instead it is about knowing your limitations and competence:

> …this is a message which I would like to send to anyone that trains that it is not what we call the trade, but to know that when I am working with a client, to know that there is a point where I need to stop and ask myself, am I the best person to offer this to the person? …depends on the place if I was in a small rural set-up, you know maybe I would make it my business to read a little bit more about psychopharmacology knowing that it would be hard for people to go to the city but in a set up like this, there is someone else who can do that, then why should I take it on? So to know the limits of my competence is very important. (R1)

R1 explains that the title is not of great importance and that professions within the field can resemble each other so what is important is self-reflection about one's own competence and knowing when it is not enough.

R3 says that boundaries and regulations help keep people accountable. It also puts the counsellor in a straight jacket. She says that conscientious people are needed "…for it to be working for everybody otherwise systems comes into place, it can become robotic eventually. But that is what a governing body constantly has to endeavour." R3 places the responsibility on a structural level and says that it is the governing body's responsibility and that it is a challenge to balance systematisation and professional freedom.

In Bangalore, the National Institution of Mental Health and Neurosciences (NIMHANS) is an important organisation within the field. Several counsellors talk about it as a great influence to reduce stigma and raise awareness about mental health problems and counselling. R5 continues and describes NIMHANS as an "amazing institute" though it is associated with a mental hospital.

> They do a lot of research, very robust model, very research-based, medical-model based…but they are what we used to call a mental hospital. So a lot of people are very resistant to go there unless it is a very severe problem that you have to go there for. (R5)

She says that the government is trying, and takes an example of how a principal was accused of inappropriate sexual behaviour and NIMHANS decided support was needed and outsourced counsellors.

> …the government got involved, the ministry for the welfare of children got involved and they actually insisted that psychological assistance be provided in the school for the children and the staff both to asses the extent of what had happened and also to provide a space for some kind of healing and closure to take place. Now this was a directive from the government. Which, made me very surprised but happily so, so there is a group of us involved with going to the school…There

> has been some part from the government to try to demystify and de-stigmatize mental health, you know, some small effort but I do not think that that has been particularly successful. (R5)

7.1.2 Analysis: the profession in context

I started all the interviews by asking for a definition of counselling. The counsellors emphasise the importance of the relationship to the client. There is an international discussion concerning: to what extent evidence-based practice is, and should be, part of social work and to what extent it is, or should be experience-based. As mentioned in previous research, the alliance between client and counsellor is very important and lays a foundation for successful treatment. Although training and conscientious decisions in choosing working methods are emphasised as variables that will affect how successful treatment is. (Mullen, Shuluk, & Soydan, 2011). The counsellors emphasise the importance of both the alliance (or in their words the relationship) as well as the use of methods, although the relationship is rated slightly higher than a method in itself.

An external institution that would impose limitations to *who* can practice *what*, such as a national body controlling licensing to counsellors does not exist in India. The counsellors have different views on this. They are not necessarily conflicting, but they engage in different perspectives. The responsibility of not working outside of one's competence is the individual counsellor's responsibility say some of the counsellors, while others emphasise that it should be the role of a governing body. There is a clear opinion that systematisation can reduce the freedom within the profession, examples are taken from the West where containment is a possible consequence. Parivarthan offers supervision and the counsellors engage in personal counselling as part of their work. It is through the client and the supervision that they evaluate their work.

This can be understood in terms of *translation*: the methods are not followed by rigorous set models of implementation, they are translated into the context in which they are practiced. They counsellors are rather free to implement them as they see fit as the norms for the profession are not nationally standardized (Johansson, 2002, p. 146).

Parivarthan is part of a complex *organisational field*. Lindqvist (2000) writes that it is the government and the profession that affects the organisation field the most (ibid., p. 87). An example of when the government is involved, through NIMHANS, is described as a nice surprise. Although NIMHANS is an important organisation and part of the progress of making the profession acknowledged. The other aspect that affects the organisation according to Lindqvist, is the profession (ibid.). Previous research indicates that a counsellor in India can be a person who attends a three-day workshop or a two-year program (Arulmani, 2009, p.

252). At Parivarthan the counsellors have a minimum of one year training and several of them more than that.

The counsellors relate to the West in what they do not want to become as well as how they are inspired by the West and use Western methods. The Western practice hence seems to be part of the surroundings that shape the *organisational field* of counselling, together with the Eastern and indigenous surroundings.

7.2 Contexts and family

In part two I describe how family and communal life play a big role in support systems and how it shapes ways of communication. I start with comparing the rural and urban setting. Even though Parivarthan is in Bangalore, I have chosen to include the rural setting to shed light on how the cultural values change in the urban context. I then present results on how conversations with family members can fill a similar function as counselling does. Finally I present the counsellors reflection about the role of the family in counselling.

7.2.1 Urban and rural

The counsellors say that the use of Western counselling methods work in different ways depending on the context, not only the culture. R5 has experience from working in a rural setting, she discusses the element of boundaries and what adaptations she had to make to reach out in a village she worked in for a month:

> I did work with an NGO in a rural area, I was living there for a period of a time. So everybody in the village knew where I lived. And in time when they learned what I was offering they would kind of pop in whenever they felt like it to chat. So what I did say is that - let's see if we can have kind of pop in times and times where you can not pop in. And then my office did not become my room, not my bedroom where I was staying. But rather it became under a tree and under a particular tree, that was next to a generator- which they wanted because then it is loud. Other people can not hear them. So that was my room and I did these groups…We would all meet together and I did the group work and then I'd say if you feel that you need a chat, this is the time where I will be at the tree and you can come and you can see if somebody else is sitting with me under the tree, then walk away and then you can come back. We would never do that in a Western counselling context, you will never be out on a field, under a tree where people randomly are walking in. But it was a context that demanded that… (R5)

She discusses different boundaries in the counselling situation; room; time; space. In the rural setting it would be inappropriate to have a counselling session with a stranger behind a closed door she says and she had to change the setting of her methods according to these aspects. She says that it would not happen in the West. Or maybe not even in an urban setting.

She continues about more differences, one being language. In the local language Tamil, she says the word for emotional and physical pain is the same. "So then you have to kind of explore that more. ..is it the pain like when you fall down and hurt your leg or is it a pain like, ehm, inside?" She also used metaphors from Indian epics like the Mahabharata[7] from which she used words and characters.

> So one of the things that we used a lot were metaphors and stories and characters from the Mahabharata. There was sort of a question of a big trail, and the characters that symbolize the trail almost like archetypical characters, you know it is very Jungian. More Jungian way of working. So I would maybe use more of that than I would in an urban context. Definitely use more physical play, because there was less physical inhibition. (R5)

R5 makes an interesting connection between archetypical characters form an Indian epic and Jungian archetypes. But she adds that she does not work with Jungian terms in her counselling, it is not something that she personally likes to utilize. Metaphors are also used by the other counsellors in the urban context but none of them refer to physical play or counselling in open spaces. They offer counselling in private rooms at the centre in Bangalore.

Another difference between rural and urban contexts, is the role of the family. In the rural setting it is common to live together with members from one's extended family. In the urban setting many have left their family behind or moved with their partner and children. They move and find themselves in a context without many relatives close by. R3 says that a client can think in terms like:

> I do not have uncle and aunts and grandmothers and grandfathers who I can go to so I find someone who is impartial. Sometimes I find someone who is impartial because my values are very different than my family's values. I do not want to get married, I want to work and I want to be independent. I want a relationship and my family will never understand that, so I can't go and talk to them about it.

And she adds:

> So there is a cultural change and the city is where counselling works really well. It does not work as well in rural settings…people want anonymity, they want to be more individualistic (in the city). (R3)

The quotes indicate different value systems, "a cultural change" between the rural and the urban context. She says that individuals seek out someone impartial, for example a counsellor where room for individuality is present.

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[7] The Mahabharata is a Sanskrit epic from ancient India.

7.2.2 Conversations and counselling

The counsellors describe the communal way of life in India. People talk openly about many issues and do not perhaps wait for a certain time and place. ”…they might just step out of their house and say hi, hello and exchange something and say - How are things, oh so your daughter is eligible? You know, they pre-empt conversations…” (R1) It might be considered rude by Westerners. But it is the nature of talking in India. “…these boundaries of how much you talk, what you talk, when you talk, where you talk are not so strict” (R1). Also big family systems allow for availability, there is always someone to talk to. “…the family is a big support system, maybe the one at home, the elderly person, whoever, is available. Now this is shrinking, that is why there is a need in another place.” (R1) Also many go and talk to a doctor, an expert.

> So culture plays a huge role, hierarchy plays a huge role, authority is respected. So someone, a doctor says this is the right way, is something that will be far more easy for someone to accept than say what do you think, what is it that you want to do? (R3)

R2 says that people might not be looking for counselling because talking is available within the community or family. ” It may not be replacing, they might not really be looking for counselling…the people are easily available for talk, and share and be.” R5 on the other hand say that there is an exotification of life in the village, concerning the availability to talk. Mental health problems are many times marginalized and hidden, and many times these people live on the fringes of society.

> …for many decades definitely for the last hundred years, mental health in India, whether it has been urban or rural – is something that has been out. That has been pushed away to the margins. And you are not supposed to have emotional problems…And there really were not mechanisms that addressed this, now yes, when it came to grief or loss, yeah we had a very codified system of how to deal with grief… (R5)

R5 explains that when it comes to normal life transitions, there are traditional rituals and support mechanisms that help. Emotional and psychological problems do not fall into that category. She thinks there are more types of mechanisms needed.

> I am not saying that it has to be a Western one-to-one counselling or psychotherapy, I think psychotherapy in its purest form would be quite useless. Because I think it is cumbersome, it is heavy. And I think that it takes to long. And I think that there is a certain sense of collectiveness about community and society that we loose when we do one- to- one psychotherapy but having said that I think that there are methods and things that we can do today for emotional well-being and mental health. I think that we need to do that. So it might look different, it should look different.

Several counsellors return to the fact that despite the Western influence on counselling, there is a context, a structure, that Western counselling methods enter into. There is a long history of doctors working with mental health and it helps the clients to think of the counsellors as doctors.

> If we go down to the historical roots, you know we do not think of it as Western influence the fact that people used to go to a medical person. In our country we have, you know, the ancient system of medicine, the doctor was called the Vaid or in other languages he would be called a Hakim they would dispense medicine or they would give something by which people could be treated so that tradition has been there. … they have been trained in that medical system so this could be the Ayurveda medicine, it could be the Unani medicine… for a long time it was the medical people who went into psychiatry, and of course there were the psychologists also, there were doctors interested in psychology. I think that so called Western influence actually came into something that was already in our country. We have people who come for counselling and call us doctor. So it helps them to think that they are going to somebody who, in some way, knows about mental health. (R1)

7.2.3 Family

Since life in India, urban and rural, is described as communal, family inevitably becomes a big part of the Indian life. Whether it is wanted or not, family ties play an important role in terms of responsibility towards family members and needing them as a support system. Respect and acceptance or roles within the family hierarchy affect many choices in Indian life. It also effects counselling. "Ehm, family even if you work with an individual the individual is part of the system. It is a family system." (R2) She also says that she ultimately asks what the client wants in terms of family involvement. Sometimes they work with only the individual but she points out that family origin is of great importance.

R1 says that in-laws, also have an important role in the family system. If a young couple marry and want to live alone it is still important to involve the in-laws and hold on to the family bond. "At the end you do not want the son to be alienated from the mother, in England I may not say this in such a big way, but now I am not in England…" In a counselling situation like that, where the couple struggle, she says she could be a bit more directive and help the couple release some burden, but at the same time she would aim at helping them endure the situation. Endurance is a part of the Eastern way she says. In the mentioned scenario she would also use system theory to help them understand.

> …because we are a very relational people, collective society and I think it is an important aspect of human beings, I think that the West is opening up …I am not a bound entity, I am part of a society, I am because I want to relate with peoples values. In how we relate to people, and how much we interact with our families, is perhaps a little bit different here and a little bit different there. But human beings are relational. (R1)

R1 points out that the expression of family life can differ from culture to culture, but the fundament is that human beings are relational, regardless of culture. R7 agrees that the family is important. As a counsellor she says, to ask the client to make decisions in isolation and only work on an individual level, does not work. What is OK with parents, grandparents and in-laws has to be considered. They are not physically involved unless the client wants it, but they are part of the framework for which the client relates to and lives within.

7.2.4 Analysis: Contexts and family

"One can discuss to what degree the relationship between the professional and the client is determined by its surroundings. If the relationship is determined by factors outside the conversation then the relationship is even more steered by surrounding factors." (Larsson & Tryggved, 2010, p. 251) R5 changed the counselling framework when she worked in a rural setting. She offered counselling under a tree, visible to others, next to a generator to drown the sound of their voices to others. The rural context demanded changes in *how* she practiced counselling but not *what* she practiced. The surrounding changed and she adapted to it. In Giddens terms this *move* can be understood as *disembedding* the counselling construct from an urban context and *embedding* it into the rural context. (Czarniawska, 2005, p. 112) Or as *translation*. R5 understood that her new clients were *culturally prepared* for certain forms of counselling (Arulmani in Gerstein et al, 2009, p. 253). For example sitting under a tree rather than in a closed room, as well as norms about time limits and space. Patel,' Chowdhary,' Rahman & Verdeli' (2011) write that other elements can be effective to change such as terminology or involving family members. The counsellor had to explore the meaning of pain as the same word describes both physical and psychological pain. Further the community is involved in the presence of a counsellor, the need for closed doors was not there.

Some of the counsellors believe that the need for anonymity and individuality is more present in the urban context. Clients are separated from their extended family and seek out an impartial person to talk to because of shifts in value systems. Individualistic and communal values exist side by side in India (ibid., p. 255). Sinha, Sinha & Sinha (2009) stress that it is the context that bring out either more collectivist or individualistic orientation. Yet the urban setting encourages for individualism because it has better infrastructure and better economic possibilities which lessens interdependence (ibid. p. 135) although the community orientation is still present, and many times it serves as a therapeutic outlet.

The counsellors explicitly say that the urban context is better suited for counselling. The counselling methods are more or less the same, but anonymity, a closed door, a private space is more needed to reflect the needs of the urban, Bangalore client. This does not mean that they are saying that counselling is better than other methods, but that it appeals to urban clients more than rural clients.

In the rural setting there is always someone around to talk too. Also, one counsellor stresses that certain problems like grief, has a place within the discourse of religion, through ceremonies, part of the life cycle. Yet other problems like a mental illness can be a taboo and does not have a given place in the discourse. There is a long history of marginalising people with mental health problems (R5). The open arms and availability of talking can sometimes be mistaken for a discourse that allows for certain subjects and not other to be discussed within the family sphere. Chowdhury et al (2001) study about cultural perceptions of mental illness, showed that there was little distinction made between severe mental illness and emotional distress, and that stigmatization was a big problem. This study shows that mental health interventions must be connected to indigenous models such as Ayurveda or Shamans and also connect to other professions, or *organisational fields* and stakeholders (Czarniawska, 2005). Perhaps counselling that would engage in rural communities in this way would be more successful in catering to the needs of potential clients.

R3 says that many seek the help of doctors because doctors have the legitimacy of being advisors. Doctors, together with authoritative figures and elderly are often sought out for help. In terms of New Institutional Theory this can be understood as a *rationalised myth* (Lindqvist, 2000, p. 85). Doctors belong to the same *organisational field* as counsellors that work with support for various mental health problems. Lindqvist (2000) writes that *rationalised myths* provide legitimacy, but it does not mean that the organisation in question is necessarily effective.

Going back to the results in part one, the standardisation of the counselling field could lead to a clearer distinction of professions and awareness of what counselling is. The organisational field is a mix of professions and the fact that clients think that counsellors are doctors indicate that it is not always clear which *domain* the counselling field belongs to. Further the legitimacy of doctors comes from a long history of ancient medical systems. Among them the Ayurveda medicine. In Ayurveda the body and mind are connected, hence going to a *doctor,* means going to someone that can help in many ways. Arlumani reasons that separating body and mind, or individual from his/her family in counselling, will be

ineffective as Indians are culturally prepared for a holistic approach and a community-based living. (2009, pp. 254)

The counsellors talk about an already existing, indigenous context that is fused with Western methods. This process can be understood as *glocalisation.* The counselling practice is institutionalized somewhere (in the West) to the extent that it can be transformed to a to an *abstract* idea that can move: globalisation. Through technological support that abstract idea is received in another context (Bangalore), and through *localization* the abstract idea becomes concrete, practiced (Czarniawska, 2005, p. 112- 113).

It also gives hints about what Indians are culturally prepared for – seeking help from authorities. It also reveals something about the unintentional, abstract process of how information is in constant motion. When the information "lands" in Bangalore- an organisation field will "grab" it and merge it to its own. By this process it could seem that simply by using Western methods in an Indian context, an adaptation will be made the to Indian context. At Parivarthan the methods are adapted in terms of what the target group – counselling clients with psychosocial problems, are culturally prepared for.

7.3 Advice and premature endings

Advice is commonly expected to be given in counselling. Several clients expect fast results and the average client comes for five sessions. In this segment I present the counsellors reflections about why clients expect advice. The counsellors do not think that advice belongs in counselling. Further I present reflections about reasons behind *premature* endings.

7.3.1 Advice oriented counselling

Many times clients expect to receive advice when they come to Parivarthan. The counsellors explain that they do not work with giving direct advice and some clients adapt to that, others quit.

R5 says that the client expects advice from the counsellor as if the counsellor would be a guru. Some clients become very annoyed, they come in for help, the pay for it and say "please tell me what to do". She firmly believes that giving advice is not counselling, because clients need to arrive at their own decisions. "It is the process of arriving at that, that is empowering." But many clients continue coming and gain a certain sense of empowerment from achieving results by themselves "…not blindly following others. So I think that this is one of the challenges that we have in India maybe more than you have in the West." (R5)

R6 thinks that the expectation to receive advice is a consequence from a (low) education level and a lack of awareness about counselling. In a rural setting, where the socioeconomical situation is often different from an urban context, individuals might be prone to reason: "…for them it is like that you go to the elder in the family for advice, they tell you what to do and you do it. And that is what they are used to, that is what they know. Whereas in an urban setting they might be exposed to, and aware of a different way." R6 says that she uses brainstorming techniques with the clients but she would not like to become more advice-oriented in her work with the client. R7 is of the same opinion, the client's expectation of advice can be met to a certain degree by exploring alternatives, and focusing on solutions but it has to be done within the counselling framework.

R1 reasons in a similar way, but goes one step further and says that she would consider being more advice-oriented after exploring the clients frame of reference:

> …it is still culled out from that edge, where the client hovers between inclination to move in one direction and feels held back due to anxieties. This 'advice' is expressed from a felt sense of the encouragement or nudge the client is looking for.

In scenarios where the client would be in danger of harm she would consider giving advice from her own frame of reference as protection. R7 would also consider advice-giving, if the client has a long-term engagement or is in some kind of a crisis.

> I think that we seek advice-giving, culturally in India that is the way our mechanisms of support have been structured right…That is similar to an Astrologer who is very specific and will give you a set of clear set of prescriptions. Do a specific puja (a Hindu religious ceremony), go to temple, make an offering. You have to do this every Saturday for one year. Or you have to wear a sapphire ring for a year, or you have to do something else or feed some fish. You know they give you a very specific prescriptive thing you have to do. They will give you an explanation, oh your life sucks, or you son is not doing well because his planetary alignment – right now there is some mercury in some place. Do this and for the next two years do not worry about your sons marriage. This gives people a lot of comfort. (R7)

R7 continues that many come in wanting the opinion of a third person, someone objective. The clients have a family conflict and there is an attitude among some that counselling is an place of non-judgment and objectivity. But they expect the process to be quick.

> …you know there is a sense that - Oh can it not be fixed like today or tomorrow? That is what we explain, it is collaborating, it is an interaction…some come to a little bit of understanding, some not at all, and some do have a fairly good idea of what it entails. (R7)

R7 also explains that they are comfortable with saying that they do not know, and want to be told. "I think that they automatically come with: I do not know…It should be quick. Because

it is what a lot of us have grown up with." And some have tried that, she says. They receive direct advice from a family member, or a guru, or Astrologer and it does not help and they find themselves in counselling with the same expectation of receiving advice.

7.3.2 Premature ending

Many of the counsellors answered that the general amount of sessions they have with clients are five. Yet some clients stay for several months, up to one and a half years. I asked for reasons to what they would categorise as *premature* endings.

R2 answered that people have other support systems, like family. That counselling in India is still at a primitive stage and many times considered a taboo. R1 also thinks that it can be a struggle for the client to be in treatment for a long time, when their surrounding does not understand why they need counselling for a longer time. R1 adds that sometimes the client starts opening up to other ways of reaching well-being such as Yoga, meditation or hypnotherapy or simply finding an openness to talk to friends or family to feel better. R6 adds that perhaps the client is not ready to make the necessary changes that counselling demands. R1 adds that the demands on time and money may be to demanding in relation to other commitments. R1 explains that the counsellor has to tune into the client's need and be flexible so that a client will not end prematurely because they receive an unexpected style of counselling.

> The rationale of the methods practiced by the counsellor must make sense to the client and his/ her rationale of why s/he has the problem. That sort of cultural tuning and goal setting language is perhaps crucial to hold the client long enough for the therapeutic outcome to be seen. Clients may come at longer intervals and derive similar benefits if the counsellor is willing to be flexible from the once a week/ 60 minute time frame. In my experience clients practice of yoga/ meditation/ music/ communal singing / family activities augments the well being and duration requested may be shortened. (R1)

R7 also talks about the expectation of fast results, that by the third session, something should have happened. She compares it to the U.K and U.S and remarks that there is a sense of long-term involvement there. "With a serious process of trying to change ingrained patterns and beliefs and it is not going to change overnight. But I think here, that there is a sense that it should be done quick and fast." She thinks this goes back to awareness, of not really knowing what a counselling process is and that it is about changing behaviour. "..there is a concept that behaviour is outside and that perhaps it is easy to change, that you yourself can decide that tomorrow morning I will do something different." Combined with a culture where people are used to being told what to do. R7 says that counselling is about helping the client find their

own strengths and some manage to make a dramatic shift in their expectations and behaviour and others, even after a long time in counselling, do not change.

> …but perhaps for some even a couple of sessions to get an idea, as I said most importantly, quite often, is the sense of personal responsibility, that this whole business of stop blaming others because there is no power there, you can not change that, you can only change this. I think for some people, just to get that idea is powerful. For young people especially I can do something different…(R7)

Several counsellors also point out that some clients come for a few sessions but then return a few months later for a few more sessions. R4 says that the counselling process can become emotionally difficult. The client may not be ready to process more at that point of time as some of the clients may resume counselling later, and some simply do not feel that it was what they needed.

R1 has an education in psychotherapy but calls her self a counsellor. She does not think that the methods are very different, what distinguishes them is the amount of sessions undertaken.

> …anybody who comes to me for the first session I do not think oh this case I will do counselling, this case I will do psychotherapy. I actually do not think of the two being very different. So what is important is that I tune into what the client is looking for and sometimes clients will engage in that for a longer time and it is psychotherapy that is happening, so I tend to think that anything that is long term is psychotherapy.

Several reasons are given for premature endings: expectation of advice, not being emotionally ready, simply not liking it, not having the time or money (even though Parivarthan practices a sliding scale and offer concessions), the clients find support within the family, community or through indigenous methods.

7.3.3 Analysis: advice and premature endings

All the counsellors describe how several clients expect advice in counselling. Not all clients seek it persistently when explained what counselling is: reaching conclusions on their own with the counsellor as a facilitator. But the theme is re-occurring in the interviews. There is a cultural expectation of receiving advice when asking for help. R5 says that this is one of the challenges for counselling in India, she speculates, more so than in the West. In Arulmani's terms of identifying what clients are culturally prepared for, advice in counselling is derived from communication structures such as being told what to do. Being part of hierarchical family structure, rather than horizontal imposes the need of accepting roles within the family

hierarchy, shapes acceptance in ones role and also creates a habit of asking for advice (Laungani, 2007, p. 63). R7 says that the mechanisms of support in India have been structured through advice and takes the example of an astrologer who would give very specific remedies for a client's problems. R6 thinks it has to do with the level of education and mental health/counselling awareness, and that the attitudes towards advice-giving differs between rural and urban settings. The latter is more tuned into process-oriented counselling. None of the counsellors express that they would give straight forward advice. Some say they would consider being somewhat directive, helping clients brainstorm, giving them a nudge into the direction they think the client needs. Although counselling is about empowerment, about the clients reaching their own solutions.

There is also a *cultural preparedness* for counselling, or advice-giving, to be quick. Several clients expect the counselling to be finished by three to five sessions. The average amount of sessions that clients attend at Parivarthan is around five, although many come for several months. The reasons given are partly structural: counselling is still considered a taboo; it is at a primitive stage as a profession; there is a lack of awareness, and partly individual reasons: not ready to make necessary changes; can't afford it; too time-consuming; other ways of increasing their well being are found (Parivarthan has a sliding scale on their fees so no client should be excluded because of lack of money).

The structural variables are part of the organisational field where it seems that it is still rather heterogeneous and forces of *institutional isformism* are not present. (Lindqvist, 2000, p. 87) R1 says that she uses "cultural tuning and goal setting language" (R1) to engage the client. Similar to the findings of Patel,' Chowdhary,' Rahman & Verdeli' (2011) concerning the adaptation of language as an important aspect to making mental health services more effective. None of the counsellors say that they would change their methods, or that the cultural heritage the methods carry lead the clients to end prematurely. None of the respondents identify that "only" five sessions is a problem.

7.4 Eastern and Western methods and approaches

Under this final section I present the results concerning the counsellors' reflections about *Eastern and indigenous* approaches: spirituality, religion and yoga; followed by the counsellors' reflections about *Western counselling methods and approaches* and finally a section about *Eastern and Western approaches and methods*.

7.4.1 Spirituality and religion

Spirituality is a re-occurring theme in the interviews. Part of the training at Parivarthan includes a three-hour work-shop on spirituality. It is short in comparison to the one-year course, but still, an obligatory part of the education. "The module is a very short one. It is called spirituality AND counselling. It is not even called spirituality IN counselling." (R1) Spirituality in counselling is connected with Carl Rogers[8]. She says that a substantial part of the training at Parivarthan is based on a person centred approach. Rogers emphasises flow, presence, empathy and respect for the client which can be translated to spiritual qualities according to R1.

Spirituality is described as a source of well-being and if the client brings it in to the counselling room, the counsellor will use it to help the client. The counsellors are clear about the fact that they would not start talking about spirituality unless they were sure it was something the client had some kind of connection to it. R6 says that people are already coping in different ways, if spirituality is part of those coping strategies she would latch on to that, but it does not have to be involved in the sessions.

R3 says that there is a big difference between religion and spirituality, religion being ritualistic while spirituality is about how one wants to live their life and achieve inner peace-something everyone is concerned with, she says.

R2 says that spirituality is everywhere and you can not separate what is and is not spiritual in your life. It is not part of the day to day work and verbalized necessarily, it is who you are and she does not connect it to Eastern or Western way or life or discourse.

> It needs to be everywhere according to me. You need not be religious but you are spiritual. It needs to be everywhere. Because you take that spirituality from the broadest perspective, it is who you are. It is Eastern, Western anyway…a holistic way of being, whether you call it mindful, or spiritual, it is a way of being. (R2)

R5 on the other hand says that spirituality is very different in the West and East and that there is not a big difference between spirituality and religion in India. She has experience from doing her master in San Francisco, at an institute with a spiritual base.

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[8] "Person-centred therapy postulates that people (a) are inherently trustworthy, (b) have a vast potential for self-understanding, and (c) have a self-directed capability to resolve their difficulties if they have a genuine, accepting, and empathetic environment. Consequently, the tenants of person-centred therapy centre on the clinician creating this environment, opposed to engaging in diagnosis, advice giving or persuasion." (Luke, 2011, pg. 157)

> I think that the way the West thinks about spirituality is very different from the way that we live it here. For me, I was in San Francisco and there it is sort of, we call it New Age, it has not like slipped in, in the same way that it exists like here. Spirituality and religion is kind of, for me it is the culture here. It is very hard to see what is cultural and what is religious. To make that distinction in India is quite difficult. (R5)

R5 identifies that spirituality and religion are part of the culture. She says it is part of a communal life and not practiced individually as in the West. People are engaged in festivals and ceremonies that play an important role for many in India.

Many have a puja room in their home, a prayer room with fresh flowers, incense, kum-kum[9], sprinkle water and it is a place in a Hindu home to sit and connect with oneself. R4 says that mantras, which are kind of like prayers, have certain rhythms and sounds which can ease anxiety. It can be categorised as a form of mindfulness or meditation, a form of relaxation. Several counsellors say that if the prayer, puja or a ritual helps the client they will explore the meaning of this with them in counselling.

R7 draws a parallel between counselling and going to a temple. In a temple the outside world is shut out, certain rituals might be performed such as lighting the lamp or saying a prayer. A person visits the temple to get connected to certain qualities such as acceptance or grace. Qualities not unfamiliar to counselling. In counselling, distractions must also be removed or shut out. "You go to church, you go to temples, you look for answers – and it is what happens here (in counselling) too." (R7)

The difference between temple-going and counselling goes back to responsibility. In a temple one feels supported and gives the responsibility to something outside themselves. "Whereas I think that in counselling it is a little bit of the reverse because counselling is about how can you do something for yourself, other people can support other things, and guide you, but ultimately it is for you to take responsibility for yourself." (R7)

Several counsellors draw a connection between empowerment and spirituality, bringing power back to themselves and choices in their life but also accepting that which you have no control over.

In the Bhagavad Gita[10] themes of not being able to control the end-result are raised, which are also connected to counselling in terms of acceptance or endurance.

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[9] A kum-kum is a dot drawn by Hindus in the forehead between the eyebrows with red paint. In religious terms it is connected to the seven chakras, this one representing the third eye; through the third eye humans can connect to the Divine. Note that there are also other meanings to the kum kum powder, it can be used at religious festival or mark the marriage status of women.

[10] The Bhagavad Gita is a Hindu scripture that is part of the ancient Sanskrit epic Mahabharata.

R3 also mentions Advaita: the non dual philosophy[11]. "A god is not on the outside, this is someone within you. That eventually becomes a very powerful feeling. It can affect choices, you know, not so much relying on destiny." (R3) And that is incorporated into counselling; of not placing blame on the outside and about taking responsibility for your life. The counsellors agree on the language use, they do not have to call it spirituality, they use the language that the clients uses, what they do focus on in terms of spiritual aspects, is tapping into what they recognize as the human energy and human potential of positive change.

7.4.2 Yoga

Several counsellors say that they use references and referrals to Yoga. None of them are Yoga therapists and therefore none of them incorporate Yoga exercises (positions) into the sessions. R2 says that breathing exercises are called Pranayama's, prana being the life of the soul, a word derived from Yoga. The pranayamas are exercises that help evolve a calm breathing, calm manner and is an aid to concentrate. "…you call it in English breathing exercise, we call it Yoga and pranayama's. So those are the words that make sense to us" (R2). She says they are very helpful to discuss in sessions and she gives recommendations on how the client can use them. They also refer to Yoga practice to help clients that suffer from anxiety.

R6 highlights the body-mind connection and that she herself practices Yoga as a means for well-being. Aside from the positive aspects R7 underlines a potential problem with spiritual and Yogi approaches to life in terms of de-attachment to the physical world. She mentions clients who strive to be in a place where they can detach their problems but find themselves not being able to. They find themselves depressed despite their spiritual endeavours. R7 explains how she handled a situation like this in counselling by referring to Maslow's hierarchy of needs[12] and compared it to the client's understanding of chakras.[13]

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[11] "Advaita Vedanta… a sub-school of the Vedānta (literally, *end or the goal of the Vedas*, Sanskrit) school of Hindu philosophy, numbers with *Dvaita* and *Viśishṭādvaita* as major sub-schools of Vedānta. *Advaita* (literally, *non-duality*) often has been called a monistic system of thought. The word "Advaita" essentially refers to the identity of the Self (Atman) and the Whole (Brahman). The key source texts for all schools of Vedanta include the Prasthanatrayi—the canonical texts consisting of the Upanishads, the Bhagavad Gita and the Brahma Sutras." (http://www.newworldencyclopedia.org/entry/Advaita_Vedanta)

[12] "(1) There are at least five sets of goals, which we may call basic needs. These are briefly physiological, safety, love, 'esteem, and self-actualization. In addition, we are motivated by the desire to achieve or maintain the various conditions upon which these basic satisfactions rest and by certain more intellectual desires." (Maslow, 1943, unnumbered) Maslow organizes these needs in a pyramid and states that when the one that is the most acute is satisfied (physiological) one can move on to satisfy the next goal and so on.

[13] Chakras are believed to be located in the body from which one can retrieve energy. The concept is found both in Hinduism and Buddhism and is part of Yogic tradition.

> …if you go with the chakras, you have seven different, you have specific energy with each and the needs that come up with that. The *mooladhara chakra or root chakra* which when compared with Maslow's hierarchy of needs connects to the first one, where all the most basic physiological needs are taken care of…food, shelter…The next level in the chakras is called *swadisthana,*…that is where people have things, blocks if they have not worked through, it corresponds to a younger age. In terms of energy, it deals with emotional/sexual identity it is up to two years. So a lot of your young childhood issues – and she realised that a lot of her issues came from that period of time. A lot of her emotional needs not having been met, in terms of her it was about having her seven chakras open and being enlightened. Where there is a strong urge towards self actualization, you have to ground yourself, to work through each stage, and all these blocks have to be removed, in terms of energy, only then can you reach that (R7).

The process of going through the different chakras was a help to the woman in the counselling. If you skip one of the chakras the mind becomes unstable, R7 says. She was able to discuss this with Eastern terminology yet she explains that the stages we need to go through are universal, and no one can jump over a stage and regard it as irrelevant.

7.4.3 Methods West

Parivarthan is based on a Rogerian person-centred and integrative foundation.[14] The majority of the units in Parivarthan's one year course is based on Western methods. All the counsellors have, at least, gone through the one year training at Parivarthan.

> My training was here at Parivarthan and I think that a lot of the theories were definitely informed by the West, the psychoanalysis, the psychodynamic, Freudian. We learned a little about CBT, the modern behavioural thing but it is largely based on a humanistic way of Rogers. That is how Parivarthan started, that was their main way of counselling. Non-directive, humanistic, Rogerian. So I think that now we have come to kind of an integrative methodology. Where we are informed of these various schools of counselling and I think that each of us here at Parivarthan have things that we employ (R7).

R2 explains that Rogers introduced unconditional positive regard. According to the Rogerian approach the counsellor shows empathy, warmth and regards the client as one that has an ability to struggle for well-being. The counsellors' role is that of a facilitator. The counsellors work with an integrative approach, using several theories/methods. To identify which method is used when or evaluating the effects of a specific approach is not that important. They talk in terms of fluid distinctions between methods and that evaluation of their work comes primarily through client feed-back and secondly through discussions in supervision. R2 says that she also uses:

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[14] Integrative counselling stems from the belief that no theory, method or approach can alone explain the facets of human behaviour, emotion and thought. An integrative approach integrates several theories. It is also based on the counsellors personality and the clients need, hence these aspects are also integrated into the counselling approach. Creating an integrative approach as a counsellor demands "knowledge, skill, art and clinical experience" (Corey, 2012, p. 2).

> CBT, I use gestalt, I use systems theory, because many people they are in a system, so system theory, I also use TA, Transactional Analysis. It depends on who I am working with, you know what is the kind of goal with my client, sometimes existential one, sometimes even the feminist approach, Pink Therapy because I also work in the LGBT[15] community.

R6 also uses an integrative approach, with Rogerian and CBT- elements. She prefers psychodynamics, drawing, and using small animals in her counselling. She says that her methods are mostly Western. Each counsellor is drawn to certain methods more than others and evolves a particular style. She mostly incorporates small animals with children up till the age of ten, but drawing is used in all age groups. She says that it helps if someone has a difficult time verbalizing their problems. If a person feels that they are verbally blocked, these methods can help untie that.

R5 who has had training abroad says that her counselling foundation comes from her Western education. She has trained in drama therapy and uses Western elements such as design, flow and progression in the group. But with time and the change of context to India, certain elements have changed.

> After that of course things change. The game that you change might be different, you adapt it, you change it, you say oh let's make a story now – all that changes but I think that the ground work of how I think of that, about a client group is for me still pretty Western because this is where I had my training. …I think that the way therapy looks today is largely Western. When we talk therapy or psychotherapy we think of goals, a Western paradigm.. We unfortunately have more Western methods and discourse available to us than Indian. It is slowly changing but this field emerged in the West and that is where the bulk of work has been done (R5).

R5 uses CBT but says it is not pure CBT. She says that she uses CBT to facilitate the client in developing a skill. She works with a combination of process work and directive skill work. If the client is depressed then perhaps the goal is to get him/her out of bed, in such cases she can be more directive in counselling or open to referrals to a psychiatrist. But she never does skills work only, she also engages in process work, looks back at the genesis of problems and how the clients sees themselves. She does not follow any method strictly and many times certain Western methods are mixed with other Western methods as a form of adaptation to the client.

R4 says that sometimes through CBT the client can see changes and is then more willing to move on to process-oriented counselling such as psychodynamic. She also can use both.

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[15] Lesbian, Gay, Bisexual, Transsexual.

R3 also says that she does not use a pure form of CBT. She does not like filling in forms and evaluating if the client has fulfilled all of their home work or their commitments. She says that it can be experienced as punitive to the client and that he/she most certainly already has a judgmental thought process about themselves. She focuses on the positive, on motivating thoughts and works with mindfulness, to be able to recognize thoughts without categorizing them as bad or good.

> But I do give them home work, I tell them five times a day to this, do that, so I keep that (part of CBT)… So when they come back for the next session I check and see. I do not want the session to be a reminder for them of what they can not do. That is why I do not use CBT in its purest form. This is a timetable you should have done this, no, I kind of see instead what happens (R3).

She adds that her base is psychological counselling based on Western research and methods and beyond methods she also looks for elements such as: "… boundaries, I watch for time, I watch for how they represent themselves, I watch for mental health issues…." (R3).

R1 also says that she uses CBT in her own way, "CBT with a heart". Traditionally, CBT involves analysis of thoughts and behaviour she says. But today "…we are not in these bracketed ways of single approaches. I am informed by psychodynamic approach also. If somebody is talking about grief I am informed by existentialism" (R1). She says that she also uses gestalt therapy to reflect that each person has many sides to them and the approach helps seeing oneself in more than extremes. She adds that anything that the client brings gets integrated into the sessions and she can adapt the method. "…in some ways sometimes the theories match…they say similar things in different ways…one gets a trans-theoretical understanding" (R1).

R3 also uses system theory. She gives an example of a family with young children. The man wants a separation but the woman is not sure, she considers her children's emotions. R3 distinguishes that at one hand she struggles with her role in the family system and responsibility for her children, and on the other hand she wants her individuality. As a counsellor she does not make a priority for her client, but she reflects back the conflict within her. She can not only look at her individual aspirations because that could make her unhappy, they also need to explore that she is part of a family that is important to her. In this example she integrates value systems of what might be important for the client as an individual as well as a mother.

> So system, yeah it works very, very well in an Indian context where the family is important and we are influenced so heavily (by it). But even in individual decisions, a lot of this does come (up) so again you are asking me how integrative works – this is how it works, and I tell them I am not here

> to shift focus away from you but I am hearing you say that this is also an important aspect when we have to look at a decision making process (R3).

7.4.4 Methods East and West

I asked the counsellors if they think that there is a clear or fluid distinction between Eastern and Western approaches/methods in their counselling work. All the counsellors say that it is fluid, as mentioned in some parts above, they work integrative, they mix units from different methods. Both R3 and R5 say that it is difficult to know if they are listening with their Western or Indian ear. R7 says that there is a growing awareness that these two systems can work together. "Counselling does primarily focus on the clients feelings and emotions and learning how to deal with them sensitively and effectively. Whether the client comes from the East or the West, as far as emotions go, there is really no difference." (R7) R4 also emphasises the universality of human emotion and empathy:

> So these methods can be used or adapted to be used in an Indian context. While applying these methods however it is important to understand and be sensitive to the context such as culture, values, beliefs etc.

R1 gives an example of how she mixes both. She uses endurance, learning to observe thoughts rather than changing them, and thinks that this comes from Eastern thinking. But if the client is struggling and she can not help them with an endurance approach, she will use a Western approach of educating the person on how their thoughts are influencing their actions.

> …your belief is such and your thoughts are such, they influence how you are feeling. We temper the belief in a self sustaining direction, we help to modify or expand the belief in a way that offers the client a flexible spectrum to function from. So it is a mix of those units and my larger goal is endurance, acceptance or change (R1).

Another example of how Eastern and Western is combined is in terms of being directive or not. R1 gives an example of problems in the family, specifically with a mother in law and how she can be interpretive and directive to a certain extent:

> So instead of going into details of thinking, feeling, behaviour (reaction), I may take a somewhat informed guess/ interpretative/ directive stance. I say: it matters a lot how MIL (mother in law) sees her, approves of her (meaning), it is hard for her (problem) to not take it to heart, (goal) to take in what MIL says through one ear & let it out through another (suggested letting go); perhaps MIL does not have the experience/ education/ insight /tact to do otherwise (reduce expectation) & she misinterprets your intent (implying that this is not client's failure).

Above is an example of directive counselling (not advice). R7 gives another example of when East and West meet and are combined. In Indian philosophy there is an aim to go

beyond the mind. While in counselling they work to understand the mind. In Indian philosophy it is good to not have an ego, but in counselling one develops ego-strength to work trough different developmental stages. So combing these two is a challenge but it is helped through Eastern approaches such as using mindfulness techniques, acceptance, chakras and relaxation. Also in Indian philosophy a re-occurring question is: "Who am I? All the saints ask this" (R7). And the same question is explored in counselling.

R3 also uses sand in her counselling. She has a rectangular box of sand that the client can draw in. "…most of us, as growing up have played with sand, it is an evocative thing, sand is beautiful way of expressing what has happened." Sand is very useful for clients that do not know what counselling is or are uncomfortable with it, she says. Sand therapy comes from the West, but then she incorporates mindfulness, which she says is an Eastern way, derived from Zen Buddhism. The picture in the sand is not analysed while it is done. "I am not analysing oh you put the ball here on the left top corner, that is not what it is…it is very powerful". Also she adds in a non-westernized setting she would add "Indian" elements such as drape the dolls in saris.

> So when someone looks at it they feel ok, the dolls are browned-skinned, or dark-skinned. They are not blue eyed, blond haired dolls and that is very important, and if you were in such a setting, there would be a blond doll that would represent you (R3).

She continues and summarizes her way of working:

> …mindfulness definitely, it is from there, aspects of yoga, breathing, for a person with anxiety to calm down, mindfulness techniques yes, but they are techniques that need to be as interventions, but counselling has to be something else, because that is what I'm trained for, that's the work, that is this centre (R3).

R3 says that aspects of Yoga and mindfulness are techniques, not counselling methods and must therefore be used in combination with the counselling, not as stand alone interventions. R1 says that the Indian context is not only an Eastern context:

> …it has allowed for integration of many Western influences for better or for the worse. In order of past and recent factors- due to its colonial history, multilingual flavour with English is an important medium of public discourse, society being multi-religious including Christianity, the obvious or subtle influences of a Western world view come through globalisation and the telecommunication boom. Contradictions are part of most contexts. Many theories propagated in the West offer practical ways for understanding possible human development processes and relational needs, these have helped me to understand people in various contexts. None of the methods are to be used like an inflexible recipe or prescription.

7.4.5 Analysis: Eastern and Western methods and approaches

Spirituality is a big part of Indian life. It is of positive nature, a source of well-being, a coping strategy, a source to connect to when looking for inner guidance. One counsellor thinks that the essence of spirituality is universal. Another counsellor who has been in U.S.A comments on the differences she experienced in how it is practiced. She says in India, spirituality is immersed in the culture, that it is even difficult to separate from culture and religion. Although spirituality is distinguished from religion by other counsellors. They separate the energy of spirituality from religious (ritualistic) ceremonies. Yet spirituality is sometimes connected to religious themes such as believing in something greater than one self, transgressing the physical world. I leave the definition behind and focus on the principles that are drawn from spirituality and inserted into counselling. Similar to what Arlumani writes about "The Centrality of Religion and Spirituality" in Indian life, the goal is not to pinpoint the "interface between religion and counselling" but to examine "how common cultural practices prime a person to engage with life" (Arlumani, 2009, p. 255).

Spiritual qualities are resembled to Carl Rogers and his emphasis on empathy, positive regard and non-judgment. Since Parivarthan works with a person-centred foundation there is a common ground for these type of values for clients, no matter what they call it. The counsellors use the vocabulary that the client uses. Such as Patel,' Chowdhary,' Rahman & Verdeli' (2011) also have found in their study.

Further, if the client practices mindfulness, meditation, works with mantras, visits the temple, has a puja room in their home etc. the counsellors explore the meaning of these practices and highlight them as coping strategies in the counselling. Spiritual qualities are connected to an inward process of reaching spiritual awareness, much like the inward process of getting to know yourself in counselling (Laungani, 2009, p. 80).

The counsellors do not describe a conflict between spiritual and/or religious beliefs and values in the counselling methods. In Laungani's model the opposite to spiritualism is materialism, in this section the counsellors descriptions correspond well with Arlumani's findings, where they seem to focus more on internal and external perceptions of reality rather than external (Western discourse) as well as reaching wisdom through reflection and an inner journey rather than perceiving reality "…through scientific enterprise" (ibid., pp. 79-81). An aspect that one of the counsellors touches upon, from her experiences in U.S.A is that she found the equivalent to be New Age, a somewhat "individualistic and shallow practice" in comparison to the culturally immersed practice of spirituality in India. Arulmani writes that counselling that is individualistic and empirical "…may not find resonance amongst Indians,

whose culture has prepared them over the ages to approach their existence in an intuitive, experiential, and community-oriented way" (Gerstein et al., 2009, p. 254). Yet the results do not indicate a distinct approach as being better than another. Since the counsellors adapt to the individual, and repeatedly say that it is the client that steers what will be integrated or not, spirituality and collectiveness are not always the best approaches. In the urban setting, clients represent a need for diversity in counselling approaches across the Spiritual- Material spectrum. Just as Laungani (2009) points out, the East and West categories should be understood along a continuum and not in either/or dichotomies (ibid., p. 57).

Also R3 draws form the Bhagavad Gita, the Indian epic where a discourse of not being able to control the end-result in one's life is raised. She connects it to the non-dual philosophy Advaita. Indians are culturally prepared for contradictions (Gerstein et al., 2009, p. 254). On the one hand believing in Gods and karma, and on the other hand believing in Advaita and self-responsibility. It is not an easy contradiction, as still many clients as mentioned in the previous section about advice, expect to be told what to do and therefore place the responsibility of their life in the hands of others. Yet there are several cultural discourses to relate to in illustrating elements that resemble empowerment, such as karma where one is thought to be able to change the course of one's life.

Yoga is used in the counselling in terms of illustrations. The example above concerning chakras and Maslow show how the counsellor draws from both East and West without contradiction. In terms of New Institutional Theory, I consider Yoga practice/Yoga Therapy to be part of the *organisational field* of counselling in Bangalore with clear *domain consensus (*Lindqvist, 2000, p. 88). The counsellors are not trained in Yoga, they refer to the philosophy about it and if the clients want to practice it the counsellors offer referrals.

Concerning Western methods, the counsellors work with an integrative approach consisting of cognitive behavioural therapy, psychodynamic approach, gestalt therapy, pink therapy, system theory, transactional analysis, person-centred approaches (Rogerian), using small animals, sand therapy and art therapy (drawing). The Western paradigm is clear, there is lack of Indian research in the field one counsellor points out. Indigenous methods are not part of the training or integrated along the way. But cultural sensitivity does not mean that indigenous methods or Eastern methods have to used. The Western methods are integrated with each other, with the context, with the client and the counsellor. The constructs of certain methods are clearly *disembedded* from the West and through a rigorous integrative process embedded into the context in Bangalore and *translated* by the counsellors into a contextual counselling form (Czarniawska, 2005, p. 112; Johansson 2002). None of the counsellors

emphasise the importance of holding on to the essence of the methods, or to distinguish which method is used when.

Cultural adaptation is high. In terms of evaluation, it would be interesting to study the effects of how successful the counselling is and how one would evaluate that since the practice is fluid. Also I would like to remind the reader that I am focusing on how the counsellors experience the use of Western methods, perhaps the clients have completely different experiences of how the counselling is adapted to the context in Bangalore.

In the final part of the section about Eastern and Western methods and approaches the counsellors say that they use elements from both cultures. Endurance and mindfulness are given as examples of Eastern elements. They oriented towards observing thoughts rather than changing or accepting thoughts as they are. If the client is not content, the Western approach is used to gain self awareness about how their thought effect their behaviour. "…we help to modify or expand the belief in a way that offers the client a flexible spectrum to function from. So it is a mix of those units and my larger goal is endurance, acceptance or change." (R1) The focus on the mind and thoughts are part of a Western paradigm. It can be understood as Laungani's model of Cognitivism and Emotionalism, where the former is part of the work-and-activity-centred society and rationality and logic are more attractive tools than feelings and intuition. (Laungani, 2007, pp. 69-72) In Indian philosophy the practitioner strives to reach a state beyond the mind. But these elements are techniques says R3, not methods. The counselling methods lie at the core.

8 Summary and discussion

In this final section I summarize my results and analysis and connect back to my research questions. Also I suggest topics for future research within the field of cross-cultural counselling.

8.1.1 Context for the profession

The research field of (mental health) counselling is dominated by the West. Theories, methods and approaches within psychology, psychotherapy and counselling are by large produced in the West and therefore produced to cater to the needs of Western problems (Gerstein et. Al, 2009; Laungani, 2009). When these methods are incorporated in Bangalore several mechanisms effect this "import". One is the organisational field made up of all the professions that have "…similar job descriptions, hence are subjugated to the same processes of change" (Lindqvist, 2000, p. 87).

Since the counselling profession in India is developing and is rather new, Parivarthan is placed in a complex organisational field where it is not clear which organisations are similar as training, ethical standards and counselling methods might vary a lot from one organisation to the next (Arulmani, 2009, p. 252).

My first research question is: How is the context for the counselling profession at Parivarthan Counselling, Training and Research Centre in Bangalore described by the counsellors? At one hand Parivarthan is strongly influenced by Western research and methodology (as many other organisations in the world) and at the other hand it is strongly influenced by the Indian context in which it is practiced. Parivarthan follows The British Association for Counselling and Psychotherapy (BACP) ethical guidelines, they use Western counselling methods but they also incorporate cultural elements into their sessions and have *domain consensus* with other professions that are part of mental health services (Lindqvist, 2000, p. 88). Examples of these are referrals to: psychiatric consultation, psychological assessment, Yoga practitioners, shelters, etc. Although I have not interviewed counsellors from other counselling organisations, and do not know if there might be *domain conflict* between them.

The interviews show that a mindless import of counselling methods is not done and it would be crude to make that assumption. Counsellors build bridges between subjective and objective epistemologies, it is contradictory within the theoretical framework of this essay to assume that counselling methods are universal per se. *Social constructivism* and *translation* show that ideas are products of their context and change when moved. So rather parts of the methods can be based on universal compatibility and parts will have to change in context. According to Arlumani, for counselling to be more efficient it is important for the counsellors to understand what his/her clients are culturally prepared for (see below 8.1.3).

Through globalisation and with a history of colonialism, the Indian context is not only an Eastern context, elements of Western discourse already exist in India as well as a long indigenous history of mental health services.

The counsellors describe how, fore mostly family, spirituality and in some aspects religion, are part of the Bangalore (Indian) context that they integrate into their counselling approach. In Laungani's model (2009), these aspects are prominent in Eastern culture. But the counsellors also emphasise that these aspects are not always the most important mechanisms that steer the client's needs. They stress the individuality of the client more so than understanding generalizing structures (gender, class, caste, religious conviction) as guiding reasons for counselling approaches. The urban counsellors and their clientele are part of a context where roles are changing. Young people have more opportunities to make careers and

live in a nuclear family, rather than in an extended family network. As a consequence, norms and expectations for behaviour change. These aspects allow for an individualistic decision-process to a larger extent, than in would in rural areas (Sinha, Sinha & Sinha, 2001).

In summary, part of the counsellor's job is to place the individual client's needs and wishes first. It seems that some clients do not want to involve their family in their decision processes, and others do. On a structural level the family is an important part of Indian life and system theory is used by many counsellors to include this aspect.

Spirituality is described by many counsellors as separated from religion and by some, that they are entwined. Spirituality is a part of the counsellors' training (although a very small part) and all the counsellors brought it up in the interviews. To use the word Spirituality is not of primary importance but rather to incorporate what it stands for: ability for positive change and harmony in life. Spirituality is an important part of the Indian context and the counsellors are culturally prepared to include it in one way or another in the counselling.

I have not conducted a study about how effective the counselling at Parivarthan is. I do not know how much these adaptations actually changes the quality of the counselling or how the methods potentially clash with cultural norms to the extent that clients quit prematurely. But the results do not indicate that the counsellors perceive the methods' Western heritage to be the problem. It has to be considered, that other variables have been raised on both structural and individual level that indicate obstacles or reasons to why clients do not go to counselling (which does not necessarily have to be connected to an exclusively Indian context):

- The lack of a governing body to systematize the profession.
- The lack of systematised demands on training.
- (Cultural) attitudes towards mental health problems causing stigmatization.
- Cultural attitudes towards sharing your problems with strangers (negative).
- Expecting advice-oriented counselling not process-oriented counselling.
- The role of the family as a support system fills some of the functions that counselling offers and therefore it becomes unnecessary.
- Cultural practices such as Yoga or community involvement help the individual with coping strategies.
- Individual is not ready.
- It takes to much time.
- Expectation of quick solutions.
- Counselling is not the solution to everything and some simply do not like it.

8.1.2 Methods used

My second research question is: What methods or approaches do the counsellors use in their counselling? The counsellors use fore mostly talk-based counselling with the exception of sand therapy, art therapy and using small animals. The methods used are: cognitive behaviour therapy, system theory, transactional theory, psychodynamic therapy, existentialism, pink therapy, person-centred approach (Rogerian) and gestalt therapy. They also use approaches, which are Eastern or Indian based such as brainstorming, directive approach but not advice, implementation of Yoga philosophy, Yoga breathing exercises, concepts of acceptance and endurance and the use of metaphors from Indian epics such as the Mahabharata.

I expected, before I went to India, to learn about hybrid elements of Western and Eastern methods. But I received few answers that indicate that which I speculate is due to several reasons:

- The indigenous methods of astrology, Ayurveda, shamans and gurus differ a lot from the paradigms within Western counselling methods and might not be easily combined.
- Parivarthan does not conduct research on such a level that it produces their own theories of counselling, nor does this seem to occur in other organisations, as counsellors have pointed out the lack of systematised, evidence-based indigenous counselling methods.
- The methods that they use are integrative and contextually adapted and the organisation seems to fill an important role for the community, there might not be a need for hybrids, cultural adaptations might be enough.
- The clientele lives in an urban context with Western influence.

8.1.3 Cultural sensitization

My third research question is: How can the methods be understood in terms of cultural sensitization? My results show that the following adaptations are made to fit the cultural preparedness of Indian clients at Parivarthan:

- Language adaptation, such as referring to phenomenon with Eastern constructs yet not changing the content of the construct as such. For example referring the spiritual qualities or Rogerian qualities to describe the same entity.

- Use of metaphors from for example the Bhagavad Gita, which is well-known in Indian culture to illustrate human conditions.
- Adapting the setting such as using toys with dark or brown skin in sand therapy.
- Adapting to the setting such as offering counselling under a tree in a rural context.
- Being culturally prepared for the importance of family ties in counselling and allowing room for both individualistic as well as collectivistic values.
- Integrating elements from spiritualism and religion, such as highlighting coping elements in going to a temple, meditating, using mantras etc.
- Integrating terminology from Yoga such as comparing the development stages in the chakras with Maslow's hierarchy of needs or referring to Yoga.
- Being culturally prepared for the need to be directive in counselling at times, without tipping over to the cultural expectation of advice-giving.
- Conveying the power in endurance rather than being informative about thought processes.
- Being integrative with culturally immersed coping strategies that the individual brings in, involving the counsellors own world-view and context.

8.1.4 Future research

Culture is a powerful variable when it comes to the efficiency of counselling. In the globalized world that we live in, and the way that ideas and practices spread by constantly moving and changing, universalism has to be questioned and the context respected. It is relevant to examine how counsellors use Western methods in an Eastern society. Most research in this field concentrates on how counsellors should meet the needs of ethnic minorities residing in Western countries. Theories about how structural positions such as gender or age effect counselling needs; that culture is a norm-producing phenomenon; that counsellors should be culturally prepared; that counselling is a product of its context, can be applied no matter if the respondents belong to an ethnic minority (Indians in Sweden) or the respondents belong to the majority culture but use methods from another culture (Western methods in India).

Even though my empirical material only focuses on one organisation, the field of cross-cultural counselling and the pressing need of cultural sensitization gives a strong indication of homogenizing effects. Lindqvist (2000) writes that when organisations have similar job descriptions and create a field that adapts to its context and the norms in that context, organisations tend to start homogenizing, *institutional isformism* is created and diversity

decreases (pp. 87- 89). I believe that research should reveal the multitude of diverse methods that exists in counselling and psychosocial treatment. Such research can help spread information about different methods and offer more of it to clients.

New institutionalism is interested in similarities and differences, stability and change within organisations. Organisational identities are shaped within organisation fields and ask questions like: "Who am I? What do I do? Who do I resemble? Who do I want to resemble?" (Johansson, 2002, p. 141). The latter question, "Who do I want to resemble?" is interesting because of the need of cultural sensitization. Because not only does Western methods dominate counselling, but Western organisational structures can spread as models for counselling organisations outside the West. Again, I do not have the empirical material to draw conclusions about this. I suggest that further research about the potential imitation of organisational structures could be analysed with the constructs of organisational fields, using Bourdieu's constructs of field, where power related elements are more protrusive than in New Institutional Theory (Johansson, 2000, p. 140).

Another aspect that future research could engage in, is comparative studies of an organisational field connected to counselling and treatment. For example comparing Western based counselling with indigenous methods such as Yoga Therapy and make an organisational analysis of institutionalising processes and treatment results.

Finally it would be of importance to interview Indian clients and their experience of the effectiveness, cultural adaptation and need for mental health services in terms of talk-based counselling or other treatment alternatives, especially one that integrates the communal way of living in India.

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10 Appendix

10.1 Appendix 1, Interview guide

Definition

1. What is counselling according to you?

Specialization

2. What kind of counselling work do you specifically do? (Couples, individual, adolescents, family, career – counselling?)

Methods and approaches

3. What methods or approaches do you use in your counselling work?

East and West

4. According to you, are these methods influenced from the Eastern part of the world or the Western, both or none?

5. Do you think that there is a clear or fluid distinction between Eastern and Western approaches/methods in your counselling work?

Indian context for counselling

Urban

6. Do you think that it is common in Bangalore, and in India, for people to seek guidance for mental health problems with Eastern/indigenous methods or approaches? If, so what would those methods be?

Awareness and availability

7. What are the biggest obstacles for counselling reaching more people in Bangalore and in India?

8. What are important factors for counselling to become more available in Bangalore and in India?

10.2 Appendix 2, Follow-up questions

Please fill in these questions. The background questions will be used as part of a introductory description about you- and all the respondents in the essay. Your name will be changed so outsiders will not be able to identify you. But you will probably recognize each other within the clinic. Please let me know if this is alright.

Background information:

Full name:

Name you want me to use in the essay, pseudonym:

Age:

Number of years in counselling field:

Number of years at Parivarthan:

Training outside Parivarthan (Bachelor, Master, where):

Training at Parivarthan (name anything longer than work-shops):

Lived abroad (duration, where):

Worked in counselling field abroad (duration, where):

Worked in counselling field outside Bangalore in India (duration, where):

Do you have clients from other countries than from India:

Follow-up questions around the same themes I have asked about before. Thank you so much for your extra time!

1. If you can generalise, what are your clients most common socio-economic background?

2. Many of you answered that the general amount of sessions you have with clients are around five. In the cases where you think that the counselling ends prematurely, what are the most common reasons?

3. If you would be more advice-oriented in your work (in the way that many clients seem to expect) would you still call it counselling? Why or why not?

4. What do you think about the fact that you use mostly, if not entirely Western methods in an Eastern or Indian context? Is this a contradiction or not? Explain.

5. Some of the previous research within the field of Western counselling methods used in the East, has criticized that this import of Western methods can impose cultural imperialism or post-colonialism (not always being effective methods because they are imposed with a western culture and values). Do you agree or disagree with this criticism when it comes to your work? Explain.

10.3 Appendix 3, Letter of consent

Background

With globalisation and colonization research methods from U.S.A. and Europe have spread to developing countries. India is a one example of this. The synergy of traditional and modern counselling methods is especially evident in urban cities, I have therefore chosen to start my study about counselling in Bangalore at Parivarthan.

Purpose

The purpose of my essay is to widen the understanding of the definition, practice and need of cross-cultural counselling from the counsellor's perspective. I want to analyse the use of Western and Eastern methods and perspectives on mental health in different clinics and/or organisations in India.

Selection

I have used a random selection. I googled counselling/therapy/social work/mental health + gender+clinic+organisation in India. Parivarthan was one of the organisations that gave me a quick response, asked for my intentions, purpose and study plan. They gave a professional impression and offer many different counselling forms which offers a range of perspectives to analyse.

How the interviews are conducted

I will conduct semi-structured interviews. The interviews are planned to last 60-90 minutes. There might be a need for shorter follow-up interviews to answer potential follow-up questions.

Risks

All participants will be made anonymous in the final essay. Participants who feel that they regret their contribution can withdraw it before the final draft of the essay. I respect the anonymity of the counsellors' clients and will not involve them. I will write the name of the organisation in the essay and a background to the organisation to give a context to the interviews so there is a risk that respondents might identify each other at the centre.

Contributions

I hope to contribute to the understanding of the use and need of cross-cultural counselling. I think this essay will be of use both in India and in Sweden and perhaps inspire further research.

Handling of the interviews

I wish to record all interviews and transcribe them personally. I will keep the recorded interviews in a safe manner and not spread them to others. All participants will be anonymous. If the participants have any questions after the interviews I can be reached by e-mail. I will send the transcriptions to each respondent for final confirmation. When the essay is finished I will erase the recorded interviews.

The final essay

All participants will be sent a digital version of the final essay.

Responsibility

My name is Eva Smoczynski and I am a student at Ersta Sköndal University College in Stockholm, Sweden. These interviews are part of a Minor Field Study that is the basis for my Bachelor essay which will be tutored and graded by Ersta Sköndal University College. Questions can be sent to my e-mail. I am not connected to a University, College or organisation in India.

Consent

I have read the information above and agree with the content. I am aware that I participate without any payment in return and give my consent to be part of this research project.

……	……	…….....
Date and city	Signature, respondent	Signature, Eva Smoczynski

APA GUIDELINES for the Undergraduate Psychology Major

VERSION 3.0

Empowering People to Make a Difference in Their Lives and Communities

APA BOARD OF EDUCATIONAL AFFAIRS TASK FORCE ON PSYCHOLOGY MAJOR COMPETENCIES

APPROVED BY APA COUNCIL OF REPRESENTATIVES
AUGUST 2023

AMERICAN PSYCHOLOGICAL ASSOCIATION

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AUGUST 2023

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VISION AND MISSION

Vision

Psychological science will be recognized as a high-impact undergraduate major that empowers people from all backgrounds to make a difference in their lives and communities.

Mission

To provide a comprehensive revision of the national recommendations regarding the knowledge and skills that undergraduate psychology majors should acquire at the associate and baccalaureate levels of study in undergraduate psychological science programs. The *APA Guidelines for the Undergraduate Psychology Major 3.0* (hereinafter referred to as the *Guidelines 3.0*) is designed to foster collaborative discussions in psychological science programs based on recommendations that reflect state-of-the-science curricular and assessment planning in psychology. Our charge from the American Psychological Association's Board of Educational Affairs was to anticipate the ways that the *Guidelines 3.0* revision needed to reflect changes in culture and context to prepare undergraduates who will function optimally prepared for contemporary life.

EXECUTIVE SUMMARY

The *APA Guidelines for the Undergraduate Psychology Major 3.0* capture a set of optimal expectations for performance by undergraduates engaged in the study of psychological science. This document builds on two decades of experience with the American Psychological Association's (APA) support of undergraduate psychology departments and programs for establishing such expectations. APA practice dictates that existing policies need to be revisited and potentially revised every 10 years. This effort represents the second revision of work that was originally approved in 2006.

Guidelines 3.0 specifies five broad educational goals and corresponding student learning outcomes that outline reasonable program expectations for the undergraduate psychology major across educational contexts. Indicators of progress on student learning outcomes represent two levels of development. "Foundation" indicators roughly represent progress that students may be expected to make midway through the major. As such, the outcomes may be helpful for psychological science programs at the two-year level or the psychology minor in a four-year program. "Baccalaureate" indicators represent an appropriate endpoint for the completion of the major. The progression describes expectations for how a student would undertake the journey of a novice in the discipline to the status of a reasonably informed and skilled undergraduate student on the completion of a four-year program.

The tradition in publication of earlier *Guidelines* was to be aspirational and positive rather than prescriptive in tone, a tradition we continue in *Guidelines 3.0*. Given that psychology programs face unprecedented demands in higher education today for accountability data to document high-quality educational programming, the *Guidelines* provide a solid foundation on which psychology educators may engage in effective curricular and assessment planning. Faculty collaboration may produce distinctive programs that integrate local institutional and program-level missions in the context of recommended national practices, as represented by *Guidelines 3.0*.

CONTEXT

History of Undergraduate Guidelines

APA began deliberations about national guidelines in 2002, convening a task force to develop a set of recommendations with official approval of the document following in 2006 and publication in 2007. The emphasis in the original *Guidelines* was on the differentiation of outcomes that were liberal arts–based from those that were more specific to the science of psychology. That focus highlighted five goals in each of those areas for a total of 10 goals with corresponding learning outcomes and indicators that captured the four-year experience in the major. The original *Guidelines* document can be accessed at this website: https://teachpsych.org/Resources/Documents/otrp/resources/apapsymajorguidelines.pdf

When the original *Guidelines* underwent review, as required by APA policy, critics suggested that the 10-goal structure was a bit cumbersome and perhaps did not highlight the distinctiveness of contributions from learning in the undergraduate experience to think like a psychologist. Educators in associate degree contexts also suggested that the document did not authentically speak to their unique needs and concerns. Consequently, *Guidelines 2.0* (APA, 2013) made some dramatic revisions based on feedback from these and other stakeholders. The original 10 goals were collapsed to five, and an emerging theme for the revision was highlighting the science foundations of the major. The task force differentiated and developed indicators for the student learning outcomes using two levels: "foundation" to represent expectations to be met at the halfway point in the degree, and "baccalaureate" to identify the skills and knowledge to be demonstrated by four-year degree students. *Guidelines 2.0* was officially approved by APA in 2013 and may be accessed at the following website: https://www.apa.org/ed/precollege/about/psymajor-guidelines.pdf

In a survey of psychological science programs in the United States, Norcross and colleagues (2016) verified that *Guidelines 2.0* produced remarkable penetration in program planning across the country. According to the survey respondents, 82% of four-year programs indicated that they used the *Guidelines* actively to revise the undergraduate curriculum and build meaningful assessment plans. Respondents in two-year contexts reported a penetration of influence at 50%. In addition, academic program reviewers routinely report that programs undergoing review regularly cite the influence of *Guidelines 2.0* in steering the curricular and assessment planning, suggesting that they have been quite influential in their impact by providing national performance benchmarks. Understandably, educators who have used *Guidelines 2.0* successfully to build, modify, and assess their programs may express some reluctance to revisit systems that appear to be satisfying local and regional accountability demands.

However, the last 10 years have also encompassed significant changes that informed our revisions regarding the goals and outcomes that may help psychology majors thrive. The traditions and boundaries of psychological science education have been challenged by the rapid growth of online learning opportunities. The consequence of the COVID-19 pandemic forced us to make rapid adaptations in how we designed and delivered the undergraduate experience. We have witnessed an explosion of interest in and commitment to social justice concerns. The replication crisis (i.e., the inability of researchers to replicate the findings of previous psychological research studies) and associated reforms have changed how psychology is understood and conducted. Accountability demands have proliferated with an emphasis on producing direct, measurable evidence in support of any claims of quality. Outcome studies support the importance of incorporating high-impact practice in the undergraduate curriculum. Regrettably, one factor that remains unchanged is the public misunderstanding of what psychologists do. All these factors beg to be addressed in the current revision to make the undergraduate psychology curriculum as functional, contemporary, and high-impact as possible.

Task Force Selection and Operations

Selection

APA recruited membership on the task force for *Guidelines 3.0* in several ways. First, we approached members from the *Guidelines 2.0* task force to see who might be willing to serve again, with the goal of having half the task force populated with experienced members to provide continuity. Five individuals volunteered. The remaining members came from a pool solicited by an open call distributed by APA's Education Directorate. Member selection focused on a balance of experience, gender, racial identity, geographical representation, and type of institution (community college vs. four-year college or university). Given the prominence of equity, diversity, and inclusion (EDI) considerations, we added two more members through an open call from the Education Directorate to people of color to enhance representation of diverse viewpoints and experiences. Once the committee membership was fully constituted, we also had LGBTQ representation. As conversations progressed, we created opportunities to hear from other colleagues who could more fully inform us regarding the utility and potential for improvement of *Guidelines 3.0* for related populations (e.g., high school psychology, international programs). We thought additional voices and contributions would lead to a more complete vision, broader adoption, and stronger influence.

Operations

The task force committed to keeping what was reported to work in prior versions of the *Guidelines,* but to develop a document that reflected contemporary needs and practices. Pandemic conditions challenged the routine mode of APA task force collaboration. Under traditional circumstances, committee members convene at APA headquarters for intense debate, policy formulation, and document production. However, pandemic conditions required task force members to collaborate remotely, which we accomplished through monthly or semi-monthly Zoom meetings over the course of a little over one year. The work began in January 2021, during the first wave of COVID-19 disruption. The task force completed the document in early 2022 and worked with the Education Directorate to seek feedback from various stakeholders.

Acknowledgments

The *Guidelines 3.0* task force wants to express appreciation to APA staff members Susan Orsillo and Martha Boenau. Although newly appointed in a leadership role in the Education Directorate at APA, Susan Orsillo dug right in, carefully reviewed the emerging work of the task force, and made insightful comments that improved the quality of the guidelines. Martha Boenau has faithfully served all the task forces working on undergraduate guidelines. Her careful attention to detail and exemplary organizational skills were not just appreciated but inspirational as well.

Other APA officials contributed to the review. We are indebted to Maysa Akbar, Chief Diversity Officer, and Mia A. Smith-Bynum, Senior Director for Science Equity, Diversity, and Inclusion, for input that helped us align the document to recent directions adopted by the APA. We further appreciated the reviews provided by Ann Springer and Donna Euben, both Deputy General Counsels in the APA Office of General Counsel.

Ten scholars with international expertise assisted us in thinking through the implications of what *Guidelines 3.0* might have for building an international psychology educator community. We recruited experts from all over the world, including American scholars with special expertise on the international scene. Although we recognize that international representation could have been more comprehensive, we are grateful to the following individuals for their assistance in this noble effort:

- Australia: Jacquelin Cranney and Tony Machin
- China: Fanli Jia
- Colombia: Andres Manuel Perez Acosta
- Hong Kong: Nancy Diehl
- Kenya: Sahaya Selvam
- Slovakia: Lenka Sokolova
- Turkey: Uzeyir Ok
- Ukraine: Illia Yahilaiev
- United States: Harold Takooshian

Several of our colleagues in the Society for the Teaching of Psychology also assisted our process. Kristin Whitlock, widely recognized as an iconic high school psychology teacher, participated in our discussions about the relationship between *Guidelines 3.0* and the recent APA Introductory Psychology Initiative. Kristin served as co-chair (along with Jennifer Thompson) of the subcommittee that developed outcomes for Introductory Psychology. Regan Gurung and Maureen McCarthy also helped to build the rationale for inclusion of details on allied APA documents that support improving undergraduate education. The task force wishes to acknowledge the contributions made by Katherine Wickes, an early appointee to the committee who was unable to continue with the project. She was an insightful and creative colleague whose absence was noticeable. We want to recognize and thank Stephen Chew for sharing the document he developed with his Samford University colleagues on diversity (Samford Faculty Senate Committee on Diversity, 2013). This document was especially useful in unpacking the term "diversity" to address both diverse backgrounds as well as diverse ideas. We are grateful for the contributions, insights, and wisdom of all our Society for the Teaching of Psychology colleagues.

Graduate student Lanae Arena provided some polishing of the document. Her eagle-eyed approach helped make the document more student-friendly and more attuned to APA writing standards.

We also appreciate the thoughtful critiques we received from various individuals and interest groups who made suggestions to strengthen the document during the public review process. We incorporated many suggestions, and we believe the final set of *Guidelines* represents a true community effort.

FRAMEWORK FOR *GUIDELINES 3.0*

Guidelines 3.0 maintains the structure that was introduced in *Guidelines 2.0.* We specify five "goals" that characterize work at the undergraduate level as the first-level organizer using the numbers 1–5. "Student learning outcomes" (SLOs) represent the second-level organizer; we designate the outcomes that correspond to each goal using decimal points to distinguish separate outcomes. Each goal encompasses from three to six outcomes. The third-level organizers constitute "indicators" that represent a developmental scaffold; we designate foundation indicators with a lower-case letter and baccalaureate indicators with a corresponding upper-case letter.

We provide two versions of the *Guidelines* to assist with curriculum review and assessment planning. The first version summarizes just the learning goals and outcomes, which provides a reasonable overview of the work for programs that may need to concentrate on outcomes that are more broadly defined. The second version provides more details and includes a conceptual scaffolding of foundation and baccalaureate indicators that may be helpful in refining curriculum and assessment planning. Foundation indicators may contribute to course design in introductory psychology and other lower-level courses. Baccalaureate indicators capture student performance in higher-level courses and capstone experiences.

Summary of Learning Goals and Outcomes

GOAL 1
Content Knowledge and Applications

1.1 Describe key concepts, principles, and theories in psychological science
1.2 Develop a working knowledge of psychology's major subfields
1.3 Portray significant aspects of the history of psychological science
1.4 Apply psychological content to solve practical problems
1.5 Provide examples of psychology's integrative themes*

GOAL 2
Scientific Inquiry and Critical Thinking

2.1 Exercise scientific reasoning to investigate psychological phenomena
2.2 Interpret, design, and evaluate psychological research
2.3 Incorporate sociocultural factors in scientific research practices
2.4 Use statistics to evaluate quantitative research findings

GOAL 3
Values in Psychological Science

3.1 Employ ethical standards in research, practice, and academic contexts
3.2 Develop and practice interpersonal and intercultural responsiveness
3.3 Apply psychological principles to strengthen community and improve quality of life

GOAL 4
Communication, Psychological Literacy, and Technology Skills

4.1 Interact effectively with others
4.2 Write and present effectively for different purposes
4.3 Provide evidence of psychological literacy
4.4 Exhibit appropriate technological skills to improve communication

GOAL 5
Personal and Professional Development

5.1 Exhibit effective self-regulation
5.2 Refine project management skills
5.3 Display effective judgment in professional interactions
5.4 Cultivate workforce collaboration skills
5.5 Demonstrate appropriate workforce technological skills
5.6 Develop direction for life after graduation

*** Psychological Science's Integrative Themes (APA, 2021a)**

A. Psychological science relies on empirical evidence and adapts as new data develop1.
B. Psychological science explains general principles that govern behavior while recognizing individual differences.
C. Psychological, biological, social, and cultural factors influence behavior and mental processes.
D. Psychological science values diversity, promotes equity, and fosters inclusion in pursuit of a more just society.
E. Our perceptions and biases filter our experiences of the world through an imperfect personal lens.
F. Applying psychological principles can change our lives, organizations, and communities in positive ways.
G. Ethical principles guide psychological science research and practice.

1 In 2005 APA approved a policy statement that defines evidence-based practice in psychology and encouraged the development of policies that reflect this view.

Framework for Expanded Goals and Student Learning Outcomes: Foundation and Baccalaureate Level Indicators with Signature Attributes

GOAL 1

Content Knowledge and Applications

Overview

Students demonstrate comprehension of the major concepts, theoretical perspectives, historical trends, and empirical or evidence-based findings to discuss how psychological principles apply to behavior and mental processes. Students completing foundation courses demonstrate breadth of their knowledge and application of psychological ideas to simple problems; students completing a baccalaureate degree show depth in their knowledge and application of psychological concepts and frameworks to problems of greater complexity. Students are able to discuss psychological science's integrative themes and the respective sociocultural and historical backgrounds of those themes.

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
1.1 Describe key concepts, principles, and theories in psychological science	1.1a Use basic psychological concepts to describe or explain behavior	1.1A Use psychological concepts to explain and predict behavior with sensitivity to the limitations of that knowledge
	1.1b Recognize that simple explanations rarely explain behavior adequately	1.1B Interpret behavioral phenomena at an appropriate level of complexity, recognizing interactions among psychological, biological, social, and cultural variables
	1.1c Provide examples in which the sociocultural context has affected research findings	1.1C Explain how research conclusions may be affected by sociocultural context
	1.1d Explain why psychology is a science	1.1D Evaluate common myths and misconceptions about psychology
	1.1e Explain why psychology is a hub science	1.1E Provide examples of psychology's influence on other disciplines (e.g., education, law)
1.2 Develop a working knowledge of psychology's major subfields	1.2a Describe psychology's major subfields	1.2A Compare and contrast psychology's major subfields
1.3 Portray significant aspects of the history of psychological science	1.3a Describe historically important perspectives (e.g., theoretical orientations) in psychological science	1.3A Justify preferences for different theoretical orientations in psychological science based on perceived advantages and limitations

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
	1.3b Recognize major historical events and their link to trends in contemporary research	1.3B Evaluate important aspects of psychology's history, including central concerns and theoretical conflicts
	1.3c Identify influential contributions made by psychologists, including those from historically marginalized groups	1.3C Explain how historical context has affected which contributions made by psychologists were deemed influential
	1.3d Identify historic examples of how psychologists have contributed to or challenged unethical outcomes or systemic discrimination	1.3D Analyze historic examples of how psychologists have contributed to or challenged unethical outcomes or systemic discrimination
1.4 **Apply psychological content to solve practical problems**	1.4a Describe examples of relevant and practical applications of psychological principles to everyday life	1.4A Apply psychological principles to clarify pressing societal needs and inform public policy
	1.4b Describe problem-solving strategies informed by psychological science	1.4B Appraise the effectiveness of psychological problem-solving strategies
	1.4c Summarize psychological factors influencing healthy lifestyles	1.4C Evaluate how psychological factors interact to influence health
	1.4d Identify how individual differences in beliefs, values, and interactions with others may give rise to conflicts, including prejudicial and discriminatory behavior	1.4D Use psychological knowledge to identify ways to prevent or resolve interpersonal and intercultural conflicts
	1.4e Describe how psychological science has helped solve problems in applied settings	1.4E Propose appropriate psychology-based solutions in applied settings
1.5 **Provide examples of psychology's integrative themes***	1.5a Describe integrative themes that appear throughout psychological science	1.5A Discuss the contributions that integrative themes make to the understanding and impact of psychological science

*Psychological Science's Integrative Themes (APA, 2021a)

A. Psychological science relies on empirical evidence and adapts as new data develop[2].
B. Psychological science explains general principles that govern behavior while recognizing individual differences.
C. Psychological, biological, social, and cultural factors influence behavior and mental processes.
D. Psychological science values diversity, promotes equity, and fosters inclusion in pursuit of a more just society.
E. Our perceptions and biases filter our experiences of the world through an imperfect personal lens.
F. Applying psychological principles can change our lives, organizations, and communities in positive ways.
G. Ethical principles guide psychological science research and practice.

Attributes Inferred from Successful Demonstration:

Knowledgeable about psychological science	Flexible in thinking
Psychologically literate	Motivated
Capable of coping with complexity and ambiguity	Open-minded
Curious	Prepared

Recommendations for Faculty Use: The attributes may be helpful when constructing appropriate descriptions for letters of recommendation that capture high-quality student performance. Describing the nature of the work accomplished that justifies the use of the attribute will produce stronger reference statements.

Recommendations for Student Use: These descriptions may be helpful in interviews where students are asked to describe their strengths and weaknesses. To provide support for self-assessment claims, students may offer specific examples of the work accomplished to maximize their effectiveness.

2 In 2005 APA approved a policy statement that defines evidence-based practice in psychology and encouraged the development of policies that reflect this view.

GOAL 2

Scientific Inquiry and Critical Thinking

Overview

Psychology is a STEM discipline that uses the same research practices found in other scientific fields (Dovidio et al., 2010). The skills in this domain involve the development of scientific reasoning and investigation, including developing proficiencies in research methods and statistics. Although these outcomes are introduced in foundation coursework, students typically develop these proficiencies mainly in required courses that focus on research methods and statistics. Students completing foundation courses learn basic skills and concepts in interpreting behavior using research, studying research, and applying research design principles to draw appropriate conclusions about behavior; students completing a baccalaureate design, evaluate, and execute research plans. Research skills reflect knowledge of and respect for diversity-related issues when targeting samples in study design. Research practice also includes an evaluation of the extent to which research findings can be generalized as applicable to groups beyond the research sample.

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
2.1 Exercise scientific reasoning to investigate psychological phenomena	2.1a Define psychological research concepts (e.g., empiricism, variables, operational definitions, measurement)	2.1A Distinguish psychological research concepts in a research study
	2.1b Recognize the potential for flaws in behavioral explanations that are based on anecdotes or pseudoscience	2.1B Develop plausible behavioral explanations that use scientific reasoning
	2.1c Describe common fallacies in thinking (e.g., confirmation bias, post hoc explanations, implying causation from correlation) that potentially impair accurate research conclusions and predictions	2.1C Implement strategies to minimize the influence of common fallacies in thinking that impair accurate research conclusions and predictions
2.2 Interpret, design, and evaluate psychological research	2.2a Compare and contrast specific research methods (e.g., archival, descriptive, correlational, experimental, qualitative)	2.2A Select and apply the appropriate research design for a given research question
	2.2b Develop a testable hypothesis based on operational definitions	2.2B Design or replicate a research study to confirm or disconfirm a testable hypothesis
	2.2c Describe research design strategies that facilitate ruling out alternative explanations	2.2C Evaluate the extent to which research strategies rule out alternative explanations and support cause-effect claims
	2.2d Define research transparency and open science practices	2.2D Use replicable and open scientific practices

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
2.3 Incorporate sociocultural factors in scientific research practices	2.3a Recognize that research emerges from the researcher's value system and worldview	2.3A Identify examples of how a researcher's value system, sociocultural characteristics, and historical context influence the development of scientific inquiry into psychological questions
	2.3b Identify potential limitations in research studies that do not appropriately consider the role of sociocultural influences	2.3B Incorporate appropriate sociocultural considerations in research design and interpretation
	2.3c Identify research conditions that allow research findings to be generalized appropriately	2.3C Evaluate the generalizability of specific findings, including caution in extending western constructs in appropriate consideration of sociocultural factors
	2.3d Recognize that the focus of psychological research may narrowly reflect western concerns and biases	2.3D Incorporate international sources, including nonwestern researchers and samples, in research processes, where appropriate
	2.3e Describe how qualitative research captures varied human experiences, particularly those of members from historically marginalized groups	2.3E Evaluate how qualitative research strategies address equity, diversity, and inclusion considerations
2.4 Use statistics to evaluate quantitative research findings	2.4a Describe the four scales of measurement (e.g., nominal, ordinal, interval, and ratio) used in research	2.4A Propose appropriate scales of measurement that can be used for different research purposes
	2.4b Describe the value of and/or calculate basic descriptive and inferential statistics	2.4B Apply the appropriate use of descriptive and inferential statistics to a specific research design
	2.4c Explain findings presented in data visualizations	2.4C Communicate research findings using data visualizations
	2.4d Describe how psychologists determine the statistical outcomes of their research from a scientific and ethical perspective	2.4D Distinguish and interpret practical and ethical aspects of statistical analysis
	2.4e Explain why measurement of research variables must be both reliable and valid	2.4E Identify, evaluate, or design high-quality measurement strategies that enhance reliability and validity

Attributes Inferred from Successful Demonstration:

Amiably skeptical	Careful	Collaborative	Constructively critical
Creative	Curious	Intentional	Inventive
Logical	Open-minded	Persistent	Precise
Self-directed	Self-starting	Systematic	Comfortable with ambiguity
Analytical			

Recommendations for Faculty Use: The attributes may be helpful when constructing appropriate descriptions for letters of recommendation that capture high-quality student performance. Describing the nature of the work accomplished that justifies the use of the attribute will produce stronger reference statements.

Recommendations for Student Use: These descriptions may be helpful in interviews where students are asked to describe their strengths and weaknesses. To provide support for self-assessment claims, students may offer specific examples of the work accomplished to maximize their effectiveness.

GOAL 3

Values in Psychological Science

Overview

This goal promotes the development of ethical and socially responsible values and behaviors in personal, professional, organizational, and institutional settings. The goal includes ethical reasoning and practices, interpersonal and intercultural responsiveness, and strategies that promote and sustain strong communities and equitable opportunities. Novice students in psychology become familiar with the formal regulations that govern ethical obligations in psychology and begin to embrace the values that will help them contribute to socially responsible outcomes in academic and work settings and in society. Advanced psychology students have more direct opportunities to embrace and adhere to ethical practices that will help them optimize their personal and professional achievements and contributions. Novice students recognize how diversity deriving from individual and intersectional differences can enrich human experience. Advanced students are adept at applying knowledge of individual and intersectional differences to improve outcomes. The final outcome addresses the ways in which psychological science can promote a more functional and fair society. Novice students explore the possibilities of using psychological knowledge to build better communities. Advanced students develop the skills to take appropriate action to improve community functions.

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
3.1 Employ ethical standards in research, practice, and academic contexts	3.1a Describe the underlying values (e.g., beneficence, privacy) addressed in ethical standards	3.1A Justify the use of ethical principles in research, practice, and academic contexts as well as everyday life
	3.1b Describe key principles in ethics codes relevant to psychological science for the protection of researchers as well as human and nonhuman participants	3.1B Evaluate psychological research for adherence to relevant ethics codes for research involving human or nonhuman participants
	3.1c Describe the ethical evaluation process for approving research proposals	3.1C Prepare a research proposal to submit to a designated ethical review process
	3.1d Identify key ethical principles governing psychological practice for the protection of clients and practitioners	3.1D Apply ethical principles to dilemmas that psychologists encounter in practice situations
	3.1e Maintain high standards for academic integrity	3.1E Explain how upholding academic integrity strengthens relationships and communities
3.2 Develop and practice interpersonal and intercultural responsiveness	3.2a Interact respectfully with people of diverse abilities, backgrounds, nationalities, and cultural perspectives	3.2A Articulate the value of and seek opportunities to interact respectfully with people of diverse abilities, backgrounds, nationalities, and cultural perspectives

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
	3.2b Describe the need for socially responsible personal values in building strong relationships with others	3.2B Promote high standards of socially responsible personal values in interpersonal and work-related relationships
	3.2c Identify how human diversity influences interpersonal interactions	3.2C Evaluate how interpersonal opportunities and challenges develop from differences related to diversity
	3.2d Recognize how heritage, power, and privilege may produce differential access to opportunity	3.2D Seek equitable decisions and actions in allocating resources and opportunities
	3.2e Describe how racism and other discriminatory beliefs and practices harm individuals and weaken society	3.2E Identify and implement ways to reduce racism and other discriminatory beliefs and practices
3.3 **Apply psychological principles to strengthen community and improve quality of life**	3.3a Describe how cultural context is considered when evaluating quality of life	3.3A Propose ways to improve quality of life using psychological principles that are respectful of cultural context
	3.3b Explain how psychological science can promote civic, social, and/or global outcomes that benefit others	3.3B Participate in activities that promote civic, social, and/or global outcomes that benefit communities
	3.3c Describe psychological issues of global concern (e.g., poverty, health, migration, human rights, international conflict, sustainability)	3.3C Apply psychological principles to address issues of global concern (e.g., poverty, health, migration, human rights, international conflict, sustainability)
	3.3d Recognize psychology's role in developing, designing, and disseminating organizational and public policy	3.3D Analyze the potential effects of psychology-based interventions on public policy issues
	3.3e Identify opportunities to serve others through civic engagement, including volunteer service	3.3E Serve others through volunteer service, practica, and apprenticeship experiences

Attributes Inferred from Successful Demonstration:

Trustworthy	Flexible	Fair-minded	Ethical	Rigorous
Generous	Respectful	Reliable	Community engaged	Inclusive
Moral	Sensitive	Courageous	Beneficent	Service-oriented
Accountable	Honest	Empathetic		

Recommendations for Faculty Use: The attributes may be helpful when constructing appropriate descriptions for letters of recommendation that capture high-quality student performance. Describing the nature of the work accomplished that justifies the use of the attribute will produce stronger reference statements.

Recommendations for Student Use: These descriptions may be helpful in interviews where students are asked to describe their strengths and weaknesses. To provide support for self-assessment claims, students may offer specific examples of the work accomplished to maximize their effectiveness.

GOAL 4

Communication, Psychological Literacy, and Technology Skills

Overview

The skills in this category address the ability of students to build and maintain effective communication skills in processing and expressing information. Novice students develop the capacity to distinguish appropriate and inappropriate communication strategies in developing interpersonal relationships. Advanced students use their knowledge of equity, diversity, and inclusion to improve the effectiveness of their communication skills. Novice students grow in their ability to express their own ideas with clarity, explain the ideas of others, discuss psychological concepts, communicate a cogent scientific argument, and present information using a scientific approach. Toward the end of their major, students are able to communicate the results of a research study or other psychology-related project, explain scientific results, and present information to professional audiences in different formats. Students develop psychological literacy, including applying knowledge of research skills necessary to be an informed consumer of research or a critic regarding unsupported claims about behavior. Ultimately, the psychology student possesses the tools and motivation to evaluate whether claims have merit. They also develop some sophistication in using appropriate technology to improve communication outcomes.

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
4.1 Interact effectively with others	4.1a Attend to key overt and covert elements in communication	4.1A Distinguish between overt and covert messages in communication
	4.1b Recognize that knowledge of culture, values, and biases may reduce misunderstandings in communication	4.1B Deploy psychological concepts to facilitate effective interactions with people of diverse backgrounds
4.2 Write and present effectively for different purposes	4.2a Recognize communication content and form differ based on purpose	4.2A Craft clear and concise communications to fulfill a purpose and address specific audiences
	4.2b Express ideas that accurately reflect basic psychological concepts and principles	4.2B Construct arguments clearly and concisely from evidence-based psychological concepts and theories
	4.2c Organize ideas to fit a basic project's purpose and length	4.2C Develop ideas in formats to fit a complex project's purpose and length
	4.2d Deliver basic communication projects that meet established conventions and professional guidelines	4.2D Deliver complex communication projects that meet established conventions and professional guidelines
	4.2e Use inclusive language and examples in communication projects	4.2E Use inclusive language and examples in communication projects to optimize audience understanding and engagement

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
	4.2f Accept feedback to improve communication quality	4.2F Revise communication projects by incorporating constructive feedback
	4.2g Ask relevant questions to clarify a communicator's intended meaning	4.2G Generate questions intended to deepen or broaden the discussion related to a communication project
	4.2h Provide relevant general feedback on a communication project	4.2H Offer constructive feedback on a communication project
4.3 **Provide evidence of psychological literacy**	4.3a Accurately summarize general ideas and conclusions from psychological sources	4.3A Accurately summarize complex ideas and conclusions from psychological sources and research
	4.3b Identify how information sources differ in credibility and objectivity, favoring expert, peer-reviewed scholarship	4.3B Describe the characteristics and relative value of different kinds of information sources (e.g., primary vs. secondary, peer reviewed vs. non-reviewed, empirical vs. nonempirical)
	4.3c Articulate criteria for identifying objective sources of psychological information	4.3C Evaluate psychological information based on the currency, reliability, validity, and generalizability of sources
	4.3d Describe the types of biases or errors that appear in various media	4.3D Evaluate the biases and errors that appear in various media
4.4 **Exhibit appropriate technological skills to improve communication**	4.4a Distinguish between professional and unprofessional electronic communication	4.4A Use electronic communication professionally
	4.4b Describe how to use digital and social media effectively and responsibly	4.4B Use digital and social media effectively and responsibly
	4.4c Identify and navigate psychology databases and other legitimate sources of information to address psychological questions	4.4C Develop comprehensive and efficient strategies for locating and using relevant scholarship to investigate psychological questions
	4.4d Use technology to create documents and presentations that professionally convey information	4.4D Use advanced features of technology to create engaging, effective, and professional documents and presentations

Attributes Inferred from Successful Demonstration:

Attentive	Comprehensible	Flexible	Investigative
Precise Prepared	Respectful	Organized	Persuasive
Technology-oriented	Adaptable		

Recommendations for Faculty Use: The attributes may be helpful when constructing appropriate descriptions for letters of recommendation that capture high-quality student performance. Describing the nature of the work accomplished that justifies the use of the attribute will produce stronger reference statements.

Recommendations for Student Use: These descriptions may be helpful in interviews where students are asked to describe their strengths and weaknesses. To provide support for self-assessment claims, students may offer specific examples of the work accomplished to maximize their effectiveness.

GOAL 5

Personal and Professional Development

Overview

The skills in this domain refer to abilities that sharpen students' readiness for the workplace whether the student's future involves graduate school or a job following the associate or baccalaureate degree. A background in psychological science may confer a workplace advantage because of the specific applicability of content that focuses on understanding human diversity and behavior. The skills related to this goal have been influenced by The Skillful Psychology Student, a document developed by APA's Committee on Associate and Baccalaureate Education that articulates what skills students will need to be successful. The emphasis in this domain involves self-regulation, project management skills, professional judgment, collaboration skills, and proficiency in workplace technology and career planning. Curriculum design within psychology programs needs to address how to provide explicit feedback to promote development of these skill sets over the duration of study in psychological science. These skills can be developed and refined in traditional academic settings and through experiences acquired during internships, full- or part-time jobs, leadership positions, and extracurricular engagement (cf. National Association of Colleges and Employers' Job Outlook, 2022). Educators commit to facilitating inclusive opportunities for psychology students from different backgrounds. Campus career professionals can be enlisted to support planning and execution of goals related to selection and pursuit of a professional direction.

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
5.1 Exhibit effective self-regulation	5.1a Describe self-regulation strategies (e.g., focused attention, time management, meeting deadlines) that can improve performance	5.1A Use self-regulation strategies (e.g., focused attention, time management, meeting deadlines) to enhance performance and develop evidence for a strong work ethic
	5.1b Accept feedback from peers, educators, and mentors to improve task performance	5.1B Incorporate suggestions from feedback from peers, educators, and mentors to improve task performance
	5.1c Identify self-awareness and self-care strategies to promote high-quality performance	5.1C Incorporate self-awareness and self-care practices to promote high-quality performance
	5.1d Describe strategies that build resilience in relation to failed efforts or unpleasant events	5.1D Persevere when appropriately challenged by using resilience-based strategies
	5.1e Describe the importance of adapting to change	5.1E Adapt to change in a flexible and proactive manner that is appropriate to the context
5.2 Refine project management skills	5.2a Follow instructions and use rubrics to inform project execution	5.2A Adhere to or exceed project criteria in project completion
	5.2b Identify resources, potential problems, or constraints that may influence project completion	5.2B Develop alternative strategies to expand resources and overcome problems and constraints

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
5.3 Display effective judgment in professional interactions	5.3a Recognize that opinions and personalities will differ in professional, cultural, and academic contexts	5.3A Accept and adapt to interaction complexity in professional, cultural, and academic contexts
	5.3b Describe the merits of science-based evidence over personal opinion in solving professional problems	5.3B Develop and implement professional solutions that emphasize the value of data as evidence
	5.3c Identify how civic engagement builds relationships that can produce a positive professional impact	5.3C Engage in civic projects that can produce a positive professional impact
	5.3d Identify how different work settings express and promote specific values, including how professionalism is defined	5.3D Discuss how well one's own personal values align with particular workplaces
5.4 Cultivate workforce collaboration skills	5.4a Give evidence of making positive contributions to team-based efforts	5.4A Collaborate effectively on team-based projects
	5.4b Recognize the potential to develop stronger solutions through collaborative problem-solving by people with diverse backgrounds	5.4B Incorporate diverse perspectives to maximize collaboration effectiveness and problem-solving
	5.4c Identify problems that typically develop when working with teams	5.4C Implement possible solutions to problems that develop when working with teams
	5.4d Assess basic strengths and weaknesses in one's own performance as a team member	5.4D Address weaknesses in one's own performance as a team member
	5.4e Describe leadership behavior that contributes to successful task completion	5.4E Exhibit leadership in successful task completion
	5.4f Identify potential personal biases that can influence professional judgment	5.4F Adopt specific strategies to mitigate personal biases that can influence professional judgment
5.5 Demonstrate appropriate workforce technological skills	5.5a Identify and use appropriate technology for completing data processing tasks	5.5A Use appropriate technology to improve work quality, efficiency, and productivity
	5.5b Express willingness to learn and adapt to changes in technology	5.5B Develop competence in adapting to changing technologies

Outcomes **Students will:**	***Foundation Indicators*** **Students will:**	***Baccalaureate Indicators*** **Students will:**
	5.5c Conduct online interactions appropriate to professional contexts	5.5C Establish a strategic online presence
5.6 **Develop direction for life after graduation**	5.6a Identify academic and career options based on personal interests and values	5.6A Refine an academic and career plan based on accurate self-assessment of abilities and feedback from others
	5.6b Identify and locate appropriate career resources	5.6B Use appropriate career resources to evaluate academic and career options
	5.6c Identify skills and qualifications preferred by graduate programs and employers who hire psychology majors	5.6C Develop evidence of skills and qualifications that graduate programs and employers desire in psychology graduates
	5.6d Articulate the purpose of a resume or curriculum vitae	5.6D Create and maintain a resume or curriculum vitae that showcases a psychology background
	5.6e Recognize the value of participating in activities that strengthen preparation for job entry or graduate school, such as cocurricular activities, securing mentors, and networking	5.6E Gain experience and develop skills in activities that strengthen preparation for job entry or graduate school admission

Attributes Inferred from Successful Demonstration:

Adaptable	Collaborative	Confident	Conscientious
Dependable	Directed	Efficient	Industrious
Intuitive	Prepared	Reflective	Resilient
Resourceful	Responsible	Sensitive	Skillful

Recommendations for Faculty Use: The attributes may be helpful when constructing appropriate descriptions for letters of recommendation that capture high-quality student performance. Describing the nature of the work accomplished that justifies the use of the attribute will produce stronger reference statements.

Recommendations for Student Use: These descriptions may be helpful in interviews where students are asked to describe their strengths and weaknesses. To provide support for self-assessment claims, students may offer specific examples of the work accomplished to maximize their effectiveness.

GUIDING PRINCIPLES FOR 3.0

The obligation to revise and update the *Guidelines* prompted members of the task force to reflect on the inherent value of the undergraduate major at this juncture in our history. This question is particularly compelling in light of negative perceptions about the value of the undergraduate psychology major (Brinthaupt et al., 2012, 2016) that may lead to those who influence students' lives, and even students themselves, questioning their choice of major. This challenge was highlighted a few years ago as a societal concern when during a campaign speech a presidential contender claimed the destiny of the psychology graduate would be working in the food service industry (Dunn & Halonen, 2024). In a commencement address, the same politician claimed the world already had too many psychology majors. Unfortunately, psychology often does emerge as a course of study students regret choosing in the regular "major regret postmortem" conducted by the *Chronicle of Higher Education* (June, 2022).

Consequently, we adopted the vision that *Guidelines 3.0* provide robust evidence that selecting the major has far-reaching, positive implications for students and the futures they choose to pursue. We believe studying psychological science has enormous potential to transform people; students who major in psychology develop the capacity to transform others and become agents of positive social change. We adopted the theme **Empowering People to Make a Difference in Their Lives and Communities** to provide inspiration for our work. In subsequent sections, we elaborate on both the philosophical and the operational principles that guided the recommendations that constitute *Guidelines 3.0.*

Philosophical Principles

Several philosophical principles undergirded our discussions and the decisions we made about the vision, mission, and content of this revision. (Throughout the document we use the terms "psychology" and "psychological science" interchangeably. We are aware that local preferences dictate whether one term conveys more rigor or prestige. We do not claim to make those distinctions in this document but wanted to acknowledge the current variations that exist favoring the use of one term over the other, which is why we intentionally use both terms. We elaborate the practical implications of this terminology in a later section of this document; see p. 50.)

- **Psychology is a transformative pursuit.** The discipline of psychology can be a transformative force, whether promoting change at the personal, professional, institutional, or community level (Sokol & Kuebli, 2011). Fostering change through therapeutic interventions, consultations, or behavioral research has historically been an obvious contribution psychologists may make to improve the quality of professional and personal lives. Students can benefit from applying psychological principles to make and sustain healthy choices and to get the most out of their academic experiences. They also need to realize the potential of psychological science as a change agent for academic momentum and success (Wang, 2017) and for social policy and cultural transformation. The undergraduate curriculum should reflect that broad potential. Additionally, students should also recognize the limits of psychological science.
- **Psychological science is an inclusive discipline.** Every person is welcome to learn about psychology and cultivate the related skills. Despite challenges in the history of psychological science with regard to equitable and fair treatment, we recognize the value of diverse voices in solving problems, large and small. In that spirit, we strove to create a document that reflects our openness and encouragement to all.
- **Psychological science should support movement toward achieving a fair, just, and equitable society.** The document showcases the way psychological science may support important social and cultural changes to improve the quality of life. We believe psychological science has a responsibility for providing an educational experience that contributes to achieving a fair, just, and equitable society (Davidson & Morrissey, 2011; Hulme, 2014). The discipline of psychology is unique in the undergraduate curriculum for the role it plays in shedding light on the intricacies of human interaction. As just one example, studies in attitude formation and change (e.g., Allport, 1954; Asch, 1956) lend themselves to some important tools in increasing awareness and facilitating more meaningful, productive, and harmonious interactions. Addressing conflicts constructively may improve and deepen interpersonal and intercultural relationships as well as produce outcomes (Deutsch, 1973).
- **Psychological science should support diversity of ideas and freedom of expression.** Support for diversity not only addresses the individual and cultural differences that exist among people but also should encompass support for the expression of diverse ideas and experiences (Samford Faculty Senate Committee on Diversity, 2013). We are careful to avoid dictating what one should believe, but instead emphasize how psychological science knowledge and skills may be applied to produce meaningful change. We also endorse the importance of critical thinking and data-informed choices that may mitigate cognitive biases and thinking fallacies inherent in human functioning.
- **Psychological science should promote attention to different global perspectives and contributions.** To thrive in an interconnected, global environment, stu-

dents need to develop skill sets that will help them function effectively in interdependent global systems (American Association of Colleges and Universities, 2007). Although psychological science has developed an intellectual stronghold in the United States, the growth of the discipline in other parts of the world is undeniable (Takooshian et al., 2016). However, we concluded that educators may not always help undergraduates recognize that psychology is a worldwide enterprise. Although we designed this document specifically to address expectations in the United States under the auspices of the APA, we acknowledge the potential the Guidelines may have in influencing policy beyond U.S. borders. A great deal of the psychological literature developed in the United States (e.g., Thalmayer et al., 2021) raises questions about the degree to which we can generalize our findings to other groups. A common historical criticism of the psychology canon is that a significant amount of published human research may have emerged from studying college sophomores. This observation reinforces that our sciences may chiefly be built on observations and measurements of Western, Educated, Industrialized, Rich, and Democratic (WEIRD) populations (Henrich et al., 2010). We need to be less insular as a discipline. As educators, we need to remind students to look beyond traditional geographic boundaries in the intellectual sources they use when constructing psychological arguments. To that extent, Guidelines 3.0 encourages educators to incorporate links to international scholarship that may broaden the value and applications of research, where appropriate. Psychological thinkers benefit from a conscientious pursuit of what we may learn from other countries and cultures.

- **Psychological science should reaffirm the central importance of operating from ethically defensible decisions.** Events on the world stage in the past few years called into question whether psychology's moral center had drifted (Craig et al., 2020; Wingen et al., 2020). We believe education needs to go beyond informing students of the existence of ethics codes by helping them understand and embrace the principles that drive ethical reasoning with the goal of building an ethical, just, fair, safe, and honorable society. Students need to recognize how behaving with integrity builds stronger interpersonal and professional relationships and learn to engage with others in a way that promotes perceptions of reliability and trustworthiness.
- **Psychological science should continue its leadership in conducting and advocating open science practices.** Recent concerns with whether the findings of psychological science are valid and reliable underscore the importance of embracing and teaching open science practices (Nosek, 2019). Rather than adopting a defensive posture regarding the existence and magnitude of reported replication failures, psychologists should feel pride in their willingness to be transparent about their research process and to have their results scrutinized. This perspective means that some of the traditions related to empirical research have been changing and need to be communicated to students as reinforcement for how contemporary psychological science should operate.
- **Psychological science students should have a well-rounded grasp of both psychology's accomplishments as well as its failings.** Psychology has a checkered history with regard to its ethical practices (Sinclair, 2017). Although we may cite historical episodes in psychology that demonstrate violation of ethics or moral codes, we also need to emphasize the degree to which contemporary psychologists undergo checks and balances to ensure that scientific conclusions are sound and therapeutic processes are properly selected and delivered. Research participants, therapy clients, researchers, and practitioners all should be protected from harm. Because negative episodes tend to garner attention, we support the strategy that the curriculum needs to balance the historical blights on the discipline with psychologists' contributions to building a stronger society. The checkered past also extends to problems with privilege and marginalization. [For more information, see the report *Examining Psychology's Contributions to the Belief in Racial Hierarchy and Perpetuation of Inequality for People of Color in the United States* (Cummings Center for the History of Psychology, 2021).] Although psychologists have been instrumental in developing insights into prejudice and discrimination and contributed to significant cultural reforms to address policies designed to reduce discrimination, the discipline owns that we could do more collectively to promote inclusion and equity as expressed in APA's (2021e) resolution on dismantling racism.
- **Undergraduate programs should do a better job in preparing students who enter the workforce after graduation.** Students who graduate with a degree in psychology should be well prepared to succeed in the workplace in assuming a psychology-related future, whether that future involves entering the workforce with an associate or baccalaureate degree or pursuing additional education in graduate or professional schools (Appleby, 2018; Dunn & Halonen, 2024). Baccalaureate programs have been fairly effective in preparing students for graduate school. However, the majority of students who earn a baccalaureate degree will enter the workforce rather than go to graduate school. Most four-year programs have not paid as much attention to the workforce pathway compared to the graduate school pathway. As a consequence, four-year programs may appropriately be criticized for failing to focus adequately on those students who do not plan to attend graduate school (Halonen, 2013).

In contrast, students completing associate degrees or career-enhancing certificate programs tend to be highly focused on what employment advantages might accrue to their new status. Lower-level coursework in psychology is especially helpful in human services, such as applied behavior analysis (ABA) programs working with autism spectrum, child development, geriatrics, and addiction. Entry-level work in these areas may ultimately lead students to return to school for a higher-level degree. At the same time, students may also be satisfied that the associate degree successfully unlocked the future opportunities they were seeking.

Programs striving to be more responsive to workforce preparation—whether at the associate or baccalaureate level—may need to pursue some broad curriculum reform to help students understand the degree to which a background in psychological science will inform and enhance their workforce lives. Consider convening some focus groups of alumni who have moved into the workforce to determine what other kinds of experiences should be incorporated in the curriculum to improve psychology major competitiveness. This emphasis will reinforce students' perceptions of the vital link between their psychology major and their occupational choices. Employers place great value on a new hire's ability to think critically, communicate, collaborate, and reason ethically (Finley, 2021), which aligns with the goals supported in *Guidelines 3.0*.

For additional support in making decisions about preferred professional pathways, we recommend the following website developed by the American Psychological Association of Graduate Students (APAGS, 2021): https://www.apa.org/apags/resources

Further information on psychology pathways is available via APA's interactive data tool *Degree Pathways in Psychology*: https://www.apa.org/workforce/data-tools/degrees-pathways.aspx

- **Psychological science majors can help correct public misperceptions about the nature of the discipline.** Psychological science suffers in the public eye from some fundamental misunderstandings about the nature of the discipline (Dunn & Halonen, 2024). Every student who completes a degree in psychology has the potential to be an ambassador for the discipline, not just in correcting the public view of the discipline, but also in shedding light on other big societal issues. Students will benefit from programmatic encouragement to "seize the narrative" in public discussions about the true nature of psychological science, both as a matter of accurate and effective self-assessment about what psychological thinkers may accomplish, but also to assist the public in avoiding misconceptions and gaining a clearer understanding of the value of psychological thinking in addressing the challenges in contemporary life.

Operational Principles

We concentrated on several design features that helped us with the *Guidelines 3.0* revision.

- **Remain aspirational rather than prescriptive.** The *Guidelines* do not rise to the level of standards that must be achieved or some negative consequence will transpire. However, the document is designed to inspire local discussion to help programs forge their optimal curricular and assessment planning informed by recommended national practices as well as local distinguishing features. Programs are encouraged to adapt or amend the guidelines to capture any distinctive features of their curriculum from an informed basis. Although the document is not prescriptive, it includes our recommendations on what students should know and be able to do upon completion of a two- or four-year experience in the psychology major. We offer some strategies to promote effective collaboration on curriculum in the implications section of this document.
- **Retain the overall goal and outcome structure.** *Guidelines 2.0* proved to be useful in curriculum planning and accountability practices; therefore, we elected not to change the fundamental structure. That configuration contributed to the widespread adoption and use of *Guidelines 2.0.* Student learning outcomes continue to provide benchmarks for preferred practices; indicators continue to illustrate how we would gather evidence to document that the outcomes have been achieved. We hope to maintain a place of central importance in national curricular/assessment planning and implementation achieved by *Guidelines 2.0* but to reflect issues of emerging importance over the past decade in *Guidelines 3.0.*
- **Remain curriculum "agnostic."** For the most part, we do not dictate a specific curriculum or endorse specific content that should be "covered" in achieving the outcomes. How educators address the goals and outcomes should reflect respect for academic freedom. The emphasis in *Guidelines 3.0* addresses additional skill development to produce well-prepared majors for the workforce as well as graduate and professional schools. Notably missing from this document are recommendations about course requirements and sequencing as well as specific content that should be taught. We believe content may be addressed with some flexibility if the outcomes themselves are discernible in curricular and assessment design.
- **Reinforce "novice to expert" continuum in skill development.** Complex skills tend to develop over time, prompting educators to design educational experiences that foster skill growth over the course of the major (Kalyuga, 2015). Thus, we recommend that programs explore how individual courses contribute to cumulative program expectations regarding what students should know and be able to do in their major. We have

designated two levels to capture novice-to-expert growth at the midpoint (foundation) and endpoint (baccalaureate) of the undergraduate career. Although skill development is a continuum, we believe that identifying indicators at two levels will be helpful to programs as they plan their curriculum. Further, identifying indicators at these two levels may promote making connections between community colleges and four-year colleges and universities. We have heavily relied on terminology from Bloom's Taxonomy (cf. Anderson & Krathwohl, 2001) to differentiate lower- versus higher-order expectations within the major. We have also tried to stay away from expressing indicators that may be problematic for measurement, such as "understand" or "appreciate." Our intention was to choose outcomes and indicators that lent themselves to observable and measurable behavior whenever possible.

- **Should be useful to students.** We want students to know about and use *Guidelines 3.0* to enhance their educational success and workforce readiness. To those ends, we encourage psychology programs to share outcomes with students in course syllabi and program resource material.
- **Make the ideas practical and accessible.** We wanted to ensure that the indicators we are suggesting were manageable and reasonable across the variable contexts in which psychology programs operate. The language in the document was designed to be user friendly for faculty and students alike. Consequently, we strive for the simplest expression possible in our recommendations. We are aware that arguments could be made to have specific skills show up in more than one goal. We attempted to use descriptions that limited the use of exemplars ("e.g.") to avoid cataloging and to minimize the risk of generating offense by omitting preferred examples of specific stakeholders. For the purposes of simplification, we occasionally consigned a skill to one specific category. When the outcomes or indicators overlapped, we tried to augment the description with qualifiers that addressed why a variation of that outcome or indicator fit in a specific category. Our goal was to reduce redundant information, where appropriate.
- **Integrate prior relevant work.** We saw *Guidelines 3.0* as an opportunity to integrate past related work from APA task forces to produce continuity among related education improvement efforts. Consequently, we align our work with recent outcome-focused work completed in the following efforts: the Introductory Psychology Initiative (APA, 2021a); *Strengthening the Common Core of the Introductory Psychology Course* (APA Board of Educational Affairs Working Group on Strengthening the Common Core of the Introductory Psychology Course, 2014); the *Equity, Diversity, and Inclusion Framework* (APA, 2021d); the current Ethics Code (APA, 2017a), among others. Our work also reflects preferred practices contributed from other organizations or disciplines (e.g., American Association of Colleges and Universities, 2007).
- **Accommodate diverse contexts that deliver undergraduate psychology programs.** We recognize that the content of the *Guidelines* has potential impact for a variety of educational contexts, including high school, college, and even graduate training. The variety of contexts that deliver the undergraduate major is significant (e.g., public vs. private, religiously affiliated, selective vs. nonselective). Program sizes differ. Access to resources differ. Programs may be strictly face-to-face or fully online. Heterogeneity of both student bodies and faculty who teach them vary as well. In this document we strive to be as inclusive as possible with a framework that may be adapted to any undergraduate context. We designed the document to be hospitable and usable across varied institutional contexts and modes of delivery, regardless of their differences.
- **Any outcome or indicator outlined in Guidelines 3.0 should be assessable.** Task forces associated with prior versions of the *Guidelines* were conscientious about assisting faculty to assess the outcomes specified in the documents. That intention has only increased in importance as regional accrediting bodies add pressure regarding the evidence psychology programs may offer about their claims for academic success. We believe any indicator may be assessed and hope *Guidelines 3.0* will encourage publication of more assessment strategies to support this claim.
- **Outcomes should represent realistic expectations for psychology majors in two- and four-year programs.** The aspirational intent of earlier versions of the *Guidelines* produced a more idealized set of expectations that did not always clearly lend themselves to precise assessment strategies. Feedback from *Guidelines 2.0* suggested that many of the indicators, especially at the baccalaureate level, may have overshot what could be accomplished by the majority of students in a four-year degree. Although we acknowledge that baccalaureate-level students are not likely to be true disciplinary experts (a term that might be better reserved for graduate education and beyond), we did envision what a reasonably competent graduate should be able to do when we constructed or revised the baccalaureate-level goals. Consequently, we focused on what could be realistically achieved by undergraduates at the two- and four-year levels. Although the focus of the document addresses our recommendations about what should be achieved by all majors, a well-designed undergraduate program will also provide opportunities for students to exceed expectations.

SUMMARY OF CHANGES AND IMPROVEMENTS FROM *GUIDELINES 2.0*

Because *Guidelines 2.0* was popularly received and drove significant curriculum and assessment discussions in the last decade, the challenge to revise encouraged us to be visionary about what the updated *Guidelines 3.0* could accomplish. We asked for feedback and also attended to emerging literature on the impact of the *Guidelines* (Norcross et al., 2016). Besides fine-tuning the outcomes and indicators that would normally transpire in a routine policy update, this document reflects some overarching themes that drove our decision-making in how undergraduate education might change to meet the demands of contemporary life.

Changes in Structure

We have revised some of the titles of the goals in keeping with some of the modifications we propose. We maintained the five-goal structure that emerged in *Guidelines 2.0* since those emphases remain at the core of undergraduate education. We are aware that significant scholarship of teaching and learning builds on *Guidelines 2.0,* including the development of APA's Project Assessment (2017). We summarize the key differences in goal titles or content below.

- Goal 1 has been retitled "Content Knowledge and Applications," which not only addresses expertise in comprehending and describing basic terminology and theories but expands to include how such psychological science content may be applied.
- Promotion of psychology as a science continues to be a central consideration in the *Guidelines,* reflected primarily in Goal 2. We retained the label of "Scientific Inquiry and Critical Thinking." However, we also expanded attention to statistical reasoning, which surfaced as a key omission from *Guidelines 2.0.* The new indicators reflect the vigorous discussion that has been transpiring about expanding considerations on how to interpret research findings statistically.
- We have modified Goal 3 with a name change to provide a showcase for "Values in Psychological Science." Equity, diversity, and inclusion were themes not just housed in Goal 3 but addressed throughout the document where relevant. We retained the importance of building and using psychological knowledge and skills to develop interpersonal and intercultural competence, but also increased the importance of psychology's role in addressing community, national, and global issues.
- The scope of Goal 4 has changed as reflected in the title, "Communication, Psychological Literacy, and Technology Skills." This goal continues to emphasize how psychology majors write and speak reflecting the discipline, but we have added attention to managing technology as well as selecting and processing information.
- Goal 5, "Personal and Professional Development," expanded to address important work accomplished in linking psychology undergraduate education with what employers seek in their hires. To those ends, we have incorporated attention to teamwork skills and the ability to adapt to organizational culture to improve the preparation of students who either head into the workforce after graduation or move into graduate or professional studies.

Changes in Emphases

- **Clarification of "psychological science" vs. "psychology."** The task force recognizes that the very designation of academic units has been undergoing review and reform. Although many still identify as "psychology" programs, many others have embraced strengthening the scientific emphasis with unit names that promote "psychological science." We sympathize with the argument that psychology should not need to make the tie to science explicit since our colleagues in the natural sciences do not feel compelled to go to these lengths. For example, we do not see a comparable movement to brand undergraduate programs as "chemical science" or "biological science." However, psychology educators face a different kind of legitimacy battle in the eye of the public since the ties of psychology to science are perceived to be more tenuous. Consequently, we have strategically applied the designation of psychological science throughout *Guidelines 3.0* to reflect emerging contemporary practice. We incorporate the term "psychology" when we allude more generally to the discipline of psychology.
- **Workforce preparation.** We recommend that students who graduate with a degree in psychology be well prepared to assume a psychology-related future, whether that future involves the workforce or additional education in graduate or professional schools. Historically, departments have done a defensible job in preparing students for graduate school, but we believe the majority of undergraduate majors—those who choose to enter the workforce upon graduation—often end up neglected in their undergraduate pursuits by faculty who are better prepared and more focused on graduate school prospects. As such, in most programs the graduate school–bound students tend to receive substantial privileges that are not accessible for workforce-oriented students (Halonen, 2013). One serious consequence of this two-tiered status is that workforce students often disconnect their professional identities with their major; if they do not go to graduate school, they encode "I'm

not doing anything with my degree." We think departments need to develop learning opportunities for workforce students that feel honorable and reinforce their connection to their undergraduate degrees. That stance encourages faculty to be explicit about how their courses have the potential to hone skills that will have value in the workplace.

- **EDI matters.** Although attention to diversity concerns has historically been incorporated into previous versions of the *Guidelines,* the current task force focused more extensively on the obligation of psychological science to contribute to fairness and justice. We addressed equity, diversity, and inclusion (EDI) issues in Goal 3 as a fundamental and deeply held value in psychology. However, we also conscientiously infused aspects of diversity into other goal areas. The stance taken in this document is more forthright about psychology's obligation to make conditions more equitable and inclusive.
- **Global considerations.** Our process involved conferring with both domestic and international experts on how educators across the globe deliver the discipline at the undergraduate level. Past versions of the *Guidelines* have been influential in setting expectations beyond the United States for undergraduate student performance. To those ends, we were careful to incorporate generic language that might be easier to apply across international boundaries.
- **Ethical prominence.** In parallel with task force work undertaken by the APA to improve ethical understanding and adherence to codes of conduct, we elaborated expectations for undergraduate performance. We expanded the focus to include research, practice, and academic contexts. We also chose to emphasize the principles that underlie ethical codes to encourage students to appreciate the practical value of having codes that govern professional behavior. Our emphasis includes the role that ethical behavior plays in building and maintaining interpersonal relationships.
- **Statistical updating.** One of the areas in which *Guidelines 2.0* received critical reviews was the underrepresentation of measurement and statistics. We have rectified that problem by elaborating the advantages of using statistics in drawing conclusions about the potential value of research. We incorporated expectations regarding scales of measurement, data visualization, and psychometric criteria that emphasize conclusions about reliability and validity. We also incorporated references to "new statistics" to reflect emerging preferred practices in courses dealing with methods and statistics.
- **Methods elaboration.** We have included expectations that draw distinctions between quantitative and qualitative research, highlighting the relevance and importance of both general approaches in addressing research questions.
- **Thematic adoption.** We incorporated the seven themes that characterize the discipline of psychology that were developed by APA's Introductory Psychology Initiative. We expect students to be conversant in those themes throughout undergraduate study, with refined ability to discuss the impact of those themes by the end of their undergraduate experience.

PUTTING THE *GUIDELINES* INTO ACTION

Engaging Program Personnel in Curricular and Assessment Planning

Guidelines 3.0 provides a framework to facilitate the development of effective undergraduate programs. We recommend a collaborative approach in which everyone involved in delivering the program is also involved in decision-making (Dunn, Troisi, et al., 2020). In addition to the *Guidelines*, helpful guidance about breadth, coherence, sequencing, and other aspects of effective programs may be found in the proposed *APA Principles for Quality Undergraduate Education in Psychology* (see Appendix A).

Faculty vary in their level of passion about program planning, but all have a stake. Curriculum and assessment procedures are more likely to be effective when they are the product of a team effort. It may be useful to remind those who are less enthusiastic about program planning that their participation is an opportunity to have more agency in the future of the program. Another helpful strategy is for program leaders to communicate regularly about assessment and recognize faculty for their efforts (Dunn, Troisi, et al., 2020).

Program assessment in particular is often perceived as a burden imposed by outside forces (Halonen, Beers, & Brown, 2020). Clearly, programs must meet expectations of their institutions, accrediting agencies, and various stakeholders. Yet faculty may tailor their program to their priorities, institution, available resources, and student population. Framing assessment as a way of supporting student learning, as opposed to additional work that generates data for reports that may go unread, can reduce the level of burden faculty perceive.

We have structured *Guidelines 3.0* to address variable accountability practices. We designed the *Guidelines* around five goals with corresponding student learning outcomes and indicators that reflect expected achievement. Assessment decision-makers can determine how best to incorporate those two levels in the development of the assessment plan. For example, a program striving to be comprehensive in its expectations for graduates can build an assessment plan from the outcomes that best illustrate the distinctive nature of its program. On the other hand, building assessment plans that treat the goals as program outcomes provides more variability in the specific assessment targets a program may pursue. In this case, multiple assessment strategies could be used to document progress made, for example, in Professional Development. Similarly, faculty who are focused on assessment within courses may find the indicators to be most helpful in developing their teaching and learning strategies. Regardless of how educators technically frame their expectations, regional accrediting bodies encourage faculty to support claims of excellence with evidence based on student performance.

Each institution is likely to have an assessment cycle that specifies when reports are due, but programs will benefit from including assessment procedures as part of their ongoing business. Being proactive about assessment work is likely to result in more thoughtful decisions. Spreading the work out over time will also reduce the onerous aspects of attempting to complete everything in one long meeting. An effective assessment infrastructure for a program will include clearly delineated responsibilities. For example, the program decides whether one person serves as the assessment point person, whether activities are coordinated by an assessment committee, and whether administrative support could be made available. Sustainability of assessment efforts may be improved by distributing the workload in an equitable way. We recommend that individuals who take on major roles in assessment receive compensation, such as stipends, release time, and recognition for promotion and tenure decisions.

A Call to Action

We recommend judicious preparation for program planning meetings. Effective preparation includes sharing an agenda that identifies specific goals for each meeting; scheduling adequate time, including breaks, to accomplish the goals; and providing relevant documents with the expectation that participants will review those materials in advance. It may be tempting to focus on refining assessment procedures, but it is also crucial to use the data for program improvement (Dunn, Coffman, et al., 2020). We recommend that a review of the data inform changes in program delivery such as curriculum revision and improved teaching methods. "Closing the loop" in this way may lead faculty to be more enthusiastic about assessment.

It is important for assessment planning to also be realistic. If the plans are too complicated or burdensome to carry out, the effort expended to design them will have been wasted (Dunn, Coffman, et al., 2020). Wherever possible, we recommend program personnel simplify and automate processes that generate meaningful data. Borrowing from the aphorism often attributed to Voltaire (1772), perfection is the enemy of the good.

Implications of *Guidelines 3.0* for Community College Contexts

Community college psychology professors teach lower-division courses, prepare graduates to enter the workforce in a variety of human service–related occupations, and facilitate academic success for students planning on transferring to upper-division psychology programs. Successful transfer experiences may be achieved more readily when the goals of the community college and their transfer institutions align. We believe that articulating the learning outcome indicators for both kinds of institutions may contribute to greater coordination of effort to foster mutual appreciation of institution goals and improve successful student transitions.

Community college faculty indicated that the original *Guidelines* did not speak well to the educational experiences offered in a two-year program. In response, *Guidelines 2.0* differentiated two-year outcomes from baccalaureate achievements. The foundation/baccalaureate differentiation proved helpful in *Guidelines 2.0.* Consequently, this task force has retained that format and refined the outcomes and indicators for this current version. The learning indicators presented in *Guidelines 3.0* reflect extensive community college input, mainly on the foundational content. Five experienced community college teachers served on the *Guidelines* task force.

Community college psychology faculty can make effective use of *Guidelines 3.0* in several ways. The foundation outcomes may be helpful when reviewing and updating two-year psychology-oriented curricula, articulating program and course student learning outcomes, designing assessment activities, and engaging in academic program reviews. *Guidelines 3.0* may also be useful for justifying requests for essential instructional resources, particularly when faculty can base program needs on preferred national practices. In addition, the *Guidelines* make a case for revisiting state regulations about the recommended courses that departments offer at the two-year level.

Tips on Program Planning

The outcomes presented in *Guidelines 3.0* are aspirational and not prescriptive. We do not propose them as a "one-size-fits-all" set of learning outcomes. Local factors will, of course, affect how the psychology faculty can incorporate *Guidelines 3.0* into their programs. For example, some community college programs offer a restricted range of the most basic psychology courses, primarily emphasizing General Psychology. In those settings, both the foundation indicators and the outcomes specified by the Introductory

Psychology Initiative will be the most useful in program planning. Other contexts offer a broad range of courses that would be comparable to the options available in four-year settings.

Using the Guidelines to Leverage Resources and Strengthen the Program

In preparing a three-year program review report, one department used *Guidelines 2.0* learning indicators to argue for and eventually hire a tenure-track faculty position. Another department used *Guidelines 2.0* to justify, equip, and staff an introductory psychology lab. Psychology faculty at another community college used *Guidelines 2.0* indicators to support placing psychology courses (e.g., General Psychology, Statistics, Biopsychology, and Critical Thinking) on their college's recommended course completion pattern for all associate degree and transfer students. Another department used the *Guidelines* to create a comprehensive transfer-ready assessment instrument designed explicitly for psychology majors. The *Guidelines* have encouraged some departments to implement new courses (e.g., Critical Thinking, Career Development, Cognition). Numerous departmental faculties refer to *Guidelines 2.0* when identifying course and program student learning outcomes and developing corresponding assessment tools and strategies.

When making a case for new resources or support, faculty may invoke *Guidelines 3.0* as an arbiter of what constitutes best practice. Many administrators may not be aware that the APA has put forth effort to produce a document that identifies what the best programs are doing to serve their students. Linking resource requests to any relevant program metrics (e.g., student retention, graduation rates, alumni earning power) tends to be more successful, so determining how specific implementation of the guidelines improves program performance metrics will have greater appeal for administrators who manage funding decisions.

Articulation Challenges

Community college psychology programs in many states offer Introductory Statistics and Research Methods courses, whereas course articulation rules in some states prohibit the inclusion of those courses. Due to such statewide restrictions, community college transfer students may arrive at their university already disadvantaged compared to "native" students (who began their studies as university first-year students). Without statistics and research course preparation, transfer students must compete with native students who have already completed those courses. Another consequence is that transfer students may find themselves less competitive when seeking research lab positions. Even more troubling is that many transfer students in psychology's academic and career pathways come from historically underrepresented ethnic backgrounds, and many are first-generation college students. Because this articulation barrier exists in contexts that prohibit these basic but essential courses, community college psychology teachers must find alternative ways to help their students acquire foundational statistics and research experiences and skills before graduating with an associate degree and transferring. Strategies include embedding research content and projects in existing courses (Jackson & Griggs, 2012; Johnson, 1996; McKelvie & Standing, 2018) or implementing a research lab in the Introductory Psychology course (Branch & Dubow, 2021; Thieman et al., 2009). Stevens et al. (2016) offer eight scientific reasoning modules designed to strengthen scientific reasoning in introductory psychology students. Other ways include, but are not limited to, forming a research committee within your psychology club or Psi Beta chapter (McCartney et al., 2020); hosting an on-campus student research conference (Carsrud et al., 1984; Lipton, 1986; Woody & Miller, 2020); establishing a research partnership with a local university (Ashcroft et al., 2021); implementing an interdisciplinary research program (Paris, 2018; Peterson et al., 2021); launching a student research journal (Dawson & Marken, 2019; Farkas & Pashkova-Balkenhol, 2021; Hart, 2012); and supporting student attendance at and participation in a professional psychology conference (Rastogi et al., 2011). One enterprising department successfully negotiated an articulation agreement with the psychology department at their primary transfer college; their community college program now provides transferable introductory statistics and research methods courses.

A Call to Action

We encourage community college educators in psychology to explore how *Guidelines 3.0* can support high-quality courses in two-year contexts. First, widespread support for *Guidelines 3.0* may help reinforce consistency in performance expectations despite differences in context so that students know what skills, experiences, and knowledge we expect them to acquire. Therefore, introducing students to *Guidelines 3.0* may be helpful to them. Second, *Guidelines 3.0* may support programs in mounting compelling arguments for securing needed resources by demonstrating aspirations for accountability and improvement. Finally, the *Guidelines* may serve educators who want to redesign articulation agreements by arguing for relevant access to courses at the two-year level. That stance might not only address the inconsistent treatment of research and statistics but might also justify expanding electives in two-year programs.

Implications of *Guidelines 3.0* for Introductory Psychology/High School

Although *Guidelines 3.0* are helpful to high school and college instructors who advise students in their pursuit of a psychology degree, the guidelines may have limited usefulness in teaching Introductory Psychology. Rather, high school teachers may rely on the APA *National Standards for High School Psychology Curricula* and Introductory Psychology instructors at colleges can look to APA's *Student Learning*

Outcomes for Introductory Psychology and the larger scope of work recommended by APA's Introductory Psychology Initiative in the book *Transforming Introductory Psychology* (Gurung & Neufeld, 2022). We include a summary of the approved outcomes from the APA-IPI project in Appendix B.

Considerations for Occupational Destination: Workforce vs. Graduate School Readiness

We recommend that students who graduate with a degree in psychology be well prepared to pursue a psychology-related future in the contemporary workplace, whether they enter the workforce with an undergraduate degree or proceed to graduate or professional school. Many students major in psychology because they are interested in the subject matter, and they have not yet selected a career path. Some students choose the psychology major because they aspire to be psychologists, counselors, or professors. After studying psychology in greater depth and learning more about their own interests and the opportunities that are available, students often realize by their senior year that continuing with graduate school is not for them. Our goal is for students to recognize that successful completion of an undergraduate degree with a major in psychology is a substantial achievement in and of itself and one that has prepared them for a wide range of career opportunities. However, savvy psychology majors recognize that they should be actively preparing for a psychology-related career throughout their undergraduate experience, including taking advantage of extracurricular and other enrichment opportunities that will help them be even more competitive in the job market.

Although this section focuses on career options for students completing four-year degrees, we also acknowledge the contribution of two-year degrees in promoting students' occupational outcomes. Certainly, completing an associate degree with coursework in psychology supports students in making informed decisions about future educational and career pursuits, helps them gain access to four-year institutions, and contributes to their understanding of behavioral principles that will apply to virtually any career they choose to pursue. Additionally, students who have earned an associate degree have lower unemployment (Bureau of Labor Statistics, 2016) and earn significantly more than students whose educational attainment is limited to graduation from high school (Bureau of Labor Statistics, 2021).

Career Paths Followed by Those Who Major in Psychology

A background in psychology may lead to a plethora of employment opportunities. The APA Center for Workforce Studies (https://www.apa.org/workforce) produces data tools that may be used to explore the psychology education and workforce pathways of students who complete an undergraduate degree in psychology. In contrast with the common criticism that "you can't get a job with just a bachelor's degree," the APA Center for Workforce Studies provides evidence of the breadth of workplace contexts that may provide meaningful and profitable employment for those who achieve a four-year degree.

Based on National Science Foundation data that includes 3.7 million students who earned a bachelor's degree in psychology (APA, 2021c), psychology majors follow three primary career paths upon graduation that prepare them for a range of occupational outcomes:

- Careers that may begin with a bachelor's degree (57%)
- Professions requiring graduate degrees in psychology (14%)
- Other professions that require graduate degrees (29%)

Figure 1 presents a snapshot of the broad range of career and career clusters those earning a baccalaureate in psychology pursue over time. Note that some of these careers may require additional education and licensure beyond the baccalaureate (e.g., social workers, counselors), while others may not (e.g., marketing and sales occupations). It is important for psychology programs to prepare students for the careers they are most likely to pursue upon graduation.

FIGURE 1.

Employment Outcomes of Psychology Majors, 2019 (APA, 2021b).

Source: American Psychological Association (2021b)

According to the APA Center for Workforce Studies (APA, 2021c), the majority of psychology majors enter the workforce with their bachelor's degree. The most common occupational outcomes include positions in social work (11%) or counseling (7%); administrative (9%), management (7%), service (6%), personnel (4%), or sales and marketing (3%); and preschool or elementary teaching (5%; APA, 2021b). These commonly held positions account for only 52% of careers pursued by psychology majors with an undergraduate degree—consequently, the range of opportunities is very broad. Note that the Center for Workforce Studies updates their online data tools approximately every two years. Whereas the overall findings have been similar with each revision, we recommend reviewing the data tools (https://apa.org/workforce/data-tools) for the most recent information. Other outstanding resources that may help psychology students consider how their undergraduate experiences may prepare them for career opportunities include Dunn and Halonen (2024), Kuther and Morgan (2019), and Landrum and Davis (2020). See Boysen (2020) for a great resource for students who wish to go on to graduate school in psychology.

Historically, psychology departments frequently have demonstrated a stronger orientation toward offering coursework and opportunities that may be most helpful to majors who wish to continue with graduate education; the pursuit of psychology careers requiring doctoral-level training is often vaunted as the ultimate goal for psychology majors. Consequently, those programs may do a very effective job of preparing future graduate students but may inadvertently neglect those who choose instead to enter the workforce. As illustrated in Figure 2, in reality, a limited number of psychology majors achieve the goal of graduate education. In fact, of the 3.5 million psychology bachelor's degree holders, only 1 in 7 go on to obtain a graduate degree in psychology (National Center for Science and Engineering Statistics, 2017).

When faculty interact with students, it is important to demonstrate an appreciation for the value of the broad diversity of career pathways open to psychology majors. We recommend that faculty commit to helping all psychology majors identify the specific knowledge and skills they are developing in their course of study so they may effectively leverage those experiences to pursue unique career goals. It is important that students who discover their own interests, nurture their strengths, and find their calling with an occupation that helps them to pursue a meaningful life believe their undergraduate psychology experiences were valuable to their life journey. It would be inaccurate for students who do not pursue psychology or psychology-adjacent professions to conclude that they are "not doing anything with their bachelor's degree in psychology." Undergraduate psychology students develop a deep understanding of behavioral science principles and skills that are applicable to almost every career pathway.

A minority of psychology majors pursue careers requiring graduate school in psychology. Of the psychology majors who complete a graduate degree in psychology, the master's degree in psychology is the most common. Only 3.8% of psychology majors earn a doctoral degree in psychology.

Preparation for graduate work in psychology is an important goal of the psychology major, but since a minority of our students follow this pathway, we recommend that programs not overemphasize this career outcome or consider it the ultimate goal for psychology majors. Fortunately, focusing on the undergraduate goals and outcomes that qualify students for entry into the workforce also will facilitate solid preparation for graduate and professional school. Many psychology majors reap benefits from their background in psychology even as they pursue careers that require graduate or professional degrees that are technically outside of psychology. APA (2021b) reports that the most popular option is education (25%), including teaching, special education, and educational administration. Other psychology-related options include law and other legal studies (21%); medicine and health professions (19%); social work (18%); counselor education (7%); and business and management (5%).

Figure 2 captures a representative year (2019) to demonstrate the professional pathways psychology majors pursued, including those in psychology as well as those in related disciplines.

FIGURE 2.

Pathways from a Bachelor's Degree in Psychology

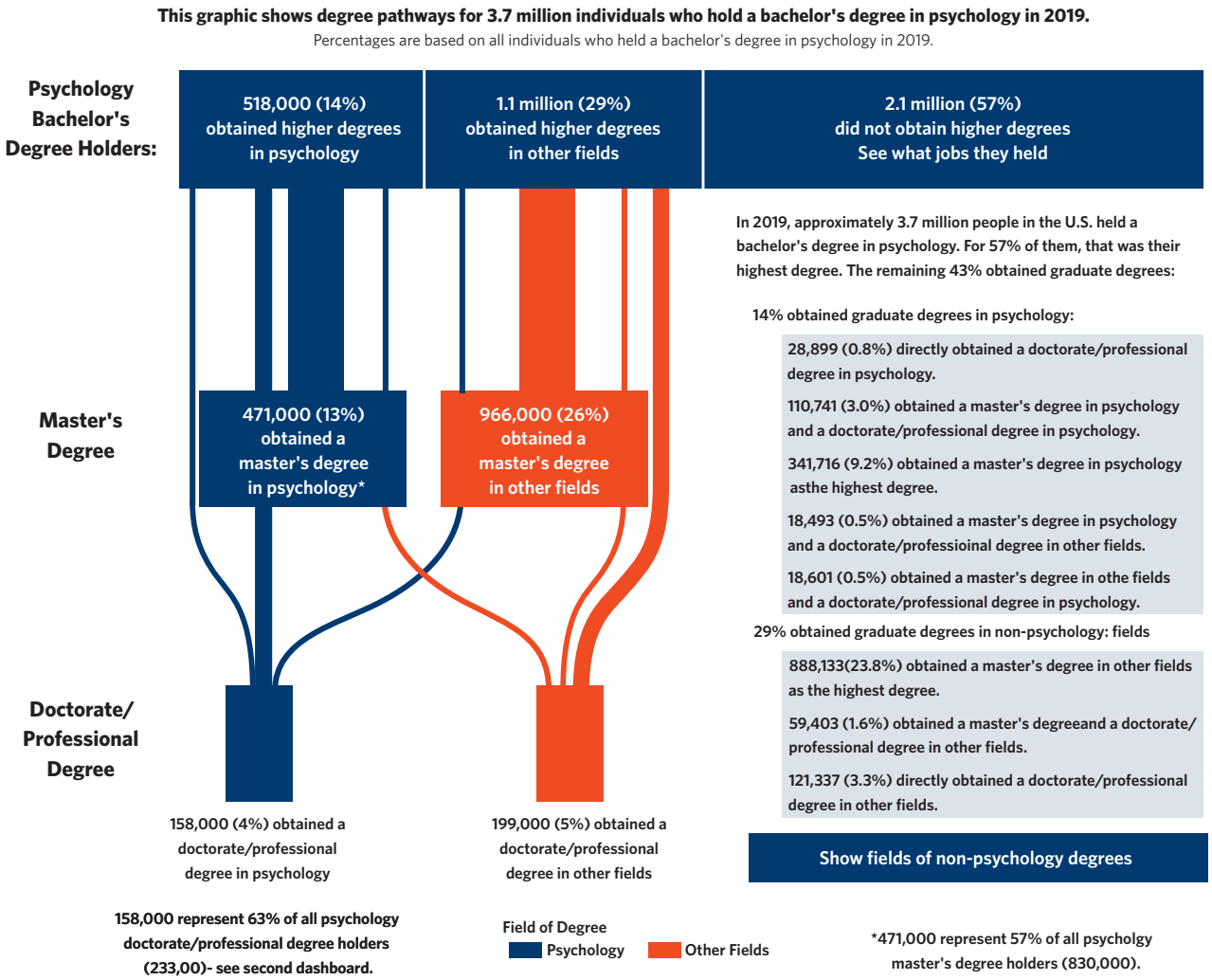

Source: American Psychological Association (2021c)

For further information on professional opportunities, see APA *Degree Pathways in Psychology*: https://www.apa.org/workforce/data-tools/degrees-pathways.aspx

Contemporary Workplace Skills

When students complete a psychology major that reflects the goals and outcomes of the *Guidelines*, they will become "skillful psychology students" (Naufel et al., 2018) who are well prepared for a wide range of professional opportunities. Psychology students may develop cognitive, communication, personal, social, and technological skills that are necessary for success in today's workplace.

Many of the skills cultivated through the undergraduate study of psychology have been identified as highly valuable by executives and hiring managers according to a survey commissioned by the American Association of Colleges and Universities (Finley, 2021), including the following:

- Critical thinking and complex problem-solving
- Locating, evaluating, and using information in decision-making
- Analyzing and interpreting data, including working with numbers and statistics
- Making sound decisions and ethical judgments
- Communicating in writing and presentations
- Communicating/working with people from different cultural backgrounds

Employers place great value on the same experiences that psychology programs and graduate program admissions committees recommend, including:

- Completing internships, apprenticeships, or work experiences
- Working with mentors individually and as part of research project experiences
- Collaborating with people from diverse backgrounds

Employers appreciate applicants who have skills and experiences that are developed during the psychology major; they particularly value candidates who can relate their skills and experiences to the positions for which they have applied.

Unfortunately, many students cannot clearly articulate what they know in ways that apply to a wide range of career options. Graduating students do not always see the connection between the psychology outcomes achieved and their value for workforce positions. The ability to articulate psychology-related skill sets may be even more important given the rise in applicant tracking systems (i.e., bots) that screen out candidates who fail to represent targeted terms. As such, psychology program faculty need to develop opportunities for all students to reflect on what they have learned during their psychology major and how the variety of information and skills applies to any career and general preparation for life. Opportunities transpire in the academic advising process as well as in many courses throughout the major. Faculty are encouraged to address specific skills promoted within their class activities in syllabi, assignments, and rubrics to help students develop greater facility in understanding the skill sets they are developing in the major. A well-designed capstone course may be especially effective at helping students integrate what they have learned and facilitate making meaningful connections to a variety of career paths.

Students pursuing any psychology-related career opportunity can feel confident that their decisions are justifiable, honorable, and consistent with the goals of an undergraduate psychology program. Psychology faculty help students to develop the knowledge and skills that prepare students for a wide range of career opportunities and to make career decisions that are right for them. We recommend that the psychology major curriculum:

- Develop students' knowledge and skills that are applicable to a wide range of career opportunities;
- Ensure that majors develop a strong working knowledge of the broad range of career options available to psychology majors;
- Help students recognize how the knowledge and skills they have developed as psychology majors are applicable to a range of careers both inside and outside the field of psychology.

Employers and post-graduate programs in all fields will appreciate the broad knowledge and skills developed by students who complete programs that include substantial focus on all five goals articulated in these guidelines.

Advice on Using the Guidelines for High-Achieving Students

Guidelines 3.0 specifically targets the kinds of outcomes we may expect of any student graduating with a degree in psychology. Achieving the outcomes represents a general statement of fitness as a psychological thinker with an undergraduate background. However, for students who have set their sights on some form of graduate or professional education or other highly competitive career opportunities, faculty need to encourage them to strive to exceed the competence levels specified in the *Guidelines* and seek opportunities for experiential learning on campus and in the community through additional classwork, research experiences, internships, volunteerism, and/or employment. Students who demonstrate their motivation and initiative are more likely to impress graduate school admission committees and potential employers.

Faculty who use the *Guidelines* to create performance rubrics may benefit from thinking about categorizing performance in one of three tiers: *Exceeding Expectations, Meeting Expectations,* or *Not Meeting Expectations.* Incorporating some judgment about exemplary performance may encourage students to invest in higher-quality work and potentially inspire greater creativity. Consistent high-level performance is more likely to generate favorable recommendation or reference letters and other high-impact opportunities to build a persuasive case for admission or hiring.

A Call to Action

Faculty must help students leverage what they have learned to pursue post-graduation opportunities (e.g., Naufel et al., 2018;

Van Kirk, 2019). As illustrated in Figure 1, presenting a wide range of career opportunities available to psychology majors during coursework and career advising throughout the psychology major program will help students recognize that the major supports diverse occupational goals, and not only for students who complete graduate school in psychology.

Experiences beyond the basic requirements of the psychology major may be critical to help students achieve their goals. To prepare for the workforce and professions requiring graduate or professional school outside of psychology, students may need to complete specific coursework or engage in internships, work, or volunteer experiences in settings relevant to the student's chosen profession. Selected coursework and extracurricular activities that may include pre-professional programs (such as pre-health or pre-law), minors, or second majors may provide persuasive evidence of fitness for specific career goals.

The quality of career advising often shows up as a common complaint when students address program weaknesses during evaluations. Most campuses provide faculty and staff advisors who focus on career and pre-professional questions; however, students' questions about how to find jobs after graduation may surface in other academic interactions in and out of the classroom. Traditionally trained faculty often feel underprepared to respond to career-related questions that do not reflect their own experiences.; however, sidestepping this critical issue is not advised since it is of paramount importance to student satisfaction with the major. This obligation becomes even more compelling when we consider the substantial debt loads many students bear upon graduation. Psychology faculty can collaborate with colleagues across campus to ensure that all program stakeholders, whether in a formal or informal advising role, may effectively address the career needs of students who major in psychology. Every faculty member does not need to know the specifics of every career option, but we recommend that all faculty be conversant in general about the kinds of opportunities that exist for baccalaureate-prepared students and be able to direct students to appropriate resources. We encourage faculty members to refrain from reinforcing misperceptions that "you can't get a job without a graduate degree."

Incorporating Open Science into *Guidelines 3.0*

In the past decade, psychological scientists have experienced significant turmoil surrounding questions about the quality of the discipline's scholarship and scientific practices; this turmoil is referred to as the replication crisis (Diener & Biswas-Diener, 2018). In 2015, the Open Science Collaboration published the results of an ambitious attempt to replicate 100 studies that had recently been published in three top psychology journals. They found that only about one-third of the studies replicated, and the observed effect sizes tended to be smaller in the replications than the original. Contemporary research teams simply were unable to match the results originally published in psychology's literature. Nosek established the Center for Open Science to advocate for strategies that would strengthen psychology's research claims.

Causes of replication failure are diverse. Explanations include sloppy or unsystematic execution of either the original study or the attempted replication, questionable research practices, differences between the original study and the replication effort, or simply chance. Some critics have suggested that researchers may have inappropriately generalized their findings while ignoring important contextual variables (i.e., findings that fit one group may not apply to another group or a different time). Unfortunately, in some worst-case scenarios, psychologists have been guilty of fabricating data to produce significant results. The pressures on academic researchers to publish or perish with regard to future tenure and promotion decisions placed a premium on generating a substantial number of publishable studies demonstrating statistically significant results. This pressure to publish discouraged researchers from attempting to build a stronger case for a psychological claim through replication.

Psychologists have responded to the turmoil of the crisis by recognizing the opportunity to enhance the credibility of psychological research (Vazire, 2018) and to promote inclusive practices.

They proposed some important changes or refinements in how research transpires that are reflected in *Guidelines 3.0.* Some of the changes represent substantially different ways of proceeding with research design, analysis, and dissemination; other recommendations emphasize the need to reaffirm a commitment to a priori theorizing. Consequently, many practical changes—some of them quite dramatic—appear to be shaping preferred practice in the open science movement. The key differences are explained below.

The New Statistics

Null hypothesis significance testing (NHST) has long dominated data analysis protocol in psychology, with an emphasis on achieving specified probability levels to determine whether a research design could claim the discovery of relationships between variables. However, critics of this practice (cf. Cumming 2014; Normile et al., 2019) suggest that traditional statistical practices may have contributed to the replication crisis. The emphasis on interpreting *p* values produces a dichotomous outcome: Was the result significant or not? Such an all-or-none conclusion provides limited interpretive value in the absence of understanding the effect size. In addition, substantial research evidence suggests that *p* values are often misinterpreted by researchers and consumers alike. Students regularly report that learning inferential statistics is anxiety provoking because the logic of NHST is not intuitive and is hard to grasp.

Another concerning tendency is the practice of *ad hoc* hypothesizing rather than developing a priori hypotheses based on theory. The practice of developing and reporting hypotheses after the data have been collected has been referred to as "HARKing" or Hypothesizing After Results are

Known (Kerr, 1998). To maximize the likelihood of getting publishable results, researchers may engage in data mining, known as "*p*-hacking," to be able to claim any significant finding that will enhance the likelihood of publication (Head et al., 2015). Such practices seem to be fueled by the dichotomous judgment that applies a probability level to determine whether a result is significant or not significant.

Challenges to NHST are not technically new; however, the replication crisis provided new fuel for rethinking how psychologists can interpret the procedures they follow in their research. Flawed statistical procedures, such as the examples described above, make replication failures much more likely. The "new statistics" shift the emphasis away from significance value to effect sizes to estimate the magnitude of differences (Normile et al., 2019). The new statistics also reinforce the specification of confidence intervals and the value of replications. In addition, meta-analyses take on greater importance to determine where the weight of evidence converges across related studies.

Open Science Practices

The ability to make claims with confidence from psychological research extends beyond statistical analysis. Some journals not only endorse the inclusion of effect sizes as a standard expectation in research but also may discourage the use of NHST interpretations altogether. In addition, many psychologists have begun preregistering their work, which involves creating a time-stamped and uneditable document before data collection that specifies the methods and analysis plan of the study. This protocol provides additional transparency about the research process and helps guard against questionable research practices like HARKing and *p*-hacking. Some journals allow researchers to submit proposals for studies such that an approved proposal guarantees that research findings will be publishable regardless of whether the results achieve significance. By changing to this strategy, the discipline does not lose important information that occurs when research studies do not achieve significant differences. Open science practices support more comprehensive treatment of phenomena and potentially help researchers avoid pursuing research strategies that produce misleading or unreliable results.

Data Ethics and Transparency

Open science reinforces the idea that science is a public good. Researchers must commit to choosing designs that maximize respect and protection for research participants. They must also apply statistical techniques that clearly communicate their findings. This approach emphasizes the importance of making research designs transparent and data available for scrutiny. Thus, many researchers participate in open science practices such as preregistration and data sharing, and some journals have added badging protocols for studies that meet open science standards. Open science practice also encourages the use of open sources to promote dissemination of research findings.

Greater Contextual Awareness

Psychologists have long prided themselves on exercising objectivity in their research. However, contemporary researchers recognize that research projects grow out of specific sociohistorical contexts. Differences in context certainly shed light on why older studies may not replicate in contemporary times. We also recognize that, despite a commitment to objectivity, psychological researchers are human beings who are likely to approach problems with their own personal and cultural biases. Consequently, peer review processes would benefit from having greater diverse representation in reviewing panels (Munafo et al., 2017).

New Software Support

Many researchers report moving away from SPSS as the standard data management software strategy and toward open-source statistical programs (e.g., JASP, R, Jamovi) that work effectively with other data management software. According to Basturk (2005), students who are skilled at software applications tend to achieve higher grades in later courses. Using open- source software may promote sound statistical practices well beyond graduation. However, making this transition may require additional professional development for psychology faculty who may be unfamiliar with the software.

Smith (2020) observed that *Guidelines 2.0* supported an open science approach. However, the refinements in Goal 2 of *Guidelines 3.0* provide even greater emphasis on open science and emerging preferred science practices. We expanded the articulation of statistical outcomes in a purposeful way to reflect the open science trends. Undergraduates do need to understand that traditional practices are evolving, and they need to learn to appreciate the practical advantages of communicating effect sizes rather than significance levels in data interpretation. This approach will be more straightforward and confidence building for students who struggle with the rationale for inferential statistics.

Departments may also consider how to teach open science practices beyond statistical courses, such as discussing the replicability of findings in topical courses and teaching open science skills to undergraduates (e.g., how to preregister studies; how to share research materials in a public repository such as the Open Science Framework). Incorporating open science practices into the undergraduate curriculum will enable students to use those techniques in their own work in the future and become more critical consumers of science. A host of open science teaching materials is available for reuse in published papers (see Kathawalla et al., 2021; Pownall et al., 2021) and on the Open Science Framework (course syllabi for open and reproducible methods, https://osf.io/vkhbt/).

Leveraging Support for Psychology as a STEM Science

Psychology programs often run into resistance in relation to claims of being a scientific enterprise. Despite the fact that

the National Science Foundation declared psychology and related social sciences as STEM (science, technology, engineering, and math) members (Dovidio et al., 2010), local authorities and administrators may not always recognize psychology as a STEM discipline.

Many undergraduate programs have been conflicted about whether to designate their programs as "psychological science" or maintain the more traditional designation of "psychology." Transforming the name of the department to include science in the title (e.g., "Department of Psychological Sciences") may be a strategic decision—rather than a defensive posture—if it persuades local and/or institutional authorities to classify psychology as a STEM discipline with corresponding competitive funding.

However, complicating psychology's claim for formal recognition as a science is the current practice of designating programs using the Classification of Instructional Programs (CIP) codes (APA, 2022). Federal agencies rely on CIP codes for determining STEM classification that produces some operational advantages for science programs. For example, the Department of Defense and the National Science Foundation use CIP codes to qualify candidates for scholarship support. Additionally, students who are pursuing psychology degrees in America under the auspices of an F-1 visa may be able to extend their visa for programs that are clearly recognized as STEM science.

Most four-year programs maintain the CIP code classification of *Psychology, General* (42.0101), which is not currently a STEM designation. However, several programs (e.g., Purdue University, Edinboro University) have successfully negotiated a change in their CIP code status to reflect a different name and number: *Research and Experimental Psychology* (42.2799).

Careful alignment of STEM-focused programs with the goals outlined in *Guidelines 3.0* may provide additional evidence for qualifying psychology as STEM. Goal 2 (Scientific Inquiry and Critical Thinking) outlines appropriate goals, learning outcomes, and performance indicators to reinforce the recognition of psychology as STEM. By incorporating the principles of open science addressed in the document, that recognition may be strengthened.

A Call to Action

Guidelines 3.0 endorse open science practices. Consequently, educators may seek some statistical reeducation to keep current with preferred practice. Normile et al. (2019) advocated that during this time of transition it may be most helpful, and perhaps least disruptive, to combine NHST interpretations with those strategies that grow out of open science practices. They recommend a six-episode video sequence developed by the Association for Psychological Science to assist faculty in becoming more well informed about open science (https://www.psychologicalscience.org/members/new-statistics).

International Implications of *Guidelines 3.0*

Psychology higher education, historically dominated by the United States, is now increasingly international. As Takooshian and colleagues (2016) reported, undergraduate psychology is extremely popular around the world; they note that the share of all psychologists who worked in the United States was 80% in the 1980s, but as of the publication of their article, the share of U.S. psychologists had dropped to 21–24%. This change is particularly notable given that the sheer number of psychologists in the United States and worldwide has been skyrocketing. The global expansion of our field suggests that we, as psychology instructors, 1) remain aware of international education trends, and 2) make our courses more international. The third iteration of the *APA Guidelines for the Undergraduate Psychology Major* emphasizes this internationalization to a greater degree than its predecessors, including soliciting input from U.S. psychologists with international experience and from psychology instructors working outside the United States.

Many scholarship of teaching and learning (SoTL) articles dedicated to international concerns have cited past versions of APA guidelines, including articles about students studying outside the United States (i.e., study abroad experiences), instructors and administrators internationalizing the U.S. psychology curriculum, and the global expansion of psychology education generally. We predict *Guidelines 3.0* will remain a popular citation source. We also hope the latest *Guidelines* will help the United States play a bigger role in an ongoing and growing international conversation about recommended competencies for the psychology major. These *Guidelines* may reduce concern that the psychology community in the United States seeks disciplinary dominance or that it is indifferent to or unaware of pedagogical advances in other nations.

International Trends in Psychology Higher Education

Harmonization. In 1999, a consortium of 29 European countries, through what came to be called the Bologna Process, committed to the development of a European Higher Education Area (EHEA) to increase the quality of higher education and facilitate international and institutional mobility of students and degree holders. The consortium aimed for flexibility through "harmonization" among institutions and countries rather than a more prescriptive standardization across its member institutions and countries. Consortium members agreed to create comparable degrees through a "tuning" process, develop explicit connections with employers, facilitate mobility, and collaborate with respect to minimum competencies, assessment, and quality assurance (Bologna Declaration, 1999). The Bologna countries have met many of these goals (Eurydice/European Commission/EACEA, 2018). (The Bologna countries also developed a diploma, the EuroPsy Certificate, that outlines minimum competencies for practicing psychologists in the

EHEA for whom the terminal degree is the master's—as it is in most parts of the world [European Federation of Psychologists' Associations, 2011]. EuroPsy facilitates quality assurance, competencies with respect to ethics, and mobility of clinician psychologists.)

The Bologna model has been widely admired and copied. With more than 4,000 psychology educational programs around the world, demands for international frameworks to promote quality and mobility have increased (Bullock, 2014). In line with this call, a Bologna Follow-up Group has led to partnerships between the EHEA and consortiums of institutions and countries in almost every part of the world, often with funding from the European Union (e.g., Dang, 2015; Knight, 2013; Nolan et al., 2020). Knight (2013) explains that Bologna "has propelled other regions and sub-regions around the world to look more seriously at the significance and modality of building closer alignment of their higher education systems" (p. 106).

Two important lessons are apparent from the EHEA and other Bologna-like initiatives. First, the range of stakeholders in higher education includes employers, community organizations, and the general public. Second, emphasizing harmonization and the related concept of "tuning" promotes mobility across institutions and countries. We hope the APA *Guidelines 3.0* will facilitate both goals because of its overlap with international trends, such as psychological literacy. Because of the possibility that faculty across the globe will review and perhaps adopt the guidelines, a more common language regarding psychology competencies and degrees may result; however, we acknowledge that even if instructors and programs outside the United States wish to implement *Guidelines 3.0,* that outcome may not be feasible. Cultural considerations and concerns that the *Guidelines* are U.S.–centric may discourage broader use. In addition, governments in many countries guide curricula with no flexibility at an institutional or departmental level to make wholesale changes in line with a document such as *Guidelines 3.0.*

Psychological literacy. In 2010, former APA president Diane Halpern and her colleagues memorably wrote:

> To bring about change in the perceptions of the general public and policy makers, all psychologists should develop the concept of psychologically literate citizens and convey this message so that policy makers and the general public will understand that the need to be psychologically literate is similar to being able to read or use numbers in thinking. (p. 172)

The simple, if somewhat radical, idea was that psychological knowledge and skills could become as familiar to people as the ability to read, write, and do basic math computations. In other words, people could be *psychologically literate*—able to use psychological theory and empirical evidence to enhance or improve everyday decisions and daily life in general at local, national, and international levels. Indeed, the concept of global citizenship is an integral part of psychological literacy (Cranney & Dunn, 2011). Thus, psychology students may be taught to recognize and to rely on the utility of psychological knowledge both in as well as beyond academic settings.

In effect, psychological literacy enables students and university graduates to use what they have learned to adjust to the stresses and strains found in their work settings, their families, and their local and global communities. The COVID-19 pandemic, beginning in spring 2020, illustrates how related behavioral compliance (e.g., lockdowns, mask wearing, vaccinations, booster shots) was more successful in some nations than others, a fact that points to the importance of applying psychological knowledge to influence the welfare of whole communities.

Psychology education may contribute to solutions for global threats like the pandemic or climate change, as well as smaller, more local issues. Universities around the world are under some pressure to educate students who can enter the workforce while acting as knowledgeable citizens who can and will contribute in meaningful ways to improve their cultures and nations. Psychology may have a large role in shaping the next generation of psychologically literate global citizens.

As Morris et al. (2021), recently noted, there

> . . . appear to be two current approaches to defining and operationalizing [psychological literacy]: (a) as a set of capabilities—knowledge, skills, and attitudes, that a student should acquire during their psychology education, and (b) as a general capacity to intentionally apply psychology to achieve personal, professional, and societal goals. Regarding the former, although there is some consensus regarding what constitutes the set of capabilities, further development is required. Regarding the latter, practical implications, challenges and opportunities require further exploration. (p. 1)

Clearly, creating psychologically literate international citizens—those who see using psychological science to benefit all of humanity—is a good idea.

Internationalizing Our Courses

Thus far, we have been discussing broad global trends. However, we want to emphasize that each of us, as instructors, has the ability to contribute to a global conversation within psychology education by internationalizing our own courses. We can apply the same tactics that we describe elsewhere in this document with respect to diversity, equity, and inclusion to internationalization. Specifically, we can consider the topics we choose, the research we cover, and the readings we assign. The Association for Psychological Science recently published an excellent essay about the grand challenges of psychology, many of them international (see https://www.psychologicalscience.org/observer/grand-challenges), as well as a three-part series from a team of international authors entitled "Psychological

Science Needs the Entire Globe" (see https://www.psychologicalscience.org/observer/global-psych-science). These essays suggest a wide range of topics and research that we can incorporate across the psychology curriculum. On a seemingly smaller level, but one that is quite important in terms of inclusion, we also can relatively easily diversify the examples we use to clarify concepts in class, including with broader representation in names and photos (Littleford & Nolan, 2013).

International Input on *Guidelines 3.0*

We invited 21 colleagues to provide input on a draft of the *Guidelines*; most were from countries outside of the United States, although some were from or working in the United States but with extensive international experience. We received feedback from 10 of these colleagues representing nine different countries from Africa, Asia, Europe, North America, Oceania, and South America.

Of these 10 psychology educators, six were previously aware of APA's *Guidelines*. Of those who were aware, some indicated that individual instructors used *Guidelines 2.0* at the course level, but noted that at the institutional level, country-specific requirements made it difficult to apply the guidelines; however, one non–U.S. colleague wrote that "this set of documents is possibly the most comprehensive readily accessible set of teaching resources for undergraduate psychology in the world." One international colleague lauded the emphases on internationalization, open science, ethics, and technological literacy, and another appreciated the "global vision." One contributor highlighted the emphasis on diversity and inclusion, and yet another praised focuses on social justice and on career development.

Criticisms included a lack of attention to "application to self," including when related to students' "values and sense of morality," particularly with respect to careers; insufficient attention to psychological literacy; and "mixed messages" with respect to minimal vs. aspirational outcomes. Another respondent commented that equity, diversity, and inclusion (EDI) as understood in the United States is not universally applicable, noting, for example, that "ethnicity" is not a viable or meaningful concept in all countries. One colleague asked for an increased emphasis on the place of psychology in the context of other fields in the social, physical, and natural sciences, as well as in the humanities and in cultural studies.

Relatively universally, the respondents viewed *Guidelines 3.0* as helpful for developing courses, curricula, and programs. Several stated that they hoped to use these guidelines to effect changes in their own countries. One colleague expressed the wish that our understanding of psychology's history expand to include an international perspective, writing, "I understand most of the theories were from Europe and United States, but also important to see how the history of psychology moves globally. It would be very difficult to go country by country but still important to see some of the benchmarks of the historical movement in Asia, Africa, and other places." We agree, and hope that the increased international emphasis in *Guidelines 3.0* will encourage broader conversations among U.S. instructors and between U.S. instructors and international colleagues.

A few respondents took the time to send additional comments, observations, and suggestions outside the survey they received. One individual wrote to express gratitude that *Guidelines 3.0* identified optimal expectations for psychology programs to consider. This individual urged that minimum expectations be highlighted, as many systems outside the United States need to know the minimum structure they must provide to pass quality reviews for accreditation or program review processes. Currently, undergraduate psychology programs in the United States do not have any sort of accreditation requirement or process, nor is one on the horizon. Nonetheless, the *Guidelines* may serve as a proxy for such a process, as they encourage some level of standards or a form of quality control. Finally, the colleague also praised the revised section on Communication, Psychological Literacy, and Technology Skills as important. The colleague suggested that the literacy skills (e.g., speaking, writing) be expanded to include careful or critical listening as well as what might be best called "media literacy," that is, attending to the veracity of the media sources being cited or relied on for information.

Another colleague identified an important distinction between U.S. training in psychology—especially training oriented toward practice—and that found elsewhere, including in Colombia and other parts of Latin America. The United States is highly focused on degree acquisition beyond the baccalaureate level; however, other nations have "historically strong social needs associated with poverty and wars" that have encouraged them to allow individuals with undergraduate degrees in psychology to perform clinical, community, and educational interventions in much of Latin America through the decades-old "Bogotá model" (Ardila, 1978; Benito, 2009). These budding psychologists work as acknowledged professionals who often use their earnings to pay for their postgraduate studies.

Finally, we asked these international colleagues whether they thought the *Guidelines* were too U.S.–centric to be useful. Most did not, with one respondent commenting that "It has a global outlook—and very conscious about it." Another respondent seemed to capture an overall perception: "I don't think it is too U.S.–centric to be useful, but it is clearly a U.S.–centric document." Another respondent noted that "It would be interesting to have an international perspective on what undergrad psychology degree can do internationally." We agree, and hope there will be ongoing research and collaborations in this area.

A Call to Action

Based on international trends and on the feedback from our international colleagues, we suggest several ways in which the *Guidelines* might be useful in a global context. First, departments (or even students on their own) might use

Guidelines 3.0 to communicate what students have learned, which could be helpful when working in international contexts in the United States or moving internationally for work or school. Relatedly, students could use *Guidelines 3.0* to shape their experiences, including choosing courses, when studying internationally. Some U.S. departments of psychology implicitly communicate that when their undergraduate majors study abroad, taking psychology courses is not necessary or even desirable (i.e., a form of the U.S.–centric concern). They speculate that finding "equivalent courses" will be difficult. Instead, students may be advised to study abroad to develop a better and broader understanding of international perspectives on psychology. Psychology programs are encouraged to be flexible in terms of accepting international psychology courses as psychology electives for their study abroad students.

Second, although the *Guidelines* might be useful in non–U.S. contexts, they would have to be interpreted based on the local culture, educational system, and approach to psychology; moreover, U.S. psychologists must be cautious about applying the guidelines when working outside the United States as they represent a U.S. perspective. See Morgan-Consoli et al. (2018) for a discussion of both general and teaching-specific competencies for U.S. instructors working internationally. The U.S. undergraduate experience is structured differently than that found in most other nations; for example, the typical American undergraduate degree is completed in four years, whereas many other nations grant a bachelor's degree in three years' time. Similarly, most U.S. undergraduates complete a set of general education courses designed to provide them with a broader understanding of other educational areas in the humanities, arts, and social and natural sciences. Other nations often focus primarily or exclusively on the major area of study.

Nonetheless, an ongoing conversation about similarities across countries and world regions might enhance both higher education quality and mobility. As Nolan and colleagues (2020) wrote, those involved in psychology higher education in the United States "could benefit from examining the complex, sometimes limited, often varied, but also inspiring Tuning projects initiated by our colleagues around the world" (p. 194). We hope *Guidelines 3.0* will inspire our colleagues to join this international conversation.

Resources

Our international colleagues wisely suggested that we include resources for international organizations related to psychology teaching and learning, as well as other relevant documents. We hope this list will grow, particularly with organizations and input from the Global South.

- APA's Office of International Affairs: https://www.apa.org/international (In particular, see the list of international organizations, networks, and meetings: https://www.apa.org/international/networks)
- APA's (2004) *Resolution on Culture and Gender Awareness in International Psychology*: http://www.apa.org/about/policy/gender.aspx
- Australian Psychology Learning and Teaching (AusPLAT):
- https://www.ausplat.com/
- European Federation of Psychology Teachers' Associations (EFPTA): https://www.efpta.org/home
- European Society of Psychology Learning and Teaching (ESPLAT): https://www.esplat.org (Note: ESPLAT has a journal, *Psychology Learning and Teaching*, that has an international editorial board and international contributors.)
- International Compilation of Human Research Standards: https://www.hhs.gov/ohrp/sites/default/files/2018-International-Compilation-of-Human-Research-Standards.pdf
- International Council of Psychology Educators (ICOPE): http://www.psychliteracy.com/icope-inc
- International Union of Psychological Science: https://www.iupsys.net/about
- *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations*: https://www.wcrif.org/downloads/main-website/montreal-statement/123-montreal-statement-english/file
- Velayo (2016) list of resources to "Internationalize Undergraduate Psychology": http://www.apa.org/education/undergrad/internationalize.aspx
- World Health Organization's mental health resources: https://www.who.int/teams/mental-health-and-substance-use

Equity, Diversity, and Inclusion in *Guidelines 3.0*

APA has the foundational goal "To advance EDI [equity, diversity, and inclusion] through psychological science that champions thought leadership, innovation, and excellence" (APA, 2021b, p. 6). Psychology instructors, by way of their roles, convey the history, values, and principles of the field to psychology students. In doing so, they teach students the norms of the field. Therefore, psychology instructors may view both the opportunity and the responsibility to incorporate equity, diversity, and inclusion (EDI) frameworks into courses and curricula. Achieving this goal will require concerted cultivation in all aspects of instruction at the associate and baccalaureate education levels. As such, we took intentional steps to ensure that the indicators of *Guidelines 3.0* align with EDI in light of the importance of empowering students to make a difference in their lives and communities.

We believe instructors help students to understand the prevailing attitudes, beliefs, and values that influence, and sometimes limit, the impact of psychological research. We created *Guidelines 3.0* with a commitment to uncover, identify, and explore implicit assumptions that have influ-

enced the field of psychology since its inception, such as objectivity, universalism, and individualism, among others. Heine and Norenzayan (2006) explained, "Few people would dispute that culture is relevant to psychology. Yet for much of the history of their field, most psychologists have sought to discover and explain human thought and behavior in terms of universal principles" (p. 251). Similarly, psychology developed with a strong preference for individualism, which encompasses ideas of individual freedom and responsibility. This bias often results in looking for and attributing observations to individual sources at the expense of other factors, including those derived in collectivistic and communal values. Although objectivity, universalism, and individualism have a place in the field, their dominance has limited the relevance and importance of psychological knowledge to the diverse U.S. and global populations.

A greater focus on EDI is associated with an abundance of favorable academic and related outcomes. Course elements that involve EDI increase student awareness of privilege and marginalization and inspire social action (Case, 2007; Weinstock, 2019). EDI activities may also help students learn about cultural diversity (Baumgartner & Johnson-Bailey, 2008). These learning opportunities augment skills in multicultural competence and reduce prejudice (Smith & Trimble, 2016). Students also show improvements in ethnocultural empathy, relinquishing claims of colorblind racial attitudes and reporting greater interest in pursuing more multicultural experiences (Patterson et al., 2018).

Incorporating EDI-informed pedagogy in educational experiences is associated with an increased sense of belonging, especially among historically marginalized student communities. Useful strategies include intentionally showing appreciation for the ideas and experiences of historically marginalized students (Good et al., 2012; Howansky et al., 2022), high-quality social learning opportunities (Surr et al., 2018), communicating the relevance of the course content to personal and collective identities (Eccles et al., 2006; Hunn, 2014), and including work by underrepresented psychologists (Good et al., 2012).

Steps Taken to Address Equity, Diversity, and Inclusion in *Guidelines 3.0*

To promote EDI throughout *Guidelines 3.0*, each change or addition included background research, consideration of APA's *Equity, Diversity, and Inclusion Framework* (2021b), consultation with experts, and extensive discussion. We elevated the importance of cultural/contextual factors with indicators that encourage the development of self- and other-awareness, knowledge, and skills. We also highlighted disparate access to opportunities, strategies to overcome discrimination, and systems and community perspectives within the indicators to counteract the historical overemphasis on universalism, individualism, and other values and practices that tend to marginalize. We discussed how an EDI focus may augment interest in policy-level interventions. We further attended to characteristics of institutions and the level at which students learned this information so that at both associate and baccalaureate levels they would enhance their knowledge, skills, and abilities pertaining to EDI.

Understanding by undergraduates of our checkered history in regard to privilege and marginalization is vital to encouraging a commitment to the importance of EDI (APA, 2021b). Psychologists have contributed meaningful scholarship in understanding bias and prejudice. Many seminal works of psychologists have shaped progressive public policies designed to reduce discrimination. However, the history of the discipline also reveals egregious examples of inappropriate and unethical practices related to systemic discriminatory practices (Cummings Center for the History of Psychology, 2021).

Additionally, higher education has practical reasons for pursuing an enlightened stance regarding equitable opportunity and supportive strategies. Implementation of EDI goals could improve retention and graduation rates, which often become a central consideration in funding allocations. Graduates who are more sophisticated with regard to EDI considerations will also be more competitive in the workforce.

Promoting Equity, Diversity, and Inclusion Using *Guidelines 3.0*

These *Guidelines* may serve as a tool to help psychology programs augment EDI in their curricula. Foremost, the *Guidelines* provide direction for what, where, and when students may acquire related EDI knowledge and skills. The *Guidelines* may also help faculty identify gaps in their own curricula where EDI topics may be addressed and fill them accordingly.

The *Guidelines* were set up not only for students to understand EDI but also to promote EDI within the psychology curriculum. Assessment of these indicators may provide evidence regarding the extent to which students are achieving and acquiring the skills they need to be able to function successfully in complex social contexts. If students are not meeting these expectations, faculty can adjust accordingly.

Following *Guidelines 3.0* creates the opportunity to strengthen EDI within both the discipline of psychology and the broader working environment. A fundamental basis for understanding EDI may be offered in introductory psychology courses. As undergraduates progress, they may acquire more skills and knowledge. When they finish courses and enter the workforce or pursue graduate degrees, they become equipped with tools to apply this knowledge and these skills in more novel contexts.

A Call to Action

Incorporating EDI into the psychology curriculum may meet the needs of current students of psychology and responsibly expand the knowledge base of psychological science toward improving lives and communities (Gillborn et al., 2021). We encourage psychology programs to consider EDI areas in the curriculum that need greater attention. For instance, syllabi reviews across undergraduate and graduate pro-

grams revealed that psychology has lagged in addressing EDI in its curriculum (Boysen, 2011; Fuentes & Shannon, 2016). Programmatic discussions about commitment to EDI principles that highlight good examples emerging from syllabi reviews may be a productive way to initiate this important conversation.

A concern often voiced among psychologists is that students may not have a good grasp of the discipline's history, particularly in relation to its role in supporting discriminatory practices that have placed marginalized groups at a disadvantage. Historians have detailed how some psychologists contributed to eugenics (Yakushko, 2019) and systematically discriminated against women and African Americans and other minorities, placing many obstacles in the way of entering a discipline initially dominated by white males (Benjamin, 2019). We recommend that psychology programs help students explore the ways in which psychologists may have worked to maintain the status quo and the negative consequences such action produced for those without privilege. Attention to the many achievements of psychologists is best balanced with attention to lessons learned from mistakes of the past. Even when students do not take a History of Psychology course, the historic problems caused by exclusionary and discriminatory practices may be addressed in a variety of courses in the standard undergraduate curriculum, including Introductory Psychology, Social Psychology, Developmental Psychology, and many others.

As we created *Guidelines 3.0,* we were intentional at every step to promote justice and equity. As our final call to action, we encourage programs, too, to model a process of being intentional and deliberate when creating curricula or adopting strategies. We encourage programs to dig deep; consider word choices; reflect on how courses and experiences will include or exclude others; and examine how traditional practices might have contributed to inequitable opportunities. We also encourage programs to seek feedback from those whose voices may not always be heard, including students; to recognize the importance of research when guiding these decisions; but also to recognize the limitations the research itself may have. In short, we encourage programs not only to use the *Guidelines* as tools to promote EDI but also to use the process to engender a stronger commitment to the principles of social justice.

ARTICULATION WITH RELATED APA DOCUMENTS

Advances in psychology's scholarship of teaching and learning (SoTL) literature, especially documents that have been produced to improve curriculum from APA, have been incorporated in *Guidelines 3.0.* This iteration of *APA Guidelines* attempted to integrate various influences in the recommendations regarding curriculum and assessment.

APA Principles for Quality Undergraduate Education Psychology

Beginning with the St. Mary's Conference in 1991, the APA has supported articulating quality principles (QP) to provide recommendations to guide programs and departments in their educational practices. Conclusions from the conference were published as the first formal principles in 1994 (McGovern & Reich, 1996). The principles were revised in 2011 in conjunction with the 2008 National Conference on Undergraduate Education in Psychology held in Tacoma, WA, and revised again in 2023.

The QPs are designed to describe best practices that faculty members, programs, and departments may adopt to facilitate student learning and development, in ways that fit their specific institutional needs and missions. They are informed by the integration of available research (e.g., scholarship of teaching and learning), diverse educator experience, and APA educational policy (e.g., *APA Guidelines for the Undergraduate Psychology Major*; dismantling systemic racism). The QPs are intended to complement, and to be used in conjunction with, the *APA Guidelines for the Undergraduate Psychology Major 3.0*. Whereas *Guidelines 3.0* describe a set of curricular goals, student learning outcomes, and foundation and baccalaureate indicators of learning progress, the QPs define the actions faculty members, programs, and departments may take, and the ongoing practices they may adopt, to create a high-quality, stimulating, and inclusive learning environment designed to maximize student learning and professional development. The new QPs are displayed in Appendix A.

The APA *Guide to College Teaching*

In 2018 APA's Committee on Associate and Baccalaureate Education (CABE) charged a working group with developing a document that would encapsulate the best research-based concepts related to teaching in higher education. The APA *Guide to College Teaching: Essential Tools and Techniques Based on Psychological Science* (APA, 2020) captures principles related to how students learn, evidence-based practices for motivation, and the importance of context in learning. In addition, the document addresses concepts in classroom management and assessment as they relate specifically to undergraduates. The principles outlined in the document (https://www.apa.org/ed/precollege/undergrad/college-teaching-guide.pdf) support high-quality instruction strategies that may optimize the achievement of outcomes outlined in *Guidelines 3.0*.

The APA Introductory Psychology Initiative

The APA Introductory Psychology Initiative (IPI) addressed outcomes for introductory psychology and mirrors many of the foundation indicators presented here. The APA IPI student learning outcomes (APA, 2021a) may be seen as precursors to many of the current *Guidelines 3.0* goals and indicators, and recommendations from the IPI are similarly content agnostic and aspirational (Gurung & Neufeld, 2022). The focus of this document is addressing content knowledge and applications (a theme we adopted in the new title for Goal 1). We also incorporate the specific themes that an education in psychological science may be designed to foster. We provide the summary of introductory psychology outcomes in Appendix B.

APA's Teaching, Learning, and Assessing in a Developmentally Coherent Curriculum

The Board of Educational Affairs convened a group of educators specifically to create a bridge between the original version of the undergraduate *Guidelines* and the challenge of crafting outcomes that would be helpful in two-year college contexts (APA Board of Educational Affairs Task Force on Strengthening the Teaching and Learning of Undergraduate Psychological Science, 2008). Their work was based on that of Bloom's Taxonomy (Anderson & Krathwohl, 2001) and provides a compendium of useful course-based outcomes. That document may be accessed at this link: https://www.apa.org/ed/governance/bea/curriculum.pdf

The Skillful Psychology Student: Prepared for Success in the 21st Century Workplace

Recognizing the need for psychology students to translate their skills to careers, the Committee on Associate and Baccalaureate Education convened a working group to examine how *Guidelines 2.0* mapped onto skills that employers often seek. Through qualitative analyses, quantitative analyses, and discussion, the working group created the *Skillful Psychology Student* document (Naufel et al., 2018; Van Kirk, 2019). The *Skillful Psychology Student* is comprised of five skill domains (e.g., cognitive, social, technological, personal, and communication) with 17 skills (e.g., analytical thinking for the cognitive domain) within these domains (Naufel et al., 2018). This document connects psychology to the language of employers, and students may use it for resume writing purposes, searching for potential psychology-related jobs, or to see how psychology is represented in a variety of career fields. Finally, the *Skillful Psychology Student* may be used in curricular development and program assessment. The document is available here: https://www.apa.org/education-career/guide/transferable-skills.pdf

APA's *Strengthening the Common Core of the Introductory Psychology Course*

Recommendations by the APA Board of Educational Affairs Working Group on Strengthening the Common Core of the Introductory Psychology Course (2014; Gurung et al., 2016) provide a guide to selecting content, suggesting instructors cover at least two topics from each of five domains or pillars. The Pillar Model evokes an architectural plan similar to an ancient Greek structure. The base of the building represents the need to teach the foundational principles of scientific inquiry. Each pillar of the structure signifies the content of psychology divided into domains (biological, cognitive, development, social and personality, and mental and physical health).

The Pillar Model takes significant pressure off instructors who may now be supported in covering 10 topics in a course, in addition to research methods. While instructors may also cover material from other chapters that fits their own department or university needs, the focus is educating students on the integrative themes of psychology and ensuring that they receive at least a basic exposure to the breadth of psychology through the field's five major domains. Although some instructors may decide to include more topics, the APA Introductory Psychology Initiative work clearly notes the value of achieving outcomes by making strategic choices about content coverage that does not require exposing students to all the available material. Here is the link to the "pillar document": https://www.apa.org/ed/precollege/psychology-teacher-network/introductory-psychology/selecting-content

APA's Assessment CyberGuide

The original *Guidelines* spurred the development of the *Assessment CyberGuide*, which was published shortly after the *Guidelines* appeared but revised in 2009 (Pusateri et al.). The *CyberGuide* offers a comprehensive discussion on making assessment decisions at the course and program level and is still regularly accessed by those dealing with contemporary assessment problems. The *CyberGuide* is available at https://www.apa.org/ed/governance/bea/assessment-cyberguide-v2.pdf

APA's Project Assessment

More recently, APA's Project Assessment established a website (pass.apa.org) to assist in implementing assessment strategies linked to *Guidelines 2.0.* The website was developed from two conferences, the Summit on National Assessment of Psychology (2016) and the Summit on High School Psychology Education (2017). Although the website was established to provide exemplars of assessment practice to illustrate outcomes in *Guidelines 2.0,* its content remains relevant to *Guidelines 3.0.* The site is organized not just by relevant outcomes but also by type of assessment and whether the exemplar reports data in support of claims (i.e., "evidence based" or merely "evidence informed"). Registration is required, but access to and use of the database is free.

The APA Assessment Guide for Psychology Teachers

The Assessment Subcommittee from the 2017 High School Psychology Summit generated a primer that provides a strong orientation to assessment practices along with exemplars. The document may be accessed at https://www.apa.org/ed/precollege/topss/assessment-guide.pdf

APA's *Equity, Diversity, and Inclusion (EDI) Framework*

The APA *Equity, Diversity, and Inclusion Framework* (2021b) presents a model for progressive action within APA, the field of psychology, and society. The model is based on an integration of decades of psychological research. It recommends various actions, including acknowledging oppression, operating from a systems perspective, including marginalized voices, and striving for continued equity, diversity, and inclusion growth in all areas of psychology, among others. The document may be accessed at https://www.apa.org/about/apa/equity-diversity-inclusion/framework.pdf

APA Ethical Principles of Psychologists and Code of Conduct

The APA has provided support to its members in navigating professional ethical standards since the publication of its first code in 1953. The code, intended to provide guidance on professional ethics for psychological professionals including educators, is regularly revisited, reviewed, and updated. The current code became effective in 2002 with minor amendments in 2010 and 2017. *Guidelines 3.0* support the importance of ethical oversight, specifically reflected in Goals 2 (Scientific Inquiry and Critical Thinking) and 3 (Values in Psychological Science). The most current version of the code may be found here: https://www.apa.org/ethics/code

ASSESSMENT RESOURCES

This non-exhaustive list of references strives to capture scholarship in accountability practices that will assist programs in curriculum design and assessment. The list includes both classic sources and more contemporary works in contexts across the undergraduate curriculum.

General Assessment Books

Finney, S. J., Wells, J. B., & Henning, G. W. (2021, March). *The need for program theory and implementation fidelity in assessment practice and standards* (Occasional Paper No. 52). University of Illinois and Indiana University, National Institute for Learning Outcomes Assessment. https://www.learningoutcomesassessment.org/wp-content/uploads/2021/03/Occ_Paper_51-1.pdf

Fulcher, K. H., Good, M. R., Coleman, C. M., & Smith, K. L. (2014, December). *A simple model for learning improvement: Weigh pig, feed pig, weigh pig* (Occasional Paper No. 23). University of Illinois and Indiana University, National Institute for Learning Outcomes Assessment. https://in.ewu.edu/facultycommons/wp-content/uploads/sites/129/2016/12/A-Simple-Model-for-Learning-Improvement_Weigh-Pig-Feed-Pig-Re-Weigh-Pig.pdf

Fulcher, K. H., & Prendergast, C. O. (2021). *Improving student learning at scale: A how-to guide for higher education.* Stylus.

Maki, P. (2004). *Assessing for learning: Building a sustainable commitment across the institution.* Stylus.

Suskie, L. (2018). *Assessing student learning: A common sense guide* (3rd ed). Wiley & Sons.

Walvoord, B. E. F. (2010). *Assessment clear and simple: A practical guide for institutions, departments, and general education* (2nd ed.). Wiley & Sons.

Equity in Assessment

Montenegro, E., & Jankowski, N. A. (2020, January). *A new decade for assessment: Embedding equity into assessment praxis* (Occasional Paper No. 42). University of Illinois and Indiana University, National Institute for Learning Outcomes Assessment. https://www.learningoutcomesassessment.org/wp-content/uploads/2020/01/A-New-Decade-for-Assessment.pdf

National Institute for Learning Outcomes. *Equity in Assessment.* https://www.learningoutcomesassessment.org/equity

Assessment Books Focused on Psychology Education

Dunn, D. S., Baker, S. C., Mehrotra, C. M., Landrum, R. E., & McCarthy, M. A. (Eds.). (2012). *Assessing teaching and learning in psychology: Current and future perspectives.* Cengage.

Dunn, D. S., Mehrotra, C., & Halonen, J. S. (Eds.). (2004). *Measuring up: Educational assessment challenges and practices for psychology*. American Psychological Association.

Halpern, D. F. (Ed.). (2010). *Undergraduate education in psychology: A blueprint for the future of the discipline.* American Psychological Association.

Nolan, S. A., Hakala, C. M., & Landrum, R. E. (Eds.). (2021). *Assessing undergraduate learning in psychology: Strategies for measuring and improving student performance.* American Psychological Association.

Assessment for Beginners

Dunn, D. S., Feldman, A. J., Franks, S. A., González, S. C., Gurung, R. A. R., Halonen, J. S., Julian, M., McEntarffer, R., & Vita, M. C. (2018). *Assessment guide for psychology teachers.* American Psychological Association. https://www.apa.org/ed/precollege/topss/assessment-guide.pdf

Pusateri, T., Halonen, J. S., Hill, W., & McCarthy, M. A. (2009). *The assessment cyberguide for learning goals and outcomes.* American Psychological Association https://www.apa.org/ed/governance/bea/assessment-cyberguide-v2.pdf

Stanny, C. J. (2015). Assessing the psychology curriculum: A primer for faculty and administrators. In D. S. Dunn (Ed.), *The Oxford handbook of undergraduate psychology education* (pp. 813–831). Oxford University Press.

Assessment Philosophy

Halonen, J. S., Beers, M. J., & Brown, A. N. (2020). Assessment at the crossroads: How did we get here and what should we do? *Scholarship of Teaching and Learning in Psychology*, *6*(3), 254–268. https://doi.org/10.1037/stl0000243

Halpern, D. F. (2013). A is for assessment: The other scarlet letter. *Teaching of Psychology, 40*(4), 358–362. https://doi.org/10.1177/0098628313501050

Promoting an Assessment Culture

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Stanny, C. J., & Halonen, J. S. (2011). Accreditation, accountability, and assessment: Addressing multiple agendas. In L. Stefani (Ed.)., *Evaluating the effectiveness of academic development practice: Principles and practice* (pp. 169–182). Routledge.

Assessment in Associates and Baccalaureate Degree Programs

Amsel, E., McGregor, L. N., Alexander, D., Leppien-Christensen, K., Gerber, B., Wilson-Doenges, G., & Hailstorks, R. (2020). Context matters: Outcome assessments for associate's degree psychology programs. *Teaching of Psychology, 47*(4), 316–326. https://doi.org/10.1177/0098628320945128

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Academic Program Reviews

Chew, S. L., Halonen, J. S., McCarthy, M. A., Gurung, R. A. R., Beers, M. J., McEntarffer, R., & Landrum, R. E. (2018). Practice what we teach: Improving teaching and learning in psychology. *Teaching of Psychology, 45*(3), 239–245. https://doi.org/10.1177/0098628318779264

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Halonen, J. S., & Dunn, D. S. (2021). The sound and fury of academic program reviews: What they reveal about assessment and accountability. In S. A. Nolan, C. M. Hakala, & R. E. Landrum (Eds.), *Assessing undergraduate learning in psychology: Strategies for measuring and improving student performance* (pp. 41–56). American Psychological Association. https://doi.org/10.1037/0000183-004

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Assessing Communication Skills

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APPENDIX A

APA Principles for Quality Undergraduate Education in Psychology

Below is a summary of the principles and recommendations for quality undergraduate education in psychology. For the full document please visit this link: https://www.apa.org/about/policy/principles-quality-undergraduate-education-psychology.pdf

Quality Principle and Recommendations for Faculty Members

Quality Principle 1

Faculty members strive to be ethical (APA, 2017a), culturally responsive scientist–educators who use their educational background, ongoing professional development, pedagogical expertise, and lived experience to teach, mentor, and support students with diverse and intersecting identities.

RECOMMENDATIONS

1. Faculty members recognize that they must have the current and relevant expertise needed to teach in their content area.
2. Faculty members understand and apply evidence-based learning principles and help students develop an understanding of the science of learning that students can apply to their own lives.
3. Faculty members seek to create accessible, inclusive, and flexible curriculum that aims to address the expected variability among learners and contexts.
4. Faculty members engage in continuous assessment of the success of their instruction and use that information to refine instructional practices to enhance student success.
5. Faculty members recognize the long history of discriminatory policies and practices embedded in higher education, engage in sustained efforts to dismantle these oppressive systems, and actively promote fairness, equity, diversity, and inclusion in their teaching practices.
6. Faculty members provide support and guidance to students.

Quality Principle and Recommendations for Psychology Programs and Departments

Quality Principle 2

Psychology departments and programs design their curriculum, offer cocurricular activities, and create learning environments that will adequately prepare students to achieve the knowledge and skills expected of undergraduates engaged in the study of psychology.

RECOMMENDATIONS

1. Psychology departments and programs provide a coherent globally informed curriculum with learning goals and outcomes informed by APA's policy documents on undergraduate education.
2. Courses are sequenced in ways that allow upper-division courses to build on concepts that are introduced in lower-division courses.
3. Psychology departments and programs recognize that their faculty must be sufficient in size and expertise to teach the depth and breadth of courses needed for students to achieve expected learning goals and outcomes.
4. Psychology departments and programs develop policies and procedures that support quality teaching.
5. Psychology departments and programs provide experiential learning opportunities and support student involvement in cocurricular activities.
6. Psychology departments and programs promote equity, diversity, and inclusion and engage in efforts to dismantle systemic oppression and reduce educational inequities.
7. Psychology departments and programs provide the advising and mentorship psychology majors need to pursue academic and career goals.
8. Psychology departments and programs engage in a periodic practice of program review aimed at ensuring that students are achieving expected learning outcomes.
9. Psychology departments and programs foster positive relationships with other institutions to support educational and career pathways for students

APPENDIX B

APA Introductory Psychology Initiative (IPI) Student Learning Outcomes for Introductory Psychology

Below is a summary of the student learning outcomes. For the full document please visit this link: https://www.apa.org/about/policy/introductory-psychology-initiative-student-outcomes.pdf

In 2021 the APA approved the student learning outcomes proposed by the Introductory Psychology Initiative (IPI) as part of its effort to transform the introductory course to meet the needs of contemporary education. These student learning outcomes (SLOs) are intended for multiple venues, formats, and contexts and are intentionally broad to apply to an introductory-level survey course. The SLOs address basic psychological concepts, methods, and themes. The SLOs do not emphasize course content; instead, they focus on the application of practical skills that will help students navigate their lives. The SLOs promote themes that are the enduring lessons students can take away from the introductory psychology course. For example, the discipline of psychology continuously examines its own history of successes and abuses, actively committing to the ethical practices that build a responsible future for the profession and contribute to building a just and equitable society.

In an introductory psychology course, students are expected to:

PSYCHOLOGY CONTENT

Identify basic concepts and research findings

1.1 Define and explain basic psychological concepts.

1.2 Interpret research findings related to psychological concepts.

1.3 Apply psychological principles to personal growth and other aspects of everyday life.

SCIENTIFIC THINKING

Solve problems using psychological methods

2.1 Describe the advantages and limitations of research strategies.

2.2 Evaluate, design, or conduct psychological research.

2.3 Draw logical and objective conclusions about behavior and mental processes from empirical evidence.

2.4 Examine how psychological science can be used to counter unsubstantiated statements, opinions, or beliefs.

KEY THEMES

Provide examples of psychology's integrative themes

A. Psychological science relies on empirical evidence and adapts as new data develop.

B. Psychology explains general principles that govern behavior while recognizing individual differences.

C. Psychological, biological, social, and cultural factors influence behavior and mental processes.

D. Psychology values diversity, promotes equity, and fosters inclusion in pursuit of a more just society.

E. Our perceptions and biases filter our experiences of the world through an imperfect personal lens.

F. Applying psychological principles can change our lives, organizations, and communities in positive ways.

G. Ethical principles guide psychology research and practice.

APPENDIX C

The Skillful Psychology Student: Prepared for Success in the 21st Century Workplace

Below is a summary of the principles and recommendations for developing the skillful psychology student. For the full document please visit this link: https://www.apa.org/education-career/guide/transferable-skills.pdf

Psychology provides skills that employers value.

COGNITIVE

Analytical thinking: Solve complex problems, attend to details, plan proactively, and display comfort with ambiguity.
Critical thinking: Display proficiency with statistics, program evaluation, and research design necessary for the study of social and technical systems.
Creativity: Use innovative and resourceful approaches to problem-solving and new tasks.
Information management: Be adept at locating, organizing, evaluating, and distributing information from multiple sources.
Judgment and decision-making: Engage in logical and systematic thinking and ethical decision-making when considering the possible outcomes of a particular action.

COMMUNICATION

Oral communication: Demonstrate strong active listening and conversational abilities in both informal and professional environments, as well as aptitude for public speaking and communicating scientific information to diverse audiences.
Written communication: Comprehend relevant reading materials to produce professional documents that are grammatically correct, such as technical or training materials and business correspondence.

PERSONAL

Adaptability: Adjust successfully to change by responding in a flexible, proactive, and civil manner when changes occur.
Integrity: Perform work in an honest, reliable, and accountable manner that reflects the ethical values and standards of an organization.
Self-regulation: Manage time and stress by completing assigned tasks with little or no supervision; display initiative and persistence by accepting and completing additional duties in a careful, thorough, and dependable manner.

SOCIAL

Collaboration: Work effectively in a team by cooperating, sharing responsibilities, and listening and responding appropriately to the ideas of others.
Inclusivity: Demonstrate sensitivity to cultural and individual differences and similarities by working effectively with diverse people, respecting and considering divergent opinions, and showing respect for others.
Leadership: Establish a vision for individuals and for the group, creating long-term plans and guiding and inspiring others to accomplish tasks in a successful manner.
Management: Manage individuals and/or teams, coordinate projects, and prioritize individual and team tasks.
Service orientation: Seek ways to help people by displaying empathy; maintaining a customer, patient, or client focus; and engaging in the community.

TECHNOLOGICAL

Flexibility/adaptability to new systems: Be willing and able to learn and/or adapt to new computer platforms, operating systems, and software programs.
Familiarity with hardware and software: Demonstrate competency in using various operating systems, programs, and/or coding protocols; troubleshoot technical errors; and use software applications to build and maintain websites, create web-based applications, and perform statistical analyses.

AMERICAN
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Stanford Law School
Three Strikes Project

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When did prisons become acceptable mental healthcare facilities?

Co-Published by:

California State Senate pro Tem, Darrell Steinberg
Stanford Law School Professor, David Mills
Stanford Law School Three Strikes Project Director, Michael Romano

Introduction

Senator Darrell Steinberg and Professor David Mills

We can no longer ignore the massive oppression we are inflicting upon the mentally ill throughout the United States. Over a century ago, Dorothea Dix began a movement to improve the deplorable conditions of mentally ill prisoners. Despite her success in changing the country's perception and treatment of the mentally ill in prison, we are now right back where we started in the nineteenth century. Although deinstitutionalization was originally understood as a humane way to offer more suitable services to the mentally ill in community-based settings, some politicians seized upon it as a way to save money by shutting down institutions without providing any meaningful treatment alternatives. This callousness has created a one-way road to prison for massive numbers of impaired individuals and the inhumane warehousing of thousands of mentally ill people.

We have created conditions that make criminal behavior all but inevitable for many of our brothers and sisters who are mentally ill. Instead of treating them, we are imprisoning them. And then, when they have completed their sentences, we release them with minimal or no support system in place, just counting the days until they are behind bars once again. This practice of seeking to save money on the backs of this population comes with huge moral and fiscal cost. It is ineffective because we spend far more on imprisonment of the mentally ill than we would otherwise spend on treatment and support. It is immoral because writing off another human being's life is utterly contrary to our collective values and principles.

Cages for mental health group therapy treatment, Mule Creek State Prison, February 7, 2013.

The numbers are staggering: over the past 15 years, the number of mentally ill people in prison in California has almost doubled.[1] Today, 45 percent of state prison inmates have been treated for severe mental illness within the past year. The Los Angeles County Jail is "the largest mental health provider in the county," according to the former official in charge of the facility.[2]

In San Francisco County Mental Health Court, prosecutors, defense attorneys, and judges work collaboratively to design treatment plans for mentally ill defendants. Photo courtesy of Loteria Films.

California was at the forefront of the spiral towards imprisonment rather than treatment, when it turned its back on community based mental health programs. As usual, what started in California spread throughout the country. In 1971 there were 20,000 people in California prisons; by 2010 the population had increased to 162,000 people, of which 45 percent are estimated to be mentally ill. We in California now have an opportunity to lead again—this time to show that there is a better approach. We can begin a counter-revolution by setting a new standard for how we deal with people whose mental illness manifests through criminal activity. We will prove to the country that there is another, better approach—an approach that saves money and saves lives from being forsaken.

Mentally ill offenders receive longer sentences than non-mentally ill offenders across all felonies.

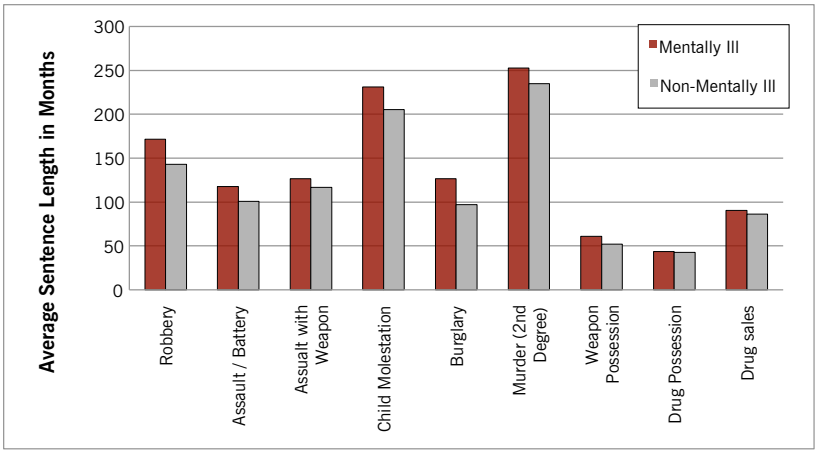

The population of mentally ill inmates in CA prisons has almost doubled since 2000.

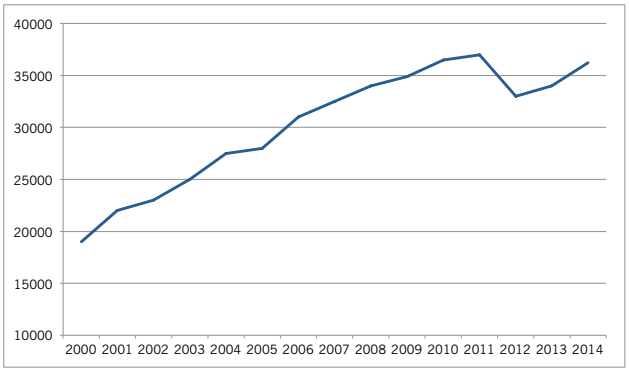

The mentally ill who fill our prisons range from the violent to the nonviolent, and from those who were born with disabilities to those who have been damaged by circumstances and environment. According to a recent report from the National Sheriff's Association and Treatment Advocacy Center, ten times as many mentally ill people are in prison and jail in America today than are in mental health treatment facilities.[3]

The problem is not only that many mentally ill people—left with no support and limited resources—tend to commit crimes (including those associated with homelessness and addiction). The problem is also that once they are in the system, they tend to be subjected to far harsher sentencing than others for the very same crimes. This may be born of a conscious sense that judges have that society is providing no meaningful "treatment" other than imprisonment. Or it may grow out of a subconscious animus or fear of those who are different in any way. Whatever the source, though, the effect is the same: despite rules of court in California designed to mitigate punishments for mentally ill offenders, the average sentence imposed on defendants suffering from mental illness is longer than the average sentence imposed on defendants who do not have mental health diagnosis but who committed the same crime. Unfortunately this is true across every category of crime in California. For example, the average sentence for burglary imposed on mentally ill defendants is 30 percent longer than the average sentence for non-mentally ill defendants convicted of the same crime.

The story grows darker still. When it comes time to be considered for release, once again the mentally ill fare miserably. For example, the number of mentally ill prisoners denied relief under new resentencing laws enacted under Proposition 36 is three times greater than the number of non-mentally-ill prisoners who have been denied relief.

And once those suffering from mental illness are released—having served longer sentences—the system delivers the ultimate knockout blow. We provide virtually no effective mental health facilities and programs to help released prisoners who are in desperate need of mental health treatment. This service deficit naturally results in higher recidivism rates and an ongoing sense of social isolation and abandonment. And the cycle then begins again with new arrests, new prosecutions, new lengthy sentences, new impediments to release, and eventual release into a system that provides nothing but an inevitable, tragic trajectory back into the criminal justice system. This cycle is as truly appalling as it is truly avoidable.

The cascade, which began so long ago, has created a new segregation—the segregation of the sick, the infirm and the helpless (many of whom are also people of color, almost all of whom are extremely poor). Not unlike other practices of segregation in our nation's history, this segregation is also hidden from the general public behind the walls of our prisons and jails. But this time it is not occurring in the form of slavery on individual farms and homes–today it is occuring behind the bars of prison cells.

Mentally ill inmates represent 45% of the total California prison population.

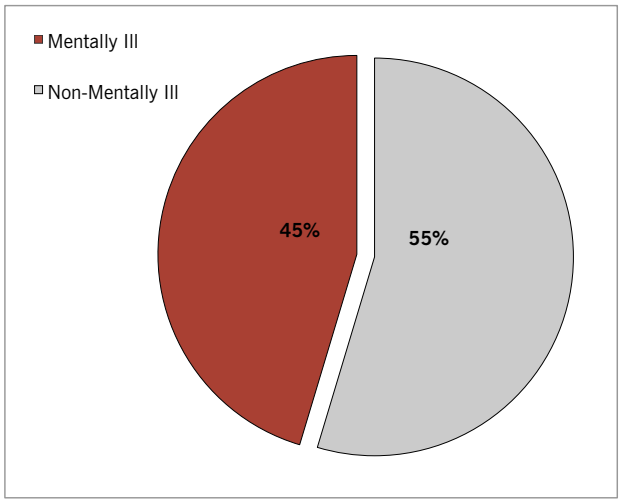

From time to time there have been efforts to expose this disaster but, until now, bold proposals for solutions have been lacking. We have seen periodic criticism, but no serious desire or determination for change. We, in California, can and will do better. Today, we jointly offer three modest but significant proposals to start us on the path of compassionate, fair and cost-effective solutions to the crisis we face:

1. **Reform the Way We Sentence the Mentally Ill:** We propose that all new sentences take into account the mental health of each defendant and, where appropriate, provide a non-prison sentence for any defendant charged with a nonviolent crime/ nonserious offense. This new sentencing would apply when the sentencing judge finds that the defense has shown by a preponderance of the evidence that the crime was likely committed as a result of the defendant's mental illness. Under such a circumstance, the defendant will be sentenced to mental health treatment and monitoring in a non-custodial setting. We propose to provide funding for mental health treatment for these defendants throughout the State. The cost of such treatment is significantly less than the cost of incarceration.

2. **Provide Meaningful Treatment in Prison**: We propose that when a sentencing judge finds (a) that a defendant's serious offense was caused in large part by his mental illness, or (b) that a defendant who committed a nonserious offense needs to be incarcerated due to the danger to himself or others, the judge will order the provision of meaningful mental health services as part of the terms and conditions of incarceration. These mental health services, although overseen and provided by the Bureau of Prisons, will nevertheless be reviewed from time to time by a special Mental Health Prison Oversight Court, which will be set up to assure that proper mental health services are being provided to each incarcerated defendant. This special court will be made up of judges and mental health professionals who will work together to

fashion and oversee the treatment of incarcerated prisoners in need of mental health services. This new Mental Health Prison Oversight Court will provide initial sentencing recommendations to trial court judges who request the court's input. Following a defendant's sentencing, the new court will have authority to oversee the mental health treatment of the incarcerated defendant, and will be empowered to order changes to the treatment plan that the court deems appropriate. This is a bold new proposal to integrate the independence of the prison system with the oversight of a special court as part of the judiciary. We recognize the problems and challenges of implementation, but we are confident that the goodwill and creative cooperation of all concerned will allow for the implementation of this change.

3. **Continue Meaningful Treatment After Prison**: Finally, we propose that all prisoners, prior to release, be evaluated for post-release mental health needs and, where appropriate, be referred to mental health centers for the ongoing provision of mental health care. These new mental health centers will be located throughout the state and will have access to the mental health records of the released prisoners, recommendations for appropriate post-release mental health care, and the funding needed to provide the recommended services for at least one year following release. As indicated above, providing these services will more than pay for itself in terms of costs saved by avoiding the extraordinary (financial and human) costs of incarceration.

We are proud that a new era marking the end of "sentencing for vengeance" and transforming the goal of being "tough on crime" with the goal of being "smart on crime" has begun to take hold. We are proud that the voters and policymakers are growing in their willingness to separate true criminals from those whose actions are not driven by aggression, violence or ill-intent. We are hopeful that the concept of vengeance is no longer being treated as the sole or primary focus of criminal sentencing, but is instead being treated as only one of several factors (including individual culpability and rehabilitation) that inform a just sentence. But amidst these positive changes, we must not ignore one of the great persistent injustices of modern criminal law: not only are poor people and people of color disproportionately imprisoned, but a dominant root cause of much criminal activity is mental illness. While the solution to that challenge of poverty or insidious discrimination is not easily in our grasp, we do have the readily available and affordable tools to help address the role that mental illness plays in criminality. Our report and modest proposals are an important first step towards that goal.

A note on methodology:
Unless otherwise specified in this report, all of the data reported herein was provided by the California Department of Corrections and Rehabilitation ("CDCR") and analyzed at Stanford Law School. The data reflects the California prison population as of March 5, 2014.

This report defines "mentally ill prisoner" as an inmate suffering from a serious mental illness, as diagnosed by the prison Mental Health Delivery System, within the past year. This definition best corresponds to the definition used by the United States Department of Justice in its national survey of mental health in prisons and jails referenced throughout this report.

A Brief History Of Deinstitutionalization In California

In the early 1950's California was the vanguard of a significant transformation of the nation's mental health system. This transformation resulted in a shift from a state-operated public mental health system to a decentralized system of care, accompanied by major changes in the funding relationship between state and local governments with regard to mental health services delivery. This transfer from state to local control, known as "deinstitutionalization," was accompanied by a sharp increase in California's state prison population—most notably, the population of mentally ill inmates.

Prior to 1957, mental health services were delivered by a state operated and funded institutional system, which included fourteen hospitals. Eight of these hospitals served the mentally ill, four cared for the developmentally disabled, and two served both populations.

In 1957, the California legislature passed the Short-Doyle Act in response to the growing number of the mentally ill being confined in public hospitals. The Act, which provided state funds to local mental health service delivery programs, was developed to address concerns that some mentally ill individuals were better served by local, outpatient services rather than 24-hour hospital care. Lawmakers believed that local programs would allow the mentally ill to remain in their communities, maintain family ties, and enjoy greater autonomy. When first enacted, the Short-Doyle Act provided state funding for 50 percent of the cost to establish and develop locally administered and controlled community mental health programs.

In 1968, the legislature passed the Lanterman-Petris-Short Act, which further reduced the population of state mental health hospitals by requiring a judicial hearing prior to any involuntary hospitalization. The Act also initiated increased financial incentives for local communities to take on the provision of mental health services.

As a result of this long-term transfer of state operation and oversight to a decentralized, community-based mental health care delivery model, the state mental hospital population declined from 36,319 in 1956 to

The incarceration rate in California skyrocketed when funding was pulled from its state mental hospitals.

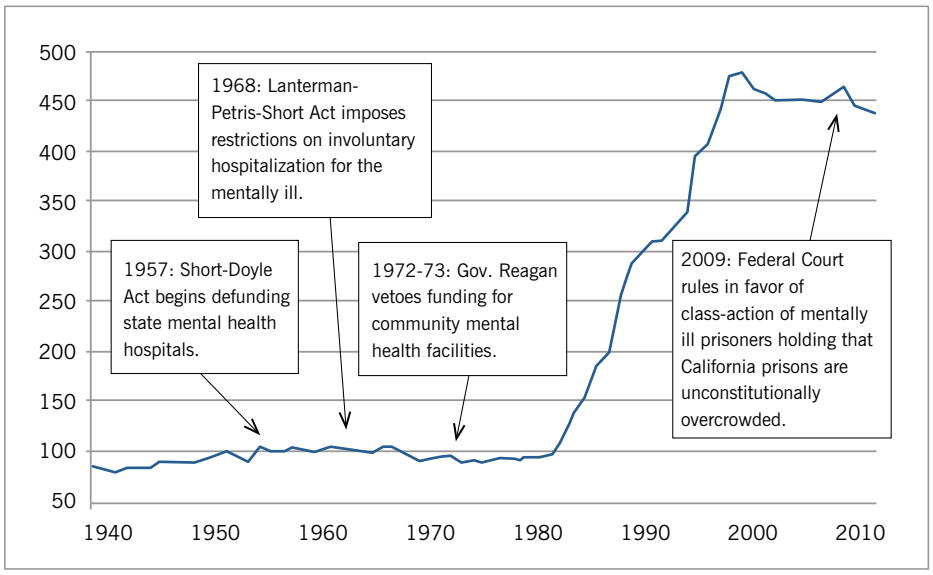

Between 1967 and 1975, Governor Ronald Reagan slashed funding to mental hospitals leading to a dramatic decline in the number of mentally ill individuals being treated in the hospital setting.

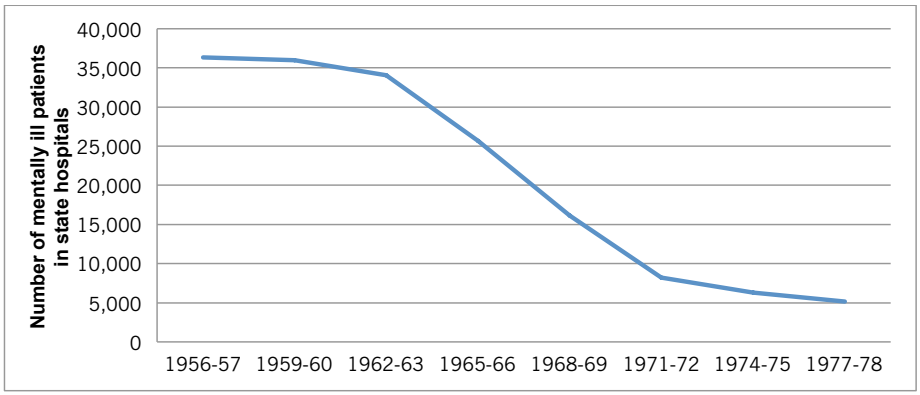

Source: Legislative Analyst's Office, "Major Milestones: 43 Years of Care and Treatment of the Mentally Ill," (2000).

8,198 in 1971.[4] Three public mental hospitals closed during this time period. The legislature intended for the savings from these closures to be distributed to community programs. However, in 1972 and 1973 then-Governor Ronald Reagan vetoed the transfer of these funds. Between 1974 and 1984, the funding of community mental health programs was in constant flux, with many counties lamenting local mental health service gaps due to lack of sufficient funding.

The shift from state to local services was unexpectedly accompanied by a sharp increase in the population of the mentally ill within California's criminal justice system. In 1973, hearings were held by the California State Senate to discuss this concern. In 1980, a study published in the *American Journal of Orthopsychiatry* concluded that emptying the public mental health hospitals had "forced a large number of these deinstitutionalized patients into the criminal justice system."[5] Two other studies published in 1982 and 1983 by researchers at the University of Southern California indicated that the problem was only getting worse.[6]

Today, according to a recent survey of public mental health services issued jointly by the National Sheriffs' Association and Treatment Advocacy Center, "[in California] there are almost no public psychiatric beds available for individuals with serious mental illnesses."[7]

EXPERT ANALYSIS: The Tragic Case Of Mentally Ill Prisoners In California

Craig Haney

Treatment of the mentally ill in the United States is in a state of crisis. The mentally ill in this country are far more likely to be treated in jail or prison than in any healthcare facility. Presently, the United States incarcerates an estimated 350,000 prisoners who suffer from serious mental illness, almost 10 times the number of persons housed in the nation's psychiatric hospitals. In California alone, there are over 30,000 seriously mentally ill prisoners presently confined in state prison, as compared to fewer than 6,000 persons in state psychiatric hospitals, making CDCR the de facto mental health treatment provider in the state. Although litigation-related reforms have resulted in a significant overhaul of prison mental health services provided by the CDCR, mental health care in prison still falls well below minimal constitutional standards in many important respects.

Craig Haney, Distinguished Professor of Psychology, University of California, Santa Cruz. Photo courtesy of Loteria Films.

Prisons and jails are singularly ill-suited to house the mentally ill. Premised on punitive forms of social control, prisons are not remotely compatible with the kind of supportive therapeutic milieus that the mentally ill require. They are austere and intimidating environments that are painful and difficult for even the strongest and most resilient prisoners to withstand. The pains of imprisonment—severe material deprivations, highly restricted movement and liberty, lack of meaningful activity, a nearly total absence of personal privacy, high levels of interpersonal uncertainty, danger, and fear—are powerful psychological stressors that can adversely impact a prisoner's well-being.

Not surprisingly, these stressful conditions take a greater psychological toll on mentally ill prisoners. They are especially sensitive to the unique stresses and

Mentally ill individuals are much more likely to experience factors that contribute to an increased risk of committing crimes.

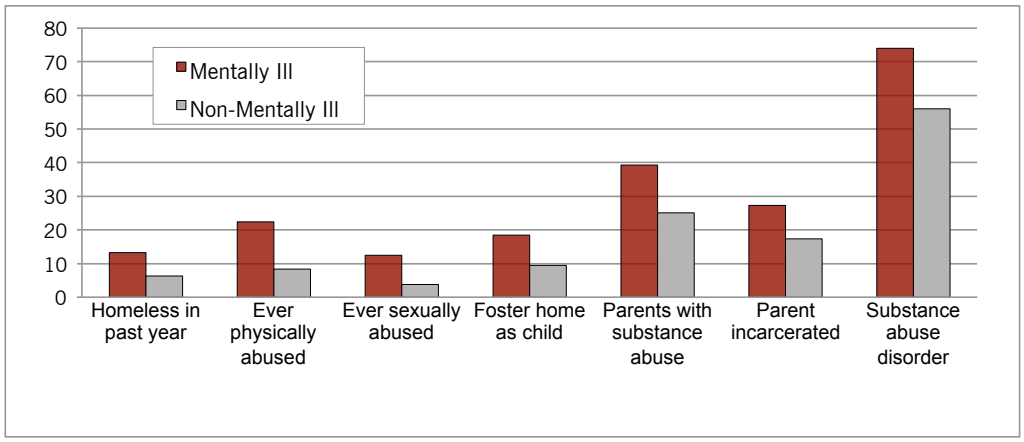

Source: United States Dept. of Justice, Bureau of Justice Statistics, "Mental Health Problems of Prison and Jail Inmates," (2006).

traumas of prison life, and their psychiatric conditions often deteriorate as a result. Their vulnerabilities place them at great risk to be victimized—for example, they are much more likely to be sexually assaulted than other prisoners. Some prisoners react to the extreme psychic stresses of imprisonment by taking their own lives. Tragically, rates of suicide inside prisons and jails are much higher among the mentally ill.

Behavioral problems that are associated with their psychiatric conditions also place the mentally ill at greater risk of committing rule violations, which typically result in the imposition of harsh disciplinary sanctions. Thus, largely because of their psychiatric illness, mentally ill prisoners are significantly more likely than other prisoners to be housed in punitive segregation units where they are subjected to solitary confinement and other severe deprivations. Extensive research has documented the range of adverse symptoms that have been consistently observed in prisoners in solitary confinement, including appetite and sleep disturbances, anxiety, panic, hopelessness, depression, rage, loss of control, paranoia, hallucinations, self-mutilations, and suicidal ideation. For those with a preexisting mental illness, psychiatric symptoms often worsen. Most punitive isolation units are operated in such a way that it is virtually impossible for mentally ill prisoners to receive adequate, effective treatment there.

Double cell with two inmate-patients, California Institute for Men, (2013). Photo courtesy of Loteria Films.

The CDCR has four levels of mental health treatment designation, ranging from long-term to emergency treatment.

Level of care	Description
Correctional Clinical Case Management System (CCCMS)	• Lowest level of mental health care • Treatment for "serious mental illness," according to certain DSM Axis I diagnoses (e.g. schizophrenia, psychotic disorder, bipolar disorder, major depressive disorder) • Prisoners stable with treatment • Treatment includes medication, individual and group therapy
Enhanced Outpatient Program (EOP)	• Segregated housing • Treatment for acute onset or significant decompensation with symptoms including delusional thinking, hallucinations, vegetative affect • Global Assessment Score less than 50 • Treatment includes medication, individual and group therapy, at least 10 hours per week of structured therapeutic activities
Mental Health Crisis Bed	• Inpatient psychiatric care, with 10-day maximum stay • Continuous therapeutic assistance to inmate-patients whose condition requires 24 hours or more to achieve stabilization • Danger to self or others • Global Assessment Score less than 30 • Treatment to control and alleviate symptoms with emergency medication if necessary
Inpatient at Dept. Mental Health Intermediate and Acute Care	• Acute exacerbation of a chronic major mental illness, marked impairment, and dysfunction in most areas (i.e. daily living activities, communication and social interaction) • Highly structured in-patient psychiatric care with 24-hour nursing supervision • Danger to self or others • May require neurological/neuropsychological consultation • Anticipated discharge within 30-45 days

At the other end of the spectrum—and particularly relevant in California—studies have shown that overcrowding greatly amplifies the stressfulness of prison life. Crowded conditions heighten the level of stress that persons experience by introducing social complexity, turnover, and interpersonal instability into an already dangerous prison world. Prison and jail settings are fraught with special dangers for vulnerable persons who cannot master the complex, and frequently violent, social dynamics of prison life.

Like most people incarcerated in prisons and jails throughout this

country, most mentally ill inmates will eventually be released back to the community. Because the state fails to provide many mentally ill prisoners with adequate mental health treatment, and subjects many of them to harsh forms of isolation, where their psychological conditions may have worsened, they confront special challenges when they are released back into free society. As a result, they are at greater risk to recidivate and return to prison. Yet, according to a recent study in *The Lancet*, the mentally ill are substantially less likely to commit a violent crime if taking appropriate psychiatric medication.[8]

These are very serious, complex, and long-standing problems that will require the implementation of a wide range of significant reforms in order to be solved. Although the vulnerabilities of mentally ill prisoners are manifested most clearly in prison, meaningful solutions must also come from beyond the prison walls. To be sure, it is critically important for the CDCR to continue to improve the quality of its mental health services to comply with constitutional mandates, and to end the practice of placing mentally ill prisoners in punitive isolation. But other critical criminal justice reforms are also necessary. These kinds of reforms require the development of a wide range of new programs: before, and in lieu of imprisonment; during imprisonment, for those mentally ill prisoners who cannot be diverted; and after imprisonment, as prisoners reintegrate into the community. They also require the training of key criminal justice personnel—attorneys, judges, correctional officers, and probation and parole officers—on the unique psychiatric needs of their clients. And they require the kind of sustained public and political attention, pressure, and resources necessary to bring them about.

The Promise Of Mental Health Courts In California

Mental health courts are a relatively recent phenomenon and one of many initiatives launched in the past two decades to address the large numbers of people with mental illness involved in the criminal justice system. There are currently approximately 40 mental health courts in 27 counties in California.[9] These courts should be expanded throughout the state to cover every defendant charged with a nonviolent offense as a result of mental illness.

A mental health court hearing in San Francisco Superior Court. Photo courtesy of Loteria Films.

A cost benefit analysis reported by Pew Charitable Trust and the MacArthur Foundation found that every $1 spent on one state's mental health court system resulted in $7 in incarceration savings.[10] In California, the annual prison cost for an inmate in the general population is $51,000, while the annual community housing and outpatient treatment costs for persons with mental illness is $20,412.[11]

In 2006, Santa Clara County estimated that its mental health court saved the state and county $20 million through reduced prison and jail sentences.[12] Sacramento County courts experienced an 88 percent decrease in the cost of serving mentally ill clients through its mental health court, as compared to serving those same clients in the traditional court system. Similar savings were realized in the mental health court operated in San Francisco County.[13] Recognition of these positive fiscal outcomes has led to the expansion of mental health courts in New York, Michigan, Washington and South Carolina.

In California, mental health courts are administered by county Superior Courts, which provide a separate docket for persons charged with nonviolent crimes who have been diagnosed with a mental illness. These courts involve collaboration between criminal justice and mental health professionals, and generally offer judicial supervision of required mental health treatment and other services in lieu of jail time.[14]

The social and public health benefits of mental health courts are also clear. The focus on early intervention allows offenders access to treatment prior to appearing before a mental health court. These offenders are more likely to stay in treatment than those whose cases are handled by a traditional court. Mental health court participants also demonstrate significant improvements in functioning and quality of life, reductions in psychological distress, and amelioration of drug and alcohol problems.[15] Studies also indicate that mental health courts reduce recidivism among mentally ill offenders. In Michigan, the State Administrative Corrections Office evaluated ten mental health courts and found that participants re-offended at a rate 300 percent lower than non-participants.[16]

Thus, the cost savings and public benefits that mental health courts provide through drastically reduced recidivism, early and less expensive intervention measures, and an overall reduction in crime demand their expansion in California.

LORENZO'S STORY

According to his mother, Lorenzo was a typical boy growing up in California. He enjoyed helping around the house and playing with his friends. But around the age of ten or eleven, Lorenzo's mother noticed a change in him. He stopped spending time with his friends and began spending more and more time alone.

His mother thought it might just be typical pre-adolescent changes until she came home one day and Lorenzo asked her, "Do you hear them? They're trying to get me!" Her first worry was that Lorenzo had begun to use drugs, so she immediately took him to the emergency room for an evaluation. That's when Lorenzo was diagnosed with schizophrenia.

Over the next two decades, Lorenzo's illness drove him to the streets where he committed petty thefts in order to survive. He spent a great deal of time in and out of jail for these offenses, but never got the treatment he needed for sustained improvement.

All of that changed when he became a participant in San Francisco's mental health court. There, working with a team of mental health practitioners and court and law enforcement officials Lorenzo was given the resources and compassionate oversight he needed to address and manage the symptoms of his mental illness. He has been a model participant in the court and is now in school to become a medical technician.

Photo courtesy of Loteria Films.

Lorenzo's mother had been praying 26 years for some relief for Lorenzo from the cycle of mental illness, homelessness and incarceration. Now, she has her son back.

Mentally Ill Inmates And The Crisis Of Prison Overcrowding

In 2011, the United States Supreme Court issued its landmark opinion affirming a lower court decision that crowding in California's prisons had reached unconstitutional levels and ordering the state to reduce its prison population to 137.5 percent of design capacity.[17]

Prison dorm unit, which houses mentally ill prisoners, California Institute for Men (2013).

The percentage of prison inmates exhibiting symptoms of mental illness is exponentially higher than that of the non-inmate population.

	Mania Disorder Symptoms	Major Depressive Disorder Symptoms	Psychotic Disorder Symptoms
Percentage of all state prison inmates experiencing symptoms within the past 12 mos.	43.2%	23.5%	15.4%
Percentage of persons age 18 or older in U.S. population experiencing symptoms in past 12 mos.	1.8%	7.9%	3.1%

Source: United States Dept. of Justice, Bureau of Justice Statistics, "Mental Health Problems of Prison and Jail Inmates," (2006).

The case began two decades earlier, in 1990, with a class action suit brought in the United States District Court on behalf of mentally ill prisoners, who brought to light deplorable conditions and medical neglect within California's prisons, amounting to a deprivation of constitutional rights and a violation of the ban against cruel and unusual punishment. In 1995, following a 39-day trial, District Court Judge Lawrence Karlton found "overwhelming evidence of the systematic failure to deliver necessary care to mentally ill inmates" who, among other illnesses, "suffer from severe hallucinations, [and] decompensate into catatonic states." Judge Karlton appointed a special master to oversee implementation of a remedial plan. Yet the situation continued to deteriorate, according to periodic reports from the special master.

Late last year, a special three-judge panel overseeing the litigation ordered the state to meet the prison population cap set by the Supreme Court in 2011. At the request of Governor Jerry Brown, this February, the three-judge panel granted the state a two-year extension to comply with the prison population reduction plan. In granting the extension request, the panel of judges required the state to implement certain immediate measures, such as expanding reentry support programs, providing additional "good time" credits to certain inmates, and implementing new parole rules, including developing a new parole process based on Proposition 36 for some nonviolent "second strike" inmates.

Mentally ill inmates experience significantly higher rates of prison discipline, and are twice as likely to be injured in a prison fight than non-mentally ill inmates.

	Prisoners with Mental Illness	Prisoners without Mental Illness
Charged with prison rule violation	57.7%	43.2%
Injured in a prison fight	20.4%	10.1%

Source: United States Dept. of Justice, Bureau of Justice Statistics, "Mental Health Problems of Prison and Jail Inmates," (2006).

This April, Judge Karlton revisited the treatment of mentally ill prisoners and in a 75-page opinion found that the state's supervision and disciplinary procedures for mentally ill prisoners remains unconstitutional. Judge Karlton determined that the state prison system had still not adequately addressed the issues raised in his 1995 opinion and that the prison system continues to use punitive measures, including solitary confinement, to control symptoms of mental illness. Judge Karlton denied the state's request to end federal oversight of the treatment of mentally ill prisoners in California, ordered new remediation measures, and directed the special master to report on the state's progress within six months.

The Mistreatment Of Mentally Ill Prisoners Under "Three Strikes"

A disproportionate number of inmates sentenced to life in prison under California's "Three Strikes" sentencing law are mentally ill. Prisoners sentenced under the Three Strikes law are roughly twice as likely to be mentally ill as other California prisoners. California law needs to be clarified by courts and the legislature, if necessary, to ensure that a defendant's illness is not used to justify longer imprisonment in any context. The problem is particularly acute in the Three Strikes context.

In some ways it is not surprising that a disproportionate number of Three Strikes prisoners are mentally ill. Compared to defendants without mental health problems, mentally ill defendants have a higher rate of homelessness and drug addiction, often have difficulty contributing to their own defense, and, as discussed elsewhere in this report, generally receive longer sentences than other defendants for the same crimes. The lack of public mental health treatment resources contributes to recidivism by the mentally ill, who eventually become subject to life sentences under the Three Strikes law. Improved public mental health services, particularly residential treatment programs for released prisoners reentering the community, will help address this problem.

In 2012, 70 percent of California voters enacted Proposition 36 to provide an opportunity for inmates sentenced to life under the Three Strikes law for non-serious, non-violent crimes to petition for early release. To date, over 1,700 prisoners have been re-sentenced and released from prison under Proposition 36. The recidivism rate of prisoners released under Proposition 36 has been astonishingly low (less than 1.5 percent). However, mentally ill prisoners sentenced under the Three Strikes law are not receiving the same benefit from the reforms to California's Three Strikes law.

Under Proposition 36, a prisoner sentenced to life for a non-serious, nonviolent crime will receive a reduced sentence unless a Superior Court judge determines that re-sentencing the prisoner would endanger public safety.[18] According to CDCR data, a large majority (95 percent) of eligible prisoners who petition for re-sentencing under Proposition 36 has received a shorter

Mentally ill prisoners are disproportionately denied shorter sentences under Proposition 36.

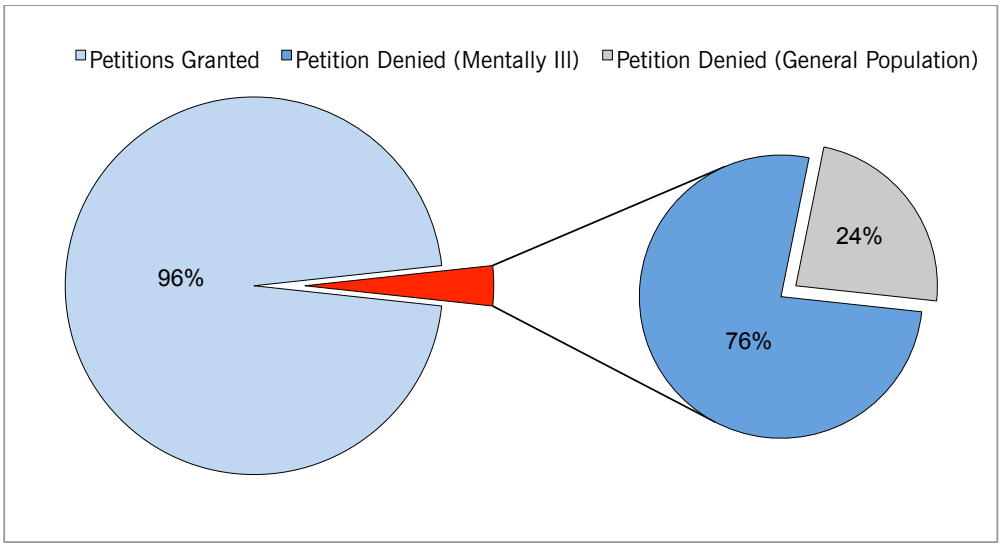

sentence. Yet, 75 percent of those prisoners who have been denied a shorter sentence under Proposition 36 are mentally ill.

One of the reasons that mentally ill Three Strikes prisoners are faring poorly under Proposition 36 has to do with prison disciplinary rules, which play a large role in a judge's determination of future risk to public safety. Mentally ill prisoners generally have more prison violations than inmates without mental health problems. While this is not surprising, it is problematic. According to the findings of the federal district court and the special master overseeing the prison disciplinary procedures in *Coleman v. Brown*, since 1995 prison officials have been using disciplinary violations and punishment to control the behavior of the mentally ill in lieu of treatment. As a result, the Coleman court has ruled that prison disciplinary procedures involving mentally ill inmates over the past 20 years have been in violation of constitutional protections and has ordered remedial action.

Superior Court judges evaluating the prison disciplinary records of mentally ill inmates petitioning for new sentences under Prop. 36 should be aware of the historic problems with the prison disciplinary rules involving mentally ill inmates and take into account the prison's failure to adequately treat and discipline mentally ill prisoners when making a dangerousness evaluation under Proposition 36.

Furthermore, California law generally needs to be clarified to ensure that judges do not impose longer sentences on defendants just because they are mentally ill. Regulations governing which prisoners should be released on parole specifically provide that a prisoner's mental health status may indicate increased public safety risk and justification for denial of parole.[19] This provision should be eliminated and brought into line with California Rules of Court governing criminal sentencing proceedings, which provide that an offender's mental illness is a mitigating factor that reduces the offender's criminal culpability and justifies a *reduced* sentence.[20] The United States Supreme Court has repeatedly held that defendants whose mental illness contributed to their crimes should not receive the same punishment as defendants who do not have mental health problems. In *Penry v. Lynaugh*, 492 U.S. 302 (1989) the Court explained:

[We affirm] the belief, long held by this society, that defendants who commit criminal acts that are attributable…to emotional and mental problems may be less culpable than defendants who have no such excuse.

This principle has been extended to limited criminal contexts, like the death penalty. The same rules should be applied to the vast majority of defendants in California and nationwide who do not face capital punishment and who may have committed their crimes as result of mental illness.

Investment In Community Mental Health

The community mental health system has been deficient for many years. We have recently made efforts to rebuild the system—which provides necessary services and programs for collaborative mental health courts, the Department of Corrections, and law enforcement to divert mentally ill offenders to mental health treatment instead of jail or prison—but progress has been slow.

The percent of California's state budget dedicated to prisons has doubled since 1976

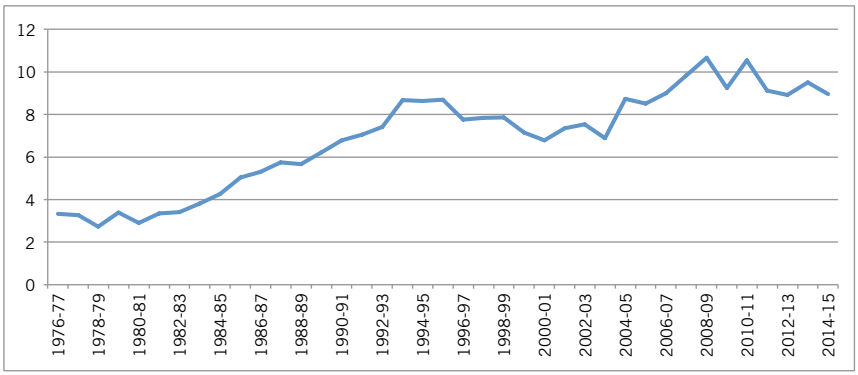

Source: California Department of Finance, California Budget Project, (2014).

In California, county governments now largely bear the responsibility for funding and providing the majority of mental health programs, including treatment services for low-income, uninsured individuals with severe mental illness and programs associated with the Mental Health Services Act of 2004 ("MHSA," also known as Proposition 63).

Passed in November 2004, Proposition 63 imposed a one percent income tax on personal income in excess of $1 million. Proposition 63 expanded mental health services for children and adults with severe mental illness whose needs were not covered by existing insurance programs or other federally sponsored programs. Proposition 63 provides funds to counties to expand and develop innovative programs for the mentally ill.

This year, over $1 billion will be allocated to county mental health programs and approximately $80 million will be allocated to state mental health programs under Proposition 63. In Los Angeles alone, programs funded by Proposition 63 provided services to over 150,000 people last year. Participants in the Full Service Partnership program funded by Proposition 63 experienced a reduction in homelessness, psychiatric hospitalization and incarcerations:

- Mentally ill adults achieved a 71% reduction in the number of days spent homeless.
- Mentally ill adults achieved a 50% reduction in the number of days spent in jail.
- Mentally ill youth achieved a 59% reduction in days spent in Juvenile Hall and a 40% reduction in the number of days psychiatrically hospitalized.

California voters overwhelmingly support the expansion of mental health services.

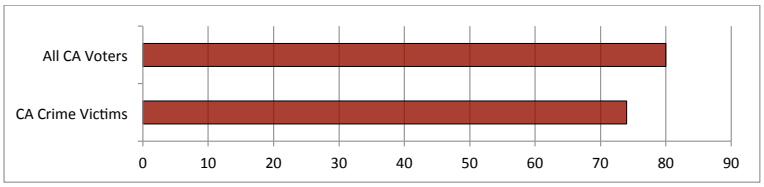

Source: Californians For Safety and Justice, (2013).

Building on this success, Senator Steinberg helped to pass SB 82, the Mental Health Wellness Act of 2013, which provided funds to increase local capacity to assist mentally ill individuals in crisis. SB 82 funds mobile crisis teams, crisis stabilization beds, and better triage for mentally ill individuals. This April, the state approved $75.3 million in

grants, adding 827 residential and crisis stabilization beds, and 39 vehicles and 60 staff for mobile support teams statewide.

In addition to these new state funding streams, the federal Affordable Care Act of 2012 expands eligibility criteria of Medi-Cal to include many mentally ill individuals in the criminal justice system. The Affordable Care Act also provides for a large expansion of mental health and substance use disorder coverage.

These programs have proven that increased support and services to indigent mentally ill individuals can help treat serious and debilitating conditions, help improve public safety (by reducing crime committed by untreated mentally ill individuals), and save money by diverting them from expensive and inappropriate placement in emergency rooms and jails. The state and counties should expand on the success of these programs that are benefits to us all.

A Plan To Stop Imprisoning And Start Treating Our Mentally Ill Citizens

From time to time there have been efforts to expose this disaster but bold proposals for solutions have been lacking. We have seen periodic criticism, but no serious desire or determination for change. We, in California, can and will do better. Recognizing the fundamental importance of a compassionate, just, safe and cost-effective solution, the legislature can take the following immediate steps to address the crisis of mental illness in California's justice system. Each of these proposals support priorities set forth earlier in the Introduction of this Report: (1) Trial courts should take into account the mental health of each defendant at sentencing; (2) Once sentenced, the Department of Corrections and a newly established court, working together, should oversee the mental health treatment of each prisoner; and (3) All prisoners must have a reentry plan that provides for continued mental health treatment upon release from prison.

These recommendations build on one another in order to achieve truly robust and comprehensive reform. Our plan to stop imprisoning and start treating mentally ill citizens consists of three modest but significant proposals:

1. **Reform the Way We Sentence the Mentally Ill:**

   We propose that all new sentences take into account the mental health of each defendant and, where appropriate, provide a non-prison sentence for any defendant charged with a nonviolent crime/non-serious offense. This new sentencing would apply when the sentencing judge finds that the defense has shown by a preponderance of the evidence that the crime was likely committed as a result of the defendant's mental illness. Under such a circumstance, the defendant will be sentenced to mental health treatment and monitoring in a non-custodial setting. We propose to provide funding for mental health treatment for these defendants throughout the state. The cost of such treatment is significantly less than the cost of incarceration.

Mental Health Court in San Francisco. Photo courtesy of Loteria Films.

   Trial Courts Should Take Into Account the Mental Health of Each Defendant at Sentencing. For many reasons the mentally ill are disproportionately involved in the criminal justice system. We must increase diversion programs to redirect mentally ill defendants away from prisons and jails—which exacerbate mental illnesses, impede treatment, and undermine public safety—toward proven mental health treatment services.

   We urge the immediate enactment of SB 1054 and the Mentally Ill Offender Crime Reduction Grant (MIOCR) Program. SB 1054 allocates $50 million from the Recidivism Reduction Fund to fund a competitive grant program for mental health courts and other programs throughout California, helping divert people with mental illness out of corrections and into services. The MIOCR grant program has been successful in the past in reducing the number of people with mental illness in jail and should be reestablished.

2. Provide Meaningful Treatment in Prison:

We propose that when a sentencing judge finds (a) that a defendant's serious offense was caused in large part by his mental illness, or (b) that a defendant who committed a nonserious offense needs to be incarcerated due to the danger to himself or others, the judge will order the provision of meaningful mental health services as part of the terms and conditions of incarceration. These mental health services, although overseen and provided by the Bureau of Prisons, will nevertheless be reviewed from time to time by a special Mental Health Prison Oversight Court, which will be set up to assure that proper mental health services are being provided to each incarcerated defendant. This special court will be made up of judges and mental health professionals who will work together to fashion and oversee the treatment of incarcerated prisoners in need of mental health treatment. This new Mental Health Prison Oversight Court will provide initial sentencing recommendations to trial court judges who request the court's input. Following a defendant's sentencing, the new court will have authority to oversee the mental health treatment of the incarcerated defendant, and will be empowered to order changes to the treatment plan that the court deems appropriate. This is a bold new proposal to integrate the independence of the prison system with the oversight of a special court as part of the judiciary. We recognize the problems and challenges of implementation, but we are confident that the goodwill and creative cooperation of all concerned will allow for the implementation of this change.

Call to Action!

Call Governor Brown and tell him to support the needs of people with mental illness. We need to treat mental illness—not criminalize it.

Tell Governor Brown to support these common sense reforms:

- Expand mental health courts statewide
- Provide mental health case managers for mentally ill parolees
- Support transitional housing for mentally ill inmates leaving prison
- Continue to provide services to Three Strikes prisoners released under Prop. 36

Call the Governor's Office at (916) 445-2841 or email him by visiting Gov.CA.Gov.

Once Sentenced, CDCR and a Newly Established Court Will Oversee the Treatment and Housing of Each Mentally Ill Prisoner. Despite two decades of federal litigation designed to improve the mental health care of California prisoners, treatment for the mentally ill in prison still falls well below minimal constitutional standards in many important respects.

We must provide the mentally ill with appropriate housing and personnel to treat their needs.

We urge expanded training for corrections officers, and mental health, healthcare, and rehabilitative programing staff. Establish an intensive training program for correctional officers, healthcare, mental health, and rehabilitative program staff. Require in-service training that integrates mental health, healthcare, and correctional officer staff.

We urge the construction of mental health treatment facilities and substance abuse treatment facilities. The Governor's Budget proposes an additional $500 million on top of the $1.2 billion already budgeted for jail construction. This funding needs to be expanded to include construction of mental health treatment facilities and substance abuse treatment facilities.

3. Continue Meaningful Treatment After Prison:

Finally, we propose that all prisoners, prior to release, be evaluated for post-release mental health needs and, where appropriate, be referred to mental health centers for the ongoing provision of mental health care. These new mental health centers will be located throughout the state and will have access to the mental health records of the released prisoners, recommendations for appropriate post-release mental health care, and the funding needed to provide these services for at least one year following release. As indicated above, providing these services will more than pay for itself in terms of costs saved by avoiding the extraordinary (financial and human) costs of incarceration.

Prisoners Will Be Provided with a Mental Health Reentry Plan Upon Release. The mentally ill confront distinct, yet treatable, challenges as they reintegrate into the community. We must provide them with support as they meet these challenges.

We urge the guarantee of transitional housing upon release for the mentally ill. Require all mentally ill parolees to be released 90 days early into an intensive transitional housing program.

We urge the creation of a corps of mental health parole officers. Create a specialized caseload for parole agents for mentally ill parolees with a caseload of 1 parole agent to 20 mentally ill parolees. The mental health parole agent should have a minimum of an Associate's Degree, at least one year of social casework experience, and training in cognitive behavior treatment and motivational interviewing.

We urge the re-establishment of Parole Out-patient Clinics (POC) as case management offices. As the parole population decreases, the state should change the mission of the Parole Out-Patient Clinic and establish three different levels of case management:

- **Initial 30 Day Case Manager**: This case manager will meet with the parolee immediately upon release, assess for needs, and establish initial essential services, including housing, sobriety maintenance, and medical and mental health care.
- **Long-term Case Manager**: This case manager will partner with multiple parole agents to assist both the parolee and the parole agent in maintaining access to services.
- **Mental Health Case Manager**: A specially trained social worker who will work with parolees identified as mentally ill and their specially-trained parole agents to develop individualized case management plans, ensure the parolee is enrolled in Medi-Cal, connect the parolee with physicians, and establish the first medical and mental health appointments for the parolee. The parole agent and the case manager will work together to address all reentry needs of the parolee, including housing, health care and employment.

We urge that mentally ill Proposition 36 offenders receive state services. A disproportionate number of prisoners sentenced to life under California's Three Strikes law are mentally ill. We should continue to provide parolee services for prisoners released under Proposition 36. Last year, CDCR and Administrative Office of the Courts established a referral process for Proposition 36 offenders to receive existing parole reentry services. These services have helped ensure a historically low recidivism rate among prisoners released under Proposition 36 and should be continued.

Footnotes

1 Unless otherwise noted, all data in this report were provided by the California Department of Corrections and Rehabilitation (2014). For purposes of this report, "mental illness" is defined as a condition that qualifies for placement in the prison's Mental Health Delivery System within the last year.

2 Los Angeles Times, "Sheriff says proposed mental health cuts would burden L.A. jails," (May 25, 2010).

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5 G.E. Witmer, *From Hospitals to Jails: The Fate of California's Deinstitutionalized Mentally Ill*, *American Journal of Orthopsychiatry* 1980; 50:65-75.

6 See H.R.Lamb and R.W. Grant, *The Mentally Ill in an Urban County Jail*, Archives of General Psychiatry 1982; 39:17-22; H.R. Lamb and R.W. Grant, *Mentally Ill Women in a County Jail*, Archives of General Psychiatry 1983; 40:363-68.

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8 "Medications cut violence among mentally ill in study," *Wall Street Journal* (May 7, 2014).

9 Task Force for Criminal Justice Collaboration on Mental Health Issues: Final Report, Administrative Office of the Courts, Judicial Council of California (April 2011).

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12 *Id*.

13 Arley Lindberg, "Costs and Benefits of Behavioral Health Court: Findings from Examining Program Costs and Outcomes of San Francisco's Behavioral Health Court," (2009).

14 *Id*.

15 Fact Sheet: Mental Health Courts, Administrative Office of the Courts, Judicial Council of California, (April 2008).

16 "Mental health courts expand to treat offenders," *Grand Rapids Business Journal*, (March 12, 2014).

17 *Brown v. Plata*, 131 S. Ct. 1910 (2011).

18 *See* Cal. Penal Code Sec. 1170.126.

19 *See* Title 15 Sec. 2281(c)(5).

20 *See* Cal. Rule of Court Sec. 4.423(b)(2).

APA Guidelines for the Undergraduate Psychology Major

APA GUIDELINES FOR THE UNDERGRADUATE PSYCHOLOGY MAJOR

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PREFACE

The *APA Guidelines for the Undergraduate Psychology Major* (hereinafter referred to as the *Guidelines*) captures a set of optimal expectations for performance at the completion of the baccalaureate degree by students who major in psychology. The document outlines 10 goals and suggested learning outcomes that represent reasonable departmental expectations for the undergraduate psychology major across educational contexts. The goals are divided into two major categories:

- Knowledge, skills, and values consistent with the science and application of psychology
- Knowledge, skills, and values consistent with liberal arts education that are further developed in psychology

Although the *Guidelines* can aid in curriculum design, goal setting, and assessment planning, faculty are encouraged to consider local factors, such as institutional and departmental missions and student characteristics, in their application. In this spirit, broad discussion of the document can facilitate departmental leadership in designing programs distinctively suited to the institution's mission and students' needs while attending to good practice benchmarks.

EXECUTIVE SUMMARY

Why Do We Need the *APA Guidelines for the Undergraduate Psychology Major*?

For some time, there has been widespread concern about the quality of education at all levels in the United States, along with increasing pressure for accountability. Current best practices in higher education rely on setting clear expectations for student learning, aligning curricula with these expectations, assessing student attainment, and using assessment results to effect changes that promote better student learning.

It was in this context that the Board of Educational Affairs (BEA) of the American Psychological Association (APA) appointed a task force to describe a set of learning goals and outcomes for student performance at the completion of the baccalaureate degree. The *APA Guidelines for the Undergraduate Psychology Major* was developed to articulate a common set of outcomes. A baccalaureate degree in psychology should document that students have the ability to think scientifically about behavior, the skills related to the conduct of research, and the values that reflect psychology as both a science and an applied discipline.

Variations in psychology's academic organization in institutions of higher education across the country make it difficult to achieve consensus on learning goals and outcomes. In some colleges and universities, psychology is part of a school or college comprising the social sciences. In others, psychology is aligned with the natural sciences, the humanities, or education. In addition to having organizational diversity, psychology departments differ with respect to programmatic emphases, student characteristics, faculty expertise, and resources. Undergraduate programs vary—as they should—to meet local, state, and regional needs. Despite these differences, the BEA task force developed goals and outcomes that could be applied broadly across diverse educational contexts (e.g., campus-based programs, online instruction) in the context of liberal education at the undergraduate level.

The *Guidelines* captures a set of optimal expectations for student performance at the completion of the baccalaureate degree. Applying

these to individual departments, faculty must take into account local factors such as institutional and departmental missions and student characteristics. Regardless of department size and resources, the *Guidelines* presents reasonable overarching goals for the undergraduate psychology curriculum. Toward this end, these guidelines were developed to aid in curriculum design, goal setting, and assessment planning for the psychology major.

In addition to providing guidance about what constitutes a high-quality undergraduate education for majors in psychology, the *Guidelines* responds to a number of other important related needs:

- The *Guidelines* firmly establishes the major as a science and reinforces a common identity within the discipline. Promoting psychology as a science is increasingly important given the enormous breadth of the discipline and the diversity of professional opportunities and psychological perspectives, including new interdisciplinary configurations.
- The *Guidelines* describes a set of learning goals and outcomes for the psychology major. By making the expectations (outcomes) clear, the *Guidelines* serves as the basis for assessment plans.
- Development of the *Guidelines* is an important step for the discipline and a means of contributing to a growing international effort to articulate goals and outcomes for the major. Dissemination and implementation of the *Guidelines* could also generate research on effective practices in undergraduate education in psychology.
- Building on APA's earlier efforts when approving the *National Standards for the Teaching of High School Psychology* (APA, 1999) and the revised *National Standards for High School Psychology Curricula* (APA, 2005), the *Guidelines* continues APA's national focus on quality improvement. Completing expectations for appropriate education at the 4-year level adds an important piece of the overall education and training context in psychology (see Benjamin, 2001).
- The *Guidelines* provides a common set of outcomes that could aid in the development and evaluation of distance-learning courses and programs by promoting expectations for student learning comparable to those used in traditional classrooms.

Assumptions Underlying the Undergraduate Learning Outcomes

The learning goals and outcomes in this document rest on several key assumptions about the psychology major, the dynamic nature of the discipline, the diversity of psychology departments across the United States, and the assessment of performance relative to outcomes. As a framework for understanding the *Guidelines*, these assumptions are that the learning goals and outcomes

- encompass the knowledge, skills, and values that are important for students to acquire in an undergraduate major in psychology within the context of a liberal education;
- incorporate the broad theoretical and research bases of psychology;
- reflect the use of a variety of pedagogical models, including service-learning, research and laboratory experiences, online applications, and traditional classroom approaches;
- foster the development of lifelong learning skills and include competencies that will prepare students for entrance into the workforce or acceptance into graduate or professional schools upon receipt of the baccalaureate degree;
- reflect the importance of diversity and cross-cultural issues in the discipline, as well as the growing internationalization of psychology and the need to prepare psychology majors to understand behavior and experience that may transcend geographic boundaries;
- apply to psychology departments across institutional settings that contribute to student achievement at the baccalaureate level;
- reflect the views that any outcome is meaningful only to the extent that it is accurately assessed and that the outcomes assessment process will focus on student performance if it is to improve learning and teaching;
- allow for many legitimate ways to reach a learning outcome, especially given that outcomes are developmental in nature; individual psychology departments determine the performance levels appropriate for their students and the assessment procedures and tools appropriate to measuring their students' performance.

Use of the Term *Guidelines*

The term *guidelines* generally refers to pronouncements, statements, or declarations that recommend or suggest specific actions, goals, or endeavors. In this spirit, they are aspirational in intent. They are not intended to be mandatory or exhaustive and may not be applicable to every situation, nor are they intended to take precedence over the judgment of college and university faculty.

This use of the term *guidelines* is consistent with general practices in the undergraduate education community. A primary consideration related to the nature of the document is the issue of academic freedom. The American Association of University Professors (AAUP) published a seminal paper articulating the principles of academic freedom meant to ensure the fundamental advancement of truth (see AAUP, 2006). Teachers are explicitly granted the right to exercise freedom in their discussions about respective disciplinary matters. Therefore, the *Guidelines* should be used only as a broad and general framework for the undergraduate psychology major.

The term *guidelines* is also consistent with terminology used by other scientific organizations. The American Chemical Society (ACS; 2003) provides guidelines for the undergraduate major in chemistry. Although the ACS guidelines are for the purpose of accreditation, they offer only general curricular goals rather than an exact curriculum. Similarly, the American Physical Society, through the American Association of Physics Teachers (see Hilborn, Howes, & Krane, 2003), provides general guidance for the undergraduate major in their report on the status of the undergraduate major in physics.

Finally, as used in this document, the term *guidelines* is consistent with the provisions of the APA policy on *Developing and Evaluating Standards and Guidelines Related to Education and Training in Psychology* (Section I C[1]) (APA, 2004), as passed by the APA Council of Representatives.

Process of Developing the *Guidelines*

Five reports preceded the development of these guidelines, and many individuals and groups contributed to their initial development. Study of the curriculum can be traced back to the summer

of 1951 with the issuance of the Cornell Conference Report. This report emphasized psychology as a science grounded in the tradition of the liberal arts. The report merely suggested that one introductory course should be followed by intermediate core courses (e.g., statistics and perception) and finally by advanced courses (e.g., social psychology and learning). The Michigan Conference Report followed approximately 10 years later, with less consensus about the structure of the undergraduate curriculum. Similarly, the Kulik Report (in 1973) and the Schreirer and Rogers Report (in 1985) provided only descriptive information about the undergraduate major (for more information on these reports, see Brewer et al., 1993). Ultimately, at the St. Mary's Conference in 1991, Charles Brewer and his committee from the APA National Conference on Enhancing the Quality of Undergraduate Education in Psychology provided a broad structure for the undergraduate curriculum. Defining seven goals for the undergraduate major, Brewer and his colleagues suggested that the curriculum should include an introductory course, methodology courses, subfield content courses, and an integrative experience.

It was in this context, together with the movement in higher education to identify competencies as learning objectives, that the BEA appointed the Task Force on Psychology Major Competencies in 2000 to develop learning goals and outcomes for the undergraduate psychology major. Members of the task force represented a variety of institutional perspectives on the nature of the undergraduate curriculum and its aims. Under the leadership of Jane S. Halonen (chair), task force members included Drew C. Appleby, Charles L. Brewer, William Buskist, Angela R. Gillem, Diane Halpern, G. William Hill IV, Margaret A. Lloyd, Jerry L. Rudmann, and Valjean M. Whitlow. APA staff who contributed their expertise included Bernard C. Beins, now at Ithaca College, Maureen McCarthy, presently at Kennesaw State University, and Martha Boenau of the APA Education Directorate.

In the early stages of their work, the task force patterned its document after the guidelines developed by the Task Force on Outcomes for the California State University System, led by Mary Allen and Diane Halpern (past president of APA). The task force prepared a document that would serve as a resource to undergraduate psychology departments and faculty to assist with academic review processes and curriculum planning. As described in the *Undergraduate Psychology Major Learning Goals and Outcomes* (APA, 2002b), the task force identified 10

goals and suggested learning outcomes representing reasonable departmental expectations for the undergraduate psychology major across educational contexts. The goals were divided into two major categories: (a) knowledge, skills, and values consistent with the science and application of psychology and (b) knowledge, skills, and values consistent with liberal arts education that are further developed in psychology.

To extend representation to a diverse array of institutions and relevant organizations, the task force assembled an advisory panel to review drafts of the document. Through this process, the document was widely distributed to faculty at research universities, comprehensive universities, 4-year colleges, 2-year colleges, and high schools. Their comments were integrated into the *Guidelines.* The task force also sought and received helpful feedback from members of related professional organizations with interests in psychology curricula. A final version of this document was endorsed by the BEA in March 2002 and made available to the undergraduate community as a report published on the APA Education Directorate Web site (see APA, 2002b).

By July 2002, the report was disseminated broadly to APA governance groups and APA divisions, with a request for review and feedback. The *Guidelines* was also reviewed for attention to individual and cultural diversity issues consistent with the *Guidelines on Multicultural Education, Research, Practice, and Organizational Change for Psychologists* (APA, 2003); in addition, it was reviewed by the APA Committee on Ethnic Minority Affairs and the Committee on Lesbian, Gay and Bisexual Concerns. APA Boards and Committees received a final draft of the document in the spring of 2006. Subsequently, upon recommendation of the APA Board of Directors, the APA Council of Representatives adopted the *Guidelines* in August 2006.

Resource Documents

In developing the *Guidelines*, the task force reviewed the existing guidelines used by science-based disciplinary societies similar to APA, such as the American Chemical Society, the American Physical Society (APS), and the American Society for Biochemistry and Molecular Biology (ASBMB). These guidelines on the undergraduate curriculum were found to be similar in structure to the APA guidelines. For example, ASBMB (see Voet et al., 2003) explicitly stated that it was

no longer recommending a course-based curriculum. Instead, ASBMB provided content and student-outcome-focused guidance. Additional resources included use of the APA *Ethical Principles of Psychologists and Code of Conduct* (APA, 2002a) and the *Handbook for Enhancing Undergraduate Education in Psychology* (McGovern, 1993). The content contained in the *Guidelines* is consistent with APA's Ethics Code.

Feedback

The *Guidelines* is a "living document." Accordingly, APA has established a systematic plan for periodically reviewing and revising such documents to reflect developments in the discipline and in education. Reviews will occur every 7 years, which is consistent with APA Association Rule 30-8.3 requiring cyclical review of approved standards and guidelines within periods not to exceed 10 years. Comments and suggestions are welcomed.

Feedback on the *Guidelines* may be sent to:
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APA GUIDELINES FOR THE UNDERGRADUATE PSYCHOLOGY MAJOR

Structure of the *Guidelines*

The *APA Guidelines for the Undergraduate Psychology Major* provides details for 10 suggested goals and related learning outcomes for the psychology major, grouped into two major categories.

Categories of Learning Goals and Outcomes

I. Knowledge, Skills, and Values Consistent With the Science and Application of Psychology

This category represents activities that provide hallmarks of psychology education. Responsibility for development in and assessment of these areas rests primarily with the psychology faculty in coursework or psychology advising.

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

This category includes activities that are usually part of a general education program or liberal education. Responsibility for student development in these areas and assessment of students' achievements tend to be shared across a broader range of disciplines than just psychology; however, psychology coursework can contribute to and expand upon these general education goals in significant ways. In turn, well-developed liberal education skills can contribute to student achievement within the psychology major.

Learning Goals

I. Knowledge, Skills, and Values Consistent With the Science and Application of Psychology

Goal 1: Knowledge Base of Psychology
Students will demonstrate familiarity with the major concepts, theoretical perspectives, empirical findings, and historical trends in psychology.

Goal 2: Research Methods in Psychology
Students will understand and apply basic research methods in

psychology, including research design, data analysis, and interpretation.

Goal 3: Critical Thinking Skills in Psychology
Students will respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

Goal 4: Application of Psychology
Students will understand and apply psychological principles to personal, social, and organizational issues.

Goal 5: Values in Psychology
Students will be able to weigh evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a discipline.

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

Goal 6: Information and Technological Literacy
Students will demonstrate information competence and the ability to use computers and other technology for many purposes.

Goal 7: Communication Skills
Students will be able to communicate effectively in a variety of formats.

Goal 8: Sociocultural and International Awareness
Students will recognize, understand, and respect the complexity of sociocultural and international diversity.

Goal 9: Personal Development
Students will develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

Goal 10: Career Planning and Development
Students will emerge from the major with realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings.

Learning Outcomes

Each of the 10 goals includes specific, numbered outcomes that articulate suggested strategies for how the goals can be demonstrated. Each goal can be addressed in departments' curriculum designs and assessment plans; however, departments may choose formally to emphasize selected goals and outcomes depending on their emphases, traditions, or resources. Separate subpoints for particular outcomes provide further assistance in developing performance expectations.

An emphasis on certain content areas included as part of the learning goals and outcomes should not be construed as dictating course requirements. For example, the emphasis on the development of career skills does not imply that these activities must transpire in a formal course on careers in psychology. Similarly, the *Guidelines* should not be interpreted as advocating that separate courses in the history of psychology or group dynamics be included in the undergraduate curriculum. Rather, these guidelines are intended to empower and encourage departments to determine contexts in which students can learn those relevant skills and perspectives.

I. Knowledge, Skills, and Values Consistent With the Science and Application of Psychology

GOAL 1: Knowledge Base of Psychology

Demonstrate familiarity with the major concepts, theoretical perspectives, empirical findings, and historical trends in psychology.

Suggested Learning Outcomes

1.1 Characterize the nature of psychology as a discipline.

a. Explain why psychology is a science

b. Identify and explain the primary objectives of psychology: describing, understanding, predicting, and controlling behavior and mental processes

c. Compare and contrast the assumptions and methods of psychology with those of other disciplines

d. Describe the contributions of psychology perspectives to interdisciplinary collaboration

1.2 Demonstrate knowledge and understanding representing appropriate breadth and depth in selected content areas of psychology:

a. Theory and research representing each of the following four general domains:

(1) Learning and cognition

(2) Individual differences, psychometrics, personality, and social processes, including those related to sociocultural and international dimensions

(3) Biological bases of behavior and mental processes, including physiology, sensation, perception, comparative, motivation, and emotion

(4) Developmental changes in behavior and mental processes across the life span

b. The history of psychology, including the evolution of methods of psychology, its theoretical conflicts, and its sociocultural contexts

c. Relevant levels of analysis: cellular, individual, group/systems, and society/culture

d. Overarching themes, persistent questions, or enduring conflicts in psychology, such as

(1) The interaction of heredity and environment

(2) Variability and continuity of behavior and mental processes within and across species

(3) Free will versus determinism

(4) Subjective versus objective perspective

(5) The interaction of mind and body

(6) Applicability of theories and measures across societal and cultural groups

e. Relevant ethical issues, including a general understanding of the APA Ethics Code

1.3 Use the concepts, language, and major theories of the discipline to account for psychological phenomena.

a. Describe behavior and mental processes empirically, including operational definitions

b. Identify antecedents and consequences of behavior and mental processes

c. Interpret behavior and mental processes at an appropriate level of complexity

d. Use theories to explain and predict behavior and mental processes
e. Integrate theoretical perspectives to produce comprehensive and multifaceted explanations

1.4 Explain major perspectives of psychology (e.g., behavioral, biological, cognitive, evolutionary, humanistic, psychodynamic, and sociocultural).
a. Compare and contrast major perspectives
b. Describe advantages and limitations of major theoretical perspectives

GOAL 2: Research Methods in Psychology

Understand and apply basic research methods in psychology, including research design, data analysis, and interpretation.

Suggested Learning Outcomes

2.1 Describe the basic characteristics of the science of psychology.

2.2 Explain different research methods used by psychologists.
a. Describe how various research designs address different types of questions and hypotheses
b. Articulate strengths and limitations of various research designs, including distinguishing between qualitative and quantitative methods
c. Distinguish the nature of designs that permit causal inferences from those that do not
d. Describe how the values system of the researcher can influence research design and decisions

2.3 Evaluate the appropriateness of conclusions derived from psychological research.
a. Interpret basic statistical results
b. Distinguish between statistical significance and practical significance
c. Describe effect size and confidence intervals
d. Evaluate the validity of conclusions presented in research reports

2.4 Design and conduct basic studies to address psychological questions using appropriate research methods.

a. Locate and use relevant databases, research, and theory to plan, conduct, and interpret results of research studies

b. Formulate testable research hypotheses, based on operational definitions of variables

c. Use reliable and valid measures of variables of interest

d. Select and apply appropriate methods to maximize internal and external validity and reduce the plausibility of alternative explanations

e. Collect, analyze, interpret, and report data using appropriate statistical strategies to address different types of research questions and hypotheses

f. Recognize that theoretical and sociocultural contexts as well as personal biases may shape research questions, design, data collection, analysis, and interpretation

2.5 Follow the APA Ethics Code in the treatment of human and nonhuman participants in the design, data collection, interpretation, and reporting of psychological research.

2.6 Generalize research conclusions appropriately based on the parameters of particular research methods.

a. Exercise caution in predicting behavior based on limitations of single studies

b. Recognize the limitations of applying normative conclusions to individuals

c. Acknowledge that research results may have unanticipated societal consequences

d. Recognize that individual differences and sociocultural contexts may influence the applicability of research findings

GOAL 3: Critical Thinking Skills in Psychology

Respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

Suggested Learning Outcomes

3.1 Use critical thinking effectively.

a. Evaluate the quality of information, including differentiating empirical evidence from speculation and the probable from the improbable
b. Identify and evaluate the source, context, and credibility of behavioral claims
c. Challenge claims that arise from myth, stereotype, or untested assumptions
d. Use scientific principles and evidence to resolve conflicting claims
e. Recognize and defend against common fallacies in thinking
f. Avoid being swayed by appeals to emotion or authority
g. Evaluate popular media reports of psychological research
h. Demonstrate an attitude of critical thinking that includes persistence, open-mindedness, tolerance for ambiguity, and intellectual engagement
i. Make linkages or connections between diverse facts, theories, and observations

3.2 Engage in creative thinking.
a. Intentionally pursue unusual approaches to problems
b. Recognize and encourage creative thinking and behaviors in others
c. Evaluate new ideas with an open but critical mind

3.3 Use reasoning to recognize, develop, defend, and criticize arguments and other persuasive appeals.
a. Identify components of arguments (e.g., conclusions, premises/assumptions, gaps, counterarguments)
b. Distinguish among assumptions, emotional appeals, speculations, and defensible evidence
c. Weigh support for conclusions to determine how well reasons support conclusions
d. Identify weak, contradictory, and inappropriate assertions
e. Develop sound arguments based on reasoning and evidence

3.4 Approach problems effectively.
a. Recognize ill-defined and well-defined problems
b. Articulate problems clearly
c. Generate multiple possible goals and solutions
d. Evaluate the quality of solutions and revise as needed
e. Select and carry out the best solution

GOAL 4: Application of Psychology

Understand and apply psychological principles to personal, social, and organizational issues.

Suggested Learning Outcomes

4.1 Describe major applied areas (e.g., clinical, counseling, industrial/organizational, school, etc.) and emerging (e.g., health, forensics, media, military, etc.) applied areas of psychology.

4.2 Identify appropriate applications of psychology in solving problems, such as:

a. The pursuit and effect of healthy lifestyles
b. Origin and treatment of abnormal behavior
c. Psychological tests and measurements
d. Psychology-based interventions in clinical, counseling, educational, industrial/organizational, community, and other settings and their empirical evaluation
e. The resolution of interpersonal and intercultural conflicts

4.3 Articulate how psychological principles can be used to explain social issues and inform public policy.

a. Recognize that sociocultural contexts may influence the application of psychological principles in solving social problems
b. Describe how applying psychological principles can facilitate appropriate change in institutions and in society
c. Articulate the role of psychology in developing, designing, and disseminating public policy

4.4 Apply psychological concepts, theories, and research findings as these relate to everyday life.

4.5 Recognize that ethically complex situations can develop in the application of psychological principles.

GOAL 5: Values in Psychology

Value empirical evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a science.

Suggested Learning Outcomes

5.1 Recognize the necessity of ethical behavior in all aspects of the science and practice of psychology.

5.2 Demonstrate reasonable skepticism and intellectual curiosity by asking questions about causes of behavior.

5.3 Seek and evaluate scientific evidence for psychological claims.

5.4 Tolerate ambiguity and realize that psychological explanations are often complex and tentative.

5.5 Recognize and respect human diversity.

a. Anticipate that psychological explanations may vary across populations and contexts

b. Exhibit sensitivity to issues of power, privilege, and discrimination

5.6 Assess and justify their engagement with respect to civic, social, and global responsibilities.

5.7 Understand the limitations of their psychological knowledge and skills.

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

GOAL 6: Information and Technological Literacy

Demonstrate information competence and the ability to use computers and other technology for many purposes.

Suggested Learning Outcomes

6.1 Demonstrate information competence at each stage in the following process:

a. Formulate a researchable topic that can be supported by database search strategies

b. Locate and choose relevant sources from appropriate media, which may include data and perspectives outside traditional psychology and Western boundaries

c. Use selected sources after evaluating their suitability based on
(1) Appropriateness, accuracy, quality, and value of the source
(2) Potential bias of the source
(3) The relative value of primary versus secondary sources, empirical versus nonempirical sources, and peer-reviewed versus non-peer-reviewed sources

d. Read and accurately summarize the general scientific literature of psychology

6.2 Use appropriate software to produce understandable reports of the psychological literature, methods, and statistical and qualitative analyses in APA or other appropriate style, including graphic representations of data.

6.3 Use information and technology ethically and responsibly.
a. Quote, paraphrase, and cite correctly from a variety of media sources
b. Define and avoid plagiarism
c. Avoid distorting statistical results
d. Honor commercial and intellectual copyrights

6.4 Demonstrate these computer skills:
a. Use basic word processing, database, e-mail, spreadsheet, and data analysis programs
b. Search the Web for high-quality information
c. Use proper etiquette and security safeguards when communicating through e-mail

GOAL 7: Communication Skills

Communicate effectively in a variety of formats.

Suggested Learning Outcomes

7.1 Demonstrate effective writing skills in various formats (e.g., essays, correspondence, technical papers, note taking) and for various purposes (e.g., informing, defending, explaining, persuading, arguing, teaching).
a. Demonstrate professional writing conventions (e.g., grammar, audience awareness, formality) appropriate to purpose and context
b. Use APA style effectively in empirically based reports, literature reviews, and theoretical papers

7.2 Demonstrate effective oral communication skills in various formats (e.g., group discussion, debate, lecture) and for various purposes (e.g., informing, defending, explaining, persuading, arguing, teaching).

7.3 Exhibit quantitative literacy.

a. Apply basic mathematical concepts and operations to support measurement strategies

b. Use appropriate and relevant probability and statistical analyses to facilitate interpretation of measurements

c. Articulate clear and appropriate rationale for choice of information conveyed in charts, tables, figures, and graphs

d. Interpret quantitative visual aids accurately, including showing vigilance about misuse or misrepresentation of quantitative information

7.4 Demonstrate effective interpersonal communication skills.

a. Listen accurately and actively

b. Use psychological concepts and theory to understand interactions with others

c. Identify the impact or potential impact of one's behaviors on others

d. Articulate ideas thoughtfully and purposefully

e. Use appropriately worded questions to improve interpersonal understanding

f. Attend to nonverbal behavior and evaluate its meaning in the communications context

g. Adapt style to communicate sensitively and effectively with diverse ethnic and cultural partners

h. Provide constructive feedback to colleagues in oral and written formats

7.5 Exhibit the ability to collaborate effectively.

a. Work with groups to complete projects within reasonable time frames

b. Solicit and integrate diverse viewpoints

c. Manage conflicts appropriately and ethically

d. Develop relevant workplace skills: mentoring, interviewing, crisis management

GOAL 8: Sociocultural and International Awareness

Recognize, understand, and respect the complexity of sociocultural and international diversity.

Suggested Learning Outcomes

8.1 Interact effectively and sensitively with people of diverse abilities, backgrounds, and cultural perspectives.

8.2 Examine the sociocultural and international contexts that influence individual differences.

8.3 Explain how individual differences influence beliefs, values, and interactions with others and vice versa.

8.4 Understand how privilege, power, and oppression may affect prejudice, discrimination, and inequity.

8.5 Recognize prejudicial attitudes and discriminatory behaviors that might exist in themselves and in others.

8.6 Predict how interaction among diverse people can challenge conventional understanding of psychological processes and behavior.

GOAL 9: Personal Development

Develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

Suggested Learning Outcomes

9.1 Reflect on their experiences and find meaning in them.

a. Identify their personal, sociocultural, and professional values

b. Demonstrate insightful awareness of their feelings, emotions, motives, and attitudes based on psychological principles

9.2 Apply psychological principles to promote personal development.

a. Demonstrate self-regulation in setting and achieving goals

b. Self-assess performance quality accurately

c. Incorporate feedback for improved performance

d. Purposefully evaluate the quality of their thinking (metacognition)

9.3 Enact self-management strategies that maximize healthy outcomes.

9.4 Display high standards of personal integrity with others.

9.5 Seek input from and experiences with diverse people to enhance the quality of solutions.

GOAL 10: Career Planning and Development

Pursue realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings that meet personal goals and societal needs.

Suggested Learning Outcomes

10.1 Apply knowledge of psychology (e.g., decision strategies, life span processes, psychological assessment, types of psychological careers) when formulating career choices.

10.2 Identify the types of academic experience and performance in psychology and the liberal arts that will facilitate entry into the workforce, postbaccalaureate education, or both.

10.3 Describe preferred career paths based on accurate self-assessment of abilities, achievement, motivation, and work habits.

10.4 Identify and develop skills and experiences relevant to achieving selected career goals.

10.5 Articulate how changing societal needs can influence career opportunities and foster flexibility about managing changing conditions.

10.6 Demonstrate an understanding of the importance of lifelong learning and personal flexibility to sustain personal and professional development as the nature of work evolves.

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Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations

Preamble. Research collaborations that cross national, institutional, disciplinary and sector boundaries are important to the advancement of knowledge worldwide. Such collaborations present special challenges for the responsible conduct of research, because they may involve substantial differences in regulatory and legal systems, organizational and funding structures, research cultures, and approaches to training. It is critically important, therefore, that researchers be aware of and able to address such differences, as well as issues related to integrity that might arise in cross-boundary research collaborations. Researchers should adhere to the professional responsibilities set forth in the *Singapore Statement on Research Integrity*. In addition, the following responsibilities are particularly relevant to collaborating partners at the individual and institutional levels and fundamental to the integrity of collaborative research. Fostering the integrity of collaborative research is the responsibility of all individual and institutional partners.

Responsibilities of Individual and Institutional Partners in Cross-Boundary Research Collaborations

General Collaborative Responsibilities

1. Integrity. Collaborating partners should take collective responsibility for the trustworthiness of the overall collaborative research and individual responsibility for the trustworthiness of their own contributions.
2. Trust. The behavior of each collaborating partner should be worthy of the trust of all other partners. Responsibility for establishing and maintaining this level of trust lies with all collaborating partners.
3. Purpose. Collaborative research should be initiated and conducted for purposes that advance knowledge to the benefit of humankind.
4. Goals. Collaborating partners should agree at the outset on the goals of the research. Changes in goals should be negotiated and agreed to by all partners.

Responsibilities in Managing the Collaboration

5. Communication. Collaborating partners should communicate with each other as frequently and openly as necessary to foster full, mutual understanding of the research.
6. Agreements. Agreements that govern collaborative research should be understood and ratified by all collaborating partners. Agreements that unduly or unnecessarily restrict dissemination of data, findings or other research products should be avoided.
7. Compliance with Laws, Policies and Regulations. The collaboration as a whole should be in compliance with all laws, policies and regulations to which it is subject. Collaborating partners should promptly determine how to address conflicting laws, policies or regulations that apply to the research.
8. Costs and Rewards. The costs and rewards of collaborative research should be distributed fairly among collaborating partners.
9. Transparency. Collaborative research should be conducted and its results disseminated transparently and honestly, with as much openness as possible under existing agreements. Sources of funding should be fully and openly declared.
10. Resource Management. Collaborating partners should use human, animal, financial and other resources responsibly.
11. Monitoring. Collaborating partners should monitor the progress of research projects to foster the integrity and the timely completion and dissemination of the work.

Responsibilities in Collaborative Relationships

12. Roles and Responsibilities. Collaborating partners should come to mutual understandings about their roles and responsibilities in the planning, conduct and dissemination of research. Such understandings should be renegotiated when roles or responsibilities change.
13. Customary Practices and Assumptions. Collaborating partners should openly discuss their customary practices and assumptions related to the research. Diversity of perspectives, expertise and methods, and differences in customary practices, standards and assumptions that could compromise the integrity of the research should be addressed openly.
14. Conflict. Collaborating partners should seek prompt resolution of conflicts, disagreements and misunderstandings at the individual or institutional level.
15. Authority of Representation. Collaborating partners should come to agreement on who has authority to speak on behalf of the collaboration.

Responsibilities for Outcomes of Research

16. Data, Intellectual Property and Research Records. Collaborating partners should come to agreement, at the outset and later as needed, on the use, management, sharing and ownership of data, intellectual property, and research records.
17. Publication. Collaborating partners should come to agreement, at the outset and later as needed, on how publication and other dissemination decisions will be made.
18. Authorship and Acknowledgement. Collaborating partners should come to agreement, at the outset and later as needed, on standards for authorship and acknowledgement of joint research products. The contributions of all partners, especially junior partners, should receive full and appropriate recognition. Publications and other products should state the contributions of all contributing parties.
19. Responding to Irresponsible Research Practices. The collaboration as a whole should have procedures in place for responding to allegations of misconduct or other irresponsible research practice by any of its members. Collaborating partners should promptly take appropriate action when misconduct or other irresponsible research practice by any partner is suspected or confirmed.
20. Accountability. Collaborating partners should be accountable to each other, to funders and to other stakeholders in the accomplishment of the research.

The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations was developed as part of the 3rd World Conference on Research Integrity, 5-8 May 2013, in Montréal, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries or organizations that funded or participated in the Conference.

AMERICAN PSYCHOLOGICAL ASSOCIATION

The APA Guide to College Teaching

Essential Tools and Techniques Based on Psychological Science

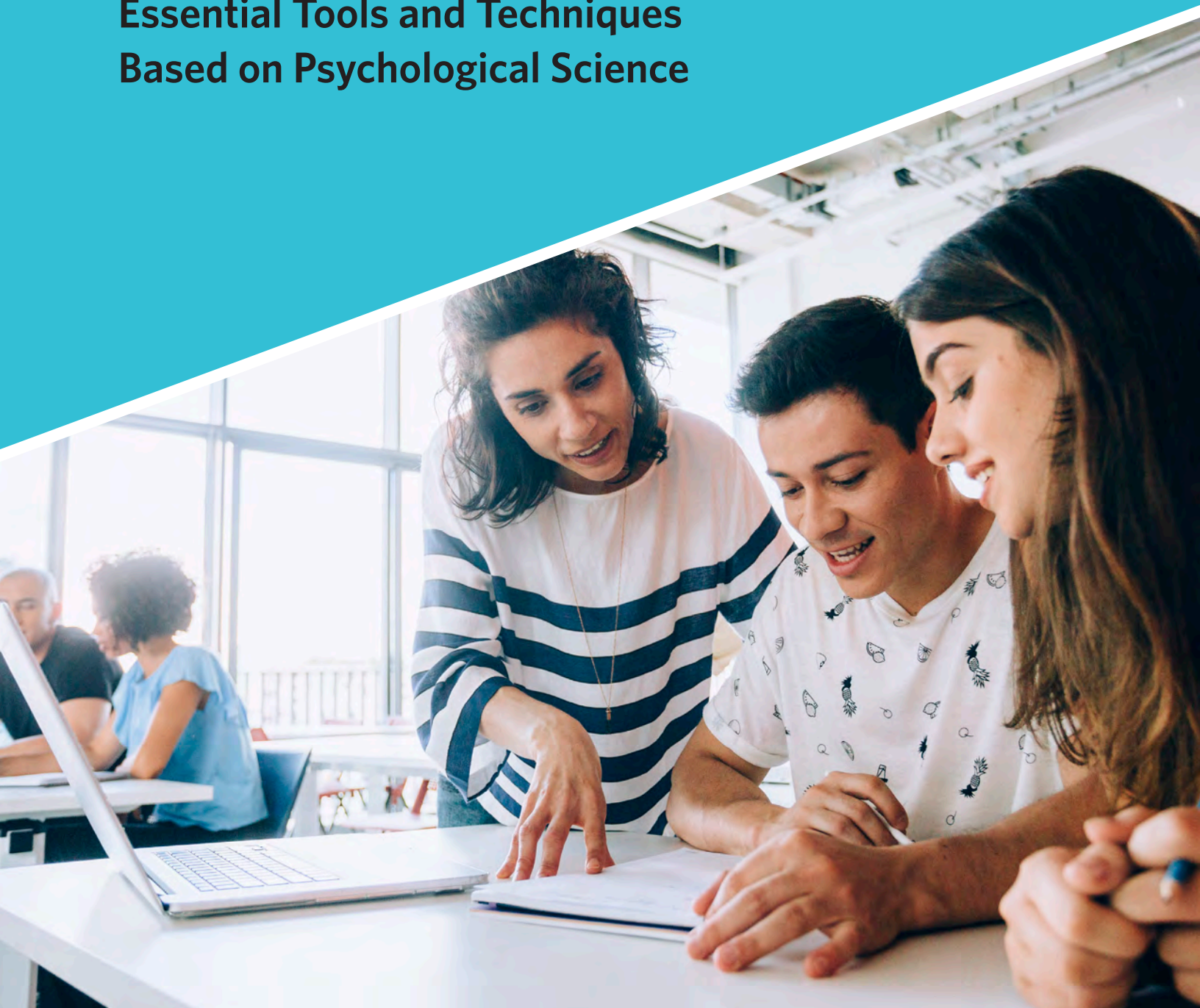

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ACKNOWLEDGEMENT

The task force patterned our work on the framework developed in the *Top 20 Principles from Psychology for PreK-12 Teaching and Learning* (accessible at http://www.apa.org/ed/schools/cpse/top-twenty-principles.pdf) by the APA Coalition for Psychology in Schools and Education (2015). Accordingly, many of the concepts included within the *APA Guide for College Teaching and Learning* were derived from that original work. Through the *APA Guide to College Teaching and Learning,* we sought to extend these contributions by describing some of the major concepts that are particularly relevant to instructors in higher education.

The task force would like to thank CABE and APA for supporting our work. Specifically, we extend our sincere gratitude to Martha Boenau and Robin Hailstorks for their leadership and support, and Rhea Smith for her assistance with copy editing the final document.

The APA Guide to College Teaching

Essential Tools and Techniques Based on Psychological Science

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Introduction

Research from psychological science can tell us a great deal about how to enhance our teaching and learning in the classroom. Because translation of the science to education is so important, various groups have created reports indicating how the science can be used in a variety of classroom settings. For example, the Institute of Education Sciences created a practice guide explaining how cognitive science can be used to improve instruction and studying (Pashler et al., 2007). And, in 2015, the American Psychological Association (APA) Coalition for Psychology in Schools and Education published *Top 20 Principles from Psychology for PreK-12 Teaching and Learning* (accessible at http://www.apa.org/ed/schools/cpse/top-twenty-principles.pdf). The report identifies 20 important principles from psychological science that can be applied in the preK-12 classroom to improve teaching and learning, including issues related to student thinking and motivation, social context, and classroom management. These principles have implications for effective instruction, classroom environments that promote learning, social interactions between teacher and student, student motivation, and the use of assessment.

Psychological science has much to offer to improve teaching and learning in higher education as well. While many of the recommendations appearing in recommendation guides such as the IES practice guide and the APA Top 20 Principles for PreK-12 teaching guide translate to adult learners in higher education settings, a complete and practical compilation of the ways in which psychological science can be utilized to promote learning specifically in higher education, including issues related to the way students process information, social context, classroom management, and even food security and homelessness, does not yet exist. To provide the greatest assistance for people working in higher education, the Committee on Associate and Baccalaureate Education (CABE) created a task force to create such a guide. Here, we identify 21 ways that instructors can implement concepts from psychological science that would be of the greatest use to those in higher education settings.

The CABE task force is an ideal group to translate the research from psychological science to develop this guide. The group represents a diverse group of individuals who teach in a range of higher education settings from community colleges to university settings, and many conduct research in higher education settings. The group also comes from a diverse range of sub-disciplines within psychology, with deep roots in studying and working in such areas as cognition and the science of learning, impacts of diversity and intersectionality on teaching and learning, human development, service learning, and experiential learning.

APA is dedicated to providing support from psychological science to education at all levels. For more resources on education, visit www.apa.org/ed/schools/coalition/index.

METHODOLOGY

This report was inspired primarily by the *Top 20 Principles from Psychology for PreK-12 Teaching and Learning* report published by the APA Coalition for Psychology in Schools and Education in 2015. In developing this work, the members of the CABE task force began by reviewing the 20 principles from the preK-12 report. Their original 20 principles were derived by having members identify kernels from psychology that they felt could be applied to preK-12 education (Embry & Biglan, 2008), and then were clustered and synthesized into the 20 most important principles. We began by carefully examining their 20 principles. We then determined whether each concept presented was relevant or could be relevant for college teaching. We considered whether there was research to support the use of these concepts with adult learners in college contexts in addition to the literature cited within the preK-12 report. Relevant concepts were carried forward for this report and rewritten to better reflect teaching and learning in higher education. Next, we identified other concepts relevant to college teaching and learning.

At this stage, we had identified 21 concepts that were highly important for college teaching and learning. The task force then created recommendations for instructors teaching in higher education, with one concept presented in each chapter. Each chapter begins with a bulleted list of ways that instructors can use the concept to promote learning and student success in their classrooms. Then, for each concept, we explain why this concept is important and some of the psychological science research backing each concept.

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How Our Students Think and Learn

- What our students believe affects how they think and learn.
- Our students' prior knowledge affects their learning.
- Retrieval practice helps our students learn.
- Choose appropriate tools for learning; newer is not always better.
- Transfer of learning to new situations, problems, and contexts is not spontaneous, but instead needs to be practiced.
- Knowledge and skill acquisition depend largely on deliberate practice.
- You can enhance students' learning by giving timely feedback that transforms evaluations into learning opportunities.
- Self-regulatory skills can be learned! And they contribute to further learning.
- We can encourage student creativity.

Motivating Our Students

- Motivating our students intrinsically is more effective than trying to motivate them extrinsically.
- Helping our students adopt mastery goals will make them more persistent and encourage deeper information processing than if they have performance goals.
- What we believe about our students and expect from them affects their learning opportunities, motivation, and learning outcomes.
- Our students should set both near-term and far-future goals

The Importance of Social Context, Interpersonal Relationships, and Emotional and Physical Well-Being

- Learning is situated within multiple social contexts.
- Interpersonal interactions in the classroom can foster learning.
- Students' performance, learning, and development are influenced by their emotional well-being.
- Students suffering from homelessness, food insecurity, and poverty require special support.

Managing Our Classrooms

- We must teach new students to adhere to basic standards of classroom behavior using direct instruction and the principles of behavioral learning.
- Classroom management is a form of mentoring.

Assessing Students' Progress

- We should use both formative and summative evaluation appropriately.
- We must be careful to use fair, high-quality assessments to measure students' skills, knowledge, and abilities.

How Our Students Think and Learn

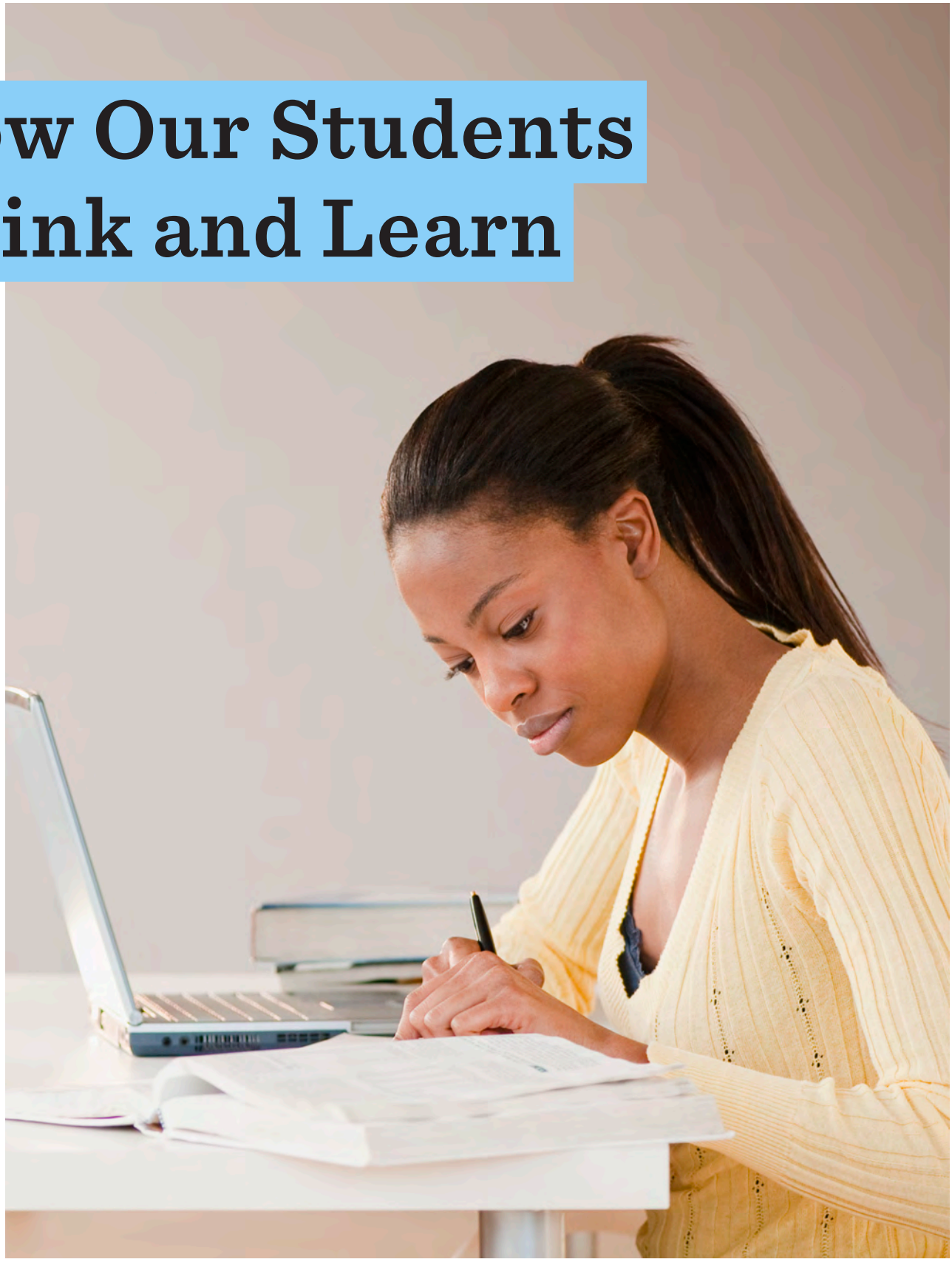

What Our Students Believe Affects How They Think and Learn.

Mindsets matter. What students believe about intelligence can influence their academic success and resilience. But research demonstrates that it's not only possible to foster a growth mindset among students, it's important to teach growth mindset alongside proper study skills to help them succeed. When we convey to our students that their poor performance is a result of factors under their control, such as lack of effort or poor strategy, we empower them to improve their future performance.

Help foster your students' beliefs that they can enhance their intelligence by applying the following strategies:

- Help students understand that failing at a task does not mean a lack of ability, and that learning any given skill takes time and effort. Immediate mastery of a task does not equal durable, long-term learning.
- While effort is important, you should emphasize to your students that they must combine their efforts with the right strategies to achieve success in any given task. When students fail at a task, find out how they approached the task and guide them through the use of more effective strategies for future success.
- Avoid attributing students' success to natural ability, such as praising a student by saying "You're so smart," especially when the task is moderately easy. Instead, praise students for their effort or for their successful use of strategies.
- Develop assignments that provide opportunities for students to build on their skills.
- Encourage a growth mindset among students by explicitly teaching them that during durable learning, the brain is developing new connections among neurons, and that research has shown that this results in better academic performance in the long-term.

WANT TO LEARN MORE?

Some people believe that we're born with the intelligence that we have, that it's a fixed trait. Students who adhere to this "fixed" or "entity" theory of intelligence tend to worry about hiding any evidence that their skills are lacking. They prefer to take on easy rather than challenging tasks in order to avoid failure, and when they do fail, they tend to attribute it to a lack of ability and give up on the task. This, in turn, undermines their immediate motivation and short- and long-term performance.

On the other hand, some people believe that we can improve our levels of intelligence through effort. Students who adopt this "incremental" or "growth" mindset enjoy taking on challenging tasks in order to boost their intelligence or ability. When they fail, they tend to attribute the failure to factors that they can control, such as insufficient effort or choosing a bad strategy. Because of this, they bounce back quickly after failure and are motivated to keep trying. As a result, these students tend to do better on various cognitive and problem-solving tasks.

Your own mindset also matters. Instructors who believe that intelligence is fixed may be more prone to tell students who struggle in a particular subject area that it isn't their "strength," or may praise high-performing students as "smart." Unfortunately, these messages promote the belief that intellectual ability is fixed, unchangeable, and uncontrollable. Ironically, this belief can undermine students' resilience after failure. On the other hand, instructors who have a growth mindset praise students for taking on challenging tasks or for trying different strategies to succeed on a task. This type of feedback suggests to students that seeking out challenge is a great way to learn and that struggling is a normal part of the learning process. Often the most effective ways to learn involve difficulty, and this difficulty should be embraced rather than avoided. When learning feels very easy, it is often a sign that learning is not durable and will be rapidly forgotten.

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Our Students' Prior Knowledge Affects Their Learning.

Students arrive to college with a variety of beliefs, knowledge and skills gained from their previous academic and life experiences, and cultural backdrops. These previous experiences and background knowledge influence how they organize and interpret new information, what and how they learn.

Here are some ways you can leverage prior knowledge in your classroom:

- Use baseline assessments to gauge students' current knowledge. Use a formative pre-test at the beginning of a course, unit or lesson, or more informal assessments such as questioning and brainstorming at the beginning of a new topic.
- Help students activate prior knowledge by asking them questions that trigger recall, using prompts and reminders, or by incorporating activities that help them connect what they already know to the new content.
- Help students become aware when prior knowledge is (or is not) applicable by:
    - Explicitly teaching the conditions and contexts in which knowledge is applicable;
    - Using analogies to help students relate new content to previous knowledge and experiences while making them aware of the limitations of these analogies; and
    - Using concrete examples to illustrate abstract concepts.
- Use a variety of strategies to encourage change in students' misconceptions. For example, instructors can use:
    - Bridging, a "gradual process of reasoning that helps [students] build on accurate facets of their knowledge as they gradually revise the inaccurate facets";
    - Activities that promote cognitive conflict or dissonance;
    - Presentations to students with actual data that challenge students' misconceptions; or
    - Student data collection on topics that will challenge their existing misconceptions.

WANT TO LEARN MORE?

Although students' prior knowledge is fundamental for the acquisition of new and more complex knowledge and its retention in memory, its role in learning is paradoxical. When prior knowledge is appropriate, consistent, and accurate, it aids learning. This knowledge facilitates learning by acting as "mental hooks" where new information anchors. Other times, students' prior knowledge might be insufficient, inappropriate, or inaccurate. In these instances, prior knowledge can thwart the acquisition of new knowledge or even distort it. Misinformation and misconceptions can interfere with new knowledge acquisition. Misconceptions, "models and theories that are deeply embedded in students' thinking" are highly resistant to change (e.g., stereotypes about groups), and thus harder to address. Changing students' misconceptions requires time, repeated exposure and ingenuity, and as such requires intentional, careful planning and numerous experiences that lead to the accommodation of previous schemas.

You can significantly increase students' opportunities for learning. Dedicate instructional time to assess students' background knowledge; activate their prior knowledge and experiences to help them make connections with new knowledge and skills and to help them retain new information; and plan activities and experiences to address knowledge gaps and misconceptions that might conflict with the course goals and content to prevent detracting from learning.

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Retrieval Practice Helps our Students Learn.

Retrieval practice, or bringing information to mind from memory, can be extremely beneficial for student learning. Retrieval practice helps students become more flexible with the material so that they can apply it in new situations, and retrieval practice produces learning in the long-term.

Here are some ways that you can use retrieval practice in your courses to help improve student learning:

- Give students frequent tests or quizzes in the classroom to improve learning.
- Design quiz questions that require the students to apply what they know in new situations or show they understand a concept more deeply, in addition to questions that ask about facts.
- Space multiple retrieval opportunities out over time for even more benefit.
- Use technology to help provide quizzes. Most class management systems can administer quizzes that students can complete on their own at home. There are also many free quiz apps that you can use in the classroom (though see the chapter about technology).
- You don't always have to grade every question that your students answer. Your objective is to create opportunities for students to retrieve the information. If you're using a format that is harder to score (e.g., short-answer questions), you can have students self-score the answers, or even have them switch with a partner.
- Use activities that encourage retrieval, such as drawing, creating concept maps, or explaining ideas to peers. These activities will require retrieval practice, but in a non-traditional test environment.

WANT TO LEARN MORE?

Historically, people have thought of tests and quizzes as ways to assess learning. Certainly, they can be used for assessment, and later in this document we discuss the importance of assessment. However, a great deal of research shows that students actually learn from the process of taking the test or quiz. When students answer questions on a quiz or a test, they are practicing retrieval, or bringing information to mind. Retrieval practice has been shown to improve learning. When students retrieve information, they are better able to remember the information later on. Retrieval practice helps students learn facts, but it also helps students learn conceptual information, and improves their ability to apply the information in new situations. There's even some evidence that open-book quizzes can help students learn too! However, students should work their way up to being able to retrieve the answers on their own. Students will get an even larger learning benefit when they practice retrieval repeatedly, and space repetitions out over time.

Practicing retrieval can also help students indirectly. Answering questions can help students learn what they know and don't know, which might allow them to allocate their study time more efficiently. Students are often overconfident in what they know and don't know, but retrieval practice reduces some of their overconfidence, highlighting what they need to study more. Providing frequent opportunities for retrieval practice can also motivate students to attend class. When students know that there will be frequent quizzes in a class, they are often more likely to come to class, and thus will at least be exposed to the material more than students who don't come to class. Finally, providing students with frequent questions can give the instructor feedback about how well they are teaching certain concepts. If a vast majority of students don't understand a given idea, instructors can use this information to inform their future teaching, and how they might reteach the idea to that class.

There are a number of ways that instructors can encourage students to practice retrieval in their classes. The most obvious is the use of frequent quizzes using short-answer or multiple-choice questions. Research has shown that both types of questions benefit student learning. Multiple-choice questions can be just as beneficial as short-answer questions, so long as the questions help the students to bring the appropriate information to mind.

A great deal of research shows that students actually learn from the process of taking the test or quiz.

However, retrieval-based learning activities don't necessarily need to involve a test or quiz. Recall that they actually just need to require students to retreive, or to bring the information to mind. Other ways to encourage students to practice retrieval include asking students to create concept maps from memory. A concept map is a graphic organization of ideas, much like a flowchart (see this website: bit.ly/concept-maps-resource). To create a concept map, students put concepts in circles and then connect appropriately related concepts with links describing the relationships among them. Instructors can also ask students to draw what they know in other formats (for example, see this website for ideas: bit.ly/vee-diagrams-resource), or even explain ideas to one another.

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Choose Appropriate Tools for Learning; Newer is not Always Better.

The way we teach and learn is constantly evolving. Instructors are often suspicious of the newest techniques appearing in our toolboxes. But even lecturing was once a new technology. Instructors have been suspicious of all sorts of new tools, such as the overhead projector or the slide rule. Current and emerging technologies, such as e-books, classroom response systems (such as clickers or students' own smartphones), laptop computers, and tablets continue to be present in our classrooms. And still others, such as lecture capture systems, online adaptive systems, learning management systems, cloud-based applications such as Dropbox or Evernote, social media, and virtual environments such as Second Life might be used in conjunction with our classes, or might even one day replace them. It's difficult to determine the best approaches to use with these technologies, let alone whether the technologies themselves are of any real value for our students.

Here are the top things to keep in mind when thinking about new educational technologies:

- Think critically. Is there any credible evidence with regard to their effectiveness?
- Does the technology align with your course objectives, teaching style, and particular subject matter?
- How will the technology help you to become more effective as an instructor?
- What are the possible trade-offs you might have to make if you choose to implement a new technology?
- Do you have the requisite knowledge and skills required to make the most of this new technology?
- Do your students have the requisite knowledge and skills required to make the most of this new technology?

WANT TO LEARN MORE?

The evidence on classroom use of technology is mixed, at best. For example, studies have shown that lecture capture systems may or may not be helpful to students. Importantly, their success depends a great deal on the types of students who will be using the lecture videos.

Technology should be used to aid effective strategies, when appropriate, but is not always necessary. For example, while we know from research in cognitive psychology that frequent quizzing is helpful for learning (see the chapter on retrieval practice), it's difficult to evaluate the actual educational value some of the sophisticated adaptive testing software and course management systems being marketed heavily by educational publishers. Current research shows that these systems may or may not be effective in advancing students' learning above and beyond instructors implementing their own quizzes in the classroom, or they may have marginal effects, again depending on students' use of the systems or

the systems' alignment with course objectives.

Also, as many authors have noted, some forms of technology may distract students from learning. This seems related to researchers' mixed results with regard to the use of computers, tablets, smart phones, or other delivery methods as opposed to paper textbooks for the delivery of information. Some studies have shown that the use of computers for taking notes tends to depress higher-level learning, although not necessarily surface-level learning. However, others have shown that when students use their computers or smartphones in appropriate or directed ways, they tend to learn better.

Some technologies have evidenced great promise when used appropriately. For example, studies have shown that students in various disciplines (especially in foreign language learning) can learn well when immersed in environments such as Second Life, and encouraged to interact and work collaboratively with other students. But even here, there are drawbacks and problems with regard to students becoming immersed in their roles, having difficulty understanding the parameters of the exercise, and not having enough background to be able to engage in the necessary processes.

Researchers have found that in order to make the most of the new technologies, students need a particular set of skills and attributes. Of these, the most important seem to be self-direction, self-efficacy, self-control, students' depth of approach to learning, and some degree of digital literacy.

Studies have shown that students in various disciplines (especially in foreign language learning) can learn well when immersed in environments such as Second Life, and encouraged to interact and work collaboratively with other students.

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Transfer of Learning to New Situations, Problems, and Contexts is not Spontaneous, but Instead Needs to be Practiced.

"Transfer" is the holy grail of education. We want students to be able to use the knowledge they acquire in class in novel situations. But learning happens within the context of a specific subject, scenario, or setting. For example, you could learn about gravity as a child sitting on a parent's lap reading a book, or you could learn about it from a video, or in a classroom doing an exercise from a textbook. Scaffold students' use of knowledge from contexts that are highly similar to the original learning context, and eventually to new, dissimilar and unfamiliar contexts.

Here are some ways to encourage transfer:

- Teach topics or concepts in multiple contexts.
- Give students many opportunities to practice transferring information learned in one context to another.
- Draw students' attention to the features that make different contexts relevant to each other and thus appropriate for transfer.
- Help students identify contextual differences that make transferring from one situation to another less helpful.
- Provide many different concrete examples and counter-examples of studied concepts.
- Ask students to make up their own examples that illustrate concepts they are learning about.
- Help students distinguish between irrelevant surface features and deep underlying features of concepts.
- Encourage students to notice how the knowledge they are acquiring applies to the real world, both by providing real-life examples and by encouraging students to generate their own.
- Allow students to demonstrate applying what they've learned in a range of situations.

WANT TO LEARN MORE?

For transfer to occur, three conditions must be met: (1) students must realize that the situation requires them to use certain prior knowledge, (2) students must remember that prior knowledge, and (3) students need to successfully apply that prior knowledge to the new situation. Rather than expecting students to automatically transfer something they have learned, instructors should give students ample opportunity to practice applying knowledge to novel and varied situations.

Not all transfer is the same. Some contexts are very similar to one another, while others are quite different. Thus, it is important to distinguish between near transfer and far transfer. Near transfer refers to situations that are very similar to the original learning situation; for example, performing the same set of mathematical operations on a different set of numbers. Far transfer might involve students realizing that the equations they learned in class would apply to solving a novel, and seemingly unrelated problem at work.

While we often talk about "teaching for transfer", what we should actually do is teach transfer itself. Transfer doesn't occur spontaneously. In fact, transfer can also be negative, when skills or information learned in one situation are misapplied to a context where they are not relevant or accurate. As such, negative transfer can actually prevent appropriate learning. Giving students practice transferring to many new contexts or situations that they may experience later can help students learn to transfer and make it more likely that they will realize that they can transfer something they have learned when they need to.

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Knowledge and Skill Acquisition Depend Largely on Deliberate Practice.

Design deliberate practice activities that account for students' current abilities, and encourage students to improve beyond where they are. Because by definition, non-experts aren't knowledgeable enough in the target domain, you'll need to scaffold these deliberate practice activities.

Here are ways to use deliberate practice in your classroom:

- Remind your students that deliberate practice can be hard, but that this difficulty helps their learning (see the chapter on how what our students believe affects their learning).
- Emphasize that "deliberate practice" isn't just another way of saying "practice makes perfect." Merely practicing a lot and putting in a lot of effort are not enough.
- Remind your students that their practice needs to be designed specifically to develop target skills (see the chapter on transfer of learning).
- Ensure that students' practice is spaced over time and not simply massed until mastery.
- Provide feedback to help scaffold deliberate practice activities (see the chapter on timely feedback).

WANT TO LEARN MORE?

We can learn a lot about skill acquisition from the domain of expertise. The main cognitive difference between experts and novices in a particular domain appears to be their mental representations—that is, how they process and store information related to their domain of expertise. For example, expert chess players are able to recognize and remember chess positions and sequences of moves much more efficiently than novice chess players.

Mental representations are shaped through what is known as "deliberate practice." In order for deliberate practice to be applicable to a skill, two conditions should be met: the skill should be one in which there is a relatively established benchmark for what counts as expertise, and there must be an instructor who can carefully guide and scaffold the process for the learner. It's important to distinguish between *deliberate* practice and repetitive practice. Repeating a task without deliberately involving attention and spacing out the repetitions may not do much to reinforce learning. To acquire new knowledge and become proficient in basic skills (and, eventually, more complex skills), one must rehearse strategically. This is where the instructor becomes invaluable in helping students distinguish between effective and ineffective practice.

As expertise in a given domain increases, mental representations might evolve from simple storage of unrelated facts to a meaningful and coherent framework. This type of sophisticated mental representation can help the learner determine when they are making errors, and in what deliberate practice they need to engage to correct them.

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You Can Enhance Students' Learning by Giving Timely Feedback that Transforms Evaluations into Learning Opportunities.

Our role as instructors is to facilitate students' learning, and assessment is an integral component of that facilitation (see the last section of this booklet). Evaluations that provide feedback that informs students about how they are doing and how they can improve can increase their motivation, their learning, and their engagement with the material, and create a more comprehensive learning opportunity. According to some research, formative feedback can transform students' work in ways that help the students to further their own learning. Appropriate formative feedback also can promote and enhance self-regulation.

You can use assessment to create learning opportunities by implementing some principles of good feedback practices:

- Discuss the goals of the course, unit, or assignment with the students, and provide examples of what good and poor responses or performances look like.
- Provide rubrics that provide evaluative criteria at different levels of achievement (though see the chapter on setting goals regarding rubrics).
- Facilitate the development of self-assessment and reflection in learning (e.g., by using rubrics for students' self-evaluation and self-reflection, and for peer review).
- Provide good, meaningful feedback that informs students about how well they are doing and how they can improve.
- Discuss with students the process they used to reach a determined answer rather than just focusing on whether the student "got the right answer."
- Allow students to use your feedback to modify their work or responses to a test (e.g., use an iterative process of work resubmission for written assignments, so that students receive feedback that helps them construct better work, or allow students to work on wrong multiple-choice items by resubmitting them with explanatory answers for some additional points).
- Provide timely feedback. Consider whether to give immediate feedback to help reduce faulty conclusions or misunderstanding, or allow more time to encourage self-reflection and self-correction. Remember that timely feedback helps reduce student stress and can enhance their engagement with the course. (i.e., students who have to wait for a long time for feedback tend to feel more negatively about the assignment and, by extension, the course).

WANT TO LEARN MORE?

Feedback works best when it is timely, targeted, and specific. Immediate feedback works best when students are learning new and complex concepts or procedural skills, as it helps reduce the risk of learning misconceptions or faulty procedural skills by allowing students to correct erroneous responses. Other times, when students are expanding their knowledge or applying it, purposefully delaying feedback allows some time for students to self-correct which can increase self-regulation, persistence, and self-confidence. In addition, meaningful feedback works best when it addresses the gap between students' current levels of performance and the targeted learning goals and expectations of the learning situation. Finally, feedback works best when it is specific. Generic evaluative labels, or grades that simply represent "how well" students performed don't tell students what they did wrong or what they need to do to improve; plus, they promote a performance rather than a learning orientation (see the chapter on helping our students adopt mastery goals).

Timely, meaningful feedback can also help students further develop introspective consideration of their own thought processes (metacognition), self-regulation, and critical thinking.

Timely, meaningful feedback can also help students further develop introspective consideration of their own thought processes (metacognition), self-regulation, and critical thinking. Researchers have argued that formative feedback in higher education should focus on empowering students as self-regulated learners. It is also important to note that while it is certainly necessary to highlight deficits in a student's work, the way in which those deficits are framed can transform an evaluation into a constructive opportunity for growth and improvement. However, when students feel that their work has been comprehensively derogated by an instructor, it can reduce motivation and disrupt engagement.

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Self-Regulatory Skills can be Learned! And They Contribute to Further Learning.

Self-regulation, or guiding one's own learning process, is an important skill for students in higher education to master. More so than in primary and secondary education, college and university students need to be able to manage more flexible schedules and determine how much time to spend reading, studying, and working on assignments outside of class; engaging in independent study; and seeking out help when they need it.

Here's how you can use a variety of strategies to help your students learn self-regulatory skills and greatly facilitate learning:

- Model self-regulatory skills by:
  - Thinking out loud to demonstrate thinking and problem-solving skills in their domains or to demonstrate the steps needed to solve a specific task;
  - Showing different ways to organize information for meaningful learning (e.g. concept maps, V-diagrams); and
  - Taking time to show students how they approach readings and what they consider important.
- Teach and provide opportunities to practice:
  - Specific strategies for learning and thinking about course content;
  - Different strategies to help organize course content in meaningful ways (e.g. concept maps or other graphic organizers); and
  - Teach effective independent learning strategies, and allow students to practice and reflect upon their effectiveness and their difficulty.
- Support students' self-regulated learning efforts by helping students:
  - Set meaningful goals for your classes and provide them with opportunities to reflect on how the course material can be useful to them;
  - Recognize and self-assess the short- and long-term implications of the decisions they make;
  - Reflect on their approaches to mastering a learning task (e.g. exam preparation, use of strategies and performance) and to consider ways to better approach next learning challenges; and
  - Recognize desirable difficulties that improve durable learning, rather than produce immediate mastery that will soon be forgotten.

- Organize the classroom environment to enhance self-regulation by:
  - Clearly stating lesson goals and tasks;
  - Breaking up lectures with questions that promote thinking and reflecting on the material;
  - Providing processing time and practice (such as summarizing, questioning, retrieval practice, etc.) for long-term remembering;
  - Introducing new material by tapping into students' previous knowledge (such as linking new material to material learned in previous courses or using analogies and multiple concrete examples);
  - Assigning reading reflections to help students with self-monitoring and reflective thinking, and to encourage retrieval practice; and
  - Clearly spelling out the criteria for successful task performance.

For more information see Svinicki and McKeachie (2014). They dedicate an entire chapter to strategies on how to teach learners to become more strategic and self-regulated learners.

Instructors can help students develop self-regulation skills through direct instruction, modeling, support and by providing classroom organization and structure.

WANT TO LEARN MORE?

Zimmerman (2002) defines self-regulation as the "self-directive process by which learners transform their mental abilities into academic skills" (p. 65). Self-regulated learners actively set task-related, doable goals; deliberately select and use cognitive and motivational strategies to achieve those goals; monitor their strategy use; and modify their strategies when needed, based on task demands. Instructors can help students develop self-regulation skills through direct instruction, modeling, support and by providing classroom organization and structure.

One aspect of self-regulation is making decisions about what to do while guiding one's own independent learning. It should be noted that students' intuitions about what helps them learn are often inaccurate. For example, repeated reading is a common strategy reported by students during independent learning; often students are overconfident in the amount they are learning while repeatedly reading their course materials. On the other hand, few students report engaging in retrieval practice (for example, self-quizzing), an effective study strategy that often makes learning feel slower. (For more on this, see the chapter on retrieval practice) Effective learning strategies are often difficult, and students need to be taught that these difficulties are desirable.

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We Can Encourage Student Creativity.

"The formulation of a problem is often more essential than its solution, which may be merely a matter of mathematical or experimental skill. To raise new questions, new possibilities, to regard old problems from a new angle requires creative imagination and marks real advances in science." – Albert Einstein.

In addition to learning content, students need to learn to think critically and creatively. Here are some ways you can encourage creative thinking in your courses:

- Remain open to creative responses from students to increase creative thinking. Bear in mind that environmental factors can affect students' creativity. These may include the general atmosphere of the class, the time permitted for creative thinking, the kinds of materials available, and even the design and layout of the classroom, among many other things.
- Encourage creative thinking by using learning activities that help students practice visualizing problems. There is a link between visualization and creativity, where those who are better able to visualize are problem are more likely to come up with creative solutions.
- Encourage diverse perspectives in the classroom. Research shows prolonged interactions with diverse ways of thinking (e.g., interactions with people from multiple countries or backgrounds) improve creativity.
- Don't expect creativity to be omnipresent. Creative ideas take deliberate thinking. In fact, often times taking a break from a problem or task can help students move away from "dead-end" solutions and come up with creative solutions to a problem. Be sure your students understand this point, as well.
- Foster intrinsic motivation in the classroom. Creativity is more likely to occur when students are intrinsically motivated to complete a task (see the chapter on intrinsic motivation). Helping students to find areas of study that they love and classes that they enjoy should increase creative thinking.
- Provide low-stakes assignments to foster students' creativity. Concentration on extrinsic reward structures, such as grades, token economies, or financial gain, can undermine intrinsic motivation. Time limits or knowing one's work will be judged can undermine intrinsic motivation, so low-stakes or even no-stakes assignments can be helpful.
- Don't lose your focus on transmitting knowledge as well as encouraging students to question what they are learning. Students still need to have a sound knowledge base to creatively apply what they know in new situations.

WANT TO LEARN MORE?

In our 21st century world there are constant changes in technology and science. Further, as we continue to become more and more specialized in our areas of expertise, the need for interdisciplinary work increases. Thus, our students need to be creative to continue propelling society forward. Creative ideas are those that are both novel and appropriate in the context. In many ways, creative thinking overlaps with critical thinking, which involves conceptualizing, applying, analyzing, or evaluating information with an unlimited number of solutions. Creativity plays a central role in today's organizations, and creative thinking is linked to improved student performance at the college level. Importantly, instructors can enhance creativity in their higher education classrooms.

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Motivating Our Students

Motivating Our Students Intrinsically is More Effective Than Trying to Motivate Them Extrinsically.

Motivation is the drive or energy that moves people to engage and persist in certain behaviors. Conceptually speaking, there are two types of motivation: intrinsic and extrinsic. In academic settings, intrinsic motivation refers to goal-directed actions students engage in because these tasks are inherently interesting and enjoyable. Extrinsic motivation, on the other hand, refers to students' actions that are driven by obtaining an external reward (e.g. grades or praise) or to avoid punishment. When students are intrinsically motivated, they tend to experience better outcomes.

You can encourage intrinsic motivation in your students by incorporating of practices and activities that support their fundamental needs for *competence*, *autonomy*, and *relatedness*:

- Monitor the messages you send to students about their grades and GPA. Instructors who connect grades and GPA to students' future success (e.g., "You need to maintain a 3.5 GPA in order to pass this class", "You won't become a teacher if you don't get your grades up") may decrease intrinsic motivation and activate threat anxiety. Instructors who connect grades and GPA to the benefits for students' learning and mastery (e.g., "Doing well in this course means that you've learned what it takes to be a great teacher", "Students who master the teaching skills in this course will get high grades") can bolster students' intrinsic motivation and recognize the extrinsic benefits of success in a way that preserves students' autonomy and control.
- Involve your students in course decision making to enhance their empowerment, engagement, and intrinsic motivation. Try integrating student feedback into the learning goals of the course by asking them what "big questions" they have for the course and what problems they want to solve. For example, in his "Blank Syllabus" approach, Walsh assigns students the task of selecting course readings from an anthology. Faculty across disciplines have reported positive outcomes from collaborative syllabi created through an interactional dialogue between faculty and students.
- You can also promote student autonomy by offering a variety of assignments (beyond exams) so that your students can select assessments that match their strengths and learning competencies. The high-impact educational practices designated by the Association of American Colleges and Universities (AAC&U) offer a menu of options that reflect higher-order learning skills that have additional benefits of promoting creativity (see the chapter on creativity) and reducing cheating behaviors. Examples of these practices include service/community-based learning, writing-based assignments, internships, global learning/study away, and collaborative learning projects.
- Praising students and providing positive feedback, although regarded as extrinsic motivation, can bolster intrinsic motivation when you offer them specifically and sincerely. Disingenuously praising students for performance (i.e., leading students to believe their performance was better than it actually was) or for their effort (e.g., commending students for working hard when they really didn't) backfires. Students engage in more goal-directed behavior when instructors convey that they have high standards, that their feedback will help students meet those standards, and that they believe students can meet those standards.

WANT TO LEARN MORE?

Overall, the most effective college instructors are not those that wield their intellect and power *over* their students, but develop a sense of competency and agency *within* their students. Instructors who convey openness in their relationships with students and classroom atmosphere will naturally promote intrinsic motivation, self-confidence, and a genuine passion for learning (see the chapter on self-regulation). Psychologically-based needs for autonomy (feelings of control and independence), competence (e.g. mastering knowledge or skills,) and/or relatedness (sense of belonging) drive students' intrinsically motivated actions. Students' efforts are frequently driven by a combination of both internal and external motives. Students might engage in academic tasks because they enjoy the activity or subject matter but also because they want to get a good grade and be praised by others. However, intrinsic, not extrinsic, motivation often correlates with students' learning efforts and success; the benefits of intrinsically motivated task engagement seem to extend far beyond task enjoyment. Intrinsic motivation is associated with less anxiety and more enduring learning, achievement, and perceived competence.

Instructors who convey openness in their relationships with students and classroom atmosphere will naturally promote intrinsic motivation, self-confidence, and a genuine passion for learning.

These learning benefits might result from the way intrinsically motivated students approach learning tasks. For example, these students might attend more closely to instruction, organize information more effectively, or associate new information to what they already know. Moreover, students' self-reports show a positive association between high intrinsic motivation and high levels of self-efficacy and a negative relationship with lower levels of achievement anxiety. By contrast, students who are driven mainly by external rewards, such as getting a good grade, seem to mainly focus their attention on such rewards rather than on mastering the material. Since the reward is the main goal, these students may take shortcuts, such as skimming the reading, taking the easier path where the stakes are not too high or even

cheating. They may even disengage from the learning task once the external rewards are no longer available or not engage at all if rewards (e.g. extra credit) are not offered or are deemed insufficient. In contrast, intrinsically motivated students may dig deeper even if no rewards are offered because mastery is the reward.

In addition to students' individual differences (or learner characteristics), how college instructors structure their classroom environment has impacts on their students' motivation. Some research shows that students who feel a lack of agency and control within their learning environment may be extrinsically driven to perform (for example, to achieve good grades or meet parental expectations) which can inadvertently undermine their autonomy and learning (see the chapter on self-regulation) and promote cheating behaviors in college. Further, instructors who emphasize ability after students have performed a task well (e.g., "you must be very smart") rather than effort (e.g., "you must have worked really hard") can undermine student motivation (See the chapter on students' beliefs about intelligence and ability).

The relationship between intrinsic and extrinsic motivation is complex because intrinsic motivation alone may not be sufficient to promote successful learning. The challenge for college instructors is how to find the appropriate balance between the two types of motivation. Too many external rewards can erode students' drive to learn for mastery. Instructors should invoke extrinsic motivation judiciously in ways that: (a) link the benefits of performance with students' learning and mastery of key skills and knowledge, (b) reward students on the *quality* of their outcomes (not just participation or completion), and (c) remind students of their overarching goals.

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Helping Our Students Adopt Mastery Goals Will Make Them More Persistent and Encourage Deeper Information Processing Than If They Have Performance Goals.

Students bring different goals to the learning context influencing their motivation, engagement, and achievement. Researchers have identified two broad types of goals related to achievement situations: mastery (also called learning or task) goals and performance (also called ego-involved, outcome or ability) goals. Students with mastery goals focus on understanding and growth, the development of new skills and competence. In contrast, students with performance-oriented goals focus on outcomes as a way to validate their abilities, particularly when they perceive their own abilities as low.

You can organize the learning environment in different ways to promote a mastery-approach to goals and help performance-oriented students develop more adaptive achievement strategies:

- Emphasize learning, improvement, and competency rather than focusing on grades, comparison or competition when evaluating student work.
- Provide timely and private feedback that allows students to see their mistakes while at the same time discussing ways to improve. Even better, provide opportunities for them to correct their mistakes.
- Reassure students that mistakes and errors are opportunities to learn and clarify misconceptions rather than reflections of their ability.
- Decrease sharing information and compliments that focus on students' relative ability (e.g. you are so smart; your essay is perfect). Instead, specify what aspects of the work were exceptional and why, so that the student can be replicate them in the future.
- Praise the process, not just the outcome. Even when students don't arrive at a solution, it's important for students to recognize that they took incremental steps to reach the eventual solution. Praising the process emphasizes mastery over performance.
- Your criteria for success should emphasize a comparison of a student's previous performance to their current performance rather than social comparisons. For example, grade on the basis of meeting defined standards rather than on a curve (which bases individual performance on the basis of other students' performance). This will also reduce competition.
- Help students interpret constructive criticism as coaching (that is, as ways to improve their work) rather than evaluation (which would be a referendum on their innate ability). All criticism involves some element of evaluation, but if you explicitly reinforce the notion that evaluation reflects a snapshot of the present time, not of your students' potentials, you can orient your students towards mastery.
- When possible, provide students with some choice and control over assignments and assessments. This will increase their sense of autonomy and motivation.
- Create learning communities or collaborative learning environments because they can promote cooperation and teamwork while minimizing competition and social referencing. These high-impact educational practices promote team-based approaches to problem-solving and interpersonal communication which enable real-life skills for career preparation.
- Be sure to foster intrinsic motivation. Given the strong relationship between intrinsic motivation and mastery goals, such an orientation could also encourage mastery-approach orientations. For example, instructors who promote student autonomy, self-efficacy, and confidence can bolster students' mastery goal orientation as well as intrinsic motivation (see the chapter on fostering intrinsic motivation).

WANT TO LEARN MORE?

Mastery oriented goals facilitate persistence, even when tasks are challenging, and mastery-oriented behaviors that lead to learning new skills or achieving competence in a content area or on a task. Performance-oriented goals lead students to focus on outcomes, using performance as a way to validate their own abilities (especially when they perceive their abilities as low). Having performance-oriented goals may lead students to avoid tasks they deem challenging, or to quit after negative feedback or a low grade. In extreme cases it may lead to feelings of helplessness. According to this framework, students' goals influence how they approach learning contexts. Students may engage in learning tasks to develop competence by learning as much as they can (mastery goals), even if the task is difficult and they confront setbacks along the way; or they may focus on trying to outperform others (performance goals), select easy tasks, or use shortcuts to succeed, with a focus on demonstrating competence. In typical classroom situations—and especially in challenging situations—research has found that students with mastery goals will perform better. Indeed, mastery goals predict better performance, and improvement over time; performance goals—particularly those associated with ability rather than outcome—predict helplessness and poor performance when students believe that success is unattainable.

Reassure students that mistakes and errors are opportunities to learn and clarify misconceptions rather than reflections of their ability.

The effects of students' goals on performance are further qualified by intersections with achievement motivation (i.e., approaching success versus avoiding failure), creating a four-square framework of goal-achievement categories:

1. **Mastery-approach:** desire to achieve personal or task competence
2. **Performance-approach:** desire to achieve competence in comparison to others
3. **Mastery-avoidance:** desire to avoid personal or task failure
4. **Performance-avoidance:** desire to avoid failure in comparison to others

Research supports that these categorical refinements predict academic outcomes differentially, such as study strategies, cognitive processing, and retention. Mastery goals predicted deeper processing, and long-term retention of course material compared to performance-avoidance goals, which predicted surface processing and worse retention and exam performance. Performance-approach goals predicted surface processing yet better exam performance. Mastery- and performance-avoidance goals appear connected to dispositions of fear of failure and low self-determination. Students with mastery-avoidance goals reported feelings of investment and interest in their class although they also reported disorganized studying and anticipatory test anxiety. Elliot and colleagues concluded that performance-avoidance goals had the most negative consequences of the four categories.

Achievement motivation is also directly related to intrinsic motivation. Performance goals predict low intrinsic motivation and mastery goals predict high intrinsic motivation. Mastery goals mediate the relationship between intrinsic motivation and academic performance. This suggests that students' intrinsic desire to learn drives their goal to attain mastery of their course material which, in turn, enables them to perform well academically. Students with performance goal orientations are more likely to cheat than students with mastery motivations.

Mastery goals predicted deeper processing, and long-term retention of course material compared to performance-avoidance goals, which predicted surface processing and worse retention and exam performance.

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What We Believe About Our Students and Expect from Them Affects Their Learning Opportunities, Motivation, and Learning Outcomes.

People are often unaware of their biases. And yet, our biases can change how we teach and how our students learn.

Here are some strategies you can use to ensure that this doesn't become a problem:

- To minimize the effect of existing expectations on student performance, implement procedures that ensure equal treatment of students. For example:
  - Randomly select students to answer questions posed in class (as opposed to inviting or encouraging "higher-performing" students to answer the more challenging questions), ensuring that everyone has a chance to participate equally in class discussions; or
  - Implement the "jigsaw classroom" in which each student is expected to learn and teach a part of the lesson to others in their group.
- Use grading methods that reduce unconscious bias. For instance:
  - Use anonymous grading, objective testing, and grading exams question by question rather than student by student; and
  - For assignments involving potentially subjective evaluation, such as essays or reports, limit bias by using anonymous grading and structured rubrics that facilitate more objective assessment (though see the chapter on setting goals regarding rubrics).
- Employ empirically validated strategies to reduce the impact of stereotype threat.
  - Present tasks as being "gender fair" or "race fair;"
  - Make students' threatened identities less salient by encouraging them to think about their unique qualities, emphasizing social identities that are associated with positive stereotypes (such as reminding female students about to take a math test that they are college students—a group associated with high math performance);
  - Create identity-safe spaces; and
  - Have students affirm important personal values they hold, and promote a growth mindset (see our section on what students believe).
- Give students "wise feedback:"
  - First describe the nature of the feedback (e.g., explaining that the submitted work has not met all the requirements);
  - Next, communicate high expectations for the student; and
  - Finally, reassure students that they have the ability to achieve those high expectations.
- Identify similarities between yourself and your students. The more similarities you find, the more likely you'll be to perceive strong relationships with those students, and the more likely those students are to succeed.

WANT TO LEARN MORE?

Instructors often have expectations about their students' abilities and potential. Having these expectations can bias instructors to seek out information that confirms those beliefs and ignore or dismiss information that contradicts those beliefs (i.e., confirmation bias). Further, instructors' existing beliefs shape how they teach, place students into work groups, formulate learning outcomes, and evaluate their students' knowledge and skills. In short, expectations influence how instructors treat students. For example, when instructors believe that a student is more likely to succeed academically, they offer more emotional support, clearer feedback, more attention, more time, and more learning opportunities. This differential treatment may contribute to widening achievement gaps over time. In effect, instructors can consciously or unconsciously create self-fulfilling prophecies, or realities, based on their expectations of their students.

Where do instructors' expectations about individual student ability come from? They may be based on students' past academic performance or preparation, but they may also derive from explicit or implicit stereotypes about race, gender, socioeconomic status, or disability. Indeed, being in a situation that activates negative stereotypes about a group that students identify with (e.g., African-American students taking an intelligence test or female students taking a math test) can cause students to ruminate about these stereotypes, dwindling cognitive resources that students could use to accurately demonstrate their knowledge and skill. This stereotype threat also can increase students' anxiety, undermine their motivation, and reduce their sense of belonging within an academic institution or within a particular classroom. Thus, instructors' expectations interact with many factors that can influence student success. Some related factors include social contexts that relate to the classroom, students' interpersonal relationships, and students' emotional well-being.

Not only do instructors' expectations affect students' performance and learning, but students' expectations about their instructors' beliefs about their students' potential could also affect student success. Emerging research suggests that students who believe that their instructors embraced a growth mindset about their students' learning of statistics performed slightly but significantly better than students who believed that their instructor had a fixed mindset towards student learning.

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Our Students Should Set Both Near-Term and Far-Future Goals

We know that setting goals can improve motivation, and so our students can benefit from setting goals in the short term and long term. You can do a lot to support a student in becoming a learner who effectively employs goal-setting, including scaffolded activities that encourage the setting of goals during a course.

Here are some ways that you can scaffold goal-setting activities in your classroom:

- Keep a written record of goal progress and check it regularly.
- Organize the written record to display the connections among the goals. Some students may benefit from using web-based tools that support self-regulation of progress through a series of related goals (for example: Nudgemail **www.nudgemail.com** or Trello **www.trello.com**).
- Frame initial goals for new, highly complex tasks as "do your best" goals, and be sure to give frequent and quick feedback on how their performance relates to the criteria being used for assessment. As students come closer to achieving proficiency on that complex task, shift to more specific, measurable language. The more proximal the goal, the more specific the language needs to be.
- Use strategies such as mental-contrasting with implementation intention (more commonly known as Wish, Outcome, Obstacle, and Plan, or WOOP), to help students actively plan strategies for overcoming anticipated obstacles. Check out this **Learning Scientists blog about WOOP** (**www.learningscientists.org/blog/2017/7/4-1**) and this **activity from Character Lab** (**www.bit.ly/woop-for-classrooms**).
- When you provide feedback, be sure to also help scaffold self-assessment in the student reflection process. When you can, give your feedback in a dialogue format, rather than in a rubric. While rubrics are helpful and can be used to guide your own grading, students will often treat the rubric as a checklist, and then fail to engage in deep reflection needed to support learning. Save the rubric for summative assignments rather than formative ones (though see the chapters on timely feedback and what we believe about our students).

WANT TO LEARN MORE?

All of us rely on goal-setting as a way of reaching some desired outcome, and students are no different. Some goals have to do with "today" (e.g., I will learn a dozen key terms in the memory chapter today and be able to give examples), and some are years away (e.g., I want to earn a Ph.D. before I am 30 years old). It's well-known that goals can serve as motivational tools, as long as they are paired with some decent self-regulatory capacity. It's those self-regulatory skills that seem to connect the goal to the outcome. The goal motivates students to reflection which leads to supporting achievement of the goal. Then the self-regulation seems to help the student put those

plans into action. Well thought out student plans connect goals in a contingent fashion, so that they can see the link between learning a dozen key terms today to the ultimate outcome of a Ph.D. years later.

Effective goals tend to include at least three important features. It is helpful first to look at how a "list" of goals really fits together as a set that is linked and sequenced. Although loads of research suggests that the "today" sort of goal (a "proximal" goal) is more effective than the far-future goal (a "distal" goal), the actuality is not that simple. Taken at face value, it suggests that a good student can really only plan for the near-term. But this approach would produce students that have to keep stopping to regroup and plan again after they achieve each goal. That sort of stop-and-start approach wouldn't help student sustain a flow of energy toward an outcome for the long haul. The more helpful way to understand this is that proximal goals are most effective when they provide a contingent link to a more distal goal. Setting proximal goals together with distal goals is developmentally appropriate for adult learners and helps keep energy moving toward both near and far goals.

Once the goals are seen in this sort of sequence and flow, it's good to check if the goal is specific enough to track progress towards it. Students often are great at identifying the general direction they want to go (e.g., "I'm going to do my best in that class!"), but may struggle to articulate the behaviors that are needed to move in that direction (e.g., "I will complete five practice problems in statistics with 80% accuracy"). Pushing learners to make goals specific enough that they articulate the behaviors that need to happen can better help them to put their energy into behaviors that make a difference. This specificity seems especially helpful when tasks are concrete. When tasks get more complex (such as writing an integrative literature review), the broader "do your best" goals may have more value as they shift attention back to the task rather than the more finite performance goals well-suited to specificity.

Pushing learners to make goals specific enough that they articulate the behaviors that need to happen can better help them to put their energy into behaviors that make a difference.

The third critical factor to incorporate into successful student goal setting is feedback. Meaningful feedback will really animate the pursuit of the goal. But what makes feedback meaningful? The most useful feedback to students will happen quickly, frequently, and will be action-oriented. Just telling them what they did wrong doesn't help them re-direct their energy. They need to know what went wrong in real-time, while it still matters to them, and it needs to point them in a better direction. This is another reason contingent goals can be so helpful. Students will really appreciate having a chance to respond to feedback with corrective action in future, contingent assignments that help them see how past failures to achieve a goal link to their current learning experiences.

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The Importance of Social Context, Interpersonal Relationships, and Emotional and Physical Well-Being

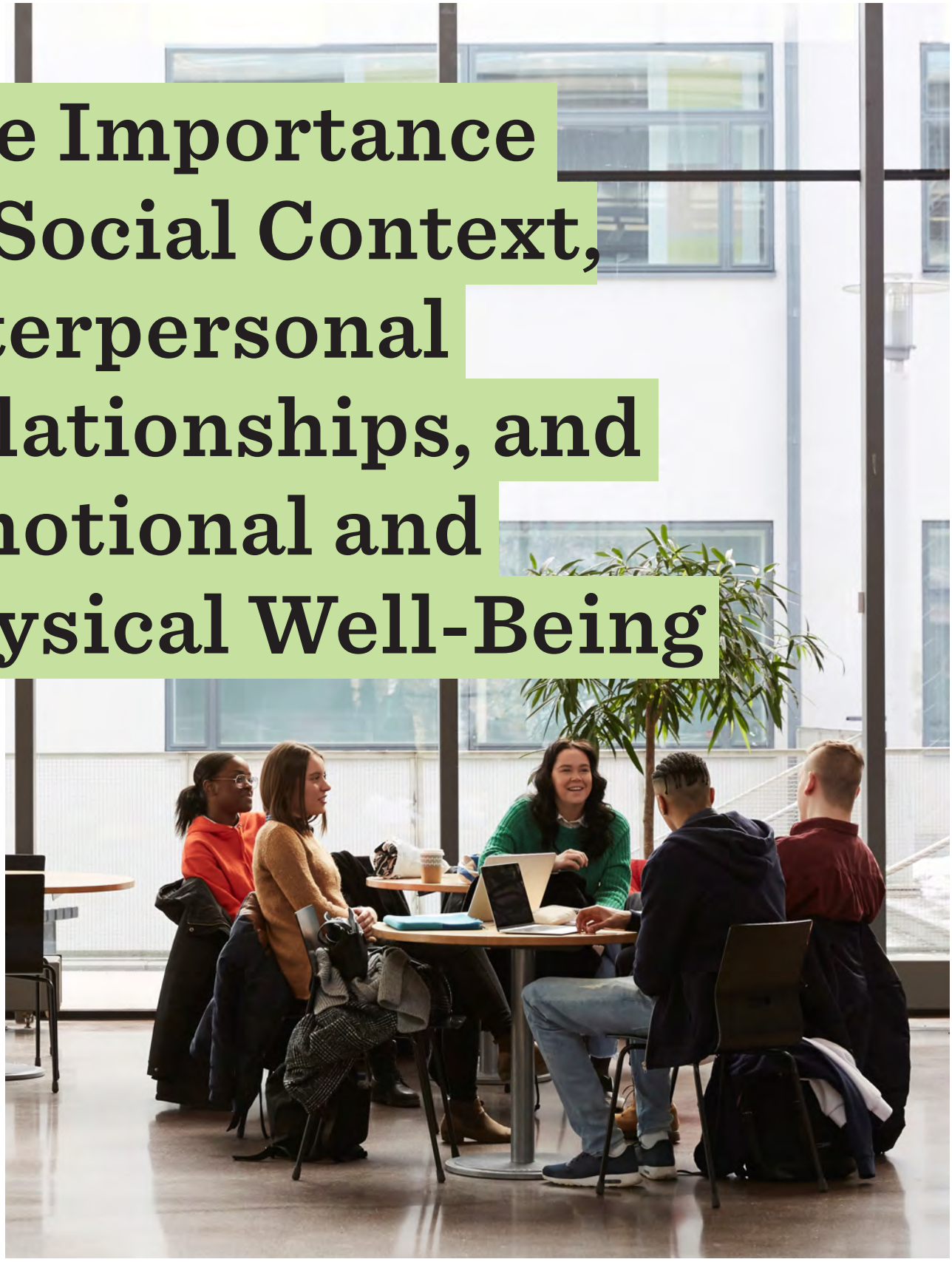

Learning is Situated within Multiple Social Contexts.

The social contexts in which your students are situated affect their learning, and understanding their backgrounds can help you communicate better with your students. Clear communication is essential. Expert educators should be mindful that classroom policies and assignment information that are clear for traditional students may be less clear for others.

Here are some ways that you can make classroom policies, assignment requirements, and grading criteria clear for all students, and ways to learn about students' backgrounds:

- Strive for clarity with classroom expectations and grading.
    - While most educators may presume students will ask questions when some expectation is unclear, empirical evidence shows that some students may be hesitant to ask for assignment or grading clarification.
- Strive for clarity on course syllabi about how students can and should communicate questions as well as what office hours are set aside for.
- Consider having multiple types of documents providing instruction for papers or assignments to communicate expectations to diverse students. One document, for example, could provide a brief outline for the assignment whereas a second provides more precise detail about what should be included.
- If you prefer a less structured approach to assignments, an alternative may be to allow students to resubmit assignments or retake exams (with different questions).
    - Interestingly, some have found that allowing exam retakes, where the retake occurs on a later date, doesn't necessarily increase faculty's amount of grading and may benefit all students, especially if students have the option of taking only one of the two exams. In this situation, students who have demanding social contexts outside of class may be able to take the exam that best fits their particular schedule.
- Communicate in a way that is clear and accessible to learners with distinct backgrounds.
    - When addressing students' questions, try to rephrase the information instead of repeating or adding additional information.
    - Ask students whether an answer has addressed their questions, and whether they have new questions.
- Seek opportunities for yourself to become better educated, to build awareness and understanding about your students. This can lead you to new insights and connections, where social connectedness and a sense of inclusion may be especially important for student retention and ultimate academic success.
    - Take part in workshops about campus diversity.
    - Learn about multicultural activities and student services on campus.
    - Be a visible member of the campus community at multicultural events.
    - Know about the student support services at your institution. Students may be unaware of the available resources. You can help vulnerable students by being familiar with these resources and able to direct them to sources of assistance.

WANT TO LEARN MORE?

Behavior is influenced by individual characteristics and situational factors. Accordingly, students' behavior (e.g., attention, classroom demeanor, willingness to seek help, study habits) emerges from their own personalities, experiences with primary and secondary education, self-relevant beliefs, self-concept, and culture, which interact with specific contexts that occur within the classroom and within students' immediate life. The complex interaction between these many contexts may influence their learning. Understanding the unique social contexts that your students have experienced and presently experience may allow you to better communicate with students and develop curricular content that students find more meaningful and engaging.

Learn as much as you can about the students that your institution serves, as basic demographic differences will relate importantly to varying social contexts that may be relevant to the classroom, and for effective pedagogy. For example, students who are at a primarily residential liberal arts college will usually exhibit marked differences in social activities, goals, motivation, and other situational factors compared to students who are enrolled at a primarily commuter-based community college or public university campus. The varied social contexts in a student's life have consequences for learning and college degree progression. Residential students who make stronger social connections at their college or university tend to persist more with their studies and are more likely to attain academic goals than those who lack social connections. On the other hand, commuter students tend to exhibit lower achievement, which may be tied to their lack of on-campus social connection. This is also true for students who are members of minority groups or are immigrants, where such students' academic success is associated with their forming social connections with other, similar students. Other social and situational factors likely influence learning and academic success among commuter students. These students may be more likely to balance work with academic responsibilities, diminishing their abilities to devote attention primarily to their education.

Understanding the unique social contexts that your students have experienced and presently experience may allow you to better communicate with students.

A student's family background is one of the most important social contexts influencing learning and academic success in higher education. People learn about expectations, values, and sources of motivation through family experiences, including those experienced as a child. These experiences can have lasting impacts on how students frame and value education. For instance, some students may learn to value knowledge whereas others learn that education is a means to an end, such as a way to enter a career with higher earning potential. Family social contexts can also play a role in how students understand their relationship with instructors. For example, students whose families have a history of college education tend to understand and approach interactions with instructors differently than first-generation college/university students. Studies have shown that first-generation students especially benefit from instructors who provide more specific information about assignments and grading.

Many other social contexts can influence students' learning. The class composition can lead some students to feel more similar or different from their class peers. This could influence their participation and sense of inclusion in the class. Learning doesn't occur in isolation from factors outside of the classroom, either. The social situations that arise in each learner's life can influence academic performance, engagement in class, and performance. Students who have significant responsibilities or sources of stress in life beyond the classroom may be particularly vulnerable. Students who are responsible for children or older adults, who work, or who have family members with a significant or chronic illness may be less able to attend fully to their studies. In sum, there are many social factors that intersect in a student's life to promote, distract from, or inhibit learning.

The diverse social contexts that students experience and have experienced carry over into the classroom in many ways. The key message with mindful teaching is that expert educators should consider the types of students in their classes and seek to understand how these students' unique backgrounds and current life circumstances may influence their learning, preparation for college success, and interaction with instructors. Awareness of these varied social contexts relevant to one's students may allow relatively minor adjustments to teaching and curricular materials that will help all students better succeed.

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Educators should consider the types of students in their classes and seek to understand how these students' unique backgrounds and current life circumstances may influence their learning, preparation for college success, and interaction with instructors.

Interpersonal Interactions in the Classroom Can Foster Learning.

The classroom environment is inherently an interpersonal one. It involves relationships between the instructor and the students, as well as relationships among students.

Here are some strategies you can use to ensure that you are successful at developing appropriate classroom interactions:

- Establish rapport:
  - Learn about your students' interests and make course material personally relevant to them if possible;
  - Arrive early and stay late to chat with students;
  - If you're comfortable with it, use humor to lighten up the mood of the classroom; and
  - Use active learning methods to encourage discussions and interactions, modeling enthusiasm toward course material, and being respectful to students.
- Incorporate cooperative learning tasks in your classroom, especially for difficult concepts.
  - Ensure that the task is well-structured;
  - Explain to students why this method helps them learn;
  - Instruct them with respect to how to interact cooperatively; and
  - Impress on them that it's crucial for each of them to participate fully.
- Ensure that groups working together are small and hold students individually accountable for their work, to avoid social loafing among group members.
- Consider the students' cultural values when designing cooperative learning tasks. For example, tasks that expect students to openly challenge each other's opinions might not work well for students from collectivist cultures, where conformity and maintaining social harmony are highly valued.
- Encourage students to engage in effective learning strategies when structuring group activities. Group activities that promote retrieval practice will be particularly effective.

WANT TO LEARN MORE?

Positive classroom experiences are associated with better learning outcomes, greater student satisfaction, and higher student retention. Greater rapport between instructor and students, in particular, predicts better academic performance as well as greater student motivation and engagement.

Interactions among individual students can matter, too. Specifically, methods that involve students learning from one another in a collaborative fashion can improve academic achievement, promote positive attitudes towards learning, increase active participation and conscientious effort, and foster motivation and persistence. Some examples of cooperative learning are "think-pair-share," which requires students first to analyze a problem independently, then to discuss it in pairs or small groups, then to share with the entire class; the "jigsaw classroom," which entails making each student responsible for teaching a part of the lesson to the rest of their group; and "peer instruction," which involves having students answer multiple-choice questions individually, then discuss their answers with a small group, and then answer the questions again. Many of these methods may promote learning by requiring students to actively discuss their reasoning rather than passively listening to the answer, and, importantly, because they provide students with ample opportunity to practice memory retrieval. While group work can be effective, the extent to which it is helpful to learning is highly dependent on the instructor's input and scaffolding of the activities.

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Students' Performance, Learning, and Development are Influenced by Their Emotional Well-Being.

Student's emotional well-being can influence their participation in the teaching-learning process, response to graded assignments, self-directed appraisals about their abilities, and approach to handling academic setbacks. Concurrently, the classroom climate and interactions with instructors can provide students with a sense of support, acceptance, security, and control over their education and academic tasks. These all contribute to students' emotional well-being. Finally, the broader college or university campus climate can influence students' emotional well-being and have implications for learning, retention, and academic success.

You can facilitate your students' emotional well-being if you:

- Establish clear channels of communication students understand, can access, and are maintained throughout the semester (for example: provide specific contact information with information on how long students should expect to wait for a response, and being available during indicated office hours).
- Establish clear expectations about grading, and assignment and exam deadlines, and avoid altering these deadlines during the semester.
- Communicate how students can access campus resources relevant for academic success (such as tutoring centers, technology-related assistance, librarians) and personal well-being (such as counseling and wellness centers).
- Reach out to students who may benefit from student success resources early and promptly when academic performance suffers (for example: attach a pamphlet or provide a URL for campus writing center if a student earns a poor grade on a writing assignment early in the semester).
- Use the "sandwich approach" for feedback when grading—identify some strengths in the student's work, then delineate areas where improvement is needed, and conclude by identifying some strengths the student can build on.
- When meeting individually with students, acknowledge the student's emotions when these are brought up, but refocus the discussion on specific, tangible information (for example: what factors determined a lower versus higher grade, what specific actions the student can take to remedy a difficult situation or improve performance).
- Emphasize specific actions students can take to achieve their goals.
- Model appraising stressors as challenges rather than threats (for instance: share an example of your own academic struggles and explain how you found ways to succeed or emphasize when students met a challenging exam or assignment and were able to do well).

- For group work, assign groups to match different types of students so that groups are comprised of some students who are academically strong with those who may be academically weaker.
- Be mindful of self-fulfilling prophecy when interacting with students—try to encourage all students to challenge themselves and strive to achieve stronger performance (see the chapter on helping students work toward mastery goals).
- Understand the campus climate as it relates to student diversity—minority students (to include those who may not be traditional minorities at some institutions) may experience situations outside of the classroom that have impacts on their emotional well-being.
- Take advantage of campus opportunities for diversity and inclusion training.
- Model inclusive teaching and critical thinking by discussing multiple perspectives and avoiding personal biases, especially when discussing difficult or controversial topics.

For further consideration about how to work with a student who is in an emotional state or otherwise distressed, consider Pryal's *Chronicle of Higher Education: Vitae* column from October, 2015 (URL: https://chroniclevitae.com/news/1144-we-are-not-prepared-for-students-in-distress)

WANT TO LEARN MORE?

People experience emotional well-being when their daily activities are accompanied by predominantly pleasant emotions. Those who experience generally more pleasant emotions associated with emotional well-being tend to better respond to new demands, experience less distress when encountering traumatic life events,

and have better physical health. Each student's emotional well-being is complexly linked to factors that manifest inside and outside of the classroom, to include life experiences, various sources of stress, family and peer relations, self-concept and self-esteem, and personality. For example, people differ in terms of how intensely they feel their emotions. Some individuals experience strong emotions (high affect intensity) while others experience more subdued emotions (low affect intensity). Those who experience high affect intensity tend to be more prone to experiencing invigoration from pleasant emotions as well as detrimental effects from unpleasant emotions (for example, tending to rate problems in life as being more severe). Accordingly, emotions have a powerful influence on how people think, which in turn influences a variety of psychological processes relevant for student success.

Foremost, emotional states relate to cognitive appraisal, stress response, and motivation. This is well-illustrated by the cognitive appraisal stress model, where an external stimulus that evokes stress (such as an exam or major assignment) elicits a mental appraisal of whether the source of stress is more a threat or more a challenge. People who have greater emotional well-being are likely to feel a greater sense of optimism in the face of stressful situations, especially when those situations are related to an obstacle or setback related to one's goals. Through their underlying optimism, people with emotional well-being are more likely to appraise stress sources as temporary problems that are tied to a specific situation and are thus able to be resolved through sustained effort. Accordingly, people who experience emotional well-being are more likely to feel motivated to engage sources of stress as challenges to be met rather than difficulties to be avoided. In contrast, people with less emotional well-being may be more prone to pessimistic thought, which tends to relate to stable (fixed and cannot be changed) and global (pervasive) ways of assessing stress-inducing situations. By interpreting the source of stress as something stable as well as something that has pervasive repercussions for one's life, people who have a more pessimistic emotional style are more prone to appraising stress sources as threats to be avoided.

People who experience emotional well-being are more likely to feel motivated to engage sources of stress as challenges to be met rather than difficulties to be avoided.

Importantly, emotional well-being is not tied to pleasant emotions alone. Indeed, contemporary research in psychology identifies how unpleasant emotions serve an adaptive purpose that aids people in successful goal pursuit. For example, unpleasant emotions seem to serve as an alert, redirecting people's awareness to situations that impair one's success at achieving goals. By redirecting attention to problems relating to goal pursuit, unpleasant emotions allow people to reconsider their actions, adjust their behaviors, and find new ways of acting and thinking to best overcome a given obstacle. In this respect, emotional well-being seems to be linked to other psychological phenomena that are important to successful goal-pursuit, including motivation, self-control, self-efficacy, coping skills, and self-awareness. In a broader sense, emotional well-being further relates to favorable outcomes related to social interactions, where a stronger ability to identify unpleasant emotions signifying a problem (such as a dispute arising in a group project) permits people to reappraise the emotions, ways of thinking, and behaviors to adjust these in service of pursuing a final, desirable outcome. In the context of social interactions, emotional well-being may thus relate to capacity for perspective-taking, empathy, and successful conflict resolution.

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Students Suffering from Homelessness, Food Insecurity, and Poverty Require Special Support

Predictability and stability are essential psychological needs that enhance one's ability to learn. Students' needs for a safe home and enough nutritious food must be met in order for them to be able to concentrate on their schoolwork. However, among the most difficult hidden problems that college students face are homelessness and food insecurity, brought on by poverty.

Here are some ways that you and your colleagues may become familiar with indicators of homelessness or food insecurity in your students, and how best to be of assistance:

- Work with your Dean of Students, Counseling Center, Student Health Center, and other appropriate offices to understand the prevalence of homelessness and food insecurity on your campus, and what signs to look for in your students.
- Learn about resources available on your campus and in your community for helping students in need of assistance. These might include:
    - Federal, state, and local assistance programs;
    - Scholarships and other financial assistance;
    - Food banks;
    - Support networks; and
    - Academic and personal advising and counseling.
- Download and familiarize yourself with the excellent materials available at College Access and Success for Students Experiencing Homelessness: A Toolkit for Educators and Service Providers (www.bit.ly/naehcy-college-access-toolkit) by Christina Dukes (2013) with the National Association for the Education of Homeless Children and Youth.

In the United States, 71% of undergraduate students reported working while enrolled in school in 2011.

WANT TO LEARN MORE?

At our community colleges, our smaller liberal arts and technical colleges, and even at our elite colleges and universities, many of our students don't have a secure place to live. Many live in their cars or spend nights sleeping on the couches of different friends, while using gym facilities to maintain their daily hygiene. This can cause sleep deprivation problems, which may have devastating effects on students' ability to perform in our classes. Many faculty members don't realize quite how many of our students are also going hungry. At some universities, as many as 39% to 48% suffer food insecurity, which has major impacts on their health, their social lives, and their ability to concentrate or perform at their best.

While many students are hungry or homeless, many more are working, sometimes full-time jobs or multiple part-time jobs, to support themselves while in school. This coincides with continuing rises in tuition and costs to attend school. In the United States, 71% of undergraduate students reported working while enrolled in school, and 20% of students reported working full-time in 2011. Working while in school, especially longer hours, is often associated with lower academic success at the college level. This relationship may be particularly strong for first-generation college students.

To combat these problems, some colleges and universities have created student food banks. A few have provided free housing for students in emergency situations. At others, an institutional commitment has not been as forthcoming, so other organizations, charities, and religious groups have taken up some of the challenge, or the colleges have partnered with such groups. However, these interventions aren't always sufficient or effective, and even when help is available, not all students know about the possibility of assistance or are willing, for whatever reason, to avail themselves of it fully.

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Managing our Classrooms

We Must Teach New Students to Adhere to Basic Standards of Classroom Behavior Using Direct Instruction and the Principles of Behavioral Learning.

Much of what we know in this area can be extrapolated from research conducted with younger students, but it's clear that appropriate behaviors in the classroom and larger educational environment are necessary for academic and personal success to be achieved.

Here are some steps you can take to encourage appropriate student behavior:

- Enumerate standards of behavior, both on campus and in the classroom, in clear and unambiguous ways that are accessible, readily available, and digestible. Student code-of-conduct resources as well as individual course syllabi are a primary avenue for delivery of such information. Further, these resources should be consistent with each other so that classroom policies exist in parallel, rather than perpendicular, to larger college policies.
- Help students understand the process by which disruptive behaviors will be addressed. These include both in-class and out-of-class interventions. This requires constant and consistent communication. Students may enter unaware that behaviors that they regard as acceptable create issues in the classroom. Don't surprise students "after the fact" with the information that they have caused disturbances in the class.
- Reinforce appropriate behaviors. This is far more effective than pejorative responses to classroom problems. Thus, as with most learning situations, the use of punishment should be the exception.
- Be sure that students whom you discipline receive fair treatment, even in the face of frustrating behaviors. This may include knowing that they have a right to appeal disciplinary decisions. Individual institutions should have set processes in place that guarantee appropriate responses that attend to a student's right to due process.
- Relate appropriate in-class behavior to its real world applications. This can help move a student from an external locus of responsibility (i.e., "I am doing this because they tell me I have to") to an internal locus of responsibility (i.e, "I am doing this because it is in my own best interest"). As an example, students may learn that being on-time to class is a skill that will serve their interests after college, when punctuality is an expected trait in the workplace.
- You can serve as a primary role model for appropriate behaviors by demonstrating what is expected both inside the classroom and in the world of work. Students take their cues from you, and as such can be expected to model both correct and incorrect practices. For example, if you are continually tardy to your class, you can't expect your students to be on time. The teacher who is always on time is modeling an appropriate behavior that can be used as a learning tool.

WANT TO LEARN MORE?

A truism of the college classroom is that the environment in which one learns is an integral, contributing factor to the quality of that learning. Student success has been found to be tied to engagement, and the classroom where student conduct operates at the highest levels facilitates such engagement and success. Many students emerge from high school or return to college after many years away (i.e., non-traditional students) sometimes with low levels of understanding of how to be a "good student" in the classroom. Academic citizenship, as it might be called, comprises a set of skills and behaviors that often need to be taught. Institutions of higher education are recognizing this fact and building College Success courses for incoming students that emphasize strategies for academic achievement. Both in and beyond such courses, students need to have appropriate classroom behaviors emphasized and reinforced, both for their own success but also for that of others in the learning environment.

Student success has been found to be tied to engagement, and the classroom where student conduct operates at the highest levels facilitates such engagement and success.

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Classroom Management is a Form of Mentoring.

There are many ways to accomplish setting high expectations alongside supportive mentoring. There certainly is not single right way to do it. Implement these practices in your classroom to cultivate a demeanor that communicates humility, humor, and care. Viewed through the mentor's lens, classroom management seems less like drudgery and more like a delight. For a "starter kit" of ideas in this vein, consider Kounin's suggestion list:

- Show your students you have high "situation awareness"...that you know what's going on in the classroom at all times;
- Cope with overlapping situations (a form of quick multitasking);
- Maintain momentum in classroom activities....think about how energy will flow through a planned activity from beginning to end;
- Keep the entire class involved, even when working with one student;
- Show enthusiasm and introduce variety; and
- Be aware of the "ripple effect"...notice how reacting to positive or negative behavior in one student can affect other students in the room positively or negatively.

Later researchers have extended and expanded on Kounin's ideas, but the basic principle remains the same: maintain control with minimal pressure or stress. For folks trying to think through how else to implement this theme, some additional ideas to think about include:

- Make sure the classroom's physical arrangements are safe and organized, built around a schedule students can anticipate, and that class rules/policies are articulated clearly and reliably applied.
- Be sure your high expectations are conveyed with positivity and warmth. Offer reasons for expectations and policies, rather than just laying down the law. Reward student comments with praise and incorporate them into class content. Show them that their ideas are worth including in the content you present.
- Be accessible. You can accomplish this in a variety of ways—arrive early to class or stay late, have a quick response time to student e-mails, and so on. It may be a small thing to you, but for them to have an answer in as close to real time as when they reach out supports the development of that mentoring relationship.
- Be sure in-class activities you plan scaffold the development of student independence, rather than dependence on instructor-provided lecture. In fact, it may be better to incorporate more innovative and interactive classroom experiences over purely lecture-based instructional time. Be willing to cover less and do it better. Explain to students how you are unpacking material so they can export those strategies to learn the material you didn't get to in class.
- Be aware of your negative-to-positive ratio in remarks or interactions in the classroom. As you reflect on this, try to intentionally keep the ratio tipped toward the positive, which will build trust and express respect.

WANT TO LEARN MORE?

Classroom management, in many ways, is not all that different from parenting. And just like research on parenting styles gives an edge to the authoritative parenting style in most Western family structures, an authoritative classroom manager brings a learning edge to his or her classroom climate. What features about the authoritative style are behind these benefits?

Diana Baumrind's authoritative parenting style is characterized by having high expectations and control alongside high encouragement. These same features help create an effective learning climate in the classroom. Instructors who use this approach provide classes with clear structures, behavioral policies, and expectations. They communicate them directly and frequently. And then they follow through an enforce them. Consistently. Visibly.

High expectations, though, work best with support and encouragement that helps students use those structures and policies to effectively meet those expectations. High expectations without support can create a sense of futility, but high expectations with support are energizing and motivating. Support is communicated through strong mentoring relationships with students. Every student-teacher interaction provides a new opportunity to communicate that the student's success is the shared goal of both. Communication has to be consistent across students so favoritism is not perceived. If every piece of communication and feedback conveys the message to each student that "I believe you can achieve this lofty goal and it's my job to help get you there," students will see the structures and policies as ladders to climb towards the high expectations, not barriers or hurdles without purpose.

The structures and policies that accompany the high expectations should have reasons behind them that can be articulated in terms of how they support student learning. Policies, assignments, goals, and other structures that can't be explained in these terms need re-thinking. Even better is if those structures and activities can be sequenced so that student can see how they lead to greater degrees of autonomy in their own learning process.

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Assessing Students' Progress

We Should use both Formative and Summative Evaluation Appropriately.

As instructors, we must assess our own students' learning. Formative assessment can be used to monitor our students' learning as we progress through a course, and summative assessment can be used to evaluate student learning overall, and compare to benchmarks. However, for formative and summative assessments to be effective, they need to be used appropriately.

Here are some ways in which you can help increase your students' levels of learning and the quality of your courses through formative assessment:

- Transparency is important. Be sure your students know and understand why you've given them each lesson and assignment. This promotes buy-in, and makes them more willing participants in their own learning processes.
- Be sure that the formative methods you choose are appropriate to the type of learning you wish to promote.
- Use the evidence you collect from formative assessment to help your students understand their strengths and weaknesses and how these best can be addressed.
- Turn around evaluations quickly, and be sure that any interventions follow as quickly as possible to ensure that they will have their maximum impact.

You can improve the effectiveness of your assessments:

- Be sure to set specific, appropriate goals before designing any evaluative measures.
- Determine how you'll know whether students have met your goals, or how you'll judge the quality of their attempts.
- Use the evidence you collect from formative assessment to evaluate whether your lessons and assignments are fulfilling their intended purposes. If not, use this evidence to redesign them appropriately.

It's also important to bear in mind that summative assessments can serve several purposes:

- Final evaluation of material or skills learned in a course or unit;
- Preparation for learning new material; and
- Motivation for students' future learning in a particular area.

WANT TO LEARN MORE?

Arthur Coladarci once described education as a form of hypothesis testing. In other words, it's an experiment. We set out with a plan that we believe will succeed in teaching particular concepts, techniques, or ways of thinking, and that may or may not be successful. We use formative and summative evaluation in order to determine whether our hypothetical method was supported.

VandenBos defines formative evaluation as "a process that is concerned with helping to improve or guide the development of a program through the use of qualitative or quantitative research methodology," and describes summative evaluation as, "...the appraisal of a student's achievement at the conclusion of an educational program." In other words, formative evaluation allows us to test our hypotheses about the success of the teaching and learning process as it progresses, allowing us to modify our teaching methods as we go. This can be done with a variety of assignments throughout the course. In comparison, summative evaluation provides a final look at the success of our process as a whole.

Formative evaluation strategies may take many forms, but are generally most successful when they mirror the format of a course's learning objectives. This would mean that courses requiring hands-on learning or critical thinking essays should use those formats for both their formative and summative assessments, rather than relying on the ubiquitous multiple-choice format. Formative evaluation strategies can be extremely effective as tools for helping student learn in online courses. Formative assessment efforts also work across many cultures. In addition to many studies done in the United States of America, successful interventions have been carried out in countries as varied as Australia, Canada, China, Colombia, Finland, Great Britain, Hong Kong, Malaysia, New Zealand, Portugal, Saudi Arabia, South Africa, and Vietnam.

Sharing formative assessments with your students can have many benefits. For example, formative strategies have been shown to increase students' learning, motivation, and levels of achievement in courses as varied as accounting, art, biology, developmental mathematics, engineering, geography, management, medical education, and psychology.

As noted, summative evaluation is our final evaluation of how well our students' learning has met our objectives. As with formative evaluation, summative evaluation can take many forms. It may come at the end of each unit in a course, where it may enhance students' motivation to learn in subsequent units. Summative assessment may also take the form of a cumulative final examination at the end of a course, or an oral examination to allow greater depth in assessing students' critical thinking abilities. Final projects and either physical or electronic portfolios can also be considered

effective forms of summative evaluation. Some researchers advocate using multiple methods when evaluating a course. An entire course of study may also be evaluated, perhaps through the use of a capstone course, project, or service learning activity. Indeed, summative assessment may also take the form of a final project for an undergraduate major, such as presenting at a conference. A masters or doctoral dissertation, with accompanying defenses, could be considered a form of summative assessment.

Final projects and either physical or electronic portfolios can be considered effective forms of summative evaluation.

Some techniques work well as both formative and summative evaluations. For example, portfolios and ongoing projects are often used productively in such diverse areas as engineering, education, or psychology. Some researchers have had excellent results when students were allowed to use their summative work as formative work, for example increasing students' learning by allowing them to resubmit final essays. This combination may be seen as a scaffolded approach, which allows students to begin as novices, and work their way up to the levels of expertise required by the curriculum.

Tests may be developed by instructors, corporations, or governments at various levels, but whether used for formative or summative evaluation, they all share the same goal. They must be designed to produce valid and reliable information about students' levels of accomplishment or understanding. As noted above, they should be closely aligned with the learning objectives and methods of the class or course of study. It is also important for any assessment to be accessible, with regard to any learning or testing disability issues.

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We Must be Careful to Use Fair, High-Quality Assessments to Measure Students' Skills, Knowledge, and Abilities.

As was discussed in the previous chapter, formative and summative assessments can be helpful tools in the classroom. However, the inferences made from assessments are only as good as the assessments themselves. When we use assessments that are reliable and valid, we are better able to use those assessments to make inferences about what students know and can do.

Here are some ways that you can improve the validity and reliability of your assessments:

- Make sure that the intent of the assessment is always kept in mind. What the assessment intends to measure should be clear to everyone involved with the assessment.
- Make sure that the assessment matches what was taught.
- More questions tend to be better (within reason), and assessing the same ideas with different types of questions can improve the assessment.
- Assessments that are appropriate in some situations may not be appropriate in others. Always evaluate whether the assessment makes sense in the given context.
- Do not make high stakes decisions (e.g., whether they continue in their education, graduate, etc.) by considering only one test. Instructors and other decision makers should take other relevant and valid information into consideration so that multiple indicators are being used.
- Once the results are in, instructors can look at student performance at the item level to help improve the assessment. Some questions may be too hard (e.g., no one got the answer correct, or many students provided the same incorrect answer) while other questions may have been too easy (e.g., almost everyone answered the question correctly). Eliminating these questions can help the assessment differentiate among students' skills, knowledge, and abilities.
- Continue to monitor scores to see whether there are consistent discrepancies for students of different cultures or belonging to different subgroups. If certain types of students consistently do well or poorly on a specific assessment, this may indicate systematic bias in the assessment that must be addressed.
- Remember that all assessments have strengths and weaknesses, and interpret the data in light of these.

WANT TO LEARN MORE?

Assessments are a constant topic of discussion and debate among educators, and higher education is no exception. Assessments, both formative and summative, can be useful so long as they are used appropriately. When we use assessments that are reliable and valid, we are better able to use those assessments to make inferences about what students know and can do.

For an assessment to be fair and useful, it must be valid. There are many different types of validity; for the purposes of assessment a valid measure means an accurate measure. An assessment will have high validity if it measures all of what the assessment is intended to measure, and does not measure anything unintended.

It is also important to use assessments that are reliable. A reliable assessment is essentially a consistent and dependable assessment. Creating a reliable assessment involves eliminating random error, or factors that affect the results of the assessment just by chance. For example, changes in the test-taking conditions can randomly affect a student's score on an assessment, making the assessment less reliable.

Assessments, both formative and summative, can be useful so long as they are used appropriately.

An assessment needs to be both reliable and valid if one wants to use the assessment to make appropriate inferences about what students know and can do.

An instructor utilizing an assessment must be able to clearly state what the assessment is intended to measure, and should be able to provide evidence that the assessment does in fact measure this well for all students taking the assessment. Further, any given assessment should only be used for its specific purpose. For example, an assessment that is designed to show areas of both strength and weakness for students should not then be used to evaluate a

department or professor's curriculum. The validity and reliability of assessments should be evaluated frequently, and the judgment as to whether a test is both valid and reliable should be made across a variety of situations.

Finally, it is important to remember that individual assessments will come with both strengths and limitations, and no one test will be able to provide all information that might be desired about a student or curriculum. Awareness of these points is critical; understanding the strengths and limitations of an assessment will allow instructors to communicate caveats to those utilizing the assessment, and emphasize the importance of using multiple sources of evidence for high-stakes decisions.

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Teaching, Learning, & Assessing in a **Developmentally Coherent Curriculum**

APA Board of Educational Affairs Task Force on Strengthening the Teaching and Learning of Undergraduate Psychological Science

American Psychological Association

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INTRODUCTION

The Task Force Charge

This report presents the work of the American Psychological Association (APA) Board of Educational Affairs (BEA) Task Force on Strengthening the Teaching and Learning of Undergraduate Psychological Sciences. This task force, appointed in April 2005, was charged with bridging the gap between the *National Standards for the Teaching of High School Psychology* (*National Standards*; APA, 1999)[1] and the *APA Guidelines for the Undergraduate Psychology Major* (*Guidelines*; APA, 2007).[2] The *National Standards* established a set of benchmark learning objectives, designed initially for use in high schools, for teaching the first course in psychology, but it quickly became apparent that the these standards could apply to the first psychology course offered at any level. The *Guidelines* set a standard for the competencies that should be expected of students graduating from colleges and universities as undergraduate psychology majors.

The two documents provided guidance in designing the beginning of the academic study of psychology and establishing behavioral expectations for outcomes upon completion of undergraduate study, but they left unaddressed the elements of development that transpire between that first course and receipt of the baccalaureate degree. Accordingly, the charge of the current task force was to consider the development of the psychology student from the first course to the bachelor's degree and to propose a set of intermediate outcomes or abilities that these students attain en route.

Background

The initiative for the task force originated with the leadership of the APA Committee of Psychology Teachers at Community Colleges (PT@CC) and was based on several practical concerns. PT@CC cited evidence that enrollment patterns have shifted over the past 10 years, with students increasingly attending more than one institution in pursuit of a bachelor's degree. Forty-six percent of all U.S. undergraduates are enrolled at public and private community colleges, and 41% of first-year students begin their academic careers at community colleges (American Association of Community Colleges, 2008). Others start out at a university/college and later transfer to a smaller liberal arts college, another university, or their local community college. Concurrent enrollment at multiple institutions is not unusual, a phenomenon referred to as "swirling" (Bordons, 2004). Further, students may enroll as "course takers" at one institution while maintaining their primary enrollment status at another. Fifty-nine percent of students completing their bachelor's degree in 1999–2000 attended more than one institution (Peter & Forrest Cataldi, 2005).

These changing enrollment patterns raise serious concerns about the coherence and integration of the course of study followed by students who engage in them. Should students string together course combinations that are not guided by the goals and objectives of a coherent curriculum, there may be gaps in the educational preparation they receive as undergraduate psychology majors. This concern guided the work of the present task force.

[1] These were revised in 2005 and titled *National Standards for High School Psychology Curricula* (see www.apa.org/ed/natlstandards.html).

[2] An earlier iteration of the *Guidelines* known as the *Undergraduate Psychology Major Learning Goals and Outcomes* (APA, 2002) was used in the early work of the current task force.

Process for Developing the Report

In 2005, the APA Council of Representatives approved a request to support the BEA Task Force on Strengthening the Teaching and Learning of Undergraduate Psychological Sciences. The six-person task force, with equal representation of community college and college/university faculty, was appointed to develop a report that would identify developmentally appropriate competencies that serve as benchmarks of student success as students progress from their first course through degree attainment, along with models for teaching, learning, and assessment.

BEA, in collaboration with PT@CC, appointed the following members to serve on this task force: Patricia Puccio, EdD; Jerry Rudmann, PhD; Joe Mayo, EdD; Drew Appleby, PhD; Ted Bosack, PhD; and Retta Poe, PhD. Jane Halonen, PhD, served as a consultant to the task force.

The task force met July 22–24, 2005, to prepare a report identifying the developmentally appropriate competencies for undergraduate psychology courses, along with models of "best practices" for teaching, learning, and assessment. The task force spent considerable time discussing trends and issues that have converged to form the current zeitgeist of accountability. Key considerations included sensitivity to creating a document that could be used by faculty to enhance their teaching. Hence, the task force determined that the report would focus on student learning outcomes across the continuum of learning. The *Guidelines* offers outcomes for the liberal arts degree and those specific to the discipline. Given the nature of the task, the group focused their efforts on extending the goals specific to psychology. Learning goals were identified as *basic, developing,* or *advanced* for each of five content areas (i.e., knowledge base, research methods, critical thinking skills, applications of psychology, and values of psychology).

Public comment on the document took place during fall 2006. APA boards and committees received a cross-cutting agenda item requesting review and comment on the report. Announcements were published in the APA *Monitor* (October 2006) and *Division Dialogue* (September/October 2006) inviting comments on the report, and responses were supportive. The Committee on Women in Psychology (CWP) and the Committee on Disability Issues in Psychology (CDIP) provided specific feedback for consideration. In early October 2007, Education Directorate staff provided these comments to the task force, along with feedback from the Society for the Teaching of Psychology (APA Division 2). The BEA task force reviewed these comments and made final edits to the report. The report was received by BEA at its meeting on March 28–30, 2008. BEA expressed thanks and appreciation to the BEA Task Force on Strengthening the Teaching and Learning of Undergraduate Psychological Sciences, which has completed its work and has been dismissed.

ORGANIZATIONAL FRAMEWORK

The task force adapted and combined the organizational frameworks from prior APA-initiated efforts as a starting point. For the developmental conceptualization, the task force selected a model constructed by Halonen, Bosack, Clay, and McCarthy (2003) to guide teaching, learning, and assessment of scientific inquiry, an important element of education at all levels of psychology. Halonen et al., working within the context of the APA-sponsored Psychology Partnerships Project (see Mathie & Ernst, 1999), defined eight domains of scientific inquiry and traced developmental outcomes

in these domains through five levels of proficiency, beginning prior to exposure to scientific training and ending at a professional level. The middle three levels of this model identified expected behavioral outcomes in the undergraduate years, and we incorporated them into our developmental curricular structure as follows:

- **Basic:** Skills that students should acquire in introductory-level psychology courses such as general psychology and psychology of adjustment
- **Developing:** Skills that should emerge as students progress through lower- and upper-division courses in an undergraduate psychology curriculum
- **Advanced:** Skill levels expected of students completing capstone educational experiences and nearing the end of a psychology major

Furthermore, to strengthen the cognitive developmental character of this model, we integrated the three levels with the sequencing elaborated by Krathwohl (2002), such that *basic* represents "retention and comprehension," *developing* represents "application and analysis," and *advanced* is associated with "evaluation and creation."

In addition, we adopted the curricular competencies model reported by the Task Force on Undergraduate Psychology Major Competencies, appointed in 2001 by the BEA. In developing the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2007), the Task Force on Undergraduate Psychology Major Competencies identified 10 goals and related learning outcomes to be achieved in the undergraduate psychology major. These goals and outcomes were grouped into two broad categories:

- *Knowledge, skills, and values consistent with the science and application of psychology*
- *Knowledge, skills, and values consistent with liberal arts education that are further developed in psychology*

Because the target of the current task force was the curricular structure of the psychology major, we limited our focus to the five goals associated directly with the science and application of psychology (*Knowledge Base of Psychology, Research Methods in Psychology, Critical Thinking Skills in Psychology, Application of Psychology,* and *Values in Psychology*). Combining these two frameworks, we sought to identify a progression of learning outcomes for each goal that moves from basic to developing to advanced levels of proficiency. The resulting developmental model offers guidance for articulation of student learning outcomes as learners progress through the undergraduate curriculum.

We adopted the stance of the earlier curricular work groups in avoiding specification of a course-based curriculum structure. Recognizing that institutions differ with respect to their missions, departmental missions, available resources, student characteristics, and level of individual program autonomy, we proposed a developmental model that provides a general framework for structuring the curriculum and setting goals and outcomes while permitting flexibility for institutional and student differences. Our model is shown in Appendix A, Tables A1–A5.

Finally because assessment is an essential part of what good teachers do, both to evaluate students' success in achieving course objectives and to guide students' learning, the task force went beyond identifying developmentally appropriate skills as benchmarks for student success to consider concomitant models for teaching, learning, and assessing those benchmarks. In the sections that follow, we present a rationale for effective assessment, characterize the components and essential conditions for effective assessment, suggest a strategy for aligning programs with the developmental outcomes that the task force has formulated, and offer samples of embedded, authentic assessments to show how these may be integrated into program assessment practices.

Individual institutions, departments, and faculty are encouraged to develop a variety of assessments to evaluate the skill development of all learners. Efforts should be made to design outcomes measures that do the following:

- Allow for multiple means of reaching the desired outcome
- Use a variety of pedagogical models
- Reflect unique institutional and departmental missions
- Maximize the unique strengths of diverse undergraduate students

ASSESSMENT OVERVIEW

As Angelo and Cross (1993) noted, "to improve their learning, students need to receive appropriate and focused feedback early and often" (p. 9). Student assessment provides evidence regarding mastery of knowledge and skills, and the results may be used to improve their performance as well as assign grades. A similar rationale for using a thoughtful approach to program assessment is that faculty need program assessment data to improve teaching, make program modifications, and provide evidence to various constituencies—administrators, alumni, legislatures, state boards of education, parents, prospective students, voters, accrediting organizations, and others—regarding the program's success. Although Halpern (2004) acknowledged the controversial role of program assessment at some higher education institutions, pressures from outside academe have necessitated some attention to program assessment at nearly all postsecondary institutions. Allen (2004a) reported that all six regional accrediting organizations require "serious examination of educational effectiveness, and they expect campuses to document their impact on student learning" (p. 18).

Psychology's emphasis on empiricism provides faculty with an awareness of the necessity for program assessment (i.e., to document that students are learning what we think we are teaching). What some faculty may lack, however, are the skills to develop a plan that accomplishes assessment goals: developing faculty consensus on program objectives; collecting data related to those objectives; determining program strengths and weaknesses; and providing guidance for making program changes (Stoloff, Apple, Barron, Reis-Bergan, & Sundre, 2004).

In other cases, environmental factors inhibit faculty willingness to collect meaningful program assessment data. For example, some faculty may fear that assessment results will be used to make decisions regarding program continuance or to make personnel decisions about individual faculty members. For this reason, the establishment of an assessment-friendly campus climate cannot occur without administrative policies that facilitate trust—for example, that program assessment data will not be analyzed in a way that identifies individual faculty, results will not be used punitively in faculty evaluations, and decisions about program continuance or resource allocation will not be based solely on program assessment results (Allen, 2004a).

Moreover, faculty members who lead assessment efforts should expect recognition that these efforts are valued and will be rewarded (Allen, 2004a). An ideal campus climate for assessment is one in which there are clear administrative expectations for assessment; written policies indicating who is responsible for assessment, what must be assessed and when, and how results will be used; commitment of resources to support assessment; and recognition of assessment efforts (Suskie, 2004).

A formal system of program assessment is a major link in the overall institutional effectiveness cycle. Program assessment data provide evidence of program strengths and weaknesses, which may lead faculty to make recommendations for curricular change. This may require creating new courses or applied experiences, modifying existing courses and experiences, revising admissions policies, or changing instructional methodology. Implementing program improvements may require hiring new faculty members, providing professional development opportunities to update skills of current faculty, and acquiring other physical, financial, and personnel resources. The commitment to making these changes may then be reflected in the strategic plan adopted for the department in which the program is housed.

Beginning or revising the program assessment planning process involves five steps. First, program faculty develop a list of learning outcomes for graduates of the program; these are descriptions of what the faculty "intend for students to know (cognitive), think (attitudinal), or do (behavioral) when they have completed their degree programs" (Nichols & Nichols, 2000, p. 17). Program outcomes should be consistent with the institutional mission; reasonable, given students' abilities; and measurable. Outcomes may be academic (e.g., critical thinking skills, content knowledge in a discipline, oral presentation skills), occupational (i.e., skills related to a particular occupation), or developmental (e.g., respect for diversity, personal development, ethical judgment) (U.S. Department of Education, 1997).

Potential program outcomes may be derived from several sources, either alone or in combination, including a review of course syllabi, standards recommended or required by professional associations or accrediting associations, outcomes developed by colleagues at other institutions, and formal or informal descriptions of employers' expectations for program graduates.

The developmental learning outcomes we present are intended to serve as a starting point for faculty efforts to create an institution-specific set of learning outcomes. Following this first step in developing learning outcomes, Steps 2–5 in the assessment-planning process:

- Examine the alignment between the selected learning outcomes and the curriculum ("Where in our program do we think students are taught the desired knowledge, skills, and attitudes?")
- Select a means of assessing the outcome and determine the criteria for success
- Collect assessment data
- Review assessment data to determine what changes are needed for program improvement

Once changes are made, the subsequent assessment cycle should be designed to provide evidence of whether the changes were successful in achieving program outcomes.

AN EMBEDDED ASSESSMENT MODEL

A typical approach to establishing a departmental or program assessment system is to plan assessment activities at the completion of a program or at the end of a course when mastery of course-specific goals is being evaluated. These summative assessments (Dockrell, 1995) often take the form of locally or commercially produced comprehensive tests, exit surveys, and observation of performance of skills. Although capable of providing an accurate assessment of student outcomes, summative program assessment has the disadvantage of typically requiring standardized administration in specially arranged time blocks, or else relying on the willingness of students to take time out of their own schedules to, for example, complete a survey or take a test. In addition, since summative evaluations are structured to occur at the end of programs and courses, there is often little that can be done after administration to remediate substandard performances that may occur, although Wininger (2005) has reported an exception to this generalization for course evaluations.

An important distinction should be made between student assessment and program assessment. Although student and program assessment are alike in the methods that may be used and in the unit of measurement (i.e., the student, or some product produced by the student), the two approaches differ in purpose, use of results, and unit of remediation. Student assessment is undertaken to determine individual students' mastery of knowledge and skills, whereas program assessment provides "big picture" data about overall instructional performance so that program improvements can be made. Faculty members use student assessment data to determine grades and/or initiate remedial action (e.g., tutoring); therefore, the unit of remediation is the individual student. By contrast, program assessment is for the purpose of ensuring the accomplishment of program objectives, and the unit of remediation is the program itself. As noted previously, program assessment is often conducted at the end of a program, such as in a capstone course, and though it often occurs as summative assessment, this is not the only option.

Adoption of the guiding developmental principles suggested in this report introduces another assessment option that may possess advantages for students, faculty, and programs. The developmental principles lend themselves to *formative assessment*—that is, determination of student progression toward meeting stated goals at preset points in courses or curricula (McAlpine, 2004). Clearly, formative assessment presents greater flexibility than does summative assessment in a number of ways:

- Evaluation before the end of courses or programs allows students and faculty to recognize deficiencies while there is still opportunity to remediate them. Additional assignments, tutoring, or other remedial instruction may be provided, and the failed goal may eventually be met.

- Formative assessments for courses or program assessment may be administered in the form of instruments or assignments integral to courses while they are being taught. This *embedded assessment* (Wilson & Sloane, 2000) may take the form of examinations, papers, oral reports, in-class writing samples, or any other product for which expected outcomes and evaluation criteria consistent with departmental goals have been clearly articulated.

- Evaluations occur as a regular part of course work and do not require commitment of additional student or faculty time typically associated with summative assessment.

- Formative assessment eliminates expenses associated with the purchase of commercial testing instruments.

For embedded assessment to be used effectively for program evaluation in departments that have adopted the developmental principles presented in this report, several conditions should be met. First, all courses offered in a program should meet specific goals of the program, and all program goals must be addressed in the curriculum. Second, multiple faculty members who are not involved in the teaching of a specific course should participate in determining whether the goals articulated for a course are actually covered in that course and in determining if the outcomes assessed truly evaluate the stated goals. Finally, there should be reliability checks on the outcome assessments used. We offer the *developmental model* as one way to meet these needs and to produce accurate and effective assessment.

The developmental model requires that teachers of all courses in a program identify which of the learning goals and outcomes each course actually meets (Levy, Burton, Mickler, & Vigorito, 1999), the assignments they employ to produce those outcomes, and the outcome assessments they use in the courses to determine that the outcomes have been achieved. Small subcommittees review these materials and subsequently meet with the instructors of the courses they reviewed to resolve any questions that may have arisen; they may also tweak assignments and assessment measures to ensure that the goals and outcomes are being appropriately addressed and measured.

Upon completion of this process, program faculty review the matrix of courses and goals to determine that all students in the program will be exposed to the teaching of all of the goals, regardless of the paths that they take through the curriculum. Should there be paths that do not produce exposure to the teaching of all the goals, faculty must agree on adjustments to courses or to the curriculum to ensure that all students have exposure to the content and skills identified as essential by the faculty.

Finally, to ensure accurate and unbiased outcome assessment, criteria for good practice suggest that program faculty implement a schedule for periodic reliability checks of the agreed upon embedded outcome assessments. In other words, faculty members other than the course instructor review a sample of student products used for embedded assessment to confirm that scoring reflects program standards. Some may view this step in the model as burdensome and intrusive. Nonetheless, it is necessary to ensure the integrity of assessment, and devising a rotating schedule of reliability checking at a frequency acceptable to the faculty may reduce any negative effect.

Authentic assessment, discussed in the next section of this report, can be an excellent means of achieving embedded assessment. Halonen et al. (2003) and Bosack, McCarthy, Halonen, and Clay (2004) illustrated ways in which authentic teaching, learning, and assessment may yield scholarly course products and applications that can be objectively evaluated by using a developmental rubric. The principles that these researchers demonstrated in the area of scientific inquiry may be readily adapted to the five goals addressed by the present task force, as indicated in the examples provided in the box on page 9.

This model of formative, embedded assessment clearly requires considerable front-loaded effort to yield a coherent curriculum. However, the reward is the integration of virtually all assessment efforts into the routine conduct of courses, and doing this saves the time and money associated with summative assessments.

APPLYING AUTHENTIC ASSESSMENT TO THE DEVELOPMENTAL MODEL

Effective assessment strategies should promote student competence (Wlodkowski & Ginsberg, 1995) and improve the quality of teaching (Austin, 1993). However, not all forms of assessment are equal in accomplishing educational goals. Traditional approaches to assessment typically rely on standardized or teacher-generated tests that focus on recall or recognition of knowledge on multiple-choice, matching, or true–false questions (Wiggins, 1990). As an alternative method of assessment, *authentic assessment* deemphasizes rote learning and passive test taking in favor of real-world situations that push students in the direction of more meaningful, task-relevant construction, integration, and application of knowledge (Mueller, 2003). Consequently, authentic assessment is both direct and performance based, requiring students to demonstrate proficiency by actually doing something in contexts that replicate the priorities and challenges faced in daily life.

As Mueller (2003) argued in support of a performance-based assessment model, teaching and learning are integrated in the practice of authentic assessment. At the same time that students are learning to solve real-life problems and teachers are facilitating this process of authentic task involvement, the solutions offered by students gauge their abilities to apply knowledge meaningfully.

Rubrics can serve as versatile tools for specifying assessment criteria (Allen, 2004b). Teachers can weave rubrics into the fabric of their courses as a way to communicate behavioral expectations, provide formative feedback, and grade students in a manner that more clearly articulates the strengths and weaknesses of their work.

The developmental model we propose allows for generation of rubric-based performance criteria in authentic assessments flowing logically from authentic teaching applications. Authentic teachers use real-life examples and problems to help students generalize learning from classroom environments to situations that they will experience in everyday life (Halonen et al., 2003). As a vehicle for evaluating higher level cognitive competencies, the instructional designs used by authentic teachers encourage active learning (Barr & Tagg, 1995) and incorporate contexts that are realistically connected to the student experience (Wiggins, 1990).

Comparable to the rubric offered by Halonen et al. (2003) that also consists of behavioral descriptors in developmental progression, the present model is sufficiently flexible to cover the gamut of assignments normally found in courses across an undergraduate psychology curriculum. Consistent with Bosack et al.'s (2004) analysis of the usefulness of the P3 developmental rubric for evaluating student performance, the current developmental paradigm also exhibits maximal utility in the context of psychology courses with well-designed learning goals.

In such courses, each performance-based assignment contributes to progress toward those goals. By relating the behavioral descriptors of the model to performance expectations embodied within their course assignments, teachers can use the rubric to appropriately match proficiency levels and learning goals to corresponding courses and the students involved. In line with the prior work of Bosack et al. (2004), who presented concrete examples of translating the general language of the P3 rubric into behavioral expectations of authentic assessments targeted for different levels of sophistication, we undertook similar efforts relative to the current developmental model.

AUTHENTIC TEACHING APPLICATIONS

To aid teachers who elect to use this schema of developmental outcomes in creating their own course assignments, we offer an example of authentic assessment at each of the three levels of proficiency outlined in the model: basic, developing, and advanced. Each example, which is derived from previously employed classroom assignments recast in the light of the current rubric, includes the following descriptive elements:

- Developmental and situational context of the assignment
- Purpose of the assignment
- Instructional methodology for assignment completion
- Learning goals consistent with the science and application of psychology that are represented in the assignment
- Component learning outcomes within each goal
- Specific student behaviors demonstrating each component outcome
- Discussion of grading criteria

It may be particularly useful when reviewing the following examples to closely examine the tables corresponding to each of the five learning goals and associated outcomes fitted to each of the three levels of proficiency (see Tables A1–A5 in Appendix A). For ease of review, we made a conscious effort to match each example with one specific level of student proficiency. However, it is important to note that when applying the proposed model to learning assignments, a flexible assessment instrument is represented in which assignments may actually cover more than one level of student proficiency, despite the course designation in the undergraduate curriculum (i.e., 1000, 2000, 3000, or 4000).

Example 1: Basic Level

As shown in Appendix B, the **observational diary** (Mayo, 2003b) taps into all five leaning goals: Knowledge Base of Psychology, Research Methods in Psychology, Critical Thinking Skills in Psychology, Application of Psychology, and Values in Psychology. In the context of an introduction to psychology course, this term-length journal-writing project requires students to identify psychological applications in their own lives and the lives of others.

Example 2: Developing Level

Appendix C describes the **analogies log** (Mayo, 2006), an assignment in a life span developmental survey course requiring students to maintain an ongoing record of co-constructed, learner-generated analogies that are reflective of important developmental principles. The primary purpose of this assignment is to improve students' conceptual understanding of prominent developmental theories. The analogies log targets the following three learning goals: Knowledge Base of Psychology, Critical Thinking Skills in Psychology, and Values in Psychology.

Example 3: Advanced Level

A classroom application of the **repertory grid technique** (Mayo, 2004a), the centerpiece for assessing conceptual systems in Kelly's (1955) personal construct theory, appears in Appendix D. In a series of assignments in a history and systems of psychology course, students rate the positions of contributors to prescientific and scientific psychology over a series of bipolar constructs (e.g., nature–nurture, mind–body). Like the observational diary, the repertory grid assignments address all of the five learning goals.

CONCLUSIONS

We have presented a tripartite framework that articulates the developmental sequence of learning outcomes across the five domains of the undergraduate curriculum. Furthermore, we have offered guidance for use of this model in a departmental or program review process. The model can be used to evaluate one aspect of program effectiveness: student learning. However, utility of this model can also be connected to the original goal of the task force—to provide helpful criteria that facilitate student transitions between institutions.

We constructed developmental student learning outcomes to aid in clarifying how students obtain skills as they progress in an undergraduate psychology curriculum. Earlier we suggested that these outcomes could be linked to specific courses. We created learning outcomes that are independent of courses because courses differ significantly by institution. Explicit articulation of learning outcomes (i.e., listed on syllabi) can provide clear guidance for students. Student expectations can be communicated early, and student evaluation can produce objective measures of program effectiveness that can inform program evaluation. Linkages of learning outcomes with specific courses can provide clear and convincing evidence that programs are indeed accomplishing their respective missions.

Extending beyond an individual program and providing developmental milestones throughout the curriculum offer an added level of clarity. This level of specificity provides objective criteria that can also be used to evaluate course work that may differ with respect to course title, number of credit hours, or level of institution. Transferability of course work among institutions is often facilitated by statewide articulation agreements, yet these agreements may not allow for every contingency. The proposed model provides an additional level of specificity to facilitate objective evaluation across institutions. For example, if the developmental outcomes are listed on a syllabus, this will enable the institution to which a student transfers to compare course outlines and determine what the student has been exposed to prior to transferring. Additionally, if authentic assessment is used consistently with these criteria, students will be expected to demonstrate competencies at the appropriate developmental level.

CONSIDERATIONS FOR THE FUTURE

This task force report should clearly not be considered the final product of the BEA's efforts to strengthen the teaching and learning of undergraduate psychology. More work remains to assist psychology faculty nationwide in articulating meaningful learning outcomes for undergraduates, providing educational experiences designed to achieve those outcomes, and assessing the results of those experiences so that program improvements are continuous and ongoing. The ultimate objectives of this work should be to provide guidance for meaningful course articulation from one institution to another and to develop a consistent framework for program design and assessment.

At some point the validity of the developemental model should be investigated. While the model has been grounded in theory, those who intend to base decisions on it will reasonably expect empirical support for it. Also, the model is likely to be more useful if it is accompanied by suggestions for assessment of each level of each outcome. As mentioned earlier, in response to accountability pressures, postsecondary faculty members

at all types of institutions are expected to provide evidence that students have achieved identified student learning outcomes; many faculty would welcome the availability of a set of model program assessment tasks addressing the accomplishment of student learning outcomes commonly viewed as desirable.

Ideally, wherever appropriate, these assessments would be authentic assessments designed for implementation at the program level, similar to the course-level authentic assessments described earlier in this report. A very useful document would be one that combines the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2007), the developmental model proposed in the present report, and links to specific assessment strategies for each outcome.

In the future, a further effort could be undertaken to develop tasks for the remaining five undergraduate psychology major goals (Goals 6–10) identified in the *Guidelines* (APA, 2007, pp. 17–21):

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

Goal 6: Information and Technological Literacy
Students will demonstrate information competence and the ability to use computers and other technology for many purposes.

Goal 7: Communication Skills
Students will be able to communicate effectively in a variety of formats.

Goal 8: Sociocultural and International Awareness
Students will recognize, understand, and respect the complexity of sociocultural and international diversity.

Goal 9: Personal Development
Students will develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

Goal 10: Career Planning and Development
Students will emerge from the major with realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings.

Further tasks could also include development of criteria for using the developmentally coherent curriculum model in curriculum design and revision, as well as empirical identification of recommended teaching strategies for facilitating student learning in each outcome area.

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APPENDIXES

APPENDIX A

TABLE A1

Goal 1: Knowledge Base of Psychology

Demonstrate familiarity with the major concepts, theoretical perspectives, empirical findings, and historical trends in psychology.

Outcome Areas	BASIC *retention and comprehension*	DEVELOPING *analysis and application*	ADVANCED *evaluation and creation*
Nature of psychology	**Define** psychology as the science that studies behavior and mental processes and the profession that applies that science	**Distinguish** the similarities and differences between the professional and scientific communities in psychology	**Evaluate** the influence of context in the evolving definition of psychology
Relationship of psychology to science	**Explain** how psychology meets the criteria of science	**Analyze** how psychological research reflects scientific principles	**Evaluate** psychological science as a means of understanding behavior and mental processes
Role of behavior in psychology	**Describe** behavior and mental processes empirically, including operational definitions **Distinguish** behavior from inferences about behavior	**Identify** antecedents and consequences of behavior and mental processes **Predict** likely patterns of behavior from context	**Interpret** behavior and mental processes at an appropriate level of complexity
Structure of psychology	**List** and **explain** the major research and applied subfields of psychology	**Differentiate** appropriate subfields to address specific research areas and/or assist in addressing specific behavioral concerns	**Speculate** about psychology's continuing evolution and refinement of subfields
Relationship of psychology to other disciplines	**Identify** the connections between psychology and other disciplines	**Compare** and **contrast** the assumptions, methods, and choice of problems of psychology with those of other disciplines	**Integrate** knowledge derived from psychological science with that of other disciplines
Objectives of psychology (Describing, understanding, predicting, and controlling behavior and mental processes)	**Identify** and **explain** the primary objectives of psychology	**Compare** and **contrast** the primary objectives of psychology	**Evaluate** the strengths and limitations of the primary objectives of psychology
Historical perspectives in psychology	**Describe** the key eras of the major schools of thought in the history of psychology (including their founders, assumptions, explanatory concepts, and methods)	**Compare** and **contrast** historical perspectives	**Assess** the relative importance of the major schools of thought in the history of psychology **Defend** a historical perspective

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Table A1 *(continued)*

Contemporary perspectives in psychology • Behavioral • Biological • Cognitive • Evolutionary • Humanistic • Psychodynamic • Sociocultural	**Identify** and **describe** the major contemporary perspectives of psychology	**Compare** and **contrast** the assumptions, methods, and other elements of the major contemporary perspectives in psychology	**Evaluate** the utility and effectiveness of contemporary psychological perspectives **Describe** how each perspective applies its findings to promote human welfare
Overarching themes of psychology • Interaction of heredity and environment • Variability and continuity of behavior and mental processes within and across species • Free will vs. determinism • Subjectivism vs. objectivism • Interaction of mind and body • Applicability of theories and measures across societal and cultural groups	**Identify** the overarching themes of psychology	**Apply** the overarching themes of psychology to explain specific behaviors **Debate** the merits of each side of the overarching themes of psychology	**Evaluate** the appropriateness of scientific explanations of behavior and mental processes from the standpoint of psychology's overarching themes
General content domains of psychology • Learning and cognition • Individual and sociocultural differences • Biological bases of behavior and mental processes • Development across the life span	**Identify** and **explain** basic concepts, theories, and research represented in the general content domains	**Apply** and **analyze** concepts, theories, and research in the general content domains	**Evaluate** and **synthesize** concepts, theories, and research in the general content domains
Role of ethics	**Describe** relevant ethical issues, as addressed by the APA code of ethics	**Apply** relevant ethical principles, as addressed by the APA code of ethics	**Evaluate** policies and procedures related to behavior and mental processes using relevant ethical principles, as addressed by the APA code of ethics
Career opportunities	**Identify** broad career opportunities associated with psychology at the bachelor's, master's, and doctoral levels	**Compare** and **contrast** the credentials, skills, and experiences required for a career in psychology	**Create** an appropriate career plan related to a specialized goal

TABLE A2

Goal 2: Research Methods in Psychology

Understand and apply basic research methods in psychology, including research design, data analysis, and interpretation.

Outcome Areas	BASIC *retention and comprehension*	DEVELOPING *analysis and application*	ADVANCED *evaluation and creation*
Scientific method	**Describe** the basic characteristics of the scientific method in psychology	**Analyze** how primary behavioral research adheres to scientific principles	**Design** research that adheres to the principles of the scientific method
General research methods • Descriptive • Correlational • Experimental	**Describe** various general research methods, including advantages and disadvantages of use **Distinguish** the nature of designs that permit causal inferences from those that do not	**Select** and **apply** general research methods to address appropriate kinds of research questions **Categorize** research articles that employ methods permitting causal and noncausal inferences	**Evaluate** the effectiveness of a general research method in addressing a research question
Correlation	**Define** correlation	**Interpret** the meaning of correlational findings	**Speculate** about and **evaluate** the significance of correlational findings
Correlation vs. causation	**Explain** the difference between correlation and causation	**Match** research questions to appropriate method	**Evaluate** whether a specific research method warrants a cause–effect conclusion
Controlled comparison	**Describe** the role of controlled comparison in justifying a cause–effect claim	**Analyze** research claims to identify legitimacy of cause–effect claims	**Develop** research strategies that appropriately address controlled comparison
Research elements	**Define** hypotheses, variables, and operational definitions	**Formulate** hypotheses, variables, and operational definitions from research articles and scenarios	**Deduce** testable research hypotheses, based on operational definitions of variables
Experimental design	**Describe** experimental design strategies to address research questions	**Compare** and **contrast** different research methods used by psychologists **Design** basic experiments	**Design** appropriate experiments to maximize internal and external validity and reduce the existence of alternative explanations
Participant selection and assignment	**Describe** random sampling and assignment	**Analyze** the potential influence of participant variables	**Design** appropriate controlled conditions to minimize their effects, including random assignment to conditions
Design quality (internal validity)	**Define** validity and **describe** conditions that enhance valid findings	**Analyze** conditions that will enhance or detract from the validity of conclusions	**Evaluate** the validity of conclusions derived from psychological research

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Table A2 *(continued)*

Generalization (external validity)	**Describe** the relationship of research design to generalizability of results	**Analyze** the generalizability of research findings based on strengths or weaknesses of research design	**Generalize** research conclusions appropriately based on the parameters of particular research methods **Recognize** that individual differences and sociocultural contexts may influence the applicability of research findings
Reporting research findings	**Apply** basic APA standards and style in writing about research	**Explain** (in writing) the methods, results, and conclusions of a data collection project	**Write** all sections of a research report applying APA writing standards
Research ethics	**Describe** the basic principles of the APA code of ethics for research with human and animal participants, including the role of an institutional review board (IRB)	**Adhere** to the APA code of ethics in the treatment of human and nonhuman participants in the design, data collection, interpretation, and reporting of psychological research	**Evaluate** the contributions and constraints entailed in adherence to the APA code of ethics and appropriatly **adjust** the research design **Complete** an IRB application
Body of evidence	**Articulate** how an individual research study addresses a behavioral question	**Analyze** differences across related research studies	**Integrate** findings from several studies to produce a coherent set of conclusions
Sociocultural context	**Identify** variations in behavior related to sociocultural differences	**Apply** sociocultural framework to research strategies and conclusions	**Incorporate** sociocultural factors in the development of research questions, design, data collection, analysis, and interpretation
Database skills	**Identify** and **locate** relevant journals and databases in psychology	**Develop** and **adjust** search strategies to represent adequate range of research	**Create** efficient and effective search strategies to address research questions
Statistical skills	**Describe** the differences between descriptive and inferential statistical analysis	**Conduct** and **interpret** simple statistics from research results and in journal articles	**Evaluate** statistical power in results by addressing effect size and confidence intervals
Statistical significance	**Define** statistical significance and its role in interpreting research findings	**Distinguish** between statistical and practical significance	**Speculate** about the implications of using the conventions of statistical significance in interpreting results
Limits of scientific reasoning and evidence	**State** how evidence is contextual and tentative	**Discuss** the reasons why empirical findings and conclusions may change or require adjustment	**Justify** the evolving nature of scientific findings

TABLE A3

Goal 3: Critical Thinking Skills in Psychology

Respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

Outcome Areas	BASIC *retention and comprehension*	DEVELOPING *analysis and application*	ADVANCED *evaluation and creation*
Use of evidence in psychology	**Discern** difference between personal views and scientific evidence in understanding behavior	**Collect** and **use** scientific evidence in drawing conclusions and in practice	**Evaluate** the quality, objectivity, and credibility of scientific evidence in drawing conclusions and in practice
Association skills	**State** connections between diverse facts and theories	**Relate** connections between diverse facts and theories **Apply** diverse facts and theories over a wide range of contexts	**Assess** the quality of connections between diverse facts and theories
Argumentation skills	**Identify** arguments based largely on anecdotal evidence and personal experience	**Deduce** contradictory and oversimplified arguments based on a growing knowledge of the available facts and theories	**Develop** sound, integrated arguments based on scientific reasoning and empirical evidence
Detection of errors in psychological reasoning	**Identify** claims arising from myths, stereotypes, common fallacies, and poorly supported assertions regarding behavior	**Detect** and **reject** claims arising from myths, stereotypes, common fallacies, and poorly supported assertions regarding behavior	**Evaluate** the errors involved in claims arising from myths, stereotypes, common fallacies, and poorly supported assertions regarding behavior
Questioning skills	**Explain** the appropriateness and relevance of questions with direction and guidance	**Differentiate** independently between ill-defined and well-defined questions	**Evaluate** and **modify** questions to eliminate ambiguity throughout the process of scientific inquiry
Creativity	**Describe** elements of creativity	**Apply** alternative strategies to known protocols	**Generate** novel insights about the psychology of humans and nonhumans
Problem solving	**Define** the stages of problem solving	**Apply** problem-solving strategies to develop solutions to problems in diverse contexts	**Appraise** the quality of solutions **Select** an optimal strategy from multiple alternatives

TABLE A4

Goal 4: Application of Psychology

Understand and apply psychological principles to personal, social, and organizational issues.

Outcome Areas	BASIC *retention and comprehension*	DEVELOPING *analysis and application*	ADVANCED *evaluation and creation*
Healthy lifestyle	**Describe** elements of healthy lifestyle	**Analyze** personal lifestyle reflecting, among other factors, awareness of alternative cultural perspectives	**Evaluate** courses of action that could produce more beneficial outcomes
Abnormal behavior	**Summarize** general criteria of abnormality	**Define** criteria for abnormality relative to a given set of symptoms or characteristics	**Evaluate** the significance of symptoms in a sociocultural context
Psychological tests	**Explain** the elements and importance of effective testing	**Differentiate** between effective and less effective methods of testing and **ensure** that these methods show respect for alternative cultures and gender	**Design** and **evaluate** strategies to assess psychological phenomena
Potential for psychology as a change agent	**List** ways that psychological principles can facilitate personal, social, and organizational change	**Apply** a psychological principle to facilitate positive change in a personal, social, or organizational behavior	**Evaluate** the power of psychological strategies to promote change
Major applied areas in psychology (e.g., clinical, counseling, school, industrial/organizational, etc.) **Emerging applied areas in psychology** (e.g., health, forensic, media, military, etc.)	**Identify** major and emerging applied areas in psychology	**Link** major and emerging applied areas to an appropriate psychological career	**Determine** whether an applied specialty can produce a solution for a given psychological problem

TABLE A5

Goal 5: Values in Psychology

Value empirical evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a science.

Outcome Areas	BASIC *retention and comprehension*	DEVELOPING *analysis and application*	ADVANCED *evaluation and creation*
Curiosity	**Describe** how curiosity assists the scientific process	**Apply** curiosity to psychological phenomena of personal interest	**Sustain** curiosity for investigating complex behavioral questions
Skepticism	**Define** skepticism and its role in psychological thinking	**Distinguish** between scientific and pseudo-scientific explanations of human behavior and **compare** their relative value	**Maintain** rigorous standards related to the quality of scientific evidence in support of a behavioral claim
Tolerance of ambiguity	**Define** tolerance of ambiguity and **explain** its role in psychological science	**Analyze** behavioral explanations with the intent of finding an alternative explanation	**Evaluate** psychological explanations with an expectation of complexity, tentativeness, and variance
Ethical orientation	**Describe** some elements of the ethical code	**Apply** an ethical orientation to hypothetical ethical dilemmas	**Implement** ethical orientation in novel psychological contexts
Protection of human dignity	**Describe** issues pertaining to psychological aspects of human dignity	**Predict** potential outcomes of scenarios in which protection of human dignity does not occur	**Design** psychology projects that protect human dignity and respect alternative cultural and gender perspectives
Human diversity	**Recognize** and **respect** human diversity	**Anticipate** that psychological explanations may vary across populations and contexts	**Exhibit** sensitivity to issues of power, privilege, and discrimination
Academic integrity	**Describe** academic integrity and **explain** its role to the discipline, profession, and society as a whole	**Predict** appropriate outcomes for actions that reflect academic integrity or violations thereof	**Integrate** academic integrity with personal code of honor
Personal responsibility/ service learning	**Describe** how psychology can foster positive civic, social, and global outcomes	**Identify** personal opportunities to apply psychological knowledge for enhancing positive outcomes	**Evaluate** a personal plan for engagement with respect to civic, social, and global responsibilities

APPENDIX B

BASIC LEVEL

Course: Introductory Psychology
Assignment: Observational Diary

Context

In numerous psychology courses, an effective way to match course content to learners' everyday experiences is through the use of student journals (Grasha, 1998; Hettich, 1976, 1980; Klos, 1976; Mayo, 2001a, 2002, 2003a, 2004c; McManus, 1986). The *observational diary* (Mayo, 2003b) is a term-length, case-based, journal writing assignment designed for use in introductory psychology. In composing an observational diary, students record the times that they observe basic psychology being applied in their lives and in the lives of others. When journal writing is linked to case-based methodology, journal entries serve as brief case descriptions that represent some real-life experiences through which students are offered the opportunity to identify applications of psychological principles.

Purpose of the Assignment

Because psychology is an applied science, it is important for undergraduate psychology educators to stress practical applications of psychological principles. Creating a functional connection between the classroom environment and the real world is especially important to students who are just beginning their studies in psychology. The observational diary is a pedagogical tool that helps to bridge the gap between theory and practice in the teaching of psychology.

Instructional Methodology for Assignment Completion

Each observational diary contains 40–50 entries on a variety of psychology topics. The prescribed format for writing each diary entry includes the date, source, case description (five sentences or fewer), and psychological application (five sentences or fewer). A different library reference (cited in APA style) in support of each corresponding psychological application is required in a minimum of 15 diary entries. A student-generated example appears below:

Date	Source	Case Description	Psychological Application
9-15-00	Home	For the past few weeks, my three-year-old son intently watched me set the dinner table. Unexpectedly today, when I was chatting on the telephone shortly before dinner, he took the personal initiative to correctly set the table on his own. Just as he was completing this task, he glanced over at me, pointed to the table settings, and said, "Look Daddy, just like you."	In this situation, my son learned from personal observation to imitate my behavior. This illustrates the concept of modeling through observational or vicarious learning, as discussed in Albert Bandura's (1977) social learning theory. In short, Bandura's view highlights the notion that "examples speak louder than words," which accounts for the fact that my son first watched me and then set the table on his own personal accord without verbal instructions.

Grading Rubric for the Observational Diary

Knowledge Base of Psychology: Nature of Psychology

_____ Defines psychology as the applied science that investigates behavior and mental processes

Knowledge Base of Psychology: Relationship of Psychology to Other Disciplines

_____ Identifies connections between psychology and other disciplines

Knowledge Base of Psychology: Contemporary Perspectives in Psychology

_____ Describes major contemporary perspectives for understanding behavior

Knowledge Base of Psychology: Overarching Themes of Psychology

_____ Identifies the overarching themes of psychology, such as free will vs. determinism, subjectivism vs. objectivism, and the interaction of heredity and environment and of mind and body

Knowledge Base of Psychology: General Content Domains of Psychology

_____ Identifies and explains basic psychological principles representing one or more of the following general domains: learning and cognition, individual and sociocultural differences, biological foundations of behavior and mental processes, and developmental changes across the life span

Research Methods in Psychology: Scientific Method

_____ Describes basic features of scientific methodology in psychology

Research Methods in Psychology: Correlation vs. Causation

_____ Explains the difference between correlation and causation

Research Methods in Psychology: Sociocultural Context

_____ Demonstrates an understanding that there may be variations in behavior and mental processes related to sociocultural differences

Critical Thinking Skills in Psychology: Association Skills

_____ States connections between diverse facts and theories

Critical Thinking Skills in Psychology: Argumentation Skills

_____ Identifies arguments based largely on anecdotal evidence and personal experience

Critical Thinking Skills in Psychology: Detection of Errors in Psychological Reasoning

_____ Identifies myths, stereotypes, and common fallacies in psychological reasoning

Application of Psychology: Healthy Lifestyle, Abnormal Behavior, and/or Psychological Interventions

_____ Identifies appropriate applications of psychology in solving problems that may include the pursuit and effect of healthy lifestyles, origin and treatment of abnormal behavior, and/or psychological interventions in diverse contexts

Application of Psychology: Potential for Psychology as a Change Agent

_____ Describes how psychological principles can be used to facilitate personal, social, and/or organizational change

Application of Psychology: Applied Specialties in Psychology

_____ Identifies applied specialties in psychology

Values in Psychology: Curiosity

_____ Demonstrates curiosity about the psychology of humans and nonhumans

Values in Psychology: Ethical Orientation

_____ Identifies relevant ethical principles applied in psychological contexts

Values in Psychology: Personal Responsibility/Service Learning

_____ Describes how psychology can foster positive civic, social, and/or global awareness

Grading Criteria

The observational diary assignment, which is due one week before the final examination date for the course, counts as 20% of the final course grade. Three equally weighted criteria are used in evaluating this assignment: (a) completeness in adhering to the guidelines for assignment completion; (b) accuracy between each case description and its respective psychological application; and (c) creativity and variety in the psychological applications. The grading scale appears below:

A	Reflects exemplary completion of all assignment criteria
B	Meets most criteria, but displays minor difficulties with concept accuracy and/or creativity and variety in psychological applications
C	Demonstrates limited ability to accurately and broadly apply psychological principles
D	Evidences missing entries, inaccurate psychological applications, and a general absence of variety across applications
F	Fails to meet most or all assignment criteria

APPENDIX C

DEVELOPING LEVEL

Course: Life Span Developmental Psychology
Assignment: Analogies Log

Context

Teachers from all disciplines rely on analogies as explanatory tools to integrate new information with preexisting knowledge in students' long-term memories. By prefacing their explanations with analogous expressions such as "likewise," "similarly," and "comparably," teachers routinely incorporate analogies in their classroom presentations (Glynn, Law, & Doster, 1998).

The *analogies log* (Mayo, 2006) assignment in a survey life-span developmental psychology course is grounded in the use of analogies to accurately depict the nature of human development. For example, in epitomizing the stage theories of Freud, Erikson, and Piaget, the staircase analogy (Case, 1992) portrays development as a discontinuous process of qualitative change observed at "developmental peaks" that alternate with "developmental plateaus." As another illustration of the utility of analogical reasoning within a developmental framework, the analogy of a strand of ivy in a forest (Kagan, 1992) reflects the importance of overarching sociocultural and contextual factors in Bronfenbrenner's ecological theory.

Purpose of the Assignment

In line with findings in other disciplines (e.g., McCloskey, 1995; Rayner-Canham, 1994; Sengstock, 1992; Sincar & Tandon, 1996), empirical evidence (Mayo, 2001b) favors the pedagogical efficacy of teacher-generated analogies within the context of a developmental psychology curriculum. Classroom-based evidence from Mayo's systematic investigation of analogical reasoning also points to the even greater heuristic effectiveness of individual student-generated analogies in a single assignment pertaining to a chapter on developmental theories. As a more expansive project that builds on this use of student-generated analogies in developmental psychology, the analogies log is designed to extend the learning gains that flow from the active and interactive processes of student co-construction of analogies with minimal prompting from the instructor.

Instructional Methodology for Assignment Completion

1. Each student formulates one or more analogies for each of a series of developmental theories (ethological, contextual, psychodynamic, learning, cognitive, humanistic, and sociocultural), identifying the similarities and differences between the *analog* (familiar) and *target* (unfamiliar) concepts.
2. Student exchanges his or her log with a minimum of three classmates, who constructively critique each analogy.
3. As deemed necessary, the student either modifies his or her original analogies or offers new analogies consistent with the peer feedback, providing supporting rationale for any reported changes in analogical reasoning.
4. The week before mid-term exams, each student brings his or her revised log to class to participate in a whole-class discussion in which students share their analogies, critique those of their classmates, and are exposed to facilitating comments from the instructor.
5. Student records feedback from the class discussion that led to any changes in analogical reasoning.

6. Student undertakes a final revision of the applicable analogies in accordance with the aforementioned feedback. Once again, the student offers supporting rationale for any such changes.
7. Student submits the completed log—reflecting a cumulative product of a generative process of conceptual growth and refinement—to the instructor for grading purposes.

Grading Rubric for the Analogies Log

Knowledge Base of Psychology: Contemporary Perspectives in Psychology

_____ Analyzes major contemporary perspectives in developmental psychology into their basic assumptions and explanatory concepts

_____ Compares and contrasts major contemporary perspectives in developmental psychology

Knowledge Base of Psychology: Overarching Themes of Psychology

_____ Explains behavior on the basis of overarching developmental themes, such as free will vs. determinism, subjectivism vs. objectivism, variability and continuity of behavior within and across species, and the interaction of heredity and environment

Critical Thinking Skills in Psychology: Association Skills

_____ Relates connections between developmental theories over a wide range of analogous contexts

Critical Thinking Skills in Psychology: Questioning Skills

_____ Differentiates between well-conceived and poorly conceived developmental analogies

_____ Analyzes the pitfalls inherent in each developmental analogy

Critical Thinking Skills in Psychology: Creativity

_____ Applies novel analogies to explain developmental theories

Values in Psychology: Curiosity

_____ Applies curiosity to the examination of developmental theories through a generative process of analogy refinement

Grading Criteria

The final version of the analogies log is due at midterm. The assignment is worth 15% of the final course grade. The grading scale follows:

A	Demonstrates mastery of developmental theories and significant refinement in analogical reasoning from first to last draft of the log
B	Reflects an overall understanding of developmental theories and above-average refinement in analogical reasoning
C	Evidences difficulties in comprehending developmental theories and limited refinement in analogical reasoning
D	Reflects major difficulties in theory comprehension and analogy creation and refinement
F	Fails to meet assignment criteria in most or all respects

APPENDIX D

ADVANCED LEVEL

Course: History and Systems of Psychology
Assignment: Repertory Grid Technique

Context

As the hallmark of assessment in personal construct theory, the *repertory grid technique* (RGT) is an offshoot of Kelly's (1955) Role Construct Repertory Test that was created to explore personal construct systems within clinical settings. Personal constructs are bipolar meaning dimensions (e.g., conscious–unconscious) that each person uses to organize and interpret knowledge on the basis of the perceived similarities and differences between these dichotomous extremes. Although originally intended for clinical use, successful applications of RGT have been found in various contemporary educational venues (e.g., Bezzi, 1999; Mayo, 2004b; Olsson, 1997; Winer & Vazquez-Abad, 1997). The present assignment applies RGT in the context of a history and systems of psychology course (Mayo, 2004a).

Purpose of the Assignment

Teaching a history of psychology course presents special challenges to undergraduate educators. Aside from a barrage of important names, dates, terms, and events, it calls for the integration of divergent intellectual, philosophical, and theoretical perspectives into a coherent historical mosaic of psychology that captures the spirit of the times in which competing views were put forth. At the same time, it affords an excellent opportunity to synthesize the diverse contents of other undergraduate psychology courses (Tobacyk, 1987). Because of this instructional opportunity and its accompanying classroom challenges, instructors often search for pedagogical strategies to enhance student comprehension and active involvement. As a teaching and learning instrument in a history of psychology course, RGT can be used to organize course content and bolster student understanding and enthusiasm for the subject matter.

Instructional Methodology for Assignment Completion

The course is designed to provide an overview of the intellectual history of psychology, tracing its roots from antiquity through the present. Course content is divided into three units: (a) the evolution of prescientific psychology; (b) the emergence and development of competing psychological systems during the early decades of scientific psychology; and (c) the chronological development of the principal subfields of psychology over the past century.

There are three take-home repertory grid assignments, one relating to each of the three units. Students work independently in completing each assignment as a paper-and-pencil task. Students are presented with a teacher-generated list of bipolar constructs tied to 11-point rating scales (see Figure D1) on which they rate 24 preselected contributors to the historical development of psychology (refer to Figure D2). The first six constructs (mind–body, nature–nurture, subjectivism–objectivism, holism–elementalism, free will–determinism, and utility–purity) represent ongoing debates with deep roots in the intellectual history of psychology.

Note. Portions of Appendix D were derived from "A Pilot Investigation of the Repertory Grid as a Heuristic Tool in Teaching Historical Foundations of Psychology," by Joseph A. Mayo, 2004, *Constructivism in the Human Sciences*, *9*, pp. 32–36 (www.constructivism123.com). Copyright 2004 by the Society for Constructivism in the Human Sciences. Reprinted with permission.

Figure D1

Eight, 11-Point Construct Scales Used in the Repertory Grid Assignments

	Ratings											
	1	2	3	4	5	6	7	8	9	10	11	
1. mind	__	__	__	__	__	__	__	__	__	__	__	body
2. nature	__	__	__	__	__	__	__	__	__	__	__	nurture
3. subjectivism	__	__	__	__	__	__	__	__	__	__	__	objectivism
4. holism	__	__	__	__	__	__	__	__	__	__	__	elementalism
5. free will	__	__	__	__	__	__	__	__	__	__	__	determinism
6. utility	__	__	__	__	__	__	__	__	__	__	__	purity
7. verity	__	__	__	__	__	__	__	__	__	__	__	falsity
8. major contribution	__	__	__	__	__	__	__	__	__	__	__	minor contribution

Source. From "A Pilot Investigation of the Repertory Grid as a Heuristic Tool in Teaching Historical Foundations of Psychology," by Joseph A. Mayo, 2004, *Constructivism in the Human Sciences*, *9*, p. 36. Copyright 2004 by the Society for Constructivism in the Human Sciences. Reprinted with permission.

Figure D2

Contributors Covered in Each Unit of the History of Psychology Course

Unit 1	Unit 2	Unit 3
Aristotle	Wilhelm Wundt	Gordon Allport
Saint Thomas Acquinas	William James	Jean Piaget
Rene Descartes	Mary Whiton Calkins	Francis Cecil Sumner
John Locke	Sigmund Freud	Margaret Floy Washburn
Herbert Spencer	Ivan Pavlov	Kurt Lewin
Immanuel Kant	John B. Watson	William McDougall
Hermann von Helmholtz	B. F. Skinner	Abraham Maslow
Gustav Fechner	Max Wertheimer	Richard Dawkins

Source. Adapted from "A Pilot Investigation of the Repertory Grid as a Heuristic Tool in Teaching Historical Foundations of Psychology," by Joseph A. Mayo, 2004, *Constructivism in the Human Sciences*, *9*, p. 35. Copyright 2004 by the Society for Constructivism in the Human Sciences. Reprinted with permission.

Through preliminary lectures at the start of the term, students are familiarized with the factors defining the two construct poles of each of these six meaning dimensions. The final two constructs (verity–falsity and major contribution–minor contribution) assess students' views on purely subjective matters. With regard to these last two constructs, students are asked to assign their ratings on the basis of existing sociocultural, historical, and other overtones within the context of both contemporary times and the times in which each contributor lived.

In each of the three, unit-based RGT assignments, students complete the eight, 11-point construct scales one contributor at a time and then submit their completed grids for all eight contributors at the respective due dates for each assignment. In recording their construct-specific ratings on each grid, students print an X on the appropriate line within the rating continuum—somewhere between lines 1 and 11—that best matches the perspective of each contributor. In the blank space provided at the bottom of each rating grid (continued on the back of this sheet and on additional attached sheets if more space is needed), students offer a justifying rationale for each rating.

Once each of the three repertory grid assignments is graded and returned, 30–45 minutes of class time is allotted for whole-class discussion of students' scored grids. Throughout these teacher-led discussions, students openly share their analyses and constructively critique the expressed views of their classmates.

Grading Rubric for the Repertory Grid Assignments

Knowledge Base of Psychology: Objectives of Psychology

_____ Evaluates the descriptive, explanatory, and predictive validity of different intellectual, philosophical, and theoretical perspectives throughout the history of psychology

Knowledge Base of Psychology: Overarching Themes of Psychology

_____ Evaluates the appropriateness of various intellectual, philosophical, and theoretical perspectives over the history of psychology, based on ongoing debates including nature vs. nurture, mind vs. body, free will vs. determinism, subjectivism vs. holism, holism vs. elementalism, and utility vs. purity

Knowledge Base of Psychology: General Content Domains of Psychology

_____ Evaluates and synthesizes the work of important contributors to the principal subfields of psychology

Research Methods in Psychology: Sociocultural Context

_____ Demonstrates awareness that historical and sociocultural context may shape the work of prominent intellectuals, philosophers, theorists, and researchers throughout the historical evolution of psychology

Critical Thinking Skills in Psychology: Use of Evidence in Psychology

_____ Analyzes and evaluates the quality, objectivity, and credibility of evidence in diverse contexts as it relates to the formation of influential intellectual, philosophical, and theoretical perspectives across the historical development of psychology

Critical Thinking Skills in Psychology: Argumentation Skills

_____ Develops sound, integrated supporting arguments that relate to diverse intellectual contributions throughout psychology's history

Critical Thinking Skills in Psychology: Detection of Errors in Psychological Reasoning

_____ Evaluates the errors involved in poorly supported assertions by contributors to psychology's intellectual history

Critical Thinking Skills in Psychology: Problem Solving

_____ Evaluates the quality of solutions to problems in diverse contexts offered by key contributors to the intellectual history of psychology

Application of Psychology: Potential for Psychology as a Change Agent

_____ Evaluates the intellectual, sociocultural, and other changes stemming from the work of key contributors to psychology's historical evolution

_____ Evaluates (within the context of both contemporary times and the times in which each contributor lived) contributions to societal change resulting from the work of prominent intellectuals, philosophers, theorists, and researchers throughout the historical development of psychology

Application of Psychology: Applied Specialties in Psychology

_____ Evaluates the contributions of influential historical figures throughout the chronological development of psychology's applied subfields

Values in Psychology: Curiosity

_____ Sustains curiosity for investigating psychological claims pertaining to the contributions of key figures to the emergence and development of scientific psychology

Grading Criteria

Each unit-based repertory grid assignment is worth 10% of the final course grade. The assignments allow for sufficient depth and clarity in examining each student's work because they include numerical ratings in conjunction with corresponding written justifications. Students are advised that ratings are opinions that must be backed by logical supporting arguments. Accordingly, in scoring these assignments, the instructor offers written feedback in terms of the underlying logic and connection between students' numerical ratings and accompanying written justifications. The grading scale appears below:

A Evidences thorough evaluation of each contributor's views and well-conceived arguments in support of all numerical ratings

B Reflects an overall understanding of each contributor's views, but shows a few inaccuracies in providing rating justifications

C Demonstrates limited understanding of contributor's views and inconsistencies in arguing logically in support of numerical ratings

D Reflects consistent difficulties in connecting numerical ratings to logical supporting arguments

F Fails to support numerical ratings with logical justifications in most or all instances

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COGNITIVE

Analytical thinking: Solve complex problems, attend to details, plan proactively, and display comfort with ambiguity.

Critical thinking: Display proficiency with statistics, program evaluation, and research design necessary for the study of social and technical systems.

Creativity: Use innovative and resourceful approaches to problem solving and new tasks.

Information management: Be adept at locating, organizing, evaluating, and distributing information from multiple sources.

Judgment and decision making: Engage in logical and systematic thinking and ethical decision making when considering the possible outcomes of a particular action.

COMMUNICATION

Oral communication: Demonstrate strong active listening and conversational abilities in both informal and professional environments, as well as aptitude for public speaking and communicating scientific information to diverse audiences.

Written communication: Comprehend relevant reading materials to produce professional documents that are grammatically correct, such as technical or training materials and business correspondence.

PERSONAL

Adaptability: Adjust successfully to change by responding in a flexible, proactive, and civil manner when changes occur.

Integrity: Perform work in an honest, reliable, and accountable manner that reflects the ethical values and standards of an organization.

Self-regulation: Manage time and stress by completing assigned tasks with little or no supervision; display initiative and persistence by accepting and completing additional duties in a careful, thorough, and dependable manner.

SOCIAL

Collaboration: Work effectively in a team by cooperating, sharing responsibilities, and listening and responding appropriately to the ideas of others.

Inclusivity: Demonstrate sensitivity to cultural and individual differences and similarities by working effectively with diverse people, respecting and considering divergent opinions, and showing respect for others.

Leadership: Establish a vision for individuals and for the group, creating long-term plans and guiding and inspiring others to accomplish tasks in a successful manner.

Management: Manage individuals and/or teams, coordinate projects, and prioritize individual and team tasks.

Service orientation: Seek ways to help people by displaying empathy; maintaining a customer, patient, or client focus; and engaging in the community.

TECHNOLOGICAL

Flexibility/adaptability to new systems: Be willing and able to learn and/or adapt to new computer platforms, operating systems, and software programs.

Familiarity with hardware and software: Demonstrate competency in using various operating systems, programs, and/or coding protocols; troubleshoot technical errors; and use software applications to build and maintain websites, create web-based applications, and perform statistical analyses.

For more information, visit **on.apa.org/undergrad**

About This Document

The *Skillful Psychology Student: Prepared for Success in the 21st Century Workplace* was commissioned by the American Psychological Association's Committee on Associate and Baccalaureate Education (CABE). The contributing members, listed in random order, are:

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Related Readings

Appleby, D., Young, J., Van Kirk, J., Rudman, J., Naufel, K. Z., Spencer, S. M., ... Richmond, A. S. (2019). The skillful psychology student: Skills you will need to succeed in the 21st-century workplace. *Psychology Student Network, 7(1).* Retrieved from https://www.apa.org/ed/precollege/psn/index

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AMERICAN PSYCHOLOGICAL ASSOCIATION

The Assessment CyberGuide for Learning Goals and Outcomes

(Second Edition, November 2009)

Compiled by Thomas Pusateri
with assistance from Jane Halonen, Bill Hill & Maureen McCarthy

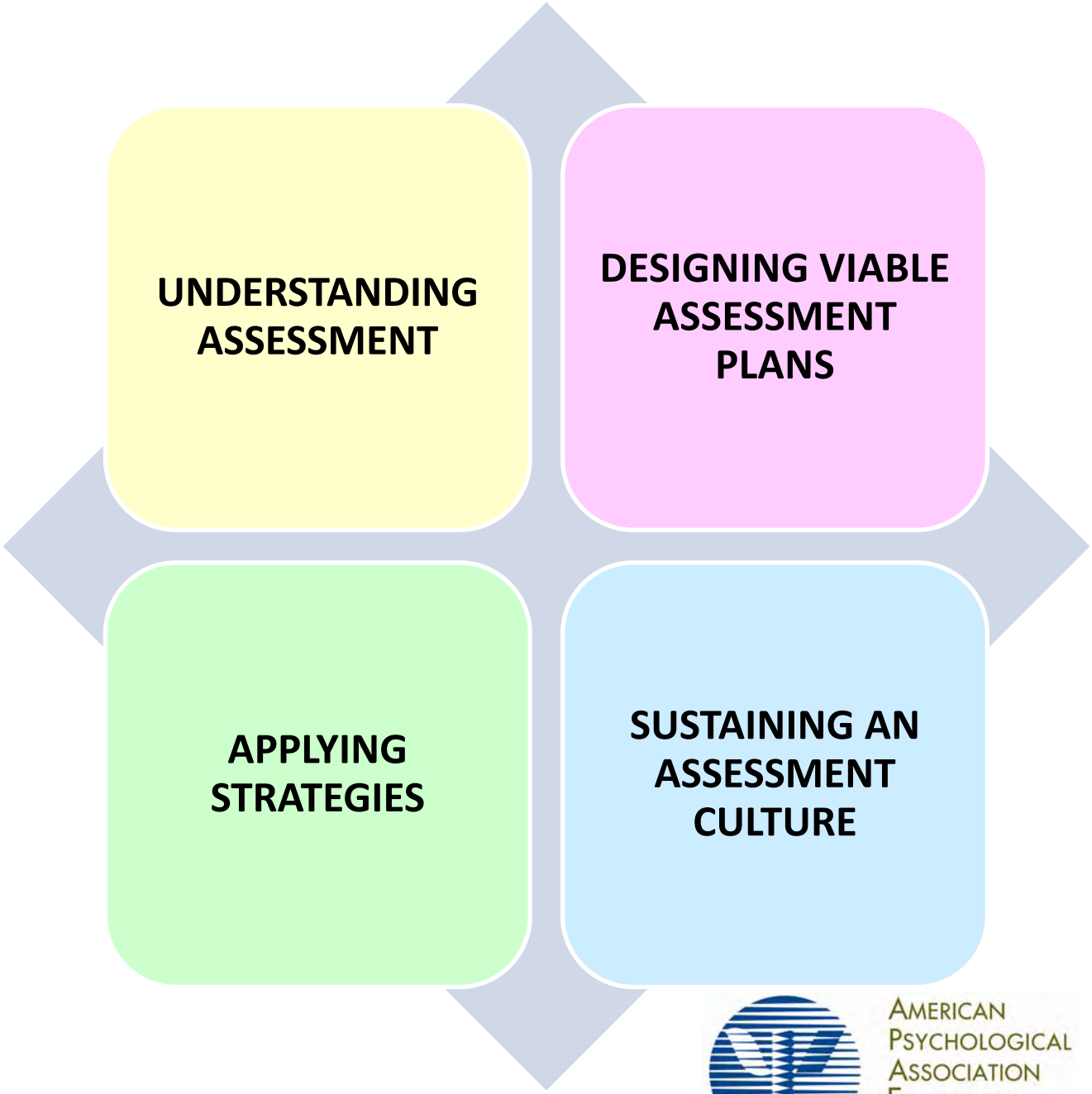

American Psychological Association Education Directorate

The Assessment CyberGuide for Learning Goals and Outcomes (Second Edition) revised October 2009

produced under the auspices of the Board of Educational Affairs (BEA), American Psychological Association (APA)

PREFACE

The Assessment CyberGuide evolved from the work of the APA Board of Education Affairs' (BEA) Task Force on Psychology Major Competencies. In March 2002, the BEA endorsed the task force's report on Undergraduate Psychology Major Learning Goals and Outcomes. Subsequently, BEA charged the task force to develop a companion document to address assessment strategies based upon these learning goals and outcomes. Members of the task force convened an Assessment CyberGuide Task Force, which produced the first version of the Assessment CyberGuide in 2002.

In 2006, the APA Council of Representatives adopted a revised version of the task force's report under the title *APA Guidelines for the Undergraduate Psychology Major* (http://www.apa.org/ed/psymajor_guideline.pdf).

In 2009, the Assessment Cyberguide Revision Task Force updated the CyberGuide to reflect current practice and revised links. The CyberGuide serves as a companion resource for implementing the APA Guidelines for the Undergraduate Major in Psychology. These resources should aid psychology departments and their faculty to design the most appropriate and effective assessment plans.

We have organized this Cyberguide into four parts that will assist departments in developing assessment plans:

A. Understanding Assessment: Departmental, Institutional, Educational, and Societal Perspectives
B. Designing Viable Assessment Plans
C. Sustaining an Assessment Culture
D. Applying Assessment Strategies in Psychology

We are taking advantage of the flexibility of the cyber medium to provide links to resources or the full-text documents when they are available. Otherwise, the recommendations and insights provided in this CyberGuide emerge from the collective experience and scholarship of the members of the Assessment CyberGuide Task Force and the Assessment CyberGuide Revision Task Force.

ACKNOWLEDGEMENTS

We are indebted to the contributions of Jane Halonen and the members of both CyberGuide Task Forces who spent countless hours working on this project. In addition, we extend special thanks and appreciation to Tom Pusateri for his extensive editing, formatting, and additions to the current revision.

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A. Understanding Assessment

1. Departmental Perspective: Questions and Recommendations from the APA Task Force

Members of the Task Force on Psychology Major Competencies provide answers to a set of questions and provide a list of recommendations for developing effective assessment processes at the departmental level.

= = = =

"Assessment Days." Many departments designate a common time to assess student progress. In some cases, classes may be canceled to facilitate completion of the work; however, care needs to be taken to insure student motivation in rendering solid performance.

After graduation. Interest in alumni satisfaction and performance skills prompts many departments to assess students after they have graduated. Length of time can range from six months after graduation (e.g., typical length of time to look at employment success) to five years (e.g. typical length of time to look at graduate school completion rates/adjustment). Employers or graduate advisors may be asked to evaluate the former student's strengths and weaknesses.

What do you assess?

Achievement in the Major. Assessment activity can establish how well students have learned the content, skills, and attitudes of the major. Quality is easiest to assess when the department has formulated explicit learning outcomes that characterize the major.

General Education Achievement. Some institutions assess the overall development within the liberal arts.

Performance Patterns. Programs may want answers to specific issues about student performance. For example, how do transfer students compare to students who have been in the program from the outset of their studies? How do female students compare to male students in their relative performances?

Impact of Faculty or Program. Program faculty may want to determine what kind of impact the program or the faculty have had on students beyond their academic achievement. Satisfaction surveys, focus groups, and other strategies may help the faculty to address these questions.

Quality of Instructional Practice. Faculty may want to evaluate whether a new instructional technique produces improved learning over other approaches. They may evaluate questions of this type through systematic comparison of student performances across semesters.

Who assesses?

Faculty. Historically, faculty have been charged with evaluating the quality of their students' work. They remain the primary source of expert feedback on student performance in assessment activities.

Expert External Judges. Assessors can provide feedback on student performance as long as they can be trained properly on performance criteria. Experts can be recruited from among other faculty or professionals in the community.

Peers. Student colleagues can provide feedback on performance if properly trained on clear criteria.

Employers. We can find out the quality of performance of our graduates by asking for a review of their work from current employers. Although the student is the focus, the attitudes being assessed are the employers.

Family. Some strategies can involve assessing parental satisfaction with changes in their children as a result of education. Although the student is the focus of the assessment, the attitudes being assessed are the parents.

Students. Students can evaluate their own performances through self-assessment strategies. Advocates of self-assessment suggest such practices can encourage student development and independence.

What is the quality of your assessment measures?

Validity and reliability of the measure. The selected strategy needs to produce both a valid and reliable measure of learning. Students should be optimally motivated to engage in the assessment.

Appropriateness for the targeted learning goal as well as the mission and goal of the program. The measure should be logically connected to the objectives of the assessment.

How will you use the assessment results?

Direct feedback to students/faculty. In most cases, the individuals who are being assessed can benefit from feedback on their performances. An assessment experience can highlight both strengths and areas of potential weakness, which can have an impact on individual plans for improvement.

Systematic feedback for program improvement. The results of assessment can be used by program faculty to determine strengths and weaknesses. Strengths can be used to enhance recruitment and procure resources. Weaknesses can be remediated once they have been recognized.

Benchmarking for program comparison. In some institutions, programs may have to provide evidence of effectiveness for continued support. Clear indications of effectiveness may secure additional support funds.

How will you manage assessment obligations with other academic tasks?

Adjust loads to reflect assessment requirements. Faculty members are unlikely to be successful or enthusiastic with assessment responsibilities treated as an "add on." Faculty loads must be adjusted to make time and space for the activities related to assessment. Provide release time for substantial assessment contributions.

Embed assessment activities, wherever possible. Taking advantage of existing structures can reduce the impression that assessment is eating up discretionary time.

Reward successful assessment activity. Assessment participation should receive public recognition and financial reward to enhance the incentive for faculty to participate.

Best Practices in Assessment: Top 10 Task Force Recommendations

from the APA Board of Educational Affairs Task Force on Psychology Major Competencies (2002)

1. Encourage department ownership to drive the process.
Faculty resistance to assessment activity can defeat the best designed assessment practices. Assessment planning should grow out of the fundamental questions the faculty have about how their contributions shape program success. This emphasis may involve addressing differences between an individual faculty member's personal goals (e.g. income, convenience, lifestyle, security, autonomy) and the collective goals of the department.

2. Define your objectives in the context of your institutional mission.
Create a shared mission and goals statement that reflects an emphasis on student learning. The values of the institution should be reflected in your department's plan. Faculty identification with the institution will reinforce assessment activities, particularly if faculty can envision that their results will have a positive impact on how the institution works.

3. Focus on collaboration and teamwork.
Faculty members must agree on assessment goals for planning to be meaningful. They may have to rise to a higher level of collaboration than may have been traditionally practiced in most departments. Collaboration within the department, across departments, and with higher administration will facilitate the best outcomes from assessment planning. All constituents must recognize that assessment skills must be developed and that colleagues can assist each other by sharing practices and strategies.

4. Clarify the purpose of assessment.
Assessment can serve dual purposes: Assessment can promote student learning or provide evidence for accountability requirements through an evaluation of strengths and weaknesses. Wherever possible, students should experience a direct, positive benefit from their participation in assessment activities.

5. Identify clear, measurable, and developmental student learning
Explicit identification of learning expectations facilitates the department's coherence about their goals. Sharing those expectations explicitly with students can provide an effective learning scaffold on which students can build their experiences and render effective performance. Outcomes can be specified in a developmental hierarchy, where possible.

6. Use multiple measures and sources consistent with resources.
Effective assessment planning can only occur when properly supported with appropriate time, money, and recognition for good work. The expansiveness of the assessment plan will depend on those resources. As resources permit, additional measures can be added to planning. These measures address variations in learning style, differences in types of learning, and interests from variable stakeholders.

7. Implement continuous assessment with clear, manageable timelines.
Better assessment practice involves spreading out assessment activity throughout the year and across years rather than conducting a marathon short-term assessment effort in a single year. Projecting a schedule of regular formal reviews can facilitate appropriate interim activity.

8. Help students succeed on assessment tasks.
Students will fare best in assessment activities when faculty make expectations explicit, provide detailed instructions, and offer samples or models of successful performance. They will benefit most with opportunities to practice prior to assessment and when given detailed feedback about the quality of their performance.

9. Interpret and use assessment results appropriately.
Assessment should be a stimulus for growth, renewal, and improvement, not an action that generates data to ensure positive outcomes. Linking funding to assessment outcomes may encourage artificial results. Assessment data should not be used for personnel decisions. If cross-institution comparisons are inevitable, care should be taken to ensure comparisons across comparable institutions (benchmarking).

10. Evaluate your assessment practices.
Results from assessment activity should be evaluated to address their reliability, validity, and utility. Poor student performance can reflect limited learning or an ill-designed assessment process. Examining how effectively the assessment strategy meets departmental needs is a critical step in the evolution of the department plan.

A. Understanding Assessment

2. Institutional Perspective: Supporting an Institution's Culture of Assessment

Peggy Maki, former Director of Assessment for the American Association for Higher Education, has written several articles that discuss strategies for institutions to develop and sustain a culture of assessment. Here are excerpts, references, and links to two of her articles.

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A. Understanding Assessment

3. Undergraduate Education Perspective: Principles for Sound Assessment Practices

In 1993, a task force from the American Association of Higher Education (AAHE) articulated some philosophical principles about enacting assessment planning. This entry summarizes nine ideas and provides a link to the original article. Lee Shulman (2007) provided a related set of principles in response to the recent Spellings Commission report.

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A. UNDERSTANDING ASSESSMENT

4. Societal Perspective: National and International Conversations on Assessment and Accountability

To provide a broader context for discussions on assessment, we briefly describe the Spellings Report, the Bologna Process, and assessment resources from some national organizations and associations.

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National Associations and Organizations of Higher Education: Assessment Resources

The following national associations and organizations prepare resources and materials on assessment and accountability in higher education that may be relevant to psychology departments in some institutions.

Association of American Colleges and Universities (AAC&U): http://www.aacu.org

AAC&U leads initiatives and disseminates publications that promote and support assessment of student learning in higher education. Here are examples of AAC&U publications on assessment:

2008 New Leadership for Student Learning and Accountability: A Statement of Principles, Commitments to Action (http://www.aacu.org/resources/assessment/documents/New_Leadership_Statement.pdf)
A joint statement with the Council on Higher Education Accreditation (CHEA) that calls upon colleges and universities to articulate goals for student learning and assesses student achievement towards those goals.

2008 Our Students' Best Work: A Framework for Accountability Worthy of Our Mission
(Available for purchase at http://tinyurl.com/StudentBestWork)
The statement calls for a focus on a broad set of learning outcomes essential for global citizenship and success in today's volatile and competitive workplace.

2005 Liberal Education Outcomes: A Preliminary Report on Student Achievement in College
(http://www.aacu.org/advocacy/pdfs/LEAP_Report_FINAL.pdf)
AAC&U proposed a core set of knowledge, skills, and values that students should achieve in college.

Association for Institutional Research (AIR)

AIR has published 3 volumes in its series, *Assessment in the Disciplines*. Although AIR has not yet published a volume in psychology, the articles in other disciplines may be useful for adaptation to psychology. Volumes in Business, Mathematics, and Engineering are available for purchase at http://www.airweb.org/page.asp?page=1222.

Council on Higher Education Accreditation (CHEA): http://www.chea.org

CHEA is "[a] national advocate and institutional voice for self-regulation of academic quality through accreditation." Since 2005, CHEA holds an annual competition for CHEA Awards for Institutional Progress in Student Learning Outcomes and publishes descriptions of awards recipients in the CHEA Chronicle (http://www.chea.org/Research/index.asp#chronicle). The Department of Psychology at Southern Illinois University, Edwardsville, was a 2006 recipient of this award for its Senior Capstone experience.

National Center for Public Policy and Higher Education

Every two years, the National Center for Public Policy and Higher Education publishes its "Measuring Up" report, which provides both national and state-by-state report cards on the status of higher education in the United States in terms of Preparation, Participation, Affordability, Completion, Benefits, and Learning. The 2008 report is available at http://measuringup2008.highereducation.org/index.php. This report grades the nation and all states with an "Incomplete" as it pertains to assessment of learning outcomes. Here is the summary statement for Learning:

"As in 2000, there are still no common benchmarks that would permit state comparisons of the knowledge and skills of college students. There are isolated instances in which learning outcomes are assessed, such as South Dakota's mandatory exam of rising college juniors. There are assessments that cover portions of the population, such as Graduate Record Examinations (GREs), which test those pursuing graduate study. And there are assessments in selected fields, such as licensure exams in nursing or WorkKeys in selected vocational fields. But there is no nationwide approach to assessing learning that would allow state-to-state comparisons. What energy was available for state assessments in 2000 has been directed to campus-level assessments in 2008, such as the Voluntary System of Accountability. This represents a step backward, not forward."

Voluntary System of Accountability (VSA)

The VSA is a joint initiative of the American Association of State Colleges and Universities and the Association of Public and Land-Grant Universities that generates a "College Portrait" with 3 sets of data elements: Consumer Information, Student Experiences and Perceptions, and Student Learning Outcomes. The Student Learning Outcomes section includes a description of each institution's methods for evaluating student learning and reports institution-wide results of student performance on standardized tests of critical thinking and written communication. The Web site for the VSA is http://www.voluntarysystem.org.

A. Understanding Assessment: Departmental, Institutional, Educational, and Societal Perspectives

5. Understanding Assessment: An Annotated Bibliography

We offer a summary of helpful print and electronic resources that introduce assessment issues, some of which are focused on psychology programs and some of which apply to any discipline.

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General Resources for Assessment of Student Learning

American Psychological Association. (1997). *Learner-centered psychological principles: A framework for school reform & redesign.* Retrieved from http://www.apa.org/ed/cpse/LCPP.pdf

Effective assessment strategies require an understanding of the learning process. The Learner-Centered Principles Work Group of the American Psychological Association's Board of Educational Affairs (BEA) articulate 14 learner-centered psychological principles that address cognitive and metacognitive factors, motivational and affective factors, developmental and social factors, and individual difference factors in learning.

Angelo, T. (1999, May). Doing assessment as if learning matters most. *AAHE Bulletin*, *51*(9), 3-6. Retrieved from http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/17/a5/10.pdf (Note: This article appears on pages 133-136 of the PDF.)

Angelo argues for assessment that is focused on learning-centered principles and that transforms the culture of the university. He advocates for shared trust, shared vision and goals, shared language and concepts, and research-based guidelines to enhance the quality of assessment practices.

Banta, T. W., Jones, E. A., and Black, K. E. (2009). *Designing effective assessment: Principles and profiles of good practice*. San Francisco, CA: Jossey-Bass.

Banta, Jones, and Black discuss good practices in planning, implementing, and sustaining assessment and provide examples from 130 institutions (49 of which are in detail) that illustrate varying approaches to assessment at the institutional, departmental, and program level. For more information, visit http://www.josseybass.com/WileyCDA/WileyTitle/productCd-0470393343.html

Biggs, J. (1999, May). Assessment: An integral part of the teaching system. *AAHE Bulletin*, *51*(9), 10-12. Retrieved from http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/17/a5/10.pdf (Note: This article appears on pages 140-142 of the PDF.)

Following a brief review of different approaches to classroom assessment, Biggs presents a model that emphasizes defining learning objectives and adopting teaching methods and assessment procedures that follow from one's objectives.

Malik, D. J., & Lees., N. D. (2009). The accountability movement: Its role, opportunities, and meaning for chairs. *The Department Chair: A Resource for Academic Administrators*, *19*(3), 3-5. Retrieved from The Tomorrow's Professor Blog, http://cgi.stanford.edu/~dept-ctl/cgi-bin/tomprof/posting.php?ID=924

Malik and Lees discuss the Spellings Commission report and recent pressures on institutions to participate in the Voluntary System of Accountability, both of which have implications for faculty roles, curriculum development, and assessment of student learning.

National Center for Academic Transformation (2005). *Five models for assessing student learning*. Sarasota Springs, NY: Author. Retrieved from http://www.thencat.org/PlanRes/R2R_ModAssess.htm

Provides recommendations for various methods of conducting assessments of student learning such as comparisons of performance on common exams among parallel sections of courses, pretest-posttest comparisons, and comparisons of student work using common rubrics.

National Research Council. (2001). Knowing what students know: The science and design of educational assessment. National Academies Press. Retrieved from http://www.nap.edu/catalog.php?record_id=10019

Links assessment reform to what cognitive science has proposed about effective learning strategies.

Quality Assurance Agency for Higher Education. (2005). *Reflections on assessment: Volume I*. Gloucester, UK: Author. Retrieved from http://www.enhancementthemes.ac.uk/themes/Assessment/outcomes.asp

Contains papers on four workshops:
Workshop 1: Streamlining assessment- how to make assessment more efficient and more effective
Workshop 2: Using assessment to motivate learning
Workshop 3: Constructive alignment of learning outcomes to assessment methods
Workshop 4: Developing a variety of assessment methods, including self and peer assessment

Quality Assurance Agency for Higher Education. (2005). *Reflections on assessment: Volume II*. Gloucester, UK: Author. Retrieved from http://www.enhancementthemes.ac.uk/themes/Assessment/outcomes.asp

Contains papers on four workshops:
Workshop 5: Assessing online
Workshop 6: Issues of validity, reliability and fairness
Workshop 7: Improving feedback to students (link between formative and summative assessment)
Workshop 8: Assessing personal transferable skills

Quality Assurance Agency for Higher Education (2007). *Integrative assessment.* Gloucester, UK: Author. Retrieved from http://www.enhancementthemes.ac.uk/themes/IntegrativeAssessment/themes.asp

Contains links to four separate guides:
Guide no. 1: Monitoring Students' Experiences of Assessment
Guide no. 2: Balancing Assessment of and Assessment for Learning
Guide no. 3: Blending Assignments and Assessments
Guide no. 4: Managing Assessment Practices and Procedures

Volkwein, J. F. (2003, May). Implementing outcomes assessment on your campus. *eJournal*, *1*. Retrieved from http://rpgroup.org/publications/eJournal/volume_1/volkwein.htm

Provides an overview of assessment planning that links institutional, departmental, and course levels.

Walvoord, B. E. (2004). *Assessment clear and simple: A practical guide for institutions, departments, and general education.* San Francisco, CA: Jossey-Bass.

Walvoord introduces the basics of assessment for both administrators and faculty members, and she includes samples of rubrics and guidelines for collecting and analyzing data and for writing assessment reports. For more information, visit http://www.josseybass.com/WileyCDA/WileyTitle/productCd-0787973114.html

Wehlburg, C. (1999, May). How to get the ball rolling: Beginning an assessment program on your campus. *AAHE Bulletin*, *51*(9), 7-9. Retrieved from http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/17/a5/10.pdf (Note: This article appears on pages 137-139 of the PDF.)

Wehlburg describes the steps necessary to implement an assessment program, including points of resistance and characteristics of effective assessment programs.

B. Designing Viable Assesment Plans

1. Linking Assessment to the Learning Outcomes in the *APA Guidelines*

The Task Force constructed the Learning Outcomes in the *APA Guidelines for the Undergraduate Psychology Major* from the standpoint that they should be assessable. In this entry, we outline the assumptions that provided the foundation for goals and outcomes and the implications these assumptions have for good practice in psychology assessment.

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B. Designing Viable Assessment Plans

2. An Overview of Assessment Strategies

The 2002 Task Force developed a taxonomy that provides a comprehensive listing of various categories of good assessment practice. This link offers a graphic depiction of the taxonomy and lists an assortment of specific strategies in each category.

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B. Designing Viable Assessment Plans

3. Evaluating Assessment Strategies

In this entry, the 2002 Task Force defines each of the categories in our taxonomy of assessment and provides an overall analysis of the advantages and disadvantages of these approaches. The Task Force offers some recommendations to promote best practices within each assessment category.

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ESSAY TESTS

Advantages:
- showcases deeper learning, higher order thought processes
- requires transfer, integration of learning from other sources
- can include applications or problem-based learning
- develops writing skills and critical thinking
- cheap and easy to administer
- faster to construct than objective tests

Disadvantages:
- questionable psychometric properties
- may disadvantage ESL, students with poor writing or thinking skills
- takes longer to grade and provide feedback
- produces narrower sample of content knowledge

Recommendations

Despite the labor intensiveness of essay evaluation, this kind of performance effectively addresses many aspects of what we want students to learn. Critical to defensible evaluation of essays is a well-designed rubric. Instructors can benefit from training to produce reliable feedback for student performance. Careful consideration should also be given to the instructions to clarify performance expectations. Some faculty provide an array of potential essay questions as a study guide, selecting a select number of those questions to comprise the actual exam.

EMBEDDED QUESTIONS AND/OR ASSIGNMENTS

Advantages:
- saves time since assignments will already be required for the course
- overcomes faculty resistance due to reduced intrusion of external assessment activity
- encourages faculty to discuss common course outcomes, goals, & objectives promotes shared responsibility for agreeing where embedding should occur
- assessment phobic faculty exhibit greater comfort with embedded designs
- obligates faculty to have public discussion about their pedagogy
- limits demand characteristics

Disadvantages:
- can be time-consuming to coordinate effort
- may be taxing to isolate key aspects of performance
- limits faculty autonomy within the course

Recommendations

Embedding departmental assessment measures in existing coursework will emphasize a strong relationship between course content and assessment content. Individual faculty autonomy is essentially preserved; however, the faculty must collaborate within the department and be responsible for reporting to department colleagues. That level of obligation may not be standard procedure. The department must also control, store, and protect data, including protection from misinterpretation and misuse by outside sources.

CLASSROOM ASSESSMENT TECHNIQUES (e.g., 1-minute papers, course focus groups, free-writing, etc.)

Advantages:
- promotes experimental attitude in faculty about course design
- convenience
- provides immediate feedback to faculty about success
- vividly demonstrates faculty commitment to student satisfaction

Disadvantages:
- focus on teacher performance
- should be combined with other methods for full picture of student learning
- perceived to sacrifice content coverage for time required to assess
- demand characteristics may compromise validity of results

Recommendations

Enthusiasts of classroom assessment advocate these techniques as a way of implementing continuous improvement efforts. Careful context-setting will avoid or minimize students making unfavorable judgments that the activities are potentially time-wasting, particularly when faculty share the conclusions drawn from the assessment data with the students and make efforts to address concerns, where appropriate.

INDIVIDUAL PROJECTS/PERFORMANCE ASSESSMENT

NATURE OF CATEGORY

Individual projects have historically provided students the opportunity to apply their learning in projects that make optimal use of their potential intrinsic interest in the subject matter. The category includes individual writing, speaking, and graphic and poster production. Performance assessment strategies, sometimes also referred to as *authentic assessment,* are also evaluated in this section.

OVERALL ANALYSIS

Advantages:
- student-centered design promotes investment, motivation
- promotes transfer of skills and integration of content
- clear expression of knowledge base
- engages active learning
- encourages time outside of class
- promotes library use
- can provide study in depth not possible during allotted class time
- student benefits directly from experience
- provides venue for creativity

Disadvantages:
- time consuming and labor intensive to design and execute both for instructor and students
- may use materials wastefully (e.g., making transparencies for one speech)
- narrows content range for which student is responsible
- student variability (ability, motivation) challenges reliability and value of performance
- labor intensive for student
- cost may be prohibitive

Recommendations

The types of projects faculty choose as assessment vehicles will depend, in part, on the expertise the faculty have in evaluating works in various modes. The clear articulation of expectations will be critical to success. Specifying student creativity as a criterion will facilitate efforts that go beyond minimum achievement of criteria. Some products may involve decisions about storage space. For example, student videos may have a limited shelf-life.

WRITTEN PRODUCTS (e.g., term papers, lab reports, critiques)

Advantages:
- facilitates student command of specific area
- provides practice in critical skill area of writing

Disadvantages:
- challenging to writing-compromised students
- labor-intensive to score and return with timely feedback
- can be plagiarized created time-consuming/strategic confrontation with serious consequences for students who are caught
- instructors can be plagued with consequences of student procrastination

Recommendations

Many professors design writing projects in stages that promote multiple drafts. Getting feedback in stages may be easier for students to incorporate and easier for faculty to see the impact of their feedback work. Learning disabled, ESL, and other writing challenged students may require additional support. Efficient feedback can be facilitated using rubrics or style sheets. Writing projects should be tailored to the developmental level of the student. For example, beginning courses can employ letters to friends to explain a concept. Formal term papers typically work best in advanced courses. Departments may adopt a style sheet based on APA writing conventions that can help students practice consistent format strategies.

ORAL PRESENTATIONS (e.g., debate, role play)

Advantages:
- builds expertise in important communication area of oral expression
- promotes importance of sharing knowledge
- enhances oral skills
- Q & A promotes thinking on your feet
- assists professor to cover course content

Disadvantages:
- may burden students with ESL, speech and language difficulties, speaking anxiety
- time consuming and time-wasting when work quality is bad or boring
- may be hard to grade

Recommendations

Students understandably resist assignments that require them to speak in classes since public speaking remains one of our most pervasive social phobias. Success in oral presentations will depend on several elements:
- *providing lots of guidance and structure beforehand*
- *normalizing speaking discomfort and pointing out that overcoming those fears can happen only through practice*
- *specifying and sticking to assigned time limits*
- *circumscribing topic areas or requiring topic approval*
- *coaching regarding use of support technologies*
- *developing appropriate performance criteria*

GRAPHIC TEST AND DISPLAYS (e.g., concept maps, outlines)

Advantages:
- provides experience in applying and organizing course concepts
- assists in thinking through organization of information
- additional grappling with the material enhances recall
- appeals to visual learners

Disadvantages:
- students have limited practice with displaying graphic skills
- students may not have sufficient experience in interpreting graphics
- technological sophistication will influence production quality
- may waste resources

Recommendations

Faculty have found some success in asking students to translate lecture input into graphic displays, such as a concept map. These strategies appeal to visual learners who may be able to encode and remember more course content by adopting this strategy.

POSTERS

Advantages:
- hold students accountable for independent project
- reduces grading burden compared to writing projects
- provides opportunity to integrate communication skills (e.g., writing,
- graphics, oral defense)
- can incorporate team effort
- expert judgment, peer review can be facilitated with criteria
- simulates typical debut venue for most psychology scholars

Disadvantages:
- may need to make special arrangements for space
- students may invest money in project for one-shot exposure
- lack of aesthetic sense may handicap poster effectiveness
- stronger social interaction skills may produce halo effect in judging quality
- numbers of posters to be judged can create quality pressures on grading
- may not motivate best effort

Recommendations

Providing models or performance criteria will facilitate better productions. Poster sessions can be scheduled within classes or across classes as a departmental event. Awarding best of show maybe a helpful strategy to enhance motivation among the best students. All-department events can become a public relations resource as well as an opportunity to work with local high school psychology teachers to recruit future students.

STRUCTURAL/SITUATIONAL ASSESSMENTS (e.g., guided learning, in-baskets, critical situations, etc.)

Advantages:

- provides realistic testing circumstance
- reality engages and motivates students
- promotes transfer of information, application
- taps complex skills

Disadvantages:

- difficult to construct and measure
- locating designed instruments is challenging
- prone to history/context/age cohort effects
- students may rely on common sense under pressure rather than their knowledge from the course

Recommendations

The situation should correspond closely to the learning conditions to promote the best transfer of knowledge. Evaluating performance will be facilitated by clearly developed criteria. The quality of the rubric and the training of the evaluators will influence validity. If inter-rater reliability is not high, the results will be of limited value. Rubrics will sometimes not provide for unexpected, creative responses.

SUMMATIVE PERFORMANCE ASSESSMENT

NATURE OF CATEGORY

Summative assessment strategies tend to be employed for purposes of evaluating program quality rather than primarily to provide developmental feedback to students. This collection of assessment strategies include methods that involve a single episode of data collection (e.g., nationally or locally normed tests) as well as those that incorporate tracking student performance over time (e.g., portfolio, case studies, longitudinal studies. Capstone courses and internships can also be appropriate contexts for summative evaluation.

OVERALL ANALYSIS

Advantages:
- promotes coherence in curriculum planning
- provides feedback loop to improve quality
- some strategies can be adapted to student interests
- supports to earlier curriculum recommendations (e.g., St. Mary's conference to provide vehicle for integrating learning)

Disadvantages:
- some options are labor and/or cost intensive
- students may not receive direct feedback regarding their performances, thus limiting their own gains from effort expended
- departments may ignore available data in their planning

Recommendations

Summative procedures can be invaluable in making the case for the overall quality of programs. Although all of the methods have advantages and drawbacks, the most benefit can be gained to all constituents when students receive direct feedback regarding their summative performance. Finding out relative scores on comprehensive exams or receiving feedback regarding performance over time can assist students with career and life planning in some instances.

STANDARDIZED TESTS

Advantages:
- typically one shot assessment
- facilitates comparisons over time
- convenient

Disadvantages:
- may not reflect gains or growth across time
- exiting students may not benefit from feedback
- existing instruments may not match to the mission and goals of departments
- expensive
- students may not be motivated to do their best work
- when test occurs may not maximize true learning
- administration may not be flexible
- not student-centered
- limited faculty ownership
- verifying bad performance can be threatening to motivation
- scores may be delayed in return, reducing the impact of feedback
- there may not be a standardized test for the identified content
- can facilitate problematic comparisons to other programs (e.g., comparisons may not take into account differential resources, student characteristics, etc.)

Recommendations

The Disadvantages of the use of standardized tests can be minimized with some additional planning. Embedding the capstone test in an existing course will enhance student motivation since the student may take the experience more seriously. When student performance can also be tied to course grading, maximum motivation to do well is likely. Describing how well the existing test matched the required curriculum will encourage faculty support and student cooperation.

LOCALLY-DEVELOPED EXAMS

Advantages:
- can be tailored to match curricular/program goals
- standardizes local use
- relatively inexpensive
- provides opportunity to develop meaningful local norms
- avoids specious comparison with other colleges
- foster coherence in department about their objectives
- speedy feedback
- cheaper than national products
- after initial investment, saves time in the long run
- may be embedded in specific standard courses

Disadvantages:
- complex, time-consuming to develop
- may impede curricular change since test would need retooling after reforms
- reliance on test bank may not inadequate due to test bank quality
- vulnerable to student theft and distribution
- can be misused by comparing faculty member's areas

Recommendations

Comprehensive local exams are very time-intensive on the front end; however, the pay-off for this activity is multiple. This strategy encourages strong collaboration across department members and will help department members learn about the academic goals of their colleagues. Security will be an important issue to keep the department test safe from test files that may exist across campus.

CAPSTONE EXPERIENCES

Advantages:
- fosters aura of importance that may motivate students throughout the curriculum
- encourages departmental endorsement of culminating experience
- promotes student responsibility for engaged course
- supports program coherence for faculty and students
- course content can be flexible
- topical design of capstone can engage faculty in planning (e.g., seminar topics can be taught in special interest areas as long as the performance goals meet department expectations)

Disadvantages:
- high stakes performance can be impaired by performance anxiety
- typically low enrollment course is expensive to provide seats for all seniors
- faculty can generate territorial concerns over right to teach capstone
- graduation may depend on successful completion of capstone which can generate some anxiety for faculty and students when performance wobbles late in the course

Recommendations

Departments can use capstone courses as a unique way to express special interests of the faculty. Departments should secure the support of administration for this expensive option before broad implementation. Typically, capstones tend to have small enrollments to maximize faculty-student interaction. Capstones provide a great opportunity to have the student reflect meaningfully over the course of the curriculum. Putting in place some checkpoints on the process may prevent last-minute difficulties in the capstone that can compromise graduation plans.

INTERNSHIPS/PROFESSIONAL APPLICATIONS

Advantages:
- popular choice for students
- provides opportunity to sample future career
- positive public relations vehicle related to well-prepared students

Disadvantages:
- time intensive for faculty mentors to connect with on-site mentors and coordinate opportunities
- challenging to foster learning experiences across multiple sites
- poorly prepared students create public relations problems

Recommendations

Departments may reduce the public relations strain by screening students for their readiness to represent the program in public contexts. Qualifying criteria that stress quality and quantity of course experience as well as professional expectations in the intern role can set a positive, appropriate tone. Maintaining close contact with on-site mentors can also reduce unsuccessful student performance.

PORTFOLIOS

Advantages:
- shows sophistication in student performance
- illustrates longitudinal trends
- highlight student strengths
- identify student weaknesses for remediation, if timed properly

Disadvantages:
- collection will be no better than the quality of collected instruments
- time consuming and challenging to evaluate
- space and ownership challenges making evaluation difficult
- content will vary widely with students
- students fail to remember to collect items
- transfer students may not be in position to provide complete portfolio
- time intensive to convert to meaningful data

Recommendations

Clear expectations about the purpose and collection responsibilities will help students succeed in using the portfolio method. The works that student select will be more satisfying if the students can compare to established criteria. If the faculty want student portfolios to represent student development over time, they will need to be scrupulous about setting forth the performance demand of collecting and examining works throughout the student's career. The success of the portfolio may be enhanced when students reflect on how all the pieces work together to express their learning or meet department criteria.

ASSESSMENT CENTER METHODS (e.g, in-baskets, guided problem-solving)

Advantages:
- complex tasks can enhance student motivation
- designing relevant authentic assessment practices challenging
- facilitates integration of diverse skills and content areas

Disadvantages:
- expensive in material preparation and time
- students may not always perceive relevance of assessment to their studies

Recommendations

Not all disciplines may lend themselves as readily to problem solving situations that seem to be at the center of those challenges.

CASE OR LONGITUDINAL STUDIES

Advantages:
- can provide rich detail
- level of attention can build esteem
- builds allegiance

Disadvantages:
- transfer students may be omitted
- expensive and time-consuming
- small sample limits generalization
- attribution of historical or cohort effects may taint participant reports
- selection for tracking may influence outcome and change student experience

Recommendations

Departments need to clarify selection criteria if only a sample of students will be tracked. The results simply may not be representative of the group as a whole. Special care must be taken to have a satisfying instrument if results will be compared across cohorts. A department member may need to coordinate this activity if the department commits to this strategy.

SELF-ASSESSMENT/REFLECTION

STUDENT JOURNALS OR SELF-CRITIQUES

Advantages:

- multiple modes and variable sophistication possible
- quality of self-assessment related to quality of content knowledge
- flexible in format; prompts provided or not
- might ask about change over time
- empowers students to practice self-evaluation
- promotes transfer of accountability to other situations

Disadvantages:

- student judgment may not be accurate
- self-assessment are prone to evaluative biases (e.g., Lake Woebegone Effect, underestimation due to self-esteem issues)
- students have limited experience being held accountable to judge their own work
- students may define assessment as job of teacher
- faculty may perceive this practice to set up more grade conflicts

Recommendations

Students should receive feedback on the accuracy of their self-evaluations. Early assignments might fare best with more global criteria. For example, "what aspects of your performance were effective?" and "What would you do differently if you had more time?" may engage the student in being reflective. Over time, students should be able to apply more discrete criteria to their own performance, and eventually they should be able to help formulate criteria by which performances should be judge. The quality of self-assessment may be very dependent on the careful construction of the self-assessment prompts.

COLLABORATION

RESEARCH TEAMS & GROUP PROJECTS (e.g., written and oral)

Advantages:
- student-centered designs promote engagement
- provides opportunity to practice group skills, time management
- promotes independent work at deeper level
- breadth of assignments can address content coverage issue
- simulates how professional activities/achievement transpires
- produces synergy and excitement around project completion
- creates a venue to synthesize content bases from multiple courses

Disadvantages:
- - students have limited training in group dynamics
- - social loafers can tax equitable judgments about grading
- - erroneous ideas that are not caught and corrected spread across group members
- - challenging to faculty to judge when to redirect or rescue student groups in trouble
- - time-consuming

Recommendations

Selection of the group members will influence group outcomes. For example, some projects will work best when the groups are heterogeneous with regard to student characteristics. Other projects might be most efficient when groups are homogeneous. Students may need assistance in understanding how groups work. Their work will improve with some prompts to pay attention to the process of the group in addition to solving the problem at hand or creating the product. Students will fare best in research teams where they clearly understand group norms and expectations. For example, what are the penalties for nonparticipation? Whenever possible, students should be given feedback on the quality of their participation.

ONLINE ACTIVITIES (e.g., maintaining print record of interactions in chat room or other internet-based contact)

Advantages:
- the data already exist as part of regular course
- records trends in collaborative skill
- tracks process
- cheap and convenient
- demand characteristics may be reduced
- students have equal opportunity to participate
- faculty monitoring can be unobtrusive
- appeals to some students who may have greater difficulty in oral expression
- provides archive through automatic recording
- documents feedback for instructor on what has been covered or what is still unclear

Disadvantages:
- - content analysis is time-consuming
- - privacy issues can be compromised
- - students may be handicapped by computer savvy and tech patterns
- - faculty need to be computer savvy

Recommendations

Instructors using online strategies may need to overcome individual differences in using this mode by requiring participation. Circumscribing the content may help to avoid some ethical challenges that result in chat room participation. Students should be informed that their discussions are being monitored for assessment purposes from the outset. This strategy may entail IRB review to confer the best protection. Faculty also need to assess ease of web access for students before making on-line participation a requirement.

INTERVIEWS AND SURVEYS (ATTITUDE MEASUREMENT)

OVERALL ANALYSIS

Advantages:
- easy to administer
- cheap
- easy to score
- quick feedback
- can be reliable but not valid

Disadvantages:
- validity hinges on good design
- may not be valid
- demand characteristics may distort results
- participants may not have good knowledge about their own attitudes
- participants may demonstrate response bias or dishonesty
- labor intensive to interpret

Recommendations

Valid attitude measures depend on quality of design and implementation. For example, the participants must be motivated, careful, and candid to generate data that will be meaningful. Care should be exercised to produce to design appropriate measures for intended purposes that minimize sources of error (e.g., selection bias, demand characteristics, literacy challenges, etc.).

SATISFACTION SURVEYS (e.g., seniors, alumni, employers, graduate school advisors, parents)

Advantages:
- fosters positive public relations because activity signals faculty concern for quality
- targets of survey may be prompted to other positive actions (e.g, donations, hiring, recruitment of new students)
- external judges may be more objective in their appraisal of student abilities, achievements
- recurring insights may point to some problems that need remediation
- provides important perspective on relevance of program to various occupations

Disadvantages:
- tracking down and engaging targets may be problematic
- low return rates compromise validity
- some respondents may be motivated not to tell the truth (e.g., don't want to bear bad news, demand characteristics)

Recommendations

Long surveys will influence completion rate. The return rate also provides some indication of how robust the results are. For example, in alumni surveys, the students who are most successful will be more motivated to complete the surveys and may produce an overestimate. When appropriate, a lie scale or some other strategy to verify truthfulness in response will also increase validity. In designing satisfaction instruments, instructors need to think through the quality of education from the perspective of the interview subject. Well-designed surveys are difficult to create so some pilot data may help identify trouble spots in proposed instruments.

PERFORMANCE REVIEWS (e.g., alumni, employers, graduate school advisors)

Advantages:
- promotes evaluation based on objective appraisal of behavior
- builds positive public relations
- external judges may be more objective in their appraisal of student abilities, achievements
- recurring insights may point to some problems that need remediation
- provides important perspective on relevance of program to various occupations

Disadvantages:
- tracking down and engaging targets may be problematic
- low return rates compromise validity
- some respondents may be motivated not to tell the truth (e.g., don't want to bear bad news, demand characteristics)

Recommendations

Departments committed to evaluating their graduate's performance from interested stakeholders are likely to find the time invested to be worthwhile, both in terms of data gathered as well as public relations impact.

EXIT INTERVIEWS

Advantages:

- provides realistic picture
- provides catharsis
- provides in-depth, personal perspective on experience of major
- can be embedded in existing courses to capture broad range of student experience
- demonstrates overt department commitment to high quality
- may promote long-term allegiance among graduating students
- can generate reinforcing feedback to help departments sustain effectiveness

Disadvantages:

- volunteers may have a negative or a positive agenda that may not be representative, producing a selection bias
- time-consuming to coordinate and evaluate the results
- students may not show up for discussion
- negative discussion may influence formerly neutral students to redefine their experience negatively
- completion challenge
- participants may paint too rosy a picture partially due to timing
- expensive
- results can be influenced by the quality of the interviewer and protocol

Recommendations

Departments will need to decide on the scale and format of focus exit interviews. These activities can be conducted individually or in small groups. Departments can commit to interviewing every graduating seniors or elect to sample from the group. Instructors need to determine how much credence to place on the results of group discussions with students based on sample size and representation. Questions should target the data that the department wishes to gather. The department should also determine how to interpret the results of the interview. Collaborative design of the interview protocol will promote greater enthusiasm by department members to deal with the consequences of the interview. Conducting the interviews with department faculty may influence student participation since they may be more candid with an external reviewer.

FOCUS GROUPS

Advantages:

- small discussion groups promote engagement
- can be employed to provide feedback on a class, course, or program
- participants can benefit directly from changes that result from their feedback
- demonstrates overt department commitment to high quality
- can generate reinforcing feedback to help departments sustain effectiveness
- development of protocol can be involving for faculty
- may tap unforeseen areas of concern

Disadvantages:

- current students may feel some pressure not be completely candid for fear of retribution
- volunteers may have a negative or a positive agenda that may not be representative
- time-consuming to coordinate and evaluate the results
- students may not show up for discussion

Recommendations

Departments should develop a good rationale for selecting students for focus group linked to the purpose for which the group is being convened. The discussion protocol can produce both quantitative and qualitative data that can be beneficial to the department. However, student commentary in a focus group may not be representative of the typical student's experience.

FOLLOW-UP ALUMNI INTERVIEWS

(This method involves telephone follow-up to graduates to assess information other than satisfaction with the major. Graduates can be contacted and interviewed on various outcome measures, including knowledge of the major, civic practices, or other indices of interest to the department. Demand characteristics are strong in this strategy.)

Advantages:

- facilitates spontaneous assessment of student's application of knowledge & skill
- measures enduring learning and skill transfer
- scope can be broad-ranging

Disadvantages:

- could be construed as deceptive practice
- might require IRB oversight

Recommendations

Avoiding demand characteristics is a significant problem with this approach. Alumni may feel compelled to help out by inflating their accomplishments or satisfactions in response to a phone interview.

EXTERNAL EXAMINER INTERVIEWS (exit interviews conducted by objective, external expert)

Advantages:

- promotes objective reports where students are assured of anonymity
- data summary and interpretation conducted external to regular department activities
- improves face validity of assessment activities
- supports department courage regarding willingness to expose their practices to outsider

Disadvantages:

- expensive to employ qualified consultant
- sensitive information is at some risk for getting beyond control of department

Recommendations

Departments may want to involve the external examiner in the construction of the interview protocol to avoid problems of drift toward the examiner's own interests and values in the interview. Qualified external examiners can be identified through the Psychology Department Consulting Bureau operated by the Society for the Teaching of Psychology.

ARCHIVAL MEASURES

TRANSCRIPT ANALYSIS / ANALYSIS OF TRANSFER PATTERNS

Advantages:
- can answer questions about prerequisites, transfer patterns
- existing data
- provides overall picture
- trends of targeted students at particular times
- exposes problematic trends for transfer, including drop out rates, time to degree completion, course articulation success, subsequent courses performance

Disadvantages:
- time-consuming
- potentially boring in level of detail required
- may require cooperation to gain access to data

Recommendations

The analysis of course patterns by itself may not address directly the questions regarding quality. Transcript analysis can answer narrowly focused questions that should be well thought through to justify the time required.

SYLLABUS AUDIT

Advantages:
- promotes coherence within the department
- can identify areas of neglect or overemphasis
- facilitates adoption of similar writing standards and other expectations
- promotes student understanding of cognitive goals

Disadvantages:
- time-consuming
- may be difficult to engage all department members fully in review/consensus
- students may pay little attention to the syllabus as overall learning guide

Recommendations

Although this practice is time-consuming, many departments find a syllabus audit is fundamental to answering all kinds of questions about the manner in which the faculty implement the curriculum.

DEMOGRAPHIC DATA ANALYSIS/ALUMNI DATABASE

Advantages:
- facilitates thorough understanding of student body
- prepares department for unusual trends that might affect course scheduling
- predicts where recruitment efforts will pay off
- points to specific remediation needs
- identifies potential donors for ongoing program needs

Disadvantages:
- time-consuming
- possible too have too much data

Recommendations

With careful planning, departments can execute well-crafted strategies to collect data that will be useful for their planning in recruitment, retention, and fund-raising.

LIBRARY USE STATISTICS / WEB HITS

Advantages:
- provides input about how seriously students take assignments
- allows analysis of trends in use
- presents overall picture of value

Disadvantages:
- contaminated with faculty use
- interpretation is difficult, boring, and time-consuming
- students may get sources from other than the library

Recommendations

This measure may be most helpful feedback from the library to assist in future ordering. Combining library use and web hit statistics with other measures may provide more meaningful measure.

B. Designing Viable Assessment Plans

4. Overview of Optimal Assessment Strategies in Psychology

In this entry, we offer a matrix that estimates the potential of different assessment categories with the Task Force's learning goals. We differentiate categories that may be optimal for a specific goal from those strategies that offer little advantage in documenting quality.

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B. Designing Viable Assessment Plans

5. Critique of Assessment Strategies Applied to Goals and Outcomes

In the largest entry in the Assessment Cyberguide, we provide an estimate of the assessment potential for each category and practice within each category in relation to the psychology goals. Suggestions from this entry can help departments pick beneficial approaches and avoid strategies that will have little pay-off.

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GOAL 1: Knowledge Base of Psychology (continued)	
ORAL PRESENTATIONS	**Strong potential.** Oral presentations also provide insight into student learning of the content. In addition, the opportunity to engage students in questions allows faculty and classmates to probe the depth of student knowledge while building oral communications skills.
GRAPHIC TESTS AND DISPLAYS	**Strong potential.** Concept maps can reveal the nature of associations that students develop regarding specified content in the discipline.
POSTERS	**Strong potential.** Posters can provide a more global sense of what students understand due to the brevity of the medium. However, informal questioning can fill in the gaps about what students have not communicated in the poster.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** Although situational assessments tend to emphasize application of learning, applications are built on a disciplinary foundation. The success of assessment of content learning will depend on the expertise demonstrated in the design of the applied assessment.
SUMMATIVE PERFORMANCE ASSESSMENT	**Overall Mixed potential.** Assessments that occur at the end of a program vary in their effectiveness for assessing content. In some cases, depth of knowledge required by some demonstrations will not allow an estimate of broad knowledge in the discipline.
STANDARDIZED TESTS	**Mixed potential.** Currently there are two primary standardized exams that allow for comparison across institutions as well as tracking changes in program achievement over time: the Academic Concentration Applied Test (ACAT) and the Major Fields Test by ETS. Each exam measures knowledge in the subdisciplines of psychology, but student course selection may adversely affect overall performance on either instrument. Care must be exercised in interpreting the results.
LOCALLY DEVELOPED TESTS	**Strong potential.** Developing a department examination is a time-consuming but effective way to track changes in student knowledge over time but does not provide normative comparison with other programs. In addition, test security and changes in content knowledge make this practice complex.
CAPSTONE EXPERIENCES	**Mixed potential.** The utility of capstone performance to assess content knowledge greatly depends on the scope of the course design. Students are more likely to develop deep levels of expertise in more narrowly defined areas of psychology in most capstone designs. To the extent that their performance represents what they can do within specific performance parameters, the capstone may be a satisfying method to assess the ability to deal with content in sophisticated ways. However, more broadly conceived capstone courses (e.g., history, systems of psychology) may provide broader assessment opportunities.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Moderate potential.** Internships and professional applications facilitate specific types of applications. For example, an industrial-organizational internship may be an optimal way for a student to demonstrate the knowledge base related to the subdiscipline, but it may not be satisfying as a broad assessment.
PORTFOLIOS	**Strong potential.** Selecting and justifying selections from explicit departmental criteria will facilitate student reflection regarding the level of expertise they have developed in the content of psychology.
ASSESSMENT CENTER METHODS	**Strong potential.** Similar to structured assessments, the in-basket strategies of assessment center methods can provide insight into student abilities to apply principles from the content of psychology.
CASE AND LONGITUDINAL STUDIES	**Limited potential.** Because much of content learning is fragile, longitudinal studies of content retention are likely to be disappointing sources of student learning. In addition, merely reporting how sturdy content learning is over time rather than directly assessing may be content learning will be a less reliable measure.

GOAL 1: Knowledge Base of Psychology (continued)	
SELF-ASSESSMENT	**Overall Mixed potential.** As can be seen from student anticipation of how well they performed on an exam, student ability to judge their own expertise is variable.
STUDENT JOURNALS	**Moderate potential.** Journal instructions can specify the manner in which students should interact with the content of the discipline. For example, instructions might require that students demonstrate the appropriate application of five concepts or principles from the discipline. Students will vary in their own expert judgment on the success of addressing the concepts or principles in the manner anticipated by the faculty.
SELF-CRITIQUES	**Mixed potential.** Students have limited experience in making judgments about how well they have met the content criteria of a given assignment. Students often drift to the easier-to-judge aspects of performance, such a format concerns, interest generation, or comfort level rather than exploring how well they have reflected content expertise.
COLLABORATION	**Mixed potential.** Some methods offer effective avenues for examining content and theory, while others are less promising.
RESEARCH TEAMS	**Strong potential.** Research teams give students an opportunity to demonstrate content expertise in two dimensions: research methods and the subject matter that the research is designed to explore. Students can receive separate evaluations on the extent to which they have collectively demonstrated research expertise as well as whether they have appropriately represented the target content.
GROUP PROJECTS	**Strong potential.** Group projects can also provide a content-based opportunity to develop group skills. Projects can reflect successful or unsuccessful strategies to master relevant content and principles. However, group projects suffer similar limitations to individual projects. Committing in-depth study to one arena may require the sacrifice of exposure to other content in the course.
ON-LINE ACTIVITIES	**Limited potential.** Unless students are given very constrained instructions regarding how to pursue content collaboration, the use of chat room or email exchanges to monitor content expertise may be challenging.
INTERVIEWS & SURVEYS	**Mixed potential.** In general, surveys and interviews are not recommended because the assessment of content is not likely to be direct.
SATISFACTION SURVEYS	**Poor potential.** Assessing content expertise through satisfaction surveys is too indirect to be recommended.
PERFORMANCE REVIEWS	**Moderate potential.** Although this method is time consuming, the next step (e.g., graduate school or employment) can provide for direct observation of the content of psychology.
EXIT INTERVIEWS	**Limited potential.** Exit interviews tend to focus on affective dimensions of learning as well as the collection of impressions that may facilitate program improvement. Content mastery is not routinely the focus of exit interviews.
EXTERNAL EXAMINER INTERVIEWS	**Moderate potential.** A rigorous external examiner protocol could focus on the depth of content mastery of individual students. However, the expense and time limitations of this approach tend to focus on other aspects of student performance.
FOCUS GROUPS	**Not recommended.** Focus groups typically convene to solve a specific problem rather than provide a measure of content mastery. Such academic development may be inferred but there are other more direct methods to assess mastery.
FOLLOW-UP ALUMNI INTERVIEWS	**Not recommended.** Engaging with alumni over the specifics of content that they can recall is likely to be a discouraging assessment strategy since the detail of the discipline dims with distance from graduation.

GOAL 1: Knowledge Base of Psychology (continued)	
ARCHIVAL MEASURES	**Mixed potential.** Archival measures can provide some insight into the content bases to which students have been exposed but will do little to assess more formal learning of the content in the discipline.
TRANSCRIPT ANALYSIS	**Limited potential.** Individual transcript analysis can provide not just a measure of the various content bases to which the student has been exposed but through grades can provide a gross measure of achievement in those areas. However, assessment experts recommend that other noncourse-based strategies will be more effective in providing legitimate measures of student and program achievement.
ANALYSIS OF TRANSFER PATTERNS	**Limited potential.** Examining patterns of what transfer students provide can help departments determine what and when to offer in the curriculum, but will shed little light on the quality of learning.
SYLLABUS AUDIT	**Limited potential.** A syllabus audit can isolate the range of content exposure that students experience but will be poor indicators of actual learning.
DEMOGRAPHIC DATA ANALYSIS	**Not recommended.** Understanding the characteristics of the student body will provide little insight into their content mastery.
ALUMNI DATABASE	**Not recommended.** The alumni database does not directly reveal student expertise in the content of psychology. However, many programs rely on the percentage of students who go on to graduate school in the area as an indirect measure of content expertise.
LIBRARY STATISTICS USAGE/WEB HITS	**Not recommended.** Content expertise is not apparent in this archival analysis.

GOAL 2: Research Methods in Psychology: Understand and apply basic research methods in psychology, including research design, data analysis, and interpretation.

2.1 Describe the basic characteristics of the science of psychology.

2.2 Explain different research methods used by psychologists.

2.3 Evaluate the appropriateness of conclusions derived from psychological research.

2.4 Design and conduct basic studies to address psychological questions using appropriate research methods.

2.5 Follow the APA Ethics Code in the treatment of human and nonhuman participants in the design, data collection, interpretation, and reporting of psychological research.

2.6 Generalize research conclusions appropriately based on the parameters of particular research methods.

COURSE DATA	**Mixed potential.** Useful for providing assessment of factual knowledge and some limited application. Research skills will be better assessed with other strategies that involve activities outside the traditional classroom.
OBJECTIVE TESTS	**Moderate potential.** Good method for assessing primarily factual knowledge, especially if the test questions can be demonstrated to have strong psychometric properties. Less useful in assessing application and higher level comprehension such as designing original research or performing and interpreting statistical calculations.
ESSAY TESTS	**Moderate potential.** More powerful method for assessing application and higher level comprehension, but is still limited in its ability to assess ability to design original research or perform and interpret statistical calculations because of limited time frame in testing situation.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Strong potential.** Because research methods courses are often a prerequisite for advanced courses, departments may also dictate specific assignments (e.g., research projects) that should be embedded in required coursework across different sections of the same methods and/or statistics courses and in subsequent courses in the curriculum.
CLASSROOM ASSESSMENT TECHNIQUES	**Moderate potential.** Provides quick, but often limited assessment, on student understanding and performance.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Strong potential.** Faculty can interpret sophistication in research skills from intellectual products. Because projects are done outside class, there may be some risk that a student's work is not an individual production. However, this limitation can be addressed by including a reflective piece that assesses the targeted skills.
WRITTEN PRODUCTS	**Strong potential.** Written reports of original research provide an ideal context for assessing the methodological skills and ethical issues involved in designing, conducting, and evaluating the results. Time constraints (e.g., IRB approval) and the labor intensive nature of original research may limit usefulness in some courses. Research projects may also only assess an understanding of the particular methods used, not a broader understanding.
ORAL PRESENTATIONS	**Moderate potential.** Individual oral presentations provide some opportunity to evaluate quality of research skills and ability to present a shorthand summary. However, these may be challenging to judge in the moment and they often lack details that allow for in depth assessment.
GRAPHIC TESTS AND DISPLAYS	**Moderate potential.** Graphical presentations can be useful in mapping the research process. Statistical understanding can be assessed through the accuracy and clarity of graphical presentations.
POSTERS	**Moderate potential.** The limited space available in most posters may not provide an ideal context in which to evaluate the full understanding and application of research methods.

GOAL 2: Research Methods in Psychology (continued)	
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** The presentation and interpretation of research findings in the popular media can be used to have students demonstrate their skill in addressing issues related to the design and interpretation of research. Current events can also be used as a starting point for students to design and conduct original research projects.
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential.** Strategies in this category range from poor to strong.
STANDARDIZED TESTS	**Moderate potential.** Although standardized tests assess factual knowledge related to research methods and statistics, they fail to evaluate application of skills at the level identified for these outcomes.
LOCALLY DEVELOPED TESTS	**Moderate potential.** Like standardized tests, they primarily focus on factual knowledge as opposed to application. In addition, they may lack strong psychometric properties.
CAPSTONE EXPERIENCES	**Strong potential.** Assuming that the capstone course or project has an expressive requirement (e.g., writing or speaking), it can provide an integrated demonstration opportunity.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Limited potential.** The focus of most applied internship experiences tends to be in applied areas of psychology. However, some experiences may include the opportunity to design, conduct, and evaluate research (i.e., a research internship).
PORTFOLIOS	**Strong potential.** Explicit criteria that ask students to select "works" based on what these reveal about their research skills can provide an opportunity to evaluate the evolution of their abilities through a focused reflection on why they selected the items they did.
ASSESSMENT CENTER METHODS	**Poor potential.** Assessment center methods are generally limited in time and focus. They are unlikely to provide in depth information on all the outcomes associated with this goal because of inherent time constraints.
CASE AND LONGITUDINAL STUDIES	**Limited potential.** The complexities of tracking all of these skills over time mitigates against adopting this strategy to monitor their evolution, especially where different curses in the curriculum vary in the requirement to use these skills. Programs requiring both a survey research methods course with an original research project and a capstone research experience may have a limited opportunity to evaluate longitudinal development.
SELF-ASSESSMENT	**Mixed potential.** Developing students' metacognition of their understanding of research methods has seldom been addressed self-assessment strategies.
STUDENT JOURNALS	**Moderate potential.** Although it may be unlikely that faculty would choose to invest time reading about students' struggle to learn research methods, this technique can be adapted to a research journal where students keep a record of research ideas, development and progress that reflects application of research methods knowledge.
SELF-CRITIQUES	**Limited potential.** When faculty can specify relevant performance criteria, students can provide an estimate of their research and statistical skills.
COLLABORATION	**Moderate potential.** Techniques in this category are moderate to limited in usefulness.
RESEARCH TEAMS	**Moderate potential.** Research teams can develop and evidence expertise in research skills through peer involvement and often model the collaborative nature of research at the professional level. Unfortunately, research teams may reduce a beginning or weak student's direct involvement in generating research ideas, research design, statistical analysis, and interpretation of results.

GOAL 2: Research Methods in Psychology (continued)	
GROUP PROJECTS	**Moderate potential.** Group projects involve similar issues to those of research teams.
ON-LINE ACTIVITIES	**Limited potential.** Archived on-line chat rooms, listservs, or bulletin boards can provide opportunities to assess the development and evolution of research ideas from start to finish.
INTERVIEWS & SURVEYS	**Mixed potential.** The assessment of attitudes by the students or other stakeholders may provide some feedback about research methods and statistical competence, but attitudes may not be an accurate indication of true skill attainment.
SATISFACTION SURVEYS	**Strong potential.** The abilities of students to design, conduct and evaluate research can be evaluated by employers, graduate advisors, or other stakeholders. External evaluators may explicitly need to be prompted to address these skills. This may be particularly effective for those students who continue in graduate programs in psychology.
PERFORMANCE REVIEWS	**Strong potential.** Stakeholders can provide an estimate of strengths and weaknesses within research skills with appropriate prompts for reflection.
EXIT INTERVIEWS	**Moderate potential.** Students can be asked to reflect on the evolution of their research and statistical skills.
EXTERNAL EXAMINER INTERVIEWS	**Limited potential.** External examiners can ask probe questions to evaluate student comfort levels about research and statistical skills, but the evaluation of self-report relative to actual performance quality may be problematic unless evaluators also review actual products.
FOCUS GROUPS	**Limited potential.** Although focus groups most often convene to solve specific departmental problems, this area is often core to a program and challenging to students and may be more likely to be addressed in this context.
FOLLOW-UP ALUMNI INTERVIEWS	**Limited potential.** Although a follow-up interview on this topic might invite demand characteristics, it may be useful to assess perceived skill levels in post-graduate settings.
ARCHIVAL MEASURES	**Limited potential.**
TRANSCRIPT ANALYSIS	**Moderate potential.** Transcript analysis can reveal the pattern of courses students may engage in (or avoid) in the development and use of research method s and statistical skills. The transcript analysis can provide both patterns and some in-class estimates of quality of student performance although the value of these may be limited.
ANALYSIS OF TRANSFER PATTERNS	**Limited potential.** Departments can benefit by understanding the transfer courses that students may have taken in research methods and statistics and making comparisons to students who took departmental courses in these areas.
SYLLABUS AUDIT	**Moderate potential.** An analysis of which courses include content or projects emphasizing research methods or statistics may be a helpful first step in diagnosing where these skills need to be enhanced.
DEMOGRAPHIC DATA ANALYSIS	**Not applicable.**
ALUMNI DATABASE	**Not applicable.**
LIBRARY STATISTICS USAGE/WEB HITS	**Not applicable.**

GOAL 3: Critical Thinking Skills in Psychology: Respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

3.1 Use critical thinking effectively.

3.2 Engage in creative thinking.

3.3 Use reasoning to recognize, develop, defend, and criticize arguments and other persuasive appeals.

3.4 Approach problems effectively.

COURSE DATA	**Overall Mixed potential.** Classroom and course data can be used to assess critical and creative thinking, but the quality of the assessment depends on what is measured in these settings and not the setting per se.
OBJECTIVE TESTS	**Limited potential.** Objective tests can be used to assess critical thinking, but good objective tests of critical thinking are difficult to construct and cannot be used to assess what students actually do in an unstructured setting where critical thinking is required. They cannot assess the propensity to engage in critical thought. They are better as measures of recognition memory, and hence of limited usefulness in assessing critical thinking.
ESSAY TESTS	**Strong potential.** An essay test that poses an ecologically-valid scenario (ideally somewhat complex) where students need to explain/ describe their thinking and the conclusion they reached or problem they solved can be a good way to assess critical thinking.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Strong potential.** An embedded question or assignment can provide a measure of student's propensity to think critically (i.e., do they engage in critical thinking when the need for critical thinking is not cued or labeled).
CLASSROOM ASSESSMENT TECHNIQUES	**Poor potential.** Classroom assessment techniques can include reflections on what was learned. It is more likely useful as feedback to instructors about what students believe they have learned than a measure of learning per se.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Overall good potential.** Individual projects and performance assessment can be good measures of critical thinking, assuming that the project calls for extended and careful thought. The nature of the project or performance (e.g., solve a novel problem) is what determines the quality of the assessment. The quality of a critical thinking assessment most often lies in the way the instructor crafted the assignment and explained it to students.
WRITTEN PRODUCTS	**Strong potential.** Like essay tests, a written project needs to allow the student to show the thinking process that went into a conclusion or a solution to a problem.
ORAL PRESENTATIONS	**Strong potential.** Oral presentations are just an alternative format for presenting one's thinking, and thus are similar to written products in their ability to assess critical thinking.
GRAPHIC TESTS AND DISPLAYS	**Strong potential.** A graphic display of one's thinking can be an excellent assessment of the quality of a student's thinking. There are many concept maps and other ways to map verbal information onto spatial arrays that are well suited for critical thinking assessment. A completed template that shows the parts of a persuasive argument, for example, can be used to clarify complex topics and provide a "picture" of the student's thinking.
POSTERS	**Strong potential.** A poster can, and probably should, contain a mix of verbal and graphic displays. It can be used to assess critical thinking, if the topic or reason for the poster requires critical thought.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** When this category includes activities such as role-playing, seeing problems from multiple perspectives, and similar activities, it can be a good way to demonstrate critical thinking skills.

GOAL 3: Critical Thinking Skills in Psychology (continued)	
SUMMATIVE PERFORMANCE ASSESSMENT	**Overall Mixed potential.** Summative assessments usually refer to tests that are normed to provide comparative data, usually at the completion of a program of study. The normative information can be useful, but only if the test is valid in that it relates to the way students think critically when they are not in class.
STANDARDIZED TESTS	**Moderate potential.** There are several standardized tests of critical thinking. Unfortunately, they tend to be multiple-choice tests with short problems or scenarios described in each question. They are not generally good measures because real life is much messier, and there is rarely a single correct answer to ill-defined problems. They also do not measure what student's actually do in less structured settings. A quality standardized test is possible, if it includes both constructed response and multiple-choice alternatives to show how students approach problems *and* whether they can recognize a good response when they have to select from among a small set of alternatives.
LOCALLY DEVELOPED TESTS	**Limited potential.** A locally developed test can reflect the curriculum that is taught, so it can be more useful to instructors, but locally-developed tests will rarely have the psychometric properties of good reliability and validity that a standardized test will have.
CAPSTONE EXPERIENCES	**Strong potential.** A capstone experience can be an extended project that requires the application of critical thinking skills to a wide range of issues. If well designed, capstone experiences can provide meaningful measures of critical thinking, but the instructor needs to have clear critical thinking objectives in mind when planning the capstone experience because it is not likely to assess critical thinking without deliberate planning.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Limited potential.** Ideally, an internship or other professional application would require evidence of critical thinking, but they would need to be designed with this specific outcome in mind and that rarely happens. In general, instructors do not have direct control over internship experiences, which can make the value of an internship or other application as an assessment of critical thinking hit-or-miss.
PORTFOLIOS	**Strong potential.** A portfolio that is well planned to show growth in critical thinking skills over time (e.g., four years in college) can provide a good index of gains in critical thinking. Like the other methods, the value of portfolios depends on how carefully the intended critical thinking outcomes are articulated and carried across several different courses.
ASSESSMENT CENTER METHODS	**Strong potential**. An assessment center is usually a single place where a variety of assessment activities are planned and data are collected. Often they will include simulations of real-life scenarios and problems. If the activities are well planned, they can provide valuable data about critical thinking (e.g., an in-basket exercise).
CASE AND LONGITUDINAL STUDIES	**Limited potential.** Following students' development in critical thinking over time may be somewhat challenging in the absence of objective measures of that growth.
SELF-ASSESSMENT	**Overall Mixed potential.** A self-assessment is a student's own analysis of how well he or she is thinking. We know from a large number of studies that most people are poor judges of how well or how critically they think. These techniques can be useful over time if students learn to be more accurate in their self-assessment, but there are little data to suggest that this actually happens.
STUDENT JOURNALS	**Mixed potential.** Student journals seem to work well for a subset of students who actually reflect on their thinking. For many students, they are worthless exercises in filling up paper. Some instructors like to give students the experience of student journals so that those students who benefit from this activity are not penalized by those who do not. It can be useful, but only for some students. Clear instructions for journaling are required.

GOAL 3: Critical Thinking Skills in Psychology (continued)	
SELF-CRITIQUES	**Limited potential.** Given that most people are very happy with their ability to think critically, self-critiques can only be useful if students learn to see their own weaknesses. It is difficult to change belief about how well one thinks, but not impossible. Thus, one outcome of critical thinking instruction is the seemingly paradoxical result that students often rate themselves as poorer thinkers at the end of a course than at the start. This is a positive outcome, but it tells instructors very little about the student's actual ability to think critically.
COLLABORATION	**Overall Strong potential.** When students collaborate, they think in groups. Because much of the thinking they will do outside of class will involve other people, it can be a valid approach to assess critical thinking.
RESEARCH TEAMS	**Strong potential.** If the research team is given a problem that requires critical thinking and good guidelines for teamwork are provided so that each team member must contribute to some of the thinking, it can be useful. Instructors will want to capture at least a sample of the group thinking process so that it can be reviewed with each team.
GROUP PROJECTS	**Strong potential.** Group projects may be designed so that success only can occur when the group engages in effective critical thinking. Groups can process where their critical thinking was faulty to learn from their error.
ON-LINE ACTIVITIES	**Limited potential.** An on-line collaboration offers the possibility of tracking the thinking process via the written exchanges among team members. Of course, instructors would want students to know that their exchanges are being monitored.
INTERVIEWS & SURVEYS	**Overall Limited potential.** Interviews and surveys usually ask specific questions about individual beliefs and perceptions. They are not useful in assessing what is learned because they to focus on what students believe they learned and how satisfied they are with the learning.
SATISFACTION SURVEYS	**Poor potential.** Satisfaction surveys are often called "smilies" because respondents indicate how happy they are with an assignment or course. These are not the same as actual measures of what was learned and cannot be substituted for performance indicators.
PERFORMANCE REVIEWS	**Limited potential.** Stakeholders can be asked to rate the quality of critical thinking in their evaluations of performance but may require training to understand the parameters being investigated.
EXIT INTERVIEWS	**Poor potential.** Exit interviews occur when students are leaving a course or program, most often at graduation. They are reflections about what was good or bad about a program of study. Although these measures provide useful data, they usually do not measure critical thinking.
EXTERNAL EXAMINER INTERVIEWS	**Moderate potential.** External examiners are used to provide an outside (i.e., unbiased) evaluation of the quality of learning. The ability of external evaluators to measure critical thinking depends on what they ask. If they ask satisfaction questions, then they are not assessing critical thinking, but if they ask students to think through a complex problem and explain what they are doing, the assessment can be a measure of critical thinking.
FOCUS GROUPS	**Limited potential.** Focus groups are often group evaluations of a program or course. They do not provide evidence of critical thinking unless the group is asked to solve a problem, reach a conclusion, make a complex decision or engage in some other critical thinking task.
FOLLOW-UP ALUMNI INTERVIEWS	**Moderate potential.** Alumni follow-ups tend to utilize satisfaction questions, but they could provide evidence of the long-term retention of critical thinking skills and their transfer to novel domains if the alumni are asked questions that require critical thinking.

GOAL 3: Critical Thinking Skills in Psychology (continued)	
ARCHIVAL MEASURES	**Overall Poor potential.** Archival methods use data that are already available. As in the other categories, the quality of the assessment depends on what is in the available data.
TRANSCRIPT ANALYSIS	**Limited potential.** A transcript analysis is not likely to tell us much about critical thinking skills because we do not know what was required in each of the classes. Research has shown that much of the learning that occurs in college is relatively low level direct recall of information or low-level inferences.
ANALYSIS OF TRANSFER PATTERNS	**Limited potential.** Course-taking patterns are not likely to useful by themselves, but could be useful to see how different patterns relate to more valid measures of critical thinking.
SYLLABUS AUDIT	**Mixed potential.** An audit of a syllabus can sometimes show if critical thinking skills are being taught and learned in a particular class, but most often the syllabus is a list of reading assignments, dates assignments are due, and exam dates. There is rarely any information in the syllabus that provides a clue as to what students are required to do with the information to-be-learned.
DEMOGRAPHIC DATA ANALYSIS	**Poor potential.** These analyses will not tell us anything about the quality of the thinking of any individual or group.
ALUMNI DATABASE	**Poor potential.** An alumni database that provides information about the types of careers that students enter upon graduation and where they are working in 5 to 10 years can allow us make inferences about critical thinking. In general, some careers (e.g., law, research) require better thinking skills than others (e.g., most clerical positions), but this is not a strong assessment method.
LIBRARY STATISTICS USAGE/WEB HITS	**Poor potential.** Ideally, students who read more should be better thinkers, but we do not know if this hypothesized relationship is true. A better index might be what they chose to read, but this is not a direct measure of critical thinking ability and it requires too many inferences to qualify as a valid assessment.

GOAL 4: Application of Psychology: Understand and apply psychological principles to personal, social, and organizational issues.

4.1 Describe major applied areas (e.g., clinical, counseling, industrial/organizational, school, etc.) and emerging (e.g., health, forensics, media, military, etc.) applied areas of psychology.

4.2 Identify appropriate applications of psychology in solving problems.

4.3 Articulate how psychological principles can be used to explain social issues and inform public policy.

4.4 Apply psychological concepts, theories, and research findings as these relate to everyday life.

4.5 Recognize that ethically complex situations can develop in the application of psychological principles.

COURSE DATA	**Mixed potential.** Classroom strategies show variable potential in measuring how students apply psychological principles.
OBJECTIVE TESTS	**Limited potential.** Objective tests (e.g., multiple-choice items) can assess knowledge of the roles of applied areas (e.g., employee selection, training, and evaluation in I/O psychology) and the differences among areas of applied psychology (e.g., clinical/counseling psychology).
ESSAY TESTS	**Strong potential.** Essay questions can assess knowledge of the application of psychology if they require students to describe examples of how psychological principles and methods can be used to solve specific problems (e.g., decreasing a child's tantrums, strengthening a college student's study skills, or helping an adult overcome a phobia) or how ethical issues can decrease the desirability of some applications.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Strong potential.** Embedded assessments represent activities that the department has agreed will provide a good measure of student learning or progress but take place within the confines of a class. Classroom assignments can be used to assess students ability to apply psychological principles, theories, and methods if they are designed to do so. For example, students can apply what they have learned about stress management in an assignment that requires them to (1) identify the major stressors in their lives, (2) devise a plan to improve their ability to cope with these specific stressors, and (3) evaluate the effectiveness of their plan.
CLASSROOM ASSESSMENT TECHNIQUES	**Not applicable.** Classroom assessment refers to informal methods to determine whether or not students understand course material (e.g., the end-of-class one minute paper). Thus, they are more suited to providing feedback to teachers about what is going on in their classrooms than producing data about student's ultimate ability to apply psychological principles and methods.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Mostly Strong potential.** Nearly all of the methods that address individual performance are reasonable to optimal means of addressing the application of concepts.
WRITTEN PRODUCTS	**Strong potential.** Any written assignment (e.g., a term paper, moral dilemma analysis) that requires students to describe how they would apply their psychological knowledge would be useful as a means of assessing knowledge of how psychological principles and methods can be applied. Of course, knowing how to apply psychological principles and methods and actually being able to apply them successfully are two different stories.
ORAL PRESENTATIONS	**Strong potential.** Oral presentations can be used to assess the ability to apply psychology in the same way that written products can.
GRAPHIC TESTS AND DISPLAYS	**Limited potential.** Simple graphic representations may be insufficient with regard to clarifying an application.
POSTERS	**Strong potential.** A poster can provide substantial evidence of student's ability to apply what they have learned in their methods classes. It can also provide faculty with an opportunity to evaluate students ability to "think on their feet" when they are asked questions during a poster session, which provides another venue for demonstrating application skills.

GOAL 4: Application of Psychology (continued)	
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** Simulations in which a "real world" situation is created in an artificial environment (e.g., counseling sessions in which the student "counselor" must provide counseling to a fellow student who is role playing a particular DSM category) can provide faculty with a rich opportunity to assess students ability to apply what they have learned in the classroom (e.g., listening skills, the development of rapport, professional mannerisms, etc.).
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential.** Summative methods must have a predominant focus on application to serve this goal. Some summative approaches tend to have a broader focus.
STANDARDIZED TESTS	**Limited potential.** Some nationally standardized tests (e.g., ACAT, ETS Major Field Test) contain subtests the measure student's knowledge of psychological research methods (e.g., research design, statistical analysis, and graphic interpretation), which are legitimate examples of how psychologists apply the scientific method to solvable problems. However, most question sets favor lower-order questions rather than those that involved applied skills.
LOCALLY DEVELOPED TESTS	**Limited potential.** A locally developed test will allow faculty the opportunity to collaborate to produce a locally developed test that incorporates application, but producing applied items will be as difficult locally as it is in national exams.
CAPSTONE EXPERIENCES	**Optimal potential.** There are many types of capstone experiences, but those that require enrollees to "do the discipline" are probably the most effective way for a department to assess its student's ability to apply the psychological principles and methods they have acquired in their previous class work. Capstone classes provide students with an opportunity "to demonstrate comprehensive learning in their major through some type of product or performance" (Palomba & Banta, 1999, p. 124). In a capstone class, senior majors pull together what they have learned in previous classes and use this integrating experience to demonstrate they are capable of doing what they should be able to do as they graduate from the program (e.g., perform research in a capstone laboratory or demonstrate clinical skills during an internship with a local crisis clinic). This process serves a dual purpose. It allows psychology majors with a final opportunity to practice and demonstrate the skills they will need to succeed after graduation on the job or in graduate school. It also provides the Psychology Department with a final opportunity to assess whether or not it has been successful in its mission to produce psychology majors who are capable of applying what they have learned. Palomba, C. A. & Banta, T. W. (1999). Assessment essentials: Planning, implementing, and improving assessment in higher education. San Francisco: Jossey-Bass Publishers. Available at http://www.josseybass.com/WileyCDA/WileyTitle/productCd-0787941808.html
INTERNSHIPS OR PROFESSIONAL APPLICATIONS	**Strong potential.** See Capstone Experiences above for description of internships as assessment strategies. An internship or practicum taken under the direction of an on-the-job professional can be an invaluable experience for psychology students and it can also provide quality feedback to a department about its students' ability to apply what they have learned in the classroom if their on-the-job supervisors are willing and able to provide such feedback.
PORTFOLIOS	**Moderate potential.** Portfolios can produce longitudinal information, allow students to reflect upon their progress, and give them a voice in assessment. Artifacts could include test scores in classes that covered application topics, papers written on application, journals from internships, reports of projects, etc. The degree to which application is involved in the portfolio design criteria must be departmentally determined.
ASSESSMENT CENTER METHODS	**Mixed potential.** Simulations are excellent for assessing application skills, but the necessity for thorough planning, implementation, and the expense of training or paying assessors are strong drawbacks of this method. It might be interesting to train senior psychology majors (as part of a capstone) to be assessors in simulations conducted in lower-level classes in which psychological principles, theories, and methods are applied (e.g., case studies requiring DSM diagnoses or detection of flaws such as uncontrolled variables in research designs). This would allow faculty to not only involve students in the assessment process, but also provide students with the opportunity to learn and demonstrate useful skills in assessment.

GOAL 4: Application of Psychology (continued)	
CASE AND LONGITUDINAL STUDIES	**Mixed potential.** Longitudinal assessment studies involve the collection of pre- and post-information and, as such, they can provide evidence of how students change in their ability to apply the discipline over the course of their education. *This type of assessment may be most valuable to departments in non-selective institutions whose students enter with minimal skills. These departments may seek to prove that although their students do not graduate with the same high level of skills exhibited by the graduates of more selective school, their students actually make more progress (i.e., more added value) during their undergraduate years than their more high ability counterparts. As with all types of longitudinal design, it is important to realize that pre- and post-changes may be due to factors other than academic programs (e.g., maturity), and that tracking students through the process can be challenging (e.g., students who drop out).*
SELF-ASSESSMENT	**Strong potential.** Both self-assessment methods show promise for assessing application skills in psychology.
STUDENT JOURNALS	**Strong potential.** Students engaged in internships or service learning projects can be required to journal their experiences by keeping time logs, describing their actual activities, identifying their goals, evaluating whether or not they have accomplished their goals, and illustrating how their goals have been met. A perusal of these journals can give departments an accurate idea of their student's perceptions of their ability to apply the psychological principles and methods they have acquired in the classroom. However, better journal performance is facilitated by explicit directions to reflect application of course content.
SELF-CRITIQUES	**Strong potential.** When students have criteria that delineate successful performance, they can demonstrate the ability to judge their own skills in applying psychology concepts and principles.
COLLABORATION	**Mixed potential.** Traditional group projects and research teams show great potential for illustrating application skills; on-line tracking is much more problematic.
RESEARCH TEAMS	**Strong potential.** One specialized type of group problem-solving is the research team, which requires its members to apply what they have learned in their research methods class in a collaborative setting. The research team can empower students to learn how to apply methods to solve problems without having the full responsibility involved in solo projects. In addition, the number of team members has the potential to enhance the quality of the application just as it has the potential to make completing the project more challenging.
GROUP PROJECTS	**Strong potential.** Group projects allow faculty to assess their students ability to apply the principles they have acquired in two ways. When students work together to solve problems, they can demonstrate applications in content such as using Kohlberg's stages to determine moral reasoning. Their group work can also illustrate what principles from social psychology can be brought to bear to make the work satisfying (e.g., how to minimize social loafing). Applying these principles is an excellent example of the application of psychological knowledge to both everyday life (e.g., persuading children to do household chores rather than being waited upon by their mothers as if they were members of the royal family) and organizational situations (e.g., getting maximum performance from all members of a committee or work team). Carefully devised rubrics to assess collaboration attitudes and skills (e.g., willingness to volunteer and consensus-building) can be used by both faculty and peers at strategic stages of a project.
ON-LINE ACTIVITIES	**Limited potential.** Tracking group problem-solving process through online discussion can be a rich source of data for determining the evolution of application skills; however, the Disadvantages involved in deconstructing the qualitative materials make this strategy less desirable.

GOAL 4: Application of Psychology (continued)	
INTERVIEWS & SURVEYS	**Moderate potential.** Interview methods generally can have application skills as a target but this strategy requires making the assessment of application skills a prominent part of the design.
SATISFACTION SURVEYS	**Moderate potential.** Satisfaction surveys can be used to determine how well current students or alumni perceive they are learning or learned how to apply psychology. However, the survey must be carefully crafted to reflect an estimate of the student's application skills.
PERFORMANCE REVIEWS	**Strong potential.** Subsequent work settings provide good contexts in which generalization of skills can be evaluated.
EXIT INTERVIEWS	**Moderate potential.** Exit interviews can be designed to focus on the aspects of application outlined in this goal.
EXTERNAL EXAMINER INTERVIEWS	**Moderate potential.** External examiner interviewers usually work from a protocol that should be shaped by the department's interest in the effectiveness of application skills.
FOCUS GROUPS	**Strong potential.** Focus groups can be used to gather initial data that may zero in on a specific problem. As such, the purpose of the group may be to solve a problem and provide feedback to the department based on the expressed purpose. As such, students can apply principles and concepts in psychology both in the process and product of the focus group.
FOLLOW-UP ALUMNI INTERVIEWS	**Limited potential.** Calling alumni and identifying examples of successful or not so successful applications of psychology can be a source of data, but the demand characteristics of the situation may produce false positive data. If the purpose is not expressly identified by the researcher, the interview may be suspect on the basis of its potential deception.
ARCHIVAL MEASURES	**Mixed potential.** In most cases, archival measures cannot provide information about the student's ability to apply psychology. At best, archival records may reveal the intention of course design to address application skills.
TRANSCRIPT ANALYSIS	**Limited potential.** Transcript analysis might yield the percentage of students engaged in "applied" courses (e.g., internships) as well as the quality of their performance in the class, which could provide a diffuse measure of application skills.
ANALYSIS OF TRANSFER PATTERNS	**Not applicable.**
SYLLABUS AUDIT	**Strong potential.** A syllabus audit would be a good first step in determining whether or not faculty are requiring students to engage in assignments that require the application of psychological principles and methods. Where application skills have been identified as a goal by the department, this outcome should be reflected in a reasonable number of syllabi or the department will need to re-examine their curriculum offerings or mission.
DEMOGRAPHIC DATA ANALYSIS	**Not applicable.**
ALUMNI DATABASE	**Limited potential.** Determining the percentage of alumni who enter professions that require the application of psychological knowledge and skills would allow a department to get a sense of how successful its curriculum is in preparing students to apply psychology on-the-job. However, the link between job title and application of psychology principles may be fuzzy even for the former student.
LIBRARY STATISTICS USAGE/WEB HITS	**Not applicable.**

GOAL 5: Values in Psychology: Value empirical evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a science.

5.1 Recognize the necessity of ethical behavior in all aspects of the science and practice of psychology.

5.2 Demonstrate reasonable skepticism and intellectual curiosity by asking questions about causes of behavior.

5.3 Seek and evaluate scientific evidence for psychological claims.

5.4 Tolerate ambiguity and realize that psychological explanations are often complex and tentative.

5.5 Recognize and respect human diversity.

5.6 Assess and justify their engagement with respect to civic, social, and global responsibilities.

5.7 Understand the limitations of their psychological knowledge and skills.

COURSE DATA	**Not recommended overall.** Although the subtypes demonstrate differential opportunities for assessing values, in general, classroom and course data support other goals more effectively. Direct inquiry into values may be vulnerable to demand characteristics. Inferring values from indirect methods may be prone to interpretive error.
OBJECTIVE TESTS	**Not recommended.** It may be possible to assess values using this technique but it is unlikely to yield an accurate assessment of the student's true commitment to scientific values.
ESSAY TESTS	**Limited potential.** Questions that are specifically targeted to inferring and discussing relevant science values may be somewhat helpful, but again the demand characteristics may distort validity.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Limited potential.** Departments can embed values checkpoints at various points in required courses, but demand characteristics may influence students to respond in socially desirable ways rather than what they truly believe.
CLASSROOM ASSESSMENT TECHNIQUES	**Not recommended.** Most classroom techniques concentrate on capturing student understanding of content or appraisal of class effectiveness. Their values may be inferred in the latter purpose but those data tend to be of secondary interest in this application.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Mixed potential overall.** Individual projects and other forms of performance assessment do provide some opportunity to assess values based on how students develop their arguments and express what they have learned. Errors (e.g., reliance on personal experience vs. empirical evidence) may provide the basis for a strong inference about which scientific values have not been embraced. Faculty may feel uncomfortable offering feedback based on inferences, no matter how compelling.
WRITTEN PRODUCTS	**Strong potential.** Written work can assess values in psychology either by addressing explicit values as the focus of the writing or by making errors that reveal the notable absence of an expected value (e.g., when students reports that an experiment "proves" a hypothesis. The presence of designated scientific values in writing projects tends to enhance the overall evaluation of quality of the work since the voice of the paper reflects the values of the community.
ORAL PRESENTATIONS	**Strong potential.** Oral presentations can also provide significant information about the degree to which students adhere to the values of the psychological community either by the direct values espoused in the presentation or the errors that reveal either a misunderstanding or rejection of those values. Typically, faculty do not directly grade presentations based on the values expressed; however, speeches and presentation that more accurately reflect psychology values may exert a positive influence on the grade and feedback.
GRAPHIC TESTS AND DISPLAYS	**Limited potential.** The abstract nature of values does not lend itself as readily to this type of assessment.

GOAL 5: Values in Psychology (continued)	
POSTERS	**Limited potential.** Unless the assigned poster addresses values in an explicit way, faculty may have to infer relevant values from **posters** designed to address other more concrete concepts. In addition, spontaneous discussion about the poster production can probe student values as one source of data about how the students solved the problem. However, this situation lends itself to strong demand characteristics so students may report the values that will make the instructor happy, not necessarily the true values that motivate their behavior.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** Structured problem-solving scenarios can be designed around the scientific values specified in this goal. Students can be asked to resolve some value conflicts in ways that will illustrate whether they have integrated the common values psychologists most typically espouse.
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential overall.** This category contains some methods that show especially good potential for assessing the values that the student has learned to honor, but other methods are less profitable. The department will need to determine their comfort level with whether and how to assess scientific values.
STANDARDIZED TESTS	**Not recommended.** There are no commonly used tests of psychological values. There may be more generic scientific value inventories but these have not been implemented.
LOCALLY DEVELOPED TESTS	**Not recommended.** There are no known inventories on psychological values that have been developed in local contexts.
CAPSTONE EXPERIENCES	**Strong potential.** The design of the capstone experience can and perhaps should include a component in which the student actively identifies the ways in which their work in the course actively expresses scientific values. Values and ethics may be the content base for the capstone as well, which provides several venues to assess what the student recognizes, understands, and practices among scientific ethics.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Strong potential.** Settings in which students can make practical applications of the psychology content they have learned can illustrate the degree to which they have accepted and practiced scientific values. However, not all internship supervisors are likely to have a keenly developed sense of the values expectations. Therefore, a survey or set of criteria may be most useful in framing feedback on the degree to which students illustrate those principles.
PORTFOLIOS	**Strong potential.** One criterion that can drive selection of work for the student portfolio is the degree to which those products illustrate psychological values. The criteria add legitimacy to faculty comments about the salience of the values in student performance. Including a self-assessment dimension may further foster student's understanding of the critical values.
ASSESSMENT CENTER METHODS	**Mixed potential.** Not all assessment center methods directly address values. However, it may be possible for students to justify the actions they take in performance assessment situations from the values to which they subscribe. For example, the student might be asked to simulate serving as an editor who needs to choose among three articles, which differ dramatically in the degree to which those papers adhere to the prescribed values. The justification for the selection would reveal the student's values.
CASE AND LONGITUDINAL STUDIES	**Strong potential.** Qualitative studies of student's changes over time could capture shifts in their adherence to scientific values although traditionally the emphasis in such studies tends to be more focused on the value of the content base itself. Departments would benefit from knowing what elements of the curriculum foster improvements in the practice of scientific values. For example, in which courses are students likely to become comfortable with complexity and ambiguity? Well-framed qualitative investigation would yield such answers.

GOAL 5: Values in Psychology (continued)	
SELF-ASSESSMENT	**Mixed potential overall.** Many departments do not pay direct attention to the assessment of psychological values since these may be regarded as abstract or esoteric. In such situations, students will be less well prepared to self-assess. However, to the extent that departments can clarify their expectations about the ways in which they expect student values to change toward greater appreciation of the scientific aspects of psychology, the more student self-assessment can be facilitated.
STUDENT JOURNALS	**Mixed potential.** In **student journals**, values can be addressed directly or they may be inferred based on student discussion of related phenomena. Better journal entries will be framed in ways that students can directly discuss their practice of identified values.
SELF-CRITIQUES	**Strong potential.** Where departments make their values & expectations explicit, students should be able to evaluate the extent to which their own work matches these expectations.
COLLABORATION	**Limited potential overall.** The assessment of the degree to which individuals express scientific values may be challenging to assess in group contexts. Even when the focus of the group activity is directly linked to values, discussion about values may not predict individual behavior. On the other hand, conflict situations may clarify the degree to which students differ in the values that they profess.
RESEARCH TEAMS	**Limited potential.** Students who work under the direction of a research mentor are likely to receive indirect training on the scientific values that undergird high quality research. When students are challenged to explain why certain actions are required as part of the research process, their understanding and adherence to scientific values can be assessed.
GROUP PROJECTS	**Limited potential.** Most group projects that transpire in the undergraduate curriculum are unlikely to address scientific values directly. However, some projects could be designed that would allow students to solve problems in such a way that their collective grasp of scientific principles could be demonstrated.
ON-LINE ACTIVITIES	**Poor potential.** Values may be inferred from group process but the amount of work required makes this assessment approach untenable.
INTERVIEWS & SURVEYS	**Mixed potential overall.** Various approaches in this goal produce differential outcomes in identifying values.
SATISFACTION SURVEYS	**Limited potential.** Satisfaction surveys do not tend to focus on values related to psychology education. Perhaps some survey items could be crafted to address values, but that might detract from the main purpose.
PERFORMANCE REVIEWS	**Limited potential.** Inferring other's values from their performance is dicey business. Perhaps it is not best to describe definitively what the values related to psychology education might be.
EXIT INTERVIEWS	**Strong potential.** Although assessing values will be determined by the concentration of the interview protocol, it is possible to have students conduct some targeted reflection on the values that they have embraced during the course of their education. An additional problem is that the values reported during an interview may not be the values of practice.
EXTERNAL EXAMINER INTERVIEWS	**Strong potential.** Again, the success in identifying values is dependent on the design of the protocol. It is possible to gain some insight about how values have changed, but personal reports may not correspond to performance realities beyond the interview.
FOCUS GROUPS	**Strong potential.** A focus group can be convened to address how values change as part of education. However, focus groups tend to have a problem-solving focus apart from values.
FOLLOW-UP ALUMNI INTERVIEWS	**Limited potential.** Discussing values-related issues with alumni may be a window into their values structure, but the complications of this method, including the problem of deception, make it a less.

GOAL 5: Values in Psychology (continued)	
ARCHIVAL MEASURES	**Not recommended overall.** Archival measures generally cannot provide a good gauge of values professed or practiced by psychology students.
TRANSCRIPT ANALYSIS	**Not recommended.** Although it is possible to infer some values from course selections, there are too many variables that influence course choice for the inferences to be meaningful. In addition, adhering to scientific values cannot be assumed just because science courses have been completed.
ANALYSIS OF TRANSFER PATTERNS	**Not recommended.** Values cannot be inferred from past coursework.
SYLLABUS AUDIT	**Not recommended.** Most faculty do not explicitly address the values that a course promotes so an audit is unlikely to produce helpful data about values in psychology education.
DEMOGRAPHIC DATA ANALYSIS	**Not recommended.** Demographic databases are unlikely to address values in a direct and meaningful manner.
ALUMNI DATABASE	**Not recommended.** Tracking values explicitly is not a typical feature for the alumni database and doing so could be construed as invasive.
LIBRARY USE/WEB HITS STATISTICS	**Not recommended.** A checked-out library book or evidence of a web hit does not guarantee that the content has been examined or has created any influence.

GOAL 6: Information and Technological Literacy: Demonstrate information competence and the ability to use computers and other technology for many purposes.

6.1 Demonstrate information competence at each stage in the following process: formulate a researchable topic; locate and choose relevant sources from appropriate media, use selected sources after evaluating their suitability; read and accurately summarize the general scientific literature of psychology.

6.2 Use appropriate software to produce understandable reports of the psychological literature, methods, and statistical and qualitative analyses in APA or other appropriate style, including graphic representations of data.

6.3 Use information and technology ethically and responsibly.

6.4 Demonstrate these computer skills: use basic software programs, search the Web, use proper etiquette and security safeguards when communicating through e-mail.

COURSE DATA	**Mixed potential.** The only venue in which classroom and course data might reveal information technology expertise would be classes that are heavily mediated. For example, computer labs might be used for on-line testing that would allow some opportunity to gauge student expertise with this method. For the most part, information skills will be better assessed with other strategies that involve activities outside the classroom.
OBJECTIVE TESTS	**Limited potential.** Knowledge of information and literacy skills could be tested through objective test questions; however, other methods will demonstrate their understanding more directly.
ESSAY TESTS	**Poor potential.** In-class essays would have to focus on student reports of their information retrieval and technological strategies that would produce extremely boring reading.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Strong potential.** Departments may dictate specific milestones that should be embedded in required coursework. For example, faculty may specify that exposure to a psychology research database might be embedded in required 101 classes. In smaller contexts, librarians can be enlisted to help conduct information skills training. Later in the curriculum, faculty might identify a courses or set of courses in which they can commit to a particular length of paper with an explicit minimum of high quality scientific sources. The quality of information skills can be inferred from the product; the quality of technological expertise might require more digging or more explicit reporting mechanisms.
CLASSROOM ASSESSMENT TECHNIQUES	**Limited potential.** This approach may be helpful only in classes specifically focused on the development of information and technology skills.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Mixed potential.** Intellectual products provide a stimulus from which faculty can interpret sophistication in information and technological skills. When construction is remote, there may be some risk that the student's work is not an individual production. However, faculty can address this limitation by including a reflective piece that directly addresses the targeted skills.
WRITTEN PRODUCTS	**Optimal potential.** Written projects provide an ideal context in which to look at research generation, information evaluation, and technology skills.
ORAL PRESENTATIONS	**Moderate potential.** Individual oral presentations provide some opportunity to evaluate quality of resources; however, these may be challenging to judge in the moment. Oral presentations do provide an opportunity to examine PowerPoint or overhead management. In addition, the coherence and development of an oral presentation can reveal research strategies.
GRAPHIC TESTS AND DISPLAYS	**Limited potential.** Exploring concepts through graphics tends to be an intermediate step in developing research ideas. These may be difficult to assess quality. Such displays may or may not provide an opportunity to assess technology skills,

GOAL 6: Information and Technological Literacy (continued)	
POSTERS	**Moderate potential.** The limited space available in most posters may not provide an ideal context in which to evaluate the process of generating research ideas. The poster normally produces highlights so errors or suspect variations may be harder to determine. The execution of the poster will require some technological and aesthetic skills to be successful.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Limited potential.** Situational assessments move remote activities into observable territory to facilitate faculty assessment. However, a situational assessment that covers all the outcomes associated with the goal is likely to be fairly intimidating. Performance anxieties may complicate student's ability to perform these complex skills in a situational assessment.
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential.** Strategies in this category range from zero to maximally helpful.
STANDARDIZED TESTS	**Not available.** Although there is no standardized approach for measuring research skills, this gap represents an interesting development opportunity.
LOCALLY DEVELOPED TESTS	**Limited potential.** Some departments have developed methods to assess information skills and research summarizing skills. Assessing these abilities using objective means will be efficient. Asking students to summarize literature will be more challenging and time-consuming but still do-able.
CAPSTONE EXPERIENCES	**Strong potential.** Assuming that the capstone course has an expressive requirement (e.g., writing or speaking), the capstone course can provide an integrated demonstration opportunity.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Limited potential.** The focus of most applied summative experiences will not be focused on the development of the targeted skills.
PORTFOLIOS	**Strong potential.** Providing explicit criteria that ask students to select works based on what these reveal about their skills. The evolution of their abilities can be the focus of reflection on why they selected the items they did.
ASSESSMENT CENTER METHODS	**Limited potential. Assessment center methods**, like situational assessments, move remote activities into observable territory to facilitate faculty assessment. However, a situational assessment that covers all the outcomes associated with the goal is likely to be fairly intimidating. Performance anxieties may complicate student's ability to perform these complex skills.
CASE AND LONGITUDINAL STUDIES	**Limited potential.** The complexities of tracking these skills over time mitigates against adopting this strategy to monitor their evolution.
SELF-ASSESSMENT	**Mixed potential.** Developing student's metacognition of their achievement in information and technology skills has not been overtly addressed through self-assessment strategies.
STUDENT JOURNALS	**Limited potential.** It is unlikely that faculty would choose to invest time reading about student's struggle to learn information and technology skills. However, engaging in student journal writing might provide some keys to faculty about where the particular points of struggle might be.
SELF-CRITIQUES	**Strong potential.** Where faculty can specify relevant performance criteria, students can provide an estimate of their research conceptualization skills, their sophistication in evaluating information, and their polish in technological execution.

GOAL 6: Information and Technological Literacy (continued)	
COLLABORATION	**Mixed potential.** The range of potential in this category ranges from strong to poor.
RESEARCH TEAMS	**Strong potential.** A research team can develop expertise in research skills through peer involvement. Ironically, research teams may reduce a student's direct involvement in finding resources or producing polished copy. However, the opportunity to brainstorm with peers about developing concepts and executing research strategies makes this an attractive alternative.
GROUP PROJECTS	**Moderate potential.** Group projects can still involve many of the elements in this target area related to research teams.
ON-LINE ACTIVITIES	**Poor potential.** Tracking student skill development online will be a complex undertaking unless there is explicit direction for the online traffic to focus on this area of skill development.
INTERVIEWS & SURVEYS	**Mixed potential.** The assessment of attitudes by the students or other stakeholders may provide some feedback about information/technological competence, but attitudes may not be an accurate indication of true skill attainment.
SATISFACTION SURVEYS	**Strong potential.** The abilities of students to process information and use technology responsibly can be evaluated by their employers, their graduate advisors, or other stakeholders. External critics may require prompting explicitly to address this skill, but the context in which the critics work provides a reasonable normative comparison.
PERFORMANCE REVIEWS	**Strong potential.** Graduate school advisors and employers can readily provide comments on the quality of technological preparation for their setting.
EXIT INTERVIEWS	**Moderate potential.** Students can reflect on the evolution of their information processing and technological execution as part of the interview protocol.
EXTERNAL EXAMINER INTERVIEWS	**Limited potential.** External examiners can ask probe questions to evaluate student comfort levels about the target skills, but it may be much more challenging to evaluate the quality of their performance from self-report in the absence of concrete evidence. If examiners also review printed materials or tapes of student work, they may be able to make reasonable judgment about student competence.
FOCUS GROUPS	**Limited potential.** Focus groups most often convene to solve specific problems for a department. Although the topic might be the target of a focus group, it is more likely used for other broader problems.
FOLLOW-UP ALUMNI INTERVIEWS	**Not recommended.** A follow-up interview on this topic would be hard to execute without inviting demand characteristics that might distort the real skill levels attained.
ARCHIVAL MEASURES	**Limited potential.**
TRANSCRIPT ANALYSIS	**Moderate potential.** Transcript analysis can reveal the pattern of courses students may engage in (or avoid) in the development of relevant research skills. The transcript analysis can provide both patterns and some in-class estimates of quality of student performance although the value of these may be limited.
ANALYSIS OF TRANSFER PATTERNS	**Limited potential.** Departments can benefit by understanding how transfer students may be prepared to engage in research and information activities.
SYLLABUS AUDIT	**Moderate potential.** Departmental activity examining where research and information skills are taught may be a helpful first step in diagnosing where these skills need to be enhanced.

GOAL 6: Information and Technological Literacy (continued)	
DEMOGRAPHIC DATA ANALYSIS	**Not applicable.**
ALUMNI DATABASE	**Not applicable.**
LIBRARY STATISTICS USAGE/WEB HITS	**Not applicable.**

GOAL 7: Communication Skills: Communicate effectively in a variety of formats.

7.1 Demonstrate effective writing skills in various formats (e.g., essays, correspondence, technical papers, note taking) and for various purposes (e.g., informing, defending, explaining, persuading, arguing, teaching).

7.2 Demonstrate effective oral communication skills in various formats (e.g., group discussion, debate, lecture) and for various purposes (e.g., informing, defending, explaining, persuading, arguing, teaching).

7.3 Exhibit quantitative literacy.

7.4 Demonstrate effective interpersonal communication skills.

7.5 Exhibit the ability to collaborate effectively.

COURSE DATA	**Moderate to strong potential overall.** These methods can be used to assess student's communication skills but only if writing, speaking, and presentation assignments are made part of the coursework.
OBJECTIVE TESTS	**Not recommended. O**bjective tests can be used to assess student's factual knowledge of psychology but have no merit as a metric of student's writing and speaking skills. Poor means of assessing interpersonal skills.
ESSAY TESTS	**Strong potential.** Essay tests permit careful assessment of student's writing skills.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Moderate potential.** This method can be used in any psychology course to assess student's writing skills. Embedding specific departmental assessments to evaluate communication skills in selected courses may be a sound strategy.
CLASSROOM ASSESSMENT TECHNIQUES	**Moderate potential. C**lassroom assessment techniques that focus on measuring student's writing, speaking, interpersonal, and presentation skills may be effective tools for this purpose.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Strong potential overall.** All assessment strategies in this category provide direct measures of skills in these areas.
WRITTEN PRODUCTS	**Strong potential.** Essays, term papers, and laboratory assignments offer perfect opportunities to assess student's conceptual understanding of material; their ability to develop rationale arguments in support of a theory, data, or issues; their understanding of APA style; and language use.
ORAL PRESENTATIONS	**Strong potential.** Oral reports represent the perfect means of assessing student's public speaking/oral communication abilities.
GRAPHIC TESTS AND DISPLAYS	**Strong potential.** This method permits assessment of student's abilities to communicate information, particularly numerical data, in a visual medium.
POSTERS	**Strong potential.** This method permits simultaneous assessment of student's writing skills, graphic display skills, and oral communication skills.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** Placing students in situations that require them to role play, participate in mock interviews, and so on, may be an effective means of assessing their ability to think on their feet, speak extemporaneously, and interact with each other.

GOAL 7: Communication Skills (continued)	
SUMMATIVE PERFORMANCE ASSESSMENT	**Limited to moderate potential overall.** Recommendations vary in this category from strong potential to not recommended.
STANDARDIZED TESTS	**None available.** There are no existing national normed tests to address communication skills in psychology in summative performance.
LOCALLY DEVELOPED TESTS	**Limited to Strong potential.** Locally developed essay tests permit assessment of student's writing skills; objective tests do not.
CAPSTONE EXPERIENCES	**Moderate to Strong potential.** Capstone courses that include a writing or speaking component represent excellent opportunities to assess senior student's communication abilities. Group activities may be useful in assessing student's interpersonal skills.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Limited potential.** Unless the internship/professional application involves writing or speaking components that are directly assessed, this method holds little promise for assessing student's communication skills. However, this method may be useful for assessing student's abilities to collaborate with others in a real-life setting, thus providing information on their interpersonal skills.
PORTFOLIOS	**Strong potential.** Portfolios entail collections of written work that has been created over time and thus represent an effective means of assessing the development of student writing skills.
ASSESSMENT CENTER METHODS	**Limited potential.** In-basket strategies and other assessment methods need to build in explicit communication tasks to qualify for consideration.
CASE AND LONGITUDINAL STUDIES	**Mixed potential** Longitudinal tracking of student's communication abilities over time can be a useful source of information, however, the complexities of this approach (e.g., storage, feedback intensiveness) discourages its use.
SELF-ASSESSMENT	**Moderate to Strong potential overall.** Self-assessment can be used effectively in almost any psychology course. While self-assessment strategies permit insight into student's academic experiences, they vary in value for assessing student's communication abilities. In many cases, faculty construct self-assessment documents casually and this practice may limit opportunity to examine student's polished communication skills.
STUDENT JOURNALS	**Moderate to Strong potential.** The usual purpose of journal assignments is to encourage personal expression and insight rather than as a vehicle for assessing communication skills; however, adding specific communication criteria to journal directions can facilitate assessment in this area.
SELF-CRITIQUES	**Moderate to Strong potential.** Students can provide judgments of their own communication strengths and weaknesses although personal bias may limit the accuracy of their judgments. Clearly established communication criteria and developmental practice in using the criteria will facilitate the best results.
COLLABORATION	**Limited to Moderate potential overall.** Group projects offer students a chance to collaborate, but do not guarantee the chance to assess individual student communication skills. However, these methods do hold potential for assessing student's abilities to work in groups.
RESEARCH TEAMS	**Limited potential.** The primary objective of most research teams concentrates on the product (i.e., empirical research, data collection). Although the development of communication skills can be assessed, such comprehensive attention to student contributions is not typical.

GOAL 7: Communication Skills (continued)	
GROUP PROJECTS	**Moderate potential.** Group projects permit attention to both product and process. However, in practice most faculty pay greater attention to the quality of the product than the process.
ON-LINE ACTIVITIES	**Not recommended** Monitoring electronic communication archives to assess communication skills seems indirect and time-consuming.
INTERVIEWS & SURVEYS	**Mixed potential overall.** Evaluating communication through interview or survey presents mixed potential, influenced substantially by selected format. Objective/Likert type surveys permit almost no opportunity to measure students' communication skills; open-ended survey questions are limited in assessing students' written communication skills because they generally require very short "quick" responses.
SATISFACTION SURVEYS	**Limited potential.** These types of surveys only marginally examine written communication skills.
PERFORMANCE REVIEWS	**Moderate potential.** External assessors can provide feedback on quality of communication skills that will reflect their specific communication concerns (e.g., employers can provide feedback on the effectiveness of communication abilities within the worksite).
EXIT INTERVIEWS	**Strong potential.** Although this type of interview can be time-consuming, it may permit effective assessment of senior student's oral communication and interpersonal skills.
EXTERNAL EXAMINER INTERVIEWS	**Strong potential.** External examiners can also assess oral communication and interpersonal skills with the potential additional advantage of greater objectivity.
FOCUS GROUPS	**Limited to Moderate potential.** This method may permit assessment of student's social interaction abilities and skills but is generally of limited use because of time and logistical considerations.
FOLLOW-UP ALUMNI INTERVIEWS	**Limited to Moderate potential.** This approach can be problematic since communication skills would be indirectly assessed in this approach.
ARCHIVAL MEASURES	**Not recommended overall.** These methods reveal little useful information about student's communication abilities.
TRANSCRIPT ANALYSIS	**Not recommended.** A transcript can provide information on formal coursework that should contribute to communication skill development but does not address individual achievement.
ANALYSIS OF TRANSFER PATTERNS	**Not recommended.** Transfer patterns may alert faculty to gaps in student's communication course preparation, but do not directly address skill levels.
SYLLABUS AUDIT	**Limited potential.** Departments can determine the extent to which specific communication skills are built into the curriculum but quality of experience is not directly observable.
DEMOGRAPHIC DATA ANALYSIS	**Not recommended.** No pertinent data can be gained through this process.
ALUMNI DATABASE	**Not recommended.** No pertinent data can be gained through this process.
LIBRARY USE/WEB HITS STATISTICS	**Not recommended.** An analysis of this type can reflect student's formal interest in communication related books or websites, but does not provide direct information on skill attainment.

GOAL 8: Sociocultural and International Awareness: Recognize, understand, and respect the complexity of sociocultural and international diversity.

8.1 Interact effectively and sensitively with people of diverse abilities, backgrounds, and cultural perspectives.

8.2 Examine the sociocultural and international contexts that influence individual differences.

8.3 Explain how individual differences influence beliefs, values, and interactions with others and vice versa.

8.4 Understand how privilege, power, and oppression may affect prejudice, discrimination, and inequity.

8.5 Recognize prejudicial attitudes and discriminatory behaviors that might exist in themselves and in others.

8.6 Predict how interaction among diverse people can challenge conventional understanding of psychological processes and behavior.

COURSE DATA	**Overall Mixed potential.** In class strategies vary in their effectiveness in gauging learning in this diversity-related goal.
OBJECTIVE TESTS	**Mixed potential.** Objective tests can provide in-class assessment of facts and principles, but other approaches are likely to produce greater gains.
ESSAY TESTS	**Mixed potential.** Essay questions can provide a great vehicle for evaluating student knowledge of diversity-oriented facts and also for allowing students the opportunity to reflect on key ideas in coherent essays. The drawback is that the topics may produce strong demand characteristics that may produce discrepant predictions from real behavior.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Strong potential.** Many departments have opted to designate specific courses as "diversity oriented" and entrust these courses to provide the learning experiences and associated assessments to accomplish the outcomes related to this goal. If a department collaborates on the design of the outcomes or learning experiences, this approach can be profitable. Sharing outcomes across a small number of courses may help this goal become more manageable.
CLASSROOM ASSESSMENT TECHNIQUES	**Moderate potential.** Private reactions at critical moments in a course may be a powerful learning vehicle for students. When teachers collect those observations, anonymous reactions may allow students to be more candid. From that collection, the faculty member may get a meaningful index about how the students are relating to topics as a whole but are unlikely to provide individual feedback to students in this very personal domain.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Overall Strong potential.** Because insights related to this goal are intensely personal, individual performances may be one of the most effective routes for assessing achievement in this area.
WRITTEN PRODUCTS	**Strong potential.** Whether the projects focus on cultural/ethnic differences or merely emphasize this area as part of a larger effort, written projects provide an opportunity to explore content as well as personal reactions. Better assignments will be driven by a rubric in which performance related to this goal can be made specific.
ORAL PRESENTATIONS	**Strong potential.** The advantages are similar to written products with the additional advantage that student learning can be probed by the audience members.
GRAPHIC TESTS AND DISPLAYS	**Moderate potential.** Concept maps can produce some preliminary ideas related to this goal, but are unlikely to serve as final products.
POSTERS	**Strong potential.** Posters can provide a great way for many students to demonstrate their learning. Rubrics can provide clear expectations about criteria for achievement.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Moderate potential.** The demand characteristics of an assessment in diversity related learning runs some risk of producing artificial responses that may not be a true representation of student's attitudes. However, a situational assessment can be a reasonable measure of content knowledge in this area.

GOAL 8: Sociocultural and International Awareness (continued)	
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential.** Although summative approaches can be used to address this area, none of the methods in this category produce optimal strategies.
STANDARDIZED TESTS	**None available.** At the present time, there is no standardized assessment instrument to address diversity knowledge and attitudes.
LOCALLY DEVELOPED TESTS	**Poor potential.** It is hard to imagine that departments would concentrate on sociocultural and international dimensions in a locally developed objective test. Dedicating even just a few items on a broader test is unlikely to produce a helpful picture of student development in this arena.
CAPSTONE EXPERIENCES	**Moderate potential.** A capstone course can be dedicated to cross-cultural, ethnic, or international concerns so performance in a capstone can be assessed for this dimension.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Limited potential.** Internships and field experiences can provide students with an opportunity to engage with populations that are divergent from their own, providing a rich venue in which to develop diversity-related skills.
PORTFOLIOS	**Moderate potential.** A diversity component can be a required feature in a portfolio. This requirement will only be workable in programs in which learning experiences produce meaningful opportunities to demonstrate diversity-related content and skills.
ASSESSMENT CENTER METHODS	**Moderate potential.** In-basket strategies or other assessment center methods can provide diversity-oriented learning opportunities; however, the demand characteristics of this approach may render performances that are more staged than genuine.
CASE AND LONGITUDINAL STUDIES	**Moderate potential.** The expense and time requirements of case and longitudinal studies of how students achieve their learning goals militate against the use of this method to address diversity concerns. In addition, changes in attitude and knowledge may not be a direct function of the curriculum so the findings of such studies may be misleading. However, examining attitude and content knowledge in this area would produce valuable information about the role of curriculum in facilitating this change.
SELF-ASSESSMENT	**Mixed potential.** Self-awareness can be a critical component of successful educational experiences in diversity-related content and skill development.
STUDENT JOURNALS	**Strong potential.** When students have the opportunity to learn about diversity-related issues, a journal may be a strong, if not optimal, way to allow personal exploration of controversial matters.
SELF-CRITIQUES	**Moderate potential.** Self-review can be a meaningful form of assessment in this arena when faculty develop clear and meaningful criteria for performance.
COLLABORATION	**Overall favorable potential.** Learning about differences by actual participation in groups may be an ideal way to develop diversity-related skills assuming that students get objective feedback based on their performances.
RESEARCH TEAMS	**Strong potential.** Research teams devoted to solving problems related to intercultural and international issues can provide an excellent vehicle for students to develop expertise in the content of this area.
GROUP PROJECTS	**Strong potential.** Group projects can provide direct experience for students who are learning to work with others who may be different from themselves. The nature of the project may also lend itself to enhanced learning of the content in this area.

GOAL 8: Sociocultural and International Awareness (continued)	
ON-LINE ACTIVITIES	**Moderate potential.** Online archives provide concrete evidence of social interaction across participants, which can be very useful in deconstructing conflict or otherwise understanding what makes diverse people work more effectively. Unfortunately, this method of assessment is quite labor intensive and may feel deceptive unless the students understand that their communications will be monitored for learning purposes.
INTERVIEWS & SURVEYS	**Mixed potential.** Interviews and surveys may not be the most strategic way to assess genuine diversity-related gains due to demand characteristics of the situation.
SATISFACTION SURVEYS	**Limited potential.** Surveying attitudes about diversity-related skills is likely to be perilous due to strong demand characteristics. However, it may be reasonable to include satisfaction items with the content and skills that encourage positive relating to diverse others.
PERFORMANCE REVIEWS	**Limited potential.** Stakeholders may not be able to describe sociocultural values and behaviors beyond the most basic of behaviors.
EXIT INTERVIEWS	**Moderate potential.** Although it may be reasonable to incorporate questions as part of an exit interview regarding how well the curriculum has prepared students to deal with diversity, the demand characteristics complicate the interpretation of the results.
EXTERNAL EXAMINER INTERVIEWS	**Limited potential.** Students are likely to report attitudes that are consistent with creating a favorable impression. However, an external examiner's neutrality may provide a greater opportunity to assess realistic attitudes than methods that rely on program faculty.
FOCUS GROUPS	**Strong potential.** When a focus group is convened for the specific purpose of solving problems related to diversity, students can experience a rich learning opportunity that also provides markers of their growth. For example, a focus group might be designed to address ways to increase exposure to different peoples and cultures, which would allow for the assessment of attitudes and content.
FOLLOW-UP ALUMNI INTERVIEWS	**Poor potential.** A follow-up with alumni that assesses attitudes or skills without necessarily disclosing that purpose is fraught with problems. Although a well-designed protocol may produce realistic responses, the ethical complications of this approach discourage its use.
ARCHIVAL MEASURES	
TRANSCRIPT ANALYSIS	**Limited potential.** A transcript analysis can only provide gross information about the presence or absence of courses devoted to diversity-related themes.
ANALYSIS OF TRANSFER PATTERNS	**Limited potential.** Transcripts of transfers can provide some information about the degree to which new students may be bringing in diversity-related coursework. Understanding whether transfer students will have already engaged in such coursework can facilitate more targeted planning for the new institution.
SYLLABUS AUDIT	**Moderate potential.** Departments would benefit from an audit of existing syllabi to determine the extent to which this outcome is a routine part of the curriculum.
DEMOGRAPHIC DATA ANALYSIS	**Moderate potential.** Analysis of the demographics of students may be helpful in determining what kinds of experiences with other cultures or ethnic traditions would be useful in building awareness and related skills.
ALUMNI DATABASE	**Limited potential.** Tracking the characteristics of the database may be useful in terms of linking the student body with the alumni. It may be useful to target alums from specific traditions to assist in diversity training.
LIBRARY STATISTICS USAGE/WEB HITS	**Limited potential.** Faculty can learn whether international, cultural, and ethnic resource books see much action from the students, but user rates don't reliably indicate what has been learned by the students. More direct strategies are preferable.

GOAL 9: Personal Development: Develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

9.1 Reflect on their experiences and find meaning in them.

9.2 Apply psychological principles to promote personal development.

9.3 Enact self-management strategies that maximize healthy outcomes.

9.4 Display high standards of personal integrity with others.

9.5 Seek input from and experiences with diverse people to enhance the quality of solutions.

COURSE DATA	**Mixed potential.** Departments will naturally vary in relation to the importance of the personal development goal; however, the primary emphasis in most classroom activity and course assignments will be mastery of the appropriate content. Unless the courses itself has a particular or purposeful personal development focus or feature, it is unlikely much assessment of related outcomes will occur in courses.
OBJECTIVE TESTS	**Limited potential.** Personality inventories, such as the Myers-Briggs SIGI-PLUS, or assorted learning inventories can be used to develop some developmental strategies in classes that have a personal development emphasis (e.g., college success courses). The Multimedia Integrity Test (MIT) also provides an inventory related to integrity. However, a specific inventory has not been developed for this category, would be very expensive to develop, and would have narrow use in a typical psychology curriculum.
ESSAY TESTS	**Strong potential.** Although the quality of feedback will depend on the clarity of instructions, well-designed essay questions can be used to prompt personal reflection.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Strong potential.** Self-assessment strategies that are routinely embedded in course assignments will help develop strengths regarding self-evaluation, goal-setting, and other aspects of meta-cognition and self-regulation.
CLASSROOM ASSESSMENT TECHNIQUES	**Strong potential.** Classroom strategies that require students to construct meaning and make active connections to prior learning have the potential to build personal development skills if the items are designed to produce that outcome.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Mixed potential.** Personal development goals may be relevant to only a limited range of courses of educational experiences. However, individual projects provide good samples for personal reflection.
WRITTEN PRODUCTS	**Strong potential.** Journals, essays with a personal focus, letters, or other means of personal expression are better adapted to this goal than formats designed for scientific communication. Such work will necessarily have a strong emphasis on self-assessment.
ORAL PRESENTATIONS	**Limited potential.** The emphasis on oral presentation training in most programs is geared toward professional speeches on research or concepts. Self-assessment strategies deployed to evaluate the success or weaknesses of presentations can enhance student understanding of self-development, but it is unlikely that speeches would be devoted to student exploration of personal development insights, which would likely be viewed as a narcissistic, boring, or time-wasting enterprise.
GRAPHIC TESTS AND DISPLAYS	**Limited potential.** Due to the personal nature of the objectives in this category, graphic representation would have little appeal for broad audiences. Metaphor work may provide a reasonable expression about how students experience personal development challenges.
POSTERS	**Limited potential.** Due to the personal nature of the objectives in this category, it is hard to imagine that a poster would have appeal for broad audiences.

GOAL 9: Personal Development (continued)	
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** Authentic problem-solving situations can be structured to promote student learning in self-development. Design of performance assessments need to incorporate careful rubric development to foster on-target developmental feedback related to this skill development area.
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential.** Assessment designed to capture penultimate achievement can include personal development dimensions although not all formats do so with equal success.
STANDARDIZED TESTS	**Not available/recommended.** There is no national test of personal development skills in psychology per se. Should such an exam be developed in this area, it would provide some interesting opportunities for benchmarking how students develop metacognitively. Some aspects of this goal can be addressed by values inventories.
LOCALLY DEVELOPED TESTS	**Not available/recommended.** There are no current exemplars of personal development exams developed locally.
CAPSTONE EXPERIENCES	**Strong potential.** Capstone courses offer an ideal venue in which students can review how their personal development has unfolded during the undergraduate education. The review of self-regulation competence should also assist in the preparation of students for job interviews or graduate school application.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Strong potential.** Applied settings offer an ideal context in which to practice self-monitoring, application of criteria, strategies for self-regulation, etc. Feedback protocol will need to focus on these reflective aspects of performance to elicit appropriate measurement.
PORTFOLIOS	**Strong potential.** Assembled works and the processes used to produce them are the heart of the portfolio process. A reflective protocol (e.g., asking students to explain how a selected work provides evidence for a claim about personal development) facilitates student and faculty commentary on the personal development patterns exhibited by students over time.
ASSESSMENT CENTER METHODS	**Strong potential.** Authentic problem-solving situations can be structured to simulate the choices that students will make related to time-management (e.g., in-basket strategies) or ethical behavior (e.g., moral dilemma discussions). Feedback can be structured about personal development based on the design of the performance assessment.
CASE AND LONGITUDINAL STUDIES	**Strong potential.** The qualitative aspects of longitudinal studies lend themselves more readily to assessment of personal development. Some values inventories may provide assistance to track the course of personal development over time.
SELF-ASSESSMENT	**Optimal.** The personal nature of the goals and objectives in this category lend themselves in an ideal way to the promotion of self-assessment skills. Programs that emphasize this approach strive to build self-assessment as a development skill that begins with students making general judgments about the quality of their work and progresses to higher level demands, including creating and applying performance criteria to evaluate what students have accomplished.
STUDENT JOURNALS	**Strong potential.** With appropriately designed prompts, student journals can address any of the objectives in this category. Although this strategy is a good match, it is also very vulnerable to the personal biases and filters that may not make self-reports a valid interpretation. Faculty report best success when rubrics specify the criteria by which students will be effective in personal development goals.
SELF-CRITIQUES	**Strong potential.** Holding students accountable for judging their own performances promotes metacognitive development. Practice with self-assessment may promote habitual reflection and self-criticism. Personal biases (e.g., self-esteem issues, grandiosity) may make interpretations less reliable and valid.

GOAL 9: Personal Development (continued)	
COLLABORATION	**Mixed potential.** Personal development outcomes express individual achievement; however, group contexts can provide opportunities for development of an effective group persona. Emphasis on production or solution may obscure effective evaluation of personal achievement as a group member.
RESEARCH TEAMS	**Strong potential.** Participating in groups that must be sustained over time provide a particularly helpful opportunity to monitor personal development related to interaction skills. This outcome will be enhanced where students receive explicit feedback on the quality of their contributions as well as the quality of their product or solution.
GROUP PROJECTS	**Limited potential.** Short-term projects offer some opportunity to gain insight into interpersonal skills. However, most faculty may not feel comfortable or have access to the mechanics of the group to provide developmental feedback on group skills.
ON-LINE ACTIVITIES	**Limited potential.** Online interactive exchanges provide solid evidence of skills or deficits in group communication. However, faculty may feel offering uncomfortable about offering developmental feedback on this skill unless they make it an explicit feature of this learning opportunity and are prepared to invest the time that it would take to decode the online exchanges.
INTERVIEWS & SURVEYS	**Mixed potential.** The purpose of these strategies tends to be straightforward program evaluation as opposed to methods that can more directly influence student learning. Progress in personal development or success in its dimensions can be designed as a central feature of a specific process. Quality of results will be dependent on the design features of the survey instrument or interview protocol.
SATISFACTION SURVEYS	**Mixed potential.** Employers, parents, and other stakeholders in a student's education may be able to comment accurately about many aspects of personal development (e.g., ethics, time management, insightfulness); however, the demand characteristics and selection challenges may threaten the validity of the results.
PERFORMANCE REVIEWS	**Mixed potential.** Stakeholders may not be able to link current behaviors to personal development status without substantial training.
EXIT INTERVIEWS	**Strong potential.** Although the timing of the interview may encourage a positive response bias, exit interviews can be a good opportunity to incorporate student review of achievements in personal development.
EXTERNAL EXAMINER INTERVIEWS	**Strong potential.** A protocol that directly addresses personal development can provide an opportunity for the interviewer to probe suspect responses from the student potentially to improve the validity of the student's responses. Personal development objectives need to be made explicit in the interview protocol to produce consistent departmental data on how they facilitate these outcomes.
FOCUS GROUPS	**Limited potential.** Focus groups are unlikely to address personal development concerns unless that is the express objective of the department's convening the group. The group format may be sufficiently inhibiting in relation to self-disclosure that this strategy is not recommended.
FOLLOW-UP ALUMNI INTERVIEWS	**Limited potential.** Phone interviews designed to collect data about the personal development accomplishment of the alumni are likely to be suspect. The rationale for contacting the alumni may be difficult to address without creating a demand situation in which the alum feels some pressure to respond positively.

GOAL 9: Personal Development (continued)	
ARCHIVAL MEASURES	**Not recommended.** Archival measures would typically not allow for direct measurement of personal development objectives.
TRANSCRIPT ANALYSIS	**Limited potential.** A transcript analysis would only reveal student grades in courses that might be designated more for personal development. Such analyses would tell us little about the actual skills and values students would demonstrate.
ANALYSIS OF TRANSFER PATTERNS	**Not appropriate.** The question of transfer patterns does not have a direct bearing on personal development.
SYLLABUS AUDIT	**Limited potential.** To the extent that faculty completely address the goals that they may have for student development, a syllabus audit can provide good information about the extent to which this is a highly valued outcome for the department.
DEMOGRAPHIC DATA ANALYSIS	**Not appropriate.** Demographics do not directly address dimensions of personal development.
ALUMNI DATABASE	**Limited potential.** Depending on the scope of data maintained in the database, some personal development characteristics could be gleaned but it is likely to be labor intensive and inferential under the best of circumstances.
LIBRARY STATISTICS USAGE/WEB HITS	**Limited potential.** Faculty could track check-out patterns for books that are devoted to personal development or web sites, but these data would be quite remote from giving direct information about student development patterns.

GOAL 10: Career Planning and Development: Pursue realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings that meet personal goals and societal needs.

10.1 Apply knowledge of psychology (e.g., decision strategies, life span processes, psychological assessment, types of psychological careers) when formulating career choices.

10.2 Identify the types of academic experience and performance in psychology and the liberal arts that will facilitate entry into the workforce, postbaccalaureate education, or both.

10.3 Describe preferred career paths based on accurate self-assessment of abilities, achievement, motivation, and work habits.

10.4 Identify and develop skills and experiences relevant to achieving selected career goals.

10.5 Articulate how changing societal needs can influence career opportunities and foster flexibility about managing changing conditions.

10.6 Demonstrate an understanding of the importance of lifelong learning and personal flexibility to sustain personal and professional development as the nature of work evolves.

COURSE DATA	**Overall potential: Limited.** Departments that have Careers in Psychology course will find these methods more useful than departments that do not. Even in such courses, however, this method has limited potential because it does not typically lend itself to assessing individual student's career plans and development.
OBJECTIVE TESTS	**Limited potential.** Objective tests can be used to assess student's factual knowledge of career/educational options and related information, but they do not permit an in-depth assessment of individual student's post-baccalaureate plans.
ESSAY TESTS	**Mixed potential. E**ssay tests permit personalized assessment of post-baccalaureate plans of students. Nonetheless, other methods can more effectively assess this information.
EMBEDDED QUESTIONS AND ASSIGNMENTS	**Limited potential.** This method can be used in Careers in Psychology courses, but other methods can more directly assess this information. This method is less practical in other courses.
CLASSROOM ASSESSMENT TECHNIQUES	**Mixed potential.** This method can be used in any course to assess student's understanding of career planning and development; faculty may object to using class time for this purpose.
INDIVIDUAL PROJECTS/ PERFORMANCE ASSESSMENT	**Strong potential overall.** These methods can be used quite effectively in Careers in Psychology, Psychology of Adjustment, some developmental psychology course, and some capstone courses. It offers a number of useful means by which to assess individual student's post-baccalaureate career planning. Uses outside these courses are limited.
WRITTEN PRODUCTS	**Strong potential.** Students can prepare résumés, plot out courses they need to take prior to graduation, calculate their likely and highest possible grade-point averages, conduct informational interviews, and report on selected graduate schools.
ORAL PRESENTATIONS	**Strong potential.** Students can give oral reports on careers relevant to psychology.
GRAPHIC TESTS AND DISPLAYS	**Limited potential.** Concept maps can illustrate some key features of career planning, but other methods show more promise.
POSTERS	**Strong potential.** Students can prepare "posters" that detail key aspects of one or more careers or graduate schools.
STRUCTURAL/ SITUATIONAL ASSESSMENTS	**Strong potential.** Some Career Services offices conduct mock job interviews with students; these can videotaped to facilitate feedback.

GOAL 10: Career Planning and Development (continued	
SUMMATIVE PERFORMANCE ASSESSMENT	**Mixed potential overall.** Approaches in this category vary from "strong" to "not recommended."
STANDARDIZED TESTS	**Not recommended.** No national instrument to address career knowledge and planning exists.
LOCALLY DEVELOPED TESTS	**Not recommended.** It is unlikely a department would devote time to this kind of assessment project.
CAPSTONE EXPERIENCES	**Mixed potential.** Some capstone courses might include a project wherein students research and write about their career goals and/or graduate school plans.
INTERNSHIP/ PROFESSIONAL APPLICATIONS	**Strong potential.** These experiences can help students clarify their career goals and develop knowledge, skills, and values that will facilitate their entry into the workforce.
PORTFOLIOS	**Limited potential.** One objective of the construction of portfolios is for assistance in career planning but it is unlikely that a portfolio would be devoted solely to career pursuits.
ASSESSMENT CENTER METHODS	**Strong potential.** In-basket simulations can mirror closely the kinds of skills students might need to demonstrate in different career paths. As such, these methods can provide important data to students and their programs.
CASE AND LONGITUDINAL STUDIES	**Mixed potential.** Following the career goals and paths of graduates may provide a rich source of data but changing historical contexts may limit the value of investing faculty time in this type of assessment.
SELF-ASSESSMENT	**Strong potential overall.** These methods can be used effectively in Careers in Psychology, Psychology of Adjustment, some developmental psychology courses, and some capstone courses. They allow for in-depth assessment of individual student's post-baccalaureate career plans.
STUDENT JOURNALS	**Strong potential.** Students can reflect on their career and educational goals, ascertain what additional information they need, obtain this information, incorporate it into their planning, refine their goals, and report their progress over the term.
SELF-CRITIQUES	**Strong potential.** Although self-critiques may lack objectivity, systematic use of this practice can enhance student's ability to develop insight into the quality of their own performances.
COLLABORATION	**Limited potential overall.** Because students must develop their own goals, group projects are not particularly helpful.
RESEARCH TEAMS	**Limited potential.** Research teams can convene to develop expertise on career research but such activities will be limited to correlational and survey methods.
GROUP PROJECTS	**Good potential.** Student groups can complete projects related to career goals to enhance their understanding and promote their own career planning.
ON-LINE ACTIVITIES	**Limited potential.** Monitoring web-based activities to assess career awareness seems misdirected.

GOAL 10: Career Planning and Development (continued	
INTERVIEWS & SURVEYS	**Strong potential overall.** These methods can be used in Careers in Psychology, Psychology of Adjustment, some developmental psychology courses, and some capstone courses. These methods can also be used to gather data in other classes or in non-classroom settings, but faculty may object to using class time for this purpose.
SATISFACTION SURVEYS	**Strong potential.** There is a problem of where to administer surveys if not given in career-relevant courses.
PERFORMANCE REVIEWS	**Not recommended.** Asking employers to comment on student's career preparation may seem invasive.
EXIT INTERVIEWS	**Strong potential.** These can be used to assess student's post-baccalaureate plans and their views of departmental resources for and support of career planning and development. These can be time-consuming.
EXTERNAL EXAMINER INTERVIEWS	**Limited potential.** Other methods are more effective. External examiner time is usually invested in verifying other skills.
FOCUS GROUPS	**Limited potential.** Focus groups represent a relatively inefficient way to gather information about student's views of departmental resources for and support of career planning and development; some concerns about student's objectivity in a group setting.
FOLLOW-UP ALUMNI INTERVIEWS	**Strong potential.** Although time-consuming, this method can provide useful information regarding the department's effectiveness in preparing students for entry-level careers or graduate study.
ARCHIVAL MEASURES	**Limited potential overall.** Options in this category range from inappropriate to highly desirable.
TRANSCRIPT ANALYSIS	**Not recommended.** It is unlikely that this information would be helpful in assessing student's career goals and development.
ANALYSIS OF TRANSFER PATTERNS	**Not recommended.** Career concerns cannot be interpreted from transfer patterns.
SYLLABUS AUDIT	**Limited potential.** Departments might benefit from examining whether there are specific career-related goals present in the curriculum, especially in advanced coursework.
DEMOGRAPHIC DATA ANALYSIS	**Not recommended.** There is no direct value from this kind of analysis.
ALUMNI DATABASE	**Strong potential.** Tracking students regarding employment and graduate degrees can provide useful (aggregated) data regarding the variety and level of jobs that majors typically obtain and the proportion of majors who attend graduate/professional school. These data can be tracked over time in relation to career-relevant changes in the curriculum, development of new advising resources, etc.
LIBRARY USE/WEB HITS STATISTICS	**Not recommended.** A checked-out library book or evidence of a web hit does not guarantee that the content has been examined or has created any influence.

B. Designing Viable Assessment Plans

6. Avoiding Assessment Pitfalls

Assessment planning is a complicated process. Learn how to avoid some common problems that beset departments by reading this entry.

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C. Applying Strategies

1. Articles that Illustrate Assessment Strategies

We identify articles from *Teaching of Psychology*, and other sources that illustrate how psychology departments have conducted assessments for one or more of the Learning Goals.

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1 Knowledge Base 7 Communication Skills	Course data					Interviews and Surveys	

Lundy, B. L. (2007). Service learning in life-span developmental psychology: Higher exam scores and increased empathy.*Teaching of Psychology*, *34*, 23-27. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a788039135

Abstract: This article describes research conducted to evaluate the impact of service learning on exam scores and emotional empathy in a life-span development course. Service learning was 1 of 3 project options offered in the course; others included an interview project and a research paper. With the exception of the first exam, scores were significantly higher for the service learning students compared to those who completed other projects. In addition, only the service-learning group demonstrated a significant increase in emotional empathy as measured by the Emotional Empathetic Tendency Scale (EETS; Mehrabian & Epstein, 1972). I discuss the results in terms of the relations among practical experience, reflection, and emotional empathy.

1 Knowledge Base 10 Career Planning	Course data					Interviews and Surveys	

Maynard, A. M., Maynard, D. C., & Rowe, K. A. (2004). Exposure to the fields of psychology: Evaluation of an introductory psychology project. *Teaching of Psychology*, *31*, 37-40. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834135

Abstract: We evaluated a project designed to expose introductory psychology students to the fields of psychology. We created this project to foster student learning about the various fields of psychology, careers that psychologists have, the psychology program on their campus, and courses available at their home institution. Evaluative data included knowledge of the definitions of the fields, measured at 3 time points, as well as students' self-reported reactions. Results indicated that students found the project interesting and would recommend it for future classes. More important, knowledge tests revealed significant increases in knowledge that persisted over a 4-week period.

1 Knowledge Base							Archival measures

Meeker, F., Fox, D., & Whitley, Jr., B. E. (1994). Predictors of academic success in the undergraduate psychology major. *Teaching of Psychology*, *21*, 238-241. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857043

Abstract: Transcript data were compiled on 288 recent college graduates majoring in psychology to determine the variables that correlated best with grade point average in psychology (PSYGPA). The graduates were a highly diverse group in terms of high school academic backgrounds, grades in high school, and Scholastic Aptitude Test scores. Factor analysis of 26 predictor variables revealed three clusters of variables: high school grades/verbal, general studies, and mathematics. Multiple regression analyses revealed PSYGPA to be predicted by the grade in Introductory Psychology, general studies coursework, and mathematics factors, which together accounted for 67% of the variance. The prediction equation differed somewhat from that obtained for students at another university; consequently, prediction equations used to screen majors should be based only on students at a particular institution.

1 Knowledge Base 2 Research Methods			Summative performance			Interviews and Surveys	

Scepansky, J., & Carkenord, D. M. (2004). Senior year retention of methods and statistics concepts. *Teaching of Psychology*, *31*, 9-12. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834129

Abstract: This article describes an empirical investigation of whether performance on a senior-level assessment of methodological and statistical knowledge related to elapsed rime since students took prerequisite methods and statistics courses. In a senior-capstone course, 50 students completed a 50-item multiple-choice assessment measuring their knowledge of methods and statistics. We also measured elapsed time (number of months) since students completed Research Methods and Quantitative Methods (statistics). Results revealed that performance on the assessment showed no significant correlation with elapsed time from the Research Methods course or with elapsed time from the Quantitative Methods course. On a self-report Self-report survey, however, student reported they believed the elapsed time negatively affected their performance.

1 Knowledge Base			Summative performance				Archival measures

Stoloff, M., L, & Feeney, L, J. The Major Field Test as an assessment tool for an undergraduate psychology program. *Teaching of Psychology*, *29*, 92-98. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861538

Abstract: Senior psychology majors completed the Major Field Test in Psychology (MFT) produced by the Educational Testing Service as a component of program assessment at James Madison University. We related MFT performance to student characteristics including academic success indicators and specific psychology courses completed. MFT performance strongly correlated with other measures of academic success such as Scholastic Assessment Test scores and grade point average. There was a weak but significant positive correlation between number of psychology courses completed and MFT score. Only 4 content courses appeared to improve MFT subtest scores: Abnormal Psychology, Social Psychology, Biopsychology, and Counseling Psychology. We discuss the use and interpretation of MFT scores for program assessment and the implications of these findings for curriculum design, academic advising, and preparation of students for the Graduate Record Examination Advanced Psychology Test.

Goal 2: Research Methods in Psychology: Students will understand and apply basic research methods in psychology, including research design, data analysis, and interpretation.

2 Research Methods	Course data					Interviews and Surveys	

Burkley, E., & Burkley, E. (2009). Mythbusters: A tool for teaching research methods in psychology. *Teaching of Psychology*, *36,* 179-184. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a912648402

Abstract: *Mythbusters* uses multiple research methods to test interesting topics, offering research methods students an entertaining review of course material. To test the effectiveness of *Mythbusters* clips in a psychology research methods course, we systematically selected and showed 4 clips. Students answered questions about the clips, offered their opinions of them, and ultimately responded to *Mythbusters*-related exam items. Students indicated that the clips helped them understand course concepts, helped them apply their knowledge to real-world research studies, and provided them with an enjoyable educational experience. More important, students performed better on *Mythbusters*-related exam items than on control items, suggesting the clips were effective pedagogical tools for psychology research methods courses. We discuss specific *Mythbusters* clips that are relevant to psychological concepts.

2 Research Methods				Self-assessment		Interviews and Surveys	

Friedrich, J. (1996). Assessing student's perceptions of psychology as a science: Validation of a self-report measure. *Teaching of Psychology*, *23*, 6-13. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834219

Abstract: Training in psychology emphasizes the scientific method as the basis for knowledge claims about thought and behavior. Students are regularly evaluated in terms of their mastery of methodological and statistical principles, but little attention has been paid to assessing the degree to which students endorse the notion that psychology is, indeed, a science. Several studies are reported that validate a self-report measure of this construct. The Psychology as Science Scale is shown to be a reliable measure that predicts a range of construct-relevant attitudinal and performance criteria. Possible research uses of the measure, as well as broader issues surrounding the general public's epistemological assumptions concerning psychology, are discussed.

2 Research Methods							Archival measures

Lauer, J. B., Rajecki, D. W., & Minke, K. A. (2006). Statistics and methodology courses: Interdepartmental variability in undergraduate majors' first enrollments.*Teaching of Psychology*, *33*, 24-30. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861648

Abstract: Transcripts of 784 psychology alumni from 4 universities revealed that students' timing of first enrollments in a statistics or methodology course was the result of an interaction between personal preferences and differences in program requirements. Where only a single methodological course was mandatory, first enrollments were especially late in students' careers. In departments having multiple methodological requirements, negative correlations between the timing of first method course versus first content course (e.g., clinical, developmental) indicated that the precedence of 1 category meant a delay for the other. We offer recommendations for increasing students' direct early exposure to scientific methodology in psychology.

1 Knowledge Base 2 Research Methods			Summative performance			Interviews and Surveys	

Scepansky, J., & Carkenord, D. M. (2004). Senior year retention of methods and statistics concepts. *Teaching of Psychology*, *31*, 9-12. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834129

Abstract: This article describes an empirical investigation of whether performance on a senior-level assessment of methodological and statistical knowledge related to elapsed rime since students took prerequisite methods and statistics courses. In a senior-capstone course, 50 students completed a 50-item multiple-choice assessment measuring their knowledge of methods and statistics. We also measured elapsed time (number of months) since students completed Research Methods and Quantitative Methods (statistics). Results revealed that performance on the assessment showed no significant correlation with elapsed time from the Research Methods course or with elapsed time from the Quantitative Methods course. On a self-report Self-report survey, however, student reported they believed the elapsed time negatively affected their performance.

2 Research Methods						Interviews and Surveys	

Sizemore, O. J., & Lewandowski, G. W., Jr. (2009). Learning might not equal liking: Research methods course changes knowledge but not attitudes. *Teaching of Psychology*, *36,* 90-95. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a909503910

Abstract: Students completed surveys at the beginning and end of a sophomore-level course on research and statistics. We hypothesized that the course would produce advances in knowledge of research and statistics and that those changes would be accompanied by more favorable attitudes toward the subject matter. Results showed that knowledge did increase significantly, but 4 of 6 attitude measures showed no change. Two attitude measures (perceived utility of research and statistics) showed significant declines. These results demonstrate the independence of knowledge and attitudes and show that attitudinal change is not monolithic. We argue that students' misconceptions about research might underlie the declines in perceived utility of research and statistics.

2 Research Methods	Course data					Interviews and Surveys	

Thieman, T. J., Clary, E. G., Olson, A. M., Dauner, R. C., & Ring, E. E. (2009). Introducing students to Psychological research: General psychology as a laboratory course. *Teaching of Psychology*, *36,* 160-168. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a912648626

Abstract: For 6 years, we have offered an integrated weekly laboratory focusing on research methods as part of our general psychology course. Through self-report measures and controlled comparisons, we found that laboratory projects significantly increase students' knowledge and comfort level with scientific approaches and concepts, sustain interest in psychology, and increase critical thinking about psychological research. Implementing a laboratory component in the introductory course increases students' scientific literacy, reinforces psychology's claim to scientific status, encourages active learning, promotes quantitative reasoning, and benefits multiple constituencies.

2 Research Methods							Archival measures

Tomcho, T., Rice, D., Foels, R., Folmsbee, L., Vladescu, J., Lissman, R., Matulewicz, R., & Bopp, K. (2009). APA's learning objectives for research methods and statistics in practice: A multimethod analysis. *Teaching of Psychology*, *36*, 84-89. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a909502535

Abstract: Research methods and statistics courses constitute a core undergraduate psychology requirement. We analyzed course syllabi and faculty self-reported coverage of both research methods and statistics course learning objectives to assess the concordance with APA's learning objectives (American Psychological Association, 2007). We obtained a sample of 64 research methods and 56 statistics syllabi (return rates: 16%, 14%) from 400 randomly selected psychology departments in colleges and universities in the United States. Course syllabi generally contained appropriate research methods and statistics content. However, certain APA learning objectives consistently were absent from course syllabi, and we found discrepancies between listed objectives and faculty self-reports of topics covered.

2 Research Methods						Interviews and Surveys	Archival measures

Wayment, H. A., & Dickson, K. L. (2008). Increasing student participation in undergraduate research benefits students, faculty, and department. *Teaching of Psychology*, *35*, 194-197. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a795059220

Abstract: Little information is available about how departments might improve undergraduate students' access to research experience. At a midsized psychology department (550 majors, 21 full-time faculty), we identified 5 barriers in our existing program (lack of student awareness, unequal student access, poor curricular timing, lack of publicity, and uneven access/incentives for faculty) and implemented 5 changes (application procedures, advertisement, assessment and communication with majors, establishment of a departmental newsletter, and restructured faculty teaching assignments). Following implementation, the number of involved students increased from 40 (11-year average) to 87 (Year 1) and to 117 (Year 2) and number of involved faculty increased from 60% to 94%. Our findings suggest that implementing systematic and programmatic changes may help to increase undergraduate involvement in research.

Goal 3: Critical Thinking Skills in Psychology: Students will respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

3 Critical Thinking	Course data						

Hall, S. S. & Seery, B. L. (2006). Behind the facts: Helping students evaluate media reports of psychological research. *Teaching of Psychology*, *33*, 101-104. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785862670

Abstract: This article describes an activity that can help students (a) understand how the research process influences the outcomes of that research and (b) appreciate the media's limitations of reporting research findings. Students read about research reported in an online newspaper and in a scholarly journal and responded to questions that guided their critique of the research methods and their comparison of the 2 sources. Quantitative and qualitative evaluations suggested that this activity can help students understand the impact of research procedures on a study's findings and to appreciate the limitations in the reporting of such findings from mainstream media sources.

3 Critical Thinking			Summative performance				

Lawson, T. J. (1999). Assessing psychological critical thinking as a learning outcome for psychology majors. *Teaching of Psychology*, *26*, 207–209. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863557

Abstract: Psychological critical thinking involves evaluating claims using the basic principles of psychological science. Because it is such an important skill, psychological critical thinking should be evaluated as part of an overall outcomes assessment for psychology majors. I describe the procedure my institution uses for assessing psychological critical thinking, and I provide evidence that senior psychology majors score higher on our critical thinking test than do either introductory psychology students or seniors majoring in chemistry or biology.

3 Critical Thinking	Course data		Summative performance				

Penningroth, S L., Despain, L. H., & Gray, M. J. (2007). A course designed to improve psychological critical thinking.*Teaching of Psychology*, *34*, 153-157. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a788034823

Abstract: We developed a 1-credit freshman-level course designed to enhance psychological critical thinking. We based the new curriculum on Stanovich's (2004) text, with an emphasis on active learning and critically evaluating claims by applying scientific concepts. To assess the effectiveness of this course, we used a pretest—posttest design with a quasi-experimental control group. At posttest, students in the psychological science course showed greater improvement on psychological critical thinking than students in a comparison group. Therefore, we recommend the techniques used in this instructional intervention to help college students improve their critical thinking skills.

3 Critical Thinking						Interviews and Surveys	

Holmes, J. D., Beins, B. C. (2009). Psychology Is a science: at least some students think so. *Teaching of Psychology*, *36,* 5-11. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a907768203

Abstract: The American Psychological Association's (2007) curricular guidelines recommend that students develop both an understanding of how psychologists do research and an appreciation for why scientific thinking is necessary. We surveyed a large sample of psychology majors on specific interests, as well as individual difference variables relevant to scientific thinking. Our results suggest that over time, students' knowledge of scientific thinking increased, whereas their tendency to see psychology as a science did not. Further, students reported greater interest in practitioner activities than scientific ones, and these divergent interests were associated with differential ways of thinking and of viewing the field of psychology. We discuss some implications for conceptualizing undergraduate instruction given that some student characteristics are more malleable than others.

3 Critical Thinking	Course data					Interviews and Surveys	

Williams, R. L., Oliver, R., Allin, J. L., Winn, B., & Booher, C. S. (2003). Psychological critical thinking as a course predictor and outcome variable. *Teaching of Psychology*, *30*, 220–223. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785856629

Abstract: Students' scores on a psychological critical thinking instrument administered at the beginning and end of a large human development course significantly correlated with multiple-choice exam scores, with the posttest critical thinking scores being the better predictor of exam performance. The sample as a whole gained significantly on critical thinking, but students with high and low exam scores differed in their patterns of change on critical thinking. Students who scored high (As and B+s) on the exams significantly improved their critical thinking scores, whereas students who scored low (Ds and Fs) on the exams did not. An explicit practice and feedback procedure implemented through an existing course activity presumably contributed to gains in critical thinking.

Goal 4: Application of Psychology: Students will understand and apply psychological principles to personal, social, and organizational issues.

4 Application		Individual projects				Interviews and Surveys	

Greene, E. (2008). An advocacy exercise for a psychology and law course. *Teaching of Psychology*, *35*, 210-213. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a795059145

Abstract: This article describes an active learning component of an advanced course in psychology and law. The assignment is to present, in the context of a mock appellate court, the best available psychological data in support of one party in a legal case. Students choose one side of a hypothetical case, locate and review the relevant scientific literature, prepare written analyses and arguments, and present those analyses to a panel of student-justices who question them about the nature of their evidence and the validity of their conclusions. Postcourse assessments showed that the exercise enhanced students' conceptual knowledge of psychology and law as well as their ability to organize and synthesize empirical data, form an argument on the basis of data, and present that argument to the public.

4 Application				Self-assessment		Interviews and Surveys	

Kogan, L. R., & Kellaway, J. A. (2004). Applied animal behavior course: A service-learning collaboration with the Humane Society. *Teaching of Psychology*, *31*, 202-204. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857676

Abstract: Service-learning programs apply classroom principles to real-world situations and help communities by providing an often untapped resource of volunteers. This article describes how we applied the service-learning teaching approach to an undergraduate psychology animal behavior class in conjunction with a local humane society. Undergraduate psychology students learned operant conditioning techniques and applied this knowledge to 52 dogs housed at a local humane society. Students viewed the course as a positive experience and believed it offered them the opportunity to practice classroom knowledge in an applied setting. The article describes the course and the effects of this service-learning program on the community.

4 Application						Interviews and Surveys	

Kowalski, R. M. & Lakey, C. E. (2004). Teaching application and personal relevance through writing in courses on gender. *Teaching of Psychology*, *31*, 279-281. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857501

Abstract: Bloom (1956) included "application" in his taxonomy of educational objectives. Consistent with this goal, this study examined the effectiveness of 2 writing exercises in a gender class, keeping a journal and completing a cross-gender question exercise, in increasing students' awareness of both the personal relevance and the applicability of course material outside the classroom. Students found the exercises to be effective both personally and pedagogically. Students perceived the journal and the questions as effective means of gaining insight into societal issues confronting men and women and into the other sex.

1 Knowledge Base 4 Application 10 Career Planning	Course data					Interviews and Surveys	

Maynard, A. M., Maynard, D. C., & Rowe, K. A. (2004). Exposure to the fields of psychology: Evaluation of an introductory psychology project. *Teaching of Psychology*, *31*, 36-39. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834135

Abstract: We evaluated a project designed to expose introductory psychology students to the fields of psychology. We created this project to foster student learning about the various fields of psychology, careers that psychologists have, the psychology program on their campus, and courses available at their home institution. Evaluative data included knowledge of the definitions of the fields, measured at 3 time points, as well as students' self-reported reactions. Results indicated that students found the project interesting and would recommend it for future classes. More important, knowledge tests revealed significant increases in knowledge that persisted over a 4-week period.

4 Application						Interviews and Surveys	

Sheldon, J. P. (2004). Using Radio Diaries to teach developmental psychology concepts. *Teaching of Psychology*, *31*, 46-48. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834120

Abstract: Applying psychological theories and concepts to case studies is an effective way for students to learn and understand course material. For an adolescent development course students accessed National Public Radio's Teenage Diaries Web site and chose 1 diary to analyze. They applied psychoanalytic, learning, cognitive, ecological, and sociobiological theories to the teenager's diary. Students liked the assignment and rated it helpful for understanding and applying psychological theories.

4 Application			Summative performance			Interviews and Surveys	

Weis, R. (2004). Using an undergraduate human-service practicum to promote unified psychology. *Teaching of Psychology*, *31*, 43-46. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834120

Abstract: This article describes an undergraduate capstone course with practicum designed to integrate students' previous knowledge of psychology, research methods, and statistics and to apply this knowledge to the benefit of others. Specifically, students administered at 10-week reading intervention and behavior modification program to children with Reading Disorder. Students conducted assessments before and after intervention and statistically evaluated the effectiveness of their work. Students addressed ethical issues and collaborated with other professionals. Outcome data suggested the course was beneficial form pedagogical and service-oriented perspectives.

Goal 5: Values in Psychology: Students will be able to weigh evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a discipline.

5 Values	Course data					Interviews and Surveys	

Fisher, C. B., & Kuther, T. L. (1997). Integrating research ethics into the introductory psychology course curriculum. *Teaching of Psychology*, *24*, 172-175. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859805

Abstract: Faculty at 2 universities integrated 6 case studies on research ethics into their introductory psychology curricula. Students who received the ethics modules were better able to identify ethical issues and consider moral ambiguities than students who received standard instruction. Students and faculty favorably evaluated the curriculum, and students indicated that the ethics instruction increased their interest in research psychology and scientific ethics.

5 Values						Interviews and Surveys	

Standing, L. G., & Huber, H. (2003). Do psychology courses reduce beliefs in psychological myths? *Social Behavior & Personality: An International Journal*, *31*, 585-592.
Retrieved from http://www.sbp-journal.com/default.aspx?pageid=46&JournalArticleID=1360

Abstract: This study examined the degree to which psychology students accept popular psychology myths that are rejected by mainstream researchers (e.g., "people use only 10% of their brain's capacity"), and the effect of psychology courses on myth acceptance. Using a twenty-item, true-false myth belief questionnaire, it examined the levels of gullibility among 94 undergraduates at different stages of their education, and related these to their educational and demographic backgrounds. High overall levels of myth acceptance (71%) were found, in line with earlier research. Myth acceptance decreased with the number of psychology courses that students had taken in university, but increased with the number that they had taken in junior college. Belief in myths was lower among students who were majoring in psychology, were older, had higher grades, and had advanced training in research methods, but it was not related to gender, geographical origin, or university year. It is concluded that university courses appear beneficial in encouraging methodological skepticism, whereas taking specialized psychology courses in junior college may hinder rather than promote critical thinking among undergraduates.

5 Values						Interviews and Surveys	

Strohmetz, D. B. (1992). The use of role-play in teaching research ethics: A validation study.*Teaching of Psychology*, *19*, 106-108. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863481

Abstract: Rosnow's (1990) role-play exercise for teaching research ethics was used in undergraduate research methods courses, and its effectiveness was evaluated. Results indicate that the exercise can be a valuable tool for sensitizing students to the factors involved in judging the ethics of research.

Goal 6: Information and Technological Literacy: Students will demonstrate information competence and the ability to use computers and other technology for many purposes.

6 Info/Tech Literacy	Course data					Interviews and Surveys	

Connor-Greene, P. A. & Greene, D. J. (2002). Science or snake oil? Teaching critical evaluation of 'research' reports on the Internet. *Teaching of Psychology*, *29*, 321-324. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863895

Abstract: The proliferation of information on the Internet introduces new challenges for educators. Although the Internet can provide quick and easy access to a wealth of information, it has virtually no quality control. Consequently, the Internet has rendered faculty more essential than ever as teachers of the analytic and evaluative skills students need to become educated consumers of information. In this article we describe an exercise using small-group discussion and individual problem-based learning to teach critical thinking about the Internet. Data from the exercise and from student evaluations support both its need and students' perceptions of its effectiveness.

6 Info/Tech Literacy	Course data					Interviews and Surveys	

Landau, J. D., Druen, P. B., & Arcuri, J. A. (2002). Methods for helping students avoid plagiarism. *Teaching of Psychology*, *29*, 112-115. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861543

Abstract: Evidence has suggested that some forms of plagiarism might result from students' inadequate knowledge of proper citation techniques (Roig, 1997). We taught students about plagiarism identification and proper paraphrasing skills. Undergraduates who received no treatment, feedback, plagiarism examples, or a combination of feedback and examples completed 2 versions of a plagiarism knowledge survey, paraphrased a literary passage, and rated their knowledge of plagiarism. Participants in all conditions except the control condition were better able to identify plagiarism. In the paraphrasing exercise, the example conditions showed a reduction in plagiarism. Thus, we identify an exercise that can help students identify and avoid plagiarism.

6 Info/Tech Literacy	Course data					Interviews and Surveys	

Leshowitz, B, DiCerbo, K. E., & Okun, M. A. (2002). Effects of instruction in methodological reasoning on information evaluation. *Teaching of Psychology*, *29*, 5-10. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859214

Abstract: In this article we describe an instructional program that focuses on applying causal reasoning and related principles of the scientific method to problems faced in daily life. In a highly interactive classroom setting, the instructor gives students repeated opportunities to apply methodological reasoning to real-world scenarios for the purpose of making informed decisions. In addition to describing the program, we report the findings of a capstone exercise that examined changes in students' beliefs toward legalization of marijuana after reading persuasive communications. Students who experienced the instructional program exhibited less bias in evaluating information and less attitude polarization than students in a comparison group. We discuss the implications of these findings for developing and evaluating instructional programs in methodological reasoning in psychology.

6 Info/Tech Literacy 7 Communication Skills		Individual projects				Interviews and Surveys	

Schuetze, P. (2004). Evaluation of a brief homework assignment designed to reduce citation problems. *Teaching of Psychology*, *31*, 257-259. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857499

Abstract: I evaluated a brief homework assignment designed to reduce citation problems in research-based term papers. Students in 2 developmental psychology classes received a brief presentation and handout defining plagiarism with tips on how to cite sources to avoid plagiarizing. In addition, students in 1 class completed 2 brief homework assignments in which they had to identify information in 1 page of text that required a citation. Results found that students who completed the homework assignments had fewer problems with citations, believed that they had a better understanding of situations that comprised plagiarism, and had more confidence in their ability to avoid plagiarism.

Additional Resources

Education and Behavioral Sciences Section Psychology Committee Task Force on Information Literacy Standards. (n.d.). *Information litearcy standards for psychology students*. Current draft retrieved from http://connect.ala.org/files/29837/info_lit_psych_pdf_4a60828636.pdf

Upon final approval, these standards will appear at http://www.ala.org/ala/mgrps/divs/acrl/standards/

Goal 7: Communication Skills: Students will be able to communicate effectively in a variety of formats.

Oral communication skills

7 Communication Skills						Interviews and Surveys	

Burchfield, C. M., & Sappington, J. (1999). Participation in classroom discussion.*Teaching of Psychology*, *26*, 290-291. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863015

Abstract: Students ranked themselves and peers on perceived class participation (i.e., unsolicited questions and comments during class). The instructor also ranked students. Results suggested that students ranked themselves higher, on average, than did their peers and instructor. Students' self-rankings did not correlate well with either peer or instructor ranks, although the latter 2 agreed substantially. We recommend using multiple measures of student participation and self-monitoring in classroom discussions.

7 Communication Skills						Interviews and Surveys	

Muir, G. M., & van der Linden, G. J. (2009). Students teaching students: An experiential learning opportunity for large introductory psychology classes in collaboration with local elementary schools.*Teaching of Psychology*, *36*, 169-173. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a912649130

Abstract: Students in large, lecture-based introductory psychology classes often do not have the benefit of experiential learning (EL) opportunities due to logistical constraints. To overcome this obstacle, we developed an EL project in which introductory psychology students in small groups present some aspect of the course material to local elementary school classes. The project challenges undergraduate students to demonstrate a deep level of understanding of the presentation material. Such depth of understanding enables them to flexibly communicate material in an age-appropriate manner to kindergarten through 5th-grade students. Feedback results from undergraduate students, elementary school students, and teachers demonstrated that this project supported learning outcomes in undergraduates in a positive and enjoyable way for both student groups.

7 Communication Skills				Self-assessment			

Zaremba, S. B., & Dunn, D. S. (2004) Assessing class participation through self-evaluation: Method and measure. *Teaching of Psychology*, *31*, 191-193. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857676

Abstract: We describe a method for assessing class participation by having students evaluate their daily verbal and nonverbal contributions and completion of reading assignments. Easy to reproduce and use for record keeping, the measure allows students and faculty to understand each other's perspective on the quality of the student's participation. Students reported that the measure encouraged regular class attendance, active verbal and nonverbal participation, and completion of reading assignments.

Interpersonal communication/Collaborative skills

7 Communication Skills					Collaboration	Interviews and Surveys	

Cathey, C. (2007). Power of peer review: An online collaborative learning assignment in social psychology. *Teaching of Psychology*, *34*, 97-99. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a788015147

Abstract: In a semester-long, peer review assignment, undergraduates enrolled in a social psychology course wrote essays that applied course concepts to life experiences. Students anonymously posted essays for the entire class to view, and peers posted commentaries on classmates' essays using an online discussion board. Students rated the assignment as enjoyable and useful for improving their writing skills and conceptual understanding. For the instructor, the online nature of the assignment afforded all the benefits of peer review without increasing workload.

7 Communication Skills						Interviews and Surveys	

Connor-Greene, P. A. (2002). Problem-based service learning: The evolution of a team project. *Teaching of Psychology*; *29*, 193-197. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861246

Abstract: In this article, I describe the evolution of a problem-based service learning project in an undergraduate Abnormal Psychology course. Students worked in teams on a semester-long project to locate and evaluate information and treatment for specific psychiatric disorders. As part of the project, each team selected relevant bibliographic materials, made site visits to area treatment facilities, and prepared resource materials for people in the community seeking information on psychiatric disorders. I modified the process but not the content of the project over 4 semesters. Student evaluations improved significantly after I implemented students' suggested changes.

7 Communication Skills				Self-assessment		Interviews and Surveys	

Dunn, D. (1996). Collaborative writing in a statistics and research methods course.*Teaching of Psychology*, *23*, 38-40. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834263

Abstract: I apply two writing techniques – collaborative writing and peer review – to an experimental project in a statistics and research methods course. Student reactions to the collaboration and peer exercise are discussed.

1 Knowledge Base 7 Communication Skills	Course data					Interviews and Surveys	

Lundy, B. L. (2007). Service learning in life-span developmental psychology: Higher exam scores and increased empathy.*Teaching of Psychology*, *34*, 23-27. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a788039135

Abstract: This article describes research conducted to evaluate the impact of service learning on exam scores and emotional empathy in a life-span development course. Service learning was 1 of 3 project options offered in the course; others included an interview project and a research paper. With the exception of the first exam, scores were significantly higher for the service learning students compared to those who completed other projects. In addition, only the service-learning group demonstrated a significant increase in emotional empathy as measured by the Emotional Empathetic Tendency Scale (EETS; Mehrabian & Epstein, 1972). I discuss the results in terms of the relations among practical experience, reflection, and emotional empathy.

7 Communication Skills						Interviews and Surveys	

Melvin, K. B. (1988). Rating class participation: The prof/peer method. *Teaching of Psychology*, *15*, 137-139. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861732

Abstract: To reduce the subjectivity of class participation grades, a method was devised that combined forced-distribution peer ratings with professor grades. In seven seminar courses, correlations between professor and peer ratings ranged from .83 to .90. Course/teacher evaluations were high and the prof/peer technique was generally perceived as a fair way to evaluate participation.

7 Communication Skills						Interviews and Surveys	

Poorman, P. B. (2002). Biography and role playing: Fostering empathy in abnormal psychology. *Teaching of Psychology*, *29*, 32-36. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859220

Abstract: In this article I describe a method of fostering empathy in undergraduate and graduate students of abnormal psychology. Students depicted a psychological disorder by writing a brief biography and then role playing the characters they developed. Students demonstrated understanding of the disorders by acting and interacting in a manner consistent with their character and diagnosing other student "characters" using criteria from the Diagnostic and Statistical Manual of Mental Disorders-IV (American Psychiatric Association, 1994). Interpersonal Reactivity Index (Davis, 1980) results indicated student empathy increased significantly after the exercises. Qualitative analyses of focus group interview data supported and augmented the quantitative findings. Students attributed complex gains to the exercises.

7 Communication Skills						Interviews and Surveys	

Smith, R. A. (1990). Are peer ratings of student debates valid? *Teaching of Psychology*, *17*, 188-189. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785858403

Abstract: Although many instructors use debates in various courses, little information is available regarding debate grading. This article reports an evaluation of student participation in grading debates. In most respects, student and instructor ratings correlated highly. In addition, students reported that they liked debates, that debates helped them to learn, and that evaluating other students was valuable experience. These data support the use of peer ratings in grading classroom debates.

7 Communication Skills		Individual projects		Self-assessment	Collaboration		

Sung, Y., Lin, C., Lee, C., & Chang, K. (2003). Evaluating proposals for experiments: An application of Web-based self-assessment and peer assessment. *Teaching of Psychology*, *30*, 331-334. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861520

Abstract: Thirty-four undergraduates used Web-based self- and peer-assessment procedures for evaluating proposals in experimental psychology courses. Students presented their proposals and commented on the proposals of others on the Web. Results indicated that proposal observation and peer interaction enhanced the quality of students' proposals. These procedures also enhanced the interrater reliability of within-group members' proposal ratings.

Written communication skills

7 Communication Skills		Individual projects					

Fallahi, C. R., Wood, R. M., Austad, C. S., & Fallahi, H. (2006). A program for improving undergraduate psychology students' basic writing skills. *Teaching of Psychology*, *33*, 171-175). Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785862161

Abstract: We examined the effects of in-class writing instruction, practice, peer review, and feedback on writing skills of undergraduates enrolled in a general psychology course. We rated writing for grammar, writing style, mechanics, and American Psychological Association referencing style. Significant differences emerged on the 4 writing skill domains (p <.001). Improvement occurred immediately for referencing, whereas other skills did not improve significantly until the 4th paper. The results show that teaching writing in content courses such as general psychology can yield significant improvement in students' writing. We believe that writing instruction by psychology professors is worth the time and effort to help undergraduate psychology students develop better writing skills.

6 Info/Tech Literacy 7 Communication Skills		Individual projects				Interviews and Surveys	

Schuetze, P. (2004). Evaluation of a brief homework assignment designed to reduce citation problems. *Teaching of Psychology*, *31*, 257-259. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857499

Abstract: I evaluated a brief homework assignment designed to reduce citation problems in research-based term papers. Students in 2 developmental psychology classes received a brief presentation and handout defining plagiarism with tips on how to cite sources to avoid plagiarizing. In addition, students in 1 class completed 2 brief homework assignments in which they had to identify information in 1 page of text that required a citation. Results found that students who completed the homework assignments had fewer problems with citations, believed that they had a better understanding of situations that comprised plagiarism, and had more confidence in their ability to avoid plagiarism.

7 Communication Skills		Individual projects					

Stellmack, M., Konheim-Kalkstein, Y., Manor, J., Massey, A. R.., & Schmitz, J. A. P. (2009). An assessment of reliability and validity of a rubric for grading APA-style introductions. *Teaching of Psychology*, *36,* 102-107. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a909502194

Abstract: This article describes the empirical evaluation of the reliability and validity of a grading rubric for grading APA-style introductions of undergraduate students. Levels of interrater agreement and intrarater agreement were not extremely high but were similar to values reported in the literature for comparably structured rubrics. Rank-order correlations between graders who used the rubric and an experienced instructor who ranked the papers separately and holistically provided evidence for the rubric's validity. Although this rubric has utility as an instructional tool, the data underscore the seemingly unavoidable subjectivity inherent in grading student writing. Instructors are cautioned that merely using an explicit, carefully developed rubric does not guarantee high reliability.

7 Communication Skills		Individual projects					

Thaler, N., Kazemi, E,. Huscher, Cr,. (2009). Developing a rubric to assess student learning outcomes using a class assignment. *Teaching of Psychology*, *36*, 113-116. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a909506000

Abstract: We developed a rubric to assess several of our department's undergraduate student learning outcomes (SLOs). Target SLOs include applications of principles of research methodology, using appropriate statistics, adherence to the Publication Manual of the American Psychological Association, and written communication skills. We randomly sampled 20 percent (N = 55) of the final written manuscripts from several sections of a research methods course and trained 2 graduate-level raters to use the rubric to score the students' papers. We found statistically significant interrater reliability and convergent validity coefficients. These findings are discussed to encourage the development and evaluation of such rubrics to be used across colleges and universities.

Other forms of communication

7 Communication Skills						Interviews and Surveys	

Baird, B. N. (1991). In-class poster sessions. *Teaching of Psychology*, *18*, 27-29. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857949

Abstract: In-class poster sessions offer an attractive alternative to traditional term paper assignments. Poster sessions are suitable for classes of all sizes, promote collaborative learning, encourage creativity and independent thought, develop research and communication skills, and ease the grading burden on instructors. This article describes the logistics of conducting poster sessions and discusses their possible uses. When asked to compare poster sessions with traditional term papers, 100% of the students responding preferred the poster session.

Goal 8: Sociocultural and International Awareness: Students will recognize, understand, and respect the complexity of sociocultural and international diversity.

8 Sociocultural/Internat.						Interviews and Surveys	

Case, K. A (2007). Raising white privilege awareness and reducing racial prejudice: Assessing diversity course effectiveness. *Teaching of Psychology*, 34, 231-235. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a790482085

Abstract: Many diversity courses in psycholog*34*y originally aimed to reduce student racial bias and raise their awareness of racism. However, quantitative data testing the effectiveness of such courses are lacking. This study assessed a required diversity course's effectiveness in raising awareness of White privilege and racism; increasing support for affirmative action; and reducing prejudice, guilt, and fear of other races. Students (N = 146) completed identical surveys during the first and last weeks of the semester. Results indicated greater awareness of White privilege and racism and more support for affirmative action by the end of the term. White students (n = 131) also expressed greater White guilt after completing the course.

8 Sociocultural/Internat. 9 Personal Development						Interviews and Surveys	

Marchel, C. A. (2004). Evaluating reflection and sociocultural awareness in service learning classes.*Teaching of Psychology*, *31*, 120-123. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859070

Abstract: Many service learning classes offer students experiences with diverse cultures. Journal writing encourages student reflection and provides information about the changes occurring in student sociocultural awareness prompted by service learning experience. This article presents a rubric useful in assessing the quality of reflection and changes in sociocultural thinking in service learning journals. Text samples illustrate the use of the rubric for evaluating journal quality as well as changes in sociocultural awareness during service experiences. I present pedagogical implications for instruction, dynamic assessment, and grading.

Additional Resources

American Psychological Association. (2002). Guidelines on multicultural education, training, research, practice, and organizational change for psychologists. Washington, DC: Author. Retrieved from http://www.apa.org/ed/resources.html. Scheduled to expire by 2009.

McGury, S., Shallenberger, D., & Tolliver, D. E. (2008). It's new, but is it learning? Assessment rubrics for intercultural learning programs. *Assessment Update*, *20*(4), 6-9. Retrieved from http://www3.interscience.wiley.com/journal/121371691/abstract?CRETRY=1&SRETRY=0

Prieto, Loreto R., Whittlesey, V., Herbert, D., Ocampo, C., Schomburg, A., & So, D. (2009). Dealing with diversity issues in the classroom: A survey of the STP membership. *Teaching of Psychology*, *36*, 77-83. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a909503752

Abstract: We examined how psychology educators regarded and addressed diversity issues in their classrooms. The approximately 650 psychology educators who took part in this survey indicated a high level of personal acceptance of diverse persons and acknowledged the importance of infusing diversity issues into courses across the psychology curriculum. Our findings indicated that the level of importance instructors attached to incorporating diversity issues into their course work accounted for the largest amount of variance in the time they reported discussing diversity issues in their classes. We discuss implications for teachers of psychology.

Goal 9: Personal Development: Students will develop insight into their own and others'behavior and mental processes and apply effective strategies for self-management and self-improvement.

9 Personal Development						Interviews and Surveys	

Bolin, A. U., Khramtsova, I., & Saarnio, D. (2005). Using student journals to stimulate authentic learning: Balancing Bloom's cognitive and affective domains. *Teaching of Psychology*, *32*, 154-159. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785862876

Abstract: Bloom (1956) pioneered the measurement of learning outcomes with a taxonomy of educational objectives, but educators often ignore affective learning objectives and focus on attaining cognitive objectives. This study examined student journals as a way to correct the overemphasis on cognitive objectives. Results suggested that course expectations and affective journal outcomes were important correlates of student evaluations of course outcomes even after controlling for the instructor, student gender, and student achievement. These findings have important implications for the use of student journals and for interventions aimed at increasing student evaluations of course outcomes.

9 Personal Development						Interviews and Surveys	Archival measures

Buch, K., & Spaulding, S. (2008). A longitudinal assessment of an initial cohort in a psychology learning community. *Teaching of Psychology*, *35*, 189-193. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a795059237

Abstract: Discipline-based learning communities have become a popular strategy for improving student performance and satisfaction. This article describes the goals and features of a university-based, first-year psychology learning community (PLC) implemented in Fall 2003. We also report the results of a longitudinal assessment of the impact of the PLC on student retention and progression, academic performance, cocurricular involvement, and satisfaction with the major. Finally, we discuss the benefits and challenges of implementing a PLC.

8 Sociocultural/Internat. 9 Personal Development						Interviews and Surveys	

Marchel, C. A. (2004). Evaluating reflection and sociocultural awareness in service learning classes.*Teaching of Psychology*, *31*, 120-123. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859070

Abstract: Many service learning classes offer students experiences with diverse cultures. Journal writing encourages student reflection and provides information about the changes occurring in student sociocultural awareness prompted by service learning experience. This article presents a rubric useful in assessing the quality of reflection and changes in sociocultural thinking in service learning journals. Text samples illustrate the use of the rubric for evaluating journal quality as well as changes in sociocultural awareness during service experiences. I present pedagogical implications for instruction, dynamic assessment, and grading.

9 Personal Development		Individual projects		Self-assessment			

Peden, B. F., & Carroll, D. W. (2008). Ways of writing: Linguistic analysis of self-assessment and traditional assignments. *Teaching of Psychology*, *35*, 313-318. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a905076695

Abstract: Scholars of teaching and learning have endorsed self-assessment assignments as a way to encourage greater reflection by students. However, no studies to date have compared writing in self-assessment with traditional academic assignments. We performed a quantitative text analysis of students' language in self-assessment versus traditional assignments from 3 courses. Self-assessment assignments included more references to cognitive words (i.e., words related to insight) than traditional academic assignments. In addition, self-assessments included more emotion words and pronouns and were linguistically simpler than traditional academic assignments. We conclude that self-assessment assignments encourage students to become more reflective, a goal of the American Psychological Association (2007) curricular guidelines.

Additional Resources

Dunn, d. S., McEntarffer, R., & Halonen, J. S. (2004). Empowering psychology students through self-assessment. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 171-186). Washington, DC: American Psychological Association. Retrieved from http://books.apa.org/books.cfm?id=4318011

Goal 10: Career Planning and Development: Students will emerge from the major with realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings.

10 Career Planning						Interviews and Surveys	

Borden, V.M.H., & Rajecki, D.W. (2000). First-year employment outcomes of psychology baccalaureates: Relatedness, preparedness, and prospects. *Teaching of Psychology*, *27*, 164-168. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859407

Abstract: Surveys of recent baccalaureate degree recipients confirmed earlier findings that, compared with other alumni, psychology baccalaureates ranked low on ratings of the relatedness of their current job to the major. Psychology baccalaureates also rated low on whether their education had prepared them for that job and enhanced their future prospects. Correlations across all majors suggested that employment relatedness predicted judgments of preparedness, and preparedness predicted future prospects. Comparable correlations for psychology majors suggested that they entered the job market with expectations similar to graduates of more occupationally oriented programs. We offer specific recommendations to prepare students for more satisfying outcomes in the postbaccalaureate job market.

10 Career Planning						Interviews and Surveys	Archival measures

Landrum, R. E. & Mulcock, S. D. Use of pre- and postcourse surveys to predict student outcomes . *Teaching of Psychology*, *34*, 163-166. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a788034825

Abstract: We obtained data from pre- and postcourse questionnaires given in an Introduction to the Psychology Major course taught for 10 semesters and compared these data with institutional outcomes concerning the students' last known major and their graduation status. We found the questionnaire reliably measured (a) vocational identity, (b) knowledge of course content, and (c) students' knowledge of information-finding strategies. Generally, students who entered the course with high commitment to psychology or who demonstrated the greatest growth in commitment tended to remain psychology majors and earned the bachelor's degree in psychology. We discuss factors that affect these predictive outcomes

10 Career Planning						Interviews and Surveys	

Lunneborg, P. W. (1986). Assessing students' career needs at a large state university. *Teaching of Psychology*, *13*, 189-192. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785860938

Abstract: The results of this needs assessment indicate that not enough students used our departmental career advising program. Comparing our results with those at Creighton University underscored the necessity to increase student usage of all our sources of information (e.g., consulting with peer advisers and attending departmental presentations), as well as their usage of all types of information (e.g., finding out about career opportunities outside of human services and learning how to write a resumé). This article offers practical strategies to promote greater use of both sources and types of information.

1 Knowledge Base 4 Application 10 Career Planning	Course data					Interviews and Surveys	

Maynard, A. M., Maynard, D. C., & Rowe, K. A. (2004). Exposure to the fields of psychology: Evaluation of an introductory psychology project. *Teaching of Psychology*, *31*, 36-39. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785834135

Abstract: We evaluated a project designed to expose introductory psychology students to the fields of psychology. We created this project to foster student learning about the various fields of psychology, careers that psychologists have, the psychology program on their campus, and courses available at their home institution. Evaluative data included knowledge of the definitions of the fields, measured at 3 time points, as well as students' self-reported reactions. Results indicated that students found the project interesting and would recommend it for future classes. More important, knowledge tests revealed significant increases in knowledge that persisted over a 4-week period.

10 Career Planning						Interviews and Surveys	

Nauta, M. M. (2002). A career research project for undergraduate psychology students. *Teaching of Psychology*, *29* 288-291. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863877

Abstract: I describe a career research project designed to increase students' knowledge of careers in psychology. Following a detailed outline, undergraduates enrolled in a senior seminar conducted research on a career of their choice, prepared a written summary of the career information, and presented the summary orally to their classmates. Reactions to the activity were quite positive, and students indicated that the project should be retained for future semesters. I provide an outline of areas I required students to investigate, and I offer recommendations to enhance the activity based on my experiences and students' feedback.

10 Career Planning						Interviews and Surveys	

Neimeyer, G. J., Lee, G. A., Saferstein, J., & Pickett, Y. (2004). Effects of a graduate preparation program on undergraduate psychology majors. *Teaching of Psychology*, *31*, 247-252. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857497

Abstract: We conducted 2 studies to assess and enhance levels of graduate preparation. In Study 1, 248 undergraduates and 28 graduate students completed a new measure of graduate preparation, the Grad Prep Quiz. Results documented the psychometric utility and the predictive validity of the measure, with graduate students scoring significantly higher on this measure than undergraduates. Study 2 provided a controlled study of a graduate preparation program. Compared to the control group, participants in the graduate preparation program demonstrated a significant increase in their Grad Prep Quiz scores. These results support efforts to enhance effective preparation for graduate study in psychology.

10 Career Planning							Archival measures

Rajecki, D. W., & Metzner, B. S. (1991). Declaring the psychology major: An archival, general model from an urban university. *Teaching of Psychology*, *18*, 4-8. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785857822

Abstract: The records of 806 psychology majors were analyzed to determine their academic profiles at the point of acceptance to the program. Seven descriptive categories adequately encompassed the students' background: (a) direct entry from high school, (b) internal transfer from within the university, (c) external transfer from outside the university, (d) transfer who pursued the major elsewhere, (e) short-term returnee, (f) long-term returnee, and (g) prior degree earned. The number, age, gender, and academic characteristics of the students within these seven categories are reported. Of more general interest, a prototype of the "traditional" psychology major is proposed; based on a certain subset of the records at hand, a generic model of the curricular path to the psychology major is offered.

10 Career Planning						Interviews and Surveys	

Roscoe, L. J., & Strapp, C. M. (2009). Increasing psychology students' satisfaction with preparedness through a professional issues course. *Teaching of Psychology*, *36*, 18-23. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a907765761

Abstract: The current studies evaluated a capstone course, Professional Issues in Psychology, designed to prepare students for a career in psychology. The first study examined course topics and student evaluations of assignments across 4 terms. Overall, students reported that the assignments were very helpful. The second study found that students who had completed the course felt more satisfied with their preparation for graduate school and for entering the job market relative to a sample of graduating seniors who did not take the course. These results suggest that the course is associated with increased self-efficacy for entering the job market and applying to graduate school. Suggestions for developing a careers capstone course are discussed.

Multiple Goals. The following articles discuss assessment strategies that address multiple goals using multiple measures.

1 Knowledge Base 3 Critical Thinking 4 Application 5 Values 7 Communication Skills 8 Sociocultural/Internat. 9 Personal Development 10 Career Planning				Self-assessment		Interviews and Surveys	

Duffy, D. K. (2004). Service learning, resilience, and community: The challenges of authentic assessment. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 243-256). Washington, DC: American Psychological Association. Retrieved from http://books.apa.org/books.cfm?id=4318011

1 Knowledge Base 2 Research Methods 3 Critical Thinking 4 Application 5 Values 7 Communication Skills 10 Career Planning	Course data	Individual projects	Summative performance			Interviews and Surveys	

Firment, M., Devine, P. J., & Whittlesey, V. (2004). Learning outcomes assessment of the undergraduate psychology major: A model in progress. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 47-63). Washington, DC: American Psychological Association. Retrieved from http://books.apa.org/books.cfm?id=4318011

1 Knowledge Base 2 Research Methods 3 Critical Thinking 4 Application 5 Values 6 Info/Tech Literacy 7 Communication Skills 8 Sociocultural/Internat. 10 Career Planning	Course data	Individual projects	Summative performance	Self-assessment	Collaboration		

Keller, P. A., Craig, F. W., Launius, M. H., Loher, B. T., & Cooledge, N. J. (2004). Using student portfolios to assess program learning outcomes. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 187-207). Washington, DC: American Psychological Association. Retrieved from http://books.apa.org/books.cfm?id=4318011

2 Research Methods 3 Critical Thinking 4 Application 6 Info/Tech Literacy 7 Communication Skills 8 Sociocultural/Internat. 9 Personal Development				Self-assessment		Interviews and Surveys	

Kruger, D. J., & Zechmeister, E. B. (2001). A skills-experience inventory for the undergraduate psychology major. *Teaching of Psychology*, *28*, 249-253. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785858531

Abstract: Psychology majors develop a number of academic skills during their studies that are valuable in future careers and other domains. However, assessment of experiences related to skill development can be quite difficult and resource intense. We present results of 2 studies using a skills-experience inventory to assess academic skill exposure. In the first study, graduating senior psychology majors reported greater exposure than freshmen in 7 skill-experience areas. The second study showed significant differences in exposure to 5 skill areas among graduating seniors in 4 academic areas. A skills-experience inventory may be an efficient tool for documenting the skills and experiences students encounter when majoring in psychology.

1 Knowledge Base 2 Research Methods 3 Critical Thinking 4 Application 5 Values 6 Info/Tech Literacy 7 Communication Skills 8 Sociocultural/Internat. 9 Personal Development 10 Career Planning	Course data	Individual projects	Summative performance			Interviews and Surveys	Archival measures

Marsh, P. A., & Poepsel, D. L. (2008). Perceived usefulness of learning outcomes predicts ratings of departmental helpfulness. *Teaching of Psychology*, *35*, 335-342. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a905077131

Abstract: Psychology seniors at a Midwest university reflected on the student learning outcomes (SLOs) for the major. This study examined the relations among students' perceived usefulness of the SLOs, measures of learning, ratings of self-confidence in their knowledge of psychology, and evaluations of the department's helpfulness in students' skill development. Correlations showed few significant relations between usefulness of the SLOs and measures of learning and no relations with ratings of self-confidence. Perceived usefulness of the outcomes was a significant predictor of the department's perceived helpfulness in students' skill development. However, students' perceptions of the department dropped significantly by the end of the capstone course. We discuss implications related to activities teachers might use to enhance learning.

1 Knowledge Base 2 Research Methods 7 Communication Skills 10 Career Planning			Summative performance			Interviews and Surveys	Archival measures

Stoloff, M. L., Apple, K. J., Barron, K. E., Reis-Bergan, M., & Sundre, D. (2004). Seven goals for effective program assessment. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 29-46). Washington, DC: American Psychological Association. Retrieved from http://books.apa.org/books.cfm?id=4318011

Additional Resources

American Psychological Association. (1997). Learner-centered psychological principles: A framework for school reform & redesign. Washington, DC: American Psychological Association, Board of Educational Affairs. Retrieved from http://www.apa.org/ed/cpse/LCPP.pdf

American Psychological Association. (2007). *APA guidelines for the undergraduate psychology major*. Washington, DC: Author. Retrieved from http://www.apa.org/ed/psymajor_guideline.pdf

American Psychological Association. (2008). *Teaching, learning, and assessing in a developmentally coherent curriculum*. Washington, DC: American Psychological Association, Board of Educational Affairs. Retrieved from http://www.apa.org/ed/Teaching-Learning-Assessing-Report.pdf

American Psychological Association. (2005). National standards for high school psychology curricula. Washington, DC: Author. Retrieved from http://www.apa.org/ed/natlstandards.html

C. Applying Assessment Strategies in Psychology

2. Using the New Bloom's Taxonomy to Design Meaningful Learning

This entry explores recent revisions in Bloom's Taxonomy along with a tool to promote active learning strategies that can help translate abstract outcomes into practical strategies. This entry also links to a recent APA Task Force report that demonstrates how psychology programs may apply Bloom's Taxonomy in constructing a developmentally coherent curriculum and embedding assessment within that curriculum.

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How the Taxonomy Promotes Active Learning

Clark (2002) provided an adaptation of Bloom's work to facilitate active learning. Although originally the tool was developed by a class of teachers for use in curriculum building in the high school level, the suggestions would work for college level classes as well. The inner ring contains the original levels of Bloom's taxonomy. The middle ring offers synonyms for the various academic processes that comprise that taxonomic level. The outer ring links process to product. For example, if you wanted to increase application skills, you might ask students to construct diagrams of the key concepts involved in the content of the class. If you wish to improve evaluation skills, you might ask students to produce an editorial for the student newspaper in which they discuss the strengths and weaknesses of a particular side of a controversial issue. We have modernized the language of the original circle to reflect the latest version of Bloom's Taxonomy.

Cognitive Taxonomy Circle

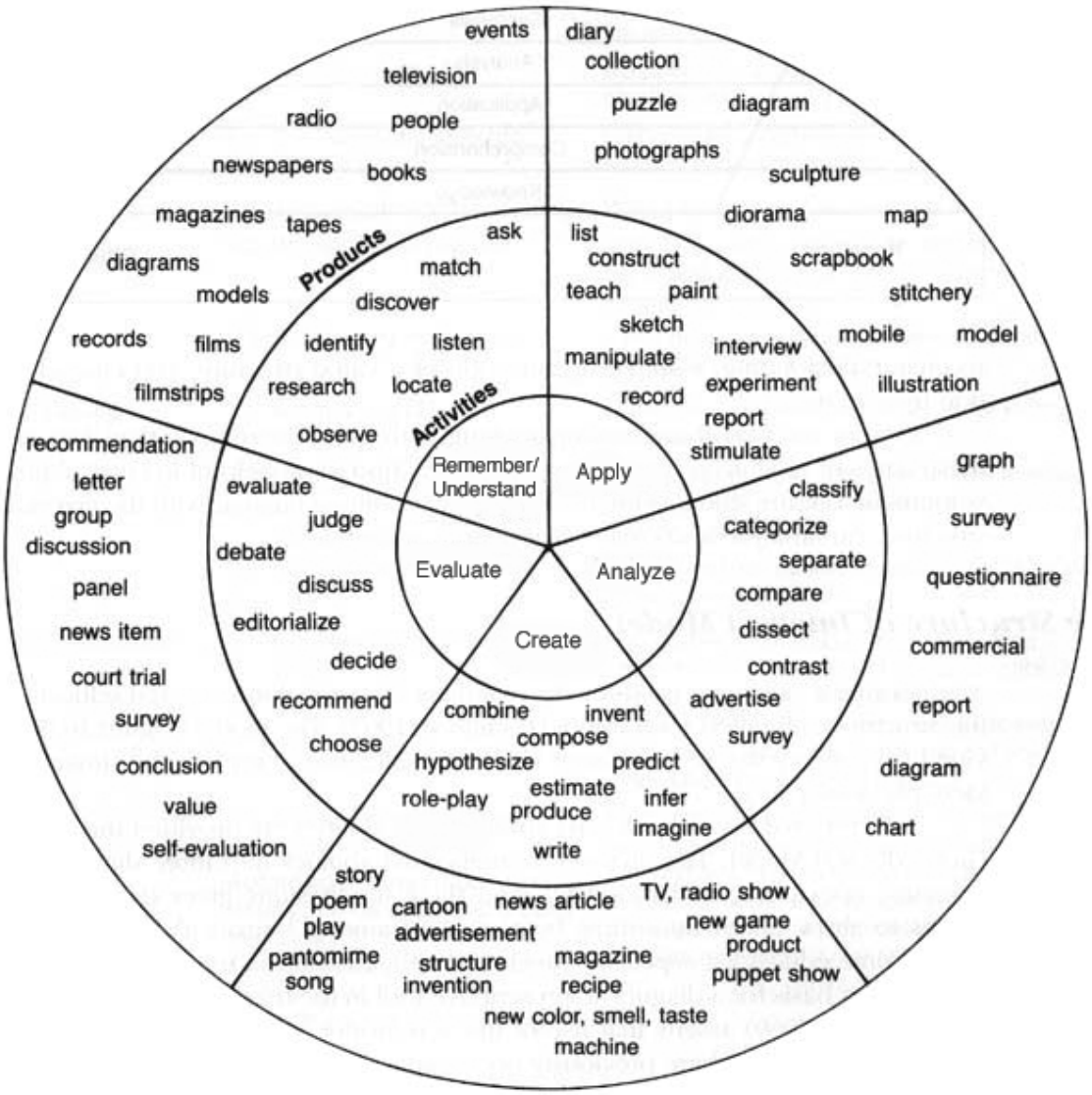

Based on:

Clark, B. (2002). *Growing up gifted: Developing the potential of children at home and at school*. Upper Saddle River, NJ: Merrill Prentice Hall. For more information, visit http://www.allynbaconmerrill.com/store/product.aspx?isbn=0131185721

Applying Bloom's Taxonomy to Assessment of Student Learning in Psychology Programs

American Psychological Association. (2008). Teaching, learning, and assessing in a developmentally coherent curriculum. Washington, DC: American Psychological Association, Board of Educational Affairs. Retrieved from http://www.apa.org/ed/resources.html

This is a report from the APA Board of Educational Affairs Task Force on Strengthening the Teaching and Learning of Undergraduate Psychological Science. The Task Force advocates for psychology programs to design their curricula in ways that promote students' development along Bloom's taxonomy from basic (retention and comprehension) to intermediate (analysis and application), and advanced (evaluation and creation) levels. The Task Force also argues for the use of authentic assessments embedded within core courses that may be used to track student development through the curriculum.

The appendices in the Task Force's report include rubrics that translate the APA Guidelines for the Undergraduate Psychology Major *into learning outcomes at the basic, intermediate, and advanced levels. Additional appendices provide examples of authentic assessments of the learning outcomes in several psychology courses.*

C. Applying Assessment Strategies in Psychology

3. Rubrics

We provide references and descriptions of several articles that include scoring rubrics for assessing student work and Web sites for locating and developing rubrics.

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Scientific Inquiry Skills

LEVELS OF PROFICIENCY: Before training – Basic Intro Psych – Developing - Advanced Undergrad - Professional Grad

DOMAINS (Components within each domain)
- **Descriptive skills** (Observation; Measurement; Interpretation)
- **Conceptualization skills** (Concept skills; Basic theory skills; Advanced theory skills)
- **Problem solving skills** (Methods skills; Statistical reasoning; Bias detection and management)
- **Ethical reasoning** (Awareness of ethical standards; Evaluation of ethical practices; Adherence to ethical standards)
- **Scientific attitudes and values** (Enthusiasm; Objectivity/subjectivity; Parsimony; Skepticism; Tolerance of ambiguity)
- **Communication skills** (Resource gathering; Argumentation; Conventional expression)
- **Collaboration skills** (Project completion; Process management; Leadership; Consensus building; Brainstorming)
- **Self-assessment** (Self-regulation; Self-reflection)

Bosack, T. N., McCarthy, M. A., Halonen, J. S., & Clay, S. P. (2004). Developing scientific inquiry skills in psychology: Using authentic assessment strategies. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 141-169). Washington, DC: American Psychological Association. Retrieved from http://books.apa.org/books.cfm?id=4318011

Presents a development rubric for assessing scientific inquiry skills along eight domains and recommends strategies for conducting authentic assessments in courses that use the rubric.

Halonen, J. S., Bosack, T., Clay, S., & McCarthy, M. (with Dunn, D. S., Hill, IV, G. W., McEntarffer, R., Mehrotra, C., Nesmith, R., Weaver, K., & Whitlock, K.). (2003). A rubric for learning, teaching, and assessing scientific inquiry in psychology. *Teaching of Psychology*, *30*, 196-208. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785856626

Abstract: Accountability pressures influence all levels of psychology instruction. In this article we explore how to meet those pressures with integrity, focusing on authentic assessment and teaching as a primary solution. We propose a rubric to describe the progress of students' acquisition of scientific inquiry skills applied to behavior and provide an example of an authentic assessment that demonstrates use of the rubric. Application of the rubric can enhance active learning, promote more sophisticated scientific inquiry, improve metacognitive development, support program evaluation, and enrich faculty development.

Tomcho, T. J., Foels, R., Rice, D., Johnson, J., Moses, T. P., Warner, D. J., Wetherbee, R. A., & Amalfi, T. (2008). Review of ToP teaching strategies: links to students' scientific inquiry skills development. *Teaching of Psychology*, *35*, 147-159. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a795059446

Abstract: A major function of instruction in psychology is to convey complex phenomena in a manner accessible to students. Instructors using well-designed teaching activities can help to make complex material accessible. We content analyzed teaching activities reported in the first 33 years of *Teaching of Psychology*. We identified 15 general teaching strategies in 681 teaching activity articles and coded strategies' potential impact on student development of scientific inquiry skills. We found that ToP authors have consistently used learner-centered strategies and have significantly increased their use of active evaluation strategies. We discuss implications of instructor use of the most frequently encountered strategies.

Self-reflection

LEVELS: Descriptive, Analytic, Integrated
CONTENT: Self, Client, Context

Marchel, C. A. (2004). Evaluating reflection and sociocultural awareness in service learning classes.*Teaching of Psychology*, *31*, 120-123. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785859070

Abstract: Many service learning classes offer students experiences with diverse cultures. Journal writing encourages student reflection and provides information about the changes occurring in student sociocultural awareness prompted by service learning experience. This article presents a rubric useful in assessing the quality of reflection and changes in sociocultural thinking in service learning journals. Text samples illustrate the use of the rubric for evaluating journal quality as well as changes in sociocultural awareness during service experiences. I present pedagogical implications for instruction, dynamic assessment, and grading.

Additional Rubrics

Gottfried, G. M. (2009). *Assessing student learning: A collection of evaluation tools*. Office of Teaching Resources in Psychology. Retrieved from http://tinyurl.com/Gottfried2009

This 31-page resource provides three assessment measures:
1. A Rubric for Evaluating a Psychology Research Report
2. Evaluating Students' Process Knowledge: Measuring Understanding of Inter-Rater Reliability
3. Reading a Journal Article: An Assessment Tool
Each includes an introduction that describes the development of the tool and a scoring rubric. The second and third measures also include reproduction-ready assignments for activities

Rubric Web Sites

Authentic Assessment Toolbox: http://jonathan.mueller.faculty.noctrl.edu/toolbox/

This site provides an online tutorial with recommendations for articulating standards, developing assignments, and designing rubrics to assess student work.

RubiStar: http://rubistar.4teachers.org/index.php

At this site, you may create a rubric online and print it out for use in your class, or open up and modify one of the example rubrics available at the site. If you register (for free), you may save your rubrics online for later use.

RCampus: http://www.rcampus.com/

This site contains several online resources for faculty members, including rubrics. For a list of rubrics for courses in psychology, visit http://www.rcampus.com/indexrubric.cfm

C. Applying Assessment Strategies in Psychology

4. Helping our Students Understand Our Goals

Student learning benefits from explicit understanding of our assessment plan. In this entry, Drew Appleby discusses strategies for bringing students into the conversation to assist department planning and improve their learning and metacognition.

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that is not its goal. The goal of a college education is to prepare a person to lead a fulfilling and productive personal, social, civic, and professional life after graduation.

I wrote the section of this paper titled *Understanding the IUPUI Undergraduate Psychology Curriculum* for my students to explain how their curriculum can help them achieve their post-baccalaureate aspirations (i.e., the attainment of admission into graduate school, a satisfying career, and/or a fulfilling personal life). If they read it carefully and comprehend it fully, it will help them to become more "mindful" (Langer, 1989) of the nature and purposes of the psychology courses they are required to take so they can engage in these courses in an active, thoughtful, and goal-oriented manner, rather than simply attempting to 'get them out of the way' as quickly and mindlessly as possible. In other words, it will help them to experience the benefits of a greater sense of control (Rodin & Langer, 1977) over their undergraduate educations.

The APA's Board of Educational Affairs Task Force on Undergraduate Psychology Major Competencies has identified ten crucial SLOs for psychology majors and our department has used these SLOs as the foundation of its curricular assessment process. The development of this combination of SLOs is congruent with the fundamental goal of education in psychology, which is "to teach students to think as scientists about behavior" (Brewer, 1993, p. 169). The attainment of these SLOs is based on the acquisition and demonstration of the fundamental knowledge and skills underlying the six Principles of Undergraduate Learning (Indiana University-Purdue University Indianapolis, 2007) that my university urges all its undergraduates to achieve. The substance and depth of the first five SLOs distinguish psychology majors from their peers who major in other disciplines. The second five SLOs are those that can be achieved when students take full advantage of the general education courses they are required to take (e.g., English Composition and Speech) and apply what they have learned in these courses to their psychology classes and electives.

The remainder of this paper is the document I created to explain my department's curriculum to our students. I wrote it in a very personal manner (i.e., in the first and second person) in order to be as clear and compelling as possible. It is important to keep in mind that our curriculum is only one example of many that could result in the accomplishment of the achievement of the SLOs suggested by the APA task force. For a set of other equally valid curricula, please see Brewer (1993). I want other departments to feel free to use the following document as a model for communicating the purpose, organization, and requirements of their own unique curricula to their students.

Understanding the IUPUI Undergraduate Psychology Curriculum:
An Open Letter to Students from Their Advisors

The IUPUI undergraduate psychology curriculum was created to enable psychology majors to accomplish a set of student learning outcomes (SLOs) whose successful accomplishment will prepare them to continue their education in graduate school, to secure fulfilling employment, and/or to lead satisfying personal, social, and civic lives after graduation. Our curriculum is divided into five sets of courses: introductory courses, methods courses, content courses, specialization courses, and capstone courses. The successful completion of each of these sets serves to enable psychology majors to develop one or more of our department's SLOs, which are listed and explained below.

1. Content of Psychology: Students should show familiarity with the major concepts, theories, empirical findings, and historical trends in psychology.

2. Research Methods in Psychology: Students should understand and apply basic research methods in psychology, including research design, data analysis, and interpretation.

3. Critical Thinking Skills in Psychology: Students should respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

4. Application of Psychology: Students should understand and apply psychological principles to personal, social, and organizational issues.

5. Values in Psychology: Students should be able to evaluate empirical evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a discipline.

6. Information and Technological Literacy: Students should demonstrate information competence and the ability to use computers and other technology for many purposes.

7. Communication Skills: Students should be able to communicate effectively in a variety of formats.

8. Socio-Cultural and International Awareness: Students should recognize, understand, and respect the complexity of socio-cultural and international diversity.

9. Personal Development: Students should develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

10. Career Planning and Development: Students should emerge from the major with realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings.

The remainder of this paper will identify and explain the purpose of each of the five types of courses that make up your curriculum. I have underlined the key words from each of the ten SLOs to bring them to your attention and to create the connections between the SLOs and what you will accomplish in your required courses. I hope this information will enable you to understand the rationale behind your curriculum and lead you to a state of increased awareness of the value of the courses it contains. Once you become aware of why you are taking the courses you are required to take and how they can help you to develop the knowledge, skills, and characteristics (KSCs) you will need to accomplish your personal, educational, and career objectives, I believe you will begin to view your coursework as an integrated whole that will help you achieve your future goals.

Introductory Courses

The purposes of introductory courses are to introduce you to the content of psychology; to familiarize you with the department's faculty, curriculum, organizations, resources, and programs; and to engage you in active career planning and development. There are three introductory courses.

B103 Orientation to a Major in Psychology
B104 Introduction to Psychology as a Social Science
B105 Introduction to Psychology as a Biological Science

The successful completion of B103 enables you to understand your strengths, weakness, values, and goals and to identify, clarify, and create a plan to accomplish your post-baccalaureate aspirations. Many students choose psychology as their major before they fully comprehend its nature as a research-based science. B103 will insure that you are fully aware of the nature of your major and what your major will enable you to do after you graduate. You will also begin to strengthen the written and oral communication skills you will need in all your remaining psychology courses.

B104 and B105 introduce you to the full spectrum of areas of specialization that exist within psychology. B104 covers topics that represent the social science side of psychology (i.e., personality, lifespan development, social psychology, abnormal psychology, psychotherapy, intelligence, psychological testing, and industrial-organizational psychology). B105 covers topics that represent the biological science side of psychology (i.e., behavioral neuroscience, motivation, emotion, memory, sensation, perception, cognition, language, and consciousness). Because of the importance of crucial topics such as learning, research methods, and the history of psychology, both B104 and B105 cover these topics.

The successful completion of these three introductory courses paves the way for you to continue your study of psychology with a fundamental awareness of its basic history, empirical findings, principles, concepts, theories, specializations, methods, and applications and an understanding of how a psychology major can prepare you for your future. These courses will also provide you with an understanding of how psychological principles can be applied to personal, social, and organizational issues; help you develop insight into your own and others' behaviors and mental processes; and provide you with strategies for self-management and self-improvement. Another important outcome of the successful completion of these introductory courses is that it will allow you to make informed decisions when you select your subsequent psychology courses.

Methods Courses

The purpose of methods courses is to provide you with opportunities to learn and apply research methods used by psychologists during their scientific investigations of behavior and mental processes. These courses encourage critical and creative thinking during the scientific approach to problem solving. They require you to provide plausible

explanations for psychological observations, comprehend and critique the findings of previous research, produce novel hypotheses derived from the existing psychological literature, create ethical research designs to test these hypotheses, demonstrate technological numeracy by analyzing empirical evidence with statistical software, and provide logical interpretations of the results of your research. You will also demonstrate information literacy by utilizing bibliographic technologies to identify and evaluate information relevant to your research).

There are two required methods courses.

B305 Statistics
B311 Introductory Laboratory in Psychology

B305 focuses on the fundamentals of statistical data analysis, which enable you to organize and summarize data (descriptive statistics) and to interpret and draw conclusions from data (inferential statistics). B311 requires and builds upon the statistical knowledge gained in B305 as it introduces you to the research methods used by psychologists, the ethics of research, and experimental report writing. The successful completion of these two courses is crucial to the further success of a psychology major. Those students who aspire to graduate school will use the critical thinking skills they acquire in these courses to design and perform the research projects that will serve as evidence to graduate admissions committees of their ability to conduct themselves as scientific psychologists. Those who do not perform research themselves can employ the skills to understand and evaluate the research of others. As you progress from your introductory courses to your more advanced courses, you will be required to read, comprehend, and evaluate original psychological research (i.e., primary sources such as articles in professional journals) rather than learning from secondary sources such as textbooks in which the authors have done all the interpreting and evaluating for you. If you have not mastered the vocabulary and techniques from your methods courses, and not carried it with you into the next group of courses I will describe (Core Courses), the results section of a journal article will appear to you as if it had been written in an alien language from a planet far beyond our galaxy.

Core Courses

The purpose of core courses is to provide you with a broad and deep exposure to the main content areas that define the discipline of psychology. You will select six courses from a set of twelve that represents the full range of biological and the social approaches to psychology, including both theoretical and applied areas. There are twelve core courses.

B307 Tests and Measurement
B310 Life Span Development
B320 Behavioral Neuroscience
B334 Perception
B340 Cognition
B344 Learning
B356 Motivation
B358 Industrial/Organizational Psychology
B370 Social Psychology
B380 Abnormal Psychology
B398 Brain Mechanisms of Behavior
B424 Theories of Personality

Core courses provide you with an opportunity to choose a coherent set of courses that will provide you with the KSCs you will need to achieve your post-baccalaureate aspirations. Suppose you are preparing to become a school psychologist whose job will be to test the cognitive capabilities of children in order to determine if their ability to learn falls within the normal range. In this case, B307, B310, B340, B344, and B380 would provide an excellent foundation. The addition of B320, which provides a basic knowledge of how the anatomy and physiology of the nervous system controls behavior and mental processes, would enable you to identify and understand the effects of the drugs that your young clients may be taking either legally (e.g., Ritalin or Prozac) or illegally (e.g., alcohol or marijuana). No matter what career you plan to pursue, the core courses you take will enable you to understand how psychology can be applied to a wide variety of individual, social, and organizational issues and encourage you to recognize, understand, and respect socio-cultural complexity and international diversity.

Specialization Courses

The purpose of specialization courses is to provide you with an opportunity to continue your intellectual self-improvement by focusing your studies on the contents, methods, and applications of a particular area of psychology

by choosing and completing two 300-level or above psychology classes you have not used to satisfy your Methods, Core, or Capstone requirements. Continuing our school psychologist plan from the preceding section, you could build on the knowledge you gained in B310 by taking B360 Child and Adolescent Psychology and become even more knowledgeable about the effects of drugs after completing B320 by enrolling in B394 Drugs and Behavior or B396 Alcohol, Alcoholism, and Drug Abuse. The addition of these courses to your already impressive constellation of core courses will help to set you apart from other graduate school applicants. Distinguishing yourself in this manner is becoming increasingly important because of the huge number (approximately 88,000) of psychology majors who graduate each year in the United States with a bachelor's degree. Courses you could take to satisfy this requirement include the following.

B322 Introduction to Clinical Psychology
B365 Stress and Health
B360 Childhood and Adolescence
B366 Concepts and Applications in Organizational Psychology
B367 Concepts and Applications in Personnel Psychology
B375 Psychology and Law
B376 Psychology of Women
B386 Introduction to Counseling
B394 Drugs and Behavior
B396 Alcohol, Alcoholism, and Drug Abuse
B420 Humanistic Psychology
B421 Internship in Psychology
B422 Professional Practice
B492 Readings and Research in Psychology

A unique feature of IUPUI's psychology curriculum is the option to earn a Track Concentration in one or more of the following four areas of psychological specialization: clinical psychology, behavioral neuroscience, industrial/organizational psychology, and the psychology of addictions. You must complete a set of core, specialization, and capstone courses described in the Psychology Track Concentration table contained in the Purdue School of Science section of the most recent issue of *the IUPUI Campus Bulletin* to earn one of these concentrations.

Capstone Courses

In architecture, a capstone is the top-most stone that completes a building. In an academic context, a capstone is the final class that completes a psychology major's curriculum. The purpose of capstone classes is to provide students with an opportunity "to demonstrate comprehensive learning in their major through some type of product or performance" (Palomba & Banta, 1999, p. 124). In other words, a capstone is a class in which senior psychology majors are required to pull together what they have learned in their previous classes and use this integrating experience to demonstrate they are capable of doing what they should be able to do as they graduate from the program (i.e., to demonstrate accomplishment of the department's SLOs). This process serves a dual purpose. First, it will provide you with a final opportunity to practice and demonstrate the skills you will need to succeed after graduation on the job or in graduate school. Second, it provides the Psychology Department a final opportunity to assess whether or not we have been successful in our mission to produce competent psychology majors and to use the results of this assessment to improve our curriculum for future psychology majors.

Most academic departments offer only one type of capstone class and some offer no capstone at all. The IUPUI Psychology Department offers you three types of capstone courses. If you are pursuing a BA degree, you may complete a capstone laboratory research project, a capstone practicum, or a capstone seminar. If you are pursuing a BS degree, you must complete a capstone laboratory.

A capstone laboratory offers you the opportunity to <u>design, perform, analyze, and report an empirical research project</u> on a topic of your choosing. You may conduct this research (a) in a laboratory class dedicated to the study of a particular subdiscipline of psychology (e.g., developmental or social psychology), (b) in a laboratory class dedicated to applied research, or (c) in an honors research class. The classes that will satisfy this requirement are as follows.

B433 Capstone Laboratory in Applied Psychology
B461 Capstone Laboratory in Developmental Psychology
B471 Capstone Laboratory in Social Psychology
B499 Capstone Honors Research

A capstone practicum allows you to engage in the application what you have learned about a particular sub-disciple of psychology (e.g., industrial/organizational or clinical psychology) in a workplace or clinical setting. The classes that will satisfy this requirement are as follows.

B462 Capstone Practicum in Industrial Psychology
B482 Capstone Practicum in Clinical Psychology

A capstone seminar provides you with opportunities to (a) perform an in-depth examination of the history, concepts, theories, methods, and applications of a sub-discipline of psychology in which you have an occupational interest, (b) engage in a collaborative research project with your classmates, and (c) create a professional career planning portfolio designed to facilitate your transition to life after college (i.e., employment or graduate school). The following class will fulfill this requirement.

B454 Capstone Seminar in Psychology

The purpose of this paper has been to provide you with a clear understanding of the rationale behind the IUPUI Psychology Department's undergraduate curriculum. You can approach your undergraduate education as a psychology major in a more active and purposeful manner once you understand why the department created its curriculum, how you can accomplish its SLOs, and who you can become as a result of their accomplishment. Successful undergraduate educations take place when well-qualified faculty lead well-informed students through a well-designed curriculum. The IUPUI Psychology Department possesses a well-qualified faculty and a well-designed curriculum. I hope this paper has helped to further transform you into a well-informed student.

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Costello, R. B. (Ed.). (1993). *The American heritage college dictionary*. Boston: Houghton Mifflin.

Halpern, D. F. (1993). Targeting outcomes: Covering your assessment concerns and needs. In T. V. McGovern (Ed.), *Handbook for enhancing undergraduate education in psychology* (pp. 23-46). Washington, DC: American Psychological Association.

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Rodin, J., & Langer, E. J. (1977). Long-term effects of a control-relevant intervention with the institutionalized aged. *Journal of Personality and Social Psychology*, 35, 897-902.

C. Applying Assessment Strategies in Psychology

5. Assessment and the Scholarship of Teaching and Learning (SoTL)

We provide lists of books and articles that discuss the relationship between assessment and SoTL, conferences focused on assessment and SoTL, and journals that publish research on assessment and SoTL.

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Halpern, D.F., & Reich, J.N. (1999), Scholarship in psychology: Conversations about change and constancy. *American Psychologist*, *54*, 347-349. Retrieved from http://psycnet.apa.org/journals/amp/54/5/347/

Abstract: Mounting pressures on higher education led the Task Force of the Society for the Teaching of Psychology to propose changes in the way the work of faculty is defined and in the criteria used to identify scholarship (D. F. Halpern et al., 1998). Prominent psychologists representing undergraduate universities, research institutions, and professional schools of psychology contributed commentary on the proposals in the Task Force Report. Although there was disagreement concerning some of the recommendations made by the Task Force, there was general agreement on the need to reflect on the roles and rewards of psychology faculty, with special emphasis on the diversity of institutional missions and faculty needs and abilities.

Smith, R. A. (2008). Moving toward the scholarship of teaching and learning: The classroom can be a lab, too! *Teaching of Psychology*, *35*, 262-266. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a905075871

Abstract: Division 2 of the American Psychological Association was practicing the scholarship of teaching long before Boyer (1990) coined the term, but Boyer brought the idea to academe's consciousness. Over time, however, the scholarship of teaching and “scholarly teaching” have become confused. Based on Richlin's (2001) work, I attempt to resolve this confusion by equating the scholarship of teaching with scholarly work by faculty. In addition, I point out the parallels between assessment and the scholarship of teaching and learning (SoTL) and provide tips for faculty who want to engage in SoTL research but see roadblocks in their way.

Tomcho, T. J., & Foels, R. (2008). Assessing effective teaching of psychology: A meta-analytic integration of learning outcomes. *Teaching of Psychology*, *35*, 286-296. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a905077425

Abstract: Teaching researchers can assess learning outcome effectiveness as a function of students' graded performance or changes in knowledge, skills and behaviors, or attitudes. We meta-analyzed 197 studies to determine the effectiveness of teaching activities in Teaching of Psychology (ToP) both overall and also as a function of type of learning outcome assessment. We found that, on average, studies evidenced a medium effect size across types of learning outcomes. Given the effectiveness of ToP teaching activities, researchers should address the (a) potential confounding role of teacher rapport, immediacy, and alliance in evaluating teaching effectiveness; (b) ethics of teaching activity development; and (c) appropriateness of using course grades to assess teaching activity effectiveness.

Conferences on Assessment and SoTL

(For additional conferences, visit http://www.kennesaw.edu/cetl/resources/na_conf_list.html)

Assessment Institute (Indiana University Purdue University Indianapolis): http://www.planning.iupui.edu/institute

Atlantic Assessment Conference: http://www.meredith.edu/rpa2009/aac/index.html

International Society for the Scholarship of Teaching and Learning: http://www.issotl.org/conferences.html

SoTL Commons: http://academics.georgiasouthern.edu/ijsotl/conference/.

Texas A&M Annual Assessment Conference: http://assessment.tamu.edu/conference/

SoTL Journals

(For additional journals that publish SoTL research, visit http://www.kennesaw.edu/cetl/resources/journals.html)

International Journal of the Scholarship of Teaching and Learning: http://academics.georgiasouthern.edu/ijsotl/

Journal of the Scholarship of Teaching and Learning: http://www.iupui.edu/~josotl/

MountainRise: http://www.wcu.edu/facctr/mountainrise/index.html

Psychology Learning and Teaching: http://www.psychology.heacademy.ac.uk/s.php?p=55&menu=publications

Teaching of Psychology: http://www.tandf.co.uk/journals/authors/htopauth.asp

D. Sustaining an Assessment Culture

1. Components of Effective Evaluation at the Department Level

We summarize and provide links to articles that discuss principles of good practice principles in developing and maintaining effective departmental processes for assessment of student learning.

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D. Sustaining an Assessment Culture

2. Program Audit Measures

Departments routinely must produce evidence to document the quality of their work. This entry summarizes both quantitative and qualitative measures that often capture evidence of the quality of department programs.

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D. Sustaining an Assessment Culture

3. Quality Benchmarks in Undergraduate Psychology Programs for Assessing Student Learning

Dunn, McCarthy, Baker, Halonen & Hill (2007) proposed a set of quality benchmarks for conducting program reviews of undergraduate psychology programs. This section includes narrative and tables from that article that focus on assessment of student learning outcomes.

= = = =

ASSESSMENT ISSUES DOMAIN				
Issue	**Underdeveloped**	**Developing**	**Effective**	**Distinguished**
Assessment planning	Does not engage in assessment planning; demonstrates no proactive thinking about program effectiveness	Generates minimal assessment plan to satisfy external mandate with no intention of follow-through	Accommodates external mandates but focuses on getting legitimate evidence about program quality	Engages proactively about program effectiveness through continuous, vigorous, and consensual assessment planning
Data gathering	Does not gather minimal effectiveness data	Gathers limited range of data only when externally mandated; relies on sources of data external to the department	Gathers broad range of data on semiregular basis and analyzes periodically as required	Collects and analyzes range of data continuously to answer program quality questions; multiple methods and sources may include student and alumni input
Program improvement	Makes changes in program based on whim or personal agenda rather than program effectiveness data	Makes changes in program that minimally link directly to program effectiveness data	Improves program based on data analysis of program effectiveness prompted by external mandates	Regularly improves program based on systematic data analysis prompted by faculty-owned assessment process
Program promotion	Does not use assessment data in public relations, outreach activities, and resource requests	Reacts to program promotion opportunities with haphazard use of assessment data	Incorporates some elements of program effectiveness data in program promotion activities	Integrates assessment practices into program promotion activities to enhance program

STUDENT LEARNING OUTCOMES DOMAIN				
Outcome	**Underdeveloped**	**Developing**	**Effective**	**Distinguished**
Writing skills	Requires no systematic writing projects	Offers writing projects consistent with individual faculty commitment to writing in some courses	Develops writing skills through limited requirements in targeted classes (e.g., may include foundation or writing-intensive courses)	Implements systematic developmental plan for required writing (e.g., all senior-level courses are writing intensive)
Speaking skills	Does not provide systematic opportunities for developing oral abilities	Provides haphazard opportunities consistent with individual faculty commitment to develop oral abilities	Implements limited formal or informal opportunities to develop oral abilities	Requires developmental oral performances to facilitate oral skills that may culminate in presentations in professional contexts
Research skills	Provides no systematic opportunities or support for student scholarship	Offers selected elective opportunities (e.g., research team) for motivated students but minimal mentorship of students	Incorporates variable research experience as part of the curriculum that accommodates student skill and motivation levels	Requires scholarship from all majors as a performance obligation that integrates content and skill
Collaborative skills	Offers no systematic instruction or opportunity related to collaborative work	Facilitates opportunities but fails to provide instruction or feedback to facilitate collaborative skills	Provides some training in and feedback for improvement in collaborative skills	Embeds multiple required collaborative activities supported by sound preparation and developmental feedback
Information literacy and technology skills	Does not facilitate students' effective use of information literacy and technology	Provides limited exposure to technology, usually in the context of a single course	Requires experience in multiple contexts to develop a minimum set of technology and information literacy skills	Facilitates refined and creative use of technology and information literacy for professional activities through systematic learning opportunities

Student Learning Outcomes

The APA Task Force on Undergraduate Major Competencies (Halonen et al., 2002a) provided guidelines for structure of the undergraduate major. Programs should demonstrate that they are providing students with developmentally appropriate writing, speaking, research, collaborative, and technology opportunities. Table 3 describes the range of performance in student learning outcomes.

Writing skills. Psychology programs in liberal arts colleges have historically valued writing as an essential component of an undergraduate degree. Despite the importance of writing, few programs clearly articulate mechanisms to ensure the competence of student writing (Dunn, 2006). For example, although a program may include writing as an important goal, frequently there is no systematic plan to ensure that students engage in discipline-specific writing tasks.

Programs functioning at a minimal level require at least one “writing-intensive” course. Outstanding programs provide a systematic plan for developing writing skills by offering more than one writing-intensive course and by integrating other writing-related activities (e.g., APA style, outlining and drafting, online searching using PsycINFO) into several courses in the curriculum. Several innovative liberal arts schools have implemented sequenced writing intensive programs (Hillard & Harris, 2003; Wolfe & Haynes, 2003). Wolfe and Haynes acknowledged the difficulty of assessing development in writing and presented a model for linking the general education core with psychology. The critical element of their program is a sequencing of writing experiences; the drawback is the labor-intensive effort devoted to the project.

Speaking skills. Many programs provide students with opportunities to develop speaking skills through informal mechanisms (e.g., oral reports in class). A distinguished program emphasizes the importance of speaking skills and provides opportunities for all students to present their work in a public setting (e.g., an undergraduate psychology conference, a classroom symposium). Students would also be encouraged to participate in professional conversations that might be available in a structured seminar course.

Research skills. Seymour, Hunter, Laursen, and Deantoni (2004) provided strong support for enhancing communication skills in students who participate in undergraduate research. A unified and coordinated effort to offer authentic, engaging undergraduate research experiences is essential. These experiences might begin with students working closely with a faculty member to assist in research that has already been established, but with discrete responsibilities assigned to the student. The ideal culmination of the experience would result in a student-directed independent research project, an honors thesis, or a similarly engaging research activity.

Collaborative skills. In addition to a program that provides students with skills-based research opportunities, students should also be provided with collaborative learning opportunities that mirror professional experiences. Recent advances in the study of collaborative learning (Springer, Stanne, & Donovan, 1999) suggest that collaborative experiences enhance learning and improve sociobehavioral skills. Although Springer et al. concluded that collaborative learning is beneficial for students in science, mathematics, engineering, and technology (STEM) fields, use of this technique and empirical support for this approach is neoteric. Collaboration is an essential skill that students should demonstrate at the completion of a degree insofar as it is possible to do so, and therefore programs should systematically provide structured collaborative activities (Thompson, Vermette, & Wisniewski, 2004).

Information literacy and technology skills. Technology plays a critical role in virtually every discipline (Laird & Kuh, 2005). Merriam, LaBaugh, and Butterfield (1992) proposed minimum training guidelines for instructing psychology students. The Association of College and Research Libraries offers psychology-specific outcomes that include (a) developing a research plan, (b) identifying keywords and related terms, (c) carefully selecting terms relative to the database, and (d) using appropriate commands (e.g., Boolean operators). McCarthy and Pusateri (2006) offered psychology-specific student learning outcomes for information literacy. In addition to traditional information literacy skills, we suggest that programs consider the role of technology in the professional development of students. Students should be provided with opportunities to become technologically literate (e.g., about statistical software). Distinguished programs ensure that students are provided with opportunities to develop technological expertise that generalizes beyond the university.

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Halonen, J. S., Appleby, D. C., Brewer, C. L., Buskist, W., Gillem, A. R., Halpern, D. F., et al. (APA Task Force on Undergraduate Major Competencies). (2002b). *Assessment CyberGuide for learning goals & outcomes in the undergraduate psychology major.* Retrieved July 8, 2005, from http://www.apa.org/ed/guidehomepage.html

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Hillard, V., & Harris, J. (2003). Making writing visible at Duke University. *Peer Review, 6*(1), 15–17.

Laird, T. F., & Kuh, G. D. (2005). Student experiences with information technology and their relationship to other aspects of student engagement. *Research in Higher Education, 46,* 211–233.

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McCarthy, M. A., & Pusateri, T. P. (2006). Teaching students to use electronic databases. In W. Buskist & S. Davis (Eds.), *Handbook of the teaching of psychology* (pp. 107–111). Oxford, England: Blackwell.

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D. Additional Resources on Assessment

4. Resources for Program Review of Undergraduate Programs in Psychology Departments

We identify Web sites and articles that departments may consult when preparing self-study reports for program reviews.

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Levy, J., Burton, G., Mickler, S., & Vigorito, M. (1999). A curriculum matrix for psychology program review. *Teaching of Psychology, 26,* 291-294. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863015

Abstract: Program review and outcomes assessment have become institutionalized as processes to promote accountability for most psychology departments. It is frequently problematic to demonstrate the relation between the content coverage and assessment taking place in individual courses and the broad curricular goals and objectives. We describe a matrix depicting the relation between desired perspectives, skills, knowledge, and attitudes and an undergraduate psychology curriculum to address this problem. Such a matrix is valuable to detect critical omissions or unnecessary redundancies, to examine the consistency across sections of individual courses in covering instructional objectives, and to compare faculty and student impressions of course and curricular coverage.

McGovern, T. V., & Carr, K. F. (1989). Carving out the niche: A review of alumni surveys on undergraduate psychology majors. *Teaching of Psychology*, *16*, 52-57. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785864510

Abstract: Information about psychology majors' activities after graduation is an important ingredient in the evaluation and renewal of undergraduate programs. In this article, we review the survey research on psychology alumni, analyzing the various survey objectives, samples, results, and program implementations. Based on this review, we make recommendations about the design of future studies, the role of APA's Educational Affairs Office, and the use of life-span development theory and methodology to refine future alumni research in undergraduate psychology.

Messer, W. S., Griggs, R .A., & Jackson, S. L. (1999). A national survey of undergraduate psychology degree options and major requirements. *Teaching of Psychology*, *26*, 164-171. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863497

Abstract: We examined the catalogs of a random sample of 292 national and regional universities and liberal arts colleges to collect curricular data on the prevalence of focused specialty versus general degrees in psychology and on the course requirements for the various degree options. We analyzed the data by type of degree and institution. Requirements for the various psychology majors were in general agreement with recommendations by the curriculum committee of the recent St. Mary's Conference. We also found that a substantial number of schools offer options other than general degrees. Given trends such as rising undergraduate enrollments and concern for career relevance and job preparation, we believe that the number of these alternative degree options may increase in the future.

Perlman, B., & McCann, L. I. (1999). The structure of the psychology undergraduate curriculum. *Teaching of Psychology*, *26*, 171-176. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863498

Abstract: A review of 500 college catalogs for 4 institutional types found the modal undergraduate psychology program follows the traditional model. It is taught in the liberal arts tradition as recommended by the St. Mary's Conference (Brewer et al., 1993), balancing natural and social science content. The major typically requires 34 credits including introductory, statistics, and a capstone course (either a senior seminar, colloquium or history); at least one content course; and limited laboratory experience. It neither necessarily requires the integrative capstone course nor psychometric methods courses recommended by the St. Mary's Conference. Prerequisites for methodology and capstone courses are limited.

Perlman, B., & McCann, L. I. (1999). The most frequently listed courses in the undergraduate psychology curriculum. *Teaching of Psychology*, *26*, 177-182. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785863499

Abstract: Continuing research with a 60-year history, we read 400 college catalogs and identified the most frequently listed undergraduate psychology courses for 4 institutional types. Results suggested ongoing segmentation in the research methodology and developmental areas, with an increasing number of courses listed in each. Experimental content courses (e.g., experimental, biological), clinical (e.g., abnormal, personality), and social/developmental courses are listed with about equal frequencies, and no movement toward additional vocational content is evident. We noted emerging subdisciplinary areas and courses.

Perlman, B., & McCann, L. I. (2005). Undergraduate research experiences in psychology: A national survey of courses and curricula. *Teaching of Psychology*, *32*, 5-14. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785856796

Abstract: We surveyed departments nationally to better understand the extent of scientific opportunities and experiences for undergraduate psychology students. Results showed intradepartmental variability, but overall students can expect 7 courses that offer research experiences in the typical psychology curriculum. Nonetheless, research is often not the primary course focus; some students must wait until their junior year to take such a course, and most such courses are elective, not required. We discuss implications for departments' curricula and the goals and outcomes for undergraduate education as well as future research directions.

Pusateri, T. P, Poe, R. E, Addison, W. & Goedel G. D. (2004). Designing and implementing psychology program reviews. In D. S. Dunn, C. M. Mehrotra, & J. S. Halonen (Eds.), *Measuring up: Educational assessment challenges and practices for psychology* (pp. 65-89). Washington, DC: American Psychological Association.

Discusses the purpose of program review and makes recommendations for preparing a self-study, scheduling a review by an external consultant, and following up on the reviewer's report. For more information, visit http://books.apa.org/books.cfm?id=4318011

Quereshi, M. Y. (1988). Evaluation of an undergraduate psychology program: Occupational and personal benefits. *Teaching of Psychology*, *15*, 119-123. Retrieved from http://www.informaworld.com/smpp/content~db=all~content=a785861725

Abstract: A 30-item questionnaire completed by 272 psychology graduates from Marquette University, between May 1972 and May 1983, provided an updated evaluation of the undergraduate program. This study investigated (a) differences between male and female graduates, (b) graduates' evaluation of the psychology curriculum and faculty, and (c) occupational benefits of the psychology major for those who pursued graduate work in psychology or professional fields and for those who sought employment with the terminal bachelor's degree. Results of this study are compared with those of other alumni surveys published between 1961 and 1987.

Vigorito, M. (2008). *An electronic workbook for assessing the Dunn et al. (2007) Quality Benchmarks in Undergraduate Psychology Programs*. Office of Teaching Resources in Psychology Online. Retrieved from: http://teachpsych.org/otrp/resources/resources.php?category=Outcomes

Provides electronic worksheets by which faculty can enter data relevant to the domains and criteria in Dunn et al.

Assessment Guide for Psychology Teachers

2018

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ASSESSMENT GUIDE FOR PSYCHOLOGY TEACHERS

This guide was developed by the Working Group on Assessing Student Knowledge and Skills in Psychology from the APA Summit on High School Psychology Education (July 2017). This guide was specifically written for high school psychology teachers, but its content may be useful to all psychology teachers (K-12, undergraduate, and graduate) as well as to teachers from other disciplines.

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INTRODUCTION AND GOALS

How do you know students are learning what you want them to learn? How can you determine when a teaching strategy is working to produce the best effects or when it is time to make some changes to produce better results? How can you document your professional growth as a teacher? Assessment is the process of gathering evidence of student success and teaching effectiveness. Assessment outcomes are how we operationally define learning in our classroom—we attempt to measure what students know and are able to do through our classroom assessment processes.

The *Assessment Guide for Psychology Teachers* broadly conceives assessment to include both traditional strategies for testing and grading as well as approaches that focus more specifically on skill development through performance or "authentic" assessment. Sometimes the term authentic assessment is used to communicate the "real life" aspect of a simulation or other more complex performance expectations.

Teachers know that assessment is a vital part of the teaching and learning process. The overarching goal of this guide is to help teachers continue to build confidence in their assessment skills in order to provide useful feedback to students about their intellectual progress. These skills include creating or refining assessment strategies to evaluate students' knowledge and skills. This guide is also intended to help teachers assess the effectiveness of their teaching strategies in the spirit of continuous improvement. In the following sections, we provide guidance on assessment to facilitate useful, fair, and efficient assessment processes to benefit students and teachers.

It is our hope that this resource will not only provide much needed assistance in mastering evidence-based processes in teaching and learning but will also help engender both respect and enthusiasm for the power of assessment.

1. IDENTIFY THE PURPOSE OF ASSESSMENT

Carefully defining the purpose of an assessment clarifies what kind of assessment a teacher might deploy. For example, if the purpose of an assessment is a quick check for understanding or to use the data to make a teaching decision or get students to fix misconceptions, the assessment is going to look different from one designed to provide data for an evaluation at the "end" of learning.

Assessment experts often make a distinction between "formative" assessment, which represents more informal, low-stakes measurement or practice opportunities, and "summative" assessment, in which measurement directly contributes to a formal final

judgment of what has been achieved (e.g., a grade). Summative assessments tend to have higher stakes for the person being assessed. The distinction between formative and summative assessment applies to the performance of both students and teachers.

STUDENT PERFORMANCE

Formative assessments require students to demonstrate what they know in a low-stakes context, such as a practice exam or an ungraded pop quiz. Summative assessments for students define an outcome with higher stakes, such as a final grade or judgment about the success of a specific performance that will substantially influence a final judgment (e.g., a grade on a heavily-weighted project).

The following chart provides examples of student assessments for diverse purposes. The list is not meant to be exhaustive but may help teachers think broadly about assessment and making assessment choices.

Student Assessment

Formative assessment helps students develop their knowledge and skills in a low-stakes context.	**Examples** Pretests Practice examinations Project progress reports Self-assessment Peer feedback Ungraded checks for understanding Feedback on quality of ungraded class discussion
Summative assessment produces a high-stakes judgment about student knowledge and skills at the conclusion of a process.	**Examples** Major project completion Posttests Content assessments (e.g., unit tests, midterms, finals) Portfolio presentations

See Karbach (2014) for further clarification of differences and examples.

TEACHER PERFORMANCE

Teacher formative assessment provides feedback on how well teachers may have taught a concept or theory to help them determine which concepts or skills might need more work. In such low-stakes cases, the teacher may not provide individual feedback to students on how they did, since the question focuses on the "aggregate" performance—that is, how the group did as a whole. In contrast, teacher summative assessment produces a high-stakes outcome (e.g., a teacher might examine and report the patterns of student achievement for the year to justify claims of successful teaching to an administrator). Implications of teacher summative assessment are addressed toward the end of this guide.

Teacher Assessment

Formative assessment involves low-stakes activities that shape teaching direction drawn from student performance or stakeholder opinion	**Examples** Ungraded checks for understanding Patterns emerging in student discussion "Exit ticket": forming or answering a question that yields conclusions about mastery "One-minute paper": summarizing and synthesizing key or difficult ideas in a time-limited fashion through end-of-class free writing Midterm student evaluations of teaching Peer review Personal reflections
Summative assessment produces high-stakes outcomes regarding teaching achievement	**Examples** Grade distributions Patterns of student outcome achievement Pretest/posttest comparisons End-of-term teaching evaluations Teaching award competition processes

The categories are not mutually exclusive. For example, a pretest to establish a baseline can inform students about the limited scope of their knowledge before learning some targeted material while also identifying areas that may need attention as a teacher designs the learning experiences in the course. Similarly, a peer review conducted to help teachers improve (formative) might also serve as evidence of quality in a high-stakes decision, such as a teaching award competition (summative).

In conclusion, you need to know WHY you are assessing to make the best judgments about HOW to gather evidence of student achievement. The next section explores how to choose the right tool for the right assessment question.

2. CHOOSE AN APPROPRIATE ASSESSMENT FORMAT

After defining the purpose of the assessment, the next step is choosing an appropriate assessment format for your items/tasks. Assessment specialists refer to this step as the "match" between assessment format and measurement goal. An appropriate choice takes into account the following dimensions:

DIRECT VERSUS INDIRECT METHODS

Direct methods measure some observable aspect of performance, whereas indirect methods assess an opinion, belief, or attitude. For example, applying a rubric to a project report represents direct measurement of a student performance; an indirect measurement would explore student satisfaction with the work. Generally, direct performance measures carry more weight as evidence of achievement than do indirect measures. However, some questions may be more suited to indirect than direct strategies (e.g., "Rank order the value of contributions of members of your project group").

OBJECTIVE VERSUS SUBJECTIVE STRATEGIES

Assessment experts distinguish between objective and subjective formats. Objective strategies constrain how students can show their understanding. For example, multiple-choice and fill-in-the-blank approaches limit the options students can choose to reflect their knowledge or acquired skills. Grading of objective work tends to be easy and typically is evaluated electronically; however, most instructors recognize that significant time must be invested in the design of a high-quality objective test and may focus on simpler cognitive skills, such as recall and recognition. Performance feedback in objective strategies tends to be expressed in "quantitative" terms, such as total of correct responses or percentiles.

In contrast, subjective strategies (e.g., open-ended essay questions) are typically categorized as more "qualitative"; these tend to be easier to create and harder to grade, since a grader must render individual attention to produce a fair conclusion about what the students have mastered in content or skills.

THINKING SKILL LEVEL

Traditional testing and performance assessment tend to focus on different levels of cognitive complexity. Traditional testing measures currently emphasize the most basic of cognitive abilities. High school teachers report that their school systems often endorse a formal framework to promote cognitive development. Two popular frameworks in current high school practice are **Webb's depth of knowledge model** and **Bloom's taxonomy.**

Webb's depth of knowledge

Webb's depth of knowledge (DOK) approach uses four levels of analysis to cast cognitive levels as going from shallow to deep abilities (Webb, 1997). The first level provides an overall description of cognitive levels in sequential development: Students acquire knowledge, stressing more basic skills of recall and memorization; students use knowledge, emphasizing skills such as explaining, analyzing, or evaluating; and students extend their thinking by solving complex problems, completing an investigation, or making creative connections. The second-level analysis provides more detail by taking into account transitions from one major function to the next. These terms may be more familiarly used in school settings that support the DOK as their primary cognitive framework.

The levels are as follows:

- Level 1: *Recall/recognition* emphasizes demonstrating acquired knowledge by retrieving relevant information or procedure.
- Level 2: *Skill/concept* use involves acquiring and using information or conceptual knowledge.
- Level 3: *Strategic thinking/reasoning* incorporates greater complexity that uses reasoning, planning, or coping with more than one possible answer.
- Level 4: *Extended thinking* is the deepest level, which entails the completion of an investigation or project exploring complicated problems.

The final DOK level of analysis focuses on action verbs that might be deployed in developing student learning outcomes, such as analyze, generalize, and solve (see Figure 1 for a depiction of the overall skills, skill levels, and specific cognitive abilities).

ACQUIRE		USE	EXTEND
LEVEL 1: Recall	**LEVEL 2: Skill/Concept**	**LEVEL 3: Strategic Thinking**	**LEVEL 4: Extended Thinking**
Recall of a fact, information or procedure	**Use information or conceptual knowledge, two or more steps, etc.**	**Requires reasoning, developing a plan or sequence of steps, some complexity, more than one possible answer**	**Requires an investigation, time to think and process multiple conditions of the problem**
☐ Memorize ☐ Recall ☐ Perform Procedures ☐ Conduct Investigations ☐ Demonstrate/Explain	☐ Perform Procedures ☐ Conduct Investigations ☐ Demonstrate/Explain ☐ Demonstrate Understanding ☐ Communicate Understanding ☐ Analyze/Investigate	☐ Demonstrate Understanding ☐ Communicate Understanding ☐ Analyze/Investigate ☐ Conjecture ☐ Generalize ☐ Prove ☐ Analyze Information ☐ Evaluate	☐ Conjecture ☐ Generalize ☐ Prove ☐ Analyze Information ☐ Evaluate ☐ Solve ☐ Non-routine/make connections ☐ Apply concepts/make connections, ☐ Generate/create

Figure 1. DOK levels, transition characteristics, and cognitions.
From *Webb Leveling: Expectations for Student Performance (n.d).*

Bloom's Taxonomy

Another popular cognitive framework, Bloom's Taxonomy (Bloom, 1956; revised by Anderson & Krathwohl, 2001), provides a six-level framework that describes "lower order thinking" through "higher order thinking" (see Figure 2). Like the DOK, Bloom's Taxonomy emphasizes basic skills as lower order and highlights creative thinking as the higher order skill. Bloom's Taxonomy tends to be used more often in college settings.

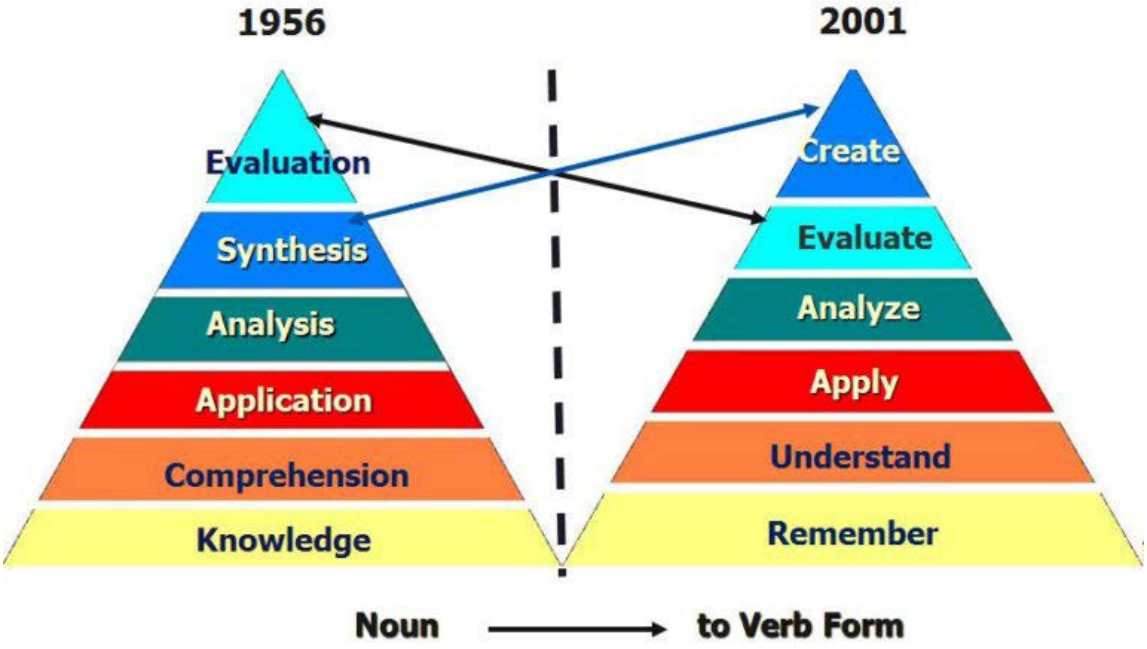

Figure 2. Bloom's Taxonomy.
From Wilson (2016).

Teachers should keep cognitive complexity in mind when designing both pedagogical activities and assessment. For example, “forced-response” items (like multiple-choice and fill-in-the-blank questions) lend themselves to assessing lower level cognition, such as recalling facts and understanding and applying concepts. Skilled test creators can develop multiple-choice items that tap more complex thinking skills, such as analyzing and evaluating, but these are much harder to create. Essay questions more typically ramp up cognitive demand to the mid-range skills of applying knowledge, analyzing information, and making evaluative judgments. These approaches contrast with highest level cognitive demand found in strategies that focus on project development in which students typically create some kind of product or performance. Performance assessment or authentic assessment are terms used to address measuring the outcomes related to higher level cognitive demands.

Beyond the simple characterization of shallow vs. deep (DOK) and lower vs. higher order (Bloom), there is significant overlap in the approaches of these two frameworks. Note how both approaches foster an understanding that students’ cognitive performances can range from relatively simple, low-demand thinking to that which is much more complex. Both approaches highlight how the nature of evaluating student learning depends on the cognitive outcome targeted by the teaching strategy (see Table 1).

Depth of Knowledge	**Bloom’s Taxonomy**	**Assessment Focus**
Acquire	Remember Understand	Testing
Use	Apply Analyze	Performance Assessment
Extend	Evaluate Create	Performance Assessment

Table 1
Comparing the Goals and Corresponding Assessment Strategies of Webb’s Depth of Knowledge to Bloom’s Taxonomy
Adapted from Brookhart (2017).

SOFTWARE VERSUS HUMANWARE

The degree to which evaluation might be automated also influences the choice of an assessment strategy. Objective measures easily lend themselves to grading that does not require ongoing human attention once the programming bugs have been resolved. Progress has also been made in applying algorithms to produce automated feedback on such measures as essay writing. Substantial work will be required to create the evaluative structure, but a "plug and play" assessment strategy has a lot of appeal for time-strapped teachers. Some systems may even include automated notification of results to students, including relative performance standing in the class, to reduce teachers' workload further. We refer to the work of the technology group from the APA Summit on High School Psychology Education for current examples of technological supports for pedagogy and assessment (e.g., White, 2018).

ACCOMMODATIONS

Accommodations are changes to an assessment (or the way an assessment is administered) that help students better represent what they know or can do. Accommodations are different from modifications:

- **Modifications** change what is being measured (e.g., changing essay questions to fill-in-the-blank questions for students with limited writing ability).
- **Accommodations** change how learning is measured, not what is being measured (e.g., allowing students extended time to finish a test).

Some students have documentation (individual education plans, etc.) that describe what accommodations are recommended (or even required) during testing. These plans are often associated with diagnosed learning disabilities or other learning issues. Usually these accommodations can be provided in ways that do not disrupt or inconvenience the rest of the class. Some accommodations may require testing the student in a small group or an individual setting. Ideally, teachers and students will discuss testing at the beginning of a course and decide how best to provide the accommodations to which students are accustomed and which allow them to demonstrate what they have learned. Students usually have had experiences using these accommodations in other classes and should be able to help plan how accommodations can be used efficiently during testing.

Different schools or institutions use different lists and labels for accommodations, and it would be impractical to try to include a complete list here. Most accommodations can be organized into one of the following four categories:

- **Presentation:** A change to the way test items are presented.
  Example: Students might listen to an audiofile rather than read a text passage before answering questions about the passage.
- **Response:** A change to the way a student responds to test items.
  Example: Allowing a student to submit a typed response rather than a handwritten one.
- **Setting:** A change to the environment in which a student completes an assessment.
  Example: A student tests in a separate room with fewer distractions, or in a smaller group.
- **Timing and scheduling:** A change to the amount of time a student has to complete a task or a change to the schedule.
  Example: Providing extra time on tests or allowing a student to take breaks.

3. ADOPT/WRITE/REVISE ASSESSMENT ITEMS OR TASKS

You know about what you want your assessment to do (purpose) and how you want to do it (assessment format); now is the time to adopt, revise, or create your items/tasks. In this section, we provide advice on selecting, revising, and designing high-quality assessment strategies.

HOW DO I DEFINE SUCCESS IN STUDENT PERFORMANCE?

Any assessment is likely to produce variable student performance. How you establish your own expectations for success will shape the nature of the feedback you provide to the student.

Norm-referenced grading
Traditional grading practices typically assume that collective student effort will be distributed normally. The industry standard for grading assumes a bell curve despite the fact that much has been written about grade inflation over recent years. Generally speaking, faculty derive some comfort from the standard practice of assigning grades based on accuracy percentages (e.g., an "A" is 90% or above of available points). Assuming the existence of a competitively derived bell curve tends to support an expectation that some students will do very well and some will do poorly (see Figure 3).

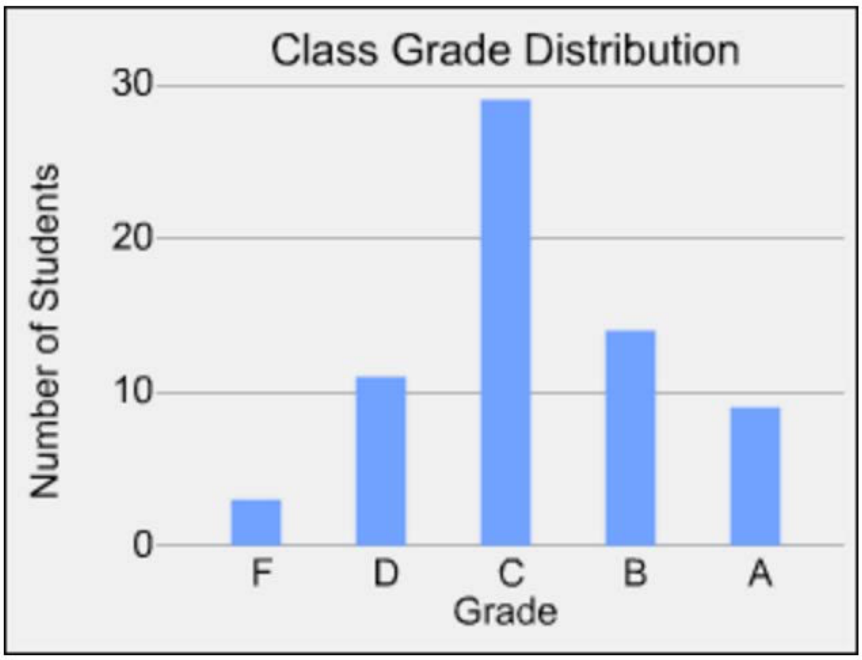

Figure 3. Example of a class grade distribution.
From Gramoll, K. (n.d.)

Criterion-referenced grading

An alternative to norm-referenced grading, criterion-referenced approaches tend to be used in situations involving performance. In this approach, the teacher determines what appropriate performance should look like ("student learning outcomes") and then describes that performance using action verbs to constitute criteria. For example, in exploring psychology's use of the scientific method, a good exemplar of a measurable outcome is "Interpret simple graphs and statistical findings." Assessment experts refer to this strategy as criterion based because it describes the essential elements of performance. When students render a performance, each criterion is judged on a continuum of high to low quality. To support instructional clarity and consistent grading, the assessor develops a "rubric," a matrix that links the list of criteria to expected levels of performance. A simple performance rubric might designate three performance levels:

- Exceeds expectations (alternative terminology: Exemplary, Outstanding, Mastery, Excellent)
- Meets expectations (Proficient, Competent, Satisfactory, Good, Acceptable)
- Does not meet expectations (Insufficient, Novice, Developing, Emerging, Needs Work)

Here is how this scheme might apply to the example of a specific criterion about effective writing mechanics in a paper:

	Does not meet expectations	**Meets expectations**	**Exceeds expectations**
Writing mechanics	Commits many errors in grammar/ spelling	Commits a few errors in grammar/ spelling	Commits no errors in grammar/spelling

Performance-based assessment does not presuppose that a certain percentage of students will fail or necessarily promote competition for a grade but typically measures more complex levels of cognition. For these reasons, many educators strongly prefer criterion-based approaches over norm-referenced strategies. In addition, criterion-referenced grading tends to move the emphasis toward the development of skills in the context of the discipline's content, which is likely to produce longer lasting gains from the learning experience than do norm-based, content-focused approaches.

Although it is useful to set some performance benchmarks ahead of time to determine whether student learning has achieved the objective you had in mind, seasoned assessors recognize that criterion-referenced grading tends to produce continuous refinement of the process. Student performance provides clues as to whether the instructions were clear or the expectations too high. We address the specifics of rubric design later in this section.

HOW DO I CHOOSE HIGH-QUALITY STUDENT LEARNING OUTCOMES?

You do not have to start from scratch—APA has done substantial work on generating relevant student learning outcomes and supporting pedagogy for introductory courses. The prevailing standards are represented in the *National Standards for High School Psychology Curricula* (APA, 2011). The curriculum design detailed in this document provided the infrastructure for the exemplars of good assessment design that were developed at the APA Summit on High School Psychology Education. APA requires that official policy undergo evaluation and, if appropriate, revision every 10 years. The National Standards will expire 2021; the next revision is expected by August 2021. In 2017, an APA task force specifically addressed the outcomes of the introductory psychology course in *Assessment of the Outcomes of the Introductory Course in Psychology* (APA, 2017). Although this work was originally geared to address college-level courses, the curricular architecture offered in this report may influence the direction taken in the next revision of the *National Standards*.

Here are some tips for crafting your own student learning outcomes specific to the projects you create and subsequently assess:

- Use language crafted for ease of understanding for the individual whose performance will be measured.
- Limit the number of criteria on which your evaluation will focus to avoid overwhelming the student.
- Limit the number of levels to distinguish quality of performance so that you won't be trapped into making distinctions that are too hard to draw.
- Focus on action verbs, such as analyze or evaluate, and avoid verbs for which it is harder to provide evidence, such as understand or appreciate.
- Observe local practices in terminology. For example, some schools discourage the use of the word "fail" to describe student performance and may advocate for the less harsh "developing" to communicate that the student needs more development.
- Think about student learning outcomes as "evolving" because student performance helps establish gaps or problems with the protocol.

An example of a student learning outcome taken from the *National Standards* (APA, 2011) is: Students will be able to identify factors that influence encoding. The 2017 *Assessment of the Outcomes of the Introductory Course in Psychology* mentioned previously provides numerous student learning outcomes for teachers.

HOW DO I WRITE HIGH-QUALITY MULTIPLE-CHOICE QUESTIONS?

Some general tips about constructing multiple-choice questions that produce the best measurement of learning include the following:

- Focus on the disciplinary content you covered, or content validity will suffer (see Section 4 for a discussion of content validity).
- Select test questions that reflect important concepts rather than trivial details.
- Include test items that might be a bit easier early in the test to build student confidence.
- Incorporate more difficult/challenging items to help differentiate students who learned the material more effectively.
- Write items that depend on course experiences and/or course readings (e.g., can someone who has not taken your course answer the question?)
- Choose the number of items according to how many slower readers can manage in the allotted time.
- Craft well-worded and easy-to-understand items (i.e., avoid the use of jargon).
- Be careful with items that require a cultural context (e.g., not everyone may understand multiple-choice questions that involve the Super Bowl or World Series).
- Avoid having the longest answer or the shortest answer as the correct answer.
- Derive distractors (wrong options) from related content.
- Include no more than three or four distractors (incorrect answers).
- Use humorous alternatives carefully as these may harm performance for some distractible students.
- Consider rewriting “Which of the following is not” stems to emphasize the content rather than the logical relationships between alternatives.
- Avoid using “all of the above” and “none of the above” as options, since students are technically right if they choose only A or B but will be penalized for lack of comprehensiveness or failure to read thoroughly.
- Consider using a “set question” in which a more complex stem (question), short writing passage, or description of research, etc., serves as the stimulus for multiple questions.

Additional information along with sample questions that illustrate multiple-choice questions designed to address different levels of cognitive complexity can be found in Appendix A. This document represents advice for teachers who develop items for the Advanced Placement Psychology exam from the Educational Testing Service, although the advice is relevant to any psychology teacher.

HOW CAN I DEVELOP ESSAY QUESTIONS THAT ENCOURAGE THE RIGHT COGNITIVE COMPLEXITY?

Essay questions can facilitate students' development of greater cognitive complexity if the questions are well designed. Consider the following tips for optimizing the results of essay question strategies:

- Write the stem as clearly and concisely as possible.
- Select the most appropriate verb that corresponds to the cognitive level you want to see. For example, list and describe will produce less complex answers than explain or compare and contrast.
- State explicitly whether students can use notes to support their thinking and writing.
- Develop an objective, measurable scoring guide before you begin grading. Be clear about what counts beyond conceptual clarity and accuracy (e.g., good grammar, complete sentences). In some cases, you may able to share the guide or rubric with students ahead of time to facilitate their best answers.
- Grade essays blind (cover up student identification indicators) to protect against "halo effects" (bias about specific students that might influence teacher evaluation).
- Be direct, but gentle, with feedback. Be sure your comments address what the student did right rather than only what the student did wrong.
- Emphasize the biggest or most important improvements that need to take place in developmental feedback so students will not feel overwhelmed. Grading a response to promote student growth is different from editing to perfect the production.
- Ask for a follow-up reflection on what students learned or accept a revision for partial credit to improve the likelihood that they will read and benefit from feedback.
- Consider the initial use of an essay question as field testing. The results will allow you to revise the question and the rubric in relation to exposed weaknesses in the future.

For further information on writing effective essay questions, see Reiner (2002).

WHEN SHOULD I USE TRUE–FALSE QUESTIONS?

True–false testing enables broad and fast coverage of targeted content. However, from an assessment standpoint, true–false testing may not be very informative about what students actually have learned, since each question offers a 50% chance of scoring accurately without really knowing the answer.

In addition, psychology does not always lend itself readily to the black-and-white world of true–false questions. The evolving nature of science leaves open the possibility that what is taught as truth at one point may need to be revised as we learn more about phenomenon. Here are some tips about preferred practices when using true–false questions:

- Use true–false items when you need quick feedback on basic, relatively simple concepts.
- True–false items can expose students' misconceptions about erroneous ideas they hold about behavior, as demonstrated in empirical literature.
- You may be able to use true–false items with complex concepts to illustrate concept complexity when a simple answer is not appropriate.
- Encourage students to justify their answers to push more complex thinking (e.g., reasoning).

WHAT ARE THE BEST STRATEGIES FOR PERFORMANCE RUBRIC DESIGN?

In performance assessment, teachers have the opportunity to evaluate both content and skills. Some assessment experts describe the process as evaluating a performance in the context of targeted content. Rubrics differ in their complexity and use to achieve desired student learning outcomes. Some relevant distinctions follow.

Holistic vs. analytic design
Holistic rubrics focus on the quality of the entire performance. Because they tend to be less detailed, these can be better deployed when the expected performance is simple or the students are less able to handle complexity. Grading transpires when the assessor looks at the pattern of performance and decides how that pattern might justify an overall grade. In contrast, analytic rubrics produce a judgment about the work quality by looking at its component parts (e.g., criteria). For grading in the analytic rubric, each criterion contributes an explicit value toward the overall grade. The more specific the rubric, the greater likelihood that judgments derived using the rubric will be reliable.

Single use vs. generic use
Teachers will create some rubrics in response to a given set of instructions about student performance and may use the rubric just once in relation to this circumstance. Some rubrics, however, may have more generic applications. For example, a well-designed writing quality rubric might be used in relation to multiple writing projects during a student's development.

Single opportunity vs. multiple opportunity
A rubric can be used to promote an appropriate revision approach in projects for which revision is needed. The initial application of the rubric results in feedback that should be addressed in any subsequent submission.

Single-point rubrics
An emerging popular design is an analytic rubric that restricts the evaluative dimension of the rubric to just three levels (see Figure 4). The target criterion or standard for the performance occupies the middle column. Achievement at an acceptable level can be circled. If unsuccessful, the evaluator can make notes for improvement in the "Concerns" column. If particularly well executed, that achievement can be noted in the "Advanced" column.

Concerns *Areas that Need Work*	**Criteria** *Standards for This Performance*	**Advanced** *Evidence of Exceeding Standards*
	Criteria #1: Description reflecting achievement of mastery level of performance	
	Criteria #2: Description reflecting achievement of mastery level of performance	
	Criteria #3: Description reflecting achievement of mastery level of performance	
	Criteria #4: Description reflecting achievement of mastery level of performance	

Figure 4. An analytic rubric in which the evaluative dimension is restricted to three levels.
From Gonzalez (2014).

ADDITIONAL TIPS FOR CREATING POWERFUL AND EFFECTIVE RUBRICS

- Avoid making a dense (too many words in each cell) or too complex (too many elements) rubric. Try to invoke “Miller’s magic number” (7 + / - 2) to limit how many criteria or judgment levels you use.
- Use language that speaks to the student. Avoid the use of terms they will not understand.
- Consider getting feedback from students on how effectively the rubric communicates your expectations either before you finalize the rubric or after its first application.
- Focus on providing feedback that students can use to improve. Overwhelmingly critical feedback will be dismissed or ignored.

HOW CAN I CREATE MEANINGFUL INDIRECT ASSESSMENTS?

Indirect assessments generally concentrate on perception or opinion rather than on skill development. In an era in which nearly all businesses follow up transactions with customer satisfaction surveys, we can assume that most students will understand the value of asking their opinions about teaching and learning processes. Some indirect assessments fare better using open-ended items, although the data may be more difficult to aggregate at the conclusion of the questions. Consequently, many indirect assessments tend to be more quantitative, using a Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree), for example. Best practices for creating opinion surveys include the following:

- Avoid using biased or loaded questions.
- Consider what type of question best suits your purpose.
- Limit rating scales to no more than seven points if using a Likert-type scale. Length and ease of completion will influence response quality.
- Temper conclusions according to the response rate. For example, if fewer than 25% of individuals targeted offer feedback, the information gathered may be of questionable validity.

HOW CAN I INCORPORATE MEANINGFUL SELF-ASSESSMENT?

Teachers often praise the use of self-assessment (e.g., having students submit a judgment about the quality of the work they have accomplished) as part of the assessment process in promoting the best learning outcomes. Using this approach may facilitate students’ taking greater responsibility for the quality of their work and improve internal locus of control.

The simplest way to promote self-assessment is to ask students to identify whether they have achieved their best work. If time allows, some teachers might reward an honest but negative self-assessment (e.g., “This is not my best work”) with additional time in order to drive home the importance of students’ taking pride in their work.

A slightly more sophisticated approach is to ask students to explain a strength and/or weakness in the work. Some teachers have found that sharing the evaluation rubric with the students and asking them to fill the rubric out according to what they think they have achieved is a good way to stimulate stronger performance.

For more information and classroom activities on incorporating metacognition into the psychology classroom, please see the resources developed by a working group at the APA Summit on High School Psychology Education that focused on metacognition skills. These resources will be available online by the fall of 2018 through the APA website.

4. EVALUATE THE EFFECTIVENESS OF ASSESSMENTS

Once you have designed and implemented your assessment, you need to establish whether the results have value: Are you measuring what you want to measure? Is the measurement stable? Psychometrics is the branch of psychology that focuses on the quality of test design and implementation. Specifically, a good assessment instrument must produce valid (truthful) distinctions as well as reliable (consistent) findings.

A good measuring strategy must be both reliable and valid. For example, if you weigh yourself and your scale is in good working order, you should be able to have confidence that the scale is producing accurate results; the measurement is both valid (it measures your actual weight) and reliable (it produces a consistent estimate every time you step onto the scale). Suppose your scale goes out of whack and adds 10 pounds to your real weight every time you step on the scale. In this case, your measurement is reliable (the scale adds 10 pounds every time you step on the scale), but it is not valid (the measurement is going to be off by 10 pounds every time). Poor tests produce problematic validity and reliability.

An important aspect of psychometrics also addresses whether the assessment produces fair judgments—that is, all students should have an equal opportunity to demonstrate their knowledge regardless of advantage or disadvantage. In this section, we explore strategies for producing the most satisfying results.

WHY YOU NEED TO UNDERSTAND CORRELATION COEFFICIENTS

Judgments involved in evaluating the quality of quantitative assessment involve comparing one set of numbers to another set to establish their strength of association (i.e., comparing data from a newly developed test to a different, well-established test to check validity). Correlation coefficients determine the strength of association between those two sets of numbers and are expressed numerically as a number between -1.0 and +1.0. The closer the correlation is to +1.0, the more confidence you can have that the two sets of data are strongly correlated, which would be the goal in deriving most correlation coefficients involved in psychometrics. Figure 5 illustrates how to interpret correlation coefficients.

Figure 5. Correlation coefficient showing strength and direction of correlation.

For example, if two data sets produce a correlation (strength of association) of +.89 and another comparison of two data sets produces a correlation of +.44, then you can say with confidence that the first comparison documents a stronger association between the compared data sets. As the correlation coefficient approaches zero, the association becomes weaker. Correlations that are on the negative side demonstrate that when the scores in one data set are high, the scores in the other data set are low. For example, a correlation between two data sets of -.78 would be a stronger association than a correlation between two other data sets of -.52.

In most cases, psychometricians strive to produce correlation coefficients that are on the high positive end of correlations. Although it is unlikely that correlations involving human behavior ever produce a perfect positive correlation of +1.0, the closer the correlation is to that number, the stronger the evidence is for determining test quality.

WHAT YOU NEED TO KNOW ABOUT RELIABILITY AND VALIDITY

You want to design effective assessment strategies so that you will be confident in the judgments you draw from the results. How do reliability and validity apply to assessment decisions?

Reliability
Several kinds of reliability determine whether you can have confidence in the consistency of an assessment strategy.

- **Test–retest reliability.** A test should produce similar results on subsequent use of the same test. For example, if you test a group of students on concepts on Wednesday, the test should produce the same results on Friday if the students have not been exposed to new information in the interval.
- **Parallel forms reliability.** You might turn to a large test bank of multiple-choice questions to produce a test. In a very large class it might be worth your trouble to construct two separate tests from the test bank so that students seated next to each other are discouraged from copying, since the neighboring student's test would be different. Running a correlation coefficient between the two data sets will tell you whether the tests were equally difficult and might dictate that some adjustment should be made to make their scores equivalent if the correlation is not strong (see earlier section on correlation coefficients).
- **Interrater reliability.** When a test has indisputable answers (a strong answer key), there is no need to determine whether different raters would come to different conclusions. However, when a test circumstance depends on expert judgment, such as grading an essay question, experts may differ in their judgments even when they have been trained on the rubric. A high positive correlation coefficient provides assurance that the experts are coming to the same conclusions about the quality of a performance.
- **Split-half reliability.** This strategy provides some assurance that the elements of a given test are consistent. Test items are divided in half, and the results of the first half are correlated with the second half. Internally consistent tests produce high positive correlations.

Validity
Several kinds of validity inform whether you can have confidence in the truthfulness of the measurement.

- **Face validity.** Does the test look like it is a plausible measure of what it claims to measure? Although this type of validity does not involve statistics, a good test will motivate test takers because they believe the content of the test appears to be a good match for the knowledge they are expected to demonstrate.
- **Content validity.** Do all of the elements of the tests correspond to the appropriate content used to assess learning? For example, if your test is supposed to cover chapters 5–7 and a few questions from chapter 8 end up on the exam, you have violated content validity.
- **Construct validity.** Does the test actually measure the psychological constructs you intended? For example, if you construct an essay test in which the vocabulary used in the questions far exceeds the knowledge base of students to be tested, then you will not be able to assess what students actually know about the targeted content. You will have violated construct validity.
- **Criterion-related validity.** To what degree do your test results correlate with some other relevant measure? For example, how well a student performs in the first semester of college should show a high correlation with college entrance tests if the tests are sound. Sometimes this form of validity is referred to as predictive validity because the results of a test can predict some external outcome (e.g., success on the job, likelihood of graduating).

HOW DO I ENSURE THAT MY MULTIPLE-CHOICE QUESTIONS ARE SOUND?

If you choose to assess using multiple-choice questions, you want to ensure that your test questions are effective in revealing what students know and how they think. You have several options for how you can evaluate whether your multiple-choice questions are doing the job:

Low-tech indicators
In this approach, you can determine by listening or observing where problem areas might lie.

- Students may ask clarification questions about an item during the test. The student's vantage point may alert you to an inadvertent error or poorly constructed item, or vocabulary or wording issues, that can be fixed before scoring or later when you want to revise the item.
- If the normal distribution of scores is badly skewed or lopsided, it means that the test may have been too rigorous or too easy.

- If all students get the item right, the item doesn't offer much discrimination among learners, so it may be of limited value for differentiating how well students know the material. However, an item or two may be purposefully included, especially early in the exam, to build confidence.
- If all students get an item wrong, either the question is poorly designed or the target content could have been presented better.
- If several students who mostly do well on the test as a whole get an item wrong, it is an indication that something could be amiss, but it doesn't necessarily guarantee that the item is bad.

High-tech indicators

If you have the capacity for item analysis in the automated grading system you use, you should be able to tap statistical data to help you determine where improvements might lie.

- **Item analysis.** This information displays the distribution of all student answers, which can inform you about which distractors seemed to be most appealing. Ideally, the majority of students should pick the correct answer.
- **Difficulty score.** This is simply the percentage (usually expressed as a decimal) of students who answer an item correctly. Test items with difficulty scores that are too low (indicating that very few students found the correct answer) or too high (indicating that almost all students got the item right) may need to be rewritten to better measure what you want to measure.
- **Discrimination index.** This statistic provides a calculation that compares students' overall scores to how they did on individual items. A test item with high discrimination "differentiates" between students well: Students who did well on that test item did well on the test overall, and students who did poorly on that item didn't do well on the test overall. If you find test items that have discrimination indexes close to zero or that are negative, you may want to rewrite those items because there may be something about the wording of the stem or the possible answers that confused your students.

Enrichment strategies

Some teachers find they can use student errors as the basis for pushing students' understanding in a second stage of review. For example, you might offer students an opportunity to earn back a portion of lost credit for an item by explaining why they made the wrong choice to begin with and why the correct answer would have been better (these are sometimes call "test correction" strategies).

HOW DO I KNOW IF AN OVERALL TEST MEETS MY NEEDS?

- **Get feedback from students.** They can pinpoint elements of the test that were confusing or unexpected to help you with revising the test for future use.
- **Look at the grade distribution.** Chances are good that a sound quantitative test will produce a distribution of scores. You may not be looking for an exact "bell curve" (see the How Do I Define Success in Student Performance section on page 13), but usually you would expect a valid test to produce a range of scores in your class. A very skewed (lopsided) distribution may demonstrate that the test is too hard or too easy.

WHAT ARE OTHER STRATEGIES YOU CAN USE TO IMPROVE TEST VALIDITY?

- Review how your test intentions fit with the goals and objectives you formulated for the course.
- Proofread your test carefully to catch typos, avoid queuing of correct answers, verify the test questions are numbered properly, and so on. Tip: Consider having students generate sample multiple-choice items, answer them together in class, and then use a sampling of the student-generated items on the actual test.
- Get students or some other external reader to look over your assessment stimulus to determine if instructions are clear (i.e., the wording is appropriate and easy to understand).
- If relevant, compare your results to other targets that correspond to your test plans.
- Consider examining item statistics (see Low- and High-Tech Indicators sections on pages 25-26) to identify items that need revision.
- Consider using a "think aloud" strategy: Ask students to choose the answer they think is correct, and provide them with space to explain why they chose that answer. You can use students' input to change items so that they better measure the kinds of thinking you want to assess.

HOW CAN I DETERMINE IF MY PERFORMANCE ASSESSMENT STRATEGY IS EFFECTIVE?

If your focus is performance assessment, there are many parameters to consider either in developing your own or in adapting someone else's assessment. The group of educators who met at the APA Summit on National Assessment in Psychology (2016) developed a rubric, included in Appendix B, to help you make good decisions about whether an instrument will meet your needs.

WHAT IF MY STUDENTS SEEM TO BE UNMOTIVATED TO PERFORM WELL ON THE ASSESSMENT?

A common problem reported in the assessment literature is that students may not be strongly motivated take assessments seriously. They may already have developed an attitude of learned helplessness that they cannot master what is required to do well in school, or they may not care much for the discipline they are studying. Some suggestions for ramping up motivation include the following:

- Ask students to self-assess.
- Involve students in the design of the assessment or evaluation rubric.
- Ensure that the assessment makes a reasonable contribution to the grade judgment.

HOW DO I JUDGE SUCCESS ON THE WHOLE?

When determining the overall success of an assessment or program, two strategies have emerged as prominent: the use of a target benchmark and achievement of an improvement rate:

- **Target benchmark strategy.** In this approach, you average the achievement of all students on the assessment measure. If the average exceeds 70%, you can feel reasonably confident that students are learning the knowledge and skills you have identified as important. Of course, bragging rights can attend to average performances that greatly exceed 70%. Adopting a 70% benchmark is a preferred solution for programs that are reasonably strong.
- **Improvement rate strategy.** Once a baseline level has been established, another strategy is to target a low-level percent improvement. For example, a program can declare a goal of 2% improvement in reaching a performance level. Over time, consistent use of an improvement rate strategy can eventually pull student performance into acceptable ranges. This strategy is preferable for programs that originally produce lower quality results.

CAN STUDENT FEEDBACK BE USED TO IMPROVE OVERALL ASSESSMENT PRACTICE?

To improve the learning gains from any assessment or learning activity, debriefing will be helpful to both student and teacher. Students can provide feedback either before or after testing that can influence changes that might need to be made. Requiring that students discuss the impact of the testing will improve their retention related to the assessment.

Another strategy that particularly helps involves student feedback. At the conclusion of a course, ask students which activities and tests should be kept, which should be revised, and which should be replaced for improvement in helping students meet their goals. Ask each student to pick one in each category, compile the results, and make recommended refinements.

5. USE ASSESSMENT DATA EFFECTIVELY AND ETHICALLY

The final step in the assessment process involves taking action based on the results, particularly in relation to making a judgment about whether both the teaching and learning that transpired are sufficient. In this section, we explore what it means to "close the loop" on assessment. On a practical level, this decision means that the results reflect one of the following conditions:

- The results are satisfying; the students have learned what was expected and, conversely, you have taught them well.
- Their results are disappointing; the flaw may lie with incompetent responses by the students, ineffective teaching, and/or problematic assessment design.

Regardless of the level of achievement, most assessment strategies provide feedback about possibilities for improvement. Next we consider each of these scenarios with regard to the use of assessment results.

WHAT ARE MY ETHICAL OBLIGATIONS RELATED TO ASSESSMENT OF STUDENTS?

Ethical behavior is involved in preparing and executing the assessment as well as in processing the results.

Before
Be sure to design the assessment with the idea of making the assessment a level playing field. Students should be assessed on content and skills directly related to the course. Wherever possible, you should strive to rule out inflating performance due to privilege or other facts not specifically related to the course (i.e., make sure test items don't rely on cultural references unfamiliar to some of your students).

During
Assessment conditions should foster optimal performance. Provide clear instructions and a quiet environment. Be on hand to answer questions for clarification. Encourage students to do their best work.

After
Score performances quickly to maximize learning from the experience. Construct respectful and encouraging feedback referencing student successes and what they can do to improve their performance. Student performance is a private matter. Exercise caution regarding how you describe assessment results in public. Individual identity should remain anonymous.

HOW DO I EXPLOIT SUCCESSFUL RESULTS?

Positive assessment results have enormous value. Good assessment results serve as evidence of high-quality teaching and learning and can be used to advocate for new resources in the program (e.g., field trip funding). Strong evidence of learning can also assist you in making the case that you are doing your job well.

When your results are successful, you can declare a new "maintenance" goal and continue the assessment with future students. Your objective is ensuring that the solid achievement remains sturdy over time. Especially when an assessment strategy measures some central feature of the curriculum, it is easy to justify repeating the same goals in future terms. However, a different institutional assessment strategy is to explore a specific assessment question (e.g., "How well do my students write?"). When assessment provides an answer to that question, the program may be expected to move on to a new assessment question.

WHAT IF MY RESULTS ARE DISAPPOINTING?

You have to decide where the problem lies. Disappointing results are not necessarily "bad" results, since the evidence can point to real problems that need to be addressed. An analysis of performance weaknesses can dictate what might need to be changed.

The learning factor
An assessment that reveals disappointing performance may accurately capture the gaps in student knowledge and skill. Instructors need to determine whether the problem rests with inadequate exposure, insufficient practice, fatigue, distraction, unmotivated performance, or any number of student variables that could contribute to lackluster performance.

The teaching factor
Poor results can indicate that the problem lies with the teacher. Perhaps the teaching was rushed or pitched at too high a level for the students to grasp. For example, suboptimal performances in writing might inspire the instructor to think of other strategies that could build that skill to produce stronger performances the next time the assessment transpires.

The assessment design factor
Poor performance can also be an indicator that the assessment is not well designed or may not be a good match for the intended goals. Assessment is an iterative process; it is normal for procedures to undergo continuous refinement to improve confidence in its use. The "low tech" and "high tech" suggestions mentioned earlier are helpful tools teachers can use to diagnose possible problems and revise assessments.

HOW SHOULD I REPORT MY RESULTS?

Most education programs have developed vehicles for reporting assessment results. Typically, a school specifies a strategy for collecting the conclusions about assessment results that facilitate comparisons of success across units within the organization. Follow the reporting requirements, but take advantage of any opportunities to include easy-to-understand attachments or graphs that readily communicate your success. It is also helpful to create a one-page executive summary to capture high-quality achievement or articulate where your assessment planning will take you. For example, teachers could use this kind of executive summary to share overall test results with students, modeling effective data presentation and providing potentially useful overall suggestions about common misconceptions. Websites can also showcase assessment success.

HOW CAN I PROTECT MYSELF IF THE RESULTS ARE DISAPPOINTING?

If teachers are to take assessment seriously, assessment should not be threatening. The results of assessment should not be grounds for punitive action taken by administration. Such conditions are likely to give rise to problematic execution and even misrepresentation of results. However, if administrations provide evidence that assessment is underway in the spirit of continuous improvement, teachers should have greater motivation to use assessment as the powerful tool that it is to promote student learning and improve teaching. Technically, administrations should support teacher assessment activities as long as teachers are making legitimate efforts to gather relevant data and work with those data to help them determine teaching strategy.

If results are problematic, then as a matter of ethics they should not be ignored, downplayed, or distorted. However, the following steps can mitigate negative consequences from disappointing student outcome performance.

- Lead with the strengths observed in the assessment.
- Fine-tune goals based on what the data reveal.
- Be clear that actions will be taken to address the deficits. Promise better outcomes the following year and then deliver.
- Work with a mentor whose outcome performance is satisfying to help you craft an improvement strategy.

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APPENDIX A

A Guide to Writing Higher Order Multiple-Choice Questions for the AP Psychology Test

The purpose of this guide is to assist item writers in developing more challenging test questions. In the tradition of Bloom's Taxonomy, we refer to those questions as "higher order." We offer some pointers and examples to facilitate the development of such questions.

PROMOTING COGNITIVE COMPLEXITY IN APPLYING BLOOM'S TAXONOMY

Bloom's Taxonomy (1956) presents a way to think about increasing levels of cognitive complexity. Krathwohl and colleagues (2001) modified Bloom's original taxonomy to correct for some operational difficulties of the original taxonomy. The modified taxonomy is as follows.

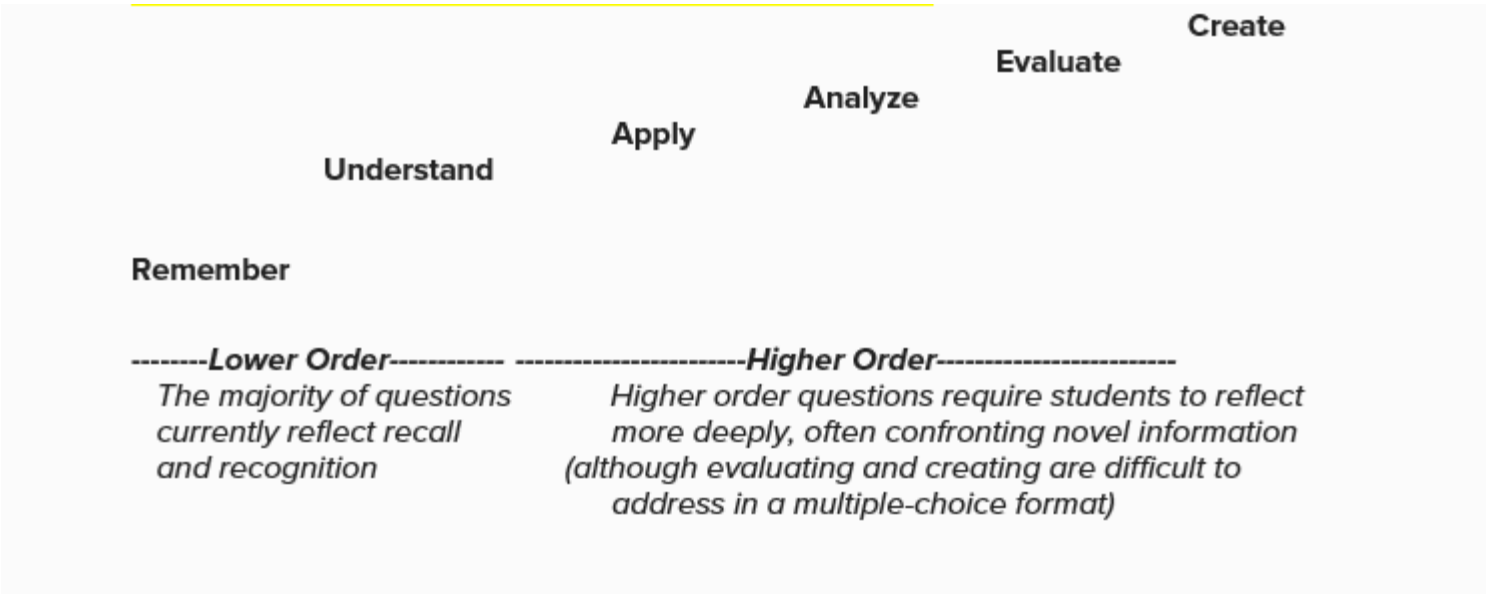

CREATING LOWER ORDER QUESTIONS

Lower order questions tend to reflect two kinds of structures. The concept or principle is in the stem of the question that has a number of potential answers (the examples we offer have five alternatives). The correct answer (denoted with an asterisk in the examples) represents a clear attribute of the concept or principle.

Obsessive-compulsive disorder is characterized by which primary symptom?

1. Hallucination
2. Memory loss
3. Intense specific fear
4. Delusion
5. Unwanted repetitive thoughts*

The second format places the attribute in the stem of the question; the correct alternative is the target concept or principle.

Which disorder is characterized by unwanted, intrusive thoughts and repetitive behavior?

1. Phobia
2. Obsessive-compulsive disorder*
3. Dissociative identity disorder
4. Major depressive disorder
5. Schizophrenia

A third example offers a slightly more challenging lower level question:

Jane checks 10 times to see whether she has set her alarm clock before going to sleep. This behavior may be symptomatic of which of the following disorders?

1. Phobia
2. Obsessive-compulsive disorder*
3. Dissociative identity disorder
4. Major depressive disorder
5. Schizophrenia

When creating lower order questions, question writers should

- identify a concept that is meaningful and discussed by the majority of textbooks;
- create real and plausible alternatives that reflect the same category of responses;
- clearly distinguish the correct alternative; and
- use key verbs such as recognize, recall, interpret, classify, summarize, infer, compare, explain.

CREATING HIGHER ORDER QUESTIONS

The key to creating higher order questions is requiring students to mediate their answers by coming up with an extra step that they had not previously learned in their studies. It is not always easy to distinguish application questions from analysis questions. In general, application and analysis questions ask students to transfer their recalled knowledge to a new situation, break apart and reassemble concepts in new ways, or combine the content of two areas in a novel way to answer a question.

Application questions

A student who misses deadlines in school while striving for perfection may be exhibiting the symptoms of which of the following disorders?

1. Phobia
2. Obsessive-compulsive disorder*
3. Dissociative identity disorder
4. Major depressive disorder
5. Schizophrenia

Which of the following could be expected to be a problem for a student with obsessive-compulsive disorder?

1. Cheating without remorse
2. Oversleeping and missing class
3. Missing deadlines while striving for perfection*
4. Alienating classmates due to inflated self-importance
5. Being distracted by fear of persecution by classmates

Analysis questions

The following examples involve combining content from two or more areas of psychology, which forces the student to consider concepts in a novel manner:

Gene is always late for school because he spends an hour organizing his closet each morning. Which of the following treatments would be most effective for Gene's problem?

1. In-depth interpretation of dreams
2. Electroconvulsive therapy
3. Medication affecting serotonin levels*
4. Systematic desensitization
5. Regular exposure to bright lights

Amanda washes her hands until they bleed. This causes her distress, but she still cannot stop washing her hands. A behaviorist would explain the persistence of Amanda's behavior as a result of

1. positive reinforcement due to increased anxiety*
2. the extinction of her interest in other activities
3. generalization from taking long showers
4. negative reinforcement due to decreased anxiety
5. time out from other meaningful activities

When creating higher order questions, question writers should

- pose a problem that needs to be solved;
- consider eliciting interpretation of a chart, graph, or picture;
- ensure that situations described in the question are novel; and
- use keywords such as execute, organize, apply.

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APPENDIX B

Evaluating Assessment Strategies

The group of educators who met at the APA Summit on National Assessment of Psychology (2016) developed a rubric to help instructors make good decisions about whether an instrument will meet their needs. Based on the works of Fulks (2004), Rhode Island Department of Education (2012), and CAST (n.d.), this is a tool that may be used to evaluate assessments. The tool includes an assessment profile (e.g., cost of instrument, time for implementation, cognitive taxonomy), supporting information (e.g., teacher directions, student directions), delivery method (e.g., whole group, individual, electronic), how it maps onto the APA Guidelines for the Undergraduate Psychology Major and Universal Design for Learning Guidelines (see CAST, n.d.), a scoring guide for rubrics, and evaluation of strengths and weaknesses for assessment.

Assessment Profile	Response
Method (I = Indirect and D = Direct)	
Level of Assessment (SaS = Students as Scholars, SaSC = Students as Savvy Consumers, and SaP = Students as Producers)	
Cognitive Taxonomy (R = Remembering, U = Understanding, A = Applying, AN = Analyzing, E = Evaluating, C = Creating	
Usage (F = Formative and S = Summative)	
Constructed Response (essay, multistep response with explanation and/or rationale required for tasks, etc.)	
Product (research paper, editorial, log, journal, play, poem, model, multimedia, art products, script, musical score, portfolio pieces, etc.)	
Performance (demonstration, presentation, science lab, dance or music performance, athletic performance, debate, etc.)	
Short Answer (short constructed response, fill in a graphic organizer or diagram, explain your thinking or solution, make and complete a table, etc.)	
Selected Response (multiple choice, multiple select, evidence-based selected response (EBSR), true–false, matching, etc.)	
Cost	
Time (in minutes)	

Supporting Information	Yes/No
Teacher Directions (may include prerequisites/description of instruction before giving the assessment; e.g., This assessment should be given after students have learned...)	
Scoring Guide/Rubric	
Sample Evidence for Student Performance	
Student Materials	
Estimated Time for Administration	
Student Directions	
Assessment Task/Prompt	

Delivery Method	Yes/No
Whole Group	
Small Group	
Individual	
Paper and Pencil	
Electronic	

APA Guidelines for the Undergraduate Psychology Major 2.0 Evaluation	Fully	Partially	N/A
1. Knowledge Base in Psychology			
2. Scientific Inquiry and Critical Thinking			
3. Ethical and Social Responsibility in a Diverse World			
4. Communication			
5. Professional Development			
Describe the content knowledge/concepts assessed:			
Describe the skills/performance assessed:			

Scoring Guide to Be Used With the Assessment:	Yes/No
Generalized Rubric (e.g., for writing an argument, for all science labs)	
Task-Specific Rubric (only used for the particular task)	
Scoring Guidelines (e.g., checklist with score points for each part)	
Answer Key, Scoring Template, Computerized or Machine Scored	
Anchor Papers (student samples at each score point)	
Are the score categories clearly defined and coherent across performance levels? If no, please explain.	
Does the rubric/scoring criteria address all of the demands within the task or item? If no, please explain.	
Are directions for the items or tasks presented in as straightforward a manner as possible for a range of learners? If no, identify problematic items/tasks and provide suggestions for improvement.	
Is the vocabulary and context(s) presented free from cultural or other unintended bias? If no, identify problematic items/tasks and provide suggestions for improvement.	

Universal Design for Learning	Yes/No
Provide multiple means of accessing the assessment (e.g., allow students to access information in ways that do not require them to visually read standard print).	
Provide multiple means of responding to the assessment (e.g., allow students to complete activities, assignments, and assessments in different ways or to solve or organize problems using some type of assistive device or organizer).	

Recommendations for This Assessment:
What are the strengths of this assessment?
What are the weaknesses of this assessment?
☐ This assessment can be used without revisions.
☐ This assessment can be used with minor revisions (explain below)
☐ This assessment can be used with significant revisions (explain below)
☐ This assessment should not be used (explain below)

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International Compilation of Human Research Standards

2018 Edition

Compiled By:
Office for Human Research Protections
U.S. Department of Health and Human Services

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as standards) that govern human subjects research in 130 countries, as well as standards from a number of international and regional organizations. This Compilation was developed for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects research around the world.

Content experts from around the world, listed at the back of the Compilation, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered in this Edition. Four new countries are featured in the 2018 Edition: Algeria, Madagascar, Mali, and Saint Lucia. For the first time, this year's Compilation includes a section on Social-Behavioral Research.

ORGANIZATION

The Table of Contents is on pages 3-4. For each country, the standards are categorized by row as:

1. General, i.e., applicable to most or all types of human subjects research
2. Drugs and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection (also see Privacy International reports: https://www.privacyinternational.org/reports)
7. Human Biological Materials
8. Genetic (also see the HumGen International database: http://www.humgen.umontreal.ca/int/)
9. Embryos, Stem Cells, and Cloning

These nine categories often overlap, so it may be necessary to review the other standards to obtain an accurate understanding of the country's requirements.

The information is then organized into four columns:

1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research.
2. Legislation – encompasses statutes, statutory instruments, and legislative decrees, as well as any pertinent constitutional provisions.
3. Regulations – refer to instruments that are created and issued in the name of governmental administrative bodies.
4. Guidelines – pertain to non-binding instruments.

The year of the document's most recent version (or date of initial approval, if never amended) is indicated in parenthesis when that information is available, unless the date is part of the document's title, e.g., Act 46/2012.

HOW TO ACCESS A DOCUMENT

Documents can be accessed in four possible ways:

1. Link to the web address (URL).
2. Search for a document at the website of the agency listed in the Key Organizations column.
3. Perform an Internet search on the document title.
4. Request a local research ethics committee to provide the document.

In many cases the documents are available in English. Sometimes the English translation is a non-official version. When the citation links to a non-English document, the language is indicated in parenthesis, e.g., (Spanish).

TOPICS NOT COVERED

In order to focus its scope, the International Compilation of Human Research Standards does not include standards from the state, provincial, or local levels. Nor does the Compilation cover:

1. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations.
2. Laws, regulations, or guidelines specific to research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice.
3. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: http://ethics.iit.edu/ecodes/about
4. Working papers, drafts, commentaries, or discussion papers.

NEW STANDARDS, UPDATES, AND BROKEN LINKS

To request inclusion of a new standard in the Compilation, or to report updates or broken links, contact Edward E. Bartlett, PhD, International Human Research Liaison, Office for Human Research Protections, U.S. Department of Health and Human Services: edward.bartlett@hhs.gov .

DISCLAIMER

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to human subject protections. While in-country persons have been requested to review listings to assure their accuracy and completeness, researchers and other individuals should check with local authorities and/or research ethics committees before commencing research activities.

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General	Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/			International Ethical Guidelines for Health-related Involving Humans (2016): https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/
	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	World Health Organization: http://www.who.int/en/			1. Operational Guidelines for Ethics Committees that Review Biomedical Research (2000): http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf 2. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf 3. Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013): http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf 4. Guidelines on Ethical Issues in Public Health Surveillance (2017): http://www.who.int/ethics/publications/public-health-surveillance/en/
	United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO): https://en.unesco.org/			Universal Declaration on Bioethics and Human Rights (2005): http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
	UNAIDS: http://www.unaids.org/			1. Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011): http://www.unaids.org/sites/default/files/media_asset/JC1853_GPP_Guidelines_2011_en_0.pdf 2. Ethical Considerations in Biomedical HIV Prevention Trials (2012): http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1

Country	Key Organizations	Legislation	Regulations	Guidelines
				399_ethical_considerations_en.pdf
	Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/	International Covenant on Civil and Political Rights, Article 7 (1976): http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx		
	International Committee of the Red Cross (ICRC): www.icrc.org	1. Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fef854a3517b75ac125641e004a9e68 2. Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079		
Drugs, Biologics, and Devices	*Drugs*			
	International Conference on Harmonization (ICH): http://www.ich.org/			Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (2016): https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf
	World Health Organization (WHO): http://www.who.int/en/			1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2005): http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf 2. Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005)
	Devices			
	International Medical Device Regulators Forum (IMDRF): http://www.imdrf.org/			IMDRF: Statement Regarding Use of ISO 14155:2011 "Clinical Investigation of Medical Devices for Human Subjects-Good Clinical Practice" (2015): http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-150326-statement-iso141552011.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				Archived Documents from the Global Harmonization Task Force (GHTF), replaced by the IMDRF in 2012: 1. Clinical Evaluation (2007) 2. Clinical Evidence – Key Definitions and Concepts (2007) 3. Post-Market Clinical Follow-Up Studies (2010) 4. Clinical Investigations (2010) 5. Reportable Events During Pre-Market Clinical Investigations (2012) 6. Clinical Evidence for IVD Medical Devices (2012) 7. Scientific Validity Determination and Performance Evaluation (2012) 8. Clinical Performance Studies for IVD Medical Devices (2012) Access: http://www.imdrf.org/ghtf/ghtf-archived-docs.asp
	International Standards Organization: http://www.iso.org/iso/home.html			Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice. Standard Number 14155:2011: http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557
Clinical Trials Registry	World Health Organization – International Clinical Trials Registry Platform: http://www.who.int/ictrp/en/			Resolution WHA 58.34 (2005): http://www.wpro.who.int/health_research/policy_documents/ministerial_summit_on_health_research_may2005.pdf?ua=1
	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki, Article 35 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	International Committee of Medical Journal Editors: http://www.icmje.org/			Clinical Trial Registration: http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
Research Injury	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki, Paragraph 15 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	International Conference on Harmonization (ICH): http://www.ich.org/			Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ,

Country	Key Organizations	Legislation	Regulations	Guidelines
				Section 5.8 (2016): https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf
	Council for International Organizations of Medical Sciences: http://www.cioms.ch/			International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guideline 19 (2002): https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/
Social-Behavioral Research	UNESCO: http://www.unesco.org/			Code of Conduct and Ethical Guidelines for Social Science Research: http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Soc_Sci_Code.pdf
Privacy/Data Protection	World Medical Association: http://www.wma.net/e/index.htm			1. Declaration on Ethical Considerations Regarding Health Databases (2002): http://www.wma.net/en/30publications/10policies/d1/index.html 2. Declaration of Helsinki, Paragraph 24 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
Human Biological Materials	World Health Organization: http://www.who.int/en/			1. Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997): www.who.int/csr/emc97_3.pdf 2. Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003): http://www.who.int/reproductivehealth/topics/ethics/human_tissue_use.pdf
	International Air Transport Association: http://www.iata.org/			Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)
	International Society for Biological and Environmental Repositories: http://www.isber.org			Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2012): http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf
Genetic Research	Human Genome Organization: http://www.hugo-international.org/			1. Statement on the Principled Conduct of Genetic Research (1996): http://www.eubios.info/HUGO.htm 2. Statement on DNA Sampling: Control and Access (1998): http://www.hugo-

Country	Key Organizations	Legislation	Regulations	Guidelines
				international.org/img/dna_1998.pdf 3. Statement on Gene Therapy Research (2001): http://www.hugo-international.org/img/gene_2001.pdf 4. Statement on Human Genomic Databases (2002): http://www.hugo-international.org/img/genomic_2002.pdf
	UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			1. Universal Declaration on the Human Genome and Human Rights Section 16 of III Programme for 1998-1999 (1997): http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47 2. International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): http://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45
Embryos, Stem Cells, and Cloning	International Society for Stem Cell Research: http://www.isscr.org/			Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006): http://www.isscr.org/docs/default-source/hesc-guidelines/isscrhescguidelines2006.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada Note: Several Canadian provinces and territories also have human subject research standards.				
General	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. National Defence and the Canadian Armed Forces: http://www.forces.gc.ca/en/index.page 3. Correctional Service of Canada: http://www.csc-scc.gc.ca/index-eng.shtml			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/ National Defence and the Canadian Armed Forces: Research Involving Human Subjects (1998): http://www.forces.gc.ca/en/about-policies-standards-defence-admin-orders-directives-5000/5061-0.page Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2004): http://www.csc-scc.gc.ca/politiques-et-lois/009-cd-eng.shtml
Drugs, Biologics, and Devices	*Drugs*			
	1. Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index		1. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2001): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf 2. Good Clinical Practice Consolidated Guideline (2004): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 11: Clinical Trials (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/
	Devices			
	Health Canada, Medical Devices: http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php		Medical Devices Regulations (SOR/98-282) (1998): http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html	
Clinical Trials Registry	1. Health Canada Clinical Trial Database: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php 2. Interagency Advisory Panel on			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 11.3 (2014): http://www.pre.ethics.gc.ca/eng/policy-

Country	Key Organizations	Legislation	Regulations	Guidelines
	Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			politique/initiatives/tcps2-eptc2/chapter11-chapitre11/
Research Injury	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Article 3.2(j) (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/
Social-Behavioral Research	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans. Exemptions (Chapter 2) and Qualitative Research (Chapter 10) (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
Privacy/Data Protection Note: Each of the Canadian provinces and territories also has enacted privacy legislation.	1. Office of the Privacy Commissioner of Canada (OPC): https://www.priv.gc.ca/en 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 3. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	1. Privacy Act, Sections 7-8 (1983): http://laws-lois.justice.gc.ca/PDF/P-21.pdf 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://laws-lois.justice.gc.ca/PDF/P-8.6.pdf	OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (September 29, 2014)	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 5: Privacy and Confidentiality (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/ CIHR: CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
Genetic Research	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. Canadian Biotechnology Advisory Committee (CBAC): http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php 3. Biologics and Genetic Therapies			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 13: Human Genetic Research (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-

Country	Key Organizations	Legislation	Regulations	Guidelines
	Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			chapitre13/
Embryos, Stem Cells, and Cloning	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index	Assisted Human Reproduction Act (2004): http://laws-lois.justice.gc.ca/eng/acts/A-13.4/	Assisted Human Reproduction (Section 8 Consent) Regulations (2007): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12, Sections E and F (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
United States All of the following departments and agencies subscribe to subpart A, often referred to as the Common Rule (last updated in 2009), and codified in the relevant section of the Code of Federal Regulations: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html Some departments and agencies subscribe to additional subparts: • Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) • Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) • Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) • Subpart E: Institutional Review Board Registration Requirements (2009)				
General	Agency for International Development: www.usaid.gov/		22 CFR 225, Subpart A	Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (2015): https://www.usaid.gov/sites/default/files/documents/1870/200.pdf
	Central Intelligence Agency: https://www.cia.gov/index.html		Executive Order 12333, Subparts A, B, C, and D	
	Consumer Product Safety Commission: www.cpsc.gov/		16 CFR 1028, Subpart A	
	Department of Agriculture: www.usda.gov/wps/portal/usdahome/		1. 7 CFR 1c, Subpart A 2. 45 CFR 46, Subparts B, C, and D	Protection of Human Subjects (2011): https://www.afm.ars.usda.gov/media/10444/pp605-1.pdf
	Department of Commerce, National Institute of Standards and Technology: www.commerce.gov/		15 CFR 27, Subpart A	
	Department of Defense, Human and Animal RDT&E Protection Programs: http://www.acq.osd.mil/rd/hptb/programs/regulatory/	United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects	1. 32 CFR 219, Subpart A 2. DoDI 3216.02 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf	
	Department of Education: www.ed.gov/	1. Protection of Pupil Rights Amendment (1974) 2. Family Educational Rights	1. 34 CFR 97 subparts A (1991) and D (1997) 2. 34 CFR 98 (1984)	

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		and Privacy Act (1974)	3. 34 CFR 99 (2000) 4. 34 CFR 350.4(c) (1991) 5. 34 CFR 356.3(c) (1991)	
	Department of Energy: http://science.energy.gov/ber/human-subjects/		1. 10 CFR 745 (1991), Subpart A 2. DOE Order 443.1B 3. DOE Order 481.1	
	Department of Health and Human Services, Office for Human Research Protections: www.hhs.gov/ohrp/	Public Health Service Act (1993): http://history.nih.gov/research/downloads/PL103-43.pdf	45 CFR 46, Subparts A, B, C, D, and E: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	Various: http://www.hhs.gov/ohrp/regulations-and-policy/
	Department of Health and Human Services, Food and Drug Administration: https://www.fda.gov/		*For studies funded by FDA:* 45 CFR 46, Subparts A, D, and E: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306	1. 45 CFR 46, Subparts A-D 2. DHS Directive 026-04, Human Subjects Research (2007): https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf	
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60.101, which cites 45 CFR part 46, subpart A.	
	1. Department of Justice Office of Justice Programs: http://ojp.gov/ 2. Bureau of Prisons: www.bop.gov		1. 28 CFR 22 Privacy Regulation (1976): http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl 2. 42 U.S.C. § 3789g Confidentiality of Information (1984) http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm 3. 28 CFR 46 (1991), Subpart A: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl	
	Department of Transportation: www.dot.gov/		49 CFR 11, Subpart A	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://www1.va.gov/oro/ 2. Office of Research and		1. 38 FR 16 (1991), Subpart A 2. 38 CFR 17.85 (1998)	Various: https://www.research.va.gov/resources/policies/human_research.cfm

Country	Key Organizations	Legislation	Regulations	Guidelines
	Development: www.research.va.gov			
	Environmental Protection Agency, Program in Human Research Ethics: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0		40 CFR 26 1. Subpart A: Common Rule 2. Subpart B: Prohibition of Intentional Exposure Research Conducted or Supported by EPA in Children and Pregnant or Nursing Women (2006) 3. Subpart C: Additional Protections for Observational Research Conducted or Supported by EPA in Pregnant Women and Fetuses (2006) 4. Subpart D: Additional Protections for Observational Research Conducted or Supported by EPA in Children (2006) 5. Subpart K: Regulation of Third-Party Intentional Exposure Research for Pesticides in Non-Pregnant, Non-Nursing Adults (2013) 6. Subpart L: Prohibition of Third-Party Intentional Exposure Research for Pesticides in Children and Pregnant or Nursing Women (2013)	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	
	Social Security Administration: http://www.ssa.gov/		45 CFR 46, Subpart A: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	
Drugs, Biologics, and Devices	*Drugs and Biologics*			
	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm#Part_A 2. Public Health Service Act, 42	1. 21 CFR 50 (Informed Consent) 2. 21 CFR 312 (Investigational New Drug Application) 3. 21 CFR 56 (Institutional Review Boards) 4. 21 CFR 314 (Applications for Approval to Market a New Drug) 5. 21 CFR 54 (Financial	General: Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm Other: http://www.fda.gov/Drugs/GuidanceCompliance

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		USC Section 262 (1998): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/ucm149278.htm 3. 21st Century Cures Act, Section 3024 (2016): https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf	Disclosure by Clinical Investigators) 6. 21 CFR 320 (Bioavailability and Bioequivalence Requirements)	eRegulatoryInformation/Guidances/default.htm
	Devices			
	Food and Drug Administration, Center for Devices and Radiological Health: http://www.fda.gov/MedicalDevices/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Section 360 (2012): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm#Part_A 2. 21st Century Cures Act, Section 3024 (2016): https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf	1. 21 CFR 50 (Informed Consent) 2. 21 CFR 56 (Institutional Review Boards) 3. 21 CFR 807, Subpart E 4. 21 CFR 812 (Investigational Device Exemptions) 5. 21 CFR 814 (Premarket Approval of Medical Devices) 6. 21 CFR 54 (Financial Disclosure by Clinical Investigators)	Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm Other: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
Clinical Trials Registry	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food and Drug Administration Modernization Act, Section 113 (1997): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDAMA/FullTextofFDAMAlaw/default.htm 2. Food and Drug Administration Amendments Act, Section 801 (2007): https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf		
	National Institutes of Health ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home		1. Clinical Trials Regulation and Results Information Submission, 42 CFR 11 (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission 2. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2016):	FAQs on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/manage-recs/faq

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://www.federalregister.gov/documents/2016/09/21/2016-22379/dissemination-of-nih-funded-clinical-trial-information	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov			FAQ: http://www.research.va.gov/resources/ORD_Admin/clinical_trials/registration-faq.pdf
Research Injury	Same as *General*, listed above.		Sections 116(a)(6) and (7) of the Common Rule.	
	Department of Defense, Regulatory Affairs: http://www.acq.osd.mil/rd/hptb/programs/regulatory/		DoDI 3216.02 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov	38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects: https://www.gpo.gov/fdsys/pkg/CFR-2013-title38-vol1/pdf/CFR-2013-title38-vol1-sec17-85.pdf	Handbook 1200.5, Appendix F, Paragraph 2a(11)	
Social-Behavioral Research	All Common Rule agencies		Exempt research (categories 1, 2, 3, and 4) and Expedited research (categories 6 and 7)	
	National Science Foundation: https://www.nsf.gov/			Frequently Asked Questions and Vignettes: https://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp
Privacy/Data Protection	1. DHHS National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/ 2. DHHS Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa/	1. Privacy Act, 5 U.S.C. § 552a (1974): http://www.justice.gov/opcl/privacyact1974.htm 2. Health Insurance Portability and Accountability Act (1996): https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html 3. Confidential Information Protection and Statistical Efficiency Act (CIPSEA) (2002): http://www.eia.gov/cipsea/cipsea.pdf 4. Health Information Technology for Economic and Clinical Health (HITECH) Act (2009): https://www.gpo.gov/fdsys/pkg/PL	1. HIPAA Privacy Rule, 45 CFR parts 160 and 164, Subparts A and C (2002): http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164 (2009): http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html 3. HIPAA Breach Notification Rule, 45 CFR §164.400-414: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html	NIH: Various: http://privacyruleandresearch.nih.gov/ OCR: Various: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html and https://www.hhs.gov/hipaa/for-professionals/faq/research-uses-and-disclosures

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		AW-111publ5/pdf/PLAW-111publ5.pdf		
	Department of Homeland Security: www.dhs.gov/	Public Law 107-347: https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf		
	Social Security Administration: http://www.ssa.gov/	Privacy Act (1974): http://www.hhs.gov/foia/privacy/index.html		
Human Biological Materials	Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/			1. Issues to Consider in the Research Use of Stored Data or Tissues (1997) 2. Guidance on Research Involving Coded Private Information or Biological Specimens (2008)
	Food and Drug Administration: a. Office of In Vitro Diagnostic Device Evaluation and Safety: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm b. Center for Biologics Research and Evaluation (CBER): - Office of Cellular, Tissue and Gene Therapies - Office of Blood Research and Review: http://www.fda.gov/BiologicsBloodVaccines/default.htm			1. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm 2. In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (2010) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf 3. CBER-Specific: Various: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm
Genetic Research	1. DHHS Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. DHHS National Institutes of Health, Office of Science Policy, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division: https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/	1. Research on Transplantation of Fetal Tissue, Public Law 103-43 (1993): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html 2. Genetic Information Nondiscrimination Act (2008): https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/content-detail.html		OHRP: Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html NIH: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2016): https://osp.od.nih.gov/wp-

Country	Key Organizations	Legislation	Regulations	Guidelines
				content/uploads/2013/06/NIH_Guidelines.pdf
Embryos, Stem Cells, and Cloning	Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/BiologicsBloodVaccines/default.htm			Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248: http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/UCM148113.pdf
	National Academy of Sciences (NAS): http://www.nationalacademies.org/nrc/			1. Guidelines for Human Embryonic Stem Cell Research (2005): http://www.nap.edu/catalog.php?record_id=11278 2. 2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=12260 3. 2010 Final Report of the National Academies Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies Guidelines for Human Embryonic Stem Cell Research: http://www.nap.edu/catalog.php?record_id=12923
	National Institutes of Health: http://stemcells.nih.gov/	Research on Transplantation of Fetal Tissue. Public Law 103-43 (1993): https://history.nih.gov/research/downloads/PL103-43.pdf		1. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009): https://www.gpo.gov/fdsys/pkg/DCPD-200900136/pdf/DCPD-200900136.pdf 2. NIH Guidelines on Human Stem Cell Research (2009): http://stemcells.nih.gov/policy/2009-guidelines.htm 3. NIH Human Embryonic Stem Cell Registry (2016): https://grants.nih.gov/stem_cells/registry/current.htm Access: http://stemcells.nih.gov/

Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
Regionwide				
General	European Commission: 1. European Group on Ethics in Science and New Technologies (EGE): https://ec.europa.eu/research/ege/index.cfm 2. Directorate-General for Research and Innovation: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm			EGE: 1. Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf 2. Horizon 2020: How to Complete your Ethics Self –Assessment (2015): http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-if-2015/1645175-h2020_-_guidance_ethics_self_assess_en.pdf
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		
Drugs, Biologics, and Devices	*Drugs*			
	European Commission: DG SANTE: Directorate-General for Health and Food Safety: http://ec.europa.eu/health/index_en.htm	1. Directive 2001/20/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf 2. Directive 2005/28/EC Laying		EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/

Country	Key Organizations	Legislation	Regulations	Guidelines
		Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal Products for Human Use, as Well as the Requirements for Authorization of the Manufacturing or Importation of Such Products: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf 3. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf		
	European Medicines Agency: http://www.ema.europa.eu/		Policy on Publication of Clinical Data for Medicinal Products for Human Use (2015): http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1#	1. Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/3cc1aen_en.pdf 2. Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA and Submitted in Marketing Authorization Applications to the EU Regulatory Authorities (2012): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125437.pdf 3. Questions and Answers on the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use (2015): http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500174378.pdf 4. Guideline for Good Clinical Practice E6(R2) (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				5. Q&A: Good Clinical Practice (GCP): http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000016.jsp&mid=WC0b01ac05800296c5 6. Inspections Procedure - Recommendations and Guidance Related to the Implementation of GCP: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000140.jsp&mid=WC0b01ac05800296c6 7. GCP Inspectors Working Group: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000136.jsp&mid=WC0b01ac05800296c4
	Devices			
	DG GROWTH: Internal Market, Industry, Entrepreneurship, SMEs: https://ec.europa.eu/growth/sectors/medical-devices_en	1. Directive 93/42/EEC Concerning Medical Devices: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF 2. Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVD): https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en 3. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 Amending Council Directive 90/385/EEC on Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0047&from=EN		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm
Clinical Trials Registry	EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/			FAQs: https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf
Research Injury	European Commission: DG SANTE: Directorate-General for	1. Clinical Trials Directive 2001/20/EC:		

Country	Key Organizations	Legislation	Regulations	Guidelines
	Health and Food Safety: http://ec.europa.eu/health/index_en.htm	http://ec.europa.eu/health/human-use/clinical-trials/directive/index_en.htm 2. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf		
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		
Privacy/Data Protection	1. European Commission: Directorate-General for Justice and Consumers: http://ec.europa.eu/justice/mission/index_en.htm 2. European Medicines Agency (EMA): http://www.ema.europa.eu/	1. Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995): http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf 2. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data		EMA: External Guidance on the Implementation of the European Medicines Agency Policy on the Publication of Clinical Data for Medicinal Products for Human Use (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/12/WC500218567.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		Protection Regulation): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN		
	Council of Europe: Data Protection and Cybercrime Division: http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp	Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=108&CL=ENG		1. Recommendation No. R (97) 5 on the Protection of Medical Data (1997): https://wcd.coe.int/ViewDoc.jsp?id=571075&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383 2. Article 29 Working Party Documentation: http://ec.europa.eu/justice/data-protection/article-29/index_en.htm
Human Biological Samples	European Commission: European Group on Ethics in Science and New Technologies: http://ec.europa.eu//research/ege/index.cfm	Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage, and Distribution of Human Tissues and Cells: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0023:EN:HTML		
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG		Recommendation Rec (2016) 6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff
Genetic Research	European Medicines Agency: http://www.ema.europa.eu/	Regulation (EC) No. 1394/2007 on Advanced Therapy Medicinal Products and Amending Directive 2001/83/EC and Regulation (EC) No. 726/2004: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf		Various: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Co		1. Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackCo

Country	Key Organizations	Legislation	Regulations	Guidelines
		mmun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		lorIntranet=FFBB55&BackColorLogged=FFAC75 2. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biological Materials of Human Origin (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff 5. Recommendation Rec(2016)8 of the Committee of Ministers to Member States on the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f
Embryos, Stem Cells, and Cloning	European Commission: European Group on Ethics in Science and New Technologies: http://ec.europa.eu//research/ege/index.cfm	1. Statements by the Commission Re: Article 6 (2006): http://www.uv.es/operuv/docs_7pm/FP7ECStatementsComm_Ethical.pdf 2. Statement of the Commission Related to Research Activities Involving Human Embryonic Stem Cells (2013): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF		1. Commission Staff Working Paper Report on Human Embryonic Stem Cell Research (2003): https://ec.europa.eu/research/press/2003/pdf/sec2003-441report_en.pdf 2. Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): http://bookshop.europa.eu/ga/recommendations-on-the-ethical-review-of-hesc-fp7-research-projects-pbKAAJ07022/downloads/KA-AJ-07-022-EN-C/KAAJ07022ENC_002.pdf;pgid=y8dIS7GUWMdSR0EAlMEUUsWb0000dz-kvfzb;sid=Iexx3tq0IOFxyokBytfvebiRJj93DZfXP54=?FileName=KAAJ07022ENC_002.pdf&SKU=KAAJ07022ENC_PDF&CatalogueNumber=KA-AJ-07-022-EN-C
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol on Prohibition of Human Cloning, ETS No. 168 (1998): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=7&DF=9/15/2008&CL=ENG		Statement on Genome Editing Technologies by the Committee on Bioethics (2015): https://rm.coe.int/168049034a

Country	Key Organizations	Legislation	Regulations	Guidelines
Armenia For an overview of human subject protections in Armenia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 1: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf Note: All websites and documents are in Armenian.				
Drugs, Biologics, and Devices	1. Drug and Medical Technology Agency: http://www.pharm.am/ 2. Ethics Committee of the Ministry of Health	1. Law of the Republic of Armenia of May 4, 1996: About Medical Aid, The Maintenance of the Population, Article 21: http://www.arlis.am/DocumentView.aspx?DocID=71619 2. Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia: http://www.arlis.am/DocumentView.aspx?docID=9154		
Human Biological Materials	Ethical Committee of the National Center for AIDS Prevention: http://www.armaids.am/main/index.php?lng=1	RA Law on Prevention of Disease Caused by HIV (2012): http://www.arlis.am/DocumentView.aspx?DocID=78616		Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013)
Austria For an overview of human subject protections in Austria, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Austria%20definitive.pdf				
General	1. Ministry of Health (German): http://www.bmg.gv.at 2. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 3. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. University Act (2011): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf 2. Hospitals Act (2014) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True	Regulation on Leading Ethics Committees (2004) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003352&ShowPrintPreview=True	Bioethics Commission: 1. Codification of Legislation on Medical Research (2011) 2. Research on Persons without the Capacity to Consent (2013) Access: http://www.bundeskanzleramt.at/site/4070/default.aspx
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health (German): http://www.bmg.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 3. Austrian Federal Office for Safety in Health Care: http://www.basg.gv.at/en/basg-austrian-federal-office-for-safety-in-health-care/	Austrian Drug Law (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True		Various (German): http://www.basg.at/arzneimittel/vor-der-zulassung/klinische-pruefungen/
	Devices			
	1. Ministry of Health (German):	Medical Devices Act (2014)		Various (German):

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.bmg.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 3. Austrian Federal Office for Safety in Health Care: http://www.basg.gv.at/en/basg-austrian-federal-office-for-safety-in-health-care/	(German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003		http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/
Research Injury	1. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 2. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	1. Austrian Drug Law, Article 32 (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True 2. Austrian Medical Devices Law, Article 47 (2017) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003&ShowPrintPreview=True		
Privacy/Data Protection Note: The Austrian states also have privacy/data protection laws	Austrian Data Protection Authority: https://www.dsb.gv.at/DesktopDefault.aspx?alias=dsken	Federal Act Concerning the Protection of Personal Data (2014): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf		
Human Biological Materials	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. Law on Safety of Blood (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011145&ShowPrintPreview=True 2. Law on Quality and Safety of Human Tissue and Cells (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True	Regulation on Tissue Banks (2014) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005848&ShowPrintPreview=True	Bioethics Commission: 1. Opinion of the Bioethics Commission at the Federal Chancellery: Biobanks for Medical Research (2007) 2. Biobanks for Medical Research - Amendments to the Bioethics Commission Report of May 2007 (2011) Access: http://www.bundeskanzleramt.at/site/4070/default.aspx
Genetic Research	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575	Gene Technology Act (2012) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen		

Country	Key Organizations	Legislation	Regulations	Guidelines
	/default.aspx	&Gesetzesnummer=10010826&ShowPrintPreview=True		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Reproductive Medicine Act (2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True		Bioethics Commission: 1. Stem Cell Research in the Context of the EU's Sixth Framework Programme Research (2002) 2. Research on Human Embryonic Stem Cells (2009) (German): http://www.bundeskanzleramt.at/DocView.axd?CobId=34240
Belarus For an overview of human subject protections in Belarus, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 3: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 25 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Articles 40, 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Ordinance No. 274 on Establishing the National Bioethics Committee (2006) 2. Decree No. No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html	MOH: 1. Code of Medical Ethics (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37726.html 2. Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000) (Russian): http://www.levonevski.net/pravo/norm2009/num35/d35896/index.html 3. Methodological Guidelines of Health Ministry (2000)
Drugs, Biologics, and Devices	*Drugs* 1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. State Pharmacological Committee 3. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	1. Law on Drugs, Articles 15,16 (2009) (Russian): http://pravo.by/webnpa/text.asp?RN=h10600161 2. Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html 2. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html 3. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Country	Key Organizations	Legislation	Regulations	Guidelines
			4. Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)	
	Devices			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html 2. Decree No. 216 on Certain Aspects of Clinical Trials of Medical Devices (2008) (Russian): http://86.57.250.247/data/pravo/ipb_prikazmz/N216_2008.htm	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html
Privacy/Data Protection	1. Ministry of Health: http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 28 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Article 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435		
Human Biological Materials	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee 3. State Service of Forensic Medicine (SSFM)	Law on Health Care System, Articles 40 and 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: Ordinance No. 111 on Further Development of National Pathology Service (1993) (Russian): http://86.57.250.247/data/pravo/ipb_prikaznew/N111_1993(1994).doc SSFM: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)	
Belgium For an overview of human subject protections in Belgium, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Belgium%20definitive.pdf				
General	Belgium Advisory Committee on Bioethics (BACB):	Law Relating to Experimentation on Humans		BACB: 1. Opinion No. 13: Regarding

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.health.belgium.be/en	(2004): http://www.erasme.ulb.ac.be/page.asp?id=11365&langue=EN		Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004) 3. Opinion 36: Ethical Evaluation of Research in Certain Areas of the Humanities (French and Dutch) (2006) 4. Opinion No. 40: Scope of the Law Relating to Experimentation on Humans (French and Dutch) (2007) 5. Opinion No. 51: Publication of the Results of Human Experimentation (2012) Access: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics
Drugs, Biologics, and Devices	Medicines Directorate-General: http://www.health.belgium.be/eportal		1. Royal Decree of September 27, 1994 2. Royal Decree of June 30, 2004 Determining the Implementation Measures of the Law 3. Royal Decree of June 30, 2004 Modifying the Royal Decree of June 6, 1960 4. Royal Decree of July 15, 2004 Determining Payments for Ethical Opinions or Authorization for the Conduct of a Clinical Trial or Experiment 5. Application of the Law of May 7, 2004 Relating to Experiments on Human Volunteers who Participate in Phase I Trials (2004) 6. Explanations Concerning the Submission of a Request for an Ethical Opinion or Authorization for the Conduct of a Clinical Trial (2004)	
Research Injury		Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	Commission for the Protection of Privacy: http://www.privacycommission.be/	Privacy Act: http://www.privacycommission.be/en/privacy-act	Decree of February 13, 2001 Implementing the Law of December 8, 1999: http://www.privacycommission.be/sites/privacycommission/files/documents/Royal_Decree_2001.pdf	
Human Biological Materials	1. Belgian Advisory Committee on Bioethics: http://www.health.belgium.be/en 2. Superior Health Council (CSS): http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/index.htm 3. Federal Public Service: www.health.fgov.be	1. Royal Decree (1987) Regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors 2. Royal Decree (1997) Regarding the Removal and Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) 4. 2007 Amendment		Belgian Advisory Committee on Bioethics: Opinion No. 54: Post Mortem Removal of Human Body Material for Human Medical Applications or for Scientific Research Purposes (2012): http://www.health.belgium.be/en/opinion-no-54-post-mortem-removal-human-body-material-human-medical-applications-or-scientific CSS: Various: http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/domains/cellstissuesorgans/index.htm#.Viovr88XQ0U
Embryos, Stem Cells, and Cloning	1. Belgian Advisory Committee on Bioethics: https://www.health.belgium.be/en/belgian-advisory-committee-bioethics 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro: http://health.belgium.be/eportal/Healthcare/Consultativebodies/Commissions/Embryoinvitro/19076630?ie2Term=research&ie2section=83	1. Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15/02/1999) 2. Act on Research on Embryos in Vitro (2003): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Belgium/page.aspx/164 3. Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007) (French): http://www.staatsbladclip.be/lois/2007/07/17/loi-2007023090.html		Belgian Advisory Committee on Bioethics: Opinion No. 52: Use of Human Tissues and Cells in Reproductive Medicine (2012): http://www.health.belgium.be/en/opinion-no-52-use-human-tissues-and-cells-reproductive-medicine

Country	Key Organizations	Legislation	Regulations	Guidelines
Bosnia and Herzegovina Note: All websites and documents are in Bosnian.				
General		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (2007): 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007) 3. Law on Health Protection, MoH Republic of Srpska (2015): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20zdravstvenoj%20zastiti%20sa%20izmjenama%20106-99%20%2044-15.pdf 4. Law on Health Protection, MoH Federation of Bosnia and Herzegovina, No 46/10: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-zdravstvenoj-zastiti		
Drugs, Biologics, and Devices	*Federation of Bosnia and Herzegovina*			
	1. Ministry of Health: http://www.fmoh.gov.ba/ 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of the Law on Drugs No. 29/05: http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_29-05.pdf 3. Law on Drugs Federation of Bosnia and Herzegovina, No 109/2012: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-fbih	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf 4. Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016): http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Republic of Srpska			
	1. Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of Law on Drugs No. 34/08: http://www.almbih.gov.ba/_doc/regulative/rs/ID_Zakona_o_lijekovima_34_08.pdf	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf 4. Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016): http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf	
Research Injury	*Federation of Bosnia and Herzegovina*			
	Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Medicinal Products and Medicinal Devices Act, Articles 52 and 116 (2008): http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
	Republic of Srpska			
	Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	1. Medicinal Products and Medicinal Devices Act, Article 52 and 116 2. Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 106/09: http://www.farmaceutska-komora.org/images/stories/5Zakon_o_zdravstvenoj_zastiti.pdf	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
Privacy/Data	Personal Data Protection Agency of	1. Law on the Protection of	Regulation on the Manner of	

Country	Key Organizations	Legislation	Regulations	Guidelines
Protection	Bosnia and Herzegovina: http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	Personal Data in Bosnia and Herzegovina (2005): http://www.azlp.gov.ba/propisi/Default.aspx?id=5&langTag=en-US&pageIndex=1 2. Law on Amendments to the Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11 (2011): http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009): http://www.azlp.gov.ba/propisi/default.aspx?id=1321&langTag=bs-BA	
Embryos, Stem Cells and Cloning	*Federation of Bosnia and Herzegovina*			
	Ministry of Health: http://www.fmoh.gov.ba/	1. Law on Transplantation of Organs and Tissues, Official Gazette of Bosnia and Herzegovina No. 75/09: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-transplantaciji-organa-i-tkiva-u-svrhu-lijecenja 2. Law on Blood and Blood Products, Official Gazette of Bosnia and Herzegovina No. 09/10: http://www.fbihvlada.gov.ba/bosanski/zakoni/2010/zakoni/8bos.htm		
	Republic of Srpska			
	Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	1. Law on Transplantation of Organs (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20organa.pdf 2. Law on Transplantation of human tissues and cells (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20tkiva%20i%20celija.pdf		Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which can be Transmitted by Transplantation (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba_%d0%be_%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%b8%d0%bc%d0%b0_%d0%b7%d0%b0_%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5_%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b0_%d1%99%d1%83%d0%b4%d1

Country	Key Organizations	Legislation	Regulations	Guidelines
				%81%d0%ba%d0%b8%d1%85_%d0%be%d1%80%d0%b3%d0%b0%d0%bd%d0%b0_64_10.pdf
Bulgaria				
General	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Amendment SG. 18/25, Article 29 (2015) (Bulgarian): http://www.parliament.bg/bg/const 2. Oviedo Convention on Human Rights and Biomedicine (2003) 3. Law Ratifying the Additional Protocol on Biomedical Research (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf 4. Medicinal Products in Human Medicine Act (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf 5. Healthcare Act, Articles 197-206 (2017) (Bulgarian): http://www.lex.bg/laws/ldoc%20/2135489147		
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Healthcare (MOH) (Bulgarian): http://www.mh.government.bg/ 2. Bulgarian Drug Agency (BDA): http://www.bda.bg/en/	Medicinal Products in Human Medicine Act, Chapter 4 (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf	Regulation No. 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice (2012) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/naredba31.pdf	
	Devices			
	Bulgarian Drug Agency (BDA): http://www.bda.bg/en/	Medical Devices Act (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZMI_en_20160308.pdf	Ordinance No. 10 of 2008 on the Documents Required from the Principal/Coordinating Investigator or Sponsor for Obtaining an Ethics Committee Statement and on the Procedure	Various: http://www.bda.bg/en/114-information-for-companies-section/medical-devices-category

Country	Key Organizations	Legislation	Regulations	Guidelines
			for Safety Monitoring of Medical Devices During Clinical Investigations and Assessment of the Clinical Data Collected During such Investigations (2010): http://www.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf	
Research Injury	Bulgarian Drug Agency (BDA): http://www.bda.bg/en/	Medicinal Products in Human Medicine Act, Chapter 4, Articles 91 and 92 (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf	Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/naredba31.pdf	
Privacy/Data Protection	1. Bulgarian Commission for Personal Data Protection: https://www.cpdp.bg/en/index.php?p=rubric&aid=2 2. Ombudsman: www.ombudsman.bg	Law for Protection of Personal Data (2016): https://www.cpdp.bg/en/index.php?p=element&aid=373		
Human Biological Materials:	1. Executive Agency for Transplantation (Bulgarian): http://www2.bgtransplant.bg/bg 2. Council of Ministers, Ethics Committee for Transplantation	1. Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf 2. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/docs/Zakoni_ZTOTK.doc	Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells (Bulgarian): http://www2.bgtransplant.bg/sites/default/files/docs/naredbi/Naredba_no13_ot_04_april_2007_g.rtf	
Embryos, Stem Cells, and Cloning	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) (Bulgarian): https://www.mh.government.bg/me		

Country	Key Organizations	Legislation	Regulations	Guidelines
		dia/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf 2. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/docs/Zakoni_ZTOTK.doc		
Croatia Note: All websites and documents are in Croatian. For an overview of human subject protections standards in Croatia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Croatia%20definitive%20Updated.pdf				
General		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Patient Protection Act, Article 20 (2008): http://www.zakon.hr/z/255/Zakon-o-za%C5%A1titi-prava-pacijenata		
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health: https://zdravlje.gov.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/	1. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html 2. Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html	Ordinance on Clinical Trials and Good Clinical Practice (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
	Devices			
	1. Ministry of Health: https://zdravlje.gov.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/	Medical Devices Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html		
Research Injury	1. Agency for Medicinal Products and Medical Devices of Croatia: http://www.halmed.hr/	1. Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/wp-	Ordnance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8. and	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health: https://zdravlje.gov.hr/ 3. Croatian Health Insurance Fund: http://www.hzzo.hr/en/	content/uploads/2013/10/ZOZO_PROCISCENI_TEKSTv2.pdf?6d8ad4 2. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html 3. Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html	8.2.5 (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
Privacy/Data Protection	Croatian Personal Data Protection Agency: http://www.azop.hr/	1. Personal Data Protection Act (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_09_106_2300.html 2. Law about the Right to Access Personal Information (2015): http://www.zakon.hr/z/126/Zakon-o-pravu-na-pristup-informacijama		
Human Biological Materials	Ministry of Health: https://zdravlje.gov.hr/	1. Law about Blood and Blood Products (2006): http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html 2. Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html 3. Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html 4. Law on Transplantation of Human Organs for the Purpose of Treatment (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3071.html	Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354	
Embryos, Stem Cells, and Cloning	Ministry of Health: https://zdravlje.gov.hr/	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and	Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing,	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Medicine, on the Prohibition of Cloning Human Beings (2003): http://zakon.poslovna.hr/public/Konvencija-o-zastiti-ljudskih-prava-i-dostojanstva-ljudskog-bica-u-pogledu-primjene-biologije-i-medicine-u-vezi-presadivanja-organa-i-tkiva-ljudskog-porijekla/243337/zakoni.aspx 2. Medical Fertilization Act, Article 32: (2012): http://www.hzzo-net.hr/dload/zakoni/20_01.pdf 3. Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html	Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354	
Cyprus For an overview of human subject protections in Cyprus, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Cyprus%20definitive%20Updated.pdf				
General		1. Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine 2. The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/745717D26F068582C2257CCA003B350F/$file/Patients%20Rights%20Law-English%20translation.pdf		
Drugs, Biologics, and Devices	1. Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/Moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument 2. Ministry of Health, National Bioethics Committee: http://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index_en/index_en?OpenDocument	Law for Good Clinical Practice (2004) (Greek): http://www.moh.gov.cy/Moh/phs/phs.nsf/All/9C064264122B82BEC22572FA003433A5/$file/%CE%9A.%CE%94.%CE%A0.%20452%20%CF%84%CE%BF%CF%85%202004.pdf?OpenElement		
Research Injury	Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument	Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice) No. 452/2004 Article 11 (8) (Greek): http://www.moh.gov.cy/Moh/phs/ph		

Country	Key Organizations	Legislation	Regulations	Guidelines
		s.nsf/All/9C064264122B82BEC22572FA003433A5/$file/%CE%9A.%CE%94.%CE%A0.%20452%20%CF%84%CE%BF%CF%85%202004.pdf?OpenElement		
Privacy/Data Protection	Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument	1. Processing of Personal Data (Protection of Individuals) Law of 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf 2. 2003 Amendments: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37(I)-2003_en.pdf		
Embryos, Stem Cells, and Cloning		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)		
Czech Republic For an overview of human subject protections in the Czech Republic, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Czech%20definitive%20Updated.pdf				
General	Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz	1. Oviedo Convention on Human Rights and Biomedicine (2001) 2. Act No. 130/2002 Collection on Research and Development Support, as Amended 3. Act No. 372/2011 on Healthcare Services 4. Act. No. 373/2011 on Specific Healthcare Services		
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lr	Act No. 378/2007 Collection on Pharmaceuticals	MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	SUKL: Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1

Country	Key Organizations	Legislation	Regulations	Guidelines
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	Devices			
	State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	1. Act No 268/2014 Coll., on Medical Devices and on Amendment to Act. 634/2004 Coll., on Administrative Fees 2. Decree No 62/2015 Coll. Implementing Certain Provisions of the Act on Medical Devices	Various: http://www.sukl.cz/medical-devices?highlightWords=501%2F2000	Various: http://www.sukl.cz/medical-devices-guidelines
Research Injury		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001) 2. Law No. 89/2012 Coll. Civil Code: http://www.czechlegislation.com/en/89-2012-sb		
Privacy/Data Protection	Office for Personal Data Protection: https://www.uoou.cz/en/	Act No. 101/2000 Coll., On Protection of Personal Data and Amending Certain Laws, As Amended (2015) (Czech): http://www.uoou.cz/uoou.aspx?menu=4&submenu=5	Position No. 3/2004 Personal Data Processing in the Context of Clinical Testing of Drugs and Other Medical Substances	
Embryos, Stem Cells, and Cloning	1. Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1 2. Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb. (Coll.)		
Denmark For an overview of human subject protections in Denmark, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Denmark%20definitive.pdf				
General	National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english	Act No. 1083 on Research Ethics Review of Health Research Projects (2017) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=192671 2013 version (English): http://www.nvk.dk/english/act-on-research	Executive Order No. 1464 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2016) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=185233	Guidelines about Notification (Checklist) (2017): http://www.nvk.dk/forsker/forskervejledning
Drugs, Biologics, and Devices	Danish Medicines Agency: https://laegemiddelstyrelsen.dk/en/	1. Act No. 506 on Medicinal Products (2013) (Danish):	1. Executive Order No. 295 on Clinical Trials of Medicinal	Guidelines for Applications for Authorisation of Clinical Trials of Medical

Country	Key Organizations	Legislation	Regulations	Guidelines
		https://www.retsinformation.dk/forms/r0710.aspx?id=146586 2. Act No. 620 on Clinical trials on Medical Products No. 620 (2016) (Danish): https://www.retsinformation.dk/Forms/r0710.aspx?id=180117	Products on Humans (2006): https://www.retsinformation.dk/Forms/R0710.aspx?id=9891 2. Executive Order No. 1464 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2016) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=185233	Products in Humans (2017): https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans/
Research Injury	Patient Compensation Association: http://pebl.dk/en.aspx	1. Liability for Damages Act (2007): http://pebl.dk/Patientskader/Love-og-regler/Lov-om-klage-og-erstatningsadgang/Behandlingsskader 2. Act No. 1022 on the Right to Complain and Receive Compensation within the Health Service (2017): https://www.retsinformation.dk/Forms/R0710.aspx?id=192623		
Privacy/Data Protection	Danish Data Protection Agency (DPA): https://www.datatilsynet.dk/english/the-danish-data-protection-agency/introduction-to-the-danish-data-protection-agency/	Act No. 429 on Processing of Personal Data (2007): https://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/read-the-act-on-processing-of-personal-data/compiled-version-of-the-act-on-processing-of-personal-data/	Executive Order No. 1188 on Health Law, Chapter 9 (2016) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=183932#idc101cee1-c9c0-4880-ac97-586a56134f56	
Human Biological Materials	National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english	1. Executive Order No. 1188 on Health Law (2016) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=183932 2. Act No. 1083 on Research Ethics Review of Health Research Projects (2017) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=192671		1. Biobanks are Covered by the Act on Processing of Personal Data (2010): https://www.datatilsynet.dk/english/health-research-and-statistics-projects/biobanks-are-covered-by-the-act-on-prcessing-of-personal-data/ 2. Guidelines on the Use of Biological Material in Health Research Projects (2017) (Danish): http://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat
Genetic Research	National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english	Act No. 1083 on Research Ethics Review of Health Research Projects (2017) (Danish):		Guidelines on Health Research Projects Involving Genome Research (2017) (Danish): http://www.nvk.dk/emner/genomer/vejledning-om-genomer

Country	Key Organizations	Legislation	Regulations	Guidelines
		https://www.retsinformation.dk/Forms/R0710.aspx?id=192671 2013 version (English): http://www.nvk.dk/english/act-on-research		
Embryos, Stem Cells, and Cloning	Danish Council of Ethics: http://www.etiskraad.dk/english	Act No. 440 on Danish Council of Ethics (2004) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=9909	Executive Order No. 93 on Medically Assisted Procreation (2015) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=167647	
Estonia For an overview of human subject protections in Estonia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Estonia%20definitive.pdf				
General	Estonian Council on Bioethics: http://www.eetikakeskus.ut.ee/en	1. Oviedo Convention on Human Rights and Biomedicine (2002) 2. Constitution of the Republic of Estonia, Paragraph 18 (2016): https://www.riigiteataja.ee/en/eli/521052015001/consolide		Code of Ethics of Estonian Scientists: http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf
Drugs, Biologics, and Devices	*Drugs:* 1. State Agency of Medicines: http://www.sam.ee/en/clinical-trials-medicinal-products-estonia 2. Minister of Social Affairs (MSA): https://www.sm.ee/en	Medicinal Products Act, Chapter 5 (2015): https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current	MSA: 1. 1 RTL 2005, 22, 298: Rules of Procedure of Medical Ethics Committee for Clinical Trials, a List of Data to be Submitted for Obtaining Approval, Procedure for Adoption of Resolutions and Format of Application for Obtaining Approval (2005): https://www.riigiteataja.ee/en/eli/502052017001/consolide 2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): https://www.riigiteataja.ee/en/eli/502052017002/consolide	
	Devices: Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html	Medical Devices Act (2004): https://www.riigiteataja.ee/en/eli/ee/509012015001/consolide/current	Regulation No 86: 2010 of the Minister of Social Affairs on the Conditions and Procedures for the Clinical Investigation of Medical Devices	
Research Injury	1. Minister of Social Affairs (MSA): https://www.sm.ee/en 2. Estonian Health Insurance Fund:	Medicinal Products Act, Section 90: https://www.riigiteataja.ee/en/eli/ee/	Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation	

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.haigekassa.ee/en	525112013005/consolide/current	No. 23 of the Minister of Social Affairs of (2005): http://www.sam.ee/en/clinical-trials-medicinal-products-estonia	
Privacy/Data Protection	Estonian Data Protection Inspectorate: http://www.aki.ee/en/inspectorate	Personal Data Protection Act (2016): https://www.riigiteataja.ee/en/eli/ee/512112013011/consolide/current		
Genetic Research		Human Genes Research Act (RT I 2000, 104, 685) (2014): https://www.riigiteataja.ee/en/eli/ee/518062014005/consolide		
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) (Estonian): https://www.riigiteataja.ee/akt/78569 2. Artificial Insemination and Embryo Protection Act, RT I 1997, 51, 824 (2011): https://www.riigiteataja.ee/en/eli/ee/530102013057/consolide/current		
Finland				
General	1. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi/en/frontpage 2. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 3. Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en	Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016: http://www.finlex.fi/en/laki/kaannokset/1999/en19990986.pdf	TUKIJA: 1. Report on Children in Medical Research (2003) 2. Operating Procedures of the National Committee on Medical Research Ethics (2017) Access*:* http://tukija.fi/en/publications1
Drugs, Biologics, and Devices	*Drugs*			
	1. Finnish Medicines Agency (FIMEA): http://www.fimea.fi/frontpage 2. Ministry of Social Affairs and Health (MSAH): http://stm.fi/en/frontpage 3. National Committee on Medical	Medicines Act No. 395/1987 (Finnish): http://www.finlex.fi/fi/laki/smur/1987/19870395	1. Decree on Clinical Trials on Medicinal Products No. 841/2010 2. Other Decrees: http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla FIMEA:	TUKIJA: Templates for Clinical Trial Information Leaflet and Consent Form (2016) Access*:* http://tukija.fi/en/publications1

Country	Key Organizations	Legislation	Regulations	Guidelines
	Research Ethics (TUKIJA): http://www.tukija.fi/en		Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012 (Finnish): http://www.fimea.fi/download/22302_Maarays_2-2012_kliiniset_laaketutkimukset.pdf	
	Devices			
	National Supervisory Authority for Welfare and Health (VALVIRA): http://www.valvira.fi/en/licensing/medical_devices	Medical Devices Act No. 629/2010 (Finnish): http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf EU Regulations: Medical Device Regulation 2017/745: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN In Vitro Diagnostic Medical Devices Regulation 2017/746: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN	1. Decree (Decision) on Clinical Investigations (2010) (Finnish): http://www.finlex.fi/data/normit/39644-maarays_3_2010_kliininen_laitetutkimus.pdf 2. Various: http://www.valvira.fi/en/licensing/medical_devices/legislation	
Research Injury	1. Finnish Patient Insurance Centre (Finnish): http://www.potilasvakuutuskeskus.fi/www/page/pvk_www_2181 2. Pharmaceutical Injuries Insurance http://www.laakevahinko.fi/in-english/	Patient Injuries Act No. 585/1986 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1986/19860585		Pharmaceutical Injuries Insurance: General Terms and Conditions (2017): http://www.laakevahinko.fi/in-english/terms-and-conditions/
Social-Behavioral Research	Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en/index.html			Ethical Principles of Research in the Humanities and Social and Behavioural Sciences and Proposals for Ethical Review (2009): http://www.tenk.fi/sites/tenk.fi/files/ethicalprinciples.pdf
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	Personal Data Act No. 523/1999 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1999/19990523		
Human Biological Materials	National Supervisory Authority for Welfare and Health (Valvira): http://www.valvira.fi/web/en	1. Act on the Medical Use of Human Organs ,Tissues and Cells No. 101/2001 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2001/20010101 2. Law on Biobanks, No	1. Decree on Consent for Biobank No. 643/2013 (Finnish and Swedish): http://www.finlex.fi/fi/laki/alkup/2013/20130643 2. Decree on information on Biobank No. 649/2013 (Finish	

Country	Key Organizations	Legislation	Regulations	Guidelines
		688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688	and Swedish): http://www.finlex.fi/fi/laki/alkup/2013/20130649	
Genetic Research	1. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 2. Board for Gene Technology http://www.geenitekniikanlautakunta.fi/en	1. Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 2. Gene Technology Act No. 377/1995: https://www.finlex.fi/fi/laki/ajantasa/1995/19950377		
Embryos, Stem Cells, and Cloning	1. National Supervisory Authority for Welfare and Health: http://www.valvira.fi/web/en 2. National Committee on Medical Research Ethics (TUKIJA) http://www.tukija.fi/en 3. Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en/index.html 4. National Advisory Board on Social Welfare and Health Care Ethics (ETENE): http://www.etene.fi/en	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Medical Research Act No. 488/1999 (amended 295/2004, 749/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 3. Act on Assisted Fertility Treatments No. 1237/2006: http://www.finlex.fi/fi/laki/ajantasa/2006/20061237 4. Criminal Code of Finland (39/1889), Chapter 22, Section 4: https://www.finlex.fi/en/laki/kaannokset/1889/en18890039.pdf		TUKIJA: Report on Stem Cells, Cloning, and Research (2005): http://tukija.fi/documents/1481661/1546647/2005cells.pdf/c14b7dd0-11b4-428d-bdae-539566ade614

France For an overview of human subject protections in France, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/France%20definitive%20Updated.pdf				
General	1. Ministry of Social affairs and Health (French): http://www.sante.gouv.fr/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr/en 3. National Commission for Informatics and Freedoms (CNIL): http://www.cnil.fr/english/the-cnil/	1. Law No. 2012-300 of 5 March 2012 on Research Involving Human Persons: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587 2. Law No. 2011-814 of 7 July 2011 on Bioethics	Public Health Code Articles R1121-1 and subsequent sections: http://legifrance.gouv.fr/	CCNE: Various: http://www.ccne-ethique.fr/en/type_publication/avis

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. National Health Products Safety Agency (ANSM): http://ansm.sante.fr/	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/	Decision on Good Clinical Practices: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000819256	CCNE: 1. Phase I Trials in Cancer (2002) 2. Transposition into French Law of the European Directive Relating to Clinical Trials on Medicinal Products: A New Ethical Framework for Human Research (2003)
Social-Behavioral Research	National Consultative Ethics Committee			Opinion on the Ethics of Research in the Sciences of Human Behavior No. 38 (1993): http://www.ccne-ethique.fr/en/publications/opinion-ethics-research-sciences-human-behaviour#.WNkybNfytEY
Privacy/Data Protection	1. National Commission of Information and Liberty (CNIL): http://www.cnil.fr/english/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr	1. Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data 2. Law No. 2016-1321 of 7 October 2016 for a Numeric Republic: https://www.legifrance.gouv.fr/affichLoiPubliee.do?idDocument=JORFDOLE000031589829&type=general&legislature=14	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)
Human Biological Materials	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr 2. Ministry of Higher Education, Research, and Innovation: http://www.enseignementsup-recherche.gouv.fr/	1. Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/ 2. Public Health Code Articles L1241-1 and following sections: (2010) (French): http://www.legifrance.gouv.fr/initRechCodeArticle.do		CCNE: 1. Umbilical Cord Blood Banks for Autologous Use for Research (2002) 2. Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks," "Biolibraries" (2003)
Genetic Research	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr 2. Biomedicine Agency (French): http://www.enseignementsup-recherche.gouv.fr/	Civil Code Articles 16-10 to 16-13 (French): http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006		1. Ethical Issues in Connection with the Development of Foetal Genetic Testing on Maternal Blood (2013) 2. Ethical Reflection on Developments in Genetic Testing in Connection with Very High Throughput Human DNA Sequencing (2016): http://www.ccne-ethique.fr/en/type_publication/avis

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr 2. Biomedicine Agency (French): http://www.enseignementsup-recherche.gouv.fr/	Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027811435&dateTexte=&categorieLien=id	Decree No. 2015-155 of 11 February, 2015: Public Health Code on Research on Embryos Article R2151-1 and Following Sections: http://legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000030233469&idSectionTA=LEGISCTA000006190409&cidTexte=LEGITEXT000006072665&dateTexte=20151015	1. Commercialization of Human Stem Cells and Other Cell Lines (2006) 2. Opinion on the Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010) Access: http://www.ccne-ethique.fr/en/type_publication/avis
Georgia For an overview of human subject protections in Georgia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 4: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	Bioethics and Health Law Studies Society: http://www.patientsrights.ge/index.php?page=385&lang=geo	1. Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001) 2. Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010) 3. Law on Health Care, Chapter XIX (2017): https://matsne.gov.ge/en/document/view/29980?publication=37		
Drugs, Biologics, and Devices	State Regulation Agency for Medical Activities (LEPL) of the Ministry of Labor, Health, and Social Affairs: http://www.moh.gov.ge/index.php?sec_id=10&lang_id=ENG	Law on Medicines and Pharmaceutical Activities No. 659 and 1586 (2015): https://matsne.gov.ge/en/document/view/29836?impose=translateEn	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005) (Georgian): http://rama.moh.gov.ge/res/docs/20160809105943176.pdf	Order of Health Minister about Implementation of "ICH: E6 Good Clinical Practice: Consolidated Guidance" (1996) including WMA: Declaration of Helsinki (2010) (Georgian): http://rama.moh.gov.ge/res/docs/9539N233.pdf
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	Office of the Personal Data Protection Inspector: https://personaldata.ge/en/data-protection-day-event-2014/177	Law on Data Protection (2017): https://matsne.gov.ge/en/document/view/1561437?publication=9		
Embryos, Stem Cells, and Cloning		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning ETS No. 168 (2001)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law on Health Care, Article 142 (2017): https://matsne.gov.ge/en/document/view/29980?publication=37		
Germany For an overview of human subject protections in Germany, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Germany%20definitive%20Updated.pdf				
General	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/weitere-sprachen/english/german-medical-association/ 2. Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/ 3. Permanent Working Party of Research Ethics Committees in Germany (German): http://www.ak-med-ethik-komm.de/ 4. German Ethics Council: http://www.ethikrat.org/?set_language=en 5. Federal Ministry of Health (BMG): http://www.bundesgesundheitsministerium.de/en/en.html 6. German Research Foundation (DFG), Permanent Senate Commission on Key Questions in Clinical Research (SCCR): http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/clinical_research/index.html			BÄK: (Model) Professional Code for Physicians in Germany, Article 15 (2011) (German): http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html4 3. Federal Ministry of Health (BMG): http://www.bmg.bund.de/ministerium/english-version.html	Medicinal Products Act (2017) (German): http://www.gesetze-im-internet.de/amg_1976/ *2016 English version, without amendments:* Medicinal Products Act, Sixth Chapter (2016): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0925	1. Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987) 2. Second Promulgation on the Clinical Trial of Drugs in Human (1997) 3. Regulation on the Application of Good Clinical Practice in the Conduct of Clinical Trials of Medicinal Products for Human Use (2012) (German): http://www.gesetze-im-	BfArM and PEI: Third Notification on the Clinical Trials of Medicinal Products for Humans (2006): http://www.pei.de/SharedDocs/Downloads/EN/pu/clinical-trials/3rd-notification-clinical-trials-2006-08-10.pdf?__blob=publicationFile&v=1

Country	Key Organizations	Legislation	Regulations	Guidelines
			internet.de/gcp-v/	
	Devices			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html4	Act on Medical Devices, Fourth Chapter (2017) (German): http://www.gesetze-im-internet.de/mpg/	Regulation on Clinical Trials of Medical Devices (2014) http://www.gesetze-im-internet.de/mpkpv/	
Clinical Trials Registry	German Clinical Trials Register (DRKS): https://www.drks.de/drks_web/setLocale_EN.do			FAQs: https://www.drks.de/drks_web/navigate.do?navigationId=faq&messageEN=FAQ
Research Injury		1. Medicinal Products Act, Section 40(3) (2016): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0926 2. Act on Medical Devices, Section 20(3) (2017) (German): http://www.gesetze-im-internet.de/mpg/__20.html		
Privacy/Data Protection Note: The 16 German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html	Federal Commissioner for Data Protection and Freedom of Information (German): https://www.bfdi.bund.de/	Federal Data Protection Act (2017) (German): https://www.gesetze-im-internet.de/bdsg_1990/ *2009 English version:* Federal Data Protection Act: http://www.gesetze-im-internet.de/englisch_bdsg/		
Human Biological Materials		1. Act of Quality and Security of Human Tissue and Cells (2007) (German): http://www.gesetze-im-internet.de/gewebeg/ 2. Transfusion Law (2017) (German): http://www.gesetze-im-internet.de/tfg/ 3. Transplantation Law (2017) (German): http://www.gesetze-im-internet.de/tpg/		
	German Ethics Council: http://www.ethikrat.org/?set_language=en			Opinion on Human Biobanks for Research (2010): http://www.ethikrat.org/files/der_opinion_hum

Country	Key Organizations	Legislation	Regulations	Guidelines
				an-biobanks.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Opinion on the (Re)Use of Human Body Material for Medical Research Purposes (2003) (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf
	German Society of Surgery (DGCH): http://www.dgch.de/index.php?id=118			DGCH Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production (German): http://www.dgch.de/fileadmin/media/pdf/servicemeldungen/069_Gewebegesetz_GFP-Leitfaden_der_DGCH_fuer_die_Gewinnung_menschlicher_Gewebe.pdf
Genetic Research		1. Embryo Protection Act (2011) (German): http://www.gesetze-im-internet.de/eschg/ 2. Genetic Engineering Act (2017): http://www.gesetze-im-internet.de/gentg/		
	German Society of Human Genetics (GfH): http://www.gfhev.de/en/gfh/			1. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004): http://www.medgenetik.de/sonderdruck/en/DNA%20Banking_engl_060605.pdf 2. Position Paper of the German Society of Human Genetics (2007) (German): http://www.medgenetik.de/sonderdruck/2007_gfh_positionspapier.pdf
	German Research Foundation (DFG), Permanent Senate Commission on Genetic Research: http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/index.html			Statements: http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/publications/index.html
Embryos, Stem Cells, and Cloning	Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php	1. Embryo Protection Act (2011) (German): http://www.gesetze-im-internet.de/eschg/ 2. Stem Cell Act (2017) (German): http://www.gesetze-im-internet.de/stzg/	Regulation on the Central Ethics Committee for Stem Cell Research and the Competent Authority Pursuant to the Stem Cell Act (2017) (German): http://www.gesetze-im-internet.de/zesv/	

Country	Key Organizations	Legislation	Regulations	Guidelines
	German Ethics Council: http://www.ethikrat.org/?set_language=en *Previously:* National Ethics Council (2001-2008): http://www.ethikrat.org/archive/national-ethics-council			1. The Import of Human Embryonic Stem Cells (2001): http://www.ethikrat.org/files/Opinion_Import-HESC.pdf 2. Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): http://www.ethikrat.org/files/Opinion_Cloning.pdf 3. Should the Stem Cell Law be Amended? (2007): http://www.ethikrat.org/files/Opinion_Should_the_Stem_Cell_Law_be_amended.pdf 4. Human-Animal Mixtures in Research (2011): http://www.ethikrat.org/files/opinion-human-animal-mixtures-in-research.pdf 5. Stem Cell Research - New Challenges for the Ban on Cloning and Treatment of Artificially Created Germ Cells? (2014): http://www.ethikrat.org/files/recommendation-stem-cell-research.pdf 6. Germline Intervention in the Human Embryo (2017): http://www.ethikrat.org/publications/ad-hoc-recommendations/files/recommendation-germline-intervention-in-the-human-embryo.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Opinion on Stem Cell Research (2002) (German): http://www.zentrale-ethikkommission.de/downloads/Stammzell.pdf
	German Research Foundation (DFG): http://www.dfg.de/en/			Opinion on Stem Cell Research (2006) (German): http://www.dfg.de/download/pdf/dfg_magazin/forschungspolitik/stammzellforschung/stammzellforschung_deutschland_lang_0610.pdf
	Central Ethics Committee for Stem Cell Research (ZES): http://www.rki.de/EN/Content/Institute/Committees/StemCell/StemCell_content.html			
Greece				
General	National Bioethics Commission (NBC): http://www.bioethics.gr/			1. Research Ethics for Biological Sciences (2008): http://www.bioethics.gr/index.php/en/gnomes/

Country	Key Organizations	Legislation	Regulations	Guidelines
				86-research-ethics-in-biological-sciences 2. A Guide for Research Ethics Committees for Biological Research (2008): http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/guide.pdf 3. Conflict of Interest in Biomedical Research (2011): http://www.bioethics.gr/images/pdf/EKDOSEIS/OPINIONS_AND_REPORTS_2008-2013_EN.pdf 4. Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/index.php/en/gnomes/983-incidental-findings-in-research-and-clinical-practice
Drugs, Biologics, and Devices	1. National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home, then click on "EN" in upper left hand section for English 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Act 3418/2005 Code on Medical Ethics	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC 2. Ministerial Decision ΔΥΓ 3 α/79602/2007: Harmonization of the Greek Legislation with EU Legislation, according to the Directive 2005/28/EC	NBC: 1. Recommendation on Clinical Trials: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_clinical_trials_en.pdf 2. Control of Non-Invasive Clinical Trials for Drugs (2013) (Greek): http://www.bioethics.gr/index.php/en/gnomes/532-control-of-non-invasive-clinical-trials-for-drugs
Research Injury	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Act 3418/2005 Code on Medical Ethics	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC 2. Ministerial Decision ΔΥΓ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC:	
Privacy/Data Protection	Hellenic Data Protection Authority (Greek): http://www.dpa.gr/	1. Greek Constitution 1975/1986/2001 Article 9.1 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Laws 2819/2000 and 2915/2000) (Greek): http://www.dpa.gr/portal/page?_pageid=33,19052&_dad=portal&_schema=PORTAL 4. Act 3418/2005 Code on Medical Ethics		
Genetic Research	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000): http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-NOV2013-EN.PDF 4. Act 3418/2005 Code on Medical Ethics		1. Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/biobanks_recom_eng.pdf 2. Recommendation on the Collection and Use of Genetic Data: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_genetic_data_eng.pdf 3. Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/1_pd_pgd_opin_eng2.pdf 4. Opinion on Direct-To-Consumer Genetic Testing (2012): http://www.bioethics.gr/index.php/en/gnomes/91-direct-to-consumer-dtc-genetic-testing 5. Opinion on Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/images/pdf/GNOMES/OPINION_Incidental_Findings_FINAL_.pdf 6. Opinion on Advances in Human Genome Editing (2016): http://www.bioethics.gr/images/pdf/GNOMES/OPINION__gene%20editing_Final_EN.pdf
Embryos, Stem Cells, and Cloning	1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 2. National Authority for Medically Assisted Reproduction (Greek)	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Civil Code (Act 3089/2002, Medically Assisted Reproduction) 3. Act 3305/2005 Application		NBC: 1. Recommendation on the Use of Stem Cells in Biomedicine and Clinical Medicine 2. Recommendation on Human Reproductive Cloning 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment

Country	Key Organizations	Legislation	Regulations	Guidelines
		of Medically Assisted Reproduction		Access: http://www.bioethics.gr/index.php/gnomes
Hungary For an overview of human subject protections in Hungary, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Hungary%20definitve.pdf Note: All webpages and documents are in Hungarian.				
General	1. Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB): https://ett.aeek.hu/en/secretariat/	1. Fundamental Law of Hungary, Updated with the Fifth Amendment (2016), Articles II-III: http://njt.hu/cgi_bin/njt_doc.cgi?docid=140968.322953 2. Act CLIV of 1997 on Health Care, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193 3. Act VI. of 2002 on the Promulgation of the Oviedo Convention on Human Rights and Biomedicine: http://njt.hu/cgi_bin/njt_doc.cgi?docid=64201.264663 4. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research 5. Act C of 2012 on the Criminal Code, Chapter XVI Medical Procedures and Criminal Offenses Against the Order of Research, Sections 168-175	1. Decree 23/2002 (V. 9.) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam 2. Decree 35/2005 (VIII.26.) of the Minister of Health on the Clinical Trials of Investigational Medicinal Products for Human Use and on the Application of Good Clinical Practice: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM 3. Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam	
Drugs, Biologics, and Devices	*Drugs*			
	1. National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu 2. Medical Research Council, Ethics Clinical Pharmacology Ethics Committee (KFEB): https://ett.aeek.hu/kfeb/	*Clinical Trials:* Act XCV of 2005 on Medicinal Products for Human Use, Section 3: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62 *Non-Interventional Trials:* Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A:	*Clinical Trials:* Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Non-Interventional Trials:* Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
	Devices			
	1. Authority for Medical Devices, National Healthcare Service System: http://www.enkk.hu/index.php/hun/ 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: https://ett.aeek.hu/kfeb/	Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Clinical Trials:* Decree 4/2009. (III. 17.) of the Minister of Health on Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900004.EUM&celpara=#xcelparam *Non-Interventional Trials:* 1. Decree 23/2002. (V. 9.) of the Minister of Health on Biomedical Research on Human Beings http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam 2. Government Decree 235/2009. (X.20.) on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam 3. Government Decree 27/2015 (II.25.) About the National Health Care Service System: http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548	
Research Injury	National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu	Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62		
Privacy/Data	Hungarian National Authority for	1. Act XLVII of 1997 on the		

Country	Key Organizations	Legislation	Regulations	Guidelines
Protection	Data Protection and Freedom of Information: http://www.naih.hu/general-information.html	Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam 2. Act CXII of 2011 on Right of Informational Self-Determination and Freedom of Information: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&celpara=#xcelparam		
Human Biological Materials	Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma	Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam	Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam	
Genetic Research	1. Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Committee for Human Reproduction (HRB): https://ett.aeek.hu/hrb/	Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0800021.TV&celpara=#xcelparam		Decree 60/2003. (X. 20.) of the Minister of Health, Social and Family Affairs on the Minimum Professional Requirements Necessary for Providing Health Services: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0300060.ESC&celpara=#xcelparam
Embryos, Stem Cells, and Cloning	1. Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB): https://ett.aeek.hu/hrb/	1. Act CLIV of 1997 on Health Care, Chapter IX 2. Act VI of 2002 on the Promulgation of the Convention on Human Rights and Medicine and the Additional Protocol on Cloning: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200006.TV&celpara=#xcelparam	Decree 30/1998. (VI. 24.) of the Minister of Welfare on Regulations on Specific Procedures for Human Reproduction: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800030.NM&celpara=#xcelparam	Decree 18/1998. (XII. 27.) of the Minister of Health on Implementing Act CLIV of 1997 on Health Care Regarding Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam
Iceland For an overview of human subject protections in Iceland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Iceland%20definitive%20Updated.pdf				
General	1. Ministry of Welfare (MOW): http://eng.velferdarraduneyti.is/ 2. National Bioethics Committee	1. Act on the Rights of Patients No. 74/1997, Article 10 (2009): http://eng.velferdarraduneyti.is/medi		NBC: 1. Vulnerable Groups Including Children: http://www.vsn.is/en/content/vulnerable-

Country	Key Organizations	Legislation	Regulations	Guidelines
	(NBC): http://www.vsn.is/en	a/acrobat-enskar_sidur/Patients-Rights-Act-No-74-1997.pdf 2. The Act on Scientific Research in the Health Sector No 44/2014: http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Health-Sector-Research-Act-No-44-2014.pdf 3. Oviedo Convention on Human Rights and Biomedicine (2004)		groups-including-children 2. Informed Consent: http://www.vsn.is/en/content/informed-consent 3. Withdrawal of Consent: http://www.vsn.is/en/content/withdrawal-consent 4. Duty to Report Unexpected Events: http://www.vsn.is/en/content/duty-report-unexpected-events 5. Advertising to Recruit Participants: http://www.vsn.is/en/content/advertising-recruit-participants
Drugs, Biologics, and Devices	*Drugs*			
	1. Icelandic Medicines Agency (MCA): http://www.ima.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Medicinal Products Act No. 93/1994 (2013): http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20128	MCA: Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Medicinal-Products-Act-NoMedicinal-Products-Act-No-93-1994-as-amended.pdf	NBC: Various: http://www.vsn.is/en/content/clinical-trials
	Devices			
	Ministry of Welfare: http://eng.velferdarraduneyti.is/	Act on Medical Devices No 16/2001 (2011): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/16012012_Act-on-Medical-Devices-No-16-2001-as-amended.pdf	1. Regulation on Medical Devices No. 934/2010 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/16012012_Act-on-Medical-Devices-No-16-2001-as-amended.pdf 2. Regulation on Active Implantable Medical Devices No. 320/2011 (Icelandic): http://www.stjornartidindi.is/Advert.aspx?ID=c50d676c-4651-46c2-83b5-ad946f3deeaa 3. Regulation on In Vitro Diagnostic Medical Devices No. 936/2011 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0	
Research Injury	Icelandic Health Insurance Agency (MCA): http://www.sjukra.is/english	1. Act on Patient Insurance No. 111/2000 (2011): https://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act-on-Patient-Insurance-as-amended.pdf 2. Act on Health Insurance No.	Regulation on Clinical Trials of Medicinal Products in Humans No 443/2004 (2010): http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-clinical-trials-of-medicinal-products-	

Country	Key Organizations	Legislation	Regulations	Guidelines
		112/2008 (2012): https://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act-on-Health-Insurance-No-112-2008-16.pdf	in-humans-no-443-2004-as-amended.pdf	
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/information-in-english/	Act on the Protection of Privacy as Regards the Processing of Personal Data, No. 77/2000 (2011): http://www.personuvernd.is/information-in-english/		
Human Biological Materials	1. Ministry of Welfare: http://eng.velferdarraduneyti.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is/en	Biobanks Act No. 110/2000 (2009): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Biobanks-Act-as-amended.pdf	Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 134 (2001)	NBC: 1. Access to and Utilisation of Health Data and Bio-Samples: http://www.vsn.is/en/content/access-and-utilisation-health-data-and-bio-samples 2. Biobanks: http://www.vsn.is/en/content/biobanks
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004) 2. Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act_No_55_1996_on_Artificial_Fertilisation_etc_as_amended.pdf	Regulation on Artificial Fertilization No. 144/2009 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=9442c80d-2b63-4a43-9526-41d03d9b2495	
Ireland For an overview of human subject protections in Ireland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Ireland%20definitive.pdf; and see this summary on Clinical Trials Involving Medical Products: http://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/				
General	Department of Health: http://health.gov.ie/			1. Operational Procedures for Research Ethics Committees: Guidance 2004: http://health.gov.ie/wp-content/uploads/2014/07/Operational_Procedures1.pdf 2. Health Service Executive National Consent Policy, Part 3: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	1. Department of Health: http://health.gov.ie/ 2. Health Products and Regulatory Authority: https://www.hpra.ie/	European Communities (Clinical Trials on Medicinal Products for Human Use) Amendment 2004 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/878/made/en/print	European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html	Various: https://www.hpra.ie/homepage/site-tools/search?query=clinical%20trials
Research Injury	Health Products and Regulatory Authority: https://www.hpra.ie/		European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html	
Privacy/Data Protection	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/4.htm	Data Protection Act (1988), as Amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
Human Biological Materials	Health Products and Regulatory Authority: https://www.hpra.ie/			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): http://health.gov.ie/wp-content/uploads/2014/07/Human_Biological_Material1.pdf
Genetic Research	Health Products and Regulatory Authority: https://www.hpra.ie/			Guidelines for Pharmacogenetic Research (2006): http://lenus.ie/hse/bitstream/10147/96983/1/Pharmacogenetic06.pdf
Italy For an overview of human subject protections in Italy, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Italy%20definitive%20Updated.pdf				
General	1. National Bioethics Committee (CNB): http://www.governo.it/bioetica/eng/index.html 2. National Monitoring Center for Clinical Trials (OSS): http://oss-sper-clin.agenziafarmaco.it/		OSS: Ministerial Decree of 12 May 2006: Terms of Reference for the Establishment and the Functioning of Ethics Committees	CNB: Various: http://www.governo.it/bioetica/eng/opinions.html
Drugs, Biologics, and Devices	*Drugs*			
	1. National Monitoring Center for Clinical Trials: http://www.agenziafarmaco.com/en/content/national-monitoring-centre-clinical-trials 2. Italian Medicines Agency (Italian):	1. Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001)	1. Ministerial Decree of 21 December 2007: Directions for Submitting the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.agenziafarmaco.it/ 3. Ministry of Health (MOH) (Italian): http://www.ministerosalute.it	(Italian) 2. Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003) 3. Legislative Decree No. 200: Transposition of Directive 2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as Well as the Requirements for Authorizing of Manufacturing or Importing of such Products (2007) (Italian): http://www.aifa.gov.it/allegati/dlgs_200-6nov2007.pdf	Authority, for Communicating Substantial Amendments, for Declaring the End of the Trial and for the Request of an Opinion to the Ethics Committee 2. Ministerial Decree of 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to Work within Clinical Trials on Medicinal Products	
	Devices			
	Ministry of Health, Directorate General for Medicines and Medical Devices (Italian): http://www.ministerosalute.it		Ministerial Decree 2 of August 2005: Procedures for the Presentation of Documentation to Notify about Clinical Investigations with Medical Devices	Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007)
Research Injury	Ministry of Labour and Social Policy (Italian): www.lavoro.gov.it		Ministerial Decree 14 of July 2009: Minimum Requirements for Insurance Policies Which Safeguard Participants to Clinical Trials of Medicinal Products	
Privacy/Data Protection	Italian Data Protection Independent Authority (Italian): http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?solotesto=N	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?folderpath=Normativa%2FItaliana%2FIl+Codice+in+materia+di+protezione+dei+dati+personali	1. Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000) 2. Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003 3. Ministerial Decree No. 277 (2007)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. Instituto Superiore di Sanita (ISS): http://www.iss.it/chis/?lang=2 2. Italian Society of Human Genetics (SIGU): http://www.sigu.net/			ISS: Guidelines for Phase I Clinical Trials with Investigational Medicinal Products Employed in Gene Somatic Therapy (2004) (Italian): http://www.iss.it/binary/publ/publi/0478.1106653420.pdf SIGU: Various: http://www.sigu.net/show/documenti/5/1/linee%20guida
Embryos, Stem Cells, and Cloning		Regulation of Medically Assisted Reproduction, Law No. 40, Article 13 (2004)		

Latvia For an overview of human subject protections in Latvia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Latvia%20definitive.pdf				
General	Central Medical Ethics Committee		Statutes of Central Medical Ethics Committees (1998) (Latvian): http://likumi.lv/doc.php?id=46597	
Drugs, Biologics, and Devices	*Drugs*			
	1. State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large 2. Central Medical Ethics Committee	1. Law on Pharmacy, Section 26 (2013): http://www.zva.gov.lv/?id=355&top=333&large=0 2. Law on the Rights of Patients, Section 11 (2013) http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc	Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice: http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._289_-_Procedures_for_Conduct_of_Clinical_Trials_and_Non-interventional_Trials_of_Medicinal_Productsx.doc	
	Devices			
	State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large=	Medical Treatment Law, Section 34 (2014): http://www.vvc.gov.lv/export/sites/	Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for	

Country	Key Organizations	Legislation	Regulations	Guidelines
		default/docs/LRTA/Likumi/Medical_Treatment_Law.pdf	Human Use (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
Research Injury	State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large=		*Drugs:* Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice, Sections 22, 31.6, 54.10, 55.9, and 61.14 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._289_-_Procedures_for_Conduct_of_Clinical_Trials_and_Non-interventional_Trials_of_Medicinal_Productsx.doc *Devices:* Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
Privacy/Data Protection	1. Data State Inspectorate: http://www.dvi.gov.lv/en/ 2. Central Medical Ethics Committee	1. Personal Data Protection Law (2014): http://www.dvi.gov.lv/en/wp-content/uploads/legal-acts/Personal_Data_Protection_Law.doc	Cabinet Regulation No. 446: Procedures for Using Patient Data in a Specific Research (2015): http://likumi.lv/wwwraksti/VVC_TULKOJUMI/LRTA/MK_NOTEIKUMI/CAB_REG_NO_446_PROCEDUR	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law on the Rights of Patients, Section 10 (2013): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc	ES_FOR_USING_THE_PATIENT_DATA.DOC	
Human Biological Materials	Central Medical Ethics Committee	Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue (2008): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/On_the_Protection_of_the_Body_of_Deceased_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc	Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells (Latvian): http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba	
Genetic Research	1. Ministry of Health: http://www.vm.gov.lv/en/ 2. Data State Inspectorate: http://www.dvi.gov.lv/en/ 3. Central Medical Ethics Committee	1. Human Genome Research Law (2005): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Human_Genome_Research_Law.doc 2. Law on the Development and Use of the National DNA Database (2006): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Development_and_Use_of_the_National_DNA_Database.doc	Regulation of the Cabinet of Ministers: "Procedures for Genetic Research" (2004) (Latvian): http://likumi.lv/doc.php?id=92330	
Embryos, Stem Cells, and Cloning	1. Ministry of Health: http://www.vm.gov.lv/en/ 2. Central Medical Ethics Committee	Sexual and Reproductive Health Law, Sections 15-20 (2004): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Sexual_and_Reproductive_Health_Law.doc	Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells (Latvian): http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba	
Lithuania Note: All standards are in Lithuanian. For an overview of human subject protections in Lithuania, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Lithuania%20definitive%20Updated.pdf				
General	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/treaties/html/164.htm 2. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 3. Decree on Changes of Law on	1. V-405, Decree on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=372121&p_query=&p_tr2= 2. Government of the Republic of	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	Lithuania: Decree No. 1458 on State Fees (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E3A145C8DD49/adJtSaHbRM 3. V-15, Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent (2016): https://www.e-tar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b 4.V-28, Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2016): https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b 5. V-1483, Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=1002481&p_tr2=2 6. V-235/A1-83, Decree on the Procedure for a Minor's Participation in Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/104c2540d3e711e583a295d9366c7ab3	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?1608991497		1. V-28, Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28 (2011): https://www.e-	Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2017): http://bioetika.sam.lt/index.php?3315136866

Country	Key Organizations	Legislation	Regulations	Guidelines
			tar.lt/portal/lt/legalAct/TAR.480CDD584ADB 2. V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2017): https://www.e-tar.lt/portal/lt/legalAct/352d55b0c44111e583a295d9366c7ab3/Maiuzzfyns 3. V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/3790a050be7e11e5a6588fb85a3cc84b 4. V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/f6caecd0be8511e5a6588fb85a3cc84b/hqOKwHTIBs	
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG 2. State Medicines Control Agency (SMCA): http://www.vvkt.lt/lit/English	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Law on Pharmacy (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.FF33B3BF23DD/gRoLvrgCbW 3. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-	1. Decree No. 320 on the Rules of Good Clinical Practice (2004): https://www.e-tar.lt/portal/lt/legalAct/TAR.EF5F8A32B830/WkRbILGNxF 2. Corrections of GCP Terminology in Lithuanian (2006) https://www.e-tar.lt/portal/lt/legalAct/TAR.1C6613E02B96 3. Decree No. 435 on the Procedure for Issuing a Favorable	

Country	Key Organizations	Legislation	Regulations	Guidelines
		tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2017): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.277308/QPLLKpOUKw	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?1608991497		V-6, Decree on the Sample Form of the Request to Issue Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366c7ab3/qcrDrSCSCJ	Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2007)
	Devices			
	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG		Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.47B235393D3A/zpczrvbOOR	
	State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386		
Research Injury	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	MOH: Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2015): https://www.e-tar.lt/portal/lt/legalAct/c86cf490b3be11e598c4c7724bda031b/IaIhDiebov	
Privacy/Data Protection	State Data Protection Inspectorate: https://www.ada.lt/go.php/lit/English	Law on Legal Protection of Personal Data (2017):		

Country	Key Organizations	Legislation	Regulations	Guidelines
		https://www.e-tar.lt/portal/lt/legalAct/TAR.5368B592234C/XSpzxvEjIg		
Human Biological Materials	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386		
Embryos, Stem Cells, and Cloning	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002): http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168 2. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 3. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	1. Decree No. V-660 on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania (2007): https://www.e-tar.lt/portal/lt/legalAct/TAR.8A75E79827FD 2. Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E2473B1958CA/gEtbNSRzzc	
Luxembourg For an overview of human subject protections in Luxembourg, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Luxembourg%20definitive%20Updated.pdf Note: All websites and documents are available in French.				
General	National Ethics Consultative Commission:			Various: http://www.cne.public.lu/fr/publications/avis.ht

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.cne.public.lu/fr/commission/statut.html			ml
Drugs, Biologics, and Devices	1. Ministry of Health: http://www.ms.public.lu and http://www.sante.lu 2. National Research Ethics Committee: http://www.cner.lu 3. Division of Pharmacy and Medicines of the Ministry of Health: http://www.sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/div-pharmacie-medicaments/index.html	Hospitals Act of 1998, Article 25 (2010): http://www.legilux.public.lu/leg/a/archives/1998/0078/a078.pdf	Grand-Ducal Decree of May 30, 2005 on the Conduct of Clinical Trials on Medicinal Products for Human Use: http://www.legilux.public.lu/leg/a/archives/2005/0084/2005A15161.html	
Privacy/Data Protection	National Commission for Data Protection: http://www.cnpd.public.lu/fr/index.html	Law of August 2, 2002 on the Protection of Persons with Regard to the Processing of Personal Data as amended by a law of July 27, 2007: http://www.cnpd.public.lu/fr/legislation/droit-lux/doc_loi02082002_en.pdf	Grand-Ducal Decree of October 2, 1992 on the Use of Personal Medical Data in IT Processing: http://www.legilux.public.lu/leg/a/archives/1992/0074/a074.pdf#page=12	
Macedonia Note: All websites and documents are in Macedonian.				
Drugs and Devices	*Drugs*			
	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/ 3. Drug Agency http://malmed.gov.mk/	1. Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016, according to year of amendment): Click on file folder 1., then open sub-folders: https://lekovi.zdravstvo.gov.mk/documents/2 2. Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law, Article 275: http://www.fzo.org.mk/default.asp?ItemID=37115BDC6DEF524D877A8C36F95A85F6	1. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1 1.1. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/879452170?t:ac=1/1 1.2. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation	1. Guideline for the Clinical Trial Applicant (Annex 3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1 (Sub-folder 23.2) 2.Guideline for Good Clinical Practice, Official Gazette No.62/2009, Document No. 19: https://lekovi.zdravstvo.gov.mk/documents/1/1

Country	Key Organizations	Legislation	Regulations	Guidelines
			Contents (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/880033320?t:ac=1/1 1.3. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents and Annex No.3 (Guideline for the Clinical Trial Applicant) (Document No. 23.3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1 1.4. Rulebook on Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2016) (Document No. 23.4): https://lekovi.zdravstvo.gov.mk/documents/1/1 2. Regulation on the Manner of Reporting, Contents of the Reporting Form for Adverse Reactions to Medicinal Products and the Manner of Organisation of Pharmacovigilance System (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/880287913?t:ac=1/1	
	Devices			
	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/ 3. Drug Agency http://malmed.gov.mk/	Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016): Click on file folder 1., then open sub-folders: https://lekovi.zdravstvo.gov.mk/documents/2	1. Rulebook for the Required Documentation and the Method of Application for Clinical Trials on Medical Devices and the Amendments, and Reporting of Drug Adverse Reactions and Events (Official Gazette No. 62/2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/844338380?t:ac=1/2	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2. Rulebook on the Manner of Reporting Adverse Effects During the Use of Medical Devices, Types of Reactions they Cause, the Actions of Health Workers and Suppliers, As Well as the Manner of Organizing the System of Monitoring Adverse Effects and Reactions to Medical Devices (Official Gazette No.100/2016) (Document No.8): https://lekovi.zdravstvo.gov.mk/documents/1/2	
Research Injury	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug Agency: http://malmed.gov.mk/		Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1	
Privacy/Data Protection	Directorate for Personal Data Protection: www.dzlp.mk	1. Law on Personal Data Protection, Consolidated (2016): http://www.dzlp.mk/sites/default/files/u4/ZZLP_konsolidiran_tekst_2016.pdf 2. Law on Ratification on Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2005): http://www.dzlp.mk/sites/default/files/pdf/Zakon_za_ratifikacija_na_Konvencijata_108.pdf 3. Law on Ratification on Additional Protocol to the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2008): http://www.dzlp.mk/sites/default/files/pdf/Dopolnitelen_protokol_Konvencija_108.pdf	Regulations on Protection of Personal Data: http://www.dzlp.mk/mk/podzakonski_akti	
Human Biological Materials	1. Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/ 2. Health Insurance Fund of Republic	1. Law on Health Protection: (Official Gazette No. 43/2012) and Laws Amending and	Regulations for Transplantation of Tissues and Organs: http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887	Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs

Country	Key Organizations	Legislation	Regulations	Guidelines
	of Macedonia: http://www.fzo.org.mk	Supplementing the Law (2012-2015): http://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/ 2. Law on Taking and Transplanting of Human Body Organs (Official Gazette No. 47/2011) and Laws Amending and Supplementing the Law (2011-2015): http://zdravstvo.gov.mk/zakon-za-zemanje-i-presaduvanje-na-delovi-na-chovechkoto-telo-zaradi-lekuvanje/ Sub-Law Acts : http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996 3. Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2009): http://www.pravo.org.mk/documentDetail.php?id=5543	C57131D996	and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from Human Body for Treatment Purposes (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/za_pobliskite_kriteriumi_vo_odnos_na_prostorot_kadarot_i_opremata_za_zemawe_presaduvawe_i_razmenuvawe_na_organite_i_tkivata_za_potrebniot_pr.pdf
Genetic Research	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Patient Rights Protections, Article 21: Action on Human Genome (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2009): http://www.pravo.org.mk/documentDetail.php?id=5543		
Malta For an overview of human subject protections in Malta, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Malta%20definitive%20Updated.pdf				
General	Bioethics Committee: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/CommitteeMembers.aspx			Various: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/Opinions.aspx
Drugs, Biologics, and Devices	*Drugs*			
	Medicines Authority: http://medicinesauthority.gov.mt/	1. Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1 2. Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1 3. Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11285&l=1		Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm
	Devices			
	1. Medicines Authority: http://medicinesauthority.gov.mt/ 2. Malta Competition and Consumer Affairs Authority, Technical Regulations Division, Regulatory Affairs Directorate: http://www.mccaa.org.mt/en/regulatory-affairs-directorate	1. Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1 2. Subsidiary Legislation, 427.16, *In Vitro* Diagnostic Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemi		

Country	Key Organizations	Legislation	Regulations	Guidelines
		d=10756&l=1 3. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1 4. Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10753&l=1		
Privacy/Data Protection	Office of the Information and Data Protection Commissioner: http://idpc.gov.mt/index.aspx	Data Protection Act, 2002: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8906&l=1		
Moldova For an overview of human subject protections in Moldova, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 7: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf Note: All websites and documents are in Moldovian.				
General	Ministry of Health, National Committee for Ethical Expertise of Clinical Trials: http://ms.gov.md/?q=comitetul-national-etica	Oviedo Convention on Human Rights and Biomedicine (2002)		
Drugs, Biologics, and Devices	1. Ministry of Health , National Committee for Ethical Expertise of Clinical Trials: http://ms.gov.md/?q=comitetul-national-etica 2. Medicines and Medical Devices Agency: http://www.amed.md/	1. Law No. 1409 Dated 17.12.1997 on Medicines, Articles 11 and 12: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311586 2. Law No. 263 Dated 27.10.2005 on Patients' Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313060	MOH: 1. Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trial: http://lex.justice.md/md/362783/ 2. Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
Research Injury	Ministry of Health (MOH): http://www.ms.gov.md/	Law No. 411-XIII Dated 28.03.1995 on Health: http://lex.justice.md/viewdoc.php?action=view&view=doc&id=312823	1. Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trials:	

Country	Key Organizations	Legislation	Regulations	Guidelines
		&lang=1	http://lex.justice.md/md/362783/ 2. Order No. 648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
Privacy/Data Protection	National Center for Personal Data Protection of the Republic of Moldova: http://www.datepersonale.md/en/start/	1. Convention No. 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): http://datepersonale.md/en/international003/ 2. Decision of Parliament No. 483-XIV Dated 02.07.1999 on Ratification of Convention No. 108: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=309121 3. Law No. 982 Dated 11.05.2000 on Access to Information: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759 4. Law No.133 Dated 08.07.2011 on the Protection of Personal Data: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=340495	Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: http://www.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf	
Human Biological Materials	1. Ministry of Health (MOH): http://www.ms.gov.md/ 2. Transplant Agency http://lex.justice.md/md/334622	Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709	MOH: Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.ms.gov.md/ 2. National Commission on	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of		

Country	Key Organizations	Legislation	Regulations	Guidelines
	Biological Security: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353	the Human Being, on the Prohibition of Cloning Human Beings (2002) 2. Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709		
Montenegro				
Drugs, Biologics, and Devices	1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat 2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavna?_adf.ctrl-state=rsbe35pln_83	1. Law on Medicines ("Official Gazette of Montenegro", No. 56/2011 and 06/13): https://www.calims.me/Portal/faces/servlet1?putanja=CG_Zakon_o_ljekovima.pdf&_afrWindowMode=0&_afrLoop=3654755254077715&_adf.ctrl-state=13nzchbscd_171 2. Law on Medical Devices ("Official Gazette of Montenegro" No. 79/2004, 53/09, and 40/11): https://www.calims.me/Portal/faces/servlet1?putanja=CG-Zakon%2520o%2520medicinskim%2520sredstvima.pdf&_afrWindowMode=0&_afrLoop=3654994298177994&_adf.ctrl-state=13nzchbscd_181	Rulebook on More Detailed Conditions and Documentation Required for Approval and Conduct of Clinical Trials of Medicines for Human Use (2013): https://www.calims.me/Portal/faces/servlet1?_afrLoop=26656243505641585&_afrWindowMode=0&putanja=Rulebook%2520on%2520Clinial%2520trials.pdf&_adf.ctrl-state=wdqo8wvwo_214	
Research Injury	1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat 2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavna?_adf.ctrl-state=rsbe35pln_83	1. Law on Medicines ("Official Gazette of Montenegro", No. 56/2011 and 06/13): https://www.calims.me/Portal/faces/servlet1?putanja=CG_Zakon_o_ljekovima.pdf&_afrWindowMode=0&_afrLoop=3654755254077715&_adf.ctrl-state=13nzchbscd_171 2. Law on Medical Devices ("Official Gazette of Montenegro" No. 79/2004, 53/09, and 40/11): https://www.calims.me/Portal/faces/servlet1?putanja=CG-Zakon%2520o%2520medicinskim%2520sredstvima.pdf&_afrWindowMode=0&_afrLoop=365499429817		

Country	Key Organizations	Legislation	Regulations	Guidelines
		7994&_adf.ctrl-state=13nzchbscd_181		
Privacy/Data Protection	National Security Agency: http://www.anb.gov.me/en/Home?alphabet=lat	Law on the Protection of Personal Data (Official Gazette of Montenegro No. 79/08, 70/09, 44/12): http://www.azlp.me/docs/zajednicka/zakoni/zakon-o-zastiti-podataka-o-licnosti.pdf		
Human Biological Materials	Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat	Law on the Collection and Use of Biological Samples (Official Gazette of Montenegro No. 14/2010): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57491&rType=2&file=ZAKON%20O%20UZIMANJU%20I%20KORI%C5%A0%C4%86ENJU%20BIOLO%C5%A0KIH%20UZORAKA.pdf		
Genetics	Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat	Law on the Protection of Genetic Data (Official Gazette of Montenegro No. 25/2010): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57566&rType=2&file=ZAKON%20O%20ZA%C5%A0TITI%20GENETI%C4%8CKIH%20PODATAKA%20.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat		Rulebook on the Collection, Storage, and Use of Stem Cells (2012): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=222783&rType=2&file=Pravilnik%20o%20postupku%20prikupljanja,%20%C4%8Duvanja%20i%20upotrebe%20mati%C4%8Dnih%20%C4%87elija%2056-2012.pdf	
Netherlands For an overview of human subject protections in the Netherlands, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Netherlands%20definitive%20Updated.pdf				
General	Central Committee for Research	1. Population Screening Act	1. Concerning the Use of a	Various (Dutch): http://www.ccmo.nl/en/publications-of-the-

Country	Key Organizations	Legislation	Regulations	Guidelines
	Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	(1996): http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_24-09-2015 2. Medical Research Involving Human Subjects Act (2012): 2006 English version: http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf	Special Form (2002) 2. Concerning Requirements of Expertise of Accredited Review Board Members (2002) 3. Concerning the Organization and Working Method of Accredited Review Board Members (2003) 4. External Review Guideline (2004) 5. Research Contract Review Guideline (2009)	ccmo
Drugs, Biologics, and Devices	1. Ministry of Health, Welfare, and Sport (VWS): http://www.government.nl/ministries/vws#ref-minvws 2. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/ 3. Medicines Evaluation Board (MEB): http://english.cbg-meb.nl/	Medicines Act (2007) (Dutch): http://wetten.overheid.nl/BWBR0021505	VWS: 1. Medicines Act Decree (2007): http://www.ccmo.nl/attachments/files/eng-decree-on-scientific-research-with-medicinal-products.pdf 2. Medicines Act Regulation (2007) (Dutch): http://wetten.overheid.nl/BWBR0022160	CCMO: Clinical Research with Medicinal Products in the Netherlands: Instructional Manual (2005): http://www.vumc.nl/afdelingen-themas/1646433/7876770/7876776/7955410/Clinical_research_with_medi1.pdf
Clinical Trials Registry	1. Netherlands Trial Register (Dutch): http://www.trialregister.nl/trialreg/index.asp 2. Central Committee Register (Dutch): https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm			
Research Injury	Ministry of Health, Welfare and Sport: http://www.government.nl/ministries/vws#ref-minvws	Medical Research Involving Human Subjects Act, Article 7 (2006): http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf	Regulation on Mandatory Insurance Regarding Medical Research Involving Human Subjects (2003): https://zoek.officielebekendmakingen.nl/stb-2014-477.html	
Privacy/Data Protection	1. Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.federa.org/ 2. Dutch Data Protection Authority: https://cbpweb.nl/en	Personal Data Protection Act (2004) (Dutch): http://wetten.overheid.nl/BWBR0011468		FMWV: 1. Code for Adequate Secondary Use of Data (2004): http://www.federa.org/sites/default/files/bijlagen/coreon/code_of_conduct_for_medical_research_1.pdf 2. Explanatory Report Accompanying the Code (2004): http://www.federa.org/sites/default/files/bijlagen/coreon/explanatory_report1.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.federa.org/	Civil Code, Article 467 (1994) (Dutch): http://www.ccmo.nl/attachments/files/wgbo-pdf.pdf		Code for Proper Secondary Use of Human Tissue in the Netherlands (2002): http://www.federa.org/sites/default/files/bijlagen/coreon/codepropersecondaryuseofhumantissue1_0.pdf
Genetic Research	1. Ministry of Infrastructure and the Environment (IenM): http://www.government.nl/ministries/ienm 2. Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/english/ 3. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	Medical Research Involving Human Subjects Act (2006): http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf		IenM, VWS, and CCMO: Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2012): http://www.ggo-vergunningverlening.nl/dsresource?type=pdf&objectid=rivmp:193539&versionid=&subobjectname=
Embryos, Stem Cells, and Cloning	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	1. Foetal Tissue Act (2001) (Dutch): http://wetten.overheid.nl/BWBR0012983/ 2. Embryos Act (2002): http://www.ccmo.nl/attachments/files/embryos-act.pdf		
Norway For an overview of human subject protections in Norway, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Norway%20definitive%20Updated.pdf				
General	National Committee for Medical and Health Research Ethics (NEM): http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/	1. Oviedo Convention on Human Rights and Biomedicine (2006) 2. Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		1. Guidelines for Research on Persons with Impaired Informed Consent Capacity (2005) 2. Payment for Research Participants in Medical and Health Research (2009) 3. Guidelines for Research Ethical and Scientific Evaluation of Qualitative Research Projects in Medical and Health Research (2009) (Norwegian): https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/Kvalitativ-forskning/
	National Committee for Research Ethics in the Social Sciences and the Humanities: http://www.etikkom.no/en/In-English/			Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2001)
	National Committee for Research Ethics in Science and Technology: https://www.etikkom.no/en/In-English/Committee-for-Research-Ethics-in-Science-and-Technology/			Research Ethics Guidelines for Science and Technology (2007) (Norwegian): https://www.etikkom.no/Forskningsetikk/Etiske-retningslinjer/Naturvitenskap-og-teknologi/

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	*Drugs*			
	Norwegian Medicines Agency: http://www.legemiddelverket.no/English/Sider/default.aspx		Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2009-10-30-1321?q=forskrift+om+kliniske+utpr%C3%B8vning	Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999) (Norwegian): http://www.legemiddelverket.no/Godkjenning_og_regelverk/Klinisk-utproving/Regelverk%20og%20veiledninger/Documents/Veiledning%20-%20revidert%20versjon%202.2%2006.11.2012.pdf
	Devices			
	1. Norwegian Directorate of Health: http://www.helsedirektoratet.no/kvalitet-planlegging/medisinsk-utstyr/klinisk-utprovning/Sider/default.aspx 2. Regional Committees for Medical and Health Research Ethics: https://helseforskning.etikkom.no/ikbViewer/page/forside	Act of 12 January 1995 No. 6 Relating to Medical Devices (1995) (Norwegian): http://lovdata.no/dokument/NL/lov/1995-01-12-6?q=lov+om+medisinsk+utstyr	Regulation of December 15th 2005 No. 1690 Relating to Medical Devices (2005) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2005-12-15-1690?q=forskrift+medisinsk+utstyr	Guidelines on Notification for Clinical Investigation of Medical Devices in Norway (2010): https://helsedirektoratet.no/Documents/Medisinsk%20utstyr/Guidance%20for%20completing%20the%20Notification%20form.pdf
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2007)		
Social-Behavioral Research	National Committee for Research Ethics in the Social Sciences and the Humanities			Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2016): https://www.etikkom.no/globalassets/documents/english-publications/60127_fek_guidelines_nesh_digital_corr.pdf
	Norwegian National Research Ethics Committees			Ethical Guidelines for Internet Research (2014): https://www.etikkom.no/en/ethical-guidelines-for-research/ethical-guidelines-for-internet-research/
Privacy/Data Protection	Data Inspectorate: http://www.datatilsynet.no/English	Personal Data Act No. 31 (2000): http://lovdata.no/dokument/NL/lov/2000-04-14-31	Regulations on the Processing of Personal Data (2003)	
Human Biological Materials	1. Ministry of Health and Care Services (MHCS): https://www.regjeringen.no/en/dep/hod/id421/ 2. Ministry of Education and Research (MER): http://www.regjeringen.no/en/dep/kd.html?id=586	1. Act on Biobanks (February 21, 2003, No. 12): http://lovdata.no/dokument/NL/lov/2003-02-21-12?q=biobank 2. Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100)	MHCS: Guidelines for the Norwegian Act on Biobanks (2003)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		
Genetic Research	1. Ministry of Health and Care Services (MHCS): https://www.regjeringen.no/en/dep/hod/id421/ 2. Norwegian Biotechnology Advisory Board: http://www.bion.no/english/ 3. Regional Committees for Medical Research Ethics (REK): https://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/	Act Relating to the Application of Biotechnology in Human Medicine, Etc. (December 5, 2003, No. 100): https://www.regjeringen.no/globalassets/upload/kilde/hod/red/2005/0081/ddd/pdfv/242718-biotechnology_act_master.pdf		
Embryos, Stem Cells, and Cloning	Directorate for Health and Social Affairs: http://www.helsedirektoratet.no/kvalitet-planlegging/bio-genteknologi/Sider/default.aspx	1. Revised Act Relating to the Application of Biotechnology in Human Medicine (June 15, 2007) Regarding Changes in the Act Related to Stem Cell Research and Pre-implantation Diagnostics (2007) 2. Norwegian Law on the Human-Medical Use of Biotechnology, Chapter 3		
Poland For an overview of human subject protections in Poland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Poland%20definitive.pdf				
General	1. Ministry of Health, Bioethics Appeals Commission (MOH): http://www.mz.gov.pl/en 2. Center of Bioethics, Polish Chamber of Physicians and Dentists (NIL) (Polish): http://www.nil.org.pl/dzialalnosc/orodek-bioetyki	1. Constitution of the Republic of Poland, Article 39 (1997) 2. Medical Profession Act, Articles 21-29 (1997): http://isap.sejm.gov.pl/Download?id=WDU19970280152&type=3	MOH: Order of the Minister of Health and Social Welfare on How to Establish, Finance, and the Mode of Action of Bioethics Committees (1999) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU19990470480	NIL: Code of Medical Ethics, Chapter II (2003): http://www.nil.org.pl/dokumenty/kodeks-etyki-lekarskiej
Drugs, Biologics, and Devices	*Drugs*			
	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en	1. Pharmaceutical Law (2016): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20160002142 2. Law of 20/04/2004 on Amendment of the	1. Decree of the Minister of Health on Clinical Trials on Minors (2004) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041041108	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Pharmaceutical Law, Law on the Profession of Medical Doctor, and Regulations Introducing the Pharmaceutical Law, Law on Medical Devices, and Law on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 92, Item 882)	2. March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20120000489 3. May 9, 2012 Order of the Minister of Health Concerning the Application Forms of Documents Submitted Due to the Clinical Trial of Medicinal Products and about the Amount of Charges and the Way of their Payments for the Commencement of Clinical Trial: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20120000491	
	Devices			
	Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products: http://en.urpl.gov.pl/general-information	1. Act on Medical Devices (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101070679 2. Act Amending the Act on Medical Devices and Certain Other Acts: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20170000211&min=1	1. Regulation of the Minister of Health on Detailed Conditions to be Met for Clinical Evaluation of Medical Devices or Active Implantable Medical Devices (2011) (Polish): isap.sejm.gov.pl/DetailsServlet?id=WDU20110630331 Various (Polish): http://www.urpl.gov.pl/	
Research Injury		Pharmaceutical Law, Chapter 36b(2)(6) (2008)	1. Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2004) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041011034 2. Order of the Minister of Finance Amending the Regulation Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2005) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051010845 3. Order of the Minister of Finance Concerning the	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Mandatory Civil Liability Insurance of Researchers and Sponsors in Clinical Trials of Medicinal Products (2010) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101941290	
Privacy/Data Protection	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (2006): http://www.giodo.gov.pl/data/filemanager_en/61.doc		
Human Biological Materials		1. Act of 22 August 1997 on the Public Blood Service: http://isap.sejm.gov.pl/DetailsServlet?id=WDU19971060681 2. July 1, 2005 Act Regarding Sampling, Storage, and Transplanting of Cells, Tissues, and Organs: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051691411&min=1		

Portugal For an overview of human subject protections in Portugal, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Portugal%20definitive%20Updated.pdf				
General	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine (2001)		Various: http://www.cnecv.gov.pt/cnecv/en/opinions/
Drugs, Biologics, and Devices	*Drugs*			
	1. National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH 2. Ethics Commission for Clinical Research (CEIC): http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC	1. Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004 2. Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005 (Portuguese): http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf	Decree-Law No. 102/2007 of April 2	
	Devices			

Country	Key Organizations	Legislation	Regulations	Guidelines
	National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS	Various: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II		Various: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	National Data Protection Commission: http://www.cnpd.pt/english/index_en.htm	1. Constitution, Article 35 (1997) 2. Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM		
Genetic Research	Ministry of Health: http://www.portugal.gov.pt/en/the-ministries/ministry-of-health.aspx	Law 12/2005		
Embryos, Stem Cells, and Cloning	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	1. Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2001) 2. Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006)		1. Opinion 15/CNECV/95 on Embryo Research (1995) 2. Opinion 47/CNECV/2005 on Stem Cell Research (2005): http://www.cnecv.gov.pt/NR/rdonlyres/F13B34FD-F9F7-4C9D-96DC-419999D9B693/0/47CNECV2005.pdf 3. Opinion 48/CNECV/2006 on Human Cloning (2006): http://www.cnecv.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-D70A7E9AD961/0/p048_en.pdf
Romania For an overview of human subject protections in Romania, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Romania%20definitive.pdf				
General	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Oviedo Convention on Human Rights and Biomedicine (2001)	Ordinance No. 57/16.08.2002 (2002): http://www.research.ro/ro/articol/1021/despre-ancs-legislatie	
Drugs, Biologics, and Devices	1. Ministry of Health (MOH) (Romanian): http://www.ms.ro/ 2. National Agency for Medicines and Medical Devices: http://www.anm.ro/anmdm/en/index.html 3. National Bioethics Committee for Medicines and Medical Devices		MOH: Order 904/25July 2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use --	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
	(Romanian): http://www.bioetica-medicala.ro/		Transposition of 2001/20/EC Directive Access: http://www.anm.ro/anmdm/en/med_legislatie_ordine.htm	
Research Injury	1. National Agency for Medicines and Medical Devices: http://www.anm.ro/anmdm/en/index.html 2. National Bioethics Committee for Medicines and Medical Devices (Romanian): http://www.bioetica-medicala.ro/	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en	Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: http://www.dataprotection.ro/servlet/ViewDocument?id=174		
Human Biological Materials	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Law No. 95/2006 Regarding the Reform in Health Field. Title VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://www.transplant.ro/Lege/Lege-2006-95.pdf	Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation: http://europa.eu/legislation_summaries/public_health/threats_to_health/sp0008_ro.htm	
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2001) 2. Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation: http://www.codpenal.ro/legislatie/document/lege-301-din-2004-codul-penal-capitol-4-crime-si-delicte-		

Country	Key Organizations	Legislation	Regulations	Guidelines
		privind-manipularea-genetica-1260-63259.html		
Russia For an overview of human subject protections in Russia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Russia%20definitive%20Updated.pdf				
General	1. Ministry of Healthcare of the Russian Federation (MOH): http://www.rosminzdrav.ru 2. Federal Service on Surveillance in Healthcare (Roszdravnadzor): (Russian): http://www.roszdravnadzor.ru/ 3. Russian Committee for Bioethics: http://www.bioethics.ru/eng/	1. Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/en/10003000-03.htm 2. Federal Law #FZ 323 "On Foundations of Protection of Citizen's Health in the Russian Federation" (2011): http://acto-russia.org/en/index.php?option=com_content&task=view&id=105 3. Federal Law #FZ55 "On Introduction of Changes in FZ "On Foundations of Protection of Citizens' Health in the Russian Federation" with Regard to Questions of Organization of Medical Aid Administered in the Course of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation" (2015) (Russian): http://www.consultant.ru/document/cons_doc_LAW_176159		MOH: 1. Ministry of Health Order 433n (July 10, 2015) "On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients' Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation" (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847 2. Ministry of Health Order 435h (July 10, 2015) "On Ethics Committee of the Ministry of Health of the Russian Federation" (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183677
Drugs, Biologics, and Devices	1. Council of Ethics of the Ministry of Healthcare of the Russian Federation (MOH) (Russian): http://www.grls.rosminzdrav.ru/ 2. Association of Clinical Trials Organizations: http://acto-russia.org/en/ 3. Federal Agency for Technical Regulation and Metrology (GOST): http://www.gost.ru/wps/portal/pages.en.Main	Federal Law #61FZ "On Circulation of Medicines" (2011): http://acto-russia.org/files/zakon_ob_obr_ls_en.docx	MOH: 1. Ministry of Health Order No. 753n (August 26, 2010) "On Assertion of Order of Organization and Carrying out of Ethical Review…" (Russian): http://base.garant.ru/12178437/ 2. Ministry of Health Order No. 774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.rg.ru/2013/02/22/etika-dok.html 3. Ministry of Health Order of April 1, 2016 № 200н "On Approval of the Rules of Good	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Clinical Practice: http://acto-russia.org/files/prikaz_200n.docx GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005) (Russian): http://acto-russia.org/index.php?option=com_content&task=view&id=17	
Research Injury		Federal Law #61FZ "On Circulation of Medicines" (2011), Art. 38-44: http://acto-russia.org/files/zakon_ob_obr_ls_en.docx		
Privacy/Data Protection		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006) (Russian): http://www.consultant.ru/document/cons_doc_LAW_165971/ 2. Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): http://base.garant.ru/12148567/		
Genetic	Interdepartmental Commission on Genetic-Engineering Activity	Federal Law of July 5, 1996, N OF 8'-FZ "About the State Control in the Area of Genetic-Engineering Activity" (Russian): http://base.garant.ru/10135402/	Order of the Ministry of Education and Science of the Russian Federation #154 (2005): "Statute of the Inter-Departmental Commission on Genetic-Engineering Activity" (Russian): http://www.zakonprost.ru/content/base/part/438157	
Embryos, Stem Cells, and Cloning		Federal Law #30-FZ "On Introduction of Change in Art. 1 of the Federal Law "On Temporary Ban on Human Cloning" (2010) (Russian): http://base.garant.ru/184467/		
San Marino				
General	San Marino Bioethics Committee (Italian): http://www.sanita.sm/on-	Oviedo Convention on Human Rights and Biomedicine (1998)		

Country	Key Organizations	Legislation	Regulations	Guidelines
	line/home/comitato-bioetica/comitato-sammarinese-di-bioetica.html			
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999)		
Serbia For an overview of human subject protections in Serbia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Serbia%20definitive%20Updated.pdf				
Drugs, Biologics, and Devices	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.gov.rs/eng/	Law on Medicines and Medical Devices, Official Gazette of RS No. 30/2010 and 107/2012: https://www.alims.gov.rs/eng/files/2013/04/Law-on-Medicines-and-Medical-Devices-2010.pdf	MOH: 1. Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 64/2011 and 91/2013: http://www.alims.gov.rs/ciril/files/2014/01/pravilnik-ki-91-2013.pdf 2. Regulation on Amendment to Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 60/2016 (Serbian): http://www.alims.gov.rs/ciril/files/2016/07/KI-60-16-izmena.pdf	
Research Injury	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/index.php? 2. Serbian Drug Agency http://www.alims.gov.rs	Law on Medicines and Medical Devices, Article 72 (Serbian): http://www.alims.gov.rs/ciril/files/2012/11/zakon-30-2010-107-2012.pdf	MOH: 1. Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 64/2011, 31 August 2011 2. Law on Patients' Rights, Article 25 Official Gazette of RS, 45/13: http://www.zdravlje.gov.rs/downloads/2013/Jun/Jul2013ZakonOPravimaPacijenata.pdf	
Privacy/Data Protection	Commissioner for Information of Public Importance and Personal Data Protection: http://www.poverenik.rs/en/the-commissioners-authority-di.html	Law on the Protection of Personal Data, Official Gazette 97/08, 104/09, 68/20 and 107/12 (Serbian): http://www.minrzs.gov.rs/files/doc/porodica/ostali/Zakon%20o%20zast		

Country	Key Organizations	Legislation	Regulations	Guidelines
		iti%20podataka%20o%20licnosti.pdf		
Genetics	Ministry of Health (MOH): http://www.zdravlje.gov.rs/index.php?	Law on the Prevention and Diagnosis of Genetically Conditioned Diseases, Genetically Caused Anomalies and Rare Diseases (2015) (Serbian): http://www.parlament.gov.rs/upload/archive/files/lat/pdf/zakoni/2015/2245-14%20lat.pdf		
Embryos, Stem Cells, and Cloning	National Health Insurance Fund: http://www.rfzo.rs/	1. Law on Organ Transplantation, Official Gazette No. 72/2009 (Serbian): http://www.rfzo.rs/download/zakoni/Zakon_transplantacija.pdf 2. Law on Transplantation of Cells and Tissues, Official Gazette No. 72/2009 (Serbian): http://www.rfzo.rs/download/zakoni/Zakon_celije_tkiva.pdf		
Slovakia For an overview of human subject protections in Slovakia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovakia%20definitive%20Updated.pdf				
General	1. Ministry of Health (Slovak): http://www.health.gov.sk/ 2. Institute of Medical Ethics and Bioethics: http://www.bioethics.sk/	1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2005) 3. Act No. 576/2004 Coll on Health Care, as amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.		
Drugs, Biologics, and Devices	State Institute for Drug Control: http://www.sukl.sk/en	Act No. 140/1998 Coll. on Drugs and Medical Devices, as amended by Acts No. 9/2004 and 542/2006, 489/2008, and 402/2009 Coll.	Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice, as Amended by Ministerial Regulation No. 148/2009 Coll.	
Research Injury		Law 277/1994 on Health Care, Section 44		
Privacy/Data Protection	Office for Personal Data Protection: https://dataprotection.gov.sk/uoou/en	Act No. 428/2002 Coll. on Protection of Personal Data, as amended by Act No. 90/2005 Coll.		
Human Biological		1. Act No. 576/2004 Coll. on	Governmental Regulation No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
Materials		Health Care, Sections 35-39. 2. Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).	20/2007 Coll. on Tissue and Cell Collection	
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) 2. Act No. 576/2004 Coll. on Health Care, Section 26.10.a.		
Slovenia Note: All websites and documents are in Slovenian.				
General	Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/	1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2006) 3. Patient Rights Act, Official Gazette No. 15/2008: http://www.uradni-list.si/1/objava.jsp?sop=2008-01-0455 4. Mental Health Act, Official Gazette Nos. 77/2008 and 46/2015: http://www.uradni-list.si/1/objava.jsp?sop=2008-01-3448 and http://www.uradni-list.si/1/objava.jsp?sop=2015-01-1881		Slovenian Code of Medical Deontology, Articles 47-50 (1997)
Drugs, Biologics, and Devices	*Drugs*			
	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Medicinal Products Act, Official Gazette No. 17/2014: http://www.uradni-list.si/1/objava.jsp?sop=2014-01-0539 2. Rules on Clinical Testing of Medicinal Products, Official Gazette, No. 54/2006: http://www.uradni-list.si/1/objava.jsp?sop=2006-01-2304	NMEC: 1. Statutory Notes (1998) 2. Rules on the Composition, Duties, Responsibilities, and Working Methods of the Commission for Medical Ethics, Official Gazette Nos. 30/1995, 69/2009, and 47/2017.	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Act on Medical Devices, Official Gazette No. 98/2009: http://www.uradni-list.si/1/objava.jsp?sop=2009-01-4284 2. Rules on Medical Devices, Official Gazette Nos. 37/2010 and 66/2012: http://www.uradni-list.si/1/objava.jsp?sop=2010-01-1842 and http://www.uradni-list.si/1/objava.jsp?sop=2012-01-2622		
Research Injury	Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999) 2. Additional Protocol Concerning Biomedical Research, Article 13, CETS No. 195 (2007)		
Privacy/Data Protection	Information Commissioner of the Republic of Slovenia: http://www.ip-rs.si/	Personal Data Protection Act No. 94/2007: http://www.uradni-list.si/1/objava.jsp?sop=2007-01-4690		
Human Biological Materials	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin (2006) 2. Act on Quality and Safety of Human Tissues and Cells, for the Purposes for Medical Treatment, Official Gazette No. 61/2007: http://www.uradni-list.si/1/objava.jsp?sop=2007-01-3297 3. Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014 4. Act Regulating the Collection and Transplantation of Human Body Parts for the Purposes of Medical Treatment, Official Gazette No. 56/2015:	On Interventions into the Human Corpse Which are Not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004): http://kme-nmec.sazu.si/Docu/O_truplih_Isis.pdf	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.uradni-list.si/1/objava.jsp?sop=2015-01-2357		
Genetic	Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (2009)		
Embryos, Stem Cells, and Cloning	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) 2. Infertility Treatment and Procedures of Biomedically-Assisted Procreation Act, Official Gazette No. 70/2000, Section 9 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2000-01-3307 3. Act on Quality and Safety of Human Tissues and Cells, for the Purposes for Medical Treatment, Official Gazette No. 61/2007 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2007-01-3297 4. Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014		
Spain For an overview of human subject protections in Spain, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Spain%20definitive%20Updated.pdf Note: Many of the 17 Spanish autonomous regions have their own laws and regulations on human subject protections.				
General	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/	1. Oviedo Convention on Human Rights and Biomedicine (1999): http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Spanish.pdf 2. Law 14/2007 on Biomedical		

Country	Key Organizations	Legislation	Regulations	Guidelines
	ceic/home.htm 3. Institute of Health Carlos III, Ministry of Science and Innovation http://www.isciii.es/htdocs/en/index.jsp	Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Drugs, Biologics, and Devices	*Drugs*			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm	1. Royal Decree 1015/2009: Drug Availability for Special Purposes (Spanish): http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf 2. Royal Decree 577/2013, Regulating Pharmacovigilance in Human Use Medicines: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8191 3. Law 10/2013, Incorporating into Spanish Laws Certain EU Directives About Monitoring and Preventing Commercialization of Counterfeit Medicines (Spanish): http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8083 4. Royal Decree 1/2015 of Guarantees and Rational Use of Medicines and Health Products (Spanish): http://www.boe.es/diario_boe/txt.php?id=BOE-A-2015-8343 5. Royal Decree 1090/2015, of 4 December, Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf	1. Order SCO/256/2007 That Establishes the Principles and Detailed Directives on Good Clinical Practice, and the Requirements to Approve the Manufacture and Import of Research Medications for Human Use (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2007_270.pdf 2. Order SCO/362/2008 that Modifies Order SCO/256/2007 (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2008_410.pdf 3. Order SAS/3470/2009 on Drugs Post Authorization Research (Spanish): http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/docs/farmacovigilancia/rcl_2009_2577.pdf	
	Devices			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacion	Royal Decree 1591/2009, Regulating Sanitary Devices: http://www.ont.es/infesp/Legislacin/	Various (Spanish): http://www.aemps.es/actividad/pschb/implantables1.htm#circulares	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Clinica/productosSanitarios/home.htm	RD_1591_2009.pdf		
Research Injury	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/home.htm	1. Law 14/2007 on Biomedical Research, Article 18: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf 2. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0536&from=EN 3. Royal Decree 1090/2015, of 4 December, Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf		
Privacy/Data Protection	Spanish Data Protection Authority (Spanish): https://www.agpd.es/portalweb/index-ides-idphp.php	1. Organic Law 15/1999 of December 13 on the Protection of Personal Data: http://www.legislationline.org/documents/id/9044 2. Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf	1. Royal Decree 1720/2007 (Spanish): http://www.davara.com/documentos/relacionados/proteccion/RD_1720-2007_english.pdf 2. Royal Decree of 19 January 2008	
Human Biological Materials	Ministry of Health and Consumption: http://www.msc.es/en/home.htm	1. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues 2. Royal Decree 1301/2006 of November 10 Regarding the Use	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006) (Spanish): http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
		of Cells and Human Tissue 3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf 4. Royal Decree 1716/2011 on Biobanks: http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf 5. Royal Decree 9/2014, of July 4 on Quality and Security Rules Regarding Donating, Gathering, Evaluation, Processing, Storage, Preservation and Distribution of Human Cells and Tissues and Rules Regarding Coordination and Functioning of their Use in Human Beings: http://www.boe.es/buscar/doc.php?id=BOE-A-2014-7065		
Genetic	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Embryos, Stem Cells, and Cloning	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. National Commission for the Donation and Use of Embryos, Cells, and Human Tissues for Biomedical Research: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/organizacion.shtml 3. National Biobank Register: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/organizacion.shtml	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2000) 2. Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V 3. Law 14/2007 of July 3 on Biomedical Research, Title III:		

Country	Key Organizations	Legislation	Regulations	Guidelines
	4. National Stem Cell Bank: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-centros-unidades/banco-nacional-lineas-celulares.shtml	http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf 4. Royal Decree 1527/2010, of November 15, By Which the Guarantees Commission for the Donation and Use of Human Cells and Tissues and Registration Research Projects is Regulated: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2010-18654		
Sweden For an overview of human subject protections in Sweden, see "CODEX: Rules and Guidelines for Research:" http://www.codex.uu.se/en/index.shtml				
General	Central Ethical Review Board: http://www.epn.se/en/start/	Act No. 460 on the Ethical Review of Research Involving Humans (2003): http://www.epn.se/media/2348/the_ethical_review_act.pdf	1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003): http://www.epn.se/media/1204/2003_615.pdf 2. Statute No. 2007:1068 Containing Instructions for the Central Ethical Review Board (2007): http://www.epn.se/media/1202/1068.pdf 3. Statute No. 2007:1069 Containing Instructions for Regional Ethical Review Boards (2007): http://www.epn.se/media/1203/1069.pdf	Information for Research Participants
	Swedish Research Council: http://www.vr.se/english		Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research (Swedish): http://www.vr.se/download/18.7ef6967137343483870280/1340207447175/VRFS+2012.1.pdf	1. Guidelines for the Ethical Evaluation of Medical Research on Humans (2003) 2. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to Undergo Invasive Operations (2003) 3. Good Research Practice (2017): https://publikationer.vr.se/en/product/good-research-practice/
Drugs, Biologics, and Devices	*Drugs*			
	Medical Products Agency: https://lakemedelsverket.se/english/	1. Pharmaceuticals Act No. No 2015:315 (Swedish):	MPA Regulations on Clinical Trials in Humans -- LVFS	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.notisum.se/rnp/sls/lag/20150315.htm 2. Pharmaceuticals Ordinance 2015:458 (Swedish): http://www.notisum.se/rnp/sls/lag/20150458.htm	2011:19 (Swedish): http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf	
	Devices			
	Medical Products Agency: http://www.lakemedelsverket.se/english/product/Medical-devices/Clinical-Investigations/	1. Swedish Medical Devices Act (SFS 1993:584): http://www.notisum.se/rnp/sls/lag/19930584.htm 2. Medical Devices Ordinance (SFS1993:876): http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-1993876-om-medicintekniska_sfs-1993-876	Swedish Implementation of Directive 93/42/EEC -- LVFS 2003:11 with Amendment LVFS 2004:11: https://lakemedelsverket.se/upload/lvfs/konsoliderade/LVFS_2003_11_konsoliderad_tom_2011_13.pdf	
Social-Behavioral Research	Swedish Research Council			Good Research Practice: Observational Studies Conducted Through Participating, Observing, and Recording (2011): https://publikationer.vr.se/en/product/good-research-practice/
Privacy/Data Protection	1. Swedish Data Protection Agency: http://www.datainspektionen.se/in-english/ 2. Swedish Research Council (SRC): http://www.vr.se/english	1. Patient Data Act: SFS 2008:355 (Swedish): http://www.notisum.se/rnp/sls/lag/20080355.htm 2. SFS 2009:400 - Public Access to Information and Secrecy Act (Swedish): http://www.notisum.se/rnp/sls/lag/20090400.htm 3. Act on Certain Health Research Registers, SFS 2013:794 (Swedish): http://www.notisum.se/Pub/Doc.aspx?url=/rnp/sls/lag/20130794.htm	SFS 2009:641 - Public Access to Information and Secrecy Ordinance (Swedish): http://www.notisum.se/rnp/sls/lag/20090641.htm	Swedish Data Protection Agency Report 2004:2: http://www.datainspektionen.se/Documents/rapport-biobanker.pdf SRC: Policy Document: Handling Personal Data (2003) (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000342/Personuppgifter_7.pdf
Human Biological Materials	1. National Board of Health and Welfare (SOS): http://www.socialstyrelsen.se/english 2. Swedish Research Council (SRC): http://www.vr.se/english 3. BBMRI Sweden: http://bbmri.se/en/ 4. National Biobank Council: http://biobanksverige.se/info/basic-information-in-english/	1. Biobanks in Medical Care Act No. 297 (2002): http://vavnad.se/files/live/sites/Biobanken/files/biobanksverige/9.%20Documetns%20in%20English/Biobanks%20in%20medical%20care%20act%20(2002-297).pdf 2. Regulation No. 746 (2002): http://www.notisum.se/rnp/sls/lag/20020746.htm	SOS: Consolidated regulations (Swedish): http://www.socialstyrelsen.se/sosfs/2002-11	SRC: Research Ethics Guidelines for Using Biobanks (Swedish) (2003) http://www.vr.se/download/18.6b2f98a910b3e260ae28000350/Riktlinjer_Biobanker_11.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. Medical Products Agency: https://lakemedelsverket.se/english/ 2. The Swedish Gene Technology Advisory Board (SGTAB): https://www.genteknik.se/	Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	Drug Administration Regulations and Guidelines (LVFS 2004:10) on the Intentional Release of Clinical Trials of Medicinal Products Containing or Consisting of Genetically Modified Organisms: http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf	SGTAB: Advice for Ethical Assessments (Swedish): https://www.genteknik.se/wp-content/uploads/2017/09/072_2010-Etisk-v%C3%A4gledning.pdf
Embryos, Stem Cells, and Cloning	1. Swedish Research Council (SRC): http://www.vr.se/english 2. National Board of Health and Welfare (SOS): http://www.socialstyrelsen.se/english	Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	1. Legal Regulation of Stem Cell Research 2002:119 (Swedish): http://www.regeringen.se/sb/d/108/a/2717 2. Regulations and Guidelines for the Use of Tissues and Cells in Healthcare and Clinical Research - SOSFS 2009:32 (Swedish): http://www.socialstyrelsen.se/sosfs/2009-32	SRC: Guidelines for Ethical Vetting of Human Stem Cell Research (2004) (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000362/human_stamcellsforskning_16.pdf
Switzerland For an overview of human subject protections in Switzerland, see: http://kofam.ch/en/home/				
General	1. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en 2. Federal Office of Public Health, Portal for Human Research (FOPH): http://kofam.ch/en/home/ 3. National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/homepage/ 3. Swiss Ethics Committees on Research Involving Humans: http://www.swissethics.ch/index_e.html	1. Council of Europe Convention on Human Rights and Biomedicine of 4 April 1997, ETS No. 164, Articles 15-18: http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Federal Constitution of the Swiss Confederation of 18 April, 1999, RS 101, Article 118b: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html 3. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September 2013 on Organizational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html	Swiss Clinical Trial Organisation, Guidelines for Good Operational Practice (GGOP) (2014): http://www.scto.ch/dms/SCTO/de/Publikationen/Richtlinien/Guidelines-for-Good-Operational-Practice_V2-0/Guidelines%20for%20Good%20Operational%20Practice_V2.0.pdf Access: http://www.scto.ch/en/News.html

Country	Key Organizations	Legislation	Regulations	Guidelines
		compilation/20061313/index.html		
Drugs, Biologics, and Devices	*Drugs*			
	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	1. Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21, Articles 53-54: http://www.admin.ch/opc/en/classified-compilation/20002716/index.html 2. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7 (2014): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September 2013 on Organisational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html	
	Devices			
	Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en	1. Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21, Articles 1-2, 45-67: https://www.admin.ch/opc/en/classified-compilation/20002716/index.html 2. Federal Act of 30 September 2011on Research involving Human Beings, (Human Research Act, HRA), RS. 810.30: https://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305 articles 20, 32, 37, 42-45 and Annexes 1, 3 and 4: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September	Swissmedic Guide to the Regulation of Medical Devices: https://www.swissmedic.ch/medizinprodukte/00287/index.html?lang=en

Country	Key Organizations	Legislation	Regulations	Guidelines
			2013 on Organisation Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html	
Clinical Trials Registry	Swiss National Clinical Trials Portal: http://kofam.ch/en/swiss-clinical-trials-portal/	Federal Act on Research Involving Human Beings, Articles 56, 64, 65, and 67 (2014): https://www.admin.ch/opc/en/classified-compilation/20061313/index.html		
Research Injury	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 19-20: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Articles 8, 12, 13, and 15, and Annexes 1-2: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305, Articles 7, 10-13, 25, and 71, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
Privacy/Data Protection Note: Most Swiss cantons have enacted laws regarding data collection in the public sector that are similar to the Federal Act on Data Protection.	Federal Data Protection and Information Commissioner (FDPIC): http://www.edoeb.admin.ch/index.html?lang=en	1. Federal Act of 19 June 1992 on Data Protection (FADP), RS 235.1: http://www.admin.ch/opc/en/classified-compilation/19920153/index.html 2. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63: http://www.admin.ch/opc/en/classifi	1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 5 - 8, 10, 15, 21, 24-34, 37-39, 41, and 44-45, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305	

Country	Key Organizations	Legislation	Regulations	Guidelines
		ed-compilation/20061313/index.html	Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
Human Biological Materials	1. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en 2. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/en/News/News.html	Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 17, 18, 31, 32 - 35, 41-43, 45, 47, 49, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 5 - 8, 10, 15, 21, 24-30, 33-34, 37 - 39, 41, 44-45 and Annex 2): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 7, 9, 12, 16 - 18 and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html	SAMS: Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006): http://www.samw.ch/en/Ethics/Guidelines/Archive.html
Genetic Research	Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	1. Federal Constitution of the Swiss Confederation of 18 April 1999, RS 101, Article 119: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html 2. Federal Act of 8 October 2004 on Human Genetic Testing (HGTA), RS 810.12: http://www.admin.ch/opc/en/classified-compilation/20011087/index.html 3. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 3, 32 - 35, 42, and 49: http://www.admin.ch/opc/en/classifi	1. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 28 - 32: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 22 and 35, and Annexes	

Country	Key Organizations	Legislation	Regulations	Guidelines
		ed-compilation/20061313/index.html	3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
Embryos, Stem Cells, and Cloning	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/homepage/	*Embryos in Vivo:* Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 25 - 27, 39, 40, 44, and 62: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html *Others:* Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.31: http://www.admin.ch/opc/en/classified-compilation/20022165/index.html	*Embryos in Vivo:* 1. Ordinance of 2 February 2005 on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311: http://www.admin.ch/opc/en/classified-compilation/20042542/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 44 – 46, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 49, 53, 55, and 56, and Annexes 3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html	NEK-CNE: 1. Pre-Implantation Genetic Diagnosis, 2007/9 (French): http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/en/pid_en.pdf 2. Research Involving Human Embryos and Fetuses. Opinion No. 11/2006: http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/en/embryonen_en.pdf 3. Pre-Implantation Genetic Diagnosis II, Opinion No. 14/2007 (German): http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/PID_II_d.pdf Access: http://www.nek-cne.ch/en/topics/opinions/
Ukraine				
General	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Constitution of Ukraine Art. 28 (1996) 2. Health Care Law, Article 45 (1992) 3. Criminal Code of Ukraine 2001, Article 141 and 142		
Drugs, Biologics, and Devices	1. Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua 2. National Academy of Sciences Bioethics Committee: http://biomed.nas.gov.ua/index-en/bioethics-committee	1. Ministry of Health Act On Procedure of Clinical Trials and Basic Statute of Ethics Commission 23.09/2009 No. 690 (2014) (Ukrainian): http://zakon5.rada.gov.ua/laws/show/z1010-09 2. On Medicines, Articles 7 and 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality Assurance of Medicines (2009) (Ukrainian): http://zakon5.rada.gov.ua/rada/show/v0095282-09 2. Ministry of Health Act 14.12.2009 N 944 on Approval of the Clinical Trial and Expertise of Clinical Trials	Bioethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007) 3. Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007) 4. Ethical Aspects of Placebo Controlled Clinical Trials in Patients with MS (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
			(Ukrainian): http://zakon4.rada.gov.ua/laws/show/z0053-10	5. Optimization of Local Ethics Committee Activities (2009) Guidelines for Pre-Clinical and Clinical Trials (Ukrainian): http://www.dec.gov.ua/index.php/ekspertiza-materialiv-doklinichnikh-ta-klinichnikh-viprobuvan/metodichni-rekomendatsiji-shchodo-provedennya-doklinichnikh-ta-klinichnikh-viprobuvan
Research Injury	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	On Medicines, Article 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80		
Privacy/Data Protection	1. State Service of Ukraine on Personal Data Protection 2. Ukrainian Parliament Commissioner for Human Rights: www.ombudsman.gov.ua	1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2010) 2. On Protection of Personal Data Act, 01.06.2010 with changes from 13.05.2014: http://zakon3.rada.gov.ua/laws/show/2297-17		
Human Biological Materials	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Cabinet Ministry of Ukraine Act № 286 on 02.03.2016 License Conditions on Providing Activities of Banks of Cord Blood and Other Human Tissues and Cells (Ukrainian): http://zakon2.rada.gov.ua/laws/show/286-2016-%D0%BF 2. Ministry of Health Act 20.04.12 No. 276 On Approving the List of Human Tissues and Cells, Allowing the Use of Banks of Cord Blood and Other Human Tissues and Cells (Ukrainian): http://zakon3.rada.gov.ua/laws/show/z1124-12	Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690 (Ukrainian): http://zakon1.rada.gov.ua/laws/show/z1206-07	
Genetic Research	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
Embryos, Stem Cells, and Cloning	1. National Academy of Sciences Bioethics Committee: http://biomed.nas.gov.ua/index-	1. Act on the Banning of Human Reproductive Cloning (2004) (Ukrainian):	1. Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for	

Country	Key Organizations	Legislation	Regulations	Guidelines
	en/bioethics-committee 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	http://zakon0.rada.gov.ua/laws/show/2231-15 2. Act on Organs and Other Human Materials Transplantology No. 1007-XIV (2007) (Ukrainian): http://zakon0.rada.gov.ua/laws/show/1007-14	the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) (Ukrainian): http://zakon1.rada.gov.ua/laws/show/z1206-07 2. Ukrainian Ministry of Health Order No. 787 on Approval of the Use of Reproductive Technologies in Ukraine 09.09.2013: http://zakon4.rada.gov.ua/laws/show/z1697-13	
United Kingdom Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom. For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=226				
General	*England:*			
	Health Research Authority (HRA): http://www.hra.nhs.uk/	Care Act (2014): http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted/data.htm		1. Directory of HRA Guidance: http://www.hra.nhs.uk/resources/ 2. Integrated Research Application System: https://www.myresearchproject.org.uk/
	Department of Health (DH): https://www.gov.uk/government/organisations/department-of-health	1. Mental Capacity Act (2005) (England and Wales only): http://www.legislation.gov.uk/ukpga/2005/9/contents 2. Health and Social Care Act (2012): http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted	1. Research Governance Framework for Health and Social Care (2005) https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition 2. Governance Arrangements for NHS Research Ethics Committees (2012): https://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements	
	Medical Research Council (MRC): https://www.mrc.ac.uk/			1. Research Involving Human Participants in Developing Societies (2004): https://www.mrc.ac.uk/publications/browse/research-involving-human-participants-in-developing-societies/ 2. Medical Research Involving Children (2004): https://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/

Country	Key Organizations	Legislation	Regulations	Guidelines
				3. Medical Research Involving Adults Who Cannot Consent (2007): http://www.mrc.ac.uk/documents/pdf/medical-research-involving-adults-who-cannot-consent/ 4. Good Research Practice: Principles and Guidelines (2012): https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/
	Scotland:			
	1. NHSScotland, Chief Scientist Office (CSO): http://www.cso.scot.nhs.uk/ 2. NHS Research Scotland: http://www.nhsresearchscotland.org.uk/	Adults with Incapacity (Scotland) Act 2000, Section 51: http://www.scotland.gov.uk/Topics/Justice/law/awi/legislation	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/ssi2002/20020190.htm	CSO: 1. Research Governance Framework for Health and Community Care (2006): http://www.cso.scot.nhs.uk/wp-content/uploads/2013/02/RGF-Second-Edition-February-06.pdf
	Wales:			
	Health and Care Research Wales: http://www.healthandcareresearch.gov.wales/			Research Governance Framework for Health and Social Care in Wales Second Edition (2009): http://www.wales.nhs.uk/sites3/Documents/952/Research%20Governance%20Framework%202009%20%28English%291.pdf
	Northern Ireland:			
	1. Department of Health, Social Services and Public Safety: http://www.dhsspsni.gov.uk/ 2. Office for Research Ethics. Committees Northern Ireland: http://www.hscbusiness.hscni.net/orecni.htm			Research Governance Framework for Health and Social Care (Northern Ireland) (2007): https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/research-governance-framework-2007.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency 2. Administration of Radioactive Substances Advisory Committee (ARSAC) (UK): https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee 3. Department of Environment, Food & Rural affairs (DEFRA) https://www.gov.uk/government/organisations/department-for-environment-food-	Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents	1. Ionising Radiation (Medical Exposure) Regulations IR(ME)R) (2000): http://www.legislation.gov.uk/uksi/2000/1059/contents/made *Amended by:* IR(ME)R (Amendment) Regulations (2006) http://www.legislation.gov.uk/uksi/2006/2523/contents/made IR(ME)R (Amendment) Regulations (2011) http://www.legislation.gov.uk/uksi/2011/1567/made 2. Medicines for Human Use	Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003): http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con007629.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	rural-affairs 4. Health and Safety Executive (HSE) http://www.hse.gov.uk/		(Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made 3. Amendment Regulations (SI 2006/1928) http://www.legislation.gov.uk/uksi/2006/1928/contents/made 4. Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings (SI 2006/2984): http://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf 5. SI 2008 No.941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008: http://www.legislation.gov.uk/uksi/2008/941/contents/made 6. Genetically Modified Organisms (Deliberate Release) Regulations 2002: http://www.legislation.gov.uk/uksi/2002/2443/contents/made 7. Genetically Modified Organisms (Contained Use) Regulations 2014 (England, Scotland and Wales): http://www.legislation.gov.uk/uksi/2014/1663/part/1/made 8. The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015: http://www.legislation.gov.uk/nisr/2015/339/contents/made	
	Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk			Guidelines for Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-

Country	Key Organizations	Legislation	Regulations	Guidelines
				work/library/guidelines/Pages/phase-1-trials-2012.aspx
	National Institute for Health Research: http://www.nihr.ac.uk/			Clinical Trials Toolkit: http://www.ct-toolkit.ac.uk/
	Health Research Authority (HRA): http://www.hra.nhs.uk/			Clinical Trials of Investigational Medicinal Products (CTIMPs) – Resource page: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/
	Devices			
	Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices		1. Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm 2. Medical Devices (Amendment) Regulations 2008 No 2936: http://www.legislation.gov.uk/uksi/2008/2936/contents/made	1. Clinical Trials for Medical Devices: https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices 2. Notify MHRA About a Clinical Investigation for a Medical Device: https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device
	Health Research Authority (HRA): http://www.hra.nhs.uk/			Medical Devices Guidance: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/medical-devices-research-2/
Clinical Trials Registry	1. ISRCTN: http://www.isrctn.com/ 2. Health Research Authority (HRA): http://www.hra.nhs.uk/			ISRCTN: FAQs: http://www.isrctn.com/page/faqs HRA: Transparency, Registration, and Publication: http://www.hra.nhs.uk/resources/during-and-after-your-study/transparency-registration-and-publication/
Research Injury	Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency		Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031, Regulation 15(5)(i)(j)(k) and Schedule 3 Part 1, Paragraphs 1(g) and 3(c) (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made	
	Department of Health (DH): https://www.gov.uk/government/organisations/department-of-health			NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS: www.nhsla.com/claims/Documents/NHS%20Indemnity.pdf
	Association of the British Pharmaceutical Industry (ABPI):			1. Insurance and Compensation in the Event of Injury in Phase I Clinical Trials

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.abpi.org.uk			(2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/clinical-trials-insurance.aspx 2. Clinical Trial Compensation Guidelines (2014): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx
	Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/			Clinical Investigations Compensation Guidelines (2014): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Social-Behavioral Research	Economic and Social Research Council			ESRC Framework for Research Ethics (2015): http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/
	UK Research Integrity Office			Good Practice in Research: Internet-Mediated Research (2016): http://ukrio.org/wp-content/uploads/UKRIO-Guidance-Note-Internet-Mediated-Research-v1.0.pdf
Privacy/Data Protection	*United Kingdom:*			
	Information Commissioner's Office: https://ico.org.uk/	Data Protection Act (1998): http://www.legislation.gov.uk/ukpga/1998/29/contents		
	Medical Research Council (MRC): http://www.mrc.ac.uk/			1. Personal Information in Medical Research (2003): http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/ 2. Use of Personal Health Information in Medical Research General Public Consultation Final Report (2007) https://www.mrc.ac.uk/documents/pdf/the-use-of-personal-health-information-in-medical-research-june-2007/ 3. Data and Tissues Tool Kit: http://www.dt-toolkit.ac.uk/home.cfm
	England and Wales:			
	1. Health Research Authority (HRA) (England): http://www.hra.nhs.uk/ 2. Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-	Health Service (Control of Patient Information) Regulations 2002 (HS (CPI) Regs): http://www.legislation.gov.uk/uksi/2002/1438/made?view=plain		1. Ethical Review of Research Databases: http://www.hra.nhs.uk/documents/2013/09/ethical-review-of-research-databases.pdf 2. Section 251 and the Confidentiality Advisory Group (CAG):

Country	Key Organizations	Legislation	Regulations	Guidelines
	committees/section-251			http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/
Human Biological Materials	*United Kingdom:*			
	Human Tissue Authority (HTA): http://www.hta.gov.uk/	1. Human Tissue Act (2004): http://www.legislation.gov.uk/ukpga/2004/30/contents *(Applies to England, Wales, and Northern Ireland. Section 45 also applies in Scotland.)* 2. Statutory Instrument 2006 No. 1260: The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006: http://www.legislation.gov.uk/uksi/2006/1260/contents/made *(Applies to England, Wales, and Northern Ireland.)* 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 *(Different provisions apply to England, Wales, Northern Ireland, and/or Scotland.):* http://www.legislation.gov.uk/uksi/2006/1659/contents/made		Guidance for Professionals: https://www.hta.gov.uk/guidance-professionals
	Medical Research Council (MRC): https://www.mrc.ac.uk/			Human Tissue and Biological Samples for Use in Research (2014)
	Scotland:			
	Healthcare Improvement Scotland: http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/human_tissue_banks.aspx	Human Tissue (Scotland) Act 2006: http://www.legislation.gov.uk/asp/2006/4/contents		
	Medical Research Council (MRC): https://www.mrc.ac.uk/			1. Human Tissue and Biological Samples for Use in Research (2014) http://www.mrc.ac.uk/publications/browse/human-tissue-and-biological-samples-for-use-in-research/ 2. Data and Tissues Tool Kit: http://www.dt-toolkit.ac.uk/home.cfm
Genetics Research	1. Public Health Genetics Foundation: http://www.phgfoundation.org/			

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Gene Therapy Advisory Committee: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/ 3. Genomics England: https://www.genomicsengland.co.uk/			
Embryos, Stem Cells, and Cloning	1. Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/ 2. Human Tissue Authority (HTA): https://www.hta.gov.uk/regulated-sectors	1. Human Fertilisation and Embryology Act (1990): http://www.legislation.gov.uk/ukpga/1990/37/contents 2. HFE Act (2008): http://www.legislation.gov.uk/ukpga/2008/22/contents	Human Fertilisation and Embryology Regulation and Chronology: https://www.hfea.gov.uk/about-us/how-we-regulate/	HFEA Code of Practice 8th Edition (2016): https://www.hfea.gov.uk/code-of-practice/

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC				
Australia				
General	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Australian Research Council (ARC): http://www.arc.gov.au	National Health and Medical Research Council Act 1992 (2014): http://www.comlaw.gov.au/Details/C2014C00364	National Health and Medical Research Regulation 2016: https://www.legislation.gov.au/Details/F2016L00682	NHMRC: 1. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) http://www.nhmrc.gov.au/guidelines/publications/e52 2. Keeping Research on Track: A Guide for Aboriginal and Torres Strait Islander Peoples about Health Research Ethics (2006): http://www.nhmrc.gov.au/guidelines/publications/e65 NHMRC, ARC, and Universities Australia: 1. Australian Code for the Responsible Conduct of Research (2007): http://www.nhmrc.gov.au/guidelines/publications/r39 2. National Statement on Ethical Conduct in Human Research, 2007 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
	Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://aiatsis.gov.au/			Guidelines for Ethical Research in Australian Indigenous Studies (2012): http://www.aiatsis.gov.au/research/ethics/GERAIS.html
Drugs, Biologics, and Devices	*Drugs*			
	Therapeutic Goods Administration (TGA): http://www.tga.gov.au	Therapeutic Goods Act 1989 (2016): https://www.legislation.gov.au/Details/C2016C00269	Therapeutic Goods Regulations 1990 (2016): https://www.legislation.gov.au/Details/F2016C00801	TGA: 1. Human Research Ethics Committees and the Therapeutic Goods Administration (2001): http://www.tga.gov.au/hp/access-hrec.htm 2. Australian Clinical Trial Handbook (2006): https://www.tga.gov.au/sites/default/files/clinical-trials-handbook.pdf NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2015): http://www.nhmrc.gov.au/guidelines/publicatio

Country	Key Organizations	Legislation	Regulations	Guidelines
				ns/e72 Australian States and Territories: National Mutual Acceptance of Scientific and Ethical Review of Multi-Centre Human Research (2017): http://www.health.nsw.gov.au/ethics/Pages/nma.aspx
	Devices			
	Therapeutic Goods Administration: http://www.tga.gov.au/industry/devices.htm	Therapeutic Goods Act 1989 (2016): https://www.legislation.gov.au/Details/C2016C00269	Therapeutic Goods (Medical Devices) Regulations 2002 (2016): https://www.legislation.gov.au/Details/F2016C00801	Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): http://www.tga.gov.au/industry/devices-argmd.htm
Clinical Trials Registry	1. National Health and Medical Research Council and the Department of Industry, Innovation, and Science: https://www.australianclinicaltrials.gov.au 2. Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			1. National Statement on Ethical Conduct in Human Research, 3.3.12 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72 2. FAQs: http://www.anzctr.org.au/Faq.aspx
Research Injury	1. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/ 2. Medicines Australia https://medicinesaustralia.com.au 3. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au			TGA: Guidance on Good Clinical Practice (CPMP/ICH-135/95). Paragraphs 5.8.1, 5.11.1, 8.2.5 , 8.2.7 (2000): https://www.tga.gov.au/publication/note-guidance-good-clinical-practice Medicines Australia: Industry Standard Compensation Guidelines (2012): https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/ NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research. Paragraphs 3.3.24 and 3.3.25 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
Social-Behavioral Research	National Health and Medical Research Council			National Statement on Ethical Conduct in Human Research, Chapter 3.1 (2015): https://www.nhmrc.gov.au/book/chapter-3-1-qualitative-methods
Privacy/Data Protection	Office of the Australian Information Commissioner: http://www.oaic.gov.au/	Privacy Act 1988 (2016): https://www.legislation.gov.au/Deta	1. Australian Privacy Principles Guidelines (2014):	1. Australian Privacy Principles Guidelines (2015):

Country	Key Organizations	Legislation	Regulations	Guidelines
Note: All Australian states and territories have privacy/data protection laws: http://www.oaic.gov.au/privacy/other-privacy-jurisdictions/state-and-territory-privacy-law		ils/C2016C00838	http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles 2. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1 3. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 4. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3 5. Privacy Regulation 2013 (2016): https://www.legislation.gov.au/Details/F2016C00599	http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles 2. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1 3. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 4. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3
Human Biological Materials Note: All Australian states and territories have laws on human biological materials.	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/			NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research (2015): Chapters 3.2 and 3.4: http://www.nhmrc.gov.au/guidelines/publications/e72 TGA: Australian Regulatory Guidelines for Biologicals (2017): http://www.tga.gov.au/industry/biologicals-argb.htm
Genetic Research	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Office of the Gene Technology Regulator: http://www.ogtr.gov.au/	Gene Technology Act 2000 (2016): https://www.legislation.gov.au/Details/C2016C00792	Gene Technology Regulations 2001 (2016): https://www.legislation.gov.au/Details/F2016C00615	NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. National Health and Medical Research Council: Embryo Research Licensing Committee https://www.nhmrc.gov.au/about/nhmrc-committees/embryo-research-licensing-committee	1. Prohibition of Human Cloning for Reproduction Act 2002 (2008): http://www.comlaw.gov.au/Details/C2008C00694 2. Research Involving Human Embryos Act 2002 (2017): http://www.comlaw.gov.au/Details/C2014C00605	Research Involving Human Embryos Regulations (2008): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/53B9DAE14F396A2CCA25744E0005E313	NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.4 (2015): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm NHMRC: Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical

Country	Key Organizations	Legislation	Regulations	Guidelines
				Practice and Research (2017): https://www.nhmrc.gov.au/guidelines-publications/e79
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
Drugs, Biologics, and Devices	Bangladesh Directorate of Drug Administration: http://www.dgda.gov.bd/	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://bdlaws.minlaw.gov.bd/pdf_part.php?id=623		
Human Biological Materials	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
Burma (Myanmar)				
General	1. Department of Medical Research (DMR): http://www.dmrlm.gov.mm/ 2. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm			DMR: Operational Guidelines for Institutional Ethical Review Committee (2005)
Drugs, Biologics, and Devices	Ministry of Health, Food and Drug Administration: http://www.fdamyanmar.gov.mm/index.php/en/	National Drug Law (1992)		
Human Biological Materials		1. Blood and Blood Products Law (2003) (Burmese): http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20(2003).pdf 2. Body Organ Donation Law (2004)		
China, People's Republic of For an overview of clinical research regulations in China, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=44				
General	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://en.nhfpc.gov.cn 2. Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37 (Mandarin): http://www.gov.cn/banshi/2005-08/01/content_18970.htm		NHFPC: Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016) (Mandarin): http://www.moh.gov.cn/fzs/s3576/201610/84b33b81d8e747eaaf048f68b174f829.shtml NHFPC, CFDA, and State Administration of TCM: Management Guidelines for Conducting Clinical Research at Medical/Health

Country	Key Organizations	Legislation	Regulations	Guidelines
				Institutions (Mandarin) (2014): http://www.nhfpc.gov.cn/yzygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml
Drugs, Biologics, and Devices	*Drugs*			
	Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Drug Administration Law of the People's Republic of China (2001): http://eng.sfda.gov.cn/WS03/CL0766/61638.html	1. Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2002): http://eng.sfda.gov.cn/WS03/CL0767/61640.html 2. Chinese Good Clinical Practice (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24473.html 3. Special Review and Approval Procedure for Drug Registration of the State Food and Drug Administration (2005): http://eng.sfda.gov.cn/WS03/CL0768/61646.html 4. Provisions for Drug Registration (2007): http://eng.sfda.gov.cn/WS03/CL0768/61645.html 5. Qualification and Evaluation of Clinical Trial Sites (2008) (Mandarin): http://www.sfda.gov.cn/WS01/CL0121/29571.html 6. Rules on the Administration of Report and Supervision of Adverse Drug Reactions (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/62621.html	1. Guideline for HIV Vaccine Research Technology (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0237/15705.html 2. Guideline for Vaccine Research Technology (2004) (Mandarin): http://www.sfda.gov.cn/WS01/CL0055/10307.html 3. Guidelines on Ethical Review of Drug Clinical Trials (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0058/55613.html 4. Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015) (Mandarin): http://www.sda.gov.cn/WS01/CL0087/114002.html
	Devices			
	Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/		CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/148101.html	CFDA: Guiding Principles of the Clinical Trail Technology on In Vitro Diagnostic (IVD) Reagents (2014) (Mandarin): http://www.sda.gov.cn/WS01/CL0087/106241.html Templates for Medical Device Clinical Trials (Mandarin):

Country	Key Organizations	Legislation	Regulations	Guidelines
				1. Ethical Review Application And Review Form 2. Informed Consent Form 3. CRF Template 4. Protocol Template 5. Report Template 6. Required Documents List Access: http://www.sda.gov.cn/WS01/CL0087/148126.html
Clinical Trials Registry	Chinese Clinical Trial Registry: http://www.chictr.org.cn/index.aspx			FAQs: http://www.chictr.org.cn/question.aspx
Privacy/Data Protection	*Hong Kong:*			
	1. Office of the Privacy Commissioner for Personal Data: http://www.pcpd.org.hk 2. eHealth Record Office: http://www.ehealth.gov.hk/en/home/index.html	Personal Data (Privacy) Ordinance (2013): http://www.blis.gov.hk/blis_pdf.nsf/CurAllEngDoc/B4DF8B4125C4214D482575EF000EC5FF/$FILE/CAP_486_e_b5.pdf		1. Electronic Health Record Sharing System and Your Personal Data Privacy (10 Privacy Protection Tips): https://www.pcpd.org.hk/english/data_privacy_law/electronic_health_record_sharing_system/files/eHRSS_10_Tips_ENG.pdf 2. Personal Data (Privacy) Ordinance and Electronic Health Record Sharing System (Points to Note for Healthcare Providers and Healthcare Professionals): https://www.pcpd.org.hk/english/data_privacy_law/electronic_health_record_sharing_system/files/eHRSS_Points_to_Notes_ENG.pdf
Research Injury	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Chinese Food and Drug Administration (CFDA): http://eng.sfda.gov.cn/WS03/CL0755/	Chinese Good Clinical Practice, Article 43 (2003) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/24473.html	NHFPC: 1. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.gov.cn/flfg/2011-06/13/content_1882686.htm 2. Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016), Articles 18.5, 20.8, 36.6, 37. (Mandarin): http://www.moh.gov.cn/fzs/s3576/201610/84b33b81d8e747eaaf048f68b174f829.shtml CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016), Articles 10, 22, 33, and 48; (Mandarin):	SFDA: 1. Guideline on Vaccine Clinical Trials, Part 6 (2004) (Mandarin): http://www.sda.gov.cn/WS01/CL0844/10307.html 2. Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010) (Mandarin): http://www.sda.gov.cn/WS01/CL0058/55613.html

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.sda.gov.cn/WS01/CL0053/148101.html	
Genetic Research	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC and MOST: 1. Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rlyc/wjxz/200512/t20051226_55327.htm 2. Regulations for the Administration of Human Genetic Resources (2012, public comment version) (Mandarin): http://www.gov.cn/gzdt/2012-10/31/content_2254379.htm	MOST: Service Guidelines for the Collection, Selling, Export and Admission Application of Human Genetic Resources (2015) (Mandarin): http://www.most.gov.cn/tztg/201507/t20150703_120547.htm
Embryos, Stem Cells, and Cloning	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC: 1. Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies. (2003) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200805/f69a925d55b44be2a9b4ada7fcdec835.shtml 2. Regulation on the Clinical Application of Medical Technique (2009) http://www.moh.gov.cn/yzygj/s3589/201308/0c579ba3babf47dc8f0e811810d438a2.shtml NHFPC and CFDA Interim Measures for the Management of Stem Cell Clinical Research (2015) (Mandarin): http://www.nhfpc.gov.cn/qjjys/s3581/201508/28635ef99c5743e294f45e8b29c72309.shtml	NHFPC and MOST: Ethical Guidelines for Research on Human Embryo Stem Cells (2003) (Mandarin): http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm
	Hong Kong:			
	Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China: http://www.legco.gov.hk/index.html		Human Reproductive Technology (Amendment) Ordinance 2016: http://www.legco.gov.hk/yr15-16/english/ord/ord020-2016-e.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
India For an overview of the clinical research regulations in India, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=100				
General	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			1. National Ethical Guidelines For Biomedical and Health Research Involving Human Participants (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf 2. National Ethical Guidelines for Biomedical Research Involving Children (2017): http://icmr.nic.in/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Schedule Y of the Drugs and Cosmetics Act (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	DCGI: 1. Good Clinical Practices for Clinical Research in India (2001): http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf 2. Permission for Clinical Trials: General Statutory Rules 63(E) 3. Ethics Committee Registration: General Statutory Rules 72(E) 4. A/V Consent – General Statutory Rules 611 (E) (2015) 5. Phytopharmaceutical Drug: General Statutory Rules 918(E) 6. Exemption for Academic Research and Animal Toxicity: General Statutory Rules 313(E) (2016)	ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
	Devices			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Drugs & Cosmetics Act, 1940 (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	1. Rules: Schedule D & K (2014): http://www.cdsco.nic.in/writereaddata/GSR%20690(E),%2025th%20Sep,%202014.pdf 2. Rules: Schedule MIII (2016): http://www.cdsco.nic.in/writereaddata/GSR%20640%20(E)%20dated%2029_06_2016%20-%20Copy.pdf	ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7.7 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Clinical Trials Registry	Clinical Trials Registry – India: http://ctri.nic.in/			Clinical Trials Registry – India: FAQs: http://ctri.nic.in/Clinicaltrials/faq.php Office of Drugs Controller General:

Country	Key Organizations	Legislation	Regulations	Guidelines
				Registration of Clinical Trial in ICMR Clinical Trial Registry: http://www.cdsco.nic.in/writereaddata/CTRegistration.doc
Research Injury	1. Central Drugs Standard Control Organization (CDSCO): http://www.cdsco.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Drugs & Cosmetics Act, 1940 (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	DCGI: Compensation: General Statutory Rules 53 (E): http://www.manupatra.com/manufeed/contents/PDF/634969625902580076.pdf CDSCO: 1. Compensation and Reporting of SAE timelines GSR 889 (E) 2014 (scroll down to see English version): http://www.cdsco.nic.in/writereaddata/Notificatiohn%20on%20Compensation%20on%20clincial%20trial%20(1).pdf 2. Compensation in Case of Injury or Death During Clinical Trial, Schedule Y, Appendix XII (2013) (Scroll down to see English version): http://www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2013/February/Clinical%20Trials%20Compensation%20Guidelines.pdf 3. Compensation Formula for Clinical Trial Injury Other than Death (2014) : http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trial%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf	ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Social-Behavioral Research				ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 9 (2017):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Human Biological Materials	Ministry of Health and Family Welfare: http://mohfw.nic.in/		Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19th November, 1997 on Exchange of Human Biological Material for Biomedical Research Purposes	ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 11 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Genetic Research	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Environmental Protection Act (1986)		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002) ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 10 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Embryos, Stem Cells, and Cloning	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			National Guidelines for Stem Cell Research (2017): http://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.pdf
Indonesia				
General	Ministry of Health, National Institute of Health Research and Development: http://indonesia.go.id/en	Indonesian Health Act No. 23/1992 Section on Health Research, Article 69	Regulation No. 39/1995 on Health Research & Development	National Guidelines on Ethics in Health Research (2003)
Drugs, Biologics, and Devices	National Agency of Drug and Food Control: http://www.pom.go.id/index.php/home/en		Guidelines on Good Clinical Practice (2001)	
Human Biological Materials			National Guidelines on Use of Stored Biological Materials (2005)	
Japan				
General	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 2. Ministry of Health, Labor, and Welfare (MHLW):	Clinical Research Act (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf		MEXT and MHLW: Ethics Guidelines for Medical and Health Research Involving Human Subjects (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n18

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.mhlw.go.jp/english/index.html			59_01.pdf 2015 version (English): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	1. Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html 2. Clinical Research Act (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf	MHLW: Ministerial Ordinance on Good Clinical Practice for Drugs (2016) (Japanese): http://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=409M50000100028&openerCode=1	
	Devices			
	1. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	1. Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html 2. Clinical Research Act (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf	MHLW: Ministerial Ordinance on Good Clinical Practice for Medical Devices (2016) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html 2009 version (English): https://www.pmda.go.jp/files/000153732.pdf	
Clinical Trials Registry	National Institute of Public Health: https://www.niph.go.jp/index_en.html			NIPH Clinical Trials Search: http://rctportal.niph.go.jp/en/
Privacy/Data Protection	1. Personal Information Protection Commission: http://www.ppc.go.jp/en/ 2. Office of Healthcare Policy of the Cabinet Secretariat: http://www.kantei.go.jp/jp/singi/kenkouiryou/en/	1. Amended Act on the Protection of Personal Information (2017): https://www.ppc.go.jp/files/pdf/Act_on_the_Protection_of_Personal_Information.pdf 2. Act Regarding Anonymized Medical Data to Contribute to R&D in the Medical Field (2017) (Japanese): http://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/pdf/170310_shiryou3.pdf	1. Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/Cabinet_Order.pdf 2. Enforcement Rules for the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/PPC_rules.pdf	Guideline for Act on the Protection of Personal Information (2016)(Japanese): https://www.ppc.go.jp/files/pdf/guidelines01.pdf https://www.ppc.go.jp/files/pdf/guidelines02.pdf https://www.ppc.go.jp/files/pdf/guidelines03.pdf https://www.ppc.go.jp/files/pdf/guidelines04.pdf
Research Injury	Ministry of Health, Labor, and	Pharmaceuticals, Medical	1. Ministerial Ordinance on Good	Ethics Guidelines for Medical and Health

Country	Key Organizations	Legislation	Regulations	Guidelines
	Welfare (MHLW): http://www.mhlw.go.jp/english/index.html	Devices, and Other Therapeutic Products Act (2016) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	Clinical Practice for Drugs, Article 14 (2016): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html 2. Ministerial Ordinance on Good Clinical Practice for Medical Devices, Article 14 and 23 (2016): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html	Research Involving Human Subjects, Chapter 2, No. 5, 1-(3) and No. 6, 2-(2) (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
Human Biological Materials	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			On Research and Development Utilizing Human Tissues Removed by Surgery and Other Procedures (1998) (Japanese): http://www1.mhlw.go.jp/shingi/s9812/s1216-2_10.html
Genetic Research	1. Council for Science, Technology, and Innovation (CSTI): http://www8.cao.go.jp/cstp/english/index.html 2. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 3. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 4. Ministry of Economy, Trade, and Industry (METI): http://www.meti.go.jp/english/			CSTI: Fundamental Principles of Research on the Human Genome (2000): http://www.lifescience.mext.go.jp/files/pdf/43_137.pdf MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1432_01_01.pdf 2008 version (English): http://www.lifescience.mext.go.jp/files/pdf/n796_00.pdf MHLW: Guidelines for Clinical Research in Gene Therapy and Others (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/150812_rinrisisin.pdf
Embryos, Stem Cells, and Cloning	1. Council for Science, Technology, and Innovation (CSTI): http://www8.cao.go.jp/cstp/english/index.html 2. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/	1. Act on Regulation of Human Cloning Techniques (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H12/H12HO146.html 2000 version (English):	1. Ordinance for Enforcement of Act on Regulation of Human Cloning Techniques (2009): http://www.lifescience.mext.go.jp/files/pdf/n1564_01.pdf 2. Ordinance for Enforcement of	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_28.pdf MEXT:

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.cas.go.jp/jp/seisaku/hourei/data/htc.pdf 2. Act on Safety of Regenerative Medicine (2013) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000030847.pdf	Act on Safety of Regenerative Medicine (2014) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000065532.pdf	1. Guidelines on the Handling of a Specified Embryo (2009): http://www.lifescience.mext.go.jp/files/pdf/n1564_02.pdf 2. Guidelines on the Derivation of Human Embryonic Stem Cells (2014): http://www.lifescience.mext.go.jp/files/pdf/n1553_01.pdf 3. Guidelines on the Distribution and Utilization of Human Embryonic Stem Cells (2014): http://www.lifescience.mext.go.jp/files/pdf/n1553_02.pdf 4. Guidelines on Research on Producing Germ Cells from Human Induced Pluripotent Stem Cells or Human Tissue Stem Cells (2015) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_01.pdf 2010 version (English): http://www.lifescience.mext.go.jp/files/pdf/n1567_02.pdf MEXT and MHLW: Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_03.pdf 2010 version (English): http://www.lifescience.mext.go.jp/files/pdf/n1567_01.pdf
Kazakhstan Note: For an overview of human subject protections in Kazakhstan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 5: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	Ministry of Healthcare and Social Development, Central Commission on Research Ethics: http://www.mzsr.gov.kz/en			1. Guidelines on Ethics in Health Research. (2007) 2. Local Ethics Committees: Policy, Rules and Procedures (2014) 3. Guidelines on Ethics in Biomedical Research (2015)
Drugs, Biologics, and Devices	Ministry of Healthcare and Social Development, Control Committee of Medical and Pharmacy Activity:	Code of the Republic of Kazakhstan "On People's Health and the Health Care System"	1. Order of the MHSD of the RK Dated 12.11.2009 No. 697 on the Approval of Regulations on the	Guidelines on Clinical Trials in Kazakhstan (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.mzsr.gov.kz/en/taxonomy/term/674	(18.09.2009 No.193-IV), Articles 74 and 180 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8	Medical-Biological Experiments, Preclinical (Non-Clinical) and Clinical Trials 2. Order of the MHSD of the RK dated 19.11.2009 No. 744 on the Approval of Regulations on the Conduct of Clinical Trials and/or Trials on Pharmaceutical and Drug Products, Medical Devices, and Medical Equipment 3. Order of the MHSD Dated 20.05.2014 No.272 on the Approval of Regulations on the Implementation of the New Methods of Diagnostic, Treatment, and Rehabilitation	
Privacy/Data protection	Ministry of Healthcare and Social Development: http://www.mzsr.gov.kz/en	Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Article 28 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8		
Korea Note: All documents are in Korean.				
General	Ministry of Health and Welfare: http://www.mohw.go.kr/eng/	Bioethics and Safety Act No. No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	1. Enforcement Decree of Bioethics and Safety Act No. No. 28211 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령 2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙	
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/ 2. Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	MOHW: Pharmaceutical Affairs Act No. 14839 (2017): http://www.law.go.kr/법령/약사법	MOHW: 1. Enforcement Decree of Pharmaceutical Affairs Act No. 28211 (2017): http://www.law.go.kr/법령/약사법시행령 2. Enforcement Rule of	MFDS: Guidelines on Human Research Protection Program (2014): http://www.mfds.go.kr/index.do?mid=1162&seq=7877&cmd=v 2. IND regulations No 2017-23 (2017): http://www.law.go.kr/admRulSc.do?menuId=1

Country	Key Organizations	Legislation	Regulations	Guidelines
			Pharmaceutical Affairs Act No. 503 (2017): http://www.law.go.kr/법령/약사법시행규칙 MFDS: 1. Enforcement Rule of Medicinal Product Safety No. 1330 (2017): http://www.law.go.kr/법령/의약품등의안전에관한규칙 2. 임상시험 및 생물학적 동등성시험 종사자 교육 및 교육실시기관 지정에 관한 규정 2. Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution No. 2016-133 (2016): http://www.law.go.kr/행정규칙/임상시험및생물학적동등성시험종사자교육및교육실시기관지정에관한규정	&query=%EC%9D%98%EC%95%BD%ED%92%88%20%EC%9E%84%EC%83%81%EC%8B%9C%ED%97%98%20%EA%B3%84%ED%9A%8D%20%EC%8A%B9%EC%9D%B8%EC%97%90%20%EA%B4%80%ED%95%9C%20%EA%B7%9C%EC%A0%95#liBgcolor0
	Devices			
	Ministry of Food and Drug Safety: http://www.mfds.go.kr/eng	Medical Device Act No. 14330 (2016): http://www.law.go.kr/법령/의료기기법	1. Enforcement Decree of the Medical Device Act No. 28224 (2017): http://www.law.go.kr/법령/의료기기법시행령 2. Enforcement Regulations of the Medical Device Act No. 1389 (2017): http://www.law.go.kr/법령/의료기기법시행규칙	
Clinical Trials Registry	Korea Centers for Disease Control and Prevention (KCDC), Clinical Research Information Service: https://cris.nih.go.kr/cris/en/use_guide/cris_introduce.jsp			
Research Injury	Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng		Enforcement Rule of Medicinal Product Safety No. 1330 (2017): http://www.law.go.kr/법령/의약품등의안전에관한규칙	Guidelines for Clinical Trial Indemnity and Its Process (2013): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1769&searchDivision=&searchClass=&searchword=임상시험%20피

Country	Key Organizations	Legislation	Regulations	Guidelines
				해자&y=0&searchSubDivision=&pageNo=1&seq=13069&sitecode=2017-06-01&cmd=v 2. Guidance for Sponsors; Safety Reporting Requirements (2017): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1769&searchDivision=&searchClass=&searchword=임상시험&y=0&searchSubDivision=&pageNo=1&seq=13317&sitecode=2017-08-31&cmd=v
Privacy/Data Protection	1. Ministry of the Interior and Safety (MOIS): http://www.mois.go.kr/eng/ 2. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/	MOIS: Personal Information Protection Act No. 14839 (2017): http://www.law.go.kr/법령/개인정보보호법 MOHW: Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	MOIS: 1. Enforcement Rules to Personal Information Protection Act No. 28211 (2017): http://www.law.go.kr/법령/개인정보보호법시행령 2. Enforcement Decrees to Personal Information Protection Act No. 26140 (2017): http://www.law.go.kr/법령/개인정보보호법시행규칙 MOHW: Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙	MOIS: Guidelines on Standard Personal Information Protection (2017): http://www.law.go.kr/행정규칙/표준개인정보보호지침
Human Biological Materials	1. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	1. Enforcement Decree of Bioethics and Safety Act No. 28211 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령 2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙	
Genetic Research	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 28211 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령 2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리	MFDS: Guideline on the Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (2005): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전&x=0&mid=1769&pageNo=1&seq=12480&sitec

Country	Key Organizations	Legislation	Regulations	Guidelines
			및안전에관한법률시행규칙	ode=2006-01-01&cmd=v 2. Guidelines on the Evaluation of Quality, Safety, and Efficacy of Recombinant Protein Products (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전&x=0&mid=1769&pageNo=1&seq=12542&sitecode=2017-06-01&cmd=v
Embryos, Stem Cells, and Cloning	1. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline on Sponsor-Investigator Trials of Cell Therapy Products for Academic Purpose (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=세포&x=0&mid=1161&pageNo=1&seq=8730&cmd=v
Kyrgyzstan Note: All websites and documents are in Russian.				
General	1. Government of the Kyrgyz Republic: http://www.gov.kg 2. Ministry of Health: http://www.med.kg 3. Ministry of Justice of the Kyrgyz Republic: http://cbd.minjust.gov.kg	1. Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): http://www.gov.kg/?page_id=263 2. Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6): Articles 34 and 73: http://www.pharm.kg/ru/legislation	1. Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004): http://www.med.kg/index.php/dokumenty-2/kodex-prof-etiki-2.html 2. Code of Administrative Responsibility of the Kyrgyz Republic №114 from 04.08.1998г. (Updated June 11, 2008 N 115 and June 23, 2008 N 136) Chapters 7 and 10: http://www.pharm.kg/ru/legislation/	
Drugs, Biologics, and Devices	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee 3. Pharmaceutical Union of Kyrgyzstan, Ethics Committee: http://farmunion.kg/o-nas/eticheskij-komitet/	Law on the Circulation of Medicinal Products of the Kyrgyz Republic (August 2, 2017 No. 165) Chapter VII, Articles 24-25.	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices: Rules for Clinical Trials (2010): http://www.pharm.kg/ru/legislation/ 2. Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order # 74 from February 1, 2012:	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.pharm.kg/ru/legislation/	
Research Injury	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on the Circulation of Medicinal Products of the Kyrgyz Republic (August 2, 2017 No. 165) Chapter VII, Articles 24-25.	DDMDP: National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): http://www.pharm.kg/ru/legislation/	
Human Biological Materials	1. Ministry of Health, Department of Drug and Medical Devices Provision: http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 39: http://www.pharm.kg/ru/legislation	Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/	
Social-Behavioral Research	Ministry of Justice	Law On the Protection of Traditional Knowledge (2014): http://cbd.minjust.gov.kg/act/view/ru-ru/202149/20?cl=ru-ru		
Privacy/Data Protection	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 91: http://www.pharm.kg/ru/legislation	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): http://www.pharm.kg/ru/legislation/ 2. Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/	
Malaysia				
Drugs, Biologics, and Devices	National Committee for Clinical Research: http://www.nccr.gov.my/			1. Guidelines for Ethical Review of Clinical Research or Research Involving Human Subjects (2006): http://www.nccr.gov.my/view_file.cfm?fileid=16 2. Malaysian Guidelines of Good Clinical Practice (2011): http://www.nih.gov.my/mrec/documents/Malaysian%20GCP.pdf
Privacy/Data Protection		Act 709: Personal Data Protection Act 2010: http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf		
Human Biological Materials	National Committee for Clinical Research: http://www.nccr.gov.my/	1. Act 130: Human Tissues Act (1974):	DNA Identification Regulations 2012. Malaysian Government	Guideline on the Use of Human Biological Tissues for Research (2006):

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.agc.gov.my/Akta/Vol.%203/Act%20130.pdf 2. Act 699: DNA Identification Act 2009. Malaysian Government Gazette of 3 September 2009	Gazette of 30 Aug 2012.	http://www.nccr.gov.my/index.cfm?menuid=25&parentid=17
Genetic Research	Malaysian Medical Council: http://www.mmc.gov.my/v1/			Medical Genetics and Genetic Services. MMC Guidelines 010/2006: http://www.mmc.gov.my/v1/docs/Medical%20Genetics%20&%20Genetic%20Services.pdf
Embryos, Stem Cells and Cloning	Ministry of Health, Medical Research and Ethics Committee			Checklist for Research on Stem Cell and Cell-Based Therapies: http://www.nih.gov.my/mrec/documents/Research_On_Stem_cell_and_Cell_based_Therapies.pdf
Nepal				
General	Nepal Health Research Council, Ethical Review Board: http://www.nhrc.org.np/	Nepal Health Research Council Act, 1991, Section 3(1): http://www.lawcommission.gov.np/en/documents/2015/08/nepal-health-research-council-act-2047-1991.pdf		1. National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedure (2011): http://nhrc.org.np/guidelines 2. Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal (2016): http://nhrc.org.np/guidelines
Drugs, Biologics, and Devices	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): http://nhrc.org.np/guidelines
New Zealand				
General	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ 2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/ 3. Ministry of Health (MOH): http://www.moh.govt.nz/ 4. Health and Disability Commissioner (HDC): http://www.hdc.org.nz/ 5. Health and Disability Ethics Committees: http://www.ethics.health.govt.nz/ 6. Ministry of Business, Innovation and Employment: http://www.mbie-govt.nz/	1. Health Research Council Act 1990, Sections 24 and 25 2. New Zealand Bill of Rights Act, Article 10 (1990) 3. Health and Disability Commissioner Act 1994 4. New Zealand Public Health and Disability Act 2000, Section 16 5. Accident Compensation Act 2001 Access: All New Zealand acts, bills, and regulations can be found here: http://www.legislation.govt.nz/	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): http://www.hdc.org.nz/the-act--code/the-code-of-rights	HRC: 1. Guidelines for Researchers on Health Research Involving Māori (2010) 2. Te Ara Tika. Guidelines for Māori Research Ethics: A Framework for Researchers and Ethics Committee Members (2010) 3. HRC Research Ethics Guidelines (2017) 4. Pacific Health Research Guidelines (2014) Access: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval NEAC: 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2003) 2. Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012) 3. Ethical Guidelines for Intervention Studies (2012) Access*:* http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications MOH: Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures
Drugs, Biologics, and Devices	*Drugs*			
	1. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 2. Medicines New Zealand: http://www.medicinesnz.co.nz/ 3. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott	1. Accident Compensation Act 2001, Section 32 (2010) 2. Medicines Act 1981(2012)	Medsafe: Medicines Regulations 1984 http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html	Medsafe: Good Clinical Research Practice and Obtaining Approval for Clinical Trials (2013): http://www.medsafe.govt.nz/medicines/clinical-trials.asp Medicines New Zealand: Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2015): https://ethics.health.govt.nz/system/files/documents/pages/2015-medicines-new-zealand-compensation-guidelines.pdf
	Devices			
	New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz		Medicines (Database of Medical Devices) Regulations (2003): http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html	1. Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures 2. Various: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp
Clinical Trials Registry	Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			FAQs: http://www.anzctr.org.au/Faq.aspx
Privacy/Data Protection	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act 1982 (2012)	Health Information Privacy Code 1994: http://www.privacy.org.nz/assets/File	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Public Records Act (2005) 3. Privacy Act 1993 (2012)	s/Codes-of-Practice-materials/Health-Information-Privacy-Code-1994-including-Amendment.pdf	
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.govt.nz/ 2. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval 3. Te Puni Kokiri (TPK): http://www.tpk.govt.nz/ 4. Office of the Health and Disability Commissioner (HDC): http://www.hdc.org.nz 5. Ministry of Business, Innovation and Employment: http://www.mbie-govt.nz/	1. Health Act 1956 (2012) 2. Human Tissue Act 2008		MOH: Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes
Genetic Research	1. Environmental Protection Authority: http://www.epa.govt.nz/ 2. Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committee-gtac	Hazardous Substances and New Organisms Act 1996 (2012)		
Embryos, Stem Cells, and Cloning	1. Advisory Committee on Assisted Reproductive Technology (ACART): http://acart.health.govt.nz/ 2. Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.health.govt.nz/ 3. Ministry of Health: http://www.moh.govt.nz/	Human Assisted Reproductive Technology Act 2004 (2009)	Human Assisted Reproductive Technology (HART) Order (2005): http://www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html	ACART: 1. Guidelines on the Use, Storage, and Disposal of Sperm from a Deceased Man (2000) 2. Guidelines for Research on Gametes and Non-viable Embryos (2005) 3. Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research (2005) 4. Guidelines on Embryo Donation for Reproductive Purposes (2008) 5. Guidelines on Extending the Storage Period of Gametes and Embryos (2012) 6. Guidelines on Donation of Eggs or Sperm between Certain Family Members (2013) 7. Guidelines on Surrogacy Arrangements Involving Assisted Reproductive Procedures (2013) 8. Guidelines on Preimplantation Genetic

Country	Key Organizations	Legislation	Regulations	Guidelines
				Diagnosis with Human Leucocyte Antigen Tissue Typing (2014) Access: https://acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart
Pakistan				
General	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Various: http://nbcpakistan.org.pk/guidelines.html
Drugs, Biologics, and Devices	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Guidelines For Healthcare Professionals Interaction with Pharmaceutical Trade and Industry (PPI Guidelines): http://nbcpakistan.org.pk/?page_id=61
Human Biological Materials	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (HBM): http://nbcpakistan.org.pk/assets/hbm-nbc-guidelines-final-18june-2016.pdf
Embryos, Stem Cells, and Cloning	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan: http://nbcpakistan.org.pk/?page_id=61
Philippines				
General	1. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph 2. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 3. Department of Health (DOH): http://www.doh.gov.ph/ 4. Commission of Higher Education (CHED): www.ched.gov.ph/	Republic Act No. 10532: An Act Institutionalizing the Philippine National Health Research System (2013): http://www.gov.ph/2013/05/07/republic-act-no-10532/	PHREB: Memorandum: Registration and Accreditation of all Ethics Review Committees in the Philippines (2015): http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/226-phreb-memo DOST: 1. Administrative Order 001 Series 2007: Requirement for Review of All Research Involving Human Subjects/Participants (2007): http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/112-ao-001-2007 2. Administrative Order 001 Series 2008: Registration of All Ethics Review Committee at the PHREB (2008):	PHREB: National Ethical Guidelines for Health Research (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/111-ao-001 3. PCHRD Special Order No. 146 Series of 2013: Reactivation and Amendment of Functions of the National Ethics Committee http://nec.pchrd.dost.gov.ph/components/com_ethics/pdf_files/nec_so.pdf DOH: Department Circular No. 2015-0059: Research Ethics Review Committees Registration and Accreditation: http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/217-doh-circular CHED: 1. Memo 34 Series 2007: Policy Requirement in the Conduct of Health Research involving Human Subjects: http://www.ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/130-ched-memorandum 2. Memorandum from the CHED Chairperson: Philippine Health Research Ethics Board – Registration and Accreditation of All Ethics Review Committees: http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/225-ched-memo	
Drugs, Biologics, and Devices	*Drugs*			
	Food and Drug Administration (FDA): http://www.fda.gov.ph/		FDA: 1. Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products(Administrative	Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			Order No. 47-a) (2001) 2. FDA Circular 2015-026: Adoption of the ICH Harmonised Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C: http://www.fda.gov.ph/attachments/article/118205/FC2013-026.pdf DOST, DOH, CHED, and UPM: Joint Memorandum Order 001 Series of 2012: http://www.ethics.healthresearch.ph/index.php/component/content/article/10-orders-and-memos/215-joint-memo-01 DOST, DOH, CHED, and UPM-NIH: Joint Administrative Order No. 001: The Implementing Rules and Regulations of Republic Act 10532 Otherwise Known as "The Philippine National Health Research System Act of 2013:" http://www.ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/214-implementing-rules-of-pnhrs	
	Devices			
	Food and Drug Administration: http://www.fda.gov.ph/			FDA Guidelines: Regulation of Clinical Trials in the Philippines http://www.pcrp.org.ph/pdf/GuidelinesversionLR.PDF
Clinical Trials Registry	Philippine Health Research Registry: http://registry.healthresearch.ph/			FAQs: http://registry.healthresearch.ph/index.php?option=com_content&view=article&id=7&Itemid=185
Research Injury	1. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 2. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph			PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
Social-Behavioral Research	Philippine Council for Health Research and Development			Ethical Guidelines for Social and Behavioral Research (2006): https://www.pogsinc.org/files/research/pnhrs-national-ethical-guidelines.pdf
Embryos, Stem Cells, and Cloning	Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Ministry of Health, National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/ 2. Human Biomedical Research Bill No. 25/2015: http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0	MOH: Directive of June 25, 1998: Hospital Ethics Committees	MOH: 1. Governance Framework for Human Biomedical Research (2007): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2007/Governance%20Frwk%20for%20HBR_14-12-07_formatted.pdf 2. Operational Guidelines for IRBs (2007): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2007/IRB%20Operational%20Guidelines_14-12-07_formatted.pdf 3. Code of Ethical Practice in Human Biomedical Research (2009): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2009/Code%20of%20Ethical%20Practice%20in%20Human%20Biomedical%20Research_Apr%2009_final.pdf NMEC: Ethical Guidelines on Research Involving Human Subjects (1997): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/1997/nmec_ethical_guidelines_on_research_involving_human_subjects.html BAC: 1. Research Involving Human Subjects: Guidelines for IRBs (2004): http://www.bioethics-singapore.org/index/publications/reports/172-

Country	Key Organizations	Legislation	Regulations	Guidelines
				research-involving-human-subjects-guidelines-for-irbs.html 2. Ethics Guidelines for Human Biomedical Research (2015): http://www.bioethics-singapore.org/index/publications/reports/86-reports/ethics-guidelines-for-human-biomedical-research.html
Drugs, Biologics, and Devices	*Drugs*			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 2. Ministry of Health, National Medical Ethics Committee (NMEC): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html	Medicines Act (1975): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	HSA: Singapore Guideline for Good Clinical Practice (1990): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf NMEC: Recommendations on Clinical Trials: Update Focusing On Phase I Trials (2007): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/2007.html
	Devices			
	1. Health Sciences Authority (HSA): http://www.hsa.gov.sg 2. National Environment Agency, Centre For Radiation Protection And Nuclear Science: http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection	1. Health Products Act (2007): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	1. Health Products (Medical Device) Regulations (2010): http://www.emergogroup.com/sites/default/files/file/singapore-health-products-medical-devices-regulations-2010.pdf 2. Radiation Protection Regulations (2014): http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection/regulatory/summary-of-radiation-protection-(amendment)-act-2014	
Research Injury	1. Health Sciences Authority: http://www.hsa.gov.sg 2. Ministry of Health, National Medical Ethics Committee (NMEC): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html	1. Medicines Act (1975): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	HSA: Singapore Guideline for Good Clinical Practice (1999): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
Privacy/Data Protection	1. Ministry of Communications and Information (MCI): http://www.mci.gov.sg/web	1. Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/		BAC: Personal Information in Biomedical Research (2007): http://www.bioethics-

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	2. Personal Data Protection Act (2012): http://statutes.agc.gov.sg/		singapore.org/index/publications/reports/170-personal-information-in-biomedical-research.html
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Health Sciences Authority: http://www.hsa.gov.sg 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Medical (Therapy, Education, and Research) Act (1973): http://statutes.agc.gov.sg/ 2. Medicines Act (1975): http://statutes.agc.gov.sg/ 3. Human Biomedical Research Bill No. 25/2015, Part 6: http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	BAC: Human Tissue Research (2002): http://www.bioethics-singapore.org/index/publications/reports/173-human-tissue-research.html
Genetic Research	1. Ministry of Health, National Medical Ethics Committee (NMEC) 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org			NMEC: Ethical Guidelines for Gene Technology (2001): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/2001.html BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/index/publications/reports/171-genetic-testing-and-genetic-research.html
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org/	Human Cloning and Other Prohibited Practices Act (2004): http://statutes.agc.gov.sg/	Licensing Terms and Conditions on Assisted Reproduction Services (2011): http://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Private%20healthcare%20institutions/2011/AR_LTCs_260411.pdf	BAC: 1. Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002): http://www.bioethics-singapore.org/index/publications/reports/86-reports/174-stem-cell-research.html 2. Donation of Human Eggs for Research (2008): http://www.bioethics-singapore.org/index/publications/reports/86-reports/168-donation-of-human-eggs-for-research.html 3. Human-Animal Combinations in Stem-Cell Research (2010): http://www.bioethics-singapore.org/index/publications/reports/86-reports/167-human-animal-combinations-in-stem-cell-research.html
Sri Lanka				

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials: http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en	National Medicines Regulatory Authority Act of 2015: http://www.cdda.gov.lk/images/stories/new/pdf/legislations/5e_nmdra.pdf		Guidelines for the Conduct of Clinical Trials in Sri Lanka (2014): http://www.cdda.gov.lk/images/pdf/clinical%20trials%20guidelines_oct2014.pdf
Clinical Trials Registry	Sri Lanka Clinical Trials Registry: http://www.slctr.lk/			FAQs: http://slctr.lk/faq
Taiwan				
General	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 2. Medical Care Act (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Enforcement Rules of the Medical Care Act (2010): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020023 3. Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020179 4. Exempt Review Categories for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 5. Informed Consent Exemptions for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 6. Expedited Review Categories for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 7. Partial Amended Articles of Enforcement Rules of Medical Care Act (2016) http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp	Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (2012): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020179
Drugs, Biologics, and Devices	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Taiwan Food and Drug	MOHW: Medical Care Act (2014): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021	MOHW: 1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Administration (FDA): http://www.fda.gov.tw/EN/index.aspx	FDA: Pharmaceutical Affairs Act (2015): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030001	2. Pharmaceutical Affairs Act Enforcement Rules (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030002 3. Regulations for Drug Safety Monitoring (2013) http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=516&KeyWord= 4. Guideline for Good Clinical Practice (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030056 5. Regulations for Governing the Management of Medical Devices (2014): http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=528&KeyWord= 6. Regulations for Bioavailability and Bioequivalence Studies (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030065	
Research Injury	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA), MOHW: http://www.fda.gov.tw/EN/index.aspx	Medical Care Act (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	FDA: Guideline for Good Clinical Practice (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030056	
Social-Behavioral Research	Ministry of Health and Welfare		Exempt Review Categories for Human Research (2012) http://www.mohw.gov.tw/EN/Ministry/	
Privacy/Data Protection	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Personal Information Protection Act (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=I0050021		
Human Biological Materials	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162	1. Good Tissue Practice (2002) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1153&chk=342a5c73-c206-4756-ade9-9c63265c859d&mid=46&name=fdContent 2. Guidelines for Collection and Use of

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164 3. Medical Care Act (2015): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021	2. Administrative Regulations on the Establishment of Human Biobanks (2011) http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020173	Human Specimens for Research (2006) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent
Genetic Research	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA): http://www.fda.gov.tw/EN/index.aspx 3. Ministry of Science and Technology: https://www.most.gov.tw/en/public	MOHW: Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	MOHW: 1. Regulations on Commercial Benefit Feedback of Human Biobanks (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContentIf.aspx?PCODE=L0020170 2. Administrative Regulations on the Establishment of Human Biobanks (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020173	MOHW: Guidance for Information Safety of Human Biobank (2010) (Chinese): http://mohwlaw.mohw.gov.tw/Chi/FLAW/FLAWDAT0202.asp
Embryos, Stem Cells, and Cloning	Health Promotion Administration, MOHW: http://www.hpa.gov.tw/BHPNet/English/Index.aspx	Artificial Reproduction Act (2007): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0070024		
Tajikistan Note: For an overview of human subject protections in Tajikistan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 9: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf Note: All websites and documents are in Russian.				
General	Ministry of Public Health: http://www.health.tj/		Order of the Ministry of Public Health of the Republic Tajikistan of 10 March, 2005 No. 118: About the Assertion of the Normative Documents of Republic Committee on Medical Ethics	
Thailand For an overview of the clinical research regulations in Thailand, see: https://clinregs.niaid.nih.gov/single_country.php?c_id=213				
General	1. National Research Council of Thailand (NCRT): http://en.nrct.go.th/en/home.aspx 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php 3. Forum for Ethical Review	Medical Professions Act (2009), Articles 47-50: http://www.fercit.org/SIDCER-FERCAP/Handout_10/4.%20Accreditation-update_surveyor_aj.Sopit.pdf	NCRT: Regulation on the Permission of Foreign Researchers (1982): http://www.dnp.go.th/otec/eng_laws_regs/NRCT_Reg2525E.pdf MCT:	MCT: National Guideline for Ethical Research on Human Subjects (2002) FERCIT: Ethical Guidelines for Research on Human Subject in Thailand (2007):

Country	Key Organizations	Legislation	Regulations	Guidelines
	Committees in Thailand (FERCIT) (Thai): http://www.fercit.org/		Rule of the Medical Council on the Observance of Medical Ethics (1983): http://thailaws.com/law/t_laws/tlaw0510.pdf	http://www.fercit.org/file/Guideline_English_version.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php	Consumer Protection Act (2007)		MCT: Thailand Good Clinical Practice Guidelines (2002)
	Devices			
	Food and Drug Administration, Medical Device Control Division: http://www.fda.moph.go.th/eng/medical/pre.stm	1988 Medical Device Act: http://www2.fda.moph.go.th/Exporters/law/Document/Mdc/36-MEDICAL%20DEVICE%20ACT.htm		
Clinical Trials Registry	Thai Clinical Trials Registry: http://www.clinicaltrials.in.th/			FAQs: http://www.clinicaltrials.in.th/index.php?meun=home&smenu=4&task=home&task1=openpage&task2=view&topid=4
Privacy/Data Protection	Office of the Information Commission: http://www.oic.go.th/content_eng/default_eng.asp	Official Information Act, B.E. 2540 (1997): http://www.oic.go.th/content_eng/act.htm		
Uzbekistan Note: All websites and documents are in Uzbek and Russian.				
General	1. Government of the Republic of Uzbekistan: http://www.gov.uz 2. Ministry of Health: http://www.minzdrav.uz	1. Constitution of Republic of Uzbekistan, Articles 24, 26, 40, 44 (1992): http://www.gov.uz 2. Law on Protection of Citizens' Health (1997): http://www.minzdrav.uz		
Drugs, Biologics, and Devices	1. Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: http://www.minzdrav.uz 2. Ministry of Health, National Ethics Committee 3. Scientific Boards of Medical Institutes	1. Law on Protection of Citizens' Health (1997): http://www.minzdrav.uz 2. Law on Drugs and Pharmaceutical Activity (1997) 3. Law on Narcotic and Psychoactive Drugs (2000)	1. Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	
Human Biological	1. Ministry of Health,		1. Guidelines on Conducting	

Country	Key Organizations	Legislation	Regulations	Guidelines
Materials	Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: http://www.minzdrav.uz 2. Ministry of Health, National Ethics Committee 3. Scientific Boards of Medical Institutes		Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	
Vietnam For an overview of the clinical research regulations in Vietnam, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=233				
General	1. Ministry of Health (MOH): http://www.moh.gov.vn/homebyt/en/portal/index.jsp 2. Ministry of Health, Independent Ethics Committee (MOH) (Vietnamese): http://iecmoh.vn	MOH: Decision No. 111/QD-BYT – On Promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at Grass-Roots Level, Chapter I (Articles 3 and 4), Chapter II, and Chapter III (2013): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo111-QD-BYT.pdf	MOH: Decision No. 460/QD-BYT – On the Promulgation of Regulations on Organization and Operation of Ethical Evaluation Committee in Biomedical Research of the Ministry of Health, Period 2012-2017, Chapters I-III (2012): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo460-QD-BYT.pdf	
Drugs, Biologics, and Devices	Ministry of Health: http://www.moh.gov.vn/homebyt/en/portal/index.jsp	1. Law on Pharmacy (No. 34/2005/QH11), Chapter II (Section III, Article 20), Chapter VIII (Articles 54 and 59) (2005): http://www.vertic.org/media/National%20Legislation/Vietnam/VN_Law_on_Pharmacy.pdf 2. Decision No. 799/QD-BYT on the Issuance of Guideline on Good Clinical Practice, Chapter III, Articles 1 and 2 (2008): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf	1. Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the Guidelines on Good Clinical Practice of Clinical Trials (2008): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf 2. Circular – Guidelines for Clinical Trials on Drugs (C-ClinDrugTrial), Articles 2, 4, 5, 9, 17, 18, 31, and 39 (2012): http://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf	Guidelines for Clinical Trials of Drugs, Chapter III, Articles 10, 16, and 17 (2012): https://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
MIDDLE EAST/NORTH AFRICA				
Egypt				
General	Medical Professionals Union	Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/Newvr/Dustor-en001.pdf	Professional Ethics Regulations: Conducting Medical Research on Human Beings, Articles 52-61 (2003)	
Drugs, Biologics, and Devices	Egyptian Drug Authority: http://www.eda.mohp.gov.eg/			
Iran				
General	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: http://www.mohme.gov.ir/		Protection Code for Human Subjects in Medical Research (1999)	
Clinical Trials Registry	Iranian Registry of Clinical Trials: http://www.irct.ir/			FAQs: http://www.irct.ir/faq.php
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew)	
Drugs, Biologics, and Devices	Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human Subjects) – 1980 2. 1990 Amendment 3. 1992 Amendment 4. 2005 Amendment	Guidelines for Clinical Trials in Human Subjects (2006): https://firstclinical.com/regdocs/doc/?db=INT_Israel_Clinical_Trials
Privacy/Data Protection	Israeli Law, Information, and Technology Authority: http://www.justice.gov.il/MOJEng/ILITA/	1. Privacy Protection Act No. 5741 (1981): http://www.justice.gov.il/NR/rdonlyres/6A5EC09A-BDBC-419F-8007-5FD6A6B8E0A5/18334/ProtectionofPrivacyLaw57411981unofficialtranslatio.pdf 2. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985)		
Genetic Research	Ministry of Health: http://www.health.gov.il/english/	Genetic Information Law (2000) (Hebrew): http://www.moital.gov.il/NR/exeres/66F4DD4E-FA4A-4B76-94BC-DC29543471DE.htm		1. The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2005) 2. Amendment (2007)
Embryos, Stem Cells, and Cloning		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		
Jordan Note: All documents are in Arabic.				
Drugs, Biologics, and Devices	1. Ministry of Health: http://www.moh.gov.jo/en/Pages/default.aspx 2. Jordan Food and Drug Administration: http://www.jfda.jo/Default.aspx	1. Law of Clinical Studies, Law No. 2 (2011) http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50_211.pdf 2. Drug and Pharmacy Law No. 12 (2013) http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugDirectorate/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D8%A1%20%D9%88%D8%A7%D9%84%D8%B5%D9%8A%D8%AF%D9%84%D8%A9.pdf 3. Narcotic and Psychotropic Law No. 23 (2016) http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D9%85%D8%AE%D8%AF%D8%B1%D8%A7%D8%AA%20%D9%88%D8%A7%D9%84%D9%85%D8%A4%D8%AB%D8%B1%D8%A7%D8%AA%20%D8%A7%D9%84%D8%B9%D9%82%D9%84%D9%8A%D8%A9.pdf		
Research Injury			Regulations for Insurance on Research-Related Injury (2013):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22_252.pdf	
Embryos, Stem Cells, and Cloning		Stem Cell By-law No. 10 (2014)		
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Qatar				
General	Supreme Council of Health: https://www.sch.gov.qa/home-en			Various: https://www.sch.gov.qa/about-sch/departments/research
Saudi Arabia				
General	National Committee of BioEthics: http://bioethics.kacst.edu.sa/?lang=en-US	Law of Ethics of Research on Living Creatures (Arabic): http://bioethics.kacst.edu.sa/getattachment/4bd0d4e2-1b93-4c32-b483-57902227fae2/Bioethic-Rgl-fin-bks.aspx	Implementing Regulations of the Law of Ethics of Research on Living Creatures (2016): http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committee_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf	
Social-Behavioral Research	National Committee of BioEthics		Implementing Regulations of the Law of Ethics of Research on Living Creatures, Expedited Research (Article 10.18g) and Categories of social-behavioral research that do not require continuing review (Article 10.32) (2016): http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committee_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf	
Sudan				
General	Federal Ministry of Health: http://www.fmoh.gov.sd/			1. National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines 2. National Accreditation Guidelines for Ethics Committees (2016)

Country	Key Organizations	Legislation	Regulations	Guidelines
				3. Operation Guidelines, Functions, and Procedures (2016)
Drugs, Biologics, and Devices	National Medicines and Poisons Board: http://www.nmpb.gov.sd/en/	Act on Pharmaceuticals and Poisons (2009) (Arabic): http://www.nmpb.gov.sd/index.php/2015-08-05-11-05-04/regulations/113-laws2009		
Human Biological Materials	1. Federal Ministry of Health: http://www.fmoh.gov.sd/ 2. National Council on Biosafety	1. Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978) Act on Biosafety (2010)		
Genetic Research	University of Khartoum, Institute of Endemic Diseases: http://iend.uofk.edu/index.php?lang=en			Guidelines for Genetics Research on Sudanese Subjects (2005)
Tunisia				
Drugs, Biologics, and Devices	Ministry of Public Health, Institut Pasteur: www.pasteur.tn		Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans	Disposals and Director's Principles Related to Good Practices in Clinical Trials
Clinical Trials Registry	Tanzania Clinical Trial Registry: http://www.tzctr.or.tz/			FAQs: http://www.tzctr.or.tz/faq.php
Turkey For an overview of human subject protections in Turkey, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Turkey%20definitive%20Updated.pdf				
General	Ministry of Health (Turkish): http://www.saglik.gov.tr/	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine (2004) 4. Update on the Law of the Support of Research and Development Activities (2016). Official Gazette (Turkish): http://www.resmigazete.gov.tr/eskiler/2016/02/20160226.htm	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	
Drugs, Biologics, and Devices	*Drugs*			
	1. Turkey Pharmaceuticals and Medical Devices Agency (Turkish) (TITCK): http://www.titck.gov.tr 2. Clinical Research Association (CRA): http://www.klinikarastirmalar.org.tr/en/	Turkish Penal Law, Article 90 (2005)	1. Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials	CRA: Various: http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=0

Country	Key Organizations	Legislation	Regulations	Guidelines
			with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_345.docx 3. Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_346.pdf 4. Update on the Regulation of the Management and Inspection of the Support of Research and Development Activities (2016). Official Gazette (Turkish): http://www.resmigazete.gov.tr/eskiler/2016/08/20160810-7.htm	
	Devices			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr		Regulation on Research on Medical Devices (2014) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_318.pdf	
Research Injury	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004)		Guidance on Insuring Volunteers in a Clinical Trial (2011)
Human Biological Materials		1. Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Regulation on Blood and Blood Products, No. 7314 (1983)	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999) 2. Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
Genetic Research			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
Embryos, Stem Cells, and Cloning			1. Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987) 2. Regulation on Organ and Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
United Arab Emirates				
General	Health Authority - Abu Dhabi: http://www.haad.ae/haad/			Standard Operating Procedures for Research Ethics Committees (2012): http://www.haad.ae/HAAD/LinkClick.aspx?fileticket=UL7o8f5mukc%3D&tabid=820

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and the CARIBBEAN				
Regionwide				
General	Caribbean Public Health Agency: http://carpha.org/What-We-Do/Research-Training-and-Policy-Development			
Drugs, Biologics, and Devices	*Drugs*			
	Pan American Health Organization: http://www.paho.org/			Good Clinical Practices: Document for the Americas (2004): http://www.paho.org/english/ad/ths/ev/GCP-Eng-doct.pdf
	Devices			
	Pan American Health Organization: http://www.paho.org/			A Model Regulatory Program for Medical Devices: An International Guide (2001): http://www.paho.org/English/HSP/HSE/medical_devices.pdf
Argentina Notes: Several provinces have their own regulations pertaining to human subjects research. All websites and documents are in Spanish.				
General	Ministry of Health: http://www.msal.gov.ar	Civil and Commercial Code, Articles 26, 58, and 59 (2015): http://servicios.infoleg.gob.ar/infolegInternet/anexos/235000-239999/235975/norma.htm	Ministerial Resolution 1480/2011 Approving the Guidelines for Human Health Research and Creating the National Register for Human Health Research: http://www.anmat.gov.ar/webanmat/legislacion/medicamentos/Resolucion_1480-2011.pdf	Resolution 1480/2011: Guidelines for Investigators Working with Human Beings: http://www.fecicla.org/archivos/regulaciones/Resolucion1480-11.pdf
Drugs, Biologics, and Devices	*Drugs*			
	National Administration of Medications, Foods, and Medical Technology (ANMAT): http://www.anmat.gov.ar/index.asp		1. Provision 2247/09: Guide for the Study of Clinical Trials of Type II Diabetes (2009): http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disposicion_ANMAT_2247-2009.pdf 2. Provision ANMAT 6677/10 on Good Research Practices in Clinical Pharmaceutical Studies (2010): http://www.anmat.gov.ar/Comunicados/Dispo_6677-10.pdf	
	Devices			
	National Administration of Medications, Foods, and Medical Technology (ANMAT): http://www.anmat.gov.ar/index.asp		1. Provision 969/97 on the Regulation of Good Clinical Practice with Medical Technology Products (1997)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2. Disposition Nº 969/97(Including Modifications of Disposition ANMAT Nº 6550/2008)	
Privacy/Data Protection	National Directorate for the Protection of Personal Data (Spanish): http://www.jus.gob.ar/datos-personales.aspx	Personal Data Protection Act No. 25.326 (2000): http://www.protecciondedatos.com.ar/law25326.htm		
Barbados				
	University of the West Indies – Cave Hill / Ministry of Health: http://www.cavehill.uwi.edu/researchethics/home.aspx			Research Ethics Policy and Guidelines
Bermuda				
General	Department of Health: https://www.gov.bm/department/health			Research Governance Framework (2008): http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.592.8671&rep=rep1&type=pdf
Bolivia				
General	1. Ministry of Health and Sport (MHS): http://www.sns.gob.bo 2. National Bioethics Committee (NBC)	1. Legal Decree No. 15.629 of July 18, 1978, Articles 147 and 148. 2. New Political Constitution of the State, Article 44 (2009): https://www.constituteproject.org/constitution/Bolivia_2009.pdf	1. Regulations on Public Health Research, Chapter V (1978) 2. Rules and Regulations of the National Bioethics Committee	MHS: Guidelines for the Development of Health Research and Ethical Norms (2002) NBC: 1. Requirements for the Evaluation of Research Projects 2. Code of Ethics and Medical Deontology
Drugs, Biologics, and Devices	1. Ministry of Health and Sport, National Pharmacological Commission (MHS): http://www.sns.gob.bo 2. National Bioethics Committee (NBC)			MHS: Rule on Clinical Studies with Medicines or Products in the Clinical Investigation Stage (2005) NBC: Projects that Involve Drugs or Therapeutic Products
Brazil For an overview of clinical research regulations in Brazil, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=30				
General	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		CNS/CONEP: 1. Resolution CNS No. 240/97 - Defining "Participating User" According to IRB (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/reso240.doc 2. Regulation of Resolution CNS No. 292/99 on Research with	CNS/CONEP: Operational Standard Nº 001/2013: http://conselho.saude.gov.br/arquivos/NO_01-12_english.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			Foreign Cooperation: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc 3. Resolution CNS No. 304/2000: http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf 4. Internal CONEP Regulation (2001) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc 5. Resolution CNS No. 301, 16th March 2002: http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf 6. Resolution CNS No. 346/2005 on Multicenter Research: http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 7. Resolution CNS No. 370/07 on Registration and Accreditation or Renewal of Registration and Accreditation of CEP (Portuguese): http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc 8. Resolution CNS No. 446/2011on Composition of the National Commission on Research Ethics: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf 9. Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf 10. Resolution CNS Nº 506/2016 Accreditation of CEP: http://conselho.saude.gov.br/resolucoes/2016/Reso_506.pdf 11. Operational Rule 001/2013 (Intern Norm): http://conselho.saude.gov.br/web_co	

Country	Key Organizations	Legislation	Regulations	Guidelines
			missoes/conep/aquivos/CNS%20%20Norma%20Operacional%20001%20-%20conep%20finalizada%2030-09.pdf	
Drugs, Biologics, and Devices	*Drugs and Biologics*			
	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 4. National Secretary on Science, Technology and Innovation (Portuguese): http:www.saude.gov.br/sctie/	Law Nº 9782/99 Defining the National Health Surveillance System (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/L9782.htm	CNS: 1. Resolution CNS No. 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests: http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution CFM Nº 1.885, 2008 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2008/1885_2008.htm 3. Resolution ANVISA 09/15 - Regulations for Clinical Trials with Drugs (Portuguese): https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf 4. Resolution RDC No. 9, 20 February 2015 Regarding Regulation for Realization of Clinical Trials of Medication in Brazil: https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf	
	Devices			
			Resolution ANVISA 10/15 - Regulations for Clinical Trials with Medical Devices (Portuguese): http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=03/03/2015&jornal=1&pagina=73&totalArquivos=140	
Clinical Trials Registry	Brazilian Clinical Trials Registry: http://www.ensaiosclinicos.gov.br/			FAQs: http://www.ensaiosclinicos.gov.br/assistance/faq/
Research Injury	1. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles	ANVISA: Law Nº 6360/76 (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/l6360.htm	CNS/CONEP: 1. Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving	CNS/CONEP: Orientation of Adverse Event Reporting in Clinical Trials (2011) (Portuguese): http://conselho.saude.gov.br/web_comissoes/co

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		Human Beings - Resolution CNS No. 251/97 (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution CNS No. 346/2005 on Multicenter Research (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 3. Resolution MS/CNS No. 466/2012 - Guidelines and Rules for Research Involving Human Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf	nep/carta_circular/Informacoes_sobre_o_formulario_para_submissao_de_Eventos_Adversos_Serios_a_CONEP.pdf ANVISA: Manual of Adverse Event Notification and Safety Monitoring in Clinical Trials Involving Medical Devices (2016) (Portuguese): http://portal.anvisa.gov.br/documents/33912/2785629/MANUAL+PARA+NOTIFICA%C3%87%C3%83O+DE+EVENTOS+ADVERSOS+E+MONITORAMENTO+DE+SEGURAN%C3%87A+EM+ENSAIOS+CL%C3%8DNICOS+ENVOLVENDO+DISPOSITIVOS+M%C3%89DICOS+EM+INVESTIGA%C3%87%C3%83O/df22b9ac-688d-4e6a-8207-faf862a05994
Social-Behavioral Research	National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		Resolution No. 510 of April 7, 2016: http://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf	
Privacy/Data Protection	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. Federal Council of Medicine: http://portal.cfm.org.br		Resolution CFM Nº 1.821, 23 November 2007 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2007/1821_2007.htm	
Human Biological Materials	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. National Secretary on Science, Technology and Innovation (Portuguese): http:www.saude.gov.br/sctie/	Ordinance No. 2.201/11: Establishing the National Guidelines for Biobanks of Human Biological Material for Research Purposes (2011) (Portuguese): http://www2.inca.gov.br/wps/wcm/connect/8b19d5804eb688ee9cb39ef11fae00ee/portaria_2201_de_14_de_set_2011.pdf?MOD=AJPERES&CACHEID=8b19d5804eb688ee9cb39ef11fae00ee	CONEP: 1. Resolution CNS No. 441 of 12 May 2011: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolution441_English_contribuicao_pesquisadora.doc 2. Resolution – RDC No. 20 of 10 April 2014 (Portuguese): http://www.saude.pr.gov.br/arquivos/File/RDC_20_de_10_de_abril_2014_Transporte_de_material_Biologico.pdf	
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 2. National Biosafety Technical	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of	CTNBio: 1. Instruction CTNBio No. 8 of 9 July 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11971.html	1. Guidance to Researchers and Ethics Committees about the Item V.1.a of CNS Resolution 340 2004 (Portuguese): http://conselho.saude.gov.br/web_comissoes/co

Country	Key Organizations	Legislation	Regulations	Guidelines
	Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	2. Instruction CTNBio No. 9 of 10 October 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11972.html 3. Resolution CNS No. 340/2004: On Research on Human Genetics (2004): http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf	nep/aquivos/documentos/Carta_Circular_041_Orientacoes_pesquisadores_comites.pdf 2. Statement on Pharmacogenetic Studies in Brazil N/° 011/2012/CONEP, 12 January 2012: http://www.fcm.unicamp.br/fcm/sites/default/files/11_-_Comunicado_sobre_estudos_farmacogeneticos_no_Brasil.pdf
Embryos, Stem Cells, and Cloning	1. National Biosafety Technical Commission (Portuguese): http://www.ctnbio.gov.br 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	1. Resolution RDC No. 9, 14 March 2011 (Portuguese): http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/prt0009_14_03_2011.html 2. Resolution RDC No. 29, 12 May 2008 (Portuguese): http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/rdc0029_12_05_2008.html	
Chile Note: All websites and documents are in Spanish.				
General	1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	1. Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): http://www.leychile.cl/Navegar?idNorma=253478 2. Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): http://www.leychile.cl/Navegar?idNorma=1039348 3. Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014): http://www.leychile.cl/Navegar?idNorma=1058373	1. Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919 2. Supreme Decree Nº 30/2013 Regulation on Law Nº20.120 Modifying Supreme decree Nº114/2010, Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning Official Diary January 14, 2013: http://www.leychile.cl/Navegar?idNorma=1048008&	
Drugs, Biologics, and Devices	1. Ministry of Health : http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014):	1. Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.leychile.cl/Navegar?idNorma=1058373	Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919 2. Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official Diary of June 25, 2011: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf 3. Exempt Resolution 2263, July 30th 2015 Modifying Resolution Nº 403 Ex. February 5, 2015 that Approves the Guidelines for Use Control of Pharmaceuticals Products in Scientific Research: http://www.leychile.cl/Navegar?idNorma=1080011	
Research Injury	1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): http://www.leychile.cl/Navegar?idNorma=253478	1. Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official Diary of Jun 25, 2011: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf 2. General Technical Rule No. 140 Regarding the National System of Pharmacovigilance of Pharmaceutical Products for Human Use. June 20, 2012: http://web.minsal.cl/portal/url/item/c4a31ad6db50e085e040010165017a39.pdf 3. Resolution No. 441, Notification of Adverse events in Clinical Research in Chile, February13, 2012: http://www.ispch.cl/sites/default/files/res_441.pdf	
Privacy/Data Protection	1. Ministry of Health: http://www.minsal.cl	1. Law for the Protection of Private Life No. 19.628 (1999):	Supreme Decree No. 41 of 2012: Regulation Regarding Clinical	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of the Secretary General of the Government: http://www.msgg.gob.cl	http://www.bcn.cl/leyes/141599 2. Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): http://www.leychile.cl/Navegar?idNorma=1039348	Records of December 15, 2012: http://www.leychile.cl/Navegar?idNorma=1046753	
Genetic Research	Ministry of Health: http://www.minsal.cl	Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): http://www.leychile.cl./Navegar?idNorma=253478	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919	
Embryos, Stem Cells, and Cloning	Ministry of Health: http://www.minsal.cl	Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): http://www.leychile.cl./Navegar?idNorma=253478	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919	
Colombia Note: All websites and documents are in Spanish.				
General	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 8430 (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	1. Guide for Research Ethics Committees. Code: ASS-RSA-GU040 Version: 00 (2015): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU040.pdf 2. Guide for Assessing and Monitoring of Research Protocols. Code: ASS-RSA-GU039 Version: 02 (2016): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU039.pdf
Drugs, Biologics, and Devices	*Drugs*			
	National Institute of Drug and Food Surveillance: http://www.invima.gov.co/		1. Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings: http://www.alcaldiabogota.gov.co/sisj	1. ABC Good Clinical Practice (2009) https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/ABCBPCultima_version.pdf 2. Circular No 600-5776-14: Processes of Good Clinical Practice (2014):

Country	Key Organizations	Legislation	Regulations	Guidelines
			ur/normas/Norma1.jsp?i=31169 2. Resolution No. 2011020764 of June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: https://www.invima.gov.co/index.php?option=com_content&view=article&id=725:resolucion-no-2011020764-del-10-de-junio-de-2011&catid=58:2011&Itemid=105	https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/CIRCULAR_600-5776-14-2.pdf 3. Guide of Medications and Supplies for Clinical Research (2015): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU045.pdf 4. Guide for the Evaluation and Follow-up of Research Protocols (2016): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU039.pdf 5. External Circular No. 600-2006-16: National Reporting Serious Adverse Events (2016): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/Circular-600-1081-16-Reporte-de-Eventos-adversos-serios-Nacionales-Febrero2016.pdf 6. External Circular No. 600-1414-16: Notification of Deviations (2016): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/Circular_600-2006-16_Alcance-Circular-600-1081-16_Abril2016.pdf
	Devices			
	National Institute of Drug and Food Surveillance: http://www.invima.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Research Injury	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 13 (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Privacy/Data Protection	Ministry of Health and Social Protection: http://www.minsalud.gov.co	1. Constitution of Colombia, Article 15 (2003): http://www.corteconstitucional.gov.	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
		co/inicio/Constitucion%20politica%20de%20Colombia%20-%202015.pdf 2. Law 1581 of 2012: General Regimen of Protection of Personal Data: https://www.mintic.gov.co/portal/604/articles-4274_documento.pdf	008430, Title II, Chapter I, Article 8 (1993)	
Human Biological Materials	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Genetic Research	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapter II (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Costa Rica Note: All websites and documents are in Spanish.				
Drugs, Biologics, and Devices	National Health Research Council: http://www.ministeriodesalud.go.cr/index.php/consejos/conis	Regulatory Law of Biomedical Research No. 9234 (2014): http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC	1. Regulatory Decree N° 39061-S (2016) on the Regulatory Law of Biomedical Research N° 39533-S: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC 2. Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC	Various: http://www.ministeriodesalud.go.cr/index.php/consejos/conis

Country	Key Organizations	Legislation	Regulations	Guidelines
Clinical Trials Registry	National Health Research Council (Spanish): http://www.ministeriodesalud.go.cr/index.php/consejos/conis (scroll to bottom of page to Investigaciones Registradas)			
Cuba Note: All websites and documents are in Spanish.				
Drugs, Biologics, and Devices	Center for State Control of Medications: http://www.cecmed.cu/			Various: http://www.cecmed.cu/ensayos-clinicos/autorizos
Clinical Trials Registry	Public Cuban Registry of Clinical Trials: http://registroclinico.sld.cu/en/home			
Dominica				
General	Ministry of Health: http://www.dominica.gov.dm/cms/index.php?q=node/21			Guidelines for the Conduct of Research on Human Subjects (2005)
Dominican Republic				
General	National Council on Health Bioethics: http://conabios.gob.do/	National Health Law 42-01, Chapter VI: https://www.dol.gov/ilab/submissions/pdf/20100408-10.pdf	Regulation for Evaluation Request for a Clinical Investigation Project: http://conabios.gob.do/index.php/reglamentos	
Biological Materials		National Health Law 42-01, Book Five: https://www.dol.gov/ilab/submissions/pdf/20100408-10.pdf		
Ecuador Note: All websites and documents are in Spanish.				
General	Ministry of Public Health : http://www.salud.gob.ec/	1. Constitution of the Republic: http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf 2. Organic Health Law of 22 December 2006, Articles 207-208: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		National Policy on Scientific Research. Ministerial Agreement 209, Public Registry No. 87 of August 23, 2005
Drugs, Biologics, and Devices	1. Ministry of Public Health: http://www.salud.gob.ec/ 2. National Health Agency for Regulation, Control, and Oversight: http://www.controlsanitario.gob.ec/ensayos-clinicos/		1. Regulation for the Approval, Development, Oversight, and Control of Clinical Trials (2017): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/	

Country	Key Organizations	Legislation	Regulations	Guidelines
			08/Normativa-Ensayos-Cli%CC%81nicos-Registro-Oficial.pdf 2. Regulation for the Approval of Ethics Committees (2014): http://instituciones.msp.gob.ec/images/Documentos/CNBS/1%20normativa/Registro%20Oficial%20Comites%20de%20Etica%20julio%202014.pdf 3. Regulation on Research, Ministerial Agreement No. 0066, Public Registry No. 292 (March 11, 2008): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/A.M.-66-REGLAMENTO-DE-PROYECTOS-EN-INVESTIGACION-DE-SALUD.pdf	
Privacy/Data Protection	Ministry of Public Health: http://www.salud.gob.ec/	Constitution of the Republic of Ecuador 2008 (Article: 92): http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf	Ministerial Agreement No. 005216, Public Registry No. 427, Confidential Information in National Health System (January, 29, 2015): http://instituciones.msp.gob.ec/cz6/images/lotaip/Enero2015/Acuerdo%20Ministerial%205216.pdf	
Biological Materials	National Institute on Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/	1. Organic Health Law of December 22, 2006, Articles 81-86: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf 2. Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2011): http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	1. Executive Order 1205, July 13, 2012: Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf 2. Import and Export of Human Biological Samples for research. Ministerial Agreement No. 0088, Public Registry No. 34, (July 12, 2017): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/08/Acuerdo-Ministerial-0088-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2017_Autorizaci%C3%B3n-de-importaci%C3%B3n-y-exportaci%C3%B3n-de-muestras-biol%C3%B3gicas.pdf	
Genetic Research	Ministry of Public Health: http://www.salud.gob.ec/	Organic Health Law, December 22, 2006, Articles 209-210 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		
Embryos, Stem Cells, and Cloning	1. Ministry of Public Health: http://www.salud.gob.ec/ 2. National Institute of Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/	Organic Health Law of 22 December 2006, Article 214 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf	Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells. Executive Order 1205, July 13, 2012: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	
Grenada				
General	St. George's University/Windward Islands Research and Education Foundation: http://www.sgu.edu/school-of-medicine/institutional-review-board.html			45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Guyana				
General			Medical Research Involving Human Subjects Regulations (2007)	
Guatemala Note: All websites and documents are in Spanish.				
Drugs, Biologics, and Devices	Ministry of Public Health and Social Assistance: http://www.mspas.gob.gt/		Rules for the Regulation of Human Clinical Trials. Ministerial Accord SP-M-466-2007: http://medicamentos.com.gt/index.php/legislacion-vigente/acuerdos	
Haiti				
General	Ministry of Public Health and Population (French): http://mspp.gouv.ht/newsite/			Internal Regulations (2010) (French)

Country	Key Organizations	Legislation	Regulations	Guidelines
Honduras Note: All websites and documents are in Spanish.				
General	Secretariat of Health: http://www.salud.gob.hn/		Health Code, Decree No. 65-91, Articles 175 and 176	
Human Biological Materials		Law of Donation and Transplantation of Anatomical Organs in Human Beings (2014): http://www.tsc.gob.hn/leyes/Ley_donacion_transp_organos_2014.pdf n. 329-2013		
Jamaica				
General	Ministry of Health, Ethics and Medico-Legal Affairs Panel: http://moh.gov.jm/			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2010): http://moh.gov.jm/guidelines/guidelines-for-the-conduct-of-research-on-human-subjects/
Drugs, Biologics, and Devices	Ministry of Health, Standards and Regulation Division: http://moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/	Food and Drugs Act (1975): http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf	Food and Drugs Regulations (1975): http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf	
México Note: All websites and documents are in Spanish.				
General	1. Secretariat of Health: http://www.salud.gob.mx/ 2. General Health Council: www.csg.salud.gob.mx/ 3. National Bioethics Commission (CNB): http://www.conbioetica-mexico.salud.gob.mx/ 4. Federal Commission for Protection Against Health Risks: http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2014)	1. Rule NOM-012-SSA3-2012 Establishing Criteria for the Conduct of Health Research Projects (2013): http://dof.gob.mx/nota_detalle.php?codigo=5284148&fecha=04/01/2013 2. Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf	CNB: National Guidelines for the Integration and Operation of Research Ethics Committees (2016): http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI_paginada_con_forros.pdf
Drugs, Biologics, and Devices	Federal Commission for Protection Against Health Risks (COFEPRIS): http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2014)	Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf	1. Guidelines to Fulfill Good Clinical Practice in Health Research 2. Technical Rule No. 314 for Registration and Follow-up in the Area of Health Research 3. Technical Rule 315 for the Operation of Research Commissions in Healthcare Institutions: http://www.cofepris.gob.mx/AS/Documents/Moléculas%20Nuevas/Formatos/CONFIDENCI

Country	Key Organizations	Legislation	Regulations	Guidelines
				ALIDAD%20CMN%20CAS-CAS-P-02-F-02.pdf
Privacy/Data Protection	Federal Institute on Access to Public Information (Spanish): www.ifai.org.mx/	1. Federal Law for the Protection of Personal Data in the Possession of Private Individuals (2010): http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf 2. Federal Law on Transparency and Access to Public Information (2017): http://www.diputados.gob.mx/LeyesBiblio/pdf/244_140714.pdf		
Human Biological Materials	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-342 (2005): http://www.diputados.gob.mx/LeyesBiblio/pdf/142_040615.pdf	Regulation of the General Law of Health in Matter of Transplants (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf	
Genetic Research	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/es/	1. Biosafety Law on Genetically Modified Organisms (2005): http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf 2. Regulation of the Biosafety Law on Genetically Modified Organisms (2008) http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LBOGM.pdf 3. Modifications to the General Health Law to Protect Genomic Sovereignty (2008) 4. Modifications to the General Health Law to Protect Genomic Sovereignty (2008)	Regulation on the General Health Law in the Matter of Health Research, Title Four, Chapter Two (1984): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
Panamá				
General	1. Ministry of Health (MINSA) (Spanish): http://www.minsa.gob.pa/ 2. ICGES Bioethics Research Committee (CBI): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es		MINSA: 1. Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) 2. Executive Decree N°1843 on the National Research Ethics Committee of Panama (2014) (Spanish): https://www.gacetaoficial.gob.pa/.../GacetaNo_27716_20150206.pdf	CBI : Various (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es

Country	Key Organizations	Legislation	Regulations	Guidelines
			3. Executive Decree N° 6 on the National Research Ethics Committee of Panama (2015) (Spanish): https://www.gacetaoficial.gob.pa/pdfTemp/27716/GacetaNo_27716_20150206.pdf	
Drugs, Biologics, and Devices		Law 1 of 2001, Official Gazette 24,218 (Spanish): http://www.perezcarrera.com/leyes/ley-registro-sanitario-panama.pdf		
Privacy/Data Protection		Law 68 of 2003, Official Gazette 24,935		
Human Biological Materials		Law 3 of 2010, Official Gazette 26,468-B on Transplant of Organs and Tissues: https://www.gacetaoficial.gob.pa/pdfTemp/26468_B/GacetaNo_26468b_20100210.pdf		
Embryos, Stem Cells, and Cloning			Executive Decree No. 2 on Stem Cells (2013) (Spanish): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf	
Perú For an overview of clinical research regulations in Peru, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=170				
General	National Institute of Health (Spanish): http://www.ins.gob.pe/	General Health Law No. 26842, Article 28 (1997) (Spanish): http://www.wipo.int/wipolex/en/text.jsp?file_id=203140		
Drugs, Biologics, and Devices	1. National Institute of Health (Spanish): http://www.ins.gob.pe/ 2. National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe		Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials (2017) (Spanish): http://busquedas.elperuano.com.pe/download/url/aprueban-reglamento-de-ensayos-clinicos-decreto-supremo-n-021-2017-sa-1538902-2	Various: http://www.ensayosclinicos-repec.ins.gob.pe/otros-repec/216-comunicados
Clinical Trials Registry	Peruvian Registry of Clinical Trials: http://www.ensayosclinicos-repec.ins.gob.pe/en/about-repec/clinical-trial-search		Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials, Title III, Chapter I, Articles 16 - 32 (2017) (Spanish): http://busquedas.elperuano.com.pe/download/url/aprueban-reglamento-de-ensayos-clinicos-decreto-supremo-n-021-2017-sa-1538902-2	
Research Injury	National Institute of Health (Spanish):		Regulation on Clinical Trials in	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.ins.gob.pe/		Peru: Articles 26, 27 and 28 (Spanish): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
Privacy/Data Protection	National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe	1. Law 29733 for the Protection of Personal Information: http://www.minjus.gob.pe/legislacion/ 2. Law for Electronic Medical Charts (2013): http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html		
Saint Lucia				
Drugs, Biologics, and Devices		Clinical Trials Act (2016): http://slugovprintery.com/template/files/document_for_sale/laws/3742/Act%2010%20of%202016.pdf		
Trinidad and Tobago				
	1. Ministry of Health http://www.health.gov.tt/ 2. University of the West Indies (UWI), St. Augustine: http://sta.uwi.edu/fms/research/ethics.asp			UWI: 1. UWI Policy on Research Ethics 2. Application Guidelines 3. Ethics Committee Protocols Access*:* http://sta.uwi.edu/fms/research/ethics.asp
Uruguay Note: All websites and documents are in Spanish.				
General	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html	Decree No. 370/2008: Regulation Concerning Research with Humans	
Drugs, Biologics, and Devices	Ministry of Public Health: http://www.msp.gub.uy/	Decree 189/998: http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF		
Research Injury	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/No		

Country	Key Organizations	Legislation	Regulations	Guidelines
		rmas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html		
Privacy/Data Protection	Ministry of Public Health: http://www.msp.gub.uy/	1. Law 18.331: http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18331 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html		
Human Biological Materials	1. Ministry of Public Health: http://www.msp.gub.uy/ 2. National Institute on Donation and Transplantation: www.indt.edu.uy	Decree 160/006: http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf		
Venezuela Note: All websites and documents are in Spanish.				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT): www.fonacit.gov.ve/ 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC): http://www.ivic.gob.ve/bioetica/?mod=home.php	Constitution, Article 46 (3): http://www.venezuelaemb.or.kr/english/ConstitutionoftheBolivarianingles.pdf	Resolution No. 48 (1998): http://www.ivic.gob.ve/bioetica/?mod=bioeticahome.php	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons: http://www.ivic.gob.ve/bioetica/?mod=Anexo.php 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research: http://www.ivic.gob.ve/bioetica/?mod=Anexo.php 3. Informed Consent: http://www.ivic.gob.ve/bioetica/?mod=manual.php
Drugs, Biologics, and Devices	National Institute of Hygiene "Rafael Rangel": http://www.inhrr.gob.ve/	Medicines Act, Title III, Chapter II: http://www.ginecoweb.com/PDF/Ley-del-Ejercicio-de-la-Medicina.pdf		
Genetic Research	Venezuelan Institute of Scientific Research, Bioethics Commission: http://www.ivic.gob.ve/bioetica/?mod=home.php			1. Contract for Accessing Genetic Resources (2003): http://www.ivic.gob.ve/bioetica/contrato.pdf 2. Revised Outline of the International Declaration of Human Genetic Data (2003): http://www.ivic.gob.ve/bioetica/chapter3.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
AFRICA				
Regionwide				
Clinical Trials Registry	Pan African Clinical Trials Registry: http://www.pactr.org/		1. Order No. 387 of July 31, 2006 Regarding Clinical Trials: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0387-388_31_juil_2006.pdf 2. Order No. 00200 of July 25, 2009 Modfying Order No. 112 of October 22, 1995 Establishing Rules on Good Clinical Practice: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0200%20_25_Juil_2009.pdf	FAQs: http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_pageLabel=atmportal_page_FAQ
Algeria				
Drugs, Biologics, and Devices	Directorate of Pharmacy and Medicine: http://www.ands.dz/		1. Order No. 387 of 31 July 2006 Relating to Clinical Trials: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0387-388_31_juil_2006.pdf 2. Order No. 00200 of 25 July 2009 Amending Order No. 112 of 22 October 1995 Setting the Rules of Good Clinical Practice: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0200%20_25_Juil_2009.pdf	
Benin				
General		Law No. 2010-40 of 8 December, 2010 Regarding the Ethical Code and Duties in Health Research in the Republic of Benin (French): http://ethique-sante.org/pdf/loi-portant-code-ethique.pdf		
Botswana				
General	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967): http://www.elaws.gov.bw/docs/statutes/Botswana%20Statute%20Law%201967.pdf		1. Guidelines for Application for Research Permit (2004): http://www.gov.bw/Global/OP%20Ministry/RESEARCH%20PERMIT%20GUIDELINES.pdf 2. Guide for a Consent Form (2005) 3. Guidelines for the Review of Research Proposals (2005)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	1. SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006) 2. Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human Participants (2012): http://www.moh.gov.bw/Publications/drug_regulation/CLINICAL%20TRIAL%20GUIDELINES%20botswana%20v4-060312.pdf
Social-Behavioral Research	Ministry of Health and Wellness, Research and Development Committee	Anthropological Research Act 45 (1967): http://webcache.googleusercontent.com/search?q=cache:A7aea2ZEMhkJ:static1.1.sqspcdn.com/static/f/723732/25889598/1422112465653/ch59-02%2BANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTSMJNydkWHdUJ7iPvvm7Qkzk4uU%253D+&cd=1&hl=en&ct=clnk&gl=us		
Burkina Faso Note: All websites and documents are in French.				
General	Ethics Committee for Health Research		Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso	
Drugs, Biologics, and Devices			Order No. 2010-292/MS /CAB of 1 October 2010 on the Conditions for Granting Authorizations for Clinical Trials: http://elearning.trree.org/pluginfile.php/34806/mod_folder/content/0/19_Arrete_autorisations_essais_cliniques.pdf?forcedownload=1	
Cameroon For an overview of human subject protections in Cameroon, see: http://elearning.trree.org/mod/nationalsupplement/view.php?id=227				
General	Cameroon Bioethics Initiative: www.cambin.org		Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987) (French): http://elearning.trree.org/pluginfile.php/34735/mod_folder/content/0/cm-arrete-079-MSP-CreationComiteEthique-1987.pdf?forcedownload=1	Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research

Country	Key Organizations	Legislation	Regulations	Guidelines
Congo, Democratic Republic of				
General		National Policy on Health Systems Research (2004) (French)		
Côte-d'Ivoire				
For an overview of human subject protections in Côte-d'Ivoire, see: http://elearning.trree.org/course/view.php?id=19 Note: All websites and documents are in French.				
Drugs, Biologics, and Devices	National Committee on Ethics and Research		Decree No 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast: http://elearning.trree.org/pluginfile.php/34816/mod_folder/content/0/20_Arrete_Regl_exp_clinique_des_substances_med.pdf?forcedownload=1	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2014): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Drugs and Devices	Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et		Drug Administration and Control Proclamation No. 176/1999, Article 21	
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Gambia				
Genetic Research	MRC: Gambia Unit: http://www.mrc.gm/			Guidelines of the National DNA Bank (2001)
Ghana				
For an overview of the clinical trial information in Ghana, see: http://www.fdaghana.gov.gh/index.php?option=com_content&view=article&id=71&Itemid=55				
Drugs, Biologics, and Devices	Food and Drugs Authority: http://www.fdaghana.gov.gh	Public Health Act, 2012	Act 851, Sections 150-166: http://www.fdaghana.gov.gh/images/stories/pdfs/Clinical%20Trials/REGULATION%20OF%20CLINICAL%20TRIALS%20IN%20GHANA.pdf	1. Guidelines for Good Clinical Practice in Ghana (2015): http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/Clinical%20Trials/GUIDELINES%20ON%20GOOD%20CLINICAL%20PRACTICE%20IN%20GHANA.pdf 2. Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices (2015):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/Clinical%20Trials/GUIDELINES%20FOR%20AUTHORIZATION%20OF%20CLINICAL%20TRIALS%20OF%20MEDICINES,%20GHANA.pdf 3. Guidelines for Conduct of Clinical Trials in Paediatric Population (2016): http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/Clinical%20Trials/GUIDELINES%20FOR%20CONDUCT%20OF%20CLINICAL%20TRIALS%20WITH%20PAEDIATRIC%20POPULATION%20IN%20GHANA.pdf 4. Guidelines for Conduct of Clinical Trials During Emergencies (2016): http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/GUIDELINES%20FOR%20TRIALS%20IN%20EMERGENCIES1.pdf
Guinea For an overview of the clinical research regulations in Guinea, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=90 Note: All websites and documents are in French.				
General	National Ethics Committee on Health Research (CNERS): http://cners-guinee.org/	Public Health Code, Articles 237-316 (1997): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf	Decree No. D/218/PRG/SGG: On the Establishment, Functions and Organization of the National Ethics Committee for Research in Health (CNERS), Chapters I and II (1998): http://cners-guinee.org/wp-content/uploads/2014/02/Decret-.pdf	CNERS: Frequently Asked Questions: http://cners-guinee.org/faq/
Research Injury	National Ethics Committee on Health Research: http://cners-guinee.org/	Public Health Code, Articles 301-302 (1997): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf		
Kenya For an overview of the clinical research regulations in Kenya, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=111				
General	1. National Council for Science and Technology (NCST): http://www.nacosti.go.ke/ 2. Ministry of Health (MOH): www.health.go.ke/	1. Science and Technology Act (2001) 2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006)		MOH: National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): https://healthresearchweb.org/?action=download&file=Final%20national%20ethical%20guidelines-last%20draft.pdf
Drugs, Biologics, and Devices	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2009):	MOH: Kenya National Guidelines for	Guidelines for Applications to Conduct Clinical Trials in Kenya (2014):

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://apps.who.int/medicinedocs/documents/s18245en/s18245en.pdf	Research and Development of HIV/AIDS Vaccines (2005)	http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf
Human Biological Materials	Ministry of Health (MOH): www.health.go.ke/		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	
Liberia For an overview of the clinical research regulations in Liberia, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=122				
General	Ministry of Health and Social Welfare: http://www.mohsw.gov.lr/		1. Institutional Review Board (IRB) Policies and Procedures Handbook (2008): http://www.ul-acre.org/wp-content/uploads/2013/03/UL-IRB-Policy-Handbook.pdf 2. Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011): http://clinregs.niaid.nih.gov/documents/liberia/G-LIBR-NHSREC.pdf	
Drugs, Biologics, and Devices	Liberia Medicines and Health Products Regulatory Authority			Guideline for Application to Conduct Clinical Trials in Liberia (2014): https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf
Madagascar				
Drugs and Devices		Law No. 2011-002, Article 122 Regarding Clinical Trials (French): https://www.ilo.org/dyn/natlex/docs/ELECTRONIC/97799/116199/F1071917999/MDG-97799.pdf		
Malawi For an overview of the clinical research regulations in Malawi, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=129				
General	1. National Commission for Science and Technology (NCST): http://www.ncst.mw/ 2. National Health Sciences Research Committee (NHSRC): http://www.ncst.mw/national-health-science-research-committee-nhsrc/ 3. College of Medicine Research and Ethics Committee (COMREC):	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398 3. Constitution of Malawi, Article 19(5) (1994)		NCST: 1. The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011) 2. Policy Requirements, Procedures and Guidelines for the Conduct and Review of Research (2012) 3. National Policy Measures and Requirements for the Improvement of

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.medcol.mw/ 4. Ministry of Health: www.malawi.gov.mw			Health Research Co-ordination in Malawi (2012) 4. National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012) NHSRC: 1. Operational Guidelines (2001) 2. Summary Guidelines for Writing Research Proposals (2001) COMREC: General Guidelines on Health Research (2014): http://www.medcol.mw/comrec/wp-content/uploads/2014/07/comrec_guidelines.pdf
Drugs, Biologics, and Devices	Pharmacy, Medicines, and Poisons Board of Malawi	1. Pharmacy, Medicines, and Poisons Act, Act 15 of 1988: http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CB0QFjAAahUKEwi3qf2P2vLIAhUEqh4KHfyNBvw&url=http%3A%2F%2Fwww.malawilii.org%2Ffiles%2Fmw%2Flegislation%2Fconsolidated-act%2F35%3A01%2Fpharmacy_medicines_poisons_act_pdf_19885.pdf&usg=AFQjCNFJR-Y4F7y3eoC6DV0H7Jr77s5Msg 2. Section 42(1) of PMPB Act, 2003 Supplement			
Social-Behavioral Research	National Committee on Research in the Social Sciences and Humanities			Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011): http://www.ncst.mw/wp-content/uploads/2014/03/NATIONAL-FRAMEWORK-OF-GUIDELINES-IN-SSH.pdf
Human Biological Materials	National Commission for Science and Technology: www.ncst.mw		National Regulatory Requirement and Position on Accessing, Collection, Storage, and Use of Human Biological Specimens for Research (2014): https://www.ncst.mw/wp-content/uploads/2014/03/National-regulatory-requirement-on-human-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			samples.pdf	
Genetic Research	National Research Council of Malawi (NRCM): www.sdnp.org.mw/nrcm/		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Mali For an overview of human subject protections in Mali, see: https://clinregs.niaid.nih.gov/single_country.php?c_id=132&utm_medium=GovDelivery&utm_source=ClinRegs&utm_campaign=MaliPublication#_top				
Drugs, Biologics, and Devices	Directorate of Pharmacy and Medicine	Law No. 09-059 of 28 December 2009 Governing Biomedical Research on Humans (French): https://clinregs.niaid.nih.gov/documents/LawNo09-059.pdf		
Mozambique For an overview of human subject protections in Mozambique, see: http://elearning.trree.org/course/view.php?id=14&lang=en				
General				Science and Technology Ethics Code (2007) (Portuguese): http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1
Nigeria For an overview of human subject protections in Nigeria, see: http://elearning.trree.org/mod/page/view.php?id=142				
General	National Health Research Ethics Committee: http://nhrec.net/	National Health Act 2014		Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf Various: http://nhrec.net/download-guides-and-forms/
Drugs, Biologics, and Devices	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/	Decree No. 15 of 1993		Good Clinical Practice Guidelines (2016): http://www.nafdac.gov.ng/images/GUIDELINES/DRUG%20GUIDELINES/NAFDAC%20GOOD%20CLINICAL%20PRACTICE%20GUIDELINES%202016%20V%2013.pdf
Clinical Trial Registries	National Health Research Ethics Committee: http://nhrec.net/			Frequently Asked Questions: http://nhrec.net/nctr/FAQ.php
Social-Behavioral Research	National Health Research Ethics Committee			Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf
Human Biological Materials	National Health Research Ethics Committee: http://nhrec.net/			Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (2013): http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Rwanda				
General	Ministry of Health, National Ethics Committee: http://www.moh.gov.rw/index.php?id=2			Standard Operating Procedures (2009): http://www.moh.gov.rw/index.php?option=com_docman&task=doc_download&gid=126&Itemid=81
Senegal				
General	National Committee on Health Research Ethics	Law Supporting the Code of Ethics for Health Research (2009) (French): http://www.sante.gouv.sn/document/1432205899.pdf		
Sierra Leone For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=193				
General	Sierra Leone Ethics and Scientific Review Committee			1. Application Guidelines http://health.gov.sl/wp-content/uploads/2015/01/Guidelines-and-Checklist-for-Ethical-Clearance-2016.pdf 2. Application Form: https://www.healthresearchweb.org/?action=download&file=SierraLeoneEthicsandScientificReviewCommittee.docx
Drugs, Biologics, and Devices	1. Ministry of Health (French): http://www.sante.gov.bf/ 2. Pharmacy Board of Sierra Leone: http://pharmacyboard.gov.sl/		1. Guidelines for Conducting Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices in Sierra Leone, Sections: 3.1.7 and 3.2 (2014): http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=9jeTGC2WIZ8%3d&tabid=316&portalid=1&mid=934 2. Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2014): http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=9jeTGC2WIZ8%3d&tabid=316&portalid=1&mid=934 2. Guideline for Conducting Clinical Trials: http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=YrGQkXzfLP8%3d&tabid=316&portalid=1&mid=934&forcedownload=true 3.	Forms: http://pharmacyboard.gov.sl/site/Downloads/Forms.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
South Africa For an overview of human subject protections in South Africa, see: http://elearning.trree.org/course/view.php?id=9&lang=en For an overview of the clinical research regulations, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=199				
General	1. Department of Health (DH): http://www.doh.gov.za 2. National Health Research Ethics Council: http://www.nhrec.org.za/ 3. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 4. Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/index.phtml	1. Constitution of South Africa, Section 12 (2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): http://www.saflii.org/za/legis/consol_act/nha2003147.pdf	Regulations Relating to Research with Human Participants No. R719 (2014): http://www.google.co.za/url?url=http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/national-health-act-61-of-2003/regulations-and-notices/61-of-2003-national-health-act-regs-gnr-719-19-sept-2014-to-date-pdf/download&rct=j&frm=1&q=&esrc=s&sa=U&ei=W6UtVOOvLa6S7Aa34YDwAg&ved=0CBUQFjAA&usg=AFQjCNFpKA9W0jNyeWhk0n0l0Q-WxazBtg	DH: Ethics in Health Research: Principles, Structures, and Processes (2015): http://www.nhrec.org.za/docs/Documents/EthicsHealthResearchFinalAused.pdf MRC: 1. Guidelines on Ethics in Medical Research: General Principles (2002) 2. Guidelines on Ethics in the Use of Biohazards and Radiation (2003) 3. Guidelines on Ethics in HIV Vaccine Trials (2003)
Drugs, Biologics, and Devices	1. Department of Health (DH): http://www.doh.gov.za 2. Medicines Control Council: http://www.mccza.com	Medicines and Related Substances Control Act, 101 of 1965 http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf	General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003): http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf	DH: Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006): http://www.nhrec.org.za/docs/trainingrequirements/gcp.pdf
Clinical Trials Registry	South African National Clinical Trials Register: http://www.sanctr.gov.za/			FAQs: http://www.sanctr.gov.za/InvestigatorbrnbspInformation/FAQ/tabid/200/Default.aspx
Social-Behavioral Research	Department of Health			Ethics in Health Research: Principles, Processes, and Structures, Section 3.3.7(i) (2015): http://www.commerce.uct.ac.za/Downloads/Ethics%20in%20Health%20Research%20Final%20A%20used.pdf
Human Biological Materials	Department of Health (DH): http://www.doh.gov.za	National Health Act No. 61, Chapter 8, Sections 53-68 (2003): http://www0.sun.ac.za/ruralhealth/ukwandahome/rudasaresources2009/DOH/ethics/app5.pdf	1. Regulations Relating to the Use of Human Biological Material, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 2. Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012 3. Regulations Relating to Blood and Blood Products, 2 March	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 4. Regulations Relating to Artificial Insemination of Persons, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf	
Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Embryos, Stem Cells, and Cloning	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za	National Health Act No. 61, Chapter 8, Section 57 (2003): http://www0.sun.ac.za/ruralhealth/ukwandahome/rudasaresources2009/DOH/ethics/app5.pdf	Regulations relating to Stem Cell Banks, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf	Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.kznhealth.gov.za/research/ethics2.pdf
Tanzania For an overview of human subject protections in Tanzania, see: http://elearning.trree.org/mod/resource/view.php?id=41&lang=en For an overview of the clinical research regulations in Tanzania, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=212				
General	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/ 3. Tanzania Commission for Science and Technology (COSTECH): www.costech.or.tz	1. National Institute for Medical Research, Act of Parliament No. 23, of 1979: http://www.parliament.go.tz/Polis/PAMS/Docs/23-1979.pdf 2. Tanzania Commission for Science and Technology, Act No. 7 of 1986 3. Amendment of NIMR Act 1997, Tanzania Government Gazette, No. 675	NIMR: 1. Coordination of Health Research in Tanzania 2. Coordination of Formation of Institutional Health Research Committees to Formally Approve for Local Health Research 3. Coordination of Research in Tanzania	NHREC: 1. Brochure for Health Researchers in Tanzania (2006) 2. Guidelines on Ethics for Health Research in Tanzania (2009): https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)
Drugs, Biologics, and Devices	*Drugs*			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&download=44:tfdc-acts-2003&id=52:tfdc-acts-2003&Itemid=417		
	Devices			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Medical Device Act (1988)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Uganda				
For an overview of the clinical research regulations in Uganda, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=223				
General	Uganda National Council for Science and Technology (UNCST): http://www.uncst.go.ug/	Uganda National Council for Science and Technology Act (CAP 209)		National Guidelines for Research Involving Humans as Research Participants (2014): http://www.uncst.go.ug/dmdocuments/Human%20Subjects%20Protection%20Guidelines%20July%202014.pdf
Drugs, Biologics, and Devices	National Drug Authority: http://www.nda.or.ug/	National Drug Policy and Authority Act (CAP 206) (1993)		
Zambia				
General	Ministry of Health: http://www.moh.gov.zm/	National Health Research Act (2013): http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf		
Drugs, Biologics, and Devices	Zambia Medicines Regulatory Authority: http://www.zamra.co.zm/	Medicines and Allied Substances Act, Part VI: Regulation of Clinical Trials, 2013: http://www.zamra.co.zm/wp-content/uploads/2016/10/MASA-No-3-2013.pdf		Guidelines on Regulating the Conduct of Clinical Trials in Human Participants: http://www.zamra.co.zm/wp-content/uploads/2016/10/Guidelines-on-Application-for-Clincal-Trial-Authorisation.pdf
Human Biological Materials		National Health Research Act, Part VI (2013): http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Medical Research Government Notice Act (1974) 2. Research Act (1986)		Various: http://www.mrcz.org.zw/faqs/
Drugs, Biologics, and Devices	*Drugs*			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/	Medicines and Allied Substances Control Act, Chapter 15:03 (1997)	1. Medicines and Allied Substances Control Act, General Regulations (1991) 2. Statutory Instrument 150 of 1991	1. Guidelines for Good Clinical Practice (2012): http://www.medbox.org/guidelines-for-good-clinical-trial-practice-in-zimbabwe-2012/download.pdf 2. Pharmacy Guidelines for Investigational Drugs (2016): http://www.mcaz.co.zw/index.php/downloads/file/114-pharmacy-guidelines-for-investigational-drugs-draft-1
	Devices			

Country	Key Organizations	Legislation	Regulations	Guidelines
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/devices.html	Medicines and Allied Substances Control Act, Chapter 15:03 (1997): https://www.unodc.org/res/cld/document/zwe/medicines-and-allied-substances-control-act_html/Zimbabwe_Medicines_and_Allied_Substances_Control_Act.pdf	Medicines and Allied Substances Control (Condom) Regulations (2005): http://www.mcaz.co.zw/index.php/downloads/category/15-regulations-and-guidelines?download=29:condom-regulations	
Human Biological Materials	Research Council of Zimbabwe: www.rcz.ac.zw	Research Act (2001): http://faolex.fao.org/docs/pdf/zim93551.pdf		Various: http://www.rcz.ac.zw/research-registration/
Genetic Research	National Biotechnology Authority of Zimbabwe: http://www.nba.ac.zw/	National Biotechnology Authority Act, Chapter 14:31 (2006): http://www.nba.ac.zw/index.php/our-resources/finish/1-national-biotechnology-association/2-national-biotechnolgy-authority-act		

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AMERICAN PSYCHOLOGICAL ASSOCIATION

Equity, Diversity, *and* Inclusion

FRAMEWORK

As a mission-driven organization that applies the best available psychological science to benefit society and improve lives, we recognize that the inclusion of diverse people, viewpoints and experiences are key to our success. I strongly believe that championing equity, diversity, and inclusion (EDI) is not just the right thing to do, it is the smart thing to do. As we implement our strategic plan, EDI serves as a critical lens to drive our strategic priorities and measure the magnitude of our impact. It is essential that we embed EDI throughout all aspects of our work.

APA has devoted significant attention to EDI since the late 1960s. For several decades, our boards, committees, divisions, and staff have worked diligently to advance EDI. While our work has been a high priority, it has not always been coordinated and integrated. In June 2018, APA began to develop an EDI Framework to guide APA's future EDI planning and the work of our Chief Diversity Officer, Dr. Maysa Akbar.

This process consisted of multiple rounds of input from staff, leadership, and experts across our membership base. This evolving EDI Framework draws on APA's 2005 diversity policy, its 2007 diversity plans and reports, and best practices from the field of organizational EDI. APA's EDI Framework reflects our view that equity, diversity, and inclusion are vital to the progress of our Association, the field of psychology, and broader society.

The EDI Framework also builds upon the work done to date and provides the foundation for the next phase of EDI strategic planning, including the development of iterative goals and metrics. The critical work ahead will enable us to maximize the impact of our EDI efforts. We commit to engaging in a collaborative process that systematically and comprehensively advances EDI, our strategic priorities, and APA's vision and mission.

Arthur C. Evans, Jr., PhD
CEO, American Psychological Association

This report is being issued by APA's Equity, Diversity, and Inclusion Office in the Executive Office on April 8, 2021.

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The release of this framework could not have been possible without invaluable input and feedback from APA members, governance leaders, and staff. This ambitious and ever-evolving document will be central to the transformative change we all seek as an Association and as a field.

This document stands on the shoulders of decades of research and advocacy by many. To move those efforts into a guiding framework took enormous effort. For that, we want to acknowledge APA volunteer leaders, including members of the APA Board of Directors and Council of Representatives, the Council Diversity Leadership Group, the EDI Collaborative, and the Ethnic Minority Psychological Associations. We are also grateful for the powerful input from the Committee on Ethnic Minority Affairs, the Committee on Women in Psychology, and the Committee on Sexual Orientation and Gender Diversity. We cherish the contributions of APA's Staff Diversity Workgroup, the leadership and support in the Public Interest Directorate and the stewardship of the Equity, Diversity, and Inclusion Office in the Executive Office. Lastly, sincere appreciation to Shorter-Gooden Consulting, Kumea Shorter-Gooden, Ph.D., and Jacqueline Mac, M.A. for working with APA members, governance leaders, and staff in the development of this Framework.

We are committed to working collaboratively with our stakeholders across the organization and field to advance the EDI Framework and related initiatives to create a more equitable, diverse, and inclusive Association, discipline, and society.

A BRIEF HISTORY OF PSYCHOLOGY

The 2020 report on "Protecting and defending our people: Nakni tushka anowa (The warrior's path)," written by APA's Division 45, Society for the Psychological Study of Culture, Ethnicity and Race, recounts the history of psychology's adoption and perpetuation of U.S. colonialism and its contribution to systemic and structural barriers for Black, Indigenous, and People of Color (BIPOC).

The report states that, mainstream psychology in the US has at its foundation a White Eurocentric perspective. Although research suggests that BIPOC scientists tend to produce more innovative scholarship, these innovations have been systemically discounted by the field of psychology, academic institutions, and the publication process in ways that diminish representation and impact in the field. BIPOC perspectives in theory, research and applied contexts have not been seriously considered to have the disciplinary rigor assumed for the mainstream perspective. Race and ethnicity have been significantly underemphasized in peer-reviewed publications of psychological science. The demographics of psychology faculty and of new doctoral graduates in psychology do not mirror the diverse population of the US. Similarly, the membership of the APA does not reflect the diverse demographics of the US, and the racial and ethnic demographics of APA have changed little since 2007.

For a detailed history please read the **full report**: APA Division 45 Warrior's Path Presidential Task Force (2020). Protecting and defending our people: Nakni tushka anowa (The warrior's path)

RATIONALE FOR EDI FRAMEWORK

Beginning in the 1960s, grassroots activism groups, Black psychologists throughout the nation, as well as various APA members and EDI- focused divisions, challenged APA to reflect and respond to the lack of diversity of its membership and improve oppressive structures within the organization and profession. Their leadership, advocacy, and involvement contributed significantly to APA's acknowledgement and advancement with respect to EDI.

Since the late 1960s, APA has created boards and committees, divisions, and headquarters offices, focused on the concerns of marginalized groups (e.g., BIPOC communities; women; older adults; lesbian, gay, bisexual, and transgender persons; and individuals with disabilities) within the organization, within psychology, and in the broader society beyond the field of psychology. The representation and full participation of APA members and other psychologists from these groups within the leadership and membership of APA and in the field is an important objective for APA. APA will examine its history and will begin to engage in a process towards reconciliation and healing. Additionally, APA will continue its work to broaden the representation of diverse groups within the organization and profession—understanding that a heterogeneous association of people of diverse backgrounds and standpoints is critical for excellence and that embedding a focus on EDI is essential for APA to fulfill its mission to advance the creation, communication, and application of psychological knowledge to benefit society and improve lives (APA, Office of Ethnic Minority Affairs, 2005; see APA, Presidential Task Force, 2012).

Thus, for several decades, APA boards and committees, divisions, and offices have engaged in important and substantive EDI work. However, these efforts have been largely uncoordinated (APA, Office of Ethnic Minority Affairs, 2005; Leong et al., 2017). With the engagement of its membership and staff, APA has participated in a wide range of diversity activities, including the development of an Interim Diversity Implementation Plan in 2007 to guide and coordinate them. However, the diversity plan was never fully implemented. For that reason, the chief executive officer of APA commissioned this framework in 2018.

A systemic approach to organizational EDI needs to be intentional and engage all areas of the organization, thus incorporating an EDI lens into all aspects of the organization (APA, 2008; Church et al., 2014; Cox, 2001; Smith, 2009; Sue, 2008; Williams, 2013). More than a disparate set of activities and events is vital (Smith, 2012; Williams, 2013). Instead, structural and cultural shifts, including organizational accountability, are important to create substantive, transformative, and sustainable change (Holvino et al., 2004; Williams, 2013). And it is important to address both first order and second order (or transformative) change—the former reflecting minor, incremental adjustments and the latter indicating new assumptions and patterns governing organizational life (APA, Office of Ethnic Minority Affairs, 2005).

More than a disparate set of activities and events is required. Instead, structural and cultural shifts are important to create substantive, transformative, and sustainable change.

EDI STRATEGIC PLAN COMPONENTS

VISION STATEMENT

APA's vision for EDI articulates the organization's ultimate aspirations and thus provides a guide to the desired outcomes of EDI activities (See Esty, Griffin, & Hirsch, 1995; Holvino et al., 2004). The following statement, based on APA's ***strategic plan****, articulates APA's EDI vision to successfully integrate EDI across the organization and the discipline. The EDI Framework is an ever-evolving document and should be used as a foundational tool to support the achievement of APA's vision for EDI, including creating a common language and long-term coordinated strategy towards dismantling racism.*

APA strives for:

An accessible, equitable, and inclusive psychology that promotes human rights, fairness, and dignity for *all*.

MISSION STATEMENT

To advance EDI through psychological science that champions thought leadership, innovation and excellence.

GUIDING PRINCIPLES

The guiding principles of APA's EDI Framework address the basic assumptions that are associated with the best practices in organizational EDI work. (See Hayles, 2013; Williams, 2013). The guiding principles are a prerequisite for achieving success in EDI as articulated in APA's strategic plan.

APA Itself

- Will take account for the Association's contribution to social hierarchies and inequities within the Association and profession. APA is committed to uplifting the voices of those who have been harmed and will learn from its history to create a more inclusive, equitable, and diverse field of psychology.
- Is a global partner in the promotion of psychological practice, science, and education to address societal and global challenges, including structural racism, White supremacy, xenophobia, nativism, and other forms of discrimination.
- Actively champions EDI throughout the entire organization and establishes procedures to ensure that APA's institutional practices are grounded in our commitment to promote diversity, and to advance equity, and inclusion (see Cox, 2001; Holvino et al., 2004; Kalev, Dobbin & Kelly, 2006; Smith, 2009).
- Fosters an organizational culture that opposes destructive social hierarchies of all forms, including but not limited to racism, sexism, classism, heterosexism, ageism, and ableism; thereby developing norms in which social hierarchies, racism, injustice, inequity, and exclusion are discussed candidly, while proactively and constructively addressed. (see Borrayo, 2008; APA CDWG, 2017).
- Utilizes a strategic EDI roadmap that includes goals and objectives, and monitors, evaluates, and evolves those goals in an iterative fashion. (see Smith, 2009; Williams, 2013).
- Uses a matrixed organizational strategy to support the EDI agenda—for example, promoting collaborative EDI implementation between and across directorates, boards, and committees; accountability mechanisms and reward systems to incentivize constituents to engage in EDI work. (See APA, 2008; CDWG, 2017; Cox. 2001; Holvino et al., 2004; Kalev et al., 2006; Sue, 2008; Williams, 2013).

The Field of Psychology

- Works toward deconstructing inequalities and inequities that exist within psychological science, including how science is conducted, reported, reviewed, and disseminated.
- Recognizes that all human beings have biases, privileges, and prejudices and that the task is to develop awareness of biases, to strive to mitigate and diminish the impact of those biases, and to develop skills to engage and work effectively with people and communities from diverse and underrepresented social identity groups. (See Banaji & Greenwald, 2013).
- Advocates that learning institutions incorporate essential pedagogy about racism and health into standard coursework, as a step toward leading learning institutions to acknowledge their supportive roles in the system of structural racism. (See Bailey, Zinzi D et al., 2017).
- Champions the study of individual and institutional racism in order to measure exposure to systems and structures by identifying the historical harms, testing the connections between psychological mechanisms and outcomes, and providing recommendations for systems of change. (See Trawalter, Sophie et al., 2020).
- Promotes a culture of evidence-based and holistic approaches, while applying a learning orientation, where the status of EDI is continuously evaluated and oriented toward ongoing growth, development, and improvement. (See APA, 2008; Cox, 2001; Holvino et al., 2004; Smith, 2009, 2012; Williams, 2013).
- Actively seeks to center the perspectives and voices of social identity groups that are or have been disenfranchised or marginalized. (See APA, 2005).

Society

- Understands that EDI, human rights, racial justice, and social change are never fully achieved; that they must be continually sought after, reexamined, and embraced; and that new areas of inequity and exclusion will inevitably emerge and need to be addressed. (See Adams et al., 2013).
- Commits to applying psychological science to create a more equitable and inclusive world.
- Elevates and honors the voices and perspectives of marginalized social and intersectional identities.

THE EDI MODEL

The APA EDI model has three levels, as articulated in the vision statement:

a) **APA itself**, including volunteer leaders, members, and staff;
b) **Field of Psychology**, as a discipline and profession, including pathway programs, educational/training programs, and institutions, offices, and programs that shape and determine policies and practices for the discipline; and
c) **Society**, all people and communities throughout society whom psychological science, scholarship, education, advocacy, and practice benefit.

This tripartite approach differentiates internally focused work (APA as an organization and entity) from externally focused work (the field of psychology and society).

Figure 1 depicts the EDI model, which is influenced by **Sue's (2001) conceptual framework** for incorporating multidimensional facets of cultural competence into psychology. Sue's model examines cultural competency at the micro level (e.g., the individual) and at the macro level (e.g., the profession of psychology, organizations, and the broader society), highlighting the criticality of working in a collaborative fashion to remove major barriers along the four levels: individual, professional, organizational, and societal in order to move toward cultural competence. Sue's model has been adapted to reflect how APA will approach the pursuit of equity, diversity, and inclusion within the Association, the field of psychology, and throughout society.

Figure one identifies APA at the center of the model, and the field of psychology, society, and the work of APA are in the surrounding circles. The positions of the circles reflect that APA has internal constituencies with which it engages, whereas much of APA's work aims to shape and influence the field of psychology, which then fosters the application of psychological work throughout society. **APA's efforts radiate outward through these levels.** However, the influence is bidirectional: APA both affects and is affected by the field and society. For example, the Association's knowledge of how best to serve communities that have been marginalized is intimately tied to active hearing, listening, and internalizing a model of being responsive. In an iterative fashion, APA is committed to engaging in a multidirectional feedback model, which is essential to fulfilling our mission.

The work of EDI identified across institutions and industries has tended to fall into the following broad categories:

a) leadership and infrastructure;
b) access, equity, and success;
c) organizational climate; and
d) core work of the institution (Henderson, 2014; Shorter-Gooden, 2014; Smith, 2009; Williams, 2013).

This common set of broad categories provided the foundation for the domains in APA's EDI model that are represented within the three levels. The core EDI work of APA as an institution is identified in the model as science, practice, education, and advocacy that is inclusive and equitable, while responding to the unique challenges and opportunities of social cultural diversity.

The APA level addresses the experiences and outcomes for APA's volunteer leaders, members, and staff at all levels. Sustained work toward excellence in all five domains, across the breadth of APA, will ensure that APA is an equitable, diverse, and inclusive organization. The five domains at the APA level are as follows:

» **Leadership & Infrastructure**
The center of the APA model denotes the vital importance of a leadership structure for EDI and an organizational infrastructure that supports the work.

» **Psychological Safety**
The climate in which the experience of APA is safe, welcoming, engaging, and affirming by volunteer leaders, members, and staff of all social identity groups and intersections, especially those most impacted by systemic oppression. It includes being courageous to express vulnerability, to own mistakes and transform them into learning opportunities, and to trust that judgement will not be issued for doing so. This will require a deep understanding of the historical challenges in the field of psychology, an acknowledgement of who has been harmed, the impact of that harm, and a commitment to cultivating an honest and transparent relationship with marginalized communities.

» **Inclusive Policies & Practices**
The maintenance, further creation and implementation of inclusive policies, procedures, and practices within the organization.

» **Cultural and Emotional Intelligence**
The capability to provide education and training that is culturally responsive, adaptable, relatable, and provided with cultural and social humility and competence, for APA volunteer leaders, members, and staff.

» **Access & Equity**
The commitment to diversity, social justice, and equity within APA.

The Field of Psychology level represents the array of policies and practices grounded in psychological science for the discipline, as well as the pathway of academic and internship programs and institutions that serve to educate and train prospective psychologists and that provide postdoctoral continuing education and professional support for existing psychologists. APA will advocate for education and training to be grounded in *Cultural and Emotional Intelligence* for all students/trainees/pre-and post-docs across the range of content, curricula, and training/degree programs; for *Inclusive Policies & Practices* in all areas of the discipline and in the profession, including the elimination of policies and practices that reinforce structural injustices and amplify inequities; that embodies *Psychological Safety* by cultivating a culture and climate that is welcoming and engaging across the field of psychology; and for *Access & Equity* throughout the field.

The Society level is the sphere in which the mission to advance psychological science and knowledge to benefit society and improve lives is realized—in the United States and globally. The level comprises an integrated EDI paradigm in the following four domains: *Science, Education, Advocacy,* and *Practice*, which all work in tandem to achieve APA's strategic priorities. The Society level signifies that APA's ultimate goal is to shape the creation, communication, access to, and application of psychological knowledge and information, the practice of psychology, and the policies that impact psychological well-being in ways that benefit and promote equity.

FIGURE 1.
The APA Equity, Diversity, and Inclusion Model

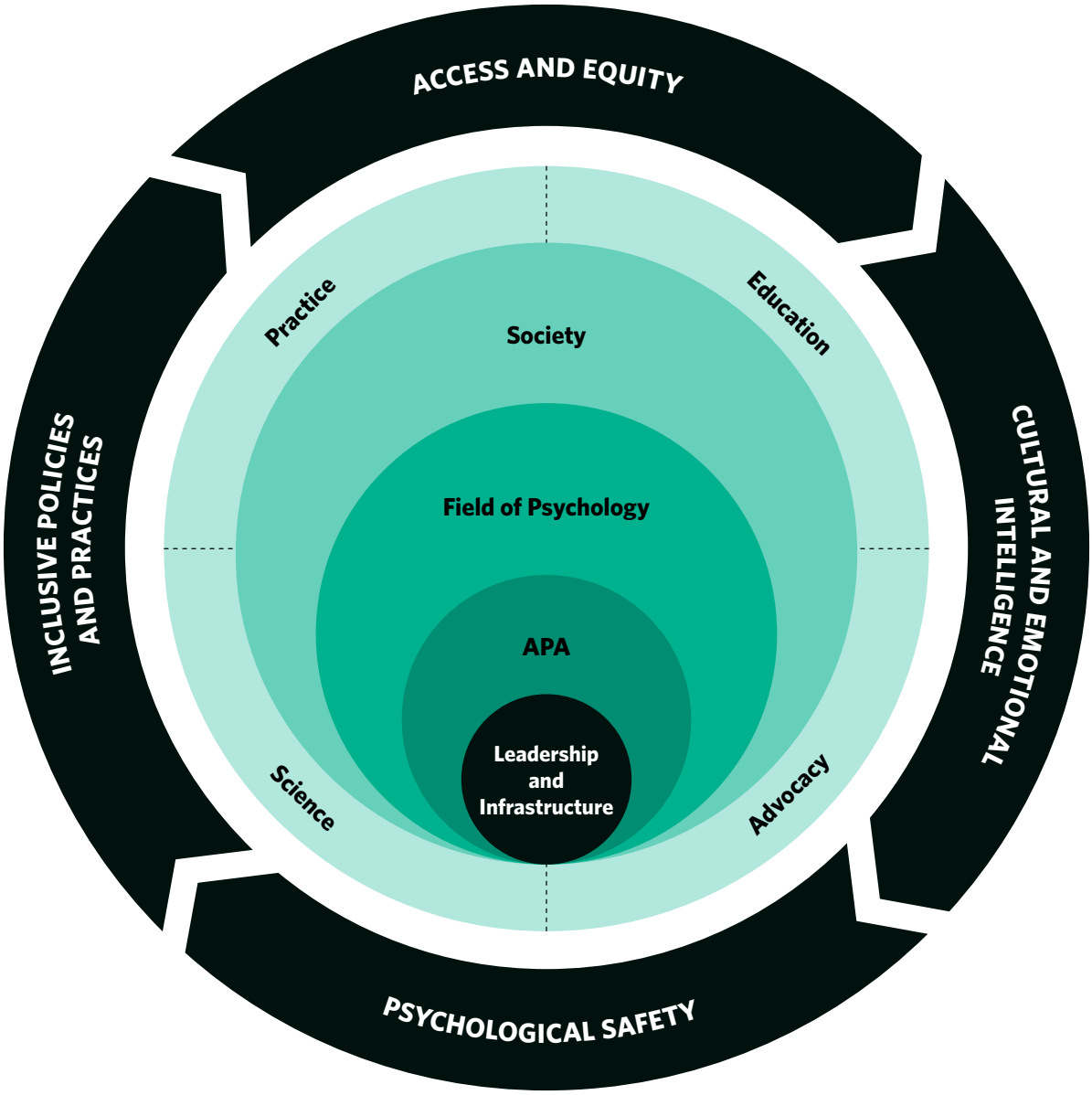

TABLE 1.

Levels and Domains of the APA Equity, Diversity, and Inclusion (EDI) Model

Levels	Domains	Definitions
APA		Internally focused EDI work aimed at building the capacity of the organization itself. Work in this area addresses staff, volunteer leaders, and members, with the specific intention of strengthening APA and its work.
	Leadership and Infrastructure	Maintenance, further creation, and implementation within APA of structures (e.g., offices, committees), job positions, policies, procedures, and practices that support leadership for EDI and build and support an infrastructure for EDI influence.
	Psychological Safety	A psychologically safe environment within APA—among the staff, members, and volunteers; in governance groups, boards, and committees, and divisions; and at all gatherings (in person or virtual), such as conventions and meetings, that foster the full inclusion and safe engagement of people of all social identities and social identity intersections, prioritizing those who are societally marginalized and/or underrepresented.
	Inclusive Policies and Practices	Maintenance, further creation, and implementation of inclusive policies, procedures, and practices within the organization.
	Cultural and Emotional Intelligence	Education and training of APA volunteer leaders, members, and staff to enhance their knowledge, skills, and capability to adapt in diverse environments with confidence, and to make informed judgements based on observations and evidence as opposed to stereotypes and biases. Focuses on centering the values, beliefs, and attitudes of people from different cultures, while responding with informed empathy and real understanding.
	Access and Equity	APA will continue promoting diversity, social justice, and equity in the organization. The organization prioritizes its commitment to fostering the engagement and participation in APA of marginalized groups and groups that have been historically underrepresented in our society.
Field		APA's work to contribute to a more diverse, equitable, and inclusive field of psychology, including initiatives that impact pathways into the field; the education and training of undergraduate and graduate students, trainees, interns, postdocs, and psychologists; and policies and practices for the discipline. Focuses on the work that APA does to build the capacity of the discipline and its personnel. Initiatives in the field of psychology are expected to have a capacity-building impact now and in the future.
	Access and Equity	Compositional diversity, social justice, and equitable outcomes for students, trainees, postdocs, and psychologists at all levels in the field of psychology. Focus on representation, fair treatment, access, opportunity, and advancement for those who are societally marginalized and historically underrepresented in the field of psychology—eliminating structural barriers and scientific practices that have prevented the full participation of these groups (e.g., eliminating White supremacy in psychological science; eliminating barriers for women accessing leadership positions in psychology).
	Psychological Safety	Create and sustain psychological safety in various environments across the field of psychology— in the education and training of undergraduate and graduate students, trainees, interns, postdocs, and psychologists that fosters the full inclusion and safe engagement of all, especially those from marginalized social identities and social identity intersections.
	Inclusive Policies and Practices	Maintenance, further creation, and implementation of inclusive policies, procedures, and practices in the discipline and profession of psychology.
	Cultural and Emotional Intelligence	Education and training, including faculty/supervisor development, that addresses cross-cultural and diversity issues across the range of topics, curricula, and training/degree programs in the field of psychology, implemented with cultural and emotional intelligence.

Levels and Domains of the APA Equity, Diversity, and Inclusion (EDI) Model

Levels	Domains	Definitions
Society		Where APA's mission to advance psychological science and knowledge to benefit society and improve people's lives is realized—in the United States and globally. The level of programs and activities that are externally focused—beyond the association and the field of psychology—and have a direct impact on, or advocate directly for, clients, consultees, organizations, communities, and the public, with a particular focus on reaching those who are societally marginalized. EDI will be integrated into all areas of psychological practice.
	Advocacy	Efforts to advocate and affect change on issues related to the well-being and psychological health of diverse (and particularly societally marginalized) communities, including access to and provision of inclusive and equitable psychological services and the use of psychological science to advocate for the dismantling of systemic oppression that creates and perpetuates health disparities. Advocacy work through the inclusion of marginalized voices in research, policies, and legislation in the courts, in government, in intergovernmental organizations, and in media.
	Education	Investment in development and evolution of psychological information and educational resources, while centering the voices of those who are societally marginalized to appropriately enhance the public's capacity to inform and apply psychological knowledge to enhance individual and community well-being.
	Practice	Psychological practice, including clinical, counseling, school, community, consulting, organizational, and other professional services, as well as organizational leadership by psychologists—all aimed at improving the well-being and psychological health of individuals, organizations, and/or communities, particularly those who are societally marginalized.
	Science	Development, implementation, and dissemination of equitable psychological science, while centering the voices of those who are societally marginalized with the aim of a process and outcome that has a positive and equitable impact on the well-being and psychological health of individuals and communities, particularly those who are societally marginalized.

GLOSSARY OF TERMS

Ableism
Stereotyping, prejudicial attitudes, discriminatory behavior, and social oppression toward people with disabilities in order to inhibit the rights and well-being of people with disabilities, which is currently the largest minority group in the United States.

Access
The elimination of discrimination and other barriers that contribute to inequitable opportunities to join and be a part of a work group, organization, or community.

Bias
APA defines bias as partiality: an inclination or predisposition for or against something. Motivational and cognitive biases are two main categories studied in decision-making analysis. Motivational biases are conclusions drawn due to self-interest, social pressures, or organization-based needs, whereas cognitive biases are judgements that go against what is considered rational, and some of these are attributed to implicit reasoning.

Climate
The degree to which community members feel included or excluded in the work group, organization, or community.

Discrimination
The differential treatment of the members of different gender, racial, ethnic, religious, national, or other groups. Discrimination is usually the behavioral manifestation of prejudice and therefore involves negative, hostile, and injurious treatment of the members of rejected groups.

Diverse
Involving the representation or composition of various social identity groups in a work group, organization, or community. The focus is on social identities that correspond to societal differences in power and privilege, and thus to the marginalization of some groups based on specific attributes—e.g., race, ethnicity, culture, gender, gender identity and expression, sexual orientation, socioeconomic status, religion, spirituality, disability, age, national origin, immigration status, and language. (Other identities may also be considered where there is evidence of disparities in power and privilege.) There is a recognition that people have multiple identities and that social identities are intersectional and have different salience and impact in different contexts.

Equity
Providing resources according to the need to help diverse populations achieve their highest state of health and other functioning. Equity is an ongoing process of assessing needs, correcting historical inequities, and creating conditions for optimal outcomes by members of all social identity groups.

Gender
The socially constructed ideas about behavior, actions, and roles a particular sex performs.

Human rights
Defined by the United Nations as "universal legal rights that protect individuals and groups from those behaviors that interfere with freedom and human dignity."

Inclusion
An environment that offers affirmation, celebration, and appreciation of different approaches, styles, perspectives, and experiences, thus allowing all individuals to bring in their whole selves (and all of their identities) and to demonstrate their strengths and capacity.

Intersectionality
The ways in which forms of oppression (e.g., racism, sexism, homophobia, transphobia, ableism, xenophobia, classism, etc.) are interconnected and cannot be examined separately from one another.

Oppression
Occurs when one group has more access to power and privilege than another group, and when that power and privilege is used to maintain the status quo (i.e., domination of one group over another). Thus, oppression is both a state and a process, with the state of oppression being unequal group access to power and privilege, and the process of oppression being the ways in which inequality between groups is maintained.

Pathway programs
Programs (e.g., in secondary schools and colleges) that foster increased access by underrepresented groups to education, training, or a profession.

Prejudice
A negative attitude toward another person or group formed in advance of any experience with that person or group. Prejudices include an affective component (emotions that range from mild nervousness to hatred), a cognitive component (assumptions and beliefs about groups, including stereotypes), and a behavioral component (negative behaviors, including discrimination and violence). They tend to be resistant to change because they distort the prejudiced individual's perception of information pertaining to the group. For example, prejudice based on racial grouping is racism; prejudice based on perceived sex, or perceived gender is sexism; prejudice based on chronological age is ageism; and prejudice based on disability is ableism.

Race and Ethnicity
Race and ethnicity are social constructions that powerfully shape social identity, but also influence our interactions, how we view others, and our social arrangements. According to APA's Racial & Ethnic Guidelines (2019), **race** is defined as the social construction and categorization of people based on perceived shared physical traits that result in the maintenance of a sociopolitical hierarchy. The guidelines also define **ethnicity** as a characterization of people based on having a shared culture (e.g., language, food, music, dress, values, and beliefs) related to common ancestry and shared history.

Racism
Behavior, both individual and institutional, that is based on the belief in the superiority of one group of people and the inferiority of another because of national and ethnic origins.

Sexual orientation
A multidimensional aspect of human experience, comprised of gendered patterns in attraction and behavior, identity related to these patterns, and associated experiences, such as fantasy.

Social justice
Commitment to creating fairness and equity in resources, rights, and treatment of marginalized individuals and groups of people who do not share equal power in society.

Structural racism
Results from laws, policies, and practices that produce cumulative, durable, and race-based inequalities, and includes the failure to correct previous laws and practices that were explicitly racist.

White privilege
Unearned power that is afforded to White people on the basis of status rather than earned merit and protects White people from the consequences of being racist and benefitting from systemic racism; such power may come in the form of rights, benefits, social comforts, opportunities, or the ability to define what is normative or valued.

White supremacy
The ideological belief that biological and cultural Whiteness is superior, as well as normal and healthy—is a pervasive ideology that continues to polarize our nation and undergird racism.

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A Simple Model for Learning Improvement: Weigh Pig, Feed Pig, Weigh Pig

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Abstract

Assessing learning does not by itself result in increased student accomplishment, much like a pig never fattened up because it was weighed. Indeed, recent research shows that while institutions are more regularly engaging in assessment, they have little to show in the way of stronger student performance. This paper clarifies how assessment results are related to improved learning – assess, effectively intervene, re-assess – and contrasts this process with mere changes in assessment methodology and changes to pedagogy and curriculum. It also explores why demonstrating improvement has proven difficult for higher education. We propose a solution whereby faculty, upper administration, pedagogy/curriculum experts, and assessment specialists collaborate to enhance student learning.

A Simple Model for Learning Improvement: Weigh Pig, Feed Pig, Weigh Pig

Keston H. Fulcher, Megan R. Good, Chris M. Coleman, and Kristen L. Smith

A pig never fattened up only because it was weighed. A racehorse never ran faster because a stopwatch was clicked. A fevered dog's temperature never dropped as a result of reading a thermometer. Brown and Knight (1994) made this point twenty years ago. Nevertheless, some infer that student learning will automatically improve as a result of assessment. Indeed, test vendors often convince administrators that new instruments X and Y will bring about student learning. Such tools have not, do not, and will not by themselves improve learning.

A more refined version of this perspective is that faculty members and administrators will understand their programs better through assessment and, in turn, they will make policy or programmatic decisions that positively impact student learning. Unfortunately, recent findings suggest that regardless of the assumed process, little action is generally taken on results (Blaich & Wise, 2011). In other words, the promise of assessment is not realized. Often, emphasis is placed on assessment *mechanics* rather than effective pedagogy and curricula. Assessment, pedagogy, and curriculum are not mutually exclusive. In fact, they should work hand in hand, yet most institutions have yet to intentionally connect them effectively. For these reasons Hersh and Keeling (2013) argued that higher education should strive for a culture of learning rather than a culture of assessment. In this vein, we propose integrating the three pillars of learning– assessment, pedagogy, and curriculum– at the program level with the aim of evidencing learning improvement.

Often, emphasis is placed on assessment mechanics rather than effective pedagogy and curricula.

First, to put our observations in context, we clarify different interpretations of "using assessment results" and discuss a model for conceptualizing learning improvement. We then examine why higher education currently falls short of evidencing learning improvement.

The phrase, *use of results* is often used, but it is not always clear what use means. For example, some people interpret use of results as (a) changes to assessment mechanics (such as better sampling), while others cite (b) changes made to a program (e.g., curricular or pedagogical modification). In this paper, we define use of results as (c) making a change to a program *and then* re-assessing to determine that the change positively influenced student learning. The latter definition is consistent with how Banta and Blaich (2011) define "closing the loop." Many faculty and staff in higher education, as well as assessment professionals, confuse (a) and (b) with (c). They make statements like, "We made x, y, and z *improvements* to the program." But they really mean that they made x, y, and z *changes*. A change is only an improvement when one can demonstrate its positive effect on student learning.

For this article, we define assessment as everything typically encompassed in the process – defining learning outcomes, mapping them to the curriculum, selecting an instrument, collecting data, analyzing results, reporting results, and communicating with stakeholders – *with the exception* of using results for improvement. The purpose of doing so is to separate the assessment mechanics from use of results for improvement (i.e., faculty- or staff-driven changes to programming/curricula that are re-assessed and then deemed improvements).

PLAIR is the Program Learning Assessment, Intervention, and Re-assessment model.

Learning Improvement: The Simple Model

In a nutshell, the simplest model[1] for *evidencing* improvement is: assess, intervene, re-assess. Or: weigh pig, feed pig, weigh pig; henceforth referred to as Program Learning Assessment, Intervention, and Re-assessment (PLAIR). Improved learning is demonstrated when a re-assessment suggests greater learning proficiency than did the initial assessment.

Although the model sounds simple, evidence of using results in this way is surprisingly rare. Banta, Jones, and Black (2009) reviewed almost 150 profiles of good assessments in higher education. They found that only 6% could demonstrate improved learning. Even more sobering, one would assume that this modest percentage would be far lower in a random sample of academic programs. Regarding the Wabash study, where universities were provided with ample assessment resources, Kuh (2011) observed that few schools showed how they intentionally changed their policy or practice based on assessment information. He further stated, "Rarer still were colleges or universities where changes in policies or practices made a positive difference in student attainment" (p. 4). In this context, Kuh's use of "attainment" refers to improved student learning outcomes as captured by the Collegiate Learning Assessment.

Why Learning Improvement is Rare

Our institution, James Madison University, has a rich history of high quality student learning outcomes assessment. We have some examples of evidenced learning improvement, but far fewer than we would like. We have read assessment reports or heard stories that encompass almost all combinations of assess, intervene, and re-assess where one or more of the critical three components is missing. We illustrate such basic breakdowns of PLAIR through hypothetical examples where programs attempt to improve students' writing. We follow these examples with more nuanced ways in which the model can fail. While the examples are based on a skill – writing - the PLAIR is equally applicable to other kinds of outcomes such as knowledge or dispositions, and could be implemented in academic programs or student affairs units.

[1] As a technical aside, this simple model can be operationalized as a pseudo-longitudinal design where, for example, seniors are assessed and then, after the program has made substantial changes, a later cohort of seniors is assessed. In this case, a Cohen's d would suggest the difference in proficiency between the two cohorts. If the latter cohort performs better than the former, then the model was executed successfully. The model could also be implemented as a comparison of growth (i.e., pre-post results) between two different cohorts with one receiving the new intervention. In this case, two effect sizes (Cohen's d) are computed: one for the growth of each cohort. If the effect size for the second group is larger than the first then the model has been successfully implemented.

Basic Breakdowns in the Model

~~*Assess*~~*, intervene, re-assess.* Program A's faculty are not satisfied with students' writing proficiency. To address this issue, the faculty met numerous times. From these meetings, several initiatives were launched. A course in writing was added. Students wrote more papers in existing classes too. After students went through this new curriculum, the program implemented a program-level writing assessment rubric. They found that students on average met their expectations around writing.

This story sounds like a good one. The problem is that Program A would have difficulty demonstrating that this new curriculum was more effective at fostering student learning in relation to writing than the previous one because no pre-assessment was implemented. Back to the pig example, the pig was fed and then weighed. It is unknown how much weight the pig actually gained, if any.

Assess, ~~*intervene,*~~ *re-assess.* Program B's faculty were dissatisfied with students' writing. Year after year they implemented a robust writing assessment. And, every year, the results suggested the same problem: students were graduating with sub-standard writing skills. Nevertheless, no systematic change in curriculum or pedagogy was made. Some faculty tweaked their individual sections but did not coordinate with other faculty.

In this scenario, despite good methodology, learning improvement was not evidenced because no coordinated intervention was implemented. The pig was weighed and then weighed again. However, no weight gain was evidenced because the pig was not fed.

Assess, intervene, ~~*re-assess*~~. Program C assessed their students' writing and were not pleased. In response they required additional papers through their curriculum. Also, the department head paid for several in-service workshops where faculty learned from writing experts how to provide better feedback to students. Unfortunately, before the first affected student cohort received the full intervention, the assessment coordinator took a job at a different university. Unfortunately, the program did not assess subsequent cohorts.

Given that no follow-up assessment was conducted after the intervention was implemented, the efficacy of the new curriculum and better trained faculty was unknown. The pig was weighed and then fed. Unfortunately, the pig was not weighed after the feeding, thus obfuscating legitimate claims about weight gain.

Although none of these programs successfully implemented the PLAIR, some benefits accrued nonetheless. For Programs A and C, it is quite possible that students wrote better because of the programmatic changes. Indeed, the faculty could relay anecdotes of student success. Unfortunately, they could not demonstrate persuasively this improvement to an external audience. For Program B, some individual sections may have improved, which is good for individual faculty and some students, but at the program level the needle did not move. The point is that, to evidence writing improvement at the program level, the pedagogical or curricular intervention must be implemented consistently in all pertinent sections and the assessment must be administered before and after.

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Nuanced Breakdowns in the Model

In addition to the aforementioned basic process breakdowns, more nuanced problems can undermine the model. In the methodology context, sampling may be unrepresentative, instruments unproven, students unmotivated, incorrect analyses performed, etc. In other words, the data may not accurately reflect the targeted student learning.

From the intervention perspective, problems arise as well. Two notable ones include lack of alignment and lack of successful implementation. For some programs, there is little alignment or mapping between curricular/co-curricular activities and outcomes. Basically, students engage in activities but there is no clear plan about how these activities relate to program-level outcomes.

Even if the program has clear student learning outcomes and a logical curriculum to engender them, students still may not improve on those program-level outcomes for any number of reasons. Perhaps the program-level curriculum map – while looking good on paper – has little in common with what is actually taught by faculty across several sections; perhaps the pedagogical techniques used in courses don't effectively help students learn the desired skills.[2]

Acknowledging many of the same shortcomings, Banta and Blaich (2011) suggested that colleges evaluate their assessments to ascertain how such processes can help programs reach their aims. We have conducted such meta-assessment at our institution (Fulcher & Bashkov, 2012). We found that, in general, the *quality* of programs' assessment – in terms of methodology and communication – has improved dramatically. Unfortunately, evidence of improved learning has not increased proportionally. Referencing the earlier scenarios, we feel it is the Program B example that is most common to our institution: assessment but no difference in intervention. Most programs are caught in a yearly ritual of weighing the pig without feeding it more in the time in between.

Banta and Blaich (2011) offered their take on why learning improvement is rare: "…the current state of affairs at almost every institution is based on a delicate set of compromises and optimizations in which many parties have participated and which few care to alter" (p. 27). While we agree with Banta and Blaich that many programs are unable to evidence improved learning due to a variety of issues, including campus cultures that privilege the status quo, we propose an additional hypothesis: Faculty and student affairs practitioners are not well trained in *how to improve learning*, particularly at the *program level*. Note the emphasis on program. In conversations we have had with faculty and staff, a common theme is that many if not most educators make adjustments to their pedagogy or curricula. Unfortunately, these changes are rarely implemented at a program level.

On this topic, former Harvard President Derek Bok (2013) roundly criticized graduate schools for their lack of teaching preparation. Indeed, relative to research, master's and doctoral students receive far less training in teaching

In conversations we have had with faculty and staff, a common theme is that many if not most educators make adjustments to their pedagogy or curricula. Unfortunately, these changes are rarely implemented at a program level.

[2] For those who wish to read more about these issues, we recommend Gerstner and Finney (2013) as a primer on implementation fidelity.

during their graduate programs. In fact, it seems that conversations about teaching are taboo compared to frequent conversations about scholarship. Even if a faculty member adopts an evidence-based pedagogy, that lone faculty member will not bring about *programmatic changes*. Programs are made up of teams of faculty, and everyone must be on board (a challenge within itself) to generate meaningful changes.

In sum, a program must overcome many obstacles to evidence learning improvement. A program that overlooks any part of *assess, intervene, re-assess* will de facto be unable to evidence improvement. Even if the PLAIR model is adopted, there is no guarantee that the program will be able to tell a story about learning improvement. Breakdowns in assessment methodology and/or intervention can thwart the best intentions. With those obstacles in mind, the next section opens with a realization that drew our attention to program learning improvement. It then provides our current thoughts regarding how a university could truly close the loop and demonstrate improved learning at the program level.

A program that overlooks any part of assess, intervene, re-assess will de facto be unable to evidence improvement.

Structuring a University for Learning Improvement: Our "Aha" Moment

We had an epiphany recently at our institution. When programs needed help with assessment, the Center for Assessment and Research Studies provided state-of-the-art consultation. Challenged and strongly supported by the administration, faculty put forth great effort with assessment mechanics. They worked together to articulate program learning outcomes; curriculum maps identified where students theoretically learned these skills; instruments were specifically developed to map to the program outcomes; data were collected at the program level; clear reports were written. In other words, the assessment "gears" were in place and effectively spinning at the program level. Missing in the assessment consultation, however, was guidance on how a program could use results to improve student learning. Our assessment consultants had little training in this area, and thus faculty received little support. Perhaps not surprisingly, the "use of results" section in assessment reports most typically featured changes to assessment mechanics and an occasional programmatic change. Rarely did we see improvement to student learning a la the PLAIR model.

On the other side of campus – literally and figuratively – the faculty development office was helping individual faculty develop better classes and providing support for best practices in pedagogy, course design, and alignment at the course-section level. Unfortunately, up to that point, the assessment office and the faculty development office coordinated in only nominal ways. Further, the assessment office provided methodological assistance at the program level, whereas the faculty development office provided help at the individual section level. In other words, there were two problems: the offices were not collaborating, and they were helping faculty at different levels (program vs. section). When these two offices began to talk, however, a synergistic solution seemed obvious. Properly coordinated, with support from administration, these units could help faculty create a system whereby effective interventions could be implemented and assessed *at the program level.*

While focusing on interventions was a revelation to us, we discovered others had arrived at similar conclusions. Blaich and Wise (2011) realized that the first iteration of the Wabash Study "…focused too much on gathering, analyzing, and reporting assessment evidence and not enough on helping institutions use it" (p. 11). Banta and Blaich (2011) further explored the issue of underuse of results. One of their finest suggestions was that institutions should "…spend more time and money on using data than on gathering it" (p. 26).

More specific to combining assessment and faculty development, Hutchings (2011) suggested that a faculty development office facilitate conversations with faculty and assessment practitioners. She hypothesized that jointly these groups could think about assessment and interventions as the scholarship of teaching and learning. Doing so would lead to a deeper engagement of faculty and affect, for the better, an institution's culture toward improving student learning. Baker et al. (2012) conducted a series of case studies focused on institutions that use assessment results well. Juniata College stands out in particular. As Hutchings imagined, this institution established a scholarship of teaching and learning center, which has helped align interests among faculty, learning, and assessment.

At James Madison University we are in the process of coordinating the work of the assessment unit with the faculty development unit within a larger university strategy. The main goal is to facilitate faculty- and staff-driven improvement efforts with synchronized assessment and intervention consultation. Although still in the planning stages, the logic underlying the PLAIR is worth sharing. While several authors (e.g., Baker, Jankowski, Provezis, & Kinzie, 2012; Blaich & Wise, 2011; Hersh & Keeling, 2013) have provided excellent suggestions about how assessment could be more useful, we believe our model is the most concrete regarding how to do so. Specifically, the PLAIR is a two-part process that breaks down into smaller steps: readiness and implementation. In this context, *readiness* refers to the degree to which the university environment is primed for program-level improvement to occur. *Implementation* refers to the strategic steps a program takes to evidence learning improvement.

The PLAIR is a two-part process that breaks down into smaller steps: readiness and implementation.

PLAIR Part 1: Readiness for Evidenced Learning Improvement

The readiness nucleus comprises a team of student learning advocates (e.g., faculty or student affairs staff) representing a particular program. They seek a more effective learning environment for students and are content experts in their respective areas. The group must be willing to work together, conceptually and pragmatically. While we acknowledge that Banta and Blaich (2011) are on target – many programs are content with status quo – every university or college is likely to have at least a few programs with a disposition for improvement.

A key facilitating condition is a campus administration that encourages and praises improvement. In a sense, while program faculty tackle the effort from the bottom up, the administration can meet them in the middle in a

couple of ways: (1) endorse the PLAIR – assess, intervene, re-assess – as the university standard for learning improvement and communicate it to faculty, administration, and other stakeholders; (2) provide resources to faculty and staff to help them prepare for and implement the PLAIR. This support could include access to assessment expertise, pedagogy and curriculum expertise, dedicated time/space to work through the various PLAIR components, as well as program-specific support like course releases or funding over the summer.

Another part of readiness is sound assessment methodology. As illustrated in the *assess, intervene, re-assess* example, programs that roll out a learning intervention but lack a "pre-assessment" will be unable to tell a compelling improvement story. On the other hand, programs that have clearly articulated outcomes and a quality methodology to evaluate them are well positioned to progress to interventions. Because there are technical aspects to assessment methodology, consultation with assessment experts can help programs with the readiness component.

A key facilitating condition is a campus administration that encourages and praises improvement.

PLAIR Part 2: Plan an Intervention

If the program faculty and the university are "ready," then the next part of the learning improvement process is to strategically plan an intervention. We suggest the following steps:

1. Identify Targeted Objective(s). What area of learning does your program endeavor to improve, and what is your rationale for making the change?

A) Include the specific learning objective(s) that will be targeted.

B) Indicate why each objective is important for your program/field, linking it with long-term benefits related to graduate school, job preparedness, civic engagement, etc.

C) Reference assessment results that suggest this area needs improvement. The results MUST include direct measures of student learning. Programs are also encouraged to reference indirect measures (e.g., self-report surveys), disciplinary trends, or program review recommendations.

2. Investigate Current Efforts. What is your program currently doing to help students attain these learning objectives? What are your hypotheses about why this approach is not as effective as it could be? (Note: Please do not mention particular faculty members' names. This process is NOT about singling out particular instructors.)

A) Include the curriculum map showing where the objectives are theoretically addressed.

B) Is the curriculum map accurate? Are those objectives truly covered in the classes/activities?

C) If so, is it simply that insufficient time is spent on the area?

D) If not, is there a breakdown in communication or coordination across sections?

3. Propose Learning Modifications. Based on what was discovered in step 2, what interventions (i.e., curricular or pedagogical changes) does the program intend to make to enhance the learning environment with regard to the targeted learning objective(s)?

4. Lay Out Improvement Timetable. Provide a specific timeline showing when the changes will be implemented in the curriculum and when they will be assessed. From this plan, a reader should be able to ascertain (A) when the pre-assessment will be implemented, (B) the intervention "dosage" across cohorts, and (C) when the post-assessment will be administered to gauge the full effect of the modified curriculum/programming.

What is your program currently doing to help students attain program learning outcomes?

To illustrate these steps, we provide a hypothetical example in which an academic degree program takes action to improve students' oral communication skills. The example is adopted from an online help package provided to faculty at James Madison University.

1. Identify Targeted Objective(s). For the 80s pop culture program (B. A.), we endeavor to improve students' oral communication skills. While students are performing well on most program-level objectives, they have struggled with oral communication.

A. These skills are articulated via the fourth program objective.

"Students graduating from the BA program in 80s pop culture will (A) deliver effectively a presentation with an (B) engaging introduction, (C) a logical and fluid body, (D) a conclusion that reinforces the main ideas of the presentation and closes smoothly."

B. Why are these skills important? According to our alumni survey results, our students often pursue marketing jobs where presentation skills are critical. Additionally, the *Journal of Pop Culture Education* cited oral communication as the third most important skill for graduate students in the field.

C. According to work samples rated using our Oral Communication Rubric, for the last several years seniors' skills have fallen below faculty standards in three of the four sub-areas (delivery skills, introduction, and conclusion). Additionally, among all program objectives, students self-report that their lowest gains are in oral communication. See table 1 for a summary of these results.

Scale or Subscale	Corresponding Objective(s)	2011 Results Mean	2012 Results Mean	*2013 Results Mean (sd)	Desired Results 2013	**2013 Different from 2012?
Oral Communication Rubric (n=25): 1 = unsatisfactory, 2 = emerging, 3 = competent, 4 = highly competent						
Delivery Skills	4	2.8	2.5	2.6(.42)	3	No
Introduction	4	2.7	2.9	2.8(.55)	3	No
Body	4	3.1	2.9	3.0(.38)	3	No
Conclusion	4	2.9	2.7	2.7(.49)	3	No
Graduation Survey (n = 91): 1 = no gain, 2 = small gain, 3 = moderate gain, 4 = large gain, 5 = tremendous gain						
Oral Comm	4	2.7	2.6	2.6(.8)	3	No

Table 1. Oral Communication Senior Assessment Results of Three Cohorts.

* Green color coding represents the degree to which the observed results were better than the desired results (the darker green, the better). Red coding indicates the degree to which results were worse than desired.

** Based on independent t-tests, using $p < .01$ as signifance level (lower alpha due to multiple comparisons).

2. Investigate Current Efforts. We have included the curriculum map (see Table 2) showing where and how intensively our program objective are theoretically addressed.

Course/Learning Experiences	Obj 1 (Identification of 80s Components)	Obj 2 (Research Methodology)	Obj 3 (Writing Critically)	Obj 4 (Oral Comm)
PCUL201(Introduction to the 80s)	3	0	1	0
PCUL301 (80s Music)	3	0	1	2
PCUL302 (80s Fads)	3	0	1	0
PCUL303 (80s TV and Movies)	3	0	0	2
PCUL304 (80s Technology)	3	1	1	0
PCUL361 (Methods and Analysis)	0	3	1	0
PCUL401 (80s Politics and Culture)	1	1	3	0
PCUL402 (Profiles of 80s Icons)	1	0	1	3
PCUL403 (The Music Video)	2	0	0	0
PCUL404 (The 80s and Today)	0	2	3	0
PCUL480 (Capstone)	0	2	2	2

Table 2. Curriculum Map of Pop Culture Program (Oral Communication is Objective 4).

Coverage of objective: 0 = No Coverage, 1 = Slight Coverage, 2 = Moderate Coverage, 3 = Major Coverage

According to the curriculum map, four courses address oral communication: three with moderate coverage, and one with major coverage. On paper, it would seem students have ample opportunity to learn these skills.

Nevertheless, the assessment evidence clearly indicates that students are not as proficient as the program faculty expect. To dig deeper, the six faculty members teaching these courses met with the program coordinator three times in the month of March to investigate, as a program, why students were falling short. What follows is a summary of these discussions:

- Indeed, students did present orally in all of the aforementioned courses.

- However, how these oral communication experiences were implemented varied greatly by course and instructor. More often than not, the emphasis both in preparation and in grading was more heavily weighted toward the content of the course rather than oral communication skills per se. One professor characterized this trend as follows:

  *If the presentation was reasonably accurate, the student would receive an *A* despite lackluster oral communication skills. I would make comments on the feedback sheet like, 'seemed a bit nervous and spoke too quickly…' but that was about it. On the other hand, I would provide much more specific feedback regarding the accuracy of content. Nevertheless, the presentation quality was far, far away from what would be considered professional or polished.*

- Although we use the program-level oral communication rubric for the capstone class, professors teaching other courses were unaware of its existence. Many said that the rubric would have been helpful in providing feedback to students in their classes.

- Several of the faculty, while acknowledging the importance of oral communication skills, revealed that they did not feel comfortable providing feedback in that area. Indeed, they had received little or no training regarding how to do so effectively.

3. Propose Learning Modifications. This plan has been discussed and supported by all six faculty who teach program courses with an oral communication component. Note that ALL four of those courses will be affected to some degree; however, the biggest interventions will be in PCUL301 (80s Music) and PCUL480 (capstone). What follows is a short description of each intervention.

(1) Intervention 1. *Clarify Expectations Early.* One of the first required courses in the major is PCUL301 (80s Music). In this class, students present on their final project at the end of the semester. The three faculty who teach 301 will explain both the importance of oral communication and the expectations of program faculty. They will communicate that this has, in general, been an area of weakness for graduates; furthermore, employers and graduate schools desire students to have competency with such skills. To ensure mastery, both faculty and students will need to

On paper, it would seem students have ample opportunity to learn these skills, but the faculty dig deeper to investigate, as a program.

work hard. Students will watch videos of the three best senior capstone presentations from the previous year. Faculty will then describe to their students how each of these presentations would be evaluated on the oral communication rubric.

(2) Intervention 2: *Align Class-Level Assessments, Using Program-Level Oral Communication Rubric.* Presentations will be evaluated on content (70% of the task grade) but also specifically on oral communication (30%). Each faculty member will use the oral communication rubric for that 30% of the grade.

(3) Intervention 3. *Emphasize Practice.* In all classes with an oral communication component, faculty will urge students to practice their presentations at least four times before the in-class performance. Students will be encouraged to work with their classmates to receive feedback using the rubric and to tape and review their practice efforts.

(4) Intervention 4. *Increase the Rigor of Capstone Presentations.* For the capstone, the ante will be raised. The final oral presentation will be open to all program faculty and to all majors; it will also be recorded. The three capstone professors will emphasize to students that this presentation will demonstrate not only what students have learned in the program, but also how well prepared they are for jobs or graduate school.

Special Note: While not an intervention that directly impacts students, faculty will spend three days of in-service training prior to the first week of classes in Fall 2014. There they will discuss how to encourage students to practice before presentations and how to use the oral communication rubric consistently across courses. The faculty development office will help facilitate this training module.

To ensure mastery, both faculty and students will need to work hard.

4. Lay Out Improvement Timetable. To coordinate the interventions with assessment, we created an improvement timetable (see Table 3). Because the interventions affect several courses that span students' juniors and senior years, the total effect will not be realized for several years. We will collect data each year, which corresponds to differing levels of intervention. In Year 0 we collect data on seniors (Class of 14') who have not experienced any new intervention. In Year 1, we collect data on students (Class of 15') who will receive partial intervention: only senior-level courses are enhanced for this group (PCUL 402 and 480). In Year 3, we collect assessment data on seniors (Class of 16') who will receive oral-communication-enhanced classes as juniors and seniors (301, 303, 402, and 480). We hope to find that oral communication scores move higher every year, consistent with the amount of intervention each successive cohort will receive.

The improvement table reminds the reader that once the intervention is implemented, it is necessary to re-assess. Assuming the intervention plan is effective, the last step is to celebrate. Everyone on campus should hear about this story. The program is featured prominently on the university website. The president mentions the faculty in his yearly opening speech. The faculty

Table 3

Learning Intervention and Assessment Sequencing for Oral Communication in Pop Culture Program

	Year 0		Year 1		Year 2		Year 3	
Class	**2013-2014**		**2014-2015**		**2015-2016**		**2016-2017**	
	Fall	**Spring (Baseline)**	Fall	Spring	Fall	Spring	Fall	Spring
PCUL301 (80s Music)			1,2,3		1,2,3		1,2,3	
PCUL303 (80s TV and Movies)				2,3		2,3		2,3
PCUL402 (Profiles of 80s Icons)			2,3		2,3,		2,3	
PCUL480 (Capstone)		**Assessment, Pre-intervention**		2,3,4 Assessment here captures partial intervention		2,3,4 Assessment here captures full intervention		2,3,4 Assessment here captures full intervention plus any additional tweaks
Comments: PCUL301 and PCUL402 offered only in fall. PCUL303 and PCUL480 offered only in spring.	This year serves as a baseline. The capstone oral communication assessment serves as the pre- assessment (i.e., before intervention.)		Class of 2015 has received part of intervention battery. Note that faculty participate in oral communication inservice the week before fall classes.		Class of 2016 has received all of intervention battery. (They were juniors in 2014-2015.) Assessment captures full intervention.		Class of 2017 has received all of intervention battery and may benefit from faculty tweaks to process.	

1 = ***Early and Clear Expectations***
2 = ***Aligned Class-Level Assessments, Using Program-Level Oral communication Rubric***
3 = ***Emphasis on Practice***
4 = ***Higher-Stakes Capstone Presentations***

publish an article about their important work leading to improved student outcomes. They receive travel stipends to present in their own discipline. Upper administration communicates such stories to the Board of Visitors and the state and federal governments. Further, everyone celebrates what is most important: students learned more. They are better positioned for post-college endeavors such as graduate school and the job market.

Higher education has an obligation to continuously improve, especially regarding student learning.

Conclusion

Higher education has an obligation to continuously improve, especially regarding student learning. Unfortunately, evidence of learning improvement is virtually non-existent. While assessment certainly has a role in the improvement process, it alone is insufficient.

In this article, we provided a model of how a university might take strategic steps to facilitate learning improvement (i.e., the PLAIR). Will the process work at any institution? We hope so, but we will not immediately know its effectiveness. It takes a few years for the typical program to assess, identify an area to improve, research and create an intervention, implement that intervention, and then re-assess to determine whether learning actually improved. One thing we do know is that currently few universities can evidence even one example of improved learning. We encourage more universities to work towards evidencing improved learning and share conceptual and applied processes. Even if these efforts are not at first successful, at least academe will be focused on the right problem.

Returning to our original examples, a pig will fatten up if it eats more. A racehorse will run faster if it trains well. A dog's temperature will drop given the right medication. In a similar vein, students will learn better if provided a more coherent learning environment. Much like a scale, a stopwatch, or a thermometer, learning outcomes assessment is merely a measurement tool. In and of itself, it will not produce change; but a good assessment process can document the state of student learning at a given time and, following an intervention, quantify the extent to which learning improved. The challenge for higher education is to coordinate resources to focus on "fattening the pig."

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NILOA's primary objective is to discover and disseminate ways that academic programs and institutions can productively use assessment data internally to inform and strengthen undergraduate education, and externally to communicate with policy makers, families and other stakeholders.

NILOA Occasional Paper Series

NILOA Occasional Papers are commissioned to examine contemporary issues that will inform the academic community of the current state-of-the art of assessing learning outcomes in American higher education. The authors are asked to write for a general audience in order to provide comprehensive, accurate information about how institutions and other organizations can become more proficient at assessing and reporting student learning outcomes for the purposes of improving student learning and responsibly fulfilling expectations for transparency and accountability to policy makers and other external audiences.

Comments and questions about this paper should be sent to njankow2@illinois.edu.

About NILOA

- The National Institute for Learning Outcomes Assessment (NILOA) was established in December 2008.
- NILOA is co-located at the University of Illinois and Indiana University.
- The NILOA website contains free assessment resources and can be found at http://www.learningoutcomesassessment.org/.
- The NILOA research team has scanned institutional websites, surveyed chief academic officers, and commissioned a series of occasional papers.
- One of the co-principal NILOA investigators, George Kuh, founded the National Survey for Student Engagement (NSSE).
- The other co-principal investigator for NILOA, Stanley Ikenberry, was president of the University of Illinois from 1979 to 1995 and of the American Council of Education from 1996 to 2001.

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APA Guidelines for the Undergraduate Psychology Major

APA GUIDELINES FOR THE UNDERGRADUATE PSYCHOLOGY MAJOR

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PREFACE

The *APA Guidelines for the Undergraduate Psychology Major* (hereinafter referred to as the *Guidelines*) captures a set of optimal expectations for performance at the completion of the baccalaureate degree by students who major in psychology. The document outlines 10 goals and suggested learning outcomes that represent reasonable departmental expectations for the undergraduate psychology major across educational contexts. The goals are divided into two major categories:

- Knowledge, skills, and values consistent with the science and application of psychology
- Knowledge, skills, and values consistent with liberal arts education that are further developed in psychology

Although the *Guidelines* can aid in curriculum design, goal setting, and assessment planning, faculty are encouraged to consider local factors, such as institutional and departmental missions and student characteristics, in their application. In this spirit, broad discussion of the document can facilitate departmental leadership in designing programs distinctively suited to the institution's mission and students' needs while attending to good practice benchmarks.

EXECUTIVE SUMMARY

Why Do We Need the *APA Guidelines for the Undergraduate Psychology Major*?

For some time, there has been widespread concern about the quality of education at all levels in the United States, along with increasing pressure for accountability. Current best practices in higher education rely on setting clear expectations for student learning, aligning curricula with these expectations, assessing student attainment, and using assessment results to effect changes that promote better student learning.

It was in this context that the Board of Educational Affairs (BEA) of the American Psychological Association (APA) appointed a task force to describe a set of learning goals and outcomes for student performance at the completion of the baccalaureate degree. The *APA Guidelines for the Undergraduate Psychology Major* was developed to articulate a common set of outcomes. A baccalaureate degree in psychology should document that students have the ability to think scientifically about behavior, the skills related to the conduct of research, and the values that reflect psychology as both a science and an applied discipline.

Variations in psychology's academic organization in institutions of higher education across the country make it difficult to achieve consensus on learning goals and outcomes. In some colleges and universities, psychology is part of a school or college comprising the social sciences. In others, psychology is aligned with the natural sciences, the humanities, or education. In addition to having organizational diversity, psychology departments differ with respect to programmatic emphases, student characteristics, faculty expertise, and resources. Undergraduate programs vary—as they should—to meet local, state, and regional needs. Despite these differences, the BEA task force developed goals and outcomes that could be applied broadly across diverse educational contexts (e.g., campus-based programs, online instruction) in the context of liberal education at the undergraduate level.

The *Guidelines* captures a set of optimal expectations for student performance at the completion of the baccalaureate degree. Applying

these to individual departments, faculty must take into account local factors such as institutional and departmental missions and student characteristics. Regardless of department size and resources, the *Guidelines* presents reasonable overarching goals for the undergraduate psychology curriculum. Toward this end, these guidelines were developed to aid in curriculum design, goal setting, and assessment planning for the psychology major.

In addition to providing guidance about what constitutes a high-quality undergraduate education for majors in psychology, the *Guidelines* responds to a number of other important related needs:

- The *Guidelines* firmly establishes the major as a science and reinforces a common identity within the discipline. Promoting psychology as a science is increasingly important given the enormous breadth of the discipline and the diversity of professional opportunities and psychological perspectives, including new interdisciplinary configurations.
- The *Guidelines* describes a set of learning goals and outcomes for the psychology major. By making the expectations (outcomes) clear, the *Guidelines* serves as the basis for assessment plans.
- Development of the *Guidelines* is an important step for the discipline and a means of contributing to a growing international effort to articulate goals and outcomes for the major. Dissemination and implementation of the *Guidelines* could also generate research on effective practices in undergraduate education in psychology.
- Building on APA's earlier efforts when approving the *National Standards for the Teaching of High School Psychology* (APA, 1999) and the revised *National Standards for High School Psychology Curricula* (APA, 2005), the *Guidelines* continues APA's national focus on quality improvement. Completing expectations for appropriate education at the 4-year level adds an important piece of the overall education and training context in psychology (see Benjamin, 2001).
- The *Guidelines* provides a common set of outcomes that could aid in the development and evaluation of distance-learning courses and programs by promoting expectations for student learning comparable to those used in traditional classrooms.

Assumptions Underlying the Undergraduate Learning Outcomes

The learning goals and outcomes in this document rest on several key assumptions about the psychology major, the dynamic nature of the discipline, the diversity of psychology departments across the United States, and the assessment of performance relative to outcomes. As a framework for understanding the *Guidelines*, these assumptions are that the learning goals and outcomes

- encompass the knowledge, skills, and values that are important for students to acquire in an undergraduate major in psychology within the context of a liberal education;
- incorporate the broad theoretical and research bases of psychology;
- reflect the use of a variety of pedagogical models, including service-learning, research and laboratory experiences, online applications, and traditional classroom approaches;
- foster the development of lifelong learning skills and include competencies that will prepare students for entrance into the workforce or acceptance into graduate or professional schools upon receipt of the baccalaureate degree;
- reflect the importance of diversity and cross-cultural issues in the discipline, as well as the growing internationalization of psychology and the need to prepare psychology majors to understand behavior and experience that may transcend geographic boundaries;
- apply to psychology departments across institutional settings that contribute to student achievement at the baccalaureate level;
- reflect the views that any outcome is meaningful only to the extent that it is accurately assessed and that the outcomes assessment process will focus on student performance if it is to improve learning and teaching;
- allow for many legitimate ways to reach a learning outcome, especially given that outcomes are developmental in nature; individual psychology departments determine the performance levels appropriate for their students and the assessment procedures and tools appropriate to measuring their students' performance.

Use of the Term *Guidelines*

The term *guidelines* generally refers to pronouncements, statements, or declarations that recommend or suggest specific actions, goals, or endeavors. In this spirit, they are aspirational in intent. They are not intended to be mandatory or exhaustive and may not be applicable to every situation, nor are they intended to take precedence over the judgment of college and university faculty.

This use of the term *guidelines* is consistent with general practices in the undergraduate education community. A primary consideration related to the nature of the document is the issue of academic freedom. The American Association of University Professors (AAUP) published a seminal paper articulating the principles of academic freedom meant to ensure the fundamental advancement of truth (see AAUP, 2006). Teachers are explicitly granted the right to exercise freedom in their discussions about respective disciplinary matters. Therefore, the *Guidelines* should be used only as a broad and general framework for the undergraduate psychology major.

The term *guidelines* is also consistent with terminology used by other scientific organizations. The American Chemical Society (ACS; 2003) provides guidelines for the undergraduate major in chemistry. Although the ACS guidelines are for the purpose of accreditation, they offer only general curricular goals rather than an exact curriculum. Similarly, the American Physical Society, through the American Association of Physics Teachers (see Hilborn, Howes, & Krane, 2003), provides general guidance for the undergraduate major in their report on the status of the undergraduate major in physics.

Finally, as used in this document, the term *guidelines* is consistent with the provisions of the APA policy on *Developing and Evaluating Standards and Guidelines Related to Education and Training in Psychology* (Section I C[1]) (APA, 2004), as passed by the APA Council of Representatives.

Process of Developing the *Guidelines*

Five reports preceded the development of these guidelines, and many individuals and groups contributed to their initial development. Study of the curriculum can be traced back to the summer

of 1951 with the issuance of the Cornell Conference Report. This report emphasized psychology as a science grounded in the tradition of the liberal arts. The report merely suggested that one introductory course should be followed by intermediate core courses (e.g., statistics and perception) and finally by advanced courses (e.g., social psychology and learning). The Michigan Conference Report followed approximately 10 years later, with less consensus about the structure of the undergraduate curriculum. Similarly, the Kulik Report (in 1973) and the Schreirer and Rogers Report (in 1985) provided only descriptive information about the undergraduate major (for more information on these reports, see Brewer et al., 1993). Ultimately, at the St. Mary's Conference in 1991, Charles Brewer and his committee from the APA National Conference on Enhancing the Quality of Undergraduate Education in Psychology provided a broad structure for the undergraduate curriculum. Defining seven goals for the undergraduate major, Brewer and his colleagues suggested that the curriculum should include an introductory course, methodology courses, subfield content courses, and an integrative experience.

It was in this context, together with the movement in higher education to identify competencies as learning objectives, that the BEA appointed the Task Force on Psychology Major Competencies in 2000 to develop learning goals and outcomes for the undergraduate psychology major. Members of the task force represented a variety of institutional perspectives on the nature of the undergraduate curriculum and its aims. Under the leadership of Jane S. Halonen (chair), task force members included Drew C. Appleby, Charles L. Brewer, William Buskist, Angela R. Gillem, Diane Halpern, G. William Hill IV, Margaret A. Lloyd, Jerry L. Rudmann, and Valjean M. Whitlow. APA staff who contributed their expertise included Bernard C. Beins, now at Ithaca College, Maureen McCarthy, presently at Kennesaw State University, and Martha Boenau of the APA Education Directorate.

In the early stages of their work, the task force patterned its document after the guidelines developed by the Task Force on Outcomes for the California State University System, led by Mary Allen and Diane Halpern (past president of APA). The task force prepared a document that would serve as a resource to undergraduate psychology departments and faculty to assist with academic review processes and curriculum planning. As described in the *Undergraduate Psychology Major Learning Goals and Outcomes* (APA, 2002b), the task force identified 10

goals and suggested learning outcomes representing reasonable departmental expectations for the undergraduate psychology major across educational contexts. The goals were divided into two major categories: (a) knowledge, skills, and values consistent with the science and application of psychology and (b) knowledge, skills, and values consistent with liberal arts education that are further developed in psychology.

To extend representation to a diverse array of institutions and relevant organizations, the task force assembled an advisory panel to review drafts of the document. Through this process, the document was widely distributed to faculty at research universities, comprehensive universities, 4-year colleges, 2-year colleges, and high schools. Their comments were integrated into the *Guidelines.* The task force also sought and received helpful feedback from members of related professional organizations with interests in psychology curricula. A final version of this document was endorsed by the BEA in March 2002 and made available to the undergraduate community as a report published on the APA Education Directorate Web site (see APA, 2002b).

By July 2002, the report was disseminated broadly to APA governance groups and APA divisions, with a request for review and feedback. The *Guidelines* was also reviewed for attention to individual and cultural diversity issues consistent with the *Guidelines on Multicultural Education, Research, Practice, and Organizational Change for Psychologists* (APA, 2003); in addition, it was reviewed by the APA Committee on Ethnic Minority Affairs and the Committee on Lesbian, Gay and Bisexual Concerns. APA Boards and Committees received a final draft of the document in the spring of 2006. Subsequently, upon recommendation of the APA Board of Directors, the APA Council of Representatives adopted the *Guidelines* in August 2006.

Resource Documents

In developing the *Guidelines*, the task force reviewed the existing guidelines used by science-based disciplinary societies similar to APA, such as the American Chemical Society, the American Physical Society (APS), and the American Society for Biochemistry and Molecular Biology (ASBMB). These guidelines on the undergraduate curriculum were found to be similar in structure to the APA guidelines. For example, ASBMB (see Voet et al., 2003) explicitly stated that it was

no longer recommending a course-based curriculum. Instead, ASBMB provided content and student-outcome-focused guidance. Additional resources included use of the APA *Ethical Principles of Psychologists and Code of Conduct* (APA, 2002a) and the *Handbook for Enhancing Undergraduate Education in Psychology* (McGovern, 1993). The content contained in the *Guidelines* is consistent with APA's Ethics Code.

Feedback

The *Guidelines* is a "living document." Accordingly, APA has established a systematic plan for periodically reviewing and revising such documents to reflect developments in the discipline and in education. Reviews will occur every 7 years, which is consistent with APA Association Rule 30-8.3 requiring cyclical review of approved standards and guidelines within periods not to exceed 10 years. Comments and suggestions are welcomed.

Feedback on the *Guidelines* may be sent to:
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APA GUIDELINES FOR THE UNDERGRADUATE PSYCHOLOGY MAJOR

Structure of the *Guidelines*

The *APA Guidelines for the Undergraduate Psychology Major* provides details for 10 suggested goals and related learning outcomes for the psychology major, grouped into two major categories.

Categories of Learning Goals and Outcomes

I. Knowledge, Skills, and Values Consistent With the Science and Application of Psychology

This category represents activities that provide hallmarks of psychology education. Responsibility for development in and assessment of these areas rests primarily with the psychology faculty in coursework or psychology advising.

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

This category includes activities that are usually part of a general education program or liberal education. Responsibility for student development in these areas and assessment of students' achievements tend to be shared across a broader range of disciplines than just psychology; however, psychology coursework can contribute to and expand upon these general education goals in significant ways. In turn, well-developed liberal education skills can contribute to student achievement within the psychology major.

Learning Goals

I. Knowledge, Skills, and Values Consistent With the Science and Application of Psychology

Goal 1: Knowledge Base of Psychology
Students will demonstrate familiarity with the major concepts, theoretical perspectives, empirical findings, and historical trends in psychology.

Goal 2: Research Methods in Psychology
Students will understand and apply basic research methods in

psychology, including research design, data analysis, and interpretation.

Goal 3: Critical Thinking Skills in Psychology
Students will respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

Goal 4: Application of Psychology
Students will understand and apply psychological principles to personal, social, and organizational issues.

Goal 5: Values in Psychology
Students will be able to weigh evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a discipline.

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

Goal 6: Information and Technological Literacy
Students will demonstrate information competence and the ability to use computers and other technology for many purposes.

Goal 7: Communication Skills
Students will be able to communicate effectively in a variety of formats.

Goal 8: Sociocultural and International Awareness
Students will recognize, understand, and respect the complexity of sociocultural and international diversity.

Goal 9: Personal Development
Students will develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

Goal 10: Career Planning and Development
Students will emerge from the major with realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings.

Learning Outcomes

Each of the 10 goals includes specific, numbered outcomes that articulate suggested strategies for how the goals can be demonstrated. Each goal can be addressed in departments' curriculum designs and assessment plans; however, departments may choose formally to emphasize selected goals and outcomes depending on their emphases, traditions, or resources. Separate subpoints for particular outcomes provide further assistance in developing performance expectations.

An emphasis on certain content areas included as part of the learning goals and outcomes should not be construed as dictating course requirements. For example, the emphasis on the development of career skills does not imply that these activities must transpire in a formal course on careers in psychology. Similarly, the *Guidelines* should not be interpreted as advocating that separate courses in the history of psychology or group dynamics be included in the undergraduate curriculum. Rather, these guidelines are intended to empower and encourage departments to determine contexts in which students can learn those relevant skills and perspectives.

I. Knowledge, Skills, and Values Consistent With the Science and Application of Psychology

GOAL 1: Knowledge Base of Psychology

Demonstrate familiarity with the major concepts, theoretical perspectives, empirical findings, and historical trends in psychology.

Suggested Learning Outcomes

1.1 Characterize the nature of psychology as a discipline.

a. Explain why psychology is a science

b. Identify and explain the primary objectives of psychology: describing, understanding, predicting, and controlling behavior and mental processes

c. Compare and contrast the assumptions and methods of psychology with those of other disciplines

d. Describe the contributions of psychology perspectives to interdisciplinary collaboration

1.2 Demonstrate knowledge and understanding representing appropriate breadth and depth in selected content areas of psychology:

a. Theory and research representing each of the following four general domains:

(1) Learning and cognition

(2) Individual differences, psychometrics, personality, and social processes, including those related to sociocultural and international dimensions

(3) Biological bases of behavior and mental processes, including physiology, sensation, perception, comparative, motivation, and emotion

(4) Developmental changes in behavior and mental processes across the life span

b. The history of psychology, including the evolution of methods of psychology, its theoretical conflicts, and its sociocultural contexts

c. Relevant levels of analysis: cellular, individual, group/systems, and society/culture

d. Overarching themes, persistent questions, or enduring conflicts in psychology, such as

(1) The interaction of heredity and environment

(2) Variability and continuity of behavior and mental processes within and across species

(3) Free will versus determinism

(4) Subjective versus objective perspective

(5) The interaction of mind and body

(6) Applicability of theories and measures across societal and cultural groups

e. Relevant ethical issues, including a general understanding of the APA Ethics Code

1.3 Use the concepts, language, and major theories of the discipline to account for psychological phenomena.

a. Describe behavior and mental processes empirically, including operational definitions

b. Identify antecedents and consequences of behavior and mental processes

c. Interpret behavior and mental processes at an appropriate level of complexity

d. Use theories to explain and predict behavior and mental processes
e. Integrate theoretical perspectives to produce comprehensive and multifaceted explanations

1.4 Explain major perspectives of psychology (e.g., behavioral, biological, cognitive, evolutionary, humanistic, psychodynamic, and sociocultural).
a. Compare and contrast major perspectives
b. Describe advantages and limitations of major theoretical perspectives

GOAL 2: Research Methods in Psychology

Understand and apply basic research methods in psychology, including research design, data analysis, and interpretation.

Suggested Learning Outcomes

2.1 Describe the basic characteristics of the science of psychology.

2.2 Explain different research methods used by psychologists.
a. Describe how various research designs address different types of questions and hypotheses
b. Articulate strengths and limitations of various research designs, including distinguishing between qualitative and quantitative methods
c. Distinguish the nature of designs that permit causal inferences from those that do not
d. Describe how the values system of the researcher can influence research design and decisions

2.3 Evaluate the appropriateness of conclusions derived from psychological research.
a. Interpret basic statistical results
b. Distinguish between statistical significance and practical significance
c. Describe effect size and confidence intervals
d. Evaluate the validity of conclusions presented in research reports

2.4 Design and conduct basic studies to address psychological questions using appropriate research methods.

a. Locate and use relevant databases, research, and theory to plan, conduct, and interpret results of research studies

b. Formulate testable research hypotheses, based on operational definitions of variables

c. Use reliable and valid measures of variables of interest

d. Select and apply appropriate methods to maximize internal and external validity and reduce the plausibility of alternative explanations

e. Collect, analyze, interpret, and report data using appropriate statistical strategies to address different types of research questions and hypotheses

f. Recognize that theoretical and sociocultural contexts as well as personal biases may shape research questions, design, data collection, analysis, and interpretation

2.5 Follow the APA Ethics Code in the treatment of human and nonhuman participants in the design, data collection, interpretation, and reporting of psychological research.

2.6 Generalize research conclusions appropriately based on the parameters of particular research methods.

a. Exercise caution in predicting behavior based on limitations of single studies

b. Recognize the limitations of applying normative conclusions to individuals

c. Acknowledge that research results may have unanticipated societal consequences

d. Recognize that individual differences and sociocultural contexts may influence the applicability of research findings

GOAL 3: Critical Thinking Skills in Psychology

Respect and use critical and creative thinking, skeptical inquiry, and, when possible, the scientific approach to solve problems related to behavior and mental processes.

Suggested Learning Outcomes

3.1 Use critical thinking effectively.

a. Evaluate the quality of information, including differentiating empirical evidence from speculation and the probable from the improbable
b. Identify and evaluate the source, context, and credibility of behavioral claims
c. Challenge claims that arise from myth, stereotype, or untested assumptions
d. Use scientific principles and evidence to resolve conflicting claims
e. Recognize and defend against common fallacies in thinking
f. Avoid being swayed by appeals to emotion or authority
g. Evaluate popular media reports of psychological research
h. Demonstrate an attitude of critical thinking that includes persistence, open-mindedness, tolerance for ambiguity, and intellectual engagement
i. Make linkages or connections between diverse facts, theories, and observations

3.2 Engage in creative thinking.
a. Intentionally pursue unusual approaches to problems
b. Recognize and encourage creative thinking and behaviors in others
c. Evaluate new ideas with an open but critical mind

3.3 Use reasoning to recognize, develop, defend, and criticize arguments and other persuasive appeals.
a. Identify components of arguments (e.g., conclusions, premises/assumptions, gaps, counterarguments)
b. Distinguish among assumptions, emotional appeals, speculations, and defensible evidence
c. Weigh support for conclusions to determine how well reasons support conclusions
d. Identify weak, contradictory, and inappropriate assertions
e. Develop sound arguments based on reasoning and evidence

3.4 Approach problems effectively.
a. Recognize ill-defined and well-defined problems
b. Articulate problems clearly
c. Generate multiple possible goals and solutions
d. Evaluate the quality of solutions and revise as needed
e. Select and carry out the best solution

GOAL 4: Application of Psychology

Understand and apply psychological principles to personal, social, and organizational issues.

Suggested Learning Outcomes

4.1 Describe major applied areas (e.g., clinical, counseling, industrial/organizational, school, etc.) and emerging (e.g., health, forensics, media, military, etc.) applied areas of psychology.

4.2 Identify appropriate applications of psychology in solving problems, such as:

a. The pursuit and effect of healthy lifestyles
b. Origin and treatment of abnormal behavior
c. Psychological tests and measurements
d. Psychology-based interventions in clinical, counseling, educational, industrial/organizational, community, and other settings and their empirical evaluation
e. The resolution of interpersonal and intercultural conflicts

4.3 Articulate how psychological principles can be used to explain social issues and inform public policy.

a. Recognize that sociocultural contexts may influence the application of psychological principles in solving social problems
b. Describe how applying psychological principles can facilitate appropriate change in institutions and in society
c. Articulate the role of psychology in developing, designing, and disseminating public policy

4.4 Apply psychological concepts, theories, and research findings as these relate to everyday life.

4.5 Recognize that ethically complex situations can develop in the application of psychological principles.

GOAL 5: Values in Psychology

Value empirical evidence, tolerate ambiguity, act ethically, and reflect other values that are the underpinnings of psychology as a science.

Suggested Learning Outcomes

5.1 Recognize the necessity of ethical behavior in all aspects of the science and practice of psychology.

5.2 Demonstrate reasonable skepticism and intellectual curiosity by asking questions about causes of behavior.

5.3 Seek and evaluate scientific evidence for psychological claims.

5.4 Tolerate ambiguity and realize that psychological explanations are often complex and tentative.

5.5 Recognize and respect human diversity.

a. Anticipate that psychological explanations may vary across populations and contexts

b. Exhibit sensitivity to issues of power, privilege, and discrimination

5.6 Assess and justify their engagement with respect to civic, social, and global responsibilities.

5.7 Understand the limitations of their psychological knowledge and skills.

II. Knowledge, Skills, and Values Consistent With Liberal Arts Education That Are Further Developed in Psychology

GOAL 6: Information and Technological Literacy

Demonstrate information competence and the ability to use computers and other technology for many purposes.

Suggested Learning Outcomes

6.1 Demonstrate information competence at each stage in the following process:

a. Formulate a researchable topic that can be supported by database search strategies

b. Locate and choose relevant sources from appropriate media, which may include data and perspectives outside traditional psychology and Western boundaries

c. Use selected sources after evaluating their suitability based on
(1) Appropriateness, accuracy, quality, and value of the source
(2) Potential bias of the source
(3) The relative value of primary versus secondary sources, empirical versus nonempirical sources, and peer-reviewed versus non-peer-reviewed sources

d. Read and accurately summarize the general scientific literature of psychology

6.2 Use appropriate software to produce understandable reports of the psychological literature, methods, and statistical and qualitative analyses in APA or other appropriate style, including graphic representations of data.

6.3 Use information and technology ethically and responsibly.
a. Quote, paraphrase, and cite correctly from a variety of media sources
b. Define and avoid plagiarism
c. Avoid distorting statistical results
d. Honor commercial and intellectual copyrights

6.4 Demonstrate these computer skills:
a. Use basic word processing, database, e-mail, spreadsheet, and data analysis programs
b. Search the Web for high-quality information
c. Use proper etiquette and security safeguards when communicating through e-mail

GOAL 7: Communication Skills

Communicate effectively in a variety of formats.

Suggested Learning Outcomes

7.1 Demonstrate effective writing skills in various formats (e.g., essays, correspondence, technical papers, note taking) and for various purposes (e.g., informing, defending, explaining, persuading, arguing, teaching).
a. Demonstrate professional writing conventions (e.g., grammar, audience awareness, formality) appropriate to purpose and context
b. Use APA style effectively in empirically based reports, literature reviews, and theoretical papers

7.2 Demonstrate effective oral communication skills in various formats (e.g., group discussion, debate, lecture) and for various purposes (e.g., informing, defending, explaining, persuading, arguing, teaching).

7.3 Exhibit quantitative literacy.

a. Apply basic mathematical concepts and operations to support measurement strategies

b. Use appropriate and relevant probability and statistical analyses to facilitate interpretation of measurements

c. Articulate clear and appropriate rationale for choice of information conveyed in charts, tables, figures, and graphs

d. Interpret quantitative visual aids accurately, including showing vigilance about misuse or misrepresentation of quantitative information

7.4 Demonstrate effective interpersonal communication skills.

a. Listen accurately and actively

b. Use psychological concepts and theory to understand interactions with others

c. Identify the impact or potential impact of one's behaviors on others

d. Articulate ideas thoughtfully and purposefully

e. Use appropriately worded questions to improve interpersonal understanding

f. Attend to nonverbal behavior and evaluate its meaning in the communications context

g. Adapt style to communicate sensitively and effectively with diverse ethnic and cultural partners

h. Provide constructive feedback to colleagues in oral and written formats

7.5 Exhibit the ability to collaborate effectively.

a. Work with groups to complete projects within reasonable time frames

b. Solicit and integrate diverse viewpoints

c. Manage conflicts appropriately and ethically

d. Develop relevant workplace skills: mentoring, interviewing, crisis management

GOAL 8: Sociocultural and International Awareness

Recognize, understand, and respect the complexity of sociocultural and international diversity.

Suggested Learning Outcomes

8.1 Interact effectively and sensitively with people of diverse abilities, backgrounds, and cultural perspectives.

8.2 Examine the sociocultural and international contexts that influence individual differences.

8.3 Explain how individual differences influence beliefs, values, and interactions with others and vice versa.

8.4 Understand how privilege, power, and oppression may affect prejudice, discrimination, and inequity.

8.5 Recognize prejudicial attitudes and discriminatory behaviors that might exist in themselves and in others.

8.6 Predict how interaction among diverse people can challenge conventional understanding of psychological processes and behavior.

GOAL 9: Personal Development

Develop insight into their own and others' behavior and mental processes and apply effective strategies for self-management and self-improvement.

Suggested Learning Outcomes

9.1 Reflect on their experiences and find meaning in them.

a. Identify their personal, sociocultural, and professional values

b. Demonstrate insightful awareness of their feelings, emotions, motives, and attitudes based on psychological principles

9.2 Apply psychological principles to promote personal development.

a. Demonstrate self-regulation in setting and achieving goals

b. Self-assess performance quality accurately

c. Incorporate feedback for improved performance

d. Purposefully evaluate the quality of their thinking (metacognition)

9.3 Enact self-management strategies that maximize healthy outcomes.

9.4 Display high standards of personal integrity with others.

9.5 Seek input from and experiences with diverse people to enhance the quality of solutions.

GOAL 10: Career Planning and Development

Pursue realistic ideas about how to implement their psychological knowledge, skills, and values in occupational pursuits in a variety of settings that meet personal goals and societal needs.

Suggested Learning Outcomes

10.1 Apply knowledge of psychology (e.g., decision strategies, life span processes, psychological assessment, types of psychological careers) when formulating career choices.

10.2 Identify the types of academic experience and performance in psychology and the liberal arts that will facilitate entry into the workforce, postbaccalaureate education, or both.

10.3 Describe preferred career paths based on accurate self-assessment of abilities, achievement, motivation, and work habits.

10.4 Identify and develop skills and experiences relevant to achieving selected career goals.

10.5 Articulate how changing societal needs can influence career opportunities and foster flexibility about managing changing conditions.

10.6 Demonstrate an understanding of the importance of lifelong learning and personal flexibility to sustain personal and professional development as the nature of work evolves.

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APA PRINCIPLES FOR Quality UNDERGRADUATE EDUCATION *in* PSYCHOLOGY

American Psychological Association

APA PRINCIPLES FOR Quality in UNDERGRADUATE EDUCATION PSYCHOLOGY

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Approved by the APA Council of Representatives, February 18, 2011

The *APA Principles for Quality Undergraduate Education in Psychology* was approved as APA policy by the APA Council of Representatives in February 2011. It is available online at http://www.apa.org/education/undergrad/principles.aspx.

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PREFACE

The *American Psychological Association (APA) Principles for Quality Undergraduate Education in Psychology* was approved as APA policy by the APA Council of Representatives in February 2011. The principles were developed by the Board of Educational Affairs (BEA) Steering Committee for the 2008 APA National Conference on Undergraduate Education in Psychology, held in Tacoma, WA. Participants at the 2008 conference articulated a number of recommendations for enhancing the teaching and learning of undergraduate psychology. These principles were patterned after the *Principles for Quality Undergraduate Psychology Programs*, adopted by APA in 1994 and archived in February 2011. Initial development of these principles resulted in a book chapter published in *Undergraduate Education in Psychology: A Blueprint for the Future of the Discipline* (Halpern, 2010). As recommended by the participants and the BEA Steering Committee for the 2008 APA National Conference on Undergraduate Education in Psychology, there are five important principles, along with 30 recommendations:

- **Quality Principle 1:** Students are responsible for monitoring and enhancing their own learning.
- **Quality Principle 2:** Faculty strive to become scientist-educators who are knowledgeable about and use the principles of the science of learning.
- **Quality Principle 3:** Psychology departments and programs create a coherent curriculum.
- **Quality Principle 4:** Academic administrators support and encourage quality practices in teaching and learning.
- **Quality Principle 5:** Policymakers and the general public understand why psychological literacy is necessary for informed citizens and an effective workforce.

Although these principles were designed to enhance teaching and learning in undergraduate education in psychology, they have broad application and could be used to promote high-quality teaching and learning in any academic discipline.

EXECUTIVE SUMMARY

Why Do We Need the APA Principles for Quality Undergraduate Education in Psychology?

The APA Board of Educational Affairs (BEA) Steering Committee for the 2008 National Conference on Undergraduate Education in Psychology designed these principles for quality teaching and learning for all stakeholders in higher education—students, faculty, departments, academic administrators, public policymakers, and the general public—to ensure that students are prepared for the challenges they will encounter as workers, family members, and concerned citizens in the new global century. These principles describe a set of recommendations for creating a world-class educational system that provides students with the workplace skills needed in this information age; a solid academic background that prepares them for advanced study in a wide range of fields; and the knowledge, skills, and values they will need to enter and succeed in the workforce and thrive in their daily lives.

The *APA Principles for Quality Undergraduate Education in Psychology* represents an important statement from the national disciplinary association during a time when undergraduate education in the United States is under much scrutiny from the public. This document follows several related major projects of the last decade that have focused on quality improvement in psychology education. For example, in 2005, the APA Council of Representatives approved the *National Standards for High School Psychology Curricula* (APA, 2005); approval of the revised *National Standards* occurred in 2011. In 2006, the APA Council of Representatives approved the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2007) to describe a set of optimal expectations for student performance at the completion of the baccalaureate degree. The APA Council of Representatives also received a *Report on Teaching, Learning, and Assessing in a Developmentally Coherent Curriculum* (APA, 2008). In 2008, APA convened the National Conference on Undergraduate Education in Psychology on the campus of the University of Puget Sound in Tacoma, WA. As a result of these important initiatives and the deliberations at this conference, the BEA Steering Committee prepared this new set of *APA Principles for Quality Undergraduate Education in Psychology*.

Use of the Term *Principles*

In the context of this document, the term *principles* is used to describe these recommendations for quality undergraduate education in psychology. The term *principles* can be interpreted in the same way as the term *guidelines*. Use of the term *guidelines* generally refers to recommendations that are aspirational in intent. As noted in the *APA Guidelines for the Undergraduate Psychology*

Major (APA, 2007), the higher education community and other scientific disciplines use the term *guidelines* in a similar way. Moreover, as used in this document, use of the term *principles* is consistent with the provisions of the APA policy on *Developing and Evaluating Standards and Guidelines Related to Education and Training in Psychology: Context, Procedures, Criteria, and Format*, Section I C (1)(2004), as passed by the APA Council of Representatives.

Process of Developing the Quality Principles

The *APA Principles for Quality Undergraduate Education in Psychology* was developed to offer recommendations for enhancing the teaching and learning of undergraduate psychology, yet the principles can be used as guidelines for other disciplines. These principles were patterned after an earlier set of recommendations, the *Principles for Quality Undergraduate Psychology Programs* (APA, 1994), developed after the 1991 APA National Conference on Enhancing the Quality of Undergraduate Education in Psychology at St. Mary's College of Maryland.

A copy of the unapproved *Principles for Quality Undergraduate Education in Psychology* was published in *Undergraduate Education in Psychology: A Blueprint for the Future of the Discipline* (Halpern, 2010), a major outcome of the 2008 APA National Conference on Undergraduate Education in Psychology. The conference steering committee provided leadership for the final version of the *APA Principles for Quality Undergraduate Education in Psychology*. The steering committee members represented a variety of institutional perspectives on the nature of the undergraduate curriculum and its aims and included Diane F. Halpern (Chair), Barry Anton, Bernard C. Beins, Charlie T. Blair-Broeker, Charles L. Brewer, William Buskist, Bettina J. Casad, Wallace E. Dixon, Jr., Yolanda Y. Harper, Mary E. Kite, Patricia Puccio, and Courtney A. Rocheleau.

The BEA Steering Committee was informed by the comments provided by many individuals, APA governance groups, APA divisions, undergraduate psychology departments, and many other organizations in psychology, including the Council of Graduate Departments of Psychology (COGDOP); the Council of Undergraduate Programs in Psychology (CUPP); the Council on Undergraduate Research (CUR); regional psychological associations; and the state, provincial, and territorial psychological associations.

Under the leadership of Diane Halpern, members of the BEA Steering Committee reviewed all of the submitted comments and developed a revised draft of the *APA Principles for Quality Undergraduate Education in Psychology* in early 2010. Subsequent to legal review, this revised document was available for 90 days of public comment. APA governance groups and subsequently, the

APA Board of Directors, received the revised document in the fall of 2010. In February 2011, the APA Council of Representatives adopted the *APA Principles for Quality Undergraduate Education in Psychology*.

Resource Documents

Resources used to create the *APA Principles for Quality Undergraduate Education in Psychology* included drafts of book chapters reporting on the recommendations of the 2008 National Conference on Undergraduate Education in Psychology. In addition, the BEA Steering Committee consulted the earlier recommendations from the 1991 APA National Conference on Enhancing the Quality of Undergraduate Education in Psychology. Information about the St. Mary's Conference was published in an APA book entitled *Handbook on Enhancing Undergraduate Psychology* (McGovern, 1993).

Members of the BEA Steering Committee reviewed the document to ensure its consistency with other APA policy documents, such as the *APA Ethical Principles of Psychologists and Code of Conduct* (APA, 2002) and the *Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists* (APA, 2003). This procedure is specified in the APA Policy on *Developing and Evaluating Standards and Guidelines Related to Education and Training in Psychology: Context, Procedures, Criteria, and Format* (APA, 2004).

Feedback

The BEA Steering Committee views the *APA Principles for Quality Undergraduate Education in Psychology* as a "living document." Accordingly, the Education Directorate will implement a systematic plan for the future review and revision of this document to reflect national and international developments in the discipline and in education. These principles are scheduled to expire 10 years from the date of their adoption, in February 2021. This is consistent with provisions of APA Association Rule 30-8.3, requiring cyclical review of approved standards and guidelines within periods not to exceed 10 years. After this date, users are encouraged to contact the APA Education Directorate to determine whether this document remains in effect.

Comments and suggestions on these principles are welcome. Feedback may be sent to:

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The following principles for undergraduate education in psychology are designed for creating a world-class educational system that provides students with the workplace skills needed in this information age; a solid academic background that prepares them for advanced study in a wide range of fields; and the knowledge, skills, and abilities that will enhance their personal lives. A quality undergraduate education is designed to produce psychologically literate citizens who apply the principles of psychological science at work and at home. The American Psychological Association (APA) urges all stakeholders in undergraduate education in psychology to incorporate these principles in establishing goals and objectives that fit their specific institutional needs and missions.

QUALITY PRINCIPLE 1: Students are responsible for monitoring and enhancing their own learning.

The entire educational enterprise centers on the learner and ways to make learning effective, durable, and transferable across academic domains and to out-of-school contexts. The most important variable in learning outcomes is what students do to make learning effective, durable, and transferable.

Recommendations

1. Students know how to learn.

Knowing how to learn includes using learning strategies such as spacing study sessions; processing information for meaning; generating responses to enhance memory; explaining concepts; using visual-spatial, verbal, and kinesthetic strategies; and becoming actively engaged in the effortful process of learning. Students can reasonably expect faculty and support staff at their institution to assist them in learning to learn.

2. Students assume increasing responsibility for their own learning.

Students need to develop the skilled habit of metacognition, which includes knowing when they need help with learning and when they are learning well on their own. Early in the semester, students who need assistance with learning should seek help from their professors and others on campus who can support learning (e.g., staff at student learning centers).

3. Students take advantage of the rich diversity that exists in educational institutions and learn from individuals who are different from them.

Projections suggest that there will be no single majority group in the United States by the year 2050 (U. S. Census Bureau, 2008), when most of today's students will still be in the workforce. Demographers expect other regions of the world to become increasingly diverse as well. People vary in multiple ways, including extent of ability and differences in race, ethnicity, country of origin, age, religious beliefs, sexual orientation, gender, and socioeconomic status. The diverse characteristics of other students and faculty members provide learning experiences for the real-world tasks of understanding people who view events in the world from varying

perspectives. Learning from diverse students and faculty members is an important component of a quality education.

4. Students are responsible for seeking advice for academic tasks, such as selecting courses in the approved sequence that satisfy the institution's requirements for the major and general education. They are also responsible for seeking advice about planning for a career that is realistic and tailored to their individual talents, aspirations, and situations.

A corollary of this principle is that faculty and staff will be available to students and knowledgeable about requirements for the major and career options for majors in psychology.

5. Students strive to become psychologically literate citizens.

The goal of becoming psychologically literate citizens is to prepare students for the demands of a global 21st century. Psychological literacy includes having a basic knowledge of the subject matter of psychology, valuing scientific thinking, acting ethically, recognizing and fostering respect for diversity, and being insightful about one's own and others' behavior and mental processes. Access to information from distant countries has made students global citizens, even if they have never traveled outside their home towns, and enhances their ability to see issues from multiple perspectives. Thus, psychologically literate citizens value international perspectives on psychology and willingly engage with citizens from countries other than their own.

QUALITY PRINCIPLE 2: Faculty strive to become scientist–educators who are knowledgeable about and use the principles of the science of learning.

Students need knowledgeable and caring faculty to achieve their learning goals. Thus, the quality principles for faculty in higher education and other places where students learn are closely tied to the principles of the science of learning. The science of learning refers to the body of knowledge about how people learn, including how brains develop and what works to enhance comprehension, retention, transfer, and creative use of information. To be effective educators, faculty should know and apply the principles from the science of learning.

Recommendations

1. Faculty provide instruction in the ethical standards that undergird the discipline of psychology and model this behavior across professional settings.

Faculty behave ethically in all of their interactions with students, in their research, and in all aspects of their professional and personal lives, thereby serving as excellent role models for their students. Faculty can infuse across the curriculum opportunities for students to think about new and old ethical dilemmas. To develop ethical standards in students, faculty provide them with a framework in which they can analyze new and emerging ethical issues, such as the use of memory-enhancing drugs, the use of psychosurgery as a means of treating some mental disorders, and the issue of whether teens should be held responsible as adults for criminal behavior.

2. Faculty understand and apply a variety of learning principles and modes of learning, such as spaced practice, generation of responses, active engagement by students, group exercises, and explaining as a way of understanding, among others.

Expertise in one's specialized subdiscipline in psychology is necessary but not sufficient to promote quality learning. A large and growing literature applies empirically derived outcomes from the science of learning to college settings and other places where people learn (e.g., high schools, media at home, the workplace). Faculty should know how to teach the information in their specialty content areas and in general psychology in ways that promote deep understanding, long-lasting knowledge, and the ability to apply what is learned to disciplines outside of psychology and in settings outside the formal classroom. Faculty should know how to alter their teaching, depending on faculty and student learning goals,

background preparation, institutional mission, and personal preferences. Faculty should be responsive to the multiple ways in which students differ, including their racial and ethnic context, gender, gender identity and gender expression, and disabilities.

3. Faculty make the same commitment to using the science of learning in their teaching as is required of scientist–practitioners who use the scientific findings of psychological research in their practice with clients and in other aspects of their professional lives.

There are numerous ways to meet the objective of this principle. Faculty may collect teaching-related data to determine the effectiveness of various modes of teaching. In addition, they may become familiar with the scholarly literature on effective teaching and learning at their level of education. APA encourages all faculty to do both and to apply their knowledge of how people learn.

4. Faculty engage in continuous, iterative inquiry into the success of their instruction in promoting appropriate learning, and they use that evidence to refine instructional practices to enhance the success of future students.

Once evidence-based teaching practices are implemented, faculty should evaluate their success in ensuring that students are achieving course objectives. Over time the proportion of students achieving all course objectives and the proportion of students achieving each course objective should increase. Faculty should use the experience of other instructors and the principles of learning to identify and implement more effective teaching practices as indicated by successful student learning. Continuous adaptation of teaching practices to facilitate appropriate student success is an essential feature of excellent instruction.

5. Faculty foster critical thinking by identifying the critical thinking skills and abilities they wish to promote in their classes and in the psychology major as a whole. Faculty periodically review these skills and abilities throughout the term and through all years of undergraduate education.

Today's students get their information from many sources, including both credible and less than credible websites. The Internet is filled with misinformation (unintentional inaccuracy), disinformation (intentional inaccuracy), propaganda, and just plain nonsense. More than ever, the most important outcome for an undergraduate education is the ability to think critically, which includes skills such as identifying the credibility of information, providing reasons and counterarguments for conclusions, identifying and solving problems, recognizing propaganda and persuasive appeals, and using evidence when making decisions. Faculty should teach

critical thinking by identifying the skills and abilities they wish to promote in their classes and in the major as a whole. Involving students in research projects is an effective way to promote critical thinking. Thus, quality programs will include a variety of opportunities for student involvement in research. After identifying these skills, abilities, and research opportunities, faculty should periodically review them throughout the term and at graduation (or the end point of their psychology program, if it is not graduation).

6. Faculty ensure that students develop basic skills in communication, numeracy, working cooperatively with others, and acknowledging and respecting diverse perspectives.

The ability to think critically is an essential outcome of a quality education, but it is not the only basic skill that should be developed through challenging course work. Other essential skills include effective writing; fluent speaking; thinking with numbers; and working with others who may have diverse perspectives, values, attitudes, and skills. Faculty should concentrate on their students' development of these skills and provide systematic learning opportunities so that students can build on earlier skills as they become more proficient.

7. Faculty ensure that diversity issues are carefully considered and infused throughout the curriculum.

Culturally competent faculty will be (or will strive to become) at ease with and knowledgeable about the full range of students, staff, and other faculty on their campus and will communicate that knowledge to their students. Faculty are not providing their students with a quality education if they avoid or deny the importance of diversity that includes gender, race, age, ability, ethnicity, and other types of diversity as a central topic in psychology. We cannot teach about topics such as human development, love and sexual attraction, motivation, mental disorders, effective treatments for mental disorders, health and well-being, or the multitude of other topics in psychology without including diversity issues. Diversity is not simply an add-on to an otherwise overcrowded curriculum; it is central to understanding psychology. Inclusive excellence in academia exists when diversity and educational quality efforts are fully integrated and embedded into the core of the academic mission and institutional functioning both inside and outside of the classroom. Care should be taken to select textbooks and other learning materials that incorporate multicultural approaches and research and theories from multiple countries throughout the world in the presentation of material for the course. Psychology can only be a psychology for all people when it incorporates international perspectives throughout the discipline.

8. Faculty become proficient in their use of commonly used technologies as a means to promote learning, and they encourage their students to develop these proficiencies as well.

Today's students are *digital natives,* a term that is used to highlight the fact that they have never known a time when computers were not used for finding information, communicating with people around the world, or playing games and listening to music. Despite having been born during the decades of increasing computer use, not all students are proficient in using word processors, spreadsheets, presentation software, and other common programs that will be indispensable to their work lives. Students who do not have these necessary skills should be identified and strongly encouraged to learn the essential tools of their trade: computer programs needed for success as students and later as workers. Regardless of the students' level of expertise, their interests and abilities have been shaped by their technology-related experiences. Faculty should recognize that technology is a language that we need to communicate with our students. Faculty have a responsibility to assist students in learning these new technologies and in helping students adjust their learning behaviors in response to technology-mediated learning opportunities.

QUALITY PRINCIPLE 3: Psychology departments and programs create a coherent curriculum.

Quality teaching and learning for undergraduates take place in an organizational context. Psychology departments and programs should be organized to support the learning goals of students and faculty.

Recommendations

1. Psychology as a scientific discipline is reinforced throughout the curriculum.

We urge departments to consider ways to communicate psychology as a science to present and prospective students, to faculty in other departments on campus, and to the general public because of common misunderstandings about the nature of psychology. Psychology as a science can be made more prominent in several ways. These include changing a department's name to "Psychological Science"; seeking greater affiliation with departments in schools of science; or using other ways that are appropriate for each department's structure, history, and setting.

Research methods are at the heart of psychological inquiry and knowledge. They distinguish psychology as a science from psychology as a pseudoscience. For this reason, students should have a foundational understanding of basic research design and statistics early in their careers. Students can then build on their understanding in higher-level courses. When students acquire knowledge about the research basis of psychology early in their education, statistics and research topics can be included in later courses throughout the curriculum.

2. Ethics and issues related to diversity are incorporated throughout the curriculum.

Although specific courses may be offered that focus on ethics and/or different types of diversity (e.g., Asian American Psychology, Psychology of Women, Ethics in Psychology), ethics and diversity should be integrated within the context of most courses in psychology. International perspectives are essential because today's students communicate around the globe with the same ease that they communicate across campus. They need to understand how concepts such as need for harmony, filial piety, and communal good

differ around the globe and how people from various countries differ in their understanding of human thought and behavior.

3. The introductory course and the psychology major provide a broad foundational understanding of the field from the perspective of content areas spanning levels of organization from cellular to ecological.

Regardless of the structure of an individual department's curriculum, the major should incorporate multiple core perspectives on psychology. Because the introductory course is the only formal exposure to psychology that most educated citizens will have, this course should reflect the nature of psychology as a scientific discipline and include sections from different basic domains. Integration across perspectives should be incorporated into the introductory course by, for example, organizing the course topically or providing an in-depth topical "case study" of integration. Many of the controversies in psychology result from different perspectives on human thought and behavior, so in teaching about controversies (e.g., nature/nurture issues), faculty should expose students to theoretically diverse perspectives. Departments should consider carefully the depth and breadth of topics to cover in their classes. Content coverage has become a critical factor in the psychology curriculum as a result of the explosion of research findings and the plethora of important topics that could be included in any course.

4. Curricula in psychology are designed to include course work in writing, speaking, and listening across the curriculum and courses that teach students how to think critically across a broad range of situations (see *APA Guidelines for the Undergraduate Psychology Major* (APA, 2007)).

The psychology curriculum as a whole should be designed to foster high-level learning outcomes that include essential skills such as thinking critically, learning effectively, writing, listening actively, and speaking fluently. The development of these essential skills should be coordinated across classes and systematically developed in the curriculum. Faculty should identify specific courses that enhance each of these skills and assess learning gains for students who take those courses. Large class size is often an impediment to the development of speaking and writing skills in psychology courses. When possible, students should have the opportunity to participate in seminar classes, laboratory experiences, or recitation sections in which the number of students is limited.

5. Courses are sequenced in ways that allow upper division courses to build on concepts that are introduced in lower division courses.

Students develop their ability to handle advanced concepts and procedures as they progress through the curriculum. For this reason, we recommend an initial broad course that introduces students to the discipline. Departments may wish to follow this course with statistics and research methods as soon as is feasible for a department's local conditions (e.g., within the constraints of transfer agreements between community colleges and four-year institutions), so that other, more content-oriented courses can illustrate the application of basic research design principles to specific domains of study. Other lower division courses may then follow, and they can be built on by the advanced requirements of upper-division courses.

A comprehensive introductory psychology course should be a prerequisite for all subsequent psychology courses. The introductory psychology course is one of the cornerstones of social science general education programs, and it should represent the entire field of psychology accurately and reinforce the basic premise that psychology is a scientific discipline. A quality curriculum in undergraduate education will also include an integrative capstone experience that allows students to see both the unity and differentiation of psychology's many subfields. There are many ways to achieve an integrative experience, including a course on the history and systems of psychology that allows students to trace the development of psychological thought, a contemporary issues approach in which current events are viewed from a psychological perspective, a senior-level overview course, or a research project in collaboration with a faculty member.

6. Members of psychology departments work as a team to identify the desired learning outcomes and assessment of learning outcomes for the major, as well as any minor programs of study or concentrations they offer.

Clearly articulated learning outcomes promote the development of a coherent curriculum in which students understand what they need to learn and in which faculty can examine what students actually learn. Undergraduate education cannot be improved without assessing what and how much students know when they complete programs. Learning outcomes can be assessed by numerous methods. Faculty members should be familiar with some of the ways academic learning outcomes are assessed, the strengths and weaknesses of each method, and the ways to use the methods that will improve teaching and learning.

7. Being committed to quality undergraduate education, graduate programs ensure that all students are exposed to evidence-based strategies for communicating about psychology and that all those who teach as graduate students, or plan to have academic careers, receive instruction about effective teaching strategies. All graduate students need to learn how to communicate effectively with a broad range of stakeholders in psychology, including students, media, policymakers, funding agencies, and juries.

Psychology faculty receive most of their advanced education in graduate programs in psychology, which is where they should receive instruction in how different modes of teaching lead to quality learning. Instruction in communicating about psychology is needed by all graduate students, whether or not they intend to become academic psychologists. Most doctoral students will teach in formal or informal settings at some point in their careers and be called on to educate diverse constituencies, including funding agencies, policymakers, and the media. Some graduate programs rely on a mentoring relationship with a single faculty member to foster teaching and communication skills. Although mentoring relationships are highly desirable, they are not sufficient for teaching graduate students about the science and art of teaching and communicating with diverse audiences in ways that take into account their prior knowledge and biases and promote understanding and retention of information. This recommendation is essential for educating the general public about the scientific underpinnings of psychology and its application to a wide range of contemporary challenges, such as energy consumption, intergroup conflict and prejudice, and mental disorders, to name just a few.

8. As a contribution of psychology to the public good, courses include knowledge and skill acquisition that is relevant to students' lives (e.g., an applied experience and/or study abroad).

Students should acquire knowledge and skills that they can use in their personal lives, families, careers, and communities. Psychologically literate citizens will be able to apply what they have learned in their psychology courses in planning their professional lives, meeting family obligations, and engaging in civic activities.

Learning is more durable and more likely to transfer when applied to relevant, real-world problems. Student internships, externships, volunteer activities, service learning, and work in a research laboratory along with certain types of paid employment allow students to apply what they are learning to real-world problems. APA recommends an applied learning experience in the major, whenever this is possible. Study abroad can provide a life-changing experience as students learn from and with peers whose life views may differ from their own.

QUALITY PRINCIPLE 4: Academic administrators support and encourage quality practices in teaching and learning.

Academic leadership plays a pivotal role in encouraging quality practices that enhance teaching and learning. Quality institutions have high-quality leaders who encourage and support the teaching and learning activities on their campuses.

Recommendations

1. Faculty are encouraged to engage in the scholarship of teaching and learning.

The scholarship of teaching and learning is gaining increased credibility as a legitimate form of scholarly activity on many college and university campuses. But inquiry into practices that support excellence in teaching and learning will be sustained only if these activities are supported by the academic administration. Scholarship and excellence in teaching and learning should be rewarded in ways that are appropriate for each campus. Regardless of an institution's mission, some amount of high-quality research on topics that promote teaching and learning should be recognized as scholarly contributions.

2. Teaching assignments take into account the needs of each campus, but institutions should assign courses to faculty members who are academically prepared to teach these courses.

Everyone loses when faculty are inadequately prepared for the courses they teach. If there is a need for faculty to teach in subject areas that they are not prepared to teach, they should be given time and support to gain the necessary knowledge. Support may include, for example, paying for an advanced (or basic) class in the needed content area, sending faculty to conferences where they can learn about the needed area, and arranging mentoring with someone who has the necessary expertise.

3. Psychology departments receive adequate support for their laboratories and laboratory-based classes.

As teachers of a scientific discipline, psychologists need space and equipment for data collection and analysis, and students need laboratory courses that teach these skills. Adequate investments in laboratory space and equipment as well as

routine upgrading of equipment, computers, and software are essential for a quality undergraduate education. Providing appropriate laboratory space and equipment for student learning and faculty research is a tangible commitment to the teaching and learning of psychological science.

4. Academic administrators encourage faculty to engage in lifelong learning to stay current in their field.

The knowledge base of psychology is constantly changing, and new technologies are used in teaching and research. New methods of data collection and analysis are changing the nature of psychology. Academic administrators should support the learning activities of faculty by funding advanced course work and attendance at symposia, conferences, and other places where faculty can stay abreast of the rapid changes in their field (e.g., emerging technologies, changes in our understanding of mental disorders, and developments in telehealth and integrated health care on the cutting edge of our field). In many instances, adjunct faculty teach for decades at the same institution, so administrators who care about the quality of instruction their students are receiving will extend some continuing education benefits to their long-term adjuncts as well as tenure-track faculty.

5. Administrators support faculty experimentation to enhance teaching and learning, and they ensure that faculty are not punished if student evaluations are uneven.

In general, learning will be improved when faculty try out different modes of instruction, with the goal of selecting appropriate modes that depend on the propensities of individual faculty (e.g., some may prefer to do mostly lecturing; others, mostly group work around problems they pose in class), the nature of the students in their classes, the types of classes, and the learning goals of faculty members and students. Faculty will use various modes of instruction only when there is a clear understanding that if student ratings of faculty effectiveness temporarily drop as a result of the experimentation (e.g., an attempt at cooperative learning does not work as well as expected), there will be no negative consequences for their promotion, tenure, or salary decisions. Faculty members should be free to experiment with different teaching and learning approaches without fear of reprisal. Teaching evaluations should be tailored to the different modes of instruction because students will have qualitatively different learning experiences in large lecture classes, laboratory classes, and seminars. For these reasons among others, student evaluations should not be used as the sole criterion for promotion and tenure. Moreover, student evaluations should include items representing all modes of instruction. Evidence of student learning, samples of student

work, syllabi, and evaluations by peer faculty are important sources of data when evaluating faculty members' teaching effectiveness.

6. To encourage diverse points of view in college classrooms, administrators consider diversity issues in hiring and retention decisions.

The quality of teaching and learning may be biased if diverse points of view are not represented in the classrooms of academic departments of psychology. A good way to create diversity of views in classrooms is to ensure that students learn from a diverse faculty. Thus, all aspects of diversity should be considered when making decisions about hiring and retaining faculty.

7. Administrative support is essential to foster positive relationships among high schools, community colleges, four-year institutions, and graduate and professional schools.

Students arrive on campus from a wide range of backgrounds. To ensure that they are prepared to learn, administrators should work cooperatively with "feeder schools" and with those programs that our students aspire to attend after graduation, including graduate and professional schools.

QUALITY PRINCIPLE 5: Policymakers and the general public understand why psychological literacy is necessary for informed citizens and an effective workforce.

Principles for quality in teaching and learning need support outside of academia. We need public policies and informed citizens to support improvement in undergraduate education.

Recommendations

1. To affect change in the perceptions of the general public and policymakers, all psychologists develop and espouse the concept of psychologically literate citizens. They then convey this message so that policymakers and the general public will understand that being psychologically literate is similar to being able to read or use numbers in thinking.

Psychologically literate citizens have a well-defined vocabulary and basic knowledge of the critical subject matter of psychology. They value the intellectual challenges required to use scientific thinking and the disciplined analysis of information to evaluate alternative courses of action. They act ethically. They recognize and foster diversity. They are insightful and reflective about their own and others' behavior and mental processes. Psychologically literate citizens know how to cooperate and to help a group come to consensus, and they can discriminate between science and pseudoscience. They can apply their knowledge of psychological science to a broad range of situations, such as making educational decisions, assisting older adults with retirement planning, using appropriate disciplinary practices with their children, applying research findings to a problem, and using leadership skills in group settings. Literacy in psychology will help individuals, families, and larger groups in countless ways. The general public and policymakers need to understand and value what psychologists know and do. Psychology educators and their students have a responsibility to educate the media on the accurate depiction of psychological science and to encourage public policymakers to use findings from psychological research when forming policies.

2. Psychologists call on the media for accurate depictions of psychological science and on policymakers to use psychologists' findings to inform public policies.

For the most part, the general public, including policymakers, misunderstand psychology, thinking that it is a profession that helps emotionally disturbed people cope with their problems or that deals with the paranormal. These misunderstandings are not surprising given the widespread images of psychologists in the media, where they are very rarely shown as scientists and practitioners who apply psychological research. APA urges the media to more accurately depict the science of psychology and urges public policymakers to use psychologists' research findings when crafting public policies and deciding how to act in the public good.

CONCLUSIONS

Taken together, these principles offer recommendations that will have positive and long-lasting effects on the millions of students worldwide who enroll in undergraduate psychology classes. They will advance psychology in ways "that benefit society and improve people's lives" (APA, 2008). APA calls upon all of the stakeholders in undergraduate education—students, faculty, departments, academic administrators, public policymakers, and the general public—to adopt these principles for quality teaching and learning.

For additional information about these principles and related topics, please see the edited book *Undergraduate Education in Psychology: A Blueprint for the Future of the Discipline* (Halpern, 2010), which was produced in conjunction with these *Principles for Quality Undergraduate Education in Psychology.*

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AMERICAN PSYCHOLOGICAL ASSOCIATION

APA Introductory Psychology Initiative (IPI) Student Learning Outcomes for Introductory Psychology

OCTOBER 2021

In an introductory psychology course, students are expected to:

PSYCHOLOGY CONTENT

Identify basic concepts and research findings

1.1 Define and explain basic psychological concepts.

1.2 Interpret research findings related to psychological concepts.

1.3 Apply psychological principles to personal growth and other aspects of everyday life.

SCIENTIFIC THINKING

Solve problems using psychological methods

2.1 Describe the advantages and limitations of research strategies.

2.2 Evaluate, design, or conduct psychological research.

2.3 Draw logical and objective conclusions about behavior and mental processes from empirical evidence.

2.4 Examine how psychological science can be used to counter unsubstantiated statements, opinions, or beliefs.

KEY THEMES

Provide examples of psychology's integrative themes

A. Psychological science relies on empirical evidence and adapts as new data develop.

B. Psychology explains general principles that govern behavior while recognizing individual differences.

C. Psychological, biological, social, and cultural factors influence behavior and mental processes.

D. Psychology values diversity, promotes equity, and fosters inclusion in pursuit of a more just society.

E. Our perceptions and biases filter our experiences of the world through an imperfect personal lens.

F. Applying psychological principles can change our lives, organizations, and communities in positive ways.

G. Ethical principles guide psychology research and practice.

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Principles for Quality Undergraduate Education in Psychology

FEBRUARY 2023

AMERICAN PSYCHOLOGICAL ASSOCIATION

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AMERICAN PSYCHOLOGICAL ASSOCIATION

Principles for Quality Undergraduate Education in Psychology

FEBRUARY 2023

APA Board of Educational Affairs Working Group to Revise the APA Principles for Quality Undergraduate Education in Psychology

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Executive Summary

The American Psychological Association (APA) promotes excellence in psychology education for undergraduate students through the development of principles[1] and guidelines that faculty members, programs, and departments can use to design a quality curricular experience. The overarching goal is to support educators in developing psychologically literate citizens who can apply the principles of psychological science across career paths and in their everyday lives.

The current document delineates a set of principles and recommendations for quality education in psychology. We recognize that *quality* is a broad concept that can be operationally defined in multiple ways. For the purpose of the current document, we define quality education as practices that faculty members, programs, and departments can adopt to facilitate student learning and development in ways that fit their specific institutional needs and missions. The practices we de scribe are informed by integration of available research (e.g., scholarship of teaching and learning), diverse educator experience and APA educational policy (e.g., Role of Psychology and APA in Dismantling Systemic Racism Against People of Color in U.S., APA Guidelines for the Undergraduate Psychology Major, the Resolution on Promoting Global Perspectives in U.S. Psychology).

The *Principles for Quality Undergraduate Education in Psychology* is designed to complement, and to be used in conjunction with, the *APA Guidelines for the Undergraduate Psychology Major.* Whereas *Guidelines* describe a set of curricular goals, student learning outcomes, and foundation and baccalaureate indicators of learning progress, the *Quality Principles* define the actions that faculty members, programs, and departments can take, and the ongoing practices they can adopt, to create a high-quality, stimulating, and inclusive learning environment designed to maximize student learning and professional development.

Although there have been considerable growth and changes in the field of psychology, the higher education landscape, the job market, and our global society since *Principles for Quality Undergraduate Education in Psychology* were adopted as policy by the APA Council of Representatives in 2011, many of the fundamental components that define a quality education remain unchanged. The goal of this revision was to build on the strong foundation of the original document, to be responsive to feedback from educators regarding the usability and value of the *Quality Principles*, and to update the document so that it reflects current knowledge and best practices. Finally, although the *Quality Principles* are designed to be aspirational rather than prescriptive, this revision focused on creating recommendations that interested faculty members, programs, and departments should be able to adopt across a range of institutional settings.

[1]In the context of this document, the term principles may be interpreted the same way as the term guidelines, which is used to describe recommendations that are aspirational in intent as provided in APA Association Rule 30-8.1.

Introduction

History of Principles for Quality Undergraduate Education in Psychology

The previous version of the *Principles for Quality Undergraduate Education in Psychology,* approved as APA policy by the APA Council of Representatives in February 2011, was developed by the Board of Educational Affairs (BEA) Steering Committee for the 2008 APA National Conference on Undergraduate Education in Psychology, held in Tacoma, WA. Participants at the 2008 conference articulated a number of recommendations for enhancing the teaching and learning of undergraduate psychology. These principles were patterned after the *Principles for Quality Undergraduate Psychology Programs,* adopted by APA in 1994 and archived in February 2011. They were also informed by several related documents focused on quality improvement in psychology education, such as the *National Standards for High School Psychology Curricula* (APA, 2005) and the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2007). The steering committee comprised:

Diane F. Halpern, *Claremont McKenna College, Conference Chair*
Barry Anton, *University of Puget Sound, APA Board of Directors Liaison*
Bernard C. Beins, *Ithaca College*
Charlie T. Blair-Broeker, *Cedar Falls High School*
Charles L. Brewer, *Furman University, APA Board of Educational Affairs Liaison*
William Buskist, *Auburn University*
Bettina J. Casad, *California Polytechnic Institute, Pomona*
Wallace E. Dixon, Jr., *East Tennessee State University*
Yolanda Y. Harper, *The University of Memphis*
Mary E. Kite, *Ball State University*
Patricia Puccio, *College of DuPage*
Courtney A. Rocheleau, *Appalachian State University*

To ensure that this policy remained a "living document," the *Principles for Quality Undergraduate Education in Psychology* were initially scheduled to expire 10 years from the date of their adoption, in February 2021. This is consistent with provisions of APA Association Rule 30-8.3, requiring cyclical review of approved standards and guidelines within periods not to exceed 10 years. However, due to delays related to the global pandemic, the Policy and Planning Board granted an extension, such that the 2011 guidelines were set to expire in February 2023.

Working Group Selection

A call for nominations to serve on the *Principles for Quality Undergraduate Education in Psychology* working group was circulated in 2021. Members of the APA Committee on Associate and Baccalaureate Education (CABE) prepared a slate of candidates for BEA approval and made a recommendation regarding the chair. Member selection was focused on providing a balance of representation across experience, personal identity characteristics, and type of institution (community college vs. 4-year college or university).

Description of the Revision Process

Overview of the Process

Before their first meeting, the working group invited educators and department heads to submit feedback on the 2011 *Quality Principles*. At their first meeting in August 2021, they reviewed and discussed this feedback and generated a list of resources (see the list below) that they deemed important to review before initiating revisions. The working group met virtually each month between August 2021 and March 2022. Between meetings, working group members reviewed resource documents, worked in pairs to suggest revisions, and reviewed working drafts of the document.

Following legal review and BEA approval, a 60-day public comment period was held in the spring/summer of 2022 and the *Quality Principles* working group reviewed all submitted comments and made additional changes to the draft document as appropriate. In August 2022, the *Quality Principles* working group provided the revised policy document to the Office of the General Counsel for a second legal review, which was followed by a second 60-day public comment period. Again, the *Quality Principles* working group reviewed and discussed all submitted feedback and final revisions were completed. After the Office of the General Counsel completed a final review, BEA reviewed and approved sending the *Quality Principles* to the APA Board of Directors and Council of Representatives. Following review by the APA Board of Directors in December 2022, the APA Council of Representatives approved the revision of the *Quality Principles* in February 2023.

Resources

The working group consulted several APA resources on undergraduate education in their revision of the *APA Principles for Quality Undergraduate Education in Psychology* including the *APA Principles for Quality Undergraduate Psychology Programs* (Adopted by APA in 1994, archived in 2011, published in McGovern & Reich, 1996), the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2013), the *APA Guide to College Teaching: Essential Tools and Techniques Based on Psychological Science* (APA, 2020), *Strengthening the Common Core of the Introductory Psychology Course* (APA, 2014), and the *Assessment of Outcomes of the Introductory Course in Psychology* (APA Working Group on Introductory Psychology Assessment, 2017). The working group also drew from the *APA Equity, Diversity, and Inclusion Framework* (APA, 2021a) and *Role of Psychology and APA in Dismantling Systemic Racism Against People of Color in U.S.* (APA, 2021b).

The working group also reviewed quality principles, guidelines, and curriculum standards from other STEM and related disciplines including the *American Chemical Society Guidelines for Bachelor's Degree Programs* (ACS, 2015), *Characteristics of Exemplary Life Science Teaching* (National Association of Biology Teachers, 2012), *Undergraduate Guidelines Workgroup Curriculum Guidelines for Undergraduate Programs in Statistical Science* (American Statistical Association, 2014), the *Committee on the Undergraduate Program in Mathematics Curriculum Guide to Majors in the Mathematical Sciences* (Math Association of America, 2015) and *The*

Sociology Major in the Changing Landscape of Higher Education: Curriculum, Careers, and Online Learning (Pike et al., 2017).

Principles Guiding the Revision Process

Several guiding principles informed the revisions made to this document. First and foremost, the working group wanted the document to provide added value to psychology faculty members, programs, and departments engaged in undergraduate education over and above what is provided by the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2013). As noted in the *Executive Summary,* whereas *Guidelines* focus on curriculum goals, student learning outcomes, and indicators, the *Quality Principles* describe the essential elements of a quality learning environment. However, the feedback the working group received from faculty members and department heads suggested some challenges in integrating these two documents. Thus, one goal of the revision process was to directly address these challenges.

Second, the working group wanted to create a policy document characterized by clear recommendations that psychology faculty members, programs, and departments could enact across a range of institutional contexts. Multiple intersecting forces can impact the quality of a learning experience, from individual students' historical and current contexts to broader societal views about the value of education and psychology. Therefore, for this revision, the working group focused on identifying principles that could govern the specific actions that psychology faculty members, programs, and departments can take at a local level to deliver a quality psychology education.

Revisions were also guided by the principle that psychology education should be responsive to ongoing research that advances disciplinary knowledge and informs best practices in teaching and learning. Additionally, increased recognition of the ways in which systemic oppression has harmed people and communities of color informed the working group's focus on dismantling racism and other forms of discrimination and bias in psychology education. Finally, informed by APA's *Resolution on Promoting Global Perspectives in U.S. Psychology* (APA, 2017b), the document acknowledges the importance of promoting a globally focused curriculum.

Summary of Changes

The 2011 version of the *Principles for Quality Undergraduate Education in Psychology* identified five overarching principles of a quality education that included responsibilities of (1) students, (2) faculty members, (3) psychology departments and programs, (4) administrators, and (5) policy makers and the general public. Specific recommendations were generated for each principle, yielding a total of 30 recommendations.

In this 2023 revision, although the document acknowledges the broader ecological framework that influences educational quality, the principles and recommendations were narrowed to focus primarily on the responsibilities that faculty members, psychology programs, and departments have in creating a quality education. This choice was informed by the desire to create a practical guide with actionable items that educators could adopt across institutional contexts.

Revisions were also focused on removing redundancies between the *Quality Principles* and *Guidelines.* For example, several recommendations from the 2011 version focused on knowledge and skills that faculty should teach and/or students should learn or develop (e.g., psychological literacy, time management skills, communication skills, use of feedback to improve performance, working with diverse perspectives and viewpoints). Instead of retaining these items that represented a subset of the educational goals and student learning outcomes described in *Guidelines*, the *Quality Principles* now make specific reference to how *Guidelines* can be used to create a coherent and consistent curriculum.

The final *Quality Principles* document consists of two overarching principles and 15 recommendations.

Quality Principles and Recommendations

The following principles and recommendations are designed to describe best practices that **faculty members, programs, and departments** can adopt to facilitate student learning and development in psychological science, in ways that best fit their specific institutional needs and missions. This document is designed to complement, and to be used in conjunction with, the *APA Guidelines for the Undergraduate Psychology Major.* Whereas *Guidelines* describe a set of curricular goals, student learning outcomes, and foundation and baccalaureate indicators of learning progress, the *Quality Principles* define the actions that faculty members, programs, and departments can take, and the ongoing practices they can adopt, to create a high-quality, stimulating, and inclusive learning environment designed to maximize student learning and professional development.

Although this document defines quality principles and offers recommendations specifically for faculty members, psychology programs, and psychology departments, it is essential to acknowledge that multiple, intersecting forces outside of these domains impact the quality of undergraduate learning. At the person level, learning outcomes are dependent on students' readiness and willingness to learn that are influenced by a variety of historical and current contextual factors. Institutional policies and resource allocation significantly influence the environment in which faculty members, programs, and departments operate. Moreover, at the very broadest level, the public's perception of psychology, the value society places on education, and the actions of policymakers all affect education quality. Through their multiple roles as scientists, educators, health service providers, and consultants, psychologists have the expertise to demonstrate the value of psychology as a discipline grounded in science with the potential to solve society's biggest challenges and improve people's lives.

Quality Principle and Recommendations for Faculty Members

Quality Principle 1

Faculty members strive to be ethical (APA, 2017a), culturally responsive scientist–educators who use their educational background, ongoing professional development, pedagogical expertise, and lived experience to teach, mentor, and support students with diverse and intersecting identities.

RECOMMENDATIONS

1. **Faculty members recognize that they must have the current and relevant expertise needed to teach in their content area.**

   Consistent with the APA Ethical Principles of Psychologists and Code of Conduct (APA, 2017a), educators teach within the boundaries of their competence. Although faculty members most often teach in areas consistent with their educational background and training, they may also develop expertise through ongoing professional development and research.

   Faculty are intentional about incorporating diversity, science, and a global perspective into their courses. They engage in ongoing professional development that promotes equity, diversity, fairness, and inclusion in their course policies and content.

2. **Faculty members understand and apply evidence-based learning principles and help students develop an understanding of the science of learning that students can apply to their own lives.**

   Faculty members recognize and correct any biases or misconceptions they have about how learning occurs, draw on the current literature on the science of learning to inform their teaching, and employ methods that promote deep understanding and long-lasting knowledge. Faculty members also recognize the limitations of the science of learning, including the lack of diversity in this body of research.

   Faculty members are aware of new technologies that help students successfully achieve learning outcomes, especially those that become widely adopted. Understanding how a specific technological teaching tool draws on scientific principles of learning may help faculty members make informed decisions about whether to adopt them.

   Finally, faculty members recognize and correct misconceptions that students commonly hold about how learning occurs and support student learning practices that are evidence-based.

3. **Faculty members seek to create accessible, inclusive, and flexible curriculum that aims to address the expected variability among learners and contexts.**

   Faculty members are intentional in selecting modes of teaching and delivery that will maximize learning for students with a diverse range of abilities and enable an inclusive learning environment. Working with disability advocacy offices will help faculty members use modes of teaching and delivery that meet not only the letter of the law, but also its spirit.

4. **Faculty members engage in continuous assessment of the success of their instruction and use that information to refine instructional practices to enhance student success.**

   Faculty members engage in ongoing evaluation of the extent to which students are achieving defined student learning outcomes or course objectives and determine if current teaching practices are effective and equitable. Additionally, faculty members actively seek, and are responsive to, formative and summative feedback on all facets of their teaching, including course policies and content, teaching and evaluation strategies, pace, and climate.

   The methods and sources (e.g., student, peer) that faculty members use to evaluate their instruction and collect feedback are guided by available data and best practices.

   Faculty members seek mentorship and professional development opportunities to identify and implement effective teaching practices.

   Faculty members also collect summative feedback from students, reflect on that feedback, and make changes to course design and teaching practices, when appropriate. Faculty consider collecting formative feedback (e.g., midsemester) and make incremental adjustments as needed.

   Faculty members engage in ongoing professional development to enhance their learning about equity, diversity, fairness, and inclusion as they relate to instructional practices to enhance student success.

5. **Faculty members recognize the long history of discriminatory policies and practices embedded in higher education; engage in sustained efforts to dismantle these oppressive systems; and actively promote fairness, equity, diversity, and inclusion in their teaching practices.**

   Faculty members work to create an inclusive learning environment in their classrooms and ensure that their teaching methods and course policies are equitable, fair, culturally relevant and accessible.

   Faculty members engage in the systematic review of instructional materials to identify and acknowledge psychology's historical role in perpetuating racism and prejudice and discrimination related to other identity characteristics. They strive for a diverse representation in the theorists and researchers whose work they draw from in their teaching and recognize the role of intersecting social identities and impact of institutionalized oppression/power dynamics on identity groups, when discussing course material. Faculty members also demonstrate how psychology and psychological science can be, and has been, used to address and combat racism and the related psychological consequences, appropriately crediting scholars and practitioners of color engaged in this work.

   Faculty members recognize that the body of knowledge frequently represented in course materials disproportionately reflects research conducted with Western, educated, industrialized, rich, and democratic (WEIRD) populations (Henrich et al., 2010) that may also exclude other historically underrepresented groups, acknowledge those limitations, and strive to represent global perspectives in their curriculum.

   Using instructional materials and methods that are accessible to all learners is another essential component of inclusive teaching. Barriers to access may include differences in abilities and socioeconomic status, as well as technological inequities (i.e., differences among students in their experience with technology and access to high-speed internet and reliable devices). Faculty members strive to ensure that all students have access to the course materials and technology required for their class.

6. **Faculty members provide support and guidance to students.**

   Although faculty responsibilities may vary considerably within and across institutions (e.g., advising responsibilities; expectations about office hours), all faculty members are accessible to the students they teach. Faculty members also strive to cultivate psychological safety in their faculty-student relationships.

   When requiring students to use course technology, faculty members provide the instruction and support students need, which may include guiding students toward appropriate institutional resources.

Faculty members are also encouraged to support students in their career aspirations and professional development. When faculty members do not have the professional experience or expertise to advise students about how to prepare for and enter the workforce immediately after graduation, they are encouraged to refer students to campus faculty and staff members who have professional training in this area. Faculty members recognize that minoritized students who hold oppressed identities may need enhanced support given the multiple barriers to learning and advancement in higher education spaces they often face. Faculty members seek to use cultural humility and awareness in an effort to tailor support and guidance to meet students' unique needs, minimize barriers, and provide equitable access to support.

Quality Principle and Recommendations for Psychology Programs and Departments

Quality Principle 2

Psychology departments and programs design their curriculum, offer cocurricular activities, and create learning environments that will adequately prepare students to achieve the knowledge and skills expected of undergraduates engaged in the study of psychology.

RECOMMENDATIONS

1. **Psychology departments and programs provide a coherent globally informed curriculum with learning goals and outcomes informed by APA's policy documents on undergraduate education.**

   Programs offer an introductory course in psychology that provides an overview of the core content areas of the discipline (e.g., biological, cognitive, developmental, social and personality, and mental and physical health), emphasizes how scientific inquiry serves as a foundation for all content, describes the different contexts in which psychological science is applied (e.g., occupational, educational, and legal settings), and highlights cross-content integrative themes (APA, 2021c). The curriculum is also designed to prepare students to achieve the foundation- and baccalaureate-level knowledge and skills delineated in the *APA Guidelines for the Undergraduate Psychology Major.* Although these policy documents provide guidance regarding the student learning outcomes psychology majors are expected to achieve, psychology departments and programs are encouraged to engage in curriculum planning that also reflects program and institutional missions.

   Programs and departments learn from APA's resolutions on the ways in which the field of psychology can work toward dismantling systemic racism against people of color in U.S. educational contexts, including teaching about psychology's historical role in promoting, perpetuating, and failing to challenge racism (APA, 2021b), and promote global perspectives in psychology education (APA, 2017b). Programs and departments support the adoption of coursework, textbooks, and supplementary resources that provide culturally responsive paradigms for understanding psychology, emphasize the impacts of structural racism, and highlight the contributions of minoritized psychologists, including those living outside of the United States.

2. **Courses are sequenced in ways that allow upper division courses to build on concepts that are introduced in lower division courses.**

   Students who gain foundational knowledge and develop basic skills before being exposed to more advanced concepts are more prepared to deeply

engage with complex material and effectively respond to challenges. Thus, students may benefit from taking coursework in scientific methods early in the curriculum so that they can use the concepts and skills acquired in these courses to evaluate the material more critically in advanced coursework.

A quality curriculum in undergraduate education culminates with a capstone experience designed to encourage students to reflect on and integrate the knowledge and skills they have acquired as a psychology major.

3. **Psychology departments and programs recognize that their faculty must be sufficient in size and expertise to teach the depth and breadth of courses needed for students to achieve expected learning goals and outcomes.**

   Psychology departments and programs have sufficient faculty to support students in attaining the knowledge and skills expected of undergraduate psychology majors as defined by the *APA Guidelines for the Undergraduate Psychology Major.* To the degree possible, faculty expertise reflects the curricular diversity of the discipline. Psychology departments and programs also leverage community resources to provide diversity of perspectives, experiences, and identities to complement faculty expertise.

4. **Psychology departments and programs develop policies and procedures that support quality teaching.**

   Psychology departments and programs aim to ensure that all faculty, including adjunct faculty members and graduate students, have adequate preparation and supervision to serve in their roles. All faculty members also have the opportunity to engage in professional development and continuing education to stay abreast of advances in teaching pedagogy and strategy.

   Psychology departments and programs support ongoing assessment of faculty teaching effectiveness and encourage changes and innovations that may improve student learning outcomes. Psychology departments and programs recognize and consider demonstrated biases in student evaluations of teaching related to irrelevant criteria including gender, racialized identity, and course subject. Finally, psychology departments and programs strive to balance the demands on faculty so that faculty members have sufficient resources to devote to quality teaching. They develop policies and practices aimed at preventing educator burnout, increasing well-being, and supporting self-care. Service assignments are fairly and equitably distributed.

5. **Psychology departments and programs provide experiential learning opportunities and support student involvement in cocurricular activities.**

   Student learning is reinforced and enhanced through activities that require the application of knowledge and skills to "real-world" challenges and contexts. Moreover, cocurricular activities may enrich student learning and facilitate the development of essential skills such as leadership, collaboration, community engagement, communication, interpersonal skills, and time management.

   Psychology departments and programs provide opportunities for students to participate in research activities, attend colloquia, attend and present at local, regional or national conferences, engage in service-learning opportunities, and complete internships. Psychology departments and programs are also encouraged to develop and support social and academic groups, clubs, and honor societies that allow students to engage more deeply with the discipline. Students are also provided with the flexibility to take advantage of institution-level activities that enrich learning, such as study-abroad and leadership development programs.

   Psychology departments and programs are intentional and explicit in building community partnerships where the quality of experiential learning programs/trainings will promote the values of the home program and provide psychologically safe and fully accessible experiential learning opportunities. Finally, events that promote positive climate, such as gatherings that welcome new students or celebrate student success (e.g., graduation ceremonies), are highly encouraged.

6. **Psychology departments and programs promote equity, diversity, and inclusion and engage in efforts to dismantle systemic oppression and reduce educational inequities.**

   Psychology departments and programs engage in systematic, coherent, and ongoing efforts to recruit and retain faculty members and students with diverse and intersecting identities. Departments and programs also work collaboratively, with student input and feedback, to develop policies and practices aimed at dismantling racism and other systemic forces of oppression while creating a safe and inclusive learning environment where individuals are free from harassment and discrimination. Psychology departments and programs also provide, and communicate to students, the ways in which students may raise concerns and file complaints.

Psychology departments and programs offer evidence-based training and professional development opportunities to raise awareness of and mitigate against, biases that negatively affect learning among students of color and students from other marginalized communities. Ongoing training and professional development are also essential to retain and promote the success of faculty from marginalized communities.

7. **Psychology departments and programs provide the advising and mentorship psychology majors need to pursue academic and career goals.**

   Providing a high-quality education in psychology through attentive, personalized advising and mentorship may help to attract a talented and diverse workforce into the discipline. Psychology departments foster opportunities for mentoring networks or other resources that work to provide adequate representation of psychologists with intersecting identities.

   However, it is equally, if not more, important for psychology departments and programs to provide advising and mentorship to the large percentage of psychology majors who do not pursue graduate education in psychology.

   Psychology departments and programs provide students with a developmentally sequenced plan that includes the advising, coursework, and resources they need to reflect on their interests and strengths, identify possible career paths, and select courses, areas of focus or minors, and engage in cocurricular activities that will prepare them for career success. This may include specific courses aimed at promoting career engagement or graduate study.

   Despite the high value employers across a range of sectors place on the knowledge and skills students develop in undergraduate psychology programs, students often need assistance in identifying and marketing these attributes. Faculty members, psychology departments, and programs are encouraged to explicitly identify the skills students are expected to acquire through specific assignments and curricular activities to increase students' awareness of their skill development (Naufel et al., 2018).

8. **Psychology departments and programs engage in a periodic practice of program review aimed at ensuring that students are achieving expected learning outcomes.**

   The primary role of a department or program in psychological science is to ensure that faculty are engaged in sound teaching practices that reflect the discipline of psychology. To fully realize this goal, departments periodically engage in a review of their practices and resources. Departments evaluate their effectiveness in achieving expected student learning outcomes, infusing diversity, science and a global perspective into the curriculum, promoting an inclusive and equitable environment, and helping students to achieve their educational and career goals postgraduation. Student feedback and input is an essential component of this process.

9. **Psychology departments and programs foster positive relationships with other institutions to support educational and career pathways for students.**

   Building strong, collaborative relationships across institutions of learning (among high schools, community colleges, and 4-year institutions) that promote access and support student advancement is an essential step toward diversifying the pathway into psychology. Curriculum alignment, and faculty-informed articulation agreements[2] between 2- and 4-year institutions, may boost student retention and promote academic success.

   Cultivating partnerships with community organizations and local employers can result in rich applied learning opportunities that may promote a range of the desired student learning outcomes outlined in the *APA Guidelines for the Undergraduate Psychology Major* (e.g., gain experience and develop skills in activities that strengthen preparation for job entry or graduate school admission, participate in activities that promote civic, social, and/or global outcomes that benefit communities).

[2]Articulation agreements specify the courses completed at a community college that will be considered for acceptance at the bachelor's degree level, as well the standard of performance (e.g., grade) that must be met in order for the credits to be accepted (U.S. Department of Education, 2008).

Conclusion

These principles offer recommendations that faculty members, programs, and departments may use to create a high-quality, stimulating, and inclusive learning environment. Within this context, students will be able to achieve the curricular goals, student learning outcomes, and foundation and baccalaureate indicators of learning progress delineated in the *APA Guidelines for the Undergraduate Psychology Major.* Taken together, the Quality Principles and Undergraduate Guidelines are designed to support educators promoting "the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives" (APA, 2019).

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APPENDIX A

List of Quality Principles and Recommendations

Quality Principle and Recommendations for Faculty Members

Quality Principle 1

Faculty members strive to be ethical (APA, 2017), culturally responsive scientist–educators who use their educational background, ongoing professional development, pedagogical expertise, and lived experience to teach, mentor, and support students with diverse and intersecting identities.

RECOMMENDATIONS

1. Faculty members recognize that they must have the current and relevant expertise needed to teach in their content area.
2. Faculty members understand and apply evidence-based learning principles and help students develop an understanding of the science of learning that students can apply to their own lives.
3. Faculty members seek to create accessible, inclusive, and flexible curriculum that aims to address the expected variability among learners and contexts.
4. Faculty members engage in continuous assessment of the success of their instruction and use that information to refine instructional practices to enhance student success.
5. Faculty members recognize the long history of discriminatory policies and practices embedded in higher education, engage in sustained efforts to dismantle these oppressive systems, and actively promote fairness, equity, diversity, and inclusion in their teaching practices.
6. Faculty members provide support and guidance to students.

Quality Principle and Recommendations for Psychology Programs and Departments

Quality Principle 2

Psychology departments and programs design their curriculum, offer cocurricular activities, and create learning environments that will adequately prepare students to achieve the knowledge and skills expected of undergraduates engaged in the study of psychology.

RECOMMENDATIONS

1. Psychology departments and programs provide a coherent globally informed curriculum with learning goals and outcomes informed by APA's policy documents on undergraduate education.
2. Courses are sequenced in ways that allow upper division courses to build on concepts that are introduced in lower division courses.
3. Psychology departments and programs recognize that their faculty must be sufficient in size and expertise to teach the depth and breadth of courses needed for students to achieve expected learning goals and outcomes.
4. Psychology departments and programs develop policies and procedures that support quality teaching.
5. Psychology departments and programs provide experiential learning opportunities and support student involvement in cocurricular activities.
6. Psychology departments and programs promote equity, diversity, and inclusion and engage in efforts to dismantle systemic oppression and reduce educational inequities.
7. Psychology departments and programs provide the advising and mentorship psychology majors need to pursue academic and career goals.
8. Psychology departments and programs engage in a periodic practice of program review aimed at ensuring that students are achieving expected learning outcomes.
9. Psychology departments and programs foster positive relationships with other institutions to support educational and career pathways for students.

AMERICAN
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ASSOCIATION

STRENGTHENING **THE COMMON CORE** OF THE INTRODUCTORY PSYCHOLOGY COURSE

AMERICAN PSYCHOLOGICAL ASSOCIATION • MARCH 2014

APA Board of Educational Affairs Working Group on
Strengthening the Common Core of the Introductory Psychology Course

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STRENGTHENING THE COMMON CORE OF THE INTRODUCTORY PSYCHOLOGY COURSE

Participants at the 2008 APA National Conference on Undergraduate Education held at the University of Puget Sound articulated several high-priority recommendations that were later published in *Undergraduate Education in Psychology: A Blueprint for the Future of the Discipline* (Halpern, 2010) and embodied in the *Principles for Quality Undergraduate Education in Psychology* (APA, 2011). Conference participants made two strong recommendations about the importance of the introductory psychology course (henceforth Intro Psych). The first was that the Intro Psych course should be a prerequisite for all other psychology courses. The second was that the Intro Psych course should mirror the core model for the psychology major.

To address these recommendations, APA's Board of Educational Affairs (BEA) established the Working Group to Strengthen the Common Core of the Introductory Psychology Course. BEA charged the working group to:

1. Examine the common core of the Intro Psych course at the college level, including the content, outcomes, possibility of a laboratory component, and implications for a major versus a nonmajor directed course.
2. Recommend potential action steps to BEA on strengthening the common core.

BACKGROUND

Psychology has been an active scientific area for more than 100 years (Shaughnessy J. J., Zechmeister, E. B., & Zechmeister, J. S., 2009). The field has made significant technological and methodological innovations, with new areas evolving and preexisting areas merging. Yet, most Intro Psych textbooks are composed of the same 14–16 chapters (Griggs & Jackson, 2013), although the amount of coverage of each topic has varied somewhat over the last three decades (Griggs, 2014). Correspondingly, the structure of the Intro Psych course has remained relatively consistent.

Although there have been major studies of the psychology curriculum over the years (e.g., Brewer et al., 1993; Perlman & McCann, 1999; Stoloff et al., 2010), most did not focus on the content or organization of Intro Psych. However, one notable exception, Homa and colleagues (2013) examined the objectives and content of Intro Psych courses and found considerable variability nationally, with some courses focused more on psychology as a science, and others focused on psychology as a means of self-understanding and improvement.

Psychological research explores the enormous complexity of human behavior and contributes in important ways to solving a wide range of problems. For example, many pressing contemporary social problems (and likely problems of the next century) reflect, to an appreciable extent, modifiable cognitions, emotions, and behaviors (Zimbardo, 2004). These problems include prejudice and discrimination, exploitation and violence, depression and dysphoria, child neglect and parental divorce, and the rising medical costs associated with behavioral and cultural factors. More young people die or become disabled from unfortunate behavioral choices (e.g., drug use, gang violence, drinking and driving) than from all diseases combined (Gurung, 2014). In addition, many intriguing scientific problems humankind faces—ranging from the

neural basis of thought, emotion, and a sense of the self to the cognitive operations underlying effective problem solving and optimal decision making; the sociocultural factors that make education effective and enjoyable; and the best means of dealing with life's stressors—fall within the purview of psychology (Zimbardo, 2004).

At the same time, psychological science has a demonstrated track record of enhancing human functioning at both the micro and macro levels (e.g., APA, 2005; 2010). The procedures for optimizing human potential—successful parenting and aging, athletic and artistic flow, extraordinary memory and reasoning, maximizing the development of intelligence, environmental conservation—are but a few topics that have received attention in psychological laboratories.

The contemporary Intro Psych course structure may not accurately reflect the discipline as it stands today. Specifically, most textbooks still treat different areas of psychology (e.g., social, personality) as if they are distinct and studied in isolation of other areas. Whereas, psychology, as represented in the *National Standards for High School Psychology Curricula* (henceforth, *Standards*; APA, 2011) and *Guidelines for the Undergraduate Psychology Major* (henceforth, *Guidelines*; APA, 2007; 2013), is divided into "domains." However, with few exceptions, these documents and the concept of domains have not been well translated to textbooks.

Few attempts have been made to capture the evolving nature of our discipline. Many contemporary textbooks include sections and

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writing styles that connect areas of the field (e.g., Cacioppo & Freberg, 2013; Myers, 2013; Tavris & Wade, 2001; Weiten, 2012) and begin to reflect domains versus silos. Tavris and Wade (2001) presented one early approach for reconceptualizing psychology, organizing the content of psychology around five major approaches (biological, learning, cognitive, sociocultural, and psychodynamic), and then including a section on "putting the perspectives together." As textbook publishing has changed, it is also possible for individual instructors to personalize their text and create options that include major components of their preferred introductory text but exclude chapters or content they may prefer to emphasize in an alternative or integrative manner.

More recently, Cacioppo (2007) presented another alternative representation of modern psychology. In his view, many of the most exciting advances in psychology today are emerging at the intersections—across traditional training areas within psychology and across disciplines. For example, understanding romantic relationships (a perennial student favorite) can involve neurochemistry (e.g., oxytocin) and social (self-fulfilling prophecies), personality (e.g., traits), and cognitive psychology (e.g., automatic thoughts). Comprehensive understanding of the mind and behavior requires a combination of perspectives. A student cannot develop a comprehensive understanding of behavior by focusing on only a biological or a social perspective (Cacioppo, 2013). No longer simply a collection of independent domains based on historical or administrative distinctions, psychology in the 21st century appears to be becoming an integrative multilevel science. Specifically, there has been a trend in the direction of partitioning the science of mind and behavior into different levels of organization (e.g. biological, cognitive, and social), with each level contributing to our understanding of human behavior. Additionally, there are cross-cutting perspectives that offer valuable insights into the mind and behavior (e.g., cross-cultural, diversity, individual variations).

In this report, we summarize previous efforts to create a common core for the Intro Psych course and address the question of whether such a core is desirable. We first review historical attempts to create a common core and research on what is taught in Intro Psych. Then, based on a 2-year review of extant information on the Intro Psych course from a variety of sources (e.g., Homa et al., 2013, publisher surveys, expert teachers), we advance five recommendations regarding Intro Psych. These recommendations are intended to help teachers of Intro Psych design a high-quality foundation for the discipline of psychology as it exists today.

HISTORICAL ATTEMPTS TO CREATE A COMMON CORE

There have been many calls for national guidelines and/or a common core relating to different aspects of Intro Psych. More than 70 years ago, Wolfle (1942, p. 687) suggested Intro Psych should have five goals: (a) teach facts and principles of psychology, (b) develop scientific methods or habits of critical thoughts, (c) provide better ability in making personal adjustments, (d) prepare students for later courses or interest them in psychology, and (e) teach what psychology is and is not or eliminate popular superstitions. Given the emergence of psychology as a hub science (Boyack et al., 2005), the goal of providing nonmajors as well as majors an appreciation for the reach of psychological science into nearly every facet of human life could be added to this list. More recently, Smith and Fineburg (2006) drew attention to the lack of consistency in Intro Psych and suggested using the *Standards* and the *Guidelines* to help shape Intro Psych.

The *Standards* (APA, 2011), first published by APA in 1999 and revised in 2005 and 2011, defines psychology content for the high school classroom. In the document, the standards are structured as seven overarching content domains (i.e., scientific inquiry, biopsychological, development and learning, sociocultural context, cognition, individual differences, and applications of psychological science), with each domain including standard areas that cover the breadth of Intro Psych. Each domain's standard areas include relevant unit topics such that by instructors' teaching at least one unit from each domain, students in high school psychology courses receive a representative picture of contemporary psychology. The *Standards* could consequently also be used to organize, plan, and direct college-level Intro Psych (Smith & Fineburg, 2006).

The *Guidelines* (APA, 2007) captures "a set of optimal expectations for performance at the completion of the baccalaureate degree by students who major in psychology. The document outlines 10 goals and suggested learning outcomes that represent reasonable departmental expectations for the undergraduate psychology major across educational contexts" (APA, 2007, p. v).

The most recent revision of the *Guidelines—APA Guidelines for the Undergraduate Psychology Major 2.0* (APA, 2013, hereafter *Guidelines 2.0*) — incorporates changes that reflect emerging best practices and integrates psychology's work with benchmarking scholarship in higher education. *Guidelines 2.0* abandoned the original distinction between psychology-focused skills and psychology skills that enhance liberal arts development. Instead, the new *Guidelines 2.0* describes five inclusive goals for the undergraduate major that represent more robust learning and assessment activities (APA, 2013). Like the *Standards, Guidelines 2.0* (especially Outcome 1.2a, p. 18) can also help shape a common core for Intro Psych.

Conceivably, Intro Psych could mirror the core model for the psychology major, but there is little consistency in requirements for the major (Stoloff et al., 2010). The undergraduate psychology major differs markedly from one institution to another in areas such as semester hours needed, the implementation of capstone courses, or even required and elective class topics. Dunn and colleagues (2010) suggested a curricular model for the psychology major and recommended that Intro Psych mirror the same model. But their recommendation from the 2008 APA National Conference on Undergraduate Education remains just that—a recommendation without implementation or other action.

Given the emergence of psychology as a hub science (Boyack et al., 2005), the goal of providing nonmajors as well as majors an appreciation for the reach of psychological science into nearly every facet of human life could be added to this list.

SHOULD INTRO PSYCH COURSES HAVE GREATER COMMONALITY?

In short, yes. "Given the ubiquitous relevance of psychology to other majors and fields, most jobs, and the world in general, as well as the many contributions an understanding of psychology can have to personal growth and development, all students need to receive a common core of content" (Dunn et al., 2010, p. 59).

Intro Psych enrolls between 1.2 and 1.6 million students annually (Steuer & Ham, 2008); it is the second most popular college course in the nation, second only to English composition (Adelman, 2004). Intro Psych is required for the psychology major in 98% of U.S. colleges (Stoloff et al., 2010) and has been taken in high school by 60% of college students (Adelman, 2004). Intro Psych serves not only as a prerequisite for other courses in the discipline, but for many college students, as their only formal exposure to psychological science.

Greater commonality across courses provides a singular message to students and the public about what constitutes the field of psychology. High commonality across all institutions offering the course maintains consistency in what majors and students taking the course as a general education requirement receive. "Internal and external pressures on the discipline … suggest a need for a common, coherent core curriculum for the undergraduate psychology major" (Dunn et al., 2010, p. 53). Having more conceptual consistency for Intro Psych will map nicely onto calls for a common curriculum (for the major), the use of quality benchmarks (Dunn, McCarthy, Baker, Halonen, & Hill, 2007), and the *Guidelines 2.0* (APA, 2013). Having conceptual consistency in Intro Psych should also help students prepare for the forthcoming behavioral components in entrance exams for medical school (i.e., MCAT 2015).

There is also an additional compelling reason to have greater conceptual consistency. Currently, psychology lacks a universal assessment of knowledge. Assessment, whether across instructors or across time, at the department level or across institutions, necessitates a similar, if not standardized experience. Fields

such as physics have common content assessments such as the Force Concept Inventory (Hestenes, Wells, & Swackhamer, 1992). Chemistry, through the American Chemical Society's Division of Chemical Education Examination Institute, also has examinations used by campuses nationally (**http://chemexams.chem.iastate.edu/about-us**). The *Guidelines 2.0* (APA, 2013) reminds us that the discipline of psychology has three assessment instruments related to content (Psychology Areas Concentration Achievement Test, GRE Subject Test in Psychology, Major Field Test in Psychology), but none of these are commonly used to measure the extent to which Intro Psych students master content. It will benefit the field to have a universal assessment.

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WHAT IS BEING TAUGHT IN THE INTRO PSYCH COURSE?

There is a surprising dearth of information on this point. The majority of research focuses on content analyses of Intro Psych textbooks. Textbooks have little similarity in content and vary in length and comprehensiveness (Griggs, Bujak-Johnson, & Proctor, 2004; Landrum, Gurung, & Spann, 2012). Miller and Gentile (1998) found little consensus among instructor ratings regarding important topics and those topics covered in the class. Our working group found only one published article on whether Intro Psych courses share learning objectives or a common core.

Homa et al. (2013) examined student learning objectives and course content in 158 Intro Psych syllabi. Student learning objectives were mapped to the 2007 version of the *Guidelines.* More than 50% of the syllabi contained objectives specific to the science and application of psychology (knowledge base, research methods, application). Analysis of content coverage revealed that instructors spent significantly more time on topics related to physiological and cognitive psychology and significantly less time on topics related to the history and scope of psychology, research methods, and developmental psychology. Importantly, this practice occurred across instructors in all specialty areas. Instructors spent a disproportionate amount of time on certain content areas. Additionally, instructors whose expertise was in social and clinical/counseling psychology spent more lecture time on their own areas than on some other content areas.

WORKING GROUP RECOMMENDATIONS

Based on the review of the material described above and in line with the BEA charge, the working group advances the following five recommendations:

1. Foster greater conceptual consistency in Intro Psych content
2. Provide similar content for Intro Psych for both psychology majors and nonmajors
3. Incorporate research experiences in the Intro Psych course
4. Foster special training opportunities for Intro Psych instructors
5. Offer a national assessment plan for Intro Psych

RECOMMENDATION 1
Foster Greater Conceptual Consistency in Intro Psych Content

The working group examined existing domain models for psychology (e.g., *Standards, Guidelines*) and created a new conceptualization of the course with explicit ways to better reflect the contemporary state of the field (e.g., a call for integration). We explicitly used the five domains outlined in the *Guidelines* and each of the seven domains outlined in the *Standards,* although we modified some of the labels and changed where in the model each domain is covered, as described below. To provide instructors and institutions with the maximum amount of flexibility and choice, our recommended model demarcates key conceptual areas of the field instead of specific content. This conceptual level allows individual instructors academic flexibility in topic selection and precludes the need for multiple models while still allowing for the creation of courses that share a common basis.

Intro Psych should be designed to serve as a stand-alone structure (for students taking it as part of a general education requirement) or as the foundation for the psychology major. We build on this metaphor and represent recommendations for teaching the course using an architectural analogy.

The content of Intro Psych can be conceptualized using the schematic of a classic Greek structure complete with pillars—the fundamental precepts of the field (see Figure, p. 14). Consistent with national recommendations for the major and with reviews of the contemporary nature of the field, the working group recommends that instructors of Intro Psych cover the following.

1. THE SCIENTIFIC METHOD: The scientific method is the true foundational building block and core of our discipline. Consistent with Goal 2 of *Guidelines 2.0* (APA, 2013, pp. 20-25), students in Intro Psych should learn skills involving the development of scientific reasoning and problem solving, including effective research methods. Students should learn basic skills and concepts for interpreting behavior, studying research, and applying research design principles to drawing conclusions about behavior.

2. CROSS-CUTTING THEMES: Consistent with our goal to move away from a silo model of psychology to better represent the cross-cutting themes in our field today and to honor calls for infusion of certain topics across the course (e.g., Dunn et al., 2010; Littleford & Nolan, 2013; Trimble, Stevenson, & Worell, 2003), we recommend the following should be covered for each topic included in the course. Just as concrete is a composite of different ingredients, each pillar is composed of different elements that are cross-cutting common themes in the field. This recommendation explicitly elevates the importance of the cross-cutting themes over that of specific content topic areas (e.g., those seen in the pillars that follow). This practice should ensure that important issues such as diversity and ethics are frequently on students' radar versus seen as only solitary requirements, boxes to be checked off as completed.

    - CULTURAL AND SOCIAL DIVERSITY: What are variations across individuals and roles, including those based on age, gender, sexual orientation, gender identity, race, ethnicity, culture, national origin, religion, disability status, language, and socioeconomic status? Choose at least two.
    - ETHICS: What are the major ethical considerations for conducting research or applying the topic or phenomenon?
    - VARIATIONS IN HUMAN FUNCTIONING: What are the positive and negative extremes of the phenomenon being studied? Highlight failures and successful examples.
    - APPLICATIONS: How does the content of the course apply to everyday life? How can the content of the course contribute to improving one's life and addressing societal problems?

3. GENERAL CONTENT COMMONALITY: We recommend that the Intro Psych syllabus include at least two topics from each of the main pillars of the field modified from the domains specified in the *Standards* and *Guidelines 2.0*. The pillars encompass all chapters in psychology textbooks (material within parentheses below) while also mapping onto course names, contemporary political structures, PhD training programs, and departmental core courses. We desired pillar labels to be easily identifiable as major chapters and sections in Intro Psych textbooks, providing students with points of connection that prior domain language did not easily afford.

    - PILLAR 1: BIOLOGICAL (e.g., Neuroscience, Sensation, Consciousness, Motivation)
    - PILLAR 2: COGNITIVE (e.g., Cognition, Memory, Perception)
    - PILLAR 3: DEVELOPMENT (e.g., Learning, Life Span Development, Language)
    - PILLAR 4: SOCIAL AND PERSONALITY (e.g., Social, Personality, Intelligence, Emotion, Multicultural, Gender)
    - PILLAR 5: MENTAL AND PHYSICAL HEALTH (e.g., Abnormal, Health, Therapies)

4. INTEGRATION: The structure is capped by an explicit focus on integration that ties together the different areas into a coherent whole and represents the integrative nature of contemporary psychology. In contrast to focusing on just cognition or biology or social situations, modern psychology integrates different approaches. Just as was recommended for the call for capstone courses for the major (Dunn et al., 2010), the working group recommends that students in Intro Psych receive explicit examples of how the different pillars of psychological science are integrated. For example, conflict in close relationships can be better understood by personality characteristics, social or situational factors, developmental histories of each partner, and underpinning biological factors. The point is to underscore that each pillar/domain has substantive implications for the others in the pursuit of comprehensive psychological explanations and applications. The in-depth study of any one of these domains is essential, but a comprehensive understanding of the mind and

behavior is more likely to be achieved by an integration of what we know and can learn across multiple levels/perspectives than by focusing on individual domains.

We acknowledge this content recommendation may present an imposing task to many faculty members, although many others will already be covering content consistent with our recommendation. These recommendations are textbook agnostic and do not necessitate the adoption of one book over another. Covering two topics from each of five pillars and also including the four common elements whenever possible may seem a difficult task. We believe with better resources for training (see Recommendation 4 below) and reorganizing or pruning the extent to which some topics are currently covered (e.g., an instructor need not always lecture on an entire chapter), this recommendation is manageable. If an instructor keeps to the minimum requirement and selects two topics from each pillar, he or she will still have a little more than a week to cover each topic in a standard 14-15

FIGURE
A Structure for the Undergraduate Introductory Psychology Course

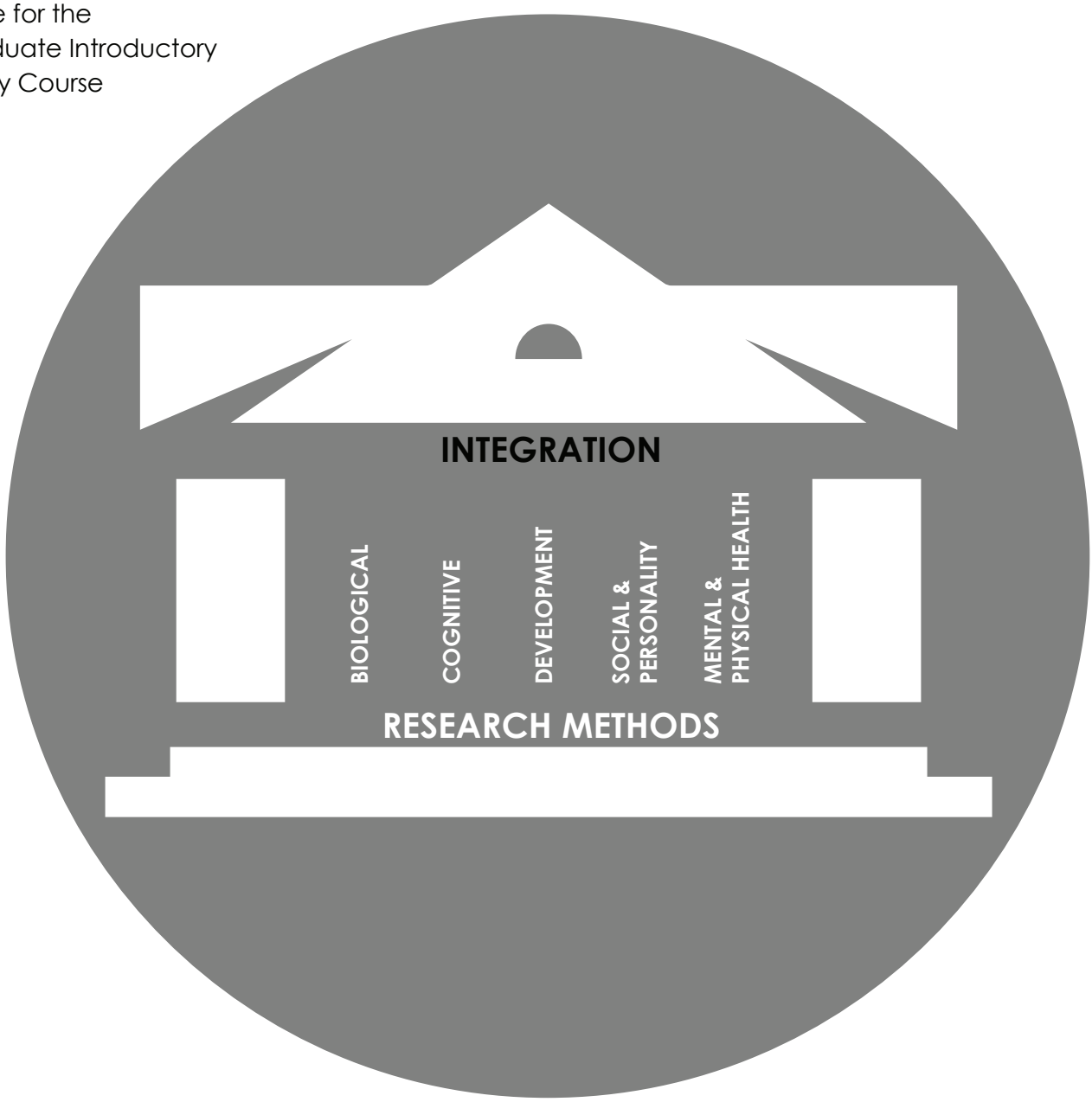

week course. We provide examples for how this recommendation can be followed in Appendixes 1 and 2.

Appendix 1 has a simple assignment to aid with the integration aspect, and Appendix 2 has specific examples of how the four common elements can be conveyed for each topic in each pillar. Whereas an instructor or department may consider teaching the course over two semesters to better capture all elements of the recommended model, there is little evidence to suggest two semesters of Intro Psych benefit student learning (Thornton, 2006), and we envision this model suitable for single-semester delivery.

In offering these recommendations for Intro Psych content selection, the BEA Working Group has tried to strike a nuanced balance by providing flexibility yet guidance. We aimed to avoid either a prescriptive, overly standardized approach on the one hand and the extant idiosyncratic approach on the other. We explicitly linked and meshed our recommendations with existing APA documents such as the *APA Guidelines for the Undergraduate Psychology Major 2.0,* the *APA National Standards for High School Psychology Curricula,* and documents emerging from the Puget Sound conference. Whereas we considered presenting a number of different models for instructors or departments to pick from, we believe one model will better enable national consistency. The working group unanimously agreed that a single but flexible model would better serve instructors of psychology. This decision was supported by feedback on the model from participants at the 2014 NITOP meeting and the 2013 Stanford Psychology One Conference.

That said, we note that our single model has considerable flexibility built into it. There are many topics to pick from within each pillar and a multitude of ways an instructor could feature the recommended common elements. We also provide examples of alternative ways to conceptualize and cover central pillars within the introductory course. There are many different ways of teaching Intro Psych under the banner of one strong single model. We cherish academic freedom and recognize the diversity of faculty members, teaching situations, and student audiences. At the same time, a mature science should be able to agree upon and communicate its unifying conceptual core while embracing diversity.

RECOMMENDATION 2

Provide Similar Content for Intro Psych for Psychology Majors and Nonmajors

The Intro Psych course should contain the same content and experiences for all students at a given institution regardless of why students are taking the course (Halpern, 2010). Although some psychology departments may be tempted to create an Intro Psych course specifically for psychology majors, there is no evidence in the literature that suggests having two courses is needed.

Departments that want a more robust Intro Psych course for their majors may instead modify other requirements and sequencing. For example, although most psychology departments require their majors to take research methods courses early in their undergraduate experience (Stoloff et al., 2010), departments that want to provide more early experiences might be better served by creating another course, such as one that addresses career preparation (Atchley, Hooker, Kroska, & Gilmour, 2012; Brinthaupt, 2010; Thomas & McDaniel, 2004), preparation for the major (Atchley et al., 2012; Dillinger & Landrum, 2002), or writing in the major (Goddard, 2003).

RECOMMENDATION 3
Incorporate Research Experiences in Intro Psych

Introductory courses in most sciences are joined with required laboratories to foster a deeper, integrated understanding of the science. It is not sufficient to learn the laws and equations of chemistry or physics without hands-on experience with classic and contemporary methods. In fact, offering Intro Psych with a lab component has been shown to be effective at increasing scientific literacy (Thieman, Clary, Olson, Dauner, & Ring, 2009), and a call to do so has been issued before (Berthold, Hakala, & Goff, 2003). However, most institutions do not or could not offer a lab component for the Intro Psych course. In a sample of 364 institutions, only 6% offered a lab component (Stoloff et al., 2010). Instructors of introductory psychology courses may not include laboratory experiences in part because of limited resources and in part because the methods and content are thought to be self-evident.

Exposure to research or including a laboratory component in some form in introductory psychology may be particularly important because students arrive with so many misconceptions about the discipline. For instance, many students begin Intro Psych believing that psychology is mostly about psychotherapy and relationships (Stalder & Stec, 2007), when in fact it is also about the brain, information processing, genetics, behavioral plasticity, and social determinants and moderators. Students also tend to arrive believing they already know the causes of behavior. For example, it is commonly said that birds of a feather flock together, but of course it is also commonly said that opposites attract. Everyone knows that two heads are better than one but also that too many cooks spoil the broth. Students are often surprised to learn they hold many logically inconsistent beliefs about the causes of behavior.

The BEA Working Group is well aware that many smaller colleges or departments will not be able to fund separate lab courses or complex research assignments; nonetheless, there are a number of creative ways to integrate more scientific research throughout the course. One option is to use virtual experiments as class assignments. APA maintains the Online Psychology Laboratory (OPL), which can

help with this. Simple assignments using OPL can give Intro Psych students a hands-on taste of doing research.

A second option is to provide lab-related activities through existing departmental resources. For example, students at the University of Chicago are introduced to the discipline through a foundations in psychology course in which faculty work with each student to design a simple study for which they do a literature search, collect data, conduct rudimentary statistical analyses, and prepare a poster for a science fair similar to those seen at psychology national meetings. Other innovative models for integrating lab-like, hands-on experiences for Intro Psych students can be developed with existing faculty, graduate students, and even advanced undergraduates under supervision.

A third option is to provide students an opportunity to participate in upper level students' and faculty research or other experiential learning experiences (Vespia, Wilson-Doenges, Martin, & Radosevich, 2012). A fourth option may be to require students to read, summarize, and critique research articles.

RECOMMENDATION 4

Foster Special Training Opportunities for Intro Psych Instructors

Psychological science has changed dramatically over the past few decades, and Intro Psych should reflect the evolving science of psychology. Faculty members who teach Intro Psych may need to adjust both the content of the course and their methods of teaching it. In particular, it is important for faculty to understand and implement new technologies from clickers to Mechanical Turk (an online system run by Amazon.com to provide quick, easy, and inexpensive access to online research participants; Goodman, Cryder, & Cheema, 2013) in their courses. The teachers of Intro Psych have a variety of existing resources for their continuing education (e.g., Society of Teaching Psychology conferences, APA programming, *Teaching of Psychology, Current Directions, Scholarship of Teaching and Learning in Psychology*), but we believe the larger challenge involves convincing faculty members of the importance of changing their textbooks or teaching styles instead of relying on what has worked reasonably well in the past. Given the strong relationship between faculty development activities, on the one hand, and their influence on changes in teaching behavior, classroom performance, and students' learning outcomes on the other hand (Chism, Palmer, & Price, 2012), additional training opportunities are of great importance.

Below is an initial list of suggestions and resources for faculty members' and teaching assistants' (TAs) ongoing learning to support teaching a contemporary Intro Psych course.

1. **Seek out training in interdisciplinary science (or attend conferences that focus on integrative science).** Interdisciplinary science was the focus of the 2011 APA Education Leadership Conference, and related training is likely to become more available in the future. Some interdisciplinary meetings are quite narrow (intersection of fields), and others are quite broad. Attendance at the latter types of conferences is more likely to foster integration.
2. **Complete an Intro Psych-focused teaching practicum or teaching assistantship during graduate training.** Consider developing a "Teaching of Psycholo-

gy" course for TAs linked to Intro Psych so that the TAs' time with the students serves as a practicum for their teaching.

3. **Attend conference sessions throughout your career relevant to the teaching and learning of psychology.** At present, a variety of excellent training opportunities are available at the APA and APS national conferences and multiple regional teaching conferences. The Society for the Teaching of Psychology held two best practices conferences on Intro Psych. Stanford University is now offering a summer conference that focuses exclusively on Intro Psych. Within these conferences, workshop and exchange opportunities that allow for the sharing of creative ideas about teaching Intro Psych would also be useful. Perhaps a larger challenge is to convince more professors and TAs to attend these types of teaching conferences.
4. **Maintain current knowledge of psychology through journal articles focusing on the theory and scholarship of the practice of teaching.** Some journals already include regular features about teaching Intro Psych (e.g., *APS Observer, Teaching of Psychology,* and more specialized journals such as the *Psychology of Women*). In addition, a variety of review journals offer integrated updates of the field and can serve as excellent continuing education opportunities. Some of these journals include *Annual Reviews of Psychology, Current Directions,* and *Psychological Bulletin*. Once the findings of this BEA Working Group are disseminated, a series of relevant journal articles seems appropriate.
5. **Make use of the many online psychology teaching resources.** Information sharing has become increasingly efficient through the various websites and Internet-based options available to psychologists. For example, the APA Division 2 Project Syllabus could be used to model creative ways of organizing Intro Psych. The expansion of a catalogue of useful Internet-based resources is likely to be of value to Intro instructors (**http://intropsychresources.com/**).
6. **Create and use mentoring networks within national organizations and local communities of learning.** Mentoring relationships can be useful for enhancing creativity. APA's Membership Board has created a group to put together a set of recommendations for creating mentoring programs with APA divisions as the target audience. Mentoring can also occur more locally, within colleges and universities, for example.
7. **Attend the many teaching-related workshops and conversations within one's local teaching community.** Faculty from different fields and disciplines share common challenges in teaching introductory courses, and interdisciplinary workshops that focus on good pedagogy for the teaching of the social/natural sciences can be quite valuable. Cornell College, for instance, is part of a multi-institutional consortium that provides regular workshops on pedagogy, and "conversations about teaching" are held routinely on the local campus. The University of Chicago, for another instance, has a Center for Teaching and Learning (**http://teaching.uchicago.edu**) that provides a wide array of classes, workshops, resources, certification programs, and seminars to promote excellence in teaching. Most institutions of higher education have programs to develop and support excellence in teaching. However, many graduate students and faculty are unaware of these programs, and many of those familiar with the programs do not attend them.
8. **Read books on the scholarship of teaching and learning.** A variety of publishers (including APA Press) publish excellent sources on teaching. In the future, a book that provides examples based on the model that emerges from this BEA Working Group may prove of value.

RECOMMENDATION 5

Offer a National Assessment Plan for Intro Psych

Although our recommended model does not specify explicit content topics, the components of the pillars need to be assessed. As stated previously, the research is limited on what exactly takes place in the Intro Psych class. Most information on the Intro Psych course comes from publishers' market research (e.g., PubTracker®) and textbook extrapolations. To establish how our students perform or where reform is needed, we first need basic information on how the course is taught, how students perform on learning outcomes, and how reliable and valid the assessments are.

Guidelines 2.0 and the *Assessment Cyberguide for Learning Goals and Outcomes in the Undergraduate Psychology Major* (APA, 2009) provide learning outcomes. *Guidelines 2.0* also identifies potential assessment instruments for each of the outcomes. Regardless of whether instructors use the learning outcomes in *Guidelines 2.0* or their own, the working group believes a nationally coordinated focus on the assessment of Intro Psych learning outcomes in general is sorely needed. That can be better accomplished once a conceptual consistency becomes established across the discipline.

At the intro level, it would be beneficial for psychology to have a standard set of assessment questions, perhaps tied to the *Standards,* which can be used to assess student knowledge. Having a standard assessment would allow departments to compare their students directly with those of other programs. It would also be extremely useful as a research tool for studying effective pedagogies. Departments or faculty could pick and choose specific modules they want to assess, but there is no easy way to compare student accomplishments if there is no consistency of content.

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APPENDIX 1:

Psychology as an Integrated Science Assignment

Instructors can use this assignment to help integrate the different domains of psychology.

Why did Facebook become so popular? Why can't Congress work together to pass a federal budget? Why was I not invited to the party last Saturday night? Human behavior has multiple causes, sometimes involving interactions among two or more factors from different areas of psychology. This is the case for everyday behavior and for the big problems society faces today.

Pollution, global warming, education, poverty, terrorism, natural resource depletion, population growth, nuclear proliferation, pandemics, social injustice, hunger, and crime all involve behavioral processes shaped by factors moderated by or in interaction with other factors, ranging from biological to sociocultural perspectives. Because human behavior plays such an important role in each of these problems, psychology as an integrated, hub science has much to contribute to understanding and controlling them. Your challenge in this assignment is to show how different psychological factors or processes, individually or in combination, can influence an issue.

Specifically, your task is to pick a big problem from the list below and indicate theory and research in psychology that describe and explain the role people play in the creation of and solution to the problem. Your paper should be three double-spaced pages. Begin by defining the issue/topic. Look over your notes for the course so far and the chapters you have read and skim topics in the chapters remaining. Think about the areas of psychology that relate or pertain to your topic. Locate where your topic (or a related topic) is discussed in the text or in your notes. You do not need references beyond your class notes or the textbook.

Think about and include, where applicable, three of these five areas of content that may be interconnected in the overall system of your selected problem:

- Biological (e.g., neuroscience, sensation, consciousness, motivation)
- Cognitive (e.g., cognition, memory, perception)
- Development (e.g., learning, the needs and capabilities of children, adolescents, adults, and older adults)
- Social and personality (e.g., social, personality, intelligence, emotion, cultural, and gender differences)
- Mental and physical health (e.g., abnormal, health, clinical)

Pollution Global warming (Ineffective) Education Poverty Terrorism Natural Resource Depletion	Population Growth Nuclear Proliferation Pandemics Social Injustice Hunger Crime

Also for this task, consider the following questions and how ethics, diversity, and applications may influence the resolution of the problem. For instance, what are the major ethical considerations of conducting research or investigating the behavioral aspects of the big problem you have chosen? What does psychological science have to say about how variations across individuals and roles (including those based on age, gender, sexual orientation, gender identity, race, ethnicity, culture, national origin, religion, disability status, language, and socioeconomic status) contribute to the problem and/or to the solution? What role do the variations you see across individuals (e.g., in terms of their capabilities and vulnerabilities) play in the creation or solution to the big problem you've chosen? How might this big problem affect our everyday lives if it gets much worse, and how might our everyday lives differ if we were to behave in ways that were to help solve this big problem?

APPENDIX 2:
Addressing the Four Common Themes by Topic/Pillar

In this table, the APA Board of Educational Affairs Working Group on Strengthening the Common Core of the Introductory Psychology Course suggests discussion topics and demonstrates how each satisfies one or more of the four cross-cutting themes recommended for coverage in the course. The working group recommends that instructors first cover the scientific method and then select at least two topics from each of five pillars (i.e., biological, cognitive, development, social and personality, and mental and physical health) based on instructor preference.

Each pillar encompasses four common cross-cutting themes: social and cultural diversity, ethics, variations in human functioning, and applications. Note that one topic within a pillar may cover multiple themes. The examples provided are designed to illustrate how instructors might incorporate the different elements for each major topic in psychology and may serve as starting points for discussion; they are not intended to be prescriptive.

SCIENTIFIC METHOD	**Social and Cultural Diversity**	**Ethics**	**Variations in Human Functioning**	**Applications**
Discuss some examples of how the APA Code of Ethics pertains to psychological research.		X		X
Discuss the importance of conducting psychological research with groups other than just undergraduates in the U.S.	X	X		
Provide an example of experimental research with infants.	X	X		X
Provide an example of correlational research from personality psychology.	X	X	X	
Discuss some examples of research examining learning and memory and how that research can benefit both students and tolder adults.	X			X

PILLAR 1: BIOLOGICAL **Choose at least two content areas, such as Neuroscience and Sensation.**		**Diversity**	**Ethics**	**Variations in Human Functioning**	**Applications**
Neuroscience	Discuss some of the gender differences and gender similarities in brain structure and function.	X	X		X
	What are some ways in which the brain of a person diagnosed with schizophrenia has been determined to be different from the brain of a person without schizophrenia?	X		X	X
	Discuss what we have learned about the brain from treatment needs of individuals whose corpus callosum was severed due to severe epilepsy.	X	X	X	X
	Discuss how our knowledge of brain plasticity can help explain rehabilitation following a stroke.	X		X	X
Sensation	Discuss the ethical considerations of cochlear implants and their impact on the deaf community.	X	X		X
	People with certain physical disabilities suffer with constant pain. How can pain research help?	X		X	X
	People with synesthesia have a mixing of the senses. Can people without synesthesia imagine what it is like to see sounds? How are these experiences similar or different?	X		X	
	How has research on hearing influenced policy about loud work environments? How has hearing impairment been reduced?		X		X
Consciousness	Discuss the impact of shift work on circadian rhythms.	X			X
	Discuss the ethical complexity of conducting research on illegal drug use.		X		X
	Discuss narcolepsy—what is it and what do we know about it?	X		X	
	How can students use the information derived from the research on sleep to improve their own sleep habits?				X
Motivation	Discuss the tendency for both medical professionals and the general public to asexualize people with physical disabilities.	X			
	What are the ethical considerations of conducting sexuality research?		X		
	Discuss paraphilias.			X	
	How can psychological research on sexuality improve people's lives?				X

PILLAR 2: COGNITIVE **Choose at least two content areas, such as Memory and Perception**		**Diversity**	**Ethics**	**Variations in Human Functioning**	**Applications**
Cognition	How has the combination of the availability heuristic and terroristic acts affected perceptions of different cultural and religious groups?	X			X
	Do psychology students have an ethical obligation to share what they know about cognitive biases with friends and family?		X		
	Share examples of experts using intuition appropriately.			X	X
	Discuss how cognition research is helping to build smart computer systems.				X
Memory	Some people who have experienced the trauma of war have flashbacks. Discuss the memory processes that produce these memories and their unbidden recall.	X			X
	Discuss the ethical considerations of research with individuals who have long-term memory deficits.		X		
	Discuss the World Memory Championship. What skills have the participants developed that make them especially good at these memory tasks?			X	X
	Discuss how courts are more skeptical of eyewitness testimony based on memory construction research.				X
Perception	Discuss some ways in which culture influences the perception of illusions.	X			X
	What are the ethical considerations of giving people in pain a placebo in treatment studies?		X		
	Discuss synesthesia.			X	
	Discuss how perception research can help us understand why we are fooled by magicians.				X

PILLAR 3: DEVELOPMENT **Choose at least two content areas, such as Learning and Lifespan Development**		**Diversity**	**Ethics**	**Variations in Human Functioning**	**Applications**
Learning	Discuss cultural differences regarding the use of corporal punishment.	X			
	How might we evaluate the research conducted by Watson and Rayner on Little Albert in light of the current APA Ethics Code? How does this evaluation differ if based on ethical standards from their time?		X		
	What are the implications from research that suggests people with psychopathy respond to reinforcement and are affected little by punishment?			X	X
	How can a self-reinforcement program help us make changes in our own behavior?				X
Lifespan Development	Given what we know about adolescent development, is it appropriate to give life sentences for crimes committed by teenagers? What role should psychologists play in this discussion?		X		X
	Discuss temperament in infants and its relationship to the development of personality.			X	
	What are some cultural differences in the experience of aging?	X			
	What are the ethical considerations for conducting research with children?		X		
Language	Discuss how sense of self differs for people who are bilingual depending on the language they are speaking.	X			
	Given how easy it is to pick up a second language as a child, should all/more schools introduce a second language before high school?		X		
	Why it is that some people seem to be able to learn languages much more quickly than others?			X	
	Given what is known about language development, what advice is supported by research about how parents can help their children become proficient in reading, writing, and speaking?				X

PILLAR 4: SOCIAL AND PERSONALITY **Choose at least two content areas, such as Social and Gender.**		**Diversity**	**Ethics**	**Variations in Human Functioning**	**Applications**
Social	Discuss some real life impacts of cultural differences in attribution given that research suggests that Western cultures lean more toward dispositional attributions and Eastern cultures lean more toward situational attributions.	X			
	Some social psychological research uses deception. What are the ethical considerations when conducting such research?		X		
	Discuss what research tells us about how a few people can influence larger groups. Provide examples.			X	X
	What are the dangers of "groupthink" in a business environment? How can groupthink be avoided?				X
Personality	The personality profiles that result from testing may differ for the same individual based on which language they used to take the test. What are the implications of this finding?	X			
	Discuss the ethical considerations of using personality tests for hiring decisions.		X		X
	Discuss the Big Five personality traits.			X	
	Discuss how some matchmaking agencies use personality tests to make their matches. Do you think their approach is justified by the research? Are there some risks?				X
Intelligence	What is your interpretation of the consistent finding that the correlation between general mental ability (GMA) and work performance increases as occupations are rated higher on prestige?			X	X
	What are the ethical considerations of how intelligence test results are used?		X		
	Why might society wish to consider intellectual appraisals when determining punishment/treatment for crimes committed by people with developmental delays?	X	X	X	X
	How might children benefit from what psychological science tells us about environmental influences on intelligence?		X		X

Emotion	What evidence is there regarding gender differences in reading emotion in others?	X			
	Is it appropriate to prescribe drugs to people who are perceived to be too emotional?		X	X	
	Discuss characteristics that might predispose an individual to road rage and the ways in which these individuals could more appropriately manage their emotions.			X	X
	How can emotion research help law enforcement officers detect lies? What are the ethical limitations of this research?		X		X
Multicultural	Discuss differences between collectivist and individualistic cultures.	X			
	Do you believe there are basic human rights, regardless of culture? If so, what are these basic rights?		X		
	Give examples of behaviors that are acceptable in one culture but may be viewed as symptomatic of a psychological disorder in another.			X	
	How can an appreciation of different cultural values benefit an employee in a business environment?				X
Gender	How do gender roles differ across cultures?	X			
	What are the ethical considerations around gender assignment surgery for intersex infants?		X	X	X
	How are people who are very masculine or very feminine perceived, regardless of gender?			X	
	How do we learn gender roles? How do those gender roles affect our relationships with others?				X

PILLAR 5: MENTAL AND PHYSICAL HEALTH **Choose at least two content areas, such as Abnormal and Health.**		**Diversity**	**Ethics**	**Variations in Human Functioning**	**Applications**
Abnormal	Discuss cultural differences in the expression of depression.	X		X	
	What are the ethical considerations of conducting research on people who are currently experiencing psychosis?		X	X	
	What factors make a person more or less likely to develop PTSD?			X	X
	How might our knowledge of the epigenetics of schizophrenia improve treatment?				X
Health	How do cultural and religious communities affect health behavior?	X			
	What are the ethical considerations for putting volunteers in highly stressful situations to investigate the impact on health?		X		
	Discuss individual variations in the ability to cope with stress.			X	
	How can health psychology help people engage in more healthy behaviors?				X
Therapies	Discuss different cultural attitudes toward psychotherapy.	X			
	When researching the effects of psychotherapy with people who are suicidal, what are the ethical considerations of withholding treatment from the control group?		X	X	
	Discuss the difficulty in providing psychotherapy to people with personality disorders.			X	
	Can our knowledge of effective psychotherapeutic techniques help us teach people psychological first aid?		X		X

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La formación en Psicología: revisión y perspectivas

Ezequiel Benito

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NOTA | ¿QUÉ ES?

LA FORMACIÓN EN PSICOLOGÍA: REVISIÓN Y PERSPECTIVAS

Ezequiel Benito

Centro de Investigaciones sobre Formación y Entrenamiento en Psicología

Resumen: Los procesos de revisión de la formación y el entrenamiento en Psicología comienzan poco después de creadas las primeras carreras de Psicología, aunque su abordaje sistemático se inicia hacia mediados del siglo XX y es desde 1990 que se encuentra un aumento sostenido de la producción a nivel mundial. El presente artículo busca delinear concisamente la historia de los cuestionamientos acerca de cómo debe formarse un psicólogo. Se presenta en primera instancia una revisión de la manera en que ha sido abordado este tópico en los Estados Unidos, donde se encuentran los primeros planteos al respecto, para pasar luego a Europa y presentar el Diploma Europeo en Psicología. A continuación, abordamos el desarrollo de la cuestión en América Latina con las consecuencias de la adopción del modelo científico-profesional, considerando luego el proceso que a través del Mercosur se orienta hacia la elaboración de un currículo mínimo para llegar a nuestro país, donde revisaremos las características especiales de las condiciones de formación. Finalmente, se plantean los alcances del debate vigente y las direcciones futuras que pueden trazarse a partir del escenario actual.

***Palabras clave**: formación, Psicología, revisión, perspectivas*

Introducción

Las aproximaciones iniciales a la revisión de la formación y el entrenamiento en Psicología tienen lugar poco después de creadas las primeras carreras de grado, aunque su abordaje sistemático comienza a mediados del siglo XX y es desde la década de 1990 que se encuentra un aumento sostenido de la producción a nivel mundial plasmado en una gran cantidad de estudios. Klappenbach (2003) señala que un grupo de estos trabajos se ha centrado en el análisis y definición de las competencias y capacidades que reúnen los psicólogos tras el entrenamiento universitario, mientras que otra línea de investigaciones le ha dado prioridad a la

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definición de los estándares de formación. Por otro lado, el autor indica que hay quienes señalan la imposibilidad de acordar un núcleo común para la formación en Psicología.

El presente artículo busca delinear concisamente la historia de los cuestionamientos acerca de cómo debe formarse un psicólogo. Para ello, se presentará en primera instancia una revisión de la manera en que ha sido abordado este tópico en los Estados Unidos, donde se encuentran los primeros planteos al respecto, para pasar luego a Europa y reseñar la creación del Diploma Europeo en Psicología. A continuación, seguiremos el desarrollo de la cuestión en América Latina con las consecuencias de la adopción del modelo científico-profesional, considerando luego el proceso que a través del Mercosur se orienta hacia la elaboración de un currículo mínimo para llegar a nuestro país, donde revisaremos las características especiales de las condiciones de formación. Finalmente, se plantearán los alcances del debate vigente y las direcciones futuras que pueden trazarse a partir del escenario actual.

Aclaraciones preliminares

Con el objetivo de mejorar la comprensión de algunas cuestiones desarrolladas en este artículo, mencionaremos brevemente cómo está estructurado el sistema educativo en gran parte de los países anglosajones Para empezar, cuando un estudiante termina la *high school* [escuela media o el colegio secundario] ingresa a un nivel llamado *undergraduate* [de pregrado] que al término de tres años le otorga el diploma de *bachelor* [bachiller]. Luego, tendrá la posibilidad de cursar dos años de *graduate studies* [estudios de grado] que lo conducirán a un *master* [maestría], donde podrá elegir una orientación científica o profesional más definida. Este título no equivale a una maestría latinoamericana, que generalmente conlleva 7 años de estudio, sino que en algún punto es equiparable al nivel de la licenciatura. Finalmente, el doctorado es muy estructurado, incluyendo materias específicas, a diferencia de lo que ocurre localmente, donde los planes son generalmente abiertos y contemplan pocos cursos obligatorios.

Los inicios del modelo científico-profesional

En Estados Unidos encontramos los primeros intentos de revisión de las características presentes y requeridas en relación con la capacitación de los psicólogos. Esto no es extraño, debido a que es en este país donde encuentra su principal cuna el desarrollo de la Psicología como disciplina profesional autónoma. Es allí donde se crean las primeras revistas especializadas del área y se constituye la primera asociación de psicólogos del mundo, la American Psychological Association (APA) [Asociación Psicológica Americana] en 1892. Este escenario tan activo es el que probablemente lleva a los psicólogos estadounidenses a comenzar a formularse las primeras preguntas acerca de su formación, como indica Boring en su texto clásico sobre historia de la disciplina (1929). La primera referencia la encontramos en el psicólogo Lightmer Witmer, quien expresaba su preocupación por determinar cómo sería la

formación ideal (Sanchez, 2003). Esto sucedía en 1897, es decir, más de 50 años antes de que en Argentina se crearan las primeras carreras de Psicología. Estos planteos iniciales encuentran un desarrollo posterior en el marco de la APA, que en 1918, desde su División 1 (Psicología clínica), convoca a sus miembros a aportar ideas en materia de formación. Ese mismo año, en el *Journal of Applied Psychology* [Revista de Psicología Aplicada] Geisler planteaba un modelo de formación para que los psicólogos puedan estar al nivel de las nuevas demandas generadas por la Primera Guerra Mundial con respuestas de varios profesionales (Sanchez, 2003)

Considerando estos eventos como antecedentes, encontramos hacia 1930 el comienzo de una sistematización en torno a las pautas generales de formación en Psicología. En 1933, Walter Hunter en la APA, lidera un comité que estudia los estándares mínimos y comunes para el doctorado cuyo informe final fue publicado al año siguiente bajo el nombre de *Standards for the PhD Degree in Psychology* [Estándares para el doctorado en Psicología] (Benjamin, 2001). En él, a partir de un relevamiento hecho en 22 programas de doctorado, se delimitan 3 áreas que casi por unanimidad constituyen parte del plan de estudios: Psicología experimental, Estadística y formación teórico-histórica. Esta puede considerarse la primera aproximación a la identificación de contenidos mínimos para la formación.

Al término de la Segunda Guerra Mundial, en 1945, el entonces presidente de la Universidad de Harvard, James Conant, auspició la formación de un grupo de expertos para indagar acerca del lugar y el papel que debería tener la Psicología en la formación universitaria. Esta comisión fue conocida como la *Comission of Twelve* o *Comisión de los Doce Notables*, ya que estaba formada por doce reconocidas personalidades, seis del campo de la Psicología y seis miembros no psicólogos. El estudio realizado por la Comisión señaló que la enseñanza universitaria de la Psicología no debía quedar reservada sólo al ámbito de los psicólogos sino que debía plantearse interdisciplinariamente por su interés y relevancia para otras ciencias, como la Medicina, el Derecho, la Ingeniería y la Teología ya que se la consideraba una disciplina vinculante de las ciencias sociales y las ciencias biológicas.

En 1949, basándose en el trabajo de David Shakow al frente de un comité sobre la formación en Psicología Clínica de la APA, tiene lugar una conferencia en Boulder. Este espacio fue auspiciado y financiado por el gobierno de los Estados Unidos y la Administración de Veteranos de Guerra, a través del Nacional Institute of Mental Health (NIMH) [Instituto Nacional de Salud Mental] y se centró en la consideración del problema de las consecuencias mentales inhabilitantes y los trastornos psicológicos que sufrían los ex-combatientes y la posibilidad de los psicólogos de responder a semejante demanda en salud pública. En el marco de esta reunión fue definido el *modelo científico-profesional*, llamado también *Modelo Boulder*, el cual recomienda una formación doble para el psicólogo, que incluya el entrenamiento práctico, así como la instrucción en los fundamentos y procedimientos científicos de la disciplina. El argumento era que la Psicología se trata tanto de una ciencia como de una profesión, por lo que deben contemplarse ambos aspectos en el plan de estudios de la carrera.

Casi diez años más tarde, en 1958, la APA convoca y financia una conferencia que tiene lugar en Miami Beach, con el objetivo de revisar las pautas mínimas de formación para el nivel de maestría y doctorado. A diferencia de los encuentros anteriores, la principal preocupación de la reunión fue la formación en los diferentes campos de aplicación de la Psicología, no sólo en el área clínica.

El interés por la utilidad social de la Psicología toma protagonismo en Conferencia de Vail, en 1973, en donde se insiste en la diversificación de las especialidades y la consideración del mercado de trabajo. Se señala que debería buscarse un balance entre la teoría y la práctica, con una orientación a mejorar las posibilidades de atención a la población y que deberían establecerse sistemas de evaluación de la educación y de su incidencia en la población.

En 1987, se reúne una Conferencia en Utah, bajo el nombre de *National Conference on Graduate Education in Psychology* [Conferencia Nacional sobre Educación de Posgrado en Psicología]. Este encuentro tiene lugar en medio de las polémicas acerca de la importancia relativa de una formación más científica-investigativa o un entrenamiento más bien profesional en las especialidades. De los temas tratados se destaca el currículo troncal que plantea, que tenía como base la estadística, los métodos de investigación y diseños, la psicobiología, la percepción, los procesos cognoscitivos, el aprendizaje, la personalidad, el desarrollo, la Psicología social, la Psicología anormal y la historia y los sistemas de Psicología.

Desde entonces, se ha continuado trabajando en relación con los estándares para la acreditación de programas y una fecha importante al respecto es el año 1995, cuando la APA presenta las *Guidelines and Principles for the Accreditation of Psychology Programs in Professional Psychology* [Lineamientos y principios para la acreditación de programas en Psicología profesional] (APA Committee on Accreditation, 1995). Varios autores plantean la importancia de considerar la responsabilidad de la Psicología a nivel social. Entre ellos, Altman (1996) propone incluir, junto con los contenidos científicos y profesionales, una formación *socialmente responsable*, que prepare al estudiante en relación a la consideración de su práctica en el contexto de las necesidades poblaciones contemporáneas. Otros temas en revisión incluyen la estructura de los doctorados, en particular en relación con su duración y su orientación. En lo referido a la duración, el objetivo es acortarlos para permitir una inserción profesional más temprana, en especial en los casos de áreas con una urgente demanda social. Por el lado de la orientación, se está buscando que sus contenidos se adecuen más al mercado de trabajo, permitiendo una mejor inserción profesional y no sólo una formación centrada en la investigación.

El Diploma Europeo en Psicología

Hacia fines de 1980, en Europa existían grandes diferencias en la formación de psicólogos de un país a otro. Esto comienza a cambiar a partir de que los procesos de integración política y económica que se desarrollaron incluyen en la agenda la convergencia a nivel del sistema educativo.

A través de la Directiva 89/48/EEC, que entra en efecto en 1988, se instaura un sistema general para el reconocimiento de los títulos de educación superior por los países miembros de la entonces Comunidad Económica Europea, lo cual permitiría una libre circulación de profesionales. Sin embargo, esta normativa no alcanza una implementación real ya que en ese momento no se contaba con un respaldo académico que permita tan importante cambio.

A nivel disciplinar, el proceso más importante se inicia en 1990, cuando la European Federation of Psychologists' Associations (EFPA) [Federación Europea de Asociaciones de Psicólogos) establece los *Optimal Standards for Professional Training in Psychology* [Estándares Óptimos para el Entrenamiento Profesional en Psicología], que definen algunas de las características básicas para la formación y promoviendo su consideración en las instancias de acreditación de los países miembros.

Por otro lado, el marco político más importante para estos desarrollos lo han dado el Acuerdo de La Sorbona, en 1998 y el Acuerdo de Bolonia, en 1999. El primero, tuvo por objetivo constituir un área europea para el aprendizaje en los niveles superiores para lo cual se acordó, entre otras cosas, el establecimiento del *European Credit Transfer Scheme* (ECTS) [Esquema Europeo de Transferencia de Créditos] y la adopción del sistema semestral para la organización del año académico. Por otro lado, el Acuerdo de Bologna propone especificar una mayor convergencia entre los sistemas de educación de los países firmantes y tiene por objetivo facilitar las transferencias de una institución a otra para consolidar una gran área europea de educación superior. Ese mismo año, la EFPA presenta un comunicado llamado *Standards for professional training in psychology higher than the Bologna declaration* [Estándares para el entrenamiento profesional en Psicología más elevados que la declaración de Bolonia] donde remarca la necesidad de una formación de grado un tanto más exigente que la señalada por tal documento.

A partir del Acuerdo de Bolonia se pone en funcionamiento el Programa Leonardo Da Vinci, destinado a mejorar la calidad del entrenamiento profesional en Europa, que va a ser el marco para los Proyectos EuroPsyT y EuroPsy. Estos dos desarrollos, surgen en vistas de que las directivas de libre circulación profesional no estaban siendo efectivamente sustentadas por los modelos de formación disponibles. El Proyecto EuroPsyT, que funcionó de 1999 a 2001, estableció los criterios de formación mínima a nivel europeo para los psicólogos, y éstos fueron aceptados por la EFPA como *Declaration on the European Standards of education and training in professional Psychology* [Declaración de los estándares europeos de formación y entrenamiento en Psicología profesional]. Este proceso es continuado por el Proyecto EuroPsy, que tuvo una duración de dos años, de 2001 a 2003 finalizando con el establecimiento formal de los criterios para la creación de un Diploma Europeo en Psicología.

Así también, para reforzar las políticas de apertura profesional, la Directiva 2005/36/EC, que entró en efecto en 2007, consolida y moderniza las directivas anteriores en materia de reconocimiento de las credenciales profesionales intentando reducir las reticencias al libre tránsito profesional al señalar que aun mientras no esté funcional un sistema de armonización de las condiciones mínimas de entrenamiento, un estado miembro no puede negar el empleo a

los profesionales inmigrantes. Sin embargo, puede requerirle que rinda un examen de aptitud o que observe un período de adaptación, lo que todavía podría considerarse como una prohibición encubierta.

Actualmente, el *EuroPsy* (European Diploma in Psychology) [Diploma Europeo en Psicología] se encuentra en fase de prueba en Alemania, España, Finlandia, Gran Bretaña, Hungría e Italia. Antes de fin de año se habría completado la evaluación para pasar a la etapa de consolidación y se espera que el sistema entre en funcionamiento completo para toda la Unión Europea a mediados de 2010. Mientras tanto, sólo los psicólogos de los países mencionados pueden aplicar a él. Se han dispuesto una serie de requisitos (Cuadro 1) que de ser aprobados y luego del pago de un importe por la solicitud le permiten obtener al interesado el Diploma Europeo en Psicología y ser inscripto en el Registro Europeo de Psicólogos. En el proceso de aplicación, el interesado deberá elegir uno de los cuatro contextos profesionales que distingue el EuroPsy: Educación, Clínica y Salud, Organización y Trabajo y "otros" (una cuarta categoría para aquellos que no encajan en ninguna de los anteriores). Luego del otorgamiento podrá desarrollar su práctica en esa área en todos los países de la Unión Europea y en cualquier otro país que haya aceptado el EuroPsy, superando de esta forma las limitaciones aun presentes en la Directiva 2005/36/EC.

Cuadro 1. Requisitos para la solicitud del Diploma Europeo en Psicología

1) Haber completado satisfactoriamente un currículum académico en Psicología de por lo menos cinco años de estudio a tiempo completo.

2) Demostrar haber desarrollado prácticas supervisadas como psicólogo-profesional en formación como mínimo a tiempo completo (o su equivalente) y con un desempeño satisfactorio, evaluado por sus supervisores.

3) Presentar una declaración por escrito a través de la cual acepte los principios de conducta profesional establecidos en el Metacódigo de Ética profesional de la EFPA y por la que se comprometa a desarrollar su actividad profesional de acuerdo con el código ético de la asociación nacional de Psicología del país en el que practique

El Modelo Bogotá

Las primeras carreras de Psicología en Latinoamérica surgen alrededor de 1950 considerando en su mayoría los planteos de Boulder para la estructuración de los contenidos. En 1974, más de 20 años después, se reúne una conferencia en Bogotá para plantear una revisión crítica de la formación vigente. Allí se formaliza lo que comenzaría a conocerse como *Modelo latinoamericano* o *Modelo Bogotá*. En ese espacio se señalan los problemas generados por el déficit de personal entrenado en las áreas de educación, salud mental, investigación sobre el comportamiento y por la confusión del rol profesional del psicólogo con el del psiquiatra, el psicoanalista o el pedagogo. Frente a esta situación, se propone el reconocimiento del doble carácter de la Psicología como ciencia y profesión, la necesidad de un entrenamiento de los psicólogos según pautas similares en todos los países de la región, el entrenamiento en todas las áreas de intervención profesional, un perfeccionamiento en los últimos semestres en alguna de dichas áreas, la necesidad de un título generalista que permitiese desempeñarse en todas las áreas y la obtención del titulo luego de dos requisitos:

escritura de una tesis y entrenamiento práctico (practicum o pasantía) en un área de intervención (Ardila, 1978).

El Mercosur educativo y el currículo mínimo

En el contexto del Mercosur, el primer avance en dirección a un currículo mínimo tiene lugar en 1997, cuando se establece el *Protocolo de Admisión de Títulos y Grados Universitarios para el Ejercicio de Actividades Académica en Países del Mercosur* que constituye un primer paso en la dirección de la libre circulación de psicólogos en la región. De acuerdo con lo establecido en él, los "Estados Partes, a través de sus organismos competentes admitirán, al solo efecto del ejercicio de actividades académicas, los títulos de grado y posgrado, conferidos por las instituciones debidamente reconocidas". La limitación al ámbito académico es explícita y está ratificada en el artículo cuarto del protocolo que señala que "La admisión que se otorgue en virtud de lo establecido en el Articulo Primero, no conferirá, de por sí, derecho a otro ejercicio profesional que no sea el académico". Este primer marco internacional es lo que se conoce como Mercosur Educativo (Mercosur, 1997)

En 1998, en el VII Encuentro Integrador de Psicólogos del Mercosur, se firma el *Primer Protocolo de Acuerdo Marco sobre Formación de Psicólogos en el Mercosur,* señalando varios principios importantes para la formación, que recogen las ideas del varios de los procesos anteriores. Siguiendo la misma línea de trabajo, en 2001 se firma el *Protocolo sobre Criterios Generales de Formación,* que se elabora con el objetivo de presentar propuestas orientadas al mejoramiento de la calidad en la formación de psicólogos, en el contexto de los procesos de acreditación de carreras de Psicología. En él se plantea que los criterios de acreditación de las carreras de Psicología deberán ser lo suficientemente homogéneos a fin de posibilitar e incentivar el intercambio y circulación de psicólogos en los países miembros y asociados del Mercosur. A su vez, concordando con los criterios sustentados en el *Protocolo* de 1998, se propone una sólida formación generalista que garantice una amplia visión disciplinaria integrando la diversidad de los temas y problemas psicológicos y su relación con áreas afines.

El caso de Argentina

En Argentina, las carreras de Psicología comienzan a surgir a mediados del siglo XX. Sin embargo, los principales estudios sobre formación universitaria del psicólogo se han venido realizando de forma sistemática desde comienzos de los noventa.

Desde el punto de vista institucional, son de destacar los Informes y propuestas generados por la Asociación de Unidades Académicas en Psicología (AUAPsi), fundada en 1991 con el objetivo de favorecer la comunicación entre las unidades académicas de Psicología del país y mejorar la formación de grado y posgrado, la investigación y la extensión universitaria. Esta institución se orienta a la búsqueda de acuerdos comunes en relación al perfil del graduado, para adaptarlo a las necesidades nacionales y regionales así como a los desarrollos actuales

de la Psicología en el mundo tendiendo a la homogeneización de los contenidos curriculares. Estos objetivos, declarados en el acto fundacional de AUAPsi indican que la consideración de la necesidad de encontrar estándares comunes y homogéneos para la formación del psicólogo estaba entre los objetivos fundantes de la institución y es previo a la constitución del Mercosur educativo.

El evento a nivel nacional que da lugar al interés actual específico por la investigación en torno a la formación en Psicología es la inclusión de la Licenciatura en Psicología, en el régimen del artículo 43° de la Ley de Educación Superior en 2003. Dicho artículo establece que aquellas carreras correspondientes a profesiones reguladas por el Estado, cuyo ejercicio pudiere comprometer el interés público, poniendo en riesgo de modo directo la salud, la seguridad y los bienes de los habitantes, requieren para su reglamentación, la explicitación de sus contenidos curriculares básicos, la especificación de una carga horaria mínima, el establecimiento de criterios de intensidad de la formación práctica, la creación de estándares para la acreditación de la carrera y la determinación de las actividades reservadas al título.

En correspondencia con esta normativa, y teniendo en cuenta los desarrollos anteriores se presenta un trabajo que lleva por título *Documentos para la Acreditación de la Carrera de Psicología*. Esta es la más reciente presentación conjunta, compuesta por los documentos elaborados independientemente en reuniones plenarias realizadas por decanos y directivos de Psicología de AUAPsi y UVAPsi (Unidad de Vinculación Académica de Psicología de Universidades de Gestión Privada). Sobre la base de estos documentos, en septiembre de 2009 se aprueba la Resolución 343/2009, del Ministerio de Educación (2009), que fija el plazo de un año para la acreditación de las carreras de grado en Psicología. Reproducimos en el Cuadro 2 un resumen del ANEXO I de dicho documento, que señala los contenidos curriculares básicos dispuestos como referencia para la evaluación de las carreras. Otros de los puntos que

Cuadro 2. Contenidos curriculares básicos

Procesos biopsicosociales. Procesos biológicos y neuropsicológicos, psicológicos y socioculturales

Desarrollos de la Psicología en relación a cada ámbito de aplicación. Procesos intersubjetivos, interactivos y dinámicos de cada ámbito de aplicación específico.

Procesos psicopatológicos. Procesos psicopatológicos y estructuras psicopatológicas.

Historia de la Psicología. Construcción y desarrollo de los paradigmas, teorías y enfoques de la Psicología, desde sus orígenes; constitución como ciencia y profesión.

Metodología de la investigación psicológica. Producción y validación de los conocimientos científicos, fundamentos epistemológicos, estrategias metodológicas y diseños de investigación en Psicología.

Evaluación y diagnóstico psicológicos. Conocimientos teórico-instrumentales que permiten adquirir las destrezas necesarias para la evaluación, diagnóstico y pronóstico psicológico, según la edad del sujeto y las diferentes demandas de cada ámbito de aplicación.

Intervenciones en Psicología. Conocimiento de las diferentes estrategias, métodos y técnicas de abordaje e intervención referidas a las problemáticas de aplicación teniendo en cuenta la promoción de la salud. Conocimiento de todos los modelos teóricos y técnicos psicoterapéuticos.

Formación complementaria en otras disciplinas. Contenidos filosóficos, antropológicos, sociológicos, lingüísticos, entre otros, que permiten integrar, situar y delimitar el conocimiento de lo psíquico y ampliar su horizonte de comprensión.

Ética y deontología profesional. Conocimientos éticos y deontológicos, legislación y cuestiones jurídicas que se relacionan con el ejercicio profesional responsable de la Psicología.

merece destacarse corresponde al ANEXO II, donde se establece que la carga horaria total mínima sea de 3200 horas, divididas en 2700 de formación teórica y 500 de formación práctica.

Alcances

Los procesos que han sido relevados en el presente artículo parecerían mostrar un creciente interés por otorgar a la Psicología cierta madurez institucional frente a las demás disciplinas a través de la generación de lineamientos estandarizados a nivel académico y profesional. Sin embargo, un análisis crítico podría indicar que el trabajo actual haya su fundamento únicamente en esos objetivos administrativos y de gestión, dejando relegada la consideración global y transversal de las limitaciones y problemas intrínsecos de la formación del psicólogo, en especial en cuanto a la reflexión sobre la función científica y social de la disciplina.

Por lo general las decisiones en la dirección del establecimiento de criterios mínimos no suelen basarse en estudios del impacto de la Psicología en la sociedad, ni en estudios que releven los problemas potenciales que podrían resolver psicólogos con mejor formación. La cuestión científica, en tanto producción y evaluación de conocimientos parece estar al menos parcialmente relegada. Si bien esta omisión es entendible siendo el objetivo primero alcanzar acuerdos y lograr un trabajo factible, sería deseable que en los procesos futuros se pueda avanzar sobre consideraciones más específicas de la responsabilidad social del psicólogo.

Por otra parte, si bien los nuevos modelos de formación basados en competencias, parecen acercar la formación a una realidad más tangible y pueden significar una alternativa muy eficiente para la regulación de la educación, aquello también podría dejar en segundo plano la expectativa de una práctica basada en la ciencia, dando lugar a marcos de entrenamiento regulados primariamente por el contexto ya establecido, incluso más allá de los principios en los que se funda cada intervención o las posibilidades de cambio existentes.

Posiblemente, sea necesario que quienes se encuentran trabajando en el campo de la formación en Psicología dediquen una parte considerable de su tiempo a realizar estudios complementarios sobre Epistemología, Filosofía y Sociología de la ciencia, y que suplementen las necesidades administrativas, necesarias para la gestión de la ciencia, aportando a la reflexión acerca de las dimensiones sociales que implica esta área de investigación.

Formación global

Existen áreas de la formación que generalmente son poco desarrolladas en los programas de investigación o en los procesos reflexión sobre el cambio curricular que deberían tener una consideración especial. Por un lado, se encuentra el entrenamiento en las habilidades cognitivo-emocionales del psicólogo. Esto no implicaría someterse a un tratamiento psicológico durante la carrera, sino disponer un entrenamiento personal que lo habilite a responder no sólo con conocimiento teórico y técnicas, sino con su personalidad integral a las demandas que se

le presenten. Sería es esperable que un psicólogo pueda manejarse en su vida con una mejor comprensión de los procesos sociales de los cuáles es partícipe y que a partir de ello pueda también ser un modelo más completo del *ethos* profesional. Actualmente, este entrenamiento, es parcialmente contemplado por los programas de formación de posgrado en Psicología clínica (no en Argentina), pero no suele estar presente en los planes generales de formación de grado o de posgrado en otras áreas.

Por otra parte, nos encontramos con la propuesta de una *formación socialmente responsable* (Altman, 1996), a partir de la cual los estudiantes sean entrenados, no sólo en la fundamentación científica y práctica de la Psicología, sino también en la relevancia social de su aplicación. Este planteo es clave también y tiene bastante consideración en varios países, pero no ha encontrado tratamiento en Argentina, aun cuando una gran cantidad de congresos se han organizado bajo el lema de un *Compromiso de la Psicología con la sociedad.*

Otros contenidos que deberían ser considerados en la formación son aquellos tendientes al fortalecimiento de la Psicología Organizada, es decir, la forma en que los psicólogos se organizan para el desarrollo de la Psicología como ciencia y profesión. Estos contenidos incluyen instrucción sobre la historia de las organizaciones y su vinculación actual, la gestión de la ciencia psicológica, su autorregulación, su reconocimiento social y la articulación científico-política (Urra, 2009)

El futuro de la Psicología: formación basada en competencias

La formación basada en competencias se presenta como un modelo innovador que reuniría en el espacio de formación, los diferentes requerimientos, tanto teóricos, como prácticos y contextuales. Este modelo permitiría reducir las distancias que existen entre el conocimiento que el estudiante adquiere y las posibilidades de utilizarlo eficazmente en el medio social donde es necesario. En un modelo basado en competencias el aprendizaje está sustentado en resultados que se apoyan en estándares. Las competencias pueden ser definidas como un conjunto identificable y evaluable de capacidades que permiten desempeños satisfactorios en situaciones reales de trabajo. Una de las ventajas de este modelo es que permitiría mayor transparencia en los perfiles profesionales y enfatizaría los resultados del aprendizaje con un mayor acercamiento del estudiante al proceso educativo.

Por otro lado, está presente la necesidad de alcanzar niveles más altos de empleabilidad y de formación ciudadana. Un modelo basado en competencias que permita identificar la demanda social y la traslade a la formación de los recursos humanos en Psicología podría ser una solución posible para las brechas intelectuales que soslayan actualmente nuestro campo. Este proceso es altamente deseable, pero posiblemente requiera un trabajo tan extenso y una modificación curricular tal que excedería por mucho los cambios necesarios por los criterios de acreditación, que se plantean desde la lógica de mínimos. Quizás en el largo plazo algo así esté en nuestra *zona de desarrollo próximo*, por el momento, permanece en ideal.

Conclusiones

Como se ha visto, la investigación sobre formación y entrenamiento en Psicología constituye un campo de trabajo con bastante desarrollo al día de hoy, pero que requiere aun de mucho trabajo para seguir aportando a la generación de una mejor Psicología.

En Argentina, la formación del psicólogo ha reclamado durante años una transformación profunda y es importante que actualmente se estén comenzando a registrar procesos tendientes a ello. Esto, sin dudas, es un muy bien signo, pero requiere también mucha atención y participación de nuestra parte. Como se indicó, en el próximo tiempo tendrá lugar la acreditación de las carreras de grado, luego de lo cual quedará definido un nuevo escenario sobre el cual deberemos seguir realizando diagnósticos y análisis para asegurar la continuación del proceso de mejoramiento. El objetivo es sostener el trabajo en el tiempo para que perduren los avances logrados e involucrarnos en el establecimiento de mecanismos internos y permanentes de revisión.

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Drs. Nicholas and Dorothy Cummings

CENTER FOR THE HISTORY OF PSYCHOLOGY

AT THE UNIVERSITY OF AKRON

Historical Chronology

EXAMINING PSYCHOLOGY'S CONTRIBUTIONS TO THE BELIEF IN RACIAL HIERARCHY AND PERPETUATION OF INEQUALITY FOR PEOPLE OF COLOR IN U.S.

Developed for the American Psychological Association by the Cummings Center for the History of Psychology (CCHP) at the University of Akron. Learn more at apa.org/about/apa/addressing-racism.

Project background

Since the early months of 2020, COVID-19 has resulted in more than 4.6 million deaths worldwide (World Health Organization, 2021). People of color have been disproportionately affected by this pandemic, with some of these groups being twice as likely as White, non-Hispanic groups to become infected, three times as likely to be hospitalized, and twice as likely to die from COVID-19 (Centers for Disease Control, 2021). It is an understatement to say that this pandemic has laid bare serious racial health inequities in the United States, a situation that results not from simple variables such as health care access, but rather from a long history of structural racism (Khazanchi, Evans, & Marcelin, 2020).

During this devastating global health crisis, the country also witnessed the murder of George Floyd by Minneapolis police officers in May of 2020. Floyd's death was historically one of many, but it sparked protests across the country and internationally. COVID-19 also highlighted and reinforced existing systemic racism, xenophobia, blaming, and othering of Asian Americans throughout the pandemic (Starks, 2021). Racist ideologies, the glaring inequities highlighted by COVID-19, and a polarized political climate led many to describe the United States as simultaneously battling a "pandemic of racism" (American Psychological Association, 2020, May 29).

In 2020, APA launched a series of efforts aimed at dismantling racism in psychology, in APA, and in society more generally. As part of this effort, the Association sought a historical review of how psychology and APA have harmed people of color since the formal institutionalization of U.S. psychology in the late 1800s. The goal of the review was to document the long history of harm to these communities, and to provide a resource that could inform APA's work on an apology.

The Cummings Center for the History of Psychology (CCHP) at The University of Akron conducted the historical review. The CCHP is a research and humanities center that collects, preserves, and shares the history of psychology with a variety of audiences through the National Museum of Psychology and the Archives of the History of American Psychology. It is home to more than 3,000 linear feet of unpublished papers, artifacts, and media documenting psychology's history from the 1800s to the present.

Overview and approach

The review was conducted by a writing group and a working group with psychologists from across the country. The writing group is comprised of Cummings Center staff and faculty, including three historians of psychology and an archives assistant with a background in American history and archival theory and practice. We have relied on primary and secondary sources in the history of psychology and related human sciences.

The writing group has relied on feedback from and discussion with a working group comprised of seven academics, including historians of psychology and psychologists with long and valuable experience with the field and its historical and present relationship with people of color. This working group represents many communities of color and has lived and studied psychology's history in relation to race, culture, ethnicity, class, and social and political issues. They have worked to create, preserve, and advance psychologies that

emanate from, attend to, and serve communities of color.

The following review begins with a summary of our findings, followed by a chronology representing the historical data used to inform those findings. It is important to note that silences—moments when the field could have spoken or acted on behalf of communities of color but failed to do so—were difficult to demonstrate with historical actions, particularly in a timeline format. We fully acknowledge that silences, omissions, and failures to act are underrepresented in this account.

It is also important to note that the data in the chronology are necessarily incomplete. It is nearly impossible to document every instance of harm in one chronology. The historical data are comprised of examples of harm that we and other historians have deemed most salient and impactful based on our assessment of the extent to which they serve as exemplars of repeated and prominent trends in the field's history and their degree of direct connection with organized psychology. We stress, however, that these specific harms are part of a larger problematic culture in psychology, rooted in oppressive and exclusionary psychological science and practice.

In addition, it is important to note that this review does not constitute a complete history of psychology or of APA. We specifically focused on moments of harm and did not attend to actions that have promoted equity, advanced people of color within the field, and addressed the concerns of communities of color. This focus was necessary for the purpose of informing an apology. Psychology's history contains examples of both harm and help. Nonetheless, our review of the literatures suggests that moments of harm have been the dominant theme in psychology's history.

This review focuses broadly on harms done to racial and ethnic groups and does not fully attend to the unique experiences of each group or to the specific historical harms central for mixed-race, biracial, and multiethnic persons. Many individuals with intersectional identities have been harmed by psychologists through some of these same patterns of exclusion, othering, and pathologizing and some that are more unique to each group.

A note on language

In many places in this review, we have chosen to retain phrasing as it appears in the historical literature to demonstrate the ways in which people of color were in fact dehumanized through language used by psychology and other fields of inquiry. When using this language, we do so in quotations.

In all other cases, we use contemporary language, following APA's guidelines for writing about racial and ethnic identity (American Psychological Association, 2020).

Throughout this document, we use common socially referenced racial categories such as White, Black, Asian, and First Peoples. We acknowledge that this kind of categorization is artificial and does not account for the great diversity of history, experience, and ways of being within each category. In the context of this review, "White" refers to people of European ancestry, though we note that Southern and Eastern Europeans have been discriminated against and harmed by mainstream, Western-oriented psychology.

Executive summary

Psychologists have contributed directly and indirectly to the belief in human hierarchies through scientific racism, defined as "the use of scientific concepts and data to create and justify ideas of an enduring, biologically based hierarchy" (Winston, 2020, p. 2). Results from a century's worth of psychological studies of individual difference were interpreted as evidence of innate, hereditary difference in ability between racial and ethnic groups, an interpretation that runs counter to current findings from genetic research demonstrating significant variability within traditional racial groupings and considerable variability between different traditional racial groups (Baker, 2021). Historically, groups found to score differently on assessments designed by White psychologists and normalized on White populations were deemed inferior based on those results. These interpretations have created and upheld existing racial stereotypes and prejudices against people of color and reinforced the belief in White supremacy. Such beliefs found strong support in the early 20th century among psychologists and other social scientists, particularly those involved in the eugenics movement.

Psychological data have been used by psychologists and others to justify social policies that harmed people of color, including racial segregation, diminished educational opportunities, restrictions on immigration, institutionalization, forced sterilization, and antimiscegenation laws. In the face of ongoing critiques of methods and practices that discriminate against people of color, psychologists have often failed to listen, speak up, or create change. This is difficult to document in a historical study, but psychology's history includes many critical moments of silence and in-

action at times when proactive acts or speaking out were warranted. Psychology has sustained and failed to challenge research, practice, and policy frameworks rooted in White normativity that support the continued belief in White superiority.

Finally, people of color have been marginalized and excluded in the field of psychology in a multitude of ways, from educational and employment opportunities to gatekeeping (e.g., journal editorships, student supervision) and governance roles. In addition, issues of central concern to these communities have not been adequately addressed. Throughout our work, we were repeatedly confronted by the fact that the entire narrative of psychology—from textbooks to histories to journal articles—often excludes people of color and their voices. This chronology fails in this same manner: in an attempt to document the harms done to people of color, we often gave too much voice to White psychologists.

Our analysis of the historical record suggests that one of the central issues for U.S. psychology, both past and present, is its strong ties to hegemonic science and practice. Such an approach privileges certain ways of knowing, being, and doing as natural, normative, and progressive (Adams, Kurtiș, Gómez, Molina, & Dobles, 2018). Historically, psychology has accepted Whiteness as a standard or norm and presented other modes of being as marginal, unnatural, or in some way straying from the norm. Recently, this has appeared in the psychological literature as a WEIRD (Western, educated, industrial, rich, democratic) approach (Henrich, Heine, & Norenzayan, 2010), but people of color have noted versions of it in the literature since at least the beginning of the 20th century (Du Bois, 1903).

It is important to distinguish between our historical review and the legacies resulting from that history as reflected in contemporary policies and practices. History is dynamic and there are often prospective consequences of history. We were charged with conducting a retrospective review of the history of harm to people of color and have therefore not included the many ways in which this history has left a legacy in our present. We acknowledge that history is not simply a thing of the past: it is the very foundation for our current cultural mindset and our present modes of thinking, being, and doing as psychologists. There is a common notion that we should learn history so that we can avoid repeating past mistakes. We would argue, with historian Avner Segall (1999), that "it is not the repetitive past we ought to fear… but rather, the legacy of the past in our present" (p. 366). The harms identified in this review are part of our past, but they continue to provide the platform for contemporary psychology.

This chronology demonstrates ways in which research and practice have focused on White culture and used it as a global standard. This culture, evident from the very beginnings of the field, is inseparable from the social and political landscape of the United States at the end of the 19th century. Organized psychology grew up in these conditions, helped to create and sustain them, and continues to bear their indelible imprint.

In sum, our historical review of psychology's harms to people of color indicates that psychologists have, in both the past and present:

- Established and participated in scientific models and approaches rooted in scientific racism;
- Created, sustained, and promulgated ideas of human hierarchy through the construction, study, and interpretation of racial difference;
- Promoted the idea that racial difference is biologically based and fixed;
- Used psychological science and practice to support segregated and subpar education for people of color;
- Created and promoted widespread use of psychological tests and instruments that discriminated against people of color;
- Failed to take concerted action in response to calls for an end to testing and psychometric racism;
- Supported the widespread use of educational assessments and interventions that were lucrative for the field of psychology, but harmed people of color;
- Provided ideological support for and failed to speak out against the colonial framework of the boarding and day school systems for First Peoples of the Americas;
- Created, sustained, and promoted a view of people of color as deficient or damaged;
- Applied psychological science and practice to oppose "race-mixing" and to support segregation, sterilization, and antimarriage laws, using the ideas of early 20th century eugenics;
- Failed to represent the approaches, practices, voices, and concerns of people of color within the field of psychology and within society;
- Failed to respond or responded too slowly in the face of clear social harms to people of color

Psychology and the Belief in Racial Hierarchy: A Chronology

1850–1900

The formal institutionalization of U.S. psychology (as indicated by the creation of programs, departments, degrees, societies, and schools) occurred in the years surrounding the Civil War, centered on national debates about slavery; the passing of the Indian Appropriations Act, which removed First Peoples from their tribal lands to government reservations; the Chinese Exclusion Act, which suspended Chinese immigration; and the Supreme Court's *Plessy v. Ferguson* decision, which held that segregation laws did not violate the equal protection clause of the Fourteenth Amendment. The formalized psychology established at this time was led primarily by White men and leaned heavily on evolutionary theory, with its emphasis on survival and adaptation of the species. The field almost immediately lent its support to the notion of White superiority, with its focus on demonstrating individual differences among different racial groups.

1869: Francis Galton, who was recognized as an early leader in psychology (among other professions) publishes *Hereditary Genius*, a central early event in the study of individual differences and psychometrics in European and U.S. psychology. In this work, he ranked the "comparative worth of different races" and concluded that "the average intellectual standard of the negro race is some two grades below our own" (Galton, 1869, pp. 336–338). In 1883, Galton would introduce the word "eugenics," described as a science of improving "racial stock." This work was heavily cited and used by the first generation of psychologists who established APA, the first recognized psychology journals, and the most influential research programs.

1892: The American Psychological Association is founded, with G. Stanley Hall as president and 31 White males elected to membership.

1895: One of the earliest examples of scientific racism—defined as the use of scientific concepts and data to create and justify ideas of an enduring biologically based hierarchy (Winston, 2020)—is published in *Psychological Review*, one year after the journal is first established (Bache, 1895). First Peoples and Black participants were reported to have faster reaction times than White participants. The author argued that reaction time was a primitive reflex and that the superior, more evolved intelligence of White participants resulted in more contemplative thought and slower reaction times.

1897: In a study of Black and White children, Stetson (1897) found that Black children outperformed White children on a memory task. The author attributed this to the greater mnemonic ability of their "primitive brains." He further described Black children as being deficient in reasoning.

1897: APA funds a Committee on Physical and Mental Tests, its first financial commitment to an activity other than its own administration (Baldwin, Cattell, & Jastrow, 1898).

1900–1925

As U.S. psychology established itself in the early 1900s, the U.S. experienced the First World War, massive growth, and unprecedented immigration. More than 15 million new immigrants, the majority of whom arrived from southern and eastern Europe, came to the U.S. in the first quarter of the century. Antiimmigration sentiment increased, fueling the eugenics movement, which sought to "improve the human race" using principles of heredity. Scholars and lawmakers debated the "Negro Question," which often focused on schooling and curriculum for people of color. Education was also a question at the forefront with First Peoples of the Americas, as more than 6,000 students were enrolled in federal boarding schools that attempted to replace First Peoples culture with an education that fit Anglo-American standards. Many psychologists continued to focus on individual differences among races and became actively involved in the eugenics movement, using their science to support eugenical aims.

1904: APA forms an ad hoc committee on testing standards, forming the Association's first committee on standards for apparatus, procedures, and results of group and individual tests. The resulting Committee on Measurement consists of early psychologists who frequently supported ideas of racial hierarchy and/or eugenics, including James R. Angell, Charles H. Judd, Walter B. Pillsbury, and Carl E. Seashore.

1904: G. Stanley Hall, founding president of APA, publishes the highly influential text, *Adolescence.* In it, he described First Peoples as childlike, with adults from this group being more similar to White children or adolescents in their development. Hall supported the development of "civilizing programs" tailored to what he deemed to be the needs of First Peoples (Hall, 1904; 1905; Richards, 1997). These programs, once enacted, were attempted to eradicate First Peoples' culture, language, and spiritual life. Hall's views were echoed by other psychologists during this period (e.g., Chamberlain, 1909).

1910: The Eugenics Record Office is established as a department of the Carnegie Institution of Washington's Station for Experimental Evolution. It became the center for eugenics advocacy, research, and publication in the U.S. Leaders of organized psychology, including Edward Thorndike, Robert Yerkes, Arthur Estabrook, Paul Achilles, and Lewis Terman were founders and active members of this office. They also led and contributed to other eugenics-based organizations in this period, including the Cold Spring Harbor Laboratory, the Galton Society, and the American Eugenics Society (Zenderland, 2001). Through these groups, they promoted sterilization initiatives for "unfit and inferior races" and supported race-based immigration policies and negative heredity laws (Brigham, 1923; Engs, 2005). Psychological tests were regularly used in the work of these organizations. Between 1892 and 1947, 31 presidents of APA acted in leadership positions in eugenics organizations, during their time as president, but also in the years surrounding their presidencies (Yakushko, 2019).

1913: A 70-page psychological monograph reports inferiority of school performance among Black children in integrated schools in New York, a finding the author attributes to "race heredity" (Mayo, 1913). Early papers like this set the tone and pattern for later work on difference and were used to argue against improved schooling opportunities for Black children (Richards, 1997).

1914: Psychologist William McDougall, writing in the *Eugenical Review*, lays out a plan for how experimental psychology can serve the goals of eugenics, focusing on the study of the hereditary basis of mental qualities (McDougall, 1914). McDougall, chair of psychology at Harvard, argued in favor of restrictions on interracial marriage, claiming that mixed race individuals are mentally defective and that such mixing would produce a "race of submen" (McDougall, 1921, p. 132). He further argued for the creation of a separate territory for Black Americans to prevent "race amalgamation" (McDougall, 1925, p. 162).

1914: Psychological research, tests, and instruments are used at some boarding schools with First Peoples during this period. For example, a teacher at the Phoenix Indian School described psychological testing and research in education in the *Indian School Journal*, noting use of the early Binet scales and citing the work of psychologists J. Wallace Wallin and Stuart Appleton Courtis (Scott, 1914).

1914: Psychologist Henry Goddard, a pioneer of the U.S. testing movement, serves as the psychology representative on the *Committee to Study and Report on the Best Practical Means of Cutting Off the Defective Germ-Plasm in the American Population.* The Committee, established by the Research Committees of the Eugenics Section of the American Breeders Association, recommended segregation, and sterilization as the best methods of preserving "the blood of the American people" (Laughlin, 1914, p. 6). The Committee called on psychology to help determine standards and tests for identifying "mental degenerates and defectives proposed for sterilization" (p. 7). By 35,000 ,1930 people in the U.S. had been sterilized, mostly individuals who had been deemed "feebleminded" or socially or mentally unfit (Greenwood, 2017). Many of these individuals were immigrants, Black people, First Peoples of the Americas, poor White people, and people with disabilities (Kevles, 1998).

1915: Psychologists leading the California Bureau of Juvenile Research at Whittier State School oversee some of the earliest eugenics fieldwork projects, examining the family trees and conducting psychological testing of boys confined at the institution. Psychologist J. Harold Williams, a student of Lewis Terman, directed the project and presented results on "White, Mexican, and Colored children." Historians have documented the biased procedures and results of this project that harmed hundreds or perhaps thousands of youths incarcerated in California by increasing the incarceration rate of these youth and promoting sterilization (Chávez-García, 2015).

1916: Lewis Terman creates the Stanford-Binet Scale. He used differences on this scale as a justification for a segregated system of education geared toward building Black, Mexican, and First Peoples children into "efficient workers" (Terman, 1916), a proposal supported by other psychologists in the early 20th century (Young, 1922). This model was adopted in predominantly Mexican American schools throughout the American Southwest (Gonzalez, 2013, p. 82).

1916: G. O. Ferguson (1916) publishes "The psychology of the Negro," considered to be a classic example in the history of scientific racism (Guthrie, 1998). Ferguson linked performance (including reasoning, association, memory, and intelligence) with skin color and argued that Black people are more emotionally volatile, unstable, and less capable of abstract thought. Ferguson also espoused the prominent "mulatto hypothesis," the idea that the mental characteristics of Black people were greater among those who had a higher proportion of "White blood."

1917: APA president Robert Yerkes launches the Committee on the Psychological Examination of Recruits during the First World War. The Committee was created under the auspices of the National Research Council and headed by Yerkes, reporting to the Office of the Surgeon General. Yerkes and a team of psychologists recommended mental examination of every soldier, and by the end of the War, they had administered psychological tests to nearly 2 million men. Culturally biased test questions and examination procedures, along with an assumption of White, American normativity, led to results that established a clear racial hierarchy of performance with White, American-born recruits scoring highest on IQ tests and Black recruits, particularly those from the American south, scoring the lowest. 89% of Black recruits were labelled by the Committee as "morons" (Kevles, 1968; Rury, 1988; Yerkes, 1921). These tests are the forerunners of the National Intelligence Test and the Scholastic Aptitude Test (SAT). Concerns about large racial gaps in SAT scores continue in the present (see Brookings Institution, 2017)

1917: During this time, APA president Robert Yerkes served as chairman of the Committee on the Inheritance of Mental Traits at Cold Spring Harbor. He also served on the Committee on Eugenics of the National Commission on Prisons and the Board of Directors for the Human Betterment Foundation under eugenicist Paul Popenoe (Engs, 2005; Paul, 1965). In the years after the War, APA's work in supporting the war effort and in "segregating the incompetent" was praised (Riley, 1919, p. 2).

1921: Many psychologists continue to examine racial difference and a formal definition of "racial psychology" appears in the *Journal of Applied Psychology.* Work contrasting "mixed" and "full blood" First Peoples on a battery of psychological tests concluded that those with "White blood" outperform those without (Garth, 1921). Though Garth would later become a critic of scientific racism, his early work contributed significantly to its prevalence.

1921: At the Second International Congress of Eugenics in New York City, APA president-elect Knight Dunlap hosts an exhibit on using psychology to better the human race both physically and mentally. The exhibit presented racial differences between White, Black, and First Peoples. Psychology journals like the *Journal of Applied Psychology* are exhibited alongside eugenics publications (Doyle, 2014).

1922: Many psychologists continue to support the idea of White superiority in both public and academic outlets. Psychologist James Rowland Angell, president of Yale University, delivered a series of addresses describing the hierarchy of the races, espousing White superiority, and discussing the low intelligence of "savages lowest in the human scale" (Angell, 1922, p. 115). This same year, the *Journal of Comparative Psychology* published research linking the degree of "White blood" in First Peoples to higher intelligence test scores (Hunter & Sommermeier, 1922). Five years later, an additional study on intelligence and "White blood" among First Peoples was published in the same journal (Fitzgerald & Ludeman, 1927). In 1933, further research was published arguing that First Peoples children demonstrate more dishonesty than White children and describing the entire Navajo Nation as "notoriously dishonest" (Pressey & Pressey, 1933, p. 129).

1923: Lewis Terman, widely known for his promotion of eugenics and his belief in racial hierarchy, becomes president of APA.

1924: The Johnson-Reed Act passes, limiting immigration from Southern and Eastern Europe and favoring immigrants from Northern and Western Europe. The goal of the Act, as stated, was to preserve American homogeneity. Italians, Greeks, and Eastern European Jews were heavily impacted and Syrian immigration was limited to 100 people per year. It further extended a ban on Asian immigration. Psychological research was cited by eugenics leaders in congressional testimony leading up to passage of the Act. It was argued that immigrants from Southern and Eastern Europe were endowed with inherently poor genetic material and that restriction was needed to preserve American racial stock (Doyle, 2014; Laughlin, 1923; Tucker, 1994; Gelb, Allen, Futterman, & Mehler, 1986).

1925–1950

The U.S. exited one war, contended with the Great Depression, and then entered another global conflict. Under Executive Order 9066, more than 120,000 Americans of Japanese ancestry were forced from their homes into internment camps around the United States. During this time, communities of color around the United States began challenging the racist and exclusionary structure of the country. There were several challenges to segregated schooling, with cases arising regarding schooling for Black and Latinx children. First Peoples of the Americas continued to organize and dispute government control of lands and education, forming the National Congress of American Indians in 1944. Similarly, the Congress of Spanish Speaking People formed in 1939. The second World War resulted in massive growth in psychology across a wide variety of areas, including assessment and treatment of war-related trauma, as well as occupational classification, leading to close ties between psychology and the military. More people of color begin receiving PhDs in psychology, and psychologists of color begin challenging the findings and practices of predominantly White mainstream psychology (Guthrie, 1998). Psychology grew and changed in unprecedented ways during this time and many psychologists began a public retreat from their explicitly stated views of White supremacy in the years following World War II. The Society for the Psychological Study of Social Issues was established in 1936, with the intention of directly addressing social issues and issuing public statements, including statements on racism. Nonetheless, leaders of psychological science and practice continued to support the idea of a natural human hierarchy to a greater extent than other social and behavioral sciences.

1926: Psychologists Stanley Porteus and Marjorie Babcock publish *Temperament and Race,* reporting on studies of Chinese, Hawaiian, Portuguese, Filipino, and Puerto Rican people in Hawaii. While some of these individuals were born in Hawaii, some were immigrants. The results reinforced stereotypes of these groups, and the authors argued that racial hierarchy and racial differences are rooted in genetics. Porteus continued to publish on this topic, and his work inspired further research in this area. In 1929, for example, Pratt compared the school achievement of Japanese, Chinese, Hawaiian, and Part-Hawaiian school children using achievement tests and reports that Hawaiians have lower achievement scores. The author concludes that Hawaiians are "by native abilities and interests, completely unfitted" to education (Pratt, 1929, p. 667).

1927: Research on racial differences continues. An article in the *Journal of Experimental Psychology*, a journal then edited by eugenicist psychologist Madison Bentley, compared First Peoples to White people and describes them as slower at decision making, less confident, and having poorer coordination of impulses (Downey, 1927). This is one of many examples of this kind of research during this time (see Garth & Barnard, 1927; Jamieson & Sandiford, 1928).

1927: The College Entrance Examination Board's Scholastic Aptitude Test (SAT) is first administered. The test was developed by Carl Brigham, rooted in the work of military psychologists in the World War I testing program.

1932: George I. Sanchez, known as the founder of Chicano psychology, challenges biased research literature on the intelligence of Mexican American children in a *Journal of Applied Psychology* article, "Group differences in Spanish-speaking children: A critical review."

1933: Inez Beverly Prosser completes her doctorate in psychology from the College of Education at the University of Cincinnati, becoming on the first African American women to earn the degree.

1933: Psychologist Raymond Cattell argues against the "mixture of blood between racial groups" (Cattell, 1933, p. 155). A few years later, he declared that Black individuals have "contributed practically nothing to social progress and culture" and argued against their full citizenship (Cattell, 1937, p. 56). Cattell argued that these individuals should "be brought to euthanasia" for this inferiority. In 1972, he again argued that such "race mixing" would result in "the intelligent maintainers of the culture being completely replaced by lower intelligences" (Cattell, 1972, p. 154). He continued to maintain the dangers of race-mixing through the early 1990s.

1933: Black psychologists publish a number of studies countering the findings of White psychologists. Albert Beckham published a study of 1,100 schoolchildren, presenting results that suggest environment plays a central role in shaping intelligence scores (Beckham, 1933). Similar research was published by Howard Hale Long in 1935. In 1936, Herman Canady outlined the impact White examiners have on the test scores of Black test takers. Studies like these, conducted by leading Black psychologists, were often dismissed, and testing continued to be used to support ideas regarding innate racial hierarchy (see Guthrie, 1998; Richards, 1997).

1934: A survey indicates that 25% of psychologists believe that data supports the inherent mental inferiority of Black people (Thompson, 1934). This is compared to 24% of those working in education and 5% of sociologists and anthropologists.

1939: Mamie Phipps Clark and Kenneth Clark conduct experiments on children's perception of race, finding that children become aware of race at a very young age and are attuned to positive and negative attributes associated with racial categories (Clark & Clark, 1939).

1943: A chapter on "The Hopi Child" describes delayed age of walking among the Hopi children compared to White children. This study is just one of many examples of social and behavioral scientists comparing people of color to White populations and using Whiteness as a cultural, racial, and normative standard (Dennis, 1943).

1945: Alexander H. Leighton publishes *The Governing of Men: General Principles and Recommendations Based on Experience at a Japanese Relocation Camp.* Navy psychiatrist Alexander H. Leighton applied the tools of social psychological theory and human management to the administration of the Poston Relocation Center for Japanese Americans. Psychological science strengthened eugenic ideologies of mental inferiority which contributed to the internment of Japanese Americans during World War II. (Herman, 2020, Tyner, 1998)

1950: Despite continuous concerns regarding cultural and racial bias in psychological testing (Canady, 1943), APA establishes the Committee on Test Standards, which issues technical recommendations for test administration and design that some believed did not adequately address race, ethnicity, and culture (Holliday & Holmes, 2003; Jackson, 1975; Simpkins & Raphael, 1970). The same year, the Graduate Record Examination (GRE) was published (Holliday & Holmes, 2003). One year later, anthropologist Allison Davis examined the effects of race and social class on test performance and reiterated ongoing critiques centered on the cultural bias inherent in common psychological tests. Davis noted few differences between groups when controlling for social class (Eels et al., 1951).

1950: From the 1950s on, psychologists received money from the Pioneer Fund, created in the 1930s to promote racial homogeneity, "repatriation" of Black Americans to Africa, and segregation. Money was funneled to White Citizens Councils for "massive resistance" to the *Brown* decision, and later funded nearly all major scientific racist projects (Tucker, 2002). From the 1960s on, psychologists gave explicit assistance to and participated in racial extremist, White nationalist, and neo-Nazi groups, including organizations promoting Holocaust denial (Jackson, 2005; Jackson & Winston 2021; Tucker, 2009 ,2002 ,1994).

1951–1975

The Civil Rights movement, played out against the backdrop of the Vietnam War, gained traction in the U.S., culminating in legislation such as the McCarran-Walter Act of 1952, the Civil Rights Act of 1964, and the Voting Rights Act of 1965. The famous 1954 *Brown v. Board of Education* Supreme Court decision rendered segregated schooling unconstitutional. Despite these gains, people of color continued to experience direct harm. The U.S. Congress continued to abolish tribal lands and relocate First Peoples of the Americas. However, continued organization and resistance among First Peoples during the Civil Rights era resulted in the McCarran-Walter Act that reinstituted basic rights and returned some power to tribes. Asian Americans, though given citizenship through the 1952 Act, experienced hostility and xenophobia and came under suspicion during the McCarthy era. In the 1960s, the myth of Asian Americans as a "model minority" in comparison to other communities of color publicly emerges in popular print. The Watts Uprising occurred in 1965, when 14,000 members of the National Guard were deployed to a primarily Black and impoverished neighborhood in Los Angeles to respond to the largest urban rebellion of the Civil Rights era. The 1960s also saw the development and expansion of nationwide community mental health programs, many of which were beginning to seek out ways of serving diverse communities. Throughout this period, some leading psychologists continue to support eugenics and explore racial inferiority in their work. Research, including cross-cultural research, done in this period sometimes fails to acknowledge culture, context, and tradition in different communities, positing instead universal human traits and universal patterns of development. APA begins to grapple with the lack of diversity in the field, which continued to be dominated by White men. Many psychologists of color begin forming associations and societies of their own, expressing dissatisfaction with APA's attention to the concerns of communities of color.

1951: Efrain Sanchez-Hidalgo is the first Puerto Rican to be awarded a PhD in psychology, by Columbia University. In 1954, he becomes the founding president of the Puerto Rican Psychological Association.

1952: Carolyn Lewis Attneave becomes the first American Indian to earn a doctorate in psychology, from Stanford University.

1952: Former APA president Henry E. Garrett provides judicial testimony in support of segregation in *Davis v. County School Board,* a precursor to *Brown v. Board of Education* (Winston, 1998). He argued that segregation would not harm Black or White students if school facilities were equal. This idea was later echoed by the three judges who ruled in favor of continued segregation. Garrett's own writings promoted the idea of an innate racial hierarchy until his death in 1973 (Garrett, 1973; Tucker, 1994). During this period, Garrett worked with racial extremist and neo-Nazi groups (Tucker, 2002; Winston, 1998).

1954: *Brown v. Board of Education* is decided, ending legal segregation in the United States. The work and testimony of psychologists Mamie Phipps Clark and Kenneth Clark, along with other social science research, was used to support desegregation and cited in the final decision (Kluger, 1975, Jackson, 2001). Some psychologists opposed desegregation. In 1963, psychologists testified in support of segregation in *Stell v. Savannah Board of Education,* a case brought to challenge the 1954 Brown decision (Jackson, 2005).

1958: Psychologist Audrey Shuey, former student of Henry Garrett, publishes *The Testing of Negro Intelligence,* summarizing existing work on racial differences and concluding that White people are innately superior to other races (Shuey, 1958).

1958: The Indian Adoption Project begins, allowing U.S. government officials and others to remove First Peoples children from their parents and communities to be adopted by White families. Transracial adoption practices also impacted children of all racial backgrounds and continue to the present day. Lee (2003) demonstrates that psychological research on transracial adoption has failed to directly attend to the well-being of adoptees. Peters et al. (2015) argue that all such cases must take cultural considerations into account to protect a child's best interests. Further, the Society of Indian Psychologists has outlined the need for any expert testifying in such cases to be an expert in a tribe's culture and customs.

1959: The International Association for the Advancement of Ethnology and Eugenics is founded. The group promoted race science, lobbied to overturn the *Brown* decision, and fought to preserve segregation. The Board and editors include noted academics and neo-Nazi activists. The group actively assisted White Citizens Councils during Southern "massive resistance" to integration (Winston, 1998; Tucker, 2002). Throughout its history, several psychologists (including Henry Garrett, Stanley Porteus, Frank McGurk, Audrey Shuey, and Raymond Cattell) were involved in its leadership and led and contributed to its journal, *Mankind Quarterly* (Winston, 2020).

1962: Martha Bernal is the first Mexican American woman awarded a PhD in psychology, from Indiana University. In 1979, she helped to establish the National Hispanic Psychological Association. In 1979, she examined how APA-accredited clinical psychology programs prepare for treating multicultural populations and she finds the curricula inadequate.

1963: The APA Ad Hoc Committee on Equality of Opportunity in Psychology is established to review challenges in training and employment in psychology in relation to race. They found that there are few opportunities for training Black students, few opportunities for employment for Black psychologists, and little representation within APA governance and Central Office (Pickren & Tomes, 2002; Wispe et al., 1969).

1966: Psychologist Kenneth Clark becomes the first Black president of APA, 74 years after the organization was established.

1966: APA's Standards for Educational and Psychological Tests and Manuals are published. The standards addressed test bias primarily through a focus on test validity. These standards were used by the Equal Employment Opportunity Commission in establishing guidelines for test use, centered primarily on test validity. However, concerns regarding discriminatory use of tests that nonetheless met these validity guidelines continued to be voiced (Plotkin, 1972).

1966: Arthur McDonald becomes the first American Indian man to earn a doctorate in psychology, from the University of South Dakota.

1967: Psychological research continues to be used to justify "acculturation" in residential, boarding, and day school systems in hearings before the U. S. Senate's Special Subcommittee on Indian Education of the Committee on Labor and Public and Public Welfare (Indian Education, 1967). Psychologists were also employed at the schools into the 1970s ("Presentation of Navajo," 1975).

1967: Cross-cultural research, rooted in tests and hypotheses that are developed with urban U.S. samples and then transferred to other cultural contexts, concludes that key aspects of development are transcultural. This work continued into the early 2000s and was extended from race and ethnicity to gender (see Gutmann, 1964, 1967).

1967: Psychologist Henry E. Garrett testifies in opposition to the passage of the Civil Rights Act. Garrett argued that Black people cannot reach the intelligence levels or abilities of White people. He further argues that equal rights will only confuse and frustrate the Black community. Garrett, listed in the Congressional Senate hearing record as "past President, American Psychological Association," had served as APA president in 1946 and was the only psychologist on record to testify (U.S. Government Printing Office, 1967).

1967: Head Start is launched by an interdisciplinary team and included psychologist Edward Zigler among its architects and early leaders. Some psychologists voiced opposition to the program, using SAT scores and other standardized test results to argue that compensatory education programs make no difference for people of color (Jensen, 1985).

1967: The Society for the Psychological Study of Social Issues, along with Kenneth Clark, invites Martin Luther King Jr. to give an invited address at the annual APA convention (Pickren & Tomes, 2002).

1967: Psychologist Arthur Jensen delivers an address, "Social class, race and genetics: Implications for education," to the American Educational Research Association's annual meeting. The address, and much of Jensen's ensuing work, emphasized the genetic roots of group differences in the educability in children of color. The address, delivered in the social context of the Coleman Report exploring educational equality, fueled considerable debate regarding group differences in IQ and ability (Jensen, 1967).

1968: The Association of Black Psychologists (ABPsi) is formed when 75 Black psychologists leave APA, charging that APA had failed to address poverty, racism, and social concerns. (Holliday, 2009; Nelson, 1968). The group asks that APA help increase representation of Black psychologists in the field. ABPsi also called for a moratorium on testing, charging that such tests were culturally biased, racist, and unfair (Williams & Mitchell, 1978). In response, APA formed the *APA Ad Hoc Committee on Educational Uses of Tests with Disadvantaged Students*. The Committee issued a report acknowledging the problems with testing but claimed that the central problem was the misuse and misinterpretation of tests, not the tests themselves.

1969: Psychologist Arthur Jensen revives arguments of hereditary influence on racial differences in IQ scores in the *Harvard Educational Review*, claiming that compensatory education programs have failed (Jensen, 1969). His work is widely used by racist and neo-Nazi groups.

1969: The Black Student Psychology Association (BSPA) raises a series of demands from APA, emphasizing the need for recruitment, retention, and training of Black students and Black faculty. (Holliday & Holmes, 2003; Simpkins & Raphael, 1970). A resolution was submitted to the APA Council of Representatives calling for proportional representation of "minority" groups at all job levels in firms working with APA. A substitute resolution passed, specifying that APA would adopt a strategy of supplier diversity, aiming to work with firms that are actively trying to increase representation of minority groups in their organizations (Sawyer & Senn, 1973).

1970: The Association of Psychologists Por La Raza is founded at the annual APA convention.

1971: APA members Jack Sawyer and David J. Senn (1971) accuse APA of institutional racism, stating that APA had ignored systemic racism in the organizations with which it affiliates. They note that APA's largest printer, Lancaster Press, employed only a single Black employee, a man who served as the washup man in the pressroom (see also Pickren & Tomes, 2002).

1971: Psychologist Anderson J. Franklin publishes an article in *The Counseling Psychologist*, arguing that counseling research and training, along with psychology education more generally, fails to prepare students for understanding and working with Black clients (Franklin, 1971).

1972: The Asian American Psychological Association is founded, inspired by the civil rights movement and the founding of ABPsi (Alvarez, Singh, & Wu, 2012).

1973: A national survey finds only 15 Chicano psychology faculty in a total of 1,335 psychology faculty. The survey also found only 51 Latino graduate students enrolled in master's programs in psychology and 37 in PhD programs (Ramirez, 2004).

1974: APA sponsors the Vail Conference, leading to recommendations that any psychologist counseling persons of culturally diverse backgrounds must be trained and competent to work with such groups. This led to the establishment of several boards and committees, along with guidelines and further recommendations. However, few institutions offered training in this skill, and in 1977, fewer than 1% of psychologist counselor educators required students to study diverse cultures. Practitioners representing these groups called for specific ethical requirements and reflection of those requirements in accreditation and licensing (Casas, Ponterotto, & Gutierrez, 1986).

1974: APA announces a Minority Fellowship Program, funded with a $1 million grant from the National Institute of Mental Health Center for Minority Group Mental Health Programs.

1975: Psychological testing continues to be the subject of legal arguments. In *Albemarle Paper Co v. Moody* (1975), the Supreme Court ruled that intelligence tests used in employment testing discriminated against Black employees, and those tests must be proven to be reasonable measures of job performance (see also Holliday & Holmes, 2003).

1975: The Society of Indian Psychologists (SIP) is formed independently of APA, merging the American Indian Interest Group and the Network of Indian Psychologists. The group was concerned with the lack of representation of First Peoples within APA (Gray, 2012).

1975–2020

Over the past 50 years, critics contend that U.S. psychology has failed to fully represent people of color and the concerns of communities of color. Furthermore, it has failed to address ongoing concerns about White normativity in psychology and the use of instruments and practices that discriminate against people of color. Between 1975 and the present, several guidelines and recommendations were issued, which do not have the force of professional ethics codes, and compliance remains voluntary. Separate associations and societies continued to be formed during this time to create space for psychologists of color and the issues that are central for communities of color.

1978: The first report from the President's Commission on Mental Health is issued, documenting overrepresentation of people of color in mental health statistics and the lack of effective services for these communities. Subpanels attending to individual ethnic and racial groups stressed the presence of discriminatory barriers for people of color seeking services and the need for policies that accounted for the needs and experiences of each group (Grob, 2005).

1978: Thirty representatives of the Ethnic Minority Psychology Associations (EMPAs) convene with APA leadership to urge APA to provide a strong presence for ethnic minority concerns in the organization (Jones, 1999; Smith & Pickren, 2018; Sue, 1983). They recommended the formation of a Board of Ethnic Minority Affairs (BEMA). Council rejected this proposal, and APA formed the Office of Ethnic Minority Affairs. The following year, the APA Board proposed creating a standing bylaws committee instead of BEMA, but Council rejected this and put the issue to the membership (Conger, 1980). It passed, and APA established the Board of Ethnic Minority Affairs in 1980. In 1990, BEMA was sunset, and the Committee on Ethnic Minority Affairs took its place.

1979: Several organizations coalesce to form the National Hispanic Psychological Association, which later became the National Latinx Psychological Association.

1979: Congressional hearings for the Truth in Testing Act are held. White psychologists testified regarding the utility of ability-based scoring and the generalizability of testing. Black psychologists reiterated that standardized testing is problematic and discriminatory (US Government Printing Office, 1980). This same year, the Federal District Court of Northern California rules in favor of five Black students who had been placed in special education classes due to their performance on psychological tests. The case centered on the use of psychological tests and their role in blocking educational and economic opportunities for Black youth in California (*Larry P. v. Riles,* 1979).

1980: Chicano Studies professors James Vásquez and Clotilde Gold publish *Counseling and Minorities: A Bibliography*. They noted that limited amount of work had been done on counseling with communities of color and that the work that did exist often went unnoticed by practitioners, professors, and students. Less than 4% of the articles in the bibliography were from psychology journals and only three were from either the flagship or mainstream journals of APA.

1983: Rogler (1983) provides data demonstrating Puerto Rican and Black people are more frequently diagnosed with mental illness and more frequently admitted to community mental health centers.

1985: APA, along with the American Educational Research Association and the National Council on Measurement in Education, issues a new set of *Standards for Educational and Psychological Testing.* This is the fifth set of standards spanning a -30year period. The new edition highlights rights and privileges of test takers and includes attention to nonnative English speakers, along with race, ethnicity, and culture (Wagner, 1987)

1985: In *Personality and Individual Differences*, psychologist J. Philippe Rushton publishes the first of more than 150 articles claiming that compared to Whites, Africans evolved to have lower intelligence, have more children and care for them poorly, and have a greater tendency to commit crime.

1986: Logan Wright becomes the first American Indian to serve as president of APA, 93 years after the Association's founding (Gray, 2012).

1986: Division 45, the Society for the Psychological Study of Ethnic Minority Issues, was established to draw attention to issues related to ethnic minority psychology (Holliday & Holmes, 2003; Morales, Lau, & Ballesteros, 2012).

1988: Ponteretto (1988) reviews articles published in the *Journal of Counseling Psychology* between 1976 and 1986 and finds that %5.7 of the articles focus on people of color. Furthermore, people of color made up only 6.5 to %11.1 of regular editorial board reviewers.

1990: Psychologist Arthur Jensen is invited as keynote speaker for the Society for General Psychology at the annual APA convention. At this time, Jensen was continuing to assert the importance of heredity in explaining the social position of Black Americans and continued to speak publicly of the dangers of compensatory social programs until his death in 2012.

1990: Throughout the 1990s and 2000s, people of color are grossly underrepresented in APA and in the field more generally due to historical marginalization and exclusion (Bernal & Castro, 1994). They represented only 17% of members of boards and committees (primarily serving on public interest boards and committees) and only 6% of the Council of Representatives (Hall, 1997). During this time, people of color represented 26.3% of the U.S. population. In 2000, racial/ethnic minority psychologists represented 5.8% of APA's total membership. This includes .3% American Indian, 1.7% Asian, 2.1% Hispanic, 1.7% Black, and <.1% Multiracial/Multiethnic. Numbers in the U. S. workforce were similar in 2000: 90% White, 2% Asian, 5% Hispanic, and 2% Black (American Psychological Association, 2020b). In a 2007 report, Division 45 summarized the number of awards given to people of color, demonstrating that members of these groups have been historically marginalized and excluded within APA. They also note disparities in governance and Council participation, Fellow status, and distribution of NIH funding (Division 45 Science Committee, 2007).

1990: Sue and Sue report that 50% of people identified as minority group members terminate counseling after the first session. This is compared to 30% of White people. Further research suggested this was related to negative experiences and lack of cultural sensitivity on the part of therapists (Fukuyama, 1990).

1992: Reviews of APA's Ethical Principles of Psychologists and Code of Conduct find little mention of race and ethnicity (Hall, 1997). The following year, APA issues Guidelines for Providers of Psychological Services to Ethnic, Linguistic, and Culturally Diverse Populations (American Psychological Association, 1993).

1992: Graham (1992) reviews literature in six top APA journals and finds that, between 1970 and 1989, 3.6% of published articles are focused on African Americans, a number that showed a steady decrease. She further finds that most of the published work is focused on complexities of using standardized instruments with Black people and notes that while it is important to attend to these complexities, it means that little to no work is published addressing healthy personality development and competent intellectual functioning.

1994: Alice Chang becomes the first person of color to serve on APA's Board of Directors.

1997: Raymond Cattell is selected the winner of the APA Gold Medal Award for Life Achievement in Psychological Science. A small group of psychologists protested the award, charging that Cattell's work was racist, promoted White supremacy, and supported eugenics and neo-Nazi activists. APA delayed the award in order to form a committee to investigate the charges. A larger group of APA members protested its postponement. The following year, Cattell withdrew his name from consideration. Cattell died in 1998 but remains one of the few psychologists (along with Arthur Jensen, Linda Gottfredson, and Richard Lynn) listed on the Southern Poverty Law Center's Extremist Files (Southern Poverty, n.d.; Tucker, 2009).

1998: Psychologist Glayde Whitney writes the foreword to *My Awakening,* the autobiography of racial extremist and former Klansman David Duke. Whitney blames "organized Jewry" for suppressing the "truth" about racial differences.

1999: Psychologist Richard Suinn is elected the first Asian American president of APA, more than a century after the Association's founding.

2001: The U.S. Surgeon General report on Mental health: Culture, race, and ethnicity—A supplement to mental health showed evidence and reported concerns that the gap between research and practice is particularly wide for racial and ethnic minorities. (Sue & Zane, 2006)

2003: The President's New Freedom Commission on Mental Health finds racial and ethnic differences in rates of psychopathology and points to continued inaccessibility and ineffectiveness of treatment options. Echoing previous reports, the Commission found that clients of color often saw psychotherapists or received treatments that did not consider the clients' experiences, cultural and linguistic backgrounds, and race-based life circumstances. (Sue & Zane, 2006)

2003: APA files an amicus brief in support of the University of Michigan's right to consider race in admissions procedures in order to achieve a diverse student body. The Supreme Court ruled in favor of the University.

2005: Representatives of the EMPAs begin attending APA Council of Representatives meetings as observers. Council requests that APA Boards and Committees begin exploring bylaw changes to provide voting seats for EMPA representatives on Council. The issue went in front of Council, Boards and Committees, and the membership three times over 15 years, failing to pass. The bylaw change was finally approved by the membership in 2020. (American Psychological Association, 2012; 2020a).

2005: Jessica Henderson Daniels becomes the first Black woman elected to the APA Board of Directors

2006–2015: Psychologist Richard Lynn's books on racial differences are published by Washington Summit Publishers, designated a hate group by the SPLC.

2007: Research shows that Black clients' experiences of microaggressions from White therapists have a significant impact on therapeutic alliances and their ratings of satisfaction with both the counselor and counseling in general. Constantine notes that "in the face of perceived racial microaggressions in counseling, African American clients, in fact, might feel much worse after their counseling experiences than before." (Constantine, 2007, p. 13; see also Helms & Cook, 1999).

2011: Melba J. T. Vasquez is elected the first Latina president of APA.

2013: Members of racial/ethnic minority groups account for 16.4%of the psychology workforce, compared to 39.6% of the overall workforce and 25.8% of the doctoral/professional workforce (American Psychological Association, 2015).

2014: APA, along with the American Educational Research Association and the National Council on Measurement in Education, issues a new set of Standards for Educational and Psychological Testing. This is the sixth set of standards spanning a 30-year period. The new edition elevates considerations of fairness alongside considerations of reliability and validity in educational and psychological testing (Worrell & Roberson, 2016).

2017: APA membership data provides the following demographics of APA members in 2017: American Indian, .2%; Hispanic, 1.7%; Black, 2.0%; White, 60.1%; Pacific Islander, 0%; Multiracial/multi-ethnic, 0.7%; Other, 0.2%; Not specified, 32.6% (American Psychological Association, 2017).

2017: The American Arab, Middle Eastern, and North African Psychological Association (AMENAPsy) is established.

2018: Jessica Henderson Daniel elected first Black woman president of APA.

2018: Examining the editorship of six top-tier psychology journals from 1974 to 2018, researchers find that only 5% of editors were people of color (Roberts et al., 2020). The authors chose these journals based on their strong reputation as top journals in social, cognitive, and developmental psychology.

2019: The APA Center for Workforce Studies reports the following demographic statistics for the field of psychology: Asian, 4% (4,887); Black/AA, 3% (3,733); Hispanic, 7% (8,203); Other, 2% (2,145); White 83% (91,302). According to the report, "Other includes American Indian, Alaska Native, Native Hawaiian and other Pacific Islander, other race and those with two or more." Population data in the United States from this same period provides the following demographics: Asian, 5.9%; Black/AA, 13.4%; Hispanic, 18.5%; Other, 4.3%; and White, 60.1%. While all groups (other than non-Hispanic Whites) represented approximately 42% of the general population, they represented only 16% of psychologists. (American Psychological Association, 2020b; U.S. Census Bureau, 2021).

2021: The APA Council of Representatives votes to adopt the APA Resolution on Racism: *Harnessing Psychology to Combat Racism: Adopting a Uniform Definition and Understanding.*

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American Psychological Association

TOP 20 PRINCIPLES FROM PSYCHOLOGY FOR PreK–12 TEACHING AND LEARNING

Coalition for Psychology in Schools and Education

TOP 20 PRINCIPLES FROM PSYCHOLOGY FOR PreK–12 TEACHING AND LEARNING

COALITION FOR PSYCHOLOGY IN SCHOOLS AND EDUCATION

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TOP 20 PRINCIPLES FROM PSYCHOLOGY FOR PREK–12 TEACHING AND LEARNING

PRINCIPLE 1 Students' beliefs or perceptions about intelligence and ability affect their cognitive functioning and learning.

PRINCIPLE 2 What students already know affects their learning.

PRINCIPLE 3 Students' cognitive development and learning are not limited by general stages of development.

PRINCIPLE 4 Learning is based on context, so generalizing learning to new contexts is not spontaneous but instead needs to be facilitated.

PRINCIPLE 5 Acquiring long-term knowledge and skill is largely dependent on practice.

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PRINCIPLE 7 Students' self-regulation assists learning, and self-regulatory skills can be taught.

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PRINCIPLE 9 Students tend to enjoy learning and perform better when they are more intrinsically than extrinsically motivated to achieve.

PRINCIPLE 10 Students persist in the face of challenging tasks and process information more deeply when they adopt mastery goals rather than performance goals.

PRINCIPLE 11 Teachers' expectations about their students affect students' opportunities to learn, their motivation, and their learning outcomes.

PRINCIPLE 12 Setting goals that are short term (proximal), specific, and moderately challenging enhances motivation more than establishing goals that are long term (distal), general, and overly challenging.

PRINCIPLE 13 Learning is situated within multiple social contexts.

PRINCIPLE 14 Interpersonal relationships and communication are critical to both the teaching–learning process and the social-emotional development of students.

PRINCIPLE 15 Emotional well-being influences educational performance, learning, and development.

PRINCIPLE 16 Expectations for classroom conduct and social interaction are learned and can be taught using proven principles of behavior and effective classroom instruction.

PRINCIPLE 17 Effective classroom management is based on (a) setting and communicating high expectations, (b) consistently nurturing positive relationships, and (c) providing a high level of student support.

PRINCIPLE 18 Formative and summative assessments are both important and useful but require different approaches and interpretations.

PRINCIPLE 19 Students' skills, knowledge, and abilities are best measured with assessment processes grounded in psychological science with well-defined standards for quality and fairness.

PRINCIPLE 20 Making sense of assessment data depends on clear, appropriate, and fair interpretation.

INTRODUCTION

Psychological science has much to contribute to enhancing teaching and learning in the classroom. Teaching and learning are intricately linked to social and behavioral factors of human development, including cognition, motivation, social interaction, and communication. Psychological science can also provide key insights on effective instruction, classroom environments that promote learning, and appropriate use of assessment, including data, tests, and measurement, as well as research methods that inform practice. We present here the most important principles from psychology—the "Top 20"—that would be of greatest use in the context of preK–12 classroom teaching and learning, as well as the implications of each as applied to classroom practice. Each principle is named and described, relevant supporting literature is provided, and its relevance for the classroom is discussed.

This work of identifying and translating psychological principles for use by preK–12 practitioners was conducted by a coalition of psychologists, known as the **Coalition for Psychology in Schools and Education**, that is supported by the American Psychological Association (APA). The coalition is an ideal group for translating psychological science for classroom use because its members collectively represent a wide spectrum of subdisciplines in psychology, including evaluation, measurement, and statistics; developmental psychology; personality and social psychology; the psychology of aesthetics, creativity, and the arts; consulting psychology; educational psychology; school psychology; counseling psychology; community psychology; psychology of women; media psychology and technology; group psychology and group psychotherapy; psychological study of men and masculinity; and clinical child and adolescent psychology.

Also involved in the coalition are psychologists representing communities of educators and scientists, as well as specialists in ethnic minority affairs; testing and assessment; teachers of psychology in secondary schools; children, youth, and families; and psychology honor societies. Coalition members are employed in K–12 schools and in colleges and universities in education, liberal arts, and science divisions. Some members are in independent practice. All hold expertise in psychology's application to early childhood, elementary, secondary, or special education.

This coalition specifically, and APA generally, has been putting psychological science to work for preK–12 education for over a decade. There are many modules and white papers for teachers on the APA website (**http://www.apa.org/ed/schools/cpse**). The Top 20 project was modeled after APA's earlier effort of identifying *Learner-Centered Psychological Principles* (1997). This initiative updates and broadens those principles.

METHODOLOGY

The method to derive the Top 20 principles was as follows. The coalition, operating in the mode of a National Institutes of Health consensus panel, engaged in a series of activities. **First, each member was asked to identify two constructs, or "kernels"** (Embry & Biglan, 2008), **from psychology thought to be most essential for facilitating successful classroom teaching and learning.** This process led to the identification of approximately 45 kernels/principles.

Next, steps were taken to categorize, validate, and consolidate these principles. The first step was to cluster the 45 principles according to key domains of classroom application (e.g., How do students think and learn?). This was conducted in an iterative process across several meetings of the coalition.

Second, a validation procedure for the 45 principles was undertaken. Several national blueprint publications related to teaching were analyzed to assess whether each of these principles also had been identified by the broader community of educators as critical to teacher practice. Cross-checking analyses were conducted on APA's standards for high school curriculum in psychology; the PRAXIS Principles of Learning and Teaching examination from the Educational Testing Service; documents from the National Council for the Accreditation of Teacher Education; the InTASC (Interstate Teacher Assessment and Support Consortium) standards; a popular educational psychology textbook; and the National Association of School Psychologists' *Blueprint for Training and Practice*. These documents were searched for evidence of what teachers were expected to know or be able to do and whether these expectations could be linked to the principles that the coalition had identified. There was support for all principles in one or more documents. Hence, all were retained for the next step in the validation process.

To identify the most important of the 45 principles/kernels, we used a modified Delphi process (modeled after the Institute of Medicine's report *Improving Medical Education: Enhancing the Behavioral and Social Science Content of Medical School Curricula*). Using a scale system, four coalition members rated each of the principles and assigned each a high, medium, or low priority score (1–3). Mean scores for each item were calculated. On the basis of the mean scores, low-priority principles were discarded, leaving 22 principles. These were then analyzed for their relation to each other and were synthesized into the final 20 presented here.[1]

These Top 20 were then placed into five areas of psychological functioning. The first eight principles relate to cognition and learning and address the question **How do students think and learn?** The next four (9–12) discuss the question **What motivates students?** The following three (13–15) pertain to the social context and emotional dimensions that affect learning and focus on the question **Why are social**

[1] We also wish to acknowledge the invaluable contributions of the following authors to our conceptualization of the work: Henry Roediger III (2013); John Dunlosky, Katherine Rawson, Elizabeth Marsh, Mitchell Nathan, and Daniel Willingham (2013); the Society for the Teaching of Psychology (Benassi, Overson, & Hakala, 2014); and Lucy Zinkiewicz, Nick Hammond, and Annie Trapp (2003) from the University of York.

context, interpersonal relationships, and emotional well-being important to student learning? The next two principles (16–17) relate to how context can affect learning and address the question **How can the classroom best be managed?** Finally, the last three principles (18–20) examine the question **How can teachers assess student progress?**

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How do students think and learn?

PRINCIPLE 1 Students' beliefs or perceptions about intelligence and ability affect their cognitive functioning and learning.

EXPLANATION

Students who believe intelligence is malleable and not fixed are more likely to adhere to an "incremental" or "growth" mind-set about intelligence. Those who hold the opposite view, that intelligence is a fixed trait, tend to adhere to the "entity" theory of intelligence. Students holding to the latter view focus on performance goals and believe they continually need to demonstrate and prove their intelligence, making them more hesitant to take on highly challenging tasks and more vulnerable to negative feedback than students holding an incremental view. Students with an incremental mind-set generally focus on learning goals and are more willing to take on challenging tasks in an effort to test and expand (as opposed to defensively prove) their intelligence or ability. Hence, they rebound more easily from negative feedback and failure. Accordingly, students who believe that intelligence and ability can be enhanced tend to perform better on a variety of cognitive tasks and in problem-solving situations.

One evidence-based approach to fostering a growth mind-set is framed in terms of the attributions teachers assign to student performance. When students experience failure, they are likely to ask "why?" The answer to that question is a causal attribution. Causal attributions, which relate to growth and entity mind-sets, respectively, distinguish motivated from unmotivated students. Attributions that tend to blame one's *ability* ("I failed because I'm just not smart enough") are associated with the view that intelligence is fixed. In contrast, attributions that blame lack of *effort* ("I failed because I didn't try hard enough") generally reflect an incremental or growth view of intelligence. Students are better able to cope when failure is attributed to a lack of effort rather than to low ability because the former is unstable (effort fluctuates over time) and controllable (students can generally try harder if they want to).

RELEVANCE FOR TEACHERS

When teachers attribute a student's poor performance to controllable and modifiable causes, such as lack of effort or poor choice of strategy, they afford students the expectation or hope that things can be different in the future. **Teachers can foster student beliefs that their intelligence and ability can be developed through effort and experiences with applying different strategies:**

- Teachers can convey to students that their failure at any given task is not due to lack of ability but rather that their performance can be enhanced, particularly with added effort or through the use of different strategies. Attributing failure to low ability often leads students to give up when they encounter failure. Hence, when students believe their performance can be improved, they are fostering a growth mind-set that can bring motivation and persistence to bear on challenging problems or material.

- Teachers should avoid generating ability-based attributions when a task is moderately easy. For example, when teachers praise a student by saying "You're so smart" after the student has finished a task or quickly figured out an answer to a relatively unchallenging problem, the teacher may inadvertently encourage that student to associate smartness with speed and lack of effort. These associations become problematic when students are later presented with more challenging material or tasks that require more time, effort, and/or the use of different approaches.

- Teachers need to be judicious in their use of praise, making sure the content of that praise is tied to effort or successful strategies and not ability. Indirect and subtle cues about low ability can be unintentionally communicated by teachers, especially when they are attempting to protect the self-esteem of failure-prone students. For example, offering praise for success on a relatively easy task may not be reassuring or reinforcing to the student. In fact, such praise may undermine motivation because it suggests a student does not have the ability to succeed at a more difficult task (e.g., "Why is my teacher praising me for getting these easy problems right?). [2]

- When presenting students with challenging materials and tasks, teachers may want to be aware of situations in which students expend minimal, modest, or incomplete effort. This self-handicapping may reflect a student's fear of embarrassment or failure ("If I don't even try, people will not think I'm dumb if I fail").

- When teachers are consistent in their offer of help to all students and communicate mild and constructive criticism following failure, students are more likely to attribute their failure to lack of effort and to believe teachers' expressions of high expectations that they will do better in the future. Unsolicited offers of help by a teacher, especially when other students do not receive help, and sympathetic affect from a teacher following student failure can be interpreted by students as indirect and subtle cues about low ability.

To be clear, we are not suggesting that teachers should never praise or help their students or that they should always express disappointment (rather than sympathy) or offer constructive criticism (rather than compliments). The appropriateness of any feedback will depend on many factors based on teacher judgment of the situation. The general message is that attribution principles, which are intricately linked to mind-set, help explain how some well-intentioned teacher behaviors may have unexpected, or even negative, effects on students' beliefs about their own abilities.

[2] See APA module on praise: http://www.apa.org/education/k12/using-praise.aspx.

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PRINCIPLE 2 What students already know affects their learning.

EXPLANATION

Students come to classrooms with knowledge based on their everyday experiences, social interactions, intuitions, and what they have been taught in other settings and in the past. This prior knowledge affects how they will incorporate new learning because what students already know interacts with the material being learned. **Accordingly, learning consists of either adding to existing student knowledge, known as *conceptual growth*, or transforming or revising student knowledge, known as *conceptual change*.** Learning as conceptual growth occurs when student knowledge is consistent with material to be learned. Conceptual change is required when student knowledge is inconsistent or erroneous with respect to correct information. In these cases, students' knowledge consists of "misconceptions" or "alternative conceptions." Many common misconceptions are held by both students and adults, particularly in subjects such as mathematics

and science.[3] Teachers can gain an understanding of students' current understanding of a specific subject area by administering an initial assessment of student knowledge prior to instruction on a topic. This type of assessment, called a formative assessment, can be used as a type of a pretest or as a baseline for student knowledge.

When the baseline assessment shows students to be harboring misconceptions, learning will require conceptual change—that is, revision or transformation of student knowledge. Achieving conceptual change in students is far more challenging for teachers than inducing conceptual growth because misconceptions tend to be entrenched in reasoning and resistant to change. Students, like anyone, can be very reluctant to alter their thinking, since it is familiar to them. Also, students are generally unaware that their concepts are erroneous and hence believe them to be correct.

RELEVANCE FOR TEACHERS

Teachers can be instrumental in achieving both conceptual growth and conceptual change in students:

- When the baseline assessment shows students' current knowledge to be consistent with the curricular concepts to be taught, teachers can facilitate conceptual growth by engaging students in meaningful, thoughtful interaction with the information to be learned. This might include having students engage in activities such as reading, defining, summarizing, synthesizing, applying concepts, and participating in hands-on activities.

- Simply telling students they need to think differently or using teaching strategies for inducing conceptual growth will generally not lead to substantial change in student thinking. Bringing about conceptual change requires teachers' use of specific instructional strategies. Many of these entail methods that precipitate cognitive conflict or dissonance in the minds of students by helping make them aware of the discrepancy between their own thinking and correct curricular material or concepts. For example:

  - Teachers can have students play an active role in predicting solutions or processes and then show these predictions to be faulty.

  - Teachers can present students with credible information or data that run counter to their misconceptions.

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[3] For a more detailed discussion and a list and definition of these misconceptions/alternative conceptions, see "How Do I Get My Students Over Their Alternative Conceptions (Misconceptions) for Learning?": http://www.apa.org/education/k12/misconceptions.aspx?item=1.

PRINCIPLE 3 Students' cognitive development and learning are not limited by general stages of development.

EXPLANATION

Student reasoning is not limited or determined by an underlying cognitive stage of development linked to an age or a grade level. Instead, newer research on cognitive development has supplanted these stage theory accounts. Infants have been found to have early, possibly native, competencies (biologically based) in certain domains. For example, children can show knowledge of principles related to the physical world (e.g., that stationary objects are displaced when they come into contact with moving objects or that inanimate objects need to be propelled into motion), biological causality (e.g., animate and inanimate entities differ), and numbers/numeracy (e.g., an understanding of numerical values up to three items). Studies of cognitive development and learning that emphasize the background knowledge or knowledge base of students reveal that they have many structures in place. For example, students have a structure, known as *schemas* (i.e., mental representations), which guide their understanding when encountering text and events.

Contextualist approaches to cognitive development and learning describe how context affects cognition. Supporters of cognitive approaches point out that cognition can be interpersonally based, such that student reasoning can be facilitated to more advanced levels when students interact with more capable others and/or with more advanced materials. This strategy is especially effective when materials are pitched not too near or too far from students' current level of functioning. This principle is captured in what is called the *zone of proximal development*. Contextualist approaches also support the idea that cognition can be "situated," whereby knowledge accrues through the lived practice of people in a society. That is, learning is conceived as participation in communities, with students progressively acquiring situated actions (such as farming, learning a craft, or adapting to societal expectations). Formal schooling can be viewed as a practice.

In sum, students are capable of higher level thinking and behavior when (a) there is some biological base (early competency) for knowledge in the domain, (b) they already have some familiarity or expertise with a knowledge domain, (c) they interact with more capable others or challenging materials, and (d) in sociocultural contexts with which they are familiar through experience. Conversely, when students are not familiar with a particular knowledge domain, are not challenged by the interpersonal context or learning materials, or find the context of learning to be unfamiliar, their reasoning may be less sophisticated.

RELEVANCE FOR TEACHERS

Teachers' estimation of what material should be presented and the method of presentation are more effective when they can take into account the domain-relevant and contextual knowledge of their students. Baseline assesssments can be used to assess this knowledge, and the results can be very informative for instructional design. Students' developmental levels can help teachers decide which instructional experiences might be appropriate and relevant, but age should not necessarily be viewed as the main or sole determinant of what a student is capable of knowing or reasoning.[4] In designing instruction, teachers can facilitate student reasoning by the following:

- Encouraging students' reasoning in familiar areas—that is, in knowledge domains and contexts in which students already have substantial knowledge. For example, students are able to comprehend reading material at a higher level and are able to write with greater sophistication when they have substantial knowledge relevant to the topic of the reading or writing assignment.

- Presenting topics and domains pitched at a moderate distance from students' current level of functioning. Providing information that is not too elementary to be easily understood and not too complex to be out of range of understanding even with assistance represents the perfect level of entry for new material. If a topic is unfamiliar, teachers may want to link that topic to what students

[4] See http://www.apa.org/education/k12/brain-function.aspx.

already know to foster more advanced levels of reasoning.

- Using heterogeneous groupings, whereby students are placed in mixed-ability groups to allow for interaction with higher level thinkers in learning and problem solving.

- Helping students already at very high levels of functioning achieve even higher levels by facilitating their interaction with still more advanced peers or with instructors and by using advanced learning materials (as noted in the third bulleted entry above).

- Familiarizing students with the culture of classrooms and schooling practices. Although not all classroom work can be approached by relying on peer collaboration, when possible this approach can help students whose background experiences have not familiarized them with schooling and classroom practices in the United States.

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PRINCIPLE 4 Learning is based on context, so generalizing learning to new contexts is not spontaneous but instead needs to be facilitated.

EXPLANATION

Learning occurs in context. Contexts can consist of subject-matter domains (e.g., science), specific tasks/problems (e.g., a textbook problem to solve), social interactions (e.g., caretaking routines between a parent and child), and situational/physical settings (e.g., home, classrooms, museums, labs). Hence, for learning to be more effective or powerful, it needs to generalize to new contexts and situations. **Student transfer or generalization of their knowledge and skills is not spontaneous or automatic; it becomes progressively more difficult the more dissimilar the new context is from the original learning context.** Notably, transfer or generalization of student knowledge can be facilitated and supported. Moreover, students' ability to transfer learning is an important indicator of the quality of their learning—its depth, adaptability, and flexibility.

RELEVANCE FOR TEACHERS

Teachers can support student transfer of knowledge and skills across contexts—from highly similar to highly dissimilar contexts. This is best done by the following:

- Identifying and building on strengths that students bring to a learning situation and thereby making connections between students' current knowledge and the teachers' learning goals.

- Teaching a topic or concept in multiple contexts.

- Helping students compare and contrast contexts and noting contextual similarities that make transfer appropriate.

- Taking the time to focus on deep, underlying concepts in a domain and promoting learning by understanding rather than focusing on surface-level elements in a learning situation or by memorizing the specific elements. For example, in biology, the ability to remember the physical properties of veins and arteries (e.g., that arteries are thicker, more elastic, and carry blood from the heart) is not equivalent to understanding why they have these properties. Understanding is critical for transfer problems, such as, "Imagine trying to design an artery. Would it have to be elastic? Why or why not?" Organizing facts around general principles aligns with how experts organize knowledge. For example, while physics experts approach problem solving by way of major principles or laws that apply to the problem, beginners focus on the equations and plugging numbers into the formulas.

- Helping students see the application of their knowledge to the real world (e.g., using multiplication and division to understand the cost of purchases in a store) or assisting them in transferring real-world knowledge when trying to understand academic principles. Teachers can provide occasions and multiple contexts in which students can use and practice their knowledge. For example, students may not spontaneously recognize the relevance of their learning about solving division problems unless it is applied to computing gas mileage in a real-world context. Teachers can help students generalize/apply their knowledge by regularly providing real-life instances of the academic behaviors in which they are engaged.

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PRINCIPLE 5 Acquiring long-term knowledge and skill is largely dependent on practice.

EXPLANATION

What people *know* (their knowledge base) is inscribed in long-term memory. Most information, particularly when related to academic content and highly skilled activities (e.g., sports; artistic endeavors such as playing a musical instrument), must be processed in some way before being stored in long-term memory. At any given moment, students experience an enormous amount of stimuli in the environment, but only a small portion is further processed in the form of attention and encoding, ultimately moving into a time-constrained and limited-capacity memory-storage area known as *short-term* or *working memory*. To be retained more permanently, information must be transferred into *long-term memory*, which by definition is of relatively long duration (e.g., decades), has very large capacity, and is highly organized (e.g., categorized). The transfer of information from short-term to long-term memory is accomplished through different strategies, and *practice* is key to this transfer process.[5]

Studies comparing the performance of experts and novices have uncovered important distinctions between deliberate practice and other activities, such as play or "drill and kill" repetition. Rote repetition—simply repeating a task—will not by itself improve performance or long-term retention of content. **Instead, deliberate practice involves attention, rehearsal, and repetition over time and leads to new knowledge or skills that can later be developed into more complex knowledge and skills.** Although other factors such as intelligence and motivation also affect performance, practice and rehearsal are necessary, if not sufficient, activities for acquiring expertise.

Overall, learning is improved in at least five ways through rehearsal and deliberate practice. Evidence demonstrates that (a) the likelihood that learning will be long term and retrievable is increased, (b) student ability to apply elements of knowledge automatically and without reflection is enhanced, (c) skills that become automatic free up students' cognitive resources for learning more challenging tasks, (d) transfer of practiced skills to new and more complex problems is increased, and (e) gains often bring about motivation for more learning.

RELEVANCE FOR TEACHERS

Student practice can be elicited and encouraged by teachers in a variety of ways. Because practice requires intense, focused effort, students may not find it inherently enjoyable; therefore, teachers need to encourage students to practice by pointing out that expending effort leads to improved performance.

Teachers can motivate students to engage in practice by expressing confidence in their ability to do well in solving practice problems and by designing activities

[5] See http://www.apa.org/education/k12/practice-acquisition.aspx.

that maximize students' opportunities to succeed. Unrealistic or poorly designed practice problems may lead to student frustration and less motivation to attempt future practice problems. Tests (or quizzes) that are given immediately after a learning exercise give students opportunities to practice, and they tend to do well because the learning is recent. However, their success in this case does not ensure long-term retention. Effective methods of implementing practice in the classroom include:

- Using reviews and tests (*practice testing*). The value of testing or any kind of practice exercise is enhanced by conducting them at spaced intervals (distributive practice) and giving them frequently. Brief tests with open-ended questions are particularly effective because they require that students not only recall information from long-term memory but also generate new information from that retrieval.

- Providing students with a schedule of repeated opportunities (*interleaved practice*) to rehearse and transfer skills or content by practicing with tasks that are similar to the target task or using several methods to approach the same task.

- Designing tasks with students' existing knowledge in mind (see Principle 2).

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PRINCIPLE 6 Clear, explanatory, and timely feedback to students is important for learning.

EXPLANATION

Student learning can be increased when students receive regular, specific, explanatory, and timely feedback on their work. Feedback that is occasional and perfunctory (e.g., saying "good job") is neither clear nor explanatory and does not increase student motivation or understanding. Clear learning goals help to increase the effectiveness of feedback to students because the comments can be directly tied to the goals, and regular feedback prevents students from getting off track in their learning.

RELEVANCE FOR TEACHERS

The feedback teachers offer can be most effective when it provides students with specific information about their current state of knowledge and performance as related to learning goals. For example:

- Teachers can tell students what they are (or are not) understanding and the strength of their performance by relating their progress to *specific* learning goals.

- Feedback can also incorporate information on what students can do in the future to achieve those goals. For example, rather than general remarks, such as "good job" or "you do not appear to be getting this," teachers can make more directed comments, such as "Your topic sentences provided a good summary of the main idea in each paragraph. In the future, you also need to address the meaning of the text as a whole by generating and explaining a few points that take into account how all the main ideas interact with one another."

- Feedback on quizzes and practice tests is helpful to students and appears to improve classroom performance in the future. Examples of such feedback include providing the correct response when students answer incorrectly or, alternatively, providing guidance that helps students discover the correct response themselves.

- Providing feedback in a timely way (e.g., as quickly as possible after a quiz) assists learning and is usually more effective than providing delayed feedback.

- The tone and targeting of feedback affect student motivation. Students tend to respond better if feedback minimizes negativity and addresses significant aspects of their work and understanding, in contrast to feedback that is negative in tone and focused excessively on details of student performance that are less relevant to the learning goals.

- When students are learning a new task or struggling with an existing one, frequent praise following small degrees of improvement is very important, and when progress is evident, encouragement to persist can matter a great deal. Targeted feedback can also motivate students to continue to practice learning a new skill (see Principle 5).[6]

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[6] See *Using Classroom Data to Give Systematic Feedback to Students to Improve Learning*: http://www.apa.org/education/k12/classroom-data.aspx.

PRINCIPLE 7 Students' self-regulation assists learning, and self-regulatory skills can be taught.

EXPLANATION

Self-regulatory skills, which include attention, organization, self-control, planning, and memory strategies, can facilitate mastery of the material to be learned. Although these skills may increase over time, they are not subject only to maturation. **These skills also can be taught or enhanced, specifically through direct instruction, modeling, support, and classroom organization and structure.**

RELEVANCE FOR TEACHERS

Teachers can help students learn self-regulatory skills by introducing teaching strategies to enhance attention, organization, self-control, planning, and remembering, all of which can greatly facilitate learning. Moreover, the classroom environment itself can be organized to enhance self-regulation. Organizational assistance can be provided in several ways:

- Teachers can present the goals of lessons and tasks very clearly to students.

- They can break down tasks into smaller, "bite-size," meaningful components and clearly spell out the criteria for successful task performance.

- Teachers also can provide time and opportunities for students to engage in practice.

- Some processing time and activity (e.g., summarizing, questioning, rehearsing, and practice) are necessary for long-term remembering.

- Teachers can help students plan by helping them identify and evaluate the short- and long-term consequences of their decisions.

- Teachers can use cues to alert students that important information is to follow when introducing a new concept to increase student attention.

- Teachers can organize classroom time by incorporating periods of focused time, interactive periods, and so forth, so students are able to practice intense focusing followed by more socially interactive methods of learning.

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PRINCIPLE 8 Student creativity can be fostered.

EXPLANATION

Creativity—defined as the generation of ideas that are new and useful in a particular situation—is a critical skill for students in the information-driven economy of the 21st century. Being able to identify problems, generate potential solutions, evaluate the effectiveness of those strategies, and then communicate with others about the value of the solutions are all highly relevant to educational success, workforce effectiveness, and quality of life. Creative approaches to teaching can inspire enthusiasm and joy in the learning process by increasing student engagement and modeling of real-world application of knowledge across domains. Contrary to the conventional wisdom that creativity is a stable trait (you either have it or you don't), **creative thinking can be developed and nurtured in students, making it an important outcome of the learning process for students and educators.**

RELEVANCE FOR TEACHERS

A variety of strategies are available for teachers to foster creative thinking in students:

- Educators can allow for a wide range of student approaches to completing tasks and solving problems, as the strategies being taught may not be the only ways to answer a specific question.
- Teachers should emphasize the value of diverse perspectives as fuel for discussion, reinforcing that such perspectives are clearly valued and not penalized in the classroom.
- Teachers should also avoid the tendency to see highly creative students as disruptive; instead, student enthusiasm can be channeled into solving real-world problems or taking leadership roles on certain tasks.

The creative process is often misconstrued as being purely spontaneous or even frivolous, yet extensive research provides evidence that creativity and innovation are the result of disciplined thinking. For this reason, other instructional strategies that can foster creativity include:

- Varying activities by including prompts in assignments, such as *create, invent, discover, imagine if*, and *predict*.
- Using methods that focus on questioning, challenging prevailing beliefs, making unusual connections, envisioning radical alternatives, and critically exploring ideas and options.
- Providing opportunities for students to solve problems in groups and communicate their creative ideas to a wide range of audiences (peers, teachers, community members).
- Modeling creativity. Teachers are powerful models, and as such they should share with students their own creativity—including the use of multiple strategies to solve problems across various aspects of their lives. This modeling can also involve examples of how creativity is not necessary in all situations, which may help students develop an improved sense of confidence in their judgment

as to when it is appropriate to focus on getting one right answer and when to pursue alternative approaches.

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What motivates students?

PRINCIPLE 9 Students tend to enjoy learning and to do better when they are more intrinsically rather than extrinsically motivated to achieve.

EXPLANATION

Intrinsic motivation refers to engaging in an activity for its own sake. To be intrinsically motivated means to feel both competent and autonomous (e.g., "I can do it for myself"). Students who are intrinsically motivated work on tasks because they find them enjoyable. In other words, participation is its own reward and is not contingent on tangible rewards such as praise, grades, or other external factors. In contrast, students who are extrinsically motivated engage in learning tasks as a means to an end, such as to get a good grade, to get praise from their parents, or to avoid punishment. It is not the case that intrinsic and extrinsic motivation are at opposite ends of a motivation continuum, such that having more of one means having less of the other. Instead, students engage in academic tasks for both intrinsic and extrinsic reasons (e.g., because they enjoy it and to get a good grade). Nonetheless, intrinsically motivated task engagement is not only more enjoyable, it is positively related to more enduring learning, achievement, and perceived competence and is negatively related to anxiety.

These benefits occur because students who are intrinsically motivated are more likely to approach their tasks in ways that enhance learning, such as attending more closely to instruction, organizing new information effectively, and relating it to what they already know. They also feel more self-efficacious and are not burdened by achievement anxiety. On the other hand, students who are more extrinsically motivated may be so focused on the reward (e.g., getting a high grade) that learning is superficial (e.g., the student may resort to shortcuts such as skimming the reading for specific terms rather than absorbing the entire lesson), or they may become discouraged if the pressures are too high. Furthermore, externally motivated students may disengage once the external rewards are no longer provided, whereas intrinsically motivated students show more long-lived mastery of learning goals.[7]

Notably, however, a substantial body of experimental research studies shows that extrinsic motivation, when properly used, is very important to producing positive educational outcomes. Research also shows that students develop academic competence when they do tasks repeatedly in carefully constructed ways so that the basic skills become automatic. As more basic skills become automatic, the tasks require less effort and are more enjoyable. Just as in sports, students improve their reading, writing, and mathematics skills when they do these activities repeatedly with teacher guidance and feedback, gradually progressing from less complex tasks to more difficult ones. Students' engagement in these activities often requires teacher encouragement and praise for making progress. **As students develop increasing competence, the knowledge and skills that have been developed provide a foundation to support the more complex tasks, which become less effortful and more enjoyable. When students have reached this point, learning often becomes its own intrinsic reward.**

RELEVANCE FOR TEACHERS

Promoting intrinsic motivation requires the incorporation of practices and activities that support students' fundamental need to feel competent and autonomous:

[7] See also http://www.apa.org/education/k12/learners.aspx.

- When using grades, teachers might want to highlight their informational (feedback) rather than controlling (rewarding/punishing) function.

- A useful strategy when using any external constraints such as deadlines is to think about whether the constraints will be perceived by students as too controlling. Much of the perception of control can be managed by the way in which a task is communicated to students. Autonomy needs are more likely to be satisfied when students have choices. Allowing students to select from an array of achievement activities and to have a role in establishing rules and procedures helps foster perceptions of autonomy. This approach can also help students learn the value of choosing tasks that are of intermediate difficulty for them. Tasks are optimally challenging when they are neither too easy nor too hard.

- Because intrinsic motivation involves enjoying a task for its own sake, teachers might want to incorporate the ideas presented for Principle 8 on creativity so as to introduce novelty by providing some level of surprise or incongruity and allowing for creative problem solving.

Supporting students' intrinsic motivation to achieve does not mean that teachers should completely eliminate the use of rewards. Certain tasks in the classroom and in life, like practicing new skills, are going to be inherently uninteresting to students. It is important to teach students that some tasks, even tasks that are necessary to master, might be uninteresting at first yet require consistent, sometimes tedious, engagement for learning. Once learned, new skills may become their own reward.

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PRINCIPLE 10 Students persist in the face of challenging tasks and process information more deeply when they adopt mastery goals rather than performance goals.

EXPLANATION

Goals are the rationale for why students engage in particular learning activities. Researchers have identified two broad types of goals: *mastery goals* and *performance goals*. Mastery goals are oriented toward acquiring new skills or improving levels of competence. Students who hold mastery goals are motivated to learn new skills or achieve mastery in a content area or on a task. In contrast, students who adopt performance goals are motivated to demonstrate that they have adequate ability or to avoid tasks in an effort to conceal a perception of having low ability. **According to this analysis, individuals can engage in achievement activities for two very different reasons: They may strive to develop competence by learning as much as they can (mastery goals), or they may strive to display their competence by trying to outperform others (performance goals). Performance goals can lead to students' avoiding challenges if they are overly concerned about performing as well as other students. In typical classroom situations, when students encounter challenging materials, mastery goals are generally more useful than performance goals.**

RELEVANCE FOR TEACHERS

There are specific ways in which teachers can organize instruction to foster mastery goals:

- Try to emphasize individual effort, current progress over past performance, and improvement when evaluating student work rather than rely on normative standards and comparison with others.
- In classroom settings, student evaluations are best delivered privately.
- Praise like "perfect," "brilliant," and "amazing" that provides no specific information to the student about what was done so well is best avoided because it does not promote guidance for replicating high-quality work.
- It is best to avoid social comparisons. Whereas high-achieving students often enjoy public recognition of their accomplishments and should be praised when their level of achievement exceeds previous personal levels, those who are struggling or who worry about appearing "dumb" can be discouraged by social comparisons. Instead, teachers could consider the progress each student has made on his or her individual work in a manner that does not compare one student's work to another.
- Encourage students to see mistakes or wrong answers as opportunities to learn rather than as sources of evaluation or evidence of ability. If teachers focus too much attention (through praise) on perfect scores and make mistakes too visible (e.g., red marks on students' papers), students can come to devalue mistakes and be reluctant to view them as a natural part of learning.
- Individualize the pacing of instruction as much as possible. Some students take longer to master the material than others and should be given that extra time. Allowing students a role in setting timelines for completing tasks and monitoring their own progress helps them focus on process (acquiring mastery) in addition to the outcome (performance).

It is important to consider the context of different environments when planning for learning and motivation in classroom settings:

- Organizing instructional activities that allow students to work cooperatively in small mixed-ability groups can downplay ability differences between students and encourage them to develop as a community of learners. Cooperation is one of the best ways to promote a mastery goal orientation.
- Rather than using cooperation and competition as incompatible learning tools in the classroom, teachers could sometimes use teams of mixed-ability groups that compete with each other to reach a common goal.
- There are times when performance goals can work well in situations that are themselves a performance. These situations may be more competitive, such as a science fair where students are organized into teams and given the task of designing a robot, machine, or other device that will then be entered into competition for reward or recognition.

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PRINCIPLE 11 Teachers' expectations about their students affect students' opportunities to learn, their motivation, and their learning outcomes.

EXPLANATION

Teachers often hold expectations about the abilities of their students. These beliefs shape the kinds of instruction delivered to students, the grouping practices that are used, anticipated learning outcomes, and methods of evaluation. Most teacher expectations about individual student ability are based on students' past academic performance and, for the most part, may be an accurate representation. In some cases, however, teachers come to hold inaccurate beliefs, such as expecting less of the student than he or she can actually achieve. **If faulty expectations are communicated to a student (whether verbally or nonverbally), that student may begin to perform in ways that confirm the teacher's original expectation.** An inaccurate teacher expectation that creates its own reality has been labeled a *self-fulfilling prophecy*. When these inaccurate expectations do occur, they are more likely to be directed toward stigmatized groups (e.g., ethnic minority youth, economically disadvantaged youth), because negative beliefs or stereotypes about the intellectual abilities of these groups exist in our society.

These faulty expectations are more likely to occur in the earlier grades, at the beginning of a school year, and at times of school transitions—in other words, when the contexts in which information about prior achievement may be least available or reliable and when students may have grounds to question their abilities. Whether accurate or not, expectations influence how teachers treat students. For example, teachers appear to provide a more supportive emotional climate, clearer feedback, more attention, more instructional time, and more learning opportunities overall for their high-expectancy versus low-expectancy students. Such differential treatment may increase the actual differences in achievement between high- and low-performing students over time.

RELEVANCE FOR TEACHERS

It is best for teachers to communicate high expectations to all students and maintain appropriately high standards for everyone in order to avoid negative self-fulfilling prophecies:

- Teachers can continually assess the reliability of the information they are using to form their expectations. A student's weak academic history should not be perceived as the absolute last word about a student (i.e., there may be mitigating factors that may have impaired the student's ability in the past but no longer apply) but rather as a working hypothesis about a student that the teacher has an opportunity to disprove. Also, race, gender, and social class are not solid bases on which to form expectations of student ability.

- Because teachers can sometimes be unaware that they are treating students differently on the basis of their expectations (high-expectancy students vs. low-expectancy students), it can be helpful for teachers to do a self-check. For example, teachers can ask themselves whether (a) only high-expectancy students are seated in the front of the classroom, (b) everyone is getting a chance to participate in class discussions, and (c) written feedback on assignments is comparably detailed for high- and low-expectancy students.

Probably the best antidote to negative expectancy effects is to never give up on a student.

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PRINCIPLE 12 Setting goals that are short term (proximal), specific, and moderately challenging enhances motivation more than establishing goals that are long term (distal), general, and overly challenging.

EXPLANATION

Goal setting is the process by which a person establishes a standard of performance (e.g., "I want to learn 10 new words every day"; "I want to graduate from high school in 4 years"). This process is important for motivation because students with a goal and adequate self-efficacy are likely to engage in the activities that lead to attainment of that goal. Self-efficacy is also increased as students monitor the progress they are making toward their goals, especially when they are acquiring new skills in the process.

Three properties of goal setting are important for motivation. First, short-term, or proximal, goals are more motivating than long-term, or distal, goals because it is easier to judge progress toward proximal goals. Developmentally, at least until middle adolescence, students tend to be less skilled at thinking concretely about the distant future. Second, specific goals (e.g. "I will finish 20 addition facts today with 100% accuracy), are preferable to more general goals (e.g., "I will try to do my best") because they are easier to quantify and monitor. Third, moderately difficult goals rather than very hard or very easy goals are the most likely to motivate students because moderately difficult goals typically will be perceived as challenging but attainable. Research has documented the benefits of proximal, specific, and moderately challenging goals on achievement outcomes.

RELEVANCE FOR TEACHERS

Students need to be provided with many opportunities to set short-term, specific, and moderately difficult goals in their classroom work:

- Keeping a written record of goal progress that is regularly checked by both the student and the teacher is especially desirable.
- **As students become proficient at setting moderately challenging proximal goals, they will learn to become intermediate risk takers (not aspiring too low or too high), which is one of the most important characteristics of achievement-oriented individuals.**
- Teachers can also help students begin to think about more distal goals by developing contracts with them that specify a series of subgoals leading to the larger, more distal goal.

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Why are social context, interpersonal relationships, and emotional well-being important to student learning?

PRINCIPLE 13 Learning is situated within multiple social contexts.

EXPLANATION

Learners are a part of families, peer groups, and classrooms that are situated in larger social contexts of schools, neighborhoods, communities, and society. All of these contexts are influenced by culture, including shared language, beliefs, values, and behavioral norms. Furthermore, these layers of context interact with each other (e.g., schools and families). Appreciating the potential influence of these contexts on learners can enhance the effectiveness of instruction and communication across contexts (e.g., between teachers and parents).

RELEVANCE FOR TEACHERS

Teachers who are aware of the potential influence of the classroom's social context on learners and the teaching–learning process can facilitate effective interpersonal relationships and communication with and between students and thereby affect learning:

- The more teachers know about the cultural backgrounds of students and how differences in values, beliefs, language, and behavioral expectations can influence student behavior, including interpersonal dynamics, the better they will be able to facilitate effective teaching–learning interactions in their classrooms. For example, for students whose culture is more collectivist than individualistic, teachers can enhance learning experiences through more frequent use of cooperative learning activities.

- Teachers can relate the curriculum to students' cultural backgrounds—for example, through incorporating local history into social studies lessons or gearing science toward local health problems.

Given potential variations in cultural experiences, it is critical that the teacher facilitate a "classroom culture" that ensures shared meanings, values, beliefs, and behavioral expectations and provides a safe and secure environment for all students.

- Establishing connections with families and local communities can help enhance understanding of student cultural experiences and facilitate shared understandings about learning. Family involvement facilitates student learning, so creating opportunities for family and community involvement in the work of the classroom is vital.

- Seeking opportunities to participate in the local community (e.g., attending local cultural events) can help connect the relevance of learning to students' everyday lives and enhance teachers' understanding of the cultural background and experiences of their students.

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PRINCIPLE 14 Interpersonal relationships and communication are critical to both the teaching–learning process and the social-emotional development of students.

EXPLANATION

The teaching–learning process in preK–12 classrooms is inherently interpersonal, encompassing both teacher–student and peer connections. These relationships are essential for facilitating healthy social-emotional development of students. **Given their social nature, classrooms provide a critical context for teaching social skills such as communication and respect for others.** Developing successful relationships with peers and adults is highly dependent on one's ability to communicate thoughts and feelings through verbal and nonverbal behavior.[8]

RELEVANCE FOR TEACHERS

Given the interpersonal nature of preK–12 teaching and learning, teachers should attend to the relational aspects of the classroom:

- A safe and secure environment, both physical and social, and shared classroom culture (e.g., ensuring that everyone in the classroom is clear about relevant vocabulary, values, and norms) provide the foundation for healthy teacher–student and peer relationships.
- Teachers can provide clear behavioral expectations related to social interactions (e.g., respect for others, use of clear communication, nonviolent conflict resolution) and opportunities for all students to experience successful social exchanges.
- Not only can teachers establish cooperative and supportive classroom norms but it is also critical that teachers set clear injunctions against bullying in any form.
- Opportunities to learn effective social skills should include planned instruction and opportunities for practice and feedback. These social skills include cooperation/collaboration, perspective taking and seeking, respect for others' views, constructive feedback, interpersonal problem solving, and conflict resolution.
- Teachers are responsible for ensuring that a positive social climate is maintained, promoting peaceful resolution of student conflicts, and intervening early should bullying occur.

One of the foundational skills for the more complex interactions described above is the development of clear and thoughtful communication. Effective student communication requires teaching and practice of component skills. Teachers may incorporate lessons in communication basics as part of the routine curriculum. For example, they might incorporate specific skills into a lesson (such as how to ask relevant questions) and provide opportunities to apply those skills, such as during cooperative learning. In addition, teachers can:

- Prompt students to elaborate on their responses.
- Engage in give-and-take with other students during discussions.
- Seek clarification from others.
- Listen carefully to others.
- Read nonverbal cues.
- Provide opportunities for students to practice communication in both academic and social contexts.
- Provide feedback to enhance skill development.
- Model effective verbal and nonverbal communication by using active listening, matching facial expression with verbal messages, using questions effectively, providing elaboration in response to student questions, and seeking student perspectives.

[8] See also http://www.apa.org/education/k12/relationships.aspx.

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PRINCIPLE 15 Emotional well-being influences educational performance, learning, and development.

EXPLANATION

Emotional well-being is integral to successful, everyday functioning in the classroom and influences academic performance and learning. It is also important to interpersonal relationships, social development, and overall mental health. The components of emotional well-being include sense of self (self-concept, self-esteem), a sense of control over oneself and one's environment (self-efficacy, locus of control), general feelings of well-being (happiness, contentment, calm), and capacity for responding in healthy ways to everyday stresses (coping skills). Being emotionally healthy depends on understanding, expressing, and regulating or controlling one's own emotions, as well as perceiving and understanding others' emotions (empathy). Understanding others' emotions is influenced by how students perceive external expectations and acceptance on the part of significant others in their classroom, family, peer group, community, and societal environment (see Principles 13 and 14).

RELEVANCE FOR TEACHERS

The emotional well-being of students can influence the quality of their participation in the teaching–learning process, their interpersonal relationships, the effectiveness of their communication, and their responsiveness to classroom climate. Concurrently, the classroom climate can influence students' sense of security and acceptance, perceptions of social support, sense of control, and overall emotional well-being. The teacher plays a key role in establishing a climate in which all students are accepted, valued, and respected; have opportunities for academic success and relevant support; and have opportunities for positive social relationships with adults and peers. Teachers can help facilitate emotional development by:

- Using emotional vocabulary—for example, facilitating student labeling of emotions (e.g., *happy, sad, fearful, angry*).
- Modeling appropriate emotional expression and reactions.
- Teaching emotion regulation strategies, such as "stop and think before acting" and deep breathing.
- Promoting emotional understanding of others, such as empathy and compassion.
- Monitoring their expectations to ensure they are equally encouraging to all students, regardless of past performance.

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How can the classroom best be managed?

PRINCIPLE 16 Expectations for classroom conduct and social interaction are learned and can be taught using proven principles of behavior and effective classroom instruction.

EXPLANATION

Students' ability to learn is as much affected by their interpersonal and intrapersonal behavior as it is by their academic skills. Student behavior that does not conform to classroom rules or teacher expectations cannot simply be regarded as a distraction to be eliminated before instruction can take place. Rather, **behaviors conducive to learning and appropriate social interaction are best taught at the beginning of the academic year and reinforced throughout the year.** These behaviors can be taught using proven behavioral principles. For students exhibiting more serious or consistent problem behaviors, understanding the context and function of the behavior is a key element in teaching appropriate replacement behaviors.[9]

RELEVANCE FOR TEACHERS

A common assumption is that instruction is only intended for those who are "ready to learn" and that the learning environment will be improved if those who disrupt or distract from it are removed.

- Improved social and classroom behavior, like academic skill, can be shaped and taught. In the most effective classrooms, classroom rules and expectations represent a social curriculum that is taught and retaught throughout the academic year. The first 2 weeks of school are considered a crucial time for teachers to establish their rules and expectations.

- Proactive disciplinary strategies that avoid behavior problems are always better than reactive strategies that try to reduce problem behaviors after they are already present. Thereafter, student behavior that does not conform to classroom rules becomes an opportunity to bring student attention back to classroom expectations.

- Classroom rules and expectations can be taught and retaught using the same principles as those used in academic instruction, including clear presentation of a goal, task, or behavior; opportunities for practice, with timely and specific feedback; reinforcement of desired behavior; and behavioral correction as needed.

- A range of behavioral principles, including praise of appropriate behavior, differential reinforcement (desired behaviors or responses are reinforced and inappropriate behaviors or responses are ignored), correction, and planned consequences, can be used to consistently teach and remind students of their expectations.

- On the schoolwide level, these same principles can be used to clarify expectations and reward positive behavior through programs such as Positive Behavior Interventions and Supports (PBIS).

- The problem-solving process known as functional behavioral assessment (FBA) has enabled teachers and school psychologists to identify the antecedent events and functional relationships associated with inappropriate behavior. The information drawn from an FBA enables school personnel to identify appropriate replacement behaviors—that is, more

[9] See also http://www.apa.org/education/k12/classroom-mgmt.aspx and http://www.apa.org/ed/schools/cpse/activities/class-management.aspx).

adaptive behaviors that allow students to reach the same behavioral goal in a more acceptable way.

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PRINCIPLE 17 Effective classroom management is based on (a) setting and communicating high expectations, (b) consistently nurturing positive relationships, and (c) providing a high level of student support.

EXPLANATION

At both the classroom and the school level, the development of an effective learning climate is based on structure and support. In terms of structure, students need to have a clear understanding of the behavioral rules and expectations of the classroom, and these expectations must be communicated directly and frequently and consistently enforced. Yet we also know that support is essential. To be both effective and culturally responsive, teachers can develop and maintain strong, positive relationships with their students by consistently communicating that they are firmly committed to supporting all of their students in meeting those high academic and behavioral expectations.

RELEVANCE FOR TEACHERS

Students profit from a predictable structure and high expectations for both academic achievement and classroom behavior.

For example:

- A safe and well-arranged physical environment, a predictable schedule, and rules that are clearly explained and consistently enforced all contribute to a safe and orderly learning climate that reduces distraction and keeps the focus on academic instruction.
- High expectations, especially when communicated in a punitive manner, are not sufficient to establish and maintain a positive and productive learning climate. The most effective teachers, schools, and programs also emphasize the development of supportive and nurturing relationships with students.
- Maintaining a high ratio of positive statements and rewards to negative consequences, as well as expressing respect for all students and their heritage, builds trust in the classroom.

At the school level:

- Programs such as Restorative Practices[10] enable students to gain an understanding of how to restore relationships damaged by disruption and violence through strategies such as collaborative decision making.
- Social-emotional learning strategies[11] explicitly teach students interpersonal and intrapersonal skills (e.g., managing emotions, establishing positive relationships, and making responsible decisions) needed to succeed in school and society.

[10] See http://www.iirp.edu/what-is-restorative-practices.php.

[11] See, e.g., http://www.casel.org/social-and-emotional-learning.

Balancing structure and support is central to culturally responsive classroom management and is associated with lower levels of suspension and bullying when applied at the school level.

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How to assess student progress?

PRINCIPLE 18 Formative and summative assessments are both important and useful but require different approaches and interpretations.

EXPLANATION

Formative assessments are used to guide and shape classroom instruction directly. *Summative assessments* are used to produce an overall judgment of student learning progress or the effectiveness of educational programs. Formative assessments take place before or during instruction, can be "on the fly," and have the explicit purpose of improving current learning. Summative assessments measure learning at a particular point, usually at the end of a unit of study, semester, or academic year, and by design provide limited opportunities to influence current learning activities.

The approach used to collect information is likely to differ between the two types of assessment as well, given their different purposes. Formative assessments, in the service of achieving learning goals, are more likely to incorporate learning progressions and include discussion, collaboration, self- and peer assessment, and descriptive feedback. Summative assessments, given their purpose of evaluating progress against a benchmark, are more likely to be high-stakes, standardized large-scale assessments that evaluate individual work to yield an overall score or performance-level designation.

Both formative and summative assessments can be developed by teachers or those outside of the classroom—for example, by a testing company on behalf of a state agency. In general, however, formative assessments are more likely to be developed by teachers, and large-scale, high-stakes assessments are more likely to be developed by an external organization. Overall, the goal of both types of assessments is fundamentally the same—to produce valid, fair, useful, and reliable sources of information.

RELEVANCE FOR TEACHERS

Employing formative assessments can result in important increases in student learning when teachers:

- Clearly communicate to students the purposes of each lesson.
- Use lessons and other classroom experiences to collect evidence on student learning.
- Use this evidence to help understand what students know and promptly redirect students as needed.

Teachers can improve the effectiveness of formative assessments when they:

- Focus systematically on setting goals for their students.
- Determine whether students have met these goals.
- Consider how to improve their instruction in the future.
- Keep the length of time between the formative assessment and subsequent interventions relatively short; this is when effects on student learning will be strongest.

Teachers can make better use of both formative and summative assessments when they understand basic concepts related to educational measurement. Teachers can also use assessment data to evaluate their own instruction to consider whether they adequately covered the material they intended to cover and wheth-

er they were effective in meeting their instructional goals. Teachers will also want to ensure that their assessments align with overall learning goals to elicit questions in different ways to assess students' level of knowledge.

Principle 19 provides a discussion of the importance of validity and fairness in assessments and how they affect the appropriateness of inferences that may be made from test results. Furthermore, it is important to consider the length of the test when making important or irrevocable decisions, since test length is one factor related to the reliability, or consistency, of test results. Principle 20 describes how the meaning of assessment outcomes depends on clear, appropriate, and fair interpretation of test results.

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PRINCIPLE 19 Students' skills, knowledge, and abilities are best measured with assessment processes grounded in psychological science with well-defined standards for quality and fairness.

EXPLANATION

PreK–12 teachers and leaders are working in an era when assessments are a constant topic of discussion and debate. It is important to remember, however, that there are clear standards for judging the quality of assessments of any type. This is true of both formative and summative assessment (see the *Standards for Educational and Psychological Testing*; AERA, APA, & NCME, 2014). **Assessments that are both reliable and valid help test score users make appropriate inferences about students' knowledge, skills, and abilities.**

The validity of an assessment can be thought of in relation to four essential questions:

- How much of what you want to measure is actually being measured?
- How much of what you did not intend to measure is actually being measured?
- What are the intended and unintended consequences of the assessment?
- What evidence do you have to support your answers to the first three questions?

The validity of an assessment tool is not simply a number. It is a judgment, over time and across a variety of situations, about the inferences that can be drawn from test data, including the intended or unintended consequences of using the test. For example, test users need to be able to infer from a test score that it accurately reflects student learning and not other factors. For this to be true, the test must be validated for the purpose and population for which it is being used. Further, individual test takers must be motivated to show what they can actually do. Otherwise, school personnel

cannot tell if student learning is being measured or if what is being measured is the degree of effort put into taking the test.

Fairness is a component of validity. Valid assessment requires saying clearly what an assessment is and is not supposed to measure and requires evidence of this for all test takers. Tests showing real, relevant differences are fair; tests showing differences that are unrelated to the purpose of the test are not.

Reliability of an assessment is also a key factor. A reliable assessment is one whose results are consistent indicators of student knowledge, skills, and abilities. Scores should not be affected by chance factors associated with, for example, student motivation or interest as it relates to a given set of test questions, variations in testing conditions, or other things that are not part of what test givers intend to measure. In general, longer tests are more reliable than shorter tests.

RELEVANCE FOR TEACHERS

Whenever teachers give an assessment, it is best to consider its strengths and limitations with respect to what they hope it will tell them about their students' learning. Teachers can apply strategies to improve the reliability of their assessments and be cognizant of why some assessments will be more reliable than others. Ways in which teachers can improve the quality of the assessments they use include:

- Carefully aligning assessments with what is taught.
- Using a sufficient number of questions overall and variety of questions and types of questions on the same topic.
- Using item analysis to target questions that are too hard or too easy and are not providing sufficient differentiation in knowledge (e.g., 100% of students answered correctly).
- Being mindful that tests that are valid for one use or setting may not be valid for another.
- Basing high-stakes decisions on multiple measures instead of a single test.
- Monitoring outcomes to determine whether there are consistent discrepancies across performance or outcomes of students from different cultural groups. For example, are some subgroups of students routinely overrepresented in certain types of programming (e.g., special education)?

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PRINCIPLE 20 Making sense of assessment data depends on clear, appropriate, and fair interpretation.

EXPLANATION

The meaning of assessment outcomes depends on clear, appropriate, and fair interpretation. **Scores from any assessment should generally be used only for the specific purposes for which they were designed.** For example, tests intended to rank order students for a competition may be valid, fair, and useful for that purpose, but at the same time these tests would likely be misleading for determining the strengths and weaknesses of each individual student's mastery of material in a particular subject-matter area.

RELEVANCE FOR TEACHERS

Effective teaching depends heavily on teachers being informed consumers of educational research, effective interpreters of data for classroom use, and good communicators with students and their families about assessment data and decisions that affect students. Teachers can weigh curriculum and assessment choices to evaluate whether those resources are supported by research evidence and are suitable for use with diverse learners.

To effectively interpret assessment data, teachers should address the following about any assessment they use:

- What was the assessment intended to measure?
- What comparisons are the assessment data based on? Are students being compared to one another? Or, instead, are students' responses being directly compared to samples of acceptable and unacceptable responses that the teacher or others have provided?
- What are the criteria for cut-points or standards? Are the students' scores being classified using a standard or cut-point, such as a pass/fail category, letter grades, or some other indicator of satisfactory/unsatisfactory performance?

Data gathered from any assessment are best interpreted in light of their suitability for addressing specific questions about students or educational programs, their appropriateness for individuals from a variety of different backgrounds and educational circumstances, and the intended and unintended consequences that result from using the assessment. Because both higher- and lower-stakes tests can have significant impact on students, it is important to make careful interpretations of the results of either type of test.

Awareness of the strengths and limitations of any assessment is critical. Such awareness also enables teachers to communicate caveats, such as the imperfect reliability of scores (see more on this in Principle 19) and the importance of using multiple sources of evidence for high-stakes decisions.

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Use of traditional and smartphone app flashcards in an introductory psychology class

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ABSTRACT

The use of traditional and smart phone flashcards was examined in two Introductory Psychology college classes. Student use of flashcards of some type increased significantly when they were provided by the instructor. Flashcards available via smartphone app were not used by many students even when provided by the instructor. The results are discussed in terms of the use of mobile devices for studying by college students.

Keywords: mobile technology, smartphone apps, studying, flashcards, notecards

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INTRODUCTION

Flashcard use is a standard study technique where traditional flashcards are typically pieces of paper or notecards that have a term written on one side and a definition on the other side. When one studies using flashcards, users often look at one side and try to recall information on the other side. Advantages of flashcards include their portability and their ease of use in various locations.

Golding, Wasarhaley, and Fletcher (2012) found that approximately 70% of the 415 general psychology study students studied used flashcards for at least one exam with 65.5% using written flashcards and 3.9% using computer flashcards. Forty-eight percent of the same students reported using written flashcards in other classes, 2% used computer-based flashcards, and 6.5% used both written and computer flashcards. No research studies were identified that examined the use of flashcard apps on smartphones.

It is estimated that at least 80% of college mobile phone users own smart phones and that by 2016, about 90% of college students will own a smart phone (emarketer.com, 2012). With the increased popularity of smartphones there has been an increase in apps designed to facilitate studying. Among these are apps that permit the creation or use of flashcards (e.g., Study Blue, Quizlet, Flashcards +). The advantages to using app-based flashcards include that many students have their smart phones with them most of the time and smart phones are more portable than large stacks of traditional flashcards. Seventy-five percent of college students report using a smartphone during breaks, meetings, etc, 55% while waiting in line, and 45% of those surveyed for school related uses (Dean, 2012). This pattern of use leaves open the possibility of increasing study time if students use a flashcard app during these opportunities.

When compared to traditional flashcards, flashcards used on smartphones have the additional advantages of being available whenever the smartphone is in use, ability to carry as many cards as desired for multiple classes, and collaboration with other students to create large groups of flashcards. Also, smartphone technology enables the students to set reminders to study. Golding, et al. (2012) suggested that the almost universal availability of mobile technology could lead to an increase in use of computer flashcards.

Historically, students would make their own flashcards, but more recently textbooks have started making flashcards available on their websites. These programs require internet access and may require the user to log in each time. Smartphone apps have the advantage of being self-contained on the phone and immediately available without internet access. Additionally, many flashcard apps have an option to make users' flashcards available for general use or sharing. This means that the flashcards for many classes are already available (Gikas & Grant, 2013).

The use of smartphones for educational purposes is an understudied area even though their accessibility and potential as educational tools is expanding rapidly. A 2012 survey of approximately 1,000 teens in 6th through 8th grades found the students reported using their mobile devices for school related purposes such as completing their homework (TRU, 2012). These activities seem to focus on searching for information rather than using mobile devices to facilitate the process of studying. Little research has examined how mobile technology may be used to facilitate other academic activities such as studying using flashcards or other study aides.

The present study was designed to explore the use of traditional flashcards and a flashcard app when provided to college students in a general psychology class. The correlation of flashcard with both exam performance and overall class average was also examined.

STUDY 1

Method

Participants

Ninety-two General Psychology students from 2 classes, with an average age of 19.12 (*SD* = 2.03), participated. The 2 instructors (1 male and 1 female) used the same course outline, content, notes, and exam content.

Materials

Flashcards with all the vocabulary words in each chapter from the course textbook grouped by exam were created. Flashcards were either 3x5 traditional paper notecards or app-based flashcards using the app StudyBlue. Each traditional flashcard contained the vocabulary word printed in 14 point Times New Roman font on one side and the definition from the textbook on the other side. The app StudyBlue can be accessed via a smartphone (iPhone or Android) or a computer and also included the vocabulary word on one side and the textbook definition on the other.

The flashcard use survey was patterned after Golding, et al. (2012) and modified to include additional questions about smartphone app flashcards. Students were asked whether they used flashcards for each exam. They were asked whether they created their own, used the paper flashcards provided, or used the flashcard app provided. They were also asked why they did or did not use flashcards when they studied.

Design & Procedure

Students were not provided flashcards in any form for the first and final exams. For the second and third exams students were provided with traditional and app-based flashcards. For the fourth exam students were provided with only the app-based flashcards. Instructions were provided to the students on how to access and use the app-based flashcards. The instructors gave no special instructions or encouragement to use the provided flashcards once they were handed out beyond general reminders to use the course notes and study materials, as the purpose was to assess the baseline use of the materials. Following each exam, students were given the flashcard use survey. All students were treated in accordance with APA ethical guidelines and the university human subjects review board approved the study.

Results

There were not significant differences between the two classes in the pattern of results. Therefore only the analyses for the combined classes are reported. The use of flashcards of some type varied greatly by exam overall. For exam one, where neither paper nor app flashcards were provided, 15% of students used flashcards of some type. For exam two, where traditional and app flashcards were provided, flashcard use increased to 74.2%. For exam three, where traditional and app flashcards were provided, flashcard use increased to 90.6%. For the fourth exam, where only the app was provided, flashcard use decreased with 40% of students reporting

flashcard use of some type. It is noteworthy that flashcard use increased dramatically when paper and app were provided. It is also interesting that flashcard use decreased dramatically when the paper flashcards were not provided. A chi-square analysis found that the change in flashcard use between exams was significant, $\chi^2(df = 3, n = 60) = 139.78, p < .05$.

Additionally the type of flashcards used by students for each exam was examined. App flashcard use also varied greatly by exam. For exam one, where neither paper nor app flashcards were provided, no students used a flashcard app. For exam two 19.4% of students used the flashcard app while none used it for exam three even though it was provided. For the fourth exam 10.9% of students used the flashcard app.

The paper flashcards were used much more often than the app flashcards. This was observed even for exam 4 where the app flashcards were provided but the paper flashcards were not. For exam one, where neither paper nor app flashcards were provided, 15% of students used paper flashcards. For both exams two and three, paper flashcards were provided to the students. For exam two 54.8% of students used paper flashcards and for exam three 90.6% of students used paper flashcards. For exam four where no paper flashcards were provided, flashcard use decreased dramatically to 29.1% of students reporting using paper flashcard use.

Group differences in exam performance based on overall flashcard use and type of flashcard used were also examined. Overall flashcard use was coded for use (yes/no). Type of flashcard was coded by type of flashcard used (traditional, app, both, or none). There were no significant differences in exam grades as a function of use or type for each exam. However, students who used flashcards on the first exam had a significantly higher final average than those who did not, $F(1,29) = 6.413, p < .05$. Of note, the first exam was the only exam where no flashcards of any type were provided by the researchers.

Several open-ended questions were completed by participants regarding reasons for using versus not using flashcards in general as well as the flashcard app. Students reported using traditional flashcards because they were a good way to study, were repetitive and useful, and were portable. Students reported not using traditional flashcards because they did not like to study using them, they did not have time to use them, forgot about them, or they lost them.

Students who responded that they did not use the app-based flashcards for studying focused on smart phone technical issues such as it used too much of their battery, that they were easily distracted by other things they could do on their smart phones, and that they would forget about the app availability. Students who did like the app-based flashcards for studying indicated that the portability, ability to study almost everywhere, and availability on their smartphone was convenient.

Discussion Study 1

Flashcard use by college students was examined when traditional and smart phone app flashcards were provided. Overall flashcard use increased when flashcards were provided. This increase was mainly true for the use of the provided traditional flashcards. The provided app flashcards were not used by most students.

The use of flashcards increased when flashcards were provided. Flashcard use increased greatly from exam one to exams two and three. It could be questioned whether this change was due to the provided flashcards or whether students realized that they needed to study differently following the first exam. To answer this question study 2 was designed and conducted in a comparable class.

STUDY 2

Method

Participants

Two General Psychology classes taught by the same instructor were used. Fifty-seven General Psychology students with an average age of 19.51 (*SD* = 4.71) participated, 33 were female and 24 were male.

Materials

The Flashcard use survey patterned after Golding, et al. (2012) was completed after each exam. The survey was modified to include questions about flashcard app usage as well as traditional flashcards. The survey asked students to report their flashcard use for each of the first 3 exams in the course.

Design & Procedure

Students were not provided flashcards for the first three exams. The instructor only encouraged students to use flashcards if they asked for study tips after class. All students were treated in accordance with APA ethical guidelines and the university human subjects review board approved the study.

Results

The percentage of students who used some form of flashcards on exam one was 37.5%, on exam two was 35.7%, and on exam three was 33.9%. A chi-square analysis showed that this difference in flashcard use was not significant, $\chi^2(df = 2, n = 57) = .16, p > .05$. The percentage of students who used app-based flashcards for exam one was 7.3%, for exam two was 5.3%, and for exam three was 3.6%.

Discussion Study 2

This study was conducted to examine baseline flashcard use when students were not provided with flashcards by the instructor. Flashcard use remained stable across tests, suggesting that poor performance alone does not increase flashcard use.

GENERAL DISCUSSION

Overall use of flashcards increased when traditional or app-based flashcards were provided to the students as indicated in Study 1. However, even with the convenience of smartphone-based flashcards, students used the app flashcards less frequently than the traditional flashcards both when traditional flashcards were provided and when they had to make their own. Study 2 suggests the increased use of flashcards seen in Study 1 was not associated with

performance on exam one as students did not increase their use of flashcards when they were not provided by the instructor.

Interestingly, when only app flashcards were made available to the students (exam 4 in study 1) most students did not utilize them. Reasons for not using the app included technical issues such as battery consumption, simply forgetting about it, using entertainment apps instead of studying, and a preference for traditional flashcards. Often, students stated making flashcards was too time-consuming which would help explain why flashcard use was so low when flashcards were not available. Furthermore, in both studies students often stated that they didn't know flashcards were available, suggesting that emphasizing the availability of pre-made flashcards on the textbook website would increase the likelihood that students will use them. Lastly, students reported that the app drained the battery on their phone too quickly. These responses are consistent with the idea students used or planned to use the app in long study sessions as opposed to short sessions that would add to time spent studying per day. It also suggests the students were not using the app to study during the short times they have available standing in line, between classes, or other places an entertainment app (e.g., Twitter, Facebook, or Instagram) might be used.

Long sessions as a method of studying are less effective than shorter, more frequent study sessions. A meta-analysis of 317 experiments located in 184 articles found that spacing effects positively improved memory in 259 of the 271 comparisons (Cepeda, Pashler, Vul, Wixted, & Rohrer, 2006). Additionally, the researchers found that spacing studying across several weeks or months also positively improved memory as opposed to learning material in one day.

Students do not have a history of using smartphones for studying purposes. There are apps available for smartphones that are designed to encourage and facilitate studying, but most apps appear to be designed for entertainment.

Two areas for future investigation involve how to encourage students to study for shorter periods of time more frequently and how to encourage students to utilize the smartphone app accessibility and portability in the times they might otherwise use an entertainment app. For example when standing in line for a few minutes several times a day reviewing flashcards instead of accessing a social media site. Limitations of the study include that the survey did not ask in detail how the flashcards were used. Future research should look at whether apps can be used to encourage students to study over several days or weeks to facilitate learning. Additionally future research should study the effect of making your own flashcards versus using supplied ones. The researchers speculate that providing students with flashcards may not be as beneficial as them making their own for studying.

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Collaborative Note-Taking: The Impact of Cloud Computing on Classroom Performance

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This article presents the early findings of an experimental design to see if students perform better when taking collaborative notes in small groups as compared to students who use traditional notes. Students are increasingly bringing electronic devices into social science classrooms. Few instructors have attempted robustly and systematically to implement this technology to facilitate student learning. This study examines the efficacy of using technology to improve student note-taking. Cloud-based collaborative software makes it possible for the first time to break down the most basic walls that separate students during the process of taking and encoding notes. Collaborative note participants used Google Drive under direction of an instructor to assess performance differences. Strong evidence is found that such groups improve grades and related learning outcomes.

Content in most social science classrooms is still primarily delivered via lecture. That quintessential collegiate institution, the classroom, remains familiar in its static delivery of content. Students individually and in isolation take notes while a professor speaks. If students are encouraged to collaborate, that interaction is solely outside the confines of the class and typically not encouraged during the lecture. While there are often times of group discussion or interaction, these are not typically during the lecture, movie, or multimedia event. Current research demonstrates that interaction actually decreases the amount of note-taking during a class session (Boch & Piolat, 2005). From chalk to PowerPoint, technology has not disrupted the normal classroom environment.

Yet there are pedagogical reasons for wanting to overcome the isolation inherent in the contemporary classroom. Modern cognitive theory has uncovered that "learners must be actively engaged in learning" to achieve deep understanding (Barkley, Cross, & Major, 2005, p. 10). Pedagogical research has demonstrated that good undergraduate education includes meaningful and extensive contact between students as well as between students and faculty, both of which encourage active learning. As early as 1994 there was evidence that collaboration could advance problem solving and critical thinking skills (Alavi, 1994). Earlier still Johnson, Mesch, and Johnson (1988) found that cooperative learning arrangements increase measures of achievement, higher-level reasoning, frequency of new ideas, and situational transfer. In his seminal work on writing across the curriculum, critical thinking, and active learning, Bean (2011) emphatically emphasized the need for small group collaboration in the classroom. In short, there is an emerging consensus that our creativity and learning are enhanced by social interactions (Resta & Laferrière, 2007).

Nowhere has the isolating effects, so devastating for critical thinking, been so pronounced as during the act of note-taking. Note-taking, at its most basic, has been defined by educational psychology as the condensation of material while simultaneously interacting in other ways with a given material set (Piolat, Olive, & Kellogg, 2005). During a traditional lecture students have time limitations which requires unique summarization and leads to "much diversification in note-taking practices" (Piolat et al., 2005, p. 293). But how effective are these practices? What are students actually gaining from this skill set quantitatively?

Typically, students are involved in a form of "copy-regurgitate" strategies (Boch & Piolat, 2005, p. 102). Students copy lecture material down in order to later perform well on tests. These kinds of notes are about the passive production of information, and the notes are a process of enhancing internal storage (Kiewra, 1987). It is also a way to focus attention. Note-taking requires a listener to be more connected to a speaker or document (Piolat et al., 2005). The problem is that although students rely on this method, its efficacy has been demonstrated to be inadequate in the classroom setting (Ambruster, 2000; Kiewra, 1985; Makany, Kemp, & Dror, 2009). The problem found in the literature is that students are not efficient note takers, meaning they only successfully capture information about 20% of the time, and they are organizationally flawed and therefore miss how information should fit together. These shortcomings, efficiency and organization, are particularly acute in individuals taking notes on a computer alone (Mueller & Oppenheimer, 2014). Mueller and Oppenheimer (2014) specifically find that computers – when used in isolation – lead to lower levels of information retention, and they postulate this is due to students trying to be stenographers with keyboards instead of actively engaging with the material.

Given the numerous problems of normal note-taking practices, much research has examined the effects of particular note-taking techniques in order to assess how it might be improved (Makany et al., 2009). Makany et al. (2009) are particularly interested in

finding ways to help improve information retention. These include clustering, concept mapping, the Cornell system, idea mapping, instant replays, knowledge maps, learning maps, mind mapping, model maps, and others. There is a consensus emerging that the key to note-taking is the ability to select, encode, and organize information (Robinson, Katayama, DuBois, & DeVaney, 1998; Samarawickrema & O'Reilly, 2003) and that well-structured notes lead to better learning outcomes (Titsworth & Kiawra, 1998, 2004). Traditional lectures and notes have been demonstrated to lead to less information transfer, less structure, and less learning than was previously thought.

Within the context of these many options, much pedagogical research has focused on creating and proposing systems for improving note-taking. Among the suggestions is the use of collaborative notes (Kam et al., 2005; Kobayashi, 2006; Miyake & Masukawa, 2000; Wu, Chen, Chen, & Chiu, 2009). Collaborative notes are mechanisms by which students summarize lecture (or other material) jointly and simultaneously. Typically such collaboration occurs in small groups (three to four students) who work together to produce a single notes document.

Unfortunately, the techniques presented in the literature are often implemented by obscure, expensive, technical software or forms not immediately user friendly (Kittle & Hicks, 2009). Additionally, prior proposals have had pricing and familiarity issues. Expensive and unfamiliar software is simply not a realistic possibility for many universities and colleges. Despite many suggestions for changing how students take notes, none have displaced the normal model. The few suggestions that do exist are not readily available in most academic settings.

As a result of these shortcomings, those interested in writing pedagogy and collaboration have recently turned to Google Drive (Kittle & Hicks, 2009). Their reasoning is Google offers three primary services not available with other tools (like wikis or specialized software): (a) users can interact inside the program, (b) Google saves are made automatically and simultaneously, and (c) Google Drive informs users of changes by other writers. Writing pedagogy—highlighted by the now ubiquitous Writing Across the Curriculum (WAC) and Writing in the Disciplines (WID) programs—now makes a strong case for the use of digital collaboration, but that work has not yet extended its research to the broader classroom environment or the process of note-taking.

The goal of this work is twofold: to bring small groups into the classroom and improve student learning via collaborative notes using non-specialized software. Given that half of the variance of students' test scores are related to lecture notes (Titsworth & Kiewra, 1998), professors should be deeply interested in ways of improving the note-taking process. This project begins where the varying research threads have left off. How can we increase student collaboration while improving note-taking practices? Further, how is this accomplished without disadvantaging students and colleges who may not have access to expensive or specialized software? The current work attempts to bridge an unfortunate gap between the well-intentioned goal of collaboration and improved note-taking in earlier pedagogical work and the pragmatic reality that faculty face in the classroom.

Project Overview

One of the most important technological advances has been the advent of the *cloud*. Cloud computing has altered the way data is processed and stored. Instead of computers being isolated units, cloud computers run software and functions on remote servers that can be accessed by any local client. The unique possibility presented by such a paradigm shift is that multiple users can run the same program simultaneously and thereby interact with one another. For word processing, this means that multiple users could access, create, and edit the same document.

A variety of cloud software is available for word processing, but for the purposes of creating a collaborative space in which students can take notes together, Google Drive was chosen due to the literature on writing noted earlier (Kittle & Hicks, 2009). It must be noted that a variety of other software could also be used; the newest versions of iWork allow for collaborative real-time editing (including for tablets). Microsoft Office 360 is working on implementing real-time editing. Emergent tools such as QUIP are also becoming potential editing packages. For the purposes of this study the goal was something that was device agnostic: there are versions of Google Drive for iPhone, iPad, Android phones and tablets, and even for every variety of laptop including Linux. It was also desirable to use software that had been previously tested in earlier studies.

Google Drive is a hard drive in the cloud. It allows files to be stored remotely and accessed from any computer. In addition, Google Drive comes with a free tool, Google Documents. Documents allows for editing remotely in a word processor that is on any tablet or computer. Multiple users can edit the same document, chat, and work together in real time. Importantly for student buy-in, unlike other office suites (such as the dominant Microsoft Office), Google Drive is completely free. The no-cost entry means that any student, at any level of institution, can participate. Expensive software is possible at some universities, but for many teaching institutions such costs are prohibitive.

Unlike traditional, locally based word processors, Google Drive can be used by a nearly unlimited number of individuals at the same time. Central to the current context, users can actually edit a single document simultaneously. One of the key failings of traditional notes is trying to record information while simultaneously processing that same information. But what if more than one student were able to work together? Could this offload some of the mental shortcomings of traditional, individualized notes? This research tests the effects of collaborative note-taking on class performance both qualitatively and quantitatively across a spectrum of classes.

The experiment was relatively simple: allow students to use collaborative notes in small groups (three to four students) and compare experiences and performances between those who used collaborative notes and those who did not. Further, compare outcomes between classrooms that participated in the experiment and control classrooms. It was also possible to administer a pre-/post-test in order to evaluate if the notes themselves were a defining factor in learning outcomes. The classes in the experiment were introductory political science and psychology classes. All classes were from state colleges.

Students freely volunteered at the beginning of each semester to participate in the collaborative note-taking. Professors (or a teaching assistant) who participated would explain to their classes about Google Drive and the possibility of joining small groups to take notes simultaneously in class. This presentation was done during the first week of each semester. Students then opted into the study if they so chose and remained part of the process for the duration of the semester. From the larger body of participants, students then freely entered into smaller note-taking groups however they wished or were randomly assigned into smaller groups by the professor or teaching assistant.

Each professor (or teaching assistant) created a blank file in Google Drive for each small group in the class. As a result, classes had multiple small groups. One American government class in the fall of 2012, for example, had four small note-taking groups of three to four students. These collaborative note groups had their own independent Google Drive document. Therefore, each class had multiple collaborative small groups, and this was constant across all classes.

Letting the professor or teaching assistant author the file granted the instructor access and ownership of each group's notes in case of disputes or issues during the semester. It also allowed for the instructor to get real-time feedback on how well students understood any particular set of lectures. Professors were able to engage students in a new way by having the ability to tailor content and get a feeling for the performance of students by the notes they were taking—a feature not possible with traditional notes. For example, in the spring of 2013, I modified and altered lectures on a section on civil liberties due to the way students were taking notes (such changes were implemented the following semester).

Methodology and Results

In order to assess the effects of collaborative note-taking, the following two strategies were employed:

- A quantitative controlled study focused on a survey tool and student grade data to assess the actual impact of collaborative notes. Did students benefit from using collaborative notes? How did students' self-reports compare to received grades? To mitigate the issue of the self-selection bias there is also a comparison between participating classes and non-participating classes.

- Standardized open-ended interviews were administered to each student participant (Turner, 2010). These interviews involved asking students identical questions during the course of the semester while using collaborative notes. In this way it was possible to see how students themselves assessed collaborative note-taking, and what, if any, benefits or discouragements they encountered. Students were asked a serious of open ended-questions and were not restricted in how to respond.

Student Performance Findings

Phase one of the experiment looked for evidence that small groups taking notes collaboratively performed better than their peers. There were two primary measures: grades and independent learning outcome performance. Ten classes participated in the experiment that included a total of 247 students where 51 students were in an experimental group (small groups using collaborative notes) and 196 students were in the control group (students in the same class who took notes individually). The benefit of the first control group was that all participants received an identical stimulus. The problem is that, given the voluntary nature of student involvement, there is a potential for selection bias. To account for the issue of selection bias a second control group, a class of an additional 32 students, was used. The control class was taught identically to the experimental sections, but the offer to take notes collaboratively was never extended. By using two control groups it was possible to minimize selection bias.

A final experimental design looked to content knowledge measures outside grades. In one of the experimental classes the college performed a student learning outcomes pre-test and post-test. These tests are designed by a panel of instructors to assess the effectiveness of classes in achieving their learning outcomes. In conjunction with the experimental design, the pre-tests and post-tests helped to detect if either the experimental or control population started at different baseline knowledge levels and to compare – apart from grades – how the groups performed after the stimuli.

Table 1 shows the class breakdowns. Unsurprisingly, each section had slightly larger female populations. The largest population of students came from American government sections. All students were either freshmen or sophomores. Further demographic information was not collected due to privacy concerns.

Table 2 shows that the average grade across all classes and groups (experimental and control) was 72.02%. Students in the experimental group had an average grade of 79.66%, while the control group average was a 71.87% (a difference of 7.79%). Students who participated in collaborative notes performed nearly a single letter grade better than did their peers in the same classes. The ANOVA result found significance at the .01 level ($F = 5.47$, $p < 0.01$). Further, Bartlett's test for equal variance returned a non-significant value, indicating a reliable ANOVA model. It is possible to say there was a statistically significant difference between the control group and the experimental group.

Is this difference due to a selection bias? The control class (a population of 32 as noted earlier) was compared to the experimental group. The average grade for the control class was 70.3%, nearly identical to that of the average control group (71.87%), and there was no significant difference in ANOVA results. As a result, it is possible to say that the grade data is probably not skewed and that the improvement to grades was likely due to the influence of collaborative notes as a variable. See Table 3.

But did the notes result in additional learning? In one experimental class, as already described, a pre-test and post-test, independent of the instructor, was administered by the department. The college in question administers these tests to students during the first week of classes to assess their baseline knowledge of a particular subject. During the last week of the semester students are then given the same test again. The post-test is required to be worth a certain percentage of a student's grade. This allows the school to measure student-learning outcomes. These tests are applied to all instructors and are not created by any one instructor but a panel of faculty in the discipline. One of the experimental classes for collaborative notes was also selected by the department to be administered a pre-/post-test. It was possible to use this data to see how the experimental group compared to the control group on an independent, professor agnostic, metric. Results are shown on Table 4.

Students who were part of the experimental group (35.41%, N = 7) performed worse than their peers (38.54%, N = 43) on the pre-test. On the post-test students who participated in collaborative note-taking did significantly better (72.49%) than their peers (64.17%). Presumably this means that the students who participated in the study had lower levels of baseline knowledge at the outset, but they had a more robust level of knowledge by the end of the class and the experiment than did their peers who had taken notes individually. The difference of 8.28% is strikingly similar to the difference in grades. As the results indicate, these are difficult tests for students. The experimental group did not just perform almost a letter grade better in grades; they also performed almost a letter grade better on the pre/post tests.

In addition to grade and pre-/post-test data, additional questionnaires were distributed to students online at the end of each semester to see what students believed about their performance and technological skill. Students were asked about the propensity to use technology, to self-report on the usefulness of collaborative notes, to consider the likelihood of using collaborative notes in the future, and to identify the areas in which they self-reported improvements using collaborative notes compared to other methods. Unsurprisingly, students who participated were at least moderately interested in technology overall. Students who participated indicated they at least sometimes turned to technology to solve problems. See Figure 1.

In order to assess student outcomes, we asked a series of questions with Likert scale responses. It was important to assess students' perception of usefulness, likelihood of using again, likelihood of use in future classes, and areas of use. The first question asked students for their enjoyment. Did students like using collaborative notes? If students did not find the experience likable, the probability that they would employ them would be low—an important measure if a faculty member wants to implement a practical solution. On this measure students overwhelmingly said yes. Seventy students (71.43%) agreed, or strongly agreed, that they enjoyed collaborative notes. See Figure 2.

Another important question was whether students would want to use this method in another class. Even if under testing conditions students found the notes useful, would they continue to employ the tool without assistance or aid from the professor? Again overwhelmingly students answered yes. Sixty-seven students (81.71%) indicated they were planning on using collaborative notes again in a future class. See Figure 3.

Table 1
Class Overviews

Class	Student Participants		Number of Sections	Male	Female
	Total	Test Group			
American Government	120	29	4	55	65
State and Local Politics	50	7	2	20	30
Comparative Politics	27	4	2	10	17
Introduction to Psychology	26	5	1	10	16
Research Methods (Psychology)	24	6	1	11	13
Total	247	51	10	106	141

Table 2
Class Grades

	Total Participants	Average Grade	Std. Dev.	Minimum Grade	Maximum Grade
All Students	247	72.02%	16.47	35.33%	99.97%
Test Group	51	79.66%	9.33	59.74%	91.57%

Table 3
Control Class

	Total Students	Average Grade	Std. Dev.	Minimum Grade	Maximum Grade
Control Class (American Government)	32	70.30%	15.32	44.46%	93.50%

Table 4
Pre-Post Test Results

State and Local Politics	Total Participants	Pre Test Avg. (Control Group)	Post Test Avg. (Control Group)
Control Group	43	38.54%	64.17%
Experimental Group	7	35.41%	72.49%

Figure 1
Employment of Technology

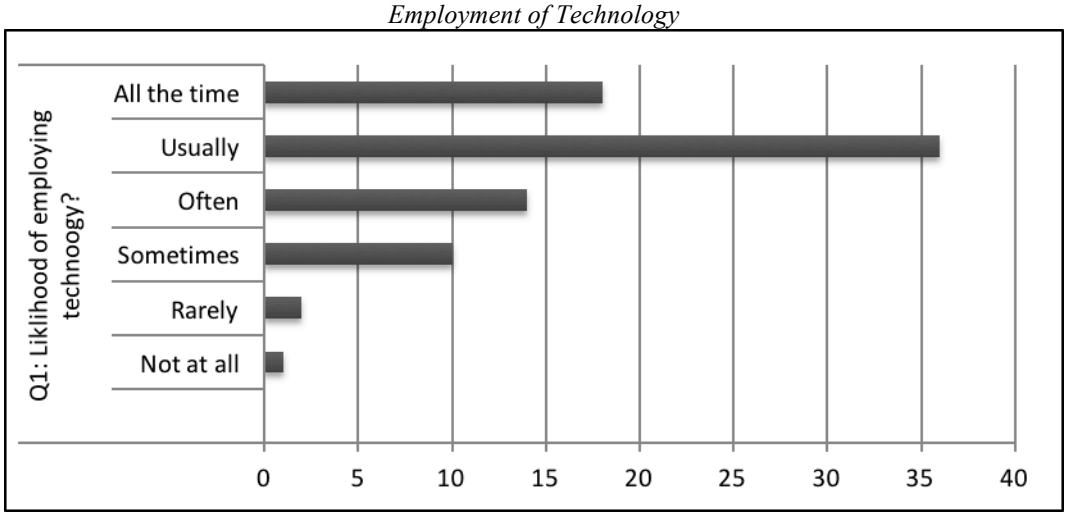

Figure 2
Collaborative Note Enjoyment

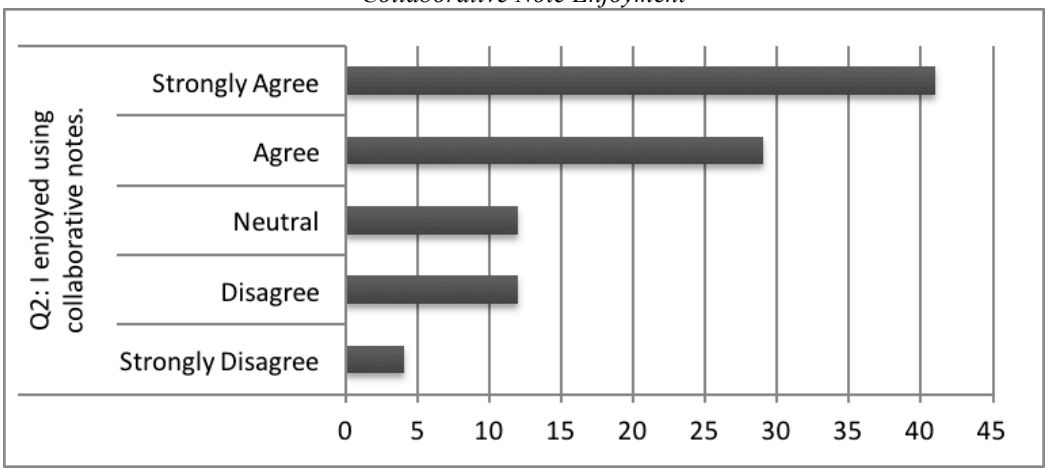

Figure 3
Likelihood of Future Use

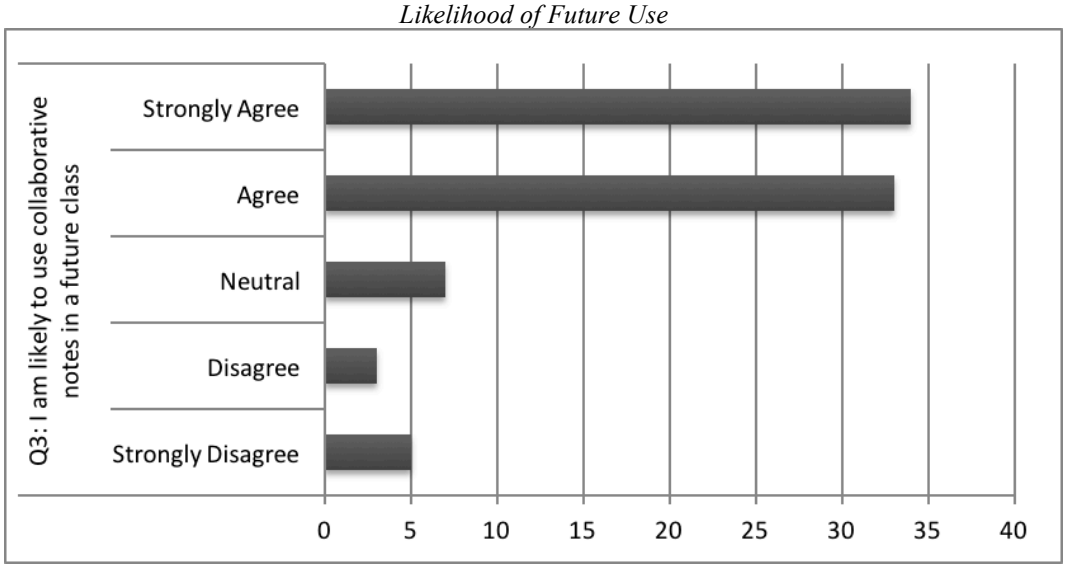

Would students have used notes again in the current class? Almost universally participants said yes. This is interesting because it means that students increased their likelihood of collaborative notes if a professor or teaching assistant is taking an active role. This is fascinating because students did not rank professor interaction highly in their evaluation of collaborative notes. In this case, seventy-three students (89%) reported they would use collaborative notes again in their current class. See Figure 4.

It was also enlightening to see what students reported as the most useful aspects of collaborative notes. The highest marks went to *preparing for tests*, *learning*, and *interacting with classmates*. In a close fourth came *pay attention*. Clearly, students found similar benefits as to those that were postulated. Although we thought students might feel closer to the professor, this did not appear highly ranked by students. See Figure 5.

Student Interview Findings

In phase two of the experiment, a standardized open-ended interview design was employed. At the end of each semester students submitted their responses to a number of questions concerning their feelings and thoughts on the small groups and the collaborative notes. Questions were structured to elicit honest and student-worded responses from the participants in the experimental population. Across all classes, 51

Figure 4
Would Students Use Collaborative Notes Again?

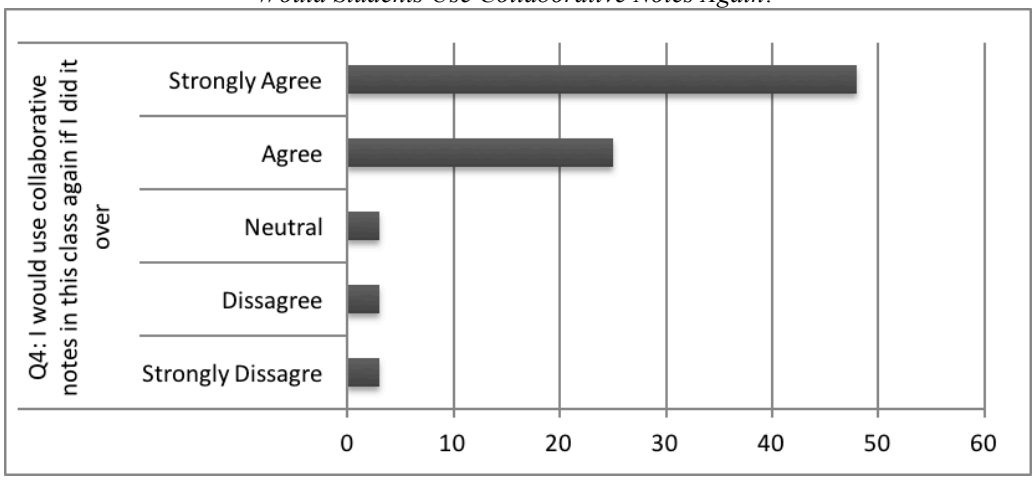

Figure 5
Students' Perceived Impact

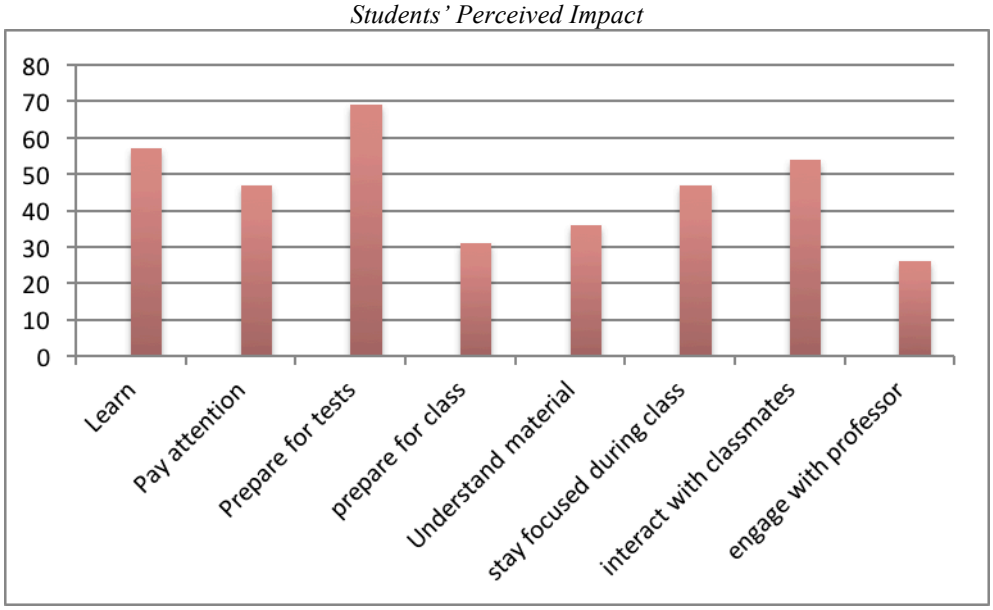

participating students were interviewed (the entire experiment group population). Of those, 38 students provided responses. The interviews were conducted online at the conclusion of each semester. Classes were asked the listed questions in random order to avoid ordering bias.

There seemed to be general agreement that there were positive benefits to using collaborative notes (See Table 5). This seemed consistent with the fact that no students dropped from the program in any class. But student answers coalesced around three areas: organization, group learning, and improved studying. Students nearly universally liked the ability to create structure.

Shared responsibility meant that students could specialize in their note-taking. Especially fascinating and unanticipated in the research was that the division of labor allowed students to learn from each other. Students found watching the note-taking habits of their group not only useful for content learning, but also for perfecting the skill of note-taking in other classes. Students generally expressed they were able to take better individual notes in non-experiment classes by learning a wider range of note-taking techniques.

Table 5
What, if any, are the positive benefits of using collaborative notes?

	Student Responses
Keywords	Organization, Structure, and Studying
Key Concepts	Division of Labor
	"If one person is typing and another is listening, they can add on to the notes to better understand. Most teachers talk while things are [visually] presented, this way you can have a listener, typer, and catcheruper."
	"It's very helpful when studying for the test. It's hard to miss anything when three people are taking notes on something instead of just one."
	Shared Responsibility
	Easy to "add and delete highlighting" and "making changes after or during class easily." This allowed students to have "a chance to hear what [the professor] says."
	Communication
	"Can talk on it outside or inside of class"
	"Interacting with classmates."
	Learning How to Take Notes
	"You can see how others take notes."
	"We each bring good habits, so we can learn from each other"
	"You get different takes on, on how people take notes. Great to see different strategies, highlighting, etc. different ways of taking notes. [You] can apply the styles of note-taking [of] others."

Given the lack of note-taking preparation in most institutions, this was a useful finding.

Table 6 reports data about problems or issues students faced. The most reported issue was the fact that the first few classes could seem unorganized. Many students reported the coordinating with others was a new skill set. Students had to adjust to a very real mental hurdle—notes are supposed to be individualized. Working together required communication with others, and this is something that took time. Students reported it took one or two days to get together. It would appear then, that until students learned to work as a team, the organizational benefits were not present. This would indicate early help from the professor might be necessary to assist students in accepting the idea of collaborative notes.

Some students also struggled with using technology. They did not like typing and actually preferred a pen and paper. When asked follow-up questions on why this was the case, these students simply reverted to noting they were *non-tech students* and never offered any indication of why that was their preference. Many of the students in the samples came from primarily two-year institutions. Another limiting factor was access to a laptop or tablet. These students would likely want to participate, but were be barred from doing so for technological reasons. One of the advantages of Google Drive is the fact it is free. Unfortunately, student access to a computing device is a shortcoming that is not currently possible to overcome at many institutions.

Students universally perceived themselves as earning better grades than they were expecting (See Table 7). This issue is analyzed statistically and reported in detail later, but here the main interest was in students' perceptions of their grade. Students self-

Table 6
What problems or issues have you encountered with using the collaborative notes?

	Student Responses
Keywords	Coordination, Organization, Size, and Technology
Key Concepts	Collaboration vs. Individualists "In the beginning it was confusing because nobody knew what they were doing [and] everyone all at once would try to do the same thing until with time everyone knew what they were doing and eventually got organized." "Hard in the beginning to get on the same page. Took one or two days to get together." Early in the semester it "can be unstructured if you don't get together." Groups need to be teams Groups should "sit down and decide who should do what task beforehand" instead of leaving it to the process of trial and error. Group Size "Need to be in smaller groups (of three or four); need assigned positions" "Like three people is good." Groups should be student determined "Don't force us [about] how to do it" Desire to use pen and paper "Prefer paper" "Non-tech students"

Table 7
Do you believe, or notice, that collaborative notes improved your grades in this class?

	Student Responses
Keywords	Achievement, Passing, and Performance
Key Concepts	"It has helped me achieve the grades I want." "[Collaborative notes] helped me to pass."

reported they were doing better, or performing better, than they had intended or expected.

Of particular interest was the likelihood that students would use collaborative notes again in future classes (See Table 8). Some students indicated they would be taking classes together in the future to maintain their newly found group. But nearly all participants noted in some form that they would do it again. To assess this, students who took classes together again in order to use collaborative notes were interviewed in subsequent semesters—an issue handled in the next section.

Issues Raised by Students

Students were also asked to raise their own issues and questions, as well as to provide information for those thinking about collaborative notes. Technologically, students seemed to prefer laptops or iPads. Interestingly, although not related to the

Table 8
Would you use collaborative notes again in another class?

	Student Responses
Keywords	Yes
Key Concepts	"I would do [collaborative] notes again" "I would take notes with others again . . . and I grew up in the paper and pencil era!"

research here, students preferred laptops or iPads to Android tablets.

Another problem not foreseen was the difficulty of graphing on laptops. Tablets could draw, but for those using traditional laptops, a student noted, "Graphs can be difficult to incorporate." While it is possible to create graphs in Google Drive, this was apparently not intuitive enough. A review of students' notes revealed that no one had opted to do so. Several groups, however, did take a photograph of a graph drawn by hand and inserted that picture into the notes file.

There were also a variety of positive issues raised. Many students liked that electronic notes were "eco-friendly" and saved the need for paper. Others wanted to express that it was not necessary to be a computer hacker to take collaborative notes. "Don't worry about needing to be too tech savvy," said a student. For those who were technically inclined, a participant noted, "Think it's cool that professors allow the use of laptops in the classroom." For those professors who used PowerPoint, students liked the ability to mesh those file types with their electronic notes, as a student wrote, "Can put PowerPoint and notes together."

Conclusion and Future Research

It is clear from prior research that one of the focal points for pedagogical inquiry should be note-taking (Ambruster, 2000; Kiewra, 1985; Makany, Kemp, & Dror, 2009). What the research has lacked is a clear direction and pragmatic strategy professors can actually use in their classes. First is an overview of the studying findings and implications, then a review of software, discussion on the limitations of the study and lastly a few concluding comments.

Study Findings

The results here highlight a number of important insights. First, student performance can be affected by note-taking strategies. This finding is in agreement with the prior literature (Titsworth & Kiewra, 1998). These gains manifest themselves both in grades and conceptual retention. Second, students, it appears from the data, can learn from both working with others in note taking and watching others take notes. The isolation of traditional notes is probably most acute in at risk populations. Faculty rarely guide students, at-risk or otherwise, in the art of note-taking. Unless fellow students simply take the initiative to help, poor note takers have no opportunity to improve. Collaborative notes offer students the opportunity to improve a rarely modeled skill.

Third, students who take notes together can spend more cognitive energy on class material. This particular insight should help faculty who worry about the rows of computers they face in today's classroom and the potential shortcoming traditional, individualized, notes have in that environment. As Mueller and Oppenheimer (2014) have demonstrated, students who take notes individually on computers do worse at learning material than their longhand counterparts. The data here indicates that these effects might disappear if students take notes together in small groups. Given that the laptop is not likely to be toppled by the pen, it would be fruitful if future research compared student cognitive performance on laptops in small groups. The assumption in the Mueller and Oppenheimer study was that students would be taking notes in isolation. Under such conditions they apparently become stenographers and not deep thinkers. But as the qualitative research shows here, collaborative notes force students to do one job only and one job well during note-taking. In this environment, no one student is wasting cognitive energy writing everything down. Instead, they are simply playing their individual role, leaving the rest of their time to think more deeply on the material presented.

Software, Realism, and Education

Another insight is that software selection for higher education needs a healthy dose of realism. Most prior experiments concerning technology have used expensive and obscure software (Kittle & Hicks, 2009). Further studies are rarely conducted, and the average college cannot afford the potential solution even if more data could be collected. Any collegiate institution, in contrast, can implement free consumer-based software such as Google Drive (or QUIP or iWork). Far too

much experimentation in previous research has focused on tools that the average classroom cannot access. Software needs to be targeted at widespread adoption if it is to be considered a realistic tool. Future research would do well to expand on the size of the experiment performed here. Such an experiment, by design, is easily performed at a wide range of schools given the low entry cost.

Classrooms of all types—from lecture based to flipped—assume that students are, and are capable of, taking effective notes. Yet very little time is spent pedagogically attempting to improve this aspect of student learning. The data here indicates that investing more time in note-taking strategies could continue to improve student success, which is an area of deep concern in higher education today and will likely remain so for the foreseeable future. Imagine the possibilities if student success could be shifted—even slightly—by a low cost intervention such as collaborative note-taking. Small groups and Google Drive can be implemented and tested anywhere.

Limitations

There are also several limitations of the current research. As is often the case with pedagogical studies, the total population of the study is relatively low. Further, despite the attempts to control for the issue of selection bias, the lower sample size increases the probability of extreme results. Future research, however, by starting from the basic model presented here, could expand the work to a larger population to see if the effects found continue to measure significantly. The findings are also limited in their scope: social science classes. While it is reasonable to assume the effects would manifest themselves across the curriculum, the limited nature of the study cannot demonstrate that possibility with certainty. But there are two big reasons to be optimistic in the face of these limitations. First, by having classes across a number of content areas it is possible to control for professorial variation. Many pedagogical studies are often limited to a single case study. Here, while the total population is limited, it does extend across a number of classes, fields, and professors. Second, the pre- and post-test data helps demonstrate that the sample population did not start off with higher baseline knowledge. To the contrary, the experimental population apparently had lower knowledge levels. Future research could expand on the pre- and post-test measures to see how deep or widespread this collaborative learning penetrates. Given this, the results of such a significant difference are encouraging for future research.

Conclusion

The early evidence indicates that collaborative student note-taking in small groups has improved student performance both as measured by grades and by external student learning outcomes. Collaborative note-taking appears to improve note-taking skills which are crucial in academia. The data suggests there is a potentially simple and pragmatic way for faculty to improve student learning and implement laptops and mobile devices in their classrooms. Small groups learning and taking notes together appear to be a potent academic tool.

Students will continue to use computers and mobile devices, and they will increasingly use these devices in class. The rise in use is inevitable as more digital natives, and post-digital natives, enter higher education. How will faculty manage this shift? One possibility, and the easiest, is to simply continue the classical formula: lecture and individualized notes. The data here suggestions that professors should not be passive agents as mobile technologies enter into the classroom. Instead, they should harness this new technology to improve student note-taking and in the process improve student success.

Students will be most successful if we recognize the importance of small groups. Students need a space to learn how to take notes. Small groups create a space where students can not only better learn the current content, but also improve on the skill of note-taking itself. Mobile technology is allowing students to interact in a way never before possible. Faculty will need to assist if we want these devices used in positive ways that will enhance and not detract from learning. In short, it might be worth considering using small groups for taking notes together online in your next class.

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Using clickers in large college psychology classes: Academic achievement and perceptions

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Abstract: This research study explored the effects of the use of clicker technology as a means of formative assessment in large, college introductory psychology courses. Academic achievement, as measured by performance on tests of knowledge, was compared between students who used clickers and students that did not use clickers. There was a significant difference between the two groups, although a small effect was noted. Students using the clickers responded to survey items created to solicit information regarding student perceptions of increased understanding, ability to self-identify content deficits, fun, and financial value of clickers. Data from the survey indicated that the majority of students perceived the usage of clickers increased their understanding of and ability to self-identify concept areas. All of the students reported that using clickers was fun, although approximately only one third of those same students reported that purchasing a clicker was worthwhile. Implications for administrators are discussed and alternative technologies are explored.

Keywords: clickers, psychology, formative assessment, education technology

It is not uncommon for undergraduates in public colleges and universities to find themselves faced with their first college lecture in an auditorium-style classroom (Kenwright, 2009; Mayer et al., 2009). Lecture-hall classrooms accommodate large numbers of learners, and lessons are delivered using a teacher-centered lecture format. Within this context, researchers and faculty from a small public college in the southeast United States located in a diverse urban community sought to establish effective instructional supports for large, lecture-style classes, specifically through the use of class wide electronic response systems. The purpose of this research is to examine the use of clicker technology on student achievement and perception. In the spirit of Boyer's (1990) call to action, the research team examined classroom teaching practice as a means of "transforming and extending" the knowledge base for instructors with large class enrollments (p.24).

I. Background.

Instructors of mass classes rely on traditional, lecture-style lessons to deliver information to large numbers of students; however this lesson format provides little or no interaction or discussion (Geske, 1992; Gleason, 1986). Although large lecture halls may accommodate more students by making efficient use of faculty and facility resources, student understanding of content can be compromised. This learning environment may seem passive and impersonal for undergraduates (Hoekstra, 2008). Hall, Collier, Thomas, and Hilgers (2005) identified two problems that

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students in mass class settings face: (1) lack of engagement in the lesson and (2) lack of meta-cognitive awareness or ability to self-identify deficits in subject area awareness. The lack of engagement coupled with the students' inability to self-identify deficits in subject area knowledge may result in an inability to master course content. Furthermore, Edmonds and Edmonds (2008) stated that mass class learning environments do not provide opportunity for instructors to gauge students' understanding of subject areas until the exam results are presented, a scenario leaving instructors and students in the dark regarding subject area understanding until it is too late to remediate misconceptions.

According to generative theory of learning, learners actively engage in cognitive processing during learning by attending to relevant material, mentally organizing the selected material, and integrating the organized material with prior knowledge (Mayer, 2001; Mayer et al., 2009; Wittrock, 1974). Therefore, instructors optimize learning by engaging in instructional activities which "prime active cognitive processing in learners" (Mayer et al., 2009, p.53). The research on generative learning theory indicates that the outcome of active cognitive processing is a meaningful learning outcome (Mayer et al., 2009). Anderson et al. (2001) theorize that learning outcomes, including the knowledge and skills learned in class, can be evaluated using a variety of measures, including academic test items of class content.

To foster the generative learning process, instructors may use questioning methods (King, 1992; Rosenshine, Meister, & Chapman, 1996). Yet, faced with the challenge of assessing student knowledge and increasing engagement in mass classrooms, how do instructors gain knowledge about student understanding to provide responsive instruction? In classes with smaller groups of students, instructors may use questioning methods to assess student understanding, as incorrect student responses provide opportunity for instructors to provide corrective feedback to change student misconceptions (Kenwright, 2009; Mayer et al., 2009). However, in large, lecture-style class's students may be intimidated by asking or responding to questions (Poirier & Feldman, 2007). One method for increasing student understanding and engagement is through the use of electronic clickers, a tool for generative learning.

Clickers, also referred to as electronic response systems, personal response systems, audience response systems, classroom communication systems, or student response systems, allow students to individually respond to closed-ended questions posed by the instructor. Anonymous student responses are gathered via a remote handheld device, commonly referred to as a "clicker", and responses are immediately provided to the instructor. The instructor may then broadcast the results to the class using a multi-media projection device. Publicly examining student responses achieves a variety of objectives, which include but are not limited to, assessment of student understanding, increasing student engagement in the lesson, and providing students with a venue for objectively self-assessing their knowledge of the subject area (Mayer et al., 2009). The clicker system is comprised of two parts: a classroom-wide response system and a set of individual, handheld, remote clicker devices. Colleges generally incur several thousand dollars in initial cost to install the classroom-wide response system, passing along the cost of the reusable handheld clicker device (between $10 and $40) to students. Periodic maintenance as well as technical support costs are incurred by the college over time.

Clicker-based pedagogy has the potential to counteract the passive, teacher-centered instruction often encountered in mass classes of today's colleges and universities. Teachers and students may benefit from the real-time assessment of subject area knowledge. Additionally, increased student engagement in class may result in increased perceptions of fun, providing motivation to return to class. Although there is evidence to suggest that clickers increase

academic achievement, as measured by performance on tests of knowledge, as well as provide ability to assess student knowledge, and increase student perceptions of fun, it is also critical to understand student perceptions of the value of clickers as a learning tool.

A. Utilization Of Clicker-Based Pedagogy Increases Academic Achievement.

A growing body of research has been used to provide evidence for increased academic achievement, as measured by performance on tests of knowledge, using clickers. Active learning has been linked to increased student achievement, which can be measured by final grades (United States Department of Education, 1996). A study of 11 parallel courses taught at the University of Wisconsin over two years showed a statistically significant impact of clicker use on student academic achievement (Kaleta & Joosten, 2007). Similarly, Salmonson, Andrew, and Everett (2009) reported that increasing the engagement of non-participatory students through the use of clickers resulted in an increase in grades. El-Rady (2006) found statistically significant differences in exam scores between classes compared in two consecutive semesters and furthermore found evidence to suggest that clickers improved student retention. In a comparison of clicker technology versus paper pencil technology, Mayer et al. (2009) found that students who experienced in-class questioning and responded with paper and pencil scored significantly lower on class exams than those who responded using clickers. Therefore, the research team hypothesized that the use of clickers would increase students' performance. Thus, the first research question is:

RQ_1: To what extent does the use of clickers increase student academic achievement in a large, college-level introductory psychology class as measured by final grade percentage score?

B. Increased Understanding Of Content Through Formative Assessment.

Clickers ostensibly serve as vehicles to increase student understanding of content by providing instructors with the opportunity to take on the role of agile teachers who can quickly assess student comprehension and modify instruction to student needs (Beatty, Garace, Leonard & Dufrense, 2006; Mayer et al, 2009; Mula & Kavanaugh, 2009). Researchers distinguish between pedagogy and technology, highlighting the clicker's role as a piece of formative assessment technology (Beatty et al., 2006), which provides "college instructors with a non-intrusive, effective pedagogy and students with a more engaging learning format" (Mula & Kavanagh, 2009, p. 2). Researchers suggest that clickers alone do not increase academic achievement, but rather the utilization of clickers increases opportunities for instructors to engage students by using interactive questioning methods which, in turn, are related to increased academic achievement (Mayer et al., 2009). Kaleta and Joosten (2007) reported survey results yielding that 100% of instructors appreciated the ability to assess student knowledge and understanding, while 74% agreed or strongly agreed that clickers improved student learning. The research team hypothesized that students using clicker technology would perceive an increase in understanding of the topic based on the use of clickers. Thus, the second research question is:

RQ_2: Did students using clicker technology in a large, college-level introductory psychology class perceive that clickers increased "understanding of the topic"?

C. Using Clickers To Self-Identify Content Knowledge Deficits.

While instructors report value in assessing understanding of content, clicker responses also provide valuable information for students to identify personal deficits in understanding. In an examination of meta-cognition skills of individuals, Flavell (1979) identified limitations in the ability to self-monitor comprehension, reporting that individuals were often unable to identify holes in understanding. The use of clickers may reveal misconceptions to students; when instructors broadcast anonymous responses to questions using clickers, students are able to compare individual responses to the correct answers in an unobtrusive setting. In this way, each student has the opportunity to practice formative assessment at the individual level (Beatty et al., 2006). Student-identified deficits in content knowledge have the potential to allow students to create a customized, focused plan of study. Clickers may provide one method for students to gather objective information about their learning. The research team hypothesized that students using clicker technology would perceive an increase in their ability to identify areas of deficit in their subject matter knowledge. Thus, the third research question is:

RQ_3: Did students using clicker technology in a large, college-level introductory psychology class perceive that the use of clickers helped them find out what they "still needed to study"?

D. Using Clickers to Increase Student Perception of Fun.

Although there is minimal research related to student perception of fun in a clicker-based classroom (Fies & Marshall, 2006), investigating student perceptions of clicker use is worthwhile to establish social validity of the utilization of clickers (Wolf, 1978). Beatty et al. (2006) writes, "By fostering an active, interactive classroom environment, classroom communication system-based pedagogy helps keeps students interested and attentive" (p. 6). In a large introductory psychology class, Poirier and Feldman (2007) found that students using clickers earned higher final exam scores and reported positive attitudes toward utilizing clickers in class. Researchers report that students find clicker-based classes to be more fun than non-clicker based classes (Burnstein & Lederman, 2001; Dufresne, Gerace, Leonard, Mestre, & Wenk, 1996; Fies, 2005). Based on these results, the research team hypothesized that students using clicker technology would perceive using clickers as fun. Thus, the fourth research question is:

RQ_4: Did students using clicker technology in a large, college-level introductory psychology class perceive that the use of clickers to respond to questions was "fun"?

E. Financial Value of Clickers.

A primary concern of colleges and universities using the clickers is the issue of cost. Students enrolled in classes using clicker-based pedagogy are required to purchase the handheld clicker device that may cost between $10 and $40. Students may re-use the device each semester, but if lost, students must purchase and register another. Although some researchers report that students "appreciate the system's value" (Beatty, 2004, p.6), researchers of two recent literature reviews of clicker technology did not discuss whether or not students perceived the clicker was worth purchasing (Fies & Marshall, 2006; Roschelle, Abrahamson, & Penuel, 2004). Because students must incur the cost of utilizing clickers after the decision to invest in the system has already been

made by administrators, it is important to investigate whether or not students perceive the clicker is worth purchasing to establish social validity of the utilization of clickers (Wolf, 1978). The research team hypothesized that students using clicker technology would indicate that they would be willing to purchase a clicker for a class to help them learn. Thus, the fifth research question is:

RQ_5: Did students using clicker technology indicate that they would be "willing to purchase a clicker that cost $30 - $40" to help them learn?

II. Methodology.

A. Participants.

Participants in this study were enrolled in an urban public college located in the southeast United States in introductory psychology classes and were grouped according the section of the course in which they were enrolled. The same instructor taught both of the sections sampled for this study. The sample (N = 145) was established when students met the criteria of enrollment in the introductory course in psychology and completion of the final exam. Students self-selected their participation in the study and were not provided monetary compensation, nor were they promised any benefits not normally associated with using a learning tool. Participant information was numerically coded to maintain anonymity and all identifiable information was maintained in a secure location by the principal investigator. Participation for this study totaled 183 students across two separate introductory psychology classes and students were assigned into control and treatment groups. Of the 183 participating students, 145 students received a final grade in the course and were subsequently involved in the analysis. The control group did not receive clickers and consisted of 78 students from one class. The treatment group received clickers at varied intervals and consisted of 67 participants from two other classes. Participants responded to a demographic questionnaire, information on gender was broken down as follows: 56 of the participants were male while 127 of the participants were female, while responses to questions about ethnicity were as follows: Caucasian, 91; African–American, 52; Hispanic, 24; Asian, 2; Other, 14. Only 7 of the participants were under the age of 18, while the preponderance of the participants were between the ages of 18-24 (152), and 24 students were over 25 years old.

B. Instruments.

Primary outcomes were academic and measured by final class grades. For the purposes of this study, a common grading rubric was used for both of the introductory classes as defined in PASW as: A = 100-90%, B = 89-80%, C = 79-70%, D = 69-60%, and F = 59% or less.

Data on student perception was collected using a researcher-created questionnaire comprised of 11 items with responses on a 5-point *Likert* scale. Questions selected for use in this research study were as follows: a) Using a clicker increased my understanding of the topic, b) Using a clicker helped me find out what I still needed to study, c) Using a clicker to respond to questions was fun, and d) I would be willing to purchase a clicker that cost $30-$40 to help me learn. *Likert* responses were as follows: 1) I strongly disagree, 2) I somewhat disagree, 3) Neutral, 4) I somewhat agree, and 5) I strongly agree. Demographic information for all participants was collected using a 21-question survey at the beginning of the course. At the

completion of the course, the group who used the clicker technology completed a questionnaire that consisted of 10 items related to attitude toward using the clickers.

C. Data Collection and Analysis Procedures.

In this quasi-experimental study, measures of academic performance were compared across two groups of students: one class utilizing clickers (consisting of embedded questions and procedures for responding using clickers) and one class that did not utilize clickers. The same doctoral level professor with 10 years of experience taught each class, and each of the classes participating in this study met over the course of a semester. In all the courses, content was delivered via PowerPoint and lecture in a face-to-face setting. For the course with embedded questions, the average percentage of question to content slides was 21%, and the professor utilized clickers throughout the delivery of the lecture. Upon response to question, results were immediately displayed on a bar graph. If the distribution showed 10% or more of incorrect student responses, the feedback would be used to re-teach the topic by providing additional explanations or responding to questions. If more than 90% of students chose the correct response, the instructor would confirm the correct response, giving a brief explanation and then moving on. In both courses, online review quizzes allowed students to review content prior to administering class exams. The clickers system employed for the study was the iClicker manufactured in partnership with the Worth-Freeman Publishing Company.

III. Findings.

Participants in all the psychology classes totaled 183 students. Of the total student participation, 145 received a final grade for the course, 78 of the participants were in the control group and 67 participants were in the experimental group. Due to missing data, 38 cases were not included in the analysis. Thus, data was analyzed using 78.2% of the 183 total students (N=145). Using Predictive Analytics Software (PASW), the researchers compared the 38 missing cases to determine if the ratios of missing data were similar between groups. Results yielded similar rates of missing data when compared across groups. Of the 38 cases, 20 cases of missing data occurred in the control group (accounting for 20.5% of the total control group), while 18 cases of missing data occurred in the experimental group (accounting for a loss of 21.2% of the experimental group). Inferential statistical analysis was performed for the first research question comparing experimental and control groups. Descriptive statistics on the perception of clicker technology usage were collected on the experimental group only for research questions two through five.

RQ_1: To what extent does the use of clickers increase student performance in a large, college-level introductory psychology class as measured by final grade percentage score?

Student performance was measured by final grades, defined by a percentage score of cumulative total points earned divided by cumulative total points possible. An independent *t* test was conducted to determine if there was a significant difference ($p < 0.05$) in mean score of final percentage course grades of students in a college-level introductory psychology class using a clicker system versus students who did not using a clicker system. The test was conducted using an alpha of 0.05. Levene's test indicated that the assumption of homogeneity of variances was met ($F = 2.029$, $p = 0.157$). The test was statistically significant, $t(143) = 8.367$, $p < 0.05$. Students using the clicker system scored higher on average ($M = 83.43$, $SD = 11.88$) than

students not using the clicker system (*M* = 76.82, *SD* = 15.13). The 95% confidence interval for the difference between means was -11.13 to -2.09. The effect size was calculated by eta squared and found to be 0.055 indicating that approximately 6% of the variance in scores was accounted for by whether or not the student used clickers. Approximately 81.27% of the treatment group (n = 67) received a grade of C or better compared to 76.92% of the non-treatment group (n = 78). The results provide evidence to support the hypothesis that students using clickers score higher in measures of academic performance.

RQ_2: Did students using clicker technology in a large, college-level introductory psychology class perceive that clickers increased "understanding of the topic"?

In order to address the second research question, the questionnaire results (n = 67) from the treatment group were dichotomized based on responses. The responses of 1 or 2 were classified as "disagree" and the responses of 4 or 5 were classified as "agree," and the response of 3 was neutral and not included in this comparison. Based on analysis, approximately 91% of students perceive that clickers increased their understanding of a topic, leaving only 9% of students in disagreement with the statement that using clickers increased their understanding. The survey results provide evidence to support the hypothesis that the majority of students perceive that using clickers increase their understanding of the topic.

RQ_3: Did students using clicker technology in a large, college-level introductory psychology class perceive that the use of clickers helped them find out what they "still needed to study"?

In response to the third research question and based on the dichotomized responses, approximately 81% of the students (n = 67) who responded to the survey agreed that clickers improved their ability to identify their individual deficits in the subject matter during the lecture. Only approximately 6% disagree that clickers had an impact on their ability to identify their individual deficits in the content. Once again, the survey results support the hypothesis that the majority of students perceive that clickers improved their ability to self-identify subject matter they still need to study.

RQ_4: Did students using clicker technology in a large, college-level introductory psychology class perceive that the use of clickers to respond to questions was "fun"?

Based on the dichotomized results of the survey, the fourth research question had an overwhelming positive response, with 100% of the students (n = 67) reporting that the use of clickers was fun as related to learning the content in an introductory Psychology course. The results of the survey support the hypothesis that using clickers in the course was fun.

RQ_5: Did students using clicker technology indicate that they would be "willing to purchase a clicker that cost $30 to $40" to help them learn?

Finally, for the last research question, the responses were dichotomized, however, this time the majority, approximately 35% of those who responded to the survey (n = 67) disagree that purchasing a clicker was worthwhile, with approximately 32% of students agreeing that purchasing a clicker was worthwhile. The results of this question on this survey were not in line with the original hypothesis.

IV. Conclusion.

Overall, there is evidence to suggest that the use of clickers in a large, college level introductory psychology class contributed positively to learning. Students using clickers performed significantly better when compared with a group of students not using clickers, although the

effect size was minimal. Students using clicker technology reported that they felt utilization of clickers increased their understanding of the topic and allowed them to self-identify areas of deficit in their learning. All of the students in the experimental group agreed that using clickers to respond to questions was fun; however, only approximately one-third of those same students thought that purchasing a clicker was worthwhile. While these students may have benefited from and enjoyed using the clickers, they do not seem to be willing to bear the expense.

This study contained limitations that may bring in to question the validity of the findings. The results may not be generalizable to other instructional settings because this research was conducted with large, college level introductory psychology classes. Researcher bias may also exist, as this study was conceptualized and conducted by researchers who were also involved in delivering instruction to the experimental and control groups. Another limitation in this study may be a consequence of the fact that the sample was not randomly selected and the conditions were not randomly assigned, leading to unequal groups. Error in measurement may exist for research questions two through five, as the measure was researcher-generated and not field-tested for reliability and validity.

Future research into the use of clickers should engage methods to compare procedures for embedding questions in lecture (e.g., pre-post lecture, throughout the lecture, etc.). To further explore the academic achievement of students using clickers, it would be worthwhile to link questions presented using the clicker system to questions on course tests, to determine if utilization of the clickers contributes to specific knowledge acquisition. Examining the reliability and validity of the researcher created measure would decrease measurement error and lend credibility to the findings of students' perceptions.

V. Implications for Higher Education Administrators and Faculty.

Since this research was conducted by professors engaging in scholarship of teaching and learning (Boyer, 1990), the researchers' aim was to improve instructional practice within the college, while at the same time informing purchasing decisions of clickers. Currently, clickers are often used in large, college-level classes to increase student engagement, allowing teachers to poll classes by posing a question and providing an opportunity for students to respond in real-time via individual clickers. It appears that the utilization of clicker technology supports the generative theory of learning, by priming the cognitive processes used when learning, as demonstrated by improved academic performance. Faculty of large, lecture-style classes seeking to engage students may be able to use clicker technology as one means of increasing generative learning, and therefore increasing student performance.

Yet, teachers, administrators, and students may question the efficacy of clickers because of the costs associated with adoption of the technology. Students are often required to purchase clickers, which range in cost from $10 to $40, while administrators must adopt the clickers, which require a substantial financial investment. Before assuming these costs and requiring students to make financial commitments, administrators are wise to ask whether or not the use of clickers increases student academic achievement, as well as what other options are available for formative assessment. Other options, such as Polleverywhere.com, provide instant audience feedback using mobile devices of audience members at significantly less expense (e.g., the cost of a text message). Polleverywhere.com provides free templates for PowerPoint slides which can be customized with questions about course content and embedded into existing PowerPoint presentations. Audience members are able to respond using SMS texting for the cost of a text

message, with no cost to the higher education institution for groups of up to 30 participants at a time, and $65 per month for 250 participants at a time. As new technologies develop, higher education administrators, instructors, and students have increasingly diverse options to improve academic achievement. New developments in technology should be evaluated to determine if perceived benefits outweigh the costs.

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Digital Literacy: A Prerequisite for Effective Learning in a Blended Learning Environment?

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Abstract: Blended learning has propelled into mainstream education in recent years with the help of digital technology. Commonly available digital devices and the Internet have made access to learning resources such as learning management systems, online libraries, digital media, etc. convenient and flexible for both lecturers and students. Beyond the physical classroom walls, learning can still continue at another place and time. However, although today's students generally face no difficulties in using technology for everyday social and entertainment activities, it would be constructive to understand if the students can make effective use of technology for learning as well. It has been posited that to make effective use of technology for learning, one needs to have a certain level of digital literacy. Digital literacy for learning is more than just knowing how to operate the technology, but also having the right information management and critical thinking skills, as well as proper online behaviours. This study aims to answer the question: Do students require digital literacy to be effective in learning in a blended learning environment? To answer this question, this study examined the relationships between effective learning and four digital literacy constructs; i.e. underpinnings, background knowledge, central competencies, and attitudes and perspectives. Responses were first collected from the students who were taking courses in a blended learning environment at a local university and then analysed using partial least squares. Analyses show that the four digital literacy constructs could be reduced to three, and the three digital literacy constructs each had a statistically significant relationship with the effective learning construct. This study provides evidence that digital literacy is a prerequisite for students to be effective in learning in a blended learning environment.

Keywords: blended learning, digital literacy, effective learning, higher education, online learning, partial least squares

1 Introduction

Digital technology has become an integrated part of education (Benson and Kolsaker, 2015) and is changing the ways today's students learn (Coccoli et al., 2014). Digital technology includes a wide range of computing hardware and software, e.g. mobile devices, web tools, application software, communications and storage services, etc. (Mohammadyari and Singh, 2015; Ng, 2012). Students use digital technology for such learning activities as reading and sending email, accessing learning management systems, reading e-journals or e-books, doing online quizzes, participating in discussion forums, and so on (Jones et al., 2010; Waycott et al., 2010).

Educational institutions are taking advantage of advances in digital technology to engage their students with various teaching and learning modes. One such mode is blended learning (Porter et al., 2014) which integrates technologies into the learning delivery process, and hopefully overcomes some limitations of face-to-face classroom learning (Akkoyunlu and Yılmaz-Soylu, 2008). Blended learning allows students to learn anytime, anywhere, and in the way they want to. Complementing face-to-face classroom teaching with online learning (Coccoli et al., 2014), blended learning has become popular among educational institutions.

However, Joy and Garcia (2000) caution educators against assuming that students would learn better from technology-based learning delivery systems. Although students use technology in their everyday activities, they might not necessarily be familiar with or use technology for learning (Waycott et al., 2010). Students might use technology more for social or entertainment purposes but not for learning (Prior et al., 2016). Gurung and Rutledge (2014) share the view that digital learners need help on how to use technology effectively for learning. Ng (2012) contends that students might not know how to use technology for learning. Already possessing certain level of digital literacy, however, they should be able to learn to use technology for learning easily.

People who have multiple literacies to use digital technology efficiently and effectively are deemed to be digitally literate (Mohammadyari and Singh, 2015). As digital technology plays a key role in blended learning, it is expected that students need a certain level of digital literacy for them to learn effectively (Eshet, 2004). Hence, it is essential for educators to ask the question: Do students require digital literacy to be effective in learning in a blended learning environment? This study aims to answer this question.

The following sections provide an overview of blended learning, review the concept of digital literacy and its components, explain the measurement of effective learning, describe the research design and method, present the data analyses and results, and conclude the paper.

2 Research background

2.1 Blended learning

A learning delivery approach which blends face-to-face classroom learning and online learning, blended learning provides such flexibility as anytime and anywhere access to learning management systems (LMS). An LMS provides an online delivery platform for lecturers and students to share learning resources, equipping them with useful system tools and functions (Glogowska et al., 2011; De Smet et al., 2012). Blended learning promotes independent learning and online cooperation, and yet retains some face-to-face classroom teaching (Deschacht and Goeman, 2015). The basic premise is to complement face-to-face classroom learning by giving students the learning flexibility as enabled by digital technology.

Given limited classroom space and increasing student number, blended learning seems to be a feasible solution (Garrison and Vaugha, 2013) which meets the needs of students, educators, and universities (Moskal, Dziuban and Hartman, 2013). Blended learning brings some benefits, e.g. higher classroom efficiency, greater teaching flexibility, more convenience for students, and better learning engagement (Owston, York and Murtha, 2013). Deschacht and Goeman (2015) analysed two groups of first-year university students to understand if blended learning had an effect on their academic performance. Both groups took the same courses and exams, but the course delivery mode was different. One group followed the blended learning approach and the other, face-to-face classroom learning. The findings showed that blended learning improved academic performance.

However, adopting blended learning does not necessarily improve the student learning experience (Cortizo et al., 2010). Benson and Kolsaker (2015) contend that technology is only one part of blended learning, and more understanding is still needed about its pedagogical benefits. In addition, the digital environment that students are in today could have caused them to develop different learning attitudes and styles (Coccoli et al., 2014). Jones et al. (2010) collected data from some 500 first-year students at five UK universities to study their use of technology for social and learning activities. Students born after 1983 were compared to those born before 1983. The findings showed that there were differences in terms of the use of technology among the students, not just between the groups but within the groups as well. Margaryan, Littlejohn and Vojt (2011) surveyed 160 third-year university students to understand what digital technologies the students used and how they used them. They compared students born in or after 1980 with those born before 1980. The findings showed that those born in or after 1980 were not more advanced in their use of digital technologies nor did they have very different learning styles from those born before 1980.

Kember et al. (2010) find that blended learning is not just about using LMS as an online repository of learning materials. Instead, educators should incorporate learning activities that engage students to foster active learning. Coccoli et al. (2014) explain that knowing technology alone is not enough for success in learning; equally important is that one needs to have the right competencies and attitudes. A study by Owston, York and Murtha (2013), which analysed how student perceptions of blended learning could have affected their course grade, showed that compared to low-achieving students, high-achieving students were more satisfied with their blended learning courses, claiming that these courses were more convenient, more engaging, and they learned better. Low-achieving students might find blended learning courses challenging if they lack independent study skills or if the difficulty level of the subject matter is high.

Blended learning can have different configurations of face-to-face classroom learning and online learning in different learning contexts (Garrison and Kanuka, 2004) and a good integration is always a challenge (McKenzie et al., 2013). Staker and Horn (2012) identifies four blended learning models for primary and secondary education: Rotation, Flex, Self-Blend, and Enriched-Virtual. D2L (2014), a company that specialises in developing integrated learning platforms, proposes five blended learning models: Face-to-Face Driver, Rotation, Flex, Online Lab, and Online Driver. Moskal, Dziuban and Hartman (2013) suggest that there is no one best blended learning model. Instead, there are a set of critical success factors, such as institutional goals and objectives; alignment between goals of administrators and faculty members; organisational capacity; faculty development and course development support; support for online students and faculty; robust and reliable infrastructure; longitudinal data collection and assessment; policy development; and funding model.

2.2 Digital literacy

Today's students are familiar with digital technology and generally know how to access, create, and share digital information (Ting, 2015). Greene, Yu and Copeland (2014) suppose that to be digitally literate, one not only needs to be able to search and manage, but also to scrutinise and integrate digital information. Although today's students are generally considered tech-savvy, many of them find it difficult to do so effectively. They conclude that students need to acquire planning, monitoring, and controlling skills in relation to information management, as well as critical thinking skills. Gilster (1997) supports the notion that to be digitally literate, one does not just know how to find information from the web, but also has the ability to understand and assemble information from different print or digital sources. Digital literacy involves the mastery of ideas, and is not just about using the technology itself.

The European Framework for Digital Literacy (EFDL), an outcome of the DigEuLit project and initiated to recognise the importance of digital literacy, defines digital literacy as follows:

> *Digital literacy is the awareness, attitude and ability of individuals to appropriately use digital tools and facilities to identify, access, manage, integrate, evaluate, analyse and synthesize digital resources, construct new knowledge, create media expressions, and communicate with others, in the context of specific life situations, in order to enable constructive social action; and to reflect upon this process." (Martin, 2006, p.155)*

Jisc (2014) emphasises that digital literacy is context-dependent and suggests a seven-element digital literacy model: media literacy, information literacy, digital scholarship, learning skills, communications and collaboration, career and identify management, and ICT literacy. Ng (2012) explains that digital literacy comprises three key dimensions: technical, cognitive, and social-emotional. The technical dimension concerns the skills needed to use IT proficiently. The cognitive dimension concerns the skills needed to search, evaluate, and synthesise digital information critically, and at the same time, to be conscious of any ethical, moral, and legal issues. The social-emotional dimension concerns the skills needed to socialise online in a proper manner.

Bawden (2008) explains that the concept of digital literacy is very broad and can include very specific skills and competencies to general awareness and perspectives. He distinguishes four components of digital literacy: (1) underpinnings - the ability to read and write as well as to use software packages and computers; (2) background knowledge - an understanding of how digital and non-digital information is created from various forms of resources and communicated; (3) central competencies - the ability to assemble knowledge from multiple sources; and (4) attitudes and perspectives - the ability to learn independently as well as to exhibit good behaviour in a digital environment.

Digital literacy needs to be renewed as digital technology evolves over time. It can be classified into three levels (Martin, 2006): (1) digital competence - digital know-how; (2) digital usage - applications of digital competence; and (3) digital transformation - creation of new knowledge as a result of digital usage. Prior et al. (2016) observe that students can exhibit different levels of digital literacy. Thus, assuming that all students have the same level or a certain level of digital literacy can lead to a problem in online learning – What the students are capable of doing might be different from the expectations of teachers.

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2.3 Effective learning

To assess how effective learning is as a result of adopting blended learning, the revised Bloom's taxonomy provides some good pointers. Commonly used as a reference framework when designing learning activities, objectives, and outcomes (Blooma et al., 2013), the original Bloom's taxonomy was first published in 1956 (Bloom et al., 1956). As a cognitive taxonomy, Bloom's taxonomy categorises learning outcomes, from the lowest to the highest, into six levels: knowledge, comprehension, application, analysis, synthesis, and evaluation (Tyran, 2010). The taxonomy was revised in 2001 with changes to its category names: remembering, understanding, applying, analysing, evaluating, and creating (Krathwohl, 2002).

2.4 Research model

Using the four digital literacy constructs; i.e. underpinnings, background knowledge, central competencies, and attitudes and perspectives, as conceptualised by Bawden (2008) and the revised Bloom's taxonomy as a point of departure, this study proposed a research model (Figure 1). Another of our study adopted Jisc's digital literacy model; this study included only Bawden's digital literacy components.

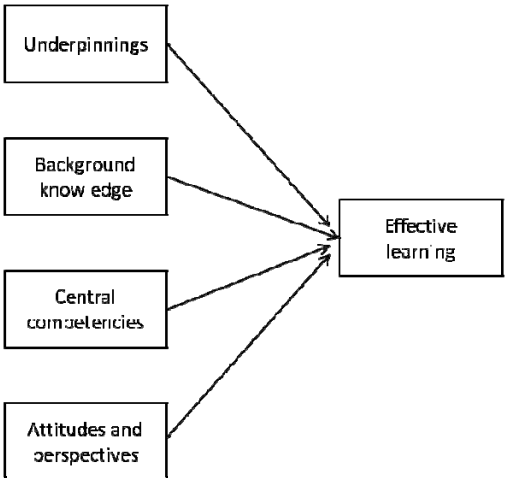

Figure 1: Research model

3 Research method

3.1 Construct operationalisation

To develop a scale for a construct, the construct must first be conceptualised theoretically (Segars, 1997). Following that, a group of scale items can then be developed based on the conceptual domain of the construct (MacKenzie et al., 2005). After a review of past literature and a questionnaire pretest, this study developed a 5-item scale for each of the four digital literacy constructs and a 6-item scale for the effective learning construct.

3.2 Data collection

An online questionnaire was used to collect data from the students of a university that had adopted blended learning. An invitation, with a link to the questionnaire, for the students to fill in the questionnaire was made on the LMS commonly accessed by them. The questionnaire consisted of four sections. Section A asked two questions about learning delivery. Section B consisted of two questions. One question was about the four digital literacy constructs (a total of 20 scale items, coded as D1 to D20, in random order) and the other the effective learning construct. All items were measured using a 5-point Likert-type scale, 5 being "strongly agree" and 1 being "strongly disagree." Section C asked four questions about usage of LMS. Section D asked two demographic questions. A total of 176 respondents provided the responses. 15 responses were removed as outliners in subsequent analyses. Thus, there were only 161 valid responses. Of the 161 respondents, 87 were male students (54%) and 74 female (46%).

4 Data analysis and results

4.1 Learning delivery and LMS usage

Table 1 provides a summary of the respondents' preference for different learning delivery modes. In order of preference ("prefer" and "strongly prefer"), a higher percentage of the respondents preferred classroom learning (74.5%), as compared to blended learning (64%) or online learning (63.9%).

Table 1: Preference for individual learning delivery modes

	Classroom learning		Online learning		Blended learning	
	N	%	N	%	N	%
Strongly not prefer	2	1.2	2	1.2	0	0.0
Not prefer	2	1.2	12	7.5	8	5.0
Maybe	37	23.0	44	27.3	50	31.1
Prefer	72	44.7	82	50.9	60	37.3
Strongly prefer	48	29.8	21	13.0	43	26.7
Total	161	100.0	161	100.0	161	100.0

Table 2 provides a summary of what the respondents thought about the effectiveness of different learning activities or resources. In order of effectiveness ("effective" and "very effective"), a higher percentage of the respondents thought that face-to-face meetings (82%) were more effective than online interactions (45.9%); and online resources (70.2%) were more effective than physical resources (63.4%).

Table 2: Effectiveness of delivery methods

	Face-to-face meetings (e.g. in-class lecture, consultation with lecturer, group discussion)		Online interaction (e.g. blog, forum, chat, email)		Physical resources (e.g. print book, school library)		Online resources (e.g. e-book, digital database, audio or video webcast)	
	N	%	N	%	N	%	N	%
Not very effective	2	1.2	3	1.9	2	1.2	0	0.0
Not effective	1	0.6	15	9.3	14	8.7	9	5.6
Maybe	26	16.1	69	42.9	43	26.7	39	24.2
Effective	67	41.6	63	39.1	80	49.7	83	51.6
Very effective	65	40.4	11	6.8	22	13.7	30	18.6
Total	161	100.0	161	100.0	161	100.0	161	100.0

Table 3 provides a summary of the features the respondents liked the most about LMS (they could choose more than one feature). In order of frequency, the three largest percentages were online resources (78.5%), online course announcements (52.1%), and online assignment submission (47.9%).

Table 3: LMS features

LMS features	N	%
Online resources (e.g. lecture notes, PowerPoint slides, tutorial questions)	128	78.5
Online course announcements	85	52.1
Online assignment submission	78	47.9
Online assessment (e.g. quiz)	73	44.8
Online grade centre	59	36.2
Online discussion (e.g. blog, forum, chat)	34	20.9

Table 4 provides a summary of the usage of LMS.

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Table 4: Usage of LMS

Demographic information		N	%
Semesters using the LMS	1 semester	50	31.1
	2 semesters	69	42.9
	3 semesters	28	17.4
	4 semesters	5	3.1
	5 semesters	2	1.2
	More than 5 semesters	7	4.3
Hours using the LMS per day	Less than 1 hour	93	57.8
	Between 1 to 2 hours	48	29.8
	Between 2 to 3 hours	16	9.9
	Between 3 to 4 hours	2	1.2
	More than 4 hours	2	1.2
Primary device accessing the LMS	Desktop computer	57	35.4
	Notebook	45	28.0
	Smartphone	47	29.2
	Tablet	12	7.5

4.2 Exploratory factor analysis

An exploratory factor analysis (EFA) is necessary to examine dimensionality of a scale before a confirmatory factor analysis (CFA) (Gerbing and Anderson, 1988). The analysis attempts to examine loadings of individual scale items across factors, identifying scale items that load strongly on a particular factor (Gefen and Straub, 2005). In this study, a factor analysis assessed the four digital literacy constructs using the principal axis factoring extraction method. A separate factor analysis assessed the effective learning construct. Straub, Boudreau and Gefen (2004) advise against mixing independent and dependent constructs in EFA but instead, suggest examining the constructs separately. Assuming that there were correlations among the constructs, the Promax rotation method was used (Hair et al., 2005). Before a factor analysis of the four digital literacy constructs, a check for multivariate outliers was performed. Following the rule that a case is considered a multivariate outlier if the probability of its squared Mahalanobis distance is equal or less than 0.001 (Tabachnick and Fidell, 2007), of the 176 cases, 10 cases were removed. KMO (> 0.5) and Barlett's test ($p < 0.05$) were checked first for appropriateness for factor analysis (Hair et al., 2005). Both KMO and Barlett's tests satisfied the criteria. Two criteria were used to decide deletion of scale items: (1) scale items loaded < 0.5 on any one of the factors, or (2) scale items cross-loaded > 0.5 on two or more factors (Hair et al., 2005). Iteration 1 showed scale item D10 cross-loaded on two factors. Thus, it was removed from further analysis. In iteration 2, a simple structure was obtained. Factor scores were then calculated to check for outliers. Those scale items that had a factor score of larger than +/- 3.0 were considered as outliners (Deneshkumar et al., 2014). Of the 166 cases, 5 cases were removed. Thus, the remaining 161 cases were kept for further analysis. Subsequent 7 iterations deleted 7 scale items (D14, D19, D6, D3, D7, D9, and D11) and obtained a simple structure. Table 5 provides a summary of the factors.

EFA revealed that the four digital literacy constructs proposed originally had been reduced to three. While the construct underpinnings retained its original scale items, scale items of the other three digital literacy constructs loaded on just two factors. In relation to knowledge acquisition in organisational learning, Huber (1991) identifies five processes: congenital learning (acquired in the form of prior knowledge); experiential learning (acquired by learning from doing); vicarious learning (acquired by observing others); grafting (acquired by hiring people who know); and searching (acquired by actively searching for information). With reference to the concepts of knowledge acquisition in organisational learning (Huber, 1991) and to better reflect the meaning of the scale items of each, these two newly-identified factors were labelled as experiential learning and searching respectively. In factor analysis, it is common to find the number of constructs originally proposed in a research model to change as a result of factor analysis; that is, the number of constructs may be reduced (Gable, Sedera and Chan, 2003) or added (Cohen, Thiraios and Kandilorou, 2008). After deciding on the number of factors to be retained, it is then necessary to interpret and label the factors based on the meaning of the scale items loaded on the respective factors (Hair et al., 2005).

A factor analysis of the effective learning construct showed a one-factor simple structure (L1 to L6, Eigenvalue = 4.526, % of variance explained = 70.590, Cronbach's alpha = .935).

Table 5: EFA results

Scale item	Mean	SD	1	2	3
(D17) I am motivated in learning new information both online and offline.	3.84	.821	.803		
(D16) I am comfortable with sharing information with others in discussion.	3.84	.757	.792		
(D18) I can critically evaluate the information that I gather for its usefulness.	3.69	.785	.642		
(D5) I know where to find information from different sources (e.g. school library, online database, web).	3.78	.724	.592		
(D13) I am confident in using application software (e.g. email, office suite, web browser).	3.93	.826		.788	
(D20) I have the skills to use digital technology (e.g. computer, tablet, smartphone) effectively.	3.90	.768		.722	
(D12) I use digital technology (e.g. computer, tablet, smartphone) often both at home and at school.	4.12	.839		.670	
(D8) I am familiar with the web.	3.82	.843		.586	
(D2) I can distinguish the differences between print and online resources.	3.77	.744			.730
(D1) I know how and where to search for useful information both online and offline.	3.74	.763			.663
(D4) I am one of the members in the learning community.	3.57	.992			.623
(D15) I can integrate information that comes from different sources (e.g. school library, online database, web).	3.73	.748			.533
% of variance explained			45.236	6.595	5.090
Eigenvalue			5.841	1.228	1.068
Cronbach's alpha			.827	.846	.782

4.3 Confirmatory factor analysis

Unlike EFA, in confirmatory factor analysis (CFA), the relationships between a construct and its scale items are prescribed before the statistical analysis (Gefen and Straub, 2005). This study performed a CFA with the partial least squares (PLS) approach. PLS approach aims to examine variances and significance of relationships, and is appropriate for making predictions (Fornell and Bookstein, 1982; Gefen, Straub and Boudreau, 2000). Gerbing and Anderson (1988) propose a two-step modelling approach to PLS analysis. They contend that a two-step approach that examines both the measurement model and structural model makes a complete confirmatory assessment of construct validity. The first step examines the measurement model, and the second step examines both the measurement and structural models simultaneously. Following Gerbing and Anderson (1988), in this study, the measurement model was tested first for internal consistency reliability, convergent validity, and discriminant validity (Dunn, Seaker and Waller, 1994). Next, by estimating the path coefficients and R^2, the structural model was examined for the relationships between the exogenous and endogenous constructs (Gerbing and Anderson, 1988). To perform the PLS analysis, this study used the SmartPLS software.

4.3.1 Measurement model

First, the loadings of individual items were examined. Those that did not load more than 0.7 on the intended construct were deleted to establish unidimensionality (Chin, 1998). Scale item D4 of the construct central competencies did not meet the threshold value (0.599). Thus, it was removed from further analyses. After D4 was removed, loadings of all scale items on their intended constructs were above 0.7.

Having established that all scale items had satisfactory loading, subsequent analyses checked for internal consistency reliability, convergent validity, and discriminant validity.
Internal consistency reliability - For satisfactory internal consistency reliability, composite reliability of a construct should exceed 0.7 (Chin, 1998, Fornell and Larcker, 1981). As depicted in Table 6, composite reliability of all constructs was above 0.7. Thus, internal consistency reliability of individual constructs was satisfactory.

Table 6: CR, AVE, and construct correlations

Constructs	CR	AVE	Experiential learning	Searching	Effective learning	Under-pinnings
Experiential learning	0.885	0.658	0.811			
Searching	0.883	0.716	0.643	0.846		
Effective learning	0.948	0.754	0.688	0.657	0.868	
Underpinnings	0.897	0.685	0.592	0.642	0.572	0.828

Note: CR: composite reliability; AVE: average variance extracted; square roots of average variances extracted (AVE) are shown on diagonal; correlations between constructs are shown on off-diagonal.

Convergent validity - For satisfactory convergent validity, three criteria should be met: (1) composite reliability of a construct should exceed 0.7 (Chin, 1998; Fornell and Larcker, 1981); (2) average variance extracted (AVE) of a construct should exceed 0.5 (Chin, 1998; Fornell and Larcker, 1981); and (3) loading of scale items should exceed 0.7 on the intended construct (Barclay, Higgins and Thompson, 1995; Chin, 1998). When AVE is more than 0.5, the variance of individual constructs is larger than that contributed by the measurement error (Segars, 1997). As depicted in Table 6, composite reliability of all constructs was above 0.7. In addition, AVEs of all constructs were above 0.5. As depicted in Table 7, loadings of all scale items on the intended constructs were above 0.7. Thus, it was evident that all constructs had satisfactory convergent validity.

Table 7: Factor loadings and cross loadings

Scale items	Experiential learning	Searching	Effective learning	Under-pinnings
(D5) I know where to find information from different sources (e.g. school library, online database, web).	0.758	0.558	0.504	0.418
(D16) I am comfortable with sharing information with others in discussion.	0.828	0.537	0.541	0.480
(D17) I am motivated in learning new information both online and offline.	0.813	0.423	0.514	0.434
(D18) I can critically evaluate the information that I gather for its usefulness.	0.843	0.561	0.653	0.569
(D2) I can distinguish the differences between print and online resources.	0.415	0.777	0.449	0.512
(D15) I can integrate information that comes from different sources (e.g. school library, online database, web).	0.572	0.879	0.635	0.600
(D1) I know how and where to search for useful information both online and offline.	0.624	0.879	0.562	0.512
(L1) I am able to recall the material that I have learned.	0.570	0.532	0.874	0.419
(L2) I am able to explain the material that I have learned.	0.557	0.588	0.878	0.531
(L3) I am able to apply the material that I have learned.	0.644	0.610	0.893	0.539
(L4) I am able to critically analyse a problem situation to suggest solutions.	0.617	0.514	0.851	0.409
(L5) I am able to evaluate the quality of information that I receive.	0.642	0.564	0.889	0.522
(L6) I am able to integrate material from different resources to create useful information.	0.548	0.610	0.824	0.547
(D8) I am familiar with the web.	0.466	0.591	0.413	0.813
(D12) I use digital technology (e.g. computer, tablet, smartphone) often both at home and at school.	0.472	0.486	0.434	0.799
(D13) I am confident in using application software (e.g. email, office suite, web browser).	0.504	0.602	0.529	0.883
(D20) I have the skills to use digital technology (e.g. computer, tablet, smartphone) effectively.	0.514	0.449	0.501	0.813

Discriminant Validity - For satisfactory discriminant validity, two criteria should be met: (1) scale items should load > 0.50 on the intended construct, but lower or weakly on the other unintended constructs (Straub, Boudreau and Gefen, 2004); and (2) the square root of AVE of a latent construct should be larger than the

correlation between that particular construct and any other constructs in the model (Chin, 1998; Fornell and Larcker, 1981; Gefen and Straub, 2005). As depicted in Table 6, it was evident that individual scale items loaded > 0.50 on their intended constructs and significantly lower on any other constructs. Table 6 provides evidence that the square root of AVE of individual constructs was higher than the correlation between it and any other constructs in the model.

4.3.2 Structural model

The structural model was examined next. A bootstrapping procedure of 500 sub-samples was used to calculate t-statistics of path coefficients between the exogenous and endogenous constructs (Gefen, Straub and Boudreau, 2000). As depicted in Figure 2, two-tailed t-statistics showed all path coefficients between the constructs were significant at $p < 0.01$ (t-statistics > 2.57 were significant at $p < 0.01$). It was evident that the constructs of underpinnings, experiential learning, and searching explained about 56% of the variance in the effective learning construct ($R^2 = 0.561$).

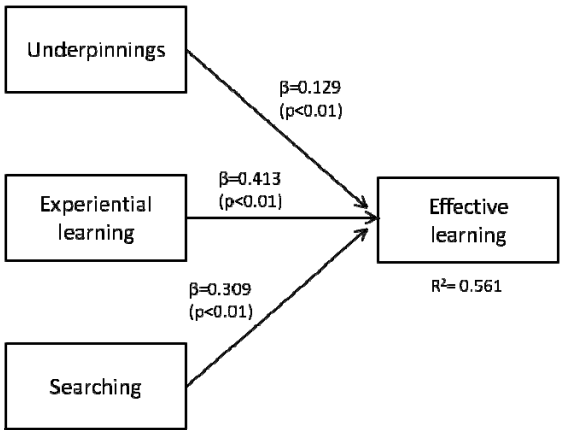

Figure 2: Structural model

5 Discussion and conclusions

This study set off to answer the question: Do students require digital literacy to be effective in learning in a blended learning environment? This study provides evidence that for blended learning to be successful, there is a need for students to be digitally literate. As concluded by Mohammadyari and Singh (2015), people who have high digital literacy can adapt well to e-learning as they would find it easy to learn the technologies specific for educational purposes, and are more efficient and effective in information management.

Analyses show that the four digital literacy constructs conceptualised by Bawden (2008) can be reduced to three. These three constructs are: underpinnings, experiential learning, and searching, and together they account for more than half of the learning effectiveness of respondents in a blended learning environment at the local university. It is quite clear that to be digitally literate, a very basic requirement is possessing the skills to use digital technology. The similarities between Bawden's (2008) digital literacy components and Huber's (1991) knowledge acquisition processes explain how students can acquire knowledge in order to become digitally literate. In searching for information, students learn how and where to search for information effectively from different sources - this helps build their background knowledge. In learning to synthesise information for new knowledge and sharing information with others, students gain experiences to build their competencies and develop the right attitudes and perspectives. These three constructs are also consistent with Ng's (2012) digital literacy dimensions, i.e. technical, cognitive, and social-emotional.
This study also highlights a notable observation. A higher percentage (74.5% vs. 63.9%) of the respondents prefer classroom learning as compared to online learning. In online learning, students and teachers do not normally meet physically but instead are connected on an online learning platform such as LMS (Prior et al., 2016). Phillips, Turnbull and He (2015) suppose that although online learning is becoming common these days because of its accessibility and flexibility, one needs a high level of self-directed learning readiness in order to do well. Considering that 74% of the respondents have used LMS for just one or two semesters, it is likely that they have just joined the university from secondary schools where face-to-face classroom teaching is common. Thus, some respondents might lack the confidence and skills for self-directed learning. The percentage of respondents who prefer blended learning (64%) is very close to that of online learning though.

It is also interesting to note that a higher percentage (82% vs. 45.9%) of the respondents find that face-to-face meetings (e.g. in-class lectures, consultations with lecturers, group discussions, etc.) are more effective than online interactions (e.g. blogs, forums, chats, emails, etc.). Despite the convenience brought by digital technology and the respondents having a certain level of digital literacy, they still find the need to meet in classrooms. This might be due to the urge for some physical community connection with other students as well as lecturers amid the virtual world enabled by digital technology.

Given that today's young university students (most respondents are below 25 years old at the university this study was conducted) generally have good knowledge of using digital technology in their everyday activities (e.g. finding information online, watching videos, listening to music, using social media, etc.), it is not a surprise that a higher percentage (70.2% vs. 63.4%) of the respondents find online resources (e.g. e-books, digital databases, audio or video webcasts, etc.) more effective than physical resources (e.g. print books, school libraries, etc.). The top three most liked LMS features are online resources, online course announcements, and online assignment submission. Only 20.9% of the respondents like online discussions (e.g. blogs, forums, chats, etc.).

Learning from the findings of this study, when planning or delivering blended learning courses, lecturers need to first understand the students in terms of their level of digital literacy for learning. A good fit of digital literacy level to course expectations is necessary for successful blended learning. If some students have low digital literacy levels, additional exercises and tutorials can be used to help these students improve their digital literacy capabilities. Ng (2012) supports that students can learn to use educational technologies not familiar to them for learning if they are introduced to and given a chance to use these technologies. He reasons that the students would normally not use educational technologies unless there is such a need.

In addition, blended learning is reported to have increased student dropout rates (Deschacht and Goeman, 2015). One reason could be that unlike face-to-face classroom learning, blended learning requires a certain level of self-directed learning. Phillips, Turnbull and He (2015) propose that self-directed learning readiness is linked to three factors, i.e. self-control, self-management, and desire for learning. Prior et al. (2016) find that students who have strong self-efficacy are more confident, independent, and motivated. They conclude that a positive student attitude and high digital literacy can improve self-efficacy, which in turn contributes positively to such online behaviours as peer engagement, learning management system interaction, and convener interaction. Thus, by helping students to develop digital literacy, lecturers can also help foster self-directed learning among the students.

5.1 Research limitations

The respondents in this study had different LMS usage experience. The majority of them (60.3%) had used the LMS for two or three semesters, but about a third for only one semester. How familiar they were with the LMS could influence their views of how useful the LMS was in their learning process. In addition, the respondents were from different courses. The types and levels of digital literacy capabilities required of them could be diverse across subject matter areas.

5.2 Future research directions

The study context was a local university that had adopted blended learning. Future studies can examine the original research model in different contexts, e.g. primary or secondary schools, professional courses, working adults, full-time young students, etc. Also, the factors, i.e. underpinnings, experiential learning, and searching, explained slightly more than 50% of the variance in effective learning. There are other factors that could contribute to effective learning, e.g. environmental factors. Future studies can consider new factors, investigate interactions among the factors, and introduce moderators.

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The Use of Scaffolds for Teaching Higher-Level Cognitive Strategies

Not only are scaffolds useful for teaching well-structured skills, but they also provide the support students need to tackle higher-level thinking strategies.

BARAK ROSENSHINE AND CARLA MEISTER

The teaching of higher-level thinking operations is a topic that interests many of today's educators. These operations include comprehension and interpretation of text, scientific processes, and mathematical problem solving. While much has been written on the need for students to perform higher-level thinking operations in all subject areas, the teaching of these operations often fails, not because the idea is poor, but because the instruction is inadequate.

How does one help students perform higher-level operations? One solution that researchers have developed is to teach students cognitive strategies (Pressley et al. 1990; Perkins et al. 1989; Weinstein 1979). A strategy is not a direct procedure; it is not an algorithm. Rather a strategy is a heuristic that supports or facilitates the learner as he or she learns to perform the higher-level operations.

For example, to facilitate reading comprehension, students may be taught to use cognition strategies such as generating questions about their reading. To generate questions, students need to search the text and combine information, which in turn helps them comprehend what they read. To help students in the writing process, they may be taught how to organize their writing and how to use self-talk prompts to facilitate the revision process. These cognitive strategies are more like supports or suggestions than actual step-by-step directives.

But how does one teach cognitive strategies? Our review of about 50 studies in which students ranging from 3rd grade through college were taught cognitive strategies showed that successful teachers of such strategies frequently used instructional procedures called *scaffolds* (Palincsar and Brown 1984; Paris et al. 1986; Wood et al. 1976). Scaffolds are forms of support provided by the teacher (or another student) to help students bridge the gap between their current abilities and the intended goal. Scaffolds may be tools, such as cue cards, or techniques, such as teacher modeling. Although scaffolds can be applied to the teaching of all skills, they are particularly useful, and often indispensable, for teaching higher-level cognitive strategies, where many of the steps or procedures necessary to carry out these strategies cannot be specified. Instead of providing explicit steps, one supports, or scaffolds, the students as they learn the skill.

The support that scaffolds provide is both temporary (Tobias 1982) and adjustable, allowing learners "to participate at an ever-increasing level of competence" (Palincsar and Brown 1984, p.122). Scaffolding gradually decreases as the learning process unfolds and students become proficient.

Before using scaffolds, it is important to determine whether students have sufficient background ability to learn a new cognitive strategy. Researchers (particularly Palincsar and Brown 1984) note that scaffolds are only useful within the student's "zone of proximal development" (Vygotsky 1978), that is, the area where the student cannot proceed alone, but can proceed when guided by a teacher using scaffolds. When Palincsar and Brown (1984) taught strategies designed to foster reading comprehension, they selected students whose decoding skills were near grade level, but whose comprehension was below grade level. They did not select students with poor decoding skills, because such students did not have sufficient background skills to profit from this instruction. Similarly, scaffolds cannot help students read a physics text or history text for which they do not have the necessary background knowledge.

Presenting a New Cognitive Strategy

In the studies we reviewed, teachers typically began teaching a cognitive strategy by introducing and explaining a concrete prompt. Concrete prompts,

also called procedural facilitators (Scardamalia et al. 1984), are scaffolds specific to the strategy being taught, yet general enough to allow application to a variety of different contexts. For example, to help students learn the strategy of generating questions, some teachers first gave students "question words" — *who, what, when, where, why, how* — and taught them to use these words as prompts. These six simple question words were the concrete prompts. In the study by King (1989), students used a list of general question stems that could be used to form questions about a particular passage:

> How are ___ and ___ alike?
> What is the main idea of _____?
> What do you think would happen if _____?
> What are the strengths and weaknesses of _____?
> In what way is ___ related to ___?
> How does ___ affect ___ ?
> Compare ___ and ___ with regard to _____.
> What do you think causes ___?
> How does _____ tie in with what we have learned before?
> Which one is the best ___ and why?
> What are some possible solutions for the problem of _____?
> Do you agree or disagree with this statement: _____? Support your answer.
> What do I (you) still not understand about _____ ?

Several different concrete prompts have also been developed for teaching the strategy of summarizing. Baumann (1984) and Taylor (1985) used the following prompt:

> Identify the topic.
> Write two or three words that reflect the topic.
> Use these words as a prompt to help figure out the main idea of the paragraph.
> Select two details that elaborate on the main idea and are important to remember.
> Write two or three sentences that best incorporate these important ideas.

Palincsar (1987) used a different prompt for teaching summarizing:

> Step 1: Identify the topic sentence.
> Step 2: If there is not a topic sentence, identify the topic and the most important information about that topic.
> Rule 1: Leave out unimportant information.
> Rule 2: Give steps or lists a title.
> Rule 3: Cross out information that is redundant/repeated.

To assist students during the writing process, Scardamalia, Bereiter, and Steinbach (1984) offered students cues to stimulate their thinking about the planning of compositions. These cues took the form of introductory phrases and were grouped according to the function they served: planning a new idea, improving, elaborating, goal setting, and putting it all together. Students first determined the type of cue needed, then chose a particular cue to incorporate into a silent planning monologue (see box, page 29, for cues for opinion essays).

Other investigators developed specific prompts to help students improve their writing. For example, Englert, Raphael, Anderson, Anthony, and Stevens (1991) provided Plan Think-Sheets that cued students to consider their audience ("Who am I writing for?" "Why am I writing this?"), and Organize Think-Sheets to help students sort their ideas into categories ("What is being explained?" "What are the steps?").

After presenting the concrete prompt, the teacher modeled its application as the students observed. Thus, when teaching students to generate questions, the teacher modeled how to use the cues to think of questions related to a particular passage. When teaching students to write a summary, the teacher identified the details of a paragraph or passage, used the details

How to Teach Higher-Order Cognitive Strategies

1. Present the new cognitive strategies.
(a) Introduce the concrete prompt.
(b) Model the skill.
(c) Think aloud as choices are made.

2. Regulate difficulty during guided practice.
(a) Start with simplified material and gradually increase the complexity of the task.
(b) Complete part of the task for the student.
(c) Provide cue cards.
(d) Present the material in small steps.
(e) Anticipate student errors and difficult areas.

3. Provide varying contexts for student practice.
(a) Provide teacher-led practice.
(b) Engage in reciprocal teaching.
(c) Have students work in small groups.

4. Provide feedback.
(a) Offer teacher-led feedback.
(b) Provide checklists.
(c) Provide models of expert work.

5. Increase student responsibility.
(a) Diminish prompts and models.
(b) Gradually increase complexity and difficulty of the material.
(c) Diminish student support.
(d) Practice putting all the steps together (consolidation).
(e) Check for student mastery.

6. Provide independent practice.
(a) Provide extensive practice.
(b) Facilitate application to new examples.

Thinking aloud by the teacher and more capable students provided novice learners with a way to observe "expert thinking" usually hidden from the student.

to form a main idea, and stated the details in the summary. In writing an explanation paper, the teacher used the planning cues in a self-talk (monologue) style. The teacher modeled how to use the Plan Think-Sheet to record ideas and thoughts about the topic.

Modeling of the process by the teacher gradually diminished as students began to take on more of the responsibility for completing the task. The teacher continued to model only the part(s) of the process that students were unable to complete at a particular time. Often during the transitional stage, when the students were ready to take on another part of the task, the teacher continued to model, but requested hints or suggestions from the students on how to complete the next step in the task. Several studies also relied on more capable students to provide the modeling.

Another scaffold, similar to modeling, is "thinking aloud." For example, when teaching students to generate questions, the teacher describes the thought processes that occur as a question word is selected and integrated with text information to form a question.

Anderson (1991) provides illustrations of think-alouds for several cognitive strategies in reading:

> *For clarifying difficult statements or concepts:* I don't get this. It says that things that are dark look smaller. I know that a white dog looks smaller than a black elephant, so this rule must only work for things that are about the same size. Maybe black shoes would make your feet look smaller than white ones would.
>
> *For summarizing important information:* I'll summarize this part of the article. So far, it tells where the Spanish started in North America and what parts they explored. Since the title is "The Spanish in California," the part about California must be important. I'd sum up by saying that Spanish explorers from Mexico discovered California. They didn't stay in California, but lived in other parts of America. These are the most important ideas so far.
>
> *For thinking ahead:* So far this has told me that Columbus is poor, the trip will be expensive, and everyone's laughing at his plan. I'd predict that Columbus will have trouble getting the money he needs for his exploration.

In a mathematics study by Schoenfeld (1985), the teacher thought aloud as he went through the steps in solving mathematical problems. He also identified and labeled the problem-solving procedures he was using (for example, making diagrams, breaking the problem into parts). Thus, as Schoenfeld points out, thinking aloud may also provide labels that students can use to call up the same processes in their own thinking.

When teaching mathematical problem solving, Schoenfeld (1985) asked the college students in his class to provide him with particularly difficult problems. Each class began with his attempt to solve one of the problems. Through modeling and thinking aloud, he applied problem-solving procedures and revealed his reasoning about the problems he encountered. Students saw the flexibility of the strategies as they were applied to a range of problems and observed that the use of a strategy did not guarantee success.

The following excerpt is an example of Schoenfeld modeling his thinking process as he gets a feel for a problem:

> What do you do when you face a problem like this? I have no general procedure for finding the roots of a polynomial, much less for comparing the roots of two of them. Probably the best thing to do for the time being is to look at some simple examples and hope I can develop some intuition from them. Instead of looking at a pair of arbitrary polynomials, maybe I should look at a pair of quadratics: at least I can solve those. Now, what happens if . . .

As individual students accepted more responsibility in the completion of a task, they often modeled and thought aloud for their less capable classmates. Not only did student modeling and think-alouds involve the students actively in the process, but it allowed the teacher to better assess student progress in the use of the strategy. Thinking aloud by the teacher and more capable students provided novice learners with a way to observe "expert thinking" usually hidden from the student.

Regulating Difficulty During Guided Practice

In order to help the learner, many teachers began with simpler exercises and then gradually increased the diffi-

culty of the task. This allowed the learner to begin participating very early in the process. For example, in a study by Palincsar (1987), an early task consisted of generating questions about a *single sentence*. The teacher first modeled how to generate questions, and this was followed by student practice. Then the complexity was increased to generating questions after reading a *paragraph*, followed by more student practice. Finally, the teacher modeled and the class practiced generating questions after reading an entire *passage*.

When learning the strategy of summarizing, students in the study by Dermody (1988) first learned how to write summary statements on single paragraphs. After students received guided practice on this task, teachers showed them how to combine several summary statements to produce a single summary for a longer passage and had them practice this more difficult task.

In many of the studies, instruction on the cognitive strategy began with the teacher completing most or all of the task through modeling and thinking aloud. The teacher continued to carry out the parts of the task not yet introduced to the students or those parts students were unable to complete at the time. Additional components were added to the students' responsibilities as they became more skillful. Sometimes, their participation began at a very simple level. For example, as the teacher modeled the strategy, the students were asked to provide the label. Or students were requested to state the next step in the process the teacher needed to model. As student involvement increased, teacher involvement was withdrawn. Teachers provided hints, prompts, suggestions, and feedback when students encountered difficulty in their attempts to complete part of the task. Sometimes these difficulties required the temporary increase of teacher involvement until students were able to overcome the difficulty.

Planning Cues Used for Opinion Essays

New Idea

An even better idea is . . .
An important point I haven't considered yet is . . .
A better argument would be . . .
A whole new way to think of this topic is . . .
No one will have thought of . . .

Improve

I'm not being very clear about what I just said so . . .
A criticism I should deal with in my paper is . . .
I really think this isn't necessary because . . .

Putting it Together

If I want to start off with my strongest idea, I'll . . .
I can tie this together by . . .
My main point is . . .

Elaborate

An example of this . . .
This is true, but it's not sufficient so . . .
My own feelings about this are . . .
I'll change this a little by . . .
The reason I think so . . .
Another reason that's good . . .
I could develop this idea by adding . . .
Another way to put it would be . . .
A good point on the other side of the argument is . . .

Goals

A goal I think I could write is . . .
My purpose is . . .

In some studies, students received cue cards containing the concrete prompts they had been taught. Having a cue card allows the student to put more effort into *applying* the prompt, rather than *remembering* it. For example, in the study by Billingsley and Wildman (1984), the students were provided with a card containing the list of question words (*who, what, why*) they could use to generate questions. Singer and Donlon (1982) taught students to use the elements of story grammar (for example, leading character, goal, obstacles, outcomes, and theme) as a prompt to generate questions and gave them lists of these story elements for reference. Wong and Jones (1982) provided students with cue cards printed with a concrete prompt to use as they generated questions on the main idea of a passage. Eventually the cue cards were removed, and students were asked to formulate questions or write summaries without them. Below is a Self-Questioning Cue Card:

(a) Why are you studying this passage? (So you can answer some questions you will be given later.)
(b) Find the main idea/ideas in the paragraph and underline it/them.
(c) Think of a question about the main idea you have underlined. Remember what a good question should be like.
(d) Learn the answer to your question.
(e) Always look back at the questions and answers to see how each successive question and answer provides you with more information.

When presenting a prompt that has several steps, the difficulty can be regulated by "teaching in small steps," that is, first teaching one step and providing for student practice before teaching the next step. In this way, students deal with manageable, yet meaningful, bits. In a study (Blaha 1979) in which students were taught a strategy for summarizing paragraphs, the teacher explained and modeled the

first step, identifying the topic of a paragraph, and provided for student practice on new paragraphs. Then she taught the concept of main idea, and students practiced both finding the topic and locating the main idea. Following this, she taught students to identify the supporting details, and the students practiced that part of the task. Finally, the students practiced doing all three steps of the strategy.

Another way to regulate the difficulty of learning a new cognitive strategy is to anticipate and discuss potential student errors. For example, in one study the teacher anticipated errors in summarizing by presenting a summary with a poorly written topic sentence and asking students to identify the problem. In a questioning study, the teacher showed questions that were inappropriate because they were about a minor detail and then asked students to state why they were inappropriate. The students then used these hints and suggestions as they generated their questions.

Another example of anticipating errors occurs in the study conducted by Brady (1990). The investigator noticed that students had a tendency to produce summary statements that were too broad, often providing only the general topic of the passage (for example, "This paragraph was about toads.") To help students avoid this error, Brady developed a simple yet successful concrete prompt; he suggested students begin their summary statements with the phrase "This paragraph tells us that _____." This prompt significantly improved the quality of summary statements.

Dialogue and Scaffolded Instruction

Teacher: Today we are going to do something using those four things we talked about last week. Does anyone remember those four activities that we were talking about when we were talking about thinking as we listen to the story?

Student 1: We give a summary.

Teacher: One was summary, right. And what do we do when we talk about summarizing? T _____?

Student 2: Tell about the story.

Teacher: Yes, and you don't have to tell all about it, just the most important ideas. What was another thing we talked about? B _____?

Student 3: Questions.

Teacher: Yes, we talked about questioning. And do you remember what we did when we were talking about questioning? What do we ask questions about? About anything at all?

Student 3: About the story and to see if we understand.

Teacher: Right. We will ask questions that will give us information about the story and that will help us see if we were listening or if we fell asleep. What is something else we did? We did two more things. Summarizing, questioning. . . . Remember we talked about the weatherman, and we said that the weatherman does this? What does the weatherman do?

Student 4: Give a . . .

Teacher: What does he do when he tells us it's going to be a beautiful weekend?

Student 4: Prediction!

Teacher: Right. You remembered that big word. And what do we do when we predict about the story?

Student 4: We think about what might happen.

Teacher: Next in the story. Right. And then we did one more. The last thing was . . . if you don't know something you might raise your hand and ask that it be . . . clarified. That was a big word, wasn't it? So, we're going to start today with some stories, and we're going to use those four different activities . . . summaries, questioning, predicting, and clarifying to help us understand the story.

Source: Palinscar, A.S. (1986). "The Role of Dialogue in Providing Scaffolded Instruction." *Educational Psychologist* 21, 73-98.

Varying the Context for Practice

Students in most studies practiced the application of cognitive strategies in one or more of three different contexts: teacher-guided practice, reciprocal teaching, and work in small groups. When teaching cognitive strategies, the teachers guided students by providing hints, reminders of the concrete prompts, reminders of what was overlooked, and suggestions on how something could be improved. Students participated by giving answers and deciding upon the correctness of other students' answers. Where appropriate, students were asked to justify their procedures by explaining their thinking. Through this process, students' "oversimplified and naive conceptions are revealed" (Brown and Campione 1986). Such dialogue may also aid in understanding. As Brown and Campione (1986) write, "Understanding is more likely to occur when a student is required to explain, elaborate, or defend his or her position to others; the burden of explanation is often the push needed to make him or her evaluate, integrate, and elaborate knowledge in new ways."

In some studies, guided practice took place in the context of a dialogue among teacher and students — reciprocal teaching (Palincsar and Brown 1984) — with students and teacher rotating the role of teacher. This allowed for shifting of responsibility to the students and gradual internalization of the cognitive strategies. As the student took on the role of the teacher in the process of applying the strategies to a text, the teacher was able to evaluate the student's progress and provide feedback or assistance (see box, page 30, for an example of a dialogue).

Collaborative social dialogue was also emphasized in Englert and colleagues' (1991) Cognitive Strategy Instruction in Writing. During guided practice, students were invited to participate in a dialogue about a class writing project. Students and teacher worked collaboratively to generate self-questions, apply the new cognitive strategies, and carry on the dialogue to complete a class paper. The students progressively took on more responsibility for completing the writing task. The investigators contend that as students accept more responsibility in the exchange that takes place during the instructional dialogues, they begin to internalize the dialogue. The investigators suggest that this inner dialogue allows students to (1) talk to themselves about their own writing, (2) hear what their own writing has to say, and (3) talk to others about their writing.

In some studies, notably those conducted with high school and college students, the students practiced the task in small groups without the teacher. For example, King (1989) reported that after hearing a lecture, students met in small groups and practiced generating questions about the lecture. Students in Schoenfeld's (1985) study had opportunities to participate in small group mathematical problem solving. Schoenfeld suggests small group work facilitates the learning process in four ways. First, it provides an opportunity for the teacher to assess students, to provide support and assistance as students actively engage in problem solving. Second, group decision making facilitates the articulation of knowledge and reasoning as students justify to group members their reasons for choosing alternative solutions. Third, students receive practice in collaboration, a skill required in real-life problem solving. Fourth, students who are insecure about their abilities to solve problems have the opportunity to see more capable peers struggle over difficult problems.

Providing Feedback

Feedback is important in teaching cognitive strategies as it is for all forms of learning. Traditional feedback from teachers and other students on the correctness of response took place throughout the lessons on cognitive strategies.

In several studies the teacher provided self-checking procedures to increase student independence. For example, as part of their instruction in teaching students to summarize a passage, Rinehart, Stahl, and Erickson (1986) had students use the following list of questions to check their summaries:

> Have I found the overall idea that the passage is about?
> Have I found the most important information that tells me more about the overall idea?
> Have I used any information that is not directly about the main idea?
> Have I used any information more than once?

Checklists for writing programs ranged from checklists on punctuation ("Does every sentence start with a capital letter?") to checklists on style elements. For example, students being taught to write explanations were taught to ask, "Did I tell what materials you need?" "Did I make the steps clear?" (Englert et al. 1991). Teachers usually presented these checklists at the end of guided practice. The teacher modeled the use of the checklist and provided students with guidance as they began to use the checklists.

In some studies, students were provided with expert models to compare their work to. For example, where students were taught to generate questions, they could compare their questions with those generated by the teacher. Similarly, when learning to write summaries, students could compare their summaries on a passage with those generated by an expert.

Increasing Student Responsibility

Just as it is important to simplify material and provide support for students in the initial stages of learning a cognitive strategy, it is also important to reduce the number of prompts and provide students with practice using more complex material. Thus, the responsibility for learning shifts from the teacher to the student. This gradual decrease in supports and gradual increase in student responsibility has been described as a shift in the teacher's role from that of coach to that of supportive and sympathetic audience (Palincsar and Brown 1984).

After the students in the study by Wong and Jones (1982) had used cue cards to develop fluency in writing a summary, the cue cards were removed and students wrote summaries without these prompts. In the studies by King (1989), in which students used half-

completed sentences as references when generating questions, the teacher withdrew the supports after the guided practice, and students were left to generate questions on their own.

Increasing the complexity of material was evident in the study by Palincsar (1987), in which students learning to generate questions began by working on a single sentence, then a paragraph, and finally, an entire passage. Schoenfeld (1985) sequenced the problems he presented to his students when teaching mathematical problem solving. He first gave students problems they were incapable of solving on their own; this provided the motivation for learning the strategy he planned to introduce. After presenting the strategy, he provided problems that were easily solved when the strategy was applied. As students became skilled at applying the strategy, he introduced a new strategy. Interspersed among these new problems were several problems requiring the application of previously taught problem-solving strategies, forcing students to discriminately apply the strategies learned to the type of problems encountered. As the course progressed, students were expected to combine strategies to solve complex problems.

In some studies, the support that students received from other students was also diminished as work progressed. For example, in the study by Nolte and Singer (1985), the students first spent three days working in groups of five or six and then three days working in pairs before working alone on the task.

In the study by Englert and colleagues (1991), in which students were taught cognitive strategies in writing, students first participated in a collaborative dialogue that centered on the application of the newly learned strategies to a whole-class writing project. Students then chose their own topic, applying the same strategies used in the group writing. Students were encouraged to collaborate with a peer or peers by sharing ideas, discussing each other's writing, asking questions, getting feedback, reporting progress, or asking advice. The teacher provided additional support by finding examples of strategy use or problems found in the students' writing, displaying them on the overhead. The teacher initiated a class dialogue on the student examples, focusing the discussion on the strategies used, the problems encountered by the students, and possible solutions. After the students completed this piece of writing, the teacher asked them to independently write another paper for publication in a class book.

When series of steps have been taught and practiced separately, as in some summarizing and writing strategies, one of the final tasks during guided practice is having the students practice putting the component parts of the strategy together. A teacher can then assess student implementation of the complete strategy, correct errors, and determine whether additional teaching or practice is necessary. Such assessment is important before students begin independent practice.

Providing Independent Practice

The goal of independent practice is to develop *unitization* of the strategy, that is, the blending of elements of the strategy into a single, unified whole.The extensive practice, and practice with a *variety* of material — alone, in groups, or in pairs — also *decontextualizes* the learning. That is, the strategies become free of their original "bindings" and can now be applied, easily and unconsciously, to various situations (Collins et al. 1990). Cognitive Strategy Instruction in Writing (the program implemented in the Englert et al. 1991 study) provided students with several opportunities to apply the strategies they had been taught, first in a whole-group setting, then individually with peer and teacher assistance, and then a third time independently.

The goal of independent practice is to develop *unitization* of the strategy, that is, the blending of elements into a single, unified whole.

Toward a Broader Application?

Scaffolds and the procedures for using them provide us with many ways to think about how to help students learn cognitive strategies (see box, page 27). Such concepts as modeling, thinking aloud, using cue cards, anticipating errors, and providing expert models can also be applied to the teaching of well-structured skills. This suggests that instead of a dichotomy, there is a continuum from well-structured explicit skills to cognitive strategies. At all points in the continuum, some instructional processes, such as presenting information in small steps and providing guided practice, are important. Yet, as one moves from well-structured skills to cognitive strategies, the value of providing students with scaffolds — models, concrete prompts, think-alouds, simplified problems, suggestions, and hints — increases.

The tools and techniques we refer to as scaffolds are at a middle level of

specificity. That is, they provide support for the student, but they do not specify each and every step to be taken. There is something appealing about this middle level. It lies somewhere between the specificity of behavioral objectives that seemed overly demanding to some, and the lack of instruction that many criticized in discovery learning settings. Perhaps it is the beginning of a synthesis. □

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Authors' note: We hope that the ideas presented here can serve as a heuristic for teachers to support their classroom instruction in cognitive strategies. The teaching of cognitive strategies is a higher-level operation itself; there is no specific, predetermined, or guaranteed path of instructional procedures to follow. Rather, there are sets of procedures, suggestions and scaffolds that a teacher selects, develops, presents, attempts, modifies, and even abandons in order to help students learn the cognitive strategy.

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What they don't know can hurt them: The role of prior knowledge in learning

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Admit it. You've watched the broadcasts of the Olympics and had your eyes glaze over while Dick Button waxed rhapsodic about the different between a double axle and a triple lutz. They looked pretty much the same to you, didn't they? You were experiencing what many students face every day in our classrooms, a distressing lack of the prior knowledge necessary to help them understand or appreciate a new experience or content. Current research on learning has offered more and more evidence for the extent to which new learning is determined by what the learner already knows about the topic or related topics. The effect can be either positive or negative, positive if the pre-existing knowledge is correct and consistent with the new information or negative if it is full of misconceptions or conflicts with the new information.

Prior knowledge & current learning.
Prior knowledge affects how the learner perceives new information. This phenomenon is readily demonstrated by a simple experiment. What is the first image that you associate with the word "cardinal"? Some people think immediately of football, some of baseball, birds, Roman Catholic priests, or the color red. In the absence of a context, the association you make will depend on your prior knowledge. Your interpretation of this new information, the word "cardinal," was dependent on what you brought to the situation.

Fortunately, in most learning tasks, words occur in a context to assist in interpretation. If the word "cardinal" had occurred in the context of a discussion about the Inquisition, the number of associations which you could choose from would be dramatically circumscribed. But sometimes the context is no more meaningful than the word itself. If you had never heard of the Inquisition, that context would be no help.

Much the same thing happens in the classroom every day. Instructors use terms and concepts of which students have no prior knowledge to provide an adequate context for interpretation. Used at the rapid pace of the expert, this is what they complain about as "jargon" and its over-use leaves gaps in student ability to process new information. The phenomenon is similar to that experienced by the average computer novice attempting to obtain help from an expert. Half of the words are totally unfamiliar and the other half are used in an entirely new and illogical way. After two or three sentences, the listener is left in the dust and feeling hopelessly ignorant and hostile. This may be the stuff of great comedy routines, but it is disaster in a classroom.

Alternatively, an incorrect bit of prior knowledge which is not corrected could keep the students from understanding an entire lecture. This is frequently the case in science classes, where naive conceptions of natural laws must be unlearned before the correct version can be understood. For example, in chemistry, instructors must somehow convince students that air exists just as liquids and solids exist even though it can't be detected by the senses.

Intellectually students know this, but they often behave as if air was simply the absence of matter. This concept which seems simple, almost automatic, to an expert can be a stumbling block to understanding a whole range of phenomena for a novice.

Prior knowledge affects how a student organizes new information. Remember that a goal of learning is to incorporate new information into the existing organization of memory. A student uses that existing structure to assimilate new information. For example, in the absence of any strong signals to the contrary, a student in a history class is going to organize new historical information chronologically because that is the way history had been organized in earlier classes.

History instructors trying to organize around a different conceptual structure must fight against the students' tendency to see everything as happening in a straight timeline.

Instructors can use this prior knowledge of structure to their advantage when they use analogies or examples. The analogy represents a known organizational structure of information. That organizational structure is what is transferred to the new information. For example, in trying to explain how a gland works, an instructor might say that the gland is like a thermostat. Most students already know that a thermostat controls the temperature by monitoring the presence of heat. They transfer this understanding to the functioning of a gland. It monitors and controls the level of a hormone in the body in the same fashion. If the analogy is a good one, the student can take it from there to intuit all sorts of properties of the gland which parallels the thermostat.

Prior knowledge affects how easily students make connections for new information.
One of the keys to learning and memory is the richness of the connections a bit of information has. The more connections, the easier it is to remember. When new information gets hooked up with a particularly rich and well-organized portion of memory, it inherits all the connections that already exist. This is why it is much easier to learn information that is in one's existing field of expertise than to learn information from a brand new field. There are many more ways to access the system. When a student has nothing to hook new information to, he or she is thrown back on the most basic characteristics of the information such as sound, or form, or straight rote memorization.

Using prior knowledge in instruction To begin, it is helpful to *know what prior knowledge students bring to the learning setting*. Have they had certain common courses? It pays to know what those courses contained. What are their other common experiences? Are they all from similar backgrounds, similar environments? How will that affect the way they interpret the content? Do they have common aspirations and goals? Are they all going in the same direction? What does this information tell you about the prior knowledge they will bring to your class? The use of a pretest of critical concepts and

terms can alert both the instructor and the students to gaps or misconceptions that could prove inconvenient later.

Prior knowledge need not be only knowledge of the content, although that is the most critical type of knowledge to monitor. Knowledge of popular culture or current events can be used to great advantage as well in the same ways, especially in the context of analogies. Some would say that knowledge of popular culture is simply another form of cultural literacy.

Use prior knowledge deliberately in the presentation of new information. Beginning a class with a review of what has gone before helps activate prior knowledge. Presenting new information in its relationship to old not only helps students learn the new information but strengthens the old. Introducing new concepts by contrasting them with some that have already been learned makes use of prior knowledge to aid in the learning of new. Better yet, having the students make those comparisons teaches them something about the way to approach the learning of new material and about the structure of the discipline..

It is also desirable to *get the students to monitor their own prior experiences* and consciously use them in learning new information. Asking students to recall past courses that are related to the present course is an interesting way to encourage this. In a graduate course I ask students to produce a personal bibliography from the readings of their previous courses that relate to the present course. They find this an interesting experience which has never been asked of them before, but it makes the point that what they know is related to what they are learning.

Finally it is always a good idea to *check for faulty prior knowledge regularly* so that it is not allowed to continue to detract from learning. There is a wonderfully apocalyptic story about an astronomy class in which the instructor drew many beautiful orbital diagrams and still the students had trouble understanding celestial motions. Finally, by accident, the instructor discovered that several of the students were interpreting the ovals he drew as being in reality ovals rather than the circles shown in perspective. Until you ask the students what they understand about what is being taught, you will

never really know what is being learned. Structure the learning to bring those misconceptions to the attention of the students. Often they will not realize their confusion until it is too late.

Final thoughts The lesson we take from the research on prior knowledge is simply this: students are not blank slates on which our words on inscribed. The students bring more to the interpretation of the situation than we realize. What they learn is conditioned by what they already know. What they know can be as damaging as what they don't know.

Student Motivation and Assessment of Applied Skills in an Equine Studies Program

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Student motivation is a universal teaching challenge. A holistic approach to assessment was developed for cognitive and psychomotor tasks in equine studies. First-year students (n=55) were either randomly provided (PR) or not provided (NP) a rubric 3 weeks prior to skills testing. The PR students earned lower total scores ($p < 0.05$) than NP students (12.8 and 17.1 ± 5.3, respectively). In individual categories, PR and NP students had similar ($p > 0.05$) pass superior scores. Third-year students ($n = 7$) self-rated task performance using an affective rubric and reflection exercises. Although the original goal was to promote standardization of hands-on skills, these data indicate that students are more goal-oriented than process-oriented; furthermore, use of affective rubrics for self-assessment promoted a learner-centered approach to motivation.

Midway College held a virtual monopoly on equine programs in Kentucky when its program was started over 20 years ago. As student and industry demand for equine academics has increased, approximately 185 institutions in the United States have launched programs with diverse offerings as degrees, concentrations, or coursework focusing on the horse industry (National Association of Equine Affiliated Academ-

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ics, 2009). This demand has followed the growth of the equine industry in the United States. The American Horse Council (2005) reported in a national study targeted at horse owners that there are approximately 9.2 million horses, which is higher (3.6 million) than the untargeted study by the United States Department of Agriculture, National Agriculture Statistics Service (USDA, 2002). In addition to horse numbers, the American Horse Council concluded that the equine industry has a dramatic impact on the United States economy. In terms of the Gross Domestic Product (GDP), this industry contributes a total of $39 billion, which is greater than the motion picture industry, railroad transportation, furniture manufacturing and tobacco product manufacturing services (The American Horse Council, 2005). In Kentucky alone, the equine industry has a reported economic impact of more than one billion dollars (Center for Business and Economic Research, 2004). For the first time, the 2010 World Equestrian Games will be hosted in the United States in Lexington, Kentucky. This event will create jobs and internship opportunities in several aspects of the industry. Recently, as a greater percentage of students from urbanized communities have enrolled in applied animal science programs (Britt et al., 2008; Hoover & Marshall, 1998; Reiling et al., 2003), development of standardized curriculum and assessment to meet the needs of students with either extensive or non-existent animal handling skills is necessitated.

Although educational opportunities in the equine industry have increased over the last 20 years, there is no universally adopted skill set required for graduates of existing equine programs. Potential career paths require mastery of both hands-on skills and business knowledge (Conners & Brady, 2009; Houge-Davies, 2004; Kretler, 1995). For instance, an equine professional having direct contact with horses should be able to assess the health and welfare of the horse, sense and interpret physical changes with their hands and visual inspections, interpret behavior, perform training of the horse for a specific purpose, assess and manage feeding and nutritional needs, communicate with clients and medical professionals, and perform accounting tasks plus many more business management activities (Conners & Brady, 2009; Houge-Davies,

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2004; Landers, 2002). Clearly, the wide array of skills necessitated for such careers confounds development of academic standards for teaching equine studies.

The Equine Studies Program at Midway College consists of two Baccalaureate degrees and one Associate degree. The Baccalaureate degrees are Bachelor of Science in Equine Studies with Concentration in Equine Health and Rehabilitation and Bachelor of Arts in Equine Studies with Concentration in Applied Equine Management. All degree programs require mastery of hands-on skills in addition to specific cognitive and assessment tasks. At entry, the majority of students display some level of equine experience, but there is neither a common level of proficiency nor a similar training background among students. To address these differences, a four course sequence of Practicum classes is required of all equine studies students at Midway College.

Hands-on skill learning is often evaluated only by achievement of the assigned task after repetitive practices. Similar to rote memorization of facts, this repetitive performance can be perceived as boring or insignificant, thereby decreasing intrinsic motivation to learn a new skill (Char, 2009). Further, pre-existing knowledge of equine handling does not correlate to re-learning skills in a safe method (Meek et al., 2005). When students do not perform a skill following the in-house method, it is more difficult to reduce potential safety hazards. Besides safety, the learning process is often disrupted because inexperienced students are initially not as comfortable handling horses and look for guidance from experienced students (Meek et al., 2005). Applied learning with horses is unlike chemistry experiments where mixing of specific chemicals provides a predictable reaction (or no reaction). Horses are unpredictable animals that react to the environment to satisfy basic survival needs. Therefore, this unpredictability poses a problem in standardizing the teaching and learning process and can present interference as less confident students express lower motivation in situations that are perceived to be unsafe. In consideration of these challenges, a teaching tool was investigated as a means to link the process of critical thinking to action.

Generally, rubrics are part of a teacher's daily routine in which rubrics are created and utilized to accurately achieve a grading standard. Rubrics are a form of authenticity set to guide both students and teachers in assignment evaluation and are often subjective in nature. They are commonly seen in writing courses and used for assessment testing in primary schools (Andrade, 2000; Andrade & Du, 2005; Char, 2009; Loveland, 2005). According to Loveland (2005), rubrics are vital because of the need for clear descriptions of project expectations, and upon review, rubrics provide a clearly delineated path for students to improve their work. Loveland also stated the benefits of a well-planned and thorough rubric for teachers. Development of an original rubric requires

instructors to take a retrospective view of a task for which they are writing the rubric (Leonhardt, 2005). Other authors echoed the need for rubrics to be clear and concise (Andrade, 2005; Andrade & Du, 2005; Issaacson & Stacy, 2009). If students do not have prior knowledge of the categories defined on a rubric, then rubric usage can create frustration, be dismissed, or be used only in a partial format (Andrade & Du, 2005). To increase effective use of rubrics, students should practice using the assessment tool (Andrade, 2000; Hafner & Hafner, 2003; Tan & Towndrow, 2009). Often students will use a rubric as a study guide or outline for developing written projects (Andrade & Du, 2005), medical task performance (Brown et al., 2006), and formative development of music skills (Leonhardt, 2005) indicating that such an assessment tool is useful in the teaching process.

For this research project, a rubric was chosen as a teaching and assessment tool because each hands-on task, or psychomotor skill, could be subdivided into parts and performance measures could be evaluated; thereby the process of teaching and learning the task would be standardized. In theory, providing the assessment tool prior to a task should improve student scores; therefore, the objective of Phase I was to determine if prior knowledge of the assessment tool would increase overall scores as well as scores on individual steps as compared to groups that did not receive the rubric. Based on results from Phase I, a second objective was developed to determine if student motivation to perform hands-on skills is enhanced when provided with an affective rubric for self-assessment.

METHOD

PHASE I

A faculty-derived rubric was developed for a showmanship pattern, which is a skill commonly found in showing horses for competition and sale. This task is universal in that all breeds and disciplines in the industry use showmanship for marketing their horses and/or service businesses. Although some variations in horse presentation and handler dress exist, efforts were made to prepare a rubric which would be applicable across breeds and disciplines. The showmanship skill involves the student making preparations with a horse several weeks prior to completing the task; therefore, students would require adequate time to prepare for assessment. Steps to create an original rubric were modified using a previously described method (Leonhardt, 2005). The rubric was subsequently revised, based on student and faculty feedback following an initial review as previously suggested (Murthy & Etkina, 2005). First-year students (n = 55) were either randomly provided (PR) or not provided (NP) the rubric three weeks prior to skills testing. In this instance, the

task was desegregated into 11 categories with a pass superior, pass, or fail scoring category worth 2, 1, and 0 points, respectively (Table 1). Once the students were assessed using the rubric, data were analyzed by the Proc GLM procedure of SAS with judge and whether or not the rubric was provided as test variables. Significances were determined at $p < 0.05$ with tendencies noted between $p = 0.05$ and $p = 0.10$.

PHASE II—PILOT STUDY

As the equine industry incorporates non-invasive performance enhancing techniques such as hydrotherapy, massage, and water treadmill exercise, there is increased demand for individuals with both knowledge and the ability to synthesize and evaluate healing and physical condition visually and through tactile sensations. Unlike human rehabilitation, horses do not provide reliable feedback on how the student is applying touch; furthermore, educating students to have 'thinking hands' presents a challenge. A holistic approach to teaching sensory perception was implemented in a series of manual integration courses. The activities were designed in a sequential format to promote movement through all six cognitive levels (Bloom, 1956), and using methods from an experiential learning model previously applied in a large-animal practical course (Reiling et al., 2003). Tools for teaching touch in other fields, such as nursing, were used in conjunction with lecture materials. Further, laboratories were developed using heating packs and false hair samples to simulate heat and cold perception. During a touch laboratory students were expected to apply self-massage techniques on the arms, hands, shoulders, and head to explore feeling. Students were also assigned to apply massage techniques on a project horse for the course of two semesters. Students were required to self-assess affective characteristics of "comfort" and "feeling" (Table 2) immediately following completion of aforementioned exercises. Students were then asked to reflect on the experience in a written format and were led in an informal group discussion regarding the affective rubric to determine usefulness and motivation to learn the novel tasks.

RESULTS

PHASE I

Sample tasks and assessment standards included a measurable outcome for many of the showmanship steps (Table 1). For example, the task of pivoting a horse 90 degrees is measurable by the amount of pivot. However, some tasks were considered more subjective by the raters than those with a clearly quantifiable value. For each task category, students

Table 1: Rubric for the showmanship task

Task	Pass Superior	Pass	Fail
Stand horse at cone 1; ready and waiting to be judged	Horse is standing quietly in the proper stance for the breed/type shown. Horse's shoulder is at the cone. Handler is showing in the appropriate quarter, exhibiting a precise show stance.	Horse is standing quietly in the proper stance for the breed/type shown. Horse's shoulder is near the cone. Handler is showing in the appropriate quarter, exhibiting a loose but technically correct show stance.	Horse is not standing in the proper stance for the breed/type shown. Horse's shoulder is uneven with the cone. Handler is not showing in the appropriate quarter. Handler is not exhibiting a proper show stance.
Wait for the judge to nod in acknowledgment of the handler	Handler waits for the judge to nod. After the nod, the handler moves promptly into the pattern.	Handler waits for the judge to nod. There is a slight hesitation before the handler moves into the pattern	Handler does not wait for the judge to nod. There is an obvious hesitation before the handler moves into the pattern.
Walk from first to second cone	Line of travel is straight. Horse moves off without hesitation with a brisk forward motion. Handler maintains a proper distance away from the horse and even with the horse's ear.	Line of travel is fairly straight. Horse moves off with slight hesitation with forward motion. Handler maintains a proper distance away from the horse and even with the horse's ear.	Line of travel is not straight. Horse shows obvious hesitation in starting forward. Horse may exhibit backward motion. Forward motion is sluggish and lacks energy. Handler does not maintain proper positioning in relation to the horse.
Halt; Pivot 90 degrees to the right at cone 2	Horse halts squarely with shoulder even at cone 2. No backward movement is observed. Horse moves smoothly into the pivot, keeping forward motion with the front feet and left hind foot, and planting the right hind foot. The haunch turn is exactly 90 degrees.	Horse halts squarely with shoulder even to cone 2. No backward movement is observed. Horse shows slight hesitation moving into the pivot, keeping forward motion with the front feet, and planting one of the hind feet. The haunch turn is exactly 90 degrees.	Horse does not halt squarely. Horse's shoulder is not even with cone 2. Backward movement is observed. Horse shows obvious hesitation moving into the pivot and shows backwards motion with the front feet. The haunch turn is not equal to 90 degrees.
Trot/jog from cone 2 to cone 3	Line of travel is straight to the judge. Horse moves off without hesitation with a brisk forward motion. Handler maintains a proper distance away from the horse even with the horse's ear.	Line of travel is fairly straight to the judge. Horse moves off with slight hesitation with forward motion. Handler maintains a proper distance away from the horse even with the horse's ear.	Line of travel is not straight to the judge. Horse shows obvious hesitation in starting forward. Horse may exhibit backward motion. Forward motion is sluggish and lacks energy. Handler does not maintain proper positioning in relation to the horse.

Handler and horse halt at cone 3; handler stands horse	Horse halts squarely with shoulder even at cone 3. No backward movement is observed. Horse is standing in the proper breed stance within 6 seconds of the halt. Handler is showing in the appropriate quarter, exhibiting a precise show stance.	Horse halts squarely with shoulder even at cone 3. No backward movement is observed. Horse is standing in the proper breed stance within 15 seconds of the halt. Handler is showing in the appropriate quarter, exhibiting a loose but technically correct show stance.	Horse does not halt squarely. Horse's shoulder is not even with cone 3. Backward movement is observed. Horse is not standing in the proper breed stance. Handler is not showing in the appropriate quarter. Handler is not exhibiting a proper show stance.
Handler presents horse in quarters	Handler consistently stands in the appropriate quarter in relation to the judge. Movement in front of the horse is precise and quick, using a minimum of steps.	Handler consistently stands in the appropriate quarter in relation to the judge. Movement in front of the horse is smooth, but lacks preciseness and energy.	Handler does not stand in the appropriate quarter in relation to the judge. Movement in front of the horse lack smoothness and looks stilted and awkward.
Handler turns horse 270 degrees to the right; walks to line up area	Horse moves smoothly into the pivot, keeping forward motion with the front feet and left hind foot, and planting the right hind foot. The haunch turn is exactly 270 degrees. Horse departs smoothly into a forward, energetic walk.	Horse shows slight hesitation moving into the pivot, keeping forward motion with the front feet, and planting one of the hind feet. The haunch turn is exactly 270 degrees. Horse departs fairly smoothly into a forward walk.	Horse shows obvious hesitation moving into the pivot and shows backwards motion with the front feet. The haunch turn is not equal to 270 degrees. Handler turns horse the wrong direction. Horse shows hesitation at the walk and does not exhibit an energetic gait.
Handler lines up and remains showing horse	Horse is standing quietly in the proper stance for the breed/type shown. Handler is showing in the appropriate quarter, exhibiting a precise show stance.	Horse is standing quietly in the proper stance for the breed/type shown. Handler is showing in the appropriate quarter, exhibiting a loose but technically correct show stance.	Horse is not standing in the proper stance for the breed/type shown. Handler is not showing in the appropriate quarter. Handler is not exhibiting a proper show stance.
Overall - Handler's attire	Handler is dressed in the appropriate attire for the breed/type being shown. Attire is of the highest show caliber.	Handler is dressed in the appropriate attire for the breed/type being shown. Attire is functional, clean and fitted.	Handler is not dressed in the appropriate attire for the breed/type being shown. Attire is dirty, has holes in it, and does not fit well.
Overall - Horse's appearance	Horse is very clean and passes the white glove test. All markings are gleaming white. Horse is appropriately clipped. Mane and tail are braided/banded appropriately. All equipment is clean.	Horse is clean, with some dust showing on the white glove test. All markings are clean. Horse is appropriately clipped. Mane and tail are clean, brushed and free from tangles. All equipment is clean.	Horse has obvious dirt showing and does not pass the white glove test. Markings have stains or visible dirt. Horse is not clipped. Mane and tail are tangled and dirty. Equipment clearly has not been cleaned.
Final Score:	Number of “Pass Superior” x 2 =	Number of “Pass” x 1 =	Number “Fail” x 0 =

earned a score (Fail = 0, Pass = 1, Pass Superior = 2) that was compiled to equate to a total score. An overall score of 11 was considered passing for the assessment. The results demonstrated that the PR students earned a lower ($p < 0.05$) total score of 12.8 than the NP students earned of 17.1 (Table 3). In consideration of individual score categories (Table 4), the PR and NP students had similar ($p > 0.05$) pass superior scores. Interestingly, PR students demonstrated higher ($p < 0.05$) pass scores than the NP students. Conversely, higher ($p < 0.05$) fail scores (1.4) were noted in NP students as compared to PR students (0.1).

Table 2: Assessment rubric for comfort and feeling

Comfort	I was/am 20% comfortable with performing this exercise.	I was/am 40% comfortable with performing this exercise.	I was/am 70% comfortable with performing this exercise.	I was/am 100% comfortable with performing this exercise.
Personal Feeling	I am exhausted; I feel drained; I feel sore in my hands and shoulders; I am 100% dissatisfied with the session	I am neutral; I feel neither drained nor energized; I feel sore in my hands and shoulders; I am only 25 % satisfied with the session	I am neutral; I feel neither drained nor energized; I feel good overall; I feel sore in my hands and shoulders; I am only 70% satisfied with the session	I am energized or at least feel the same as I started the session; I feel grounded; I feel only minor soreness in my hands and shoulders; I am 100% satisfied with the session.

Table 3: Total scores for students (n = 55) either provided the rubric (PR) or not provided the rubric (NP) prior to the skill assessment.

Student Group	Total Score[1]
PR	12.8[b]
NP	17.1[a]
	(5.3)

[1]Total scores for all rubric categories (mean square error for total scores)
[ab] Values with unlike superscripts within a column are significantly different at $p < 0.05$

Table 4: Individual score categories for students (n = 55) either provided the rubric (PR) or not provided the rubric (NP) prior to the skill assessment.

	Score Category[1]		
Student Group	Pass Superior	Pass	Fail
PR	2.3[a]	6.1[a]	0.1[b]
NP	3.3[a]	2.0[b]	1.4[a]
	(3.5)	(2.9)	(0.2)

[1]Individual scores for all rubric categories (mean square error for total scores)
[ab] Values with unlike superscripts within a column are significantly different at $p < 0.05$

PHASE II

A standardized rubric (Table 2) for assessing affective values in performing tactile skills was rated as 100% (7 of 7 responses) useful by students. When asked to analyze individual progress over the semester, students indicated that their comfort and personal feeling scores decreased under two conditions: when a task was novel or when external stressors (exams, personal situations, lack of rest) impacted their participation. Faculty observations of student involvement in course activities noted that as students realized that their peers were also feeling uncomfortable or tired, the class was more likely to participate in discussions and expressed more eagerness to apply the techniques in a practicum setting.

DISCUSSION

Results from the initial study agree with the concepts identified in both the arts and music fields (Mason & Steedly, 2006; Meier et al., 2006; Leonhardt, 2005). There were notable discrepancies in the use of individual steps of the rubric, making assessment complicated. However, based on focus group discussions with raters, the faculty-derived rubric was desegregated into appropriate categories and considered useful, although measurement of 'usefulness' was not determined in Phase I.From these discussions, the importance of providing a method for quantifying performance under each task category was noted.

Although not clearly addressed, other works utilizing rubrics for psychomotor skills often include some form of quantitative measure (Brown et al., 2006; Seybert & Barton, 2007), although such values were not consistently included in rubrics used for writing skills (Andrade, 2005; Loveland, 2005). By nature, the rubric as an assessment tool should make grading less redundant by limiting the number of times a professor writes the same comment and provides a means for student understanding of grading standards (Brookhart, 2003). Descriptors such as "few," "wide variety," "slowly," "many," are open to interpretation resulting in differences between rater and student interpretation. The differences between the need for quantitative measure in rubrics for cognitive skills as compared to psychomotor skills may be related more to field of study. For instance, in nursing, a "likely harmful" score in a rubric dealing with application of aseptic technique for preparation of aseptic products may result in injury, illness or death depending on the ultimate use of the product (Brown et al., 2006). In consideration of an increased risk to humans or animals, rubric categories should be quantifiable by time, proportions, or other forms of measure to limit rater interpretation and subjectivity. As a means to address clarity in rubric use, proportions were implemented into the rubric developed for Phase II. The use of

proportions gave raters the ability to assess the value of their affective response on a commonly known scale. These alterations aided in creating clarity of the assessment tool, which is in agreement with previous work (Andrade & Du, 2005; Meier et al., 2006).

Murthy and Etkina (2005) designed a rubric to assess their students' abilities in devising solutions to a laboratory problem and conveying their solution in a written format reports in a large enrollment introductory laboratory course. The average final exam score for the sample group was 78.3 as compared to the class average of 75 out of 100 possible points. The authors indicated a need for development and revision of the rubric prior to use and suggested that student performance improved after receiving the rubric (Murthy & Etkina, 2005). These data contradict the findings in Phase I. Apparently students in Phase I PR group were motivated to accomplish a "passing" score, but not motivated enough to achieve a "pass superior" score. Further, there were more students to both "fail" and "pass superior" in the NP groups reflecting the highest and lowest motivation for achieving the overall skill.

Compilation of student reflections into several themes demonstrated in both phases of this study that the overall experience of using a rubric was positive and alleviated much of the confusion often associated with the "how-to's" of hands-on skills. The students in Phase II reflected that the rubrics should be created for all equine courses to help alleviate subjectivity in assessment. This theme supports the faculty observation that perception of fairness in assessment and clearness of expectations enhances motivation and willingness to learn these skills and agrees with similar findings in the writing field (Andrade & Du, 2005) and for oral presentations (Hafner & Hafner, 2003). Despite this positive theme, there were student-derived recommendations for improvement of the assessment tools. The first recommendation theme was that some steps in the skills rubric should be weighted as critical points, and the skill steps should be even more detailed to make the teaching and assessment tool more effective. Another recommendation was that all students could have benefited from having the tool in advance for practicing hands-on skills; however, based on student scores in this trial, this perception does not result in achievement of the highest possible score. This discrepancy between attitude towards the rubric use and perception of performance level was also observed in the application of music skills (Char, 2009; Schmidt, 2005). Assessment of a student's motivation to practice a task as compared to performance of that task may be a better means to differentiate intrinsic from extrinsic motivators (Schmidt, 2005).

USE OF RUBRICS AND STUDENT DEVELOPMENT IN APPLIED LEARNING

Bloom's Taxonomy of Learning dictates that learning occurs in three different manners: cognitive (knowledge), affective (attitude), and psychomotor (skills) (Bloom, 1956). In an equine studies program, a base level of cognitive learning is necessary so that the student understands theory and background common to the industry. Also necessary is a high level of psychomotor learning in an effort to achieve practical applications. This presents a challenge to the instructor who must balance the levels and application of cognitive and psychomotor learning within a given lesson. In addition to complicating the teaching process, the combination of cognitive and psychomotor elements creates a challenge in assessing student performance. Students demonstrating a particular task (evidence of the skill) are not usually expected to also demonstrate cognitive learning (either in verbal or written format). Conversely, students demonstrating cognitive learning generally are not required to demonstrate psychomotor learning with a horse in the classroom environment.

A framework describing the different stages of psychomotor learning has been previously described (Simpson, 1972). Within this framework a student progresses through the steps of perception, set, guided response, mechanism, complex overt response, adaptation, and origination. These divisions progress from basic learning of a skill (perception and set) to advanced mastery of the skill resulting in spontaneous improvement as a response to specific problems (origination). Within an equine studies program, professors encourage students to progress from guided response to at least the mechanism step. As students progress to the mechanism category, they have moved into the intermediate stages of learning. During this type of psychomotor learning, response and actions become habitual, and the student displays a moderate amount of confidence when displaying skills (Simpson, 1972). Students in equine programs are traditionally assessed by demonstration and subsequent comparison of the psychomotor skill to a standard, which is defined in-house or by a respected equine professional. However, achievement of the skill is not always the entire purpose of teaching the task, and some methods of performing individual skills put both the horse and student in potentially dangerous situations. These skills are often not intuitive or inherently logical; therefore, safety issues and program inconsistencies dictate the need for these skills and the learning experience to be standardized. In the equine industry, judging standards associated with showing of various breeds and disciplines exist; however, clear holistic standards that reach across all breeds or disciplines do not. In other fields, there are standardized tests for outcome-based cognitive learning.

The data presented in this trial indicate a combination of an assessment rubric developed for a specific psychomotor task and an affective rubric for self-assessment are viable options for teaching and assessing applied skills in the equine studies field.

Previous experiences with handling horses affect student comfort in performing applied tasks (Meek et al., 2005). Through further development of rubrics for other equine studies skills, as indicated in this study, the hands-on experience could be standardized. Furthermore, well-constructed rubrics may also assist in developing intrinsic motivation for learning these skills when students demonstrate pre-existing horse experiences. Inexperienced students could benefit from these tools by having a clearly delineated step-wise process. Both Andrade and Du (2005) and Brookhart (2003) reported that formative assessment of "good writing" results in students transferring their rubric-based conceptions of quality work into other courses and to other students. As academic programs in the equine studies field grow, further development of teaching and assessment tools which standardize hands-on skill learning and the critical thinking process would promote cohesiveness of equine studies programs, enhance student motivation, and provide a means for documenting student progress. Other fields of study that do not have the benefit of multiple leading generations might also benefit from development of similar tools to promote standardization, motivation, and documentation of student learning.

Experiential learning and more specifically active learning is an instructional method which engages students in the learning process and requires that students think about what they are doing instead of solely memorizing facts (Lohuis et al., 1999; Prince, 2004; Tan & Towndrow, 2009). In this study, rubrics were used as applications of universal intellectual standards (Paul & Elder, 2001) for teaching and assessment of hands-on skills. Based on focus group discussions, the student learning experience was positive, and the tools served as effective means for linking critical thought to action. Students were encouraged not only to perform a skill, but to evaluate how to perform that skill. This observation has also been recently documented in students learning music skills (Char, 2009). By using rubrics in this method, the process of critical thinking was introduced in a non-threatening manner. Students clearly struggled with converting from cognitive to affective and self-reflective activities as indicated through observable expressions of frustration and dissatisfaction in Phase II. These observations support the data from Phase I of students being more goal-oriented than process-oriented. The results from Phase I clearly delineated that first-year students may not work to the highest score level when provided with the assessment tool, which is in agreement with results in the music (Char, 2009) and writing (Andrade & Du, 2005) fields. Motivation in third- and fourth-year stu-

dents is often perceived as less about comfort and more about focusing on graduation or employment goals. Clayton (2009) stressed the development of learning objectives for "critical reflection [that] generates, deepens and documents learning" (p. 7). Similarly, in nursing clinical education, the use of rubrics aided not only in instructor feedback, but also student application of critical thinking and reflection (Isaacson & Stacy, 2009). In making the shift from Phase I to Phase II, course activities were aligned with moving students through a clearly delineated, step-wise learning experience. Although a small data set ($n = 7$), student feedback in Phase II supports the need for critical reflection previously outlined (Andrade, 2000; Clayton, 2009; Isaccson & Stacy, 2009), not only for documentation, but also to enhance motivation and engagement in the learning process.

One student's reflection regarding the use of rubrics in Phase II stated, "…creativity in teaching starts with the ability to teach in unexpected or unlikely situations. Teaching is not a matter of the quantity of the content, but the quality of learning. Although at first I disliked the tasks and found them cumbersome, as the semester progressed, these tools helped me assess my quality of learning in a way that had not been previously given to me. I find myself now thinking—what proportion of the task did I really complete? Am I comfortable and prepared? What did I learn?" This reflection exemplifies the concept of an engaged pedagogy and a shift in student perspective. Both engagement and perspective shifts are goals of applied learning and critical reflection (Clayton, 2009). As further evidence of this shift in perspective, anonymous sharing of student responses fostered discussion and greater willingness of student participation as observed by increased discussion in the classroom and peer-to-peer interactions in Phase II. Students rated their comfort level greater when the task was associated with the knowledge or comprehension levels than when the activity required analysis, synthesis, or evaluation. These reflections also raised interesting data regarding specific tactile sensations. The most difficult sensory perception to teach is temperature sensitivity. This perception is confounded when the ambient temperature is near freezing, such as that found in an unheated stable during the winter months. Development of standardized models aided in teaching this sense, although more work on developing reliable models is necessitated. Application of affective rubrics in other fields may aid in further elucidating the issue of student motivation.

FUTURE DIRECTIONS AND CONCLUSIONS

As an unexpected result, when techniques were demonstrated students focused more on trying to mimic exact movements, instead of reflecting on their own perceptions. When techniques were not dem-

onstrated, students developed their own approach to the task. The authors are currently investigating demonstration of a skill as compared to written or verbal explanation of skills, in relation to the learning and assessment process. This research direction builds on previous research (Meek et al., 2005) in combination with the questions regarding assessment found in this study. As a model for distance learning (either online or video conferencing), previously unpublished data regarding student perception of PowerPoint presentations was investigated in a small group of students ($n = 14$). For the test course, the content was presented solely through verbal explanation and writing on a white board. All students had previously been in equine studies classes which were taught using primarily PowerPoint lectures. Two questions were asked on a voluntary survey to determine student preference of delivery method: 1) I preferred that the professor wrote on the dry-erase board for teaching the course content; 2) I would have preferred that the professor had prepared all PowerPoint presentations for teaching the course content. Students evaluated these questions using a five-point scale from "strongly agree" to "strongly disagree". Student preference of dry-erase board was 100% "strongly agree" or "agree". Interestingly, only a total of 33% of students "agree" with the use of PowerPoint presentations for teaching content, without any "strongly agree" answers. The next step was to discern why students preferred the use of the dry-erase board. During an informal discussion, a main theme emerged. Students preferred the hand-written material because the course pace was slower and discussion more interactive than when using PowerPoint or other technology. This feedback conflicts with use of digital video technology in biology as an assessment of student-teacher interaction (Tan & Towndrow, 2009) and use of music recording software to motivate beginner musicians (Char, 2009). In equine studies, there is an increased pressure to be competitive with online programs such as business or health care administration. The experiential learning aspect of equine studies and other agricultural fields is what draws students to these programs (Lohuis et al., 1999; Meek & Marean, 2006; Reiling et al., 2003). In consideration of student feedback regarding PowerPoint utilization in the traditional classroom and Phase II observations presented, delivery method of applied skills and subsequent cognition of "how-to" perform that skill are not equitable in terms of learning and attitude towards learning. Therefore, the value of assessment tools, such as skills rubrics, combined with method of delivery warrants further investigation in an applied learning model.

Although the overall research objective was to promote standardization of hands-on skills, these data raise several interesting questions regarding applied learning pedagogy. Rubrics aided in student motivation to learn and perform skills when provided early in the learning process;

however, students may only work to a passing level or other level which they feel is acceptable for their personal goals. The assessment rubric assisted students in de-mystifying a novel task in the equine studies field, as documented in the focus group discussions. Tasks should be aligned with well-defined objectives which provide purposeful progression, and have measureable outcomes. Demonstration as compared to description of tasks delineated on an assessment rubric warrants more research. Students expressed motivation for and engagement in the learning process when using affective rubrics for self-assessment.

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A Service Learning Structural Engineering Capstone Course and the Assessment of Technical and Non-technical Objectives

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ABSTRACT

The primary role of a civil engineer is to serve the community; thus, it is essential that students understand the impact of engineering projects on, and the context of engineering projects within, society. One goal of an engineering capstone design course should be to mesh the technical knowledge of the discipline with an encompassing engineering problem that incorporates "real world" issues and challenges. With all of the aforementioned criteria in mind, the objective of Villanova University's structural capstone course described herein is to integrate technical and non-technical issues through a challenging real world project. This paper presents the development, implementation, objectives, and assessment of a structural engineering capstone course that incorporates an international service project. All data indicates that the students participating on the service trip achieve significantly higher non-technical outcomes compared to those students that work solely on the design project.

Keywords: Service learning, capstone, structural engineering, learning objectives, assessment

INTRODUCTION

Engineering capstone courses are often an integral part of an ABET accredited program. As evidenced at the National Capstone Design Course Conference in June 2007 at the University of Colorado at Boulder, the pedagogy of teaching capstone courses is very diverse (Todd et al., 1995, Dutson et al., 1997, Howe, 2007). Some universities have dedicated faculty to teach capstone, while others involve all faculty members. Many schools have established programs where 100 percent of the projects are externally funded, and many more programs are attempting to move to this model to have students solve real problems while generating revenue for their college (Jones, 2007, Zable, 2007).

At the other end of the spectrum there has been an increase in the number of service related capstone projects aimed at helping local communities and those without the financial resources to procure engineering services (Martin and Haque, 2001, Dekker et al., 2007). The nature of the service projects is also very diverse. Many projects have focused on providing technical solutions to the needs of local communities (Padmanabhan and Katti, 2002, Grisso et al., 2007), while many look to aid individuals in Third World countries around the world (Silliman and Ketchum, 1998.)

The current generation of students seems to have a passion for answering the call to serve a global population, as evidenced by the popularity and growth of organizations such as Engineers Without Borders (EWB) and Engineers for a Sustainable World (ESW). In fact, there are universities that partner their capstone efforts with those of their EWB sections (Aidoo, 2007, Bielefeldt, 2007). There are more fundamental needs within the Third World, such as providing clean water, safe housing, and education, than the entirety of capstone courses in our university system can solve (Johnson et al., 2007). The benefits of service projects are many, but one of note is the fulfillment of both technical and non-technical learning objectives.

There is also the omnipresent need for assessment of objectives for capstone courses. This is often a challenging endeavor for technical learning in project based courses and can be even more difficult for non-technical objectives. Typical instruments include evaluation of student work, rubrics for specific objectives, and student surveys (Beyerlein et al., 2007). It is also clear that there is no one-size-fits-all model for capstone courses or the assessment of learning objectives. Each course (and assessment strategy) must be tailored to fit the curricula needs of the department and college within the educational mission of their university.

The mission of Villanova University includes developing an environment in which students may experience a Christian intellectual and moral perspective. A medium-sized comprehensive university, founded by the Augustinian Order of the Roman Catholic Church, Villanova University emphasizes undergraduate instruction and is committed to a strong liberal arts component in each of its degree programs, including engineering. The University is committed to the development of well-rounded students and has a strong service culture. Hundreds of students, faculty, and staff participate in extracurricular service activities including week-long mission trips over spring, summer, fall and winter breaks, and the University has a number of service learning opportunities embedded within its curricula.

This paper discusses the development, implementation, objectives, and assessment of one of those opportunities—a service learning capstone course in structural engineering offered by the Department of Civil and Environmental Engineering. Civil Engineering Design Project II (CEE 4606) is a team-based design course that serves as the capstone course for the undergraduate curriculum. Students work on a comprehensive design project in one or more of the department's five specialty areas: environmental, geotechnical, structural, transportation, and water resources. In the structural

engineering specialty area, the design project has included a service learning component since 2000 and a one credit service learning course (CEE 4611) that parallels the capstone course.

DEVELOPMENT

One of the poorest countries in the Western Hemisphere, Honduras is a country still trying to recover from decades of guerilla warfare, and has an overwhelming number of children whose parents are unable to provide for them. Amigos de Jesus (Friends of Jesus) is a Catholic orphanage that offers a refuge for abandoned and abused boys in a remote area of Western Honduras. The orphanage was co-founded in 1997 by Sister Teresita, S.S.N.D., a Honduran nun, Reverend Dennis O' Donnell, a Catholic priest, and Anthony and Christine Granese, a 1990 Villanova Civil Engineering alumnus and his wife. The mission of the orphanage is to provide boys the opportunity to grow up in a loving environment where they will receive a formal education and a lifelong skill such as farming, welding, or carpentry.

In late December 1999, Anthony Granese approached the College of Engineering with the idea of developing a relationship with the orphanage. At that time, work on a two-story reinforced concrete structure to house the six children and the two administrators was nearing completion, and construction of a dormitory structure had been initiated. The idea of building a reinforced concrete cross on a hill overlooking the orphanage was discussed. The cross would serve as a symbol of hope for the boys and the surrounding villages in the valley. The structural engineering capstone course seemed to be a natural fit for the scope of the design needs of Amigos de Jesus. Consequently, plans were made to focus the 2000 course around the design and construction of a 25-foot tall reinforced concrete cross. The selection of this project in a Third World country offered the students some interesting design challenges, tied directly to the University's Catholic mission, and provided the feasibility of being constructed in one week. Photographs of the final concrete being placed via buckets and the final product are shown in Figure 1.

Student feedback regarding both the technical and non-technical learning from the cross project in 2000 was overwhelmingly positive as seen in this quote from a student on that trip.

"From an engineering standpoint, it was extremely valuable. Normally, you would work on engineering-related projects and that's where it stops. You never get to see things take physical shape. The construction helped us better understand what we were doing and made us realize what kind of considerations you might never have thought of if you did only the design work. The personal side of the experience was by far the most valuable part of the trip. The work we were doing was something that had value in the real world. Traveling to a country far different from our own, and working with people so different from others whom we deal with everyday, was a unique experience."

Figure 1: The concrete cross during construction and as it looks today.

Consequently, it was decided that the partnership between Villanova and Amigos de Jesus would continue. The 2001 through 2003 capstone projects focused on the design and construction of a split-level volunteer center and chapel. The students were given some rough architectural sketches to aid them in developing their final designs. Progress on this three year project is shown in Figure 2.

From 2004 through 2007 students surveyed a site, developed designs, and aided in the construction of an eight building elementary school complex. The construction of the school complex has been supervised by two different Villanova University civil engineering graduates that volunteered for long term service at the site. When completed, the complex will include an administration building, three classroom buildings, a computer laboratory, two special use buildings for science, music, and art classes, and a restroom facility. The school opened in 2006 when the administration building and one classroom were completed. The school not only serves the boys living at Amigos de Jesus, but the boys and girls of the surrounding community as well. Figure 3 shows the architectural rendering the students were given as a starting point for the classroom building and a photo taken on the first day of school. Figure 4 shows a view of the school in the spring of 2007. Currently, all designs for the school complex are finalized and five buildings are operational.

In an effort to broaden the impact on the surrounding area, Amigos de Jesus recently decided to open their doors to young girls in need. Consequently, the 2008 structural engineering capstone

Figure 2: The volunteer center/chapel from foundations to completion.

project was the design of a new girls' dormitory. The students submitted their completed designs in May 2008. A link is provided to view a virtual tour of the final design.

IMPLEMENTATION: CEE 4606 – CAPSTONE DESIGN

The capstone course (CEE 4606) at Villanova University is structured to allow groups of between three and five students to complete a design that solves a "real-world" engineering problem over the course of one semester. This three credit course is offered in the spring semester of senior year and generally has five different sections, each focusing on a civil engineering discipline (environmental, geotechnical, structural, transportation, and water resources). The following is a description of the format and requirements of the structural engineering offering of the course.

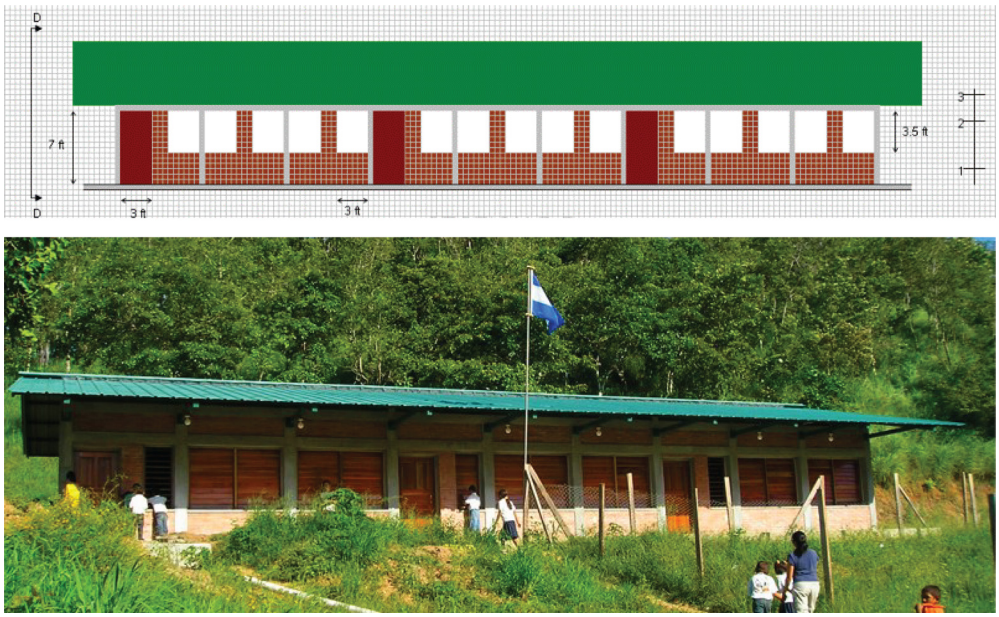

Figure 3: Classroom building from concept to reality.

The class is divided into project groups. The groups act as independent design firms working for the client (the authors serve as the client's representatives). Self selection of the groups is allowed provided that all class members are satisfied with the groups and each group has at least one representative willing to travel to Honduras. The authors have never had to assign the groups. Each group is responsible for the complete structural design, including development of appropriate load magnitudes and combinations, an appropriate analysis, and the design of all beams, columns, foundations, walls, roofs, stairs, and slabs as necessary for the building. The design must conform to the appropriate US building codes to size the structural elements.

The students start the project by interacting with the client to define the design problem and by researching the site in Honduras to develop design criteria such as material properties, building loads, wind speeds, and seismic ground accelerations. They then develop a complete design for the structure. Halfway through the semester, at least one student from each design group travels to Honduras and spends one week at Amigos de Jesus as part of a week-long departmental mission trip. During this time, the site representatives gather additional information from the client to facilitate their design and participate in the construction of one of the structure's elements. The students are required to have a completed design of the structural element (typically a foundation) completed by spring break. This real world need essentially translates to requiring a complete preliminary design of the structure to be finalized in the first six weeks of the semester.

Figure 4: Bi-lingual elementary school campus under construction.

To maximize the student-faculty interaction during class time, all lectures for the course have been pre-recorded (since 2006). These lectures include background information on the site such as material availability, construction limitations, typical practices, and material properties (determined by previous classes). Recorded lectures also include technical topics that are required to complete the design that are not part of previous courses in the undergraduate curriculum. These lectures include guidance on using the structural codes, lateral load design, connection detailing, and masonry design. A link to examples of one technical and one non-technical lecture is provided. Course time is used to meet with the individual design teams and answer their questions and get formal progress reports. Design teams can also request a meeting at any time outside of the scheduled class time.

Five technical progress reports and presentations are required throughout the semester. Each group member is responsible for presenting at least one progress report. The final submittal includes a technical report with all calculations, a complete set of engineering drawings in both English and Spanish, and a presentation to faculty, professional engineers, students, and parents. The grading for the course is divided between four components: 1. Individual Grade (20%), 2. Progress Reports and

Presentations (30%), 3. Final Presentation (20%), and 4. Final Report and Drawings (30%). Group members grade one another at the mid-semester and end of the course; these grades are averaged to determine the individual grade.

IMPLEMENTATION: CEE 4611 – SERVICE LEARNING

Historically, the emphasis of engineering capstone projects has been on technical work. However, the nature of service-oriented design projects allows for the added benefit of non-technical learning. In an effort to further formalize the link between education and service, a parallel one credit service learning course, CEE 4611, was introduced in 2003 for all students participating on the Honduras trip. The course meets one hour per week (in addition to the trip itself), and is structured around a simple pedagogy of service learning that includes four key elements: preparation, service, reflection, and celebration, as shown in Figure 5.

As part of the ***preparation*** for the trip, students work in groups of two or three and are responsible for conducting background research on Honduras and presenting it to the group. The groups are assigned one topic and get to choose an additional topic of interest. These topics have included politics, geography, history, economics, religion, art, music, etc. Based on the information presented

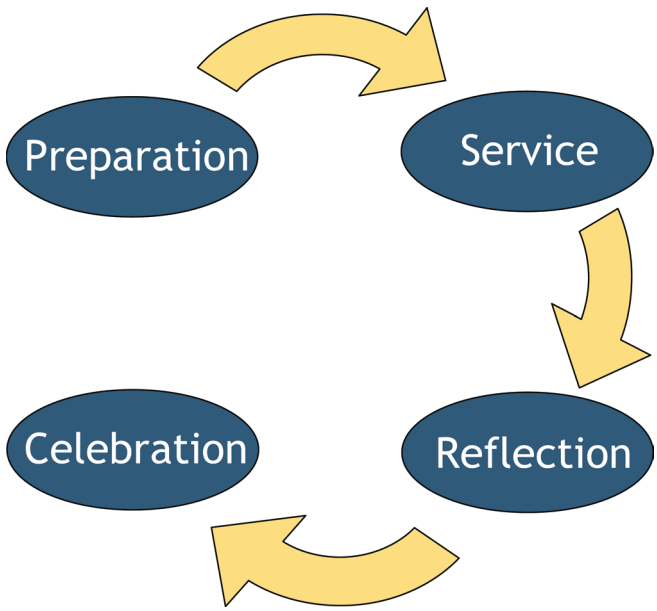

Figure 5: Implementation of service learning pedagogy in CEE 4611.

by the students the authors host a "Jeopardy" style game show to reinforce their knowledge. Prior to the trip a guest lecturer from the Latin American studies department presents information on Honduras. The final piece of the preparation is the organization of fundraising events. Each student is responsible for paying for their food and travel to Honduras, and students work individually and as a group to raise these funds. The cost of the trip has historically been between $600 and $700 per student, depending on airfare, plus the costs of immunizations. In many years the students have raised enough money to cover all expenses, but it is typical for the student to pay between $200 and $300 out of pocket.

The ***service*** provided by the students includes the design work as well as the construction work done in Honduras. A typical construction day begins at 8:00 AM with a lunch break at 12:30 PM. Following an afternoon rest, work resumes at 2:30 PM and continues until 5:30 PM. The students generally spend the final hours of the day playing with the boys. Students are also assigned daily chores of assisting in meal preparation, washing dishes, scrubbing floors, and cleaning bathrooms.

An integral element of service learning is the ***reflection*** on the service experience. As part of the service learning course students keep a personal journal where specific questions are asked and entries are made prior to the trip, during the trip, and after the trip. A copy of the journal is provided for review. A web site of the trip activities is also maintained while in Honduras. Students leave daily messages to their family and friends reflecting on the day's events. Family, friends, trip alumni, and local elementary schools follow the groups' progress through the week and leave messages for the students. The link to this website is provided and also contains photos from previous trips. This website is very active the first week of March when followers of the project check for daily updates and leave messages for the students. The day for the children of Amigos de Jesus ends with a group prayer just prior to bedtime to thank God for the gifts they have received. This nightly ritual is a moving experience as boys that have so little compared to us are so thankful for what they have been given. Their prayers of thanks always include that they had food to eat and a place to sleep. The day ends many hours later for the students with a group reflection. Groups of two students plan and lead the reflection. These sessions can last between one and four hours.

The last element of service learning is the ***celebration*** of the service. The first celebration is during the first class meeting following their return, where the group representatives present to those students that did not travel to Honduras. The guidelines provided by the professors are simple: provide an update of what you learned during the week in Honduras. Every year the Honduran travelers provide their classmates with a thorough presentation. Inevitably the presentation is relatively brief in regards to the technical update on their designs and the construction progress report, and the vast majority of the presentation focuses on the non-technical aspects of the trip such as having to cross a river on foot when going to church in town, playing soccer with the boys, discussing

the beauty of this poverty stricken country, or how gracious their hosts were. Most students find it challenging to fully describe the essence of Amigos de Jesus and the full impact of their week of experiences in Honduras.

The main deliverables for the service learning course are the creation of two posters and one oral presentation. Students work in groups to create one poster focusing on the construction work (technical) and one focusing on the relationships developed with the boys (non-technical). Links to the two posters have been provided. Additionally, a presentation is prepared on the non-technical aspects of the trip. The trip leaders present at CEE Day, the year end departmental conference that includes technical presentations of all capstone courses and undergraduate research projects. Students are also asked to talk about their experiences at engineering open houses and on-campus high school recruiting events. In addition to these formal celebratory events there are also many planned group social events.

PARTICIPATION

Table 1 presents the enrollment in the capstone course (CEE 4606) and affiliated service learning course (CEE 4611), between 2000 and 2008. The demographic of trip participants is also presented. A typical trip might include two faculty members, six seniors, and four underclassmen interested in structural engineering and/or service. The authors have participated in all trips. Graduate students and alumni that have previously been to the site have served as mentors on trips as well. Overall about 42% of all CEE seniors have enrolled in the structural engineering capstone section, and one-third of these students have elected to go to Honduras. Approximately 58% of the students who go on the trip and enroll in the CEE 4611 service learning course are also enrolled in the CEE 4606 capstone course, with the remainder being other seniors, juniors, or sophomores. A significant portion of the sophomores and juniors who participate on the trip will return to Honduras with their own graduating class when they become seniors.

ASSESSMENT

In order to focus the teaching strategies within the capstone (CEE 4606) course, a list of eight technical and eight non-technical objectives were developed in 2001. These objectives are listed in Table 2. Many of these objectives coincide with the attributes that are required for ABET and ASCE accreditation. A survey was developed and is given to all students enrolled in CEE 4606 in order to

Semester	Total CEE Seniors	Seniors enrolled in CEE 4606	Students enrolled in CEE 4611	Went to Honduras							
				TOTAL	Faculty	Graduate Students	Seniors enrolled in CEE 4606	Other Seniors	Juniors	Sophomores	Alumni
Spring 2000	39	7	N/A	10	2	0	4	0	4	0	0
Spring 2001	40	18	N/A	11	2	0	6	1	2	0	0
Spring 2002	45	25	N/A	15	2	3	5	0	4	0	1
Spring 2003	51	25	10	13	2	0	7	0	3	0	1
Spring 2004	39	14	11	14	2	0	3	2	5	1	1
Spring 2005	33	15	10	15	4	1	5	0	5	0	0
Spring 2006	48	18	9	12	2	1	4	0	5	0	0
Spring 2007	41	15	10	13	2	1	6	0	4	0	0
Spring 2008	52	27	16	18	2	0	13	0	3	0	0
TOTAL	388	164	66	121	20	6	53	3	35	1	3

Table 1: Course enrollment and trip participant descriptions.

formally measure how well the course satisfies the objectives of both the technical and non-technical elements of the course. The survey was adapted from Eyler et al., 1999. To date, eight years of data has been generated and collected.

The survey is administered as a requirement at the end of the capstone course, thus the rate of return is extremely high. In all, 94% (147 out of 157) of students enrolled in the course completed the survey. Note that the survey data does not include students such as juniors who only enrolled in the service learning course but were not part of the capstone design course, nor does it include seniors from 2000 since the survey was first administered in 2001. The data is presented in Table 2, and is shown separately for students who went to Honduras and students who did not go to Honduras. The survey scale ranged from 1 to 5, with 1 defined as the objective not being satisfied at all and 5 defined as the objective being satisfied very well.

The data for technical objectives is presented graphically in Figure 6, which show the annual mean response for the eight technical objectives combined. The annual mean responses for the eight individual technical objectives are presented in Figure A-1 in the Appendix. The figures clearly show that the technical objectives are being satisfied very well by all students participating in the capstone course. In fact, the mean response for all eight technical learning objectives is higher than 4.00. Though the overall scores have always been relatively high, a slight improvement over the first three to four years can be seen, during which time the format of the course was being refined by the authors.

Further evaluation shows that for the first four to five years, evaluation scores for all technical objectives tended to be marginally higher for those students that went to Honduras. This indicates that initially, students who went to Honduras felt they learned technical skills better, perhaps as a

Course Objectives (T = Technical; N = Non-Technical)		Survey Responses [1]			Difference in Means [2]
		All Students Surveyed (n = 147)	Students Who Did Not Go to Honduras (n = 102)	Students Who Did Go to Honduras (n = 45)	
T1	In this course, I was able to synthesize and apply previous coursework in Structural Engineering.	4.41 (0.68)	4.35 (0.73)	4.56 (0.55)	**0.20**
T2	In this course, I developed a better understanding of how different components of a structure fit together.	4.46 (0.72)	4.42 (0.76)	4.56 (0.62)	0.13
T3	In this course, I developed a better understanding of how real world constraints (cost, scheduling, material availability, etc.) affect a structural design.	4.24 (0.85)	4.21 (0.85)	4.33 (0.85)	0.13
T4	In this course, I was able to develop a professional work ethic.	4.05 (0.82)	4.00 (0.88)	4.16 (0.67)	0.16
T5	In this course, I was able to practice technical presentation skills, including presentation of technical drawings, calculations, reports, and oral presentations.	4.60 (0.60)	4.58 (0.65)	4.64 (0.48)	0.07
T6	In this course, I was able to further my problem solving skills.	4.33 (0.69)	4.31 (0.69)	4.38 (0.68)	0.07
T7	In this course, I was able to function as part of a team and work on teamwork skills.	4.56 (0.68)	4.55 (0.64)	4.60 (0.78)	0.05
T8	After taking this course, I feel more competent entering the work force as a Structural Engineer.	4.27 (0.82)	4.20 (0.91)	4.44 (0.55)	**0.24**
N1	After taking this course, I am more aware of global issues.	3.63 (0.90)	3.43 (0.86)	4.09 (0.82)	**0.66**
N2	After taking this course, I am more likely to become involved in service-related activities.	3.50 (1.12)	3.16 (1.06)	4.27 (0.84)	**1.11**
N3	After taking this course, I feel that I am a more well-rounded individual.	3.73 (0.96)	3.50 (0.93)	4.27 (0.81)	**0.77**
N4	After taking this course, I feel better about myself.	3.76 (1.02)	3.56 (1.06)	4.22 (0.77)	**0.66**
N5	After taking this course, I have a better understanding of myself.	3.44 (1.19)	3.15 (1.16)	4.11 (0.96)	**0.96**
N6	After taking this course, I have a better understanding of others.	3.81 (0.96)	3.56 (0.96)	4.38 (0.68)	**0.82**
N7	After taking this course, I feel more spiritual.	2.76 (1.28)	2.35 (1.09)	3.69 (1.18)	**1.34**
N8	After taking this course, I feel a sense of accomplishment.	4.56 (0.74)	4.47 (0.80)	4.76 (0.53)	**0.28**

[1] Mean response reported, with sample standard deviation in parenthesis [1 = Not Satisfied at All, 2 = Satisfied Only a Little Bit, 3 = Satisfied Adequately, But Room for Improvement, 4 = Satisfied Reasonably Well, 5 = Satisfied Very Well]

[2] Underlined bold typeface indicates difference in means that is statistically significant to 90% confidence level.

Table 2: Technical course objectives and post-course survey results.

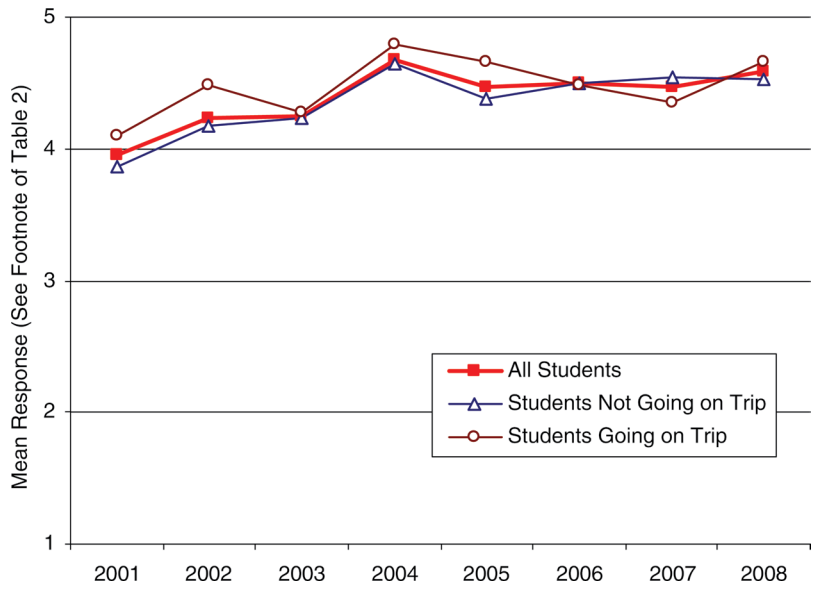

Figure 6: Average of all technical course objectives.

result of the hands-on work on site and direct interaction with the clients while in Honduras. However, in later years the scores tend to be very similar or in some cases even higher for students that did not travel to Honduras.

Figure 7 presents the mean responses for the non-technical course objectives. Figure A-2 in the appendix shows the data broken down by individual objective. It is evident that while the non-technical objectives are on the whole rated lower than the technical objectives, they are still rated as "adequately satisfied" by all students (indicated by a score of 3 out of 5). Only non-technical objective N7 related to feeling more spiritual failed to reach a rating of 3 in recent years. On the other hand, nearly all students leave the capstone experience feeling a sense of accomplishment as a result of applying their engineering education in a comprehensive project with a service element (Objective N8).

As might be expected, the figures clearly show that the students that participate on the trip feel that these non-technical objectives are satisfied to a significantly higher degree than do the students that do not participate on the trip. This would suggest that while there is a carry-over effect in which students that do not go to Honduras still see some non-technical development because of the nature of the project, the structured one-credit service learning course is vital in developing this non-technical learning to a significant degree. It is worth noting that ratings for non-technical objectives among students have generally increased from year to year, both for students who have gone on the trip as well as for students who have not gone on the trip.

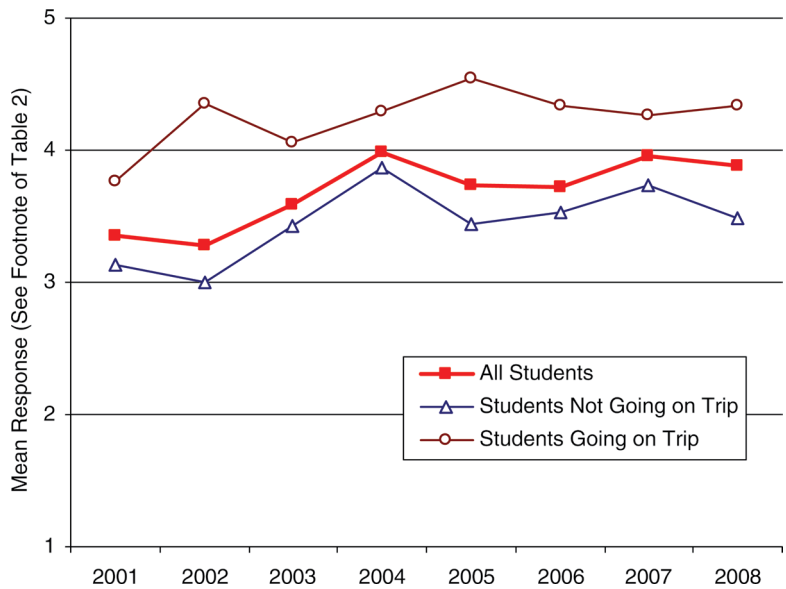

Figure 7: Average of all non-technical course objectives.

In order to more formally evaluate the impact of the service learning experience on the technical and non-technical outcomes, the difference in the mean responses of the "Did Go to Honduras" and "Did Not Go to Honduras" student groups is tabulated for each outcome in the last column of Table 2. For all eight technical and all eight non-technical outcomes there is a higher mean score for the group of students who went to Honduras. For all eight non-technical outcomes the difference in the mean is statistically significant at a 99% confidence level, confirming that there is a clear benefit in non-technical learning for the students who go to Honduras. In addition, the differences in the mean are statistically significant at a 90% confidence level for two technical outcomes (T1 and T8) which respectively relate to synthesizing previous Structural Engineering coursework and feeling more competent entering the workforce as a Structural Engineer. The authors suspect that these differences relate to the unique experience in which students are able to construct (and later refine) their own designs (i.e. the transfer of these designs from paper and CAD to real life).

An important outcome not captured by the data is that to date there have been five civil engineering graduates that have volunteered for long-term (one year or longer) work assignments at the site. These students supervise construction, teach English, and coordinate ongoing student design efforts, while living in a volunteer center that they designed and built. A 2008 graduate is currently onsite and will initiate the construction of the girls' dormitory at the end of 2008. Additionally, numerous other alumni of the course have participated in long-term service activity

immediately after graduation, many of which allowed them to apply their engineering skills to better serve society.

CONCLUSION

The stated mission of the Department of Civil and Environmental Engineering is to provide students with a high quality, contemporary, broad-based, civil engineering education within a Judeo-Christian, humanistic context. The unique structural engineering capstone course described in this paper builds on the inherent service-oriented nature of the civil engineering profession in a manner that is consistent with the Department and University's mission and culture of service.

The technical challenges for this course include those typical of most real-world projects: design constraints, building code compliance, schedules, and final deliverables. The nature of this project including the client being from a rural area in a Third World country provides many additional real challenges: extreme financial constraints, unknown material properties, design requirements for an active hurricane and seismic region, and communication of the final product in a foreign language. Following successful completion of this project, students understand how a structural design takes shape and the professional responsibilities that go along with it. They can work successfully in teams and present their technical outcomes. Data shows that even students that did not travel to Honduras feel well prepared to enter the workforce as a structural engineer at the conclusion of this course.

The project and associated trip serve as an important means toward exposing our students to important issues, issues more important than the technical ones that they have learned in the process. Clearly, the non-technical benefits of this project are numerous. As demonstrated by the survey data collected over the last eight years, this capstone course has fostered a learning environment where students are able to simultaneously apply their technical skills, directly serve others in need, and continue their own personal development and growth as members of a global community.

NOTE FROM THE AUTHORS

The last ten years has been a labor of love for the authors, and we have reaped far more rewards than we could have imagined; however, it has been a great labor nevertheless. We challenge University, College, and Department administrators to encourage, support, and foster their faculty members to develop similar experiences for their students. Ask yourself the following questions: How would this work be valued in your academic environment? How would it be valued in the rank and tenure

process? Would you rather have a junior faculty member write a journal paper and give a presentation at a conference or develop a course like this? We would submit that the development of this program has served our traditional scholarly research program far more than getting an industry or government grant would have, but that is a topic for another paper.

ACKNOWLEDGEMENTS

The authors thank Amigos de Jesus, our most gracious clients and hospitable friends from the beautiful country of Honduras. The authors also thank the many students that have elected to participate in the structural engineering capstone project with special thanks to those that have traveled with us to Honduras. Further thanks are given Villanova University, the College of Engineering, and the Department of Civil and Environmental Engineering for their incredible support of this work. The authors acknowledge the financial support of the Villanova Institute of Teaching And Learning for development of the course objectives and the surveys. The authors also thank Lammey & Giorgio, P.A. for the client presentation and fly over of the site that is linked to this paper. Additionally, a Powerpoint show of Dinehart and Gross, 2007 is linked.

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BIOGRAPHICAL SKETCH OF AUTHORS

David W. Dinehart is a Professor of Civil and Environmental Engineering at Villanova University, Villanova, PA. He earned a BSCE and MSCE from Bucknell University in 1990 and 1991, respectively. He earned a PhD from the University of Delaware in 1998, following a few years of designing power facilities for Bechtel. His research interests include the design of castellated and cellular steel beams, the design and behavior of open web steel joists, and the seismic evaluation of wood structures. He is a member of ASEE, ASCE, and AISC.

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APPENDIX A

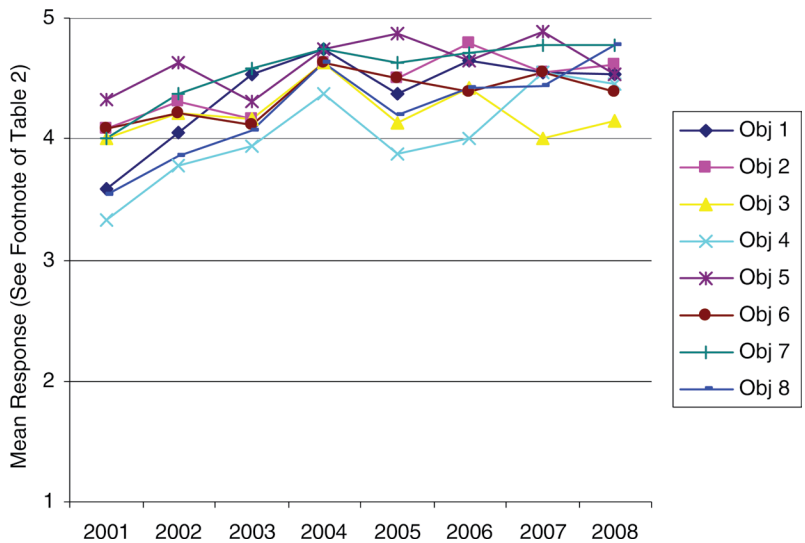

Figure A-1.a: Individual technical objectives for students* not *going on trip.

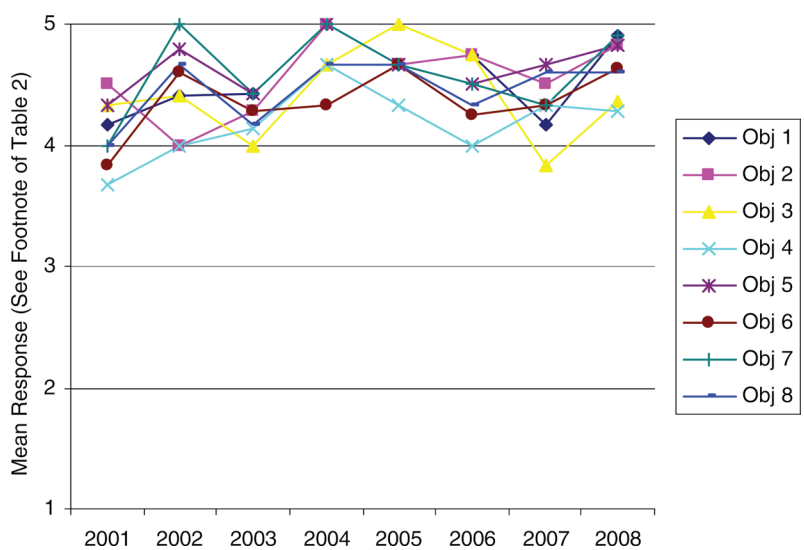

Figure A-1.b: Individual technical objectives for students going on trip.

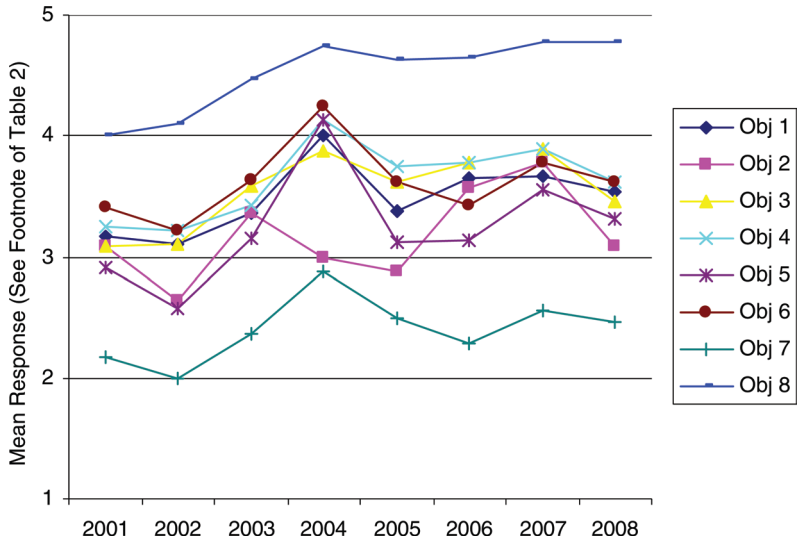

Figure A-2.a: Individual non-technical objectives for students* not *going on trip.

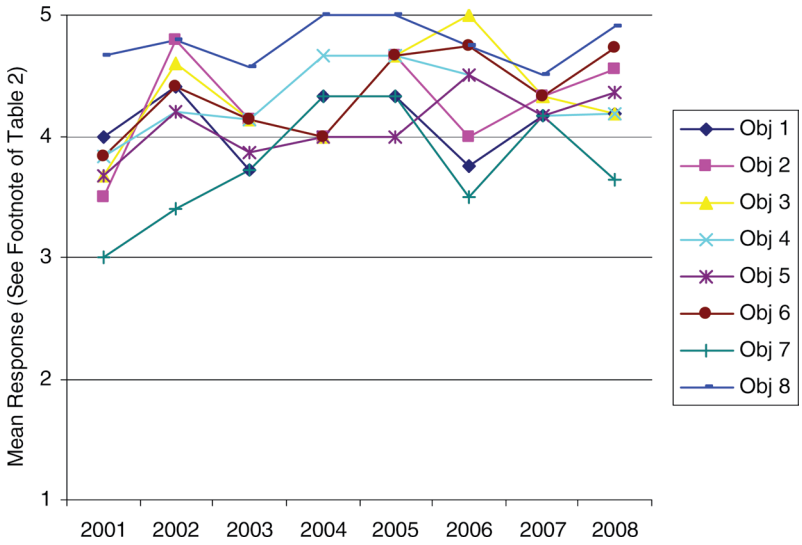

Figure A-2.b: Individual non-technical objectives for students going on trip.

Engaging students in online courses

Pearl Jacobs
Sacred Heart University

ABSTRACT

Online education is gradually being incorporated into college and university programs. It is proving to be an effective educational tool for our rapidly changing global marketplace. The fact that online courses operate differently than on ground courses cannot be ignored. Thus, they require teaching techniques and assessment techniques specifically geared for this educational experience. Group projects are quite familiar to students taking courses in the classroom. They are less familiar and perhaps feared by students taking courses online. The fact that participants in online courses do not physically interact with each other leads some to believe that this approach is not viable in an online course. This paper dispels this belief by discussing how group projects can be successfully incorporated into online courses. The paper also describes specific assessment tools which can be used to determine the success of online courses. Specifically, some formative assessment techniques are presented as particularly useful and appropriate for online courses.

Keywords: Formative assessment, feedback, group selection process, self-assessment, group norms, slacker.

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INTRODUCTION

The technological advances leading into the 21st century present many challenges for higher education. College are concerned and deeply involved in the changes that are occurring in higher education. One dramatic change involves the development and increasing use of online education. Most university departments offer online courses. As the incorporation of such courses are increased in college programs educators recognize that they cannot be taught the same way as traditional classroom courses. They require the development of new and different teaching techniques. Such activities are well on their way. One activity which has been found to benefit students is group work (Rau and Heyl, 1990; Rinehart, 1999). Instructors of online courses often hesitate to have their students engage in this activity because of perceived drawbacks (Brooks and Ammons, 2003; Payne and Monk-Turner, 2005). However, this is a most beneficial learning tool which can and should be utilized in online courses. This paper will discuss the effective incorporation of this technique into online courses.

Associated with this is the need to develop and use effective assessment techniques. Assessment in online courses is quite different since instructors and students do not share physical space. Researchers have suggested that assessment techniques that determine the extent of student learning are very important for the student. They tell the student exactly what is important and, "how they should approach learning." (Garrison, 2011:14). This paper will also discuss some assessment tools that can improve online teaching.

The Benefits of Group Projects

Group projects serve many purposes and have many advantages for students. Research indicates that students can increase their body of knowledge by working with other students (Jones, 2006; Payne and Monk-Turner, 2006). Group projects enable students to develop skills that are needed for successful professional careers such as critical thinking, problem solving, and interpersonal skills. The ever changing global markets are making these skills vital. Thus, collaboration is a key factor in a successful career. Group projects provide the opportunity for students to experience the importance of collaboration. Students engaged in group projects learn how to communicate effectively with other students. They learn how to identify goals and objectives. They learn how to assign tasks and deal with conflicts. They learn how to share the credit for work done. The students are actually learning what they need to be successful. They are learning how to traverse interpersonal relationships

A successful educational experience requires students to feel integrated in the educational environment. Students taking online courses often feel disconnected from the institution. Group projects give students the opportunity to reduce this distance and become more familiar with their fellow students. This familiarity is achieved through working together during the course of the semester. The students begin to develop relationships which would not have occurred otherwise. These relationships are not only beneficial to the students but to the institution as well. When students feel connected they are more likely to continue their education at the institution and, thus, increase retention (Hartman, Bjerregaard, and Lord, 2009).

Yet another benefit of group projects is that they allow students to really learn specific aspects of a topic. Group projects involve intensive examination and collaboration. It is through this process that students gain a better understanding of the subject matter.

There are also criticisms of group work. Students often feel it is unfair to have their grades determined by the work of other students who may not be pulling their weight. Students often deal with this by ignoring the "slacker" and assuming the extra work in order to complete the project on time. This contributes to students negative feelings about group projects. There are ways to deal with the criticisms of group work.

Dealing With the Challenges to Group Projects

It is most important for the instructor to understand that simply labeling an assignment as a group project does not insure that it will be a successful group project. The instructor must design the project to require collective participation. Scherling (2011: 15) provides a good example of a collaborative project:

> For example, analyzing an individual's behavior from the perspective of multiple theories and recommending an appropriate response to the behavior requires students to collectively reach a consensus. A group project requiring students to examine multiple theories and present a PowerPoint presentation on the theories allows students to distribute the workload with each group member creating a slide reporting on a particular theory.

The characteristics of the online learning experience must also be considered. Students may have different schedules. It is unreasonable to expect all group members to be able to respond to a request within 24 hours. It is, therefore, essential that the instructor provide enough time for groups to discuss and reach an agreement on decisions affecting the project. Even two or three weeks may not provide sufficient time for group decisions. It is recommended that group projects extend over several weeks and incorporate the general content of the course.

Group selection and formation are critical to creating a valuable group learning experience. This process could begin with an online forum in which students introduce themselves, discuss approaches to the group project, and ultimately select their team mates. It is important to have the students select their own teams based on the information they obtain from the forum. The instructor should provide information on the various roles group members can play such as leader or editor. The instructor may want to go further and suggest roles for the group members. This is fine, however, it is important to urge students to construct and allocate these roles based on their own unique experiences in online courses. Students may consider their individual strengths and weaknesses and self-select the role they want to play in the group. The instructor must keep in mind that, "each group is unique and the group process is an interaction between individual characteristic, experience, and understanding of the assignment." (Morgan, Cameron, and Williams, 2009:292).

The first requirement of the group should be the establishment of group norms. This is essential to the success of the project. The students should decide what acceptable and unacceptable behavior for the group is. This will give group members the self-assurance to confront group members not obeying the norms since they were created and agreed upon by the group.

Successful groups require that the members develop a sense of trust. If trust is not developed with group members, it may prevent other important social interactions from occurring. Research has also identified other characteristics which are important to online group work. They include decision-making skills, consensus building, collegiality, active participation, and conflict resolution. (Morgan, Cameron, and Williams, 2009). "Students in online settings may look for these skills in their fellow group members as they work toward developing familiarity and supportive relationships." (Morgan, Cameron, and Williams, 2009:286).

A theory of group development created by Tuckman in 1965 describes the three stages of group development. "The forming stage involves the review of the project and the attempt by all members to understand and accept each other. The storming stage involves disagreements about team roles, opportunities, and direction. In the norming stage the group roles become clearer. The group has more structure and members begin to trust each other. In the final stage, the performing stage, the group is working well and the members trust and are committed to the group." (Hansen, 2006:13). The development of specific roles for group members reduces the chances that any group member will become a slacker. It is essential that students understand the stages of group development as they begin to form their work groups.

Successful group projects require meaningful assignments. The best group projects are those that deal with real-world problems. This motivates students because it gives them an opportunity to use the knowledge they have acquired to solve problems. It allows them to put the theories and concepts they have learned to the real test. Real world problems also include encouraging the development of conflict management skills among the group members. It will enable the students to deal with "slackers" within the group rather than ignoring them and assuming additional work. This is an important skill to develop and transfer to the professional workplace.

In addition to projects being meaningful and significant the workload expected should be manageable. If students feel that they have been assigned too much work, they will not view the group project experience as the valuable learning tool it is.

The group project process requires group members to participate. If group members request information or feedback from other members, it should be provided. It is up to the instructor to monitor this flow of information and evaluate its content in order to ensure that each group member is contributing to the final product. Research suggests the use of interim reports to assess the progress of the group. It is recommended that there be three reports submitted during the course of the project. Each report should indicate the group achievements. The first report should concentrate on reporting about team management. The second report concentrates on the progress towards project completion. The third report which should be due approximately two weeks before the final project is due should report on dealing with the final aspects of the project. (Hansen, 2006). The instructor would be providing feedback after each report. This would provide "slacking" students with a warning and an opportunity to improve their performance.

Another technique which may make group members less inclined to engage in "slacking" would be to have the instructor require each group member to evaluate the other members as part of the grade for the project. The group members would then be aware that every member does not receive the same grade unless every member contributes to the final product. It is, of course, possible that students may not be fair in their evaluations of other students. It is up to the instructor to review these evaluations carefully and determine their weight towards the final grade.

The project should end with the requirement that each participant complete a self-assessment of their work. This allows students to carefully examine their experience and consider any changes or modification they would make in future group projects. "Self-reflection promotes learning built on previous experiences in order to enhance future experiences."(Scherling, 2011:16).

It is also important for the instructor to know how the students felt about their collaborative experience. How effective was it as a learning tool? This information is vital to the instructor. It would allow the instructor to make any adjustments necessary to improve the learning experience of the students.

Formative Assessment

It is clear that online education will continue to be a part of higher education. Its continued success requires careful assessment to insure that the educational objectives are met. There are various assessment tools. Online courses require assessment tools that meet the needs of an online course. Instructors are familiar with the various summative assessment techniques. They are used to determine how much students have learned about a particular subject. They are important as a means of grading students. Formative assessments are assessments for learning. They indicate what the student is learning and how the student is learning. They serve to support learning during the process of learning. Such assessments do not involve grading. They check the student's understanding and help the instructor with future instruction. They also provide information to the students so they can improve. The feedback students receive from formative assessments can encourage student engagement and increase their enthusiasm to learn. Formative assessment works well for online courses.

Feedback is an essential component of the assessment of online courses. There are certain precautions which must be observed. Brown, Bull, and Pendlebury (1997) explain that, "the feedback provided has to be specific, accurate, timely, clear, focused upon the attainable and expressed in a way which will encourage a person to think and if he or she thinks it is necessary, to change." (Jenkins, 2010:566).

The feedback provided must be carefully considered for it to be of value in the assessment process. Formative assessment can be a valuable learning tool but its effectiveness as such is reduced significantly if students are not adequately instructed as to what they are expected to produce. Appropriate information reduces the chances of the student misinterpreting the assessment and presenting an assignment for formative feedback that does not address the question. (Rust, Price, and O'Donovan, 2003). In addition, feedback should emphasize the development and mastery of skills rather than focusing on mistakes. Mistakes should be treated as a learning opportunity.

> By showing students specific misunderstandings or errors that frequently occur in a content area or skill set, and showing them how they can adjust their approach to the task, students can see what they need to do to maximize their performance. Feedback about their progress in learning gives students hope and positive expectations for themselves. (Cauley and McMillan, 2010:3).

Formative assessment in online courses should emphasize mastering the task and achieving the goal. This includes encouraging the student to work toward a better understanding of the subject. Evaluations should avoid the use of practices that make the student afraid of failure. It is better to praise and reward students who learn from their mistakes.

> Thus, when giving feedback for formative assessment activities, teachers should attribute results to student efforts and then explore changes in instruction and learning tasks, which suggests that a lack of success is also related to a factor that a student can modify. Formative assessment without effort attributions and instruction modifications that support developing understanding can leave students feeling hopeless. Examples of the right kind of feedback include: "It looks like the extra effort that you put into studying has paid off" and "Look how you've improved since you tried a different strategy.' (Cauley and McMillan, 2010:4).

There is a tendency to resist the use of formative assessment because of the time factor. Instructors may fear that they will not be able to cover all the material if they engage in formative assessment. Attempting to cover as much material as possible does not ensure that students are learning. Without understanding what is being retained, the push to cover more material may be a wasted effort. Formative assessments do not take a long time. They can be quite efficient for use on a regular basis. The importance of such assessment is described by Chase (1999:9) as, "an essential part of teaching effectiveness by engaging students and their instructors in a wide range of learning opportunities that acknowledge student achievement, while informing changes in instructional plans and strategies, as well as leading to curriculum improvements." Thus, it may include any techniques that both instructors and students can use to improve teaching and learning. Boston (2002) suggests that assessment becomes formative when the data collected is used to adjust teaching and learning to meet the needs of the students. This data can be used to promote active and engaged learning because the instructor now has a better idea of the students' learning style, needs, and interests.

EXAMPLES OF FORMATIVE ASSESSMENT

Student self-assessment

Formative assessment provides a great opportunity for student self-assessment. Student self-assessment is not just checking test responses. It is a learning process. Students evaluate their thinking process and begin to develop techniques to improve understanding. Student assessment has been described as a three step process. It includes:

1. Self-monitoring. This is where the students evaluate their own work.
2. Self-evaluation. They look for differences between their current work and preferred performance.
3. They develop and use new learning activities to improve their skills.

One critical advantage of student self-assessment is that it provides students with a better understanding of assignments and what is needed to master the task (the learning goal). "When students work toward meeting clear learning targets, they have high expectations for success." (Cauley and McMillan, 2010:5). Self-assessment also supports students in their decision making process. Students learn to decide what has to be done and when to do it.

Self-assessment encourages self-efficacy which is defined as, "the belief an individual holds about their ability to perform the task at hand." (Cauley and McMillan, 2010:5). A student achieves a sense of high efficacy when they have the confidence to believe that if they complete the task appropriately, they can be successful.

Reflection Paper

The reflection paper allows the student to reflect and analyze a particular assignment or discussion. It can include a summary of the various discussion posts. This technique allows students to really learn the material. It is, in effect, incorporated into the student's knowledge base.

The Minute Paper

This tool allows instructors to understand the learning requirements of the class and adjust his or her instruction accordingly. The minute paper might include such questions as:

1. What is the most important thing you learned today?
2. Do you still have questions? If so, what are they? (Angelo and Cross, 1993).

"The first question in the Minute Paper directs learners to focus on what is being learned. The second question seeks to determine how well student learning is proceeding." (Vonderwell, 2004:29).

The use of the minute paper allows for ongoing assessment of both learning and teaching practices. The responses given by the students provide a means for identifying specific learning needs. It then helps the instructor modify instruction accordingly. The minute paper creates a way of communicating between student and teacher. Students think about what they have learned and look for areas to continue their analysis.

Mosteller (1989) suggests the muddiest point technique. The question asked is, "what was the muddiest point?" which intends to find out what students find most confusing or least confusing about the lesson." (Vonderwell and Boboc, 2013:24).

Role Play

Instructors can assign specific roles to students in discussion posts. Such roles can help students assess their own work as well as support peer learning. The roles might include facilitator of the discussion or summarizer. Students can then monitor their own learning and progress.

Hook Questions

They may be defined as questions arising from a particular topic discussed or a reading assignment. The hook question can be posted prior to the discussion to give students a chance to prepare. The instructor can analyze the responses and possibly discover misconceptions which can be addressed.

Questions Wall

This features different questions from both students and instructors on topics of interest to them yet part of the course. It works well because the distinctions between student and instructor are not there. It is informal and non-structured. It, thus, provides greater opportunity for interaction.

CONCLUDING REMARKS

The growth of online education makes the development of teaching techniques that work well in a non-classroom setting essential. Group projects provide students with a good learning experience as well as an opportunity to engage in activities which are transferable to the workplace. Assessment is a particularly important part of online education. The lack of face to face contact can make it difficult to determine the extent to which material has been successfully delivered and understood by the students. Meaningful formative assessments incorporated within the activities of the course allow the instructors and the students to better understand their progress.

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Systematically Evaluating the Effectiveness of an Information Systems Capstone Course: Implications for Practice

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Executive Summary

The information systems capstone experience for undergraduate majors is a topic frequently discussed in academic circles within the field. Though very little consensus exists on this topic, there are core themes that emerge in the design, development, and delivery of the undergraduate capstone courses. Our analysis of prior literature reveals four components to capstone experiences that are often used in these courses, which include 1) a focus on real-world, complex information systems design, development, and integration; 2) the use of the case method to engage students in critical thinking, problem-solving, and decision-making; 3) the use of ePortfolios to assist students in integrating knowledge across the discipline and showcasing their learning to potential employers; and 4) an emphasis with the undergraduate information systems majors interacting with seasoned professionals in the field. These dimensions were carefully considered in the implementation of a capstone course at a large research extensive university in the southeastern United States. This project was funded by a *National Science Foundation* (NSF) grant program.

The paper presents a novel information systems undergraduate capstone course that includes two major design themes: case pedagogy and individual projects. The course is carefully described in terms of the student learning objectives, salient features, and philosophy. Further, the course was systematically evaluated using a multi-method approach, involving five distinct data sources: the *Critical Thinking Assessment Test* (CAT), the *Student Assessment of Learning Gains* (SALG), the *Student Assessment of Instruction* (SAI), faculty review of mini-cases, and student and instructor reviews of final projects. These data were examined both descriptively and inferentially. Results indicate that students were generally satisfied with the course design. However, some negative comments were made. Students did not show significant increases in critical thinking skills as measured by the CAT. However, faculty review of the pre- and post-mini-case submissions shows that students had significant gains in evaluating information, creative thinking, and learning and problem-solving. Implications for practice are provided in light of the findings.

Keywords: Information systems, capstone, case pedagogy, evaluation, IS curriculum, critical thinking, education.

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Introduction

Many academic programs in the broad field of information systems offer a capstone experience for their students, and many of these faculty members share the discourse on how best to facilitate such a course for their diverse populations (Astani, 2006; Brandon, Pruett, & Wade, 2002; Gupta, & Wachter, 1998; Harper, Lamb, & Buffington, 2008; Hashemi, & Kellersberger, 2009; Janicki, Fischetti, & Burns, 2006; Kumar, 2006; McGann, & Cahill, 2005; Morgan, & Aitken, 2006; Schwieger, & Surendran, 2010; Shih, LeClair, & Varden, 2010; Surendran, & Schwieger, 2011; Tuttle, 2000, 2001). After more than a decade of discourse on the topic, there is still very little agreement on how best to design, develop, and deliver an information systems capstone experience for undergraduate majors. The objectives of an information systems capstone course have been described as follows: "a means for students to apply knowledge gained in previous courses and integrate those experiences in a more realistic setting, where concepts are applied simultaneously, rather than sequentially and in isolation" (Denton & Spangler, 2001, p. 150). Such a broad mandate has necessarily led to a variety of unique approaches offered by the various academic programs in our field.

One solution, presented in the undergraduate IS 2002 model curriculum (Gorgone, Davis, Valacich, Topi, Feinstein, & Longenecker 2003) has been to build the course around project management. An alternative approach has been to structure the course around student presentations of case studies, situation analysis reports and team projects (Brandon et al., 2002; Gupta & Wachter, 1998). Still other courses have emphasized the use of guest speakers and student research projects (Kumar, 2006). Yet another approach is for students to develop an ePortfolio to demonstrate their competency across the curriculum (Shih et al., 2010). In most of these examples, evidence supports the view that students and faculty alike were satisfied with the course outcomes. What is less clear is the degree to which the actual learning outcomes could be demonstrated. Of particular concern is how these outcomes map to the expectations we set forth for our capstone experience.

The course that is the focus of this paper is the undergraduate capstone course for information systems majors. The course and program is situated within a College of Business at a large, research extensive state university. As of spring 2012, the first offering of the course, approximately 300 students were declared for the 2-year upper level major, meaning that course enrollment was typically between 40 and 50 students in each of the fall, spring, and summer sessions. The previous version of the capstone course - offered in a more traditional lecture-based format - received relatively high student evaluations. There were concerns, however, that the full range of learning outcomes intended for a capstone course was not necessarily being achieved. These concerns motivated a redesign of that course.

Although the two core activities in the redesigned course - case pedagogy (e.g., Brandon et al., 2002; Gupta, & Wachter, 1998; Harper et al., 2008) and student projects (e.g., Gupta, & Wachter, 1998; Hashemi, & Kellersberger, 2009; McGann & Cahill, 2005 Tuttle, 2000, 2001) - have frequently been included in capstone courses, the course here described introduced many features that were quite novel. The paper begins by providing a synthesis across information systems capstone courses, then summarizes the key learning objectives of the course. The design of the course is then presented along with a philosophy, after which initial learning outcomes are described. The paper then describes a multi-method approach to systematically evaluate the course features. The paper concludes with some thoughts on the broader impacts of the project and how the project might be extended as well as implications for practice in the field of information systems at other institutions of higher education.

Relevant Literature

Within the information systems literature, a significant disconnect exists between what we research and what we teach has been observed (Gill & Bhattacherjee, 2009). The source of the problem seems to be that much of what we teach, particularly in undergraduate programs, is technical subjects such as programming, databases, data communications, and systems analysis and design. What we research, on the other hand, tends towards the behavioral sciences (although exceptions obviously exist). Compounding the problem is the fact that we are increasingly being asked to assess learning on core skill dimensions that do not directly relate to either activity - such as problem solving, communications, collaboration, and ability to learn (Gill, 2010). Many have suggested the undergraduate capstone as a place for this assessment to occur.

The capstone experience for undergraduate information systems majors has been a topic of interest for more than a decade. As previously mentioned and as clearly illustrated in Table 1, very little agreement exists on what topics should be covered and the pedagogy for such a course. However, when examining across these various descriptions, a few pertinent themes emerge. First, across several of the course descriptions, there is an emphasis on the design, development, and implementation of real-world technology solutions for real-world clients (e.g., Gupta, & Wachter, 1998; Hashemi, & Kellersberger, 2009; McGann & Cahill, 2005 Tuttle, 2000, 2001). This theme emphasizes the importance of information systems students working on authentic problems within a business domain and integrating technology with real clients to better grasp the complex process of systems analysis, design, development, and integration. Further, the emphasis on student working in teams is consistent with the belief that information system majors should be well-versed in the soft-skills of collaborating, leadership, diplomacy, and more.

A second theme to emerge from these vast course implementations is the use of the case method to engage students in complex discussions surrounding both the technology and management type decisions facing information systems professionals (e.g., Brandon et al., 2002; Harper et al., 2008). The case method is a pedagogical approach that has been widely adopted in several disciplines, including business, medicine, law, and education. In the context of information systems, we are concerned with encouraging students to engage in critical thinking, problem-solving, expression of complex ideas, synthesis and analysis, and decision-making abilities. The case method is a novel way to address these concerns by posing semi-structured and authentic problems, usually written in a way that highlights the decisions a protagonist must address. The case method is a key focus of the course design described here.

A third theme to emerge from these data is an emphasis on student portfolios (e.g., McGann & Cahill, 2005; Shih et al., 2010), particularly ePortfolios, which involve students' representation, reflection, and revision (Ritzhaupt, Singh, Seyferth, & Dedrick, 2008). ePortfolios are a newer approach to an old problem: helping students synthesize and integrate knowledge across their academic program and helping students showcase their knowledge, skills, and dispositions to potential employers. ePortfolios are still in their infancy in the field of information systems, but accrediting agencies like Accreditation Board for Engineering and Technology (ABET) (Brumm, Ellertson, & Mickelson, 2003) are already exploring the utility of these tools for accreditation and student learning outcomes. We anticipate that ePortfolios will have a significant role to play in information systems programs in the near future.

A fourth and final theme to arise from the literature is an emphasis on undergraduate information systems students interacting with professionals already practicing in the field (e.g., Astani, 2006; Brandon et al., 2002; Kumar, 2006; McGann & Cahill, 2005). Whether students are soliciting requirements from real-world clients or interviewing seasoned professionals, the contact between a student and professional is a valuable component to a capstone experience. Professional can share their experiences to help students make explicit connections between theory and practice.

Further, this form of engagement engenders a sense of professionalism within the student body. Part of our course design emphasizes students interacting with the protagonists in the cases they read as part of the capstone course.

Table 1. Descriptions and key features of information systems capstone courses.

Author(s)	Key Features and Description
Astani (2006)	Students were required to interview local Chief Information Officers face-to-face to better understand the key issues in information technology management. Students shared the findings in class.
Brandon, Pruett, and Wade (2002)	A combination of case pedagogy, guest speakers, and lectures to deliver content. Students would engage in discussions and would produce a research report on a specific company and industry to the rest of the class. An advanced graduate textbook was used.
Gupta, and Wachter (1998)	Lectures, targeted assignments, case studies, situation analysis report, and a major team project. The course integrates several business functions and assignments to provide a comprehensive experience.
Harper, Lamb, and Buffington (2008)	A focus on using case pedagogy to delivery content. A comprehensive evaluation of the case method using a valid and reliable survey instrument. The course embraces discussions and case analysis.
Hashemi, and Kellersberger (2009)	A focus on information systems development of a complex information systems spanning multiple semesters with multiple students. A focus on learning several business functions. The course is an ongoing information systems development project.
Janicki, Fischetti, and Burns (2006)	An emphasis on project management and emerging technology. The course focuses on working with real-world clients to identify stakeholder needs. The real-world projects come from the institution and local not-for-profits.
Kumar (2006)	The paper focuses on the recommendations of using a systems approach, focusing on student-centered activities, using multiple modes of assessment, providing research opportunities, and inviting guest graduates to speak about the course.
McGann and Cahill (2005)	A description of a comprehensive course that covers real-world client projects, traditional readings and case studies, project management, individual development assignments, research readings, electronic portfolios and a career readiness emphasis.
Morgan and Aitken (2006)	A description of a capstone course for information systems majors and other business majors involving the cross-functional teams and consulting experiences. The course is organized around six modules.
Schwieger and Surendran (2010)	A description of a capstone course focusing on teamwork and developing real-world technology solutions for real clients. The course emphasizes soft skills, knowledge integration, and cooperative learning.
Shih, LeClair, and Varden (2010)	A focus on students developing an electronic portfolio (ePortfolio) to demonstrate technical competence in their academic studies. The course integrates across the curriculum following a pedagogical model. Students in the program must complete the ePortfolio to graduate.
Surendran and Schwieger (2011)	Implications of the IS2010 curriculum standards for an integrated undergraduate capstone course for information systems majors. The proposed course design emphasizes client-sponsored projects, enterprise system based projects, instructor-directed apprenticeships in industry, and cross-discipline focused independent study.
Tuttle (2000 and 2001)	An emphasis on a large-scale programming project involving a complex database design and class discussions are surrounding Frederick Brooks Jr.'s "The Mythical Man Month". Implications for the field are emphasized and students engage in team-based challenges in class.

Across these discussions on undergraduate information systems capstone experiences, we can see that the field is still struggling with how best to synthesize and integrate knowledge in the various areas that constitute the information systems undergraduate major. What we can garner from these discussions is that there are several distinct ways to achieve the learning objectives of these courses ranging from traditional pedagogy to more authentic forms of engagement. In the remainder of this manuscript, we present our approach to the information systems undergraduate capstone experience by highlighting our design and systematically evaluating the effectiveness of this eclectic approach.

Course Design

Broadly speaking, an information systems program within a business school seeks to build two categories of skills in its students: *technical skills* and *core skills*. The technical skills typically involve being able to employ IT artifacts (e.g., databases, programming languages) and techniques (e.g., project development methodologies) in practical situations. The core skills, on the other hand, are those that allow the individual to contribute in a work environment and include 1) the ability to communicate effectively, 2) the ability to work effectively with people, 3) good problem solving skills, and 4) the ability to learn while on the job (Gill, 2010, pp. 416-417). Ironically, we find that it is these skills - rather than the technical skills that we most emphasize in our teaching - that employers most often mention when asked what they desire when they hire our students.

Taking into consideration the dimensions discussed in our literature review, the capstone course design consisted of two components: case pedagogy and individual projects. The case pedagogy involved rich cases written by faculty members in the program and highlighted protagonists that either physically or virtually attended class on the day the cases were discussed by the students. Our vision was to have the student interact with the professional (protagonists) and ask more in depth questions about the case situation. The individual project was designed to accommodate students that would either 1) enter the workforce upon completion of their degree program or 2) apply to graduate school to pursue a career of research in the field. Further, we envisioned the project being easily integrated into a student's ePortfolio for showcasing to potential employers. Because these two components focused on separate learning objectives and were largely independent of each other, they are discussed separately. Regular course evaluations were also treated as evidence of the overall effectiveness of the course, but could not be separated with respect to learning objectives.

Learning Objectives

Given that the capstone course had two goals - i) to provide students with a further opportunity for learning, and ii) to assess what students have learned in the program - it made sense to establish different objectives for the two skill types:

- *Technical skills*: The capstone would primarily be used as a means of assessing technical competence acquired over the course of the entire program. No specific attempt would be made to introduce specific new tools or techniques. This made sense since the information systems major already had four required courses plus a number of electives devoted primarily to technical skill development.
- *Core skills*: The capstone would specifically assess skill development in these areas over the duration of the course. Because such skills are notoriously difficult to measure, triangulation employing a variety of different assessment tools would be used.

In the design section, how we attempted to accomplish these objectives is further discussed.

Case Pedagogy

To understand our position, it is useful to think of the course as an informing system involving three key stakeholders: the faculty, the students, and the practice community. As illustrated on the left side of Figure 1, the pure lecture course - admittedly a "straw man" since relatively few enlightened instructors would rely solely on such an approach - can be characterized as a series of one way information flows. The main flows are from the lecturer to the student and from the researchers (who contributed the knowledge that makes up the content of the textbook) to the instructor, since the roles of content generation and content dissemination tend not to be one and the same in such courses. Secondary informing flows occur, presumably, from practice to the researchers and, as students graduate and join practice, from students to practice.

In the traditional case method course, shown in the center, we see a substantial number of new flows arise. The informing flows in a facilitated discussion are clearly bi-directional between students and the facilitator. In addition, substantial student-to-student flows exist. The influence of practice informing the researcher/case writer also becomes much more evident for a discussion case than for the type of theory we produce, at least in the information systems field. The informing flow from case writer to facilitator still tends to be unidirectional, however, and direct links from students to practice remain secondary.

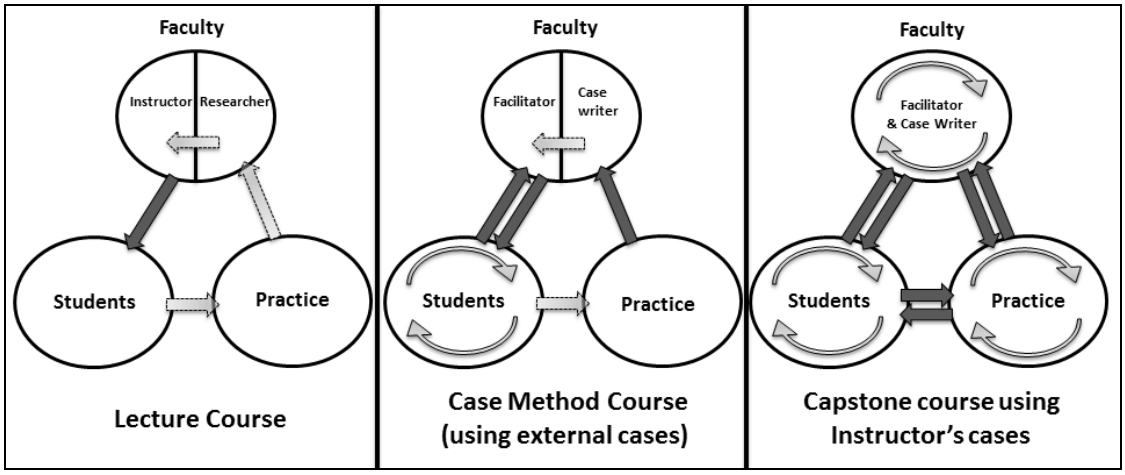

Figure 1. Three course designs expressed as informing systems.

Where the situation really gets interesting is when the facilitator develops cases for his or her own institution, and where case protagonists become participants in the discussion. In this setting – the one that we targeted for our undergraduate capstone course – informing can occur in every possible direction, at least in theory. During case development, the case writer and protagonists engage in active mutual informing. With the case protagonists in the room during the discussion, both students and practitioners can become informed. As the case writer works with other faculty members facilitating the case, each informs the other. It is even possible for practitioners to be informing each other in some venues, such as an executive program. Furthermore, in the long term, the informing activities described here could lead to the formation of lasting relationships between academics, students, and practice that could become channels for future informing. A few institutions, such as Harvard Business School, have long understood the symbiotic relationship between discussion case development, students, research, and practice; they have leveraged that knowledge to great effect. Our long term goal was to build a broader understanding of this process throughout the information systems research community (HBS, 2013). In the process, we also hoped to learn a little bit more about what case discussions accomplish in terms of learning.

Case Discussions

Until the last two weeks of the semester – which were set aside for project poster presentations – virtually all class time was utilized in discussing a single case study each week. During the first offering of the course, the class met nightly from 6:20 PM to 9:05 PM. The semester timeline is presented in **Figure 2**.

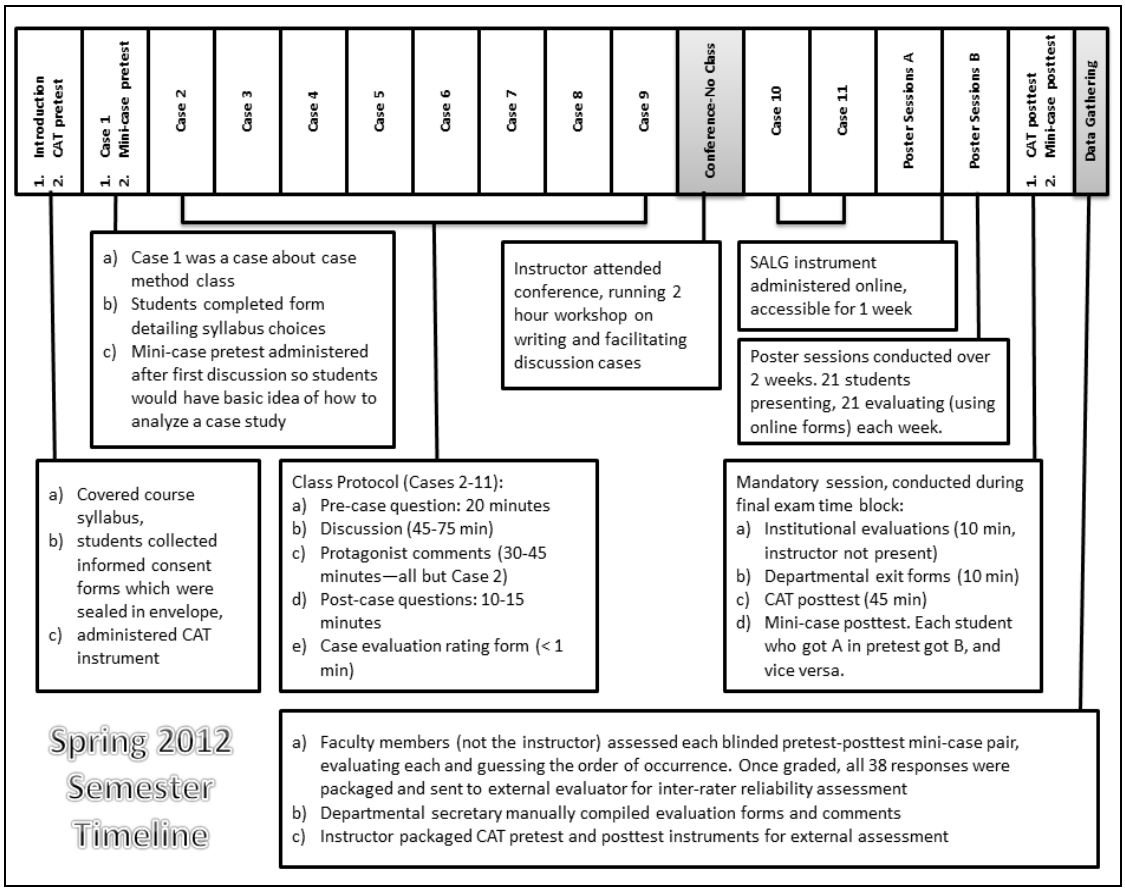

Figure 2. Activity timeline for information systems capstone course, spring semester 2012.

Protocol

We followed a consistent protocol for each class session. On a typical evening, the schedule would be as follows:

- ***6:20-6:45 PM: Pre-case question***. A question related to that evening's case was written on the whiteboard by the instructor. Students had 20-25 minutes to write a response and upload it to Blackboard, the institution's course management system. Laptops were made available to the 2-3 students who did not have their own.
- ***6:45-7:45 PM: Case discussion***. A student would be called upon to open the case without prior warning (referred to as a cold call) while the instructor wrote notes on the board. Once the opening was complete, the facilitated discussion began.
- ***7:45 PM to 8:15 PM: Wrap-up***. Originally, it was planned that the instructor would provide a short summary and reflections on what was covered in the discussion. In practice, the actual protagonist from the case being discussed sat in on all but one of the discus-

sions throughout the entire semester. As a consequence, it was normally that individual who led the discussion.

- ***8:15 PM to 8:30 PM***: ***Post-case forms.*** Students prepared and submitted a case reflection form to Blackboard. This form always consisted of the same two questions: 1) What are the three most important things you learned from the case? and 2) How did the discussion of the case change your views? In addition, students had to fill in a brief case study rating form that was administered online.

The remainder of each class period was set aside for questions about specific projects, and students were free to leave after they had completed their post-case forms. Each week, the instructor evaluated the students' pre- and post-case submissions on a 3 point scale: W=weak, S=satisfactory, and E=excellent. These completed forms were also sent to the protagonist of each case.

The only major variation from the just-described protocol occurred for two cases where the protagonist was non-local, one located in Boston, Massachusetts, and one located in West Palm Beach, Florida. For these two cases, the entire class was conducted online using Elluminate, which provided a conferenced audio channel and a shared whiteboard. This venue allowed case protagonists to participate in the discussion without travelling and to share their observations with the class. The same schedule for the class period was maintained, however.

To prepare students for the case method pedagogy to be used over the course of the semester, the first case study that was discussed was a case about the design of the course itself. That case, which featured the instructor as the protagonist, presented the students with a series of decisions that included:

- Should the course contain an online component or be entirely face-to-face?
- Should progress deadlines within the class be strictly enforced or flexible?
- Should a detailed grading rubric with specific point values for each activity be established or should a more subjective approach be taken?

At the end of the case discussion – which demonstrated a surprisingly large diversity of opinion – students were given the opportunity to vote anonymously using an online survey and their choices became the new course policy. Their choices were as follows:

- 60% weight for case discussion participation in final grade (73% percent of the class selected that participation should count for either 60% or 70%; choices went as high as 70% and as low as 30%)
- Flexible grading as opposed to firm rubric (70% voted for flexible)
- Participation balanced between oral and written forms (57% voted for balance)
- Project grades balanced between written report and poster presentation (65%)
- Late work accepted but with substantial penalty (59%; 11% voted for not accepting late submissions, 30% voted for no penalty on late work)
- Classes to be held online whenever doing so made it possible for the case protagonist to attend (57%; 27% voted for no online classes and 16% voted that online classes should be allowed only if scheduled at the beginning of the semester).

Unfortunately, regardless of whatever virtues case discussions might offer, classroom discussions alone were to help us much in understanding the success of technical component of our undergraduate program – particularly in the form of evidence that could be used for outcomes assess-

ment for the program as a whole. For this reason, we added an individual project component. This was less driven by any literature than by our need for data: by looking at the quality of projects and distribution of project types, we hoped to learn about our effectiveness in preparing students. For this information to be useful, however, we needed to offer students considerable latitude in their choice of projects.

Final Projects

The decision was made that each project be an individual, rather than team, effort. There were two compelling reasons for this choice. First, our intention was to use the distribution of projects as an indicator of where our technical focus was strongest and weakest. The second was our interest in using the quality of these projects as a basis for evaluating the overall performance of our major for purposes of accreditation and state-mandated programs. These agencies invariably looked for evidence that documented individual work. It was also felt that the program already had so much group work that additional team-related activities in the capstone were not mandatory. The purpose of the project is to demonstrate the technological and research skill that students have acquired over the course of the information systems major. The project was intended to involve substantial complexity but students were given substantial freedom in project type. Instructions provided in the course syllabus were as follows:

- *A programming project:* A stand-alone or web-based project that involves substantial coding in a programming language such as C#, VB, or Java. Mobile apps or a web-based project involving PHP or some other environment (ASP, Ruby-on-Rails) were also allowed.
- *A database project:* A project built around designing an SQL-based database (as well as related forms, queries, and reports) for a particular business situation. Real-world or test data was used.
- *An analysis and design project:* A project built around designing a system or application. Appropriate diagrams (entity-relationship diagrams, unified modeling language notation) were prepared, along with form layouts, business process diagrams, and project plans.
- *A real-world web site*: For pure web site projects, a real-world client was required. Such a client may have been identified by the student or, from time to time, supplied by the instructor. A thorough needs analysis and approach to determining the effectiveness of such a site was required for this category of project.
- *A real-world case study*: Students working in business or facing complex career decisions may choose to develop a case study that is intended for use in subsequent offerings of the course. These projects had to be developed in close collaboration with the instructor and necessarily demanded a very high standard of quality.
- *A research white paper*: An in-depth research paper—20 pages in length or more—that explores a particular technology, such as WiMax, or information systems issue, such as outsourcing. *Safe Assignment* was used to ensure that the work is original. Students should have a substantial number of sources and should cite them.

Throughout the semester, the instructor met with students after class to discuss the progress of their project proposals and their final projects. Early in the semester, students submitted a project proposal. The instructor provided comments on these proposals and approved them when they were in a form that made sense. Students were not allowed to begin their projects until they were approved by the instructor. A month or so before the end of the semester, students were required to submit a draft of their project that included all their work to that point. The instructor graded and commented on the draft. Students were encouraged to incorporate these comments into their final submissions.

Each student prepared a PowerPoint presentation describing his or her project. The individual slides were posted on a "science fair" style board. For database, programming and other "runnable" projects, computer versions were generally demonstrated as well. Half the class presented during each poster session, and the other half (and the instructor) acted as "judges" using a rotation scheme akin to "speed dating". Half the students – the ones not presenting – evaluated each student's poster during the poster session using a formal rubric provided by the instructor. Six to ten of the best poster presentations were selected for presentation at the meeting of the Department Executive Advisory Board. This board consists of over 20 of the top information technology executives in the region. Projects were graded based upon the difficulty of the project and the quality of its components. Presentation peer evaluations were included in this assessment. **Figure 3** illustrates the layout for the poster sessions.

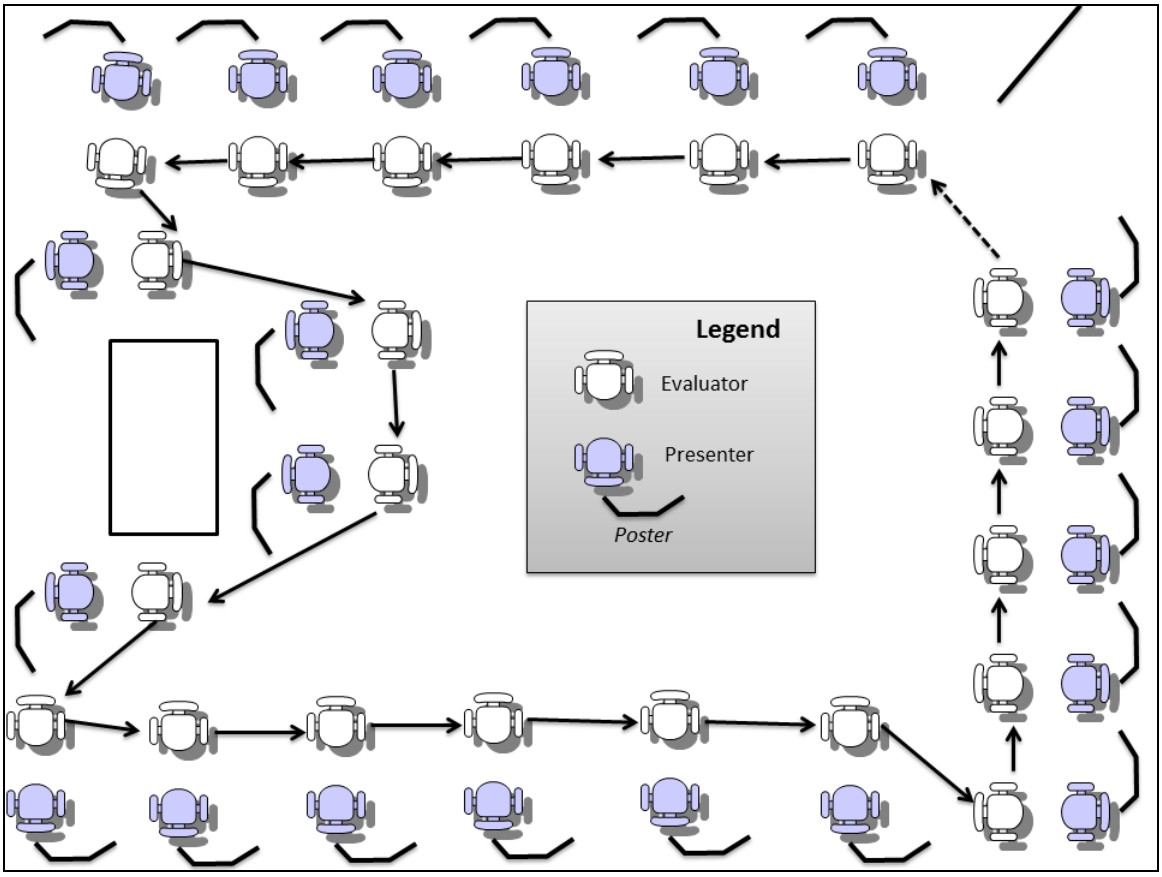

Figure 3. Poster Presentation Classroom Layout.

Students responsible for the top eight posters were invited to the spring 2012 meeting of the department's *Executive Advisory Board* (EAB). This board, consisting of roughly 20 of the top IT executives in the university's service area, then acted as judges during a 1 hour session scheduled during the board meeting. This offered the students considerable visibility while, at the same time, providing the basis for an external evaluation of our program as a whole (or, at least, the top quintile of our program). The three strongest student presentations were then awarded cash prizes.

Method of Evaluation

This paper relies on several data sources using a multi-method approach (Bryman, 2006) for the evaluation of this eclectic course. The evaluation system included several data sources to triangulate findings, indulging faculty mini-case evaluations, the *Critical Thinking Assessment Test* (CAT), the *Student Assessment of Learning Gains* (SALG), the *Student Assessment of Instruction* (SAI), and student and instructor reviews of final projects. This paper evaluates the Spring 2012 offering of the course, which included 42 information systems undergraduate students. Figure 2, presented earlier, presents a timeline of the data collection procedures for this evaluation.

Student Assessment of Instruction

We used the final course evaluations completed by students at the end of the semester to evaluate the student perception of the course. Specifically, the instrument is titled the *Student Assessment of Instruction* (SAI). This instrument is used university-wide for all courses and consists of eight items and a general open-ended item for free-form responses. The instrument has been shown to demonstrate both validity and reliability across disciplines and course levels (e.g., undergraduate versus graduate). These data were analyzed descriptively.

Faculty Mini-Case Evaluations

Each student was randomly assigned to analyze one of the two cases on the first day, and the other on the last day. Faculty members in information systems (who were not the instructor) then assessed both responses on a series of dimensions and were required to guess the order in which the student had performed the analyses (first or last). In addition, an external evaluator at a different university performed the same rating and guessing task on all of the responses, allowing inter-rater reliability to be established. The correlations between the faculty members rating and the external evaluator ratings follow: evaluating information was .23, for creative thinking was .14, for learning and problem-solving was .39, for communication was .06, and overall was .30. We report the faculty member assessments within this manuscript. These data were analyzed both descriptively and inferentially. We included an example mini-case in the Appendix to give the reader an understanding of the tasks involved as well as the structure of the cases in general.

Critical Thinking Assessment Test (CAT)

A NSF-funded instrument intended to measure overall changes in critical thinking and its individual components was used in this evaluation. These four components were 1) Evaluating information, 2) Creative thinking, 3) Learning and problem solving, and 4) Communication (see http://www.tntech.edu/cat/home/). Each student completed the same instrument before and after the course, after which the results were sent to external graders trained by the institution that developed the instrument. The CAT instrument has been shown to demonstrate both validity and reliability under several different conditions (Stein, Haynes, Redding, Ennis, & Cecil, 2007; Stein, Haynes, Redding, Harris, Tylka, & Lisic, 2010). The results are illustrated to gauge student gains in each of the dimensions listed. A random sample of 20 CATs was analyzed for this evaluation program. These data were analyzed descriptively and inferentially.

Student Assessment of Learning Gains

With a week left in the semester, students also were asked to fill out an online form modeled after the *Student Assessment of Learning Gains* (SALG; http://www.salgsite.org/) instrument, which rates elements of a course based upon how helpful to learning they are perceived to be. This instrument has been used in the information systems context in other studies and has been shown to

have an internally consistent structure (Ritzhaupt & Gill, 2008). The SALG was administered via an online survey. These data were analyzed descriptively.

Student and Instructor Final Project Evaluation

Both the instructor of the course and the students within the course participated in an evaluation of the final student projects using well-understood criteria. These criteria were communicated to students prior to the evaluation, and students were informed that their peer evaluation would be used to calculate the final grades in the course. These criteria included difficulty, quality, and presentation. We also counted the distribution of final projects types in each category as listed in the descriptions above. The peer and instructor evaluations were conducted at the end of the semester after the final projects had been presented at the poster session. These data were analyzed descriptively.

Evaluation Results

Student Assessment of Instruction

Although not necessarily measuring learning, student evaluation results are critical to instructors for two reasons: 1) they provide a consistent measure of student reaction that can be compared from semester to semester, and 2) they are often used as the principal basis for assessing a faculty members teaching performance. The summary evaluation results for Spring 2012 are presented in **Table 2** and **Table 3**. The quantitative results were substantially higher than departmental averages for undergraduate courses. Specifically, the Fall 2011 semester overall average of all 8-items across undergraduate courses taught by the instructor's department was 4.24, while the last column of Table 1 averaged 4.51.

Table 2. Results of institution's 8 item student evaluation of instruction.

Item	Excellent (5)	Very Good (4)	Good (3)	Fair (2)	Poor (1)	Average
1. Description of course objectives and assignments	26 (65%)	10 (25%)	4 (10%)	0 (0%)	0 (0%)	4.55
2. Communication of ideas and information	24 (57%)	13 (31%)	5 (12%)	0 (0%)	0 (0%)	4.45
3. Expression of expectations for performance in this class	28 (70%)	4 (10%)	6 (15%)	2 (5%)	0 (0%)	4.45
4. Availability to assist students in or out of class	26 (63%)	10 (24%)	3 (7%)	1 (2%)	1 (2%)	4.44
5. Respect and concern for students	31 (78%)	6 (15%)	1 (3%)	2 (5%)	0 (0%)	4.65
6. Stimulation of interest in the class	24 (60%)	12 (30%)	2 (5%)	2 (5%)	0 (0%)	4.45
7. Facilitation of learning	23 (61%)	11 (29%)	4 (11%)	0 (0%)	0 (0%)	4.50
8. Overall assessment of instructor	27 (68%)	9 (23%)	3 (8%)	1 (3%)	0 (0%)	4.55

Student comments reflected a similarly positive attitude towards the course, with some qualifications. Of 21 comments (about 50% of the class), 16 were almost entirely positive in tone, two were negative and three could best be characterized as mixed. The five most positive and all the negative and mixed comments (as judged by the instructor) are presented in **Table 3**. A consistent theme in nearly all the negative comments was the repetitive nature of the poster presentations,

since each student had to present his or her work 21 times. This theme also appeared in some positive comments, framed as a suggestion to have students present once to the entire class.

Table 3. Five most positive and least positive student comments on course evaluations.

Most Positive	Least Positive
The class was a major refresher compared to the other courses. The instructor treated all students as adults rather than children. His teaching method was very "rebellious" for this school. Allowing the students to act out and show what they know versus lectures and exams made the class a great experience.	*Negative:* Wasted money on a class to learn nothing - case studies which taught me nothing. Asked for help with project and he couldn't help. I taught myself everything. I learned from this class why did I pay someone for education.
Really enjoyed the class study structure of the class. The case studies help me to better analyze business problems and situations while learning more about current ISM technology.	*Negative:* The cases were too long and take a long time out of class to prepare. Also the descriptions for the project were a little vague, needs more structure as a whole.
Overall this was an interesting course. Some of the tools I learned will be put into action in my future job positions. This type of class structure should be in all business majors.	*Mixed:* Presentation of cases to half of the class, 21 students to be exact was a lot. Needs some adjustment. Case preparation is a lot - also maybe cut down on the number of cases.
Great class! I loved having the discussions about the cases because it gave me the opportunity to learn more about technology in our society & how to manage it well & to take it to the next level to help people. I loved how the cases were from different industries. I think an area of improvement would be to either have a small class or a better room that can facilitate more interactive conversations.	*Mixed:* I enjoyed the format of the class, it was very unconventional. Most of the cases were interesting and related to the MIS field. There were quite a few spelling and grammar errors throughout them. The Project section of the class gave me time to explore my own interests in the field and to learn more about a specific topic. The poster session however was not helpful to our learning, just to everyone losing their voice. Perhaps just presenting the projects to the entire class at once would be a better way to handle the presentations.
This was my favorite class. I felt like I learned more in this class than I have in the last two years.	*Mixed:* I did not enjoy the poster session. I did not like having to present 20 times. I would have rather presented once. I did enjoy the guests and case studies.

Student Assessment of Learning Gains

With a week left in the semester, students also were asked to fill out an online form modeled after the *Student Assessment of Learning Gains* (SALG) instrument, which rates elements of a course based upon how helpful to learning they are perceived to be. These results are presented in **Table 4**. While it is difficult to make general statements about how such results should be interpreted, in mathematics and the sciences scores of three or better are considered positive, and averages approaching four are viewed as highly favorable (FLAG, 2012; Seymour, Weise, Hunter, & Daffinrud, 2000). In a SALG survey of a programming course within an MIS program (Ritzhaupt & Gill, 2008, p. 290), a list of 20 instructional items yielded a mean of 3.61, a median of 3.47 and a maximum of 4.42. These were viewed as positive outcomes.

Broadly speaking, these results suggest that students perceived the cases to be particularly valuable in the context of understanding information systems and "real world" issues, while projects and cases were roughly equivalent with respect to core skills. Projects had a distinct edge with respect to technical skills, not surprisingly. More surprisingly, perhaps, they also showed a slight edge in the area of communications skills – almost certainly a result of the poster sessions. Interestingly, poster sessions were rated among the least helpful of the innovations, although the divergence in opinion was substantial (consistent with student comments). This finding comes with

an important caveat, however, since the large range of difficulty and quality in projects virtually guaranteed that some people would be uncomfortable presenting what they had submitted. The low online session rating was probably the result of both technical issues and the fact that they were being compared with the highly successful face-to-face classes involving protagonists. The perceived helpfulness of both *local companies* and *protagonists sitting in* were both very high.

Table 4. Results of SALG survey (35 responses out of 42 students; 83% response rate).

Item	1	2	3	4	5	Average
How helpful were the case studies and discussions in the following areas 1=Not at all helpful, 2=A little, 3=Somewhat, 4=A lot, 5=A great deal						
Understanding MIS concepts	0%	5.71%	11.43%	37.14%	45.71%	4.23
Understanding relationships between concepts	0%	2.86%	8.57%	48.57%	40%	4.26
Understanding real world issues	0%	0%	0%	22.86%	77.14%	4.77
Improving my problem solving	0%	0%	25.71%	37.14%	37.14%	4.11
Improving my creativity	0%	0%	42.86%	14.29%	42.86%	4.00
Improving my analytical ability	0%	2.86%	8.57%	42.86%	45.71%	4.31
Improving my technical skills	0%	25.71%	25.71%	22.86%	25.71%	3.49
Improving my communications skills	0%	11.43%	37.14%	25.71%	25.71%	3.66
How helpful were the projects and poster presentations in the following areas 1=Not at all helpful, 2=A little, 3=Somewhat, 4=A lot, 5=A great deal						
Understanding MIS concepts	5.71%	5.71%	20%	31.43%	37.14%	3.89
Understanding relationships between concepts	2.86%	17.14%	11.43%	34.29%	34.29%	3.80
Understanding real world issues	2.86%	8.57%	31.43%	14.29%	42.86%	3.86
Improving my problem solving	2.86%	8.57%	22.86%	20%	45.71%	3.97
Improving my creativity	2.94%	11.76%	8.82%	26.47%	50%	4.09
Improving my analytical ability	2.86%	5.71%	17.14%	28.57%	45.71%	4.09
Improving my technical skills	2.86%	14.29%	8.57%	20%	54.29%	4.09
Improving my communications skills	5.88%	8.82%	11.76%	44.12%	29.41%	3.82
How helpful were the following innovations introduced in the course 1=Not at all helpful, 2=A little, 3=Somewhat, 4=A lot, 5=A great deal						
Pre and post case surveys	5.71%	14.29%	20%	31.43%	28.57%	3.63
Local companies as cases	0%	2.86%	5.71%	25.71%	65.71%	4.54
Protagonists sitting in as guests	0%	0%	5.71%	22.86%	71.43%	4.66
Online sessions with protagonists	17.14%	14.29%	31.43%	20%	17.14%	3.06
Flexibility in types of project allowed	2.86%	0%	8.57%	11.43%	77.14%	4.60
Science fair poster sessions	14.29%	17.14%	20%	17.14%	31.43%	3.34

One survey result was entirely unambiguous. The first survey question asked students if they preferred a) the new structure or b) reverting back to the previous lecture-intensive structure. Thirty-two out of 35 respondents (91%) indicated that they preferred the reinvented format. This finding was particularly important since the course had been entirely re-designed.

Mini-Case Results

A total of 38 mini-case pairs were evaluated by four NSF grant participants (co-PIs or senior personnel) from the project team. Prior to the assessment, the instructor had grouped the two responses for each student in the same order (A-case then B-case). The evaluators then rated each response (2 per student) using the same four criteria employed by the CAT instrument on a one to five scale. The instructor then took the evaluators' forms and determined if each rated case was a *before* or *after* rating, based upon when the student took the test. These ratings are summarized in **Table 5**. All differences between post- and pre-test averages were positive. With the exception of

Communication, all differences were also significant at the .05 level, with *Creative Thinking* and *Overall* differences significant at $p < .01$.

Table 5. Results of mini-case ratings for before and after course (1=Poor to 5=Excellent).

Item	Average before course	Average after course	p-value for T-Test
1) Evaluating information	2.92	3.45	.018
2) Creative thinking	2.63	3.19	.003
3) Learning and problem solving	2.82	3.26	.045
4) Communication	2.97	3.34	.056
5) Overall	2.79	3.43	.004

The second approach to assessing learning was to ask the rater – for each pair – to guess which analysis appeared to have been done *after* the course. Of the 38 pairs analyzed, the evaluators guessed correctly overall 27 times (71%). Because each evaluator filled out only 9 or 10 forms, the scores for individual evaluators were computed. These differed widely: 50%, 89%, 70% and 78%. The overall result proved to be slightly below our targeted value of 80%, but still important.

One factor that clearly influenced the evaluation results was the nature of the mini-case being evaluated. The A-case described a situation where a development project was falling behind schedule without providing a list of clear alternative actions. For this case, the average difference between before and after overall scores was relatively small (0.23). As a result, the most common error was for raters to misjudge when A was the second case (error rate: 7 out of 19). The B-case centered on a website design problem offering the student a choice between a clear set of technology alternatives. Here the before and after difference was over three times larger (0.78) and raters misjudged far less often (error rate: 4 out of 19). The distinction here is important, because all the actual case studies developed for the course included a list of options *by design* – a decision made to tailor the cases to undergraduates.

Student Project Results

Two results with respect to student projects of particular interest were 1) the distribution of project types (and relative quality in each category), and 2) how instructor perceptions of project difficulty and quality differed from the ratings compiled by students (half of whom rated each project poster session). The summary results are presented in **Table 6**.

The correlation between the instructor's evaluations and student evaluation averages for each project was quite reasonable – .68 for difficulty, .52 for quality, and .56 for presentation. Generally speaking, student scores between items were much more highly correlated (e.g., .81, .82, and .60 for difficulty-quality, quality-presentation and presentation-difficulty) than the instructor's (.50, .40, and .10). The top 8 projects were invited to present at the department's EAB meeting; 6 students were able to attend in person. These posters were scored by executives using the same form used by students. The executive average overall rating was 3.67, contrasted with average student ratings of 4.65 for the same set of 6 projects. The EAB's self-reported perception of the projects was, nevertheless, highly positive.

Table 6. Project distributions, instructor ratings and student ratings.

	#	Instructor Difficulty	Student Difficulty	Instructor Quality	Student Quality	Instructor Presentation	Student Presentation
Programming	5	4.80	4.87	4.20	4.62	3.60	4.39
Database	14	3.79	4.15	4.36	4.36	4.43	4.32
Systems A&D	1	3.00	4.20	3.00	4.40	4.00	4.55
Website	8	3.63	4.12	4.38	4.53	4.63	4.33
Case study	2	3.50	3.23	4.00	3.60	4.00	3.75
Research	12	2.92	3.79	3.67	4.11	4.00	4.08

With respect to the distribution of projects, the large number of database entries was consistent with the department's focus on business intelligence and the substantial number of course offerings in the database area (including data warehousing and data mining topics). The distribution also suggested that programming offerings might need to be strengthened and that demand existed for a course that dealt with the construction of websites and the use of open source code. Also important to note was the high distribution of research projects submitted. This suggests that several of the students might pursue advanced study in the field. However, it might also be indicative of the fact that the students were attending a research extensive university.

Critical Thinking Assessment Test (CAT)

Although aggregate scores increased on the Critical Thinking Assessment Test (CAT) from pre-test to post-test, the change in the scores was statistically insignificant. The scores broken down by question type can be gleaned in **Table 7**. In fact, in some areas, we actually observed decreases from pre-test to post-test. For instance, we observed a decrease in a students' ability to identify additional information needed to evaluate a hypothesis, determine whether an invited inference is supported by specific information, separate relevant from irrelevant information when solving a real-world problem, provide alternative explanations for spurious associations, and identify and explain the best solution for a real-world problem using relevant information. This was a disappointment in that the case method is intended to refine a student's ability to use information and make sound judgments. The only area that showed a statistically significant increase was the students' ability to summarize the pattern of results in a graph without making inappropriate inferences. We see this as a spurious finding since the case studies themselves did not explicitly focus on a student's ability to interpret complex information from a graph.

Table 7. Pre and post means on the CAT by question type.

Skill Assessed by CAT Question	Score Breakdown	
	Pre Mean	Post Mean
Summarize the pattern of results in a graph without making inappropriate inferences.	0.60	0.95*
Evaluate how strongly correlational-type data supports a hypothesis.	1.25	1.50
Provide alternative explanations for a pattern of results that has many possible causes.	0.80	0.65
Identify additional information needed to evaluate a hypothesis.	0.65	0.60
Evaluate whether spurious information strongly supports a hypothesis.	0.85	0.80
Provide alternative explanations for spurious associations.	1.60	1.57
Identify additional information needed to evaluate a hypothesis.	0.25	0.35
Determine whether an invited inference is supported by specific information.	0.90	0.75
Provide relevant alternative interpretations for a specific set of results.	1.10	0.95
Separate relevant from irrelevant information when solving a real-world problem.	3.35	2.95
Use and apply relevant information to evaluate a problem.	0.70	1.00
Use basic mathematical skills to help solve a real-world problem.	0.80	0.85
Identify suitable solutions for a real-world problem using relevant information.	1.05	1.35
Identify and explain the best solution for a real-world problem using relevant information.	2.45	2.40
Explain how changes in a real-world problem situation might affect the solution.	0.50	0.65
CAT Total Score	**16.85**	**17.32**

** p<.05 **p<.01 ***p<.001 (2 –tailed)*

Discussion

The evaluation results must be interpreted within the limitations and delimitations of the evaluation program. First, it is important to recognize that these results are specific to one institution's implementation of an undergraduate information systems capstone course. As clearly articulated earlier, there are many approaches to the capstone experience and we did not include all those dimensions within our course design. Second, we did not collect any demographic information from the participants in this course, which might have provided some context for the results of this evaluation. Third, some of these data are self-reported, which are subject to the honesty of the participants. It is possible that the participants supplied us with what could be considered socially acceptable responses. Fourth, some of the results provide inconsistent findings in that the CAT showed no significant gains in critical thinking whereas the results from the mini-cases suggest significant gains in several areas. Finally, we could only provide limited evidence of validity and reliability of the instruments used in this evaluation program. Notwithstanding these limitations and delimitations, we believe the results of our evaluation provide some useful insights.

The results from the student course evaluations (SAI) and the SALG show that most students that completed the course had a favorable perception about the course design. The average across all eight items on the student course evaluation was 4.51 on a five-point scale, which is a noticeable increase from the previous semester's average at 4.24. The student course evaluation, however, was largely focused on the student's perspective of the instructor. As we know, an instructor's teaching practice can largely influence student perceptions. Therefore, more data is necessary to gain a complete understanding of the student disposition, which is why the SALG is such a useful tool to evaluate the course. The SALG demonstrated that the students had more favorable views of the case pedagogy within the course as oppose to the final project and presentations. Further, students indicated that the case pedagogy helped them understand real-world issues ($M = 4.77$), and understand the relationships between concepts ($M = 4.26$). Also noteworthy is that students had high perceptions of the cases being written from local companies ($M = 4.54$) and the protagonists of the cases actually sitting in the course during discussion ($M = 4.66$).

The qualitative responses from the student course evaluations were generally positive, but some mixed and negative comments were made about the course design and instructor. One student brought up the alternative structure of the course: "Allowing the students to act out and show what they know versus lectures and exams made the class a great experience." Another student reinforced this view by saying, "Overall this was an interesting course. Some of the tools I learned will be put into action in my future job positions. This type of class structure should be in all business majors." However, some negative views were also observed, particularly about the case method and the final project presentations. One student said "the cases were too long and take a long time out of class to prepare." Another student commented about the presentations saying that "I did not enjoy the poster session. I did not like having to present 20 times. I would have rather presented once." We take these comments seriously and think that improvements to the course design can be made.

Perhaps the most troubling findings from our evaluation come from the actual student learning gains as measured by the CAT and the mini-cases. As a reminder, the CAT and mini-cases were administered both before and after the course so that we could examine change in student ability to evaluate information, think creatively, learn and problem-solve, and communicate effectively. Put simply, the two data sources show inconsistent findings. While the analysis of the mini-cases showed promise in students' ability to evaluate information, creative thinking, learning and problem-solving, and overall; the CAT results were stagnant and in some cases, diminished; except for a students' ability to summarize the pattern of results in a graph without making inappropriate inferences, which we think is a spurious finding. This inconsistency points to further research, particularly on the efficacy of case pedagogy in information systems classrooms.

We think the final project distributions are indicative of the faculty in which the program resides. Some of our faculty members specialize in areas related to database design, data warehousing, and data mining. Most students pursued database projects and followed second by research projects. However, some decided to conduct comprehensive programming projects or website implementations, which involved real-world clients. What's more important about this particular facet of the evaluation is that both the students within the course and the instructor influenced the final grade on the project. Essentially, we were able to create a more authentic form of assessment based on peer-evaluation. Indeed, meta-analytic studies have verified the use of peer-evaluation closely resembles teacher assessment when judgments are made on well-understood criteria (Falchikov & Goldfinch, 2000). We think that the use of peer-evaluation in information systems courses is a salient design feature that can be replicated across our programs and courses.

In summary, we believe we have provided a rich description of a novel information systems capstone course for undergraduate majors. We have reviewed several implementations of capstone courses offered at other intuitions of higher education and have identified common themes in these courses. Further, we have provided evidence of student learning gains and perceptions within this course based on a multi-method approach to evaluation. We believe this paper contributes to the body of knowledge in information systems education by providing several important considerations for information systems faculty members. In light of this objective, we provide some implications for practice in the subsequent section.

Implications for Practice

Though our implementation of the information systems capstone experience did not include all those possible dimensions (e.g., comprehensive team-based project), we do feel that we were successful in providing students an integrated and comprehensive experience. Information systems instructors must consider several important features of their capstone experience in light of how other courses are taught within the program. We were able to create a course design that emphasized the creation of a complex project, interaction with professionals in the field, and the effective integration of case pedagogy. Based on our experiences, we make the following recommendations to other faculty members in the field:

- We are advocates of the case method to stimulate fruitful dialog among students, encourage in-depth analysis and synthesis, and to build more integrated learning experiences for information systems students. Thus, we recommend that faculty adopt the case method in their instruction. This form of pedagogy requires a shift in perspective of faculty members from the sage-on-stage perpetuating traditional methods like lecture to more of a guide-on-the-side embracing interactive pedagogies (King, 1993). Opportunities are available to learn more about the case method (e.g., conferences) and to identify quality cases that can be used in the classroom.
- Using the case method in information systems curriculum requires quality cases be written on a variety of technical and managerial topics. Further, since technology changes so quickly, keeping these cases up-to-date is problematic. Therefore, we recommend that faculty share their teaching cases in a repository like the one supported by the *Informing Science Institute*. This practice not only provides a publication venue for faculty scholarship, but it also provides venue to gather quality instructional materials (cases) that can be seamlessly integrated into information systems courses.
- Providing flexibility in learning is an infrequently used design feature, but offers a lot of promise in that it gains buy-in from your learners. In this course, we essentially enabled the students to make the choices about the course policies via consensus through an online survey. Students made choices about the grading policy, the structure of the as-

signments, the late work policy, and whether classes would be offered via online using a virtual classroom (we use Elluminate Live). We believe that giving students the choice to determine their own destiny gains buy-in and holds the students accountable to those policies later in the course. While this is one extreme, instructors might use some combination of this design strategy to meet the diverse need of their learners.

- The necessity for quality assessment in information systems is of paramount concern. In particular, there has been a call in our field for more alternative (a.k.a. authentic) methods of assessment as oppose to traditional methods (e.g., exams) which have been rightfully criticized for a lack of validity in measuring students' ability to apply knowledge to real-world situations (Wellington, Thomas, Powell, & Clarke, 2002). Alternative methods of assessment attempt to overcome the limitation by developing authentic contexts in which students can demonstrate their mastery. A method often overlooked in the context of information systems includes the use of peer-evaluation as a mechanism to provide formative assessment to improve the quality of their peers' work, and provide a summative assessment of the work according to guidelines which meet course objectives. We encourage faculty to establish well-understood criteria to enable peer-evaluation within their courses.
- Speaking of alternative assessments, the use of ePortfolios is another option that offers several advantages over traditional methods. Though the use of ePortfolios was not emphasized in our course design, we believe the final projects reached the goal of representation, reflection, and revision – the essence of an ePortfolio initiative. Further, the final project was intended to be easily added to a student's ePortfolio. As we are still struggling with how to effectively evaluate our courses and programs, especially for accreditation purposes, we need to think about alternative forms of assessment that are authentic and strong indicators of quality. We believe that ePortfolios are a powerful way for faculty in information systems to accomplish these simultaneous goals. Our future course design will likely include an ePortfolio component.
- Information systems faculty should employ several methods to measure the outcomes of their courses, especially a capstone experience designed to be a culminating experience. Not only is this an expectation of accrediting agencies (e.g., ABET or AACSB), this is also an opportunity to help others in the field and conduct the scholarship of teaching and learning within our courses. The course design presented in this paper used a multi-method approach to document both student perceptions and student learning gains using both valid and reliable instruments. Similar approaches can be integrated into other courses seamlessly. Further, by doing so, faculty members can share their course design and evaluations in venues like the *Journal of Information Technology in Education* or the *Journal of Information Systems Education*.
- Information systems faculty should encourage intentional interactions between students and professionals in the field. In this course design, we invited the protagonists in the cases to class in which the students discussed the case studies in their presence. The protagonists were encouraged to engage in the conversation to make the experience more authentic for the students. Further, those students that achieved the highest scores on the final project had the opportunity to share their work with members of the advisory board for the department, a group of professionals throughout the region that the university serves. However, there are other ways to accomplish this goal. For instance, faculty members might invite recent graduates that are working in the field as guest speakers.
- Technology is not just a function of business today. We have widely adopted several emerging technologies in higher education to facilitate both face-to-face and online

courses. One new strand that has emerged in recent years is the effectiveness of blended learning environments that fuse together both face-to-face and online components. We now have strong evidence that blended learning is perhaps the most effective model we have in higher education as evidenced by a Department of Education commissioned meta-analysis (Means, Toyama, Murphy, Bakia, & Jones, 2010). Thus, we encourage faculty to thoughtfully integrate technology into the teaching and learning process (Learning Management Systems, Virtual Classrooms, etc.). As innovators and early adopters of technology (Rogers, 2003), we believe this integration process is feasible for our colleagues in a technology-centric field.

Conclusions

What can be concluded from this systematic evaluation of an information systems capstone experience for undergraduates? We believe our results suggest that the use of authentic case studies in information systems capstone courses for undergraduate students is an effective approach. We base this conclusion on the fact that the students had an overall high favorable perception the course design features and that the mini-cases demonstrated growth in critical areas. Though the use of the CAT did not demonstrate significant gains, we believe that one possible explanation for this is that the students were not graded on this activity and therefore perceived the activity to be a low-stakes assessment as oppose to a high-stakes assessment. We also believe that our paper presents the use of peer-evaluation as a viable alternative to traditional methods. We provided students the opportunity to evaluate their peers' work via well-established criteria. This approach can be easily and seamlessly integrated in other courses and programs.

This paper adds to a limited knowledge base about the efficacy of the case method in information systems education. Though the case method has existed for several decades, there is limited research on the effectiveness of this instructional method, particularly in information system education. We believe that the capstone course for the undergraduate information systems major is an appropriate venue for the case method. Further, we feel that this paper should serve as a catalyst for other information systems educators and researchers to innovatively study the case method within their own instructional practices.

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Appendix: Mini-Case Example

Turnaround LLC

Janet Washington was frustrated. In her role of CIO of Turnaround LLC, a medium-sized real estate company that specialized in turning around foreclosed properties, she had promised her boss Ellen—the company's CEO—that she would have a new application to manage the rapidly growing business in place by April. It was now June and, according to the project's lead developer, Fred, completion was still two weeks away. The problem was this: completion had been "two weeks" away for the last three months! What was she going to do?

The Company

Turnaround was a participant in the residential real estate industry. Its original principals were three real estate agents whose brokerage firms had gone out of business during the collapse in real estate that occurred within Florida starting in 2008. Rather than leave the business entirely, as many of the unemployed agents within the state had done, the trio had decided to get into the business of taking properties under the imminent threat of foreclosure and packaging them for rapid sales. Their business model was to work collaboratively with both owners and lenders to achieve a compromise that was beneficial to both and then to aggressively market the properties to buyers. The major source of the company's buyers was international investors and individuals seeking vacation properties. Boosted by a combination of rapidly dropping property values, low interest rates and a declining U.S. dollar, it was often possible for these customers to acquire properties at a 60% discount from what they would have paid in 2007, at the peak of the Florida real estate bubble.

In the two years since the company's inception, it had grown from the three founders to over 100 employees. The key to success in the foreclosure industry was information. To put together a deal, Turnaround needed to be first to identify attractive properties that were likely to enter foreclosure. It then needed to contact the owners of the property to determine if they were amenable to working with Turnaround and also contact the lenders to determine if they would consider a short sale (i.e., a sale where the price paid for the property was less than the amount owed on the mortgage, meaning that the bank would need to write down its loan). Finally, the company had to determine whether or not the property was a match for any of the potential clients who had signed up for the service. When all three conditions were right, a deal could be structured. Typically, Turnaround received a 6% commission on any deal that closed, 2% paid by the seller, 2% by the purchaser and 2% by the lender. Such a commission structure was unusual in the industry—where the seller was usually responsible for the entire commission—but it was attractive for all three parties in the event of the challenging type of sale that Turnaround usually put together.

By early 2011, the time of the case, Turnaround was brokering roughly 1400 properties a year, averaging $8000 in commission from each transaction. The company had worked successfully with 11 different lenders and in six different Florida counties—a significant factor since rules for closing properties and responsibility for closing fees varied by county. To assist in the transaction volume, the company had acquired a title company in 2009 to help perform the closings. Generally speaking, Florida law, however, mandated that the purchaser have the right to choose its own title company to close a purchase sale. About 90% of purchasers chose to use the Turnaround affiliate title company. Those who chose to pick their own closing agent were required to pay a $500 consulting fee to Turnaround. The purpose of this fee was to verify the quality of the closing documents, since errors in a near-foreclosure situation could be very costly.

The MIS Department

Within a year of Turnaround's founding, the company was swamped in paperwork. Since none of its founders had an MIS background, all their processes had been manual. They did use the computer—e.g., to do their bookkeeping, to search county records for liens on properties (often a precursor to foreclosures), to perform credit checks on both buyers and sellers, and to perform online appraisals—but their use was task-driven, with no integrated workflow. In late 2008, the company hired Janet Washington, the MIS supervisor for a local mortgage broker that was cutting staff. She developed a series of spreadsheets to help keep track of business flows, set up a wireless network to handle the multiple workstations that were being added, installed a fax server and developed the company's web site. As the company grew, however, she found that she was spending nearly all her time training new hires on how to operate the various pieces of software used by the company and on keeping the system up and running.

By mid-2010, the company decided it needed a professional developer. Fred Eccles, a recent graduate of a local MS-MIS program, had applied for the job and everyone had been impressed by his "can do" attitude and his easygoing personality. His first month on the job, he successfully installed a Microsoft SharePoint server that was then used as a portal for document tracking and business process management. The installation was major success, allowing individual agents to identify and qualify potential buyers/sellers/properties 27% faster. Average turnaround time on each deal also declined from 11 weeks to 9 weeks. By December 2010, the installation was completed. By that time, Janet had another project in mind for him.

The "Turnaround Central" Project

The "Turnaround Central" project was originally based on something that Fred had read about on the Google site[1]. In November 2011, the company had introduced a product referred to as "Google Bust" that could be used to identify properties likely to enter foreclosure across the country. The product, currently in beta release (as was typical for Google), accessed county online records covering about 94% of the U.S. population (99% of Florida) and used a proprietary algorithm to assess the likelihood that they would enter foreclosure. More importantly, Google provided a free application program interface (API) that developers could embed into their code, making it possible to bring the data into the application, analyze it, then display it on a map (using another Google API for mapping). What Janet immediately perceived when Fred brought the API to her attention was that it could be the core of a new application that could be used to match client requests to suitable properties in real time. Fred further suggested that, using another API from Skype and an open source text-to-voice product, the product could be made to automatically call out to clients when a match appeared likely to determine if they were interested. In addition, he proposed that the system could be used to create and populate with data (e.g., property location, owner information, lender and mortgage facts) all the documents needed to initiate a workflow using SharePoint. This last activity alone, Janet estimated, could save the company up to 4 hours per property.

Fred, who had taken two programming courses as part of his undergraduate degree in MIS had suggested the program be developed using agile methods. Specifically, he planned to create a series of prototype applications with successively increasing functionality until a useful tool had been reached. From that point on, he planned to add features as needed. He was really excited about building the system and worked 12+ hours per day over the holiday period to develop the first prototype, intended to demonstrate the interface. Janet and her boss, Ellen Sanchez, had been

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1 Note: The "Google Bust" product described is fictional and is introduced solely for the purposes of the example case.

so impressed that the two decided to hire another MIS employee so that Fred could complete the development as fast as possible.

In February 2011, Fred had demonstrated the system using test data—a little ahead of the informal schedule. At that time, Ellen had expressed her pleasure with how things were going. She had also suggested a few more features, ones that would be easy to implement (in Fred's opinion). Since bringing in real data seemed to be a largely mechanical activity—Fred had extensive database experience from three classes in his Master's program—he had estimated two weeks to completion. Since that time, however, the project had seemed to advance in fits and spurts. Certain features, such as the generation and loading of documents to SharePoint had been implemented rapidly. Other functionality, such as acquiring data from the Google API had caused problems from the very start—the amount of data was huge and the format in which it arrived seemed to vary from county to county. The potential customer database had been successfully imported from the spreadsheet where it was stored, but it was not clear how the system would be kept up-to-date.

The Current Situation

After hearing Fred's most recent two week estimate, Janet was very concerned. In anticipation of the productivity increases expected from the system, Turnaround had been very conservative in its hiring. As a result of the delays, however, average turnaround on a property had crept up to 12 weeks. This was serious, since part of the incentive for banks to work with Turnaround was to get delinquent properties off their books quickly. Moreover, the bad real estate market was not going to last forever. If they missed opportunities now, they might be gone forever.

Meanwhile, she could see that Fred realized the issue and was working like mad to try to get the project completed. And, to be sure, he was making progress. But was two weeks more work believable? Unfortunately, there was no documentation on the system—Fred ensured her the tools he was using were self-documenting—so she was having a very hard time getting a handle on what remained to be done.

Questions

Answer the two questions. Both explanations should refer to the facts as stated in the case.

1. What is your assessment of the "Turnaround Central" project and where it now stands?
2. If you were Janet Washington, what actions would you consider taking at this point and what do you think would be your best choice?

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How To Enable Asian Teachers To Empower Students To Adopt Student-Centred Learning

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How To Enable Asian Teachers To Empower Students To Adopt Student-Centred Learning

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Abstract: Asian teachers' reluctance to empower students has been claimed to be an significant barrier preventing their students from practising student-centred learning. To promote student-centredness in Asian classrooms, this study aimed to develop strategies that could enable Asian teachers to delegate part of their authority to students. Twelve college teachers and six hundred and fifteen Vietnamese college students participated in this one-semester study. The results revealed that 'artificial' innovations such as forming group work and regularly questioning students in class did not mean empowering students in active learning. Students were only positioned and given opportunities to engage in proper student-centredness when Asian teachers were able to promote students' complex knowledge, minimize individual instruction but maximize group supervision, employing formative assessment and adopting complimentary verbal behaviours. The study strongly suggested that reformers need to take teachers' comments into consideration to design culturally appropriate strategies that could assist teachers to make real changes.

Introduction

The literature presents two main perspectives about Asian students' learning approaches. The first argues that Asian students are rote and/or surface learners (Ballard & Clanchy, 1994; Burns, 1991; Gow & Kember, 1990; Ramsden, 1992; Robertson, Line, Jones & Thomas, 2000; Samuelowicz, 1987). Freire (1993) describes this approach to learning as the "banking concept of education" which means that students are "receptacles" and "filled" with the "content of the teachers narration" (p. 1). Various researchers have argued that this approach to learning is not effective (Gow & Kember, 1990; Robertson, Line, Jones & Thomas, 2000). However, a number of studies have, in fact, shown that many Asian students are very successful at Western institutions and consistently outperform their Western counterparts on international examinations (Biggs, 1998; Jensen, Hunter, Sonnemann & Burns, 2012). Therefore, various researchers have questioned the stereotyped perception which sees Asian students as 'mindless machines' and claim that learning approaches adopted by Asian students should not be analysed and understood based on the logic of thought adopted by Westerners. Specifically, researchers supporting this second perspective (e.g., Biggs, 1998, 1996; Pratt, Kelly & Wong, 1999; Watkins, 1996; Renshaw & Volet, 1995; Tang, 1991; Gow & Kember, 1990) explain that when facing an academic task, Western and Asian students actually have the same primary goal of trying to reach understanding, but Asian students use memorisation, rehearsal and repetition as a means to achieve this goal in a distinct way – a concept which Westerners find difficult to understand. Although the use of repetition and memorisation strategies by Western students has been found to indicate a surface approach to learning, the use of these same strategies by Asian students does not necessarily indicate that they are adopting a surface approach (Renshaw &

Volet, 1995). The studies of Tang (1991) and Gow and Kember (1990) both found while Western students attempt to relate the new information to previous or other knowledge or to make sense of the new information in the light of personal or real life experiences, Asian learners only seem to understand information contained within the text, or supplied by the lecturer. They may not incorporate elaborative processes such as critically analysing the new information or relating it to other subject matter or to the real world. Unfortunately, it is lack of these critical thinking skills, in-depth conceptual understanding, real-world problem-solving abilities, and communication skills that limit Asian students in today's global economy (Darling-Hammond & Falk, 1997; Newmann & Associates, 1996; Shepard, 2000). Therefore, Asian countries have recently tried to change the traditional teacher-directed learning approach to student-centred learning practices such as active learning, collaborative learning, inquiry-based learning, cooperative learning, small group learning and project-based learning. This is because there is mounting evidence demonstrating that these learning practices can help students effectively develop the kind of knowledge and skills that Asian students often lack as aforementioned (Cooper, MacGregor, Smith & Robinson, 2000; Handelsman et al., 2004).

In attempting to achieve this change, every year Asian governments spend millions of dollars in staff development such as organising workshops and conferences to train teachers in student-centred practice. They have also funded and sent thousands of teachers overseas to learn about student-centredness. It is not an exaggeration to say that Asian teachers have been through the 'school wars' where, over the last two decades, they have faced constant demands to change not only what they are teaching but also how they are teaching. Noticeably, Asian educators and researchers tend to be interested in appropriating Western philosophies and practices instead of developing their own in the belief that this short cut could, according to Phuong-Mai (2008), enable them to skip the painfully long research stage and be able to quickly modernise the education systems.

Unfortunately, in spite of these continuous efforts, the image of Asian classrooms is still seen as passive, non-participative and teacher-dominated (Adamson, Kwan & Chan, 2000; Luke et al., 2005; Jackson, 2002; Jones, 2007). Resistance to change occurred mainly because Asian teachers often found it hard to accept Western-developed student-centred practices that possess many values contrasting with their deeply held beliefs of teaching (Phuong-Mai, 2008). For instance, the main philosophy of student-centredness is to encourage students' participatory and active learning (Dewey, 1963), empower students to think independently, construct their own knowledge and draw their own conclusions (Brooks & Brooks, 1993; Eggen & Kauchak, 2001; Holt & Kysilka, 2006; Kornell & Bjork, 2007) and develop students as critical thinkers (Shor, 1992; Brookfield, 1995). In contrast, Asian teachers are, to a large extent, still influenced by Confucian philosophy that constructs teachers as authority figures who can decide what and how students should learn. As a consequence, students should accept and follow teachers' authoritative knowledge (Brick, 1991; Jin & Cortazzi, 1995).

It is clear that Asian nations have modernised and westernised their economy and society significantly during the last century. However, there remains a significant historical Confucian legacy embedded in the mind-set of the peoples developed over many centuries. Therefore, Alt (1994) and Jia (2001) claim that many Confucian values still play dominant roles in Asian life today despite the striking inroads of modernisation and westernisation. Due to the deeply entrenched Confucian hierarchical cultures, Asian teachers are often explicitly and implicitly required to implement whatever educational reform is launched by the top whether they support it or not. This has led to the situation where many reforms have not been taken seriously by Asian teachers. Phuong-Mai (2008), for instance, found that despite continuous pressure for change in teaching, Vietnamese teachers tend to implement cooperative learning only on special occasions, for decoration, when their class has visitors (e.g., the headmaster, inspectors, their colleagues). This explains why only minor and short-

term changes in some classrooms are often seen but innovations that result in major and long-lasting change within the school organisation are rarely evident.

The ineffectiveness of many educational reforms in Asian countries during the last decade clearly demonstrates that simply importing and imposing a new practice on Asian teachers does not guarantee success. Reformers need to take teachers' voices, especially their cultural beliefs in teaching and learning into consideration. This is a 'need' because teaching and learning processes, according to Renshaw (2002), cannot be analysed in isolation from the values that are privileged in a culture at any particular historical moment. Unfortunately, the current trends in educational reforms in Asian countries reveal that educators and researchers tend to be interested only in the outcomes but do not pay attention to and take sufficient care of the impact of local cultures. This is why Ng (2009) strongly urges that reform in the Asia Pacific region (Asian nations included) must employ a more participatory and negotiated approach that allows voices of different stakeholders to be raised.

To improve the present situation, this study aimed to explore how to take the voices of Asian college teachers into consideration in order to develop strategies for them to promote student-centredness effectively. The study was guided by two main questions:

1. How effectively do Asian college teachers implement student-centred practice?
2. What strategies assist Asian college teachers to implement student-centred practice effectively?

Methodology

Design Research

The study was conducted within a design-based research methodology. Design research addresses both theory and practice – it can be summarised as an approach to educational research that regards theory as fundamental to understanding and improving practice in local contexts. It focuses on consideration of local unique contexts and treats the change process, not as a technical challenge but as a central part of the research process that needs to be investigated collaboratively with participants through cycles of planning, implementation, collection of evidence and revision. The development of the strategies in the present study was based on a thoughtful consideration of various factors including heritages of Confucian cultures, institutional constraints, and especially Asian teachers' beliefs about teaching and learning. These strategies were, therefore, not simply theoretical but demonstrably applicable.

Participants

The study involved twelve college teachers from two universities in Vietnam. The participating teachers had 1-10 years of teaching experience. All the teachers were volunteers and many regarded the opportunity to participate in the study as a way of extending their professional knowledge by learning new skills. Twelve classes consisting of six hundred and fifteen second-year students (males = 306, females = 309; mean age for males = 18.86 years and mean age for females = 18.68 years) also participated in the study. These students were from the classes of these twelve teachers. At the beginning of the study, all participants were given a consent form and explained that participation was voluntary and anonymous. Data from all sources were de-identified and the analysis was only based on aggregated data.

Context

The courses used in the study had been traditionally taught in a similar format for many years. Lectures were delivered in a standard lecture hall with slides and each student was provided with a hard copy. Usually teachers only had enough time to complete the required content of the lessons. Therefore, students' questions were not encouraged and were answered by either repeating the lecture notes or deflecting the question to a future time. In order to encourage the participating teachers to promote student-centredness, the researchers introduced them to, and then trained them in the application of different student-centred learning techniques. The study was implemented in two phases, as detailed below.

Phase 1

At the start of the intervention, a one-day workshop was organised to train all teacher participants with skills to implement basic student-centred activities such as forming small groups (size and composition), setting tasks and expectations for student behaviours, clarifying individual and group responsibilities, monitoring both the process and outcomes of the group experience and how the teachers should perform their roles in student-centred learning classes. Depending on the nature of each lesson, the teachers could intersperse lecturing with different student-centred activities. The teachers were introduced to and instructed in the use of the main student-centred activities as follows.

- Multiple-choice tests: The teachers prepared short multiple-choice tests that covered content of and beyond each lesson. The students were asked to work in small groups to complete the tests after each part of the lesson or at the end of each lesson. This aimed to test their conceptual understanding.
- Questioning formulation strategy: Whenever the students worked on the readings, they were required to work in small groups. Group members helped each other to understand the readings not simply by summarising a set of facts given in the text but by formulating a set of questions about the text. The students were encouraged to formulate as many clear questions as possible including both questions from within the text and questions that were related to the text but were not discussed in it.
- In-class questions: The teachers posed a more general question to the class and asked the students to discuss this with their group members before the teachers solicited responses from several groups.
- Journal article discussion: On some occasions, the teachers devoted an entire class period to discussing a recent relevant journal article, which the teachers had provided for the students to read prior to class with a specific set of questions to answer.
- Case studies: After covering the key concepts of the chapter, the students read cases from the textbook, then worked in their groups to discuss the case using the questions provided. This was followed by a whole-class discussion.
- Student presentation with class discussion: The students prepared a term paper in groups, then gave a class presentation. The students were encouraged to foster a class discussion as 20% or 30% of their presentation assessment depended on their class discussion stimulating good questions as well as answers.

Data Collection Methods

Audiotapes

The teachers and two focus groups in each class were audio-taped for the full class period three times during the second half of each phase. This aimed to identify how the teachers interacted with their students and how students interacted with each other and with the teachers during lessons.

Observations

Observations were undertaken of all participating teachers and the two focus groups in each class. The teachers and the focus groups were observed once per week by the researcher and an assistant for a period of 30 minutes. Two groups were chosen from each classroom for audiotapes and observations as Gillies (2006) has shown that it is possible to obtain a representative sample of the students' discourse across classes by sampling the discussions of two groups from each class.

Analysis

Audiotapes

Students Verbal Behaviours

The students' verbal behaviours were identified on a schedule adapted from Cohen and Intili (1982). The schedule identified eight categories of the students' verbal behaviours: task-related talk (i.e., talking about their work; responding to the teacher's question); non-task related talk (i.e., talking about their families); engages with others around the topic (i.e., affirming another student's response); interrupts (i.e., using negative disruption to the discussion); short responses (i.e., using unelaborated responses); elaborations (i.e., providing detailed help including reasons and justifications); questions (i.e., asking each other tentative, challenging, open and closed questions); and directions (i.e., guiding each other's new ideas). Students' verbal behaviours were coded according to frequency across the recorded group session. A total of 96 h of students' verbal behaviours was collected across the two phases. An assistant, who was experienced in coding discourse, coded a common 6 h of students' verbal behaviours and inter-rater agreement was 100%.

Teachers' Verbal Behaviours

The teachers' verbal behaviours were identified based on a schedule adapted from Cohen and Intili (1982) but modified to suit the purpose of this study. The schedule identified five categories of the teachers' verbal behaviours including demonstrating control (i.e., instructing and directing); extending the activities (i.e., explaining the current lessons and giving comments on students' previous work and skills); disciplining (i.e., controlling students' behaviours, reprimands directed at students); mediating learning (i.e., using questions to challenge and scaffold children's learning); encouraging (i.e., praising students). These categories of verbal behaviours were coded according to frequency across recorded class session and represent 100% of each teacher's talk during that session. A total of 36 h of teachers' verbal behaviours was taped across the two phases. The same assistant (as mentioned previously) coded a common 3 h of audiotape. When there were any coding disagreements, the assistant and the researchers reviewed their coding until there was 100% agreement.

Observations
Student Observations

Observations were only applied to two focus groups in each class. The observation schedule was adapted from Gillies and Haynes (2011) to measure Behaviour States. The schedule contained four Behaviour State categories: working with other students (i.e., talking with or listening to other students); individual on-task behaviour (i.e., working alone on task); off-task behaviour (i.e., not either participating in group activities or working individually); and waiting for the teacher (i.e., either raising hands or calling the teacher for help). These behaviour patterns were coded for frequency and the frequency was converted into percentage.

Teacher Observations

The observations aimed to count the number of different individuals contacted by each teacher during each 30-min period and the language used by the teachers in speaking to those individuals.

Results
Audiotapes

Teachers' verbal behaviours were coded and the frequency of each type of verbal interaction is presented in Table 1.

Behaviours	n = 12 Total
1. Demonstrating control	28
2. Extending the activities	8
3. Disciplining	15
4. Mediating learning	22
5. Encouraging	14

Table 1: Frequency of teachers' verbal behaviours in Phase 1

Similarly, verbal behaviours of the students were coded and the frequency of each type of verbal interaction is presented in Table 2.

Behaviours	n = 120
	Frequency
1. Task-related talk	74
2. Non-task related talk	29
3. Engages with others around the topic	59
4. Interrupts	38
5. Short responses	29
6. Elaborations	19
7. Questions	21
8. Directions	27

Table 2: Frequency of the students' verbal interactions in the focus groups in Phase 1

Observations

Behaviour patterns of the students were coded for frequency and the frequency was converted into percentage as presented in Table 3.

Behaviours	n = 120
Working with other students	45%
Individual on-task behaviours	30%
Off-task behaviours	11%
Waiting for teacher	14%

Table 3: Percentage of behaviour states of the students in the focus groups in Phase 1

More Autonomy

On the surface, it was, in general, seen that the teachers tried to employ different discussion practices and active tasks. For instance, in each lesson the students were asked to do a range of group practices such as gauging each other's understanding of the readings via a set of questions and discussing how to formulate the questions correctly and how to find information to answer peers' questions. It appeared that these activities helped the students work cooperatively with each other well because the observation findings showed that the students had 45% of their behaviour states classified as "working with other students". This was the highest percentage compared to other states. The teachers also tried to reduce lecturing by interspersing different techniques to mediate the students' learning. For instance, instead of lecturing the whole class, the teachers sometimes asked the groups to take a turn to present the readings in front of the class as a formal presentation, then challenged the presenting group by posing complex questions. When the presenting groups could not answer questions raised by other groups, the teachers jumped in to help by giving the presenters useful hints to find the answers. After each part of the lesson, the teachers reinforced the students' understandings by summarising key ideas. The teachers were involved in many mediating learning behaviours as shown in the audiotaped findings which revealed that the teachers had 22 behaviours classified as mediating the students' learning. This was the second highest number compared to other behaviours.

However, after undertaking a deeper investigation into all verbal interactions and behaviours, the researcher found that in Phase 1 student-centredness had not actually been adopted and applied appropriately by both the teachers and students. There were two points

in particular which demonstrated this argument. The first was that the teachers had not truly changed their authoritative teaching style and empowered students to engage in the learning process as active and independent learners. The second was that the teachers did not extend the students' activities and promote higher-order knowledge.

The Teachers Still Performed Authoritative Teaching Styles

There was, in fact, no dramatic change in teaching and learning activities. It was still textbook-based and the teachers dominated the process. The teachers followed the same format in every lesson: explaining and illustrating the new lessons, setting exercises, leading the students to complete the tasks in the textbook, guiding the pace and content of each activity and finishing lessons. When working in groups, the students were often required to review those sections that they had learned and had been explained by the teachers with the main purpose of helping them memorise the text better. The teachers and students did not intend to use student-centred learning activities as a tool to promote the students' creative and high-level knowledge. This contrasts with philosophies and principles of student-centredness that aim to encourage students to develop their own knowledge, and encourage them to become creative (Eggen & Kauchak, 2001; Holt & Kysilka, 2006; Kornell & Bjork, 2007).

Furthermore, in many cases the teachers thought they did use student-centred practice to gauge the students' deep understanding but they actually did not. The scenario below was an example.

Scenario 1: In one lesson, Mrs Lan, a history teacher, was talking about the topic "Problems of the overwhelmed importation of products made in China in Vietnam". She told the class "These days we see products made in China everywhere in Vietnam. This phenomenon has both advantages and disadvantages. Discuss with your group and list three advantages and three disadvantages. Then, explain why?" In this case, the teacher thought the students were asked to develop their complex knowledge by answering the question "Explain why?". However, this question actually did not adequately promote students' inquiry learning because all groups had almost similar reasons. They all listed three main advantages and the reasons as 'cheap' (because Chinese products are often half price compared to Vietnamese ones), 'attractive' (because Chinese products are nicely designed and colourful), and 'convenient' (because Chinese products can be bought anywhere). Three main disadvantages of Chinese products and the reasons were: (1) Vietnamese products sell slowly because the Vietnamese tend to use goods made in China; (2) The Vietnamese are betrayed because of low quality Chinese products; and (3) Many Chinese foods are unhealthy. After the first two or three groups presented their products, the other groups appeared bored and simply said "We had similar ideas". Then, the teacher moved to the next topic. Obviously, the teacher thought she was using inquiry-based learning but she actually only stopped at scaffolding the surface level because the case given was not challenging enough to encourage the students to adopt an inquiry thinking process. The students were implicitly 'guided' to give nearly uniform answers.

The domination of the teachers in the learning process was also reflected by the high number of instructing and directing verbal behaviours performed by the teachers (28 behaviours – this is the highest number compared to other verbal behaviours). Compared to "encouraging verbal behaviours", surprisingly the teachers used instructing and directing verbal behaviours at twice the frequency than they praised and expressed spontaneous emotion to encourage the students. This finding agreed with the results of a study conducted by Gillies (2004a) who found that when teachers engaged in a large number of lecturing and disciplinary verbal behaviours, they often used fewer encouraging and mediated-learning behaviours and vice versa.

When observing in the class the researchers found that, because the teachers were the only ones who taught new knowledge and chose the right answer, the students seemed very dependent on the teachers whenever they faced a problem. They always waited for the teachers to come over to confirm their choice of difficult multiple-choice questions, to be a referee if their group had conflicts, to evaluate information if some group members presented new information and to model the solving process for a problem. This was why the observation findings show that 12% of the students' behaviour patterns involved "waiting for teacher" behaviours. The hierarchical authority that the teachers exerted over the students was also seen through the way the teachers responded to the students. Whenever the students raised questions or expressed their own opinions, the teachers seemed willing to listen but rarely encouraged the students to explore the answers themselves. The teachers often adopted a variety of strategies to get the students to follow their decisions. For instance, when the teachers talked, the students mandatorily stopped all they were doing to listen to the teachers. When the students expressed their own ideas or offered a new way to solve a problem, the teachers listened but then further advised them to follow the standard formats that would be used in exams.

Below is an exemplary conversation between the teacher and a student. Although the teacher complemented the students on working out a creative strategy, she eventually steered the student to the conventional technique to deal with the exam.

> The teacher (T): Would you think the text could be understood more easily if they are summarised via dots?
>
> The student (S): I've tried to present it by a graphic that could show the numbers very nicely and clearly. You can see.
>
> T: Fantastic: I never thought that you could find this way. However, if you take an exam, you need to think about whether you have enough time to draw a graphic.

In summary, although the teachers did appear to promote the students' autonomy, they were still the main instructor who decided almost all learning activities in the class. The students did not have much power when choosing what they liked or disliked doing. Such an authoritative teaching style prevented the students from actively engaging in the student-centred learning process significantly. Prince (2004) and Di Vesta and Smith (1979) claim that the defining feature of active student-centredness is to promote thoughtful engagement on the part of the student and enable students to develop deep understanding of what is learned; simply introducing activities into the classroom and requiring students to practise does not mean active student-centred learning has been implemented. If the students were limited to only learning facts and low-level knowledge, they could do this, even do better, in Asian traditional teacher-centred classes because one of the main purposes of teacher-domination lecturing is to train students with skills of mastering the content and recalling facts (Pratt, 1992).

The teachers did not extend the students' activities and promote high-level knowledge

One of the main principles of student-centredness is to give students opportunities to teach and share information with each other, which enables them to not only review the current lesson but also achieve deeper understanding and gain new knowledge (Alexander, Daffinrud, Lewis & Millar, 1995; Biggs, 1999; Dole & Sinatra, 1998). Johnson and Johnson (1999) even claim that cooperative learners can exceed the teacher's knowledge if they work in cooperative learning groups effectively. Therefore, the researcher expected that the teachers could stimulate the students to develop complex knowledge by extending their activities. This could be achieved by challenging students with argumentative, comparative and analytic questions or scaffolding their ideas by reminding them about prior knowledge or simplifying tasks and then encouraging them to develop explanations of and connections

between new and previous information. To achieve this expectation, before each lesson the researcher and the teachers worked together to prepare a list of complex questions which would provoke further inquiry by the students.

However, the result showed that the teachers rarely used these comprehensive and extended questions to scaffold the students' ideas. Specifically, the teachers had only 8 verbal behaviours classified as "extending the activities". This was the lowest number compared to other verbal behaviours. This may have happened because all teachers spent a lot of time moving around the classroom to answer individual students' questions and solve group conflicts. Whenever the students had a problem (i.e. getting stuck with a question, being confused about the ideas presented by their partners), they raised their hand to call the teacher. To respond to all students' inquiries, the teachers often responded to each student very abruptly and quickly by telling them facts or directions but not challenging them with complicated questions. After reviewing the audiotape transcript of a lesson, the researcher found that half of the interactions between the teachers and students were over in less than 10 seconds. To have enough time to answer the students' questions, the teachers also rarely followed the original procedures of student-centred activities properly. Instead, they tended to either override or simplify time-consuming activities. For instance, they rarely gave groups enough time to have long and thoughtful discussions.

The teachers explained they needed to limit the time spent on students' group work and questions because they must complete the curriculum to prepare the students for upcoming exams. No matter what and how the teachers taught, they needed to complete the textbook because all exams were based on these textbooks. There was no occasion during the lessons observed where the students had any choice of the content, and most of their work, including topics for group practice, was drawn directly from the textbooks that are published by the Ministry of Education and Training. Asian teachers' reputations are often measured by their students' success on textbook-based exams (Pong-Wing-Yan & Chow, 2002; Phuong-Mai, 2008; Gow & Kember, 1990; Morris, 1985). Therefore, to ensure everyone understood the lessons accurately and could provide the correct answers on the exam, the teacher found that a quick way was a 'right answer' approach. This explained why they often quickly told the students the right answers instead of allowing them to work it out for themselves. It seems that the learning concepts in Asian nations are still contained in the Confucian classics, which are "studied, memorized, and then expounded at the examinations" (Hu, 1960, p. 412).

To summarise, in Phase 1 although student-centred activities were brought to the classes, the teachers and students had not actually been involved in these practices effectively. To improve this situation, at the start of Phase 2 the researchers organised the second workshop. The main purpose of the workshop was to create opportunities for the teachers to discuss the problems facing them in Phase 1 and develop ways to work out strategies to solve these problems. The researchers also brought to the workshop comments that the teachers and students raised in informal conversations during the course. In general, the main issues considered were how to enable the students to be more engaged in the learning process and how to develop their higher-order knowledge. Both the researchers and the teachers discussed with each other thoughtfully and endeavoured to make use of each other's strengths. Specifically, the researchers introduced the teachers to effective strategies reported in the literature. In return, the teachers worked out solutions that they thought were feasible in a real-life context based on their teaching experience. The researchers specifically pointed out and analysed situations in which the teachers had not incorporated student-centred learning techniques effectively in Phase 1 and discussed with the teachers how to deal with similar situations Phase 2 more democratically. To ensure the teachers could apply the change, the researchers used the teachers attending this workshop as a real class and asked them to practise newly-developed techniques. In sum, the main strategies developed and brought to Phase 2 are:

1. To promote the students' deep and complex knowledge, the teachers tried to limit giving direct and detailed instruction but maximise scaffolding the students' responses and facilitating group discussions. To make this change, the teachers needed to move from supervising individuals to instructing groups because such a movement would give them more time to create tasks and activities that could gauge the students' complicated knowledge. The researchers employed this logic because, as discussed in Phase 1, the teachers tended to design only those tasks and activities that mainly required factual and recalled knowledge because they were developed easily and quickly. In their Phase 1 observations, the researchers found that the teachers wasted a lot of time supervising the students individually. The analysis of audiotaped lessons reported that the teachers rarely used "các em" (plural noun 'you') but mostly used "em" (single noun 'you') when responding to the students. This indicates that the majority of their interactions took place with individual students but not with a group.

2. To give the teachers more time to develop activities that could promote the students' higher-order knowledge, the students were instructed to develop complex questions by themselves to challenge each other instead of passively receiving these questions from the teachers as happened in Phase 1. Specifically, they were asked to apply the Think-Tel Why (King, 1997) with five types of questions including review questions, probing questions, hint questions, intelligent-thinking questions, and self-monitoring as they took turns questioning each other during group discussion. This strategy also aimed to assist the students to develop their argumentative, analytic and comparative knowledge and become more active in the learning process.

3. The students were not allowed to approach the teachers whenever they wanted. They were told that they first needed to engage in thoughtful discussion with each other in their group on any topic given. If the whole group could not solve the problem, a group member (working as a secretary) took note of the problem. Then when the teacher came over to help, the teacher randomly appointed a group member to present the problem out loud. This requires all group members to share information equally and work with each other wholeheartedly to ensure that everyone understood the group discussions and problems. This ensures that any randomly-called member could be able to answer the teacher's questions. This practice requires the students to study independent of the teacher. This technique also helped give less able students a greater opportunity to improve their understanding by actively engaging in group discussions. This idea was supported by Vygotsky (1978) who claims that participating in social interaction only, via watching or observing passively, does not help improve cognition as much as actively representing thinking/ideas in language. The crucial step which students need to take in order to develop independent intellectual functioning is to use speech as a means of making sense of experiences with other participants (Renshaw, 1992).

4. To encourage and condition the students to adopt more active and deeper learning practices, assessment practice was also redesigned. Specifically, instead of using only one end-semester assessment as initially planned, formative assessment practices like short essays and group projects were incorporated during Phase 2. These practices aimed to gauge the understanding level of the students, and also to provide opportunities for discussion and peer instruction. Importantly, these formative assessment practices were seen as preparation for the final exam because their content was closely related to what would be tested. Therefore, it was expected that the students would perform on the final exam better after they practised these formative assessment practices. In this way the teachers and students were encouraged to see assessment as a tool to promote on-going learning but not a method to evaluate the final outcomes.

5. Last but not least, the teachers were also encouraged to use more complimentary verbal behaviours. This was considered necessary because Turner and Patrick (2004) emphasised that teachers' encouragement and support had a great influence on students'

patterns of participation. In the Asian context, this type of verbal behaviour could have an even stronger effect on students because there was evidence showing that Asian students are very much influenced by teachers' appraisals. For instance, Niles (1995) claims that social praise might be the most potent force that could motivate Asian students to maximise their efforts to achieve better outcomes. This implies that to encourage students to be more involved in their own learning process, teachers should use verbal praises frequently. Ironically, in Phase 1 the teachers used only 14 encouraging verbal behaviours. This was the second smallest number compared to other types of verbal behaviours. Therefore, in Phase 2 the teachers were advised to compliment the students more frequently. If the teachers provided a high level of complimentary appreciation of the student's self-learning work, they would also be willingly delegating part of their authority to the student. This is a crucial prerequisite to promoting student-centredness

Phase 2

Procedures

Entering Phase 2, all teaching and learning activities were designed in the same format used in Phase 1 but involved changes as discussed above.

Results

Audiotapes

Verbal behaviours of the teachers were coded and the frequency of each type of these verbal interactions is presented in Table 5.6.

Behaviours	n = 12 Total
1. Demonstrating control	18
2. Extending the activities	28
3. Disciplining	12
4. Mediating learning	35
5. Encouraging	22

Table 4: Frequency of teachers' verbal behaviours in Phase 2

Verbal behaviours of the students were coded and the frequency of each type of these verbal interactions is presented in Table 5.7.

Behaviours	n = 120 Frequency
1. Task-related talk	70
2. Non-task related talk	20
3. Engages with others around the topic	77
4. Interrupts	25
5. Short responses	23
6. Elaborations	27
7. Questions	18
8. Directions	20

Table 5. Frequency of the students' verbal interactions in the focus groups in Phase 2

Observations

The students' behaviour patterns were coded for frequency and the frequency was converted into percentage and is presented in Table 5.8.

Behaviours	n = 120
Working with other students	70%
Individual on-task behaviours	8%
Off-task behaviours	16%
Waiting for teacher	6%

Table 6. Percentage of behaviour states of the students in the focus groups in Phase 2

Changes on the Teachers' Side

In general, the pattern of interactions that emerged made it clear the teachers engaged in more verbal behaviours which are generally regarded as helpful and supportive of group endeavours than they did in Phase 1. They had more time to listen and observe the students' discussions and used various techniques to extend their activities. The teachers paid particular attention to connecting the content of the current and previous lessons, challenging the students' questions to enable them to find their own answers, and giving the students hints to develop and challenge each other with complicated questions. It was a surprise to see a dramatic increase in "Extending the activities" verbal behaviours that the teachers performed in Phase 2 (28 in Phase 2 compared to 8 in Phase 1). Similarly, the teachers' mediating learning and encouraging verbal behaviours also increased markedly in Phase 2 (from 22 in Phase 1 to 35 in Phase 2 and from 14 in Phase 1 to 22 in Phase 2, respectively). It was very nice to see that the teachers created a very different studying atmosphere. They complimented the students very frequently by encouraging words that were never or rarely seen in Phase 1. Some samples of these words were "*Good. What you are saying shows that you've got what I said*", "*Yeah. That's what I am looking for*", "*You see you've discovered a couple of things that the author figuratively implies and only smart readers could understand*". Galton et al. (1999) and Mercer et al. (1999) claim that the use of such language is important for learning because it enables ways of scaffolding dialogues so that students learn to engage with others on the issues at hand. By contrast, the teachers' verbal behaviours involved fewer controlling and disciplining verbal behaviours (18 in Phase 2 compared to 28 in Phase 1 and 12 in Phase

2 compared to 15 in Phase 1, respectively). The researchers also found that when the teachers used mediating-learning and encouraging verbal behaviours, their manner and tone became very soft, friendly and personal. The teachers often smiled and joked with the students when listening to their answers.

Importantly, in Phase 2 the observations provided some indications that the teachers were willing to empower the students to develop their organisational ability. They no longer ran around to manage group conflicts and answer the students' questions. Instead, before group tasks, the students were clearly instructed in what they needed to do and the teachers only examined the final product provided by the group leader. The researchers had several informal talks with the teachers during the lesson breaks and knew that the teachers had started to realise that to gauge the students' high-level cognition, they should only focus on facilitating the students' understanding and reduce their involvement in such tasks as controlling groups and dividing and assigning tasks to group members.

In general, although the students were still mainly required to follow the tasks designed in the textbook instead of choosing their own, changes in the teachers' practices did appear to promote the students' autonomy. Littlewood (1999) claims that by this method the teacher has given students a sense of "reactive autonomy" that "does not create its own directions but, once a direction has been initiated, enables learners to organise their resources autonomously in order to reach their goal" (p. 75). Interestingly, to encourage the students to improve each other's work, the teachers strongly encouraged critical judgments. They even gave bonus marks to those individuals and groups who provided most high-quality feedback. This action reflected a significantly radical change because as Pratt (1992) and Saito and Fujita (2004) claim that criticism is traditionally not encouraged in Asian classes.

Changes on the Students' Side

It was interesting to see that the students' language patterns also underwent significant change. Their verbal behaviours involved fewer behaviours that are seen as unsupportive of group discussions. Specifically, the students reduced questioning, short responses and interrupting verbal behaviours (from 21, 29 and 38 in Phase 1 to 18, 23 and 25 in Phase 2, respectively). In contrast, they increased elaborative verbal behaviours from 19 in Phase 1 to 29 in Phase 2. These behaviours are generally seen as evidence reflecting effective and productive interactions among group members. It appeared that the change in the students' verbal behaviours might have partially emerged from the types of reciprocal interactions that the teachers adopted when interacting with the students. Palinscar and Brown (1988), Palinscar and Herrenkohl (2002) and Gillies (2006) noted that when teachers use strategies and questions to encourage students to develop deep understandings about an issue, students will need to use complex knowledge like argumentative, elaborative and analytic skills to find the answer. According to the authors, the teachers' mediated-learning interactions may have triggered similar responses in the students so they learned through social modelling to provide more explanations and detailed responses to other students' requests for help or their perceived need for help.

The observations also revealed that there was a marked change in the students' behaviours reflecting that the students used each other as a studying source rather than entirely depending on the teachers. In detail, they had a marked increase in behaviours classified as "Working with other students" (from 45% in Phase 1 to 70% in Phase 2). In contrast, "Individual on-task behaviours" categories decreased (from 23% in Phase 1 to 8% in Phase 2). Surprisingly, the regulation forcing students to work with each other before seeking assistance from the teachers seemed to have a very influential effect on the students as, compared to Phase 1, the students engaged in only half the number of "Waiting for teacher" behaviours (6% in Phase 2 compared to 12% in Phase 1). It was noted that the students' off-

task behaviours in this phase slightly increased (16% in Phase 2 compared to 11% in Phase 1). This increase may have occurred because in this phase the students were not allowed to approach the teachers for help as an individual but needed to do this as a representative of his/her group. Therefore, there were many moments when some groups could not work out their joint agreement, they started having some chats as a short rest while waiting for the teacher.

Discussion and Conclusion

To implement student-centredness in Asian classrooms successfully, there must be changes at different levels. Of ultimate importance, the teachers' willingness and ability to change their teaching conceptions and classroom practices in order to adopt a student-centred approach is crucial in mediation and bringing about success in constructivist learning reform. This is because, as Richards (1998) claims, what teachers think and believe determines all the activities and actions they perform in the classroom. Hence, to promote student-centredness, the key issue that reformers need to address is how to assist Asian teachers to shift their beliefs and conceptions from seeing learning as a process of regurgitating information given in class, on tests, quizzes and from what the teacher says (Freire, 1993) to viewing learning as a process of promoting critical thinking and emancipatory learning. Brookfields (1995) explains that when teachers are able to make this shift, they will encourage students to explore new understanding and find their own way to control their own learning process. This change is crucially important to developing deep learning. Sharing a similar point of view, Smyth (1993) claims that to make the change, teachers should and need to engage in reflective practice. This is a process where teachers empower students to give their voice to the reasons that lie behind what they do.

Beliefs are comparatively static, and the core of these beliefs can be difficult to change, but not impossible (Nespor, 1987; Peacock, 2001; Raths, 2001). An effective approach that could help and enable teachers to change their thoughts and actions in teaching and learning, according to Freeman (1999), is to participate in teacher-training courses. Freeman found that teachers' instructions can be influenced by teaching methods learnt through their teacher-training course. This occurs because teaching is not simply following a recipe. When teachers are introduced to a new method, they may have different views on a method and consequently make necessary changes to improve their teaching. This view is compatible with the concepts described in Vygotsky's cultural-historical theory. Brookfields (2011), for instance, argues that both teachers and students can be taught to become critical thinkers when they are instructed with techniques of how to achieve this. In his book, Brookfields has also provided various techniques to train learners to become critical thinkers in various disciplines.

In Vietnam and many other Asian countries, assisting teachers to know about and becoming familiar with student-centredness in training workshops is an optimal method because instructions and guidelines for the use of student-centredness in these countries are often lacking in both quantity and quality (Phuong-Mai, 2008). However, as aforementioned elsewhere in this paper, despite the huge efforts Asian governments have put into training their teaching staff at hundreds of workshops, the traditional teacher-centredness in Asian classrooms has not changed much.

The findings of the present study revealed that simply placing teachers in workshops, teaching them the new practice and then requiring them to transfer it to their students did not guarantee any change because what is said in papers is often inadequate in preparing the teachers for the reality. Training workshops should not be organised only once at the beginning of each intervention to teach the teachers the new practice. More effectively, several workshops need to be held during the implementation process to create opportunities

for teachers to speak out and discuss difficulties facing them. Then, techniques that could help teachers adjust their practices in a culturally appropriate way must be developed. This aims to keep teachers interested in carrying out the reform.

For instance, in Phase 1 although the participating teachers were required, and agreed, to reduce their lecturing and adopt student-centred learning practices, they did not actually change their role as the authoritative knowledge provider. This problem occurred because the teachers were unable to change their traditional concepts that the students were far from self-sufficient in their learning and that they needed to depend upon the teachers in their quest for knowledge. Consequently, the teachers tried to "spoon-feed" the students with the right answers by busily running about the class to answer every single question that the students raised. If the teachers were consistently required to change this authoritative supervision habit, they were very likely to withdraw from the study (meaning reject the reform). To avoid this problem from happening, the technique in Phase 2 was to assist the teachers to move from supervising individuals to facilitating groups. The teachers were also assured that they could engage in making a decision if group members could not reach a consensus (this technique showed the teachers that all their power had not been removed). The results obtained in Phase 2 demonstrated that the teachers were happy with this adjustment and subsequently delegated more authority to the students.

Similarly, when the teachers were asked to apply and develop complicated activities to promote the students' high-level knowledge, they did not comply because they realised this task was not mandatory but was very time-consuming. From their point of view, it was more important to focus on completing the curriculum to help their students deal with coming exams. To solve this problem, the researchers provided precise instruction to the teachers, providing techniques to create complex questions which the students could use within their group to gauge their deep knowledge. This technique could give the teachers more time so that they could develop comprehensive tasks to extend the students' activities. Bloom's Taxonomy indicates that this technique provided the students with a good opportunity to practice and develop their complicated knowledge. Unfortunately, organising workshops to train teachers or help them remove barriers emerging during the implementation process is often difficult because this activity requires funding, time, appropriate infrastructure and material and intellectual sources.

As underpinned by design-based research, in the present study more formal workshops and meetings should have been organised so that the researchers and the teachers could cooperatively work out timely solutions to solve problems occurring during the intervention process. This would then have helped the teachers and students deploy student-centred practices more effectively. However, the teachers' workload did not allow them to meet more regularly. This was a limitation this study owned.

Finally, findings of the present study revealed that to influence Asian teachers to adopt student-centredness, reformers also need to pay attention to the impact of assessment on the new practice. Results in Phase 1 reported that the teachers did not pay much attention to group activities because they wanted to spend time completing the curriculum to prepare their students for exams. This was a 'must' because in Asian countries teachers' success is often measured by their students' exam scores and grades. 'Good' teachers still need to ensure that students will perform well in examinations. Chan (2001) claims that in Asian classrooms constructivist teachers' views of qualitative gains in understanding and intrinsic interest in the subject must also include the condition that their students do not fall behind in examination results. This was why many Hong Kong teachers acknowledged learning facilitation was essentially constructivist but most of them still adopted an examination preparation teaching concept (Tang, 2001). Watkins and Biggs (2001) and Wong (2003) explain Asian teachers tend to make this safe choice because at the end of the day, despite all of the sweet talking of educational ideals and instructional inventions, what administrators, parents, and even officials that advocate for education reforms are really concerned about are

students' exam results. And teachers know it very well. Students know it well, too. Asian students have been well recognised as being highly alert to teachers' cues and examination requirements that may lead to achieving high scores (Biggs & Watkins, 1996). Students are very sensitive to what they perceive as teachers' 'real' demands. If teachers' 'real' demands are to complete the curriculum to prepare them well for exams in order to get high scores, they will focus on finishing the required lessons first no matter what other learning practices teachers ask of them.

These are two exemplary techniques the present study attempted to develop to enable the teachers to adopt student-centredness properly and effectively. Such techniques were powerful in terms of keeping the teachers interested in implementing the reform. Findings of the present study once again demonstrated that to encourage and persuade Asian teachers to implement the reform, reformers should not simply impose the new practice on teachers and students. It would certainly be more effective and culturally appropriate if reformers and researchers could investigate what prevents the teachers from implementing the reform, then develop strategies to enable them to overcome the barriers. This would require frequent negotiations among and mutual support of people at different levels of the implementation process.

Finally, despite the contributions the study has attempted to make, the study faced several limitations. First, the participating teachers were only officially trained in two workshops. Such short training barely helped the teacher participants familiarize themselves with basic student-centred learning principles and activities. Second, the study recruited participants from colleges in the South of Vietnam. Hence, the results obtained may only correctly represent the southern part and not suitably represent other parts of the country. This is because Vietnam is characterised by cultural differences in different parts of the country – the South, Central and North. In reality, these three parts own many different cultural characteristics including daily practices, beliefs, languages and ways of working. Finally, the study used Vietnam as a case study to represent other Asian countries. While many Asian countries share the same predominant Confucian cultural values, these cultures have now changed to different degrees subject to social, cultural, economic and political developments in each part of the country. Consequently, the empirical findings in this study may not always apply to other Asian contexts. This is a gap that future research should fill. More studies should be conducted to investigate the extent that findings of this study can generalise.

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An Investigation of Saudi English-Major Learners' Perceptions of Formative Assessment Tasks and Their Learning

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Abstract

The effect of standardised and summative assessment on teaching and learning has been explored in various settings. Formative assessment or classroom assessment, however, has not captured considerable attention of washback researchers. The prime goal of the inclusion of formative assessment in the assessment regime of a curriculum is to allow learners to grow as independent learners. This study investigated if learners' perceptions of formative assessment tools influenced their learning strategies, the scope of what they learned, and the depth of their learning. The results of a survey, distributed among 400 Taif University English-major female learners (TUEMFL) showed that the respondents preferred formative assessment tasks to comprise expected questions in the form of multiple-choice questions. In addition, formative assessment tasks narrowed down the scope of the syllabus the learners studied. However, the participants deemed formative assessment helpful in diagnosing and improving their mistakes. Therefore, it is suggested that the nature formative assessment tasks should synchronise with their course objectives to help learners improve their academic skills. This may mean that the assessment tasks should be more authentic in nature and should have a greater consequential validity replacing the multiple-choice questions which often culminate in surface-level learning.

Keywords: formative assessment, learners' perceptions, learning strategies, washback

1. Introduction

Universities in Saudi Arabia use formative assessment along with its summative counterpart to assess their learners' performance during a course. The reason why formative assessment or small scale tests become a part of the assessment component of a curriculum is that they help learners know how far they have achieved the objectives of a course and where they have to be by the end of the course (Black & William, 1998).Therefore, the basic purpose of formative assessment is raising the standard of learners' learning by helping them know their progress and improve themselves where needed. However, the situation is not that straightforward as it might appear on paper. There are factors that might hinder learners' successful learning despite the presence of formative assessment in a curriculum. This study attempted to investigate the factors that tended to minimise the positive effect of formative assessment in the context of Taif University, a public sector university in Saudi Arabia.

2. Literature Review

Washback studies have been conducted in various settings investigating the influence of tests on teaching, learning, and even learning materials, e.g., Sri Lanka (Wall & Alderson, 1993), Japan (Watanabe, 1997, 2004), UK (Green, 2006a, 2006b, 2007), Australia (Burrows, 2004), Canada (Saif, 2006), Greece (Tsagari, 2009), China (Chu & Gao, 2006), Hong Kong (Cheng, 2004), New Zealand (Hayes & Read, 2004), US (Stecher, Chun & Barron, 2004). One feature shared by all these studies has been their focus on the washback of high-stakes or standardised tests such as IELTS, TOFEL, university entrance examinations, and school-leaving certificates etc.

Previous research indicates that tests may have either positive or negative effect on teaching and learning, or even both depending on the nature of the tests and their tasks. For instance, if a test is poor it will have an undesirable effect on both teaching and learning (Alderson & Wall, 1993). In addition, they are of the view that tests will affect the way learners learn and the depth of their learning. Nonetheless, like Cheng and Curtis (2004)

they have argued that language tests are known, especially for their negative effect on teaching and learning which is called negative washback.

Washback literature shows that the way learners are assessed drives their learning strategies. However, the difference in the degree and depth of the influence of how different assessment tasks shape students' learning strategies may vary. Irrespective of the difference in the degree and depth of the effect, it surfaces clearly from the available body of washback literature that assessment methods bear a strong effect on how learners learn (Alderson & Wall, 1993; Saif, 2006; Green, 2007; Gijbles, Sergers, & Struyf, 2008). However, most of the available washback studies have investigated the effect of standardised tests on teachers and learners and very little has been explored about the influence formative assessment, particularly on learners (Watanabe, c.f. Newfield, 2005, p. 7)

Formative assessment, according to Lynch (2003), implies decisions being made concerning the progress and needs of students in a language program to determine what elements of the program are working well and what needs to be modified. Black and William (1998) have stated that formative assessment is a crucial component of classroom work. They have argued that improved formative assessment can raise the standards of learners' achievements and serve more as a teaching and learning tool rather than merely assessing learners' achievements. In addition, effective formative assessment serves as one of the best means to enhance the quality of an educational system (Sadler 1989, c.f. Gijbles & Dochy, 2006). The open secret of all such quality improvement is the feedback given to students about their progress, i.e., informing them about where they are and where they have to be, which allows them to be better self-regulated learners eventually (Sadler, 1998; Assessment Reform Group [ARG], 2002).

Formative assessment can successfully serve all educational settings provided that it is used diligently (Black & William, 1998). Only quantitative application of formative assessment such as giving students their grades and marks might culminate in reverse effects on learners, particularly the slow ones. Therefore, like ARG (2002), they strongly cautioned that the qualitative aspect of the feedback received by learners has to be ensured to improve their standard of learning. Empirical studies, though very limited in number, have confirmed this observation. For instance, Gijbles et al. (2008) studied university students' perceptions in Belgium concerning assessment demands through a student-survey questionnaire. Based on their findings, they have divided learning into two types: depth learning and surface-level learning. They found that examinations with short-answer questions, particularly multiple-choice questions, result in low level of intellectual abilities compared to essay-type questions which promotes higher-level intellectual abilities. Similarly, Scouller (1998) investigated the association between learners' learning strategies and their perceptions of formative assessment tasks via a three-part questionnaire together with analyzing the students' course results. Like Gijbles et al. (2008), the findings of the study led her to divide learning strategies into two kinds; surface learning and deep learning. The first strategy is based on bringing together generic facts and knowledge which does not involve adequate reflection, analysis, and originality of work whereas the learners who apply the second type of strategy show more reflection on assessment tasks and critical examination of learning materials. She found that multiple-choice-questions given in formative assessment tasks triggered surface-level learning unlike assignments and essay type questions which made the students use deep learning strategies. In addition, the study found that the students had their preferred learning styles which had a strong relationship with their perceptions of the formative assessment tasks. Likewise, Gijbels and Dochy (2006) studied the influence of formative assessment on learners' learning strategies and their preferences with regard to formative assessment tests. Like the two studies reported above, the researcher in this study used a student-survey questionnaire for collecting data from 108 undergraduate students. The results showed that the learners' preferences about assessment had a clear effect on their learning strategies, e.g., not showing any likeness for those assessment tasks that could examine higher-order academic skills which involved analysing, reflection and synthesis of information.

In a nutshell, one of the factors hindering the desired effect of formative assessment is learners' narrow perception of assessment tasks which, finally, shape their learning strategies (Tsagari, 2009). Since students are one of the most important stakeholders of a "testing community" (Saville & Hawkey, 2004), their perceptions cannot be ignored. Their perceptions have been noted to have a strong impact on teachers' teaching strategies too. For example, Vallette (1994, c.f. Chen, 2002, p. 32) has argued that in education environments where "students' performance on a test determines future career options...teachers often feel obliged to teach for the test". The results of Qi (2004) have confirmed the argument of Vallette (1994) who has found that though the examination required the teachers to develop the students' communicative skills, the teachers focused on "decontextualized linguistic" materials because they believed that by not doing so both students and parents would complain that

the material taught in school did not look like the forthcoming expected assessment tasks. Keeping in view the significance of the relationship that exists between learners' perceptions of assessment tasks and their learning strategies, the current study attempted to investigate how Taif University English major female students' perceptions of formative assessment tasks influenced their learning strategies and in what ways.

3. Research Questions

1) Is there any significant relationship between Taif University English major female students' perceptions of formative assessment tasks and their learning strategies?

2) Is there any significant relationship between Taif University English major female students' perceptions of formative assessment tasks and the scope of the learning materials they use?

3) Is there any significant relationship between Taif University English major female students' perceptions of formative assessment tasks and the depth of their learning?

4. Method

The researcher used survey as a research strategy to investigate the learners' perceptions of formative assessment methods used at Taif University (Denscombe, 2007). The instrument used to measure their perceptions and opinions was a self-reporting questionnaire with 24-five-point Likert scale items to investigate the learners' preferences with regard to quizzes, presentations, and mid-term examinations and the reasons behind their preferences and their association with the learners' learning strategies and the learning materials they studied. The items on the scale were coded as Strongly Disagree, Disagree, Undecided, Agree, and Strongly Agree.

For the face validity check of the instrument, it was given to three senior colleagues in the department of foreign languages of the university. Their feedback was incorporated. Keeping in mind the learners' low level of English the questionnaire was translated into Arabic. Thereafter, for the reliability check, the questionnaire was piloted among 30 second year English-major female learners. However, this group was not given the questionnaire during the main study. The pilot data were entered to Microsoft Excel from where it was transferred to SPSS (17). The Cronbach's alpha of the total items was 0.7277 which showed an acceptable level of internal consistency or reliability being above 0.70.

The population of the study comprised Taif University undergraduate students who followed the same assessment method as the sample did and the English-major female students served as a purposive sample for the study. Therefore, the questionnaire was distributed among the 400 students studying in the Department of Foreign Languages (FLD) of the university at the time of the study. Non-probability purposive sampling technique was used (Denscombe, 2007). The questionnaire was returned by 289 participants with the return rate of 72%. The responses were analyzed with the help of SPSS 17 for frequencies, percentages and standard deviation.

5. Results

Table 1. Items ranked very high by the participants

No	Item	Cases	Mean	SD
1	Recommended course books	289	4.1849	1.00603
3	Specific pages and paragraphs	289	4.5336	.76647
8	True/false and multiple-choice questions	289	4.0714	1.13216
9	MCQs are easy to answer.	289	4.1597	1.07117
10	MCQs helpful to getting good grades	289	4.1387	1.06423
11	Memorising materials	289	3.8025	1.07860
12	No good job if grades are low	289	3.9076	1.21518
18	Expressing personal ideas, experience and knowledge	289	3.8655	.98875
20	Knowing progress on the course and improvement	289	4.1092	.94837
22	Improving reading and writing skills	289	3.9748	1.15076

Table 1 indicates that some of the questionnaire items were ranked very high by the participants. Most of them highly agreed that they used a single course to study for the formative assessment tasks given in the midterm examinations, quizzes, and presentations. They have further reported that they preferred their teachers to inform them about the exact pages of the book that would cover the assessment tasks or questions. In addition to preferring very limited amount of learning materials, they showed a strong preference MCQs in assessment tasks. MCQs, from their point of view, are easier to answer and allow them to get good grades. Achieving good grades help them in getting good jobs. However, at the same time most of them also view the formative assessment tasks as a source of learning. For example, they agreed that the midterm examinations and quizzes helped them know their mistakes together with improving the standard of their learning, particularly reading and writing skills. Furthermore, they think that essay type questions are better than MCQs, because such questions allow them to use their own ideas and experiences.

Table 2. Items ranked high

No	Items	Cases	Mean	SD
4	No understanding of learning materials	289	3.6050	1.20979
5	Memorising longer texts	289	3.4580	1.37960
7	Easy to pass quizzes and mid-term exams even if I do not understand what my teachers teach me in class	289	3.3361	1.26476
15	Difficult to answer essay-type questions	289	3.1723	1.28926
16	Essay writing is difficult because of spellings	289	3.3277	1.36013
17	Essay writing is difficult because of lack of ideas	289	3.2857	1.36034
19	Final exam is more important than midterm	289	3.5798	1.35942
21	Similar learning strategies for final exams and midterm	289	3.7773	1.01299

Table 2 includes the items ranked high mean. For example, the first item in the table shows that a majority of the learners memorised material even if they did not understand it. In addition, they reported that they passed their courses without adequate understanding of the materials they studied. However, if the assessment tasks happened to be of essay-type it was difficult for them to solve the tasks. The main reason they gave for not being able to pass essay-type questions was their weak spellings and insufficient grammatical competence to compose correct sentences. The most interesting perception of the respondents was with regard to the final assessment which they considered more important compared to its formative counterpart. Furthermore, they reported that they applied the same learning strategy for the final examinations that they used formative assessment, i.e., memorising materials.

Table 3. Items ranked moderately

No	Items	Cases	Mean	SD
2	Studying different aspects of a topic	289	2.9202	1.38327
6	The reason of losing grades	289	2.7511	1.45601
13	Grades more important than English	289	2.5210	1.44578
14	Essay-type questions difficult to answer	289	2.5672	1.36321
23	Worried about tests	289	2.2269	1.29222
24	Worried for the final exams only	289	2.4412	1.38204

Six of the questionnaire items as shown in Table 3 were ranked moderately by the respondents. For instance, with regard to the depth of their learning, the respondents reported that many of them did not try to understand what they studied from different aspects and did not use more than one source or book. The reason they gave for why they did not solve the formative assessment tasks in their own language was the fear of losing grades. This finding seems to be related with the result of item number 12 in table 3 where they reported difficulty in getting

jobs if their grades were low. Besides, some of the participants thought that it was more important for them to have good grades than good English to get a good job. Finally, the respondents reported that almost half of them worried about the final assessment more than its summative counterpart, i.e., quizzes, midterm examinations and writing assignments.

6. Discussion

The findings of previous research strongly suggest that assessment tasks will influence students' learning strategies and the learning materials they study (Alderson & Wall, 1993). With regard to formative assessment in particular, past research shows that learners' perceptions of assessment tasks play a strong role in shaping their learning strategies (Vallette, 1994; Qi, 2004). The findings of this study confirmed that the respondents expected and preferred the formative assessment tasks to be easy, having multiple-choice questions rather than essay-type questions which they deemed difficult to attempt because of their weak writing skills such as poor vocabulary, spellings, and weak grammar. In addition, the participants strongly agreed that they applied memorisation as a learning strategy not only for the during-the-course assessment, namely; quizzes, midterm exams, and presentations, but also for the final examinations. Thus, they reported the interesting as well as alarming truth that they memorised materials and managed to pass the tests, sometimes with no understanding. This shows that they preferred to pass the assessment tasks by all means and considered passing the tests as an end of coming to the university. The evidence gathered strongly indicates that it did not seriously matter for the students whether they understood what they were taught as long as they managed to pass. Hence, this study confirmed that learners' learning strategies have a correlation with how they are assessed (Tsagari, 2009; Watanabe, 1997; Qi, 2004). Munoz and Alvarez (2010) have stated that one of the weaknesses of multiple-choice assessment tasks is that they encourage students to memorize materials. In such a situation, teachers while grading students' answers cannot easily decide if their students have actually understood the concepts. Therefore, assessment tasks should be authentic to allow learners to apply what they have been taught to new situations (Messick, 1996).

Previous research shows that the nature of assessments tasks influence learning materials. One type of influence is the narrowing down of the scope of the learning materials being studied. For example, Ferman (2004) has found that formative assessment tasks can also constrict the scope of materials that students learn. The results of the present study confirmed that the formative assessment methods in the context of this study appeared to make the students studied a very limited part of the learning materials they were supposed to study. A big majority of the survey respondents agreed with the statement ' I like to know the specific pages and paragraphs that will cover the questions of quizzes and midterm exams'. This situation seconds the finding of Ferman (2004) that the scope of learning materials can be narrowed down to an undesirable extent by formative assessment too. One of the solutions of the problem is to have a greater congruence between the objectives of a course and the assessment tasks (Green, 2007) which allows learners to apply the skills they learn to new situations instead of encouraging the memorisation of a limited amount of materials to pass a course.

Alderson and Wall (1993) stated that tests will affect the depth of what learners' learn. This hypothesis has strongly been supported by Stecher et al. (2004) that performance-based assessment results in deep learning whereas multiple-choice questions result in surface-level learning (Gijbles et al., 2008). The current research showed that the respondents did not benefit fully from the formative assessment tools. They memorised materials and preferred MCQs. Furthermore, they mostly relied on a single course book or even a few pages of books to pass tests. This shows that there is a serious need to make sure that the formative tests students get have a high level of content validity.

7. Conclusion and Recommendations

The findings of this small-scale-case study may not be easily generalisable to other similar settings; however, it did highlight the need of further empirical research in the area of formative assessment, particularly in traditional educational settings where tangible differences between formative and summative assessment at operational level do not exist. The results confirmed that respondents' preferences and perceptions of formative assessment methods tend to have a significant effect on their learning (Gibels & Dochy, 2006; Scouler, 1998). The findings robustly confirm that only improved formative assessment can raise the standard of learning (Black & William, 1998). Formative assessment for the sake of formative assessment may not necessarily have any positive washback on students' learning. In addition, factors beyond classroom situations such as job providers (Saville & Hawkey, 2004) also seem to have a role in shaping the effect of formative assessment tasks on learners in this context more or less in the same way as they do in the contexts of exotic tests (Watanabe, 1997; Cheng, 2004). Therefore, like standardised tests, formative assessment tools deserve a serious attention of washback researchers (Watanabe, c.f. Newfield, 2005, p. 7) and there must be further empirical research in the area to help teachers,

school administrators, and policy makers make the most of formative assessment by raising the standard of students' learning.

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ASSESSMENT OF OUTCOMES OF THE INTRODUCTORY COURSE IN PSYCHOLOGY

American Psychological Association

APA BOARD OF EDUCATIONAL AFFAIRS

WORKING GROUP ON
INTRODUCTORY PSYCHOLOGY ASSESSMENT

ASSESSMENT OF OUTCOMES OF THE INTRODUCTORY COURSE IN PSYCHOLOGY

AMERICAN PSYCHOLOGICAL ASSOCIATION
APRIL 2017

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EXECUTIVE SUMMARY

The American Psychological Association's (APA's) Board of Educational Affairs (BEA) Working Group on Strengthening the Common Core of the Introductory Psychology Course (henceforth the Common Core Working Group) examined the current scope of the Introductory Psychology course and provided five major recommendations relating to its content and delivery. In particular, the Common Core Working Group (APA, 2014) recommended the development of a plan for a universal assessment of Introductory Psychology. The BEA subsequently commissioned a second working group to address the need for a universal assessment of the Introductory Psychology course and charged it with "developing a plan and identifying the necessary steps to create a universal assessment to measure introductory psychology students' mastery of content knowledge and skills." The five members of this Working Group on Introductory Psychology Assessment (henceforth the Working Group) included psychology instructors teaching at 4-year, 2-year, and high-school institutions who were either teacher affiliates or members of APA. This document serves as their final report and includes their recommendations.

The Working Group began by considering the multiple purposes that the Introductory Psychology course typically serves on a college campus and identified three primary ones: (a) as a gateway course to the psychology major, (b) as a general education service course, and (c) as a vehicle (often underutilized) for educating the public about the discipline of psychology. Thus, a comprehensive strategy for assessing the Introductory Psychology course needs to address each of these purposes. A clear articulation of the purpose of the course, along with suggested methods for measuring its outcomes, will provide both departments and institutions with the tools necessary to meet calls for accountability.

Measuring student learning outcomes of the Introductory Psychology course has not traditionally been a priority for departments of psychology. Introductory Psychology is typically a campus service course involving large sections of students, and assessing student learning in those large sections both poses a signif-

icant challenge and is a low-reward enterprise. Although reliable and valid multimethod measures would be ideal for such an undertaking, their use would be both unlikely and unwieldy.

The Working Group acknowledges that the most expedient product for assessing the outcomes of the Introductory Psychology course would be a nationally standardized instrument. Such a standardized, reliable, and valid measure would be the gold standard for any assessment, and it would provide departments, colleges, and universities with a common metric for evaluating outcomes of the introductory course. Comprehensive standardized measures of the Introductory Psychology course already exist (e.g., the Advanced Placement Introductory Psychology exam from the College Board's College Level Examination Program), yet they are not normed for students completing the course in a college setting. A nationally standardized instrument would also provide benchmarks for comparing success in achieving student learning outcomes across sections and institutions.

The Working Group concedes that creating a sound assessment instrument would be time consuming, expensive, and beyond the scope of its charge from the BEA. In addition to the pragmatic challenges, a unique set of challenges is presented by the variable and autonomous nature of campuses and academic units. Nonetheless, the fact remains that the creation of a national assessment measure would solve many problems for the field of psychology and undergraduate education in general (American Council on Education, 2010). After weighing the multiple considerations involved in assessment of the Introductory Psychology course, the Working Group advances the following recommendations:

1. We recommend that APA pursue an investment in developing a nationally standardized instrument designed to measure the student learning outcomes of the Introductory Psychology course. Such an instrument could be an existing instrument renormed and standardized on students completing the Introductory Psychology course in representative college settings.

2. We recommend that departments systematically use learning outcomes for the Introductory Psychology course based on the framework provided by the BEA Working Group on Strengthening the Common Core of the Introductory Psychology Course (APA, 2014) and the *APA Guidelines for the Undergraduate Psychology Major: Version 2.0* (APA, 2013).

3. We recommend using both standardized instruments to measure students' content knowledge and embedded assessments to evaluate the skills that they develop in the context of the general education curriculum. These skills are clearly articulated in the Common Core Working Group's report (APA, 2014) and are consistent with the LEAP (Liberal Education and America's Promise) recommendations of the Association of American Colleges and Universities (n.d.-a).

4. We recommend the creation of a resource similar to the *Assessment CyberGuide for Learning Goals and Outcomes* (Pusateri, Halonen, Hill, & McCarthy, 2009) to help Introductory Psychology instructors better assess their courses by shoring up existing assessments using best practices and backward design principles.

5. We recommend the development of a clearinghouse to share Introductory Psychology assessments and to provide needed comparisons and baseline data on learning outcomes in Introductory Psychology.

In support of these recommendations, we provide an overview of outcomes that should be measured and suggestions for campus-based assessment activities. Specifically, we suggest clearly articulating student learning outcomes by employing embedded assessments, and we outline ways in which assessment data can be used by students, faculty, departments, and colleges and universities.

INTRODUCTION AND CONTEXT OF THE CHARGE TO THE WORKING GROUP

After reflecting on more than a century of scholarship that defined the highly diverse discipline of psychology, the American Psychological Association's (APA's) Board of Educational Affairs (BEA) concluded that the discipline's current range of content was not adequately reflected in the textbooks typically used in the Introductory Psychology course. A review of existing introductory texts suggested that the introductory course included approximately 16 content-based domains of psychology and that the vast subject matter in the evolving discipline of psychology might be too broad to be covered in a single-semester introductory course. Accordingly, the BEA charged its Working Group on Strengthening the Common Core of the Introductory Psychology Course (i.e., the Common Core Working Group) to examine the current scope of the Introductory Psychology course and provide recommendations to define a common core for its content.

In 2014 the Common Core Working Group, rather than providing an exhaustive specification of content, recommended a more parsimonious and integrative approach to the introductory course content spanning four themes (Cultural and Social Diversity; Ethics; Variations in Human Functioning; and Applications) and five overarching domains. The scientific foundation of the discipline (Research Methods) underlies the domains, which are coupled with an integrated body of content-based literature organized into five pillars of psychology (Biological; Cognitive; Development; Social and Personality; and Mental and Physical Health). The Common Core Working Group (APA, 2014) also recommended that a subsequent step be taken to develop a plan for a universal assessment of the Introductory Psychology course. Therefore, the BEA commissioned a second working group to address the need for a universal assessment of the Introductory Psychology course. Specifically, the BEA charged the Working Group on Introduc-

tory Psychology Assessment to make recommendations for creating a national assessment plan for introductory psychology. This new task force will be charged with developing a plan and identifying the necessary steps to create a universal assessment to measure introductory psychology students' mastery of content knowledge and skills. This document serves as the final report, including the recommendations, of the BEA Working Group on Introductory Psychology Assessment.

As we considered the BEA charge, it seemed the most expedient product would be a nationally standardized assessment that could be used to assess the outcomes of the Introductory Psychology course. A nationally standardized instrument would provide faculty, departments, and institutions with a common metric for evaluating outcomes of the introductory course in psychology. Such an instrument would also provide a set of standards for comparing success in achieving student learning outcomes across sections and institutions.

The Advanced Placement (AP) Introductory Psychology exam from the College Board's College Level Examination Program can arguably be described as an existing measure of the outcomes of Introductory Psychology that is highly reliable and valid. However, the challenges of creating an instrument specifically normed for students enrolled in Introductory Psychology at the college level are daunting and multifaceted. First, the development of such an instrument would be both time consuming and expensive. For example, as reported by GuideStar (n.d.), the Educational Testing Service, the world's largest nonprofit testing company, generates more than $1 billion in revenue each year, and a significant amount of that revenue must go toward developing its outcomes-based assessment products. In addition to the pragmatic challenges (e.g., the cost) of developing a high-quality college-level measure, more obstacles are presented by the variable and autonomous nature of college campuses and academic units. In fact, scholars (e.g., APA, 2010b, 2013; Dunn et al., 2010; Halpern, 2010) have long supported autonomy for undergraduate programs in psychology, which must work within their own campus contexts. Although programs should be autonomous in curriculum matters, we believe it is possible to develop a standardized instrument that allows for autonomy while maintaining a common set of learning outcomes. However, such an instrument would require a significant investment, and such an activity was beyond the scope of the charge to the Working Group on Introductory Psychology Assessment. We recommend that APA pursue the development of a nationally standardized instrument as a long-term strategy for addressing the national assessment plan for Introductory Psychology. In the interim, we offer campus-based solutions for addressing the current assessment challenges.

SCOPE OF THE INTRODUCTORY PSYCHOLOGY COURSE

The Common Core Working Group (APA, 2014) offered an innovative five-pillar model for conceptualizing the scope of the introductory course across contexts (i.e., high school, 2-year colleges, and 4-year institutions). Clearly defining what one is attempting to measure is a critical first step in developing recommendations for any type of assessment. Therefore, we began by considering the multiple purposes that the Introductory Psychology course typically serves on a college campus. We identified three primary purposes: (a) as a gateway course to the psychology major, (b) as a general education service course, and (c) as a (perhaps underutilized) vehicle for educating the public about the discipline of psychology.

INTRODUCTORY PSYCHOLOGY AS A GATEWAY TO THE MAJOR

Many faculty members believe that the Introductory Psychology course is a foundation course for students majoring in psychology. Hence, the vast majority of undergraduate programs require the introductory course as a prerequisite to upper division coursework for the major (Norcross et al., 2016; Stoloff et al., 2010). Yet, it is unlikely that such a broad survey course provides students with an enduring, detailed understanding of the discipline. Any assessment of student learning outcomes in the introductory course will by necessity reflect a broad understanding of the material.

How well does the Introductory Psychology course provide the foundation for the future development of psychology knowledge and skills? As a prerequisite to upper-level courses, most introductory courses tend to focus on knowledge-based or content goals fairly well. Establishing agreement on a smaller

domain of psychological content will enable development of an assessment that addresses how well the introductory course provides the foundation for future learning in the major and to what extent the learning goals are standardized within departments and across institutions.

Yet, standardization of content and syllabi can prove to be a divisive topic, seemingly at odds with traditions of academic freedom, individual creativity, course ownership, and professor autonomy. At the same time, shared course goals and collaboration enable faculty to create a course that may serve as a foundation for additional study in the discipline. The sheer magnitude of the course content, the number of students (many of whom do not intend to major in psychology) taking the introductory course, the practice of utilizing contingent faculty to teach multiple sections, and the increased regulatory demands of accreditors are all persuasive arguments for some level of standardization in the Introductory Psychology course. Such is already the case for introductory courses in many other scientific disciplines (e.g., chemistry, mathematics, biology).

To balance professor autonomy and disciplinary standardization, we suggest a minimum number of foundational areas to be covered for each course and a common set of learning outcomes as the basis for their assessment. Departments may then choose to further standardize the course beyond a common set of shared content areas. For example, common assignments and assessment tools can be adapted for content modules that address overall outcomes for the major (e.g., critical thinking, ethics, professional development, intercultural competence, communication). These overarching goals of the psychology major may also dovetail with many common goals of the general education curriculum.

How should overall learning outcomes of the major be included in the course that will serve as a foundation for the major? The *APA Guidelines for the Undergraduate Psychology Major: Version 2.0* (APA, 2013) recommends five explicit goals for students majoring in psychology: (1) knowledge base in psychology; (2) scientific inquiry and critical thinking; (3) ethical and social responsibility; (4) communication; and (5) professional development. We suggest that departments use these five goals as a guide for developing high-level student learning outcomes that can be used as the basis for designing assessments of student learning in the introductory course.

INTRODUCTORY PSYCHOLOGY AS A GENERAL EDUCATION SERVICE COURSE

The Introductory Psychology course introduces the scientific method, provides a broad overview of the discipline's content, and perhaps piques the interest of students who might be interested in critically thinking about behavior. However, it is unlikely that a course that is also offered as a general education elective results in a comprehensive foundation for the psychology major. If the course is designed to provide an overview of the discipline, then an assessment of learning outcomes should be conducted at a global level rather than measuring detailed knowledge that would otherwise serve as a proxy for course credit (e.g., such as provided by the AP Introductory Psychology exam).

The Working Group adopted the perspective that the Introductory Psychology course provides a broad overview of the discipline to undergraduates in all areas of study. We also adopted the position that the introductory course, and concomitant assessment of the course, could provide evidence of the development of critical thinking.

The Introductory Psychology course is most often taken by undergraduates to meet the requirements for the general education core of an undergraduate degree; in other words, it is a service course offered for the larger mission of the university. In all likelihood, this course will be the only exposure that college students graduating with a host of degrees unrelated to psychology will have to the discipline.

In addition to providing students with the basic understanding of the scientific method, Introductory Psychology typically includes an overview of the range of topics that the discipline of psychology comprises. The sheer volume of the individual content areas presented in an introductory course can be overwhelming. However, the Common Core Working Group offered a more parsimonious model for organizing content that can be broadly characterized using the five pillars: Biological, Cognitive, Development, Social and Personality, and Mental and Physical Health (APA, 2014).

Introductory Psychology also offers great potential for fulfilling the general education goal of developing critical thinking skills. The course has the potential to effect positive change in individuals, societies, and humanity as a whole by dispelling myths and misconceptions about a host of important everyday behavioral concepts. At the same time, it is possible to measure improvements in critical thinking that are likely to occur as a result of completing a single course in Introductory Psychology.

The purpose of general education courses, or the "core curriculum," is to produce a well-educated individual. Defining what a well-educated individual is and operationalizing what knowledge, skills, and values should be acquired as a result of an educational experience are complex endeavors. Institutions typically develop their own set of general education outcomes, informed by their unique cultural and sociopolitical contexts. The American Association of Colleges and Universities (AAC&U) broadly defines the general outcomes of a liberal education as "empowering" and equipping graduates with abilities that help navigate "complexity, diversity and change" through the development of social responsibility, intellectual skills, and practical application of knowledge (AAC&U, n.d.-c). This endeavor is accomplished through providing educational breadth and depth, with breadth represented by several courses in the core curriculum and depth expressed through a major in a discipline. The data and constructs developed by organizations such as the AAC&U can assist us in examining the role of Introductory Psychology in service to general education.

In 2005, the AAC&U embarked on a project to define the essential learning outcomes of a liberal education through its Liberal Education and America's Promise initiative, also known as LEAP (AAC&U, n.d.-a). This initiative recommended that liberal education curricula focus on four outcome areas: knowledge of human cultures and the physical and natural world; intellectual and practical skills; personal and social responsibility; and integrative and applied learning.

Each general outcome is accompanied by a set of measurable objectives and pedagogical implications. The AAC&U (n.d.-b) also developed rubrics to accompany its liberal education learning outcomes, which can be accessed at http://www.aacu.org/value-rubrics. The rubrics measure 16 competencies. These outcomes and competencies can be linked with those from the *APA Guidelines for the Undergraduate Psychology Major: Version 2.0* (APA, 2013; see **Figure 1**). Although the discipline-specific outcomes for the undergraduate major in psychology (knowledge base in psychology, scientific inquiry and critical thinking, ethical and social responsibility in a diverse world, communication, and professional development) do not perfectly align with the LEAP essential outcomes for the liberal arts, there are significant areas of overlap. Such robust overlap highlights the possibility of standardized assessment on common goals/outcomes for Introductory Psychology as a general education course.

In addition to the AAC&U's LEAP initiative, the Association of General and Liberal Studies (AGLS) embraces a core mission of enhancing the general education experience. In an attempt to identify the areas of convergence of the most commonly espoused student learning outcomes of general education nationally, the AGLS analyzed the content of learning outcomes from the websites of six major regional accrediting bodies in the United States (i.e., the Middle States Commission on Higher Education,

FIGURE 1. AAC&U AND *APA GUIDELINES 2.0* LEARNING OUTCOMES

APA GUIDELINES 2.0 LEARNING GOALS	AAC&U LEAP ESSENTIAL LEARNING OUTCOMES
KNOWLEDGE BASE IN PSYCHOLOGY Describe key concepts, principles, and themes Develop a knowledge of content domains Describe applications of psychology	**KNOWLEDGE OF HUMAN CULTURES & THE PHYSICAL AND NATURAL WORLD** Thorough study in the disciplines of the liberal arts
SCIENTIFIC INQUIRY/CRITICAL THINKING Scientific reasoning Information literacy Innovative thinking & problem solving Basic research skills Incorporate sociocultural factors in scientific inquiry	**INTELLECTUAL AND PRACTICAL SKILLS** Inquiry and analysis* Critical* and creative* thinking Written* and oral* communication Quantitative literacy* Information literacy* Teamwork* and problem solving*
ETHICAL AND SOCIAL RESPONSIBILITY IN A DIVERSE WORLD Apply ethical standards to science and practice Build interpersonal relationships Adopt values at local, national, and global levels	**PERSONAL AND SOCIAL RESPONSIBILITY** Civic knowledge and engagement* Intercultural knowledge and competence* Ethical reasoning and action* Skills for life-long learning*
COMMUNICATION Effective writing Effective presentation skills Interact with others	
PROFESSIONAL DEVELOPMENT Apply learning to career goals Exhibit self-efficacy and self-regulation Refine project management Enhance teamwork capacity Develop meaningful professional direction	**INTEGRATIVE AND APPLIED LEARNING** Synthesis across general and specialized studies*

Note. AAC&U = American Association of Colleges and Universities; LEAP = Liberal Education and America's Promise.
*AAC&U has created rubrics for these outcomes, available here: http://www.aacu.org/value/rubrics

the New England Association of Schools and Colleges, the North Central Association of Colleges and Schools, the Northwest Commission on Colleges and Universities, the Southern Association of Colleges and Schools, and the Western Association of Schools and Colleges). All six accrediting associations endorsed only one common general education competency: computer/technological competency (ironically, the one outcome not specifically addressed by LEAP or the *APA Guidelines for the Undergraduate Psychology Major: Version 2.0*).

Taken together, the LEAP recommendations and the AGLS results provide a consensus view on learning outcomes of general education, many of which also interface with the outcomes of the psychology major. Thus, choosing to assess

Introductory Psychology outcomes that serve the dual purposes of the course as the gateway to the major and as a general education course will increase the utility of the assessment. The results of such an assessment could be used for both program reviews as well as institutional accreditation purposes. Assessment of the introductory course outcomes would seem to fall most naturally into the following skill areas: scientific reasoning/critical thinking, problem solving, communication, and possibly cultural awareness/diversity.

INTRODUCTORY PSYCHOLOGY AS A VEHICLE FOR PUBLIC EDUCATION

Beginning in 1996, APA launched a public education campaign to educate the public about the discipline of psychology. As a targeted, public relations initiative, the campaign provided the public with information about specific topics in psychology and health care. More recently, the campaign has been expanded to include a specific emphasis on psychology as a science (APA, n.d.). Although the formal campaign does not intersect with the largest potential audience (students enrolled in Introductory Psychology), the introductory course offers a promising vehicle for educating the larger public about the discipline, and a national assessment of the course would provide evidence of success in meeting the goals of such a campaign.

Psychology has an extraordinary opportunity to educate the public about the true nature of the discipline through the enrollment of the more than 1 million students (APA, 2014; Steuer & Ham, 2008) who take the Introductory Psychology course each year. To devise a national assessment plan for the introductory course, we also need to consider how instructors deliver the course to students who will eventually compose the citizenry—that is, to graduates with a variety of college degrees. First and foremost, it is important that the discipline be recognized as the scientific study of behavior. The scientific method, whether presented in the biological sciences or the psychological sciences, provides an evidence-based tool for solving complex problems. Any assessment of the Introductory Psychology course should include some measure of an individual's ability to apply the scientific method using empirical tools.

CONSTRUCTING AN INSTRUMENT TO MEASURE OUTCOMES OF INTRODUCTORY PSYCHOLOGY

Researchers, accrediting bodies, organizations, and individual constituents have called for increasing accountability across the educational landscape, yet measuring student learning outcomes of an Introductory Psychology course has typically not been a priority for departments of psychology. The dearth of attention to this issue may be attributable to the confusing multitude of purposes the introductory course serves, to the large number of instructors teaching multiple sections of the course, to the low priority accorded to the introductory course in promotion and tenure decisions, and to other considerations. Regardless, accrediting bodies, the public, and multiple stakeholders advocate for a systematic evaluation of student learning.

A nationally standardized, reliable, and valid measure is the gold standard for any assessment instrument. In fact, the AP Introductory Psychology exam reflects this standard as a well-developed measure of high school psychology courses. While the content tested is similar to that delivered in a college-level Introductory Psychology course, the test would require restandardization and renorming for routine use on the college level. Although this is one viable solution, the cost of the exam ($92.00 per student in 2016) would likely be prohibitive for use on individual campuses. It would also be necessary to work with the Educational Testing Service to make such an adaptation. In other words, it would be expensive to develop a second instrument to measure the content-based student learning outcomes of the Introductory Psychology course. Until or if such a sound standardized measure becomes available, we recommend that departments apply sound measurement principles to existing assessments already used for the introductory course.

Earlier we identified three primary elements of the Introductory Psychology course—scientific method, content knowledge, and critical thinking—as out-

comes that students should demonstrate at the conclusion of the course. Establishing student learning outcomes is the first step in developing any assessment (Wiggins & McTighe, 1998).

Researchers have examined student learning outcomes in Introductory Psychology using a sample of syllabi and self-reported surveys completed by faculty from across the nation. Using the first iteration of the *APA Guidelines for the Undergraduate Psychology Major* (APA, 2007) as a framework, Homa and colleagues (2013) calculated which of the 10 APA goals instructors included in their syllabi. More than half of the syllabi contained objectives specific to the science and application of psychology. Sixty-six percent included the knowledge base, 60% included scientific inquiry and critical thinking, 10% included ethical and social responsibility in a diverse world, 7% included communication, and 4% included professional development as a goal. Almost 20% of course syllabi did not contain any student learning outcomes.

When asked about the practice of using student learning outcomes, one third of the faculty reported that their departments or institutions required inclusion of student learning outcomes for Introductory Psychology, with scientific inquiry and critical thinking and content knowledge being the most regulated objectives (Homa et al., 2013). When asked if they believed there should be a standard way to teach Introductory Psychology, 60.4% of the faculty responded "yes." When asked who is best suited to unify or regulate the teaching of Introductory Psychology, 70.6% chose psychology departments, 19.1% identified APA, 1.5% chose a university or college, and 2.6% reported "no one."

In order to facilitate national comparisons of the Introductory Psychology course, it would be preferable if all courses reflected student learning outcomes from a common set. To aid departments in selecting a set of common objectives for the Introductory Psychology course, the *APA Guidelines for the Undergraduate Psychology Major: Version 2.0* (*APA Guidelines 2.0;* APA, 2013) can be used to derive a common set of established student learning outcomes. **Table 1** includes the higher order learning goals from the *APA Guidelines 2.0*, their accompanying student learning outcomes, and those student learning outcomes that are specific to Introductory Psychology (foundational indicators). Instructors or departments could have flexibility to determine which of these student learning outcomes fit their introductory course.

TABLE 1. STUDENT LEARNING OUTCOMES FOR INTRODUCTORY PSYCHOLOGY DERIVED FROM THE *APA GUIDELINES FOR THE UNDERGRADUATE MAJOR IN PSYCHOLOGY: VERSION 2.0*

LEARNING GOALS

GOAL 1: KNOWLEDGE BASE IN PSYCHOLOGY
GOAL 2: SCIENTIFIC INQUIRY AND CRITICAL THINKING
GOAL 3: ETHICAL AND SOCIAL RESPONSIBILITY IN A DIVERSE WORLD
GOAL 4: COMMUNICATION
GOAL 5: PROFESSIONAL DEVELOPMENT

STUDENT LEARNING OUTCOMES

1.1 Describe key concepts, principles, and overarching themes in psychology
1.2 Develop a working knowledge of psychology's content domains
1.3 Describe applications of psychology

2.1 Use scientific reasoning to interpret psychological phenomena
2.2 Demonstrate psychology information literacy
2.3 Engage in innovative and integrative thinking and problem solving
2.4 Interpret, design, and conduct basic psychological research
2.5 Incorporate sociocultural factors in scientific inquiry

3.1 Apply ethical standards to evaluate psychological science and practice
3.2 Build and enhance interpersonal relationships
3.3 Adopt values that build community at local, national, and global levels

4.1 Demonstrate effective writing for different purposes
4.2 Exhibit effective presentation skills for different purposes
4.3 Interact effectively with others

continued on next page

5.1 Apply psychological content and skills to career goals
5.2 Exhibit self-efficacy and self-regulation
5.3 Refine project-management skills
5.4 Enhance teamwork capacity
5.5 Develop meaningful professional direction for life after graduation

FOUNDATIONAL INDICATORS SPECIFIC TO INTRODUCTORY PSYCHOLOGY

1.1a Use basic psychological terminology, concepts, and theories in psychology to explain behavior and mental processes
1.1b Explain why psychology is a science with the primary objectives of describing, understanding, predicting, and controlling behavior and mental processes
1.1c Interpret behavior and mental processes at an appropriate level of complexity
1.1d Recognize the power of the context in shaping conclusions about individual behavior
1.1e Identify fields other than psychology that address behavioral concerns

1.2a Identify key characteristics of major content domains in psychology (e.g., cognition and learning, developmental, biological, and sociocultural)
1.2b Identify principal methods and types of questions that emerge in specific content domains
1.2c Recognize major historical events, theoretical perspectives, and figures in psychology and their link to trends in contemporary research
1.2d Provide examples of unique contributions of content domain to the understanding of complex behavioral issues
1.2e Recognize content domains as having distinctive sociocultural origins and development

1.3a Describe examples of relevant and practical applications of psychological principles to everyday life
1.3b Summarize psychological factors that can influence the pursuit of a healthy lifestyle
1.3c Correctly identify antecedents and consequences of behavior and mental processes
1.3d Predict how individual differences influence beliefs, values, and interactions with others, including the potential for prejudicial and discriminatory behavior in oneself and others

2.1a Identify basic biological, psychological, and social components of psychological explanations (e.g., inferences, observations, operational definitions, interpretations)
2.1b Use psychology concepts to explain personal experiences and recognize the potential for flaws in behavioral explanations based on simplistic, personal theories
2.1c Use an appropriate level of complexity to interpret behavior and mental processes
2.1d Ask relevant questions to gather more information about behavioral claims
2.1e Describe common fallacies in thinking (e.g., confirmation bias, post hoc explanations, implying causation from correlation) that impair accurate conclusions and predictions

2.2a Read and summarize general ideas and conclusions from psychological sources accurately
2.2b Describe what kinds of additional information beyond personal experience are acceptable in developing behavioral explanations (i.e., popular press reports vs. scientific findings)
2.2c Identify and navigate psychology databases and other legitimate sources of psychology information
2.2d Articulate criteria for identifying objective sources of psychology information
2.2e Interpret simple graphs and statistical findings

2.3a Recognize and describe well-defined problems
2.3b Apply simple problem-solving strategies to improve efficiency and effectiveness
2.3c Describe the consequences of problem-solving attempts

2.4a Describe research methods used by psychologists including their respective advantages and disadvantages
2.4b Discuss the value of experimental design (i.e., controlled comparisons) in justifying cause– effect relationships
2.4c Define and explain the purpose of key research concepts that characterize psychological research (e.g., hypothesis, operational definition)
2.4d Replicate or design and conduct simple scientific studies (e.g., correlational or two-factor) to confirm a hypothesis based on operational definitions
2.4e Explain why conclusions in psychological projects must be both reliable and valid
2.4f Explain why quantitative analysis is relevant for scientific problem solving
2.4g Describe the fundamental principles of research design

2.5a Relate examples of how a researcher's value system, sociocultural characteristics, and historical context influence the development of scientific inquiry on psychological questions
2.5b Analyze potential challenges related to sociocultural factors in a given research study

2.5c Describe how individual and sociocultural differences can influence the applicability/ generalizability of research findings
2.5d Identify under what conditions research findings can be appropriately generalized

3.1a Describe key regulations in the APA Ethics Code for protection of human or nonhuman research participants
3.1b Identify obvious violations of ethical standards in psychological contexts
3.1c Discuss relevant ethical issues that reflect principles in the APA Ethics Code
3.1d Define the role of the institutional review board (IRB)

3.2a Describe the need for positive personal values (e.g., integrity, benevolence, honesty, respect for human dignity) in building strong relationships with others
3.2b Treat others with civility
3.2c Explain how individual differences, social identity, and worldview may influence beliefs, values, and interaction with others and vice versa
3.2d Maintain high standards for academic integrity, including honor code requirements

3.3a Identify aspects of individual and cultural diversity and the interpersonal challenges that often result from diversity and context
3.3b Recognize potential for prejudice and discrimination in oneself and others
3.3c Explain how psychology can promote civic, social, and global outcomes that benefit others
3.3d Describe psychology-related issues of global concern (e.g., poverty, health, migration, human rights, rights of children, international conflict, sustainability)
3.3e Articulate psychology's role in developing, designing, and disseminating public policy
3.3f Accept opportunity to serve others through civic engagement, including volunteer service

4.1a Express ideas in written formats that reflect basic psychological concepts and principles
4.1b Recognize writing content and format differ based on purpose (e.g., blogs, memos, journal articles) and audience
4.1c Use standard English, including generally accepted grammar
4.1e Recognize and develop overall organization (e.g., beginning, development, ending) that fits the purpose
4.1f Interpret quantitative data displayed in statistics, graphs, and tables, including statistical symbols in research reports
4.2e Pose questions about psychological content

4.3b Recognize that culture, values, and biases may produce misunderstandings incommunication
4.3e Respond appropriately to electronic communications

5.1a Recognize the value and application of research and problem-solving skills in providing evidence beyond personal opinion to support proposed solutions
5.1b Identify range of possible factors that influence beliefs and conclusions
5.1c Expect to deal with differing opinions and personalities in the college environment
5.1d Describe how psychology's content applies to business, health care, educational, and other workplace settings
5.1e Recognize and describe broad applications of information literacy skills obtained in the psychology major
5.1f Describe how ethical principles of psychology have relevance to non-psychology settings

5.2a Recognize the link between efforts in self-management and achievement
5.2b Accurately self-assess performance quality by adhering to external standards (e.g., rubric criteria, teacher expectations)
5.2c Incorporate feedback from educators and mentors to change performance
5.2d Describe self-regulation strategies (e.g., reflection, time management)

5.3a Follow instructions, including timely delivery, in response to project criteria
5.3b Identify appropriate resources and constraints that may influence project completion
5.3c Anticipate where potential problems can hinder successful project completion
5.3d Describe the processes and strategies necessary to develop a project to fulfill its intended purpose

5.5a Describe the types of academic experiences and advanced course choices that will best shape career readiness
5.5b Articulate the skill sets desired by employers who hire or select people with psychology backgrounds
5.5c Describe settings in which people with backgrounds in psychology typically work
5.5d Recognize the importance of having a mentor

ASSESSING SKILLS DEVELOPED IN INTRODUCTORY PSYCHOLOGY

The Working Group recommends that departments of psychology use the framework provided by the Common Core Working Group (APA, 2014) along with the student learning outcomes from the *APA Guidelines 2.0* (APA, 2013; listed here in Table 1) in developing department-wide assessments for the Introductory Psychology course. Using these student learning outcomes, a department can employ an agreed-upon set of measurement outcomes as the basis for assessing skills developed in the introductory course.

A necessary step in assessing outcomes is to identify an assessment methodology. One efficient method is a multiple-choice instrument administered at the conclusion of the course. A well-constructed standardized instrument is effective for measuring student learning. However, because the introductory course in psychology is typically a campus service course involving large sections (i.e., 50–500 students), assessing student learning is a significant challenge even when the instrument used is a multiple-choice exam. Many schools use brief instruments that are administered at the beginning and end of the course to obtain a measure of student learning. Such an instrument can be administered as a stand-alone measure or embedded in a common final examination across multiple sections. This approach may prove a realistic option given the large numbers of students enrolled in Introductory Psychology each year.

To evaluate skills in scientific reasoning and critical thinking, departments may also consider evaluating student learning outcomes using locally developed multimethod measures. Despite the fact that this approach does not contribute to a national assessment plan, is limited in reliability and validity, and is both unlikely and unwieldy, it does provide limited campus-based data regarding student learning. Such embedded assessments can be locally and reliably administered (e.g., exercises) to supplement the ubiquitous multiple-choice exams used across introductory courses today.

EMBEDDED ASSESSMENTS

Consistent with national trends (Sullivan, 2015), we offer examples of embedded assessments to assess student learning outcomes in the introductory course. We provide five exemplars that can be used to assess the skills developed in Introductory Psychology. We use the Research Methods foundation and the five content pillars from *Strengthening the Common Core of the Introductory Psychology Course* (APA, 2014) as the framework and link specific student learning outcomes from the *APA Guidelines 2.0* (APA, 2013) to that framework. Ultimately, we recommend creating a clearinghouse of embedded assessments that could be applied nationally.

Exemplar 1 is a class assignment that can be used in a moderately sized Introductory Psychology course delivered either in a face-to-face setting or online. The assignment is designed to assess content from the Cognitive pillar (cognition, memory, perception, learning, lifespan development, language). In this case, the focus is on the Applications theme (writing) rather than on specific content. Using the learning goals from the *APA Guidelines 2.0*, we provide a sample rubric to grade the assignment. As illustrated in the rubric, each paper would be graded on the nine foundational indicators with ratings ranging from "meets all expectations" to "does not meet expectations." Grades and feedback could be provided to students using the detailed rubric.

EXEMPLAR 1

Your friend has been struggling on her psychology exams. She can't figure out what she is doing wrong, so she approaches you for advice. In talking with the friend, you learn that:

- She sleeps, on average, 4 hours per night.
- All of her studying is done in one big cram session the evening before the exam.
- Her primary study technique is just rereading her notes and the chapters.
- She checks her phone about every 2 minutes for text messages or social media updates.

Using the information presented in class and your textbook, explain in an email to your friend why each of the items above does not help with learning and, in fact, may harm learning.

PILLAR:

RESEARCH METHODS | BIOLOGICAL | **COGNITIVE** | DEVELOPMENT | SOCIAL & PERSONALITY | MENTAL & PHYSICAL HEALTH

COMMON THEME:

CULTURAL & SOCIAL DIVERSITY | ETHICS | VARIATIONS IN HUMAN FUNCTIONING | **APPLICATIONS**

LEARNING GOALS:

GOAL 1: Knowledge Base in Psychology
GOAL 3: Ethical and Social Responsibility in a Diverse World
GOAL 4: Communication
GOAL 5: Professional Development

EXEMPLAR 1 CONTINUED

[Each element in the rubric may be weighted differently.]

Meets all expectations	Partially meets expectations	Does not meet expectations	FOUNDATIONAL INDICATORS
			1.1a Use basic psychological terminology, concepts, and theories in psychology to explain behavior and mental processes
			1.1c Interpret behavior and mental processes at an appropriate level of complexity
			3.2b Treat others with civility
			3.2d Maintain high standards for academic integrity, including honor code requirements
			4.1a Express ideas in written format that reflect basic psychological concepts and principles
			4.1b Recognize writing content and format differ based on purpose (e.g., blogs, memos, journal articles) and audience
			4.1c Use standard English, including generally accepted grammar
			4.1e Recognize and develop overall organization (e.g., beginning, development, ending) that fits the purpose
			5.3a Follow instructions, including timely delivery, in response to project criteria

Exemplar 2 reflects skills from the Research Methods pillar and two themes, Ethics and Applications. Students are asked to consider the ethical conduct of research and to apply the *Ethical Principles of Psychologists and Code of Conduct* (APA, 2010a). In this applied activity students are asked not only to use the five general ethical principles but also to provide examples that reflect violations of the principles. Using the grading rubric format illustrated in the previous exemplar, we provide seven grading criteria (foundational indicators) consistent with student learning outcomes from the *APA Guidelines 2.0* (APA, 2013; Table 1).

EXEMPLAR 2

The *Ethical Principles of Psychologists and Code of Conduct* (APA, 2010a) contains five general principles:

A. Beneficence and nonmaleficence
B. Fidelity and responsibility
C. Integrity
D. Justice
E. Respect for people's rights and dignity

Before continuing, read more about each of these principles here: **http://www.apa.org/ethics/code/index.aspx?item=3**

Create the most unethical psychological researcher you can imagine. Your researcher must have violated all five general ethical principles. Imagine that after meeting with the researcher's department chair, you have been asked by the chair to document the researcher's violations in writing. Give specific examples of the researcher's unethical behavior and for each example identify which ethical principle has been violated.

PILLAR:

RESEARCH METHODS | **BIOLOGICAL** | **COGNITIVE** | **DEVELOPMENT** | **SOCIAL & PERSONALITY** | **MENTAL & PHYSICAL HEALTH**

COMMON THEME:

CULTURAL & SOCIAL DIVERSITY | **ETHICS** | **VARIATIONS IN HUMAN FUNCTIONING** | **APPLICATIONS**

LEARNING GOALS:

GOAL 3: Ethical and Social Responsibility in a Diverse World

GOAL 4: Communication

GOAL 5: Professional Development

[Each element in the rubric may be weighted differently.]

Meets all expectations	Partially meets expectations	Does not meet expectations	FOUNDATIONAL INDICATORS
			3.1b Identify obvious violations of ethical standards in psychological contexts
			3.1c Discuss relevant ethical issues that reflect principles in the APA Ethics Code
			3.2d Maintain high standards for academic integrity, including honor code requirements
			4.1b Recognize writing content and format differ based on purpose (e.g., blogs, memos, journal articles) and audience
			4.1c Use standard English, including generally accepted grammar
			4.1e Recognize and develop overall organization (e.g., beginning, development, ending) that fits the purpose
			5.3a Follow instructions, including timely delivery, in response to project criteria

Exemplar 3 reflects skills from three content pillars, Cognitive, Development, and Social & Personality, and two themes, Cultural & Social Diversity and Applications. This assignment requires students to integrate content across multiple domains. Students are asked to imagine themselves in a work setting applying the principles of psychology to assist clients in developing healthy behaviors. Using the grading rubric format, we provide 10 grading criteria (foundational indicators) that are consistent with the *APA Guidelines 2.0* for the undergraduate major.

EXEMPLAR 3

Imagine that you are a behavioral assistant working in a physician's office. Part of your job is to encourage your patients to engage in healthier behaviors. After briefly defining each of the following terms, explain how you, as a behavioral assistant, could use your knowledge of those terms to help your patients.

- Operant conditioning
- Observational learning
- Framing
- Availability heuristic
- Cognitive dissonance
- Collectivist cultures

PILLAR:

RESEARCH METHODS **BIOLOGICAL** **COGNITIVE** **DEVELOPMENT** **SOCIAL & PERSONALITY** **MENTAL & PHYSICAL HEALTH**

COMMON THEME:

CULTURAL & SOCIAL DIVERSITY **ETHICS** **VARIATIONS IN HUMAN FUNCTIONING** **APPLICATIONS**

LEARNING GOALS:

GOAL 1: Knowledge Base in Psychology
GOAL 3: Ethical and Social Responsibility in a Diverse World
GOAL 4: Communication
GOAL 5: Professional Development

[Each element in the rubric may be weighted differently.]

Meets all expectations	Partially meets expectations	Does not meet expectations	FOUNDATIONAL INDICATORS
			1.1a Use basic psychological terminology, concepts, and theories in psychology to explain behavior and mental processes
			1.3a Describe examples of relevant and practical applications of psychological principles to everyday life
			3.2b Treat others with civility
			3.2d Maintain high standards for academic integrity, including honor code requirements
			3.3c Explain how psychology can promote civic, social, and global outcomes that benefit others
			4.1a Express ideas in written format that reflect basic psychological concepts and principles
			4.1c Use standard English, including generally accepted grammar
			4.1e Recognize and develop overall organization (e.g., beginning, development, ending) that fits the purpose
			5.1d Describe how psychology's content applies to business, health care, educational, and other workplace settings
			5.3a Follow instructions, including timely delivery, in response to project criteria

Exemplar 4 involves three different activities designed to assess the understanding of long-term memory (from the Cognitive pillar). In the first two activities, students define terms and identify the conceptual relationships among the terms. In the third activity, students then write a short paper and apply the terms to an event in their personal lives.

EXEMPLAR 4

THOUGHT PAPER ASSIGNMENT: MEMORY

We discussed the multistore model of memory, a classic model of the storage of information processing. Atkinson and Shiffrin (1968) identified three stages of memory storage in their model: sensory memory, short-term memory, and long-term memory.

Since the time when the model was articulated, cognitive psychologists have conducted multiple studies on memory stores, using diverse methodologies and participant populations. The converging evidence from this research indicates that each store can be broken into several component parts. In this assignment, we will focus on the subdivisions of **long-term memory**.

PART I:

In your own words, define the following terms:

- Long-term memory
- Declarative memory
- Episodic memory
- Semantic memory
- Procedural memory

PART II:

Label the parts of the diagram below to illustrate the conceptual relationship among the subdivisions of long-term memory (Atkinson & Shiffrin, 1968) that you defined in Part I.

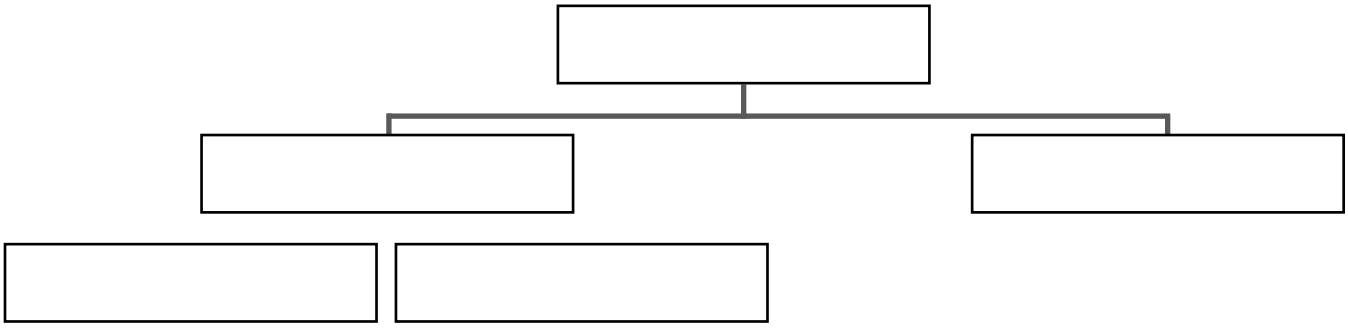

PART III:

Choose an event from your life that you've stored in your long-term memory. The event should not be too personal. In other words, identify an event that involves a memory that is relatively innocuous. Using each of the terms you defined in Part I, write a one- to two-page paper in which you do the following: (1) *Describe* the memory in narrative form; (2) *identify* which elements of the memory can be classified as episodic, which as semantic, and which as procedural; and (3) *explain* why each element is episodic, semantic, or procedural by tying the memory to the definition of each term.

EXEMPLAR 4 CONTINUED

PILLAR:

RESEARCH METHODS | BIOLOGICAL | **COGNITIVE** | DEVELOPMENT | SOCIAL & PERSONALITY | MENTAL & PHYSICAL HEALTH

COMMON THEME:

CULTURAL & SOCIAL DIVERSITY | ETHICS | VARIATIONS IN HUMAN FUNCTIONING | **APPLICATIONS**

LEARNING GOALS:

GOAL 1: Knowledge Base in Psychology
GOAL 2: Scientific Inquiry and Critical Thinking
GOAL 4: Communication
GOAL 5: Professional Development

[Each element in the rubric may be weighted differently.]

Meets all expectations	Partially meets expectations	Does not meet expectations	FOUNDATIONAL INDICATORS
			1.1a Use basic psychological terminology, concepts, and theories in psychology to explain behavior and mental processes
			1.3a Describe examples of relevant and practical applications of psychological principles to everyday life
			2.2a Read and summarize general ideas and conclusions from psychological sources accurately
			4.1a Express ideas in written formats that reflect basic psychological concepts and principles
			4.1c Use standard English, including generally accepted grammar
			4.1e Recognize and develop overall organization (e.g., beginning, development, ending) that fits the purpose
			5.3a Follow instructions, including timely delivery, in response to project criteria

Finally, Exemplar 5 is an applied exercise linked to the Development pillar as another assessment to measure student learning outcomes.

EXEMPLAR 5

Use the following excerpt from a journal article as you answer the questions in Parts 1-4.

Skinner, B. F. (1948). "Superstition" in the pigeon. *Journal of Experimental Psychology*, *38*, 168–172. (Reproduced at **http://psychclassics.yorku.ca/Skinner/Pigeon/**)

To say that a reinforcement is contingent upon a response may mean nothing more than that it follows the response. It may follow because of some mechanical connection or because of the mediation of another organism; but condi-

tioning takes place presumably because of the temporal relation only, expressed in terms of the order and proximity of response and reinforcement. Whenever we present a state of affairs which is known to be reinforcing at a given drive, we must suppose that conditioning takes place, even though we have paid no attention to the behavior of the organism in making the presentation. A simple experiment demonstrates this to be the case.

A pigeon is brought to a stable state of hunger by reducing it to 75 percent of its weight when well fed. It is put into an experimental cage for a few minutes each day. A food hopper attached to the cage may be swung into place so that the pigeon can eat from it. A solenoid and a timing relay hold the hopper in place for five sec. at each reinforcement.

If a clock is now arranged to present the food hopper at regular intervals *with no reference whatsoever to the bird's behavior* … conditioning usually takes place. In six out of eight cases the resulting responses were so clearly defined that two observers could agree perfectly in counting instances. One bird was conditioned to turn counter-clockwise about the cage, making two or three turns between reinforcements. Another repeatedly thrust its head into one of the upper corners of the cage. A third developed a 'tossing' response, as if placing its head beneath an invisible bar and lifting it repeatedly. Two birds developed a pendulum motion of the head and body, in which the head was extended forward and swung from right to left with a sharp movement followed by a somewhat slower return.

PART 1: What kind of conditioning is Skinner describing in this journal article? A. Classical conditioning B. Operant conditioning (positive reinforcement) C. Operant conditioning (negative reinforcement) D. Observational learning E. Second-order conditioning	**PART 2:** Find a quote from the excerpt that supports your answer to Part 1. Rewrite that quote in your own words here.
PART 3: Which of the following statements is the best summary of the "research question" for the experiment described in the study? A. Operant conditioning exerts powerful influences on the behaviors of living organisms. B. Dramatic examples of conditioning occur when carefully chosen stimuli are administered after responses. C. Conditioning occurs even when no specific behaviors are focused on or deliberately reinforced. D. Principles of learning control behaviors more significantly than internal factors, like intention. E. Organisms will acquire conditioned behaviors in response to reinforcements.	**PART 4:** Select a quote from the article that you think is the best evidence for your answer in Part 3, and rewrite in your own words here.

EXEMPLAR 5 CONTINUED

PILLAR:

RESEARCH METHODS | BIOLOGICAL | COGNITIVE | **DEVELOPMENT** | SOCIAL & PERSONALITY | MENTAL & PHYSICAL HEALTH

COMMON THEME:

CULTURAL & SOCIAL DIVERSITY | ETHICS | VARIATIONS IN HUMAN FUNCTIONING | **APPLICATIONS**

LEARNING GOALS:

GOAL 1: Knowledge Base in Psychology

GOAL 2: Scientific Inquiry and Critical Thinking

[Each element in the rubric may be weighted differently.]

Meets all expectations	Partially meets expectations	Does not meet expectations	STUDENT LEARNING OUTCOMES
			1.1 Describe key concepts, principles, and overarching themes in psychology
			1.2 Develop a working knowledge of psychology's content domains
			1.3 Describe applications of psychology
			2.2 Demonstrate psychology information literacy
			2.4 Interpret, design, and conduct basic psychological research

USING ASSESSMENT DATA

The Introductory Psychology course serves multiple purposes—as a prerequisite course to the psychology major, as a general education course, and as a vehicle for educating the general public. In all three instances, it is important to consider the overarching goals for the course. Departments can use the five content pillars (APA, 2014) to identify a limited set of content knowledge reflecting a global understanding of the discipline. Foundational indicators (APA, 2013) can be identified as outcomes for the course.

Regardless of the type of assessment (e.g., multiple-choice items, activities, exercises), the resulting data can be used for a variety of purposes. For example, faculty can use the data to evaluate their effectiveness in teaching and for the purpose of improving instruction across semesters. By using such locally developed instruments, institutions may be able to evaluate student learning at a campus level (Schulman, 2007) and use the data for purposes of regional accreditation; however, there are serious limitations to using such data in making any regional or national comparisons.

VALUE OF EMBEDDED ASSESSMENTS

Embedded assessments can be used as both formative and summative assessments of student learning outcomes. Introductory Psychology assessments can provide information about student knowledge and/or skills so that teachers and students can make "course corrections." For example, instructors could use information about their students' achievement in, say, the scientific method, knowledge content, and critical thinking to redesign lectures or class activities based on areas of apparent weakness. Such information could also be gathered toward the beginning of the course (diagnostic assessment) or later, after instruction has occurred (checking for understanding). If the data indicate that the class as a whole is fairly strong on content knowledge but is having difficulty using that knowledge to think critically about psychological claims,

instructors could design learning activities to help students practice these critical thinking applications.

Similarly, students could use data from the assessment to modify their own learning. It is possible (and likely) that some students within a class might continue to struggle with content mastery. Using a formative assessment allows an instructor to provide individual feedback about specific content-area weaknesses along with advice about how to remedy those weaknesses (e.g., studying advice specific to that content area, help with graphic organizers to conceptualize the information; Greenberg, 2015).

Data about student achievement may also inform many important department discussions and decisions. Departments could use data in making decisions about course offerings, in planning course objectives, and in overall discussions regarding what students should know and do. Departments may evaluate their success at various points and track longitudinal progress over time on specific goals.

A NATIONAL PLAN

Developing a nationally standardized instrument to assess outcomes of the Introductory Psychology course that possesses strong reliability, validity, and normative data will prove both difficult and expensive. In the meantime, we have provided a set of student learning outcomes that can be used as an initial step for creating a nationally standardized assessment plan. If faculty across the nation use a common set of student learning outcomes for Introductory Psychology, then the initial step in creating a national plan will be achieved.

In the absence of funding that would allow campuses to employ these nationally standardized measures of student learning, campuses may wish to continue assessing student learning outcomes using locally developed multiple-choice examinations. This type of assessment data provides campuses with an initial measure of student learning that can be used locally and as an initial step in responding to regional accreditation bodies. However, locally developed instruments are unique to the campus; they are not nationally standardized and will probably not possess adequate reliability and validity.

At a minimum, we suggest that campuses use embedded assessments that are designed to measure a subset of student learning outcomes associated with Introductory Psychology. Embedded assessments do not provide an ideal solution, but this incremental approach would provide campuses with data regarding higher level learning outcomes (e.g., critical thinking, scientific reasoning). A repository of these assessments could then be developed and maintained by APA to provide some level of national comparison.

Although we recommend that some form of assessment and data (i.e., embedded assessment) be maintained in a national clearinghouse, we do so with an abundance of caution. First, a repository would merely allow institutions to access a set of assessments with no assurances of their reliability or validity. It is possible that institutions would be willing to submit data from their respective campuses, as a way to begin to collect national data. However, institutions would first need to commit to participating in such an initiative. Institutions

would also need to consider local institutional review board regulations, which might limit their willingness to participate in a national project.

Ultimately, the Working Group recognizes that assessment of student learning outcomes for Introductory Psychology, and the major in psychology, is of the highest importance for the undergraduate community. We recommend investing in the development of a nationally standardized instrument for assessing student learning in the Introductory Psychology course. In the interim, we recommend that campuses employ sound measurement practices: define the constructs to be measured, create instruments for campus-based use, and evaluate the psychometric properties of those instruments. Ultimately we encourage departments to increase campus-based assessment initiatives that can serve as a basis for measuring the student learning that occurs in the introductory course.

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ASSESSMENT REVIEW TOOL

A PART OF THE ASSESSMENT TOOLKIT

To be used by: a team of grade or content-alike educators

Required time: Approximately 3 hours (can be completed over several sessions)

Required materials:

- Copy of the Assessment Review Tool (this document) for each member of the review team
- Copy of the assessment for each member of the review team
- At least one copy of the standards to be assessed
- At least one copy of the Companion Document
- Optional: A copy of the Student Learning Objective if the assessment being reviewed is for consideration for an SLO

Assessment Review Tool: The tool provides a framework for educators to use when evaluating an assessment for a given purpose, particularly whether or not an assessment is appropriate as evidence for a Student Learning Objective. It can be used to review commercially-, district-, or teacher-developed assessments. The tool prompts educators to consider type, alignment, scoring, administration, and bias.

This review should be completed by a team of educators and will take several hours to complete in its entirety. Given the scheduling constraints most teams face, the review can be completed over several sessions, each of which could be dedicated to a different aspect of the assessment (e.g. Alignment).

Companion Document: The companion document is a sample review of an assessment being considered for use in an SLO. It includes a completed Assessment Review Tool as well as annotations on the assessment's construct validity, format, directions, and potential biases. It can be used as an instructional tool during professional development on assessment and/or as practice by a team planning to use the Assessment Review Tool.

Content Area: _____ Name of Assessment: _____
Grade Level: _____ Date of Review: _____
Reviewer(s): _____

Assessment Review Tool

Part 1: Assessment Profile
Purpose of Assessment Explain the purpose the assessment is intended to serve (e.g. to inform instruction, to screen/diagnose, to measure outcomes.). *Note that assessments used as evidence for SLOs should be primarily designed to measure outcomes.*
Item Types – check all that apply (Note: There is often overlap among certain item types) ☐ **Constructed Response** (essay, multi-step response with explanation and/or rationale required for tasks) ☐ **Product** (research paper, editorial, log, journal, play, poem, model, multimedia, art products, script, musical score, portfolio pieces, etc.) ☐ **Performance** (demonstration, presentation, science lab, dance or music performance, athletic performance, debate, etc.) ☐ **Short Answer** (short constructed response, fill in a graphic organizer or diagram, explain your thinking or solution, make and complete a table, etc.) ☐ **Selected Response** (multiple choice, multiple select, evidence-based selected response (EBSR), true-false, matching, etc.)
Supporting Information – check all that are available (Note: Include as much information as possible to provide a clear picture of the assessment) ☐ **Teacher Directions** (may include prerequisites/description of instruction before giving the assessment; e.g., this assessment should be given after students have learned…) ☐ **Scoring Guide/Rubric** ☐ **Sample Evidence for Student Performance** ☐ **Student Materials** ☐ **Estimated Time for Administration** ☐ **Student Directions** ☐ **Assessment Task/Prompt** ☐ **Other:**
Administration – check all that apply ☐ **Whole Group** ☐ **Small Group** ☐ **Individual** ☐ **Paper and Pencil** ☐ **Computer** ☐ **Other** _____

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A high quality assessment should be … Aligned

Part 2: Alignment

Identify the SLO for which this assessment is being considered:

Identify the standards included in the SLO:

SLO Standards	Evaluated by Assessment		
	Fully	Partially	No
1.			
2.			
3.			
4.			
5.			

Identify additional standards measured by this assessment that are not included in the SLO:

Additional Standards	Check if scores can be partitioned
1.	
2.	
3.	
4.	
5.	

Describe the content knowledge/concepts assessed:

Describe the skills/performance assessed:

Are there a sufficient number of items or tasks on the assessment for each standard being assessed? If no, please identify which standards are underrepresented.

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To what extent do you see a strong content match between the task or items and the corresponding state-adopted standards?

- ☐ **Full match** – all tasks or items fully address the relevant skills and knowledge described in the corresponding state-adopted standard(s)
- ☐ **Close/Partial match** – most tasks or items address or partially address the relevant skills and knowledge described in the corresponding state-adopted standard(s)
- ☐ **Minimal match** – some tasks or items match some relevant skills and knowledge described in the corresponding state-adopted standard(s)
- ☐ **No match** – tasks or most items are not related to the skills and knowledge described in the corresponding state-adopted standard(s)

Are the items or tasks reviewed as cognitively complex as the state-adopted standards? Use the definitions below to select your rating.

- ☐ **More complex** – most items or the tasks reviewed are at a higher level of complexity than the range indicated for the state-adopted standard(s)
- ☐ **Similarly complex**– most items or the task reviewed are similar to the level of complexity indicated for the state-adopted standard(s)
- ☐ **Less complex** – most items or the task reviewed are lower than the level of complexity indicated for the state-adopted standard(s)

Comments/Suggestions for Improvement
Provide evidence to support your responses:

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A high quality assessment should be … Scored using Clear Guidelines and Criteria
Part 3: Rubric/Scoring Guide
Scoring Guide to be used with the assessment: ☐ **Generalized Rubric** (e.g., for writing an argument, for all science labs, etc.) ☐ **Task-specific Rubric** (only used for the particular task) ☐ **Scoring Guidelines** (e.g., checklist with score points for each part) ☐ **Answer key, Scoring Template, Computerized or Machine Scored** ☐ **Anchor Papers** (student samples at each score point) ☐ **Teacher Observation Sheet/Observation Checklist**
Are the rubric/scoring criteria aligned to the state-adopted standards? If no, please explain.
Are the score categories clearly defined and coherent across performance levels? If no, please explain.
Do the rubric/scoring criteria address all of the demands within the task or item? If no, please explain.
Based on your review of the rubric/scoring criteria, would the scoring rubric most likely lead different raters to arrive at the same score for a given response? If no, please explain.
Consider how long it will likely take the teacher(s) to score each assessment. Is this practical given the number of students and the type of assessment?
Are student work samples available that illustrate different levels of performance? If not, explain what additions are needed.
Comments/Suggestions for Improvement
Provide evidence to support your responses:

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A high quality assessment should be…Fair and Unbiased
Part 4: Fair and Unbiased (the areas below should be discussed relative to the needs of ELLs, gifted and talented students, and students with disabilities)
To what extent are the items or tasks visually clear and uncluttered (e.g., appropriate white space and/or lines for student responses, graphics and/or illustrations are clear and support the test content, the font size seems appropriate for the students)? Formatting is: ☐ Visually clear and uncluttered ☐ Somewhat clear and uncluttered ☐ Unclear, cluttered, and inappropriate for students Provide an explanation of your response, if needed:
Are directions for the items or tasks presented in as straightforward a manner as possible for a range of learners? If no, identify problematic items/tasks and provide suggestions for improvement.
Is the vocabulary and context(s) presented free from cultural or other unintended bias? If no, identify problematic items/tasks and provide suggestions for improvement.
Does the assessment use appropriate levels of academic language for the grade and content area? If no, identify problematic areas and provide suggestion for improvement.

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Accommodations are commonly categorized in five ways: presentation, response, setting, timing and scheduling, and linguistics. In the table below, identify any additional accommodations that should be provided to ensure that English Learners and/or Students with Disabilities can access the content represented by the task or items.

☐ ***Presentation Accommodations*** *– Allow students to access information in ways that do not require them to visually read standard print. These alternate modes of access are auditory, multi-sensory, tactile, and visual.*	
☐ ***Response Accommodations****—Allow students to complete activities, assignments, and assessments in different ways or to solve or organize problems using some type of assistive device or organizer.*	
☐ ***Setting Accommodations****—Change the location in which a test or assignment is given or the conditions of the assessment setting.*	
☐ ***Timing and Scheduling Accommodations****—Increase the allowable length of time to complete an assessment or assignment and perhaps change the way the time is organized.*	
☐ ***Linguistic Accommodations****—Allow English language learners (ELLs) to access academic construct measured by reducing the linguistic load of an assessment. The accommodation is based on an ELL's limited English language proficiency, which is different than an accommodation based on a student's disability or a cognitive need.*	

**Please reference "Defining Features of Academic Language in WIDA's Standards"* (See RIDE website)

Comments/Suggestions for Improvement

Provide evidence to support your responses:

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Recommendations for this assessment:

- ☐ **This assessment can be used for this SLO without revisions**
- ☐ **This assessment can be used for this SLO with minor revisions** (explain below)
- ☐ **This assessment can be used for this SLO with significant revisions** (explain below)
- ☐ **This assessment should not be used for this SLO** (explain below)

Comments/Suggestions for Revisions

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Ethical considerations

in biomedical HIV prevention trials

[Additional guidance point added in 2012]

UNAIDS/WHO guidance document

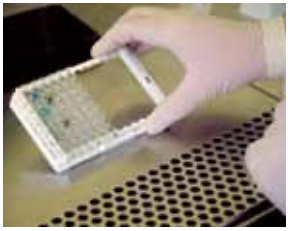

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Additional guidance point added in 2012

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Ethical considerations
in biomedical HIV prevention trials

[Additional guidance point added in 2012]

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Catherine Hankins, Carmel Shalev and Jolene Nakao finalized revisions after the Montreux meeting. Mihika Acharya and Constance Kponvi assisted with editing and Lon Rahn did the layout.

A companion document which readers may wish to consult is the UNAIDS/AVAC *Good Participatory Practice for Biomedical HIV Prevention Trials*. It covers core principles and essential activities throughout the research life-cycle, providing a foundation for community engagement in research. It is available on the UNAIDS website in a number of languages. For more information please contact gpp@unaids.org.

Comments on the *Ethical considerations in biomedical HIV prevention trials* and experience with implementation of this guidance are welcome. Please send them to ethics@unaids.org

In 2010-11, UNAIDS and WHO convened three key stakeholder consultations in Istanbul, Kuala Lumpur, and Buenos Aires for the Eastern Europe/Central Asia, Asia, and Americas regions where injecting drugs with contaminated equipment is an important HIV transmission mode. Recommendations from these consultations informed the development of guidance point 20 addressing the meaningful engagement in biomedical HIV prevention trials of people who inject drugs.

* Those who did not attend the Montreux meeting

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Guidance Point 1: Development of Biomedical HIV Prevention Interventions

Given the human, public health, social, and economic severity of the HIV epidemic, countries, development partners, and relevant international organisations should promote the establishment and strengthening of sufficient capacity and incentives to foster the early and ethical development of additional safe and effective biomedical HIV prevention methods, both from the point of view of countries and communities in which biomedical HIV prevention trials take place, and from the point of view of trial sponsors and researchers.

Guidance Point 2: Community Participation

To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials.

Guidance Point 3: Capacity Building

Development partners and relevant international organisations should collaborate with and support countries in strategies to enhance capacity so that countries and communities in which trials are being considered can practice meaningful self-determination in decisions about the scientific and ethical conduct of biomedical HIV prevention trials and can function as equal partners with trial sponsors, local and external researchers, and others in a collaborative process.

Guidance Point 4: Scientific and Ethical Review

Researchers and trial sponsors should carry out biomedical HIV prevention trials only in countries and communities that have appropriate capacity to conduct independent and competent scientific and ethical review.

Guidance Point 5: Clinical Trial Phases

As phases I, II, and III in the clinical development of a biomedical HIV preventive intervention all have their own particular scientific requirements and specific ethical challenges, researchers and trial sponsors should justify in advance the choice of study populations for each trial phase, in scientific and ethical terms in all cases, regardless of where the study population is found. Generally, early clinical phases of biomedical HIV prevention research should be conducted in communities that are less vulnerable to harm or exploitation, usually within the sponsor country. However, countries may choose, for valid

scientific and public health reasons, to conduct any trial phase within their populations, if they are able to ensure sufficient scientific infrastructure and sufficient ethical safeguards.

Guidance Point 6: Research Protocols and Study Populations

In order to conduct biomedical HIV prevention trials in an ethically acceptable manner, researchers and relevant oversight entities should ensure that the research protocol is scientifically appropriate and that the interventions used in the experimental and control arms are ethically justifiable.

Guidance Point 7: Recruitment of Participants.

In order to conduct biomedical HIV prevention trials in an ethically acceptable manner, participation of individuals should be voluntary and the selection of participating communities and individuals must be fair and justified in terms of the scientific goals of the research.

Guidance Point 8: Vulnerable Populations

The research protocol should describe the social contexts of a proposed research population (country or community) that create conditions for possible exploitation or increased vulnerability among potential trial participants, as well as the steps that will be taken to overcome these and protect the rights, the dignity, the safety, and the welfare of the participants.

Guidance Point 9: Women

Researchers and trial sponsors should recruit women into clinical trials in order to verify safety and efficacy from their standpoint, including immunogenicity in the case of vaccine trials, since women throughout the life span, including those who may become pregnant, be pregnant or be breastfeeding, should be recipients of future safe and effective biomedical HIV prevention interventions. During such research, women should receive adequate information to make informed choices about risks to themselves, as well as to their foetus or breastfed infant, where applicable.

Guidance Point 10: Children and Adolescents

Children and adolescents should be included in clinical trials in order to verify safety and efficacy from their standpoint, in addition to immunogenicity in the case of vaccines, since they should be recipients of future biomedical HIV preventive interventions. Researchers, trial sponsors, and countries should make efforts to design and implement biomedical HIV prevention product development programmes that address the particular safety, ethical, and legal considerations relevant for children and adolescents, and safeguard their rights and welfare during participation.

Guidance Point 11: Potential Harms

Research protocols should specify, as fully as reasonably possible, the nature, magnitude, and probability of all potential harms resulting from participation in a biomedical HIV prevention trial, as well as the modalities by which to minimise the harms and mitigate or remedy them.

Guidance Point 12: Benefits

The research protocol should provide an accurate statement of the anticipated benefit of the procedures and interventions required for the scientific conduct of the trial. In addition, the protocol should outline any services, products, and other ancillary interventions provided in the course of the research that are likely to be beneficial to persons participating in the trials.

Guidance Point 13: Standard of Prevention

Researchers, research staff, and trial sponsors should ensure, as an integral component of the research protocol, that appropriate counselling and access to all state of the art HIV risk reduction methods are provided to participants throughout the duration of the biomedical HIV prevention trial. New HIV-risk-reduction methods should be added, based on consultation among all research stakeholders including the community, as they are scientifically validated or as they are approved by relevant authorities.

Guidance Point 14: Care and Treatment

Participants who acquire HIV infection during the conduct of a biomedical HIV prevention trial should be provided access to treatment regimens from among those internationally recognised as optimal. Prior to initiation of a trial, all research stakeholders should come to agreement through participatory processes on mechanisms to provide and sustain such HIV-related care and treatment.

Guidance Point 15: Control Groups

Participants in both the control arm and the intervention arm should receive all established effective HIV risk reduction measures. The use of a placebo control arm is ethically acceptable in a biomedical HIV prevention trial only when there is no HIV prevention modality of the type being studied that has been shown to be effective in comparable populations.

Guidance Point 16: Informed Consent

Each volunteer being screened for eligibility for participation in a biomedical HIV prevention trial should provide voluntary informed consent based on complete, accurate, and appropriately conveyed and understood information

before s/he is actually enrolled in the trial. Researchers and research staff should take efforts to ensure throughout the trial that participants continue to understand and to participate freely as the trial progresses. Informed consent, with pre- and post-test counselling, should also be obtained for any testing for HIV status conducted before, during, and after the trial.

Guidance Point 17: Monitoring Informed Consent and Interventions

Before a trial commences, researchers, trial sponsors, countries, and communities should agree on a plan for monitoring the initial and continuing adequacy of the informed consent process and risk-reduction interventions, including counselling and access to proven HIV risk-reduction methods.

Guidance Point 18: Confidentiality

Researchers and research staff must ensure full respect for the entitlement of potential and enrolled participants to confidentiality of information disclosed or discovered in the recruitment and informed consent processes, and during conduct of the trial. Researchers have an ongoing obligation to participants to develop and implement procedures to maintain the confidentiality and security of information collected.

Guidance Point 19: Availability of Outcomes

During the initial stages of development of a biomedical HIV prevention trial, trial sponsors and countries should agree on responsibilities and plans to make available as soon as possible any biomedical HIV preventive intervention demonstrated to be safe and effective, along with other knowledge and benefits helping to strengthen HIV prevention, to all participants in the trials in which it was tested, as well as to other populations at higher risk of HIV exposure in the country, potentially by transfer of technology.

Guidance Point 20: People Who Inject Drugs

Researchers and sponsors should include people who inject drugs in biomedical HIV prevention trials in order to verify safety, efficacy, and effectiveness from their standpoint, including immunogenicity in the case of vaccines. As with other key populations at higher risk of HIV exposure, providing people who inject drugs with access to proven, effective HIV preventive interventions is a public health imperative. Researchers and trial sponsors should engage meaningfully with people who inject drugs and with other stakeholders to overcome the complex legal, ethical, and regulatory challenges to the participation in biomedical HIV prevention trials of people who inject drugs. Trial conduct that is ethical is informed by the latest scientific evidence on proven HIV prevention strategies and ensures that participants' human rights, safety, and welfare are protected.

INTRODUCTION

Well into the third decade of the HIV pandemic, there remains no effective HIV preventive vaccine, microbicide, product or drug to reduce the risk of HIV acquisition. As the numbers of those infected by HIV and dying from AIDS continue to increase, the need for such biomedical HIV preventive interventions becomes ever more urgent. Several such products are at various stages of development, including some currently in phase III efficacy trials. The successful development of effective HIV preventive interventions requires that many different candidates be studied simultaneously in different populations around the world. This in turn will require a large international cooperative effort drawing on partners from various health sectors, inter-governmental organisations, government, research institutions, industry, and affected populations. It will also require that these partners be able and willing to address the difficult ethical concerns that arise during the development of biomedical HIV prevention products.

Following deliberations during 1997-99 involving lawyers, activists, social scientists, ethicists, vaccine scientists, epidemiologists, non-governmental organisation (NGO) representatives, people living with HIV, and people working in health policy from a total of 33 countries, UNAIDS published a guidance document on ethical considerations in HIV preventive vaccine research in 2000. Since then there have been numerous developments related to the conduct of biomedical HIV prevention trials, including vaccine trials. Consultations have been held to explore key issues such as:

- Creating effective partnerships, collaboration and community participation in HIV prevention trials (International AIDS Society (IAS) 2005; UNAIDS 2006; UNAIDS/AIDS Vaccine Advocacy Coalition (AVAC) 2007);

- The inclusion of adolescents in HIV vaccine trials (WHO/IVR 2002; WHO/UNAIDS 2004; WHO/UNAIDS/African AIDS Vaccine Program 2006);
- Gender considerations related to enrolment and informed consent (WHO/UNAIDS 2004);
- Provision of support, care and treatment to participants and the community engaged in HIV prevention trials (WHO/UNAIDS 2003; IAS 2005; UNAIDS 2006; Forum for Collaborative Research 2006; International AIDS Society Industry Liaison Forum 2007;
- Post-trial responsibilities of sponsors, researchers and local providers (AVAC and the International Council of AIDS Service Organizations, 2005).

In light of these consultations, and evolution in the level of prevention, treatment and care available in the era of 'Towards Universal Access', the 2000 guidance document was revised and updated. The revision incorporates developments which have taken place since the original publication, including lessons learned in the field of biomedical HIV prevention research. Many different strategies for HIV prevention are now being explored, including microbicides, vaccines, female-initiated barrier methods, herpes simplex virus-2 (HSV-2) treatment/suppression, index partner treatment, antiretroviral pre-exposure prophylaxis, prevention of mother-to-child transmission and drug substitution/maintenance for injecting drug users. Of note, following the compelling evidence of a 50 to 60 per cent reduction in HIV acquisition for men who became circumcised in three randomised controlled trials in South Africa, Kenya and Uganda, WHO/UNAIDS produced recommendations in 2007 judging adult male circumcision to be an accepted risk reduction measure in men, particularly in high prevalence generalised HIV epidemics in which heterosexual transmission predominates. Finally, the guidelines in this document specifically address trials of biomedical HIV preventive interventions but are relevant to those engaged in trials of various behavioural HIV prevention methods.

This document does not purport to capture the extensive discussion, debate, consensus, and disagreement which have taken place among stakeholders in HIV prevention research. Rather it highlights, from the perspective of UNAIDS and WHO, some of the critical ethical elements that must be considered during the development of safe and effective biomedical HIV prevention interventions. Where these are adequately addressed, in the view of UNAIDS/WHO, by other existing texts, there is no attempt to duplicate or replace these texts, which should be consulted extensively throughout biomedical HIV prevention product development activities. Such texts include: the *Nuremberg Code* (1947); the *Declaration of Helsinki*, first adopted by the World Medical Association in 1964 and most recently amended in 2000 ; the revised International *Ethical Guidelines for Biomedical Research Involving Human Subjects*, issued in 2002 by the Council for International Organisations of Medical Sciences (CIOMS) (and developed in close cooperation with WHO); the World Health Organization's *Handbook for Good Clinical Research Practice* (2005); the *International Conference on Harmonisation's Good Clinical Practice (ICH GCP) Guideline* (1996); and the UNAIDS *Interim Guidelines on Protecting the Confidentiality and Security of HIV Information* (2007).

Systematic guidance on the role and responsibilities of entities funding and conducting biomedical HIV prevention trials towards participants, and their communities can be found in the UNAIDS/AVAC *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* (2007).

It is hoped that this document will be of use to potential research volunteers and trial participants, investigators, research staff, community members, government representatives, pharmaceutical companies and other industry partners and trial sponsors, and ethical and scientific review committees involved in the development of biomedical HIV prevention products and interventions. It suggests standards, as well as processes for arriving at standards which can be used as a frame of reference from which to conduct further discussion at the local, national, and international levels and can inform the development of national guidelines for the conduct of biomedical HIV prevention trials.

CONTEXT

The HIV pandemic is characterised by unique biological, social and geographical factors that, among other things, affect the balance of risks and benefits for individuals and communities who participate in biomedical HIV prevention trials. These factors may require that additional efforts be taken to address the needs of participating individuals and communities. They have an urgent need for additional HIV prevention choices for use at various stages of the life-cycle, a need to have their rights protected and their welfare promoted in the context of the development and testing of novel HIV prevention modalities, and a need to be able to participate fully as equal participants in the research process. These factors include the following:

- The global burden of disease and death related to HIV continues to increase at a rate unmatched by any other pathogen. For many countries, AIDS is the leading cause of death. Currently available treatments do not lead to cure, but do slow the progression of disease. The most effective treatment for slowing HIV-related disease progression, antiretroviral medication, is a life-long treatment which requires close medical monitoring, is still very costly, especially for 2nd line regimens, and can cause significant adverse effects. Because of this, antiretroviral medication is not readily available to the vast majority of people living with HIV who need it. More than 2 million people had access to antiretroviral treatments in low- and middle-income countries in 2006, five times more people than in 2003. But despite this tremendous progress in the roll-out of antiretroviral treatment, global coverage of needs is below 30%.

- For every person placed on antiretroviral treatment in 2006, another six people became newly infected with HIV. There is therefore an ethical imperative to seek, as urgently as possible, effective and accessible biomedical HIV prevention technologies, to complement existing prevention strategies. This ethical

imperative demands that these technologies be developed to address the situation of those people and populations most vulnerable to exposure to HIV infection.

- Genetically distinct subtypes of HIV have been described, and different HIV subtypes are predominant in different regions and countries. The relevance of these sub-types to probabilities of HIV transmission and acquisition, speed of disease progression and potential protection is not clearly understood.

- For the conduct of efficacy trials of any biomedical HIV prevention product, the populations with the highest incidence of HIV will be those most likely to be considered for participation and would be those most likely to benefit from an effective intervention. However, for a variety of reasons, these populations may be relatively vulnerable to exploitation and harm in the context of biomedical HIV prevention trials. Trial sponsors, countries, researchers, research staff and community leaders must make additional efforts to overcome this vulnerability.

- In some biomedical HIV prevention trials, individuals other than the trial participants may experience risks if they are exposed to the experimental product and may experience benefits if the product is effective. For example in trials of prophylaxis of mother-to-child transmission, the foetus is exposed to the prophylactic antiretroviral regimen in addition to the mother. If the mother develops antiretroviral resistance, she may transmit resistant virus to the infant. When the intervention is effective, the newborn baby is protected. In trials of vaginal microbicides, male sexual partners may be exposed to the product even when condoms are used. In trials of successful vaccine candidates, not only sexual partners benefit but communities may benefit from population level effects.

- Some biomedical HIV prevention modalities may be conceived and manufactured in laboratories of one country (sponsor country or countries), usually in high-income countries, and tested in human populations in another country, often low- and middle-income countries. The potential imbalance of such a

situation demands particular attention to ways to address the differing perspectives, interests and capacities of trial sponsors, countries, and communities engaged in trials with the goal of encouraging the urgent development of additional safe and effective biomedical HIV prevention tools, in ethically acceptable manners, and their early distribution to populations most in need. Countries and communities considering participation in biomedical HIV prevention trials should be encouraged and given the capacity to make decisions for themselves regarding their participation, based on their own health and human development priorities, in a context of equal collaboration with sponsors.

- HIV infection is both highly feared and stigmatised. This is in large part because it is associated with blood, death, sex, and activities which may not be legally sanctioned, such as commercial sex, men having sex with men, and illicit substance use. These are issues which are often difficult to address openly – at a societal and individual level. As a result, people living with HIV and those affected by AIDS may experience stigma, discrimination, and even violence; some communities continue to deny the existence and prevalence of HIV infection. Furthermore, vulnerability to HIV exposure and to the impact of AIDS is greater where people are marginalized due to their social, economic, and legal status. These factors increase the risk of social and psychological harm for people participating in biomedical HIV prevention trials. Additional efforts must be made to address these increased risks and to ensure that the risks participants take are justified by the anticipated benefits of the preventive intervention to the participants themselves or to others in the future.

- A key means by which to protect participants and the communities from which they come is to ensure that the community in which the research is carried out is meaningfully involved in the design, implementation, monitoring, and dissemination of results of HIV prevention trials, including the involvement of representatives from marginalized communities from which participants are drawn.

- Site selection for moving forward into empirical efficacy trials of biomedical HIV prevention technologies is a major challenge. Part of this challenge is the need to integrate biomedical HIV prevention tool development with other HIV prevention modalities, all of which need to be integrated with HIV treatment and care as provided by the local health care system. It is imperative that appropriate financial arrangements are in place to implement agreements made between partners at the time a study is initiated. These agreements should cover the period of the trial but also address what will be provided to study participants once the study is completed. Advance planning and collaboration between partners is also needed to facilitate timely product licensure and distribution once a method has been proven safe and effective.

- It has been the experience to date that HIV incidence in both the experimental and control arms of biomedical HIV prevention trials tends to fall below the pre-trial incidence, presumably as a result of sustained risk-reduction counselling and provision of effective HIV prevention tools. The discovery of additional safe and effective biomedical HIV preventive interventions will necessitate discussions among all research stakeholders involved in planned or active trials of other biomedical HIV prevention tools. A decision to introduce the new method in a trial that is already underway has to be made collectively as it may have implications for resource requirements, sample sizes, and potential futility of continuing the trial. The possibility that such a decision could be required should be anticipated during initial discussions among the research stakeholders.

- No single biomedical HIV prevention product or intervention is now or will be 100 per cent effective. This is in part because none are expected to achieve 100 per cent efficacy in the controlled circumstances of a trial and in part because behaviour will influence both consistency and correctness of uptake for many of the interventions being investigated, with the result that the efficacy seen in the trial will not lead to effectiveness at the same level in the real world. Furthermore, the manner in which an effective biomedical HIV prevention product is introduced into comprehensive HIV prevention programming will affect the

extent to which risk compensation[1] will occur. Therefore, social change communication strategies which emphasize combination prevention will be crucial to ensure that a new biomedical HIV prevention product truly does add to the existing tools when it is introduced. [2]

Selected circumstances in which biomedical HIV prevention trials should not be conducted

- ✘ when the product to be tested would not be appropriate for use, should it be proven safe and effective, in the community that would participate in the trial (see ***Guidance Point 1***);
- ✘ when capacity to conduct independent and competent scientific and ethical review does not exist (see ***Guidance Point 4***);
- ✘ where truly voluntary participation and ongoing free informed consent cannot be obtained (see ***Guidance Point 7***);
- ✘ when conditions affecting potential vulnerability or exploitation may be so severe that the risk outweighs the benefit of conducting the trial in that population (see ***Guidance Point 8***);
- ✘ when a survey of protective local laws and regulations applicable at the trial site has not been conducted or when such a survey indicates insurmountable legal barriers (see ***Guidance Point 10***);
- ✘ when agreements have not been reached among all research stakeholders on standard of prevention (see ***Guidance Point 13***) and access to care and treatment (see ***Guidance Point 14***);
- ✘ when agreements have not been arrived at on responsibilities and plans to make a trial product which proves safe and effective affordably available to communities and countries where it has been tested (see ***Guidance Point 19***).

[1] Risk compensation: an increase in risk-taking as a result of a decrease in perception of risk.

[2] The term "combination prevention" refers to the combination of various strategies that individuals can choose at different times in their lives to reduce their risks of sexual exposure to the virus.

SUGGESTED GUIDANCE

Guidance Point 1:

Development of Biomedical HIV Prevention Interventions

Given the human, public health, social, and economic severity of the HIV epidemic, countries, development partners, and relevant international organisations should promote the establishment and strengthening of sufficient capacity and incentives to foster the early and ethical development of additional safe and effective biomedical HIV prevention methods, both from the point of view of countries and communities in which biomedical HIV prevention trials take place, and from the point of view of trial sponsors and researchers.

Given the global nature of the epidemic, the devastation being wrought in some countries by it, the fact that biomedical HIV preventive interventions may be the best long term solution by which to control the epidemic, especially in low- and middle-income countries, and the potentially universal benefits of effective biomedical HIV prevention tools, there is an ethical imperative for global support to develop these modalities. This effort requires intense international collaboration and coordination over time among countries with scientific expertise and resources, and countries in which candidate products could be tested but whose infrastructure, resource base, and scientific and ethical capacities may need strengthening. Though potential HIV prevention tools such as microbicides, vaccines, herpes simplex virus-2 (HSV-2) suppression/treatment, female-initiated barrier methods, index partner treatment, antiretroviral drugs for prophylaxis, and biomedical interventions for injecting drug users should benefit all those in need, it is imperative that they benefit the populations at greatest risk of exposure to HIV. Thus, HIV prevention

product development should ensure that products are appropriate for use among such populations, among which it will be necessary to conduct trials; and, when developed, they should be made available and affordable to such populations.

Because HIV prevention product development activities take time, are complex, and require infrastructure, resources, and international collaboration,

- countries who may sponsor trials and countries who may participate in trials should include biomedical HIV prevention product development in their national HIV prevention and control plans.
- countries who may participate in trials should assess how they can and should take part in biomedical HIV prevention product development activities either nationally or on a regional basis, including identifying resources, establishing partnerships, conducting national information and research literacy campaigns, strengthening their scientific and ethical sectors, and including biomedical HIV prevention product research to complement current comprehensive HIV prevention programming.
- development partners, international agencies, and governments should make early and sustained commitments to allocate sufficient funds to make biomedical HIV preventive interventions a reality. This includes funds to strengthen ethical and scientific capacity in countries where multiple trials will have to be conducted, to enhance South-South as well as North-South capacity building and technology transfer, and to purchase and distribute future biomedical HIV prevention tools.
- potential trial sponsors and countries who may participate in trials should establish partnerships with each other, initiate community consultations, support the strengthening of necessary scientific and ethical components, and make plans with all stakeholders for equitable distribution of the benefits of research.

Guidance Point 2:

Community Participation[2]

To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, and distribution of results of biomedical HIV prevention trials.

It is highly important to engage in consultations with communities who will participate in the trial from the beginning of the research concept, in an open, iterative, collaborative process that involves a wide variety of participants and takes place under public scrutiny. Participatory management benefits all parties; helps ensure smooth trial functioning; and builds community capacity to understand and inform the research process, raise concerns, and help find solutions to unexpected issues that may emerge once the trial is underway. Failure to properly and genuinely engage communities early in the stages of research planning may result in an inability to properly conduct and complete important trials. Furthermore, active community participation should strengthen not only local ownership of the research, but also the negotiating power of communities, the research skills of local investigators, and the social leverage that can be useful in areas of the society beyond the research trial site. Communities of people affected by research should conversely play an active, informed role in all aspects of its planning and conduct, as well as the dissemination of results. Achieving meaningful participation requires

[2] Consider further the UNAIDS/AVAC Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials (2007).

the acknowledgement of structural power imbalances between certain communities and researchers and/or research sponsors, and striving to overcome them. In practical terms, this means putting in place outreach and engagement measures to support participation. Special attention should be paid to the inclusion and empowerment of women for active involvement throughout the research process, as well as to the representation of populations at higher risk of HIV exposure, including adolescents.

The nature of community involvement should be one of continuous mutual education and respect, partnership, and consensus-building regarding all aspects of the testing of potential biomedical HIV prevention products. A continuing forum should be established for communication and problem-solving on all aspects of the HIV prevention product development programme from phase I through phase III and beyond (see ***Guidance Point 6***), to the distribution of a safe and effective HIV prevention tool. All participating parties should define the nature of this ongoing relationship. It should include appropriate representation from the community on committees charged with the review, approval, and monitoring of a biomedical HIV prevention trial. As with investigators and sponsors, communities should also assume appropriate responsibility to assure the successful completion of the trial and the product development programme.

Defining the relevant community for consultation and partnership is a complex and evolving process that should be discussed with relevant local authorities. As more groups and people define themselves as part of the interested community, the concept needs to be broadened to civil society so as to include advocates, media, human rights organizations, national institutions and governments, as well as researchers and community representatives from the trial site. Partnership agreements should include a clear delineation of roles for all stakeholders and should specify the responsibilities of sponsors, governments, community, advocacy organizations, and media, as well as researchers and research staff.

Appropriate community representatives should be determined through a process of broad consultation. An agreement should be reached among stakeholders about the definition of a "community" and ways that it can be effectively represented in decision-making early in the design of the study protocol. The process for determining who will be credible and legitimate community representatives should be addressed through a preliminary consultative process between researchers and key members of the community in which the research is proposed to take place. Members of the community who may contribute to development of a safe and effective HIV prevention product include representatives of the research population eligible to serve as research participants, other members of the community who would be among the intended beneficiaries of the developed product, relevant non-government organisations, persons living with HIV, community leaders, public health officials, and those who provide health care and other services to people living with and affected by HIV.

Formal community meetings need to be organised in a way that facilitates the active participation of those most affected by the research being proposed. The principal investigator and site research staff should work with representatives of affected communities to identify needs related to their participation, including logistical requirements such as transportation to the meeting site. Educational materials should be designed in an accessible format, using easy to understand language. Adequate consultation and full participation in the planning process will require more than formal community meetings, as such meetings may alienate some people or be inaccessible to others due to the timing or the format. The principal investigator and site research staff should make efforts to reach out to affected communities, meeting at community centres, workplaces, and other frequented locations. In both formal and informal consultations, the timing and length of the meetings should be convenient for community members, using approaches that facilitate two-way communication with two goals in mind: (1) to identify and

understand community concerns and needs, as well as their knowledge and experience, and (2) to clearly describe the research being proposed, related benefits and risks, and other practical implications.

Participation of the community in the planning and implementation of a biomedical HIV prevention product development strategy can provide at least these favourable consequences:

- information regarding the health beliefs and understanding of the study population
- information regarding the cultural norms and practices of the community
- input into the design of the protocol
- input into the design of an effective recruitment and informed consent process
- insight into the design of risk reduction interventions
- effective methods for disseminating information about the trial and its outcomes
- information to the community-at-large on the proposed research
- trust between the community and researchers
- equity in eligibility criteria for participation
- equity in decisions regarding level of care and treatment and its duration, and
- equity in plans for releasing results and distributing safe and efficacious HIV prevention products.

Researchers may lack the requisite language, communication skills, and experience to respond to community concerns, while communities may be unfamiliar with research concepts, such as "double blind" and "cause and effect", and may not define HIV prevention research as a priority. This underscores the need for "joint literacy", whereby researchers and community groups become sufficiently fluent in the requisite concepts and language to work productively together. Research literacy programs that include ethics training for study staff can facilitate and enhance cooperation with civil society groups.

Guidance Point 3:

Capacity Building

Development partners and relevant international organisations should collaborate with and support countries in strategies to enhance capacity so that countries and communities in which trials are being considered can practice meaningful self-determination in decisions about the scientific and ethical conduct of biomedical HIV prevention trials and can function as equal partners with trial sponsors, local and external researchers, and others in a collaborative process.

Countries and communities who choose to participate in biomedical HIV prevention trials have the right, and the responsibility, to make decisions regarding the nature of their participation. Yet disparities in economic wealth, scientific experience, and technical capacity among countries and communities have raised concern about possible exploitation of participant countries and communities. The development and testing of biomedical HIV preventive interventions requires international cooperative research, which should transcend, in an ethical manner, such disparities. Real or perceived disparities should be resolved in a way that ensures equality in decision-making and action. The desired relationship is one of equals, whose common aim is to develop a long-term partnership through South-South as well as North-South collaboration that sustains site research capacity.

Factors that affect perceptions of disparity in power between sponsors and the countries and communities in which research takes place may include, but are not limited to, the following:

- level of the proposed community's economic capacity and social power;
- community/cultural experience with and/or understanding of scientific research and of their responsibilities;

- research staff experience with and/or understanding of the community/culture;
- local political awareness of the importance and process of biomedical HIV prevention trials;
- local infrastructure, personnel, and technical capacity for providing comprehensive HIV health care and treatment options;
- ability of individuals in the community to freely provide informed consent, in light of cultural norms, socio-economic status, gender, and other social factors (see ***Guidance Points 16 and 17***);
- level of experience and capacity for conducting ethical and scientific review (see ***Guidance Point 4***); and
- local infrastructure, personnel, and laboratory and technical capacity for conducting the proposed research.

Strategies to overcome these disparities and empower communities could involve:

- characterisation of the local epidemic through prevalence/incidence studies and behavioural assessments
- scientific exchange, and knowledge and skills transfer, between sponsors, researchers, communities and their counterparts, and the countries in which the research takes place, including in the field of social science;
- capacity-building programmes in the science and ethics of biomedical HIV prevention research by relevant scientific institutions and local and international organisations;
- support to develop national and local ethical review capacity (see ***Guidance Point 4***);
- support to communities from which participants are drawn regarding information, education, and consensus-building in biomedical HIV prevention trials;
- early involvement of communities in the design and implementation of HIV prevention product development plans and protocols (see ***Guidance Point 2***); and
- development of laboratory capacity that can support health care provision as well as research.

In the coming years, there will be increasing demands on clinical sites so that national governments, sponsors, and researchers should think

about how to sustain site capacity and retain research staff expertise. Site development may build capacity for a specific trial or enhance the ability of a site to compete more broadly for a range of trials. Given the long time frames of biomedical HIV prevention research, special attention to communication and transparency is needed in order to build and maintain trust with participating communities, and to sustain site capacity even after the end of a trial.

Guidance Point 4:

Scientific and Ethical Review

Researchers and trial sponsors should carry out biomedical HIV prevention trials only in countries and communities that have appropriate capacity to conduct independent and competent scientific and ethical review.

Proposed biomedical HIV prevention trial protocols should be reviewed by scientific and ethical review committees that are located in, and include membership from, the country in which researchers wish to operate. Trials should register with an international trial registry prior to committee review as a condition of approval. Community representatives should also be involved in review of the trial protocol to insure that the research is informed by the concerns and priorities of the community in which the study is to take place. This process ensures that the proposed research is analysed in scientific and ethical terms by individuals who are familiar with the conditions prevailing in the potential research population. Reviewers should not allow research to begin unless the potential benefits of the experimental intervention outweigh the risks to participating individuals and groups. Independent ethical review of research protocols ensures public accountability and also minimizes concerns with regard to researchers' conflicts of interest because of relationships with the sponsors or pressures from those promoting the research. The scientific and ethical review should involve individuals with training in science, statistics, ethics, and law.

Some countries do not currently have the capacity to conduct independent, competent, and meaningful scientific and ethical review. If the country's capacity for scientific and ethical review is judged to be inadequate, the sponsor should be responsible for ensuring that adequate structures for scientific and ethical review prior to the start of the research are developed in the country in which the trial will take place — or the research should not take place. Care should be taken to minimise the potential for conflicts of interest, while providing assistance in capacity-building for scientific and ethical review. Capacity-building in scientific and ethical review may also be developed in collaboration with international agencies, organisations within the host country, and other relevant parties.

Scientific and ethical review prior to approval of a trial protocol should take into consideration these issues:

- ✔ the value and validity of the research protocol
- ✔ community participation and involvement
- ✔ risk-benefit ratio
- ✔ recruitment strategies and methods
- ✔ inclusion and exclusion criteria and screening of participants
- ✔ informed consent procedures and written information sheets
- ✔ provision of support, care, and treatment to participants, and in the community
- ✔ respect for potential recruits and enrolled trial participants and protection of participants' rights
- ✔ confidentiality, privacy, and data protection measures
- ✔ prevention of stigma and discrimination
- ✔ sensitivity to gender
- ✔ procedures for monitoring enrolled participants
- ✔ quality assurance and safety control
- ✔ plans for post-trial distribution and benefit sharing.

Guidance Point 5:

Clinical Trial Phases

As phases I, II, and III in the clinical development of a biomedical HIV preventive intervention all have their own particular scientific requirements and specific ethical challenges, researchers and trial sponsors should justify in advance the choice of study populations for each trial phase, in scientific and ethical terms in all cases, regardless of where the study population is found. Generally, early clinical phases of biomedical HIV prevention research should be conducted in communities that are less vulnerable to harm or exploitation, usually within the sponsor country. However, countries may choose, for valid scientific and public health reasons, to conduct any trial phase within their populations, if they are able to ensure sufficient scientific infrastructure and sufficient ethical safeguards.

The initial pre-clinical phase in the development of a biomedical HIV prevention product entails research in laboratories and among animals. The transition to a phase I clinical trial in which testing involves the administration of the product to human subjects to assess safety, and in the case of vaccines to assess immunogenicity, is a time when risks may not yet be well-defined. Hence, specific infrastructures are often required in order to ensure the safety and care of the research participants at these stages. For these reasons, the first administration of a candidate biomedical HIV prevention product in humans should generally be conducted in populations which are not at risk of HIV acquisition, usually in the country of the trial sponsor.

Clinical trial researchers have been designing trials that fall somewhere between phase II (expanded safety and immunogenicity) and phase III (large scale trials to assess efficacy) – called phase IIB trials, or proof of concept trials. Phase IIB trials may provide an indication of

an experimental candidate's efficacy but are less costly in terms of money, time, and number of trial participants. However, such phase IIB trials are not designed to provide enough information for regulatory approval at the end of the trial for an HIV prevention product subject to regulation; instead, these trials test the general concept of the candidate product and efficiently filter out products that lack efficacy. Eventually, a phase III trial would have to be conducted to develop a useable and licensable HIV product.

There may be situations where low- and middle-income countries choose to conduct phases I/II and/or IIB and III among their populations that are relatively vulnerable to risk and exploitation. For instance, this could occur where an experimental HIV vaccine is directed primarily toward a viral strain that does not exist in the trial sponsor's country but does exist in the country in which it is proposed the trial be conducted. Conducting phase I/II trials in the country where the strain exists may be the only way to determine whether safety and immunogenicity are acceptable in that particular population, prior to conducting a phase III trial. Another example might be a country that decides that, due to the high level of HIV risk to its population and the gravity of HIV prevalence in the country, it is willing to test a biomedical HIV prevention product concept that has not or is not being tested in another country. Such a decision may result in obvious benefits to the country in question if an effective product is eventually found. If phase I or phase II trials are conducted in the country intending to participate in an eventual phase III trial, if phases I and II are satisfactory, this may assist in building capacity for phase III trial conduct, including increasing levels of research literacy in the population.

Establishing a biomedical HIV prevention product development programme that entails the conduct of some, most, or all of its clinical trial components in a country or community that is relatively vulnerable to harm or exploitation is ethically justified if:

- the product is a vaccine anticipated to be effective against a strain of HIV that is an important public health problem in the country;
- the country and the community either have, or with assistance can develop or be provided with, adequate scientific and ethical capability and administrative and health infrastructure for the successful conduct of the proposed research;
- community members, policy makers, ethicists, and investigators in the country have determined that their residents will be adequately protected from harm and exploitation, and that the biomedical HIV prevention product development programme is necessary for and responsive to the health needs and priorities in their country; and
- all other conditions for ethical justification as set forth in this document are satisfied.

In cases in which it is decided to carry out phase I or phase II trials first in a country other than the trial sponsor's country, due consideration should be given to conducting them simultaneously in the country of the trial sponsor, where this is practical and ethical. Also, as a general rule, phase I/II trials that have been performed in the country of the trial sponsor should ordinarily be repeated in the community in which the phase III trials are to be conducted, although this may not be needed, particularly in situations in which a product has demonstrated unexpectedly high efficacy.

Guidance Point 6:

Research Protocols and Study Populations

In order to conduct biomedical HIV prevention trials in an ethically acceptable manner, researchers and relevant oversight entities should ensure that the research protocol is scientifically appropriate and that the interventions used in the experimental and control arms are ethically justifiable.

In order to be ethical, clinical trials of novel biomedical HIV prevention tools should be based on scientifically valid research protocols, and the scientific questions posed should be rigorously formulated in a research protocol that is capable of providing reliable responses.Valid scientific questions relevant to biomedical HIV prevention product development are those that seek:

- to gain scientific information on the safety and efficacy (degree of protection) of candidate biomedical HIV prevention products, and, in the case of vaccine candidates, immunogenicity (ability to induce immune responses against HIV);
- to determine correlates or surrogates of safety and protection in order to better characterise and elicit protective mechanisms;
- to compare different candidate products; and
- to test whether biomedical HIV prevention products effective in one population are effective in other populations.

Furthermore, the selection of the research population should be based on the fact that its characteristics are relevant to the scientific issues raised; and the results of the research will potentially benefit the selected population. In this sense, the research protocol should:

- justify the selection and size of the research population from a scientific point of view;

- demonstrate how the candidate biomedical HIV prevention intervention being tested is expected to be beneficial to the population in which testing occurs;
- establish safeguards for the protection of research participants from potential harm arising from the research (see ***Guidance Point 11***); and
- be sensitive to issues of privacy and confidentiality in recruitment procedures (see ***Guidance Point 17***).

Guidance Point 7:

Recruitment of Participants

In order to conduct biomedical HIV prevention trials in an ethically acceptable manner, participation of individuals should be voluntary and the selection of participating communities and individuals must be fair and justified in terms of the scientific goals of the research.

Selection and recruitment of communities and individuals for participation in a trial must be fair and should create a research climate which shows respect for all persons. This encompasses decisions about who will be included through the formulation of inclusion and exclusion criteria, and through the strategy adopted for recruiting participants. The scientific goals of the study should be the primary basis for determining the individuals who will be recruited and enrolled. Individuals should not be excluded from the opportunity to participate without a good scientific reason or a susceptibility to risk that justifies their exclusion. Social and cultural factors should be considered to determine the vulnerability within the community of individuals who are either included or excluded. In particular, gender-sensitive approaches are key when designing recruitment procedures and special attention needs to be paid to the inclusion or exclusion of pregnant women.

In some situations, voluntariness of participation may be compromised by factors such as social marginalization, political powerlessness, and economic dependence. Voluntariness of participation may also be compromised where there is a cultural tradition of men holding decision making authority in marital relationships, parental control of women, and other forms of social subjugation and coercion (see ***Guidance Point 9***). In some communities, it is customary to require the authorization of a third party, such as a community elder or head of a family, in order for investigators to enter the community or to approach individuals. However, the third party only gives permission to invite individuals to participate and such authorisation or influence must not be used as a substitute for individual informed consent. Trials should not be conducted where truly voluntary participation and ongoing free informed consent cannot be obtained. Authorisation by a third party in place of individual informed consent is permissible only in the case of some minors who have not attained the legal age of consent to participate in a trial. In cases where it is proposed that minors will be enrolled as research participants, specific and full justification for their enrolment must be given, and their own assent or consent must be obtained in light of their evolving capacities (see ***Guidance Point 10***).

Guidance Point 8:

Vulnerable Populations

The research protocol should describe the social contexts of a proposed research population (country or community) that create conditions for possible exploitation or increased vulnerability among potential trial participants, as well as the steps that will be taken to overcome these and protect the rights, the dignity, the safety, and the welfare of the participants.

By definition, HIV prevention research must follow the epidemic. In order to test if a biomedical HIV prevention intervention works, large numbers of individuals at high risk for HIV infection must be recruited for clinical trials. Sites based in communities with mature HIV epidemics have lower incidence rates and may be most appropriate for safety studies. Sites in communities with younger epidemics may be better suited for efficacy trials. However, participating communities and populations, particularly for large-scale efficacy trials, will generally be characterized by multiple vulnerabilities. The same factors that put these individuals at higher risk for exposure to HIV also make them vulnerable to cultural exclusion, social inequality, economic exploitation, and political oppression. Examples of populations that may have an increased vulnerability include women, children and adolescents, men who have sex with men, injecting drug users, sex workers, transgender persons, indigenous populations, the poor, the homeless, and communities from resource-poor settings in high-income and low- and middle-income countries. At the same time, it is precisely these populations who stand to benefit most from the successful development of a new biomedical HIV prevention product or method. For these reasons, it is imperative to ensure protection of the rights of participants in biomedical HIV prevention trials, and respect for their dignity, safety, and welfare.

Decision-making around conducting a biomedical HIV prevention trial needs to consider in what ways the trial might increase or decrease vulnerabilities. On the one hand, a trial might increase a participant's risk of exposure to stigmatisation and discrimination if it highlights a population's increased vulnerability to HIV exposure. On the other hand, a trial might decrease vulnerability, if it empowers the community or provides tangible assistance to participants, for example by improving the accessibility, affordability, and quality of appropriate healthcare services in the community. A social and political analysis should be carried out early on in planning the research process, to assess determinants of vulnerability, such as poverty, gender, age, ethnicity, sexuality, health, employment, education, and legal conditions in potential participating communities. Findings from this analysis should inform the design of research protocols, which should be sensitive to emerging information on incidental risks of social harm throughout the course of a trial. Research protocols might also include ongoing independent monitoring of a trial in relation to its impact on the vulnerabilities of communities participating in the study (see ***Guidance Point 17***).

The *particular* aspects of a social context that create conditions for exploitation or increased vulnerability should be described in the research protocol, as should the safeguards and measures that will be taken to prevent and overcome them. In some potential research populations (countries or communities), conditions affecting potential vulnerability or exploitation may be so severe that the risk outweighs the benefit of conducting the study in that population. In such populations, biomedical HIV prevention trials should not be conducted.

Sensitivity to factors of potential vulnerability, including language and cultural barriers, should inform procedures for recruiting and screening potential participants, informed consent processes, and the support, care, and treatment that participants receive in relation to the trial. If a scientifically appropriate population is identified as vulnerable to social harm, specific safeguards should be implemented to protect individual participants, such as ensuring confidentiality, the freedom to decline joining the study and the right to withdraw at any time without penalty.

Guidance Point 9:

Women

Researchers and trial sponsors should include women in clinical trials in order to verify safety and efficacy from their standpoint, including immunogenicity in the case of vaccine trials, since women throughout the life span, including those who are sexually active and may become pregnant, be pregnant or be breastfeeding, should be recipients of future safe and effective biomedical HIV prevention interventions. During such research, women's autonomy should be respected and they should receive adequate information to make informed choices about risks to themselves, as well as to their foetus or breastfed infant, where applicable.

Women throughout the life span, including those who are sexually active and may become pregnant, be pregnant or be breastfeeding, should be recipients of future safe and effective biomedical HIV prevention products and therefore should be eligible for enrolment in biomedical HIV prevention trials, both as a matter of equity and because in many communities throughout the world women, particularly young women, are at higher risk of HIV exposure. Therefore, the efficacy of candidate biomedical HIV prevention products, and their immunogenicity in the case of vaccines, should be established for women. Clinical trials should also be designed with the intent of establishing the safety of candidate biomedical prevention products for the health of the woman and, where applicable, her foetus, breastfed infant and, in the case of vaginal or rectal microbicides, her sexual partners.

If the safety of the biomedical HIV prevention product for a pregnant women and her foetus has not been established prior to commencement of the trial, women who become pregnant in the course of the trial might be discontinued from using the product, which would

result in loss to follow-up of the participating women. Therefore the question of whether a safety study for pregnant women should be conducted early on in the research, at the stage when a candidate has sufficient promise to advance into a Phase IIB or Phase III efficacy trial in adults or only after the trial product has been shown to be effective should be discussed and resolved on a case-by-case basis early on in the planning of the research design. In any event, researchers should monitor adverse events among pregnant women and women who become pregnant in the course of the trial, notably in the case of a miscarriage, to determine their relatedness to the biomedical HIV preventive intervention.

The most notable data gap in the evaluation of some prevention methods, particularly in phase I and II trials, is adequate evaluation of safety and efficacy among women. Barriers for women participating in trials include contraceptive requirements, issues related to current or future fertility, concerns about safety for the foetus, and fear of being labelled as being at higher risk for HIV exposure. Also, women present issues of particular complexity with regard to recruitment and informed consent. In some cultures, women and girl adolescents may not be able to exercise true autonomy in light of the influence of their parents or sexual partners (see ***Guidance Point 7***). In others, young people may be more informed than their parents, and their view and their parents' or partners' views on their participation may differ. Further, the need for HIV testing or pregnancy testing to assess eligibility for inclusion in a trial may raise difficult issues regarding the maintenance of appropriate confidentiality. Researchers and research staff should improve recruitment strategies by anticipating and finding solutions to address and overcome these barriers (see ***Guidance Point 7***). Appropriate reproductive and sexual health counselling and ancillary services, including family planning, should be provided to trial participants.

Although the enrolment of pregnant or breastfeeding women complicates the analysis of risks and benefits, because both the woman and the foetus or infant could be benefited or harmed, such women should be viewed as autonomous decision-makers, capable of making an informed choice for themselves and for their foetus or child. In order for pregnant women to be able to make an informed choice for their foetus/breastfed infant, they should be duly informed about any potential for teratogenesis and other known or unknown risks to the foetus and/or the breastfed infant. If there are risks related to breastfeeding, women should be informed of the availability of nutritional substitutes and other supportive services. Researchers should observe and study the positive and adverse effects on the children of these women. They should maintain pregnancy registries to collect data on outcomes of pregnancies that inadvertently occur during the trial, follow-up babies born to women participants, and take due measures for protection of privacy and personal data. In the particular case of trials of prevention of mother-to-child transmission, both women and their infants who became infected should also be assessed for the development of antiretroviral resistance and its potential for effects on subsequent therapeutic options.

Guidance Point 10:

Children and Adolescents

Children and adolescents should be included in clinical trials in order to verify safety and efficacy from their standpoint, in addition to immunogenicity in the case of vaccines, since they should be recipients of future biomedical HIV preventive interventions. Researchers, trial sponsors, and countries should make efforts to design and implement biomedical HIV prevention product development programmes that address the particular safety, ethical, and legal considerations relevant for children and adolescents, and safeguard their rights and welfare during participation.

Children[3], including infants and adolescents, should be eligible for enrolment in biomedical HIV preventive intervention trials, both as a matter of equity and because in many communities throughout the world children are at a higher risk of HIV exposure. Infants born to HIV-infected mothers are at risk of becoming infected during birth and during the postpartum period through breastfeeding. Many adolescents are also at higher risk of HIV infection due to sexual activity, lack of access to HIV prevention education and means, and through injecting drugs with non-sterile equipment.

Therefore, biomedical HIV prevention product development programmes should consider the needs of children for a safe and effective preventive intervention; should research the legal, ethical, and health considerations relevant to their participation in biomedical trials; and should enrol children in clinical trials designed to establish safety and efficacy for their age groups, including establishing immunogenicity in the case of vaccines, if their health needs and the ethical considerations relevant to their

[3] As defined by the Convention on the Rights of the Child, Article 1: "… a child means every human being below the age of eighteen years unless, under the law applicable to the child, majority is attained earlier."

situation can be met. Those designing biomedical HIV prevention product development programmes that might include children should do so in consultation with groups dedicated to the protection and promotion of the rights and welfare of children, both at international and national levels.

It is generally understood that adolescents, prior to initiation of sexual activity and exposure to any risk of HIV infection, will be the primary target for any public health intervention involving a successful biomedical intervention. In the case of HIV vaccine candidates and other products requiring licensure that would have an indication for use in both adolescents and adults, it is imperative that there be no delays in achieving simultaneous licensure/registration for both populations. It is therefore recommended in such cases, that adolescents be included in trials as soon as possible when a candidate has sufficient promise to advance into a Phase IIB or Phase III efficacy trial in adults (see ***Guidance Point 5***). The use of bridging studies designed for safety (and, in the case of an HIV vaccine, immunogenicity testing), but not including HIV infection as a primary endpoint could be considered as an alternative for younger adolescents, to be carried out in parallel to Phase III trials in adults.

There may be legal barriers to enrolment of younger adolescents into a clinical trial in which sexual activity is directly linked to achieving primary endpoints. It is imperative that trials are conducted in compliance with the protective laws and regulations applicable at the trial sites, including those related to legal age of consent, the age of majority, the legal age for consensual sex, legal obligations to report abuse or neglect, and other aspects which may have an impact on the conduct of biomedical HIV preventive intervention trials. Thus, undertaking a survey of applicable local laws is an essential requirement to ensure required compliance prior to making plans for such trials in a particular country.

As with all other trials involving children, the permission of a parent or legal guardian is required along with the assent of the child. Unless exceptions are authorised by national legislation, consent to participate in a biomedical HIV preventive intervention trial must be secured from the parent or guardian of a child who is a minor, before the enrolment of the child as a participant in a vaccine trial. The consent of one parent is generally sufficient, unless national law requires the consent of both. Every effort should be made to obtain assent to participate in the trial also from the child according to the evolving capacities of the child, and his or her refusal to participate should be respected.

In some jurisdictions, individuals who are below the age of consent are authorised to receive, with their active consent and without the consent or awareness of their parents or guardians, such medical services as therapeutic abortion, contraception, treatment for illicit drug use or alcohol abuse, and treatment of sexually transmitted infections. In some of these jurisdictions, such minors are also authorised to consent to serve as participants in research in the same categories without the agreement or the awareness of their parents or guardians, provided the research presents no more than "minimal risk". However, such authorisation does not justify the enrolment of minors as participants in biomedical HIV prevention trials without the consent of their parents or guardians.

In some jurisdictions, some individuals who are below the general age of consent are regarded as "emancipated" or "mature" minors and are authorised to consent without the agreement or even the awareness of their parents or guardians. These may include those who are married, parents, pregnant or living independently. When authorised by national legislation, minors in these categories may consent to participation in biomedical HIV prevention trials without the permission of their parents or guardians.

During the informed consent process, it is recommended that investigators conduct the consent (parent) and assent (adolescent) processes separately. This would ensure confidential counselling for the adolescent and protect the adolescent's privacy (see ***Guidance Point 18***). It is also important to inform adolescents of all the elements disclosed to an adult, and to determine that the adolescent understands what s/he is assenting to (see ***Guidance Point 16***). The consent process and document should describe clearly what information regarding the adolescent will or will not be disclosed to the parent(s) or legal guardian, as well as what medical or other services will be provided to the adolescent, as needed, without further parental permission.

In some settings, children may have guardians who have not been legally recognized by a court as such. Adolescents who do not have parents or legally recognized guardians should not be automatically excluded from participation in a biomedical HIV preventive intervention trial. Participation could be considered for such adolescents who wish to participate in a trial, as long as a protective ethical oversight mechanism can be established in compliance with the local law. In addition, mechanisms should be established for an independent evaluation of the capacity of such adolescents to give informed consent.

Guidance Point 11:

Potential Harms

Research protocols should specify, as fully as reasonably possible, the nature, magnitude, and probability of all potential harms resulting from participation in a biomedical HIV prevention trial, as well as the modalities by which to minimise the harms and mitigate or remedy them.

Participation in biomedical HIV prevention trials may involve physiological, psychological, and social risks. Participation in a complicated, lengthy trial involving intensely intimate matters, repeated HIV testing, and exposure to culturally different scientific and medical concepts may cause anxiety, stress, depression, as well as stress between partners in a relationship. Legal regulations for HIV disclosure may require partner notification when volunteers test-positive or trial participants acquire HIV infection (see ***Guidance Point 18***).

Participation, if it becomes publicly known, may also cause stigma and discrimination against the participant if s/he is perceived to be HIV-infected or at higher risk of acquiring HIV infection, particularly for women and adolescents, and already marginalised populations. HIV has been associated with illicit behaviour, including injecting drug use, sex work, and sexual relations between men, as well as with behaviours which may not be condoned such as premarital or extramarital sexual activity. Discrimination can take the form of accusations or abuse, can affect marriage prospects, and can result in social ostracism, job loss, denial of property or inheritance rights, or the denial of health care. Women may be at heightened risk of domestic violence as a result of trial participation. Trial sponsors, countries, and researchers should ensure that trials take place only in communities where confidentiality can be maintained and where participants will

have access to, and can be referred to, ongoing psycho-social services, including counselling, social support groups, and legal support.

In addition to the risk of negative social impact of participation in HIV-related research, particularly for individuals and communities which are already stigmatised and marginalised, physical injuries may be sustained due to research-related activities, such as blood drawing or other medical interventions. Injections may result in pain, occasional skin reactions, and possibly other biological adverse events, such as fever and malaise.

In trials of microbicides, vaccines, HSV-2 suppression and antiretroviral pre-exposure prophylaxis, there may be unknown risks to a foetus exposed to the product. In trials of prevention of mother-to-child transmission, mothers may develop antiretroviral drug resistance and may transmit resistance virus to their infants; infants may develop resistance during prophylaxis while breastfeeding.

Despite previous safety testing of microbicide products, trial participants and/or sexual partners who are exposed to the product may experience adverse effects, including those which may increase risk of HIV acquisition. In the case of microbicides containing antiretroviral drugs, there may be systemic absorption of active ingredients with possible development of antiretroviral resistance should HIV infection be acquired. In pre-exposure prophylaxis trials, individuals who acquire HIV infection may develop resistance to the antiretroviral drug in the experimental product.

Vaccine trial participants who are exposed to HIV may have a greater risk of developing established infection, or of progressing more rapidly once infected, than if the vaccine had not been administered. If a vaccine candidate elicits a positive HIV antibody test in the absence of HIV infection, i.e. a "false positive" HIV test, negative social consequences similar to those that may exist for those actually HIV-infected may result. Informed consent procedures should

include discussion of the possibility of testing HIV antibody–positive without being HIV–infected. Laboratory techniques that differentiate vaccine-induced antibodies and actual HIV infection should be provided at the clinical site and trial participants should be provided with necessary documentation to demonstrate that their participation in an HIV vaccine trial may be the cause of their HIV-antibody seropositivity. Consideration should be given to appointing an ombudsperson who can intervene on behalf of participants with outside parties, if necessary and requested.

The potential for adverse reactions to a candidate biomedical HIV prevention product, as well as possible injuries related to the conduct of biomedical HIV prevention research, should be described, as far as possible, in the research protocol and fully explained in the informed consent process. Both the protocol and the informed consent process should describe the nature of medical treatment to be provided for injuries, as well as compensation for harm incurred due to research-related activities and the process by which it will be decided whether an injury will be compensated. HIV infection acquired during participation in a biomedical HIV prevention trial should not be considered a compensable injury unless directly attributable to the prevention product being tested itself, or to direct contamination through a research-related activity. In addition to compensation for trial-related biological/medical injuries, appropriate consideration should be given to compensation for social or economic harms.

Guidance Point 12:

Benefits

The research protocol should provide an accurate statement of the anticipated benefit of the procedures and interventions required for the scientific conduct of the trial. In addition, the protocol should outline any services, products, and other ancillary interventions provided in the course of the research that are likely to be beneficial to persons participating in the trials.

Clinical research inherently entails uncertainty about the degree of risk and benefits, with earlier phases of research having greater uncertainty. Proceeding to a human trial can be justified only if there is reasonable biological plausibility that a product could be safe and effective, and there is equipoise – meaning that whether a product will actually work is unknown but there is a favourable risk-benefit ratio. Only anticipated benefits of study-related procedures required for the safe and scientific conduct of the trial should be considered in the risk-benefit analysis, that is, only health care benefits derived directly from the study design. Extraneous benefits, such as payment or ancillary services, such as HIV risk-reduction interventions or reproductive health care services, should not be considered in the risk-benefit analysis. Scientific and ethical review committees must be satisfied that the potential risks to individual subjects are minimized, the potential benefits to individual participants are enhanced, and the potential benefits to individual participants and the community are proportionate to or outweigh the risks.

There should be an ongoing iterative consultative process to facilitate local or national decision-making about the appropriate level of support, care, and treatment provided to potential and enrolled participants. Some of the activities related to the conduct of HIV biomedical HIV prevention trials which may benefit those who participate may actually be rights. At a minimum, participants should:

- have regular and supportive contact with health care workers and counsellors throughout the course of the trial;
- receive comprehensive information regarding HIV transmission and how it can be prevented;
- receive access to HIV testing and prevention methods, including male and female condoms, sterile injecting equipment, and sexual and reproductive health care services; and
- have access to a pre-defined care and treatment package for HIV-related illness if they become HIV-infected while enrolled in the trial (see ***Guidance Point 14***).

Participants should also receive reimbursement for travel and other expenses related to participation in a biomedical HIV prevention trial. In recognising the time and inconvenience their participation entails, the appropriate form and level of extraneous non-health incentives will depend on the local economic and social context.

Some have contended that to promise antiretroviral treatment to HIV prevention trial participants who become infected would constitute an undue inducement to participate in the trial. That supposition is most unlikely, since biomedical HIV prevention trials enrol healthy people, not individuals who are already sick and need treatment. If anything, the possibility of being protected from acquiring HIV by the preventive method itself could conceivably be considered an undue inducement; however, if that were the case, clinical trials of preventive methods could never be ethically carried out. Concerns that any form of care and treatment promised to participants in research on biomedical HIV preventive interventions could be an undue inducement are unwarranted.

Some may argue that provision of state-of-the-art prevention, care, and treatment services for participants introduces local inequalities and is therefore unjust when non-participants do not receive those services. However, all scale-up programmes involve temporary inequalities in the community until universal access can be attained. Achieving a perfect system of equal justice is a long-term process.

Guidance Point 13:

Standard of Prevention

Researchers, research staff, and trial sponsors should ensure, as an integral component of the research protocol, that appropriate counselling and access to all state of the art HIV risk reduction methods are provided to participants throughout the duration of the biomedical HIV prevention trial. New HIV-risk-reduction methods should be added, based on consultation among all research stakeholders including the community, as they are scientifically validated or as they are approved by relevant authorities.

The ethical principle of beneficence obligates researchers and sponsors to maximise benefits and minimise risks to participants in clinical trials. This obligation pertains not only to the preventive method being studied, but also to reducing the risk that any trial participant will acquire HIV infection during a biomedical HIV prevention trial.

Protocols for HIV prevention research obligate researchers to provide the full range of information and services for risk reduction, although they vary in defining the package of services and modes of delivery. If the study aims to test a product by comparing its additive effects to those of routinely practiced prevention, in all cases this prevention standard should be defined in the study protocol as well as in informed consent documents. If researchers are unable to guarantee that this standard is met, it is unethical to conduct the proposed trial.

Risk-reduction packages should include provision for family planning, pregnancy and childbirth services. Women may become pregnant during a trial. Some of these women may wish to carry the babies to term, some might have miscarriages, and some might elect to have therapeutic abortions. Researchers should guarantee that all communities engaged in biomedical HIV prevention trials have state of the art reproductive health care services.

Researchers should engage appropriate stakeholders in tailoring the design, implementation, and oversight of risk-reduction interventions addressing the specific needs and risks of trial participants in a given community. Trial sponsors, researchers, and advocates should continue efforts to resolve ongoing conflicts about legal constraints on public health practice, such as the provision of therapeutic abortion services or the provision of appropriate risk-reduction interventions for trial participants who inject drugs, including sterile injecting equipment and drug substitution treatment.

All trial participants should receive HIV risk-reduction counselling, as well as access and entitlement to proven prevention methods, and to post-exposure prophylaxis in the event of a known likely exposure. Comprehensive counselling should include the basic principles of safer sexual practice and safer injecting practices, as well as education concerning general health and treatment of sexually transmitted infections (STIs), reproductive health (contraception, pregnancy care etc.), and strategies to reduce domestic violence. Investigators should provide trial participants appropriate access to male and female condoms, sterile injecting equipment, medical substitution therapy such as methadone or buprenorphine maintenance, and treatment for other STIs. All trial participants should also be counselled at the beginning of a biomedical HIV prevention trial regarding the potential benefits and risks of post-exposure prophylaxis with antiretroviral medication, and how it can be accessed in the community. Ways should be explored with local authorities to provide trial volunteers and participants with information about HIV prevention and treatment services available in the community. Referral mechanisms should be established and follow-up mechanisms instituted to ensure quality case management services.

The technique, frequency, and message content of counselling sessions should be agreed upon by the community-government-investigator-sponsor partnership, and should be based upon reliable information about the prevailing social and behavioural characteristics of the study population. The provision of HIV risk reduction counselling should be monitored to ensure quality and to minimise the potential conflict of interest between risk-reduction goals and the biomedical prevention trial's scientific goals. Consideration should be given to providing counselling through an agency or organisation that is independent of the investigators in order to prevent any real or perceived conflict of interest. If such an arrangement is put in place the researchers and community must ensure that the services are of a high enough standard to meet the trial's ethical obligations. Local capacity may need to be developed to provide such services in a culturally suitable and sustainable fashion, guided by the best scientific data. National and international research oversight groups should evaluate the pros and cons of independent organizations implementing risk-reduction interventions in biomedical HIV prevention trials; where such efforts are warranted and feasible, they should be undertaken and rigorously evaluated.

Mechanisms for negotiation among all research stakeholders, including the community, about the standards for enhancement of the risk-reduction package during the trial as new biomedical HIV prevention modalities are scientifically validated or are approved by national authorities need to be set in the study protocol. Negotiations should take into consideration feasibility, expected impact, and the ability to isolate the efficacy of the biomedical HIV modality being tested, as other prevention activities improve.

Guidance Point 14:

Care and Treatment

Participants who acquire HIV infection during the conduct of a biomedical HIV prevention trial should be provided access to treatment regimens from among those internationally recognised as optimal. Prior to initiation of a trial, all research stakeholders should come to agreement through participatory processes on mechanisms to provide and sustain such HIV-related care and treatment.

The obligation on the part of sponsors and investigators to ensure access to HIV care and treatment, including antiretroviral treatment, for participants who become infected derives from some or all of three ethical principles. The principle of *beneficence* requires that the welfare of participants be actively promoted. The principle of *justice as reciprocity* calls for providing something in return to participants who have volunteered their time, been inconvenienced or experienced discomfort by enrolling in the trial. The principle of *justice*, meaning *treating like cases alike*, requires that trial participants in high-income and low- and middle-income countries be treated equally regarding access to treatment and care.

A consensus on the level of care and treatment that should be provided to trial participants has emerged in recent years with increasing accessibility of antiretroviral treatment in low- and middle-income countries, based on strong commitments from countries, development partners and multilateral organizations; dramatic decreases in drug prices; and evidence that treatment programmes in resource-poor settings are feasible and sustainable. There is consensus that sponsors need to ensure access to internationally recognised optimal care and treatment regimens, including antiretroviral therapy, for participants who become HIV infected during the course of the trial. There is also agreement that prevention trials ought to contribute constructively to the development of HIV service provision in countries participating

in biomedical HIV prevention research, for the sustainable provision of care and treatment after the completion of a trial.

The provision of antiretroviral treatment to trial participants who acquire HIV infection during the trial requires planning for logistics and implementation. Most such participants will not need antiretroviral treatment until years after sero-conversion. However they may benefit from a comprehensive care and prevention package including cotrimoxasole prophylaxis, isoniazid, nutritional advice, and positive prevention counselling. Biomedical HIV prevention trials should undertake to support such therapy until individuals become eligible for the national program of care and treatment in their country. Countries should include participants in biomedical HIV prevention trials in their priority list for access to antiretroviral treatment under the "Towards Universal Access" programme.

Trial sponsors and researchers should collaborate with governments in low- and middle-income countries to explore, develop, and strengthen national and local capacity to deliver the highest possible level of HIV prevention, care, and treatment services through strategic investment and development of trial-related resources. In most situations, no one stakeholder should bear the entire burden of providing resources for such services and the central responsibility for delivery should lie with local health systems.

Decisions on how these obligations are to be met are best made for each specific trial through a transparent and participatory process that should involve all research stakeholders before a trial starts to recruit participants (see ***Guidance Point 2***). This process should explore options and determine the core obligations applicable to the given situation, in terms of the level, scope, and duration of the care and treatment package, equity in eligibility to access services, and responsibility for provision and delivery. Agreements on who will finance, deliver, and monitor care and treatment should be documented. All stakeholders should recognize that this is a critically important and highly uncertain

area that requires all partners to commit themselves to experimentation and the careful documentation of approaches, successes, and failures.

Clinical trials should be integrated into national prevention, treatment, and care plans so that services provided through clinical trials or arrangements brokered for trial participants serve to improve the health conditions of both the trial participants and the community from which they are drawn, and support and to strengthen a country's comprehensive response to the epidemic. Strengthening mechanisms to provide care, treatment, and support for people who acquire HIV infection during the course of a trial will assist in ensuring referral and care provision for people who are deemed ineligible at recruitment to a biomedical HIV prevention trial because they already have HIV infection.

A care and treatment package should include, but not be limited to, some or all of the following items, depending on the type of research, the setting, and the consensus reached by all interested parties before the trial begins:

- counselling
- preventive methods and means
- treatment for other sexually transmitted infections
- prevention of mother to child transmission
- prevention/treatment of tuberculosis
- prevention/treatment of opportunistic infections
- nutrition
- palliative care, including pain control and spiritual care
- referral to social and community support
- family planning
- reproductive health care for pregnancy and childbirth
- home-based care
- antiretroviral therapy

Guidance Point 15:

Control Groups

Participants in both the control arm and the intervention arm should receive all established effective HIV risk reduction measures. The use of a placebo control arm is ethically acceptable in a biomedical HIV prevention trial only when there is no HIV prevention modality of the type being studied that has been scientifically validated in comparable populations or approved by relevant authorities.

Aside from male circumcision, a biomedical HIV prevention intervention with proven efficacy in preventing HIV acquisition or HIV-related disease does not currently exist. Therefore, until an efficacious intervention is developed, the use of a placebo control arm could be ethically acceptable in appropriately designed protocols, such as three-arm trials. For example, there may be compelling scientific reasons which justify the use of a placebo rather than a known effective biomedical HIV intervention in the following instances:

- An effective HIV vaccine exists but it is not known to be effective against the virus that is prevalent in the research population.
- The biological conditions that prevailed during the initial trial demonstrating efficacy of a biomedical HIV prevention product are so different from the conditions in the proposed research population that the results of the initial trial are not generalizable and cannot be directly applied to the research population under consideration.
- A microbicide shown to be effective for vaginal intercourse may not be effective for rectal intercourse.
- Effectiveness of an intervention in one population may not be reproduced in the context of another population if the success of the intervention is strongly related to behaviour or behavioural modification and conditions of product utilisation. For example, a partially effective, coitally dependent microbicide evaluated among women in stable partnerships may not be generalizable to women with multiple casual partners.

Guidance Point 16:

Informed Consent

Each volunteer being screened for eligibility for participation in a biomedical HIV prevention trial should provide voluntary informed consent based on complete, accurate, and appropriately conveyed and understood information before s/he is actually enrolled in the trial. Researchers and research staff should take efforts to ensure throughout the trial that participants continue to understand and to participate freely as the trial progresses. Informed consent, with pre- and post-test counselling, should also be obtained for any testing for HIV status conducted before, during, and after the trial.

Biomedical HIV prevention trials require informed consent for all components of participation at a number of stages. The first stage consists of screening candidates for eligibility for participation in the trial. The screening process involves interviews on personal matters, such as sexual behaviour and drug use, which are protected by a right to privacy. To guarantee this right, secrecy and confidentiality must be strictly observed and appropriate measures of personal data protection should be set in place (see ***Guidance Point 18***). The screening process also involves medical tests (such as blood draws, pregnancy and HIV tests, vaginal examinations, and a general physical examination), the results of which are also private and should be kept in confidence. Informed consent should be obtained to undergo this screening process, based on a full divulgence of all material information regarding the screening procedures, as well as an outline of the biomedical HIV prevention trial in which they will be invited to enrol, if found eligible. Fully informed consent should also be given for the test for HIV status, which should be accompanied by pre-and post-test counselling and, if the result is HIV positive, referral to clinical and social support services.

The second stage at which informed consent is required occurs once a person is judged eligible for enrolment. That individual should then be given full information concerning the nature and length of participation in the trial, including the risks and benefits posed by participation, so that s/he is able to give informed consent to participate. Time should be allowed to consider participation, discuss with others such as partners, and ask questions. Candidates should also be informed of their rights as participants, including the right to confidentiality (see ***Guidance Point 18)*** and the right to refuse to participate or to withdraw at any time from the study without penalty.

Once enrolled, efforts should then be made throughout the trial to obtain assurance that the participation continues to be on the basis of free consent and understanding of what is happening. Informed consent, with pre- and post-test counselling, should also be given for any repeated tests for HIV status. Throughout all stages of the trial and consent process, there should be assurance by the investigator that the information is understood by the participant before consent is given. Informed consent is a process, not just a piece of paper to be read and signed. The information should be presented in appropriate forms and languages, including written information sheets. In addition, there should be oral communication of information, especially for participants who may be illiterate, and standardized tests for assessment of comprehension, where necessary.

In addition to the standard content of informed consent prior to participation in a biomedical HIV preventive intervention trial, each prospective participant must be informed, using appropriate language and technique, of the following specific details:

- the reasons they have been chosen as prospective participants, including whether they are at higher risk of HIV exposure;
- that the biomedical HIV prevention product is experimental and it is not known that it will prevent HIV infection or disease, and

further, when such is the case, that some of the participants will receive a placebo instead of the candidate HIV prevention product through random assignment;

- that they will receive counselling concerning how to reduce their risk of HIV exposure and access to risk-reduction means (in particular, male and female condoms, clean injecting equipment, and where relevant, male circumcision); and that, in spite of these risk-reduction efforts, some of the participants may become infected, particularly in the case of phase III trials where large numbers of participants at higher risk of HIV exposure are participating;
- the specific risks for physical harm, as well as for psychological and social harm (see ***Guidance Point 11***), the types of treatment and compensation that are available for harm, and the services to which they may be referred should harm occur;
- the nature and duration of care and treatment that is available, and how it can be accessed, if they become infected with HIV during the course of the trial (see ***Guidance Point 14***);
- the collection, use, and period of storage of biological samples and specimens provided by participants, and the options for their disposal at the conclusion of the trial, including the option to refuse to allow use of such samples or specimens beyond the scope of the specific trial in which they have participated.
- the use, confidentiality, period of storage, and disposal of personal data including genetic information, including the option to refuse to allow use of such data beyond the scope of the specific trial in which they participated (see ***Guidance Point 18***).

Special Measures

Researchers and research staff should take special measures to protect persons who are, or may be, limited in their ability to participate voluntarily in a biomedical HIV prevention trial due to their social or legal status. The presumption is that all adults are legally competent to give informed consent to participate in a biomedical HIV prevention trial. However, there are several categories of

persons who are legally competent and who have sufficient cognitive capacity to consent, but who may have limitations in their freedom to make independent choices (see ***Guidance Point 8***).

The following are individuals or groups who should be given extra consideration with regard to their ability to voluntarily participate in biomedical HIV prevention trials:

- persons who are junior or subordinate members of hierarchical structures, who may be vulnerable to undue influence or coercion and may fear retaliation if they refuse cooperation with authorities, including members of the armed forces, students, government employees, prisoners, and refugees;
- persons who engage in illegal or socially stigmatised activities, who are vulnerable to undue influence and threats presented by possible breaches of confidentiality and action by law enforcement authorities, including sex workers, injecting drug users, and men who have sex with men;
- persons who are impoverished or dependent on welfare programmes, who are vulnerable to being unduly influenced by offers of what others may consider modest material or health inducements.

Those who plan, review, and conduct biomedical HIV prevention trials should be alert to the problems presented by the involvement of such persons, and take appropriate steps to ensure meaningful and independent ongoing informed consent, and to respect their rights, foster their well being, and protect them from harm. Such steps would include community involvement in the design of recruitment and informed consent processes, along with the sensitization and training of research staff and counsellors on these issues.

Guidance Point 17:

Monitoring Informed Consent and Interventions

Before a trial commences, researchers, trial sponsors, countries, and communities should agree on a plan for monitoring the initial and continuing adequacy of the informed consent process and risk-reduction interventions, including counselling and access to proven HIV risk-reduction methods.

Methods for monitoring the adequacy of recruitment and informed consent processes, including evaluation of participants' comprehension of information, should be designed and agreed upon by the community- government-investigator-sponsor partnership. The value of informed consent depends primarily on the ongoing quality of the process by which it is conducted and not solely on the structure and content of the informed consent document. The informed consent process should be designed and monitored to empower participants to allow them to make appropriate decisions about continuing or withdrawing from the study. Special attention should be given to ensure that individuals are aware of their right to withdraw from a trial without any penalty, and that they are actually free to do so. Similarly, there are many ways in which risk-reduction interventions (counselling and access to means of HIV prevention) can be conducted, with some methods being more effective than others in conveying the relevant information and in reducing risk of HIV exposure for different individuals and study populations.

Monitoring should include quality assurance of gender- and culture-sensitive counselling services, appropriate procedures for adolescents, and evaluation of the impact of the trial on the vulnerabilities of the communities involved in the study. It should also cover the welfare of participants throughout the trial, including when discontinuing participation in case of adverse reactions, untoward events or changes in clinical status.

Consideration should be given to expansion of the responsibilities of the clinical trial monitor to include adherence to the recruitment and informed consent processes and to counselling standards. Consideration could also be given to the appointment of an independent ombudsperson who would handle any complaints from participants related to the conduct of the trial and suggest appropriate responses.

The appropriateness of such plans should be determined by the scientific and ethical review committees that are responsible for providing prior and continuing review of the trial. This recommendation supplements the usual guidelines for the monitoring of biomedical HIV prevention trials for safety and compliance with scientific and ethical standards and regulatory requirements.

Guidance Point 18:

Confidentiality

Researchers and research staff must ensure full respect for the entitlement of potential and enrolled participants to confidentiality of information disclosed or discovered in the recruitment and informed consent processes, and during conduct of the trial. Researchers have an ongoing obligation to participants to develop and implement procedures to maintain the confidentiality and security of information collected.

A lot of information about a volunteer or a study participant is collected as part of participation in HIV vaccine and prevention research. Very personal information, like sexual behaviour, drug use, HIV status, medical conditions or even association with the trial could be highly stigmatizing and might be socially harmful if other people wrongly discover it. It is therefore of particular importance in biomedical HIV prevention trials that researchers and research staff commit to keeping confidential all personal information of all

potential and enrolled participants so as to minimise the likelihood of such harm, and that they explain to volunteers and participants what measures they will be taking to protect privacy and personal information, and what limitations may exist on their ability to do so.

All participants are entitled to confidentiality of information disclosed or discovered in the recruitment and informed consent processes, and during conduct of the trial. Community involvement should not compromise the confidentiality of study participants. This is of particular importance with respect to participants from vulnerable populations, women and adolescents, who may be socially susceptible to stigma and discrimination (see ***Guidance Points 8, 9, 10***). There may be specific exceptions to the duty of confidentiality for legal or ethical reasons, but those exceptions should be prospectively identified and disclosed to the participant during the informed consent process.

Legal exceptions to the duty to maintain confidentiality might exist, for example, where disclosure is mandated by a court order or where there is a duty to report to public health authorities. In the case of children and adolescents, reporting of abuse and neglect might be required under child protection laws. Similarly, the reporting of domestic violence might be a legal duty. Trial staff should be trained to identify instances where there is such a mandatory reporting duty.

Breach of confidentiality might also be warranted on ethical grounds, so as to notify sexual partners. For example, where women participate in microbicide trials, there may be unknown risks of harm to male partners. The sponsor and researcher should have a mechanism for them to come forward to report possible negative consequences and make sure that they are notified of such, preferably by the female participants. Likewise, when participants become HIV positive, sexual partners at ongoing risk should be notified for referral to testing programmes and treatment facilities. However, researchers and research staff should be sensitive to the possibility of domestic violence as a result of partner notification.

Researchers have an ongoing obligation to participants and the host community to develop and implement procedures to protect

the privacy of participants and to maintain the confidentiality of information collected. Such procedures might include interviewing participants outside, where they cannot be overheard, or permitting participants to not receive HIV test results. Both health care workers and research staff may need explicit training on how to maintain confidentiality. To protect confidentiality, workers in the clinic or programme setting where recruitment is taking place should first ask potential volunteers whether they would be willing to speak to a researcher who will provide information about trial participation. In the case of adolescents being recruited for endpoint efficacy trials, researchers should inquire whether their parents are aware of their sexual behaviour and explain that parental permission will be required for enrolment. In the case of media interest in the trial, research staff members should also advise participants of possible negative impact that may result from public exposure. Community advisory boards may need training to enable members to interview about the trial in ways that do not compromise the duty of confidentiality owed to individual participants or jeopardise their right to privacy.

Research may involve collecting and storing private and sensitive data relating to individuals and communities including data derived from biological samples (see ***Guidance Point 16***). Measures of data protection are of major importance in large-scale studies such as HIV prevention trials which establish large databases to integrate clinical data and monitor public health effect. Decisions regarding which personal data are to be collected and stored must be based on the requirements of the trial design and the medical needs of participants. Personal identifiable data should be collected only by people who have signed a confidentiality agreement. The collection of personal identifiable data should be kept at a minimum and such data should not be stored longer than necessary. Procedures should be in place to monitor the use of the system where the data are stored in order to detect potential or actual security threats. Systematic guidance on security of data can be found in the UNAIDS *Interim Guidelines on Protecting the Confidentiality and Security of HIV Information* (2007).

Guidance Point 19:

Availability of Outcomes

Researchers should inform trial participants and their communities of the trial results. During the initial stages of development of a biomedical HIV prevention trial, trial sponsors and countries should agree on responsibilities and plans to make available as soon as possible any biomedical HIV preventive intervention demonstrated to be safe and effective, along with other knowledge and benefits helping to strengthen HIV prevention, to all participants in the trials in which it was tested, as well as to other populations at higher risk of HIV exposure in the country.

To respect and recognize the contribution of trial participants and their communities to clinical research, researchers should inform them of the trial results, whether the biomedical intervention does or does not demonstrate efficacy, or the trial is stopped prematurely. Once a trial product has proven safe and effective, sponsors and researchers should work with development partners, national governments, local authorities, and industry where relevant, to ensure planning for its manufacturing, regulatory approval, fair distribution, and efficient delivery in the community engaged in the trial and the country.

Given the severity of the HIV epidemic, it is imperative that sufficient incentives exist, both through financial rewards in the marketplace and through public subsidies, to foster development of safe and effective biomedical HIV prevention products and ensure that they are produced and made readily and affordably available to the communities and countries where a product is tested, as well as to populations at higher risk of HIV exposure in other countries.

Some argue that fair benefits to the population where clinical trials are conducted need not include making successful products of the

research available to that population. Critics contend that it is paternalistic to specify the benefits, and that the country may identify other benefits that have a higher priority. However, given the severity of the epidemic (see ***Guidance Point 1***) making a successful HIV biomedical HIV prevention product or intervention reasonably available to the population where it was tested can be sustained as a basic ethical requirement.

Health and research communities building biomedical HIV prevention product development programmes should initiate before trials commence, and carry on through the course of the research, a process of discussion and negotiation about how products will be made available, along with other benefits resulting from the research, if the HIV preventive intervention is effective. This discussion should include representatives from relevant country stakeholders, such as representatives from the executive branch, health ministry, local health authorities, and relevant scientific and ethical groups, as well as from community advisory mechanisms and other key stakeholders. It should address issues such as payments, royalties, subsidies, technology and intellectual property, as well as distribution costs, channels and modalities, including delivery strategies, target populations, demand estimates, and supply chain requirements.

The discussion concerning availability and distribution of an effective biomedical HIV prevention product should further engage the national government, international organisations, development partners, representatives from wider affected communities, local authorities, international and regional non-governmental organizations, and the private sector. In addition to considering financial assistance to make biomedical HIV prevention products available, these partners should respect and help build governments and community capacity to negotiate for and implement distribution plans. Among the issues to be addressed well in advance to ensure that novel effective HIV prevention products have the greatest impact are:

- ongoing communication with regulatory agencies to ensure timely licensing of proven safe and efficacious methods which require regulatory approval;
- planning for capacity building, including transfer of technology, to mass produce an effective biomedical HIV prevention product well in advance of product licensing, so as to minimize manufacturing delays;
- preparing in advance the infrastructures needed for delivery of new products through existing distribution systems for other currently available HIV prevention products, such as male and female condoms or prophylaxis for mother-to-child transmission;
- instituting advance purchase commitments or other supply side planning to deliver product for those people and populations which it has been agreed should enjoy first the benefit of a new proven HIV prevention intervention.

Guidance Point 20:

People Who Inject Drugs[6]

Researchers and sponsors should include people who inject drugs in biomedical HIV prevention trials in order to verify safety, efficacy, and effectiveness from their standpoint, including immunogenicity in the case of vaccines.[7] As with other key populations at higher risk of HIV exposure, providing people who inject drugs with access to proven, effective HIV preventive interventions is a public health imperative. Researchers and trial sponsors should engage meaningfully with people who inject drugs and with other stakeholders to overcome the complex legal, ethical, and regulatory challenges to the participation in biomedical HIV prevention trials of people who inject drugs. Trial conduct that is ethical is informed by the latest scientific evidence on proven HIV prevention strategies and ensures that participants' human rights, safety, and welfare are protected.

People who inject drugs are at higher risk of acquiring blood-borne HIV infection, primarily because legal and logistical barriers impede safer use and access to sterile injecting equipment, such as needles, syringes, and cookers. They are also at increased risk of acquiring and transmitting HIV through unsafe sexual practices. Women who inject drugs or who have a partner who injects drugs are at higher risk of HIV acquisition and of subsequent mother-to-child transmission during pregnancy, labour and delivery, and breastfeeding.

As with other key populations at higher risk of HIV acquisition, people who inject drugs should be included and meaningfully engaged (see ***Guidance Point 2***) in biomedical HIV prevention trials

[6] A broader term that may apply is 'people who use drugs' when such use places individuals at higher risk of HIV exposure through non-injecting modes of transmission.

[7] As for all the guidance points in this document, this guidance point is relevant to trials of various behavioural HIV prevention methods and structural interventions.

in order to ensure that novel prevention methods are proven to be safe, efficacious, and accessible for them, both as a matter of equity and as an expression of their right to health. However, prevention trials involving people who inject drugs pose complex challenges that may increase risks to trial participants. Researchers and sponsors should take necessary steps to safeguard participants' human rights, safety, and welfare.

The ethical principles of beneficence and non-maleficence obligate researchers and sponsors to maximize benefits and minimize risks to participants in HIV clinical trials. This is done in part by providing appropriate counselling and facilitating access to proven state-of-the-art risk reduction methods (see ***Guidance Point 13***). However, legal barriers, punitive law enforcement practices, logistical challenges, and discrimination often prevent people who inject drugs from accessing proven risk reduction methods, including those comprising the comprehensive package of core interventions for people who inject drugs developed by WHO, UNODC, and UNAIDS.[8] In addition to provision of condoms, counselling, and access to educational information on safe-injecting practices, a key risk reduction method for people who inject drugs is the use of sterile injecting equipment. Where there are insurmountable barriers to ensuring access to sterile needles and syringes for all trial participants, HIV prevention trials among people who inject drugs should not proceed.

Any enhancements to the standard of prevention package as the scientific evidence base evolves should be discussed by all trial stake-

[8] WHO, UNODC and UNAIDS. Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. Geneva, 2009. The comprehensive package comprises the following nine interventions: needle syringe programmes; drug dependence treatment (opioid substitution treatment and other); HIV testing and counselling; antiretroviral therapy; prevention and treatment of sexually transmitted infections; programmes with condom for people who inject drugs and their sexual partners; targeted information, education, and communication for people who inject drugs and their sexual partners; diagnosis and treatment of or vaccination for viral hepatitis; prevention, diagnosis, and treatment of tuberculosis.

holders, taking into consideration feasibility, expected impact, and the ability to isolate the efficacy of the biomedical HIV modality being tested (see ***Guidance Point 13***).

In settings where possession of injecting equipment is illegal, researchers and sponsors should negotiate agreements with relevant authorities so that risk reduction tools provided through the trial as standard of prevention do not increase the risk that trial participants will be subject to punitive legal or extra-legal enforcement measures. Some potential risk reduction interventions, for example opioid substitution treatment, may carry additional risks for trial participants, such as breaches of privacy and confidentiality resulting from mandatory registration. Further, painful opioid withdrawal may result if medication-assisted substitution programmes are not properly resourced and sustained. Trial sponsors, researchers, and advocates should continue efforts to determine whether and how risks associated with components of the risk reduction package could be mitigated in both the short- and long-term.

Researchers and sponsors have an obligation to ensure access to HIV care and treatment, including antiretroviral therapy, for participants who acquire HIV infection during a trial (see ***Guidance Point 14***). In addition, they should negotiate with national and local governments appropriate referral mechanisms to ensure access to care and treatment for those people who volunteer to participate in a trial but who are screened out as ineligible when they are found to be HIV-positive. In some settings, people who inject drugs may not be seen as priority recipients for limited HIV care and treatment resources. The ethical principle of justice requires *both* that researchers and sponsors work to ensure that access to care and treatment is available to people who inject drugs as equitably as it is to others in the community and that the standard of care and treatment is equivalent across high-, low- and middle-income countries (See ***Guidance Point 14***). Care for trial participants may also involve the treatment of co-morbidities, ready

access to overdose management, and provision of a safe place of respite where participants may be provided with food or other amenities. A transparent and inclusive process to determine logistics and to assign responsibilities for providing this care package should take place in advance of trial commencement.

People who inject drugs suffer several layers of vulnerability (see ***Guidance Point 8***). Criminalization of their drug use renders them vulnerable to punitive, often harsh, law enforcement practices including incarceration. They may experience additional vulnerability because of generalized stigma and discrimination, including from some health care professionals and policy-makers; personal mental health issues, preceding or resulting from their drug use; poverty; racism, if they are members of certain racially-defined groups; and marginalization. Gender adds an additional layer of vulnerability for people who inject drugs who are women, men who have sex with men, or people who are transgender or intersex. They may experience increased vulnerability to unprotected sex and unsafe injections, exploitation, discrimination, lack of sensitivity to their specific needs, and under-resourcing of services to meet their needs.

Prior to commencing a trial, researchers and sponsors should conduct formative research to gain understanding of particular contextual challenges and vulnerabilities that people who inject drugs face and to begin building trust with people who inject drugs and their networks. The research protocol should describe the vulnerabilities identified, as well as steps that have been or will be taken to create a safe enabling environment for trial participants. HIV prevention trials should not be conducted where there are insurmountable barriers to ensure safety, protection, and confidentiality of trial participants (see ***Guidance Point 18***). For this reason, and because adherence to the principle of autonomy cannot be guaranteed, HIV prevention trials should not be conducted in compulsory drug detention centres.

In many settings around the world, the consequences of being identified as a person who injects drugs are extremely serious. Precautions should be taken to ensure that recruitment and retention are voluntary, and that people's right to confidentiality and privacy is not breached (see ***Guidance Point 18***). Recruitment within voluntary drug treatment centres, especially by service providers upon whom people who inject drugs are dependent for on-going care, may pose special problems regarding voluntariness of trial participation. Generally, potential trial participants should not be recruited by their service providers. Where respondent-driven recruitment and other snowball-type recruitment techniques are used, confidentiality should be emphasized to recruiters. Research teams should be trained to identify when a potential participant is unable to make a voluntary, informed decision about trial participation. Being under the influence may alone not be sufficient reason to assume lack of capacity to decide. Participants should be clearly informed of any limits to confidentiality to which researchers are bound by regulation.

It is not uncommon for people who inject drugs to be incarcerated because of their drug use or for peripheral reasons such as sex work, theft, and vagrancy. Researchers should anticipate that some trial participants could be incarcerated during the course of the trial and should develop an incarceration protocol describing the conditions to be followed to ensure that on-going ethical trial participation is preserved. This should include an option and procedures for voluntary withdrawal of the participant from the trial. The protocol should address confidentiality and voluntariness, access to risk reduction measures while incarcerated, access to a physician, and post-release planning including for consent to re-join the trial. In particular, mechanisms should be put in place to ensure that there is no interruption of antiretroviral therapy or opioid substitution treatment. All relevant stakeholders, including prison authorities, should agree to these provisions in advance of a trial.

In choosing the form of reimbursement for travel and other expenses related to trial participation (see ***Guidance Point 12***), researchers should take into consideration participants' preferences and local conditions in order to reach an agreement upon the form and amount of reimbursement. Based on the principle of non-maleficence and concern for undue inducement, caution should be applied when using cash compensations in all clinical trials[9]. Assuming that participants who inject drugs should be provided only with vouchers or in-kind compensation, rather than cash reimbursement equivalent to that provided in trials involving other populations, is discriminatory.

When the biomedical HIV prevention product or intervention tested in a trial is proven to be safe and efficacious, provision should be made to offer it to all trial participants, and to the communities from which they are drawn, following trial completion, regulatory approval, and licencing (see ***Guidance Point 19***).

[9] Council for International Organisations of Medical Sciences (CIOMS) 2002. Ethical Guidelines for Biomedical Research Involving Human Subjects. Guideline 7.

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2011

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Good participatory practice

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Section 1:
The Importance of Good Participatory Practice

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- What is Stakeholder Engagement?
- The Wider Context of HIV
- The Dynamics of Biomedical HIV Prevention Trials
- Rationale for GPP Guidelines
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Section 2:
Guiding Principles of GPP in Biomedical HIV Prevention Trials

- Respect
- Mutual Understanding
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- Community Stakeholder Autonomy

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- Formative Research Activities
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Introduction

Objective of the good participatory practice (GPP) guidelines

The good participatory practice (GPP) guidelines provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials.

In the GPP guidelines, "design and conduct of biomedical HIV prevention trials" refers to activities required for the development, planning, implementation, and conclusion of a trial, including dissemination of trial results.

Intended audience of the GPP guidelines

The GPP guidelines are primarily written for trial funders, trial sponsors, and trial implementers. Trial funders, sponsors, and implementers include investigators, research staff, and all others involved in designing, financing, and executing biomedical HIV prevention trials. They can include governments, government-sponsored research networks, non-governmental organisations, academic institutions, foundations, public–private partnerships, and pharmaceutical or other companies.

Stakeholders not directly involved in funding, sponsoring, or implementing trials can use the guidelines to better understand the objectives, expectations, and methods of stakeholder engagement and to better evaluate such efforts.

Scope of the GPP guidelines

The GPP guidelines provide a framework for development of effective stakeholder engagement programmes. The goal of effective stakeholder engagement programmes is to build mutually beneficial, sustained relationships between trial funders, sponsors, and implementers and other stakeholders that are transparent and respectful, that address interests of community stakeholders, and that support the conduct of scientifically rigorous and ethical biomedical HIV prevention trials.

This GPP guidelines publication is a companion document to the UNAIDS/WHO *Ethical considerations in biomedical HIV prevention trials,*[1] which contains explicit guidance on community participation, capacity building, monitoring, informed consent, standard of prevention, and other key ethical issues. The GPP guidelines were developed to enable trial funders, sponsors, and implementers to adhere to Guidance Point 2 of *Ethical considerations*, "Community Participation", which states: "To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials".

The GPP guidelines provide comprehensive guidance on the participatory conduct of biomedical HIV prevention trials and are not intended to provide guidance on all scientific and ethical aspects of these trials. Multiple guidance documents already exist that address overall scientific and ethical trial conduct, such as *Good Clinical Practice*,[2, 3] *Good Clinical Laboratory Practice*,[4] the *Declaration of Helsinki*,[5] *The Belmont Report*,[6] *Guidelines of the Council for International Organizations of Medical Sciences (CIOMS),*[7] the *Nuffield Council Guidance on ethics of research related to health care in developing countries*,[8,9] *the UNAIDS/WHO Ethical considerations in biomedical HIV prevention trials*,[1] and various national guidelines.

GPP is unique, as it is the only global guidance document to provide guidance about the relationship between a trial's funders, sponsors, and implementers, and other stakeholders in the context of biomedical HIV prevention trials. *Good Clinical Practice* (GCP), in contrast, provides ethical guidance specifically for the relationship between investigators and trial participants and for ensuring the integrity of trial data.

The principles of GPP in Section 2 apply to all biomedical HIV prevention trials, as they outline expectations and the foundations for building meaningful partnerships among stakeholders in biomedical HIV prevention research.

The good participatory practices outlined in the 16 topic areas of Section 3 of these guidelines are applicable to all large-scale effectiveness and efficacy trials.

The complete GPP guidelines are most relevant for trials that are larger and have substantial impacts on individuals and areas where trials are conducted. However, the GPP guidelines can also serve as a guide for other types of trials and studies. Examples of these can include smaller safety studies, follow-on studies, behavioural studies, HIV treatment trials, and studies of other diseases.

Development of the GPP guidelines

The GPP guidelines were born out of a recommendation from the UNAIDS Creating Effective Partnerships in Research process in 2005[10] that was a response to the controversies and debates of pre-exposure prophylaxis (PrEP) trials in Cambodia and Cameroon.[11, 12, 13]

Development of the original guidelines, led by an international working group, involved exploration and analysis of different viewpoints and the creation of objective measures of community stakeholder engagement in the design and conduct of biomedical HIV prevention trials. Feedback on the draft set of guidelines was provided via interviews, e-mail requests, and listserv postings and represented a diverse range of perspectives, geography, and expertise including advocates, trial site staff, researchers, clinical trial investigators, community liaison officers, members of community advisory boards, policy-makers, industry representatives, research funders, and sponsors.

The GPP guidelines were published in 2007, applied in different settings, and were the subject of formal consultations with stakeholder groups in Africa, the Americas, Asia, and Europe. These AVAC-supported consultations validated the importance of the adoption of the GPP guidelines by trial sponsors and of their implementation at trial sites around the world. Recommendations from the consultations have been incorporated in this second edition of the GPP guidelines.

The GPP guidelines are dynamic and will change over time. Recommendations for modifications and refinements based on experience and reflection can be sent to gpp@unaids.org or avac@avac.org. They will be gratefully received and considered in future updates of the guidelines.

Figure 1. GPP Timeline

Timeline of GPP and Ethical Considerations		
GPP Guidelines		*Ethical Considerations*
	2000	***February:*** UNAIDS regional consultations on ethical considerations in international HIV vaccine trials[14] ***May:*** *Ethical considerations in HIV preventive vaccine research* UNAIDS guidance document published[15]
July: Cambodia government decides not to support PrEP trial[16]	2004	
February: Cameroon stops PrEP trial in progress[16] ***March:*** Nigerian PrEP trial is discontinued[16] ***May:*** IAS global PrEP consultation with trial sponsors, researchers, and advocates[17] ***April & June:*** UNAIDS 'Creating Effective Partnerships' regional consultations[10] ***June:*** UNAIDS 'Creating Effective Partnerships' international consultation[10]	2005	
September: UNAIDS/AVAC working group starts drafting *GPP guidelines for biomedical HIV prevention trials*	2006	
May – June: Multiple global stakeholders review draft of *GPP guidelines* ***July:*** Pre-publication draft of *GPP guidelines* released for comments ***November:*** UNAIDS/AVAC *GPP guidelines*, 1st Edition published[18]	2007	***May:*** UNAIDS/WHO establish working group to revise *Ethical considerations* ***July:*** UNAIDS/WHO Expert Committee Meeting to revise *Ethical considerations* ***July:*** Pre-publication draft of *Ethical considerations* released for comments ***November:*** UNAIDS/WHO *Ethical considerations in biomedical HIV prevention trials* published[7]
August 2008 – May 2009: Global GPP consultations sponsored by AVAC with multiple stakeholder groups	2008	
May: AVAC report-back meeting from global consultations	2009	
May 2009 – May 2010: Synthesis of recommendations from global consultations; revision of *GPP guidelines* ***March:*** AVAC/UNAIDS GPP Revision Working Group Meeting ***July:*** Draft version of *GPP guidelines*, 2nd Edition released for public comment	2010	***June:*** UNAIDS/WHO Eastern Europe-Central Asia expert consultation on the ethical engagement of people who inject drugs in HIV prevention trials ***December:*** UNAIDS/WHO Asia region expert consultation on the ethical engagement of people who inject drugs in HIV prevention trials
GPP guidelines, 2nd Edition published	2011	***April:*** UNAIDS/WHO Latin America-Caribbean expert consultation on the ethical engagement of people who inject drugs in HIV prevention trials Guidance Point 20: People who inject drugs

This timeline shows the development of the UNAIDS/AVAC *Good Participatory Practice guidelines for biomedical HIV prevention trials* and the UNAIDS/WHO *Ethical considerations for biomedical HIV prevention trials.* The GPP guidelines document was developed after a series of regional consultations in 2005 that focused on defining the key elements needed for creating effective partnerships for HIV prevention trials. The first GPP guidelines document was published in 2007. It was developed as a companion to the UNAIDS/WHO guidance document *Ethical considerations* that addresses key ethical issues in a set of guidance points with commentaries.

Organisation and how to use the GPP guidelines

The GPP guidelines are presented in three main sections that are colour-coded to enable users to easily navigate the document:

Section 1: The importance of good participatory practice defines the key terms used in the document and describes the realities and the underlying determinants of the HIV epidemic, the context of conducting biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials.

Section 2: Guiding principles of GPP in biomedical HIV prevention trials outlines the set of principles that serve as the foundation of the relationships among trial funders, sponsors, and implementers and other stakeholders. These principles include respect, mutual understanding, integrity, transparency, accountability, and community stakeholder autonomy.

Section 3: Good participatory practices in biomedical HIV prevention trials describes optimal practices to follow when designing and conducting biomedical HIV prevention trials. Under 16 topic areas, this section outlines expected stakeholder engagement activities that take place at each stage of the research life-cycle. The topic areas are:

1. Formative research activities
2. Stakeholder advisory mechanisms
3. Stakeholder engagement plan
4. Stakeholder education plan
5. Communications plan
6. Issues management plan
7. Site selection
8. Protocol development
9. Informed consent process
10. Standard of HIV prevention
11. Access to HIV care and treatment
12. Non HIV-related care
13. Policies on trial-related harms
14. Trial accrual, follow-up, and exit
15. Trial closure and results dissemination
16. Post-trial access to trial products or procedures

Topic areas in the good participatory practices section are divided into the following subsections:

A. Definition.
B. Relevance to good participatory practice.
C. Special considerations.
D. Good participatory practices.
E. Additional guidance.

After the Conclusion (pages 66-67), the reader will find three useful annexes:

Annex 1 presents the acronyms and abbreviations used in this document.
Annex 2 is a glossary of the essential terms used throughout the GPP guidelines.
Annex 3 introduces other international reference guidelines and key documents, for further reading.

Section 1:
The Importance of Good Participatory Practice

The Importance of Good Participatory Practice defines the key terms used in the document and describes the realities and the underlying determinants of the HIV epidemic, the context of conducting biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials.

Section 2:
Guiding Principles of GPP in Biomedical HIV Prevention Trials

Guiding Principles of GPP in Biomedical HIV Prevention Trials outlines the set of principles that serve as the foundation of the relationships among trial funders, sponsors, and implementers and other stakeholders.

Section 3:
Good Participatory Practices in Biomedical HIV Prevention Trials

Good Participatory Practices in Biomedical HIV Prevention Trials describes optimal practices for trial funders, sponsors, and implementers to follow when designing, conducting, and concluding biomedical HIV prevention trials. Under 16 topic areas, this section outlines expected stakeholder engagement activities that take place at each stage of the research life-cycle.

Section 1:
The Importance of Good Participatory Practice

Use this section to understand the meaning of stakeholder engagement, the context of biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials

- Who are Stakeholders?
- What is Stakeholder Engagement?
- The Wider Context of HIV
- The Dynamics of Biomedical HIV Prevention Trials
- Rationale for GPP Guidelines
- Applying GPP

Section 2:
Guiding Principles of GPP in Biomedical HIV Prevention Trials

Use this section to understand the principles that guide the foundation of the relationships among biomedical HIV prevention stakeholders

- Respect
- Mutual Understanding
- Integrity
- Transparency
- Accountability
- Community Stakeholder Autonomy

Section 3:
Good Participatory Practices in Biomedical HIV Prevention Trials

Use this section and its optimal practices to guide specific stakeholder engagement activities when conducting biomedical HIV prevention trials

- Formative Research Activities
- Stakeholder Advisory Mechanisms
- Stakeholder Engagement Plan
- Stakeholder Education Plan
- Communications Plan
- Issues Management Plan
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- Post-trial Access to Trial Products or Procedures

1. The importance of good participatory practice

1.1 Who are stakeholders?

The starting point of good participatory practice is the identification of key stakeholders in the conduct of a biomedical HIV prevention trial. **Stakeholders** are individuals, groups, organisations, government bodies, or any other individuals or collections of individuals who can influence or are affected by the conduct or outcome of a biomedical HIV prevention trial. In this guidance document, the term "stakeholders" is all-encompassing. It describes any individual or collection of individuals who have a stake in a biomedical HIV prevention trial.

Examples of stakeholders are illustrated in Figure 2 and can include trial participants, families of trial participants, prospective trial participants, individuals resident within, or surrounding, the area where research is conducted, people living with HIV or affected by HIV, prevention and treatment advocates and activists, non-governmental organisations (NGOs), community-based organisations (CBOs), community groups, religious leaders, opinion leaders, media, government bodies, national and local health-care authorities, service providers, trial funders, trial sponsors, and trial implementers.

The definition of "community" is more complicated, as it is a dynamic term that has different meanings to different people.[19] This term is often used to refer to a group of people who have a common set of interests, share a common set of characteristics, or live in a common area. Individuals can be a part of multiple "communities" at the same time. The term "community" is also used to refer to the public at large or to a physical location.

In the GPP guidelines, the preferred term is **"community stakeholders"**, rather than "community", and refers to both individuals and groups that are ultimately representing the interests of people who would be recruited to or participate in a trial, and others locally

affected by a trial. Examples of "community stakeholders" are the population to be recruited, trial participants, people living in the area where the research is conducted, people living with HIV in the area, local HIV-positive groups or networks, people in the area who are affected by the HIV epidemic, local non-governmental organisations, community groups, and community-based organisations. Trial funders, sponsors, and implementers, as well as government bodies or representatives of high-level authority structures, are explicitly excluded from the term "community stakeholders" but are clearly considered trial stakeholders.

Figure 2. Layers of Biomedical HIV Prevention Trial Stakeholders

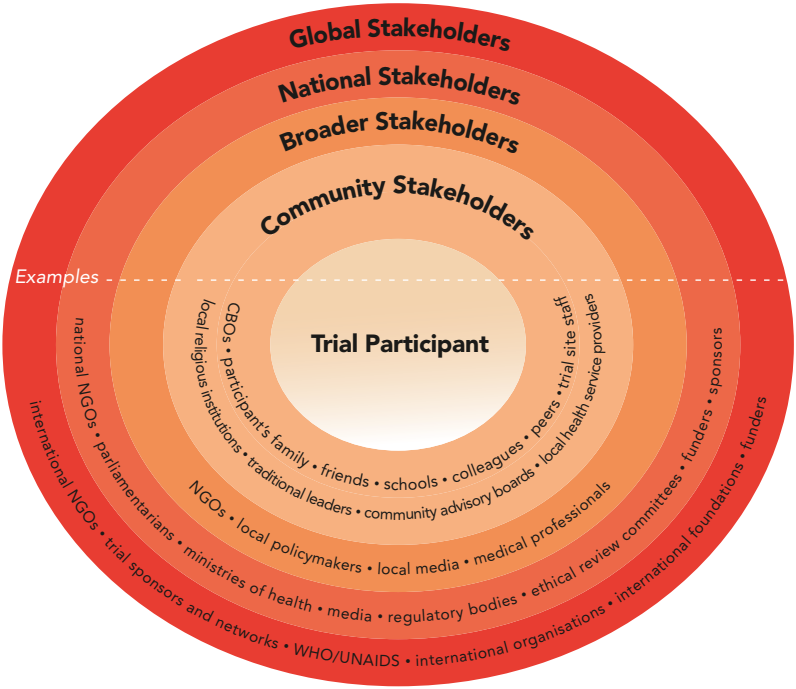

Various stakeholders may influence or be affected by a biomedical HIV prevention trial. Stakeholders include trial participants and other community stakeholders as well as a broader range of national and international stakeholders.

1.2 What is stakeholder engagement?

Of key importance in good participatory practice is sustained, collaborative partnering with stakeholders. In the GPP guidelines, the term "stakeholder engagement" refers to processes through which trial funders, sponsors, and implementers build transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organisations, with the ultimate goal of shaping research collectively.

Successful stakeholder engagement requires a broad, inclusive, and multifaceted understanding of the context in which a biomedical HIV prevention trial is conducted. It begins with an inclusive perspective for identification of potential stakeholders. Stakeholder identification is a dynamic process, as stakeholders, interests, priorities, perspectives, and aspects of culture may change over time. Research teams are responsible for identifying stakeholders, a process which begins by determining the trial population to be recruited, considering those who are affected by the trial in the local area, consulting with already known stakeholders, and building on that expertise to develop a richer understanding of potential and known stakeholders.

Different stakeholders will have different perspectives. Some stakeholders will have competing interests or power imbalances within groups, as well as differences in social organisation, hierarchies, gender issues, and relative social and economic status that may then create division and disagreement during the course of a trial. If there is opposition or disagreement among stakeholders, then those issues must be addressed in a way that is honest, transparent, and respectful to all parties.

Stakeholders in biomedical HIV prevention research can learn from other fields that have successfully adopted participatory research approaches, which seek to engage community stakeholders as equal members who share control over all aspects of the research process.[20, 21, 22, 23, 24]

1.3 The wider context of HIV

There is an urgent need to develop additional strategies to address the HIV pandemic. Along with necessary behavioural and structural changes, a broad range of biomedical HIV prevention and treatment options is required to meet the diverse needs of individuals and populations. There are many inherent complexities in conducting biomedical HIV prevention trials. By acknowledging and understanding these challenges and complexities, trial funders, sponsors, and implementers can more appropriately and effectively facilitate a mutually beneficial participatory approach to conducting biomedical HIV prevention trials.

Biomedical HIV prevention research cannot succeed without meaningful stakeholder engagement, particularly given the need to involve large numbers of healthy, HIV-negative volunteers as trial participants. It is optimal that experimental HIV prevention options are tested for safety and effectiveness in populations who need these interventions the most and are likely to use them should they prove effective. However, the very factors that increase HIV risk in such populations may contribute to increased vulnerability to exploitation. This underscores the importance of meaningful partnerships with community stakeholders.

A wide range of factors creates, enhances, and perpetuates the risk of HIV infection. Structural determinants can increase vulnerability to HIV at an individual or population level by undermining ability to avoid HIV exposure. Underlying determinants of the HIV epidemic can be entrenched in the social, cultural, legal, institutional, or economic fabric of society. Examples of these determinants include gender and other power inequalities, gender-based violence, economic instability including poverty, migration, human rights violations, homophobia, discriminatory practices, HIV-related stigma, social marginalisation, and criminalisation of HIV transmission. Recognition of these factors is the first step in developing practices

that avoid inadvertently replicating or reinforcing them in the design and conduct of biomedical HIV prevention trials. While stakeholder engagement helps empower and equip community stakeholders to engage in the research process in a meaningful fashion, it also harnesses the expertise that community stakeholders can contribute to the design and conduct of research.

1.4 The dynamics of biomedical HIV prevention trials

Power inequalities always exist between funders and funding recipients with respect to a range of issues, such as decision-making processes, priority setting, control of resources, and equitable recognition of input. Biomedical HIV prevention trials are often funded by institutions in developed countries and conducted with multiple partner institutions worldwide, including those in developing countries. Disparities among these institutions and partners can introduce or reinforce power inequalities between and among trial implementers and the funders or sponsors of trials. This can then translate into inequalities between trial implementers and other stakeholders.

The fact that many biomedical HIV prevention trials are conducted in multiple settings and countries introduces another level of complexity. Variation in cultures, physical environments, infrastructure, research experience, health policies, and national laws can introduce inequalities among research teams and between research teams and site-level community stakeholders. Power inequalities between research teams and community stakeholders can include imbalances in literacy, education, and economic resources, as well as those inherent in patient–provider relationships. National, racial, ethnic, and linguistic differences between members of research teams and community stakeholders can also exacerbate inequalities.

In order to achieve meaningful community stakeholder participation and partnership, it is essential to recognise these various power inequalities and address them.

Figure 3. Example of a Trial Network

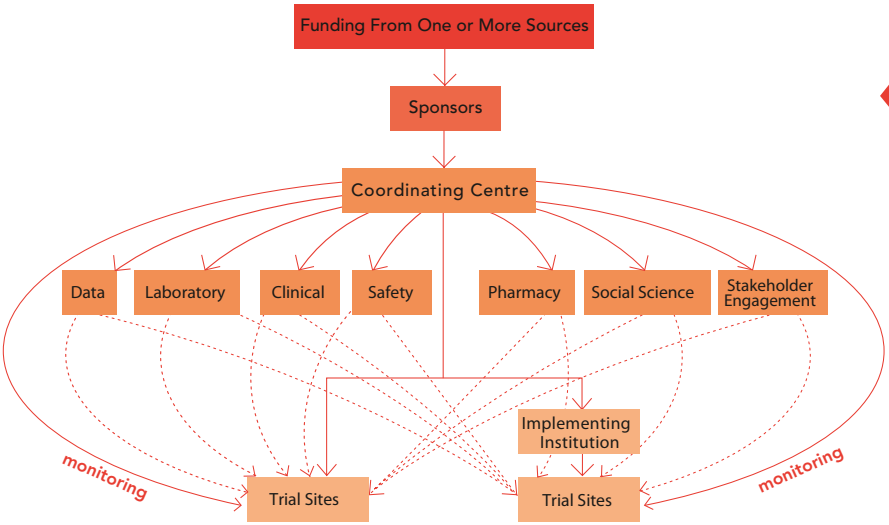

Basic structure of a typical biomedical HIV prevention trial network. Funding from one or more sources is distributed through a network coordinating centre directly to trial sites or to implementing institutions such as universities that then send funds to trial sites. Trial networks may have several centres responsible for different aspects of trial conduct: data management, laboratory, pharmacy, clinical, safety, social science, and stakeholder engagement. Monitoring of trial conduct may be executed through the coordinating centre or outsourced to an independent monitoring organisation.

1.5 Rationale for GPP guidelines

Constructive long-term stakeholder engagement helps ensure the ethical and scientific quality of research as well as its relevance to community stakeholders.[1,25] Stakeholders, in particular community stakeholders, have unique expertise to contribute to the research process. They possess critical knowledge and understandings of local cultures and perspectives, languages, dynamics of the local HIV epidemic, concerns of vulnerable or marginalised populations, and local priorities that trial funders, sponsors, and implementers may lack.

Stakeholder collaboration can help ensure that research questions and procedures are culturally sensitive and appropriate, thus improving recruitment, retention, adherence, and other trial outcomes. It can help avoid reinforcing existing inequalities and increase sensitivity to the needs of vulnerable populations. An essential component of stakeholder engagement is improving stakeholder knowledge and understanding of the research process, building research literacy and competencies. This, in turn, enables stakeholders to contribute more effectively to the process of guiding research and helps to address the power imbalance between research teams and community stakeholders.

Strengthening meaningful collaboration among stakeholders fosters greater trust and respect between trial funders, sponsors, and implementers, and other stakeholders. Stakeholder engagement that is transparent and mutually respectful can minimise misunderstandings and reduce the chances of unnecessary conflict or controversy. Following good participatory practices through the entire research life-cycle helps facilitate local ownership of research, enables more equitable relationships, and increases the likelihood of successful research conduct, trial completion, and application of research results.

1.6 Applying GPP

The GPP guidelines broadly describe systematic ways to establish and maintain effective stakeholder engagement that can be applied in diverse locations globally. The specificity of the content of the GPP guidelines enables monitoring of stakeholder engagement activities.

The most effective way for the GPP guidelines to be implemented is for trial sponsors to adopt them as a requirement in trial conduct and to monitor their implementation and evaluate their effectiveness. As an essential element of successful trial implementation, effective

stakeholder engagement requires that trial sponsors provide ample time allocation, adequate human resources, and sufficient funds in site budgets for implementation of Section 3 of the GPP guidelines.

Other stakeholders, such as national authorities, institutions, ethics committees, institutional review boards, and community stakeholders can also require that the GPP guidelines be followed when research is conducted in their country, institution, or area.

Monitoring stakeholder engagement is a complex process. To measure whether the GPP guidelines are being followed, stakeholders can first consult the list of optimal practices in each topic area of Section 3 and determine if the various activities have been executed. Because stakeholder engagement is based on relationships, it may be perceived differently by different stakeholders and may be difficult to measure. Comprehensive monitoring of GPP compliance includes documenting and analysing how well practices have been followed as well as to what extent stakeholders feel the practices have been followed. Comprehensive evaluation of stakeholder engagement requires determining how stakeholders feel regarding the impact of those participatory practices on research and stakeholder relationships. This information can be gained through site records, meeting minutes, monitoring report forms, surveys, interviews, focus group discussions, and other methods.

A variety of other resources and tools may help stakeholders understand, implement, and monitor GPP. Users can refer to AVAC's website for new or revised materials. UNAIDS and AVAC welcome requests for additional tools as well as submissions of materials that are already in use.

2. Guiding principles of GPP in biomedical HIV prevention trials

The guiding principles of good participatory practice described below reflect a set of values that constitute the foundation for positive, collaborative, and mutually beneficial relationships that trial funders, sponsors, and implementers can foster with all other stakeholders. These principles are fundamental to sustaining partnerships and ensuring that collectively identified goals are achieved. They also serve to strengthen the foundation for conducting research that contributes to the identification of additional HIV prevention options. The GPP guidelines have been developed within the framework of these principles.

2.1 Respect

Respect among stakeholders is key to communicating effectively, fostering trust, and developing partnerships to achieve collective goals. Respect is demonstrated when stakeholders communicate and act in ways that value and honour each other's perspectives and realities.

Ethical research requires fundamental respect for human rights and for confidentiality of trial participants. It also requires respect for local values, cultures, and perspectives as well as respect for the scientific process.

2.2 Mutual understanding

A common understanding about objectives and how to achieve them is essential to effective partnerships among stakeholders. This requires stakeholders to develop competency in both socio-cultural issues and research processes. The initial competency level of different stakeholders will depend on their prior exposure to specific socio-cultural environments and to biomedical HIV prevention trials.

Socio-cultural competency includes understanding the norms, practices, and beliefs of relevant local cultures, and local social circum-

stances, as well as diverse community stakeholder perspectives, priorities, and research needs. Building socio-cultural competency enables collaboration among stakeholders with diverse priorities and informs the development of appropriate trial designs and procedures.

Research competency includes understanding the scientific process of defining research questions, developing appropriate trial designs, and collecting, analysing, and disseminating data to ensure valid results. Building research competency enables and empowers stakeholders to provide meaningful input into the research process and enhances understanding of the concepts, purposes, practices, limitations, and results of biomedical HIV prevention trials.

Figure 4. Trial Competency Range

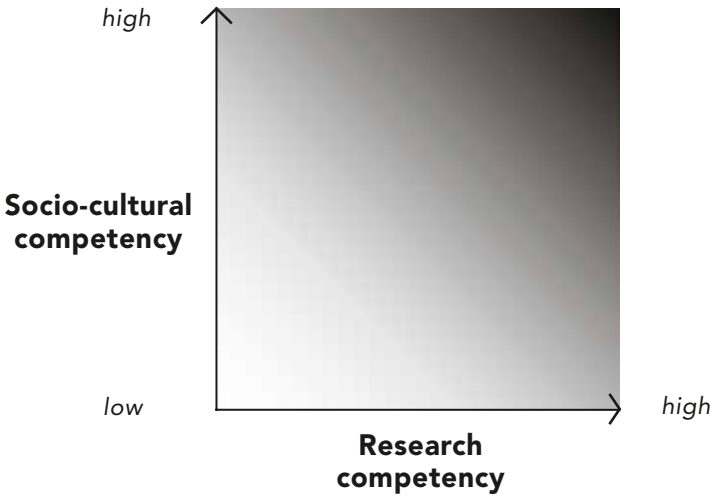

Socio-cultural and research competency are shown as gradients along two axes. Individual stakeholders start their involvement at a particular position on the graph, based on their socio-cultural competency and their research competency. A principal investigator new to a particular location may have high research competency but low socio-cultural competency at the start of the design phase of a trial. A community stakeholder new to biomedical HIV prevention research may have high socio-cultural competency but low research competency when their involvement with a trial begins. All stakeholders share ongoing responsibility to review and strengthen both socio-cultural and research competencies in order to improve mutual understanding.

2.3 Integrity

Maintaining the highest standards of scientific and ethical integrity is fundamental to achieving the scientific goals of a biomedical HIV prevention trial, maximising benefits for community stakeholders, and advancing global HIV prevention science.

Scientific integrity requires adherence to scientific processes in order to ensure that trials meet the highest scientific standards and achieve valid results.

Ethical integrity requires consideration of broader societal and ethical issues as well as adherence to universal ethical principles that include respect for persons, beneficence, and justice.[6]

2.4 Transparency

Open, honest, timely, and clear communication enables transparency and fosters collaborative, trusting, and constructive relationships. Transparency is relevant to the research process as well as to the roles of stakeholders.

Transparency about research includes ensuring that stakeholders receive open, honest, and understandable information about the objectives and processes of a trial. Transparency means ensuring that feedback from a broad range of stakeholders is acknowledged and addressed.

Transparency about the role of stakeholders includes ensuring that stakeholders are clear on their respective roles and responsibilities; the constituents, if any, they each represent; and the extent to which their input may influence trial-related decisions. Adherence to the principle of transparency means that stakeholders communicate about circumstances that may affect previously agreed levels of consultation, involvement, collaboration, and decision-making.

2.5 Accountability

Accountability is fundamental to sustaining relationships built on trust and mutual respect.

Trial funders, sponsors, and implementers are accountable to the society at large for conducting scientifically valid and ethical research. They are accountable to all research stakeholders for the use of participatory practices and for responding to input from relevant stakeholders as mutually agreed. They are also accountable for ensuring that funding is adequate to enable optimal engagement between research teams and other stakeholders.

Community stakeholders and other relevant stakeholders are accountable for ensuring that their input into the research process is fair and constructive, respects the scientific process, and is in the best self-identified interests of community stakeholders. Where stakeholders accept the responsibility to act as liaisons or representatives between research teams and other stakeholders, they are accountable for representing the interests of those they represent, sharing information about planned or ongoing trials with them, and expressing their needs and concerns to research teams.

2.6 Community stakeholder autonomy

Community stakeholder autonomy describes the community stakeholders' right to support or refuse proposals to conduct research in a particular area, depending on the community stakeholders' self-identified interests and desires. Different stakeholder groups may well have different perspectives on the relevance or appropriateness of a specific trial, adding complexity to the situation.

Good participatory practice strives to maximise the opportunity for stakeholders to understand the local, national, and global benefits of a specific trial and to make informed decisions regarding the appropriateness of a proposed trial.

While a wide range of stakeholders generally participates in the design, approval, and implementation of a particular trial protocol, the self-identified interests of community stakeholders ultimately determine whether or not a trial is conducted in a particular area.

3. Good participatory practices in biomedical HIV prevention trials

Introduction to good participatory practices

The design, planning, and implementation of biomedical HIV prevention trials are guided by a range of standards such as *Good Clinical Practice*,[2,3] *Good Clinical Laboratory Practice*,[4] and *Good Manufacturing Practice*.[26] This section describes a systematic framework that trial funders, sponsors, and implementers can use to develop meaningful and sustained partnerships with relevant stakeholders in the planning and conduct of biomedical HIV prevention trials. The good participatory practices are intended to be adopted by trial sponsors, implemented at trial sites globally, and monitored.

Appropriate and meaningful stakeholder engagement occurs at all stages of the research life-cycle—from trial design to results dissemination—and is not limited to the specific topic areas highlighted in this section. While this section describes stakeholder engagement processes in the general sequence in which they may occur, these processes are not necessarily sequential or time-limited; they can take place as parallel, overlapping, or ongoing activities.

The application of each practice or set of practices will vary by location, the type of trial being conducted, and trial site experience with respect to previously established stakeholder engagement programmes and activities.

The good participatory practices section is divided into 16 topic areas covering the course of the research life-cycle. Topic areas in section 3 are divided into the following subsections:

A. Definition.
B. Relevance to good participatory practice.
C. Special considerations.
D. Good participatory practices.
E. Additional guidance.

3.1 Formative research activities

3.1.A. Definition

Formative research activities enable research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, channels of communication and decision-making, and local history of research, as well as the needs and priorities of people who are locally affected by and able to influence the trial. Formative research activities usually constitute the initial phase of stakeholder outreach and engagement.

3.1.B. Relevance to good participatory practice

Collaborating with community stakeholders to devise questions, gather information, and analyse results related to formative research activities ensures that stakeholders' expertise and understanding of local perceptions, cultures, and traditions inform trial design and conduct. Collaborating with community stakeholders on formative research activities builds trust and lays the foundation for meaningful engagement.

3.1.C. Special considerations

1. Formative research activities can be conducted informally to gather information about local populations and research areas or formally as a part of approved, funded protocols.
2. Different sites will have specific needs regarding formative research activities. Whereas new trial sites may require extensive formative research activities, experienced trial sites may require more focused activities. Studying an experimental option new to the area, recruiting from a new location or population, gathering stakeholder feedback regarding previous trials, and the changing nature of cultures are all reasons why experienced trial sites may benefit from formative research activities.

3.1.D. Good participatory practices for formative research activities

1. Research teams identify key informants and relevant stakeholders that can assist in planning, implementing, and reviewing the process and results of formative research activities (see also Section 1.2).
2. Research teams designate trial site staff responsible for managing formative research activities.
3. Research teams and relevant stakeholders develop a formative research activity plan that describes:
   a. Key information and questions that need to be gathered and answered in order to support effective planning and implementation of the trial.
   b. The most appropriate methods to collect the required information.
   c. Research team members and community stakeholders best suited to collect the required information.
   d. Approval or notification processes that are required for specific activities.
   e. Implementation plans, including timelines and required resources.
4. Research teams and relevant stakeholders discuss the findings and their implications for trial design, conduct, and development of meaningful stakeholder engagement.
5. Research teams document formative research activities and findings, including techniques used, information collected, areas where clarification or attention is needed, and how findings will inform the trial planning and implementation process.
6. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to conduct formative research activities.

3.2 Stakeholder advisory mechanisms

3.2.A. Definition

The term "stakeholder advisory mechanisms" refers to strategies or approaches that facilitate meaningful dialogue among research teams and relevant stakeholders about planned or ongoing clinical trials. Stakeholder advisory mechanisms provide research teams with information about relevant stakeholders' perspectives on the design, planning, and implementation of a specific clinical trial and facilitate open communication about research goals, processes, and results. These mechanisms also provide relevant stakeholders with the opportunity to engage with research teams during the life-cycle of a trial.

Stakeholder advisory mechanisms may be informal or formal. They can be built and sustained by the trial site or may already exist in the area.

1. Informal stakeholder advisory mechanisms may be events or less formal means by which research teams seek relevant stakeholders' views on proposed or ongoing research. Examples include stakeholder meetings, local events, focus group discussions, interviews, consultations, and suggestion boxes. They may involve individuals, existing organisations, local employer associations, local government or traditional committees, or other advocacy, charitable, cultural, political, religious, or social groups.
2. Formal stakeholder advisory mechanisms typically involve established groups that develop an ongoing relationship with the research team at a particular trial site. Examples are trial participant groups (former or current participants), professional groups (local scientists, service providers, media, or experts on local socio-cultural issues), non-governmental organisation advisory groups (with representatives from different non-governmental organisations or community-based organisations), and community advisory boards (see definition below).
3. Community advisory boards (CABs), also referred to as community advisory groups (CAGs), are a common example of a formal stakeholder advisory mechanism. They are composed of individuals or stakeholder representatives

and provide an independent advisory voice. They facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise during specific trials.

The composition of community advisory boards or groups varies from site to site but is intended to reflect the diversity of community stakeholder interests and needs. They may include members or representatives of the surrounding area, individuals in the population from which participants will be recruited, people living with or affected by HIV, current or former trial participants, religious or opinion leaders, and representatives of other sections of society as determined by the trial's location and eligibility criteria.

Figure 5. Examples of Stakeholder Advisory Mechanisms

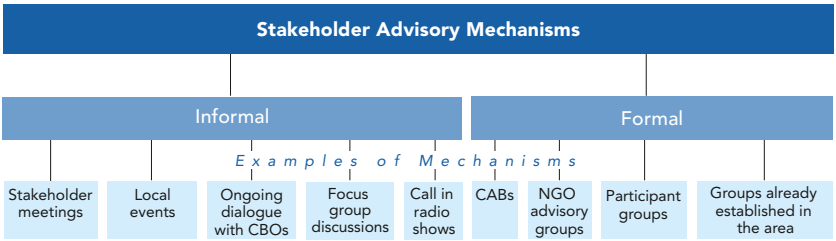

Stakeholder advisory mechanisms can include informal and formal stakeholder advisory mechanisms (see definition 3.2.A). All of these mechanisms, as well as others, may be used to facilitate important dialogue between research teams and other stakeholders. While community advisory boards (CABs) are one example of a stakeholder advisory mechanism, there are many other ways that research teams can effectively engage with stakeholders.

3.2.B. Relevance to good participatory practice

Establishment, maintenance, and engagement of stakeholder advisory mechanisms throughout the research process are key to establishing meaningful partnerships with community stakeholders and to ensuring continuous dialogue about biomedical HIV prevention research and specific trials.

3.2.C. Special considerations

1. Community advisory boards or groups were first developed in the context of HIV research in the United States of America and Europe. Over the past two decades, they have become a standard element of HIV research worldwide. Nonetheless, the establishment of a community advisory board or group may not always translate as best practice in all locations globally. In many settings, they are necessary but not sufficient for gaining adequate and appropriate community stakeholder input. Careful consideration needs to be given to the range of stakeholder advisory mechanisms that are required to best support effective participatory practices.
2. The need to identify and establish new stakeholder advisory mechanisms may vary from site to site and within a single site, over time. Stakeholder identification and inclusion considers the dynamic stakeholder landscape, as well as whether a trial is conducted in a research-naïve area or at a well-established research facility.
3. Formative research activities (see Section 3.1) help research teams to comprehensively identify which groups or individuals are relevant stakeholders and why.
4. While community advisory boards or groups can assist research teams in thinking about best strategies for trial recruitment, individual members of community advisory boards or groups are not research staff and do not participate in implementing actual trial procedures such as recruitment of prospective participants.
5. While community advisory boards or groups are often funded by research networks or trial sites, they are intended to be an independent advisory voice that is free to express concerns about proposed or ongoing research.

Figure 6. The Role of Community Advisory Boards

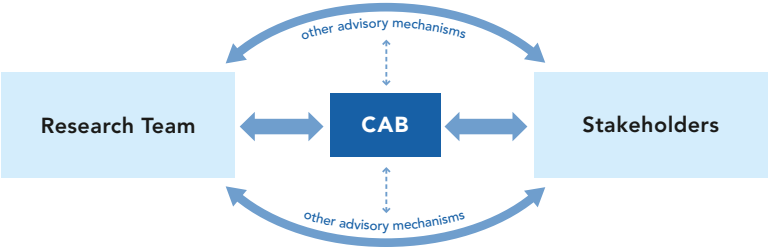

Community advisory boards (CABs) can play an important role in translating information between research teams and stakeholders. While community advisory boards are a key mechanism by which research teams inform stakeholders and receive their feedback, research teams are responsible for using other advisory mechanisms in addition to CABs to reach a broader range of stakeholders.

Figure 7. Examples of How Research Teams can Engage with Stakeholders

Examples of advisory mechanisms that research teams may use to engage with stakeholders to facilitate ongoing communication and collaboration.

3.2.D. Good participatory practices for stakeholder advisory mechanisms

1. Research teams comprehensively identify and map local stakeholders in order to determine which are relevant to trial implementation and key to sustained stakeholder engagement (see Section 1.2).
2. Research teams designate trial site staff responsible for managing activities and relationships involving stakeholder advisory mechanisms.
3. Research teams ensure that the development or identification of stakeholder advisory mechanisms is transparent to community stakeholders.
4. Research teams and relevant stakeholders identify stakeholder advisory mechanisms needed to ensure greater and more inclusive involvement of relevant stakeholders, in addition to community advisory boards or groups.
5. Research teams ensure that representation of stakeholders is comprehensive, including representatives of populations that will be recruited into trials, and that interactions with stakeholders are meaningful and responsive for all parties.
6. Research teams and relevant stakeholders identify the training needs of members of advisory mechanisms and build their capacity to understand concepts, purposes, practices, and limitations of clinical trials, increasing their ability to provide meaningful input to the research process.
7. Research teams review on an ongoing basis the composition of existing mechanisms and the need for new advisory mechanisms to ensure that relevant stakeholders continue to be represented during the course of a trial.
8. Research teams describe in their stakeholder engagement plans (see Section 3.3) strategies for the identification, establishment, and maintenance of stakeholder advisory mechanisms.
9. Research teams maintain clear written records of discussions and agreements with relevant stakeholders, including requests, concerns, recommendations, actions taken by the research team, and any unresolved issues that require follow-up.

10. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support establishment, ongoing capacity-building, maintenance, and activities of stakeholder advisory mechanisms.
11. For formal stakeholder advisory mechanisms, research teams and relevant stakeholders determine:
    a. The purpose of each stakeholder advisory mechanism, which may result in establishing terms of reference or by-laws.
    b. The scope of responsibilities of each stakeholder advisory mechanism, such as the responsibility to develop, review, discuss, and provide input on relevant trial documents and procedures.
    c. The structure of each stakeholder advisory mechanism, which may result in establishing guidelines to elect a chairperson and define the duration of service for members.
    d. The frequency of meetings, the frequency with which principal investigators or other key trial staff members attend meetings, and the ways in which members can communicate with research teams between meetings.
    e. Reimbursement policies, if appropriate.
    f. Mechanisms by which individuals or groups can raise concerns with research teams and with off-site trial sponsors in the event that a conflict or concern related to the site emerges.

3.2.E. Additional guidance

See *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research*.[27]

3.3 Stakeholder engagement plan[a]

3.3.A. Definition

The stakeholder engagement plan describes strategies and mechanisms for building relationships and constructively engaging with a broad range of local, national, and international stakeholders.

3.3.B. Relevance to good participatory practice

A comprehensive stakeholder engagement plan enables research teams to collaborate with stakeholders and facilitate a more participatory approach to biomedical HIV prevention research. An effective stakeholder engagement plan will help research teams design and implement research that is effective and locally acceptable, and also lays the foundation for a supportive environment for research that extends beyond the lifespan of a specific biomedical HIV prevention trial.

Figure 8. Stakeholder Engagement through the Research Life-cycle

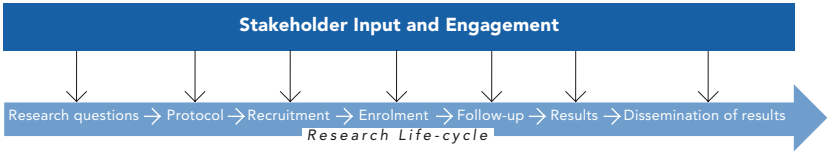

Robust stakeholder engagement occurs at all stages of the research life-cycle, including during trial design, recruitment, implementation, trial closure, results dissemination, negotiations of next steps, and development of future research questions.

a Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

3.3.C. Special considerations

Being familiar with and appreciating the relationship dynamics among different stakeholders increases the research team's ability to effectively and constructively engage with a broad range of relevant stakeholders, deepens understanding of local context, and will inform the development of the stakeholder engagement plan.

3.3.D. Good participatory practices for stakeholder engagement planning

1. Research teams comprehensively identify relevant stakeholders (see Section 1.2 and Section 3.1) within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams designate trial site staff responsible for managing activities and relationships involving stakeholder engagement planning.
3. Research teams and relevant stakeholders discuss and negotiate a stakeholder engagement plan to cover the lifecycle of the trial. The plan defines the following:
   a. The range of different stakeholders to be engaged, specifically ensuring inclusion of relevant non-governmental organisations and community-based organisations and groups.
   b. The type of engagement that is appropriate for each stakeholder, such as being informed, consulted, collaborated with, or empowered to make decisions.
   c. The frequency and type of engagement methods to be used, such as public meetings, workshops, joint decision-making models, or delegated decision-making.
   d. The process by which new relevant stakeholders will be identified and engaged.
   e. The frequency with which the engagement plan will be reviewed.
   f. The criteria by which to review the success of the engagement plan.

4. Research teams implement the plan and maintain clear written records of discussions and agreements, as well as stakeholder engagement activities. This includes stakeholder recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to manage activities and relationships involved in stakeholder engagement plans.

3.4 Stakeholder education plan[b]

3.4.A. Definition

The stakeholder education plan describes strategies and mechanisms for providing relevant education about a specific planned trial—and about biomedical HIV prevention research in general—in order to enhance research literacy.

3.4.B. Relevance to good participatory practice

Effective stakeholder education is key to building research literacy and, ultimately, empowering community stakeholders as decision-making agents. Building research literacy lays the foundation for a supportive environment for research that extends beyond the lifespan of a specific biomedical HIV prevention trial.

3.4.C. Special considerations

1. While it is important that all relevant stakeholders improve their knowledge of research processes, enhancing research literacy for community stakeholders will foster more equitable relationships.
2. The goals and outcomes of stakeholder education are different from those of recruitment activities. While stakeholder

b Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

education can positively influence trial recruitment activities, a stakeholder education plan can help clarify the differences between participant recruitment and stakeholder education.

3.4.D. Good participatory practices for stakeholder education planning

1. Research teams, with input from relevant stakeholders, determine what education is needed in order to enhance stakeholder understanding of, and engagement with, a specific planned trial and biomedical HIV prevention research more generally.
2. Research teams and relevant stakeholders discuss and negotiate a stakeholder education plan to cover the life-cycle of the trial. The plan defines the following:
   a. The range of different stakeholders that could benefit from specific education about HIV, HIV prevention options, and general research literacy.
   b. The level of knowledge that is optimal and desired by stakeholders to support effective engagement. This will be influenced by the type of engagement defined for each stakeholder in the stakeholder engagement plan (see Section 3.3).
   c. The methods and frequency of educational activities.
   d. The stakeholders who could also deliver or facilitate the delivery of activities in the stakeholder education plan.
   e. The frequency with which the stakeholder education plan will be reviewed.
   f. The criteria by which to review the success of the stakeholder education plan.
3. Research teams implement the plan and document stakeholder education activities, including questions that arise, topics that cause confusion, and suggestions for future educational activities.
4. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the stakeholder education plan.

3.5 Communications plan[c]

3.5.A. Definition

The communications plan describes policies and strategies that will increase broad awareness of the trial, facilitate dissemination and understanding of correct information about trial design, conduct, and results, and coordinate communication between the research team and relevant stakeholders.

3.5.B. Relevance to good participatory practice

Ongoing, transparent, and accurate communication with relevant stakeholders about proposed and ongoing research is essential for respectful, transparent relationships and builds trust among stakeholders. Additionally, consultation with relevant stakeholders will help research teams design communications strategies that are effective and help create a supportive and conducive environment for trial initiation and implementation.

3.5.C. Special considerations

The communications plan exclusively addresses external communication. However, effective internal communication, especially across multidisciplinary teams, is a prerequisite to attaining effective external communications.

3.5.D. Good participatory practices for communications planning

1. Research teams and relevant stakeholders comprehensively identify potential audiences within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams and relevant stakeholders discuss and negotiate a communications plan to support open channels

c Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

of communication about the trial throughout its life-cycle. The plan describes the following:

a. The information needs of the different stakeholders at various stages of the research life-cycle, from early phases of stakeholder engagement to recruitment, enrolment, trial closure, and results dissemination.

b. The key messages to be communicated about the trial, such as the purpose, risks, benefits, ongoing progress, closure, and results dissemination.

c. The various communication methods that will be used for specific stakeholders, taking into account literacy levels and language needs.

d. Local stakeholders who could deliver or facilitate communications activities.

e. Specific training needs necessary to effectively deliver messages.

f. Procedures and timelines for disseminating information and procedures for actively addressing inquiries about the trial or HIV prevention research.

g. The frequency with which the communications plan will be reviewed.

h. The criteria by which to review the success of the communications plan.

3. Research teams develop communication materials in understandable language and translate them as needed, seeking input from relevant stakeholders.

4. Research teams implement the plan and maintain clear written records of discussions, agreements, and communication activities. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues that require further follow-up.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the communications plan.

3.5.E. Additional guidance

See *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results*.[28]

3.6 Issues management plan[d]

3.6.A. Definition

The issues management plan describes how research teams intend to manage issues of concern or any unexpected developments that may emerge before, during, or after the trial, including those that could limit the support for, or success of, the specific trial or future biomedical HIV prevention trials.

Examples of the types of issues that may emerge are negative media coverage, rumours about the trial, socio-cultural taboos around certain trial procedures, developments in other HIV prevention trials, premature closure of a trial for reasons of harm, futility, or proven efficacy in interim analyses, recruitment challenges, or protocol issues.

3.6.B. Relevance to good participatory practice

The risk that unexpected developments will negatively affect a trial can be mitigated if research teams work closely with relevant stakeholders to identify and plan for such risks and if relevant stakeholders provide advice and direction on how to resolve issues when they do arise. By developing an issues management plan prior to trial implementation, research teams are better equipped to deal with issues or risks as they arise and are more likely to avert a crisis.

d Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

3.6.C. Special considerations

Research teams may find it helpful to participate in communications networks of biomedical HIV prevention trials to share and discuss emerging issues and their potential management.

3.6.D. Good participatory practices for issues management planning

1. Research teams identify and list all known issues that could emerge and undermine the success of the trial before, during, or after trial completion.
2. Research teams and relevant stakeholders discuss and negotiate an issues management plan to cover the life-cycle of the trial. The plan defines the following:
   a. A site-level strategy to manage unexpected developments and emerging concerns.
   b. Key trial site staff who are responsible for addressing emerging issues.
   c. A chain of communication within the research team and with relevant stakeholders for emerging issues.
   d. Relevant stakeholders who can act as advisers and help implement steps of the issues management plan.
   e. Key messages created to address anticipated concerns.
   f. Clear processes by which media reports and media requests will be addressed.
3. Research teams implement the plan and maintain clear written records of issues that emerge, how they are responded to, and their outcome.
4. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the issues management plan.

3.6.E. Additional guidance

See *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results*.[28]

3.7 Site selection

3.7.A. Definition

Site selection is the process by which trial funders, sponsors, or networks evaluate sites for funding for a trial protocol, inclusion in a multisite trial, or inclusion in a trial network.

3.7.B. Relevance to good participatory practice

Site assessment of stakeholder engagement programmes or plans for their development is critical to anticipating a site's ability to conduct a trial according to good participatory practice.

3.7.C. Special considerations

New sites may not have the full range of stakeholder engagement plans and advisory mechanisms in place. Optimal sites for selection already have established stakeholder engagement processes and programmes or, in the case of new sites, have demonstrated commitment to establishing such processes.

3.7.D. Good participatory practices for site selection

1. Trial funders, sponsors, or network representatives assess sites with respect to stakeholder engagement programmes, taking into account the following issues:
   a. Evidence of or plans for development and maintenance of meaningful relationships with relevant stakeholders.
   b. Evidence of previous stakeholder engagement activities for sites that have conducted research.
   c. Findings from formative research activities or a workplan for completing formative research activities.
   d. Previous development of multiple stakeholder advisory mechanisms or a workplan to develop them.
   e. Demonstrated awareness and consideration of human rights issues that may be raised by the trial, particularly as they relate to vulnerable, marginalised, or criminalised groups.

2. Trial funders, sponsors, or network representatives continue to monitor site progress towards developing appropriate plans, resolving identified issues, and following good participatory practices during the site development phase of the trial.

3.8 Protocol development

3.8.A. Definition

Protocol development is the process of creating and modifying a trial protocol. The protocol describes the rationale, objectives, design, methodology, statistical considerations, ethical considerations, and organisation of a trial.

3.8.B. Relevance to good participatory practice

A range of stakeholders can provide meaningful input into many aspects of trial protocol development. In particular, community stakeholders bring expertise that can assist research teams in ensuring that protocol designs and procedures are locally appropriate, are acceptable to the trial population, and optimise successful implementation of the trial.

3.8.C. Special considerations

1. Opportunities for protocol review and input by local research teams and relevant stakeholders vary by trial. In some circumstances, particularly multicountry or multisite trials, protocol development may be largely centralised. It is good practice in the protocol development process to incorporate mechanisms to facilitate stakeholder input early in the process.
2. Research teams can consider documenting community stakeholder input into protocol development and sharing these recommendations with protocol review bodies, even when not explicitly required by such bodies.

3.8.D. Good participatory practices for protocol development

1. Trial sponsors and network leadership provide opportunities and time for local research teams to contribute to trial protocol development.

2. Trial sponsors, network leadership, and local research teams provide opportunities and time for local stakeholders, in particular community stakeholders, to contribute to trial design issues and procedures such as products to be tested, trial objectives, recruitment strategies, informed consent materials and procedures, reimbursement policies, counselling approaches, follow-up procedures, and post-trial access to trial products or procedures.
3. Research teams maintain clear and transparent communication about the protocol development process with relevant stakeholders, in particular, formal stakeholder advisory mechanisms.
4. Research teams provide relevant stakeholders with draft versions of the protocol and make technical information as accessible as possible by providing protocol summaries and translated materials, or by facilitating workshops, as necessary.
5. Research teams inform relevant stakeholders of protocol reviews and approval processes and provide regular updates.
6. Trial sponsors or implementers make full, final protocols of trials available and easily accessible to stakeholders.
7. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholders' recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
8. Trial sponsors ensure sufficient funding and research teams allocate resources and time to support stakeholder engagement in the protocol development process.

3.9 Informed consent process

3.9.A. Definition

Informed consent is a process by which a competent individual is provided with enough information about a trial to make an independent decision whether or not to participate in the trial. In this process, research staff members educate the prospective participant about the trial, including about the potential risks and benefits, trial procedures, and what is expected of the participant.

When an individual provides consent, this is documented on the informed consent form. Informed consent is an ongoing process. Participants may decide to drop out of the trial at any point, even after providing consent to enrol in the trial.

3.9.B. Relevance to good participatory practice

The informed consent process is relevant to good participatory practice because a wide range of stakeholders can help research teams develop locally acceptable and effective informed consent procedures and materials.

3.9.C. Special considerations

Community stakeholders can provide research teams with invaluable advice to improve the informed consent process and materials. However, the actual implementation of the informed consent process between an individual and the research staff is confidential. Only designated research staff members have access to confidential information about the identity of trial participants. The informed consent process itself is conducted in accordance with *Good Clinical Practice*.[2]

3.9.D. Good participatory practices for the informed consent process

1. Research teams discuss the following topics with community stakeholders during development of the informed consent materials and procedures:
   a. Who needs to be consulted locally to enable research teams to invite individuals to join the trial.
   b. What local cultural practices may affect individual decision-making ability, and how working within these structures can be facilitated while ensuring protection of individual autonomy to provide informed consent.
   c. The general literacy level of the population to be recruited and how to assess the literacy level of prospective participants.

d. Considerations and requirements for illiterate participants, including discussion of possibilities of who may serve appropriately as a witness to the informed consent process.

e. The prevalence of different languages in the area and which languages are required for obtaining informed consent from individuals.

f. Local and legal forms of identity (name and age) verification and local practices around the use of names.

g. The legal, local, and trial sponsor definitions of a "minor" and consideration of legal and local determinations of who can serve as a minor's guardian.

h. Locally appropriate reimbursement and compensation.

i. Appropriate strategies to ensure participant rights are protected, including voluntariness of participation, ensuring undue inducement is avoided, and mitigating the influence of social desirability in influencing individual agreement to enrol.

j. Strategies to ensure comprehension of informed consent materials and critical trial-related terms and concepts, including the use of visual or audio formats, flipcharts, props, analogies, and other supportive materials and methods.

k. Techniques to assess comprehension of trial participation and the frequency with which they are to be used.

l. Explanation of potential trial-related harms and how such harms will be addressed (see Section 3.13).

m. Strategies to ensure that follow-up of participants after missed visits respects agreements between the participant and research team about how to contact the participant.

n. Consideration of the length of informed consent forms and the estimated time required to complete the informed consent process.

o. Preferred ways for participants to contact research teams and stakeholders independent from the research team to ask questions or express concerns about trial participation.

p. Ways to pilot informed consent materials.

2. Research teams maintain clear written records of discussions and agreements. This includes community stakeholder recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
3. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to allow informed consent materials to be properly developed, piloted, translated, and implemented, including materials to assess participants' ongoing consent.

3.9.E. Additional guidance

1. Informed consent is the cornerstone of ethically conducted research and is explicitly discussed in guidance documents that address the overall ethical conduct of research, such as the *Declaration of Helsinki*,[5] *CIOMS* guidelines,[7] *The Belmont Report*,[6] *Good Clinical Practice*,[2] the World Health Organization *Handbook for Good Clinical Research Practice*,[3] the *Nuremberg Code*,[29] the *Nuffield Council Guidance on health research in developing countries*,[8, 9] and UNAIDS/WHO *Ethical considerations in biomedical HIV prevention trials,*[10] and in relevant national guidelines.
2. There are extensive literature and other resources on the development of informed consent processes in multiple contexts, including a range of innovative approaches to measure and assess participant understanding, to address literacy issues, and to accommodate the desire of participants to consult with families and friends. [30, 31, 32, 33, 34]

3.10 Standard of HIV prevention

3.10.A. Definition

The term "standard of HIV prevention" refers to the package of comprehensive counselling and state-of-the-art HIV risk reduction methods provided or made available to participants in biomedical HIV prevention trials.

3.10.B. Relevance to good participatory practice

Helping trial participants reduce their risk of acquiring HIV is a key ethical obligation of research teams. Determining the components of the HIV prevention package is a joint effort between research teams and relevant stakeholders. Trial sponsors and implementers must work with relevant stakeholders in establishing the type, scope, and process by which participants are provided with, or referred to, services to access the full HIV prevention package. How trial sites help participants prevent HIV acquisition is often at the forefront of community stakeholder concerns. Therefore, successful negotiation with stakeholders about the prevention package to be provided to trial participants is likely to have a significant influence on community stakeholder perceptions of a trial.

3.10.C. Special considerations

1. Deviations from expected standard HIV prevention packages at a trial site or among trial sites in multisite studies may be caused by national legal restrictions.
2. When funding-body restrictions limit which prevention methods can be paid for by trial funds, research teams have the responsibility to find other ways to provide these methods, such as through alternative funding streams or linkages with non-governmental organisations or community-based organisations.
3. Research teams may need to review the HIV prevention package regularly, taking into consideration new HIV counselling models and risk reduction methods that are scientifically validated and, when appropriate, approved by national bodies for use.
4. To improve relevant stakeholder understanding of the prevention package offered and the clinical trial process, research teams can describe the trial as comparing the study product plus the HIV prevention package, with the placebo (or comparator arm) plus the HIV prevention package.

3.10.D. Good participatory practices for standard of HIV prevention

1. Research teams and relevant stakeholders negotiate the HIV prevention package during the protocol development phase of the trial.
2. Research teams determine which stakeholders already provide HIV prevention services, what types of services they provide, and their capacity to provide adequate services. This will enable research teams to provide optimal referrals and make linkages when necessary.
3. Research teams and relevant stakeholders discuss and negotiate the comprehensive HIV prevention package and consult local HIV prevention service providers when appropriate. All scientifically validated methods are discussed, and their appropriateness for the trial design and population assessed, including:
   a. Risk assessment and risk-reduction counselling—including partner and couple counselling.
   b. Male and female condoms—with appropriate instructions and demonstrations.
   c. Testing for and treatment of sexually transmitted infections.
   d. Sterile injecting equipment and drug substitution treatment.
   e. Medical male circumcision.
   f. Post-exposure prophylaxis.
   g. Other novel HIV risk-reduction strategies as they become available.
4. Research teams and relevant stakeholders discuss and negotiate the comprehensive HIV prevention package, taking account of the following:
   a. The HIV prevention package required as a minimum for the trial protocol.
   b. Current HIV prevention standards and services available nationally and locally.

c. Current national laws on HIV prevention strategies and services, as well as national ethical guidance on research.

d. The trial's funding source, any implications this may have for the prevention package, and how these will be addressed to ensure participants are offered a comprehensive package.

e. The HIV prevention services and options that will be offered through referral mechanisms.

f. The HIV prevention services that will be available to partners of trial participants.

g. The impact that any services offered by the trial, as well as those to which participants will be referred by the trial, could have on local services.

5. Research teams and relevant stakeholders discuss how the HIV prevention package will be implemented and monitored, including uptake and standards of referral services.
6. Research teams maintain clear written records of discussions and agreements. This includes recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
7. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure provision of the comprehensive HIV prevention package.

3.10.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 13, page 45, Standard of HIV Prevention).[1]
2. *Ethical considerations in biomedical HIV prevention trials* (page 13, selected circumstances in which biomedical HIV prevention trials should not be conducted).[1]
3. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]
4. *The challenge of defining standards of prevention in HIV prevention trials*.[36]

3.11 Access to HIV care and treatment

3.11.A. Definition

Access to comprehensive HIV care and treatment refers to care and treatment services made available to individuals who are identified as HIV-positive during the screening process and to trial participants who acquire HIV infection during the trial. Comprehensive HIV care includes all preventive, psychosocial, psychological, and clinical components of HIV care. HIV treatment refers to antiretroviral therapy regimens internationally recognised as optimal for the management of HIV.

3.11.B. Relevance to good participatory practice

Trial sponsors and implementers are ethically obligated to ensure that participants who acquire HIV during trial participation have access to clinical evaluation, and stage-appropriate HIV care and treatment. This issue is often at the forefront of community stakeholder concerns. Therefore, how access to HIV care and treatment is negotiated with relevant stakeholders and how it is provided to trial participants are likely to have a significant influence on community stakeholder perceptions of a trial.

3.11.C. Special considerations

1. HIV care and treatment guidelines vary by country.
2. Treatment options may improve over time and research teams may need to modify their HIV care and treatment access plans in line with updated national guidelines.
3. Mechanisms to provide HIV care and treatment require long-term logistics planning as people living with HIV require lifelong care and treatment, and, for some participants, HIV treatment may begin after trial exit or completion.

3.11.D. Good participatory practices for access to HIV care and treatment

1. Research teams identify local HIV care and treatment services, local HIV non-governmental organisations or community-based organisations, and HIV support groups, determine

their capacities, and seek their views and perspectives. This enables research teams to design optimal referral mechanisms in consultation with service providers.

2. During protocol development, research teams and relevant stakeholders discuss access to HIV care and treatment for the following:
   a. Individuals who are identified as HIV-positive during the screening process.
   b. Individuals who become HIV-positive during the trial.
   c. Women who are identified as HIV-positive during the screening process or who acquire HIV during the trial, and when appropriate HIV-positive men, for provision of information about the risk of mother-to-child HIV transmission and the benefits of vertical transmission prevention services.
3. Research teams and relevant stakeholders discuss the HIV care and treatment package, taking account of the following:
   a. The HIV care and treatment package required as a minimum for the trial protocol.
   b. Current national HIV care and treatment guidelines and policies and local provision of HIV care and treatment services.
   c. Anticipated numbers of people likely to be found HIV-positive during screening and the anticipated numbers of participants likely to seroconvert during the trial.
   d. Current national laws that could affect a person's right or ability to access HIV care and treatment.
   e. HIV care and treatment services that will be offered through referral mechanisms.
   f. The possibility of negotiating provisions for priority access to national care and treatment programmes, at the time needed, for individuals who become HIV-positive during a trial.

g. Treatment regimens that will be available if the technology under study has the potential to give rise to antiretroviral resistance.

h. Local health institution responsibilities and proposed trial sponsor and implementer commitments regarding:

- Who will finance and who will deliver specific HIV care and treatment services.
- The duration of HIV care and treatment services being provided by each partnering stakeholder.

i. The impact that any services offered by the trial, or to which participants will be referred, could have on local services.

4. Research teams include a description of the HIV care and treatment package in informed consent forms for screening and enrolment.
5. Research teams and relevant stakeholders discuss optimal referral procedures and the most appropriate way to ensure that all individuals screened and enrolled are aware of how to access the HIV care and treatment services.
6. Research teams and relevant stakeholders discuss how to monitor access to HIV care and treatment services. They consider how to gather and analyse information on numbers of seroconverters who access HIV care, barriers to accessing HIV care and treatment programmes and other issues that may arise.
7. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholder recommendations, actions taken by the research team, aspects of HIV care and treatment that will not be offered and why, and any unresolved issues that require follow-up.
8. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure that the locally agreed HIV care and treatment package can be effectively delivered.

3.11.E. Additional guidance

1. *The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*.[5]
2. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 14, page 48, Care and Treatment).[1]
3. *Ethical considerations in biomedical HIV prevention trials* (page 13, selected circumstances in which biomedical HIV prevention trials should not be conducted).[1]
4. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]

3.12 Non HIV-related care

3.12.A. Definition

Non HIV-related care refers to health and social care services provided or made available to trial participants that are not directly related to HIV prevention, HIV care and treatment, or trial-related harm. The non HIV-related care services appropriate for trial participants will depend on the trial population and local health priorities. Examples could include provision of female or male sexual and reproductive health care, management of infectious diseases, nutritional health, psychiatric care, and psychosocial services.

3.12.B. Relevance to good participatory practice

Access to non HIV-related care can provide benefits for participants, contribute to their welfare, and improve clinical trial outcomes. Negotiating the range of non HIV-related services available to participants at the trial site or via referral will assist in ensuring that relevant stakeholders clearly understand the breadth of services available and reasons for inclusion and exclusion of certain services.

3.12.C. Special considerations

Non HIV-related care packages may vary from site to site, depending on local health priorities and local standards of care.

3.12.D. Good participatory practices for non HIV-related care

1. Research teams identify the existence and capacity of local social care and primary health-care services and of secondary and tertiary diagnostic and treatment services. This enables the provision of appropriate referrals and linkages, should the need arise.
2. Research teams and relevant stakeholders discuss access to non HIV-related care services during the trial's protocol development phase.
3. Research teams and relevant stakeholders discuss non HIV-related care services to be offered to participants and consult with local social and health-care service providers when appropriate. Discussions take account of the following:
   a. Non HIV-related care services required by the trial protocol.
   b. Additional non HIV-related care services that community stakeholders would like to see the trial site offer to participants.
   c. Services that will be offered through referral.
   d. Whether any non HIV-related services will be available to partners of trial participants.
   e. The impact on local service delivery of any services offered or referred to by the trial.
4. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds to ensure provision of the locally discussed, non HIV-related care package.

3.12.E. Additional guidance

See *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]

3.13 Policies on trial-related harms

3.13.A. Definition

Policies on trial-related harms describe how research teams will treat and compensate trial participants should they experience physical or social harms that are determined to be associated with trial participation, as well as how such harms will be addressed and mitigated.

3.13.B. Relevance to good participatory practice

A key ethical obligation of research teams is to maximise benefits and minimise harms for trial participants. Relevant stakeholders can provide valuable input about possible social harms of trial participation. These are of particular concern for individuals or groups who may be vulnerable, marginalised, stigmatised, or who have less power in society. Relevant stakeholders can also provide advice about local expectations of research team obligations to address trial-related physical and social harms. Discussing with stakeholders before a trial starts and clearly explaining how trial-related harms will be addressed and mitigated can significantly influence community stakeholder perceptions of the trial and of how well community stakeholder concerns will be addressed.

3.13.C. Special considerations

Sponsors typically give specific and binding guidance to research teams on how to determine and report physical harms as adverse events. It is good practice to define similarly stringent procedures for the determination, documentation, reporting, and management of social harms that trial participants may experience. Examples of social harms due to trial participation include stigma, discrimination, and verbal, emotional, physical, or sexual abuse.

3.13.D. Good participatory practices for policies on trial-related harms

1. Research teams and relevant stakeholders list anticipated physical and social harms that might occur due to trial participation.

2. Research teams and relevant stakeholders discuss and develop policies on trial-related physical and social harms, considering the following issues:
   a. Strategies to prevent or reduce the risk of trial-related harms.
   b. Procedures to encourage and facilitate reporting of social harms.
   c. Procedures to investigate events that have been reported indirectly, such as through a third party, taking confidentiality issues into account.
   d. Procedures for reporting social harms and whether these are to be reported to sponsors, ethics committees, and regulatory bodies, even if not specifically required by them.
   e. Procedures for ensuring optimal referrals to appropriate services for trial-related harms.
   f. Strategies to inform trial participants of the potential risks of engaging with media.
   g. Compensation or insurance policies, when applicable, for specific trial-related harms, coverage provided by the policies, how claims are made, and how participants are informed of their rights in relation to the policies.
3. Research teams and relevant stakeholders review follow-up strategies to reduce trial-related physical and social harms over the course of the trial.
4. Research teams maintain clear written records of discussions and agreements. This includes recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure the effective management of physical and social harms related to participation in a trial.

3.13.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 11, page 40, Potential Harms).[1]

2. *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Guideline 19, page 78 right of injured subjects to treatment and compensation).[7]

3.14 Trial accrual, follow-up, and exit

3.14.A. Definition

Trial accrual, follow-up, and exit activities include the recruitment, screening, enrolment, follow-up, and exit of trial participants in biomedical HIV prevention trials.

3.14.B. Relevance to good participatory practice

Community stakeholders can provide the best information on how to design socially and culturally acceptable strategies for recruitment, screening, enrolment, follow-up, and exit. Community stakeholders included in the process of developing these strategies can play an important role in identifying and mitigating trial-related stigma, misconceptions, or miscommunication.

3.14.C. Special considerations

1. Follow-up of participants after missed visits must respect agreements between the participant and research team about how to contact the participant.
2. Exiting a trial may present changes in what participants have become accustomed to with regard to clinical care and the impact of the trial on their social relationships. Anticipation and discussion of these issues between research teams and community stakeholders will help in the development of appropriate strategies to support participants upon trial exit.

3.14.D. Good participatory practices for trial accrual, follow-up, and exit

1. Research teams consult with relevant stakeholders about accrual, follow-up, and exit processes, taking account of the following:

a. Strategies and messages that are socially and culturally appropriate, meet the needs of specific stakeholders in terms of language and literacy, and draw on a range of communication modes, including written, oral, and visual.

b. Procedures to anticipate, monitor, and mitigate trial-related stigma resulting from ineligibility to enrol or from enrolment itself.

c. Procedures for training and supervising trial site staff on creating respectful relationships with participants and fostering an environment that is nonjudgmental and welcoming.

d. Strategies to ensure the confidentiality of participants during trial visits, while following up participants outside of the trial clinic, and after trial exit.

e. Procedures for informing participants about trial results and trial product assignment, when available.

f. Procedures for transfer of care at the end of follow-up or trial closure, such as providing participants with referrals to HIV counselling and testing and to other supportive services.

2. Research teams provide relevant stakeholders with ongoing updates on trial accrual, follow-up, and trial exit.

3. Research teams seek advice from relevant stakeholders on how to improve accrual, follow-up and exit processes, and messages.

4. Research teams maintain clear written records of discussions and agreements, as well as ongoing discussions about ways to modify strategies.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support stakeholder engagement in the development of locally acceptable trial procedures.

3.15 Trial closure and results dissemination

3.15.A. Definition

Trial closure occurs when all participants have exited from the trial and all trial procedures are completed. Results dissemination

involves dissemination of trial results to participants, community stakeholders, and the public at large, as well as the unblinding of participants to trial group or arm assignment.

3.15.B. Relevance to good participatory practice

Effectively engaging relevant stakeholders about trial closure and results dissemination in a transparent process is essential for building trust and lays a positive foundation for future research. In the event that a trial is stopped early or unexpectedly, research team-initiated dialogue with relevant stakeholders will minimise the risk of misinformation.

3.15.C. Special considerations

1. Trials may run to completion per protocol or may be stopped early. Reasons for stopping early may be evidence of a clear protective effect, evidence of harm, or evidence of futility. Trials may also stop early due to other unforeseen circumstances, such as administrative or financial reasons, local objection, or sudden social unrest.
2. In multicountry or multisite trials, sites may complete participant follow-up at different times. Thus, while some sites might be closed for participant follow-up, research teams at other locations may continue to see participants.
3. Where trial product manufacturers are publicly traded companies, there may be legal requirements that affect the timing and methods for public announcement of a trial closure.
4. Ownership of data, issues of publication, and release of trial results vary by trial and may be strictly delineated in non-negotiable terms by sponsors or product manufacturers.

3.15.D. Good participatory practices for trial closure and results dissemination

1. Research teams consult with relevant stakeholders early in the research life-cycle to develop a trial closure plan. The plan addresses a range of possible closure scenarios, including:
   a. Trial closure as scheduled per protocol.

b. Early closure due to evidence of harm, futility, or clear protective benefit in interim analyses of trial data.

c. Early closure because of evidence of harm or of clear protective benefit from a different trial evaluating the same product.

d. Early closure due to unforeseen circumstances, such as administrative or financial reasons, stakeholder objection, or sudden social unrest.

2. Research teams ensure that trial participants are provided opportunities to learn trial results before they are announced publicly.

3. Research teams consult with relevant stakeholders to develop a results dissemination plan, detailing the following issues:

a. Strategies to manage expectations about trial results, including by preparing participants and relevant stakeholders for all possible outcomes.

b. Planned timelines for trial closure at the site and at other sites, completion of data analyses, and availability of results.

c. Procedures and timelines for those who will be informed of trial results in confidence prior to public release and how results will be disseminated publicly.

d. Development and piloting of key messages, how the messages will be finalised when the results are known, and the range of communication methods to be used.

e. How the messages will explain implications of the results for the area where the trial was conducted, limitations of the trial, and its ability to generalise findings for specific aspects, such as by sex, behaviours, or location.

f. How best to disseminate trial results that may be of a sensitive nature or that may put certain individuals or groups at risk of harm or stigmatisation.

g. Procedures for contacting and informing trial participants of research results before they are announced publicly.

h. Whether and how to disseminate additional findings that are not related to the primary trial question but may be of interest to some stakeholders, such as reported patterns

of sexual networks, rates of various infections, or demographic data.

i. How and when participants will be informed of their trial group assignment.

j. How community stakeholder responses to the results will be systematically collected and documented. Although community stakeholder agreement may not be a prerequisite for publishing or sharing research in a scientific forum, it is important that community stakeholder interpretations be noted, particularly if they differ from predominant scientific analyses.

k. Issues around ownership of the data, data access, and publication, including how the research team will facilitate community stakeholder access to published results of the trial.

4. Research teams maintain clear written records of discussions regarding trial closure and dissemination messages, as well as documentation of responses to the results.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure comprehensive dissemination of results for participants, community stakeholders and other relevant stakeholders.

3.16 Post-trial access to trial products or procedures

3.16.A. Definition

The term "post-trial access to trial products or procedures" refers to making the prevention product or procedure tested in the trial available to trial participants and local community stakeholders (1) should the new product or procedure be scientifically validated or approved by relevant authorities, and (2) in the form of follow-on, open label, or other such studies before product licensure or approval, should an efficacy or effectiveness trial have a compelling positive finding, with no safety concerns.

3.16.B. Relevance to good participatory practice

Research ethics call for maximising benefits to stakeholders who participate in research. Thus, local community stakeholders are to be among the first to gain access to new prevention products should they be found safe and effective. How trial sites communicate and interact with community stakeholders about issues of access to the prevention product or procedure studied is likely to have a significant influence on community stakeholder perceptions of a trial.

3.16.C. Special considerations

1. Availability of newly identified products or procedures to trial participants and other community stakeholders will depend on the biomedical HIV prevention strategy being tested.
2. After a trial is completed, other trials may be needed to corroborate findings.
3. After results from relevant trials are available, it may take time for normative agencies and appropriate regulatory authorities, including national governments, to approve the new product or procedure. Approval processes and timelines will differ by product or procedure and by country.
4. National regulatory authorities make the ultimate decision about whether a new product or procedure will be approved for use within a particular country.
5. Availability and pricing of new products or procedures may be affected by product-manufacturer parameters as well as by agreements with trial sponsors.

3.16.D. Good participatory practice practices for post-trial access to trial products or procedures

1. Research teams discuss with relevant stakeholders, early in the trial process, issues affecting future product or procedure availability, including the need for corroborated biomedical evidence, pursuit of licensure, production rights, and additional marketing and distribution research.

2. Trial funders, sponsors, and research teams conducting efficacy or effectiveness trials discuss with relevant stakeholders, early in the trial life-cycle, expectations about possible pre-licensure access, plans for follow-on, open label, or other such studies, and how such pre-licensure access will be funded, in the event that a compelling positive result, with no safety concerns, is observed.
3. Trial sponsors and research teams discuss, negotiate, and agree on responsibilities and funding requirements with national governments concerning licensure requirements and access issues, should the HIV prevention product or option under investigation be shown to be safe and effective.
4. Trial sponsors and research teams develop a clear strategy and funding mechanisms for how the HIV prevention product or procedure will be made available to participants (at a minimum) rapidly, affordably, and sustainably, should the HIV prevention product or procedure be shown to be safe and effective. Sponsors and research teams can collaborate with multiple stakeholders, such as UN organisations, development partners, local governments, and non-governmental organisations to design and support the overall access strategy.
5. Research teams inform community stakeholders of their rights, the access plan, and the factors that could postpone or prevent their gaining access to the new prevention product or procedure, such as the need to secure regulatory approvals or parameters related to the product manufacturer. Research teams give community stakeholders updates as they are available.

3.16.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 19, page 60, Availability of Outcomes).[1]
2. *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation* (Chapter 10, After the trial: continued access and post-approval studies).[37]
3. *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (Recommendation 4.1).[38]

Conclusion

Well-conducted biomedical HIV prevention trials are essential to discovering additional options to reduce new HIV infections. The GPP guidelines set global standard practices for stakeholder engagement. When applied during the entire life-cycle of a biomedical HIV prevention trial, they enhance both the quality and outcomes of research. While there is much guidance in the field on how to conduct trials, the GPP guidelines are the only set of global guidelines that directly address how to engage stakeholders in the design, conduct, and outcome of biomedical HIV prevention trials.

Adherence to good participatory practices is an investment that benefits the research process. These practices facilitate the engagement of relevant stakeholders to achieve mutual gains in local capacity building for biomedical HIV prevention research. Significant power imbalances exist between trial funders, sponsors, and implementers and community stakeholders—the GPP guidelines are a critical resource to help address and mitigate these disparities. A core aim of the guidelines is to enhance the skills of individuals and groups who are most vulnerable to both HIV and to exploitation. The GPP guidelines help build community stakeholder capacity for more robust engagement in the research process and improved decision-making abilities.

Effective stakeholder engagement can exist only when appropriate funds and resources are made available to research teams so they may adhere to good participatory practice. Sponsors of biomedical HIV prevention trials are responsible for enabling GPP by ensuring ample budget allocations and staff time to facilitate participatory approaches.

Investment in establishing mutually respectful relationships and building capacity of community stakeholders is a long-term process that extends throughout and beyond the life-cycle of any single clinical trial. Although it is highly beneficial to maintain and support key staff at trial sites and

sustain relationships that have been developed with local partners during the course of a trial, sponsors of biomedical HIV prevention trials often only support implementation of specific clinical trials. Investing in collaborative long-term, sustained relationships between research teams and relevant stakeholders, such as academic institutions, ministries of health, and non-governmental organisations, can improve research literacy, enhance the success of stakeholder engagement, and provide the foundation for future trials.

The GPP guidelines are intended to provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with relevant stakeholders in the design and conduct of biomedical HIV prevention trials. Developing participatory processes that balance the opinions of all stakeholders while achieving the scientific goals of a trial can ensure that the needs of both community stakeholders and the broader HIV prevention field are met.

In a forward-looking approach, it is important to gather and analyse stakeholders' experiences with the implementation of the GPP guidelines. Recommendations for modifications and refinements based on experience and reflection can be sent to gpp@unaids.org or avac@avac.org, where they will be gratefully received and considered in future updates of these guidelines.

Annex 1. Acronyms and abbreviations

AE – Adverse event
AIDS – Acquired Immunodeficiency Syndrome
ARV – Antiretroviral drug
CAB – Community Advisory Board
CAG – Community Advisory Group
CBO – Community-Based Organisation
CIOMS – Council for International Organizations of Medical Science
EC – Ethics committee
DSMB – Data safety monitoring board
DSMC – Data safety monitoring committee
GCLP– Good Clinical Laboratory Practice
GCP – Good Clinical Practice
GMP – Good Manufacturing Practice
GPP – Good Participatory Practice
HIV – Human Immunodeficiency Virus
IDMC – Independent data monitoring committee
IDU – Injecting drug use
IRB – Institutional review board
MSM – Men who have sex with men
NGO – Non-governmental organisation
PEP – Post-exposure prophylaxis
PMTCT – Prevention of mother-to-child transmission
PrEP – Pre-exposure prophylaxis
REC – Research ethics committee
SOP – Standard operating procedure
STI – Sexually transmitted infection
UNAIDS – Joint United Nations Programme on HIV/AIDS
WHO – World Health Organization

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Annex 2. Glossary

Accrual. The process of recruiting participants into a clinical trial in order to reach target participant numbers.

Acquired immunodeficiency syndrome (AIDS). The most severe manifestation of infection with human immunodeficiency virus (HIV), characterised by deterioration of the immune system and susceptibility to a range of opportunistic infections and cancers. (See **human immunodeficiency virus**.)

Activist. A person or group who acts on the behalf of a cause in order to bring about change.

Adverse event (AE). An unwanted effect experienced by a participant in a clinical trial. This may or may not be related to the product or procedure being studied.

Advocate. A person or group who advocates on the behalf of individuals, groups, or a specific cause.

Antiretroviral (ARV) drug. A drug or medication that acts against or suppresses a retrovirus such as HIV.

AVAC. An international, non-profit organisation that uses education, policy analysis, advocacy, and community mobilisation to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic.

Biomedical HIV prevention trial. A clinical trial that aims to discover safe and effective products or procedures to prevent HIV transmission.

Blinded trial or masked trial. A clinical trial designed to prevent the participants, research teams, or both, from knowing which participants are in the experimental arm or group and which are in the control arm or group of a trial, in order to reduce bias.

Clinical trial. A research study that uses human volunteers to answer specific questions about the safety, efficacy or effectiveness, and medical effects of a specific procedure, medication, product, or treatment. A clinical trial process may include Phases I, II, IIb, III, and IV (post-marketing evaluation).

Community advisory boards (CABs) or **community advisory groups (CAGs).** Boards or groups composed of individuals or stakeholder representatives that act as an independent advisory voice and facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise in specific trials.

Community groups. Groups of individuals who come together to act on behalf of common interests, goals, and values but whose organisation does not require formal designation or registration.

Community stakeholders (per the GPP guidelines). Individuals and groups who are ultimately representing the interests of people who would be recruited to or participate in a clinical trial, and others locally affected by a trial. Examples of "community stakeholders" are the population to be recruited, trial participants, people living in the area where the research is conducted, people living with HIV in the area, local HIV-positive groups or networks, people in the area affected by the HIV epidemic, local non-governmental organisations, community groups, and community-based organisations. (See **stakeholders**.)

Confidentiality. The principle that protects the rights of trial participants regarding prevention of unauthorised disclosure of personal information to third parties during data collection, storage, transfer, and use.

Condom. A sheath or pouch that is worn either over the penis (male condom) or inside the vagina (female condom) during sexual intercourse, for the purpose of protecting against sexually transmitted infections (including HIV) or preventing pregnancy. (See **female condom** or **male condom**.)

Control arm or group. The group of participants in a clinical trial who receive the placebo or control product or procedure. (See **placebo**.)

Data and safety monitoring board (DSMB) or independent data monitoring committee (IDMC). An independent committee established by a trial sponsor to assess, at intervals, the progress of a clinical trial, safety data, and critical efficacy or effectiveness endpoints. A data and safety monitoring board may recommend to the sponsor that a

trial be stopped or modified if there are safety concerns, if trial objectives have been achieved, or if assessment of trial progress reveals that continuing the trial would be futile since it will no longer be possible to answer the research question that the trial is addressing.

Ethics committee. See **research ethics committee.**

Experimental arm or group. The group of participants in a clinical trial who receive the procedure, product, or drug being studied.

Female condom. A pouch that when inserted in the vagina before vaginal intercourse, provides protection against most sexually transmitted infections, including HIV, and pregnancy. During anal sex, the female condom, when placed on the penis after removing the inner ring, provides protection against most sexually transmitted infections, including HIV. Currently made of polyurethane (female condom 1) or a synthetic latex (female condom 2), it is stronger than the natural latex used in male condoms, odourless, non-allergenic, and usable with oil-based and water-based lubricants. For vaginal intercourse, it can be inserted vaginally prior to intercourse, is not dependent on male erection, and does not require immediate withdrawal after ejaculation. (See also **male condom**.)

Formative research activities. Activities that enable research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, channels of communication and decision-making, and local history of research, as well as the needs and priorities of people locally affected by or able to influence a clinical trial. Formative research activities usually constitute the initial phase of stakeholder outreach and engagement.

Futility. The inability of a clinical trial to achieve one or more of its objectives. This determination may be suggested, for example, during an interim analysis of a trial by a data safety monitoring board.

Good Clinical Laboratory Practice (GCLP). Guidelines that set a standard for compliance by laboratories involved in the analysis of samples from clinical trials. These guidelines provide guidance to ensure that trial laboratory data are reliable, repeatable, auditable, and easily reconstructed in a research setting.

Good Clinical Practice (GCP). Internationally recognised guidelines for designing, conducting, recording, and reporting clinical trials in which humans participate. GCP provides guidance to ensure that trial data are credible and to protect the rights, safety, and well-being of trial participants. The guidelines were issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Good Manufacturing Practice (GMP). Quality assurance practices that ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation. Good manufacturing practices are aimed primarily at diminishing the risks inherent in any pharmaceutical or medical device production.

Good Participatory Practice (GPP). Guidelines that provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials.

HIV vaccine (or AIDS vaccine). A vaccine designed to prevent HIV infection. (See **vaccine**.)

Human immunodeficiency virus (HIV). The virus that weakens the immune system, ultimately leading to acquired immunodeficiency syndrome (AIDS).

Implementer. See **trial implementer**.

Informed consent. A process by which a competent individual voluntarily confirms his or her willingness to participate in a particular clinical trial after having been informed of all aspects of the trial that are relevant to the individual's decision to participate. Informed consent is an ongoing process throughout the course of a clinical trial.

Institutional review board (IRB). See **ethics committee**.

Male condom. A sheath designed to be worn over the penis during vaginal, anal, or oral intercourse as a means of preventing sexually transmitted infections, including HIV, or preventing pregnancy in the case of vaginal intercourse. (See also **female condom**.)

Medical male circumcision. The surgical removal of the entire foreskin of the penis. Three clinical trials conducted in sub-Saharan Africa have shown that medically performed male circumcision is safe and can reduce men's risk of HIV infection during vaginal sex by about 60%. Prevalence of male circumcision varies by geography, religion, and cultural practices.

Men who have sex with men (MSM). Men who have sexual contact with other men, regardless of whether or not they also have sex with women or have a personal or social gay or bisexual identity. This concept also includes men who self-identify as heterosexual but have sex with other men.

Microbicides. A range of products that could be used vaginally or rectally (such as a gel, cream, ring, film, suppository or sponge) that are being tested to determine if they reduce or prevent the transmission of HIV and other disease-causing organisms during vaginal and anal intercourse.

Network or **research network.** A cooperative of research institutions or centres conducting clinical trials under a common research agenda.

Non-governmental organisation (NGO). A not-for-profit, registered entity or group that is organised on local, national, or international levels but is not an agency of local or national governments.

Placebo. An inactive substance that is designed to appear like an experimental product being studied in all aspects except for the absence of the active ingredient under study. In clinical trials, the safety and effectiveness of an experimental product are assessed by comparing data from the experimental product trial arm to those from the placebo arm.

Post-exposure prophylaxis (PEP). Antiretroviral medicines prescribed and taken after exposure or possible exposure to HIV, to reduce the risk of acquiring HIV. The exposure may be occupational, as in a needle stick injury, or non-occupational, as in the case of rape.

Pre-exposure prophylaxis (PrEP). Antiretroviral drugs used by a person who does not have HIV infection to be taken before possible exposure to HIV in order to reduce the risk of acquiring HIV infection.

Product or trial arm assignment. The specific study product or procedure, such as the experimental or 'active' arm or the placebo arm,

to which a participant is assigned for the designated follow-up period. (See **placebo** and **experimental arm**.)

Protocol. A document that details the rationale, goals, design, methodology, statistical considerations, and organisation of a study or clinical trial. A protocol describes a scientific study designed to answer specific research questions and describes how the health of the trial participants will be safeguarded.

Randomisation. A method based on chance alone by which trial participants are assigned to a trial arm or group. Randomisation ensures that the only intended difference between trial arms or groups is which product or procedure a trial participant is exposed to during the trial.

Randomised trial. A clinical trial in which participants are assigned by chance to one of the trial arms or groups. (See **randomisation**.)

Regulatory authorities. Government agencies charged with carrying out the intent of legislation that constrains the actions of private individuals, businesses, organisations, institutions, or government bodies. In most countries, one or more regulatory agency may be responsible for ensuring the safety and effectiveness of health products and the correct conduct of clinical trials.

Research ethics committee (REC) or institutional review board (IRB). An independent body made up of medical, scientific, and non-scientific members whose responsibility is to protect the rights, safety, and well-being of human participants involved in a clinical trial. Research ethics committees review and approve the initial protocol, review materials to be used in recruiting and consenting trial participants, and provide continuing review of a trial protocol and any amendments. The term "institutional review board" is common in the United States of America, whereas other countries commonly use the term "research ethics committee" or "independent ethics committee".

Research network. See **network**.

Research team. A group of investigators and staff involved in implementing biomedical HIV prevention trials. Research teams can include investigators and staff at a specific trial site as well as investigators and staff working at coordinating centres, institutions, or agencies.

Scientific process. A recognised systematic way to form and test hypotheses by designing controlled experiments to collect data, analyse results, and draw conclusions in order to acquire new knowledge or to correct, refine, and integrate previous knowledge.

Seroconversion. The process by which a newly infected person develops antibodies that can be detected by an HIV antibody test. Development of antibodies may occur anywhere from weeks or months following HIV infection.

Sexually transmitted infections (STIs). Infections caused by microorganisms that are transmitted from one person to another during sexual or intimate contact.

Stakeholders or trial stakeholders. Individuals, groups, organisations, governments, or other entities that are affected by the outcome of a biomedical HIV prevention trial or that can influence proposed research through their input and actions. (See **community stakeholders**.)

Standard operating procedure (SOP). A document that gives step-by-step instructions for how to conduct a procedure, in order to ensure that each staff member can perform the procedure in the same way.

Stigma. AIDS-related stigma refers to a pattern of prejudice, discounting, discrediting, and discrimination directed at people perceived to have HIV or AIDS, their significant others and close associates or their social groups.

Therapeutic HIV vaccine. A compound designed to stimulate the immune response to HIV in a person already infected with the virus, in order to control the infection. Also referred to as an immunotherapeutic vaccine. (See **vaccine** and **HIV vaccine**.)

Trial arm or group. A group within a clinical trial formed of participants who have been assigned a particular product or procedure during a trial. (See **control arm or group**, **experimental arm or group**.)

Trial funder. An individual or entity responsible for financing the cost of a trial.

Trial implementer. Investigators, research staff, and all others specifically responsible for executing biomedical HIV prevention trials. Implementers may be employed by governments, government-spon-

sored networks, non-governmental organisations, academic institutions, the pharmaceutical industry or other companies, foundations, or public–private partnerships.

Trial life-cycle. The entire process of a trial, starting from developing the initial concept and writing the protocol and continuing through to the implementation and conduct of the trial to completion, exiting of participants, and dissemination and reporting of results.

Trial participant. A competent individual who voluntarily provides informed consent to participate in a clinical trial. Trial participants are assigned to a particular trial arm or group, in which they receive a particular product or procedure.

Trial sponsor. An entity that is responsible for a trial but that does not actually conduct it. The sponsor may be a pharmaceutical company, governmental agency, academic institution, or private or other organisation.

UNAIDS (Joint United Nations Programme on HIV/AIDS). UNAIDS brings together the resources of the UNAIDS Secretariat and 10 UN system organisations to lead and inspire the world in achieving universal access to HIV prevention, treatment, care, and support.

Unblinding or unmasking. The process of revealing trial participants' product or procedure assignments. Unblinding involves informing participants about which product they were assigned to during the trial.

Vaccine. A compound that stimulates the body's immune response in order to prevent or control an infection. A vaccine is typically made up of parts of a bacterium or virus that cannot itself cause an infection. (See **HIV vaccine**.)

Annex 3. Additional guidance

International reference guidelines

The Belmont Report, 1979

This report was written by the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was established after the public learned about the Tuskegee Syphilis Study. The Belmont Report established the foundational ethical principles of respect for persons, beneficence, and justice for research involving human volunteers.

Citation: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC, Department of Health, Education and Welfare, 1979.

Declaration of Helsinki, 1964

This Declaration of the World Medical Association is often considered to be the first document to set world standards for research involving human volunteers.

Citation: World Medical Association General Assembly. *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. Helsinki, World Medical Association, 2008.

Ethical Considerations in Biomedical HIV Prevention Trials, 2007

This is an ethical guidance document, issued by UNAIDS and WHO, for biomedical HIV prevention trials. This document is a revision of *Ethical Considerations in HIV Preventive Vaccine Research: UNAIDS Guidance Document*. Geneva, UNAIDS, 2000.

Citation: UNAIDS and WHO. *Ethical Considerations in Biomedical HIV Prevention Trials*. Geneva, UNAIDS, 2007.

Guideline for Good Clinical Practice, 1996

This guidance document was issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and outlines an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human volunteers.

Citation: *Guideline for Good Clinical Practice: ICH Harmonised Tripartite Guideline*. Geneva, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2006.

International Ethical Guidelines for Biomedical Research Involving Human Subjects, 1993

These guidelines, published by the Council for International Organizations of Medical Sciences (CIOMS), added guidance on conducting research in developing countries to the body of ethical guidelines. The 2002 version supersedes the 1982 and 1993 guidelines.

Citation: *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva, Council for International Organizations of Medical Sciences, 2002.

Nuffield Council on Bioethics, 2002

The 2002 Nuffield Council on Bioethics report on The Ethics of Research Related to Healthcare in Developing Countries provides an ethical framework for designing or conducting externally sponsored research in the developing world. The 2004 follow-up report, co-hosted with the Medical Research Council of South Africa, discusses how the guidelines could be applied in practice, particularly in light of conflicting ethical advice.

Citation: *The Ethics of Research Related to Healthcare in Developing Countries*. London, Nuffield Council on Bioethics, 2002; and *The Ethics of Healthcare Related Research in Developing Countries: A Follow-up Discussion Paper*. London, Nuffield Council on Bioethics, 2005.

***Nuremberg Code*, 1949**

This code of research ethics came out of the ruling of the International Military Tribunal that prosecuted Nazi war criminals at the end of the Second World War.

Citation: *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10.* Vol. 2. Washington, DC, United States Government Printing Office, 1949:181–182.

Other references

***Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results*, 2010**

The *Communications Handbook for Clinical Trials* is a practical guide developed for site-level research teams, communicators, advocates, and others working on HIV prevention trials. It provides guidance on how to anticipate and respond to the special communication challenges posed by the conduct of clinical research.

Citation: Robinson ET et al. *Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results.* Washington, DC, Microbicides Media Communications Initiative and Research Triangle Park, NC, FHI, 2010.

***Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, 2001**

This is a report and set of recommendations published by the United States National Bioethics Advisory Commission for United States policy on conducting clinical trials in developing countries.

Citation: *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries.* Vol. I. *Report and Recommendations of the National Bioethics Advisory Commission.* Washington, DC, United States National Bioethics Advisory Commission, 2001.

Mapping the Standards of Care at Microbicide Clinical Trial Sites, 2008

The Global Campaign for Microbicides mapped the standard of care being provided across various microbicide clinical trial sites. The report resulted in a set of recommendations relating to the standard of care that is appropriate to provide to participants in microbicide clinical trials.

Citation: Heise L, Shapiro K, West Slevin K. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*. Washington, DC, Global Campaign for Microbicides, 2008.

Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases, HIV/AIDS Clinical Trials Research, 2009

The Division of AIDS of the United States National Institute of Allergy and Infectious Diseases and Community Partners (a global group of community representatives affiliated with the National Institute of Allergy and Infectious Diseases HIV/AIDS clinical trials networks) developed these recommendations as a tool for research teams and community representatives to further expand and deepen community involvement in HIV clinical trials research.

Citation: Community Recommendations Working Group, Community Partners. *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research*. Bethesda, MD, 2009.

Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation, 2005

In 2003, the Global Campaign for Microbicides held a consultation to rethink the issues and ethical dilemmas facing the field of microbicide development. The report addresses ethical issues such as informed consent, standards of care, and post-trial access.

Citation: *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation*. Washington, DC, Global Campaign for Microbicides, 2005.

Standards of Prevention in HIV Prevention Trials, 2010

In March 2009, the Global Campaign for Microbicides, UNAIDS, and the United States Centers for Disease Control and Prevention jointly convened a consultation on the standards of prevention in HIV prevention trials in Kampala, Uganda. The resultant report summarises points of agreement and proposes a range of recommendations for standards of prevention in future HIV prevention clinical trials.

Citation: *Standards of Prevention at HIV Prevention Trials: Consultation Report and Recommendations*. Seattle, Global Campaign for Microbicides, PATH, 2010; and Philpott S et al. The Challenge of Defining Standards of Prevention in HIV Prevention Trials. *Journal of Medical Ethics*, 2011, 37:244–248.

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3 *Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation*. Geneva, World Health Organization, 2002.

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The Joint United Nations Programme on HIV/AIDS (UNAIDS) brings together ten UN agencies in a common effort to fight the epidemic: the Office of the United Nations High Commissioner for Refugees (UNHCR), the United Nations Children's Fund (UNICEF), the World Food Programme (WFP), the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the United Nations Office on Drugs and Crime (UNODC), the International Labour Organization (ILO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO), and the World Bank.

Leveraging the AIDS response, UNAIDS works to build political action and to promote the rights of all people for better results for global health and development. Globally, it sets policy and is the source of HIV-related data. In countries, UNAIDS brings together the resources of the UNAIDS Secretariat and 10 UN system organizations for coordinated and accountable efforts to unite the world against AIDS.

UNAIDS
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Uniting the world against AIDS

CANADA

CONSOLIDATION

CODIFICATION

Privacy Act

Loi sur la protection des renseignements personnels

R.S.C., 1985, c. P-21

L.R.C. (1985), ch. P-21

Current to June 17, 2026

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OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (2) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence
31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

Inconsistencies in Acts
(2) In the event of an inconsistency between a consolidated statute published by the Minister under this Act and the original statute or a subsequent amendment as certified by the Clerk of the Parliaments under the *Publication of Statutes Act*, the original statute or amendment prevails to the extent of the inconsistency.

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (2) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1er juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve
31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

Incompatibilité — lois
(2) Les dispositions de la loi d'origine avec ses modifications subséquentes par le greffier des Parlements en vertu de la *Loi sur la publication des lois* l'emportent sur les dispositions incompatibles de la loi codifiée publiée par le ministre en vertu de la présente loi.

LAYOUT

The notes that appeared in the left or right margins are now in boldface text directly above the provisions to which they relate. They form no part of the enactment, but are inserted for convenience of reference only.

MISE EN PAGE

Les notes apparaissant auparavant dans les marges de droite ou de gauche se retrouvent maintenant en caractères gras juste au-dessus de la disposition à laquelle elles se rattachent. Elles ne font pas partie du texte, n'y figurant qu'à titre de repère ou d'information.

NOTE

This consolidation is current to June 17, 2026. The last amendments came into force on June 2, 2025. Any amendments that were not in force as of June 17, 2026 are set out at the end of this document under the heading "Amendments Not in Force".

NOTE

Cette codification est à jour au 17 juin 2026. Les dernières modifications sont entrées en vigueur le 2 juin 2025. Toutes modifications qui n'étaient pas en vigueur au 17 juin 2026 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

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R.S.C., 1985, c. P-21

An Act to extend the present laws of Canada that protect the privacy of individuals and that provide individuals with a right of access to personal information about themselves

Short Title

Short title

1 This Act may be cited as the *Privacy Act*.

1980-81-82-83, c. 111, Sch. II "1".

Purpose of Act

Purpose

2 The purpose of this Act is to extend the present laws of Canada that protect the privacy of individuals with respect to personal information about themselves held by a government institution and that provide individuals with a right of access to that information.

1980-81-82-83, c. 111, Sch. II "2".

Interpretation

Definitions

3 In this Act,

administrative purpose, in relation to the use of personal information about an individual, means the use of that information in a decision making process that directly affects that individual; (*fins administratives*)

alternative format, with respect to personal information, means a format that allows a person with a sensory disability to read or listen to the personal information; (*support de substitution*)

Court means the Federal Court; (*Cour*)

L.R.C., 1985, ch. P-21

Loi visant à compléter la législation canadienne en matière de protection des renseignements personnels et de droit d'accès des individus aux renseignements personnels qui les concernent

Titre abrégé

Titre abrégé

1 *Loi sur la protection des renseignements personnels*.

1980-81-82-83, ch. 111, ann. II « 1 ».

Objet de la loi

Objet

2 La présente loi a pour objet de compléter la législation canadienne en matière de protection des renseignements personnels relevant des institutions fédérales et de droit d'accès des individus aux renseignements personnels qui les concernent.

1980-81-82-83, ch. 111, ann. II « 2 ».

Définitions

Définitions

3 Les définitions qui suivent s'appliquent à la présente loi.

Commissaire à la protection de la vie privée Le commissaire nommé en vertu de l'article 53. (*Privacy Commissioner*)

Cour La Cour fédérale. (*Court*)

déficience sensorielle Toute déficience liée à la vue ou à l'ouïe. (*sensory disability*)

fichier de renseignements personnels Tout ensemble ou groupement de renseignements personnels défini à l'article 10. (*personal information bank*)

designated Minister means a person who is designated as the Minister under subsection 3.1(1); (*ministre désigné*)

government institution means

(a) any department or ministry of state of the Government of Canada, or any body or office, listed in the schedule, and

(b) any parent Crown corporation, and any wholly-owned subsidiary of such a corporation, within the meaning of section 83 of the *Financial Administration Act*; (*institution fédérale*)

head, in respect of a government institution, means

(a) in the case of a department or ministry of state, the member of the Queen's Privy Council for Canada who presides over the department or ministry, or

(b) in any other case, either the person designated under subsection 3.1(2) to be the head of the institution for the purposes of this Act or, if no such person is designated, the chief executive officer of the institution, whatever their title; (*responsable d'institution fédérale*)

personal information means information about an identifiable individual that is recorded in any form including, without restricting the generality of the foregoing,

(a) information relating to the race, national or ethnic origin, colour, religion, age or marital status of the individual,

(b) information relating to the education or the medical, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved,

(c) any identifying number, symbol or other particular assigned to the individual,

(d) the address, fingerprints or blood type of the individual,

(e) the personal opinions or views of the individual except where they are about another individual or about a proposal for a grant, an award or a prize to be made to another individual by a government institution or a part of a government institution specified in the regulations,

fins administratives Destination de l'usage de renseignements personnels concernant un individu dans le cadre d'une décision le touchant directement. (*administrative purpose*)

institution fédérale

a) Tout ministère ou département d'État relevant du gouvernement du Canada, ou tout organisme, figurant à l'annexe;

b) toute société d'État mère ou filiale à cent pour cent d'une telle société, au sens de l'article 83 de la *Loi sur la gestion des finances publiques*. (*government institution*)

ministre désigné Personne désignée à titre de ministre en vertu du paragraphe 3.1(1). (*designated Minister*)

renseignements personnels Les renseignements, quels que soient leur forme et leur support, concernant un individu identifiable, notamment :

a) les renseignements relatifs à sa race, à son origine nationale ou ethnique, à sa couleur, à sa religion, à son âge ou à sa situation de famille;

b) les renseignements relatifs à son éducation, à son dossier médical, à son casier judiciaire, à ses antécédents professionnels ou à des opérations financières auxquelles il a participé;

c) tout numéro ou symbole, ou toute autre indication identificatrice, qui lui est propre;

d) son adresse, ses empreintes digitales ou son groupe sanguin;

e) ses opinions ou ses idées personnelles, à l'exclusion de celles qui portent sur un autre individu ou sur une proposition de subvention, de récompense ou de prix à octroyer à un autre individu par une institution fédérale, ou subdivision de celle-ci visée par règlement;

f) toute correspondance de nature, implicitement ou explicitement, privée ou confidentielle envoyée par lui à une institution fédérale, ainsi que les réponses de l'institution dans la mesure où elles révèlent le contenu de la correspondance de l'expéditeur;

g) les idées ou opinions d'autrui sur lui;

h) les idées ou opinions d'un autre individu qui portent sur une proposition de subvention, de récompense ou de prix à lui octroyer par une institution, ou

(f) correspondence sent to a government institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to such correspondence that would reveal the contents of the original correspondence,

(g) the views or opinions of another individual about the individual,

(h) the views or opinions of another individual about a proposal for a grant, an award or a prize to be made to the individual by an institution or a part of an institution referred to in paragraph (e), but excluding the name of the other individual where it appears with the views or opinions of the other individual, and

(i) the name of the individual where it appears with other personal information relating to the individual or where the disclosure of the name itself would reveal information about the individual,

but, for the purposes of sections 7, 8 and 26 and section 19 of the *Access to Information Act*, does not include

(j) information about an individual who is or was an officer or employee of a government institution that relates to the position or functions of the individual including,

(i) the fact that the individual is or was an officer or employee of the government institution,

(ii) the title, business address and telephone number of the individual,

(iii) the classification, salary range and responsibilities of the position held by the individual,

(iv) the name of the individual on a document prepared by the individual in the course of employment, and

(v) the personal opinions or views of the individual given in the course of employment,

(j.1) the fact that an individual is or was a *ministerial adviser* or a member of a *ministerial staff*, as those terms are defined in subsection 2(1) of the *Conflict of Interest Act*, as well as the individual's name and title,

(k) information about an individual who is or was performing services under contract for a government institution that relates to the services performed, including the terms of the contract, the name of the individual and the opinions or views of the individual given in the course of the performance of those services,

subdivision de celle-ci, visée à l'alinéa e), à l'exclusion du nom de cet autre individu si ce nom est mentionné avec les idées ou opinions;

i) son nom lorsque celui-ci est mentionné avec d'autres renseignements personnels le concernant ou lorsque la seule divulgation du nom révélerait des renseignements à son sujet;

toutefois, il demeure entendu que, pour l'application des articles 7, 8 et 26, et de l'article 19 de la *Loi sur l'accès à l'information*, les renseignements personnels ne comprennent pas les renseignements concernant :

j) un cadre ou employé, actuel ou ancien, d'une institution fédérale et portant sur son poste ou ses fonctions, notamment :

(i) le fait même qu'il est ou a été employé par l'institution,

(ii) son titre et les adresse et numéro de téléphone de son lieu de travail,

(iii) la classification, l'éventail des salaires et les attributions de son poste,

(iv) son nom lorsque celui-ci figure sur un document qu'il a établi au cours de son emploi,

(v) les idées et opinions personnelles qu'il a exprimées au cours de son emploi;

j.1) un *conseiller ministériel*, au sens du paragraphe 2(1) de la *Loi sur les conflits d'intérêts*, actuel ou ancien, ou un membre, actuel ou ancien, du *personnel ministériel*, au sens de ce paragraphe, en ce qui a trait au fait même qu'il soit ou ait été tel et à ses nom et titre;

k) un individu qui, au titre d'un contrat, assure ou a assuré la prestation de services à une institution fédérale et portant sur la nature de la prestation, notamment les conditions du contrat, le nom de l'individu ainsi que les idées et opinions personnelles qu'il a exprimées au cours de la prestation;

l) des avantages financiers facultatifs, notamment la délivrance d'un permis ou d'une licence accordés à un individu, y compris le nom de celui-ci et la nature précise de ces avantages;

m) un individu décédé depuis plus de vingt ans. (*personal information*)

responsable d'institution fédérale

(l) information relating to any discretionary benefit of a financial nature, including the granting of a licence or permit, conferred on an individual, including the name of the individual and the exact nature of the benefit, and

(m) information about an individual who has been dead for more than twenty years; (*renseignements personnels*)

personal information bank means a collection or grouping of personal information described in section 10; (*fichier de renseignements personnels*)

Privacy Commissioner means the Commissioner appointed under section 53; (*Commissaire à la protection de la vie privée*)

sensory disability means a disability that relates to sight or hearing. (*déficience sensorielle*)

R.S., 1985, c. P-21, s. 3; 1992, c. 1, s. 144(F), c. 21, s. 34; 2002, c. 8, s. 183; 2006, c. 9, s. 181; 2019, c. 18, s. 47.

a) Le membre du Conseil privé de la Reine pour le Canada sous l'autorité duquel est placé un ministère ou un département d'État;

b) la personne désignée en vertu du paragraphe 3.1(2) à titre de responsable, pour l'application de la présente loi, d'une institution fédérale autre que celles visées à l'alinéa a) ou, en l'absence d'une telle désignation, le premier dirigeant de l'institution, quel que soit son titre. (*head*)

support de substitution Tout support permettant à une personne ayant une déficience sensorielle de lire ou d'écouter des renseignements personnels. (*alternative format*)

L.R. (1985), ch. P-21, art. 3; 1992, ch. 1, art. 144(F), ch. 21, art. 34; 2002, ch. 8, art. 183; 2006, ch. 9, art. 181; 2019, ch. 18, art. 47.

For greater certainty

3.01 (1) For greater certainty, any provision of this Act that applies to a government institution that is a parent Crown corporation applies to any of its wholly-owned subsidiaries within the meaning of section 83 of the *Financial Administration Act*.

For greater certainty

(2) For greater certainty, the Canadian Race Relations Foundation and the Public Sector Pension Investment Board are parent Crown corporations for the purposes of this Act.

2006, c. 9, s. 182.

Application

3.02 Paragraph (j.1) of the definition *personal information* in section 3 applies only to records created on or after the day on which that paragraph comes into force.

2019, c. 18, s. 47.1.

Précision

3.01 (1) Il est entendu que toute disposition de la présente loi qui s'applique à une institution fédérale qui est une société d'État mère s'applique également à ses filiales à cent pour cent au sens de l'article 83 de la *Loi sur la gestion des finances publiques*.

Précision

(2) Il est entendu que la Fondation canadienne des relations raciales et l'Office d'investissement des régimes de pensions du secteur public sont des sociétés d'État mères pour l'application de la présente loi.

2006, ch. 9, art. 182.

Portée

3.02 L'alinéa j.1) de la définition de *renseignements personnels* à l'article 3 ne s'applique qu'à l'égard de documents créés à la date d'entrée en vigueur de cet alinéa ou après cette date.

2019, ch. 18, art. 47.1.

Designation

Power to designate Minister

3.1 (1) The Governor in Council may designate a member of the Queen's Privy Council for Canada to be the Minister for the purposes of any provision of this Act.

Désignation

Désignation d'un ministre

3.1 (1) Le gouverneur en conseil peut désigner tout membre du Conseil privé de la Reine pour le Canada à titre de ministre pour l'application de toute disposition de la présente loi.

Power to designate head

(2) The Governor in Council may, by order, designate a person to be the head of a government institution, other than a department or ministry of state, for the purposes of this Act.

2006, c. 9, s. 182.

Collection, Retention and Disposal of Personal Information

Collection of personal information

4 No personal information shall be collected by a government institution unless it relates directly to an operating program or activity of the institution.

1980-81-82-83, c. 111, Sch. II "4".

Personal information to be collected directly

5 (1) A government institution shall, wherever possible, collect personal information that is intended to be used for an administrative purpose directly from the individual to whom it relates except where the individual authorizes otherwise or where personal information may be disclosed to the institution under subsection 8(2).

Individual to be informed of purpose

(2) A government institution shall inform any individual from whom the institution collects personal information about the individual of the purpose for which the information is being collected.

Exception

(3) Subsections (1) and (2) do not apply where compliance therewith might

(a) result in the collection of inaccurate information; or

(b) defeat the purpose or prejudice the use for which information is collected.

1980-81-82-83, c. 111, Sch. II "5".

Retention of personal information used for an administrative purpose

6 (1) Personal information that has been used by a government institution for an administrative purpose shall be retained by the institution for such period of time after it is so used as may be prescribed by regulation in order to ensure that the individual to whom it relates has a reasonable opportunity to obtain access to the information.

Désignation du responsable d'une institution fédérale

(2) Il peut aussi désigner, par décret, toute personne à titre de responsable d'une institution fédérale — autre qu'un ministère ou un département d'État — pour l'application de la présente loi.

2006, ch. 9, art. 182.

Collecte, conservation et retrait des renseignements personnels

Collecte des renseignements personnels

4 Les seuls renseignements personnels que peut recueillir une institution fédérale sont ceux qui ont un lien direct avec ses programmes ou ses activités.

1980-81-82-83, ch. 111, ann. II « 4 ».

Origine des renseignements personnels

5 (1) Une institution fédérale est tenue de recueillir auprès de l'individu lui-même, chaque fois que possible, les renseignements personnels destinés à des fins administratives le concernant, sauf autorisation contraire de l'individu ou autres cas d'autorisation prévus au paragraphe 8(2).

Mise au courant de l'intéressé

(2) Une institution fédérale est tenue d'informer l'individu auprès de qui elle recueille des renseignements personnels le concernant des fins auxquelles ils sont destinés.

Exceptions

(3) Les paragraphes (1) et (2) ne s'appliquent pas dans les cas où leur observation risquerait :

a) soit d'avoir pour résultat la collecte de renseignements inexacts;

b) soit de contrarier les fins ou de compromettre l'usage auxquels les renseignements sont destinés.

1980-81-82-83, ch. 111, ann. II « 5 ».

Conservation des renseignements personnels utilisés à des fins administratives

6 (1) Les renseignements personnels utilisés par une institution fédérale à des fins administratives doivent être conservés après usage par l'institution pendant une période, déterminée par règlement, suffisamment longue pour permettre à l'individu qu'ils concernent d'exercer son droit d'accès à ces renseignements.

Accuracy of personal information

(2) A government institution shall take all reasonable steps to ensure that personal information that is used for an administrative purpose by the institution is as accurate, up-to-date and complete as possible.

Disposal of personal information

(3) A government institution shall dispose of personal information under the control of the institution in accordance with the regulations and in accordance with any directives or guidelines issued by the designated minister in relation to the disposal of that information.

1980-81-82-83, c. 111, Sch. II "6".

Exactitude des renseignements

(2) Une institution fédérale est tenue de veiller, dans la mesure du possible, à ce que les renseignements personnels qu'elle utilise à des fins administratives soient à jour, exacts et complets.

Retrait des renseignements personnels

(3) Une institution fédérale procède au retrait des renseignements personnels qui relèvent d'elle conformément aux règlements et aux instructions ou directives applicables du ministre désigné.

1980-81-82-83, ch. 111, ann. II « 6 ».

Protection of Personal Information

Use of personal information

7 Personal information under the control of a government institution shall not, without the consent of the individual to whom it relates, be used by the institution except

(a) for the purpose for which the information was obtained or compiled by the institution or for a use consistent with that purpose; or

(b) for a purpose for which the information may be disclosed to the institution under subsection 8(2).

1980-81-82-83, c. 111, Sch. II "7".

Protection des renseignements personnels

Usage des renseignements personnels

7 À défaut du consentement de l'individu concerné, les renseignements personnels relevant d'une institution fédérale ne peuvent servir à celle-ci :

a) qu'aux fins auxquelles ils ont été recueillis ou préparés par l'institution de même que pour les usages qui sont compatibles avec ces fins;

b) qu'aux fins auxquelles ils peuvent lui être communiqués en vertu du paragraphe 8(2).

1980-81-82-83, ch. 111, ann. II « 7 ».

Disclosure of personal information

8 (1) Personal information under the control of a government institution shall not, without the consent of the individual to whom it relates, be disclosed by the institution except in accordance with this section.

Where personal information may be disclosed

(2) Subject to any other Act of Parliament, personal information under the control of a government institution may be disclosed

(a) for the purpose for which the information was obtained or compiled by the institution or for a use consistent with that purpose;

(b) for any purpose in accordance with any Act of Parliament or any regulation made thereunder that authorizes its disclosure;

(c) for the purpose of complying with a subpoena or warrant issued or order made by a court, person or body with jurisdiction to compel the production of

Communication des renseignements personnels

8 (1) Les renseignements personnels qui relèvent d'une institution fédérale ne peuvent être communiqués, à défaut du consentement de l'individu qu'ils concernent, que conformément au présent article.

Cas d'autorisation

(2) Sous réserve d'autres lois fédérales, la communication des renseignements personnels qui relèvent d'une institution fédérale est autorisée dans les cas suivants :

a) communication aux fins auxquelles ils ont été recueillis ou préparés par l'institution ou pour les usages qui sont compatibles avec ces fins;

b) communication aux fins qui sont conformes avec les lois fédérales ou ceux de leurs règlements qui autorisent cette communication;

c) communication exigée par *subpœna*, mandat ou ordonnance d'un tribunal, d'une personne ou d'un organisme ayant le pouvoir de contraindre à la

information or for the purpose of complying with rules of court relating to the production of information;

(d) to the Attorney General of Canada for use in legal proceedings involving the Crown in right of Canada or the Government of Canada;

(e) to an investigative body specified in the regulations, on the written request of the body, for the purpose of enforcing any law of Canada or a province or carrying out a lawful investigation, if the request specifies the purpose and describes the information to be disclosed;

(f) for the purpose of administering or enforcing any law or carrying out a lawful investigation, under an agreement or arrangement between the Government of Canada or any of its institutions and any of the following entities or any of their institutions:

(i) the government of a foreign state,

(ii) an international organization of states or an international organization established by the governments of states,

(iii) the government of a province,

(iv) the council of the Westbank First Nation,

(v) the *council of a participating First Nation* as defined in subsection 2(1) of the *First Nations Jurisdiction over Education in British Columbia Act*,

(vi) the council of a *participating First Nation* as defined in section 2 of the *Anishinabek Nation Education Agreement Act*,

(vii) a *First Nation Government* or the *Anishinabek Nation Government*, as defined in section 2 of the *Anishinabek Nation Governance Agreement Act*, or an Anishinaabe Institution, within the meaning of section 1.1 of the *Agreement*, as defined in section 2 of that Act,

(vii.1) the *Whitecap Dakota Government*, as defined in section 2 of the *Self-Government Treaty Recognizing the Whitecap Dakota Nation / Wapaha Ska Dakota Oyate Act*;

(g) to a member of Parliament for the purpose of assisting the individual to whom the information relates in resolving a problem;

(h) to officers or employees of the institution for internal audit purposes, or to the office of the

production de renseignements ou exigée par des règles de procédure se rapportant à la production de renseignements;

d) communication au procureur général du Canada pour usage dans des poursuites judiciaires intéressant la Couronne du chef du Canada ou le gouvernement fédéral;

e) communication à un organisme d'enquête déterminé par règlement et qui en fait la demande par écrit, en vue de faire respecter des lois fédérales ou provinciales ou pour la tenue d'enquêtes licites, pourvu que la demande précise les fins auxquelles les renseignements sont destinés et la nature des renseignements demandés;

f) communication, en vue de l'application des lois ou pour la tenue d'enquêtes licites, aux termes d'accords ou d'ententes conclus, d'une part, entre le gouvernement du Canada ou l'un de ses organismes et, d'autre part, l'une des entités ci-après ou l'un de ses organismes :

(i) le gouvernement d'un État étranger,

(ii) une organisation internationale d'États ou de gouvernements,

(iii) le gouvernement d'une province,

(iv) le conseil de la première nation de Westbank,

(v) le *conseil de la première nation participante*, au sens du paragraphe 2(1) de la *Loi sur la compétence des premières nations en matière d'éducation en Colombie- Britannique*,

(vi) le conseil de la *première nation participante*, au sens de l'article 2 de la *Loi sur l'accord en matière d'éducation conclu avec la Nation des Anishinabes*,

(vii) le *gouvernement de la première nation* ou le *gouvernement de la Nation des Anishinabes*, au sens de l'article 2 de la *Loi sur l'accord en matière de gouvernance conclu avec la Nation des Anishinabes*, ou une institution anishinabe, au sens de l'article 1.1 de l'*accord*, au sens de l'article 2 de cette loi,

(vii.1) le *gouvernement des Dakotas de Whitecap*, au sens de l'article 2 de la *Loi sur le traité concernant l'autonomie gouvernementale et la reconnaissance de la Nation dakota de Whitecap / Wapaha Ska Dakota Oyate*;

Comptroller General or any other person or body specified in the regulations for audit purposes;

(i) to the Library and Archives of Canada for archival purposes;

(j) to any person or body for research or statistical purposes if the head of the government institution

(i) is satisfied that the purpose for which the information is disclosed cannot reasonably be accomplished unless the information is provided in a form that would identify the individual to whom it relates, and

(ii) obtains from the person or body a written undertaking that no subsequent disclosure of the information will be made in a form that could reasonably be expected to identify the individual to whom it relates;

(k) to any aboriginal government, association of aboriginal people, Indian band, government institution or part thereof, or to any person acting on behalf of such government, association, band, institution or part thereof, for the purpose of researching or validating the claims, disputes or grievances of any of the aboriginal peoples of Canada;

(l) to any government institution for the purpose of locating an individual in order to collect a debt owing to Her Majesty in right of Canada by that individual or make a payment owing to that individual by Her Majesty in right of Canada; and

(m) for any purpose where, in the opinion of the head of the institution,

(i) the public interest in disclosure clearly outweighs any invasion of privacy that could result from the disclosure, or

(ii) disclosure would clearly benefit the individual to whom the information relates.

g) communication à un parlementaire fédéral en vue d'aider l'individu concerné par les renseignements à résoudre un problème;

h) communication pour vérification interne au personnel de l'institution ou pour vérification comptable au bureau du contrôleur général ou à toute personne ou tout organisme déterminé par règlement;

i) communication à Bibliothèque et Archives du Canada pour dépôt;

j) communication à toute personne ou à tout organisme, pour des travaux de recherche ou de statistique, pourvu que soient réalisées les deux conditions suivantes :

(i) le responsable de l'institution est convaincu que les fins auxquelles les renseignements sont communiqués ne peuvent être normalement atteintes que si les renseignements sont donnés sous une forme qui permette d'identifier l'individu qu'ils concernent,

(ii) la personne ou l'organisme s'engagent par écrit auprès du responsable de l'institution à s'abstenir de toute communication ultérieure des renseignements tant que leur forme risque vraisemblablement de permettre l'identification de l'individu qu'ils concernent;

k) communication à tout gouvernement autochtone, association d'autochtones, bande d'Indiens, institution fédérale ou subdivision de celle-ci, ou à leur représentant, en vue de l'établissement des droits des peuples autochtones ou du règlement de leurs griefs;

l) communication à toute institution fédérale en vue de joindre un débiteur ou un créancier de Sa Majesté du chef du Canada et de recouvrer ou d'acquitter la créance;

m) communication à toute autre fin dans les cas où, de l'avis du responsable de l'institution :

(i) des raisons d'intérêt public justifieraient nettement une éventuelle violation de la vie privée,

(ii) l'individu concerné en tirerait un avantage certain.

Personal information disclosed by Library and Archives of Canada

(3) Subject to any other Act of Parliament, personal information under the custody or control of the Library and Archives of Canada that has been transferred there

Communication par Bibliothèque et Archives du Canada

(3) Sous réserve des autres lois fédérales, les renseignements personnels qui relèvent de Bibliothèque et Archives du Canada et qui y ont été versés pour dépôt ou à

by a government institution for historical or archival purposes may be disclosed in accordance with the regulations to any person or body for research or statistical purposes.

des fins historiques par une institution fédérale peuvent être communiqués conformément aux règlements pour des travaux de recherche ou de statistique.

Copies of requests under paragraph (2)(e) to be retained

(4) The head of a government institution shall retain a copy of every request received by the government institution under paragraph (2)(e) for such period of time as may be prescribed by regulation, shall keep a record of any information disclosed pursuant to the request for such period of time as may be prescribed by regulation and shall, on the request of the Privacy Commissioner, make those copies and records available to the Privacy Commissioner.

Copie des demandes faites en vertu de l'al. (2)e)

(4) Le responsable d'une institution fédérale conserve, pendant la période prévue par les règlements, une copie des demandes reçues par l'institution en vertu de l'alinéa (2)e) ainsi qu'une mention des renseignements communiqués et, sur demande, met cette copie et cette mention à la disposition du Commissaire à la protection de la vie privée.

Notice of disclosure under paragraph (2)(m)

(5) The head of a government institution shall notify the Privacy Commissioner in writing of any disclosure of personal information under paragraph (2)(m) prior to the disclosure where reasonably practicable or in any other case forthwith on the disclosure, and the Privacy Commissioner may, if the Commissioner deems it appropriate, notify the individual to whom the information relates of the disclosure.

Avis de communication dans le cas de l'al. (2)m)

(5) Dans le cas prévu à l'alinéa (2)m), le responsable de l'institution fédérale concernée donne un préavis écrit de la communication des renseignements personnels au Commissaire à la protection de la vie privée si les circonstances le justifient; sinon, il en avise par écrit le Commissaire immédiatement après la communication. La décision de mettre au courant l'individu concerné est laissée à l'appréciation du Commissaire.

Definition of *Indian band*

(6) In paragraph (2)(k), ***Indian band*** means

(a) a band, as defined in the *Indian Act*;

(b) the band, as defined in subsection 2(1) of the *Naskapi and the Cree-Naskapi Commission Act*;

(c) the *shíshálh Nation*, as defined in subsection 2(1) of the *shíshálh Nation Self-Government Act*; or

(d) a first nation named in Schedule II to the *Yukon First Nations Self-Government Act*.

Définition de *bande d'Indiens*

(6) L'expression ***bande d'Indiens*** à l'alinéa (2)k) désigne :

a) soit une bande au sens de la *Loi sur les Indiens*;

b) soit la *bande* au sens du paragraphe 2(1) de la *Loi sur les Naskapis et la Commission crie-naskapie*;

c) soit la *Nation shishalhe*, au sens du paragraphe 2(1) de la *Loi sur l'autonomie gouvernementale de la Nation shishalhe*;

d) la première nation dont le nom figure à l'annexe II de la *Loi sur l'autonomie gouvernementale des premières nations du Yukon*.

Definition of *aboriginal government*

(7) The expression ***aboriginal government*** in paragraph (2)(k) means

(a) Nisga'a Government, as defined in the Nisga'a Final Agreement given effect by the *Nisga'a Final Agreement Act*;

(b) the council of the Westbank First Nation;

Définition de *gouvernement autochtone*

(7) L'expression ***gouvernement autochtone*** à l'alinéa (2)k) s'entend :

a) du gouvernement nisga'a, au sens de l'Accord définitif nisga'a mis en vigueur par la *Loi sur l'Accord définitif nisga'a*;

b) du conseil de la première nation de Westbank;

(c) the Tlicho Government, as defined in section 2 of the *Tlicho Land Claims and Self-Government Act*;

(d) the Nunatsiavut Government, as defined in section 2 of the *Labrador Inuit Land Claims Agreement Act*;

(e) the council of a participating First Nation as defined in subsection 2(1) of the *First Nations Jurisdiction over Education in British Columbia Act*;

(e.1) the Tla'amin Government, as defined in subsection 2(2) of the *Tla'amin Final Agreement Act*;

(f) the Tsawwassen Government, as defined in subsection 2(2) of the *Tsawwassen First Nation Final Agreement Act*;

(f.1) the *Cree Nation Government*, as defined in subsection 2(1) of the *Cree Nation of Eeyou Istchee Governance Agreement Act* or a *Cree First Nation*, as defined in subsection 2(2) of that Act;

(g) a Maanulth Government, within the meaning of subsection 2(2) of the *Maanulth First Nations Final Agreement Act*;

(h) Sioux Valley Dakota Oyate Government, within the meaning of subsection 2(2) of the *Sioux Valley Dakota Nation Governance Act*;

(h.1) the *Whitecap Dakota Government*, as defined in section 2 of the *Self-Government Treaty Recognizing the Whitecap Dakota Nation / Wapaha Ska Dakota Oyate Act*;

(i) the council of a *participating First Nation* as defined in section 2 of the *Anishinabek Nation Education Agreement Act*; or

(j) a *First Nation Government* or the *Anishinabek Nation Government*, as defined in section 2 of the *Anishinabek Nation Governance Agreement Act*, or an Anishinaabe Institution, within the meaning of section 1.1 of the *Agreement*, as defined in section 2 of that Act.

c) du gouvernement tlicho, au sens de l'article 2 de la *Loi sur les revendications territoriales et l'autonomie gouvernementale du peuple tlicho*;

d) du gouvernement nunatsiavut, au sens de l'article 2 de la *Loi sur l'Accord sur les revendications territoriales des Inuit du Labrador*;

e) du conseil de la première nation participante, au sens du paragraphe 2(1) de la *Loi sur la compétence des premières nations en matière d'éducation en Colombie-Britannique*;

e.1) du gouvernement tlaamin, au sens du paragraphe 2(2) de la *Loi sur l'accord définitif concernant les Tlaamins*;

f) du gouvernement tsawwassen, au sens du paragraphe 2(2) de la *Loi sur l'accord définitif concernant la Première Nation de Tsawwassen*;

f.1) du *Gouvernement de la nation crie*, au sens du paragraphe 2(1) de la *Loi sur l'accord concernant la gouvernance de la nation crie d'Eeyou Istchee*, ou d'une *première nation crie*, au sens du paragraphe 2(2) de cette loi;

g) de tout gouvernement maanulth, au sens du paragraphe 2(2) de la *Loi sur l'accord définitif concernant les premières nations maanulthes*;

h) du gouvernement de l'oyate dakota de Sioux Valley, au sens du paragraphe 2(2) de la *Loi sur la gouvernance de la nation dakota de Sioux Valley*;

h.1) du *gouvernement des Dakotas de Whitecap*, au sens de l'article 2 de la *Loi sur le traité concernant l'autonomie gouvernementale et la reconnaissance de la Nation dakota de Whitecap / Wapaha Ska Dakota Oyate*;

i) du conseil de la *première nation participante*, au sens de l'article 2 la *Loi sur l'accord en matière d'éducation conclu avec la Nation des Anishinabes*;

j) du *gouvernement de la première nation* ou du *gouvernement de la Nation des Anishinabes*, au sens de l'article 2 de la *Loi sur l'accord en matière de gouvernance conclu avec la Nation des Anishinabes*, ou d'une institution anishinabe, au sens de l'article 1.1 de l'*accord*, au sens de l'article 2 de cette loi.

Definition of *council of the Westbank First Nation*

(8) The expression ***council of the Westbank First Nation*** in paragraphs (2)(f) and (7)(b) means the council, as

Définition de *conseil de la première nation de Westbank*

(8) L'expression ***conseil de la première nation de Westbank*** aux alinéas (2)f) et (7)b) s'entend du conseil

defined in the Westbank First Nation Self-Government Agreement given effect by the *Westbank First Nation Self-Government Act*.

R.S., 1985, c. P-21, s. 8; R.S., 1985, c. 20 (2nd Supp.), s. 13, c. 1 (3rd Supp.), s. 12; 1994, c. 35, s. 39; 2000, c. 7, s. 26; 2004, c. 11, s. 37, c. 17, s. 18; 2005, c. 1, ss. 106, 109, c. 27, ss. 21, 25; 2006, c. 10, s. 33; 2008, c. 32, s. 30; 2009, c. 18, s. 23; 2014, c. 1, s. 19, c. 11, s. 24; 2017, c. 32, s. 18; 2018, c. 4, s. 132; 2022, c. 9, s. 4; 2022, c. 9, s. 45; 2023, c. 22, s. 20.

Record of disclosures to be retained

9 (1) The head of a government institution shall retain a record of any use by the institution of personal information contained in a personal information bank or any use or purpose for which that information is disclosed by the institution where the use or purpose is not included in the statements of uses and purposes set forth pursuant to subparagraph 11(1)(a)(iv) and subsection 11(2) in the index referred to in section 11, and shall attach the record to the personal information.

Limitation

(2) Subsection (1) does not apply in respect of information disclosed pursuant to paragraph 8(2)(e).

Record forms part of personal information

(3) For the purposes of this Act, a record retained under subsection (1) shall be deemed to form part of the personal information to which it is attached.

Consistent uses

(4) Where personal information in a personal information bank under the control of a government institution is used or disclosed for a use consistent with the purpose for which the information was obtained or compiled by the institution but the use is not included in the statement of consistent uses set forth pursuant to subparagraph 11(1)(a)(iv) in the index referred to in section 11, the head of the government institution shall

(a) forthwith notify the Privacy Commissioner of the use for which the information was used or disclosed; and

(b) ensure that the use is included in the next statement of consistent uses set forth in the index.

1980-81-82-83, c. 111, Sch. II "9"; 1984, c. 21, s. 89.

au sens de l'Accord d'autonomie gouvernementale de la première nation de Westbank mis en vigueur par la *Loi sur l'autonomie gouvernementale de la première nation de Westbank*.

L.R. (1985), ch. P-21, art. 8; L.R. (1985), ch. 20 (2e suppl.), art. 13, ch. 1 (3e suppl.), art. 12; 1994, ch. 35, art. 39; 2000, ch. 7, art. 26; 2004, ch. 11, art. 37, ch. 17, art. 18; 2005, ch. 1, art. 106 et 109, ch. 27, art. 21 et 25; 2006, ch. 10, art. 33; 2008, ch. 32, art. 30; 2009, ch. 18, art. 23; 2014, ch. 1, art. 19, ch. 11, art. 24; 2017, ch. 32, art. 18; 2018, ch. 4, art. 132; 2022, ch. 9, art. 4; 2022, ch. 9, art. 45; 2023, ch. 22, art. 20.

Relevé

9 (1) Le responsable d'une institution fédérale fait un relevé des cas d'usage, par son institution, de renseignements personnels versés dans un fichier de renseignements personnels, ainsi que des usages ou fins auxquels ils ont été communiqués par son institution si ceux-ci ne figurent pas parmi les usages et fins énumérés dans le répertoire prévu au paragraphe 11(1), en vertu du sous-alinéa 11(1)a)(iv) et du paragraphe 11(2); il joint le relevé aux renseignements personnels.

Exception

(2) Le paragraphe (1) ne s'applique pas aux renseignements communiqués en vertu de l'alinéa 8(2)e).

Appartenance du relevé aux renseignements personnels

(3) Le relevé mentionné au paragraphe (1) devient lui-même un renseignement personnel qui fait partie des renseignements personnels utilisés ou communiqués.

Usages compatibles

(4) Dans les cas où des renseignements personnels versés dans un fichier de renseignements personnels relevant d'une institution fédérale sont destinés à un usage, ou communiqués pour un usage, compatible avec les fins auxquelles les renseignements ont été recueillis ou préparés par l'institution, mais que l'usage n'est pas l'un de ceux qui, en vertu du sous-alinéa 11(1)a)(iv), sont indiqués comme usages compatibles dans le répertoire visé au paragraphe 11(1), le responsable de l'institution fédérale est tenu :

a) d'aviser immédiatement le Commissaire à la protection de la vie privée de l'usage qui a été fait des renseignements ou pour lequel ils ont été communiqués;

b) de faire insérer une mention de cet usage dans la liste des usages compatibles énumérés dans l'édition suivante du répertoire.

1980-81-82-83, ch. 111, ann. II « 9 »; 1984, ch. 21, art. 89.

Personal Information Banks

Personal information to be included in personal information banks

10 (1) The head of a government institution shall cause to be included in personal information banks all personal information under the control of the government institution that

(a) has been used, is being used or is available for use for an administrative purpose; or

(b) is organized or intended to be retrieved by the name of an individual or by an identifying number, symbol or other particular assigned to an individual.

Exception for Library and Archives of Canada

(2) Subsection (1) does not apply in respect of personal information under the custody or control of the Library and Archives of Canada that has been transferred there by a government institution for historical or archival purposes.

R.S., 1985, c. P-21, s. 10; R.S., 1985, c. 1 (3rd Supp.), s. 12; 2004, c. 11, s. 38.

Personal Information Index

Index of personal information

11 (1) The designated Minister shall cause to be published on a periodic basis not less frequently than once each year, an index of

(a) all personal information banks setting forth, in respect of each bank,

(i) the identification and a description of the bank, the registration number assigned to it by the designated Minister pursuant to paragraph 71(1)(b) and a description of the class of individuals to whom personal information contained in the bank relates,

(ii) the name of the government institution that has control of the bank,

(iii) the title and address of the appropriate officer to whom requests relating to personal information contained in the bank should be sent,

(iv) a statement of the purposes for which personal information in the bank was obtained or compiled and a statement of the uses consistent with

Fichiers de renseignements personnels

Renseignements personnels versés dans les fichiers de renseignements personnels

10 (1) Le responsable d'une institution fédérale veille à ce que soient versés dans des fichiers de renseignements personnels tous les renseignements personnels qui relèvent de son institution et qui :

a) ont été, sont ou peuvent être utilisés à des fins administratives;

b) sont marqués de façon à pouvoir être retrouvés par référence au nom d'un individu ou à un numéro, symbole ou autre indication identificatrice propre à cet individu.

Exception : Bibliothèque et Archives du Canada

(2) Le paragraphe (1) ne s'applique pas aux renseignements personnels qui relèvent de Bibliothèque et Archives du Canada et qui y ont été versés par une institution fédérale pour dépôt ou à des fins historiques.

L.R. (1985), ch. P-21, art. 10; L.R. (1985), ch. 1 (3e suppl.), art. 12; 2004, ch. 11, art. 38.

Répertoire de renseignements personnels

Publication du répertoire

11 (1) Le ministre désigné fait publier, selon une périodicité au moins annuelle, un répertoire :

a) d'une part, de tous les fichiers de renseignements personnels, donnant, pour chaque fichier, les indications suivantes :

(i) sa désignation, son contenu, la cote qui lui a été attribuée par le ministre désigné, conformément à l'alinéa 71(1)b), ainsi que la désignation des catégories d'individus sur qui portent les renseignements personnels qui y sont versés,

(ii) le nom de l'institution fédérale de qui il relève,

(iii) les titre et adresse du fonctionnaire chargé de recevoir les demandes de communication des renseignements personnels qu'il contient,

(iv) l'énumération des fins auxquelles les renseignements personnels qui y sont versés ont été recueillis ou préparés de même que l'énumération des usages, compatibles avec ces fins, auxquels les

those purposes for which the information is used or disclosed,

(v) a statement of the retention and disposal standards applied to personal information in the bank, and

(vi) an indication, where applicable, that the bank was designated as an exempt bank by an order under section 18 and the provision of section 21 or 22 on the basis of which the order was made; and

(b) all classes of personal information under the control of a government institution that are not contained in personal information banks, setting forth in respect of each class

(i) a description of the class in sufficient detail to facilitate the right of access under this Act, and

(ii) the title and address of the appropriate officer for each government institution to whom requests relating to personal information within the class should be sent.

Statement of uses and purposes

(2) The designated Minister may set forth in the index referred to in subsection (1) a statement of any of the uses and purposes, not included in the statements made pursuant to subparagraph (1)(a)(iv), for which personal information contained in any of the personal information banks referred to in the index is used or disclosed on a regular basis.

Index to be made available

(3) The designated Minister shall cause the index referred to in subsection (1) to be made available throughout Canada in conformity with the principle that every person is entitled to reasonable access to the index.

1980-81-82-83, c. 111, Sch. II "11".

renseignements sont destinés ou pour lesquels ils sont communiqués,

(v) l'énumération des critères qui s'appliquent à la conservation et au retrait des renseignements personnels qui y sont versés,

(vi) s'il y a lieu, le fait qu'il a fait l'objet d'un décret pris en vertu de l'article 18 et la mention de la disposition des articles 21 ou 22 sur laquelle s'appuie le décret;

b) d'autre part, de toutes les catégories de renseignements personnels qui relèvent d'une institution fédérale mais ne sont pas versés dans des fichiers de renseignements personnels, donnant, pour chaque catégorie, les indications suivantes :

(i) son contenu, en termes suffisamment précis pour faciliter l'exercice du droit d'accès prévu par la présente loi,

(ii) les titre et adresse du fonctionnaire de l'institution chargé de recevoir les demandes de communication des renseignements personnels qu'elle contient.

Énumération des usages et fins

(2) Le ministre désigné peut insérer, dans le répertoire, des usages ou fins non prévus au sous-alinéa (1)a)(iv) mais s'appliquant, dans le cadre de communications courantes, à des renseignements personnels versés dans les fichiers de renseignements personnels.

Diffusion

(3) Le ministre désigné est responsable de la diffusion du répertoire dans tout le Canada, étant entendu que toute personne a le droit d'en prendre normalement connaissance.

1980-81-82-83, ch. 111, ann. II « 11 ».

Access to Personal Information

Right of Access

Right of access

12 (1) Subject to this Act, every individual who is a Canadian citizen or a permanent resident within the meaning of subsection 2(1) of the *Immigration and Refugee Protection Act* has a right to and shall, on request, be given access to

(a) any personal information about the individual contained in a personal information bank; and

(b) any other personal information about the individual under the control of a government institution with respect to which the individual is able to provide sufficiently specific information on the location of the information as to render it reasonably retrievable by the government institution.

Other rights relating to personal information

(2) Every individual who is given access under paragraph (1)(a) to personal information that has been used, is being used or is available for use for an administrative purpose is entitled to

(a) request correction of the personal information where the individual believes there is an error or omission therein;

(b) require that a notation be attached to the information reflecting any correction requested but not made; and

(c) require that any person or body to whom that information has been disclosed for use for an administrative purpose within two years prior to the time a correction is requested or a notation is required under this subsection in respect of that information

(i) be notified of the correction or notation, and

(ii) where the disclosure is to a government institution, the institution make the correction or notation on any copy of the information under its control.

Accès aux renseignements personnels

Droit d'accès

Droit d'accès

12 (1) Sous réserve des autres dispositions de la présente loi, tout citoyen canadien et tout résident permanent au sens du paragraphe 2(1) de la *Loi sur l'immigration et la protection des réfugiés* ont le droit de se faire communiquer sur demande :

a) les renseignements personnels le concernant et versés dans un fichier de renseignements personnels;

b) les autres renseignements personnels le concernant et relevant d'une institution fédérale, dans la mesure où il peut fournir sur leur localisation des indications suffisamment précises pour que l'institution fédérale puisse les retrouver sans problèmes sérieux.

Autres droits

(2) Tout individu qui reçoit communication, en vertu de l'alinéa (1)a), de renseignements personnels qui ont été, sont ou peuvent être utilisés à des fins administratives, a le droit :

a) de demander la correction des renseignements personnels le concernant qui, selon lui, sont erronés ou incomplets;

b) d'exiger, s'il y a lieu, qu'il soit fait mention des corrections qui ont été demandées mais non effectuées;

c) d'exiger :

(i) que toute personne ou tout organisme à qui ces renseignements ont été communiqués pour servir à des fins administratives dans les deux ans précédant la demande de correction ou de mention des corrections non effectuées soient avisés de la correction ou de la mention,

(ii) que l'organisme, s'il s'agit d'une institution fédérale, effectue la correction ou porte la mention sur toute copie de document contenant les renseignements qui relèvent de lui.

Extension of right of access by order

(3) The Governor in Council may, by order, extend the right to be given access to personal information under subsection (1) to include individuals not referred to in that subsection and may set such conditions as the Governor in Council deems appropriate.

R.S., 1985, c. P-21, s. 12; 2001, c. 27, s. 269.

Extension par décret

(3) Le gouverneur en conseil peut, par décret, étendre, conditionnellement ou non, le droit d'accès visé au paragraphe (1) à des individus autres que ceux qui y sont mentionnés.

L.R. (1985), ch. P-21, art. 12; 2001, ch. 27, art. 269.

Requests for Access

Demandes de communication

Request for access under paragraph 12(1)(a)

13 (1) A request for access to personal information under paragraph 12(1)(a) shall be made in writing to the government institution that has control of the personal information bank that contains the information and shall identify the bank.

Demande de communication prévue à l'al. 12(1)a)

13 (1) La demande de communication des renseignements personnels visés à l'alinéa 12(1)a) se fait par écrit auprès de l'institution fédérale de qui relève le fichier de renseignements personnels où ils sont versés et doit comporter la désignation du fichier.

Request for access under 12(1)(b)

(2) A request for access to personal information under paragraph 12(1)(b) shall be made in writing to the government institution that has control of the information and shall provide sufficiently specific information on the location of the information as to render it reasonably retrievable by the government institution.

1980-81-82-83, c. 111, Sch. II "13".

Demande de communication prévue à l'al. 12(1)b)

(2) La demande de communication des renseignements personnels visés à l'alinéa 12(1)b) se fait par écrit auprès de l'institution fédérale de qui relèvent les renseignements; elle doit contenir sur leur localisation des indications suffisamment précises pour que l'institution puisse les retrouver sans problèmes sérieux.

1980-81-82-83, ch. 111, ann. II « 13 ».

Notice where access requested

14 Where access to personal information is requested under subsection 12(1), the head of the government institution to which the request is made shall, subject to section 15, within thirty days after the request is received,

(a) give written notice to the individual who made the request as to whether or not access to the information or a part thereof will be given; and

(b) if access is to be given, give the individual who made the request access to the information or the part thereof.

1980-81-82-83, c. 111, Sch. II "14".

Notification

14 Le responsable de l'institution fédérale à qui est faite une demande de communication de renseignements personnels en vertu du paragraphe 12(1) est tenu, dans les trente jours suivant sa réception, sous réserve de l'article 15 :

a) d'aviser par écrit la personne qui a fait la demande de ce qu'il sera donné ou non communication totale ou partielle des renseignements personnels;

b) le cas échéant, de procéder à la communication.

1980-81-82-83, ch. 111, ann. II « 14 ».

Extension of time limits

15 The head of a government institution may extend the time limit set out in section 14 in respect of a request for

(a) a maximum of thirty days if

(i) meeting the original time limit would unreasonably interfere with the operations of the government institution, or

Prorogation du délai

15 Le responsable d'une institution fédérale peut proroger le délai mentionné à l'article 14 :

a) d'une période maximale de trente jours dans les cas où :

(i) l'observation du délai entraverait de façon sérieuse le fonctionnement de l'institution,

(ii) consultations are necessary to comply with the request that cannot reasonably be completed within the original time limit, or

(b) such period of time as is reasonable, if additional time is necessary for translation purposes or for the purposes of converting the personal information into an alternative format,

by giving notice of the extension and the length of the extension to the individual who made the request within thirty days after the request is received, which notice shall contain a statement that the individual has a right to make a complaint to the Privacy Commissioner about the extension.

R.S., 1985, c. P-21, s. 15; 1992, c. 21, s. 35.

(ii) les consultations nécessaires pour donner suite à la demande rendraient pratiquement impossible l'observation du délai;

b) d'une période qui peut se justifier dans les cas de traduction ou dans les cas de transfert sur support de substitution.

Dans l'un ou l'autre de ces cas, le responsable de l'institution fédérale envoie à la personne qui a fait la demande, dans les trente jours suivant sa réception, un avis de prorogation de délai en lui faisant part du nouveau délai ainsi que de son droit de déposer une plainte à ce propos auprès du Commissaire à la protection de la vie privée.

L.R. (1985), ch. P-21, art. 15; 1992, ch. 21, art. 35.

Where access is refused

16 (1) Where the head of a government institution refuses to give access to any personal information requested under subsection 12(1), the head of the institution shall state in the notice given under paragraph 14(a)

(a) that the personal information does not exist, or

(b) the specific provision of this Act on which the refusal was based or the provision on which a refusal could reasonably be expected to be based if the information existed,

and shall state in the notice that the individual who made the request has a right to make a complaint to the Privacy Commissioner about the refusal.

Refus de communication

16 (1) En cas de refus de communication de renseignements personnels demandés en vertu du paragraphe 12(1), l'avis prévu à l'alinéa 14a) doit mentionner, d'une part, le droit de la personne qui a fait la demande de déposer une plainte auprès du Commissaire à la protection de la vie privée et, d'autre part :

a) soit le fait que le dossier n'existe pas;

b) soit la disposition précise de la présente loi sur laquelle se fonde le refus ou sur laquelle il pourrait vraisemblablement se fonder si les renseignements existaient.

Existence not required to be disclosed

(2) The head of a government institution may but is not required to indicate under subsection (1) whether personal information exists.

Dispense de divulgation de l'existence du document

(2) Le paragraphe (1) n'oblige pas le responsable de l'institution fédérale à faire état de l'existence des renseignements personnels demandés.

Deemed refusal to give access

(3) Where the head of a government institution fails to give access to any personal information requested under subsection 12(1) within the time limits set out in this Act, the head of the institution shall, for the purposes of this Act, be deemed to have refused to give access.

1980-81-82-83, c. 111, Sch. II "16".

Présomption de refus

(3) Le défaut de communication de renseignements personnels demandés en vertu du paragraphe 12(1) dans les délais prévus par la présente loi vaut décision de refus de communication.

1980-81-82-83, ch. 111, ann. II « 16 ».

Access

Form of access

17 (1) Subject to any regulations made under paragraph 77(1)(o), where an individual is to be given access to personal information requested under subsection 12(1), the government institution shall

Exercice de l'accès

Exercice de l'accès

17 (1) Sous réserve des règlements pris en vertu de l'alinéa 77(1)o), une institution fédérale donne communication des renseignements personnels de la façon suivante :

(a) permit the individual to examine the information in accordance with the regulations; or

(b) provide the individual with a copy thereof.

a) soit par la permission de consulter les renseignements conformément aux règlements;

b) soit par la délivrance de copies.

Language of access

(2) Where access to personal information is to be given under this Act and the individual to whom access is to be given requests that access be given in a particular one of the official languages of Canada,

(a) access shall be given in that language, if the personal information already exists under the control of a government institution in that language; and

(b) where the personal information does not exist in that language, the head of the government institution that has control of the personal information shall cause it to be translated or interpreted for the individual if the head of the institution considers a translation or interpretation to be necessary to enable the individual to understand the information.

Version de la communication

(2) Un individu reçoit communication des renseignements personnels dans la langue officielle qu'il a précisée dans les cas suivants :

a) il en existe une version dans cette langue et elle relève d'une institution fédérale;

b) il n'en existe pas de version dans cette langue mais le responsable de l'institution fédérale dont ils relèvent juge nécessaire de les faire traduire ou de fournir à l'individu les services d'un interprète afin qu'il puisse les comprendre.

Access to personal information in alternative format

(3) Where access to personal information is to be given under this Act and the individual to whom access is to be given has a sensory disability and requests that access be given in an alternative format, access shall be given in an alternative format if

(a) the personal information already exists under the control of a government institution in an alternative format that is acceptable to the individual; or

(b) the head of the government institution that has control of the personal information considers the giving of access in an alternative format to be necessary to enable the individual to exercise the individual's right of access under this Act and considers it reasonable to cause the personal information to be converted.

R.S., 1985, c. P-21, s. 17; 1992, c. 21, s. 36.

Communication sur support de substitution

(3) Un individu ayant une déficience sensorielle qui a demandé que communication des renseignements personnels lui soit faite sur un support de substitution reçoit communication de ceux-ci sur un tel support dans les cas suivants :

a) une version des renseignements existe sur un support de substitution qui lui soit acceptable et elle relève d'une institution fédérale;

b) le responsable de l'institution fédérale dont relèvent les renseignements juge nécessaire de communiquer les renseignements sur un support de substitution afin que la personne puisse exercer ses droits en vertu de la présente loi et raisonnable de les transférer sur un tel support.

L.R. (1985), ch. P-21, art. 17; 1992, ch. 21, art. 36.

Exemptions

Exempt Banks

Governor in Council may designate exempt banks

18 (1) The Governor in Council may, by order, designate as exempt banks certain personal information banks that contain files all of which consist predominantly of personal information described in section 21 or 22.

Exceptions

Fichiers inconsultables

Fichiers inconsultables

18 (1) Le gouverneur en conseil peut, par décret, classer parmi les fichiers de renseignements personnels inconsultables, dénommés fichiers inconsultables dans la

présente loi, ceux qui sont formés de dossiers dans chacun desquels dominent les renseignements visés aux articles 21 ou 22.

Disclosure may be refused

(2) The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) that is contained in a personal information bank designated as an exempt bank under subsection (1).

Contents of order

(3) An order made under subsection (1) shall specify

(a) the section on the basis of which the order is made; and

(b) where a personal information bank is designated that contains files that consist predominantly of personal information described in subparagraph 22(1)(a)(ii), the law concerned.

1980-81-82-83, c. 111, Sch. II "18".

Autorisation de refuser

(2) Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui sont versés dans des fichiers inconsultables.

Éléments que doit contenir le décret

(3) Tout décret pris en vertu du paragraphe (1) doit porter :

a) une mention de l'article sur lequel il se fonde;

b) de plus, dans le cas d'un fichier de renseignements personnels formé de dossiers dans chacun desquels dominent des renseignements visés au sous-alinéa 22(1)a)(ii), la mention de la loi dont il s'agit.

1980-81-82-83, ch. 111, ann. II « 18 ».

Responsibilities of Government

Personal information obtained in confidence

19 (1) Subject to subsection (2), the head of a government institution shall refuse to disclose any personal information requested under subsection 12(1) that was obtained in confidence from

(a) the government of a foreign state or an institution thereof;

(b) an international organization of states or an institution thereof;

(c) the government of a province or an institution thereof;

(d) a municipal or regional government established by or pursuant to an Act of the legislature of a province or an institution of such a government;

(e) the council, as defined in the Westbank First Nation Self-Government Agreement given effect by the *Westbank First Nation Self-Government Act*;

(e.1) the *Whitecap Dakota Government*, as defined in section 2 of the *Self-Government Treaty Recognizing the Whitecap Dakota Nation / Wapaha Ska Dakota Oyate Act*;

(f) the council of a participating First Nation as defined in subsection 2(1) of the *First Nations*

Responsabilités de l'État

Renseignements personnels obtenus à titre confidentiel

19 (1) Sous réserve du paragraphe (2), le responsable d'une institution fédérale est tenu de refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui ont été obtenus à titre confidentiel :

a) des gouvernements des États étrangers ou de leurs organismes;

b) des organisations internationales d'États ou de leurs organismes;

c) des gouvernements provinciaux ou de leurs organismes;

d) des administrations municipales ou régionales constituées en vertu de lois provinciales ou de leurs organismes;

e) du conseil, au sens de l'Accord d'autonomie gouvernementale de la première nation de Westbank mis en vigueur par la *Loi sur l'autonomie gouvernementale de la première nation de Westbank*;

e.1) du *gouvernement des Dakotas de Whitecap*, au sens de l'article 2 de la *Loi sur le traité concernant l'autonomie gouvernementale et la reconnaissance de la Nation dakota de Whitecap / Wapaha Ska Dakota Oyate*;

Jurisdiction over Education in British Columbia Act; or

(g) a *First Nation Government* or the *Anishinabek Nation Government*, as defined in section 2 of the *Anishinabek Nation Governance Agreement Act*, or an Anishinaabe Institution, within the meaning of section 1.1 of the *Agreement*, as defined in section 2 of that Act.

f) du conseil de la première nation participante, au sens du paragraphe 2(1) de la *Loi sur la compétence des premières nations en matière d'éducation en Colombie-Britannique*;

g) du *gouvernement de la première nation* ou du *gouvernement de la Nation des Anishinabes*, au sens de l'article 2 de la *Loi sur l'accord en matière de gouvernance conclu avec la Nation des Anishinabes*, ou d'une institution anishinabe, au sens de l'article 1.1 de l'*accord*, au sens de l'article 2 de cette loi.

Where disclosure authorized

(2) The head of a government institution may disclose any personal information requested under subsection 12(1) that was obtained from any government, organization or institution described in subsection (1) if the government, organization or institution from which the information was obtained

(a) consents to the disclosure; or

(b) makes the information public.

R.S., 1985, c. P-21, s. 19; 2004, c. 17, s. 19; 2006, c. 10, s. 34; 2022, c. 9, s. 5; 2023, c. 22, s. 21.

Cas où la divulgation est autorisée

(2) Le responsable d'une institution fédérale peut donner communication des renseignements personnels visés au paragraphe (1) si le gouvernement, l'organisation, l'administration ou l'organisme qui les a fournis :

a) consent à la communication;

b) rend les renseignements publics.

L.R. (1985), ch. P-21, art. 19; 2004, ch. 17, art. 19; 2006, ch. 10, art. 34; 2022, ch. 9, art. 5; 2023, ch. 22, art. 21.

Federal-provincial affairs

20 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) the disclosure of which could reasonably be expected to be injurious to the conduct by the Government of Canada of federal-provincial affairs.

1980-81-82-83, c. 111, Sch. II "20".

Affaires fédéro-provinciales

20 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) dont la divulgation risquerait vraisemblablement de porter préjudice à la conduite par le gouvernement du Canada des affaires fédéro-provinciales.

1980-81-82-83, ch. 111, ann. II « 20 ».

International affairs and defence

21 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) the disclosure of which could reasonably be expected to be injurious to the conduct of international affairs, the defence of Canada or any state allied or associated with Canada, as defined in subsection 15(2) of the *Access to Information Act*, or the efforts of Canada toward detecting, preventing or suppressing subversive or hostile activities, as defined in subsection 15(2) of the *Access to Information Act*, including, without restricting the generality of the foregoing, any such information listed in paragraphs 15(1)(a) to (i) of the *Access to Information Act*.

1980-81-82-83, c. 111, Sch. II "21".

Affaires internationales et défense

21 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) dont la divulgation risquerait vraisemblablement de porter préjudice à la conduite des affaires internationales, à la défense du Canada ou d'États alliés ou associés avec le Canada, au sens du paragraphe 15(2) de la *Loi sur l'accès à l'information*, ou à ses efforts de détection, de prévention ou de répression d'activités hostiles ou subversives, au sens du paragraphe 15(2) de la même loi, notamment les renseignements visés à ses alinéas 15(1)a) à i).

1980-81-82-83, ch. 111, ann. II « 21 ».

Law enforcement and investigation

22 (1) The head of a government institution may refuse to disclose any personal information requested under subsection 12(1)

Enquêtes

22 (1) Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) :

(a) that was obtained or prepared by any government institution, or part of any government institution, that is an investigative body specified in the regulations in the course of lawful investigations pertaining to

(i) the detection, prevention or suppression of crime,

(ii) the enforcement of any law of Canada or a province, or

(iii) activities suspected of constituting threats to the security of Canada within the meaning of the *Canadian Security Intelligence Service Act*,

if the information came into existence less than twenty years prior to the request;

(b) the disclosure of which could reasonably be expected to be injurious to the enforcement of any law of Canada or a province or the conduct of lawful investigations, including, without restricting the generality of the foregoing, any such information

(i) relating to the existence or nature of a particular investigation,

(ii) that would reveal the identity of a confidential source of information, or

(iii) that was obtained or prepared in the course of an investigation; or

(c) the disclosure of which could reasonably be expected to be injurious to the security of penal institutions.

a) soit qui remontent à moins de vingt ans lors de la demande et qui ont été obtenus ou préparés par une institution fédérale, ou par une subdivision d'une institution, qui constitue un organisme d'enquête déterminé par règlement, au cours d'enquêtes licites ayant trait :

(i) à la détection, la prévention et la répression du crime,

(ii) aux activités destinées à faire respecter les lois fédérales ou provinciales,

(iii) aux activités soupçonnées de constituer des menaces envers la sécurité du Canada au sens de la *Loi sur le Service canadien du renseignement de sécurité*;

b) soit dont la divulgation risquerait vraisemblablement de nuire aux activités destinées à faire respecter les lois fédérales ou provinciales ou au déroulement d'enquêtes licites, notamment :

(i) des renseignements relatifs à l'existence ou à la nature d'une enquête déterminée,

(ii) des renseignements qui permettraient de remonter à une source de renseignements confidentielle,

(iii) des renseignements obtenus ou préparés au cours d'une enquête;

c) soit dont la divulgation risquerait vraisemblablement de nuire à la sécurité des établissements pénitentiaires.

Policing services for provinces or municipalities

(2) The head of a government institution shall refuse to disclose any personal information requested under subsection 12(1) that was obtained or prepared by the Royal Canadian Mounted Police while performing policing services for a province or municipality pursuant to an arrangement made under section 20 of the *Royal Canadian Mounted Police Act*, where the Government of Canada has, on the request of the province or municipality, agreed not to disclose such information.

Fonctions de police provinciale ou municipale

(2) Le responsable d'une institution fédérale est tenu de refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui ont été obtenus ou préparés par la Gendarmerie royale du Canada, dans l'exercice de fonctions de police provinciale ou municipale, qui lui sont conférées par une entente conclue sous le régime de l'article 20 de la *Loi sur la Gendarmerie royale du Canada*, si, à la demande de la province ou de la municipalité, le gouvernement du Canada a consenti à ne pas divulguer ces renseignements.

Definition of *investigation*

(3) For the purposes of paragraph (1)(b), ***investigation*** means an investigation that

(a) pertains to the administration or enforcement of an Act of Parliament;

Définition de *enquête*

(3) Pour l'application de l'alinéa (1)b), ***enquête*** s'entend de celle qui :

a) se rapporte à l'application d'une loi fédérale;

b) est autorisée sous le régime d'une loi fédérale;

(b) is authorized by or pursuant to an Act of Parliament; or

(c) is within a class of investigations specified in the regulations.

1980-81-82-83, c. 111, Sch. II "22"; 1984, c. 21, s. 90, c. 40, s. 79(E).

c) fait partie d'une catégorie d'enquêtes précisée dans les règlements.

1980-81-82-83, ch. 111, ann. II « 22 »; 1984, ch. 21, art. 90, ch. 40, art. 79(A).

Information obtained by Privacy Commissioner

22.1 (1) The Privacy Commissioner shall refuse to disclose any personal information requested under this Act that was obtained or created by the Commissioner or on the Commissioner's behalf in the course of an investigation conducted by, or under the authority of, the Commissioner or that was obtained by the Commissioner in the course of a consultation with the Information Commissioner under subsection 36(1.1) or section 36.2 of the *Access to Information Act*.

Exception

(2) However, the Commissioner shall not refuse under subsection (1) to disclose any personal information that was created by the Commissioner or on the Commissioner's behalf in the course of an investigation conducted by, or under the authority of, the Commissioner once the investigation and all related proceedings, if any, are finally concluded.

2006, c. 9, s. 183; 2019, c. 18, s. 48.

Renseignements obtenus par le Commissaire à la protection de la vie privée

22.1 (1) Le Commissaire à la protection de la vie privée est tenu de refuser de communiquer les renseignements personnels demandés en vertu de la présente loi qui ont été créés ou obtenus par lui ou pour son compte dans le cadre de toute enquête faite par lui ou sous son autorité, ou qui ont été obtenus par lui dans le cadre d'une consultation par le Commissaire à l'information en vertu du paragraphe 36(1.1) ou de l'article 36.2 de la *Loi sur l'accès à l'information*.

Exception

(2) Toutefois, il ne peut s'autoriser du paragraphe (1) pour refuser de communiquer les renseignements personnels créés par lui ou pour son compte dans le cadre de toute enquête faite par lui ou sous son autorité une fois que l'enquête et toute instance afférente sont terminées.

2006, ch. 9, art. 183; 2019, ch. 18, art. 48.

Public Sector Integrity Commissioner

22.2 The Public Sector Integrity Commissioner shall refuse to disclose any personal information requested under subsection 12(1) that was obtained or created by him or her or on his or her behalf in the course of an investigation into a disclosure made under the *Public Servants Disclosure Protection Act* or an investigation commenced under section 33 of that Act.

2005, c. 46, s. 58.

Commissaire à l'intégrité du secteur public

22.2 Le commissaire à l'intégrité du secteur public est tenu de refuser la communication des renseignements personnels demandés au titre du paragraphe 12(1) qui ont été créés ou obtenus par lui ou pour son compte dans le cadre de toute enquête menée sur une divulgation faite au titre de la *Loi sur la protection des fonctionnaires divulgateurs d'actes répréhensibles* ou de toute enquête commencée au titre de l'article 33 de cette loi.

2005, ch. 46, art. 58.

Public Servants Disclosure Protection Act

22.3 The head of a government institution shall refuse to disclose personal information requested under subsection 12(1) that was created for the purpose of making a disclosure under the *Public Servants Disclosure Protection Act* or in the course of an investigation into a disclosure under that Act.

2005, c. 46, s. 58.

Loi sur la protection des fonctionnaires divulgateurs d'actes répréhensibles

22.3 Le responsable d'une institution fédérale est tenu de refuser la communication des renseignements personnels demandés au titre du paragraphe 12(1) qui ont été créés en vue de faire une divulgation au titre de la *Loi sur la protection des fonctionnaires divulgateurs d'actes répréhensibles* ou dans le cadre d'une enquête menée sur une divulgation en vertu de cette loi.

2005, ch. 46, art. 58.

Secretariat of National Security and Intelligence Committee of Parliamentarians

22.4 The Secretariat of the National Security and Intelligence Committee of Parliamentarians shall refuse to disclose personal information requested under subsection 12(1) that was obtained or created by it or on its behalf in the course of assisting the National Security and Intelligence Committee of Parliamentarians in fulfilling its mandate.

2017, c. 15, s. 45.

Secrétariat du Comité des parlementaires sur la sécurité nationale et le renseignement

22.4 Le Secrétariat du Comité des parlementaires sur la sécurité nationale et le renseignement est tenu de refuser la communication des renseignements personnels demandés au titre du paragraphe 12(1) qui ont été créés ou obtenus par lui ou pour son compte dans le cadre du soutien qu'il apporte au Comité des parlementaires sur la sécurité nationale et le renseignement dans l'exercice de son mandat.

2017, ch. 15, art. 45.

Security clearances

23 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) that was obtained or prepared by an investigative body specified in the regulations for the purpose of determining whether to grant security clearances

(a) required by the Government of Canada or a government institution in respect of individuals employed by or performing services for the Government of Canada or a government institution, individuals employed by or performing services for a person or body performing services for the Government of Canada or a government institution, individuals seeking to be so employed or seeking to perform those services, or

(b) required by the government of a province or a foreign state or an institution thereof,

if disclosure of the information could reasonably be expected to reveal the identity of the individual who furnished the investigative body with the information.

1980-81-82-83, c. 111, Sch. II "23".

Enquêtes de sécurité

23 Le responsable d'une institution fédérale peut, dans les cas où leur communication risquerait vraisemblablement d'entraîner la divulgation de l'identité de l'informateur à l'origine des renseignements en question, refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) et qui ont été recueillis ou préparés, par un organisme d'enquête déterminé par règlement, lors des enquêtes de sécurité :

a) qu'exige le gouvernement fédéral ou une institution fédérale à l'égard des individus qu'ils emploient ou qu'emploient des personnes ou organismes qui leur prêtent leurs services, des individus qui prêtent leurs services au gouvernement ou à l'institution ou à ces personnes ou organismes ou de ceux qui sont candidats à ces emplois ou désireux de prêter ces services;

b) qu'exigent des administrations provinciales ou étrangères ou leurs organismes.

1980-81-82-83, ch. 111, ann. II « 23 ».

Individuals sentenced for an offence

24 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) that was collected or obtained by the Correctional Service of Canada or the Parole Board of Canada while the individual who made the request was under sentence for an offence against any Act of Parliament, if the disclosure could reasonably be expected to

(a) lead to a serious disruption of the individual's institutional, parole or statutory release program; or

(b) reveal information about the individual originally obtained on a promise of confidentiality, express or implied.

R.S., 1985, c. P-21, s. 24; 1994, c. 26, s. 56; 2012, c. 1, s. 160.

Individus condamnés pour une infraction

24 Le responsable d'une institution fédérale peut refuser à un individu la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui ont été recueillis ou obtenus par le Service correctionnel du Canada ou la Commission des libérations conditionnelles du Canada pendant qu'il était sous le coup d'une condamnation à la suite d'une infraction à une loi fédérale, dans les cas où la communication risquerait vraisemblablement :

a) soit d'avoir de graves conséquences sur son programme pénitentiaire, son programme de libération conditionnelle ou son programme de libération d'office;

b) soit d'entraîner la divulgation de renseignements qui, à l'origine, ont été obtenus expressément ou implicitement à titre confidentiel.

L.R. (1985), ch. P-21, art. 24; 1994, ch. 26, art. 56; 2012, ch. 1, art. 160.

Safety of individuals

25 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) the disclosure of which could reasonably be expected to threaten the safety of individuals.

1980-81-82-83, c. 111, Sch. II "25".

Sécurité des individus

25 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) dont la divulgation risquerait vraisemblablement de nuire à la sécurité des individus.

1980-81-82-83, ch. 111, ann. II « 25 ».

Personal Information

Information about another individual

26 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) about an individual other than the individual who made the request, and shall refuse to disclose such information where the disclosure is prohibited under section 8.

1980-81-82-83, c. 111, Sch. II "26".

Renseignements personnels

Renseignements concernant un autre individu

26 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui portent sur un autre individu que celui qui fait la demande et il est tenu de refuser cette communication dans les cas où elle est interdite en vertu de l'article 8.

1980-81-82-83, ch. 111, ann. II « 26 ».

Privilege and Professional Secrecy

Protected information — solicitors, advocates and notaries

27 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) that is subject to solicitor-client privilege or the professional secrecy of advocates and notaries or to litigation privilege.

R.S., 1985, c. P-21, s. 27; 2019, c. 18, s. 49.

Protected information — patents and trademarks

27.1 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) that is subject to the privilege set out in section 16.1 of the *Patent Act* or section 51.13 of the *Trademarks Act*.

2018, c. 27, s. 274; 2014, c. 20, s. 366(E).

Secret professionnel et privilège

Renseignements protégés : avocats et notaires

27 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui sont protégés par le secret professionnel de l'avocat ou du notaire ou par le privilège relatif au litige.

L.R. (1985), ch. P-21, art. 27; 2019, ch. 18, art. 49.

Renseignements protégés : brevets et marques de commerce

27.1 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui sont protégés aux termes des articles 16.1 de la *Loi sur les brevets* ou 51.13 de la *Loi sur les marques de commerce*.

2018, ch. 27, art. 274; 2014, ch. 20, art. 366(A).

Medical Records

Medical record

28 The head of a government institution may refuse to disclose any personal information requested under subsection 12(1) that relates to the physical or mental health of the individual who requested it where the examination of the information by the individual would be contrary to the best interests of the individual.

1980-81-82-83, c. 111, Sch. II "28".

Dossiers médicaux

Dossiers médicaux

28 Le responsable d'une institution fédérale peut refuser la communication des renseignements personnels demandés en vertu du paragraphe 12(1) qui portent sur l'état physique ou mental de l'individu qui en demande communication, dans les cas où la prise de connaissance par l'individu concerné des renseignements qui y figurent desservirait celui-ci.

1980-81-82-83, ch. 111, ann. II « 28 ».

Complaints

Receipt and investigation of complaints

29 (1) Subject to this Act, the Privacy Commissioner shall receive and investigate complaints

(a) from individuals who allege that personal information about themselves held by a government institution has been used or disclosed otherwise than in accordance with section 7 or 8;

(b) from individuals who have been refused access to personal information requested under subsection 12(1);

(c) from individuals who allege that they are not being accorded the rights to which they are entitled under subsection 12(2) or that corrections of personal information requested under paragraph 12(2)(a) are being refused without justification;

(d) from individuals who have requested access to personal information in respect of which a time limit has been extended pursuant to section 15 where they consider the extension unreasonable;

(e) from individuals who have not been given access to personal information in the official language requested by the individuals under subsection 17(2);

(e.1) from individuals who have not been given access to personal information in an alternative format pursuant to a request made under subsection 17(3);

(f) from individuals who have been required to pay a fee that they consider inappropriate;

(g) in respect of the index referred to in subsection 11(1); or

(h) in respect of any other matter relating to

(i) the collection, retention or disposal of personal information by a government institution,

(ii) the use or disclosure of personal information under the control of a government institution, or

(iii) requesting or obtaining access under subsection 12(1) to personal information.

Plaintes

Réception des plaintes et enquêtes

29 (1) Sous réserve des autres dispositions de la présente loi, le Commissaire à la protection de la vie privée reçoit les plaintes et fait enquête sur les plaintes :

a) déposées par des individus qui prétendent que des renseignements personnels les concernant et détenus par une institution fédérale ont été utilisés ou communiqués contrairement aux articles 7 ou 8;

b) déposées par des individus qui se sont vu refuser la communication de renseignements personnels, demandés en vertu du paragraphe 12(1);

c) déposées par des individus qui se prétendent lésés des droits que leur accorde le paragraphe 12(2) ou qui considèrent comme non fondé le refus d'effectuer les corrections demandées en vertu de l'alinéa 12(2)a);

d) déposées par des individus qui ont demandé des renseignements personnels dont les délais de communication ont été prorogés en vertu de l'article 15 et qui considèrent la prorogation comme abusive;

e) déposées par des individus qui n'ont pas reçu communication de renseignements personnels dans la langue officielle qu'ils ont demandée en vertu du paragraphe 17(2);

e.1) déposées par des individus qui n'ont pas reçu communication des renseignements personnels sur un support de substitution en application du paragraphe 17(3);

f) déposées par des individus qui considèrent comme contre-indiqué le versement exigé en vertu des règlements;

g) portant sur le répertoire visé au paragraphe 11(1);

h) portant sur toute autre question relative à :

(i) la collecte, la conservation ou le retrait par une institution fédérale des renseignements personnels,

(ii) l'usage ou la communication des renseignements personnels qui relèvent d'une institution fédérale,

(iii) la demande ou l'obtention de renseignements personnels en vertu du paragraphe l2(1).

Complaints submitted on behalf of complainants

(2) Nothing in this Act precludes the Privacy Commissioner from receiving and investigating complaints of a nature described in subsection (1) that are submitted by a person authorized by the complainant to act on behalf of the complainant, and a reference to a complainant in any other section includes a reference to a person so authorized.

Entremise de représentants

(2) Le Commissaire à la protection de la vie privée peut recevoir les plaintes visées au paragraphe (1) par l'intermédiaire d'un représentant du plaignant. Dans les autres articles de la présente loi, les dispositions qui concernent le plaignant concernent également son représentant.

Privacy Commissioner may initiate complaint

(3) Where the Privacy Commissioner is satisfied that there are reasonable grounds to investigate a matter under this Act, the Commissioner may initiate a complaint in respect thereof.

R.S., 1985, c. P-21, s. 29; 1992, c. 21, s. 37.

Plaintes émanant du Commissaire

(3) Le Commissaire à la protection de la vie privée peut lui-même prendre l'initiative d'une plainte s'il a des motifs raisonnables de croire qu'une enquête devrait être menée sur une question relative à l'application de la présente loi.

L.R. (1985), ch. P-21, art. 29; 1992, ch. 21, art. 37.

Written complaint

30 A complaint under this Act shall be made to the Privacy Commissioner in writing unless the Commissioner authorizes otherwise.

1980-81-82-83, c. 111, Sch. II "30".

Plaintes écrites

30 Les plaintes sont, sauf dispense accordée par le Commissaire à la protection de la vie privée, déposées devant lui par écrit.

1980-81-82-83, ch. 111, ann. II « 30 ».

Investigations

Notice of intention to investigate

31 Before commencing an investigation of a complaint under this Act, the Privacy Commissioner shall notify the head of the government institution concerned of the intention to carry out the investigation and shall inform the head of the institution of the substance of the complaint.

1980-81-82-83, c. 111, Sch. II "31".

Enquêtes

Avis d'enquête

31 Le Commissaire à la protection de la vie privée, avant de procéder aux enquêtes prévues par la présente loi, avise le responsable de l'institution fédérale concernée de son intention d'enquêter et lui fait connaître l'objet de la plainte.

1980-81-82-83, ch. 111, ann. II « 31 ».

Regulation of procedure

32 Subject to this Act, the Privacy Commissioner may determine the procedure to be followed in the performance of any duty or function of the Commissioner under this Act.

1980-81-82-83, c. 111, Sch. II "32".

Procédure

32 Sous réserve des autres dispositions de la présente loi, le Commissaire à la protection de la vie privée peut établir la procédure à suivre dans l'exercice de ses pouvoirs et fonctions.

1980-81-82-83, ch. 111, ann. II « 32 ».

Investigations in private

33 (1) Every investigation of a complaint under this Act by the Privacy Commissioner shall be conducted in private.

Secret des enquêtes

33 (1) Les enquêtes menées sur les plaintes par le Commissaire à la protection de la vie privée sont secrètes.

Right to make representation

(2) In the course of an investigation of a complaint under this Act by the Privacy Commissioner, the person who made the complaint and the head of the government institution concerned shall be given an opportunity to make representations to the Commissioner, but no one is entitled as of right to be present during, to have access to

Droit de présenter des observations

(2) Au cours d'une enquête relative à une plainte, le plaignant et le responsable de l'institution fédérale concernée doivent avoir la possibilité de présenter leurs observations au Commissaire à la protection de la vie privée; toutefois, nul n'a le droit absolu d'être présent lorsqu'une

or to comment on representations made to the Commissioner by any other person.

1980-81-82-83, c. 111, Sch. II "33".

Powers of Privacy Commissioner in carrying out investigations

34 (1) The Privacy Commissioner has, in relation to the carrying out of the investigation of any complaint under this Act, power

(a) to summon and enforce the appearance of persons before the Privacy Commissioner and compel them to give oral or written evidence on oath and to produce such documents and things as the Commissioner deems requisite to the full investigation and consideration of the complaint, in the same manner and to the same extent as a superior court of record;

(b) to administer oaths;

(c) to receive and accept such evidence and other information, whether on oath or by affidavit or otherwise, as the Privacy Commissioner sees fit, whether or not the evidence or information is or would be admissible in a court of law;

(d) to enter any premises occupied by any government institution on satisfying any security requirements of the institution relating to the premises;

(e) to converse in private with any person in any premises entered pursuant to paragraph (d) and otherwise carry out therein such inquiries within the authority of the Privacy Commissioner under this Act as the Commissioner sees fit; and

(f) to examine or obtain copies of or extracts from books or other records found in any premises entered pursuant to paragraph (d) containing any matter relevant to the investigation.

Access to information

(2) Despite any other Act of Parliament, any privilege under the law of evidence, solicitor-client privilege or the professional secrecy of advocates and notaries and litigation privilege, and subject to subsection (2.1), the Privacy Commissioner may, during the investigation of any complaint under this Act, examine any information recorded in any form under the control of a government institution, other than a confidence of the Queen's Privy Council for Canada to which subsection 70(1) applies, and no information that the Commissioner may examine under this subsection may be withheld from the Commissioner on any grounds.

autre personne présente des observations au Commissaire, ni d'en recevoir communication ou de faire des commentaires à leur sujet.

1980-81-82-83, ch. 111, ann. II « 33 ».

Pouvoirs du Commissaire à la protection de la vie privée pour la tenue des enquêtes

34 (1) Le Commissaire à la protection de la vie privée a, pour l'instruction des plaintes déposées en vertu de la présente loi, le pouvoir :

a) d'assigner et de contraindre des témoins à comparaître devant lui, à déposer verbalement ou par écrit sous la foi du serment et à produire les pièces qu'il juge indispensables pour instruire et examiner à fond les plaintes dont il est saisi, de la même façon et dans la même mesure qu'une cour supérieure d'archives;

b) de faire prêter serment;

c) de recevoir des éléments de preuve ou des renseignements par déclaration verbale ou écrite sous serment ou par tout autre moyen qu'il estime indiqué, indépendamment de leur admissibilité devant les tribunaux;

d) de pénétrer dans les locaux occupés par une institution fédérale, à condition de satisfaire aux normes de sécurité établies par l'institution pour ces locaux;

e) de s'entretenir en privé avec toute personne se trouvant dans les locaux visés à l'alinéa d) et d'y mener, dans le cadre de la compétence que lui confère la présente loi, les enquêtes qu'il estime nécessaires;

f) d'examiner ou de se faire remettre des copies ou des extraits des livres ou autres documents contenant des éléments utiles à l'enquête et trouvés dans les locaux visés à l'alinéa d).

Accès aux renseignements

(2) Malgré toute autre loi fédérale, toute immunité reconnue par le droit de la preuve, le secret professionnel de l'avocat ou du notaire et le privilège relatif au litige, mais sous réserve du paragraphe (2.1), le Commissaire à la protection de la vie privée a, pour les enquêtes qu'il mène en vertu de la présente loi, accès à tous les renseignements, quels que soient leur forme et leur support, qui relèvent d'une institution fédérale, à l'exception des renseignements confidentiels du Conseil privé de la Reine pour le Canada auxquels s'applique le paragraphe 70(1); aucun des renseignements auxquels il a accès en vertu du présent paragraphe ne peut, pour quelque motif que ce soit, lui être refusé.

Protected information — solicitors, advocates and notaries

(2.1) The Privacy Commissioner may examine information that is subject to solicitor-client privilege or the professional secrecy of advocates and notaries or to litigation privilege only if the head of a government institution refuses to disclose the information under section 27.

For greater certainty

(2.2) For greater certainty, the disclosure by the head of a government institution to the Privacy Commissioner of information that is subject to solicitor-client privilege or the professional secrecy of advocates and notaries or to litigation privilege does not constitute a waiver of those privileges or that professional secrecy.

Evidence in other proceedings

(3) Except in a prosecution of a person for an offence under section 131 of the *Criminal Code* (perjury) in respect of a statement made under this Act, in a prosecution for an offence under this Act or in a review before the Court under this Act or an appeal therefrom, evidence given by a person in proceedings under this Act and evidence of the existence of the proceedings is inadmissible against that person in a court or in any other proceedings.

Witness fees

(4) Any person summoned to appear before the Privacy Commissioner pursuant to this section is entitled in the discretion of the Commissioner to receive the like fees and allowances for so doing as if summoned to attend before the Federal Court.

Return of documents, etc.

(5) Any document or thing produced pursuant to this section by any person or government institution shall be returned by the Privacy Commissioner within ten days after a request is made to the Commissioner by that person or government institution, but nothing in this subsection precludes the Commissioner from again requiring its production in accordance with this section.

R.S., 1985, c. P-21, s. 34; R.S., 1985, c. 27 (1st Supp.), s. 187; 2019, c. 18, s. 50.

Findings and recommendations of Privacy Commissioner

35 (1) If, on investigating a complaint under this Act in respect of personal information, the Privacy Commissioner finds that the complaint is well-founded, the Commissioner shall provide the head of the government institution that has control of the personal information with a report containing

Renseignements protégés : avocats et notaires

(2.1) Le Commissaire à la protection de la vie privée n'a accès qu'aux renseignements protégés par le secret professionnel de l'avocat ou du notaire ou par le privilège relatif au litige dont le responsable d'une institution fédérale refuse la communication au titre de l'article 27.

Précision

(2.2) Il est entendu que la communication, au Commissaire à la protection de la vie privée, par le responsable d'une institution fédérale, de renseignements protégés par le secret professionnel de l'avocat ou du notaire ou par le privilège relatif au litige ne constitue pas une renonciation au secret professionnel ou au privilège.

Inadmissibilité de la preuve dans d'autres procédures

(3) Sauf les cas où une personne est poursuivie soit pour une infraction à l'article 131 du *Code criminel* (parjure) se rapportant à une déclaration faite en vertu de la présente loi, soit pour infraction à la présente loi, ou sauf les cas de recours prévus par la présente loi devant la Cour ou les cas d'appel de la décision rendue par la Cour, les dépositions faites au cours de procédures prévues par la présente loi ou le fait de l'existence de ces procédures ne sont pas admissibles contre le déposant devant les tribunaux ni dans aucune autre procédure.

Frais des témoins

(4) Les témoins assignés à comparaître devant le Commissaire à la protection de la vie privée en vertu du présent article peuvent recevoir, si le Commissaire le juge indiqué, les frais et indemnités accordés aux témoins assignés devant la Cour fédérale.

Renvoi des documents, etc.

(5) Les personnes ou les institutions fédérales qui produisent des pièces demandées en vertu du présent article peuvent exiger du Commissaire à la protection de la vie privée qu'il leur renvoie ces pièces dans les dix jours suivant la requête qu'elles lui présentent à cette fin, mais rien n'empêche le Commissaire d'en réclamer une nouvelle production.

L.R. (1985), ch. P-21, art. 34; L.R. (1985), ch. 27 (1er suppl.), art. 187; 2019, ch. 18, art. 50.

Conclusions et recommandations du Commissaire à la protection de la vie privée

35 (1) Dans les cas où il conclut au bien-fondé d'une plainte portant sur des renseignements personnels, le Commissaire à la protection de la vie privée adresse au responsable de l'institution fédérale de qui relèvent les renseignements personnels un rapport où :

(a) the findings of the investigation and any recommendations that the Commissioner considers appropriate; and

(b) where appropriate, a request that, within a time specified therein, notice be given to the Commissioner of any action taken or proposed to be taken to implement the recommendations contained in the report or reasons why no such action has been or is proposed to be taken.

a) il présente les conclusions de son enquête ainsi que les recommandations qu'il juge indiquées;

b) il demande, s'il le juge à propos, au responsable de lui donner avis, dans un délai déterminé, soit des mesures prises ou envisagées pour la mise en œuvre de ses recommandations, soit des motifs invoqués pour ne pas y donner suite.

Report to complainant

(2) The Privacy Commissioner shall, after investigating a complaint under this Act, report to the complainant the results of the investigation, but where a notice has been requested under paragraph (1)(b) no report shall be made under this subsection until the expiration of the time within which the notice is to be given to the Commissioner.

Compte rendu au plaignant

(2) Le Commissaire à la protection de la vie privée rend compte au plaignant des conclusions de son enquête; toutefois, dans les cas prévus à l'alinéa (1)b), le Commissaire à la protection de la vie privée ne peut faire son compte rendu qu'après l'expiration du délai imparti au responsable de l'institution fédérale.

Matter to be included in report to complainant

(3) Where a notice has been requested under paragraph (1)(b) but no such notice is received by the Commissioner within the time specified therefor or the action described in the notice is, in the opinion of the Commissioner, inadequate or inappropriate or will not be taken in a reasonable time, the Commissioner shall so advise the complainant in his report under subsection (2) and may include in the report such comments on the matter as he thinks fit.

Éléments à inclure dans le compte rendu

(3) Le Commissaire à la protection de la vie privée mentionne également dans son compte rendu au plaignant, s'il y a lieu, le fait que, dans les cas prévus à l'alinéa (1)b), il n'a pas reçu d'avis dans le délai imparti ou que les mesures indiquées dans l'avis sont, selon lui, insuffisantes, inadaptées ou non susceptibles d'être prises en temps utile. Il peut en outre y inclure tous commentaires qu'il estime utiles.

Access to be given

(4) Where, pursuant to a request under paragraph (1)(b), the head of a government institution gives notice to the Privacy Commissioner that access to personal information will be given to a complainant, the head of the institution shall give the complainant access to the information forthwith on giving the notice.

Communication accordée

(4) Dans les cas où il fait suite à la demande formulée par le Commissaire à la protection de la vie privée en vertu de l'alinéa (1)b) en avisant le Commissaire qu'il donnera communication de renseignements personnels au plaignant, le responsable d'une institution fédérale est tenu de donner cette communication sur le champ.

Right of review

(5) Where, following the investigation of a complaint relating to a refusal to give access to personal information under this Act, access is not given to the complainant, the Privacy Commissioner shall inform the complainant that the complainant has the right to apply to the Court for a review of the matter investigated.

1980-81-82-83, c. 111, Sch. II "35".

Recours en révision

(5) Dans les cas où l'enquête portait sur un refus de communication et que, à l'issue de l'enquête, communication n'est pas donnée au plaignant, le Commissaire à la protection de la vie privée informe celui-ci de l'existence de son droit de recours en révision devant la Cour.

1980-81-82-83, ch. 111, ann. II « 35 ».

Review of Exempt Banks

Investigation of exempt banks

36 (1) The Privacy Commissioner may, from time to time at the discretion of the Commissioner, carry out investigations of the files contained in personal information banks designated as exempt banks under section 18.

Sections 31 to 34 apply

(2) Sections 31 to 34 apply, where appropriate and with such modifications as the circumstances require, in respect of investigations carried out under subsection (1).

Report of findings and recommendations

(3) If, following an investigation under subsection (1), the Privacy Commissioner considers that any file contained in a personal information bank should not be contained therein within the terms of the order designating the bank as an exempt bank, the Commissioner shall provide the head of the government institution that has control of the bank with a report containing

(a) the findings of the Commissioner and any recommendations that the Commissioner considers appropriate; and

(b) where appropriate, a request that, within a time specified therein, notice be given to the Commissioner of any action taken or proposed to be taken to implement the recommendations or reasons why no such action has been or is proposed to be taken.

Reports to be included in annual or special reports to Parliament

(4) Any report made by the Privacy Commissioner under subsection (3), together with any notice given to the Commissioner in response thereto, may be included in a report made pursuant to section 38 or 39.

Review of exempt banks by Court

(5) Where the Privacy Commissioner requests a notice under paragraph (3)(b) in respect of any file contained in a personal information bank designated under section 18 as an exempt bank and no notice is received within the time specified therefor or the action described in the notice is, in the opinion of the Commissioner, inadequate or inappropriate or will not be taken in a reasonable time, the Privacy Commissioner may make an application to the Court under section 43.

1980-81-82-83, c. 111, Sch. II "36".

Examen des fichiers inconsultables

Enquêtes sur les fichiers inconsultables

36 (1) Le Commissaire à la protection de la vie privée peut, à son appréciation, tenir des enquêtes sur les dossiers versés dans les fichiers inconsultables classés comme tels en vertu de l'article 18.

Application des art. 31 à 34

(2) Les articles 31 à 34 s'appliquent, si c'est indiqué et compte tenu des adaptations de circonstance, aux enquêtes menées en vertu du paragraphe (1).

Rapport des conclusions et recommandations

(3) Dans les cas où, à l'issue de son enquête, il considère que les dispositions du décret de classement ne justifient pas la présence de certains dossiers dans le fichier inconsultable, le Commissaire à la protection de la vie privée adresse au responsable de l'institution fédérale de qui relève le fichier un rapport où :

a) il présente ses conclusions ainsi que les recommandations qu'il juge indiquées;

b) il demande, s'il le juge à propos, de lui donner avis, dans un délai déterminé, soit des mesures prises ou envisagées pour la mise en œuvre de ses recommandations, soit des motifs invoqués pour ne pas y donner suite.

Incorporation des rapports

(4) Les rapports établis par le Commissaire à la protection de la vie privée en vertu du paragraphe (3), de même que les réponses qu'il a obtenues, peuvent être incorporés dans les rapports prévus aux articles 38 ou 39.

Révision des fichiers inconsultables par la Cour

(5) Dans les cas où il a demandé l'avis prévu à l'alinéa (3)b), mais qu'il ne l'a pas reçu dans le délai imparti ou que les mesures indiquées dans l'avis sont, selon lui, insuffisantes, inadaptées ou non susceptibles d'être prises en temps utile, le Commissaire à la protection de la vie privée peut exercer un recours devant la Cour en vertu de l'article 43.

1980-81-82-83, ch. 111, ann. II « 36 ».

Review of Compliance with Sections 4 to 8

Investigation in respect of sections 4 to 8

37 (1) The Privacy Commissioner may, from time to time at the discretion of the Commissioner, carry out investigations in respect of personal information under the control of government institutions to ensure compliance with sections 4 to 8.

Sections 31 to 34 apply

(2) Sections 31 to 34 apply, where appropriate and with such modifications as the circumstances require, in respect of investigations carried out under subsection (1).

Report of findings and recommendations

(3) If, following an investigation under subsection (1), the Privacy Commissioner considers that a government institution has not complied with sections 4 to 8, the Commissioner shall provide the head of the institution with a report containing the findings of the investigation and any recommendations that the Commissioner considers appropriate.

Reports to be included in annual or special reports

(4) Any report made by the Privacy Commissioner under subsection (3) may be included in a report made pursuant to section 38 or 39.

Coordination with Review Agency

(5) The Privacy Commissioner may coordinate his or her activities under subsection (1) with those of the National Security and Intelligence Review Agency under any of paragraphs 8(1)(a) to (c) of the *National Security and Intelligence Review Agency Act* to avoid any unnecessary duplication of work.

R.S., 1985, c. P-21, s. 37; 2019, c. 13, s. 37.1.

Contrôle d'application des articles 4 à 8

Enquêtes

37 (1) Pour le contrôle d'application des articles 4 à 8, le Commissaire à la protection de la vie privée peut, à son appréciation, tenir des enquêtes quant aux renseignements personnels qui relèvent des institutions fédérales.

Application des art. 31 à 34

(2) Les articles 31 à 34 s'appliquent, si c'est indiqué et compte tenu des adaptations de circonstance, aux enquêtes menées en vertu du paragraphe (1).

Rapport des conclusions et recommandations du Commissaire

(3) Le Commissaire à la protection de la vie privée, s'il considère à l'issue de son enquête qu'une institution fédérale n'a pas appliqué les articles 4 à 8, adresse au responsable de l'institution un rapport où il présente ses conclusions ainsi que les recommandations qu'il juge indiquées.

Incorporation des rapports

(4) Les rapports établis par le Commissaire à la protection de la vie privée en vertu du paragraphe (3) peuvent être incorporés dans les rapports prévus aux articles 38 ou 39.

Coordination avec l'Office de surveillance

(5) Le Commissaire à la protection de la vie privée peut coordonner les activités qu'il mène en vertu du paragraphe (1) avec celles que mène l'Office de surveillance des activités en matière de sécurité nationale et de renseignement au titre de l'un ou l'autre des alinéas 8(1)a) à c) de la *Loi sur l'Office de surveillance des activités en matière de sécurité nationale et de renseignement* pour éviter tout double emploi.

L.R. (1985), ch. P-21, art. 37; 2019, ch. 13, art. 37.1.

Reports to Parliament

Annual report

38 The Privacy Commissioner shall, within three months after the termination of each financial year, submit an annual report to Parliament on the activities of the office during that financial year.

1980-81-82-83, c. 111, Sch. II "38".

Rapports au Parlement

Rapport annuel

38 Dans les trois mois suivant la fin de chaque exercice, le Commissaire à la protection de la vie privée présente au Parlement le rapport des activités du commissariat au cours de l'exercice.

1980-81-82-83, ch. 111, ann. II « 38 ».

Special reports

39 (1) The Privacy Commissioner may, at any time, make a special report to Parliament referring to and commenting on any matter within the scope of the powers, duties and functions of the Commissioner where, in the opinion of the Commissioner, the matter is of such urgency or importance that a report thereon should not be deferred until the time provided for transmission of the next annual report of the Commissioner under section 38.

Where investigation made

(2) Any report made pursuant to subsection (1) that relates to an investigation under this Act shall be made only after the procedures set out in section 35, 36 or 37 have been followed in respect of the investigation.

1980-81-82-83, c. 111, Sch. II "39".

Transmission of reports

40 (1) Every report to Parliament made by the Privacy Commissioner under section 38 or 39 shall be made by being transmitted to the Speaker of the Senate and to the Speaker of the House of Commons for tabling in those Houses.

Reference to Parliamentary committee

(2) Every report referred to in subsection (1) shall, after it is transmitted for tabling pursuant to that subsection, be referred to the committee designated or established by Parliament for the purpose of subsection 75(1).

1980-81-82-83, c. 111, Sch. II "40".

Rapports spéciaux

39 (1) Le Commissaire à la protection de la vie privée peut, à toute époque de l'année, présenter au Parlement un rapport spécial sur toute question relevant de ses pouvoirs et fonctions et dont l'urgence ou l'importance sont telles, selon lui, qu'il serait contre-indiqué d'en différer le compte rendu jusqu'à l'époque du rapport annuel suivant.

Cas des enquêtes

(2) Le Commissaire à la protection de la vie privée ne peut présenter de rapport spécial sur des enquêtes qu'après observation des formalités prévues à leur sujet aux articles 35, 36 ou 37.

1980-81-82-83, ch. 111, ann. II « 39 ».

Remise des rapports

40 (1) La présentation des rapports du Commissaire à la protection de la vie privée au Parlement s'effectue par remise au président du Sénat et à celui de la Chambre des communes pour dépôt devant leurs chambres respectives.

Renvoi en comité

(2) Les rapports visés au paragraphe (1) sont, après leur dépôt, renvoyés devant le comité désigné ou constitué par le Parlement en application du paragraphe 75(1).

1980-81-82-83, ch. 111, ann. II « 40 ».

Review by the Federal Court

Review by Federal Court where access refused

41 Any individual who has been refused access to personal information requested under subsection 12(1) may, if a complaint has been made to the Privacy Commissioner in respect of the refusal, apply to the Court for a review of the matter within forty-five days after the time the results of an investigation of the complaint by the Privacy Commissioner are reported to the complainant under subsection 35(2) or within such further time as the Court may, either before or after the expiration of those forty-five days, fix or allow.

1980-81-82-83, c. 111, Sch. II "41".

Privacy Commissioner may apply or appear

42 The Privacy Commissioner may

Révision par la Cour fédérale

Révision par la Cour fédérale dans les cas de refus de communication

41 L'individu qui s'est vu refuser communication de renseignements personnels demandés en vertu du paragraphe 12(1) et qui a déposé ou fait déposer une plainte à ce sujet devant le Commissaire à la protection de la vie privée peut, dans un délai de quarante-cinq jours suivant le compte rendu du Commissaire prévu au paragraphe 35(2), exercer un recours en révision de la décision de refus devant la Cour. La Cour peut, avant ou après l'expiration du délai, le proroger ou en autoriser la prorogation.

1980-81-82-83, ch. 111, ann. II « 41 ».

Exercice du recours par le Commissaire à la protection de la vie privée, etc.

42 Le Commissaire à la protection de la vie privée a qualité pour :

(a) apply to the Court, within the time limits prescribed by section 41, for a review of any refusal to disclose personal information requested under subsection 12(1) in respect of which an investigation has been carried out by the Privacy Commissioner, if the Commissioner has the consent of the individual who requested access to the information;

(b) appear before the Court on behalf of any individual who has applied for a review under section 41; or

(c) with leave of the Court, appear as a party to any review applied for under section 41.

1980-81-82-83, c. 111, Sch. II "42".

Application respecting files in exempt banks

43 In the circumstances described in subsection 36(5), the Privacy Commissioner may apply to the Court for a review of any file contained in a personal information bank designated as an exempt bank under section 18.

1980-81-82-83, c. 111, Sch. II "43".

Hearing in summary way

44 An application made under section 41, 42 or 43 shall be heard and determined in a summary way in accordance with any special rules made in respect of such applications pursuant to section 46 of the *Federal Courts Act*.

R.S., 1985, c. P-21, s. 44; 2002, c. 8, s. 182.

Access to information

45 Despite any other Act of Parliament, any privilege under the law of evidence, solicitor-client privilege or the professional secrecy of advocates and notaries and litigation privilege, the Court may, in the course of any proceedings before it arising from an application under section 41, 42 or 43, examine any information recorded in any form under the control of a government institution, other than a confidence of the Queen's Privy Council for Canada to which subsection 70(1) applies, and no information that the Court may examine under this section may be withheld from the Court on any grounds.

R.S., 1985, c. P-21, s. 45; 2019, c. 18, s. 51.

Court to take precautions against disclosing

46 (1) In any proceedings before the Court arising from an application under section 41, 42 or 43, the Court shall take every reasonable precaution, including, when appropriate, receiving representations *ex parte* and conducting hearings *in camera*, to avoid the disclosure by the Court or any person of

(a) any information or other material that the head of a government institution would be authorized to refuse to disclose if it were requested under subsection

a) exercer lui-même, à l'issue de son enquête et dans les délais prévus à l'article 41, le recours en révision pour refus de communication de renseignements personnels, avec le consentement de l'individu qui les avait demandés;

b) comparaître devant la Cour au nom de l'individu qui a exercé un recours devant elle en vertu de l'article 41;

c) comparaître, avec l'autorisation de la Cour, comme partie à une instance engagée en vertu de l'article 41.

1980-81-82-83, ch. 111, ann. II « 42 ».

Recours concernant les fichiers inconsultables

43 Dans les cas visés au paragraphe 36(5), le Commissaire à la protection de la vie privée peut demander à la Cour d'examiner les dossiers versés dans un fichier inconsultable classé comme tel en vertu de l'article 18.

1980-81-82-83, ch. 111, ann. II « 43 ».

Procédure sommaire

44 Les recours prévus aux articles 41, 42 ou 43 sont entendus et jugés en procédure sommaire conformément aux règles de pratique spéciales adoptées à leur égard en vertu de l'article 46 de la *Loi sur les Cours fédérales*.

L.R. (1985), ch. P-21, art. 44; 2002, ch. 8, art. 182.

Accès aux renseignements

45 Malgré toute autre loi fédérale, toute immunité reconnue par le droit de la preuve, le secret professionnel de l'avocat ou du notaire et le privilège relatif au litige, la Cour a, pour les recours prévus aux articles 41, 42 ou 43, accès à tous les renseignements, quels que soient leur forme et leur support, qui relèvent d'une institution fédérale, à l'exception des renseignements confidentiels du Conseil privé de la Reine pour le Canada auxquels s'applique le paragraphe 70(1); aucun des renseignements auxquels la Cour a accès en vertu du présent article ne peut, pour quelque motif que ce soit, lui être refusé.

L.R. (1985), ch. P-21, art. 45; 2019, ch. 18, art. 51.

Précautions à prendre contre la divulgation

46 (1) À l'occasion des procédures relatives aux recours prévus aux articles 41, 42 ou 43, la Cour prend toutes les précautions possibles, notamment, si c'est indiqué, par la tenue d'audiences à huis clos et l'audition d'arguments en l'absence d'une partie, pour éviter que ne soient divulgués de par son propre fait ou celui de quiconque :

a) des renseignements qui justifient un refus de communication de renseignements personnels demandés en vertu du paragraphe 12(1) ou de renseignements

12(1) or contained in a record requested under the *Access to Information Act*; or

(b) any information as to whether personal information exists where the head of a government institution, in refusing to disclose the personal information under this Act, does not indicate whether it exists.

contenus dans un document demandé sous le régime de la *Loi sur l'accès à l'information*;

b) des renseignements faisant état de l'existence de renseignements personnels que le responsable d'une institution fédérale a refusé de communiquer sans indiquer s'ils existaient ou non.

Disclosure of offence authorized

(2) The Court may disclose to the appropriate authority information relating to the commission of an offence against a law of Canada or a province by a director, an officer or an employee of a government institution if, in the Court's opinion, there is evidence of such an offence.

R.S., 1985, c. P-21, s. 46; 2006, c. 9, s. 184.

Autorisation de dénoncer des infractions

(2) Si, à son avis, il existe des éléments de preuve touchant la perpétration d'une infraction fédérale ou provinciale par un administrateur, un dirigeant ou un employé d'une institution fédérale, la Cour peut faire part à l'autorité compétente des renseignements qu'elle détient à cet égard.

L.R. (1985), ch. P-21, art. 46; 2006, ch. 9, art. 184.

Burden of proof

47 In any proceedings before the Court arising from an application under section 41, 42 or 43, the burden of establishing that the head of a government institution is authorized to refuse to disclose personal information requested under subsection 12(1) or that a file should be included in a personal information bank designated as an exempt bank under section 18 shall be on the government institution concerned.

1980-81-82-83, c. 111, Sch. II "47".

Charge de la preuve

47 Dans les procédures découlant des recours prévus aux articles 41, 42 ou 43, la charge d'établir le bien-fondé du refus de communication de renseignements personnels ou le bien-fondé du versement de certains dossiers dans un fichier inconsultable classé comme tel en vertu de l'article 18 incombe à l'institution fédérale concernée.

1980-81-82-83, ch. 111, ann. II « 47 ».

Order of Court where no authorization to refuse disclosure found

48 Where the head of a government institution refuses to disclose personal information requested under subsection 12(1) on the basis of a provision of this Act not referred to in section 49, the Court shall, if it determines that the head of the institution is not authorized under this Act to refuse to disclose the personal information, order the head of the institution to disclose the personal information, subject to such conditions as the Court deems appropriate, to the individual who requested access thereto, or shall make such other order as the Court deems appropriate.

1980-81-82-83, c. 111, Sch. II "48".

Ordonnance de la Cour dans les cas où le refus n'est pas autorisé

48 La Cour, dans les cas où elle conclut au bon droit de l'individu qui a exercé un recours en révision d'une décision de refus de communication de renseignements personnels fondée sur des dispositions de la présente loi autres que celles mentionnées à l'article 49, ordonne, aux conditions qu'elle juge indiquées, au responsable de l'institution fédérale dont relèvent les renseignements d'en donner communication à l'individu; la Cour rend une autre ordonnance si elle l'estime indiqué.

1980-81-82-83, ch. 111, ann. II « 48 ».

Order of Court where reasonable grounds of injury not found

49 Where the head of a government institution refuses to disclose personal information requested under subsection 12(1) on the basis of section 20 or 21 or paragraph 22(1)(b) or (c) or 24(a), the Court shall, if it determines that the head of the institution did not have reasonable grounds on which to refuse to disclose the personal information, order the head of the institution to disclose the personal information, subject to such conditions as the

Ordonnance de la Cour dans les cas où le préjudice n'est pas démontré

49 Dans les cas où le refus de communication des renseignements personnels s'appuyait sur les articles 20 ou 21 ou sur les alinéas 22(1)b) ou c) ou 24a), la Cour, si elle conclut que le refus n'était pas fondé sur des motifs raisonnables, ordonne, aux conditions qu'elle juge indiquées, au responsable de l'institution fédérale dont relèvent les renseignements d'en donner communication à l'individu qui avait fait la demande; la Cour rend une autre ordonnance si elle l'estime indiqué.

1980-81-82-83, ch. 111, ann. II « 49 ».

Court deems appropriate, to the individual who requested access thereto, or shall make such other order as the Court deems appropriate.

1980-81-82-83, c. 111, Sch. II "49".

Order to remove file from exempt bank

50 Where the Privacy Commissioner makes an application to the Court under section 43 for a review of a file contained in a personal information bank designated as an exempt bank under section 18, the Court shall, if it determines

(a) in the case of a file contained in the bank on the basis of personal information described in paragraph 22(1)(a) or subsection 22(2), that the file should not be included therein, or

(b) in the case of a file contained in the bank on the basis of personal information described in section 21 or paragraph 22(1)(b) or (c), that reasonable grounds do not exist on which to include the file in the bank,

order the head of the government institution that has control of the bank to remove the file from the bank or make such other order as the Court deems appropriate.

1980-81-82-83, c. 111, Sch. II "50"; 1984, c. 40, s. 60.

Ordonnance visant à exclure des dossiers d'un fichier

50 La Cour, saisie d'un recours en vertu de l'article 43, ordonne au responsable de l'institution fédérale dont relève le fichier inconsultable qui contient le dossier en litige de retirer celui-ci du fichier, ou rend toute autre ordonnance qu'elle estime indiquée, si elle conclut :

a) dans le cas d'un dossier contenant des renseignements personnels visés à l'alinéa 22(1)a) ou au paragraphe 22(2), que le dossier n'aurait pas dû être versé dans le fichier;

b) dans le cas d'un dossier contenant des renseignements personnels visés à l'article 21 ou aux alinéas 22(1)b) ou c), qu'il n'y a pas de motifs raisonnables justifiant le versement du dossier dans le fichier.

1980-81-82-83, ch. 111, ann. II « 50 »; 1984, ch. 40, art. 60.

Actions relating to international affairs and defence

51 (1) Any application under section 41 or 42 relating to personal information that the head of a government institution has refused to disclose by reason of paragraph 19(1)(a) or (b) or section 21, and any application under section 43 in respect of a file contained in a personal information bank designated as an exempt bank under section 18 to contain files all of which consist predominantly of personal information described in section 21, shall be heard and determined by the Chief Justice of the Federal Court or by any other judge of the Court that the Chief Justice may designate to hear the applications.

Affaires internationales et défense

51 (1) Les recours visés aux articles 41 ou 42 et portant sur les cas où le refus de donner communication de renseignements personnels est lié aux alinéas 19(1) a) ou b) ou à l'article 21 et sur les cas concernant la présence des dossiers dans chacun desquels dominent des renseignements visés à l'article 21 dans des fichiers inconsultables classés comme tels en vertu de l'article 18 sont exercés devant le juge en chef de la Cour fédérale ou tout autre juge de cette Cour qu'il charge de leur audition.

Special rules for hearings

(2) An application referred to in subsection (1) or an appeal brought in respect of such application shall

(a) be heard *in camera*; and

(b) on the request of the head of the government institution concerned, be heard and determined in the National Capital Region described in the schedule to the *National Capital Act*.

Règles spéciales

(2) Les recours visés au paragraphe (1) font, en premier ressort ou en appel, l'objet d'une audition à huis clos; celle-ci a lieu dans la région de la capitale nationale définie à l'annexe de la *Loi sur la capitale nationale* si le responsable de l'institution fédérale concernée le demande.

Ex parte representations

(3) During the hearing of an application referred to in subsection (1) or an appeal brought in respect of such

Présentation d'arguments en l'absence d'une partie

(3) Le responsable de l'institution fédérale concernée a, au cours des auditions en première instance ou en appel

application, the head of the government institution concerned shall, on the request of the head of the institution, be given the opportunity to make representations *ex parte*.

R.S., 1985, c. P-21, s. 51; 2002, c. 8, s. 159.

et sur demande, le droit de présenter des arguments en l'absence d'une autre partie.

L.R. (1985), ch. P-21, art. 51; 2002, ch. 8, art. 159.

Costs

52 (1) Subject to subsection (2), the costs of and incidental to all proceedings in the Court under this Act shall be in the discretion of the Court and shall follow the event unless the Court orders otherwise.

Idem

(2) Where the Court is of the opinion that an application for review under section 41 or 42 has raised an important new principle in relation to this Act, the Court shall order that costs be awarded to the applicant even if the applicant has not been successful in the result.

1980-81-82-83, c. 111, Sch. II "52".

Frais et dépens

52 (1) Sous réserve du paragraphe (2), les frais et dépens sont laissés à l'appréciation de la Cour et suivent, sauf ordonnance contraire de la Cour, le sort du principal.

Idem

(2) Dans les cas où elle estime que l'objet du recours a soulevé un principe important et nouveau quant à la présente loi, la Cour accorde les frais et dépens à la personne qui a exercé le recours devant elle, même si cette personne a été déboutée de son recours.

1980-81-82-83, ch. 111, ann. II « 52 ».

Office of the Privacy Commissioner

Privacy Commissioner

Appointment

53 (1) The Governor in Council shall, by commission under the Great Seal, appoint a Privacy Commissioner after consultation with the Leader of the Government in the Senate or Government Representative in the Senate, the Leader of the Opposition in the Senate, the Leader or Facilitator of every other recognized party or parliamentary group in the Senate and the leader of every recognized party in the House of Commons and approval of the appointment by resolution of the Senate and House of Commons.

Tenure

(2) Subject to this section, the Privacy Commissioner holds office during good behaviour for a term of seven years, but may be removed for cause by the Governor in Council at any time on address of the Senate and House of Commons.

Further terms

(3) The Privacy Commissioner, on the expiration of a first or any subsequent term of office, is eligible to be reappointed for a further term not exceeding seven years.

Commissariat à la protection de la vie privée

Commissaire à la protection de la vie privée

Nomination

53 (1) Le gouverneur en conseil nomme le Commissaire à la protection de la vie privée par commission sous le grand sceau, après consultation du leader ou représentant du gouvernement au Sénat, du leader de l'opposition au Sénat, du leader ou facilitateur de chacun des autres partis ou groupes parlementaires reconnus au Sénat et du chef de chacun des partis reconnus à la Chambre des communes et approbation par résolution du Sénat et de la Chambre des communes.

Durée du mandat et révocation

(2) Sous réserve des autres dispositions du présent article, le Commissaire à la protection de la vie privée occupe sa charge à titre inamovible pour un mandat de sept ans, sauf révocation motivée par le gouverneur en conseil sur adresse du Sénat et de la Chambre des communes.

Renouvellement du mandat

(3) Le mandat du Commissaire à la protection de la vie privée est renouvelable pour des périodes maximales de sept ans chacune.

Interim appointment

(4) In the event of the absence or incapacity of the Privacy Commissioner, or if that office is vacant, the Governor in Council may appoint any qualified person to hold that office in the interim for a term not exceeding six months, and that person shall, while holding office, be paid the salary or other remuneration and expenses that may be fixed by the Governor in Council.

R.S., 1985, c. P-21, s. 53; 2006, c. 9, s. 118; 2022, c. 10, s. 247.

Intérim

(4) En cas d'absence ou d'empêchement du Commissaire à la protection de la vie privée ou de vacance de son poste, le gouverneur en conseil peut confier l'intérim à toute personne compétente pour un mandat maximal de six mois et fixer la rémunération et les indemnités auxquelles cette personne aura droit.

L.R. (1985), ch. P-21, art. 53; 2006, ch. 9, art. 118; 2022, ch. 10, art. 247.

Rank, powers and duties generally

54 (1) The Privacy Commissioner shall rank as and have all the powers of a deputy head of a department, shall engage exclusively in the duties of the office of Privacy Commissioner under this Act or any other Act of Parliament and shall not hold any other office under Her Majesty for reward or engage in any other employment for reward.

Rang, pouvoirs et fonctions

54 (1) Le Commissaire à la protection de la vie privée a rang et pouvoirs d'administrateur général de ministère; il se consacre exclusivement à la charge que lui confère la présente loi ou une autre loi fédérale, à l'exclusion de toute autre charge rétribuée au service de Sa Majesté ou de tout autre emploi rétribué.

Salary and expenses

(2) The Privacy Commissioner shall be paid a salary equal to the salary of a judge of the Federal Court, other than the Chief Justice, and is entitled to be paid reasonable travel and living expenses incurred in the performance of duties under this Act or any other Act of Parliament.

Traitement et frais

(2) Le Commissaire à la protection de la vie privée reçoit le même traitement qu'un juge de la Cour fédérale autre que le juge en chef; il a droit aux frais de déplacement et de séjour entraînés par l'exercice des fonctions que lui confèrent la présente loi ou une autre loi fédérale.

Pension benefits

(3) The provisions of the *Public Service Superannuation Act*, other than those relating to tenure of office, apply to the Privacy Commissioner, except that a person appointed as Privacy Commissioner from outside the public service, as defined in the *Public Service Superannuation Act*, may, by notice in writing given to the President of the Treasury Board not more than sixty days after the date of appointment, elect to participate in the pension plan provided in the *Diplomatic Service (Special) Superannuation Act*, in which case the provisions of that Act, other than those relating to tenure of office, apply to the Privacy Commissioner from the date of appointment and the provisions of the *Public Service Superannuation Act* do not apply.

Régime de pension

(3) Les dispositions de la *Loi sur la pension de la fonction publique* qui ne traitent pas d'occupation de poste s'appliquent au Commissaire à la protection de la vie privée; toutefois, s'il est choisi en dehors de la fonction publique, au sens de la loi mentionnée ci-dessus, il peut, par avis adressé au président du Conseil du Trésor dans les soixante jours suivant sa date de nomination, choisir de cotiser au régime de pension prévu par la *Loi sur la pension spéciale du service diplomatique*; dans ce cas, il est assujetti aux dispositions de cette loi qui ne traitent pas d'occupation de poste.

Other benefits

(4) The Privacy Commissioner is deemed to be employed in the public service of Canada for the purposes of the *Government Employees Compensation Act* and any regulations made under section 9 of the *Aeronautics Act*.

R.S., 1985, c. P-21, s. 54; 2002, c. 8, s. 160; 2003, c. 22, s. 225(E).

Autres avantages

(4) Le Commissaire à la protection de la vie privée est réputé faire partie de l'administration publique fédérale pour l'application de la *Loi sur l'indemnisation des agents de l'État* et des règlements pris en vertu de l'article 9 de la *Loi sur l'aéronautique*.

L.R. (1985), ch. P-21, art. 54; 2002, ch. 8, art. 160; 2003, ch. 22, art. 225(A).

Information Commissioner may be appointed as Privacy Commissioner

55 (1) The Governor in Council may appoint as Privacy Commissioner under section 53 the Information Commissioner appointed under the *Access to Information Act*.

Salary

(2) In the event that the Information Commissioner is appointed in accordance with subsection (1) as Privacy Commissioner, the Privacy Commissioner shall, notwithstanding subsection 54(2), be paid the salary of the Information Commissioner but not the salary of the Privacy Commissioner.

1980-81-82-83, c. 111, Sch. II "55".

Cumul de postes

55 (1) La personne nommée au poste de Commissaire à l'information aux termes de la *Loi sur l'accès à l'information* peut aussi être nommée par le gouverneur en conseil au poste de Commissaire à la protection de la vie privée en vertu de l'article 53.

Traitement

(2) Dans l'éventualité de l'application du paragraphe (1), le paragraphe 54(2) serait sans effet et le Commissaire à la protection de la vie privée ne recevrait que le traitement prévu pour le Commissaire à l'information.

1980-81-82-83, ch. 111, ann. II « 55 ».

Assistant Privacy Commissioner

Appointment of Assistant Privacy Commissioner

56 (1) The Governor in Council may, on the recommendation of the Privacy Commissioner, appoint one or more Assistant Privacy Commissioners.

Tenure of office and removal of Assistant Privacy Commissioner

(2) Subject to this section, an Assistant Privacy Commissioner holds office during good behaviour for a term not exceeding five years.

Further terms

(3) An Assistant Privacy Commissioner, on the expiration of a first or any subsequent term of office, is eligible to be re-appointed for a further term not exceeding five years.

1980-81-82-83, c. 111, Sch. II "56"; 1984, c. 40, s. 79(E).

Commissaires adjoints à la protection de la vie privée

Nomination

56 (1) Le gouverneur en conseil peut, sur recommandation du Commissaire à la protection de la vie privée, nommer un ou plusieurs commissaires adjoints à la protection de la vie privée.

Durée du mandat

(2) Sous réserve des autres dispositions du présent article, l'adjoint occupe son poste à titre inamovible pour un mandat maximal de cinq ans.

Renouvellement du mandat

(3) Le mandat de l'adjoint est renouvelable pour des périodes maximales de cinq ans chacune.

1980-81-82-83, ch. 111, ann. II « 56 »; 1984, ch. 40, art. 79(A).

Duties generally

57 (1) An Assistant Privacy Commissioner shall engage exclusively in such duties or functions of the office of the Privacy Commissioner under this Act or any other Act of Parliament as are delegated by the Privacy Commissioner to that Assistant Privacy Commissioner and shall not hold any other office under Her Majesty for reward or engage in any other employment for reward.

Salary and expenses

(2) An Assistant Privacy Commissioner is entitled to be paid a salary to be fixed by the Governor in Council and such travel and living expenses incurred in the

Fonctions

57 (1) L'adjoint se consacre exclusivement aux fonctions de la charge du Commissaire à la protection de la vie privée que celui-ci lui délègue, à l'exclusion de toutes autres fonctions rétribuées au service de Sa Majesté ou de tout autre emploi rétribué.

Traitement et frais

(2) L'adjoint reçoit le traitement que fixe le gouverneur en conseil et il a droit aux frais de déplacement et de séjour que le Commissaire à la protection de la vie privée

performance of duties under this Act or any other Act of Parliament as the Privacy Commissioner considers reasonable.

Pension benefits

(3) The provisions of the *Public Service Superannuation Act*, other than those relating to tenure of office, apply to an Assistant Privacy Commissioner.

Other benefits

(4) An Assistant Privacy Commissioner is deemed to be employed in the public service of Canada for the purposes of the *Government Employees Compensation Act* and any regulations made under section 9 of the *Aeronautics Act*.

1980-81-82-83, c. 111, Sch. II "57".

Staff

Staff of the Privacy Commissioner

58 (1) Such officers and employees as are necessary to enable the Privacy Commissioner to perform the duties and functions of the Commissioner under this Act or any other Act of Parliament shall be appointed in accordance with the *Public Service Employment Act*.

Technical assistance

(2) The Privacy Commissioner may engage on a temporary basis the services of persons having technical or specialized knowledge of any matter relating to the work of the Commissioner to advise and assist the Commissioner in the performance of the duties and functions of the Commissioner under this Act or any other Act of Parliament and, with the approval of the Treasury Board, may fix and pay the remuneration and expenses of such persons.

R.S., 1985, c. P-21, s. 58; 2006, c. 9, s. 185(F).

Delegation

Delegation by Privacy Commissioner

59 (1) Subject to subsection (2), the Privacy Commissioner may authorize any person to exercise or perform, subject to such restrictions or limitations as the Commissioner may specify, any of the powers, duties or functions of the Commissioner under this Act except

(a) in any case other than a delegation to an Assistant Privacy Commissioner, the power to delegate under this section; and

(b) in any case, the powers, duties or functions set out in sections 38 and 39.

estime entraînés par l'exercice des fonctions que lui confèrent la présente loi ou une autre loi fédérale.

Régime de pension

(3) Les dispositions de la *Loi sur la pension de la fonction publique* qui ne traitent pas d'occupation de poste s'appliquent à l'adjoint.

Autres avantages

(4) L'adjoint est réputé faire partie de l'administration publique fédérale pour l'application de la *Loi sur l'indemnisation des agents de l'État* et des règlements pris en vertu de l'article 9 de la *Loi sur l'aéronautique*.

1980-81-82-83, ch. 111, ann. II « 57 ».

Personnel

Personnel

58 (1) La *Loi sur l'emploi dans la fonction publique* s'applique au personnel dont le Commissaire à la protection de la vie privée a besoin pour l'exercice des pouvoirs et fonctions que lui confèrent la présente loi ou une autre loi fédérale.

Assistance technique

(2) Le Commissaire à la protection de la vie privée peut retenir temporairement les services d'experts ou de spécialistes dont la compétence lui est utile dans l'exercice des fonctions que lui confèrent la présente loi ou une autre loi fédérale; il peut fixer et payer, avec l'approbation du Conseil du Trésor, leur rémunération et leurs frais.

L.R. (1985), ch. P-21, art. 58; 2006, ch. 9, art. 185(F).

Délégation

Pouvoir de délégation

59 (1) Sous réserve du paragraphe (2), le Commissaire à la protection de la vie privée peut, dans les limites qu'il fixe, déléguer les pouvoirs et fonctions que lui confèrent la présente loi ou une autre loi fédérale, sauf :

a) le pouvoir même de délégation, qui ne peut être délégué qu'à un commissaire adjoint;

b) les pouvoirs et fonctions énoncés aux articles 38 et 39, qui ne peuvent être délégués à quiconque.

Delegations of investigations relating to international affairs and defence

(2) The Privacy Commissioner may not, nor may an Assistant Privacy Commissioner, delegate

(a) the investigation of any complaint resulting from a refusal by the head of a government institution to disclose personal information by reason of paragraph 19(1)(a) or (b) or section 21, or

(b) the investigation under section 36 of files contained in a personal information bank designated under section 18 as an exempt bank on the basis of personal information described in section 21

except to one of a maximum of four officers or employees of the Commissioner specifically designated by the Commissioner for the purpose of conducting those investigations.

Affaires internationales et défense

(2) Le Commissaire à la protection de la vie privée ou un commissaire adjoint ne peuvent déléguer qu'à un de leurs collaborateurs choisis parmi quatre des cadres ou employés du commissariat et que le Commissaire désigne spécialement à cette fin la tenue des enquêtes suivantes :

a) les enquêtes portant sur les cas où le refus de communication de renseignements personnels est lié aux alinéas 19(1)a) ou b) ou à l'article 21;

b) les enquêtes prévues à l'article 36 et portant sur les dossiers versés dans les fichiers inconsultables classés comme tels en vertu de l'article 18 et contenant des renseignements personnels visés à l'article 21.

Delegation by Assistant Privacy Commissioner

(3) An Assistant Privacy Commissioner may authorize any person to exercise or perform, subject to such restrictions or limitations as the Assistant Privacy Commissioner may specify, any of the powers, duties or functions of the Privacy Commissioner under this Act that the Assistant Privacy Commissioner is authorized by the Privacy Commissioner to exercise or perform.

1980-81-82-83, c. 111, Sch. II "59".

Pouvoir de subdélégation de l'adjoint

(3) Un commissaire adjoint à la protection de la vie privée peut, dans les limites qu'il fixe, subdéléguer les pouvoirs et fonctions que lui délègue le Commissaire en vertu de la présente loi ou d'une autre loi fédérale.

1980-81-82-83, ch. 111, ann. II « 59 ».

Special Studies

Special studies

60 (1) The Privacy Commissioner shall carry out or cause to be carried out such studies as may be referred to the Commissioner by the Minister of Justice

(a) relating to the privacy of individuals,

(b) concerning the extension of the rights to which individuals are entitled under this Act in respect of personal information about themselves, and

(c) relating to the collection, retention, disposal, use or disclosure of personal information by persons or bodies, other than government institutions, that come within the legislative authority of Parliament,

and the Privacy Commissioner shall report thereon to the Minister of Justice from time to time.

Études spéciales

Études spéciales

60 (1) Le Commissaire à la protection de la vie privée effectue ou fait effectuer les études que lui confie le ministre de la Justice et en fait rapport à celui-ci; ces études peuvent porter sur les sujets suivants :

a) la protection de la vie privée;

b) l'élargissement des droits que la présente loi accorde aux individus quant aux renseignements personnels qui les concernent;

c) la collecte, la conservation, le retrait, l'utilisation et la communication des renseignements personnels par des personnes ou organismes relevant de la compétence législative du Parlement mais extérieurs aux institutions fédérales.

Reports to be tabled

(2) The Minister of Justice shall cause each report by the Privacy Commissioner under subsection (1) to be laid before Parliament on any of the first fifteen days after receipt thereof that either House of Parliament is sitting.

1980-81-82-83, c. 111, Sch. II "60".

Dépôt des rapports

(2) Le ministre de la Justice fait déposer devant le Parlement les rapports établis en application du paragraphe (1) dans les quinze premiers jours de séance de l'une ou l'autre chambre qui suivent leur réception.

1980-81-82-83, ch. 111, ann. II « 60 ».

General

Principal office

61 The principal office of the Privacy Commissioner shall be in the National Capital Region described in the schedule to the *National Capital Act*.

1980-81-82-83, c. 111, Sch. II "61".

Dispositions générales

Siège

61 Le siège du Commissariat à la protection de la vie privée est fixé dans la région de la capitale nationale définie à l'annexe de la *Loi sur la capitale nationale*.

1980-81-82-83, ch. 111, ann. II « 61 ».

Security requirements

62 The Privacy Commissioner and every person acting on behalf or under the direction of the Commissioner who receives or obtains information relating to any investigation under this Act or any other Act of Parliament shall, with respect to access to and the use of that information, satisfy any security requirements applicable to, and take any oath of secrecy required to be taken by, persons who normally have access to and use of that information.

1980-81-82-83, c. 111, Sch. II "62".

Normes de sécurité

62 Le Commissaire à la protection de la vie privée et les personnes agissant en son nom ou sous son autorité qui reçoivent ou recueillent des renseignements dans le cadre des enquêtes prévues par la présente loi ou une autre loi fédérale sont tenus, quant à l'accès à ces renseignements et leur utilisation, de satisfaire aux normes applicables en matière de sécurité et de prêter les serments imposés à leurs usagers habituels.

1980-81-82-83, ch. 111, ann. II « 62 ».

Confidentiality

63 Subject to this Act, the Privacy Commissioner and every person acting on behalf or under the direction of the Commissioner shall not disclose any information that comes to their knowledge in the performance of their duties and functions under this Act.

1980-81-82-83, c. 111, Sch. II "63".

Secret

63 Sous réserve des autres dispositions de la présente loi, le Commissaire à la protection de la vie privée et les personnes agissant en son nom ou sous son autorité sont tenus au secret en ce qui concerne les renseignements dont ils prennent connaissance dans l'exercice des pouvoirs et fonctions que leur confère la présente loi.

1980-81-82-83, ch. 111, ann. II « 63 ».

Disclosure authorized

64 (1) The Privacy Commissioner may disclose or may authorize any person acting on behalf or under the direction of the Commissioner to disclose information

(a) that, in the opinion of the Commissioner, is necessary to

(i) carry out an investigation under this Act, or

(ii) establish the grounds for findings and recommendations contained in any report under this Act; or

(b) in the course of a prosecution for an offence under this Act, a prosecution for an offence under section 131 of the *Criminal Code* (perjury) in respect of a statement made under this Act or a review before the

Divulgation autorisée

64 (1) Le Commissaire à la protection de la vie privée peut divulguer, ou autoriser les personnes agissant en son nom ou sous son autorité à divulguer, les renseignements :

a) qui, à son avis, sont nécessaires pour :

(i) mener une enquête prévue par la présente loi,

(ii) motiver les conclusions et recommandations contenues dans les rapports et comptes rendus prévus par la présente loi;

b) dont la divulgation est nécessaire, soit dans le cadre des procédures intentées pour infraction à la présente loi ou pour une infraction à l'article 131 du *Code criminel* (parjure) se rapportant à une

Court under this Act or Part 1 of the *Access to Information Act* or an appeal from a review of that Court.

déclaration faite en vertu de la présente loi, soit lors d'un recours en révision prévu par la présente loi ou la partie 1 de la *Loi sur l'accès à l'information* devant la Cour ou lors de l'appel de la décision rendue par celle-ci.

Disclosure of offence authorized

(2) The Privacy Commissioner may disclose to the Attorney General of Canada information relating to the commission of an offence against a law of Canada or a province by a director, an officer or an employee of a government institution if, in the Commissioner's opinion, there is evidence of such an offence.

Dénonciation autorisée

(2) Si, à son avis, il existe des éléments de preuve touchant la perpétration d'une infraction fédérale ou provinciale par un administrateur, un dirigeant ou un employé d'une institution fédérale, le Commissaire à la protection de la vie privée peut faire part au procureur général du Canada des renseignements qu'il détient à cet égard.

Provision of information

(3) The Privacy Commissioner may disclose or may authorize any person acting on behalf or under the direction of the Commissioner to disclose — to the extent that the Commissioner or the authorized person, as the case may be, considers necessary for the purpose of subsection 37(5) — information concerning the Commissioner's activities under subsection 37(1) to the National Security and Intelligence Review Agency.

R.S., 1985, c. P-21, s. 64; R.S., 1985, c. 27 (1st Supp.), s. 187; 2006, c. 9, s. 186; 2019, c. 13, s. 37.2; 2019, c. 18, s. 52.

Communication de renseignements

(3) Le Commissaire à la protection de la vie privée peut divulguer, ou autoriser les personnes agissant en son nom ou sous son autorité à divulguer, à l'Office de surveillance des activités en matière de sécurité nationale et de renseignement les renseignements liés aux activités que mène le Commissaire en vertu du paragraphe 37(1) si le Commissaire ou la personne autorisée l'estime nécessaire pour l'application du paragraphe 37(5).

L.R. (1985), ch. P-21, art. 64; L.R. (1985), ch. 27 (1er suppl.), art. 187; 2006, ch. 9, art. 186; 2019, ch. 13, art. 37.2; 2019, ch. 18, art. 52.

Information not to be disclosed

65 In carrying out an investigation under this Act, in notifying an individual of a disclosure under subsection 8(5) and in any report made to Parliament under section 38 or 39, the Privacy Commissioner and every person acting on behalf or under the direction of the Privacy Commissioner shall take every reasonable precaution to avoid the disclosure of, and shall not disclose,

(a) any information that the head of a government institution would be authorized to refuse to disclose if it were requested under subsection 12(1) or contained in a record requested under the *Access to Information Act*; or

(b) any information as to whether personal information exists where the head of a government institution, in refusing to disclose the personal information under this Act, does not indicate whether it exists.

1980-81-82-83, c. 111, Sch. II "65".

Précautions à prendre

65 Lors des enquêtes prévues par la présente loi, dans la transmission à un individu de l'avis prévu au paragraphe 8(5) et dans la préparation des rapports au Parlement prévus aux articles 38 ou 39, le Commissaire à la protection de la vie privée et les personnes agissant en son nom ou sous son autorité ne peuvent divulguer et prennent toutes les précautions pour éviter que ne soient divulgués :

a) des renseignements qui justifient un refus de communication de renseignements personnels demandés en vertu du paragraphe 12(1) ou de renseignements contenus dans un document demandé sous le régime de la *Loi sur l'accès à l'information*;

b) des renseignements faisant état de l'existence de renseignements personnels que le responsable d'une institution fédérale a refusé de communiquer sans indiquer s'ils existaient ou non.

1980-81-82-83, ch. 111, ann. II « 65 ».

No summons

66 The Privacy Commissioner or any person acting on behalf or under the direction of the Commissioner is not a competent or compellable witness, in respect of any matter coming to the knowledge of the Commissioner or that person as a result of performing any duties or functions under this Act, in any proceeding other than a

Non-assignation

66 En ce qui concerne les questions venues à leur connaissance dans l'exercice des pouvoirs et fonctions qui leur sont conférés en vertu de la présente loi, le Commissaire à la protection de la vie privée et les personnes qui agissent en son nom ou sur son ordre n'ont qualité pour témoigner ou ne peuvent y être contraints que dans

prosecution for an offence under this Act, a prosecution for an offence under section 131 of the *Criminal Code* (perjury) in respect of a statement made under this Act, a review before the Court under this Act or an appeal from a review of that Court.

R.S., 1985, c. P-21, s. 66; R.S., 1985, c. 27 (1st Supp.), s. 187; 2019, c. 18, s. 53.

For greater certainty

66.1 For greater certainty, sections 63 and 66 apply if the Privacy Commissioner is consulted by the Information Commissioner under subsection 36(1.1) or section 36.2 of the *Access to Information Act*.

2019, c. 18, s. 53.

Protection of Privacy Commissioner

67 (1) No criminal or civil proceedings lie against the Privacy Commissioner, or against any person acting on behalf or under the direction of the Commissioner, for anything done, reported or said in good faith in the course of the exercise or performance or purported exercise or performance of any power, duty or function of the Commissioner under this Act.

Libel or slander

(2) For the purposes of any law relating to libel or slander,

(a) anything said, any information supplied or any document or thing produced in good faith in the course of an investigation carried out by or on behalf of the Privacy Commissioner under this Act is privileged; and

(b) any report made in good faith by the Privacy Commissioner under this Act and any fair and accurate account of the report made in good faith in a newspaper or any other periodical publication or in a broadcast is privileged.

1980-81-82-83, c. 111, Sch. II "67".

Offences

Obstruction

68 (1) No person shall obstruct the Privacy Commissioner or any person acting on behalf or under the direction of the Commissioner in the performance of the Commissioner's duties and functions under this Act.

le cadre des procédures intentées pour infraction à la présente loi ou pour une infraction visée à l'article 131 du *Code criminel* (parjure) se rapportant à une déclaration faite en vertu de la présente loi, ou que lors d'un recours prévu par la présente loi devant la Cour ou lors de l'appel de la décision rendue par celle-ci.

L.R. (1985), ch. P-21, art. 66; L.R. (1985), ch. 27 (1er suppl.), art. 187; 2019, ch. 18, art. 53.

Précision

66.1 Il est entendu que les articles 63 et 66 s'appliquent dans les cas où le Commissaire à la protection de la vie privée est consulté par le Commissaire à l'information en vertu du paragraphe 36(1.1) ou de l'article 36.2 de la *Loi sur l'accès à l'information*.

2019, ch. 18, art. 53.

Immunité du Commissaire à la protection de la vie privée

67 (1) Le Commissaire à la protection de la vie privée et les personnes qui agissent en son nom ou sous son autorité bénéficient de l'immunité en matière civile ou pénale pour les actes accomplis, les rapports ou comptes rendus établis et les paroles prononcées de bonne foi dans l'exercice effectif ou censé tel des pouvoirs et fonctions qui lui sont conférés en vertu de la présente loi.

Diffamation

(2) Ne peuvent donner lieu à poursuites pour diffamation verbale ou écrite :

a) les paroles prononcées, les renseignements fournis ou les pièces produites de bonne foi au cours d'une enquête menée par le Commissaire à la protection de la vie privée ou en son nom dans le cadre de la présente loi;

b) les rapports ou comptes rendus établis de bonne foi par le Commissaire à la protection de la vie privée dans le cadre de la présente loi, ainsi que les relations qui en sont faites de bonne foi par la presse écrite ou audio-visuelle.

1980-81-82-83, ch. 111, ann. II « 67 ».

Infractions

Entrave

68 (1) Il est interdit d'entraver l'action du Commissaire à la protection de la vie privée ou des personnes qui agissent en son nom ou sous son autorité dans l'exercice des pouvoirs et fonctions qui lui sont conférés en vertu de la présente loi.

Offence and punishment

(2) Every person who contravenes this section is guilty of an offence and liable on summary conviction to a fine not exceeding one thousand dollars.

1980-81-82-83, c. 111, Sch. II "68".

Infraction et peine

(2) Quiconque contrevient au présent article est coupable d'une infraction et passible, sur déclaration de culpabilité par procédure sommaire, d'une amende maximale de mille dollars.

1980-81-82-83, ch. 111, ann. II « 68 ».

Exclusions

Act does not apply to certain materials

69 (1) This Act does not apply to

(a) library or museum material preserved solely for public reference or exhibition purposes; or

(b) material placed in the Library and Archives of Canada, the National Gallery of Canada, the Canadian Museum of History, the Canadian Museum of Nature, the National Museum of Science and Technology, the Canadian Museum for Human Rights or the Canadian Museum of Immigration at Pier 21 by or on behalf of persons or organizations other than government institutions.

Exclusions

Non-application de la loi

69 (1) La présente loi ne s'applique pas aux documents suivants :

a) les documents de bibliothèque ou de musée conservés uniquement à des fins de référence ou d'exposition pour le public;

b) les documents déposés à Bibliothèque et Archives du Canada, au Musée des beaux-arts du Canada, au Musée canadien de l'histoire, au Musée canadien de la nature, au Musée national des sciences et de la technologie, au Musée canadien des droits de la personne ou au Musée canadien de l'immigration du Quai 21 par des personnes ou organisations extérieures aux institutions fédérales ou pour ces personnes ou organisations.

Sections 7 and 8 do not apply to certain information

(2) Sections 7 and 8 do not apply to personal information that is publicly available.

R.S., 1985, c. P-21, s. 69; R.S., 1985, c. 1 (3rd Supp.), s. 12; 1990, c. 3, s. 32; 1992, c. 1, s. 143(E); 2004, c. 11, s. 39; 2008, c. 9, s. 10; 2010, c. 7, s. 9; 2013, c. 38, s. 18.

Non-application des art. 7 et 8

(2) Les articles 7 et 8 ne s'appliquent pas aux renseignements personnels auxquels le public a accès.

L.R. (1985), ch. P-21, art. 69; L.R. (1985), ch. 1 (3e suppl.), art. 12; 1990, ch. 3, art. 32; 1992, ch. 1, art. 143(A); 2004, ch. 11, art. 39; 2008, ch. 9, art. 10; 2010, ch. 7, art. 9; 2013, ch. 38, art. 18.

Canadian Broadcasting Corporation

69.1 This Act does not apply to personal information that the Canadian Broadcasting Corporation collects, uses or discloses for journalistic, artistic or literary purposes and does not collect, use or disclose for any other purpose.

2006, c. 9, s. 188.

Société Radio-Canada

69.1 La présente loi ne s'applique pas aux renseignements personnels que la Société Radio-Canada recueille, utilise ou communique uniquement à des fins journalistiques, artistiques ou littéraires.

2006, ch. 9, art. 188.

Confidences of the Queen's Privy Council for Canada

70 (1) This Act does not apply to confidences of the Queen's Privy Council for Canada, including, without restricting the generality of the foregoing, any information contained in

(a) memoranda the purpose of which is to present proposals or recommendations to Council;

(b) discussion papers the purpose of which is to present background explanations, analyses of

Renseignements confidentiels du Conseil privé de la Reine pour le Canada

70 (1) La présente loi ne s'applique pas aux renseignements confidentiels du Conseil privé de la Reine pour le Canada, notamment aux :

a) notes destinées à soumettre des propositions ou recommandations au Conseil;

b) documents de travail destinés à présenter des problèmes, des analyses ou des options politiques à l'examen du Conseil;

problems or policy options to Council for consideration by Council in making decisions;

(c) agenda of Council or records recording deliberations or decisions of Council;

(d) records used for or reflecting communications or discussions between ministers of the Crown on matters relating to the making of government decisions or the formulation of government policy;

(e) records the purpose of which is to brief ministers of the Crown in relation to matters that are before, or are proposed to be brought before, Council or that are the subject of communications or discussions referred to in paragraph (d); and

(f) draft legislation.

c) ordres du jour du Conseil ou procès-verbaux de ses délibérations ou décisions;

d) documents employés en vue ou faisant état de communications ou de discussions entre ministres sur des questions liées à la prise des décisions du gouvernement ou à la formulation de sa politique;

e) documents d'information à l'usage des ministres sur des questions portées ou qu'il est prévu de porter devant le Conseil, ou sur des questions qui font l'objet des communications ou discussions visées à l'alinéa d);

f) avant-projets de loi ou projets de règlement.

Definition of *Council*

(2) For the purposes of subsection (1), ***Council*** means the Queen's Privy Council for Canada, committees of the Queen's Privy Council for Canada, Cabinet and committees of Cabinet.

Définition de *Conseil*

(2) Pour l'application du paragraphe (1), ***Conseil*** s'entend du Conseil privé de la Reine pour le Canada, du Cabinet et de leurs comités respectifs.

Exception

(3) Subsection (1) does not apply to

(a) confidences of the Queen's Privy Council for Canada that have been in existence for more than twenty years; or

(b) discussion papers described in paragraph (1)(b)

(i) if the decisions to which the discussion papers relate have been made public, or

(ii) where the decisions have not been made public, if four years have passed since the decisions were made.

R.S., 1985, c. P-21, s. 70; 1992, c. 1, s. 144(F).

Exception

(3) Le paragraphe (1) ne s'applique pas :

a) aux renseignements confidentiels du Conseil privé de la Reine pour le Canada dont l'existence remonte à plus de vingt ans;

b) aux documents de travail visés à l'alinéa (1)b), dans les cas où les décisions auxquelles ils se rapportent ont été rendues publiques ou, à défaut de publicité, ont été rendues quatre ans auparavant.

L.R. (1985), ch. P-21, art. 70; 1992, ch. 1, art. 144(F).

Certificate under *Canada Evidence Act*

70.1 (1) If a certificate under section 38.13 or 38.41 of the *Canada Evidence Act* prohibiting the disclosure of personal information of a specific individual is issued before a complaint is filed by that individual under this Act in respect of a request for access to that information, the provisions of this Act respecting that individual's right of access to their personal information do not apply to the information that is subject to the certificate.

Certificat en vertu de la *Loi sur la preuve au Canada*

70.1 (1) Dans le cas où a été délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada* un certificat interdisant la divulgation de renseignements personnels concernant un individu donné avant le dépôt par celui-ci d'une plainte au titre de la présente loi relative à la demande de communication de ces renseignements, les dispositions de cette loi concernant le droit d'accès de l'individu aux renseignements personnels le concernant ne s'appliquent pas aux renseignements visés par le certificat.

Certificate following filing of complaint

(2) Despite any other provision of this Act, if a certificate under section 38.13 or 38.41 of the *Canada Evidence Act* prohibiting the disclosure of personal information of a specific individual is issued in respect of personal information after the filing of a complaint under this Act in relation to a request for access to that information,

(a) all proceedings under this Act in respect of that information, including an investigation, audit, appeal or judicial review, are discontinued;

(b) the Privacy Commissioner shall not disclose the information and shall take all necessary precautions to prevent its disclosure; and

(c) the Privacy Commissioner shall, within 10 days after the certificate is published in the *Canada Gazette*, return the information to the head of the government institution that controls the information.

Certificat postérieur au dépôt d'une plainte

(2) Malgré les autres dispositions de la présente loi, dans le cas où a été délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada* un certificat interdisant la divulgation de renseignements personnels concernant un individu donné après le dépôt d'une plainte de refus d'accès au titre de la présente loi relative à la communication de ces renseignements :

a) toute procédure — notamment une enquête, une vérification, un appel ou une révision judiciaire — prévue par la présente loi et portant sur ces renseignements est interrompue;

b) le Commissaire à la protection de la vie privée ne peut communiquer les renseignements et prend les précautions nécessaires pour empêcher leur communication;

c) le Commissaire à la protection de la vie privée renvoie les renseignements au responsable de l'institution fédérale de qui ils relèvent dans les dix jours suivant la publication du certificat dans la *Gazette du Canada*.

Information not to be disclosed

(3) The Privacy Commissioner and every person acting on behalf or under the direction of the Privacy Commissioner, in carrying out their functions under this Act, shall not disclose information subject to a certificate issued under section 38.13 or 38.41 of the *Canada Evidence Act* and shall take every reasonable precaution to avoid the disclosure of that information.

Précautions à prendre

(3) Dans l'exercice de leurs attributions prévues par la présente loi, le Commissaire à la protection de la vie privée et les personnes agissant en son nom ou sous son autorité ne peuvent communiquer, et prennent toutes les précautions pour éviter que ne soient communiqués, les renseignements visés par un certificat délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada*.

Limited power of delegation

(4) The Privacy Commissioner may not, nor may an Assistant Privacy Commissioner, delegate the investigation of any complaint respecting information subject to a certificate issued under section 38.13 or 38.41 of the *Canada Evidence Act* except to one of a maximum of four officers or employees of the Commissioner specifically designated by the Commissioner for the purpose of conducting that investigation.

2001, c. 41, s. 104; 2024, c. 16, s. 92.

Pouvoir de délégation

(4) Le Commissaire à la protection de la vie privée ou un commissaire adjoint ne peuvent déléguer la tenue d'une enquête concernant des renseignements visés par un certificat délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada* qu'à un de leurs collaborateurs choisi parmi quatre des cadres ou employés du commissariat et que le Commissaire à la vie privée désigne spécialement à cette fin.

2001, ch. 41, art. 104; 2024, ch. 16, art. 92.

General

Duties and functions of designated Minister

71 (1) Subject to subsection (2), the designated Minister shall

(a) cause to be kept under review the manner in which personal information banks are maintained and managed to ensure compliance with the provisions of

Dispositions générales

Responsabilités du ministre désigné

71 (1) Sous réserve du paragraphe (2), le ministre désigné est responsable :

a) du contrôle des modalités de tenue et de gestion des fichiers de renseignements personnels dans le but d'en assurer la conformité avec la présente loi et ses

this Act and the regulations relating to access by individuals to personal information contained therein;

(b) assign or cause to be assigned a registration number to each personal information bank;

(c) prescribe such forms as may be required for the operation of this Act and the regulations;

(d) cause to be prepared and distributed to government institutions directives and guidelines concerning the operation of this Act and the regulations; and

(e) prescribe the form of, and what information is to be included in, reports made to Parliament under section 72.

règlements pour ce qui est de l'accès des individus aux renseignements personnels qui y sont versés;

b) de l'attribution d'une cote à chacun des fichiers de renseignements personnels;

c) de l'établissement des formulaires nécessaires à la mise en œuvre de la présente loi et de ses règlements;

d) de la rédaction des directives nécessaires à la mise en œuvre de la présente loi et de ses règlements et de leur diffusion auprès des institutions fédérales;

e) de la détermination de la forme et du fond des rapports au Parlement visés à l'article 72.

Exception for Bank of Canada

(2) Anything that is required to be done by the designated Minister under paragraph (1)(a) or (d) shall be done in respect of the Bank of Canada by the Governor of the Bank of Canada.

Exception dans le cas de la Banque du Canada

(2) Les responsabilités du ministre désigné définies aux alinéas (1)a) et d) incombent, dans le cas de la Banque du Canada, au gouverneur de celle-ci.

Review of existing and proposed personal information banks

(3) Subject to subsection (5), the designated Minister shall cause to be kept under review the utilization of existing personal information banks and proposals for the creation of new banks, and shall make such recommendations as he considers appropriate to the heads of the appropriate government institutions with regard to personal information banks that, in the opinion of the designated Minister, are under-utilized or the existence of which can be terminated.

Contrôle des fichiers existants ou à constituer

(3) Sous réserve du paragraphe (5), le ministre désigné exerce un contrôle sur l'utilisation des fichiers existants de renseignements personnels ainsi que sur les projets de constitution de nouveaux fichiers et présente aux responsables des institutions fédérales en cause ses recommandations quant aux fichiers qui, à son avis, sont utilisés d'une manière insuffisante ou dont l'existence ne se justifie plus.

Establishment and modification of personal information banks

(4) Subject to subsection (5), no new personal information bank shall be established and no existing personal information banks shall be substantially modified without approval of the designated Minister or otherwise than in accordance with any term or condition on which such approval is given.

Constitution ou modification de fichiers

(4) Sous réserve du paragraphe (5), la constitution de nouveaux fichiers de renseignements personnels de même que toute modification importante des fichiers existants sont subordonnées à l'approbation du ministre désigné et à l'observation des conditions qu'il stipule.

Application of subsections (3) and (4)

(5) Subsections (3) and (4) apply only in respect of personal information banks under the control of government institutions that are departments as defined in section 2 of the *Financial Administration Act*.

Application des par. (3) et (4)

(5) Les paragraphes (3) et (4) ne s'appliquent qu'aux fichiers de renseignements personnels relevant des institutions fédérales qui sont des ministères au sens de l'article 2 de la *Loi sur la gestion des finances publiques*.

Delegation to head of government institution

(6) The designated Minister may authorize the head of a government institution to exercise and perform, in such manner and subject to such terms and conditions as the designated Minister directs, any of the powers, functions and duties of the designated Minister under subsection (3) or (4).

1980-81-82-83, c. 111, Sch. II "71".

Délégation au responsable d'une institution fédérale

(6) Le ministre désigné peut, selon les modalités et dans les limites qu'il fixe, déléguer au responsable d'une institution fédérale les pouvoirs et fonctions que lui confèrent les paragraphes (3) et (4).

1980-81-82-83, ch. 111, ann. II « 71 ».

Designated Minister's power

71.1 The designated Minister may provide services with respect to the administration of this Act to the public and to any government institution.

2019, c. 18, s. 54.

Pouvoir du ministre désigné

71.1 Le ministre désigné peut fournir au public et à toute institution fédérale des services relatifs à l'application de la présente loi.

2019, ch. 18, art. 54.

Annual report — government institutions

72 (1) Every year the head of every government institution shall prepare a report on the administration of this Act within the institution during the period beginning on April 1 of the preceding year and ending on March 31 of the current year.

Rapport annuel des institutions fédérales

72 (1) Chaque année, le responsable de chaque institution fédérale établit un rapport sur l'application de la présente loi, en ce qui concerne son institution, au cours de la période commençant le 1er avril de l'année précédente et se terminant le 31 mars de l'année en cours.

Tabling of report

(2) Every report prepared under subsection (1) shall be laid before each House of Parliament on any of the first 15 days on which that House is sitting after September 1 of the year in which the report is prepared.

Dépôt

(2) Chaque rapport est déposé devant chaque chambre du Parlement dans les quinze premiers jours de séance de cette chambre suivant le 1er septembre de l'année de l'établissement du rapport.

Reference to Parliamentary committee

(3) Every report prepared under subsection (1) shall, after it is laid before the Senate and the House of Commons, under subsection (2), be referred to the committee designated or established by Parliament for the purpose of subsection 75(1).

Renvoi en comité

(3) Les rapports déposés conformément au paragraphe (2) sont renvoyés devant le comité désigné ou constitué par le Parlement en application du paragraphe 75(1).

Copy of report to designated Minister

(4) The head of every government institution shall provide a copy of the report to the designated Minister immediately after it is laid before both Houses.

R.S., 1985, c. P-21, s. 72; 2019, c. 18, s. 55.

Copie du rapport au ministre désigné

(4) Dès le dépôt du rapport devant chaque chambre du parlement, le responsable de l'institution fédérale en fournit une copie au ministre désigné.

L.R. (1985), ch. P-21, art. 72; 2019, ch. 18, art. 55.

Delegation by head of government institution

73 (1) The head of a government institution may, by order, delegate any of their powers, duties or functions under this Act to one or more officers or employees of that institution.

Pouvoir de délégation du responsable d'une institution

73 (1) Le responsable d'une institution fédérale peut, par arrêté, déléguer certaines de ses attributions à des cadres ou employés de l'institution.

Delegation to officers or employees of other government institution

(2) The head of a government institution may, for the purposes of subsection 73.1(1), by order, delegate any of their powers, duties or functions under this Act to one or more officers or employees of another government institution.

R.S., 1985, c. P-21, s. 73; 2019, c. 18, s. 56.

Délégation : cadres ou employés d'autres institutions fédérales

(2) Il peut, par arrêté, pour l'application du paragraphe 73.1(1), déléguer certaines de ses attributions à des cadres ou employés d'une autre institution fédérale.

L.R. (1985), ch. P-21, art. 73; 2019, ch. 18, art. 56.

Provision of services related to privacy

73.1 (1) A government institution may provide services related to any power, duty or function conferred or imposed on the head of a government institution under this Act to another government institution that is presided over by the same Minister or that is under the responsibility of the same Minister and may receive such services from any other such government institution.

Fourniture de services liés à la protection des renseignements personnels

73.1 (1) Toute institution fédérale peut fournir des services relatifs aux attributions conférées au responsable d'une institution fédérale au titre de la présente loi à une autre institution fédérale placée sous l'autorité du même ministre ou dont le même ministre est responsable, et recevoir de tels services d'une telle institution.

Written agreement

(2) A government institution may provide services under subsection (1) to another government institution only if it enters into an agreement in writing with the other government institution in respect of those services before it provides the services.

Accord écrit

(2) Une institution fédérale ne peut fournir les services visés au paragraphe (1) à une autre institution fédérale que si elle conclut avec celle-ci, au préalable, un accord écrit à cet égard.

Notice

(3) The head of a government institution that receives the services shall provide a copy of the agreement to the Privacy Commissioner and the designated Minister as soon as possible after the agreement is entered into. The head of the institution shall also notify the Commissioner and the designated Minister of any material change to that agreement.

Avis

(3) Le responsable de l'institution fédérale à qui les services sont fournis transmet une copie de l'accord au Commissaire à la protection de la vie privée ainsi qu'au ministre désigné le plus tôt possible après sa conclusion. En outre, il informe ces derniers de toute modification importante à l'accord.

Fees

(4) The head of a government institution that provides the services may charge a fee for those services. The fee is not to exceed the cost of providing the service.

Droits

(4) Le responsable de l'institution fédérale qui fournit les services peut exiger des droits pour la fourniture des services. Les droits ne peuvent toutefois excéder le coût des services fournis.

Spending authority

(5) The head of the institution that charges the fee may spend the revenues that are received from the provision of the services for any purpose of that institution. If the head of the institution spends the revenues, he or she must do so in the fiscal year in which they are received or, unless an appropriation Act provides otherwise, in the next fiscal year.

2019, c. 18, s. 56.

Dépense des recettes

(5) Il peut dépenser pour les besoins de l'institution fédérale dont il est responsable les recettes provenant de la fourniture des services. S'il les dépense, il doit le faire pendant l'exercice au cours duquel elles ont été reçues ou, sauf disposition contraire d'une loi de crédits, pendant l'exercice suivant.

2019, ch. 18, art. 56.

Personal information not under control of institution

73.2 The personal information that the head of a government institution provides to the head of another government institution for the purpose of the other institution providing the services referred to in subsection 73.1(1) is not under the control of that other institution.

2019, c. 18, s. 56.

Renseignements personnels ne relevant pas d'une institution

73.2 Les renseignements personnels que le responsable d'une institution fédérale transmet au responsable d'une autre institution fédérale en vue de la fourniture, par cette dernière, des services visés au paragraphe 73.1(1) ne relèvent pas de cette autre institution.

2019, ch. 18, art. 56.

Protection from civil proceeding or from prosecution

74 Notwithstanding any other Act of Parliament, no civil or criminal proceedings lie against the head of any government institution, or against any person acting on behalf or under the direction of the head of a government institution, and no proceedings lie against the Crown or any government institution, for the disclosure in good faith of any personal information pursuant to this Act, for any consequences that flow from that disclosure, or for the failure to give any notice required under this Act if reasonable care is taken to give the required notice.

1980-81-82-83, c. 111, Sch. II "74".

Immunité

74 Nonobstant toute autre loi fédérale, le responsable d'une institution fédérale et les personnes qui agissent en son nom ou sous son autorité bénéficient de l'immunité en matière civile ou pénale, et la Couronne ainsi que les institutions fédérales bénéficient de l'immunité devant toute juridiction, pour la communication de renseignements personnels faite de bonne foi dans le cadre de la présente loi ainsi que pour les conséquences qui en découlent; ils bénéficient également de l'immunité dans les cas où, ayant fait preuve de la diligence nécessaire, ils n'ont pu donner les avis prévus par la présente loi.

1980-81-82-83, ch. 111, ann. II « 74 ».

Permanent review of this Act by Parliamentary committee

75 (1) The administration of this Act shall be reviewed on a permanent basis by such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established by Parliament for that purpose.

Examen permanent par un comité parlementaire

75 (1) Le Parlement désigne ou constitue un comité, soit de la Chambre des communes, soit du Sénat, soit mixte, chargé spécialement de l'examen permanent de l'application de la présente loi.

Review and report to Parliament

(2) The committee designated or established by Parliament for the purpose of subsection (1) shall, not later than July 1, 1986, undertake a comprehensive review of the provisions and operation of this Act, and shall, within a year after the review is undertaken or within such further time as the House of Commons may authorize, submit a report to Parliament thereon including a statement of any changes the committee would recommend.

1980-81-82-83, c. 111, Sch. II "75".

Rapport au Parlement

(2) Le comité prévu au paragraphe (1) entreprend, au plus tard le 1er juillet 1986, un examen approfondi des dispositions de la présente loi ainsi que des conséquences de son application en vue de la présentation d'un rapport au Parlement où seront consignées ses conclusions ainsi que ses recommandations, s'il y a lieu, quant aux modifications qui seraient souhaitables; le rapport doit être présenté au Parlement dans l'année suivant le commencement de l'examen, ce délai pouvant être prorogé par la Chambre des communes.

1980-81-82-83, ch. 111, ann. II « 75 ».

Binding on Crown

76 This Act is binding on Her Majesty in right of Canada.

1980-81-82-83, c. 111, Sch. II "76".

La Couronne est liée

76 La présente loi lie Sa Majesté du chef du Canada.

1980-81-82-83, ch. 111, ann. II « 76 ».

Regulations

77 (1) The Governor in Council may make regulations

Règlements

77 (1) Le gouverneur en conseil peut, par règlement :

(a) specifying government institutions or parts of government institutions for the purpose of paragraph (e) of the definition ***personal information*** in section 3;

(b) prescribing the period of time for which any class of personal information is to be retained under subsection 6(1);

(c) prescribing the circumstances and the manner in which personal information under the control of a government institution is to be disposed of under subsection 6(3);

(d) specifying investigative bodies for the purposes of paragraph 8(2)(e) and sections 22 and 23;

(e) prescribing the circumstances in which and the conditions under which personal information may be disclosed under subsection 8(3);

(f) prescribing the period of time for which copies of requests received under paragraph 8(2)(e) and records of information disclosed pursuant to the requests are to be retained under subsection 8(4);

(g) specifying persons or bodies for the purpose of paragraph 8(2)(h);

(h) prescribing procedures to be followed in making and responding to a request for access to personal information under paragraph 12(1)(a) or (b);

(i) prescribing procedures to be followed by an individual or a government institution where the individual requests under subsection 12(2) a correction of personal information or a notation of a correction requested, including the period of time within which the correction or notation must be made;

(j) prescribing any fees, or the manner of calculating any fees, to be paid for being given access to personal information requested under subsection 12(1) or for the making of copies of such personal information;

(k) prescribing the procedures to be followed by the Privacy Commissioner and any person acting on behalf or under the direction of the Privacy Commissioner in examining or obtaining copies of records relevant to an investigation of a complaint in respect of a refusal to disclose personal information under paragraph 19(1)(a) or (b) or section 21;

(l) specifying classes of investigations for the purpose of paragraph 22(3)(c);

a) déterminer les institutions fédérales ou subdivisions de celles-ci visées à l'alinéa e) de la définition de ***renseignements personnels*** à l'article 3;

b) fixer la période pendant laquelle les renseignements personnels visés au paragraphe 6(1), doivent, selon leur catégorie, être conservés;

c) déterminer les circonstances et les modalités du retrait des renseignements personnels relevant d'une institution fédérale et visés au paragraphe 6(3);

d) déterminer les organismes d'enquête prévus à l'alinéa 8(2)e) et aux articles 22 et 23;

e) déterminer les circonstances et les conditions de la communication de renseignements visée au paragraphe 8(3);

f) déterminer pour l'application du paragraphe 8(4), la période de conservation des copies des demandes visées à l'alinéa 8(2)e) et des mentions des renseignements communiqués;

g) déterminer les personnes ou organismes prévus à l'alinéa 8(2)h);

h) établir les formalités à suivre pour les demandes de communication de renseignements personnels présentées en vertu des alinéas 12(1)a) ou b) ainsi que pour les réponses à y apporter;

i) établir les formalités à suivre par un individu ou une institution fédérale, en vertu du paragraphe 12(2), pour la correction de renseignements personnels ou la mention de corrections non effectuées et fixer le délai de correction ou de mention;

j) fixer, ou déterminer la façon de calculer, le montant du versement éventuellement exigible pour l'exercice de l'accès aux renseignements personnels demandés en vertu du paragraphe 12(1) ou pour la reproduction de copies à délivrer;

k) établir les règles à suivre par le Commissaire à la protection de la vie privée et les personnes agissant en son nom ou sous son autorité en ce qui a trait à la consultation et à l'obtention de copies des documents dont il a à prendre connaissance au cours des enquêtes portant sur un refus de communication fondé sur les alinéas 19(1)a) ou b) ou sur l'article 21;

l) préciser les catégories d'enquêtes pour l'application de l'alinéa 22(3)c);

(m) prescribing the class of individuals who may act on behalf of minors, incompetents, deceased persons or any other individuals under this Act and regulating the manner in which any rights or actions of individuals under this Act may be exercised or performed on their behalf;

(n) authorizing the disclosure of information relating to the physical or mental health of individuals to duly qualified medical practitioners or psychologists in order to determine whether disclosure of the information would be contrary to the best interests of the individuals, and prescribing any procedures to be followed or restrictions deemed necessary with regard to the disclosure and examination of the information; and

(o) prescribing special procedures for giving individuals access under subsection 12(1) to personal information relating to their physical or mental health and regulating the way in which that access is given.

Amendments to schedule

(2) The Governor in Council may, by order,

(a) add to the schedule the name of any department, ministry of state, body or office of the Government of Canada;

(b) replace in the schedule the former name of any department, ministry of state, body or office of the Government of Canada with its new name; and

(c) delete from the schedule the name of any department, ministry of state, body or office of the Government of Canada that has ceased to exist or has become part of another department, ministry of state, body or office of the Government of Canada.

R.S., 1985, c. P-21, s. 77; 2019, c. 18, s. 57.

m) déterminer les catégories d'individus qui ont qualité pour agir au nom d'autrui, notamment des mineurs, des incapables ou des personnes décédées, et fixer les modalités d'exercice des droits et recours d'un individu par son représentant;

n) autoriser la communication de renseignements concernant l'état physique ou mental d'un individu à des médecins ou psychologues en situation légale d'exercice pour que soit décidée la question de savoir si la prise de connaissance de ces renseignements par l'individu lui porterait préjudice et établir, en fixant au besoin les restrictions jugées nécessaires, les formalités à suivre pour la consultation et la communication de ces renseignements;

o) établir des règles spéciales quant à la communication aux individus, en vertu du paragraphe 12(1), des renseignements concernant leur état physique ou mental et fixer les modalités de cette communication.

Modification de l'annexe

(2) Le gouverneur en conseil peut, par décret :

a) ajouter à l'annexe le nom de tout ministère, département d'État ou organisme relevant du gouvernement du Canada;

b) remplacer à l'annexe l'ancien nom de tout ministère, département d'État ou organisme relevant du gouvernement du Canada par le nouveau;

c) supprimer de l'annexe le nom de tout ministère, département d'État ou organisme relevant du gouvernement du Canada ayant cessé d'exister ou étant intégré à un autre ministère, département d'État ou organisme relevant du gouvernement du Canada.

L.R. (1985), ch. P-21, art. 77; 2019, ch. 18, art. 57.

SCHEDULE

(Section 3)

Government Institutions

Departments and Ministries of State

Department for Women and Gender Equality
Ministère des Femmes et de l'Égalité des genres

Department of Agriculture and Agri-Food
Ministère de l'Agriculture et de l'Agroalimentaire

Department of Canadian Heritage
Ministère du Patrimoine canadien

Department of Citizenship and Immigration
Ministère de la Citoyenneté et de l'Immigration

Department of Crown-Indigenous Relations and Northern Affairs
Ministère des Relations Couronne-Autochtones et des Affaires du Nord

Department of Employment and Social Development
Ministère de l'Emploi et du Développement social

Department of the Environment
Ministère de l'Environnement

Department of Finance
Ministère des Finances

Department of Fisheries and Oceans
Ministère des Pêches et des Océans

Department of Foreign Affairs, Trade and Development
Ministère des Affaires étrangères, du Commerce et du Développement

Department of Health
Ministère de la Santé

Department of Housing, Infrastructure and Communities
Ministère du Logement, de l'Infrastructure et des Collectivités

Department of Indigenous Services
Ministère des Services aux Autochtones

Department of Industry
Ministère de l'Industrie

Department of Justice
Ministère de la Justice

Department of National Defence (including the Canadian Forces)
Ministère de la Défense nationale (y compris les Forces canadiennes)

Department of Natural Resources
Ministère des Ressources naturelles

Department of Public Safety and Emergency Preparedness
Ministère de la Sécurité publique et de la Protection civile

Department of Public Works and Government Services
Ministère des Travaux publics et des Services gouvernementaux

Department of Transport
Ministère des Transports

Department of Veterans Affairs
Ministère des Anciens Combattants

ANNEXE

(article 3)

Institutions fédérales

Ministères et départements d'État

Ministère de la Citoyenneté et de l'Immigration
Department of Citizenship and Immigration

Ministère de la Défense nationale (y compris les Forces canadiennes)
Department of National Defence (including the Canadian Forces)

Ministère de la Diversification de l'économie de l'Ouest canadien
Department of Western Economic Diversification

Ministère de l'Agriculture et de l'Agroalimentaire
Department of Agriculture and Agri-Food

Ministère de la Justice
Department of Justice

Ministère de la Santé
Department of Health

Ministère de la Sécurité publique et de la Protection civile
Department of Public Safety and Emergency Preparedness

Ministère de l'Emploi et du Développement social
Department of Employment and Social Development

Ministère de l'Environnement
Department of the Environment

Ministère de l'Industrie
Department of Industry

Ministère des Affaires étrangères, du Commerce et du Développement
Department of Foreign Affairs, Trade and Development

Ministère des Anciens Combattants
Department of Veterans Affairs

Ministère des Femmes et de l'Égalité des genres
Department for Women and Gender Equality

Ministère des Finances
Department of Finance

Ministère des Pêches et des Océans
Department of Fisheries and Oceans

Ministère des Relations Couronne-Autochtones et des Affaires du Nord
Department of Crown-Indigenous Relations and Northern Affairs

Ministère des Ressources naturelles
Department of Natural Resources

Ministère des Services aux Autochtones
Department of Indigenous Services

Ministère des Transports
Department of Transport

Ministère des Travaux publics et des Services gouvernementaux
Department of Public Works and Government Services

Ministère du Logement, de l'Infrastructure et des Collectivités
Department of Housing, Infrastructure and Communities

Department of Western Economic Diversification
Ministère de la Diversification de l'économie de l'Ouest canadien

Other Government Institutions

Administrative Tribunals Support Service of Canada
Service canadien d'appui aux tribunaux administratifs

Asia-Pacific Foundation of Canada
Fondation Asie-Pacifique du Canada

Atlantic Canada Opportunities Agency
Agence de promotion économique du Canada atlantique

Belledune Port Authority
Administration portuaire de Belledune

British Columbia Treaty Commission
Commission des traités de la Colombie-Britannique

Canada Border Services Agency
Agence des services frontaliers du Canada

Canada Emission Reduction Incentives Agency
Agence canadienne pour l'incitation à la réduction des émissions

Canada Employment Insurance Commission
Commission de l'assurance-emploi du Canada

Canada Foundation for Innovation
Fondation canadienne pour l'innovation

Canada Foundation for Sustainable Development Technology
Fondation du Canada pour l'appui technologique au développement durable

Canada–Newfoundland and Labrador Offshore Energy Regulator
Régie Canada — Terre-Neuve-et-Labrador de l'énergie extracôtière

Canada–Nova Scotia Offshore Energy Regulator
Régie Canada — Nouvelle-Écosse de l'énergie extracôtière

Canada Revenue Agency
Agence du revenu du Canada

Canada School of Public Service
École de la fonction publique du Canada

Canada Water Agency
Agence canadienne de l'eau

Canadian Accessibility Standards Development Organization
Organisation canadienne d'élaboration de normes d'accessibilité

Canadian Centre for Occupational Health and Safety
Centre canadien d'hygiène et de sécurité au travail

Canadian Energy Regulator
Régie canadienne de l'énergie

Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Canadian Grain Commission
Commission canadienne des grains

Canadian High Arctic Research Station
Station canadienne de recherche dans l'Extrême-Arctique

Canadian Human Rights Commission
Commission canadienne des droits de la personne

Ministère du Patrimoine canadien
Department of Canadian Heritage

Autres institutions fédérales

Administration du pipe-line du Nord
Northern Pipeline Agency

Administration du Régime de soins de santé de la fonction publique fédérale
Federal Public Service Health Care Plan Administration Authority

Administration portuaire de Belledune
Belledune Port Authority

Administration portuaire de Halifax
Halifax Port Authority

Administration portuaire de Montréal
Montreal Port Authority

Administration portuaire de Nanaïmo
Nanaimo Port Authority

Administration portuaire de Port-Alberni
Port Alberni Port Authority

Administration portuaire de Prince-Rupert
Prince Rupert Port Authority

Administration portuaire de Québec
Quebec Port Authority

Administration portuaire de Saint-Jean
Saint John Port Authority

Administration portuaire de Sept-Îles
Sept-Îles Port Authority

Administration portuaire de St. John's
St. John's Port Authority

Administration portuaire de Thunder Bay
Thunder Bay Port Authority

Administration portuaire de Toronto
Toronto Port Authority

Administration portuaire de Trois-Rivières
Trois-Rivières Port Authority

Administration portuaire de Vancouver Fraser
Vancouver Fraser Port Authority

Administration portuaire de Windsor
Windsor Port Authority

Administration portuaire du Saguenay
Saguenay Port Authority

Administration portuaire Hamilton-Oshawa
Hamilton-Oshawa Port Authority

Agence canadienne de développement économique du Nord
Canadian Northern Economic Development Agency

Agence canadienne de l'eau
Canada Water Agency

Agence canadienne d'évaluation d'impact
Impact Assessment Agency of Canada

Agence canadienne d'inspection des aliments
Canadian Food Inspection Agency

Agence canadienne pour l'incitation à la réduction des émissions
Canada Emission Reduction Incentives Agency

Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

Canadian Museum for Human Rights
Musée canadien des droits de la personne

Canadian Museum of Immigration at Pier 21
Musée canadien de l'immigration du Quai 21

Canadian Northern Economic Development Agency
Agence canadienne de développement économique du Nord

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canadian Radio-television and Telecommunications Commission
Conseil de la radiodiffusion et des télécommunications canadiennes

Canadian Security Intelligence Service
Service canadien du renseignement de sécurité

Canadian Space Agency
Agence spatiale canadienne

Canadian Transportation Accident Investigation and Safety Board
Bureau canadien d'enquête sur les accidents de transport et de la sécurité des transports

Canadian Transportation Agency
Office des transports du Canada

Civilian Review and Complaints Commission for the Royal Canadian Mounted Police
Commission civile d'examen et de traitement des plaintes relatives à la Gendarmerie royale du Canada

College of Immigration and Citizenship Consultants
Collège des consultants en immigration et en citoyenneté

College of Patent Agents and Trademark Agents
Collège des agents de brevets et des agents de marques de commerce

Communications Security Establishment
Centre de la sécurité des télécommunications

Copyright Board
Commission du droit d'auteur

Correctional Service of Canada
Service correctionnel du Canada

Director of Soldier Settlement
Directeur de l'établissement de soldats

The Director, The Veterans' Land Act
Directeur des terres destinées aux anciens combattants

Economic Development Agency of Canada for the Regions of Quebec
Agence de développement économique du Canada pour les régions du Québec

Energy Supplies Allocation Board
Office de répartition des approvisionnements d'énergie

Federal Economic Development Agency for Northern Ontario
Agence fédérale de développement économique pour le Nord de l'Ontario

Federal Economic Development Agency for Southern Ontario
Agence fédérale de développement économique pour le Sud de l'Ontario

Agence de développement économique du Canada pour les régions du Québec
Economic Development Agency of Canada for the Regions of Quebec

Agence de développement économique du Pacifique Canada
Pacific Economic Development Agency of Canada

Agence de la consommation en matière financière du Canada
Financial Consumer Agency of Canada

Agence de la santé publique du Canada
Public Health Agency of Canada

Agence de promotion économique du Canada atlantique
Atlantic Canada Opportunities Agency

Agence des services frontaliers du Canada
Canada Border Services Agency

Agence du revenu du Canada
Canada Revenue Agency

Agence fédérale de développement économique pour le Nord de l'Ontario
Federal Economic Development Agency for Northern Ontario

Agence fédérale de développement économique pour le Sud de l'Ontario
Federal Economic Development Agency for Southern Ontario

Agence Parcs Canada
Parks Canada Agency

Agence spatiale canadienne
Canadian Space Agency

Bibliothèque et Archives du Canada
Library and Archives of Canada

Bureau canadien d'enquête sur les accidents de transport et de la sécurité des transports
Canadian Transportation Accident Investigation and Safety Board

Bureau de l'administrateur de la Caisse d'indemnisation des dommages dus à la pollution par les hydrocarbures causée par les navires
Office of the Administrator of the Ship-source Oil Pollution Fund

Bureau de l'administrateur de la Caisse d'indemnisation pour les accidents ferroviaires impliquant des marchandises désignées
Office of the Administrator of the Fund for Railway Accidents Involving Designated Goods

Bureau de l'enquêteur correctionnel du Canada
Office of the Correctional Investigator of Canada

Bureau du commissaire au renseignement
Office of the Intelligence Commissioner

Bureau du Conseil privé
Privy Council Office

Bureau du directeur des poursuites pénales
Office of the Director of Public Prosecutions

Bureau du directeur général des élections
Office of the Chief Electoral Officer

Bureau du surintendant des institutions financières
Office of the Superintendent of Financial Institutions

Federal Public Service Health Care Plan Administration Authority
Administration du Régime de soins de santé de la fonction publiquefédérale

Financial Consumer Agency of Canada
Agence de la consommation en matière financière du Canada

Financial Transactions and Reports Analysis Centre of Canada
Centre d'analyse des opérations et déclarations financières du Canada

First Nations Financial Management Board
Conseil de gestion financière des premières nations

First Nations Infrastructure Institute
Institut des infrastructures des premières nations

First Nations Tax Commission
Commission de la fiscalité des premières nations

Gwich'in Land and Water Board
Office gwich'in des terres et des eaux

Gwich'in Land Use Planning Board
Office gwich'in d'aménagement territorial

Halifax Port Authority
Administration portuaire de Halifax

Hamilton-Oshawa Port Authority
Administration portuaire Hamilton-Oshawa

Historic Sites and Monuments Board of Canada
Commission des lieux et monuments historiques du Canada

Immigration and Refugee Board
Commission de l'immigration et du statut de réfugié

Impact Assessment Agency of Canada
Agence canadienne d'évaluation d'impact

Invest in Canada Hub
Investir au Canada

Law Commission of Canada
Commission du droit du Canada

Library and Archives of Canada
Bibliothèque et Archives du Canada

Mackenzie Valley Environmental Impact Review Board
Office d'examen des répercussions environnementales de la vallée du Mackenzie

Mackenzie Valley Land and Water Board
Office des terres et des eaux de la vallée du Mackenzie

Military Grievances External Review Committee
Comité externe d'examen des griefs militaires

Military Police Complaints Commission
Commission d'examen des plaintes concernant la police militaire

Miscarriage of Justice Review Commission
Commission d'examen des erreurs du système judiciaire

Montreal Port Authority
Administration portuaire de Montréal

Nanaimo Port Authority
Administration portuaire de Nanaïmo

The National Battlefields Commission
Commission des champs de bataille nationaux

Bureau du vérificateur général du Canada
Office of the Auditor General of Canada

Centre canadien d'hygiène et de sécurité au travail
Canadian Centre for Occupational Health and Safety

Centre d'analyse des opérations et déclarations financières du Canada
Financial Transactions and Reports Analysis Centre of Canada

Centre de la sécurité des télécommunications
Communications Security Establishment

Collège des agents de brevets et des agents de marques de commerce
College of Patent Agents and Trademark Agents

Collège des consultants en immigration et en citoyenneté
College of Immigration and Citizenship Consultants

Comité externe d'examen de la Gendarmerie royale du Canada
Royal Canadian Mounted Police External Review Committee

Comité externe d'examen des griefs militaires
Military Grievances External Review Committee

Commissariat à la protection de la vie privée
Office of the Privacy Commissioner

Commissariat à l'information
Office of the Information Commissioner

Commissariat à l'intégrité du secteur public
Office of the Public Sector Integrity Commissioner

Commissariat au lobbying
Office of the Commissioner of Lobbying

Commissariat aux langues officielles
Office of the Commissioner of Official Languages

Commission canadienne des droits de la personne
Canadian Human Rights Commission

Commission canadienne des grains
Canadian Grain Commission

Commission canadienne de sûreté nucléaire
Canadian Nuclear Safety Commission

Commission civile d'examen et de traitement des plaintes relatives à la Gendarmerie royale du Canada
Civilian Review and Complaints Commission for the Royal Canadian Mounted Police

Commission d'aménagement du Nunavut
Nunavut Planning Commission

Commission de la fiscalité des premières nations
First Nations Tax Commission

Commission de la fonction publique
Public Service Commission

Commission de l'assurance-emploi du Canada
Canada Employment Insurance Commission

Commission de l'immigration et du statut de réfugié
Immigration and Refugee Board

Commission de révision des lois
Statute Revision Commission

Commission des champs de bataille nationaux
The National Battlefields Commission

Commission des libérations conditionnelles du Canada
Parole Board of Canada

National Farm Products Council
Conseil national des produits agricoles

National Film Board
Office national du film

National Research Council of Canada
Conseil national de recherches du Canada

National Security and Intelligence Review Agency Secretariat
Secrétariat de l'Office de surveillance des activités en matière de sécurité nationale et de renseignement

Natural Sciences and Engineering Research Council
Conseil de recherches en sciences naturelles et en génie

Northern Pipeline Agency
Administration du pipe-line du Nord

Nunavut Impact Review Board
Commission du Nunavut chargée de l'examen des répercussions

Nunavut Planning Commission
Commission d'aménagement du Nunavut

Nunavut Surface Rights Tribunal
Tribunal des droits de surface du Nunavut

Nunavut Water Board
Office des eaux du Nunavut

Office of the Administrator of the Fund for Railway Accidents Involving Designated Goods
Bureau de l'administrateur de la Caisse d'indemnisation pour les accidents ferroviaires impliquant des marchandises désignées

Office of the Administrator of the Ship-source Oil Pollution Fund
Bureau de l'administrateur de la Caisse d'indemnisation des dommages dus à la pollution par les hydrocarbures causée par les navires

Office of the Auditor General of Canada
Bureau du vérificateur général du Canada

Office of the Chief Electoral Officer
Bureau du directeur général des élections

Office of the Commissioner of Lobbying
Commissariat au lobbying

Office of the Commissioner of Official Languages
Commissariat aux langues officielles

Office of the Correctional Investigator of Canada
Bureau de l'enquêteur correctionnel du Canada

Office of the Director of Public Prosecutions
Bureau du directeur des poursuites pénales

Office of the Information Commissioner
Commissariat à l'information

Office of the Intelligence Commissioner
Bureau du commissaire au renseignement

Office of the Privacy Commissioner
Commissariat à la protection de la vie privée

Office of the Public Sector Integrity Commissioner
Commissariat à l'intégrité du secteur public

Office of the Superintendent of Financial Institutions
Bureau du surintendant des institutions financières

Commission des lieux et monuments historiques du Canada
Historic Sites and Monuments Board of Canada

Commission des traités de la Colombie-Britannique
British Columbia Treaty Commission

Commission d'examen des erreurs du système judiciaire
Miscarriage of Justice Review Commission

Commission d'examen des plaintes concernant la police militaire
Military Police Complaints Commission

Commission du droit d'auteur
Copyright Board

Commission du droit du Canada
Law Commission of Canada

Commission du Nunavut chargée de l'examen des répercussions
Nunavut Impact Review Board

Conseil de gestion financière des premières nations
First Nations Financial Management Board

Conseil de la radiodiffusion et des télécommunications canadiennes
Canadian Radio-television and Telecommunications Commission

Conseil de recherches en sciences humaines
Social Sciences and Humanities Research Council

Conseil de recherches en sciences naturelles et en génie
Natural Sciences and Engineering Research Council

Conseil des subventions au développement régional
Regional Development Incentives Board

Conseil d'examen du prix des médicaments brevetés
Patented Medicine Prices Review Board

Conseil national de recherches du Canada
National Research Council of Canada

Conseil national des produits agricoles
National Farm Products Council

Directeur de l'établissement de soldats
Director of Soldier Settlement

Directeur des terres destinées aux anciens combattants
The Director, The Veterans' Land Act

École de la fonction publique du Canada
Canada School of Public Service

Fondation Asie-Pacifique du Canada
Asia-Pacific Foundation of Canada

Fondation canadienne pour l'innovation
Canada Foundation for Innovation

Fondation du Canada pour l'appui technologique au développement durable
Canada Foundation for Sustainable Development Technology

Gendarmerie royale du Canada
Royal Canadian Mounted Police

Institut des infrastructures des premières nations
First Nations Infrastructure Institute

Instituts de recherche en santé du Canada
Canadian Institutes of Health Research

Investir au Canada
Invest in Canada Hub

Pacific Economic Development Agency of Canada
Agence de développement économique du Pacifique Canada

Parks Canada Agency
Agence Parcs Canada

Parole Board of Canada
Commission des libérations conditionnelles du Canada

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

The Pierre Elliott Trudeau Foundation
La Fondation Pierre-Elliott-Trudeau

Port Alberni Port Authority
Administration portuaire de Port-Alberni

Prince Rupert Port Authority
Administration portuaire de Prince-Rupert

Privy Council Office
Bureau du Conseil privé

Public Health Agency of Canada
Agence de la santé publique du Canada

Public Service Commission
Commission de la fonction publique

Quebec Port Authority
Administration portuaire de Québec

Regional Development Incentives Board
Conseil des subventions au développement régional

Royal Canadian Mounted Police
Gendarmerie royale du Canada

Royal Canadian Mounted Police External Review Committee
Comité externe d'examen de la Gendarmerie royale du Canada

Saguenay Port Authority
Administration portuaire du Saguenay

Sahtu Land and Water Board
Office des terres et des eaux du Sahtu

Sahtu Land Use Planning Board
Office d'aménagement territorial du Sahtu

Saint John Port Authority
Administration portuaire de Saint-Jean

Secretariat of the National Security and Intelligence Committee of Parliamentarians
Secrétariat du Comité des parlementaires sur la sécurité nationale et le renseignement

Sept-Îles Port Authority
Administration portuaire de Sept-Îles

Shared Services Canada
Services partagés Canada

Social Sciences and Humanities Research Council
Conseil de recherches en sciences humaines

Statistics Canada
Statistique Canada

Statute Revision Commission
Commission de révision des lois

St. John's Port Authority
Administration portuaire de St. John's

Thunder Bay Port Authority
Administration portuaire de Thunder Bay

La Fondation Pierre-Elliott-Trudeau
The Pierre Elliott Trudeau Foundation

Musée canadien de l'immigration du Quai 21
Canadian Museum of Immigration at Pier 21

Musée canadien des droits de la personne
Canadian Museum for Human Rights

Office d'aménagement territorial du Sahtu
Sahtu Land Use Planning Board

Office de répartition des approvisionnements d'énergie
Energy Supplies Allocation Board

Office des droits de surface du Yukon
Yukon Surface Rights Board

Office des eaux du Nunavut
Nunavut Water Board

Office des terres et des eaux de la vallée du Mackenzie
Mackenzie Valley Land and Water Board

Office des terres et des eaux du Sahtu
Sahtu Land and Water Board

Office des transports du Canada
Canadian Transportation Agency

Office d'évaluation environnementale et socioéconomique du Yukon
Yukon Environmental and Socio-economic Assessment Board

Office d'examen des répercussions environnementales de la vallée du Mackenzie
Mackenzie Valley Environmental Impact Review Board

Office gwich'in d'aménagement territorial
Gwich'in Land Use Planning Board

Office gwich'in des terres et des eaux
Gwich'in Land and Water Board

Office national du film
National Film Board

Organisation canadienne d'élaboration de normes d'accessibilité
Canadian Accessibility Standards Development Organization

Régie Canada — Nouvelle-Écosse de l'énergie extracôtière
Canada–Nova Scotia Offshore Energy Regulator

Régie Canada — Terre-Neuve-et-Labrador de l'énergie extracôtière
Canada–Newfoundland and Labrador Offshore Energy Regulator

Régie canadienne de l'énergie
Canadian Energy Regulator

Secrétariat de l'Office de surveillance des activités en matière de sécurité nationale et de renseignement
National Security and Intelligence Review Agency Secretariat

Secrétariat du Comité des parlementaires sur la sécurité nationale et le renseignement
Secretariat of the National Security and Intelligence Committee of Parliamentarians

Secrétariat du Conseil du Trésor
Treasury Board Secretariat

Service canadien d'appui aux tribunaux administratifs
Administrative Tribunals Support Service of Canada

Toronto Port Authority
Administration portuaire de Toronto

Treasury Board Secretariat
Secrétariat du Conseil du Trésor

Trois-Rivières Port Authority
Administration portuaire de Trois-Rivières

Vancouver Fraser Port Authority
Administration portuaire de Vancouver Fraser

Veterans Review and Appeal Board
Tribunal des anciens combattants (révision et appel)

Windsor Port Authority
Administration portuaire de Windsor

Yukon Environmental and Socio-economic Assessment Board
Office d'évaluation environnementale et socioéconomique du Yukon

Yukon Surface Rights Board
Office des droits de surface du Yukon

R.S., 1985, c. P-21, Sch.; R.S., 1985, c. 22 (1st Supp.), s. 11, c. 44 (1st Supp.), s. 5, c. 46 (1st Supp.), s. 9; SOR/85-612; R.S., 1985, c. 8 (2nd Supp.), s. 27, c. 19 (2nd Supp.), s. 52; SOR/86-136; R.S., 1985, c. 1 (3rd Supp.), s. 12, c. 3 (3rd Supp.), s. 2, c. 18 (3rd Supp.), s. 39, c. 20 (3rd Supp.), s. 39, c. 24 (3rd Supp.), s. 53, c. 28 (3rd Supp.), s. 308, c. 1 (4th Supp.), s. 48, c. 7 (4th Supp.), s. 7, c. 10 (4th Supp.), s. 22, c. 11 (4th Supp.), s. 15, c. 21 (4th Supp.), s. 5, c. 28 (4th Supp.), s. 36, c. 31 (4th Supp.), s. 101, c. 41 (4th Supp.), s. 53, c. 47 (4th Supp.), s. 52; SOR/88-110; 1989, c. 3, s. 47, c. 27, s. 22; 1990, c. 1, s. 31, c. 3, s. 32, c. 13, s. 25; SOR/90-326, 345; 1991, c. 3, s. 12, c. 6, s. 24, c. 16, s. 23, c. 38, ss. 29, 38; SOR/91-592; 1992, c. 1, ss. 114, 145(F), 155, c. 33, s. 70, c. 37, s. 78; SOR/92-97, 99; 1993, c. 1, ss. 10, 20, 32, 42, c. 3, ss. 17, 18, c. 28, s. 78, c. 31, s. 26, c. 34, ss. 104, 148; 1994, c. 26, ss. 57, 58, c. 31, s. 20, c. 38, ss. 21, 22, c. 41, ss. 29, 30, c. 43, s. 91; 1995, c. 1, ss. 54 to 56, c. 5, ss. 20, 21, c. 11, ss. 31, 32, c. 12, s. 11, c. 18, ss. 89, 90, c. 28, ss. 54, 55, c. 29, ss. 15, 31, 35, 75, 84, c. 45, s. 24; 1996, c. 8, ss. 27, 28, c. 9, s. 28, c. 10, ss. 253, 254, c. 11, ss. 77 to 80, c. 16, ss. 46 to 48; SOR/96-357, 539; 1997, c. 6, s. 84, c. 9, ss. 112, 113, c. 20, s. 55; 1998, c. 9, ss. 44, 45, c. 10, ss. 190 to 194, c. 25, s. 167, c. 26, ss. 77, 78, c. 31, s. 57, c. 35, s. 123; SOR/98-119, 150; SOR/98-321, s. 1; SOR/98-567; 1999, c. 17, ss. 174, 175, c. 31, ss. 177, 178; 2000, c. 6, ss. 45, 46, c. 17, s. 90, c. 28, s. 50, c. 34, s. 94(F); SOR/2000-176; 2001, c. 9, s. 590, c. 22, ss. 18, 19, c. 33, ss. 25, 26, c. 34, ss. 16, 78; SOR/2001-144, s. 1; SOR/2001-201, 330; 2002, c. 7, s. 228, c. 10, s. 191, c. 17, ss. 14, 25; SOR/2002-44, 72, 175, 292, 344; 2003, c. 7, s. 129, c. 22, ss. 189, 248, 255, 256; SOR/2003-149, 422, 427, 434, 439; 2004, c. 2, s. 75, c. 7, s. 35, c. 11, ss. 40, 41; SOR/2004-23, 206; 2005, c. 9, s. 152, c. 10, ss. 30, 31, c. 30, s. 90, c. 34, s. 72 to 74, c. 35, s. 63, c. 38, s. 138, c. 46, s. 58.1; SOR/2005-252; 2006, c. 4, s. 212, c. 9, ss. 97, 98, 140, 190 to 193; SOR/2006-25, 29, 33, 71, 100, 218; SOR/2007-216; 2008, c. 9, s. 11, c. 22, s. 50, c. 28, s. 99; SOR/2008-131, 136; SOR/2009-175, 244, 249; 2010, c. 7, s. 10, c. 12, s. 1677; 2011, c. 25, s. 63; SOR/2011-163, 259; 2012, c. 1, s. 160, c. 19, ss. 276, 387, 472, 502, 576, 590, 679, 749, c. 31, ss. 262, 294; 2013, c. 14, ss. 4, 19, c. 18, ss. 55, 56, c. 24, ss. 124, 125, c. 33, ss. 185 to 187, c. 40, ss. 227, 228, 285, 459; 2014, c. 2, s. 26, c. 13, ss. 103, 104, c. 20, ss. 366(E), 421 to 427, c. 39, ss. 165, 166; SOR/2014-67; 2015, c. 3, s. 147; 2017, c. 15, s. 46, c. 20, s. 448; SOR/2017-258; 2018, c. 27, ss. 254, 670, 671; SOR/2018-24; 2019, c. 10, s. 204; 2019, c. 13, s. 38; 2019, c. 13, s. 39; 2019, c. 13, s. 71; 2019, c. 28, s. 143; 2019, c. 28, s. 144; 2019, c. 29, s. 299; 2019, c. 29, s. 359; 2019, c. 29, s. 360; 2019, c. 29, s. 361; SOR/2021-189, s. 1; SOR/2021-194, s. 1; 2023, c. 16, s. 59; 2024, c. 15, s. 214; 2024, c. 15, s. 334; 2024, c. 15, s. 335; 2024, c. 20, s. 215; 2024, c. 20, s. 217; 2024, c. 33, s. 17; SOR/2024-185, s. 1.

Service canadien du renseignement de sécurité
Canadian Security Intelligence Service

Service correctionnel du Canada
Correctional Service of Canada

Services partagés Canada
Shared Services Canada

Station canadienne de recherche dans l'Extrême-Arctique
Canadian High Arctic Research Station

Statistique Canada
Statistics Canada

Tribunal des anciens combattants (révision et appel)
Veterans Review and Appeal Board

Tribunal des droits de surface du Nunavut
Nunavut Surface Rights Tribunal

L.R. (1985), ch. P-21, ann.; L.R. (1985), ch. 22 (1er suppl.), art. 11, ch. 44 (1er suppl.), art. 5, ch. 46 (1er suppl.), art. 9; DORS/85-612; L.R. (1985), ch. 8 (2e suppl.), art. 27, ch. 19 (2e suppl.), art. 52; DORS/86-136; L.R. (1985), ch. 1 (3e suppl.), art. 12, ch. 3 (3e suppl.), art. 2, ch. 18 (3e suppl.), art. 39, ch. 20 (3e suppl.), art. 39, ch. 24 (3e suppl.), art. 53, ch. 28 (3e suppl.), art. 308, ch. 1 (4e suppl.), art. 48, ch. 7 (4e suppl.), art. 7, ch. 10 (4e suppl.), art. 22, ch. 11 (4e suppl.), art. 15, ch. 21 (4e suppl.), art. 5, ch. 28 (4e suppl.), art. 36, ch. 31 (4e suppl.), art. 101, ch. 41 (4e suppl.), art. 53, ch. 47 (4e suppl.), art. 52; DORS/88-110; 1989, ch. 3, art. 47, ch. 27, art. 22; 1990, ch. 1, art. 31, ch. 3, art. 32, ch. 13, art. 25; DORS/90-326, 345; 1991, ch. 3, art. 12, ch. 6, art. 24, ch. 16, art. 23, ch. 38, art. 29 et 38; DORS/91-592; 1992, ch. 1, art. 114, 145(F) et 155, ch. 33, art. 70, ch. 37, art. 78; DORS/92-97, 99; 1993, ch. 1, art. 10, 20, 32 et 42, ch. 3, art. 17 et 18, ch. 28, art. 78, ch. 31, art. 26, ch. 34, art. 104 et 148; 1994, ch. 26, art. 57 et 58, ch. 31, art. 20, ch. 38, art. 21 et 22, ch. 41, art. 29 et 30, ch. 43, art. 91; 1995, ch. 1, art. 54 à 56, ch. 5, art. 20 et 21, ch. 11, art. 31 et 32, ch. 12, art. 11, ch. 18, art. 89 et 90, ch. 28, art. 54 et 55, ch. 29, art. 15, 31, 35, 75 et 84, ch. 45, art. 24; 1996, ch. 8, art. 27 et 28, ch. 9, art. 28, ch. 10, art. 253 et 254, ch. 11, art. 77 à 80, ch. 16, art. 46 à 48; DORS/96-357, 539; 1997, ch. 6, art. 84, ch. 9, art. 112 et 113, ch. 20, art. 55; 1998, ch. 9, art. 44 et 45, ch. 10, art. 190 à 194, ch. 25, art. 167, ch. 26, art. 77 et 78, ch. 31, art. 57, ch. 35, art. 123; DORS/98-119, 150; DORS/98-321, art. 1; DORS/98-567; 1999, ch. 17, art. 174 et 175, ch. 31, art. 177 et 178; 2000, ch. 6, art. 45 et 46, ch. 17, art. 90, ch. 28, art. 50, ch. 34, art. 94(F); DORS/2000-176; 2001, ch. 9, art. 590, ch. 22, art. 18 et 19, ch. 33, art. 25 et 26, ch. 34, art. 16 et 78; DORS/2001-144, art. 1; DORS/2001-201, 330; 2002, ch. 7, art. 228, ch. 10, art. 191, ch. 17, art. 14 et 25; DORS/2002-44, 72, 175, 292, 344; 2003, ch. 7, art. 129, ch. 22, art. 189, 248, 255 et 256; DORS/2003-149, 422, 427, 434, 439; 2004, ch. 2, art. 75, ch. 7, art. 35, ch. 11, art. 40 et 41; DORS/2004-23, 206; 2005, ch. 9, art. 152, ch. 10, art. 30 et 31, ch. 30, art. 90, ch. 34, art. 72 à 74, ch. 35, art. 63, ch. 38, art. 138, ch. 46, art. 58.1; DORS/2005-252; 2006, ch. 4, art. 212, ch. 9, art. 97, 98, 140, 190 à 193; DORS/2006-25, 29, 33, 71, 100, 218; DORS/2007-216; 2008, ch. 9, art. 11, ch. 22, art. 50, ch. 28, art. 99; DORS/2008-131, 136; DORS/2009-175, 244, 249; 2010, ch. 7, art. 10, ch. 12, art. 1677; 2011, ch. 25, art. 63; DORS/2011-163, 259; 2012, ch. 1, art. 160, ch. 19, art. 276, 387, 472, 502, 576, 590, 679 et 749, ch. 31, art. 262 et 294; 2013, ch. 14, art. 4 et 19, ch. 18, art. 55 et 56, ch. 24, art. 124 et 125, ch. 33, art. 185 à 187, ch. 40, art. 227, 228, 285 et 459; 2014, ch. 2, art. 26, ch. 13, art. 103 et 104, ch. 20, art. 366(A), 421 à 427, ch. 39, art. 165 et 166; DORS/2014-67; 2015, ch. 3, art. 147; 2017, ch. 15, art. 46, ch. 20, art. 448; DORS/2017-258; 2018, ch. 27, art. 254, 670 et 671; DORS/2018-24; 2019, ch. 10, art. 204; 2019, ch. 13, art. 38; 2019, ch. 13, art. 39; 2019, ch. 13, art. 71; 2019, ch. 28, art. 143; 2019, ch. 28, art. 144; 2019, ch. 29, art. 299; 2019, ch. 29, art. 359; 2019, ch. 29, art. 360; 2019, ch. 29, art. 361; DORS/2021-189, art. 1; DORS/2021-194, art. 1; 2023, ch. 16, art. 59; 2024, ch. 15, art. 214; 2024, ch. 15, art. 334; 2024, ch. 15, art. 335; 2024, ch. 20, art. 215; 2024, ch. 20, art. 217; 2024, ch. 33, art. 17; DORS/2024-185, art. 1.

RELATED PROVISIONS

— 2005, c. 26, s. 18(1), as amended by 2005, c. 26, par. 27(2)(a)(E)

Definitions

18 (1) The following definitions apply in this section.

former agency means the portion of the federal public administration known as the Economic Development Agency of Canada for the Regions of Quebec. (*ancienne agence*)

new agency means the Economic Development Agency of Canada for the Regions of Quebec established by section 8. (*nouvelle agence*)

— 2005, c. 26, par. 18(7)(c)

References

18 (7) A reference to the former agency in any of the following is deemed to be a reference to the new agency:

(c) the schedule to the *Privacy Act*, under the heading "*Other Government Institutions*";

— 2005, c. 38, s. 16, as amended by 2005, c. 38, par. 144(8)(a)(E)

Definitions

16 The following definitions apply in sections 17 to 19 and 21 to 28.

former agency means the portion of the federal public administration known as the Canada Border Services Agency. (*ancienne agence*)

new agency means the Canada Border Services Agency established under subsection 3(1). (*nouvelle agence*)

order P.C. 2003-2064 means Order in Council P.C. 2003-2064 of December 12, 2003, registered as SI/2003-216. (*décret C.P. 2003-2064*)

— 2005, c. 38, par. 19(1)(b), (g)

References

19 (1) A reference to the former agency in any of the following is deemed to be a reference to the new agency:

(b) the schedule to the *Privacy Act*;

DISPOSITIONS CONNEXES

— 2005, ch. 26, par. 18(1), modifié par 2005, ch. 26, al. 27(2)a)(A)

Définitions

18 (1) Les définitions qui suivent s'appliquent au présent article.

ancienne agence Le secteur de l'administration publique fédérale appelé Agence de développement économique du Canada pour les régions du Québec. (*former agency*)

nouvelle agence L'Agence de développement économique du Canada pour les régions du Québec constituée par l'article 8. (*new agency*)

— 2005, ch. 26, al. 18(7)c)

Mentions

18 (7) La mention de l'ancienne agence dans les dispositions ci-après vaut mention de la nouvelle agence :

c) l'annexe de la *Loi sur la protection des renseignements personnels*, sous l'intertitre « *Autres institutions fédérales* »;

— 2005, ch. 38, art. 16, modifié par 2005, ch. 38, al. 144(8)a)(A)

Définitions

16 Les définitions qui suivent s'appliquent aux articles 17 à 19 et 21 à 28.

ancienne agence Le secteur de l'administration publique fédérale appelé Agence des services frontaliers du Canada. (*former agency*)

décret C.P. 2003-2064 Le décret C.P. 2003-2064 du 12 décembre 2003 portant le numéro d'enregistrement TR/2003-216. (*order P.C. 2003-2064*)

nouvelle agence L'Agence des services frontaliers du Canada constituée par le paragraphe 3(1). (*new agency*)

— 2005, ch. 38, al. 19(1)b) et g)

Mentions

19 (1) La mention de l'ancienne agence dans les textes ci-après vaut mention de la nouvelle agence :

(g) any order of the Governor in Council made under paragraph (b) of the definition *head* in section 3 of the *Privacy Act*; and

— 2006, c. 5, s. 16

Definitions

16 The following definitions apply in sections 17 to 19.

former agency means the portion of the federal public administration known as the Public Health Agency of Canada. (*ancienne agence*)

new agency means the Public Health Agency of Canada established under section 3. (*nouvelle agence*)

— 2006, c. 5, s. 19

References

19 (1) A reference to the former agency in any of the following schedules and orders is deemed to be a reference to the new agency:

(c) the schedule to the *Privacy Act*, under the heading "Other Government Institutions";

Deputy head

(2) The designation of a person as deputy head of the former agency in any order of the Governor in Council made pursuant to paragraph 29(e) of the *Canadian Security Intelligence Service Act* or to the definition *deputy head* in subsection 2(1) of the *Public Service Employment Act* is deemed to be a designation of the Chief Public Health Officer as deputy head of the new agency.

— 2006, c. 9, par. 120(d)

Transitional — continuation in office

120 A person who holds office under one of the following provisions immediately before the day on which this section comes into force continues in office and is deemed to have been appointed under that provision, as amended by sections 109 to 111, 118 and 119, to hold office for the remainder of the term for which he or she had been appointed:

(d) the Privacy Commissioner under section 53 of the *Privacy Act*; and

b) l'annexe de la *Loi sur la protection des renseignements personnels*;

g) tout décret pris en vertu de l'alinéa b) de la définition de *responsable d'institution fédérale*, à l'article 3 de la *Loi sur la protection des renseignements personnels*;

— 2006, ch. 5, art. 16

Définitions

16 Les définitions qui suivent s'appliquent aux articles 17 à 19.

ancienne agence Le secteur de l'administration publique fédérale appelé l'Agence de la santé publique du Canada. (*former agency*)

nouvelle agence L'Agence de la santé publique du Canada constituée par l'article 3. (*new agency*)

— 2006, ch. 5, art. 19

Mentions

19 (1) La mention de l'ancienne agence dans les dispositions ci-après vaut mention de la nouvelle agence :

c) l'annexe de la *Loi sur la protection des renseignements personnels*, sous l'intertitre « Autres institutions fédérales »;

Administrateur général

(2) La désignation de toute personne à titre d'administrateur général de l'ancienne agence dans tout décret pris en vertu de l'alinéa 29e) de la *Loi sur le Service canadien du renseignement de sécurité* ou de la définition de *administrateur général* au paragraphe 2(1) de la *Loi sur l'emploi dans la fonction publique* vaut désignation de l'administrateur en chef à titre d'administrateur général de la nouvelle agence.

— 2006, ch. 9, al. 120d)

Maintien en fonction

120 L'entrée en vigueur des articles 109 à 111, 118 et 119 est sans effet sur le mandat des titulaires des charges ci-après, qui demeurent en fonctions et sont réputés avoir été nommés en vertu de la disposition mentionnée ci-après pour chacune, dans sa version modifiée par l'un ou l'autre de ces articles, selon le cas :

d) le commissaire à la protection de la vie privée nommé en vertu de l'article 53 de la *Loi sur la protection des renseignements personnels*;

— 2019, c. 9, s. 25

Definitions

25 The following definitions apply in this section and in sections 26 to 28.

commencement day means the day on which this Act receives royal assent. (*date d'entrée en vigueur*)

copy means a copy referred to in subsection 29(1) or (2) of the *Ending the Long-gun Registry Act*. (*copie*)

personal information means any *personal information*, as defined in section 3 of the *Privacy Act*, that is contained in a record or copy. (*renseignements personnels*)

record means, other than in section 28, a record referred to in subsection 29(1) or (2) of the *Ending the Long-gun Registry Act*. (*registres*)

specified proceeding means any request, complaint, investigation, application, judicial review, appeal or other proceeding under the *Access to Information Act* or the *Privacy Act* that is with respect to a record or copy or to personal information and that

(a) was made or initiated on or before June 22, 2015 and was not concluded, or in respect of which no decision was made, on or before that day; or

(b) was made or initiated after June 22, 2015 but before the commencement day. (*procédure désignée*)

— 2019, c. 9, s. 26

Non-application — *Access to Information Act*

26 (1) Subject to section 27, the *Access to Information Act* does not apply as of the commencement day with respect to records and copies.

Non-application — *Privacy Act*

(2) Subject to section 27, the *Privacy Act*, other than its subsections 6(1) and (3), does not apply as of the commencement day with respect to personal information.

— 2019, ch. 9, art. 25

Définitions

25 Les définitions qui suivent s'appliquent au présent article et aux articles 26 à 28.

copie Copie visée aux paragraphes 29(1) ou (2) de la *Loi sur l'abolition du registre des armes d'épaule*. (*copy*)

date d'entrée en vigueur La date de sanction de la présente loi. (*commencement day*)

procédure désignée Toute procédure — notamment les demandes, plaintes, enquêtes, recours en révision, révisions judiciaires ou appels — qui est engagée sous le régime de la *Loi sur l'accès à l'information* ou de la *Loi sur la protection des renseignements personnels*, qui est relative aux registres, copies ou renseignements personnels et qui, selon le cas :

a) a été introduite ou a débuté au plus tard le 22 juin 2015 et n'a pas été conclue ou à l'égard de laquelle aucune décision n'a encore été prise à cette date;

b) a été introduite ou a débuté après le 22 juin 2015 mais avant la date d'entrée en vigueur. (*specified proceeding*)

registres Registres et fichiers visés aux paragraphes 29(1) ou (2) de la *Loi sur l'abolition du registre des armes d'épaule*. (*record*)

renseignements personnels Les *renseignements personnels*, au sens de l'article 3 de la *Loi sur la protection des renseignements personnels*, versés dans les registres et copies. (*personal information*)

— 2019, ch. 9, art. 26

Non-application — *Loi sur l'accès à l'information*

26 (1) Sous réserve de l'article 27, la *Loi sur l'accès à l'information* ne s'applique pas, à compter de la date d'entrée en vigueur, relativement aux registres et copies.

Non-application — *Loi sur la protection des renseignements personnels*

(2) Sous réserve de l'article 27, la *Loi sur la protection des renseignements personnels*, à l'exception de ses paragraphes 6(1) et (3), ne s'applique pas, à compter de la date d'entrée en vigueur, relativement aux renseignements personnels.

Non-application — subsections 6(1) and (3) of the *Privacy Act*

(3) For greater certainty, by reason of subsection 29(3) of the *Ending the Long-gun Registry Act*, subsections 6(1) and (3) of the *Privacy Act* do not apply as of April 5, 2012 with respect to personal information.

— 2019, c. 9, s. 27

Continued application

27 (1) The *Privacy Act*, other than its subsections 6(1) and (3), and the *Access to Information Act* continue to apply with respect to any specified proceeding and to any complaint, investigation, application, judicial review or appeal that results from a specified proceeding.

Period running on June 22, 2015 restarts

(2) A time limit, or other period of time, under the *Access to Information Act* or the *Privacy Act* that was running on June 22, 2015 with respect to a specified proceeding described in paragraph (a) of the definition of that expression in section 25 is deemed to restart, from the beginning, on the commencement day.

Specified proceeding initiated after June 22, 2015

(3) A specified proceeding described in paragraph (b) of the definition of that expression in section 25 is deemed to be made or initiated on the commencement day.

For greater certainty

(4) For greater certainty, no destruction of records or copies that are the subject of proceedings referred to in subsection (1) is to occur until all proceedings referred to in that subsection are finally disposed of, settled or abandoned.

— 2019, c. 13, par. 82(1)(c)

References

82 (1) A reference to the former department in any of the following is deemed to be a reference to the new department:

(c) the schedule to the *Privacy Act* under the heading "Other Government Institutions";

Non-application — paragraphes 6(1) et (3) de la *Loi sur la protection des renseignements personnels*

(3) Il est entendu qu'en application du paragraphe 29(3) de la *Loi sur l'abolition du registre des armes d'épaule*, les paragraphes 6(1) et (3) de la *Loi sur la protection des renseignements personnels* ne s'appliquent pas, à compter du 5 avril 2012, relativement aux renseignements personnels.

— 2019, ch. 9, art. 27

Application continue

27 (1) La *Loi sur la protection des renseignements personnels,* à l'exception de ses paragraphes 6(1) et (3), et la *Loi sur l'accès à l'information* continuent de s'appliquer relativement à toute procédure désignée et aux plaintes, enquêtes, recours en révision, révisions judiciaires ou appels qui découlent d'une procédure désignée.

Recommencement des délais en cours le 22 juin 2015

(2) Le délai — ou la période — prévu sous le régime de la *Loi sur l'accès à l'information* ou de la *Loi sur la protection des renseignements personnels*, en cours le 22 juin 2015 relativement à une procédure désignée visée à l'alinéa a) de la définition de ce terme à l'article 25 est réputé recommencer à zéro à la date d'entrée en vigueur.

Procédure désignée introduite après le 22 juin 2015

(3) Toute procédure désignée visée à l'alinéa b) de la définition de ce terme à l'article 25 est réputée être introduite ou avoir débuté à la date d'entrée en vigueur.

Précision

(4) Il est entendu que les registres ou copies faisant l'objet de toute procédure visée au paragraphe (1) ne peuvent être détruits avant le prononcé d'une décision définitive à l'égard de l'ensemble des procédures qui y sont visées ou le règlement ou l'abandon de celles-ci.

— 2019, ch. 13, al. 82(1)c)

Mentions

82 (1) La mention de l'ancien ministère dans les textes ci-après vaut mention du nouveau ministère :

c) l'annexe de la *Loi sur la protection des renseignements personnels*, sous l'intertitre « Autres institutions fédérales »;

— 2019, c. 18, s. 59

59 The following amendments to the schedule to the *Privacy Act* are deemed to have been validly made:

(a) the deletion of "Federal Office of Regional Development – Quebec/Bureau fédéral de développement régional (Québec)" under the heading "Other Government Institutions" by Order in Council P.C. 1998-186 of February 13, 1998, registered as SOR/98-119;

(b) the deletion of "The Leadership Network/Le Réseau du leadership" under the heading "Other Government Institutions" by Order in Council P.C. 1998-956 of June 3, 1998, registered as SOR/98-321;

(c) the deletion of "The Leadership Network/Le Réseau du leadership" under the heading "Other Government Institutions" by Order in Council P.C. 2001-616 of April 11, 2001, registered as SOR/2001-144;

(d) the deletion of "Canada Information Office/Bureau d'information du Canada" under the heading "Other Government Institutions" by Order in Council P.C. 2001-1577 of August 28, 2001, registered as SOR/2001-330;

(e) the deletion of "Millennium Bureau of Canada/Bureau du Canada pour le millénaire" under the heading "Other Government Institutions" by Order in Council P.C. 2002-188 of February 7, 2002, registered as SOR/2002-72;

(f) the deletion of "Office of Infrastructure and Crown Corporations of Canada/Bureau de l'infrastructure et des sociétés d'État du Canada" under the heading "Departments and Ministries of State" by Order in Council P.C. 2002-1326 of August 6, 2002, registered as SOR/2002-292;

(g) the deletion of "Communication Canada/Communication Canada" under the heading "Other Government Institutions" by Order in Council P.C. 2004-105 of February 16, 2004, registered as SOR/2004-23;

(h) the deletion of "Department of Social Development/Ministère du Développement social" under the heading "Departments and Ministries of State" by Order in Council P.C. 2006-39 of February 6, 2002, registered as SOR/2006-25;

(i) the deletion of "Department of International Trade/Ministère du Commerce international" under the heading "Other Government Institutions" by Order in Council P.C. 2006-45 of February 6, 2006, registered as SOR/2006-29;

— 2019, ch. 18, art. 59

59 Les modifications ci-après de l'annexe de la *Loi sur la protection des renseignements personnels* sont réputées avoir été valablement faites :

a) la suppression, sous l'intertitre « Autres institutions fédérales », de « Bureau fédéral de développement régional (Québec)/Federal Office of Regional Development – Quebec » par le décret C.P. 1998-186 du 13 février 1998 portant le numéro d'enregistrement DORS/98-119;

b) la suppression, sous l'intertitre « Autres institutions fédérales », de « Le Réseau du leadership/The Leadership Network » par le décret C.P. 1998-956 du 3 juin 1998 portant le numéro d'enregistrement DORS/98-321;

c) la suppression, sous l'intertitre « Autres institutions fédérales », de « Le Réseau du leadership/The Leadership Network » par le décret C.P. 2001-616 du 11 avril 2001 portant le numéro d'enregistrement DORS/2001-144;

d) la suppression, sous l'intertitre « Autres institutions fédérales », de « Bureau d'information du Canada/Canada Information Office » par le décret C.P. 2001-1577 du 28 août 2001 portant le numéro d'enregistrement DORS/2001-330;

e) la suppression, sous l'intertitre « Autres institutions fédérales », de « Bureau du Canada pour le millénaire/Millennium Bureau of Canada » par le décret C.P. 2002-188 du 7 février 2002 portant le numéro d'enregistrement DORS/2002-72;

f) la suppression, sous l'intertitre « Ministères et départements d'État », de « Bureau de l'infrastructure et des sociétés d'État du Canada/Office of Infrastructure and Crown Corporations of Canada » par le décret C.P. 2002-1326 du 6 août 2002 portant le numéro d'enregistrement DORS/2002-292;

g) la suppression, sous l'intertitre « Autres institutions fédérales », de « Communication Canada/Communication Canada » par le décret C.P. 2004-105 du 16 février 2004 portant le numéro d'enregistrement DORS/2004-23;

h) la suppression, sous l'intertitre « Ministères et départements d'État », de « Ministère du Développement social/Department of Social Development » par le décret C.P. 2006-39 du 6 février 2006 portant le numéro d'enregistrement DORS/2006-25;

(j) the deletion of "Canadian Firearms Centre/Centre canadien des armes à feu" under the heading "Other Government Institutions" by Order in Council P.C. 2006-383 of May 17, 2006, registered as SOR/2006-100;

(k) the deletion of "Indian Residential Schools Truth and Reconciliation Commission Secretariat/Secrétariat de la Commission de vérité et de réconciliation relative aux pensionnats indiens" under the heading "Other Government Institutions" by Order in Council P.C. 2008-801 of April 25, 2008, registered as SOR/2008-131;

(l) the deletion of "Office of Indian Residential Schools Resolution of Canada/Bureau du Canada sur le règlement des questions des pensionnats autochtones" under the heading "Other Government Institutions" by Order in Council P.C. 2008-810 of April 25, 2008, registered as SOR/2008-136.

i) la suppression, sous l'intertitre « Autres institutions fédérales », de « Ministère du Commerce international/Department of International Trade » par le décret C.P. 2006-45 du 6 février 2006 portant le numéro d'enregistrement DORS/2006-29;

j) la suppression, sous l'intertitre « Autres institutions fédérales », de « Centre canadien des armes à feu/Canadian Firearms Centre » par le décret C.P. 2006-383 du 17 mai 2006 portant le numéro d'enregistrement DORS/2006-100;

k) la suppression, sous l'intertitre « Autres institutions fédérales », de « Secrétariat de la Commission de vérité et de réconciliation relative aux pensionnats indiens/Indian Residential Schools Truth and Reconciliation Commission Secretariat » par le décret C.P. 2008-801 du 25 avril 2008 portant le numéro d'enregistrement DORS/2008-131;

l) la suppression, sous l'intertitre « Autres institutions fédérales », de « Bureau du Canada sur le règlement des questions des pensionnats autochtones/Office of Indian Residential Schools Resolution of Canada » par le décret C.P. 2008-810 du 25 avril 2008 portant le numéro d'enregistrement DORS/2008-136.

AMENDMENTS NOT IN FORCE

— 2002, c. 7, s. 227

1994, c. 43, s. 91.

227 The schedule to the *Privacy Act* is amended by striking out the following under the heading "*Other Government Institutions*":

Yukon Surface Rights Board
Office des droits de surface du Yukon

— 2024, c. 25, s. 127

127 The schedule to the *Privacy Act* is amended by striking out the following under the heading "Other Government Institutions":

Civilian Review and Complaints Commission for the Royal Canadian Mounted Police
Commission civile d'examen et de traitement des plaintes relatives à la Gendarmerie royale du Canada

— 2024, c. 25, s. 128

128 The schedule to the Act is amended by adding the following in alphabetical order under the heading "Other Government Institutions":

Public Complaints and Review Commission
Commission d'examen et de traitement des plaintes du public

MODIFICATIONS NON EN VIGUEUR

— 2002, ch. 7, art. 227

1994, ch. 43, art. 91.

227 L'annexe de la *Loi sur la protection des renseignements personnels* est modifiée par suppression, sous l'intertitre « *Autres institutions fédérales* », de ce qui suit :

Office des droits de surface du Yukon
Yukon Surface Rights Board

— 2024, ch. 25, art. 127

127 L'annexe de la *Loi sur la protection des renseignements personnels* est modifiée par suppression, sous l'intertitre « Autres institutions fédérales », de ce qui suit :

Commission civile d'examen et de traitement des plaintes relatives à la Gendarmerie royale du Canada
Civilian Review and Complaints Commission for the Royal Canadian Mounted Police

— 2024, ch. 25, art. 128

128 L'annexe de la même loi est modifiée par adjonction, selon l'ordre alphabétique, sous l'intertitre « Autres institutions fédérales », de ce qui suit :

Commission d'examen et de traitement des plaintes du public
Public Complaints and Review Commission

CANADA

CONSOLIDATION

CODIFICATION

Personal Information Protection and Electronic Documents Act

Loi sur la protection des renseignements personnels et les documents électroniques

S.C. 2000, c. 5

L.C. 2000, ch. 5

Current to June 17, 2026

Last amended on March 4, 2025

À jour au 17 juin 2026

Dernière modification le 4 mars 2025

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OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (2) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence
31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

Inconsistencies in Acts
(2) In the event of an inconsistency between a consolidated statute published by the Minister under this Act and the original statute or a subsequent amendment as certified by the Clerk of the Parliaments under the *Publication of Statutes Act*, the original statute or amendment prevails to the extent of the inconsistency.

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (2) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1er juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve
31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

Incompatibilité — lois
(2) Les dispositions de la loi d'origine avec ses modifications subséquentes par le greffier des Parlements en vertu de la *Loi sur la publication des lois* l'emportent sur les dispositions incompatibles de la loi codifiée publiée par le ministre en vertu de la présente loi.

LAYOUT

The notes that appeared in the left or right margins are now in boldface text directly above the provisions to which they relate. They form no part of the enactment, but are inserted for convenience of reference only.

MISE EN PAGE

Les notes apparaissant auparavant dans les marges de droite ou de gauche se retrouvent maintenant en caractères gras juste au-dessus de la disposition à laquelle elles se rattachent. Elles ne font pas partie du texte, n'y figurant qu'à titre de repère ou d'information.

NOTE

This consolidation is current to June 17, 2026. The last amendments came into force on March 4, 2025. Any amendments that were not in force as of June 17, 2026 are set out at the end of this document under the heading "Amendments Not in Force".

NOTE

Cette codification est à jour au 17 juin 2026. Les dernières modifications sont entrées en vigueur le 4 mars 2025. Toutes modifications qui n'étaient pas en vigueur au 17 juin 2026 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

TABLE OF PROVISIONS

An Act to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in certain circumstances, by providing for the use of electronic means to communicate or record information or transactions and by amending the Canada Evidence Act, the Statutory Instruments Act and the Statute Revision Act

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An Act to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in certain circumstances, by providing for the use of electronic means to communicate or record information or transactions and by amending the Canada Evidence Act, the Statutory Instruments Act and the Statute Revision Act

[*Assented to 13th April 2000*]

Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

Short Title

Short title

1 This Act may be cited as the *Personal Information Protection and Electronic Documents Act*.

PART 1

Protection of Personal Information in the Private Sector

Interpretation

Definitions

2 (1) The definitions in this subsection apply in this Part.

alternative format, with respect to personal information, means a format that allows a person with a sensory

L.C. 2000, ch. 5

Loi visant à faciliter et à promouvoir le commerce électronique en protégeant les renseignements personnels recueillis, utilisés ou communiqués dans certaines circonstances, en prévoyant l'utilisation de moyens électroniques pour communiquer ou enregistrer de l'information et des transactions et en modifiant la Loi sur la preuve au Canada, la Loi sur les textes réglementaires et la Loi sur la révision des lois

[*Sanctionnée le 13 avril 2000*]

Sa Majesté, sur l'avis et avec le consentement du Sénat et de la Chambre des communes du Canada, édicte :

Titre abrégé

Titre abrégé

1 *Loi sur la protection des renseignements personnels et les documents électroniques*.

PARTIE 1

Protection des renseignements personnels dans le secteur privé

Définitions

Définitions

2 (1) Les définitions qui suivent s'appliquent à la présente partie.

activité commerciale Toute activité régulière ainsi que tout acte isolé qui revêtent un caractère commercial de

disability to read or listen to the personal information. (*support de substitution*)

breach of security safeguards means the loss of, unauthorized access to or unauthorized disclosure of personal information resulting from a breach of an organization's security safeguards that are referred to in clause 4.7 of Schedule 1 or from a failure to establish those safeguards. (*atteinte aux mesures de sécurité*)

business contact information means any information that is used for the purpose of communicating or facilitating communication with an individual in relation to their employment, business or profession such as the individual's name, position name or title, work address, work telephone number, work fax number or work electronic address. (*coordonnées d'affaires*)

business transaction includes

(a) the purchase, sale or other acquisition or disposition of an organization or a part of an organization, or any of its assets;

(b) the merger or amalgamation of two or more organizations;

(c) the making of a loan or provision of other financing to an organization or a part of an organization;

(d) the creating of a charge on, or the taking of a security interest in or a security on, any assets or securities of an organization;

(e) the lease or licensing of any of an organization's assets; and

(f) any other prescribed arrangement between two or more organizations to conduct a business activity. (*transaction commerciale*)

commercial activity means any particular transaction, act or conduct or any regular course of conduct that is of a commercial character, including the selling, bartering or leasing of donor, membership or other fundraising lists. (*activité commerciale*)

Commissioner means the Privacy Commissioner appointed under section 53 of the *Privacy Act*. (*commissaire*)

Court means the Federal Court. (*Cour*)

federal work, undertaking or business means any work, undertaking or business that is within the legislative authority of Parliament. It includes

par leur nature, y compris la vente, le troc ou la location de listes de donneurs, d'adhésion ou de collecte de fonds. (*commercial activity*)

atteinte aux mesures de sécurité Communication non autorisée ou perte de renseignements personnels, ou accès non autorisé à ceux-ci, par suite d'une atteinte aux mesures de sécurité d'une organisation prévues à l'article 4.7 de l'annexe 1 ou du fait que ces mesures n'ont pas été mises en place. (*breach of security safeguards*)

commissaire Le Commissaire à la protection de la vie privée nommé en application de l'article 53 de la *Loi sur la protection des renseignements personnels*. (*Commissioner*)

coordonnées d'affaires Tout renseignement permettant d'entrer en contact — ou de faciliter la prise de contact — avec un individu dans le cadre de son emploi, de son entreprise ou de sa profession, tel que son nom, son poste ou son titre, l'adresse ou les numéros de téléphone ou de télécopieur de son lieu de travail ou son adresse électronique au travail. (*business contact information*)

Cour La Cour fédérale. (*Court*)

document Tous éléments d'information, quels que soient leur forme et leur support, notamment correspondance, note, livre, plan, carte, dessin, diagramme, illustration ou graphique, photographie, film, microforme, enregistrement sonore, magnétoscopique ou informatisé, ou toute reproduction de ces éléments d'information. (*record*)

entreprises fédérales Les installations, ouvrages, entreprises ou secteurs d'activité qui relèvent de la compétence législative du Parlement. Sont compris parmi les entreprises fédérales :

a) les installations, ouvrages, entreprises ou secteurs d'activité qui se rapportent à la navigation et aux transports par eau, notamment l'exploitation de navires et le transport par navire partout au Canada;

b) les installations ou ouvrages, notamment les chemins de fer, canaux ou liaisons télégraphiques, reliant une province à une autre, ou débordant les limites d'une province, et les entreprises correspondantes;

c) les lignes de transport par bateaux à vapeur ou autres navires, reliant une province à une autre, ou débordant les limites d'une province;

d) les passages par eaux entre deux provinces ou entre une province et un pays étranger;

(a) a work, undertaking or business that is operated or carried on for or in connection with navigation and shipping, whether inland or maritime, including the operation of ships and transportation by ship anywhere in Canada;

(b) a railway, canal, telegraph or other work or undertaking that connects a province with another province, or that extends beyond the limits of a province;

(c) a line of ships that connects a province with another province, or that extends beyond the limits of a province;

(d) a ferry between a province and another province or between a province and a country other than Canada;

(e) aerodromes, aircraft or a line of air transportation;

(f) a radio broadcasting station;

(g) a bank or an authorized foreign bank as defined in section 2 of the *Bank Act*;

(h) a work that, although wholly situated within a province, is before or after its execution declared by Parliament to be for the general advantage of Canada or for the advantage of two or more provinces;

(i) a work, undertaking or business outside the exclusive legislative authority of the legislatures of the provinces; and

(j) a work, undertaking or business to which federal laws, within the meaning of section 2 of the *Oceans Act*, apply under section 20 of that Act and any regulations made under paragraph 26(1)(k) of that Act. (*entreprises fédérales*)

organization includes an association, a partnership, a person and a trade union. (*organisation*)

personal health information, with respect to an individual, whether living or deceased, means

(a) information concerning the physical or mental health of the individual;

(b) information concerning any health service provided to the individual;

(c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or

e) les aéroports, aéronefs ou lignes de transport aérien;

f) les stations de radiodiffusion;

g) les banques ou les banques étrangères autorisées au sens de l'article 2 de la *Loi sur les banques*;

h) les ouvrages qui, bien qu'entièrement situés dans une province, sont, avant ou après leur réalisation, déclarés par le Parlement être à l'avantage général du Canada ou à l'avantage de plusieurs provinces;

i) les installations, ouvrages, entreprises ou secteurs d'activité ne ressortissant pas au pouvoir législatif exclusif des législatures provinciales;

j) les installations, ouvrages, entreprises ou secteurs d'activité auxquels le droit, au sens de l'alinéa a) de la définition de ***droit*** à l'article 2 de la *Loi sur les océans*, s'applique en vertu de l'article 20 de cette loi et des règlements pris en vertu de l'alinéa 26(1)k) de la même loi. (*federal work, undertaking or business*)

organisation S'entend notamment des associations, sociétés de personnes, personnes et organisations syndicales. (*organization*)

renseignement personnel Tout renseignement concernant un individu identifiable. (*personal information*)

renseignement personnel sur la santé En ce qui concerne un individu vivant ou décédé :

a) tout renseignement ayant trait à sa santé physique ou mentale;

b) tout renseignement relatif aux services de santé fournis à celui-ci;

c) tout renseignement relatif aux dons de parties du corps ou de substances corporelles faits par lui, ou tout renseignement provenant des résultats de tests ou d'examens effectués sur une partie du corps ou une substance corporelle de celui-ci;

d) tout renseignement recueilli dans le cadre de la prestation de services de santé à celui-ci;

e) tout renseignement recueilli fortuitement lors de la prestation de services de santé à celui-ci. (*personal health information*)

support de substitution Tout support permettant à une personne ayant une déficience sensorielle de lire ou

examination of a body part or bodily substance of the individual;

(d) information that is collected in the course of providing health services to the individual; or

(e) information that is collected incidentally to the provision of health services to the individual. (*renseignement personnel sur la santé*)

personal information means information about an identifiable individual. (*renseignement personnel*)

prescribed means prescribed by regulation. (*Version anglaise seulement*)

record includes any correspondence, memorandum, book, plan, map, drawing, diagram, pictorial or graphic work, photograph, film, microform, sound recording, videotape, machine-readable record and any other documentary material, regardless of physical form or characteristics, and any copy of any of those things. (*document*)

Notes in Schedule 1

(2) In this Part, a reference to clause 4.3 or 4.9 of Schedule 1 does not include a reference to the note that accompanies that clause.

2000, c. 5, s. 2; 2002, c. 8, s. 183; 2015, c. 32, s. 2.

d'écouter des renseignements personnels. (*alternative format*)

transaction commerciale S'entend notamment des transactions suivantes :

a) l'achat, la vente ou toute autre forme d'acquisition ou de disposition de tout ou partie d'une organisation, ou de ses éléments d'actif;

b) la fusion ou le regroupement d'organisations;

c) le fait de consentir un prêt à tout ou partie d'une organisation ou de lui fournir toute autre forme de financement;

d) le fait de grever d'une charge ou d'une sûreté les éléments d'actif ou les titres d'une organisation;

e) la location d'éléments d'actif d'une organisation, ou l'octroi ou l'obtention d'une licence à leur égard;

f) tout autre arrangement prévu par règlement entre des organisations pour la poursuite d'activités d'affaires. (*business transaction*)

Notes de l'annexe 1

(2) Dans la présente partie, la mention des articles 4.3 ou 4.9 de l'annexe 1 ne vise pas les notes afférentes.

2000, ch. 5, art. 2; 2002, ch. 8, art. 183; 2015, ch. 32, art. 2.

Purpose

Purpose

3 The purpose of this Part is to establish, in an era in which technology increasingly facilitates the circulation and exchange of information, rules to govern the collection, use and disclosure of personal information in a manner that recognizes the right of privacy of individuals with respect to their personal information and the need of organizations to collect, use or disclose personal information for purposes that a reasonable person would consider appropriate in the circumstances.

Objet

Objet

3 La présente partie a pour objet de fixer, dans une ère où la technologie facilite de plus en plus la circulation et l'échange de renseignements, des règles régissant la collecte, l'utilisation et la communication de renseignements personnels d'une manière qui tient compte du droit des individus à la vie privée à l'égard des renseignements personnels qui les concernent et du besoin des organisations de recueillir, d'utiliser ou de communiquer des renseignements personnels à des fins qu'une personne raisonnable estimerait acceptables dans les circonstances.

Application

Application

4 (1) This Part applies to every organization in respect of personal information that

Champ d'application

Champ d'application

4 (1) La présente partie s'applique à toute organisation à l'égard des renseignements personnels :

(a) the organization collects, uses or discloses in the course of commercial activities; or

(b) is about an employee of, or an applicant for employment with, the organization and that the organization collects, uses or discloses in connection with the operation of a federal work, undertaking or business.

Application

(1.1) This Part applies to an organization set out in column 1 of Schedule 4 in respect of personal information set out in column 2.

Limit

(2) This Part does not apply to

(a) any government institution to which the *Privacy Act* applies;

(b) any individual in respect of personal information that the individual collects, uses or discloses for personal or domestic purposes and does not collect, use or disclose for any other purpose; or

(c) any organization in respect of personal information that the organization collects, uses or discloses for journalistic, artistic or literary purposes and does not collect, use or disclose for any other purpose.

Other Acts

***(3)** Every provision of this Part applies despite any provision, enacted after this subsection comes into force, of any other Act of Parliament, unless the other Act expressly declares that that provision operates despite the provision of this Part.

* [Note: Subsection 4(3) in force January 1, 2001, *see* SI/2000-29.]

2000, c. 5, s. 4; 2015, c. 32, s. 3, c. 36, s. 164.

Business contact information

4.01 This Part does not apply to an organization in respect of the business contact information of an individual that the organization collects, uses or discloses solely for the purpose of communicating or facilitating communication with the individual in relation to their employment, business or profession.

2015, c. 32, s. 4.

Certificate under *Canada Evidence Act*

4.1 (1) If a certificate under section 38.13 or 38.41 of the *Canada Evidence Act* prohibiting the disclosure of personal information of a specific individual is issued before a complaint is filed by that individual under this Part in respect of a request for access to that information, the provisions of this Part respecting that individual's right

a) soit qu'elle recueille, utilise ou communique dans le cadre d'activités commerciales;

b) soit qui concernent un de ses employés ou l'individu qui postule pour le devenir et qu'elle recueille, utilise ou communique dans le cadre d'une entreprise fédérale.

Application

(1.1) La présente partie s'applique à toute organisation figurant à la colonne 1 de l'annexe 4 à l'égard des renseignements personnels figurant à la colonne 2.

Limite

(2) La présente partie ne s'applique pas :

a) aux institutions fédérales auxquelles s'applique la *Loi sur la protection des renseignements personnels*;

b) à un individu à l'égard des renseignements personnels qu'il recueille, utilise ou communique à des fins personnelles ou domestiques et à aucune autre fin;

c) à une organisation à l'égard des renseignements personnels qu'elle recueille, utilise ou communique à des fins journalistiques, artistiques ou littéraires et à aucune autre fin.

Autre loi

***(3)** Toute disposition de la présente partie s'applique malgré toute disposition — édictée après l'entrée en vigueur du présent paragraphe — d'une autre loi fédérale, sauf dérogation expresse de la disposition de l'autre loi.

* [Note : Paragraphe 4(3) en vigueur le 1er janvier 2001, *voir* TR/2000-29.]

2000, ch. 5, art. 4; 2015, ch. 32, art. 3, ch. 36, art. 164.

Coordonnées d'affaires

4.01 La présente partie ne s'applique pas à une organisation à l'égard des coordonnées d'affaires d'un individu qu'elle recueille, utilise ou communique uniquement pour entrer en contact — ou pour faciliter la prise de contact — avec lui dans le cadre de son emploi, de son entreprise ou de sa profession.

2015, ch. 32, art. 4.

Certificat en vertu de la *Loi sur la preuve au Canada*

4.1 (1) Dans le cas où a été délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada* un certificat interdisant la divulgation de renseignements personnels concernant un individu donné avant le dépôt par celui-ci d'une plainte au titre de la présente partie relative à la communication de ces renseignements, les

of access to their personal information do not apply to the information that is subject to the certificate.

Certificate following filing of complaint

(2) Despite any other provision of this Part, if a certificate under section 38.13 or 38.41 of the *Canada Evidence Act* prohibiting the disclosure of personal information of a specific individual is issued after the filing of a complaint under this Part in relation to a request for access to that information:

(a) all proceedings under this Part in respect of that information, including an investigation, audit, appeal or judicial review, are discontinued;

(b) the Commissioner shall not disclose the information and shall take all necessary precautions to prevent its disclosure; and

(c) the Commissioner shall, within 10 days after the certificate is published in the *Canada Gazette*, return the information to the organization that provided the information.

Information not to be disclosed

(3) The Commissioner and every person acting on behalf or under the direction of the Commissioner, in carrying out their functions under this Part, shall not disclose information subject to a certificate issued under section 38.13 or 38.41 of the *Canada Evidence Act*, and shall take every reasonable precaution to avoid the disclosure of that information.

Power to delegate

(4) The Commissioner may not delegate the investigation of any complaint relating to information subject to a certificate issued under section 38.13 or 38.41 of the *Canada Evidence Act* except to one of a maximum of four officers or employees of the Commissioner specifically designated by the Commissioner for the purpose of conducting that investigation.

2001, c. 41, s. 103; 2024, c. 16, s. 93.

dispositions de cette partie concernant le droit d'accès de l'individu aux renseignements personnels le concernant ne s'appliquent pas aux renseignements visés par le certificat.

Certificat postérieur au dépôt d'une plainte

(2) Malgré les autres dispositions de la présente partie, dans le cas où a été délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada* un certificat interdisant la divulgation de renseignements personnels concernant un individu donné après le dépôt d'une plainte de refus d'accès au titre de la présente partie relativement à la demande de communication de ces renseignements :

a) toute procédure — notamment une enquête, une vérification, un appel ou une révision judiciaire — prévue par la présente partie et portant sur ces renseignements est interrompue;

b) le commissaire ne peut communiquer les renseignements et prend les précautions nécessaires pour empêcher leur communication;

c) le commissaire renvoie les renseignements à l'organisation qui les a fournis dans les dix jours suivant la publication du certificat dans la *Gazette du Canada*.

Précaution à prendre

(3) Dans l'exercice de leurs attributions prévues par la présente partie, le commissaire et les personnes agissant en son nom ou sous son autorité ne peuvent communiquer, et prennent toutes les précautions pour éviter que ne soient communiqués, les renseignements visés par un certificat délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada*.

Pouvoir de délégation

(4) Le commissaire ne peut déléguer la tenue d'une enquête portant sur des renseignements visés par un certificat délivré au titre des articles 38.13 ou 38.41 de la *Loi sur la preuve au Canada* qu'à un de ses collaborateurs choisi parmi quatre des cadres ou employés du commissariat et qu'il désigne spécialement à cette fin.

2001, ch. 41, art. 103; 2024, ch. 16, art. 93.

DIVISION 1

Protection of Personal Information

Compliance with obligations

5 (1) Subject to sections 6 to 9, every organization shall comply with the obligations set out in Schedule 1.

Meaning of *should*

(2) The word ***should***, when used in Schedule 1, indicates a recommendation and does not impose an obligation.

Appropriate purposes

(3) An organization may collect, use or disclose personal information only for purposes that a reasonable person would consider are appropriate in the circumstances.

Effect of designation of individual

6 The designation of an individual under clause 4.1 of Schedule 1 does not relieve the organization of the obligation to comply with the obligations set out in that Schedule.

Valid consent

6.1 For the purposes of clause 4.3 of Schedule 1, the consent of an individual is only valid if it is reasonable to expect that an individual to whom the organization's activities are directed would understand the nature, purpose and consequences of the collection, use or disclosure of the personal information to which they are consenting.

2015, c. 32, s. 5.

Collection without knowledge or consent

7 (1) For the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, an organization may collect personal information without the knowledge or consent of the individual only if

(a) the collection is clearly in the interests of the individual and consent cannot be obtained in a timely way;

(b) it is reasonable to expect that the collection with the knowledge or consent of the individual would

SECTION 1

Protection des renseignements personnels

Obligation de se conformer aux obligations

5 (1) Sous réserve des articles 6 à 9, toute organisation doit se conformer aux obligations énoncées dans l'annexe 1.

Emploi du conditionnel

(2) L'emploi du conditionnel dans l'annexe 1 indique qu'il s'agit d'une recommandation et non d'une obligation.

Fins acceptables

(3) L'organisation ne peut recueillir, utiliser ou communiquer des renseignements personnels qu'à des fins qu'une personne raisonnable estimerait acceptables dans les circonstances.

Conséquence de la désignation d'une personne

6 La désignation d'une personne en application de l'article 4.1 de l'annexe 1 n'exempte pas l'organisation des obligations énoncées dans cette annexe.

Validité du consentement

6.1 Pour l'application de l'article 4.3 de l'annexe 1, le consentement de l'intéressé n'est valable que s'il est raisonnable de s'attendre à ce qu'un individu visé par les activités de l'organisation comprenne la nature, les fins et les conséquences de la collecte, de l'utilisation ou de la communication des renseignements personnels auxquelles il a consenti.

2015, ch. 32, art. 5.

Collecte à l'insu de l'intéressé ou sans son consentement

7 (1) Pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, l'organisation ne peut recueillir de renseignement personnel à l'insu de l'intéressé ou sans son consentement que dans les cas suivants :

a) la collecte du renseignement est manifestement dans l'intérêt de l'intéressé et le consentement ne peut être obtenu auprès de celui-ci en temps opportun;

b) il est raisonnable de s'attendre à ce que la collecte effectuée au su ou avec le consentement de l'intéressé compromette l'exactitude du renseignement ou l'accès à celui-ci, et la collecte est raisonnable à des fins liées à

compromise the availability or the accuracy of the information and the collection is reasonable for purposes related to investigating a breach of an agreement or a contravention of the laws of Canada or a province;

(b.01) it was disclosed under paragraph (3)(d.21);

(b.1) it is contained in a witness statement and the collection is necessary to assess, process or settle an insurance claim;

(b.2) it was produced by the individual in the course of their employment, business or profession and the collection is consistent with the purposes for which the information was produced;

(c) the collection is solely for journalistic, artistic or literary purposes;

(d) the information is publicly available and is specified by the regulations; or

(e) the collection is made for the purpose of making a disclosure

(i) under subparagraph (3)(c.1)(i) or (d)(ii), or

(ii) that is required by law.

Use without knowledge or consent

(2) For the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, an organization may, without the knowledge or consent of the individual, use personal information only if

(a) in the course of its activities, the organization becomes aware of information that it has reasonable grounds to believe could be useful in the investigation of a contravention of the laws of Canada, a province or a foreign jurisdiction that has been, is being or is about to be committed, and the information is used for the purpose of investigating that contravention;

(b) it is used for the purpose of acting in respect of an emergency that threatens the life, health or security of an individual;

(b.1) the information is contained in a witness statement and the use is necessary to assess, process or settle an insurance claim;

(b.2) the information was produced by the individual in the course of their employment, business or profession and the use is consistent with the purposes for which the information was produced;

une enquête sur la violation d'un accord ou la contravention au droit fédéral ou provincial;

b.01) la communication est faite au titre de l'alinéa (3)d.21);

b.1) il s'agit d'un renseignement contenu dans la déclaration d'un témoin et dont la collecte est nécessaire en vue de l'évaluation d'une réclamation d'assurance, de son traitement ou de son règlement;

b.2) il s'agit d'un renseignement produit par l'intéressé dans le cadre de son emploi, de son entreprise ou de sa profession, et dont la collecte est compatible avec les fins auxquelles il a été produit;

c) la collecte est faite uniquement à des fins journalistiques, artistiques ou littéraires;

d) il s'agit d'un renseignement réglementaire auquel le public a accès;

e) la collecte est faite en vue :

(i) soit de la communication prévue aux sous-alinéas (3)c.1)(i) ou d)(ii),

(ii) soit d'une communication exigée par la loi.

Utilisation à l'insu de l'intéressé ou sans son consentement

(2) Pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, l'organisation ne peut utiliser de renseignement personnel à l'insu de l'intéressé ou sans son consentement que dans les cas suivants :

a) dans le cadre de ses activités, l'organisation découvre l'existence d'un renseignement dont elle a des motifs raisonnables de croire qu'il pourrait être utile à une enquête sur une contravention au droit fédéral, provincial ou étranger qui a été commise ou est en train ou sur le point de l'être, et l'utilisation est faite aux fins d'enquête;

b) l'utilisation est faite pour répondre à une situation d'urgence mettant en danger la vie, la santé ou la sécurité de tout individu;

b.1) il s'agit d'un renseignement contenu dans la déclaration d'un témoin et dont l'utilisation est nécessaire en vue de l'évaluation d'une réclamation d'assurance, de son traitement ou de son règlement;

b.2) il s'agit d'un renseignement produit par l'intéressé dans le cadre de son emploi, de son entreprise ou de sa profession, et dont l'utilisation est compatible avec les fins auxquelles il a été produit;

(c) it is used for statistical, or scholarly study or research, purposes that cannot be achieved without using the information, the information is used in a manner that will ensure its confidentiality, it is impracticable to obtain consent and the organization informs the Commissioner of the use before the information is used;

(c.1) it is publicly available and is specified by the regulations; or

(d) it was collected under paragraph (1)(a), (b), (b.01) or (e).

Disclosure without knowledge or consent

(3) For the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, an organization may disclose personal information without the knowledge or consent of the individual only if the disclosure is

(a) made to, in the Province of Quebec, an advocate or notary or, in any other province, a barrister or solicitor who is representing the organization;

(b) for the purpose of collecting a debt owed by the individual to the organization;

(c) required to comply with a subpoena or warrant issued or an order made by a court, person or body with jurisdiction to compel the production of information, or to comply with rules of court relating to the production of records;

(c.1) made to a government institution or part of a government institution that has made a request for the information, identified its lawful authority to obtain the information and indicated that

(i) it suspects that the information relates to national security, the defence of Canada or the conduct of international affairs,

(ii) the disclosure is requested for the purpose of enforcing any law of Canada, a province or a foreign jurisdiction, carrying out an investigation relating to the enforcement of any such law or gathering intelligence for the purpose of enforcing any such law,

(iii) the disclosure is requested for the purpose of administering any law of Canada or a province, or

(iv) the disclosure is requested for the purpose of communicating with the next of kin or authorized

c) l'utilisation est faite à des fins statistiques ou à des fins d'étude ou de recherche érudites, ces fins ne peuvent être réalisées sans que le renseignement soit utilisé, celui-ci est utilisé d'une manière qui en assure le caractère confidentiel, le consentement est pratiquement impossible à obtenir et l'organisation informe le commissaire de l'utilisation avant de la faire;

c.1) il s'agit d'un renseignement réglementaire auquel le public a accès;

d) le renseignement a été recueilli au titre des alinéas (1)a), b), b.01) ou e).

Communication à l'insu de l'intéressé ou sans son consentement

(3) Pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, l'organisation ne peut communiquer de renseignement personnel à l'insu de l'intéressé ou sans son consentement que dans les cas suivants :

a) la communication est faite à un avocat — dans la province de Québec, à un avocat ou à un notaire — qui représente l'organisation;

b) elle est faite en vue du recouvrement d'une créance que celle-ci a contre l'intéressé;

c) elle est exigée par assignation, mandat ou ordonnance d'un tribunal, d'une personne ou d'un organisme ayant le pouvoir de contraindre à la production de renseignements ou exigée par des règles de procédure se rapportant à la production de documents;

c.1) elle est faite à une institution gouvernementale — ou à une subdivision d'une telle institution — qui a demandé à obtenir le renseignement en mentionnant la source de l'autorité légitime étayant son droit de l'obtenir et le fait, selon le cas :

(i) qu'elle soupçonne que le renseignement est afférent à la sécurité nationale, à la défense du Canada ou à la conduite des affaires internationales,

(ii) que la communication est demandée aux fins du contrôle d'application du droit canadien, provincial ou étranger, de la tenue d'enquêtes liées à ce contrôle d'application ou de la collecte de renseignements en matière de sécurité en vue de ce contrôle d'application,

(iii) qu'elle est demandée pour l'application du droit canadien ou provincial,

representative of an injured, ill or deceased individual;

(c.2) made to the government institution mentioned in section 7 of the *Proceeds of Crime (Money Laundering) and Terrorist Financing Act* as required by that section;

(d) made on the initiative of the organization to a government institution or a part of a government institution and the organization

(i) has reasonable grounds to believe that the information relates to a contravention of the laws of Canada, a province or a foreign jurisdiction that has been, is being or is about to be committed, or

(ii) suspects that the information relates to national security, the defence of Canada or the conduct of international affairs;

(d.1) made to another organization and is reasonable for the purposes of investigating a breach of an agreement or a contravention of the laws of Canada or a province that has been, is being or is about to be committed and it is reasonable to expect that disclosure with the knowledge or consent of the individual would compromise the investigation;

(d.2) made to another organization and is reasonable for the purposes of detecting or suppressing fraud or of preventing fraud that is likely to be committed and it is reasonable to expect that the disclosure with the knowledge or consent of the individual would compromise the ability to prevent, detect or suppress the fraud;

(d.21) made to another organization under subsection 11.01(1) of the *Proceeds of Crime (Money Laundering) and Terrorist Financing Act*;

(d.3) made on the initiative of the organization to a government institution, a part of a government institution or the individual's next of kin or authorized representative and

(i) the organization has reasonable grounds to believe that the individual has been, is or may be the victim of financial abuse,

(ii) the disclosure is made solely for purposes related to preventing or investigating the abuse, and

(iii) it is reasonable to expect that disclosure with the knowledge or consent of the individual would compromise the ability to prevent or investigate the abuse;

(iv) qu'elle est demandée afin d'entrer en contact avec le plus proche parent d'un individu blessé, malade ou décédé, ou avec son représentant autorisé;

c.2) elle est faite au titre de l'article 7 de la *Loi sur le recyclage des produits de la criminalité et le financement des activités terroristes* à l'institution gouvernementale mentionnée à cet article;

d) elle est faite, à l'initiative de l'organisation, à une institution gouvernementale ou une subdivision d'une telle institution et l'organisation :

(i) soit a des motifs raisonnables de croire que le renseignement est afférent à une contravention au droit fédéral, provincial ou étranger qui a été commise ou est en train ou sur le point de l'être,

(ii) soit soupçonne que le renseignement est afférent à la sécurité nationale, à la défense du Canada ou à la conduite des affaires internationales;

d.1) elle est faite à une autre organisation et est raisonnable en vue d'une enquête sur la violation d'un accord ou sur la contravention au droit fédéral ou provincial qui a été commise ou est en train ou sur le point de l'être, s'il est raisonnable de s'attendre à ce que la communication effectuée au su ou avec le consentement de l'intéressé compromettrait l'enquête;

d.2) elle est faite à une autre organisation et est raisonnable en vue de la détection d'une fraude ou de sa suppression ou en vue de la prévention d'une fraude dont la commission est vraisemblable, s'il est raisonnable de s'attendre à ce que la communication effectuée au su ou avec le consentement de l'intéressé compromettrait la capacité de prévenir la fraude, de la détecter ou d'y mettre fin;

d.21) elle est faite à une autre organisation au titre du paragraphe 11.01(1) de la *Loi sur le recyclage des produits de la criminalité et le financement des activités terroristes*;

d.3) elle est faite, à l'initiative de l'organisation, à une institution gouvernementale ou à une subdivision d'une telle institution, au plus proche parent de l'intéressé ou à son représentant autorisé, si les conditions ci-après sont remplies :

(i) l'organisation a des motifs raisonnables de croire que l'intéressé a été, est ou pourrait être victime d'exploitation financière,

(ii) la communication est faite uniquement à des fins liées à la prévention de l'exploitation ou à une enquête y ayant trait,

(d.4) necessary to identify the individual who is injured, ill or deceased, made to a government institution, a part of a government institution or the individual's next of kin or authorized representative and, if the individual is alive, the organization informs that individual in writing without delay of the disclosure;

(e) made to a person who needs the information because of an emergency that threatens the life, health or security of an individual and, if the individual whom the information is about is alive, the organization informs that individual in writing without delay of the disclosure;

(e.1) of information that is contained in a witness statement and the disclosure is necessary to assess, process or settle an insurance claim;

(e.2) of information that was produced by the individual in the course of their employment, business or profession and the disclosure is consistent with the purposes for which the information was produced;

(f) for statistical, or scholarly study or research, purposes that cannot be achieved without disclosing the information, it is impracticable to obtain consent and the organization informs the Commissioner of the disclosure before the information is disclosed;

(g) made to an institution whose functions include the conservation of records of historic or archival importance, and the disclosure is made for the purpose of such conservation;

(h) made after the earlier of

(i) one hundred years after the record containing the information was created, and

(ii) twenty years after the death of the individual whom the information is about;

(h.1) of information that is publicly available and is specified by the regulations; or

(h.2) [Repealed, 2015, c. 32, s. 6]

(i) required by law.

(iii) il est raisonnable de s'attendre à ce que la communication effectuée au su ou avec le consentement de l'intéressé compromettrait la capacité de prévenir l'exploitation ou d'enquêter sur celle-ci;

d.4) elle est nécessaire aux fins d'identification de l'intéressé qui est blessé, malade ou décédé et est faite à une institution gouvernementale ou à une subdivision d'une telle institution, à un proche parent de l'intéressé ou à son représentant autorisé et, si l'intéressé est vivant, l'organisation en informe celui-ci par écrit et sans délai;

e) elle est faite à toute personne qui a besoin du renseignement en raison d'une situation d'urgence mettant en danger la vie, la santé ou la sécurité de toute personne et, dans le cas où la personne visée par le renseignement est vivante, l'organisation en informe par écrit et sans délai cette dernière;

e.1) il s'agit d'un renseignement contenu dans la déclaration d'un témoin et dont la communication est nécessaire en vue de l'évaluation d'une réclamation d'assurance, de son traitement ou de son règlement;

e.2) il s'agit d'un renseignement produit par l'intéressé dans le cadre de son emploi, de son entreprise, ou de sa profession, et dont la communication est compatible avec les fins auxquelles il a été produit;

f) la communication est faite à des fins statistiques ou à des fins d'étude ou de recherche érudites, ces fins ne peuvent être réalisées sans que le renseignement soit communiqué, le consentement est pratiquement impossible à obtenir et l'organisation informe le commissaire de la communication avant de la faire;

g) elle est faite à une institution dont les attributions comprennent la conservation de documents ayant une importance historique ou archivistique, en vue d'une telle conservation;

h) elle est faite cent ans ou plus après la constitution du document contenant le renseignement ou, en cas de décès de l'intéressé, vingt ans ou plus après le décès, dans la limite de cent ans;

h.1) il s'agit d'un renseignement réglementaire auquel le public a accès;

h.2) [Abrogé, 2015, ch. 32, art. 6]

i) la communication est exigée par la loi.

Use without consent

(4) Despite clause 4.5 of Schedule 1, an organization may use personal information for purposes other than those for which it was collected in any of the circumstances set out in subsection (2).

Disclosure without consent

(5) Despite clause 4.5 of Schedule 1, an organization may disclose personal information for purposes other than those for which it was collected in any of the circumstances set out in paragraphs (3)(a) to (h.1).

2000, c. 5, s. 7, c. 17, s. 97; 2001, c. 41, s. 81; 2004, c. 15, s. 98; 2015, c. 32, s. 6; 2024, c. 17, s. 347.

Definitions

7.1 (1) The following definitions apply in this section.

access means to program, to execute programs on, to communicate with, to store data in, to retrieve data from, or to otherwise make use of any resources, including data or programs on a computer system or a computer network. (*utiliser*)

computer program has the same meaning as in subsection 342.1(2) of the *Criminal Code*. (*programme d'ordinateur*)

computer system has the same meaning as in subsection 342.1(2) of the *Criminal Code*. (*ordinateur*)

electronic address means an address used in connection with

(a) an electronic mail account;

(b) an instant messaging account; or

(c) any similar account. (*adresse électronique*)

Collection of electronic addresses, etc.

(2) Paragraphs 7(1)(a) and (b.1) to (d) and (2)(a) to (c.1) and the exception set out in clause 4.3 of Schedule 1 do not apply in respect of

(a) the collection of an individual's electronic address, if the address is collected by the use of a computer program that is designed or marketed primarily for use in generating or searching for, and collecting, electronic addresses; or

(b) the use of an individual's electronic address, if the address is collected by the use of a computer program described in paragraph (a).

Utilisation sans le consentement de l'intéressé

(4) Malgré l'article 4.5 de l'annexe 1, l'organisation peut, dans les cas visés au paragraphe (2), utiliser un renseignement personnel à des fins autres que celles auxquelles il a été recueilli.

Communication sans consentement

(5) Malgré l'article 4.5 de l'annexe 1, l'organisation peut, dans les cas visés aux alinéas (3)a) à h.1), communiquer un renseignement personnel à des fins autres que celles auxquelles il a été recueilli.

2000, ch. 5, art. 7, ch. 17, art. 97; 2001, ch. 41, art. 81; 2004, ch. 15, art. 98; 2015, ch. 32, art. 6; 2024, ch. 17, art. 347.

Définitions

7.1 (1) Les définitions qui suivent s'appliquent au présent article.

adresse électronique Toute adresse utilisée relativement à l'un des comptes suivants :

a) un compte courriel;

b) un compte messagerie instantanée;

c) tout autre compte similaire. (*electronic address*)

ordinateur S'entend au sens du paragraphe 342.1(2) du *Code criminel*. (*computer system*)

programme d'ordinateur S'entend au sens du paragraphe 342.1(2) du *Code criminel*. (*computer program*)

utiliser S'agissant d'un ordinateur ou d'un réseau informatique, le programmer, lui faire exécuter un programme, communiquer avec lui, y mettre en mémoire, ou en extraire, des données ou utiliser ses ressources de toute autre façon, notamment ses données et ses programmes. (*access*)

Collecte, utilisation et communication d'adresses électroniques

(2) Les alinéas 7(1)a) et b.1) à d) et (2)a) à c.1) et l'exception prévue à l'article 4.3 de l'annexe 1 ne s'appliquent pas :

a) à la collecte de l'adresse électronique d'un individu effectuée à l'aide d'un programme d'ordinateur conçu ou mis en marché principalement pour produire ou rechercher des adresses électroniques et les recueillir;

b) à l'utilisation d'une telle adresse recueillie à l'aide d'un programme d'ordinateur visé à l'alinéa a).

Accessing a computer system to collect personal information, etc.

(3) Paragraphs 7(1)(a) to (d) and (2)(a) to (c.1) and the exception set out in clause 4.3 of Schedule 1 do not apply in respect of

(a) the collection of personal information, through any means of telecommunication, if the collection is made by accessing a computer system or causing a computer system to be accessed in contravention of an Act of Parliament; or

(b) the use of personal information that is collected in a manner described in paragraph (a).

2010, c. 23, s. 82; 2015, c. 32, s. 26.

Collecte et utilisation de renseignements personnels

(3) Les alinéas 7(1)a) à d) et (2)a) à c.1) et l'exception prévue à l'article 4.3 de l'annexe 1 ne s'appliquent pas :

a) à la collecte de renseignements personnels, par tout moyen de télécommunication, dans le cas où l'organisation qui y procède le fait en utilisant ou faisant utiliser un ordinateur en contravention d'une loi fédérale;

b) à l'utilisation de renseignements personnels dont la collecte est visée à l'alinéa a).

2010, ch. 23, art. 82; 2015, ch. 32, art. 26.

Prospective business transaction

7.2 (1) In addition to the circumstances set out in subsections 7(2) and (3), for the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, organizations that are parties to a prospective business transaction may use and disclose personal information without the knowledge or consent of the individual if

(a) the organizations have entered into an agreement that requires the organization that receives the personal information

(i) to use and disclose that information solely for purposes related to the transaction,

(ii) to protect that information by security safeguards appropriate to the sensitivity of the information, and

(iii) if the transaction does not proceed, to return that information to the organization that disclosed it, or destroy it, within a reasonable time; and

(b) the personal information is necessary

(i) to determine whether to proceed with the transaction, and

(ii) if the determination is made to proceed with the transaction, to complete it.

Transaction commerciale éventuelle

7.2 (1) En plus des cas visés aux paragraphes 7(2) et (3), pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, les organisations qui sont parties à une éventuelle transaction commerciale peuvent utiliser et communiquer des renseignements personnels à l'insu de l'intéressé ou sans son consentement si, à la fois :

a) elles ont conclu un accord aux termes duquel l'organisation recevant des renseignements s'est engagée :

(i) à ne les utiliser et à ne les communiquer qu'à des fins liées à la transaction,

(ii) à les protéger au moyen de mesures de sécurité correspondant à leur degré de sensibilité,

(iii) si la transaction n'a pas lieu, à les remettre à l'organisation qui les lui a communiqués ou à les détruire, dans un délai raisonnable;

b) les renseignements sont nécessaires pour décider si la transaction aura lieu et, le cas échéant, pour l'effectuer.

Completed business transaction

(2) In addition to the circumstances set out in subsections 7(2) and (3), for the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, if the business transaction is completed, organizations that are parties to the transaction may use and disclose personal information, which was disclosed under

Transaction commerciale effectuée

(2) En plus des cas visés aux paragraphes 7(2) et (3), pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, si la transaction commerciale est effectuée, les organisations y étant parties peuvent utiliser et

subsection (1), without the knowledge or consent of the individual if

(a) the organizations have entered into an agreement that requires each of them

(i) to use and disclose the personal information under its control solely for the purposes for which the personal information was collected, permitted to be used or disclosed before the transaction was completed,

(ii) to protect that information by security safeguards appropriate to the sensitivity of the information, and

(iii) to give effect to any withdrawal of consent made under clause 4.3.8 of Schedule 1;

(b) the personal information is necessary for carrying on the business or activity that was the object of the transaction; and

(c) one of the parties notifies the individual, within a reasonable time after the transaction is completed, that the transaction has been completed and that their personal information has been disclosed under subsection (1).

Agreements binding

(3) An organization shall comply with the terms of any agreement into which it enters under paragraph (1)(a) or (2)(a).

Exception

(4) Subsections (1) and (2) do not apply to a business transaction of which the primary purpose or result is the purchase, sale or other acquisition or disposition, or lease, of personal information.

2015, c. 32, s. 7.

Employment relationship

7.3 In addition to the circumstances set out in section 7, for the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, a federal work, undertaking or business may collect, use and disclose personal information without the consent of the individual if

(a) the collection, use or disclosure is necessary to establish, manage or terminate an employment relationship between the federal work, undertaking or business and the individual; and

communiquer les renseignements personnels, communiqués en vertu du paragraphe (1), à l'insu de l'intéressé ou sans son consentement dans le cas où :

a) elles ont conclu un accord aux termes duquel chacune d'entre elles s'est engagée :

(i) à n'utiliser et ne communiquer les renseignements dont elle a la gestion qu'aux fins auxquelles ils ont été recueillis ou auxquelles il était permis de les utiliser ou de les communiquer avant que la transaction ne soit effectuée,

(ii) à les protéger au moyen de mesures de sécurité correspondant à leur degré de sensibilité,

(iii) à donner effet à tout retrait de consentement fait en conformité avec l'article 4.3.8 de l'annexe 1;

b) les renseignements sont nécessaires à la poursuite de l'entreprise ou des activités faisant l'objet de la transaction;

c) dans un délai raisonnable après que la transaction a été effectuée, l'une des parties avise l'intéressé du fait que la transaction a été effectuée et que ses renseignements personnels ont été communiqués en vertu du paragraphe (1).

Valeur contraignante des accords

(3) L'organisation est tenue de se conformer aux modalités de tout accord conclu aux termes des alinéas (1)a) ou (2)a).

Exception

(4) Les paragraphes (1) et (2) ne s'appliquent pas à l'égard de la transaction commerciale dont l'objectif premier ou le résultat principal est l'achat, la vente ou toute autre forme d'acquisition ou de disposition de renseignements personnels, ou leur location.

2015, ch. 32, art. 7.

Relation d'emploi

7.3 En plus des cas visés à l'article 7, pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, une entreprise fédérale peut recueillir, utiliser ou communiquer des renseignements personnels sans le consentement de l'intéressé si cela est nécessaire pour établir ou gérer la relation d'emploi entre elle et lui, ou pour y mettre fin, et si elle a au préalable informé l'intéressé que ses renseignements personnels seront ou pourraient être recueillis, utilisés ou communiqués à ces fins.

2015, ch. 32, art. 7.

(b) the federal work, undertaking or business has informed the individual that the personal information will be or may be collected, used or disclosed for those purposes.

2015, c. 32, s. 7.

Use without consent

7.4 (1) Despite clause 4.5 of Schedule 1, an organization may use personal information for purposes other than those for which it was collected in any of the circumstances set out in subsection 7.2(1) or (2) or section 7.3.

Disclosure without consent

(2) Despite clause 4.5 of Schedule 1, an organization may disclose personal information for purposes other than those for which it was collected in any of the circumstances set out in subsection 7.2(1) or (2) or section 7.3.

2015, c. 32, s. 7.

Written request

8 (1) A request under clause 4.9 of Schedule 1 must be made in writing.

Assistance

(2) An organization shall assist any individual who informs the organization that they need assistance in preparing a request to the organization.

Time limit

(3) An organization shall respond to a request with due diligence and in any case not later than thirty days after receipt of the request.

Extension of time limit

(4) An organization may extend the time limit

(a) for a maximum of thirty days if

(i) meeting the time limit would unreasonably interfere with the activities of the organization, or

(ii) the time required to undertake any consultations necessary to respond to the request would make the time limit impracticable to meet; or

(b) for the period that is necessary in order to be able to convert the personal information into an alternative format.

In either case, the organization shall, no later than thirty days after the date of the request, send a notice of extension to the individual, advising them of the new time

Utilisation sans le consentement de l'intéressé

7.4 (1) Malgré l'article 4.5 de l'annexe 1, l'organisation peut, dans les cas visés aux paragraphes 7.2(1) ou (2) ou à l'article 7.3, utiliser un renseignement personnel à des fins autres que celles auxquelles il a été recueilli.

Communication sans le consentement de l'intéressé

(2) Malgré l'article 4.5 de l'annexe 1, l'organisation peut, dans les cas visés aux paragraphes 7.2(1) ou (2) ou à l'article 7.3, communiquer un renseignement personnel à des fins autres que celles auxquelles il a été recueilli.

2015, ch. 32, art. 7.

Demande écrite

8 (1) La demande prévue à l'article 4.9 de l'annexe 1 est présentée par écrit.

Aide à fournir

(2) Sur requête de l'intéressé, l'organisation fournit à celui-ci l'aide dont il a besoin pour préparer sa demande.

Délai de réponse

(3) L'organisation saisie de la demande doit y donner suite avec la diligence voulue et, en tout état de cause, dans les trente jours suivant sa réception.

Prorogation du délai

(4) Elle peut toutefois proroger le délai visé au paragraphe (3) :

a) d'une période maximale de trente jours dans les cas où :

(i) l'observation du délai entraverait gravement l'activité de l'organisation,

(ii) toute consultation nécessaire pour donner suite à la demande rendrait pratiquement impossible l'observation du délai;

b) de la période nécessaire au transfert des renseignements visés sur support de substitution.

Dans l'un ou l'autre cas, l'organisation envoie au demandeur, dans les trente jours suivant la demande, un avis de

limit, the reasons for extending the time limit and of their right to make a complaint to the Commissioner in respect of the extension.

prorogation l'informant du nouveau délai, des motifs de la prorogation et de son droit de déposer auprès du commissaire une plainte à propos de la prorogation.

Deemed refusal

(5) If the organization fails to respond within the time limit, the organization is deemed to have refused the request.

Présomption

(5) Faute de répondre dans le délai, l'organisation est réputée avoir refusé d'acquiescer à la demande.

Costs for responding

(6) An organization may respond to an individual's request at a cost to the individual only if

(a) the organization has informed the individual of the approximate cost; and

(b) the individual has advised the organization that the request is not being withdrawn.

Coût

(6) Elle ne peut exiger de droits pour répondre à la demande que si, à la fois, elle informe le demandeur du montant approximatif de ceux-ci et celui-ci l'avise qu'il ne retire pas sa demande.

Reasons

(7) An organization that responds within the time limit and refuses a request shall inform the individual in writing of the refusal, setting out the reasons and any recourse that they may have under this Part.

Refus motivé

(7) L'organisation qui refuse, dans le délai prévu, d'acquiescer à la demande notifie par écrit au demandeur son refus motivé et l'informe des recours que lui accorde la présente partie.

Retention of information

(8) Despite clause 4.5 of Schedule 1, an organization that has personal information that is the subject of a request shall retain the information for as long as is necessary to allow the individual to exhaust any recourse under this Part that they may have.

2000, c. 5, s. 8; 2015, c. 32, s. 8(F).

Conservation des renseignements

(8) Malgré l'article 4.5 de l'annexe 1, l'organisation qui détient un renseignement faisant l'objet d'une demande doit le conserver le temps nécessaire pour permettre au demandeur d'épuiser tous les recours qu'il a en vertu de la présente partie.

2000, ch. 5, art. 8; 2015, ch. 32, art. 8(F).

When access prohibited

9 (1) Despite clause 4.9 of Schedule 1, an organization shall not give an individual access to personal information if doing so would likely reveal personal information about a third party. However, if the information about the third party is severable from the record containing the information about the individual, the organization shall sever the information about the third party before giving the individual access.

Cas où la communication est interdite

9 (1) Malgré l'article 4.9 de l'annexe 1, l'organisation ne peut communiquer de renseignement à l'intéressé dans le cas où cette communication révélerait vraisemblablement un renseignement personnel sur un tiers. Toutefois, si ce dernier renseignement peut être retranché du document en cause, l'organisation est tenue de le retrancher puis de communiquer à l'intéressé le renseignement le concernant.

Limit

(2) Subsection (1) does not apply if the third party consents to the access or the individual needs the information because an individual's life, health or security is threatened.

Non-application

(2) Le paragraphe (1) ne s'applique pas si le tiers consent à la communication ou si l'intéressé a besoin du renseignement parce que la vie, la santé ou la sécurité d'un individu est en danger.

Information related to paragraphs 7(3)(c), (c.1) or (d)

(2.1) An organization shall comply with subsection (2.2) if an individual requests that the organization

Renseignements relatifs aux al. 7(3)c), c.1) ou d)

(2.1) L'organisation est tenue de se conformer au paragraphe (2.2) si l'intéressé lui demande :

(a) inform the individual about

(i) any disclosure of information to a government institution or a part of a government institution under paragraph 7(3)(c), subparagraph 7(3)(c.1)(i) or (ii) or paragraph 7(3)(c.2) or (d), or

(ii) the existence of any information that the organization has relating to a disclosure referred to in subparagraph (i), to a subpoena, warrant or order referred to in paragraph 7(3)(c) or to a request made by a government institution or a part of a government institution under subparagraph 7(3)(c.1)(i) or (ii); or

(b) give the individual access to the information referred to in subparagraph (a)(ii).

a) de l'aviser, selon le cas :

(i) de toute communication faite à une institution gouvernementale ou à une subdivision d'une telle institution en vertu de l'alinéa 7(3)c), des sous-alinéas 7(3)c.1) (i) ou (ii) ou des alinéas 7(3)c.2) ou d),

(ii) de l'existence de renseignements détenus par l'organisation et relatifs soit à toute telle communication, soit à une assignation, un mandat ou une ordonnance visés à l'alinéa 7(3)c), soit à une demande de communication faite par une institution gouvernementale ou une subdivision d'une telle institution en vertu de ces sous-alinéas;

b) de lui communiquer ces renseignements.

Notification and response

(2.2) An organization to which subsection (2.1) applies

(a) shall, in writing and without delay, notify the institution or part concerned of the request made by the individual; and

(b) shall not respond to the request before the earlier of

(i) the day on which it is notified under subsection (2.3), and

(ii) thirty days after the day on which the institution or part was notified.

Notification et réponse

(2.2) Le cas échéant, l'organisation :

a) notifie par écrit et sans délai la demande à l'institution gouvernementale ou à la subdivision d'une telle institution concernée;

b) ne peut donner suite à la demande avant le jour où elle reçoit l'avis prévu au paragraphe (2.3) ou, s'il est antérieur, le trentième jour suivant celui où l'institution ou la subdivision reçoit notification.

Objection

(2.3) Within thirty days after the day on which it is notified under subsection (2.2), the institution or part shall notify the organization whether or not the institution or part objects to the organization complying with the request. The institution or part may object only if the institution or part is of the opinion that compliance with the request could reasonably be expected to be injurious to

(a) national security, the defence of Canada or the conduct of international affairs;

(a.1) the detection, prevention or deterrence of money laundering or the financing of terrorist activities; or

(b) the enforcement of any law of Canada, a province or a foreign jurisdiction, an investigation relating to the enforcement of any such law or the gathering of intelligence for the purpose of enforcing any such law.

Opposition

(2.3) Dans les trente jours suivant celui où la demande lui est notifiée, l'institution ou la subdivision avise l'organisation du fait qu'elle s'oppose ou non à ce que celle-ci acquiesce à la demande. Elle ne peut s'y opposer que si elle est d'avis que faire droit à la demande risquerait vraisemblablement de nuire :

a) à la sécurité nationale, à la défense du Canada ou à la conduite des affaires internationales;

a.1) à la détection, à la prévention ou à la dissuasion du recyclage des produits de la criminalité ou du financement des activités terroristes;

b) au contrôle d'application du droit canadien, provincial ou étranger, à une enquête liée à ce contrôle d'application ou à la collecte de renseignements en matière de sécurité en vue de ce contrôle d'application.

Prohibition

(2.4) Despite clause 4.9 of Schedule 1, if an organization is notified under subsection (2.3) that the institution or part objects to the organization complying with the request, the organization

(a) shall refuse the request to the extent that it relates to paragraph (2.1)(a) or to information referred to in subparagraph (2.1)(a)(ii);

(b) shall notify the Commissioner, in writing and without delay, of the refusal; and

(c) shall not disclose to the individual

(i) any information that the organization has relating to a disclosure to a government institution or a part of a government institution under paragraph 7(3)(c), subparagraph 7(3)(c.1)(i) or (ii) or paragraph 7(3)(c.2) or (d) or to a request made by a government institution under either of those subparagraphs,

(ii) that the organization notified an institution or part under paragraph (2.2)(a) or the Commissioner under paragraph (b), or

(iii) that the institution or part objects.

When access may be refused

(3) Despite the note that accompanies clause 4.9 of Schedule 1, an organization is not required to give access to personal information only if

(a) the information is protected by solicitor-client privilege or the professional secrecy of advocates and notaries or by litigation privilege;

(b) to do so would reveal confidential commercial information;

(c) to do so could reasonably be expected to threaten the life or security of another individual;

(c.1) the information was collected under paragraph 7(1)(b);

(d) the information was generated in the course of a formal dispute resolution process; or

(e) the information was created for the purpose of making a disclosure under the *Public Servants*

Refus d'acquiescer à la demande

(2.4) Malgré l'article 4.9 de l'annexe 1, si elle est informée que l'institution ou la subdivision s'oppose à ce qu'elle acquiesce à la demande, l'organisation :

a) refuse d'y acquiescer dans la mesure où la demande est visée à l'alinéa (2.1)a) ou se rapporte à des renseignements visés à cet alinéa;

b) en avise par écrit et sans délai le commissaire;

c) ne communique à l'intéressé :

(i) ni les renseignements détenus par l'organisation et relatifs à toute communication faite à une institution gouvernementale ou à une subdivision d'une telle institution en vertu de l'alinéa 7(3)c), des sous-alinéas 7(3)c.1)(i) ou (ii) ou des alinéas 7(3)c.2) ou d) ou à une demande de communication faite par une institution gouvernementale ou une subdivision d'une telle institution en vertu de ces sous-alinéas.

(ii) ni le fait qu'il y a eu notification de la demande à l'institution gouvernementale ou à une subdivision en application de l'alinéa (2.2)a) ou que le commissaire en a été avisé en application de l'alinéa b),

(iii) ni le fait que l'institution ou la subdivision s'oppose à ce que l'organisation acquiesce à la demande.

Cas où la communication peut être refusée

(3) Malgré la note afférente à l'article 4.9 de l'annexe 1, l'organisation n'est pas tenue de communiquer à l'intéressé des renseignements personnels dans les cas suivants seulement :

a) les renseignements sont protégés par le secret professionnel de l'avocat ou du notaire ou par le privilège relatif au litige;

b) la communication révélerait des renseignements commerciaux confidentiels;

c) elle risquerait vraisemblablement de nuire à la vie ou la sécurité d'un autre individu;

c.1) les renseignements ont été recueillis au titre de l'alinéa 7(1)b);

d) les renseignements ont été fournis uniquement à l'occasion d'un règlement officiel des différends;

Disclosure Protection Act or in the course of an investigation into a disclosure under that Act.

However, in the circumstances described in paragraph (b) or (c), if giving access to the information would reveal confidential commercial information or could reasonably be expected to threaten the life or security of another individual, as the case may be, and that information is severable from the record containing any other information for which access is requested, the organization shall give the individual access after severing.

Limit

(4) Subsection (3) does not apply if the individual needs the information because an individual's life, health or security is threatened.

Notice

(5) If an organization decides not to give access to personal information in the circumstances set out in paragraph (3)(c.1), the organization shall, in writing, so notify the Commissioner, and shall include in the notification any information that the Commissioner may specify.

2000, c. 5, s. 9, c. 17, s. 97; 2001, c. 41, s. 82; 2005, c. 46, s. 57; 2006, c. 9, s. 223; 2015, c. 32, s. 9; 2019, c. 18, s. 61.

Sensory disability

10 An organization shall give access to personal information in an alternative format to an individual with a sensory disability who has a right of access to personal information under this Part and who requests that it be transmitted in the alternative format if

(a) a version of the information already exists in that format; or

(b) its conversion into that format is reasonable and necessary in order for the individual to be able to exercise rights under this Part.

DIVISION 1.1

Breaches of Security Safeguards

Report to Commissioner

10.1 (1) An organization shall report to the Commissioner any breach of security safeguards involving personal information under its control if it is reasonable in the circumstances to believe that the breach creates a real risk of significant harm to an individual.

e) les renseignements ont été créés en vue de faire une divulgation au titre de la *Loi sur la protection des fonctionnaires divulgateurs d'actes répréhensibles* ou dans le cadre d'une enquête menée sur une divulgation en vertu de cette loi.

Toutefois, dans les cas visés aux alinéas b) ou c), si les renseignements commerciaux confidentiels ou les renseignements dont la communication risquerait vraisemblablement de nuire à la vie ou la sécurité d'un autre individu peuvent être retranchés du document en cause, l'organisation est tenue de faire la communication en retranchant ces renseignements.

Non-application

(4) Le paragraphe (3) ne s'applique pas si l'intéressé a besoin des renseignements parce que la vie, la santé ou la sécurité d'un individu est en danger.

Avis

(5) Si elle décide de ne pas communiquer les renseignements dans le cas visé à l'alinéa (3)c.1), l'organisation en avise par écrit le commissaire et lui fournit les renseignements qu'il peut préciser.

2000, ch. 5, art. 9, ch. 17, art. 97; 2001, ch. 41, art. 82; 2005, ch. 46, art. 57; 2006, ch. 9, art. 223; 2015, ch. 32, art. 9; 2019, ch. 18, art. 61.

Déficience sensorielle

10 L'organisation communique les renseignements personnels sur support de substitution à toute personne ayant une déficience sensorielle qui y a droit sous le régime de la présente partie et qui en fait la demande, dans les cas suivants :

a) une version des renseignements visés existe déjà sur un tel support;

b) leur transfert sur un tel support est raisonnable et nécessaire pour que la personne puisse exercer les droits qui lui sont conférés sous le régime de la présente partie.

SECTION 1.1

Atteintes aux mesures de sécurité

Déclaration au commissaire

10.1 (1) L'organisation déclare au commissaire toute atteinte aux mesures de sécurité qui a trait à des renseignements personnels dont elle a la gestion, s'il est raisonnable de croire, dans les circonstances, que l'atteinte présente un risque réel de préjudice grave à l'endroit d'un individu.

Report requirements

(2) The report shall contain the prescribed information and shall be made in the prescribed form and manner as soon as feasible after the organization determines that the breach has occurred.

Notification to individual

(3) Unless otherwise prohibited by law, an organization shall notify an individual of any breach of security safeguards involving the individual's personal information under the organization's control if it is reasonable in the circumstances to believe that the breach creates a real risk of significant harm to the individual.

Contents of notification

(4) The notification shall contain sufficient information to allow the individual to understand the significance to them of the breach and to take steps, if any are possible, to reduce the risk of harm that could result from it or to mitigate that harm. It shall also contain any other prescribed information.

Form and manner

(5) The notification shall be conspicuous and shall be given directly to the individual in the prescribed form and manner, except in prescribed circumstances, in which case it shall be given indirectly in the prescribed form and manner.

Time to give notification

(6) The notification shall be given as soon as feasible after the organization determines that the breach has occurred.

Definition of *significant harm*

(7) For the purpose of this section, ***significant harm*** includes bodily harm, humiliation, damage to reputation or relationships, loss of employment, business or professional opportunities, financial loss, identity theft, negative effects on the credit record and damage to or loss of property.

Real risk of significant harm — factors

(8) The factors that are relevant to determining whether a breach of security safeguards creates a real risk of significant harm to the individual include

(a) the sensitivity of the personal information involved in the breach;

(b) the probability that the personal information has been, is being or will be misused; and

Modalités de la déclaration

(2) La déclaration contient les renseignements prévus par règlement et est faite, selon les modalités réglementaires, le plus tôt possible après que l'organisation a conclu qu'il y a eu atteinte.

Avis à l'intéressé

(3) À moins qu'une règle de droit ne l'interdise, l'organisation est tenue d'aviser l'intéressé de toute atteinte aux mesures de sécurité qui a trait à des renseignements personnels le concernant et dont elle a la gestion, s'il est raisonnable de croire, dans les circonstances, que l'atteinte présente un risque réel de préjudice grave à son endroit.

Contenu de l'avis

(4) L'avis contient suffisamment d'information pour permettre à l'intéressé de comprendre l'importance, pour lui, de l'atteinte et de prendre, si cela est possible, des mesures pour réduire le risque de préjudice qui pourrait en résulter ou pour atténuer un tel préjudice. Il contient aussi tout autre renseignement réglementaire.

Modalités de l'avis

(5) L'avis est manifeste et est donné à l'intéressé directement, selon les modalités réglementaires. Dans les circonstances prévues par règlement, il est donné indirectement, selon les modalités réglementaires.

Délai de l'avis

(6) L'avis est donné le plus tôt possible après que l'organisation a conclu qu'il y a eu atteinte.

Définition de *préjudice grave*

(7) Pour l'application du présent article, ***préjudice grave*** vise notamment la lésion corporelle, l'humiliation, le dommage à la réputation ou aux relations, la perte financière, le vol d'identité, l'effet négatif sur le dossier de crédit, le dommage aux biens ou leur perte, et la perte de possibilités d'emploi ou d'occasions d'affaires ou d'activités professionnelles.

Risque réel de préjudice grave : facteurs

(8) Les éléments servant à établir si une atteinte aux mesures de sécurité présente un risque réel de préjudice grave à l'endroit de l'intéressé sont notamment le degré de sensibilité des renseignements personnels en cause, la probabilité que les renseignements aient été mal utilisés ou soient en train ou sur le point de l'être et tout autre élément prévu par règlement.

2015, ch. 32, art. 10.

(c) any other prescribed factor.

2015, c. 32, s. 10.

Notification to organizations

10.2 (1) An organization that notifies an individual of a breach of security safeguards under subsection 10.1(3) shall notify any other organization, a government institution or a part of a government institution of the breach if the notifying organization believes that the other organization or the government institution or part concerned may be able to reduce the risk of harm that could result from it or mitigate that harm, or if any of the prescribed conditions are satisfied.

Time to give notification

(2) The notification shall be given as soon as feasible after the organization determines that the breach has occurred.

Disclosure of personal information

(3) In addition to the circumstances set out in subsection 7(3), for the purpose of clause 4.3 of Schedule 1, and despite the note that accompanies that clause, an organization may disclose personal information without the knowledge or consent of the individual if

(a) the disclosure is made to the other organization, the government institution or the part of a government institution that was notified of the breach under subsection (1); and

(b) the disclosure is made solely for the purposes of reducing the risk of harm to the individual that could result from the breach or mitigating that harm.

Disclosure without consent

(4) Despite clause 4.5 of Schedule 1, an organization may disclose personal information for purposes other than those for which it was collected in the circumstance set out in subsection (3).

2015, c. 32, s. 10.

Records

10.3 (1) An organization shall, in accordance with any prescribed requirements, keep and maintain a record of every breach of security safeguards involving personal information under its control.

Provision to Commissioner

(2) An organization shall, on request, provide the Commissioner with access to, or a copy of, a record.

2015, c. 32, s. 10.

Avis à une organisation

10.2 (1) L'organisation qui, en application du paragraphe 10.1(3), avise un individu d'une atteinte aux mesures de sécurité est tenue d'en aviser toute autre organisation, ou toute institution gouvernementale ou subdivision d'une telle institution, si elle croit que l'autre organisation, l'institution ou la subdivision peut être en mesure de réduire le risque de préjudice pouvant résulter de l'atteinte ou d'atténuer ce préjudice, ou s'il est satisfait à des conditions précisées par règlement.

Délai de l'avis

(2) Elle le fait le plus tôt possible après avoir conclu qu'il y a eu atteinte.

Communication de renseignements personnels

(3) En plus des cas visés au paragraphe 7(3), pour l'application de l'article 4.3 de l'annexe 1 et malgré la note afférente, l'organisation peut communiquer des renseignements personnels à l'insu de l'intéressé ou sans son consentement si :

a) d'une part, la communication est faite à l'autre organisation, ou à l'institution gouvernementale ou la subdivision d'une telle institution qui a été avisée de l'atteinte en application du paragraphe (1);

b) d'autre part, elle n'est faite que pour réduire le risque de préjudice pour l'intéressé qui pourrait résulter de l'atteinte ou atténuer ce préjudice.

Communication sans consentement

(4) Malgré l'article 4.5 de l'annexe 1, l'organisation peut, dans le cas visé au paragraphe (3), communiquer un renseignement personnel à des fins autres que celles auxquelles il a été recueilli.

2015, ch. 32, art. 10.

Registre

10.3 (1) L'organisation tient et conserve, conformément aux règlements, un registre de toutes les atteintes aux mesures de sécurité qui ont trait à des renseignements personnels dont elle a la gestion.

Accès au registre ou copie

(2) Sur demande du commissaire, l'organisation lui donne accès à son registre ou lui en remet copie.

2015, ch. 32, art. 10.

DIVISION 2

Remedies

Filing of Complaints

Contravention

11 (1) An individual may file with the Commissioner a written complaint against an organization for contravening a provision of Division 1 or 1.1 or for not following a recommendation set out in Schedule 1.

Commissioner may initiate complaint

(2) If the Commissioner is satisfied that there are reasonable grounds to investigate a matter under this Part, the Commissioner may initiate a complaint in respect of the matter.

Time limit

(3) A complaint that results from the refusal to grant a request under section 8 must be filed within six months, or any longer period that the Commissioner allows, after the refusal or after the expiry of the time limit for responding to the request, as the case may be.

Notice

(4) The Commissioner shall give notice of a complaint to the organization against which the complaint was made.

2000, c. 5, s. 11; 2015, c. 32, s. 11.

Investigations of Complaints

Examination of complaint by Commissioner

12 (1) The Commissioner shall conduct an investigation in respect of a complaint, unless the Commissioner is of the opinion that

(a) the complainant ought first to exhaust grievance or review procedures otherwise reasonably available;

(b) the complaint could more appropriately be dealt with, initially or completely, by means of a procedure provided for under the laws of Canada, other than this Part, or the laws of a province; or

(c) the complaint was not filed within a reasonable period after the day on which the subject matter of the complaint arose.

Exception

(2) Despite subsection (1), the Commissioner is not required to conduct an investigation in respect of an act

SECTION 2

Recours

Dépôt des plaintes

Violation

11 (1) Tout intéressé peut déposer auprès du commissaire une plainte contre une organisation qui contrevient à l'une des dispositions des sections 1 ou 1.1, ou qui omet de mettre en œuvre une recommandation énoncée dans l'annexe 1.

Plaintes émanant du commissaire

(2) Le commissaire peut lui-même prendre l'initiative d'une plainte s'il a des motifs raisonnables de croire qu'une enquête devrait être menée sur une question relative à l'application de la présente partie.

Délai

(3) Lorsqu'elle porte sur le refus d'acquiescer à une demande visée à l'article 8, la plainte doit être déposée dans les six mois suivant, selon le cas, le refus ou l'expiration du délai pour répondre à la demande, à moins que le commissaire n'accorde un délai supplémentaire.

Avis

(4) Le commissaire donne avis de la plainte à l'organisation visée par celle-ci.

2000, ch. 5, art. 11; 2015, ch. 32, art. 11.

Examen des plaintes

Examen des plaintes par le commissaire

12 (1) Le commissaire procède à l'examen de toute plainte dont il est saisi à moins qu'il estime celle-ci irrecevable pour un des motifs suivants :

a) le plaignant devrait d'abord épuiser les recours internes ou les procédures d'appel ou de règlement des griefs qui lui sont normalement ouverts;

b) la plainte pourrait avantageusement être instruite, dans un premier temps ou à toutes les étapes, selon des procédures prévues par le droit fédéral — à l'exception de la présente partie — ou le droit provincial;

c) la plainte n'a pas été déposée dans un délai raisonnable après que son objet a pris naissance.

Exception

(2) Malgré le paragraphe (1), le commissaire n'a pas à examiner tout acte allégué dans la plainte qui, à son avis,

alleged in a complaint if the Commissioner is of the opinion that the act, if proved, would constitute a contravention of any of sections 6 to 9 of *An Act to promote the efficiency and adaptability of the Canadian economy by regulating certain activities that discourage reliance on electronic means of carrying out commercial activities, and to amend the Canadian Radio-television and Telecommunications Commission Act, the Competition Act, the Personal Information Protection and Electronic Documents Act and the Telecommunications Act* or section 52.01 of the *Competition Act* or would constitute conduct that is reviewable under section 74.011 of that Act.

Notification

(3) The Commissioner shall notify the complainant and the organization that the Commissioner will not investigate the complaint or any act alleged in the complaint and give reasons.

Compelling reasons

(4) The Commissioner may reconsider a decision not to investigate under subsection (1), if the Commissioner is satisfied that the complainant has established that there are compelling reasons to investigate.

2000, c. 5, s. 12; 2010, c. 23, s. 83.

Powers of Commissioner

12.1 (1) In the conduct of an investigation of a complaint, the Commissioner may

(a) summon and enforce the appearance of persons before the Commissioner and compel them to give oral or written evidence on oath and to produce any records and things that the Commissioner considers necessary to investigate the complaint, in the same manner and to the same extent as a superior court of record;

(b) administer oaths;

(c) receive and accept any evidence and other information, whether on oath, by affidavit or otherwise, that the Commissioner sees fit, whether or not it is or would be admissible in a court of law;

(d) at any reasonable time, enter any premises, other than a dwelling-house, occupied by an organization on satisfying any security requirements of the organization relating to the premises;

(e) converse in private with any person in any premises entered under paragraph (d) and otherwise carry out in those premises any inquiries that the Commissioner sees fit; and

constituerait, s'il était prouvé, une contravention à l'un des articles 6 à 9 de la *Loi visant à promouvoir l'efficacité et la capacité d'adaptation de l'économie canadienne par la réglementation de certaines pratiques qui découragent l'exercice des activités commerciales par voie électronique et modifiant la Loi sur le Conseil de la radiodiffusion et des télécommunications canadiennes, la Loi sur la concurrence, la Loi sur la protection des renseignements personnels et les documents électroniques et la Loi sur les télécommunications* ou à l'article 52.01 de la *Loi sur la concurrence* ou un comportement susceptible d'examen visé à l'article 74.011 de cette loi.

Avis aux parties

(3) S'il décide de ne pas procéder à l'examen de la plainte ou de tout acte allégué dans celle-ci, le commissaire avise le plaignant et l'organisation de sa décision et des motifs qui la justifient.

Raisons impérieuses

(4) Le commissaire peut réexaminer sa décision de ne pas examiner la plainte aux termes du paragraphe (1) si le plaignant le convainc qu'il existe des raisons impérieuses pour ce faire.

2000, ch. 5, art. 12; 2010, ch. 23, art. 83.

Pouvoirs du commissaire

12.1 (1) Le commissaire peut, dans le cadre de l'examen des plaintes :

a) assigner et contraindre des témoins à comparaître devant lui, à déposer verbalement ou par écrit sous la foi du serment et à produire les documents ou pièces qu'il juge nécessaires pour examiner la plainte dont il est saisi, de la même façon et dans la même mesure qu'une cour supérieure d'archives;

b) faire prêter serment;

c) recevoir les éléments de preuve ou les renseignements — fournis notamment par déclaration verbale ou écrite sous serment — qu'il estime indiqués, indépendamment de leur admissibilité devant les tribunaux;

d) visiter, à toute heure convenable, tout local — autre qu'une maison d'habitation — occupé par l'organisation, à condition de satisfaire aux normes de sécurité établies par elle pour ce local;

e) s'entretenir en privé avec toute personne se trouvant dans le local visé à l'alinéa d) et y mener les enquêtes qu'il estime nécessaires;

(f) examine or obtain copies of or extracts from records found in any premises entered under paragraph (d) that contain any matter relevant to the investigation.

f) examiner ou se faire remettre des copies ou des extraits des documents contenant des éléments utiles à l'examen de la plainte et trouvés dans le local visé à l'alinéa d).

Dispute resolution mechanisms

(2) The Commissioner may attempt to resolve complaints by means of dispute resolution mechanisms such as mediation and conciliation.

Mode de règlement des différends

(2) Il peut tenter de parvenir au règlement de la plainte en ayant recours à un mode de règlement des différends, notamment la médiation et la conciliation.

Delegation

(3) The Commissioner may delegate any of the powers set out in subsection (1) or (2).

Délégation

(3) Il peut déléguer les pouvoirs que les paragraphes (1) et (2) lui confèrent.

Return of records

(4) The Commissioner or the delegate shall return to a person or an organization any record or thing that they produced under this section within 10 days after they make a request to the Commissioner or the delegate, but nothing precludes the Commissioner or the delegate from again requiring that the record or thing be produced.

Renvoi des documents

(4) Le commissaire ou son délégué renvoie les documents ou pièces demandés en vertu du présent article aux personnes ou organisations qui les ont produits dans les dix jours suivant la requête que celles-ci lui présentent à cette fin, mais rien n'empêche le commissaire ou son délégué d'en réclamer une nouvelle production.

Certificate of delegation

(5) Any person to whom powers set out in subsection (1) are delegated shall be given a certificate of the delegation and the delegate shall produce the certificate, on request, to the person in charge of any premises to be entered under paragraph (1)(d).

2010, c. 23, s. 83.

Certificat

(5) Chaque personne à qui les pouvoirs visés au paragraphe (1) sont délégués reçoit un certificat attestant sa qualité, qu'il présente, sur demande, au responsable du local qui sera visité en application de l'alinéa (1)d).

2010, ch. 23, art. 83.

Discontinuance of Investigation

Reasons

12.2 (1) The Commissioner may discontinue the investigation of a complaint if the Commissioner is of the opinion that

(a) there is insufficient evidence to pursue the investigation;

(b) the complaint is trivial, frivolous or vexatious or is made in bad faith;

(c) the organization has provided a fair and reasonable response to the complaint;

(c.1) the matter is the object of a compliance agreement entered into under subsection 17.1(1);

(d) the matter is already the object of an ongoing investigation under this Part;

Fin de l'examen

Motifs

12.2 (1) Le commissaire peut mettre fin à l'examen de la plainte s'il estime, selon le cas :

a) qu'il n'existe pas suffisamment d'éléments de preuve pour le poursuivre;

b) que la plainte est futile, vexatoire ou entachée de mauvaise foi;

c) que l'organisation a apporté une réponse juste et équitable à la plainte;

c.1) que la question qui a donné lieu à la plainte fait l'objet d'un accord de conformité conclu en vertu du paragraphe 17.1(1);

d) que la plainte fait déjà l'objet d'une enquête au titre de la présente partie;

(e) the matter has already been the subject of a report by the Commissioner;

(f) any of the circumstances mentioned in paragraph 12(1)(a), (b) or (c) apply; or

(g) the matter is being or has already been addressed under a procedure referred to in paragraph 12(1)(a) or (b).

Other reason

(2) The Commissioner may discontinue an investigation in respect of an act alleged in a complaint if the Commissioner is of the opinion that the act, if proved, would constitute a contravention of any of sections 6 to 9 of *An Act to promote the efficiency and adaptability of the Canadian economy by regulating certain activities that discourage reliance on electronic means of carrying out commercial activities, and to amend the Canadian Radio-television and Telecommunications Commission Act, the Competition Act, the Personal Information Protection and Electronic Documents Act and the Telecommunications Act* or section 52.01 of the *Competition Act* or would constitute conduct that is reviewable under section 74.011 of that Act.

Notification

(3) The Commissioner shall notify the complainant and the organization that the investigation has been discontinued and give reasons.

2010, c. 23, s. 83; 2015, c. 32, s. 12.

e) qu'il a déjà dressé un rapport sur l'objet de la plainte;

f) que les circonstances visées à l'un des alinéas 12(1)a) à c) existent;

g) que la plainte fait ou a fait l'objet d'un recours ou d'une procédure visés à l'alinéa 12(1)a) ou est ou a été instruite selon des procédures visées à l'alinéa 12(1)b).

Autre motif

(2) Le commissaire peut mettre fin à l'examen de tout acte allégué dans la plainte qui, à son avis, constituerait, s'il était prouvé, une contravention à l'un des articles 6 à 9 de la *Loi visant à promouvoir l'efficacité et la capacité d'adaptation de l'économie canadienne par la réglementation de certaines pratiques qui découragent l'exercice des activités commerciales par voie électronique et modifiant la Loi sur le Conseil de la radiodiffusion et des télécommunications canadiennes, la Loi sur la concurrence, la Loi sur la protection des renseignements personnels et les documents électroniques et la Loi sur les télécommunications* ou à l'article 52.01 de la *Loi sur la concurrence* ou un comportement susceptible d'examen visé à l'article 74.011 de cette loi.

Avis aux parties

(3) Le commissaire avise le plaignant et l'organisation de la fin de l'examen et des motifs qui la justifient.

2010, ch. 23, art. 83; 2015, ch. 32, art. 12.

Commissioner's Report

Contents

13 (1) The Commissioner shall, within one year after the day on which a complaint is filed or is initiated by the Commissioner, prepare a report that contains

(a) the Commissioner's findings and recommendations;

(b) any settlement that was reached by the parties;

(c) if appropriate, a request that the organization give the Commissioner, within a specified time, notice of any action taken or proposed to be taken to implement the recommendations contained in the report or reasons why no such action has been or is proposed to be taken; and

(d) the recourse, if any, that is available under section 14.

Rapport du commissaire

Contenu

13 (1) Dans l'année suivant, selon le cas, la date du dépôt de la plainte ou celle où il en a pris l'initiative, le commissaire dresse un rapport où :

a) il présente ses conclusions et recommandations;

b) il fait état de tout règlement intervenu entre les parties;

c) il demande, s'il y a lieu, à l'organisation de lui donner avis, dans un délai déterminé, soit des mesures prises ou envisagées pour la mise en œuvre de ses recommandations, soit des motifs invoqués pour ne pas y donner suite;

d) mentionne, s'il y a lieu, l'existence du recours prévu à l'article 14.

(2) [Repealed, 2010, c. 23, s. 84]

Report to parties

(3) The report shall be sent to the complainant and the organization without delay.

2000, c. 5, s. 13; 2010, c. 23, s. 84.

Hearing by Court

Application

14 (1) A complainant may, after receiving the Commissioner's report or being notified under subsection 12.2(3) that the investigation of the complaint has been discontinued, apply to the Court for a hearing in respect of any matter in respect of which the complaint was made, or that is referred to in the Commissioner's report, and that is referred to in clause 4.1.3, 4.2, 4.3.3, 4.4, 4.6, 4.7 or 4.8 of Schedule 1, in clause 4.3, 4.5 or 4.9 of that Schedule as modified or clarified by Division 1 or 1.1, in subsection 5(3) or 8(6) or (7), in section 10 or in Division 1.1.

Time for application

(2) A complainant shall make an application within one year after the report or notification is sent or within any longer period that the Court may, either before or after the expiry of that year, allow.

For greater certainty

(3) For greater certainty, subsections (1) and (2) apply in the same manner to complaints referred to in subsection 11(2) as to complaints referred to in subsection 11(1).

2000, c. 5, s. 14; 2010, c. 23, s. 85; 2015, c. 32, s. 13.

Commissioner may apply or appear

15 The Commissioner may, in respect of a complaint that the Commissioner did not initiate,

(a) apply to the Court, within the time limited by section 14, for a hearing in respect of any matter described in that section, if the Commissioner has the consent of the complainant;

(b) appear before the Court on behalf of any complainant who has applied for a hearing under section 14; or

(c) with leave of the Court, appear as a party to any hearing applied for under section 14.

Remedies

16 The Court may, in addition to any other remedies it may give,

(2) [Abrogé, 2010, ch. 23, art. 84]

Transmission aux parties

(3) Le rapport est transmis sans délai au plaignant et à l'organisation.

2000, ch. 5, art. 13; 2010, ch. 23, art. 84.

Audience de la Cour

Demande

14 (1) Après avoir reçu le rapport du commissaire ou l'avis l'informant de la fin de l'examen de la plainte au titre du paragraphe 12.2(3), le plaignant peut demander que la Cour entende toute question qui a fait l'objet de la plainte — ou qui est mentionnée dans le rapport — et qui est visée aux articles 4.1.3, 4.2, 4.3.3, 4.4, 4.6, 4.7 ou 4.8 de l'annexe 1, aux articles 4.3, 4.5 ou 4.9 de cette annexe tels qu'ils sont modifiés ou clarifiés par les sections 1 ou 1.1, aux paragraphes 5(3) ou 8(6) ou (7), à l'article 10 ou à la section 1.1.

Délai de la demande

(2) La demande est faite dans l'année suivant la transmission du rapport ou de l'avis ou dans le délai supérieur que la Cour autorise avant ou après l'expiration de l'année.

Précision

(3) Il est entendu que les paragraphes (1) et (2) s'appliquent de la même façon aux plaintes visées au paragraphe 11(2) qu'à celles visées au paragraphe 11(1).

2000, ch. 5, art. 14; 2010, ch. 23, art. 85; 2015, ch. 32, art. 13.

Exercice du recours par le commissaire

15 S'agissant d'une plainte dont il n'a pas pris l'initiative, le commissaire a qualité pour :

a) demander lui-même, dans le délai prévu à l'article 14, l'audition de toute question visée à cet article, avec le consentement du plaignant;

b) comparaître devant la Cour au nom du plaignant qui a demandé l'audition de la question;

c) comparaître, avec l'autorisation de la Cour, comme partie à la procédure.

Réparations

16 La Cour peut, en sus de toute autre réparation qu'elle accorde :

(a) order an organization to correct its practices in order to comply with Divisions 1 and 1.1;

(b) order an organization to publish a notice of any action taken or proposed to be taken to correct its practices, whether or not ordered to correct them under paragraph (a); and

(c) award damages to the complainant, including damages for any humiliation that the complainant has suffered.

2000, c. 5, s. 16; 2015, c. 32, s. 14.

Summary hearings

17 (1) An application made under section 14 or 15 shall be heard and determined without delay and in a summary way unless the Court considers it inappropriate to do so.

Precautions

(2) In any proceedings arising from an application made under section 14 or 15, the Court shall take every reasonable precaution, including, when appropriate, receiving representations ex parte and conducting hearings in camera, to avoid the disclosure by the Court or any person of any information or other material that the organization would be authorized to refuse to disclose if it were requested under clause 4.9 of Schedule 1.

Compliance Agreements

Compliance agreement

17.1 (1) If the Commissioner believes on reasonable grounds that an organization has committed, is about to commit or is likely to commit an act or omission that could constitute a contravention of a provision of Division 1 or 1.1 or a failure to follow a recommendation set out in Schedule 1, the Commissioner may enter into a compliance agreement, aimed at ensuring compliance with this Part, with that organization.

Terms

(2) A compliance agreement may contain any terms that the Commissioner considers necessary to ensure compliance with this Part.

Effect of compliance agreement — no application

(3) When a compliance agreement is entered into, the Commissioner, in respect of any matter covered under the agreement,

a) ordonner à l'organisation de revoir ses pratiques en vue de se conformer aux sections 1 et 1.1;

b) lui ordonner de publier un avis énonçant les mesures prises ou envisagées pour corriger ses pratiques, que ces dernières aient ou non fait l'objet d'une ordonnance visée à l'alinéa a);

c) accorder au plaignant des dommages-intérêts, notamment en réparation de l'humiliation subie.

2000, ch. 5, art. 16; 2015, ch. 32, art. 14.

Procédure sommaire

17 (1) Le recours prévu aux articles 14 ou 15 est entendu et jugé sans délai et selon une procédure sommaire, à moins que la Cour ne l'estime contre-indiqué.

Précautions à prendre

(2) À l'occasion des procédures relatives au recours prévu aux articles 14 ou 15, la Cour prend toutes les précautions possibles, notamment, si c'est indiqué, par la tenue d'audiences à huis clos et l'audition d'arguments en l'absence d'une partie, pour éviter que ne soient divulgués, de par son propre fait ou celui de quiconque, des renseignements qui justifient un refus de communication de renseignements personnels demandés en vertu de l'article 4.9 de l'annexe 1.

Accord de conformité

Conclusion d'un accord de conformité

17.1 (1) Le commissaire peut, s'il a des motifs raisonnables de croire à l'existence, à l'imminence ou à la probabilité d'un fait — acte ou omission — pouvant constituer une contravention à l'une des dispositions des sections 1 ou 1.1 ou une omission de mettre en œuvre une recommandation énoncée dans l'annexe 1, conclure avec l'organisation intéressée un accord, appelé « accord de conformité », visant à faire respecter la présente partie.

Conditions

(2) L'accord de conformité est assorti des conditions que le commissaire estime nécessaires pour faire respecter la présente partie.

Effet de l'accord de conformité

(3) Lorsqu'un accord de conformité a été conclu, le commissaire :

(a) shall not apply to the Court for a hearing under subsection 14(1) or paragraph 15(a); and

(b) shall apply to the court for the suspension of any pending applications that were made by the Commissioner under those provisions.

a) ne peut demander à la Cour, aux termes du paragraphe 14(1) ou de l'alinéa 15a), une audition à l'égard de toute question visée par l'accord;

b) demande la suspension de toute demande d'audition d'une question visée par l'accord qu'il a faite et qui est pendante au moment de la conclusion de l'accord.

For greater certainty

(4) For greater certainty, a compliance agreement does not preclude

(a) an individual from applying for a hearing under section 14; or

(b) the prosecution of an offence under the Act.

2015, c. 32, s. 15.

Précision

(4) Il est entendu que la conclusion de l'accord n'a pas pour effet d'empêcher les poursuites pour infraction à la présente loi, ou d'empêcher un plaignant — autre que le commissaire — de faire une demande d'audition de la question aux termes de l'article 14.

2015, ch. 32, art. 15.

Agreement complied with

17.2 (1) If the Commissioner is of the opinion that a compliance agreement has been complied with, the Commissioner shall provide written notice to that effect to the organization and withdraw any applications that were made under subsection 14(1) or paragraph 15(a) in respect of any matter covered under the agreement.

Accord respecté

17.2 (1) S'il estime que l'accord de conformité a été respecté, le commissaire en fait part à l'organisation intéressée par avis écrit et il retire toute demande d'audition, faite aux termes du paragraphe 14(1) ou de l'alinéa 15a), d'une question visée par l'accord.

Agreement not complied with

(2) If the Commissioner is of the opinion that an organization is not complying with the terms of a compliance agreement, the Commissioner shall notify the organization and may apply to the Court for

(a) an order requiring the organization to comply with the terms of the agreement, in addition to any other remedies it may give; or

(b) a hearing under subsection 14(1) or paragraph 15(a) or to reinstate proceedings that have been suspended as a result of an application made under paragraph 17.1(3)(b).

Accord non respecté

(2) S'il estime que l'accord de conformité n'a pas été respecté, le commissaire envoie à l'organisation intéressée un avis de défaut. Il peut alors demander à la Cour :

a) soit une ordonnance enjoignant à l'organisation de se conformer aux conditions de l'accord de conformité, en sus de toute autre réparation que la Cour peut accorder;

b) soit une audition de la question, aux termes du paragraphe 14(1) ou de l'alinéa 15a) ou, en cas de suspension de l'audition à la suite d'une demande faite en application de l'alinéa 17.1(3)b), le rétablissement de l'audition.

Time for application

(3) Despite subsection 14(2), the application shall be made within one year after notification is sent or within any longer period that the Court may, either before or after the expiry of that year, allow.

2015, c. 32, s. 15.

Délai de la demande

(3) Malgré le paragraphe 14(2), la demande est faite dans l'année suivant l'envoi de l'avis de défaut ou dans le délai supérieur que la Cour autorise avant ou après l'expiration de l'année.

2015, ch. 32, art. 15.

DIVISION 3

Audits

To ensure compliance

18 (1) The Commissioner may, on reasonable notice and at any reasonable time, audit the personal information management practices of an organization if the Commissioner has reasonable grounds to believe that the organization has contravened a provision of Division 1 or 1.1 or is not following a recommendation set out in Schedule 1, and for that purpose may

(a) summon and enforce the appearance of persons before the Commissioner and compel them to give oral or written evidence on oath and to produce any records and things that the Commissioner considers necessary for the audit, in the same manner and to the same extent as a superior court of record;

(b) administer oaths;

(c) receive and accept any evidence and other information, whether on oath, by affidavit or otherwise, that the Commissioner sees fit, whether or not it is or would be admissible in a court of law;

(d) at any reasonable time, enter any premises, other than a dwelling-house, occupied by the organization on satisfying any security requirements of the organization relating to the premises;

(e) converse in private with any person in any premises entered under paragraph (d) and otherwise carry out in those premises any inquiries that the Commissioner sees fit; and

(f) examine or obtain copies of or extracts from records found in any premises entered under paragraph (d) that contain any matter relevant to the audit.

Delegation

(2) The Commissioner may delegate any of the powers set out in subsection (1).

Return of records

(3) The Commissioner or the delegate shall return to a person or an organization any record or thing they produced under this section within ten days after they make a request to the Commissioner or the delegate, but nothing precludes the Commissioner or the delegate from again requiring that the record or thing be produced.

SECTION 3

Vérifications

Contrôle d'application

18 (1) Le commissaire peut, sur préavis suffisant et à toute heure convenable, procéder à la vérification des pratiques de l'organisation en matière de gestion des renseignements personnels s'il a des motifs raisonnables de croire que celle-ci a contrevenu à l'une des dispositions des sections 1 ou 1.1 ou n'a pas mis en œuvre une recommandation énoncée dans l'annexe 1; il a, à cette fin, le pouvoir :

a) d'assigner et de contraindre des témoins à comparaître devant lui, à déposer verbalement ou par écrit sous la foi du serment et à produire les documents ou pièces qu'il juge nécessaires pour procéder à la vérification, de la même façon et dans la même mesure qu'une cour supérieure d'archives;

b) de faire prêter serment;

c) de recevoir les éléments de preuve ou les renseignements — fournis notamment par déclaration verbale ou écrite sous serment — qu'il estime indiqués, indépendamment de leur admissibilité devant les tribunaux;

d) de visiter, à toute heure convenable, tout local — autre qu'une maison d'habitation — occupé par l'organisation, à condition de satisfaire aux normes de sécurité établies par elle pour ce local;

e) de s'entretenir en privé avec toute personne se trouvant dans le local visé à l'alinéa d) et d'y mener les enquêtes qu'il estime nécessaires;

f) d'examiner ou de se faire remettre des copies ou des extraits des documents contenant des éléments utiles à la vérification et trouvés dans le local visé à l'alinéa d).

Délégation

(2) Il peut déléguer les pouvoirs que le paragraphe (1) lui confère.

Renvoi des documents

(3) Le commissaire ou son délégué renvoie les documents ou pièces demandés en vertu du présent article aux personnes ou organisations qui les ont produits dans les dix jours suivant la requête que celles-ci lui présentent à cette fin, mais rien n'empêche le commissaire ou son délégué d'en réclamer une nouvelle production.

Certificate of delegation

(4) Any person to whom powers set out in subsection (1) are delegated shall be given a certificate of the delegation and the delegate shall produce the certificate, on request, to the person in charge of any premises to be entered under paragraph (1)(d).

2000, c. 5, s. 18; 2015, c. 32, s. 16.

Certificat

(4) Chaque personne à qui les pouvoirs visés au paragraphe (1) sont délégués reçoit un certificat attestant sa qualité, qu'il présente, sur demande, au responsable du local qui sera visité en application de l'alinéa (1)d).

2000, ch. 5, art. 18; 2015, ch. 32, art. 16.

Report of findings and recommendations

19 (1) After an audit, the Commissioner shall provide the audited organization with a report that contains the findings of the audit and any recommendations that the Commissioner considers appropriate.

Rapport des conclusions et recommandations du commissaire

19 (1) À l'issue de la vérification, le commissaire adresse à l'organisation en cause un rapport où il présente ses conclusions ainsi que les recommandations qu'il juge indiquées.

Reports may be included in annual reports

(2) The report may be included in a report made under section 25.

Incorporation du rapport

(2) Ce rapport peut être incorporé dans le rapport visé à l'article 25.

DIVISION 4

General

SECTION 4

Dispositions générales

Confidentiality

20 (1) Subject to subsections (2) to (7), 12(3), 12.2(3), 13(3), 19(1), 23(3) and 23.1(1) and section 25, the Commissioner or any person acting on behalf or under the direction of the Commissioner shall not disclose any information that comes to their knowledge as a result of the performance or exercise of any of the Commissioner's duties or powers under this Part other than those referred to in subsection 10.1(1) or 10.3(2).

Secret

20 (1) Sous réserve des paragraphes (2) à (7), 12(3), 12.2(3), 13(3), 19(1), 23(3) et 23.1(1) et de l'article 25, le commissaire et les personnes agissant en son nom ou sous son autorité sont tenus au secret en ce qui concerne les renseignements dont ils prennent connaissance par suite de l'exercice des attributions que la présente partie confère au commissaire, à l'exception de celles visées aux paragraphes 10.1(1) ou 10.3(2).

Confidentiality — reports and records

(1.1) Subject to subsections (2) to (7), 12(3), 12.2(3), 13(3), 19(1), 23(3) and 23.1(1) and section 25, the Commissioner or any person acting on behalf or under the direction of the Commissioner shall not disclose any information contained in a report made under subsection 10.1(1) or in a record obtained under subsection 10.3(2).

Secret — déclarations et registre

(1.1) Sous réserve des paragraphes (2) à (7), 12(3), 12.2(3), 13(3), 19(1), 23(3) et 23.1(1) et de l'article 25, le commissaire et les personnes agissant en son nom ou sous son autorité sont tenus au secret en ce qui concerne les renseignements figurant dans une déclaration obtenue en application du paragraphe 10.1(1) ou dans un registre obtenu en application du paragraphe 10.3(2).

Public interest

(2) The Commissioner may, if the Commissioner considers that it is in the public interest to do so, make public any information that comes to his or her knowledge in the performance or exercise of any of his or her duties or powers under this Part.

Intérêt public

(2) Le commissaire peut rendre publique toute information dont il prend connaissance par suite de l'exercice des attributions que la présente partie lui confère, s'il estime que cela est dans l'intérêt public.

Disclosure of necessary information

(3) The Commissioner may disclose, or may authorize any person acting on behalf or under the direction of the

Communication de renseignements nécessaires

(3) Il peut communiquer — ou autoriser les personnes agissant en son nom ou sous son autorité à communiquer

Commissioner to disclose, information that in the Commissioner's opinion is necessary to

(a) conduct an investigation or audit under this Part; or

(b) establish the grounds for findings and recommendations contained in any report under this Part.

Disclosure in the course of proceedings

(4) The Commissioner may disclose, or may authorize any person acting on behalf or under the direction of the Commissioner to disclose, information in the course of

(a) a prosecution for an offence under section 28;

(b) a prosecution for an offence under section 132 of the *Criminal Code* (perjury) in respect of a statement made under this Part;

(c) a hearing before the Court under this Part;

(d) an appeal from a decision of the Court; or

(e) a judicial review in relation to the performance or exercise of any of the Commissioner's duties or powers under this Part.

Disclosure of offence authorized

(5) The Commissioner may disclose to the Attorney General of Canada or of a province, as the case may be, information relating to the commission of an offence against any law of Canada or a province on the part of an officer or employee of an organization if, in the Commissioner's opinion, there is evidence of an offence.

Disclosure of breach of security safeguards

(6) The Commissioner may disclose, or may authorize any person acting on behalf or under the direction of the Commissioner to disclose to a government institution or a part of a government institution, any information contained in a report made under subsection 10.1(1) or in a record obtained under subsection 10.3(2) if the Commissioner has reasonable grounds to believe that the information could be useful in the investigation of a contravention of the laws of Canada or a province that has been, is being or is about to be committed.

— les renseignements qui, à son avis, sont nécessaires pour :

a) examiner une plainte ou procéder à une vérification en vertu de la présente partie;

b) motiver les conclusions et recommandations contenues dans les rapports prévus par la présente partie.

Communication dans le cadre de certaines procédures

(4) Il peut également communiquer — ou autoriser les personnes agissant en son nom ou sous son autorité à communiquer — des renseignements :

a) dans le cadre des procédures intentées pour l'infraction visée à l'article 28;

b) dans le cadre des procédures intentées pour l'infraction visée à l'article 132 du *Code criminel* (parjure) se rapportant à une déclaration faite en vertu de la présente partie;

c) lors d'une audience de la Cour prévue par cette partie;

d) lors de l'appel de la décision rendue par la Cour;

e) dans le cadre d'un contrôle judiciaire à l'égard de l'exercice des attributions que la présente partie confère au commissaire.

Dénonciation autorisée

(5) Dans les cas où, à son avis, il existe des éléments de preuve touchant la perpétration d'infractions au droit fédéral ou provincial par un cadre ou employé d'une organisation, le commissaire peut faire part au procureur général du Canada ou d'une province, selon le cas, des renseignements qu'il détient à cet égard.

Communication — atteinte aux mesures de sécurité

(6) Le commissaire peut communiquer — ou autoriser les personnes agissant en son nom ou sous son autorité à communiquer — tout renseignement figurant dans une déclaration obtenue en application du paragraphe 10.1(1) ou dans un registre obtenu en application du paragraphe 10.3(2) à une institution gouvernementale ou à une subdivision d'une telle institution, si le commissaire a des motifs raisonnables de croire qu'il pourrait être utile à une enquête sur une contravention au droit fédéral ou provincial qui a été commise ou est en train ou sur le point de l'être.

Disclosure

(7) The Commissioner may disclose information, or may authorize any person acting on behalf or under the direction of the Commissioner to disclose information, in the course of proceedings in which the Commissioner has intervened under paragraph 50(c) of *An Act to promote the efficiency and adaptability of the Canadian economy by regulating certain activities that discourage reliance on electronic means of carrying out commercial activities, and to amend the Canadian Radio-television and Telecommunications Commission Act, the Competition Act, the Personal Information Protection and Electronic Documents Act and the Telecommunications Act* or in accordance with subsection 58(3) or 60(1) of that Act.

2000, c. 5, s. 20; 2010, c. 23, s. 86; 2015, c. 32, ss. 17, 26.

Communication de renseignements

(7) Le commissaire peut communiquer — ou autoriser les personnes agissant en son nom ou sous son autorité à communiquer — des renseignements soit dans le cadre des procédures où il est intervenu au titre de l'alinéa 50c) de la *Loi visant à promouvoir l'efficacité et la capacité d'adaptation de l'économie canadienne par la réglementation de certaines pratiques qui découragent l'exercice des activités commerciales par voie électronique et modifiant la Loi sur le Conseil de la radiodiffusion et des télécommunications canadiennes, la Loi sur la concurrence, la Loi sur la protection des renseignements personnels et les documents électroniques et la Loi sur les télécommunications*, soit en conformité avec les paragraphes 58(3) ou 60(1) de cette loi.

2000, ch. 5, art. 20; 2010, ch. 23, art. 86; 2015, ch. 32, art. 17 et 26.

Not competent witness

21 The Commissioner or person acting on behalf or under the direction of the Commissioner is not a competent witness in respect of any matter that comes to their knowledge as a result of the performance or exercise of any of the Commissioner's duties or powers under this Part in any proceeding other than

(a) a prosecution for an offence under section 28;

(b) a prosecution for an offence under section 132 of the *Criminal Code* (perjury) in respect of a statement made under this Part;

(c) a hearing before the Court under this Part; or

(d) an appeal from a decision of the Court.

Qualité pour témoigner

21 En ce qui concerne les questions venues à leur connaissance par suite de l'exercice des attributions que la présente partie confère au commissaire, le commissaire et les personnes agissant en son nom ou sous son autorité n'ont qualité pour témoigner que dans le cadre des procédures intentées pour l'infraction visée à l'article 28 ou pour l'infraction visée à l'article 132 du *Code criminel* (parjure) se rapportant à une déclaration faite en vertu de la présente partie, lors d'une audience de la Cour prévue par cette partie ou lors de l'appel de la décision rendue par celle-ci.

Protection of Commissioner

22 (1) No criminal or civil proceedings lie against the Commissioner, or against any person acting on behalf or under the direction of the Commissioner, for anything done, reported or said in good faith as a result of the performance or exercise or purported performance or exercise of any duty or power of the Commissioner under this Part.

Immunité du commissaire

22 (1) Le commissaire et les personnes agissant en son nom ou sous son autorité bénéficient de l'immunité en matière civile ou pénale pour les actes accomplis, les rapports établis et les paroles prononcées de bonne foi par suite de l'exercice effectif ou censé tel des attributions que la présente partie confère au commissaire.

Defamation

(2) No action lies in defamation with respect to

(a) anything said, any information supplied or any record or thing produced in good faith in the course of an investigation or audit carried out by or on behalf of the Commissioner under this Part; and

Diffamation

(2) Ne peuvent donner lieu à poursuites pour diffamation :

a) les paroles prononcées, les renseignements fournis ou les documents ou pièces produits de bonne foi au cours d'une vérification ou de l'examen d'une plainte effectué par le commissaire ou en son nom dans le cadre de la présente partie;

(b) any report made in good faith by the Commissioner under this Part and any fair and accurate account of the report made in good faith for the purpose of news reporting.

2000, c. 5, s. 22; 2015, c. 32, s. 18.

Consultations with provinces

23 (1) If the Commissioner considers it appropriate to do so, or on the request of an interested person, the Commissioner may, in order to ensure that personal information is protected in as consistent a manner as possible, consult with any person who, under provincial legislation, has functions and duties similar to those of the Commissioner with respect to the protection of such information.

Agreements or arrangements with provinces

(2) The Commissioner may enter into agreements or arrangements with any person referred to in subsection (1) in order to

(a) coordinate the activities of their offices and the office of the Commissioner, including to provide for mechanisms for the handling of any complaint in which they are mutually interested;

(b) undertake and publish research or develop and publish guidelines or other instruments related to the protection of personal information;

(c) develop model contracts or other instruments for the protection of personal information that is collected, used or disclosed interprovincially or internationally; and

(d) develop procedures for sharing information referred to in subsection (3).

Sharing of information with provinces

(3) The Commissioner may, in accordance with any procedure established under paragraph (2)(d), share information with any person referred to in subsection (1), if the information

(a) could be relevant to an ongoing or potential investigation of a complaint or audit under this Part or provincial legislation that has objectives that are similar to this Part; or

(b) could assist the Commissioner or that person in the exercise of their functions and duties with respect to the protection of personal information.

b) les rapports établis de bonne foi par le commissaire dans le cadre de la présente partie, ainsi que les relations qui en sont faites de bonne foi pour des comptes rendus d'événements d'actualités.

2000, ch. 5, art. 22; 2015, ch. 32, art. 18.

Consultation

23 (1) S'il l'estime indiqué ou si tout intéressé le lui demande, le commissaire peut, pour veiller à ce que les renseignements personnels soient protégés de la façon la plus uniforme possible, consulter toute personne ayant, au titre d'une loi provinciale, des attributions semblables à celles du commissaire en matière de protection de tels renseignements.

Accords ou ententes avec les provinces

(2) Il peut conclure des accords ou ententes avec toute personne visée au paragraphe (1) en vue :

a) de coordonner l'activité de leurs bureaux respectifs, notamment de prévoir des mécanismes pour instruire les plaintes dans lesquelles ils ont un intérêt mutuel;

b) d'effectuer des recherches ou d'élaborer des lignes directrices ou d'autres documents en matière de protection des renseignements personnels et de publier ces lignes directrices ou autres documents ou les résultats de ces recherches;

c) d'élaborer des contrats ou autres documents types portant sur la protection des renseignements personnels recueillis, utilisés ou communiqués d'une province à l'autre ou d'un pays à l'autre;

d) d'élaborer la procédure à suivre pour la communication des renseignements au titre du paragraphe (3).

Communication de renseignements aux provinces

(3) Le commissaire peut, conformément à toute procédure élaborée au titre de l'alinéa (2)d), communiquer des renseignements à toute personne visée au paragraphe (1) dans le cas où ceux-ci :

a) soit pourraient être utiles à l'examen d'une plainte ou à une vérification — en cours ou éventuelle — au titre de la présente partie ou d'une loi provinciale dont les objectifs sont similaires à ceux de la présente loi;

b) soit pourraient aider la personne ou le commissaire à exercer ses attributions en matière de protection des renseignements personnels.

Purpose and confidentiality

(4) The procedures referred to in paragraph (2)(d) shall

(a) restrict the use of the information to the purpose for which it was originally shared; and

(b) stipulate that the information be treated in a confidential manner and not be further disclosed without the express consent of the Commissioner.

2000, c. 5, s. 23; 2010, c. 23, s. 87.

Fins d'utilisation et confidentialité

(4) La procédure visée à l'alinéa (2)d) :

a) précise que les renseignements ne peuvent être utilisés qu'aux fins auxquelles ils ont été communiqués;

b) prévoit que les renseignements seront traités de manière confidentielle et ne seront pas autrement communiqués sans le consentement exprès du commissaire.

2000, ch. 5, art. 23; 2010, ch. 23, art. 87.

Disclosure of information to foreign state

23.1 (1) Subject to subsection (3), the Commissioner may, in accordance with any procedure established under paragraph (4)(b), disclose information referred to in subsection (2) that has come to the Commissioner's knowledge as a result of the performance or exercise of any of the Commissioner's duties or powers under this Part to any person or body who, under the legislation of a foreign state, has

(a) functions and duties similar to those of the Commissioner with respect to the protection of personal information; or

(b) responsibilities that relate to conduct that is substantially similar to conduct that would be in contravention of this Part.

Communication de renseignements à des États étrangers

23.1 (1) Sous réserve du paragraphe (3), le commissaire peut, conformément à toute procédure établie au titre de l'alinéa (4)b), communiquer les renseignements mentionnés au paragraphe (2) dont il a pris connaissance à la suite de l'exercice des attributions que lui confère la présente partie à toute personne ou à tout organisme qui, au titre d'une loi d'un État étranger :

a) soit a des attributions semblables à celles du commissaire en matière de protection de renseignements personnels;

b) soit est chargé de réprimer des comportements essentiellement semblables à ceux qui constituent des contraventions au titre de la présente partie.

Information that can be shared

(2) The information that the Commissioner is authorized to disclose under subsection (1) is information that the Commissioner believes

(a) would be relevant to an ongoing or potential investigation or proceeding in respect of a contravention of the laws of a foreign state that address conduct that is substantially similar to conduct that would be in contravention of this Part; or

(b) is necessary to disclose in order to obtain from the person or body information that may be useful to an ongoing or potential investigation or audit under this Part.

Renseignements

(2) Les renseignements que le commissaire est autorisé à communiquer au titre du paragraphe (1) sont les suivants :

a) ceux qui, selon lui, pourraient être utiles à une enquête ou à une poursuite — en cours ou éventuelle — relative à une contravention à une loi de l'État étranger visant des comportements essentiellement semblables à ceux qui constituent des contraventions au titre de la présente partie;

b) ceux dont il croit que la communication est nécessaire afin d'obtenir de la personne ou de l'organisme des renseignements qui pourraient être utiles à l'examen d'une plainte ou à une vérification — en cours ou éventuelle — au titre de la présente partie.

Written arrangements

(3) The Commissioner may only disclose information to the person or body referred to in subsection (1) if the Commissioner has entered into a written arrangement with that person or body that

Ententes écrites

(3) Le commissaire ne peut communiquer les renseignements à la personne ou à l'organisme visé au paragraphe (1) que s'il a conclu avec la personne ou l'organisme une entente écrite qui, à la fois :

(a) limits the information to be disclosed to that which is necessary for the purpose set out in paragraph (2)(a) or (b);

(b) restricts the use of the information to the purpose for which it was originally shared; and

(c) stipulates that the information be treated in a confidential manner and not be further disclosed without the express consent of the Commissioner.

a) précise que seuls les renseignements nécessaires aux fins prévues aux alinéas (2)a) et b) peuvent être communiqués;

b) précise que les renseignements ne peuvent être utilisés qu'aux fins auxquelles ils ont été communiqués;

c) prévoit que les renseignements seront traités de manière confidentielle et ne seront pas autrement communiqués sans le consentement exprès du commissaire.

Arrangements

(4) The Commissioner may enter into arrangements with one or more persons or bodies referred to in subsection (1) in order to

(a) provide for cooperation with respect to the enforcement of laws protecting personal information, including the sharing of information referred to in subsection (2) and the provision of mechanisms for the handling of any complaint in which they are mutually interested;

(b) establish procedures for sharing information referred to in subsection (2);

(c) develop recommendations, resolutions, rules, standards or other instruments with respect to the protection of personal information;

(d) undertake and publish research related to the protection of personal information;

(e) share knowledge and expertise by different means, including through staff exchanges; or

(f) identify issues of mutual interest and determine priorities pertaining to the protection of personal information.

2010, c. 23, s. 87.

Conclusion d'ententes

(4) Le commissaire peut conclure des ententes avec toute personne ou tout organisme visés au paragraphe (1), ou avec plusieurs d'entre eux, en vue :

a) d'assurer une coopération en matière de contrôle d'application des lois portant sur la protection des renseignements personnels, notamment la communication des renseignements visés au paragraphe (2) et la mise en place de mécanismes pour l'instruction des plaintes dans lesquelles ils ont un intérêt mutuel;

b) d'établir la procédure à suivre pour communiquer les renseignements mentionnés au paragraphe (2);

c) d'élaborer des documents — recommandations, résolutions, règles, normes ou autres — relativement à la protection des renseignements personnels;

d) d'effectuer des recherches en matière de protection des renseignements personnels et d'en publier les résultats;

e) de partager les connaissances et l'expertise, notamment par l'échange de personnel;

f) de préciser des questions d'intérêt commun et de fixer des priorités en matière de protection des renseignements personnels.

2010, ch. 23, art. 87.

Promoting the purposes of the Part

24 The Commissioner shall

(a) develop and conduct information programs to foster public understanding, and recognition of the purposes, of this Part;

(b) undertake and publish research that is related to the protection of personal information, including any such research that is requested by the Minister of Industry;

Promotion de l'objet de la partie

24 Le commissaire :

a) offre au grand public des programmes d'information destinés à lui faire mieux comprendre la présente partie et son objet;

b) fait des recherches liées à la protection des renseignements personnels — et en publie les résultats —, notamment toutes telles recherches que le ministre de l'Industrie demande;

(c) encourage organizations to develop detailed policies and practices, including organizational codes of practice, to comply with Divisions 1 and 1.1; and

(d) promote, by any means that the Commissioner considers appropriate, the purposes of this Part.

2000, c. 5, s. 24; 2015, c. 32, s. 19.

c) encourage les organisations à élaborer des politiques détaillées — notamment des codes de pratiques — en vue de se conformer aux sections 1 et 1.1;

d) prend toute autre mesure indiquée pour la promotion de l'objet de la présente partie.

2000, ch. 5, art. 24; 2015, ch. 32, art. 19.

Annual report

25 (1) The Commissioner shall, within three months after the end of each financial year, submit to Parliament a report concerning the application of this Part, the extent to which the provinces have enacted legislation that is substantially similar to this Part and the application of any such legislation.

Consultation

(2) Before preparing the report, the Commissioner shall consult with those persons in the provinces who, in the Commissioner's opinion, are in a position to assist the Commissioner in making a report respecting personal information that is collected, used or disclosed interprovincially or internationally.

2000, c. 5, s. 25; 2015, c. 32, s. 20.

Rapport annuel

25 (1) Dans les trois mois suivant la fin de chaque exercice, le commissaire dépose devant le Parlement son rapport sur l'application de la présente partie, sur la mesure dans laquelle les provinces ont édicté des lois essentiellement similaires à celle-ci et sur l'application de ces lois.

Consultation

(2) Avant de rédiger son rapport, le commissaire consulte les personnes dans les provinces qui, à son avis, sont en mesure de l'aider à faire un rapport concernant les renseignements personnels recueillis, utilisés ou communiqués d'une province à l'autre ou d'un pays à l'autre.

2000, ch. 5, art. 25; 2015, ch. 32, art. 20.

Regulations

26 (1) The Governor in Council may make regulations for carrying out the purposes and provisions of this Part, including regulations

(a) specifying, by name or by class, what is a government institution or part of a government institution for the purposes of any provision of this Part;

(a.01) [Repealed, 2015, c. 32, s. 21]

(a.1) specifying information or classes of information for the purpose of paragraph 7(1)(d), (2)(c.1) or (3)(h.1);

(b) specifying information to be kept and maintained under subsection 10.3(1); and

(c) prescribing anything that by this Part is to be prescribed.

Règlements

26 (1) Le gouverneur en conseil peut, par règlement, prendre toute mesure d'application de la présente partie, notamment :

a) préciser, pour l'application de toute disposition de la présente partie, les institutions gouvernementales et les subdivisions d'institutions gouvernementales, à titre particulier ou par catégorie;

a.01) [Abrogé, 2015, ch. 32, art. 21]

a.1) préciser tout renseignement ou toute catégorie de renseignements pour l'application des alinéas 7(1)d), (2)c.1) ou (3)h.1);

b) préciser les renseignements qui doivent être tenus et conservés au titre du paragraphe 10.3(1);

c) prendre toute mesure d'ordre réglementaire prévue par la présente partie.

Orders

(2) The Governor in Council may, by order,

(a) provide that this Part is binding on any agent of Her Majesty in right of Canada to which the *Privacy Act* does not apply;

Décret

(2) Il peut par décret :

a) prévoir que la présente partie lie tout mandataire de Sa Majesté du chef du Canada qui n'est pas assujetti à la *Loi sur la protection des renseignements personnels*;

(b) if satisfied that legislation of a province that is substantially similar to this Part applies to an organization, a class of organizations, an activity or a class of activities, exempt the organization, activity or class from the application of this Part in respect of the collection, use or disclosure of personal information that occurs within that province; and

(c) amend Schedule 4.

2000, c. 5, s. 26; 2015, c. 32, s. 21, c. 36, s. 165.

Whistleblowing

27 (1) Any person who has reasonable grounds to believe that a person has contravened or intends to contravene a provision of Division 1 or 1.1 may notify the Commissioner of the particulars of the matter and may request that their identity be kept confidential with respect to the notification.

Confidentiality

(2) The Commissioner shall keep confidential the identity of a person who has notified the Commissioner under subsection (1) and to whom an assurance of confidentiality has been provided by the Commissioner.

2000, c. 5, s. 27; 2015, c. 32, s. 22.

Prohibition

27.1 (1) No employer shall dismiss, suspend, demote, discipline, harass or otherwise disadvantage an employee, or deny an employee a benefit of employment, by reason that

(a) the employee, acting in good faith and on the basis of reasonable belief, has disclosed to the Commissioner that the employer or any other person has contravened or intends to contravene a provision of Division 1 or 1.1;

(b) the employee, acting in good faith and on the basis of reasonable belief, has refused or stated an intention of refusing to do anything that is a contravention of a provision of Division 1 or 1.1;

(c) the employee, acting in good faith and on the basis of reasonable belief, has done or stated an intention of doing anything that is required to be done in order that a provision of Division 1 or 1.1 not be contravened; or

(d) the employer believes that the employee will do anything referred to in paragraph (a), (b) or (c).

b) s'il est convaincu qu'une loi provinciale essentiellement similaire à la présente partie s'applique à une organisation — ou catégorie d'organisations — ou à une activité — ou catégorie d'activités —, exclure l'organisation, l'activité ou la catégorie de l'application de la présente partie à l'égard de la collecte, de l'utilisation ou de la communication de renseignements personnels qui s'effectue à l'intérieur de la province en cause;

c) modifier l'annexe 4.

2000, ch. 5, art. 26; 2015, ch. 32, art. 21, ch. 36, art. 165.

Dénonciation

27 (1) Toute personne qui a des motifs raisonnables de croire qu'une autre personne a contrevenu à l'une des dispositions des sections 1 ou 1.1, ou a l'intention d'y contrevenir, peut notifier au commissaire des détails sur la question et exiger l'anonymat relativement à cette dénonciation.

Caractère confidentiel

(2) Le commissaire est tenu de garder confidentielle l'identité du dénonciateur auquel il donne l'assurance de l'anonymat.

2000, ch. 5, art. 27; 2015, ch. 32, art. 22.

Interdiction

27.1 (1) Il est interdit à l'employeur de congédier un employé, de le suspendre, de le rétrograder, de le punir, de le harceler ou de lui faire subir tout autre inconvénient, ou de le priver d'un avantage lié à son emploi parce que :

a) l'employé, agissant de bonne foi et se fondant sur des motifs raisonnables, a informé le commissaire que l'employeur ou une autre personne a contrevenu à l'une des dispositions des sections 1 ou 1.1, ou a l'intention d'y contrevenir;

b) l'employé, agissant de bonne foi et se fondant sur des motifs raisonnables, a refusé ou a fait part de son intention de refuser d'accomplir un acte qui constitue une contravention à l'une des dispositions des sections 1 ou 1.1;

c) l'employé, agissant de bonne foi et se fondant sur des motifs raisonnables, a accompli ou a fait part de son intention d'accomplir un acte nécessaire pour empêcher la contravention à l'une des dispositions des sections 1 ou 1.1;

d) l'employeur croit que l'employé accomplira un des actes prévus aux alinéas a), b) ou c).

Saving

(2) Nothing in this section impairs any right of an employee either at law or under an employment contract or collective agreement.

Definitions

(3) In this section, ***employee*** includes an independent contractor and ***employer*** has a corresponding meaning.

2000, c. 5, s. 27.1; 2015, c. 32, s. 23.

Offence and punishment

28 Every organization that knowingly contravenes subsection 8(8), section 10.1 or subsection 10.3(1) or 27.1(1) or that obstructs the Commissioner or the Commissioner's delegate in the investigation of a complaint or in conducting an audit is guilty of

(a) an offence punishable on summary conviction and liable to a fine not exceeding $10,000; or

(b) an indictable offence and liable to a fine not exceeding $100,000.

2000, c. 5, s. 28; 2015, c. 32, s. 24.

Review of Part by parliamentary committee

***29 (1)** The administration of this Part shall, every five years after this Part comes into force, be reviewed by the committee of the House of Commons, or of both Houses of Parliament, that may be designated or established by Parliament for that purpose.

* [Note: Part 1 in force January 1, 2001, *see* SI/2000-29.]

Review and report

(2) The committee shall undertake a review of the provisions and operation of this Part and shall, within a year after the review is undertaken or within any further period that the House of Commons may authorize, submit a report to Parliament that includes a statement of any changes to this Part or its administration that the committee recommends.

Précision

(2) Le présent article n'a pas pour effet de restreindre les droits d'un employé, que ce soit en général ou dans le cadre d'un contrat de travail ou d'une convention collective.

Définitions

(3) Dans le présent article, ***employé*** s'entend notamment d'un travailleur autonome et ***employeur*** a un sens correspondant.

2000, ch. 5, art. 27.1; 2015, ch. 32, art. 23.

Infraction et peine

28 Quiconque contrevient sciemment au paragraphe 8(8), à l'article 10.1 ou aux paragraphes 10.3(1) ou 27.1(1) ou entrave l'action du commissaire — ou de son délégué — dans le cadre d'une vérification ou de l'examen d'une plainte commet une infraction et encourt, sur déclaration de culpabilité :

a) par procédure sommaire, une amende maximale de 10 000 $;

b) par mise en accusation, une amende maximale de 100 000 $.

2000, ch. 5, art. 28; 2015, ch. 32, art. 24.

Examen par un comité parlementaire

***29 (1)** Le Parlement désigne ou constitue un comité, soit de la Chambre des communes, soit mixte, chargé spécialement de l'examen, tous les cinq ans suivant l'entrée en vigueur de la présente partie, de l'application de celle-ci.

* [Note : Partie 1 en vigueur le 1er janvier 2001, *voir* TR/2000-29.]

Rapport

(2) Le comité examine les dispositions de la présente partie ainsi que les conséquences de son application en vue de la présentation, dans un délai d'un an à compter du début de l'examen ou tout délai supérieur autorisé par la Chambre des communes, d'un rapport au Parlement où seront consignées ses conclusions ainsi que ses recommandations, s'il y a lieu, quant aux modifications de la présente partie ou de ses modalités d'application qui seraient souhaitables.

DIVISION 5

Transitional Provisions

Application

30 (1) This Part does not apply to any organization in respect of personal information that it collects, uses or discloses within a province whose legislature has the power to regulate the collection, use or disclosure of the information, unless the organization does it in connection with the operation of a federal work, undertaking or business or the organization discloses the information outside the province for consideration.

Application

(1.1) This Part does not apply to any organization in respect of personal health information that it collects, uses or discloses.

Expiry date

***(2)** Subsection (1) ceases to have effect three years after the day on which this section comes into force.

* [Note: Section 30 in force January 1, 2001, *see* SI/2000-29.]

Expiry date

***(2.1)** Subsection (1.1) ceases to have effect one year after the day on which this section comes into force.

* [Note: Section 30 in force January 1, 2001, *see* SI/2000-29.]

SECTION 5

Dispositions transitoires

Application

30 (1) La présente partie ne s'applique pas à une organisation à l'égard des renseignements personnels qu'elle recueille, utilise ou communique dans une province dont la législature a le pouvoir de régir la collecte, l'utilisation ou la communication de tels renseignements, sauf si elle le fait dans le cadre d'une entreprise fédérale ou qu'elle communique ces renseignements pour contrepartie à l'extérieur de cette province.

Application

(1.1) La présente partie ne s'applique pas à une organisation à l'égard des renseignements personnels sur la santé qu'elle recueille, utilise ou communique.

Cessation d'effet

***(2)** Le paragraphe (1) cesse d'avoir effet trois ans après l'entrée en vigueur du présent article.

* [Note : Article 30 en vigueur le 1er janvier 2001, *voir* TR/2000-29.]

Cessation d'effet

***(2.1)** Le paragraphe (1.1) cesse d'avoir effet un an après l'entrée en vigueur du présent article.

* [Note : Article 30 en vigueur le 1er janvier 2001, *voir* TR/2000-29.]

PART 2

Electronic Documents

Interpretation

Definitions

31 (1) The definitions in this subsection apply in this Part.

data means representations of information or concepts, in any form. (*données*)

electronic document means data that is recorded or stored on any medium in or by a computer system or other similar device and that can be read or perceived by a person or a computer system or other similar device. It includes a display, printout or other output of that data. (*document électronique*)

PARTIE 2

Documents électroniques

Définitions

Définitions

31 (1) Les définitions qui suivent s'appliquent à la présente partie.

autorité responsable S'agissant d'une disposition d'un texte législatif, s'entend de ce qui suit :

a) si le texte législatif est une loi fédérale, le ministre responsable de la disposition;

b) si le texte législatif est un texte pris sous le régime d'une loi fédérale ou en vertu d'une prérogative royale, la personne ou l'organisme qui l'a pris;

electronic signature means a signature that consists of one or more letters, characters, numbers or other symbols in digital form incorporated in, attached to or associated with an electronic document. (*signature électronique*)

federal law means an Act of Parliament or an instrument, regardless of its name, issued, made or established under an Act of Parliament or a prerogative of the Crown, other than an instrument issued, made or established under the *Yukon Act*, the *Northwest Territories Act* or the *Nunavut Act*. (*texte législatif*)

responsible authority, in respect of a provision of a federal law, means

(a) if the federal law is an Act of Parliament, the minister responsible for that provision;

(b) if the federal law is an instrument issued, made or established under an Act of Parliament or a prerogative of the Crown, the person or body who issued, made or established the instrument; or

(c) despite paragraph (a) or (b), the person or body designated by the Governor in Council under subsection (2). (*autorité responsable*)

secure electronic signature means an electronic signature that results from the application of a technology or process prescribed by regulations made under subsection 48(1). (*signature électronique sécurisée*)

Designation

(2) The Governor in Council may, by order, for the purposes of this Part, designate any person, including any member of the Queen's Privy Council for Canada, or body to be the responsible authority in respect of a provision of a federal law if the Governor in Council is of the opinion that it is appropriate to do so in the circumstances.

Purpose

Purpose

32 The purpose of this Part is to provide for the use of electronic alternatives in the manner provided for in this Part where federal laws contemplate the use of paper to record or communicate information or transactions.

c) malgré les alinéas a) et b), toute personne ou tout organisme désigné par le gouverneur en conseil en vertu du paragraphe (2). (*responsible authority*)

document électronique Ensemble de données enregistrées ou mises en mémoire sur quelque support que ce soit par un système informatique ou un dispositif semblable et qui peuvent être lues ou perçues par une personne ou par un tel système ou dispositif. Sont également visés tout affichage et toute sortie imprimée ou autre de ces données. (*electronic document*)

données Toute forme de représentation d'informations ou de notions. (*data*)

signature électronique Signature constituée d'une ou de plusieurs lettres, ou d'un ou de plusieurs caractères, nombres ou autres symboles sous forme numérique incorporée, jointe ou associée à un document électronique. (*electronic signature*)

signature électronique sécurisée Signature électronique qui résulte de l'application de toute technologie ou de tout procédé prévu par règlement pris en vertu du paragraphe 48(1). (*secure electronic signature*)

texte législatif Loi fédérale ou tout texte, quelle que soit son appellation, pris sous le régime d'une loi fédérale ou en vertu d'une prérogative royale, à l'exception d'un texte pris sous le régime de la *Loi sur le Yukon*, de la *Loi sur les Territoires du Nord-Ouest* ou de la *Loi sur le Nunavut*. (*federal law*)

Désignation

(2) Le gouverneur en conseil peut par décret, pour l'application de la présente partie, désigner toute personne, notamment un membre du Conseil privé de la Reine pour le Canada, ou tout organisme comme autorité responsable d'une disposition d'un texte législatif, s'il est d'avis que les circonstances le justifient.

Objet

Objet

32 La présente partie a pour objet de prévoir l'utilisation de moyens électroniques, de la manière prévue dans la présente partie, dans les cas où les textes législatifs envisagent l'utilisation d'un support papier pour enregistrer ou communiquer de l'information ou des transactions.

Electronic Alternatives

Collection, storage, etc.

33 A minister of the Crown and any department, branch, office, board, agency, commission, corporation or body for the administration of affairs of which a minister of the Crown is accountable to the Parliament of Canada may use electronic means to create, collect, receive, store, transfer, distribute, publish or otherwise deal with documents or information whenever a federal law does not specify the manner of doing so.

Electronic payment

34 A payment that is required to be made to the Government of Canada may be made in electronic form in any manner specified by the Receiver General.

Electronic version of statutory form

35 (1) If a provision of an Act of Parliament establishes a form, the responsible authority in respect of that provision may make regulations respecting an electronic form that is substantially the same as the form established in the provision, and the electronic form may be used for the same purposes as the form established in the provision.

Statutory manner of filing documents

(2) If a non-electronic manner of filing a document is set out in a provision of an Act of Parliament, the responsible authority in respect of that provision may make regulations respecting the filing of an electronic version of the document, and an electronic version of the document filed in accordance with those regulations is to be considered as a document filed in accordance with the provision.

Statutory manner of submitting information

(3) If a non-electronic manner of submitting information is set out in a provision of an Act of Parliament, the responsible authority in respect of that provision may make regulations respecting the manner of submitting the information using electronic means, and information submitted in accordance with those regulations is to be considered as information submitted in accordance with the provision.

Authority to prescribe form, etc.

(4) The authority under a federal law to issue, prescribe or in any other manner establish a form, or to establish the manner of filing a document or submitting information, includes the authority to issue, prescribe or

Moyens électroniques

Collecte, mise en mémoire, etc.

33 Tout ministre, ministère, direction, bureau, conseil, commission, office, service, personne morale ou autre organisme dont un ministre est responsable devant le Parlement peut faire usage d'un moyen électronique pour créer, recueillir, recevoir, mettre en mémoire, transférer, diffuser, publier ou traiter de quelque autre façon des documents ou de l'information, si aucun moyen particulier n'est prévu à l'égard de ces actes par un texte législatif.

Paiements par voie électronique

34 Tout paiement qui doit être remis au gouvernement du Canada peut être fait sous forme électronique, de la manière que le receveur général précise.

Version électronique des formulaires d'origine législative

35 (1) L'autorité responsable, à l'égard de toute disposition d'une loi fédérale dans laquelle figure un formulaire, peut prendre des règlements prévoyant une version électronique essentiellement semblable, qui peut être utilisée aux mêmes fins que le formulaire figurant dans la disposition.

Mode de dépôt électronique d'origine législative

(2) L'autorité responsable, à l'égard de toute disposition d'une loi fédérale qui prévoit un mode de dépôt non électronique d'un document, peut prendre des règlements prévoyant le dépôt d'une version électronique du document. La version électronique du document déposée conformément à ces règlements est assimilée au document déposé conformément à la disposition.

Mode de transmission de l'information d'origine législative

(3) L'autorité responsable, à l'égard de toute disposition d'une loi fédérale qui prévoit un mode de transmission non électronique de l'information, peut prendre des règlements en prévoyant un mode de transmission électronique. L'information transmise conformément à ces règlements est assimilée à l'information transmise conformément à la disposition.

Pouvoir de prescrire des formulaires

(4) Le pouvoir conféré par un texte législatif de publier, de prescrire ou d'établir un formulaire, ou d'établir un mode de dépôt d'un document ou un mode de transmission de l'information comprend le pouvoir de publier, de

establish an electronic form, or to establish an electronic manner of filing the document or submitting information, as the case may be.

prescrire ou d'établir une version électronique du formulaire, ou d'établir un mode de dépôt électronique du document ou un mode de transmission électronique de l'information, selon le cas.

Meaning of *filing*

(5) In this section, ***filing*** includes all manner of submitting, regardless of how it is designated.

Définition de *dépôt*

(5) Au présent article, est assimilée au dépôt toute forme de transmission, quelle que soit la désignation de celle-ci.

Documents as evidence or proof

36 A provision of a federal law that provides that a certificate or other document signed by a minister or public officer is proof of any matter or thing, or is admissible in evidence, is, subject to the federal law, satisfied by an electronic version of the certificate or other document if the electronic version is signed by the minister or public officer with that person's secure electronic signature.

Preuve par documents

36 La disposition d'un texte législatif qui prévoit qu'un certificat ou autre document portant la signature d'un ministre ou d'un fonctionnaire public fait foi de son contenu et est admissible en preuve vise également, sous réserve du texte législatif, la version électronique du certificat ou autre document si la version électronique porte la signature électronique sécurisée du ministre ou du fonctionnaire public.

Retention of documents

37 A requirement under a provision of a federal law to retain a document for a specified period is satisfied, with respect to an electronic document, by the retention of the electronic document if

(a) the electronic document is retained for the specified period in the format in which it was made, sent or received, or in a format that does not change the information contained in the electronic document that was originally made, sent or received;

(b) the information in the electronic document will be readable or perceivable by any person who is entitled to have access to the electronic document or who is authorized to require the production of the electronic document; and

(c) if the electronic document was sent or received, any information that identifies the origin and destination of the electronic document and the date and time when it was sent or received is also retained.

Conservation des documents

37 Dans le cas où une disposition d'un texte législatif exige la conservation d'un document pour une période déterminée, à l'égard d'un document électronique, la conservation du document électronique satisfait à l'obligation si les conditions suivantes sont réunies :

a) le document électronique est conservé pour la période déterminée sous la forme dans laquelle il a été fait, envoyé ou reçu, ou sous une forme qui ne modifie en rien l'information qu'il contient;

b) cette information sera lisible ou perceptible par quiconque a accès au document électronique et est autorisé à exiger la production de celui-ci;

c) si le document électronique est envoyé ou reçu, l'information qui permet de déterminer son origine et sa destination, ainsi que la date et l'heure d'envoi ou de réception, doit être conservée.

Notarial act

38 A reference in a provision of a federal law to a document recognized as a notarial act in the province of Quebec is deemed to include an electronic version of the document if

(a) the electronic version of the document is recognized as a notarial act under the laws of the province of Quebec; and

(b) the federal law or the provision is listed in Schedule 2 or 3.

Actes notariés

38 La mention, dans une disposition d'un texte législatif, d'un document reconnu dans la province de Québec comme un acte notarié vaut également mention de la version électronique du document si les conditions suivantes sont réunies :

a) la version électronique du document est reconnue par les lois de la province de Québec comme un acte notarié;

b) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3.

Seals

39 A requirement under a provision of a federal law for a person's seal is satisfied by a secure electronic signature that identifies the secure electronic signature as the person's seal if the federal law or the provision is listed in Schedule 2 or 3.

Requirements to provide documents or information

40 A provision of a federal law requiring a person to provide another person with a document or information, other than a provision referred to in any of sections 41 to 47, is satisfied by the provision of the document or information in electronic form if

(a) the federal law or the provision is listed in Schedule 2 or 3;

(b) both persons have agreed to the document or information being provided in electronic form; and

(c) the document or information in electronic form will be under the control of the person to whom it is provided and will be readable or perceivable so as to be usable for subsequent reference.

Writing requirements

41 A requirement under a provision of a federal law for a document to be in writing is satisfied by an electronic document if

(a) the federal law or the provision is listed in Schedule 2 or 3; and

(b) the regulations respecting the application of this section to the provision have been complied with.

Original documents

42 A requirement under a provision of a federal law for a document to be in its original form is satisfied by an electronic document if

(a) the federal law or the provision is listed in Schedule 2 or 3;

(b) the electronic document contains a secure electronic signature that was added when the electronic document was first generated in its final form and that can be used to verify that the electronic document has not been changed since that time; and

Sceaux

39 Dans le cas où une disposition d'un texte législatif exige l'apposition du sceau d'une personne, la signature électronique sécurisée qui s'identifie comme le sceau de cette personne satisfait à l'obligation si la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3.

Obligation de fournir des documents ou de l'information

40 Dans le cas où une disposition d'un texte législatif — à l'exclusion d'une disposition visée aux articles 41 à 47 — exige qu'une personne fournisse à une autre un document ou de l'information, la fourniture du document ou de l'information sous forme électronique satisfait à l'obligation si les conditions suivantes sont réunies :

a) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

b) les intéressés ont convenu de la fourniture du document ou de l'information sous forme électronique;

c) le document ou l'information sous forme électronique sera mis à la disposition exclusive de la personne à qui le document ou l'information est fourni et sera lisible ou perceptible de façon à pouvoir servir à la consultation ultérieure.

Documents sous forme écrite

41 Dans le cas où une disposition d'un texte législatif exige qu'un document soit fait par écrit, un document électronique satisfait à l'obligation si les conditions suivantes sont réunies :

a) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

b) les règlements visant l'application du présent article à la disposition ont été observés.

Documents originaux

42 Dans le cas où une disposition d'un texte législatif exige l'original d'un document, un document électronique satisfait à l'obligation si les conditions suivantes sont réunies :

a) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

b) le document électronique comporte une signature électronique sécurisée, ajoutée lors de la production originale du document électronique dans sa forme définitive, pouvant être utilisée pour établir que le document électronique n'a pas été modifié depuis;

(c) the regulations respecting the application of this section to the provision have been complied with.

Signatures

43 Subject to sections 44 to 46, a requirement under a provision of a federal law for a signature is satisfied by an electronic signature if

(a) the federal law or the provision is listed in Schedule 2 or 3; and

(b) the regulations respecting the application of this section to the provision have been complied with.

Statements made under oath

44 A statement required to be made under oath or solemn affirmation under a provision of a federal law may be made in electronic form if

(a) the person who makes the statement signs it with that person's secure electronic signature;

(b) the person before whom the statement was made, and who is authorized to take statements under oath or solemn affirmation, signs it with that person's secure electronic signature;

(c) the federal law or the provision is listed in Schedule 2 or 3; and

(d) the regulations respecting the application of this section to the provision have been complied with.

Statements declaring truth, etc.

45 A statement required to be made under a provision of a federal law declaring or certifying that any information given by a person making the statement is true, accurate or complete may be made in electronic form if

(a) the person signs it with that person's secure electronic signature;

(b) the federal law or the provision is listed in Schedule 2 or 3; and

(c) the regulations respecting the application of this section to the provision have been complied with.

Witnessed signatures

46 A requirement under a provision of a federal law for a signature to be witnessed is satisfied with respect to an electronic document if

c) les règlements visant l'application du présent article à la disposition ont été observés.

Signatures

43 Sous réserve des articles 44 à 46, dans le cas où une disposition d'un texte législatif exige une signature, la signature électronique satisfait à l'obligation si les conditions suivantes sont réunies :

a) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

b) les règlements visant l'application du présent article à la disposition ont été observés.

Déclarations sous serment

44 Dans le cas où une disposition d'un texte législatif exige une déclaration sous serment ou une affirmation solennelle, celle-ci peut être faite sous forme électronique si les conditions suivantes sont réunies :

a) l'auteur appose à la déclaration ou à l'affirmation sa signature électronique sécurisée;

b) le commissaire aux serments devant qui a été faite la déclaration ou l'affirmation appose à celle-ci sa signature électronique sécurisée;

c) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

d) les règlements visant l'application du présent article à la disposition ont été observés.

Déclarations

45 Dans le cas où une disposition d'un texte législatif exige une déclaration attestant la véracité, l'exactitude ou l'intégralité d'une information fournie par le déclarant, la déclaration peut être faite sous forme électronique si les conditions suivantes sont réunies :

a) le déclarant y appose sa signature électronique sécurisée;

b) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

c) les règlements visant l'application du présent article à la disposition ont été observés.

Signatures devant témoin

46 Dans le cas où une disposition d'un texte législatif exige la signature d'un témoin, un document électronique satisfait à l'obligation si les conditions suivantes sont réunies :

(a) each signatory and each witness signs the electronic document with their secure electronic signature;

(b) the federal law or the provision is listed in Schedule 2 or 3; and

(c) the regulations respecting the application of this section to the provision have been complied with.

Copies

47 A requirement under a provision of a federal law for one or more copies of a document to be submitted is satisfied by the submission of an electronic document if

(a) the federal law or the provision is listed in Schedule 2 or 3; and

(b) the regulations respecting the application of this section to the provision have been complied with.

Regulations and Orders

Regulations

48 (1) Subject to subsection (2), the Governor in Council may, on the recommendation of the Treasury Board, make regulations prescribing technologies or processes for the purpose of the definition ***secure electronic signature*** in subsection 31(1).

Characteristics

(2) The Governor in Council may prescribe a technology or process only if the Governor in Council is satisfied that it can be proved that

(a) the electronic signature resulting from the use by a person of the technology or process is unique to the person;

(b) the use of the technology or process by a person to incorporate, attach or associate the person's electronic signature to an electronic document is under the sole control of the person;

(c) the technology or process can be used to identify the person using the technology or process; and

(d) the electronic signature can be linked with an electronic document in such a way that it can be used to determine whether the electronic document has been changed since the electronic signature was incorporated in, attached to or associated with the electronic document.

a) chacun des signataires et témoins appose au document électronique sa signature électronique sécurisée;

b) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

c) les règlements visant l'application du présent article à la disposition ont été observés.

Exemplaires

47 Dans le cas où une disposition d'un texte législatif exige la transmission d'un ou de plusieurs exemplaires d'un document, la transmission d'un document électronique satisfait à l'obligation si les conditions suivantes sont réunies :

a) la disposition ou le texte législatif est inscrit sur la liste figurant à l'annexe 2 ou 3;

b) les règlements visant l'application du présent article à la disposition ont été observés.

Règlements et décrets

Règlements

48 (1) Sous réserve du paragraphe (2), le gouverneur en conseil peut, sur recommandation du Conseil du Trésor, prendre des règlements pour prévoir des technologies ou des procédés pour l'application de la définition de ***signature électronique sécurisée*** au paragraphe 31(1).

Critères

(2) Le gouverneur en conseil ne peut prévoir une technologie ou un procédé que s'il est convaincu qu'il peut être établi ce qui suit :

a) la signature électronique résultant de l'utilisation de la technologie ou du procédé est propre à l'utilisateur;

b) l'utilisation de la technologie ou du procédé pour l'incorporation, l'adjonction ou l'association de la signature électronique de l'utilisateur au document électronique se fait sous la seule responsabilité de ce dernier;

c) la technologie ou le procédé permet d'identifier l'utilisateur;

d) la signature électronique peut être liée au document électronique de façon à permettre de vérifier si le document a été modifié depuis que la signature électronique a été incorporée, jointe ou associée au document.

Effect of amendment or repeal

(3) An amendment to or repeal of any provision of a regulation made under subsection (1) that has the effect of removing a prescribed technology or process from the regulation does not, by itself, affect the validity of any electronic signature resulting from the use of that technology or process while it was prescribed.

Amendment of schedules

49 For the purposes of sections 38 to 47, the responsible authority in respect of a provision of a federal law may, by order, amend Schedule 2 or 3 by adding or striking out a reference to that federal law or provision.

Regulations

50 (1) For the purposes of sections 41 to 47, the responsible authority in respect of a provision of a federal law may make regulations respecting the application of those sections to the provision.

Contents

(2) Without restricting the generality of subsection (1), the regulations that may be made may include rules respecting any of the following:

(a) the technology or process that must be used to make or send an electronic document;

(b) the format of an electronic document;

(c) the place where an electronic document is to be made or sent;

(d) the time and circumstances when an electronic document is to be considered to be sent or received and the place where it is considered to have been sent or received;

(e) the technology or process to be used to make or verify an electronic signature and the manner in which it is to be used; and

(f) any matter necessary for the purposes of the application of sections 41 to 47.

Minimum rules

(3) Without restricting the generality of subsection (1), if a provision referred to in any of sections 41 to 47 requires a person to provide another person with a document or information, the rules set out in the regulations respecting the application of that section to the provision may be that

Effet d'une disposition modifiée ou abrogée

(3) La modification ou l'abrogation d'une disposition d'un règlement pris en vertu du paragraphe (1) qui a pour effet de supprimer une technologie ou un procédé du règlement n'a pas pour effet d'invalider la signature électronique résultant de l'utilisation de la technologie ou du procédé qui était mentionné dans le règlement.

Modification des annexes

49 Pour l'application des articles 38 à 47, l'autorité responsable, à l'égard d'une disposition d'un texte législatif, peut par décret modifier l'annexe 2 ou 3 par adjonction ou suppression de la mention du texte législatif ou de la disposition.

Règlements

50 (1) Pour l'application des articles 41 à 47, l'autorité responsable, à l'égard d'une disposition d'un texte législatif, peut prendre des règlements visant l'application de ces articles à la disposition.

Contenu

(2) Sans que soit limitée la portée générale du paragraphe (1), les règlements qui y sont prévus peuvent comprendre des règles visant notamment :

a) la technologie ou le procédé à utiliser pour faire ou envoyer le document électronique;

b) le format du document électronique;

c) le lieu où le document électronique est fait ou envoyé;

d) les délais et les circonstances dans lesquels le document électronique est présumé avoir été envoyé ou reçu, ainsi que le lieu où le document est présumé avoir été envoyé ou reçu;

e) la technologie ou le procédé à utiliser pour faire ou vérifier une signature électronique et la manière d'utiliser cette signature;

f) tout ce qui est utile à l'application des articles 41 à 47.

Règles minimales

(3) Sans que soit limitée la portée générale du paragraphe (1), si une disposition visée à l'un des articles 41 à 47 exige qu'une personne fournisse à une autre un document ou une information, les règles établies dans les règlements visant l'application de cet article à la disposition peuvent exiger que :

(a) both persons have agreed to the document or information being provided in electronic form; and

(b) the document or information in electronic form will be under the control of the person to whom it is provided and will be readable or perceivable so as to be usable for subsequent reference.

a) les intéressés aient convenu de la fourniture du document ou de l'information sous forme électronique;

b) le document ou l'information sous forme électronique soit mis à la disposition de la personne à qui le document ou l'information est fourni et soit lisible ou perceptible de façon à pouvoir servir à la consultation ultérieure.

Incorporation by reference

(4) Regulations may incorporate by reference the standards or specifications of any government, person or organization, either as they read at a fixed time or as they are amended from time to time.

Incorporation par renvoi

(4) Les règlements peuvent incorporer par renvoi une version déterminée dans le temps ou la dernière version modifiée des normes ou spécifications adoptées par des personnes physiques ou morales, de droit privé ou de droit public.

Effect of striking out listed provision

51 The striking out of a reference to a federal law or provision in Schedule 2 or 3 does not affect the validity of anything done in compliance with any regulation made under section 50 that relates to that federal law or provision while it was listed in that Schedule.

Effet d'une disposition supprimée de la liste

51 La suppression de l'inscription d'une disposition ou d'un texte législatif sur la liste figurant à l'annexe 2 ou 3 n'a pas pour effet d'invalider un acte accompli conformément aux règlements relatifs à cette disposition ou à ce texte législatif, pris en vertu de l'article 50, alors que la disposition ou le texte était inscrit sur la liste figurant à l'annexe.

PART 3

Amendments to the Canada Evidence Act

52 to 57 [Amendments]

PARTIE 3

Modification de la Loi sur la preuve au Canada

52 à 57 [Modifications]

PART 4

Amendments to the Statutory Instruments Act

58 and 59 [Amendments]

PARTIE 4

Modification de la Loi sur les textes réglementaires

58 et 59 [Modifications]

PART 5

Amendments to the Statute Revision Act

60 to 71 [Amendments]

PARTIE 5

Modification de la Loi sur la révision des lois

60 à 71 [Modifications]

PART 6

Coming into Force

Coming into force

***72 Parts 1 to 5 or any provision of those Parts come into force on a day or days to be fixed by order of the Governor in Council made on the recommendation of**

(a) in the case of Parts 1 and 2 or any provision of those Parts, the Minister of Industry; and

(b) in the case of Parts 3 to 5 or any provision of those Parts, the Minister of Justice.

*** [Note: Parts 2, 3 and 4 in force May 1, 2000; Part 1 in force January 1, 2001, *see* SI/2000-29; Part 5 in force June 1, 2009, *see* SI/2009-42.]**

PARTIE 6

Entrée en vigueur

Entrée en vigueur

***72 Les parties 1 à 5 ou telle de leurs dispositions entrent en vigueur à la date ou aux dates fixées par décret, sur la recommandation :**

a) dans le cas des parties 1 et 2 ou de telle de leurs dispositions, du ministre de l'Industrie;

b) dans le cas des parties 3 à 5 ou de telle de leurs dispositions, du ministre de la Justice.

*** [Note : Parties 2, 3 et 4 en vigueur le 1er mai 2000; partie 1 en vigueur le 1er janvier 2001, *voir* TR/2000-29; partie 5 en vigueur le 1er juin 2009, *voir* TR/2009-42.]**

SCHEDULE 1

(Section 5)

Principles Set Out in the National Standard of Canada Entitled Model Code for the Protection of Personal Information, CAN/CSA-Q830-96

4.1 Principle 1 — Accountability

An organization is responsible for personal information under its control and shall designate an individual or individuals who are accountable for the organization's compliance with the following principles.

4.1.1

Accountability for the organization's compliance with the principles rests with the designated individual(s), even though other individuals within the organization may be responsible for the day-to-day collection and processing of personal information. In addition, other individuals within the organization may be delegated to act on behalf of the designated individual(s).

4.1.2

The identity of the individual(s) designated by the organization to oversee the organization's compliance with the principles shall be made known upon request.

4.1.3

An organization is responsible for personal information in its possession or custody, including information that has been transferred to a third party for processing. The organization shall use contractual or other means to provide a comparable level of protection while the information is being processed by a third party.

4.1.4

Organizations shall implement policies and practices to give effect to the principles, including

(a) implementing procedures to protect personal information;

(b) establishing procedures to receive and respond to complaints and inquiries;

(c) training staff and communicating to staff information about the organization's policies and practices; and

(d) developing information to explain the organization's policies and procedures.

ANNEXE 1

(article 5)

Principes énoncés dans la norme nationale du Canada intitulée Code type sur la protection des renseignements personnels, CAN/CSA-Q830-96

4.1 Premier principe — Responsabilité

Une organisation est responsable des renseignements personnels dont elle a la gestion et doit désigner une ou des personnes qui devront s'assurer du respect des principes énoncés ci-dessous.

4.1.1

Il incombe à la ou aux personnes désignées de s'assurer que l'organisation respecte les principes même si d'autres membres de l'organisation peuvent être chargés de la collecte et du traitement quotidiens des renseignements personnels. D'autres membres de l'organisation peuvent aussi être délégués pour agir au nom de la ou des personnes désignées.

4.1.2

Il doit être possible de connaître sur demande l'identité des personnes que l'organisation a désignées pour s'assurer que les principes sont respectés.

4.1.3

Une organisation est responsable des renseignements personnels qu'elle a en sa possession ou sous sa garde, y compris les renseignements confiés à une tierce partie aux fins de traitement. L'organisation doit, par voie contractuelle ou autre, fournir un degré comparable de protection aux renseignements qui sont en cours de traitement par une tierce partie.

4.1.4

Les organisations doivent assurer la mise en œuvre des politiques et des pratiques destinées à donner suite aux principes, y compris :

a) la mise en œuvre des procédures pour protéger les renseignements personnels;

b) la mise en place des procédures pour recevoir les plaintes et les demandes de renseignements et y donner suite;

c) la formation du personnel et la transmission au personnel de l'information relative aux politiques et pratiques de l'organisation; et

d) la rédaction des documents explicatifs concernant leurs politiques et procédures.

4.2 Principle 2 — Identifying Purposes

The purposes for which personal information is collected shall be identified by the organization at or before the time the information is collected.

4.2.1

The organization shall document the purposes for which personal information is collected in order to comply with the Openness principle (Clause 4.8) and the Individual Access principle (Clause 4.9).

4.2.2

Identifying the purposes for which personal information is collected at or before the time of collection allows organizations to determine the information they need to collect to fulfil these purposes. The Limiting Collection principle (Clause 4.4) requires an organization to collect only that information necessary for the purposes that have been identified.

4.2.3

The identified purposes should be specified at or before the time of collection to the individual from whom the personal information is collected. Depending upon the way in which the information is collected, this can be done orally or in writing. An application form, for example, may give notice of the purposes.

4.2.4

When personal information that has been collected is to be used for a purpose not previously identified, the new purpose shall be identified prior to use. Unless the new purpose is required by law, the consent of the individual is required before information can be used for that purpose. For an elaboration on consent, please refer to the Consent principle (Clause 4.3).

4.2.5

Persons collecting personal information should be able to explain to individuals the purposes for which the information is being collected.

4.2.6

This principle is linked closely to the Limiting Collection principle (Clause 4.4) and the Limiting Use, Disclosure, and Retention principle (Clause 4.5).

4.3 Principle 3 - Consent

The knowledge and consent of the individual are required for the collection, use, or disclosure of personal information, except where inappropriate.

Note: In certain circumstances personal information can be collected, used, or disclosed without the knowledge and consent of the individual. For example, legal, medical, or security reasons may make it impossible or impractical to seek consent. When information is being collected for the

4.2 Deuxième principe — Détermination des fins de la collecte des renseignements

Les fins auxquelles des renseignements personnels sont recueillis doivent être déterminées par l'organisation avant la collecte ou au moment de celle-ci.

4.2.1

L'organisation doit documenter les fins auxquelles les renseignements personnels sont recueillis afin de se conformer au principe de la transparence (article 4.8) et au principe de l'accès aux renseignements personnels (article 4.9).

4.2.2

Le fait de préciser les fins de la collecte de renseignements personnels avant celle-ci ou au moment de celle-ci permet à l'organisation de déterminer les renseignements dont elle a besoin pour réaliser les fins mentionnées. Suivant le principe de la limitation en matière de collecte (article 4.4), l'organisation ne doit recueillir que les renseignements nécessaires aux fins mentionnées.

4.2.3

Il faudrait préciser à la personne auprès de laquelle on recueille des renseignements, avant la collecte ou au moment de celle-ci, les fins auxquelles ils sont destinés. Selon la façon dont se fait la collecte, cette précision peut être communiquée de vive voix ou par écrit. Par exemple, on peut indiquer ces fins sur un formulaire de demande de renseignements.

4.2.4

Avant de se servir de renseignements personnels à des fins non précisées antérieurement, les nouvelles fins doivent être précisées avant l'utilisation. À moins que les nouvelles fins auxquelles les renseignements sont destinés ne soient prévues par une loi, il faut obtenir le consentement de la personne concernée avant d'utiliser les renseignements à cette nouvelle fin. Pour obtenir plus de précisions sur le consentement, se reporter au principe du consentement (article 4.3).

4.2.5

Les personnes qui recueillent des renseignements personnels devraient être en mesure d'expliquer à la personne concernée à quelles fins sont destinés ces renseignements.

4.2.6

Ce principe est étroitement lié au principe de la limitation de la collecte (article 4.4) et à celui de la limitation de l'utilisation, de la communication et de la conservation (article 4.5).

4.3 Troisième principe — Consentement

Toute personne doit être informée de toute collecte, utilisation ou communication de renseignements personnels qui la concernent et y consentir, à moins qu'il ne soit pas approprié de le faire.

Note : Dans certaines circonstances, il est possible de recueillir, d'utiliser et de communiquer des renseignements à

detection and prevention of fraud or for law enforcement, seeking the consent of the individual might defeat the purpose of collecting the information. Seeking consent may be impossible or inappropriate when the individual is a minor, seriously ill, or mentally incapacitated. In addition, organizations that do not have a direct relationship with the individual may not always be able to seek consent. For example, seeking consent may be impractical for a charity or a direct-marketing firm that wishes to acquire a mailing list from another organization. In such cases, the organization providing the list would be expected to obtain consent before disclosing personal information.

4.3.1

Consent is required for the collection of personal information and the subsequent use or disclosure of this information. Typically, an organization will seek consent for the use or disclosure of the information at the time of collection. In certain circumstances, consent with respect to use or disclosure may be sought after the information has been collected but before use (for example, when an organization wants to use information for a purpose not previously identified).

4.3.2

The principle requires "knowledge and consent". Organizations shall make a reasonable effort to ensure that the individual is advised of the purposes for which the information will be used. To make the consent meaningful, the purposes must be stated in such a manner that the individual can reasonably understand how the information will be used or disclosed.

4.3.3

An organization shall not, as a condition of the supply of a product or service, require an individual to consent to the collection, use, or disclosure of information beyond that required to fulfil the explicitly specified, and legitimate purposes.

4.3.4

The form of the consent sought by the organization may vary, depending upon the circumstances and the type of information. In determining the form of consent to use, organizations shall take into account the sensitivity of the information. Although some information (for example, medical records and income records) is almost always considered to be sensitive, any information can be sensitive, depending on the context. For example, the names and addresses of subscribers to a newsmagazine would generally not be considered sensitive information. However, the names and addresses of

l'insu de la personne concernée et sans son consentement. Par exemple, pour des raisons d'ordre juridique ou médical ou pour des raisons de sécurité, il peut être impossible ou peu réaliste d'obtenir le consentement de la personne concernée. Lorsqu'on recueille des renseignements aux fins du contrôle d'application de la loi, de la détection d'une fraude ou de sa prévention, on peut aller à l'encontre du but visé si l'on cherche à obtenir le consentement de la personne concernée. Il peut être impossible ou inopportun de chercher à obtenir le consentement d'un mineur, d'une personne gravement malade ou souffrant d'incapacité mentale. De plus, les organisations qui ne sont pas en relation directe avec la personne concernée ne sont pas toujours en mesure d'obtenir le consentement prévu. Par exemple, il peut être peu réaliste pour une œuvre de bienfaisance ou une entreprise de marketing direct souhaitant acquérir une liste d'envoi d'une autre organisation de chercher à obtenir le consentement des personnes concernées. On s'attendrait, dans de tels cas, à ce que l'organisation qui fournit la liste obtienne le consentement des personnes concernées avant de communiquer des renseignements personnels.

4.3.1

Il faut obtenir le consentement de la personne concernée avant de recueillir des renseignements personnels à son sujet et d'utiliser ou de communiquer les renseignements recueillis. Généralement, une organisation obtient le consentement des personnes concernées relativement à l'utilisation et à la communication des renseignements personnels au moment de la collecte. Dans certains cas, une organisation peut obtenir le consentement concernant l'utilisation ou la communication des renseignements après avoir recueilli ces renseignements, mais avant de s'en servir, par exemple, quand elle veut les utiliser à des fins non précisées antérieurement.

4.3.2

Suivant ce principe, il faut informer la personne au sujet de laquelle on recueille des renseignements et obtenir son consentement. Les organisations doivent faire un effort raisonnable pour s'assurer que la personne est informée des fins auxquelles les renseignements seront utilisés. Pour que le consentement soit valable, les fins doivent être énoncées de façon que la personne puisse raisonnablement comprendre de quelle manière les renseignements seront utilisés ou communiqués.

4.3.3

Une organisation ne peut pas, pour le motif qu'elle fournit un bien ou un service, exiger d'une personne qu'elle consente à la collecte, à l'utilisation ou à la communication de renseignements autres que ceux qui sont nécessaires pour réaliser les fins légitimes et explicitement indiquées.

4.3.4

La forme du consentement que l'organisation cherche à obtenir peut varier selon les circonstances et la nature des renseignements. Pour déterminer la forme que prendra le consentement, les organisations doivent tenir compte de la sensibilité des renseignements. Si certains renseignements sont presque toujours considérés comme sensibles, par exemple les dossiers médicaux et le revenu, tous les renseignements peuvent devenir sensibles suivant le contexte. Par exemple, les nom et adresse des abonnés d'une revue d'information ne seront généralement pas considérés comme des renseignements

subscribers to some special-interest magazines might be considered sensitive.

4.3.5

In obtaining consent, the reasonable expectations of the individual are also relevant. For example, an individual buying a subscription to a magazine should reasonably expect that the organization, in addition to using the individual's name and address for mailing and billing purposes, would also contact the person to solicit the renewal of the subscription. In this case, the organization can assume that the individual's request constitutes consent for specific purposes. On the other hand, an individual would not reasonably expect that personal information given to a health-care professional would be given to a company selling health-care products, unless consent were obtained. Consent shall not be obtained through deception.

4.3.6

The way in which an organization seeks consent may vary, depending on the circumstances and the type of information collected. An organization should generally seek express consent when the information is likely to be considered sensitive. Implied consent would generally be appropriate when the information is less sensitive. Consent can also be given by an authorized representative (such as a legal guardian or a person having power of attorney).

4.3.7

Individuals can give consent in many ways. For example:

(a) an application form may be used to seek consent, collect information, and inform the individual of the use that will be made of the information. By completing and signing the form, the individual is giving consent to the collection and the specified uses;

(b) a checkoff box may be used to allow individuals to request that their names and addresses not be given to other organizations. Individuals who do not check the box are assumed to consent to the transfer of this information to third parties;

(c) consent may be given orally when information is collected over the telephone; or

(d) consent may be given at the time that individuals use a product or service.

4.3.8

An individual may withdraw consent at any time, subject to legal or contractual restrictions and reasonable notice. The organization shall inform the individual of the implications of such withdrawal.

sensibles. Toutefois, les nom et adresse des abonnés de certains périodiques spécialisés pourront l'être.

4.3.5

Dans l'obtention du consentement, les attentes raisonnables de la personne sont aussi pertinentes. Par exemple, une personne qui s'abonne à un périodique devrait raisonnablement s'attendre à ce que l'entreprise, en plus de se servir de son nom et de son adresse à des fins de postage et de facturation, communique avec elle pour lui demander si elle désire que son abonnement soit renouvelé. Dans ce cas, l'organisation peut présumer que la demande de la personne constitue un consentement à ces fins précises. D'un autre côté, il n'est pas raisonnable qu'une personne s'attende à ce que les renseignements personnels qu'elle fournit à un professionnel de la santé soient donnés sans son consentement à une entreprise qui vend des produits de soins de santé. Le consentement ne doit pas être obtenu par un subterfuge.

4.3.6

La façon dont une organisation obtient le consentement peut varier selon les circonstances et la nature des renseignements recueillis. En général, l'organisation devrait chercher à obtenir un consentement explicite si les renseignements sont susceptibles d'être considérés comme sensibles. Lorsque les renseignements sont moins sensibles, un consentement implicite serait normalement jugé suffisant. Le consentement peut également être donné par un représentant autorisé (détenteur d'une procuration, tuteur).

4.3.7

Le consentement peut revêtir différentes formes, par exemple :

a) on peut se servir d'un formulaire de demande de renseignements pour obtenir le consentement, recueillir des renseignements et informer la personne de l'utilisation qui sera faite des renseignements. En remplissant le formulaire et en le signant, la personne donne son consentement à la collecte de renseignements et aux usages précisés;

b) on peut prévoir une case où la personne pourra indiquer en cochant qu'elle refuse que ses nom et adresse soient communiqués à d'autres organisations. Si la personne ne coche pas la case, il sera présumé qu'elle consent à ce que les renseignements soient communiqués à des tiers;

c) le consentement peut être donné de vive voix lorsque les renseignements sont recueillis par téléphone; ou

d) le consentement peut être donné au moment où le produit ou le service est utilisé.

4.3.8

Une personne peut retirer son consentement en tout temps, sous réserve de restrictions prévues par une loi ou un contrat et d'un préavis raisonnable. L'organisation doit informer la personne des conséquences d'un tel retrait.

4.4 Principle 4 — Limiting Collection

The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means.

4.4.1

Organizations shall not collect personal information indiscriminately. Both the amount and the type of information collected shall be limited to that which is necessary to fulfil the purposes identified. Organizations shall specify the type of information collected as part of their information-handling policies and practices, in accordance with the Openness principle (Clause 4.8).

4.4.2

The requirement that personal information be collected by fair and lawful means is intended to prevent organizations from collecting information by misleading or deceiving individuals about the purpose for which information is being collected. This requirement implies that consent with respect to collection must not be obtained through deception.

4.4.3

This principle is linked closely to the Identifying Purposes principle (Clause 4.2) and the Consent principle (Clause 4.3).

4.5 Principle 5 —Limiting Use, Disclosure, and Retention

Personal information shall not be used or disclosed for purposes other than those for which it was collected, except with the consent of the individual or as required by law. Personal information shall be retained only as long as necessary for the fulfilment of those purposes.

4.5.1

Organizations using personal information for a new purpose shall document this purpose (see Clause 4.2.1).

4.5.2

Organizations should develop guidelines and implement procedures with respect to the retention of personal information. These guidelines should include minimum and maximum retention periods. Personal information that has been used to make a decision about an individual shall be retained long enough to allow the individual access to the information after the decision has been made. An organization may be subject to legislative requirements with respect to retention periods.

4.4 Quatrième principe — Limitation de la collecte

L'organisation ne peut recueillir que les renseignements personnels nécessaires aux fins déterminées et doit procéder de façon honnête et licite.

4.4.1

Les organisations ne doivent pas recueillir des renseignements de façon arbitraire. On doit restreindre tant la quantité que la nature des renseignements recueillis à ce qui est nécessaire pour réaliser les fins déterminées. Conformément au principe de la transparence (article 4.8), les organisations doivent préciser la nature des renseignements recueillis comme partie intégrante de leurs politiques et pratiques concernant le traitement des renseignements.

4.4.2

L'exigence selon laquelle les organisations sont tenues de recueillir des renseignements personnels de façon honnête et licite a pour objet de les empêcher de tromper les gens et de les induire en erreur quant aux fins auxquelles les renseignements sont recueillis. Cette obligation suppose que le consentement à la collecte de renseignements ne doit pas être obtenu par un subterfuge.

4.4.3

Ce principe est étroitement lié au principe de détermination des fins auxquelles la collecte est destinée (article 4.2) et à celui du consentement (article 4.3).

4.5 Cinquième principe — Limitation de l'utilisation, de la communication et de la conservation

Les renseignements personnels ne doivent pas être utilisés ou communiqués à des fins autres que celles auxquelles ils ont été recueillis à moins que la personne concernée n'y consente ou que la loi ne l'exige. On ne doit conserver les renseignements personnels qu'aussi longtemps que nécessaire pour la réalisation des fins déterminées.

4.5.1

Les organisations qui se servent de renseignements personnels à des fins nouvelles doivent documenter ces fins (voir article 4.2.1).

4.5.2

Les organisations devraient élaborer des lignes directrices et appliquer des procédures pour la conservation des renseignements personnels. Ces lignes directrices devraient préciser les durées minimales et maximales de conservation. On doit conserver les renseignements personnels servant à prendre une décision au sujet d'une personne suffisamment longtemps pour permettre à la personne concernée d'exercer son droit d'accès à l'information après que la décision a été prise. Une organisation peut être assujettie à des exigences prévues par la loi en ce qui concerne les périodes de conservation.

4.5.3

Personal information that is no longer required to fulfil the identified purposes should be destroyed, erased, or made anonymous. Organizations shall develop guidelines and implement procedures to govern the destruction of personal information.

4.5.4

This principle is closely linked to the Consent principle (Clause 4.3), the Identifying Purposes principle (Clause 4.2), and the Individual Access principle (Clause 4.9).

4.6 Principle 6 — Accuracy

Personal information shall be as accurate, complete, and up-to-date as is necessary for the purposes for which it is to be used.

4.6.1

The extent to which personal information shall be accurate, complete, and up-to-date will depend upon the use of the information, taking into account the interests of the individual. Information shall be sufficiently accurate, complete, and up-to-date to minimize the possibility that inappropriate information may be used to make a decision about the individual.

4.6.2

An organization shall not routinely update personal information, unless such a process is necessary to fulfil the purposes for which the information was collected.

4.6.3

Personal information that is used on an ongoing basis, including information that is disclosed to third parties, should generally be accurate and up-to-date, unless limits to the requirement for accuracy are clearly set out.

4.7 Principle 7 — Safeguards

Personal information shall be protected by security safeguards appropriate to the sensitivity of the information.

4.7.1

The security safeguards shall protect personal information against loss or theft, as well as unauthorized access, disclosure, copying, use, or modification. Organizations shall protect personal information regardless of the format in which it is held.

4.7.2

The nature of the safeguards will vary depending on the sensitivity of the information that has been collected, the amount, distribution, and format of the information, and the method of storage. More sensitive information should be

4.5.3

On devrait détruire, effacer ou dépersonnaliser les renseignements personnels dont on n'a plus besoin aux fins précisées. Les organisations doivent élaborer des lignes directrices et appliquer des procédures régissant la destruction des renseignements personnels.

4.5.4

Ce principe est étroitement lié au principe du consentement (article 4.3), à celui de la détermination des fins auxquelles la collecte est destinée (article 4.2), ainsi qu'à celui de l'accès individuel (article 4.9).

4.6 Sixième principe — Exactitude

Les renseignements personnels doivent être aussi exacts, complets et à jour que l'exigent les fins auxquelles ils sont destinés.

4.6.1

Le degré d'exactitude et de mise à jour ainsi que le caractère complet des renseignements personnels dépendront de l'usage auquel ils sont destinés, compte tenu des intérêts de la personne. Les renseignements doivent être suffisamment exacts, complets et à jour pour réduire au minimum la possibilité que des renseignements inappropriés soient utilisés pour prendre une décision à son sujet.

4.6.2

Une organisation ne doit pas systématiquement mettre à jour les renseignements personnels à moins que cela ne soit nécessaire pour atteindre les fins auxquelles ils ont été recueillis.

4.6.3

Les renseignements personnels qui servent en permanence, y compris les renseignements qui sont communiqués à des tiers, devraient normalement être exacts et à jour à moins que des limites se rapportant à l'exactitude de ces renseignements ne soient clairement établies.

4.7 Septième principe — Mesures de sécurité

Les renseignements personnels doivent être protégés au moyen de mesures de sécurité correspondant à leur degré de sensibilité.

4.7.1

Les mesures de sécurité doivent protéger les renseignements personnels contre la perte ou le vol ainsi que contre la consultation, la communication, la copie, l'utilisation ou la modification non autorisées. Les organisations doivent protéger les renseignements personnels quelle que soit la forme sous laquelle ils sont conservés.

4.7.2

La nature des mesures de sécurité variera en fonction du degré de sensibilité des renseignements personnels recueillis, de la quantité, de la répartition et du format des renseignements personnels ainsi que des méthodes de conservation. Les

safeguarded by a higher level of protection. The concept of sensitivity is discussed in Clause 4.3.4.

4.7.3

The methods of protection should include

(a) physical measures, for example, locked filing cabinets and restricted access to offices;

(b) organizational measures, for example, security clearances and limiting access on a "need-to-know" basis; and

(c) technological measures, for example, the use of passwords and encryption.

4.7.4

Organizations shall make their employees aware of the importance of maintaining the confidentiality of personal information.

4.7.5

Care shall be used in the disposal or destruction of personal information, to prevent unauthorized parties from gaining access to the information (see Clause 4.5.3).

4.8 Principle 8 — Openness

An organization shall make readily available to individuals specific information about its policies and practices relating to the management of personal information.

4.8.1

Organizations shall be open about their policies and practices with respect to the management of personal information. Individuals shall be able to acquire information about an organization's policies and practices without unreasonable effort. This information shall be made available in a form that is generally understandable.

4.8.2

The information made available shall include

(a) the name or title, and the address, of the person who is accountable for the organization's policies and practices and to whom complaints or inquiries can be forwarded;

(b) the means of gaining access to personal information held by the organization;

(c) a description of the type of personal information held by the organization, including a general account of its use;

(d) a copy of any brochures or other information that explain the organization's policies, standards, or codes; and

(e) what personal information is made available to related organizations (e.g., subsidiaries).

renseignements plus sensibles devraient être mieux protégés. La notion de sensibilité est présentée à l'article 4.3.4.

4.7.3

Les méthodes de protection devraient comprendre :

a) des moyens matériels, par exemple le verrouillage des classeurs et la restriction de l'accès aux bureaux;

b) des mesures administratives, par exemple des autorisations sécuritaires et un accès sélectif; et

c) des mesures techniques, par exemple l'usage de mots de passe et du chiffrement.

4.7.4

Les organisations doivent sensibiliser leur personnel à l'importance de protéger le caractère confidentiel des renseignements personnels.

4.7.5

Au moment du retrait ou de la destruction des renseignements personnels, on doit veiller à empêcher les personnes non autorisées d'y avoir accès (article 4.5.3).

4.8 Huitième principe — Transparence

Une organisation doit faire en sorte que des renseignements précis sur ses politiques et ses pratiques concernant la gestion des renseignements personnels soient facilement accessibles à toute personne.

4.8.1

Les organisations doivent faire preuve de transparence au sujet de leurs politiques et pratiques concernant la gestion des renseignements personnels. Une personne doit pouvoir obtenir sans efforts déraisonnables de l'information au sujet des politiques et des pratiques d'une organisation. Ces renseignements doivent être fournis sous une forme généralement compréhensible.

4.8.2

Les renseignements fournis doivent comprendre :

a) le nom ou la fonction de même que l'adresse de la personne responsable de la politique et des pratiques de l'organisation et à qui il faut acheminer les plaintes et les demandes de renseignements;

b) la description du moyen d'accès aux renseignements personnels que possède l'organisation;

c) la description du genre de renseignements personnels que possède l'organisation, y compris une explication générale de l'usage auquel ils sont destinés;

d) une copie de toute brochure ou autre document d'information expliquant la politique, les normes ou les codes de l'organisation; et

e) la définition de la nature des renseignements personnels communiqués aux organisations connexes (par exemple, les filiales).

4.8.3

An organization may make information on its policies and practices available in a variety of ways. The method chosen depends on the nature of its business and other considerations. For example, an organization may choose to make brochures available in its place of business, mail information to its customers, provide online access, or establish a toll-free telephone number.

4.9 Principle 9 — Individual Access

Upon request, an individual shall be informed of the existence, use, and disclosure of his or her personal information and shall be given access to that information. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate.

Note: In certain situations, an organization may not be able to provide access to all the personal information it holds about an individual. Exceptions to the access requirement should be limited and specific. The reasons for denying access should be provided to the individual upon request. Exceptions may include information that is prohibitively costly to provide, information that contains references to other individuals, information that cannot be disclosed for legal, security, or commercial proprietary reasons, and information that is subject to solicitor-client or litigation privilege.

4.9.1

Upon request, an organization shall inform an individual whether or not the organization holds personal information about the individual. Organizations are encouraged to indicate the source of this information. The organization shall allow the individual access to this information. However, the organization may choose to make sensitive medical information available through a medical practitioner. In addition, the organization shall provide an account of the use that has been made or is being made of this information and an account of the third parties to which it has been disclosed.

4.9.2

An individual may be required to provide sufficient information to permit an organization to provide an account of the existence, use, and disclosure of personal information. The information provided shall only be used for this purpose.

4.9.3

In providing an account of third parties to which it has disclosed personal information about an individual, an organization should attempt to be as specific as possible. When it is not possible to provide a list of the organizations to which it has actually disclosed information about an individual, the

4.8.3

Une organisation peut rendre l'information concernant sa politique et ses pratiques accessibles de diverses façons. La méthode choisie est fonction de la nature des activités de l'organisation et d'autres considérations. Par exemple, une organisation peut offrir des brochures à son établissement, poster des renseignements à ses clients, offrir un accès en ligne ou établir un numéro de téléphone sans frais.

4.9 Neuvième principe — Accès aux renseignements personnels

Une organisation doit informer toute personne qui en fait la demande de l'existence de renseignements personnels qui la concernent, de l'usage qui en est fait et du fait qu'ils ont été communiqués à des tiers, et lui permettre de les consulter. Il sera aussi possible de contester l'exactitude et l'intégralité des renseignements et d'y faire apporter les corrections appropriées.

Note : Dans certains cas, il peut être impossible à une organisation de communiquer tous les renseignements personnels qu'elle possède au sujet d'une personne. Les exceptions aux exigences en matière d'accès aux renseignements personnels devraient être restreintes et précises. On devrait informer la personne, sur demande, des raisons pour lesquelles on lui refuse l'accès aux renseignements. Ces raisons peuvent comprendre le coût exorbitant de la fourniture de l'information, le fait que les renseignements personnels contiennent des détails sur d'autres personnes, l'existence de raisons d'ordre juridique, de raisons de sécurité ou de raisons d'ordre commercial exclusives et le fait que les renseignements sont protégés par le secret professionnel ou dans le cours d'une procédure de nature judiciaire.

4.9.1

Une organisation doit informer la personne qui en fait la demande du fait qu'elle possède des renseignements personnels à son sujet, le cas échéant. Les organisations sont invitées à indiquer la source des renseignements. L'organisation doit permettre à la personne concernée de consulter ces renseignements. Dans le cas de renseignements médicaux sensibles, l'organisation peut préférer que ces renseignements soient communiqués par un médecin. En outre, l'organisation doit informer la personne concernée de l'usage qu'elle fait ou a fait des renseignements et des tiers à qui ils ont été communiqués.

4.9.2

Une organisation peut exiger que la personne concernée lui fournisse suffisamment de renseignements pour qu'il lui soit possible de la renseigner sur l'existence, l'utilisation et la communication de renseignements personnels. L'information ainsi fournie doit servir à cette seule fin.

4.9.3

L'organisation qui fournit le relevé des tiers à qui elle a communiqué des renseignements personnels au sujet d'une personne devrait être la plus précise possible. S'il lui est impossible de fournir une liste des organisations à qui elle a effectivement communiqué des renseignements au sujet d'une personne, l'organisation doit fournir une liste des

organization shall provide a list of organizations to which it may have disclosed information about the individual.

4.9.4

An organization shall respond to an individual's request within a reasonable time and at minimal or no cost to the individual. The requested information shall be provided or made available in a form that is generally understandable. For example, if the organization uses abbreviations or codes to record information, an explanation shall be provided.

4.9.5

When an individual successfully demonstrates the inaccuracy or incompleteness of personal information, the organization shall amend the information as required. Depending upon the nature of the information challenged, amendment involves the correction, deletion, or addition of information. Where appropriate, the amended information shall be transmitted to third parties having access to the information in question.

4.9.6

When a challenge is not resolved to the satisfaction of the individual, the substance of the unresolved challenge shall be recorded by the organization. When appropriate, the existence of the unresolved challenge shall be transmitted to third parties having access to the information in question.

4.10 Principle 10 — Challenging Compliance

An individual shall be able to address a challenge concerning compliance with the above principles to the designated individual or individuals accountable for the organization's compliance.

4.10.1

The individual accountable for an organization's compliance is discussed in Clause 4.1.1.

4.10.2

Organizations shall put procedures in place to receive and respond to complaints or inquiries about their policies and practices relating to the handling of personal information. The complaint procedures should be easily accessible and simple to use.

4.10.3

Organizations shall inform individuals who make inquiries or lodge complaints of the existence of relevant complaint procedures. A range of these procedures may exist. For example, some regulatory bodies accept complaints about the personal-information handling practices of the companies they regulate.

organisations à qui elle pourrait avoir communiqué de tels renseignements.

4.9.4

Une organisation qui reçoit une demande de communication de renseignements doit répondre dans un délai raisonnable et ne peut exiger, pour ce faire, que des droits minimes. Les renseignements demandés doivent être fournis sous une forme généralement compréhensible. Par exemple, l'organisation qui se sert d'abréviations ou de codes pour l'enregistrement des renseignements doit fournir les explications nécessaires.

4.9.5

Lorsqu'une personne démontre que des renseignements personnels sont inexacts ou incomplets, l'organisation doit apporter les modifications nécessaires à ces renseignements. Selon la nature des renseignements qui font l'objet de la contestation, l'organisation doit corriger, supprimer ou ajouter des renseignements. S'il y a lieu, l'information modifiée doit être communiquée à des tiers ayant accès à l'information en question.

4.9.6

Lorsqu'une contestation n'est pas réglée à la satisfaction de la personne concernée, l'organisation prend note de l'objet de la contestation. S'il y a lieu, les tierces parties ayant accès à l'information en question doivent être informées du fait que la contestation n'a pas été réglée.

4.10 Dixième principe — Possibilité de porter plainte à l'égard du non-respect des principes

Toute personne doit être en mesure de se plaindre du non-respect des principes énoncés ci-dessus en communiquant avec le ou les personnes responsables de les faire respecter au sein de l'organisation concernée.

4.10.1

La question de la désignation de la personne responsable du respect des principes dans l'organisation fait l'objet de l'article 4.1.1.

4.10.2

Les organisations doivent établir des procédures pour recevoir les plaintes et les demandes de renseignements concernant leurs politiques et pratiques de gestion des renseignements personnels et y donner suite. Les procédures relatives aux plaintes devraient être facilement accessibles et simples à utiliser.

4.10.3

Les organisations doivent informer les personnes qui présentent une demande de renseignements ou déposent une plainte de l'existence des procédures pertinentes. Il peut exister un éventail de ces procédures. Par exemple, certaines autorités réglementaires acceptent les plaintes concernant les pratiques de gestion des renseignements personnels des entreprises relevant de leur compétence.

4.10.4

An organization shall investigate all complaints. If a complaint is found to be justified, the organization shall take appropriate measures, including, if necessary, amending its policies and practices.

4.10.4

Une organisation doit faire enquête sur toutes les plaintes. Si une plainte est jugée fondée, l'organisation doit prendre les mesures appropriées, y compris la modification de ses politiques et de ses pratiques au besoin.

SCHEDULE 2

(Sections 38 to 47, 49 and 51)

Acts of Parliament

Item	Column 1 Act of Parliament	Column 2 Provisions
1	*Federal Real Property and Federal Immovables Act*	Sections 3, 5 to 7, 11 and 16
2	*Canada Labour Code*	Subsection 254(1)
3	*Canada Lands Surveys Act*	Subsection 3(2)

2000, c. 5, Sch. 2; SOR/2004-309, s. 1; SOR/2008-114; SOR/2019-84, s. 1.

ANNEXE 2

(articles 38 à 47, 49 et 51)

Lois fédérales

Article	Colonne 1 Loi fédérale	Colonne 2 Dispositions
1	*Loi sur les immeubles fédéraux et les biens réels fédéraux*	Articles 3, 5 à 7, 11 et 16
2	*Code canadien du travail*	Paragraphe 254(1)
3	*Loi sur l'arpentage des terres du Canada*	Paragraphe 3(2)

2000, ch. 5, ann. 2; DORS/2004-309, art. 1; DORS/2008-114; DORS/2019-84, art. 1.

SCHEDULE 3

(Sections 38 to 47, 49 and 51)

Regulations and Other Instruments

Item	Column 1 Regulations or Other Instrument	Column 2 Provisions
1	*Federal Real Property Regulations*	Sections 9 and 11 **[SOR/2005-407]**
1	*Federal Real Property Regulations*	Sections 9 and 11 **[SOR/2004-309, s. 2]**

2000, c. 5, Sch. 3; SOR/2004-309, s. 2; SOR/2005-407.

ANNEXE 3

(articles 38 à 47, 49 et 51)

Règlements et autres textes

Article	Colonne 1 Règlement ou autre texte	Colonne 2 Dispositions
1	*Règlement concernant les immeubles fédéraux*	Articles 9 et 11 **[DORS/2005-407]**
1	*Règlement concernant les immeubles fédéraux*	Articles 9 et 11 **[DORS/2004-309, art. 2]**

2000, ch. 5, ann. 3; DORS/2004-309, art. 2; DORS/2005-407.

SCHEDULE 4

(Subsection 4(1.1) and paragraph 26(2)(c))

Organizations

Item	Column 1 Organization	Column 2 Personal Information
1	World Anti-Doping Agency *Agence mondiale antidopage*	Personal information that the organization collects, uses or discloses in the course of its interprovincial or international activities

2015, c. 36, s. 166.

ANNEXE 4

(paragraphe 4(1.1) et alinéa 26(2)c))

Organisations

Article	Colonne 1 Organisation	Colonne 2 Renseignements personnels
1	Agence mondiale antidopage *World Anti-Doping Agency*	Renseignements personnels recueillis, utilisés ou communiqués par l'organisation dans le cadre de ses activités interprovinciales ou internationales

2015, ch. 36, art. 166.

AMENDMENTS NOT IN FORCE

— 2026, c. 3, s. 389

389 The *Personal Information Protection and Electronic Documents Act* is amended by adding the following after section 10.3:

DIVISION 1.2

Mobility of Personal Information

Data mobility framework

10.4 Subject to the regulations, on the request of an individual, an organization shall, as soon as feasible, disclose the personal information that it has collected from the individual to an organization designated by the individual if both organizations are subject to a data mobility framework.

Regulations

10.5 The Governor in Council may, after consulting with the Office of the Privacy Commissioner, make regulations respecting the disclosure of personal information under section 10.4, including regulations

(a) respecting data mobility frameworks and prescribing

(i) safeguards that must be put in place by organizations to enable the secure disclosure of personal information under section 10.4 and the secure collection of that information, and

(ii) parameters for the technical means for ensuring interoperability in respect of the disclosure and collection of that information;

(b) specifying organizations that are subject to a data mobility framework; and

(c) providing for exceptions to the requirement to disclose personal information, including exceptions related to the protection of proprietary or confidential commercial information.

MODIFICATIONS NON EN VIGUEUR

— 2026, ch. 3, art. 389

389 La *Loi sur la protection des renseignements personnels et les documents électroniques* est modifiée par adjonction, après l'article 10.3, de ce qui suit :

SECTION 1.2

Mobilité des renseignements personnels

Cadre de mobilité des données

10.4 Sous réserve des règlements, l'organisation, à la demande de l'individu auprès duquel elle a recueilli des renseignements personnels, communique dès que possible ces renseignements à l'organisation que l'individu désigne si les deux organisations sont assujetties à un cadre de mobilité des données.

Règlements

10.5 Le gouverneur en conseil peut, après consultation du Commissariat à la protection de la vie privée, prendre des règlements concernant la communication de renseignements personnels au titre de l'article 10.4, notamment des règlements :

a) concernant les cadres de mobilité des données et prévoyant :

(i) les mesures de sécurité que l'organisation doit mettre en place afin de permettre la communication sécuritaire des renseignements personnels au titre de l'article 10.4 ainsi que la collecte sécuritaire de ces renseignements,

(ii) les paramètres des moyens techniques permettant d'assurer l'interopérabilité de systèmes à l'égard de la communication et de la collecte de ces renseignements;

b) précisant les organisations qui sont assujetties à un cadre de mobilité des données;

c) prévoyant des exceptions à l'obligation de communiquer des renseignements personnels, notamment en ce qui a trait à la protection des renseignements commerciaux exclusifs ou confidentiels.

Distinguishing among classes

10.6 Regulations made under section 10.5 may distinguish among different classes of activities, information or organizations.

— 2026, c. 3, s. 390

390 Subsection 11(1) of the Act is replaced by the following:

Contravention

11 (1) An individual may file with the Commissioner a written complaint against an organization for contravening a provision of Division 1, 1.1 or 1.2 or for not following a recommendation set out in Schedule 1.

— 2026, c. 3, s. 391

391 Subsection 14(1) of the Act is replaced by the following:

Application

14 (1) A complainant may, after receiving the Commissioner's report or being notified under subsection 12.2(3) that the investigation of the complaint has been discontinued, apply to the Court for a hearing in respect of any matter in respect of which the complaint was made, or that is referred to in the Commissioner's report, and that is referred to in clause 4.1.3, 4.2, 4.3.3, 4.4, 4.6, 4.7 or 4.8 of Schedule 1, in clause 4.3, 4.5 or 4.9 of that Schedule as modified or clarified by Division 1 or 1.1, in subsection 5(3) or 8(6) or (7), in section 10 or in Division 1.1 or 1.2.

— 2026, c. 3, s. 392

392 Paragraph 16(a) of the Act is replaced by the following:

(a) order an organization to correct its practices in order to comply with Divisions 1 to 1.2;

— 2026, c. 3, s. 393

393 Subsection 17.1(1) of the Act is replaced by the following:

Compliance agreement

17.1 (1) If the Commissioner believes on reasonable grounds that an organization has committed, is about to commit or is likely to commit an act or omission that could constitute a contravention of a provision of Division 1, 1.1 or 1.2 or a failure to follow a recommendation

Traitement différent : catégories

10.6 Les règlements pris en vertu de l'article 10.5 peuvent traiter différemment les catégories d'activités, de renseignements ou d'organisations.

— 2026, ch. 3, art. 390

390 Le paragraphe 11(1) de la même loi est remplacé par ce qui suit :

Violation

11 (1) Tout intéressé peut déposer auprès du commissaire une plainte contre une organisation qui contrevient à l'une des dispositions des sections 1, 1.1 ou 1.2 ou qui omet de mettre en œuvre une recommandation énoncée dans l'annexe 1.

— 2026, ch. 3, art. 391

391 Le paragraphe 14(1) de la même loi est remplacé par ce qui suit :

Demande

14 (1) Après avoir reçu le rapport du commissaire ou l'avis l'informant de la fin de l'examen de la plainte au titre du paragraphe 12.2(3), le plaignant peut demander que la Cour entende toute question qui a fait l'objet de la plainte — ou qui est mentionnée dans le rapport — et qui est visée aux articles 4.1.3, 4.2, 4.3.3, 4.4, 4.6, 4.7 ou 4.8 de l'annexe 1, aux articles 4.3, 4.5 ou 4.9 de cette annexe tels qu'ils sont modifiés ou clarifiés par les sections 1 ou 1.1, aux paragraphes 5(3) ou 8(6) ou (7), à l'article 10 ou aux sections 1.1 ou 1.2.

— 2026, ch. 3, art. 392

392 L'alinéa 16a) de la même loi est remplacé par ce qui suit :

a) ordonner à l'organisation de revoir ses pratiques en vue de se conformer aux sections 1 à 1.2;

— 2026, ch. 3, art. 393

393 Le paragraphe 17.1(1) de la même loi est remplacé par ce qui suit :

Conclusion d'un accord de conformité

17.1 (1) Le commissaire peut, s'il a des motifs raisonnables de croire à l'existence, à l'imminence ou à la probabilité d'un fait — acte ou omission — pouvant constituer une contravention à l'une des dispositions des sections 1, 1.1 ou 1.2 ou une omission de mettre en

set out in Schedule 1, the Commissioner may enter into a compliance agreement, aimed at ensuring compliance with this Part, with that organization.

— 2026, c. 3, s. 394

394 The portion of subsection 18(1) of the Act before paragraph (a) is replaced by the following:

To ensure compliance

18 (1) The Commissioner may, on reasonable notice and at any reasonable time, audit the personal information management practices of an organization if the Commissioner has reasonable grounds to believe that the organization has contravened a provision of Division 1, 1.1 or 1.2 or is not following a recommendation set out in Schedule 1 and for that purpose may

— 2026, c. 3, s. 395

395 Paragraph 24(c) of the Act is replaced by the following:

(c) encourage organizations to develop detailed policies and practices, including organizational codes of practice, to comply with Divisions 1 to 1.2; and

— 2026, c. 3, s. 396

396 Subsection 27(1) of the Act is replaced by the following:

Whistleblowing

27 (1) Any person who has reasonable grounds to believe that a person has contravened or intends to contravene a provision of Division 1, 1.1 or 1.2 may notify the Commissioner of the particulars of the matter and may request that their identity be kept confidential with respect to the notification.

— 2026, c. 3, s. 397

397 Paragraphs 27.1(1)(a) to (c) of the Act are replaced by the following:

(a) the employee, acting in good faith and on the basis of reasonable belief, has disclosed to the Commissioner that the employer or any other person has contravened or intends to contravene a provision of Division 1, 1.1 or 1.2;

œuvre une recommandation énoncée dans l'annexe 1, conclure avec l'organisation intéressée un accord, appelé « accord de conformité », visant à faire respecter la présente partie.

— 2026, ch. 3, art. 394

394 Le passage du paragraphe 18(1) de la même loi précédant l'alinéa a) est remplacé par ce qui suit :

Contrôle d'application

18 (1) Le commissaire peut, sur préavis suffisant et à toute heure convenable, procéder à la vérification des pratiques de l'organisation en matière de gestion des renseignements personnels s'il a des motifs raisonnables de croire que celle-ci a contrevenu à l'une des dispositions des sections 1, 1.1 ou 1.2 ou n'a pas mis en œuvre une recommandation énoncée dans l'annexe 1; il a, à cette fin, le pouvoir :

— 2026, ch. 3, art. 395

395 L'alinéa 24c) de la même loi est remplacé par ce qui suit :

c) encourage les organisations à élaborer des politiques détaillées — notamment des codes de pratiques — en vue de se conformer aux sections 1 à 1.2;

— 2026, ch. 3, art. 396

396 Le paragraphe 27(1) de la même loi est remplacé par ce qui suit :

Dénonciation

27 (1) Toute personne qui a des motifs raisonnables de croire qu'une autre personne a contrevenu à l'une des dispositions des sections 1, 1.1 ou 1.2, ou a l'intention d'y contrevenir, peut notifier au commissaire des détails sur la question et exiger l'anonymat relativement à cette dénonciation.

— 2026, ch. 3, art. 397

397 Les alinéas 27.1(1)a) à c) de la même loi sont remplacés par ce qui suit :

a) l'employé, agissant de bonne foi et se fondant sur des motifs raisonnables, a informé le commissaire que l'employeur ou une autre personne a contrevenu à l'une des dispositions des sections 1, 1.1 ou 1.2, ou a l'intention d'y contrevenir;

(b) the employee, acting in good faith and on the basis of reasonable belief, has refused or stated an intention of refusing to do anything that is a contravention of a provision of Division 1, 1.1 or 1.2;

(c) the employee, acting in good faith and on the basis of reasonable belief, has done or stated an intention of doing anything that is required to be done in order that a provision of Division 1, 1.1 or 1.2 not be contravened; or

b) l'employé, agissant de bonne foi et se fondant sur des motifs raisonnables, a refusé ou a fait part de son intention de refuser d'accomplir un acte qui constitue une contravention à l'une des dispositions des sections 1, 1.1 ou 1.2;

c) l'employé, agissant de bonne foi et se fondant sur des motifs raisonnables, a accompli ou a fait part de son intention d'accomplir un acte nécessaire pour empêcher la contravention à l'une des dispositions des sections 1, 1.1 ou 1.2;

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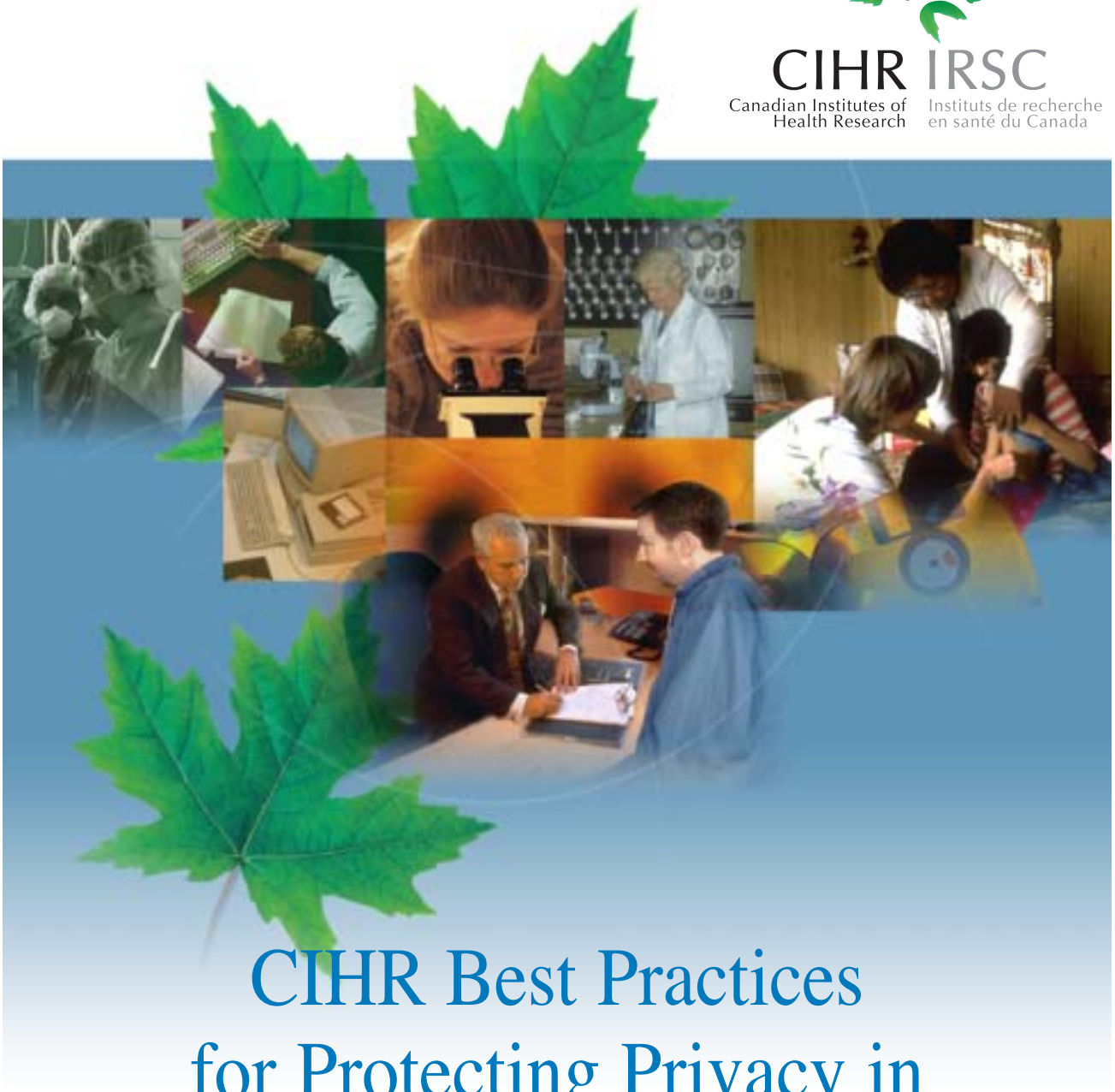

CIHR Best Practices for Protecting Privacy in Health Research

September 2005

Canada

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Acronyms

CIHR	Canadian Institutes of Health Research
CSA	Canadian Standards Association
ICH GCP	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use- Good Clinical Practice: Consolidated Guideline
NCEHR	National Council on Ethics in Human Research
NIH	National Institutes of Health (United States of America)
NSERC	Natural Sciences and Engineering Research Council of Canada
PAC	CIHR Privacy Advisory Committee
PRE	Interagency Advisory Panel on Research Ethics
REB	Research Ethics Board
RMGA	Quebec Network of Applied Genetic Medicine
SSHRC	Social Sciences and Humanities Research Council of Canada
TCPS	Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 1998 (with 2000, 2002, 2005 amendments)
U.S.	United States of America

CIHR Privacy Advisory Committee[1]

Recommendations

Background

Recognizing that one of the key ethical challenges for the health research community is to appropriately protect the privacy of those individuals whose information is used for research purposes, CIHR has promoted and initiated dialogue with the broad health research community on a range of privacy-related matters for many years. In particular, a multi-stakeholder workshop in November 2002 entitled *Privacy in Health Research: Sharing Perspectives and Paving the Way Forward* resulted in a number of recommendations, including that CIHR initiate the development of privacy best practices and promote the harmonization of privacy laws and policies that impact on health research.

Privacy Advisory Committee

Following on these recommendations, CIHR established a Privacy Advisory Committee (PAC) in 2003 to advise CIHR on the development of privacy best practices for health research, and on strategies for consultation, communication and knowledge translation. The Committee's mandate ends with the public release of the Privacy Best Practices in 2005.

PAC members are drawn from across Canada and include an international advisor. They represent themselves, not their organizations or institutions. Members bring the perspectives of the following interested groups: privacy commissioners, research ethics boards, health researchers, voluntary health organizations, patients/consumers, policy-makers, data providers, law/ethics, Aboriginal communities, and health service providers. Ex-officio members are drawn from key groups involved in developing or implementing research ethics policy/regulations, namely the Interagency Advisory Panel for Research Ethics, the National Council on Ethics in Human Research, Health Canada, and the Social Sciences and Humanities Research Council of Canada. The Natural Sciences and Engineering Research Council of Canada was invited to appoint a member on PAC but preferred to assume a consultative role. PAC members agreed by consensus to have the CIHR Ethics Office chair the Committee in the role of facilitator.

An earlier version of the current document was the subject of public consultations through 2004. The current document was revised based on feedback received.

[1] Privacy Advisory Committee members are listed in Appendix A-1.

Recommendations

The following recommendations are intended to promote the effective implementation of these Privacy Best Practices in the health research community and to ensure that these best practices continue to respond to the evolving nature of health research and challenges of privacy protection.

Continuous learning and evaluation

- These Privacy Best Practices must continue to evolve to reflect improved practices and innovative solutions over time, and to reflect and influence ongoing legislative developments. Recognizing that important issues have yet to be addressed (see *Key Outstanding Issues*), these should be tackled by developing supporting modules with the active engagement of the relevant communities and through targeted research.

- There should be an assessment of the impact that the Best Practices will have over time on research ethics board decision-making and researcher practice. Mechanisms should be put in place to enable this assessment. These mechanisms should include a formal process, such as a CIHR Standing Committee, to assess implementation and the need for improvement of the Best Practices over time. A web tool should be considered for channelling research findings and capturing practical experiences to inform the ongoing evolution of the Best Practices.

Implementation strategy

- These Privacy Best Practices should be revised in two years. With ongoing feedback and evaluation, PAC expects that the Best Practices will be adapted, as necessary, for the purpose of becoming mandatory CIHR funding policy. These Best Practices should also be referred to the Interagency Advisory Panel on Research Ethics with a view to encouraging their eventual application, in revised form, as Tri-Agency funding policy. For this to happen, the social science perspective needs to be strengthened.

Support for implementation

- Underpinning the implementation strategy for these Privacy Best Practices, there should be a strong emphasis on the importance of training and education support for institutions, research ethics boards and researchers. CIHR should consider developing a web-based document as an educational resource.

- In addition, institutions should be encouraged to provide adequate support for the infrastructure needed to implement and operationalize these Best Practices on a systematic basis. PAC recommends that there be a line item in the budget of researchers' grant applications to

accurately reflect the increased cost involved in adhering to these Best Practices so as to enhance commitment and feasibility.

Harmonization of oversight framework

- There should be continuing efforts by CIHR to support and influence the federal, provincial and territorial legislative harmonization agenda as well as the development of a national system of research ethics oversight.

Key outstanding issues

- Privacy concerns related to the transnational flow of data need to be addressed. These could include clear interpretive provisions and the development of coherent and reciprocal minimum standards to be included in international data transfer agreements.

- A separate process or initiative should be undertaken to develop a policy framework for the physical collection, use and storage of human biological specimens (in contrast to the personal information that may be derived from those specimens) as these are critically important and complex areas of activity that are having increasing importance in research.

- As one important means of responding to public concerns over potential unauthorized uses of personal information gathered for research, CIHR should consider raising discussion among stakeholders and governments about the desirability and feasibility of introducing in Canada instruments such as the Certificates of Confidentiality issued in the United States to protect sensitive information on research participants from forced disclosure.[2]

[2] Under section 301(d) of the U.S. *Public Health Service Act* (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health (NIH) and other Health and Human Services Agencies. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for research participants, such as damage to their financial standing, employability, insurability, or reputation. A Certificate allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. See U.S. Office of Human Subject Protection – Guidance online at http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm.

Privacy Best Practices
10 Elements in Summary Form

These Privacy Best Practices are intended to provide guidance for the health research community in Canada on the application of fair information principles to research involving personal information, and to assist in the interpretation of the *Tri-Council Policy Statement: Ethical Conduct for Research involving Humans* (TCPS) by offering additional detail and practicality.

In turn, as these Best Practices evolve in light of practice, they have the potential to inform the ongoing development of the TCPS and relevant laws and policy.

These Privacy Best Practices do not replace existing laws, policies and professional codes of conduct that apply to certain types of personal information, designated organizations and/or specific kinds of activity.

Privacy Best Practices

The Elements are presented in summary in this section to provide a quick reference for the reader. Full descriptions of each Element along with links to selected excerpts from the TCPS are in the main body of this document.

Tables of Concordances are included in the Appendices to supplement key provisions in the Elements with cross-references to related requirements under Canadian privacy legislation. The Tables should be used only as preliminary guidance. The application of the information in the Tables to a particular research project should be determined in consultation with a legal advisor.

ELEMENT #1: Determining the research objectives and justifying the data needed to fulfill these objectives

At the outset of the research design process, and as thoroughly as possible given the proposed research method, researchers should:

- identify and document research objectives and questions as a basis for determining what data will be needed;
- anticipate and document research questions related to the primary research objective, which might become relevant after the initial data analyses; and
- anticipate and document likely future uses of the data, including possible collaborations with other researchers or possible commercial uses.

In the case of a *database created for general research purposes*, researchers should define the scope and purpose in a way that will be meaningful for research ethics boards (REBs) and any prospective research participants,

even if the boundaries are at a relatively general level. This is an opportunity to be as open and transparent as possible about the proposed research, and to reassure research participants and REBs that although future research purposes are not specified in detail, data management, storage and use will occur within a defined framework, including review and approval by an REB.

If appropriate, setting up an *advisory committee* drawn from the scientific community, other relevant areas (such as ethics, policy, or information technology) and those affected by the condition or health event under study, can assist in defining the scope and strategic priorities for a research project in the context of both short and long-term initiatives.

All potential relevant and useful research questions cannot always be foreseen at the outset of a research project. For example, researchers using *inductive methods* of research may discover an "emergent" research approach through encounters with and in collaboration with research participants. In such research, the development of research questions and procedures is an ongoing process. While planning their research, researchers should attempt to foresee both obvious and emerging issues related to privacy. These should be included in the submission to an REB. Researchers should also document for an REB any amendments to the protocol and consequent privacy protection strategies emerging over the course of the study.

ELEMENT #2: Limiting the collection of personal data

Researchers should plan to collect personal data only as necessary for the research. The amount of personal information collected and the level of identifiability and sensitivity of this information should be restricted to what is necessary to achieve the research objectives.

Consider first whether individually identifiable data are needed, or whether non-identifiable data or aggregate data would serve the research objectives (e.g. data on individuals grouped by age or some other meaningful variable).

For research involving *secondary use of data* for research, if identifiable data are required for the research, direct identifiers should be avoided or concealed to the extent that is reasonably practical (e.g. as soon as a data linkage has been completed). Data without direct identifiers can be:

- *coded* to allow a trace-back to individuals, by means of:
  - *single-coding* (the researcher has the key to the code to link the research data back to direct identifiers, which are held separately); or
  - *double-coding* (an increased level of confidentiality protection over single coding because the data holder does not give the researcher the key to re-identify individuals); or

- *without a code*, if the capacity to trace the research data or results back to individuals is not required for the research purpose.

Even if the direct identifiers in shared data have been removed or coded, consider how to *minimize the collection or sharing of potentially identifying data elements*.

For *inductive data collection*, for example where open-ended interview techniques are used, the extent of personal data to be collected may not always be foreseeable in detail at the outset of the interview. In these cases, the ongoing negotiation of consent with research participants is the best way to ensure that the privacy of individuals and the community is being appropriately protected.

ELEMENT #3: Determining whether consent from individuals is required

Voluntary and informed consent from legally competent individuals or authorized third parties is a fundamental principle in research involving humans, and specifically for the use of their personal data.

Under specified circumstances, given a satisfactory rationale by the researcher, an REB may approve the waiver of a consent requirement, or a partial waiver of some elements of a consent requirement. According to TCPS Article 2.1(c), the REB must find and document that:

"(i) The research involves no more than minimal risk to the subjects;
(ii) The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
(iii) The research could not practicably be carried out without the waiver or alteration;
(iv) Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
(v) The waived or altered consent does not involve a therapeutic intervention."

In addition to REB approval, access to personal data for research without consent will be subject to specific legal requirements in relevant jurisdictions.

When a research objective requires the *collection of personal information directly from individuals to whom the data belong and linking to other sources to form a combined file*, consent should be sought for both types of data collection at the time of direct contact with prospective research participants.

For secondary use of data for research, an REB should consider the following factors in determining whether a research proposal meets the requirements for waiver of consent:

- necessity of personal data for the research purposes;
- potential harms and benefits of the research;
- inappropriateness or impracticability of consent;

- expectations of individuals;
- views of relevant groups;
- legal requirements; and
- openness (informing the public).

These factors, and the description in the Elements, expand on TCPS Article 2.1(c)(i)- (iii).

An REB may determine that seeking consent from individuals is *inappropriate* because there is potential harm to individuals from direct contact, or contact with individuals is not permitted under a previous data-sharing agreement, law or policy.

Seeking consent from individuals for the use of their personal data may be considered *impracticable* when there are difficulties in contacting or notifying individuals for reasons such as:

- the size of the population being researched;
- the proportion of prospective participants likely to have relocated or died since the time the personal information was originally collected; or
- the lack of an existing or continuing relationship between prospective participants and the data holder who would need to contact them (e.g. a patient database that does not have a regular follow-up program to maintain a complete and accurate record of changes in registrants' contact information over time);

such that:

- there is a risk of introducing bias into the research because of the loss of data from segments of the population that cannot be contacted to seek their consent, thereby affecting the validity of results and/or defeating the purpose of the study; or
- the additional financial, material, human, organizational and other resources needed to obtain consent could impose a hardship or burden on the researchers or organization so burdensome that the research could not be done.

ELEMENT # 4: Managing and documenting consent

Consent is an ongoing process that begins upon first contact with prospective participants or authorized third parties, and ends only with the conclusion of their participation in the research or use of their information. Participants should understand that their consent is voluntary, to be obtained without manipulation, undue influence or coercion, and can be withdrawn at any time.

Evidence of initial and ongoing consent and the withdrawal of consent should be *documented* as appropriate for audit and legal purposes.

The majority of research studies use an *opt-in consent*. Opting-in means that prior to the start of the research or data collection, informed individuals give clear indication that they voluntarily agree to participate in the research.

Presumed consent with an opt-out mechanism should be used only when an REB considers prior opt-in consent to be inappropriate or impracticable. A valid opt-out mechanism means that individuals have the opportunity at some time during the research or data collection process to give a clear indication (in writing or orally) that they do not want to be participants in the research or to have their data used in the research. If individuals do not choose to opt-out of the research, their consent is presumed as long as they were given reasonable notice of the research and meaningful opportunity to opt-out.

Collection of data without direct personal identifiers may be necessary or proposed when the research deals with highly sensitive conditions or activities. In such circumstances, consent should be documented but the identity of research participants should not be linkable to their data or to results of analyses.

The researcher may need *information on who does not want to participate in research or who withdraws from research*, for example to document who is not to be included in follow-up research activities; and/or to take into consideration relevant characteristics of the population not included in the study, when reporting possible bias in research results. In these circumstances, researchers may obtain information about non-participants or those withdrawing consent only with individuals' consent or the approval of an REB to waive the consent requirement in the particular circumstances.

Participants in *qualitative studies* are especially vulnerable to unintended identification. For example, in quoting interviewees, biographical details may be revealed that make protecting identities difficult. Therefore, paying attention to the trust relationship between researcher and participant, and obtaining ongoing consent, are very important.

ELEMENT #5: Informing prospective research participants about the research

Researchers should provide to prospective participants or to authorized third parties disclosure of all information relevant to voluntary and informed consent.

Information should be communicated to prospective participants in *plain language*, in oral and/or written form, so that it is easily understood.

The *amount of time* taken to communicate information to prospective participants should be appropriate to the need, not excessive nor too brief. For example, the information could be layered, with a one-page summary of the research, a short consent form, an appendix with more detailed information and instructions on how to obtain more information.

During the consent process, the researcher should determine whether the participant wishes to be *informed of any meaningful research results* that specifically relate to them.

Researchers, particularly those in the areas of health services, population and public health, and genetics/genomic research who study whole populations, should strive to *communicate with the relevant population and governmental authorities regarding results* that are pertinent to the improvement of health and/or the prevention of disease. The population studied should be made aware of possible socio-economic discrimination or group stigmatization as a result of the research results, such as because of perceptions of genetic risks. In the context of genetic research, the population should also be informed of the means taken to minimize the risks.

In the consent process and discussion, researchers using *qualitative methods* may consider involving participants in the writing and reporting process, depending on the circumstances.

For a hybrid project involving the *direct collection of data from individuals and secondary use of data from other sources*, the prospective research participant should also be informed of all expected types and sources of personal data to be used, any expected linkages and the expected purposes for which data will be used.

When personal data are to be entered into a *database for multiple research uses* over an extended period, research participants should also be informed of such things as: expected types of studies, expected data types and purposes, expected commercial uses, data retention period, and the process for overseeing the use and security of data. Participants may also be given the opportunity to provide *authorization for future uses*, with or without re-contact, including the opportunity to withdraw consent (and any identifying information) in the future. Additional options may include:

- to be re-contacted on a regular (or as needed basis) to seek consent for new research uses of the data, if desired and practicable; and/or
- to not be re-contacted, but to authorize the researchers to use the data only in certain ways in the future (e.g. with or without direct identifiers, coded or in non-identifiable form; or for certain areas of research).

ELEMENT #6: Recruiting prospective research participants

The proposed recruitment procedure and materials should be included in the submission for *REB approval*. The procedure and materials should *foster the conditions for voluntary consent*, and not exert undue influence on prospective participants to agree to take part in research.

Initial contact with individuals about a research project should be made by someone that individuals would expect to have relevant information about them, or in other ways that do not inappropriately intrude on their life or privacy.

Wherever possible, the researcher should *anticipate at the time of the original collection* the future uses of personal information for

further recruitment purposes, and seek consent from individuals for these purposes.

The REB will need to determine if consent is required for the *secondary use of personal information for recruitment purposes*. Researchers and REBs should be aware of any legal restrictions on contacting individuals in these circumstances.

When a researcher is making a *request for access to data* to recruit participants, the preferred option is for the data holder to determine eligibility of individuals for the research on the basis of criteria provided by the researchers, and to make the initial contact to:

- inform eligible individuals about the research so that they can contact the researcher, if interested, or
- to seek consent from individuals to release their nominal information to the researcher who will contact them to inform them about the research.

When the preferred option is impracticable or inappropriate, an REB may consider whether a researcher should be permitted access to minimal personal data only for the purposes of determining eligibility for the research or contacting individuals to invite them to join the study. If it is legally permissible and the REB considers it appropriate, personal information may be released with appropriate confidentiality protection such as a signed confidentiality agreement with access restricted to the data holder's site and use limited to the stated purpose.
Researchers should avoid situations where eligible individuals are not aware, prior to being contacted, of information about themselves that makes them eligible for participation in the research, such as a cancer diagnosis.

Typical *scenarios* for recruiting participants, including *community-based research* and *genetics research*, and preferred approaches are briefly described.

ELEMENT #7: Safeguarding personal data

Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards. Data security safeguards should include organizational, technological and physical measures.

Researchers should take a risk assessment and management approach to protecting research data from loss, corruption, theft or unauthorized disclosure, as appropriate for the sensitivity and identifiability of the data.

REBs should review and approve researchers' proposed measures for safeguarding any personal data to be collected.

ELEMENT #8: Controlling access and disclosure of personal data

Data sharing for research purposes— whether of linked or unlinked data sets— is an important way of enabling socially valuable research. It avoids unnecessary duplication of data collection, which reduces the burden on research participants and permits researchers to use limited or scarce resources more productively.

However, once approved by an REB, there should be strict limits on access to data and secure procedures for data linkage, subject to data-sharing agreements.

When personal data are essential to research objectives and questions, researchers need a plan for making public the results of research in ways that do not permit tracing back to individuals if they do not wish their identities to be known.

The most secure way of conducting *data linkages* requested by external researchers is for the data holder to conduct the linkage and provide linked data sets to the researcher without direct identifiers and at the minimum level of identifiability necessary for the research purpose. If that is not practicable, a trusted third party may conduct the linkage or the researcher may conduct the linkage on the data holder's site. As a last option, a researcher may be permitted to conduct the linkage at a secure site but under strict controls, as specified in a data-sharing agreement.

Following the linkage of datasets, the person doing the data linkage should reduce datasets to the lowest level of identifiability needed to accomplish the research objectives.

Data-sharing agreements bind data providers and researchers to their respective responsibilities and obligations for protecting personal data. Data-sharing agreements should set out the terms and conditions under which data providers will allow researchers to access personal data for research purposes.

In assessing the privacy aspects of research, researchers and REBs should also be aware of the possibility that in some instances *individuals may want their identities to be known*—for example, when individuals want their contribution to research as participants to be recognized, or where they want to help others afflicted with a similar condition. In some *qualitative research*, individual participants may understand and willingly accept the possibility that their identities may be revealed in the public reporting of research results.

ELEMENT #9: Setting reasonable limits on retention of personal data

Personal data should be retained as long as is necessary to fulfill the research purposes. Personal data may then be destroyed or returned to the data provider, if appropriate, as set out in the terms of the original collection, data-sharing agreement, institutional policies, and legal requirements.

Retention periods for personal data should be defined in writing. Researchers should be explicit about what they plan to do with the data they collect and have storage, management and access policies in place.

When personal data are collected in a *database to support general health research purposes* in the future, personal data may be retained for the general purposes originally consented to, subject to security safeguards proportionate to the identifiability and sensitivity of the data.

Administrative databases such as hospital discharge records and vital statistics registries, which may be used to support health research, may retain personal data over the long-term, provided that this is permitted according to legislation or the mandate of a public body such as a government health department.

Any long-term retention of personal data established for general health research purposes should be subject to periodic audits and effective oversight by independent third parties including REBs.

ELEMENT #10: Ensuring accountability and transparency in the management of personal data

Individuals and organizations engaged in health research involving personal data are accountable for the proper conduct of such research in accordance with applicable funding policies, privacy principles and/or legislation. Processes and practices must be clearly established and implemented in order to give meaningful effect to these policies, principles or laws. Proper accountability and transparency practices require adequate resources for such things as communication, education and training relating to privacy.

Roles and responsibilities of all those involved in the conduct and evaluation of research should be clearly defined and understood, including those of researchers, their employing institutions, REBs, any data stewardship committees, Privacy Commissioners and other legally-designated privacy oversight agencies. Their concerted efforts should aim to provide a coherent governance structure for effective and efficient data stewardship.

Recognizing that transparency may enhance public support for, and interest in, socially valuable research, individuals and organizations engaged in the conduct and evaluation of health research should:

- be open to the public with respect to the objectives of the research;
- be open about the policies and practices relating to the protection of personal data used in the research;
- promote ongoing dialogue between the research community and privacy oversight agencies; and
- promote ongoing dialogue between the research community and the community at large (the public).

When a *database is created for multiple research purposes, or across multiple sites or jurisdictions*, researchers and institutional data holders should promote coordinated and streamlined approaches to the review of privacy and confidentiality concerns, and to data stewardship over the long term.

A *centralized data stewardship committee* could be put in place to authorize future uses of the database in accordance with the research objectives and, where applicable, within the parameters set by the consent obtained from participants. The responsibilities of this committee could include the review of data access requests; long-term management of the database; coordination of reviews by local REBs (e.g. by means of agreements between REBs, institutions and researchers, as appropriate); and provision of information to the public (e.g. on a web site).

How to navigate the document: Areas of special interest*

Areas of special interest	Element #. section #. subsection #	TCPS excerpts at end of element #
Type of project		
Single research project	1.1, 9.1.1	
Database created for long-term research use	1.2, 5.7, 9.1.2	
Qualitative (e.g. inductive analysis)	1.4, 2.4, 4.3, 5.4, 8.4.1	Element #3
Genetics/Genomics	2.1.2, 3.5, 5.3, 6.3.3	Element #5, 8
Data collection (sources)		
Individuals (legally competent)	2.2, 3.1, 4.1, 5.3.1, 5.5, 6.1.1, 6.2, 6.3	Element #5
Individuals not legally competent		Element #3
Children		Element #3
From individuals & secondary use or disclosure	3.2, 5.6	
Communities	3.3.5, 5.3.2, 6.3.2	
Secondary use or disclosure	2.3, 3.3, 6.1, 8.1	Element #2, 3, 5, 6
Data linkage	2-Summary guide (b), 8.2	Element #8
Real world case studies	Appendix A-3	
Examples of studies recruiting individuals or communities	Appendix A-4 Table 1	
Examples of databases with research potential, in diverse settings	Appendix A-4 Table 2	
Additional stewardship, oversight		
Advisory committee on research priorities	1.3	
Data stewardship committee	10.2.4	
Legal requirements		
Tables of concordance with privacy legislation	Appendix A-7	

* based on feedback during 2004 consultations on draft CIHR privacy best practice guidelines.

Introduction

CIHR'S Mandate

The Canadian Institutes of Health Research (CIHR) is Canada's main federal funding agency for health research. CIHR's mandate is to invest in research that has the potential to lead to improved health[3] for Canadians, more effective health services and products, and a strengthened Canadian health care system. CIHR-funded health research must also meet the highest standards of scientific excellence and ethics.

In the area of ethics, one of the key challenges for the health research community is to protect the privacy of individuals and the confidentiality of personal information, at a time of great change in research. For example, technological advances in information technology and the advance of genetic research are challenging existing standards and mechanisms for privacy protection. Also, the sheer number, diversity and complexity of new privacy laws and policies within and beyond Canada's borders are increasing the practical challenges faced by researchers, particularly for those conducting studies across jurisdictions. And, while there are increasing demands for privacy protection in health research, there is also clear recognition that health research plays a critical role in improving the health of Canadians and supporting an evidence-based health care system.

Goals

These Best Practices are intended to be innovative approaches to the challenge of protecting the privacy of individuals and the confidentiality of personal information in the context of health research. These Best Practices are meant to:

- provide guidance for health researchers in the design and conduct of health research involving personal information;
- be a resource for research ethics boards and institutions to consult when reviewing and evaluating health research involving personal information; and
- through the uptake and application of these Best Practices in the development of privacy laws or policies across Canada, contribute toward a more coherent and harmonized framework for addressing privacy and confidentiality issues in health research.

[3] The World Health Organization defines "health" as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". From *Preamble to the Constitution of the World Health Organization* as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948). Online at: http://www.who.int/about/definition/en/.

Statement of Values

These Best Practices primarily reflect the values articulated in two foundational documents: the *Tri-Council Policy Statement: Ethical Conduct for Research involving Humans* (TCPS), Canada's national ethics guidelines for research funded by the three main federal funding agencies, and internationally accepted fair information principles codified by the Canadian Standards Association.

Tri-Council Policy Statement (TCPS)

The Best Practices are firmly embedded in CIHR's ongoing commitment to support TCPS.[4] Compliance with TCPS is mandatory for all research funded through the three main federal research funding agencies: Canadian Institutes of Health Research (formerly Medical Research Council of Canada), Natural Sciences and Engineering Research Council of Canada (NSERC) and Social Sciences and Humanities Research Council of Canada (SSHRC). Research ethics boards (REBs) also use the TCPS as guidance in the review of research funded through other sources.

The broad ethical framework of the TCPS is based on recognition of the need for and social value of research, along with moral imperatives to respect human dignity, ethical guiding principles and the law.[5] Ethical guiding principles for research include respect for privacy and confidentiality, among the following fundamental and interrelated ethical guiding principles in the TCPS:

Respect for human dignity
Respect for justice and inclusiveness
Respect for free and informed consent
Balancing harms and benefits
Respect for vulnerable persons
Respect for privacy and confidentiality
Minimizing harm
Maximizing benefit[6]

The TCPS acknowledges privacy as a fundamental value, and dignity and autonomy of individuals as the ethical basis of respect for the privacy of research subjects. These national research ethics guidelines also recognize that the right to privacy is not absolute and that compelling and specifically identified public interests may justify an infringement of that right, specifically the requirement to obtain consent before collecting, using or disclosing personal information.[7]

[4] The TCPS can be accessed on the Interagency Advisory Panel for Research Ethics web site at http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm.
[5] TCPS, pg. i.4.
[6] TCPS, *Context of an Ethics Framework*, Section C, pg. i.5.
[7] TCPS, Section 3- *Privacy and Confidentiality*, pg. 3.1.

Fair information principles

These Best Practices are also grounded in internationally recognized fair information principles, which are at the heart of Canadian privacy legislation and form the basis of the Canadian Standards Association (CSA) *Model Code for the Protection of Personal Information*.[8] These ten core principles are:

1) *Accountability* – An organization is responsible for personal information under its control and shall designate an individual or individuals who are accountable for the organization's compliance with the following principles.

2) *Identifying Purposes* – The purposes for which personal information is collected shall be identified by the organization at or before the time the information is collected.

3) *Consent* – The knowledge and consent of the individual are required for the collection, use or disclosure of personal information, except where inappropriate.

4) *Limiting Collection* – The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means.

5) *Limiting Use, Disclosure, and Retention* – Personal information shall not be used or disclosed for purposes other than those for which it was collected, except with the consent of the individual or as required by law. Personal information shall be retained only as long as necessary for the fulfillment of those purposes.

6) *Accuracy* – Personal information shall be as accurate, complete and up-to-date as is necessary for the purposes for which it is to be used.

7) *Safeguards* – Personal information shall be protected by security safeguards appropriate to the sensitivity of the information.

8) *Openness* – An organization shall make readily available to individuals specific information about its policies and practices relating to the management of personal information.

9) *Individual Access* – Upon request, an individual shall be informed of the existence, use and disclosure of his or her personal information and shall be given access to that information. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate.

[8] The core principles and associated sub-principles of the CSA Model Code were incorporated into the *Personal Information Protection and Electronic Documents Act* (PIPEDA), Schedule 1, accessible on the Department of Justice website at: http://laws.justice.gc.ca/en/P-8.6/index.html.

10) *Challenging Compliance* – An individual shall be able to address a challenge concerning compliance with the above principles to the designated individual or individuals accountable for the organization's compliance.

The CSA Code was not designed specifically for the research context. Thus, these Best Practices are intended to provide guidance on the application of these fair information principles to health research.

Scope of Application

Voluntary guidance in the Canadian context

These Best Practices are intended as voluntary guidance for the health research community in Canada. They are based on and are consistent with the TCPS, and they are designed to assist in the interpretation of the TCPS by offering additional detail and practicality. In turn, as these Best Practices evolve in light of practice, they have the potential to inform the ongoing development of the TCPS and relevant laws and policy.

Applicable legislation and policy

These Privacy Best Practices do not replace existing laws, policies and professional codes of conduct that apply to certain types of personal information, designated organizations and/or specific kinds of activity. Researchers, REBs and institutions should be aware of, and continue to comply with, the relevant laws, policies and codes, including the TCPS, that govern research activities in their respective jurisdictions. In the case of multi-centre research crossing provincial, territorial or even national borders, several privacy laws and policies may have to be considered and complied with.

To help health researchers, REBs and others navigate the sea of privacy laws and policies, a series of tables are included in the Appendix highlighting existing requirements relating to privacy in selected legislation.

Health research

Consistent with CIHR's mandate, these Privacy Best Practices are intended to be a resource primarily for the health research community, and are relevant to health research that requires ethics review under the TCPS.[9]

[9] Research is defined in the TCPS as "a systematic investigation designed to develop or establish principles, facts or generalizable knowledge" (TCPS, pg. 1.1). The range of research requiring ethics review in the TCPS is listed in Appendix 1 (TCPS, pg. A.1).

Health research is interdependent on a range of knowledge-generating activities that are generally perceived to be outside the boundaries of research, but which are related to the improvement of health and health services. These "non-research" activities, such as public health surveillance, health service management, and program quality assurance and improvement, are beyond the manageable scope of the present document. In the future, however, these Best Practices could potentially serve as models for best practices in these related areas, with the necessary adaptations.

Personal information

These Best Practices cover identifiable personal information. Identifiable personal information may contain a direct link to a specific individual (e.g. name and street address, personal health number, etc.) or any element or a combination of elements that allows indirect identification of an individual (e.g. if birth date combined with postal code and other personal information on the record such as ethnicity could lead to the identification of an individual).

The TCPS definition of identifiable personal information covers a wide range of personal information that may be used in the conduct of research.[10] For example, health researchers may need information about such things as a person's clinical history and use of health care services, but also about broad determinants of health, such as a person's education, employment, and income level.

The scope of personal information covered in these Privacy Best Practices includes personal information **derived** from blood and other human biological materials (e.g. information such as blood type, DNA code and the presence or absence of disease), but not the materials themselves. The privacy issues related to the banking, storage and use of those biological materials are beyond the scope of this document.

Commitment to Continuous Learning and Review

These Privacy Best Practices are expected to evolve over time in response to changes in the circumstances of research and as new best practices emerge. One of the valuable ways in which researchers, REBs and institutions can assist the evolution of this document is by bringing to the attention of the CIHR Ethics Office lessons learned through the application of these Best Practices and suggesting areas for further development.

Emailed feedback can be sent to the CIHR Ethics Office at *ethics-ethique@cihr-irsc.gc.ca*.

[10] "Identifiable personal information" is defined in TCPS as: "information relating to a reasonably identifiable person who has a reasonable expectation of privacy. It includes information about personal characteristics such as culture, age, religion and social status, as well as their life experiences and educational, medical or employment histories." TCPS, Section 3, pg. 3.2.

Privacy Best Practices

Privacy Best Practices: 10 Elements

How to read these elements

These Best Practices are organized into a series of elements that should be considered in the design, conduct and evaluation of health research to address privacy and confidentiality concerns. These elements are not meant to represent a step-by-step process, since many of the elements are interdependent.

As noted in the Introduction, the TCPS and the laws of Canada are the minimum standard for protecting privacy and confidentiality in health research. To indicate the links between these Best Practices and the TCPS, and as another vehicle for promoting wider knowledge of that national Policy Statement, excerpts from TCPS are provided at the end of most Element sections. These are relatively short excerpts and do not include all text related to a particular topic. Readers are encouraged to use these excerpts merely as guides toward a more comprehensive review of the TCPS.[11]

In addition, concordance tables of selected privacy legislation are presented in the Appendix, organized by the corresponding Best Practice Element and by jurisdiction. These concordance tables are intended to supplement the Best Practices and should only be used as preliminary guidance. The application of the legal provisions in the tables to a particular research project must be determined in consultation with a legal advisor. In addition, any health professional belonging to a regulatory college has the responsibility of complying with that college's code of ethics.

In addition to the TCPS and applicable laws, CIHR-funded researchers conducting clinical trials intended for use in seeking regulatory approval for pharmaceuticals must review and be in compliance with the Food and Drug Regulations – *Division 5 Drugs for clinical trials involving human subjects, the ICH*[12] *Guidance E6: Good Clinical Practice: Consolidated Guideline* (ICH GCP), and other Health Canada guidance.[13]

Please note the distinction made in these Elements between a "research participant" and "data subject". In the Best Practices, a **research participant** is an individual who consents to participation in research and who is the subject of personal data or information collected for research. A **data subject** is an individual who is the subject of personal data/information collected for research purposes, but who has not been directly approached to provide consent.

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[11] The current version of the TCPS and information about its further evolution are accessible on the Interagency Advisory Panel on Research Ethics (PRE) web site at: http://www.pre.ethics.gc.ca/english/aboutus/aboutus.cfm.
[12] International Conference on Harmonization of Technical Requirements of the Registration of Pharmaceuticals for Human Use.
[13] These documents are accessible on the Health Canada Therapeutic Products Directorate website at: http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/drug_gcp_e.html. The Food and Drug Regulations, ICH GCP and further Health Canada guidance documents cover such privacy-related topics as the roles of investigators, industry sponsors and ethics review committees; informed consent of trial subjects; information to be collected from subjects; information to be included in the study protocol; access to trial records and data for quality assurance purposes; and record retention periods. The ICH GCP is also referenced in the TCPS – Section 7 – *Clinical Trials*, pg. 7.3.

ELEMENT #1: Determining the research objectives and justifying the data needed to fulfill these objectives

General statement

At the outset of the research design process, and as thoroughly as possible given the proposed research method, researchers should:

- identify and document research objectives and questions as a basis for determining what data will be needed;
- anticipate and document research questions related to the primary research objective, which might become relevant after the initial data analyses; and
- anticipate and document likely future uses of the data, including possible collaborations with other researchers or possible commercial uses.

1.1 Research study

For each research study, researchers should identify and document the specific research objectives and related research questions.

Researchers should also describe and justify the data needed to fulfill the research objectives and to answer any related research questions.

Example:

Research study: *Impact of ethnic group membership and age on health*

Study objectives: To examine and compare the health status, health care, and social involvement of distinct ethnic groups living in [region X of province Y], to inform policy development by community organizations and governments.

Research questions: (examples) What is the association between health status, experience of health care and ethnicity? What are the impacts of personal support networks and activity level on health status and perceived well-being?

Personal data needed and justification:
Initials: To assist in checking for duplicate records, using a combination of initials and demographic data.

Demographics (date of birth, gender, ethnicity…): Needed to make between-group comparisons on health variables by ethnicity, and between- and within-group comparisons by other demographic variables.

Physical health and sense of well-being/Use of health services: Needed to investigate and compare health status and perceived health status by health care-related knowledge, behaviours, attitudes and use.

Meaning of health and of aging: Needed to explore the meanings of health and illness and the cultural context of aging in the ethnic community.

Family and friends/Social activities: Needed to investigate the impact of family structure and interaction and environmental factors on measures of health and well-being.

1.2 Creation of a database for general research purposes

Define the scope and purpose of the database in a way that will be meaningful for REBs and any prospective research participants, even if the boundaries are at a relatively general level.

Even though all of the research studies that may use data from this database cannot be anticipated or explained in detail at the time the database is being created, try to describe the types of studies that could be undertaken.

In addition to the scope and purpose, describe what the database will not be used for. This is an opportunity to be as open and transparent as possible about the proposed research, and to reassure research participants and REBs that although future research purposes are not specified in detail, data management, storage and use will occur within a defined framework, including review and approval by an REB.

Describe the general types of personal data that are necessary for these general research objectives (e.g. diagnoses, risk factors, outcomes). Include data that are expected to be collected over the lifespan of the database, particularly if there will be multiple data collection periods per participant, or data that will be requested from secondary sources. Be as specific as possible.

Example:

Research database on disease X

Research objectives:
1. Compiling statistics on population trends in disease X and in its risk factors.
2. Conducting health and epidemiological research to improve screening and treatment programs for disease X.

Types of research questions (examples):
1. What is the association between disease X and risk factors such as diet, tobacco use, physical activity level, education, income or gender?
2. What is the risk of developing disease X after exposure to environmental risk factors, such as pollutants in the area of residence?
3. What is the cost-effectiveness and efficacy of screening programs for disease X?

Types of personal data to be collected over multiple collection periods	Research justification
Name, address, telephone number	Contact participants for further data collection
Demographic information	Assess other variables by demographics of the population
Family history	Disease X is known to have an inherited basis
Diet, reproductive factors, physical activity, anthropometric measures, education, income, gender	Assess risk factors for disease X
Medical conditions, medication use	Assess impact of other existing conditions on disease X and effectiveness of medications.

Limits on data uses (examples):
Access to data will be restricted to academic and health researchers with a primary purpose of public (non-commercial) benefit, for the purpose of research on disease X or related conditions. The database will be managed by an independent data stewardship committee[14] to ensure that the confidentiality of the information is maintained and access is controlled, consistent with the consents obtained from participants. Any future use of the data for new purposes will require approval by an REB.

[14] A data stewardship committee could be established to oversee and authorize future uses of the database in accordance with the research objectives. This committee could also assist in coordinating reviews by local REBs, in the case of multi-site studies. See Element #10, 10.2.4.

1.3 Advisory committee for defining the scope and strategic priorities of the research

If appropriate, setting up an advisory committee drawn from the scientific community, other relevant areas (such as ethics, policy, or information technology) and those affected by the condition or health event under study, can assist in defining the scope and strategic priorities for a research project in the context of both short and long-term initiatives.

Data stewardship tasks could be addressed by this advisory committee or by another body, as described in Element #10, 10.4.

Example:

Multi-year family-centered study on childhood condition X

Research objectives

1. Track and assess the factors that facilitate or hinder the development of family-centered provincial services for children with condition X and their family members.
2. Provide guidance to community organizations and provincial governments.
3. Validate questionnaire and interview methods for creating individualized family service plans.
4. Assess long term effectiveness and adverse effects of standard and emerging treatments for Condition X.

Setting the scope of research

- Initial partnership between the research team and Provincial Ministry of Children's Services results in agreement on key objectives.
- A Local Advisory Committee is established to assist in setting out the scope and strategic priorities for the research program, to review research progress, to facilitate the achievement of study objectives, and to assist with the dissemination of results; with representatives from the Ministry, provincial clinic for childhood condition X, two community advocacy groups for persons with condition X, and parent representatives.
- A National Project Advisory Committee with representation from provinces actively interested in this initiative meets annually to advance services to young children with condition X, and to plan and disseminate research findings.

1.4 Qualitative research using inductive data collection and analysis

It is important to recognize that all potential relevant and useful research questions cannot always be foreseen at the outset of a research project. For example, researchers using inductive methods of research may discover an "emergent" research approach through encounters with and in

collaboration with research participants. In such research, the development of research questions and procedures is an ongoing process. For example, open-ended interviewing often goes down avenues not anticipated leading to new questions and new approaches.

The wide range of methods in inductive approaches makes it difficult to document detailed and specific strategies for protection of privacy. Therefore, while planning their research, researchers should attempt to foresee both obvious and emerging issues related to privacy. These should be included in the submission to a research ethics board.

Researchers should also document for a research ethics board any amendments to the protocol and consequent privacy protection strategies emerging over the course of the study. For relatively junior researchers, mentorship can be especially helpful for ensuring adherence to REB requirements.

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Informing prospective participants of purposes]

Article 2.4 "...researchers or their qualified designated representatives shall provide prospective subject with the following: …(b)…"A comprehensible statement of the research purpose…" (pg. 2.5)

[Informing REBs of purposes]

Article 3.2 "…researchers shall secure REB approval for obtaining identifiable personal information about subjects. Approval for such research shall include such considerations as: (a) The type of data to be collected; (b) The purpose for which the data will be used;…" (pg. 3.3)

ELEMENT #2: Limiting the collection of personal data

General statement

Researchers should plan to collect personal data only as necessary for the research. The amount of personal information collected and the level of identifiability and sensitivity of this information should be restricted to what is necessary to achieve the research objectives.[15]

2.1 Personal data: Identifiability and sensitivity

2.1.1 Identifiability

Limiting data identifiability means minimizing as much as possible, the collection of:

- direct identifiers (e.g. name, street address) and
- other data items that could potentially be used to identify an individual.

Data identifiability can be characterized as being on a continuum, in which the division between degrees of "identifiability" are not always clear-cut. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the dataset contains sufficient information about the individuals concerned.

For example, data items that may increase the likelihood of an individual's identity being inadvertently revealed include:

- geographic location (e.g. location of residence, location of health event),
- named facilities and service providers,
- dates (e.g. date of an automobile accident),
- uncommon characteristics of the individual (e.g. a rare health condition or occupation), or
- highly visible characteristics of the individual (e.g. ethnicity in certain locales).

These types of data items, if needed for the research, should be collected at a minimum level of detail consistent with the research objectives.

[15] See the table of concordance for Element #2 in Appendix A-7 referring to the statutory provisions regarding the general requirement to collect a limited amount of personal information.

2.1.2 Sensitivity

The sensitivity of personal data is related to the potential for harm or stigma that might attach to the identification of an individual because of the nature of the information.[16] The type of information that an individual may consider sensitive could relate to:

- sexual attitudes, practices and orientation;
- use of alcohol, drugs, or other addictive substances;
- illegal activities;
- suicide;
- sexual abuse;
- sexual harassment;
- an individual's psychological well-being or mental health;
- some types of genetic information (e.g. information that predicts future illness or disability and raises concerns around future employability or insurability); and
- any other information that, if released, might lead to social stigmatization or discrimination.

Researchers should also be aware of information that communities may consider sensitive because, for example, of its potential to stigmatize a community.

2.2 Collection from individuals

2.2.1 Consider first whether individually identifiable data are needed, or whether non-identifiable data or aggregate data would serve the research objectives (e.g. data on individuals grouped by age or some other meaningful variable).

2.2.2 If identifiable data are needed to meet the research objectives, determine the minimum level of identifiability that will be needed.

Does the researcher need to do any or all of the following:

- Contact the research participant for follow-up data collection?
- Provide data, with consent, to a health care provider to ensure clinical monitoring of the participant?

[16] See TCPS excerpt (Article 3.3, explanatory note) at the end of Element #2.

- Return individual results to the participant?
- Conduct data linkage with a high degree of accuracy?

If yes, the researcher will likely propose the collection of direct identifiers.

If these are not requirements of the research, the researcher should not collect direct identifiers. However, other potentially identifying elements may be needed to answer the research questions and for other data management reasons, such as to check for duplicate records. The lowest level of identifiability of these other data items should be used, consistent with the research objectives.

Examples of reducing personal detail in specific data items collected:

Personal details	Most identifiable Least identifiable
Subject name • Full name • Partial name • Initials • Code • Blank **Age** • Birth day/month/year • Birth month/year • Birth year; Age at time of data collection • Age range (e.g. 5 or 10-year age groups) **Facilities and service providers** • Name of institution/provider • Specific type of facility, provider (university hospital, family physician) • Generic class (hospital, medical doctor)	**Location of residence** • Street address • 6-character postal code (e.g. one side of a city street; average of 15 households) • first 3 characters of postal code/Forward Sortation Area (average of 7,000 households) • first character of postal code (province or region: e.g. A= Nfld/Lab.; J = Que. West; K = Eastern Ont.) **Census area** • Block (an area equivalent to a city block bounded by intersecting streets; the smallest geographic area for which population and dwelling counts are disseminated) • Census enumeration or dissemination area (small area composed of one or more neighbouring blocks, used by Statistics Canada for distributing questionnaires to households and dwellings for the census collection) • Census subdivision (e.g. municipality, village) • Census agglomeration (urban core: min. 10,000 pop.) • Census metropolitan area (urban core: min. 100,000 pop.)

2.3 Secondary use

2.3.1 As in 2.2.1, consider whether aggregate data on groups of individuals would serve the research objective. If not, consider whether non-identifiable data relating to individuals would serve the purpose.

2.3.2 Removal or coding of direct identifiers

If identifiable data are required for the research purpose, direct identifiers should be avoided or concealed to the extent that is reasonably practical (e.g. as soon as a data linkage has been completed). Data without direct identifiers can be:

- coded to allow a trace-back to individuals, by means of:
  - single-coding (the researcher has the key to the code to link the research data back to direct identifiers, which are held separately); or
  - double-coding (an increased level of confidentiality protection over single coding because the data holder does not give the researcher the key to re-identify individuals); or
- without a code, if the capacity to trace the research data or results back to individuals is not required for the research purpose.

Even if the direct identifiers in shared data have been removed or coded, consider how to minimize the collection or sharing of potentially identifying data elements.

2.4 Inductive data collection

For inductive data collection, for example where open-ended interview techniques are used, the extent of personal data to be collected may not always be foreseeable in detail at the outset of the interview. In these cases, the ongoing negotiation of consent with research participants is the best way to ensure that the privacy of individuals and the community is being appropriately protected.

Definition of terms: Individual identifiability of data

Levels of data identifiability by capacity to identity or re-identify individuals
In rank order from most to least identifiable

1) Directly identifiable: The data contains direct identifiers of an individual (e.g. name, address, health number).

2) Coded:

i) **Single coded**: A participant's data are assigned a random code. Direct identifiers are removed from the dataset and held separately. The key linking the code back to direct identifiers is available only to a limited number (e.g. senior members) of the research team.

ii) **Double or multiple coded** Two or more codes are assigned to the same participant's data held in different datasets (e.g. health administrative data, clinical data, genetic samples and data). The key connecting the codes back to participants' direct identifiers is held by a third party (such as the data holder) and is not available to the researchers.

3) Not directly identifiable and not coded: Direct identifiers were never collected or have been deleted, and there is no code linking the data back to the individual's identity.

4) Non-identifiable: Any element or combination of elements that allows direct or indirect identification of an individual was never collected or has been removed, although some elements may indirectly identify a group or region. There is no code linking the data back to the individual's identity.

Summary guide: Levels of data identifiability needed for research-related purposes

Research-related purposes	Specific examples	Data requested for these purposes when:	
		Collecting data directly from individuals:	Requesting data for secondary use:
a) Contact individuals	Recruit individuals for a research project	Direct identifiers	Coded (Single coding is a more efficient mechanism for linking back to individuals than double-coding. Linking back becomes increasingly difficult for investigators who receive double or multiple-coded data, and therefore do not have the key to the code.)
	Contact the participant for follow-up data collection		
	Provide data, with consent, to health care provider for clinical monitoring of the participant		
	Return individual results to the participant		
b) Data linkage[17]	Conduct a data linkage with a high degree of accuracy	Preferred: Direct identifiers (e.g. name and street address; or personal health number)[18]	Preferred: Data holder conducts linkage and provides to researcher the linked dataset without direct identifiers. Data to be provided at the lowest level of identifiability needed, consistent with the research objectives.
	Conduct a data linkage with a measurable degree of accuracy sufficient for the particular research	Direct identifiers or potentially identifying data items (e.g. date of birth, initials, 3-character or full postal code, gender, specific health data)	
c) Data accuracy check	Eliminate duplicate records	Direct identifiers or potentially identifying data items	Coded data so that the data holder (preferred) or researcher can use the key to check direct identifiers for duplication
d) No contact with individuals and no data linkage needed		No direct identifiers need to be collected.	No direct identifiers. Data to be provided at the lowest level of identifiability needed, consistent with the research objectives.

[17] See also Element #8, 8.2.
[18] See the legal concordance table for Element #2 in Appendix A-7 regarding the collection of health numbers under Ontario's health privacy legislation.

LINK TO TRI-COUNCIL POLICY STATEMENT:

[REB approval of type of data]

Article 3.2 "..researchers shall secure REB approval for obtaining identifiable personal information about subjects. Approval for such research shall include such considerations as: (a) the type of data to be collected…" (pg. 3.3)

[Secondary use of data]

Article 3.3 "If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that: (a) identifying information is essential to the research…" (pg. 3.5)

Article 3.3 Explanatory text: "Databases can vary greatly in the degree to which personal information is identifiable. A proportionate approach should be applied by the REB to evaluate the sensitivity of the information in the database and to modulate its requirements accordingly. If it is impossible to identify individuals whose records exist within a database, then researchers should be allowed access to that database. The REB must carefully appraise the possibility of identification, in particular with regard to the extent of the harm of stigma that might be attached to identification. The REB and the researcher should also be aware of legal provisions that affect the database(s) to be used in the research.

REBs and researchers should also be sensitive to the context in which the database was created, such as a confidential relationship, as well as to the expectations of the groups or individuals at the time of the collection of the data with regard to its use, retention and disclosure. When it is unclear as to whether information is to be regarded as personal, researchers should consult their REBs. Confidential information collected in this manner should normally not be transmitted to authorities, unless required by law, the courts or similar legally constituted bodies." (pg. 3.5)

ELEMENT #3 : Determining whether consent from individuals is required

General statement

Voluntary and informed consent from legally competent individuals or authorized third parties is a fundamental principle in research involving humans, and specifically for the use of their personal data.[19]

Under specified circumstances, given a satisfactory rationale by the researcher, an REB may approve the waiver of a consent requirement, or a partial waiver of some elements of a consent requirement. According to TCPS Article 2.1(c), the REB must find and document that: "(i)The research involves no more than minimal risk[20] to the subjects; (ii) The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects; (iii) The research could not practicably be carried out without the waiver or alteration; (iv) Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and (v) The waived or altered consent does not involve a therapeutic intervention."

In addition to REB approval, disclosure of personal data for research without consent will be subject to other specific legal requirements in relevant jurisdictions.[21]

3.1 Collection from individuals

The requirement for consent from participants applies to research involving:

- Collection of personal (including genetic) information from persons (e.g. in face-to-face meetings, by mail, telephone or email).
- Procedures to screen for, prevent or treat disease.
- Medical examinations.
- Clinical trials of new drugs or other health care products. [22]

[19] See TCPS excerpts at the end of Element #3 regarding the definition of "competence" in the research context. See also the legal concordance table for Element #4-Part 2, Consent by Substitute Decision Makers, in Appendix A-7.
[20] For a definition of minimal risk, the TCPS states: "if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater that those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk" (TCPS Section 1, C1, pg. 1.5). For secondary use of information, the researcher must, among other conditions, have appropriate measures "to minimize harms to subjects" (TCPS Article 3.3 (b)).
[21] See the legal concordance table for Element #3 in Appendix A-7.
[22] As required under the Food and Drug Regulations and ICH GCP.

3.2 Direct collection and secondary use (Hybrid model)

When a research objective requires the collection of personal information directly from individuals to whom the data belong and subsequent linking to other sources to form a combined file, consent should be sought for both types of data collection at the time of direct contact with prospective research participants.

If the secondary use involves identifying individuals eligible to be invited into a study, the procedures under Element #6 are applicable. As described in Element #6, the preferred practice is for a data holder to assess the eligibility of individuals for a particular research project (e.g. on the basis of criteria provided by the researcher). The data holder would then make the initial contact with individuals to seek their permission for disclosure of contact information to a researcher or to inform them as to how to contact a researcher. An REB will need to determine if consent is required for this secondary use of data and for the contacting of individuals.

3.3 Secondary use

When personal data are to be collected from sources other than the individuals to whom the data relate, consent should be obtained from those individuals unless an REB determines that a waiver of consent is appropriate in the specified circumstances. These circumstances should include that a waiver of the consent requirement is permitted by law.[23]

For secondary use of data for research, an REB should consider the factors set out in the following table in determining whether a research proposal meets the requirements for waiver of consent. These factors, and their description in the table, expand on TCPS Article 2.1(c)(i)- (iii).

[23] For conditions in privacy legislation under which a waiver of the consent requirement may be permitted see the legal concordance table for Element #3 in Appendix A-7.

Factors to consider in determining whether a research proposal meets the requirement for waiver of consent		
	Factor	***Explanation***
3.3.1	Necessity of the personal data.	Personal data, in the proposed amount and at the proposed level of identifiability and sensitivity, are necessary to fulfill the research objectives. (See Element #2)
3.3.2	Harm-benefit analysis, where (1) the risk of harm is minimal, and (2) potential benefits of the research to the public and individuals outweigh any potential harm to research participants or data subjects.	1) The research should present minimal risk of harm to individuals and, if appropriate, particular groups or communities. In assessing potential harm, REBs should consider: • the probability of harm (related to the identifiability of data[24] and the adequacy of security measures)[25], and • the magnitude of potential harm (related to the sensitivity of data),[26] including potential: – physical injury; – emotional or psychological harm; – social harm (e.g. stigmatization); – financial harm (e.g. insurability, employability); – loss of trust; – harm from a perceived invasion of privacy, such as when a researcher has made secondary use of existing records with an REB waiver of the consent requirement, and then proposes to contact individuals for additional data collection; or – negative impact of the findings of the research. 2) Potential benefits of the research to individuals, groups, communities or the public outweigh potential harms. Where there is only minimal risk of harm, the REB need only ensure that there is public interest or other merit in the proposed research (e.g. as determined by a peer-review committee).[27]
3.3.3	A consent requirement being (1) inappropriate or (2) impracticable.[28]	1) Seeking consent from individuals may be considered **inappropriate** because: (a) there is potential harm to individuals from direct contact where there is: (i) a risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions (e.g. where

[24] See Element #2, 2.1.
[25] The REB should review and approve the researcher's proposed measures for safeguarding personal data. See also Element #7, Element #8, and Element #10, 10.2.3.
[26] See Element #2, 2.2.
[27] Note that the TCPS (Article 1.5 and explanatory text) states that REBs are normally to avoid duplicating previous professional peer-review assessments of the scientific merit of a research proposal unless there is a good and specified reason to do so. REBs may have specific criteria, set out in legislation, to take into account in assessing the potential benefits of research proposing to use health sector data without consent (e.g. the requirements set out in Alberta's *Health Information Act*, referenced in the legal concordance table for Element #3, in Appendix A-7.)
[28] See real world examples summarized in Appendix A-3, from *CIHR Secondary Use of Personal Information in Health Research: Case Studies* (November 2002), online at http://www.cihr-irsc.gc.ca/e/1475.html.

		making contact might reveal an individual's condition to others, against the individual's wishes; or research with minors, which would normally require parental consent, when the minors are street youth who have left home to escape abuse) or in certain circumstances (e.g. during a hospital emergency room visit); or (ii) a risk of creating additional threats to privacy by having to link otherwise usable coded data with identifiers in order to contact individuals to seek their consent; or (b) contact with individuals is not permitted under a previous data-sharing agreement, law or policy.[29] 2) Seeking consent from individuals for the use of their personal data may be considered **impracticable**[30] when there are difficulties in contacting or notifying individuals for reasons such as: • the size of the population being researched; • the proportion of prospective participants likely to have relocated or died since the time the personal information was originally collected; or • the lack of an existing or continuing relationship between prospective participants and the data holder who would need to contact them (e.g. a patient database that does not have a regular follow-up program to maintain a complete and accurate record of changes in registrants' contact information over time); such that: (a) there is a risk of introducing bias into the research because of the loss of data from segments of the population that cannot be contacted to seek their consent, thereby affecting the validity of results and/or defeating the purpose of the study; or (b) the additional financial, material, human, organizational and other resources needed to obtain consent could impose a hardship or burden on the researchers or organization so burdensome that the research could not be done.

[29] For legal prohibitions against contacting individuals see the legal concordance table for Element #6 in Appendix A-7. For an example of prohibitions against contact in policy, see CIHR *Secondary Use of Personal Information in Health Research: Case studies* (November 2002), Case Study #10, in which researchers investigating cancer screening services were unable to institute a consent process in part because of an existing policy which prevented physicians (who were the data holders) from contacting patients.
[30] These conditions are characteristic of much health services and population and public health research where whole populations (not specific individuals) are being studied.

3.3.4	Expectations of individuals.	In general, the expectations of a reasonable person in the circumstances should be taken into account (considering, for example, the nature of the research, the type of data to be collected and the context in which the data were originally collected). If individuals have previously objected to the secondary use of their data for research or to the use of their contact information, their directions should be respected.
3.3.5	Views of relevant groups.	Privacy concerns may extend beyond the individual to include well-defined groups or communities, e.g. remote communities and Aboriginal peoples.[31] Also, genetic information about individuals is more than **personal** information—it may also be intimate information about those who share a common genetic lineage—family members, other relatives and, in some cases, well-defined communities.[32] The REB may require that efforts be made to consult with family groups, Aboriginal peoples, community representatives, consumer associations, and/or special populations such as the homeless or under-housed, as appropriate, to address possible concerns of affected individuals and communities. These concerns may relate to the design and scope of the research, the recruitment of individuals, and the analysis and disseminations of results of research. This consultation process will be a high priority when dealing with controversial issues and/or individuals, groups or communities in vulnerable circumstances.
3.3.6	Legal requirements.	In addition to REB approval, access to personal data for research without consent will be subject to specific legal requirements in relevant jurisdictions. For example, some jurisdictions require some or all of the following: • a data-sharing agreement between the data holder and the researcher;[33] • notification and/or approval by other relevant oversight bodies;[34] and/or • agreement that personal data will not be used to contact individuals.[35]
3.3.7	Openness: Informing the public.	In the spirit of openness, the researcher should have an appropriate strategy for informing the general public about the research.[36]

[31] See TCPS Chapter 6-*Research Involving Aboriginal Peoples* (under review).
[32] See TCPS Article 8.1 for more on this topic.
[33] See Element #8; and the legal concordance table for Element #8, Part 2, in Appendix A-7 for legal references to data-sharing agreements for research purposes.
[34] As above.
[35] See the legal concordance table for Element #6 in Appendix A-7 for statutory prohibitions to contacting individuals.
[36] See also Element #10.

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Requirements for consent]

Article 2.1 "(a) Research governed by this Policy... may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation…

(c) The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent… or waive the requirement to obtain informed consent, provided that the REB finds and documents that: (i)The research involves no more than minimal risk to the subjects; (ii) The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects; (iii) The research could not practicably be carried out without the waiver or alteration; (iv) Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and (v) The waived or altered consent does not involve a therapeutic intervention." (pg. 2.1)

[Randomized clinical trials]

Article 2.1 "... (d) In studies including randomization and blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another." (pg. 2.1)

[Naturalistic observation]

Article 2.3 "REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility." Explanatory text: "Naturalistic observation is used to study behaviour in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observations generally implies that the subjects do not know that they are being observed, and hence cannot have given their free and informed consent...In considering research involving naturalistic observation, researchers and REBs should pay close attention to the ethical implications of such factors as: the nature of the activities to be observed; the environment in which the activities are to be observed (in particular, whether it is to be staged

for the purposes of the research); and the means of recording the observations (in particular, if the records will allow subsequent identification of the subjects). Naturalistic observation that does not allow for the identification of the subjects, and that is not staged, should normally be regarded as of minimal risk..." (pg. 2.5)

[Legal competence]

"Competence refers to the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent…It does not require prospective subjects to have the capacity to make every kind of decision. It requires that they be competent to make an informed decision about participation in particular research…The law on competence varies between jurisdictions. Researchers must comply with all applicable legislative requirements. Ethical consideration around research involving those who are not competent to give a free and informed consent on their own behalf must seek to balance (1) the vulnerability that arises from their incompetence with (2) the injustice that would arise from their exclusion from the benefits of research…" (pg. 2.9)

Article 2.5 "Subject to applicable legal requirements, individuals who are not legally competent shall be asked to become research subjects only when: (a) The research question can only be addressed using individuals within the identified group(s); and (b) Free and informed consent will be sought from their authorized representative(s); and (c) The research does not expose them to more than minimal risks without the potential for direct benefits for them." (pg 2.9)

Article 2.6 "For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met: (a) The researcher shall show that free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected. (b) The authorized third party may not be the researcher or any other member of the research team. (c) The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent. (d) When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation." (pg. 2.10)

Article 2.7 "Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual

concerning participation. The potential subject's dissent will preclude his or her participation." (pg. 2.10)

[Research with children]

"..the notion of harm applied to children should be understood differently from harm in adults. Harm induced in children may have longer-term consequences to their growth and development. Furthermore, harms and benefits for children with chronic disabilities and terminal illnesses require special consideration. Every researcher working with child subjects must consider the possibility of the children suffering pain, anxiety or injury, and must develop and implement suitable precautions and ameliorating measures. Cumulative physical, moral, psychological and social consequences (relevant to pain, anxiety and injury) should be reviewed by REBs when assessing the probability, magnitude and character of any harmful impact the research may have on the child." (pg 2.10)

[Secondary use of data]

Article 3.3 "If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that: (a) identifying information is essential to the research;(b) They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects; and (c) Individuals to whom the data refer have not objected to secondary use." (pg. 3.5)

Article 3.4 "The REB may also require that a researcher's access to secondary use of data involving identifying information be dependent on (a) The informed consent of those who contributed data or of authorized third parties; or (b) An appropriate strategy for informing the subjects; or (c) Consultation with representatives of those who contributed data." (pg. 3.5)

ELEMENT # 4: Managing and documenting consent

General statement

Consent is an ongoing process that begins upon first contact with prospective participants or authorized third parties, and ends only with the conclusion of their participation in the research or the use of their information. Participants should understand that their consent is voluntary, to be obtained without manipulation, undue influence or coercion, and can be withdrawn at any time.[37]

Evidence of initial and ongoing consent and the withdrawal of consent should be documented as appropriate for audit and legal purposes.

4.1 Forms of consent

4.1.1 Opt-in consent

The majority of research studies use an opt-in consent. Opting-in means that prior to the start of the research or data collection, informed individuals give clear indication that they voluntarily agree to participate in the research.

Opt-in consent can be indicated in writing (e.g. by signing a consent form), orally (e.g. in a face-to-face or telephone encounter with the researcher) or by conduct (e.g. by filling out and returning a questionnaire received by mail). Consent is only voluntary if it can be withdrawn at any time.[38]

4.1.2 Presumed consent with opt-out

Presumed consent with an opt-out mechanism should be used only when an REB considers prior opt-in consent to be inappropriate or impracticable.

A valid opt-out mechanism means that individuals have the opportunity at some time during the research or data collection process to give a clear indication (in writing or orally) that they do not want to be participants in the research or to have their data used in the research.

If individuals do not choose to opt-out of the research, their consent is presumed as long as they were given reasonable notice of the research and meaningful opportunity to opt-out.

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[37] See table of concordance for Element#4, Part 1, in Appendix A-7 for statutory references to the general consent requirement. Part 2 of the concordance table sets out the statutory references to consent by substitute decision-makers.

[38] Note that participants should understand what withdrawal of consent will mean to the use of their previously collected information and that non-identifiable data cannot be retrieved and withdrawn from the database.

Ranked forms of consent and associated conditions

Type of consent	Specific forms of consent	Required conditions for REB consideration
(i) Opt-in consent (preferred)	**Ways of opting in:** 1. Written (preferred) 2. Oral 3. Conduct (e.g. returning a questionnaire)	**All of the following:** • Voluntary. • Informed. • Unambiguous. • Obtained before beginning the research. • Consent can be withdrawn at any time, with a clear understanding of what that means, for example: – no further collection of additional data; – no further analyses using the already collected data; or, – removal of data from the database to the extent possible (Note: Non-identifiable data will be impossible to isolate and retrieve). • The process of consent to be documented by the researcher.
(ii) Presumed consent, with opt-out mechanism	Consent is presumed unless the person opts out **Ways of opting out:** 1. Written (preferred) 2. Oral	**All of the following:** • Voluntary. • Informed (e.g. through notices, brochures, letters, media announcements): – of the research – of the opportunity to opt-out – of the means of opting out. • Accessible means for opting out. • Opt-out may be done at any time before or during the research, with a clear understanding of what opting out means, for example: – no further collection of additional data; or – no further analyses using the already collected data; or, – removal of data from the database to the extent possible (Note: Non-identifiable data will be impossible to isolate and retrieve). • The process of opting-out to be documented by the researcher.

4.2 Documenting consent

4.2.1 Written documentation signed by the research participant (preferred)

Whenever appropriate and practicable, a written documentation of opting-in or opting-out of research is preferred. This should be documented using a consent form or refusal statement signed by the individual.

4.2.2 Oral consent documented by the researcher

Where oral consent is obtained for telephone interviews, where written documentation is culturally unacceptable, or where there are good reasons for not recording opt-in or opt-out in writing using a form that the participant signs, an oral procedure should be managed and documented, indicating that the opt-in or opt-out was conducted orally.

4.2.3 Documented consent and collection of data without direct personal identifiers

Collection of data without direct personal identifiers may be necessary or proposed when the research deals with highly sensitive conditions or activities. In such circumstances, consent should be documented but the identity of research participants should not be linkable to their data or to results of analyses.

Example: Oral consent and non-identifiable data and results

Disease X prevalence study among women undergoing abortion in City Y. Before undergoing therapeutic abortions, women must necessarily have a blood test.

Women who were scheduled for therapeutic abortions were approached in a hospital clinic about their willingness to participate in the study on Disease X. Those who gave oral consent to participate in this study agreed to fill out questionnaires (without providing their names) about certain risk factors for disease X, and to permit the testing of leftover blood from the blood test for the presence of disease X.

For each participant, the computer generated a specific scrambled code linking the blood sample for the disease test and the answers to the questionnaire. Once the results of the disease tests were linked to the corresponding questionnaire, the computer-generated code was removed. In this way, it was not possible to identify the research participants, even if one had used the same computer program to try to retrace the scrambled codes.

The linked information for each person was thus non-identifiable so that the researchers could look at risk factors and determine the incidence of disease X but could not identify any of the research participants.

Example: Documented consent and non-identifiable data and results

From a study on workplace injuries in nursing and laboratory staff

…The study questionnaire had no name or code number on it and participants were asked not to write their name on it. The cover letter from the researcher asked participants to fill out the questionnaire, put it in the provided envelope and return it through internal [staff] mail. The letter also asked participants to then sign a response card that had their name on it, put it in a separate envelope that was also provided and deposit it into slotted drop boxes located in each work area.

The researcher did not need to know the names of persons who had responded; it was the content of the responses that was of interest. The only identifying information required was on the response card in order to allow the researcher to send targeted reminder letters to those persons who had still not responded. In addition, general reminders to return the questionnaires were also posted in designated work areas in an effort to increase response rates.

To minimize the risk of linking questionnaire responses with the names provided on the response cards, the researcher picked up the cards regularly throughout the week and the questionnaires only once every week or two. Furthermore, no data were entered until the end of data collection to reduce the possibility of identifying late respondents. With this method, the researcher could not identify who had filled out each questionnaire, but she would know from the response cards who on the list had or had not returned a questionnaire.

In this study sensitive information could be revealed about those staff who had suffered an injury at work but who had not reported it, contrary to mandatory hospital reporting policies. Some respondents may not have reported injuries because they did not want to appear careless; others may have wished to avoid the fairly lengthy follow-up procedures required of persons with certain injuries. The researchers had anticipated that this might be the case and understood that this information would be considered quite sensitive. It was for this reason that the survey was conducted with no ability to link the data collected to individuals' identities.

4.3 Qualitative research

Participants in qualitative studies are especially vulnerable to unintended identification. For example, in quoting interviewees, biographical details may be revealed that make protecting identities difficult. Deleting all possible identifiers may rob the quote of its impact and research value. Changing names and places is not a guarantee that individuals' identities will be concealed.

Therefore, paying attention to the trust relationship between researcher and participant, and obtaining ongoing consent, are very important in qualitative research. Constant sensitivity to

participants' behaviour and reactions during data collection is essential. Unsolicited and unanticipated disclosures of information by participants can easily fall outside the original consent agreement.

As the interaction between a researcher and participants progresses, there may be situations where the researcher will need to recognize that participants should be given the opportunity to reiterate their consent, to withdraw from the research, or to withdraw their particular comments.[39] Thus, obtaining informed consent should be an ongoing negotiation.

4.4 Documenting non-participation or withdrawal of consent

The researcher may need information on who does not want to participate in research or who withdraws from research, for example to:

- document who is not to be included in follow-up research activities; and/or
- take into consideration relevant characteristics of the population not included in the study, when reporting possible bias in research results.

In these circumstances, researchers may obtain information about non-participants or those withdrawing consent only with:

- individuals' consent or
- the approval of an REB to waive the consent requirement in the particular circumstances.[40]

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Voluntary consent: No manipulation, undue influence or coercion]

Article 2.2 "Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion". Explanatory text: "...Undue influence may take the form of inducement, deprivation or the exercise of control, or authority over prospective subjects. Voluntariness is especially relevant in research involving restricted or dependent subjects, and is absent if consent is secured by the order of authorities or as a result of coercion or manipulation….REBS should also pay particular attention to the elements of trust and dependency, for example, within doctor/patient or professor/student relationships, because these can constitute undue influence

[39] See Element #5, 5.4.
[40] See Element #3.

on the patient to participate in research projects, especially those involving residents in long-term care facilities or psychiatric institutions…" (pg. 2.4)

Article 2.4 "… researchers or their qualified designated representatives shall provide prospective subjects with the following:.. (d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether to continue to participate.." Explanatory text:"..Articles 2.2 and 2.4(d) help to ensure that a prospective subject's choice to participate is voluntary. Pre-existing entitlement to care, education and other services shall not be prejudiced by the decision on whether to participate. Accordingly, a physician should ensure that continued clinical care is not linked to research participation, and teachers should not recruit prospective subjects from their classes, or students under their supervision, without REB approval. Nothing in this Section should be interpreted as meaning that normal classroom assessments of course work require REB approval…" (pg. 2.6)

[Evidence of consent]

Article 2.1 "…(b) Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented…" Explanatory text: "Free and informed consent… encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project. As used in this Policy, the process of free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research that involves themselves. " (pg. 2.1)

[Written and oral documentation]

Article 2.1 Explanatory text: "Article 2.1 (b) states the preference for written evidence of free and informed consent. The article acknowledges that written consent is not always appropriate. For most people in our society, a signed statement is the normal evidence of consent. However, for some groups or individuals, a verbal agreement, perhaps with a handshake, is evidence of trust, and a request for a signature may imply distrust. Nonetheless, in most cases a written statement of the information conveyed in the consent process, signed or not, should be left with the subject. In some types of research, oral consent may be preferable. In others, written consent is mandatory. Where oral consent is appropriate, the researcher may wish to make a contemporaneous journal entry of the event and circumstances. These and like elements may

sometimes need to be refined in concert with the REB, which plays an essential education and consultative role in the process of seeking free and informed consent. When in doubt about an issue involving free and informed consent, researchers should consult their REB." (pg. 2.2)

[Witness of signatures]

Article 2.4 Explanatory Text: "In some circumstances, having a witness to the signatures on the consent form may be felt to be appropriate. In law, the role of a witness is only to attest that the person actually signed the form; a witness is not responsible for certifying such factors as the signature being obtained under defined conditions or that the signers were competent. However, a court might subsequently seek the opinions of the witness on such issues". (pg. 2.8)

[Time allocation]

Article 2.4 Explanatory Text: "Rushing the process of free and informed consent or treating it as a perfunctory routine violates the principles of respect for persons, and may cause difficulty for potential subjects. The time required for the process of free and informed consent can be expected to depend on such factors as the magnitude and probability of harms, the setting where the information is given (e.g. hospital or home) and the subject's situation (e.g., level of anxiety, maturity or seriousness of disease)." (pg. 2.8)

[Translating materials]

Article 2.1 Explanatory text: "The requirement for free and informed consent should not disqualify research subjects who are not proficient in the language used by the researchers from the opportunity to participate in potential research. Such individuals may give consent provided that one or more of the following are observed to the extent deemed necessary by the REB, in the context of a proportionate approach to the harms envisaged in the research and the consent processes that are to be used: An intermediate not involved in the research study, who is competent in the language used by the researchers as well as that chosen by the research subject, is involved in the consent process; The intermediary has translated the consent document or approved an existing translation of the information relevant to the prospective subject; The intermediary has assisted the research subject in the discussion of the research study; The research subject has acknowledged, in his or her own language, that he or she understands the research study, and the nature and extent of his or her participation, including the risks involved, and freely gives consent…"

ELEMENT #5: Informing prospective research participants about the research

General statement

Researchers should provide to prospective participants or to authorized third parties disclosure of all information relevant to voluntary and informed consent.

As part of the consent process, the researcher or other appropriate person (depending on the approved recruitment procedure) should explain such things as the nature of the research, what information will be collected and how it will be used in this study and possible future studies, as well as the risks and benefits of the research, so that they can make an informed decision about whether they wish to participate.

Researchers must ensure that prospective participants are given adequate opportunities to ask questions, discuss their concerns and consider their participation.[41]

5.1 Understandable language

Information should be communicated to prospective participants in plain language, in oral and/or written form, so that it is easily understood.[42]

5.2 Reasonable time allocation

The amount of time taken to communicate information to prospective participants should be appropriate to the need, and should be neither excessive nor too brief. For example, the information could be layered, so that participants are given a one-page summary, a short consent form with headings corresponding to core elements (e.g. requirements of participation, right to refuse and withdraw), and more detailed information in an appendix. Participants should also be informed about how to obtain more details if desired (e.g. via a web site or a toll-free telephone number).

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[41] See table of concordance for Element #5 in Appendix A-7 for cross-reference to statutory provisions regarding notice/information requirements.

[42] According to the results of the international *Adult Literacy and Life Skills Survey* (2003), a joint project of the Government of Canada, the U.S. National Center for Education Statistics and the Organization for Economic Cooperation and Development, some 15% of Canadians, about one out of every seven, have problems dealing with printed materials and score at the lowest performance level in reading prose. From Statistics Canada, *The Daily,* Wednesday, May 11, 2005, reporting on *Learning a Living: First Results of the Adult Literacy and Life Skills Survey,* 2003 (89-603-XWE, free), available online at: http://www.statcan.ca/english/freepub/89-603-XIE/89-603-XIE2005001.htm

5.3 Communicating results back to research participants

5.3.1 Informing research participants about results specifically relating to themselves

During the consent process, the researcher should determine whether the participant wishes to be informed of any meaningful research results that specifically relate to them.[43] Also, there should be agreement on how any results relating to the participant will be communicated to the participant (e.g. whether the information will be provided first to a genetic counsellor or a health care provider).

5.3.2 Informing populations of general results and potential negative impacts

The results of research should be made public to contribute towards better understanding of the health issue under investigation. Researchers, particularly those in the areas of health services, population and public health, and genetics or genomic research, who study whole populations, should strive to communicate with the relevant population and governmental authorities regarding results that are pertinent to the improvement of health and/or the prevention of disease. Where appropriate, researchers, in collaboration with the population concerned, should facilitate the development and the implementation of a follow-up plan in response to the research findings.[44]

The population studied should be made aware of possible socio-economic discrimination or group stigmatization as a result of the research results, for example, due to perceptions of genetic risks. In the context of genetic research, the population should also be informed of the means taken to minimize the risks. To avoid misleading or unrealistic expectations, the researchers should make known the limitations of the research results and of their practical or potential application.[45]

5.4 Qualitative research

Researchers using qualitative methods may consider involving participants in the writing and reporting process, depending on the circumstances. For example, during the process of informing prospective research participants about the research, it may be appropriate:

- to provide participants with the opportunity to look at transcripts and to delete or footnote what they consider to be inaccurate or sensitive information (known as member-checking);

[43] When results of research tests are determined to be scientifically valid, have significant implications for the health of the participant, and prevention or treatment is available, these results should be communicated to the participant through his or her treating physician, unless the participant has chosen not to receive any results. In communicating results to the participant, particularly with respect to genetic research, the choices of each participant, the extent of available clinical services, the availability of counselling, and the implications for family members, should be taken into account (based on Quebec's Network of Applied Genetic Medicine (RMGA) *Statement of Principles: Human Genome Research* Version 2000, part IV *Professionalism*, part 3 Communication *of Specific Results*, pg. 12).
[44] Based on Quebec Network of Applied Genetic Medicine (RMGA) *Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations* (2002), Section 6, *Communication of Research Results*, pg. 3.
[45] As above.

- to ask participants if they wish to be publicly acknowledged in articles coming from the research; or
- to invite community leaders or representatives to help interpret the findings to their constituencies.

5.5 Providing information about privacy to prospective research participants

The following categories of information relating to privacy matters should be included in the information provided to prospective research participants:

Basic information	Explanation
1) Research objectives[46] and procedure	• Specific research objectives and related questions.
2) Data types and uses[47]	• Types of data to be collected and why. • Any planned or foreseeable commercial uses of the data. • If appropriate, a statement indicating whether test results are for research purposes only or if they can serve other non-research purposes (e.g. clinical care).
3) Voluntary basis for to participation[48]	• Voluntary basis for participation, and ongoing meaningful opportunities decide whether to continue. • Withdrawal, without any negative effect on a person's reasonable expectations of rights and benefits, being possible at any time (but be clear that data which have already been made non-identifiable cannot be retrieved and destroyed). • Option of contacting other family members to ask their willingness to be contacted by the researcher (e.g. in genetic research, participants should make first contact with related family members). • Circumstances under which the researcher may terminate the participant's involvement in the research (e.g. in clinical drug trials).
4) Risks, benefits, compensation	• Possible risks or discomforts to the research participant (including physical, emotional and psychological impacts, or privacy intrusion).

[46] See also Element #1.
[47] See also Element #2. We recognize that certain types of research may not be compatible with full disclosure of data to be collected, for example in some psychology research. This is an area that requires further reflection, and CIHR welcomes suggestions from those for whom these exceptions may apply.
[48] See also Element #4.

	• Benefits of the research in general and, if relevant, the benefits to the individual participant. • Any compensation offered to participants should not constitute an undue influence to agree to participate.[49]
5) Confidentiality and safeguards[50]	• Protection of data confidentiality (e.g. affirmation that genetic data will not be given to third parties) • General description of security measures (e.g. coding of data,[51] locked storage).
6) Data access and legal disclosure requirements[52]	• Who will have access to the data and for what purposes (include any legal requirements, such as mandatory public health reporting of certain diseases or obligation to produce evidence on court order; access required for scientific integrity such as auditing or verification of data; and any plans to archive or destroy the data).
7) Reporting of results[53]	• Explanation of the conditions, if any, under which personal results are to be reported back (e.g. results of genetic testing should normally be reported back to the participant through a physician and with provision of genetic counseling; conditions for informing implicated family members of research results should be clearly stated). • A clear statement, if relevant, of conditions under which results will not be given to the participant (e.g. exploratory research for which results are not clinically meaningful or community-based research where results are applicable only to the community). • Explanation of the impossibility for researchers to trace results from non-identifiable data back to individuals.
8) Data retention[54]	• Time period that data will be retained (e.g. provide a specified time period or, if for an extended/indefinite period, provide a specified time for REB review).
9) Inquiries and complaints[55]	• Who is available to answer questions about the research. • Who to contact about the ethics of the research. • Who to complain to about the research. • Who to contact if the participant decides to withdraw consent.

[49] TCPS states that " undue influence may take the form of inducement, deprivation or the exercise of control or authority over prospective subjects." (TCPS Article 2.2, pg. 2.4)
[50] See also Element #7.
[51] See Element #2, 2.3.2 and Box- Definition of terms.
[52] See also Element #8.
[53] See also Element #8.
[54] See also Element #9.
[55] See also Element #10.

5.6 Collection from individuals and secondary use (Hybrid model)

For a hybrid project involving the direct collection of data from individuals and secondary use of data from other sources, the prospective research participant should also be informed of:

- all expected types and sources of personal data to be accessed and used;
- any expected linkages; and
- the expected purposes for which data will be used (e.g. health survey data to be collected and linked, with consent, to health records to investigate health care use in the population).

5.7 Creation of a database for general research purposes

5.7.1 Information to be provided at time of collection

When personal data are to be entered into a database for multiple research uses over an extended period, research participants should also be informed, at the time of collection, of the following:

Basic information	Explanation
1) Expected types of studies	• The type of studies that might be conducted, with possible examples (e.g. research on cardio-vascular disease).
2) Expected data types and purposes	• The types of data to be collected from all sources including data linkages, and for what research purposes.
3) Expected commercial uses	• Any anticipated commercial uses.
4) Data retention period	• For how long the data will be retained (if for an extended/indefinite period, provide a specified time for REB review).
5) The process for overseeing the use and security of data	• The process being implemented to ensure proper data stewardship and data security, including: – the main rules governing future uses of the database; – the process by which requests for data access will be reviewed and monitored; and – the organization or persons to whom the researcher is accountable for the proper management of the data.

6) Authorization for future uses, with or without re-contact	• Options for the participant to control future uses of personal data in the database. These options should include the opportunity to withdraw consent (and any identifying information) in the future, and may also include the options: – To be re-contacted on a regular (or as needed basis) to seek consent for new research uses of the data, if desired and practicable; and/or – To not be re-contacted, but to authorize the researchers to use the data only in certain ways in the future, for example: ◦ only for certain research purposes (to be determined with the participant during the consent process); ◦ only for the original broad purposes for establishing the database; ◦ for any purposes as long as a research ethics board has approved the proposed research; ◦ at what level of identifiability (e.g. with or without direct identifiers, coded, or in non-identifiable form):[56] and ◦ with or without linkages to other data sources (e.g. with controls over what can be linked, and who can access the linked data).

Example: Informing participants and presenting options for control of new uses of data

The invitation to participate in the study is made by a dedicated nurse coordinator employed by, and accountable to, the participating hospital. The nurse coordinator arranges, at a convenient time for the patient (and his/her family), to explain the study and seek the patient's consent to participate. Patients can refuse or can agree to any or all of the following:

- Access to their current hospitalization records by the nurse coordinator to collect information relevant to their condition, for future research uses.
- A follow-up telephone call by the nurse coordinator 6 months after the onset of their health event to determine longer-term changes in their functional ability—this survey information is also intended for inclusion in the registry for future research purposes.
- Linkage of their data in the study database, with administrative files from the provincial Ministry of Health, and other sources such as laboratory and physician records, in order to collect information about physician and laboratory services, subsequent hospitalizations,

[56] See Box – *Definition of terms: Individual Identifiability of Data*, in Element #2.

and causes of death. The linked data will be used for research on the use of health care services and effects on health for patients with condition X; and

- Use of their non-identifiable records in future analyses performed at the independent not-for-profit research organization based in City Y. The results of these analyses are to be released in aggregate form to third-party private companies seeking to improve services and products related to condition X.

5.7.2 Promotion of openness and accountability[57]

Researchers should endeavour to keep participants informed of future data uses through continuing means (e.g. web site information), as part of an ongoing commitment to openness and to the maintenance of informed consent.

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Information to be provided to research participants]

Article 2.4 "Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researchers must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1 (c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

(a) Information that the individual is being invited to participate in a research project;

(b) A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;

(c) A comprehensive description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

[57] See Element #10, 10.2.1

(d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether to continue to participate; and

(e) The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors." (pg. 2.5, 2.6)

"..REBs may require researchers to provide prospective subjects with additional information, such as that detailed in Table 1..." (pg. 2.6)

"Table 1: Additional Information that may be required for some projects

1. *An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation;*
2. *The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;*
3. *Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;*
4. *An indication of who will have access to information collected on the identity of subjects, description of how confidentiality will be protected, and anticipated uses of data;*
5. *An explanation of the subject's responsibilities;*
6. *Information on the circumstances under which the researcher may terminate the subject's participation in the research;*
7. *Information on any costs, payments, reimbursement for expenses or compensation for injury;*
8. *In the case of randomized trials, the probability of assignment to each option;*
9. *For research on biomedical procedures, including health care interventions: information about (a) forgoing alternative procedures that might be advantageous to the subject; (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and (c) particularly in trials of therapeutic interventions, the care provided if the potential subject decides not to consent to participation in the study;*
10. *The ways in which the research results will be published, and how the subjects will be informed of the results of the research." (pg. 2.7)*

[Genetic counseling]

Article 8.4 "Genetics researchers and the REB shall ensure that the research protocol makes provision for access to genetic counseling for the subjects, where appropriate." Explanatory note: "Genetic counselors who are formally trained to impart genetic information have two main roles in dealing with a family: The first is to educate regarding the condition in question, and the second is to counsel by presenting options or possible action scenarios in a non-directive manner. The complexity of genetic information along with its social implications usually requires that free and informed consent be supplemented with genetic counseling." (pg. 8.4)

[Conditions for less than full disclosure]

Article 2.1 Explanatory text: "... the REB should exercise judgment on whether the needs for research justify limited and/or temporary exception to the general requirements for full disclosure of information relevant for a research subject's meaningful exercise of free and informed consent. In such cases, subjects may be given only partial information or they may be temporarily led to believe that the research has some other purpose because full disclosure would likely colour the responses of the subjects and thus invalidate the research. For example, social science research that critically probes the inner workings of publicly accountable institutions might never be conducted without limited recourse to partial disclosure. Also some research in psychology seeks to learn about human responses to situations that have been created experimentally. Such research can only be carried out if the subjects do not know in advance about the true purpose of the research...Another scenario, in questionnaire research, embeds questions that are central to the researcher's hypotheses within distractor questions, decreasing the likelihood that subjects will adapt their responses to their perceptions of the true objective of the research. For such techniques to fall within the exception to the general requirements of full disclosure for free and informed consent, the research must meet the requirements of Article 2.1 (c)..." (pg. 2.2- 2.3)

[Secondary uses]

Article 3.2 Explanatory text: "It is essential that subsequent uses of data be specified in sufficient detail that prospective subjects may give free and informed consent; it is inappropriate to seek blanket permission for "research in general". (pg. 3.4)

ELEMENT #6: Recruiting prospective research participants

General statement

To recruit research participants, the researcher will typically need to complete the following steps, each of which involves the researcher or another more appropriate person having access to personal information:

Step A: Assess eligibility criteria for the research and assemble a list of eligible individuals.

Step B: Establish initial contact with eligible individuals.

Step C: Inform eligible individuals about the research, as part of the informed consent process.

The proposed recruitment procedure and materials should be included in the submission for REB approval.

The procedure and materials should foster conditions for voluntary consent, and not exert undue influence on prospective participants to agree to take part in the research.[58]

Initial contact with individuals about a research project should be made by someone that individuals would expect to have relevant information about them, or in other ways that do not inappropriately intrude on their life or privacy.

If permitted by law[59] and subject to REB approval, the data holder who would normally have access to the required personal information is the preferred person to access that information to assess eligibility of individuals for the research (Step A) and to make initial contact with those individuals (Step B), unless the REB considers this approach to be impracticable or inappropriate.

Typical scenarios for recruiting participants and preferred approaches are described under 6.3.

[58] See also Element #4 regarding managing and documenting the consent process.
[59] See the legal concordance table for Element #6 in Appendix A-7.

6.1 Consent and secondary use of personal information to assess eligibility and contact individuals

The REB will need to determine if consent from individuals is required for the secondary use of their personal information for assembling a list of eligible individuals for research or contacting these individuals to seek their consent for participation.[60] Researchers and REBs should be aware of any legal restrictions on contacting individuals in these circumstances.[61]

6.1.1 Anticipating future uses of personal information at the time of the original collection

Wherever possible at the time of the original collection of personal information from individuals, the researcher and/or data custodian should anticipate the future uses of this information to assemble eligibility lists for research or to contact eligible individuals, and should seek consent for these future uses at that time.

For example, patients could be asked at the time of the original collection of their personal information whether they consent to the health care provider reviewing their records and contacting them to inform them of research for which they are eligible. If such a prior opt-in consent procedure is not a practicable option, a health care provider could inform patients through notices that their personal information may be reviewed from time to time for recruitment purposes, and that they have the opportunity to opt-out. If patients do not opt-out, their consent for the use of their personal information to assess their eligibility for research or to contact them about the research project would be presumed.

6.2 Initial contacting and informing prospective participants

6.2.1 Trust vs. undue influence

Recruitment raises complex issues around who is the appropriate person to make initial contact and inform eligible individuals about the research. On the one hand, individuals may feel more comfortable if approached by a data holder, such as a clinic physician or nurse, whom they trust and accept as having access to their personal information. On the other hand, individuals may be unduly influenced to agree to participate in research if approached by someone on whom they are dependent, for example, their employer, health provider, community leader or program director.

In some cases, someone who has a relationship of some influence over prospective research participants may be the preferred person to contact individuals and inform them of the research

[60] See Element #3 regarding determining if consent is required.
[61] See the legal concordance table for Element #6 in Appendix A-7.

where this is considered the best way to ensure that prospective research participants fully understand the risks and the benefits of the research to themselves. For example, a health care provider or professional (who may or may not be involved in the research) may be the preferred person to contact individuals and inform them about the research because of a relationship of medical confidence, special expertise and/or in-depth knowledge of the patients' situations. It is critical in such cases that the participants are reassured that their reasonable expectations of care will be met whether or not they take part in the research.[62]

6.2.2 Prior communication

Researchers should avoid situations where eligible individuals are not aware, prior to being contacted, of information about themselves that makes them eligible for participation in the research. For example, a health care provider may not yet have informed the patient of a diagnosis (e.g. cancer) that is in the patient health record and that is used to determine eligibility. The researcher should confirm with the data holder that individuals have been informed of relevant health-related information before initiating contact.

6.3 Selected scenarios and preferred recruitment practices

Index to recruitment scenarios

6.3.1 Scenario: ■ Eligible research participants are in a city telephone directory.

6.3.2 Scenario: ■ A research team proposes to recruit research participants from members of an Aboriginal community.

6.3.3 Scenario: ■ A genetics researcher proposes to recruit the family members of research participants.

6.3.4 Scenarios: ■ The researcher has access to personal data from prior research studies. ■ The research unit of a hospital is proposing to conduct research on patients. ■ The researcher is the health care provider of eligible individuals.

6.3.5 Scenario: ■ The researcher is external to the data-holding organization, and is submitting a proposal to conduct research on patients, employees or students of the organization.

6.3.6 Scenario: ■ A clinician-researcher at a health care facility wants to conduct research on patients being treated by another physician in the same facility. ■ An academic wants to conduct research on students in his or her university department or program, but not in a class that he or she is currently teaching.

[62] See also TCPS Article 4.1 and Section 4-A *Conflicts of Interest Involving Researchers* (pg. 4.1); TCPS Section 7-*Clinical Trials*; and TCPS Articles 7.1, 7.2 and explanatory text regarding recruitment and informed consent (pg. 7.2).

6.3.1 Scenario: ■ Eligible research participants are in a city telephone directory.

When eligibility information and the means of notifying individuals about the research are publicly available, the researcher should normally be able to make the initial contact without needing an intermediary.

6.3.2 Scenario: ■ A research team proposes to recruit research participants from members of an Aboriginal community.

As a general rule, researchers planning to work in a community should make contact with and inform community leaders and groups relevant to their research, prior to initiating the recruitment or informed consent process with members of that community.

For many Aboriginal communities and groups, approval by local authorities may be required prior to beginning the recruitment of research participants.[63]

6.3.3 Scenario: ■ A genetics researcher proposes to recruit the family members of research participants.

For the purpose of recruiting relatives for genetic or genomic research, there should be no direct contact between the researcher and the family members of the initial research participant. In order to respect the privacy of the participant and his family, only the participant or his/her spouse or a designated family member should contact other family members to ask their willingness to be approached by the researcher. The principal researcher (or a member of the research team) should not directly contact the family.[64]

6.3.4 Scenarios: ■ The researcher has access to personal data from prior research studies. ■ The research unit of a hospital is proposing to conduct research on patients. ■ The researcher is the health care provider of eligible individuals.

In these scenarios, the researcher is the data holder or is employed by the data holder. If permitted by law[65] and subject to REB approval, the data holder may assess the eligibility of individuals for the research.

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[63] TCPS Section 6 (*Research Involving Aboriginal Peoples)* is currently under review, coordinated by the Interagency Advisory Panel on Research Ethics and including CIHR Aboriginal health research guidelines (in development). See also the articulation of First Nations' principles: *Ownership, Control, Access and Possession (OCAP) or Self-determination Applied to Research*, online at: http://www.research.utoronto.ca/OCAP%20principles.pdf.

[64] Based on Quebec Network of Applied Genetic Medicine (RMGA) *Statement of Principles: Human Genome Research* Version 2000-Section 3 (pg. 7).

[65] Where this access would be a secondary use of data, see 6.1. The data holder's access to data for recruitment purposes must be in accordance with applicable legislation. See the legal concordance table for Element #6, Appendix A-7.

The data holder should have rules nevertheless to limit the number of people permitted access to data for this purpose.[66]

Preferred options for **contacting** individuals will depend on whether the REB considers that the researcher/data holder has undue influence over prospective research participants (see the Options table).

Options for contacting individuals according to whether the researcher/data holder has influence over prospective research participants

Option	Contacting prospective research participants
A) If the researcher/ data holder **is not** in a position of undue influence.	If the researcher/data holder **is not** in a position of undue influence over prospective participants with regard to the research, the researcher should make the initial contact and inform prospective participants about the research, if permitted by law and subject to REB approval.
B) If the researcher/ data holder **is** in a position of undue influence.	In some cases, the researcher/data holder **is** considered to potentially be in a position of undue influence over eligible individuals with regard to the research or there is a potential conflict of interest. For example, an REB may decide that patients who will be recruited for a clinical trial being conducted by their health care provider may not understand the difference between the research treatment and the standard treatment provided at the health centre. In such cases, initial contact with prospective research participants should be made by neutral means, so that there is no undue influence exerted on individuals to participate. For example, a neutral person on the research team or in the data holder's agency who is not in a position of authority over prospective research participants, could contact eligible individuals. Alternatively, it may be possible to make initial contact with eligible individuals by advertising in newspapers or in public locations, and then having a neutral member of the research team or staff provide further information to interested individuals.

[66] See also Element #8.

6.3.5 Scenario: ■ The researcher is external to the data-holding organization, and is submitting a proposal to conduct research on patients, employees or students of the organization.

In this scenario, the researcher is not the data holder, and does not have undue influence over prospective research participants. If permitted by law,[67] the preferred recruitment approach is for the data holder to assess eligibility for research and to make initial contact with eligible individuals, unless the REB considers that the preferred approach is impracticable or inappropriate (see the ranked Options table).

Ranked options for assessing eligibility and contacting prospective participants, when the researcher is not the data holder and does not have undue influence

Option	Assessing eligibility and contacting prospective research participants
A) The data holder assesses eligibility and makes initial contact. (Preferred)	If permitted by law and subject to REB approval, the data holder should determine eligibility of individuals for the research on the basis of criteria provided by the researcher. The data holder should make the initial contact to: (i) inform eligible individuals about the research so that they can contact the researcher, if interested, or (ii) to seek consent from individuals to release their nominal information to the researcher who will contact them to inform them about the research.
B) If the REB considers option A impracticable or inappropriate, the REB may permit the researcher to access minimal personal information for assessing eligibility and/or making contact with eligible individuals, if permitted by law and under strict controls (e.g.	In some cases, the preferred option above may be considered impracticable or inappropriate. For example, the preferred option may be impracticable if: • the data holder does not, despite funding from the researcher, have the resources to assess eligibility and make initial contact, and therefore the research could not proceed unless an alternative recruitment procedure is used; or • the data holder does not have an ongoing relationship with eligible individuals to make contact (e.g. as may the case for a registrar of a population records database, or a government agency holding health insurance registration and billing information). The preferred option may be considered inappropriate where the data holder has undue influence over eligible individuals; professional or

[67] See the legal concordance table for Element #6, Appendix A-7.

access restricted to data holder's site).	other legal requirements makes the data custodian's involvement in the recruitment process inappropriate; or the data holder's contacting of eligible individuals would defeat the purpose of the research.[68] When the preferred option is impracticable or inappropriate, an REB may consider whether a researcher should be permitted access to minimal personal data only for the purposes of determining eligibility for the research or contacting individuals to invite them to join the study[69]. If it is legally permissible and the REB gives approval, the researcher may be given access to personal information with appropriate confidentiality protections such as a signed confidentiality agreement with access restricted to the data holder's site, and use limited to the stated purpose. Minimal personal data provided to the researcher should normally contain only contact information and no other personal information related to health status. However, if health-related data are inherent in the eligibility criteria used to assemble the list of individuals to be contacted, an REB may determine that camouflage sampling or other masking techniques should be used to enable researchers to contact individuals while preventing researchers from viewing any identifiable health-related information of eligible individuals prior to gaining consent.[70]

Option A: Examples of recruitment methods:

Health professional society makes contact with members

Prospective research participants are members of a health professional society. The Society mails out a letter (drafted by the researcher) to its members, which explains how to contact the researcher to learn more about the research.

Health professionals assess eligibility and make contact

Given the criteria provided by the researchers, pharmacists are automatically notified by a computer flag in a centralized database, at the time of filling a prescription, of any patient eligible

[68] For example, see Case Study #10 in CIHR's *Secondary Use of Personal Information in Health Research: Case Studies*, November 2002 in which initial contact by physicians of "hard-to-reach" patients would have confounded the results of the study which was investigating effective strategies for contacting patients. Also, because this study involved contacting patients about visiting their physicians for cancer screening services, physicians' involvement in the research was limited by a policy that existed at that time which prevented them from soliciting patients to come in for services.
[69] The REB should weigh the benefits of the research and the potential for a perceived invasion of privacy and any legal prohibitions against researchers' contacting individuals. See Element #3, 3.3.2 (b). See also the legal concordance table for Element #6, in Appendix A-7.
[70] See references to *Camouflage* techniques in the following: Element #7, 7.2.2 4th bullet; and the Glossary, Appendix A-6.

for the research study (e.g. receiving a certain number of concurrent medications). This automatic flag of eligible individuals for the study is visible only to pharmacists in participating pharmacies. Once the eligible persons are identified, the pharmacists seek consent from these individuals to release their contact information to the researcher.

Option B: Examples of recruitment methods

Researcher assesses eligibility and makes initial contact for data holder

Hospital administrators do not have the personnel necessary to search through files in order to identify potentially eligible research participants according to selection criteria provided by the researcher, or to establish prior contact with these individuals on behalf of the researcher. Therefore, with the approval of the REB and a signed undertaking of confidentiality by the researcher, hospital administrators provide the researcher with the names of staff, their work location and full or part-time status, in the form of a computer file. The researcher then uses the computer file to exclude staff that do not fit the eligibility criteria and to select a random sample of eligible staff. Senior hospital staff explain the study in general terms to their staff members and inform them that the researcher will be writing in the near future to individuals eligible to be included in the study. Senior staff emphasize that participation is on a purely voluntary basis. Accordingly, the researcher sends letters of invitation to participate in the research only to eligible staff members.

Data holder assesses eligibility and provides camouflaged list to researcher to make initial contact

The study is approved by the REB and the privacy branch of the Ministry of Health. Ministry of Health staff produces a "camouflaged" list of patient names for the researchers, containing scrambled personal health numbers of patients potentially affected by a new health care policy with scrambled numbers of a random sample of patients who are not affected by the policy. When the scrambled numbers are unscrambled and converted to names, addresses and telephone numbers by the Ministry of Health's Client Registry, the health status of each patient remains unknown to the researchers and to the Ministry of Health staff. The addition of persons not affected by the health condition prevents the researchers from knowing who is affected and who is not; only those who respond are identified. In order to be most effective, camouflaging should aim to protect the privacy of targeted patients, while limiting the total number of patients who need to be contacted.

6.3.6 Scenario: ■ A clinician/researcher at a health care facility wants to conduct research on patients being treated by another physician in the same facility. ■ An academic wants to conduct research on students in his or her university department or program, but not in a class that he or she is currently teaching.

In these scenarios, the researcher is not the data holder, but does potentially have undue influence over prospective participants with regard to the research.

Preferred approaches to assessing eligibility for research and contacting eligible individuals will depend on whether the REB considers the data holder to have undue influence over prospective research participants (see the Options table).

Options for assessing eligibility and making contact with individuals when the researcher has undue influence over prospective individuals

Option	Assessing eligibility and contacting individuals
A) If the data holder **is not** in a position of undue influence.	If the data holder is not in a position of undue influence over prospective research participants, the REB may permit the data holder to assess eligibility and make the initial contact with these individuals, if the data holder is permitted to do so by law (see scenario 6.3.5, option A).
B) If the data holder **is** in a position of undue influence.	If the data holder is considered by an REB to have undue influence on prospective participants, the researcher could make initial contact with eligible individuals by neutral means such as by putting up notices in public areas of the facility or institution with information on how to contact the research team, and a neutral member of the research team or staff could inform interested individuals about the research (see scenario 6.3.4, option B).

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Secondary use of data for prospective collection]

Article 3.5 "Researchers who wish to contact individuals to whom data refer shall seek the authorization of the REB prior to contact." Explanatory text: "In certain cases, the research goal may only be achieved by follow-up contact and interviews with persons. It is evident that individuals or groups might be sensitive if they discover that research was conducted on their data without their knowledge; others may not want any further contact. This potential harm underlines the importance for researchers to make all efforts to allow subjects the right to consent that their data and private information be part of a study." (pg. 3.6)

ELEMENT #7: Safeguarding personal data

General statement

Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards. Data security safeguards should include organizational, technological and physical measures.[71]

Researchers should take a risk assessment and management approach to protecting research data from loss, corruption, theft or unauthorized disclosure, as appropriate for the sensitivity and identifiability of the data. Formal privacy impact assessments (PIAs) are required in some institutions and under legislation or policy in some jurisdictions.[72]

REBs should review and approve researchers' proposed measures for safeguarding any personal data to be collected.

The safeguards described in this Element are particularly relevant to research conducted within large institutions or other organizations. However, smaller scale projects should also demonstrate acceptable ways of protecting the confidentiality of data.

7.1 Threat-risk vulnerability assessment[73]

A vulnerability assessment assists researchers and institutions in determining an appropriate level of security for research data and the means by which the data should be received, used, stored, and managed. The following are the main steps in a vulnerability assessment:

Assessment	Examples
a) Determine what assets need to be protected	• Databases and files of personal and other confidential data • Database management software • Computer hardware, fax machines
b) Determine what to protect against	• Five main classes of threats are: disclosure, interruption, modification, destruction and removal or loss

[71] See the table of concordance for Element #7, Part 1, in Appendix A-7, for statutory references to general safeguarding obligations.
[72] See the legal concordance table for Element #7, Part 2, in Appendix A-7.
[73] Adapted from RCMP *Security Information Publication 5, Guide to Threat and Risk Assessment for Information Technology*, November 1994. Online at: http://www.rcmp-grc.gc.ca/tsb/pubs/it_sec/g2-001_e.pdf.

Assessment	Examples
c) Assess the probability of the threat occurring	• Low, medium or high
d) Assess the magnitude of the impact and consequences of the threat if it occurs	• Loss of public trust • Harms to individuals (loss of privacy or trust; social stigmatization; social discrimination affecting financial, employment, insurance, or other status; loss of benefits) • Loss of data or equipment.
e) Assess existing safeguards and need for additional safeguards	• Direct identifiers are separated from personal records as soon as reasonably practicable • Highly identifiable and sensitive data are stored at the highest level of security, e.g. on stand-alone servers. • Pledge of confidentiality signed by all research staff.
f) Recommend the appropriate security safeguards to protect the assets from threats	• See security measures proposed in 7.2 below
g) Update and regularly review these safeguards (at least annually)	• Respond to changes in: – the internal technological environment (including improvements in security strategies), – the research project and the institution, – technologies available to threat agents and – the profile of potential threats.

7.2 Security measures

7.2.1 Organizational safeguards

- There should be ongoing commitment to privacy and continued emphasis of its importance by all involved in the research and the institutional/organizational management.
- All involved in the research project should be subject to a pledge of confidentiality.
- Access to personal information should be strictly limited in terms of numbers of persons, for legitimate purposes, and strictly on a realistic need-to-know basis.

- Data-sharing agreements between the researcher/institution and all involved should be signed prior to providing any access to data.
- Consequences for breach of confidentiality, including dismissal and/or loss of institutional privileges, should be clearly stipulated.
- Institutions and organizations housing research projects and archived data should, with ongoing commitment of adequate resources:
  - develop, monitor and enforce privacy and security policies and procedures;
  - appoint privacy officers and create data stewardship committees as needed; and
  - implement internal and external privacy reviews and audits.

7.2.2 Technological measures

- Encryption, scrambling of data and other methods of reducing the identifiability of data should be used to eliminate unique profiles of potentially identifying information.
- Direct identifiers should be removed or destroyed at the earliest possible opportunity.
- If direct identifiers must be retained, they should be isolated on a separate dedicated server/network without external access.
- Camouflage sampling[74] or other techniques should be used, when appropriate, to prevent researchers from viewing health-related information of eligible individuals prior to gaining their consent.
- Authentication measures (such as computer password protection, unique log-on identification, etc.) should be implemented to ensure only authorized personnel can access data.
- Special protection for remote electronic access to data should be installed.
- Virus-checking programs and disaster recovery safeguards such as regular back-ups should be implemented.
- Where possible, a detailed audit trail monitoring system should be instituted to document the person, time, and nature of data access, with flags for aberrant use and “abort” algorithms to end questionable or inappropriate access.

[74] See the Glossary in Appendix A-6 for the definition of *Camouflaged Contacting*.

7.2.3 Physical security

- Computers and files that hold personal information should be housed in secure settings in rooms protected by such methods as combination lock doors or smart card door entry, with paper files stored in locked storage cabinets.
- The number of locations in which personal information is stored should be minimized.
- Architectural space should be designed to preclude public access to areas where sensitive data are held.
- Routine surveillance should be conducted.
- Physical security measures should be in place to protect data from hazards such as floods or fire.

LINK TO TRI-COUNCIL POLICY STATEMENT:

Article 3.2 Explanatory Text: "Researchers should ensure that the data obtained are stored with all the precautions appropriate to the sensitivity of the data…Accordingly, information that identifies individuals or groups should be kept in different databases with unique identifiers. Researchers should take reasonable measures to ensure against inadvertent identification of individuals or groups, and must address this issue to the satisfaction of the REB." (pg. 3.4)

ELEMENT #8: Controlling access and disclosure of personal data

General statement

Data sharing for research purposes- whether of linked or unlinked data sets- is an important way of enabling socially valuable research. It avoids unnecessary duplication of data collection, which reduces the burden on research participants and permits researchers to use limited or scarce resources more productively.

However, there should be strict limits on access to data and secure procedures for data linkage, subject to REB approval and data-sharing agreements.

When personal data are essential to research objectives and questions, researchers need a plan for making public the results of research in ways that do not permit tracing back to individuals if they do not wish their identities to be known.

8.1 Controlled levels of data access within research team and for secondary use

Researchers and institutions should protect against unauthorized disclosure and use of sensitive data or data subjects' identities, by controlling access to personal data.

Controlling access to data for research purposes means, under most circumstances, that:

- sensitive and/or highly identifiable data are accessible to the minimum number of persons necessary on the research team on a need-to-know basis (e.g. for cleaning data, conducting data linkages, and verifying the accuracy of data matches);
- team members have appropriate training in, and comply with, security safeguards;
- access to coded data, or to data where the direct identifiers are removed but potentially identifying elements remain in the dataset, may be permitted for researchers outside the research team only under strictly controlled conditions described in a written agreement and following REB approval; and
- non-identifiable data about individuals and aggregated data are made available to the general scientific community and for public use after appropriate scrutiny to minimize or avoid risks of inadvertent disclosure of individuals' identities.

Controlled access to personal data for research purposes

Access to:	Who should be permitted access: (examples)	Required safeguards to include:
Direct identifiers	• Selected members of the research team • Selected institution employees • "Deemed employees" or trusted third parties, subject to the same undertaking of confidentiality as the data holder (e.g. institution employees)	• REB review and approval • Review by institution data privacy committees where relevant • Access on need-to-know basis • Appropriate training • Undertaking of confidentiality by employees or research team • No direct access for researchers external to the research team, except for linkage purposes in exceptional circumstances (see 8.2) • Audit trails on access (where possible)
Not directly identifiable data (single or double coded; or without codes)	• Research team • Collaborators at local sites of a multi-site study • External researchers, with limitations (see required safeguards).	• REB-approved projects • Review by institution data privacy committees where relevant • Data-sharing agreement, including undertaking of confidentiality (see 8.3) • Disclosure of only enough data to answer the intended research question
Non-identifiable data in public use files (where data have been scrutinized and altered to protect against risks of inadvertent disclosure of individuals)' identities).[75]	• Scientific community • General public • Universities	• There may be no restrictions on use, or there may be a basic form of data sharing agreement, requiring an undertaking, for example, to not attempt to re-identify the records so as to relate the information on the file to a particular person.[76]

[75] For more information on disclosure control, refer to Statistics Canada Research Data Centres (RDCs) *Guide for Researchers Under Agreement with Statistics Canada*, July 2004, online at: http://www.statcan.ca/english/rdc/rdc_guides.htm.
[76] See, for example, the data acquisition and use agreement for Statistics Canada public use microdata files under the Data Liberation Initiative, online at: http://www.statcan.ca/english/Dli/reports.htm.

8.2 Conducting data linkages

The most secure way of conducting data linkages requested by external researchers is for the data holder to conduct the linkage and provide linked datasets to the researcher without identifiers, and at the minimum level of identifiability required for the research purpose.[77] If that is not practicable, a trusted third party may conduct the linkage or the researcher may conduct the linkage on the data holder's site. As a last option, a researcher may be permitted to conduct the linkage at a secure site but under strict controls, as specified in a data-sharing agreement.[78]

Ranked options for conducting data linkages

Who should conduct the linkage	Conditions for REB consideration
A) Data holder (Preferred)	The data holder performs the linkage(s) and subsequently removes all direct identifiers, or replaces direct identifiers with a code, prior to releasing the linked data set to the external researcher.
B) A trusted third party (e.g. a statistical agency) or C) The researcher conducts the linkage on the data holder's site	When the original data holder does not have the technical capacity or resources to perform linkages in-house: • a trusted third party acting as an information manager may conduct the linkage off site; or • the researcher as a "deemed employee" (e.g. the Statistics Canada model) may conduct the linkage on the data holder's site. The third party and the researchers should be bound by equivalent conditions of confidentiality and security as apply to the data holder and the data holder's employees.
D) The researcher conducts the linkage off site	If Options A, B or C are demonstrably impracticable, the researcher may conduct the linkage in compliance with a data-sharing/ confidentiality agreement with the data holder, setting out their respective and shared obligations, including restrictions on use and disclosure and appropriate security requirements (see 8.3 below). In this situation, any direct identifiers or other personal data not required to answer the research question should be destroyed or returned to the original data holder as soon as is practicable, and in compliance with the terms of the data-sharing agreement.

[77] The linked dataset may have direct identifiers removed or coded, or be made non-identifiable, depending on the needs of the research. See Element #2, 2.2.2, 2.3, and Summary Guide in that section.
[78] Refer to table of concordance for Element #8, Part 1, in Appendix A-7, for statutory cross-references to data matching/linking provisions.

Following the linkage of datasets, the person doing the data linkage should reduce datasets to the lowest level of identifiability needed to accomplish the research objectives.

For example, direct identifiers (e.g. name or personal health number) or potentially identifying elements when combined (e.g. a full date of birth or full postal code) may be needed for data linkage but may not be needed to answer the research questions. In such cases, these identifiers should be destroyed as soon as is reasonably practicable or returned to the data holder, as per the terms of the data-sharing agreement.

Universities may have specified retention periods for research data. Researchers should either destroy the new linked dataset at the end of the specified period, or use enhanced security measures to store it as per the terms of the data-sharing agreement. Within some research or statistical agencies it may not be practicable to unlink datasets after each use. However these institutions should document a process to ensure that the linked datasets are used only for authorized purposes (e.g. for REB-approved projects).

8.3 Data-sharing agreements

Data-sharing agreements bind data providers and researchers to their respective responsibilities and obligations for protecting personal data.

Data-sharing agreements should set out the terms and conditions under which data providers will allow researchers to access personal data for research purposes.[79]

Data-sharing agreements typically include the following information related to privacy concerns:

Basic information	Explanation
1) Research purposes[80]	• A meaningful description of the research objectives and methods.
2) Data elements and uses[81]	• A meaningful explanation of why the research objectives cannot reasonably be accomplished without access to these personal data. • Identification of data sources for the project and any linkages to be conducted. • A statement that the researcher will not use the data for any other purpose without prior authorization by the data provider.

[79] Refer to the table of concordance for Element #8, Part 2, in Appendix A-7, for statutory provisions for research data-sharing agreements.
[80] See also Element #1.
[81] See also Element #2.

Basic information	Explanation
3) Informed consent materials and form[82]	• Copies of the explanatory material and consent form to be provided to prospective participants, if appropriate (see #4 below).
4) Contact[83]	• Statement that the researcher will not attempt to contact data subjects without prior authorization by the data provider, if appropriate.
5) Data access and disclosure	• A listing of who will have access to personal data within the research team or the institution, and a requirement that each of these individuals have signed an undertaking of confidentiality. • A statement that the researcher will not disclose the data to other parties without prior authorization by the data provider.
6) Reporting results	• A requirement that results and data not be released in a form that identifies individuals to whom the information relates.
7) Security[84]	• A description of the physical, organizational and technological security measures in place to safeguard against risks of unauthorized use, disclosure, corruption or destruction.
8) Retention/ destruction of data[85]	• The time period for data retention and conditions for the return or the destruction of direct identifiers at the earliest reasonable time consistent with the research objectives. • The possibility for the data provider to authorize an extended retention period. • Statement that the researcher will not attempt to re-identify the data subjects without prior authorization by the data provider, if appropriate.
9) Required approvals/ authorizations[86]	• The requirement to have obtained REB approval and other relevant authorizations. • The duration of the agreement or a date designated for the parties to review the agreement.
10) Compliance with laws and policies[87]	• Obligation of recipients to comply with applicable laws and any of the data holder's policies and procedures relating to the confidentiality of personal information.

[80] See also Element #1.
[81] See also Element #2.
[82] See also Element #4 and #5.
[83] See also Element #3 (3.3) and #6; and the legal concordance table for Element #6 in Appendix A-7 for restrictions on contact.
[84] See also Element #7
[85] See also Element #9.
[86] See also Element #10.
[87] See also Element #10.

Basic information	Explanation
11) Accountability[88]	• The data provider reserves the right to conduct on-site visits, to monitor or audit data use or to respond to allegations of breach. • If the conditions of the data-sharing agreement are breached, penalties should be imposed, such as no further data to be provided by the data holder to the researcher(s) in question; legal recourse against the researcher for breach of contract; referral of matters to federal or provincial oversight or regulatory bodies for investigation and possible sanctions, and/or a report of the researcher's conduct to the relevant REB and/or federal research sponsor, where relevant and applicable (for example, where a breach of the data-sharing agreement also amounts to a breach of the TCPS).[89]

8.4 Controls over disclosure in public reports of research findings

Appropriate measures should be taken to avoid or minimize the identifiability of data in publications or public databases. Statistics Canada guidance in this area is available online.[90]

8.4.1 Reporting qualitative research results when concealing individuals' identities is not desired

In assessing the privacy aspects of research, researchers and REBs should also be aware of the possibility that in some instances individuals may want their identities to be known—for example, when individuals want their contribution to research as participants to be recognized, or where they want to help others afflicted with a similar condition. In some qualitative research, individual participants may understand and willingly accept the possibility that their identities may be revealed in the public reporting of research results.

[88] See also Element #10.
[89] For example, see CIHR's *Procedure for Addressing Allegations of Non-compliance with Research Policies*, online at http://www.cihr-irsc.gc.ca/e/25178.html.
[90] See Statistics Canada *Quality Guidelines* (4th Edition- Oct 2003), pg. 61-66, on line at http://www.statcan.ca/english/freepub/12-539-XIE/index.htm. Also, see Statistics Canada's *Guide for Researchers under Agreement with Statistics Canada* (July 2004), Appendix 2- *More on Disclosure and Disclosure Risk*, online at: http://www.statcan.ca/english/rdc/rdc_guides.htm.

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Disclosure controls]

"Data released should not contain names, initials or other identifying information. While it may be important to preserve certain types of identifiers (e.g., region of residence), these should be masked as much as possible using a standardized protocol before the data are released for research purposes. However, legitimate circumstances may exist where such information is critical for the research project..." (pg. 3.4)

[Human genetic research]

Article 8.2 "The researchers and the REB shall ensure that the results of genetic testing and genetic counseling records are protected from access by third parties, unless free and informed consent is given by the subject. Family information in databanks shall be coded so as to remove the possibility of identification of subjects within the bank itself." (pg. 8.2)

[Secondary uses]

Article 3.3, 3.4 – See Element #3

[Data linkage]

Article 3.6 "The implications of approved data linkage in which research subjects may be identifiable shall be approved by the REB." Explanatory note: "...Only a restricted number of individuals should perform the function of merging databases; researchers should either destroy the merged file immediately after use, or use enhanced security measures to store it. Whether the data are to be used statistically or otherwise, confidentiality of the information must be maintained by all members of the research team." (pg. 3.6)

ELEMENT #9: Setting reasonable limits on retention of personal data

General statement

Personal data should be retained as long as is necessary to fulfill the research purposes.[91] Personal data may then be destroyed or returned to the data provider, if appropriate, as set out in the terms of the original collection, data-sharing agreement, institutional policies and legal requirements.

There is a tension between the privacy principle of limiting the retention of data and the scientific principle of preserving research data so that published research results can be replicated and verified, and opportunities for further investigation of valuable data are maximized. While this is a very complex area in need of further reflection and development, the default principle is to define retention periods for personal data, in writing. Researchers should be explicit about what they plan to do with the data they collect and have storage, management and access policies in place.

9.1 Retention of personal data

9.1.1 Specific research project

Where personal data are collected and used in the context of a specific research project, identifying personal data should be retained by the researcher as long as necessary to fulfill the original research objectives,[92] including related purposes such as tracing, validating or auditing research results as may be required by regulators, study sponsors and/or publishers. [93]

9.1.2 Database for general health research purposes

When personal data are collected in a database to support general health research purposes in the future, personal data may be retained for the general purposes originally consented to, subject to security safeguards proportionate to the identifiability, sensitivity and amount of the data, as well as its format and method of storage.

[91] Note that under the Food and Drug Regulations- Division 5- C.05.012 (4) records for clinical trials must be retained for 25 years. Universities may have specified retention periods for research data.
[92] See Element #1.
[93] See the legal concordance table for Element #9 in Appendix A-7 for general obligations in privacy legislation with respect to retention of personal information.

Administrative databases such as hospital discharge records and vital statistics registries, which may be used to support health research, may retain personal data over the long term, provided that this is permitted according to legislation or the mandate of a public body such as a government health department.

Any long-term retention of personal data established for general health research purposes should be subject to periodic audits and effective oversight by independent third parties including REBs.

ELEMENT #10: Ensuring accountability and transparency in the management of personal data

General statement

Individuals and organizations engaged in health research involving personal data are accountable for the proper conduct of such research in accordance with applicable funding policies, privacy principles and/or legislation. Processes and practices must be clearly established and implemented in order to give meaningful effect to these policies, principles or laws. Proper accountability and transparency practices require adequate resources for such things as communication, education and training relating to privacy.

Roles and responsibilities of all those involved in the conduct and evaluation of research should be clearly defined and understood, including those of researchers, their employing institutions, REBs, any data stewardship committees, Privacy Commissioners and other legally-designated privacy oversight agencies. Their concerted efforts should aim to provide a coherent governance structure for effective and efficient data stewardship.[94]

10.1 Transparency

Recognizing that transparency may enhance public support for, and interest in, socially valuable research, individuals and organizations engaged in the conduct and evaluation of health research should:

- be open to the public with respect to the objectives of the research;
- be open about the policies and practices relating to the protection of personal data used in the research;
- promote ongoing dialogue between the research community and privacy oversight agencies; and
- promote ongoing dialogue between the research community and the community at large (the public).

[94] See the table of concordance for Element #10, Part 1, in Appendix A-7, for general statutory accountability and transparency obligations as well as Part 2 for statutory references to research ethics boards.

10.2 Accountability

Key roles and responsibilities with respect to privacy concerns of those involved in designing, conducting and approving publicly-funded health research are outlined below.

10.2.1 Researchers (Principal investigator, researchers)

Privacy-related responsibilities include:

- being aware of all applicable policies and laws in the jurisdictions in which the research is conducted and conducting their research in accordance with such requirements;
- seeking REB and institutional approval and, where required or considered appropriate, the review or approval of other relevant legal privacy oversight bodies;
- providing a mechanism to handle queries and complaints from participants about the privacy aspects of the research (e.g. REB contact information in the consent form); and
- promoting openness and accountability through publicly available information which describes the purpose and conduct of the research project(s) and how privacy concerns are being managed.

10.2.2 Academic and other affiliated or hosting institutions

Privacy-related responsibilities include:

- developing and applying institutional privacy policies and procedures for the conduct and review of research that meet, as a minimum, the requirements set out in the TCPS and other applicable funding policies and laws;
- designating an individual who is accountable for the institution's compliance with those policies and procedures;
- providing for the education and training of researchers and REB members on how to manage personal data in health research;
- providing a mechanism for handling queries and complaints about the privacy and confidentiality aspects of research;
- demonstrating impartial and accountable procedures to investigate allegations of individual non-compliance, with appropriate sanctions for non-compliance;

- being open with the public about research supported by the institution; processes and practices for managing personal information; and procedures for receiving and handling complaints; and
- fostering coordinated data stewardship and institutional review processes within and between institutions.

10.2.3 REBs

Privacy-related responsibilities include:

- reviewing any proposed and ongoing research involving humans in accordance with the TCPS and its principles,[95] as well as other applicable laws and policies, including:
  - the institution's own policies;
  - federal, provincial and territorial legislation; and
  - relevant laws, regulations, policies and/or research contexts of other countries, when research is to be conducted in those countries;
- serving as a consultative body to the research community and thus contributing to education in research ethics;
- fostering coordinated and consistent REB review processes, particularly with respect to multi-jurisdictional and multi-site research; and
- undertaking regular monitoring of research and coordinating reviews of multi-centre research to ensure equivalencies in standards across jurisdictions, by conducting:
  - an annual review of the research (required under TCPS);
  - an audit of critical aspects of the research protocol including the consent process, safeguards and, where relevant, methods of reducing the identifiability of data prior to disclosure; and
  - other effective monitoring mechanisms, as appropriate.

10.2.4 Independent data stewardship committees

When a database is created for multiple research purposes, or across multiple sites or jurisdictions, researchers and institutional data holders should promote coordinated and streamlined approaches

[95] The TCPS ethical framework includes a general principle that the more potentially invasive or harmful the research, particularly from the individual participants' perspective, the greater should be the REB's care in assessing the research. This is the concept of proportionate review.

to data stewardship over the long term. A centralized data stewardship committee could be put in place to authorize future uses of the database in accordance with the research objectives, REB approval and, where applicable, within the parameters set by the consent obtained from participants.

The responsibilities of this advisory committee could include:

- the review of data access requests;
- long-term management of the database;
- coordination of reviews by local REBs, for example, by means of agreements between REBs, institutions and researchers, as appropriate; and
- provision of information to the public (e.g. on a web site).

The composition of the committee should include scientific experts in the field and representatives from the population being studied.

10.3 Legally-designated privacy oversight agencies

As specified in legislation, the responsibilities of privacy oversight agencies, such as the Office of the Privacy Commissioner or Ombudsman in each jurisdiction, may include all or any of the following:

- monitoring and investigating compliance with legal requirements;
- issuing findings and recommendations and/or adjudicating complaints from the public with regard to non-compliance;
- initiating and/or participating in court action for breach of legal requirements for privacy protection;
- conducting audits of organizations' information management practices;
- reviewing privacy impact assessments for proposed research;
- reviewing and/or approving the collection of personal information without consent;[96]
- reporting publicly on matters of privacy compliance;
- reviewing and providing comments or approvals on proposed laws or policies; and
- promoting public education with respect to privacy issues.

[96] See the legal concordance table for Element #3 in Appendix A-7, in particular Quebec privacy laws.

LINK TO TRI-COUNCIL POLICY STATEMENT:

[Mandate of the three federal research granting agencies: CIHR, SSHRC and NSERC]

"The...Agencies have adopted this Policy as their standard of ethical conduct for research involving human subjects. As a condition of funding, the Agencies require, as a minimum, that researchers and their institutions apply the ethical principles and the articles of this policy." (pg. i.2)

Article 1.1 "(a) All research that involves living human subjects requires review and approval by an REB in accordance with their Policy Statement, before the research is started, except as stipulated.." (pg. 1.1)

[Review procedures for ongoing research]

Article 1.13 "(a) Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment. (b) As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.(c) Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes." (pg. 1.10)

"In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.13(b), in addition to annual review (Article 1.13 (c)) might include:

- *formal review of the process of free and informed consent*
- *establishment of a safety monitoring committee*
- *periodic review by a third party of the documents generated by the study*
- *review of reports of adverse events*
- *review of patients' charts or*
- *a random audit of the process of free and informed consent.*

Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.

The process of a continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. Research institutions should strive to educate researchers on the process of a continuing ethics review through workshops, seminars and other educational opportunities." (pg. 1.10- 1.11)

[Review of multi-centered research]

"Principles of institutional accountability require each local REB to be responsible for the ethical acceptability of research undertaken within its institution. However, in multi-centred research, when several REBs consider the same proposal from the perspectives of their respective institutions, they may reach different conclusions on one or more aspects of the proposed research. To facilitate coordination of ethics review, when submitting a proposal for multi-centered research, the researcher may wish to distinguish between core elements of the research—which cannot be altered without invalidating the pooling of data from the participating institutions—and those elements that can be altered to comply with local requirements without invalidating the research project. REBs may also wish to coordinate their review of multi-centred projects, and to communicate any concerns that they may have with other REBs reviewing the same project. The needed communication would be facilitated if the researcher provides information on the institutional REBs that will consider the project." (pg. 1.11)

[Equivalence level of protection in multi-jurisdictional research]

Article 1.14 "Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; and (b) by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done." (pg. 1.12)

LINK TO: Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards (MOU). Schedule 2- Ethics Review of Research Involving Humans.

1.0 Policy "The Agencies developed, approved and implemented a joint policy statement to promote the ethical conduct of research involving human subjects – the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). The Agencies will only fund researchers, Institutions or partnering organizations that comply with the ethical principles and articles of the TCPS. In addition CIHR will only fund human pluripotent stem cells research that adheres to its recently published guidelines.

In addition to the TCPS, the ethics review of research involving humans may, where appropriate, be subject to other legislation and policies, such as:

- *the Institution's own policy on research involving human subjects;*
- *the Québec Civil Code;*
- *provincial and federal legislation on privacy, confidentiality, intellectual property, competence and other areas;*
- *Canada Food and Drug Act and Regulations;*
- *guidelines and policies of the Therapeutic Products Directorate of Health Canada;*
- *relevant laws, regulations and/or policies of other countries, when research is to be conducted in those countries;*
- *Good Clinical Practices: Consolidated Guidelines for clinical trials sponsored by industry, published by the International Conference on Harmonization.*

Researchers, Institutions and research ethics boards (REBs) should be aware of all applicable policies, regulations and guidelines. In some cases, it may be necessary for Institutions to have recourse to specific expertise to identify legal and other issues in the ethics review process..."

See web link for updates – *http://www.nserc.gc.ca/institution/mou_sch2_e.htm*

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A-1 CIHR Privacy Advisory Committee

MEMBERS

Privacy Commissioners
David Loukidelis
Information and Privacy Commissioner of British Columbia

(Privacy-enhancing Technologies)
Debra Grant
Senior Health Privacy Specialist
Information and Privacy Commissioner/Ontario

Research ethics boards (REBs)
Sharon Buehler
Co-Chair, Research Ethics Board, Memorial University

Don Willison
(CIHR-funded research on REBs)
Scientist, Centre for Evaluation of Medicines, McMaster University

Health researchers
Charlyn Black (Health Services Research)
Director, BC Centre for Health Services and Policy Research

Colin L. Soskolne (Epidemiology)
Professor, Department of Public Health Sciences, University of Alberta

Voluntary health organizations
Roy West
Co-Chair, Science and Research Committee, Health Charities Council of Canada

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Mary Vachon
Psychotherapist and Consultant in Private Practice
Professor, Depts. of Psychiatry and Public Health Science, University of Toronto
Clinical Consultant, Wellspring

Phil Upshall
Chair, Canadian Alliance on Mental Illness and Mental Health
President- The Mood Disorders Society of Canada

Policy-makers
Heather McLaren
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Manitoba Health

Data producers/custodians
Joan Roch
Former Chief Privacy Officer, CIHI
Privacy Consultant

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Aboriginal interests
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CIHR Institute Advisory Board Member- Institute of Aboriginal People's Health,
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Brent Windwick
Partner, Field LLP
Former Executive Director, Health Law Institute

Bartha Maria Knoppers
Canada Research Chair in Law and Medicine;
Professor, Public Law Research Centre, Faculty of Law, University of Montreal

Ex officio members

Interagency Advisory Panel on Research Ethics (PRE):
Pierre Deschamps, PRE member
Member of the Canadian Human Rights Tribunal

Social Sciences and Humanities Research Council of Canada (SSHRC)
Christian Sylvain (alternate : Jocelyn Girard)
Director, SSHRC Corporate Policy and Planning

National Council on Ethics in Human Research (NCEHR)
Fern Brunger, NCEHR Member
Assistant Professor, Health Care Ethics, Faculty of Medicine
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Sheila Chapman
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Mylène Deschênes
Former Senior Ethics Policy Advisor

Sylvie Burion
Project Officer

A-2 Drafting process and consultations in 2004

The Canadian Institutes of Health Research (CIHR) is Canada's main federal funding agency for health research. CIHR's mandate is to invest in research that has the potential to lead to improved health for Canadians, more effective health services and products, and a strengthened Canadian health care system. CIHR-funded health research must also meet the highest standards of scientific excellence and ethics.

Recognizing that one of the key ethical challenges for the health research community is to appropriately protect the privacy of those individuals whose information is used for research purposes, CIHR has initiated and promoted dialogue with the broad health research community on a range of privacy-related matters for many years. In particular, a multi-stakeholder workshop in November 2002 entitled *Privacy in Health Research: Sharing Perspectives and Paving the Way Forward* resulted in a number of recommendations including that CIHR initiate the development of privacy best practices and promote the harmonization of privacy laws and policies that impact on health research.

Following on these recommendations, CIHR established a Privacy Advisory Committee (PAC) in 2003 to advise CIHR on the development of privacy best practices for health research, and on strategies for consultation, communication and knowledge translation. CIHR, with the advice of PAC, developed *Guidelines for protecting privacy and confidentiality in the design, conduct and evaluation of health research- Best Practices, Consultation Draft*, April 2004.[97] A wide range of stakeholders was consulted on this draft from March through September, 2004. The current version of the Privacy Best Practices was revised to reflect the feedback received.

Response to consultations in 2004

We thank the many organizations and individuals who provided feedback on the 2004 draft Guidelines.[98] The consultation period extended from March through September, 2004, with some written comments being received through mid-October. There were three streams for providing feedback: (1) written comments received in response to invitations sent to key stakeholders, and through an on-line feedback questionnaire; (2) three multi-stakeholder workshops on specific themes aimed at addressing potential gaps in coverage; and (3) two small group dialogue sessions with citizens.

We heard that the broad health research community, including review and oversight bodies, were generally supportive of this initiative, while also making a number of suggestions for improvements of the draft Best Practices. We also were reminded that there is a diversity of points of view within and between stakeholder groups on privacy and confidentiality issues. Some respondents commented that the draft privacy best practices were too restrictive and could impede research, and others thought they were not restrictive enough. We heard from discussions with citizens that there appears to be generally strong support for health research, but also concern about potential unauthorized uses of personal information.

In response to feedback received, we have made the following main changes for this 2005 release:

- A change in the title to: "*Best Practices for Protecting Privacy in Health Research*". Respondents noted that the previous title was too long, and combined both "guidelines" and "best practices" concepts. Also, it was noted that the document is meant to be recommended practices, which aspire in the future to the status of mandatory policy; thus there was general agreement that the term "best practices" was most appropriate at this stage.
- A revision of the Executive Summary to better reflect the main text.
- A clearer explanation of CIHR's mandate – to promote health research that meets the highest standards of excellence and ethics.
- Addition of accompanying tables on relevant legal requirements, as guideposts for health researchers, research ethics boards and others, but not intended to serve as formal legal advice.

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[97] The *Guidelines for protecting privacy and confidentiality in the design, conduct and evaluation of health research- Best Practices, Consultation Draft,* April 2004 are accessible on CIHR's web site at: http://www.cihr-irsc.gc.ca/e/22085.html

[98] Summary reports of feedback received, and an evaluation of the 2004 consultation process, are accessible on CIHR's web site at: http://www.cihr-irsc.gc.ca/e/28350.html.

- Addition of an accompanying table on different research areas, user groups, data collection methods, and activities, to demonstrate the applicability of this document to a wide range of target users.
- Addition of an index to research methods covered in the Privacy Best Practices, to help researchers navigate the document to find relevant sections.
- A more explicit acknowledgement of the different fundamental values in play, such as the rights and responsibilities of individuals, and the ethical framework articulated in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).
- A clear recognition that the default position in health research should be the requirement for consent from individual participants.
- Acknowledgement that the reality of researchers in such fields as health services and population health differs significantly from that of clinical researchers, with reference to CIHR *Secondary Use of Personal Information in Health Research: Case Studies* document.
- Strengthened recognition of the privacy concerns of communities and groups.
- Strengthened coverage of privacy issues for qualitative methods and inductive data collection and analysis.
- Strengthened coverage of genetic data, and confirmation that the scope of the Privacy Best Practices does not extend to the management and governance of human biological materials.
- Recognition of the tension between the principles of limiting access and retention of personal data, and the growing importance of making research data (particularly from publicly-funded research) available for broad research use and social benefit, with encouragement for researchers to think about these issues and to be explicit about what they plan to do with the data they collect.

Not surprisingly, given the extent of feedback received, the diversity in points of view, and the need to limit the scope and size of the document, not all requests for changes could be met. For example, these Best Practices do not specifically address privacy issues associated with health surveillance, program quality assurance studies, or private industry-funded research. Nevertheless, these Best Practices could serve as models for best practices developed in these other areas. And in response to requests for more focus on Aboriginal research and qualitative research methods, we provide some additional coverage in this 2005 document. However, we look forward to the more detailed work in these areas being coordinated through the Interagency Advisory Panel on Research Ethics.

As we note throughout this document, these Best Practices will need to continually evolve to reflect new best practices, refinements of existing practices, the findings of research on privacy, and changes in the legal and policy framework for health research in Canada.

A-3 Real world case studies and links to the elements

In 2002, CIHR published *Secondary Use of Personal Information in Health Research: Case Studies* (November 2002).[99] Nineteen case studies were developed to describe real-life examples of actual research involving secondary use of data in Canada. These case studies highlighted the practical challenges that arise when applying various legal and ethical norms in the specific context of population health and health services research. The case studies identified a number of ethical and legal issues that warranted further consideration and discussion.

The summary table of issues from the *Case Studies* is reprinted below, with an additional column on the far right providing a link to relevant sections of the Best Practices.[100]

Case study #	Title of case study	Collection / use / linkage of data	Issues raised	Relevant to Privacy Best Practices Element #:
1	*The computerization of medical practices for the enhancement of therapeutic effectiveness*	Collection and use of coded data from patient medical records contained in doctors' offices; no direct patient contact involved; implied consent with possibility of opting out.	Prior contact by original data custodian. Form of consent required	3, 4, 6 , 7
2	*Seasonal patterns of Winnipeg hospital use*	Linkage and analyses of coded data contained in provincial databases routinely collected for other purposes (i.e. hospital discharge data and population registry file); no direct contact involved; no consent obtained.	Impracticability of obtaining consent. Long-term retention of data for future research purposes.	3, 7, 8, 9
3	*Assessing the accuracy of the Nova Scotia health survey*	Linkage and analyses of coded data contained in provincial databases routinely collected for other purposes (i.e. hospital discharge data and physician claims database); no direct contact involved; no consent obtained.	Impracticability of obtaining consent.	3, 4, 7, 8
4	*National diabetes surveillance system*	Creation of a national diabetes database of aggregate data by linking and assembling coded data contained in provincial databases routinely collected for other purposes (i.e. hospital files, physician billing records and drug claims data); no direct contact involved; no consent obtained.	Impracticability of obtaining consent. Need for harmonization of laws and policies across jurisdictions. Long-term retention of data for future research purposes.	3, 7, 8, 9, 10
5	*Use of RFLP molecular epidemiology to find out how tuberculosis is spread among people infected with HIV*	Linkage and analyses of TB bacteria grown from individual sputum samples in a public health laboratory, with non-identifying demographic data held by the province's health ministry; no direct contact involved; no consent obtained.	What constitutes personal information. Form of consent required.	2, 3, 4, 7, 8

[99] See CIHR's web site, online at: http://www.cihr-irsc.gc.ca/e/1475.html.
[100] The table is reprinted verbatim from pg. 39 of the *Case Studies* document except for changes to terms referring to the level of identifiability of data, to be consistent with terms defined in Element #2, Box-*Definition of terms: Individual identifiability of data*, and in the Glossary, in Appendix A-6.

Case study #	Title of case study	Collection / use / linkage of data	Issues raised	Relevant to Privacy Best Practices Element #:
6	*HIV seroprevalence among women undergoing abortion*	Linkage of non-identifying questionnaires with non-identifying test results of blood samples obtained for therapeutic abortion purposes; direct patient contact; written consent obtained.	Form of consent required. Need for harmonization of laws and policies across jurisdictions.	3, 4, 6, 10
7	*New use of anti-arrhythmia drugs in Saskatchewan*	Linkage and analyses of coded data contained in provincial databases routinely collected for other purposes (i.e. drug claims database, hospital discharge data and physician billing records); no direct contact involved; no consent obtained.	Impracticability of obtaining consent.	3, 7, 8
8	*Barriers to accessing health care in Canada: is the System Fair?*	Linkage and analyses of personal information contained in Statistics Canada's National Population Health Survey, with provincial databases routinely collected for other purposes (i.e. hospital discharge data and physician billing data); direct contact involved; express consent obtained.	Validity of informed consent. Need for harmonization of laws and policies across jurisdictions.	5, 7, 8, 10
9	*Needle stick injuries in nursing and laboratory staff*	Collection and use of non-identifying questionnaires, combined with general statistics at each participating hospital; direct contact involved; express consent obtained.	Prior contact by original data custodian. Mandatory reporting and the researchers' duty of confidentiality.	4, 6, 7, 9
10	*A randomized controlled trial of call/recall of 'hard-to-reach' women for Pap tests*	Linkage of personal information from electronic medical records, with provincial cancer and cytology registries for purpose of assembling study population; direct contact involved; no individual consent obtained but physician authorization granted.	Prior contact by original data custodian. Impracticability of obtaining consent. Long-term retention of data for consistent research purposes.	6, 7, 8, 9
11	*The impact of having elderly and welfare patients in Quebec pay a greater share in the costs of their prescription drugs*	Linkage and analyses of coded data routinely collected in provincial databases for other purposes (i.e. prescriptions claims data, hospital discharge data, physician billing data and mortality data); no direct contact involved; no consent obtained.	Distinction between policy evaluation and research. Impracticability of obtaining consent.	2, 3, 8
12	*A randomized drug policy trial with camouflaged contacting of patients*	Linkage of coded data routinely collected in provincial databases for other purposes (i.e. prescriptions claims data, hospital discharge data, physician billing data and mortality data) for the purpose of assembling a study population; quality of life questionnaires then sent to potentially eligible research subjects through camouflaged contacting method; consent obtained for linking questionnaires with administrative data.	Distinction between policy evaluation and research. Prior contact by original data custodian.	5, 6, 8
13	*Cancer and other health problems associated with breast implants*	Linkage and analysis of personal information obtained from hospital records and clinical records, with data obtained from provincial cancer registries and registrars of vital statistics; no direct contact involved; no individual consent obtained, but nation-wide publicity program conducted.	Unique legal status of cancer registries. Prior contact by original data custodian. Impracticability of obtaining consent.	2, 3, 4, 7

Case study #	Title of case study	Collection / use / linkage of data	Issues raised	Relevant to Privacy Best Practices Element #:
14	*Second cancers following treatment for non-Hodgkin lymphoma*	Linkage and analysis of personal information obtained from a provincial cancer registry with personal information contained in hospital and radiotherapy center records; no direct contact involved; no individual consent obtained as 75% of the study cohort had died.	Unique legal status of cancer registries. Prior contact by original data custodian. Impracticability of obtaining consent.	3, 5, 6
15	*Ontario familial colon cancer registry*	Reviewing tumour pathology report forwarded to a provincial cancer registry, as validated by attending surgeons, in order to first identify and invite eligible patients and families for inclusion in the registry; survey data and tissue samples then collected; direct contact involved; consent obtained.	Unique legal status of cancer registries. Prior contact by original data custodian. Implications of assembling genetic information as a particularly sensitive category of personal information.	2, 5, 6, 7
16	*Rapid surveillance of cancer in neighbourhoods and near point sources of pollution*	Linkage and analysis of personal information contained in a provincial cancer registry with a provincial property assessment file and mortality database; no direct contact involved; no consent obtained; community-wide publicity and consultation process are planned.	Unique legal status of cancer registries. Impracticability of obtaining consent. Community interests.	2, 3, 7, 8
17	*Patient outreach via PharmaNet*	Automatic flagging of eligible research subjects in the province's drug claims database through the use of a computerized algorithm in order to assemble a study population without any human intervention; direct patient contact involved; consent obtained.	Prior contact by original data custodian.	3, 6
18	*The registry of the Canadian Stroke Network*	Creation of a national stroke registry by collecting, linking and assembling patients' survey data, health care utilization data and mortality data; direct patient contact involved; consent obtained.	Prior contact by original data custodian. Validity of informed consent. Long-term retention of data for future research purposes. Need for harmonization of laws and policies across jurisdictions.	3, 4, 5, 7, 10
19	*Studying the health of health care workers*	Linkage and analyses of coded health data contained in provincial databases routinely collected for other purposes (i.e. hospital records, physician billing data, and drug claims data); no direct contact involved; no consent obtained.	Impracticability of obtaining consent. Long-term retention of data for future research purposes.	3, 7, 8, 9

A-4 Diversity of health research and future considerations

To understand the scope of these Best Practices, it is helpful to consider the multi-faceted landscape of CIHR-funded health research in this country.

Health research projects span a spectrum of disciplines and methods.

These Best Practices are intended to address the full spectrum of CIHR-funded research.[101] CIHR categorizes health research in four broad themes, as defined in its Grants and Awards Guide:[102]

- **Bio-medical research**
  Research with the goal of understanding normal and abnormal human functioning, at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that improve health or the quality of life of individuals, up to the point where they are tested on human subjects. Studies on human subjects that do not have a diagnostic or therapeutic orientation.

- **Clinical research**
  Research with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Research on, or for the treatment of, patients.

- **Health services research**
  Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and, ultimately, Canadians' health and well-being.

- **Social, cultural, environmental and population health**
  Research with the goal of improving the health of the Canadian population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.

CIHR encourages multi-disciplinary research that cuts across these broad thematic areas.

CIHR-funded health research also spans a range of research methods, including quantitative methods (typically based on large numbers of participants, involving hypothesis generation and testing, and statistical analyses of data) and qualitative methods (typically not involving the testing of hypotheses, but rather more open-ended and inductive analysis and collaborative observation techniques, often with smaller numbers of individuals).[103]

Health research projects may cross community, provincial, territorial or national boundaries.

Health research may involve particular cultural groups or communities, such as Aboriginal groups or remote communities.

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[101] Note that the scope of these Privacy Best Practices does not necessarily extend to particular issues of privacy and confidentiality, and related legal requirements, in research that is entirely funded by private industry.

[102] CIHR's Grants and Awards Guide, 2005-2006.

[103] A search of the CIHR funding database on the search term "qualitative methods" elicited over a hundred CIHR-funded research projects using qualitative methods as of 2004-2005. These CIHR-funded projects were investigations into such areas as public, community and family values, and in some cases involved the community in the development and conduct of the research.

A single health research study may have multiple sites in more than one province or territory. Research teams may be composed of a network of investigators drawn from across the country and across disciplines. CIHR's 13 "virtual" institutes are founded on this model, promoting collaboration among investigators in various jurisdictions, working on similar questions from different perspectives.

And, because health is a global issue, health research can have an international dimension. Researchers collaborate with colleagues in other countries as they have in the multi-year international Human Genome Project and in CIHR's Global Health initiative.

Health research is conducted in various settings, often supported by a mix of public and private funds.

A great deal of research is based at universities where investigators may have both public and private funding sources. Governments and affiliated research or statistical agencies conduct research on such things as emerging public health issues and the effectiveness of the health care system. They increasingly look for private-public partnerships in sponsorship. Statistical and research agencies with a public mandate conduct research within their agencies and frequently also serve as data stewards permitting, under strict controls, access to their data by external researchers such as those with CIHR funding.

Potential data sources for health research are also diverse.

Individuals are one essential source of health-related data. Individuals are recruited, for example, for clinical trials of new treatments and therapies; and for surveys (conducted by telephone, by mail or in person) on personal lifestyles and attitudes and on the health status of the population. Sometimes the interactions of individuals or groups are simply observed and documented.

Existing databases that were not originally created for research purposes are also important sources of data for health research. These databases have the potential to provide data that are difficult to obtain or cannot be obtained directly from individuals, such as physician diagnoses and records of hospital treatment (in health administrative databases), official registration of births, deaths and cause of death (in population registries), and disease trends and geographic "hot spots" in the population over time (in health surveillance databases).

Thus, these Best Practices have a broad scope, encompassing the wide spectrum of CIHR-funded health research intended to contribute generalizable knowledge to protect and improve human health.

For a more detailed description of the diversity of health research methods, the tables in this section provide examples of studies recruiting individuals or communities, and the wide range of important sources of research data.

Table 1: Examples of studies recruiting individuals or communities

Examples of participants	Examples of data items collected	Examples of research potential	Examples of data collection methods
Residents of a rural community	• Age, sex and other demographic information • Length of residence • Attitudes toward a new teen drop-in health service • Use of new service • Health history	• To identify factors that influence community acceptance and use of teen drop-in health services • To assess the impact over time of the new clinic on reducing health problems and teen pregnancies among teens in rural communities	• Observation of teen activities or review of service records in a number of rural communities, some with new teen health services and some without • Interviews with health care providers and patients • Interviews or surveys of teens and adults in the community
Individuals with asthma	• Age, sex and other demographic information • History of asthma and other medical conditions	• To assess the impact on health of a new asthma drug • To identify barriers to proper use of a drug	• Clinical trials (see TCPS, Section 7 for more information about clinical trials) • Interviews with asthma patients

Examples of participants	Examples of data items collected	Examples of research potential	Examples of data collection methods
	• Medication history • Meaning of illness	• To identify the impact of asthma on quality of life • To explore the meaning of illness in asthma patients	and parents • Survey of asthma patients • Focus groups of clinic personnel
Individuals with colon cancer	• Age, sex and other demographic information • Family history • Health and treatment history • Dietary habits • Exposures to cancer risks in the environment • Blood sample • Meaning of "hereditary" and "risk", in relation to genetic screening	• To examine interactions of genes and the environment in causing cancer • To determine the need for education materials (for physicians and patients) about the risk of inheriting cancer • To assess the impact on family members of screening for disease	• Telephone or mailed surveys • In-depth interviews • Laboratory analyses of blood samples collected at the time of the interview • Long-term follow up by telephone or mail
Tamil refugees in the Greater Toronto area	• Age, sex and other demographic information • Length of residence • Refugee status • Health history • Use of health resources	• To identify barriers to accessing health care • To identify psychosocial and health issues associated with resettlement • To assess use of complementary and alternative medicines	• Participant observation research • In-depth interviews • Analysis of patient files • Analysis of personal letters and journals

Table 2: Examples of databases with research potential, held in diverse settings

Databases	Examples of data[104]	Examples of research potential	Examples of data holders
Health administrative databases	• Health insurance registration • Physician diagnoses in billing records for provincial health insurance plans • Hospital records	• To examine interactions between the environment and health • To describe trends in disease and wellness over time • To evaluate the impact of changes in the health care system	• Government Ministries of Health • Hospitals • Statistical agencies
Population registries	• Records of all births, deaths, cause of death in a geographically defined population (e.g. a province)	• To assess the burden of disease in a geographic area • Linked with health records, to assess prenatal and post-natal care and health outcomes, and long-term outcomes of health conditions (e.g. length of survival and cause of death)	• Provincial and Territorial registrars • Statistical agencies

[104] Differing amounts of data elements (e.g. age, sex, residence, occupation) will be found in each of these datasets.

Databases	Examples of data[104]	Examples of research potential	Examples of data holders
Disease registries	• A database that holds permanent, ongoing personal data about a population group affected by a particular disease (e.g. cancer) or condition, for statistical, surveillance and/or research purposes.	• To identify potential research participants • To look at trends in new cases of disease • To look for associations of disease and risk factors • To assess the effectiveness of treatment • Linked with death records, to assess survival and ultimate cause of death	• Government agencies • Disease agencies • Hospitals • Statistical agencies
Clinical research databases	• Detailed data on medical history, psychosocial factors, patient status, care and associated health outcomes	• To identify potential research participants • To evaluate the efficacy of treatment • To look at continuity of care	• Physicians • Disease clinics and institutes (e.g. diabetes, heart disease) • Industry sponsors
Human genetic material banks	• Primary materials (blood, bone and cultured tissue) • Secondary materials (copies of primary samples such as cellular protein) • Tertiary materials (electronically stored information such as DNA sequences) • Linked clinical information	• To develop diagnostic methods • To assess the genetic basis of variability in drug efficacy and safety (pharmacogenetics) • To discover the genetic and biochemical causes of disease (often linked to hospital data and/or genealogy information)	• Government public health and research laboratories • Private companies • Universities • Hospitals • Clinical genetics clinics
Health surveillance databases	• Public health data on chronic and communicable disease • Reports of adverse health effects from marketed products	• To search for causes of disease outbreaks or increasing numbers of new cases • To document the burden of disease in populations • To describe long-term trends in health status at the community or population level.	• Government Ministries of Health • World Health Organization • Statistical agencies
Survey databases	• Demographic information, workplace conditions, health services availability • Self-reported personal behaviours, health status, medical conditions, lifestyle, attitudes, values, and experiences	• To describe and assess the broad determinants of health (individual, biological, social, cultural, and environmental) and their impact on populations and individuals • To describe and assess psychosocial factors in illness and disease and their individual, biological, social, cultural and environmental determinants	• Government departments • Statistical agencies • Researchers • Universities • Research centres

Future considerations: The changing landscape of health research

The research landscape is an evolving one, as our knowledge and technological capacities continue to advance. In particular, the impact of new developments on research is still to be determined in areas such as:

- the projected implementation of electronic health records across Canada over the next decade;
- discoveries in genomics and research on genetic-environmental interactions;
- emerging standards for Aboriginal research;[105]
- increasing use of health-related databases, such as hospital and vital statistics records, for multiple purposes including patient care and management, program management, public health functions and services (e.g. cancer screening, vaccinations, chronic disease risk factor surveillance, obesity interventions) and research; and
- government-led initiatives toward a harmonized legal framework for protecting the privacy and confidentiality of health information across all jurisdictions in Canada.

[105] Developments relevant to research in Aboriginal settings include the current review of TCPS Section 6 (*Research Involving Aboriginal Peoples*), coordinated by the Interagency Advisory Panel on Research Ethics and including CIHR-led development of guidance on Aboriginal health research.

A-5 Selected documents and web links

Selected international and national guidelines

• Council for International Organization of Medical Societies (CIOMS):

- *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002)
  Online: http://www.cioms.ch/frame_guidelines_nov_2002.htm

- *International Ethical Guidelines for the Ethical Review of Epidemiological Studies* (1991)
  Online: http://www.cioms.ch/frame_1991_texts_of_guidelines.htm (Currently under revision. See http://www.cioms.ch/index.htm)

• European Commission- Data protection:
Online: http://europa.eu.int/comm/justice_home/fsj/privacy/index_en.htm

• Interagency Advisory Panel on Research Ethics:

- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada: *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), 1998 (with 2000, 2002, 2005 amendments)
  Online: http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

- TCPS tutorial
  On-line: http://www.pre.ethics.gc.ca/english/tutorial/

• Medical Research Council (United Kingdom):

- *Ethics Series- Personal Information in Medical Research* (2000)
  Online: http://www.mrc.ac.uk/pdf-pimr.pdf

• Quebec Network of Applied Genetic Medicine (RMGA):
All policies online: http://www.rmga.qc.ca/en/index.htm

- *Statement of Principles on the Ethical Conduct of Research Involving Populations*
- *Statement of Principles: Human Genome Research, Version 2000*
- *Research in Human Genetics and Consent* (French only)

• UK Biobank Project:

- *Ethics and Governance Framework*
  Online: http://www.ukbiobank.ac.uk/ethics/egf.php

For other key guidance documents see the Interagency Advisory Panel for Research Ethics web site at: http://www.pre.ethics.gc.ca/english/links/links.cfm.

Privacy legislation

• **CIHR A Compendium of Canadian Legislation Respecting the Protection of Personal Information in Health Research** (April 2000, to be updated 2005)
Online: http://www.cihr-irsc.gc.ca/e/6824.html

• **Federal/Provincial/Territorial Oversight Offices-web links:**

- Canada (Federal)- http://www.privcom.gc.ca/index_e.asp
- British Columbia- http://www.oipc.bc.ca/
- Alberta- http://www.oipc.ab.ca/home/
- Saskatchewan- http://www.oipc.sk.ca
- Manitoba- http://www.ombudsman.mb.ca/
- Ontario- http://www.ipc.on.ca/
- Quebec- http://www.cai.gouv.qc.ca/index-en.html
- Prince Edward Island- http://www.assembly.pe.ca/foipp/index.php
- Nova Scotia- http://www.foipop.ns.ca
- New Brunswick- http://www.gnb.ca/0073/index-e.asp
- Newfoundland and Labrador- http://www.oipc.gov.nl.ca/default.htm
- Yukon- http://www.ombudsman.yk.ca/
- Northwest Territories- Email : atippcomm@theedge.ca
- Nunavut- Email : atippcomm@theedge.ca

Disclosure controls

• **Statistics Canada:**

- *Quality Guidelines* (4th Edition- Oct 2003), pg. 61-66,
  Online: http://www.statcan.ca/english/freepub/12-539-XIE/index.htm

- *Guide for Researchers under Agreement with Statistics Canada* (July 2004), Appendix 2- *More on Disclosure and Disclosure Risk*
  Online: http://www.statcan.ca/english/rdc/rdc_guides.htm

Related documents

• **CIHR *Procedure for Addressing Allegations of Non-compliance with Research Policies.***
Online: http://www.cihr-irsc.gc.ca/e/25178.html

• **CIHR *Secondary Use of Personal Information in Health Research: Case Studies*** (November, 2002).
Online: http://www.cihr-irsc.gc.ca/e/1475.htm

• **CIHR *Selected International Legal Norms on the Protection of Personal Information in Health Research*** (December, 2001).
Online: http://www.cihr-irsc.gc.ca/e/pdf_24017.htm

• **W. Lowrance, *Learning from Experience: Privacy and the Secondary use of Data in Health Research,*** November 28, 2002.
Online: http://www.nuffieldtrust.org.uk/publications/detail.asp?id=O&Prid=45

A-6 Glossary

The following terms are defined here as used in this document. Readers should be aware, however, that these terms are not yet standardized and may be used somewhat differently in other contexts.

Aggregate data. The data have been averaged or grouped into ranges (e.g. 5 or 10-year age groupings).

Camouflaged contacting. This is an approach to sampling and contacting patients with particular medical conditions in such a way that the individual making the contacting is not aware of the health status of that individual at the time of contacting. Records of individuals with and without the condition of interest are sampled in some pre-determined proportion from the original source (e.g. administrative or clinical records). Contact information about the combined-sample group is then released without any information about the health status of the individual being disclosed to the person making contact (by telephone or mail). The health status of the individual remains concealed until such time as the individual agrees to participate in the research and to disclose whether or not he or she has the condition of interest.

Coded data. Single code: A participant's data are assigned a random code. Direct identifiers are removed from the dataset and held separately. The key linking the code back to direct identifiers is available only to a limited number (e.g. senior members) of the research team. Double or multiple codes. Two or more codes are assigned to the same participant's data held in different datasets (e.g. health administrative data, clinical data, genetic samples and data). The key connecting the codes back to participants' direct identifiers is held by a third party (such as the data holder) and is not available to the researchers. Coded data refers to data that are at least single coded. (See Element #2, Section 2.2.2, Box-*Definition of terms*).

Consent. Agreement to participate in research (which may include the collection, use or disclosure of personal data) by a legally competent person, or by authorized third parties on behalf of those who lack legal competence. Consent, to be valid, must be voluntary and informed. For consent to be voluntary, the consent must be given without the exertion of undue influence on the person, and with the option of withdrawing from the research at any time without penalty. For consent to be informed, the person must be given information about the research, and must understand this information. (See TCPS, Section 3)

Confidentiality. Confidentiality is the obligation of an organization or custodian to protect the information entrusted to it and not misuse or wrongfully disclose it. (From *The Pan-Canadian Health Information Privacy and Confidentiality Framework*, January 27, 2005. Accessible on the Health Canada- Health and the Information Highway Division-Ehealth Resource Centre web page, under Reports 2005, at: http://www.hc-sc.gc.ca/ohih-bsi/about_apropos/hcpubssc_e.html).

Data. Facts or figures from which conclusions can be drawn. Data can take various forms, but are often numerical, such as daily weight measurements of each person in a group (ref. Statistics: *Power from data!* - Statistics Canada On-line: http://www.statcan.ca/english/edu/power/toc/contents.htm). See also definitions for *Information*.

Data custodian. See *Data holder*.

Data holder. The Data holder may have custodianship and/or stewardship functions. These functions may be executed within the same institution/body or may be delegated to distinct but coordinated institutions/bodies. Data custodianship relates primarily to responsibility for data storage and integrity. Data stewardship relates primarily to responsibility for data definition and access authorization, particularly data access and disclosure to third parties.

Data steward. See *Data holder*.

Data subject. The individual who is the subject of personal data/information collected for research purposes. Distinguished from Research Participant.

Direct collection. Collection of data directly from individuals.

Direct identifiers. These are variables such as name and address, health insurance number, etc., that provide an explicit link to a respondent. (Statistics Canada)

Indirect identifiers. These are variables such as date of birth, sex, marital status, area of residence, occupation, type of business, etc. that, in combination, could be used to identify an individual. (Adapted from Statistics Canada)

Impracticable. For the purposes of this document, "impracticable" means a degree of difficulty in doing something under present conditions, where the degree of difficulty is greater than would arise if something is merely inconvenient to do but may be less than if something is impossible. The conditions for assessing "impracticability" of consent are described in Element #3.

Information. Data that have been recorded, classified, organized, related, or interpreted within a framework so that meaning emerges. Information, like data, can take various forms. An example of the type of information that can be derived from data is the number of persons in a group in each weight category or changes in weight over time.(ref. Statistics: *Power from data!* - Statistics Canada On-line: http://www.statcan.ca/english/edu/power/toc/contents.htm). See also definitions for *Data* and *Statistics*.

Member-checking. This is when a researcher provides participants with the opportunity to look at transcripts of what they have said or done, and to delete or footnote what they consider to be inaccurate or sensitive information.

Non-identifiable data. Any element or combination of elements that allows direct or indirect identification of an individual was never collected or has been removed, although some elements may indirectly identify a group or region. There is no code linking the data back to the individual's identity. (See Element #2, Section 2.2.2, Box-*Definition of terms*)

Personal data/information. Personal data or information may contain a direct link to a specific individual (e.g. name and street address, personal health number, etc.) or any element or a combination of elements that allows indirect identification of an individual (e.g. if birth date combined with postal code and other personal information on the record such as ethnicity could lead to the identification of an individual). The scope of personal information covered in these Privacy Best Practices includes personal information derived from blood and other human biological materials (e.g. information such as blood type, DNA code and the presence or absence of disease), but not the materials themselves.

Privacy. Privacy includes a right to be free from intrusion and interruption. It is linked with other fundamental rights such as freedom and personal autonomy. In relation to information, privacy involves the right of individuals to determine when, how and to what extent they share information about themselves with others. (From *The Pan-Canadian Health Information Privacy and Confidentiality Framework*, January 27, 2005. Accessible on the Health Canada- Health and the Information Highway Division- Ehealth Resource Centre web page, under Reports 2005, at: http://www.hc-sc.gc.ca/ohih-bsi/about_apropos/hcpubssc_e.html).

Research. Research is defined in the TCPS as "a systematic investigation designed to develop or establish principles, facts or generalizable knowledge" (TCPS, pg. 1.1). The range of research requiring ethics review in the TCPS is listed in Appendix 1 (TCPS, pg. A.1).

Research participant. The individual who consents to participation in research and who is the subject of personal data or information collected for research. See *Data Subject*.

Secondary use of data for research. The data may have been collected originally for (i) a non-research purpose (e.g. for health care administrative purposes or for health care insurance billing purposes), or (ii) a different research purpose (e.g. for a study on a different but related disease).

Sensitivity. The sensitivity of personal data is related to the potential for harm or stigma that might attach to the identification of an individual because of the nature of the information. The type of information that an individual may consider sensitive could relate to: sexual attitudes, practices and orientation; use of alcohol, drugs, or other addictive substances; illegal activities; suicide; sexual abuse; sexual harassment; an individual's psychological well-being or mental health; some types of genetic information (e.g. information that predicts future illness or disability

and raises concerns around future employability or insurability); and any other information that, if released, might lead to social stigmatization or discrimination. Researchers should also be aware of information that communities may consider sensitive because, for example, of its potential to stigmatize a community.

Tables of Concordance with Privacy Legislation

A-7 Tables of concordance with privacy legislation

Explanatory note[106]

- The Tables of Concordance supplement key provisions of the Privacy Best Practices with cross-references to related requirements under Canadian privacy legislation. The Tables also briefly summarize requirements under Canadian privacy legislation which are supplemental to the Privacy Best Practices. A full text of the provisions referred to in the Tables of Concordance can be found in the CIHR's "Compendium of Canadian Legislation Respecting the Protection of Personal Information in Health Research".[107]

- The Tables are for reference purposes only and are intended to be read in conjunction with the Privacy Best Practices. References to specific Tables are found throughout the Privacy Best Practices.

- The requirements under privacy legislation will vary depending on the factual circumstances. As such, the Tables should not be relied upon as legal advice. Readers should consult the relevant privacy statute(s) and, depending on the circumstances, other applicable legal requirements as well as professional codes of ethics.

- The Tables only refer to Canadian federal, provincial and territorial privacy legislation. Municipal and local public sector privacy statutes have also been included.

- The legislation included in the Tables is current through to June 2005.

[106] These Tables of Concordance were prepared by Adam Kardash and Antonella Penta at Heenan Blaikie LLP in consultation with the Ethics Office, privacy regulatory authorities and Ministries of Health.
[107] The Compendium is accessible on CIHR's web site at: http://www.cihr-irsc.gc.ca/e/6824.html

APPLICATION OF CANADIAN PRIVACY LEGISLATION

Jurisdiction	Legislation	Entities covered by Legislation
Federal	*Personal Information Protection and Electronic Documents Act*	▪ Organizations that collect, use and disclose personal information in the course of a commercial activity (e.g., health care providers in private practice, pharmacies, pharmaceutical companies, etc.)[108] which takes place within a province unless the province has enacted legislation deemed by the Governor in Council to be substantially similar to the Act.[109] ▪ Federal works, undertakings and businesses that collect, use or disclose personal information, including personal information about employees in any province or territory. ▪ All personal information collected, used or disclosed in cross-border commercial transactions. ▪ Does not apply to government institutions subject to the *Privacy Act*.
	Privacy Act	▪ Federal government institutions (any department or ministry of state of the Government of Canada listed in the schedule to the Act or any body or office listed in the schedule to the Act).
British Columbia	*Personal Information Protection Act*	▪ All organizations (e.g., health care providers in private practice, pharmacies, pharmaceutical companies, not-for-profit organizations). ▪ Does not apply to personal information if Freedom of Information and Protection of Privacy Act applies.
	Freedom of Information and Protection of Privacy Act	▪ Public bodies (e.g., governmental bodies, health authorities, hospitals, mental health facilities and universities).
Alberta	*Health Information Act*	▪ Applies to custodians with respect to health information (e.g., health professionals, health care facilities, regional health authorities, provincial health boards). ▪ Legislation also impacts ethics committees and researchers.
	Personal Information Protection Act	▪ All organizations, including not-for-profit, corporations, professional regulatory associations. ▪ Does not apply to health information (as defined in the *Health Information Act*) where the information is collected, used or disclosed by an organization for health care purposes including health research and management of the health care system.
	Freedom of Information and Protection of Privacy Act	▪ Public bodies (e.g., government departments, educational bodies, health care bodies and designated agencies, boards and commissions). ▪ Does not apply to health information in records of a public body that is a custodian as defined in the *Health Information Act*.
	Municipal Government Act	▪ Municipalities.

[108] The precise application of the *Personal Information Protection and Electronic Documents Act* ("PIPEDA") to the health care sector has not yet been considered by a court of law. See Industry Canada's "PIPEDA Awareness Raising Tools (PARTs) Initiative for the Health Sector" at: http://ecom.ic.gc.ca/epic/internet/inecic-ceac.nsf/vwapj/PARTS_QandA-e.pdf/$FILE/PARTS_QandA-e.pdf.

[109] Note that the *Personal Information Protection Act* (Alberta), the *Personal Information Protection Act* (British Columbia) and *An act respecting the protection of personal information in the private sector* (Quebec) have each been deemed substantially similar. The provincial health privacy legislation in each of Alberta, Saskatchewan, Manitoba and Ontario have not been deemed substantially similar, although the Governor in Council has proposed to exempt health information custodians subject to the *Personal Health Information Protection Act* (Ontario) from the application of PIPEDA. Note also that PIPEDA will always apply to federal undertakings (e.g., broadcasting or telecommunications, banks, etc.) and to an organization's transfer of personal information outside the province.

Jurisdiction	Legislation	Entities covered by Legislation
Saskatchewan	*The Health Information Protection Act*	▪ Trustees with respect to personal health information (e.g., government institutions, regional health authorities, health professionals, health care organizations, professional regulatory bodies). ▪ Legislation also impacts researchers.
	Freedom of Information and Protection of Privacy Act	▪ Government institutions (e.g., government departments, Crown Corporations, designated provincial boards, bodies and agencies). ▪ Does not apply to information that constitutes personal health information as defined in *The Health Information Protection Act*.
	The Local Authority Freedom of Information and Protection of Privacy Act	▪ Local authorities (e.g., municipalities, universities, regional health authorities, special care homes, designated boards, commissions and bodies). ▪ Does not apply to information that constitutes personal health information as defined in *The Health Information Protection Act*.
Manitoba	*The Personal Health Information Act*	▪ Trustees with respect to personal health information (e.g., health professionals, health care facilities, public bodies (including government departments and universities), health services agencies). ▪ Legislation also impacts health information privacy committees, the institutional research review committees and researchers.
	The Freedom of Information and Protection of Privacy Act	▪ Public bodies (e.g. universities, certain hospitals, regional health authorities, municipalities, government departments and agencies). ▪ Does not apply to personal health information to which *The Personal Health Information Act* applies.
Ontario	*Personal Health Information Protection Act*	▪ Health information custodians, and agents of health information custodians, with respect to personal health information (e.g., Ontario Ministry of Health and Long-Term Care, public health units, hospitals, health care practitioners who provide health care, long-term care facilities, pharmacies, medical laboratories, ambulances, community health and mental health programs whose primary purpose is health care, Canadian Blood Services). ▪ Legislation also provides rules for research ethics boards, health data institutes, prescribed registries, persons who provide goods and services that enable a custodian to use electronic means to collect, use, modify, disclose, retain or dispose of personal health information, recipients of health information (e.g. researchers, employers and insurers). ▪ The legislation also applies to all persons with respect to the collection, use and disclosure of the health number.
	Freedom of Information and Protection of Privacy Act	▪ Institutions (e.g., ministries, agencies, boards and most commissions of the government of Ontario, community colleges). ▪ Where a health information custodian is also an institution under the *Freedom of Information and Protection of Privacy Act* ("FIPPA") or a part of an institution under FIPPA, FIPPA continues to apply to such a health information custodian only in some circumstances. ▪ Where a FIPPA institution is not a health information custodian, only FIPPA applies, even where information at issue is health information.
	Municipal Freedom of Information and Protection of Privacy Act	▪ Institutions (e.g. municipalities, boards of health, designated agencies, boards, commissions, corporations or other bodies)

Jurisdiction	Legislation	Entities covered by Legislation
Quebec	*An act respecting access to documents held by public bodies and the protection of personal information*	▪ Public bodies (e.g., universities, cegeps, health care facilities, government departments and agencies).
	An act respecting the protection of personal information in the private sector	▪ Persons carrying on an enterprise (e.g., health care providers in private practice, pharmacies and private research companies).
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	▪ Public bodies (e.g., government departments, agencies, boards, designated education and health bodies).
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	▪ Public bodies (e.g., universities, hospitals, government departments and agencies).
	Municipal Government Act	▪ Municipalities.
New Brunswick	*Protection of Personal Information Act*	▪ Public bodies (e.g., government departments, school boards, regional health authorities).
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[110]	▪ Public bodies (e.g., universities, health boards, municipalities, government departments).
Yukon	*Access to Information and Protection of Privacy Act*	▪ Public bodies (e.g., government departments, agencies, boards, commissions and corporations).
Northwest Territories	*Access to Information and Protection of Privacy Act*	▪ Public bodies (e.g., government departments, agencies, boards).
Nunavut	*Access to Information and Protection of Privacy Act*	▪ Public bodies (e.g., government departments, agencies, boards).

[110] Part IV to be proclaimed.

ELEMENT #1 – DETERMINING THE RESEARCH OBJECTIVES AND JUSTIFYING THE DATA NEEDED TO FULFILL THESE OBJECTIVES

Element #1 provides that researchers should, at the outset of the research design process, identify and document research objectives as a basis for determining what data will be needed for the research. The precise identification and documentation of the purposes for collection, use and disclosure of personal (health) information is critical for the purpose of complying with various requirements under privacy legislation, including requirements relating to the principles of limiting collection of personal information, obtaining consent for collection, use and disclosure of personal (health) information, and accountability and transparency. Statutory references to each of these requirements under Canadian privacy legislation can be found in the following concordance tables in this section:

- Element #2 - Limiting the Collection of Personal Data
- Element #4 - Managing and Documenting Consent
- Element #5 - Informing Prospective Research Participants about the Research
- Element #10 - Ensuring Accountability and Transparency in the Management of Personal Data

ELEMENT #2 – LIMITING THE COLLECTION OF PERSONAL DATA[111,112]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.4 (Limiting Collection)
	Privacy Act	Section 4 (Collection of personal information) Section 5 (Personal information to be collected directly from individual)
British Columbia	*Personal Information Protection Act*	Section 11 (Limitations on collection of personal information) Section 12 (Collection from source other than the individual)
	Freedom of Information and Protection of Privacy Act	Section 26 (Purposes for which information may be collected) Section 27(1) (How personal information is to be collected)
Alberta	*Health Information Act*	Sections 18 to 21 (Collection of health information) Section 22 (Duty to collect health information from individual directly) Section 24 (Collection of health information by affiliate) Section 57 (Duty to collect, use or disclose health information with highest degree of anonymity possible) Section 58 (Duty to collect, use or disclose health information in a limited manner) Section 68(a) (Health information to be used in data matching to be collected in accordance with the Act)
	Health Information Regulation	Section 5(2) (Persons authorized to collect personal health number)
	Personal Information Protection Act	Section 7(1)(b) (Direct collection) Section 11 (Limitations on collection)
	Freedom of Information and Protection of Privacy Act	Section 33 (Purposes for which information may be collected) Section 34(1) (Direct collection)
	Municipal Government Act	__
Saskatchewan	*The Health Information Protection Act*	Section 11 (Collection of health numbers) Section 23 (Collection on a need to know basis) Section 24 (Restrictions on collection) Section 25(1) (Direct collection)
	The Freedom of Information and Protection of Privacy Act	Section 25 (Purpose of information) Section 26 (Manner of collection)
	The Local Authority Freedom of Information and Protection of Privacy Act	__
Manitoba	*The Personal Health Information Act*	Section 13(1) (Restrictions on collection) Section 13(2) (Limit on amount of information collected) Section 14 (Source of information) Section 26 (Collection of health numbers)

[111] This table cross references the statutory provisions for collecting only the personal information needed to fulfill the purpose of the collection. As a general rule, consent is required for collection of personal information, which consent must be voluntary and informed. For statutory provisions relating to the elements and form of consent, please refer to the table for Element #4. For the statutory provisions relating to the notice required for voluntary and informed consent, please refer to the table for Element #5.

[112] This table also includes provisions dealing with the requirement to collect personal information directly from the person the information is about. Note that there are various exceptions to this requirement which have not been included in this table.

ELEMENT #2 – LIMITING THE COLLECTION OF PERSONAL DATA[111,112]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Manitoba	*The Freedom of Information and Protection of Privacy Act*	Section 36 (1) (Purpose of collection) Section 36(2) (Limit on amount of information collected) Section 37(1) (Manner of collection)
Ontario	*Personal Health Information Protection Act*	Section 30 (Extent of information) Section 34 (2) (Limits on collecting health numbers) Section 36(1) (Indirect collection)
	Freedom of Information and Protection of Privacy Act	Section 38(2) (Collection of personal information) Section 39(1) (Direct collection)
	Municipal Freedom of Information and Protection of Privacy Act	__
Quebec	*An act respecting the protection of personal information in the private sector*	Section 5 (Necessary information) Section 6 (Collection from the person concerned)
	An act respecting access to documents held by public bodies and the protection of personal information	Section 64 (Unnecessary information)
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 31 (Purpose of Collection of Information) Section 32 (Direct collection)
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 24(1) (Treatment of Personal Information)
	Municipal Government Act	__
New Brunswick	*Protection of Personal Information Act*	Schedule A, Principle 4 (Limiting Collection) Schedule B, Principle 4 (Individuals from whom personal information may be collected)
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[113]	Section 32 (Purpose for which personal information may be collected) Section 33 (How personal information is to be collected)
Yukon	*Access to Information and Protection of Privacy Act*	Section 29 (Purpose for which personal information may be collected) Section 30 (How personal information is to be collected)
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 40 (Purpose of collection of information) Section 41 (Collection of information from individual concerned)
Nunavut	*Access to Information and Protection of Privacy Act*	Section 40 (Purpose of collection of information) Section 41 (Collection of information from individual concerned)

[113] Part IV to be proclaimed.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*[115]	Sections 7(2)(c): Conditions for use by an organization for statistical, or scholarly study or research purposes: ▪ purpose cannot be achieved without using the information; ▪ information is used in a manner that ensures confidentiality; ▪ impracticable to obtain consent; and ▪ organization informs the Commissioner of the use before information is used. Section 7(3)(f): Conditions for disclosure by an organization for statistical, or scholarly study or research purposes: ▪ purpose cannot be achieved without disclosing the information; ▪ impracticable to obtain consent; and ▪ organization informs the Commissioner of the disclosure before information is disclosed.
	Privacy Act	Section 8(2)(j): Conditions for use and disclosure by a government institution for research or statistical purposes: Head of the government institution: ▪ is satisfied that the purpose for disclosure cannot reasonably be accomplished unless the information is provided in identifiable form; and ▪ obtains from the person or body a written undertaking that no subsequent disclosure of the information will be made in identifiable form.
British Columbia	*Personal Information Protection Act*	Section 21: Conditions for disclosure by organizations: ▪ Research purpose cannot be accomplished unless the personal information is provided in an identifiable form; ▪ information will not be used to contact persons to ask them to participate in the research; ▪ linkage of the personal information to other information is not harmful to the individuals and the benefits to be derived from the linkage are clearly in the public interest; ▪ the organization to which the personal information is to be disclosed has signed a data sharing agreement; and ▪ it is impracticable for the organization to seek the consent of the individual.

[114] Consent is generally required under privacy legislation for the use and disclosure of personal information for any purpose, including research purposes, subject to limited exceptions. This chart sets out the conditions upon which personal information may be used or disclosed for research purposes without consent. Reference should also be made to the statutory requirements for data sharing agreements and data matching/linking detailed in the concordance table for Element #8.

[115] Note that the consent exemptions noted only apply for the use and disclosure of personal information for statistical, scholarly study or research purposes. There is no equivalent consent exemption in the statute for collecting personal information for such purposes.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
British Columbia	*Freedom of Information and Protection of Privacy Act*	Section 35: Conditions for disclosure by public bodies: ▪ Research purpose cannot reasonably be accomplished unless information is provided in identifiable form or research purpose is approved by Commissioner; ▪ information is disclosed on condition that it not be used to contact a person to participate in the research; ▪ any record linkage is not harmful to the individuals and the benefits to be derived from the record linkage are clearly in the public interest; ▪ head of the public body concerned has approved conditions relating to (i) security and confidentiality; (ii) removal or destruction of individual identifiers at the earliest reasonable time; (iii) prohibition of any subsequent use or disclosure of the information in individually identifiable form without express authorization of the public body; and ▪ recipient has signed an agreement to comply with the approved conditions, the Act and any of the public body's policies and procedures relating to the confidentiality of personal information.
Alberta	*Health Information Act*	Sections 27(1)(d) and 35(1)(a): Conditions for use and disclosure by a custodian: ▪ Custodian submits a proposal to an ethics committee; ▪ ethics committee is satisfied with respect to importance of research, qualifications of researcher, safeguards and that it is not reasonable or practical to obtain consent; and ▪ custodian has complied with/agreed to conditions suggested by the ethics committee. See also section 49 (Research proposal), section 50 (Role of ethics committee), section 51 (Bar to research), section 52 (Application for disclosure of health information), section 53 (Conditions and consents), section 54 (Agreement between custodian and researcher) and section 55 (Consent of the individual is required if additional information is needed).
	Personal Information Protection Act Regulation	Section 12(2): Conditions for disclosure by an archival institution: ▪ Disclosure is necessary for the research purpose; ▪ disclosure is not harmful to the individual concerned; ▪ research purpose is not contrary to the purposes and intent of the Act; and ▪ either (i)a reasonable person, taking into consideration all relevant circumstances, would find that disclosure of the personal information was appropriate at the time, or (ii) the information is disclosed under a research agreement. Section 14(3): Conditions for disclosure by an organization that is not an archival institution: ▪ Research agreement required; ▪ recipient agrees to comply with the same requirements as those established in respect of archival institutions; ▪ research has been approved by a research ethics review committee; and ▪ researcher has agreed to any additional conditions imposed by the ethics review committee.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Alberta	*Freedom of Information and Protection of Privacy Act*	Section 42: Conditions for disclosure by public bodies: ▪ Research purpose cannot reasonably be accomplished unless that information is provided in identifiable form or research purpose has been approved by Commissioner, ▪ record linkage is not harmful to individuals and benefits to be derived from record linkage are clearly in public interest, ▪ head of public body has approved conditions relating to (i) security and confidentiality, (ii) removal or destruction of identifiers at the earliest reasonable time, and (iii) prohibition of subsequent use or disclosure without express authorization of that public body, and ▪ recipient signed an agreement to comply with approved conditions, Act and public body's policies and procedures relating to confidentiality of personal information.
	Municipal Government Act	—
Saskatchewan	*The Health Information Protection Act*	Section 29(2): Conditions for disclosure by a trustee or designated archive: ▪ Only where not reasonably practicable for consent to be obtained and if: a) research purposes cannot reasonably be accomplished using de-identified personal health information or other information; b) reasonable steps are taken to protect privacy of individual by removing all personal health information that is not required for the purposes of the research; c) in the opinion of research ethics committee, the potential benefits of the research project clearly outweigh the potential risk to the privacy of the individual; and d) (i) in the opinion of the trustee or designated archive, the research project is not contrary to public interest; (ii) research project is approved by a research ethics committee approved by minister; and (iii) recipient enters into an agreement with trustee or designated archive.
	The Freedom of Information and Protection of Privacy Act	Section 29(2)(k): Conditions for disclosure by public body: ▪ Head of public body must be satisfied that purpose for disclosure is not contrary to public interest and cannot reasonably be accomplished unless information is provided in identifiable form; and ▪ agreement must be signed by recipient not to make a subsequent disclosure of the information in identifiable form.
	The Local Authority Freedom of Information and Protection of Privacy Act	Section 28(2)(k): Conditions for disclosure by local body: ▪ Head of local body must be satisfied that purpose for disclosure is not contrary to public interest and purpose cannot reasonably be accomplished unless information is provided in identifiable form; and ▪ recipient provides written agreement not to make subsequent disclosure of the information in identifiable form.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Manitoba	*The Personal Health Information Act*	Section 24: Conditions for disclosure by trustees: ▪ Research project must be approved by: (a) health information privacy committee if personal health information is maintained by government or a government agency; and (b) institutional research review committee, if personal health information is maintained by a trustee other than the government or a government agency. ▪ Approval may be given only if applicable committee has determined that: (a) research is of sufficient importance to outweigh the intrusion into privacy; (b) research purpose cannot reasonably be accomplished unless personal health information is provided in identifiable form; (c) unreasonable or impractical for researcher to obtain consent; and (d) research project contains (i) reasonable safeguards to protect confidentiality and security of the personal health information, and (ii) procedures to destroy the information or remove all identifying information at earliest opportunity consistent with the purposes of the project. ▪ Agreement required between trustee and recipient. ▪ Consent required for direct contact with individuals except where information consists only of individuals' names and addresses.
	The Freedom of Information and Protection of Privacy Act	Section 47(4): Conditions for disclosure by public body: ▪ Advice requested from review committee has been received and considered; ▪ head is satisfied that (i) the information is requested for bona fide research purpose, (ii) research cannot reasonably be accomplished unless information is provided in identifiable form, (iii) unreasonable or impractical for recipient to obtain consent, and (iv) disclosure of information, and any information linkage, is not likely to harm individuals and benefits to be derived from research and any information linkage are clearly in the public interest; ▪ head of public body has approved conditions relating to (i) protection of personal information, including use, security and confidentiality, (ii) removal or destruction of identifiers at earliest reasonable time, and (iii) prohibition of subsequent use or disclosure of personal information in identifiable form without written authorization of the public body; and ▪ recipient has entered into a written agreement to comply with approved conditions.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Ontario	*Personal Health Information Protection Act*	Section 44(1): Conditions for use by health information custodians and disclosure by health information custodians to researchers: ▪ Researcher must submit to custodian (i) an application in writing, (ii) a research plan, and (iii) a copy of the decision of a research ethics board that approves research plan; and ▪ researcher must enter into an agreement with custodian agreeing to comply with conditions and restrictions that custodian may impose relating to use, disclosure, return or disposal of information. See also sections 34(2) and (3) (Use and disclosure of health numbers) 37(1)(j) and (3) (Permitted use for research), section 44(2) (Elements of Research plan), section 44(3) and (4) (Consideration and decision of board), section 44(5) (Content of research agreement), section 44(6) (Compliance by researcher), sections 44(10) and (11) (Research approved outside Ontario) and section 50(1)(b) (Disclosure outside Ontario). See also section 39(1)(c) (Disclosure to prescribed person who compiles or maintains a registry of personal health information for purposes of facilitating or improving the provision of health care or that relates to the storage or donation of body parts or bodily substances), section 45 (Disclosure to prescribed entities for planning and management of health systems) and section 47 (Disclosure for analysis of health system).
	Personal Health Information Protection Act, General Regulation	Section 12 (Disclosure of health number): ▪ Researchers with custody or control of health numbers, by reason of a use or disclosure authorized under the Act for research purposes, may disclose the health number to a registry prescribed under the Act, an entity prescribed for the purposes of planning and management of health systems or another researcher if, o the disclosure is part of a research plan approved under the Act, or o the disclosure is necessary for the purpose of verifying or validating the information or the research. Section 15 (Requirement for research ethics board) Section 16 (Requirement for a research plan) Section 17 (Disclosure by researcher) Section 18(3) and (4) (Rules applicable to section 45 prescribed entities for use and disclosure of personal health information for research purposes)[116] Section 13(4) and (5) (Rules applicable to registries of personal health information for use and disclosure of personal health information for research purposes)[117]

[116] The following are prescribed for the purposes of section 45:
1. Cancer Care Ontario.
2. Canadian Institute for Health Information.
3. Institute for Clinical Evaluative Sciences.
4. Pediatric Oncology Group of Ontario.

[117] The following are prescribed registries:
1. Cardiac Care Network of Ontario in respect of its registry of cardiac services.
2. INSCYTE (Information System for Cytology etc.) Corporation in respect of CytoBase.
3. London Health Sciences Centre in respect of the Ontario Joint Replacement Registry.
4. Canadian Stroke Network in respect of the Canadian Stroke Registry.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Ontario	*Freedom of Information and Protection of Privacy Act*	Section 21(1)(e): Conditions for disclosure by public body: ▪ Disclosure is consistent with conditions or reasonable expectations of disclosure under which the personal information was provided, collected or obtained; ▪ research cannot be reasonably accomplished unless information is provided in identifiable form; and ▪ recipient has agreed to comply with the conditions relating to security and confidentiality prescribed by the regulations.[118]
	Municipal Freedom of Information and Protection of Privacy Act	—
	Municipal Freedom of Information and Protection of Privacy Act, General Regulation	Section 10(1): Terms and conditions a person must agree to before a head may disclose personal information to that person for a research purpose: ▪ Person shall use the information only for a research purpose set out in the agreement or for which the person has written authorization from the institution; ▪ the person shall name in the agreement any other persons who will be given access to personal information in a form in which the individual to whom it relates can be identified; ▪ before disclosing personal information to other persons, the person shall enter into an agreement with those persons to ensure that they will not disclose it to any other person; ▪ the person shall keep the information in a physically secure location to which access is given only to the person and to the persons given access; ▪ the person shall destroy all individual identifiers in the information by the date specified in the agreement; ▪ the person shall not contact any individual to whom personal information relates directly or indirectly without the prior written authority of the institution; ▪ the person shall ensure that no personal information will be used or disclosed in a form in which the individual to whom it relates can be identified without the written authority of the institution; and ▪ the person shall notify the institution in writing immediately if the person becomes aware that any of the conditions set out in this section have been breached.
Quebec	*An act respecting the protection of personal information in the private sector*	Section 21: Conditions for disclosure: ▪ Written request must be made to the commission. ▪ Commission must be satisfied that (i) intended use is not frivolous and the ends contemplated cannot be achieved unless the information is communicated in identifiable form and (ii) information will be used in manner that ensures its confidentiality. ▪ Authorization is granted for such period and on such conditions as may be fixed by the Commission. It may be revoked before the expiry of the period granted if Commission has reason to believe that the authorized person or body does not respect the confidentiality of the information disclosed or the other conditions.

[118] Conditions relating to security and confidentiality are prescribed by section 10 of Regulation 460.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Quebec	*An act respecting access to documents held by public bodies and the protection of personal information*	Section 125: Conditions for disclosure: ▪ Same conditions as above.
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 39: Conditions for disclosure by public body: ▪ Research purpose cannot reasonably be accomplished unless information is provided in identifiable form or research purpose has been approved by Commissioner; ▪ any record linkage is not harmful to individuals and benefits to be derived from record linkage are clearly in public interest; ▪ head of a public body has approved conditions relating to (i) security and confidentiality, (ii) removal or destruction of individual identifiers at earliest reasonable time, and (iii) prohibition of subsequent use or disclosure of information in identifiable form without express authorization of that public body; and ▪ recipient signs agreement to comply with approved conditions, Act and public body's policies and procedures relating to confidentiality of personal information.
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 29: Conditions for disclosure by public body: ▪ Research purpose cannot reasonably be accomplished unless information is provided in identifiable form; ▪ any record linkage is not harmful to individuals and benefits to be derived from record linkage are clearly in public interest; ▪ head of a public body has approved conditions relating to (i) security and confidentiality, (ii) removal or destruction of individual identifiers at earliest reasonable time, and (iii) prohibition of subsequent use or disclosure of information in identifiable form without express authorization of that public body; and ▪ recipient signs agreement to comply with approved conditions, Act and public body's policies and procedures relating to confidentiality of personal information.
	Municipal Government Act	Section 485(4): Conditions for disclosure by municipality: ▪ Research purpose cannot reasonably be accomplished unless information is provided in individually identifiable form; ▪ any record linkage is not harmful to individuals the information is about and the benefits to be derived from record linkage are clearly in the public interest; ▪ the responsible officer has approved conditions relating to (i) security and confidentiality, (ii) the removal or destruction of individual identifiers at the earliest reasonable time, and (iii) the prohibition of any subsequent use or disclosure of that information in individually identifiable form without the express authority of the municipality; and ▪ the person to whom the information is disclosed has signed an agreement to comply with the approved conditions, this Part of the Act, and any of the municipality's policies and procedures relating to the confidentiality of personal information.
New Brunswick	*Protection of Personal Information Act*	Schedule B, section 3.4: Consent not required when public body collects, uses or discloses personal information for purposes of legitimate research in the interest of science, of learning or of public policy, or for archival purposes.

ELEMENT #3 – DETERMINING IF CONSENT FROM INDIVIDUALS IS REQUIRED		
Conditions For Use And Disclosure For Research Purposes Without Consent[114]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*	Section 41: Conditions for disclosure by public body: ▪ Same conditions as for Nova Scotia
Yukon	*Access to Information and Protection of Privacy Act*	Section 38: Conditions for disclosure by public body: ▪ Same conditions as for Nova Scotia
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 49: Conditions for disclosure by public body: ▪ Same conditions as for Nova Scotia
Nunavut	*Access to Information and Protection of Privacy Act*	Section 49: Conditions for disclosure by public body: ▪ Same conditions as for Nova Scotia

ELEMENT #4 – MANAGING AND DOCUMENTING CONSENT[119]		
Part 1 - Consent Requirement and Elements of Consent		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.3 and 4.3.1 (Consent Requirement) Schedule 1, 4.3.4, 4.3.6 and 4.3.7 (Form of Consent) Schedule 1, 4.3.2, 4.3.5, 4.3.8 (Elements of Consent)
	Privacy Act	Sections 7 and 8 (Consent Requirement)
British Columbia	*Personal Information Protection Act*	Sections 6 and 7 (Consent Requirement) Section 8 (Form of Consent) Section 9 (Elements of Consent)
	Freedom of Information and Protection of Privacy Act	Sections 32(b) and 33.1(1)(b) (Consent Requirement)
	Freedom of Information and Protection of Privacy Regulation	Section 6 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to disclosure of personal information must be in writing and specify to whom the personal information may be disclosed and how the personal information may be used.
Alberta	*Health Information Act*	Section 34(1) and (3) (Consent Requirement) Section 34(2), (4), (5) and (6) (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to disclosure of personal health information must be in writing or be provided electronically and must include: (a) authorization for custodian to disclose the health information specified in the consent; (b) purpose for which the health information may be disclosed; (c) identity of person to whom health information may be disclosed; (d) acknowledgment that individual providing consent has been made aware of reasons why the health information is needed and the risks and benefits to the individual of consenting or refusing to consent; (e) date consent is effective and date, if any, on which consent expires; and (f) statement that consent may be revoked at any time by the individual providing it.[120] • Revocation of consent must be provided in writing or electronically.
	Health Information Regulation	Section 6(2) (Electronic Consent) Supplemental Requirement to CIHR Privacy Best Practices: An electronic consent or a revocation of an electronic consent is valid only if the level of authentication is sufficient to identify the individual who is granting the consent or revoking the consent, as the case may be.

[119] Canadian privacy statutes generally require consent for collection, use and disclosure of personal information for research purposes, subject to exceptions set out in the legislation. This table sets out the form and elements of consent where consent is required for the protection of privacy. See the exceptions to consent requirement for research purposes in table of concordance for Element #3. See also the statutory notice requirements for informed consent in the table of concordance for Element #5. See also the table following this chart for statutory references to consent by substitute decision makers.

[120] Section 23 of the *Health Information Act* (Alberta) states that if a custodian collects health information from an individual using a recording device or camera or any other device that may not be obvious to the individual, the custodian must, before collecting the information, obtain the written consent of the individual to the use of the device or camera.

ELEMENT #4 – MANAGING AND DOCUMENTING CONSENT[119]		
Part 1 - Consent Requirement and Elements of Consent		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Alberta	*Personal Information Protection Act*	Section 7 (Consent Requirement) Section 8 (Form of Consent) Section 9 (Withdrawal or variation of consent) Section 10 (Consent obtained by deception)
	Freedom of Information and Protection of Privacy Act	Sections 39(1)(b) and 40(1)(d) (Consent Requirement)
	Freedom of Information and Protection of Privacy Regulation	Section 6(1) (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to use or disclosure of personal information must be in writing and must specify to whom the personal information may be disclosed.
	Municipal Government Act	__
Saskatchewan	*The Health Information Protection Act*	Sections 5, 26 and 27 (Consent Requirement) Sections 6(1) and (2), and 7 (Elements of Consent) Sections 6(3),(4) and (5) (Form of Consent)
	The Freedom of Information and Protection of Privacy Act	Sections 28 and 29 (Consent Requirement)
	The Freedom of Information and Protection of Privacy Regulations	Section 18 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to be in writing unless the head of the public body determines that it is not reasonably practicable.
	The Local Authority Freedom of Information and Protection of Privacy Act	__
	The Local Authority Freedom of Information and Protection of Privacy Regulations	Section 11 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to be in writing unless the head of the local body determines that it is not reasonably practicable.
Manitoba	*The Personal Health Information Act*	Sections 21(b) and 22(1)(b) (Consent Requirement)
	The Freedom of Information and Protection of Privacy Act	Sections 43(b) and 44(1)(b) (Consent Requirement)
Ontario	*Personal Health Information Protection Act*	Section 29 (Consent Requirement) Sections 18(1), 18(5), 18(6) and 19 (Elements of Consent) Section 18(2), (3) and (4) (Form of Consent)
	Freedom of Information and Protection of Privacy Act	Section 41(a) and 42(b) (Consent Requirement)
	Municipal Freedom of Information and Protection of Privacy Act	__

ELEMENT #4 – MANAGING AND DOCUMENTING CONSENT[119]		
Part 1 - Consent Requirement and Elements of Consent		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Quebec	*An act respecting the protection of personal information in the private sector*	Sections 12 and 13 (Consent Requirement) Section 14 (Elements and Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent must be manifest, free and enlightened[121]
	An act respecting access to documents held by public bodies and the protection of personal information	Section 53(1) and 59 (Consent Requirement)
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 36(1)(b) and 37(1)(c) (Consent Requirement)
	Freedom of Information and Protection of Privacy Act, General Regulations	Section 6 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to use or disclose personal information must (a) be in writing and (b) specify to whom the personal information may be disclosed and how the personal information may be used.
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Sections 26(b) and 27(b) (Consent Requirement)
	Freedom of Information and Protection of Privacy Regulations	Sections 7(2) and 8 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: Consent to use of personal information must (i) be in writing, (ii) identify the information, and (iii) specify to whom the information may be disclosed and how the information may be used.[122]
	Municipal Government Act	—
New Brunswick	*Protection of Personal Information Act*	Schedule A, Principle 3 (Consent Requirement) Schedule B, 3.1 and 3.2 (Form of Consent)
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[123]	Sections 38(1)(b) and 39(1)(b) (Consent Requirement)
Yukon	*Access to Information and Protection of Privacy Act*	Sections 35 (b) and 36 (b) (Consent Requirement)
	Access to Information Regulation	Section 2 (Consent to disclosure of personal information) Supplemental Requirement to CIHR Privacy Best Practices: Consent to disclosure to be in writing and specify to whom the personal information may be disclosed and how it may be used.
Northwest Territories	*Access to Information and Protection of Privacy Act*	Sections 43 (b) and 48 (b) (Consent Requirement)
Northwest Territories	*Access to Information and Protection of Privacy Regulations*	Section 5 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: The consent of an individual to a public body's use or disclosure of his or her personal information must be in writing and specify to whom the personal information may be disclosed and how it may be used.

[121] This is often interpreted as requiring express consent.
[122] Consent to disclosure of personal information may be in prescribed form 3 and consent to use of personal information may be in prescribed form 4, each of which are set out in the Regulations to the Act.
[123] Part IV to be proclaimed.

ELEMENT #4 – MANAGING AND DOCUMENTING CONSENT[119]		
Part 1 - Consent Requirement and Elements of Consent		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Nunavut	*Access to Information and Protection of Privacy Act*	Sections 43 (b) and 48 (b) (Consent Requirement)
	Access to Information and Protection of Privacy Regulations	Section 5 (Form of Consent) Supplemental Requirement to CIHR Privacy Best Practices: The consent of an individual to a public body's use or disclosure of his or her personal information must be in writing and specify to whom the personal information may be disclosed and how it may be used.

ELEMENT #4 – MANAGING AND DOCUMENTING CONSENT		
Part 2 - Consent by Substitute Decision Makers[124]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.3.6 – (Consent by authorized representatives)
	Privacy Act Privacy Regulations	Section 10 (Exercise of rights on behalf of minors, persons deemed incompetent, or deceased persons)
British Columbia	*Personal Information Protection Act Regulations*	Section 2 (Who may act for minors and others) Section 3 (Who may act for deceased persons) Section 4 (Determination of nearest relative)
	Freedom of Information and Protection of Privacy Regulation	Section 3 (Who can act for young people and others)
Alberta	*Health Information Act*	Section 104(1) (Exercise of rights by other persons)
	Personal Information Protection Act	Section 61(1) (Exercise of rights by other persons)
	Freedom of Information and Protection of Privacy Act	Section 84 (Exercise of rights by other persons)
Saskatchewan	*The Health Information Protection Act*	Section 56 (Exercise of rights by other persons)
	The Freedom of Information and Protection of Privacy Act	Section 59 (Exercise of rights by other persons)
Manitoba	*The Personal Health Information Act*	Section 60 (Exercising rights of another person)
	The Freedom of Information and Protection of Privacy Act	Section 79 (Exercising rights of another person)
Ontario	*Personal Health Information Protection Act*	Section 5 (Substitute decision-maker) Sections 23 and 26 (Persons who are entitled to consent to the collection, use, or disclosure of personal health information) Section 25 (Authority of substitute decision-maker) Section 27 (Appointment of representative)
	Freedom of Information and Protection of Privacy Act	Section 66 (Exercise of rights of deceased, etc., persons)
Quebec	*An act respecting the protection of personal information in the private sector*	—
	An act respecting access to documents held by public bodies and the protection of personal information	Section 53 (Person with parental authority may authorize disclosure for a minor)
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 71 (Exercise of rights by other persons)
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 43 (Exercise of right or power by other persons)
New Brunswick	*Protection of Personal Information Act*	Schedule B, section 3.3 (Consent can be given by a parent, guardian or other representative of the individual in appropriate circumstances)

[124] This chart cross references the statutory provisions for substitute consent.

ELEMENT #4 – MANAGING AND DOCUMENTING CONSENT		
Part 2 - Consent by Substitute Decision Makers[124]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[125]	Section 65 (Exercising rights of another person)
Yukon	*Access to Information and Protection of Privacy Act*	Section 62 (Personal Representation)
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 52 (Exercise of Rights by other persons)
Nunavut	*Access to Information and Protection of Privacy Act*	Section 52 (Exercise of Rights by other persons)

[125] Part IV to be proclaimed.

ELEMENT #5 – INFORMING PROSPECTIVE RESEARCH PARTICIPANTS ABOUT THE RESEARCH[126]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.2 (Purpose for collection must be identified at the time of collection and must be documented) Schedule 1, 4.3.2 (Knowledge and consent)
	Privacy Act	Section 5(2) (Individual to be informed of purpose of collection)
British Columbia	*Personal Information Protection Act*	Section 8(3) 10(1), 14 and 17 (Notice requirements for collection, use and disclosure)
	Freedom of Information and Protection of Privacy Act	Section 27(2) (Information to be given regarding purposes for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.
Alberta	*Health Information Act*	Sections 21(2) and 22(3) (Information to be given regarding purposes for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the specific legal authority for the collection.
	Personal Information Protection Act	Section 8(3) and 13 (Notification requirements for collection, use and disclosure)
	Freedom of Information and Protection of Privacy Act	Section 34(2) (Information to be given regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.
	Municipal Government Act	__
Saskatchewan	*The Health Information Protection Act*	Sections 6 and 9 (Individual must be informed of purposes for collection use, and disclosure of the individual's personal health information)
	The Freedom of Information and Protection of Privacy Act	Section 26(2) (Individual must be informed of the purposes for the collection)
	The Local Authority Freedom of Information and Protection of Privacy Act	Section 25(2) (Individual to be informed of purposes of collection) Section 57(l) (Lieutenant Governor in Council may make regulations prescribing any matter to be included in notice)
Manitoba	*The Personal Health Information Act*	Section 15 (Notice of collection practices)
	The Freedom of Information and Protection of Privacy Act	Section 37(2) (Individual must be informed of the purposes for the collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information
Ontario	*Personal Health Information Protection Act*	Section 18(5) and (6) (Knowledge of purposes of collection)

[126] This chart sets out the notice/information provision requirements under applicable privacy statutes. For statutory cross reference to other elements of consent, refer to the table of concordance for Element #4. For general notice obligations, refer to the accountability and transparency provisions set out in the table of concordance for Element #10.

ELEMENT #5 – INFORMING PROSPECTIVE RESEARCH PARTICIPANTS ABOUT THE RESEARCH[126]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Ontario	*Freedom of Information and Protection of Privacy Act*	Section 39(2) (Information to be given regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.
	Municipal Freedom of Information and Protection of Privacy Act	Section 29(2) (Individual must be informed of primary purposes of collection) Supplemental Requirement to CIHR Best Practices: ▪ Individual must be told of the legal authority for collecting the information
	Municipal Freedom of Information and Protection of Privacy Act, General Regulation	Section 4(1) (When notice not required) ▪ Institutions not required to give notice of collection if providing notice would frustrate purpose of the collection or might result in an unjustifiable invasion of another individual's privacy. Head of institution must make available a statement describing purpose of collection and reason why notice not given.
Quebec	*An act respecting the protection of personal information in the private sector*	Section 8 (Information to be given regarding purpose for collection)
	An act respecting access to documents held by public bodies and the protection of personal information	Section 65 (Information to be given regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Every person who, on behalf of a public body, collects nominative information from the person concerned or from a third person must first identify himself and inform the person concerned that the collection is either mandatory or optional and of the consequences of failing to provide the information.
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 32(2) (Right to be informed regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.
Nova Scotia	*Freedom of Information and Protection of Privacy Regulations*	Section 8 (Requirement before use) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Before information about an individual may be used, the individual must identify the information and give consent in writing specifying to whom the information may be disclosed and how the information may be used
	Municipal Government Act	__
New Brunswick	*Protection of Personal Information Act*	Schedule A, Principle 2 and Schedule B, section 2.1 (Purposes for collection must be identified)
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[127]	Section 33(2) (Information regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.

[127] Part IV to be proclaimed.

ELEMENT #5 – INFORMING PROSPECTIVE RESEARCH PARTICIPANTS ABOUT THE RESEARCH[126]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Yukon	*Access to Information and Protection of Privacy Act*	Section 30(2) (Information regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 41(2) (Information regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.
Nunavut	*Access to Information and Protection of Privacy Act*	Section 41(2) (Information regarding purpose for collection) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual must be told of the legal authority for collecting the information.

ELEMENT #6 – RECRUITING PROSPECTIVE RESEARCH PARTICIPANTS		
Statutory Prohibitions to Secondary Use/Disclosure of Personal Information to Contact Individuals to Participate in Research[128]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	—
	Privacy Act	—
British Columbia	*Personal Information Protection Act*	Section 21(b): An organization may disclose, without the consent of the individual, personal information for a research purpose if the disclosure is on condition that it will not be used to contact persons to ask them to participate in the research.
	Freedom of Information and Protection of Privacy Act	Section 35 (a.1): A public body may disclose personal information for a research purpose without the consent of the individual only if the information is disclosed on condition that it not be used for the purpose of contacting a person to participate in the research.
Alberta	*Health Information Act*	Section 55: If the researcher wishes to contact the individuals who are the subjects of the information disclosed for research purposes to obtain additional health information, the custodian or an affiliate of the custodian must first obtain consents from those individuals to their being contacted for that purpose.
	Personal Information Protection Act Regulation	Section 12(3)(d): If personal information is to be disclosed by an organization under a research agreement, the person to whom the information is to be disclosed must agree to not contact any individual to whom the information relates.
	Freedom of Information and Protection of Privacy Regulation	Section 8(f): The agreement required by the Act for disclosure of personal information without consent of the individual for research purposes must include provision that recipient will not contact any individual to whom the personal information relates, directly or indirectly, without the prior written authority of the public body.
	Municipal Government Act	—
Saskatchewan	*The Health Information Protection Act*	—
	The Freedom of Information and Protection of Privacy Act	—
	The Local Authority Freedom of Information and Protection of Privacy Act	—
Manitoba	*The Personal Health Information Act*	Section 24(5): If a research project will require direct contact with individuals, a trustee must not disclose personal health information about those individuals without first obtaining their consent. Trustee need not obtain their consent if the information consists only of the individuals' names and addresses.
	The Freedom of Information and Protection of Privacy Act	—

[128] Consent is generally required under privacy legislation for secondary uses and disclosures of personal information for any purpose, including for contacting a prospective research participant, subject to limited statutory exceptions. Reference should accordingly be made to the concordance table for Element #3 for the conditions where personal information may be disclosed for research purposes without consent. The above chart sets out the specific statutory prohibitions on the use or disclosure of personal information to contact individuals in circumstances where the statute otherwise permits/authorizes the use and disclosure of personal information for research purposes without consent.

ELEMENT #6 – RECRUITING PROSPECTIVE RESEARCH PARTICIPANTS		
Statutory Prohibitions to Secondary Use/Disclosure of Personal Information to Contact Individuals to Participate in Research[128]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Ontario	*Personal Health Information Protection Act*	Section 44(6)(e): Researcher shall not make contact or attempt to make contact with the individual, directly or indirectly, unless the custodian obtains the individual's consent to being contacted.[129]
	Freedom of Information and Protection of Privacy Act, General Regulation	Section 10(1)6: Before a head may disclose personal information for a research purpose to a person, that person must agree not to contact any individual to whom personal information relates, directly or indirectly, without the prior written authority of the institution.
	Municipal Freedom of Information and Protection of Privacy Act	—
Quebec	*An act respecting the protection of personal information in the private sector*	—
	An act respecting access to documents held by public bodies and the protection of personal information	—
PEI	*Freedom of Information and Protection of Privacy Act*	—
Nova Scotia	*Freedom of Information and Protection of Privacy Regulations*	Section 9: Research agreement must contain condition that recipient not contact any individual to whom personal information relates, directly or indirectly, without the prior written authority of the public body.
	Municipal Government Act	—
New Brunswick	*Protection of Personal Information Act*	—
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*	—
Yukon	*Access to Information and Protection of Privacy Act*	—
Northwest Territories	*Access to Information and Protection of Privacy Regulations*	Section 8: Research agreement must contain condition that the recipient must not contact any individual to whom the personal information relates, directly or indirectly, without the prior written authority of the public body.
Nunavut	*Access to Information and Protection of Privacy Regulations*	Section 8: Research agreement must contain condition that the recipient must not contact any individual to whom the personal information relates, directly or indirectly, without the prior written authority of the public body.

[129] Note that section 37(1)(g) allows a health information custodian to use the name and contact information of an individual for the purpose of seeking the individual's consent.

ELEMENT #7 – SAFEGUARDING PERSONAL DATA[130,131]		
Part 1 – General Safeguarding Requirements		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.7 (Safeguards for protecting personal information) Schedule 1, 4.1.4 (Policies and practices to be implemented to protect personal information)
	Privacy Act	Section 62 (Security Requirements)
British Columbia	*Personal Information Protection Act*	Section 5 (Policies and practices) Section 34 (Protection of personal information)
	Freedom of Information and Protection of Privacy Act	Section 30 (Protection of personal information) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Information must be stored in Canada and accessed only in Canada unless the individual the information is about has identified the information and has consented, in the prescribed manner[132], to it being stored in or accessed from, as applicable, another jurisdiction or if it is stored in or accessed from another jurisdiction for the purpose of disclosure allowed under the Act (section 30.1). ▪ Where a public body receives a foreign demand for disclosure, the head of the public body must inform the Minister responsible for the Act (section 30.2(2)).
Alberta	*Health Information Act*	Section 60 (Duty to protect health information) Section 63 (Duty to establish or adopt policies and procedures)
	Health Information Regulation	Section 8 (Record of safeguards to be maintained) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Written agreement required with respect to safeguards for health information that is to be stored, used or disclosed outside Alberta unless used for continuing treatment and care (section 8(4) and (5)).
	Personal Information Protection Act	Section 6 (Policies and practice) Section 34 (Protection of information)
	Freedom of Information and Protection of Privacy Act	Section 38 (Protection of personal information) Sections 40(1)(h)and(i) and 40(4) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions)
	Municipal Government Act	—
Saskatchewan	*The Health Information Protection Act*	Section 16 (Duty to protect) Section 23 (Collection, use and disclosure on a need-to-know basis) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Individual to be informed about disclosures of personal health information made without consent (section 10(1)).
	The Freedom of Information and Protection of Privacy Act	—

[130] This table sets out the statutory references to general safeguarding obligations. See also the statutory requirements for data-sharing agreements in table of concordance for Element #8, statutory requirements for disposal and destruction in table of concordance for Element #9, and table of concordance for Element #10 regarding the obligation to develop and implement policies and procedures regarding safeguarding of personal information. In addition, see the following table for Element #7 which sets out the statutory requirement to conduct a privacy impact assessment.

[131] Note that public bodies/institutions governed by such legislation may be obligated to comply with governmental security policies or guidelines as a matter of administrative practice.

[132] No requirements have been prescribed by regulations as at the date of this publication.

ELEMENT #7 – SAFEGUARDING PERSONAL DATA[130,131]		
Part 1 – General Safeguarding Requirements		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Saskatchewan	*The Local Authority Freedom of Information and Protection of Privacy Act*	—
Manitoba	*The Personal Health Information Act*	Section 18 and 19 (Security Safeguards) Section 20(3) (Limitation on trustee's employees)
	Personal Health Information Regulation	Section 2 (Written security policy and procedure) Section 3 (Access restrictions and other precautions) Section 4 (Additional safeguards for electronic health information systems) Section 5 (Authorized access for employees and agents) Section 6 (Orientation and training for employees) Section 7 (Pledge of confidentiality for employees) Section 8 (Audit) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Audit of security safeguards to be conducted every 2 years (sections 2 and 8). ▪ Each employee and agent must sign a pledge of confidentiality that includes an acknowledgement that he or she is bound by the policy and procedures and is aware of the consequences of breaching them (section 7).
	The Freedom of Information and Protection of Privacy Act	Section 41 (Protection of personal information)
Ontario	*Personal Health Information Protection Act*	Section 10 (Information Practices) Section 12 (Security) Section 13 (Handling of Records) Supplemental Requirements to CIHR Privacy Best Practices: ▪ An individual shall be notified at the first reasonable opportunity if the information is stolen, lost, or accessed by unauthorized persons. However, a researcher shall not notify the individual unless the health information custodian obtains the individual's consent to having the researcher contact the individual and informs the researcher that the individual has given consent (section 12(2) and(3)). ▪ A health information custodian may disclose personal health information to an entity prescribed pursuant to section 45 of the Act[133], if the Commissioner has approved the practices and procedures of the entity (sections 45(3)). ▪ The Commissioner must approve the practices and procedures of a health data institute (sections 47(9) and (10)).

[133] The following entities are prescribed for the purposes of section 45 of the Act:
1. Cancer Care Ontario
2. Canadian Institute of Health Information
3. Institute for Clinical Evaluation Sciences
4. Pediatric Oncology Group of Ontario

ELEMENT #7 – SAFEGUARDING PERSONAL DATA[130,131]		
Part 1 – General Safeguarding Requirements		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Ontario	*Personal Health Information Protection Act, General Regulation*	Section 6(3) (Prescribed requirements for health information network provider.) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Health information custodian may transfer records of personal health information for archive purposes to a person who, (a) has put in place reasonable measures to ensure that personal health information in the person's custody or control is protected against theft, loss and unauthorized use or disclosure and to ensure that the records containing the information are protected against unauthorized copying, modification or disposal (section 14(1)). ▪ Prescribed registries[134] must put in place practices and procedures approved by the Commissioner and summary of the practices and procedures must be made available to the public (sections 13(2) and 13(3)).
	Freedom of Information and Protection of Privacy Act, General Regulation	Section 4 (Measures to protect records)
	Municipal Freedom of Information and Protection of Privacy Act	__
Quebec	*An act respecting the protection of personal information in the private sector*	Section 10 (Safety measures) Section 20 (Authorized employee access to personal information without consent for the performance of duties of employees)
	An act respecting access to documents held by public bodies and the protection of personal information	Section 62 (Authorization to receive personal information for the discharge of duties) Section 76 (Declaration to the Commission required when establishing a file on individual) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Anytime a file is established concerning an individual, the public body must make a declaration to the Commission containing, among other things, the categories of persons who have access to the file in carrying on their duties.
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 35 (Protection of personal information) Section 37(1)(g) and (g.1) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions)
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 24(3) (Treatment of personal information) Section 27(f) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions)
	Municipal Government Act	__

[134] The following are prescribed registries:
1. Cardiac Care Network of Ontario in respect of its registry of cardiac services.
2. INSCYTE (Information System for Cytology etc.) Corporation in respect of CytoBase.
3. London Health Sciences Centre in respect of the Ontario Joint Replacement Registry.
4. Canadian Stroke Network in respect of the Canadian Stroke Registry.

ELEMENT #7 – SAFEGUARDING PERSONAL DATA[130,131]		
Part 1 – General Safeguarding Requirements		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
New Brunswick	*Protection of Personal Information Act*	Schedule A and B, Principle 7 (Safeguards)
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[135]	Section 36 (Protection of personal information) Section 39(1)(f) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions) Section 51(e) (Commissioner's power to comment on privacy implications of using information technology in the storage of personal information)
Yukon	*Access to Information and Protection of Privacy Act*	Section 33 (Protection of Personal Information) Section 36(1)(f) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions)
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 42 (Protection of Personal Information) Section 48(k) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions)
	Access to Information and Protection of Privacy Regulations	Section 6 (Disclosure to employees and service providers)
Nunavut	*Access to Information and Protection of Privacy Act*	Section 42 (Protection of Personal Information) Section 48(k) (Authorization to disclose personal information to officers and employees for purposes of carrying out their functions)
	Access to Information and Protection of Privacy Regulations	Section 6 (Disclosure to employees and service providers)

[135] Part IV to be proclaimed.

ELEMENT #7 – SAFEGUARDING PERSONAL DATA		
Part 2 - Requirement for a Privacy Impact Assessment[136]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	—
	Privacy Act	—
British Columbia	*Personal Information Protection Act*	—
	Freedom of Information and Protection of Privacy Act	Section 69(5): Public bodies which are ministries (i.e., excludes regional health authorities and hospitals) are required to conduct a privacy impact assessment for all new enactments, systems, projects or programs to determine whether the requirements of the Act are met. The privacy impact assessment must be conducted in accordance with the process/tool referenced in Schedule A attached hereto.
Alberta	*Health Information Act*	Sections 64, 70(2) and (3) and 71(2) and (3): Each custodian must prepare a privacy impact assessment and must submit it to the Information and Privacy Commissioner for review and comment before implementing any proposed administrative practices and information systems or any proposed change to any such existing practices and systems in accordance with the privacy impact assessment tool referenced in Schedule A attached hereto. Section 46(5) (Requirement for the Department to conduct a privacy impact assessment in certain situations)
	Personal Information Protection Act	—
	Freedom of Information and Protection of Privacy Act	—
	Municipal Government Act	—
Saskatchewan	*The Health Information Protection Act*	—
	The Freedom of Information and Protection of Privacy Act	—
	The Local Authority Freedom of Information and Protection of Privacy Act	—
Manitoba	*The Personal Health Information Act*	—
	The Freedom of Information and Protection of Privacy Act	—
Ontario	*Personal Health Information Protection Act*	—

[136] While Canadian privacy legislation may be silent on the requirement to perform privacy impact assessments or risk vulnerability assessments, as a matter of administrative practice, many public sector entities may by required to perform privacy impact assessments in connection with the design and implementation of programs and/or systems involving the collection, use or disclosure of personal information.
A list of privacy impact assessment tools developed by Canadian governmental or regulatory authorities is set out at Schedule A.

ELEMENT #7 – SAFEGUARDING PERSONAL DATA		
Part 2 - Requirement for a Privacy Impact Assessment[136]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Ontario	*Personal Health Information Protection Act, General Regulation*	Section 6(3) subparagraph 5: A person who provides goods or services for the purpose of enabling a custodian to use electronic means to collect, use, modify, disclose, retain or dispose of personal health information shall perform, and provide to each applicable health information custodian a written copy of the results of, an assessment of the services provided to the health information custodians, with respect to, (i) threats, vulnerabilities and risks to the security and integrity of the personal health information, and (ii) how the services may affect the privacy of the individuals who are the subject of the information.
	Freedom of Information and Protection of Privacy Act	—
	Municipal Freedom of Information and Protection of Privacy Act	—
Quebec	*An act respecting the protection of personal information in the private sector*	—
	An act respecting access to documents held by public bodies and the protection of personal information	—
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	—
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	—
New Brunswick	*Protection of Personal Information Act*	—
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[137]	—
Yukon	*Access to Information and Protection of Privacy Act*	—
Northwest Territories	*Access to Information and Protection of Privacy Act*	—
Nunavut	*Access to Information and Protection of Privacy Act*	—

[137] Part IV to be proclaimed.

Schedule A

Jurisdiction	Privacy Impact Assessment Tools
Federal	Treasury Board of Canada Secretariat - *Privacy Impact Assessment Policy* (http://www.tbs-sct.gc.ca/pubs_pol/ciopubs/pia-pefr/paipg-pefrld2_e.asp#1.Introduction)
British Columbia	Ministry of Management Services for British Columbia, Information Policy and Privacy Branch - *Privacy Impact Assessment (PIA) Process* (http://www.mser.gov.bc.ca/privacyaccess/PIA/PIAprocess.htm)
Alberta	Information and Privacy Commissioner of Alberta - *Privacy Impact Assessment: Instructions and Annotated Questionnaire* (http://www.oipc.ab.ca/ims/client/upload/pia-instructions-1.1.pdf)
Saskatchewan	Office of the Saskatchewan Information and Privacy Commissioner - *Privacy Impact Assessment (Short Form)* (http://www.oipc.sk.ca/Web%20Site%20Documents/PIA%20Short%20Form%20--%20Official%20Version%20April,%202004.pdf)
Manitoba	Ombudsman Manitoba, Access and Privacy Division - *Privacy Compliance Tool Checklist* (http://www.ombudsman.mb.ca/pdf/Final%20Version%20PCT%20Checklist%20PDF%202003-10-07.pdf) Manitoba Health - *Privacy Impact Assessment (PIA) Guide* (Not available on-line)
Ontario	Information and Privacy Commissioner/Ontario - *Privacy Diagnostic Tool (PDT) Workbook* (http://www.ipc.on.ca/userfiles/page_attachments/pdt.pdf) Management Board of Cabinet - *Privacy Impact Assessment Guidelines* (http://www.accessandprivacy.gov.on.ca/english/pia/index.html)
Quebec	Ministère des Relations avec les citoyens et de L'immigration (Québec) - *Modèle de pratiques de protection des renseignements personnels – dans le contexte du développement des systèmes d'information par les organismes publics* (http://www.aiprp.gouv.qc.ca/publications/pdf/PRP_net.pdf)
Prince Edward Island	N/A
Nova Scotia	N/A
New Brunswick	N/A
Newfoundland and Labrador	Office of the Information and Privacy Commissioner for Newfoundland and Labrador – *Privacy Audit, A Compliance Review Tool* (www.oipc.gov.nl.ca) Centre for Health Information – *Privacy Impact Assessment for Researchers* (http://www.nlchi.nf.ca/pdf/pia.pdf)
Yukon	N/A
Northwest Territories	N/A
Nunavut	N/A

ELEMENT #8 – CONTROLLING ACCESS AND DISCLOSURE OF PERSONAL DATA		
Part 1 – Specific Data Matching/Linkage Provisions[138,139]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	—
	Privacy Act	—
British Columbia	*Personal Information Protection Act*	Section 21 - Any linkage of personal information to other information must not be harmful to the individuals and the benefits to be derived from the linkage must clearly be in the public interest.
	Freedom of Information and Protection of Privacy Act	Section 35 - Any record linkage must not be harmful to the individuals and the benefits to be derived from the record linkage must clearly be in the public interest.
Alberta	*Health Information Act*	Section 1(1)(g) (Definition of "data matching")[140] Section 68 (General prohibition on data matching) Section 69 (Permitted data matching by custodians) Section 70 (Data matching between custodians; privacy impact assessment required) Sections 71 and 32 (Data matching between custodians and non-custodians; privacy impact assessment required; obligation to notify Privacy Commissioner) Section 72 (Data matching for research; obligation to comply with provisions regarding disclosure for research purposes without consent (sections 48-56)) Section 107(5) (Offence to fail to notify Commissioner)
	Personal Information Protection Act	—
	Freedom of Information and Protection of Privacy Act	Section 42(b) - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest
	Municipal Government Act	—
Saskatchewan	*The Health Information Protection Act*	—
	The Freedom of Information and Protection of Privacy Act	—
	The Local Authority Freedom of Information and Protection of Privacy Act	—
Manitoba	*The Personal Health Information Act*	—

[138] This table cross references provisions dealing specifically with "data matching" or "data linking". Any data linkage/matching activity involving the use and/or disclosure of personal information requires a consideration of other statutory provisions, including the consent requirements for use and disclosure of personal information for research purposes. See table of concordance for Element #3. Public institutions may also need to consider governmental administrative guidelines/policies on data matching/linkage. See, for instance, the policy of the Treasury Board of Canada Secretariat regarding data matching available at: http://www.tbs-sct.gc.ca/pubs_pol/gospubs/TBM_128/CHAP2_5-2_e.asp#pre

[139] Reference should be made to the table of concordance for Element #7 which sets out safeguarding provisions, including statutory restrictions on access to personal information.

[140] The *Health Information Act* (Alberta) defines "data matching" as "the creation of individually identifying health information by combining individually identifying or non-identifying health information or other information from 2 or more electronic databases, without the consent of the individuals who are the subjects of the information".

ELEMENT #8 – CONTROLLING ACCESS AND DISCLOSURE OF PERSONAL DATA		
Part 1 – Specific Data Matching/Linkage Provisions[138,139]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Manitoba	*The Freedom of Information and Protection of Privacy Act*	Section 46 - Approval must be obtained from head of the public body to use or disclose personal information for linking or matching purposes. The head may have to refer the proposal to the review committee for advice. Section 47(4) - Any information linkage, must not be likely to harm individuals and benefits to be derived from research and any information linkage must clearly be in the public interest.
Ontario	*Personal Health Information Protection Act, General Regulation*	Section 16(3) – A research plan must include a description of how personal health information will be used in the research, and if it will be linked to other information, a description of the other information as well as how the linkage will be done.
	Freedom of Information and Protection of Privacy Act	—
	Municipal Freedom of Information and Protection of Privacy Act	—
Quebec	*An act respecting the protection of personal information in the private sector*	—
	An act respecting access to documents held by public bodies and the protection of personal information	Section 68.1 (Permitted data matching/Requirement for written agreement) Section 69 (Obligation to maintain confidentiality) Section 70 (Submission of data matching agreements to Commission/ Public body; Tabling of agreement in National Assembly; Obligation to publish in Gazette)
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 39(b) - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest.
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 29(b) - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest.
	Municipal Government Act	Section 485(4)(b) - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest.
New Brunswick	*Protection of Personal Information Act*	—
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[141]	Section 41 - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest. Section 51(e) – Commissioner may comment on implications for protection of privacy of using or disclosing personal information for record linkage.
Yukon	*Access to Information and Protection of Privacy Act*	Section 38 - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest.

[141] Part IV to be proclaimed.

ELEMENT #8 – CONTROLLING ACCESS AND DISCLOSURE OF PERSONAL DATA		
Part 1 – Specific Data Matching/Linkage Provisions[138,139]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 49 - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest
Nunavut	*Access to Information and Protection of Privacy Act*	Section 49 - Record linkages cannot be harmful to the individuals the information is about and the benefits to be derived from the linkage must be clearly in the public interest

ELEMENT #8 – CONTROLLING ACCESS AND DISCLOSURE OF PERSONAL DATA		
Part 2 - Data-sharing Agreements for Research Purposes[142]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.1.3 (Organization must use contractual means to provide for comparable level of protection when personal information is being processed by a third party)
	Privacy Act	Section 8(2)(j) (Requirement and content of data sharing agreements)
British Columbia	*Personal Information Protection Act*	Section 21(1) (Requirement and content of data sharing agreements) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Prohibition from using personal information to contact a person to participate in the research (section 21(1)(c)).
	Freedom of Information and Protection of Privacy Act	Section 35 (Requirement and content of data sharing agreements) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Prohibition from using personal information to contact a person to participate in the research.
Alberta	*Health Information Act*	Section 54(1) (Agreement between researcher and custodian) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Data sharing agreement must include obligation of recipient to pay the costs of (i) preparing information for disclosure, (ii) making copies of health information, and (iii) obtaining consents. Data sharing agreement must also contain obligation of researcher not to attempt to contact an individual who is the subject of the information in order to obtain additional information unless the individual has consented.
	Health Information Regulation	Section 8(4) (Additional requirements when health information is used or disclosed outside Alberta)
	Personal Information Protection Act Regulation	Sections 12(2), 12(3) and 14(3) (Requirement and content of data sharing agreement) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Data sharing agreement must include obligation of recipient of information to not contact any individual to whom the personal information relates, directly or indirectly, without the prior written authority of the public body and that the person must notify the public body in writing immediately if the person becomes aware that any of the conditions set out in the agreement have been breached.
	Freedom of Information and Protection of Privacy Act	Section 42 (Requirement for data sharing agreement)
	Freedom of Information and Protection of Privacy Regulation	Section 8 (Content of data sharing agreement) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Data sharing agreement must include obligation of recipient of information to not contact any individual to whom the personal information relates, directly or indirectly, without the prior written authority of the public body and notify the public body in writing immediately if the person becomes aware that any of the conditions set out in the agreement have been breached and that, if a person fails to meet the conditions of the agreement, the agreement may be immediately cancelled and that the person may be guilty of an offence pursuant to the Act.

[142] This table deals with data sharing agreements entered into specifically for research purposes. Privacy statutes may also contain a requirement to enter into written agreements for other purposes.

ELEMENT #8 – CONTROLLING ACCESS AND DISCLOSURE OF PERSONAL DATA		
Part 2 - Data-sharing Agreements for Research Purposes[142]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Alberta	*Municipal Government Act*	__
Saskatchewan	*The Health Information Protection Act*	Section 29(1) (Requirement and content of data sharing agreements)
	The Freedom of Information and Protection of Privacy Act	Section 29(2)(k) (Requirement for data sharing agreements)
	The Local Authority Freedom of Information and Protection of Privacy Act	__
Manitoba	*The Personal Health Information Act*	Section 24(4) (Requirement and content of data sharing agreement)
	Personal Health Information Regulation	Section 8.3 (Content of data sharing agreements)
	The Freedom of Information and Protection of Privacy Act	Section 47(4)(c) and (d) (Requirement for data sharing agreements)
Ontario	*Personal Health Information Protection Act*	Section 44(1) and (5) (Requirement for data sharing agreements)
	Freedom of Information and Protection of Privacy Act, General Regulation	Section 10 (Content of data sharing agreements)
	Municipal Freedom of Information and Protection of Privacy Act	__
Quebec	*An act respecting the protection of personal information in the private sector*	Section 21 (No requirement for data sharing agreement although the Commission may impose conditions on disclosure of information for research purposes)
	An act respecting access to documents held by public bodies and the protection of personal information	Section 125 (No requirement for data sharing agreement although the Commission may impose conditions on disclosure of information for research purposes)
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 39 (Requirement for data sharing agreements – no content specified)
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 29 (Requirement for data sharing agreements – no content specified)
	Freedom of Information and Protection of Privacy Regulations	Section 9 (Content of data sharing agreement) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Data sharing agreement must include agreement of recipient not to contact any individual to whom personal information relates, directly or indirectly, without the prior written authority of the public body and to notify the public body in writing immediately if the person becomes aware that any of the conditions set out in this section have been breached. Agreement must be in prescribed form.
	Municipal Government Act	__

ELEMENT #8 – CONTROLLING ACCESS AND DISCLOSURE OF PERSONAL DATA		
Part 2 - Data-sharing Agreements for Research Purposes[142]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
New Brunswick	*Protection of Personal Information Act*	—
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*	Section 41 (Requirement for data sharing agreements)
Yukon	*Access to Information and Protection of Privacy Act*	Section 38 (d) (Requirement for data sharing agreements)
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 49 (c) and (d) (Requirement for data sharing agreements)
	Access to Information and Protection of Privacy Regulations	Section 8 (Content of data sharing Agreements) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Data sharing agreement must include provisions requiring: an identification of any other persons who will be given access to the personal information by the recipient; a condition that the recipient must not contact any individual to whom the personal information relates, directly or indirectly, without the prior written authority of the public body; notice to the public body in writing immediately if the person becomes aware that any of the conditions set out in the agreement have been breached; a condition that, if a recipient fails to meet the conditions of the agreement, the agreement may be immediately terminated by the public body.
Nunavut	*Access to Information and Protection of Privacy Act*	Section 49(c) and (d) (Requirement for data sharing agreements)
	Access to Information and Protection of Privacy Regulations	Section 8 (Content of data sharing Agreements) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Same as for the Northwest Territories

ELEMENT #9 – SETTING REASONABLE LIMITS ON RETENTION OF PERSONAL DATA		
Retention and Destruction of Personal Information[143,144]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.5, 4.5.2 and 4.5.3 (Limiting use, disclosure and retention) Supplemental Requirements to CIHR Privacy Best Practices: Data retention guidelines should include minimum and maximum retention periods.
	Privacy Act	Section 6 (Retention of personal information used for an administrative purpose)
	Privacy Act Privacy Regulations	Section 4 (Retention of personal information that has been used by a government institution for an administrative purpose) Supplemental Requirements to CIHR Privacy Best Practices: Personal Information shall be retained (a) for at least two years following the last time the personal information was used for an administrative purpose unless the individual consents to its disposal and (b) where a request for access to the information has been received, until such time as the individual has had the opportunity to exercise all his rights under the Act. However, the information may be destroyed in an emergency in order to prevent the removal of the information from the control of the institution (section 4). A copy of every request for access received as well as a record of any information disclosed pursuant to such a request must be maintained for a period of 2 years following the date of the request (section 7).
British Columbia	*Personal Information Protection Act*	Section 35 (Retention of personal information) Supplemental Requirements to CIHR Privacy Best Practices: If an individual's personal information is being used to make a decision that directly affects the individual, the information must be retained for at least one year.
	Freedom of Information and Protection of Privacy Act	Section 31 (Retention of personal information) Supplemental Requirements to CIHR Privacy Best Practices: If an individual's personal information is being used to make a decision that directly affects the individual, the information must be retained for at least one year.
Alberta	*Health Information Act*	Section 3 (Storage and Destruction, Other Enactments) Section 41 (Maintaining certain disclosure information) Section 60(2)(b) (Safeguards for proper disposal) Supplemental Requirements to CIHR Privacy Best Practices: A custodian that discloses a record containing individually identifying diagnostic, treatment and care information must retain that information for a period of 10 years following the date of the disclosure (section 41(2).
	Personal Information Protection Act	Section 35 (Retention of information)

[143] This table sets out the statutory requirements for the general obligation in privacy legislation with respect to retention and destruction of personal information. Note that retention, return and disposal of records may be addressed in the research agreement entered into between the custodian and researcher, as required under applicable privacy legislation. Note also that under the Food and Drug Regulations – Division 5 – C.05.012 (4) records for clinical trials must be retained for 25 years.

[144] See statutory requirements regarding the obligation to have written policies and procedures, including for retention and destruction of personal information, in table of concordance for Element # 7.

ELEMENT #9 – SETTING REASONABLE LIMITS ON RETENTION OF PERSONAL DATA		
Retention and Destruction of Personal Information[143,144]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Alberta	*Freedom of Information and Protection of Privacy Act*	Section 35 (Accuracy and retention) Supplemental Requirements to CIHR Privacy Best Practices: If an individual's personal information is being used to make a decision that directly affects the individual, the information must be retained for at least one year or such shorter time as approved by the individual in writing, the public body and the body that approved the retention and disposition schedule if applicable.
	Municipal Government Act	Sections 214(2) and (3) (Destruction of records) Supplemental Requirements to CIHR Privacy Best Practices: ▪ A council may pass a bylaw respecting destruction of records and documents of the municipality. The bylaw must provide that if an individual's personal information will be used by the municipality to make a decision that directly affects the individual, the municipality must retain the personal information for at least one year after using it so that the individual has a reasonable opportunity to obtain access to it.
Saskatchewan	*The Health Information Protection Act*	Section 17 (Retention and destruction policy)
	The Freedom of Information and Protection of Privacy Act	—
	The Local Authority Freedom of Information and Protection of Privacy Act	—
Manitoba	*The Personal Health Information Act*	Section 17 (Retention and destruction of information) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Written retention policy must be established. ▪ Trustee who destroys personal health information must keep a record of (i) the individual whose personal information is destroyed (ii) the time period to which the information relates, (iii) the method of destruction, and (iv) the person responsible for supervising the destruction.
	Personal Health Information Regulations	Section 2 (Written policy to be established)
	The Freedom of Information and Protection of Privacy Act	Section 40 (Retention of information) Supplemental Requirement to CIHR Privacy Best Practices: ▪ If personal information about an individual is used to make a decision that affects the individual, the public body must establish and comply with a written policy concerning the retention of the personal information (subsections 40(1) and (2)).
Ontario	*Personal Health Information Protection Act*	Section 13 (Handling of records) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Information shall be retained for as long as necessary to allow the individual to exhaust any recourse under the Act where a request for access has been made.
	Freedom of Information and Protection of Privacy Act	Section 40(1) (Retention of personal information) Section 40(4) (Disposal of personal information)

ELEMENT #9 – SETTING REASONABLE LIMITS ON RETENTION OF PERSONAL DATA		
Retention and Destruction of Personal Information[143,144]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Ontario	*Freedom of Information and Protection of Privacy Act, General Regulations*	Section 5 (Retention) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Information shall be retained for at least one year after use, unless the individual to whom the information relates consents to its earlier disposition. ▪ The minimum period of retention of personal information contained in a telecommunications logger tape is 45 days rather than one year.
	Freedom of Information and Protection of Privacy Act, Disposal of Personal Information Regulation	Sections 2 to 6 (Disposal of personal information) Supplemental Requirements to CIHR Privacy Best Practices: ▪ Authorization of the head of the institution must authorize the destruction of the information. ▪ The head shall ensure that the institution maintains a disposal record setting out what personal information has been destroyed and the date.
	Municipal Freedom of Information and Protection of Privacy Act	Section 30(1) (Retention of personal information) Section 30(4) (Disposal of personal information)
	Municipal Freedom of Information and Protection of Privacy Act, General Regulation	Section 5 (Retention of personal information) Supplemental Requirement to CIHR Privacy Best Practices: Personal information to be retained for the shorter of one year after use or the period set out in a by-law or resolution made by the institution or made by another institution affecting the institution, unless the individual to whom the information relates consents to its earlier disposal.
Quebec	*An act respecting the protection of personal information in the private sector*	Section 12 (Use of file) Section 36 (Retention where request for access or rectification has been denied)
	An act respecting access to documents held by public bodies and the protection of personal information	Section 73 (Destruction) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Section 73 does not apply to the processing of personal information collected and used as a working tool by a natural person and which is used by him for scientific research purposes to the extent that the information is not disclosed to any person other than the person concerned or to a body other than that to which he belongs, and that it is used judiciously (section 78).
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 33 (Retention when information is used to make a decision) Supplemental Requirement to CIHR Privacy Best Practices: ▪ If an individual's personal information is being used to make a decision that directly affects the individual, the information must be retained for at least one year.
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 24(4) (Treatment of personal information) Supplemental Requirement to CIHR Privacy Best Practices: ▪ If an individual's personal information is being used to make a decision that directly affects the individual, the information must be retained for at least one year.

ELEMENT #9 – SETTING REASONABLE LIMITS ON RETENTION OF PERSONAL DATA		
Retention and Destruction of Personal Information[143,144]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance and Selected Supplemental Requirements**
Nova Scotia	*Municipal Government Act*	Section 483(4) (Retention of personal information) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Where a municipality uses an individual's personal information to make a decision that directly affects the individual, the municipality shall retain that information for at least one year after using it so that the individual has a reasonable opportunity to obtain access to it.
New Brunswick	*Protection of Personal Information Act*	Schedule A, Principle 5 and Schedule B, Principle 5 (Limiting use, disclosure and rentention)
Newfoundland	*Access to Information and Protection of Privacy Act*[145]	Section 37 (Retention of personal information) Supplemental Requirement to CIHR Privacy Best Practices: ▪ If an individual's personal information is being used to make a decision that directly affects the individual, the information must be retained for at least one year.
Yukon	*Access to Information and Protection Privacy Act*	Section 34 (Retention of personal information) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Public body must retain information it uses to make a decision affecting an individual for at least one year after such use.
Northwest Territories	*Access to Information and Protection Privacy Act*	Section 44 (Duties of public body) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Public body must retain information it uses to make a decision affecting an individual for at least one year after such use.
Nunavut	*Access to Information and Protection Privacy Act*	Section 44 (Duties of public body) Supplemental Requirement to CIHR Privacy Best Practices: ▪ Public body must retain information it uses to make a decision affecting an individual for at least one year after such use.

[145] Part IV to be proclaimed.

ELEMENT #10 – ENSURING ACCOUNTABILITY AND TRANSPARENCY IN THE MANAGEMENT OF PERSONAL DATA		
Part 1- Accountability and Transparency[146]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	Schedule 1, 4.1 (Accountability) Schedule 1, 4.8 (Openness)
	Privacy Act	Sections 10 and 11 (Obligations regarding personal information banks)
British Columbia	*Personal Information Protection Act*	Section 4 (Compliance with the Act) Section 5 (Policies and Procedures)
	Freedom of Information and Protection of Privacy Act	Section 2 (Purposes of this Act) Section 69(2) and (3) (Personal information directory of ministries) Section 69(5) (Duty of a ministry to prepare privacy impact assessment) Section 69(6) (Directory of personal information banks to be maintained by public body that is not a ministry) Section 70 (Policy manuals to be made available)
Alberta	*Health Information Act*	Section 2 (Purposes of the Act) Section 62 (Duty to identify responsible affiliate) Section 63 (Duty to establish or adopt policies and procedures) Section 64 (Duty to prepare privacy impact assessment) Section 66(6) (Accountability for information disclosed to an information manager)
	Health Information Regulation	Section 8(2) (Designating responsible individual) Section 8(6) (Custodian responsible for affiliates' compliance)
	Personal Information Protection Act	Section 5 (Compliance with Act) Section 6 (Policies and Procedures)
	Freedom of Information and Protection of Privacy Act	Section 2 (Purposes of this Act) Section 87 (Directory of public bodies) Section 87.1 (Directory of personal information banks) Section 88 (Records available without request) Section 89 (Access to manuals)
	Municipal Government Act	__
Saskatchewan	*The Health Information Protection Act*	Preamble (Accountability obligations) Section 9 (Right to be informed)
	Freedom of Information and Protection of Privacy Act	Section 64 (Directory to be produced) Section 65 (Access to manuals)
	Local Authority Freedom of Information and Protection of Privacy Act	Section 53 (Directory of local authorities including place at which applications for access to records should be made for each)
Manitoba	*The Personal Health Information Act*	Section 2 (Purposes of this Act) Section 25(5) (Information transferred to information manager for processing deemed to be maintained by the transferring trustee)

[146] This table cross references statutory provisions regarding the general accountability and transparency requirements set out in privacy legislation. Privacy legislation also provides individuals with a right of access to their personal information, which this table does not address. Also, privacy legislation may provide that the body/organization must inform the relevant regulatory authority before personal information may be used or disclosed for research purposes. Such requirements have been referenced in the table of concordance for Element #3.

ELEMENT #10 – ENSURING ACCOUNTABILITY AND TRANSPARENCY IN THE MANAGEMENT OF PERSONAL DATA		
Part 1- Accountability and Transparency[146]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Manitoba	*Personal Health Information Regulation*	Section 2 (Written security policy and procedures) Section 6 (Orientation and training of employees)
	The Freedom of Information and Protection of Privacy Act	Section 2 (Purposes of this Act) Sections 75(1) and (2) (Directory to be maintained) Section 75(3) (Obligations regarding personal information bank) Section 76 (Records to be made available)
Ontario	*Personal Health Information Protection Act*[147]	Section 10 (Information Practices) Sections 15 to 17 (Accountability and Openness)
	Personal Health Information Protection Act, General Regulation	Sections 6(3) subparagraph 2 (Health information network provider to provide plain language description of services provided and safeguards in place to protect against unauthorized use and disclosure) Sections 6(3) subparagraph 3 (Information to be made available to the public by health information network provider) Sections 6(3) subparagraph 4 (Information to be made available to health information custodians) Sections 6(3) subparagraph 5 (Health information network provider to perform assessment of risks to security and integrity of personal health information in providing services and detailing affect on privacy)
	Freedom of Information and Protection of Privacy Act	Sections 31 to 36 (Information to be published or available) Sections 44 to 46 (Obligations regarding Personal Information Banks)
	Municipal Freedom of Information and Protection of Privacy Act	Section 1 (Purposes of this Act) Section 24 (Publications of information re institutions) Section 25 (Information available for inspection) Section 26 (Head shall make annual report) Section 34 (Obligations re personal information bank index)
	Municipal Freedom of Information and Protection of Privacy Act, General Regulation	Section 4(2) (Where notice re collection of personal information has not been given, the head shall make available for public inspection a statement describing the purpose of the collection of personal information and the reason that notice has not been given)
Quebec	*An act respecting the protection of personal information in the private sector*	Section 17 (Accountability for information disclosed outside Quebec)
	An act respecting access to documents held by public bodies and the protection of personal information	Section 67.3 (Register to be kept of every disclosure of personal information) Section 71 (Personal information files must be established) Section 76 (Declaration to the Commission required when establishing a file on individual)
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	Section 2 (Purposes of this Act) Section 73 (Records available without request)
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	Section 2 (Purposes of this Act) Section 48 (Directory respecting records of public body)
	Municipal Government Act	Section 462 (Purpose of this Part)

[147] Note that the privacy practices and procedures of entities prescribed for the purposes of section 45 and 39(1)(c) of the Act, as well as health data institutes, must be approved by the Information and Privacy Commissioner.

ELEMENT #10 – ENSURING ACCOUNTABILITY AND TRANSPARENCY IN THE MANAGEMENT OF PERSONAL DATA		
Part 1- Accountability and Transparency[146]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
New Brunswick	*Protection of Personal Information Act*	Schedule A, Principle 1 (Accountability) Schedule A, Principle 8 (Openness)
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act*[148]	Section 3 (Purpose) Section 67(1)(c) (Designation and delegation by the head of public body) Section 69 (Directory of information)
Yukon	*Access to Information and Protection of Privacy Act*	Section 1(1) (Purpose of the Act) Section 63 (Information Directory) Section 64 (Records available without request)
Northwest Territories	*Access to Information and Protection of Privacy Act*	Section 1 (Purpose of this Act) Section 70 (Directory of public bodies and records) Section 71 (Policy manuals must be made available to the public) Section 72 (Records available without request)
Nunavut	*Access to Information and Protection of Privacy Act*	Section 1 (Purpose of this Act) Section 70 (Directory of public bodies and records) Section 71 (Policy manuals must be made available to the public) Section 72 (Records available without request)

[148] Part IV to be Proclaimed

ELEMENT #10 – ENSURING ACCOUNTABILITY AND TRANSPARENCY IN THE MANAGEMENT OF PERSONAL DATA		
Part 2 - Statutory References to Research Ethics Board[149]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Federal	*Personal Information Protection and Electronic Documents Act*	—
	Privacy Act	—
British Columbia	*Personal Information Protection Act*	—
	Freedom of Information and Protection of Privacy Act	—
Alberta	*Health Information Act*	Section 27(1)(d) (Approval of Ethics Committee)[150] Section 50 (Role of Ethics Committee)
	Personal Information Protection Act Regulation	Section 14(3) (Approval of Research Ethics Review Committee)
	Freedom of Information and Protection of Privacy Act	—
	Municipal Government Act	—
Saskatchewan	*The Health Information Protection Act*	Section 29(2)(ii) (Approval of research ethics committee)
	The Freedom of Information and Protection of Privacy Act	—
	The Local Authority Freedom of Information and Protection of Privacy Act	—
Manitoba	*The Personal Health Information Act*	Section 24 (Approval of health information privacy committee and institutional research review committee)
	Personal Health Information Regulation	Section 8.1 (Functions of health information privacy committee)
	The Freedom of Information and Protection of Privacy Act	—
Ontario	*Personal Health Information Protection Act*	Section 44(1) (Approval of Research Ethics Board) Section 44(3) and (4) (Considerations and Decisions of Research Ethics Board)
	Freedom of Information and Protection of Privacy Act	—

[149] This table cross references the statutory provisions to research ethics bodies. Note that while Canadian privacy statutes may be silent with respect to ethics boards or committees, there is a requirement under many public sector statutes for research to be approved by the head or the Minister in charge of the administration of the particular statute. Refer to table of concordance for Element # 3 regarding statutory conditions that research ethics bodies or other approving bodies/persons must consider before allowing the use or disclosure of personal information without consent for research purposes.

[150] The following committees and boards are designated as ethics committees by the Health Information Act Designation Regulation:

- Alberta Cancer Board – Research Ethics Committee
- College of Physicians and Surgeons of Alberta – Research Ethics Review Committee;
- Alberta Heritage Foundation for Medical Research – Community Health Ethics Research Review Committee;
- University of Alberta – Health Research Ethics Board;
- University of Calgary – Conjoint Health Research Ethics Board;
- University of Lethbridge – Human Subject Research Committee

ELEMENT #10 – ENSURING ACCOUNTABILITY AND TRANSPARENCY IN THE MANAGEMENT OF PERSONAL DATA		
Part 2 - Statutory References to Research Ethics Board[149]		
Jurisdiction	**Legislation**	**Privacy Legislation Concordance**
Ontario	*Municipal Freedom of Information and Protection of Privacy Act*	—
Quebec[151]	*An act respecting the protection of personal information in the private sector*	—
	An act respecting access to documents held by public bodies and the protection of personal information	—
Prince Edward Island	*Freedom of Information and Protection of Privacy Act*	—
Nova Scotia	*Freedom of Information and Protection of Privacy Act*	—
	Municipal Government Act	—
New Brunswick	*Protection of Personal Information Act*	—
Newfoundland and Labrador	*Access to Information and Protection of Privacy Act[152]*	—
Yukon	*Access to Information and Protection of Privacy Act*	—
Northwest Territories	*Access to Information and Protection of Privacy Act*	—
Nunavut	*Access to Information and Protection of Privacy Act*	—

[151] Article 21 of the Quebec Civil Code states that research may be conducted involving minors and incapacitated adults only with the approval and monitoring of an ethics committee. Ethics committees are formed or designated by the Minister of Health and Social Services.
[152] Part IV to be Proclaimed

Department of Homeland Security
DHS Directives System
MD Number: 026-04
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PROTECTION OF HUMAN SUBJECTS

I. Purpose

This Management Directive (MD) establishes the Department of Homeland Security (DHS) policy for the protection of human subjects in research. In particular, this MD adopts the Department of Health and Human Services (HHS) policies and procedures set forth in 45 Code of Federal Regulations (CFR) Part 46, Subparts A-D. Subpart A of 45 CFR Part 46 is HHS' codification of the Federal Policy for the Protection of Human Subjects (also known as The Common Rule) which represents the basic foundation for the protection of human subjects in most research conducted or supported by U.S. Federal departments and agencies.

II. Scope

This MD applies to all research involving human subjects conducted by any Component, i.e., intramural research, or research sponsored by any Component through a contract, grant, cooperative agreement, cooperative research and development agreement (CRADA), Other Transaction agreement, or other arrangement, i.e., extramural research.

III. Authorities

A. Public Law 103-43, "National Institutes of Health Revitalization Act of 1993"

B. Public Law 108-458, "Intelligence Reform and Terrorism Prevention Act of 2004"

C. Title 42, U.S.C., Sections 289g – 289g-2, "Fetal Research, Research on Transplantation of Fetal Tissue, and Prohibitions Regarding Human Fetal Tissue"

D. Title 45, CFR, Part 46, Subpart A, "Basic HHS Policy for Protection of Human Research Subjects (The Common Rule)"

E. Title 45, CFR, Part 46, Subpart B, "Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research"

F. Title 45, CFR, Part 46, Subpart C, “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”

G. Title 45, CFR, Part 46, Subpart D, “Additional Protections for Children Involved as Subjects in Research”

H. Federal Register (December 6, 2000), Volume 65, Number 235, Pages 76260-76264, “Federal Policy on Research Misconduct, Office of Science and Technology Policy”

IV. Definitions

Unless otherwise defined herein, definitions of words and phrases in 45 CFR Part 46 apply to this MD:

A. ***Assurance***: A written document provided by an institution engaged in research involving human subjects that is conducted or sponsored by a Federal department or agency that has adopted The Common Rule. Through this document, an institution assures the relevant department or agency head that it will comply with the requirements set forth in The Common Rule. For DHS-conducted or -sponsored research, in lieu of requiring submission of an Assurance to DHS, DHS will accept the existence of an Assurance approved for federal wide use (i.e., available to all federal agencies) by the Office for Human Research Protections (OHRP).

B. ***Components***: All the entities that directly report to the Office of the Secretary, which includes the Secretary and his or her staff, Counselors and their staff, Deputy Secretary and his or her staff, and Chief of Staff and his or her staff.

C. ***Common Rule***: The regulation adopted by multiple Federal Agencies for the protection of human subjects in research. The HHS implementation of the Common Rule is at 45 CFR Part 46, Subpart A.

D. ***Extramural Research***: DHS-managed or -funded research that is conducted at non-DHS sites by non-DHS investigators.

E. ***Human Subject***: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to obtain the information to constitute research involving human subjects.

F. ***Intramural Research***: Research that is conducted at DHS sites or is conducted by DHS personnel.

G. ***Institutional Review Board (IRB)***: An IRB established in accord with and for the purposes expressed in The Common Rule.

H. ***IRB Approval***: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by any other institutional and federal requirements.

I. ***Research***: A systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to general knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

J. ***U.S. Department of Health and Human Services, Office for Human Research Protections***: OHRP provides leadership and oversight on all matters related to the protection of human subjects in research conducted or supported by HHS. OHRP helps ensure that such research is carried out in accordance with the highest ethical standards in an environment where all who are involved in the conduct or oversight of human subjects research understand their primary responsibility for protecting the rights, welfare, and well-being of subjects.

V. Responsibilities

A. The ***Secretary of DHS*** (the Secretary) exercises ultimate authority and responsibility for DHS with respect to ensuring the safety and protection of human subjects in research conducted or sponsored by DHS.

B. The ***Under Secretary for Science and Technology*** is designated by the Secretary as the DHS Human Subjects Protection Official (HSPO) and has the authority to fulfill the Secretary's objectives by ensuring that DHS fully understands, implements, and complies with both the letter and spirit of The Common Rule, any other applicable statutory requirements, and the related regulatory mandates to protect human subjects involved in research conducted or supported by DHS. To this end, HSPO may delegate specific authority to train for, monitor, and oversee human use compliance within DHS to activities and offices within the Science and Technology Directorate.

1. In exercising the authority delegated from the Secretary, the HSPO will establish executive oversight. To do so the HSPO will:

a. Closely coordinate all programmatic activities with the Chief Medical Officer (CMO) to ensure that all oversight of research involving human subjects incorporates the highest medical and ethical standards.

b. Ensure that the Heads of Components incorporate the provisions of this MD into their policies, procedures, and programs that involve the use of human subjects in research as defined herein.

c. Exercise any authority for DHS with respect to any requirements of 45 CFR Part 46, Subparts B-D that would require any action by an official of HHS.

d. Approve any further DHS-wide policy, procedure, or guidance to ensure the safety and protection of human subjects used in DHS research.

e. Develop procedures and standards for the prevention of research misconduct in DHS that are consistent with Federal Policy on Research Misconduct.

f. Closely coordinate all programmatic procedures and policies with the Officers for Privacy and Civil Rights and Civil Liberties to ensure that all oversight of research involving human subjects incorporates civil rights and civil liberties protections.

g. Consider recommendations for additional plans, policies, and actions with regard to reported issues of research-related injuries and serious noncompliance with this MD and take action as deemed appropriate.

h. Designate a permanent DHS representative to the Interdepartmental Human Subjects Research Subcommittee of the Committee of Science, National Science and Technology Council.

i. Support budget requests to meet the requirements of this MD.

2. To ensure operational compliance the HSPO will:

a. Develop training and training guidance, as needed, to enable the consistent and effective application of human subjects protection policy DHS-wide and conduct such training for DHS.

b. Monitor Component compliance with the provisions of this MD, as appropriate.

c. Approve any policy, procedure, or guidance concerning the safety and protection of human subjects used in DHS research developed by any Component prior to implementation.

d. Collect and store all Assurance requests submitted by Components to and approved by the OHRP, HHS.

e. Monitor remedial action, as appropriate, with regard to reported issues of research-related injuries and serious non-compliance with this MD.

f. Act as the DHS point of contact for the coordination and response to external requests concerning the conduct and support of human subjects research by DHS.

g. Work with the Privacy Office to develop procedures associated with human subjects research to ensure that individual privacy interests are fully respected.

C. ***Office of the General Counsel (OGC)*** (primarily through counsel at Science and Technology) will:

1. Conduct legal reviews of all DHS activities, including activities conducted under contracts, grants, and cooperative agreements, CRADAs, and Other Transaction agreements, to ensure compliance with applicable federal laws and regulations pertaining to human subjects research.

2. Support along with the CMO the participation of DHS in the Interdepartmental Human Subjects Research Subcommittee of the Committee of Science, National Science and Technology Council, and other affiliated bodies and any other group pertaining to human subjects research.

3. Be responsible along with the CMO for conducting oversight of the policies and procedures of both internal and external IRBs that review human subjects research conducted or funded by DHS.

D. The ***CMO*** has general responsibility to support the HSPO in the effort to ensure that the DHS fully understands and implements this MD, The Common Rule, any other applicable statutory requirements, and the related regulatory mandates to protect human subjects involved in research conducted or supported by DHS. The CMO will:

1. Assist in establishing agency-wide policies and procedures to ensure effective implementation of The Common Rule for DHS sponsored human subjects research and prior to implementation, review any policy, procedure, or guidance concerning the safety and protection of human subjects used in DHS research.

2. Be responsible along with the OGC for conducting oversight of the policies and procedures of both internal and external IRBs that review human subjects research conducted or funded by DHS.

3. Support along with the OGC the participation of DHS in the Interdepartmental Human Subjects Research Subcommittee of the Committee of Science, National Science and Technology Council, and other affiliated bodies and any other group pertaining to human subjects research.

4. Coordinate the medical response to any research-related injuries or unanticipated problems that involve risks to human subjects.

E. ***Components*** will ensure that all human subjects research they conduct or sponsor complies with this MD, The Common Rule, any other applicable statutory requirements, and the related regulatory mandates. In exercising this authority, each Component will:

1. Establish, as needed, any further organization-wide policy, procedure, or guidance to ensure the safety and protection of human subjects used in DHS research and submit such policies, procedures, or guidance through the CMO to the HSPO for approval.

2. Monitor compliance with the provisions of this MD.

3. Prepare all required documentation to gain a federal wide assurance and submit it to OHRP for approval.

4. Provide approved Assurance documentation to the HSPO and upon request provide data on all human subjects research to the HSPO.

5. Ensure that all assigned personnel involved in the conduct or sponsorship of human subjects research are fully trained to ensure the protection of said subjects in accordance with the provisions of this MD.

6. Ensure and document that all extramural research involving human subjects research under contracts, grants, cooperative agreements, CRADAs, Other Transaction agreements, and other arrangements is conducted under an assurance of compliance and reviewed by a properly constituted IRB.

7. Ensure that an accredited IRB reviews all research involving human subjects as required by The Common Rule. Components are not expected to constitute their own IRBs given the highly technical nature of membership and detailed record keeping requirements; however, any referrals to outside IRBs shall be coordinated with the HSPO.

8. Ensure that any issues of research-related injuries and serious noncompliance with this MD within the Component are reported to the CMO and HSPO.

9, Forward all external requests concerning the conduct and support of human subjects research through the CMO to the HSPO for coordination and response.

VI. Policy & Procedures

A. ***Policy***.

1. In research conducted or supported by DHS, the safety and protection of human subjects are paramount concerns that are founded on the basic ethical principles of respect for persons, beneficence, and justice. These considerations will also apply to research that involves the experimental or prototype testing of detection or similar equipment in which humans may pass through some type of energy field.

2. All research involving human subjects conducted or supported by DHS shall comply with the requirements of The Common Rule at 45 CFR Part 46, Subpart A.

3. All research conducted or supported by DHS involving vulnerable classes of subjects including pregnant women, human fetuses, neonates, prisoners, and children will comply with the provisions of 45 CFR Part 46, Subparts B, C, and D.

4. All human subjects research (not otherwise exempt) conducted or supported by DHS will be accomplished under an Assurance of compliance approved for federal wide use by OHRP.

5. No research involving human subjects will be initiated until it has been reviewed and approved by an IRB operating under a current federal-wide assurance, unless it has been determined to be exempt under the provisions of 45 CFR 46.101(b) by an appropriate official, above the level of a principal investigator, at the institution engaged in the research.

6. Any fetal tissue research supported or conducted by DHS will comply with 42 U.S.C. 289g – 289g-2.

7. Components that conduct or support research shall ensure that the research is conducted in an ethical manner and will monitor and review said research in accordance with the procedures and standards established by the HSPO.

8. All DHS personnel involved in the conduct, review, or approval of human subjects research will be made aware of the human subjects protection requirements that are commensurate with their duties in the process and compatible with OHRP policies.

9. Issues related to research-related injuries and noncompliance with this MD from any Component or activity thereof will be referred immediately to the next higher management level, and the OGC, CMO, and HSPO to resolve. No action, administrative or disciplinary, will be taken against a person for the act of reporting any such noncompliance.

10. Human subjects research conducted outside the United States, including that performed or jointly sponsored by a foreign government, will comply with U.S. regulatory and legal standards and requirements, unless the standards of the host country are more stringent. All such human subjects research will be cleared in advance by the HSPO, CMO, and OGC.

B. ***Procedures***.

All officials and employees shall conduct themselves in accordance with the responsibilities set forth in Section V as well as with any subsequently developed and properly approved policy, procedure, or guidance to ensure the safety and protection of human subjects used in DHS research.

VII. Questions

Any questions or concerns regarding this MD should be addressed to the Under Secretary for S&T.

Public Law 114–255
114th Congress

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Dec. 13, 2016
[H.R. 34]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

21st Century Cures Act.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

Sec. 1001. Beau Biden Cancer Moonshot and NIH innovation projects.
Sec. 1002. FDA innovation projects.
Sec. 1003. Account for the state response to the opioid abuse crisis.
Sec. 1004. Budgetary treatment.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

Sec. 2001. National Institutes of Health Reauthorization.
Sec. 2002. EUREKA prize competitions.

Subtitle B—Advancing Precision Medicine

Sec. 2011. Precision Medicine Initiative.
Sec. 2012. Privacy protection for human research subjects.
Sec. 2013. Protection of identifiable and sensitive information.
Sec. 2014. Data sharing.

Subtitle C—Supporting Young Emerging Scientists

Sec. 2021. Investing in the next generation of researchers.
Sec. 2022. Improvement of loan repayment program.

Subtitle D—National Institutes of Health Planning and Administration

Sec. 2031. National Institutes of Health strategic plan.
Sec. 2032. Triennial reports.
Sec. 2033. Increasing accountability at the National Institutes of Health.
Sec. 2034. Reducing administrative burden for researchers.
Sec. 2035. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
Sec. 2036. High-risk, high-reward research.
Sec. 2037. National Center for Advancing Translational Sciences.
Sec. 2038. Collaboration and coordination to enhance research.
Sec. 2039. Enhancing the rigor and reproducibility of scientific research.
Sec. 2040. Improving medical rehabilitation research at the National Institutes of Health.

Sec. 2041. Task force on research specific to pregnant women and lactating women.
Sec. 2042. Streamlining National Institutes of Health reporting requirements.
Sec. 2043. Reimbursement for research substances and living organisms.
Sec. 2044. Sense of Congress on increased inclusion of underrepresented populations in clinical trials.

Subtitle E—Advancement of the National Institutes of Health Research and Data Access

Sec. 2051. Technical updates to clinical trials database.
Sec. 2052. Compliance activities reports.
Sec. 2053. Updates to policies to improve data.
Sec. 2054. Consultation.

Subtitle F—Facilitating Collaborative Research

Sec. 2061. National neurological conditions surveillance system.
Sec. 2062. Tick-borne diseases.
Sec. 2063. Accessing, sharing, and using health data for research purposes.

Subtitle G—Promoting Pediatric Research

Sec. 2071. National pediatric research network.
Sec. 2072. Global pediatric clinical study network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

Sec. 3001. Patient experience data.
Sec. 3002. Patient-focused drug development guidance.
Sec. 3003. Streamlining patient input.
Sec. 3004. Report on patient experience drug development.

Subtitle B—Advancing New Drug Therapies

Sec. 3011. Qualification of drug development tools.
Sec. 3012. Targeted drugs for rare diseases.
Sec. 3013. Reauthorization of program to encourage treatments for rare pediatric diseases.
Sec. 3014. GAO study of priority review voucher programs.
Sec. 3015. Amendments to the Orphan Drug grants.
Sec. 3016. Grants for studying continuous drug manufacturing.

Subtitle C—Modern Trial Design and Evidence Development

Sec. 3021. Novel clinical trial designs.
Sec. 3022. Real world evidence.
Sec. 3023. Protection of human research subjects.
Sec. 3024. Informed consent waiver or alteration for clinical investigations.

Subtitle D—Patient Access to Therapies and Information

Sec. 3031. Summary level review.
Sec. 3032. Expanded access policy.
Sec. 3033. Accelerated approval for regenerative advanced therapies.
Sec. 3034. Guidance regarding devices used in the recovery, isolation, or delivery of regenerative advanced therapies.
Sec. 3035. Report on regenerative advanced therapies.
Sec. 3036. Standards for regenerative medicine and regenerative advanced therapies.
Sec. 3037. Health care economic information.
Sec. 3038. Combination product innovation.

Subtitle E—Antimicrobial Innovation and Stewardship

Sec. 3041. Antimicrobial resistance monitoring.
Sec. 3042. Limited population pathway.
Sec. 3043. Prescribing authority.
Sec. 3044. Susceptibility test interpretive criteria for microorganisms; antimicrobial susceptibility testing devices.

Subtitle F—Medical Device Innovations

Sec. 3051. Breakthrough devices.
Sec. 3052. Humanitarian device exemption.
Sec. 3053. Recognition of standards.
Sec. 3054. Certain class I and class II devices.

Sec. 3055. Classification panels.
Sec. 3056. Institutional review board flexibility.
Sec. 3057. CLIA waiver improvements.
Sec. 3058. Least burdensome device review.
Sec. 3059. Cleaning instructions and validation data requirement.
Sec. 3060. Clarifying medical software regulation.

Subtitle G—Improving Scientific Expertise and Outreach at FDA

Sec. 3071. Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service.
Sec. 3072. Hiring authority for scientific, technical, and professional personnel.
Sec. 3073. Establishment of Food and Drug Administration Intercenter Institutes.
Sec. 3074. Scientific engagement.
Sec. 3075. Drug surveillance.
Sec. 3076. Reagan-Udall Foundation for the Food and Drug Administration.

Subtitle H—Medical Countermeasures Innovation

Sec. 3081. Medical countermeasure guidelines.
Sec. 3082. Clarifying BARDA contracting authority.
Sec. 3083. Countermeasure budget plan.
Sec. 3084. Medical countermeasures innovation.
Sec. 3085. Streamlining Project BioShield procurement.
Sec. 3086. Encouraging treatments for agents that present a national security threat.
Sec. 3087. Paperwork Reduction Act waiver during a public health emergency.
Sec. 3088. Clarifying Food and Drug Administration emergency use authorization.

Subtitle I—Vaccine Access, Certainty, and Innovation

Sec. 3091. Predictable review timelines of vaccines by the Advisory Committee on Immunization Practices.
Sec. 3092. Review of processes and consistency of Advisory Committee on Immunization Practices recommendations.
Sec. 3093. Encouraging vaccine innovation.

Subtitle J—Technical Corrections

Sec. 3101. Technical corrections.
Sec. 3102. Completed studies.

TITLE IV—DELIVERY

Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients.
Sec. 4002. Transparent reporting on usability, security, and functionality.
Sec. 4003. Interoperability.
Sec. 4004. Information blocking.
Sec. 4005. Leveraging electronic health records to improve patient care.
Sec. 4006. Empowering patients and improving patient access to their electronic health information.
Sec. 4007. GAO study on patient matching.
Sec. 4008. GAO study on patient access to health information.
Sec. 4009. Improving Medicare local coverage determinations.
Sec. 4010. Medicare pharmaceutical and technology ombudsman.
Sec. 4011. Medicare site-of-service price transparency.
Sec. 4012. Telehealth services in Medicare.

TITLE V—SAVINGS

Sec. 5001. Savings in the Medicare Improvement Fund.
Sec. 5002. Medicaid reimbursement to States for durable medical equipment.
Sec. 5003. Penalties for violations of grants, contracts, and other agreements.
Sec. 5004. Reducing overpayments of infusion drugs.
Sec. 5005. Increasing oversight of termination of Medicaid providers.
Sec. 5006. Requiring publication of fee-for-service provider directory.
Sec. 5007. Fairness in Medicaid supplemental needs trusts.
Sec. 5008. Eliminating Federal financial participation with respect to expenditures under Medicaid for agents used for cosmetic purposes or hair growth.
Sec. 5009. Amendment to the Prevention and Public Health Fund.
Sec. 5010. Strategic Petroleum Reserve drawdown.
Sec. 5011. Rescission of portion of ACA territory funding.
Sec. 5012. Medicare coverage of home infusion therapy.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

Sec. 6000. Short title.

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

Sec. 6001. Assistant Secretary for Mental Health and Substance Use.
Sec. 6002. Strengthening the leadership of the Substance Abuse and Mental Health Services Administration.
Sec. 6003. Chief Medical Officer.
Sec. 6004. Improving the quality of behavioral health programs.
Sec. 6005. Strategic plan.
Sec. 6006. Biennial report concerning activities and progress.
Sec. 6007. Authorities of centers for mental health services, substance abuse prevention, and substance abuse treatment.
Sec. 6008. Advisory councils.
Sec. 6009. Peer review.

Subtitle B—Oversight and Accountability

Sec. 6021. Improving oversight of mental and substance use disorders programs through the Assistant Secretary for Planning and Evaluation.
Sec. 6022. Reporting for protection and advocacy organizations.
Sec. 6023. GAO study.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

Sec. 6031. Interdepartmental Serious Mental Illness Coordinating Committee.

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

Sec. 7001. Encouraging innovation and evidence-based programs.
Sec. 7002. Promoting access to information on evidence-based programs and practices.
Sec. 7003. Priority mental health needs of regional and national significance.
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TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

Sec. 8001. Community mental health services block grant.
Sec. 8002. Substance abuse prevention and treatment block grant.
Sec. 8003. Additional provisions related to the block grants.
Sec. 8004. Study of distribution of funds under the substance abuse prevention and treatment block grant and the community mental health services block grant.

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

Sec. 9001. Grants for treatment and recovery for homeless individuals.
Sec. 9002. Grants for jail diversion programs.
Sec. 9003. Promoting integration of primary and behavioral health care.
Sec. 9004. Projects for assistance in transition from homelessness.
Sec. 9005. National Suicide Prevention Lifeline Program.
Sec. 9006. Connecting individuals and families with care.
Sec. 9007. Strengthening community crisis response systems.
Sec. 9008. Garrett Lee Smith Memorial Act reauthorization.
Sec. 9009. Adult suicide prevention.
Sec. 9010. Mental health awareness training grants.
Sec. 9011. Sense of Congress on prioritizing American Indians and Alaska Native youth within suicide prevention programs.
Sec. 9012. Evidence-based practices for older adults.
Sec. 9013. National violent death reporting system.
Sec. 9014. Assisted outpatient treatment.
Sec. 9015. Assertive community treatment grant program.
Sec. 9016. Sober truth on preventing underage drinking reauthorization.
Sec. 9017. Center and program repeals.

Subtitle B—Strengthening the Health Care Workforce

Sec. 9021. Mental and behavioral health education and training grants.

Sec. 9022. Strengthening the mental and substance use disorders workforce.
Sec. 9023. Clarification on current eligibility for loan repayment programs.
Sec. 9024. Minority fellowship program.
Sec. 9025. Liability protections for health professional volunteers at community health centers.
Sec. 9026. Reports.

Subtitle C—Mental Health on Campus Improvement

Sec. 9031. Mental health and substance use disorder services on campus.
Sec. 9032. Interagency Working Group on College Mental Health.
Sec. 9033. Improving mental health on college campuses.

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

Sec. 10001. Programs for children with a serious emotional disturbance.
Sec. 10002. Increasing access to pediatric mental health care.
Sec. 10003. Substance use disorder treatment and early intervention services for children and adolescents.
Sec. 10004. Children's recovery from trauma.
Sec. 10005. Screening and treatment for maternal depression.
Sec. 10006. Infant and early childhood mental health promotion, intervention, and treatment.

TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

Sec. 11001. Sense of Congress.
Sec. 11002. Confidentiality of records.
Sec. 11003. Clarification on permitted uses and disclosures of protected health information.
Sec. 11004. Development and dissemination of model training programs.

TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

Sec. 12001. Rule of construction related to Medicaid coverage of mental health services and primary care services furnished on the same day.
Sec. 12002. Study and report related to Medicaid managed care regulation.
Sec. 12003. Guidance on opportunities for innovation.
Sec. 12004. Study and report on Medicaid emergency psychiatric demonstration project.
Sec. 12005. Providing EPSDT services to children in IMDs.
Sec. 12006. Electronic visit verification system required for personal care services and home health care services under Medicaid.

TITLE XIII—MENTAL HEALTH PARITY

Sec. 13001. Enhanced compliance with mental health and substance use disorder coverage requirements.
Sec. 13002. Action plan for enhanced enforcement of mental health and substance use disorder coverage.
Sec. 13003. Report on investigations regarding parity in mental health and substance use disorder benefits.
Sec. 13004. GAO study on parity in mental health and substance use disorder benefits.
Sec. 13005. Information and awareness on eating disorders.
Sec. 13006. Education and training on eating disorders.
Sec. 13007. Clarification of existing parity rules.

TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

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Sec. 14001. Law enforcement grants for crisis intervention teams, mental health purposes.
Sec. 14002. Assisted outpatient treatment programs.
Sec. 14003. Federal drug and mental health courts.
Sec. 14004. Mental health in the judicial system.
Sec. 14005. Forensic assertive community treatment initiatives.
Sec. 14006. Assistance for individuals transitioning out of systems.
Sec. 14007. Co-occurring substance abuse and mental health challenges in drug courts.
Sec. 14008. Mental health training for Federal uniformed services.
Sec. 14009. Advancing mental health as part of offender reentry.
Sec. 14010. School mental health crisis intervention teams.
Sec. 14011. Active-shooter training for law enforcement.

Sec. 14012. Co-occurring substance abuse and mental health challenges in residential substance abuse treatment programs.
Sec. 14013. Mental health and drug treatment alternatives to incarceration programs.
Sec. 14014. National criminal justice and mental health training and technical assistance.
Sec. 14015. Improving Department of Justice data collection on mental illness involved in crime.
Sec. 14016. Reports on the number of mentally ill offenders in prison.
Sec. 14017. Codification of due process for determinations by secretary of veterans affairs of mental capacity of beneficiaries.
Sec. 14018. Reauthorization of appropriations.

Subtitle B—Comprehensive Justice and Mental Health

Sec. 14021. Sequential intercept model.
Sec. 14022. Prison and jails.
Sec. 14023. Allowable uses.
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Sec. 14025. Federal law enforcement training.
Sec. 14026. GAO report.
Sec. 14027. Evidence based practices.
Sec. 14028. Transparency, program accountability, and enhancement of local authority.
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DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

Sec. 15000. Short title.

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

Sec. 15001. Development of Medicare HCPCS version of MS–DRG codes for similar hospital services.
Sec. 15002. Establishing beneficiary equity in the Medicare hospital readmission program.
Sec. 15003. Five-year extension of the rural community hospital demonstration program.
Sec. 15004. Regulatory relief for LTCHs.
Sec. 15005. Savings from IPPS MACRA pay-for through not applying documentation and coding adjustments.
Sec. 15006. Extension of certain LTCH Medicare payment rules.
Sec. 15007. Application of rules on the calculation of hospital length of stay to all LTCHs.
Sec. 15008. Change in Medicare classification for certain hospitals.
Sec. 15009. Temporary exception to the application of the Medicare LTCH site neutral provisions for certain spinal cord specialty hospitals.
Sec. 15010. Temporary extension to the application of the Medicare LTCH site neutral provisions for certain discharges with severe wounds.

TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

Sec. 16001. Continuing Medicare payment under HOPD prospective payment system for services furnished by mid-build off-campus outpatient departments of providers.
Sec. 16002. Treatment of cancer hospitals in off-campus outpatient department of a provider policy.
Sec. 16003. Treatment of eligible professionals in ambulatory surgical centers for meaningful use and MIPS.
Sec. 16004. Continuing Access to Hospitals Act of 2016.
Sec. 16005. Delay of implementation of Medicare fee schedule adjustments for wheelchair accessories and seating systems when used in conjunction with complex rehabilitation technology (CRT) wheelchairs.
Sec. 16006. Allowing physical therapists to utilize locum tenens arrangements under Medicare.
Sec. 16007. Extension of the transition to new payment rates for durable medical equipment under the Medicare program.
Sec. 16008. Requirements in determining adjustments using information from competitive bidding programs.

TITLE XVII—OTHER MEDICARE PROVISIONS

Sec. 17001. Delay in authority to terminate contracts for Medicare Advantage plans failing to achieve minimum quality ratings.

Sec. 17002. Requirement for enrollment data reporting for Medicare.
Sec. 17003. Updating the Welcome to Medicare package.
Sec. 17004. No payment for items and services furnished by newly enrolled providers or suppliers within a temporary moratorium area.
Sec. 17005. Preservation of Medicare beneficiary choice under Medicare Advantage.
Sec. 17006. Allowing end-stage renal disease beneficiaries to choose a Medicare Advantage plan.
Sec. 17007. Improvements to the assignment of beneficiaries under the Medicare Shared Savings Program.

TITLE XVIII—OTHER PROVISIONS

Sec. 18001. Exception from group health plan requirements for qualified small employer health reimbursement arrangements.

DIVISION A—21ST CENTURY CURES

21st Century Cures Act.

SEC. 1000. SHORT TITLE.

42 USC 201 note.

This Division may be cited as the "21st Century Cures Act".

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

SEC. 1001. BEAU BIDEN CANCER MOONSHOT AND NIH INNOVATION PROJECTS.

(a) IN GENERAL.—The Director of the National Institutes of Health (referred to in this section as the "Director of NIH") shall use any funds appropriated pursuant to the authorization of appropriations in subsection (b)(3) to carry out the National Institutes of Health innovation projects described in subsection (b)(4) (referred to in this section as the "NIH Innovation Projects").

(b) NATIONAL INSTITUTES OF HEALTH INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF NIH INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the "NIH Innovation Account" (referred to in this subsection as the "Account"), for purposes of carrying out the NIH Innovation Projects described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $352,000,000.
(ii) For fiscal year 2018, $496,000,000.
(iii) For fiscal year 2019, $711,000,000.
(iv) For fiscal year 2020, $492,000,000.
(v) For fiscal year 2021, $404,000,000.
(vi) For fiscal year 2022, $496,000,000.
(vii) For fiscal year 2023, $1,085,000,000.
(viii) For fiscal year 2024, $407,000,000.
(ix) For fiscal year 2025, $127,000,000.
(x) For fiscal year 2026, $226,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2026, there is authorized

to be appropriated from the Account to the Director of NIH, for the purpose of carrying out the NIH Innovation Projects, an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2026, for any discretionary appropriation under the heading "NIH Innovation Account" provided to the Director of NIH pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the NIH Innovation Projects, the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) NIH INNOVATION PROJECTS.—NIH Innovation Projects authorized to be funded under this section shall consist of the following and, of the total amounts authorized to be appropriated under paragraph (3), there are authorized to be appropriated to each such project a total amount not to exceed the following, over the period of fiscal years 2017 through 2026:

(A) For the Precision Medicine Initiative, including for the advancement of a cohort of individuals to support the goals of the Precision Medicine Initiative, not to exceed a total of $1,455,000,000, as follows:

(i) For fiscal year 2017, $40,000,000.
(ii) For fiscal year 2018, $100,000,000.
(iii) For fiscal year 2019, $186,000,000.
(iv) For fiscal year 2020, $149,000,000.
(v) For fiscal year 2021, $109,000,000.
(vi) For fiscal year 2022, $150,000,000.
(vii) For fiscal year 2023, $419,000,000.
(viii) For fiscal year 2024, $235,000,000.
(ix) For fiscal year 2025, $36,000,000.
(x) For fiscal year 2026, $31,000,000.

(B) For the Brain Research through Advancing Innovative Neurotechnologies Initiative (known as the "BRAIN Initiative"), not to exceed a total of $1,511,000,000, as follows:

(i) For fiscal year 2017, $10,000,000.
(ii) For fiscal year 2018, $86,000,000.
(iii) For fiscal year 2019, $115,000,000.
(iv) For fiscal year 2020, $140,000,000.
(v) For fiscal year 2021, $100,000,000.
(vi) For fiscal year 2022, $152,000,000.
(vii) For fiscal year 2023, $450,000,000.
(viii) For fiscal year 2024, $172,000,000.
(ix) For fiscal year 2025, $91,000,000.
(x) For fiscal year 2026, $195,000,000.

(C) To support cancer research, such as the development of cancer vaccines, the development of more sensitive

diagnostic tests for cancer, immunotherapy and the development of combination therapies, and research that has the potential to transform the scientific field, that has inherently higher risk, and that seeks to address major challenges related to cancer, not to exceed a total of $1,800,000,000, as follows:

(i) For fiscal year 2017, $300,000,000.

(ii) For fiscal year 2018, $300,000,000.

(iii) For fiscal year 2019, $400,000,000.

(iv) For fiscal year 2020, $195,000,000.

(v) For fiscal year 2021, $195,000,000.

(vi) For fiscal year 2022, $194,000,000.

(vii) For fiscal year 2023, $216,000,000.

(D) For the National Institutes of Health, in coordination with the Food and Drug Administration, to award grants and contracts for clinical research to further the field of regenerative medicine using adult stem cells, including autologous stem cells, for which grants and contracts shall be contingent upon the recipient making available non-Federal contributions toward the costs of such research in an amount not less than $1 for each $1 of Federal funds provided in the award, not to exceed a total of $30,000,000, as follows:

(i) For fiscal year 2017, $2,000,000.

(ii) For each of fiscal years 2018 and 2019, $10,000,000.

(iii) For fiscal year 2020, $8,000,000.

(iv) For each of fiscal years 2021 through 2026, $0.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds authorized to be appropriated pursuant to subsection (b)(3) for each of fiscal years 2017 through 2026 for the NIH Innovation Projects and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) recommendations from the Advisory Committee described in subparagraph (C);

(ii) the amount of money to be obligated or expended in each fiscal year for each NIH Innovation Project;

(iii) a description and justification of each such project; and

(iv) a description of how each such project supports the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Director of NIH shall seek recommendations from the Advisory Committee to the Director of NIH appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a) on—

(i) the allocations of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2026; and

(ii) on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2027, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

(i) the amount of money obligated or expended in the prior fiscal year for each NIH Innovation Project;

(ii) a description of any such project using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and

(iii) whether such projects are advancing the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Director of NIH shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the NIH Innovation Projects.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (b)(3) may not be used for any purpose other than a NIH Innovation Project.

(e) SUNSET.—This section shall expire on September 30, 2026.

SEC. 1002. FDA INNOVATION PROJECTS.

(a) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the "Commissioner") shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) to carry out the activities described in subsection (b)(4).

(b) FDA INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF FDA INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the "FDA Innovation Account" (referred to in this subsection as the "Account"), for purposes of carrying out the activities described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—For each of fiscal years 2017 through 2025, the following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $20,000,000.
(ii) For fiscal year 2018, $60,000,000.
(iii) For fiscal year 2019, $70,000,000.
(iv) For fiscal year 2020, $75,000,000.
(v) For fiscal year 2021, $70,000,000.
(vi) For fiscal year 2022, $50,000,000.
(vii) For fiscal year 2023, $50,000,000.
(viii) For fiscal year 2024, $50,000,000.
(ix) For fiscal year 2025, $55,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2025, there is authorized to be appropriated from the Account to the Commissioner, for the purpose of carrying out the activities described in paragraph (5), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2025, for any discretionary appropriation under the heading "FDA Innovation Account" provided to the Commissioner pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the projects activities described in paragraph (4), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) FDA ACTIVITIES.—The activities authorized to be funded under this section are the activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal Food, Drug, and Cosmetic Act, as added by section 3073 of this Act.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) recommendations from the Advisory Committee described in subparagraph (C);

(ii) the amount of money to be obligated or expended in each fiscal year for each activity described in subsection (b)(4); and

(iii) a description and justification of each such project activity.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Commissioner shall seek recommendations from the Science Board to the Food and Drug Administration, on the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2026, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

(i) the amount of money obligated or expended in the prior fiscal year for each activity described in subsection (b)(4);

(ii) a description of all such activities using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and

(iii) how the activities are advancing public health.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the activities undertaken with such funding.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations in subsection (b)(3) shall not be used for any purpose other than an activity described in subsection (b)(4).

(e) SUNSET.—This section shall expire on September 30, 2025.

42 USC 290ee–3 note.

SEC. 1003. ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b) to carry out the grant program described in subsection (c) for purposes of addressing the opioid abuse crisis within the States.

(b) ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.—

(1) ESTABLISHMENT.—There is established in the Treasury an account, to be known as the "Account For the State Response to the Opioid Abuse Crisis" (referred to in this subsection as the "Account"), to carry out the opioid grant program described in subsection (c).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $500,000,000.

(ii) For fiscal year 2018, $500,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—In each of the fiscal years 2017 and 2018, there is authorized to be appropriated from the Account to the Secretary, for the grant program described in subsection (c), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—In each of fiscal years 2017 and 2018, for any discretionary appropriation under the heading "Account For the State Response to the Opioid Abuse Crisis" for the grant program described in subsection (c), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(c) OPIOID GRANT PROGRAM.—

(1) STATE RESPONSE TO THE OPIOID ABUSE CRISIS.—Subject to the availability of appropriations, the Secretary shall award grants to States for the purpose of addressing the opioid abuse crisis within such States, in accordance with subparagraph (B). In awarding such grants, the Secretary shall give preference to States with an incidence or prevalence of opioid use disorders that is substantially higher relative to other States.

(2) OPIOID GRANTS.—Grants awarded to a State under this subsection shall be used for carrying out activities that supplement activities pertaining to opioids undertaken by the State agency responsible for administering the substance abuse prevention and treatment block grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.), which may include public health-related activities such as the following:

(A) Improving State prescription drug monitoring programs.

(B) Implementing prevention activities, and evaluating such activities to identify effective strategies to prevent opioid abuse.

(C) Training for health care practitioners, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance abuse, referral of patients to treatment programs, and overdose prevention.

(D) Supporting access to health care services, including those services provided by Federally certified opioid treatment programs or other appropriate health care providers to treat substance use disorders.

(E) Other public health-related activities, as the State determines appropriate, related to addressing the opioid abuse crisis within the State.

(d) ACCOUNTABILITY AND OVERSIGHT.—A State receiving a grant under subsection (c) shall include in a report related to substance abuse submitted to the Secretary pursuant to section 1942 of the Public Health Service Act (42 U.S.C. 300x–52), a description of—

(1) the purposes for which the grant funds received by the State under such subsection for the preceding fiscal year were expended and a description of the activities of the State under the program; and

(2) the ultimate recipients of amounts provided to the State in the grant.

(e) LIMITATIONS.—Any funds made available pursuant to the authorization of appropriations under subsection (b)—

(1) notwithstanding any transfer authority in any appropriations Act, shall not be used for any purpose other than the grant program in subsection (c); and

(2) shall be subject to the same requirements as substance abuse prevention and treatment programs under titles V and XIX of the Public Health Service Act (42 U.S.C. 290aa et seq., 300w et seq.).

(f) SUNSET.—This section shall expire on September 30, 2026.

SEC. 1004. BUDGETARY TREATMENT.

(a) STATUTORY PAYGO SCORECARDS.—The budgetary effects of division A of this Act shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay-As-You-Go Act of 2010.

(b) SENATE PAYGO SCORECARDS.—The budgetary effects of division A of this Act shall not be entered on any PAYGO scorecard maintained for purposes of section 201 of S. Con. Res. 21 (110th Congress).

(c) RESERVATION OF SAVINGS.—None of the funds in the NIH Innovation Account, the FDA Innovation Account, or the Account For the State Response to the Opioid Abuse Crisis established by this title shall be made available except to the extent provided in advance in appropriations Acts, and legislation or an Act that rescinds or reduces amounts in such accounts shall not be estimated as a reduction in direct spending under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

SEC. 2001. NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION.

Section 402A(a)(1) of the Public Health Service Act (42 U.S.C. 282a(a)(1)) is amended—

(1) in subparagraph (B), by striking "and" at the end;

(2) in subparagraph (C), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following new subparagraphs:

"(D) $34,851,000,000 for fiscal year 2018;

"(E) $35,585,871,000 for fiscal year 2019; and

"(F) $36,472,442,775 for fiscal year 2020.".

SEC. 2002. EUREKA PRIZE COMPETITIONS. 42 USC 283q.

(a) IN GENERAL.—Pursuant to the authorities and processes established under section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), the Director of the National Institutes of Health shall support prize competitions for one or both of the following goals:

(1) Identifying and funding areas of biomedical science that could realize significant advancements through a prize competition.

(2) Improving health outcomes, particularly with respect to human diseases and conditions—

(A) for which public and private investment in research is disproportionately small relative to Federal Government expenditures on prevention and treatment activities with respect to such diseases and conditions, such that Federal expenditures on health programs would be reduced;

(B) that are serious and represent a significant disease burden in the United States; or

(C) for which there is potential for significant return on investment to the United States.

(b) TRACKING; REPORTING.—The Director of the National Institutes of Health shall—

(1) collect information on—

(A) the effect of innovations funded through the prize competitions under this section in advancing biomedical science or improving health outcomes pursuant to subsection (a); and

(B) the effect of the innovations on Federal expenditures; and

(2) include the information collected under paragraph (1) in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032).

Subtitle B—Advancing Precision Medicine

SEC. 2011. PRECISION MEDICINE INITIATIVE. 42 USC 289g–5.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end the following:

"SEC. 498E. PRECISION MEDICINE INITIATIVE.

"(a) IN GENERAL.—The Secretary is encouraged to establish and carry out an initiative, to be known as the 'Precision Medicine Initiative' (in this section referred to as the 'Initiative'), to augment efforts to address disease prevention, diagnosis, and treatment.

"(b) COMPONENTS.—The Initiative described under subsection (a) may include—

"(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

"(2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;

"(3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;

"(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

"(5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

"(c) AUTHORITY OF THE SECRETARY.—In carrying out this section, the Secretary may—

"(1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;

"(2) develop and utilize public-private partnerships; and

"(3) leverage existing data sources.

"(d) REQUIREMENTS.—In the implementation of the Initiative under subsection (a), the Secretary shall—

"(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;

"(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

"(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;

"(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;

"(5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and

"(6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.

"(e) REPORT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report

on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.".

SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

"(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

"(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

"(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

"(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

"(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

"(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

"(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

"(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

"(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

"(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

"(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used

for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

"(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

"(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

"(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

"(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.

"(4) For purposes of this subsection, the term 'identifiable, sensitive information' means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

"(A) through which an individual is identified; or

"(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.".

42 USC 241 note.

(b) APPLICABILITY.—Beginning 180 days after the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

"(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

"(A) an individual is identified; or

"(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

"(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

"(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

"(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.".

SEC. 2014. DATA SHARING.

(a) IN GENERAL.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (23), by striking "and" at the end;

(2) in paragraph (24), by striking the period and inserting "; and"; and

(3) by inserting after paragraph (24) the following:

"(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

"(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

"(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.".

(b) CONFIDENTIALITY.—Nothing in the amendments made by subsection (a) authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information. 42 USC 282 note.

Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404M. NEXT GENERATION OF RESEARCHERS. 42 USC 283o.

"(a) NEXT GENERATION OF RESEARCHERS INITIATIVE.—There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the 'Initiative'), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

"(b) ACTIVITIES.—The Director of the National Institutes of Health, through the Initiative shall—

"(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

"(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

"(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

"(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.".

(b) CONSIDERATION OF RECOMMENDATIONS.—In carrying out activities under section 404M(b) of the Public Health Service Act, the Director of the National Institutes of Health shall take into consideration the recommendations made by the National Academies of Sciences, Engineering, and Medicine as part of the comprehensive study on policies affecting the next generation of researchers under the Department of Health and Human Services Appropriations Act, 2016 (Public Law 114–113), and submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, with respect to any actions taken by the National Institutes of Health based on the recommendations not later than 2 years after the completion of the study required pursuant to the Department of Health and Human Services Appropriations Act, 2016.

SEC. 2022. IMPROVEMENT OF LOAN REPAYMENT PROGRAM.

(a) INTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487A of the Public Health Service Act (42 U.S.C. 288–1) is amended—

(1) by amending the section heading to read as follows: "**INTRAMURAL LOAN REPAYMENT PROGRAM**";

(2) in subsection (a)—

(A) by striking "The Secretary shall carry out a program" and inserting "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))";

(B) by striking "conduct" and inserting "conduct research";

(C) by striking "research with respect to acquired immune deficiency syndrome"; and

(D) by striking "$35,000" and inserting "$50,000";

(3) by redesignating subsection (b) as subsection (d);

(4) by inserting after subsection (a), the following:

"(b) SUBCATEGORIES OF RESEARCH.—

"(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

"(A) shall continue to focus on—

"(i) general research;

"(ii) research on acquired immune deficiency syndrome; and

"(iii) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

"(B) may focus on an area of emerging scientific or workforce need.

"(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

"(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).''; and

(5) by adding at the end the following:

"(e) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts are made available.''.

(b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487B of the Public Health Service Act (42 U.S.C. 288–2) is amended—

(1) by amending the section heading to read as follows: "**EXTRAMURAL LOAN REPAYMENT PROGRAM**";

(2) in subsection (a)—

(A) by striking "The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program" and inserting "IN GENERAL.—The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)),";

(B) by striking "(including graduate students)";

(C) by striking "with respect to contraception, or with respect to infertility,"; and

(D) by striking "service, not more than $35,000" and inserting "research, not more than $50,000";

(3) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively;

(4) by inserting after subsection (a), the following:

"(b) SUBCATEGORIES OF RESEARCH.—

"(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

"(A) shall continue to focus on—

"(i) contraception or infertility research;

"(ii) pediatric research, including pediatric pharmacological research;

"(iii) minority health disparities research;

"(iv) clinical research; and

"(v) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

"(B) may focus on an area of emerging scientific or workforce need.

"(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

"(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).";

(5) in subsection (d) (as so redesignated), by striking "The provisions" and inserting "APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—The provisions"; and

(6) in subsection (e) (as so redesignated), by striking "Amounts" and inserting "AVAILABILITY OF APPROPRIATIONS.—Amounts".

(c) TECHNICAL AND CONFORMING AMENDMENTS.—Title IV of the Public Health Service Act is amended—

(1) by striking section 464z–5 (42 U.S.C. 285t–2);

(2) by striking section 487C (42 U.S.C. 288–3);

(3) by striking section 487E (42 U.S.C. 288–5);

(4) by striking section 487F (42 U.S.C. 288–5a), as added by section 205 of Public Law 106–505, relating to loan repayment for clinical researchers; and

(5) by striking section 487F (42 U.S.C. 288–6), as added by section 1002(b) of Public Law 106–310 relating to pediatric research loan repayment.

(d) GAO REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the efforts of the National Institutes of Health to attract, retain, and develop emerging scientists, including underrepresented individuals in the sciences, such as women, racial and ethnic minorities, and other groups. Such report shall include an analysis of the impact of the additional authority provided to the Secretary of Health and Human Services under this Act to address workforce shortages and gaps in priority research areas, including which centers and research areas offered loan repayment program participants the increased award amount.

Subtitle D—National Institutes of Health Planning and Administration

SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.

(a) STRATEGIC PLAN.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) in subsection (b)(5), by inserting before the semicolon the following: ", and through the development, implementation,

and updating of the strategic plan developed under subsection (m)"; and

(2) by adding at the end the following:

"(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the 'National Institutes of Health Strategic Plan') to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

"(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

"(A) identify strategic research priorities and objectives across biomedical research, including—

"(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

"(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

"(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

"(iv) the identification of near-, mid-, and long-term scientific needs;

"(B) consider, in carrying out subparagraph (A)—

"(i) disease burden in the United States and the potential for return on investment to the United States;

"(ii) rare diseases and conditions;

"(iii) biological, social, and other determinants of health that contribute to health disparities; and

"(iv) other factors the Director of National Institutes of Health determines appropriate;

"(C) include multi-institute priorities, including coordination of research among institutes and centers;

"(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

"(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

"(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

"(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

"(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.".

(b) CONFORMING AMENDMENT.—Section 402A(c)(1)(C) of the Public Health Service Act (42 U.S.C. 282a(c)(1)(C)) is amended by striking "Not later than June 1, 2007, and every 2 years thereafter," and inserting "As part of the National Institutes of Health Strategic Plan required under section 402(m),".

(c) STRATEGIC PLAN.—Section 492B(a) of the Public Health Service Act (42 U.S.C. 289a–2(a)) is amended by adding at the end the following:

"(3) STRATEGIC PLANNING.—

"(A) IN GENERAL.—The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women's Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

"(B) STRATEGIC PLANS.—Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).".

SEC. 2032. TRIENNIAL REPORTS.

Section 403 of the Public Health Service Act (42 U.S.C. 283) is amended—

(1) in the section heading, by striking "**BIENNIAL**" and inserting "**TRIENNIAL**" ; and

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "biennial" and inserting "triennial";

(B) by amending paragraph (3) to read as follows:

"(3) A description of intra-National Institutes of Health activities, including—

"(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

"(B) recommendations for promoting coordination of information among the centers of excellence.";

(C) in paragraph (4)—

(i) in subparagraph (B), by striking "demographic variables and other variables" and inserting "demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health,"; and

(ii) in subparagraph (C)(v)—

(I) by striking "demographic variables and such" and inserting "demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each

national research institute and national center to the Director of National Institutes of Health under section 492B(f), and such"; and

(II) by striking "(regarding inclusion of women and minorities in clinical research)" and inserting "and other applicable requirements regarding inclusion of demographic groups"; and

(D) in paragraph (6)—

(i) in the matter preceding subparagraph (A), by striking "the following:" and inserting "the following—";

(ii) in subparagraph (A)—

(I) by striking "An evaluation" and inserting "an evaluation"; and

(II) by striking the period and inserting "; and";

(iii) by striking subparagraphs (B) and (D);

(iv) by redesignating subparagraph (C) as subparagraph (B); and

(v) in subparagraph (B), as redesignated by clause (iv), by striking "Recommendations" and inserting "recommendations".

SEC. 2033. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

(a) APPOINTMENT AND TERMS OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—Subsection (a) of section 405 of the Public Health Service Act (42 U.S.C. 284) is amended to read as follows:

"(a) APPOINTMENT.—

"(1) IN GENERAL.—The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

"(2) APPOINTMENT.—

"(A) TERM.—A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

"(B) REAPPOINTMENT.—At the end of the term of a Director of a national research institute or national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

"(C) VACANCIES.—If the office of a Director of a national research institute or national center becomes vacant before the end of such Director's term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

"(D) CURRENT DIRECTORS.—Each Director of a national research institute or national center who is serving on the date of enactment of the 21st Century Cures Act shall

be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

"(E) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director's 5-year term.

"(F) NATURE OF APPOINTMENT.—Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant.

"(3) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.".

(b) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—Section 405(b) of the Public Health Service Act (42 U.S.C. 284(b)) is amended by adding at the end the following:

"(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an 'R-series grant'), other than an award constituting a noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

"(A) review and make the final decision with respect to making the award; and

"(B) take into consideration, as appropriate—

"(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m);

"(ii) programs or projects funded by other agencies on similar research topics; and

"(iii) advice by staff and the advisory council or board of such national research institute or national center.".

(c) REPORT ON DUPLICATION IN FEDERAL BIOMEDICAL RESEARCH.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), shall, not later than 2 years after the date of enactment of this Act, submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is not necessary for scientific purposes. Such report shall—

(1) describe the procedures in place to identify such duplicative research, including procedures for monitoring research applications and funded research awards to prevent unnecessary duplication;

(2) describe the steps taken to improve the procedures described in paragraph (1), in response to relevant recommendations made by the Comptroller General of the United States;

(3) describe how the Secretary operationally distinguishes necessary and appropriate scientific replication from unnecessary duplication; and

(4) provide examples of instances where the Secretary has identified unnecessarily duplicative research and the steps taken to eliminate the unnecessary duplication.

SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS. 42 USC 3501 note.

(a) PLAN PREPARATION AND IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall—

(A) lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest;

(B) make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants; and

(C) confer with the Office of the Inspector General about the activities of such office related to financial conflicts of interest involving research funding agencies.

(2) CONSIDERATIONS.—In updating policies under paragraph (1)(B), the Secretary shall consider—

(A) modifying the timelines for the reporting of financial conflicts of interest to just-in-time information by institutions receiving grant or cooperative agreement funding from the National Institutes of Health;

(B) ensuring that financial interest disclosure reporting requirements are appropriate for, and relevant to, awards that will directly fund research, which may include modification of the definition of the term "investigator" for purposes of the regulations and policies described in subparagraphs (A) and (B) of paragraph (1); and

(C) updating any applicable training modules of the National Institutes of Health related to Federal financial interest disclosure.

(b) MONITORING OF SUBRECIPIENTS OF FUNDING FROM THE NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health (referred to in this section as the "Director of National Institutes of Health") shall implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees of funding from the National Institutes of Health, which may incorporate findings and recommendations from existing and ongoing activities. Such measures may include, as appropriate—

(1) an exemption from subrecipient monitoring requirements, upon request from the primary awardees, provided that—

(A) the subrecipient is subject to Federal audit requirements pursuant to the Uniform Guidance of the Office of Management and Budget;

(B) the primary awardee conducts, pursuant to guidance of the National Institutes of Health, a pre-award

evaluation of each subrecipient's risk of noncompliance with Federal statutes and regulations, the conditions of the subaward, and any recurring audit findings; and

(C) such exemption does not absolve the primary awardee of liability for misconduct by subrecipients; and

(2) the implementation of alternative grant structures that obviate the need for subrecipient monitoring, which may include collaborative grant models allowing for multiple primary awardees.

(c) REPORTING OF FINANCIAL EXPENDITURES.—The Secretary, in consultation with the Director of National Institutes of Health, shall evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients.

(d) ANIMAL CARE AND USE IN RESEARCH.—Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall—

(1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

(2) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

(3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

(e) DOCUMENTATION OF PERSONNEL EXPENSES.—The Secretary shall clarify the applicability of the requirements under the Office of Management and Budget Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants through the Department of Health and Human Services regarding documentation of personnel expenses, including clarification of the extent to which any flexibility to such requirements specified in such Uniform Guidance applies to entities receiving grants through the Department of Health and Human Services.

(f) RESEARCH POLICY BOARD.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the "Research Policy Board" (referred to in this subsection as the "Board"), to provide Federal Government officials with information on the effects of regulations related to Federal research requirements.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Board shall include not more than 10 Federal members, including each of the following Federal members or their designees:

(i) The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(ii) The Director of the Office of Science and Technology Policy.

(iii) The Secretary of Health and Human Services.

(iv) The Director of the National Science Foundation.

(v) The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

(B) NON-FEDERAL MEMBERS.—The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates—

(i) nomination by members of the nonprofit scientific research community, including academic research institutions; and

(ii) procedures to fill membership positions vacated before the end of a member's term.

(3) PURPOSE AND RESPONSIBILITIES.—The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include—

(A) providing thorough and informed analysis of regulations and policies;

(B) identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;

(C) making recommendations with respect to efforts within the Federal Government to improve coordination of regulation and policy related to research;

(D) creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and

(E) conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

(4) EXPERT SUBCOMMITTEES.—The Board may form temporary expert subcommittees, as appropriate, to develop timely analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including challenges emerging from new scientific advances.

(5) REPORTING REQUIREMENTS.—Not later than 2 years after the date of enactment of this Act, and once thereafter, the Board shall submit a report to the Director of the Office of Management and Budget, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the heads of relevant Federal departments and agencies, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policy, including the regulatory benefits and burdens.

(6) SUNSET.—The Board shall terminate on September 30, 2021.

(7) GAO REPORT.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out by the Board pursuant to this subsection and submit to the appropriate committees of Congress a report regarding the results of the independent evaluation. Such report shall review and assess the Board's activities with respect to the responsibilities described in paragraph (3).

SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2013, is further amended by adding at the end the following:

"(g) Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.".

SEC. 2036. HIGH-RISK, HIGH-REWARD RESEARCH.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282), as amended by section 2031, is further amended by adding at the end the following:

"(n) UNIQUE RESEARCH INITIATIVES.—

"(1) IN GENERAL.—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

"(A) the Precision Medicine Initiative under section 498E; or

"(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions.

"(2) REQUIREMENTS.—The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

"(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

"(B) receives approval for the use of such authority from the Director of NIH; and

"(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.".

(b) REPORT TO CONGRESS.—Not later than September 30, 2020, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct an evaluation of the activities under subsection (n) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by subsection (a), and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the results of such evaluation.

(c) DUTIES OF DIRECTORS OF INSTITUTES.—Section 405(b)(1) of the Public Health Service Act (42 U.S.C. 284(b)(1)) is amended—

(1) by redesignating subparagraphs (C) through (L) as subparagraphs (D) through (M), respectively; and

(2) by inserting after subparagraph (B), the following:

"(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;".

SEC. 2037. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

(a) IN GENERAL.—Section 479(b) of the Public Health Service Act (42 U.S.C. 287(b)) is amended—

(1) in paragraph (1), by striking "phase IIA" and inserting "phase IIB"; and

(2) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking "phase IIB" and inserting "phase III";

(B) in subparagraph (A), by striking "phase IIB" and inserting "phase III";

(C) in subparagraph (B), by striking "phase IIA" and inserting "phase IIB"; and

(D) in subparagraph (C), by striking "phase IIB" and inserting "phase III".

(b) INCREASED TRANSPARENCY.—Section 479 of the Public Health Service Act (42 U.S.C. 287) is amended—

(1) in subsection (c)—

(A) in paragraph (4)(D), by striking "and" at the end;

(B) in paragraph (5), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

"(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

"(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews."; and

(2) by adding at the end the following:

"(d) INCLUSION OF LIST.—The first biennial report submitted under this section after the date of enactment of the 21st Century Cures Act shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

"(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.".

SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.

(a) RESEARCH PRIORITIES; COLLABORATIVE RESEARCH PROJECTS.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) by amending paragraph (4) to read as follows:

"(4) shall assemble accurate data to be used to assess research priorities, including—

"(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

"(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

"(i) specifies the inclusion of—

"(I) women;

"(II) members of minority groups;

"(III) relevant age categories, including pediatric subgroups; and

"(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

"(ii) is disaggregated by research area, condition, and disease categories; and

"(iii) is to be made publicly available on the Internet website of the National Institutes of Health;"; and

(2) in paragraph (8)—

(A) in subparagraph (A), by striking "and" at the end; and

(B) by adding at the end the following:

"(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

"(i) conduct research involving human subjects; and

"(ii) collect similar data; and

"(D) encourage the collaboration described in subparagraph (C) to—

"(i) allow for an increase in the number of subjects studied; and

"(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;".

(b) REPORTING.—Section 492B(f) of the Public Health Service Act (42 U.S.C. 289a–2(f)) is amended—

(1) by striking "biennial" each place such term appears and inserting "triennial";

(2) by striking "The advisory council" and inserting the following:

"(1) IN GENERAL.—The advisory council"; and

(3) by adding at the end the following:

"(2) CONTENTS.—Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

"(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

"(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

"(C) For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—

"(i) have been completed during such reporting period; and

"(ii) are being carried out during such reporting period and have not been completed.

"(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).".

(c) COORDINATION.—Section 486(c)(2) of the Public Health Service Act (42 U.S.C. 287d(c)(2)) is amended by striking "designees" and inserting "senior-level staff designees".

(d) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 2021, is further amended by adding at the end the following:

"SEC. 404N. POPULATION FOCUSED RESEARCH. 42 USC 283p.

"The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

"(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

"(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

"(3) addressing methodological challenges.".

(e) REPORTING.— 42 USC 283p note.

(1) IN GENERAL.—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

(B) not later than 2 years after the date of enactment of this Act, disseminate and make public such measures.

(2) NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine.

(f) IMPROVING COORDINATION RELATED TO MINORITY HEALTH AND HEALTH DISPARITIES.—Section 464z–3 of the Public Health Service Act (42 U.S.C. 285t) is amended—

(1) by redesignating subsection (h), relating to interagency coordination, that follows subsection (j) as subsection (k); and

(2) in subsection (k) (as so redesignated)—

(A) in the subsection heading, by striking "INTER-AGENCY" and inserting "INTRA-NATIONAL INSTITUTES OF HEALTH";

(B) by striking "as the primary Federal officials" and inserting "as the primary Federal official";

(C) by inserting a comma after "review";

(D) by striking "Institutes and Centers of the National Institutes of Health" and inserting "national research institutes and national centers"; and

(E) by adding at the end the following: "The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.".

42 USC 284r.

(g) BASIC RESEARCH.—

(1) DEVELOPING POLICIES.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health (referred to in this section as the "Director of the National Institutes of Health"), taking into consideration the recommendations developed under section 2039, shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) REVISING POLICIES.—The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) CONSULTATION AND OUTREACH.—In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback

on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) ADDITIONAL REQUIREMENTS.—The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(h) CLINICAL RESEARCH.— 42 USC 289a–2 note.

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women's Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of Public Health Service Act (42 U.S.C. 289a–2(d)) in accordance with paragraph (2).

(2) REQUIREMENTS.—The updated guidelines described in paragraph (1) shall—

(A) reflect the science regarding sex differences;

(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a–2), including the reporting requirements under subsection (f) of such section; and

(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences.

(i) APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.— 42 USC 282 note.

(1) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatric and older populations to provide input on—

(A) appropriate age groups to be included in research studies involving human subjects; and

(B) acceptable justifications for excluding participants from a range of age groups from human subjects research studies.

(2) POLICY UPDATES.—Not later than 180 days after the conclusion of the workshop under paragraph (1), the Director of the National Institutes of Health shall make a determination with respect to whether the policies of the National Institutes of Health on the inclusion of relevant age groups in clinical studies need to be updated, and shall update such policies as appropriate. In making the determination, the Director of the National Institutes of Health shall take into consideration whether such policies—

(A) address the consideration of age as an inclusion variable in research involving human subjects; and

(B) identify the criteria for justification for any age-related exclusions in such research.

(3) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

(A) make the findings and conclusions resulting from the workshop under paragraph (1) and updates to policies in accordance with paragraph (2), as applicable, available to the public on the Internet website of the National Institutes of Health; and

(B) ensure that age-related data reported in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) are made available to the public on the Internet website of the National Institutes of Health.

42 USC 282 note.

SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH.

(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the "Advisory Committee"), appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

(b) CONSIDERATIONS.—In developing and issuing recommendations through the Advisory Committee under subsection (a), the working group established under such subsection shall consider, as appropriate—

(1) preclinical experiment design, including analysis of sex as a biological variable;

(2) clinical experiment design, including—

(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

(3) applicable levels of rigor in statistical methods, methodology, and analysis;

(4) data and information sharing in accordance with applicable privacy laws and regulations; and

(5) any other matter the working group determines relevant.

(c) POLICIES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group

and issued by the Advisory Committee under subsection (a) and develop or update policies as appropriate.

(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health shall issue a report to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under subsection (a) and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

(e) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 2040. IMPROVING MEDICAL REHABILITATION RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—Section 452 of the Public Health Service Act (42 U.S.C. 285g–4) is amended—

(1) in subsection (b), by striking "conduct and support" and inserting "conduct, support, and coordination";

(2) in subsection (c)(1)(C), by striking "of the Center" and inserting "within the Center";

(3) in subsection (d)—

(A) by striking "(d)(1) In consultation" and all that follows through the end of paragraph (1) and inserting the following:

"(d)(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall develop a comprehensive plan (referred to in this section as the 'Research Plan') for the conduct, support, and coordination of medical rehabilitation research.";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).";

(C) by striking paragraph (4) and inserting the following:

"(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and updated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives."; and

(D) by adding at the end the following:

"(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Institute shall consult with the Director of the National Institutes of Health.";

(4) in subsection (e)—

(A) in paragraph (2), by inserting "periodically host a scientific conference or workshop on medical rehabilitation research and" after "The Coordinating Committee shall"; and

(B) in paragraph (3), by inserting "the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health," after "shall be composed of";

(5) in subsection (f)(3)(B)—

(A) by redesignating clauses (ix) through (xi) as clauses (x) through (xii), respectively; and

(B) by inserting after clause (viii) the following:

"(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives."; and

(6) by adding at the end the following:

"(g)(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

"(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

"(h) For purposes of this section, the term 'medical rehabilitation research' means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.".

(b) CONFORMING AMENDMENT.—Section 3 of the National Institutes of Health Amendments of 1990 (42 U.S.C. 285g–4 note) is amended—

(1) in subsection (a), by striking "IN GENERAL.—"; and

(2) by striking subsection (b).

42 USC 289a–2 note.

SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

(a) TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a task force, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the "Task

Force on Research Specific to Pregnant Women and Lactating Women" (in this section referred to as the "Task Force").

(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

(3) MEMBERSHIP.—

(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

(i) The Director of the Centers for Disease Control and Prevention.

(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

(iii) The Commissioner of Food and Drugs.

(iv) The Director of the Office on Women's Health.

(v) The Director of the National Vaccine Program Office.

(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

(ii) nonprofit organizations with expertise related to the health of women and children;

(iii) relevant industry representatives; and

(iv) other representatives, as appropriate.

(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

(ii) be appointed by the Secretary.

(4) TERMINATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

(D) Identification of Federal activities, including—

(i) the state of research on pregnancy and lactation;

(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.

SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF HEALTH REPORTING REQUIREMENTS.

(a) TRANS-NATIONAL INSTITUTES OF HEALTH RESEARCH REPORTING.—Section 402A(c)(2) of the Public Health Service Act (42 U.S.C. 282a(c)(2)) is amended—

(1) by amending subparagraph (B) to read as follows:

"(B) REPORTING.—Not later than 2 years after the date of enactment of 21st Century Cures Act, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers."; and

(2) in subparagraphs (D) and (E) by striking "(B)(i)" each place it appears and inserting "(B)".

(b) FRAUD AND ABUSE REPORTING.—Section 403B of the Public Health Service Act (42 U.S.C. 283a–1) is amended—

(1) by striking subsection (b);

(2) by redesignating subsection (c) as subsection (b); and

(3) in subsection (b) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (a)".

(c) DOCTORAL DEGREES REPORTING.—Section 403C(a)(2) of the Public Health Service Act (42 U.S.C. 283a–2(a)(2)) is amended by striking "(not including any leaves of absence)".

(d) VACCINE REPORTING.—Section 404B of the Public Health Service Act (42 U.S.C. 283d) is amended—

(1) by striking subsection (b); and

(2) by striking "(a) DEVELOPMENT OF NEW VACCINES.—The Secretary" and inserting "The Secretary".

(e) NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.—Section 479(c) of the Public Health Service Act (42 U.S.C. 287(c)) is amended—

(1) in the subsection heading, by striking "ANNUAL" and inserting "BIENNIAL"; and

(2) in the matter preceding paragraph (1), by striking "an annual report" and inserting "a report on a biennial basis".

(f) REVIEW OF CENTERS OF EXCELLENCE.—

(1) REPEAL.—Section 404H of the Public Health Service Act (42 U.S.C. 283j) is repealed.

(2) CONFORMING AMENDMENT.—Section 399EE(c) of the Public Health Service Act (42 U.S.C. 280–4(c)) is amended by striking "399CC, 404H," and inserting "399CC".

(g) RAPID HIV TEST REPORT.—Section 502(a) of the Ryan White CARE Act Amendments of 2000 (42 U.S.C. 300cc note) is amended—

(1) by striking paragraph (2); and

(2) by redesignating paragraph (3) as paragraph (2).

(h) NATIONAL INSTITUTE OF NURSING RESEARCH.—

(1) REPEAL.—Section 464Y of the Public Health Service Act (42 U.S.C. 285q–3) is repealed.

(2) CONFORMING AMENDMENT.—Section 464X(g) of the Public Health Service Act (42 U.S.C. 285q–2(g)) is amended by striking "biennial report made under section 464Y," and inserting "triennial report made under section 403".

SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2035, is further amended—

(1) in the flush matter at the end of subsection (a)—

(A) by redesignating such matter as subsection (h)(1); and

(B) by moving such matter so as to appear at the end of such section; and

(2) in subsection (h) (as so redesignated), by adding at the end the following:

"(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

"(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.".

SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDER-REPRESENTED POPULATIONS IN CLINICAL TRIALS.

It is the sense of Congress that the National Institute on Minority Health and Health Disparities should include within its strategic plan under section 402(m) of the Public Health Service Act (42 U.S.C. 282(m)) ways to increase representation of underrepresented populations in clinical trials.

Subtitle E—Advancement of the National Institutes of Health Research and Data Access

SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS DATABASE.

Section 402(j)(2)(D) of the Public Health Service Act (42 U.S.C. 282(j)(2)(D)) is amended—

(1) in clause (ii)(I), by inserting before the semicolon ", unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval"; and

(2) by adding at the end the following:

"(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

"(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

"(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

"(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.".

SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.

(a) DEFINITIONS.—In this section:

(1) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" has the meaning given the term in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLIANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that describes education and outreach, guidance, enforcement, and other activities undertaken to encourage compliance with section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(c) REPORTS ON CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 2 years after the final compliance date under the final rule implementing section 402(j) of the Public Health Service Act, and every 2 years thereafter for the next 4 years, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing—

(A) the total number of applicable clinical trials with complete data bank registration information registered during the period for which the report is being prepared (broken down by each year of such reporting period);

(B) the total number of applicable clinical trials registered during the period for which the report is being prepared for which results have been submitted to the data bank (broken down by each year of such reporting period);

(C) the activities undertaken by the Secretary to educate responsible persons about data bank registration and results submission requirements, including through issuance of guidance documents, informational meetings, and training sessions; and

(D) the activities described in the report submitted under subsection (b).

(2) ACTIONS TO ENFORCE COMPLIANCE.—After the Secretary has undertaken the educational activities described in paragraph (1)(C), the Secretary shall include in subsequent reports

submitted under paragraph (1) the number of actions taken by the Secretary during the period for which the report is being prepared to enforce compliance with data bank registration and results submission requirements.

SEC. 2053. UPDATES TO POLICIES TO IMPROVE DATA.

Section 492B(c) of the Public Health Service Act (42 U.S.C. 289a–2(c)) is amended—

(1) by striking "In the case" and inserting the following: "(1) IN GENERAL.—In the case"; and

(2) by adding at the end the following:

"(2) REPORTING REQUIREMENTS.—For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after the date of enactment of the 21st Century Cures Act, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

"(A) and which is an applicable clinical trial as defined in section 402(j), the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 402(j)(3), and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 402(j)(5)(A)(ii) when applicable; and

"(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.".

SEC. 2054. CONSULTATION.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with relevant Federal agencies, including the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the National Institutes of Health, as well as other stakeholders (including patients, researchers, physicians, industry representatives, and developers of health information technology) to receive recommendations with respect to enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), including with respect to usability, functionality, and search capability.

Subtitle F—Facilitating Collaborative Research

SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SURVEILLANCE SYSTEM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by inserting after section 399S the following:

"SEC. 399S–1. SURVEILLANCE OF NEUROLOGICAL DISEASES. 42 USC 280g–7a.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

"(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

"(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

"(b) RESEARCH.—The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

"(c) CONTENT.—In carrying out subsection (a), the Secretary—

"(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

"(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

"(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

"(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

"(C) diagnosis and progression markers;

"(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

"(A) the natural history of the diseases;

"(B) the prevention of the diseases;

"(C) the detection, management, and treatment approaches for the diseases; and

"(D) the development of outcomes measures;

"(4) may address issues identified during the consultation process under subsection (d); and

"(5) initially may address a limited number of neurological diseases.

"(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

"(1) epidemiologists with experience in disease surveillance or registries;

"(2) representatives of national voluntary health associations that—

"(A) focus on neurological diseases; and

"(B) have demonstrated experience in research, care, or patient services;

"(3) health information technology experts or other information management specialists;

"(4) clinicians with expertise in neurological diseases; and

"(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

"(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

"(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall—

"(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

"(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

"(B) to State and local agencies; and

"(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

"(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

"(h) PRIVACY.—The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

"(i) REPORTS.—

"(1) REPORT ON INFORMATION AND ANALYSES.—Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

"(2) IMPLEMENTATION REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

"(A) the development and maintenance of the National Neurological Conditions Surveillance System;

"(B) the type of information collected and stored in the surveillance system;

"(C) the use and availability of such information, including guidelines for such use; and

"(D) the use and coordination of databases that collect or maintain information on neurological diseases.

"(j) DEFINITION.—In this section, the term 'national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

"(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.".

SEC. 2062. TICK-BORNE DISEASES. 42 USC 284s.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as "the Secretary") shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) REPORTS.—The Secretary shall ensure that each triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) TICK-BORNE DISEASES WORKING GROUP.—

(1) ESTABLISHMENT.—The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the "Working Group"), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) RESPONSIBILITIES.—The working group shall—

(A) not later than 2 years after the date of enactment of this Act, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(3) MEMBERSHIP.—The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) NON–FEDERAL PUBLIC MEMBERS.—Seven non–Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(4) MEETINGS.—The Working Group shall meet not less than twice each year.

(5) REPORTING.—Not later than 2 years after the date of enactment of this Act, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

(6) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(7) SUNSET.—The Working Group under this section shall terminate 6 years after the date of enactment of this Act.

42 USC 1320d–2 note.

SEC. 2063. ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES.

(a) GUIDANCE RELATED TO REMOTE ACCESS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue guidance clarifying that subparagraph (B) of section 164.512(i)(1)(ii) of part 164 of the Rule (prohibiting the removal of protected health information by a researcher) does not prohibit remote access to health information by a researcher for such purposes as described in section 164.512(i)(1)(ii) of part 164 of the Rule so long as—

(1) at a minimum, security and privacy safeguards, consistent with the requirements of the Rule, are maintained by the covered entity and the researcher; and

(2) the protected health information is not copied or otherwise retained by the researcher.

(b) GUIDANCE RELATED TO STREAMLINING AUTHORIZATION.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance on the following:

(1) AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION.—Clarification of the circumstances under which the authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes contains a sufficient description of the purpose of the use or disclosure, such as if the authorization—

(A) sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research;

(B) either—

(i) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

(ii) states that the authorization will remain valid unless and until it is revoked by the individual; and

(C) provides instruction to the individual on how to revoke such authorization at any time.

(2) REMINDER OF THE RIGHT TO REVOKE.—Clarification of the circumstances under which it is appropriate to provide an individual with an annual notice or reminder that the individual has the right to revoke such authorization.

(3) REVOCATION OF AUTHORIZATION.—Clarification of appropriate mechanisms by which an individual may revoke an authorization for future research purposes, such as described in paragraph (1)(C).

(c) WORKING GROUP ON PROTECTED HEALTH INFORMATION FOR RESEARCH.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall convene a working group to study and report on the uses and disclosures of protected health information for research purposes, under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191).

(2) MEMBERS.—The working group shall include representatives of—

(A) relevant Federal agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Office for Civil Rights;

(B) the research community;

(C) patients;

(D) experts in civil rights, such as privacy rights;

(E) developers of health information technology;

(F) experts in data privacy and security;

(G) health care providers;

(H) bioethicists; and

(I) other experts and entities, as the Secretary determines appropriate.

(3) REPORT.—Not later than 1 year after the date on which the working group is convened under paragraph (1), the working group shall conduct a review and submit a report to the Secretary containing recommendations on whether the uses and disclosures of protected health information for research purposes should be modified to allow protected health information to be available, as appropriate, for research purposes, including studies to obtain generalizable knowledge, while protecting individuals' privacy rights. In conducting the review and making recommendations, the working group shall—

(A) address, at a minimum—

(i) the appropriate manner and timing of authorization, including whether additional notification to the individual should be required when the individual's protected health information will be used or disclosed for such research;

(ii) opportunities for individuals to set preferences on the manner in which their protected health information is used in research;

(iii) opportunities for patients to revoke authorization;

(iv) notification to individuals of a breach in privacy;

(v) existing gaps in statute, regulation, or policy related to protecting the privacy of individuals, and

(vi) existing barriers to research related to the current restrictions on the uses and disclosures of protected health information; and

(B) consider, at a minimum—

(i) expectations and preferences on how an individual's protected health information is shared and used;

(ii) issues related to specific subgroups of people, such as children, incarcerated individuals, and individuals with a cognitive or intellectual disability impacting capacity to consent;

(iii) relevant Federal and State laws;

(iv) models of facilitating data access and levels of data access, including data segmentation, where applicable;

(v) potential impacts of disclosure and non-disclosure of protected health information on access to health care services; and

(vi) the potential uses of such data.

(4) REPORT SUBMISSION.—The Secretary shall submit the report under paragraph (3) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and shall post such report on the appropriate Internet website of the Department of Health and Human Services.

(5) TERMINATION.—The working group convened under paragraph (1) shall terminate the day after the report under paragraph (3) is submitted to Congress and made public in accordance with paragraph (4).

(d) DEFINITIONS.—In this section:

(1) THE RULE.—References to "the Rule" refer to part 160 or part 164, as appropriate, of title 45, Code of Federal Regulations (or any successor regulation).

(2) PART 164.—References to a specified section of "part 164", refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

Subtitle G—Promoting Pediatric Research

SEC. 2071. NATIONAL PEDIATRIC RESEARCH NETWORK.

Section 409D(d) of the Public Health Service Act (42 U.S.C. 284h(d)) is amended—

(1) in paragraph (1), by striking "in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of" and inserting "in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support"; and

(2) in paragraph (2)(A) and the first sentence of paragraph (2)(E), by striking "may" each place such term appears and inserting "shall".

SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical study network by providing grants, contracts, or cooperative agreements to support new and early stage investigators who participate in the global pediatric clinical study network;

(2) the Secretary of Health and Human Services (referred to in this section as the "Secretary") should engage with clinical investigators and appropriate authorities outside of the United States, including authorities in the European Union, during the formation of the global pediatric clinical study network to encourage the participation of such investigator and authorities; and

(3) once a global pediatric clinical study network is established and becomes operational, the Secretary should continue to encourage and facilitate the participation of clinical investigators and appropriate authorities outside of the United States, including in the European Union, to participate in the network with the goal of enhancing the global reach of the network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

SEC. 3001. PATIENT EXPERIENCE DATA.

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended—

(1) in subsection (a)—

(A) in the subsection heading, by striking "IN GENERAL" and inserting "PATIENT ENGAGEMENT IN DRUGS AND DEVICES";

(B) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and moving such subparagraphs 2 ems to the right; and

(C) by striking "The Secretary" and inserting the following:

"(1) IN GENERAL.—The Secretary";

(2) by redesignating subsections (b) through (e) as paragraphs (2) through (5), respectively, and moving such paragraphs 2 ems to the right; and

(3) by adding at the end the following:

"(b) STATEMENT OF PATIENT EXPERIENCE.—

"(1) IN GENERAL.—Following the approval of an application that was submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act at least 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

"(2) DATA AND INFORMATION.—The data and information referred to in paragraph (1) are—

"(A) patient experience data;

"(B) information on patient-focused drug development tools; and

"(C) other relevant information, as determined by the Secretary.

"(c) PATIENT EXPERIENCE DATA.—For purposes of this section, the term 'patient experience data' includes data that—

"(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

"(2) are intended to provide information about patients' experiences with a disease or condition, including—

"(A) the impact of such disease or condition, or a related therapy, on patients' lives; and

"(B) patient preferences with respect to treatment of such disease or condition.".

21 USC 360bbb–8c note.

SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUIDANCE.

(a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue a draft version of at least one such guidance document. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(b) PATIENT EXPERIENCE DATA.—For purposes of this section, the term "patient experience data" has the meaning given such term in section 569C of the Federal Food, Drug, and Cosmetic Act (as added by section 3001).

(c) CONTENTS.—The guidance documents described in subsection (a) shall address—

(1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decisionmaking may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis;

(2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease;

(3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials;

(4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decisionmaking;

(5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary;

(6) the format and content required for submissions under this section to the Secretary, including with respect to the information described in paragraph (1);

(7) how the Secretary intends to respond to submissions of information described in paragraph (1), if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

(8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)), to inform regulatory decisionmaking.

SEC. 3003. STREAMLINING PATIENT INPUT.

21 USC 360bbb–8c note.

Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002.

SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVELOPMENT.

21 USC 355 note.

Not later than June 1 of 2021, 2026, and 2031, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall prepare and publish on the Internet website of the Food and Drug Administration a report assessing the use of patient experience data in regulatory decisionmaking, in particular with respect to the review of patient experience data and information on patient-focused drug development tools as part

of applications approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

Subtitle B—Advancing New Drug Therapies

SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following new section:

21 USC 357.

"SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

"(a) PROCESS FOR QUALIFICATION.—

"(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

"(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

"(ii) the Secretary accepts or declines to accept such letter of intent;

"(B)(i) if the Secretary accepts the letter of intent, a requestor submits a qualification plan to the Secretary; and

"(ii) the Secretary accepts or declines to accept the qualification plan; and

"(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

"(ii) the Secretary determines whether to accept such qualification package for review; and

"(iii) if the Secretary accepts such qualification package for review, the Secretary conducts such review in accordance with this section.

"(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

"(A) IN GENERAL.—Subparagraphs (B), (C), and (D) shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as 'qualification submissions').

"(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

"(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

"(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug

development tool and the availability or lack of alternative treatments for such disease or condition; and

"(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

"(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

"(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

"(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

"(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

"(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

"(b) EFFECT OF QUALIFICATION.—

"(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

"(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

"(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

"(B) supporting the investigational use of a drug or biological product under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

"(3) RESCISSION OR MODIFICATION.—

"(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

"(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall, on request, be granted a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

"(c) TRANSPARENCY.—

"(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet website of the Food and Drug Administration the following:

"(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

"(i) the stage of the review process applicable to the submission;

"(ii) the date of the most recent change in stage status;

"(iii) whether external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

"(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

"(B) The Secretary's formal written determinations in response to such qualification submissions.

"(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

"(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

"(E) A comprehensive list of—

"(i) all drug development tools qualified under subsection (a); and

"(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.

"(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

"(3) APPLICABILITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to alter the standards of evidence under subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act (as applicable); or

"(2) to limit the authority of the Secretary to approve or license products under this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).

"(e) DEFINITIONS.—In this section:

"(1) BIOMARKER.—The term 'biomarker'—

"(A) means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

"(B) includes a surrogate endpoint.

"(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

"(3) CLINICAL OUTCOME ASSESSMENT.—The term 'clinical outcome assessment' means—

"(A) a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

"(B) includes a patient-reported outcome.

"(4) CONTEXT OF USE.—The term 'context of use' means, with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.

"(5) DRUG DEVELOPMENT TOOL.—The term 'drug development tool' includes—

"(A) a biomarker;

"(B) a clinical outcome assessment; and

"(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

"(6) PATIENT-REPORTED OUTCOME.—The term 'patient-reported outcome' means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

"(7) QUALIFICATION.—The terms 'qualification' and 'qualified' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

"(8) REQUESTOR.—The term 'requestor' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

"(9) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

"(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

"(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).".

(b) GUIDANCE.— 21 USC 357 note.

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, in consultation with biomedical research consortia (as defined in subsection (e) of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—

(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);

(B) with respect to the qualification process under such section 507—

(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

(ii) outlines reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and

(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification plans and full qualification submissions under such section; and

(C) includes such other information as the Secretary determines appropriate.

(2) TIMING.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

(3) TAXONOMY.—

(A) IN GENERAL.—For purposes of informing guidance under this subsection, the Secretary shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.

(B) PUBLIC AVAILABILITY.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 1 year after the close of the public comment period.

(c) MEETING AND REPORT.—

(1) MEETING.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall make publicly available on the Internet website of the Food and Drug Administration a report. Such report shall include, with respect to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), information on—

(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (e) of such section 507);

(B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package (as such terms are defined in subsection (e) of such section 507), respectively;

(C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package;

(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and

(E) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment (as such terms are defined in subsection (e) of such section 507).

SEC. 3012. TARGETED DRUGS FOR RARE DISEASES.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by inserting after section 529 the following:

"SEC. 529A. TARGETED DRUGS FOR RARE DISEASES. 21 USC 360ff–1.

"(a) PURPOSE.—The purpose of this section, through the approach provided for in subsection (b), is to—

"(1) facilitate the development, review, and approval of genetically targeted drugs and variant protein targeted drugs to address an unmet medical need in one or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening; and

"(2) maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for such purposes.

"(b) LEVERAGING OF DATA FROM PREVIOUSLY APPROVED DRUG APPLICATION OR APPLICATIONS.—The Secretary may, consistent with applicable standards for approval under this Act or section 351(a) of the Public Health Service Act, allow the sponsor of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for a genetically targeted drug or a variant protein targeted drug to rely upon data and information—

"(1) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information); and

"(2) submitted by a sponsor described in paragraph (1) in support of one or more previously approved applications that were submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act,

for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject

of an application or applications described in paragraph (2) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug, as the drug or drugs that are the subject of an application or applications described in paragraph (2).

"(c) DEFINITIONS.—For purposes of this section—

"(1) the term 'genetically targeted drug' means a drug that—

"(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

"(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

"(C) incorporates or utilizes a genetically targeted technology;

"(2) the term 'genetically targeted technology' means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene; and

"(3) the term 'variant protein targeted drug' means a drug that—

"(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

"(B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and

"(C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the 21st Century Cures Act), including the standards of evidence, and applicable conditions, for approval under such applicable Act; or

"(2) confer any new rights, beyond those authorized under this Act or the Public Health Service Act prior to enactment of this section, with respect to the permissibility of a sponsor referencing information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) IN GENERAL.—Section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended by striking paragraph (5) and inserting the following:

"(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after September 30, 2020, unless the rare pediatric disease product application—

"(A) is for a drug that, not later than September 30, 2020, is designated under subsection (d) as a drug for a rare pediatric disease; and

"(B) is, not later than September 30, 2022, approved under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

(b) REPORT.—The Advancing Hope Act of 2016 (Public Law 114–229) is amended by striking section 3.

SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER PROGRAMS.

(a) STUDY.—The Comptroller General of the United States (referred to in this section as the "Comptroller General") shall conduct a study addressing the effectiveness and overall impact of the following priority review voucher programs, including any such programs amended or established by this Act:

(1) The neglected tropical disease priority review voucher program under section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n).

(2) The rare pediatric disease priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff).

(3) The medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act, as added by section 3086.

(b) ISSUANCE OF REPORT.—Not later than January 31, 2020, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study under subsection (a).

(c) CONTENTS OF REPORTS.—The report submitted under subsection (b) shall address—

(1) for each drug for which a priority review voucher has been awarded as of initiation of the study—

(A) the indications for which the drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(B) whether, and to what extent, the voucher impacted the sponsor's decision to develop the drug; and

(C) whether, and to what extent, the approval or licensure of the drug, as applicable and appropriate—

(i) addressed a global unmet need related to the treatment or prevention of a neglected tropical disease, including whether the sponsor of a drug coordinated with international development organizations;

(ii) addressed an unmet need related to the treatment of a rare pediatric disease; or

(iii) affected the Nation's preparedness against a chemical, biological, radiological, or nuclear threat, including naturally occurring threats;

(2) for each drug for which a priority review voucher has been used—

(A) the indications for which such drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262);

(B) the value of the voucher, if transferred; and

(C) the length of time between the date on which the voucher was awarded and the date on which the voucher was used; and

(3) an analysis of the priority review voucher programs described in subsection (a), including—

(A) the resources used by the Food and Drug Administration in reviewing drugs for which vouchers were used, including the effect of the programs on the Food and Drug Administration's review of drugs for which priority review vouchers were not awarded or used;

(B) whether any improvements to such programs are necessary to appropriately target incentives for the development of drugs that would likely not otherwise be developed, or developed in as timely a manner, and, as applicable and appropriate—

(i) address global unmet needs related to the treatment or prevention of neglected tropical diseases, including in countries in which neglected tropical diseases are endemic; or

(ii) address unmet needs related to the treatment of rare pediatric diseases; and

(C) whether the sunset of the rare pediatric disease program and medical countermeasure program has had an impact on the program, including any potential unintended consequences.

(d) PROTECTION OF NATIONAL SECURITY.—The Comptroller General shall conduct the study and issue reports under this section in a manner that does not compromise national security.

SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.

Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a), by striking paragraph (1) and inserting the following: "(1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses,"; and

(2) in subsection (b)(1)—

(A) in subparagraph (A)(ii), by striking "and" after the semicolon;

(B) in subparagraph (B), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

"(i) develop or validate a drug development tool related to a rare disease or condition; or

"(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.".

SEC. 3016. GRANTS FOR STUDYING CONTINUOUS DRUG MANUFACTURING. 21 USC 399h.

(a) IN GENERAL.—The Secretary of Health and Human Services may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) DEFINITIONS.—In this section—

(1) the term "drug" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(2) the term "biological product" has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)); and

(3) the term "institution of higher education" has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

Subtitle C—Modern Trial Design and Evidence Development

SEC. 3021. NOVEL CLINICAL TRIAL DESIGNS. 21 USC 355 note.

(a) PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF NOVEL CLINICAL TRIAL DESIGNS.—

(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall update or issue guidance addressing the use of complex adaptive and other novel trial design in the development and regulatory review and approval or licensure for drugs and biological products.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) the use of complex adaptive and other novel trial designs, including how such clinical trials proposed or submitted help to satisfy the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

(B) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to—

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

(3) PUBLIC MEETING.—Prior to updating or issuing the guidance required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, consumer groups, and disease research foundations, through a public meeting to be held not later than 18 months after the date of enactment of this Act.

(4) TIMING.—The Secretary shall update or issue a draft version of the guidance required by paragraph (1) not later than 18 months after the date of the public meeting required by paragraph (3) and finalize such guidance not later than 1 year after the date on which the public comment period for the draft guidance closes.

SEC. 3022. REAL WORLD EVIDENCE.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505E (21 U.S.C. 355f) the following:

21 USC 355g.

"SEC. 505F. UTILIZING REAL WORLD EVIDENCE.

"(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of real world evidence—

"(1) to help to support the approval of a new indication for a drug approved under section 505(c); and

"(2) to help to support or satisfy postapproval study requirements.

"(b) REAL WORLD EVIDENCE DEFINED.—In this section, the term 'real world evidence' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials.

"(c) PROGRAM FRAMEWORK.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall establish a draft framework for implementation of the program under this section.

"(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

"(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

"(B) the gaps in data collection activities;

"(C) the standards and methodologies for collection and analysis of real world evidence; and

"(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

"(3) CONSULTATION.—

"(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

"(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

"(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate;

"(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

"(iii) public workshops with the entities described in such subparagraph.

"(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 2 years after the date of enactment of the 21st Century Cures Act and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

"(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

"(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

"(A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

"(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

"(2) not later than 5 years after the date of enactment of the 21st Century Cures Act, issue draft guidance for industry as described in paragraph (1); and

"(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

"(f) RULE OF CONSTRUCTION.—

"(1) IN GENERAL.—Subject to paragraph (2), nothing in this section prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

"(2) STANDARDS OF EVIDENCE AND SECRETARY'S AUTHORITY.—This section shall not be construed to alter—

"(A) the standards of evidence under—

"(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

"(ii) section 351(a) of the Public Health Service Act; or

"(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.".

42 USC 289 note.

SEC. 3023. PROTECTION OF HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—The Secretary shall, as appropriate—

(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

(A) to reduce regulatory duplication and unnecessary delays;

(B) to modernize such provisions in the context of multisite and cooperative research projects; and

(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

(A) use joint or shared review;

(B) rely upon the review of—

(i) an independent institutional review board; or

(ii) an institutional review board of an entity other than the sponsor of the research; or

(C) use similar arrangements to avoid duplication of effort.

(c) CONSULTATION.—In harmonizing or modifying regulations or guidance under this section, the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, patient groups, and others).

(d) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act.

(e) PROGRESS REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

(f) DEFINITIONS.—

(1) HUMAN SUBJECT REGULATIONS.—In this section:

(A) FDA HUMAN SUBJECT REGULATIONS.—The term "FDA Human Subject Regulations" means the provisions

of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

(B) HHS HUMAN SUBJECT REGULATIONS.—The term "HHS Human Subject Regulations" means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

(C) VULNERABLE POPULATION RULES.—The term "vulnerable population rules" means—

(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

(2) INSTITUTIONAL REVIEW BOARD DEFINED.—In this section, the term "institutional review board" has the meaning that applies to the term "institutional review board" under the HHS Human Subject Regulations.

SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION FOR CLINICAL INVESTIGATIONS.

(a) DEVICES.—Section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is amended—

(1) in subparagraph (D), by striking "except where subject to such conditions as the Secretary may prescribe, the investigator" and inserting the following: "except where, subject to such conditions as the Secretary may prescribe—

"(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

"(ii) the investigator"; and

(2) in the matter following subparagraph (D), by striking "subparagraph (D)" and inserting "subparagraph (D)(ii)".

(b) DRUGS.—Section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended by striking "except where it is not feasible or it is contrary to the best interests of such human beings" and inserting "except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings".

Subtitle D—Patient Access to Therapies and Information

SEC. 3031. SUMMARY LEVEL REVIEW.

(a) FFDCA.—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following:

"(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect

to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

"(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

"(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

"(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

"(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

"(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

"(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

"(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

"(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

"(D) In this paragraph—

"(i) the term 'qualified indication' means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

"(ii) the term 'qualified data summary' means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.".

(b) PHSA.—Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended by adding at the end the following:

"(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

"(ii) In this subparagraph, the terms 'qualified indication' and 'qualified data summary' have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 3032. EXPANDED ACCESS POLICY.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:

21 USC 360bbb–0.

"SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

"(a) IN GENERAL.—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug.

"(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS POLICY.—The policies under subsection (a) shall be made public and readily available, such as by posting such policies on a publicly available Internet website. Such policies may be generally applicable to all investigational drugs of such manufacturer or distributor.

"(c) CONTENT OF POLICY.—A policy described in subsection (a) shall include—

"(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

"(2) procedures for making such requests;

"(3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;

"(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and

"(5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 402(j)(2)(A)(ii)(II)(gg) of the Public Health Service Act.

"(d) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

"(e) REVISED POLICY.—Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

"(f) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

"(1) the date that is 60 calendar days after the date of enactment of the 21st Century Cures Act; or

"(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational drug.".

SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE ADVANCED THERAPIES.

(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by transferring subsection (e) (relating to construction) so that it appears before subsection (f) (relating to awareness efforts); and

(2) by adding at the end the following:

"(g) REGENERATIVE ADVANCED THERAPY.—

"(1) IN GENERAL.—The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, such drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

"(2) CRITERIA.—A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

"(A) the drug is a regenerative medicine therapy (as defined in paragraph (8));

"(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

"(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

"(3) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

"(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary shall include with the determination a written description of the rationale for such determination.

"(5) ACTIONS.—The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of such therapy under subsection (a)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).

"(6) ACCESS TO EXPEDITED APPROVAL PATHWAYS.—An application for a regenerative advanced therapy under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act may be—

"(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012; and

"(B) eligible for accelerated approval under subsection (c), as agreed upon pursuant to subsection (a)(3)(B), through, as appropriate—

"(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

"(ii) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

"(7) POSTAPPROVAL REQUIREMENTS.—The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the postapproval requirements under subsection (c) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

"(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records;

"(B) the collection of larger confirmatory data sets, as agreed upon pursuant to subsection (a)(3)(B); or

"(C) postapproval monitoring of all patients treated with such therapy prior to approval of the therapy.

"(8) DEFINITION.—For purposes of this section, the term 'regenerative medicine therapy' includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.".

(b) RULE OF CONSTRUCTION.—Nothing in this section and the amendments made by this section shall be construed to alter the authority of the Secretary of Health and Human Services— 21 USC 356 note.

(1) to approve drugs pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. 262) as authorized prior to the date of enactment of the 21st Century Cures Act, including the standards of evidence, and applicable conditions, for approval under such Acts; or

(2) to alter the authority of the Secretary to require postapproval studies pursuant to such Acts, as authorized prior to the date of enactment of the 21st Century Cures Act.

(c) CONFORMING AMENDMENT.—Section 506(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)(1)) is amended by inserting "and the 21st Century Cures Act" after "Food and Drug Administration Safety and Innovation Act".

SEC. 3034. GUIDANCE REGARDING DEVICES USED IN THE RECOVERY, ISOLATION, OR DELIVERY OF REGENERATIVE ADVANCED THERAPIES. 21 USC 356g note.

(a) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance clarifying how, in the context of regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the Secretary shall specifically address—

(1) how the Food and Drug Administration intends to simplify and streamline regulatory requirements for combination device and cell or tissue products;

(2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device;

(3) when the Food and Drug Administration considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and

(4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

(b) FINAL GUIDANCE.—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.

SEC. 3035. REPORT ON REGENERATIVE ADVANCED THERAPIES. 21 USC 356 note.

(a) REPORT TO CONGRESS.—Before March 1 of each calendar year, the Secretary of Health and Human Services shall, with

respect to the previous calendar year, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) the number and type of applications for approval of regenerative advanced therapies filed, approved or licensed as applicable, withdrawn, or denied; and

(2) how many of such applications or therapies, as applicable, were granted accelerated approval or priority review.

(b) REGENERATIVE ADVANCED THERAPY.—In this section, the term "regenerative advanced therapy" has the meaning given such term in section 506(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 3033 of this Act.

SEC. 3036. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following:

21 USC 356g.

"SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

"(a) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

"(b) ACTIVITIES.—

"(1) IN GENERAL.—In carrying out this section, the Secretary shall continue to—

"(A) identity opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

"(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

"(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

"(2) REGULATIONS AND GUIDANCE.—Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

"(c) DEFINITIONS.—For purposes of this section, the terms 'regenerative medicine therapy' and 'regenerative advanced therapy' have the meanings given such terms in section 506(g).".

SEC. 3037. HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by striking "(a) If its" and inserting "(a)(1) If its";

(2) by striking "a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations" and inserting "a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement";

(3) by striking "directly relates" and inserting "relates";

(4) by striking "and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph" and inserting ", is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph"; and

(5) by striking "In this paragraph, the term" and all that follows and inserting the following:

"(2)(A) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

"(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.".

SEC. 3038. COMBINATION PRODUCT INNOVATION.

(a) IN GENERAL.—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) by striking paragraph (3);

(2) by redesignating paragraph (2) as paragraph (7);

(3) by redesignating paragraphs (4) and (5) as paragraphs (8) and (9), respectively;

(4) by striking "(g)(1)" and all that follows through the end of paragraph (1) and inserting the following:

"(g)(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

"(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

"(C) For purposes of this subsection, the term 'primary mode of action' means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

"(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

"(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

"(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

"(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

"(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body.

"(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

"(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

"(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

"(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

"(III) if an agreement is reached under subclause (II) and the sponsor conducts one or more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

"(2)(A)(i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than

75 calendar days after receiving such request, meet with the sponsor of such combination product.

"(ii) A meeting under clause (i) may—

"(I) address the standards and requirements for market approval or clearance of the combination product;

"(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

"(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

"(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

"(iv) Any such agreement shall remain in effect, except—

"(I) upon the written agreement of the Secretary and the sponsor or applicant; or

"(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this Act or the Public Health Service Act applicable to the combination product has been identified since the agreement was reached, or that deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

"(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this Act or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

"(4) For purposes of paragraph (3), an approved constituent part is—

"(A) a drug constituent part of a combination product being reviewed in a single application or request under section 515, 510(k), or 513(f)(2) (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

"(B) a device constituent part approved under section 515 that is referenced by the sponsor and that is available for use by the Secretary under section 520(h)(4); or

"(C) any constituent part that was previously approved, cleared, or classified under section 505, 510(k), 513(f)(2), or 515 of this Act for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 760(a)(2).

"(5)(A) If an application is submitted under section 515 or 510(k) or a request is submitted under section 513(f)(2), consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

"(i) the application or request shall include the certification or statement described in section 505(b)(2); and

"(ii) the applicant or requester shall provide notice as described in section 505(b)(3).

"(B) For purposes of this paragraph and paragraph (4), the term 'approved drug' means an active ingredient—

"(i) that was in an application previously approved under section 505(c);

"(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

"(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

"(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

"(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request were an application described in section 505(b)(2) that referenced the approved drug:

"(i) Subparagraphs (A), (B), (C), and (D) of section 505(c)(3).

"(ii) Clauses (ii), (iii), and (iv) of section 505(c)(3)(E).

"(iii) Subsections (b) and (c) of section 505A.

"(iv) Section 505E(a).

"(v) Section 527(a).

"(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 505(b)(2) for purposes of section 271(e)(2)(A) of title 35, United States Code.

"(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.";

(5) in paragraph (8) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) by amending clause (i) to read as follows:

"(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.";

(ii) in clause (ii), by inserting "and alignment" after "the timeliness" each place it appears; and

(iii) by adding at the end the following new clauses:

"(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency

center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

"(iv) The Office shall, with respect to the premarket review of a combination product—

"(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;

"(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and

"(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

"(v) In seeking agency action with respect to a combination product, the sponsor of such product—

"(I) shall identify the product as a combination product; and

"(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

"(vi) Not later than 4 years after the date of enactment of the 21st Century Cures Act, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes—

"(I) the structured process for managing pre-submission interactions with sponsors developing combination products;

"(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during such pre-submission interactions;

"(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2);"; and

(B) in subparagraph (G)—

(i) in the matter preceding clause (i), by inserting "(except with respect to clause (iv), beginning not later than one year after the date of the enactment of the 21st Century Cures Act)" after "enactment of this paragraph";

(ii) in clause (ii), by striking "and" at the end;

(iii) in clause (iii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following new clause:

"(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor."; and

(6) in paragraph (9) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) in clause (i), by striking the comma at the end and inserting a semicolon;

(ii) in clause (ii), by striking ", and" at the end and inserting a semicolon;

(iii) in clause (iii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following:

"(iv) de novo classification under section 513(a)(1)."; and

(B) by adding at the end the following:

"(D) The terms 'premarket review' and 'reviews' include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 505, 510(k), 513(f)(2), 515, or 520 of this Act or under section 351 of the Public Health Service Act, including with respect to investigational use of the product.".

(b) INFORMATION FOR APPROVAL OF COMBINATION PRODUCTS.—Section 520(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amended—

(1) in subparagraph (A), by striking "Any information" and inserting "Subject to subparagraph (C), any information"; and

(2) by adding at the end the following new subparagraph:

"(C) No information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) may be used to approve or clear any application submitted under section 515 or 510(k) or to classify a product under section 513(f)(2) for a combination product containing as a constituent part an approved drug (as defined in section 503(g)(5)(B)) unless—

"(i) the application includes the certification or statement referenced in section 503(g)(5)(A);

"(ii) the applicant provides notice as described in section 503(g)(5)(A); and

"(iii) the Secretary's approval of such application is subject to the provisions in section 503(g)(5)(C).".

21 USC 355 note.

(c) VARIATIONS FROM CGMP STREAMLINED APPROACH.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall identify types of combination products and manufacturing processes with respect to which the Secretary proposes that good manufacturing processes may be adopted that vary from the requirements set forth in section 4.4 of title 21, Code of Federal Regulations (or any successor regulations) or that the Secretary proposes can satisfy the requirements in section 4.4 through alternative or streamlined mechanisms. The Secretary shall identify such types, variations from such requirements, and such mechanisms, in a proposed list published in the Federal Register. After a public comment period regarding the appropriate good manufacturing practices for such types, the Secretary shall publish a final list in the Federal Register, notwithstanding section 553 of title 5, United States Code. The Secretary shall evaluate such types, variations, and mechanisms using a risk-based approach. The Secretary shall periodically review such final list.

Subtitle E—Antimicrobial Innovation and Stewardship

SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.

(a) IN GENERAL.—Section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended—

(1) by redesignating subsections (f) and (g) as subsections (l) and (m), respectively; and

(2) by inserting after subsection (e), the following:

"(f) MONITORING AT FEDERAL HEALTH CARE FACILITIES.—The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

"(g) REPORT ON ANTIMICROBIAL RESISTANCE IN HUMANS AND USE OF ANTIMICROBIAL DRUGS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, and annually thereafter, the Secretary shall prepare and make publicly available data and information concerning—

"(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act;

"(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

"(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

"(A) any applicable resistance under paragraph (1); and

"(B) drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act.

"(h) INFORMATION RELATED TO ANTIMICROBIAL STEWARDSHIP PROGRAMS.—The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

"(i) SUPPORTING STATE-BASED ACTIVITIES TO COMBAT ANTIMICROBIAL RESISTANCE.—The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

"(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

"(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

"(3) promoting antimicrobial stewardship.

"(j) ANTIMICROBIAL RESISTANCE AND STEWARDSHIP ACTIVITIES.—

"(1) IN GENERAL.—For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 506(h) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

"(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

"(B) evaluate—

"(i) antimicrobial resistance data using a standardized approach; and

"(ii) trends in the utilization of drugs approved under such section 506(h) with respect to patient populations.

"(2) USE OF SYSTEMS.—The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

"(k) ANTIMICROBIAL.—For purposes of subsections (f) through (j), the term 'antimicrobial' includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.".

42 USC 247d–5 note.

(b) AVAILABILITY OF DATA.—The Secretary shall make the data collected pursuant to this subsection public. Nothing in this subsection shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 3042. LIMITED POPULATION PATHWAY.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by section 3033, is further amended by adding at the end the following:

"(h) LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—

"(1) IN GENERAL.—The Secretary may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug pursuant to this subsection only if—

"(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

"(B) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the Public Health Service Act, as applicable, are met; and

"(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

"(2) BENEFIT-RISK CONSIDERATION.—The Secretary's determination of safety and effectiveness of an antibacterial or antifungal drug shall reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population. Such drug may be

approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

"(3) ADDITIONAL REQUIREMENTS.—A drug approved under this subsection shall be subject to the following requirements, in addition to any other applicable requirements of this Act:

"(A) LABELING.—To indicate that the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to a limited population—

"(i) all labeling and advertising of an antibacterial or antifungal drug approved under this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than—

"(I) the proprietary name of such drug, if any; or

"(II) if there is no proprietary name, the established name of the drug, if any, as defined in section 503(e)(3), or, in the case of a drug that is a biological product, the proper name, as defined by regulation; and

"(ii) the prescribing information for the drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

"(B) PROMOTIONAL MATERIAL.—The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.

"(4) OTHER PROGRAMS.—A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of such drug under other applicable sections or subsections of this Act or the Public Health Service Act.

"(5) GUIDANCE.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. The Secretary shall publish final guidance within 18 months of the close of the public comment period on such draft guidance. The Secretary may approve antibacterial and antifungal drugs under this subsection prior to issuing guidance under this paragraph.

"(6) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval under this subsection to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

"(7) TERMINATION OF LIMITATIONS.—If, after approval of a drug under this subsection, the Secretary approves a broader indication for such drug under section 505(b) or section 351(a) of the Public Health Service Act, the Secretary may remove

any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

"(8) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act, including the standards of evidence and applicable conditions for approval under such Acts, the standards of approval of a drug under such Acts, or to alter the authority of the Secretary to monitor drugs pursuant to such Acts.

"(9) REPORTING AND ACCOUNTABILITY.—

"(A) BIENNIAL REPORTING.—The Secretary shall report to Congress not less often than once every 2 years on the number of requests for approval, and the number of approvals, of an antibacterial or antifungal drug under this subsection.

"(B) GAO REPORT.—Not later than December 2021, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the coordination of activities required under section 319E of the Public Health Service Act. Such report shall include a review of such activities, and the extent to which the use of the pathway established under this subsection has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if such pathway has functioned as intended, if such pathway has helped provide for safe and effective treatment for patients, if such premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.".

21 USC 356 note.

SEC. 3043. PRESCRIBING AUTHORITY.

Nothing in this subtitle, or an amendment made by this subtitle, shall be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under subsection (h) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as added by section 3042), by health care professionals, or to limit the practice of health care.

SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS; ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 511 the following:

21 USC 360a–2.

"SEC. 511A. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

"(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

"(1) PURPOSE.—The purpose of this section is to clarify the Secretary's authority to—

"(A) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public

health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;

"(B) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and

"(C) clear under section 510(k), classify under section 513(f)(2), or approve under section 515, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

"(2) IDENTIFICATION OF CRITERIA.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

"(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

"(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

"(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

"(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

"(B) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; and

"(C) such other evidence and information as the Secretary considers appropriate.

"(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

"(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards and interpretive criteria in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

"(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS AND INTERPRETIVE CRITERIA.—

"(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

"(i) established by a nationally or internationally recognized standard development organization that—

"(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

"(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decision-making; and

"(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

"(ii) recognized in whole, or in part, by the Secretary under subsection (c).

"(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect to legally marketed antimicrobial drugs, where—

"(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

"(ii) the Secretary withdraws under subsection (c)(1)(A) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

"(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

"(iv) because the characteristics of such a drug differ from other drugs with the same active ingredient, the interpretive criteria with respect to such drug—

"(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph (A) or interpretive criteria otherwise listed under this subparagraph; and

"(II) are determined by the Secretary to be appropriate for the drug.

"(C) REQUIRED STATEMENTS.—The Interpretive Criteria Website shall include statements conveying—

"(i) that the website provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to a certain drug (or drugs);

"(ii) that—

"(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the susceptibility information described in clause (i) to be included on the website; and

"(II) the clinical significance of such susceptibility information in such instances is unknown;

"(iii) that the approved product labeling for specific drugs provides the uses for which the Secretary has approved the product; and

"(iv) any other information that the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria included on the website.

"(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

"(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502.

"(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

"(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA.—

"(1) EVALUATION AND PUBLICATION.—

"(A) IN GENERAL.—Beginning on the date of the establishment of the Interpretive Criteria Website, and at least every 6 months thereafter, the Secretary shall—

"(i) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

"(ii) publish on the public website of the Food and Drug Administration a notice—

"(I) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

"(II) recognizing the new or updated standards;

"(III) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

"(IV) making any necessary updates to the lists under subsection (b)(2).

"(B) UPON APPROVAL OF A DRUG.—Upon the approval of an initial or supplemental application for an antimicrobial drug under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, where such approval is based on susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to this subsection, or for which there are no relevant interpretive criteria standards recognized, or interpretive criteria otherwise listed, by the Secretary pursuant to this subsection, the Secretary shall update the lists under subparagraphs (A) and (B) of subsection (b)(2) to include the susceptibility test interpretive criteria upon which such approval was based.

"(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

"(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

"(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

"(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

"(D) such other information or factors as the Secretary determines appropriate.

"(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(A) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary shall review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards or criteria—

"(A) recognized by the Secretary under this subsection; or

"(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to subsection (b)(2).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—

"(A) IN GENERAL.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, for each such drug, not later than 1 year after establishment of the Interpretive Criteria Website described in subsection (b)(1), shall remove susceptibility test interpretive criteria, if any, and related information from the approved drug labeling and replace it with a reference to the Interpretive Criteria Website.

"(B) LABELING CHANGES.—The labeling changes required by this section shall be considered a minor change

under section 314.70 of title 21, Code of Federal Regulations (or any successor regulations) that may be implemented through documentation in the next applicable annual report.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs approved on or after the date of the establishment of the Interpretive Criteria Website described in subsection (b)(1), the labeling for such a drug shall include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

"(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

"(1) IN GENERAL.—Notwithstanding sections 501, 502, 505, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

"(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

"(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

"(i) included in a standard recognized by the Secretary under subsection (c); or

"(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(B) The labeling of such device includes statements conveying—

"(i) that the device provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to antimicrobial drugs;

"(ii) that—

"(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the device to report the susceptibility of such bacteria, fungi, or other microorganisms, as applicable, to such drugs; and

"(II) the clinical significance of such susceptibility information in those instances is unknown;

"(iii) that the approved labeling for drugs tested using such a device provides the uses for which the Secretary has approved such drugs; and

"(iv) any other information the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria described in subparagraph (A).

"(C) The antimicrobial susceptibility testing device meets all other requirements to be cleared under section

510(k), classified under section 513(f)(2), or approved under section 515.

"(f) DEFINITIONS.—In this section:

"(1) The term 'antimicrobial susceptibility testing device' means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

"(2) The term 'qualified infectious disease product' means a qualified infectious disease product designated under section 505E(d).

"(3) The term 'susceptibility test interpretive criteria' means—

"(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

"(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

"(4)(A) The term 'antimicrobial drug' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

"(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

"(ii) may include a qualified infectious disease product designated under section 505E(d); and

"(iii) is subject to section 503(b)(1).

"(B) If provided by the Secretary through regulations, such term may include—

"(i) drugs other than systemic antibacterial and antifungal drugs; and

"(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

"(5) The term 'interpretive criteria standard' means a compilation of susceptibility test interpretive criteria developed by a standard development organization that meets the criteria set forth in subsection (b)(2)(A)(i).

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard under section 505(d)) or under section 351 of the Public Health Service Act (as applicable); or

"(2) with respect to clearing devices under section 510(k), classifying devices under section 513(f)(2), or approving devices under section 515—

"(A) apply with respect to any drug, device, or biological product, in any context other than an antimicrobial drug and an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the susceptibility of certain bacteria, fungi, or other microorganisms, as applicable, to such drug to reflect patient morbidity and mortality in accordance with this section; or

"(B) unless specifically stated, have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.".

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF PRIOR RELATED AUTHORITY.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a), relating to identification of clinically susceptible concentrations of antimicrobials, is repealed.

(2) ADDITION TO CATEGORIES OF MISBRANDED DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following: "(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).".

(3) RECOGNITION OF INTERPRETIVE CRITERIA STANDARD AS DEVICE STANDARD.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after "the Secretary shall, by publication in the Federal Register" the following: "(or, with respect to a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section)".

(c) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the progress made in implementing section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as added by subsection (a).

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding updating the lists established under section 511A(b) of the Federal Food, Drug, and Cosmetic Act and posted on the Interpretive Criteria Website established under section 511A(c) of such Act. 21 USC 360a–2 note.

Subtitle F—Medical Device Innovations

SEC. 3051. BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515B, as added by section 3034(b), the following:

"SEC. 515C. BREAKTHROUGH DEVICES. 21 USC 360e–3.

"(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

"(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

"(2)(A) that represent breakthrough technologies;

"(B) for which no approved or cleared alternatives exist;

"(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

"(D) the availability of which is in the best interest of patients.

"(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a notification under section 510(k), or a petition for classification under section 513(f)(2).

"(d) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

"(2) REVIEW.—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

"(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

"(A) was designated under this section; or

"(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

"(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

"(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

"(C) adopt an efficient process for timely dispute resolution;

"(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

"(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

"(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

"(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

"(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

"(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

"(A) coordinate with the sponsor regarding early agreement on a data development plan;

"(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

"(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

"(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

"(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

"(f) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (d);

"(B) provide a template for requests under subsection (c);

"(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

"(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

"(1) the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B) and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

"(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

"(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

"(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.".

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by inserting "a request for designation under section 515C," after "application under section 515,".

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking "515(d)(6)" and inserting "515(d)(5)".

(d) REPORT.—On January 1, 2019, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in paragraph (1) by striking "fewer than 4,000" and inserting "not more than 8,000";

(2) in paragraph (2)(A) by striking "fewer than 4,000" and inserting "not more than 8,000"; and

(3) in paragraph (6)(A)(ii), by striking "4,000" and inserting "8,000".

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that defines the criteria for establishing "probable benefit" as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)). 21 USC 360j note.

SEC. 3053. RECOGNITION OF STANDARDS.

(a) IN GENERAL.—Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

"(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

"(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

"(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

"(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

"(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

"(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

"(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition."; and

(2) by adding at the end the following:

"(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.".

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the 21 USC 360d note.

device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking "A report under subsection (k)" and inserting "(1) A report under subsection (k)"; and

(2) by adding at the end the following new paragraph:

"(2) Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

"(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking "(m)(1)" and all that follows through "by the Secretary." and inserting the following:

"(m)(1) The Secretary shall—

"(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

"(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

"(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

"(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).."; and

(2) in paragraph (2)—

(A) by striking "1 day after the date of publication of a list under this subsection," and inserting "1 calendar day after the date of publication of the final list under paragraph (1)(B),"; and

(B) by striking "30-day period" and inserting "60-calendar-day period"; and

(C) by adding at the end the following new paragraph:

"(3) Upon the publication of the final list under paragraph (1)(B)—

"(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

SEC. 3055. CLASSIFICATION PANELS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking "(5)" and inserting "(5)(A)"; and

(2) by adding at the end the following:

"(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

"(i) ensure that adequate expertise is represented on the classification panel to assess—

"(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device; and

"(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

"(C) For purposes of subparagraph (B)(i), the term 'adequate expertise' means that the membership of the classification panel includes—

"(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

"(ii) at least one voting member who is knowledgeable about the technology of the device.

"(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.".

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end ", including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided"; and

(2) by striking subparagraph (B) and inserting the following new subparagraph:

"(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

"(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

"(II) encourage free and open participation by all interested persons.

"(ii) Following the initial presentations described in clause (i), the panel may—

"(I) pose questions to a designated representative described in subparagraph (A)(iii); and

"(II) consider the responses to such questions in the panel's review of the device.".

SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in subsection (g)(3)—

(A) in subparagraph (A)(i)—

(i) by striking "local"; and

(ii) by striking "which has been"; and

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(2) in subsection (m)(4)—

(A) by striking subparagraph (A) and inserting the following:

"(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and";

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(C) in the matter following subparagraph (B), by striking "local".

42 USC 263a note.

SEC. 3057. CLIA WAIVER IMPROVEMENTS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

(1) revises "Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy" of the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" and dated January 30, 2008; and

(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.

SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

"(1) The Secretary shall—

"(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

"(B) periodically assess the implementation of the least burdensome requirements, including the employee training

under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

"(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

"(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

"(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

"(D) summarize the findings of such audit in a final audit report; and

"(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

"(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

"(ii) on the Internet website of the Food and Drug Administration.".

(b) PREMARKET APPLICATIONS.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

"(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

"(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

"(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

"(D) Nothing in this paragraph alters the standards for premarket approval of a device.".

(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by adding at the end the following:

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.".

SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION DATA REQUIREMENT.

(a) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

"(q) REUSABLE MEDICAL DEVICES.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

"(A) instructions for use, which have been validated in a manner specified by the Secretary; and

"(B) validation data, the types of which shall be specified by the Secretary;

regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

"(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

"(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.".

21 USC 360 note.

(b) DEVICE MODIFICATIONS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device. Such final guidance shall be issued not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.

SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

"(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

"(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

"(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

"(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats,

or display the equivalent of a paper medical chart, so long as—

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

"(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

"(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

"(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

"(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

"(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

"(2) In the case of a product with multiple functions that contains—

"(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

"(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

"(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1)

shall not be excluded from the definition of device under section 201(h) if—

"(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

"(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

"(B) Subparagraph (A) shall apply only if the Secretary—

"(i) publishes a notification and proposed order in the Federal Register;

"(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

"(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

"(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

"(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

"(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

"(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

"(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

"(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

"(A) exercise enforcement discretion as to any device subject to regulation under this Act;

"(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

"(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).".

21 USC 360j note.

(b) REPORTS.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act and every 2 years thereafter, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and

(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.

(c) CLASSIFICATION OF ACCESSORIES.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding at the end the following:

"(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.".

(d) CONFORMING AMENDMENT.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: "The term 'device' does not include software functions excluded pursuant to section 520(o).".

Subtitle G—Improving Scientific Expertise and Outreach at FDA

SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH AND BIOMEDICAL PRODUCT ASSESSMENT SERVICE.

(a) HIRING AND RETENTION AUTHORITY.—Section 228 of the Public Health Service Act (42 U.S.C. 237) is amended—

(1) in the section heading, by inserting "**AND BIOMEDICAL PRODUCT ASSESSMENT**" after "**RESEARCH**";

(2) in subsection (a)—

(A) in paragraph (1), by striking "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members" and inserting "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment";

(B) by amending paragraph (2) to read as follows:

"(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service."; and

(C) by adding at the end the following:

"(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "or clinical research evaluation" and inserting ", clinical research evaluation, or biomedical product assessment"; and

(B) in paragraph (1), by inserting "or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field," after the comma;

(4) in subsection (d)(2), by striking "and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code" and inserting "and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code";

(5) by striking subsection (e); and

(6) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

(b) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a) and the impact of such amendments, if any, on all agencies or departments of the Department of Health and Human Services, and, not later than 4 years after the date of enactment of this Act, shall submit a report based on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENT OF STUDY AND REPORT.—The study and report under paragraph (1) shall include an examination of the extent to which recruitment and retention of outstanding and qualified scientific, medical, or technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment have improved or otherwise have been affected by the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a), including by determining, during the period between the date of enactment of this Act and the completion of the study—

(A) the total number of members recruited and retained under the Senior Biomedical Research and Biomedical Product Assessment Service under such section 228, and the effect of increasing the number of members eligible for such Service;

(B) the number of members of such Senior Biomedical Research and Biomedical Product Assessment Service hired with a doctoral level degree in biomedicine or a related field, and the number of such members hired with a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and

(C) the number of Senior Biomedical Research and Biomedical Product Assessment Service members that have been hired by each agency or department of the Department of Health and Human Services, and how such Department assigns such members to each agency or department.

SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 714 (21 U.S.C. 379d–3) the following:

"SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL. 21 USC 379d–3a.

"(a) IN GENERAL.—The Secretary may, notwithstanding title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

"(b) COMPENSATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set—

"(A) the annual rate of pay of any individual appointed under subsection (a); and

"(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of the 21st Century Cures Act.

"(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

"(3) PUBLIC AVAILABILITY.—The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

"(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

"(d) REPORT ON WORKFORCE PLANNING.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

"(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

"(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

"(i) recruitment through nongovernmental recruitment or placement agencies;

"(ii) recruitment through academic institutions;

"(iii) recruitment or hiring bonuses, if applicable;

"(iv) recruitment using targeted direct hiring authorities; and

"(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

"(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.".

(b) GAO STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the ability of the Food and Drug Administration to hire, train, and retain qualified scientific, technical, and professional staff, not including contractors, necessary to fulfill the mission of the Food and Drug Administration to protect and promote public health. Not later than January 1, 2022, the Comptroller General shall submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENTS OF STUDY.—The Comptroller General shall include in the study and report under paragraph (1)—

(A) information about the progress of the Food and Drug Administration in recruiting and retaining qualified scientific, technical, and professional staff outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment;

(B) the extent to which critical staffing needs exist at the Food and Drug Administration, and barriers to hiring, training, and retaining qualified staff, if any;

(C) an examination of the recruitment and retention strategies of the Food and Drug Administration, including examining any strategic workforce plan, focused on improving scientific, technical, and professional staff recruitment and retention; and

(D) recommendations for potential improvements that would address staffing needs of the Food and Drug Administration.

SEC. 3073. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

21 USC 399g.

"SEC. 1014. FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

"(a) IN GENERAL.—The Secretary shall establish one or more Intercenter Institutes within the Food and Drug Administration (referred to in this section as an 'Institute') for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, among the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the 'Centers'). Such activities may include—

"(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

"(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the specific diseases relevant to the major disease area of focus of the Institute, applying relevant standards under sections 505, 510(k), 513(f)(2), and 515 of this Act and section 351 of the Public Health Service Act, and other applicable authorities;

"(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

"(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

"(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

"(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

"(b) PUBLIC PROCESS.—The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

"(c) TIMING.—The Secretary shall establish at least one Institute under subsection (a) before the date that is 1 year after the date of enactment of the 21st Century Cures Act.

"(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.".

(b) TECHNICAL AMENDMENTS.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended—

(1) by redesignating section 1012 as section 1013; and

(2) by redesignating the second section 1011 (with respect to improving the training of State, local, territorial, and tribal food safety officials), as added by section 209(a) of the FDA Food Safety Modernization Act (Public Law 111–353), as section 1012.

SEC. 3074. SCIENTIFIC ENGAGEMENT. 42 USC 3506a.

(a) IN GENERAL.—Scientific meetings that are attended by scientific or medical personnel, or other professionals, of the Department of Health and Human Services for whom attendance at such meeting is directly related to their professional duties and the mission of the Department—

(1) shall not be considered conferences for the purposes of complying with Federal reporting requirements contained in annual appropriations Acts or in this section; and

(2) shall not be considered conferences for purposes of a restriction contained in an annual appropriations Act, based on Office of Management and Budget Memorandum M-12-12 or any other regulation restricting travel to such meeting.

(b) LIMITATION.—Nothing in this section shall be construed to exempt travel for scientific meetings from Federal regulations relating to travel.

(c) REPORTS.—Not later than 90 days after the end of the fiscal year, each operating division of the Department of Health and Human Services shall prepare, and post on an Internet website of the operating division, an annual report on scientific meeting attendance and related travel spending for each fiscal year. Such report shall include—

(1) general information concerning the scientific meeting activities involved;

(2) information concerning the total amount expended for such meetings;

(3) a description of all such meetings that were attended by scientific or medical personnel, or other professionals, of each such operating division where the total amount expended by the operating division associated with each such meeting were in excess of $30,000, including—

(A) the total amount of meeting expenses incurred by the operating division for such meeting;

(B) the location of such meeting;

(C) the date of such meeting;

(D) a brief explanation on how such meeting advanced the mission of the operating division; and

(E) the total number of individuals whose travel expenses or other scientific meeting expenses were paid by the operating division; and

(4) with respect to any such meeting where the total expenses to the operating division exceeded $150,000, a description of the exceptional circumstances that necessitated the expenditure of such amounts.

SEC. 3075. DRUG SURVEILLANCE.

(a) NEW DRUGS.—Section 505(k)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as amended by section 2074, is further amended—

(1) in subparagraph (A), by striking ", bi-weekly screening" and inserting "screenings";

(2) in subparagraph (B), as redesignated by section 2074(1)(C), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(C) make available on the Internet website of the Food and Drug Administration—

"(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

"(ii) criteria for public posting of adverse event signals.".

(b) FAERS REVISION.—Section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)(2)(D)) is amended by striking ", by 18 months" and all that follows through the semicolon at the end of the subparagraph and inserting "and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;".

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)(5)) is amended—

(1) in the matter preceding subparagraph (A), by inserting "or other advisory committee" after "(or successor committee)"; and

(2) in subparagraph (B), by striking "at least annually," and inserting "periodically".

SEC. 3076. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries."; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking "The ex officio members shall ensure" and inserting "The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure".

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: "For purposes of this section, the term 'employee of the Federal Government' does not include a special Government employee, as that term is defined in section 202(a) of title 18, United States Code.".

(3) STAGGERED TERMS.—Subparagraph (A) of section 770(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended to read as follows:

"(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

"(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i)

shall expire on a staggered basis as determined by the ex officio members; and

"(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.".

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking "but shall not be greater than the compensation of the Commissioner".

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking "are held in separate accounts from funds received from entities under subsection (i)" and inserting "are managed as individual programmatic funds under subsection (i), according to best accounting practices".

Subtitle H—Medical Countermeasures Innovation

SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a), by adding at the end the following:

"(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile."; and

(2) in subsection (g)—

(A) by amending paragraph (4) to read as follows:

"(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).".

SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.

(a) IN GENERAL.—Section 319F–2(g) of the Public Health Service Act (42 U.S.C. 247d–6b(g)) is amended by adding at the end the following:

"(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.".

(b) BARDA CONTRACTING AUTHORITY.—Section 319L(c)(3) of the Public Health Service Act (42 U.S.C. 247d–7c) is amended by inserting ", including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section" before the period.

SEC. 3083. COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) of the Public Health Service Act (42 U.S.C. 300hh–10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A), by striking the first sentence and inserting "Develop, and update not later than March 1 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) for each such threat.";

(2) in subparagraph (C), by striking "; and" and inserting a semicolon;

(3) in subparagraph (D), by striking "to the appropriate committees of Congress upon request." and inserting ", not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and"; and

(4) by adding at the end the following:

"(E) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.".

SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.

Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(4)) is amended by adding at the end the following:

"(E) MEDICAL COUNTERMEASURES INNOVATION PARTNER.—

"(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

"(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and

the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

"(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

"(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

"(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

"(ii) ELIGIBILITY.—

"(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

"(aa) be an independent, nonprofit entity;

"(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

"(cc) have experience in promoting novel technology innovation;

"(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

"(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

"(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

"(gg) not be within the Department of Health and Human Services.

"(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

"(iii) NOT AGENCY.—An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

"(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

"(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

"(II) develop a description of work to be performed by the entity under the agreement;

"(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

"(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

"(V) ensure, as a condition of the agreement that the entity—

"(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

"(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

"(cc) provides monthly accounting on the use of funds provided under such agreement; and

"(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

"(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

"(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

"(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

"(viii) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities

conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

"(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2022.".

SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCUREMENT.

Section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)) is amended—

(1) in paragraph (4)(A)(ii), by striking "make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure" and inserting "and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable";

(2) in paragraph (6)—

(A) by striking subparagraphs (A), (B), and (E);

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (A) and (B), respectively;

(C) by amending subparagraph (A), as so redesignated, to read as follows:

"(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection."; and

(D) in the heading, by striking "RECOMMENDATION FOR PRESIDENT'S APPROVAL" and inserting "RECOMMENDATIONS FOR PROCUREMENT"; and

(3) in paragraph (7)—

(A) by striking subparagraphs (A) and (B) and inserting the following:

"(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph."; and

(B) by redesignating subparagraph (C) as subparagraph (B).

SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT PRESENT A NATIONAL SECURITY THREAT.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 565 the following:

"SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS. 21 USC 360bbb–4a.

"(a) DEFINITIONS.—In this section:

"(1) HUMAN DRUG APPLICATION.—The term 'human drug application' has the meaning given such term in section 735(1).

"(2) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

"(3) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the material threat medical countermeasure application.

"(4) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term 'material threat medical countermeasure application' means an application that—

"(A) is a human drug application for a drug intended for use—

"(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act; or

"(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

"(B) the Secretary determines eligible for priority review;

"(C) is approved after the date of enactment of the 21st Century Cures Act; and

"(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351(a) of the Public Health Service Act.

"(b) PRIORITY REVIEW VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

"(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351(a) of the Public Health Service Act will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times

a priority review voucher may be transferred before such voucher is used.

"(3) NOTIFICATION.—

"(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

"(c) PRIORITY REVIEW USER FEE.—

"(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

"(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

"(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

"(6) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

"(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

"(1) The Secretary issues a priority review voucher under this section.

"(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher issued under this section.

"(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this Act with respect to such drug.

"(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.

"(g) SUNSET.—The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.".

SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(f) DETERMINATION WITH RESPECT TO PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.—

"(1) DETERMINATION.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

"(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

"(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

"(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public

health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

"(2) TRANSPARENCY.—If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

"(3) EFFECTIVENESS OF WAIVER.—Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

"(4) TERMINATION OF WAIVER.—Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

"(5) LIMITATIONS.—

"(A) PERIOD OF WAIVER.—The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

"(B) SUBSEQUENT COMPLIANCE.—An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44, United States Code, and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.".

SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION EMERGENCY USE AUTHORIZATION.

(a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) in subsection (a)(2)—

(A) in subparagraph (A)—

(i) by striking "or 515" and inserting "512, or 515"; and

(ii) by inserting "or conditionally approved under section 571 of this Act" after "Public Health Service Act"; and

(B) in subparagraph (B), by inserting "conditionally approved under section 571," after "approved," each place the term appears;

(2) in subsection (b)(4), by striking the second comma after "determination";

(3) in subsection (e)(3)(B), by striking "section 503(b)" and inserting "subsection (b) or (f) of section 503 or under section 504";

(4) in subsection (f)(2)—

(A) by inserting ", or an animal to which," after "to a patient to whom"; and

(B) by inserting "or by the veterinarian caring for such animal, as applicable" after "attending physician";

(5) in subsection (g)(1), by inserting "conditional approval under section 571," after "approval,";

(6) in subsection (h)(1), by striking "or section 520(g)"and inserting "512(j), or 520(g)"; and

(7) in subsection (k), by striking "section 520(g),"and inserting "512(j), or 520(g)".

(b) NEW ANIMAL DRUGS.—Section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(1)) is amended—

(1) in subparagraph (B), by striking "or" at the end;

(2) in subparagraph (C), by striking the period and inserting "; or"; and

(3) by inserting after subparagraph (C) the following:

"(D) there is in effect an authorization pursuant to section 564 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to any conditions of such authorization.".

(c) EMERGENCY USE OF MEDICAL PRODUCTS.—Section 564A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a) is amended—

(1) in subsection (a)(1)(A), by inserting ", conditionally approved under section 571," after "chapter"; and

(2) in subsection (d), by striking "sections 503(b) and 520(e)" and inserting "subsections (b) and (f) of section 503, section 504, and section 520(e)".

(d) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b(2)) is amended—

(1) in subparagraph (A)—

(A) by inserting "or conditionally approved under section 571 of this Act" after "Public Health Service Act"; and

(B) by striking "or 515" and inserting "512, or 515"; and

(2) in subparagraph (B), by striking "or 520" and inserting "512, or 520".

Subtitle I—Vaccine Access, Certainty, and Innovation

SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

21 USC 360bbb–4 note.

(a) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory

Committee on Immunization Practices (in this section referred to as the "Advisory Committee") shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

(b) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of such committee's review.

(c) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) could be used in a public health emergency.

(d) DEFINITION.—In this section, the terms "Advisory Committee on Immunization Practices" and "Advisory Committee" mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.".

SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES RECOMMENDATIONS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the processes used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines, including with respect to consistency.

(b) CONSIDERATIONS.—The review under subsection (a) shall include an assessment of—

(1) the criteria used to evaluate new and existing vaccines, including the identification of any areas for which flexibility in evaluating such criteria is necessary and the reason for such flexibility;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the work groups of the Advisory Committee on Immunization Practices are consistent among such groups, including the identification of reasons for any variation.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress, and make publicly available, a report on the results of the review under subsection (a), including any recommendations

on improving the consistency of the processes described in such subsection.

(e) DEFINITION.—In this section, the term "Advisory Committee on Immunization Practices" means the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 3093. ENCOURAGING VACCINE INNOVATION.

42 USC 300aa–2 note.

(a) VACCINE MEETINGS.—The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics.

(b) REPORT ON VACCINE INNOVATION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), in collaboration with appropriate agencies or offices within the Department of Health and Human Services, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post publicly on the Internet website of the Department of Health and Human Services, a report on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease.

(2) CONTENTS.—The report described in paragraph (1) shall review the current status of vaccine development and, as appropriate—

(A) consider the optimal process to determine which vaccines would be beneficial to public health and how information on such vaccines is disseminated to key stakeholders;

(B) examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and

(C) make recommendations about how best to remove any obstacles identified under subparagraph (B) in order to promote and incentivize vaccine innovation and development.

(3) CONSULTATION.—In preparing the report under this subsection, the Secretary may consult with—

(A) representatives of relevant Federal agencies and departments, including the Department of Defense and the Department of Veterans Affairs;

(B) academic researchers;

(C) developers and manufacturers of vaccines;

(D) medical and public health practitioners;

(E) representatives of patient, policy, and advocacy organizations; and

(F) representatives of other entities, as the Secretary determines appropriate.

(c) UPDATES RELATED TO MATERNAL IMMUNIZATION.—

(1) ADDITIONAL VACCINES.—Section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) is amended by adding at the end the following:

"(3) VACCINES RECOMMENDED FOR USE IN PREGNANT WOMEN.—The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.".

(2) PETITION CONTENT.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended by adding at the end the following:

"(f) MATERNAL IMMUNIZATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

"(2) DEFINITION.—As used in this subsection, the term 'child' shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term 'include' in subsection (a) of such section were replaced with the term 'mean'.".

(3) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amended by adding "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine." at the end.

Subtitle J—Technical Corrections

SEC. 3101. TECHNICAL CORRECTIONS.

(a) FFDCA.—

(1) REFERENCES.—Except as otherwise expressly provided, whenever in this subsection an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) AMENDMENTS.—

(A) PROHIBITED ACTS.—Section 301(r) (21 U.S.C. 331(r)) is amended by inserting ", drug," after "device" each place the term appears.

(B) NEW DRUGS.—Section 505 (21 U.S.C. 355) is amended—

(i) in subsection (d), in the last sentence, by striking "premarket approval" and inserting "marketing approval"; and

(ii) in subsection (q)(5)(A), by striking "subsection (b)(2) or (j) of the Act or 351(k)" and inserting "subsection (b)(2) or (j) of this section or section 351(k)".

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(h)(21 U.S.C. 355–1(h)) is amended—

(i) in paragraph (2)(A)(iii)—

(I) in the clause heading, by striking "LABEL" and inserting "LABELING";

(II) by striking "label" each place the term appears and inserting "labeling"; and

(III) by striking "sponsor" and inserting "responsible person"; and

(ii) in paragraph (8), by striking "and (7)." and inserting "and (7)".

(D) PEDIATRIC STUDY PLANS.—Section 505B (21 U.S.C. 355c) is amended—

(i) in subsection (e)—

(I) in paragraph (2)—

(aa) in subparagraph (A), by inserting "study" after "initial pediatric" each place the term appears; and

(bb) in subparagraph (B), in the subparagraph heading, by striking "INITIAL PLAN" and inserting "INITIAL PEDIATRIC STUDY PLAN";

(II) in paragraph (5), in the paragraph heading, by inserting "AGREED INITIAL PEDIATRIC STUDY" before "PLAN"; and

(III) in paragraph (6), by striking "agreed initial pediatric plan" and inserting "agreed initial pediatric study plan"; and

(ii) in subsection (f)(1), by inserting "and any significant amendments to such plans," after "agreed initial pediatric study plans,".

(E) DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIVE-SAVING DRUGS.—Section 506C (21 U.S.C. 356c) is amended—

(i) in subsection (c), by striking "discontinuation" and inserting "discontinuance"; and

(ii) in subsection (g)(1), by striking "section 505(j) that could help" and inserting "section 505(j), that could help".

(F) ANNUAL REPORTING ON DRUG SHORTAGES.—Section 506C–1(a) (21 U.S.C. 331(a)) is amended, in the matter before paragraph (1)—

(i) by striking "Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter," and inserting "Not later than March 31 of each calendar year,"; and

(ii) by inserting ", with respect to the preceding calendar year," after "a report".

(G) DRUG SHORTAGE LIST.—Section 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is amended by striking "discontinuation" and inserting "discontinuance".

(H) INSPECTIONS OF ESTABLISHMENTS.—Section 510(h) (21 U.S.C. 360(h)) is amended—

(i) in paragraph (4), in the matter preceding subparagraph (A), by striking "establishing the risk-based scheduled" and inserting "establishing a risk-based schedule"; and

(ii) in paragraph (6)—

(I) in subparagraph (A), by striking "fiscal" and inserting "calendar" each place the term appears; and

(II) in subparagraph (B), by striking "an active ingredient of a drug, a finished drug product, or an excipient of a drug" and inserting "an active ingredient of a drug or a finished drug product".

(I) CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE.—Section 513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is amended—

(i) in clause (i), by striking "within 30 days"; and

(ii) in clause (iv), by striking "low-moderate" and inserting "low to moderate".

(J) PREMARKET APPROVAL.—Section 515(a)(1) (21 U.S.C. 360e(a)(1)) is amended by striking "subject to a an order" and inserting "subject to an order".

(K) PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.—Section 518A (21 U.S.C. 360h–1) is amended—

(i) by striking subsection (c); and

(ii) by redesignating subsection (d) as subsection (c).

(L) UNIQUE DEVICE IDENTIFIER.—Section 519(f) (21 U.S.C. 360i(f)) is amended by striking "and life sustaining" and inserting "or life sustaining".

(M) PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.—Section 524(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(c)(4)(A)) is amended by striking "Services Act" and inserting "Service Act".

(N) PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.—Section 524A (21 U.S.C. 360n–1) is amended—

(i) by striking "If the Secretary" and inserting the following:

"(a) IN GENERAL.—If the Secretary";

(ii) by striking "any" and inserting "the first"; and

(iii) by adding at the end the following:

"(b) CONSTRUCTION.—Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 505(b) that otherwise meets the criteria for the Secretary to grant priority review.".

(O) CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.—Section 569(a)(2)(A) (21 U.S.C. 360bbb–8(a)(2)(A)) is amended, in the first sentence, by striking "subsection (c)" and inserting "subsection (b)".

(P) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(c) (21 U.S.C. 360bbb–8a(c)) is amended by inserting "or under the Public Health Service Act" after "this Act".

(Q) USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.—Section 569B (21 U.S.C. 360bbb–8b) is amended by striking "drug or device" and inserting "drug, biological product, or device" each place the term appears.

(R) MEDICAL GASES DEFINITIONS.—Section 575(1)(H) (21 U.S.C. 360ddd(1)(H)) is amended—

(i) by inserting "for a new drug" after "any period of exclusivity"; and

(ii) by inserting "or any period of exclusivity for a new animal drug under section 512(c)(2)(F)," after "section 505A,".

(S) REGULATION OF MEDICAL GASES.—Section 576(a) (21 U.S.C. 360ddd–1(a)) is amended—

(i) in the matter preceding subparagraph (A) of paragraph (1), by inserting "who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce" after "any person"; and

(ii) in paragraph (3)—

(I) in subparagraph (A)—

(aa) in clause (i)(VIII), by inserting "for a new drug" after "any period of exclusivity"; and

(bb) in clause (ii), in the matter preceding subclause (I), by inserting "the" before "final use"; and

(II) in subparagraph (B)—

(aa) in clause (i), by inserting "for a new drug" after "any period of exclusivity"; and

(bb) in clause (ii), by inserting a comma after "drug product".

(T) INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.—Section 577 (21 U.S.C. 360ddd–2) is amended by inserting "or 740(a)" after "section 736(a)".

(U) CONFLICTS OF INTEREST.—Section 712(e)(1)(B) (21 U.S.C. 379d–1(e)(1)(B)) is amended by striking "services" and inserting "service".

(V) AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.—Section 744H(a) (21 U.S.C. 379j–52(a)) is amended—

(i) in paragraph (1)(A)(v), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012"; and

(ii) in paragraph (2)(B), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012".

(W) REGISTRATION OF COMMERCIAL IMPORTERS.—

(i) AMENDMENT.—Section 801(s)(2) (21 U.S.C. 381(s)(2)) is amended by adding at the end the following:

"(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good

importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.".

(ii) CONFORMING AMENDMENT.—Section 714 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1074) is amended by striking subsection (d).

(X) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(2) (21 U.S.C. 384e(a)(2)) is amended by striking "conduction" and inserting "conducting".

(b) FDASIA.—

(1) FINDINGS RELATING TO DRUG APPROVAL.—Section 901(a)(1)(A) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 21 U.S.C. 356 note) is amended by striking "serious and life-threatening diseases" and inserting "serious or life-threatening diseases".

(2) REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS.—Section 907 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1092, 1093) is amended—

(A) in the section heading, by striking "**BIOLOGICS**" in the heading and inserting "**BIOLOGICAL PRODUCTS**"; and

(B) in subsection (a)(2)(B), by striking "applications for new drug applications" and inserting "new drug applications".

(3) COMBATING PRESCRIPTION DRUG ABUSE.—Section 1122 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1112, 1113) is amended—

(A) in subsection (a)(2), by striking "dependance" and inserting "dependence"; and

(B) in subsection (c), by striking "promulgate" and inserting "issue".

SEC. 3102. COMPLETED STUDIES.

The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505(k)(5) (21 U.S.C. 355(k)(5))—

(A) in subparagraph (A), by inserting "and" after the semicolon;

(B) by striking subparagraph (B); and

(C) by redesignating subparagraph (C) as subparagraph (B);

(2) in section 505A (21 U.S.C. 355a), by striking subsection (p);

(3) in section 505B (21 U.S.C. 355c)—

(A) by striking subsection (l); and

(B) by redesignating subsection (m) as subsection (l); and

(4) in section 523 (21 U.S.C. 360m), by striking subsection (d).

TITLE IV—DELIVERY

SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—The Health Information Technology for Economic and Clinical Health Act (title XIII of division A of Public Law 111–5) is amended—

(1) by adding at the end of part 1 of subtitle A the following:

"SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

42 USC 300jj–11 note.

"(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

"(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

"(2) develop a strategy for meeting the goal established under paragraph (1); and

"(3) develop recommendations for meeting the goal established under paragraph (1).

"(b) STRATEGY AND RECOMMENDATIONS.—

"(1) IN GENERAL.—To achieve the goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall, not later than 1 year after the date of enactment of the 21st Century Cures Act, develop a strategy and recommendations to meet the goal in accordance with this subsection.

"(2) STRATEGY.—The strategy developed under paragraph (1) shall address the regulatory and administrative burdens (such as documentation requirements) relating to the use of electronic health records. Such strategy shall include broad public comment and shall prioritize—

"(A)(i) incentives for meaningful use of certified EHR technology for eligible professionals and hospitals under sections 1848(a)(7) and 1886(b)(3)(B)(ix), respectively, of the Social Security Act (42 U.S.C. 1395w–4(a)(7), 1395ww(b)(3)(B)(ix));

"(ii) the program for making payments under section 1903(a)(3)(F) of the Social Security Act (42 U.S.C. 1396b(a)(3)(F)) to encourage the adoption and use of certified EHR technology by Medicaid providers;

"(iii) the Merit-based Incentive Payment System under section 1848(q) of the Social Security Act (42 U.S.C. 1395w–4(q));

"(iv) alternative payment models (as defined in section 1833(z)(3)(C) of the Social Security Act (42 U.S.C. 1395l(z)(3)(C));

"(v) the Hospital Value-Based Purchasing Program under section 1886(o) of the Social Security Act (42 U.S.C. 1395ww(o)); and

"(vi) other value-based payment programs, as the Secretary determines appropriate;

"(B) health information technology certification;

"(C) standards and implementation specifications, as appropriate;

"(D) activities that provide individuals access to their electronic health information;

"(E) activities related to protecting the privacy of electronic health information;

"(F) activities related to protecting the security of electronic health information;

"(G) activities related to facilitating health and clinical research;

"(H) activities related to public health;

"(I) activities related to aligning and simplifying quality measures across Federal programs and other payers;

"(J) activities related to reporting clinical data for administrative purposes; and

"(K) other areas, as the Secretary determines appropriate.

"(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall address—

"(A) actions that improve the clinical documentation experience;

"(B) actions that improve patient care;

"(C) actions to be taken by the Secretary and by other entities; and

"(D) other areas, as the Secretary determines appropriate, to reduce the reporting burden required of health care providers.

"(4) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development of the goal, strategies, or recommendations described in this section.

"(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—A physician (as defined in section 1861(r)(1) of the Social Security Act), to the extent consistent with applicable State law, may delegate electronic medical record documentation requirements specified in regulations promulgated by the Centers for Medicare & Medicaid Services to a person performing a scribe function who is not such physician if such physician has signed and verified the documentation."; and

(2) in the table of contents in section 13001(b), by inserting after the item relating to section 13102 the following:

"13103. Assisting doctors and hospitals in improving the quality and care for patients.".

(b) CERTIFICATION OF HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended by adding at the end the following:

"(C) HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—

"(i) IN GENERAL.—The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under

subparagraph (A) for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed.

"(ii) SPECIFIC MEDICAL SPECIALTIES.—The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

"(iii) HEALTH INFORMATION TECHNOLOGY FOR PEDIATRICS.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to support the health care of children. Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall adopt certification criteria under section 3004 to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.".

(c) MEANINGFUL USE STATISTICS.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the HIT Advisory Committee of the Office of the National Coordinator for Health Information Technology, a report concerning attestation statistics for the Medicare and Medicaid EHR Meaningful Use Incentive programs to assist in informing standards adoption and related practices. Such statistics shall include attestation information delineated by State, including, to the extent practicable, the number of providers who did not meet the minimum criteria necessary to attest for the Medicare and Medicaid EHR Meaningful Use Incentive programs for a calendar year, and shall be made publicly available on the Internet website of the Secretary on at least a quarterly basis.

(2) AUTHORITY TO ALTER FORMAT.—The Secretary of Health and Human Services may alter the format of the reports on the attestation of eligible health care professionals following the first performance year of the Merit-based Incentive Payment System to account for changes arising from the implementation of such payment system.

SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SECURITY, AND FUNCTIONALITY.

(a) ENHANCEMENTS TO CERTIFICATION.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11), as amended by section 4001(b), is further amended by adding at the end the following:

"(D) CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other

conditions and requirements under this title, that the health information technology developer or entity—

"(i) does not take any action that constitutes information blocking as defined in section 3022(a);

"(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

"(iii) does not prohibit or restrict communication regarding—

"(I) the usability of the health information technology;

"(II) the interoperability of the health information technology;

"(III) the security of the health information technology;

"(IV) relevant information regarding users' experiences when using the health information technology;

"(V) the business practices of developers of health information technology related to exchanging electronic health information; and

"(VI) the manner in which a user of the health information technology has used such technology;

"(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

"(v) has successfully tested the real world use of the technology for interoperability (as defined in section 3000) in the type of setting in which such technology would be marketed;

"(vi) provides to the Secretary an attestation that the developer or entity—

"(I) has not engaged in any of the conduct described in clause (i);

"(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);

"(III) does not prohibit or restrict communication as described in clause (iii);

"(IV) has published information in accordance with clause (iv);

"(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and

"(VI) has undertaken real world testing as described in clause (v); and

"(vii) submits reporting criteria in accordance with section 3009A(b).".

"(E) COMPLIANCE WITH CONDITIONS OF CERTIFICATION.—The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.".

(b) EHR SIGNIFICANT HARDSHIP EXCEPTION.—

(1) APPLICATION TO ELIGIBLE PROFESSIONALS.—

(A) IN CASE OF DECERTIFICATION.—Section 1848(a)(7)(B) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(B)) is amended by inserting after the first sentence the following new sentence: "The Secretary shall exempt an eligible professional from the application of the payment adjustment under subparagraph (A) with respect to a year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such professional has been decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.".

(B) CONTINUED APPLICATION UNDER MIPS.—Section 1848(o)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(D)) is amended by adding at the end the following new sentence: "The provisions of subparagraphs (B) and (D) of subsection (a)(7), shall apply to assessments of MIPS eligible professionals under subsection (q) with respect to the performance category described in subsection (q)(2)(A)(iv) in an appropriate manner which may be similar to the manner in which such provisions apply with respect to payment adjustments made under subsection (a)(7)(A).".

(2) APPLICATION TO ELIGIBLE HOSPITALS.—Section 1886(b)(3)(B)(ix)(II) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended by inserting after the first sentence the following new sentence: "The Secretary shall exempt an eligible hospital from the application of the payment adjustment under subclause (I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such hospital is decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.".

(c) ELECTRONIC HEALTH RECORD REPORTING PROGRAM.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following:

"SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING PROGRAM. 42 USC 300jj–19a.

"(a) REPORTING CRITERIA.—

"(1) CONVENING OF STAKEHOLDERS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall convene stakeholders, as described in paragraph (2), for the purpose of developing the reporting criteria in accordance with paragraph (3).

"(2) DEVELOPMENT OF REPORTING CRITERIA.—The reporting criteria under this subsection shall be developed through a public, transparent process that reflects input from relevant stakeholders, including—

"(A) health care providers, including primary care and specialty care health care professionals;

"(B) hospitals and hospital systems;

"(C) health information technology developers;

"(D) patients, consumers, and their advocates;

"(E) data sharing networks, such as health information exchanges;

"(F) authorized certification bodies and testing laboratories;

"(G) security experts;

"(H) relevant manufacturers of medical devices;

"(I) experts in health information technology market economics;

"(J) public and private entities engaged in the evaluation of health information technology performance;

"(K) quality organizations, including the consensus based entity described in section 1890 of the Social Security Act;

"(L) experts in human factors engineering and the measurement of user-centered design; and

"(M) other entities or individuals, as the Secretary determines appropriate.

"(3) CONSIDERATIONS FOR REPORTING CRITERIA.—The reporting criteria developed under this subsection—

"(A) shall include measures that reflect categories including—

"(i) security;

"(ii) usability and user-centered design;

"(iii) interoperability;

"(iv) conformance to certification testing; and

"(v) other categories, as appropriate to measure the performance of electronic health record technology;

"(B) may include categories such as—

"(i) enabling the user to order and view the results of laboratory tests, imaging tests, and other diagnostic tests;

"(ii) submitting, editing, and retrieving data from registries such as clinician-led clinical data registries;

"(iii) accessing and exchanging information and data from and through health information exchanges;

"(iv) accessing and exchanging information and data from medical devices;

"(v) accessing and exchanging information and data held by Federal, State, and local agencies and other applicable entities useful to a health care provider or other applicable user in the furtherance of patient care;

"(vi) accessing and exchanging information from other health care providers or applicable users;

"(vii) accessing and exchanging patient generated information;

"(viii) providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format;

"(ix) providing accurate patient information for the correct patient, including exchanging such information, and avoiding the duplication of patients records; and

"(x) other categories regarding performance, accessibility, as the Secretary determines appropriate; and

"(C) shall be designed to ensure that small and startup health information technology developers are not unduly disadvantaged by the reporting criteria.

"(4) MODIFICATIONS.—After the reporting criteria have been developed under paragraph (3), the Secretary may convene stakeholders and conduct a public comment period for the purpose of modifying the reporting criteria developed under such paragraph.

"(b) PARTICIPATION.—As a condition of maintaining certification under section 3001(c)(5)(D), a developer of certified electronic health records shall submit to an appropriate recipient of a grant, contract, or agreement under subsection (c)(1) responses to the criteria developed under subsection (a), with respect to all certified technology offered by such developer.

"(c) REPORTING PROGRAM.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall award grants, contracts, or agreements to independent entities on a competitive basis to support the convening of stakeholders as described in subsection (a)(2), collect the information required to be reported in accordance with the criteria established as described subsection (a)(3), and develop and implement a process in accordance with paragraph (5) and report such information to the Secretary.

"(2) APPLICATIONS.—An independent entity that seeks a grant, contract, or agreement under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a description of—

"(A) the proposed method for reviewing and summarizing information gathered based on reporting criteria established under subsection (a);

"(B) if applicable, the intended focus on a specific subset of certified electronic health record technology users, such as health care providers, including primary care, specialty care, and care provided in rural settings; hospitals and hospital systems; and patients, consumers, and patients and consumer advocates;

"(C) the plan for widely distributing reports described in paragraph (6);

"(D) the period for which the grant, contract, or agreement is requested, which may be up to 2 years; and

"(E) the budget for reporting program participation, and whether the eligible independent entity intends to continue participation after the period of the grant, contract, or agreement.

"(3) CONSIDERATIONS FOR INDEPENDENT ENTITIES.—In awarding grants, contracts, and agreements under paragraph (1), the Secretary shall give priority to independent entities with appropriate expertise in health information technology usability, interoperability, and security (especially entities with such expertise in electronic health records) with respect to—

"(A) health care providers, including primary care, specialty care, and care provided in rural settings;

"(B) hospitals and hospital systems; and

"(C) patients, consumers, and patient and consumer advocates.

"(4) LIMITATIONS.—

"(A) ASSESSMENT AND REDETERMINATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act and every 2 years thereafter, the Secretary, in consultation with stakeholders, shall—

"(i) assess performance of the recipients of the grants, contracts, and agreements under paragraph (1) based on quality and usability of reports described in paragraph (6); and

"(ii) re-determine grants, contracts, and agreements as necessary.

"(B) PROHIBITIONS ON PARTICIPATION.—The Secretary may not award a grant, contract, or cooperative agreement under paragraph (1) to—

"(i) a proprietor of certified health information technology or a business affiliate of such a proprietor;

"(ii) a developer of certified health information technology; or

"(iii) a State or local government agency.

"(5) FEEDBACK.—Based on reporting criteria established under subsection (a), the recipients of grants, contracts, and agreements under paragraph (1) shall develop and implement a process to collect and verify confidential feedback on such criteria from—

"(A) health care providers, patients, and other users of certified electronic health record technology; and

"(B) developers of certified electronic health record technology.

"(6) REPORTS.—

"(A) DEVELOPMENT OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall report on the information reported to such recipient pursuant to subsection (a) and the user feedback collected under paragraph (5) by preparing summary reports and detailed reports of such information.

"(B) DISTRIBUTION OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall submit the reports prepared under subparagraph (A) to the Secretary for public distribution in accordance with subsection (d).

"(d) PUBLICATION.—The Secretary shall distribute widely, as appropriate, and publish, on the Internet website of the Office of the National Coordinator—

"(1) the reporting criteria developed under subsection (a); and

"(2) the summary and detailed reports under subsection (c)(6).

"(e) REVIEW.—Each recipient of a grant, contract, or agreement under paragraph (1) shall develop and implement a process through which participating electronic health record technology developers may review and recommend changes to the reports created under subsection (c)(6) for products developed by such developer prior to the publication of such report under subsection (d).

"(f) ADDITIONAL RESOURCES.—The Secretary may provide additional resources on the Internet website of the Office of the National

Coordinator to better inform consumers of health information technology. Such reports may be carried out through partnerships with private organizations with appropriate expertise.".

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $15,000,000 for purposes of carrying out subparagraph (D) of section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11) (as added by subsection (a)) and section 3009A of the Public Health Service Act (as added by subsection (b)), including for purposes of administering any contracts, grants, or agreements, to remain available until expended.

SEC. 4003. INTEROPERABILITY.

(a) DEFINITION.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended—

(1) by redesignating paragraphs (10) through (14), as paragraphs (11) through (15), respectively; and

(2) by inserting after paragraph (9) the following:

"(10) INTEROPERABILITY.—The term 'interoperability', with respect to health information technology, means such health information technology that—

"(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

"(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

"(C) does not constitute information blocking as defined in section 3022(a).".

(b) SUPPORT FOR INTEROPERABLE NETWORK EXCHANGE.—Section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)) is amended by adding at the end the following:

"(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

"(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

"(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

"(i) IN GENERAL.—Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

"(I) a common method for authenticating trusted health information network participants;

"(II) a common set of rules for trusted exchange;

"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

"(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement.

"(ii) TECHNICAL ASSISTANCE.—The National Coordinator, in collaboration with the National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

"(iii) PILOT TESTING.—The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

"(C) PUBLICATION OF A TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—Not later than 1 year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

"(D) DIRECTORY OF PARTICIPATING HEALTH INFORMATION NETWORKS.—

"(i) IN GENERAL.—Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph (B).

"(ii) PROCESS.—The Secretary shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

"(E) APPLICATION OF THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—As appropriate, Federal agencies contracting or entering into agreements with

health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

"(F) RULE OF CONSTRUCTION.—

"(i) GENERAL ADOPTION.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

"(ii) ADOPTION WHEN EXCHANGE OF INFORMATION IS WITHIN NETWORK.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

"(iii) EXISTING FRAMEWORKS AND AGREEMENTS.—The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

"(iv) APPLICATION BY FEDERAL AGENCIES.—Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

"(v) CONSIDERATION OF ONGOING WORK.—In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.".

(c) PROVIDER DIGITAL CONTACT INFORMATION INDEX.— 42 USC 300jj–11 note.

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall, directly or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.

(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary may utilize an existing provider directory to make such digital contact information available.

(3) CONTACT INFORMATION.—An index established under this subsection shall ensure that contact information is available at the individual health care provider level and at the health facility or practice level.

(4) RULE OF CONSTRUCTION.—

(A) IN GENERAL.—The purpose of this subsection is to encourage the exchange of electronic health information by providing the most useful, reliable, and comprehensive

index of providers possible. In furthering such purpose, the Secretary shall include all health professionals and health facilities applicable to provide a useful, reliable, and comprehensive index for use in the exchange of health information.

(B) LIMITATION.—In no case shall exclusion from the index of providers be used as a measure to achieve objectives other the objectives described in subparagraph (A).

(d) STANDARDS DEVELOPMENT ORGANIZATIONS.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14) is amended by adding at the end the following:

"(c) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this section, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.".

(e) HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.—

(1) IN GENERAL.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended by striking sections 3002 (42 U.S.C. 300jj–12) and 3003 (42 U.S.C. 300jj–13) and inserting the following:

42 USC 300jj–12.

"SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—There is established a Health Information Technology Advisory Committee (referred to in this section as the 'HIT Advisory Committee') to recommend to the National Coordinator, consistent with the implementation of the strategic plan described in section 3001(c)(3), policies, and, for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Such Committee shall serve to unify the roles of, and replace, the HIT Policy Committee and the HIT Standards Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

"(b) DUTIES.—

"(1) RECOMMENDATIONS ON POLICY FRAMEWORK TO ADVANCE AN INTEROPERABLE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing the target areas described in this subsection. Such policy framework shall seek to prioritize achieving advancements in the target areas specified in subparagraph (B) of paragraph (2) and may, to the extent consistent with this section, incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

"(B) UPDATES.—The HIT Advisory Committee shall propose updates to such recommendations to the policy framework and make new recommendations, as appropriate.

"(2) GENERAL DUTIES AND TARGET AREAS.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information across disparate systems including user vetting, authentication, privilege management, and access control.

"(B) PRIORITY TARGET AREAS.—For purposes of this section, the HIT Advisory Committee shall make recommendations under subparagraph (A) with respect to at least each of the following target areas:

"(i) Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

"(ii) The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.

"(iii) The facilitation of secure access by an individual to such individual's protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.

"(iv) Subject to subparagraph (D), any other target area that the HIT Advisory Committee identifies as an appropriate target area to be considered under this subparagraph.

"(C) ADDITIONAL TARGET AREAS.—For purposes of this section, the HIT Advisory Committee may make recommendations under subparagraph (A), in addition to areas described in subparagraph (B), with respect to any of the following areas:

"(i) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, reducing medical errors, improving population health,

reducing chronic disease, and advancing research and education.

"(ii) The use of technologies that address the needs of children and other vulnerable populations.

"(iii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including at a minimum, race, ethnicity, primary language, and gender information.

"(iv) The use of self-service, telemedicine, home health care, and remote monitoring technologies.

"(v) The use of technologies that meet the needs of diverse populations.

"(vi) The use of technologies that support—

"(I) data for use in quality and public reporting programs;

"(II) public health; or

"(III) drug safety.

"(vii) The use of technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in a health information network or transported outside of the secure facilities or systems where the disclosing covered entity is responsible for security conditions.

"(viii) The use of a certified health information technology for each individual in the United States.

"(D) AUTHORITY FOR TEMPORARY ADDITIONAL PRIORITY TARGET AREAS.—For purposes of subparagraph (B)(iv), the HIT Advisory Committee may identify an area to be considered for purposes of recommendations under this subsection as a target area described in subparagraph (B) if—

"(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and

"(ii) at least 30 days prior to treating such area as if it were a target area described in subparagraph (B), the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

"(E) FOCUS OF COMMITTEE WORK.—It is the sense of Congress that the HIT Advisory Committee shall focus its work on the priority areas described in subparagraph (B) before proceeding to other work under subparagraph (C).

"(3) RULES RELATING TO RECOMMENDATIONS FOR STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a), which may include standards, implementation specifications, and certification criteria that have been developed, harmonized, or recognized by the HIT Advisory Committee or predecessor committee.

The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the Committee.

"(B) HARMONIZATION.—The HIT Advisory Committee may recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specification.

"(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Advisory Committee for purposes of recommendations under paragraph (2)(B), shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

"(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under paragraph (2)(B) shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

"(E) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Advisory Committee after the date of the enactment of this subparagraph with respect to interoperability of health information technology shall be consistent with interoperability as described in section 3000.

"(4) FORUM.—The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies, including technical expertise, relating to the matters described in paragraphs (1), (2), and (3) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of health information technology infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information.

"(5) SCHEDULE.—Not later than 30 days after the date on which the HIT Advisory Committee first meets, such HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations developed under paragraph (1). The HIT Advisory Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

"(6) PUBLIC INPUT.—The HIT Advisory Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (5) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

"(c) MEASURED PROGRESS IN ADVANCING PRIORITY AREAS.—

"(1) IN GENERAL.—For purposes of this section, the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and benchmarks for advancing and measuring the advancement of the priority target areas described in subsection (b)(2)(B).

"(2) ANNUAL PROGRESS REPORTS ON ADVANCING INTEROPERABILITY.—

"(A) IN GENERAL.—The HIT Advisory Committee, in consultation with the National Coordinator, shall annually submit to the Secretary and Congress a report on the progress made during the preceding fiscal year in—

"(i) achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information; and

"(ii) meeting the objectives and benchmarks described in paragraph (1).

"(B) CONTENT.—Each such report shall include, for a fiscal year—

"(i) a description of the work conducted by the HIT Advisory Committee during the preceding fiscal year with respect to the areas described in subsection (b)(2)(B);

"(ii) an assessment of the status of the infrastructure described in subparagraph (A), including the extent to which electronic health information is appropriately and readily available to enhance the access, exchange, and the use of electronic health information between users and across technology offered by different developers;

"(iii) the extent to which advancements have been achieved with respect to areas described in subsection (b)(2)(B);

"(iv) an analysis identifying existing gaps in policies and resources for—

"(I) achieving the objectives and benchmarks established under paragraph (1); and

"(II) furthering interoperability throughout the health information technology infrastructure;

"(v) recommendations for addressing the gaps identified in clause (iii); and

"(vi) a description of additional initiatives as the HIT Advisory Committee and National Coordinator determine appropriate.

"(3) SIGNIFICANT ADVANCEMENT DETERMINATION.—The Secretary shall periodically, based on the reports submitted under this subsection, review the target areas described in subsection (b)(2)(B), and, based on the objectives and benchmarks established under paragraph (1), the Secretary shall determine if significant advancement has been achieved with respect to such an area. Such determination shall be taken into consideration by the HIT Advisory Committee when determining to what extent the Committee makes recommendations for an area other than an area described in subsection (b)(2)(B).

"(d) MEMBERSHIP AND OPERATIONS.—

"(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Advisory Committee.

"(2) MEMBERSHIP.—The membership of the HIT Advisory Committee shall—

"(A) include at least 25 members, of which—

"(i) no fewer than 2 members are advocates for patients or consumers of health information technology;

"(ii) 3 members are appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official;

"(iii) 2 members are appointed by the majority leader of the Senate;

"(iv) 2 members are appointed by the minority leader of the Senate;

"(v) 2 members are appointed by the Speaker of the House of Representatives;

"(vi) 2 members are appointed by the minority leader of the House of Representatives; and

"(vii) such other members are appointed by the Comptroller General of the United States; and

"(B) at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

"(3) PARTICIPATION.—The members of the HIT Advisory Committee shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Committee.

"(4) TERMS.—

"(A) IN GENERAL.—The terms of the members of the HIT Advisory Committee shall be for 3 years, except that the Secretary shall designate staggered terms of the members first appointed.

"(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.

"(C) LIMITS.—Members of the HIT Advisory Committee shall be limited to two 3-year terms, for a total of not to exceed 6 years of service on the Committee.

"(5) OUTSIDE INVOLVEMENT.—The HIT Advisory Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies and standards for the electronic exchange and use of health information,

including in the areas of health information privacy and security.

"(6) QUORUM.—A majority of the members of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

"(7) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

"(8) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Advisory Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not-for-profit entities that work in the public interest as a party of their mission.

"(e) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Advisory Committee.

"(f) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Advisory Committee under this section.".

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended—

(A) by striking—

(i) "HIT Policy Committee" and "HIT Standards Committee" each place that such terms appear (other than within the term "HIT Policy Committee and the HIT Standards Committee" or within the term "HIT Policy Committee or the HIT Standards Committee") and inserting "HIT Advisory Committee";

(ii) "HIT Policy Committee and the HIT Standards Committee" each place that such term appears and inserting "HIT Advisory Committee"; and

(iii) "HIT Policy Committee or the HIT Standards Committee" each place that such term appears and inserting "HIT Advisory Committee";

(B) in section 3000 (42 U.S.C. 300jj)—

(i) by striking paragraphs (7) and (8) and redesignating paragraphs (9) through (14) as paragraphs (8) through (13), respectively; and

(ii) by inserting after paragraph (6) the following paragraph:

"(7) HIT ADVISORY COMMITTEE.—The term 'HIT Advisory Committee' means such Committee established under section 3002(a).";

(C) in section 3001(c) (42 U.S.C. 300jj–11(c))—

(i) in paragraph (1)(A), by striking "under section 3003" and inserting "under section 3002";

(ii) in paragraph (2), by striking subparagraph (B) and inserting the following:

"(B) HIT ADVISORY COMMITTEE.—The National Coordinator shall be a leading member in the establishment

and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.";

(D) in section 3004(b)(3) (42 U.S.C. 300jj–14(b)(3)), by striking "3003(b)(2)" and inserting "3002(b)(4)";

(E) in section 3007(b) (42 U.S.C. 300jj–17(b)), by striking "3003(a)" and inserting "3002(a)(2)"; and

(F) in section 3008 (42 U.S.C. 300jj–18)—

(i) in subsection (b), by striking "or 3003"; and

(ii) in subsection (c), by striking "3003(b)(1)(A)" and inserting "3002(b)(2)".

(3) TRANSITION TO THE HIT ADVISORY COMMITTEE.—The Secretary of Health and Human Services shall provide for an orderly and timely transition to the HIT Advisory Committee established under amendments made by this section. 42 USC 300jj–12 note.

(f) PRIORITIES FOR ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), as amended by subsection (e), is further amended by inserting after section 3002 the following:

"SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPTION. 42 USC 300jj–13.

"(a) IDENTIFYING PRIORITIES.—

"(1) IN GENERAL.—Not later than 6 months after the date on which the HIT Advisory Committee first meets, the National Coordinator shall periodically convene the HIT Advisory Committee to—

"(A) identify priority uses of health information technology, focusing on priorities—

"(i) arising from the implementation of the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary;

"(ii) related to the quality of patient care;

"(iii) related to public health;

"(iv) related to clinical research;

"(v) related to the privacy and security of electronic health information;

"(vi) related to innovation in the field of health information technology;

"(vii) related to patient safety;

"(viii) related to the usability of health information technology;

"(ix) related to individuals' access to electronic health information; and

"(x) other priorities determined appropriate by the Secretary;

"(B) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in subparagraph (A); and

"(C) publish a report summarizing the findings of the analysis conducted under subparagraphs (A) and (B) and make appropriate recommendations.

"(2) PRIORITIZATION.—In identifying such standards and implementation specifications under paragraph (1)(B), the HIT Advisory Committee shall prioritize standards and implementation specifications developed by consensus-based standards development organizations.

"(3) GUIDELINES FOR REVIEW OF EXISTING STANDARDS AND SPECIFICATIONS.—In consultation with the consensus-based entity described in section 1890 of the Social Security Act and other appropriate Federal agencies, the analysis of existing standards under paragraph (1)(B) shall include an evaluation of the need for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.

"(b) REVIEW OF ADOPTED STANDARDS.—

"(1) IN GENERAL.—Beginning 5 years after the date of enactment of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to—

"(A) maintain the use of such standards and implementation specifications; or

"(B) phase out such standards and implementation specifications.

"(2) PRIORITIES.—The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the use or adoption of novel standards that improve upon the existing health information technology infrastructure and facilitate the secure exchange of health information.".

SEC. 4004. INFORMATION BLOCKING.

Subtitle C of title XXX of the Public Health Service Act (42 U.S.C. 300jj–51 et seq.) is amended by adding at the end the following:

42 USC 300jj–52.

"SEC. 3022. INFORMATION BLOCKING.

"(a) DEFINITION.—

"(1) IN GENERAL.—In this section, the term 'information blocking' means a practice that—

"(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

"(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

"(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is

likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

"(2) PRACTICES DESCRIBED.—The information blocking practices described in paragraph (1) may include—

"(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

"(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

"(C) implementing health information technology in ways that are likely to—

"(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

"(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

"(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

"(4) NO ENFORCEMENT BEFORE EXCEPTION IDENTIFIED.—The term 'information blocking' does not include any practice or conduct occurring prior to the date that is 30 days after the date of enactment of the 21st Century Cures Act.

"(5) CONSULTATION.—The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

"(6) APPLICATION.—The term 'information blocking', with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

"(7) CLARIFICATION.—In carrying out this section, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this title.

"(b) INSPECTOR GENERAL AUTHORITY.—

"(1) IN GENERAL.—The inspector general of the Department of Health and Human Services (referred to in this section as the 'Inspector General') may investigate any claim that—

"(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

"(i) submitted a false attestation under section 3001(c)(5)(D)(vii); or

"(ii) engaged in information blocking;

"(B) a health care provider engaged in information blocking; or

"(C) a health information exchange or network engaged in information blocking.

"(2) PENALTIES.—

"(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

"(B) PROVIDERS.—Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

"(C) PROCEDURE.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b) of such section) shall apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1128A(a).

"(D) RECOVERED PENALTY FUNDS.—The amounts recovered under this paragraph shall be allocated as follows:

"(i) ANNUAL OPERATING EXPENSES.—Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

"(ii) APPLICATION TO OTHER PROGRAMS.—The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act, in such proportion as the Secretary determines appropriate.

"(E) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office of the Inspector General to carry out this section $10,000,000, to remain available until expended.

"(3) RESOLUTION OF CLAIMS.—

"(A) IN GENERAL.—The Office of the Inspector General, if such Office determines that a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) will resolve an information blocking claim, may refer such instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

"(B) LIMITATION ON LIABILITY.—If a health care provider or health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and Human Services pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

"(c) IDENTIFYING BARRIERS TO EXCHANGE OF CERTIFIED HEALTH INFORMATION TECHNOLOGY.—

"(1) TRUSTED EXCHANGE DEFINED.—In this section, the term 'trusted exchange' with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

"(2) GUIDANCE.—The National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal, governance, and security barriers that prevent the trusted exchange of electronic health information.

"(3) REFERRAL.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is technically capable of trusted exchange and under conditions when exchange is legally permissible.

"(d) ADDITIONAL PROVISIONS.—

"(1) INFORMATION SHARING PROVISIONS.—The National Coordinator may serve as a technical consultant to the Inspector General and the Federal Trade Commission for purposes of carrying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

"(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

"(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

"(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section; and

"(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

"(3) STANDARDIZED PROCESS.—

"(A) IN GENERAL.—The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

"(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

"(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

"(iii) any other act described in subsection (a).

"(B) COLLECTION OF INFORMATION.—The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

"(4) NONDUPLICATION OF PENALTY STRUCTURES.—In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before the date of the enactment of this section.".

42 USC 300jj–14 note.

SEC. 4005. LEVERAGING ELECTRONIC HEALTH RECORDS TO IMPROVE PATIENT CARE.

(a) REQUIREMENT RELATING TO REGISTRIES.—

(1) IN GENERAL.—To be certified in accordance with title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), electronic health records shall be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology, including clinician-led clinical data registries, that are also certified to be technically capable of receiving and accepting from, and where applicable, transmitting data to certified electronic health record technology in accordance with such standards.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the certification of registries beyond the technical capability to exchange data in accordance with applicable recognized standards.

(b) DEFINITION.—For purposes of this Act, the term "clinician-led clinical data registry" means a clinical data repository—

(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such

organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy;

(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;

(3) that provides feedback to participants who submit reports to the repository;

(4) that meets standards for data quality including—

(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and

(B) being subject to regular data checks or audits to verify completeness and validity; and

(5) that provides ongoing participant training and support.

(c) TREATMENT OF HEALTH INFORMATION TECHNOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—

(1) IN GENERAL.—In applying part C of title IX of the Public Health Service Act (42 U.S.C. 299b–21 et seq.), a health information technology developer shall be treated as a provider (as defined in section 921 of such Act) for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health information technology that could result in improved patient safety, health care quality, or health care outcomes.

(2) REPORT.—Not later than 4 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning best practices and current trends voluntarily provided, without identifying individual providers or disclosing or using protected health information or individually identifiable information, by patient safety organizations to improve the integration of health information technology into clinical practice.

SEC. 4006. EMPOWERING PATIENTS AND IMPROVING PATIENT ACCESS TO THEIR ELECTRONIC HEALTH INFORMATION.

(a) USE OF HEALTH INFORMATION EXCHANGES FOR PATIENT ACCESS.—Section 3009 of the Public Health Service Act (42 U.S.C. 300jj–19) is amended by adding at the end the following:

"(c) PROMOTING PATIENT ACCESS TO ELECTRONIC HEALTH INFORMATION THROUGH HEALTH INFORMATION EXCHANGES .—

"(1) IN GENERAL.—The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks and health care providers, health plans, and other appropriate entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

"(2) EDUCATION OF PROVIDERS.—The Secretary, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

"(A) educate health care providers on ways of leveraging the capabilities of health information exchanges

(or other relevant platforms) to provide patients with access to their electronic health information;

"(B) clarify misunderstandings by health care providers about using health information exchanges (or other relevant platforms) for patient access to electronic health information; and

"(C) to the extent practicable, educate providers about health information exchanges (or other relevant platforms) that employ some or all of the capabilities described in paragraph (1).

"(3) REQUIREMENTS.—In carrying out paragraph (1), the Secretary, in coordination with the Office for Civil Rights, shall issue guidance to health information exchanges related to best practices to ensure that the electronic health information provided to patients is—

"(A) private and secure;

"(B) accurate;

"(C) verifiable; and

"(D) where a patient's authorization to exchange information is required by law, easily exchanged pursuant to such authorization.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preempt State laws applicable to patient consent for the access of information through a health information exchange (or other relevant platform) that provide protections to patients that are greater than the protections otherwise provided for under applicable Federal law.

"(d) EFFORTS TO PROMOTE ACCESS TO HEALTH INFORMATION.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider involved.

"(e) ACCESSIBILITY OF PATIENT RECORDS.—

"(1) ACCESSIBILITY AND UPDATING OF INFORMATION.—

"(A) IN GENERAL.—The Secretary, in consultation with the National Coordinator, shall promote policies that ensure that a patient's electronic health information is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent.

"(B) UPDATING EDUCATION ON ACCESSING AND EXCHANGING PERSONAL HEALTH INFORMATION.—To promote awareness that an individual has a right of access to inspect, obtain a copy of, and transmit to a third party a copy of such individual's protected health information pursuant to the Health Information Portability and Accountability Act, Privacy Rule (subpart E of part 164 of title 45, Code of Federal Regulations), the Director of the Office for Civil Rights, in consultation with the National Coordinator, shall assist individuals and health care providers in understanding a patient's rights to access and protect personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including providing best practices

for requesting personal health information in a computable format, including using patient portals or third-party applications and common cases when a provider is permitted to exchange and provide access to health information.".

"(2) CERTIFYING USABILITY FOR PATIENTS.—In carrying out certification programs under section 3001(c)(5), the National Coordinator may require that—

"(A) the certification criteria support—

"(i) patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically;

"(ii) the patient's ability to electronically communicate patient-reported information (such as family history and medical history); and

"(iii) patient access to their personal electronic health information for research at the option of the patient; and

"(B) the HIT Advisory Committee develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.".

(b) ACCESS TO INFORMATION IN AN ELECTRONIC FORMAT.—Section 13405(e) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) by redesignating paragraph (2) as paragraph (3); and

(3) by inserting after paragraph (1), the following:

"(2) if the individual makes a request to a business associate for access to, or a copy of, protected health information about the individual, or if an individual makes a request to a business associate to grant such access to, or transmit such copy directly to, a person or entity designated by the individual, a business associate may provide the individual with such access or copy, which may be in an electronic form, or grant or transmit such access or copy to such person or entity designated by the individual; and".

SEC. 4007. GAO STUDY ON PATIENT MATCHING.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) review the policies and activities of the Office of the National Coordinator for Health Information Technology and other relevant stakeholders, which may include standards development organizations, experts in the technical aspects of health information technology, health information technology developers, providers of health services, health care suppliers, health care payers, health care quality organizations, States, health information technology policy experts, and other appropriate entities, to ensure appropriate patient matching to protect patient privacy and security with respect to electronic

health records and the exchange of electronic health information; and

(2) survey ongoing efforts related to the policies and activities described in paragraph (1) and the effectiveness of such efforts occurring in the private sector.

(b) AREAS OF CONCENTRATION.—In conducting the study under subsection (a), the Comptroller General shall—

(1) evaluate current methods used in certified electronic health records for patient matching based on performance related to factors such as—

(A) the privacy of patient information;

(B) the security of patient information;

(C) improving matching rates;

(D) reducing matching errors; and

(E) reducing duplicate records; and

(2) determine whether the Office of the National Coordinator for Health Information Technology could improve patient matching by taking steps including—

(A) defining additional data elements to assist in patient data matching;

(B) agreeing on a required minimum set of elements that need to be collected and exchanged;

(C) requiring electronic health records to have the ability to make certain fields required and use specific standards; and

(D) other options recommended by the relevant stakeholders consulted pursuant to subsection (a).

(c) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of Congress a report concerning the findings of the study conducted under subsection (a).

SEC. 4008. GAO STUDY ON PATIENT ACCESS TO HEALTH INFORMATION.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (referred to in this section as the "Comptroller General") shall build on prior Government Accountability Office studies and other literature review and conduct a study to review patient access to their own protected health information, including barriers to such patient access and complications or difficulties providers experience in providing access to patients. In conducting such study, the Comptroller General shall consider the increase in adoption of health information technology and the increasing prevalence of protected health information that is maintained electronically.

(2) AREAS OF CONCENTRATION.—In conducting the review under paragraph (1), the Comptroller General shall consider—

(A) instances when covered entities charge individuals, including patients, third parties, and health care providers, for record requests, including records that are requested in an electronic format;

(B) examples of the amounts and types of fees charged to individuals for record requests, including instances when the record is requested to be transmitted to a third party;

(C) the extent to which covered entities are unable to provide the access requested by individuals in the form

and format requested by the individual, including examples of such instances;

(D) instances in which third parties may request protected health information through patients' individual right of access, including instances where such requests may be used to circumvent appropriate fees that may be charged to third parties;

(E) opportunities that permit covered entities to charge appropriate fees to third parties for patient records while providing patients with access to their protected health information at low or no cost;

(F) the ability of providers to distinguish between requests originating from an individual that require limitation to a cost-based fee and requests originating from third parties that may not be limited to cost-based fees; and

(G) other circumstances that may inhibit the ability of providers to provide patients with access to their records, and the ability of patients to gain access to their records.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit a report to Congress on the findings of the study conducted under subsection (a).

SEC. 4009. IMPROVING MEDICARE LOCAL COVERAGE DETERMINATIONS.

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

"(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

"(i) Such determination in its entirety.

"(ii) Where and when the proposed determination was first made public.

"(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

"(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

"(v) An explanation of the rationale that supports such determination.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of enactment of this Act.

42 USC 1395y note.

SEC. 4010. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808 of the Social Security Act (42 U.S.C. 1395b–9) is amended by adding at the end the following new subsection:

"(d) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—

"(1) IN GENERAL.—Not later than 12 months after the date of enactment of this paragraph, the Secretary shall provide

for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

"(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

"(B) are with respect to coverage, coding, or payment under this title for such products.

"(2) APPLICATION.—The second sentence of subsection (c)(2) shall apply to the ombudsman under subparagraph (A) in the same manner as such sentence applies to the Medicare Beneficiary Ombudsman under subsection (c).".

SEC. 4011. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

"(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

"(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

"(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

"(B) the estimated amount of beneficiary liability applicable to the item or service.

"(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

"(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

"(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

"(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

"(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.".

SEC. 4012. TELEHEALTH SERVICES IN MEDICARE.

(a) PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.—Not later than 1 year after the date of enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall provide to the committees of jurisdiction of the House of Representatives and the Senate information on the following:

(1) The populations of Medicare beneficiaries, such as those who are dually eligible for the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) and those with chronic conditions, whose care may be improved most in terms of quality and efficiency by the expansion, in a manner that meets or exceeds the existing in-person standard of care under the Medicare program under such title XVIII, of telehealth services under section 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

(2) Activities by the Center for Medicare and Medicaid Innovation which examine the use of telehealth services in models, projects, or initiatives funded through section 1115A of such Act (42 U.S.C. 1315a).

(3) The types of high-volume services (and related diagnoses) under such title XVIII which might be suitable to be furnished using telehealth.

(4) Barriers that might prevent the expansion of telehealth services under section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) beyond such services that are in effect as of the date of enactment of this Act.

(b) PROVISION OF INFORMATION BY MEDPAC.—Not later than March 15, 2018, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall, using quantitative and qualitative research methods, provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—

(1) the telehealth services for which payment can be made, as of the date of enactment of this Act, under the fee-for-service program under parts A and B of title XVIII of such Act;

(2) the telehealth services for which payment can be made, as of such date, under private health insurance plans; and

(3) with respect to services identified under paragraph (2) but not under paragraph (1), ways in which payment for such services might be incorporated into such fee-for-service program (including any recommendations for ways to accomplish this incorporation).

(c) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) eligible originating sites should be expanded beyond those originating sites described in section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)); and

(2) any expansion of telehealth services under the Medicare program under title XVIII of such Act should—

(A) recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;

(B) meet or exceed the conditions of coverage and payment with respect to the Medicare program if the service

was furnished in person, including standards of care, unless specifically addressed in subsequent legislation; and

(C) involve clinically appropriate means to furnish such services.

TITLE V—SAVINGS

SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the Comprehensive Addiction and Recovery Act of 2016, is amended by striking "$140,000,000" and inserting "$270,000,000".

SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT.

Section 1903(i)(27) of the Social Security Act (42 U.S.C. 1396b(i)(27)) is amended by striking "January 1, 2019" and inserting "January 1, 2018".

SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CONTRACTS, AND OTHER AGREEMENTS.

(a) IN GENERAL.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended by adding at the end the following new subsections:

"(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

"(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

"(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

"(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

"(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

"(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than $10,000 for each specified claim; in cases under paragraph (2), not more than $50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than $50,000 for each false record or statement; in cases under paragraph (4), not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than $15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

"(p) The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

"(q) For purposes of this subsection and subsections (o) and (p):

"(1) The term 'Department' means the Department of Health and Human Services.

"(2) The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

"(3) The term 'other agreement' includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

"(4) The term 'program beneficiary' means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

"(5) The term 'recipient' includes a subrecipient or subcontractor.

"(6) The term 'specified State agency' means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

"(r) For purposes of this section, the term 'specified claim' means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

"(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

"(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department's behalf or to advance a Department program or interest, and if the Department—

"(A) provides or has provided any portion of the money or property requested or demanded; or

"(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

"(s) For purposes of subsection (o), the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.".

(b) CONFORMING AMENDMENTS.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended—

(1) in subsection (e), by inserting "or specified claim" after "claim" in the first sentence; and

(2) in subsection (f)—

(A) in the matter preceding paragraph (1)—

(i) by inserting "or specified claim (as defined in subsection (r))" after "district where the claim"; and

(ii) by inserting "(or, with respect to a person described in subsection (o), the person)" after "claimant"; and

(B) in the matter following paragraph (4), by inserting "(or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6))," after "or a State agency".

SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION DRUGS.

(a) TREATMENT OF INFUSION DRUGS FURNISHED THROUGH DURABLE MEDICAL EQUIPMENT.—Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—

(1) in subparagraph (C), by inserting "(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)" after "2005"; and

(2) in subparagraph (D)—

(A) by striking "infusion drugs" and inserting "infusion drugs or biologicals" each place it appears; and

(B) in clause (i)—

(i) by striking "2004" and inserting "2004, and before January 1, 2017"; and

(ii) by striking "for such drug".

(b) NONINCLUSION OF DME INFUSION DRUGS UNDER DME COMPETITIVE ACQUISITION PROGRAMS.—

(1) IN GENERAL.—Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)(A)) is amended—

(A) by striking "and excluding" and inserting ", excluding"; and

(B) by inserting before the period at the end the following: ", and excluding drugs and biologicals described in section 1842(o)(1)(D)".

(2) CONFORMING AMENDMENT.—Section 1842(o)(1)(D)(ii) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking "2007" and inserting "2007, and before the date of the enactment of the 21st Century Cures Act.".

SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF MEDICAID PROVIDERS.

(a) INCREASED OVERSIGHT AND REPORTING.—

(1) STATE REPORTING REQUIREMENTS.—Section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)) is amended—

(A) by redesignating paragraph (8) as paragraph (9); and

(B) by inserting after paragraph (7) the following new paragraph:

"(8) PROVIDER TERMINATIONS.—

"(A) IN GENERAL.—Beginning on July 1, 2018, in the case of a notification under subsection (a)(41) with respect to a termination for a reason specified in section 455.101 of title 42, Code of Federal Regulations (as in effect on November 1, 2015) or for any other reason specified by the Secretary, of the participation of a provider of services or any other person under the State plan (or under a waiver of the plan), the State, not later than 30 days after the effective date of such termination, submits to the Secretary with respect to any such provider or person, as appropriate—

"(i) the name of such provider or person;

"(ii) the provider type of such provider or person;

"(iii) the specialty of such provider's or person's practice;

"(iv) the date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of such provider or person (if applicable);

"(v) the reason for the termination;

"(vi) a copy of the notice of termination sent to the provider or person;

"(vii) the date on which such termination is effective, as specified in the notice; and

"(viii) any other information required by the Secretary.

"(B) EFFECTIVE DATE DEFINED.—For purposes of this paragraph, the term 'effective date' means, with respect

to a termination described in subparagraph (A), the later of—

"(i) the date on which such termination is effective, as specified in the notice of such termination; or

"(ii) the date on which all appeal rights applicable to such termination have been exhausted or the timeline for any such appeal has expired.".

(2) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u–2(d)) is amended by adding at the end the following new paragraph:

"(5) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—With respect to any contract with a managed care entity under section 1903(m) or 1905(t)(3) (as applicable), no later than July 1, 2018, such contract shall include a provision that providers of services or persons terminated (as described in section 1902(kk)(8)) from participation under this title, title XVIII, or title XXI shall be terminated from participating under this title as a provider in any network of such entity that serves individuals eligible to receive medical assistance under this title.".

(3) TERMINATION NOTIFICATION DATABASE.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following new subsection:

"(ll) TERMINATION NOTIFICATION DATABASE.—In the case of a provider of services or any other person whose participation under this title or title XXI is terminated (as described in subsection (kk)(8)), the Secretary shall, not later than 30 days after the date on which the Secretary is notified of such termination under subsection (a)(41) (as applicable), review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 1395cc note; Public Law 111–148).".

(4) NO FEDERAL FUNDS FOR ITEMS AND SERVICES FURNISHED BY TERMINATED PROVIDERS.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(A) in subsection (i)(2)—

(i) in subparagraph (A), by striking the comma at the end and inserting a semicolon;

(ii) in subparagraph (B), by striking "or" at the end; and

(iii) by adding at the end the following new subparagraph:

"(D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date on which such termination is included in the database or other system under section 1902(ll); or"; and

(B) in subsection (m), by inserting after paragraph (2) the following new paragraph:

"(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

"(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

"(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).".

(5) DEVELOPMENT OF UNIFORM TERMINOLOGY FOR REASONS FOR PROVIDER TERMINATION.—Not later than July 1, 2017, the Secretary of Health and Human Services shall, in consultation with the heads of State agencies administering State Medicaid plans (or waivers of such plans), issue regulations establishing uniform terminology to be used with respect to specifying reasons under subparagraph (A)(v) of paragraph (8) of section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)), as added by paragraph (1), for the termination (as described in such paragraph (8)) of the participation of certain providers in the Medicaid program under title XIX of such Act or the Children's Health Insurance Program under title XXI of such Act. 42 USC 1396a note.

(6) CONFORMING AMENDMENT.—Section 1902(a)(41) of the Social Security Act (42 U.S.C. 1396a(a)(41)) is amended by striking "provide that whenever" and inserting "provide, in accordance with subsection (kk)(8) (as applicable), that whenever".

(b) INCREASING AVAILABILITY OF MEDICAID PROVIDER INFORMATION.—

(1) FFS PROVIDER ENROLLMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended by inserting after paragraph (77) the following new paragraph:

"(78) provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable);".

(2) MANAGED CARE PROVIDER ENROLLMENT.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u–2(d)), as amended by subsection (a)(2), is amended by adding at the end the following new paragraph:

"(6) ENROLLMENT OF PARTICIPATING PROVIDERS.—

"(A) IN GENERAL.—Beginning not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, refers, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall

include providing to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as requiring a provider described in such subparagraph to provide services to individuals who are not enrolled with a managed care entity under this title.".

(c) COORDINATION WITH CHIP.—

(1) IN GENERAL.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (B), (C), (D), (E), (F), (G), (H), (I), (J), (K), (L), (M), (N), and (O) as subparagraphs (D), (E), (F), (G), (H), (I), (J), (K), (M), (N), (O), (P), (Q), and (R), respectively;

(B) by inserting after subparagraph (A) the following new subparagraphs:

"(B) Section 1902(a)(39) (relating to termination of participation of certain providers).

"(C) Section 1902(a)(78) (relating to enrollment of providers participating in State plans providing medical assistance on a fee-for-service basis).";

(C) by inserting after subparagraph (K) (as redesignated by subparagraph (A)) the following new subparagraph:

"(L) Section 1903(m)(3) (relating to limitation on payment with respect to managed care).''; and

(D) in subparagraph (P) (as redesignated by subparagraph (A)), by striking "(a)(2)(C) and (h)" and inserting "(a)(2)(C) (relating to Indian enrollment), (d)(5) (relating to contract requirement for managed care entities), (d)(6) (relating to enrollment of providers participating with a managed care entity), and (h) (relating to special rules with respect to Indian enrollees, Indian health care providers, and Indian managed care entities)".

(2) EXCLUDING FROM MEDICAID PROVIDERS EXCLUDED FROM CHIP.—Section 1902(a)(39) of the Social Security Act (42 U.S.C. 1396a(a)(39)) is amended by striking "title XVIII or any other State plan under this title" and inserting "title XVIII, any other State plan under this title (or waiver of the plan), or any State child health plan under title XXI (or waiver of the plan) and such termination is included by the Secretary in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act".

42 USC 1396a note.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as changing or limiting the appeal rights of providers or the process for appeals of States under the Social Security Act.

(e) OIG REPORT.—Not later than March 31, 2020, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the implementation of the amendments made by this section. Such report shall include the following:

(1) An assessment of the extent to which providers who are included under subsection (ll) of section 1902 of the Social Security Act (42 U.S.C. 1396a) (as added by subsection (a)(3))

in the database or similar system referred to in such subsection are terminated (as described in paragraph (8) of subsection (kk) of such section, as added by subsection (a)(1)) from participation in all State plans under title XIX of such Act (or waivers of such plans).

(2) Information on the amount of Federal financial participation paid to States under section 1903 of such Act in violation of the limitation on such payment specified in subparagraph (D) of subsection (i)(2) of such section and paragraph (3) of subsection (m) of such section, as added by subsection (a)(4).

(3) An assessment of the extent to which contracts with managed care entities under title XIX of such Act comply with the requirement specified in paragraph (5) of section 1932(d) of such Act, as added by subsection (a)(2).

(4) An assessment of the extent to which providers have been enrolled under section 1902(a)(78) or 1932(d)(6)(A) of such Act (42 U.S.C. 1396a(a)(78), 1396u–2(d)(6)(A)) with State agencies administering State plans under title XIX of such Act (or waivers of such plans).

SEC. 5006. REQUIRING PUBLICATION OF FEE-FOR-SERVICE PROVIDER DIRECTORY.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (81), by striking "and" at the end;

(2) in paragraph (82), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (82) the following new paragraph:

"(83) provide that, not later than January 1, 2017, in the case of a State plan (or waiver of the plan) that provides medical assistance on a fee-for-service basis or through a primary care case-management system described in section 1915(b)(1) (other than a primary care case management entity (as defined by the Secretary)), the State shall publish (and update on at least an annual basis) on the public website of the State agency administering the State plan, a directory of the physicians described in subsection (mm) and, at State option, other providers described in such subsection that—

"(A) includes—

"(i) with respect to each such physician or provider—

"(I) the name of the physician or provider;

"(II) the specialty of the physician or provider;

"(III) the address at which the physician or provider provides services; and

"(IV) the telephone number of the physician or provider; and

"(ii) with respect to any such physician or provider participating in such a primary care case-management system, information regarding—

"(I) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title; and

"(II) the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the

skilled medical interpreter providing interpretation services at the physician's or provider's office; and

"(B) may include, at State option, with respect to each such physician or provider—

"(i) the Internet website of such physician or provider; or

"(ii) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title.".

(b) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 5005(a)(3), is further amended by adding at the end the following new subsection:

"(mm) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—A physician or provider described in this subsection is—

"(1) in the case of a physician or provider of a provider type for which the State agency, as a condition on receiving payment for items and services furnished by the physician or provider to individuals eligible to receive medical assistance under the State plan, requires the enrollment of the physician or provider with the State agency, a physician or a provider that—

"(A) is enrolled with the agency as of the date on which the directory is published or updated (as applicable) under subsection (a)(83); and

"(B) received payment under the State plan in the 12-month period preceding such date; and

"(2) in the case of a physician or provider of a provider type for which the State agency does not require such enrollment, a physician or provider that received payment under the State plan (or a waiver of the plan) in the 12-month period preceding the date on which the directory is published or updated (as applicable) under subsection (a)(83).".

42 USC 1396a note.

(c) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—The amendment made by subsection (a) shall not be construed to apply in the case of a State (as defined for purposes of title XIX of the Social Security Act) in which all the individuals enrolled in the State plan under such title (or under a waiver of such plan), other than individuals described in paragraph (2), are enrolled with a medicaid managed care organization (as defined in section 1903(m)(1)(A) of such Act (42 U.S.C. 1396b(m)(1)(A))), including prepaid inpatient health plans and prepaid ambulatory health plans (as defined by the Secretary of Health and Human Services).

(2) INDIVIDUALS DESCRIBED.—An individual described in this paragraph is an individual who is an Indian (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) or an Alaska Native.

42 USC 1396a note.

(d) EXCEPTION FOR STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), which the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet one or more additional requirements imposed by amendments made by this section, the respective plan shall not be regarded as failing to comply with the requirements of such title

solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS TRUSTS.

(a) IN GENERAL.—Section 1917(d)(4)(A) of the Social Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended by inserting "the individual," after "for the benefit of such individual by".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to trusts established on or after the date of the enactment of this Act.

42 USC 1396p note.

SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPATION WITH RESPECT TO EXPENDITURES UNDER MEDICAID FOR AGENTS USED FOR COSMETIC PURPOSES OR HAIR GROWTH.

(a) IN GENERAL.—Section 1903(i)(21) of the Social Security Act (42 U.S.C. 1396b(i)(21)) is amended by inserting "section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and" after "drugs described in".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to calendar quarters beginning on or after the date of the enactment of this Act.

42 USC 1396b note.

SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC HEALTH FUND.

Section 4002(b) of the Patient Protection and Affordable Care Act (42 U.S.C. 300u–11(b)) is amended—

(1) in paragraph (3), by striking "$1,250,000,000" and inserting "$900,000,000";

(2) in paragraph (4), by striking "$1,500,000,000" and inserting "$1,000,000,000"; and

(3) by striking paragraph (5) and inserting the following:

"(5) for fiscal year 2022, $1,500,000,000;

"(6) for fiscal year 2023, $1,000,000,000;

"(7) for fiscal year 2024, $1,700,000,000; and

"(8) for fiscal year 2025 and each fiscal year thereafter, $2,000,000,000.".

SEC. 5010. STRATEGIC PETROLEUM RESERVE DRAWDOWN.

(a) DRAWDOWN AND SALE.—

42 USC 6241 note.

(1) IN GENERAL.—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), except as provided in subsections (b) and (c), the Secretary of Energy shall drawdown and sell from the Strategic Petroleum Reserve—

(A) 10,000,000 barrels of crude oil during fiscal year 2017;

(B) 9,000,000 barrels of crude oil during fiscal year 2018; and

(C) 6,000,000 barrels of crude oil during fiscal year 2019.

(2) DEPOSIT OF AMOUNTS RECEIVED FROM SALE.—Amounts received from a sale under paragraph (1) shall be deposited in the general fund of the Treasury during the fiscal year in which the sale occurs.

42 USC 6241 note.

(b) EMERGENCY PROTECTION.—The Secretary shall not draw down and sell crude oil under this section in quantities that would limit the authority to sell petroleum products under section 161(h) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)) in the full quantity authorized by that subsection.

(c) STRATEGIC PETROLEUM DRAWDOWN LIMITATIONS.—Subparagraphs (C) and (D) of section 161(h)(2) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)(2)(C) and (D)) are both amended by striking "500,000,000" and inserting "450,000,000".

SEC. 5011. RESCISSION OF PORTION OF ACA TERRITORY FUNDING.

Of the unobligated amounts available under section 1323(c)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 18043(c)(1)), $464,000,000 is rescinded immediately upon the date of the enactment of this Act.

SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION THERAPY.

(a) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (EE);

(B) by inserting "and" at the end of subparagraph (FF); and

(C) by inserting at the end the following new subparagraph:

"(GG) home infusion therapy (as defined in subsection (iii)(1));"; and

(2) by adding at the end the following new subsection:

"(iii) HOME INFUSION THERAPY.—(1) The term 'home infusion therapy' means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

"(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

"(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

"(2) The items and services described in this paragraph are the following:

"(A) Professional services, including nursing services, furnished in accordance with the plan.

"(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

"(3) For purposes of this subsection:

"(A) The term 'applicable provider' means—

"(i) a physician;

"(ii) a nurse practitioner; and

"(iii) a physician assistant.

"(B) The term 'home' means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

"(C) The term 'home infusion drug' means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

"(i) Insulin pump systems.

"(ii) A self-administered drug or biological on a self-administered drug exclusion list.

"(D)(i) The term 'qualified home infusion therapy supplier' means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

"(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

"(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

"(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

"(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

"(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.".

(b) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 4011, is further amended by adding at the end the following new subsection:

"(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

"(1) PAYMENT.—

"(A) SINGLE PAYMENT.—

"(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

"(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single

payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

"(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

"(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

"(i) a geographic wage index and other costs that may vary by region; and

"(ii) patient acuity and complexity of drug administration.

"(C) DISCRETIONARY ADJUSTMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

"(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

"(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

"(3) ANNUAL UPDATES.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

"(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

"(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply

prior authorization for home infusion therapy services under section 1861(iii)(1).

"(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

"(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

"(i) The ability of the organization to conduct timely reviews of accreditation applications.

"(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

"(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

"(iv) Such other factors as the Secretary determines appropriate.

"(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

"(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

"(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

"(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

"(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

"(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.".

(c) CONFORMING AMENDMENTS.—

(1) PAYMENT REFERENCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking "and" before "(AA)"; and

(B) by inserting before the semicolon at the end the following: ", and (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u)".

(2) DIRECT PAYMENT.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)) is amended—

(A) by striking "and" before "(H)"; and

(B) by inserting before the period at the end the following: ", and (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier".

(3) EXCLUSION FROM HOME HEALTH SERVICES.—Section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) is amended, in the first sentence, by inserting the following before the period at the end: "and home infusion therapy (as defined in subsection (iii)(i))".

42 USC 13951 note.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2021.

Helping Families in Mental Health Crisis Reform Act of 2016.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

42 USC 201 note.

SEC. 6000. SHORT TITLE.

This division may be cited as the "Helping Families in Mental Health Crisis Reform Act of 2016".

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

SEC. 6001. ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE.

(a) ASSISTANT SECRETARY.—Section 501(c) of the Public Health Service Act (42 U.S.C. 290aa(c)) is amended to read as follows:

"(c) ASSISTANT SECRETARY AND DEPUTY ASSISTANT SECRETARY.—

"(1) ASSISTANT SECRETARY.—The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this title referred to as the 'Assistant Secretary') who shall be appointed by the President, by and with the advice and consent of the Senate.

"(2) DEPUTY ASSISTANT SECRETARY.—The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.".

(b) TRANSFER OF AUTHORITIES.—The Secretary of Health and Human Services shall delegate to the Assistant Secretary for Mental Health and Substance Use all duties and authorities that— 42 USC 290aa note.

(1) as of the day before the date of enactment of this Act, were vested in the Administrator of the Substance Abuse and Mental Health Services Administration; and

(2) are not terminated by this Act.

(c) CONFORMING AMENDMENTS.—Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by the previous provisions of this section, is further amended—

(1) by striking "Administrator of the Substance Abuse and Mental Health Services Administration" each place it appears and inserting "Assistant Secretary for Mental Health and Substance Use"; and

(2) by striking "Administrator" or "ADMINISTRATOR" each place it appears (including in any headings) and inserting "Assistant Secretary" or "ASSISTANT SECRETARY", respectively, except where the term "Administrator" appears—

(A) in each of subsections (e) and (f) of section 501 of such Act (42 U.S.C. 290aa), including the headings of such subsections, within the term "Associate Administrator";

(B) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term "Administrator of the Health Resources and Services Administration";

(C) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term "Administrator of the Centers for Medicare & Medicaid Services";

(D) in section 519B(c)(1)(B) of such Act (42 U.S.C. 290bb–25b(c)(1)(B)), within the term "Administrator of the National Highway Traffic Safety Administration"; or

(E) in each of sections 519B(c)(1)(B), 520C(a), and 520D(a) of such Act (42 U.S.C. 290bb–25b(c)(1)(B), 290bb–34(a), 290bb–35(a)), within the term "Administrator of the Office of Juvenile Justice and Delinquency Prevention".

(d) REFERENCES.—After executing subsections (a), (b), and (c), any reference in statute, regulation, or guidance to the Administrator of the Substance Abuse and Mental Health Services Administration shall be construed to be a reference to the Assistant Secretary for Mental Health and Substance Use. 42 USC 290aa note.

SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by section 6001, is further amended—

(1) in subsection (b)—

(A) in the subsection heading, by striking "AGENCIES" and inserting "CENTERS"; and

(B) in the matter preceding paragraph (1), by striking "entities" and inserting "Centers";

(2) in subsection (d)—

(A) in paragraph (1)—

(i) by striking "agencies" each place the term appears and inserting "Centers"; and

(ii) by striking "such agency" and inserting "such Center";

(B) in paragraph (2)—

(i) by striking "agencies" and inserting "Centers";

(ii) by striking "with respect to substance abuse" and inserting "with respect to substance use disorders"; and

(iii) by striking "and individuals who are substance abusers" and inserting "and individuals with substance use disorders";

(C) in paragraph (5), by striking "substance abuse" and inserting "substance use disorder";

(D) in paragraph (6)—

(i) by striking "the Centers for Disease Control" and inserting "the Centers for Disease Control and Prevention,";

(ii) by striking "Administration develop" and inserting "Administration, develop";

(iii) by striking "HIV or tuberculosis among substance abusers and individuals with mental illness" and inserting "HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders,"; and

(iv) by striking "illnesses" at the end and inserting "diseases or disorders";

(E) in paragraph (7), by striking "abuse utilizing anti-addiction medications, including methadone" and inserting "use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders";

(F) in paragraph (8)—

(i) by striking "Agency for Health Care Policy Research" and inserting "Agency for Healthcare Research and Quality"; and

(ii) by striking "treatment and prevention" and inserting "prevention and treatment";

(G) in paragraph (9)—

(i) by inserting "and maintenance" after "development";

(ii) by striking "Agency for Health Care Policy Research" and inserting "Agency for Healthcare Research and Quality"; and

(iii) by striking "treatment and prevention services" and inserting "prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration";

(H) in paragraph (10), by striking "abuse" and inserting "use disorder";

(I) by striking paragraph (11) and inserting the following:

"(11) work with relevant agencies of the Department of Health and Human Services on integrating mental health promotion and substance use disorder prevention with general health promotion and disease prevention and integrating mental and substance use disorders treatment services with physical health treatment services;";

(J) in paragraph (13)—

(i) in the matter preceding subparagraph (A), by striking "this title, assure that" and inserting "this title or part B of title XIX, or grant programs otherwise funded by the Administration";

(ii) in subparagraph (A)—

(I) by inserting "require that" before "all grants"; and

(II) by striking "and" at the end;

(iii) by redesignating subparagraph (B) as subparagraph (C);

(iv) by inserting after subparagraph (A) the following:

"(B) ensure that the director of each Center of the Administration consistently documents the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;";

(v) in subparagraph (C), as so redesignated—

(I) by inserting "require that" before "all grants"; and

(II) in clause (ii), by inserting "and" after the semicolon at the end; and

(vi) by adding at the end the following:

"(D) inform a State when any funds are awarded through such a grant to any entity within such State;";

(K) in paragraph (16), by striking "abuse and mental health information" and inserting "use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders,";

(L) in paragraph (17)—

(i) by striking "substance abuse" and inserting "substance use disorder"; and

(ii) by striking "and" at the end;

(M) in paragraph (18), by striking the period and inserting a semicolon; and

(N) by adding at the end the following:

"(19) consult with State, local, and tribal governments, nongovernmental entities, and individuals with mental illness, particularly adults with a serious mental illness, children with a serious emotional disturbance, and the family members of

such adults and children, with respect to improving community-based and other mental health services;

"(20) collaborate with the Secretary of Defense and the Secretary of Veterans Affairs to improve the provision of mental and substance use disorder services provided by the Department of Defense and the Department of Veterans Affairs to members of the Armed Forces, veterans, and the family members of such members and veterans, including through the provision of services using the telehealth capabilities of the Department of Defense and the Department of Veterans Affairs;

"(21) collaborate with the heads of relevant Federal agencies and departments, States, communities, and nongovernmental experts to improve mental and substance use disorders services for chronically homeless individuals, including by designing strategies to provide such services in supportive housing;

"(22) work with States and other stakeholders to develop and support activities to recruit and retain a workforce addressing mental and substance use disorders;

"(23) collaborate with the Attorney General and representatives of the criminal justice system to improve mental and substance use disorders services for individuals who have been arrested or incarcerated;

"(24) after providing an opportunity for public input, set standards for grant programs under this title for mental and substance use disorders services and prevention programs, which standards may address—

"(A) the capacity of the grantee to implement the award;

"(B) requirements for the description of the program implementation approach;

"(C) the extent to which the grant plan submitted by the grantee as part of its application must explain how the grantee will reach the population of focus and provide a statement of need, which may include information on how the grantee will increase access to services and a description of measurable objectives for improving outcomes;

"(D) the extent to which the grantee must collect and report on required performance measures; and

"(E) the extent to which the grantee is proposing to use evidence-based practices; and

"(25) advance, through existing programs, the use of performance metrics, including those based on the recommendations on performance metrics from the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016."; and

(3) in subsection (m), by adding at the end the following:

"(4) EMERGENCY RESPONSE.—Amounts made available for carrying out this subsection shall remain available through the end of the fiscal year following the fiscal year for which such amounts are appropriated.".

SEC. 6003. CHIEF MEDICAL OFFICER.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 and 6002, is further amended—

(1) by redesignating subsections (g) through (j) and subsections (k) through (o) as subsections (h) through (k) and subsections (m) through (q), respectively;

(2) in subsection (e)(3)(C), by striking "subsection (k)" and inserting "subsection (m)";

(3) in subsection (f)(2)(C)(iii), by striking "subsection (k)" and inserting "subsection (m)"; and

(4) by inserting after subsection (f) the following:

"(g) CHIEF MEDICAL OFFICER.—

"(1) IN GENERAL.—The Assistant Secretary, with the approval of the Secretary, shall appoint a Chief Medical Officer to serve within the Administration.

"(2) ELIGIBLE CANDIDATES.—The Assistant Secretary shall select the Chief Medical Officer from among individuals who—

"(A) have a doctoral degree in medicine or osteopathic medicine;

"(B) have experience in the provision of mental or substance use disorder services;

"(C) have experience working with mental or substance use disorder programs;

"(D) have an understanding of biological, psychosocial, and pharmaceutical treatments of mental or substance use disorders; and

"(E) are licensed to practice medicine in one or more States.

"(3) DUTIES.—The Chief Medical Officer shall—

"(A) serve as a liaison between the Administration and providers of mental and substance use disorders prevention, treatment, and recovery services;

"(B) assist the Assistant Secretary in the evaluation, organization, integration, and coordination of programs operated by the Administration;

"(C) promote evidence-based and promising best practices, including culturally and linguistically appropriate practices, as appropriate, for the prevention and treatment of, and recovery from, mental and substance use disorders, including serious mental illness and serious emotional disturbances;

"(D) participate in regular strategic planning with the Administration;

"(E) coordinate with the Assistant Secretary for Planning and Evaluation to assess the use of performance metrics to evaluate activities within the Administration related to mental and substance use disorders; and

"(F) coordinate with the Assistant Secretary to ensure mental and substance use disorders grant programs within the Administration consistently utilize appropriate performance metrics and evaluation designs.".

SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL HEALTH PROGRAMS.

Section 505 of the Public Health Service Act (42 U.S.C. 290aa–4), as amended by section 6001(c), is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY.";

(2) by redesignating subsections (a) through (d) as subsections (b) through (e), respectively;

(3) before subsection (b), as redesignated by paragraph (2), by inserting the following:

"(a) IN GENERAL.—The Assistant Secretary shall maintain within the Administration a Center for Behavioral Health Statistics and Quality (in this section referred to as the 'Center'). The Center shall be headed by a Director (in this section referred to as the 'Director') appointed by the Secretary from among individuals with extensive experience and academic qualifications in research and analysis in behavioral health care or related fields.";

(4) in subsection (b), as redesignated by paragraph (2)—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(B) by striking "The Secretary, acting" and all that follows through "year on—" and inserting "The Director shall—

"(1) coordinate the Administration's integrated data strategy, including by collecting data each year on—";

(C) in the subparagraph (B), as redesignated by subparagraph (A), by striking "Assistant Secretary" and inserting "Director"; and

(D) by adding at the end the following new paragraphs:

"(2) provide statistical and analytical support for activities of the Administration;

"(3) recommend a core set of performance metrics to evaluate activities supported by the Administration; and

"(4) coordinate with the Assistant Secretary, the Assistant Secretary for Planning and Evaluation, and the Chief Medical Officer appointed under section 501(g), as appropriate, to improve the quality of services provided by programs of the Administration and the evaluation of activities carried out by the Administration.".

(5) in subsection (c), as so redesignated—

(A) by striking "With respect to the activities" and inserting "MENTAL HEALTH.—With respect to the activities";

(B) by striking "Assistant Secretary" each place it appears and inserting "Director"; and

(C) by striking "subsection (a)" and inserting "subsection (b)(1)";

(6) in subsection (d), as so redesignated—

(A) by striking the subsection designation and all that follows through "With respect to the activities" and inserting the following:

"(d) SUBSTANCE ABUSE.—

"(1) IN GENERAL.—With respect to the activities";

(B) in paragraph (1)—

(i) in the matter before subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)(1)"; and

(II) by striking "Assistant Secretary" each place it appears and inserting "Director"; and

(ii) in subparagraph (B), by inserting "in coordination with the Centers for Disease Control and Prevention" before the semicolon at the end; and

(C) in paragraph (2), by striking "ANNUAL SURVEYS" and inserting "ANNUAL SURVEYS; PUBLIC AVAILABILITY OF DATA.—Annual surveys"; and

(7) in subsection (e), as so redesignated—

(A) by striking "After consultation" and inserting "CONSULTATION.—After consultation"; and

(B) by striking "Assistant Secretary shall develop" and inserting "Assistant Secretary shall use existing standards and best practices to develop".

SEC. 6005. STRATEGIC PLAN.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 through 6003, is further amended by inserting after subsection (k), as redesignated by section 6003, the following:

"(l) STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall develop and carry out a strategic plan in accordance with this subsection for the planning and operation of activities carried out by the Administration, including evidence-based programs.

"(2) COORDINATION.—In developing and carrying out the strategic plan under this subsection, the Assistant Secretary shall take into consideration the findings and recommendations of the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016 and the report of the Interdepartmental Serious Mental Illness Coordinating Committee under section 6031 of such Act.

"(3) PUBLICATION OF PLAN.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall—

"(A) submit the strategic plan developed under paragraph (1) to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

"(B) post such plan on the Internet website of the Administration.

"(4) CONTENTS.—The strategic plan developed under paragraph (1) shall—

"(A) identify strategic priorities, goals, and measurable objectives for mental and substance use disorders activities and programs operated and supported by the Administration, including priorities to prevent or eliminate the burden of mental and substance use disorders;

"(B) identify ways to improve the quality of services for individuals with mental and substance use disorders, and to reduce homelessness, arrest, incarceration, violence, including self-directed violence, and unnecessary hospitalization of individuals with a mental or substance use disorder, including adults with a serious mental illness or children with a serious emotional disturbance;

"(C) ensure that programs provide, as appropriate, access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services, including culturally and linguistically appropriate services, as appropriate, for individuals with a mental or substance use disorder;

"(D) identify opportunities to collaborate with the Health Resources and Services Administration to develop or improve—

"(i) initiatives to encourage individuals to pursue careers (especially in rural and underserved areas and with rural and underserved populations) as psychiatrists, including child and adolescent psychiatrists, psychologists, psychiatric nurse practitioners, physician assistants, clinical social workers, certified peer support specialists, licensed professional counselors, or other licensed or certified mental health or substance use disorder professionals, including such professionals specializing in the diagnosis, evaluation, or treatment of adults with a serious mental illness or children with a serious emotional disturbance; and

"(ii) a strategy to improve the recruitment, training, and retention of a workforce for the treatment of individuals with mental or substance use disorders, or co-occurring disorders;

"(E) identify opportunities to improve collaboration with States, local governments, communities, and Indian tribes and tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act); and

"(F) specify a strategy to disseminate evidence-based and promising best practices related to prevention, diagnosis, early intervention, treatment, and recovery services related to mental illness, particularly for adults with a serious mental illness and children with a serious emotional disturbance, and for individuals with a substance use disorder.".

SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.

(a) IN GENERAL.—Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as so amended, is further amended by amending subsection (m), as redesignated by section 6003, to read as follows:

"(m) BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than September 30, 2020, and every 2 years thereafter, the Assistant Secretary shall prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and post on the Internet website of the Administration, a report containing at a minimum—

"(1) a review of activities conducted or supported by the Administration, including progress toward strategic priorities, goals, and objectives identified in the strategic plan developed under subsection (l);

"(2) an assessment of programs and activities carried out by the Assistant Secretary, including the extent to which programs and activities under this title and part B of title XIX meet identified goals and performance measures developed for the respective programs and activities;

"(3) a description of the progress made in addressing gaps in mental and substance use disorders prevention, treatment, and recovery services and improving outcomes by the Administration, including with respect to serious mental illnesses, serious emotional disturbances, and co-occurring disorders;

"(4) a description of the manner in which the Administration coordinates and partners with other Federal agencies and departments related to mental and substance use disorders, including activities related to—

"(A) the implementation and dissemination of research findings into improved programs, including with respect to how advances in serious mental illness and serious emotional disturbance research have been incorporated into programs;

"(B) the recruitment, training, and retention of a mental and substance use disorders workforce;

"(C) the integration of mental disorder services, substance use disorder services, and physical health services;

"(D) homelessness; and

"(E) veterans;

"(5) a description of the manner in which the Administration promotes coordination by grantees under this title, and part B of title XIX, with State or local agencies; and

"(6) a description of the activities carried out under section 501A(e), with respect to mental and substance use disorders, including—

"(A) the number and a description of grants awarded;

"(B) the total amount of funding for grants awarded;

"(C) a description of the activities supported through such grants, including outcomes of programs supported; and

"(D) information on how the National Mental Health and Substance Use Policy Laboratory is consulting with the Assistant Secretary for Planning and Evaluation and collaborating with the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Behavioral Health Statistics and Quality, and the Center for Mental Health Services to carry out such activities; and

"(7) recommendations made by the Assistant Secretary for Planning and Evaluation under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 to improve programs within the Administration, and actions taken in response to such recommendations to improve programs within the Administration.

The Assistant Secretary may meet reporting requirements established under this title by providing the contents of such reports as an addendum to the biennial report established under this subsection, notwithstanding the timeline of other reporting requirements in this title. Nothing in this subsection shall be construed to alter the content requirements of such reports or authorize the Assistant Secretary to alter the timeline of any such reports

to be less frequent than biennially, unless as specified in this title.".

(b) CONFORMING AMENDMENT.—Section 508(p) of the Public Health Service Act (42 U.S.C. 290bb–1(p)) is amended by striking "section 501(k)" and inserting "section 501(m)".

SEC. 6007. AUTHORITIES OF CENTERS FOR MENTAL HEALTH SERVICES, SUBSTANCE ABUSE PREVENTION, AND SUBSTANCE ABUSE TREATMENT.

(a) CENTER FOR MENTAL HEALTH SERVICES.—Section 520(b) of the Public Health Service Act (42 U.S.C. 290bb–31(b)) is amended—

(1) by redesignating paragraphs (3) through (15) as paragraphs (4) through (16), respectively;

(2) by inserting after paragraph (2) the following:

"(3) collaborate with the Director of the National Institute of Mental Health and the Chief Medical Officer, appointed under section 501(g), to ensure that, as appropriate, programs related to the prevention and treatment of mental illness and the promotion of mental health and recovery support are carried out in a manner that reflects the best available science and evidence-based practices, including culturally and linguistically appropriate services, as appropriate;";

(3) in paragraph (5), as so redesignated, by inserting ", including through programs that reduce risk and promote resiliency" before the semicolon;

(4) in paragraph (6), as so redesignated, by inserting "in collaboration with the Director of the National Institute of Mental Health," before "develop";

(5) in paragraph (8), as so redesignated, by inserting ", increase meaningful participation of individuals with mental illness in programs and activities of the Administration," before "and protect the legal";

(6) in paragraph (10), as so redesignated, by striking "professional and paraprofessional personnel pursuant to section 303" and inserting "health paraprofessional personnel and health professionals";

(7) in paragraph (11), as so redesignated, by inserting "and tele-mental health" after "rural mental health";

(8) in paragraph (12), as so redesignated, by striking "establish a clearinghouse for mental health information to assure the widespread dissemination of such information" and inserting "disseminate mental health information, including evidence-based practices,";

(9) in paragraph (15), as so redesignated, by striking "and" at the end;

(10) in paragraph (16), as so redesignated, by striking the period and inserting "; and"; and

(11) by adding at the end the following:

"(17) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded.".

(b) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE PREVENTION.—Section 515 of the Public Health Service Act (42 U.S.C. 290bb–21) is amended—

(1) in the section heading, by striking "OFFICE" and inserting "CENTER";

(2) in subsection (a)—

(A) by striking "an Office" and inserting "a Center"; and

(B) by striking "The Office" and inserting "The Prevention Center"; and

(3) in subsection (b)—

(A) in paragraph (1), by inserting "through the reduction of risk and the promotion of resiliency" before the semicolon;

(B) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), respectively;

(C) by inserting after paragraph (2) the following:

"(3) collaborate with the Director of the National Institute on Drug Abuse, the Director of the National Institute on Alcohol Abuse and Alcoholism, and States to promote the study of substance abuse prevention and the dissemination and implementation of research findings that will improve the delivery and effectiveness of substance abuse prevention activities;";

(D) in paragraph (4), as so redesignated, by striking "literature on the adverse effects of cocaine free base (known as crack)" and inserting "educational information on the effects of drugs abused by individuals, including drugs that are emerging as abused drugs";

(E) in paragraph (6), as so redesignated—

(i) by striking "substance abuse counselors" and inserting "health professionals who provide substance use and misuse prevention and treatment services"; and

(ii) by striking "drug abuse education, prevention," and inserting "illicit drug use education and prevention";

(F) by amending paragraph (7), as so redesignated, to read as follows:

"(7) in cooperation with the Director of the Centers for Disease Control and Prevention, develop and disseminate educational materials to increase awareness for individuals at greatest risk for substance use disorders to prevent the transmission of communicable diseases, such as HIV, hepatitis, tuberculosis, and other communicable diseases;";

(G) in paragraph (9), as so redesignated—

(i) by striking "to discourage" and inserting "that reduce the risk of"; and

(ii) by inserting before the semicolon "and promote resiliency";

(H) in paragraph (11), as so redesignated, by striking "and" after the semicolon;

(I) in paragraph (12), as so redesignated, by striking the period and inserting a semicolon; and

(J) by adding at the end the following:

"(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

"(14) assist and support States in preventing illicit drug use, including emerging illicit drug use issues.".

(c) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE TREATMENT.—Section 507 of the Public Health Service Act (42 U.S.C. 290bb) is amended—

(1) in subsection (a)—

(A) by striking "treatment of substance abuse" and inserting "treatment of substance use disorders"; and

(B) by striking "abuse treatment systems" and inserting "use disorder treatment systems"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by striking "abuse" and inserting "use disorder";

(C) in paragraph (4), by striking "individuals who abuse drugs" and inserting "individuals who illicitly use drugs";

(D) in paragraph (9), by striking "carried out by the Director";

(E) by striking paragraph (10);

(F) by redesignating paragraphs (11) through (14) as paragraphs (10) through (13), respectively;

(G) in paragraph (12), as so redesignated, by striking "; and" and inserting a semicolon; and

(H) by striking paragraph (13), as so redesignated, and inserting the following:

"(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

"(14) work with States, providers, and individuals in recovery, and their families, to promote the expansion of recovery support services and systems of care oriented toward recovery.".

SEC. 6008. ADVISORY COUNCILS.

Section 502(b) of the Public Health Service Act (42 U.S.C. 290aa–1(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (E), by striking "and" after the semicolon;

(B) by redesignating subparagraph (F) as subparagraph (J); and

(C) by inserting after subparagraph (E), the following:

"(F) the Chief Medical Officer, appointed under section 501(g);

"(G) the Director of the National Institute of Mental Health for the advisory councils appointed under subsections (a)(1)(A) and (a)(1)(D);

"(H) the Director of the National Institute on Drug Abuse for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C);

"(I) the Director of the National Institute on Alcohol Abuse and Alcoholism for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C); and"; and

(2) in paragraph (3), by adding at the end the following:

"(C) Not less than half of the members of the advisory council appointed under subsection (a)(1)(D)—

"(i) shall—

"(I) have a medical degree;

"(II) have a doctoral degree in psychology; or

"(III) have an advanced degree in nursing or social work from an accredited graduate school or be a certified physician assistant; and

"(ii) shall specialize in the mental health field.

"(D) Not less than half of the members of the advisory councils appointed under subsections (a)(1)(B) and (a)(1)(C)—

"(i) shall—

"(I) have a medical degree;

"(II) have a doctoral degree; or

"(III) have an advanced degree in nursing, public health, behavioral or social sciences, or social work from an accredited graduate school or be a certified physician assistant; and

"(ii) shall have experience in the provision of substance use disorder services or the development and implementation of programs to prevent substance misuse.".

SEC. 6009. PEER REVIEW.

Section 504(b) of the Public Health Service Act (42 U.S.C. 290aa–3(b)) is amended by adding at the end the following: "In the case of any such peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness treatment, not less than half of the members of such peer review group shall be licensed and experienced professionals in the prevention, diagnosis, or treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders and have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work from an accredited program, and the Secretary, in consultation with the Assistant Secretary, shall, to the extent possible, ensure such peer review groups include broad geographic representation, including both urban and rural representatives.".

Subtitle B—Oversight and Accountability

SEC. 6021. IMPROVING OVERSIGHT OF MENTAL AND SUBSTANCE USE DISORDERS PROGRAMS THROUGH THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION.

42 USC 290aa note.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation, shall ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

(b) EVALUATION STRATEGY.—In carrying out subsection (a), the Assistant Secretary for Planning and Evaluation shall, not later than 180 days after the date of enactment of this Act, develop a strategy for conducting ongoing evaluations that identifies priority programs to be evaluated by the Assistant Secretary for Planning and Evaluation and priority programs to be evaluated by other relevant offices and agencies within the Department of Health and Human Services. The strategy shall—

(1) include a plan for evaluating programs related to mental and substance use disorders, including co-occurring disorders, across agencies, as appropriate, including programs related to—

(A) prevention, intervention, treatment, and recovery support services, including such services for adults with a serious mental illness or children with a serious emotional disturbance;

(B) the reduction of homelessness and incarceration among individuals with a mental or substance use disorder; and

(C) public health and health services; and

(2) include a plan for assessing the use of performance metrics to evaluate activities carried out by entities receiving grants, contracts, or cooperative agreements related to mental and substance use disorders prevention and treatment services under title V or title XIX of the Public Health Service Act (42 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

(c) CONSULTATION.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall consult, as appropriate, with the Assistant Secretary for Mental Health and Substance Use, the Chief Medical Officer of the Substance Abuse and Mental Health Services Administration appointed under section 501(g) of the Public Health Service Act (42 U.S.C. 290aa(g)), as amended by section 6003, the Behavioral Health Coordinating Council of the Department of Health and Human Services, other agencies within the Department of Health and Human Services, and other relevant Federal departments and agencies.

(d) RECOMMENDATIONS.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall provide recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, and the Congress on improving the quality of prevention and treatment programs and activities related to mental and substance use disorders, including recommendations for the use of performance metrics. The Assistant Secretary for Mental Health and Substance Use shall include such recommendations in the biennial report required by subsection 501(m) of the Public Health Service Act, as redesignated by section 6003 of this Act.

SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY ORGANIZATIONS.

(a) PUBLIC AVAILABILITY OF REPORTS.—Section 105(a)(7) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10805(a)(7)) is amended by striking "is located a report" and inserting "is located, and make publicly available, a report".

(b) DETAILED ACCOUNTING.—Section 114(a) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10824(a)) is amended—

(1) in paragraph (3), by striking "and" at the end;

(2) in paragraph (4), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(5) using data from the existing required annual program progress reports submitted by each system funded under this title, a detailed accounting for each such system of how funds are spent, disaggregated according to whether the funds were

received from the Federal Government, the State government, a local government, or a private entity.”.

SEC. 6023. GAO STUDY.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services and the Assistant Secretary for Mental Health and Substance Use, shall conduct an independent evaluation, and submit a report, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, on programs funded by allotments made under title I of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10801 et seq.).

(b) CONTENTS.—The report and evaluation required under subsection (a) shall include—

(1) a review of the programs described in such subsection that are carried out by State agencies and such programs that are carried out by private, nonprofit organizations; and

(2) a review of the compliance of the programs described in subsection (a) with statutory and regulatory responsibilities, such as—

(A) responsibilities relating to family engagement;

(B) responsibilities relating to the grievance procedure for clients or prospective clients of the system to assure that individuals with mental illness have full access to the services of the system, for individuals who have received or are receiving mental health services, and for family members of such individuals with mental illness, or representatives of such individuals or family members, to assure that the eligible system is operating in compliance with the provisions of the Protection and Advocacy for Individuals with Mental Illness Act, as required to be established by section 105(a)(9) of such Act (42 U.S.C. 10805(a)(9));

(C) investigation of alleged abuse and neglect of persons with mental illness;

(D) availability of adequate medical and behavioral health treatment;

(E) denial of rights for persons with mental illness; and

(F) compliance with the Federal prohibition on lobbying.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the “Committee”).

(2) FEDERAL ADVISORY COMMITTEE ACT.—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

(b) MEETINGS.—The Committee shall meet not fewer than 2 times each year.

(c) RESPONSIBILITIES.—Not later than 1 year after the date of enactment of this Act, and 5 years after such date of enactment, the Committee shall submit to Congress and any other relevant Federal department or agency a report including—

(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

(B) increased rates of employment and enrollment in educational and vocational programs;

(C) quality of mental and substance use disorders treatment services; or

(D) any other criteria as may be determined by the Secretary; and

(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

(d) COMMITTEE EXTENSION.—Upon the submission of the second report under subsection (c), the Secretary shall submit a recommendation to Congress on whether to extend the operation of the Committee.

(e) MEMBERSHIP.—

(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

(B) the Assistant Secretary for Mental Health and Substance Use;

(C) the Attorney General;

(D) the Secretary of Veterans Affairs;

(E) the Secretary of Defense;

(F) the Secretary of Housing and Urban Development;

(G) the Secretary of Education;

(H) the Secretary of Labor;

(I) the Administrator of the Centers for Medicare & Medicaid Services; and

(J) the Commissioner of Social Security.

(2) NON-FEDERAL MEMBERS.—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

(D) at least 2 members shall be—

(i) a licensed psychiatrist with experience in treating serious mental illnesses;

(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

(H) at least 1 member shall be a State certified mental health peer support specialist;

(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis.

(3) TERMS.—A member of the Committee appointed under subsection (e)(2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(f) WORKING GROUPS.—In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

(g) SUNSET.—The Committee shall terminate on the date that is 6 years after the date on which the Committee is established under subsection (a)(1).

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-BASED PROGRAMS.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 501 (42 U.S.C. 290aa) the following:

42 USC 290aa–0.

"SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.

"(a) IN GENERAL.—There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the 'Laboratory').

"(b) RESPONSIBILITIES.—The Laboratory shall—

"(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016;

"(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

"(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

"(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

"(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

"(A) identify any such programs or activities that are duplicative;

"(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

"(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified

under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities; and

"(6) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices.

"(c) EVIDENCE-BASED PRACTICES AND SERVICE DELIVERY MODELS.—

"(1) IN GENERAL.—In carrying out subsection (b)(3), the Laboratory—

"(A) may give preference to models that improve—

"(i) the coordination between mental health and physical health providers;

"(ii) the coordination among such providers and the justice and corrections system; and

"(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

"(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

"(2) CONSULTATION.—In carrying out this section, the Laboratory shall consult with—

"(A) the Chief Medical Officer appointed under section 501(g);

"(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

"(C) other appropriate Federal agencies;

"(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

"(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

"(d) DEADLINE FOR BEGINNING IMPLEMENTATION.—The Laboratory shall begin implementation of this section not later than January 1, 2018.

"(e) PROMOTING INNOVATION.—

"(1) IN GENERAL.—The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

"(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

"(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

"(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

"(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

"(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

"(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

"(2) CONSULTATION.—In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 501(g), the advisory councils described in section 502, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

"(A) to carry out paragraph (1)(A), $7,000,000 for the period of fiscal years 2018 through 2020; and

"(B) to carry out paragraph (1)(B), $7,000,000 for the period of fiscal years 2018 through 2020.".

SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by inserting after section 543 of such Act (42 U.S.C. 290dd–2) the following:

42 USC 290dd–2a.

"SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

"(a) IN GENERAL.—The Assistant Secretary shall, as appropriate, improve access to reliable and valid information on evidence-based programs and practices, including information on the strength of evidence associated with such programs and practices, related to mental and substance use disorders for States, local communities, nonprofit entities, and other stakeholders, by posting on the Internet website of the Administration information on evidence-based programs and practices that have been reviewed by the Assistant Secretary in accordance with the requirements of this section.

"(b) APPLICATIONS.—

"(1) APPLICATION PERIOD.—In carrying out subsection (a), the Assistant Secretary may establish a period for the submission of applications for evidence-based programs and practices to be posted publicly in accordance with subsection (a).

"(2) NOTICE.—In establishing the application period under paragraph (1), the Assistant Secretary shall provide for the public notice of such application period in the Federal Register.

Such notice may solicit applications for evidence-based programs and practices to address gaps in information identified by the Assistant Secretary, the National Mental Health and Substance Use Policy Laboratory established under section 501A, or the Assistant Secretary for Planning and Evaluation, including pursuant to the evaluation and recommendations under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 or priorities identified in the strategic plan under section 501(l).

"(c) REQUIREMENTS.—The Assistant Secretary may establish minimum requirements for the applications submitted under subsection (b), including applications related to the submission of research and evaluation.

"(d) REVIEW AND RATING.—

"(1) IN GENERAL.—The Assistant Secretary shall review applications prior to public posting in accordance with subsection (a), and may prioritize the review of applications for evidence-based programs and practices that are related to topics included in the notice provided under subsection (b)(2).

"(2) SYSTEM.—In carrying out paragraph (1), the Assistant Secretary may utilize a rating and review system, which may include information on the strength of evidence associated with the evidence-based programs and practices and a rating of the methodological rigor of the research supporting the applications.

"(3) PUBLIC ACCESS TO METRICS AND RATING.—The Assistant Secretary shall make the metrics used to evaluate applications under this section, and any resulting ratings of such applications, publicly available.".

SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) is amended—

(1) in subsection (a)—

(A) in paragraph (4), by inserting before the period ", which may include technical assistance centers"; and

(B) in the flush sentence following paragraph (4)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations" and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or"; and

(2) by amending subsection (f) to read as follows:

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $394,550,000 for each of fiscal years 2018 through 2022.".

SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 509 of the Public Health Service Act (42 U.S.C. 290bb–2) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by inserting before the period "that permit States, local governments, communities, and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined in section 4 of the Indian Self-Determination and Education Assistance Act) to focus on emerging trends in substance abuse and co-occurrence of substance use disorders with mental illness or other conditions"; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations," and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or";

(2) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder"; and

(B) in paragraph (2), by striking "abuse" and inserting "use disorder";

(3) in subsection (e), by striking "abuse" and inserting "use disorder"; and

(4) in subsection (f), by striking "$300,000,000" and all that follows through the period and inserting "$333,806,000 for each of fiscal years 2018 through 2022.".

SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 516 of the Public Health Service Act (42 U.S.C. 290bb–22) is amended—

(1) in the section heading, by striking "**ABUSE**" and inserting "**USE DISORDER**";

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by inserting before the period ", including such programs that focus on emerging drug abuse issues"; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations," and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service,";

(3) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" at the end and inserting ";";

(ii) in subparagraph (B)—

(I) by striking "abuse" and inserting "use disorder"; and

(II) by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(C) substance use disorder prevention among high-risk groups.";

(4) in subsection (e), by striking "abuse" and inserting "use disorder"; and

(5) in subsection (f), by striking "$300,000,000" and all that follows through the period and inserting "$211,148,000 for each of fiscal years 2018 through 2022.".

TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) FORMULA GRANTS.—Section 1911(b) of the Public Health Service Act (42 U.S.C. 300x(b)) is amended—

(1) by redesignating paragraphs (1) through (3) as paragraphs (2) through (4), respectively; and

(2) by inserting before paragraph (2) (as so redesignated) the following:

"(1) providing community mental health services for adults with a serious mental illness and children with a serious emotional disturbance as defined in accordance with section 1912(c);".

(b) STATE PLAN.—Section 1912(b) of the Public Health Service Act (42 U.S.C. 300x–1(b)) is amended—

(1) in paragraph (3), by redesignating subparagraphs (A) through (C) as clauses (i) through (iii), respectively, and realigning the margins accordingly;

(2) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively, and realigning the margins accordingly;

(3) in the matter preceding subparagraph (A) (as so redesignated), by striking "With respect to" and all that follows through "are as follows:" and inserting "In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:";

(4) by inserting before subparagraph (A) (as so redesignated) the following:

"(1) SYSTEM OF CARE.—A description of the State's system of care that contains the following:";

(5) by striking subparagraph (A) (as so redesignated) and inserting the following:

"(A) COMPREHENSIVE COMMUNITY-BASED HEALTH SYSTEMS.—The plan shall—

"(i) identify the single State agency to be responsible for the administration of the program under the grant, including any third party who administers mental health services and is responsible for complying with the requirements of this part with respect to the grant;

"(ii) provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care, including services for individuals with co-occurring disorders;

"(iii) include a description of the manner in which the State and local entities will coordinate services to maximize the efficiency, effectiveness, quality, and cost-effectiveness of services and programs to produce the best possible outcomes (including health services, rehabilitation services, employment services, housing services, educational services, substance use disorder services, legal services, law enforcement services, social services, child welfare services, medical and dental care services, and other support services to be provided with Federal, State, and local public and private resources) with other agencies to enable individuals receiving services to function outside of inpatient or residential institutions, to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act;

"(iv) include a description of how the State promotes evidence-based practices, including those evidence-based programs that address the needs of individuals with early serious mental illness regardless of the age of the individual at onset, provide comprehensive individualized treatment, or integrate mental and physical health services;

"(v) include a description of case management services;

"(vi) include a description of activities that seek to engage adults with a serious mental illness or children with a serious emotional disturbance and their caregivers where appropriate in making health care decisions, including activities that enhance communication among individuals, families, caregivers, and treatment providers; and

"(vii) as appropriate to, and reflective of, the uses the State proposes for the block grant funds, include—

"(I) a description of the activities intended to reduce hospitalizations and hospital stays using the block grant funds;

"(II) a description of the activities intended to reduce incidents of suicide using the block grant funds;

"(III) a description of how the State integrates mental health and primary care using the block grant funds, which may include providing, in the case of individuals with co-occurring mental and

substance use disorders, both mental and substance use disorders services in primary care settings or arrangements to provide primary and specialty care services in community-based mental and substance use disorders settings; and

"(IV) a description of recovery and recovery support services for adults with a serious mental illness and children with a serious emotional disturbance.";

(6) in subparagraph (B) (as so redesignated)—

(A) by striking "The plan contains" and inserting "The plan shall contain"; and

(B) by striking "presents quantitative targets to be achieved in the implementation of the system described in paragraph (1)" and inserting "present quantitative targets and outcome measures for programs and services provided under this subpart";

(7) in subparagraph (C) (as so redesignated)—

(A) by striking "serious emotional disturbance" in the matter preceding clause (i) (as so redesignated) and all that follows through "substance abuse services" in clause (i) (as so redesignated) and inserting the following: "a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and substance use disorder services";

(B) by striking "Education Act);" and inserting "Education Act)."; and

(C) by striking clauses (ii) and (iii) (as so redesignated);

(8) in subparagraph (D) (as so redesignated), by striking "plan describes" and inserting "plan shall describe";

(9) in subparagraph (E) (as so redesignated)—

(A) in the subparagraph heading by striking "SYSTEMS" and inserting "SERVICES";

(B) in the first sentence, by striking "plan describes" and all that follows through "and provides for" and inserting "plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for"; and

(C) in the second sentence—

(i) by striking "further describes" and inserting "shall further describe"; and

(ii) by striking "involved." and inserting "involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III.";

(10) by striking the flush matter at the end; and

(11) by adding at the end the following:

"(2) GOALS AND OBJECTIVES.—The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.".

(c) EARLY SERIOUS MENTAL ILLNESS.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended by adding at the end the following:

"(c) EARLY SERIOUS MENTAL ILLNESS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), a State shall expend not less than 10 percent of the amount the State receives for carrying out this section for each fiscal year to support evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders, regardless of the age of the individual at onset.

"(2) STATE FLEXIBILITY.—In lieu of expending 10 percent of the amount the State receives under this section for a fiscal year as required under paragraph (1), a State may elect to expend not less than 20 percent of such amount by the end of such succeeding fiscal year.".

(d) ADDITIONAL PROVISIONS.—Section 1915(b) of the Public Health Service Act (42 U.S.C. 300x–4(b)) is amended—

(1) in paragraph (3)—

(A) by striking "The Secretary" and inserting the following:

"(A) IN GENERAL.—The Secretary";

(B) by striking "paragraph (1) if" and inserting "paragraph (1) in whole or in part if";

(C) by striking "State justify the waiver." and inserting "State in the fiscal year involved or in the previous fiscal year justify the waiver"; and

(D) by adding at the end the following:

"(B) DATE CERTAIN FOR ACTION UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under this paragraph not later than 120 days after the date on which the request is made.

"(C) APPLICABILITY OF WAIVER.—A waiver provided by the Secretary under this paragraph shall be applicable only to the fiscal year involved."; and

(2) in paragraph (4)—

(A) in subparagraph (A)—

(i) by inserting after the subparagraph designation the following: "IN GENERAL.—";

(ii) by striking "In making a grant" and inserting the following:

"(i) DETERMINATION.—In making a grant"; and

(iii) by inserting at the end the following:

"(ii) ALTERNATIVE.—A State that has failed to comply with paragraph (1) and would otherwise be subject to a reduction in the State's allotment under section 1911 may, upon request by the State, in lieu of having the amount of the allotment under section 1911 for the State reduced for the fiscal year of the grant, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement."; and

(B) in subparagraph (B)—

(i) by inserting after the subparagraph designation the following: "SUBMISSION OF INFORMATION TO THE SECRETARY.—"; and

(ii) by striking "subparagraph (A)" and inserting "subparagraph (A)(i)".

(e) APPLICATION FOR GRANT.—Section 1917(a) of the Public Health Service Act (42 U.S.C. 300x–6(a)) is amended—

(1) in paragraph (1), by striking "1941" and inserting "1942(a)"; and

(2) in paragraph (5), by striking "1915(b)(3)(B)" and inserting "1915(b)".

(f) FUNDING.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended—

(1) in subsection (a)—

(A) by striking "section 505" and inserting "section 505(c)"; and

(B) by striking "$450,000,000" and all that follows through the period and inserting "$532,571,000 for each of fiscal years 2018 through 2022."; and

(2) in subsection (b)(2) by striking "sections 505 and" and inserting "sections 505(c) and".

SEC. 8002. SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT.

(a) FORMULA GRANTS.—Section 1921(b) of the Public Health Service Act (42 U.S.C. 300x–21(b)) is amended—

(1) by inserting "carrying out the plan developed in accordance with section 1932(b) and for" after "for the purpose of"; and

(2) by striking "abuse" and inserting "use disorders".

(b) OUTREACH TO PERSONS WHO INJECT DRUGS.—Section 1923(b) of the Public Health Service Act (42 U.S.C. 300x–23(b)) is amended—

(1) in the subsection heading, by striking "REGARDING INTRAVENOUS SUBSTANCE ABUSE" and inserting "TO PERSONS WHO INJECT DRUGS"; and

(2) by striking "for intravenous drug abuse" and inserting "for persons who inject drugs".

(c) REQUIREMENTS REGARDING TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS.—Section 1924 of the Public Health Service Act (42 U.S.C. 300x–24) is amended—

(1) in subsection (a)(1)—

(A) in the matter preceding subparagraph (A), by striking "substance abuse" and inserting "substance use disorders"; and

(B) in subparagraph (A), by striking "such abuse" and inserting "such disorders";

(2) in subsection (b)—

(A) in paragraph (1)(A), by striking "substance abuse" and inserting "substance use disorders";

(B) in paragraph (2), by inserting "and Prevention" after "Disease Control";

(C) in paragraph (3)—

(i) in the paragraph heading, by striking "ABUSE" and inserting "USE DISORDERS"; and

(ii) by striking "substance abuse" and inserting "substance use disorders"; and

(D) in paragraph (6)(B), by striking "substance abuse" and inserting "substance use disorders";

(3) by striking subsection (d); and

(4) by redesignating subsection (e) as subsection (d).

(d) GROUP HOMES.—Section 1925 of the Public Health Service Act (42 U.S.C. 300x–25) is amended—

(1) in the section heading, by striking "**RECOVERING SUBSTANCE ABUSERS**" and inserting "**PERSONS IN RECOVERY FROM SUBSTANCE USE DISORDERS**"; and

(2) in subsection (a), in the matter preceding paragraph (1), by striking "recovering substance abusers" and inserting "persons in recovery from substance use disorders".

(e) ADDITIONAL AGREEMENTS.—Section 1928 of the Public Health Service Act (42 U.S.C. 300x–28) is amended—

(1) in subsection (a), by striking "(relative to fiscal year 1992)";

(2) by striking subsection (b) and inserting the following:

"(b) PROFESSIONAL DEVELOPMENT.—A funding agreement for a grant under section 1921 is that the State involved will ensure that prevention, treatment, and recovery personnel operating in the State's substance use disorder prevention, treatment, and recovery systems have an opportunity to receive training, on an ongoing basis, concerning—

"(1) recent trends in substance use disorders in the State;

"(2) improved methods and evidence-based practices for providing substance use disorder prevention and treatment services;

"(3) performance-based accountability;

"(4) data collection and reporting requirements; and

"(5) any other matters that would serve to further improve the delivery of substance use disorder prevention and treatment services within the State."; and

(3) in subsection (d)(1), by striking "substance abuse" and inserting "substance use disorders".

(f) REPEAL.—Section 1929 of the Public Health Service Act (42 U.S.C. 300x–29) is repealed.

(g) MAINTENANCE OF EFFORT.—Section 1930 of the Public Health Service Act (42 U.S.C. 300x–30) is amended—

(1) in subsection (c)(1), by striking "in the State justify the waiver" and inserting "exist in the State, or any part of the State, to justify the waiver"; and

(2) in subsection (d), by inserting at the end the following:

"(3) ALTERNATIVE.—A State that has failed to comply with this section and would otherwise be subject to a reduction in the State's allotment under section 1921, may, upon request by the State, in lieu of having the State's allotment under section 1921 reduced, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.".

(h) RESTRICTIONS ON EXPENDITURES.—Section 1931(b)(1) of the Public Health Service Act (42 U.S.C. 300x–31(b)(1)) is amended by striking "substance abuse" and inserting "substance use disorders".

(i) APPLICATION.—Section 1932 of the Public Health Service Act (42 U.S.C. 300x–32) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "subsections (c) and (d)(2)" and inserting "subsection (c)"; and

(B) in paragraph (5), by striking "the information required in section 1929, the information required in section 1930(c)(2), and";

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—In order for a State to be in compliance with subsection (a)(6), the State shall submit to the Secretary a plan that, at a minimum, includes the following:

"(A) A description of the State's system of care that—

"(i) identifies the single State agency responsible for the administration of the program, including any third party who administers substance use disorder services and is responsible for complying with the requirements of the grant;

"(ii) provides information on the need for substance use disorder prevention and treatment services in the State, including estimates on the number of individuals who need treatment, who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

"(iii) provides aggregate information on the number of individuals in treatment within the State, including the number of such individuals who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

"(iv) provides a description of the system that is available to provide services by modality, including the provision of recovery support services;

"(v) provides a description of the State's comprehensive statewide prevention efforts, including the number of individuals being served in the system, target populations, and priority needs, and provides a description of the amount of funds from the prevention set-aside expended on primary prevention;

"(vi) provides a description of the financial resources available;

"(vii) describes the existing substance use disorders workforce and workforce trained in treating co-occurring substance use and mental disorders;

"(viii) includes a description of how the State promotes evidence-based practices; and

"(ix) describes how the State integrates substance use disorder services and primary health care, which in the case of those individuals with co-occurring mental health and substance use disorders may include

providing both mental health and substance use disorder services in primary care settings or providing primary and specialty care services in community-based mental health and substance use disorder service settings.

"(B) The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

"(C) A description of how the State will comply with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend grant funds."; and

(B) in paragraph (2)—

(i) in the paragraph heading, by striking "AUTHORITY OF SECRETARY REGARDING MODIFICATIONS" and inserting "MODIFICATIONS";

(ii) by striking "As a condition" and inserting the following:

"(A) AUTHORITY OF SECRETARY.—As a condition;"; and

(iii) by adding at the end the following:

"(B) STATE REQUEST FOR MODIFICATION.—If the State determines that a modification to such plan is necessary, the State may request the Secretary to approve the modification. Any such modification shall be in accordance with paragraph (1) and section 1941."; and

(C) in paragraph (3), by inserting, ", including any modification under paragraph (2)" after "subsection (a)(6)"; and

(3) in subsection (e)(2), by striking "section 1922(c)" and inserting "section 1922(b)".

(j) DEFINITIONS.—Section 1934 of the Public Health Service Act (42 U.S.C. 300x–34) is amended—

(1) in paragraph (3), by striking "substance abuse" and inserting "substance use disorders"; and

(2) in paragraph (7), by striking "substance abuse" and inserting "substance use disorders".

(k) FUNDING.—Section 1935 of the Public Health Service Act (42 U.S.C. 300x–35) is amended—

(1) in subsection (a)—

(A) by striking "section 505" and inserting "section 505(d)"; and

(B) by striking "$2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$1,858,079,000 for each of fiscal years 2018 through 2022."; and

(2) in subsection (b)(1)(B) by striking "sections 505 and" and inserting "sections 505(d) and".

SEC. 8003. ADDITIONAL PROVISIONS RELATED TO THE BLOCK GRANTS.

Subpart III of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–51 et seq.) is amended—

(1) in section 1943(a)(3) (42 U.S.C. 300x–53(a)(3)), by striking "section 505" and inserting "subsections (c) and (d) of section 505";

(2) in section 1953(b) (42 U.S.C. 300x–63(b)), by striking "substance abuse" and inserting "substance use disorder"; and

(3) by adding at the end the following:

"SEC. 1957. PUBLIC HEALTH EMERGENCIES. 42 USC 300x–67.

"In the case of a public health emergency (as determined under section 319), the Secretary, on a State by State basis, may, as the circumstances of the emergency reasonably require and for the period of the emergency, grant an extension, or waive application deadlines or compliance with any other requirement, of a grant authorized under section 521, 1911, or 1921 or an allotment authorized under Public Law 99–319 (42 U.S.C. 10801 et seq.).

"SEC. 1958. JOINT APPLICATIONS. 42 USC 300x–68.

"The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall permit a joint application to be submitted for grants under subpart I and subpart II upon the request of a State. Such application may be jointly reviewed and approved by the Secretary with respect to such subparts, consistent with the purposes and authorized activities of each such grant program. A State submitting such a joint application shall otherwise meet the requirements with respect to each such subpart.".

SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT AND THE COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall through a grant or contract, or through an agreement with a third party, conduct a study on the formulas for distribution of funds under the substance abuse prevention and treatment block grant, and the community mental health services block grant, under part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.) and recommend changes if necessary. Such study shall include—

(1) an analysis of whether the distributions under such block grants accurately reflect the need for the services under the grants in the States;

(2) an examination of whether the indices used under the formulas for distribution of funds under such block grants are appropriate, and if not, alternatives recommended by the Secretary;

(3) where recommendations are included under paragraph (2) for the use of different indices, a description of the variables and data sources that should be used to determine the indices;

(4) an evaluation of the variables and data sources that are being used for each of the indices involved, and whether such variables and data sources accurately represent the need for services, the cost of providing services, and the ability of the States to pay for such services;

(5) the effect that the minimum allotment requirements for each such block grant have on each State's final allotment and the effect of such requirements, if any, on each State's formula-based allotment;

(6) recommendations for modifications to the minimum allotment provisions to ensure an appropriate distribution of funds; and

(7) any other information that the Secretary determines appropriate.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings and recommendations of the study conducted under subsection (a) and the study conducted under section 9004(g).

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR HOMELESS INDIVIDUALS.

Section 506 of the Public Health Service Act (42 U.S.C. 290aa–5) is amended—

(1) in subsection (a), by striking "substance abuse" and inserting "substance use disorder";

(2) in subsection (b)—

(A) in paragraphs (1) and (3), by striking "substance abuse" each place the term appears and inserting "substance use disorder"; and

(B) in paragraph (4), by striking "substance abuse" and inserting "a substance use disorder";

(3) in subsection (c)—

(A) in paragraph (1), by striking "substance abuse disorder" and inserting "substance use disorder"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "substance abuse" and inserting "a substance use disorder"; and

(ii) in subparagraph (B), by striking "substance abuse" and inserting "substance use disorder"; and

(4) in subsection (e), by striking ", $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$41,304,000 for each of fiscal years 2018 through 2022".

SEC. 9002. GRANTS FOR JAIL DIVERSION PROGRAMS.

Section 520G of the Public Health Service Act (42 U.S.C. 290bb–38) is amended—

(1) by striking "substance abuse" each place such term appears and inserting "substance use disorder";

(2) in subsection (a)—

(A) by striking "Indian tribes, and tribal organizations" and inserting "and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are

defined in section 4 of the Indian Self-Determination and Education Assistance Act)"; and

(B) by inserting "or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service," after "entities,";

(3) in subsection (c)(2)(A)(i), by striking "the best known" and inserting "evidence-based";

(4) by redesignating subsections (d) through (i) as subsections (e) through (j), respectively;

(5) by inserting after subsection (c) the following:

"(d) SPECIAL CONSIDERATION REGARDING VETERANS.—In awarding grants under subsection (a), the Secretary shall, as appropriate, give special consideration to entities proposing to use grant funding to support jail diversion services for veterans.";

(6) in subsection (e), as so redesignated—

(A) in paragraph (3), by striking "; and" and inserting a semicolon;

(B) in paragraph (4), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(5) develop programs to divert individuals prior to booking or arrest."; and

(7) in subsection (j), as so redesignated, by striking "$10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003" and inserting "$4,269,000 for each of fiscal years 2018 through 2022".

SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BEHAVIORAL HEALTH CARE.

Section 520K of the Public Health Service Act (42 U.S.C. 290bb–42) is amended to read as follows:

"SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS.

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE ENTITY.—The term 'eligible entity' means a State, or other appropriate State agency, in collaboration with 1 or more qualified community programs as described in section 1913(b)(1) or 1 or more community health centers as described in section 330.

"(2) INTEGRATED CARE.—The term 'integrated care' means collaborative models or practices offering mental and physical health services, which may include practices that share the same space in the same facility.

"(3) SPECIAL POPULATION.—The term 'special population' means—

"(A) adults with a mental illness who have co-occurring physical health conditions or chronic diseases;

"(B) adults with a serious mental illness who have co-occurring physical health conditions or chronic diseases;

"(C) children and adolescents with a serious emotional disturbance with co-occurring physical health conditions or chronic diseases; or

"(D) individuals with a substance use disorder.

"(b) GRANTS AND COOPERATIVE AGREEMENTS.—

"(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the

improvement of integrated care for primary care and behavioral health care in accordance with paragraph (2).

"(2) PURPOSES.—A grant or cooperative agreement awarded under this section shall be designed to—

"(A) promote full integration and collaboration in clinical practices between primary and behavioral health care;

"(B) support the improvement of integrated care models for primary care and behavioral health care to improve the overall wellness and physical health status of adults with a serious mental illness or children with a serious emotional disturbance; and

"(C) promote integrated care services related to screening, diagnosis, prevention, and treatment of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases.

"(c) APPLICATIONS.—

"(1) IN GENERAL.—An eligible entity seeking a grant or cooperative agreement under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

"(2) CONTENTS.—The contents described in this paragraph are—

"(A) a description of a plan to achieve fully collaborative agreements to provide services to special populations;

"(B) a document that summarizes the policies, if any, that serve as barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

"(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

"(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects; and

"(E) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

"(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

"(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be $2,000,000.

"(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of the application and the number of eligible entities that received grants under this section prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

"(3) LIMITATION.—An eligible entity receiving funding under this section may not allocate more than 10 percent of funds awarded under this section to administrative functions, and the remaining amounts shall be allocated to health facilities that provide integrated care.

"(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

"(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section shall submit an annual report to the Secretary that includes—

"(1) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c); and

"(2) a description of functional outcomes of special populations, including—

"(A) with respect to adults with a serious mental illness, participation in supportive housing or independent living programs, attendance in social and rehabilitative programs, participation in job training opportunities, satisfactory performance in work settings, attendance at scheduled medical and mental health appointments, and compliance with prescribed medication regimes;

"(B) with respect to individuals with co-occurring mental illness and physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities related to improved health and lifestyle practices; and

"(C) with respect to children and adolescents with a serious emotional disturbance who have co-occurring physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities at school and extracurricular activities.

"(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

"(1) IN GENERAL.—The Secretary may provide appropriate information, training, and technical assistance to eligible entities that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

"(A) development and selection of integrated care models;

"(B) dissemination of evidence-based interventions in integrated care;

"(C) establishment of organizational practices to support operational and administrative success; and

"(D) other activities, as the Secretary determines appropriate.

"(2) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—The information and resources provided by the Secretary under paragraph (1) shall, as appropriate, be made available to States, political subdivisions of States, Indian tribes or tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act), outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under section 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa)

of the Social Security Act, other community-based organizations, or other entities engaging in integrated care activities, as the Secretary determines appropriate.

"(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $51,878,000 for each of fiscal years 2018 through 2022.".

SEC. 9004. PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS.

(a) FORMULA GRANTS TO STATES.—Section 521 of the Public Health Service Act (42 U.S.C. 290cc–21) is amended by striking "1991 through 1994" and inserting "2018 through 2022".

(b) PURPOSE OF GRANTS.—Section 522 of the Public Health Service Act (42 U.S.C. 290cc–22) is amended—

(1) in subsection (a)(1)(B), by striking "substance abuse" and inserting "a substance use disorder";

(2) in subsection (b)(6), by striking "substance abuse" and inserting "substance use disorder";

(3) in subsection (c), by striking "substance abuse" and inserting "a substance use disorder";

(4) in subsection (e)—

(A) in paragraph (1), by striking "substance abuse" and inserting "a substance use disorder"; and

(B) in paragraph (2), by striking "substance abuse" and inserting "substance use disorder";

(5) by striking subsection (g) and redesignating subsections (h) and (i) as (g) and (h), accordingly; and

(6) in subsection (g), as redesignated by paragraph (5), by striking "substance abuse" each place such term appears and inserting "substance use disorder".

(c) DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.—Section 527 of the Public Health Service Act (42 U.S.C. 290cc–27) is amended by striking "substance abuse" each place such term appears and inserting "substance use disorder".

(d) TECHNICAL ASSISTANCE.—Section 530 of the Public Health Service Act (42 U.S.C. 290cc–30) is amended by striking "through the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse" and inserting "acting through the Assistant Secretary".

(e) DEFINITIONS.—Section 534(4) of the Public Health Service Act (42 U.S.C. 290cc–34(4)) is amended to read as follows:

"(4) SUBSTANCE USE DISORDER SERVICES.—The term 'substance use disorder services' has the meaning given the term 'substance abuse services' in section 330(h)(5)(C).".

(f) FUNDING.—Section 535(a) of the Public Health Service Act (42 U.S.C. 290cc–35(a)) is amended by striking "$75,000,000 for each of the fiscal years 2001 through 2003" and inserting "$64,635,000 for each of fiscal years 2018 through 2022".

(g) STUDY CONCERNING FORMULA.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Assistant Secretary for Mental Health and Substance Use (referred to in this section as the "Assistant Secretary") shall conduct a study concerning the formula used under section 524 of the Public Health Service Act (42 U.S.C. 290cc–24) for making allotments to States under section 521 of such Act (42 U.S.C. 290cc–21). Such study shall include an evaluation of quality indicators of need for purposes

of revising the formula for determining the amount of each allotment for the fiscal years following the submission of the study.

(2) REPORT.—In accordance with section 8004(b), the Assistant Secretary shall submit to the committees of Congress described in such section a report concerning the results of the study conducted under paragraph (1).

SEC. 9005. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.) is amended by inserting after section 520E–2 (42 U.S.C. 290bb–36b) the following:

"SEC. 520E–3. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM. 42 USC 290bb–36c.

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program (referred to in this section as the 'program'), authorized under section 520A and in effect prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016.

"(b) ACTIVITIES.—In maintaining the program, the activities of the Secretary shall include—

"(1) coordinating a network of crisis centers across the United States for providing suicide prevention and crisis intervention services to individuals seeking help at any time, day or night;

"(2) maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services resources; and

"(3) consulting with the Secretary of Veterans Affairs to ensure that veterans calling the suicide prevention hotline have access to a specialized veterans' suicide prevention hotline.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $7,198,000 for each of fiscal years 2018 through 2022.".

SEC. 9006. CONNECTING INDIVIDUALS AND FAMILIES WITH CARE.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.), as amended by section 9005, is further amended by inserting after section 520E–3 the following:

"SEC. 520E–4. TREATMENT REFERRAL ROUTING SERVICE. 42 USC 290bb–36d.

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the 'Routing Service') to assist individuals and families in locating mental and substance use disorders treatment providers.

"(b) ACTIVITIES OF THE SECRETARY.—To maintain the Routing Service, the activities of the Assistant Secretary shall include administering—

"(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis regarding local behavioral health providers and community-based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

"(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment providers and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

"(c) REMOVING PRACTITIONER CONTACT INFORMATION.—In the event that the Internet website described in subsection (b)(2) contains information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(g)(2)(B) of the Controlled Substances Act, the Assistant Secretary—

"(1) shall provide an opportunity to such practitioner to have the contact information of the practitioner removed from the website at the request of the practitioner; and

"(2) may evaluate other methods to periodically update the information displayed on such website.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the Assistant Secretary from using any unobligated amounts otherwise made available to the Administration to maintain the Routing Service.".

SEC. 9007. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

Section 520F of the Public Health Service Act (42 U.S.C. 290bb–37) is amended to read as follows:

"SEC. 520F. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

"(a) IN GENERAL.—The Secretary shall award competitive grants to—

"(1) State and local governments and Indian tribes and tribal organizations, to enhance community-based crisis response systems; or

"(2) States to develop, maintain, or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities, for adults with a serious mental illness, children with a serious emotional disturbance, or individuals with a substance use disorder.

"(b) APPLICATIONS.—

"(1) IN GENERAL.—To receive a grant under subsection (a), an entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

"(2) COMMUNITY-BASED CRISIS RESPONSE PLAN.—An application for a grant under subsection (a)(1) shall include a plan for—

"(A) promoting integration and coordination between local public and private entities engaged in crisis response, including first responders, emergency health care providers, primary care providers, law enforcement, court systems, health care payers, social service providers, and behavioral health providers;

"(B) developing memoranda of understanding with public and private entities to implement crisis response services;

"(C) addressing gaps in community resources for crisis intervention and prevention; and

"(D) developing models for minimizing hospital readmissions, including through appropriate discharge planning.

"(3) BEDS DATABASE PLAN.—An application for a grant under subsection (a)(2) shall include a plan for developing, maintaining, or enhancing a real-time, Internet-based bed database to collect, aggregate, and display information about beds in inpatient psychiatric facilities and crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities to facilitate the identification and designation of facilities for the temporary treatment of individuals in mental or substance use disorder crisis.

"(c) DATABASE REQUIREMENTS.—A bed database described in this section is a database that—

"(1) includes information on inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder facilities in the State involved, including contact information for the facility or unit;

"(2) provides real-time information about the number of beds available at each facility or unit and, for each available bed, the type of patient that may be admitted, the level of security provided, and any other information that may be necessary to allow for the proper identification of appropriate facilities for treatment of individuals in mental or substance use disorder crisis; and

"(3) enables searches of the database to identify available beds that are appropriate for the treatment of individuals in mental or substance use disorder crisis.

"(d) EVALUATION.—An entity receiving a grant under subsection (a)(1) shall submit to the Secretary, at such time, in such manner, and containing such information as the Secretary may reasonably require, a report, including an evaluation of the effect of such grant on—

"(1) local crisis response services and measures for individuals receiving crisis planning and early intervention supports;

"(2) individuals reporting improved functional outcomes; and

"(3) individuals receiving regular followup care following a crisis.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $12,500,000 for the period of fiscal years 2018 through 2022.".

SEC. 9008. GARRETT LEE SMITH MEMORIAL ACT REAUTHORIZATION.

(a) SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER.—Section 520C of the Public Health Service Act (42 U.S.C. 290bb–34), as amended by section 6001, is further amended—

(1) in the section heading, by striking "**YOUTH INTERAGENCY RESEARCH, TRAINING, AND TECHNICAL ASSISTANCE CENTERS**" and inserting "**SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER**";

(2) in subsection (a), by striking "acting through the Assistant Secretary for Mental Health and Substance Use" and all that follows through the period at the end of paragraph (2) and inserting "acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource

center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide.";

(3) by striking subsections (b) and (c);

(4) by redesignating subsection (d) as subsection (b);

(5) in subsection (b), as so redesignated—

(A) in the subsection heading, by striking "ADDITIONAL CENTER" and inserting "RESPONSIBILITIES OF THE CENTER";

(B) in the matter preceding paragraph (1), by striking "The additional research" and all that follows through "nonprofit organizations for" and inserting "The center established under subsection (a) shall conduct activities for the purpose of";

(C) by striking "youth suicide" each place such term appears and inserting "suicide";

(D) in paragraph (1)—

(i) by striking "the development or continuation of" and inserting "developing and continuing"; and

(ii) by inserting "for all ages, particularly among groups that are at a high risk for suicide" before the semicolon at the end;

(E) in paragraph (2), by inserting "for all ages, particularly among groups that are at a high risk for suicide" before the semicolon at the end;

(F) in paragraph (3), by inserting "and tribal" after "statewide";

(G) in paragraph (5), by inserting "and prevention" after "intervention";

(H) in paragraph (8), by striking "in youth";

(I) in paragraph (9), by striking "and behavioral health" and inserting "health and substance use disorder"; and

(J) in paragraph (10), by inserting "conducting" before "other"; and

(6) by striking subsection (e) and inserting the following:

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,988,000 for each of fiscal years 2018 through 2022.

"(d) ANNUAL REPORT.—Not later than 2 years after the date of enactment of this subsection, the Secretary shall submit to Congress a report on the activities carried out by the center established under subsection (a) during the year involved, including the potential effects of such activities, and the States, organizations, and institutions that have worked with the center.".

(b) YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.—Section 520E of the Public Health Service Act (42 U.S.C. 290bb–36) is amended—

(1) in paragraph (1) of subsection (a) and in subsection (c), by striking "substance abuse" each place such term appears and inserting "substance use disorder";

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking "ensure that each State is awarded only 1 grant or cooperative agreement under this section" and inserting "ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time"; and

(ii) by striking "been awarded" and inserting "received"; and

(B) by adding after paragraph (2) the following:

"(3) CONSIDERATION.—In awarding grants under this section, the Secretary shall take into consideration the extent of the need of the applicant, including the incidence and prevalence of suicide in the State and among the populations of focus, including rates of suicide determined by the Centers for Disease Control and Prevention for the State or population of focus.";

(3) in subsection (g)(2), by striking "2 years after the date of enactment of this section," and insert "2 years after the date of enactment of Helping Families in Mental Health Crisis Reform Act of 2016,"; and

(4) by striking subsection (m) and inserting the following:

"(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9009. ADULT SUICIDE PREVENTION.

42 USC 290bb–43.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.) is amended by adding at the end the following:

"SEC. 520L. ADULT SUICIDE PREVENTION.

"(a) GRANTS.—

"(1) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities described in paragraph (2) to implement suicide prevention and intervention programs, for individuals who are 25 years of age or older, that are designed to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.

"(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a community-based primary care or behavioral health care setting, an emergency department, a State mental health agency (or State health agency with mental or behavioral health functions), public health agency, a territory of the United States, or an Indian tribe or tribal organization (as the terms 'Indian tribe' and 'tribal organization' are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

"(3) USE OF FUNDS.—The grants awarded under paragraph (1) shall be used to implement programs, in accordance with such paragraph, that include one or more of the following components:

"(A) Screening for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide.

"(B) Implementing evidence-based practices to provide treatment for individuals at risk for suicide, including appropriate followup services.

"(C) Raising awareness and reducing stigma of suicide.

"(b) EVALUATIONS AND TECHNICAL ASSISTANCE.—The Assistant Secretary shall—

"(1) evaluate the activities supported by grants awarded under subsection (a), and disseminate, as appropriate, the findings from the evaluation; and

"(2) provide appropriate information, training, and technical assistance, as appropriate, to eligible entities that receive a grant under this section, in order to help such entities to meet the requirements of this section, including assistance with selection and implementation of evidence-based interventions and frameworks to prevent suicide.

"(c) DURATION.—A grant under this section shall be for a period of not more than 5 years.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $30,000,000 for the period of fiscal years 2018 through 2022.".

SEC. 9010. MENTAL HEALTH AWARENESS TRAINING GRANTS.

Section 520J of the Public Health Service Act (42 U.S.C. 290bb–41) is amended—

(1) in the section heading, by inserting "**MENTAL HEALTH AWARENESS**" before "**TRAINING**"; and

(2) in subsection (b)—

(A) in the subsection heading, by striking "ILLNESS" and inserting "HEALTH";

(B) in paragraph (1), by inserting "veterans, law enforcement, and other categories of individuals, as determined by the Secretary," after "emergency services personnel";

(C) in paragraph (5)—

(i) in the matter preceding subparagraph (A), by striking "to" and inserting "for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including"; and

(ii) by striking subparagraphs (A) through (C) and inserting the following:

"(A) recognizing the signs and symptoms of mental illness; and

"(B)(i) resources available in the community for individuals with a mental illness and other relevant resources; or

"(ii) safely de-escalating crisis situations involving individuals with a mental illness."; and

(D) in paragraph (7), by striking ", $25,000,000" and all that follows through the period at the end and inserting "$14,693,000 for each of fiscal years 2018 through 2022.".

SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMERICAN INDIANS AND ALASKA NATIVE YOUTH WITHIN SUICIDE PREVENTION PROGRAMS.

(a) FINDINGS.—The Congress finds as follows:

(1) Suicide is the eighth leading cause of death among American Indians and Alaska Natives across all ages.

(2) Among American Indians and Alaska Natives who are 10 to 34 years of age, suicide is the second leading cause of death.

(3) The suicide rate among American Indian and Alaska Native adolescents and young adults ages 15 to 34 (17.9 per

100,000) is approximately 1.3 times higher than the national average for that age group (13.3 per 100,000).

(b) SENSE OF CONGRESS.—It is the sense of Congress that the Secretary of Health and Human Services, in carrying out suicide prevention and intervention programs, should prioritize programs and activities for populations with disproportionately high rates of suicide, such as American Indians and Alaska Natives.

SEC. 9012. EVIDENCE-BASED PRACTICES FOR OLDER ADULTS.

Section 520A(e) of the Public Health Service Act (42 U.S.C. 290bb–32(e)) is amended by adding at the end the following:

"(3) GERIATRIC MENTAL DISORDERS.—The Secretary shall, as appropriate, provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance use disorders among geriatric populations, as well as disseminate information about such evidence-based practices to States and nongrantees throughout the United States.".

SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, is encouraged to improve, particularly through the inclusion of additional States, the National Violent Death Reporting System as authorized by title III of the Public Health Service Act (42 U.S.C. 241 et seq.). Participation in the system by the States shall be voluntary.

SEC. 9014. ASSISTED OUTPATIENT TREATMENT.

Section 224 of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 290aa note) is amended—

(1) in subsection (e), by striking "and 2018," and inserting "2018, 2019, 2020, 2021, and 2022,"; and

(2) in subsection (g)—

(A) in paragraph (1), by striking "2018" and inserting "2022"; and

(B) in paragraph (2), by striking "is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2018" and inserting "are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2017, $20,000,000 for fiscal year 2018, $19,000,000 for each of fiscal years 2019 and 2020, and $18,000,000 for each of fiscal years 2021 and 2022".

SEC. 9015. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.

42 USC 290bb–44.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.), as amended by section 9009, is further amended by adding at the end the following:

"SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.

"(a) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities—

"(1) to establish assertive community treatment programs for adults with a serious mental illness; or

"(2) to maintain or expand such programs.

"(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a State, political subdivision of a State, Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), mental health system, health care facility, or any other entity the Assistant Secretary deems appropriate.

"(c) SPECIAL CONSIDERATION.—In selecting among applicants for a grant under this section, the Assistant Secretary may give special consideration to the potential of the applicant's program to reduce hospitalization, homelessness, and involvement with the criminal justice system while improving the health and social outcomes of the patient.

"(d) ADDITIONAL ACTIVITIES.—The Assistant Secretary shall—

"(1) not later than the end of fiscal year 2021, submit a report to the appropriate congressional committees on the grant program under this section, including an evaluation of—

"(A) any cost savings and public health outcomes such as mortality, suicide, substance use disorders, hospitalization, and use of services;

"(B) rates of involvement with the criminal justice system of patients;

"(C) rates of homelessness among patients; and

"(D) patient and family satisfaction with program participation; and

"(2) provide appropriate information, training, and technical assistance to grant recipients under this section to help such recipients to establish, maintain, or expand their assertive community treatment programs.

"(e) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—To carry out this section, there is authorized to be appropriated $5,000,000 for the period of fiscal years 2018 through 2022.

"(2) USE OF CERTAIN FUNDS.—Of the funds appropriated to carry out this section in any fiscal year, not more than 5 percent shall be available to the Assistant Secretary for carrying out subsection (d).".

SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE DRINKING REAUTHORIZATION.

Section 519B of the Public Health Service Act (42 U.S.C. 290bb–25b) is amended—

(1) in subsection (c)(3), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(2) in subsection (d)(4), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(3) in subsection (e)(1)(I), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(4) in subsection (f)(2), by striking "$6,000,000 for fiscal year 2007" and all that follows through the period at the end and inserting "$3,000,000 for each of the fiscal years 2018 through 2022"; and

(5) by adding at the end the following new subsection:

"(g) REDUCING UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTION.—

"(1) GRANTS TO PEDIATRIC HEALTH CARE PROVIDERS TO REDUCE UNDERAGE DRINKING.—The Assistant Secretary may make grants to eligible entities to increase implementation of practices for reducing the prevalence of alcohol use among individuals under the age of 21, including college students.

"(2) PURPOSES.—Grants under this subsection shall be made to improve—

"(A) screening children and adolescents for alcohol use;

"(B) offering brief interventions to children and adolescents to discourage such use;

"(C) educating parents about the dangers of, and methods of discouraging, such use;

"(D) diagnosing and treating alcohol use disorders; and

"(E) referring patients, when necessary, to other appropriate care.

"(3) USE OF FUNDS.—An entity receiving a grant under this subsection may use such funding for the purposes identified in paragraph (2) by—

"(A) providing training to health care providers;

"(B) disseminating best practices, including culturally and linguistically appropriate best practices, as appropriate, and developing and distributing materials; and

"(C) supporting other activities, as determined appropriate by the Assistant Secretary.

"(4) APPLICATION.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information as the Assistant Secretary may require. Each application shall include—

"(A) a description of the entity;

"(B) a description of activities to be completed;

"(C) a description of how the services specified in paragraphs (2) and (3) will be carried out and the qualifications for providing such services; and

"(D) a timeline for the completion of such activities.

"(5) DEFINITIONS.—For the purpose of this subsection:

"(A) BRIEF INTERVENTION.—The term 'brief intervention' means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use, to effect the desired related behavioral change.

"(B) CHILDREN AND ADOLESCENTS.—The term 'children and adolescents' means any person under 21 years of age.

"(C) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity consisting of pediatric health care providers and that is qualified to support or provide the activities identified in paragraph (2).

"(D) PEDIATRIC HEALTH CARE PROVIDER.—The term 'pediatric health care provider' means a provider of primary health care to individuals under the age of 21 years.

"(E) SCREENING.—The term 'screening' means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.".

SEC. 9017. CENTER AND PROGRAM REPEALS.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.) is amended by striking section 506B (42 U.S.C. 290aa–5b), the second section 514 (42 U.S.C. 290bb–9) relating to methamphetamine and amphetamine treatment initiatives, and each of sections 514A, 517, 519A, 519C, 519E, 520B, 520D, and 520H (42 U.S.C. 290bb–8, 290bb–23, 290bb–25a, 290bb–25c, 290bb–25e, 290bb–33, 290bb–35, and 290bb–39).

Subtitle B—Strengthening the Health Care Workforce

SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

Section 756 of the Public Health Service Act (42 U.S.C. 294e–1) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "of higher education"; and

(B) by striking paragraphs (1) through (4) and inserting the following:

"(1) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing (which may include master's and doctoral level programs), social work, school social work, substance use disorder prevention and treatment, marriage and family therapy, occupational therapy, school counseling, or professional counseling, including such programs with a focus on child and adolescent mental health and transitional-age youth;

"(2) accredited doctoral, internship, and post-doctoral residency programs of health service psychology (including clinical psychology, counseling, and school psychology) for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, as well as the development of faculty in health service psychology;

"(3) accredited master's and doctoral degree programs of social work for the development and implementation of interdisciplinary training of social work graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, and the development of faculty in social work; and

"(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training in a behavioral health-related paraprofessional field with preference for preservice or in-service training of paraprofessional child and adolescent mental health workers.";

(2) in subsection (b)—

(A) by striking paragraph (5);

(B) by redesignating paragraphs (1) through (4) as paragraphs (2) through (5), respectively;

(C) by inserting before paragraph (2), as so redesignated, the following:

"(1) an ability to recruit and place the students described in subsection (a) in areas with a high need and high demand population;";

(D) in paragraph (3), as so redesignated, by striking "subsection (a)" and inserting "paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth";

(E) in paragraph (4), as so redesignated, by striking ";" and inserting "; and"; and

(F) in paragraph (5), as so redesignated, by striking "; and" and inserting a period;

(3) in subsection (c), by striking "authorized under subsection (a)(1)" and inserting "awarded under paragraphs (2) and (3) of subsection (a)";

(4) by amending subsection (d) to read as follows:

"(d) PRIORITY.—In selecting grant recipients under this section, the Secretary shall give priority to—

"(1) programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings for purposes of recipients under paragraphs (1), (2), and (3) of subsection (a); and

"(2) programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships for purposes of recipients under subsection (a)(4).."; and

(5) by striking subsection (e) and inserting the following:

"(e) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary shall include in the biennial report submitted to Congress under section 501(m) an assessment on the effectiveness of the grants under this section in—

"(1) providing graduate students support for experiential training (internship or field placement);

"(2) recruiting students interested in behavioral health practice;

"(3) recruiting students in accordance with subsection (b)(1);

"(4) developing and implementing interprofessional training and integration within primary care;

"(5) developing and implementing accredited field placements and internships; and

"(6) collecting data on the number of students trained in behavioral health care and the number of available accredited internships and field placements.

"(f) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2018 through 2022, there are authorized to be appropriated to carry out this section $50,000,000, to be allocated as follows:

"(1) For grants described in subsection (a)(1), $15,000,000.

"(2) For grants described in subsection (a)(2), $15,000,000.

"(3) For grants described in subsection (a)(3), $10,000,000.

"(4) For grants described in subsection (a)(4), $10,000,000.".

42 USC 294k.

SEC. 9022. STRENGTHENING THE MENTAL AND SUBSTANCE USE DISORDERS WORKFORCE.

Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.) is amended by adding at the end the following:

"SEC. 760. TRAINING DEMONSTRATION PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a training demonstration program to award grants to eligible entities to support—

"(1) training for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services;

"(2) training for nurse practitioners, physician assistants, health service psychologists, and social workers to provide mental and substance use disorders services in underserved community-based settings that integrate primary care and mental and substance use disorders services; and

"(3) establishing, maintaining, or improving academic units or programs that—

"(A) provide training for students or faculty, including through clinical experiences and research, to improve the ability to be able to recognize, diagnose, and treat mental and substance use disorders, with a special focus on addiction; or

"(B) develop evidence-based practices or recommendations for the design of the units or programs described in subparagraph (A), including curriculum content standards.

"(b) ACTIVITIES.—

"(1) TRAINING FOR RESIDENTS AND FELLOWS.—A recipient of a grant under subsection (a)(1)—

"(A) shall use the grant funds—

"(i)(I) to plan, develop, and operate a training program for medical psychiatry residents and fellows in addiction medicine practicing in eligible entities described in subsection (c)(1); or

"(II) to train new psychiatric residents and fellows in addiction medicine to provide and expand access to integrated mental and substance use disorders services; and

"(ii) to provide at least 1 training track that is—

"(I) a virtual training track that includes an in-person rotation at a teaching health center or in a community-based setting, followed by a virtual rotation in which the resident or fellow continues to support the care of patients at the teaching health center or in the community-based setting through the use of health information technology and, as appropriate, telehealth services;

"(II) an in-person training track that includes a rotation, during which the resident or fellow practices at a teaching health center or in a community-based setting; or

"(III) an in-person training track that includes a rotation during which the resident practices in a community-based setting that specializes in the

treatment of infants, children, adolescents, or pregnant or postpartum women; and

"(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

"(2) TRAINING FOR OTHER PROVIDERS.—A recipient of a grant under subsection (a)(2)—

"(A) shall use the grant funds to plan, develop, or operate a training program to provide mental and substance use disorders services in underserved, community-based settings, as appropriate, that integrate primary care and mental and substance use disorders prevention and treatment services; and

"(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such program.

"(3) ACADEMIC UNITS OR PROGRAMS.—A recipient of a grant under subsection (a)(3) shall enter into a partnership with organizations such as an education accrediting organization (such as the Liaison Committee on Medical Education, the Accreditation Council for Graduate Medical Education, the Commission on Osteopathic College Accreditation, the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Accreditation Council for Pharmacy Education, the Council on Social Work Education, American Psychological Association Commission on Accreditation, or the Accreditation Review Commission on Education for the Physician Assistant) to carry out activities under subsection (a)(3).

"(c) ELIGIBLE ENTITIES.—

"(1) TRAINING FOR RESIDENTS AND FELLOWS.—To be eligible to receive a grant under subsection (a)(1), an entity shall—

"(A) be a consortium consisting of—

"(i) at least one teaching health center; and

"(ii) the sponsoring institution (or parent institution of the sponsoring institution) of—

"(I) a psychiatry residency program that is accredited by the Accreditation Council of Graduate Medical Education (or the parent institution of such a program); or

"(II) a fellowship in addiction medicine, as determined appropriate by the Secretary; or

"(B) be an entity described in subparagraph (A)(ii) that provides opportunities for residents or fellows to train in community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services.

"(2) TRAINING FOR OTHER PROVIDERS.—To be eligible to receive a grant under subsection (a)(2), an entity shall be—

"(A) a teaching health center (as defined in section 749A(f));

"(B) a Federally qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);

"(C) a community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act);

"(D) a rural health clinic (as defined in section 1861(aa) of the Social Security Act);

"(E) a health center operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

"(F) an entity with a demonstrated record of success in providing training for nurse practitioners, physician assistants, health service psychologists, and social workers.

"(3) ACADEMIC UNITS OR PROGRAMS.—To be eligible to receive a grant under subsection (a)(3), an entity shall be a school of medicine or osteopathic medicine, a nursing school, a physician assistant training program, a school of pharmacy, a school of social work, an accredited public or nonprofit private hospital, an accredited medical residency program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant.

"(d) PRIORITY.—

"(1) IN GENERAL.—In awarding grants under subsection (a)(1) or (a)(2), the Secretary shall give priority to eligible entities that—

"(A) demonstrate sufficient size, scope, and capacity to undertake the requisite training of an appropriate number of psychiatric residents, fellows, nurse practitioners, physician assistants, or social workers in addiction medicine per year to meet the needs of the area served;

"(B) demonstrate experience in training providers to practice team-based care that integrates mental and substance use disorder prevention and treatment services with primary care in community-based settings;

"(C) demonstrate experience in using health information technology and, as appropriate, telehealth to support—

"(i) the delivery of mental and substance use disorders services at the eligible entities described in subsections (c)(1) and (c)(2); and

"(ii) community health centers in integrating primary care and mental and substance use disorders treatment; or

"(D) have the capacity to expand access to mental and substance use disorders services in areas with demonstrated need, as determined by the Secretary, such as tribal, rural, or other underserved communities.

"(2) ACADEMIC UNITS OR PROGRAMS.—In awarding grants under subsection (a)(3), the Secretary shall give priority to eligible entities that—

"(A) have a record of training the greatest percentage of mental and substance use disorders providers who enter and remain in these fields or who enter and remain in settings with integrated primary care and mental and substance use disorder prevention and treatment services;

"(B) have a record of training individuals who are from underrepresented minority groups, including native populations, or from a rural or disadvantaged background;

"(C) provide training in the care of vulnerable populations such as infants, children, adolescents, pregnant and

postpartum women, older adults, homeless individuals, victims of abuse or trauma, individuals with disabilities, and other groups as defined by the Secretary;

"(D) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; or

"(E) provide training in cultural competency and health literacy.

"(e) DURATION.—Grants awarded under this section shall be for a minimum of 5 years.

"(f) STUDY AND REPORT.—

"(1) STUDY.—

"(A) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study on the results of the demonstration program under this section.

"(B) DATA SUBMISSION.—Not later than 90 days after the completion of the first year of the training program and each subsequent year that the program is in effect, each recipient of a grant under subsection (a) shall submit to the Secretary such data as the Secretary may require for analysis for the report described in paragraph (2).

"(2) REPORT TO CONGRESS.—Not later than 1 year after receipt of the data described in paragraph (1)(B), the Secretary shall submit to Congress a report that includes—

"(A) an analysis of the effect of the demonstration program under this section on the quality, quantity, and distribution of mental and substance use disorders services;

"(B) an analysis of the effect of the demonstration program on the prevalence of untreated mental and substance use disorders in the surrounding communities of health centers participating in the demonstration; and

"(C) recommendations on whether the demonstration program should be expanded.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9023. CLARIFICATION ON CURRENT ELIGIBILITY FOR LOAN REPAYMENT PROGRAMS.

42 USC 294*l*–1 note.

The Administrator of the Health Resources and Services Administration shall clarify the eligibility pursuant to section 338B(b)(1)(B) of the Public Health Service Act (42 U.S.C. 254l–1(b)(1)(B)) of child and adolescent psychiatrists for the National Health Service Corps Loan Repayment Program under subpart III of part D of title III of such Act (42 U.S.C. 254l et seq.).

SEC. 9024. MINORITY FELLOWSHIP PROGRAM.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

"PART K—MINORITY FELLOWSHIP PROGRAM

"SEC. 597. FELLOWSHIPS.

42 USC 290*ll*.

"(a) IN GENERAL.—The Secretary shall maintain a program, to be known as the Minority Fellowship Program, under which the Secretary shall award fellowships, which may include stipends, for the purposes of—

"(1) increasing the knowledge of mental and substance use disorders practitioners on issues related to prevention, treatment, and recovery support for individuals who are from racial and ethnic minority populations and who have a mental or substance use disorder;

"(2) improving the quality of mental and substance use disorder prevention and treatment services delivered to racial and ethnic minority populations; and

"(3) increasing the number of culturally competent mental and substance use disorders professionals who teach, administer services, conduct research, and provide direct mental or substance use disorder services to racial and ethnic minority populations.

"(b) TRAINING COVERED.—The fellowships awarded under subsection (a) shall be for postbaccalaureate training (including for master's and doctoral degrees) for mental and substance use disorder treatment professionals, including in the fields of psychiatry, nursing, social work, psychology, marriage and family therapy, mental health counseling, and substance use disorder and addiction counseling.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $12,669,000 for each of fiscal years 2018 through 2022.".

SEC. 9025. LIABILITY PROTECTIONS FOR HEALTH PROFESSIONAL VOLUNTEERS AT COMMUNITY HEALTH CENTERS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

"(q)(1) For purposes of this section, a health professional volunteer at a deemed entity described in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 330 to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

"(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

"(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

"(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

"(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual, which may include travel expenses to or from the site of services.

"(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear

and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

"(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

"(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

"(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

"(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

"(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

"(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

"(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

"(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

"(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

"(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

"(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year.

"(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate

under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

"(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

"(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

"(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B) and paragraph (6).

"(B) Effective on the date of the enactment of this subsection—

"(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

"(ii) reports under paragraph (4)(B) may be submitted to Congress.

"(6) Beginning on October 1, 2022, this subsection shall cease to have any force or effect.".

SEC. 9026. REPORTS.

(a) WORKFORCE DEVELOPMENT REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, shall conduct a study and publicly post on the appropriate Internet website of the Department of Health and Human Services a report on the adult and pediatric mental health and substance use disorder workforce in order to inform Federal, State, and local efforts related to workforce enhancement.

(2) CONTENTS.—The report under this subsection shall contain—

(A) national and State-level projections of the supply and demand of the mental health and substance use disorder health workforce, disaggregated by profession;

(B) an assessment of the mental health and substance use disorder workforce capacity, strengths, and weaknesses as of the date of the report, including the extent to which primary care providers are preventing, screening, or referring for mental and substance use disorder services;

(C) information on trends within the mental health and substance use disorder provider workforce, including the number of individuals expected to enter the mental health workforce over the next 5 years; and

(D) any additional information determined by the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, to be relevant to the mental health and substance use disorder provider workforce.

(b) PEER-SUPPORT SPECIALIST PROGRAMS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on peer-support specialist programs in up to 10 States that receive funding from the Substance Abuse and Mental Health Services Administration.

(2) CONTENTS OF STUDY.—In conducting the study under paragraph (1), the Comptroller General of the United States shall examine and identify best practices, in the States selected pursuant to such paragraph, related to training and credential requirements for peer-support specialist programs, such as—

(A) hours of formal work or volunteer experience related to mental and substance use disorders conducted through such programs;

(B) types of peer-support specialist exams required for such programs in the selected States;

(C) codes of ethics used by such programs in the selected States;

(D) required or recommended skill sets for such programs in the selected States; and

(E) requirements for continuing education.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study conducted under paragraph (1).

Subtitle C—Mental Health on Campus Improvement

SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES ON CAMPUS.

Section 520E–2 of the Public Health Service Act (42 U.S.C. 290bb–36b) is amended—

(1) in the section heading, by striking "**AND BEHAVIORAL HEALTH**" and inserting "**HEALTH AND SUBSTANCE USE DISORDER**";

(2) in subsection (a)—

(A) by striking "Services," and inserting "Services and";

(B) by striking "and behavioral health problems" and inserting "health or substance use disorders";

(C) by striking "substance abuse" and inserting "substance use disorders"; and

(D) by adding after, "suicide attempts," the following: "prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk,";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "for—" and inserting "for one or more of the following:"; and

(B) by striking paragraphs (1) through (6) and inserting the following:

"(1) Educating students, families, faculty, and staff to increase awareness of mental and substance use disorders.

"(2) The operation of hotlines.

"(3) Preparing informational material.

"(4) Providing outreach services to notify students about available mental and substance use disorder services.

"(5) Administering voluntary mental and substance use disorder screenings and assessments.

"(6) Supporting the training of students, faculty, and staff to respond effectively to students with mental and substance use disorders.

"(7) Creating a network infrastructure to link institutions of higher education with health care providers who treat mental and substance use disorders.

"(8) Providing mental and substance use disorders prevention and treatment services to students, which may include recovery support services and programming and early intervention, treatment, and management, including through the use of telehealth services.

"(9) Conducting research through a counseling or health center at the institution of higher education involved regarding improving the behavioral health of students through clinical services, outreach, prevention, or academic success, in a manner that is in compliance with all applicable personal privacy laws.

"(10) Supporting student groups on campus, including athletic teams, that engage in activities to educate students, including activities to reduce stigma surrounding mental and behavioral disorders, and promote mental health.

"(11) Employing appropriately trained staff.

"(12) Developing and supporting evidence-based and emerging best practices, including a focus on culturally and linguistically appropriate best practices.";

(4) in subsection (c)(5), by striking "substance abuse" and inserting "substance use disorder";

(5) in subsection (d)—

(A) in the matter preceding paragraph (1), by striking "An institution of higher education desiring a grant under this section" and inserting "To be eligible to receive a grant under this section, an institution of higher education";

(B) by striking paragraph (1) and inserting—

"(1) A description of the population to be targeted by the program carried out under the grant, including veterans whenever possible and appropriate, and of identified mental and substance use disorder needs of students at the institution of higher education.";

(C) in paragraph (2), by inserting ", which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in order to carry out the program under the grant" before the period at the end; and

(D) by adding after paragraph (5) the following new paragraphs:

"(6) An outline of the objectives of the program carried out under the grant.

"(7) For an institution of higher education proposing to use the grant for an activity described in paragraph (8) or (9) of subsection (b), a description of the policies and procedures of the institution of higher education that are related to applicable laws regarding access to, and sharing of, treatment records of students at any campus-based mental health center or partner organization, including the policies and State laws governing when such records can be accessed and shared for non-treatment purposes and a description of the process used

by the institution of higher education to notify students of these policies and procedures, including the extent to which written consent is required.

"(8) An assurance that grant funds will be used to supplement and not supplant any other Federal, State, or local funds available to carry out activities of the type carried out under the grant.";

(6) in subsection (e)(1), by striking "and behavioral health problems" and inserting "health and substance use disorders";

(7) in subsection (f)(2)—

(A) by striking "and behavioral health" and inserting "health and substance use disorder"; and

(B) by striking "suicide and substance abuse" and inserting "suicide and substance use disorders";

(8) by redesignating subsection (h) as subsection (i);

(9) by inserting after subsection (g) the following new subsection:

"(h) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to grantees in carrying out this section."; and

(10) in subsection (i), as redesignated by paragraph (8), by striking "$5,000,000 for fiscal year 2005" and all that follows through the period at the end and inserting "$7,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9032. INTERAGENCY WORKING GROUP ON COLLEGE MENTAL HEALTH.

42 USC 290bb–36b note.

(a) PURPOSE.—It is the purpose of this section to provide for the establishment of a College Campus Task Force to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(b) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a College Campus Task Force (referred to in this section as the "Task Force") to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(c) MEMBERSHIP.—The Task Force shall be composed of a representative from each Federal agency (as appointed by the head of the agency) that has jurisdiction over, or is affected by, mental health and education policies and projects, including—

(1) the Department of Education;

(2) the Department of Health and Human Services;

(3) the Department of Veterans Affairs; and

(4) such other Federal agencies as the Assistant Secretary for Mental Health and Substance Use, in consultation with the Secretary, determines to be appropriate.

(d) DUTIES.—The Task Force shall—

(1) serve as a centralized mechanism to coordinate a national effort to—

(A) discuss and evaluate evidence and knowledge on mental and behavioral health services available to, and the prevalence of mental illness among, the age population of students attending institutions of higher education in the United States;

(B) determine the range of effective, feasible, and comprehensive actions to improve mental and behavioral health on campuses of institutions of higher education;

(C) examine and better address the needs of the age population of students attending institutions of higher education dealing with mental illness;

(D) survey Federal agencies to determine which policies are effective in encouraging, and how best to facilitate outreach without duplicating, efforts relating to mental and behavioral health promotion;

(E) establish specific goals within and across Federal agencies for mental health promotion, including determinations of accountability for reaching those goals;

(F) develop a strategy for allocating responsibilities and ensuring participation in mental and behavioral health promotion, particularly in the case of competing agency priorities;

(G) coordinate plans to communicate research results relating to mental and behavioral health amongst the age population of students attending institutions of higher education to enable reporting and outreach activities to produce more useful and timely information;

(H) provide a description of evidence-based practices, model programs, effective guidelines, and other strategies for promoting mental and behavioral health on campuses of institutions of higher education;

(I) make recommendations to improve Federal efforts relating to mental and behavioral health promotion on campuses of institutions of higher education and to ensure Federal efforts are consistent with available standards, evidence, and other programs in existence as of the date of enactment of this Act;

(J) monitor Federal progress in meeting specific mental and behavioral health promotion goals as they relate to settings of institutions of higher education; and

(K) examine and disseminate best practices related to intracampus sharing of treatment records;

(2) consult with national organizations with expertise in mental and behavioral health, especially those organizations working with the age population of students attending institutions of higher education; and

(3) consult with and seek input from mental health professionals working on campuses of institutions of higher education as appropriate.

(e) MEETINGS.—

(1) IN GENERAL.—The Task Force shall meet not fewer than three times each year.

(2) ANNUAL CONFERENCE.—The Secretary shall sponsor an annual conference on mental and behavioral health in settings of institutions of higher education to enhance coordination, build partnerships, and share best practices in mental and behavioral health promotion, data collection, analysis, and services.

(f) DEFINITION.—In this section, the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022.

SEC. 9033. IMPROVING MENTAL HEALTH ON COLLEGE CAMPUSES. 42 USC 290ee–4.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

"SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH AND EDUCATION ON COLLEGE CAMPUSES.

"(a) PURPOSE.—It is the purpose of this section to increase access to, and reduce the stigma associated with, mental health services to ensure that students at institutions of higher education have the support necessary to successfully complete their studies.

"(b) NATIONAL PUBLIC EDUCATION CAMPAIGN.—The Secretary, acting through the Assistant Secretary and in collaboration with the Director of the Centers for Disease Control and Prevention, shall convene an interagency, public-private sector working group to plan, establish, and begin coordinating and evaluating a targeted public education campaign that is designed to focus on mental and behavioral health on the campuses of institutions of higher education. Such campaign shall be designed to—

"(1) improve the general understanding of mental health and mental disorders;

"(2) encourage help-seeking behaviors relating to the promotion of mental health, prevention of mental disorders, and treatment of such disorders;

"(3) make the connection between mental and behavioral health and academic success; and

"(4) assist the general public in identifying the early warning signs and reducing the stigma of mental illness.

"(c) COMPOSITION.—The working group convened under subsection (b) shall include—

"(1) mental health consumers, including students and family members;

"(2) representatives of institutions of higher education;

"(3) representatives of national mental and behavioral health associations and associations of institutions of higher education;

"(4) representatives of health promotion and prevention organizations at institutions of higher education;

"(5) representatives of mental health providers, including community mental health centers; and

"(6) representatives of private-sector and public-sector groups with experience in the development of effective public health education campaigns.

"(d) PLAN.—The working group under subsection (b) shall develop a plan that—

"(1) targets promotional and educational efforts to the age population of students at institutions of higher education and individuals who are employed in settings of institutions of higher education, including through the use of roundtables;

"(2) develops and proposes the implementation of research-based public health messages and activities;

"(3) provides support for local efforts to reduce stigma by using the National Health Information Center as a primary point of contact for information, publications, and service program referrals; and

"(4) develops and proposes the implementation of a social marketing campaign that is targeted at the population of students attending institutions of higher education and individuals who are employed in settings of institutions of higher education.

"(e) DEFINITION.—In this section, the term 'institution of higher education' has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022.".

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.

(a) COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.—Section 561(a)(1) of the Public Health Service Act (42 U.S.C. 290ff(a)(1)) is amended by inserting ", which may include efforts to identify and serve children at risk" before the period.

(b) REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.—Section 562(b) of the Public Health Service Act (42 U.S.C. 290ff–1(b)) is amended by striking "will not provide an individual with access to the system if the individual is more than 21 years of age" and inserting "will provide an individual with access to the system through the age of 21 years".

(c) ADDITIONAL PROVISIONS.—Section 564(f) of the Public Health Service Act (42 U.S.C. 290ff–3(f)) is amended by inserting "(and provide a copy to the State involved)" after "to the Secretary".

(d) GENERAL PROVISIONS.—Section 565 of the Public Health Service Act (42 U.S.C. 290ff–4) is amended—

(1) in subsection (b)(1)—

(A) in the matter preceding subparagraph (A), by striking "receiving a grant under section 561(a)" and inserting ", regardless of whether such public entity is receiving a grant under section 561(a)"; and

(B) in subparagraph (B), by striking "pursuant to" and inserting "described in";

(2) in subsection (d)(1), by striking "not more than 21 years of age" and inserting "through the age of 21 years"; and

(3) in subsection (f)(1), by striking "$100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$119,026,000 for each of fiscal years 2018 through 2022".

SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL HEALTH CARE.

Title III of the Public Health Service Act is amended by inserting after section 330L of such Act (42 U.S.C. 254c–18) the following new section:

"SEC. 330M PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS. 42 USC 254c–19.

"(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants to States, political subdivisions of States, and Indian tribes and tribal organizations (for purposes of this section, as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)) to promote behavioral health integration in pediatric primary care by—

"(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

"(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

"(b) PROGRAM REQUIREMENTS.—

"(1) IN GENERAL.—A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, shall—

"(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

"(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

"(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

"(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

"(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

"(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

"(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

"(H) assist with referrals to specialty care and community or behavioral health resources; and

"(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health problems.

"(2) PEDIATRIC MENTAL HEALTH TEAMS.—In this subsection, the term 'pediatric mental health team' means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical

mental health professional, such as a psychologist, social worker, or mental health counselor. Such a team may be regionally based.

"(c) APPLICATION.—A State, political subdivision of a State, Indian tribe, or tribal organization seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such grant.

"(d) EVALUATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such grant to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

"(e) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

"(f) MATCHING REQUIREMENT.—The Secretary may not award a grant under this section unless the State, political subdivision of a State, Indian tribe, or tribal organization involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian tribe, or tribal organization in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the grant.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, $9,000,000 for the period of fiscal years 2018 through 2022.".

SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

The first section 514 of the Public Health Service Act (42 U.S.C. 290bb–7), relating to substance abuse treatment services for children and adolescents, is amended—

(1) in the section heading, by striking "**ABUSE TREATMENT**" and inserting "**USE DISORDER TREATMENT AND EARLY INTERVENTION**";

(2) by striking subsection (a) and inserting the following:

"(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), or health facilities or programs operated by or in accordance with a contract or grant with the Indian Health Service, for the purpose of—

"(1) providing early identification and services to meet the needs of children and adolescents who are at risk of substance use disorders;

"(2) providing substance use disorder treatment services for children, including children and adolescents with co-occurring mental illness and substance use disorders; and

"(3) providing assistance to pregnant women, and parenting women, with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so that children are in safe, stable home environments and receive appropriate health care services.";

(3) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) apply evidence-based and cost-effective methods;";

(B) in paragraph (2)—

(i) by striking "treatment"; and

(ii) by inserting "substance abuse," after "child welfare,";

(C) in paragraph (3), by striking "substance abuse disorders" and inserting "substance use disorders, including children and adolescents with co-occurring mental illness and substance use disorders,";

(D) in paragraph (5), by striking "treatment;" and inserting "services; and";

(E) in paragraph (6), by striking "substance abuse treatment; and" and inserting "treatment."; and

(F) by striking paragraph (7); and

(4) in subsection (f), by striking "$40,000,000" and all that follows through the period and inserting "$29,605,000 for each of fiscal years 2018 through 2022.".

SEC. 10004. CHILDREN'S RECOVERY FROM TRAUMA.

The first section 582 of the Public Health Service Act (42 U.S.C. 290hh–1; relating to grants to address the problems of persons who experience violence related stress) is amended—

(1) in subsection (a), by striking "developing programs" and all that follows through the period at the end and inserting the following: "developing and maintaining programs that provide for—

"(1) the continued operation of the National Child Traumatic Stress Initiative (referred to in this section as the 'NCTSI'), which includes a cooperative agreement with a coordinating center, that focuses on the mental, behavioral, and biological aspects of psychological trauma response, prevention of the long-term consequences of child trauma, and early intervention services and treatment to address the long-term consequences of child trauma; and

"(2) the development of knowledge with regard to evidence-based practices for identifying and treating mental, behavioral, and biological disorders of children and youth resulting from witnessing or experiencing a traumatic event.";

(2) in subsection (b)—

(A) by striking "subsection (a) related" and inserting "subsection (a)(2) (related";

(B) by striking "treating disorders associated with psychological trauma" and inserting "treating mental, behavioral, and biological disorders associated with psychological trauma)"; and

(C) by striking "mental health agencies and programs that have established clinical and basic research" and inserting "universities, hospitals, mental health agencies,

and other programs that have established clinical expertise and research";

(3) by redesignating subsections (c) through (g) as subsections (g) through (k), respectively;

(4) by inserting after subsection (b), the following:

"(c) CHILD OUTCOME DATA.—The NCTSI coordinating center described in subsection (a)(1) shall collect, analyze, report, and make publicly available, as appropriate, NCTSI-wide child treatment process and outcome data regarding the early identification and delivery of evidence-based treatment and services for children and families served by the NCTSI grantees.

"(d) TRAINING.—The NCTSI coordinating center shall facilitate the coordination of training initiatives in evidence-based and trauma-informed treatments, interventions, and practices offered to NCTSI grantees, providers, and partners.

"(e) DISSEMINATION AND COLLABORATION.—The NCTSI coordinating center shall, as appropriate, collaborate with—

"(1) the Secretary, in the dissemination of evidence-based and trauma-informed interventions, treatments, products, and other resources to appropriate stakeholders; and

"(2) appropriate agencies that conduct or fund research within the Department of Health and Human Services, for purposes of sharing NCTSI expertise, evaluation data, and other activities, as appropriate.

"(f) REVIEW.—The Secretary shall, consistent with the peer-review process, ensure that NCTSI applications are reviewed by appropriate experts in the field as part of a consensus-review process. The Secretary shall include review criteria related to expertise and experience in child trauma and evidence-based practices.";

(5) in subsection (g) (as so redesignated), by striking "with respect to centers of excellence are distributed equitably among the regions of the country" and inserting "are distributed equitably among the regions of the United States";

(6) in subsection (i) (as so redesignated), by striking "recipient may not exceed 5 years" and inserting "recipient shall not be less than 4 years, but shall not exceed 5 years"; and

(7) in subsection (j) (as so redesignated), by striking "$50,000,000" and all that follows through "2006" and inserting "$46,887,000 for each of fiscal years 2018 through 2022".

SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317L (42 U.S.C. 247b–13) the following:

42 USC 247b–13a.

"SEC. 317L–1. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

"(a) GRANTS.—The Secretary shall make grants to States to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.

"(b) APPLICATION.—To seek a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may

require. At a minimum, any such application shall include explanations of—

"(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for maternal depression in 1 or more communities; and

"(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal depression.

"(c) PRIORITY.—In awarding grants under this section, the Secretary may give priority to States proposing to improve or enhance access to screening services for maternal depression in primary care settings.

"(d) USE OF FUNDS.—The activities eligible for funding through a grant under subsection (a)—

"(1) shall include—

"(A) providing appropriate training to health care providers; and

"(B) providing information to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and

"(2) may include—

"(A) enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;

"(B) establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups; and

"(C) utilizing telehealth services for rural areas and medically underserved areas (as defined in section 330I(a)).

"(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.".

SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

Part Q of title III of the Public Health Service Act (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

"SEC. 399Z–2. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT. 42 USC 280h–6.

"(a) GRANTS.—The Secretary shall—

"(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

"(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

"(B) multigenerational therapy and other services that support the caregiving relationship; and

"(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and

linguistically appropriate, and can be replicated in other appropriate settings.

"(b) ELIGIBLE CHILDREN AND ENTITIES.—In this section:

"(1) ELIGIBLE CHILD.—The term 'eligible child' means a child from birth to not more than 12 years of age who—

"(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

"(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

"(2) ELIGIBLE ENTITY.—The term 'eligible entity' means a human services agency or nonprofit institution that—

"(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

"(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

"(c) APPLICATION.—An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(d) USE OF FUNDS FOR EARLY INTERVENTION AND TREATMENT PROGRAMS.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

"(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

"(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

"(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

"(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices

for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

"(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

"(e) MATCHING FUNDS.—The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $20,000,000 for the period of fiscal years 2018 through 2022.".

TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

SEC. 11001. SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) According to the National Survey on Drug Use and Health, in 2015, there were approximately 9,800,000 adults in the United States with serious mental illness.

(2) The Substance Abuse and Mental Health Services Administration defines the term "serious mental illness" as an illness affecting individuals 18 years of age or older as having, at any time in the past year, a diagnosable mental, behavioral, or emotional disorder that results in serious functional impairment and substantially interferes with or limits one or more major life activities.

(3) In reporting on the incidence of serious mental illness, the Substance Abuse and Mental Health Services Administration includes major depression, schizophrenia, bipolar disorder, and other mental disorders that cause serious impairment.

(4) Adults with a serious mental illness are at a higher risk for chronic physical illnesses and premature death.

(5) According to the World Health Organization, adults with a serious mental illness have lifespans that are 10 to 25 years shorter than those without serious mental illness. The vast majority of these deaths are due to chronic physical medical conditions, such as cardiovascular, respiratory, and infectious diseases, as well as diabetes and hypertension.

(6) According to the World Health Organization, the majority of deaths of adults with a serious mental illness that are due to physical medical conditions are preventable.

(7) Supported decision making can facilitate care decisions in areas where serious mental illness may impact the capacity of an individual to determine a course of treatment while still allowing the individual to make decisions independently.

(8) Help should be provided to adults with a serious mental illness to address their acute or chronic physical illnesses, make informed choices about treatment, and understand and follow through with appropriate treatment.

(9) There is confusion in the health care community regarding permissible practices under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (commonly known as "HIPAA"). This confusion may hinder appropriate communication of health care information or treatment preferences with appropriate caregivers.

(b) SENSE OF CONGRESS.—It is the sense of Congress that clarification is needed regarding the privacy rule promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) regarding existing permitted uses and disclosures of health information by health care professionals to communicate with caregivers of adults with a serious mental illness to facilitate treatment.

SEC. 11002. CONFIDENTIALITY OF RECORDS.

Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the "Secretary") first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.

42 USC 1320d–2 note.

SEC. 11003. CLARIFICATION ON PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Director of the Office for Civil Rights, shall ensure that health care providers, professionals, patients and their families, and others involved in mental or substance use disorder treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(b) GUIDANCE.—

(1) ISSUANCE.—In carrying out subsection (a), not later than 1 year after the date of enactment of this section, the Secretary shall issue guidance clarifying the circumstances under which, consistent with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, a health care provider or covered entity may use or disclose protected health information.

(2) CIRCUMSTANCES ADDRESSED.—The guidance issued under this section shall address circumstances including those that—

(A) require the consent of the patient;

(B) require providing the patient with an opportunity to object;

(C) are based on the exercise of professional judgment regarding whether the patient would object when the opportunity to object cannot practicably be provided because of the incapacity of the patient or an emergency treatment circumstance; and

(D) are determined, based on the exercise of professional judgment, to be in the best interest of the patient when the patient is not present or otherwise incapacitated.

(3) COMMUNICATION WITH FAMILY MEMBERS AND CAREGIVERS.—In addressing the circumstances described in paragraph (2), the guidance issued under this section shall clarify permitted uses or disclosures of protected health information for purposes of—

(A) communicating with a family member of the patient, caregiver of the patient, or other individual, to the extent that such family member, caregiver, or individual is involved in the care of the patient;

(B) in the case that the patient is an adult, communicating with a family member of the patient, caregiver of the patient, or other individual involved in the care of the patient;

(C) in the case that the patient is a minor, communicating with the parent or caregiver of the patient;

(D) involving the family members or caregivers of the patient, or others involved in the patient's care or care plan, including facilitating treatment and medication adherence;

(E) listening to the patient, or receiving information with respect to the patient from the family or caregiver of the patient;

(F) communicating with family members of the patient, caregivers of the patient, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and

(G) communicating to law enforcement and family members or caregivers of the patient about the admission of the patient to receive care at, or the release of a patient from, a facility for an emergency psychiatric hold or involuntary treatment.

SEC. 11004. DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS.

42 USC 1320d–2 note.

(a) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in consultation with appropriate experts, shall identify the following model programs and materials, or (in the case that no such programs or materials exist) recognize private or public entities to develop and disseminate each of the following:

(1) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, including child and adolescent psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) regarding the permitted uses and disclosures, consistent with the standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and such part C, of the protected health information of patients seeking or undergoing mental or substance use disorder treatment.

(2) A model program and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations specified in paragraph (1).

(b) PERIODIC UPDATES.—The Secretary shall—

(1) periodically review and update the model programs and materials identified or developed under subsection (a); and

(2) disseminate the updated model programs and materials to the individuals described in subsection (a).

(c) COORDINATION.—The Secretary shall carry out this section in coordination with the Director of the Office for Civil Rights within the Department of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, the Administrator of the Health Resources and Services Administration, and the heads of other relevant agencies within the Department of Health and Human Services.

(d) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under subsections (a) and (b), the Secretary shall solicit the input of relevant national, State, and local associations; medical societies; licensing boards; providers of mental and substance use disorder treatment; organizations with expertise on domestic violence, sexual assault, elder abuse, and child abuse; and organizations representing patients and consumers and the families of patients and consumers.

(e) FUNDING.—There are authorized to be appropriated to carry out this section—

(1) $4,000,000 for fiscal year 2018;

(2) $2,000,000 for each of fiscal years 2019 and 2020; and

(3) $1,000,000 for each of fiscal years 2021 and 2022.

TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

42 USC 1396 note.

SEC. 12001. RULE OF CONSTRUCTION RELATED TO MEDICAID COVERAGE OF MENTAL HEALTH SERVICES AND PRIMARY CARE SERVICES FURNISHED ON THE SAME DAY.

Nothing in title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) shall be construed as prohibiting separate payment under the State plan under such title (or under a waiver of the plan) for the provision of a mental health service or primary care service under such plan, with respect to an individual, because such service is—

(1) a primary care service furnished to the individual by a provider at a facility on the same day a mental health service is furnished to such individual by such provider (or another provider) at the facility; or

(2) a mental health service furnished to the individual by a provider at a facility on the same day a primary care service is furnished to such individual by such provider (or another provider) at the facility.

SEC. 12002. STUDY AND REPORT RELATED TO MEDICAID MANAGED CARE REGULATION.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare &

Medicaid Services, shall conduct a study on coverage under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) of services provided through a medicaid managed care organization (as defined in section 1903(m) of such Act (42 U.S.C. 1396b(m)) or a prepaid inpatient health plan (as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation)) with respect to individuals over the age of 21 and under the age of 65 for the treatment of a mental health disorder in institutions for mental diseases (as defined in section 1905(i) of such Act (42 U.S.C. 1396d(i))). Such study shall include information on the following:

(1) The extent to which States, including the District of Columbia and each territory or possession of the United States, are providing capitated payments to such organizations or plans for enrollees who are receiving services in institutions for mental diseases.

(2) The number of individuals receiving medical assistance under a State plan under such title XIX, or a waiver of such plan, who receive services in institutions for mental diseases through such organizations and plans.

(3) The range of and average number of months, and the length of stay during such months, that such individuals are receiving such services in such institutions.

(4) How such organizations or plans determine when to provide for the furnishing of such services through an institution for mental diseases in lieu of other benefits (including the full range of community-based services) under their contract with the State agency administering the State plan under such title XIX, or a waiver of such plan, to address psychiatric or substance use disorder treatment.

(5) The extent to which the provision of services within such institutions has affected the capitated payments for such organizations or plans.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a).

SEC. 12003. GUIDANCE ON OPPORTUNITIES FOR INNOVATION.

42 USC 1315 note.

Not later than 1 year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall issue a State Medicaid Director letter regarding opportunities to design innovative service delivery systems, including systems for providing community-based services, for adults with a serious mental illness or children with a serious emotional disturbance who are receiving medical assistance under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.). The letter shall include opportunities for demonstration projects under section 1115 of such Act (42 U.S.C. 1315) to improve care for such adults and children.

SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION PROJECT.

(a) COLLECTION OF INFORMATION.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall, to the extent practical and data is available, with respect to each State that has participated in the demonstration project established under section 2707

of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note), collect from each such State information on the following:

(1) The number of institutions for mental diseases (as defined in section 1905(i) of the Social Security Act (42 U.S.C. 1396d(i))) and beds in such institutions that received payment for the provision of services to individuals who receive medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) through the demonstration project in each such State as compared to the total number of institutions for mental diseases and beds in the State.

(2) The extent to which there is a reduction in expenditures under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) or other spending on the full continuum of physical or mental health care for individuals who receive treatment in an institution for mental diseases under the demonstration project, including outpatient, inpatient, emergency, and ambulatory care, that is attributable to such individuals receiving treatment in institutions for mental diseases under the demonstration project.

(3) The number of forensic psychiatric hospitals, the number of beds in such hospitals, and the number of forensic psychiatric beds in other hospitals in such State, based on the most recent data available, to the extent practical, as determined by such Administrator.

(4) The amount of any disproportionate share hospital payments under section 1923 of the Social Security Act (42 U.S.C. 1396r–4) that institutions for mental diseases in the State received during the period beginning on July 1, 2012, and ending on June 30, 2015, and the extent to which the demonstration project reduced the amount of such payments.

(5) The most recent data regarding all facilities or sites in the State in which any adults with a serious mental illness who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) are treated during the period referred to in paragraph (4), to the extent practical, as determined by the Administrator, including—

(A) the types of such facilities or sites (such as an institution for mental diseases, a hospital emergency department, or other inpatient hospital);

(B) the average length of stay in such a facility or site by such an individual, disaggregated by facility type; and

(C) the payment rate under the State plan (or a waivers of such plan) for services furnished to such an individual for that treatment, disaggregated by facility type, during the period in which the demonstration project is in operation.

(6) The extent to which the utilization of hospital emergency departments during the period in which the demonstration project was is in operation differed, with respect to individuals who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan), between—

(A) those individuals who received treatment in an institution for mental diseases under the demonstration project;

(B) those individuals who met the eligibility requirements for the demonstration project but who did not receive treatment in an institution for mental diseases under the demonstration project; and

(C) those adults with a serious mental illness who did not meet such eligibility requirements and did not receive treatment for such illness in an institution for mental diseases.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that summarizes and analyzes the information collected under subsection (a). Such report may be submitted as part of the report required under section 2707(f) of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note) or separately.

SEC. 12005. PROVIDING EPSDT SERVICES TO CHILDREN IN IMDS.

42 USC 1396d note.

(a) IN GENERAL.—Section 1905(a)(16) of the Social Security Act (42 U.S.C. 1396d(a)(16)) is amended—

(1) by striking "effective January 1, 1973" and inserting "(A) effective January 1, 1973"; and

(2) by inserting before the semicolon at the end the following: ", and, (B) for individuals receiving services described in subparagraph (A), early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)), whether or not such screening, diagnostic, and treatment services are furnished by the provider of the services described in such subparagraph".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to items and services furnished in calendar quarters beginning on or after January 1, 2019.

SEC. 12006. ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED FOR PERSONAL CARE SERVICES AND HOME HEALTH CARE SERVICES UNDER MEDICAID.

(a) IN GENERAL.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by inserting after subsection (k) the following new subsection:

"(l)(1) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2019 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

"(A) in the case of personal care services—

"(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

"(ii) for calendar quarters in 2021, by .5 percentage points;

"(iii) for calendar quarters in 2022, by .75 percentage points; and

"(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

"(B) in the case of home health care services—

"(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

"(ii) for calendar quarters in 2025, by .5 percentage points;

"(iii) for calendar quarters in 2026, by .75 percentage points; and

"(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

"(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

"(A) consult with agencies and entities that provide personal care services, home health care services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

"(i) is minimally burdensome;

"(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

"(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

"(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

"(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

"(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

"(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

"(i) in the case of personal care services, for calendar quarters in 2019; and

"(ii) in the case of home health care services, for calendar quarters in 2023.

"(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

"(i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and

"(ii) in implementing such a system, has encountered unavoidable system delays.

"(5) In this subsection:

"(A) The term 'electronic visit verification system' means, with respect to personal care services or home health care services, a system under which visits conducted as part of such services are electronically verified with respect to—

"(i) the type of service performed;

"(ii) the individual receiving the service;

"(iii) the date of the service;

"(iv) the location of service delivery;

"(v) the individual providing the service; and

"(vi) the time the service begins and ends.

"(B) The term 'home health care services' means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

"(C) The term 'personal care services' means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a wavier under section 1115.

"(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

"(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.".

(b) COLLECTION AND DISSEMINATION OF BEST PRACTICES.—Not later than January 1, 2018, the Secretary of Health and Human Services shall, with respect to electronic visit verification systems (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), collect and disseminate best practices to State Medicaid Directors with respect to— 42 USC 1396b note.

(1) training individuals who furnish personal care services, home health care services, or both under the State plan under title XIX of such Act (or under a waiver of the plan) on such systems and the operation of such systems and the prevention of fraud with respect to the provision of personal care services or home health care services (as defined in such subsection (l)(5)); and

(2) the provision of notice and educational materials to family caregivers and beneficiaries with respect to the use of such electronic visit verification systems and other means to prevent such fraud.

(c) RULES OF CONSTRUCTION.— 42 USC 1396b note.

(1) NO EMPLOYER-EMPLOYEE RELATIONSHIP ESTABLISHED.—Nothing in the amendment made by this section may be construed as establishing an employer-employee relationship between the agency or entity that provides for personal care services or home health care services and the individuals who, under a contract with such an agency or entity, furnish such

services for purposes of part 552 of title 29, Code of Federal Regulations (or any successor regulations).

(2) NO PARTICULAR OR UNIFORM ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED.—Nothing in the amendment made by this section shall be construed to require the use of a particular or uniform electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)) by all agencies or entities that provide personal care services or home health care under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.).

(3) NO LIMITS ON PROVISION OF CARE.—Nothing in the amendment made by this section may be construed to limit, with respect to personal care services or home health care services provided under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.), provider selection, constrain beneficiaries' selection of a caregiver, or impede the manner in which care is delivered.

(4) NO PROHIBITION ON STATE QUALITY MEASURES REQUIREMENTS.—Nothing in the amendment made by this section shall be construed as prohibiting a State, in implementing an electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), from establishing requirements related to quality measures for such system.

TITLE XIII—MENTAL HEALTH PARITY

SEC. 13001. ENHANCED COMPLIANCE WITH MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE REQUIREMENTS.

(a) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg–26(a)) is amended by adding at the end the following:

"(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled 'Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance'.

"(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

"(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

"(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

"(II) descriptions of the violations uncovered during the course of such investigations.

"(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

"(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

"(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

"(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this

section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

"(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.".

(b) ADDITIONAL GUIDANCE.—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg–26(a)), as amended by subsection (a), is further amended by adding at the end the following:

"(7) ADDITIONAL GUIDANCE.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(B) DISCLOSURE.—

"(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

"(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section,

section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

"(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

"(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

"(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

"(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

"(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

"(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

"(II) limitations with respect to prescription drug formulary design; and

"(III) use of fail-first or step therapy protocols;

"(ii) examples of methods of determining—

"(I) network admission standards (such as credentialing); and

"(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

"(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

"(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used

by such plans or issuers in performing a nonquantitative treatment limitation analysis;

"(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

"(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

"(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

"(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

"(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.".

(c) AVAILABILITY OF PLAN INFORMATION.—

(1) SOLICITATION OF PUBLIC FEEDBACK.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall solicit feedback from the public on how the disclosure request process for documents containing information that health plans or health insurance issuers are required under Federal or State law to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with existing mental health parity and addiction equity requirements can be improved while continuing to ensure consumers' rights to access all information required by Federal or State law to be disclosed.

(2) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall make such feedback publicly available.

(3) NAIC.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall share feedback obtained pursuant to paragraph (1) directly with the National Association of Insurance Commissioners to the extent such feedback includes recommendations for the development of simplified information disclosure tools to provide consistent information for consumers. Such feedback

may be taken into consideration by the National Association of Insurance Commissioners and other appropriate entities for the voluntary development and voluntary use of common templates and other sample standardized forms to improve consumer access to plan information.

(d) IMPROVING COMPLIANCE.—

(1) IN GENERAL.—In the case that the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury determines that a group health plan or health insurance issuer offering group or individual health insurance coverage has violated, at least 5 times, section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), or section 9812 of the Internal Revenue Code of 1986, respectively, the appropriate Secretary shall audit plan documents for such health plan or issuer in the plan year following the Secretary's determination in order to help improve compliance with such section.

42 USC 300gg–26 note.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority, as in effect on the day before the date of enactment of this Act, of the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury to audit documents of health plans or health insurance issuers.

SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT OF MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE.

(a) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting of stakeholders described in paragraph (2) to produce an action plan for improved Federal and State coordination related to the enforcement of section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, and any comparable provisions of State law (in this section such sections and provisions are collectively referred to as "mental health parity and addiction equity requirements").

(2) STAKEHOLDERS.—The stakeholders described in this paragraph shall include each of the following:

(A) The Federal Government, including representatives from—

(i) the Department of Health and Human Services;

(ii) the Department of the Treasury;

(iii) the Department of Labor; and

(iv) the Department of Justice.

(B) State governments, including—

(i) State health insurance commissioners;

(ii) appropriate State agencies, including agencies on public health or mental health; and

(iii) State attorneys general or other representatives of State entities involved in the enforcement of mental health parity and addiction equity requirements.

(C) Representatives from key stakeholder groups, including—

(i) the National Association of Insurance Commissioners;

(ii) health insurance issuers;

(iii) providers of mental health and substance use disorder treatment;

(iv) employers; and

(v) patients or their advocates.

(b) ACTION PLAN.—Not later than 6 months after the conclusion of the public meeting under subsection (a), the Secretary of Health and Human Services shall finalize the action plan described in such subsection and make it plainly available on the Internet website of the Department of Health and Human Services.

(c) CONTENT.—The action plan under this section shall—

(1) take into consideration the recommendations of the Mental Health and Substance Use Disorder Parity Task Force in its final report issued in October of 2016, and any subsequent Federal and State actions in relation to such recommendations;

(2) reflect the input of the stakeholders participating in the public meeting under subsection (a);

(3) identify specific strategic objectives regarding how the various Federal and State agencies charged with enforcement of mental health parity and addiction equity requirements will collaborate to improve enforcement of such requirements;

(4) provide a timeline for implementing the action plan; and

(5) provide specific examples of how such objectives may be met, which may include—

(A) providing common educational information and documents, such as the Consumer Guide to Disclosure Rights, to patients about their rights under mental health parity and addiction equity requirements;

(B) facilitating the centralized collection of, monitoring of, and response to patient complaints or inquiries relating to mental health parity and addiction equity requirements, which may be through the development and administration of—

(i) a single, toll-free telephone number; and

(ii) a new parity website—

(I) to help consumers find the appropriate Federal or State agency to assist with their parity complaints, appeals, and other actions; and

(II) that takes into consideration, but is not duplicative of, the parity beta site being tested, and released for public comment, by the Department of Health and Human Services as of the date of the enactment of this Act;

(C) Federal and State law enforcement agencies entering into memoranda of understanding to better coordinate enforcement responsibilities and information sharing—

(i) including whether such agencies should make the results of enforcement actions related to mental health parity and addiction equity requirements publicly available; and

(ii) which may include State Policy Academies on Parity Implementation for State Officials and other forums to bring together national experts to provide technical assistance to teams of State officials on strategies to advance compliance with mental health parity and addiction equity requirements in both the commercial market, and in the Medicaid program under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act; and

(D) recommendations to the Congress regarding the need for additional legal authority to improve enforcement of mental health parity and addiction equity requirements, including the need for additional legal authority to ensure that nonquantitative treatment limitations are applied, and the extent and frequency of the applications of such limitations, both to medical and surgical benefits and to mental health and substance use disorder benefits in a comparable manner.

SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and annually thereafter for the subsequent 5 years, the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the results of all closed Federal investigations completed during the preceding 12-month period with findings of any serious violation regarding compliance with mental health and substance use disorder coverage requirements under section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

(b) CONTENTS.—Subject to subsection (c), a report under subsection (a) shall, with respect to investigations described in such subsection, include each of the following:

(1) The number of closed Federal investigations conducted during the covered reporting period.

(2) Each benefit classification examined by any such investigation conducted during the covered reporting period.

(3) Each subject matter, including compliance with requirements for quantitative and nonquantitative treatment limitations, of any such investigation conducted during the covered reporting period.

(4) A summary of the basis of the final decision rendered for each closed investigation conducted during the covered reporting period that resulted in a finding of a serious violation.

(c) LIMITATION.—Any individually identifiable information shall be excluded from reports under subsection (a) consistent with protections under the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

SEC. 13004. GAO STUDY ON PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the extent to which group health plans or health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, medicaid managed care organizations with a contract under section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)), and health plans provided under the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) comply with section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, including—

(1) how nonquantitative treatment limitations, including medical necessity criteria, of such plans or issuers comply with such sections;

(2) how the responsible Federal departments and agencies ensure that such plans or issuers comply with such sections, including an assessment of how the Secretary of Health and Human Services has used its authority to conduct audits of such plans to ensure compliance;

(3) a review of how the various Federal and State agencies responsible for enforcing mental health parity requirements have improved enforcement of such requirements in accordance with the objectives and timeline described in the action plan under section 13002; and

(4) recommendations for how additional enforcement, education, and coordination activities by responsible Federal and State departments and agencies could better ensure compliance with such sections, including recommendations regarding the need for additional legal authority.

42 USC 237a note.

SEC. 13005. INFORMATION AND AWARENESS ON EATING DISORDERS.

(a) INFORMATION.—The Secretary of Health and Human Services, acting through the Director of the Office on Women's Health, may—

(1) update information, related fact sheets, and resource lists related to eating disorders that are available on the public Internet website of the National Women's Health Information Center sponsored by the Office on Women's Health, to include—

(A) updated findings and current research related to eating disorders, as appropriate; and

(B) information about eating disorders, including information related to males and females;

(2) incorporate, as appropriate, and in coordination with the Secretary of Education, information from publicly available resources into appropriate obesity prevention programs developed by the Office on Women's Health; and

(3) make publicly available (through a public Internet website or other method) information, related fact sheets, and

resource lists, as updated under paragraph (1), and the information incorporated into appropriate obesity prevention programs under paragraph (2).

(b) AWARENESS.—The Secretary of Health and Human Services may advance public awareness on—

(1) the types of eating disorders;

(2) the seriousness of eating disorders, including prevalence, comorbidities, and physical and mental health consequences;

(3) methods to identify, intervene, refer for treatment, and prevent behaviors that may lead to the development of eating disorders;

(4) discrimination and bullying based on body size;

(5) the effects of media on self-esteem and body image; and

(6) the signs and symptoms of eating disorders.

SEC. 13006. EDUCATION AND TRAINING ON EATING DISORDERS.

42 USC 237a note.

The Secretary of Health and Human Services may facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to—

(1) identify individuals with eating disorders;

(2) provide early intervention services for individuals with eating disorders;

(3) refer patients with eating disorders for appropriate treatment;

(4) prevent the development of eating disorders; and

(5) provide appropriate treatment services for individuals with eating disorders.

SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.

42 USC 300gg–26 note.

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A—Mental Health and Safe Communities

SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS INTERVENTION TEAMS, MENTAL HEALTH PURPOSES.

(a) EDWARD BYRNE MEMORIAL JUSTICE ASSISTANCE GRANT PROGRAM.—Section 501(a)(1) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3751(a)(1)) is amended by adding at the end the following:

"(H) Mental health programs and related law enforcement and corrections programs, including behavioral programs and crisis intervention teams.".

(b) COMMUNITY ORIENTED POLICING SERVICES PROGRAM.—Section 1701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796dd(b)) is amended—

(1) in paragraph (17), by striking "and" at the end;

(2) by redesignating paragraph (18) as paragraph (22);

(3) by inserting after paragraph (17) the following:

"(18) to provide specialized training to law enforcement officers to—

"(A) recognize individuals who have a mental illness; and

"(B) properly interact with individuals who have a mental illness, including strategies for verbal de-escalation of crises;

"(19) to establish collaborative programs that enhance the ability of law enforcement agencies to address the mental health, behavioral, and substance abuse problems of individuals encountered by law enforcement officers in the line of duty;

"(20) to provide specialized training to corrections officers to recognize individuals who have a mental illness;

"(21) to enhance the ability of corrections officers to address the mental health of individuals under the care and custody of jails and prisons, including specialized training and strategies for verbal de-escalation of crises; and"; and

(4) in paragraph (22), as redesignated, by striking "through (17)" and inserting "through (21)".

(c) MODIFICATIONS TO THE STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANTS.—Section 34(a)(1)(B) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229a(a)(1)(B)) is amended by inserting before the period at the end the following: "and to provide specialized training to paramedics, emergency medical services workers, and other first responders to recognize individuals who have mental illness and how to properly intervene with individuals with mental illness, including strategies for verbal de-escalation of crises".

SEC. 14002. ASSISTED OUTPATIENT TREATMENT PROGRAMS.

(a) IN GENERAL.—Section 2201 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii) is amended in paragraph (2)(B), by inserting before the semicolon the following: ", or court-ordered assisted outpatient treatment when the court has determined such treatment to be necessary".

(b) DEFINITIONS.—Section 2202 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii—1) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(3) the term 'court-ordered assisted outpatient treatment' means a program through which a court may order a treatment plan for an eligible patient that—

"(A) requires such patient to obtain outpatient mental health treatment while the patient is not currently residing in a correctional facility or inpatient treatment facility; and

"(B) is designed to improve access and adherence by such patient to intensive behavioral health services in order to—

"(i) avert relapse, repeated hospitalizations, arrest, incarceration, suicide, property destruction, and violent behavior; and

"(ii) provide such patient with the opportunity to live in a less restrictive alternative to incarceration or involuntary hospitalization; and

"(4) the term 'eligible patient' means an adult, mentally ill person who, as determined by a court—

"(A) has a history of violence, incarceration, or medically unnecessary hospitalizations;

"(B) without supervision and treatment, may be a danger to self or others in the community;

"(C) is substantially unlikely to voluntarily participate in treatment;

"(D) may be unable, for reasons other than indigence, to provide for any of his or her basic needs, such as food, clothing, shelter, health, or safety;

"(E) has a history of mental illness or a condition that is likely to substantially deteriorate if the person is not provided with timely treatment; or

"(F) due to mental illness, lacks capacity to fully understand or lacks judgment to make informed decisions regarding his or her need for treatment, care, or supervision.".

SEC. 14003. FEDERAL DRUG AND MENTAL HEALTH COURTS.

42 USC 3796ii note.

(a) DEFINITIONS.—In this section—

(1) the term "eligible offender" means a person who—

(A)(i) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders; or

(ii) manifests obvious signs of mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court;

(B) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code; and

(C) is determined by a judge to be eligible; and

(2) the term "mental illness" means a diagnosable mental, behavioral, or emotional disorder—

(A) of sufficient duration to meet diagnostic criteria within the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association; and

(B) that has resulted in functional impairment that substantially interferes with or limits 1 or more major life activities.

(b) ESTABLISHMENT OF PROGRAM.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall establish a pilot program to determine the effectiveness of diverting eligible offenders from Federal prosecution, Federal probation, or a Bureau of Prisons facility, and placing such eligible offenders in drug or mental health courts.

(c) PROGRAM SPECIFICATIONS.—The pilot program established under subsection (b) shall involve—

(1) continuing judicial supervision, including periodic review, of program participants who have a substance abuse problem or mental illness; and

(2) the integrated administration of services and sanctions, which shall include—

(A) mandatory periodic testing, as appropriate, for the use of controlled substances or other addictive substances during any period of supervised release or probation for each program participant;

(B) substance abuse treatment for each program participant who requires such services;

(C) diversion, probation, or other supervised release with the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress toward completing program requirements;

(D) programmatic offender management, including case management, and aftercare services, such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each program participant who requires such services;

(E) outpatient or inpatient mental health treatment, as ordered by the court, that carries with it the possibility of dismissal of charges or reduced sentencing upon successful completion of such treatment;

(F) centralized case management, including—

(i) the consolidation of all cases, including violations of probations, of the program participant; and

(ii) coordination of all mental health treatment plans and social services, including life skills and vocational training, housing and job placement, education, health care, and relapse prevention for each program participant who requires such services; and

(G) continuing supervision of treatment plan compliance by the program participant for a term not to exceed the maximum allowable sentence or probation period for the charged or relevant offense and, to the extent practicable, continuity of psychiatric care at the end of the supervised period.

(d) IMPLEMENTATION; DURATION.—The pilot program established under subsection (b) shall be conducted—

(1) in not less than 1 United States judicial district, designated by the Attorney General in consultation with the Director of the Administrative Office of the United States Courts, as appropriate for the pilot program; and

(2) during fiscal year 2017 through fiscal year 2021.

(e) CRITERIA FOR DESIGNATION.—Before making a designation under subsection (d)(1), the Attorney General shall—

(1) obtain the approval, in writing, of the United States Attorney for the United States judicial district being designated;

(2) obtain the approval, in writing, of the chief judge for the United States judicial district being designated; and

(3) determine that the United States judicial district being designated has adequate behavioral health systems for treatment, including substance abuse and mental health treatment.

(f) ASSISTANCE FROM OTHER FEDERAL ENTITIES.—The Administrative Office of the United States Courts and the United States Probation Offices shall provide such assistance and carry out such functions as the Attorney General may request in monitoring, supervising, providing services to, and evaluating eligible offenders placed in a drug or mental health court under this section.

(g) REPORTS.—The Attorney General, in consultation with the Director of the Administrative Office of the United States Courts, shall monitor the drug and mental health courts under this section, and shall submit a report to Congress on the outcomes of the program at the end of the period described in subsection (d)(2).

SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM.

42 USC 3796ii–8.

Part V of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii et seq.) is amended by inserting at the end the following:

"SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL SYSTEM.

"(a) PRETRIAL SCREENING AND SUPERVISION.—

"(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand pretrial services programs to improve the identification and outcomes of individuals with mental illness.

"(2) ALLOWABLE USES.—Grants awarded under this subsection may be may be used for—

"(A) behavioral health needs and risk screening of defendants, including verification of interview information, mental health evaluation, and criminal history screening;

"(B) assessment of risk of pretrial misconduct through objective, statistically validated means, and presentation to the court of recommendations based on such assessment, including services that will reduce the risk of pre-trial misconduct;

"(C) followup review of defendants unable to meet the conditions of pretrial release;

"(D) evaluation of process and results of pre-trial service programs;

"(E) supervision of defendants who are on pretrial release, including reminders to defendants of scheduled court dates;

"(F) reporting on process and results of pretrial services programs to relevant public and private mental health stakeholders; and

"(G) data collection and analysis necessary to make available information required for assessment of risk.

"(b) BEHAVIORAL HEALTH ASSESSMENTS AND INTERVENTION.—

"(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop,

implement, or expand a behavioral health screening and assessment program framework for State or local criminal justice systems.

"(2) ALLOWABLE USES.—Grants awarded under this subsection may be used for—

"(A) promotion of the use of validated assessment tools to gauge the criminogenic risk, substance abuse needs, and mental health needs of individuals;

"(B) initiatives to match the risk factors and needs of individuals to programs and practices associated with research-based, positive outcomes;

"(C) implementing methods for identifying and treating individuals who are most likely to benefit from coordinated supervision and treatment strategies, and identifying individuals who can do well with fewer interventions; and

"(D) collaborative decision-making among the heads of criminal justice agencies, mental health systems, judicial systems, substance abuse systems, and other relevant systems or agencies for determining how treatment and intensive supervision services should be allocated in order to maximize benefits, and developing and utilizing capacity accordingly.

"(c) USE OF GRANT FUNDS.—A State, unit of local government, territory, Indian Tribe, or nonprofit agency that receives a grant under this section shall, in accordance with subsection (b)(2), use grant funds for the expenses of a treatment program, including—

"(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including costs relating to enforcement;

"(2) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to program participants, including aftercare supervision, vocational training, education, and job placement; and

"(3) payments to public and nonprofit private entities that are approved by the State or Indian Tribe and licensed, if necessary, to provide alcohol and drug addiction treatment to offenders participating in the program.

"(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—

"(1) IN GENERAL.—Grants awarded under this section shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this section.

"(2) FEDERAL SHARE.—The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (e).

"(e) APPLICATIONS.—To request a grant under this section, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.

"(f) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the distribution of grants under this section is equitable and includes—

"(1) each State; and

"(2) a unit of local government, territory, Indian Tribe, or nonprofit agency—

"(A) in each State; and

"(B) in rural, suburban, Tribal, and urban jurisdictions.

"(g) REPORTS AND EVALUATIONS.—For each fiscal year, each grantee under this section during that fiscal year shall submit to the Attorney General a report on the effectiveness of activities carried out using such grant. Each report shall include an evaluation in such form and containing such information as the Attorney General may reasonably require. The Attorney General shall specify the dates on which such reports shall be submitted.

"(h) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

"(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

"(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

"(2) NONPROFIT AGENCY REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term 'nonprofit agency' means an organization that is described in section

501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

"(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

"(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—Not more than $20,000 of the amounts made available to the Department of Justice to carry out this section may be used by the Attorney General, or by any individual or entity awarded a grant under this section to host, or make any expenditures relating to, a conference unless the Deputy Attorney General provides prior written authorization that the funds may be expended to host the conference or make such expenditure.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

"(A) indicating whether—

"(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

"(iii) any reimbursements required under paragraph (1)(F) have been made; and

"(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

"(i) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare the possible grant with any other grants awarded to the applicant under this Act to determine whether the grants are for the same purpose.

"(2) REPORT.—If the Attorney General awards multiple grants to the same applicant for the same purpose, the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any such grants awarded; and

"(B) the reason the Attorney General awarded the duplicate grants.".

SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREATMENT INITIATIVES.

Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—

(1) redesignating subsection (j) as subsection (o); and

(2) inserting after subsection (i) the following:

"(j) FORENSIC ASSERTIVE COMMUNITY TREATMENT (FACT) INITIATIVE PROGRAM.—

"(1) IN GENERAL.—The Attorney General may make grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand Assertive Community Treatment initiatives to develop forensic assertive community treatment (referred to in this subsection as 'FACT') programs that provide high intensity services in the community for individuals with mental illness with involvement in the criminal justice system to prevent future incarcerations.

"(2) ALLOWABLE USES.—Grant funds awarded under this subsection may be used for—

"(A) multidisciplinary team initiatives for individuals with mental illnesses with criminal justice involvement that address criminal justice involvement as part of treatment protocols;

"(B) FACT programs that involve mental health professionals, criminal justice agencies, chemical dependency specialists, nurses, psychiatrists, vocational specialists, forensic peer specialists, forensic specialists, and dedicated administrative support staff who work together to provide recovery oriented, 24/7 wraparound services;

"(C) services such as integrated evidence-based practices for the treatment of co-occurring mental health and substance-related disorders, assertive outreach and engagement, community-based service provision at participants' residence or in the community, psychiatric rehabilitation, recovery oriented services, services to address criminogenic risk factors, and community tenure;

"(D) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to eligible offenders

participating in the program, including behavioral health services and aftercare supervision; and

"(E) training for all FACT teams to promote high-fidelity practice principles and technical assistance to support effective and continuing integration with criminal justice agency partners.

"(3) SUPPLEMENT AND NOT SUPPLANT.—Grants made under this subsection shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this subsection.

"(4) APPLICATIONS.—To request a grant under this subsection, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.".

SEC. 14006. ASSISTANCE FOR INDIVIDUALS TRANSITIONING OUT OF SYSTEMS.

Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)) is amended—

(1) in paragraph (5), by striking "and" at the end;

(2) in paragraph (6), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(7) provide mental health treatment and transitional services for those with mental illnesses or with co-occurring disorders, including housing placement or assistance; and".

SEC. 14007. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN DRUG COURTS.

Part EE of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797u et seq.) is amended—

(1) in section 2951(a)(1) (42 U.S.C. 3797u(a)(1)), by inserting ", including co-occurring substance abuse and mental health problems," after "problems"; and

(2) in section 2959(a) (42 U.S.C. 3797u–8(a)), by inserting ", including training for drug court personnel and officials on identifying and addressing co-occurring substance abuse and mental health problems" after "part".

42 USC 3797aa–1 note.

SEC. 14008. MENTAL HEALTH TRAINING FOR FEDERAL UNIFORMED SERVICES.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Health and Human Services, and the Secretary of Commerce shall provide the following to each of the uniformed services (as that term is defined in section 101 of title 10, United States Code) under their direction:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training in procedures to identify and respond appropriately to incidents in which the unique needs of individuals with mental illnesses are involved.

(2) IMPROVED TECHNOLOGY.—Computerized information systems or technological improvements to provide timely information to Federal law enforcement personnel, other branches of the uniformed services, and criminal justice system personnel to improve the Federal response to mentally ill individuals.

(3) COOPERATIVE PROGRAMS.—The establishment and expansion of cooperative efforts to promote public safety through the use of effective intervention with respect to mentally ill individuals encountered by members of the uniformed services.

SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OFFENDER REENTRY.

(a) REENTRY DEMONSTRATION PROJECTS.—Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended by section 14006, is amended—

(1) in paragraph (3)(C), by inserting "mental health services," before "drug treatment"; and

(2) by adding at the end the following:

"(8) target offenders with histories of homelessness, substance abuse, or mental illness, including a prerelease assessment of the housing status of the offender and behavioral health needs of the offender with clear coordination with mental health, substance abuse, and homelessness services systems to achieve stable and permanent housing outcomes with appropriate support service.".

(b) MENTORING GRANTS.—Section 211(b)(2) of the Second Chance Act of 2007 (42 U.S.C. 17531(b)(2)) is amended by inserting ", including mental health care" after "community".

SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVENTION TEAMS.

Section 2701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797a(b)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following:

"(4) The development and operation of crisis intervention teams that may include coordination with law enforcement agencies and specialized training for school officials in responding to mental health crises.".

SEC. 14011. ACTIVE-SHOOTER TRAINING FOR LAW ENFORCEMENT.

42 USC 3752 note.

The Attorney General, as part of the Preventing Violence Against Law Enforcement and Ensuring Officer Resilience and Survivability Initiative (VALOR) of the Department of Justice, may provide safety training and technical assistance to local law enforcement agencies, including active-shooter response training.

SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN RESIDENTIAL SUBSTANCE ABUSE TREATMENT PROGRAMS.

Section 1901(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a)) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(3) developing and implementing specialized residential substance abuse treatment programs that identify and provide appropriate treatment to inmates with co-occurring mental health and substance abuse disorders or challenges.".

SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended by striking part CC and inserting the following:

"PART CC—MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS

42 USC 3797q.

"SEC. 2901. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

"(a) DEFINITIONS.—In this section—

"(1) the term 'eligible entity' means a State, unit of local government, Indian tribe, or nonprofit organization; and

"(2) the term 'eligible participant' means an individual who—

"(A) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

"(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

"(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code;

"(B) has a history of, or a current—

"(i) substance use disorder;

"(ii) mental illness; or

"(iii) co-occurring mental illness and substance use disorder; and

"(C) has been approved for participation in a program funded under this section by the relevant law enforcement agency, prosecuting attorney, defense attorney, probation official, corrections official, judge, representative of a mental health agency, or representative of a substance abuse agency, as required by law.

"(b) PROGRAM AUTHORIZED.—The Attorney General may make grants to eligible entities to develop, implement, or expand a treatment alternative to incarceration program for eligible participants, including—

"(1) pre-booking treatment alternative to incarceration programs, including—

"(A) law enforcement training on substance use disorders, mental illness, and co-occurring mental illness and substance use disorders;

"(B) receiving centers as alternatives to incarceration of eligible participants;

"(C) specialized response units for calls related to substance use disorders, mental illness, or co-occurring mental illness and substance use disorders; and

"(D) other arrest and pre-booking treatment alternatives to incarceration models; or

"(2) post-booking treatment alternative to incarceration programs, including—

"(A) specialized clinical case management;

"(B) pre-trial services related to substances use disorders, mental illness, and co-occurring mental illness and substance use disorders;

"(C) prosecutor and defender based programs;

"(D) specialized probation;

"(E) treatment and rehabilitation programs; and

"(F) problem-solving courts, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts.

"(c) APPLICATION.—

"(1) IN GENERAL.—An eligible entity desiring a grant under this section shall submit an application to the Attorney General—

"(A) that meets the criteria under paragraph (2); and

"(B) at such time, in such manner, and accompanied by such information as the Attorney General may require.

"(2) CRITERIA.—An eligible entity, in submitting an application under paragraph (1), shall—

"(A) provide extensive evidence of collaboration with State and local government agencies overseeing health, community corrections, courts, prosecution, substance abuse, mental health, victims services, and employment services, and with local law enforcement agencies;

"(B) demonstrate consultation with the Single State Authority for Substance Abuse of the State (as that term is defined in section 201(e) of the Second Chance Act of 2007);

"(C) demonstrate that evidence-based treatment practices will be utilized; and

"(D) demonstrate that evidence-based screening and assessment tools will be used to place participants in the treatment alternative to incarceration program.

"(d) REQUIREMENTS.—Each eligible entity awarded a grant for a treatment alternative to incarceration program under this section shall—

"(1) determine the terms and conditions of participation in the program by eligible participants, taking into consideration the collateral consequences of an arrest, prosecution or criminal conviction;

"(2) ensure that each substance abuse and mental health treatment component is licensed and qualified by the relevant jurisdiction;

"(3) for programs described in subsection (b)(2), organize an enforcement unit comprised of appropriately trained law enforcement professionals under the supervision of the State, Tribal, or local criminal justice agency involved, the duties of which shall include—

"(A) the verification of addresses and other contact information of each eligible participant who participates or desires to participate in the program; and

"(B) if necessary, the location, apprehension, arrest, and return to custody of an eligible participant in the program who has absconded from the facility of a treatment provider or has otherwise significantly violated the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

"(4) notify the relevant criminal justice entity if any eligible participant in the program absconds from the facility of the treatment provider or otherwise violates the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

"(5) submit periodic reports on the progress of treatment or other measured outcomes from participation in the program of each eligible participant in the program to the relevant State, Tribal, or local criminal justice agency, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts;

"(6) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program, and specifically explain how such measurements will provide valid measures of the impact of the program; and

"(7) describe how the program could be broadly replicated if demonstrated to be effective.

"(e) USE OF FUNDS.—An eligible entity shall use a grant received under this section for expenses of a treatment alternative to incarceration program, including—

"(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including the enforcement unit;

"(2) payments for treatment providers that are approved by the relevant State or Tribal jurisdiction and licensed, if necessary, to provide needed treatment to eligible offenders participating in the program, including aftercare supervision, vocational training, education, and job placement; and

"(3) payments to public and nonprofit private entities that are approved by the State or Tribal jurisdiction and licensed, if necessary, to provide alcohol and drug addiction treatment to eligible offenders participating in the program.

"(f) SUPPLEMENT NOT SUPPLANT.—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds. The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (d).

"(g) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the geographical distribution of grants under this section is equitable and includes a grant to an eligible entity in—

"(1) each State;

"(2) rural, suburban, and urban areas; and

"(3) Tribal jurisdictions.

"(h) REPORTS AND EVALUATIONS.—Each fiscal year, each recipient of a grant under this section during that fiscal year shall submit to the Attorney General a report on the outcomes of activities carried out using that grant in such form, containing such information, and on such dates as the Attorney General shall specify.

"(i) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date on which the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used,

and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(5) PREVENTING DUPLICATIVE GRANTS.—

"(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(ii) the reason the Attorney General awarded the duplicate grants.".

SEC. 14014. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

42 USC 3797aa–1.

Part HH of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa et seq.) is amended by adding at the end the following:

"SEC. 2992. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

"(a) AUTHORITY.—The Attorney General may make grants to eligible organizations to provide for the establishment of a National Criminal Justice and Mental Health Training and Technical Assistance Center.

"(b) ELIGIBLE ORGANIZATION.—For purposes of subsection (a), the term 'eligible organization' means a national nonprofit organization that provides technical assistance and training to, and has special expertise and broad, national-level experience in, mental health, crisis intervention, criminal justice systems, law enforcement, translating evidence into practice, training, and research, and education and support of people with mental illness and the families of such individuals.

"(c) USE OF FUNDS.—Any organization that receives a grant under subsection (a) shall collaborate with other grant recipients to establish and operate a National Criminal Justice and Mental Health Training and Technical Assistance Center to—

"(1) provide law enforcement officer training regarding mental health and working with individuals with mental illnesses, with an emphasis on de-escalation of encounters between law enforcement officers and those with mental disorders or in crisis, which shall include support the development of in-person and technical information exchanges between systems and the individuals working in those systems in support of the concepts identified in the training;

"(2) provide education, training, and technical assistance for States, Indian tribes, territories, units of local government, service providers, nonprofit organizations, probation or parole officers, prosecutors, defense attorneys, emergency response providers, and corrections institutions to advance practice and knowledge relating to mental health crisis and approaches to mental health and criminal justice across systems;

"(3) provide training and best practices to mental health providers and criminal justice agencies relating to diversion initiatives, jail and prison strategies, reentry of individuals with mental illnesses into the community, and dispatch protocols and triage capabilities, including the establishment of learning sites;

"(4) develop suicide prevention and crisis intervention training and technical assistance for criminal justice agencies;

"(5) develop a receiving center system and pilot strategy that provides, for a jurisdiction, a single point of entry into the mental health and substance abuse system for assessments and appropriate placement of individuals experiencing a crisis;

"(6) collect data and best practices in mental health and criminal health and criminal justice initiatives and policies from grantees under this part, other recipients of grants under this section, Federal, State, and local agencies involved in the provision of mental health services, and nongovernmental organizations involved in the provision of mental health services;

"(7) develop and disseminate to mental health providers and criminal justice agencies evaluation tools, mechanisms, and measures to better assess and document performance measures and outcomes relating to the provision of mental health services;

"(8) disseminate information to States, units of local government, criminal justice agencies, law enforcement agencies, and other relevant entities about best practices, policy standards, and research findings relating to the provision of mental health services; and

"(9) provide education and support to individuals with mental illness involved with, or at risk of involvement with, the criminal justice system, including the families of such individuals.

"(d) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

"(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

"(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during

which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

"(2) NONPROFIT AGENCY REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term 'nonprofit agency' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

"(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

"(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the

Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

"(A) indicating whether—

"(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

"(iii) any reimbursements required under paragraph (1)(F) have been made; and

"(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

"(5) PREVENTING DUPLICATIVE GRANTS.—

"(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(ii) the reason the Attorney General awarded the duplicate grants.".

28 USC 534 note.

SEC. 14015. IMPROVING DEPARTMENT OF JUSTICE DATA COLLECTION ON MENTAL ILLNESS INVOLVED IN CRIME.

(a) IN GENERAL.—Notwithstanding any other provision of law, on or after the date that is 90 days after the date on which the Attorney General promulgates regulations under subsection (b), any data prepared by, or submitted to, the Attorney General or the Director of the Federal Bureau of Investigation with respect to the incidences of homicides, law enforcement officers killed, seriously injured, and assaulted, or individuals killed or seriously injured by law enforcement officers shall include data with respect to the involvement of mental illness in such incidences, if any.

(b) REGULATIONS.—Not later than 90 days after the date of the enactment of this Act, the Attorney General shall promulgate or revise regulations as necessary to carry out subsection (a).

SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL OFFENDERS IN PRISON.

(a) REPORT ON THE COST OF TREATING THE MENTALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report detailing the cost of imprisonment for individuals who have serious mental illness by the Federal Government or a State or unit of local government, which shall include—

(1) the number and type of crimes committed by individuals with serious mental illness each year; and

(2) detail strategies or ideas for preventing crimes by those individuals with serious mental illness from occurring.

(b) DEFINITION.—For purposes of this section, the Attorney General, in consultation with the Assistant Secretary of Mental Health and Substance Use Disorders, shall define "serious mental illness" based on the "Health Care Reform for Americans with Severe Mental Illnesses: Report" of the National Advisory Mental Health Council, American Journal of Psychiatry 1993; 150:1447–1465.

SEC. 14017. CODIFICATION OF DUE PROCESS FOR DETERMINATIONS BY SECRETARY OF VETERANS AFFAIRS OF MENTAL CAPACITY OF BENEFICIARIES. 38 USC 5501A.

(a) IN GENERAL.—Chapter 55 of title 38, United States Code, is amended by inserting after section 5501 the following new section:

"§ 5501A. Beneficiaries' rights in mental competence determinations

"The Secretary may not make an adverse determination concerning the mental capacity of a beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title unless such beneficiary has been provided all of the following, subject to the procedures and timelines prescribed by the Secretary for determinations of incompetency:

"(1) Notice of the proposed adverse determination and the supporting evidence.

"(2) An opportunity to request a hearing.

"(3) An opportunity to present evidence, including an opinion from a medical professional or other person, on the capacity of the beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title.

"(4) An opportunity to be represented at no expense to the Government (including by counsel) at any such hearing and to bring a medical professional or other person to provide relevant testimony at any such hearing.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter 55 is amended by inserting after the item relating to section 5501 the following new item: 38 USC 5501 prec.

"5501A. Beneficiaries' rights in mental competence determinations".

(c) EFFECTIVE DATE.—Section 5501A of title 38, United States Code, as added by subsection (a), shall apply to determinations made by the Secretary of Veterans Affairs on or after the date of the enactment of this Act. 38 USC 5501A note.

SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.

Subsection (o) of section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as redesignated by section 14006, is amended—

(1) in paragraph (1)(C), by striking "2009 through 2014" and inserting "2017 through 2021"; and

(2) by adding at the end the following:

"(3) LIMITATION.—Not more than 20 percent of the funds authorized to be appropriated under this section may be used for purposes described in subsection (i) (relating to veterans).".

Subtitle B—Comprehensive Justice and Mental Health

SEC. 14021. SEQUENTIAL INTERCEPT MODEL.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as amended by section 14005, is amended by inserting after subsection (j), the following:

"(k) SEQUENTIAL INTERCEPT GRANTS.—

"(1) DEFINITION.—In this subsection, the term 'eligible entity' means a State, unit of local government, Indian tribe, or tribal organization.

"(2) AUTHORIZATION.—The Attorney General may make grants under this subsection to an eligible entity for sequential intercept mapping and implementation in accordance with paragraph (3).

"(3) SEQUENTIAL INTERCEPT MAPPING; IMPLEMENTATION.—An eligible entity that receives a grant under this subsection may use funds for—

"(A) sequential intercept mapping, which—

"(i) shall consist of—

"(I) convening mental health and criminal justice stakeholders to—

"(aa) develop a shared understanding of the flow of justice-involved individuals with mental illnesses through the criminal justice system; and

"(bb) identify opportunities for improved collaborative responses to the risks and needs of individuals described in item (aa); and

"(II) developing strategies to address gaps in services and bring innovative and effective programs to scale along multiple intercepts, including—

"(aa) emergency and crisis services;

"(bb) specialized police-based responses;

"(cc) court hearings and disposition alternatives;

"(dd) reentry from jails and prisons; and

"(ee) community supervision, treatment and support services; and

"(ii) may serve as a starting point for the development of strategic plans to achieve positive public health and safety outcomes; and

"(B) implementation, which shall—

"(i) be derived from the strategic plans described in subparagraph (A)(ii); and

"(ii) consist of—

"(I) hiring and training personnel;

"(II) identifying the eligible entity's target population;

"(III) providing services and supports to reduce unnecessary penetration into the criminal justice system;

"(IV) reducing recidivism;

"(V) evaluating the impact of the eligible entity's approach; and

"(VI) planning for the sustainability of effective interventions.".

SEC. 14022. PRISON AND JAILS.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (k), as added by section 14021, the following:

"(l) CORRECTIONAL FACILITIES.—

"(1) DEFINITIONS.—

"(A) CORRECTIONAL FACILITY.—The term 'correctional facility' means a jail, prison, or other detention facility used to house people who have been arrested, detained, held, or convicted by a criminal justice agency or a court.

"(B) ELIGIBLE INMATE.—The term 'eligible inmate' means an individual who—

"(i) is being held, detained, or incarcerated in a correctional facility; and

"(ii) manifests obvious signs of a mental illness or has been diagnosed by a qualified mental health professional as having a mental illness.

"(2) CORRECTIONAL FACILITY GRANTS.—The Attorney General may award grants to applicants to enhance the capabilities of a correctional facility—

"(A) to identify and screen for eligible inmates;

"(B) to plan and provide—

"(i) initial and periodic assessments of the clinical, medical, and social needs of inmates; and

"(ii) appropriate treatment and services that address the mental health and substance abuse needs of inmates;

"(C) to develop, implement, and enhance—

"(i) post-release transition plans for eligible inmates that, in a comprehensive manner, coordinate health, housing, medical, employment, and other appropriate services and public benefits;

"(ii) the availability of mental health care services and substance abuse treatment services; and

"(iii) alternatives to solitary confinement and segregated housing and mental health screening and treatment for inmates placed in solitary confinement or segregated housing; and

"(D) to train each employee of the correctional facility to identify and appropriately respond to incidents involving inmates with mental health or co-occurring mental health and substance abuse disorders.".

SEC. 14023. ALLOWABLE USES.

Section 2991(b)(5)(I) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(b)(5)(I)) is amended by adding at the end the following:

"(v) TEAMS ADDRESSING FREQUENT USERS OF CRISIS SERVICES.—Multidisciplinary teams that—

"(I) coordinate, implement, and administer community-based crisis responses and long-term plans for frequent users of crisis services;

"(II) provide training on how to respond appropriately to the unique issues involving frequent users of crisis services for public service personnel,

including criminal justice, mental health, substance abuse, emergency room, healthcare, law enforcement, corrections, and housing personnel;

"(III) develop or support alternatives to hospital and jail admissions for frequent users of crisis services that provide treatment, stabilization, and other appropriate supports in the least restrictive, yet appropriate, environment; and

"(IV) develop protocols and systems among law enforcement, mental health, substance abuse, housing, corrections, and emergency medical service operations to provide coordinated assistance to frequent users of crisis services.".

SEC. 14024. LAW ENFORCEMENT TRAINING.

Section 2991(h) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(h)) is amended—

(1) in paragraph (1), by adding at the end the following:

"(F) ACADEMY TRAINING.—To provide support for academy curricula, law enforcement officer orientation programs, continuing education training, and other programs that teach law enforcement personnel how to identify and respond to incidents involving persons with mental health disorders or co-occurring mental health and substance abuse disorders."; and

(2) by adding at the end the following:

"(4) PRIORITY CONSIDERATION.—The Attorney General, in awarding grants under this subsection, shall give priority to programs that law enforcement personnel and members of the mental health and substance abuse professions develop and administer cooperatively.".

42 USC 3797aa–1 note.

SEC. 14025. FEDERAL LAW ENFORCEMENT TRAINING.

Not later than 1 year after the date of enactment of this Act, the Attorney General shall provide direction and guidance for the following:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training, in procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to first responders and tactical units of—

(A) Federal law enforcement agencies; and

(B) other Federal criminal justice agencies such as the Bureau of Prisons, the Administrative Office of the United States Courts, and other agencies that the Attorney General determines appropriate.

(2) IMPROVED TECHNOLOGY.—The establishment of, or improvement of existing, computerized information systems to provide timely information to employees of Federal law enforcement agencies, and Federal criminal justice agencies to improve the response of such employees to situations involving individuals who have a mental illness.

SEC. 14026. GAO REPORT.

No later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in coordination with the Attorney General, shall submit to Congress a report on—

(1) the practices that Federal first responders, tactical units, and corrections officers are trained to use in responding to individuals with mental illness;

(2) procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to Federal first responders and tactical units;

(3) the application of evidence-based practices in criminal justice settings to better address individuals with mental illnesses; and

(4) recommendations on how the Department of Justice can expand and improve information sharing and dissemination of best practices.

SEC. 14027. EVIDENCE BASED PRACTICES.

Section 2991(c) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(c)) is amended—

(1) in paragraph (3), by striking "or" at the end;

(2) by redesignating paragraph (4) as paragraph (6); and

(3) by inserting after paragraph (3), the following:

"(4) propose interventions that have been shown by empirical evidence to reduce recidivism;

"(5) when appropriate, use validated assessment tools to target preliminarily qualified offenders with a moderate or high risk of recidivism and a need for treatment and services; or".

SEC. 14028. TRANSPARENCY, PROGRAM ACCOUNTABILITY, AND ENHANCEMENT OF LOCAL AUTHORITY.

(a) IN GENERAL.—Section 2991(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(a)) is amended—

(1) in paragraph (7)—

(A) in the heading, by striking "MENTAL ILLNESS" and inserting "MENTAL ILLNESS; MENTAL HEALTH DISORDER"; and

(B) by striking "term 'mental illness' means" and inserting "terms 'mental illness' and 'mental health disorder' mean"; and

(2) by striking paragraph (9) and inserting the following:

"(9) PRELIMINARILY QUALIFIED OFFENDER.—

"(A) IN GENERAL.—The term 'preliminarily qualified offender' means an adult or juvenile accused of an offense who—

"(i)(I) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness or co-occurring mental illness and substance abuse disorders;

"(II) manifests obvious signs of mental illness or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court; or

"(III) in the case of a veterans treatment court provided under subsection (i), has been diagnosed with, or manifests obvious signs of, mental illness or a substance abuse disorder or co-occurring mental illness and substance abuse disorder;

"(ii) has been unanimously approved for participation in a program funded under this section by, when appropriate—

"(I) the relevant—

"(aa) prosecuting attorney;

"(bb) defense attorney;

"(cc) probation or corrections official; and

"(dd) judge; and

"(II) a representative from the relevant mental health agency described in subsection (b)(5)(B)(i);

"(iii) has been determined, by each person described in clause (ii) who is involved in approving the adult or juvenile for participation in a program funded under this section, to not pose a risk of violence to any person in the program, or the public, if selected to participate in the program; and

"(iv) has not been charged with or convicted of—

"(I) any sex offense (as defined in section 111 of the Sex Offender Registration and Notification Act (42 U.S.C. 16911)) or any offense relating to the sexual exploitation of children; or

"(II) murder or assault with intent to commit murder.

"(B) DETERMINATION.—In determining whether to designate a defendant as a preliminarily qualified offender, the relevant prosecuting attorney, defense attorney, probation or corrections official, judge, and mental health or substance abuse agency representative shall take into account—

"(i) whether the participation of the defendant in the program would pose a substantial risk of violence to the community;

"(ii) the criminal history of the defendant and the nature and severity of the offense for which the defendant is charged;

"(iii) the views of any relevant victims to the offense;

"(iv) the extent to which the defendant would benefit from participation in the program;

"(v) the extent to which the community would realize cost savings because of the defendant's participation in the program; and

"(vi) whether the defendant satisfies the eligibility criteria for program participation unanimously established by the relevant prosecuting attorney, defense attorney, probation or corrections official, judge and mental health or substance abuse agency representative.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—Section 2927(2) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797s–6(2)) is amended by striking "has the meaning given that term in section 2991(a)." and inserting "means an offense that—

"(A) does not have as an element the use, attempted use, or threatened use of physical force against the person or property of another; or

"(B) is not a felony that by its nature involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense.".

SEC. 14029. GRANT ACCOUNTABILITY.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (l), as added by section 14022, the following:

"(m) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date when the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(n) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(2) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(B) the reason the Attorney General awarded the duplicate grants.".

DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

Increasing Choice, Access, and Quality in Health Care for Americans Act.

SEC. 15000. SHORT TITLE.

42 USC 1305 note.

This division may be cited as the "Increasing Choice, Access, and Quality in Health Care for Americans Act".

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

SEC. 15001. DEVELOPMENT OF MEDICARE HCPCS VERSION OF MS–DRG CODES FOR SIMILAR HOSPITAL SERVICES.

Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

"(t) RELATING SIMILAR INPATIENT AND OUTPATIENT HOSPITAL SERVICES.—

"(1) DEVELOPMENT OF HCPCS VERSION OF MS–DRG CODES.—Not later than January 1, 2018, the Secretary shall develop HCPCS versions for MS–DRGs that are similar to the ICD–10–PCS for such MS–DRGs such that, to the extent possible, the MS–DRG assignment shall be similar for a claim coded with the HCPCS version as an identical claim coded with a ICD–10–PCS code.

"(2) COVERAGE OF SURGICAL MS–DRGS.—In carrying out paragraph (1), the Secretary shall develop HCPCS versions of MS–DRG codes for not fewer than 10 surgical MS–DRGs.

"(3) PUBLICATION AND DISSEMINATION OF THE HCPCS VERSIONS OF MS–DRGS.—

"(A) IN GENERAL.—The Secretary shall develop a HCPCS MS–DRG definitions manual and software that is similar to the definitions manual and software for ICD–10–PCS codes for such MS–DRGs. The Secretary shall post the HCPCS MS–DRG definitions manual and software on the Internet website of the Centers for Medicare & Medicaid Services. The HCPCS MS–DRG definitions

manual and software shall be in the public domain and available for use and redistribution without charge.

"(B) USE OF PREVIOUS ANALYSIS DONE BY MEDPAC.—In developing the HCPCS MS–DRG definitions manual and software under subparagraph (A), the Secretary shall consult with the Medicare Payment Advisory Commission and shall consider the analysis done by such Commission in translating outpatient surgical claims into inpatient surgical MS–DRGs in preparing chapter 7 (relating to hospital short-stay policy issues) of its 'Medicare and the Health Care Delivery System' report submitted to Congress in June 2015.

"(4) DEFINITION AND REFERENCE.—In this subsection:

"(A) HCPCS.—The term 'HCPCS' means, with respect to hospital items and services, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such items and services.

"(B) ICD–10–PCS.—The term 'ICD–10–PCS' means the International Classification of Diseases, 10th Revision, Procedure Coding System, and includes any subsequent revision of such International Classification of Diseases, Procedure Coding System.".

SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE MEDICARE HOSPITAL READMISSION PROGRAM.

(a) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLE POPULATION.—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)) is amended—

(1) in subparagraph (A), by inserting "subject to subparagraph (D)," after "purposes of paragraph (1),"; and

(2) by adding at the end the following new subparagraph:

"(D) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLES.—

"(i) IN GENERAL.—In determining a hospital's adjustment factor under this paragraph for purposes of making payments for discharges occurring during and after fiscal year 2019, and before the application of clause (i) of subparagraph (E), the Secretary shall assign hospitals to groups (as defined by the Secretary under clause (ii)) and apply the applicable provisions of this subsection using a methodology in a manner that allows for separate comparison of hospitals within each such group, as determined by the Secretary.

"(ii) DEFINING GROUPS.—For purposes of this subparagraph, the Secretary shall define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)). In defining groups, the Secretary shall consult the Medicare Payment Advisory Commission and may consider the analysis done by such Commission in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

"(iii) MINIMIZING REPORTING BURDEN ON HOSPITALS.—In carrying out this subparagraph, the Secretary shall not impose any additional reporting requirements on hospitals.

"(iv) BUDGET NEUTRAL DESIGN METHODOLOGY.—The Secretary shall design the methodology to implement this subparagraph so that the estimated total amount of reductions in payments under this subsection equals the estimated total amount of reductions in payments that would otherwise occur under this subsection if this subparagraph did not apply.".

(b) CHANGES IN RISK ADJUSTMENT.—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)), as amended by subsection (a), is further amended by adding at the end the following new subparagraph:

"(E) CHANGES IN RISK ADJUSTMENT.—

"(i) CONSIDERATION OF RECOMMENDATIONS IN IMPACT REPORTS.—The Secretary may take into account the studies conducted and the recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act of 2014 (Public Law 113–185; 42 U.S.C. 1395lll note) with respect to the application under this subsection of risk adjustment methodologies. Nothing in this clause shall be construed as precluding consideration of the use of groupings of hospitals.

"(ii) CONSIDERATION OF EXCLUSION OF PATIENT CASES BASED ON V OR OTHER APPROPRIATE CODES.—In promulgating regulations to carry out this subsection with respect to discharges occurring after fiscal year 2018, the Secretary may consider the use of V or other ICD-related codes for removal of a readmission. The Secretary may consider modifying measures under this subsection to incorporate V or other ICD-related codes at the same time as other changes are being made under this subparagraph.

"(iii) REMOVAL OF CERTAIN READMISSIONS.—In promulgating regulations to carry out this subsection, with respect to discharges occurring after fiscal year 2018, the Secretary may consider removal as a readmission of an admission that is classified within one or more of the following: transplants, end-stage renal disease, burns, trauma, psychosis, or substance abuse. The Secretary may consider modifying measures under this subsection to remove readmissions at the same time as other changes are being made under this subparagraph.".

(c) MEDPAC STUDY ON READMISSIONS PROGRAM.—The Medicare Payment Advisory Commission shall conduct a study to review overall hospital readmissions described in section 1886(q)(5)(E) of the Social Security Act (42 U.S.C. 1395ww(q)(5)(E)) and whether such readmissions are related to any changes in outpatient and emergency services furnished. The Commission shall submit to Congress a report on such study in its report to Congress in June 2018.

SEC. 15003. FIVE-YEAR EXTENSION OF THE RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) EXTENSION.—Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 42 U.S.C. 1395ww note) is amended—

(1) in subsection (a)(5), by striking "5-year extension period" and inserting "10-year extension period"; and

(2) in subsection (g)—

(A) in the subsection heading, by striking "FIVE-YEAR" and inserting "TEN-YEAR";

(B) in paragraph (1), by striking "additional 5-year" and inserting "additional 10-year";

(C) by striking "5-year extension period" and inserting "10-year extension period" each place it appears;

(D) in paragraph (4)(B)—

(i) in the matter preceding clause (i), by inserting "each 5-year period in" after "hospital during"; and

(ii) in clause (i), by inserting "each applicable 5-year period in" after "the first day of"; and

(E) by adding at the end the following new paragraphs:

"(5) OTHER HOSPITALS IN DEMONSTRATION PROGRAM.—During the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of paragraph (4) to rural community hospitals that are not described in paragraph (4) but are participating in the demonstration program under this section as of December 30, 2014, in a similar manner as such provisions apply to rural community hospitals described in paragraph (4).

"(6) EXPANSION OF DEMONSTRATION PROGRAM TO RURAL AREAS IN ANY STATE.—

"(A) IN GENERAL.—The Secretary shall, notwithstanding subsection (a)(2) or paragraph (2) of this subsection, not later than 120 days after the date of the enactment of this paragraph, issue a solicitation for applications to select up to the maximum number of additional rural community hospitals located in any State to participate in the demonstration program under this section for the second 5 years of the 10-year extension period without exceeding the limitation under paragraph (3) of this subsection.

"(B) PRIORITY.—In determining which rural community hospitals that submitted an application pursuant to the solicitation under subparagraph (A) to select for participation in the demonstration program, the Secretary—

"(i) shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities (as determined by the Secretary using the 2015 Statistical Abstract of the United States); and

"(ii) may consider—

"(I) closures of hospitals located in rural areas in the State in which the rural community hospital is located during the 5-year period immediately preceding the date of the enactment of this paragraph; and

"(II) the population density of the State in which the rural community hospital is located.".

(b) CHANGE IN TIMING FOR REPORT.—Subsection (e) of such section 410A is amended—

(1) by striking "Not later than 6 months after the completion of the demonstration program under this section" and inserting "Not later than August 1, 2018"; and

(2) by striking "such program" and inserting "the demonstration program under this section".

SEC. 15004. REGULATORY RELIEF FOR LTCHS.

(a) TECHNICAL CHANGE TO THE MEDICARE LONG-TERM CARE HOSPITAL MORATORIUM EXCEPTION.—

(1) IN GENERAL.—Section 114(d)(7) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by sections 3106(b) and 10312(b) of Public Law 111–148, section 1206(b)(2) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67), and section 112 of the Protecting Access to Medicare Act of 2014 (Public Law 113–93), is amended by striking "The moratorium under paragraph (1)(A)" and inserting "Any moratorium under paragraph (1)".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in the enactment of section 112 of the Protecting Access to Medicare Act of 2014.

42 USC 1395ww note.

(b) MODIFICATION TO MEDICARE LONG-TERM CARE HOSPITAL HIGH COST OUTLIER PAYMENTS.—Section 1886(m) of the Social Security Act (42 U.S.C. 1395ww(m)) is amended by adding at the end the following new paragraph:

"(7) TREATMENT OF HIGH COST OUTLIER PAYMENTS.—

"(A) ADJUSTMENT TO THE STANDARD FEDERAL PAYMENT RATE FOR ESTIMATED HIGH COST OUTLIER PAYMENTS.—Under the system described in paragraph (1), for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of high cost outlier payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

"(B) LIMITATION ON HIGH COST OUTLIER PAYMENT AMOUNTS.—Notwithstanding subparagraph (A), the Secretary shall set the fixed loss amount for high cost outlier payments such that the estimated aggregate amount of high cost outlier payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

"(C) WAIVER OF BUDGET NEUTRALITY.—Any reduction in payments resulting from the application of subparagraph (B) shall not be taken into account in applying any budget neutrality provision under such system.

"(D) NO EFFECT ON SITE NEUTRAL HIGH COST OUTLIER PAYMENT RATE.—This paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under paragraph (6).".

SEC. 15005. SAVINGS FROM IPPS MACRA PAY-FOR THROUGH NOT APPLYING DOCUMENTATION AND CODING ADJUSTMENTS.

Section 7(b)(1)(B) of the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (Public Law 110–90), as amended by section 631(b) of the American Taxpayer Relief Act of 2012 (Public Law 112–240) and section 414(1)(B)(iii) of the Medicare

Access and CHIP Reauthorization Act of 2015 (Public Law 114–10), is amended in clause (iii) by striking "an increase of 0.5 percentage points for discharges occurring during each of fiscal years 2018 through 2023" and inserting "an increase of 0.4588 percentage points for discharges occurring during fiscal year 2018 and 0.5 percentage points for discharges occurring during each of fiscal years 2019 through 2023".

SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAYMENT RULES.

(a) 25–PERCENT PATIENT THRESHOLD PAYMENT ADJUSTMENT.—Section 114(c)(1)(A) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111–5), sections 3106(a) and 10312(a) of Public Law 111–148, and section 1206(b)(1)(B) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67), is amended by striking "for a 9-year period" and inserting "through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017".

(b) PAYMENT FOR HOSPITALS-WITHIN-HOSPITALS.—Section 114(c)(2) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111–5), sections 3106(a) and 10312(a) of Public Law 111–148, and section 1206(b)(1)(A) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67), is amended—

(1) in subparagraph (A), by inserting "or any similar provision," after "Regulations,";

(2) in subparagraph (B)—

(A) in clause (i), by inserting "or any similar provision," after "Regulations,"; and

(B) in clause (ii), by inserting ", or any similar provision," after "Regulations"; and

(3) in subparagraph (C), by striking "for a 9-year period" and inserting "through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017".

SEC. 15007. APPLICATION OF RULES ON THE CALCULATION OF HOSPITAL LENGTH OF STAY TO ALL LTCHS.

(a) IN GENERAL.—Section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67; 42 U.S.C. 1395ww note) is amended—

(1) by striking subparagraph (B);

(2) by striking "SITE NEUTRAL BASIS.—" and all that follows through "For discharges occurring" and inserting "SITE NEUTRAL BASIS.—For discharges occurring";

(3) by striking "subject to subparagraph (B),"; and

(4) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and moving each of such subparagraphs (as so redesignated) 2 ems to the left.

42 USC 1395ww note.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective as if included in the enactment of section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67; 42 U.S.C. 1395ww note).

SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR CERTAIN HOSPITALS.

(a) IN GENERAL.—Subsection (d)(1)(B)(iv) of section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended—

(1) in subclause (I), by striking "or" at the end;

(2) in subclause (II)—

(A) by striking ", or" at the end and inserting a semicolon;

(B) by redesignating such subclause as clause (vi) and by moving it to immediately follow clause (v); and

(C) in clause (v), by striking the semicolon at the end and inserting ", or"; and

(3) by striking "(iv)(I) a hospital" and inserting "(iv) a hospital".

(b) CONFORMING PAYMENT REFERENCES.—The second sentence of subsection (d)(1)(B) of such section is amended—

(1) by inserting "(as in effect as of such date)" after "clause (iv)"; and

(2) by inserting "(or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification)" after "so classified".

(c) APPLICATION.— 42 USC 1395ww note.

(1) IN GENERAL.—For cost reporting periods beginning on or after January 1, 2015, in the case of an applicable hospital (as defined in paragraph (3)), the following shall apply:

(A) Payment for inpatient operating costs shall be made on a reasonable cost basis in the manner provided in section 412.526(c)(3) of title 42, Code of Federal Regulations (as in effect on January 1, 2015) and in any subsequent modifications.

(B) Payment for capital costs shall be made in the manner provided by section 412.526(c)(4) of title 42, Code of Federal Regulations (as in effect on such date).

(C) Claims for payment for Medicare beneficiaries who are discharged on or after January 1, 2017, shall be processed as claims which are paid on a reasonable cost basis as described in section 412.526(c) of title 42, Code of Federal Regulations (as in effect on such date).

(2) APPLICABLE HOSPITAL DEFINED.—In this subsection, the term "applicable hospital" means a hospital that is classified under clause (iv)(II) of section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) on the day before the date of the enactment of this Act and which is classified under clause (vi) of such section, as redesignated and moved by subsection (a), on or after such date of enactment.

(d) CONFORMING TECHNICAL AMENDMENTS.—

(1) Section 1899B(a)(2)(A)(iv) of the Social Security Act (42 U.S.C. 1395lll(a)(2)(A)(iv)) is amended by striking "1886(d)(1)(B)(iv)(II)" and inserting "1886(d)(1)(B)(vi)".

(2) Section 1886(m)(5)(F) of such Act (42 U.S.C. 1395ww(m)(5)(F)) is amended in each of clauses (i) and (ii) by striking "(d)(1)(B)(iv)(II)" and inserting "(d)(1)(B)(vi)".

SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.

(a) EXCEPTION.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)) is amended—

(1) in subparagraph (A)(i), by striking "and (E)" and inserting ", (E), and (F)"; and

(2) by adding at the end the following new subparagraph:

"(F) TEMPORARY EXCEPTION FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.—For discharges in cost reporting periods beginning during fiscal years 2018 and 2019, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge is from a long-term care hospital that meets each of the following requirements:

"(i) NOT-FOR-PROFIT.—The long-term care hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data.

"(ii) PRIMARILY PROVIDING TREATMENT FOR CATASTROPHIC SPINAL CORD OR ACQUIRED BRAIN INJURIES OR OTHER PARALYZING NEUROMUSCULAR CONDITIONS.—Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under this section, at least 50 percent were classified under MS–LTCH–DRGs 28, 29, 52, 57, 551, 573, and 963.

"(iii) SIGNIFICANT OUT-OF-STATE ADMISSIONS.—

"(I) IN GENERAL.—The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under this title and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require.

"(II) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement subclause (I) by program instruction or otherwise.

"(III) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this clause.".

(b) STUDY AND REPORT ON THE STATUS AND VIABILITY OF CERTAIN SPINAL CORD SPECIALTY LONG-TERM CARE HOSPITALS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on long-term care hospitals described in section 1886(m)(6)(F) of the Social Security Act, as added by subsection (a). Such report shall include an analysis of the following:

(A) The impact on such hospitals of the classification and facility licensure by State agencies of such hospitals.

(B) The Medicare payment rates for such hospitals.

(C) Data on the number and health care needs of Medicare beneficiaries who have been diagnosed with catastrophic spinal cord or acquired brain injuries or other paralyzing neuromuscular conditions (as described within

the discharge classifications specified in clause (ii) of such section) who are receiving services from such hospitals.

(2) REPORT.—Not later than October 1, 2018, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN DISCHARGES WITH SEVERE WOUNDS.

(a) IN GENERAL.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)), as amended by section 15009, is further amended—

(1) in subparagraph (A)(i) by striking "and (F)" and inserting "(F), and (G)";

(2) in subparagraph (E)(i)(I)(aa), by striking "the amendment made" and all that follows before the semicolon and inserting "the last sentence of subsection (d)(1)(B)"; and

(3) by adding at the end the following new subparagraph:

"(G) ADDITIONAL TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

"(i) IN GENERAL.—For a discharge occurring in a cost reporting period beginning during fiscal year 2018, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

"(I) is from a long-term care hospital identified by the last sentence of subsection (d)(1)(B);

"(II) is classified under MS–LTCH–DRG 602, 603, 539, or 540; and

"(III) is with respect to an individual treated by a long-term care hospital for a severe wound.

"(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term 'severe wound' means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.

"(iii) WOUND DEFINED.—In this subparagraph, the term 'wound' means an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.".

(c) STUDY AND REPORT TO CONGRESS.—

(1) STUDY.—The Comptroller General of the United States shall, in consultation with relevant stakeholders, conduct a study on the treatment needs of individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title who require specialized wound care, and the cost, for such individuals and the Medicare program under such title, of treating severe wounds in rural and urban areas. Such study shall include an assessment of—

(A) access of such individuals to appropriate levels of care for such cases;

(B) the potential impact that section 1886(m)(6)(A)(i) of such Act (42 U.S.C. 1395ww(m)(6)(A)(i)) will have on

the access, quality, and cost of care for such individuals; and

(C) how to appropriately pay for such care under the Medicare program under such title.

(2) REPORT.—Not later than October 1, 2020, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER HOPD PROSPECTIVE PAYMENT SYSTEM FOR SERVICES FURNISHED BY MID-BUILD OFF-CAMPUS OUTPATIENT DEPARTMENTS OF PROVIDERS.

(a) IN GENERAL.—Section 1833(t)(21) of the Social Security Act (42 U.S.C. 1395l(t)(21)) is amended—

(1) in subparagraph (B)—

(A) in clause (i), by striking "clause (ii)" and inserting "the subsequent provisions of this subparagraph"; and

(B) by adding at the end the following new clauses:

"(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

"(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term 'off-campus outpatient department of a provider' also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

"(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

"(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

"(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date

of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

"(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

"(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term 'off-campus outpatient department of a provider' under such clause.

"(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

"(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

"(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

"(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018."; and

(2) in subparagraph (E), by adding at the end the following new clause:

"(iv) The determination of an audit under subparagraph (B)(vii).".

(b) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74).

42 USC 1395*l* note.

SEC. 16002. TREATMENT OF CANCER HOSPITALS IN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER POLICY.

(a) IN GENERAL.—Section 1833(t)(21)(B) of the Social Security Act (42 U.S.C. 1395l(t)(21)(B)), as amended by section 16001(a), is amended—

(1) by inserting after clause (v) the following new clause:

"(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term 'off-campus outpatient department of a provider' also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

"(I) in the case of a department that met the requirements of section 413.65 of title 42 of the

Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

"(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.";

(2) in clause (vii), by inserting after the first sentence the following: "Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department."; and

(3) in clause (viii)(III), by adding at the end the following: "For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.".

(b) OFFSETTING SAVINGS.—Section 1833(t)(18) of the Social Security Act (42 U.S.C. 1395l(t)(18)) is amended—

(1) in subparagraph (B), by inserting ", subject to subparagraph (C)," after "shall"; and

(2) by adding at the end the following new subparagraph:

"(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.".

42 USC 1395*l* note.

(c) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74).

SEC. 16003. TREATMENT OF ELIGIBLE PROFESSIONALS IN AMBULATORY SURGICAL CENTERS FOR MEANINGFUL USE AND MIPS.

Section 1848(a)(7)(D) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(D)) is amended—

(1) by striking "HOSPITAL-BASED ELIGIBLE PROFESSIONALS" and all that follows through "No payment" and inserting the following: "HOSPITAL-BASED AND AMBULATORY SURGICAL CENTER-BASED ELIGIBLE PROFESSIONALS.—

"(i) HOSPITAL-BASED.—No payment"; and

(2) by adding at the end the following new clauses:

"(ii) AMBULATORY SURGICAL CENTER-BASED.—Subject to clause (iv), no payment adjustment may be made under subparagraph (A) for 2017 and 2018 in the case of an eligible professional with respect to whom substantially all of the covered professional services furnished by such professional are furnished in an ambulatory surgical center.

"(iii) DETERMINATION.—The determination of whether an eligible professional is an eligible professional described in clause (ii) may be made on the basis of—

"(I) the site of service (as defined by the Secretary); or

"(II) an attestation submitted by the eligible professional.

Determinations made under subclauses (I) and (II) shall be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services.

"(iv) SUNSET.—Clause (ii) shall no longer apply as of the first year that begins more than 3 years after the date on which the Secretary determines, through notice and comment rulemaking, that certified EHR technology applicable to the ambulatory surgical center setting is available.".

SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF 2016.

(a) EXTENSION OF ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2016.—Section 1 of Public Law 113–198, as amended by section 1 of Public Law 114–112, is amended—

(1) in the heading, by striking "**2014 AND 2015**" and inserting "**2016**"; and

(2) by striking "and 2015" and inserting ", 2015, and 2016".

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission (established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6)) shall submit to Congress a report analyzing the effect of the extension of the enforcement instruction under section 1 of Public Law 113–198, as amended by section 1 of Public Law 114–112 and subsection (a) of this section, on the access to health care by Medicare beneficiaries, on the economic impact and the impact upon hospital staffing needs, and on the quality of health care furnished to such beneficiaries.

SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE FEE SCHEDULE ADJUSTMENTS FOR WHEELCHAIR ACCESSORIES AND SEATING SYSTEMS WHEN USED IN CONJUNCTION WITH COMPLEX REHABILITATION TECHNOLOGY (CRT) WHEELCHAIRS.

Section 2(a) of the Patient Access and Medicare Protection Act (42 U.S.C. 1305 note) is amended by striking "January 1, 2017" and inserting "July 1, 2017".

SEC. 16006. ALLOWING PHYSICAL THERAPISTS TO UTILIZE LOCUM TENENS ARRANGEMENTS UNDER MEDICARE.

(a) IN GENERAL.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as amended by section 5012, is further amended—

(1) by striking "and" before "(I)"; and

(2) by inserting before the period at the end the following: ", and (J) in the case of outpatient physical therapy services furnished by physical therapists in a health professional shortage area (as defined in section 332(a)(1)(A) of the Public Health Service Act), a medically underserved area (as designated pursuant to section 330(b)(3)(A) of such Act), or a rural area (as defined in section 1886(d)(2)(D)), subparagraph (D) of this sentence shall apply to such services and therapists in the same manner as such subparagraph applies to physicians' services furnished by physicians".

42 USC 1395u note.

(b) EFFECTIVE DATE; IMPLEMENTATION.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished beginning not later than six months after the date of the enactment of this Act.

(2) IMPLEMENTATION.—The Secretary of Health and Human Services may implement subparagraph (J) of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as added by subsection (a)(2), by program instruction or otherwise.

SEC. 16007. EXTENSION OF THE TRANSITION TO NEW PAYMENT RATES FOR DURABLE MEDICAL EQUIPMENT UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall extend the transition period described in clause (i) of section 414.210(g)(9) of title 42, Code of Federal Regulations, from June 30, 2016, to December 31, 2016 (with the full implementation described in clause (ii) of such section applying to items and services furnished with dates of service on or after January 1, 2017).

(b) STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study that examines the impact of applicable payment adjustments upon—

(i) the number of suppliers of durable medical equipment that, on a date that is not before January 1, 2016, and not later than December 31, 2016, ceased to conduct business as such suppliers; and

(ii) the availability of durable medical equipment, during the period beginning on January 1, 2016, and ending on December 31, 2016, to individuals entitled to benefits under part A of title XVIII of the Social

Security Act (42 U.S.C. 1395 et seq.) or enrolled under part B of such title.

(B) DEFINITIONS.—For purposes of this subsection, the following definitions apply:

(i) SUPPLIER; DURABLE MEDICAL EQUIPMENT.—The terms "supplier" and "durable medical equipment" have the meanings given such terms by section 1861 of the Social Security Act (42 U.S.C. 1395x).

(ii) APPLICABLE PAYMENT ADJUSTMENT.—The term "applicable payment adjustment" means a payment adjustment described in section 414.210(g) of title 42, Code of Federal Regulations, that is phased in by paragraph (9)(i) of such section. For purposes of the preceding sentence, a payment adjustment that is phased in pursuant to the extension under subsection (a) shall be considered a payment adjustment that is phased in by such paragraph (9)(i).

(2) REPORT.—The Secretary of Health and Human Services shall, not later than January 12, 2017, submit to the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and to the Committee on Finance of the Senate, a report on the findings of the study conducted under paragraph (1).

SEC. 16008. REQUIREMENTS IN DETERMINING ADJUSTMENTS USING INFORMATION FROM COMPETITIVE BIDDING PROGRAMS.

(a) IN GENERAL.—Section 1834(a)(1)(G) of the Social Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended by adding at the end the following new sentence: "In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

"(i) solicit and take into account stakeholder input; and

"(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

"(I) The average travel distance and cost associated with furnishing items and services in the area.

"(II) The average volume of items and services furnished by suppliers in the area.

"(III) The number of suppliers in the area.".

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(1)(H)(ii) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)(ii)) is amended by striking "the Secretary" and inserting "subject to subsection (a)(1)(G), the Secretary".

(2) Section 1842(s)(3)(B) of the Social Security Act (42 U.S.C. 1395m(s)(3)(B)) is amended by striking "the Secretary" and inserting "subject to section 1834(a)(1)(G), the Secretary".

TITLE XVII—OTHER MEDICARE PROVISIONS

SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CONTRACTS FOR MEDICARE ADVANTAGE PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.

42 USC 1395w–27 note.

(a) FINDINGS.—Consistent with the studies provided under the IMPACT Act of 2014 (Public Law 113–185), it is the intent of Congress—

(1) to continue to study and request input on the effects of socioeconomic status and dual-eligible populations on the Medicare Advantage STARS rating system before reforming such system with the input of stakeholders; and

(2) pending the results of such studies and input, to provide for a temporary delay in authority of the Centers for Medicare & Medicaid Services (CMS) to terminate Medicare Advantage plan contracts solely on the basis of performance of plans under the STARS rating system.

(b) DELAY IN MA CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.—Section 1857(h) of the Social Security Act (42 U.S.C. 1395w–27(h)) is amended by adding at the end the following new paragraph:

"(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).".

SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA REPORTING FOR MEDICARE.

Section 1874 of the Social Security Act (42 U.S.C. 1395kk) is amended by adding at the end the following new subsection:

"(g) REQUIREMENT FOR ENROLLMENT DATA REPORTING.—

"(1) IN GENERAL.—Each year (beginning with 2016), the Secretary shall submit to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on Medicare enrollment data (and, in the case of part A, on data on individuals receiving benefits under such part) as of a date in such year specified by the Secretary. Such data shall be presented—

"(A) by Congressional district and State; and

"(B) in a manner that provides for such data based on—

"(i) fee-for-service enrollment (as defined in paragraph (2));

"(ii) enrollment under part C (including separate for aggregate enrollment in MA–PD plans and aggregate enrollment in MA plans that are not MA–PD plans); and

"(iii) enrollment under part D.

"(2) FEE-FOR-SERVICE ENROLLMENT DEFINED.—For purpose of paragraph (1)(B)(i), the term 'fee-for-service enrollment' means aggregate enrollment (including receipt of benefits other than through enrollment) under—

"(A) part A only;

"(B) part B only; and

"(C) both part A and part B.".

SEC. 17003. UPDATING THE WELCOME TO MEDICARE PACKAGE.

42 USC 1395a note.

(a) IN GENERAL.—Not later than 12 months after the last day of the period for the request of information described in subsection (b), the Secretary of Health and Human Services shall, taking into consideration information collected pursuant to subsection (b), update the information included in the Welcome to Medicare package to include information, presented in a clear and simple manner, about options for receiving benefits under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including through the original medicare fee-for-service program under parts A and B of such title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et seq.), Medicare Advantage plans under part C of such title (42 U.S.C. 1395w–21 et seq.), and prescription drug plans under part D of such title (42 U.S.C. 1395w–101 et seq.)). The Secretary shall make subsequent updates to the information included in the Welcome to Medicare package as appropriate.

(b) REQUEST FOR INFORMATION.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall request information, including recommendations, from stakeholders (including patient advocates, issuers, and employers) on information included in the Welcome to Medicare package, including pertinent data and information regarding enrollment and coverage for Medicare eligible individuals.

SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FURNISHED BY NEWLY ENROLLED PROVIDERS OR SUPPLIERS WITHIN A TEMPORARY MORATORIUM AREA.

(a) MEDICARE.—Section 1866(j)(7) of the Social Security Act (42 U.S.C. 1395cc(j)(7)) is amended—

(1) in the paragraph heading, by inserting "; NONPAYMENT" before the period; and

(2) by adding at the end the following new subparagraph:

"(C) NONPAYMENT.—

"(i) IN GENERAL.—No payment may be made under this title or under a program described in subparagraph (A) with respect to an item or service described in clause (ii) furnished on or after October 1, 2017.

"(ii) ITEM OR SERVICE DESCRIBED.—An item or service described in this clause is an item or service furnished—

"(I) within a geographic area with respect to which a temporary moratorium imposed under subparagraph (A) is in effect; and

"(II) by a provider of services or supplier that meets the requirements of clause (iii).

"(iii) REQUIREMENTS.—For purposes of clause (ii), the requirements of this clause are that a provider of services or supplier—

"(I) enrolls under this title on or after the effective date of such temporary moratorium; and

"(II) is within a category of providers of services and suppliers (as described in subparagraph (A)) subject to such temporary moratorium.

"(iv) PROHIBITION ON CHARGES FOR SPECIFIED ITEMS OR SERVICES.—In no case shall a provider of services or supplier described in clause (ii)(II) charge an individual or other person for an item or service described in clause (ii) furnished on or after October 1, 2017, to an individual entitled to benefits under part A or enrolled under part B or an individual under a program specified in subparagraph (A).".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID.—

(A) IN GENERAL.—Section 1903(i)(2) of the Social Security Act (42 U.S.C. 1396b(i)(2)), as amended by section 5005(a)(4), is further amended—

(i) in subparagraph (C), by striking "or" at the end; and

(ii) by adding at the end the following new subparagraph:

"(E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or".

(B) EXCEPTION WITH RESPECT TO ACCESS.—Section 1902(kk)(4)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is amended to read as follows:

"(ii) EXCEPTIONS.—

"(I) COMPLIANCE WITH MORATORIUM.—A State shall not be required to comply with a temporary moratorium described in clause (i) if the State determines that the imposition of such temporary moratorium would adversely impact beneficiaries' access to medical assistance.

"(II) FFP AVAILABLE.—Notwithstanding section 1903(i)(2)(E), payment may be made to a State under this title with respect to amounts expended for items and services described in such section if the Secretary, in consultation with the State agency administering the State plan under this title (or a waiver of the plan), determines that denying payment to the State pursuant to such section would adversely impact beneficiaries' access to medical assistance. ".

(C) STATE PLAN REQUIREMENT WITH RESPECT TO LIMITATION ON CHARGES TO BENEFICIARIES.—Section 1902(kk)(4)(A) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)) is amended by adding at the end the following new clause:

"(iii) LIMITATION ON CHARGES TO BENEFICIARIES.—With respect to any amount expended for items or services furnished during calendar quarters beginning on or after October 1, 2017, the State prohibits, during

the period of a temporary moratorium described in clause (i), a provider meeting the requirements specified in subparagraph (C)(iii) of section 1866(j)(7) from charging an individual or other person eligible to receive medical assistance under the State plan under this title (or a waiver of the plan) for an item or service described in section 1903(i)(2)(E) furnished to such an individual.".

(2) CORRECTING AMENDMENTS TO RELATED PROVISIONS.—

(A) SECTION 1866(J).—Section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) is amended—

(i) in paragraph (1)(A)—

(I) by striking "paragraph (4)" and inserting "paragraph (5)";

(II) by striking "moratoria in accordance with paragraph (5)" and inserting "moratoria in accordance with paragraph (7)"; and

(III) by striking "paragraph (6)" and inserting "paragraph (9)"; and

(ii) by redesignating the second paragraph (8) (redesignated by section 1304(1) of Public Law 111–152) as paragraph (9).

(B) SECTION 1902(KK).—Section 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is amended—

(i) in paragraph (1), by striking "section 1886(j)(2)" and inserting "section 1866(j)(2)";

(ii) in paragraph (2), by striking "section 1886(j)(3)" and inserting "section 1866(j)(3)";

(iii) in paragraph (3), by striking "section 1886(j)(4)" and inserting "section 1866(j)(5)"; and

(iv) in paragraph (4)(A), by striking "section 1886(j)(6)" and inserting "section 1866(j)(7)".

SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY CHOICE UNDER MEDICARE ADVANTAGE.

Section 1851(e)(2) of the Social Security Act (42 U.S.C. 1395w–21(e)(2)) is amended—

(1) in subparagraph (C)—

(A) in the heading, by inserting "FROM 2011 THROUGH 2018" after "45-DAY PERIOD"; and

(B) by inserting "and ending with 2018" after "beginning with 2011"; and

(2) by adding at the end the following new subparagraph:

"(G) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN 2016 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D)—

"(I) in the case of an MA eligible individual who is enrolled in an MA plan, at any time during the first 3 months of a year (beginning with 2019); or

"(II) in the case of an individual who first becomes an MA eligible individual during a year (beginning with 2019) and enrolls in an MA plan, during the first 3 months during such year in which the individual is an MA eligible individual;

such MA eligible individual may change the election under subsection (a)(1).

"(ii) LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.—An individual may change the election pursuant to clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

"(iii) LIMITED APPLICATION TO PART D.—Clauses (i) and (ii) of this subparagraph shall only apply with respect to changes in enrollment in a prescription drug plan under part D in the case of an individual who, previous to such change in enrollment, is enrolled in a Medicare Advantage plan.

"(iv) LIMITATIONS ON MARKETING.— Pursuant to subsection (j), no unsolicited marketing or marketing materials may be sent to an individual described in clause (i) during the continuous open enrollment and disenrollment period established for the individual under such clause, notwithstanding marketing guidelines established by the Centers for Medicare & Medicaid Services.".

SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENEFICIARIES TO CHOOSE A MEDICARE ADVANTAGE PLAN.

(a) REMOVING PROHIBITION.—

(1) IN GENERAL.—Section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3)) is amended—

(A) by striking subparagraph (B); and

(B) by striking "ELIGIBLE INDIVIDUAL" and all that follows through "In this title, subject to subparagraph (B)," and inserting "ELIGIBLE INDIVIDUAL.—In this title,".

(2) CONFORMING AMENDMENTS.—

(A) Section 1852(b)(1) of the Social Security Act (42 U.S.C. 1395w–22(b)(1)) is amended—

(i) by striking subparagraph (B); and

(ii) by striking "BENEFICIARIES" and all that follows through "A Medicare+Choice organization" and inserting "BENEFICIARIES.—A Medicare Advantage organization".

(B) Section 1859(b)(6) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)) is amended, in the last sentence, by striking "may waive" and all that follows through "subparagraph and".

42 USC 1395w–21 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

(b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS FROM MA BENCHMARK.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (k)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "paragraphs (2) and (4)" and inserting "paragraphs (2), (4), and (5)"; and

(ii) in subparagraph (B)(i), by striking "paragraphs (2) and (4)" and inserting "paragraphs (2), (4), and (5)"; and

(B) by adding at the end the following new paragraph:

"(5) EXCLUSION OF COSTS FOR KIDNEY ACQUISITIONS FROM CAPITATION RATES.—After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2021), the Secretary shall adjust such applicable amount to exclude from such applicable amount the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d)) in the area for the year."; and

(2) in subsection (n)(2)—

(A) in subparagraph (A)(i), by inserting "and, for 2021 and subsequent years, the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate as described in subsection (k)(5)" before the semicolon at the end;

(B) in subparagraph (E), in the matter preceding clause (i), by striking "subparagraph (F)" and inserting "subparagraphs (F) and (G)"; and

(C) by adding at the end the following new subparagraph:

"(G) APPLICATION OF KIDNEY ACQUISITIONS ADJUSTMENT.—The base payment amount specified in subparagraph (E) for a year (beginning with 2021) shall be adjusted in the same manner under paragraph (5) of subsection (k) as the applicable amount is adjusted under such subsection.".

(c) FFS COVERAGE OF KIDNEY ACQUISITIONS.—

(1) IN GENERAL.—Section 1852(a)(1)(B)(i) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(B)(i)) is amended by inserting "or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)" after "hospice care".

(2) CONFORMING AMENDMENT.—Section 1851(i) of the Social Security Act (42 U.S.C. 1395w–21(i)) is amended by adding at the end the following new paragraph:

"(3) FFS PAYMENT FOR EXPENSES FOR KIDNEY ACQUISITIONS.—Paragraphs (1) and (2) shall not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i).".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

42 USC 1395w–21 note.

(d) EVALUATION OF QUALITY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall conduct an evaluation of whether the 5-star rating system based on the data collected under section 1852(e) of the Social Security Act (42 U.S.C. 1395w–22(e)) should include a quality measure specifically related to care for enrollees in Medicare

Advantage plans under part C of title XVIII of such Act determined to have end-stage renal disease.

(2) PUBLIC AVAILABILITY.—Not later than April 1, 2020, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the results of the evaluation under paragraph (1).

(e) REPORT.—Not later than December 31, 2023, the Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall submit to Congress a report on the impact of the provisions of, and amendments made by, this section with respect to the following:

(1) Spending under—

(A) the original Medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act; and

(B) the Medicare Advantage program under part C of such title.

(2) The number of enrollees determined to have end-stage renal disease—

(A) in the original Medicare fee-for-service program; and

(B) in the Medicare Advantage program.

(3) The sufficiency of the amount of data under the original Medicare fee-for-service program for individuals determined to have end-stage renal disease for purposes of determining payment rates for end-stage renal disease under the Medicare Advantage program.

(f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER MEDICARE ADVANTAGE.—

(1) IN GENERAL.—Section 1853(a)(1) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)) is amended—

(A) in subparagraph (C)(i), by striking "The Secretary" and inserting "Subject to subparagraph (I), the Secretary"; and

(B) by adding at the end the following new subparagraph:

"(I) IMPROVEMENTS TO RISK ADJUSTMENT FOR 2019 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL.—In order to determine the appropriate adjustment for health status under subparagraph (C)(i), the following shall apply:

"(I) TAKING INTO ACCOUNT TOTAL NUMBER OF DISEASES OR CONDITIONS.—The Secretary shall take into account the total number of diseases or conditions of an individual enrolled in an MA plan. The Secretary shall make an additional adjustment under such subparagraph as the number of diseases or conditions of an individual increases.

"(II) USING AT LEAST 2 YEARS OF DIAGNOSTIC DATA.—The Secretary may use at least 2 years of diagnosis data.

"(III) PROVIDING SEPARATE ADJUSTMENTS FOR DUAL ELIGIBLE INDIVIDUALS.—With respect to individuals who are dually eligible for benefits under this title and title XIX, the Secretary shall

make separate adjustments for each of the following:

"(aa) Full-benefit dual eligible individuals (as defined in section 1935(c)(6)).

"(bb) Such individuals not described in item (aa).

"(IV) EVALUATION OF MENTAL HEALTH AND SUBSTANCE USE DISORDERS.—The Secretary shall evaluate the impact of including additional diagnosis codes related to mental health and substance use disorders in the risk adjustment model.

"(V) EVALUATION OF CHRONIC KIDNEY DISEASE.—The Secretary shall evaluate the impact of including the severity of chronic kidney disease in the risk adjustment model.

"(VI) EVALUATION OF PAYMENT RATES FOR END-STAGE RENAL DISEASE.—The Secretary shall evaluate whether other factors (in addition to those described in subparagraph (H)) should be taken into consideration when computing payment rates under such subparagraph.

"(ii) PHASED-IN IMPLEMENTATION.—The Secretary shall phase-in any changes to risk adjustment payment amounts under subparagraph (C)(i) under this subparagraph over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years.

"(iii) OPPORTUNITY FOR REVIEW AND PUBLIC COMMENT.—The Secretary shall provide an opportunity for review of the proposed changes to such risk adjustment payment amounts under this subparagraph and a public comment period of not less than 60 days before implementing such changes.".

(2) STUDIES AND REPORTS.—

(A) REPORTS ON THE RISK ADJUSTMENT SYSTEM.—

(i) MEDPAC EVALUATION AND REPORT.—

(I) EVALUATION.—The Medicare Payment Advisory Commission shall conduct an evaluation of the impact of the provisions of, and amendments made by, this section on risk scores for enrollees in Medicare Advantage plans under part C of title XVIII of the Social Security Act and payments to Medicare Advantage plans under such part, including the impact of such provisions and amendments on the overall accuracy of risk scores under the Medicare Advantage program.

(II) REPORT.—Not later than July 1, 2020, the Medicare Payment Advisory Commission shall submit to Congress a report on the evaluation under subclause (I), together with recommendations for such legislation and administrative action as the Commission determines appropriate.

(ii) REPORTS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than December 31, 2018, and every 3 years thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the risk adjustment model and the ESRD risk

42 USC 1395w–23 note.

adjustment model under the Medicare Advantage program under part C of title XVIII of the Social Security Act, including any revisions to either such model since the previous report. Such report shall include information on how such revisions impact the predictive ratios under either such model for groups of enrollees in Medicare Advantage plans, including very high and very low cost enrollees, and groups defined by the number of chronic conditions of enrollees.

(B) STUDY AND REPORT ON FUNCTIONAL STATUS.—

(i) STUDY.—The Comptroller General of the United States (in this subparagraph referred to as the "Comptroller General") shall conduct a study on how to most accurately measure the functional status of enrollees in Medicare Advantage plans and whether the use of such functional status would improve the accuracy of risk adjustment payments under the Medicare Advantage program under part C of title XVIII of the Social Security Act. Such study shall include an analysis of the challenges in collecting and reporting functional status information for Medicare Advantage plans under such part, providers of services and suppliers under the Medicare program, and the Centers for Medicare & Medicaid Services.

(ii) REPORT.—Not later than June 30, 2018, the Comptroller General shall submit to Congress a report containing the results of the study under clause (i), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF BENEFICIARIES UNDER THE MEDICARE SHARED SAVINGS PROGRAM.

Section 1899(c) of the Social Security Act (42 U.S.C. 1395jjj(c)) is amended—

(1) by striking "utilization of primary" and inserting "utilization of—

"(1) in the case of performance years beginning on or after April 1, 2012, primary";

(2) in paragraph (1), as added by paragraph (1) of this section, by striking the period at the end and inserting "; and";

(3) by adding at the end the following new paragraph:

"(2) in the case of performance years beginning on or after January 1, 2019, services provided under this title by a Federally qualified health center or rural health clinic (as those terms are defined in section 1861(aa)), as may be determined by the Secretary.".

TITLE XVIII—OTHER PROVISIONS

SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN REQUIREMENTS FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.

(a) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986 AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.—

(1) IN GENERAL.—Section 9831 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

"(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

"(1) IN GENERAL.—For purposes of this title (except as provided in section 4980I(f)(4) and notwithstanding any other provision of this title), the term 'group health plan' shall not include any qualified small employer health reimbursement arrangement.

"(2) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this subsection—

"(A) IN GENERAL.—The term 'qualified small employer health reimbursement arrangement' means an arrangement which—

"(i) is described in subparagraph (B), and

"(ii) is provided on the same terms to all eligible employees of the eligible employer.

"(B) ARRANGEMENT DESCRIBED.—An arrangement is described in this subparagraph if—

"(i) such arrangement is funded solely by an eligible employer and no salary reduction contributions may be made under such arrangement,

"(ii) such arrangement provides, after the employee provides proof of coverage, for the payment of, or reimbursement of, an eligible employee for expenses for medical care (as defined in section 213(d)) incurred by the eligible employee or the eligible employee's family members (as determined under the terms of the arrangement), and

"(iii) the amount of payments and reimbursements described in clause (ii) for any year do not exceed $4,950 ($10,000 in the case of an arrangement that also provides for payments or reimbursements for family members of the employee).

"(C) CERTAIN VARIATION PERMITTED.—For purposes of subparagraph (A)(ii), an arrangement shall not fail to be treated as provided on the same terms to each eligible employee merely because the employee's permitted benefit under such arrangement varies in accordance with the variation in the price of an insurance policy in the relevant individual health insurance market based on—

"(i) the age of the eligible employee (and, in the case of an arrangement which covers medical expenses of the eligible employee's family members, the age of such family members), or

"(ii) the number of family members of the eligible employee the medical expenses of which are covered under such arrangement.

The variation permitted under the preceding sentence shall be determined by reference to the same insurance policy with respect to all eligible employees.

"(D) RULES RELATING TO MAXIMUM DOLLAR LIMITATION.—

"(i) AMOUNT PRORATED IN CERTAIN CASES.—In the case of an individual who is not covered by an arrangement for the entire year, the limitation under subparagraph (B)(iii) for such year shall be an amount which bears the same ratio to the amount which would (but for this clause) be in effect for such individual for such year under subparagraph (B)(iii) as the number of months for which such individual is covered by the arrangement for such year bears to 12.

"(ii) INFLATION ADJUSTMENT.—In the case of any year beginning after 2016, each of the dollar amounts in subparagraph (B)(iii) shall be increased by an amount equal to—

"(I) such dollar amount, multiplied by

"(II) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting 'calendar year 2015' for 'calendar year 1992' in subparagraph (B) thereof.

If any dollar amount increased under the preceding sentence is not a multiple of $50, such dollar amount shall be rounded to the next lowest multiple of $50.

"(3) OTHER DEFINITIONS.—For purposes of this subsection—

"(A) ELIGIBLE EMPLOYEE.—The term 'eligible employee' means any employee of an eligible employer, except that the terms of the arrangement may exclude from consideration employees described in any clause of section 105(h)(3)(B) (applied by substituting '90 days' for '3 years' in clause (i) thereof).

"(B) ELIGIBLE EMPLOYER.—The term 'eligible employer' means an employer that—

"(i) is not an applicable large employer as defined in section 4980H(c)(2), and

"(ii) does not offer a group health plan to any of its employees.

"(C) PERMITTED BENEFIT.—The term 'permitted benefit' means, with respect to any eligible employee, the maximum dollar amount of payments and reimbursements which may be made under the terms of the qualified small employer health reimbursement arrangement for the year with respect to such employee.

"(4) NOTICE.—

"(A) IN GENERAL.—An employer funding a qualified small employer health reimbursement arrangement for any year shall, not later than 90 days before the beginning of such year (or, in the case of an employee who is not eligible to participate in the arrangement as of the beginning of such year, the date on which such employee is first so eligible), provide a written notice to each eligible employee which includes the information described in subparagraph (B).

"(B) CONTENTS OF NOTICE.—The notice required under subparagraph (A) shall include each of the following:

"(i) A statement of the amount which would be such eligible employee's permitted benefit under the arrangement for the year.

"(ii) A statement that the eligible employee should provide the information described in clause (i) to any health insurance exchange to which the employee applies for advance payment of the premium assistance tax credit.

"(iii) A statement that if the employee is not covered under minimum essential coverage for any month the employee may be subject to tax under section 5000A for such month and reimbursements under the arrangement may be includible in gross income.".

(2) LIMITATION ON EXCLUSION FROM GROSS INCOME.—Section 106 of such Code is amended by adding at the end the following:

"(g) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this section and section 105, payments or reimbursements from a qualified small employer health reimbursement arrangement (as defined in section 9831(d)) of an individual for medical care (as defined in section 213(d)) shall not be treated as paid or reimbursed under employer-provided coverage for medical expenses under an accident or health plan if for the month in which such medical care is provided the individual does not have minimum essential coverage (within the meaning of section 5000A(f)).".

(3) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—Section 36B(c) of such Code is amended by adding at the end the following new paragraph:

"(4) SPECIAL RULES FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

"(A) IN GENERAL.—The term 'coverage month' shall not include any month with respect to an employee (or any spouse or dependent of such employee) if for such month the employee is provided a qualified small employer health reimbursement arrangement which constitutes affordable coverage.

"(B) DENIAL OF DOUBLE BENEFIT.—In the case of any employee who is provided a qualified small employer health reimbursement arrangement for any coverage month (determined without regard to subparagraph (A)), the credit otherwise allowable under subsection (a) to the taxpayer for such month shall be reduced (but not below zero) by the amount described in subparagraph (C)(i)(II) for such month.

"(C) AFFORDABLE COVERAGE.—For purposes of subparagraph (A), a qualified small employer health reimbursement arrangement shall be treated as constituting affordable coverage for a month if—

"(i) the excess of—

"(I) the amount that would be paid by the employee as the premium for such month for self-only coverage under the second lowest cost silver plan offered in the relevant individual health insurance market, over

"(II) 1/12 of the employee's permitted benefit (as defined in section 9831(d)(3)(C)) under such arrangement, does not exceed—

"(ii) 1/12 of 9.5 percent of the employee's household income.

"(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this paragraph, the term 'qualified small employer health reimbursement arrangement' has the meaning given such term by section 9831(d)(2).

"(E) COVERAGE FOR LESS THAN ENTIRE YEAR.—In the case of an employee who is provided a qualified small employer health reimbursement arrangement for less than an entire year, subparagraph (C)(i)(II) shall be applied by substituting 'the number of months during the year for which such arrangement was provided' for '12'.

"(F) INDEXING.—In the case of plan years beginning in any calendar year after 2014, the Secretary shall adjust the 9.5 percent amount under subparagraph (C)(ii) in the same manner as the percentages are adjusted under subsection (b)(3)(A)(ii).".

(4) APPLICATION OF EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.—

(A) IN GENERAL.—Section 4980I(f)(4) of such Code is amended by adding at the end the following: "Section 9831(d)(1) shall not apply for purposes of this section.".

(B) DETERMINATION OF COST OF COVERAGE.—Section 4980I(d)(2) of such Code is amended by redesignating subparagraph (D) as subparagraph (E) and by inserting after subparagraph (C) the following new subparagraph:

"(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of applicable employer-sponsored coverage consisting of coverage under any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)), the cost of coverage shall be equal to the amount described in section 6051(a)(15).".

(5) ENFORCEMENT OF NOTICE REQUIREMENT.—Section 6652 of such Code is amended by adding at the end the following new subsection:

"(o) FAILURE TO PROVIDE NOTICES WITH RESPECT TO QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of each failure to provide a written notice as required by section 9831(d)(4), unless it is shown that such failure is due to reasonable cause and not willful neglect, there shall be paid, on notice and demand of the Secretary and in the same manner as tax, by the person failing to provide such written notice, an amount equal to $50 per employee per incident of failure to provide such notice, but the total amount imposed on such person for all such failures during any calendar year shall not exceed $2,500.".

(6) REPORTING.—

(A) W–2 REPORTING.—Section 6051(a) of such Code is amended by striking "and" at the end of paragraph (13), by striking the period at the end of paragraph (14) and inserting ", and", and by inserting after paragraph (14) the following new paragraph:

"(15) the total amount of permitted benefit (as defined in section 9831(d)(3)(C)) for the year under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)) with respect to the employee.".

(B) INFORMATION REQUIRED TO BE PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—Section 1411(b)(3) of the Patient Protection and Affordable Care Act is amended

by redesignating subparagraph (B) as subparagraph (C) and by inserting after subparagraph (A) the following new subparagraph:

"(B) CERTAIN INDIVIDUAL HEALTH INSURANCE POLICIES OBTAINED THROUGH SMALL EMPLOYERS.—The amount of the enrollee's permitted benefit (as defined in section 9831(d)(3)(C) of the Internal Revenue Code of 1986) under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of such Code).".

(7) EFFECTIVE DATES.— 26 USC 36B note.

(A) IN GENERAL.—Except as otherwise provided in this paragraph, the amendments made by this subsection shall apply to years beginning after December 31, 2016.

(B) TRANSITION RELIEF.—The relief under Treasury Notice 2015–17 shall be treated as applying to any plan year beginning on or before December 31, 2016.

(C) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—The amendments made by paragraph (3) shall apply to taxable years beginning after December 31, 2016.

(D) EMPLOYEE NOTICE.—

(i) IN GENERAL.—The amendments made by paragraph (5) shall apply to notices with respect to years beginning after December 31, 2016.

(ii) TRANSITION RELIEF.—For purposes of section 6652(o) of the Internal Revenue Code of 1986 (as added by this Act), a person shall not be treated as failing to provide a written notice as required by section 9831(d)(4) of such Code if such notice is so provided not later than 90 days after the date of the enactment of this Act.

(E) W–2 REPORTING.—The amendments made by paragraph (6)(A) shall apply to calendar years beginning after December 31, 2016.

(F) INFORMATION PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—

(i) IN GENERAL.—The amendments made by paragraph (6)(B) shall apply to applications for enrollment made after December 31, 2016.

(ii) VERIFICATION.—Verification under section 1411 of the Patient Protection and Affordable Care Act of information provided under section 1411(b)(3)(B) of such Act shall apply with respect to months beginning after October 2016.

(iii) TRANSITIONAL RELIEF.—In the case of an application for enrollment under section 1411(b) of the Patient Protection and Affordable Care Act made before April 1, 2017, the requirement of section 1411(b)(3)(B) of such Act shall be treated as met if the information described therein is provided not later than 30 days after the date on which the applicant receives the notice described in section 9831(d)(4) of the Internal Revenue Code of 1986.

(8) SUBSTANTIATION REQUIREMENTS.—The Secretary of the Treasury (or his designee) may issue substantiation requirements as necessary to carry out this subsection. 26 USC 36B note.

(b) AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Section 733(a)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(a)(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS, ETC.—Section 607(1) of such Act (29 U.S.C. 1167(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

29 USC 1167 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

(c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.—

(1) IN GENERAL.—Section 2791(a)(1) of the Public Health Service Act (42 U.S.C. 300gg–91(a)(1)) is amended by adding at the end the following: "Except for purposes of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.), such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS.—Section 2208(1) of the Public Health Service Act (42 U.S.C. 300bb–8(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

42 USC 300bb–8 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

Approved December 13, 2016.

LEGISLATIVE HISTORY—H.R. 34:

SENATE REPORTS: No. 114–146 (Comm. on Commerce, Science, and Transportation).

CONGRESSIONAL RECORD:

Vol. 161 (2015): Jan. 7, considered and passed House.
Oct. 6, considered and passed Senate, amended.

Vol. 162 (2016): Nov. 30, House concurred in Senate amendment with an amendment.
Dec. 1, 5–7, Senate considered and concurred in House amendment.

DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2016):
Dec. 13, Presidential remarks.

○

Public Law 110–85
110th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

Sept. 27, 2007
[H.R. 3580]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

Food and Drug Administration Amendments Act of 2007.
21 USC 301 note.

This Act may be cited as the "Food and Drug Administration Amendments Act of 2007".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.

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Sec. 101. Short title; references in title; finding.
Sec. 102. Definitions.
Sec. 103. Authority to assess and use drug fees.
Sec. 104. Fees relating to advisory review of prescription-drug television advertising.
Sec. 105. Reauthorization; reporting requirements.
Sec. 106. Sunset dates.
Sec. 107. Effective date.
Sec. 108. Savings clause.
Sec. 109. Technical amendment; conforming amendment.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

Sec. 201. Short title; references in title; finding.

Subtitle A—Fees Related to Medical Devices

Sec. 211. Definitions.
Sec. 212. Authority to assess and use device fees.
Sec. 213. Reauthorization; reporting requirements.
Sec. 214. Savings clause.
Sec. 215. Additional authorization of appropriations for postmarket safety information.
Sec. 216. Effective date.
Sec. 217. Sunset clause.

Subtitle B—Amendments Regarding Regulation of Medical Devices

Sec. 221. Extension of authority for third party review of premarket notification.
Sec. 222. Registration.
Sec. 223. Filing of lists of drugs and devices manufactured, prepared, propagated, and compounded by registrants; statements; accompanying disclosures.
Sec. 224. Electronic registration and listing.
Sec. 225. Report by Government Accountability Office.
Sec. 226. Unique device identification system.
Sec. 227. Frequency of reporting for certain devices.

Sec. 228. Inspections by accredited persons.
Sec. 229. Study of nosocomial infections relating to medical devices.
Sec. 230. Report by the Food and Drug Administration regarding labeling information on the relationship between the use of indoor tanning devices and development of skin cancer or other skin damage.

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

Sec. 301. Short title.
Sec. 302. Tracking pediatric device approvals.
Sec. 303. Modification to humanitarian device exemption.
Sec. 304. Encouraging pediatric medical device research.
Sec. 305. Demonstration grants for improving pediatric device availability.
Sec. 306. Amendments to office of pediatric therapeutics and pediatric advisory committee.
Sec. 307. Postmarket surveillance.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

Sec. 401. Short title.
Sec. 402. Reauthorization of Pediatric Research Equity Act.
Sec. 403. Establishment of internal committee.
Sec. 404. Government Accountability Office report.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

Sec. 501. Short title.
Sec. 502. Reauthorization of Best Pharmaceuticals for Children Act.
Sec. 503. Training of pediatric pharmacologists.

TITLE VI—REAGAN-UDALL FOUNDATION

Sec. 601. The Reagan-Udall Foundation for the Food and Drug Administration.
Sec. 602. Office of the Chief Scientist.
Sec. 603. Critical path public-private partnerships.

TITLE VII—CONFLICTS OF INTEREST

Sec. 701. Conflicts of interest.

TITLE VIII—CLINICAL TRIAL DATABASES

Sec. 801. Expanded clinical trial registry data bank.

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

Subtitle A—Postmarket Studies and Surveillance

Sec. 901. Postmarket studies and clinical trials regarding human drugs; risk evaluation and mitigation strategies.
Sec. 902. Enforcement.
Sec. 903. No effect on withdrawal or suspension of approval.
Sec. 904. Benefit-risk assessments.
Sec. 905. Active postmarket risk identification and analysis.
Sec. 906. Statement for inclusion in direct-to-consumer advertisements of drugs.
Sec. 907. No effect on veterinary medicine.
Sec. 908. Authorization of appropriations.
Sec. 909. Effective date and applicability.

Subtitle B—Other Provisions to Ensure Drug Safety and Surveillance

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TITLE XI—OTHER PROVISIONS

Subtitle A—In General

Sec. 1101. Policy on the review and clearance of scientific articles published by FDA employees.
Sec. 1102. Priority review to encourage treatments for tropical diseases.
Sec. 1103. Improving genetic test safety and quality.
Sec. 1104. NIH Technical amendments.
Sec. 1105. Severability clause.

Subtitle B—Antibiotic Access and Innovation

Sec. 1111. Identification of clinically susceptible concentrations of antimicrobials.
Sec. 1112. Orphan antibiotic drugs.
Sec. 1113. Exclusivity of certain drugs containing single enantiomers.
Sec. 1114. Report.

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

Prescription Drug User Fee Amendments of 2007.

SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Prescription Drug User Fee Amendments of 2007". 21 USC 301 note.

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record. 21 USC 379g note.

SEC. 102. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the matter before paragraph (1), by striking "For purposes of this subchapter" and inserting "For purposes of this part";

(2) in paragraph (1)—

(A) in subparagraph (A), by striking "505(b)(1)," and inserting "505(b), or";

(B) by striking subparagraph (B);

(C) by redesignating subparagraph (C) as subparagraph (B); and

(D) in the matter following subparagraph (B), as so redesignated, by striking "subparagraph (C)" and inserting "subparagraph (B)";

(3) in paragraph (3)(C)—

(A) by striking "505(j)(7)(A)" and inserting "505(j)(7)(A) (not including the discontinued section of such list)"; and

(B) by inserting before the period "(not including the discontinued section of such list)";

(4) in paragraph (4), by inserting before the period at the end the following: "(such as capsules, tablets, or lyophilized products before reconstitution)";

(5) by amending paragraph (6)(F) to read as follows:

"(F) Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities:

"(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

"(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

"(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

"(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

"(v) Carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).";

(6) in paragraph (8)—

(A) by striking "April of the preceding fiscal year" and inserting "October of the preceding fiscal year"; and

(B) by striking "April 1997" and inserting "October 1996";

(7) by redesignating paragraph (9) as paragraph (11); and

(8) by inserting after paragraph (8) the following paragraphs:

"(9) The term 'person' includes an affiliate thereof.

"(10) The term 'active', with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.".

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "2003" and inserting "2008";

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting "OR WITHDRAWN BEFORE FILING" after "REFUSED FOR FILING"; and

(ii) by inserting before the period at the end the following: "or withdrawn without a waiver before filing";

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

"(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).."; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (C)"; and

(B) by adding at the end the following:

"(C) SPECIAL RULES FOR POSITRON EMISSION TOMOGRAPHY DRUGS.—

"(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the application as producing positron emission tomography drugs under the approved application.

"(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

"(I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

"(II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

"(iii) DEFINITION.—For purposes of this subparagraph, the term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.".

(b) FEE REVENUE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE REVENUE AMOUNTS.—

"(1) IN GENERAL.—For each of the fiscal years 2008 through 2012, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

"(A) $392,783,000; and

"(B) an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).

"(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

"(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

"(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

"(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).

"(3) MODIFIED WORKLOAD ADJUSTMENT FACTOR FOR FISCAL YEAR 2007.—For purposes of paragraph (1)(B), the Secretary shall determine the modified workload adjustment factor by determining the dollar amount that results from applying the methodology that was in effect under subsection (c)(2) for fiscal year 2007 to the amount $354,893,000, except that, with respect to the portion of such determination that is based on the change in the total number of commercial investigational new drug applications, the Secretary shall count the number of such applications that were active during the most recent 12-month period for which data on such submissions is available.

"(4) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

Applicability.

"(A) IN GENERAL.—For each of the fiscal years 2008 through 2012, paragraph (1)(A) shall be applied by substituting the amount determined under subparagraph (B) for '$392,783,000'.

"(B) AMOUNT DETERMINED.—For each of the fiscal years 2008 through 2012, the amount determined under this subparagraph is the sum of—

"(i) $392,783,000; plus

"(ii)(I) for fiscal year 2008, $25,000,000;

"(II) for fiscal year 2009, $35,000,000;

"(III) for fiscal year 2010, $45,000,000;

"(IV) for fiscal year 2011, $55,000,000; and

"(V) for fiscal year 2012, $65,000,000.".

(c) ADJUSTMENTS TO FEES.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

(A) in the matter preceding subparagraph (A), by striking "The revenues established in subsection (b)" and inserting "For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)";

(B) in subparagraph (A), by striking "or" at the end;

(C) in subparagraph (B), by striking the period at the end and inserting ", or";

(D) by inserting after subparagraph (B) the following:

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years."; and

(E) in the matter following subparagraph (C) (as added by subparagraph (D)), by striking "fiscal year 2003" and inserting "fiscal year 2008".

(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in the matter preceding subparagraph (A), by striking "Beginning with fiscal year 2004," and inserting "For fiscal year 2009 and subsequent fiscal years,";

(B) in subparagraph (A), in the first sentence—

(i) by striking "human drug applications," and inserting "human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph),";

(ii) by striking "commercial investigational new drug applications,"; and

(iii) by inserting before the period the following: ", and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available";

(C) in subparagraph (B), by adding at the end the following: "Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities."; and

(D) by adding at the end the following:

"(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees and revenue amounts for fiscal year 2009 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2010 through 2012. The Secretary shall not make any adjustment for changes in review activities for any fiscal year after 2009 unless such study has been completed.".

Contracts.
Study.

Effective date.

(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

(B) by inserting after paragraph (2) the following:

"(3) RENT AND RENT-RELATED COST ADJUSTMENT.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (b) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2006. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2006 for such fiscal year, and shall not exceed $11,721,000 for any fiscal year.".

(4) FINAL YEAR ADJUSTMENT.—Paragraph (4) of section 736(c) (21 U.S.C. 379h(c)), as redesignated by paragraph (3)(A), is amended to read as follows:

"(4) FINAL YEAR ADJUSTMENT.—

"(A) INCREASE IN FEES.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2013. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2012. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

"(B) DECREASE IN FEES.—

"(i) IN GENERAL.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), decrease the fee revenues and fees established in subsection (b) by the amount determined in clause (ii), if, for fiscal year 2009 or 2010—

"(I) the amount of the total appropriations for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriations for the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1); and

"(II) the amount of the total appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1).

"(ii) AMOUNT OF DECREASE.—The amount determined in this clause is the lesser of—

"(I) the amount equal to the sum of the amounts that, for each of fiscal years 2009 and 2010, is the lesser of—

"(aa) the excess amount described in clause (i)(II) for such fiscal year; or

"(bb) the amount specified in subsection (b)(4)(B)(ii) for such fiscal year; or

"(II) $65,000,000.

"(iii) LIMITATIONS.—

"(I) FISCAL YEAR CONDITION.—In making the determination under clause (ii), an amount described in subclause (I) of such clause for fiscal year 2009 or 2010 shall be taken into account

only if subclauses (I) and (II) of clause (i) apply to such fiscal year.

"(II) RELATION TO SUBPARAGRAPH (A).—The Secretary shall limit any decrease under this paragraph if such a limitation is necessary to provide for the 3 months of operating reserves described in subparagraph (A).".

(5) LIMIT.—Paragraph (5) of section 736(c) (21 U.S.C. 379h(c)), as redesignated by paragraph (3)(A), is amended by striking "2002" and inserting "2007".

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A)—

(A) by inserting after "The Secretary shall grant" the following: "to a person who is named as the applicant in a human drug application"; and

(B) by inserting "to that person" after "one or more fees assessed";

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(3) by inserting after paragraph (1) the following:

"(2) CONSIDERATIONS.—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant."; and

(4) in paragraph (4) (as redesignated by paragraph (2)), in subparagraph (A), by inserting before the period the following: ", and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce".

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this subsection.".

(2) OFFSET.—Section 736(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:

"(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.".

(f) EXEMPTION FOR ORPHAN DRUGS.—Section 736 (21 U.S.C. 379h) is further amended by adding at the end the following:

"(k) ORPHAN DRUGS.—

"(1) EXEMPTION.—A drug designated under section 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public Health Service Act shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:

"(A) The drug meets the public health requirements contained in this Act as such requirements are applied to requests for waivers for product and establishment fees.

"(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the previous year.

"(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.".

(g) CONFORMING AMENDMENT.—Section 736(a) (21 U.S.C. 379h(a)) is amended in paragraphs (1)(A)(i), (1)(A)(ii), (2)(A), and (3)(A) by striking "(c)(4)" each place such term appears and inserting "(c)(5)".

(h) TECHNICAL AMENDMENT.—

(1) AMENDMENT.—Section 736(g)(1) (21 U.S.C. 379h(g)(1)) is amended by striking the first sentence and inserting the following: "Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.".

21 USC 379h note.

(2) EFFECTIVE DATE.—Paragraph (1) shall take effect as if included in section 504 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188; 116 Stat. 687).

SEC. 104. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following:

21 USC 379h–1.

"SEC. 736A. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

Effective date.

"(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENT REVIEW FEES.—Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

"(1) ADVISORY REVIEW FEE.—

"(A) IN GENERAL.—With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a 'DTC advertisement'), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public dissemination shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

"(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A DTC advertisement that is required to be submitted to the Secretary prior to initial public dissemination is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for advisory review.

Deadlines. Federal Register, publication.

"(C) NOTICE TO SECRETARY OF NUMBER OF ADVERTISEMENTS.—Not later than June 1 of each fiscal

year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for advisory review in the next fiscal year. Notwithstanding the preceding sentence, for fiscal year 2008, the Secretary shall publish such a notice in the Federal Register not later than 30 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

"(D) PAYMENT.— Deadlines.

"(i) IN GENERAL.—The fee required by subparagraph (A) (referred to in this section as 'an advisory review fee') shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended to be submitted for advisory review, subject to subparagraph (F)(i). Notwithstanding the preceding sentence, the advisory review fee for any DTC advertisement that is intended to be submitted for advisory review during fiscal year 2008 shall be due not later than 120 days after the date of the enactment of the Food and Drug Administration Amendments of 2007 or an earlier date as specified by the Secretary.

"(ii) EFFECT OF SUBMISSION.—Notification of the Secretary under subparagraph (C) of the number of DTC advertisements a person intends to submit for advisory review is a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. Notwithstanding the preceding sentence, the commitment shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions for fiscal year 2008 by the date specified in clause (i).

"(iii) NOTICE REGARDING CARRYOVER SUBMISSIONS.—In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for advisory review in the fiscal year involved shall be subject to the advisory review fee.

"(E) MODIFICATION OF ADVISORY REVIEW FEE.—

"(i) LATE PAYMENT.—If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) not later than November 1 of such fiscal year (or, in the case of such a notification submitted with respect to fiscal year 2008, not later than 150 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary), the fees shall be regarded as late Applicability.

and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this section. For such person, all advisory review fees for such fiscal year shall be due and payable 20 days before any direct-to-consumer advertisement is submitted to the Secretary for advisory review, and each such fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

Deadline.

"(ii) EXCEEDING IDENTIFIED NUMBER OF SUBMISSIONS.—If a person submits a number of DTC advertisements for advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding any other provision of this section. For each such DTC advertisement, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

Deadline.

"(F) LIMITS.—

"(i) SUBMISSIONS.—For each advisory review fee paid by a person for a fiscal year, the person is entitled to acceptance for advisory review by the Secretary of one DTC advertisement and acceptance of one resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over not more than one paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

"(ii) NO REFUNDS.—Except as provided by subsections (d)(4) and (f), fees paid under this section shall not be refunded.

"(iii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

"(iv) RIGHT TO ADVISORY REVIEW NOT TRANSFERABLE.—The right to an advisory review under this paragraph is not transferable, except to a successor in interest.

"(2) OPERATING RESERVE FEE.—

"(A) IN GENERAL.—Each person that on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to fee established under subsection (d)(2) (referred to in this section as an 'operating reserve fee') for the first fiscal year in which an advisory review fee is assessed to such person. The person is not subject to an operating reserve fee for any other fiscal year.

Deadlines.

"(B) PAYMENT.—Except as provided in subparagraph (C), the operating reserve fee shall be due no later than—

"(i) October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1); or

"(ii) for fiscal year 2008, 120 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary.

"(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person's participation in the program under this section, that person submits any DTC advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (a)(1)(C), that person shall pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(E)(ii). Fees required by this subparagraph shall be in addition to any fees required by subparagraph (A). Fees under this subparagraph shall be due 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

Deadline.

"(D) LATE PAYMENT.—

Deadlines.

"(i) IN GENERAL.—Notwithstanding subparagraph (B), and subject to clause (ii), an operating reserve fee shall be regarded as late if the person required to pay the fee has not paid the complete operating reserve fee by—

"(I) for fiscal year 2008, 150 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary; or

"(II) in any subsequent year, November 1.

"(ii) COMPLETE PAYMENT.—The complete operating reserve fee shall be due and payable 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

"(iii) AMOUNT.—Notwithstanding any other provision of this section, an operating reserve fee that is regarded as late under this subparagraph shall be equal to 150 percent of the operating reserve fee that otherwise would have applied pursuant to subsection (d).

"(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsections (c) and (g)(4).

"(c) ADJUSTMENTS.—

"(1) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

Effective date.
Notice.
Federal Register, publication.

"(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance

with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

Effective date.

"(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of DTC advertisements for advisory review prior to initial dissemination. With respect to such adjustment:

"(A) The adjustment shall be determined by the Secretary based upon the number of DTC advertisements identified pursuant to subsection (a)(1)(C) for the upcoming fiscal year, excluding allowable previously paid carry over submissions. The adjustment shall be determined by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

Federal Register, publication.

"(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

"(3) ANNUAL FEE SETTING FOR ADVISORY REVIEW.—

Deadlines.

"(A) IN GENERAL.—Not later than August 1 of each fiscal year (or, with respect to fiscal year 2008, not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007), the Secretary shall establish for the next fiscal year the DTC advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under paragraphs (1) and (2), and the number of DTC advertisements identified pursuant to subsection (a)(1)(C), excluding allowable previously-paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of DTC advertisements so identified, excluding allowable previously-paid carry over submissions under subsection (a)(1)(F)(i).

"(B) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for

fiscal year 2008 may not be more than $83,000 per submission for advisory review.

"(C) ANNUAL FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

"(D) LIMIT.—The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

"(d) OPERATING RESERVES.—

"(1) IN GENERAL.—The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the program under this section in the event the fees collected in any subsequent fiscal year pursuant to subsection (a)(1) do not generate the fee revenue amount established for that fiscal year.

"(2) FEE SETTING.—The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of DTC advertisements identified by that person pursuant to subsection (a)(1)(C) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year, except that in no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the program under this section in fiscal year 2008.

"(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsections (b) and (c) and the amount of fees actually collected for that fiscal year pursuant to subsection (a)(1), or to pay costs of ending the program under this section if it is terminated pursuant to subsection (f) or not reauthorized beyond fiscal year 2012.

"(4) REFUND OF OPERATING RESERVES.—Within 120 days after the end of fiscal year 2012, or if the program under this section ends early pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the program under this section, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2). Deadline.

"(e) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other requirement, a submission for advisory review of a DTC advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

"(f) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

"(1) INITIAL FUNDING.—If on November 1, 2007, or 120 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, whichever is later, Effective date.

the Secretary has not received at least $11,250,000 in advisory review fees and operating reserve fees combined, the program under this section shall not commence and all collected fees shall be refunded.

Effective date. Notification.

"(2) LATER FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of the fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below $9,000,000, adjusted for inflation (as described in subsection (c)(1)), the program under this section shall terminate, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and finally, unused advisory review fees from the relevant fiscal year.

"(g) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

"(ii) shall be available for obligation only if the amounts appropriated as budget authority for such fiscal year are sufficient to support a number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.

"(B) REVIEW EMPLOYEES.—For purposes of subparagraph (A)(ii), the term 'full-time equivalent review employees' means the total combined number of full-time equivalent employees in—

"(i) the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; and

"(ii) the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, Food and Drug Administration.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the

fiscal year, as adjusted pursuant to subsection (c) and paragraph (4) of this subsection, plus amounts collected for the reserve fund under subsection (d).

"(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

"(h) DEFINITIONS.—For purposes of this section:

"(1) The term 'advisory review' means reviewing and providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

"(2) The term 'advisory review fee' has the meaning indicated for such term in subsection (a)(1)(D).

"(3) The term 'carry over submission' means a submission for an advisory review for which a fee was paid in one fiscal year that is submitted for review in the following fiscal year.

"(4) The term 'direct-to-consumer television advertisement' means an advertisement for a prescription drug product (as defined in section 735(3)) intended to be displayed on any television channel for less than 3 minutes.

"(5) The term 'DTC advertisement' has the meaning indicated for such term in subsection (a)(1)(A).

"(6) The term 'operating reserve fee' has the meaning indicated for such term in subsection (a)(2)(A).

"(7) The term 'person' includes an individual, partnership, corporation, and association, and any affiliate thereof or successor in interest.

"(8) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on DTC advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

"(9) The term 'resources allocated for the process for the advisory review of prescription drug advertising' means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for—

"(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

"(B) management of information, and the acquisition, maintenance, and repair of computer resources;

"(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

"(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

"(E) terminating the program under this section pursuant to subsection (f)(2) if that becomes necessary.

"(10) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

"(11) The term 'submission for advisory review' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.".

SEC. 105. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.), as amended by section 104, is further amended by inserting after section 736A the following:

21 USC 379h–2.

"SEC. 736B. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) PERFORMANCE REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

"(b) FISCAL REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

Website.

"(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

"(d) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization; Federal Register, publication.

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site. Website.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register; Federal Register, publication.

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments. Deadline.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry. Website.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made

by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

SEC. 106. SUNSET DATES.

21 USC 379g note.

(a) AUTHORIZATION.—The amendments made by sections 102, 103, and 104 cease to be effective October 1, 2012.

21 USC 379h–2.

(b) REPORTING REQUIREMENTS.—The amendment made by section 105 ceases to be effective January 31, 2013.

21 USC 379g note.

SEC. 107. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2007, regardless of the date of the enactment of this Act.

21 USC 379g note.

SEC. 108. SAVINGS CLAUSE.

Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 109. TECHNICAL AMENDMENT; CONFORMING AMENDMENT.

(a) Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1) by striking "subchapter" and inserting "part".

(b) Paragraph (11) of section 739 (21 U.S.C. 379j–11) is amended by striking "735(9)" and inserting "735(11)".

Medical Device User Fee Amendments of 2007.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.

21 USC 301 note.

(a) SHORT TITLE.—This title may be cited as the "Medical Device User Fee Amendments of 2007".

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

21 USC 379i note.

(c) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy

and Commerce of the House of Representatives, as set forth in the Congressional Record.

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

Section 737 is amended— 21 USC 379i.

(1) in the matter preceding paragraph (1), by striking "For purposes of this subchapter" and inserting "For purposes of this part";

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (8), (9), (10), and (12), respectively;

(3) by inserting after paragraph (4) the following:

"(5) The term '30-day notice' means a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

"(6) The term 'request for classification information' means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

"(7) The term 'annual fee', for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.";

(4) in paragraph (10), as so redesignated—

(A) by striking "April of the preceding fiscal year" and inserting "October of the preceding fiscal year"; and

(B) by striking "April 2002" and inserting "October 2001";

(5) by inserting after paragraph (10), as so amended, the following:

"(11) The term 'person' includes an affiliate thereof."; and

(6) by inserting after paragraph (12), as so redesignated, the following:

"(13) The term 'establishment subject to a registration fee' means an establishment that is required to register with the Secretary under section 510 and is one of the following types of establishments:

"(A) MANUFACTURER.—An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

"(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that, within the meaning of section 201(ll)(2)(A), performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

"(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.".

SEC. 212. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(A) in paragraph (1), by striking "Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002" and inserting "Beginning in fiscal year 2008"; and

(B) by amending the designation and heading of paragraph (2) to read as follows:

"(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—".

(2) FEE AMOUNTS.—Section 738(a)(2)(A) (21 U.S.C. 379j(a)(2)(A)) is amended—

(A) in clause (iii), by striking "a fee equal to the fee that applies" and inserting "a fee equal to 75 percent of the fee that applies";

(B) in clause (iv), by striking "21.5 percent" and inserting "15 percent";

(C) in clause (v), by striking "7.2 percent" and inserting "7 percent";

(D) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(E) by inserting after clause (v) the following:

"(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).";

(F) in clause (viii), as so redesignated—

(i) by striking "1.42 percent" and inserting "1.84 percent"; and

(ii) by striking ", subject to any adjustment under subsection (e)(2)(C)(ii)"; and

(G) by inserting after such clause (viii) the following:

"(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

"(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).".

(3) PAYMENT.—Section 738(a)(2)(C) (21 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

"(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.".

(4) REFUNDS.—Section 738(a)(2)(D) (21 U.S.C. 379j(a)(2)(D)) is amended—

(A) in clause (iii), by striking the last two sentences; and

(B) by adding after clause (iii) the following:

"(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted

under section 515(c)(4) that is withdrawn before a second portion is submitted and before a first action on the first portion.

"(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 515(c)(4) is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

"(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.".

(5) ANNUAL ESTABLISHMENT REGISTRATION FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amended by adding after paragraph (2) the following:

"(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

"(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

"(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.".

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384
Establishment Registration	$1,706	$1,851	$2,008	$2,179	$2,364.".

(c) ANNUAL FEE SETTING.—

(1) IN GENERAL.—Section 738(c) (21 U.S.C. 379j(c)(1)) is amended—

(A) in the subsection heading, by striking "Annual Fee Setting" and inserting "ANNUAL FEE SETTING"; and

(B) in paragraph (1), by striking the last sentence.

(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT FEE.—Section 738(c) (21 U.S.C. 379j(c)), as amended by paragraph (1), is further amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(B) by inserting after paragraph (1) the following:

"(2) ADJUSTMENT.—

"(A) IN GENERAL.—When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

Federal Register, publication.

"(B) PUBLICATION.—For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination."; and

(C) in paragraph (4), as redesignated by this paragraph, in subparagraph (A)—

(i) by striking "For fiscal years 2006 and 2007, the Secretary" and inserting "The Secretary"; and

(ii) by striking "for the first month of fiscal year 2008" and inserting "for the first month of the next fiscal year".

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 738(d)(1) (21 U.S.C. 379j(d)(1)) is amended—

(A) by striking ", partners, and parent firms"; and

(B) by striking "clauses (i) through (vi) of subsection (a)(2)(A)" and inserting "clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)".

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—Section 738(d)(2)(A) (21 U.S.C. 379j(d)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates."; and

(v) by adding at the end the following:

"(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.".

Certification. Federal Register, publication.

(3) REDUCED FEES.—Section 738(d)(2)(C) (21 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

"(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

"(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or periodic reporting concerning a class III device; and

"(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.".

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—Section 738(e)(1) (21 U.S.C. 379j(e)(1)) is amended—

(A) by striking "2004" and inserting "2008"; and

(B) by striking "(a)(2)(A)(vii)" and inserting "(a)(2)(A)(viii)".

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A) (21 U.S.C. 379j(e)(2)(A)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(B)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates."; and

(v) by adding at the end the following:

Certification.
Federal Register, publication.

"(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.".

(3) REDUCED FEES.—Section 738(e)(2)(C) (21 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

"(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).".

(f) EFFECT OF FAILURE TO PAY FEES.—Section 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

"(f) EFFECT OF FAILURE TO PAY FEES.—

"(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

"(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.".

(g) CONDITIONS.—Section 738(g) (21 U.S.C. 379j(g)) is amended—

(1) by striking paragraph (1) and inserting the following:

"(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

"(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

"(B) fees were not assessed under subsection (a) for the previous fiscal year."; and

(2) by amending paragraph (2) to read as follows:

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.".

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(3) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $48,431,000 for fiscal year 2008;

"(B) $52,547,000 for fiscal year 2009;

"(C) $57,014,000 for fiscal year 2010;

"(D) $61,860,000 for fiscal year 2011; and

"(E) $67,118,000 for fiscal year 2012.".

(2) OFFSET.—Section 738(h)(4) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.".

SEC. 213. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 3 of subchapter C of chapter VII is amended by inserting after section 738 the following:

21 USC 379j–1.

"SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) REPORTS.—

"(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

"(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

Website.

"(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

"(b) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

"(A) publish a notice in the Federal Register requesting public input on the reauthorization; Federal Register, publication.

"(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site. Website.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register; Federal Register, publication.

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments. Deadline.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry. Website.

"(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.".

21 USC 379i note.

SEC. 214. SAVINGS CLAUSE.

Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and notwithstanding the amendments made by this subtitle, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS FOR POSTMARKET SAFETY INFORMATION.

For the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices, there are authorized to be appropriated to the Food and Drug Administration, in addition to the amounts authorized by other provisions of law for such purpose—

(1) $7,100,000 for fiscal year 2008;
(2) $7,455,000 for fiscal year 2009;
(3) $7,827,750 for fiscal year 2010;
(4) $8,219,138 for fiscal year 2011; and
(5) $8,630,094 for fiscal year 2012.

21 USC 379i note.

SEC. 216. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.

21 USC 379i note.

SEC. 217. SUNSET CLAUSE.

The amendments made by this subtitle cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act (regarding annual performance and financial reports) ceases to be effective January 31, 2013.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 221. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking "2007" and inserting "2012".

SEC. 222. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 360(b)) is amended—

(1) by striking "(b) On or before" and inserting "(b)(1) On or before";

(2) by striking "or a device or devices"; and

(3) by adding at the end the following:

"(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.".

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by striking "On or before December 31" and all that follows and inserting the following: "Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

"(A) upon first engaging in any such activity, immediately register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

"(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

"(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

"(ii) with respect to devices, register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.".

SEC. 223. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.

Reports. Deadlines.

Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended, in the matter preceding subparagraph (A), by striking "Each person" and all that follows through "the following information:" and inserting "Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:".

SEC. 224. ELECTRONIC REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended to read as follows:

"(p) Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.".

SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

Study.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) CONSIDERATION.—In determining the effectiveness of the premarket notification and classification authority under section 510(k) and subsections (f) and (i) of section 513 of the Federal Food, Drug, and Cosmetic Act, the study under subsection (a) shall consider the Secretary of Health and Human Services's evaluation of the respective intended uses and technologies of such devices, including the effectiveness of such Secretary's comparative assessment of technological characteristics such as device materials, principles of operations, and power sources.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.

(a) IN GENERAL.—Section 519 (21 U.S.C. 360i) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e) the following:

"Unique Device Identification System

Regulations.

"(f) The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.".

(b) CONFORMING AMENDMENT.—Section 303 (21 U.S.C. 333) is amended—

(1) by redesignating the subsection that follows subsection (e) as subsection (f); and

(2) in paragraph (1)(B)(ii) of subsection (f), as so redesignated, by striking "519(f)" and inserting "519(g)".

SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DEVICES.

Subparagraph (B) of section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended by striking "were to recur;" and inserting the following: "were to recur, which report under this subparagraph—

"(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

"(I) a class III device;

"(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

Federal Register, publication.

"(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer

or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

"(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

"(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)".

SEC. 228. INSPECTIONS BY ACCREDITED PERSONS.

Section 704(g) (21 U.S.C. 374(g)) is amended—

(1) in paragraph (1), by striking "Not later than one year after the date of the enactment of this subsection, the Secretary" and inserting "The Secretary";

(2) in paragraph (2), by—

(A) striking "Not later than 180 days after the date of enactment of this subsection, the Secretary" and inserting "The Secretary"; and

(B) striking the fifth sentence;

(3) in paragraph (3), by adding at the end the following:

"(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

Notification. Deadline.

"(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).";

(4) by amending paragraph (6) to read as follows:

"(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

"(i) The Secretary classified the results of the most recent inspection of the establishment as 'no action indicated' or 'voluntary action indicated'.

"(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

"(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

"(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

"(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

"(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

"(aa) at least 1 of such devices is marketed in the United States; and

"(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

Deadline.

"(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

"(I) denies clearance to participate as provided under subparagraph (C); or

"(II) makes a request under clause (ii).

"(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

"(I) compliance data for the establishment in accordance with clause (iii)(I); or

"(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

Deadline.

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

"(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

"(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

Deadline.

"(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues

a response that denies clearance to participate as provided under subparagraph (C).

"(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

"(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

"(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

"(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii). Notification. Applicability.

"(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree."; Deadline.

(5) in paragraph (7)—

(A) in subparagraph (A), by striking "(A) Persons" and all that follows through the end and inserting the following: "(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary."; and Records. Reports.

(B) by adding at the end the following:

Audits.

"(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods."; and

(6) in paragraph (10)(C)(iii), by striking "based" and inserting "base".

SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING TO MEDICAL DEVICES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(1) the number of nosocomial infections attributable to new and reused medical devices; and

(2) the causes of such nosocomial infections, including the following:

(A) Reprocessed single-use devices.

(B) Handling of sterilized medical devices.

(C) In-hospital sterilization of medical devices.

(D) Health care professionals' practices for patient examination and treatment.

(E) Hospital-based policies and procedures for infection control and prevention.

(F) Hospital-based practices for handling of medical waste.

(G) Other causes.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

(c) DEFINITION.—In this section, the term "nosocomial infection" means an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital.

SEC. 230. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, "Ultraviolet radiation can cause skin cancer", or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing to determine consumer understanding of label warnings.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

Pediatric Medical Device Safety and Improvement Act of 2007.

SEC. 301. SHORT TITLE.

21 USC 301 note.

This title may be cited as the "Pediatric Medical Device Safety and Improvement Act of 2007".

SEC. 302. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

"SEC. 515A. PEDIATRIC USES OF DEVICES.

21 USC 360e–1.

"(a) NEW DEVICES.—

"(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

"(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

"(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

"(B) the number of affected pediatric patients.

"(3) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

"(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

"(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

"(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

"(D) the review time for each device described in subparagraphs (A), (B), and (C).

"(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

"(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

"(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

"(c) PEDIATRIC SUBPOPULATION.—For purposes of this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).".

SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (3), by striking "No" and inserting "Except as provided in paragraph (6), no";

(2) in paragraph (5)—

(A) by inserting ", if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met," after "public health"; and

(B) by adding at the end the following: "If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing."; and

(3) by striking paragraph (6) and inserting after paragraph (5) the following new paragraphs:

"(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

"(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

"(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of the enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

"(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall

be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

"(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii). Notification.

"(iv) The request for such exemption is submitted on or before October 1, 2012. Deadline.

"(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

"(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

"(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification. Applicability.

"(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

"(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

"(I) Neonates.

"(II) Infants.

"(III) Children.

"(IV) Adolescents.

"(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

"(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee Annual review.

of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.".

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 360e) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of purchasing pediatric devices, based on a representative sampling of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption;

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

(10) an evaluation of the demonstration grants described in section 305, which shall include an evaluation of the number of pediatric medical devices—

(A) that have been or are being studied in children; and

(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as amended by this Act) and any regulatory actions taken.

Deadline.
21 USC 360j note.

(c) GUIDANCE.—Not later than 180 days after the date of the enactment of this Act, the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian

device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.

(a) CONTACT POINT FOR AVAILABLE FUNDING.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking "and" after the semicolon at the end;

(2) in paragraph (22), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (22) the following:

"(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.".

(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Secretary of Health and Human Services shall consult with individuals and organizations with appropriate expertise in pediatric medical devices. Deadline.

(2) CONTENTS.—The plan under paragraph (1) shall include—

(A) the current status of federally funded pediatric medical device research;

(B) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(C) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY. 42 USC 282 note.

(a) IN GENERAL.— Deadline.

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects; and

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

Reports.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2008 through 2012.

SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting ", including increasing pediatric access to medical devices" after "pediatric issues".

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "and 505B" and inserting "505B, 510(k), 515, and 520(m)";

(ii) by striking subparagraph (B) and inserting the following:

"(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;"; and

(iii) in subparagraph (C), by inserting "(including drugs and biological products) and medical devices" after "therapeutics".

SEC. 307. POSTMARKET SURVEILLANCE.

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) by amending the section heading and designation to read as follows:

"SEC. 522. POSTMARKET SURVEILLANCE.";

(2) by striking subsection (a) and inserting the following:

"(a) POSTMARKET SURVEILLANCE.—

"(1) IN GENERAL.—

"(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

"(i) the failure of which would be reasonably likely to have serious adverse health consequences;

"(ii) that is expected to have significant use in pediatric populations; or

"(iii) that is intended to be—

"(I) implanted in the human body for more than 1 year; or

"(II) a life-sustaining or life-supporting device used outside a device user facility.

"(B) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

"(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act."; and

(3) in subsection (b)—

(A) by striking "(b) SURVEILLANCE APPROVAL.—Each" and inserting the following:

"(b) SURVEILLANCE APPROVAL.—

"(1) IN GENERAL.—Each";

(B) by striking "The Secretary, in consultation" and inserting "Except as provided in paragraph (2), the Secretary, in consultation";

(C) by striking "Any determination" and inserting "Except as provided in paragraph (2), any determination"; and

(D) by adding at the end the following:

"(2) LONGER SURVEILLANCE FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

"(c) DISPUTE RESOLUTION.—A manufacturer may request review under section 562 of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket surveillance order or condition shall not, because of noncompliance with such order or condition, be deemed in violation of section 301(q)(1)(C), adulterated under section 501(f)(1), misbranded under section 502(t)(3), or in violation of, as applicable, section 510(k) or section 515, unless deemed necessary to protect the public health.".

Pediatric Research Equity Act of 2007.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

21 USC 301 note.

SEC. 401. SHORT TITLE.

This title may be cited as the "Pediatric Research Equity Act of 2007".

SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.

(a) IN GENERAL.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate

formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

"(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).

"(3) DEFERRAL.—

"(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(i) the Secretary finds that—

"(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

"(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

"(III) there is another appropriate reason for deferral; and

"(ii) the applicant submits to the Secretary—

"(I) certification of the grounds for deferring the assessments;

"(II) a description of the planned or ongoing studies;

"(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

"(IV) a timeline for the completion of such studies.

"(B) ANNUAL REVIEW.—

"(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

"(I) Information detailing the progress made in conducting pediatric studies.

"(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

Website.

"(ii) PUBLIC AVAILABILITY.—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration.

"(4) WAIVERS.—

"(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used in a substantial number of pediatric patients.

"(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible

to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

Public information. Website.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

"(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

"(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

"(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.

"(2) WAIVERS.—

"(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

"(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii)(I) the drug or biological product—

"(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

"(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

Public information. Website.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—

"(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

"(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

"(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

"(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

"(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

"(A) to withdraw approval for a drug under section 505(e); or

"(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.

"(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

"(1) information that the sponsor submits on plans and timelines for pediatric studies; or

"(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

"(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.—

"(1) REVIEW.—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral and waiver requests granted pursuant to this section. Deadline.

"(2) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

"(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee participated in such activity.

"(4) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.—Consultation on pediatric plans and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

"(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an Deadline.

analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

Recommendations.

"(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

Public information. Website.

"(A) the number of assessments conducted under this section;

"(B) the specific drugs and biological products and their uses assessed under this section;

"(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

"(D) the total number of deferrals requested and granted under this section and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

"(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;

"(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;

"(G) the labeling changes made as a result of assessments conducted under this section;

"(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);

"(I) an annual summary of information submitted pursuant to subsection (a)(3)(B); and

"(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed.

"(g) LABELING CHANGES.—

"(1) DISPUTE RESOLUTION.—

Deadline.

"(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—

"(i) the Commissioner shall request that the sponsor of the application make any labeling change

that the Commissioner determines to be appropriate; and

"(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee. Deadline.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall— Deadline.

"(i) review the pediatric study reports; and

"(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

"(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate. Deadline.

"(D) MISBRANDING.—If the sponsor of the application or supplement, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded. Deadline.

"(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

"(2) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the label of such product to include information about the results of the assessment and a statement of the Secretary's determination.

"(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

"(1) IN GENERAL.—Not later than 210 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration. Deadline. Public information. Website.

"(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall require that the sponsors of the assessments that result in labeling Effective date.

changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute such information to physicians and other health care providers.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(i) ADVERSE EVENT REPORTING.—

Effective date.

"(1) REPORTING IN YEAR ONE.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the one-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such reports.

"(2) REPORTING IN SUBSEQUENT YEARS.—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

"(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

"(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

"(k) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

"(l) INSTITUTE OF MEDICINE STUDY.—

Deadline.
Contracts.
Reports.

"(1) IN GENERAL.—Not later than three years after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to this section or precursor regulations since 1997 and labeling changes made as a result of such studies.

"(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, the number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.

"(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to this section from each review division within the Center for Drug Evaluation and Research in order to make the requested assessment.

"(m) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(q).".

(b) APPLICABILITY.— 21 USC 355c note.

(1) IN GENERAL.—Notwithstanding subsection (h) of section 505B of the Federal Food, Drug and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, a pending assessment, including a deferred assessment, required under such section 505B shall be deemed to have been required under section 505B of the Federal Food, Drug and Cosmetic Act as in effect on or after the date of the enactment of this Act.

(2) CERTAIN ASSESSMENTS AND WAIVER REQUESTS.—An assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under such section 505B, as in effect on or after such date of enactment, except that any such assessments submitted or waivers of such assessments requested before such date of enactment shall not be subject to subsections (a)(4)(C), (b)(2)(C), (f)(6)(F), and (h) of such section 505B.

SEC. 403. ESTABLISHMENT OF INTERNAL COMMITTEE.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

"SEC. 505C. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS. Establishment. 21 USC 355d.

"The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 505A(f) and 505B(f). Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.".

SEC. 404. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

Not later than January 1, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to the Congress a report that addresses the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested and properly labeled. Such report shall include—

(1) the number and importance of drugs and biological products for children that are being tested as a result of the amendments made by this title and title V and the importance

for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs and biological products for children that are not being tested for their use notwithstanding the provisions of this title and title V and possible reasons for the lack of testing;

(3) the number of drugs and biological products for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this title, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (42 U.S.C. 284m) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

Best Pharmaceuticals for Children Act of 2007.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

21 USC 301 note.

SEC. 501. SHORT TITLE.

This title may be cited as the "Best Pharmaceuticals for Children Act of 2007".

SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT.

(a) PEDIATRIC STUDIES OF DRUGS.—

(1) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended to read as follows:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.

"(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall

include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—

"(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

"(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

"(B)(i) if the drug is the subject of—

"(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(II) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.

"(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section

505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—

"(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

"(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

"(B)(i) if the drug is the subject of—

"(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(II) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

Deadline.

"(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) REQUEST FOR STUDIES.—

"(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the

holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.

Minorities.

Timeframe.

"(B) SINGLE WRITTEN REQUEST.—A single written request—

"(i) may relate to more than one use of a drug; and

"(ii) may include uses that are both approved and unapproved.

"(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

"(A) REQUEST AND RESPONSE.—

"(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

"(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

"(II) indicating that the applicant or holder does not agree to the request and stating the reasons for declining the request.

"(ii) DISAGREE WITH REQUEST.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

"(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as the submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

"(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

Deadline.
Notification.

"(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

Publication.

"(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).

Deadline.
Records.

Publication.

"(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within one year after the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such one year period.

Deadline.

"(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

"(1) INTERNAL REVIEW.—The Secretary shall utilize the internal review committee established under section 505C to review all written requests issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with paragraph (2).

"(2) REVIEW OF WRITTEN REQUESTS.—The committee referred to in paragraph (1) shall review all written requests issued pursuant to this section prior to being issued.

"(3) REVIEW OF PEDIATRIC STUDIES.—The committee referred to in paragraph (1) may review studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject such reports under subsection (d)(3).

"(4) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

"(5) DOCUMENTATION OF COMMITTEE ACTION.—For each drug, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (2) or (3), which members of the committee participated in such activity.

Public information.
Website.

"(6) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public, in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

"(A) the number of studies conducted under this section and under section 409I of the Public Health Service Act;

"(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under such sections;

"(C) the types of studies conducted under such sections, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

"(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

"(E) the labeling changes made as a result of studies conducted under such sections;

"(F) an annual summary of labeling changes made as a result of studies conducted under such sections for distribution pursuant to subsection (k)(2); and

"(G) information regarding reports submitted on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.

"(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the six-month period under subsection (b) or (c) has already been applied—

"(1) may receive an additional six-month period under subsection (c)(1)(A)(i)(II) for a supplemental application if all other requirements under this section are satisfied, except that such drug may not receive any additional such period under subsection (c)(1)(B); and

"(2) may not receive any additional such period under subsection (c)(1)(A)(ii).

"(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

"(i) LABELING CHANGES.—

"(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS.—Any application or supplement to an application under section 505 proposing a labeling change as a result of any pediatric study conducted pursuant to this section—

"(A) shall be considered to be a priority application or supplement; and

"(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

"(2) DISPUTE RESOLUTION.—

"(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Commissioner determines that the sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application— Deadline.

"(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

"(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request to Deadline.

make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

Deadline.

"(i) review the pediatric study reports; and

"(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

Deadline.

"(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.

Deadline.

"(D) MISBRANDING.—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.

"(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

"(j) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.

"(k) DISSEMINATION OF PEDIATRIC INFORMATION.—

Deadline.
Public information.

"(1) IN GENERAL.—Not later than 210 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).

"(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall include as a requirement of a written request that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(3)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(l) ADVERSE EVENT REPORTING.—

"(1) REPORTING IN YEAR ONE.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, during the one-year period beginning on the date a labeling change is approved pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the reports, the Director of such Office shall provide for the review of the reports by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this Act in response to such reports. Effective date.

"(2) REPORTING IN SUBSEQUENT YEARS.—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

"(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

"(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

"(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

"(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.

"(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

"(1) IN GENERAL.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under section 505C, determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following: Effective date.

Deadline.
Certification.

"(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b). Prior to making such a determination, the Secretary may not take more than 30 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate and fund all of the studies in the written request in their entirety within the timeframes specified within the written request. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer all pediatric studies in the written request to the Foundation for the National Institutes of Health for the conduct of such studies, and such Foundation shall fund such studies. If no certification has been made at the end of the 30-day period, or if the Secretary certifies that funds are not sufficient to initiate and fund all the studies in their entirety, the Secretary shall consider whether assessments shall be required under section 505B(b) for such drug.

"(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

"(2) PUBLIC NOTICE.—The Secretary shall give the public notice of a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision.

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

"(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

"(1) GENERAL RULE.—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).

"(2) LABELING.—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

"(A) a statement that, because of marketing exclusivity for a manufacturer—

"(i) the drug is not labeled for pediatric use; or

"(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

"(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.

"(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

"(A) the availability or scope of exclusivity under this section;

"(B) the availability or scope of exclusivity under section 505 for pediatric formulations;

"(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or

"(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.

"(p) INSTITUTE OF MEDICINE STUDY.—Not later than 3 years after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to this section. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to this section in order to conduct such study. Such study shall— Deadline. Contracts. Reports.

"(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c);

"(2) review and assess such representative pediatric studies conducted under subsections (b) and (c) since 1997 and labeling changes made as a result of such studies;

"(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials;

"(4) review and assess the pediatric studies of biological products as required under subsections (a) and (b) of section 505B; and

"(5) make recommendations regarding appropriate incentives for encouraging pediatric studies of biologics.

"(q) SUNSET.—A drug may not receive any 6-month period under subsection (b) or (c) unless—

"(1) on or before October 1, 2012, the Secretary makes a written request for pediatric studies of the drug; Deadline.

"(2) on or before October 1, 2012, an application for the drug is accepted for filing under section 505(b); and Deadline.

"(3) all requirements of this section are met.".

(2) APPLICABILITY.— 21 USC 355a note.

(A) IN GENERAL.—The amendment made by this subsection shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) issued on or after the date of the enactment of this Act.

(B) CERTAIN WRITTEN REQUESTS.—A written request issued under section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, which has been accepted and for which no determination under subsection (d)(2) of such section has been made before such date of enactment, shall be subject to such section 505A, except that such written requests shall be subject to subsections (d)(2)(A)(ii), (e)(1) and (2), (f), (i)(2)(A), (j), (k)(1), (l)(1), and (n) of section 505A of the Federal Food, Drug, and Cosmetic Act, as

in effect on or after the date of the enactment of this Act.

(b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended to read as follows:

"SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

"(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

Deadline. Publication.

"(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every three years.

"(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

"(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

"(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

"(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

"(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

"(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

"(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

"(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

"(ii) there is a submitted application that could be approved under the criteria of such section; and

"(B) there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act; and

"(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

"(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of such Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

"(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

Deadline. Publication.

"(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

"(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(6) REPORTING OF STUDIES.—

"(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

"(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a

docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

"(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

"(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

"(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

"(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

"(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

Federal Register, publication. Website.

"(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

"(8) DISPUTE RESOLUTION.—

"(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—

Deadline.

If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—

Deadline.

Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

"(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

Recommendations.

"(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

Deadline.

"(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

Deadline.

"(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of

Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

"(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

"(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.

Deadline.
Reports.

"(e) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

"(A) $200,000,000 for fiscal year 2008; and

"(B) such sums as are necessary for each of the four succeeding fiscal years.

"(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.".

(c) FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.—Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking "and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)'" and inserting "and studies for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act".

(d) CONTINUATION OF OPERATION OF COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following new subsection:

"(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.".

(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.—Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking "and" after the semicolon;

(ii) in subparagraph (C), by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following new subparagraph:

"(D) provide recommendations to the internal review committee created under section 505B(f) of the Federal Food, Drug, and Cosmetic Act regarding the implementation of amendments to sections 505A and 505B of the

Federal Food, Drug, and Cosmetic Act with respect to the treatment of pediatric cancers."; and

(B) by adding at the end the following new paragraph:

"(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act, the Subcommittee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007."; and

(2) in subsection (d), by striking "2003" and inserting "2009".

(f) EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

(1) IN GENERAL.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the "Administrative Procedure Act") and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products," 69 Fed. Reg. 21778, (April 22, 2004) shall take effect on January 1, 2008, unless such Commissioner issues the final rule before such date.

(2) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule described under subsection (a), shall, notwithstanding section 17(a) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(A) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(C) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

SEC. 503. TRAINING OF PEDIATRIC PHARMACOLOGISTS.

(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g–10(2)) is amended by adding before the period at the end the following: ", including pediatric pharmacological research".

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288–6(a)(1)) is amended by inserting "including pediatric pharmacological research," after "pediatric research,".

TITLE VI—REAGAN-UDALL FOUNDATION

SEC. 601. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

"SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION. 21 USC 379dd.

"(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the 'Foundation') shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

"(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

"(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

"(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including post-approval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

"(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

"(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

"(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2); Grants. Contracts. Memorandums.

"(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

"(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2); Publication.

"(7) ensure that—

"(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

"(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

"(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

"(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

"(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

"(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

"(d) BOARD OF DIRECTORS.—

"(1) ESTABLISHMENT.—

"(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

"(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

"(i) The Commissioner.

"(ii) The Director of the National Institutes of Health.

"(iii) The Director of the Centers for Disease Control and Prevention.

"(iv) The Director of the Agency for Healthcare Research and Quality.

"(C) APPOINTED MEMBERS.—

"(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of such appointed members—

"(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

"(II) 3 shall be representatives of academic research organizations;

"(III) 2 shall be representatives of patient or consumer advocacy organizations;

"(IV) 1 shall be a representative of health care providers; and

"(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

"(ii) REQUIREMENTS.—

"(I) EXPERTISE.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

"(II) FEDERAL EMPLOYEES.—No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B).

"(D) INITIAL MEETING.—

"(i) IN GENERAL.—Not later than 30 days after the date of the enactment of this subchapter, the Secretary shall convene a meeting of the ex officio members of the Board to— Deadline.

"(I) incorporate the Foundation; and

"(II) appoint the members of the Board in accordance with subparagraph (C).

"(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II)—

"(I) the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate; and

"(II) the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.

"(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

"(2) DUTIES OF BOARD.—The Board shall—

"(A) establish bylaws for the Foundation that—

"(i) are published in the Federal Register and available for public comment; Federal Register, publication.

"(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

"(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

"(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

"(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

"(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

"(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

"(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

"(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

"(x) specify a process for annual Board review of the operations of the Foundation; and

"(xi) establish specific duties of the Executive Director;

"(B) prioritize and provide overall direction to the activities of the Foundation;

"(C) evaluate the performance of the Executive Director; and

"(D) carry out any other necessary activities regarding the functioning of the Foundation.

"(3) TERMS AND VACANCIES.—

"(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

"(B) VACANCY.—Any vacancy in the membership of the Board—

"(i) shall not affect the power of the remaining members to execute the duties of the Board; and

"(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

"(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill

the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

"(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

"(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

"(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

"(f) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (g), as may be necessary to ensure that the Foundation maintains status as an organization that—

"(1) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

"(2) is, under subsection (a) of such section, exempt from taxation.

"(g) EXECUTIVE DIRECTOR.—

"(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

"(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

"(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

"(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

"(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

"(3) prescribe the manner in which—

"(A) real or personal property of the Foundation is acquired, held, and transferred;

"(B) general operations of the Foundation are to be conducted; and

"(C) the privileges granted to the Board by law are exercised and enjoyed;

"(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

"(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

"(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

"(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

"(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

"(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

"(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

"(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

"(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

"(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

"(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

"(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

"(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

"(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

"(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

"(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

"(l) ANNUAL REPORTS.—

"(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

"(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

"(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

"(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

"(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

"(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury are held in separate accounts from funds received from entities under subsection (i).

"(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).".

(b) OTHER FOUNDATION PROVISIONS.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by subsection (a)) is amended by adding at the end the following:

"SEC. 771. LOCATION OF FOUNDATION. 21 USC 379dd–1.

"The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

"SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION. 21 USC 379dd–2.

"(a) IN GENERAL.—The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 770(l)(2).

"(b) REPORT TO CONGRESS.—Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 770(l)(2) and by other recipients of grants, contracts, memoranda of understanding, or cooperative agreements into regulatory and product review activities of the Food and Drug Administration.

"(c) EXTRAMURAL GRANTS.—The provisions of this subchapter and section 566 shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after the date of the enactment of this subchapter.".

(c) CONFORMING AMENDMENT.—Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) is amended by adding at the end the following: "Any such fellowships and training programs under this section or under section 770(d)(2)(A)(ix) may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.".

SEC. 602. OFFICE OF THE CHIEF SCIENTIST.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

21 USC 399a.

"SEC. 910. OFFICE OF THE CHIEF SCIENTIST.

"(a) ESTABLISHMENT; APPOINTMENT.—The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

"(b) DUTIES OF THE OFFICE.—The Office of the Chief Scientist shall—

"(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

"(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

"(3) develop and advocate for a budget to support intramural research;

"(4) develop a peer review process by which intramural research can be evaluated;

"(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

"(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

"(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health; and

"(6) develop postmarket safety performance measures that are as measurable and rigorous as the ones already developed for premarket review.".

SEC. 603. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

21 USC 360bbb–5.

"SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

"(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

"(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means an entity that meets each of the following:

"(1) The entity is—

"(A) an institution of higher education (as such term is defined in section 101 of the Higher Education Act of 1965) or a consortium of such institutions; or

"(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

"(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

"(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

"(A) developing and critically evaluating tools, methods, and processes—

"(i) to increase efficiency, predictability, and productivity of medical product development; and

"(ii) to more accurately identify the benefits and risks of new and existing medical products;

"(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

"(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and non-federal governmental sources, foundations, and private individuals.

"(c) FUNDING.—The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

"(d) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

"(1) reviewing the operations and activities of the Partnerships in the previous year; and

"(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

"(e) DEFINITION.—In this section, the term 'medical product' includes a drug, a biological product as defined in section 351 of the Public Health Service Act, a device, and any combination of such products.

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal

year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.".

TITLE VII—CONFLICTS OF INTEREST

SEC. 701. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

21 USC 379d–1.

"SEC. 712. CONFLICTS OF INTEREST.

"(a) DEFINITIONS.—For purposes of this section:

"(1) ADVISORY COMMITTEE.—The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

"(2) FINANCIAL INTEREST.—The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

"(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

"(1) RECRUITMENT.—

"(A) IN GENERAL.—The Secretary shall—

"(i) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

"(ii) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities; and

"(iii) take into account the advisory committees with the greatest number of vacancies.

"(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

"(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

"(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

"(iii) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

"(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration

for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(2) of this section for service on the committee at a meeting of the committee.

"(c) DISCLOSURES; PROHIBITIONS ON PARTICIPATION; WAIVERS.—

"(1) DISCLOSURE OF FINANCIAL INTEREST.—Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

"(2) PROHIBITIONS AND WAIVERS ON PARTICIPATION.—

"(A) IN GENERAL.—Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

"(B) WAIVER.—If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to—

"(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

"(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.

"(C) LIMITATION ON WAIVERS AND OTHER EXCEPTIONS.—

"(i) DEFINITION.—For purposes of this subparagraph, the term 'exception' means each of the following with respect to members of advisory committees:

"(I) A waiver under section 505(n)(4) (as in effect on the day before the date of the enactment of the Food and Drug Administration Amendments Act of 2007).

"(II) A written determination under section 208(b) of title 18, United States Code.

"(III) A written certification under section 208(b)(3) of such title.

"(ii) DETERMINATION OF TOTAL NUMBER OF MEMBERS SLOTS AND MEMBER EXCEPTIONS DURING FISCAL YEAR 2007.—The Secretary shall determine—

"(I)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who participated in the meeting; and

"(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the "total number of 2007 meeting slots"); and

"(II)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who received an exception for the meeting; and

"(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the "total number of 2007 meeting exceptions").

"(iii) DETERMINATION OF PERCENTAGE REGARDING EXCEPTIONS DURING FISCAL YEAR 2007.—The Secretary shall determine the percentage constituted by—

"(I) the total number of 2007 meeting exceptions; divided by

"(II) the total number of 2007 meeting slots.

"(iv) LIMITATION FOR FISCAL YEARS 2008 THROUGH 2012.—The number of exceptions at the Food and Drug Administration for members of advisory committees for a fiscal year may not exceed the following:

"(I) For fiscal year 2008, 95 percent of the percentage determined under clause (iii) (referred to in this clause as the "base percentage").

"(II) For fiscal year 2009, 90 percent of the base percentage.

"(III) For fiscal year 2010, 85 percent of the base percentage.

"(IV) For fiscal year 2011, 80 percent of the base percentage.

"(V) For fiscal year 2012, 75 percent of the base percentage.

"(v) ALLOCATION OF EXCEPTIONS.—The exceptions authorized under clause (iv) for a fiscal year may be allocated within the centers or other organizational units of the Food and Drug Administration as determined appropriate by the Secretary.

Applicability.
Website.

"(3) DISCLOSURE OF WAIVER.—Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

"(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but (except as provided in subparagraph (B)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Web site of the Food and Drug Administration—

"(i) the type, nature, and magnitude of the financial interests of the advisory committee member to

which such determination, certification, or waiver applies; and

"(ii) the reasons of the Secretary for such determination, certification, or waiver.

"(B) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet Web site of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

"(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(3) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

"(e) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes—

"(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

"(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

"(3) with respect to such year, the number of times the disclosures required under subsection (c)(3) occurred under subparagraph (B) of such subsection; and

"(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

"(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.".

(b) CONFORMING AMENDMENTS.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

21 USC 355 note.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.

TITLE VIII—CLINICAL TRIAL DATABASES

SEC. 801. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by—

(1) redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) inserting after subsection (i) the following:

"(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

"(1) DEFINITIONS; REQUIREMENT.—

"(A) DEFINITIONS.—In this subsection:

"(i) APPLICABLE CLINICAL TRIAL.—The term 'applicable clinical trial' means an applicable device clinical trial or an applicable drug clinical trial.

"(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The term 'applicable device clinical trial' means—

"(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

"(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

"(iii) APPLICABLE DRUG CLINICAL TRIAL.—

"(I) IN GENERAL.—The term 'applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

"(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term 'clinical investigation' has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

"(III) PHASE I.—For purposes of subclause (I), the term 'phase I' has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

"(iv) CLINICAL TRIAL INFORMATION.—The term 'clinical trial information' means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

"(v) COMPLETION DATE.—The term 'completion date' means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

"(vi) DEVICE.—The term 'device' means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

"(vii) DRUG.—The term 'drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

"(viii) ONGOING.—The term 'ongoing' means, with respect to a clinical trial of a drug or a device and to a date, that—

"(I) 1 or more patients is enrolled in the clinical trial; and

"(II) the date is before the completion date of the clinical trial.

"(ix) RESPONSIBLE PARTY.—The term 'responsible party', with respect to a clinical trial of a drug or device, means—

"(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

"(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

"(B) REQUIREMENT.—The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

"(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

"(A) IN GENERAL.—

"(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the 'registry data bank'). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

Public information. Internet.

"(ii) CONTENT.—The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

"(I) descriptive information, including—

"(aa) a brief title, intended for the lay public;

"(bb) a brief summary, intended for the lay public;

"(cc) the primary purpose;

"(dd) the study design;

"(ee) for an applicable drug clinical trial, the study phase;

"(ff) study type;

"(gg) the primary disease or condition being studied, or the focus of the study;

"(hh) the intervention name and intervention type;

"(ii) the study start date;

"(jj) the expected completion date;

"(kk) the target number of subjects; and

"(ll) outcomes, including primary and secondary outcome measures;

"(II) recruitment information, including—

"(aa) eligibility criteria;

"(bb) gender;

"(cc) age limits;

"(dd) whether the trial accepts healthy volunteers;

"(ee) overall recruitment status;

"(ff) individual site status; and

"(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

"(III) location and contact information, including—

"(aa) the name of the sponsor;

"(bb) the responsible party, by official title; and

"(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

"(IV) administrative data (which the Secretary may make publicly available as necessary), including—

"(aa) the unique protocol identification number;

"(bb) other protocol identification numbers, if any; and

"(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

"(iii) MODIFICATIONS.—The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

"(B) FORMAT AND STRUCTURE.—

"(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

"(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

"(II) The name of the intervention, including any drug or device being studied in the clinical trial.

"(III) The location of the clinical trial.

"(IV) The age group studied in the clinical trial, including pediatric subpopulations.

"(V) The study phase of the clinical trial.

"(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

"(VII) The recruitment status of the clinical trial.

"(VIII) The National Clinical Trial number or other study identification for the clinical trial.

"(ii) ADDITIONAL SEARCHABLE CATEGORY.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome. Deadline.

"(iii) OTHER ELEMENTS.—The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

"(iv) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

"(C) DATA SUBMISSION.—The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of— Deadlines.

"(i) 90 days after such date of enactment;

"(ii) 21 days after the first patient is enrolled in such clinical trial; or

"(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment.

Deadlines.

"(D) POSTING OF DATA.—

"(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

"(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

"(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date; or

"(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

"(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

"(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

Deadlines.

"(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

"(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

"(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

"(ii) REQUIRED INFORMATION.—

"(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

"(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

"(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act,

a link to the posted Food and Drug Administration assessment of the results of such trial.

"(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

"(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

"(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

"(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

"(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

"(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

"(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Food and Drug Administration Amendments Act of 2007, as available.

"(B) INCLUSION OF RESULTS.—The Secretary, acting through the Director of NIH, shall—

"(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the 'registry and results data bank');

"(ii) ensure that such results are made publicly available through the Internet;

Public information. Internet.

"(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

"(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

"(C) BASIC RESULTS.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall include in

Deadline.

the registry and results data bank the following elements for drugs that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act and devices that are cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act:

"(i) DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE.—A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

"(ii) PRIMARY AND SECONDARY OUTCOMES.—The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

"(iii) POINT OF CONTACT.—A point of contact for scientific information about the clinical trial results.

"(iv) CERTAIN AGREEMENTS.—Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

"(D) EXPANDED REGISTRY AND RESULTS DATA BANK.—

Deadline.

"(i) EXPANSION BY RULEMAKING.—To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

"(ii) CLINICAL TRIALS.—

"(I) APPROVED PRODUCTS.—The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

"(aa) each applicable drug clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

"(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

"(II) UNAPPROVED PRODUCTS.—The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

"(aa) an applicable drug clinical trial for a drug that is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

"(bb) an applicable device clinical trial for a device that is not cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

"(iii) REQUIRED ELEMENTS.—The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

"(I) A summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

"(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

"(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

"(IV) Such other categories as the Secretary determines appropriate.

"(iv) RESULTS SUBMISSION.—The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine— Regulations.

"(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

"(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

"(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

"(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

"(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

"(v) ADDITIONAL PROVISIONS.—The regulations under this subparagraph shall also establish—

"(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

"(II) additional information on clinical trials and results that is written in nontechnical, understandable language for patients;

Procedures.

"(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are non-promotional;

"(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

"(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

"(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

"(vi) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

Deadline.

"(vii) PUBLIC MEETING.—The Secretary shall hold a public meeting no later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

"(E) SUBMISSION OF RESULTS INFORMATION.—

Deadline.

"(i) IN GENERAL.—Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

"(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); or

"(II) the actual date of completion.

"(ii) CLINICAL TRIALS DESCRIBED.—An applicable clinical trial described in this clause is an applicable clinical trial subject to—

"(I) paragraph (2)(C); and

"(II)(aa) subparagraph (C); or

"(bb) the regulations issued under subparagraph (D).

"(iii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

"(iv) SEEKING INITIAL APPROVAL OF A DRUG OR DEVICE.—With respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m), as applicable. Deadline.

"(v) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

"(I) IN GENERAL.—With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date— Deadlines.

"(aa) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such

section 510(k), or approved under such section 515 or 520(m);

"(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), 515, or 520(m); or

"(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(m) is withdrawn without resubmission for no less than 210 days.

"(II) REQUIREMENT THAT EACH CLINICAL TRIAL IN APPLICATION BE TREATED THE SAME.—If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable) of the use studied in the clinical trial.

"(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

"(vi) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

Deadline.

"(F) NOTICE TO DIRECTOR OF NIH.—The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

Public information. Deadline.

"(G) POSTING OF DATA.—The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

"(H) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

Deadline.
Notification.

"(I) ADVERSE EVENTS.—

"(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for drugs described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

Deadline.

"(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

Effective date.

"(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for drugs described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

"(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

"(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

"(iv) POSTING OF OTHER INFORMATION.—In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

"(v) RELATION TO SUBPARAGRAPH (C).—Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

"(4) ADDITIONAL SUBMISSIONS OF CLINICAL TRIAL INFORMATION.—

"(A) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

"(B) REQUIRED SUBMISSIONS.—

"(i) IN GENERAL.—Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

"(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

Deadline.

"(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

"(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

"(ii) CLINICAL TRIALS DESCRIBED.—A clinical trial described in this clause is—

"(I) an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

"(II) an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)).

"(C) UPDATES TO CLINICAL TRIAL DATA BANK.—

Deadlines.

"(i) SUBMISSION OF UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

"(I) shall be provided not less than once every 12 months, unless there were no changes to the

clinical trial information during the preceding 12-month period;

"(II) shall include identification of the dates of any such changes;

"(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

"(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

"(ii) PUBLIC AVAILABILITY OF UPDATES.—The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

"(5) COORDINATION AND COMPLIANCE.—

"(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

"(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.— If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3). Certification.

"(ii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

"(iii) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days Deadline.

to correct such non-compliance and submit the required clinical trial information.

"(iv) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

"(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

Procedures.

"(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

"(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

"(C) QUALITY CONTROL.—

"(i) PILOT QUALITY CONTROL PROJECT.—Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

Deadline.

"(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such non-compliance by submitting the required revised clinical trial information not later than 30 days after such notification.

"(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

"(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

"(ii) EFFECT.—Clause (i) shall not have the effect of—

"(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

"(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

"(E) PUBLIC NOTICES.—

"(i) NOTICE OF VIOLATIONS.—If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

"(I) that the responsible party is not in compliance with this Act by—

"(aa) failing to submit required clinical trial information; or

"(bb) submitting false or misleading clinical trial information;

"(II) of the penalties imposed for the violation, if any; and

"(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

"(ii) NOTICE OF FAILURE TO SUBMIT PRIMARY AND SECONDARY OUTCOMES.—If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this act, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

"(iii) FAILURE TO SUBMIT STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: 'The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.'.

"(iv) SUBMISSION OF FALSE INFORMATION STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: 'The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.'.

"(v) NON-SUBMISSION OF STATEMENT.—The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: 'The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not

have any bearing on the accuracy of the information in the entry.'.

"(vi) COMPLIANCE SEARCHES.—The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

"(6) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

"(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

"(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

"(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

"(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

"(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.".

(b) CONFORMING AMENDMENTS.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

"(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

"(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).".

(2) CIVIL MONEY PENALTIES.—Subsection (f) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as redesignated by section 226, is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (5), (6), and (7), respectively;

(B) by inserting after paragraph (2) the following:

Penalties.

"(3)(A) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

Deadline.

"(B) If a violation of section 301(jj) is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii), the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.";

(C) in paragraph (2)(C), by striking "paragraph (3)(A)" and inserting "paragraph (5)(A)";

(D) in paragraph (5), as so redesignated, by striking "paragraph (1) or (2)" each place it appears and inserting "paragraph (1), (2), or (3)";

(E) in paragraph (6), as so redesignated, by striking "paragraph (3)(A)" and inserting "paragraph (5)(A)"; and

(F) in paragraph (7), as so redesignated, by striking "paragraph (4)" each place it appears and inserting "paragraph (6)".

(3) NEW DRUGS AND DEVICES.— Certification.

(A) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: "The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.". Regulations.

(B) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

"(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.".

(C) DEVICE REPORTS UNDER SECTION 510(k).—Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended by adding at the end the following:

"A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(5)(B) of such Act. Such certification shall not be considered an element of such notification.".

(D) DEVICE PREMARKET APPROVAL APPLICATION.—Section 515(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(1)) is amended—

(i) in subparagraph (F), by striking "; and" and inserting a semicolon;

(ii) by redesignating subparagraph (G) as subparagraph (H); and

(iii) by inserting after subparagraph (F) the following:

"(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); and".

(E) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period "and such application shall include the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application)". 21 USC 360j.

(c) SURVEILLANCES.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Deadline. Guidance. 42 USC 282 note.

Services shall issue guidance on how the requirements of section 402(j) of the Public Health Service Act, as added by this section, apply to a pediatric postmarket surveillance described in paragraph (1)(A)(ii)(II) of such section 402(j) that is not a clinical trial.

42 USC 282 note.

(d) PREEMPTION.—

(1) IN GENERAL.—Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act, as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with subsection (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the registry and results data bank under such subsection (j), if submitted in compliance with such subsection, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

Subtitle A—Postmarket Studies and Surveillance

SEC. 901. POSTMARKET STUDIES AND CLINICAL TRIALS REGARDING HUMAN DRUGS; RISK EVALUATION AND MITIGATION STRATEGIES.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following subsections:

"(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

"(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

"(2) DEFINITIONS.—For purposes of this subsection:

"(A) RESPONSIBLE PERSON.—The term 'responsible person' means a person who—

"(i) has submitted to the Secretary a covered application that is pending; or

"(ii) is the holder of an approved covered application.

"(B) COVERED APPLICATION.—The term 'covered application' means—

"(i) an application under subsection (b) for a drug that is subject to section 503(b); and

"(ii) an application under section 351 of the Public Health Service Act.

"(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms 'new safety information', 'serious risk', and 'signal of a serious risk' have the meanings given such terms in section 505–1(b).

"(3) STUDIES AND CLINICAL TRIALS.—

"(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

"(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

"(i) To assess a known serious risk related to the use of the drug involved.

"(ii) To assess signals of serious risk related to the use of the drug.

"(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

"(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

"(D) DETERMINATION BY SECRETARY.—

"(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

"(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

"(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

"(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this

paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

"(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

"(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

Deadlines.

"(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

Notification.

"(A) NEW SAFETY INFORMATION.—If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

"(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

"(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information,

including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions; or

"(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

Notification.

"(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.

"(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

"(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

"(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

"(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

"(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

"(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201

and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

"(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

"(p) RISK EVALUATION AND MITIGATION STRATEGY.—

"(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

"(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

"(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

"(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

"(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).".

(b) REQUIREMENTS REGARDING STRATEGIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following section:

21 USC 355–1.

"SEC. 505–1. RISK EVALUATION AND MITIGATION STRATEGIES.

"(a) SUBMISSION OF PROPOSED STRATEGY.—

"(1) INITIAL APPROVAL.—If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

"(A) The estimated size of the population likely to use the drug involved.

"(B) The seriousness of the disease or condition that is to be treated with the drug.

"(C) The expected benefit of the drug with respect to such disease or condition.

"(D) The expected or actual duration of treatment with the drug.

"(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

"(F) Whether the drug is a new molecular entity.

"(2) POSTAPPROVAL REQUIREMENT.—

"(A) IN GENERAL.—If the Secretary has approved a covered application (including an application approved before the effective date of this section) and did not when approving the application require a risk evaluation and mitigation strategy under paragraph (1), the Secretary, in consultation with the offices described in paragraph (1), may subsequently require such a strategy for the drug involved (including when acting on a supplemental application seeking approval of a new indication for use of the drug) if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

"(B) SUBMISSION OF PROPOSED STRATEGY.—Not later than 120 days after the Secretary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other reasonable time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Deadline. Notification.

"(3) ABBREVIATED NEW DRUG APPLICATIONS.—The applicability of this section to an application under section 505(j) is subject to subsection (i). Applicability.

"(4) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

"(b) DEFINITIONS.—For purposes of this section:

"(1) ADVERSE DRUG EXPERIENCE.—The term 'adverse drug experience' means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

"(A) an adverse event occurring in the course of the use of the drug in professional practice;

"(B) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

"(C) an adverse event occurring from abuse of the drug;

"(D) an adverse event occurring from withdrawal of the drug; and

"(E) any failure of expected pharmacological action of the drug.

"(2) COVERED APPLICATION.—The term 'covered application' means an application referred to in section 505(p)(1)(A).

"(3) NEW SAFETY INFORMATION.—The term 'new safety information', with respect to a drug, means information derived from a clinical trial, an adverse event report, a postapproval study (including a study under section 505(o)(3)), or peer-reviewed biomedical literature; data derived from the postmarket risk identification and analysis system under section 505(k); or other scientific data deemed appropriate by the Secretary about—

"(A) a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of (that may be based on a new analysis of existing

information) since the drug was approved, since the risk evaluation and mitigation strategy was required, or since the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

"(B) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the last assessment of such strategy.

"(4) SERIOUS ADVERSE DRUG EXPERIENCE.—The term 'serious adverse drug experience' is an adverse drug experience that—

"(A) results in—

"(i) death;

"(ii) an adverse drug experience that places the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

"(iii) inpatient hospitalization or prolongation of existing hospitalization;

"(iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

"(v) a congenital anomaly or birth defect; or

"(B) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A).

"(5) SERIOUS RISK.—The term 'serious risk' means a risk of a serious adverse drug experience.

"(6) SIGNAL OF A SERIOUS RISK.—The term 'signal of a serious risk' means information related to a serious adverse drug experience associated with use of a drug and derived from—

"(A) a clinical trial;

"(B) adverse event reports;

"(C) a postapproval study, including a study under section 505(o)(3);

"(D) peer-reviewed biomedical literature;

"(E) data derived from the postmarket risk identification and analysis system under section 505(k)(4); or

"(F) other scientific data deemed appropriate by the Secretary.

"(7) RESPONSIBLE PERSON.—The term 'responsible person' means the person submitting a covered application or the holder of the approved such application.

"(8) UNEXPECTED SERIOUS RISK.—The term 'unexpected serious risk' means a serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically and pathophysiologically related to an adverse drug experience identified in the labeling, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

"(c) CONTENTS.—A proposed risk evaluation and mitigation strategy under subsection (a) shall—

"(1) include the timetable required under subsection (d); and

"(2) to the extent required by the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, include additional elements described in subsections (e) and (f).

"(d) MINIMAL STRATEGY.—For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy that— Deadlines.

"(1) includes an assessment, by the date that is 18 months after the strategy is initially approved;

"(2) includes an assessment by the date that is 3 years after the strategy is initially approved;

"(3) includes an assessment in the seventh year after the strategy is so approved; and

"(4) subject to paragraphs (1), (2), and (3)—

"(A) is at a frequency specified in the strategy;

"(B) is increased or reduced in frequency as necessary as provided for in subsection (g)(4)(A); and

"(C) is eliminated after the 3-year period described in paragraph (1) if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

"(e) ADDITIONAL POTENTIAL ELEMENTS OF STRATEGY.—

"(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), may under such subsection require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to each element involved.

"(2) MEDICATION GUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that, as applicable, the responsible person develop for distribution to each patient when the drug is dispensed—

"(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

"(B) a patient package insert, if the Secretary determines that such insert may help mitigate a serious risk of the drug.

"(3) COMMUNICATION PLAN.—The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy (including under this paragraph). Such plan may include—

"(A) sending letters to health care providers;

"(B) disseminating information about the elements of the risk evaluation and mitigation strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests); or

"(C) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use.

"(f) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

"(1) ALLOWING SAFE ACCESS TO DRUGS WITH KNOWN SERIOUS RISKS.—The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

"(A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

"(B) for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

"(2) ASSURING ACCESS AND MINIMIZING BURDEN.—Such elements to assure safe use under paragraph (1) shall—

"(A) be commensurate with the specific serious risk listed in the labeling of the drug;

Deadline.

"(B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

"(C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

"(i) patients with serious or life-threatening diseases or conditions; and

"(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

"(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

"(i) conform with elements to assure safe use for other drugs with similar, serious risks; and

"(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

"(3) ELEMENTS TO ASSURE SAFE USE.—The elements to assure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

"(A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);

"(B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);

"(C) the drug be dispensed to patients only in certain health care settings, such as hospitals;

"(D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

"(E) each patient using the drug be subject to certain monitoring; or

"(F) each patient using the drug be enrolled in a registry.

"(4) IMPLEMENTATION SYSTEM.—The elements to assure safe use under paragraph (1) that are described in subparagraphs (B), (C), and (D) of paragraph (3) may include a system through which the applicant is able to take reasonable steps to—

"(A) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

"(B) work to improve implementation of such elements by such persons.

"(5) EVALUATION OF ELEMENTS TO ASSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration, shall—

"(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be—

"(i) unduly burdensome on patient access to the drug; and

"(ii) to the extent practicable, minimize the burden on the health care delivery system;

"(B) at least annually, evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

"(i) assure safe use of the drug;

"(ii) are not unduly burdensome on patient access to the drug; and

"(iii) to the extent practicable, minimize the burden on the health care delivery system; and

"(C) considering such input and evaluations—

"(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

"(ii) modify elements under this subsection for 1 or more drugs as appropriate.

"(6) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this subsection. The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561. Regulations.

"(7) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this subsection during the period described in section 319(a) of the Public Health Service Act with respect to a qualified countermeasure described under section 319F–1(a)(2) of such Act, to which a requirement under this subsection has been applied, if the Secretary has—

"(A) declared a public health emergency under such section 319; and

"(B) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

"(8) LIMITATION.—No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.

"(g) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—

"(1) VOLUNTARY ASSESSMENTS.—After the approval of a risk evaluation and mitigation strategy under subsection (a), the responsible person involved may, subject to paragraph (2), submit to the Secretary an assessment of, and propose a modification to, the approved strategy for the drug involved at any time.

"(2) REQUIRED ASSESSMENTS.—A responsible person shall, subject to paragraph (5), submit an assessment of, and may propose a modification to, the approved risk evaluation and mitigation strategy for a drug—

"(A) when submitting a supplemental application for a new indication for use under section 505(b) or under section 351 of the Public Health Service Act, unless the drug is not subject to section 503(b) and the risk evaluation and mitigation strategy for the drug includes only the timetable under subsection (d);

"(B) when required by the strategy, as provided for in such timetable under subsection (d);

"(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that new safety or effectiveness information indicates that—

"(i) an element under subsection (d) or (e) should be modified or included in the strategy; or

"(ii) an element under subsection (f) should be modified or included in the strategy; or

Deadline.

"(D) within 15 days when ordered by the Secretary, in consultation with the offices described in subsection (c)(2), if the Secretary determines that there may be a cause for action by the Secretary under section 505(e).

"(3) REQUIREMENTS FOR ASSESSMENTS.—An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include—

"(A) with respect to any goal under subsection (f), an assessment of the extent to which the elements to assure safe use are meeting the goal or whether the goal or such elements should be modified;

"(B) with respect to any postapproval study required under section 505(o) or otherwise undertaken by the responsible person to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered; and

"(C) with respect to any postapproval clinical trial required under section 505(o) or otherwise undertaken by the responsible party to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act.

"(4) MODIFICATION.—A modification (whether an enhancement or a reduction) to the approved risk evaluation and mitigation strategy for a drug may include the addition or modification of any element under subsection (d) or the addition, modification, or removal of any element under subsection (e) or (f), such as—

"(A) modifying the timetable for assessments of the strategy as provided in subsection (d)(3), including to eliminate assessments; or

"(B) adding, modifying, or removing an element to assure safe use under subsection (f).

"(h) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS OF APPROVED STRATEGIES.—

"(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), shall promptly review each proposed risk evaluation and mitigation strategy for a drug submitted under subsection (a) and each assessment of an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g).

"(2) DISCUSSION.—The Secretary, in consultation with the offices described in subsection (c)(2), shall initiate discussions with the responsible person for purposes of this subsection to determine a strategy not later than 60 days after any such assessment is submitted or, in the case of an assessment submitted under subsection (g)(2)(D), not later than 30 days after such assessment is submitted. Deadlines.

"(3) ACTION.—

"(A) IN GENERAL.—Unless the dispute resolution process described under paragraph (4) or (5) applies, the Secretary, in consultation with the offices described in subsection (c)(2), shall describe any required risk evaluation and mitigation strategy for a drug, or any modification to any required strategy—

"(i) as part of the action letter on the application, when a proposed strategy is submitted under subsection (a) or a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1); or

"(ii) in an order issued not later than 90 days after the date discussions of such modification begin under paragraph (2), when a modification to the strategy is proposed as part of an assessment of the Deadline.

strategy submitted under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2).

"(B) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under subparagraph (A).

"(C) PUBLIC AVAILABILITY.—Any action letter described in subparagraph (A)(i) or order described in subparagraph (A)(ii) shall be made publicly available.

"(4) DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subsection (a)(1) in an application for initial approval of a drug and there is a dispute about the strategy, the responsible person shall use the major dispute resolution procedures as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

"(5) DISPUTE RESOLUTION IN ALL OTHER CASES.—

Deadlines.

"(A) REQUEST FOR REVIEW.—

"(i) IN GENERAL.—Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the responsible person may request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board under subsection (j), except that the determination of the Secretary to require a risk evaluation and mitigation strategy is not subject to review under this paragraph. The preceding sentence does not prohibit review under this paragraph of the particular elements of such a strategy.

"(ii) SCHEDULING.—Upon receipt of a request under clause (i), the Secretary shall schedule the dispute involved for review under subparagraph (B) and, not later than 5 business days of scheduling the dispute for review, shall publish by posting on the Internet or otherwise a notice that the dispute will be reviewed by the Drug Safety Oversight Board.

"(B) SCHEDULING REVIEW.—If a responsible person requests review under subparagraph (A), the Secretary—

"(i) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

"(ii) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application).

"(C) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

"(i) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under subparagraph (A) shall not preclude further discussions to reach agreement on the risk evaluation and mitigation strategy, and such a request shall not preclude the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including appeals as described in the letters

described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 for procedural or scientific matters involving the review of human drug applications and supplemental applications that cannot be resolved at the divisional level. At the time a review has been scheduled under subparagraph (B) and notice of such review has been posted, the responsible person shall either withdraw the request under subparagraph (A) or terminate the use of such administrative appeals.

"(ii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under subparagraph (G) , the Secretary (in consultation with the offices described in subsection (c)(2)) and the responsible person may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

"(D) MEETING OF THE BOARD.—At a meeting of the Drug Safety Oversight Board described in subparagraph (B), the Board shall—

"(i) hear from both parties via written or oral presentation; and

"(ii) review the dispute.

"(E) RECORD OF PROCEEDINGS.—The Secretary shall ensure that the proceedings of any such meeting are recorded, transcribed, and made public within 90 days of the meeting. The Secretary shall redact the transcript to protect any trade secrets and other information that is exempted from disclosure under section 552 of title 5, United States Code, or section 552a of title 5, United States Code.

Public information. Deadline.

"(F) RECOMMENDATION OF THE BOARD.—Not later than 5 days after any such meeting, the Drug Safety Oversight Board shall provide a written recommendation on resolving the dispute to the Secretary. Not later than 5 days after the Board provides such written recommendation to the Secretary, the Secretary shall make the recommendation available to the public.

Deadlines. Public information.

"(G) ACTION BY THE SECRETARY.—

Deadlines.

"(i) ACTION LETTER.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

"(I) the action deadline for the action letter on the application; or

"(II) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

"(ii) ORDER.—With respect to an assessment of an approved risk evaluation and mitigation strategy under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2), the Secretary shall issue an order, which shall be made public, that resolves the dispute not later than 7 days after

receiving the recommendation of the Drug Safety Oversight Board.

"(H) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under subparagraph (G).

"(I) EFFECT ON ACTION DEADLINE.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall be considered to have met the action deadline for the action letter on the application if the responsible person requests the dispute resolution process described in this paragraph and if the Secretary—

"(i) has initiated the discussions described under paragraph (2) not less than 60 days before such action deadline; and

"(ii) has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under subparagraphs (B), (F), and (G), respectively.

"(J) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who reviews a drug or who participated in an administrative appeal under subparagraph (C)(i) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under subparagraph (D) to review a dispute about the risk evaluation and mitigation strategy for such drug.

"(K) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under subparagraph (D) of the Drug Safety Oversight Board.

"(6) USE OF ADVISORY COMMITTEES.—The Secretary may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

"(A) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under any of subparagraphs (B) through (D) of subsection (g)(2);

"(B) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

"(C) review a dispute under paragraph (4) or (5).

"(7) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

"(A) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary, in consultation with the offices described in subsection (c)(2), may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has convened 1 or more public meetings to consider possible responses to such concern.

"(B) NOTICE.—If the Secretary defers an assessment under subparagraph (A), the Secretary shall—

"(i) give notice of the deferral to the holder of the approved covered application not later than 5 days after the deferral;

Deadline.

"(ii) publish the deferral in the Federal Register; and

Federal Register, publication.

"(iii) give notice to the public of any public meetings to be convened under subparagraph (A), including a description of the deferral.

Public information.

"(C) PUBLIC MEETINGS.—Such public meetings may include—

"(i) 1 or more meetings of the responsible person for such drugs;

"(ii) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under paragraph (6); or

"(iii) 1 or more workshops of scientific experts and other stakeholders.

"(D) ACTION.—After considering the discussions from any meetings under subparagraph (A), the Secretary may—

"(i) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

"(ii) seek public comment about such action; and

"(iii) after seeking such comment, issue an order addressing such regulatory action.

"(8) INTERNATIONAL COORDINATION.—The Secretary, in consultation with the offices described in subsection (c)(2), may coordinate the timetable for submission of assessments under subsection (d), or a study or clinical trial under section 505(o)(3), with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States. If the Secretary takes action to coordinate such timetable, the Secretary shall give notice to the responsible person.

"(9) EFFECT.—Use of the processes described in paragraphs (7) and (8) shall not be the sole source of delay of action on an application or a supplement to an application for a drug.

"(i) ABBREVIATED NEW DRUG APPLICATIONS.—

"(1) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under section 505(j) is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (a) for the applicable listed drug:

"(A) A Medication Guide or patient package insert, if required under subsection (e) for the applicable listed drug.

"(B) Elements to assure safe use, if required under subsection (f) for the listed drug. A drug that is the subject of an abbreviated new drug application and the listed drug shall use a single, shared system under subsection (f). The Secretary may waive the requirement under the preceding sentence for a drug that is the subject of an abbreviated new drug application, and permit the applicant to

use a different, comparable aspect of the elements to assure safe use, if the Secretary determines that—

"(i) the burden of creating a single, shared system outweighs the benefit of a single, system, taking into consideration the impact on health care providers, patients, the applicant for the abbreviated new drug application, and the holder of the reference drug product; or

"(ii) an aspect of the elements to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that, as a trade secret, is entitled to protection, and the applicant for the abbreviated new drug application certifies that it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug and that it was unable to obtain a license.

A certification under clause (ii) shall include a description of the efforts made by the applicant for the abbreviated new drug application to obtain a license. In a case described in clause (ii), the Secretary may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such abbreviated new drug application may use an aspect of the elements to assure safe use, if required under subsection (f) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.

"(2) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under section 505(j), the Secretary—

"(A) shall undertake any communication plan to health care providers required under subsection (e)(3) for the applicable listed drug; and

"(B) shall inform the responsible person for the drug that is so approved if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

Establishment.

"(j) DRUG SAFETY OVERSIGHT BOARD.—

"(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

"(2) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

"(A) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

"(B) include representatives from offices throughout the Food and Drug Administration, including the offices responsible for postapproval safety of drugs;

"(C) include at least 1 representative each from the National Institutes of Health and the Department of Health and Human Services (other than the Food and Drug Administration);

"(D) include such representatives as the Secretary shall designate from other appropriate agencies that wish to provide representatives; and

"(E) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.".

(c) REGULATION OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(2), by adding at the end the following:

"(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act."; and

(2) in subsection (j), by inserting ", including the requirements under sections 505(o), 505(p), and 505–1 of such Act," after ", and Cosmetic Act".

(d) ADVERTISEMENTS OF DRUGS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by section 801(b), is amended—

(1) in section 301 (21 U.S.C. 331), by adding at the end the following:

"(kk) The dissemination of a television advertisement without complying with section 503B."; and

(2) by inserting after section 503A the following:

"SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.

21 USC 353b.

Deadline.

"(a) IN GENERAL.—The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

"(b) REVIEW.—In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

"(1) on changes that are—

"(A) necessary to protect the consumer good and well-being; or

"(B) consistent with prescribing information for the product under review; and

"(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.

"(c) NO AUTHORITY TO REQUIRE CHANGES.—Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

"(d) ELDERLY POPULATIONS, CHILDREN, RACIALLY AND ETHNICALLY DIVERSE COMMUNITIES.—In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

"(e) SPECIFIC DISCLOSURES.—

"(1) SERIOUS RISK; SAFETY PROTOCOL.—In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

"(2) DATE OF APPROVAL.—In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 505 or section 351 of the Public Health Service Act, a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

"(f) RULE OF CONSTRUCTION.—Nothing in this section may be construed as having any effect on requirements under section 502(n) or on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).".

(3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

(A) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by adding at the end the following: "In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.".

Deadline.
21 USC 352 note.

(B) REGULATIONS TO DETERMINE CLEAR, CONSPICUOUS, AND NEUTRAL MANNER.—Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by subparagraph (A)) is presented in the manner required under such section.

(4) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as amended by section 801(b), is amended by adding at the end the following:

"(g)(1) With respect to a person who is a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351 of the Public Health Service Act, any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

Public record. Notification.

"(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

"(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

"(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A.

"(B) Whether the person submitted the advertisement for review if required under section 503B.

"(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

"(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

"(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

"(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

"(G) Whether the violations were material.

"(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

"(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

"(J) The scope and extent of any voluntary, subsequent remedial action by the person.

"(K) Such other matters, as justice may require.

"(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

"(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

"(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed

under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

"(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

Deadline.

"(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

"(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

"(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.".

(5) REPORT ON DIRECT-TO-CONSUMER ADVERTISING.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. The Secretary shall utilize the Advisory Committee on Risk Communication established under this Act to advise the Secretary with respect to such report. The Advisory Committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The report required by this paragraph shall recommend effective ways to present and disseminate information to these populations. Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population. The Secretary of Health and Human Services shall submit the report under this paragraph to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(6) RULEMAKING.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by striking "the procedure specified in section 701(e) of this Act" and inserting "section 701(a)".

21 USC 355a note.

(e) RULE OF CONSTRUCTION REGARDING PEDIATRIC STUDIES.—This title and the amendments made by this title may not be

construed as affecting the authority of the Secretary of Health and Human Services to request pediatric studies under section 505A of the Federal Food, Drug, and Cosmetic Act or to require such studies under section 505B of such Act.

SEC. 902. ENFORCEMENT.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(y) If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the responsible person (as such term is used in section 505–1) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505–1.

"(z) If it is a drug, and the responsible person (as such term is used in section 505(o)) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.".

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act, as amended by section 801(b), is amended—

(1) by inserting after paragraph (3), as added by section 801(b)(2), the following:

"(4)(A) Any responsible person (as such term is used in section 505–1) that violates a requirement of section 505(o), 505(p), or 505–1 shall be subject to a civil monetary penalty of—

"(i) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

"(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

"(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 505(o), 505(p), or 505–1 for which the responsible person is subject to such civil penalty."; and

(2) in paragraph (5), as redesignated by section 801(b)(2)(A), by striking "paragraph (1), (2), or (3)" each place it appears and inserting "paragraph (1), (2), (3), or (4)".

SEC. 903. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: "The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D).".

Deadline.
Reports.

SEC. 904. BENEFIT-RISK ASSESSMENTS.

Not later than 1 year after the date of the enactment of this Act, the Commissioner of Food and Drugs shall submit to the Congress a report on how best to communicate to the public the risks and benefits of new drugs and the role of the risk evaluation and mitigation strategy in assessing such risks and benefits. As part of such study, the Commissioner may consider the possibility of including in the labeling and any direct-to-consumer advertisements of a newly approved drug or indication a unique symbol indicating the newly approved status of the drug or indication for a period after approval.

SEC. 905. ACTIVE POSTMARKET RISK IDENTIFICATION AND ANALYSIS.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

"(A) DEFINITION.—In this paragraph, the term 'data' refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

Deadline.

"(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

"(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

"(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

"(I) at least 25,000,000 patients by July 1, 2010; and

"(II) at least 100,000,000 patients by July 1, 2012; and

Committee.

"(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

"(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

Deadline.
Procedures.

"(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

"(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

"(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

"(III) to provide for active adverse event surveillance using the following data sources, as available:

"(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

"(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

"(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

"(IV) to identify certain trends and patterns with respect to data accessed by the system;

"(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and Reports.

"(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

"(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

"(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities. Deadline.

"(iv) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and

participate in complementary approaches to gather and analyze such data and information, including—

"(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

"(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

"(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

"(4) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

"(A) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

"(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

"(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

"(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

"(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

"(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

"(i) priority drug safety questions; and

"(ii) mechanisms for answering such questions, including through—

"(I) active risk identification under paragraph (3); and

"(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

"(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

Deadline.

"(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

"(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

"(II) allow for prompt investigation of priority drug safety questions, including—

"(aa) unresolved safety questions for drugs or classes of drugs; and

"(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

"(III) perform advanced research and analysis on identified drug safety risks;

"(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

"(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

"(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

"(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

"(F) QUALIFIED ENTITIES.— Contracts.

"(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

"(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

"(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

"(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

"(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

"(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

"(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

"(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

"(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

"(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

"(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

"(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

"(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

"(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

"(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

Applicability.

"(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

"(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

"(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

"(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

"(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract

with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

"(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.".

21 USC 355 note.

(b) RULE OF CONSTRUCTION.—Nothing in this section or the amendment made by this section shall be construed to prohibit the lawful disclosure or use of data or information by an entity other than as described in paragraph (4)(B) or (4)(G) of section 505(k) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) REPORT TO CONGRESS.—Not later than 4 years after the date of the enactment of this Act, the Secretary shall report to the Congress on the ways in which the Secretary has used the active postmarket risk identification and analysis system described in paragraphs (3) and (4) of section 505(k) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), to identify specific drug safety signals and to better understand the outcomes associated with drugs marketed in the United States.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by this section for which funds are made available under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), there are authorized to be appropriated to carry out the amendment made by this section, in addition to such funds, $25,000,000 for each of fiscal years 2008 through 2012.

(e) GAO REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall evaluate data privacy, confidentiality, and security issues relating to accessing, transmitting, and maintaining data for the active postmarket risk identification and analysis system described in paragraphs (3) and (4) of section 505(k) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and make recommendations to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, and any other congressional committees of relevant jurisdiction, regarding the need for any additional legislative or regulatory actions to ensure privacy, confidentiality, and security of this data or otherwise address privacy, confidentiality, and security issues to ensure the effective operation of such active postmarket identification and analysis system.

SEC. 906. STATEMENT FOR INCLUSION IN DIRECT-TO-CONSUMER ADVERTISEMENTS OF DRUGS.

(a) PUBLISHED DIRECT-TO-CONSUMER ADVERTISEMENTS.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 901(d)(6), is further amended by inserting "and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: 'You are encouraged to report negative side effects of prescription

drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.'," after "section 701(a),".

21 USC 352 note.

Deadline.

(b) STUDY.—

(1) IN GENERAL.—In the case of direct-to-consumer television advertisements, the Secretary of Health and Human Services, in consultation with the Advisory Committee on Risk Communication under section 567 of the Federal Food, Drug, and Cosmetic Act (as added by section 917), shall, not later than 6 months after the date of the enactment of this Act, conduct a study to determine if the statement in section 502(n) of such Act (as added by subsection (a)) required with respect to published direct-to-consumer advertisements is appropriate for inclusion in such television advertisements.

(2) CONTENT.—As part of the study under paragraph (1), such Secretary shall consider whether the information in the statement described in paragraph (1) would detract from the presentation of risk information in a direct-to-consumer television advertisement. If such Secretary determines the inclusion of such statement is appropriate in direct-to-consumer television advertisements, such Secretary shall issue regulations requiring the implementation of such statement in direct-to-consumer television advertisements, including determining a reasonable length of time for displaying the statement in such advertisements. The Secretary shall report to the appropriate committees of Congress the findings of such study and any plans to issue regulations under this paragraph.

Reports.

21 USC 355 note.

SEC. 907. NO EFFECT ON VETERINARY MEDICINE.

This subtitle, and the amendments made by this subtitle, shall have no effect on the use of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as provided for under section 512(a)(5) of such Act.

SEC. 908. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For carrying out this subtitle and the amendments made by this subtitle, there is authorized to be appropriated $25,000,000 for each of fiscal years 2008 through 2012.

(b) RELATION TO OTHER FUNDING.—The authorization of appropriations under subsection (a) is in addition to any other funds available for carrying out this subtitle and the amendments made by this subtitle.

21 USC 331 note.

SEC. 909. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATE.—This subtitle takes effect 180 days after the date of the enactment of this Act.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this Act is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (as added by section 901) (referred to in this section as the "Act") if there are in effect on the effective date of this Act elements to assure safe use—

(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) ELEMENTS OF STRATEGY; ENFORCEMENT.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

(A) is deemed to consist of the timetable required under section 505–1(d) and any additional elements under subsections (e) and (f) of such section in effect for such drug on the effective date of this Act; and

(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505–1 of the Act, except that sections 303(f)(4) and 502(y) and (z) of the Act (as added by section 902) shall not apply to such strategy before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505–1.

(3) SUBMISSION.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary. Deadline.

Subtitle B—Other Provisions to Ensure Drug Safety and Surveillance

SEC. 911. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

"SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS. Deadlines. 21 USC 360a.

"(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. Such guidance shall indicate the appropriate models and valid surrogate markers.

"(b) REVIEW.—Not later than 5 years after the date of the enactment of this section, the Secretary shall review and update the guidance described under subsection (a) to reflect developments in scientific and medical information and technology.".

SEC. 912. PROHIBITION AGAINST FOOD TO WHICH DRUGS OR BIOLOGICAL PRODUCTS HAVE BEEN ADDED.

(a) PROHIBITION.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 901(d), is amended by adding at the end the following:

"(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted

and for which the existence of such investigations has been made public, unless—

"(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

"(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

"(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

"(A) a regulation issued under section 409 prescribing conditions of safe use in food;

"(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

"(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

"(D) a food contact substance notification that is effective under section 409(h); or

"(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

"(4) the drug is a new animal drug whose use is not unsafe under section 512.".

(b) CONFORMING CHANGES.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

21 USC 334.

(1) in section 304(a)(1), by striking "section 404 or 505" and inserting "section 301(ll), 404, or 505"; and

21 USC 381.

(2) in section 801(a), by striking "is adulterated, misbranded, or in violation of section 505," and inserting "is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll),".

SEC. 913. ASSURING PHARMACEUTICAL SAFETY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended in section 403, is amended by inserting after section 505C the following:

21 USC 355e.

"SEC. 505D. PHARMACEUTICAL SECURITY.

Standards.

"(a) IN GENERAL.—The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

"(b) STANDARDS DEVELOPMENT.—

"(1) IN GENERAL.—The Secretary shall, in consultation with the agencies specified in paragraph (4), manufacturers, distributors, pharmacies, and other supply chain stakeholders, prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.

"(2) STANDARDIZED NUMERAL IDENTIFIER.—Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. Deadline.

"(3) PROMISING TECHNOLOGIES.—The standards developed under this subsection shall address promising technologies, which may include—

"(A) radio frequency identification technology;

"(B) nanotechnology;

"(C) encryption technologies; and

"(D) other track-and-trace or authentication technologies.

"(4) INTERAGENCY COLLABORATION.—In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

"(A) the Department of Justice;

"(B) the Department of Homeland Security;

"(C) the Department of Commerce; and

"(D) other appropriate Federal and State agencies.

"(c) INSPECTION AND ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this Act to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources.

"(2) ACTIVITIES.—The Secretary shall undertake enhanced and joint enforcement activities with other Federal and State agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

"(d) DEFINITION.—In this section, the term 'prescription drug' means a drug subject to section 503(b)(1).".

SEC. 914. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 901(a), is amended by adding at the end the following:

"(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

"(1) IN GENERAL.—

"(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

"(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

"(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Deadline.

"(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

"(i) Notification of the fact that a determination under subparagraph (A) has been made.

"(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

"(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

"(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

"(i) a document; or

"(ii) a meeting with the applicant involved.

"(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

"(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

Deadline.

"(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

"(i) any determination made under subparagraph (A);

"(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

"(iii) the consent of the petitioner.

"(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

"(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.', with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

"(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.', with the date on which such information first became known

to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

"(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

"(A) FINAL AGENCY ACTION WITHIN 180 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

"(i) during the 180-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

"(ii) such period expires without the Secretary having made such a final decision.

Courts.

"(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

"(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

"(i) the petition filed under paragraph (1) and any supplements and comments thereto;

"(ii) the Secretary's response to such petition, if issued; and

"(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

"(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

"(A) the number of applications that were approved during the preceding 12-month period;

"(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

"(C) the number of days by which such applications were so delayed; and

"(D) the number of such petitions that were submitted during such period.

"(4) EXCEPTIONS.—This subsection does not apply to—

"(A) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

"(B) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

"(5) DEFINITIONS.—

"(A) APPLICATION.—For purposes of this subsection, the term 'application' means an application submitted under subsection (b)(2) or (j).

"(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term 'petition' means a request described in paragraph (1)(A)(i).".

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Congress on ways to encourage the early submission of petitions under section 505(q), as added by subsection (a).

SEC. 915. POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 914(a), is amended by adding at the end the following:

"(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that— Deadline. Website.

"(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

"(B) improves communication of drug safety information to patients and providers.

"(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

"(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

"(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

"(i) patient labeling and patient packaging inserts;

"(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

"(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

"(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

"(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

"(vi) guidance documents and regulations related to drug safety; and

"(vii) other material determined appropriate by the Secretary;

"(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

Reports.

"(D) preparing, by 18 months after approval of a drug or after use of the drug by 10,000 individuals, whichever is later, a summary analysis of the adverse drug reaction reports received for the drug, including identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number;

Reports.

"(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

"(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

"(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

Deadline.

"(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

"(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

"(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

"(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.".

SEC. 916. ACTION PACKAGE FOR APPROVAL.

Section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by—

(1) redesignating paragraphs (1), (2), (3), (4), and (5) as subparagraphs (A), (B), (C), (D), and (E), respectively;

(2) striking "(l) Safety and" and inserting "(l)(1) Safety and"; and

(3) adding at the end the following:

"(2) ACTION PACKAGE FOR APPROVAL.—

Publication. Website. Deadlines.

"(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

"(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

"(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

"(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

"(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

"(i) Documents generated by the Food and Drug Administration related to review of the application.

"(ii) Documents pertaining to the format and content of the application generated during drug development.

"(iii) Labeling submitted by the applicant.

"(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

"(v) The Division Director and Office Director's decision document which includes—

"(I) a brief statement of concurrence with the summary review;

"(II) a separate review or addendum to the review if disagreeing with the summary review; and

"(III) a separate review or addendum to the review to add further analysis.

"(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

"(I) participated in the decision to approve the application; and

"(II) consents to have his or her name included in the package.

"(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

"(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.".

SEC. 917. RISK COMMUNICATION.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended by section 603, is amended by adding at the end the following:

21 USC 360bbb–6. Establishment.

"SEC. 567. RISK COMMUNICATION.

"(a) ADVISORY COMMITTEE ON RISK COMMUNICATION.—

"(1) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the 'Advisory Committee on Risk Communication' (referred to in this section as the 'Committee').

"(2) DUTIES OF COMMITTEE.—The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

"(3) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

"(4) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

"(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

"(1) IN GENERAL.—The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

"(2) PARTNERSHIPS.—The systems developed under paragraph (1) shall—

"(A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty; and

"(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.".

21 USC 355.

SEC. 918. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 915, is further amended by adding at the end the following:

"(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

"(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

"(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary

did not refer the drug to an advisory committee prior to approval.".

SEC. 919. RESPONSE TO THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this title, the Secretary shall issue a report responding to the 2006 report of the Institute of Medicine entitled "The Future of Drug Safety—Promoting and Protecting the Health of the Public". Deadline. Reports.

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described under such subsection; and

(2) an assessment of how the Food and Drug Administration has implemented—

(A) the recommendations described in such Institute of Medicine report; and

(B) the requirement under section 505–1(c)(2) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for postapproval safety with respect to the drug work together to assess, implement, and ensure compliance with the requirements of such section 505–1.

SEC. 920. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 918, is further amended by adding at the end the following:

"(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

"(1) IN GENERAL.—

"(A) PUBLICATION.—The Commissioner shall— Deadlines.

"(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

"(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

"(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

"(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

"(3) AUTHORIZED GENERIC DRUG.—In this section, the term 'authorized generic drug' means a listed drug (as that term is used in subsection (j)) that—

"(A) has been approved under subsection (c); and

"(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.".

SEC. 921. ADVERSE DRUG REACTION REPORTS AND POSTMARKET SAFETY.

Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 905, is amended by adding at the end the following:

"(5) The Secretary shall—

"(A) conduct regular, bi-weekly screening of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter;

"(B) report to Congress not later than 2 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 on procedures and processes of the Food and Drug Administration for addressing ongoing post market safety issues identified by the Office of Surveillance and Epidemiology and how recommendations of the Office of Surveillance and Epidemiology are handled within the agency; and

"(C) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments.".

TITLE X—FOOD SAFETY

21 USC 2101.

SEC. 1001. FINDINGS.

Congress finds that—

(1) the safety and integrity of the United States food supply are vital to public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination;

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) according to the Economic Research Service of the Department of Agriculture, the United States is increasing the amount of food that it imports such that—

(A) from 2003 to 2007, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average American diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat, and 78.6 percent of fish and shellfish; and

(5) the number of full-time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. 1002. ENSURING THE SAFETY OF PET FOOD. 21 USC 2102.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the "Secretary"), in consultation with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish— Deadline. Regulations.

(1) ingredient standards and definitions with respect to pet food;

(2) processing standards for pet food; and

(3) updated standards for the labeling of pet food that include nutritional and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall— Deadline.

(1) consider using surveillance and monitoring mechanisms similar to, or in coordination with, those used to monitor human or animal health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet of the Centers for Disease Control and Prevention, the Food Emergency Response Network of the Food and Drug Administration and the Department of Agriculture, and the National Animal Health Laboratory Network of the Department of Agriculture;

(2) consult with relevant professional associations and private sector veterinary hospitals;

(3) work with the National Companion Animal Surveillance Program, the Health Alert Network, or other notification networks as appropriate to inform veterinarians and relevant stakeholders during any recall of pet food; and

(4) use such information and conduct such other activities as the Secretary deems appropriate.

SEC. 1003. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL. 21 USC 2103.

The Secretary shall, during an ongoing recall of human or pet food regulated by the Secretary—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and

Website.

(3) post information regarding recalled human and pet foods on the Internet Web site of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled pet foods, that is easily accessed and understood by the public.

21 USC 2104.

SEC. 1004. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of food, including fresh and processed produce, so that State food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

21 USC 350f note.

SEC. 1005. REPORTABLE FOOD REGISTRY.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1994, Congress passed the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417) to provide the Food and Drug Administration the legal framework which is intended to ensure that dietary supplements are safe and properly labeled foods.

(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462) to establish a mandatory reporting system of serious adverse events for nonprescription drugs and dietary supplements sold and consumed in the United States.

(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act is intended to serve as an early warning system for potential public health issues associated with the use of these products.

(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health.

(b) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 417. REPORTABLE FOOD REGISTRY. 21 USC 350f.

"(a) DEFINITIONS.—In this section:

"(1) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an article of food, means a person that submits the registration under section 415(a) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held.

"(2) REPORTABLE FOOD.—The term 'reportable food' means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

"(b) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall establish within the Food and Drug Administration a Reportable Food Registry to which instances of reportable food may be submitted by the Food and Drug Administration after receipt of reports under subsection (d), via an electronic portal, from— Deadline.

"(A) Federal, State, and local public health officials; or

"(B) responsible parties.

"(2) REVIEW BY SECRETARY.—The Secretary shall promptly review and assess the information submitted under paragraph (1) for the purposes of identifying reportable food, submitting entries to the Reportable Food Registry, acting under subsection (c), and exercising other existing food safety authorities under this Act to protect the public health.

"(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

"(1) IN GENERAL.—The Secretary shall issue, or cause to be issued, an alert or a notification with respect to a reportable food using information from the Reportable Food Registry as the Secretary deems necessary to protect the public health.

"(2) EFFECT.—Paragraph (1) shall not affect the authority of the Secretary to issue an alert or a notification under any other provision of this Act.

"(d) REPORTING AND NOTIFICATION.—

"(1) IN GENERAL.—Except as provided in paragraph (2), as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food, the responsible party shall— Deadline.

"(A) submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) (except the elements described in paragraphs (8), (9), and (10) of such subsection); and

"(B) investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

"(2) NO REPORT REQUIRED.—A responsible party is not required to submit a report under paragraph (1) if—

"(A) the adulteration originated with the responsible party;

"(B) the responsible party detected the adulteration prior to any transfer to another person of such article of food; and

"(C) the responsible party—

"(i) corrected such adulteration; or

"(ii) destroyed or caused the destruction of such article of food.

"(3) REPORTS BY PUBLIC HEALTH OFFICIALS.—A Federal, State, or local public health official may submit a report about a reportable food to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) that the official is able to provide.

"(4) REPORT NUMBER.—The Secretary shall ensure that, upon submission of a report under paragraph (1) or (3), a unique number is issued through the electronic portal established under subsection (b) to the person submitting such report, by which the Secretary is able to link reports about the reportable food submitted and amended under this subsection and identify the supply chain for such reportable food.

"(5) REVIEW.—The Secretary shall promptly review a report submitted under paragraph (1) or (3).

"(6) RESPONSE TO REPORT SUBMITTED BY A RESPONSIBLE PARTY.—After consultation with the responsible party that submitted a report under paragraph (1), the Secretary may require such responsible party to perform, as soon as practicable, but in no case later than a time specified by the Secretary, 1 or more of the following:

"(A) Amend the report submitted by the responsible party under paragraph (1) to include the data element described in subsection (e)(9).

"(B) Provide a notification—

"(i) to the immediate previous source of the article of food, if the Secretary deems necessary;

"(ii) to the immediate subsequent recipient of the article of food, if the Secretary deems necessary; and

"(iii) that includes—

"(I) the data elements described in subsection (e) that the Secretary deems necessary;

"(II) the actions described under paragraph (7) that the recipient of the notification shall perform, as required by the Secretary; and

"(III) any other information that the Secretary may require.

"(7) SUBSEQUENT REPORTS AND NOTIFICATIONS.—Except as provided in paragraph (8), the Secretary may require a responsible party to perform, as soon as practicable, but in no case later than a time specified by the Secretary, after the responsible party receives a notification under subparagraph (C) or paragraph (6)(B), 1 or more of the following:

"(A) Submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes those data elements described

in subsection (e) and other information that the Secretary deems necessary.

"(B) Investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

"(C) Provide a notification—

"(i) to the immediate previous source of the article of food, if the Secretary deems necessary;

"(ii) to the immediate subsequent recipient of the article of food, if the Secretary deems necessary; and

"(iii) that includes—

"(I) the data elements described in subsection (e) that the Secretary deems necessary;

"(II) the actions described under this paragraph that the recipient of the notification shall perform, as required by the Secretary; and

"(III) any other information that the Secretary may require.

"(8) AMENDED REPORT.—If a responsible party receives a notification under paragraph (6)(B) or paragraph (7)(C) with respect to an article of food after the responsible party has submitted a report to the Food and Drug Administration under paragraph (1) with respect to such article of food—

"(A) the responsible party is not required to submit an additional report or make a notification under paragraph (7); and

"(B) the responsible party shall amend the report submitted by the responsible party under paragraph (1) to include the data elements described in paragraph (9), and, with respect to both such notification and such report, paragraph (11) of subsection (e).

"(e) DATA ELEMENTS.—The data elements described in this subsection are the following:

"(1) The registration numbers of the responsible party under section 415(a)(3).

"(2) The date on which an article of food was determined to be a reportable food.

"(3) A description of the article of food including the quantity or amount.

"(4) The extent and nature of the adulteration.

"(5) If the adulteration of the article of food may have originated with the responsible party, the results of the investigation required under paragraph (1)(B) or (7)(B) of subsection (d), as applicable and when known.

"(6) The disposition of the article of food, when known.

"(7) Product information typically found on packaging including product codes, use-by dates, and names of manufacturers, packers, or distributors sufficient to identify the article of food.

"(8) Contact information for the responsible party.

"(9) The contact information for parties directly linked in the supply chain and notified under paragraph (6)(B) or (7)(C) of subsection (d), as applicable.

"(10) The information required by the Secretary to be included in a notification provided by the responsible party involved under paragraph (6)(B) or (7)(C) of subsection (d) or required in a report under subsection (d)(7)(A).

"(11) The unique number described in subsection (d)(4).

"(f) COORDINATION OF FEDERAL, STATE, AND LOCAL EFFORTS.—

"(1) DEPARTMENT OF AGRICULTURE.—In implementing this section, the Secretary shall—

"(A) share information and coordinate regulatory efforts with the Department of Agriculture; and

"(B) if the Secretary receives a report submitted about a food within the jurisdiction of the Department of Agriculture, promptly provide such report to the Department of Agriculture.

"(2) STATES AND LOCALITIES.—In implementing this section, the Secretary shall work with the State and local public health officials to share information and coordinate regulatory efforts, in order to—

"(A) help to ensure coverage of the safety of the food supply chain, including those food establishments regulated by the States and localities that are not required to register under section 415; and

"(B) reduce duplicative regulatory efforts.

"(g) MAINTENANCE AND INSPECTION OF RECORDS.—The responsible party shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section for 2 years. A responsible party shall, at the request of the Secretary, permit inspection of such records as provided for section 414.

Applicability.

"(h) REQUEST FOR INFORMATION.—Except as provided by section 415(a)(4), section 552 of title 5, United States Code, shall apply to any request for information regarding a record in the Reportable Food Registry.

"(i) SAFETY REPORT.—A report or notification under subsection (d) shall be considered to be a safety report under section 756 and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report or the notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

"(j) ADMISSION.—A report or notification under this section shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness.

"(k) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (d), the Secretary believes such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make relevant information from the Reportable Food Registry available to the Secretary of Homeland Security.".

(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking "section 201(g)" and inserting "sections 201(g) and 417".

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 912, is further amended—

(1) in subsection (e), by—

(A) striking "414," and inserting "414, 417(g),"; and

(B) striking "414(b)" and inserting "414(b), 417"; and

(2) by adding at the end the following:

"(mm) The failure to submit a report or provide a notification required under section 417(d).

"(nn) The falsification of a report or notification required under section 417(d).".

(e) EFFECTIVE DATE.—The requirements of section 417(d) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 1 year after the date of the enactment of this Act. 21 USC 350f note.

(f) GUIDANCE.—Not later than 9 months after the date of the enactment of this Act, the Secretary shall issue a guidance to industry about submitting reports to the electronic portal established under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section) and providing notifications to other persons in the supply chain of an article of food under such section 417. Deadline. 21 USC 350f note.

(g) EFFECT.—Nothing in this title, or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations. 21 USC 2110 note.

SEC. 1006. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION. 21 USC 2105.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—The Secretary is authorized to enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) REPORT TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall submit to Congress a report that—

(1) describes the specifics of the aquaculture and seafood inspection program;

(2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and

(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs to Federal standards regarding the importation of aquaculture and seafood.

SEC. 1007. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS. Reports. 21 USC 2106.

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service

of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

21 USC 2107.

SEC. 1008. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) Congress should work to develop a comprehensive response to the issue of food safety.

21 USC 2108.

SEC. 1009. ANNUAL REPORT TO CONGRESS.

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

21 USC 2109.

SEC. 1010. PUBLICATION OF ANNUAL REPORTS.

Website.

(a) IN GENERAL.—The Commissioner of Food and Drugs shall annually submit to Congress and publish on the Internet Web site of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled "Food and Drug Administration Pesticide Program Residue Monitoring 2003" as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page

13 of the report entitled "Food and Drug Administration Pesticide Program Residue Monitoring 2003";

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SEC. 1011. RULE OF CONSTRUCTION. 21 USC 2110.

Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417); or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462).

TITLE XI—OTHER PROVISIONS

Subtitle A—In General

SEC. 1101. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by section 701, is further amended by adding at the end the following:

"SEC. 713. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES. 21 USC 379d–2.

"(a) DEFINITION.—In this section, the term 'article' means a paper, poster, abstract, book, book chapter, or other published writing.

"(b) POLICIES.—The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear Public information.

written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

"(c) TIMING OF SUBMISSION FOR REVIEW.—If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

"(d) TIMING FOR REVIEW AND CLEARANCE.—The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

"(e) NON-TIMELY REVIEW.—If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

"(f) EFFECT.—Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.".

SEC. 1102. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

21 USC 360n.

"SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

"(a) DEFINITIONS.—In this section:

"(1) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

"(2) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the tropical disease product application.

"(3) TROPICAL DISEASE.—The term 'tropical disease' means any of the following:

"(A) Tuberculosis.

"(B) Malaria.

"(C) Blinding trachoma.

"(D) Buruli Ulcer.
"(E) Cholera.
"(F) Dengue/dengue haemorrhagic fever.
"(G) Dracunculiasis (guinea-worm disease).
"(H) Fascioliasis.
"(I) Human African trypanosomiasis.
"(J) Leishmaniasis.
"(K) Leprosy.
"(L) Lymphatic filariasis.
"(M) Onchocerciasis.
"(N) Schistosomiasis.
"(O) Soil transmitted helmithiasis.
"(P) Yaws.

"(Q) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary.

"(4) TROPICAL DISEASE PRODUCT APPLICATION.—The term 'tropical disease product application' means an application that—

"(A) is a human drug application as defined in section 735(1)—

"(i) for prevention or treatment of a tropical disease; and

"(ii) the Secretary deems eligible for priority review;

"(B) is approved after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, by the Secretary for use in the prevention, detection, or treatment of a tropical disease; and

"(C) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health Service Act.

"(b) PRIORITY REVIEW VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application.

"(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351 of the Public Health Service Act will be submitted after the date of the approval of the tropical disease product application.

"(3) LIMITATION.—

"(A) NO AWARD FOR PRIOR APPROVED APPLICATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product application was submitted to the Secretary prior to the date of the enactment of this section.

"(B) ONE-YEAR WAITING PERIOD.—The Secretary shall issue a priority review voucher to the sponsor of a tropical disease product no earlier than the date that is 1 year

after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

Deadline.

"(4) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 365 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(c) PRIORITY REVIEW USER FEE.—

"(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

"(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

"(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351 of the Public Health Services Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

"(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.".

SEC. 1103. IMPROVING GENETIC TEST SAFETY AND QUALITY.

Contracts.
Study.

(a) REPORT.—If the Secretary's Advisory Committee on Genetics, Health, and Society does not complete and submit the Regulatory Oversight of Genetic/Genomic Testing Report & Action Recommendations to the Secretary of Health and Human Services (referred to in this section as the "Secretary") by July of 2008, the Secretary shall enter into a contract with the Institute of

Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetics, Health, and Society and other groups and shall be completed not later than 1 year after the date on which the Secretary entered into such contract.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring Federal efforts with respect to regulatory oversight of genetic tests to cease or be limited or delayed pending completion of the report by the Secretary's Advisory Committee on Genetics, Health, and Society or the Institute of Medicine.

SEC. 1104. NIH TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 319C–2(j)(3)(B), by striking "section 319C–1(h)" and inserting "section 319C–1(i)"; 42 USC 247d–3b.

(2) in section 402(b)(4), by inserting "minority and other" after "reducing"; 42 USC 282.

(3) in section 403(a)(4)(C)(iv)(III), by inserting "and postdoctoral training funded through research grants" before the semicolon; 42 USC 283.

(4) by designating the second section 403C (relating to the drug diethylstilbestrol) as section 403D; and 42 USC 283a–3.

(5) in section 403C(a)— 42 USC 283a–2.

(A) in the matter preceding paragraph (1)—

(i) by inserting "graduate students supported by the National Institutes of Health" after "with respect to"; and

(ii) by deleting "each degree-granting program";

(B) in paragraph (1), by inserting "such" after "percentage of"; and

(C) in paragraph (2), by inserting "(not including any leaves of absence)" after "average time".

SEC. 1105. SEVERABILITY CLAUSE. 21 USC 301 note.

If any provision of this Act, an amendment made this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.

Subtitle B—Antibiotic Access and Innovation

SEC. 1111. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS. 42 USC 247d–5a.

(a) DEFINITION.—In this section, the term "clinically susceptible concentrations" means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), through the Commissioner of Food and Drugs, shall identify (where such

information is reasonably available) and periodically update clinically susceptible concentrations.

Deadline.

(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available, such as by posting on the Internet, not later than 30 days after the date of identification and any update under this section.

(d) EFFECT.—Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

SEC. 1112. ORPHAN ANTIBIOTIC DRUGS.

(a) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting regarding which serious and life threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under section 5(a) of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(b) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

Appropriation authorization.

"(c) For grants and contracts under subsection (a), there is authorized to be appropriated $30,000,000 for each of fiscal years 2008 through 2012.".

SEC. 1113. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 920, is further amended by adding at the end the following:

"(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

"(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

"(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

"(ii) the application submitted under subsection (b) for such non-racemic drug—

"(I) includes full reports of new clinical investigations (other than bioavailability studies)—

"(aa) necessary for the approval of the application under subsections (c) and (d); and

"(bb) conducted or sponsored by the applicant; and

"(II) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

"(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

"(i) in a therapeutic category in which the approved racemic drug has been approved; or

"(ii) for which any other enantiomer of the racemic drug has been approved.

"(2) LIMITATION.—

"(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

"(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

"(3) DEFINITION.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'therapeutic category' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

"(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

"(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2012.". Deadline.

SEC. 1114. REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this subtitle has—

(1) encouraged the development of new antibiotics and other drugs; and

(2) prevented or delayed timely generic drug entry into the market.

Approved September 27, 2007.

LEGISLATIVE HISTORY—H.R. 3580:

CONGRESSIONAL RECORD, Vol. 153 (2007):
Sept. 19, considered and passed House.
Sept. 20, considered and passed Senate.

○

the treatment program of the veterans concerned.

(Authority: 38 U.S.C. 1720A)

[47 FR 57708, Dec. 28, 1982. Redesignated and amended at 61 FR 21965, 21967, May 13, 1996; 61 FR 63720, Dec. 2, 1996; 62 FR 17072, Apr. 9, 1997; 69 FR 18803, Apr. 9, 2004; 76 FR 10249, Feb. 24, 2011]

§ 17.83 Limitations on payment for alcohol and drug dependence or abuse treatment and rehabilitation.

The authority to enter into contracts shall be effective for any fiscal year only to such extent or in such amounts as are provided in appropriation acts, and payments shall not exceed these amounts.

(Authority: Pub. L. 96–22, 38 U.S.C. 1720A)

[47 FR 57708, Dec. 28, 1982. Redesignated at 61 FR 21965, May 13, 1996]

RESEARCH-RELATED INJURIES

§ 17.85 Treatment of research-related injuries to human subjects.

(a) VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This section does not apply to:

(1) Treatment for injuries due to noncompliance by a subject with study procedures, or

(2) Research conducted for VA under a contract with an individual or a non-VA institution.

NOTE TO §17.85(a)(1) AND (a)(2): Veterans who are injured as a result of participation in such research may be eligible for care from VA under other provisions of this part.

(b) Except in the following situations, care for VA research subjects under this section shall be provided in VA medical facilities.

(1) If VA medical facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility directors shall contract for the needed care.

(2) If inpatient care must be provided to a non-veteran under this section, VA medical facility directors may contract for such care.

(3) If a research subject needs treatment in a medical emergency for a condition covered by this section, VA medical facility directors shall provide reasonable reimbursement for the emergency treatment in a non-VA facility.

(c) For purposes of this section, ''VA employee'' means any person appointed by VA as an officer or employee and acting within the scope of his or her appointment (VA appoints officers and employees under title 5 and title 38 of the United States Code).

(Authority: 38 U.S.C. 501, 7303)

[63 FR 11124, Mar. 6, 1998]

CARE DURING CERTAIN DISASTERS AND EMERGENCIES

§ 17.86 Provision of hospital care and medical services during certain disasters and emergencies under 38 U.S.C. 1785.

(a) This section sets forth regulations regarding the provision of hospital care and medical services under 38 U.S.C. 1785.

(b) During and immediately following a disaster or emergency referred to in paragraph (c) of this section, VA under 38 U.S.C. 1785 may furnish hospital care and medical services to individuals (including those who otherwise do not have VA eligibility for such care and services) responding to, involved in, or otherwise affected by that disaster or emergency.

(c) For purposes of this section, a *disaster* or *emergency* means:

(1) A major disaster or emergency declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) (Stafford Act); or

(2) A disaster or emergency in which the National Disaster Medical System established pursuant to section 2811(b) of the Public Health Service Act (42 U.S.C. 300hh–11(b)) is activated either by the Secretary of Health and Human Services under paragraph (3)(A) of that section or as otherwise authorized by law.

(d) For purposes of paragraph (b) of this section, the terms *hospital care* and *medical services* have the meanings given such terms by 38 U.S.C. 1701(5) and 1701(6).

Public Law 111–5
111th Congress

An Act

Making supplemental appropriations for job preservation and creation, infrastructure investment, energy efficiency and science, assistance to the unemployed, and State and local fiscal stabilization, for the fiscal year ending September 30, 2009, and for other purposes.

Feb. 17, 2009
[H.R. 1]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

American Recovery and Reinvestment Act of 2009.
26 USC 1 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "American Recovery and Reinvestment Act of 2009".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

DIVISION A—APPROPRIATIONS PROVISIONS

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TITLE II—COMMERCE, JUSTICE, SCIENCE, AND RELATED AGENCIES
TITLE III—DEPARTMENT OF DEFENSE
TITLE IV—ENERGY AND WATER DEVELOPMENT
TITLE V—FINANCIAL SERVICES AND GENERAL GOVERNMENT
TITLE VI—DEPARTMENT OF HOMELAND SECURITY
TITLE VII—INTERIOR, ENVIRONMENT, AND RELATED AGENCIES
TITLE VIII—DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES
TITLE IX—LEGISLATIVE BRANCH
TITLE X—MILITARY CONSTRUCTION AND VETERANS AFFAIRS AND RELATED AGENCIES
TITLE XI—STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS
TITLE XII—TRANSPORTATION, HOUSING AND URBAN DEVELOPMENT, AND RELATED AGENCIES
TITLE XIII—HEALTH INFORMATION TECHNOLOGY
TITLE XIV—STATE FISCAL STABILIZATION FUND
TITLE XV—ACCOUNTABILITY AND TRANSPARENCY
TITLE XVI—GENERAL PROVISIONS—THIS ACT

DIVISION B—TAX, UNEMPLOYMENT, HEALTH, STATE FISCAL RELIEF, AND OTHER PROVISIONS

TITLE I—TAX PROVISIONS
TITLE II—ASSISTANCE FOR UNEMPLOYED WORKERS AND STRUGGLING FAMILIES
TITLE III—PREMIUM ASSISTANCE FOR COBRA BENEFITS
TITLE IV—MEDICARE AND MEDICAID HEALTH INFORMATION TECHNOLOGY; MISCELLANEOUS MEDICARE PROVISIONS
TITLE V—STATE FISCAL RELIEF
TITLE VI—BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM
TITLE VII—LIMITS ON EXECUTIVE COMPENSATION

SEC. 3. PURPOSES AND PRINCIPLES.

26 USC 1 note.

(a) STATEMENT OF PURPOSES.—The purposes of this Act include the following:

(1) To preserve and create jobs and promote economic recovery.

(2) To assist those most impacted by the recession.

(3) To provide investments needed to increase economic efficiency by spurring technological advances in science and health.

(4) To invest in transportation, environmental protection, and other infrastructure that will provide long-term economic benefits.

(5) To stabilize State and local government budgets, in order to minimize and avoid reductions in essential services and counterproductive state and local tax increases.

(b) GENERAL PRINCIPLES CONCERNING USE OF FUNDS.—The President and the heads of Federal departments and agencies shall manage and expend the funds made available in this Act so as to achieve the purposes specified in subsection (a), including commencing expenditures and activities as quickly as possible consistent with prudent management.

1 USC 1 note.

SEC. 4. REFERENCES.

Except as expressly provided otherwise, any reference to "this Act" contained in any division of this Act shall be treated as referring only to the provisions of that division.

SEC. 5. EMERGENCY DESIGNATIONS.

(a) IN GENERAL.—Each amount in this Act is designated as an emergency requirement and necessary to meet emergency needs pursuant to section 204(a) of S. Con. Res. 21 (110th Congress) and section 301(b)(2) of S. Con. Res. 70 (110th Congress), the concurrent resolutions on the budget for fiscal years 2008 and 2009.

(b) PAY-AS-YOU-GO.—All applicable provisions in this Act are designated as an emergency for purposes of pay-as-you-go principles.

DIVISION A—APPROPRIATIONS PROVISIONS

That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the fiscal year ending September 30, 2009, and for other purposes, namely:

TITLE I—AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

DEPARTMENT OF AGRICULTURE

AGRICULTURE BUILDINGS AND FACILITIES AND RENTAL PAYMENTS

For an additional amount for "Agriculture Buildings and Facilities and Rental Payments", $24,000,000, for necessary construction, repair, and improvement activities.

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $22,500,000, to remain available until September 30, 2013, for

oversight and audit of programs, grants, and activities funded by this Act and administered by the Department of Agriculture.

AGRICULTURAL RESEARCH SERVICE

BUILDINGS AND FACILITIES

For an additional amount for "Buildings and Facilities", $176,000,000, for work on deferred maintenance at Agricultural Research Service facilities: *Provided*, That priority in the use of such funds shall be given to critical deferred maintenance, to projects that can be completed, and to activities that can commence promptly following enactment of this Act.

FARM SERVICE AGENCY

SALARIES AND EXPENSES

For an additional amount for "Farm Service Agency, Salaries and Expenses," $50,000,000, for the purpose of maintaining and modernizing the information technology system.

NATURAL RESOURCES CONSERVATION SERVICE

WATERSHED AND FLOOD PREVENTION OPERATIONS

For an additional amount for "Watershed and Flood Prevention Operations", $290,000,000, of which $145,000,000 is for necessary expenses to purchase and restore floodplain easements as authorized by section 403 of the Agricultural Credit Act of 1978 (16 U.S.C. 2203) (except that no more than $30,000,000 of the amount provided for the purchase of floodplain easements may be obligated for projects in any one State): *Provided*, That such funds shall be allocated to projects that can be fully funded and completed with the funds appropriated in this Act, and to activities that can commence promptly following enactment of this Act.

WATERSHED REHABILITATION PROGRAM

For an additional amount for "Watershed Rehabilitation Program", $50,000,000: *Provided,* That such funds shall be allocated to projects that can be fully funded and completed with the funds appropriated in this Act, and to activities that can commence promptly following enactment of this Act.

RURAL HOUSING SERVICE

RURAL HOUSING INSURANCE FUND PROGRAM ACCOUNT

For an additional amount for gross obligations for the principal amount of direct and guaranteed loans as authorized by title V of the Housing Act of 1949, to be available from funds in the rural housing insurance fund, as follows: $1,000,000,000 for section 502 direct loans; and $10,472,000,000 for section 502 unsubsidized guaranteed loans.

For an additional amount for the cost of direct and guaranteed loans, including the cost of modifying loans, as defined in section 502 of the Congressional Budget Act of 1974, as follows: $67,000,000

for section 502 direct loans; and $133,000,000 for section 502 unsubsidized guaranteed loans.

RURAL COMMUNITY FACILITIES PROGRAM ACCOUNT

For an additional amount for the cost of direct loans and grants for rural community facilities programs as authorized by section 306 and described in section 381E(d)(1) of the Consolidated Farm and Rural Development Act, $130,000,000.

RURAL BUSINESS—COOPERATIVE SERVICE

RURAL BUSINESS PROGRAM ACCOUNT

For an additional amount for the cost of guaranteed loans and grants as authorized by sections 310B(a)(2)(A) and 310B(c) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932), $150,000,000.

RURAL UTILITIES SERVICE

RURAL WATER AND WASTE DISPOSAL PROGRAM ACCOUNT

For an additional amount for the cost of direct loans and grants for the rural water, waste water, and waste disposal programs authorized by sections 306 and 310B and described in section 381E(d)(2) of the Consolidated Farm and Rural Development Act, $1,380,000,000.

DISTANCE LEARNING, TELEMEDICINE, AND BROADBAND PROGRAM

Grants.
Loans.

For an additional amount for the cost of broadband loans and loan guarantees, as authorized by the Rural Electrification Act of 1936 (7 U.S.C. 901 et seq.) and for grants (including for technical assistance), $2,500,000,000: *Provided*, That the cost of direct and guaranteed loans shall be as defined in section 502 of the Congressional Budget Act of 1974: *Provided further*, That, notwithstanding title VI of the Rural Electrification Act of 1936, this amount is available for grants, loans and loan guarantees for broadband infrastructure in any area of the United States: *Provided further*, That at least 75 percent of the area to be served by a project receiving funds from such grants, loans or loan guarantees shall be in a rural area without sufficient access to high speed broadband service to facilitate rural economic development, as determined by the Secretary of Agriculture: *Provided further,* That priority for awarding such funds shall be given to project applications for broadband systems that will deliver end users a choice of more than one service provider: *Provided further*, That priority for awarding funds made available under this paragraph shall be given to projects that provide service to the highest proportion of rural residents that do not have access to broadband service: *Provided further*, That priority shall be given for project applications from borrowers or former borrowers under title II of the Rural Electrification Act of 1936 and for project applications that include such borrowers or former borrowers: *Provided further*, That priority for awarding such funds shall be given to project applications that demonstrate that, if the application is approved, all project elements will be fully funded: *Provided further*, That priority for awarding

such funds shall be given to project applications for activities that can be completed if the requested funds are provided: *Provided further*, That priority for awarding such funds shall be given to activities that can commence promptly following approval: *Provided further*, That no area of a project funded with amounts made available under this paragraph may receive funding to provide broadband service under the Broadband Technology Opportunities Program: *Provided further*, That the Secretary shall submit a report on planned spending and actual obligations describing the use of these funds not later than 90 days after the date of enactment of this Act, and quarterly thereafter until all funds are obligated, to the Committees on Appropriations of the House of Representatives and the Senate.

Reports. Deadlines.

FOOD AND NUTRITION SERVICE CHILD NUTRITION PROGRAMS

For an additional amount for the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et. seq.), except section 21, and the Child Nutrition Act of 1966 (42 U.S.C. 1771 et. seq.), except sections 17 and 21, $100,000,000, to carry out a grant program for National School Lunch Program equipment assistance: *Provided,* That such funds shall be provided to States administering a school lunch program in a manner proportional with each States' administrative expense allocation: *Provided further,* That the States shall provide competitive grants to school food authorities based upon the need for equipment assistance in participating schools with priority given to school in which not less than 50 percent of the students are eligible for free or reduced price meals under the Richard B. Russell National School Lunch Act.

Grants.

SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC)

For an additional amount for the special supplemental nutrition program as authorized by section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786), $500,000,000, of which $400,000,000 shall be placed in reserve to be allocated as the Secretary deems necessary, notwithstanding section 17(i) of such Act, to support participation should cost or participation exceed budget estimates, and of which $100,000,000 shall be for the purposes specified in section 17(h)(10)(B)(ii): *Provided,* That up to one percent of the funding provided for the purposes specified in section 17(h)(10)(B)(ii) may be reserved by the Secretary for Federal administrative activities in support of those purposes.

COMMODITY ASSISTANCE PROGRAM

For an additional amount for the emergency food assistance program as authorized by section 27(a) of the Food and Nutrition Act of 2008 (7 U.S.C. 2036(a)) and section 204(a)(1) of the Emergency Food Assistance Act of 1983 (7 U.S.C. 7508(a)(1)), $150,000,000: *Provided,* That of the funds made available, the Secretary may use up to $50,000,000 for costs associated with the distribution of commodities, of which up to $25,000,000 shall be made available in fiscal year 2009.

GENERAL PROVISIONS—THIS TITLE

Puerto Rico. American Samoa.

SEC. 101. TEMPORARY INCREASE IN BENEFITS UNDER THE SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM. (a) MAXIMUM BENEFIT INCREASE.—

Effective date.

(1) IN GENERAL.—Beginning the first month that begins not less than 25 days after the date of enactment of this Act, the value of benefits determined under section 8(a) of the Food and Nutrition Act of 2008 and consolidated block grants for Puerto Rico and American Samoa determined under section 19(a) of such Act shall be calculated using 113.6 percent of the June 2008 value of the thrifty food plan as specified under section 3(o) of such Act.

(2) TERMINATION.—

(A) The authority provided by this subsection shall terminate after September 30, 2009.

(B) Notwithstanding subparagraph (A), the Secretary of Agriculture may not reduce the value of the maximum allotments, minimum allotments or consolidated block grants for Puerto Rico and American Samoa below the level in effect for fiscal year 2009 as a result of paragraph (1).

(b) REQUIREMENTS FOR THE SECRETARY.—In carrying out this section, the Secretary shall—

(1) consider the benefit increases described in subsection (a) to be a "mass change";

(2) require a simple process for States to notify households of the increase in benefits;

(3) consider section 16(c)(3)(A) of the Food and Nutrition Act of 2008 (7 U.S.C. 2025(c)(3)(A)) to apply to any errors in the implementation of this section, without regard to the 120-day limit described in that section;

(4) disregard the additional amount of benefits that a household receives as a result of this section in determining the amount of overissuances under section 13 of the Food and Nutrition Act of 2008 (7 U.S.C. 2022); and

(5) set the tolerance level for excluding small errors for the purposes of section 16(c) of the Food and Nutrition Act of 2008 (7 U.S.C. 2025(c)) at $50 through September 30, 2009.

(c) ADMINISTRATIVE EXPENSES.—

(1) IN GENERAL.—For the costs of State administrative expenses associated with carrying out this section and administering the supplemental nutrition assistance program established under the Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.), the Secretary shall make available $145,000,000 in fiscal year 2009 and $150,000,000 in fiscal year 2010, of which $4,500,000 is for necessary expenses of the Food and Nutrition Service for management and oversight of the program and for monitoring the integrity and evaluating the effects of the payments made under this section.

Deadline.

(2) TIMING FOR FISCAL YEAR 2009.—Not later than 60 days after the date of enactment of this Act, the Secretary shall make available to States amounts for fiscal year 2009 under paragraph (1).

Grants.

(3) ALLOCATION OF FUNDS.—Except as provided for management and oversight, funds described in paragraph (1) shall

be made available as grants to State agencies for each fiscal year as follows:

(A) 75 percent of the amounts available for each fiscal year shall be allocated to States based on the share of each State of households that participate in the supplemental nutrition assistance program as reported to the Department of Agriculture for the most recent 12-month period for which data are available, adjusted by the Secretary (as of the date of enactment) for participation in disaster programs under section 5(h) of the Food and Nutrition Act of 2008 (7 U.S.C. 2014(h)); and

(B) 25 percent of the amounts available for each fiscal year shall be allocated to States based on the increase in the number of households that participate in the supplemental nutrition assistance program as reported to the Department of Agriculture over the most recent 12-month period for which data are available, adjusted by the Secretary (as of the date of enactment) for participation in disaster programs under section 5(h) of the Food and Nutrition Act of 2008 (7 U.S.C. 2014(h)).

(d) FOOD DISTRIBUTION PROGRAM ON INDIAN RESERVATIONS.—For the costs relating to facility improvements and equipment upgrades associated with the Food Distribution Program on Indian Reservations, as established under section 4(b) of the Food and Nutrition Act of 2008 (7 U.S.C. 2013(b)), the Secretary shall make available $5,000,000: *Provided,* That administrative cost-sharing requirements are not applicable to funds provided in accordance with this provision.

(e) TREATMENT OF JOBLESS WORKERS.— Effective dates.

(1) REMAINDER OF FISCAL YEAR 2009 THROUGH FISCAL YEAR 2010.—Beginning with the first month that begins not less than 25 days after the date of enactment of this Act and for each subsequent month through September 30, 2010, eligibility for supplemental nutrition assistance program benefits shall not be limited under section 6(o)(2) of the Food and Nutrition Act of 2008 unless an individual does not comply with the requirements of a program offered by the State agency that meets the standards of subparagraphs (B) or (C) of that paragraph.

(2) FISCAL YEAR 2011 AND THEREAFTER.—Beginning on October 1, 2010, for the purposes of section 6(o) of the Food and Nutrition Act of 2008 (7 U.S.C. 2015(o)), a State agency shall disregard any period during which an individual received benefits under the supplemental nutrition assistance program prior to October 1, 2010.

(f) FUNDING.—There are appropriated to the Secretary out of funds of the Treasury not otherwise appropriated such sums as are necessary to carry out this section.

SEC. 102. AGRICULTURAL DISASTER ASSISTANCE TRANSITION. (a) FEDERAL CROP INSURANCE ACT. Section 531(g) of the Federal Crop Insurance Act (7 U.S.C. 1531(g)) is amended by adding at the end the following:

"(7) 2008 TRANSITION ASSISTANCE.—

"(A) IN GENERAL.—Eligible producers on a farm described in subparagraph (A) of paragraph (4) that failed to timely pay the appropriate fee described in that subparagraph shall be eligible for assistance under this section

in accordance with subparagraph (B) if the eligible producers on the farm—

Deadline.

"(i) pay the appropriate fee described in paragraph (4)(A) not later than 90 days after the date of enactment of this paragraph; and

"(ii)(I) in the case of each insurable commodity of the eligible producers on the farm, excluding grazing land, agree to obtain a policy or plan of insurance under subtitle A (excluding a crop insurance pilot program under that subtitle) for the next insurance year for which crop insurance is available to the eligible producers on the farm at a level of coverage equal to 70 percent or more of the recorded or appraised average yield indemnified at 100 percent of the expected market price, or an equivalent coverage; and

"(II) in the case of each noninsurable commodity of the eligible producers on the farm, agree to file the required paperwork, and pay the administrative fee by the applicable State filing deadline, for the noninsured crop assistance program for the next year for which a policy is available.

"(B) AMOUNT OF ASSISTANCE.—Eligible producers on a farm that meet the requirements of subparagraph (A) shall be eligible to receive assistance under this section as if the eligible producers on the farm—

"(i) in the case of each insurable commodity of the eligible producers on the farm, had obtained a policy or plan of insurance for the 2008 crop year at a level of coverage not to exceed 70 percent or more of the recorded or appraised average yield indemnified at 100 percent of the expected market price, or an equivalent coverage; and

"(ii) in the case of each noninsurable commodity of the eligible producers on the farm, had filed the required paperwork, and paid the administrative fee by the applicable State filing deadline, for the noninsured crop assistance program for the 2008 crop year, except that in determining the level of coverage, the Secretary shall use 70 percent of the applicable yield.

"(C) EQUITABLE RELIEF.—Except as provided in subparagraph (D), eligible producers on a farm that met the requirements of paragraph (1) before the deadline described in paragraph (4)(A) and are eligible to receive, a disaster assistance payment under this section for a production loss during the 2008 crop year shall be eligible to receive an amount equal to the greater of—

"(i) the amount that would have been calculated under subparagraph (B) if the eligible producers on the farm had paid the appropriate fee under that subparagraph; or

"(ii) the amount that would have been calculated under subparagraph (A) of subsection (b)(3) if—

"(I) in clause (i) of that subparagraph, '120 percent' is substituted for '115 percent'; and

"(II) in clause (ii) of that subparagraph, '125' is substituted for '120 percent'.

"(D) LIMITATION.—For amounts made available under this paragraph, the Secretary may make such adjustments as are necessary to ensure that no producer receives a payment under this paragraph for an amount in excess of the assistance received by a similarly situated producer that had purchased the same or higher level of crop insurance prior to the date of enactment of this paragraph.

"(E) AUTHORITY OF THE SECRETARY.—The Secretary may provide such additional assistance as the Secretary considers appropriate to provide equitable treatment for eligible producers on a farm that suffered production losses in the 2008 crop year that result in multiyear production losses, as determined by the Secretary.

"(F) LACK OF ACCESS.—Notwithstanding any other provision of this section, the Secretary may provide assistance under this section to eligible producers on a farm that—

"(i) suffered a production loss due to a natural cause during the 2008 crop year; and

"(ii) as determined by the Secretary—

"(I)(aa) except as provided in item (bb), lack access to a policy or plan of insurance under subtitle A; or

"(bb) do not qualify for a written agreement because 1 or more farming practices, which the Secretary has determined are good farming practices, of the eligible producers on the farm differ significantly from the farming practices used by producers of the same crop in other regions of the United States; and

"(II) are not eligible for the noninsured crop disaster assistance program established by section 196 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7333).".

(b) TRADE ACT OF 1974.—Section 901(g) of the Trade Act of 1974 (19 U.S.C. 2497(g)) is amended by adding at the end the following:

"(7) 2008 TRANSITION ASSISTANCE.—

"(A) IN GENERAL.—Eligible producers on a farm described in subparagraph (A) of paragraph (4) that failed to timely pay the appropriate fee described in that subparagraph shall be eligible for assistance under this section in accordance with subparagraph (B) if the eligible producers on the farm—

"(i) pay the appropriate fee described in paragraph (4)(A) not later than 90 days after the date of enactment of this paragraph; and

Deadline.

"(ii)(I) in the case of each insurable commodity of the eligible producers on the farm, excluding grazing land, agree to obtain a policy or plan of insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.) (excluding a crop insurance pilot program under that Act) for the next insurance year for which crop insurance is available to the eligible producers on the farm at a level of coverage equal to 70 percent or more of the recorded or appraised average yield

indemnified at 100 percent of the expected market price, or an equivalent coverage; and

"(II) in the case of each noninsurable commodity of the eligible producers on the farm, agree to file the required paperwork, and pay the administrative fee by the applicable State filing deadline, for the noninsured crop assistance program for the next year for which a policy is available.

"(B) AMOUNT OF ASSISTANCE.—Eligible producers on a farm that meet the requirements of subparagraph (A) shall be eligible to receive assistance under this section as if the eligible producers on the farm—

"(i) in the case of each insurable commodity of the eligible producers on the farm, had obtained a policy or plan of insurance for the 2008 crop year at a level of coverage not to exceed 70 percent or more of the recorded or appraised average yield indemnified at 100 percent of the expected market price, or an equivalent coverage; and

"(ii) in the case of each noninsurable commodity of the eligible producers on the farm, had filed the required paperwork, and paid the administrative fee by the applicable State filing deadline, for the noninsured crop assistance program for the 2008 crop year, except that in determining the level of coverage, the Secretary shall use 70 percent of the applicable yield.

"(C) EQUITABLE RELIEF.—Except as provided in subparagraph (D), eligible producers on a farm that met the requirements of paragraph (1) before the deadline described in paragraph (4)(A) and are eligible to receive, a disaster assistance payment under this section for a production loss during the 2008 crop year shall be eligible to receive an amount equal to the greater of—

"(i) the amount that would have been calculated under subparagraph (B) if the eligible producers on the farm had paid the appropriate fee under that subparagraph; or

"(ii) the amount that would have been calculated under subparagraph (A) of subsection (b)(3) if—

"(I) in clause (i) of that subparagraph, '120 percent' is substituted for '115 percent'; and

"(II) in clause (ii) of that subparagraph, '125' is substituted for '120 percent'.

"(D) LIMITATION.—For amounts made available under this paragraph, the Secretary may make such adjustments as are necessary to ensure that no producer receives a payment under this paragraph for an amount in excess of the assistance received by a similarly situated producer that had purchased the same or higher level of crop insurance prior to the date of enactment of this paragraph.

"(E) AUTHORITY OF THE SECRETARY.—The Secretary may provide such additional assistance as the Secretary considers appropriate to provide equitable treatment for eligible producers on a farm that suffered production losses in the 2008 crop year that result in multiyear production losses, as determined by the Secretary.

"(F) LACK OF ACCESS.—Notwithstanding any other provision of this section, the Secretary may provide assistance under this section to eligible producers on a farm that—

"(i) suffered a production loss due to a natural cause during the 2008 crop year; and

"(ii) as determined by the Secretary—

"(I)(aa) except as provided in item (bb), lack access to a policy or plan of insurance under subtitle A; or

"(bb) do not qualify for a written agreement because 1 or more farming practices, which the Secretary has determined are good farming practices, of the eligible producers on the farm differ significantly from the farming practices used by producers of the same crop in other regions of the United States; and

"(II) are not eligible for the noninsured crop disaster assistance program established by section 196 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7333).".

(c) FARM OPERATING LOANS.—

(1) IN GENERAL.—For the principal amount of direct farm operating loans under section 311 of the Consolidated Farm and Rural Development Act (7 U.S.C. 1941), $173,367,000.

(2) DIRECT FARM OPERATING LOANS.—For the cost of direct farm operating loans, including the cost of modifying loans, as defined in section 502 of the Congressional Budget Act of 1974 (2 U.S.C. 661a), $20,440,000.

(d) 2008 AQUACULTURE ASSISTANCE.—

(1) DEFINITIONS.—In this subsection:

(A) ELIGIBLE AQUACULTURE PRODUCER.—The term "eligible aquaculture producer" means an aquaculture producer that during the 2008 calendar year, as determined by the Secretary—

(i) produced an aquaculture species for which feed costs represented a substantial percentage of the input costs of the aquaculture operation; and

(ii) experienced a substantial price increase of feed costs above the previous 5-year average.

(B) SECRETARY.—The term "Secretary" means the Secretary of Agriculture.

(2) GRANT PROGRAM.—

(A) IN GENERAL.—Of the funds of the Commodity Credit Corporation, the Secretary shall use not more than $50,000,000, to remain available until September 30, 2010, to carry out a program of grants to States to assist eligible aquaculture producers for losses associated with high feed input costs during the 2008 calendar year.

(B) NOTIFICATION.—Not later than 60 days after the date of enactment of this Act, the Secretary shall notify the State department of agriculture (or similar entity) in each State of the availability of funds to assist eligible aquaculture producers, including such terms as determined by the Secretary to be necessary for the equitable treatment of eligible aquaculture producers. Deadline.

(C) PROVISION OF GRANTS.—

(i) IN GENERAL.—The Secretary shall make grants to States under this subsection on a pro rata basis based on the amount of aquaculture feed used in each State during the 2007 calendar year, as determined by the Secretary.

Deadline.

(ii) TIMING.—Not later than 120 days after the date of enactment of this Act, the Secretary shall make grants to States to provide assistance under this subsection.

Deadlines.

(D) REQUIREMENTS.—The Secretary shall make grants under this subsection only to States that demonstrate to the satisfaction of the Secretary that the State will—

(i) use grant funds to assist eligible aquaculture producers;

(ii) provide assistance to eligible aquaculture producers not later than 60 days after the date on which the State receives grant funds; and

Reports.

(iii) not later than 30 days after the date on which the State provides assistance to eligible aquaculture producers, submit to the Secretary a report that describes—

(I) the manner in which the State provided assistance;

(II) the amounts of assistance provided per species of aquaculture; and

(III) the process by which the State determined the levels of assistance to eligible aquaculture producers.

(3) REDUCTION IN PAYMENTS.—An eligible aquaculture producer that receives assistance under this subsection shall not be eligible to receive any other assistance under the supplemental agricultural disaster assistance program established under section 531 of the Federal Crop Insurance Act (7 U.S.C. 1531) and section 901 of the Trade Act of 1974 (19 U.S.C. 2497) for any losses in 2008 relating to the same species of aquaculture.

(4) REPORT TO CONGRESS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a report that—

(A) describes in detail the manner in which this subsection has been carried out; and

(B) includes the information reported to the Secretary under paragraph (2)(D)(iii).

SEC. 103. For fiscal years 2009 and 2010, in the case of each program established or amended by the Food, Conservation, and Energy Act of 2008 (Public Law 110–246), other than by title I of such Act, that is authorized or required to be carried out using funds of the Commodity Credit Corporation—

(1) such funds shall be available for the purpose of covering salaries and related administrative expenses, including technical assistance, associated with the implementation of the program, without regard to the limitation on the total amount of allotments and fund transfers contained in section 11 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714i); and

(2) the use of such funds for such purpose shall not be considered to be a fund transfer or allotment for purposes

of applying the limitation on the total amount of allotments and fund transfers contained in such section.

SEC. 104. In addition to other available funds, of the funds made available to the Rural Development mission area in this title, not more than 3 percent of the funds can be used for administrative costs to carry out loan, loan guarantee and grant activities funded in this title, which shall be transferred to and merged with the appropriation for "Rural Development, Salaries and Expenses": *Provided,* That of this amount $1,750,000 shall be committed to agency projects associated with maintaining the compliance, safety, and soundness of the portfolio of loans guaranteed through the section 502 guaranteed loan program.

SEC. 105. Of the amounts appropriated in this title to the "Rural Housing Service, Rural Community Facilities Program Account", the "Rural Business-Cooperative Service, Rural Business Program Account", and the "Rural Utilities Service, Rural Water and Waste Disposal Program Account", at least 10 percent shall be allocated for assistance in persistent poverty counties: *Provided,* That for the purposes of this section, the term "persistent poverty counties" means any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1980, 1990, and 2000 decennial censuses.

Definition.

TITLE II—COMMERCE, JUSTICE, SCIENCE, AND RELATED AGENCIES

DEPARTMENT OF COMMERCE

ECONOMIC DEVELOPMENT ADMINISTRATION

ECONOMIC DEVELOPMENT ASSISTANCE PROGRAMS

For an additional amount for "Economic Development Assistance Programs", $150,000,000: *Provided,* That $50,000,000 shall be for economic adjustment assistance as authorized by section 209 of the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3149): *Provided further,* That in allocating the funds provided in the previous proviso, the Secretary of Commerce shall give priority consideration to areas of the Nation that have experienced sudden and severe economic dislocation and job loss due to corporate restructuring: *Provided further*, That not to exceed 2 percent of the funds provided under this heading may be transferred to and merged with the appropriation for "Salaries and Expenses" for purposes of program administration and oversight: *Provided further*, That up to $50,000,000 of the funds provided under this heading may be transferred to federally authorized regional economic development commissions.

BUREAU OF THE CENSUS

PERIODIC CENSUSES AND PROGRAMS

For an additional amount for "Periodic Censuses and Programs", $1,000,000,000.

NATIONAL TELECOMMUNICATIONS AND INFORMATION ADMINISTRATION

BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM

Grants.

For an amount for "Broadband Technology Opportunities Program", $4,700,000,000: *Provided,* That of the funds provided under this heading, not less than $4,350,000,000 shall be expended pursuant to division B of this Act, of which: not less than $200,000,000 shall be available for competitive grants for expanding public computer center capacity, including at community colleges and public libraries; not less than $250,000,000 shall be available for competitive grants for innovative programs to encourage sustainable adoption of broadband service; and $10,000,000 shall be transferred to "Department of Commerce, Office of Inspector General" for the purposes of audits and oversight of funds provided under this heading and such funds shall remain available until expended: *Provided further,* That of the funds provided under this heading, up to $350,000,000 may be expended pursuant to Public Law 110–385 (47 U.S.C. 1301 note) and for the purposes of developing and maintaining a broadband inventory map pursuant to division B of this Act: *Provided further,* That of the funds provided under this heading, amounts deemed necessary and appropriate by the Secretary of Commerce, in consultation with the Federal Communications Commission (FCC), may be transferred to the FCC for the purposes of developing a national broadband plan or for carrying out any other FCC responsibilities pursuant to division B of this Act, and only if the Committees on Appropriations of the House and the Senate are notified not less than 15 days in advance of the transfer of such funds: *Provided further,* That not more than 3 percent of funds provided under this heading may be used for administrative costs, and this limitation shall apply to funds which may be transferred to the FCC.

Notification. Deadline.

Applicability.

DIGITAL-TO-ANALOG CONVERTER BOX PROGRAM

For an amount for "Digital-to-Analog Converter Box Program", $650,000,000, for additional coupons and related activities under the program implemented under section 3005 of the Digital Television Transition and Public Safety Act of 2005: *Provided,* That of the amounts provided under this heading, $90,000,000 may be for education and outreach, including grants to organizations for programs to educate vulnerable populations, including senior citizens, minority communities, people with disabilities, low-income individuals, and people living in rural areas, about the transition and to provide one-on-one assistance to vulnerable populations, including help with converter box installation: *Provided further,* That the amounts provided in the previous proviso may be transferred to the Federal Communications Commission (FCC) if deemed necessary and appropriate by the Secretary of Commerce in consultation with the FCC, and only if the Committees on Appropriations of the House and the Senate are notified not less than 5 days in advance of transfer of such funds.

Notification. Deadline.

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

SCIENTIFIC AND TECHNICAL RESEARCH AND SERVICES

For an additional amount for "Scientific and Technical Research and Services", $220,000,000.

CONSTRUCTION OF RESEARCH FACILITIES

For an additional amount for "Construction of Research Facilities", $360,000,000, of which $180,000,000 shall be for a competitive construction grant program for research science buildings.

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

OPERATIONS, RESEARCH, AND FACILITIES

For an additional amount for "Operations, Research, and Facilities", $230,000,000.

PROCUREMENT, ACQUISITION AND CONSTRUCTION

For an additional amount for "Procurement, Acquisition and Construction", $600,000,000.

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $6,000,000, to remain available until September 30, 2013.

DEPARTMENT OF JUSTICE

GENERAL ADMINISTRATION

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $2,000,000, to remain available until September 30, 2013.

STATE AND LOCAL LAW ENFORCEMENT ACTIVITIES

OFFICE ON VIOLENCE AGAINST WOMEN

VIOLENCE AGAINST WOMEN PREVENTION AND PROSECUTION PROGRAMS

Grants.

For an additional amount for "Violence Against Women Prevention and Prosecution Programs", $225,000,000 for grants to combat violence against women, as authorized by part T of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796gg et seq.): *Provided,* That, $50,000,000 shall be for transitional housing assistance grants for victims of domestic violence, stalking or sexual assault as authorized by section 40299 of the Violent Crime Control and Law Enforcement Act of 1994 (Public Law 103–322).

OFFICE OF JUSTICE PROGRAMS

STATE AND LOCAL LAW ENFORCEMENT ASSISTANCE

For an additional amount for "State and Local Law Enforcement Assistance", $2,000,000,000, for the Edward Byrne Memorial Justice Assistance Grant program as authorized by subpart 1 of part E of title I of the Omnibus Crime Control and Safe Streets Acts of 1968 ("1968 Act"), (except that section 1001(c), and the special rules for Puerto Rico under section 505(g), of the 1968 Act, shall not apply for purposes of this Act).

For an additional amount for "State and Local Law Enforcement Assistance", $225,000,000, for competitive grants to improve the functioning of the criminal justice system, to assist victims of crime (other than compensation), and youth mentoring grants.

For an additional amount for "State and Local Law Enforcement Assistance", $40,000,000, for competitive grants to provide assistance and equipment to local law enforcement along the Southern border and in High-Intensity Drug Trafficking Areas to combat criminal narcotics activity stemming from the Southern border, of which $10,000,000 shall be transferred to "Bureau of Alcohol, Tobacco, Firearms and Explosives, Salaries and Expenses" for the ATF Project Gunrunner.

For an additional amount for "State and Local Law Enforcement Assistance", $225,000,000, for assistance to Indian tribes, notwithstanding Public Law 108–199, division B, title I, section 112(a)(1) (118 Stat. 62), which shall be available for grants under section 20109 of subtitle A of title II of the Violent Crime Control and Law Enforcement Act of 1994 (Public Law 103–322).

For an additional amount for "State and Local Law Enforcement Assistance", $100,000,000, to be distributed by the Office for Victims of Crime in accordance with section 1402(d)(4) of the Victims of Crime Act of 1984 (Public Law 98–473).

For an additional amount for "State and Local Law Enforcement Assistance", $125,000,000, for assistance to law enforcement in rural States and rural areas, to prevent and combat crime, especially drug-related crime.

For an additional amount for "State and Local Law Enforcement Assistance", $50,000,000, for Internet Crimes Against Children (ICAC) initiatives.

COMMUNITY ORIENTED POLICING SERVICES

For an additional amount for "Community Oriented Policing Services", for grants under section 1701 of title I of the 1968 Omnibus Crime Control and Safe Streets Act (42 U.S.C. 3796dd) for hiring and rehiring of additional career law enforcement officers under part Q of such title, notwithstanding subsection (i) of such section, $1,000,000,000.

SALARIES AND EXPENSES

For an additional amount, not elsewhere specified in this title, for management and administration and oversight of programs within the Office on Violence Against Women, the Office of Justice Programs, and the Community Oriented Policing Services Office, $10,000,000.

SCIENCE

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

SCIENCE

For an additional amount for "Science", $400,000,000.

AERONAUTICS

For an additional amount for "Aeronautics", $150,000,000.

EXPLORATION

For an additional amount for "Exploration", $400,000,000.

CROSS AGENCY SUPPORT

For an additional amount for "Cross Agency Support", $50,000,000.

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $2,000,000, to remain available until September 30, 2013.

NATIONAL SCIENCE FOUNDATION

RESEARCH AND RELATED ACTIVITIES

For an additional amount for "Research and Related Activities", $2,500,000,000: *Provided*, That $300,000,000 shall be available solely for the Major Research Instrumentation program and $200,000,000 shall be for activities authorized by title II of Public Law 100–570 for academic research facilities modernization.

EDUCATION AND HUMAN RESOURCES

For an additional amount for "Education and Human Resources", $100,000,000.

MAJOR RESEARCH EQUIPMENT AND FACILITIES CONSTRUCTION

For an additional amount for "Major Research Equipment and Facilities Construction", $400,000,000.

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $2,000,000, to remain available until September 30, 2013.

GENERAL PROVISION—THIS TITLE

SEC. 201. Sections 1701(g) and 1704(c) of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796dd(g) and 3796dd–3(c)) shall not apply with respect to funds appropriated in this or any other Act making appropriations for fiscal year 2009 or 2010 for Community Oriented Policing Services authorized under part Q of such Act of 1968.

TITLE III—DEPARTMENT OF DEFENSE

OPERATION AND MAINTENANCE

OPERATION AND MAINTENANCE, ARMY

For an additional amount for "Operation and Maintenance, Army", $1,474,525,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, NAVY

For an additional amount for "Operation and Maintenance, Navy", $657,051,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, MARINE CORPS

For an additional amount for "Operation and Maintenance, Marine Corps", $113,865,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, AIR FORCE

For an additional amount for "Operation and Maintenance, Air Force", $1,095,959,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, ARMY RESERVE

For an additional amount for "Operation and Maintenance, Army Reserve", $98,269,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, NAVY RESERVE

For an additional amount for "Operation and Maintenance, Navy Reserve", $55,083,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, MARINE CORPS RESERVE

For an additional amount for "Operation and Maintenance, Marine Corps Reserve", $39,909,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, AIR FORCE RESERVE

For an additional amount for "Operation and Maintenance, Air Force Reserve", $13,187,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, ARMY NATIONAL GUARD

For an additional amount for "Operation and Maintenance, Army National Guard", $266,304,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

OPERATION AND MAINTENANCE, AIR NATIONAL GUARD

For an additional amount for "Operation and Maintenance, Air National Guard", $25,848,000, to remain available for obligation until September 30, 2010, to improve, repair and modernize Department of Defense facilities, restore and modernize real property to include barracks, and invest in the energy efficiency of Department of Defense facilities.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, ARMY

For an additional amount for "Research, Development, Test and Evaluation, Army", $75,000,000, to remain available for obligation until September 30, 2010.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, NAVY

For an additional amount for "Research, Development, Test and Evaluation, Navy", $75,000,000, to remain available for obligation until September 30, 2010.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, AIR FORCE

For an additional amount for "Research, Development, Test and Evaluation, Air Force", $75,000,000, to remain available for obligation until September 30, 2010.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, DEFENSE-WIDE

For an additional amount for "Research, Development, Test and Evaluation, Defense-Wide", $75,000,000, to remain available for obligation until September 30, 2010.

OTHER DEPARTMENT OF DEFENSE PROGRAMS

DEFENSE HEALTH PROGRAM

For an additional amount for "Defense Health Program", $400,000,000 for operation and maintenance, to remain available for obligation until September 30, 2010, to improve, repair and modernize military medical facilities, and invest in the energy efficiency of military medical facilities.

OFFICE OF THE INSPECTOR GENERAL

For an additional amount for "Office of the Inspector General", $15,000,000 for operation and maintenance, to remain available for obligation until September 30, 2011.

TITLE IV—ENERGY AND WATER DEVELOPMENT

DEPARTMENT OF DEFENSE—CIVIL

DEPARTMENT OF THE ARMY

CORPS OF ENGINEERS—CIVIL

INVESTIGATIONS

For an additional amount for "Investigations", $25,000,000: *Provided,* That funds provided under this heading in this title shall only be used for programs, projects or activities that heretofore or hereafter receive funds provided in Acts making appropriations available for Energy and Water Development: *Provided further,* That funds provided under this heading in this title shall be used for programs, projects or activities or elements of programs, projects or activities that can be completed within the funds made available in that account and that will not require new budget authority to complete: *Provided further,* That for projects that are being completed with funds appropriated in this Act that would otherwise be expired for obligation, expired funds appropriated in this Act may be used to pay the cost of associated supervision, inspection, overhead, engineering and design on those projects and on subsequent claims, if any: *Provided further,* That the Secretary of the Army shall submit a quarterly report to the Committees on Appropriations of the House of Representatives and the Senate detailing the allocation, obligation and expenditures of these funds, beginning not later than 45 days after enactment of this Act: *Provided further,* That the Secretary shall have unlimited reprogramming authority for these funds provided under this heading.

Deadlines.
Reports.

CONSTRUCTION

For an additional amount for "Construction", $2,000,000,000: *Provided,* That not less than $200,000,000 of the funds provided

shall be for water-related environmental infrastructure assistance: *Provided further,* That section 102 of Public Law 109–103 (33 U.S.C. 2221) shall not apply to funds provided in this title: *Provided further,* That notwithstanding any other provision of law, funds provided in this paragraph shall not be cost shared with the Inland Waterways Trust Fund as authorized in Public Law 99–662: *Provided further,* That funds provided under this heading in this title shall only be used for programs, projects or activities that heretofore or hereafter receive funds provided in Acts making appropriations available for Energy and Water Development: *Provided further,* That funds provided under this heading in this title shall be used for programs, projects or activities or elements of programs, projects or activities that can be completed within the funds made available in that account and that will not require new budget authority to complete: *Provided further,* That the limitation concerning total project costs in section 902 of the Water Resources Development Act of 1986, as amended (33 U.S.C. 2280), shall not apply during fiscal year 2009 to any project that received funds provided in this title: *Provided further,* That funds appropriated under this heading may be used by the Secretary of the Army, acting through the Chief of Engineers, to undertake work authorized to be carried out in accordance with section 14 of the Flood Control Act of 1946 (33 U.S.C. 701r); section 205 of the Flood Control Act of 1948 (33 U.S.C. 701s); section 206 of the Water Resources Development Act of 1996 (33 U.S.C. 2330); or section 1135 of the Water Resources Development Act of 1986 (33 U.S.C. 2309a), notwithstanding the program cost limitations set forth in those sections: *Provided further,* That for projects that are being completed with funds appropriated in this Act that would otherwise be expired for obligation, expired funds appropriated in this Act may be used to pay the cost of associated supervision, inspection, overhead, engineering and design on those projects and on subsequent claims, if any: *Provided further,* That the Secretary of the Army shall submit a quarterly report to the Committees on Appropriations of the House of Representatives and the Senate detailing the allocation, obligation and expenditures of these funds, beginning not later than 45 days after enactment of this Act: *Provided further,* That the Secretary shall have unlimited reprogramming authority for these funds provided under this heading.

Deadlines.
Reports.

MISSISSIPPI RIVER AND TRIBUTARIES

For an additional amount for "Mississippi River and Tributaries", $375,000,000: *Provided,* That funds provided under this heading in this title shall only be used for programs, projects or activities that heretofore or hereafter receive funds provided in Acts making appropriations available for Energy and Water Development: *Provided further,* That funds provided under this heading in this title shall be used for programs, projects or activities or elements of programs, projects or activities that can be completed within the funds made available in that account and that will not require new budget authority to complete: *Provided further,* That the limitation concerning total project costs in section 902 of the Water Resources Development Act of 1986, as amended (33 U.S.C. 2280), shall not apply during fiscal year 2009 to any project that received funds provided in this title: *Provided further,* That for projects that are being completed with funds appropriated

in this Act that would otherwise be expired for obligation, expired funds appropriated in this Act may be used to pay the cost of associated supervision, inspection, overhead, engineering and design on those projects and on subsequent claims, if any: *Provided further,* That the Secretary of the Army shall submit a quarterly report to the Committees on Appropriations of the House of Representatives and the Senate detailing the allocation, obligation and expenditures of these funds, beginning not later than 45 days after enactment of this Act: *Provided further,* That the Secretary shall have unlimited reprogramming authority for these funds provided under this heading.

Deadlines.
Reports.

OPERATION AND MAINTENANCE

For an additional amount for "Operation and Maintenance", $2,075,000,000: *Provided,* That funds provided under this heading in this title shall only be used for programs, projects or activities that heretofore or hereafter receive funds provided in Acts making appropriations available for Energy and Water Development: *Provided further,* That funds provided under this heading in this title shall be used for programs, projects or activities or elements of programs, projects or activities that can be completed within the funds made available in that account and that will not require new budget authority to complete: *Provided further,* That section 9006 of Public Law 110–114 shall not apply to funds provided in this title: *Provided further,* That for projects that are being completed with funds appropriated in this Act that would otherwise be expired for obligation, expired funds appropriated in this Act may be used to pay the cost of associated supervision, inspection, overhead, engineering and design on those projects and on subsequent claims, if any: *Provided further,* That the Secretary of the Army shall submit a quarterly report to the Committees on Appropriations of the House of Representatives and the Senate detailing the allocation, obligation and expenditures of these funds, beginning not later than 45 days after enactment of this Act: *Provided further,* That the Secretary shall have unlimited reprogramming authority for these funds provided under this heading.

Deadlines.
Reports.

REGULATORY PROGRAM

For an additional amount for "Regulatory Program", $25,000,000.

FORMERLY UTILIZED SITES REMEDIAL ACTION PROGRAM

For an additional amount for "Formerly Utilized Sites Remedial Action Program", $100,000,000: *Provided,* That funds provided under this heading in this title shall be used for programs, projects or activities or elements of programs, projects or activities that can be completed within the funds made available in that account and that will not require new budget authority to complete: *Provided further,* That for projects that are being completed with funds appropriated in this Act that would otherwise be expired for obligation, expired funds appropriated in this Act may be used to pay the cost of associated supervision, inspection, overhead, engineering and design on those projects and on subsequent claims, if any: *Provided further,* That the Secretary of the Army shall submit a quarterly report to the Committees on Appropriations

Deadlines.
Reports.

of the House of Representatives and the Senate detailing the allocation, obligation and expenditures of these funds, beginning not later than 45 days after enactment of this Act: *Provided further,* That the Secretary shall have unlimited reprogramming authority for these funds provided under this heading.

DEPARTMENT OF THE INTERIOR

BUREAU OF RECLAMATION

WATER AND RELATED RESOURCES

For an additional amount for "Water and Related Resources", $1,000,000,000: *Provided,* That of the amount appropriated under this heading, not less than $126,000,000 shall be used for water reclamation and reuse projects authorized under title XVI of Public Law 102–575: *Provided further,* That funds provided in this Act shall be used for elements of projects, programs or activities that can be completed within these funding amounts and not create budgetary obligations in future fiscal years: *Provided further,* That $50,000,000 of the funds provided under this heading may be transferred to the Department of the Interior for programs, projects and activities authorized by the Central Utah Project Completion Act (titles II–V of Public Law 102–575): *Provided further,* That $50,000,000 of the funds provided under this heading may be used for programs, projects, and activities authorized by the California Bay-Delta Restoration Act (Public Law 108–361): *Provided further,* That not less than $60,000,000 of the funds provided under this heading shall be used for rural water projects and shall be expended primarily on water intake and treatment facilities of such projects: *Provided further,* That not less than $10,000,000 of the funds provided under this heading shall be used for a bureau-wide inspection of canals program in urbanized areas: *Provided further,* That the costs of extraordinary maintenance and replacement activities carried out with funds provided in this Act shall be repaid pursuant to existing authority, except the length of repayment period shall be as determined by the Commissioner, but in no case shall the repayment period exceed 50 years and the repayment shall include interest, at a rate determined by the Secretary of the Treasury as of the beginning of the fiscal year in which the work is commenced, on the basis of average market yields on outstanding marketable obligations of the United States with the remaining periods of maturity comparable to the applicable reimbursement period of the project adjusted to the nearest one-eighth of 1 percent on the unamortized balance of any portion of the loan: *Provided further,* That for projects that are being completed with funds appropriated in this Act that would otherwise be expired for obligation, expired funds appropriated in this Act may be used to pay the cost of associated supervision, inspection, overhead, engineering and design on those projects and on subsequent claims, if any: *Provided further,* That the Secretary of the Interior shall submit a quarterly report to the Committees on Appropriations of the House of Representatives and the Senate detailing the allocation, obligation and expenditures of these funds, beginning not later than 45 days after enactment of this Act: *Provided further,* That the Secretary shall have unlimited reprogramming authority for these funds provided under this heading.

Deadlines.
Reports.

DEPARTMENT OF ENERGY

ENERGY PROGRAMS

ENERGY EFFICIENCY AND RENEWABLE ENERGY

For an additional amount for "Energy Efficiency and Renewable Energy", $16,800,000,000: *Provided,* That $3,200,000,000 shall be available for Energy Efficiency and Conservation Block Grants for implementation of programs authorized under subtitle E of title V of the Energy Independence and Security Act of 2007 (42 U.S.C. 17151 et seq.), of which $2,800,000,000 is available through the formula in subtitle E: *Provided further,* That the Secretary may use the most recent and accurate population data available to satisfy the requirements of section 543(b) of the Energy Independence and Security Act of 2007: *Provided further,* That the remaining $400,000,000 shall be awarded on a competitive basis: *Provided further,* That $5,000,000,000 shall be for the Weatherization Assistance Program under part A of title IV of the Energy Conservation and Production Act (42 U.S.C. 6861 et seq.): *Provided further,* That $3,100,000,000 shall be for the State Energy Program authorized under part D of title III of the Energy Policy and Conservation Act (42 U.S.C. 6321): *Provided further,* That $2,000,000,000 shall be available for grants for the manufacturing of advanced batteries and components and the Secretary shall provide facility funding awards under this section to manufacturers of advanced battery systems and vehicle batteries that are produced in the United States, including advanced lithium ion batteries, hybrid electrical systems, component manufacturers, and software designers: *Provided further,* That notwithstanding section 3304 of title 5, United States Code, and without regard to the provisions of sections 3309 through 3318 of such title 5, the Secretary of Energy, upon a determination that there is a severe shortage of candidates or a critical hiring need for particular positions, may from within the funds provided, recruit and directly appoint highly qualified individuals into the competitive service: *Provided further,* That such authority shall not apply to positions in the Excepted Service or the Senior Executive Service: *Provided further,* That any action authorized herein shall be consistent with the merit principles of section 2301 of such title 5, and the Department shall comply with the public notice requirements of section 3327 of such title 5.

Grants.

ELECTRICITY DELIVERY AND ENERGY RELIABILITY

For an additional amount for "Electricity Delivery and Energy Reliability," $4,500,000,000: *Provided*, That funds shall be available for expenses necessary for electricity delivery and energy reliability activities to modernize the electric grid, to include demand responsive equipment, enhance security and reliability of the energy infrastructure, energy storage research, development, demonstration and deployment, and facilitate recovery from disruptions to the energy supply, and for implementation of programs authorized under title XIII of the Energy Independence and Security Act of 2007 (42 U.S.C. 17381 et seq.): *Provided further,* That $100,000,000 shall be available for worker training activities: *Provided further,* That notwithstanding section 3304 of title 5, United States Code, and without regard to the provisions of sections 3309 through 3318

of such title 5, the Secretary of Energy, upon a determination that there is a severe shortage of candidates or a critical hiring need for particular positions, may from within the funds provided, recruit and directly appoint highly qualified individuals into the competitive service: *Provided further,* That such authority shall not apply to positions in the Excepted Service or the Senior Executive Service: *Provided further,* That any action authorized herein shall be consistent with the merit principles of section 2301 of such title 5, and the Department shall comply with the public notice requirements of section 3327 of such title 5: *Provided further,* That for the purpose of facilitating the development of regional transmission plans, the Office of Electricity Delivery and Energy Reliability within the Department of Energy is provided $80,000,000 within the available funds to conduct a resource assessment and an analysis of future demand and transmission requirements after consultation with the Federal Energy Regulatory Commission: *Provided further,* That the Office of Electricity Delivery and Energy Reliability in coordination with the Federal Energy Regulatory Commission will provide technical assistance to the North American Electric Reliability Corporation, the regional reliability entities, the States, and other transmission owners and operators for the formation of interconnection-based transmission plans for the Eastern and Western Interconnections and ERCOT: *Provided further,* That such assistance may include modeling, support to regions and States for the development of coordinated State electricity policies, programs, laws, and regulations: *Provided further,* That $10,000,000 is provided to implement section 1305 of Public Law 110–140: *Provided further*, That the Secretary of Energy may use or transfer amounts provided under this heading to carry out new authority for transmission improvements, if such authority is enacted in any subsequent Act, consistent with existing fiscal management practices and procedures.

FOSSIL ENERGY RESEARCH AND DEVELOPMENT

For an additional amount for "Fossil Energy Research and Development", $3,400,000,000.

NON-DEFENSE ENVIRONMENTAL CLEANUP

For an additional amount for "Non-Defense Environmental Cleanup", $483,000,000.

URANIUM ENRICHMENT DECONTAMINATION AND DECOMMISSIONING FUND

For an additional amount for "Uranium Enrichment Decontamination and Decommissioning Fund", $390,000,000, of which $70,000,000 shall be available in accordance with title X, subtitle A of the Energy Policy Act of 1992.

SCIENCE

For an additional amount for "Science", $1,600,000,000.

ADVANCED RESEARCH PROJECTS AGENCY—ENERGY

For the Advanced Research Projects Agency—Energy, $400,000,000, as authorized under section 5012 of the America COMPETES Act (42 U.S.C. 16538).

TITLE 17—INNOVATIVE TECHNOLOGY LOAN GUARANTEE PROGRAM

For an additional amount for the cost of guaranteed loans authorized by section 1705 of the Energy Policy Act of 2005, $6,000,000,000, available until expended, to pay the costs of guarantees made under this section: *Provided,* That of the amount provided for title XVII, $25,000,000 shall be used for administrative expenses in carrying out the guaranteed loan program: *Provided further,* That of the amounts provided for title XVII, $10,000,000 shall be transferred to and available for administrative expenses for the Advanced Technology Vehicles Manufacturing Loan Program.

OFFICE OF THE INSPECTOR GENERAL

For necessary expenses of the Office of the Inspector General in carrying out the provisions of the Inspector General Act of 1978, as amended, $15,000,000, to remain available until September 30, 2012.

ENVIRONMENTAL AND OTHER DEFENSE ACTIVITIES

DEFENSE ENVIRONMENTAL CLEANUP

For an additional amount for "Defense Environmental Cleanup," $5,127,000,000.

CONSTRUCTION, REHABILITATION, OPERATION, AND MAINTENANCE, WESTERN AREA POWER ADMINISTRATION

For carrying out the functions authorized by title III, section 302(a)(1)(E) of the Act of August 4, 1977 (42 U.S.C. 7152), and other related activities including conservation and renewable resources programs as authorized, $10,000,000, to remain available until expended: *Provided,* That the Administrator shall establish such personnel staffing levels as he deems necessary to economically and efficiently complete the activities pursued under the authority granted by section 402 of this Act: *Provided further,* That this appropriation is non-reimbursable.

GENERAL PROVISIONS—THIS TITLE

SEC. 401. BONNEVILLE POWER ADMINISTRATION BORROWING AUTHORITY. For the purposes of providing funds to assist in financing the construction, acquisition, and replacement of the transmission system of the Bonneville Power Administration and to implement the authority of the Administrator of the Bonneville Power Administration under the Pacific Northwest Electric Power Planning and Conservation Act (16 U.S.C. 839 et seq.), an additional $3,250,000,000 in borrowing authority is made available under the Federal Columbia River Transmission System Act (16 U.S.C. 838 et seq.), to remain outstanding at any time.

SEC. 402. WESTERN AREA POWER ADMINISTRATION BORROWING AUTHORITY. The Hoover Power Plant Act of 1984 (Public Law 98–381) is amended by adding at the end the following:

"TITLE III—BORROWING AUTHORITY

"SEC. 301. WESTERN AREA POWER ADMINISTRATION BORROWING AUTHORITY. 42 USC 16421a.

"(a) DEFINITIONS.—In this section:

"(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Western Area Power Administration.

"(2) SECRETARY.—The term 'Secretary' means the Secretary of the Treasury.

"(b) AUTHORITY.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, subject to paragraphs (2) through (5)—

"(A) the Western Area Power Administration may borrow funds from the Treasury; and

"(B) the Secretary shall, without further appropriation and without fiscal year limitation, loan to the Western Area Power Administration, on such terms as may be fixed by the Administrator and the Secretary, such sums (not to exceed, in the aggregate (including deferred interest), $3,250,000,000 in outstanding repayable balances at any one time) as, in the judgment of the Administrator, are from time to time required for the purpose of—

"(i) constructing, financing, facilitating, planning, operating, maintaining, or studying construction of new or upgraded electric power transmission lines and related facilities with at least one terminus within the area served by the Western Area Power Administration; and

"(ii) delivering or facilitating the delivery of power generated by renewable energy resources constructed or reasonably expected to be constructed after the date of enactment of this section.

"(2) INTEREST.—The rate of interest to be charged in connection with any loan made pursuant to this subsection shall be fixed by the Secretary, taking into consideration market yields on outstanding marketable obligations of the United States of comparable maturities as of the date of the loan.

"(3) REFINANCING.—The Western Area Power Administration may refinance loans taken pursuant to this section within the Treasury.

"(4) PARTICIPATION.—The Administrator may permit other entities to participate in the financing, construction and ownership projects financed under this section.

"(5) CONGRESSIONAL REVIEW OF DISBURSEMENT.—Effective upon the date of enactment of this section, the Administrator shall have the authority to have utilized $1,750,000,000 at any one time. If the Administrator seeks to borrow funds above $1,750,000,000, the funds will be disbursed unless there is enacted, within 90 calendar days of the first such request, a joint resolution that rescinds the remainder of the balance of the borrowing authority provided in this section. Effective date. Deadline.

"(c) TRANSMISSION LINE AND RELATED FACILITY PROJECTS.—

"(1) IN GENERAL.—For repayment purposes, each transmission line and related facility project in which the Western Area Power Administration participates pursuant to this section shall be treated as separate and distinct from—

"(A) each other such project; and

"(B) all other Western Area Power Administration power and transmission facilities.

"(2) PROCEEDS.—The Western Area Power Administration shall apply the proceeds from the use of the transmission capacity from an individual project under this section to the repayment of the principal and interest of the loan from the Treasury attributable to that project, after reserving such funds as the Western Area Power Administration determines are necessary—

"(A) to pay for any ancillary services that are provided; and

"(B) to meet the costs of operating and maintaining the new project from which the revenues are derived.

"(3) SOURCE OF REVENUE.—Revenue from the use of projects under this section shall be the only source of revenue for—

"(A) repayment of the associated loan for the project; and

"(B) payment of expenses for ancillary services and operation and maintenance.

"(4) LIMITATION ON AUTHORITY.—Nothing in this section confers on the Administrator any additional authority or obligation to provide ancillary services to users of transmission facilities developed under this section.

"(5) TREATMENT OF CERTAIN REVENUES.—Revenue from ancillary services provided by existing Federal power systems to users of transmission projects funded pursuant to this section shall be treated as revenue to the existing power system that provided the ancillary services.

"(d) CERTIFICATION.—

"(1) IN GENERAL.—For each project in which the Western Area Power Administration participates pursuant to this section, the Administrator shall certify, prior to committing funds for any such project, that—

"(A) the project is in the public interest;

"(B) the project will not adversely impact system reliability or operations, or other statutory obligations; and

"(C) it is reasonable to expect that the proceeds from the project shall be adequate to make repayment of the loan.

"(2) FORGIVENESS OF BALANCES.—

"(A) IN GENERAL.—If, at the end of the useful life of a project, there is a remaining balance owed to the Treasury under this section, the balance shall be forgiven.

"(B) UNCONSTRUCTED PROJECTS.—Funds expended to study projects that are considered pursuant to this section but that are not constructed shall be forgiven.

"(C) NOTIFICATION.—The Administrator shall notify the Secretary of such amounts as are to be forgiven under this paragraph.

"(e) PUBLIC PROCESSES.—

"(1) POLICIES AND PRACTICES.—Prior to requesting any loans under this section, the Administrator shall use a public

process to develop practices and policies that implement the authority granted by this section.

"(2) REQUESTS FOR INTEREST.—In the course of selecting potential projects to be funded under this section, the Administrator shall seek Requests For Interest from entities interested in identifying potential projects through one or more notices published in the Federal Register."

Notice. Federal Register, publication.

SEC. 403. SET-ASIDE FOR MANAGEMENT AND OVERSIGHT. Up to 0.5 percent of each amount appropriated in this title may be used for the expenses of management and oversight of the programs, grants, and activities funded by such appropriation, and may be transferred by the head of the Federal department or agency involved to any other appropriate account within the department or agency for that purpose: *Provided,* That the Secretary will provide a report to the Committees on Appropriations of the House of Representatives and the Senate 30 days prior to the transfer: *Provided further,* That funds set aside under this section shall remain available for obligation until September 30, 2012.

Reports. Deadline.

SEC. 404. TECHNICAL CORRECTIONS TO THE ENERGY INDEPENDENCE AND SECURITY ACT OF 2007. (a) Section 543(a) of the Energy Independence and Security Act of 2007 (42 U.S.C. 17153(a)) is amended—

(1) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5), respectively; and

(2) by striking paragraph (1) and inserting the following:

"(1) 34 percent to eligible units of local government—alternative 1, in accordance with subsection (b);

"(2) 34 percent to eligible units of local government—alternative 2, in accordance with subsection (b);".

(b) Section 543(b) of the Energy Independence and Security Act of 2007 (42 U.S.C. 17153(b)) is amended by striking "subsection (a)(1)" and inserting "subsection (a)(1) or (2)".

(c) Section 548(a)(1) of the Energy Independence and Security Act of 2007 (42 U.S.C. 17158(a)(1)) is amending by striking "; provided" and all that follows through "541(3)(B)".

SEC. 405. AMENDMENTS TO TITLE XIII OF THE ENERGY INDEPENDENCE AND SECURITY ACT OF 2007. Title XIII of the Energy Independence and Security Act of 2007 (42 U.S.C. 17381 and following) is amended as follows:

(1) By amending subparagraph (A) of section 1304(b)(3) to read as follows:

42 USC 17384.

"(A) IN GENERAL.—In carrying out the initiative, the Secretary shall provide financial support to smart grid demonstration projects in urban, suburban, tribal, and rural areas, including areas where electric system assets are controlled by nonprofit entities and areas where electric system assets are controlled by investor-owned utilities.".

(2) By amending subparagraph (C) of section 1304(b)(3) to read as follows:

"(C) FEDERAL SHARE OF COST OF TECHNOLOGY INVESTMENTS.—The Secretary shall provide to an electric utility described in subparagraph (B) or to other parties financial assistance for use in paying an amount equal to not more than 50 percent of the cost of qualifying advanced grid technology investments made by the electric utility or other party to carry out a demonstration project.".

(3) By inserting after section 1304(b)(3)(D) the following new subparagraphs:

Clearinghouse.

"(E) AVAILABILITY OF DATA.—The Secretary shall establish and maintain a smart grid information clearinghouse in a timely manner which will make data from smart grid demonstration projects and other sources available to the public. As a condition of receiving financial assistance under this subsection, a utility or other participant in a smart grid demonstration project shall provide such information as the Secretary may require to become available through the smart grid information clearinghouse in the form and within the timeframes as directed by the Secretary. The Secretary shall assure that business proprietary information and individual customer information is not included in the information made available through the clearinghouse.

"(F) OPEN PROTOCOLS AND STANDARDS.—The Secretary shall require as a condition of receiving funding under this subsection that demonstration projects utilize open protocols and standards (including Internet-based protocols and standards) if available and appropriate.".

42 USC 17384.

(4) By amending paragraph (2) of section 1304(c) to read as follows:

"(2) to carry out subsection (b), such sums as may be necessary.".

42 USC 17386.

(5) By amending subsection (a) of section 1306 by striking "reimbursement of one-fifth (20 percent)" and inserting "grants of up to one-half (50 percent)".

(6) By striking the last sentence of subsection (b)(9) of section 1306.

(7) By striking "are eligible for" in subsection (c)(1) of section 1306 and inserting "utilize".

(8) By amending subsection (e) of section 1306 to read as follows:

Deadline.
Notice.

"(e) PROCEDURES AND RULES.—(1) The Secretary shall, within 60 days after the enactment of the American Recovery and Reinvestment Act of 2009, by means of a notice of intent and subsequent solicitation of grant proposals—

"(A) establish procedures by which applicants can obtain grants of not more than one-half of their documented costs;

"(B) require as a condition of receiving funding under this subsection that demonstration projects utilize open protocols and standards (including Internet-based protocols and standards) if available and appropriate;

"(C) establish procedures to ensure that there is no duplication or multiple payment for the same investment or costs, that the grant goes to the party making the actual expenditures for the qualifying Smart Grid investments, and that the grants made have a significant effect in encouraging and facilitating the development of a smart grid;

"(D) establish procedures to ensure there will be public records of grants made, recipients, and qualifying Smart Grid investments which have received grants; and

"(E) establish procedures to provide advance payment of moneys up to the full amount of the grant award.

"(2) The Secretary shall have discretion and exercise reasonable judgment to deny grants for investments that do not qualify.".

SEC. 406. RENEWABLE ENERGY AND ELECTRIC POWER TRANSMISSION LOAN GUARANTEE PROGRAM. (a) AMENDMENT.—Title XVII of the Energy Policy Act of 2005 (42 U.S.C. 16511 et seq.) is amended by adding the following at the end:

"SEC. 1705. TEMPORARY PROGRAM FOR RAPID DEPLOYMENT OF RENEWABLE ENERGY AND ELECTRIC POWER TRANSMISSION PROJECTS. 42 USC 16516.

"(a) IN GENERAL.—Notwithstanding section 1703, the Secretary may make guarantees under this section only for the following categories of projects that commence construction not later than September 30, 2011:

"(1) Renewable energy systems, including incremental hydropower, that generate electricity or thermal energy, and facilities that manufacture related components.

"(2) Electric power transmission systems, including upgrading and reconductoring projects.

"(3) Leading edge biofuel projects that will use technologies performing at the pilot or demonstration scale that the Secretary determines are likely to become commercial technologies and will produce transportation fuels that substantially reduce life-cycle greenhouse gas emissions compared to other transportation fuels.

"(b) FACTORS RELATING TO ELECTRIC POWER TRANSMISSION SYSTEMS.—In determining to make guarantees to projects described in subsection (a)(2), the Secretary may consider the following factors:

"(1) The viability of the project without guarantees.

"(2) The availability of other Federal and State incentives.

"(3) The importance of the project in meeting reliability needs.

"(4) The effect of the project in meeting a State or region's environment (including climate change) and energy goals.

"(c) WAGE RATE REQUIREMENTS.—The Secretary shall require that each recipient of support under this section provide reasonable assurance that all laborers and mechanics employed in the performance of the project for which the assistance is provided, including those employed by contractors or subcontractors, will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor in accordance with subchapter IV of chapter 31 of part A of subtitle II of title 40, United States Code (commonly referred to as the 'Davis-Bacon Act').

"(d) LIMITATION.—Funding under this section for projects described in subsection (a)(3) shall not exceed $500,000,000.

"(e) SUNSET.—The authority to enter into guarantees under this section shall expire on September 30, 2011.".

(b) TABLE OF CONTENTS AMENDMENT.—The table of contents for the Energy Policy Act of 2005 is amended by inserting after the item relating to section 1704 the following new item:

"Sec. 1705. Temporary program for rapid deployment of renewable energy and electric power transmission projects.".

SEC. 407. WEATHERIZATION ASSISTANCE PROGRAM AMENDMENTS. (a) INCOME LEVEL.—Section 412(7) of the Energy Conservation and Production Act (42 U.S.C. 6862(7)) is amended by striking "150 percent" both places it appears and inserting "200 percent".

(b) ASSISTANCE LEVEL PER DWELLING UNIT.—Section 415(c)(1) of the Energy Conservation and Production Act (42 U.S.C. 6865(c)(1)) is amended by striking "$2,500" and inserting "$6,500".

(c) EFFECTIVE USE OF FUNDS.—In providing funds made available by this Act for the Weatherization Assistance Program, the Secretary may encourage States to give priority to using such funds for the most cost-effective efficiency activities, which may include insulation of attics, if, in the Secretary's view, such use of funds would increase the effectiveness of the program.

(d) TRAINING AND TECHNICAL ASSISTANCE.—Section 416 of the Energy Conservation and Production Act (42 U.S.C. 6866) is amended by striking "10 percent" and inserting "up to 20 percent".

(e) ASSISTANCE FOR PREVIOUSLY WEATHERIZED DWELLING UNITS.—Section 415(c)(2) of the Energy Conservation and Production Act (42 U.S.C. 6865(c)(2)) is amended by striking "September 30, 1979" and inserting "September 30, 1994".

SEC. 408. TECHNICAL CORRECTIONS TO PUBLIC UTILITY REGULATORY POLICIES ACT OF 1978. (a) Section 111(d) of the Public Utility Regulatory Policies Act of 1978 (16 U.S.C. 2621(d)) is amended by redesignating paragraph (16) relating to consideration of smart grid investments (added by section 1307(a) of Public Law 110–140) as paragraph (18) and by redesignating paragraph (17) relating to smart grid information (added by section 1308(a) of Public Law 110–140) as paragraph (19).

(b) Subsections (b) and (d) of section 112 of the Public Utility Regulatory Policies Act of 1978 (16 U.S.C. 2622) are each amended by striking "(17) through (18)" in each place it appears and inserting "(16) through (19)".

SEC. 409. RENEWABLE ELECTRICITY TRANSMISSION STUDY. In completing the 2009 National Electric Transmission Congestion Study, the Secretary of Energy shall include—

(1) an analysis of the significant potential sources of renewable energy that are constrained in accessing appropriate market areas by lack of adequate transmission capacity;

(2) an analysis of the reasons for failure to develop the adequate transmission capacity;

(3) recommendations for achieving adequate transmission capacity;

(4) an analysis of the extent to which legal challenges filed at the State and Federal level are delaying the construction of transmission necessary to access renewable energy; and

(5) an explanation of assumptions and projections made in the Study, including—

(A) assumptions and projections relating to energy efficiency improvements in each load center;

(B) assumptions and projections regarding the location and type of projected new generation capacity; and

(C) assumptions and projections regarding projected deployment of distributed generation infrastructure.

SEC. 410. ADDITIONAL STATE ENERGY GRANTS. (a) IN GENERAL.—Amounts appropriated under the heading "Department of Energy—Energy Programs—Energy Efficiency and Renewable Energy" in this title shall be available to the Secretary of Energy for making additional grants under part D of title III of the Energy Policy and Conservation Act (42 U.S.C. 6321 et seq.). The Secretary shall make grants under this section in excess of the base allocation established for a State under regulations issued pursuant to the

Notification.

authorization provided in section 365(f) of such Act only if the governor of the recipient State notifies the Secretary of Energy in writing that the governor has obtained necessary assurances that each of the following will occur:

(1) The applicable State regulatory authority will seek to implement, in appropriate proceedings for each electric and gas utility, with respect to which the State regulatory authority has ratemaking authority, a general policy that ensures that utility financial incentives are aligned with helping their customers use energy more efficiently and that provide timely cost recovery and a timely earnings opportunity for utilities associated with cost-effective measurable and verifiable efficiency savings, in a way that sustains or enhances utility customers' incentives to use energy more efficiently.

(2) The State, or the applicable units of local government that have authority to adopt building codes, will implement the following:

(A) A building energy code (or codes) for residential buildings that meets or exceeds the most recently published International Energy Conservation Code, or achieves equivalent or greater energy savings.

(B) A building energy code (or codes) for commercial buildings throughout the State that meets or exceeds the ANSI/ASHRAE/IESNA Standard 90.1–2007, or achieves equivalent or greater energy savings.

(C) A plan for the jurisdiction achieving compliance with the building energy code or codes described in subparagraphs (A) and (B) within 8 years of the date of enactment of this Act in at least 90 percent of new and renovated residential and commercial building space. Such plan shall include active training and enforcement programs and measurement of the rate of compliance each year. Deadline.

(3) The State will to the extent practicable prioritize the grants toward funding energy efficiency and renewable energy programs, including—

(A) the expansion of existing energy efficiency programs approved by the State or the appropriate regulatory authority, including energy efficiency retrofits of buildings and industrial facilities, that are funded—

(i) by the State; or

(ii) through rates under the oversight of the applicable regulatory authority, to the extent applicable;

(B) the expansion of existing programs, approved by the State or the appropriate regulatory authority, to support renewable energy projects and deployment activities, including programs operated by entities which have the authority and capability to manage and distribute grants, loans, performance incentives, and other forms of financial assistance; and

(C) cooperation and joint activities between States to advance more efficient and effective use of this funding to support the priorities described in this paragraph.

(b) STATE MATCH.—The State cost share requirement under the item relating to "Department of Energy; Energy Conservation" in title II of the Department of the Interior and Related Agencies

Appropriations Act, 1985 (42 U.S.C. 6323a; 98 Stat. 1861) shall not apply to assistance provided under this section.

(c) EQUIPMENT AND MATERIALS FOR ENERGY EFFICIENCY MEASURES AND RENEWABLE ENERGY MEASURES.—No limitation on the percentage of funding that may be used for the purchase and installation of equipment and materials for energy efficiency measures and renewable energy measures under grants provided under part D of title III of the Energy Policy and Conservation Act (42 U.S.C. 6321 et seq.) shall apply to assistance provided under this section.

TITLE V—FINANCIAL SERVICES AND GENERAL GOVERNMENT

DEPARTMENT OF THE TREASURY

TREASURY INSPECTOR GENERAL FOR TAX ADMINISTRATION

SALARIES AND EXPENSES

For an additional amount for necessary expenses of the Treasury Inspector General for Tax Administration in carrying out the Inspector General Act of 1978, $7,000,000, to remain available until September 30, 2013, for oversight and audits of the administration of the making work pay tax credit and economic recovery payments under the American Recovery and Reinvestment Act of 2009.

COMMUNITY DEVELOPMENT FINANCIAL INSTITUTIONS FUND PROGRAM ACCOUNT

For an additional amount for "Community Development Financial Institutions Fund Program Account", $100,000,000, to remain available until September 30, 2010, for qualified applicants under the fiscal year 2009 funding round of the Community Development Financial Institutions Program, of which up to $8,000,000 may be for financial assistance, technical assistance, training and outreach programs designed to benefit Native American, Native Hawaiian, and Alaskan Native communities and provided primarily through qualified community development lender organizations with experience and expertise in community development banking and lending in Indian country, Native American organizations, tribes and tribal organizations and other suitable providers and up to $2,000,000 may be used for administrative expenses: *Provided,* That for the purpose of the fiscal year 2009 funding round, the following statutory provisions are hereby waived: 12 U.S.C. 4707(e) and 12 U.S.C. 4707(d): *Provided further,* That no awardee, together with its subsidiaries and affiliates, may be awarded more than 5 percent of the aggregate funds available during fiscal year 2009 from the Community Development Financial Institutions Program: *Provided further,* That no later than 60 days after the date of enactment of this Act, the Department of the Treasury shall submit to the Committees on Appropriations of the House of Representatives and the Senate a detailed expenditure plan for funds provided under this heading.

Waiver.

Deadline. Expenditure plan.

INTERNAL REVENUE SERVICE

HEALTH INSURANCE TAX CREDIT ADMINISTRATION

For an additional amount to implement the health insurance tax credit under the TAA Health Coverage Improvement Act of 2009, $80,000,000, to remain available until September 30, 2010.

GENERAL SERVICES ADMINISTRATION

REAL PROPERTY ACTIVITIES

FEDERAL BUILDINGS FUND

LIMITATIONS ON AVAILABILITY OF REVENUE

(INCLUDING TRANSFER OF FUNDS)

For an additional amount to be deposited in the Federal Buildings Fund, $5,550,000,000, to carry out the purposes of the Fund, of which not less than $750,000,000 shall be available for Federal buildings and United States courthouses, not less than $300,000,000 shall be available for border stations and land ports of entry, and not less than $4,500,000,000 shall be available for measures necessary to convert GSA facilities to High-Performance Green Buildings, as defined in section 401 of Public Law 110–140: *Provided,* That not to exceed $108,000,000 of the amounts provided under this heading may be expended for rental of space, related to leasing of temporary space in connection with projects funded under this heading: *Provided further,* That not to exceed $127,000,000 of the amounts provided under this heading may be expended for building operations, for the administrative costs of completing projects funded under this heading: *Provided further,* That not to exceed $3,000,000 of the funds provided shall be for on-the-job pre-apprenticeship and apprenticeship training programs registered with the Department of Labor, for the construction, repair, and alteration of Federal buildings: *Provided further,* That not less than $5,000,000,000 of the funds provided under this heading shall be obligated by September 30, 2010, and the remainder of the funds provided under this heading shall be obligated not later than September 30, 2011: *Provided further,* That the Administrator of General Services is authorized to initiate design, construction, repair, alteration, and other projects through existing authorities of the Administrator: *Provided further,* That the General Services Administration shall submit a detailed plan, by project, regarding the use of funds made available in this Act to the Committees on Appropriations of the House of Representatives and the Senate within 45 days of enactment of this Act, and shall provide notification to the Committees within 15 days prior to any changes regarding the use of these funds: *Provided further*, That, hereafter, the Administrator shall report to the Committees on the obligation of these funds on a quarterly basis beginning on June 30, 2009: *Provided further*, That of the amounts provided, $4,000,000 shall be transferred to and merged with "Government-Wide Policy", for the Office of Federal High-Performance Green Buildings as authorized in the Energy Independence and Security Act of 2007 (Public Law 110–140): *Provided further,* That amounts provided under this heading that are savings or cannot be used for the activity for which originally obligated may

Deadlines.

Plans.
Deadlines.
Notification.

Reports.
Deadlines.

Deadline.
Notification.

be deobligated and, notwithstanding any other provision of law, reobligated for the purposes identified in the plan required under this heading not less than 15 days after notification has been provided to the Committees on Appropriations of the House of Representatives and the Senate.

ENERGY-EFFICIENT FEDERAL MOTOR VEHICLE FLEET PROCUREMENT

For capital expenditures and necessary expenses of acquiring motor vehicles with higher fuel economy, including: hybrid vehicles; electric vehicles; and commercially-available, plug-in hybrid vehicles, $300,000,000, to remain available until September 30, 2011: *Provided*, That none of these funds may be obligated until the Administrator of General Services submits to the Committees on Appropriations of the House of Representatives and the Senate, within 90 days after enactment of this Act, a plan for expenditure of the funds that details the current inventory of the Federal fleet owned by the General Services Administration, as well as other Federal agencies, and the strategy to expend these funds to replace a portion of the Federal fleet with the goal of substantially increasing energy efficiency over the current status, including increasing fuel efficiency and reducing emissions: *Provided further*, That, hereafter, the Administrator shall report to the Committees on the obligation of these funds on a quarterly basis beginning on September 30, 2009.

Deadline. Expenditure plan.

Reports. Deadlines.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the Office of the Inspector General, to remain available until September 30, 2013, for oversight and audit of programs, grants, and projects funded under this title, $7,000,000.

RECOVERY ACT ACCOUNTABILITY AND TRANSPARENCY BOARD

For necessary expenses of the Recovery Act Accountability and Transparency Board to carry out the provisions of title XV of this Act, $84,000,000, to remain available until September 30, 2011.

SMALL BUSINESS ADMINISTRATION

SALARIES AND EXPENSES

For an additional amount, to remain available until September 30, 2010, $69,000,000, of which $24,000,000 is for marketing, management, and technical assistance under section 7(m) of the Small Business Act (15 U.S.C. 636(m)(4)) by intermediaries that make microloans under the microloan program, and of which $20,000,000 is for improving, streamlining, and automating information technology systems related to lender processes and lender oversight: *Provided,* That no later than 60 days after the date of enactment of this Act, the Small Business Administration shall submit to the Committees on Appropriations of the House of Representatives and the Senate a detailed expenditure plan for funds provided under the heading "Small Business Administration" in this Act.

Deadline. Expenditure plan.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the Office of Inspector General in carrying out the provisions of the Inspector General Act of 1978, $10,000,000, to remain available until September 30, 2013, for oversight and audit of programs, grants, and projects funded under this title.

SURETY BOND GUARANTEES REVOLVING FUND

For additional capital for the Surety Bond Guarantees Revolving Fund, authorized by the Small Business Investment Act of 1958, $15,000,000, to remain available until expended.

BUSINESS LOANS PROGRAM ACCOUNT

For an additional amount for the cost of direct loans, $6,000,000, to remain available until September 30, 2010, and for an additional amount for the cost of guaranteed loans, $630,000,000, to remain available until September 30, 2010: *Provided,* That of the amount for the cost of guaranteed loans, $375,000,000 shall be for reimbursements, loan subsidies and loan modifications for loans to small business concerns authorized in section 501 of this title; and $255,000,000 shall be for loan subsidies and loan modifications for loans to small business concerns authorized in section 506 of this title: *Provided further,* That such costs, including the cost of modifying such loans, shall be as defined in section 502 of the Congressional Budget Act of 1974.

ADMINISTRATIVE PROVISIONS—SMALL BUSINESS ADMINISTRATION

SEC. 501. FEE REDUCTIONS. (a) ADMINISTRATIVE PROVISIONS SMALL BUSINESS ADMINISTRATION.—Until September 30, 2010, and to the extent that the cost of such elimination or reduction of fees is offset by appropriations, with respect to each loan guaranteed under section 7(a) of the Small Business Act (15 U.S.C. 636(a)) and section 502 of this title, for which the application is approved on or after the date of enactment of this Act, the Administrator shall—

(1) in lieu of the fee otherwise applicable under section 7(a)(23)(A) of the Small Business Act (15 U.S.C. 636(a)(23)(A)), collect no fee or reduce fees to the maximum extent possible; and

(2) in lieu of the fee otherwise applicable under section 7(a)(18)(A) of the Small Business Act (15 U.S.C. 636(a)(18)(A)), collect no fee or reduce fees to the maximum extent possible.

(b) TEMPORARY FEE ELIMINATION FOR THE 504 LOAN PROGRAM.—

(1) IN GENERAL.—Until September 30, 2010, and to the extent the cost of such elimination in fees is offset by appropriations, with respect to each project or loan guaranteed by the Administrator pursuant to title V of the Small Business Investment Act of 1958 (15 U.S.C. 695 et seq.) for which an application is approved or pending approval on or after the date of enactment of this Act—

(A) the Administrator shall, in lieu of the fee otherwise applicable under section 503(d)(2) of the Small Business

Investment Act of 1958 (15 U.S.C. 697(d)(2)), collect no fee;

(B) a development company shall, in lieu of the processing fee under section 120.971(a)(1) of title 13, Code of Federal Regulations (relating to fees paid by borrowers), or any successor thereto, collect no fee.

(2) REIMBURSEMENT FOR WAIVED FEES.—

(A) IN GENERAL.—To the extent that the cost of such payments is offset by appropriations, the Administrator shall reimburse each development company that does not collect a processing fee pursuant to paragraph (1)(B).

(B) AMOUNT.—The payment to a development company under subparagraph (A) shall be in an amount equal to 1.5 percent of the net debenture proceeds for which the development company does not collect a processing fee pursuant to paragraph (1)(B).

(c) APPLICATION OF FEE ELIMINATIONS.—

(1) To the extent that amounts are made available to the Administrator for the purpose of fee eliminations or reductions under subsection (a), the Administrator shall—

(A) first use any amounts provided to eliminate or reduce fees paid by small business borrowers under clauses (i) through (iii) of paragraph (18)(A), to the maximum extent possible; and

(B) then use any amounts provided to eliminate or reduce fees under paragraph (23)(A) paid by small business lenders with assets less than $1,000,000,000 as of the date of enactment; and

(C) then use any remaining amounts appropriated under this title to reduce fees paid by small business lenders other than those with assets less than $1,000,000,000.

(2) The Administrator shall eliminate fees under subsections (a) and (b) until the amount provided for such purposes, as applicable, under the heading "Business Loans Program Account" under the heading "Small Business Administration" under this Act are expended.

SEC. 502. ECONOMIC STIMULUS LENDING PROGRAM FOR SMALL BUSINESSES. (a) PURPOSE.—The purpose of this section is to permit the Small Business Administration to guarantee up to 90 percent of qualifying small business loans made by eligible lenders.

(b) DEFINITIONS.—For purposes of this section:

(1) The term "Administrator" means the Administrator of the Small Business Administration.

(2) The term "qualifying small business loan" means any loan to a small business concern pursuant to section 7(a) of the Small Business Act (15 U.S.C. 636) or title V of the Small Business Investment Act of 1958 (15 U.S.C. 695 and following) except for such loans made under section 7(a)(31).

(3) The term "small business concern" has the same meaning as provided by section 3 of the Small Business Act (15 U.S.C. 632).

(c) QUALIFIED BORROWERS.—

(1) ALIENS UNLAWFULLY PRESENT IN THE UNITED STATES.—A loan guarantee may not be made under this section for a loan made to a concern if an individual who is an alien unlawfully present in the United States—

(A) has an ownership interest in that concern; or

(B) has an ownership interest in another concern that itself has an ownership interest in that concern.

(2) FIRMS IN VIOLATION OF IMMIGRATION LAWS.—No loan guarantee may be made under this section for a loan to any entity found, based on a determination by the Secretary of Homeland Security or the Attorney General to have engaged in a pattern or practice of hiring, recruiting or referring for a fee, for employment in the United States an alien knowing the person is an unauthorized alien.

(d) CRIMINAL BACKGROUND CHECKS.—Prior to the approval of any loan guarantee under this section, the Administrator may verify the applicant's criminal background, or lack thereof, through the best available means, including, if possible, use of the National Crime Information Center computer system at the Federal Bureau of Investigation.

(e) APPLICATION OF OTHER LAW.—Nothing in this section shall be construed to exempt any activity of the Administrator under this section from the Federal Credit Reform Act of 1990 (title V of the Congressional Budget and Impoundment Control Act of 1974; 2 U.S.C. 661 and following).

(f) SUNSET.—Loan guarantees may not be issued under this section after the date 12 months after the date of enactment of this Act.

Applicability.

(g) SMALL BUSINESS ACT PROVISIONS.—The provisions of the Small Business Act applicable to loan guarantees under section 7 of that Act and regulations promulgated thereunder as of the date of enactment of this Act shall apply to loan guarantees under this section except as otherwise provided in this section.

(h) AUTHORIZATION.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 503. ESTABLISHMENT OF SBA SECONDARY MARKET GUARANTEE AUTHORITY. (a) PURPOSE.—The purpose of this section is to provide the Administrator with the authority to establish the SBA Secondary Market Guarantee Authority within the SBA to provide a Federal guarantee for pools of first lien 504 loans that are to be sold to third-party investors.

(b) DEFINITIONS.—For purposes of this section:

(1) The term "Administrator" means the Administrator of the Small Business Administration.

(2) The term "first lien position 504 loan" means the first mortgage position, non-federally guaranteed loans made by private sector lenders made under title V of the Small Business Investment Act.

(c) ESTABLISHMENT OF AUTHORITY.—

(1) ORGANIZATION.—

(A) The Administrator shall establish a Secondary Market Guarantee Authority within the Small Business Administration.

(B) The Administrator shall appoint a Director of the Authority who shall report to the Administrator.

(C) The Administrator is authorized to hire such personnel as are necessary to operate the Authority and may contract such operations of the Authority as necessary to qualified third party companies or individuals.

(D) The Administrator is authorized to contract with private sector fiduciary and custom dial agents as necessary to operate the Authority.

(2) GUARANTEE PROCESS.—

Regulations.

(A) The Administrator shall establish, by rule, a process in which private sector entities may apply to the Administration for a Federal guarantee on pools of first lien position 504 loans that are to be sold to third-party investors.

(B) The Administrator is authorized to contract with private sector fiduciary and custom dial agents as necessary to operate the Authority.

(3) RESPONSIBILITIES.—

Regulations.

(A) The Administrator shall establish, by rule, a process in which private sector entities may apply to the SBA for a Federal guarantee on pools of first lien position 504 loans that are to be sold to third-party investors.

(B) The rule under this section shall provide for a process for the Administrator to consider and make decisions regarding whether to extend a Federal guarantee referred to in clause (i). Such rule shall also provide that:

(i) The seller of the pools purchasing a guarantee under this section retains not less than 5 percent of the dollar amount of the pools to be sold to third-party investors.

(ii) The Administrator shall charge fees, upfront or annual, at a specified percentage of the loan amount that is at such a rate that the cost of the program under the Federal Credit Reform Act of 1990 (title V of the Congressional Budget and Impoundment Control Act of 1974; 2 U.S.C. 661) shall be equal to zero.

(iii) The Administrator may guarantee not more than $3,000,000,000 of pools under this authority.

(C) The Administrator shall establish documents, legal covenants, and other required documentation to protect the interests of the United States.

(D) The Administrator shall establish a process to receive and disburse funds to entities under the authority established in this section.

(d) LIMITATIONS.—

(1) The Administrator shall ensure that entities purchasing a guarantee under this section are using such guarantee for the purpose of selling 504 first lien position pools to third-party investors.

(2) If the Administrator finds that any such guarantee was used for a purpose other than that specified in paragraph (1), the Administrator shall—

(A) prohibit the purchaser of the guarantee or its affiliates (within the meaning of the regulations under 13 CFR 121.103) from using the authority of this section in the future; and

(B) take any other actions the Administrator, in consultation with the Attorney General of the United States deems appropriate.

Reports.
Deadlines.

(e) OVERSIGHT.—The Administrator shall submit a report to Congress not later than the third business day of each month setting forth each of the following:

(1) The aggregate amount of guarantees extended under this section during the preceding month.

(2) The aggregate amount of guarantees outstanding.

(3) Defaults and payments on defaults made under this section.

(4) The identity of each purchaser of a guarantee found by the Administrator to have misused guarantees under this section.

(5) Any other information the Administrator deems necessary to fully inform Congress of undue risk to the United States associated with the issuance of guarantees under this section.

(f) DURATION OF PROGRAM.—The authority of this section shall terminate on the date 2 years after the date of enactment of this section.

(g) FUNDING.—Such sums as necessary are authorized to be appropriated to carry out the provisions of this section.

(h) BUDGET TREATMENT.—Nothing in this section shall be construed to exempt any activity of the Administrator under this section from the Federal Credit Reform Act of 1990 (title V of the Congressional Budget and Impoundment Control Act of 1974; 2 U.S.C. 661 and following).

(i) EMERGENCY RULEMAKING AUTHORITY.—The Administrator shall issue regulations under this section within 15 days after the date of enactment of this section. The notice requirements of section 553(b) of title 5, United States Code shall not apply to the promulgation of such regulations. Deadlines.

SEC. 504. STIMULUS FOR COMMUNITY DEVELOPMENT LENDING. (a) LOW INTEREST REFINANCING UNDER THE LOCAL DEVELOPMENT BUSINESS LOAN PROGRAM.—Section 502 of the Small Business Investment Act of 1958 (15 U.S.C. 696) is amended by adding at the end the following:

"(7) PERMISSIBLE DEBT REFINANCING.—

"(A) IN GENERAL.—Any financing approved under this title may include a limited amount of debt refinancing.

"(B) EXPANSIONS.—If the project involves expansion of a small business concern, any amount of existing indebtedness that does not exceed 50 percent of the project cost of the expansion may be refinanced and added to the expansion cost, if—

"(i) the proceeds of the indebtedness were used to acquire land, including a building situated thereon, to construct a building thereon, or to purchase equipment;

"(ii) the existing indebtedness is collateralized by fixed assets;

"(iii) the existing indebtedness was incurred for the benefit of the small business concern;

"(iv) the financing under this title will be used only for refinancing existing indebtedness or costs relating to the project financed under this title;

"(v) the financing under this title will provide a substantial benefit to the borrower when prepayment penalties, financing fees, and other financing costs are accounted for;

"(vi) the borrower has been current on all payments due on the existing debt for not less than 1 year preceding the date of refinancing; and

"(vii) the financing under section 504 will provide better terms or rate of interest than the existing indebtedness at the time of refinancing.".

(b) JOB CREATION GOALS.—Section 501(e)(1) and section 501(e)(2) of the Small Business Investment Act (15 U.S.C. 695) are each amended by striking "$50,000" and inserting "$65,000".

SEC. 505. INCREASING SMALL BUSINESS INVESTMENT. (a) SIMPLIFIED MAXIMUM LEVERAGE LIMITS.—Section 303(b) of the Small Business Investment Act of 1958 (15 U.S.C. 683(b)) is amended as follows:

(1) By striking so much of paragraph (2) as precedes subparagraphs (C) and (D) and inserting the following:

"(2) MAXIMUM LEVERAGE.—

"(A) IN GENERAL.—The maximum amount of outstanding leverage made available to any one company licensed under section 301(c) of this Act may not exceed the lesser of—

"(i) 300 percent of such company's private capital; or

"(ii) $150,000,000.

"(B) MULTIPLE LICENSES UNDER COMMON CONTROL.—The maximum amount of outstanding leverage made available to two or more companies licensed under section 301(c) of this Act that are commonly controlled (as determined by the Administrator) and not under capital impairment may not exceed $225,000,000.";

(2) By amending paragraph (2)(C) by inserting "(i)" before "In calculating" and adding the following at the end thereof:

"(ii) The maximum amount of outstanding leverage made available to—

"(I) any 1 company described in clause (iii) may not exceed the lesser of 300 percent of private capital of the company, or $175,000,000; and

"(II) 2 or more companies described in clause (iii) that are under common control (as determined by the Administrator) may not exceed $250,000,000.

"(iii) A company described in this clause is a company licensed under section 301(c) in the first fiscal year after the date of enactment of this clause or any fiscal year thereafter that certifies in writing that not less than 50 percent of the dollar amount of investments of that company shall be made in companies that are located in a low-income geographic area (as that term is defined in section 351).".

(3) By striking paragraph (4).

(b) SIMPLIFIED AGGREGATE INVESTMENT LIMITATIONS.—Section 306(a) of the Small Business Investment Act of 1958 (15 U.S.C. 686(a)) is amended to read as follows:

"(a) PERCENTAGE LIMITATION ON PRIVATE CAPITAL.—If any small business investment company has obtained financing from the Administrator and such financing remains outstanding, the aggregate amount of securities acquired and for which commitments may be issued by such company under the provisions of this title

for any single enterprise shall not, without the approval of the Administrator, exceed 10 percent of the sum of—

"(1) the private capital of such company; and

"(2) the total amount of leverage projected by the company in the company's business plan that was approved by the Administrator at the time of the grant of the company's license.".

(c) INVESTMENTS IN SMALLER ENTERPRISES.—Section 303(d) of the Small Business Investment Act of 1958 (15 U.S.C. 683(d)) is amended to read as follows:

"(d) INVESTMENTS IN SMALLER ENTERPRISES.—The Administrator shall require each licensee, as a condition of approval of an application for leverage, to certify in writing that not less than 25 percent of the aggregate dollar amount of financings of that licensee shall be provided to smaller enterprises.". Certification.

SEC. 506. BUSINESS STABILIZATION PROGRAM. (a) IN GENERAL.—Subject to the availability of appropriations, the Administrator of the Small Business Administration shall carry out a program to provide loans on a deferred basis to viable (as such term is determined pursuant to regulation by the Administrator of the Small Business Administration) small business concerns that have a qualifying small business loan and are experiencing immediate financial hardship.

(b) ELIGIBLE BORROWER.—A small business concern as defined under section 3 of the Small Business Act (15 U.S.C. 632).

(c) QUALIFYING SMALL BUSINESS LOAN.—A loan made to a small business concern that meets the eligibility standards in section 7(a) of the Small Business Act (15 U.S.C. 636(a)) but shall not include loans guarantees (or loan guarantee commitments made) by the Administrator prior to the date of enactment of this Act.

(d) LOAN SIZE.—Loans guaranteed under this section may not exceed $35,000.

(e) PURPOSE.—Loans guaranteed under this program shall be used to make periodic payment of principal and interest, either in full or in part, on an existing qualifying small business loan for a period of time not to exceed 6 months.

(f) LOAN TERMS.—Loans made under this section shall:

(1) carry a 100 percent guaranty; and

(2) have interest fully subsidized for the period of repayment.

(g) REPAYMENT.—Repayment for loans made under this section shall—

(1) be amortized over a period of time not to exceed 5 years; and

(2) not begin until 12 months after the final disbursement of funds is made. Effective date.

(h) COLLATERAL.—The Administrator of the Small Business Administration may accept any available collateral, including subordinated liens, to secure loans made under this section.

(i) FEES.—The Administrator of the Small Business Administration is prohibited from charging any processing fees, origination fees, application fees, points, brokerage fees, bonus points, prepayment penalties, and other fees that could be charged to a loan applicant for loans under this section.

(j) SUNSET.—The Administrator of the Small Business Administration shall not issue loan guarantees under this section after September 30, 2010.

Deadline.

(k) EMERGENCY RULEMAKING AUTHORITY.—The Administrator of the Small Business Administration shall issue regulations under this section within 15 days after the date of enactment of this section. The notice requirements of section 553(b) of title 5, United States Code shall not apply to the promulgation of such regulations.

SEC. 507. GAO REPORT.

(a) REPORT.—Not later than 60 days after the enactment of this Act, the Comptroller General of the United States shall report to the Congress on the actions of the Administrator in implementing the authorities established in the administrative provisions of this title.

(b) INCLUDED ITEM.—The report under this section shall include a summary of the activity of the Administrator under this title and an analysis of whether he is accomplishing the purpose of increasing liquidity in the secondary market for Small Business Administration loans.

SEC. 508. SURETY BONDS.

(a) MAXIMUM BOND AMOUNT.— Section 411(a)(1) of the Small Business Investment Act of 1958 (15 U.S.C. 694b(a)(1)) is amended—

(1) by inserting "(A)" after "(1)";

(2) by striking "$2,000,000" and inserting "$5,000,000"; and

(3) by adding at the end the following:

"(B) The Administrator may guarantee a surety under subparagraph (A) for a total work order or contract amount that does not exceed $10,000,000, if a contracting officer of a Federal agency certifies that such a guarantee is necessary.".

(b) DENIAL OF LIABILITY—

Section 411 of the Small Business Investment Act of 1958 (15 U.S.C. 694b) is amended—

(1) by striking subsection (e) and inserting the following:

"(e) REIMBURSEMENT OF SURETY; CONDITIONS.—

Pursuant to any such guarantee or agreement, the Administration shall reimburse the surety, as provided in subsection (c) of this section, except that the Administration shall be relieved of liability (in whole or in part within the discretion of the Administration) if—

(1) the surety obtained such guarantee or agreement, or applied for such reinbursement, by fraud or material misrepresentation,

(2) the total contract amount at the time of execution of the bond or bonds exceeds $5,000,000,

(3) the surety has breached a material term or condition of such guarantee agreement, or

(4) the surety has substantially violated the regulations promulgated by the Administration pursuant to subsection (d)."

(2) by adding at the end the following:

"(k) For bonds made or executed with the prior approval of the Administration, the Administration shall not deny liability to a surety based upon material information that was provided as part of the guaranty application.".

(c) SIZE STANDARDS.—Section 410 of the Small Business Investment Act of 1958 (15 U.S.C. 694a) is amended by adding at the end the following:

"(9) Notwithstanding any other provision of law or any rule, regulation, or order of the Administration, for purposes

of sections 410, 411, and 412 the term 'small business concern' means a business concern that meets the size standard for the primary industry in which such business concern, and the affiliates of such business concern, is engaged, as determined by the Administrator in accordance with the North American Industry Classification System.".

(d) STUDY—The Administrator of the Small Business Administration shall conduct a study of the current funding structure of the surety bond program carried out under part B (15 U.S.C. 694a et seq.) of title IV of the Small Business Investment Act of 1958. The study shall include--

(1) an assessment of whether the program's current funding framework and program fees are inhibiting the program's growth;

(2) an assessment of whether surety companies and small business concerns could benefit from an alternative funding structure; and

(e) REPORT—Not later than 180 days after the date of enactment of this Act, the Administrator shall submit to Congress a report on the results of the study required under subsection (d).

(f) SUNSET.—The amendments made by this section shall remain in effect until September 30, 2010.

15 USC 694a note.

SEC. 509. ESTABLISHMENT OF SBA SECONDARY MARKET LENDING AUTHORITY.

(a) PURPOSE.—The purpose of this section is to provide the Small Business Administration with the authority to establish a Secondary Market Lending Authority within the SBA to make loans to the systemically important SBA secondary market broker-dealers who operate the SBA secondary market.

(b) DEFINITIONS.—For purposes of this section:

(1) The term "Administrator" means the Administrator of the SBA.

(2) The term "SBA" means the Small Business Administration.

(3) The terms "Secondary Market Lending Authority" and "Authority" mean the office establishedunder subsection (c).

(4) The term "SBA secondary market" meansthe market for the purchase and sale of loans originated, underwritten, and closed under the Small Business Act.

(5) The term "Systemically Important Secondary Market Broker-Dealers" mean those entities designated under subsection (c)(1) as vital to the continued operation of the SBA secondary market by reason of their purchase and sale of the government guaranteed portion of loans, or pools of loans,originated, underwritten, and closed under the Small Business Act.

(c) RESPONSIBILITIES, AUTHORITIES, ORGANIZATION, AND LIMITATIONS.—

(1) DESIGNATION OF SYSTEMICALLY IMPORTANT SBA SECONDARY MARKET BROKER-DEALERS.—The Administrator shall establish a process to designate, in consultation with the Board of Governors of the Federal Reserve and the Secretary of the Treasury, Systemically Important Secondary Market Broker-Dealers.

(2) ESTABLISHMENT OF SBA SECONDARY MARKET LENDING AUTHORITY.—

(A) ORGANIZATION.—

(i) The Administrator shall establish within the SBA an office to provide loans to Systemically Important Secondary Market Broker-dealers to be used for the purpose of financing the inventory of the government guaranteed portion of loans, originated, underwritten, and closed under the Small Business Act or pools of such loans.

(ii) The Administrator shall appoint a Director of the Authority who shall report to the Administrator.

(iii) The Administrator is authorized to hire such personnel as are necessary to operate the Authority.

(iv) The Administrator may contract such Authority operations as he determines necessary to qualified third-party companies or individuals.

(v) The Administrator is authorized to contract with private sector fiduciary and custodial agents as necessary to operate the Authority.

(B) LOANS.—

Regulations.

(i) The Administrator shall establish by rule a process under which Systemically Important SBA Secondary Market Broker-Dealers designated under paragraph (1) may apply to the Administrator for loans under this section.

(ii) The rule under clause (i) shall provide a process for the Administrator to consider and make decisions regarding whether or not to extend a loan applied for under this section. Such rule shall include provisions to assure each of the following:

(I) That loans made under this section are for the sole purpose of financing the inventory of the govern ment guaranteed portion of loans, originated, underwritten, and closed under the Small Business Act or pools of such loans.

(II) That loans made under this section are fully collateralized to the satisfaction of the Administrator.

(III) That there is no limit to the frequency in which a borrower may borrow under this section unless the Administrator determines that doing so would create an undue risk of loss to the agency or the United States.

(IV) That there is no limit on the size of a loan, subject to the discretion of the Administrator.

(iii) Interest on loans under this section shall not exceed the Federal Funds target rate as established by the Federal Reserve Board of Governors plus 25 basis points.

(iv) The rule under this section shall provide for such loan documents, legal covenants, collateral requirements and other required documentation as necessary to protect the interests of the agency, the United States, and the taxpayer.

(v) The Administrator shall establish custodial accounts to safeguard any collateral pledged to the SBA in connection with a loan under this section.

(vi) The Administrator shall establish a process to disburse and receive funds to and from borrowers under this section.

(C) LIMITATIONS ON USE OF LOAN PROCEEDS BY SYSTEMICALLY IMPORTANT SECONDARY MARKET BROKER-DEALERS.—The Administrator shall ensure that borrowers under this section are using funds provided under this section only for the purpose specified in subparagraph (B)(ii)(I). If the Administrator finds that such funds were used for any other purpose, the Administrator shall—

(i) require immediate repayment of outstanding loans;

(ii) prohibit the borrower, its affiliates, or any future corporate manifestation of the borrower from using the Authority; and

(iii) take any other actions the Administrator, in consultation with the Attorney General of the United States, deemsappropriate.

(d) REPORT TO CONGRESS.—The Administrator shall submit a report to Congress not later than the third business day of each month containing a statement of each of the following:

(1) The aggregate loan amounts extended during the preceding month under this section.

(2) The aggregate loan amounts repaid under this section during the proceeding month.

(3) The aggregate loan amount outstanding under this section.

(4) The aggregate value of assets held as collateral under this section;

(5) The amount of any defaults or delinquencies on loans made under this section.

(6) The identity of any borrower found by the Administrator to misuse funds made available under this section.

(7) Any other information the Administrator deems necessary to fully inform Congress of undue risk of financial loss to the United States in connection with loans made under this section.

(e) DURATION.—The authority of this section shall remain in effect for a period of 2 years after the date of enactment of this section.

(f) FEES.—The Administrator shall charge fees, up front, annual, or both at a specified percentage of the loan amount that is at such a rate that the cost of the program under the Federal Credit Reform Act of 1990 ((title V of the Congressional Budget and Impoundment Control Act of 1974; 2 U.S.C. 661) shall be equal to zero.

(h) BUDGET TREATMENT.—Nothing in this section shall be construed to exempt any activity of the Administrator under this section from the Federal Credit Reform Act of 1990 (title V of the Congressional Budget and Im poundment Control Act of 1974; 2 U.S.C. 661 and following).

(i) EMERGENCY RULEMAKING AUTHORITY.—The Administrator shall promulgate regulations under this section within 30 days after the date of enactment of enactment of this section. In promulgating these regulations,the Administrator the notice requirements of section 553(b) of title 5 of the United States Code shall not apply. Deadline.

TITLE VI—DEPARTMENT OF HOMELAND SECURITY

OFFICE OF THE UNDER SECRETARY FOR MANAGEMENT

For an additional amount for the "Office of the Under Secretary for Management", $200,000,000 for planning, design, construction costs, site security, information technology infrastructure, fixtures, and related costs to consolidate the Department of Homeland Security headquarters: *Provided,* That no later than 60 days after the date of enactment of this Act, the Secretary of Homeland Security, in consultation with the Administrator of General Services, shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for the expenditure of these funds.

Deadline. Expenditure plan.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the "Office of Inspector General", $5,000,000, to remain available until September 30, 2012, for oversight and audit of programs, grants, and projects funded under this title.

U.S. CUSTOMS AND BORDER PROTECTION

SALARIES AND EXPENSES

For an additional amount for "Salaries and Expenses", $160,000,000, of which $100,000,000 shall be for the procurement and deployment of non-intrusive inspection systems; and of which $60,000,000 shall be for procurement and deployment of tactical communications equipment and radios: *Provided,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for expenditure of these funds.

Deadline. Expenditure plan.

BORDER SECURITY FENCING, INFRASTRUCTURE, AND TECHNOLOGY

For an additional amount for "Border Security Fencing, Infrastructure, and Technology", $100,000,000 for expedited development and deployment of border security technology on the Southwest border: *Provided,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for expenditure of these funds.

Deadline. Expenditure plan.

CONSTRUCTION

For an additional amount for "Construction", $420,000,000 solely for planning, management, design, alteration, and construction of U.S. Customs and Border Protection owned land border ports of entry: *Provided,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for expenditure of these funds.

Deadline. Expenditure plan.

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT

AUTOMATION MODERNIZATION

For an additional amount for "Automation Modernization", $20,000,000 for the procurement and deployment of tactical communications equipment and radios: *Provided,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for expenditure of these funds.

Deadline. Expenditure plan.

TRANSPORTATION SECURITY ADMINISTRATION

AVIATION SECURITY

For an additional amount for "Aviation Security", $1,000,000,000 for procurement and installation of checked baggage explosives detection systems and checkpoint explosives detection equipment: *Provided,* That the Assistant Secretary of Homeland Security (Transportation Security Administration) shall prioritize the award of these funds to accelerate the installations at locations with completed design plans: *Provided further,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for the expenditure of these funds.

Deadline. Expenditure plan.

COAST GUARD

ACQUISITION, CONSTRUCTION, AND IMPROVEMENTS

For an additional amount for "Acquisition, Construction, and Improvements", $98,000,000 for shore facilities and aids to navigation facilities; for priority procurements due to materials and labor cost increases; and for costs to repair, renovate, assess, or improve vessels: *Provided,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for the expenditure of these funds.

Deadline. Expenditure plan.

ALTERATION OF BRIDGES

For an additional amount for "Alteration of Bridges", $142,000,000 for alteration or removal of obstructive bridges, as authorized by section 6 of the Truman-Hobbs Act (33 U.S.C. 516): *Provided*, That the Coast Guard shall award these funds to those bridges that are ready to proceed to construction: *Provided further,* That no later than 45 days after the date of enactment of this Act, the Secretary of Homeland Security shall submit to the Committees on Appropriations of the Senate and the House of Representatives a plan for the expenditure of these funds.

Deadline. Expenditure plan.

FEDERAL EMERGENCY MANAGEMENT AGENCY

STATE AND LOCAL PROGRAMS

For an additional amount for grants, $300,000,000, to be allocated as follows:

(1) $150,000,000 for Public Transportation Security Assistance and Railroad Security Assistance under sections 1406 and 1513 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Public Law 110–53; 6 U.S.C. 1135 and 1163).

(2) $150,000,000 for Port Security Grants in accordance with 46 U.S.C. 70107, notwithstanding 46 U.S.C. 70107(c).

FIREFIGHTER ASSISTANCE GRANTS

For an additional amount for competitive grants, $210,000,000 for modifying, upgrading, or constructing non-Federal fire stations: *Provided,* That up to 5 percent shall be for program administration: *Provided further,* That no grant shall exceed $15,000,000.

DISASTER ASSISTANCE DIRECT LOAN PROGRAM ACCOUNT

Notwithstanding section 417(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, the amount of any such loan issued pursuant to this section for major disasters occurring in calendar year 2008 may exceed $5,000,000, and may be equal to not more than 50 percent of the annual operating budget of the local government in any case in which that local government has suffered a loss of 25 percent or more in tax revenues: *Provided,* That the cost of modifying such loans shall be as defined in section 502 of the Congressional Budget Act of 1974 (2 U.S.C. 661a).

EMERGENCY FOOD AND SHELTER

For an additional amount to carry out the emergency food and shelter program pursuant to title III of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11331 et seq.), $100,000,000: *Provided,* That total administrative costs shall not exceed 3.5 percent of the total amount made available under this heading.

GENERAL PROVISIONS—THIS TITLE

President. Panel.

SEC. 601. Notwithstanding any other provision of law, the President shall establish an arbitration panel under the Federal Emergency Management Agency public assistance program to expedite the recovery efforts from Hurricanes Katrina and Rita within the Gulf Coast Region. The arbitration panel shall have sufficient authority regarding the award or denial of disputed public assistance applications for covered hurricane damage under section 403, 406, or 407 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170b, 5172, or 5173) for a project the total amount of which is more than $500,000.

SEC. 602. The Administrator of the Federal Emergency Management Agency may not prohibit or restrict the use of funds designated under the hazard mitigation grant program for damage caused by Hurricanes Katrina and Rita if the homeowner who is an applicant for assistance under such program commenced work

otherwise eligible for hazard mitigation grant program assistance under section 404 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170c) without approval in writing from the Administrator.

SEC. 603. Subparagraph (E) of section 34(a)(1) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229a(a)(1)(E)) shall not apply with respect to funds appropriated in this or any other Act making appropriations for fiscal year 2009 or 2010 for grants under such section 34.

SEC. 604. (a) REQUIREMENT.—Except as provided in subsections (c) through (g), funds appropriated or otherwise available to the Department of Homeland Security may not be used for the procurement of an item described in subsection (b) if the item is not grown, reprocessed, reused, or produced in the United States. 6 USC 453b.

(b) COVERED ITEMS.—An item referred to in subsection (a) is any of the following, if the item is directly related to the national security interests of the United States:

(1) An article or item of—

(A) clothing and the materials and components thereof, other than sensors, electronics, or other items added to, and not normally associated with, clothing (and the materials and components thereof);

(B) tents, tarpaulins, covers, textile belts, bags, protective equipment (including but not limited to body armor), sleep systems, load carrying equipment (including but not limited to fieldpacks), textile marine equipment, parachutes, or bandages;

(C) cotton and other natural fiber products, woven silk or woven silk blends, spun silk yarn for cartridge cloth, synthetic fabric or coated synthetic fabric (including all textile fibers and yarns that are for use in such fabrics), canvas products, or wool (whether in the form of fiber or yarn or contained in fabrics, materials, or manufactured articles); or

(D) any item of individual equipment manufactured from or containing such fibers, yarns, fabrics, or materials.

(c) AVAILABILITY EXCEPTION.—Subsection (a) does not apply to the extent that the Secretary of Homeland Security determines that satisfactory quality and sufficient quantity of any such article or item described in subsection (b)(1) grown, reprocessed, reused, or produced in the United States cannot be procured as and when needed at United States market prices. This section is not applicable to covered items that are, or include, materials determined to be non-available in accordance with Federal Acquisition Regulation 25.104 Nonavailable Articles.

(d) DE MINIMIS EXCEPTION.—Notwithstanding subsection (a), the Secretary of Homeland Security may accept delivery of an item covered by subsection (b) that contains non-compliant fibers if the total value of non-compliant fibers contained in the end item does not exceed 10 percent of the total purchase price of the end item.

(e) EXCEPTION FOR CERTAIN PROCUREMENTS OUTSIDE THE UNITED STATES.—Subsection (a) does not apply to the following:

(1) Procurements by vessels in foreign waters.

(2) Emergency procurements.

(f) EXCEPTION FOR SMALL PURCHASES.—Subsection (a) does not apply to purchases for amounts not greater than the simplified

acquisition threshold referred to in section 2304(g) of title 10, United States Code.

(g) APPLICABILITY TO CONTRACTS AND SUBCONTRACTS FOR PROCUREMENT OF COMMERCIAL ITEMS.—This section is applicable to contracts and subcontracts for the procurement of commercial items not withstanding section 34 of the Office of Federal Procurement Policy Act (41 U.S.C. 430), with the exception of commercial items listed under subsections (b)(1)(C) and (b)(1)(D) above. For the purposes of this section, "commercial" shall be as defined in the Federal Acquisition Regulation—Part 2.

(h) GEOGRAPHIC COVERAGE.—In this section, the term "United States" includes the possessions of the United States.

Internet posting.

(i) NOTIFICATION REQUIRED WITHIN 7 DAYS AFTER CONTRACT AWARD IF CERTAIN EXCEPTIONS APPLIED.—In the case of any contract for the procurement of an item described in subsection (b)(1), if the Secretary of Homeland Security applies an exception set forth in subsection (c) with respect to that contract, the Secretary shall, not later than 7 days after the award of the contract, post a notification that the exception has been applied on the Internet site maintained by the General Services Administration known as FedBizOps.gov (or any successor site).

(j) TRAINING DURING FISCAL YEAR 2009.—

(1) IN GENERAL.—The Secretary of Homeland Security shall ensure that each member of the acquisition workforce in the Department of Homeland Security who participates personally and substantially in the acquisition of textiles on a regular basis receives training during fiscal year 2009 on the requirements of this section and the regulations implementing this section.

(2) INCLUSION OF INFORMATION IN NEW TRAINING PROGRAMS.—The Secretary shall ensure that any training program for the acquisition workforce developed or implemented after the date of the enactment of this Act includes comprehensive information on the requirements described in paragraph (1).

Applicability.

(k) CONSISTENCY WITH INTERNATIONAL AGREEMENTS.— This section shall be applied in a manner consistent with United States obligations under international agreements.

(l) EFFECTIVE DATE.—This section applies with respect to contracts entered into by the Department of Homeland Security 180 days after the date of the enactment of this Act.

TITLE VII—INTERIOR, ENVIRONMENT, AND RELATED AGENCIES

DEPARTMENT OF THE INTERIOR

BUREAU OF LAND MANAGEMENT

MANAGEMENT OF LANDS AND RESOURCES

For an additional amount for "Management of Lands and Resources", for activities on all Bureau of Land Management lands including maintenance, rehabilitation, and restoration of facilities, property, trails and lands and for remediation of abandoned mines and wells, $125,000,000.

CONSTRUCTION

For an additional amount for "Construction", for activities on all Bureau of Land Management lands including construction, reconstruction, decommissioning and repair of roads, bridges, trails, property, and facilities and for energy efficient retrofits of existing facilities, $180,000,000.

WILDLAND FIRE MANAGEMENT

For an additional amount for "Wildland Fire Management", for hazardous fuels reduction, $15,000,000.

UNITED STATES FISH AND WILDLIFE SERVICE

RESOURCE MANAGEMENT

For an additional amount for "Resource Management", for deferred maintenance, construction, and capital improvement projects on national wildlife refuges and national fish hatcheries and for high priority habitat restoration projects, $165,000,000.

CONSTRUCTION

For an additional amount for "Construction", for construction, reconstruction, and repair of roads, bridges, property, and facilities and for energy efficient retrofits of existing facilities, $115,000,000.

NATIONAL PARK SERVICE

OPERATION OF THE NATIONAL PARK SYSTEM

For an additional amount for "Operation of the National Park System", for deferred maintenance of facilities and trails and for other critical repair and rehabilitation projects, $146,000,000.

HISTORIC PRESERVATION FUND

For an additional amount for "Historic Preservation Fund", for historic preservation projects at historically black colleges and universities as authorized by the Historic Preservation Fund Act of 1996 and the Omnibus Parks and Public Lands Act of 1996, $15,000,000: *Provided,* That any matching requirements otherwise required for such projects are waived.

CONSTRUCTION

For an additional amount for "Construction", for repair and restoration of roads; construction of facilities, including energy efficient retrofits of existing facilities; equipment replacement; preservation and repair of historical resources within the National Park System; cleanup of abandoned mine sites on park lands; and other critical infrastructure projects, $589,000,000.

UNITED STATES GEOLOGICAL SURVEY

SURVEYS, INVESTIGATIONS, AND RESEARCH

For an additional amount for "Surveys, Investigations, and Research", $140,000,000, for repair, construction and restoration of facilities; equipment replacement and upgrades including stream gages, and seismic and volcano monitoring systems; national map activities; and other critical deferred maintenance and improvement projects.

BUREAU OF INDIAN AFFAIRS

OPERATION OF INDIAN PROGRAMS

For an additional amount for "Operation of Indian Programs", for workforce training programs and the housing improvement program, $40,000,000.

CONSTRUCTION

For an additional amount for "Construction", for repair and restoration of roads; replacement school construction; school improvements and repairs; and detention center maintenance and repairs, $450,000,000: *Provided,* That section 1606 of this Act shall not apply to tribal contracts entered into by the Bureau of Indian Affairs with this appropriation.

INDIAN GUARANTEED LOAN PROGRAM ACCOUNT

For an additional amount for "Indian Guaranteed Loan Program Account", $10,000,000.

OFFICE OF INSPECTOR GENERAL

SALARIES AND EXPENSES

For an additional amount for "Office of Inspector General", $15,000,000, to remain available until September 30, 2012.

ENVIROMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $20,000,000, to remain available until September 30, 2012.

HAZARDOUS SUBSTANCE SUPERFUND

For an additional amount for "Hazardous Substance Superfund", $600,000,000, which shall be for the Superfund Remedial program: *Provided,* That the Administrator of the Environmental Protection Agency (Administrator) may retain up to 3 percent of the funds appropriated herein for management and oversight purposes.

LEAKING UNDERGROUND STORAGE TANK TRUST FUND PROGRAM

For an additional amount for "Leaking Underground Storage Tank Trust Fund Program", $200,000,000, which shall be for cleanup activities authorized by section 9003(h) of the Solid Waste Disposal Act: *Provided,* That none of these funds shall be subject to cost share requirements under section 9003(h)(7)(B) of such Act: *Provided further,* That the Administrator may retain up to 1.5 percent of the funds appropriated herein for management and oversight purposes.

STATE AND TRIBAL ASSISTANCE GRANTS

(INCLUDING TRANSFERS OF FUNDS)

For an additional amount for "State and Tribal Assistance Grants", $6,400,000,000, which shall be allocated as follows:

(1) $4,000,000,000 shall be for capitalization grants for the Clean Water State Revolving Funds under title VI of the Federal Water Pollution Control Act and $2,000,000,000 shall be for capitalization grants under section 1452 of the Safe Drinking Water Act: *Provided,* That the Administrator may retain up to 1 percent of the funds appropriated herein for management and oversight purposes: *Provided further,* That funds appropriated herein shall not be subject to the matching or cost share requirements of sections 602(b)(2), 602(b)(3) or 202 of the Federal Water Pollution Control Act nor the matching requirements of section 1452(e) of the Safe Drinking Water Act: *Provided further,* That the Administrator shall reallocate funds appropriated herein for the Clean and Drinking Water State Revolving Funds (Revolving Funds) where projects are not under contract or construction within 12 months of the date of enactment of this Act: *Provided further,* That notwithstanding the priority rankings they would otherwise receive under each program, priority for funds appropriated herein shall be given to projects on a State priority list that are ready to proceed to construction within 12 months of the date of enactment of this Act: *Provided further,* That notwithstanding the requirements of section 603(d) of the Federal Water Pollution Control Act or section 1452(f) of the Safe Drinking Water Act, for the funds appropriated herein, each State shall use not less than 50 percent of the amount of its capitalization grants to provide additional subsidization to eligible recipients in the form of forgiveness of principal, negative interest loans or grants or any combination of these: *Provided further,* That, to the extent there are sufficient eligible project applications, not less than 20 percent of the funds appropriated herein for the Revolving Funds shall be for projects to address green infrastructure, water or energy efficiency improvements or other environmentally innovative activities: *Provided further,* That notwithstanding the limitation on amounts specified in section 518(c) of the Federal Water Pollution Control Act, up to 1.5 percent of the funds appropriated herein for the Clean Water State Revolving Funds may be reserved by the Administrator for tribal grants under section 518(c) of such Act: *Provided further,* That up to 4 percent of the funds appropriated herein for tribal set-asides under the Revolving Funds may be transferred to the Indian

Deadline.

Health Service to support management and oversight of tribal projects: *Provided further,* That none of the funds appropriated herein shall be available for the purchase of land or easements as authorized by section 603(c) of the Federal Water Pollution Control Act or for activities authorized by section 1452(k) of the Safe Drinking Water Act: *Provided further,* That notwithstanding section 603(d)(2) of the Federal Water Pollution Control Act and section 1452(f)(2) of the Safe Drinking Water Act, funds may be used to buy, refinance or restructure the debt obligations of eligible recipients only where such debt was incurred on or after October 1, 2008;

(2) $100,000,000 shall be to carry out Brownfields projects authorized by section 104(k) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980: *Provided,* That the Administrator may reserve up to 3.5 percent of the funds appropriated herein for management and oversight purposes: *Provided further,* That none of the funds appropriated herein shall be subject to cost share requirements under section 104(k)(9)(B)(iii) of such Act; and

(3) $300,000,000 shall be for Diesel Emission Reduction Act grants pursuant to title VII, subtitle G of the Energy Policy Act of 2005: *Provided,* That the Administrator may reserve up to 2 percent of the funds appropriated herein for management and oversight purposes: *Provided further,* That none of the funds appropriated herein for Diesel Emission Reduction Act grants shall be subject to the State Grant and Loan Program Matching Incentive provisions of section 793(c)(3) of such Act.

ADMINISTRATIVE PROVISION, ENVIRONMENTAL PROTECTION AGENCY

(INCLUDING TRANSFERS OF FUNDS)

Funds made available to the Environmental Protection Agency by this Act for management and oversight purposes shall remain available until September 30, 2011, and may be transferred to the "Environmental Programs and Management" account as needed.

DEPARTMENT OF AGRICULTURE

FOREST SERVICE

CAPITAL IMPROVEMENT AND MAINTENANCE

For an additional amount for "Capital Improvement and Maintenance", $650,000,000, for priority road, bridge and trail maintenance and decommissioning, including related watershed restoration and ecosystem enhancement projects; facilities improvement, maintenance and renovation; remediation of abandoned mine sites; and support costs necessary to carry out this work.

WILDLAND FIRE MANAGEMENT

For an additional amount for "Wildland Fire Management", $500,000,000, of which $250,000,000 is for hazardous fuels reduction, forest health protection, rehabilitation and hazard mitigation activities on Federal lands and of which $250,000,000 is for State and private forestry activities including hazardous fuels reduction,

forest health and ecosystem improvement activities on State and private lands using all authorities available to the Forest Service: *Provided,* That up to $50,000,000 of the total funding may be used to make wood-to-energy grants to promote increased utilization of biomass from Federal, State and private lands: *Provided further,* That funds provided for activities on State and private lands shall not be subject to matching or cost share requirements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

INDIAN HEALTH SERVICE

INDIAN HEALTH SERVICES

For an additional amount for "Indian Health Services", for health information technology activities, $85,000,000: *Provided,* That such funds may be used for both telehealth services development and related infrastructure requirements that are typically funded through the "Indian Health Facilities" account: *Provided further,* That notwithstanding any other provision of law, health information technology funds provided within this title shall be allocated at the discretion of the Director of the Indian Health Service.

INDIAN HEALTH FACILITIES

For an additional amount for "Indian Health Facilities", for facilities construction projects, deferred maintenance and improvement projects, the backlog of sanitation projects and the purchase of equipment, $415,000,000, of which $227,000,000 is provided within the health facilities construction activity for the completion of up to two facilities from the current priority list for which work has already been initiated: *Provided,* That for the purposes of this Act, spending caps included within the annual appropriation for "Indian Health Facilities" for the purchase of medical equipment shall not apply: *Provided further,* That section 1606 of this Act shall not apply to tribal contracts entered into by the Service with this appropriation.

OTHER RELATED AGENCIES

SMITHSONIAN INSTITUTION

FACILITIES CAPITAL

For an additional amount for "Facilities Capital", for repair and revitalization of existing facilities, $25,000,000.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

NATIONAL ENDOWMENT FOR THE ARTS

GRANTS AND ADMINISTRATION

For an additional amount for "Grants and Administration", $50,000,000, to be distributed in direct grants to fund arts projects and activities which preserve jobs in the non-profit arts sector threatened by declines in philanthropic and other support during

the current economic downturn: *Provided*, That 40 percent of such funds shall be distributed to State arts agencies and regional arts organizations in a manner similar to the agency's current practice and 60 percent of such funds shall be for competitively selected arts projects and activities according to sections 2 and 5(c) of the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951, 954(c)): *Provided further*, That matching requirements under section 5(e) of such Act shall be waived.

Waiver authority.

GENERAL PROVISIONS—THIS TITLE

Deadlines. Expenditure plan.

SEC. 701. (a) Within 30 days of enactment of this Act, each agency receiving funds under this title shall submit a general plan for the expenditure of such funds to the House and Senate Committees on Appropriations.

Reports.

(b) Within 90 days of enactment of this Act, each agency receiving funds under this title shall submit to the Committees a report containing detailed project level information associated with the general plan submitted pursuant to subsection (a).

SEC. 702. In carrying out the work for which funds in this title are being made available, the Secretary of the Interior and the Secretary of Agriculture shall utilize, where practicable, the Public Lands Corps, Youth Conservation Corps, Student Conservation Association, Job Corps and other related partnerships with Federal, State, local, tribal or non-profit groups that serve young adults.

Notification. Deadline.

SEC. 703. Each agency receiving funds under this title may transfer up to 10 percent of the funds in any account to other appropriation accounts within the agency, if the head of the agency (1) determines that the transfer will enhance the efficiency or effectiveness of the use of the funds without changing the intended purpose; and (2) notifies the Committees on Appropriations of the House of Representatives and the Senate 10 days prior to the transfer.

TITLE VIII—DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

DEPARTMENT OF LABOR

EMPLOYMENT AND TRAINING ADMINISTRATION

Grants.

TRAINING AND EMPLOYMENT SERVICES

For an additional amount for "Training and Employment Services" for activities under the Workforce Investment Act of 1998 ("WIA"), $3,950,000,000, which shall be available for obligation on the date of enactment of this Act, as follows:

(1) $500,000,000 for grants to the States for adult employment and training activities, including supportive services and needs-related payments described in section 134(e)(2) and (3) of the WIA: *Provided,* That a priority use of these funds shall be services to individuals described in 134(d)(4)(E) of the WIA;

(2) $1,200,000,000 for grants to the States for youth activities, including summer employment for youth: *Provided,* That no portion of such funds shall be reserved to carry out section 127(b)(1)(A) of the WIA: *Provided further,* That for purposes

of section 127(b)(1)(C)(iv) of the WIA, funds available for youth activities shall be allotted as if the total amount available for youth activities in the fiscal year does not exceed $1,000,000,000: *Provided further,* That with respect to the youth activities provided with such funds, section 101(13)(A) of the WIA shall be applied by substituting "age 24" for "age 21": *Provided further,* That the work readiness performance indicator described in section 136(b)(2)(A)(ii)(I) of the WIA shall be the only measure of performance used to assess the effectiveness of summer employment for youth provided with such funds;

Applicability.

(3) $1,250,000,000 for grants to the States for dislocated worker employment and training activities;

(4) $200,000,000 for the dislocated workers assistance national reserve;

(5) $50,000,000 for YouthBuild activities: *Provided,* That for program years 2008 and 2009, the YouthBuild program may serve an individual who has dropped out of high school and re-enrolled in an alternative school, if that re-enrollment is part of a sequential service strategy; and

(6) $750,000,000 for a program of competitive grants for worker training and placement in high growth and emerging industry sectors: *Provided*, That $500,000,000 shall be for research, labor exchange and job training projects that prepare workers for careers in energy efficiency and renewable energy as described in section 171(e)(1)(B) of the WIA: *Provided further*, That in awarding grants from those funds not designated in the preceding proviso, the Secretary of Labor shall give priority to projects that prepare workers for careers in the health care sector:

Provided, That funds made available in this paragraph shall remain available through June 30, 2010: *Provided further,* That a local board may award a contract to an institution of higher education or other eligible training provider if the local board determines that it would facilitate the training of multiple individuals in high-demand occupations, if such contract does not limit customer choice.

COMMUNITY SERVICE EMPLOYMENT FOR OLDER AMERICANS

For an additional amount for "Community Service Employment for Older Americans" to carry out title V of the Older Americans Act of 1965, $120,000,000, which shall be available for obligation on the date of enactment of this Act and shall remain available through June 30, 2010: *Provided*, That funds shall be allotted within 30 days of such enactment to current grantees in proportion to their allotment in program year 2008: *Provided further,* That funds made available under this heading in this Act may, in accordance with section 517(c) of the Older Americans Act of 1965, be recaptured and reobligated.

Deadline.

STATE UNEMPLOYMENT INSURANCE AND EMPLOYMENT SERVICE OPERATIONS

For an additional amount for "State Unemployment Insurance and Employment Service Operations" for grants to States in accordance with section 6 of the Wagner-Peyser Act, $400,000,000, which may be expended from the Employment Security Administration Account in the Unemployment Trust Fund, and which shall be

available for obligation on the date of enactment of this Act: *Provided*, That such funds shall remain available to the States through September 30, 2010: *Provided further*, That $250,000,000 of such funds shall be used by States for reemployment services for unemployment insurance claimants (including the integrated Employment Service and Unemployment Insurance information technology required to identify and serve the needs of such claimants): *Provided further*, That the Secretary of Labor shall establish planning and reporting procedures necessary to provide oversight of funds used for reemployment services.

Procedures.

DEPARTMENTAL MANAGEMENT

SALARIES AND EXPENSES

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Departmental Management", $80,000,000, for the enforcement of worker protection laws and regulations, oversight, and coordination activities related to the infrastructure and unemployment insurance investments in this Act: *Provided*, That the Secretary of Labor may transfer such sums as necessary to "Employment and Standards Administration", "Employee Benefits Security Administration", "Occupational Safety and Health Administration", and "Employment and Training Administration—Program Administration" for enforcement, oversight, and coordination activities: *Provided further,* That prior to obligating any funds proposed to be transferred from this account, the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate an operating plan describing the planned uses of each amount proposed to be transferred.

Operating plan.

OFFICE OF JOB CORPS

For an additional amount for "Office of Job Corps", $250,000,000, for construction, rehabilitation and acquisition of Job Corps Centers, which shall be available upon the date of enactment of this Act and remain available for obligation through June 30, 2010: *Provided*, That section 1552(a) of title 31, United States Code shall not apply if funds are used for a multi-year lease agreement that will result in construction activities that can commence within 120 days of enactment of this Act: *Provided further*, That notwithstanding section 3324(a) of title 31, United States Code, the funds used for an agreement under the preceding proviso may be used for advance, progress, and other payments: *Provided further*, That the Secretary of Labor may transfer up to 15 percent of such funds to meet the operational needs of such centers, which may include training for careers in the energy efficiency, renewable energy, and environmental protection industries: *Provided further*, That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate an operating plan describing the allocation of funds, and a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than September 30, 2009 and quarterly thereafter as long as funding provided under this heading is available for obligation or expenditure.

Operating plan.
Reports.
Deadlines.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the "Office of Inspector General", $6,000,000, which shall remain available through September 30, 2012, for salaries and expenses necessary for oversight and audit of programs, grants, and projects funded in this Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH RESOURCES AND SERVICES ADMINISTRATION

HEALTH RESOURCES AND SERVICES

For an additional amount for "Health Resources and Services", $2,500,000,000 which shall be used as follows:

(1) $500,000,000 shall be for grants to health centers authorized under section 330 of the Public Health Service Act ("PHS Act");

(2) $1,500,000,000 shall be available for grants for construction, renovation and equipment, and for the acquisition of health information technology systems, for health centers including health center controlled networks receiving operating grants under section 330 of the PHS Act, notwithstanding the limitation in section 330(e)(3); and

(3) $500,000,000 to address health professions workforce shortages, of which $75,000,000 for the National Health Service Corps shall remain available through September 30, 2011: *Provided,* That funds may be used to provide scholarships, loan repayment, and grants to training programs for equipment as authorized in the PHS Act, and grants authorized in sections 330L, 747, 767 and 768 of the PHS Act: *Provided further,* That 20 percent of the funds allocated to the National Health Service Corps shall be used for field operations:

Provided, That up to 0.5 percent of funds provided in this paragraph may used for administration of such funds: *Provided further,* That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate an operating plan detailing activities to be supported and timelines for expenditure prior to making any Federal obligations of funds provided in this paragraph but not later than 90 days after the date of enactment of this Act: *Provided further,* That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded in this paragraph not later than November 1, 2009 and every 6 months thereafter as long as funding provided in this paragraph is available for obligation or expenditure.

Operating plan. Deadline.

Reports. Deadlines.

NATIONAL INSTITUTES OF HEALTH

NATIONAL CENTER FOR RESEARCH RESOURCES

For an additional amount for "National Center for Research Resources", $1,300,000,000, of which $1,000,000,000 shall be for grants or contracts under section 481A of the Public Health Service Act to construct, renovate or repair existing non-Federal research facilities: *Provided*, That sections 481A(c)(1)(B)(ii), paragraphs (1), (3), and (4) of section 481A(e), and section 481B of such Act shall

Grants. Contracts.

not apply to the use of such funds: *Provided further*, That the references to "20 years" in subsections (c)(1)(B)(i) and (f) of section 481A of such Act are deemed to be references to "10 years" for purposes of using such funds: *Provided further*, That the National Center for Research Resources may also use $300,000,000 to provide, under the authority of section 301 and title IV of such Act, shared instrumentation and other capital research equipment to recipients of grants and contracts under section 481A of such Act and other appropriate entities: *Provided further*, That the Director of the Center shall provide to the Committees on Appropriations of the House of Representatives and the Senate an annual report indicating the number of institutions receiving awards of a grant or contract under section 481A of such Act, the proposed use of the funding, the average award size, a list of grant or contract recipients, and the amount of each award.

Reports. Deadline.

OFFICE OF THE DIRECTOR

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Office of the Director", $8,200,000,000: *Provided,* That $7,400,000,000 shall be transferred to the Institutes and Centers of the National Institutes of Health ("NIH") and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act in proportion to the appropriations otherwise made to such Institutes, Centers, and Common Fund for fiscal year 2009: *Provided further,* That these funds shall be used to support additional scientific research and shall be merged with and be available for the same purposes as the appropriation or fund to which transferred: *Provided further,* That this transfer authority is in addition to any other transfer authority available to the NIH: *Provided further,* That none of these funds may be transferred to "National Institutes of Health—Buildings and Facilities", the Center for Scientific Review, the Center for Information Technology, the Clinical Center, or the Global Fund for HIV/AIDS, Tuberculosis and Malaria: *Provided further,* That the funds provided in this Act to the NIH shall not be subject to the provisions of 15 U.S.C. 638(f)(1) and 15 U.S.C. 638(n)(1): *Provided further,* That $400,000,000 may be used to carry out section 215 of division G of Public Law 110–161.

BUILDINGS AND FACILITIES

For an additional amount for "Buildings and Facilities", $500,000,000, to fund high-priority repair, construction and improvement projects for National Institutes of Health facilities on the Bethesda, Maryland campus and other agency locations.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

HEALTHCARE RESEARCH AND QUALITY

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Healthcare Research and Quality" to carry out titles III and IX of the Public Health Service Act, part A of title XI of the Social Security Act, and section

1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, $700,000,000 for comparative effectiveness research: *Provided*, That of the amount appropriated in this paragraph, $400,000,000 shall be transferred to the Office of the Director of the National Institutes of Health ("Office of the Director") to conduct or support comparative effectiveness research under section 301 and title IV of the Public Health Service Act: *Provided further*, That funds transferred to the Office of the Director may be transferred to the Institutes and Centers of the National Institutes of Health and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act: *Provided further*, That this transfer authority is in addition to any other transfer authority available to the National Institutes of Health: *Provided further*, That within the amount available in this paragraph for the Agency for Healthcare Research and Quality, not more than 1 percent shall be made available for additional full-time equivalents.

In addition, $400,000,000 shall be available for comparative effectiveness research to be allocated at the discretion of the Secretary of Health and Human Services ("Secretary"): *Provided*, That the funding appropriated in this paragraph shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data: *Provided further*, That the Secretary shall enter into a contract with the Institute of Medicine, for which no more than $1,500,000 shall be made available from funds provided in this paragraph, to produce and submit a report to the Congress and the Secretary by not later than June 30, 2009, that includes recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in this paragraph and that considers input from stakeholders: *Provided further*, That the Secretary shall consider any recommendations of the Federal Coordinating Council for Comparative Effectiveness Research established by section 804 of this Act and any recommendations included in the Institute of Medicine report pursuant to the preceding proviso in designating activities to receive funds provided in this paragraph and may make grants and contracts with appropriate entities, which may include agencies within the Department of Health and Human Services and other governmental agencies, as well as private sector entities, that have demonstrated experience and capacity to achieve the goals of comparative effectiveness research: *Provided further*, That the Secretary shall publish information on grants and contracts awarded with the funds provided under this heading within a reasonable time of the obligation of funds for such grants and contracts and shall disseminate research findings from such grants and contracts to clinicians, patients, and the general public, as appropriate: *Provided further*, That, to the extent feasible, the Secretary shall ensure that the recipients of the funds provided by this paragraph offer an opportunity for public comment on the research: *Provided further*, That research conducted with funds appropriated under this paragraph

Contracts.
Reports.
Deadline.

Publication.

Public comment.

Research and development.

Reports. Deadline.

shall be consistent with Departmental policies relating to the inclusion of women and minorities in research: *Provided further*, That the Secretary shall provide the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate with an annual report on the research conducted or supported through the funds provided under this heading: *Provided further*, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide the Committees on Appropriations of the House of Representatives and the Senate a fiscal year 2009 operating plan for the funds appropriated under this heading prior to making any Federal obligations of such funds in fiscal year 2009, but not later than July 30, 2009, and a fiscal year 2010 operating plan for such funds prior to making any Federal obligations of such funds in fiscal year 2010, but not later than November 1, 2009, that detail the type of research being conducted or supported, including the priority conditions addressed; and specify the allocation of resources within the Department of Health and Human Services: *Provided further*, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

Operating plans. Deadlines.

Reports. Deadlines.

ADMINISTRATION FOR CHILDREN AND FAMILIES

PAYMENTS TO STATES FOR THE CHILD CARE AND DEVELOPMENT BLOCK GRANT

For an additional amount for "Payments to States for the Child Care and Development Block Grant", $2,000,000,000, which shall be used to supplement, not supplant State general revenue funds for child care assistance for low-income families: *Provided,* That, in addition to the amounts required to be reserved by the States under section 658G of the Child Care and Development Block Grant Act of 1990, $255,186,000 shall be reserved by the States for activities authorized under section 658G, of which $93,587,000 shall be for activities that improve the quality of infant and toddler care.

CHILDREN AND FAMILIES SERVICES PROGRAMS

For an additional amount for "Children and Families Services Programs", $3,150,000,000, which shall be used as follows:

(1) $1,000,000,000 for carrying out activities under the Head Start Act.

(2) $1,100,000,000 for expansion of Early Head Start programs, as described in section 645A of the Head Start Act: *Provided*, That of the funds provided in this paragraph, up to 10 percent shall be available for the provision of training

and technical assistance to such programs consistent with section 645A(g)(2) of such Act, and up to 3 percent shall be available for monitoring the operation of such programs consistent with section 641A of such Act.

(3) $1,000,000,000 for carrying out activities under sections 674 through 679 of the Community Services Block Grant Act, of which no part shall be subject to section 674(b)(3) of such Act: *Provided,* That notwithstanding section 675C(a)(1) and 675C(b) of such Act, 1 percent of the funds made available to each State from this additional amount shall be used for benefits enrollment coordination activities relating to the identification and enrollment of eligible individuals and families in Federal, State, and local benefit programs: *Provided further,* That all funds remaining available to a State from this additional amount after application of the previous proviso shall be distributed to eligible entities as defined in section 673(1) of such Act: *Provided further*, That for services furnished under such Act during fiscal years 2009 and 2010, States may apply the last sentence of section 673(2) of such Act by substituting "200 percent" for "125 percent".

(4) $50,000,000 for carrying out activities under section 1110 of the Social Security Act.

ADMINISTRATION ON AGING

AGING SERVICES PROGRAMS

For an additional amount for "Aging Services Programs" under subparts 1 and 2 of part C, of title III, and under title VI, of the Older Americans Act of 1965, $100,000,000, of which $65,000,000 shall be for Congregate Nutrition Services, $32,000,000 shall be for Home-Delivered Nutrition Services and $3,000,000 shall be for Nutrition Services for Native Americans.

OFFICE OF THE SECRETARY

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Office of the National Coordinator for Health Information Technology", $2,000,000,000, to carry out title XIII of this Act, to remain available until expended: *Provided*, That of such amount, the Secretary of Health and Human Services shall transfer $20,000,000 to the Director of the National Institute of Standards and Technology in the Department of Commerce for continued work on advancing health care information enterprise integration through activities such as technical standards analysis and establishment of conformance testing infrastructure, so long as such activities are coordinated with the Office of the National Coordinator for Health Information Technology: *Provided further,* That $300,000,000 is to support regional or sub-national efforts toward health information exchange: *Provided further,* That 0.25 percent of the funds provided in this paragraph may be used for administration of such funds: *Provided further*, That funds available under this heading shall become available for obligation only upon submission of an annual operating plan by the Secretary

Operating plan.
Deadline.

Operating plans. Deadlines.

to the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That the fiscal year 2009 operating plan shall be provided not later than 90 days after enactment of this Act and that subsequent annual operating plans shall be provided not later than November 1 of each year: *Provided further*, That these operating plans shall describe how expenditures are aligned with the specific objectives, milestones, and metrics of the Federal Health Information Technology Strategic Plan, including any subsequent updates to the Plan; the allocation of resources within the Department of Health and Human Services and other Federal agencies; and the identification of programs and activities that are supported: *Provided further*, That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each major set of activities not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

Reports. Deadlines.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the "Office of Inspector General", $17,000,000 which shall remain available until September 30, 2012.

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

For an additional amount for "Public Health and Social Services Emergency Fund" to improve information technology security at the Department of Health and Human Services, $50,000,000.

PREVENTION AND WELLNESS FUND

(INCLUDING TRANSFER OF FUNDS)

For necessary expenses for a "Prevention and Wellness Fund" to be administered through the Department of Health and Human Services, Office of the Secretary, $1,000,000,000: *Provided,* That of the amount provided in this paragraph, $300,000,000 shall be transferred to the Centers for Disease Control and Prevention ("CDC") as an additional amount to carry out the immunization program ("section 317 immunization program") authorized by section 317(a), (j), and (k)(1) of the Public Health Service Act ("PHS Act"): *Provided further,* That of the amount provided in this paragraph, $650,000,000 shall be to carry out evidence-based clinical and community-based prevention and wellness strategies authorized by the PHS Act, as determined by the Secretary, that deliver specific, measurable health outcomes that address chronic disease rates: *Provided further*, That funds appropriated in the preceding proviso may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate: *Provided further*, That of the amount appropriated in this paragraph, $50,000,000 shall be provided to States for an additional amount to carry out activities to implement healthcare associated infections reduction strategies: *Provided further,* That not more than 0.5 percent of funds made available in this paragraph may be used for management and oversight expenses in the office or division of the Department of Health and Human Services administering the funds: *Provided further*,

Contracts. Evaluations. Deadline.

That the Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out with funds provided under this heading in order to determine the quality and effectiveness of the programs: *Provided further*, That the Secretary shall, not later than 1 year after the date of enactment of this Act, submit to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report summarizing the annual evaluations of programs from the preceding proviso: *Provided further*, That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate an operating plan for the Prevention and Wellness Fund prior to making any Federal obligations of funds provided in this paragraph (excluding funds to carry out the section 317 immunization program), but not later than 90 days after the date of enactment of this Act, that indicates the prevention priorities to be addressed; provides measurable goals for each prevention priority; details the allocation of resources within the Department of Health and Human Services; and identifies which programs or activities are supported, including descriptions of any new programs or activities: *Provided further*, That the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

Reports. Deadline.

Operating plan. Deadline.

Reports. Deadlines.

DEPARTMENT OF EDUCATION

EDUCATION FOR THE DISADVANTAGED

Grants.

For an additional amount for "Education for the Disadvantaged" to carry out title I of the Elementary and Secondary Education Act of 1965 ("ESEA"), $13,000,000,000: *Provided*, That $5,000,000,000 shall be available for targeted grants under section 1125 of the ESEA: *Provided further*, That $5,000,000,000 shall be available for education finance incentive grants under section 1125A of the ESEA: *Provided further*, That $3,000,000,000 shall be for school improvement grants under section 1003(g) of the ESEA: *Provided further*, That each local educational agency receiving funds available under this paragraph shall be required to file with the State educational agency, no later than December 1, 2009, a school-by-school listing of per-pupil educational expenditures from State and local sources during the 2008–2009 academic year: *Provided further,* That each State educational agency shall report that information to the Secretary of Education by March 31, 2010.

Deadline. Expenditures.

Reports. Deadline.

IMPACT AID

For an additional amount for "Impact Aid" to carry out section 8007 of title VIII of the Elementary and Secondary Education Act of 1965, $100,000,000, which shall be expended pursuant to the requirements of section 805.

Grants.

SCHOOL IMPROVEMENT PROGRAMS

For an additional amount for "School Improvement Programs" to carry out subpart 1, part D of title II of the Elementary and Secondary Education Act of 1965 ("ESEA"), and subtitle B of title VII of the McKinney-Vento Homeless Assistance Act, $720,000,000: *Provided*, That $650,000,000 shall be available for subpart 1, part D of title II of the ESEA: *Provided further,* That the Secretary shall allot $70,000,000 for grants under McKinney-Vento to each State in proportion to the number of homeless students identified by the State during the 2007–2008 school year relative to the number of such children identified nationally during that school year: *Provided further,* That State educational agencies shall subgrant the McKinney-Vento funds to local educational agencies on a competitive basis or according to a formula based on the number of homeless students identified by the local educational agencies in the State: *Provided further,* That the Secretary shall distribute the McKinney-Vento funds to the States not later than 60 days after the date of the enactment of this Act: *Provided further,* That each State shall subgrant the McKinney-Vento funds to local educational agencies not later than 120 days after receiving its grant from the Secretary.

Deadline.

Deadline.

INNOVATION AND IMPROVEMENT

For an additional amount for "Innovation and Improvement" to carry out subpart 1, part D of title V of the Elementary and Secondary Education Act of 1965 ("ESEA"), $200,000,000: *Provided*, That these funds shall be expended as directed in the fifth, sixth, and seventh provisos under the heading "Innovation and Improvement" in the Department of Education Appropriations Act, 2008: *Provided further*, That a portion of these funds shall also be used for a rigorous national evaluation by the Institute of Education Sciences, utilizing randomized controlled methodology to the extent feasible, that assesses the impact of performance-based teacher and principal compensation systems supported by the funds provided in this Act on teacher and principal recruitment and retention in high-need schools and subjects: *Provided further,* That the Secretary may reserve up to 1 percent of the amount made available under this heading for management and oversight of the activities supported with those funds.

Evaluation.

SPECIAL EDUCATION

For an additional amount for "Special Education" for carrying out parts B and C of the Individuals with Disabilities Education Act ("IDEA"), $12,200,000,000, of which $11,300,000,000 shall be available for section 611 of the IDEA: *Provided,* That if every State, as defined by section 602(31) of the IDEA, reaches its maximum allocation under section 611(d)(3)(B)(iii) of the IDEA, and there are remaining funds, such funds shall be proportionally allocated to each State subject to the maximum amounts contained in section 611(a)(2) of the IDEA: *Provided further,* That by July 1, 2009, the Secretary of Education shall reserve the amount needed for grants under section 643(e) of the IDEA, with any remaining funds to be allocated in accordance with section 643(c) of the IDEA: *Provided further,* That the total amount for each of sections 611(b)(2) and 643(b)(1) of the IDEA, under this and all other Acts,

Deadline.
Grants.

for fiscal year 2009, whenever enacted, shall be equal to the amounts respectively available for these activities under these sections during fiscal year 2008 increased by the amount of inflation as specified in section 619(d)(2)(B) of the IDEA: *Provided further,* That $400,000,000 shall be available for section 619 of the IDEA and $500,000,000 shall be available for part C of the IDEA.

REHABILITATION SERVICES AND DISABILITY RESEARCH

Grants.

For an additional amount for "Rehabilitation Services and Disability Research" for providing grants to States to carry out the Vocational Rehabilitation Services program under part B of title I and parts B and C of chapter 1 and chapter 2 of title VII of the Rehabilitation Act of 1973, $680,000,000: *Provided*, That $540,000,000 shall be available for part B of title I of the Rehabilitation Act: *Provided further*, That funds provided herein shall not be considered in determining the amount required to be appropriated under section 100(b)(1) of the Rehabilitation Act of 1973 in any fiscal year: *Provided further*, That, notwithstanding section 7(14)(A), the Federal share of the costs of vocational rehabilitation services provided with the funds provided herein shall be 100 percent: *Provided further*, That $140,000,000 shall be available for parts B and C of chapter 1 and chapter 2 of title VII of the Rehabilitation Act: *Provided further*, That $18,200,000 shall be for State Grants, $87,500,000 shall be for independent living centers, and $34,300,000 shall be for services for older blind individuals.

STUDENT FINANCIAL ASSISTANCE

For an additional amount for "Student Financial Assistance" to carry out subpart 1 of part A and part C of title IV of the Higher Education Act of 1965 ("HEA"), $15,840,000,000, which shall remain available through September 30, 2011: *Provided*, That $15,640,000,000 shall be available for subpart 1 of part A of title IV of the HEA: *Provided further*, That $200,000,000 shall be available for part C of title IV of the HEA.

The maximum Pell Grant for which a student shall be eligible during award year 2009–2010 shall be $4,860.

20 USC 1070a note.

STUDENT AID ADMINISTRATION

For an additional amount for "Student Aid Administration" to carry out part D of title I, and subparts 1, 3, and 4 of part A, and parts B, C, D, and E of title IV of the Higher Education Act of 1965, $60,000,000.

HIGHER EDUCATION

For an additional amount for "Higher Education" to carry out part A of title II of the Higher Education Act of 1965, $100,000,000.

INSTITUTE OF EDUCATION SCIENCES

For an additional amount for "Institute of Education Sciences" to carry out section 208 of the Educational Technical Assistance Act, $250,000,000, which may be used for Statewide data systems that include postsecondary and workforce information, of which

up to $5,000,000 may be used for State data coordinators and for awards to public or private organizations or agencies to improve data coordination.

DEPARTMENTAL MANAGEMENT

OFFICE OF THE INSPECTOR GENERAL

For an additional amount for the "Office of the Inspector General", $14,000,000, which shall remain available through September 30, 2012, for salaries and expenses necessary for oversight and audit of programs, grants, and projects funded in this Act.

RELATED AGENCIES

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

OPERATING EXPENSES

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Operating Expenses" to carry out the Domestic Volunteer Service Act of 1973 ("1973 Act") and the National and Community Service Act of 1990 ("1990 Act"), $160,000,000: *Provided,* That $89,000,000 of the funds made available in this paragraph shall be used to make additional awards to existing AmeriCorps grantees and may be used to provide adjustments to awards under subtitle C of title I of the 1990 Act made prior to September 30, 2010 for which the Chief Executive Officer of the Corporation for National and Community Service ("CEO") determines that a waiver of the Federal share limitation is warranted under section 2521.70 of title 45 of the Code of Federal Regulations: *Provided further,* That of the amount made available in this paragraph, not less than $6,000,000 shall be transferred to "Salaries and Expenses" for necessary expenses relating to information technology upgrades, of which up to $800,000 may be used to administer the funds provided in this paragraph: *Provided further,* That of the amount provided in this paragraph, not less than $65,000,000 shall be for programs under title I, part A of the 1973 Act: *Provided further,* That funds provided in the previous proviso shall not be made available in connection with cost-share agreements authorized under section 192A(g)(10) of the 1990 Act: *Provided further*, That of the funds available under this heading, up to 20 percent of funds allocated to grants authorized under section 124(b) of title I, subtitle C of the 1990 Act may be used to administer, reimburse, or support any national service program under section 129(d)(2) of the 1990 Act: *Provided further,* That, except as provided herein and in addition to requirements identified herein, funds provided in this paragraph shall be subject to the terms and conditions under which funds were appropriated in fiscal year 2008: *Provided further,* That the CEO shall provide the Committees on Appropriations of the House of Representatives and the Senate a fiscal year 2009 operating plan for the funds appropriated in this paragraph prior to making any Federal obligations of such funds in fiscal year 2009, but not later than 90 days after the date of enactment of this Act, and a fiscal year 2010 operating plan for such funds prior to making any Federal obligations of such funds in fiscal year 2010, but not later than

Operating plans. Deadlines.

November 1, 2009, that detail the allocation of resources and the increased number of members supported by the AmeriCorps programs: *Provided further,* That the CEO shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

Reports. Deadline.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the "Office of Inspector General", $1,000,000, which shall remain available until September 30, 2012.

NATIONAL SERVICE TRUST

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "National Service Trust" established under subtitle D of title I of the National and Community Service Act of 1990 ("1990 Act"), $40,000,000, which shall remain available until expended: *Provided,* That the Corporation for National and Community Service may transfer additional funds from the amount provided within "Operating Expenses" for grants made under subtitle C of title I of the 1990 Act to this appropriation upon determination that such transfer is necessary to support the activities of national service participants and after notice is transmitted to the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That the amount appropriated for or transferred to the National Service Trust may be invested under section 145(b) of the 1990 Act without regard to the requirement to apportion funds under 31 U.S.C. 1513(b).

Notification.

SOCIAL SECURITY ADMINISTRATION

LIMITATION ON ADMINISTRATIVE EXPENSES

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Limitation on Administrative Expenses", $1,000,000,000 shall be available as follows:

(1) $500,000,000 shall remain available until expended for necessary expenses of the replacement of the National Computer Center and the information technology costs associated with such Center: *Provided,* That the Commissioner of Social Security shall notify the Committees on Appropriations of the House of Representatives and the Senate not later than 10 days prior to each public notice soliciting bids related to site selection and construction and prior to the lease or purchase of such site: *Provided further,* That the construction plan and site selection for such center shall be subject to review and approval by the Office of Management and Budget: *Provided further*, That such center shall continue to be a government-operated facility; and

Notification. Deadline.

(2) $500,000,000 for processing disability and retirement workloads, including information technology acquisitions and research in support of such activities: *Provided*, That up to

$40,000,000 may be used by the Commissioner of Social Security for health information technology research and activities to facilitate the adoption of electronic medical records in disability claims, including the transfer of funds to "Supplemental Security Income Program" to carry out activities under section 1110 of the Social Security Act.

OFFICE OF INSPECTOR GENERAL

For an additional amount for the "Office of Inspector General", $2,000,000, which shall remain available through September 30, 2012, for salaries and expenses necessary for oversight and audit of programs, projects, and activities funded in this Act.

GENERAL PROVISIONS—THIS TITLE

SEC. 801. (a) Up to 1 percent of the funds made available to the Department of Labor in this title may be used for the administration, management, and oversight of the programs, grants, and activities funded by such appropriation, including the evaluation of the use of such funds.

(b) Funds designated for these purposes may be available for obligation through September 30, 2010.

Deadline.
Operating plan.

(c) Not later than 30 days after enactment of this Act, the Secretary of Labor shall provide an operating plan describing the proposed use of funds for the purposes described in (a).

SEC. 802. REPORT ON THE IMPACT OF PAST AND FUTURE MINIMUM WAGE INCREASES. (a) IN GENERAL.—Section 8104 of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (Public Law 110–28; 121 Stat. 189) is amended to read as follows:

29 USC 206 note.

"SEC. 8104. REPORT ON THE IMPACT OF PAST AND FUTURE MINIMUM WAGE INCREASES.

Effective date.

"(a) STUDY.—Beginning on the date that is 60 days after the date of enactment of this Act, and every year thereafter until the minimum wage in the respective territory is $7.25 per hour, the Government Accountability Office shall conduct a study to—

"(1) assess the impact of the minimum wage increases that occurred in American Samoa and the Commonwealth of the Northern Mariana Islands in 2007 and 2008, as required under Public Law 110–28, on the rates of employment and the living standards of workers, with full consideration of the other factors that impact rates of employment and the living standards of workers such as inflation in the cost of food, energy, and other commodities; and

"(2) estimate the impact of any further wage increases on rates of employment and the living standards of workers in American Samoa and the Commonwealth of the Northern Mariana Islands, with full consideration of the other factors that may impact the rates of employment and the living standards of workers, including assessing how the profitability of major private sector firms may be impacted by wage increases in comparison to other factors such as energy costs and the value of tax benefits.

"(b) REPORT.—No earlier than March 15, 2010, and not later than April 15, 2010, the Government Accountability Office shall transmit its first report to Congress concerning the findings of

the study required under subsection (a). The Government Accountability Office shall transmit any subsequent reports to Congress concerning the findings of a study required by subsection (a) between March 15 and April 15 of each year.

"(c) ECONOMIC INFORMATION.—To provide sufficient economic data for the conduct of the study under subsection (a) the Bureau of the Census of the Department of Commerce shall include and separately report on American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the Virgin Islands in its County Business Patterns data with the same regularity and to the same extent as each Bureau collects and reports such data for the 50 States. In the event that the inclusion of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the Virgin Islands in such surveys and data compilations requires time to structure and implement, the Bureau of the Census shall in the interim annually report the best available data that can feasibly be secured with respect to such territories. Such interim report shall describe the steps the Bureau will take to improve future data collection in the territories to achieve comparability with the data collected in the United States. The Bureau of the Census, together with the Department of the Interior, shall coordinate their efforts to achieve such improvements.".

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the date of enactment of this Act. 29 USC 206 note.

SEC. 803. ELIGIBLE EMPLOYEES IN THE RECREATIONAL MARINE INDUSTRY. Section 2(3)(F) of the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 902(3)(F)) is amended—

(1) by striking ", repair or dismantle"; and

(2) by striking the semicolon and inserting ", or individuals employed to repair any recreational vessel, or to dismantle any part of a recreational vessel in connection with the repair of such vessel;".

SEC. 804. FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH. 42 USC 299b–8.

(a) ESTABLISHMENT.—There is hereby established a Federal Coordinating Council for Comparative Effectiveness Research (in this section referred to as the "Council").

(b) PURPOSE.—The Council shall foster optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources.

(c) DUTIES.—The Council shall—

(1) assist the offices and agencies of the Federal Government, including the Departments of Health and Human Services, Veterans Affairs, and Defense, and other Federal departments or agencies, to coordinate the conduct or support of comparative effectiveness and related health services research; and

(2) advise the President and Congress on—

(A) strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government; and

(B) organizational expenditures for comparative effectiveness research by relevant Federal departments and agencies.

(d) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Council shall be composed of not more than 15 members, all of whom are senior Federal officers or employees with responsibility for health-related programs, appointed by the President, acting through the Secretary of Health and Human Services (in this section referred to as the "Secretary"). Members shall first be appointed to the Council not later than 30 days after the date of the enactment of this Act.

Deadline.

(2) MEMBERS.—

(A) IN GENERAL.—The members of the Council shall include one senior officer or employee from each of the following agencies:

(i) The Agency for Healthcare Research and Quality.

(ii) The Centers for Medicare and Medicaid Services.

(iii) The National Institutes of Health.

(iv) The Office of the National Coordinator for Health Information Technology.

(v) The Food and Drug Administration.

(vi) The Veterans Health Administration within the Department of Veterans Affairs.

(vii) The office within the Department of Defense responsible for management of the Department of Defense Military Health Care System.

(B) QUALIFICATIONS.—At least half of the members of the Council shall be physicians or other experts with clinical expertise.

(3) CHAIRMAN; VICE CHAIRMAN.—The Secretary shall serve as Chairman of the Council and shall designate a member to serve as Vice Chairman.

(e) REPORTS.—

(1) INITIAL REPORT.—Not later than June 30, 2009, the Council shall submit to the President and the Congress a report containing information describing current Federal activities on comparative effectiveness research and recommendations for such research conducted or supported from funds made available for allotment by the Secretary for comparative effectiveness research in this Act.

(2) ANNUAL REPORT.—The Council shall submit to the President and Congress an annual report regarding its activities and recommendations concerning the infrastructure needs, organizational expenditures and opportunities for better coordination of comparative effectiveness research by relevant Federal departments and agencies.

(f) STAFFING; SUPPORT.—From funds made available for allotment by the Secretary for comparative effectiveness research in this Act, the Secretary shall make available not more than 1 percent to the Council for staff and administrative support.

(g) RULES OF CONSTRUCTION.—

(1) COVERAGE.—Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.

(2) REPORTS AND RECOMMENDATIONS.—None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.

SEC. 805. GRANTS FOR IMPACT AID CONSTRUCTION. (a) RESERVATION FOR MANAGEMENT AND OVERSIGHT.—From the funds appropriated to carry out this section, the Secretary may reserve up to 1 percent for management and oversight of the activities carried out with those funds.

(b) CONSTRUCTION PAYMENTS.—

(1) FORMULA GRANTS.—(A) IN GENERAL.—From 40 percent of the amount not reserved under subsection (a), the Secretary shall make payments in accordance with section 8007(a) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7707(a)), except that the amount of such payments shall be determined in accordance with subparagraph (B).

(B) AMOUNT OF PAYMENTS.—The Secretary shall make a payment to each local educational agency eligible for a payment under section 8007(a) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7707(a)) in an amount that bears the same relationship to the funds made available under subparagraph (A) as the number of children determined under subparagraphs (B), (C), and (D)(i) of section 8003(a)(1) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7703(a)(1)(B), (C), and (D)(i)) who were in average daily attendance in the local educational agency for the most recent year for which such information is available bears to the number of such children in all the local educational agencies eligible for a payment under section 8007(a) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7707(a)).

(2) COMPETITIVE GRANTS.—From 60 percent of the amount not reserved under subsection (a), the Secretary—

(A) shall award emergency grants in accordance with section 8007(b) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7707(b)) to eligible local educational agencies to enable the agencies to carry out emergency repairs of school facilities; and

(B) may award modernization grants in accordance with section 8007(b) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7707(b)) to eligible local educational agencies to enable the agencies to carry out the modernization of school facilities.

(3) PROVISIONS NOT TO APPLY.—Paragraphs (2), (3), (4), (5)(A)(i), and (5)(A)(vi) of section 8007(b) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7707(b)(2), (3), (4), (5)(A)(i), and (5)(A)(vi)) shall not apply to grants made under paragraph (2).

(4) ELIGIBILITY.—A local educational agency is eligible to receive a grant under paragraph (2) if the local educational agency—

(A) was eligible to receive a payment under section 8002 or 8003 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7702 and 7703) for fiscal year 2008; and

(B) has—

(i) a total taxable assessed value of real property that may be taxed for school purposes of less than $100,000,000; or

(ii) an assessed value of real property per student that may be taxed for school purposes that is less

than the average of the assessed value of real property per student that may be taxed for school purposes in the State in which the local educational agency is located.

(5) CRITERIA FOR GRANTS.—In awarding grants under paragraph (2), the Secretary shall consider the following criteria:

(A) Whether the facility poses a health or safety threat to students and school personnel, including noncompliance with building codes and inaccessibility for persons with disabilities, or whether the existing building capacity meets the needs of the current enrollment and supports the provision of comprehensive educational services to meet current standards in the State in which the local educational agency is located.

(B) The extent to which the new design and proposed construction utilize energy efficient and recyclable materials.

(C) The extent to which the new design and proposed construction utilizes non-traditional or alternative building methods to expedite construction and project completion and maximize cost efficiency.

(D) The feasibility of project completion within 24 months from award.

(E) The availability of other resources for the proposed project.

SEC. 806. MANDATORY PELL GRANTS. Section 401(b)(9)(A) of the Higher Education Act of 1965 (20 U.S.C. 1070a(b)(9)(A)) is amended—

(1) in clause (ii), by striking "$2,090,000,000" and inserting "$2,733,000,000"; and

(2) in clause (iii), by striking "$3,030,000,000" and inserting "$3,861,000,000".

SEC. 807. (a) IN GENERAL.—Notwithstanding any other provision of law, and in order to begin expenditures and activities under this Act as quickly as possible consistent with prudent management, the Secretary of Education may—

(1) award fiscal year 2009 funds to States and local educational agencies on the basis of eligibility determinations made for the award of fiscal year 2008 funds; and

(2) require States to make prompt allocations to local educational agencies.

Time period.

(b) INTEREST NOT TO ACCRUE.—Notwithstanding sections 3335 and 6503 of title 31, United States Code, or any other provision of law, the United States shall not be liable to any State or other entity for any interest or fee with respect to any funds under this Act that are allocated by the Secretary of Education to the State or other entity within 30 days of the date on which they are available for obligation.

TITLE IX—LEGISLATIVE BRANCH

GOVERNMENT ACCOUNTABILITY OFFICE

SALARIES AND EXPENSES

For an additional amount for "Salaries and Expenses" of the Government Accountability Office, $25,000,000, to remain available until September 30, 2010.

GENERAL PROVISIONS—THIS TITLE

SEC. 901. GOVERNMENT ACCOUNTABILITY OFFICE REVIEWS AND REPORTS. (a) REVIEWS AND REPORTS.—

(1) IN GENERAL.—The Comptroller General shall conduct bimonthly reviews and prepare reports on such reviews on the use by selected States and localities of funds made available in this Act. Such reports, along with any audits conducted by the Comptroller General of such funds, shall be posted on the Internet and linked to the website established under this Act by the Recovery Accountability and Transparency Board.

Internet posting.

(2) REDACTIONS.—Any portion of a report or audit under this subsection may be redacted when made publicly available, if that portion would disclose information that is not subject to disclosure under section 552 of title 5, United States Code (commonly known as the Freedom of Information Act).

(b) EXAMINATION OF RECORDS.—The Comptroller General may examine any records related to obligations and use by any Federal, State, or local government agency of funds made available in this Act.

SEC. 902. ACCESS OF GOVERNMENT ACCOUNTABILITY OFFICE. (a) ACCESS.—Each contract awarded using funds made available in this Act shall provide that the Comptroller General and his representatives are authorized—

(1) to examine any records of the contractor or any of its subcontractors, or any State or local agency administering such contract, that directly pertain to, and involve transactions relating to, the contract or subcontract; and

(2) to interview any officer or employee of the contractor or any of its subcontractors, or of any State or local government agency administering the contract, regarding such transactions.

(b) RELATIONSHIP TO EXISTING AUTHORITY.—Nothing in this section shall be interpreted to limit or restrict in any way any existing authority of the Comptroller General.

TITLE X—MILITARY CONSTRUCTION AND VETERANS AFFAIRS

DEPARTMENT OF DEFENSE

MILITARY CONSTRUCTION, ARMY

For an additional amount for "Military Construction, Army", $180,000,000, to remain available until September 30, 2013: *Provided*, That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design

and military construction projects in the United States not otherwise authorized by law: *Provided further*, That of the amount provided under this heading, $80,000,000 shall be for child development centers, and $100,000,000 shall be for warrior transition complexes: *Provided further*, That not later than 30 days after the date of enactment of this Act, the Secretary of Defense shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

MILITARY CONSTRUCTION, NAVY AND MARINE CORPS

For an additional amount for "Military Construction, Navy and Marine Corps", $280,000,000, to remain available until September 30, 2013: *Provided*, That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further*, That of the amount provided under this heading, $100,000,000 shall be for troop housing, $80,000,000 shall be for child development centers, and $100,000,000 shall be for energy conservation and alternative energy projects: *Provided further*, That not later than 30 days after the date of enactment of this Act, the Secretary of Defense shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

MILITARY CONSTRUCTION, AIR FORCE

For an additional amount for "Military Construction, Air Force", $180,000,000, to remain available until September 30, 2013: *Provided*, That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further*, That of the amount provided under this heading, $100,000,000 shall be for troop housing and $80,000,000 shall be for child development centers: *Provided further*, That not later than 30 days after the date of enactment of this Act, the Secretary of Defense shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

MILITARY CONSTRUCTION, DEFENSE-WIDE

For an additional amount for "Military Construction, Defense-Wide", $1,450,000,000, to remain available until September 30, 2013: *Provided,* That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further,* That of the amount provided under this heading, $1,330,000,000 shall be for the construction of hospitals and $120,000,000 shall be for the Energy Conservation Investment Program: *Provided further,* That not later than 30 days after the date of enactment of this Act, the Secretary of Defense shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

MILITARY CONSTRUCTION, ARMY NATIONAL GUARD

For an additional amount for "Military Construction, Army National Guard", $50,000,000, to remain available until September 30, 2013: *Provided*, That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further*, That not later than 30 days after the date of enactment of this Act, the Secretary of Defense, in consultation with the Director of the Army National Guard, shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

MILITARY CONSTRUCTION, AIR NATIONAL GUARD

For an additional amount for "Military Construction, Air National Guard", $50,000,000, to remain available until September 30, 2013: *Provided*, That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further*, That not later than 30 days after the date of enactment of this Act, the Secretary of Defense, in consultation with the Director of the Air National Guard, shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

FAMILY HOUSING CONSTRUCTION, ARMY

For an additional amount for "Family Housing Construction, Army", $34,507,000, to remain available until September 30, 2013: *Provided,* That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further,* That within 30 days of enactment of this Act, the Secretary of Defense shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

FAMILY HOUSING OPERATION AND MAINTENANCE, ARMY

For an additional amount for "Family Housing Operation and Maintenance, Army", $3,932,000: *Provided,* That notwithstanding any other provision of law, such funds may be obligated and expended for maintenance and repair and minor construction projects in the United States not otherwise authorized by law.

FAMILY HOUSING CONSTRUCTION, AIR FORCE

For an additional amount for "Family Housing Construction, Air Force", $80,100,000, to remain available until September 30, 2013: *Provided,* That notwithstanding any other provision of law, such funds may be obligated and expended to carry out planning and design and military construction projects in the United States not otherwise authorized by law: *Provided further,* That within 30 days of enactment of this Act, the Secretary of Defense shall submit to the Committees on Appropriations of both Houses of

Deadline. Expenditure plan.

Congress an expenditure plan for funds provided under this heading.

FAMILY HOUSING OPERATION AND MAINTENANCE, AIR FORCE

For an additional amount for "Family Housing Operation and Maintenance, Air Force", $16,461,000: *Provided,* That notwithstanding any other provision of law, such funds may be obligated and expended for maintenance and repair and minor construction projects in the United States not otherwise authorized by law.

HOMEOWNERS ASSISTANCE FUND

For an additional amount for "Homeowners Assistance Fund", established by section 1013 of the Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3374), $555,000,000, to remain available until expended: *Provided,* That the Secretary of Defense shall submit quarterly reports to the Committees on Appropriations of both Houses of Congress on the expenditure of funds made available under this heading in this or any other Act.

Reports. Deadlines.

ADMINISTRATIVE PROVISION

SEC. 1001. (a) TEMPORARY EXPANSION OF HOMEOWNERS ASSISTANCE PROGRAM TO RESPOND TO MORTGAGE FORECLOSURE AND CREDIT CRISIS. Section 1013 of the Demonstration Cities and Metropolitan Development Act of 1966 (42 U.S.C. 3374) is amended—

(1) in subsection (a)—

(A) by redesignating paragraphs (1), (2), and (3) as clauses (i), (ii), and (iii), respectively, and indenting such subparagraphs, as so redesignated, 6 ems from the left margin;

(B) by striking "Notwithstanding any other provision of law" and inserting the following:

"(1) ACQUISITION OF PROPERTY AT OR NEAR MILITARY INSTALLATIONS THAT HAVE BEEN ORDERED TO BE CLOSED.—Notwithstanding any other provision of law";

(C) by striking "if he determines" and inserting "if—

"(A) the Secretary determines—";

(D) in clause (iii), as redesignated by subparagraph (A), by striking the period at the end and inserting "; or"; and

(E) by adding at the end the following:

"(B) the Secretary determines—

"(i) that the conditions in clauses (i) and (ii) of subparagraph (A) have been met;

"(ii) that the closing or realignment of the base or installation resulted from a realignment or closure carried out under the 2005 round of defense base closure and realignment under the Defense Base Closure and Realignment Act of 1990 (part XXIX of Public Law 101–510; 10 U.S.C. 2687 note);

"(iii) that the property was purchased by the owner before July 1, 2006;

"(iv) that the property was sold by the owner between July 1, 2006, and September 30, 2012, or an earlier end date designated by the Secretary;

"(v) that the property is the primary residence of the owner; and

"(vi) that the owner has not previously received benefit payments authorized under this subsection.

"(2) HOMEOWNER ASSISTANCE FOR WOUNDED MEMBERS OF THE ARMED FORCES, DEPARTMENT OF DEFENSE AND UNITED STATES COAST GUARD CIVILIAN EMPLOYEES, AND THEIR SPOUSES.—Notwithstanding any other provision of law, the Secretary of Defense is authorized to acquire title to, hold, manage, and dispose of, or, in lieu thereof, to reimburse for certain losses upon private sale of, or foreclosure against, any property improved with a one- or two-family dwelling which was at the time of the relevant wound, injury, or illness, the primary residence of—

"(A) any member of the Armed Forces in medical transition who—

"(i) incurred a wound, injury, or illness in the line of duty during a deployment in support of the Armed Forces;

"(ii) is disabled to a degree of 30 percent or more as a result of such wound, injury, or illness, as determined by the Secretary of Defense; and

"(iii) is reassigned in furtherance of medical treatment or rehabilitation, or due to medical retirement in connection with such disability;

"(B) any civilian employee of the Department of Defense or the United States Coast Guard who—

"(i) was wounded, injured, or became ill in the performance of his or her duties during a forward deployment occurring on or after September 11, 2001, in support of the Armed Forces; and

"(ii) is reassigned in furtherance of medical treatment, rehabilitation, or due to medical retirement resulting from the sustained disability; or

"(C) the spouse of a member of the Armed Forces or a civilian employee of the Department of Defense or the United States Coast Guard if—

"(i) the member or employee was killed in the line of duty or in the performance of his or her duties during a deployment on or after September 11, 2001, in support of the Armed Forces or died from a wound, injury, or illness incurred in the line of duty during such a deployment; and

"(ii) the spouse relocates from such residence within 2 years after the death of such member or employee.

"(3) TEMPORARY HOMEOWNER ASSISTANCE FOR MEMBERS OF THE ARMED FORCES PERMANENTLY REASSIGNED DURING SPECIFIED MORTGAGE CRISIS.—Notwithstanding any other provision of law, the Secretary of Defense is authorized to acquire title to, hold, manage, and dispose of, or, in lieu thereof, to reimburse for certain losses upon private sale of, or foreclosure against, any property improved with a one- or two-family dwelling situated at or near a military base or installation, if the Secretary determines—

"(A) that the owner is a member of the Armed Forces serving on permanent assignment;

"(B) that the owner is permanently reassigned by order of the United States Government to a duty station or home port outside a 50-mile radius of the base or installation;

"(C) that the reassignment was ordered between February 1, 2006, and September 30, 2012, or an earlier end date designated by the Secretary;

"(D) that the property was purchased by the owner before July 1, 2006;

"(E) that the property was sold by the owner between July 1, 2006, and September 30, 2012, or an earlier end date designated by the Secretary;

"(F) that the property is the primary residence of the owner; and

"(G) that the owner has not previously received benefit payments authorized under this subsection.";

(2) in subsection (b), by striking "this section" each place it appears and inserting "subsection (a)(1)";

(3) in subsection (c)—

(A) by striking "Such persons" and inserting the following:

"(1) HOMEOWNER ASSISTANCE RELATED TO CLOSED MILITARY INSTALLATIONS.—

"(A) IN GENERAL.—Such persons";

(B) by striking "set forth above shall elect either (1) to receive" and inserting the following: "set forth in subsection (a)(1) shall elect either—

"(i) to receive";

(C) by striking "difference between (A) 95 per centum" and all that follows through "(B) the fair market value" and inserting the following: "difference between—

"(I) 95 per centum of the fair market value of their property (as such value is determined by the Secretary of Defense) prior to public announcement of intention to close all or part of the military base or installation; and

"(II) the fair market value";

(D) by striking "time of the sale, or (2) to receive" and inserting the following: "time of the sale; or

"(ii) to receive";

(E) by striking "outstanding mortgages. The Secretary may also pay a person who elects to receive a cash payment under clause (1) of the preceding sentence an amount" and inserting "outstanding mortgages.

"(B) REIMBURSEMENT OF EXPENSES.—The Secretary may also pay a person who elects to receive a cash payment under subparagraph (A) an amount"; and

(F) by striking "best interest of the Federal Government. Cash payment" and inserting the following: "best interest of the United States.

"(2) HOMEOWNER ASSISTANCE FOR WOUNDED INDIVIDUALS AND THEIR SPOUSES.—

"(A) IN GENERAL.—Persons eligible under the criteria set forth in subsection (a)(2) may elect either—

"(i) to receive a cash payment as compensation for losses which may be or have been sustained in

a private sale, in an amount not to exceed the difference between—

"(I) 95 per centum of prior fair market value of their property (as such value is determined by the Secretary of Defense); and

"(II) the fair market value of such property (as such value is determined by the Secretary of Defense) at the time of sale; or

"(ii) to receive, as purchase price for their property an amount not to exceed 90 per centum of prior fair market value as such value is determined by the Secretary of Defense, or the amount of the outstanding mortgages.

"(B) DETERMINATION OF BENEFITS.—The Secretary may also pay a person who elects to receive a cash payment under subparagraph (A) an amount that the Secretary determines appropriate to reimburse the person for the costs incurred by the person in the sale of the property if the Secretary determines that such payment will benefit the person and is in the best interest of the United States.

"(3) HOMEOWNER ASSISTANCE FOR PERMANENTLY REASSIGNED INDIVIDUALS.—

"(A) IN GENERAL.—Persons eligible under the criteria set forth in subsection (a)(3) may elect either—

"(i) to receive a cash payment as compensation for losses which may be or have been sustained in a private sale, in an amount not to exceed the difference between—

"(I) 95 per centum of prior fair market value of their property (as such value is determined by the Secretary of Defense); and

"(II) the fair market value of such property (as such value is determined by the Secretary of Defense) at the time of sale; or

"(ii) to receive, as purchase price for their property an amount not to exceed 90 per centum of prior fair market value as such value is determined by the Secretary of Defense, or the amount of the outstanding mortgages.

"(B) DETERMINATION OF BENEFITS.—The Secretary may also pay a person who elects to receive a cash payment under subparagraph (A) an amount that the Secretary determines appropriate to reimburse the person for the costs incurred by the person in the sale of the property if the Secretary determines that such payment will benefit the person and is in the best interest of the United States.

"(4) COMPENSATION AND LIMITATIONS RELATED TO FORECLOSURES AND ENCUMBRANCES.—Cash payment";

(4) by striking subsection (g);

(5) in subsection (l), by striking "(a)(2)" and inserting "(a)(1)(A)(ii)";

(6) in subsection (m), by striking "this section" and inserting "subsection (a)(1)";

(7) in subsection (n)—

(A) in paragraph (1), by striking "this section" and inserting "subsection (a)(1)"; and

(B) in paragraph (2), by striking "this section" and inserting "subsection (a)(1)";

(8) in subsection (o)—

(A) in paragraph (1), by striking "this section" and inserting "subsection (a)(1)";

(B) in paragraph (2), by striking "this section" and inserting "subsection (a)(1)"; and

(C) by striking paragraph (4); and

(9) by adding at the end the following new subsection:

"(p) DEFINITIONS.—In this section:

"(1) the term 'Armed Forces' has the meaning given the term 'armed forces' in section 101(a) of title 10, United States Code;

"(2) the term 'civilian employee' has the meaning given the term 'employee' in section 2105(a) of title 5, United States Code;

"(3) the term 'medical transition', in the case of a member of the Armed Forces, means a member who—

"(A) is in Medical Holdover status;

"(B) is in Active Duty Medical Extension status;

"(C) is in Medical Hold status;

"(D) is in a status pending an evaluation by a medical evaluation board;

"(E) has a complex medical need requiring six or more months of medical treatment; or

"(F) is assigned or attached to an Army Warrior Transition Unit, an Air Force Patient Squadron, a Navy Patient Multidisciplinary Care Team, or a Marine Patient Affairs Team/Wounded Warrior Regiment; and

"(4) the term 'nonappropriated fund instrumentality employee' means a civilian employee who—

"(A) is a citizen of the United States; and

"(B) is paid from nonappropriated funds of Army and Air Force Exchange Service, Navy Resale and Services Support Office, Marine Corps exchanges, or any other instrumentality of the United States under the jurisdiction of the Armed Forces which is conducted for the comfort, pleasure, contentment, or physical or mental improvement of members of the Armed Forces.".

(b) CLERICAL AMENDMENT.—Such section is further amended in the section heading by inserting "and certain property owned by members of the Armed Forces, Department of Defense and United States Coast Guard civilian employees, and surviving spouses" after "ordered to be closed".

(c) AUTHORITY TO USE APPROPRIATED FUNDS.—Notwithstanding subsection (i) of such section, amounts appropriated or otherwise made available by this title under the heading "Homeowners Assistance Fund" may be used for the Homeowners Assistance Fund established under such section.

DEPARTMENT OF VETERANS AFFAIRS

VETERANS HEALTH ADMINISTRATION

MEDICAL FACILITIES

For an additional amount for "Medical Facilities" for non-recurring maintenance, including energy projects, $1,000,000,000, to remain available until September 30, 2010: *Provided*, That not later than 30 days after the date of enactment of this Act, the Secretary of Veterans Affairs shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

NATIONAL CEMETERY ADMINISTRATION

For an additional amount for "National Cemetery Administration" for monument and memorial repairs, including energy projects, $50,000,000, to remain available until September 30, 2010: *Provided*, That not later than 30 days after the date of enactment of this Act, the Secretary of Veterans Affairs shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

DEPARTMENTAL ADMINISTRATION

GENERAL OPERATING EXPENSES

For an additional amount for "General Operating Expenses", $150,000,000, to remain available until September 30, 2010, for additional expenses related to hiring and training temporary surge claims processors.

INFORMATION TECHNOLOGY SYSTEMS

For an additional amount for "Information Technology Systems", $50,000,000, to remain available until September 30, 2010, for the Veterans Benefits Administration: *Provided,* That not later than 30 days after the enactment of this Act, the Secretary of Veterans Affairs shall submit to the Committees on Appropriations of both Houses of Congress an expenditure plan for funds provided under this heading.

Deadline. Expenditure plan.

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General", $1,000,000, to remain available until September 30, 2011, for oversight and audit of programs, grants and projects funded under this title.

GRANTS FOR CONSTRUCTION OF STATE EXTENDED CARE FACILITIES

For an additional amount for "Grants for Construction of State Extended Care Facilities", $150,000,000, to remain available until September 30, 2010, for grants to assist States to acquire or construct State nursing home and domiciliary facilities and to remodel, modify, or alter existing hospital, nursing home, and domiciliary facilities in State homes, for furnishing care to veterans as authorized by sections 8131 through 8137 of title 38, United States Code.

ADMINISTRATIVE PROVISION

38 USC 107 note.

SEC. 1002. PAYMENTS TO ELIGIBLE PERSONS WHO SERVED IN THE UNITED STATES ARMED FORCES IN THE FAR EAST DURING WORLD WAR II. (a) FINDINGS.—Congress makes the following findings:

(1) The Philippine islands became a United States possession in 1898 when they were ceded from Spain following the Spanish-American War.

(2) During World War II, Filipinos served in a variety of units, some of which came under the direct control of the United States Armed Forces.

(3) The regular Philippine Scouts, the new Philippine Scouts, the Guerrilla Services, and more than 100,000 members of the Philippine Commonwealth Army were called into the service of the United States Armed Forces of the Far East on July 26, 1941, by an executive order of President Franklin D. Roosevelt.

(4) Even after hostilities had ceased, wartime service of the new Philippine Scouts continued as a matter of law until the end of 1946, and the force gradually disbanded and was disestablished in 1950.

(5) Filipino veterans who were granted benefits prior to the enactment of the so-called Rescissions Acts of 1946 (Public Laws 79–301 and 79–391) currently receive full benefits under laws administered by the Secretary of Veterans Affairs, but under section 107 of title 38, United States Code, the service of certain other Filipino veterans is deemed not to be active service for purposes of such laws.

(6) These other Filipino veterans only receive certain benefits under title 38, United States Code, and, depending on where they legally reside, are paid such benefit amounts at reduced rates.

(7) The benefits such veterans receive include service-connected compensation benefits paid under chapter 11 of title 38, United States Code, dependency indemnity compensation survivor benefits paid under chapter 13 of title 38, United States Code, and burial benefits under chapters 23 and 24 of title 38, United States Code, and such benefits are paid to beneficiaries at the rate of $0.50 per dollar authorized, unless they lawfully reside in the United States.

(8) Dependents' educational assistance under chapter 35 of title 38, United States Code, is also payable for the dependents of such veterans at the rate of $0.50 per dollar authorized, regardless of the veterans' residency.

(b) COMPENSATION FUND.—

(1) IN GENERAL.—There is in the general fund of the Treasury a fund to be known as the "Filipino Veterans Equity Compensation Fund" (in this section referred to as the "compensation fund").

(2) AVAILABILITY OF FUNDS.—Subject to the availability of appropriations for such purpose, amounts in the fund shall be available to the Secretary of Veterans Affairs without fiscal year limitation to make payments to eligible persons in accordance with this section.

(c) PAYMENTS.—

(1) IN GENERAL.—The Secretary may make a payment from the compensation fund to an eligible person who, during the one-year period beginning on the date of the enactment of this Act, submits to the Secretary a claim for benefits under this section. The application for the claim shall contain such information and evidence as the Secretary may require.

(2) PAYMENT TO SURVIVING SPOUSE.—If an eligible person who has filed a claim for benefits under this section dies before payment is made under this section, the payment under this section shall be made instead to the surviving spouse, if any, of the eligible person.

(d) ELIGIBLE PERSONS.—An eligible person is any person who—

(1) served—

(A) before July 1, 1946, in the organized military forces of the Government of the Commonwealth of the Philippines, while such forces were in the service of the Armed Forces of the United States pursuant to the military order of the President dated July 26, 1941, including among such military forces organized guerrilla forces under commanders appointed, designated, or subsequently recognized by the Commander in Chief, Southwest Pacific Area, or other competent authority in the Army of the United States; or

(B) in the Philippine Scouts under section 14 of the Armed Forces Voluntary Recruitment Act of 1945 (59 Stat. 538); and

(2) was discharged or released from service described in paragraph (1) under conditions other than dishonorable.

(e) PAYMENT AMOUNTS.—Each payment under this section shall be—

(1) in the case of an eligible person who is not a citizen of the United States, in the amount of $9,000; and

(2) in the case of an eligible person who is a citizen of the United States, in the amount of $15,000.

(f) LIMITATION.—The Secretary may not make more than one payment under this section for each eligible person described in subsection (d).

(g) CLARIFICATION OF TREATMENT OF PAYMENTS UNDER CERTAIN LAWS.—Amounts paid to a person under this section—

(1) shall be treated for purposes of the internal revenue laws of the United States as damages for human suffering; and

(2) shall not be included in income or resources for purposes of determining—

(A) eligibility of an individual to receive benefits described in section 3803(c)(2)(C) of title 31, United States Code, or the amount of such benefits;

(B) eligibility of an individual to receive benefits under title VIII of the Social Security Act, or the amount of such benefits; or

(C) eligibility of an individual for, or the amount of benefits under, any other Federal or federally assisted program.

(h) RELEASE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the acceptance by an eligible person or surviving spouse, as applicable, of a payment under this section shall be final,

and shall constitute a complete release of any claim against the United States by reason of any service described in subsection (d).

(2) PAYMENT OF PRIOR ELIGIBILITY STATUS.—Nothing in this section shall prohibit a person from receiving any benefit (including health care, survivor, or burial benefits) which the person would have been eligible to receive based on laws in effect as of the day before the date of the enactment of this Act.

(i) RECOGNITION OF SERVICE.—The service of a person as described in subsection (d) is hereby recognized as active military service in the Armed Forces for purposes of, and to the extent provided in, this section.

(j) ADMINISTRATION.—

Applications. Instructions.

(1) The Secretary shall promptly issue application forms and instructions to ensure the prompt and efficient administration of the provisions of this section.

(2) The Secretary shall administer the provisions of this section in a manner consistent with applicable provisions of title 38, United States Code, and other provisions of law, and shall apply the definitions in section 101 of such title in the administration of such provisions, except to the extent otherwise provided in this section.

(k) REPORTS.—The Secretary shall include, in documents submitted to Congress by the Secretary in support of the President's budget for each fiscal year, detailed information on the operation of the compensation fund, including the number of applicants, the number of eligible persons receiving benefits, the amounts paid out of the compensation fund, and the administration of the compensation fund for the most recent fiscal year for which such data is available.

(l) AUTHORIZATION OF APPROPRIATION.—There is authorized to be appropriated to the compensation fund $198,000,000, to remain available until expended, to make payments under this section.

TITLE XI—STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS

DEPARTMENT OF STATE

ADMINISTRATION OF FOREIGN AFFAIRS

DIPLOMATIC AND CONSULAR PROGRAMS

Deadline. Spending plan.

For an additional amount for "Diplomatic and Consular Programs" for urgent domestic facilities requirements for passport and training functions, $90,000,000: *Provided,* That the Secretary of State shall submit to the Committees on Appropriations within 90 days of enactment of this Act a detailed spending plan for funds appropriated under this heading: *Provided further,* That with respect to the funds made available for passport agencies, such plan shall be developed in consultation with the Department of Homeland Security and the General Services Administration and shall coordinate and co-locate, to the extent feasible, passport agencies with other Federal facilities.

CAPITAL INVESTMENT FUND

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Capital Investment Fund", $290,000,000, for information technology security and upgrades to support mission-critical operations, of which up to $38,000,000 shall be transferred to, and merged with, funds made available under the heading "Capital Investment Fund" of the United States Agency for International Development: *Provided,* That the Secretary of State and the Administrator of the United States Agency for International Development shall coordinate information technology systems, where appropriate, to increase efficiencies and eliminate redundancies, to include co-location of backup information management facilities, and shall submit to the Committees on Appropriations within 90 days of enactment of this Act a detailed spending plan for funds appropriated under this heading.

Deadline. Spending plan.

OFFICE OF INSPECTOR GENERAL

For an additional amount for "Office of Inspector General" for oversight requirements, $2,000,000.

INTERNATIONAL COMMISSIONS

INTERNATIONAL BOUNDARY AND WATER COMMISSION, UNITED STATES AND MEXICO

CONSTRUCTION

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Construction" for the water quantity program to meet immediate repair and rehabilitation requirements, $220,000,000: *Provided,* That up to $2,000,000 may be transferred to, and merged with, funds available under the heading "International Boundary and Water Commission, United States and Mexico—Salaries and Expenses": *Provided further,* That the Secretary of State shall submit to the Committees on Appropriations within 90 days of enactment of this Act a detailed spending plan for funds appropriated under this heading.

Deadline. Spending plan.

TITLE XII—TRANSPORTATION AND HOUSING AND URBAN DEVELOPMENT, AND RELATED AGENCIES

DEPARTMENT OF TRANSPORTATION

OFFICE OF THE SECRETARY

SUPPLEMENTAL DISCRETIONARY GRANTS FOR A NATIONAL SURFACE TRANSPORTATION SYSTEM

For an additional amount for capital investments in surface transportation infrastructure, $1,500,000,000, to remain available through September 30, 2011: *Provided,* That the Secretary of Transportation shall distribute funds provided under this heading as discretionary grants to be awarded to State and local governments or transit agencies on a competitive basis for projects that will have a significant impact on the Nation, a metropolitan area,

or a region: *Provided further,* That projects eligible for funding provided under this heading shall include, but not be limited to, highway or bridge projects eligible under title 23, United States Code, including interstate rehabilitation, improvements to the rural collector road system, the reconstruction of overpasses and interchanges, bridge replacements, seismic retrofit projects for bridges, and road realignments; public transportation projects eligible under chapter 53 of title 49, United States Code, including investments in projects participating in the New Starts or Small Starts programs that will expedite the completion of those projects and their entry into revenue service; passenger and freight rail transportation projects; and port infrastructure investments, including projects that connect ports to other modes of transportation and improve the efficiency of freight movement: *Provided further,* That of the amount made available under this paragraph, the Secretary may use an amount not to exceed $200,000,000 for the purpose of paying the subsidy and administrative costs of projects eligible for federal credit assistance under chapter 6 of title 23, United States Code, if the Secretary finds that such use of the funds would advance the purposes of this paragraph: *Provided further,* That in distributing funds provided under this heading, the Secretary shall take such measures so as to ensure an equitable geographic distribution of funds and an appropriate balance in addressing the needs of urban and rural communities: *Provided further,* That a grant funded under this heading shall be not less than $20,000,000 and not greater than $300,000,000: *Provided further,* That the Secretary may waive the minimum grant size cited in the preceding proviso for the purpose of funding significant projects in smaller cities, regions, or States: *Provided further,* That not more than 20 percent of the funds made available under this paragraph may be awarded to projects in a single State: *Provided further,* That the Federal share of the costs for which an expenditure is made under this heading may be up to 100 percent: *Provided further,* That the Secretary shall give priority to projects that require a contribution of Federal funds in order to complete an overall financing package, and to projects that are expected to be completed within 3 years of enactment of this Act: *Provided further,* That the Secretary shall publish criteria on which to base the competition for any grants awarded under this heading not later than 90 days after enactment of this Act: *Provided further,* That the Secretary shall require applications for funding provided under this heading to be submitted not later than 180 days after the publication of such criteria, and announce all projects selected to be funded from such funds not later than 1 year after enactment of this Act: *Provided further,* That projects conducted using funds provided under this heading must comply with the requirements of subchapter IV of chapter 31 of title 40, United States Code: *Provided further,* That the Secretary may retain up to $1,500,000 of the funds provided under this heading, and may transfer portions of those funds to the Administrators of the Federal Highway Administration, the Federal Transit Administration, the Federal Railroad Administration and the Maritime Administration, to fund the award and oversight of grants made under this heading.

Waiver authority.

Publication.
Criteria.
Deadline.

Applications.
Deadlines.

FEDERAL AVIATION ADMINISTRATION

SUPPLEMENTAL FUNDING FOR FACILITIES AND EQUIPMENT

For an additional amount for necessary investments in Federal Aviation Administration infrastructure, $200,000,000, to remain available through September 30, 2010: *Provided,* That funding provided under this heading shall be used to make improvements to power systems, air route traffic control centers, air traffic control towers, terminal radar approach control facilities, and navigation and landing equipment: *Provided further,* That priority be given to such projects or activities that will be completed within 2 years of enactment of this Act: *Provided further,* That amounts made available under this heading may be provided through grants in addition to the other instruments authorized under section 106(l)(6) of title 49, United States Code: *Provided further,* That the Federal share of the costs for which an expenditure is made under this heading shall be 100 percent: *Provided further,* That amounts provided under this heading may be used for expenses the agency incurs in administering this program: *Provided further,* That not more than 60 days after enactment of this Act, the Administrator shall establish a process for applying, reviewing and awarding grants and cooperative and other transaction agreements, including the form and content of an application, and requirements for the maintenance of records that are necessary to facilitate an effective audit of the use of the funding provided: *Provided further,* That section 50101 of title 49, United States Code, shall apply to funds provided under this heading.

Deadline.
Procedures.

Applicability.

GRANTS-IN-AID FOR AIRPORTS

For an additional amount for "Grants-In-Aid for Airports", to enable the Secretary of Transportation to make grants for discretionary projects as authorized by subchapter 1 of chapter 471 and subchapter 1 of chapter 475 of title 49, United States Code, and for the procurement, installation and commissioning of runway incursion prevention devices and systems at airports of such title, $1,100,000,000, to remain available through September 30, 2010: *Provided*, That such funds shall not be subject to apportionment formulas, special apportionment categories, or minimum percentages under chapter 471: *Provided further,* That the Secretary shall distribute funds provided under this heading as discretionary grants to airports, with priority given to those projects that demonstrate to his satisfaction their ability to be completed within 2 years of enactment of this Act, and serve to supplement and not supplant planned expenditures from airport-generated revenues or from other State and local sources on such activities: *Provided further,* That the Secretary shall award grants totaling not less than 50 percent of the funds made available under this heading within 120 days of enactment of this Act, and award grants for the remaining amounts not later than 1 year after enactment of this Act: *Provided further,* That the Federal share payable of the costs for which a grant is made under this heading shall be 100 percent: *Provided further,* That the amount made available under this heading shall not be subject to any limitation on obligations for the Grants-in-Aid for Airports program set forth in any Act: *Provided further,* That the Administrator of the Federal Aviation Administration may retain up to 0.2 percent of the funds provided under this

Deadlines.

heading to fund the award and oversight by the Administrator of grants made under this heading.

FEDERAL HIGHWAY ADMINISTRATION

HIGHWAY INFRASTRUCTURE INVESTMENT

For an additional amount for restoration, repair, construction and other activities eligible under paragraph (b) of section 133 of title 23, United States Code, and for passenger and freight rail transportation and port infrastructure projects eligible for assistance under subsection 601(a)(8) of such title, $27,500,000,000, to remain available through September 30, 2010: *Provided,* That, after making the set-asides required under this heading, 50 percent of the funds made available under this heading shall be apportioned to States using the formula set forth in section 104(b)(3) of title 23, United States Code, and the remaining funds shall be apportioned to States in the same ratio as the obligation limitation for fiscal year 2008 was distributed among the States in accordance with the formula specified in section 120(a)(6) of division K of Public Law 110–161: *Provided further,* That funds made available under this heading shall be apportioned not later than 21 days after the date of enactment of this Act: *Provided further,* That in selecting projects to be carried out with funds apportioned under this heading, priority shall be given to projects that are projected for completion within a 3-year time frame, and are located in economically distressed areas as defined by section 301 of the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3161): *Provided further,* That 120 days following the date of such apportionment, the Secretary of Transportation shall withdraw from each State an amount equal to 50 percent of the funds awarded to that State (excluding funds suballocated within the State) less the amount of funding obligated (excluding funds suballocated within the State), and the Secretary shall redistribute such amounts to other States that have had no funds withdrawn under this proviso in the manner described in section 120(c) of division K of Public Law 110–161: *Provided further,* That 1 year following the date of such apportionment, the Secretary shall withdraw from each recipient of funds apportioned under this heading any unobligated funds, and the Secretary shall redistribute such amounts to States that have had no funds withdrawn under this proviso (excluding funds suballocated within the State) in the manner described in section 120(c) of division K of Public Law 110–161: *Provided further,* That at the request of a State, the Secretary of Transportation may provide an extension of such 1-year period only to the extent that he feels satisfied that the State has encountered extreme conditions that create an unworkable bidding environment or other extenuating circumstances: *Provided further,* That before granting such an extension, the Secretary shall send a letter to the House and Senate Committees on Appropriations that provides a thorough justification for the extension: *Provided further,* That 3 percent of the funds apportioned to a State under this heading shall be set aside for the purposes described in subsection 133(d)(2) of title 23, United States Code (without regard to the comparison to fiscal year 2005): *Provided further,* That 30 percent of the funds apportioned to a State under this heading shall be suballocated within the State in the manner and for the purposes described in the first sentence of subsection

Deadline.

Effective date.

Effective date.

Submission.

133(d)(3)(A), in subsection 133(d)(3)(B), and in subsection 133(d)(3)(D): *Provided further,* That such suballocation shall be conducted in every State: *Provided further,* That funds suballocated within a State to urbanized areas and other areas shall not be subject to the redistribution of amounts required 120 days following the date of apportionment of funds provided under this heading: *Provided further,* That of the funds provided under this heading, $105,000,000 shall be for the Puerto Rico highway program authorized under section 165 of title 23, United States Code, and $45,000,000 shall be for the territorial highway program authorized under section 215 of title 23, United States Code: *Provided further,* That of the funds provided under this heading, $60,000,000 shall be for capital expenditures eligible under section 147 of title 23, United States Code (without regard to subsection(d)): *Provided further,* That the Secretary of Transportation shall distribute such $60,000,000 as competitive discretionary grants to States, with priority given to those projects that demonstrate to his satisfaction their ability to be completed within 2 years of enactment of this Act: *Provided further,* That of the funds provided under this heading, $550,000,000 shall be for investments in transportation at Indian reservations and Federal lands: *Provided further,* That of the funds identified in the preceding proviso, $310,000,000 shall be for the Indian Reservation Roads program, $170,000,000 shall be for the Park Roads and Parkways program, $60,000,000 shall be for the Forest Highway Program, and $10,000,000 shall be for the Refuge Roads program: *Provided further,* That for investments at Indian reservations and Federal lands, priority shall be given to capital investments, and to projects and activities that can be completed within 2 years of enactment of this Act: *Provided further,* That 1 year following the enactment of this Act, to ensure the prompt use of the $550,000,000 provided for investments at Indian reservations and Federal lands, the Secretary shall have the authority to redistribute unobligated funds within the respective program for which the funds were appropriated: *Provided further,* That up to 4 percent of the funding provided for Indian Reservation Roads may be used by the Secretary of the Interior for program management and oversight and project-related administrative expenses: *Provided further,* That section 134(f)(3)(C)(ii)(II) of title 23, United States Code, shall not apply to funds provided under this heading: *Provided further,* That of the funds made available under this heading, $20,000,000 shall be for highway surface transportation and technology training under section 140(b) of title 23, United States Code, and $20,000,000 shall be for disadvantaged business enterprises bonding assistance under section 332(e) of title 49, United States Code: *Provided further,* That funds made available under this heading shall be administered as if apportioned under chapter 1 of title 23, United States Code, except for funds made available for investments in transportation at Indian reservations and Federal lands, and for the territorial highway program, which shall be administered in accordance with chapter 2 of title 23, United States Code, and except for funds made available for disadvantaged business enterprises bonding assistance, which shall be administered in accordance with chapter 3 of title 49, United States Code: *Provided further,* That the Federal share payable on account of any project or activity carried out with funds made available under this heading shall be, at the option of the recipient, up to 100 percent of the total cost thereof: *Provided further*, That

Grants.

Effective date.
Redistribution authority.

funds made available by this Act shall not be obligated for the purposes authorized under section 115(b) of title 23, United States Code: *Provided further,* That funding provided under this heading shall be in addition to any and all funds provided for fiscal years 2009 and 2010 in any other Act for "Federal-aid Highways" and shall not affect the distribution of funds provided for "Federal-aid Highways" in any other Act: *Provided further,* That the amount made available under this heading shall not be subject to any limitation on obligations for Federal-aid highways or highway safety construction programs set forth in any Act: *Provided further,* That section 1101(b) of Public Law 109–59 shall apply to funds apportioned under this heading: *Provided further,* That the Administrator of the Federal Highway Administration may retain up to $40,000,000 of the funds provided under this heading to fund the oversight by the Administrator of projects and activities carried out with funds made available to the Federal Highway Administration in this Act, and such funds shall be available through September 30, 2012.

Applicability.

FEDERAL RAILROAD ADMINISTRATION

Grants.

CAPITAL ASSISTANCE FOR HIGH SPEED RAIL CORRIDORS AND INTERCITY PASSENGER RAIL SERVICE

For an additional amount for section 501 of Public Law 110–432 and discretionary grants to States to pay for the cost of projects described in paragraphs (2)(A) and (2)(B) of section 24401 of title 49, United States Code, subsection (b) of section 24105 of such title, $8,000,000,000, to remain available through September 30, 2012: *Provided,* That the Secretary of Transportation shall give priority to projects that support the development of intercity high speed rail service: *Provided further,* That within 60 days of the enactment of this Act, the Secretary shall submit to the House and Senate Committees on Appropriations a strategic plan that describes how the Secretary will use the funding provided under this heading to improve and deploy high speed passenger rail systems: *Provided further,* That within 120 days of enactment of this Act, the Secretary shall issue interim guidance to applicants covering grant terms, conditions, and procedures until final regulations are issued: *Provided further,* That such interim guidance shall provide separate instructions for the high speed rail corridor program, capital assistance for intercity passenger rail service grants, and congestion grants: *Provided further,* That the Secretary shall waive the requirement that a project conducted using funds provided under this heading be in a State rail plan developed under chapter 227 of title 49, United States Code: *Provided further,* That the Federal share payable of the costs for which a grant is made under this heading shall be, at the option of the recipient, up to 100 percent: *Provided further,* That projects conducted using funds provided under this heading must comply with the requirements of subchapter IV of chapter 31 of title 40, United States Code: *Provided further,* That section 24405 of title 49, United States Code, shall apply to funds provided under this heading: *Provided further,* That the Administrator of the Federal Railroad Administration may retain up to one-quarter of 1 percent of the funds provided under this heading to fund the award and oversight by the Administrator of grants made under this heading, and funds retained for said purposes shall remain available through September 30, 2014.

Deadline.
Strategic plan.

Deadline.
Guidance.

Waiver authority.

Compliance.

Applicability.

CAPITAL GRANTS TO THE NATIONAL RAILROAD PASSENGER CORPORATION

For an additional amount for the National Railroad Passenger Corporation (Amtrak) to enable the Secretary of Transportation to make capital grants to Amtrak as authorized by section 101(c) of the Passenger Rail Investment and Improvement Act of 2008 (Public Law 110–432), $1,300,000,000, to remain available through September 30, 2010, of which $450,000,000 shall be used for capital security grants: *Provided,* That priority for the use of non-security funds shall be given to projects for the repair, rehabilitation, or upgrade of railroad assets or infrastructure, and for capital projects that expand passenger rail capacity including the rehabilitation of rolling stock: *Provided further*, That none of the funds under this heading shall be used to subsidize the operating losses of Amtrak: *Provided further*, That funds provided under this heading shall be awarded not later than 30 days after the date of enactment of this Act: *Provided further,* That the Secretary shall take measures to ensure that projects funded under this heading shall be completed within 2 years of enactment of this Act, and shall serve to supplement and not supplant planned expenditures for such activities from other Federal, State, local and corporate sources: *Provided further,* That the Secretary shall certify to the House and Senate Committees on Appropriations in writing compliance with the preceding proviso: *Provided further,* That not more than 60 percent of the funds provided for non-security activities under this heading may be used for capital projects along the Northeast Corridor: *Provided further,* That of the funding provided under this heading, $5,000,000 shall be made available for the Amtrak Office of Inspector General and made available through September 30, 2013.

Deadline.

Deadline.

Certification.

FEDERAL TRANSIT ADMINISTRATION

TRANSIT CAPITAL ASSISTANCE

Grants.

For an additional amount for transit capital assistance grants authorized under section 5302(a)(1) of title 49, United States Code, $6,900,000,000, to remain available through September 30, 2010: *Provided,* That the Secretary of Transportation shall provide 80 percent of the funds appropriated under this heading for grants under section 5307 of title 49, United States Code, and apportion such funds in accordance with section 5336 of such title (other than subsections (i)(1) and (j)): *Provided further,* That the Secretary shall apportion 10 percent of the funds appropriated under this heading in accordance with section 5340 of such title: *Provided further,* That the Secretary shall provide 10 percent of the funds appropriated under this heading for grants under section 5311 of title 49, United States Code, and apportion such funds in accordance with such section: *Provided further,* That funds apportioned under this heading shall be apportioned not later than 21 days after the date of enactment of this Act: *Provided further,* That 180 days following the date of such apportionment, the Secretary shall withdraw from each urbanized area or State an amount equal to 50 percent of the funds apportioned to such urbanized areas or States less the amount of funding obligated, and the Secretary shall redistribute such amounts to other urbanized areas or States that have had no funds withdrawn under this proviso utilizing whatever method he deems appropriate to ensure that all funds

Deadline.

Effective date.

Effective date.

redistributed under this proviso shall be utilized promptly: *Provided further,* That 1 year following the date of such apportionment, the Secretary shall withdraw from each urbanized area or State any unobligated funds, and the Secretary shall redistribute such amounts to other urbanized areas or States that have had no funds withdrawn under this proviso utilizing whatever method he deems appropriate to ensure that all funds redistributed under this proviso shall be utilized promptly: *Provided further,* That at the request of an urbanized area or State, the Secretary of Transportation may provide an extension of such 1-year period if he feels satisfied that the urbanized area or State has encountered an unworkable bidding environment or other extenuating circumstances: *Provided further,* That before granting such an extension, the Secretary shall send a letter to the House and Senate Committees on Appropriations that provides a thorough justification for the extension: *Provided further,* That of the funds provided for section 5311 of title 49, United States Code, 2.5 percent shall be made available for section 5311(c)(1): *Provided further,* That of the funding provided under this heading, $100,000,000 shall be distributed as discretionary grants to public transit agencies for capital investments that will assist in reducing the energy consumption or greenhouse gas emissions of their public transportation systems: *Provided further,* That for such grants on energy-related investments, priority shall be given to projects based on the total energy savings that are projected to result from the investment, and projected energy savings as a percentage of the total energy usage of the public transit agency: *Provided further,* That applicable chapter 53 requirements shall apply to funding provided under this heading, except that the Federal share of the costs for which any grant is made under this heading shall be, at the option of the recipient, up to 100 percent: *Provided further,* That the amount made available under this heading shall not be subject to any limitation on obligations for transit programs set forth in any Act: *Provided further,* That section 1101(b) of Public Law 109–59 shall apply to funds appropriated under this heading: *Provided further,* That the funds appropriated under this heading shall not be comingled with any prior year funds: *Provided further,* That notwithstanding any other provision of law, three-quarters of 1 percent of the funds provided for grants under section 5307 and section 5340, and one-half of 1 percent of the funds provided for grants under section 5311, shall be available for administrative expenses and program management oversight, and such funds shall be available through September 30, 2012.

Submission.

Applicability.

Applicability.

FIXED GUIDEWAY INFRASTRUCTURE INVESTMENT

For an amount for capital expenditures authorized under section 5309(b)(2) of title 49, United States Code, $750,000,000, to remain available through September 30, 2010: *Provided*, That the Secretary of Transportation shall apportion funds under this heading pursuant to the formula set forth in section 5337 of title 49, United States Code: *Provided further*, That the funds appropriated under this heading shall not be commingled with any prior year funds: *Provided further*, That funds made available under this heading shall be apportioned not later than 21 days after the date of enactment of this Act: *Provided further*, That 180 days following the date of such apportionment, the Secretary shall

Deadline.

Effective date.

withdraw from each urbanized area an amount equal to 50 percent of the funds apportioned to such urbanized area less the amount of funding obligated, and the Secretary shall redistribute such amounts to other urbanized areas that have had no funds withdrawn under this proviso utilizing whatever method he or she deems appropriate to ensure that all funds redistributed under this proviso shall be utilized promptly: *Provided further*, That 1 year following the date of such apportionment, the Secretary shall withdraw from each urbanized area any unobligated funds, and the Secretary shall redistribute such amounts to other urbanized areas that have had no funds withdrawn under this proviso utilizing whatever method he or she deems appropriate to ensure that all funds redistributed under this proviso shall be utilized promptly: *Provided further*, That at the request of an urbanized area, the Secretary of Transportation may provide an extension of such 1-year period if he or she feels satisfied that the urbanized area has encountered an unworkable bidding environment or other extenuating circumstances: *Provided further*, That before granting such an extension, the Secretary shall send a letter to the House and Senate Committees on Appropriations that provides a thorough justification for the extension: *Provided further*, That applicable chapter 53 requirements shall apply except that the Federal share of the costs for which a grant is made under this heading shall be, at the option of the recipient, up to 100 percent: *Provided further*, That the provisions of section 1101(b) of Public Law 109–59 shall apply to funds made available under this heading: *Provided further*, That notwithstanding any other provision of law, up to 1 percent of the funds under this heading shall be available for administrative expenses and program management oversight and shall remain available for obligation until September 30, 2012.

Effective date.

Submission.

Applicability.

Applicability.

CAPITAL INVESTMENT GRANTS

For an additional amount for "Capital Investment Grants", as authorized under section 5338(c)(4) of title 49, United States Code, and allocated under section 5309(m)(2)(A) of such title, to enable the Secretary of Transportation to make discretionary grants as authorized by section 5309(d) and (e) of such title, $750,000,000, to remain available through September 30, 2010: *Provided*, That such amount shall be allocated without regard to the limitation under section 5309(m)(2)(A)(i): *Provided further*, That in selecting projects to be funded, priority shall be given to projects that are currently in construction or are able to obligate funds within 150 days of enactment of this Act: *Provided further*, That the provisions of section 1101(b) of Public Law 109–59 shall apply to funds made available under this heading: *Provided further*, That funds appropriated under this heading shall not be commingled with any prior year funds: *Provided further*, That applicable chapter 53 requirements shall apply, except that notwithstanding any other provision of law, up to 1 percent of the funds provided under this heading shall be available for administrative expenses and program management oversight, and shall remain available through September 30, 2012.

Applicability.

Applicability.

MARITIME ADMINISTRATION

SUPPLEMENTAL GRANTS FOR ASSISTANCE TO SMALL SHIPYARDS

To make grants to qualified shipyards as authorized under section 3508 of Public Law 110–417 or section 54101 of title 46, United States Code, $100,000,000, to remain available through September 30, 2010: *Provided,* That the Secretary of Transportation shall institute measures to ensure that funds provided under this heading shall be obligated within 180 days of the date of their distribution: *Provided further,* That the Maritime Administrator may retain and transfer to "Maritime Administration, Operations and Training" up to 2 percent of the funds provided under this heading to fund the award and oversight by the Administrator of grants made under this heading.

Deadline.

OFFICE OF INSPECTOR GENERAL

SALARIES AND EXPENSES

For an additional amount for necessary expenses of the Office of Inspector General to carry out the provisions of the Inspector General Act of 1978, as amended, $20,000,000, to remain available through September 30, 2013: *Provided,* That the funding made available under this heading shall be used for conducting audits and investigations of projects and activities carried out with funds made available in this Act to the Department of Transportation: *Provided further,* That the Inspector General shall have all necessary authority, in carrying out the duties specified in the Inspector General Act, as amended (5 U.S.C. App. 3), to investigate allegations of fraud, including false statements to the Government (18 U.S.C. 1001), by any person or entity that is subject to regulation by the Department.

Audits.
Investigations.

Fraud.

GENERAL PROVISION—DEPARTMENT OF TRANSPORTATION

SEC. 1201. (a) MAINTENANCE OF EFFORT.—Not later than 30 days after the date of enactment of this Act, for each amount that is distributed to a State or agency thereof from an appropriation in this Act for a covered program, the Governor of the State shall certify to the Secretary of Transportation that the State will maintain its effort with regard to State funding for the types of projects that are funded by the appropriation. As part of this certification, the Governor shall submit to the Secretary of Transportation a statement identifying the amount of funds the State planned to expend from State sources as of the date of enactment of this Act during the period beginning on the date of enactment of this Act through September 30, 2010, for the types of projects that are funded by the appropriation.

Deadline.
Certification.

Submission.
Time period.

(b) FAILURE TO MAINTAIN EFFORT.—

If a State is unable to maintain the level of effort certified pursuant to subsection (a), the State will be prohibited by the Secretary of Transportation from receiving additional limitation pursuant to the redistribution of the limitation on obligations for Federal-aid highway and highway safety construction programs that occurs after August 1 for fiscal year 2011.

(c) PERIODIC REPORTS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, each grant recipient shall submit to the covered agency from which they received funding periodic reports on the use of the funds appropriated in this Act for covered programs. Such reports shall be collected and compiled by the covered agency and transmitted to Congress. Covered agencies may develop such reports on behalf of grant recipients to ensure the accuracy and consistency of such reports.

(2) CONTENTS OF REPORTS.—For amounts received under each covered program by a grant recipient under this Act, the grant recipient shall include in the periodic reports information tracking-

(A) the amount of Federal funds appropriated, allocated, obligated, and outlayed under the appropriation;

(B) the number of projects that have been put out to bid under the appropriation and the amount of Federal funds associated with such projects;

(C) the number of projects for which contracts have been awarded under the appropriation and the amount of Federal funds associated with such contracts;

(D) the number of projects for which work has begun under such contracts and the amount of Federal funds associated with such contracts;

(E) the number of projects for which work has been completed under such contracts and the amount of Federal funds associated with such contracts;

(F) the number of direct, on-project jobs created or sustained by the Federal funds provided for projects under the appropriation and, to the extent possible, the estimated indirect jobs created or sustained in the associated supplying industries, including the number of job-years created and the total increase in employment since the date of enactment of this Act; and

(G) for each covered program report information tracking the actual aggregate expenditures by each grant recipient from State sources for projects eligible for funding under the program during the period beginning on the date of enactment of this Act through September 30, 2010, as compared to the level of such expenditures that were planned to occur during such period as of the date of enactment of this Act.

(3) TIMING OF REPORTS.—Each grant recipient shall submit the first of the periodic reports required under this subsection not later than 90 days after the date of enactment of this Act and shall submit updated reports not later than 180 days, 1 year, 2 years, and 3 years after such date of enactment.

(d) DEFINITIONS.—In this section, the following definitions apply:

(1) COVERED AGENCY.—The term "covered agency" means the Office of the Secretary of Transportation, the Federal Aviation Administration, the Federal Highway Administration, the Federal Railroad Administration, the Federal Transit Administration and the Maritime Administration of the Department of Transportation.

(2) COVERED PROGRAM.—The term "covered program" means funds appropriated in this Act for "Supplemental Discretionary Grants for a National Surface Transportation System"

to the Office of the Secretary of Transportation, for "Supplemental Funding for Facilities and Equipment" and "Grants-in-Aid for Airports" to the Federal Aviation Administration; for "Highway Infrastructure Investment" to the Federal Highway Administration; for "Capital Assistance for High Speed Rail Corridors and Intercity Passenger Rail Service" and "Capital Grants to the National Railroad Passenger Corporation" to the Federal Railroad Administration; for "Transit Capital Assistance", "Fixed Guideway Infrastructure Investment", and "Capital Investment Grants" to the Federal Transit Administration; and "Supplemental Grants for Assistance to Small Shipyards" to the Maritime Administration.

(3) GRANT RECIPIENT.—The term "grant recipient" means a State or other recipient of assistance provided under a covered program in this Act. Such term does not include a Federal department or agency.

(e) Notwithstanding any other provision of law, sections 3501–3521 of title 44, United States Code, shall not apply to the provisions of this section.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

PUBLIC AND INDIAN HOUSING

PUBLIC HOUSING CAPITAL FUND

For an additional amount for the "Public Housing Capital Fund" to carry out capital and management activities for public housing agencies, as authorized under section 9 of the United States Housing Act of 1937 (42 U.S.C. 1437g) (the "Act"), $4,000,000,000, to remain available until September 30, 2011: *Provided,* That the Secretary of Housing and Urban Development shall distribute $3,000,000,000 of this amount by the same formula used for amounts made available in fiscal year 2008, except that the Secretary may determine not to allocate funding to public housing agencies currently designated as troubled or to public housing agencies that elect not to accept such funding: *Provided further,* That the Secretary shall obligate funds allocated by formula within 30 days of enactment of this Act: *Provided further,* That the Secretary shall make available $1,000,000,000 by competition for priority investments, including investments that leverage private sector funding or financing for renovations and energy conservation retrofit investments: *Provided further,* That the Secretary shall obligate competitive funding by September 30, 2009: *Provided further,* That public housing authorities shall give priority to capital projects that can award contracts based on bids within 120 days from the date the funds are made available to the public housing authorities: *Provided further,* That public housing agencies shall give priority consideration to the rehabilitation of vacant rental units: *Provided further,* That public housing agencies shall prioritize capital projects that are already underway or included in the 5-year capital fund plans required by the Act (42 U.S.C. 1437c–1(a)): *Provided further,* That notwithstanding any other provision of law, (1) funding provided under this heading may not be used for operating or rental assistance activities, and (2) any restriction of funding to replacement housing uses shall be inapplicable: *Provided further,* That notwithstanding any other provision of law, the Secretary shall institute measures to ensure that funds provided under this heading

Deadline.

Deadline.
Contracts.

shall serve to supplement and not supplant expenditures from other Federal, State, or local sources or funds independently generated by the grantee: *Provided further,* That notwithstanding section 9(j), public housing agencies shall obligate 100 percent of the funds within 1 year of the date on which funds become available to the agency for obligation, shall expend at least 60 percent of funds within 2 years of the date on which funds become available to the agency for obligation, and shall expend 100 percent of the funds within 3 years of such date: *Provided further,* That if a public housing agency fails to comply with the 1-year obligation requirement, the Secretary shall recapture all remaining unobligated funds awarded to the public housing agency and reallocate such funds to agencies that are in compliance with those requirements: *Provided further,* That if a public housing agency fails to comply with either the 2-year or the 3-year expenditure requirement, the Secretary shall recapture the balance of the funds awarded to the public housing agency and reallocate such funds to agencies that are in compliance with those requirements: *Provided further,* That in administering funds appropriated or otherwise made available under this heading, the Secretary may waive or specify alternative requirements for any provision of any statute or regulation in connection with the obligation by the Secretary or the use of these funds (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment), upon a finding that such a waiver is necessary to expedite or facilitate the use of such funds: *Provided further,* That, in addition to waivers authorized under the previous proviso, the Secretary may direct that requirements relating to the procurement of goods and services arising under state and local laws and regulations shall not apply to amounts made available under this heading: *Provided further,* That of the funds made available under this heading, up to .5 percent shall be available for staffing, training, technical assistance, technology, monitoring, travel, enforcement, research and evaluation activities: *Provided further,* That funds set aside in the previous proviso shall remain available until September 30, 2012: *Provided further,* That any funds made available under this heading used by the Secretary for personnel expenses related to administering funding under this heading shall be transferred to "Personnel Compensation and Benefits, Office of Public and Indian Housing" and shall retain the terms and conditions of this account, including reprogramming provisions, except that the period of availability set forth in the previous proviso shall govern such transferred funds: *Provided further,* That any funds made available under this heading used by the Secretary for training or other administrative expenses shall be transferred to "Administration, Operations, and Management", for non-personnel expenses of the Department of Housing and Urban Development: *Provided further,* That any funds made available under this heading used by the Secretary for technology shall be transferred to "Working Capital Fund".

Deadlines.

Waiver authority.

NATIVE AMERICAN HOUSING BLOCK GRANTS

For an additional amount for "Native American Housing Block Grants", as authorized under title I of the Native American Housing Assistance and Self-Determination Act of 1996 ("NAHASDA") (25

U.S.C. 4111 et seq.), $510,000,000 to remain available until September 30, 2011: *Provided,* That $255,000,000 of the amount provided under this heading shall be distributed according to the same funding formula used in fiscal year 2008: *Provided further,* That the Secretary shall obligate funds allocated by formula within 30 days of enactment of this Act: *Provided further,* That the amounts distributed through the formula shall be used for new construction, acquisition, rehabilitation including energy efficiency and conservation, and infrastructure development: *Provided further,* That in selecting projects to be funded, recipients shall give priority to projects for which contracts can be awarded within 180 days from the date that funds are available to the recipients: *Provided further,* that the Secretary may obligate $255,000,000 of the amount provided under this heading for competitive grants to eligible entities that apply for funds authorized under NAHASDA: *Provided further,* That the Secretary shall obligate competitive funding by September 30, 2009: *Provided further,* That in awarding competitive funds, the Secretary shall give priority to projects that will spur construction and rehabilitation and will create employment opportunities for low-income and unemployed persons: *Provided further,* That recipients of funds under this heading shall obligate 100 percent of such funds within 1 year of the date funds are made available to a recipient, expend at least 50 percent of such funds within 2 years of the date on which funds become available to such recipients for obligation and expend 100 percent of such funds within 3 years of such date: *Provided further,* That if a recipient fails to comply with the 2-year expenditure requirement, the Secretary shall recapture all remaining funds awarded to the recipient and reallocate such funds through the funding formula to recipients that are in compliance with these requirements: *Provided further,* That if a recipient fails to comply with the 3-year expenditure requirement, the Secretary shall recapture the balance of the funds originally awarded to the recipient: *Provided further,* That notwithstanding any other provision of law, the Secretary may set aside up to 2 percent of funds made available under this paragraph for a housing entity eligible to receive funding under title VIII of NAHASDA (25 U.S.C. 4221 et seq.): *Provided further,* That in administering funds appropriated or otherwise made available under this heading, the Secretary may waive or specify alternative requirements for any provision of any statute or regulation in connection with the obligation by the Secretary or the use of these funds (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment), upon a finding that such a waiver is necessary to expedite or facilitate the use of such funds: *Provided further,* That of the funds made available under this heading, up to .5 percent shall be available for staffing, training, technical assistance, technology, monitoring, travel, enforcement, research and evaluation activities: *Provided further,* That funds set aside in the previous proviso shall remain available until September 30, 2012: *Provided further,* That any funds made available under this heading used by the Secretary for personnel expenses related to administering funding under this heading shall be transferred to "Personnel Compensation and Benefits, Office of Public and Indian Housing" and shall retain the terms and conditions of this account, including reprogramming provisions, except that the period of availability set forth in the

Deadline.

Deadline.

Deadlines.

Waiver authority.

previous proviso shall govern such transferred funds: *Provided further,* That any funds made available under this heading used by the Secretary for training or other administrative expenses shall be transferred to "Administration, Operations, and Management", for non-personnel expenses of the Department of Housing and Urban Development: *Provided further,* That any funds made available under this heading used by the Secretary for technology shall be transferred to "Working Capital Fund".

COMMUNITY PLANNING AND DEVELOPMENT

COMMUNITY DEVELOPMENT FUND

For an additional amount for "Community Development Fund" $1,000,000,000, to remain available until September 30, 2010 to carry out the community development block grant program under title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 et seq.): *Provided*, That the amount appropriated in this paragraph shall be distributed pursuant to 42 U.S.C. 5306 to grantees that received funding in fiscal year 2008: *Provided further*, That in administering the funds appropriated in this paragraph, the Secretary of Housing and Urban Development shall establish requirements to expedite the use of the funds: *Provided further*, That in selecting projects to be funded, recipients shall give priority to projects that can award contracts based on bids within 120 days from the date the funds are made available to the recipients: *Provided further*, That in administering funds appropriated or otherwise made available under this heading, the Secretary may waive or specify alternative requirements for any provision of any statute or regulation in connection with the obligation by the Secretary or the use by the recipient of these funds (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment), upon a finding that such waiver is necessary to expedite or facilitate the timely use of such funds and would not be inconsistent with the overall purpose of the statute.

Requirements.

Waiver authority.

For the provision of emergency assistance for the redevelopment of abandoned and foreclosed homes, as authorized under division B, title III of the Housing and Economic Recovery Act of 2008 ("the Act") (Public Law 110–289) (42 U.S.C. 5301 note), $2,000,000,000, to remain available until September 30, 2010: *Provided,* That grantees shall expend at least 50 percent of allocated funds within 2 years of the date funds become available to the grantee for obligation, and 100 percent of such funds within 3 years of such date: *Provided further,* That unless otherwise noted herein, the provisions of the Act govern the use of the additional funds made available under this heading: *Provided further,* That notwithstanding the provisions of sections 2301(b) and (c)(1) and section 2302 of the Act, funding under this paragraph shall be allocated by competitions for which eligible entities shall be States, units of general local government, and nonprofit entities or consortia of nonprofit entities, which may submit proposals in partnership with for profit entities: *Provided further,* That in selecting grantees, the Secretary of Housing and Urban Development shall ensure that the grantees are in areas with the greatest number and percentage of foreclosures and can expend funding within the period allowed under this heading: *Provided further,* That additional award criteria for such competitions shall include demonstrated grantee

Deadlines.

Award criteria.

capacity to execute projects, leveraging potential, concentration of investment to achieve neighborhood stabilization, and any additional factors determined by the Secretary of Housing and Urban Development: *Provided further,* That the Secretary may establish a minimum grant size: *Provided further,* That the Secretary shall publish criteria on which to base competition for any grants awarded under this heading not later than 75 days after the enactment of this Act and applications shall be due to HUD not later than 150 days after the enactment of this Act: *Provided further,* That the Secretary shall obligate all funding within 1 year of enactment of this Act: *Provided further,* That section 2301(d)(4) of the Act is repealed: *Provided further,* That section 2301(c)(3)(C) of the Act is amended to read "establish and operate land banks for homes and residential properties that have been foreclosed upon": *Provided further,* That funding used for section 2301(c)(3)(E) of the Act shall be available only for the redevelopment of demolished or vacant properties as housing: *Provided further,* That no amounts made available from a grant under this heading may be used to demolish any public housing (as such term is defined in section 3 of the United States Housing Act of 1937 (42 U.S.C. 1437a)): *Provided further,* That a grantee may not use more than 10 percent of its grant under this heading for demolition activities under section 2301(c)(3)(C) and (D) unless the Secretary determines that such use represents an appropriate response to local market conditions: *Provided further,* That the recipient of any grant or loan from amounts made available under this heading or, after the date of enactment under division B, title III of the Housing and Economic Recovery Act of 2008, may not refuse to lease a dwelling unit in housing with such loan or grant to a participant under section 8 of the United States Housing Act of 1937 (42 U.S.C 1437f) because of the status of the prospective tenant as such a participant: *Provided further,* That in addition to the eligible uses in section 2301, the Secretary may also use up to 10 percent of the funds provided under this heading for grantees for the provision of capacity building of and support for local communities receiving funding under section 2301 of the Act or under this heading: *Provided further,* That in administering funds appropriated or otherwise made available under this section, the Secretary may waive or specify alternative requirements for any provision of any statute or regulation in connection with the obligation by the Secretary or the use of funds except for requirements related to fair housing, nondiscrimination, labor standards and the environment, upon a finding that such a waiver is necessary to expedite or facilitate the use of such funds: *Provided further*, That in the case of any acquisition of a foreclosed upon dwelling or residential real property acquired after the date of enactment with any amounts made available under this heading or under division B, title III of the Housing and Economic Recovery Act of 2008 (Public Law 110–289), the initial successor in interest in such property pursuant to the foreclosure shall assume such interest subject to: (1) the provision by such successor in interest of a notice to vacate to any bona fide tenant at least 90 days before the effective date of such notice; and (2) the rights of any bona fide tenant, as of the date of such notice of foreclosure: (A) under any bona fide lease entered into before the notice of foreclosure to occupy the premises until the end of the remaining term of the lease, except that a successor in interest may terminate a lease effective on

Publication. Criteria. Deadlines.

Deadline.

42 USC 5301 note.

42 USC 5301 note.

Waiver authority.

Foreclosure. Notice. 42 USC 5301 note.

the date of sale of the unit to a purchaser who will occupy the unit as a primary residence, subject to the receipt by the tenant of the 90-day notice under this paragraph; or (B) without a lease or with a lease terminable at will under State law, subject to the receipt by the tenant of the 90-day notice under this paragraph, except that nothing in this paragraph shall affect the requirements for termination of any Federal- or State-subsidized tenancy or of any State or local law that provides longer time periods or other additional protections for tenants: *Provided further*, That, for purposes of this paragraph, a lease or tenancy shall be considered bona fide only if: (1) the mortgagor under the contract is not the tenant; (2) the lease or tenancy was the result of an arms-length transaction; and (3) the lease or tenancy requires the receipt of rent that is not substantially less than fair market rent for the property: *Provided further*, That the recipient of any grant or loan from amounts made available under this heading or, after the date of enactment, under division B, title III of the Housing and Economic Recovery Act of 2008 (Public Law 110–289) may not refuse to lease a dwelling unit in housing assisted with such loan or grant to a holder of a voucher or certificate of eligibility under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f) because of the status of the prospective tenant as such a holder: *Provided further*, That in the case of any qualified foreclosed housing for which funds made available under this heading or, after the date of enactment, under division B, title III of the Housing and Economic Recovery Act of 2008 (Public Law 110–289) are used and in which a recipient of assistance under section 8(o) of the U.S. Housing Act of 1937 resides at the time of foreclosure, the initial successor in interest shall be subject to the lease and to the housing assistance payments contract for the occupied unit: *Provided further*, That vacating the property prior to sale shall not constitute good cause for termination of the tenancy unless the property is unmarketable while occupied or unless the owner or subsequent purchaser desires the unit for personal or family use: *Provided further*, That if a public housing agency is unable to make payments under the contract to the immediate successor in interest after foreclosures, due to (1) an action or inaction by the successor in interest, including the rejection of payments or the failure of the successor to maintain the unit in compliance with section 8(o)(8) of the United States Housing Act of 1937 (42 U.S.C.1437f) or (2) an inability to identify the successor, the agency may use funds that would have been used to pay the rental amount on behalf of the family—(i) to pay for utilities that are the responsibility of the owner under the lease or applicable law, after taking reasonable steps to notify the owner that it intends to make payments to a utility provider in lieu of payments to the owner, except prior notification shall not be required in any case in which the unit will be or has been rendered uninhabitable due to the termination or threat of termination of service, in which case the public housing agency shall notify the owner within a reasonable time after making such payment; or (ii) for the family's reasonable moving costs, including security deposit costs: *Provided further,* That this paragraph shall not preempt any Federal, State or local law that provides more protections for tenants: *Provided further,* That of the funds made available under this heading, up to 1 percent shall be available for staffing, training, technical assistance, technology, monitoring, travel,

Contracts.

42 USC 5301 note.

enforcement, research and evaluation activities: *Provided further*, That funds set aside in the previous proviso shall remain available until September 30, 2012: *Provided further*, That any funds made available under this heading used by the Secretary for personnel expenses related to administering funding under this heading shall be transferred to "Personnel Compensation and Benefits, Community Planning and Development" and shall retain the terms and conditions of this account, including reprogramming provisions, except that the period of availability set forth in the previous proviso shall govern such transferred funds: *Provided further*, That any funds made available under this heading used by the Secretary for training or other administrative expenses shall be transferred to "Administration, Operations, and Management" for non-personnel expenses of the Department of Housing and Urban Development: *Provided further*, That any funds made available under this heading used by the Secretary for technology shall be transferred to "Working Capital Fund".

HOME INVESTMENT PARTNERSHIPS PROGRAM

For an additional amount for capital investments in low-income housing tax credit projects, $2,250,000,000, to remain available until September 30, 2011: *Provided,* That such funds shall be made available to State housing credit agencies, as defined in section 42(h) of the Internal Revenue Code of 1986, and shall be apportioned among the States based on the percentage of HOME funds apportioned to each State and the participating jurisdictions therein for Fiscal Year 2008: *Provided further,* That the housing credit agencies in each State shall distribute these funds competitively under this heading and pursuant to their qualified allocation plan (as defined in section 42(m) of the Internal Revenue Code of 1986) to owners of projects who have received or receive simultaneously an award of low-income housing tax credits under section 42(h) of the Internal Revenue Code of 1986: *Provided further,* That housing credit agencies in each State shall commit not less than 75 percent of such funds within one year of the date of enactment of this Act, and shall demonstrate that the project owners shall have expended 75 percent of the funds made available under this heading within two years of the date of enactment of this Act, and shall have expended 100 percent of the funds within 3 years of the date of enactment of this Act: *Provided further,* That failure by an owner to expend funds within the parameters required within the previous proviso shall result in a redistribution of these funds by a housing credit agency to a more deserving project in such State, except any funds not expended after 3 years from enactment shall be redistributed by the Secretary to other States that have fully utilized the funds made available to them: *Provided further,* That projects awarded low income housing tax credits under section 42(h) of the IRC of 1986 in fiscal years 2007, 2008, or 2009 shall be eligible for funding under this heading: *Provided further,* That housing credit agencies shall give priority to projects that are expected to be completed within 3 years of enactment: *Provided further,* That any assistance provided to an eligible low income housing tax credit project under this heading shall be made in the same manner and be subject to the same limitations (including rent, income, and use restrictions, in lieu of corresponding limitations under the HOME program) as required by the state housing

Deadlines.

credit agency with respect to an award of low income housing credits under section 42 of the IRC of 1986: *Provided further,* That the housing credit agency shall perform asset management functions, or shall contract for the performance of such services, in either case, at the owner's expense, to ensure compliance with section 42 of the IRC of 1986, and the long term viability of buildings funded by assistance under this heading: *Provided further,* That the term eligible basis (as such term is defined in such section 42) of a qualified low-income housing tax credit building receiving assistance under this heading shall not be reduced by the amount of any grant described under this heading: *Provided further,* That the Secretary shall be given access upon reasonable notice to a State housing credit agency to information related to the award of Federal funds from such housing credit agency pursuant to this heading and shall establish an Internet site that shall identify all projects selected for an award, including the amount of the award and such site shall provide linkage to the housing credit agency allocation plan which describes the process that was used to make the award decision: *Provided further,* That in administering funds under this heading, the Secretary may waive any provision of any statute or regulation that the Secretary administers in connection with the obligation by the Secretary or the use by the recipient of these funds except for requirements imposed by this heading and requirements related to fair housing, non-discrimination, labor standards and the environment, upon a finding that such waiver is required to expedite the use of such funds: *Provided further,* That for purposes of environmental compliance review, funds under this heading that are made available to State housing credit agencies for distribution to projects awarded low income housing tax credits shall be treated as funds under the HOME program and shall be subject to Section 288 of the HOME Investment Partnership Act.

Contracts.

Web site.

Waiver authority.

HOMELESSNESS PREVENTION FUND

For homelessness prevention and rapid re-housing activities, $1,500,000,000, to remain available until September 30, 2011: *Provided,* That funds provided under this heading shall be used for the provision of short-term or medium-term rental assistance; housing relocation and stabilization services including housing search, mediation or outreach to property owners, credit repair, security or utility deposits, utility payments, rental assistance for a final month at a location, moving cost assistance, and case management; or other appropriate activities for homelessness prevention and rapid re-housing of persons who have become homeless: *Provided further,* That grantees receiving such assistance shall collect data on the use of the funds awarded and persons served with this assistance in the HUD Homeless Management Information System ("HMIS") or other comparable database: *Provided further,* That grantees may use up to 5 percent of any grant for administrative costs: *Provided further,* That funding made available under this heading shall be allocated to eligible grantees (as defined and designated in sections 411 and 412 of subtitle B of title IV of the McKinney-Vento Homeless Assistance Act, (the "Act")) pursuant to the formula authorized by section 413 of the Act: *Provided further,* That the Secretary may establish a minimum grant size: *Provided further,* That grantees shall expend at least 60 percent

Deadlines.

of funds within 2 years of the date that funds became available to them for obligation, and 100 percent of funds within 3 years of such date, and the Secretary may recapture unexpended funds in violation of the 2-year expenditure requirement and reallocate such funds to grantees in compliance with that requirement: *Provided further,* That the Secretary may waive statutory or regulatory provisions (except provisions for fair housing, nondiscrimination, labor standards, and the environment) necessary to facilitate the timely expenditure of funds: *Provided further,* That the Secretary shall publish a notice to establish such requirements as may be necessary to carry out the provisions of this section within 30 days of enactment of this Act and that this notice shall take effect upon issuance: *Provided further,* That of the funds provided under this heading, up to .5 percent shall be available for staffing, training, technical assistance, technology, monitoring, research and evaluation activities: *Provided further,* That funds set aside under the previous proviso shall remain available until September 30, 2012: *Provided further,* That any funds made available under this heading used by the Secretary for personnel expenses related to administering funding under this heading shall be transferred to "Community Planning and Development Personnel Compensation and Benefits" and shall retain the terms and conditions of this account including reprogramming provisions except that the period of availability set forth in the previous proviso shall govern such transferred funds: *Provided further,* That any funds made available under this heading used by the Secretary for training or other administrative expenses shall be transferred to "Administration, Operations, and Management" for non-personnel expenses of the Department of Housing and Urban Development: *Provided further,* That any funding made available under this heading used by the Secretary for technology shall be transferred to "Working Capital Fund."

Waiver authority.

Publication.
Notice.
Deadline.
Effective date.

HOUSING PROGRAMS

ASSISTED HOUSING STABILITY AND ENERGY AND GREEN RETROFIT INVESTMENTS

For assistance to owners of properties receiving project-based assistance pursuant to section 202 of the Housing Act of 1959 (12 U.S.C. 17012), section 811 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 8013), or section 8 of the United States Housing Act of 1937 as amended (42 U.S.C. 1437f), $2,250,000,000, of which $2,000,000,000 shall be for an additional amount for paragraph (1) under the heading "Project-Based Rental Assistance" in Public Law 110–161 for payments to owners for 12-month periods, and of which $250,000,000 shall be for grants or loans for energy retrofit and green investments in such assisted housing: *Provided,* That projects funded with grants or loans provided under this heading must comply with the requirements of subchapter IV of chapter 31 of title 40, United States Code: *Provided further,* That such grants or loans shall be provided through the policies, procedures, contracts, and transactional infrastructure of the authorized programs administered by the Office of Affordable Housing Preservation of the Department of Housing and Urban Development, on such terms and conditions as the Secretary of Housing and Urban Development deems appropriate to ensure the

maintenance and preservation of the property, the continued operation and maintenance of energy efficiency technologies, and the timely expenditure of funds: *Provided further,* That the Secretary may provide incentives to owners to undertake energy or green retrofits as a part of such grant or loan terms, including, but not limited to, fees to cover investment oversight and implementation by said owner, or to encourage job creation for low-income or very low-income individuals: *Provided further,* That the Secretary may share in a portion of future property utility savings resulting from improvements made by grants or loans made available under this heading: *Provided further,* That the grants or loans shall include a financial assessment and physical inspection of such property: *Provided further,* That eligible owners must have at least a satisfactory management review rating, be in substantial compliance with applicable performance standards and legal requirements, and commit to an additional period of affordability determined by the Secretary, but of not fewer than 15 years: *Provided further,* That the Secretary shall undertake appropriate underwriting and oversight with respect to grant and loan transactions and may set aside up to 5 percent of the funds made available under this heading for grants or loans for such purpose: *Provided further,* That the Secretary shall take steps necessary to ensure that owners receiving funding for energy and green retrofit investments under this heading shall expend such funding within 2 years of the date they received the funding: *Provided further,* That in administering funds appropriated or otherwise made available under this heading, the Secretary may waive or specify alternative requirements for any provision of any statute or regulation in connection with the obligation by the Secretary or the use of these funds (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment), upon a finding that such a waiver is necessary to expedite or facilitate the use of such funds: *Provided further,* That of the funds provided under this heading for grants and loans, up to 1 percent shall be available for staffing, training, technical assistance, technology, monitoring, research and evaluation activities: *Provided further,* That funds set aside in the previous proviso shall remain available until September 30, 2012: *Provided further,* That funding made available under this heading and used by the Secretary for personnel expenses related to administering funding under this heading shall be transferred to "Housing Personnel Compensation and Benefits" and shall retain the terms and conditions of this account including reprogramming provisos except that the period of availability set forth in the previous proviso shall govern such transferred funds: *Provided further,* That any funding made available under this heading used by the Secretary for training and other administrative expenses shall be transferred to "Administration, Operations and Management" for nonpersonnel expenses of the Department of Housing and Urban Development: *Provided further,* That any funding made available under this heading used by the Secretary for technology shall be transferred to "Working Capital Fund."

Waiver authority.

OFFICE OF LEAD HAZARD CONTROL AND HEALTHY HOMES

For an additional amount for the "Lead Hazard Reduction Program", as authorized by section 1011 of the Residential Lead-Based Paint Hazard Reduction Act of 1992, and by sections 501

and 502 of the Housing and Urban Development Act of 1974, $100,000,000, to remain available until September 30, 2011: *Provided,* That for purposes of environmental review, pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and other provisions of law that further the purposes of such Act, a grant under the Healthy Homes Initiative, Operation Lead Elimination Action Plan (LEAP), or the Lead Technical Studies program under this heading or under prior appropriations Acts for such purposes under this heading, shall be considered to be funds for a special project for purposes of section 305(e) of the Multifamily Housing Property Disposition Reform Act of 1994: *Provided further,* That funds shall be awarded first to applicants which had applied under the Lead Hazard Reduction Program Notices of Funding Availability for fiscal year 2008, and were found in the application review to be qualified for award, but were not awarded because of funding limitations, and that any funds which remain after reservation of funds for such grants shall be added to the amount of funds to be awarded under the Lead Hazard Reduction Program Notices of Funding Availability for fiscal year 2009: *Provided further,* That each applicant for the Lead Hazard Program Notices of Funding Availability for fiscal year 2009 shall submit a detailed plan and strategy that demonstrates adequate capacity that is acceptable to the Secretary to carry out the proposed use of funds: *Provided further,* That recipients of funds under this heading shall expend at least 50 percent of such funds within 2 years of the date on which funds become available to such jurisdictions for obligation, and expend 100 percent of such funds within 3 years of such date: *Provided further,* That if a recipient fails to comply with the 2-year expenditure requirement, the Secretary shall recapture all remaining funds awarded to the recipient and reallocate such funds to recipients that are in compliance with those requirements: *Provided further,* That if a recipient fails to comply with the 3-year expenditure requirement, the Secretary shall recapture the balance of the funds awarded to the recipient: *Provided further,* That in administering funds appropriated or otherwise made available under this heading, the Secretary may waive or specify alternative requirements for any provision of any statute or regulation in connection with the obligation by the Secretary or the use of these funds (except for requirements related to fair housing, nondiscrimination, labor standards and the environment), upon a finding that such a waiver is necessary to expedite or facilitate the use of such funds: *Provided further,* That of the funds made available under this heading, up to .5 percent shall be available for staffing, training, technical assistance, technology, monitoring, travel, enforcement, research and evaluation activities: *Provided further,* That funds set aside in the previous proviso shall remain available until September 30, 2012: *Provided further,* That any funds made available under this heading used by the Secretary for personnel expenses related to administering funding under this heading shall be transferred to "Personnel Compensation and Benefits, Office of Lead Hazard Control and Healthy Homes" and shall retain the terms and conditions of this account, including reprogramming provisions, except that the period of availability set forth in the previous proviso shall govern such transferred funds: *Provided further,* That any funds made available under this heading used by the Secretary for training or other administrative expenses shall be transferred

Plans.
Strategy.

Deadlines.

Waiver authority.

to "Administration, Operations, and Management", for non-personnel expenses of the Department of Housing and Urban Development: *Provided further,* That any funds made available under this heading used by the Secretary for technology shall be transferred to "Working Capital Fund".

MANAGEMENT AND ADMINISTRATION

OFFICE OF INSPECTOR GENERAL

For an additional amount for the necessary salaries and expenses of the Office of Inspector General in carrying out the Inspector General Act of 1978, as amended, $15,000,000, to remain available until September 30, 2013: *Provided,* That the Inspector General shall have independent authority over all personnel issues within this office.

GENERAL PROVISIONS—DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SEC. 1202. FHA LOAN LIMITS FOR 2009. (a) LOAN LIMIT FLOOR BASED ON 2008 LEVELS.—For mortgages for which the mortgagee issues credit approval for the borrower during calendar year 2009, if the dollar amount limitation on the principal obligation of a mortgage determined under section 203(b)(2) of the National Housing Act (12 U.S.C. 1709(b)(2)) for any size residence for any area is less than such dollar amount limitation that was in effect for such size residence for such area for 2008 pursuant to section 202 of the Economic Stimulus Act of 2008 (Public Law 110–185; 122 Stat. 620), notwithstanding any other provision of law, the maximum dollar amount limitation on the principal obligation of a mortgage for such size residence for such area for purposes of such section 203(b)(2) shall be considered (except for purposes of section 255(g) of such Act (12 U.S.C. 1715z–20(g))) to be such dollar amount limitation in effect for such size residence for such area for 2008.

(b) DISCRETIONARY AUTHORITY FOR SUB-AREAS.—Notwithstanding any other provision of law, if the Secretary of Housing and Urban Development determines, for any geographic area that is smaller than an area for which dollar amount limitations on the principal obligation of a mortgage are determined under section 203(b)(2) of the National Housing Act, that a higher such maximum dollar amount limitation is warranted for any particular size or sizes of residences in such sub-area by higher median home prices in such sub-area, the Secretary may, for mortgages for which the mortgagee issues credit approval for the borrower during calendar year 2009, increase the maximum dollar amount limitation for such size or sizes of residences for such sub-area that is otherwise in effect (including pursuant to subsection (a) of this section), but in no case to an amount that exceeds the amount specified in section 202(a)(2) of the Economic Stimulus Act of 2008.

SEC. 1203. GSE CONFORMING LOAN LIMITS FOR 2009. (a) LOAN LIMIT FLOOR BASED ON 2008 LEVELS.—For mortgages originated during calendar year 2009, if the limitation on the maximum original principal obligation of a mortgage that may be purchased by the Federal National Mortgage Association or the Federal Home Loan Mortgage Corporation determined under section 302(b)(2) of the Federal National Mortgage Association Charter Act (12 U.S.C.

1717(b)(2)) or section 305(a)(2) of the Federal Home Loan Mortgage Corporation Act (12 U.S.C. 1754(a)(2)), respectively, for any size residence for any area is less than such maximum original principal obligation limitation that was in effect for such size residence for such area for 2008 pursuant to section 201 of the Economic Stimulus Act of 2008 (Public Law 110–185; 122 Stat. 619), notwithstanding any other provision of law, the limitation on the maximum original principal obligation of a mortgage for such Association and Corporation for such size residence for such area shall be such maximum limitation in effect for such size residence for such area for 2008.

(b) DISCRETIONARY AUTHORITY FOR SUB-AREAS.—Notwithstanding any other provision of law, if the Director of the Federal Housing Finance Agency determines, for any geographic area that is smaller than an area for which limitations on the maximum original principal obligation of a mortgage are determined for the Federal National Mortgage Association or the Federal Home Loan Mortgage Corporation, that a higher such maximum original principal obligation limitation is warranted for any particular size or sizes of residences in such sub-area by higher median home prices in such sub-area, the Director may, for mortgages originated during 2009, increase the maximum original principal obligation limitation for such size or sizes of residences for such sub-area that is otherwise in effect (including pursuant to subsection (a) of this section) for such Association and Corporation, but in no case to an amount that exceeds the amount specified in the matter following the comma in section 201(a)(1)(B) of the Economic Stimulus Act of 2008.

SEC. 1204. FHA REVERSE MORTGAGE LOAN LIMITS FOR 2009. For mortgages for which the mortgagee issues credit approval for the borrower during calendar year 2009, the second sentence of section 255(g) of the National Housing Act (12 U.S.C. 1715z–20(g)) shall be considered to require that in no case may the benefits of insurance under such section 255 exceed 150 percent of the maximum dollar amount in effect under the sixth sentence of section 305(a)(2) of the Federal Home Loan Mortgage Corporation Act (12 U.S.C. 1454(a)(2)).

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

Health Information Technology for Economic and Clinical Health Act.

42 USC 201 note.

SEC. 13001. SHORT TITLE; TABLE OF CONTENTS OF TITLE.

(a) SHORT TITLE.—This title (and title IV of division B) may be cited as the "Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act".

(b) TABLE OF CONTENTS OF TITLE.—The table of contents of this title is as follows:

Sec. 13001. Short title; table of contents of title.

Subtitle A—Promotion of Health Information Technology

PART 1—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

Sec. 13101. ONCHIT; standards development and adoption.

"TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

"Sec. 3000. Definitions.

"Subtitle A—Promotion of Health Information Technology

"Sec. 3001. Office of the National Coordinator for Health Information Technology.
"Sec. 3002. HIT Policy Committee.
"Sec. 3003. HIT Standards Committee.
"Sec. 3004. Process for adoption of endorsed recommendations; adoption of initial set of standards, implementation specifications, and certification criteria.
"Sec. 3005. Application and use of adopted standards and implementation specifications by Federal agencies.
"Sec. 3006. Voluntary application and use of adopted standards and implementation specifications by private entities.
"Sec. 3007. Federal health information technology.
"Sec. 3008. Transitions.
"Sec. 3009. Miscellaneous provisions.
Sec. 13102. Technical amendment.

PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

Sec. 13111. Coordination of Federal activities with adopted standards and implementation specifications.
Sec. 13112. Application to private entities.
Sec. 13113. Study and reports.

Subtitle B—Testing of Health Information Technology

Sec. 13201. National Institute for Standards and Technology testing.
Sec. 13202. Research and development programs.

Subtitle C—Grants and Loans Funding

Sec. 13301. Grant, loan, and demonstration programs.

"Subtitle B—Incentives for the Use of Health Information Technology

"Sec. 3011. Immediate funding to strengthen the health information technology infrastructure.
"Sec. 3012. Health information technology implementation assistance.
"Sec. 3013. State grants to promote health information technology.
"Sec. 3014. Competitive grants to States and Indian tribes for the development of loan programs to facilitate the widespread adoption of certified EHR technology.
"Sec. 3015. Demonstration program to integrate information technology into clinical education.
"Sec. 3016. Information technology professionals in health care.
"Sec. 3017. General grant and loan provisions.
"Sec. 3018. Authorization for appropriations.

Subtitle D—Privacy

Sec. 13400. Definitions.

PART 1—IMPROVED PRIVACY PROVISIONS AND SECURITY PROVISIONS

Sec. 13401. Application of security provisions and penalties to business associates of covered entities; annual guidance on security provisions.
Sec. 13402. Notification in the case of breach.
Sec. 13403. Education on health information privacy.
Sec. 13404. Application of privacy provisions and penalties to business associates of covered entities.
Sec. 13405. Restrictions on certain disclosures and sales of health information; accounting of certain protected health information disclosures; access to certain information in electronic format.
Sec. 13406. Conditions on certain contacts as part of health care operations.
Sec. 13407. Temporary breach notification requirement for vendors of personal health records and other non-HIPAA covered entities.
Sec. 13408. Business associate contracts required for certain entities.
Sec. 13409. Clarification of application of wrongful disclosures criminal penalties.
Sec. 13410. Improved enforcement.
Sec. 13411. Audits.

PART 2—RELATIONSHIP TO OTHER LAWS; REGULATORY REFERENCES; EFFECTIVE DATE; REPORTS

Sec. 13421. Relationship to other laws.

Sec. 13422. Regulatory references.
Sec. 13423. Effective date.
Sec. 13424. Studies, reports, guidance.

Subtitle A—Promotion of Health Information Technology

PART 1—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

SEC. 13101. ONCHIT; STANDARDS DEVELOPMENT AND ADOPTION.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

42 USC 300jj.

"SEC. 3000. DEFINITIONS.

"In this title:

"(1) CERTIFIED EHR TECHNOLOGY.—The term 'certified EHR technology' means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

"(2) ENTERPRISE INTEGRATION.—The term 'enterprise integration' means the electronic linkage of health care providers, health plans, the government, and other interested parties, to enable the electronic exchange and use of health information among all the components in the health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards.

"(3) HEALTH CARE PROVIDER.—The term 'health care provider' includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 1913(b)(1)), renal dialysis facility, blood center, ambulatory surgical center described in section 1833(i) of the Social Security Act, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, a covered entity under section 340B, an ambulatory surgical center described in section 1833(i) of the Social Security Act, a therapist (as defined in section 1848(k)(3)(B)(iii) of the Social Security Act), and any other category of health care facility, entity,

practitioner, or clinician determined appropriate by the Secretary.

"(4) HEALTH INFORMATION.—The term 'health information' has the meaning given such term in section 1171(4) of the Social Security Act.

"(5) HEALTH INFORMATION TECHNOLOGY.—The term 'health information technology' means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information

"(6) HEALTH PLAN.—The term 'health plan' has the meaning given such term in section 1171(5) of the Social Security Act.

"(7) HIT POLICY COMMITTEE.—The term 'HIT Policy Committee' means such Committee established under section 3002(a).

"(8) HIT STANDARDS COMMITTEE.—The term 'HIT Standards Committee' means such Committee established under section 3003(a).

"(9) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable health information' has the meaning given such term in section 1171(6) of the Social Security Act.

"(10) LABORATORY.—The term 'laboratory' has the meaning given such term in section 353(a).

"(11) NATIONAL COORDINATOR.—The term 'National Coordinator' means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a).

"(12) PHARMACIST.—The term 'pharmacist' has the meaning given such term in section 804(2) of the Federal Food, Drug, and Cosmetic Act.

"(13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term 'qualified electronic health record' means an electronic record of health-related information on an individual that—

"(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

"(B) has the capacity—

"(i) to provide clinical decision support;

"(ii) to support physician order entry;

"(iii) to capture and query information relevant to health care quality; and

"(iv) to exchange electronic health information with, and integrate such information from other sources.

"(14) STATE.—The term 'State' means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

"Subtitle A—Promotion of Health Information Technology

42 USC 300jj–11.

"SEC. 3001. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

"(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the 'Office'). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

"(b) PURPOSE.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

"(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

"(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

"(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

"(4) provides appropriate information to help guide medical decisions at the time and place of care;

"(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

"(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

"(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

"(8) facilitates health and clinical research and health care quality;

"(9) promotes early detection, prevention, and management of chronic diseases;

"(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

"(11) improves efforts to reduce health disparities.

"(c) DUTIES OF THE NATIONAL COORDINATOR.—

"(1) STANDARDS.—The National Coordinator shall—

"(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption under section 3004;

Reports.
Deadline.

"(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

"(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

"(2) HIT POLICY COORDINATION.—

"(A) IN GENERAL.—The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

"(B) HIT POLICY AND STANDARDS COMMITTEES.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.

"(3) STRATEGIC PLAN.—

"(A) IN GENERAL.—The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

"(i) The electronic exchange and use of health information and the enterprise integration of such information.

"(ii) The utilization of an electronic health record for each person in the United States by 2014.

"(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

"(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

"(v) Specifying a framework for coordination and flow of recommendations and policies under this subtitle among the Secretary, the National Coordinator, the HIT Policy Committee, the HIT Standards Committee, and other health information exchanges and other relevant entities.

"(vi) Methods to foster the public understanding of health information technology.

"(vii) Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

"(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately

addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

"(B) COLLABORATION.—The strategic plan shall be updated through collaboration of public and private entities.

"(C) MEASURABLE OUTCOME GOALS.—The strategic plan update shall include measurable outcome goals.

"(D) PUBLICATION.—The National Coordinator shall republish the strategic plan, including all updates.

"(4) WEBSITE.—The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

"(5) CERTIFICATION.—

"(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include, as appropriate, testing of the technology in accordance with section 13201(b) of the Health Information Technology for Economic and Clinical Health Act.

"(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term 'certification criteria' means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

"(6) REPORTS AND PUBLICATIONS.—

"(A) REPORT ON ADDITIONAL FUNDING OR AUTHORITY NEEDED.—Not later than 12 months after the date of the enactment of this title, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

"(B) IMPLEMENTATION REPORT.—The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

"(C) ASSESSMENT OF IMPACT OF HIT ON COMMUNITIES WITH HEALTH DISPARITIES AND UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED AREAS.—The National Coordinator shall assess and publish the impact of health

information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

"(D) EVALUATION OF BENEFITS AND COSTS OF THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION.—The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

"(E) RESOURCE REQUIREMENTS.—The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including—

"(i) the required level of Federal funding;

"(ii) expectations for regional, State, and private investment;

"(iii) the expected contributions by volunteers to activities for the utilization of such records; and

"(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

"(7) ASSISTANCE.—The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

"(8) GOVERNANCE FOR NATIONWIDE HEALTH INFORMATION NETWORK.—The National Coordinator shall establish a governance mechanism for the nationwide health information network. Establishment.

"(d) DETAIL OF FEDERAL EMPLOYEES.—

"(1) IN GENERAL.—Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

"(2) EFFECT OF DETAIL.—Any detail of personnel under paragraph (1) shall—

"(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

"(B) be in addition to any other staff of the Department employed by the National Coordinator.

"(3) ACCEPTANCE OF DETAILEES.—Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

"(e) CHIEF PRIVACY OFFICER OF THE OFFICE OF THE NATIONAL COORDINATOR.—Not later than 12 months after the date of the enactment of this title, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it Deadline.

shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

42 USC 300jj–12.

"SEC. 3002. HIT POLICY COMMITTEE.

"(a) ESTABLISHMENT.—There is established a HIT Policy Committee to make policy recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure, including implementation of the strategic plan described in section 3001(c)(3).

"(b) DUTIES.—

"(1) RECOMMENDATIONS ON HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The HIT Policy Committee shall recommend a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the strategic plan under section 3001(c)(3) and that includes the recommendations under paragraph (2). The Committee shall update such recommendations and make new recommendations as appropriate.

Recommendations.

"(2) SPECIFIC AREAS OF STANDARD DEVELOPMENT.—

"(A) IN GENERAL.—The HIT Policy Committee shall recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004 and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended. Such standards and implementation specifications shall include named standards, architectures, and software schemes for the authentication and security of individually identifiable health information and other information as needed to ensure the reproducible development of common solutions across disparate entities.

"(B) AREAS REQUIRED FOR CONSIDERATION.—For purposes of subparagraph (A), the HIT Policy Committee shall make recommendations for at least the following areas:

"(i) Technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law, and for the use and disclosure of limited data sets of such information.

"(ii) A nationwide health information technology infrastructure that allows for the electronic use and accurate exchange of health information.

"(iii) The utilization of a certified electronic health record for each person in the United States by 2014.

"(iv) Technologies that as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of such regulations).

"(v) The use of certified electronic health records to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, by reducing medical errors, by improving population health, by reducing health disparities, by reducing chronic disease, and by advancing research and education.

"(vi) Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in the nationwide health information network or physically transported outside of the secured, physical perimeter of a health care provider, health plan, or health care clearinghouse.

"(vii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender information.

"(viii) Technologies that address the needs of children and other vulnerable populations.

"(C) OTHER AREAS FOR CONSIDERATION.—In making recommendations under subparagraph (A), the HIT Policy Committee may consider the following additional areas:

"(i) The appropriate uses of a nationwide health information infrastructure, including for purposes of—

"(I) the collection of quality data and public reporting;

"(II) biosurveillance and public health;

"(III) medical and clinical research; and

"(IV) drug safety.

"(ii) Self-service technologies that facilitate the use and exchange of patient information and reduce wait times.

"(iii) Telemedicine technologies, in order to reduce travel requirements for patients in remote areas.

"(iv) Technologies that facilitate home health care and the monitoring of patients recuperating at home.

"(v) Technologies that help reduce medical errors.

"(vi) Technologies that facilitate the continuity of care among health settings.

"(vii) Technologies that meet the needs of diverse populations.

"(viii) Methods to facilitate secure access by an individual to such individual's protected health information.

"(ix) Methods, guidelines, and safeguards to facilitate secure access to patient information by a family

member, caregiver, or guardian acting on behalf of a patient due to age-related and other disability, cognitive impairment, or dementia.

"(x) Any other technology that the HIT Policy Committee finds to be among the technologies with the greatest potential to improve the quality and efficiency of health care.

"(3) FORUM.—The HIT Policy Committee shall serve as a forum for broad stakeholder input with specific expertise in policies relating to the matters described in paragraphs (1) and (2).

"(4) CONSISTENCY WITH EVALUATION CONDUCTED UNDER MIPPA.—

"(A) REQUIREMENT FOR CONSISTENCY.—The HIT Policy Committee shall ensure that recommendations made under paragraph (2)(B)(vi) are consistent with the evaluation conducted under section 1809(a) of the Social Security Act.

"(B) SCOPE.—Nothing in subparagraph (A) shall be construed to limit the recommendations under paragraph (2)(B)(vi) to the elements described in section 1809(a)(3) of the Social Security Act.

Applicability.

"(C) TIMING.—The requirement under subparagraph (A) shall be applicable to the extent that evaluations have been conducted under section 1809(a) of the Social Security Act, regardless of whether the report described in subsection (b) of such section has been submitted.

"(c) MEMBERSHIP AND OPERATIONS.—

"(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Policy Committee.

"(2) MEMBERSHIP.—The HIT Policy Committee shall be composed of members to be appointed as follows:

"(A) 3 members shall be appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official.

"(B) 1 member shall be appointed by the majority leader of the Senate.

"(C) 1 member shall be appointed by the minority leader of the Senate.

"(D) 1 member shall be appointed by the Speaker of the House of Representatives.

"(E) 1 member shall be appointed by the minority leader of the House of Representatives.

President.

"(F) Such other members as shall be appointed by the President as representatives of other relevant Federal agencies.

"(G) 13 members shall be appointed by the Comptroller General of the United States of whom—

"(i) 3 members shall advocates for patients or consumers;

"(ii) 2 members shall represent health care providers, one of which shall be a physician;

"(iii) 1 member shall be from a labor organization representing health care workers;

"(iv) 1 member shall have expertise in health information privacy and security;

"(v) 1 member shall have expertise in improving the health of vulnerable populations;

"(vi) 1 member shall be from the research community;

"(vii) 1 member shall represent health plans or other third-party payers;

"(viii) 1 member shall represent information technology vendors;

"(ix) 1 member shall represent purchasers or employers; and

"(x) 1 member shall have expertise in health care quality measurement and reporting.

"(3) PARTICIPATION.—The members of the HIT Policy Committee appointed under paragraph (2) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Policy Committee.

"(4) TERMS.—

"(A) IN GENERAL.—The terms of the members of the HIT Policy Committee shall be for 3 years, except that the Comptroller General shall designate staggered terms for the members first appointed.

"(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Policy Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Policy Committee shall be filled in the manner in which the original appointment was made.

"(5) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies for the electronic exchange and use of health information, including in the areas of health information privacy and security.

"(6) QUORUM.—A majority of the member of the HIT Policy Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

"(7) FAILURE OF INITIAL APPOINTMENT.—If, on the date that is 45 days after the date of enactment of this title, an official authorized under paragraph (2) to appoint one or more members of the HIT Policy Committee has not appointed the full number of members that such paragraph authorizes such official to appoint, the Secretary is authorized to appoint such members. Deadline.

"(8) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

"(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Policy Committee.

"(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Federal Register, publication. Web posting.

Technology of all policy recommendations made by the HIT Policy Committee under this section.

42 USC 300jj–13.

"SEC. 3003. HIT STANDARDS COMMITTEE.

"(a) ESTABLISHMENT.—There is established a committee to be known as the HIT Standards Committee to recommend to the National Coordinator standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption under section 3004, consistent with the implementation of the strategic plan described in section 3001(c)(3) and beginning with the areas listed in section 3002(b)(2)(B) in accordance with policies developed by the HIT Policy Committee.

"(b) DUTIES.—

"(1) STANDARDS DEVELOPMENT.—

Recommendations.

"(A) IN GENERAL.—The HIT Standards Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a) that have been developed, harmonized, or recognized by the HIT Standards Committee. The HIT Standards Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the HIT Policy Committee.

"(B) HARMONIZATION.—The HIT Standards Committee recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specifications.

"(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Standards Committee shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

"(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under this subsection shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

"(2) FORUM.—The HIT Standards Committee shall serve as a forum for the participation of a broad range of stakeholders to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

Deadline.

"(3) SCHEDULE.—Not later than 90 days after the date of the enactment of this title, the HIT Standards Committee shall develop a schedule for the assessment of policy recommendations developed by the HIT Policy Committee under

section 3002. The HIT Standards Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

Deadline.
Federal Register, publication.

"(4) PUBLIC INPUT.—The HIT Standards Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (3) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

"(5) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of standards.

"(c) MEMBERSHIP AND OPERATIONS.—

"(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Standards Committee.

"(2) MEMBERSHIP.—The membership of the HIT Standards Committee shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

"(3) PARTICIPATION.—The members of the HIT Standards Committee appointed under this subsection shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

"(4) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

"(5) BALANCE AMONG SECTORS.—In developing the procedures for conducting the activities of the HIT Standards Committee, the HIT Standards Committee shall act to ensure a balance among various sectors of the health care system so that no single sector unduly influences the actions of the HIT Standards Committee.

"(6) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Standards Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not for profit entities that work in the public interest as a part of their mission.

"(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14, shall apply to the HIT Standards Committee.

"(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made by the HIT Standards Committee under this section.

Federal Register, publication.
Web posting.

42 USC 300jj–14.

"SEC. 3004. PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS; ADOPTION OF INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.

"(a) PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS.—

Deadline.

"(1) REVIEW OF ENDORSED STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Not later than 90 days after the date of receipt of standards, implementation specifications, or certification criteria endorsed under section 3001(c), the Secretary, in consultation with representatives of other relevant Federal agencies, shall jointly review such standards, implementation specifications, or certification criteria and shall determine whether or not to propose adoption of such standards, implementation specifications, or certification criteria.

"(2) DETERMINATION TO ADOPT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—If the Secretary determines—

"(A) to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such grouping of standards, implementation specifications, or certification criteria; or

Notification.

"(B) not to propose adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary shall notify the National Coordinator and the HIT Standards Committee in writing of such determination and the reasons for not proposing the adoption of such recommendation.

Federal Register, publication.

"(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

"(b) ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

Deadline.

"(1) IN GENERAL.—Not later than December 31, 2009, the Secretary shall, through the rulemaking process consistent with subsection (a)(2)(A), adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 3002(b)(2)(B). The rulemaking for the initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis.

"(2) APPLICATION OF CURRENT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—The standards, implementation specifications, and certification criteria adopted before the date of the enactment of this title through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1).

"(3) SUBSEQUENT STANDARDS ACTIVITY.—The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published under section 3003(b)(2).

"SEC. 3005. APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY FEDERAL AGENCIES. 42 USC 300jj–15.

"For requirements relating to the application and use by Federal agencies of the standards and implementation specifications adopted under section 3004, see section 13111 of the Health Information Technology for Economic and Clinical Health Act.

"SEC. 3006. VOLUNTARY APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY PRIVATE ENTITIES. 42 USC 300jj–16.

"(a) IN GENERAL.—Except as provided under section 13112 of the HITECH Act, nothing in such Act or in the amendments made by such Act shall be construed—

"(1) to require a private entity to adopt or comply with a standard or implementation specification adopted under section 3004; or

"(2) to provide a Federal agency authority, other than the authority such agency may have under other provisions of law, to require a private entity to comply with such a standard or implementation specification.

"(b) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards and implementation specifications adopted under section 3004 with respect to activities not related to the contract.

"SEC. 3007. FEDERAL HEALTH INFORMATION TECHNOLOGY. 42 USC 300jj–17.

"(a) IN GENERAL.—The National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 3000) consistent with subsections (b) and (c) and make available such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.

"(b) CERTIFICATION.—In making such electronic health record technology publicly available, the National Coordinator shall ensure that the qualified electronic health record technology described in subsection (a) is certified under the program developed under section 3001(c)(3) to be in compliance with applicable standards adopted under section 3003(a).

"(c) AUTHORIZATION TO CHARGE A NOMINAL FEE.—The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subsection (a) and (b). Such fee shall take into account the financial circumstances of smaller providers, low income providers, and providers located in rural or other medically underserved areas.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require that a private or government entity adopt or use the technology provided under this section.

"SEC. 3008. TRANSITIONS. 42 USC 300jj–18.

"(a) ONCHIT.—To the extent consistent with section 3001, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order No. 13335 or the Office of such National Coordinator on the date before the

date of the enactment of this title shall be transferred to the National Coordinator appointed under section 3001(a) and the Office of such National Coordinator as of the date of the enactment of this title.

"(b) NATIONAL EHEALTH COLLABORATIVE.—Nothing in sections 3002 or 3003 or this subsection shall be construed as prohibiting the AHIC Successor, Inc. doing business as the National eHealth Collaborative from modifying its charter, duties, membership, and any other structure or function required to be consistent with section 3002 and 3003 so as to allow the Secretary to recognize such AHIC Successor, Inc. as the HIT Policy Committee or the HIT Standards Committee.

"(c) CONSISTENCY OF RECOMMENDATIONS.—In carrying out section 3003(b)(1)(A), until recommendations are made by the HIT Policy Committee, recommendations of the HIT Standards Committee shall be consistent with the most recent recommendations made by such AHIC Successor, Inc.

42 USC 300jj–19.

"SEC. 3009. MISCELLANEOUS PROVISIONS.

"(a) RELATION TO HIPAA PRIVACY AND SECURITY LAW.—

"(1) IN GENERAL.—With respect to the relation of this title to HIPAA privacy and security law:

"(A) This title may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.

"(B) The purposes of this title include ensuring that the health information technology standards and implementation specifications adopted under section 3004 take into account the requirements of HIPAA privacy and security law.

"(2) DEFINITION.—For purposes of this section, the term 'HIPAA privacy and security law' means—

"(A) the provisions of part C of title XI of the Social Security Act, section 264 of the Health Insurance Portability and Accountability Act of 1996, and subtitle D of title IV of the Health Information Technology for Economic and Clinical Health Act; and

"(B) regulations under such provisions.

"(b) FLEXIBILITY.—In administering the provisions of this title, the Secretary shall have flexibility in applying the definition of health care provider under section 3000(3), including the authority to omit certain entities listed in such definition when applying such definition under this title, where appropriate.".

SEC. 13102. TECHNICAL AMENDMENT.

Section 1171(5) of the Social Security Act (42 U.S.C. 1320d) is amended by striking "or C" and inserting "C, or D".

PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

42 USC 17901.

SEC. 13111. COORDINATION OF FEDERAL ACTIVITIES WITH ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS.

(a) SPENDING ON HEALTH INFORMATION TECHNOLOGY SYSTEMS.—As each agency (as defined by the Director of the Office of Management and Budget, in consultation with the Secretary

of Health and Human Services) implements, acquires, or upgrades health information technology systems used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as added by section 13101.

(b) FEDERAL INFORMATION COLLECTION ACTIVITIES.—With respect to a standard or implementation specification adopted under section 3004 of the Public Health Service Act, as added by section 13101, the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such standard or implementation specification, respectively, within three years after the date of such adoption.

(c) APPLICATION OF DEFINITIONS.—The definitions contained in section 3000 of the Public Health Service Act, as added by section 13101, shall apply for purposes of this part.

SEC. 13112. APPLICATION TO PRIVATE ENTITIES. 42 USC 17902.

Each agency (as defined in such Executive Order issued on August 22, 2006, relating to promoting quality and efficient health care in Federal government administered or sponsored health care programs) shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as added by section 13101.

SEC. 13113. STUDY AND REPORTS. 42 USC 17903.

(a) REPORT ON ADOPTION OF NATIONWIDE SYSTEM.—Not later than 2 years after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report that—

(1) describes the specific actions that have been taken by the Federal Government and private entities to facilitate the adoption of a nationwide system for the electronic use and exchange of health information;

(2) describes barriers to the adoption of such a nationwide system; and

(3) contains recommendations to achieve full implementation of such a nationwide system.

(b) REIMBURSEMENT INCENTIVE STUDY AND REPORT.—

(1) STUDY.—The Secretary of Health and Human Services shall carry out, or contract with a private entity to carry out, a study that examines methods to create efficient reimbursement incentives for improving health care quality in Federally qualified health centers, rural health clinics, and free clinics.

(2) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on the study carried out under paragraph (1).

(c) AGING SERVICES TECHNOLOGY STUDY AND REPORT.—

Contracts.

(1) IN GENERAL.—The Secretary of Health and Human Services shall carry out, or contract with a private entity to carry out, a study of matters relating to the potential use of new aging services technology to assist seniors, individuals with disabilities, and their caregivers throughout the aging process.

(2) MATTERS TO BE STUDIED.—The study under paragraph (1) shall include—

(A) an evaluation of—

(i) methods for identifying current, emerging, and future health technology that can be used to meet the needs of seniors and individuals with disabilities and their caregivers across all aging services settings, as specified by the Secretary;

(ii) methods for fostering scientific innovation with respect to aging services technology within the business and academic communities; and

(iii) developments in aging services technology in other countries that may be applied in the United States; and

(B) identification of—

(i) barriers to innovation in aging services technology and devising strategies for removing such barriers; and

(ii) barriers to the adoption of aging services technology by health care providers and consumers and devising strategies to removing such barriers.

(3) REPORT.—Not later than 24 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of jurisdiction of the House of Representatives and of the Senate a report on the study carried out under paragraph (1).

(4) DEFINITIONS.—For purposes of this subsection:

(A) AGING SERVICES TECHNOLOGY.—The term "aging services technology" means health technology that meets the health care needs of seniors, individuals with disabilities, and the caregivers of such seniors and individuals.

(B) SENIOR.—The term "senior" has such meaning as specified by the Secretary.

Subtitle B—Testing of Health Information Technology

42 USC 17911.

SEC. 13201. NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY TESTING.

(a) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In coordination with the HIT Standards Committee established under section 3003 of the Public Health Service Act, as added by section 13101, with respect to the development of standards and implementation specifications under such section, the Director of the National Institute for Standards and Technology shall test such standards and implementation specifications, as appropriate, in order to assure the efficient implementation and use of such standards and implementation specifications.

(b) VOLUNTARY TESTING PROGRAM.—In coordination with the HIT Standards Committee established under section 3003 of the

Public Health Service Act, as added by section 13101, with respect to the development of standards and implementation specifications under such section, the Director of the National Institute of Standards and Technology shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.

SEC. 13202. RESEARCH AND DEVELOPMENT PROGRAMS. 42 USC 17912.

(a) HEALTH CARE INFORMATION ENTERPRISE INTEGRATION RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of the National Institute of Standards and Technology, in consultation with the Director of the National Science Foundation and other appropriate Federal agencies, shall establish a program of assistance to institutions of higher education (or consortia thereof which may include nonprofit entities and Federal Government laboratories) to establish multidisciplinary Centers for Health Care Information Enterprise Integration. Establishment.

(2) REVIEW; COMPETITION.—Grants shall be awarded under this subsection on a merit-reviewed, competitive basis. Grants.

(3) PURPOSE.—The purposes of the Centers described in paragraph (1) shall be—

(A) to generate innovative approaches to health care information enterprise integration by conducting cutting-edge, multidisciplinary research on the systems challenges to health care delivery; and

(B) the development and use of health information technologies and other complementary fields.

(4) RESEARCH AREAS.—Research areas may include—

(A) interfaces between human information and communications technology systems;

(B) voice-recognition systems;

(C) software that improves interoperability and connectivity among health information systems;

(D) software dependability in systems critical to health care delivery;

(E) measurement of the impact of information technologies on the quality and productivity of health care;

(F) health information enterprise management;

(G) health information technology security and integrity; and

(H) relevant health information technology to reduce medical errors.

(5) APPLICATIONS.—An institution of higher education (or a consortium thereof) seeking funding under this subsection shall submit an application to the Director of the National Institute of Standards and Technology at such time, in such manner, and containing such information as the Director may require. The application shall include, at a minimum, a description of—

(A) the research projects that will be undertaken by the Center established pursuant to assistance under paragraph (1) and the respective contributions of the participating entities;

(B) how the Center will promote active collaboration among scientists and engineers from different disciplines, such as information technology, biologic sciences, management, social sciences, and other appropriate disciplines;

(C) technology transfer activities to demonstrate and diffuse the research results, technologies, and knowledge; and

(D) how the Center will contribute to the education and training of researchers and other professionals in fields relevant to health information enterprise integration.

(b) NATIONAL INFORMATION TECHNOLOGY RESEARCH AND DEVELOPMENT PROGRAM.—The National High-Performance Computing Program established by section 101 of the High-Performance Computing Act of 1991 (15 U.S.C. 5511) shall include Federal research and development programs related to health information technology.

Subtitle C—Grants and Loans Funding

SEC. 13301. GRANT, LOAN, AND DEMONSTRATION PROGRAMS.

Title XXX of the Public Health Service Act, as added by section 13101, is amended by adding at the end the following new subtitle:

"Subtitle B—Incentives for the Use of Health Information Technology

42 USC 300jj–31.

"SEC. 3011. IMMEDIATE FUNDING TO STRENGTHEN THE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.

"(a) IN GENERAL.—The Secretary shall, using amounts appropriated under section 3018, invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator (and as available) under section 3001. The Secretary shall invest funds through the different agencies with expertise in such goals, such as the Office of the National Coordinator for Health Information Technology, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers of Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Indian Health Service to support the following:

"(1) Health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner, including connecting health information exchanges, and which may include updating and implementing the infrastructure necessary within different agencies of the Department of Health and Human Services to support the electronic use and exchange of health information.

"(2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act for the adoption of such records.

"(3) Training on and dissemination of information on best practices to integrate health information technology, including

electronic health records, into a provider's delivery of care, consistent with best practices learned from the Health Information Technology Research Center developed under section 3012(b), including community health centers receiving assistance under section 330, covered entities under section 340B, and providers participating in one or more of the programs under titles XVIII, XIX, and XXI of the Social Security Act (relating to Medicare, Medicaid, and the State Children's Health Insurance Program).

"(4) Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine.

"(5) Promotion of the interoperability of clinical data repositories or registries.

"(6) Promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information.

"(7) Improvement and expansion of the use of health information technology by public health departments.

"(b) COORDINATION.—The Secretary shall ensure funds under this section are used in a coordinated manner with other health information promotion activities.

"(c) ADDITIONAL USE OF FUNDS.—In addition to using funds as provided in subsection (a), the Secretary may use amounts appropriated under section 3018 to carry out health information technology activities that are provided for under laws in effect on the date of the enactment of this title.

"(d) STANDARDS FOR ACQUISITION OF HEALTH INFORMATION TECHNOLOGY.—To the greatest extent practicable, the Secretary shall ensure that where funds are expended under this section for the acquisition of health information technology, such funds shall be used to acquire health information technology that meets applicable standards adopted under section 3004. Where it is not practicable to expend funds on health information technology that meets such applicable standards, the Secretary shall ensure that such health information technology meets applicable standards otherwise adopted by the Secretary.

"SEC. 3012. HEALTH INFORMATION TECHNOLOGY IMPLEMENTATION ASSISTANCE. 42 USC 300jj–32.

"(a) HEALTH INFORMATION TECHNOLOGY EXTENSION PROGRAM.—To assist health care providers to adopt, implement, and effectively use certified EHR technology that allows for the electronic exchange and use of health information, the Secretary, acting through the Office of the National Coordinator, shall establish a health information technology extension program to provide health information technology assistance services to be carried out through the Department of Health and Human Services. The National Coordinator shall consult with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology, in developing and implementing this program. Consultation.

"(b) HEALTH INFORMATION TECHNOLOGY RESEARCH CENTER.—

"(1) IN GENERAL.—The Secretary shall create a Health Information Technology Research Center (in this section referred to as the 'Center') to provide technical assistance and develop or recognize best practices to support and accelerate Establishment.

efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004.

"(2) INPUT.—The Center shall incorporate input from—

"(A) other Federal agencies with demonstrated experience and expertise in information technology services such as the National Institute of Standards and Technology;

"(B) users of health information technology, such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and

"(C) others as appropriate.

"(3) PURPOSES.—The purposes of the Center are to—

"(A) provide a forum for the exchange of knowledge and experience;

"(B) accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving Federal financial support;

"(C) assemble, analyze, and widely disseminate evidence and experience related to the adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information including through the regional centers described in subsection (c);

"(D) provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

"(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and

"(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

"(c) HEALTH INFORMATION TECHNOLOGY REGIONAL EXTENSION CENTERS.—

"(1) IN GENERAL.—The Secretary shall provide assistance for the creation and support of regional centers (in this subsection referred to as 'regional centers') to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004. Activities conducted under this subsection shall be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001.

"(2) AFFILIATION.—Regional centers shall be affiliated with any United States-based nonprofit institution or organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.

"(3) OBJECTIVE.—The objective of the regional centers is to enhance and promote the adoption of health information technology through—

"(A) assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide;

"(B) broad participation of individuals from industry, universities, and State governments;

"(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;

"(D) participation, to the extent practicable, in health information exchanges;

"(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and

"(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.

"(4) REGIONAL ASSISTANCE.—Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following:

"(A) Public or not-for-profit hospitals or critical access hospitals.

"(B) Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).

"(C) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

"(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.

"(5) FINANCIAL SUPPORT.—The Secretary may provide financial support to any regional center created under this subsection for a period not to exceed four years. The Secretary may not provide more than 50 percent of the capital and annual operating and maintenance funds required to create and maintain such a center, except in an instance of national economic conditions which would render this cost-share requirement detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

"(6) NOTICE OF PROGRAM DESCRIPTION AND AVAILABILITY OF FUNDS.—The Secretary shall publish in the Federal Register, not later than 90 days after the date of the enactment of this title, a draft description of the program for establishing regional centers under this subsection. Such description shall include the following:

Federal Register, publication. Deadline.

"(A) A detailed explanation of the program and the programs goals.

Procedures.
Criteria.

"(B) Procedures to be followed by the applicants.

"(C) Criteria for determining qualified applicants.

"(D) Maximum support levels expected to be available to centers under the program.

"(7) APPLICATION REVIEW.—The Secretary shall subject each application under this subsection to merit review. In making a decision whether to approve such application and provide financial support, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—

"(A) the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers;

"(B) the types of service to be provided to health care providers;

"(C) geographical diversity and extent of service area; and

"(D) the percentage of funding and amount of in-kind commitment from other sources.

"(8) BIENNIAL EVALUATION.—Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive.

"(9) CONTINUING SUPPORT.—After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services.

42 USC 300jj–33.

"SEC. 3013. STATE GRANTS TO PROMOTE HEALTH INFORMATION TECHNOLOGY.

"(a) IN GENERAL.—The Secretary, acting through the National Coordinator, shall establish a program in accordance with this section to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.

"(b) PLANNING GRANTS.—The Secretary may award a grant to a State or qualified State-designated entity (as described in subsection (f)) that submits an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify, for the purpose of planning activities described in subsection (d).

"(c) IMPLEMENTATION GRANTS.—The Secretary may award a grant to a State or qualified State designated entity that—

"(1) has submitted, and the Secretary has approved, a plan described in subsection (e) (regardless of whether such plan was prepared using amounts awarded under subsection (b); and

"(2) submits an application at such time, in such manner, and containing such information as the Secretary may specify.

"(d) USE OF FUNDS.—Amounts received under a grant under subsection (c) shall be used to conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards through activities that include—

"(1) enhancing broad and varied participation in the authorized and secure nationwide electronic use and exchange of health information;

"(2) identifying State or local resources available towards a nationwide effort to promote health information technology;

"(3) complementing other Federal grants, programs, and efforts towards the promotion of health information technology;

"(4) providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;

"(5) promoting effective strategies to adopt and utilize health information technology in medically underserved communities;

"(6) assisting patients in utilizing health information technology;

"(7) encouraging clinicians to work with Health Information Technology Regional Extension Centers as described in section 3012, to the extent they are available and valuable;

"(8) supporting public health agencies' authorized use of and access to electronic health information;

"(9) promoting the use of electronic health records for quality improvement including through quality measures reporting; and

"(10) such other activities as the Secretary may specify.

"(e) PLAN.—

"(1) IN GENERAL.—A plan described in this subsection is a plan that describes the activities to be carried out by a State or by the qualified State-designated entity within such State to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards and implementation specifications.

"(2) REQUIRED ELEMENTS.—A plan described in paragraph (1) shall—

"(A) be pursued in the public interest;

"(B) be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001;

"(C) include a description of the ways the State or qualified State-designated entity will carry out the activities described in subsection (b); and

"(D) contain such elements as the Secretary may require.

"(f) QUALIFIED STATE-DESIGNATED ENTITY.—For purposes of this section, to be a qualified State-designated entity, with respect to a State, an entity shall—

"(1) be designated by the State as eligible to receive awards under this section;

"(2) be a not-for-profit entity with broad stakeholder representation on its governing board;

"(3) demonstrate that one of its principal goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information;

"(4) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and

"(5) conform to such other requirements as the Secretary may establish.

"(g) REQUIRED CONSULTATION.—In carrying out activities described in subsections (b) and (c), a State or qualified State-designated entity shall consult with and consider the recommendations of—

"(1) health care providers (including providers that provide services to low income and underserved populations);

"(2) health plans;

"(3) patient or consumer organizations that represent the population to be served;

"(4) health information technology vendors;

"(5) health care purchasers and employers;

"(6) public health agencies;

"(7) health professions schools, universities and colleges;

"(8) clinical researchers;

"(9) other users of health information technology such as the support and clerical staff of providers and others involved in the care and care coordination of patients; and

"(10) such other entities, as may be determined appropriate by the Secretary.

Deadline.
Evaluation.

"(h) CONTINUOUS IMPROVEMENT.—The Secretary shall annually evaluate the activities conducted under this section and shall, in awarding grants under this section, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the Secretary, will lead towards the greatest improvement in quality of care, decrease in costs, and the most effective authorized and secure electronic exchange of health information.

"(i) REQUIRED MATCH.—

"(1) IN GENERAL.—For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under this section to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant awarded under subsection (c) in an amount equal to—

"(A) for fiscal year 2011, not less than $1 for each $10 of Federal funds provided under the grant;

"(B) for fiscal year 2012, not less than $1 for each $7 of Federal funds provided under the grant; and

"(C) for fiscal year 2013 and each subsequent fiscal year, not less than $1 for each $3 of Federal funds provided under the grant.

"(2) AUTHORITY TO REQUIRE STATE MATCH FOR FISCAL YEARS BEFORE FISCAL YEAR 2011.—For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

"SEC. 3014. COMPETITIVE GRANTS TO STATES AND INDIAN TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO FACILITATE THE WIDESPREAD ADOPTION OF CERTIFIED EHR TECHNOLOGY.

42 USC 300jj–34.

"(a) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to conduct the activities described in subsection (e).

"(b) ELIGIBLE ENTITY DEFINED.—For purposes of this subsection, the term 'eligible entity' means a State or Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act) that—

"(1) submits to the National Coordinator an application at such time, in such manner, and containing such information as the National Coordinator may require;

"(2) submits to the National Coordinator a strategic plan in accordance with subsection (d) and provides to the National Coordinator assurances that the entity will update such plan annually in accordance with such subsection;

"(3) provides assurances to the National Coordinator that the entity will establish a Loan Fund in accordance with subsection (c);

"(4) provides assurances to the National Coordinator that the entity will not provide a loan from the Loan Fund to a health care provider unless the provider agrees to—

"(A) submit reports on quality measures adopted by the Federal Government (by not later than 90 days after the date on which such measures are adopted), to—

Reports. Deadline.

"(i) the Administrator of the Centers for Medicare & Medicaid Services (or his or her designee), in the case of an entity participating in the Medicare program under title XVIII of the Social Security Act or the Medicaid program under title XIX of such Act; or

"(ii) the Secretary in the case of other entities;

"(B) demonstrate to the satisfaction of the Secretary (through criteria established by the Secretary) that any certified EHR technology purchased, improved, or otherwise financially supported under a loan under this section is used to exchange health information in a manner that, in accordance with law and standards (as adopted under section 3004) applicable to the exchange of information, improves the quality of health care, such as promoting care coordination; and

"(C) comply with such other requirements as the entity or the Secretary may require;

"(D) include a plan on how health care providers involved intend to maintain and support the certified EHR technology over time;

"(E) include a plan on how the health care providers involved intend to maintain and support the certified EHR technology that would be purchased with such loan, including the type of resources expected to be involved and any such other information as the State or Indian Tribe, respectively, may require; and

"(5) agrees to provide matching funds in accordance with subsection (h).

"(c) ESTABLISHMENT OF FUND.—For purposes of subsection (b)(3), an eligible entity shall establish a certified EHR technology loan fund (referred to in this subsection as a 'Loan Fund') and comply with the other requirements contained in this section. A grant to an eligible entity under this section shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this title to be used for other purposes specified in this title shall be deposited in any Loan Fund.

"(d) STRATEGIC PLAN.—

"(1) IN GENERAL.—For purposes of subsection (b)(2), a strategic plan of an eligible entity under this subsection shall identify the intended uses of amounts available to the Loan Fund of such entity.

"(2) CONTENTS.—A strategic plan under paragraph (1), with respect to a Loan Fund of an eligible entity, shall include for a year the following:

"(A) A list of the projects to be assisted through the Loan Fund during such year.

"(B) A description of the criteria and methods established for the distribution of funds from the Loan Fund during the year.

"(C) A description of the financial status of the Loan Fund as of the date of submission of the plan.

"(D) The short-term and long-term goals of the Loan Fund.

"(e) USE OF FUNDS.—Amounts deposited in a Loan Fund, including loan repayments and interest earned on such amounts, shall be used only for awarding loans or loan guarantees, making reimbursements described in subsection (g)(4)(A), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under subsection (c). Loans under this section may be used by a health care provider to—

"(1) facilitate the purchase of certified EHR technology;

"(2) enhance the utilization of certified EHR technology (which may include costs associated with upgrading health information technology so that it meets criteria necessary to be a certified EHR technology);

"(3) train personnel in the use of such technology; or

"(4) improve the secure electronic exchange of health information.

"(f) TYPES OF ASSISTANCE.—Except as otherwise limited by applicable State law, amounts deposited into a Loan Fund under this section may only be used for the following:

"(1) To award loans that comply with the following:

"(A) The interest rate for each loan shall not exceed the market interest rate.

"(B) The principal and interest payments on each loan shall commence not later than 1 year after the date the loan was awarded, and each loan shall be fully amortized not later than 10 years after the date of the loan.

"(C) The Loan Fund shall be credited with all payments of principal and interest on each loan awarded from the Loan Fund.

"(2) To guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible

for assistance under this subsection) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation involved.

"(3) As a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the eligible entity if the proceeds of the sale of the bonds will be deposited into the Loan Fund.

"(4) To earn interest on the amounts deposited into the Loan Fund.

"(5) To make reimbursements described in subsection (g)(4)(A).

"(g) ADMINISTRATION OF LOAN FUNDS.—

"(1) COMBINED FINANCIAL ADMINISTRATION.—An eligible entity may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with applicable State law, the financial administration of a Loan Fund established under this subsection with the financial administration of any other revolving fund established by the entity if otherwise not prohibited by the law under which the Loan Fund was established.

"(2) COST OF ADMINISTERING FUND.—Each eligible entity may annually use not to exceed 4 percent of the funds provided to the entity under a grant under this section to pay the reasonable costs of the administration of the programs under this section, including the recovery of reasonable costs expended to establish a Loan Fund which are incurred after the date of the enactment of this title.

"(3) GUIDANCE AND REGULATIONS.—The National Coordinator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this section, including— Publication.

"(A) provisions to ensure that each eligible entity commits and expends funds allotted to the entity under this section as efficiently as possible in accordance with this title and applicable State laws; and

"(B) guidance to prevent waste, fraud, and abuse.

"(4) PRIVATE SECTOR CONTRIBUTIONS.—

"(A) IN GENERAL.—A Loan Fund established under this section may accept contributions from private sector entities, except that such entities may not specify the recipient or recipients of any loan issued under this subsection. An eligible entity may agree to reimburse a private sector entity for any contribution made under this subparagraph, except that the amount of such reimbursement may not be greater than the principal amount of the contribution made.

"(B) AVAILABILITY OF INFORMATION.—An eligible entity shall make publicly available the identity of, and amount contributed by, any private sector entity under subparagraph (A) and may issue letters of commendation or make other awards (that have no financial value) to any such entity.

"(h) MATCHING REQUIREMENTS.—

"(1) IN GENERAL.—The National Coordinator may not make a grant under subsection (a) to an eligible entity unless the entity agrees to make available (directly or through donations from public or private entities) non-Federal contributions in cash to the costs of carrying out the activities for which the

grant is awarded in an amount equal to not less than $1 for each $5 of Federal funds provided under the grant.

"(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions that an eligible entity has provided pursuant to subparagraph (A), the National Coordinator may not include any amounts provided to the entity by the Federal Government.

"(i) EFFECTIVE DATE.—The Secretary may not make an award under this section prior to January 1, 2010.

42 USC 300jj–35.

"SEC. 3015. DEMONSTRATION PROGRAM TO INTEGRATE INFORMATION TECHNOLOGY INTO CLINICAL EDUCATION.

"(a) IN GENERAL.—The Secretary may award grants under this section to carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

"(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

"(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

Strategic plan.

"(2) submit to the Secretary a strategic plan for integrating certified EHR technology in the clinical education of health professionals to reduce medical errors, increase access to prevention, reduce chronic diseases, and enhance health care quality;

"(3) be—

"(A) a school of medicine, osteopathic medicine, dentistry, or pharmacy, a graduate program in behavioral or mental health, or any other graduate health professions school;

"(B) a graduate school of nursing or physician assistant studies;

"(C) a consortium of two or more schools described in subparagraph (A) or (B); or

"(D) an institution with a graduate medical education program in medicine, osteopathic medicine, dentistry, pharmacy, nursing, or physician assistance studies;

"(4) provide for the collection of data regarding the effectiveness of the demonstration project to be funded under the grant in improving the safety of patients, the efficiency of health care delivery, and in increasing the likelihood that graduates of the grantee will adopt and incorporate certified EHR technology, in the delivery of health care services; and

"(5) provide matching funds in accordance with subsection (d).

"(c) USE OF FUNDS.—

"(1) IN GENERAL.—With respect to a grant under subsection (a), an eligible entity shall—

"(A) use grant funds in collaboration with 2 or more disciplines; and

"(B) use grant funds to integrate certified EHR technology into community-based clinical education.

"(2) LIMITATION.—An eligible entity shall not use amounts received under a grant under subsection (a) to purchase hardware, software, or services.

"(d) FINANCIAL SUPPORT.—The Secretary may not provide more than 50 percent of the costs of any activity for which assistance is provided under subsection (a), except in an instance of national economic conditions which would render the cost-share requirement under this subsection detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

"(e) EVALUATION.—The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make available, and disseminate the results of such evaluations on as wide a basis as is practicable. Publication.

"(f) REPORTS.—Not later than 1 year after the date of enactment of this title, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that—

"(1) describes the specific projects established under this section; and

"(2) contains recommendations for Congress based on the evaluation conducted under subsection (e).

"SEC. 3016. INFORMATION TECHNOLOGY PROFESSIONALS IN HEALTH CARE. 42 USC 300jj–36.

"(a) IN GENERAL.—The Secretary, in consultation with the Director of the National Science Foundation, shall provide assistance to institutions of higher education (or consortia thereof) to establish or expand medical health informatics education programs, including certification, undergraduate, and masters degree programs, for both health care and information technology students to ensure the rapid and effective utilization and development of health information technologies (in the United States health care infrastructure).

"(b) ACTIVITIES.—Activities for which assistance may be provided under subsection (a) may include the following:

"(1) Developing and revising curricula in medical health informatics and related disciplines.

"(2) Recruiting and retaining students to the program involved.

"(3) Acquiring equipment necessary for student instruction in these programs, including the installation of testbed networks for student use.

"(4) Establishing or enhancing bridge programs in the health informatics fields between community colleges and universities.

"(c) PRIORITY.—In providing assistance under subsection (a), the Secretary shall give preference to the following:

"(1) Existing education and training programs.

"(2) Programs designed to be completed in less than six months.

"SEC. 3017. GENERAL GRANT AND LOAN PROVISIONS. 42 USC 300jj–37.

"(a) REPORTS.—The Secretary may require that an entity receiving assistance under this subtitle shall submit to the Secretary, not later than the date that is 1 year after the date of receipt of such assistance, a report that includes—

"(1) an analysis of the effectiveness of the activities for which the entity receives such assistance, as compared to the goals for such activities; and

"(2) an analysis of the impact of the project on health care quality and safety.

Evaluation. Deadline.

"(b) REQUIREMENT TO IMPROVE QUALITY OF CARE AND DECREASE IN COSTS.—The National Coordinator shall annually evaluate the activities conducted under this subtitle and shall, in awarding grants, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in the quality and efficiency of health care.

42 USC 300jj–38.

"SEC. 3018. AUTHORIZATION FOR APPROPRIATIONS.

"For the purposes of carrying out this subtitle, there is authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2013.".

Subtitle D—Privacy

42 USC 17921.

SEC. 13400. DEFINITIONS.

In this subtitle, except as specified otherwise:

(1) BREACH.—

(A) IN GENERAL.—The term "breach" means the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.

(B) EXCEPTIONS.—The term "breach" does not include—

(i) any unintentional acquisition, access, or use of protected health information by an employee or individual acting under the authority of a covered entity or business associate if—

(I) such acquisition, access, or use was made in good faith and within the course and scope of the employment or other professional relationship of such employee or individual, respectively, with the covered entity or business associate; and

(II) such information is not further acquired, accessed, used, or disclosed by any person; or

(ii) any inadvertent disclosure from an individual who is otherwise authorized to access protected health information at a facility operated by a covered entity or business associate to another similarly situated individual at same facility; and

(iii) any such information received as a result of such disclosure is not further acquired, accessed, used, or disclosed without authorization by any person.

(2) BUSINESS ASSOCIATE.—The term "business associate" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(3) COVERED ENTITY.—The term "covered entity" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(4) DISCLOSE.—The terms "disclose" and "disclosure" have the meaning given the term "disclosure" in section 160.103 of title 45, Code of Federal Regulations.

(5) ELECTRONIC HEALTH RECORD.—The term "electronic health record" means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.

(6) HEALTH CARE OPERATIONS.—The term "health care operation" has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(7) HEALTH CARE PROVIDER.—The term "health care provider" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(8) HEALTH PLAN.—The term "health plan" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(9) NATIONAL COORDINATOR.—The term "National Coordinator" means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a) of the Public Health Service Act, as added by section 13101.

(10) PAYMENT.—The term "payment" has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(11) PERSONAL HEALTH RECORD.—The term "personal health record" means an electronic record of PHR identifiable health information (as defined in section 13407(f)(2)) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.

(12) PROTECTED HEALTH INFORMATION.—The term "protected health information" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(13) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(14) SECURITY.—The term "security" has the meaning given such term in section 164.304 of title 45, Code of Federal Regulations.

(15) STATE.—The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(16) TREATMENT.—The term "treatment" has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(17) USE.—The term "use" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(18) VENDOR OF PERSONAL HEALTH RECORDS.—The term "vendor of personal health records" means an entity, other than a covered entity (as defined in paragraph (3)), that offers or maintains a personal health record.

PART 1—IMPROVED PRIVACY PROVISIONS AND SECURITY PROVISIONS

42 USC 17931.

SEC. 13401. APPLICATION OF SECURITY PROVISIONS AND PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES; ANNUAL GUIDANCE ON SECURITY PROVISIONS.

(a) APPLICATION OF SECURITY PROVISIONS.—Sections 164.308, 164.310, 164.312, and 164.316 of title 45, Code of Federal Regulations, shall apply to a business associate of a covered entity in the same manner that such sections apply to the covered entity. The additional requirements of this title that relate to security and that are made applicable with respect to covered entities shall also be applicable to such a business associate and shall be incorporated into the business associate agreement between the business associate and the covered entity.

(b) APPLICATION OF CIVIL AND CRIMINAL PENALTIES.—In the case of a business associate that violates any security provision specified in subsection (a), sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to the business associate with respect to such violation in the same manner such sections apply to a covered entity that violates such security provision.

(c) ANNUAL GUIDANCE.—For the first year beginning after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall, after consultation with stakeholders, annually issue guidance on the most effective and appropriate technical safeguards for use in carrying out the sections referred to in subsection (a) and the security standards in subpart C of part 164 of title 45, Code of Federal Regulations, including the use of standards developed under section 3002(b)(2)(B)(vi) of the Public Health Service Act, as added by section 13101 of this Act, as such provisions are in effect as of the date before the enactment of this Act.

42 USC 17932.

SEC. 13402. NOTIFICATION IN THE CASE OF BREACH.

(a) IN GENERAL.—A covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information (as defined in subsection (h)(1)) shall, in the case of a breach of such information that is discovered by the covered entity, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach.

(b) NOTIFICATION OF COVERED ENTITY BY BUSINESS ASSOCIATE.—A business associate of a covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information shall, following the discovery of a breach of such information, notify the covered entity of such breach. Such notice shall include the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the business associate to have been, accessed, acquired, or disclosed during such breach.

(c) BREACHES TREATED AS DISCOVERED.—For purposes of this section, a breach shall be treated as discovered by a covered entity or by a business associate as of the first day on which such breach is known to such entity or associate, respectively, (including any

person, other than the individual committing the breach, that is an employee, officer, or other agent of such entity or associate, respectively) or should reasonably have been known to such entity or associate (or person) to have occurred.

(d) TIMELINESS OF NOTIFICATION.—

(1) IN GENERAL.—Subject to subsection (g), all notifications required under this section shall be made without unreasonable delay and in no case later than 60 calendar days after the discovery of a breach by the covered entity involved (or business associate involved in the case of a notification required under subsection (b)). Deadline.

(2) BURDEN OF PROOF.—The covered entity involved (or business associate involved in the case of a notification required under subsection (b)), shall have the burden of demonstrating that all notifications were made as required under this part, including evidence demonstrating the necessity of any delay.

(e) METHODS OF NOTICE.—

(1) INDIVIDUAL NOTICE.—Notice required under this section to be provided to an individual, with respect to a breach, shall be provided promptly and in the following form:

(A) Written notification by first-class mail to the individual (or the next of kin of the individual if the individual is deceased) at the last known address of the individual or the next of kin, respectively, or, if specified as a preference by the individual, by electronic mail. The notification may be provided in one or more mailings as information is available.

(B) In the case in which there is insufficient, or out-of-date contact information (including a phone number, email address, or any other form of appropriate communication) that precludes direct written (or, if specified by the individual under subparagraph (A), electronic) notification to the individual, a substitute form of notice shall be provided, including, in the case that there are 10 or more individuals for which there is insufficient or out-of-date contact information, a conspicuous posting for a period determined by the Secretary on the home page of the Web site of the covered entity involved or notice in major print or broadcast media, including major media in geographic areas where the individuals affected by the breach likely reside. Such a notice in media or web posting will include a toll-free phone number where an individual can learn whether or not the individual's unsecured protected health information is possibly included in the breach. Web posting.

(C) In any case deemed by the covered entity involved to require urgency because of possible imminent misuse of unsecured protected health information, the covered entity, in addition to notice provided under subparagraph (A), may provide information to individuals by telephone or other means, as appropriate.

(2) MEDIA NOTICE.—Notice shall be provided to prominent media outlets serving a State or jurisdiction, following the discovery of a breach described in subsection (a), if the unsecured protected health information of more than 500 residents of such State or jurisdiction is, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach.

(3) NOTICE TO SECRETARY.—Notice shall be provided to the Secretary by covered entities of unsecured protected health information that has been acquired or disclosed in a breach. If the breach was with respect to 500 or more individuals than such notice must be provided immediately. If the breach was with respect to less than 500 individuals, the covered entity may maintain a log of any such breach occurring and annually submit such a log to the Secretary documenting such breaches occurring during the year involved.

List.

(4) POSTING ON HHS PUBLIC WEBSITE.—The Secretary shall make available to the public on the Internet website of the Department of Health and Human Services a list that identifies each covered entity involved in a breach described in subsection (a) in which the unsecured protected health information of more than 500 individuals is acquired or disclosed.

(f) CONTENT OF NOTIFICATION.—Regardless of the method by which notice is provided to individuals under this section, notice of a breach shall include, to the extent possible, the following:

(1) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known.

(2) A description of the types of unsecured protected health information that were involved in the breach (such as full name, Social Security number, date of birth, home address, account number, or disability code).

(3) The steps individuals should take to protect themselves from potential harm resulting from the breach.

(4) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate losses, and to protect against any further breaches.

(5) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

(g) DELAY OF NOTIFICATION AUTHORIZED FOR LAW ENFORCEMENT PURPOSES.—If a law enforcement official determines that a notification, notice, or posting required under this section would impede a criminal investigation or cause damage to national security, such notification, notice, or posting shall be delayed in the same manner as provided under section 164.528(a)(2) of title 45, Code of Federal Regulations, in the case of a disclosure covered under such section.

(h) UNSECURED PROTECTED HEALTH INFORMATION.—

(1) DEFINITION.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of this section, the term "unsecured protected health information" means protected health information that is not secured through the use of a technology or methodology specified by the Secretary in the guidance issued under paragraph (2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under paragraph (2) by the date specified in such paragraph, for purposes of this section, the term "unsecured protected health information" shall mean protected health information that is not secured by a technology standard that renders protected health information unusable,

unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(2) GUIDANCE.—For purposes of paragraph (1) and section 13407(f)(3), not later than the date that is 60 days after the date of the enactment of this Act, the Secretary shall, after consultation with stakeholders, issue (and annually update) guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals, including the use of standards developed under section 3002(b)(2)(B)(vi) of the Public Health Service Act, as added by section 13101 of this Act. Deadlines.

(i) REPORT TO CONGRESS ON BREACHES.—

(1) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act and annually thereafter, the Secretary shall prepare and submit to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report containing the information described in paragraph (2) regarding breaches for which notice was provided to the Secretary under subsection (e)(3).

(2) INFORMATION.—The information described in this paragraph regarding breaches specified in paragraph (1) shall include—

(A) the number and nature of such breaches; and

(B) actions taken in response to such breaches.

(j) REGULATIONS; EFFECTIVE DATE.—To carry out this section, the Secretary of Health and Human Services shall promulgate interim final regulations by not later than the date that is 180 days after the date of the enactment of this title. The provisions of this section shall apply to breaches that are discovered on or after the date that is 30 days after the date of publication of such interim final regulations. Applicability.

SEC. 13403. EDUCATION ON HEALTH INFORMATION PRIVACY. 42 USC 17933.

(a) REGIONAL OFFICE PRIVACY ADVISORS.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall designate an individual in each regional office of the Department of Health and Human Services to offer guidance and education to covered entities, business associates, and individuals on their rights and responsibilities related to Federal privacy and security requirements for protected health information. Deadline. Designation.

(b) EDUCATION INITIATIVE ON USES OF HEALTH INFORMATION.—Not later than 12 months after the date of the enactment of this Act, the Office for Civil Rights within the Department of Health and Human Services shall develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. Such programs shall be conducted in a variety of languages and present information in a clear and understandable manner. Deadline.

42 USC 17934.

SEC. 13404. APPLICATION OF PRIVACY PROVISIONS AND PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES.

(a) APPLICATION OF CONTRACT REQUIREMENTS.—In the case of a business associate of a covered entity that obtains or creates protected health information pursuant to a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations, with such covered entity, the business associate may use and disclose such protected health information only if such use or disclosure, respectively, is in compliance with each applicable requirement of section 164.504(e) of such title. The additional requirements of this subtitle that relate to privacy and that are made applicable with respect to covered entities shall also be applicable to such a business associate and shall be incorporated into the business associate agreement between the business associate and the covered entity.

(b) APPLICATION OF KNOWLEDGE ELEMENTS ASSOCIATED WITH CONTRACTS.—Section 164.504(e)(1)(ii) of title 45, Code of Federal Regulations, shall apply to a business associate described in subsection (a), with respect to compliance with such subsection, in the same manner that such section applies to a covered entity, with respect to compliance with the standards in sections 164.502(e) and 164.504(e) of such title, except that in applying such section 164.504(e)(1)(ii) each reference to the business associate, with respect to a contract, shall be treated as a reference to the covered entity involved in such contract.

(c) APPLICATION OF CIVIL AND CRIMINAL PENALTIES.—In the case of a business associate that violates any provision of subsection (a) or (b), the provisions of sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to the business associate with respect to such violation in the same manner as such provisions apply to a person who violates a provision of part C of title XI of such Act.

42 USC 17935.

SEC. 13405. RESTRICTIONS ON CERTAIN DISCLOSURES AND SALES OF HEALTH INFORMATION; ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES; ACCESS TO CERTAIN INFORMATION IN ELECTRONIC FORMAT.

(a) REQUESTED RESTRICTIONS ON CERTAIN DISCLOSURES OF HEALTH INFORMATION.—In the case that an individual requests under paragraph (a)(1)(i)(A) of section 164.522 of title 45, Code of Federal Regulations, that a covered entity restrict the disclosure of the protected health information of the individual, notwithstanding paragraph (a)(1)(ii) of such section, the covered entity must comply with the requested restriction if—

(1) except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and

(2) the protected health information pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full.

(b) DISCLOSURES REQUIRED TO BE LIMITED TO THE LIMITED DATA SET OR THE MINIMUM NECESSARY.—

(1) IN GENERAL.—

(A) IN GENERAL.—Subject to subparagraph (B), a covered entity shall be treated as being in compliance with

section 164.502(b)(1) of title 45, Code of Federal Regulations, with respect to the use, disclosure, or request of protected health information described in such section, only if the covered entity limits such protected health information, to the extent practicable, to the limited data set (as defined in section 164.514(e)(2) of such title) or, if needed by such entity, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request, respectively.

(B) GUIDANCE.—Not later than 18 months after the date of the enactment of this section, the Secretary shall issue guidance on what constitutes "minimum necessary" for purposes of subpart E of part 164 of title 45, Code of Federal Regulation. In issuing such guidance the Secretary shall take into consideration the guidance under section 13424(c) and the information necessary to improve patient outcomes and to detect, prevent, and manage chronic disease. Deadline.

(C) SUNSET.—Subparagraph (A) shall not apply on and after the effective date on which the Secretary issues the guidance under subparagraph (B).

(2) DETERMINATION OF MINIMUM NECESSARY.—For purposes of paragraph (1), in the case of the disclosure of protected health information, the covered entity or business associate disclosing such information shall determine what constitutes the minimum necessary to accomplish the intended purpose of such disclosure.

(3) APPLICATION OF EXCEPTIONS.—The exceptions described in section 164.502(b)(2) of title 45, Code of Federal Regulations, shall apply to the requirement under paragraph (1) as of the effective date described in section 13423 in the same manner that such exceptions apply to section 164.502(b)(1) of such title before such date.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the use, disclosure, or request of protected health information that has been de-identified.

(c) ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES REQUIRED IF COVERED ENTITY USES ELECTRONIC HEALTH RECORD.—

"(1) IN GENERAL.—In applying section 164.528 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information—

"(A) the exception under paragraph (a)(1)(i) of such section shall not apply to disclosures through an electronic health record made by such entity of such information; and

"(B) an individual shall have a right to receive an accounting of disclosures described in such paragraph of such information made by such covered entity during only the three years prior to the date on which the accounting is requested.

"(2) REGULATIONS.—The Secretary shall promulgate regulations on what information shall be collected about each disclosure referred to in paragraph (1), not later than 6 months after the date on which the Secretary adopts standards on accounting for disclosure described in the section Deadline.

3002(b)(2)(B)(iv) of the Public Health Service Act, as added by section 13101. Such regulations shall only require such information to be collected through an electronic health record in a manner that takes into account the interests of the individuals in learning the circumstances under which their protected health information is being disclosed and takes into account the administrative burden of accounting for such disclosures.

"(3) PROCESS.—In response to an request from an individual for an accounting, a covered entity shall elect to provide either an—

"(A) accounting, as specified under paragraph (1), for disclosures of protected health information that are made by such covered entity and by a business associate acting on behalf of the covered entity; or

"(B) accounting, as specified under paragraph (1), for disclosures that are made by such covered entity and provide a list of all business associates acting on behalf of the covered entity, including contact information for such associates (such as mailing address, phone, and email address).

A business associate included on a list under subparagraph (B) shall provide an accounting of disclosures (as required under paragraph (1) for a covered entity) made by the business associate upon a request made by an individual directly to the business associate for such an accounting.

Applicability.

"(4) EFFECTIVE DATE.—

"(A) CURRENT USERS OF ELECTRONIC RECORDS.—In the case of a covered entity insofar as it acquired an electronic health record as of January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such a record on and after January 1, 2014.

"(B) OTHERS.—In the case of a covered entity insofar as it acquires an electronic health record after January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such record on and after the later of the following:

"(i) January 1, 2011; or

"(ii) the date that it acquires an electronic health record.

"(C) LATER DATE.—The Secretary may set an effective date that is later that the date specified under subparagraph (A) or (B) if the Secretary determines that such later date is necessary, but in no case may the date specified under—

"(i) subparagraph (A) be later than 2016; or

"(ii) subparagraph (B) be later than 2013."

(d) PROHIBITION ON SALE OF ELECTRONIC HEALTH RECORDS OR PROTECTED HEALTH INFORMATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), a covered entity or business associate shall not directly or indirectly receive remuneration in exchange for any protected health information of an individual unless the covered entity obtained from the individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization that includes, in accordance with such section, a specification

of whether the protected health information can be further exchanged for remuneration by the entity receiving protected health information of that individual.

(2) EXCEPTIONS.—Paragraph (1) shall not apply in the following cases:

(A) The purpose of the exchange is for public health activities (as described in section 164.512(b) of title 45, Code of Federal Regulations).

(B) The purpose of the exchange is for research (as described in sections 164.501 and 164.512(i) of title 45, Code of Federal Regulations) and the price charged reflects the costs of preparation and transmittal of the data for such purpose.

(C) The purpose of the exchange is for the treatment of the individual, subject to any regulation that the Secretary may promulgate to prevent protected health information from inappropriate access, use, or disclosure.

(D) The purpose of the exchange is the health care operation specifically described in subparagraph (iv) of paragraph (6) of the definition of healthcare operations in section 164.501 of title 45, Code of Federal Regulations.

(E) The purpose of the exchange is for remuneration that is provided by a covered entity to a business associate for activities involving the exchange of protected health information that the business associate undertakes on behalf of and at the specific request of the covered entity pursuant to a business associate agreement.

(F) The purpose of the exchange is to provide an individual with a copy of the individual's protected health information pursuant to section 164.524 of title 45, Code of Federal Regulations.

(G) The purpose of the exchange is otherwise determined by the Secretary in regulations to be similarly necessary and appropriate as the exceptions provided in subparagraphs (A) through (F).

(3) REGULATIONS.—Not later than 18 months after the date of enactment of this title, the Secretary shall promulgate regulations to carry out this subsection. In promulgating such regulations, the Secretary— Deadline.

(A) shall evaluate the impact of restricting the exception described in paragraph (2)(A) to require that the price charged for the purposes described in such paragraph reflects the costs of the preparation and transmittal of the data for such purpose, on research or public health activities, including those conducted by or for the use of the Food and Drug Administration; and

(B) may further restrict the exception described in paragraph (2)(A) to require that the price charged for the purposes described in such paragraph reflects the costs of the preparation and transmittal of the data for such purpose, if the Secretary finds that such further restriction will not impede such research or public health activities.

(4) EFFECTIVE DATE.—Paragraph (1) shall apply to exchanges occurring on or after the date that is 6 months after the date of the promulgation of final regulations implementing this subsection.

(e) ACCESS TO CERTAIN INFORMATION IN ELECTRONIC FORMAT.—In applying section 164.524 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information of an individual—

(1) the individual shall have a right to obtain from such covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual, provided that any such choice is clear, conspicuous, and specific; and

(2) notwithstanding paragraph (c)(4) of such section, any fee that the covered entity may impose for providing such individual with a copy of such information (or a summary or explanation of such information) if such copy (or summary or explanation) is in an electronic form shall not be greater than the entity's labor costs in responding to the request for the copy (or summary or explanation).

42 USC 17936.

SEC. 13406. CONDITIONS ON CERTAIN CONTACTS AS PART OF HEALTH CARE OPERATIONS.

(a) MARKETING.—

(1) IN GENERAL.—A communication by a covered entity or business associate that is about a product or service and that encourages recipients of the communication to purchase or use the product or service shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations, unless the communication is made as described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of such title.

(2) PAYMENT FOR CERTAIN COMMUNICATIONS.—A communication by a covered entity or business associate that is described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of title 45, Code of Federal Regulations, shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations if the covered entity receives or has received direct or indirect payment in exchange for making such communication, except where—

(A)(i) such communication describes only a drug or biologic that is currently being prescribed for the recipient of the communication; and

(ii) any payment received by such covered entity in exchange for making a communication described in clause (i) is reasonable in amount;

(B) each of the following conditions apply—

(i) the communication is made by the covered entity; and

(ii) the covered entity making such communication obtains from the recipient of the communication, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization (as described in paragraph (b) of such section) with respect to such communication; or

(C) each of the following conditions apply—

(i) the communication is made by a business associate on behalf of the covered entity; and

(ii) the communication is consistent with the written contract (or other written arrangement described in section 164.502(e)(2) of such title) between such business associate and covered entity.

(3) REASONABLE IN AMOUNT DEFINED.—For purposes of paragraph (2), the term "reasonable in amount" shall have the meaning given such term by the Secretary by regulation.

(4) DIRECT OR INDIRECT PAYMENT.—For purposes of paragraph (2), the term "direct or indirect payment" shall not include any payment for treatment (as defined in section 164.501 of title 45, Code of Federal Regulations) of an individual.

(b) OPPORTUNITY TO OPT OUT OF FUNDRAISING.—The Secretary shall by rule provide that any written fundraising communication that is a healthcare operation as defined under section 164.501 of title 45, Code of Federal Regulations, shall, in a clear and conspicuous manner, provide an opportunity for the recipient of the communications to elect not to receive any further such communication. When an individual elects not to receive any further such communication, such election shall be treated as a revocation of authorization under section 164.508 of title 45, Code of Federal Regulations. Regulations.

(c) EFFECTIVE DATE.—This section shall apply to written communications occurring on or after the effective date specified under section 13423.

SEC. 13407. TEMPORARY BREACH NOTIFICATION REQUIREMENT FOR VENDORS OF PERSONAL HEALTH RECORDS AND OTHER NON-HIPAA COVERED ENTITIES. 42 USC 17937.

(a) IN GENERAL.—In accordance with subsection (c), each vendor of personal health records, following the discovery of a breach of security of unsecured PHR identifiable health information that is in a personal health record maintained or offered by such vendor, and each entity described in clause (ii), (iii), or (iv) of section 13424(b)(1)(A), following the discovery of a breach of security of such information that is obtained through a product or service provided by such entity, shall—

(1) notify each individual who is a citizen or resident of the United States whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such a breach of security; and

(2) notify the Federal Trade Commission.

(b) NOTIFICATION BY THIRD PARTY SERVICE PROVIDERS.—A third party service provider that provides services to a vendor of personal health records or to an entity described in clause (ii), (iii). or (iv) of section 13424(b)(1)(A) in connection with the offering or maintenance of a personal health record or a related product or service and that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured PHR identifiable health information in such a record as a result of such services shall, following the discovery of a breach of security of such information, notify such vendor or entity, respectively, of such breach. Such notice shall include the identification of each individual whose unsecured PHR identifiable health information

has been, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach.

(c) APPLICATION OF REQUIREMENTS FOR TIMELINESS, METHOD, AND CONTENT OF NOTIFICATIONS.—Subsections (c), (d), (e), and (f) of section 13402 shall apply to a notification required under subsection (a) and a vendor of personal health records, an entity described in subsection (a) and a third party service provider described in subsection (b), with respect to a breach of security under subsection (a) of unsecured PHR identifiable health information in such records maintained or offered by such vendor, in a manner specified by the Federal Trade Commission.

(d) NOTIFICATION OF THE SECRETARY.—Upon receipt of a notification of a breach of security under subsection (a)(2), the Federal Trade Commission shall notify the Secretary of such breach.

(e) ENFORCEMENT.—A violation of subsection (a) or (b) shall be treated as an unfair and deceptive act or practice in violation of a regulation under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57*a*(a)(1)(B)) regarding unfair or deceptive acts or practices.

(f) DEFINITIONS.—For purposes of this section:

(1) BREACH OF SECURITY.—The term "breach of security" means, with respect to unsecured PHR identifiable health information of an individual in a personal health record, acquisition of such information without the authorization of the individual.

(2) PHR IDENTIFIABLE HEALTH INFORMATION.—The term "PHR identifiable health information" means individually identifiable health information, as defined in section 1171(6) of the Social Security Act (42 U.S.C. 1320d(6)), and includes, with respect to an individual, information—

(A) that is provided by or on behalf of the individual; and

(B) that identifies the individual or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(3) UNSECURED PHR IDENTIFIABLE HEALTH INFORMATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "unsecured PHR identifiable health information" means PHR identifiable health information that is not protected through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under section 13402(h)(2) by the date specified in such section, for purposes of this section, the term "unsecured PHR identifiable health information" shall mean PHR identifiable health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and that is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(g) REGULATIONS; EFFECTIVE DATE; SUNSET.—

(1) REGULATIONS; EFFECTIVE DATE.—To carry out this section, the Federal Trade Commission shall promulgate interim final regulations by not later than the date that is 180 days

after the date of the enactment of this section. The provisions of this section shall apply to breaches of security that are discovered on or after the date that is 30 days after the date of publication of such interim final regulations.

Applicability.

(2) SUNSET.—If Congress enacts new legislation establishing requirements for notification in the case of a breach of security, that apply to entities that are not covered entities or business associates, the provisions of this section shall not apply to breaches of security discovered on or after the effective date of regulations implementing such legislation.

SEC. 13408. BUSINESS ASSOCIATE CONTRACTS REQUIRED FOR CERTAIN ENTITIES.

42 USC 17938.

Each organization, with respect to a covered entity, that provides data transmission of protected health information to such entity (or its business associate) and that requires access on a routine basis to such protected health information, such as a Health Information Exchange Organization, Regional Health Information Organization, E-prescribing Gateway, or each vendor that contracts with a covered entity to allow that covered entity to offer a personal health record to patients as part of its electronic health record, is required to enter into a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations and a written contract (or other arrangement) described in section 164.308(b) of such title, with such entity and shall be treated as a business associate of the covered entity for purposes of the provisions of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this title.

SEC. 13409. CLARIFICATION OF APPLICATION OF WRONGFUL DISCLOSURES CRIMINAL PENALTIES.

Section 1177(a) of the Social Security Act (42 U.S.C. 1320d–6(a)) is amended by adding at the end the following new sentence: "For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1180(b)(3)) and the individual obtained or disclosed such information without authorization.".

SEC. 13410. IMPROVED ENFORCEMENT.

42 USC 17939.

(a) IN GENERAL.—

(1) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—Section 1176 of the Social Security Act (42 U.S.C. 1320d–5) is amended—

(A) in subsection (b)(1), by striking "the act constitutes an offense punishable under section 1177" and inserting "a penalty has been imposed under section 1177 with respect to such act"; and

(B) by adding at the end the following new subsection:

"(c) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—

"(1) IN GENERAL.—A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

"(2) REQUIRED INVESTIGATION.—For purposes of paragraph (1), the Secretary shall formally investigate any complaint of

a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.".

(2) ENFORCEMENT UNDER SOCIAL SECURITY ACT.—Any violation by a covered entity under thus subtitle is subject to enforcement and penalties under section 1176 and 1177 of the Social Security Act.

(b) EFFECTIVE DATE; REGULATIONS.—

(1) The amendments made by subsection (a) shall apply to penalties imposed on or after the date that is 24 months after the date of the enactment of this title.

Deadline.

(2) Not later than 18 months after the date of the enactment of this title, the Secretary of Health and Human Services shall promulgate regulations to implement such amendments.

(c) DISTRIBUTION OF CERTAIN CIVIL MONETARY PENALTIES COLLECTED.—

(1) IN GENERAL.—Subject to the regulation promulgated pursuant to paragraph (3), any civil monetary penalty or monetary settlement collected with respect to an offense punishable under this subtitle or section 1176 of the Social Security Act (42 U.S.C. 1320d–5) insofar as such section relates to privacy or security shall be transferred to the Office for Civil Rights of the Department of Health and Human Services to be used for purposes of enforcing the provisions of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this Act.

(2) GAO REPORT.—Not later than 18 months after the date of the enactment of this title, the Comptroller General shall submit to the Secretary a report including recommendations for a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

(3) ESTABLISHMENT OF METHODOLOGY TO DISTRIBUTE PERCENTAGE OF CMPS COLLECTED TO HARMED INDIVIDUALS.—

Deadline.

Not later than 3 years after the date of the enactment of this title, the Secretary shall establish by regulation and based on the recommendations submitted under paragraph (2), a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

(4) APPLICATION OF METHODOLOGY.—The methodology under paragraph (3) shall be applied with respect to civil monetary penalties or monetary settlements imposed on or after the effective date of the regulation.

(d) TIERED INCREASE IN AMOUNT OF CIVIL MONETARY PENALTIES.—

(1) IN GENERAL.—Section 1176(a)(1) of the Social Security Act (42 U.S.C. 1320d–5(a)(1)) is amended by striking "who violates a provision of this part a penalty of not more than" and all that follows and inserting the following: "who violates a provision of this part—

"(A) in the case of a violation of such provision in which it is established that the person did not know (and

by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

"(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

"(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect—

"(i) if the violation is corrected as described in subsection (b)(3)(A), a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

"(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.".

(2) TIERS OF PENALTIES DESCRIBED.—Section 1176(a) of such Act (42 U.S.C. 1320d–5(a)) is further amended by adding at the end the following new paragraph:

"(3) TIERS OF PENALTIES DESCRIBED.—For purposes of paragraph (1), with respect to a violation by a person of a provision of this part—

"(A) the amount described in this subparagraph is $100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $25,000;

"(B) the amount described in this subparagraph is $1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $100,000;

"(C) the amount described in this subparagraph is $10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $250,000; and

"(D) the amount described in this subparagraph is $50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $1,500,000.".

(3) CONFORMING AMENDMENTS.—Section 1176(b) of such Act (42 U.S.C. 1320d–5(b)) is amended—

(A) by striking paragraph (2) and redesignating paragraphs (3) and (4) as paragraphs (2) and (3), respectively; and

(B) in paragraph (2), as so redesignated—

(i) in subparagraph (A), by striking "in subparagraph (B), a penalty may not be imposed under subsection (a) if" and all that follows through "the failure to comply is corrected" and inserting "in subparagraph (B) or subsection (a)(1)(C), a penalty may not be imposed under subsection (a) if the failure to comply is corrected"; and

(ii) in subparagraph (B), by striking "(A)(ii)" and inserting "(A)" each place it appears.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to violations occurring after the date of the enactment of this title.

(e) ENFORCEMENT THROUGH STATE ATTORNEYS GENERAL.—

(1) IN GENERAL.—Section 1176 of the Social Security Act (42 U.S.C. 1320d–5) is amended by adding at the end the following new subsection:

"(d) ENFORCEMENT BY STATE ATTORNEYS GENERAL.—

"(1) CIVIL ACTION.—Except as provided in subsection (b), in any case in which the attorney general of a State has reason to believe that an interest of one or more of the residents of that State has been or is threatened or adversely affected by any person who violates a provision of this part, the attorney general of the State, as parens patriae, may bring a civil action on behalf of such residents of the State in a district court of the United States of appropriate jurisdiction—

"(A) to enjoin further such violation by the defendant; or

"(B) to obtain damages on behalf of such residents of the State, in an amount equal to the amount determined under paragraph (2).

"(2) STATUTORY DAMAGES.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), the amount determined under this paragraph is the amount calculated by multiplying the number of violations by up to $100. For purposes of the preceding sentence, in the case of a continuing violation, the number of violations shall be determined consistent with the HIPAA privacy regulations (as defined in section 1180(b)(3)) for violations of subsection (a).

"(B) LIMITATION.—The total amount of damages imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

"(C) REDUCTION OF DAMAGES.—In assessing damages under subparagraph (A), the court may consider the factors the Secretary may consider in determining the amount of a civil money penalty under subsection (a) under the HIPAA privacy regulations.

"(3) ATTORNEY FEES.—In the case of any successful action under paragraph (1), the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State.

Records.

"(4) NOTICE TO SECRETARY.—The State shall serve prior written notice of any action under paragraph (1) upon the Secretary and provide the Secretary with a copy of its complaint, except in any case in which such prior notice is not

feasible, in which case the State shall serve such notice immediately upon instituting such action. The Secretary shall have the right—

"(A) to intervene in the action;

"(B) upon so intervening, to be heard on all matters arising therein; and

"(C) to file petitions for appeal.

"(5) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this section shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State.

"(6) VENUE; SERVICE OF PROCESS.—

"(A) VENUE.—Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

"(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

"(i) is an inhabitant; or

"(ii) maintains a physical place of business.

"(7) LIMITATION ON STATE ACTION WHILE FEDERAL ACTION IS PENDING.—If the Secretary has instituted an action against a person under subsection (a) with respect to a specific violation of this part, no State attorney general may bring an action under this subsection against the person with respect to such violation during the pendency of that action.

"(8) APPLICATION OF CMP STATUTE OF LIMITATION.—A civil action may not be instituted with respect to a violation of this part unless an action to impose a civil money penalty may be instituted under subsection (a) with respect to such violation consistent with the second sentence of section 1128A(c)(1).".

(2) CONFORMING AMENDMENTS.—Subsection (b) of such section, as amended by subsection (d)(3), is amended—

(A) in paragraph (1), by striking "A penalty may not be imposed under subsection (a)" and inserting "No penalty may be imposed under subsection (a) and no damages obtained under subsection (d)";

(B) in paragraph (2)(A)—

(i) after "subsection (a)(1)(C),", by striking "a penalty may not be imposed under subsection (a)" and inserting "no penalty may be imposed under subsection (a) and no damages obtained under subsection (d)"; and

(ii) in clause (ii), by inserting "or damages" after "the penalty";

(C) in paragraph (2)(B)(i), by striking "The period" and inserting "With respect to the imposition of a penalty by the Secretary under subsection (a), the period"; and

(D) in paragraph (3), by inserting "and any damages under subsection (d)" after "any penalty under subsection (a)".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to violations occurring after the date of the enactment of this Act.

(f) ALLOWING CONTINUED USE OF CORRECTIVE ACTION.—Such section is further amended by adding at the end the following new subsection:

"(e) ALLOWING CONTINUED USE OF CORRECTIVE ACTION.—Nothing in this section shall be construed as preventing the Office for Civil Rights of the Department of Health and Human Services from continuing, in its discretion, to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) of the violation involved.".

42 USC 17940.

SEC. 13411. AUDITS.

The Secretary shall provide for periodic audits to ensure that covered entities and business associates that are subject to the requirements of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this Act, comply with such requirements.

PART 2—RELATIONSHIP TO OTHER LAWS; REGULATORY REFERENCES; EFFECTIVE DATE; REPORTS

42 USC 17951.

SEC. 13421. RELATIONSHIP TO OTHER LAWS.

(a) APPLICATION OF HIPAA STATE PREEMPTION.—Section 1178 of the Social Security Act (42 U.S.C. 1320d–7) shall apply to a provision or requirement under this subtitle in the same manner that such section applies to a provision or requirement under part C of title XI of such Act or a standard or implementation specification adopted or established under sections 1172 through 1174 of such Act.

(b) HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT.—The standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under sections 262(a) and 264 of the Health Insurance Portability and Accountability Act of 1996 shall remain in effect to the extent that they are consistent with this subtitle. The Secretary shall by rule amend such Federal regulations as required to make such regulations consistent with this subtitle.

(c) CONSTRUCTION.—Nothing in this subtitle shall constitute a waiver of any privilege otherwise applicable to an individual with respect to the protected health information of such individual.

42 USC 17952.

SEC. 13422. REGULATORY REFERENCES.

Each reference in this subtitle to a provision of the Code of Federal Regulations refers to such provision as in effect on the date of the enactment of this title (or to the most recent update of such provision).

42 USC 17953.

SEC. 13423. EFFECTIVE DATE.

Except as otherwise specifically provided, the provisions of part I shall take effect on the date that is 12 months after the date of the enactment of this title.

42 USC 17954.

SEC. 13424. STUDIES, REPORTS, GUIDANCE.

(a) REPORT ON COMPLIANCE.—

(1) IN GENERAL.—For the first year beginning after the date of the enactment of this Act and annually thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report concerning complaints of alleged violations of law, including the provisions of this subtitle as well as the provisions of subparts C and E of part 164 of title 45, Code of Federal Regulations, (as such provisions are in effect as of the date of enactment of this Act) relating to privacy and security of health information that are received by the Secretary during the year for which the report is being prepared. Each such report shall include, with respect to such complaints received during the year—

(A) the number of such complaints;

(B) the number of such complaints resolved informally, a summary of the types of such complaints so resolved, and the number of covered entities that received technical assistance from the Secretary during such year in order to achieve compliance with such provisions and the types of such technical assistance provided;

(C) the number of such complaints that have resulted in the imposition of civil monetary penalties or have been resolved through monetary settlements, including the nature of the complaints involved and the amount paid in each penalty or settlement;

(D) the number of compliance reviews conducted and the outcome of each such review;

(E) the number of subpoenas or inquiries issued;

(F) the Secretary's plan for improving compliance with and enforcement of such provisions for the following year; and

(G) the number of audits performed and a summary of audit findings pursuant to section 13411.

(2) AVAILABILITY TO PUBLIC.—Each report under paragraph (1) shall be made available to the public on the Internet website of the Department of Health and Human Services. Web posting.

(b) STUDY AND REPORT ON APPLICATION OF PRIVACY AND SECURITY REQUIREMENTS TO NON-HIPAA COVERED ENTITIES.—

(1) STUDY.—Not later than one year after the date of the enactment of this title, the Secretary, in consultation with the Federal Trade Commission, shall conduct a study, and submit a report under paragraph (2), on privacy and security requirements for entities that are not covered entities or business associates as of the date of the enactment of this title, including—

(A) requirements relating to security, privacy, and notification in the case of a breach of security or privacy (including the applicability of an exemption to notification in the case of individually identifiable health information that has been rendered unusable, unreadable, or indecipherable through technologies or methodologies recognized by appropriate professional organization or standard setting bodies to provide effective security for the information) that should be applied to—

(i) vendors of personal health records;

(ii) entities that offer products or services through the website of a vendor of personal health records;

(iii) entities that are not covered entities and that offer products or services through the websites of covered entities that offer individuals personal health records;

(iv) entities that are not covered entities and that access information in a personal health record or send information to a personal health record; and

(v) third party service providers used by a vendor or entity described in clause (i), (ii), (iii), or (iv) to assist in providing personal health record products or services;

(B) a determination of which Federal government agency is best equipped to enforce such requirements recommended to be applied to such vendors, entities, and service providers under subparagraph (A); and

(C) a timeframe for implementing regulations based on such findings.

(2) REPORT.—The Secretary shall submit to the Committee on Finance, the Committee on Health, Education, Labor, and Pensions, and the Committee on Commerce of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on the findings of the study under paragraph (1) and shall include in such report recommendations on the privacy and security requirements described in such paragraph.

(c) GUIDANCE ON IMPLEMENTATION SPECIFICATION TO DE-IDENTIFY PROTECTED HEALTH INFORMATION.—Not later than 12 months after the date of the enactment of this title, the Secretary shall, in consultation with stakeholders, issue guidance on how best to implement the requirements for the de-identification of protected health information under section 164.514(b) of title 45, Code of Federal Regulations.

(d) GAO REPORT ON TREATMENT DISCLOSURES.—Not later than one year after the date of the enactment of this title, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on the best practices related to the disclosure among health care providers of protected health information of an individual for purposes of treatment of such individual. Such report shall include an examination of the best practices implemented by States and by other entities, such as health information exchanges and regional health information organizations, an examination of the extent to which such best practices are successful with respect to the quality of the resulting health care provided to the individual and with respect to the ability of the health care provider to manage such best practices, and an examination of the use of electronic informed consent for disclosing protected health information for treatment, payment, and health care operations.

(e) REPORT REQUIRED.—Not later than 5 years after the date of enactment of this section, the Government Accountability Office shall submit to Congress and the Secretary of Health and Human Services a report on the impact of any of the provisions of this

Act on health insurance premiums, overall health care costs, adoption of electronic health records by providers, and reduction in medical errors and other quality improvements.

(f) STUDY.—The Secretary shall study the definition of "psychotherapy notes" in section 164.501 of title 45, Code of Federal Regulations, with regard to including test data that is related to direct responses, scores, items, forms, protocols, manuals, or other materials that are part of a mental health evaluation, as determined by the mental health professional providing treatment or evaluation in such definitions and may, based on such study, issue regulations to revise such definition.

TITLE XIV—STATE FISCAL STABILIZATION FUND

DEPARTMENT OF EDUCATION

STATE FISCAL STABILIZATION FUND

For necessary expenses for a State Fiscal Stabilization Fund, $53,600,000,000, which shall be administered by the Department of Education.

GENERAL PROVISIONS—THIS TITLE

SEC. 14001. ALLOCATIONS.

(a) OUTLYING AREAS.—From the amount appropriated to carry out this title, the Secretary of Education shall first allocate up to one-half of 1 percent to the outlying areas on the basis of their respective needs, as determined by the Secretary, in consultation with the Secretary of the Interior, for activities consistent with this title under such terms and conditions as the Secretary may determine.

(b) ADMINISTRATION AND OVERSIGHT.—The Secretary may, in addition, reserve up to $14,000,000 for administration and oversight of this title, including for program evaluation.

(c) RESERVATION FOR ADDITIONAL PROGRAMS.—After reserving funds under subsections (a) and (b), the Secretary shall reserve $5,000,000,000 for grants under sections 14006 and 14007. Grants.

(d) STATE ALLOCATIONS.—After carrying out subsections (a), (b), and (c), the Secretary shall allocate the remaining funds made available to carry out this title to the States as follows:

(1) 61 percent on the basis of their relative population of individuals aged 5 through 24.

(2) 39 percent on the basis of their relative total population.

(e) STATE GRANTS.—From funds allocated under subsection (d), the Secretary shall make grants to the Governor of each State.

(f) REALLOCATION.—The Governor shall return to the Secretary any funds received under subsection (e) that the Governor does not award as subgrants or otherwise commit within two years of receiving such funds, and the Secretary shall reallocate such funds to the remaining States in accordance with subsection (d).

SEC. 14002. STATE USES OF FUNDS.

(a) EDUCATION FUND.—

(1) IN GENERAL.—For each fiscal year, the Governor shall use 81.8 percent of the State's allocation under section 14001(d) for the support of elementary, secondary, and postsecondary education and, as applicable, early childhood education programs and services.

(2) RESTORING STATE SUPPORT FOR EDUCATION.—

(A) IN GENERAL.—The Governor shall first use the funds described in paragraph (1)—

(i) to provide the amount of funds, through the State's primary elementary and secondary funding formulae, that is needed—

(I) to restore, in each of fiscal years 2009, 2010, and 2011, the level of State support provided through such formulae to the greater of the fiscal year 2008 or fiscal year 2009 level; and

(II) where applicable, to allow existing State formulae increases to support elementary and secondary education for fiscal years 2010 and 2011 to be implemented and allow funding for phasing in State equity and adequacy adjustments, if such increases were enacted pursuant to State law prior to October 1, 2008.

(ii) to provide, in each of fiscal years 2009, 2010, and 2011, the amount of funds to public institutions of higher education in the State that is needed to restore State support for such institutions (excluding tuition and fees paid by students) to the greater of the fiscal year 2008 or fiscal year 2009 level.

(B) SHORTFALL.—If the Governor determines that the amount of funds available under paragraph (1) is insufficient to support, in each of fiscal years 2009, 2010, and 2011, public elementary, secondary, and higher education at the levels described in clauses (i) and (ii) of subparagraph (A), the Governor shall allocate those funds between those clauses in proportion to the relative shortfall in State support for the education sectors described in those clauses.

(C) FISCAL YEAR.—For purposes of this paragraph, the term "fiscal year" shall have the meaning given such term under State law.

(3) SUBGRANTS TO IMPROVE BASIC PROGRAMS OPERATED BY LOCAL EDUCATIONAL AGENCIES.—After carrying out paragraph (2), the Governor shall use any funds remaining under paragraph (1) to provide local educational agencies in the State with subgrants based on their relative shares of funding under part A of title I of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6311 et seq.) for the most recent year for which data are available.

(b) OTHER GOVERNMENT SERVICES.—

(1) IN GENERAL.—The Governor shall use 18.2 percent of the State's allocation under section 14001 for public safety and other government services, which may include assistance for elementary and secondary education and public institutions of higher education, and for modernization, renovation, or repair of public school facilities and institutions of higher education facilities, including modernization, renovation, and repairs that are consistent with a recognized green building rating system.

(2) AVAILABILITY TO ALL INSTITUTIONS OF HIGHER EDUCATION.—A Governor shall not consider the type or mission of an institution of higher education, and shall consider any institution for funding for modernization, renovation, and repairs within the State that—

(A) qualifies as an institution of higher education, as defined in subsection 14013(3); and

(B) continues to be eligible to participate in the programs under title IV of the Higher Education Act of 1965.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall allow a local educational agency to engage in school modernization, renovation, or repair that is inconsistent with State law.

SEC. 14003. USES OF FUNDS BY LOCAL EDUCATIONAL AGENCIES.

(a) IN GENERAL.—A local educational agency that receives funds under this title may use the funds for any activity authorized by the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6301 et seq.) ("ESEA"), the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.) ("IDEA"), the Adult and Family Literacy Act (20 U.S.C. 1400 et seq.), or the Carl D. Perkins Career and Technical Education Act of 2006 (20 U.S.C. 2301 et seq.) ("the Perkins Act") or for modernization, renovation, or repair of public school facilities, including modernization, renovation, and repairs that are consistent with a recognized green building rating system.

(b) PROHIBITION.—A local educational agency may not use funds received under this title for—

(1) payment of maintenance costs;

(2) stadiums or other facilities primarily used for athletic contests or exhibitions or other events for which admission is charged to the general public;

(3) purchase or upgrade of vehicles; or

(4) improvement of stand-alone facilities whose purpose is not the education of children, including central office administration or operations or logistical support facilities.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall allow a local educational agency to engage in school modernization, renovation, or repair that is inconsistent with State law.

SEC. 14004. USES OF FUNDS BY INSTITUTIONS OF HIGHER EDUCATION.

(a) IN GENERAL.—A public institution of higher education that receives funds under this title shall use the funds for education and general expenditures, and in such a way as to mitigate the need to raise tuition and fees for in-State students, or for modernization, renovation, or repair of institution of higher education facilities that are primarily used for instruction, research, or student housing, including modernization, renovation, and repairs that are consistent with a recognized green building rating system.

(b) PROHIBITION.—An institution of higher education may not use funds received under this title to increase its endowment.

(c) ADDITIONAL PROHIBITION.—No funds awarded under this title may be used for—

(1) the maintenance of systems, equipment, or facilities;

(2) modernization, renovation, or repair of stadiums or other facilities primarily used for athletic contests or exhibitions or other events for which admission is charged to the general public; or

(3) modernization, renovation, or repair of facilities—

(A) used for sectarian instruction or religious worship; or

(B) in which a substantial portion of the functions of the facilities are subsumed in a religious mission.

SEC. 14005. STATE APPLICATIONS.

(a) IN GENERAL.—The Governor of a State desiring to receive an allocation under section 14001 shall submit an application at such time, in such manner, and containing such information as the Secretary may reasonably require.

(b) APPLICATION.—In such application, the Governor shall—

(1) include the assurances described in subsection (d);

(2) provide baseline data that demonstrates the State's current status in each of the areas described in such assurances; and

(3) describe how the State intends to use its allocation, including whether the State will use such allocation to meet maintenance of effort requirements under the ESEA and IDEA and, in such cases, what amount will be used to meet such requirements.

(c) INCENTIVE GRANT APPLICATION.—The Governor of a State seeking a grant under section 14006 shall—

(1) submit an application for consideration;

(2) describe the status of the State's progress in each of the areas described in subsection (d), and the strategies the State is employing to help ensure that students in the subgroups described in section 1111(b)(2)(C)(v)(II) of the ESEA (20 U.S.C. 6311(b)(2)(C)(v)(II)) who have not met the State's proficiency targets continue making progress toward meeting the State's student academic achievement standards;

(3) describe the achievement and graduation rates (as described in section 1111(b)(2)(C)(vi) of the ESEA (20 U.S.C. 6311(b)(2)(C)(vi)) and as clarified in section 200.19(b)(1) of title 34, Code of Federal Regulations) of public elementary and secondary school students in the State, and the strategies the State is employing to help ensure that all subgroups of students identified in section 1111(b)(2) of the ESEA (20 U.S.C. 6311(b)(2)) in the State continue making progress toward meeting the State's student academic achievement standards;

(4) describe how the State would use its grant funding to improve student academic achievement in the State, including how it will allocate the funds to give priority to high-need local educational agencies; and

(5) include a plan for evaluating the State's progress in closing achievement gaps.

(d) ASSURANCES.—An application under subsection (b) shall include the following assurances:

(1) MAINTENANCE OF EFFORT.—

(A) ELEMENTARY AND SECONDARY EDUCATION.—The State will, in each of fiscal years 2009, 2010, and 2011, maintain State support for elementary and secondary education at least at the level of such support in fiscal year 2006.

(B) HIGHER EDUCATION.—The State will, in each of fiscal years 2009, 2010, and 2011, maintain State support for public institutions of higher education (not including support for capital projects or for research and development

or tuition and fees paid by students) at least at the level of such support in fiscal year 2006.

(2) ACHIEVING EQUITY IN TEACHER DISTRIBUTION.—The State will take actions to improve teacher effectiveness and comply with section 1111(b)(8)(C) of the ESEA (20 U.S.C. 6311(b)(8)(C)) in order to address inequities in the distribution of highly qualified teachers between high- and low-poverty schools, and to ensure that low-income and minority children are not taught at higher rates than other children by inexperienced, unqualified, or out-of-field teachers.

(3) IMPROVING COLLECTION AND USE OF DATA.—The State will establish a longitudinal data system that includes the elements described in section 6401(e)(2)(D) of the America COMPETES Act (20 U.S.C. 9871).

(4) STANDARDS AND ASSESSMENTS.—The State—

(A) will enhance the quality of the academic assessments it administers pursuant to section 1111(b)(3) of the ESEA (20 U.S.C. 6311(b)(3)) through activities such as those described in section 6112(a) of such Act (20 U.S.C. 7301a(a));

(B) will comply with the requirements of paragraphs (3)(C)(ix) and (6) of section 1111(b) of the ESEA (20 U.S.C. 6311(b)) and section 612(a)(16) of the IDEA (20 U.S.C. 1412(a)(16)) related to the inclusion of children with disabilities and limited English proficient students in State assessments, the development of valid and reliable assessments for those students, and the provision of accommodations that enable their participation in State assessments; and

(C) will take steps to improve State academic content standards and student academic achievement standards consistent with section 6401(e)(1)(9)(A)(ii) of the America COMPETES Act.

(5) SUPPORTING STRUGGLING SCHOOLS.—The State will ensure compliance with the requirements of section 1116(a)(7)(C)(iv) and section 1116(a)(8)(B) of the ESEA with respect to schools identified under such sections.

SEC. 14006. STATE INCENTIVE GRANTS.

(a) IN GENERAL.—

(1) RESERVATION.—From the total amount reserved under section 14001(c) that is not used for section 14007, the Secretary may reserve up to 1 percent for technical assistance to States to assist them in meeting the objectives of paragraphs (2), (3), (4), and (5) of section 14005(d).

(2) REMAINDER.—Of the remaining funds, the Secretary shall, in fiscal year 2010, make grants to States that have made significant progress in meeting the objectives of paragraphs (2), (3), (4), and (5) of section 14005(d).

(b) BASIS FOR GRANTS.—The Secretary shall determine which States receive grants under this section, and the amount of those grants, on the basis of information provided in State applications under section 14005 and such other criteria as the Secretary determines appropriate, which may include a State's need for assistance to help meet the objective of paragraphs (2), (3), (4), and (5) of section 14005(d).

(c) SUBGRANTS TO LOCAL EDUCATIONAL AGENCIES.—Each State receiving a grant under this section shall use at least 50 percent of the grant to provide local educational agencies in the State with subgrants based on their relative shares of funding under part A of title I of the ESEA (20 U.S.C. 6311 et seq.) for the most recent year.

SEC. 14007. INNOVATION FUND.

(a) IN GENERAL.—

(1) ELIGIBLE ENTITIES.—For the purposes of this section, the term "eligible entity" means—

(A) a local educational agency; or

(B) a partnership between a nonprofit organization and—

(i) one or more local educational agencies; or

(ii) a consortium of schools.

(2) PROGRAM ESTABLISHED.—From the total amount reserved under section 14001(c), the Secretary may reserve up to $650,000,000 to establish an Innovation Fund, which shall consist of academic achievement awards that recognize eligible entities that meet the requirements described in subsection (b).

(3) BASIS FOR AWARDS.—The Secretary shall make awards to eligible entities that have made significant gains in closing the achievement gap as described in subsection (b)(1)—

(A) to allow such eligible entities to expand their work and serve as models for best practices;

(B) to allow such eligible entities to work in partnership with the private sector and the philanthropic community; and

(C) to identify and document best practices that can be shared, and taken to scale based on demonstrated success.

(b) ELIGIBILITY.—To be eligible for such an award, an eligible entity shall—

(1) have significantly closed the achievement gaps between groups of students described in section 1111(b)(2) of the ESEA (20 U.S.C. 6311(b)(2));

(2) have exceeded the State's annual measurable objectives consistent with such section 1111(b)(2) for 2 or more consecutive years or have demonstrated success in significantly increasing student academic achievement for all groups of students described in such section through another measure, such as measures described in section 1111(c)(2) of the ESEA;

(3) have made significant improvement in other areas, such as graduation rates or increased recruitment and placement of high-quality teachers and school leaders, as demonstrated with meaningful data; and

(4) demonstrate that they have established partnerships with the private sector, which may include philanthropic organizations, and that the private sector will provide matching funds in order to help bring results to scale.

(c) SPECIAL RULE.—In the case of an eligible entity that includes a nonprofit organization, the eligible entity shall be considered to have met the eligibility requirements of paragraphs (1), (2), (3) of subsection (b) if such nonprofit organization has a record of meeting such requirements.

SEC. 14008. STATE REPORTS.

For each year of the program under this title, a State receiving funds under this title shall submit a report to the Secretary, at such time and in such manner as the Secretary may require, that describes—

(1) the uses of funds provided under this title within the State;

(2) how the State distributed the funds it received under this title;

(3) the number of jobs that the Governor estimates were saved or created with funds the State received under this title;

(4) tax increases that the Governor estimates were averted because of the availability of funds from this title;

(5) the State's progress in reducing inequities in the distribution of highly qualified teachers, in implementing a State longitudinal data system, and in developing and implementing valid and reliable assessments for limited English proficient students and children with disabilities;

(6) the tuition and fee increases for in-State students imposed by public institutions of higher education in the State during the period of availability of funds under this title, and a description of any actions taken by the State to limit those increases;

(7) the extent to which public institutions of higher education maintained, increased, or decreased enrollment of in-State students, including students eligible for Pell Grants or other need-based financial assistance; and

(8) a description of each modernization, renovation and repair project funded, which shall include the amounts awarded and project costs.

SEC. 14009. EVALUATION.

The Comptroller General of the United States shall conduct evaluations of the programs under sections 14006 and 14007 which shall include, but not be limited to, the criteria used for the awards made, the States selected for awards, award amounts, how each State used the award received, and the impact of this funding on the progress made toward closing achievement gaps.

SEC. 14010. SECRETARY'S REPORT TO CONGRESS.

The Secretary shall submit a report to the Committee on Education and Labor of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committees on Appropriations of the House of Representatives and of the Senate, not less than 6 months following the submission of State reports, that evaluates the information provided in the State reports under section 14008 and the information required by section 14005(b)(3) including State-by-State information.

SEC. 14011. PROHIBITION ON PROVISION OF CERTAIN ASSISTANCE.

No recipient of funds under this title shall use such funds to provide financial assistance to students to attend private elementary or secondary schools.

SEC. 14012. FISCAL RELIEF.

Waiver authority.

(a) IN GENERAL.—For the purpose of relieving fiscal burdens on States and local educational agencies that have experienced

a precipitous decline in financial resources, the Secretary of Education may waive or modify any requirement of this title relating to maintaining fiscal effort.

(b) DURATION.—A waiver or modification under this section shall be for any of fiscal year 2009, fiscal year 2010, or fiscal year 2011, as determined by the Secretary.

(c) CRITERIA.—The Secretary shall not grant a waiver or modification under this section unless the Secretary determines that the State or local educational agency receiving such waiver or modification will not provide for elementary and secondary education, for the fiscal year under consideration, a smaller percentage of the total revenues available to the State or local educational agency than the amount provided for such purpose in the preceding fiscal year.

(d) MAINTENANCE OF EFFORT.—Upon prior approval from the Secretary, a State or local educational agency that receives funds under this title may treat any portion of such funds that is used for elementary, secondary, or postsecondary education as non-Federal funds for the purpose of any requirement to maintain fiscal effort under any other program, including part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 et seq.), administered by the Secretary.

(e) SUBSEQUENT LEVEL OF EFFORT.—Notwithstanding (d), the level of effort required by a State or local educational agency for the following fiscal year shall not be reduced.

SEC. 14013. DEFINITIONS.

Except as otherwise provided in this title, as used in this title—

(1) the terms "elementary education" and "secondary education" have the meaning given such terms under State law;

(2) the term "high-need local educational agency" means a local educational agency—

(A) that serves not fewer than 10,000 children from families with incomes below the poverty line; or

(B) for which not less than 20 percent of the children served by the agency are from families with incomes below the poverty line;

(3) the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001);

(4) the term "Secretary" means the Secretary of Education;

(5) the term "State" means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico; and

(6) any other term used that is defined in section 9101 of the ESEA (20 U.S.C. 7801) shall have the meaning given the term in such section.

TITLE XV—ACCOUNTABILITY AND TRANSPARENCY

SEC. 1501. DEFINITIONS.

In this title:

(1) AGENCY.—The term "agency" has the meaning given under section 551 of title 5, United States Code.

(2) BOARD.—The term "Board" means the Recovery Accountability and Transparency Board established in section 1521.

(3) CHAIRPERSON.—The term "Chairperson" means the Chairperson of the Board.

(4) COVERED FUNDS.—The term "covered funds" means any funds that are expended or obligated from appropriations made under this Act.

(5) PANEL.—The term "Panel" means the Recovery Independent Advisory Panel established in section 1541.

Subtitle A—Transparency and Oversight Requirements

SEC. 1511. CERTIFICATIONS.

With respect to covered funds made available to State or local governments for infrastructure investments, the Governor, mayor, or other chief executive, as appropriate, shall certify that the infrastructure investment has received the full review and vetting required by law and that the chief executive accepts responsibility that the infrastructure investment is an appropriate use of taxpayer dollars. Such certification shall include a description of the investment, the estimated total cost, and the amount of covered funds to be used, and shall be posted on a website and linked to the website established by section 1526. A State or local agency may not receive infrastructure investment funding from funds made available in this Act unless this certification is made and posted.

Web posting.

SEC. 1512. REPORTS ON USE OF FUNDS.

Jobs Accountability Act.

(a) SHORT TITLE.—This section may be cited as the "Jobs Accountability Act".

(b) DEFINITIONS.—In this section:

(1) RECIPIENT.—The term "recipient"—

(A) means any entity that receives recovery funds directly from the Federal Government (including recovery funds received through grant, loan, or contract) other than an individual; and

(B) includes a State that receives recovery funds.

(2) RECOVERY FUNDS.—The term "recovery funds" means any funds that are made available from appropriations made under this Act.

(c) RECIPIENT REPORTS.—Not later than 10 days after the end of each calendar quarter, each recipient that received recovery funds from a Federal agency shall submit a report to that agency that contains—

(1) the total amount of recovery funds received from that agency;

(2) the amount of recovery funds received that were expended or obligated to projects or activities; and

(3) a detailed list of all projects or activities for which recovery funds were expended or obligated, including—

(A) the name of the project or activity;

(B) a description of the project or activity;

(C) an evaluation of the completion status of the project or activity;

(D) an estimate of the number of jobs created and the number of jobs retained by the project or activity; and

(E) for infrastructure investments made by State and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made available under this Act, and name of the person to contact at the agency if there are concerns with the infrastructure investment.

(4) Detailed information on any subcontracts or subgrants awarded by the recipient to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 (Public Law 109–282), allowing aggregate reporting on awards below $25,000 or to individuals, as prescribed by the Director of the Office of Management and Budget.

(d) AGENCY REPORTS.—Not later than 30 days after the end of each calendar quarter, each agency that made recovery funds available to any recipient shall make the information in reports submitted under subsection (c) publicly available by posting the information on a website.

(e) OTHER REPORTS.—The Congressional Budget Office and the Government Accountability Office shall comment on the information described in subsection (c)(3)(D) for any reports submitted under subsection (c). Such comments shall be due within 45 days after such reports are submitted.

(f) COMPLIANCE.—Within 180 days of enactment, as a condition of receipt of funds under this Act, Federal agencies shall require any recipient of such funds to provide the information required under subsection (c).

(g) GUIDANCE.—Federal agencies, in coordination with the Director of the Office of Management and Budget, shall provide for user-friendly means for recipients of covered funds to meet the requirements of this section.

(h) REGISTRATION.—Funding recipients required to report information per subsection (c)(4) must register with the Central Contractor Registration database or complete other registration requirements as determined by the Director of the Office of Management and Budget.

SEC. 1513. REPORTS OF THE COUNCIL OF ECONOMIC ADVISERS.

(a) IN GENERAL.—In consultation with the Director of the Office of Management and Budget and the Secretary of the Treasury, the Chairperson of the Council of Economic Advisers shall submit quarterly reports to the Committees on Appropriations of the Senate and House of Representatives that detail the impact of programs funded through covered funds on employment, estimated economic growth, and other key economic indicators.

(b) SUBMISSION OF REPORTS.—

(1) FIRST REPORT.—The first report submitted under subsection (a) shall be submitted not later than 45 days after the end of the first full quarter following the date of enactment of this Act.

Applicability.

(2) LAST REPORT.—The last report required to be submitted under subsection (a) shall apply to the quarter in which the Board terminates under section 1530.

SEC. 1514. INSPECTOR GENERAL REVIEWS.

(a) REVIEWS.—Any inspector general of a Federal department or executive agency shall review, as appropriate, any concerns raised by the public about specific investments using funds made available in this Act. Any findings of such reviews not related to an ongoing criminal proceeding shall be relayed immediately to the head of the department or agency concerned. In addition, the findings of such reviews, along with any audits conducted by any inspector general of funds made available in this Act, shall be posted on the inspector general's website and linked to the website established by section 1526, except that portions of reports may be redacted to the extent the portions would disclose information that is protected from public disclosure under sections 552 and 552a of title 5, United States Code.

Web posting.

SEC. 1515. ACCESS OF OFFICES OF INSPECTOR GENERAL TO CERTAIN RECORDS AND EMPLOYEES.

(a) ACCESS.—With respect to each contract or grant awarded using covered funds, any representative of an appropriate inspector general appointed under section 3 or 8G of the Inspector General Act of 1978 (5 U.S.C. App.), is authorized—

(1) to examine any records of the contractor or grantee, any of its subcontractors or subgrantees, or any State or local agency administering such contract, that pertain to, and involve transactions relating to, the contract, subcontract, grant, or subgrant; and

(2) to interview any officer or employee of the contractor, grantee, subgrantee, or agency regarding such transactions.

(b) RELATIONSHIP TO EXISTING AUTHORITY.—Nothing in this section shall be interpreted to limit or restrict in any way any existing authority of an inspector general.

Subtitle B—Recovery Accountability and Transparency Board

SEC. 1521. ESTABLISHMENT OF THE RECOVERY ACCOUNTABILITY AND TRANSPARENCY BOARD.

There is established the Recovery Accountability and Transparency Board to coordinate and conduct oversight of covered funds to prevent fraud, waste, and abuse.

SEC. 1522. COMPOSITION OF BOARD.

(a) CHAIRPERSON.—

(1) DESIGNATION OR APPOINTMENT.—The President shall—

President.

(A) designate the Deputy Director for Management of the Office of Management and Budget to serve as Chairperson of the Board;

(B) designate another Federal officer who was appointed by the President to a position that required the advice and consent of the Senate, to serve as Chairperson of the Board; or

(C) appoint an individual as the Chairperson of the Board, by and with the advice and consent of the Senate.

(2) COMPENSATION.—

(A) DESIGNATION OF FEDERAL OFFICER.—If the President designates a Federal officer under paragraph (1)(A)

or (B) to serve as Chairperson, that Federal officer may not receive additional compensation for services performed as Chairperson.

(B) APPOINTMENT OF NON-FEDERAL OFFICER.—If the President appoints an individual as Chairperson under paragraph (1)(C), that individual shall be compensated at the rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(b) MEMBERS.—The members of the Board shall include—

(1) the Inspectors General of the Departments of Agriculture, Commerce, Education, Energy, Health and Human Services, Homeland Security, Justice, Transportation, Treasury, and the Treasury Inspector General for Tax Administration; and

(2) any other Inspector General as designated by the President from any agency that expends or obligates covered funds.

SEC. 1523. FUNCTIONS OF THE BOARD.

(a) FUNCTIONS.—

(1) IN GENERAL.—The Board shall coordinate and conduct oversight of covered funds in order to prevent fraud, waste, and abuse.

(2) SPECIFIC FUNCTIONS.—The functions of the Board shall include—

(A) reviewing whether the reporting of contracts and grants using covered funds meets applicable standards and specifies the purpose of the contract or grant and measures of performance;

(B) reviewing whether competition requirements applicable to contracts and grants using covered funds have been satisfied;

(C) auditing or reviewing covered funds to determine whether wasteful spending, poor contract or grant management, or other abuses are occurring and referring matters it considers appropriate for investigation to the inspector general for the agency that disbursed the covered funds;

(D) reviewing whether there are sufficient qualified acquisition and grant personnel overseeing covered funds;

(E) reviewing whether personnel whose duties involve acquisitions or grants made with covered funds receive adequate training; and

(F) reviewing whether there are appropriate mechanisms for interagency collaboration relating to covered funds, including coordinating and collaborating to the extent practicable with the Inspectors General Council on Integrity and Efficiency established by the Inspector General Reform Act of 2008 (Public Law 110–409).

(b) REPORTS.—

(1) FLASH AND OTHER REPORTS.—The Board shall submit to the President and Congress, including the Committees on Appropriations of the Senate and House of Representatives, reports, to be known as "flash reports", on potential management and funding problems that require immediate attention. The Board also shall submit to Congress such other reports as the Board considers appropriate on the use and benefits of funds made available in this Act.

(2) QUARTERLY REPORTS.—The Board shall submit quarterly reports to the President and Congress, including the Committees on Appropriations of the Senate and House of Representatives, summarizing the findings of the Board and the findings of inspectors general of agencies. The Board may submit additional reports as appropriate.

(3) ANNUAL REPORTS.—The Board shall submit annual reports to the President and Congress, including the Committees on Appropriations of the Senate and House of Representatives, consolidating applicable quarterly reports on the use of covered funds.

(4) PUBLIC AVAILABILITY.—

(A) IN GENERAL.—All reports submitted under this subsection shall be made publicly available and posted on the website established by section 1526. Web posting.

(B) REDACTIONS.—Any portion of a report submitted under this subsection may be redacted when made publicly available, if that portion would disclose information that is not subject to disclosure under sections 552 and 552a of title 5, United States Code.

(c) RECOMMENDATIONS.—

(1) IN GENERAL.—The Board shall make recommendations to agencies on measures to prevent fraud, waste, and abuse relating to covered funds.

(2) RESPONSIVE REPORTS.—Not later than 30 days after receipt of a recommendation under paragraph (1), an agency shall submit a report to the President, the congressional committees of jurisdiction, including the Committees on Appropriations of the Senate and House of Representatives, and the Board on—

(A) whether the agency agrees or disagrees with the recommendations; and

(B) any actions the agency will take to implement the recommendations.

SEC. 1524. POWERS OF THE BOARD.

(a) IN GENERAL.—The Board shall conduct audits and reviews of spending of covered funds and coordinate on such activities with the inspectors general of the relevant agency to avoid duplication and overlap of work. Audits.

(b) AUDITS AND REVIEWS.—The Board may—

(1) conduct its own independent audits and reviews relating to covered funds; and

(2) collaborate on audits and reviews relating to covered funds with any inspector general of an agency.

(c) AUTHORITIES.—

(1) AUDITS AND REVIEWS.—In conducting audits and reviews, the Board shall have the authorities provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.). Additionally, the Board may issue subpoenas to compel the testimony of persons who are not Federal officers or employees and may enforce such subpoenas in the same manner as provided for inspector general subpoenas under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(2) STANDARDS AND GUIDELINES.—The Board shall carry out the powers under subsections (a) and (b) in accordance

with section 4(b)(1) of the Inspector General Act of 1978 (5 U.S.C. App.).

(d) PUBLIC HEARINGS.—The Board may hold public hearings and Board personnel may conduct necessary inquiries. The head of each agency shall make all officers and employees of that agency available to provide testimony to the Board and Board personnel. The Board may issue subpoenas to compel the testimony of persons who are not Federal officers or employees at such public hearings. Any such subpoenas may be enforced in the same manner as provided for inspector general subpoenas under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(e) CONTRACTS.—The Board may enter into contracts to enable the Board to discharge its duties under this subtitle, including contracts and other arrangements for audits, studies, analyses, and other services with public agencies and with private persons, and make such payments as may be necessary to carry out the duties of the Board.

(f) TRANSFER OF FUNDS.—The Board may transfer funds appropriated to the Board for expenses to support administrative support services and audits, reviews, or other activities related to oversight by the Board of covered funds to any office of inspector general, the Office of Management and Budget, the General Services Administration, and the Panel.

SEC. 1525. EMPLOYMENT, PERSONNEL, AND RELATED AUTHORITIES.

(a) EMPLOYMENT AND PERSONNEL AUTHORITIES.—

(1) IN GENERAL.—

(A) AUTHORITIES.—Subject to paragraph (2), the Board may exercise the authorities of subsections (b) through (i) of section 3161 of title 5, United States Code (without regard to subsection (a) of that section).

(B) APPLICATION.—For purposes of exercising the authorities described under subparagraph (A), the term "Chairperson of the Board" shall be substituted for the term "head of a temporary organization".

(C) CONSULTATION.—In exercising the authorities described under subparagraph (A), the Chairperson shall consult with members of the Board.

(2) EMPLOYMENT AUTHORITIES.—In exercising the employment authorities under subsection (b) of section 3161 of title 5, United States Code, as provided under paragraph (1) of this subsection—

(A) paragraph (2) of subsection (b) of section 3161 of that title (relating to periods of appointments) shall not apply; and

(B) no period of appointment may exceed the date on which the Board terminates under section 1530.

(b) INFORMATION AND ASSISTANCE.—

(1) IN GENERAL.—Upon request of the Board for information or assistance from any agency or other entity of the Federal Government, the head of such entity shall, insofar as is practicable and not in contravention of any existing law, furnish such information or assistance to the Board, or an authorized designee.

(2) REPORT OF REFUSALS.—Whenever information or assistance requested by the Board is, in the judgment of the Board, unreasonably refused or not provided, the Board shall report

the circumstances to the congressional committees of jurisdiction, including the Committees on Appropriations of the Senate and House of Representatives, without delay.

(c) ADMINISTRATIVE SUPPORT.—The General Services Administration shall provide the Board with administrative support services, including the provision of office space and facilities.

SEC. 1526. BOARD WEBSITE.

Deadline. Public information.

(a) ESTABLISHMENT.—The Board shall establish and maintain, no later than 30 days after enactment of this Act, a user-friendly, public-facing website to foster greater accountability and transparency in the use of covered funds.

(b) PURPOSE.—The website established and maintained under subsection (a) shall be a portal or gateway to key information relating to this Act and provide connections to other Government websites with related information.

Contracts. Grants.

(c) CONTENT AND FUNCTION.—In establishing the website established and maintained under subsection (a), the Board shall ensure the following:

(1) The website shall provide materials explaining what this Act means for citizens. The materials shall be easy to understand and regularly updated.

(2) The website shall provide accountability information, including findings from audits, inspectors general, and the Government Accountability Office.

(3) The website shall provide data on relevant economic, financial, grant, and contract information in user-friendly visual presentations to enhance public awareness of the use of covered funds.

(4) The website shall provide detailed data on contracts awarded by the Federal Government that expend covered funds, including information about the competitiveness of the contracting process, information about the process that was used for the award of contracts, and for contracts over $500,000 a summary of the contract.

(5) The website shall include printable reports on covered funds obligated by month to each State and congressional district.

(6) The website shall provide a means for the public to give feedback on the performance of contracts that expend covered funds.

(7) The website shall include detailed information on Federal Government contracts and grants that expend covered funds, to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 (Public Law 109–282), allowing aggregate reporting on awards below $25,000 or to individuals, as prescribed by the Director of the Office of Management and Budget.

(8) The website shall provide a link to estimates of the jobs sustained or created by the Act.

(9) The website shall provide a link to information about announcements of grant competitions and solicitations for contracts to be awarded.

(10) The website shall include appropriate links to other government websites with information concerning covered funds, including Federal agency and State websites.

Plan.

(11) The website shall include a plan from each Federal agency for using funds made available in this Act to the agency.

(12) The website shall provide information on Federal allocations of formula grants and awards of competitive grants using covered funds.

(13) The website shall provide information on Federal allocations of mandatory and other entitlement programs by State, county, or other appropriate geographical unit.

(14) To the extent practical, the website shall provide, organized by the location of the job opportunities involved, links to and information about how to access job opportunities, including, if possible, links to or information about local employment agencies, job banks operated by State workforce agencies, the Department of Labor's CareerOneStop website, State, local and other public agencies receiving Federal funding, and private firms contracted to perform work with Federal funding, in order to direct job seekers to job opportunities created by this Act.

(15) The website shall be enhanced and updated as necessary to carry out the purposes of this subtitle.

(d) WAIVER.—The Board may exclude posting contractual or other information on the website on a case-by-case basis when necessary to protect national security or to protect information that is not subject to disclosure under sections 552 and 552a of title 5, United States Code.

SEC. 1527. INDEPENDENCE OF INSPECTORS GENERAL.

(a) INDEPENDENT AUTHORITY.—Nothing in this subtitle shall affect the independent authority of an inspector general to determine whether to conduct an audit or investigation of covered funds.

Deadline.
Reports.

(b) REQUESTS BY BOARD.—If the Board requests that an inspector general conduct or refrain from conducting an audit or investigation and the inspector general rejects the request in whole or in part, the inspector general shall, not later than 30 days after rejecting the request, submit a report to the Board, the head of the applicable agency, and the congressional committees of jurisdiction, including the Committees on Appropriations of the Senate and House of Representatives. The report shall state the reasons that the inspector general has rejected the request in whole or in part. The inspector general's decision shall be final.

SEC. 1528. COORDINATION WITH THE COMPTROLLER GENERAL AND STATE AUDITORS.

The Board shall coordinate its oversight activities with the Comptroller General of the United States and State auditors.

SEC. 1529. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as necessary to carry out this subtitle.

SEC. 1530. TERMINATION OF THE BOARD.

The Board shall terminate on September 30, 2013.

Subtitle C—Recovery Independent Advisory Panel

SEC. 1541. ESTABLISHMENT OF RECOVERY INDEPENDENT ADVISORY PANEL.

(a) ESTABLISHMENT.—There is established the Recovery Independent Advisory Panel.

(b) MEMBERSHIP.—The Panel shall be composed of 5 members who shall be appointed by the President.

President.

(c) QUALIFICATIONS.—Members shall be appointed on the basis of expertise in economics, public finance, contracting, accounting, or any other relevant field.

(d) INITIAL MEETING.—Not later than 30 days after the date on which all members of the Panel have been appointed, the Panel shall hold its first meeting.

Deadline.

(e) MEETINGS.—The Panel shall meet at the call of the Chairperson of the Panel.

(f) QUORUM.—A majority of the members of the Panel shall constitute a quorum, but a lesser number of members may hold hearings.

(g) CHAIRPERSON AND VICE CHAIRPERSON.—The Panel shall select a Chairperson and Vice Chairperson from among its members.

SEC. 1542. DUTIES OF THE PANEL.

The Panel shall make recommendations to the Board on actions the Board could take to prevent fraud, waste, and abuse relating to covered funds.

Recommendations.

SEC. 1543. POWERS OF THE PANEL.

(a) HEARINGS.—The Panel may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Panel considers advisable to carry out this subtitle.

(b) INFORMATION FROM FEDERAL AGENCIES.—The Panel may secure directly from any agency such information as the Panel considers necessary to carry out this subtitle. Upon request of the Chairperson of the Panel, the head of such agency shall furnish such information to the Panel.

(c) POSTAL SERVICES.—The Panel may use the United States mails in the same manner and under the same conditions as agencies of the Federal Government.

(d) GIFTS.—The Panel may accept, use, and dispose of gifts or donations of services or property.

SEC. 1544. PANEL PERSONNEL MATTERS.

(a) COMPENSATION OF MEMBERS.—Each member of the Panel who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Panel. All members of the Panel who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(b) TRAVEL EXPENSES.—The members of the Panel shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Panel.

(c) STAFF.—

(1) IN GENERAL.—The Chairperson of the Panel may, without regard to the civil service laws and regulations, appoint and terminate an executive director and such other additional personnel as may be necessary to enable the Panel to perform its duties. The employment of an executive director shall be subject to confirmation by the Panel.

(2) COMPENSATION.—The Chairperson of the Panel may fix the compensation of the executive director and other personnel without regard to chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates, except that the rate of pay for the executive director and other personnel may not exceed the rate payable for level V of the Executive Schedule under section 5316 of such title.

(3) PERSONNEL AS FEDERAL EMPLOYEES.—

(A) IN GENERAL.—The executive director and any personnel of the Panel who are employees shall be employees under section 2105 of title 5, United States Code, for purposes of chapters 63, 81, 83, 84, 85, 87, 89, 89A, 89B, and 90 of that title.

(B) MEMBERS OF PANEL.—Subparagraph (A) shall not be construed to apply to members of the Panel.

(d) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Panel without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

(e) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.—The Chairperson of the Panel may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

(f) ADMINISTRATIVE SUPPORT.—The General Services Administration shall provide the Panel with administrative support services, including the provision of office space and facilities.

SEC. 1545. TERMINATION OF THE PANEL.

The Panel shall terminate on September 30, 2013.

SEC. 1546. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as necessary to carry out this subtitle.

Subtitle D—Additional Accountability and Transparency Requirements

SEC. 1551. AUTHORITY TO ESTABLISH SEPARATE FUNDING ACCOUNTS.

Waiver authority.

Although this Act provides supplemental appropriations for programs, projects, and activities in existing Treasury accounts,

to facilitate tracking these funds through Treasury and agency accounting systems, the Secretary of the Treasury shall ensure that all funds appropriated in this Act shall be established in separate Treasury accounts, unless a waiver from this provision is approved by the Director of the Office of Management and Budget.

SEC. 1552. SET-ASIDE FOR STATE AND LOCAL GOVERNMENT REPORTING AND RECORDKEEPING.

Federal agencies receiving funds under this Act, may, after following the notice and comment rulemaking requirements under the Administrative Procedures Act (5 U.S.C. 500), reasonably adjust applicable limits on administrative expenditures for Federal awards to help award recipients defray the costs of data collection requirements initiated pursuant to this Act.

SEC. 1553. PROTECTING STATE AND LOCAL GOVERNMENT AND CONTRACTOR WHISTLEBLOWERS.

(a) PROHIBITION OF REPRISALS.—An employee of any non-Federal employer receiving covered funds may not be discharged, demoted, or otherwise discriminated against as a reprisal for disclosing, including a disclosure made in the ordinary course of an employee's duties, to the Board, an inspector general, the Comptroller General, a member of Congress, a State or Federal regulatory or law enforcement agency, a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate misconduct), a court or grand jury, the head of a Federal agency, or their representatives, information that the employee reasonably believes is evidence of—

(1) gross mismanagement of an agency contract or grant relating to covered funds;

(2) a gross waste of covered funds;

(3) a substantial and specific danger to public health or safety related to the implementation or use of covered funds;

(4) an abuse of authority related to the implementation or use of covered funds; or

(5) a violation of law, rule, or regulation related to an agency contract (including the competition for or negotiation of a contract) or grant, awarded or issued relating to covered funds.

(b) INVESTIGATION OF COMPLAINTS.—

(1) IN GENERAL.—A person who believes that the person has been subjected to a reprisal prohibited by subsection (a) may submit a complaint regarding the reprisal to the appropriate inspector general. Except as provided under paragraph (3), unless the inspector general determines that the complaint is frivolous, does not relate to covered funds, or another Federal or State judicial or administrative proceeding has previously been invoked to resolve such complaint, the inspector general shall investigate the complaint and, upon completion of such investigation, submit a report of the findings of the investigation to the person, the person's employer, the head of the appropriate agency, and the Board.

(2) TIME LIMITATIONS FOR ACTIONS.—

(A) IN GENERAL.—Except as provided under subparagraph (B), the inspector general shall, not later than 180 days after receiving a complaint under paragraph (1)— Deadline.

Determination.

(i) make a determination that the complaint is frivolous, does not relate to covered funds, or another Federal or State judicial or administrative proceeding has previously been invoked to resolve such complaint; or

Reports.

(ii) submit a report under paragraph (1).

(B) EXTENSIONS.—

(i) VOLUNTARY EXTENSION AGREED TO BETWEEN INSPECTOR GENERAL AND COMPLAINANT.—If the inspector general is unable to complete an investigation under this section in time to submit a report within the 180-day period specified under subparagraph (A) and the person submitting the complaint agrees to an extension of time, the inspector general shall submit a report under paragraph (1) within such additional period of time as shall be agreed upon between the inspector general and the person submitting the complaint.

(ii) EXTENSION GRANTED BY INSPECTOR GENERAL.—If the inspector general is unable to complete an investigation under this section in time to submit a report within the 180-day period specified under subparagraph (A), the inspector general may extend the period for not more than 180 days without agreeing with the person submitting the complaint to such extension, provided that the inspector general provides a written explanation (subject to the authority to exclude information under paragraph (4)(C)) for the decision, which shall be provided to both the person submitting the complaint and the non-Federal employer.

(iii) SEMI-ANNUAL REPORT ON EXTENSIONS.—The inspector general shall include in semi-annual reports to Congress a list of those investigations for which the inspector general received an extension.

(3) DISCRETION NOT TO INVESTIGATE COMPLAINTS.—

(A) IN GENERAL.—The inspector general may decide not to conduct or continue an investigation under this section upon providing to the person submitting the complaint and the non-Federal employer a written explanation (subject to the authority to exclude information under paragraph (4)(C)) for such decision.

(B) ASSUMPTION OF RIGHTS TO CIVIL REMEDY.—Upon receipt of an explanation of a decision not to conduct or continue an investigation under subparagraph (A), the person submitting a complaint shall immediately assume the right to a civil remedy under subsection (c)(3) as if the 210-day period specified under such subsection has already passed.

(C) SEMI-ANNUAL REPORT.—The inspector general shall include in semi-annual reports to Congress a list of those investigations the inspector general decided not to conduct or continue under this paragraph.

(4) ACCESS TO INVESTIGATIVE FILE OF INSPECTOR GENERAL.—

(A) IN GENERAL.—The person alleging a reprisal under this section shall have access to the investigation file of

the appropriate inspector general in accordance with section 552a of title 5, United States Code (commonly referred to as the "Privacy Act"). The investigation of the inspector general shall be deemed closed for purposes of disclosure under such section when an employee files an appeal to an agency head or a court of competent jurisdiction.

(B) CIVIL ACTION.—In the event the person alleging the reprisal brings suit under subsection (c)(3), the person alleging the reprisal and the non-Federal employer shall have access to the investigative file of the inspector general in accordance with the Privacy Act.

(C) EXCEPTION.—The inspector general may exclude from disclosure—

(i) information protected from disclosure by a provision of law; and

(ii) any additional information the inspector general determines disclosure of which would impede a continuing investigation, provided that such information is disclosed once such disclosure would no longer impede such investigation, unless the inspector general determines that disclosure of law enforcement techniques, procedures, or information could reasonably be expected to risk circumvention of the law or disclose the identity of a confidential source.

(5) PRIVACY OF INFORMATION.—An inspector general investigating an alleged reprisal under this section may not respond to any inquiry or disclose any information from or about any person alleging such reprisal, except in accordance with the provisions of section 552a of title 5, United States Code, or as required by any other applicable Federal law.

(c) REMEDY AND ENFORCEMENT AUTHORITY.—

(1) BURDEN OF PROOF.—

(A) DISCLOSURE AS CONTRIBUTING FACTOR IN REPRISAL.—

(i) IN GENERAL.—A person alleging a reprisal under this section shall be deemed to have affirmatively established the occurrence of the reprisal if the person demonstrates that a disclosure described in subsection (a) was a contributing factor in the reprisal.

(ii) USE OF CIRCUMSTANTIAL EVIDENCE.—A disclosure may be demonstrated as a contributing factor in a reprisal for purposes of this paragraph by circumstantial evidence, including—

(I) evidence that the official undertaking the reprisal knew of the disclosure; or

(II) evidence that the reprisal occurred within a period of time after the disclosure such that a reasonable person could conclude that the disclosure was a contributing factor in the reprisal.

(B) OPPORTUNITY FOR REBUTTAL.—The head of an agency may not find the occurrence of a reprisal with respect to a reprisal that is affirmatively established under subparagraph (A) if the non-Federal employer demonstrates by clear and convincing evidence that the non-Federal employer would have taken the action constituting the reprisal in the absence of the disclosure.

Deadline.
Determination.
Relief orders.

(2) AGENCY ACTION.—Not later than 30 days after receiving an inspector general report under subsection (b), the head of the agency concerned shall determine whether there is sufficient basis to conclude that the non-Federal employer has subjected the complainant to a reprisal prohibited by subsection (a) and shall either issue an order denying relief in whole or in part or shall take 1 or more of the following actions:

(A) Order the employer to take affirmative action to abate the reprisal.

(B) Order the employer to reinstate the person to the position that the person held before the reprisal, together with the compensation (including back pay), compensatory damages, employment benefits, and other terms and conditions of employment that would apply to the person in that position if the reprisal had not been taken.

(C) Order the employer to pay the complainant an amount equal to the aggregate amount of all costs and expenses (including attorneys' fees and expert witnesses' fees) that were reasonably incurred by the complainant for, or in connection with, bringing the complaint regarding the reprisal, as determined by the head of the agency or a court of competent jurisdiction.

Deadlines.

(3) CIVIL ACTION.—If the head of an agency issues an order denying relief in whole or in part under paragraph (1), has not issued an order within 210 days after the submission of a complaint under subsection (b), or in the case of an extension of time under subsection (b)(2)(B)(i), within 30 days after the expiration of the extension of time, or decides under subsection (b)(3) not to investigate or to discontinue an investigation, and there is no showing that such delay or decision is due to the bad faith of the complainant, the complainant shall be deemed to have exhausted all administrative remedies with respect to the complaint, and the complainant may bring a de novo action at law or equity against the employer to seek compensatory damages and other relief available under this section in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy. Such an action shall, at the request of either party to the action, be tried by the court with a jury.

(4) JUDICIAL ENFORCEMENT OF ORDER.—Whenever a person fails to comply with an order issued under paragraph (2), the head of the agency shall file an action for enforcement of such order in the United States district court for a district in which the reprisal was found to have occurred. In any action brought under this paragraph, the court may grant appropriate relief, including injunctive relief, compensatory and exemplary damages, and attorneys fees and costs.

(5) JUDICIAL REVIEW.—Any person adversely affected or aggrieved by an order issued under paragraph (2) may obtain review of the order's conformance with this subsection, and any regulations issued to carry out this section, in the United States court of appeals for a circuit in which the reprisal is alleged in the order to have occurred. No petition seeking such review may be filed more than 60 days after issuance of the order by the head of the agency. Review shall conform to chapter 7 of title 5, United States Code.

Deadline.

(d) NONENFORCEABILITY OF CERTAIN PROVISIONS WAIVING RIGHTS AND REMEDIES OR REQUIRING ARBITRATION OF DISPUTES.—

(1) WAIVER OF RIGHTS AND REMEDIES.—Except as provided under paragraph (3), the rights and remedies provided for in this section may not be waived by any agreement, policy, form, or condition of employment, including by any predispute arbitration agreement.

(2) PREDISPUTE ARBITRATION AGREEMENTS.—Except as provided under paragraph (3), no predispute arbitration agreement shall be valid or enforceable if it requires arbitration of a dispute arising under this section.

(3) EXCEPTION FOR COLLECTIVE BARGAINING AGREEMENTS.—Notwithstanding paragraphs (1) and (2), an arbitration provision in a collective bargaining agreement shall be enforceable as to disputes arising under the collective bargaining agreement.

(e) REQUIREMENT TO POST NOTICE OF RIGHTS AND REMEDIES.—Any employer receiving covered funds shall post notice of the rights and remedies provided under this section.

(f) RULES OF CONSTRUCTION.—

(1) NO IMPLIED AUTHORITY TO RETALIATE FOR NON-PROTECTED DISCLOSURES.—Nothing in this section may be construed to authorize the discharge of, demotion of, or discrimination against an employee for a disclosure other than a disclosure protected by subsection (a) or to modify or derogate from a right or remedy otherwise available to the employee.

(2) RELATIONSHIP TO STATE LAWS.—Nothing in this section may be construed to preempt, preclude, or limit the protections provided for public or private employees under State whistleblower laws.

(g) DEFINITIONS.—In this section:

(1) ABUSE OF AUTHORITY.—The term "abuse of authority" means an arbitrary and capricious exercise of authority by a contracting official or employee that adversely affects the rights of any person, or that results in personal gain or advantage to the official or employee or to preferred other persons.

(2) COVERED FUNDS.—The term "covered funds" means any contract, grant, or other payment received by any non-Federal employer if—

(A) the Federal Government provides any portion of the money or property that is provided, requested, or demanded; and

(B) at least some of the funds are appropriated or otherwise made available by this Act.

(3) EMPLOYEE.—The term "employee"—

(A) except as provided under subparagraph (B), means an individual performing services on behalf of an employer; and

(B) does not include any Federal employee or member of the uniformed services (as that term is defined in section 101(a)(5) of title 10, United States Code).

(4) NON-FEDERAL EMPLOYER.—The term "non-Federal employer"—

(A) means any employer—

(i) with respect to covered funds—

(I) the contractor, subcontractor, grantee, or recipient, as the case may be, if the contractor,

subcontractor, grantee, or recipient is an employer; and

(II) any professional membership organization, certification or other professional body, any agent or licensee of the Federal government, or any person acting directly or indirectly in the interest of an employer receiving covered funds; or

(ii) with respect to covered funds received by a State or local government, the State or local government receiving the funds and any contractor or subcontractor of the State or local government; and

(B) does not mean any department, agency, or other entity of the Federal Government.

(5) STATE OR LOCAL GOVERNMENT.—The term "State or local government" means—

(A) the government of each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, or any other territory or possession of the United States; or

(B) the government of any political subdivision of a government listed in subparagraph (A).

SEC. 1554. SPECIAL CONTRACTING PROVISIONS.

To the maximum extent possible, contracts funded under this Act shall be awarded as fixed-price contracts through the use of competitive procedures. A summary of any contract awarded with such funds that is not fixed-price and not awarded using competitive procedures shall be posted in a special section of the website established in section 1526.

TITLE XVI—GENERAL PROVISIONS—THIS ACT

RELATIONSHIP TO OTHER APPROPRIATIONS

SEC. 1601. Each amount appropriated or made available in this Act is in addition to amounts otherwise appropriated for the fiscal year involved. Enactment of this Act shall have no effect on the availability of amounts under the Continuing Appropriations Resolution, 2009 (division A of Public Law 110–329).

PREFERENCE FOR QUICK-START ACTIVITIES

SEC. 1602. In using funds made available in this Act for infrastructure investment, recipients shall give preference to activities that can be started and completed expeditiously, including a goal of using at least 50 percent of the funds for activities that can be initiated not later than 120 days after the date of the enactment of this Act. Recipients shall also use grant funds in a manner that maximizes job creation and economic benefit.

PERIOD OF AVAILABILITY

SEC. 1603. All funds appropriated in this Act shall remain available for obligation until September 30, 2010, unless expressly provided otherwise in this Act.

LIMIT ON FUNDS

SEC. 1604. None of the funds appropriated or otherwise made available in this Act may be used by any State or local government, or any private entity, for any casino or other gambling establishment, aquarium, zoo, golf course, or swimming pool.

BUY AMERICAN

SEC. 1605. USE OF AMERICAN IRON, STEEL, AND MANUFACTURED GOODS. (a) None of the funds appropriated or otherwise made available by this Act may be used for a project for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States.

Waiver authority.

(b) Subsection (a) shall not apply in any case or category of cases in which the head of the Federal department or agency involved finds that—

(1) applying subsection (a) would be inconsistent with the public interest;

(2) iron, steel, and the relevant manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or

(3) inclusion of iron, steel, and manufactured goods produced in the United States will increase the cost of the overall project by more than 25 percent.

Federal Register, publication.

(c) If the head of a Federal department or agency determines that it is necessary to waive the application of subsection (a) based on a finding under subsection (b), the head of the department or agency shall publish in the Federal Register a detailed written justification as to why the provision is being waived.

Applicability.

(d) This section shall be applied in a manner consistent with United States obligations under international agreements.

WAGE RATE REQUIREMENTS

Contracts.

SEC. 1606. Notwithstanding any other provision of law and in a manner consistent with other provisions in this Act, all laborers and mechanics employed by contractors and subcontractors on projects funded directly by or assisted in whole or in part by and through the Federal Government pursuant to this Act shall be paid wages at rates not less than those prevailing on projects of a character similar in the locality as determined by the Secretary of Labor in accordance with subchapter IV of chapter 31 of title 40, United States Code. With respect to the labor standards specified in this section, the Secretary of Labor shall have the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (64 Stat. 1267; 5 U.S.C. App.) and section 3145 of title 40, United States Code.

ADDITIONAL FUNDING DISTRIBUTION AND ASSURANCE OF APPROPRIATE USE OF FUNDS

Deadline.

SEC. 1607. (a) CERTIFICATION BY GOVERNOR.—Not later than 45 days after the date of enactment of this Act, for funds provided to any State or agency thereof, the Governor of the State shall certify that: (1) the State will request and use funds provided by this Act; and (2) the funds will be used to create jobs and promote economic growth.

(b) ACCEPTANCE BY STATE LEGISLATURE.—If funds provided to any State in any division of this Act are not accepted for use by the Governor, then acceptance by the State legislature, by means of the adoption of a concurrent resolution, shall be sufficient to provide funding to such State.

(c) DISTRIBUTION.—After the adoption of a State legislature's concurrent resolution, funding to the State will be for distribution to local governments, councils of government, public entities, and public-private entities within the State either by formula or at the State's discretion.

ECONOMIC STABILIZATION CONTRACTING

SEC. 1608. REFORM OF CONTRACTING PROCEDURES UNDER EESA. Section 107(b) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5217(b)) is amended by inserting "and individuals with disabilities and businesses owned by individuals with disabilities (for purposes of this subsection the term 'individual with disability' has the same meaning as the term 'handicapped individual' as that term is defined in section 3(f) of the Small Business Act (15 U.S.C. 632(f))," after "(12 U.S.C. 1441a(r)(4)),".

SEC. 1609. (a) FINDINGS.—

(1) The National Environmental Policy Act protects public health, safety and environmental quality: by ensuring transparency, accountability and public involvement in federal actions and in the use of public funds;

(2) When President Nixon signed the National Environmental Policy Act into law on January 1, 1970, he said that the Act provided the "direction" for the country to "regain a productive harmony between man and nature";

(3) The National Environmental Policy Act helps to provide an orderly process for considering federal actions and funding decisions and prevents ligation and delay that would otherwise be inevitable and existed prior to the establishment of the National Environmental Policy Act.

(b) Adequate resources within this bill must be devoted to ensuring that applicable environmental reviews under the National Environmental Policy Act are completed on an expeditious basis and that the shortest existing applicable process under the National Environmental Policy Act shall be utilized.

President. Reports. Deadlines.

(c) The President shall report to the Senate Environment and Public Works Committee and the House Natural Resources Committee every 90 days following the date of enactment until September 30, 2011 on the status and progress of projects and activities funded by this Act with respect to compliance with National Environmental Policy Act requirements and documentation.

SEC. 1610. (a) None of the funds appropriated or otherwise made available by this Act, for projects initiated after the effective date of this Act, may be used by an executive agency to enter into any Federal contract unless such contract is entered into in accordance with the Federal Property and Administrative Services Act (41 U.S.C. 253) or chapter 137 of title 10, United States Code, and the Federal Acquisition Regulation, unless such contract is otherwise authorized by statute to be entered into without regard to the above referenced statutes.

(b) All projects to be conducted under the authority of the Indian Self-Determination and Education Assistance Act, the Tribally-Controlled Schools Act, the Sanitation and Facilities Act, the

Native American Housing and Self-Determination Assistance Act and the Buy-Indian Act shall be identified by the appropriate Secretary and the appropriate Secretary shall incorporate provisions to ensure that the agreement conforms with the provisions of this Act regarding the timing for use of funds and transparency, oversight, reporting, and accountability, including review by the Inspectors General, the Accountability and Transparency Board, and Government Accountability Office, consistent with the objectives of this Act.

Employ American Workers Act.

SEC. 1611. HIRING AMERICAN WORKERS IN COMPANIES RECEIVING TARP FUNDING. (a) SHORT TITLE.—This section may be cited as the "Employ American Workers Act".

(b) PROHIBITION.—

(1) IN GENERAL.—Notwithstanding any other provision of law, it shall be unlawful for any recipient of funding under title I of the Emergency Economic Stabilization Act of 2008 (Public Law 110–343) or section 13 of the Federal Reserve Act (12 U.S.C. 342 et seq.) to hire any nonimmigrant described in section 101(a)(15)(h)(i)(b) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(15)(h)(i)(b)) unless the recipient is in compliance with the requirements for an H–1B dependent employer (as defined in section 212(n)(3) of such Act (8 U.S.C. 1182(n)(3))), except that the second sentence of section 212(n)(1)(E)(ii) of such Act shall not apply.

(2) DEFINED TERM.—In this subsection, the term "hire" means to permit a new employee to commence a period of employment.

(c) SUNSET PROVISION.—This section shall be effective during the 2-year period beginning on the date of the enactment of this Act.

SEC. 1612. During the current fiscal year not to exceed 1 percent of any appropriation made available by this Act may be transferred by an agency head between such appropriations funded in this Act of that department or agency: *Provided,* That such appropriations shall be merged with and available for the same purposes, and for the same time period, as the appropriation to which transferred: *Provided further,* That the agency head shall notify the Committees on Appropriations of the Senate and House of Representatives of the transfer 15 days in advance: *Provided further,* That notice of any transfer made pursuant to this authority be posted on the website established by the Recovery Act Accountability and Transparency Board 15 days following such transfer: *Provided further,* That the authority contained in this section is in addition to transfer authorities otherwise available under current law: *Provided further,* That the authority provided in this section shall not apply to any appropriation that is subject to transfer provisions included elsewhere in this Act.

Notification. Deadline.

Notification. Web posting. Deadline.

DIVISION B—TAX, UNEMPLOYMENT, HEALTH, STATE FISCAL RELIEF, AND OTHER PROVISIONS

TITLE I—TAX PROVISIONS

American Recovery and Reinvestment Tax Act of 2009.

26 USC 1 note.

SEC. 1000. SHORT TITLE, ETC.

(a) SHORT TITLE.—This title may be cited as the "American Recovery and Reinvestment Tax Act of 2009".

26 USC 1 *et seq*.

(b) REFERENCE.—Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

(c) TABLE OF CONTENTS.—The table of contents for this title is as follows:

TITLE I—TAX PROVISIONS

Sec. 1000. Short title, etc.

Subtitle A—Tax Relief for Individuals and Families

PART I—GENERAL TAX RELIEF

Sec. 1001. Making work pay credit.
Sec. 1002. Temporary increase in earned income tax credit.
Sec. 1003. Temporary increase of refundable portion of child credit.
Sec. 1004. American opportunity tax credit.
Sec. 1005. Computer technology and equipment allowed as a qualified higher education expense for section 529 accounts in 2009 and 2010.
Sec. 1006. Extension of and increase in first-time homebuyer credit; waiver of requirement to repay.
Sec. 1007. Suspension of tax on portion of unemployment compensation.
Sec. 1008. Additional deduction for State sales tax and excise tax on the purchase of certain motor vehicles.

PART II—ALTERNATIVE MINIMUM TAX RELIEF

Sec. 1011. Extension of alternative minimum tax relief for nonrefundable personal credits.
Sec. 1012. Extension of increased alternative minimum tax exemption amount.

Subtitle B—Energy Incentives

PART I—RENEWABLE ENERGY INCENTIVES

Sec. 1101. Extension of credit for electricity produced from certain renewable resources.
Sec. 1102. Election of investment credit in lieu of production credit.
Sec. 1103. Repeal of certain limitations on credit for renewable energy property.
Sec. 1104. Coordination with renewable energy grants.

PART II—INCREASED ALLOCATIONS OF NEW CLEAN RENEWABLE ENERGY BONDS AND QUALIFIED ENERGY CONSERVATION BONDS

Sec. 1111. Increased limitation on issuance of new clean renewable energy bonds.
Sec. 1112. Increased limitation on issuance of qualified energy conservation bonds.

PART III—ENERGY CONSERVATION INCENTIVES

Sec. 1121. Extension and modification of credit for nonbusiness energy property.
Sec. 1122. Modification of credit for residential energy efficient property.
Sec. 1123. Temporary increase in credit for alternative fuel vehicle refueling property.

PART IV—MODIFICATION OF CREDIT FOR CARBON DIOXIDE SEQUESTRATION

Sec. 1131. Application of monitoring requirements to carbon dioxide used as a tertiary injectant.

PART V—PLUG-IN ELECTRIC DRIVE MOTOR VEHICLES

Sec. 1141. Credit for new qualified plug-in electric drive motor vehicles.
Sec. 1142. Credit for certain plug-in electric vehicles.
Sec. 1143. Conversion kits.
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PART VI—PARITY FOR TRANSPORTATION FRINGE BENEFITS

Sec. 1151. Increased exclusion amount for commuter transit benefits and transit passes.

Subtitle C—Tax Incentives for Business

PART I—TEMPORARY INVESTMENT INCENTIVES

Sec. 1201. Special allowance for certain property acquired during 2009.
Sec. 1202. Temporary increase in limitations on expensing of certain depreciable business assets.

PART II—SMALL BUSINESS PROVISIONS

Sec. 1211. 5-year carryback of operating losses of small businesses.
Sec. 1212. Decreased required estimated tax payments in 2009 for certain small businesses.

PART III—INCENTIVES FOR NEW JOBS

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PART IV—RULES RELATING TO DEBT INSTRUMENTS

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Sec. 1232. Modifications of rules for original issue discount on certain high yield obligations.

PART V—QUALIFIED SMALL BUSINESS STOCK

Sec. 1241. Special rules applicable to qualified small business stock for 2009 and 2010.

PART VI—S CORPORATIONS

Sec. 1251. Temporary reduction in recognition period for built-in gains tax.

PART VII—RULES RELATING TO OWNERSHIP CHANGES

Sec. 1261. Clarification of regulations related to limitations on certain built-in losses following an ownership change.
Sec. 1262. Treatment of certain ownership changes for purposes of limitations on net operating loss carryforwards and certain built-in losses.

Subtitle D—Manufacturing Recovery Provisions

Sec. 1301. Temporary expansion of availability of industrial development bonds to facilities manufacturing intangible property.
Sec. 1302. Credit for investment in advanced energy facilities.

Subtitle E—Economic Recovery Tools

Sec. 1401. Recovery zone bonds.
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Subtitle F—Infrastructure Financing Tools

PART I—IMPROVED MARKETABILITY FOR TAX-EXEMPT BONDS

Sec. 1501. De minimis safe harbor exception for tax-exempt interest expense of financial institutions.
Sec. 1502. Modification of small issuer exception to tax-exempt interest expense allocation rules for financial institutions.
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PART II—DELAY IN APPLICATION OF WITHHOLDING TAX ON GOVERNMENT CONTRACTORS

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Sec. 1531. Build America bonds.

PART V—REGULATED INVESTMENT COMPANIES ALLOWED TO PASS-THRU TAX CREDIT BOND CREDITS

Sec. 1541. Regulated investment companies allowed to pass-thru tax credit bond credits.

Subtitle G—Other Provisions

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Sec. 1800. Short title.

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Sec. 1821. Qualifying Requirements for Workers.
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Sec. 1827. Administrative expenses and employment and case management services.
Sec. 1828. Training funding.
Sec. 1829. Prerequisite education; approved training programs.
Sec. 1830. Pre-layoff and part-time training.
Sec. 1831. On-the-job training.
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SUBPART D—REEMPLOYMENT TRADE ADJUSTMENT ASSISTANCE PROGRAM

Sec. 1841. Reemployment trade adjustment assistance program.

SUBPART E—OTHER MATTERS

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Sec. 1853. Verification of eligibility for program benefits.
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Sec. 1855. Fraud and recovery of overpayments.
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Sec. 1899J. Authorization of appropriations.
Sec. 1899K. Extension of national emergency grants.
Sec. 1899L. GAO study and report.

Subtitle A—Tax Relief for Individuals and Families

PART I—GENERAL TAX RELIEF

SEC. 1001. MAKING WORK PAY CREDIT.

(a) IN GENERAL.—Subpart C of part IV of subchapter A of chapter 1 is amended by inserting after section 36 the following new section:

"SEC. 36A. MAKING WORK PAY CREDIT.

"(a) ALLOWANCE OF CREDIT.—In the case of an eligible individual, there shall be allowed as a credit against the tax imposed

by this subtitle for the taxable year an amount equal to the lesser of—

"(1) 6.2 percent of earned income of the taxpayer, or

"(2) $400 ($800 in the case of a joint return).

"(b) LIMITATION BASED ON MODIFIED ADJUSTED GROSS INCOME.—

"(1) IN GENERAL.—The amount allowable as a credit under subsection (a) (determined without regard to this paragraph and subsection (c)) for the taxable year shall be reduced (but not below zero) by 2 percent of so much of the taxpayer's modified adjusted gross income as exceeds $75,000 ($150,000 in the case of a joint return).

"(2) MODIFIED ADJUSTED GROSS INCOME.—For purposes of subparagraph (A), the term 'modified adjusted gross income' means the adjusted gross income of the taxpayer for the taxable year increased by any amount excluded from gross income under section 911, 931, or 933.

"(c) REDUCTION FOR CERTAIN OTHER PAYMENTS.—The credit allowed under subsection (a) for any taxable year shall be reduced by the amount of any payments received by the taxpayer during such taxable year under section 2201, and any credit allowed to the taxpayer under section 2202, of the American Recovery and Reinvestment Tax Act of 2009.

"(d) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

"(1) ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—The term 'eligible individual' means any individual other than—

"(i) any nonresident alien individual,

"(ii) any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which the individual's taxable year begins, and

"(iii) an estate or trust.

"(B) IDENTIFICATION NUMBER REQUIREMENT.—Such term shall not include any individual who does not include on the return of tax for the taxable year—

"(i) such individual's social security account number, and

"(ii) in the case of a joint return, the social security account number of one of the taxpayers on such return.

For purposes of the preceding sentence, the social security account number shall not include a TIN issued by the Internal Revenue Service.

"(2) EARNED INCOME.—The term 'earned income' has the meaning given such term by section 32(c)(2), except that such term shall not include net earnings from self-employment which are not taken into account in computing taxable income. For purposes of the preceding sentence, any amount excluded from gross income by reason of section 112 shall be treated as earned income which is taken into account in computing taxable income for the taxable year.

"(e) TERMINATION.—This section shall not apply to taxable years beginning after December 31, 2010.".

26 USC 36A note.

(b) TREATMENT OF POSSESSIONS.—

(1) PAYMENTS TO POSSESSIONS.—

(A) MIRROR CODE POSSESSION.—The Secretary of the Treasury shall pay to each possession of the United States with a mirror code tax system amounts equal to the loss to that possession by reason of the amendments made by this section with respect to taxable years beginning in 2009 and 2010. Such amounts shall be determined by the Secretary of the Treasury based on information provided by the government of the respective possession. Effective dates.

(B) OTHER POSSESSIONS.—The Secretary of the Treasury shall pay to each possession of the United States which does not have a mirror code tax system amounts estimated by the Secretary of the Treasury as being equal to the aggregate benefits that would have been provided to residents of such possession by reason of the amendments made by this section for taxable years beginning in 2009 and 2010 if a mirror code tax system had been in effect in such possession. The preceding sentence shall not apply with respect to any possession of the United States unless such possession has a plan, which has been approved by the Secretary of the Treasury, under which such possession will promptly distribute such payments to the residents of such possession. Effective dates.

(2) COORDINATION WITH CREDIT ALLOWED AGAINST UNITED STATES INCOME TAXES.—No credit shall be allowed against United States income taxes for any taxable year under section 36A of the Internal Revenue Code of 1986 (as added by this section) to any person—

(A) to whom a credit is allowed against taxes imposed by the possession by reason of the amendments made by this section for such taxable year, or

(B) who is eligible for a payment under a plan described in paragraph (1)(B) with respect to such taxable year.

(3) DEFINITIONS AND SPECIAL RULES.—

(A) POSSESSION OF THE UNITED STATES.—For purposes of this subsection, the term "possession of the United States" includes the Commonwealth of Puerto Rico and the Commonwealth of the Northern Mariana Islands.

(B) MIRROR CODE TAX SYSTEM.—For purposes of this subsection, the term "mirror code tax system" means, with respect to any possession of the United States, the income tax system of such possession if the income tax liability of the residents of such possession under such system is determined by reference to the income tax laws of the United States as if such possession were the United States.

(C) TREATMENT OF PAYMENTS.—For purposes of section 1324(b)(2) of title 31, United States Code, the payments under this subsection shall be treated in the same manner as a refund due from the credit allowed under section 36A of the Internal Revenue Code of 1986 (as added by this section).

(c) REFUNDS DISREGARDED IN THE ADMINISTRATION OF FEDERAL PROGRAMS AND FEDERALLY ASSISTED PROGRAMS.—Any credit or refund allowed or made to any individual by reason of section 36A of the Internal Revenue Code of 1986 (as added by this section) or by reason of subsection (b) of this section shall not be taken into account as income and shall not be taken into account as resources for the month of receipt and the following 2 months, 26 USC 36A note.

for purposes of determining the eligibility of such individual or any other individual for benefits or assistance, or the amount or extent of benefits or assistance, under any Federal program or under any State or local program financed in whole or in part with Federal funds.

26 USC 6213.

(d) AUTHORITY RELATING TO CLERICAL ERRORS.—Section 6213(g)(2) is amended by striking "and" at the end of subparagraph (L)(ii), by striking the period at the end of subparagraph (M) and inserting ", and", and by adding at the end the following new subparagraph:

"(N) an omission of the reduction required under section 36A(c) with respect to the credit allowed under section 36A or an omission of the correct social security account number required under section 36A(d)(1)(B).".

(e) CONFORMING AMENDMENTS.—

(1) Section 6211(b)(4)(A) is amended by inserting "36A," after "36,".

(2) Section 1324(b)(2) of title 31, United States Code, is amended by inserting "36A," after "36,".

(3) The table of sections for subpart C of part IV of subchapter A of chapter 1 is amended by inserting after the item relating to section 36 the following new item:

"Sec. 36A. Making work pay credit.".

26 USC 36A note.

(f) EFFECTIVE DATE.—This section, and the amendments made by this section, shall apply to taxable years beginning after December 31, 2008.

SEC. 1002. TEMPORARY INCREASE IN EARNED INCOME TAX CREDIT.

26 USC 32.

(a) IN GENERAL.—Subsection (b) of section 32 is amended by adding at the end the following new paragraph:

"(3) SPECIAL RULES FOR 2009 AND 2010.—In the case of any taxable year beginning in 2009 or 2010—

"(A) INCREASED CREDIT PERCENTAGE FOR 3 OR MORE QUALIFYING CHILDREN.—In the case of a taxpayer with 3 or more qualifying children, the credit percentage is 45 percent.

"(B) REDUCTION OF MARRIAGE PENALTY.—

"(i) IN GENERAL.—The dollar amount in effect under paragraph (2)(B) shall be $5,000.

"(ii) INFLATION ADJUSTMENT.—In the case of any taxable year beginning in 2010, the $5,000 amount in clause (i) shall be increased by an amount equal to—

"(I) such dollar amount, multiplied by

"(II) the cost of living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins determined by substituting 'calendar year 2008' for 'calendar year 1992' in subparagraph (B) thereof.

Applicability.

"(iii) ROUNDING.—Subparagraph (A) of subsection (j)(2) shall apply after taking into account any increase under clause (ii).".

26 USC 32 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008.

SEC. 1003. TEMPORARY INCREASE OF REFUNDABLE PORTION OF CHILD CREDIT.

(a) IN GENERAL.—Paragraph (4) of section 24(d) is amended to read as follows: 26 USC 24.

"(4) SPECIAL RULE FOR 2009 AND 2010.—Notwithstanding paragraph (3), in the case of any taxable year beginning in 2009 or 2010, the dollar amount in effect for such taxable year under paragraph (1)(B)(i) shall be $3,000.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 24 note.

SEC. 1004. AMERICAN OPPORTUNITY TAX CREDIT.

(a) IN GENERAL.—Section 25A (relating to Hope scholarship credit) is amended by redesignating subsection (i) as subsection (j) and by inserting after subsection (h) the following new subsection:

"(i) AMERICAN OPPORTUNITY TAX CREDIT.—In the case of any taxable year beginning in 2009 or 2010—

"(1) INCREASE IN CREDIT.—The Hope Scholarship Credit shall be an amount equal to the sum of—

"(A) 100 percent of so much of the qualified tuition and related expenses paid by the taxpayer during the taxable year (for education furnished to the eligible student during any academic period beginning in such taxable year) as does not exceed $2,000, plus

"(B) 25 percent of such expenses so paid as exceeds $2,000 but does not exceed $4,000.

"(2) CREDIT ALLOWED FOR FIRST 4 YEARS OF POST-SECONDARY EDUCATION.—Subparagraphs (A) and (C) of subsection (b)(2) shall be applied by substituting '4' for '2'. Applicability.

"(3) QUALIFIED TUITION AND RELATED EXPENSES TO INCLUDE REQUIRED COURSE MATERIALS.—Subsection (f)(1)(A) shall be applied by substituting 'tuition, fees, and course materials' for 'tuition and fees'.

"(4) INCREASE IN AGI LIMITS FOR HOPE SCHOLARSHIP CREDIT.—In lieu of applying subsection (d) with respect to the Hope Scholarship Credit, such credit (determined without regard to this paragraph) shall be reduced (but not below zero) by the amount which bears the same ratio to such credit (as so determined) as—

"(A) the excess of—

"(i) the taxpayer's modified adjusted gross income (as defined in subsection (d)(3)) for such taxable year, over

"(ii) $80,000 ($160,000 in the case of a joint return), bears to

"(B) $10,000 ($20,000 in the case of a joint return).

"(5) CREDIT ALLOWED AGAINST ALTERNATIVE MINIMUM TAX.—In the case of a taxable year to which section 26(a)(2) does not apply, so much of the credit allowed under subsection (a) as is attributable to the Hope Scholarship Credit shall not exceed the excess of—

"(A) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

"(B) the sum of the credits allowable under this subpart (other than this subsection and sections 23, 25D, and 30D) and section 27 for the taxable year.

Any reference in this section or section 24, 25, 26, 25B, 904, or 1400C to a credit allowable under this subsection shall be treated as a reference to so much of the credit allowable under subsection (a) as is attributable to the Hope Scholarship Credit.

"(6) PORTION OF CREDIT MADE REFUNDABLE.—40 percent of so much of the credit allowed under subsection (a) as is attributable to the Hope Scholarship Credit (determined after application of paragraph (4) and without regard to this paragraph and section 26(a)(2) or paragraph (5), as the case may be) shall be treated as a credit allowable under subpart C (and not allowed under subsection (a)). The preceding sentence shall not apply to any taxpayer for any taxable year if such taxpayer is a child to whom subsection (g) of section 1 applies for such taxable year.

"(7) COORDINATION WITH MIDWESTERN DISASTER AREA BENEFITS.—In the case of a taxpayer with respect to whom section 702(a)(1)(B) of the Heartland Disaster Tax Relief Act of 2008 applies for any taxable year, such taxpayer may elect to waive the application of this subsection to such taxpayer for such taxable year.".

(b) CONFORMING AMENDMENTS.—

26 USC 24.

(1) Section 24(b)(3)(B) is amended by inserting "25A(i)," after "23,".

(2) Section 25(e)(1)(C)(ii) is amended by inserting "25A(i)," after "24,".

(3) Section 26(a)(1) is amended by inserting "25A(i)," after "24,".

(4) Section 25B(g)(2) is amended by inserting "25A(i)," after "23,".

(5) Section 904(i) is amended by inserting "25A(i)," after "24,".

(6) Section 1400C(d)(2) is amended by inserting "25A(i)," after "24,".

(7) Section 6211(b)(4)(A) is amended by inserting "25A by reason of subsection (i)(6) thereof," after "24(d),".

(8) Section 1324(b)(2) of title 31, United States Code, is amended by inserting "25A," before "35".

26 USC 25A note.

(c) TREATMENT OF POSSESSIONS.—

(1) PAYMENTS TO POSSESSIONS.—

Effective dates.

(A) MIRROR CODE POSSESSION.—The Secretary of the Treasury shall pay to each possession of the United States with a mirror code tax system amounts equal to the loss to that possession by reason of the application of section 25A(i)(6) of the Internal Revenue Code of 1986 (as added by this section) with respect to taxable years beginning in 2009 and 2010. Such amounts shall be determined by the Secretary of the Treasury based on information provided by the government of the respective possession.

Effective dates.

(B) OTHER POSSESSIONS.—The Secretary of the Treasury shall pay to each possession of the United States which does not have a mirror code tax system amounts estimated by the Secretary of the Treasury as being equal to the aggregate benefits that would have been provided to residents of such possession by reason of the application of section 25A(i)(6) of such Code (as so added) for taxable years beginning in 2009 and 2010 if a mirror code tax

system had been in effect in such possession. The preceding sentence shall not apply with respect to any possession of the United States unless such possession has a plan, which has been approved by the Secretary of the Treasury, under which such possession will promptly distribute such payments to the residents of such possession.

(2) COORDINATION WITH CREDIT ALLOWED AGAINST UNITED STATES INCOME TAXES.—Section 25A(i)(6) of such Code (as added by this section) shall not apply to a bona fide resident of any possession of the United States.

(3) DEFINITIONS AND SPECIAL RULES.—

(A) POSSESSION OF THE UNITED STATES.—For purposes of this subsection, the term "possession of the United States" includes the Commonwealth of Puerto Rico and the Commonwealth of the Northern Mariana Islands.

(B) MIRROR CODE TAX SYSTEM.—For purposes of this subsection, the term "mirror code tax system" means, with respect to any possession of the United States, the income tax system of such possession if the income tax liability of the residents of such possession under such system is determined by reference to the income tax laws of the United States as if such possession were the United States.

(C) TREATMENT OF PAYMENTS.—For purposes of section 1324(b)(2) of title 31, United States Code, the payments under this subsection shall be treated in the same manner as a refund due from the credit allowed under section 25A of the Internal Revenue Code of 1986 by reason of subsection (i)(6) of such section (as added by this section).

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 24 note.

(e) APPLICATION OF EGTRRA SUNSET.—The amendment made by subsection (b)(1) shall be subject to title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 in the same manner as the provision of such Act to which such amendment relates. 26 USC 24 note.

(f) TREASURY STUDIES REGARDING EDUCATION INCENTIVES.—

(1) STUDY REGARDING COORDINATION WITH NON-TAX STUDENT FINANCIAL ASSISTANCE.—The Secretary of the Treasury and the Secretary of Education, or their delegates, shall—

(A) study how to coordinate the credit allowed under section 25A of the Internal Revenue Code of 1986 with the Federal Pell Grant program under section 401 of the Higher Education Act of 1965 to maximize their effectiveness at promoting college affordability, and

(B) examine ways to expedite the delivery of the tax credit.

(2) STUDY REGARDING INCLUSION OF COMMUNITY SERVICE REQUIREMENTS.—The Secretary of the Treasury and the Secretary of Education, or their delegates, shall study the feasibility of requiring including community service as a condition of taking their tuition and related expenses into account under section 25A of the Internal Revenue Code of 1986.

(3) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of the Treasury, or the Secretary's delegate, shall report to Congress on the results of the studies conducted under this paragraph.

SEC. 1005. COMPUTER TECHNOLOGY AND EQUIPMENT ALLOWED AS A QUALIFIED HIGHER EDUCATION EXPENSE FOR SECTION 529 ACCOUNTS IN 2009 AND 2010.

26 USC 529.

(a) IN GENERAL.—Section 529(e)(3)(A) is amended by striking "and" at the end of clause (i), by striking the period at the end of clause (ii), and by adding at the end the following:

"(iii) expenses paid or incurred in 2009 or 2010 for the purchase of any computer technology or equipment (as defined in section 170(e)(6)(F)(i)) or Internet access and related services, if such technology, equipment, or services are to be used by the beneficiary and the beneficiary's family during any of the years the beneficiary is enrolled at an eligible educational institution.

Clause (iii) shall not include expenses for computer software designed for sports, games, or hobbies unless the software is predominantly educational in nature.".

26 USC 529 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to expenses paid or incurred after December 31, 2008.

SEC. 1006. EXTENSION OF AND INCREASE IN FIRST-TIME HOMEBUYER CREDIT; WAIVER OF REQUIREMENT TO REPAY.

(a) EXTENSION.—

(1) IN GENERAL.—Section 36(h) is amended by striking "July 1, 2009" and inserting "December 1, 2009".

(2) CONFORMING AMENDMENT.—Section 36(g) is amended by striking "July 1, 2009" and inserting "December 1, 2009".

(b) INCREASE.—

(1) IN GENERAL.—Section 36(b) is amended by striking "$7,500" each place it appears and inserting "$8,000".

(2) CONFORMING AMENDMENT.—Section 36(b)(1)(B) is amended by striking "$3,750" and inserting "$4,000".

(c) WAIVER OF RECAPTURE.—

(1) IN GENERAL.—Paragraph (4) of section 36(f) is amended by adding at the end the following new subparagraph:

Time period.

"(D) WAIVER OF RECAPTURE FOR PURCHASES IN 2009.—In the case of any credit allowed with respect to the purchase of a principal residence after December 31, 2008, and before December 1, 2009—

Applicability.

"(i) paragraph (1) shall not apply, and

"(ii) paragraph (2) shall apply only if the disposition or cessation described in paragraph (2) with respect to such residence occurs during the 36-month period beginning on the date of the purchase of such residence by the taxpayer.".

(2) CONFORMING AMENDMENT.—Subsection (g) of section 36 is amended by striking "subsection (c)" and inserting "subsections (c) and (f)(4)(D)".

(d) COORDINATION WITH FIRST-TIME HOMEBUYER CREDIT FOR DISTRICT OF COLUMBIA.—

(1) IN GENERAL.—Subsection (e) of section 1400C is amended by adding at the end the following new paragraph:

Time period.

"(4) COORDINATION WITH NATIONAL FIRST-TIME HOMEBUYERS CREDIT.—No credit shall be allowed under this section to any taxpayer with respect to the purchase of a residence after December 31, 2008, and before December 1, 2009, if a credit

under section 36 is allowable to such taxpayer (or the taxpayer's spouse) with respect to such purchase.".

(2) CONFORMING AMENDMENT.—Section 36(d) is amended by striking paragraph (1). 26 USC 36.

(e) REMOVAL OF PROHIBITION ON FINANCING BY MORTGAGE REVENUE BONDS.—Section 36(d), as amended by subsection (c)(2), is amended by striking paragraph (2) and by redesignating paragraphs (3) and (4) as paragraphs (1) and (2), respectively.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to residences purchased after December 31, 2008. 26 USC 36 note.

SEC. 1007. SUSPENSION OF TAX ON PORTION OF UNEMPLOYMENT COMPENSATION.

(a) IN GENERAL.—Section 85 of the Internal Revenue Code of 1986 (relating to unemployment compensation) is amended by adding at the end the following new subsection:

"(c) SPECIAL RULE FOR 2009.—In the case of any taxable year beginning in 2009, gross income shall not include so much of the unemployment compensation received by an individual as does not exceed $2,400.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 85 note.

SEC. 1008. ADDITIONAL DEDUCTION FOR STATE SALES TAX AND EXCISE TAX ON THE PURCHASE OF CERTAIN MOTOR VEHICLES.

(a) IN GENERAL.—Subsection (a) of section 164 is amended by inserting after paragraph (5) the following new paragraph:

"(6) Qualified motor vehicle taxes.".

(b) QUALIFIED MOTOR VEHICLE TAXES.—Subsection (b) of section 164 is amended by adding at the end the following new paragraph:

"(6) QUALIFIED MOTOR VEHICLE TAXES.—

"(A) IN GENERAL.—For purposes of this section, the term 'qualified motor vehicle taxes' means any State or local sales or excise tax imposed on the purchase of a qualified motor vehicle.

"(B) LIMITATION BASED ON VEHICLE PRICE.—The amount of any State or local sales or excise tax imposed on the purchase of a qualified motor vehicle taken into account under subparagraph (A) shall not exceed the portion of such tax attributable to so much of the purchase price as does not exceed $49,500.

"(C) INCOME LIMITATION.—The amount otherwise taken into account under subparagraph (A) (after the application of subparagraph (B)) for any taxable year shall be reduced (but not below zero) by the amount which bears the same ratio to the amount which is so treated as—

"(i) the excess (if any) of—

"(I) the taxpayer's modified adjusted gross income for such taxable year, over

"(II) $125,000 ($250,000 in the case of a joint return), bears to

"(ii) $10,000.

For purposes of the preceding sentence, the term 'modified adjusted gross income' means the adjusted gross income of the taxpayer for the taxable year (determined without regard to sections 911, 931, and 933).

"(D) QUALIFIED MOTOR VEHICLE.—For purposes of this paragraph—

"(i) IN GENERAL.—The term 'qualified motor vehicle' means—

"(I) a passenger automobile or light truck which is treated as a motor vehicle for purposes of title II of the Clean Air Act, the gross vehicle weight rating of which is not more than 8,500 pounds, and the original use of which commences with the taxpayer,

"(II) a motorcycle the gross vehicle weight rating of which is not more than 8,500 pounds and the original use of which commences with the taxpayer, and

"(III) a motor home the original use of which commences with the taxpayer.

"(ii) OTHER TERMS.—The terms 'motorcycle' and 'motor home' have the meanings given such terms under section 571.3 of title 49, Code of Federal Regulations (as in effect on the date of the enactment of this paragraph).

"(E) QUALIFIED MOTOR VEHICLE TAXES NOT INCLUDED IN COST OF ACQUIRED PROPERTY.—The last sentence of subsection (a) shall not apply to any qualified motor vehicle taxes.

"(F) COORDINATION WITH GENERAL SALES TAX.—This paragraph shall not apply in the case of a taxpayer who makes an election under paragraph (5) for the taxable year.

"(G) TERMINATION.—This paragraph shall not apply to purchases after December 31, 2009.".

(c) DEDUCTION ALLOWED TO NONITEMIZERS.—

26 USC 63.

(1) IN GENERAL.—Paragraph (1) of section 63(c) is amended by striking "and" at the end of subparagraph (C), by striking the period at the end of subparagraph (D) and inserting ", and", and by adding at the end the following new subparagraph:

"(E) the motor vehicle sales tax deduction.".

(2) DEFINITION.—Section 63(c) is amended by adding at the end the following new paragraph:

"(9) MOTOR VEHICLE SALES TAX DEDUCTION.—For purposes of paragraph (1), the term 'motor vehicle sales tax deduction' means the amount allowable as a deduction under section 164(a)(6). Such term shall not include any amount taken into account under section 62(a).".

(d) TREATMENT OF DEDUCTION UNDER ALTERNATIVE MINIMUM TAX.—The last sentence of section 56(b)(1)(E) is amended by striking "section 63(c)(1)(D)" and inserting "subparagraphs (D) and (E) of section 63(c)(1)".

26 USC 56 note.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to purchases on or after the date of the enactment of this Act in taxable years ending after such date.

PART II—ALTERNATIVE MINIMUM TAX RELIEF

SEC. 1011. EXTENSION OF ALTERNATIVE MINIMUM TAX RELIEF FOR NONREFUNDABLE PERSONAL CREDITS.

(a) IN GENERAL.—Paragraph (2) of section 26(a) (relating to special rule for taxable years 2000 through 2008) is amended— 26 USC 26.

(1) by striking "or 2008" and inserting "2008, or 2009", and

(2) by striking "**2008**" in the heading thereof and inserting "**2009**".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 26 note.

SEC. 1012. EXTENSION OF INCREASED ALTERNATIVE MINIMUM TAX EXEMPTION AMOUNT.

(a) IN GENERAL.—Paragraph (1) of section 55(d) (relating to exemption amount) is amended—

(1) by striking "($69,950 in the case of taxable years beginning in 2008)" in subparagraph (A) and inserting "($70,950 in the case of taxable years beginning in 2009)", and

(2) by striking "($46,200 in the case of taxable years beginning in 2008)" in subparagraph (B) and inserting "($46,700 in the case of taxable years beginning in 2009)".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 55 note.

Subtitle B—Energy Incentives

PART I—RENEWABLE ENERGY INCENTIVES

SEC. 1101. EXTENSION OF CREDIT FOR ELECTRICITY PRODUCED FROM CERTAIN RENEWABLE RESOURCES.

(a) IN GENERAL.—Subsection (d) of section 45 is amended—

(1) by striking "2010" in paragraph (1) and inserting "2013",

(2) by striking "2011" each place it appears in paragraphs (2), (3), (4), (6), (7) and (9) and inserting "2014", and

(3) by striking "2012" in paragraph (11)(B) and inserting "2014".

(b) TECHNICAL AMENDMENT.—Paragraph (5) of section 45(d) is amended by striking "and before" and all that follows and inserting " and before October 3, 2008.".

(c) EFFECTIVE DATE.— 26 USC 45 note.

(1) IN GENERAL.—The amendments made by subsection (a) shall apply to property placed in service after the date of the enactment of this Act.

(2) TECHNICAL AMENDMENT.—The amendment made by subsection (b) shall take effect as if included in section 102 of the Energy Improvement and Extension Act of 2008.

SEC. 1102. ELECTION OF INVESTMENT CREDIT IN LIEU OF PRODUCTION CREDIT.

(a) IN GENERAL.—Subsection (a) of section 48 is amended by adding at the end the following new paragraph:

"(5) ELECTION TO TREAT QUALIFIED FACILITIES AS ENERGY PROPERTY.—

"(A) IN GENERAL.—In the case of any qualified property which is part of a qualified investment credit facility—

"(i) such property shall be treated as energy property for purposes of this section, and

"(ii) the energy percentage with respect to such property shall be 30 percent.

"(B) DENIAL OF PRODUCTION CREDIT.—No credit shall be allowed under section 45 for any taxable year with respect to any qualified investment credit facility.

"(C) QUALIFIED INVESTMENT CREDIT FACILITY.—For purposes of this paragraph, the term 'qualified investment credit facility' means any of the following facilities if no credit has been allowed under section 45 with respect to such facility and the taxpayer makes an irrevocable election to have this paragraph apply to such facility:

"(i) WIND FACILITIES.—Any qualified facility (within the meaning of section 45) described in paragraph (1) of section 45(d) if such facility is placed in service in 2009, 2010, 2011, or 2012.

"(ii) OTHER FACILITIES.—Any qualified facility (within the meaning of section 45) described in paragraph (2), (3), (4), (6), (7), (9), or (11) of section 45(d) if such facility is placed in service in 2009, 2010, 2011, 2012, or 2013.

"(D) QUALIFIED PROPERTY.—For purposes of this paragraph, the term 'qualified property' means property—

"(i) which is—

"(I) tangible personal property, or

"(II) other tangible property (not including a building or its structural components), but only if such property is used as an integral part of the qualified investment credit facility, and

"(ii) with respect to which depreciation (or amortization in lieu of depreciation) is allowable.".

26 USC 48 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to facilities placed in service after December 31, 2008.

SEC. 1103. REPEAL OF CERTAIN LIMITATIONS ON CREDIT FOR RENEWABLE ENERGY PROPERTY.

26 USC 48.

(a) REPEAL OF LIMITATION ON CREDIT FOR QUALIFIED SMALL WIND ENERGY PROPERTY.—Paragraph (4) of section 48(c) is amended by striking subparagraph (B) and by redesignating subparagraphs (C) and (D) as subparagraphs (B) and (C).

(b) REPEAL OF LIMITATION ON PROPERTY FINANCED BY SUBSIDIZED ENERGY FINANCING.—

(1) IN GENERAL.—Section 48(a)(4) is amended by adding at the end the following new subparagraph:

"(D) TERMINATION.—This paragraph shall not apply to periods after December 31, 2008, under rules similar to the rules of section 48(m) (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990).".

(2) CONFORMING AMENDMENTS.—

(A) Section 25C(e)(1) is amended by striking "(8), and (9)" and inserting "and (8)".

(B) Section 25D(e) is amended by striking paragraph (9).

(C) Section 48A(b)(2) is amended by inserting "(without regard to subparagraph (D) thereof)" after "section 48(a)(4)". 26 USC 48A.

(D) Section 48B(b)(2) is amended by inserting "(without regard to subparagraph (D) thereof)" after "section 48(a)(4)".

(c) EFFECTIVE DATE.— Applicability. 26 USC 25C.

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by this section shall apply to periods after December 31, 2008, under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990).

(2) CONFORMING AMENDMENTS.—The amendments made by subparagraphs (A) and (B) of subsection (b)(2) shall apply to taxable years beginning after December 31, 2008.

SEC. 1104. COORDINATION WITH RENEWABLE ENERGY GRANTS.

Section 48 is amended by adding at the end the following new subsection:

"(d) COORDINATION WITH DEPARTMENT OF TREASURY GRANTS.—In the case of any property with respect to which the Secretary makes a grant under section 1603 of the American Recovery and Reinvestment Tax Act of 2009—

"(1) DENIAL OF PRODUCTION AND INVESTMENT CREDITS.—No credit shall be determined under this section or section 45 with respect to such property for the taxable year in which such grant is made or any subsequent taxable year.

"(2) RECAPTURE OF CREDITS FOR PROGRESS EXPENDITURES MADE BEFORE GRANT.—If a credit was determined under this section with respect to such property for any taxable year ending before such grant is made—

"(A) the tax imposed under subtitle A on the taxpayer for the taxable year in which such grant is made shall be increased by so much of such credit as was allowed under section 38,

"(B) the general business carryforwards under section 39 shall be adjusted so as to recapture the portion of such credit which was not so allowed, and

"(C) the amount of such grant shall be determined without regard to any reduction in the basis of such property by reason of such credit.

"(3) TREATMENT OF GRANTS.—Any such grant shall—

"(A) not be includible in the gross income of the taxpayer, but

"(B) shall be taken into account in determining the basis of the property to which such grant relates, except that the basis of such property shall be reduced under section 50(c) in the same manner as a credit allowed under subsection (a).".

PART II—INCREASED ALLOCATIONS OF NEW CLEAN RENEWABLE ENERGY BONDS AND QUALIFIED ENERGY CONSERVATION BONDS

SEC. 1111. INCREASED LIMITATION ON ISSUANCE OF NEW CLEAN RENEWABLE ENERGY BONDS.

26 USC 54C.

Subsection (c) of section 54C is amended by adding at the end the following new paragraph:

"(4) ADDITIONAL LIMITATION.—The national new clean renewable energy bond limitation shall be increased by $1,600,000,000. Such increase shall be allocated by the Secretary consistent with the rules of paragraphs (2) and (3).".

SEC. 1112. INCREASED LIMITATION ON ISSUANCE OF QUALIFIED ENERGY CONSERVATION BONDS.

(a) IN GENERAL.—Section 54D(d) is amended by striking "$800,000,000" and inserting "$3,200,000,000".

(b) CLARIFICATION WITH RESPECT TO GREEN COMMUNITY PROGRAMS.—

(1) IN GENERAL.—Clause (ii) of section 54D(f)(1)(A) is amended by inserting "(including the use of loans, grants, or other repayment mechanisms to implement such programs)" after "green community programs".

(2) SPECIAL RULES FOR BONDS FOR IMPLEMENTING GREEN COMMUNITY PROGRAMS.—Subsection (e) of section 54D is amended by adding at the end the following new paragraph:

"(4) SPECIAL RULES FOR BONDS TO IMPLEMENT GREEN COMMUNITY PROGRAMS.—In the case of any bond issued for the purpose of providing loans, grants, or other repayment mechanisms for capital expenditures to implement green community programs, such bond shall not be treated as a private activity bond for purposes of paragraph (3).".

PART III—ENERGY CONSERVATION INCENTIVES

SEC. 1121. EXTENSION AND MODIFICATION OF CREDIT FOR NONBUSINESS ENERGY PROPERTY.

(a) IN GENERAL.—Section 25C is amended by striking subsections (a) and (b) and inserting the following new subsections:

"(a) ALLOWANCE OF CREDIT.—In the case of an individual, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to 30 percent of the sum of—

"(1) the amount paid or incurred by the taxpayer during such taxable year for qualified energy efficiency improvements, and

"(2) the amount of the residential energy property expenditures paid or incurred by the taxpayer during such taxable year.

"(b) LIMITATION.—The aggregate amount of the credits allowed under this section for taxable years beginning in 2009 and 2010 with respect to any taxpayer shall not exceed $1,500.".

(b) MODIFICATIONS OF STANDARDS FOR ENERGY-EFFICIENT BUILDING PROPERTY.—

(1) ELECTRIC HEAT PUMPS.—Subparagraph (B) of section 25C(d)(3) is amended to read as follows:

26 USC 25C.

"(B) an electric heat pump which achieves the highest efficiency tier established by the Consortium for Energy Efficiency, as in effect on January 1, 2009.".

(2) CENTRAL AIR CONDITIONERS.—Subparagraph (C) of section 25C(d)(3) is amended by striking "2006" and inserting "2009".

(3) WATER HEATERS.—Subparagraph (D) of section 25C(d)(3) is amended to read as follows:

"(D) a natural gas, propane, or oil water heater which has either an energy factor of at least 0.82 or a thermal efficiency of at least 90 percent.".

(4) WOOD STOVES.—Subparagraph (E) of section 25C(d)(3) is amended by inserting ", as measured using a lower heating value" after "75 percent".

(c) MODIFICATIONS OF STANDARDS FOR OIL FURNACES AND HOT WATER BOILERS.—

(1) IN GENERAL.—Paragraph (4) of section 25C(d) is amended to read as follows:

"(4) QUALIFIED NATURAL GAS, PROPANE, AND OIL FURNACES AND HOT WATER BOILERS.—

"(A) QUALIFIED NATURAL GAS FURNACE.—The term 'qualified natural gas furnace' means any natural gas furnace which achieves an annual fuel utilization efficiency rate of not less than 95.

"(B) QUALIFIED NATURAL GAS HOT WATER BOILER.—The term 'qualified natural gas hot water boiler' means any natural gas hot water boiler which achieves an annual fuel utilization efficiency rate of not less than 90.

"(C) QUALIFIED PROPANE FURNACE.—The term 'qualified propane furnace' means any propane furnace which achieves an annual fuel utilization efficiency rate of not less than 95.

"(D) QUALIFIED PROPANE HOT WATER BOILER.—The term 'qualified propane hot water boiler' means any propane hot water boiler which achieves an annual fuel utilization efficiency rate of not less than 90.

"(E) QUALIFIED OIL FURNACES.—The term 'qualified oil furnace' means any oil furnace which achieves an annual fuel utilization efficiency rate of not less than 90.

"(F) QUALIFIED OIL HOT WATER BOILER.—The term 'qualified oil hot water boiler' means any oil hot water boiler which achieves an annual fuel utilization efficiency rate of not less than 90.".

(2) CONFORMING AMENDMENT.—Clause (ii) of section 25C(d)(2)(A) is amended to read as follows:

"(ii) any qualified natural gas furnace, qualified propane furnace, qualified oil furnace, qualified natural gas hot water boiler, qualified propane hot water boiler, or qualified oil hot water boiler, or".

(d) MODIFICATIONS OF STANDARDS FOR QUALIFIED ENERGY EFFICIENCY IMPROVEMENTS.—

(1) QUALIFICATIONS FOR EXTERIOR WINDOWS, DOORS, AND SKYLIGHTS.—Subsection (c) of section 25C is amended by adding at the end the following new paragraph:

"(4) QUALIFICATIONS FOR EXTERIOR WINDOWS, DOORS, AND SKYLIGHTS.—Such term shall not include any component described in subparagraph (B) or (C) of paragraph (2) unless such component is equal to or below a U factor of 0.30 and SHGC of 0.30.".

26 USC 25C.

(2) ADDITIONAL QUALIFICATION FOR INSULATION.—Subparagraph (A) of section 25C(c)(2) is amended by inserting "and meets the prescriptive criteria for such material or system established by the 2009 International Energy Conservation Code, as such Code (including supplements) is in effect on the date of the enactment of the American Recovery and Reinvestment Tax Act of 2009" after "such dwelling unit".

(e) EXTENSION.—Section 25C(g)(2) is amended by striking "December 31, 2009" and inserting "December 31, 2010".

Applicability.
26 USC 25C note.

(f) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall apply to taxable years beginning after December 31, 2008.

(2) EFFICIENCY STANDARDS.—The amendments made by paragraphs (1), (2), and (3) of subsection (b) and subsections (c) and (d) shall apply to property placed in service after the date of the enactment of this Act.

SEC. 1122. MODIFICATION OF CREDIT FOR RESIDENTIAL ENERGY EFFICIENT PROPERTY.

(a) REMOVAL OF CREDIT LIMITATION FOR PROPERTY PLACED IN SERVICE.—

(1) IN GENERAL.—Paragraph (1) of section 25D(b) is amended to read as follows:

"(1) MAXIMUM CREDIT FOR FUEL CELLS.—In the case of any qualified fuel cell property expenditure, the credit allowed under subsection (a) (determined without regard to subsection (c)) for any taxable year shall not exceed $500 with respect to each half kilowatt of capacity of the qualified fuel cell property (as defined in section 48(c)(1)) to which such expenditure relates.".

(2) CONFORMING AMENDMENT.—Paragraph (4) of section 25D(e) is amended—

(A) by striking all that precedes subparagraph (B) and inserting the following:

Regulations.
Applicability.

"(4) FUEL CELL EXPENDITURE LIMITATIONS IN CASE OF JOINT OCCUPANCY.—In the case of any dwelling unit with respect to which qualified fuel cell property expenditures are made and which is jointly occupied and used during any calendar year as a residence by two or more individuals, the following rules shall apply:

"(A) MAXIMUM EXPENDITURES FOR FUEL CELLS.—The maximum amount of such expenditures which may be taken into account under subsection (a) by all such individuals with respect to such dwelling unit during such calendar year shall be $1,667 in the case of each half kilowatt of capacity of qualified fuel cell property (as defined in section 48(c)(1)) with respect to which such expenditures relate.", and

(B) by striking subparagraph (C).

26 USC 25D note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008.

SEC. 1123. TEMPORARY INCREASE IN CREDIT FOR ALTERNATIVE FUEL VEHICLE REFUELING PROPERTY.

(a) IN GENERAL.—Section 30C(e) is amended by adding at the end the following new paragraph: 26 USC 30C.

"(6) SPECIAL RULE FOR PROPERTY PLACED IN SERVICE DURING 2009 AND 2010.—In the case of property placed in service in taxable years beginning after December 31, 2008, and before January 1, 2011—

"(A) in the case of any such property which does not relate to hydrogen— Applicability.

"(i) subsection (a) shall be applied by substituting '50 percent' for '30 percent',

"(ii) subsection (b)(1) shall be applied by substituting '$50,000' for '$30,000', and

"(iii) subsection (b)(2) shall be applied by substituting '$2,000' for '$1,000', and

"(B) in the case of any such property which relates to hydrogen, subsection (b)(1) shall be applied by substituting '$200,000' for '$30,000'.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 30C note.

PART IV—MODIFICATION OF CREDIT FOR CARBON DIOXIDE SEQUESTRATION

SEC. 1131. APPLICATION OF MONITORING REQUIREMENTS TO CARBON DIOXIDE USED AS A TERTIARY INJECTANT.

(a) IN GENERAL.—Section 45Q(a)(2) is amended by striking "and" at the end of subparagraph (A), by striking the period at the end of subparagraph (B) and inserting ", and", and by adding at the end the following new subparagraph:

"(C) disposed of by the taxpayer in secure geological storage.".

(b) CONFORMING AMENDMENTS.—

(1) Section 45Q(d)(2) is amended—

(A) by striking "subsection (a)(1)(B)" and inserting "paragraph (1)(B) or (2)(C) of subsection (a)",

(B) by striking "and unminable coal seems" and inserting ", oil and gas reservoirs, and unminable coal seams", and

(C) by inserting "the Secretary of Energy, and the Secretary of the Interior," after "Environmental Protection Agency".

(2) Section 45Q(a)(1)(B) is amended by inserting "and not used by the taxpayer as described in paragraph (2)(B)" after "storage".

(3) Section 45Q(e) is amended by striking "captured and disposed of or used as a tertiary injectant" and inserting "taken into account in accordance with subsection (a)".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to carbon dioxide captured after the date of the enactment of this Act. 26 USC 45Q note.

PART V—PLUG-IN ELECTRIC DRIVE MOTOR VEHICLES

SEC. 1141. CREDIT FOR NEW QUALIFIED PLUG-IN ELECTRIC DRIVE MOTOR VEHICLES.

26 USC 30D.

(a) IN GENERAL.—Section 30D is amended to read as follows:

"SEC. 30D. NEW QUALIFIED PLUG-IN ELECTRIC DRIVE MOTOR VEHICLES.

"(a) ALLOWANCE OF CREDIT.—There shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to the sum of the credit amounts determined under subsection (b) with respect to each new qualified plug-in electric drive motor vehicle placed in service by the taxpayer during the taxable year.

"(b) PER VEHICLE DOLLAR LIMITATION.—

"(1) IN GENERAL.—The amount determined under this subsection with respect to any new qualified plug-in electric drive motor vehicle is the sum of the amounts determined under paragraphs (2) and (3) with respect to such vehicle.

"(2) BASE AMOUNT.—The amount determined under this paragraph is $2,500.

"(3) BATTERY CAPACITY.—In the case of a vehicle which draws propulsion energy from a battery with not less than 5 kilowatt hours of capacity, the amount determined under this paragraph is $417, plus $417 for each kilowatt hour of capacity in excess of 5 kilowatt hours. The amount determined under this paragraph shall not exceed $5,000.

"(c) APPLICATION WITH OTHER CREDITS.—

"(1) BUSINESS CREDIT TREATED AS PART OF GENERAL BUSINESS CREDIT.—So much of the credit which would be allowed under subsection (a) for any taxable year (determined without regard to this subsection) that is attributable to property of a character subject to an allowance for depreciation shall be treated as a credit listed in section 38(b) for such taxable year (and not allowed under subsection (a)).

"(2) PERSONAL CREDIT.—

"(A) IN GENERAL.—For purposes of this title, the credit allowed under subsection (a) for any taxable year (determined after application of paragraph (1)) shall be treated as a credit allowable under subpart A for such taxable year.

"(B) LIMITATION BASED ON AMOUNT OF TAX.—In the case of a taxable year to which section 26(a)(2) does not apply, the credit allowed under subsection (a) for any taxable year (determined after application of paragraph (1)) shall not exceed the excess of—

"(i) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

"(ii) the sum of the credits allowable under subpart A (other than this section and sections 23 and 25D) and section 27 for the taxable year.

"(d) NEW QUALIFIED PLUG-IN ELECTRIC DRIVE MOTOR VEHICLE.—For purposes of this section—

"(1) IN GENERAL.—The term 'new qualified plug-in electric drive motor vehicle' means a motor vehicle—

"(A) the original use of which commences with the taxpayer,

"(B) which is acquired for use or lease by the taxpayer and not for resale,

"(C) which is made by a manufacturer,

"(D) which is treated as a motor vehicle for purposes of title II of the Clean Air Act,

"(E) which has a gross vehicle weight rating of less than 14,000 pounds, and

"(F) which is propelled to a significant extent by an electric motor which draws electricity from a battery which—

"(i) has a capacity of not less than 4 kilowatt hours, and

"(ii) is capable of being recharged from an external source of electricity.

"(2) MOTOR VEHICLE.—The term 'motor vehicle' means any vehicle which is manufactured primarily for use on public streets, roads, and highways (not including a vehicle operated exclusively on a rail or rails) and which has at least 4 wheels.

"(3) MANUFACTURER.—The term 'manufacturer' has the meaning given such term in regulations prescribed by the Administrator of the Environmental Protection Agency for purposes of the administration of title II of the Clean Air Act (42 U.S.C. 7521 et seq.).

"(4) BATTERY CAPACITY.—The term 'capacity' means, with respect to any battery, the quantity of electricity which the battery is capable of storing, expressed in kilowatt hours, as measured from a 100 percent state of charge to a 0 percent state of charge.

"(e) LIMITATION ON NUMBER OF NEW QUALIFIED PLUG-IN ELECTRIC DRIVE MOTOR VEHICLES ELIGIBLE FOR CREDIT.—

"(1) IN GENERAL.—In the case of a new qualified plug-in electric drive motor vehicle sold during the phaseout period, only the applicable percentage of the credit otherwise allowable under subsection (a) shall be allowed.

"(2) PHASEOUT PERIOD.—For purposes of this subsection, the phaseout period is the period beginning with the second calendar quarter following the calendar quarter which includes the first date on which the number of new qualified plug-in electric drive motor vehicles manufactured by the manufacturer of the vehicle referred to in paragraph (1) sold for use in the United States after December 31, 2009, is at least 200,000.

"(3) APPLICABLE PERCENTAGE.—For purposes of paragraph (1), the applicable percentage is—

"(A) 50 percent for the first 2 calendar quarters of the phaseout period,

"(B) 25 percent for the 3d and 4th calendar quarters of the phaseout period, and

"(C) 0 percent for each calendar quarter thereafter.

"(4) CONTROLLED GROUPS.—Rules similar to the rules of section 30B(f)(4) shall apply for purposes of this subsection. Regulations. Applicability.

"(f) SPECIAL RULES.—

"(1) BASIS REDUCTION.—For purposes of this subtitle, the basis of any property for which a credit is allowable under

subsection (a) shall be reduced by the amount of such credit so allowed.

"(2) NO DOUBLE BENEFIT.—The amount of any deduction or other credit allowable under this chapter for a new qualified plug-in electric drive motor vehicle shall be reduced by the amount of credit allowed under subsection (a) for such vehicle.

"(3) PROPERTY USED BY TAX-EXEMPT ENTITY.—In the case of a vehicle the use of which is described in paragraph (3) or (4) of section 50(b) and which is not subject to a lease, the person who sold such vehicle to the person or entity using such vehicle shall be treated as the taxpayer that placed such vehicle in service, but only if such person clearly discloses to such person or entity in a document the amount of any credit allowable under subsection (a) with respect to such vehicle (determined without regard to subsection (c)).

"(4) PROPERTY USED OUTSIDE UNITED STATES NOT QUALIFIED.—No credit shall be allowable under subsection (a) with respect to any property referred to in section 50(b)(1).

Regulations.

"(5) RECAPTURE.—The Secretary shall, by regulations, provide for recapturing the benefit of any credit allowable under subsection (a) with respect to any property which ceases to be property eligible for such credit.

"(6) ELECTION NOT TO TAKE CREDIT.—No credit shall be allowed under subsection (a) for any vehicle if the taxpayer elects to not have this section apply to such vehicle.

"(7) INTERACTION WITH AIR QUALITY AND MOTOR VEHICLE SAFETY STANDARDS.—A motor vehicle shall not be considered eligible for a credit under this section unless such vehicle is in compliance with—

"(A) the applicable provisions of the Clean Air Act for the applicable make and model year of the vehicle (or applicable air quality provisions of State law in the case of a State which has adopted such provision under a waiver under section 209(b) of the Clean Air Act), and

"(B) the motor vehicle safety provisions of sections 30101 through 30169 of title 49, United States Code.".

(b) CONFORMING AMENDMENTS.—

26 USC 30B.

(1) Section 30B(d)(3)(D) is amended by striking "subsection (d) thereof" and inserting "subsection (c) thereof".

(2) Section 38(b)(35) is amended by striking "30D(d)(1)" and inserting "30D(c)(1)".

(3) Section 1016(a)(25) is amended by striking "section 30D(e)(4)" and inserting "section 30D(f)(1)".

(4) Section 6501(m) is amended by striking "section 30D(e)(9)" and inserting "section 30D(e)(4)".

26 USC 30B note.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to vehicles acquired after December 31, 2009.

SEC. 1142. CREDIT FOR CERTAIN PLUG-IN ELECTRIC VEHICLES.

(a) IN GENERAL.—Section 30 is amended to read as follows:

"SEC. 30. CERTAIN PLUG-IN ELECTRIC VEHICLES.

"(a) ALLOWANCE OF CREDIT.—There shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to 10 percent of the cost of any qualified plug-in electric vehicle placed in service by the taxpayer during the taxable year.

"(b) PER VEHICLE DOLLAR LIMITATION.—The amount of the credit allowed under subsection (a) with respect to any vehicle shall not exceed $2,500.

"(c) APPLICATION WITH OTHER CREDITS.—

"(1) BUSINESS CREDIT TREATED AS PART OF GENERAL BUSINESS CREDIT.—So much of the credit which would be allowed under subsection (a) for any taxable year (determined without regard to this subsection) that is attributable to property of a character subject to an allowance for depreciation shall be treated as a credit listed in section 38(b) for such taxable year (and not allowed under subsection (a)).

"(2) PERSONAL CREDIT.—

"(A) IN GENERAL.—For purposes of this title, the credit allowed under subsection (a) for any taxable year (determined after application of paragraph (1)) shall be treated as a credit allowable under subpart A for such taxable year.

"(B) LIMITATION BASED ON AMOUNT OF TAX.—In the case of a taxable year to which section 26(a)(2) does not apply, the credit allowed under subsection (a) for any taxable year (determined after application of paragraph (1)) shall not exceed the excess of—

"(i) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

"(ii) the sum of the credits allowable under subpart A (other than this section and sections 23, 25D, and 30D) and section 27 for the taxable year.

"(d) QUALIFIED PLUG-IN ELECTRIC VEHICLE.—For purposes of this section—

"(1) IN GENERAL.—The term 'qualified plug-in electric vehicle' means a specified vehicle—

"(A) the original use of which commences with the taxpayer,

"(B) which is acquired for use or lease by the taxpayer and not for resale,

"(C) which is made by a manufacturer,

"(D) which is manufactured primarily for use on public streets, roads, and highways,

"(E) which has a gross vehicle weight rating of less than 14,000 pounds, and

"(F) which is propelled to a significant extent by an electric motor which draws electricity from a battery which—

"(i) has a capacity of not less than 4 kilowatt hours (2.5 kilowatt hours in the case of a vehicle with 2 or 3 wheels), and

"(ii) is capable of being recharged from an external source of electricity.

"(2) SPECIFIED VEHICLE.—The term 'specified vehicle' means any vehicle which—

"(A) is a low speed vehicle within the meaning of section 571.3 of title 49, Code of Federal Regulations (as in effect on the date of the enactment of the American Recovery and Reinvestment Tax Act of 2009), or

"(B) has 2 or 3 wheels.

"(3) MANUFACTURER.—The term 'manufacturer' has the meaning given such term in regulations prescribed by the Administrator of the Environmental Protection Agency for purposes of the administration of title II of the Clean Air Act (42 U.S.C. 7521 et seq.).

"(4) BATTERY CAPACITY.—The term 'capacity' means, with respect to any battery, the quantity of electricity which the battery is capable of storing, expressed in kilowatt hours, as measured from a 100 percent state of charge to a 0 percent state of charge.

"(e) SPECIAL RULES.—

"(1) BASIS REDUCTION.—For purposes of this subtitle, the basis of any property for which a credit is allowable under subsection (a) shall be reduced by the amount of such credit so allowed.

"(2) NO DOUBLE BENEFIT.—The amount of any deduction or other credit allowable under this chapter for a new qualified plug-in electric drive motor vehicle shall be reduced by the amount of credit allowable under subsection (a) for such vehicle.

"(3) PROPERTY USED BY TAX-EXEMPT ENTITY.—In the case of a vehicle the use of which is described in paragraph (3) or (4) of section 50(b) and which is not subject to a lease, the person who sold such vehicle to the person or entity using such vehicle shall be treated as the taxpayer that placed such vehicle in service, but only if such person clearly discloses to such person or entity in a document the amount of any credit allowable under subsection (a) with respect to such vehicle (determined without regard to subsection (c)).

"(4) PROPERTY USED OUTSIDE UNITED STATES NOT QUALIFIED.—No credit shall be allowable under subsection (a) with respect to any property referred to in section 50(b)(1).

Regulations.

"(5) RECAPTURE.—The Secretary shall, by regulations, provide for recapturing the benefit of any credit allowable under subsection (a) with respect to any property which ceases to be property eligible for such credit.

"(6) ELECTION NOT TO TAKE CREDIT.—No credit shall be allowed under subsection (a) for any vehicle if the taxpayer elects to not have this section apply to such vehicle.

"(f) TERMINATION.—This section shall not apply to any vehicle acquired after December 31, 2011.".

(b) CONFORMING AMENDMENTS.—

26 USC 24.

(1)(A) Section 24(b)(3)(B) is amended by inserting "30," after "25D,".

(B) Section 25(e)(1)(C)(ii) is amended by inserting "30," after "25D,".

(C) Section 25B(g)(2) is amended by inserting "30," after "25D,".

(D) Section 26(a)(1) is amended by inserting "30," after "25D,".

(E) Section 904(i) is amended by striking "and 25B" and inserting "25B, 30, and 30D".

(F) Section 1400C(d)(2) is amended by striking "and 25D" and inserting "25D, and 30".

(2) Paragraph (1) of section 30B(h) is amended to read as follows:

"(1) MOTOR VEHICLE.—The term 'motor vehicle' means any vehicle which is manufactured primarily for use on public

streets, roads, and highways (not including a vehicle operated exclusively on a rail or rails) and which has at least 4 wheels.".

(3) Section 30C(d)(2)(A) is amended by striking ", 30,". 26 USC 30C.

(4)(A) Section 53(d)(1)(B) is amended by striking clause (iii) and redesignating clause (iv) as clause (iii).

(B) Subclause (II) of section 53(d)(1)(B)(iii), as so redesignated, is amended by striking "increased in the manner provided in clause (iii)".

(5) Section 55(c)(3) is amended by striking "30(b)(3),".

(6) Section 1016(a)(25) is amended by striking "section 30(d)(1)" and inserting "section 30(e)(1)".

(7) Section 6501(m) is amended by striking "section 30(d)(4)" and inserting "section 30(e)(6)".

(8) The item in the table of sections for subpart B of part IV of subchapter A of chapter 1 is amended to read as follows:

"Sec. 30. Certain plug-in electric vehicles.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to vehicles acquired after the date of the enactment of this Act. 26 USC 24 note.

(d) TRANSITIONAL RULE.—In the case of a vehicle acquired after the date of the enactment of this Act and before January 1, 2010, no credit shall be allowed under section 30 of the Internal Revenue Code of 1986, as added by this section, if credit is allowable under section 30D of such Code with respect to such vehicle. Time period. 26 USC 30 note.

(e) APPLICATION OF EGTRRA SUNSET.—The amendment made by subsection (b)(1)(A) shall be subject to title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 in the same manner as the provision of such Act to which such amendment relates. 26 USC 24 note.

SEC. 1143. CONVERSION KITS.

(a) IN GENERAL.—Section 30B (relating to alternative motor vehicle credit) is amended by redesignating subsections (i) and (j) as subsections (j) and (k), respectively, and by inserting after subsection (h) the following new subsection:

"(i) PLUG-IN CONVERSION CREDIT.—

"(1) IN GENERAL.—For purposes of subsection (a), the plug-in conversion credit determined under this subsection with respect to any motor vehicle which is converted to a qualified plug-in electric drive motor vehicle is 10 percent of so much of the cost of the converting such vehicle as does not exceed $40,000.

"(2) QUALIFIED PLUG-IN ELECTRIC DRIVE MOTOR VEHICLE.—For purposes of this subsection, the term 'qualified plug-in electric drive motor vehicle' means any new qualified plug-in electric drive motor vehicle (as defined in section 30D, determined without regard to whether such vehicle is made by a manufacturer or whether the original use of such vehicle commences with the taxpayer).

"(3) CREDIT ALLOWED IN ADDITION TO OTHER CREDITS.—The credit allowed under this subsection shall be allowed with respect to a motor vehicle notwithstanding whether a credit has been allowed with respect to such motor vehicle under this section (other than this subsection) in any preceding taxable year.

"(4) TERMINATION.—This subsection shall not apply to conversions made after December 31, 2011.".

(b) CREDIT TREATED AS PART OF ALTERNATIVE MOTOR VEHICLE CREDIT.—Section 30B(a) is amended by striking "and" at the end of paragraph (3), by striking the period at the end of paragraph (4) and inserting ", and", and by adding at the end the following new paragraph:

26 USC 30B.

"(5) the plug-in conversion credit determined under subsection (i).".

(c) NO RECAPTURE FOR VEHICLES CONVERTED TO QUALIFIED PLUG-IN ELECTRIC DRIVE MOTOR VEHICLES.—Paragraph (8) of section 30B(h) is amended by adding at the end the following: ", except that no benefit shall be recaptured if such property ceases to be eligible for such credit by reason of conversion to a qualified plug-in electric drive motor vehicle.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after the date of the enactment of this Act.

26 USC 30B note.

SEC. 1144. TREATMENT OF ALTERNATIVE MOTOR VEHICLE CREDIT AS A PERSONAL CREDIT ALLOWED AGAINST AMT.

(a) IN GENERAL.—Paragraph (2) of section 30B(g) is amended to read as follows:

"(2) PERSONAL CREDIT.—

"(A) IN GENERAL.—For purposes of this title, the credit allowed under subsection (a) for any taxable year (determined after application of paragraph (1)) shall be treated as a credit allowable under subpart A for such taxable year.

"(B) LIMITATION BASED ON AMOUNT OF TAX.—In the case of a taxable year to which section 26(a)(2) does not apply, the credit allowed under subsection (a) for any taxable year (determined after application of paragraph (1)) shall not exceed the excess of—

"(i) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

"(ii) the sum of the credits allowable under subpart A (other than this section and sections 23, 25D, 30, and 30D) and section 27 for the taxable year.".

(b) CONFORMING AMENDMENTS.—

(1)(A) Section 24(b)(3)(B), as amended by this Act, is amended by inserting "30B," after "30,".

(B) Section 25(e)(1)(C)(ii), as amended by this Act, is amended by inserting "30B," after "30,".

(C) Section 25B(g)(2), as amended by this Act, is amended by inserting "30B," after "30,".

(D) Section 26(a)(1), as amended by this Act, is amended by inserting "30B," after "30,".

(E) Section 904(i), as amended by this Act, is amended by inserting "30B," after "30".

(F) Section 1400C(d)(2), as amended by this Act, is amended by striking "and 30" and inserting "30, and 30B".

(2) Section 30C(d)(2)(A), as amended by this Act, is amended by striking "sections 27 and 30B" and inserting "section 27".

(3) Section 55(c)(3) is amended by striking "30B(g)(2),".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 24 note.

(d) APPLICATION OF EGTRRA SUNSET.—The amendment made by subsection (b)(1)(A) shall be subject to title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 in the same manner as the provision of such Act to which such amendment relates. 26 USC 24 note.

PART VI—PARITY FOR TRANSPORTATION FRINGE BENEFITS

SEC. 1151. INCREASED EXCLUSION AMOUNT FOR COMMUTER TRANSIT BENEFITS AND TRANSIT PASSES.

(a) IN GENERAL.—Paragraph (2) of section 132(f) is amended by adding at the end the following flush sentence: 26 USC 132.

"In the case of any month beginning on or after the date of the enactment of this sentence and before January 1, 2011, subparagraph (A) shall be applied as if the dollar amount therein were the same as the dollar amount in effect for such month under subparagraph (B).". Applicability.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to months beginning on or after the date of the enactment of this section. 26 USC 132 note.

Subtitle C—Tax Incentives for Business

PART I—TEMPORARY INVESTMENT INCENTIVES

SEC. 1201. SPECIAL ALLOWANCE FOR CERTAIN PROPERTY ACQUIRED DURING 2009.

(a) EXTENSION OF SPECIAL ALLOWANCE.—

(1) IN GENERAL.—Paragraph (2) of section 168(k) is amended—

(A) by striking "January 1, 2010" and inserting "January 1, 2011", and

(B) by striking "January 1, 2009" each place it appears and inserting "January 1, 2010".

(2) CONFORMING AMENDMENTS.—

(A) The heading for subsection (k) of section 168 is amended by striking "JANUARY 1, 2009" and inserting "JANUARY 1, 2010".

(B) The heading for clause (ii) of section 168(k)(2)(B) is amended by striking "PRE-JANUARY 1, 2009" and inserting "PRE-JANUARY 1, 2010".

(C) Subparagraph (B) of section 168(l)(5) is amended by striking "January 1, 2009" and inserting "January 1, 2010".

(D) Subparagraph (C) of section 168(n)(2) is amended by striking "January 1, 2009" and inserting "January 1, 2010".

(E) Subparagraph (B) of section 1400N(d)(3) is amended by striking "January 1, 2009" and inserting "January 1, 2010".

(3) TECHNICAL AMENDMENTS.—

(A) Subparagraph (D) of section 168(k)(4) is amended—

(i) by striking "and" at the end of clause (i),

(ii) by redesignating clause (ii) as clause (iii), and

(iii) by inserting after clause (i) the following new clause:

"(ii) 'April 1, 2008' shall be substituted for 'January 1, 2008' in subparagraph (A)(iii)(I) thereof, and".

26 USC 6211.

(B) Subparagraph (A) of section 6211(b)(4) is amended by inserting "168(k)(4)," after "53(e),".

(b) EXTENSION OF ELECTION TO ACCELERATE THE AMT AND RESEARCH CREDITS IN LIEU OF BONUS DEPRECIATION.—

(1) IN GENERAL.—Section 168(k)(4) (relating to election to accelerate the AMT and research credits in lieu of bonus depreciation) is amended—

(A) by striking "2009" and inserting "2010"in subparagraph (D)(iii) (as redesignated by subsection (a)(3)), and

(B) by adding at the end the following new subparagraph:

"(H) SPECIAL RULES FOR EXTENSION PROPERTY.—

"(i) TAXPAYERS PREVIOUSLY ELECTING ACCELERATION.—In the case of a taxpayer who made the election under subparagraph (A) for its first taxable year ending after March 31, 2008—

"(I) the taxpayer may elect not to have this paragraph apply to extension property, but

"(II) if the taxpayer does not make the election under subclause (I), in applying this paragraph to the taxpayer a separate bonus depreciation amount, maximum amount, and maximum increase amount shall be computed and applied to eligible qualified property which is extension property and to eligible qualified property which is not extension property.

"(ii) TAXPAYERS NOT PREVIOUSLY ELECTING ACCELERATION.—In the case of a taxpayer who did not make the election under subparagraph (A) for its first taxable year ending after March 31, 2008—

"(I) the taxpayer may elect to have this paragraph apply to its first taxable year ending after December 31, 2008, and each subsequent taxable year, and

"(II) if the taxpayer makes the election under subclause (I), this paragraph shall only apply to eligible qualified property which is extension property.

"(iii) EXTENSION PROPERTY.—For purposes of this subparagraph, the term 'extension property' means property which is eligible qualified property solely by reason of the extension of the application of the special allowance under paragraph (1) pursuant to the amendments made by section 1201(a) of the American Recovery and Reinvestment Tax Act of 2009 (and the application of such extension to this paragraph pursuant to the amendment made by section 1201(b)(1) of such Act).".

(2) TECHNICAL AMENDMENT.—Section 6211(b)(4)(A) is amended by inserting "168(k)(4)," after "53(e),".

Applicability.
26 USC 168 note.

(c) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall apply to property placed in service after December 31, 2008, in taxable years ending after such date.

(2) TECHNICAL AMENDMENTS.—The amendments made by subsections (a)(3) and (b)(2) shall apply to taxable years ending after March 31, 2008.

SEC. 1202. TEMPORARY INCREASE IN LIMITATIONS ON EXPENSING OF CERTAIN DEPRECIABLE BUSINESS ASSETS.

(a) IN GENERAL.—Paragraph (7) of section 179(b) is amended— 26 USC 179.

(1) by striking "2008" and inserting "2008, or 2009", and

(2) by striking "2008" in the heading thereof and inserting "2008, AND 2009".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2008. 26 USC 179 note.

PART II—SMALL BUSINESS PROVISIONS

SEC. 1211. 5-YEAR CARRYBACK OF OPERATING LOSSES OF SMALL BUSINESSES.

(a) IN GENERAL.—Subparagraph (H) of section 172(b)(1) is amended to read as follows:

"(H) CARRYBACK FOR 2008 NET OPERATING LOSSES OF SMALL BUSINESSES.—

"(i) IN GENERAL.—If an eligible small business elects the application of this subparagraph with respect to an applicable 2008 net operating loss— Applicability.

"(I) subparagraph (A)(i) shall be applied by substituting any whole number elected by the taxpayer which is more than 2 and less than 6 for '2',

"(II) subparagraph (E)(ii) shall be applied by substituting the whole number which is one less than the whole number substituted under subclause (I) for '2', and

"(III) subparagraph (F) shall not apply.

"(ii) APPLICABLE 2008 NET OPERATING LOSS.—For purposes of this subparagraph, the term 'applicable 2008 net operating loss' means—

"(I) the taxpayer's net operating loss for any taxable year ending in 2008, or

"(II) if the taxpayer elects to have this subclause apply in lieu of subclause (I), the taxpayer's net operating loss for any taxable year beginning in 2008.

"(iii) ELECTION.—Any election under this subparagraph shall be made in such manner as may be prescribed by the Secretary, and shall be made by the due date (including extension of time) for filing the taxpayer's return for the taxable year of the net operating loss. Any such election, once made, shall be irrevocable. Any election under this subparagraph may be made only with respect to 1 taxable year.

"(iv) ELIGIBLE SMALL BUSINESS.—For purposes of this subparagraph, the term 'eligible small business' has the meaning given such term by subparagraph Applicability.

(F)(iii), except that in applying such subparagraph, section 448(c) shall be applied by substituting '$15,000,000' for '$5,000,000' each place it appears.".

26 USC 172.

(b) CONFORMING AMENDMENT.—Section 172 is amended by striking subsection (k) and by redesignating subsection (l) as subsection (k).

26 USC 172 note.

(c) ANTI-ABUSE RULES.—The Secretary of Treasury or the Secretary's designee shall prescribe such rules as are necessary to prevent the abuse of the purposes of the amendments made by this section, including anti-stuffing rules, anti-churning rules (including rules relating to sale-leasebacks), and rules similar to the rules under section 1091 of the Internal Revenue Code of 1986 relating to losses from wash sales.

26 USC 172 note.

Applicability.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall apply to net operating losses arising in taxable years ending after December 31, 2007.

(2) TRANSITIONAL RULE.—In the case of a net operating loss for a taxable year ending before the date of the enactment of this Act—

(A) any election made under section 172(b)(3) of the Internal Revenue Code of 1986 with respect to such loss may (notwithstanding such section) be revoked before the applicable date,

(B) any election made under section 172(b)(1)(H) of such Code with respect to such loss shall (notwithstanding such section) be treated as timely made if made before the applicable date, and

(C) any application under section 6411(a) of such Code with respect to such loss shall be treated as timely filed if filed before the applicable date.

Definition.

For purposes of this paragraph, the term "applicable date" means the date which is 60 days after the date of the enactment of this Act.

SEC. 1212. DECREASED REQUIRED ESTIMATED TAX PAYMENTS IN 2009 FOR CERTAIN SMALL BUSINESSES.

Paragraph (1) of section 6654(d) is amended by adding at the end the following new subparagraph:

"(D) SPECIAL RULE FOR 2009.—

Applicability.

"(i) IN GENERAL.—Notwithstanding subparagraph (C), in the case of any taxable year beginning in 2009, clause (ii) of subparagraph (B) shall be applied to any qualified individual by substituting '90 percent' for '100 percent'.

"(ii) QUALIFIED INDIVIDUAL.—For purposes of this subparagraph, the term 'qualified individual' means any individual if—

"(I) the adjusted gross income shown on the return of such individual for the preceding taxable year is less than $500,000, and

Certification.

"(II) such individual certifies that more than 50 percent of the gross income shown on the return of such individual for the preceding taxable year was income from a small business.

A certification under subclause (II) shall be in such form and manner and filed at such time as the Secretary may by regulations prescribe.

"(iii) INCOME FROM A SMALL BUSINESS.—For purposes of clause (ii), income from a small business means, with respect to any individual, income from a trade or business the average number of employees of which was less than 500 employees for the calendar year ending with or within the preceding taxable year of the individual.

"(iv) SEPARATE RETURNS.—In the case of a married individual (within the meaning of section 7703) who files a separate return for the taxable year for which the amount of the installment is being determined, clause (ii)(I) shall be applied by substituting '$250,000' for '$500,000'.

"(v) ESTATES AND TRUSTS.—In the case of an estate or trust, adjusted gross income shall be determined as provided in section 67(e).".

PART III—INCENTIVES FOR NEW JOBS

SEC. 1221. INCENTIVES TO HIRE UNEMPLOYED VETERANS AND DISCONNECTED YOUTH.

(a) IN GENERAL.—Subsection (d) of section 51 is amended by adding at the end the following new paragraph: 26 USC 51.

"(14) CREDIT ALLOWED FOR UNEMPLOYED VETERANS AND DISCONNECTED YOUTH HIRED IN 2009 OR 2010.—

"(A) IN GENERAL.—Any unemployed veteran or disconnected youth who begins work for the employer during 2009 or 2010 shall be treated as a member of a targeted group for purposes of this subpart.

"(B) DEFINITIONS.—For purposes of this paragraph—

"(i) UNEMPLOYED VETERAN.—The term 'unemployed veteran' means any veteran (as defined in paragraph (3)(B), determined without regard to clause (ii) thereof) who is certified by the designated local agency as—

"(I) having been discharged or released from active duty in the Armed Forces at any time during the 5-year period ending on the hiring date, and

"(II) being in receipt of unemployment compensation under State or Federal law for not less than 4 weeks during the 1-year period ending on the hiring date.

"(ii) DISCONNECTED YOUTH.—The term 'disconnected youth' means any individual who is certified by the designated local agency—

"(I) as having attained age 16 but not age 25 on the hiring date,

"(II) as not regularly attending any secondary, technical, or post-secondary school during the 6-month period preceding the hiring date,

"(III) as not regularly employed during such 6-month period, and

"(IV) as not readily employable by reason of lacking a sufficient number of basic skills.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to individuals who begin work for the employer after December 31, 2008.

PART IV—RULES RELATING TO DEBT INSTRUMENTS

SEC. 1231. DEFERRAL AND RATABLE INCLUSION OF INCOME ARISING FROM BUSINESS INDEBTEDNESS DISCHARGED BY THE REACQUISITION OF A DEBT INSTRUMENT.

26 USC 108.

(a) IN GENERAL.—Section 108 (relating to income from discharge of indebtedness) is amended by adding at the end the following new subsection:

"(i) DEFERRAL AND RATABLE INCLUSION OF INCOME ARISING FROM BUSINESS INDEBTEDNESS DISCHARGED BY THE REACQUISITION OF A DEBT INSTRUMENT.—

Time periods.

"(1) IN GENERAL.—At the election of the taxpayer, income from the discharge of indebtedness in connection with the reacquisition after December 31, 2008, and before January 1, 2011, of an applicable debt instrument shall be includible in gross income ratably over the 5-taxable-year period beginning with—

"(A) in the case of a reacquisition occurring in 2009, the fifth taxable year following the taxable year in which the reacquisition occurs, and

"(B) in the case of a reacquisition occurring in 2010, the fourth taxable year following the taxable year in which the reacquisition occurs.

"(2) DEFERRAL OF DEDUCTION FOR ORIGINAL ISSUE DISCOUNT IN DEBT FOR DEBT EXCHANGES.—

"(A) IN GENERAL.—If, as part of a reacquisition to which paragraph (1) applies, any debt instrument is issued for the applicable debt instrument being reacquired (or is treated as so issued under subsection (e)(4) and the regulations thereunder) and there is any original issue discount determined under subpart A of part V of subchapter P of this chapter with respect to the debt instrument so issued—

"(i) except as provided in clause (ii), no deduction otherwise allowable under this chapter shall be allowed to the issuer of such debt instrument with respect to the portion of such original issue discount which—

"(I) accrues before the 1st taxable year in the 5-taxable-year period in which income from the discharge of indebtedness attributable to the reacquisition of the debt instrument is includible under paragraph (1), and

"(II) does not exceed the income from the discharge of indebtedness with respect to the debt instrument being reacquired, and

"(ii) the aggregate amount of deductions disallowed under clause (i) shall be allowed as a deduction ratably over the 5-taxable-year period described in clause (i)(I).

If the amount of the original issue discount accruing before such 1st taxable year exceeds the income from the discharge of indebtedness with respect to the applicable debt

instrument being reacquired, the deductions shall be disallowed in the order in which the original issue discount is accrued.

"(B) DEEMED DEBT FOR DEBT EXCHANGES.—For purposes of subparagraph (A), if any debt instrument is issued by an issuer and the proceeds of such debt instrument are used directly or indirectly by the issuer to reacquire an applicable debt instrument of the issuer, the debt instrument so issued shall be treated as issued for the debt instrument being reacquired. If only a portion of the proceeds from a debt instrument are so used, the rules of subparagraph (A) shall apply to the portion of any original issue discount on the newly issued debt instrument which is equal to the portion of the proceeds from such instrument used to reacquire the outstanding instrument.

Regulations. Applicability.

"(3) APPLICABLE DEBT INSTRUMENT.—For purposes of this subsection—

"(A) APPLICABLE DEBT INSTRUMENT.—The term 'applicable debt instrument' means any debt instrument which was issued by—

"(i) a C corporation, or

"(ii) any other person in connection with the conduct of a trade or business by such person.

"(B) DEBT INSTRUMENT.—The term 'debt instrument' means a bond, debenture, note, certificate, or any other instrument or contractual arrangement constituting indebtedness (within the meaning of section 1275(a)(1)).

"(4) REACQUISITION.—For purposes of this subsection—

"(A) IN GENERAL.—The term 'reacquisition' means, with respect to any applicable debt instrument, any acquisition of the debt instrument by—

"(i) the debtor which issued (or is otherwise the obligor under) the debt instrument, or

"(ii) a related person to such debtor.

"(B) ACQUISITION.—The term 'acquisition' shall, with respect to any applicable debt instrument, include an acquisition of the debt instrument for cash, the exchange of the debt instrument for another debt instrument (including an exchange resulting from a modification of the debt instrument), the exchange of the debt instrument for corporate stock or a partnership interest, and the contribution of the debt instrument to capital. Such term shall also include the complete forgiveness of the indebtedness by the holder of the debt instrument.

"(5) OTHER DEFINITIONS AND RULES.—For purposes of this subsection—

"(A) RELATED PERSON.—The determination of whether a person is related to another person shall be made in the same manner as under subsection (e)(4).

"(B) ELECTION.—

"(i) IN GENERAL.—An election under this subsection with respect to any applicable debt instrument shall be made by including with the return of tax imposed by chapter 1 for the taxable year in which the reacquisition of the debt instrument occurs a statement which—

"(I) clearly identifies such instrument, and

"(II) includes the amount of income to which paragraph (1) applies and such other information as the Secretary may prescribe.

"(ii) ELECTION IRREVOCABLE.—Such election, once made, is irrevocable.

"(iii) PASS-THRU ENTITIES.—In the case of a partnership, S corporation, or other pass-thru entity, the election under this subsection shall be made by the partnership, the S corporation, or other entity involved.

"(C) COORDINATION WITH OTHER EXCLUSIONS.—If a taxpayer elects to have this subsection apply to an applicable debt instrument, subparagraphs (A), (B), (C), and (D) of subsection (a)(1) shall not apply to the income from the discharge of such indebtedness for the taxable year of the election or any subsequent taxable year.

"(D) ACCELERATION OF DEFERRED ITEMS.—

"(i) IN GENERAL.—In the case of the death of the taxpayer, the liquidation or sale of substantially all the assets of the taxpayer (including in a title 11 or similar case), the cessation of business by the taxpayer, or similar circumstances, any item of income or deduction which is deferred under this subsection (and has not previously been taken into account) shall be taken into account in the taxable year in which such event occurs (or in the case of a title 11 or similar case, the day before the petition is filed).

Applicability.

"(ii) SPECIAL RULE FOR PASS-THRU ENTITIES.—The rule of clause (i) shall also apply in the case of the sale or exchange or redemption of an interest in a partnership, S corporation, or other pass- thru entity by a partner, shareholder, or other person holding an ownership interest in such entity.

"(6) SPECIAL RULE FOR PARTNERSHIPS.—In the case of a partnership, any income deferred under this subsection shall be allocated to the partners in the partnership immediately before the discharge in the manner such amounts would have been included in the distributive shares of such partners under section 704 if such income were recognized at such time. Any decrease in a partner's share of partnership liabilities as a result of such discharge shall not be taken into account for purposes of section 752 at the time of the discharge to the extent it would cause the partner to recognize gain under section 731. Any decrease in partnership liabilities deferred under the preceding sentence shall be taken into account by such partner at the same time, and to the extent remaining in the same amount, as income deferred under this subsection is recognized.

"(7) SECRETARIAL AUTHORITY.—The Secretary may prescribe such regulations, rules, or other guidance as may be necessary or appropriate for purposes of applying this subsection, including—

"(A) extending the application of the rules of paragraph (5)(D) to other circumstances where appropriate,

"(B) requiring reporting of the election (and such other information as the Secretary may require) on returns of tax for subsequent taxable years, and

"(C) rules for the application of this subsection to partnerships, S corporations, and other pass-thru entities, including for the allocation of deferred deductions.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges in taxable years ending after December 31, 2008. 26 USC 108 note.

SEC. 1232. MODIFICATIONS OF RULES FOR ORIGINAL ISSUE DISCOUNT ON CERTAIN HIGH YIELD OBLIGATIONS.

(a) SUSPENSION OF SPECIAL RULES.—Section 163(e)(5) (relating to special rules for original issue discount on certain high yield obligations) is amended by redesignating subparagraph (F) as subparagraph (G) and by inserting after subparagraph (E) the following new subparagraph: 26 USC 163.

"(F) SUSPENSION OF APPLICATION OF PARAGRAPH.—

"(i) TEMPORARY SUSPENSION.—This paragraph shall not apply to any applicable high yield discount obligation issued during the period beginning on September 1, 2008, and ending on December 31, 2009, in exchange (including an exchange resulting from a modification of the debt instrument) for an obligation which is not an applicable high yield discount obligation and the issuer (or obligor) of which is the same as the issuer (or obligor) of such applicable high yield discount obligation. The preceding sentence shall not apply to any obligation the interest on which is interest described in section 871(h)(4) (without regard to subparagraph (D) thereof) or to any obligation issued to a related person (within the meaning of section 108(e)(4)). Time period.

"(ii) SUCCESSIVE APPLICATION.—Any obligation to which clause (i) applies shall not be treated as an applicable high yield discount obligation for purposes of applying this subparagraph to any other obligation issued in exchange for such obligation.

"(iii) SECRETARIAL AUTHORITY TO SUSPEND APPLICATION.—The Secretary may apply this paragraph with respect to debt instruments issued in periods following the period described in clause (i) if the Secretary determines that such application is appropriate in light of distressed conditions in the debt capital markets.".

(b) INTEREST RATE USED IN DETERMINING HIGH YIELD OBLIGATIONS.—The last sentence of section 163(i)(1) is amended—

(1) by inserting "(i)" after "regulation", and

(2) by inserting ", or (ii) permit, on a temporary basis, a rate to be used with respect to any debt instrument which is higher than the applicable Federal rate if the Secretary determines that such rate is appropriate in light of distressed conditions in the debt capital markets" before the period at the end.

(c) EFFECTIVE DATE.— 26 USC 163 note.

(1) SUSPENSION.—The amendments made by subsection (a) shall apply to obligations issued after August 31, 2008, in taxable years ending after such date.

(2) INTEREST RATE AUTHORITY.—The amendments made by subsection (b) shall apply to obligations issued after December 31, 2009, in taxable years ending after such date.

PART V—QUALIFIED SMALL BUSINESS STOCK

SEC. 1241. SPECIAL RULES APPLICABLE TO QUALIFIED SMALL BUSINESS STOCK FOR 2009 AND 2010.

(a) IN GENERAL.—Section 1202(a) is amended by adding at the end the following new paragraph:

"(3) SPECIAL RULES FOR 2009 AND 2010.—In the case of qualified small business stock acquired after the date of the enactment of this paragraph and before January 1, 2011—

"(A) paragraph (1) shall be applied by substituting '75 percent' for '50 percent', and

"(B) paragraph (2) shall not apply.".

26 USC 1202 note.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to stock acquired after the date of the enactment of this Act.

PART VI—S CORPORATIONS

SEC. 1251. TEMPORARY REDUCTION IN RECOGNITION PERIOD FOR BUILT-IN GAINS TAX.

26 USC 1374.

(a) IN GENERAL.—Paragraph (7) of section 1374(d) (relating to definitions and special rules) is amended to read as follows:

"(7) RECOGNITION PERIOD.—

"(A) IN GENERAL.—The term 'recognition period' means the 10-year period beginning with the 1st day of the 1st taxable year for which the corporation was an S corporation.

"(B) SPECIAL RULE FOR 2009 AND 2010.—In the case of any taxable year beginning in 2009 or 2010, no tax shall be imposed on the net recognized built-in gain of an S corporation if the 7th taxable year in the recognition period preceded such taxable year. The preceding sentence shall be applied separately with respect to any asset to which paragraph (8) applies.

Applicability.

"(C) SPECIAL RULE FOR DISTRIBUTIONS TO SHAREHOLDERS.—For purposes of applying this section to any amount includible in income by reason of distributions to shareholders pursuant to section 593(e)—

Applicability.

"(i) subparagraph (A) shall be applied without regard to the phrase '10-year', and

"(ii) subparagraph (B) shall not apply.".

26 USC 1374 note.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2008.

PART VII—RULES RELATING TO OWNERSHIP CHANGES

26 USC 382 note.

SEC. 1261. CLARIFICATION OF REGULATIONS RELATED TO LIMITATIONS ON CERTAIN BUILT-IN LOSSES FOLLOWING AN OWNERSHIP CHANGE.

(a) FINDINGS.—Congress finds as follows:

(1) The delegation of authority to the Secretary of the Treasury under section 382(m) of the Internal Revenue Code of 1986 does not authorize the Secretary to provide exemptions or special rules that are restricted to particular industries or classes of taxpayers.

(2) Internal Revenue Service Notice 2008–83 is inconsistent with the congressional intent in enacting such section 382(m).

(3) The legal authority to prescribe Internal Revenue Service Notice 2008–83 is doubtful.

(4) However, as taxpayers should generally be able to rely on guidance issued by the Secretary of the Treasury legislation is necessary to clarify the force and effect of Internal Revenue Service Notice 2008–83 and restore the proper application under the Internal Revenue Code of 1986 of the limitation on built-in losses following an ownership change of a bank.

(b) DETERMINATION OF FORCE AND EFFECT OF INTERNAL REVENUE SERVICE NOTICE 2008–83 EXEMPTING BANKS FROM LIMITATION ON CERTAIN BUILT–IN LOSSES FOLLOWING OWNERSHIP CHANGE.—

(1) IN GENERAL.—Internal Revenue Service Notice 2008–83—

(A) shall be deemed to have the force and effect of law with respect to any ownership change (as defined in section 382(g) of the Internal Revenue Code of 1986) occurring on or before January 16, 2009, and

(B) shall have no force or effect with respect to any ownership change after such date.

(2) BINDING CONTRACTS.—Notwithstanding paragraph (1), Internal Revenue Service Notice 2008–83 shall have the force and effect of law with respect to any ownership change (as so defined) which occurs after January 16, 2009, if such change—

(A) is pursuant to a written binding contract entered into on or before such date, or

(B) is pursuant to a written agreement entered into on or before such date and such agreement was described on or before such date in a public announcement or in a filing with the Securities and Exchange Commission required by reason of such ownership change.

SEC. 1262. TREATMENT OF CERTAIN OWNERSHIP CHANGES FOR PURPOSES OF LIMITATIONS ON NET OPERATING LOSS CARRYFORWARDS AND CERTAIN BUILT-IN LOSSES.

(a) IN GENERAL.—Section 382 is amended by adding at the end the following new subsection: 26 USC 382.

"(n) SPECIAL RULE FOR CERTAIN OWNERSHIP CHANGES.—

"(1) IN GENERAL.—The limitation contained in subsection (a) shall not apply in the case of an ownership change which is pursuant to a restructuring plan of a taxpayer which—

"(A) is required under a loan agreement or a commitment for a line of credit entered into with the Department of the Treasury under the Emergency Economic Stabilization Act of 2008, and

"(B) is intended to result in a rationalization of the costs, capitalization, and capacity with respect to the manufacturing workforce of, and suppliers to, the taxpayer and its subsidiaries.

"(2) SUBSEQUENT ACQUISITIONS.—Paragraph (1) shall not apply in the case of any subsequent ownership change unless such ownership change is described in such paragraph.

"(3) LIMITATION BASED ON CONTROL IN CORPORATION.—

"(A) IN GENERAL.—Paragraph (1) shall not apply in the case of any ownership change if, immediately after such ownership change, any person (other than a voluntary employees' beneficiary association under section 501(c)(9)) owns stock of the new loss corporation possessing 50 percent or more of the total combined voting power of all classes of stock entitled to vote, or of the total value of the stock of such corporation.

"(B) TREATMENT OF RELATED PERSONS.—

"(i) IN GENERAL.—Related persons shall be treated as a single person for purposes of this paragraph.

"(ii) RELATED PERSONS.—For purposes of clause (i), a person shall be treated as related to another person if—

"(I) such person bears a relationship to such other person described in section 267(b) or 707(b), or

"(II) such persons are members of a group of persons acting in concert.".

26 USC 382 note.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to ownership changes after the date of the enactment of this Act.

Subtitle D—Manufacturing Recovery Provisions

SEC. 1301. TEMPORARY EXPANSION OF AVAILABILITY OF INDUSTRIAL DEVELOPMENT BONDS TO FACILITIES MANUFACTURING INTANGIBLE PROPERTY.

26 USC 144.

(a) IN GENERAL.—Subparagraph (C) of section 144(a)(12) is amended—

(1) by striking "For purposes of this paragraph, the term" and inserting "For purposes of this paragraph—

"(i) IN GENERAL.—The term", and

(2) by striking the last sentence and inserting the following new clauses:

"(ii) CERTAIN FACILITIES INCLUDED.—Such term includes facilities which are directly related and ancillary to a manufacturing facility (determined without regard to this clause) if—

"(I) such facilities are located on the same site as the manufacturing facility, and

"(II) not more than 25 percent of the net proceeds of the issue are used to provide such facilities.

"(iii) SPECIAL RULES FOR BONDS ISSUED IN 2009 AND 2010.—In the case of any issue made after the date of enactment of this clause and before January 1, 2011, clause (ii) shall not apply and the net proceeds from a bond shall be considered to be used to provide a manufacturing facility if such proceeds are used to provide—

"(I) a facility which is used in the creation or production of intangible property which is described in section 197(d)(1)(C)(iii), or

"(II) a facility which is functionally related and subordinate to a manufacturing facility (determined without regard to this subclause) if such facility is located on the same site as the manufacturing facility.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to obligations issued after the date of the enactment of this Act. 26 USC 144 note.

SEC. 1302. CREDIT FOR INVESTMENT IN ADVANCED ENERGY FACILITIES.

(a) IN GENERAL.—Section 46 (relating to amount of credit) is amended by striking "and" at the end of paragraph (3), by striking the period at the end of paragraph (4), and by adding at the end the following new paragraph: 26 USC 46.

"(5) the qualifying advanced energy project credit.".

(b) AMOUNT OF CREDIT.—Subpart E of part IV of subchapter A of chapter 1 (relating to rules for computing investment credit) is amended by inserting after section 48B the following new section:

"SEC. 48C. QUALIFYING ADVANCED ENERGY PROJECT CREDIT.

"(a) IN GENERAL.—For purposes of section 46, the qualifying advanced energy project credit for any taxable year is an amount equal to 30 percent of the qualified investment for such taxable year with respect to any qualifying advanced energy project of the taxpayer.

"(b) QUALIFIED INVESTMENT.—

"(1) IN GENERAL.—For purposes of subsection (a), the qualified investment for any taxable year is the basis of eligible property placed in service by the taxpayer during such taxable year which is part of a qualifying advanced energy project.

"(2) CERTAIN QUALIFIED PROGRESS EXPENDITURES RULES MADE APPLICABLE.—Rules similar to the rules of subsections (c)(4) and (d) of section 46 (as in effect on the day before the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of this section.

"(3) LIMITATION.—The amount which is treated for all taxable years with respect to any qualifying advanced energy project shall not exceed the amount designated by the Secretary as eligible for the credit under this section.

"(c) DEFINITIONS.—

"(1) QUALIFYING ADVANCED ENERGY PROJECT.—

"(A) IN GENERAL.—The term 'qualifying advanced energy project' means a project—

"(i) which re-equips, expands, or establishes a manufacturing facility for the production of—

"(I) property designed to be used to produce energy from the sun, wind, geothermal deposits (within the meaning of section 613(e)(2)), or other renewable resources,

"(II) fuel cells, microturbines, or an energy storage system for use with electric or hybrid-electric motor vehicles,

"(III) electric grids to support the transmission of intermittent sources of renewable energy, including storage of such energy,

"(IV) property designed to capture and sequester carbon dioxide emissions,

"(V) property designed to refine or blend renewable fuels or to produce energy conservation technologies (including energy-conserving lighting technologies and smart grid technologies),

"(VI) new qualified plug-in electric drive motor vehicles (as defined by section 30D), qualified plug-in electric vehicles (as defined by section 30(d)), or components which are designed specifically for use with such vehicles, including electric motors, generators, and power control units, or

"(VII) other advanced energy property designed to reduce greenhouse gas emissions as may be determined by the Secretary, and

"(ii) any portion of the qualified investment of which is certified by the Secretary under subsection (d) as eligible for a credit under this section.

"(B) EXCEPTION.—Such term shall not include any portion of a project for the production of any property which is used in the refining or blending of any transportation fuel (other than renewable fuels).

"(2) ELIGIBLE PROPERTY.—The term 'eligible property' means any property—

"(A) which is necessary for the production of property described in paragraph (1)(A)(i),

"(B) which is—

"(i) tangible personal property, or

"(ii) other tangible property (not including a building or its structural components), but only if such property is used as an integral part of the qualified investment credit facility, and

"(C) with respect to which depreciation (or amortization in lieu of depreciation) is allowable.

"(d) QUALIFYING ADVANCED ENERGY PROJECT PROGRAM.—

"(1) ESTABLISHMENT.—

Deadline.

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, in consultation with the Secretary of Energy, shall establish a qualifying advanced energy project program to consider and award certifications for qualified investments eligible for credits under this section to qualifying advanced energy project sponsors.

"(B) LIMITATION.—The total amount of credits that may be allocated under the program shall not exceed $2,300,000,000.

"(2) CERTIFICATION.—

"(A) APPLICATION PERIOD.—Each applicant for certification under this paragraph shall submit an application containing such information as the Secretary may require during the 2-year period beginning on the date the Secretary establishes the program under paragraph (1).

Deadline.

"(B) TIME TO MEET CRITERIA FOR CERTIFICATION.—Each applicant for certification shall have 1 year from the date of acceptance by the Secretary of the application during which to provide to the Secretary evidence that the requirements of the certification have been met.

Deadline.

"(C) PERIOD OF ISSUANCE.—An applicant which receives a certification shall have 3 years from the date of issuance

of the certification in order to place the project in service and if such project is not placed in service by that time period, then the certification shall no longer be valid.

"(3) SELECTION CRITERIA.—In determining which qualifying advanced energy projects to certify under this section, the Secretary—

"(A) shall take into consideration only those projects where there is a reasonable expectation of commercial viability, and

"(B) shall take into consideration which projects—

"(i) will provide the greatest domestic job creation (both direct and indirect) during the credit period,

"(ii) will provide the greatest net impact in avoiding or reducing air pollutants or anthropogenic emissions of greenhouse gases,

"(iii) have the greatest potential for technological innovation and commercial deployment,

"(iv) have the lowest levelized cost of generated or stored energy, or of measured reduction in energy consumption or greenhouse gas emission (based on costs of the full supply chain), and

"(v) have the shortest project time from certification to completion.

"(4) REVIEW AND REDISTRIBUTION.—

"(A) REVIEW.—Not later than 4 years after the date of enactment of this section, the Secretary shall review the credits allocated under this section as of such date. Deadline.

"(B) REDISTRIBUTION.—The Secretary may reallocate credits awarded under this section if the Secretary determines that—

"(i) there is an insufficient quantity of qualifying applications for certification pending at the time of the review, or

"(ii) any certification made pursuant to paragraph (2) has been revoked pursuant to paragraph (2)(B) because the project subject to the certification has been delayed as a result of third party opposition or litigation to the proposed project.

"(C) REALLOCATION.—If the Secretary determines that credits under this section are available for reallocation pursuant to the requirements set forth in paragraph (2), the Secretary is authorized to conduct an additional program for applications for certification.

"(5) DISCLOSURE OF ALLOCATIONS.—The Secretary shall, upon making a certification under this subsection, publicly disclose the identity of the applicant and the amount of the credit with respect to such applicant.

"(e) DENIAL OF DOUBLE BENEFIT.—A credit shall not be allowed under this section for any qualified investment for which a credit is allowed under section 48, 48A, or 48B.".

(c) CONFORMING AMENDMENTS.—

(1) Section 49(a)(1)(C) is amended by striking "and" at the end of clause (iii), by striking the period at the end of clause (iv) and inserting ", and", and by adding after clause (iv) the following new clause: 26 USC 49.

"(v) the basis of any property which is part of a qualifying advanced energy project under section 48C.".

(2) The table of sections for subpart E of part IV of subchapter A of chapter 1 is amended by inserting after the item relating to section 48B the following new item:

"48C. Qualifying advanced energy project credit.".

26 USC 46 note.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to periods after the date of the enactment of this Act, under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990).

Subtitle E—Economic Recovery Tools

SEC. 1401. RECOVERY ZONE BONDS.

(a) IN GENERAL.—Subchapter Y of chapter 1 is amended by adding at the end the following new part:

"PART III—RECOVERY ZONE BONDS

"Sec. 1400U–1. Allocation of recovery zone bonds.
"Sec. 1400U–2. Recovery zone economic development bonds.
"Sec. 1400U–3. Recovery zone facility bonds.

"SEC. 1400U–1. ALLOCATION OF RECOVERY ZONE BONDS.

"(a) ALLOCATIONS.—

"(1) IN GENERAL.—

"(A) GENERAL ALLOCATION.—The Secretary shall allocate the national recovery zone economic development bond limitation and the national recovery zone facility bond limitation among the States in the proportion that each such State's 2008 State employment decline bears to the aggregate of the 2008 State employment declines for all of the States.

"(B) MINIMUM ALLOCATION.—The Secretary shall adjust the allocations under subparagraph (A) for any calendar year for each State to the extent necessary to ensure that no State receives less than 0.9 percent of the national recovery zone economic development bond limitation and 0.9 percent of the national recovery zone facility bond limitation.

"(2) 2008 STATE EMPLOYMENT DECLINE.—For purposes of this subsection, the term '2008 State employment decline' means, with respect to any State, the excess (if any) of—

"(A) the number of individuals employed in such State determined for December 2007, over

"(B) the number of individuals employed in such State determined for December 2008.

"(3) ALLOCATIONS BY STATES.—

"(A) IN GENERAL.—Each State with respect to which an allocation is made under paragraph (1) shall reallocate such allocation among the counties and large municipalities in such State in the proportion to each such county's or municipality's 2008 employment decline bears to the aggregate of the 2008 employment declines for all the counties and municipalities in such State. A county or municipality

Waiver authority.

may waive any portion of an allocation made under this subparagraph.

"(B) LARGE MUNICIPALITIES.—For purposes of subparagraph (A), the term 'large municipality' means a municipality with a population of more than 100,000.

"(C) DETERMINATION OF LOCAL EMPLOYMENT DECLINES.—For purposes of this paragraph, the employment decline of any municipality or county shall be determined in the same manner as determining the State employment decline under paragraph (2), except that in the case of a municipality any portion of which is in a county, such portion shall be treated as part of such municipality and not part of such county.

"(4) NATIONAL LIMITATIONS.—

"(A) RECOVERY ZONE ECONOMIC DEVELOPMENT BONDS.—There is a national recovery zone economic development bond limitation of $10,000,000,000.

"(B) RECOVERY ZONE FACILITY BONDS.—There is a national recovery zone facility bond limitation of $15,000,000,000.

"(b) RECOVERY ZONE.—For purposes of this part, the term 'recovery zone' means—

"(1) any area designated by the issuer as having significant poverty, unemployment, rate of home foreclosures, or general distress,

"(2) any area designated by the issuer as economically distressed by reason of the closure or realignment of a military installation pursuant to the Defense Base Closure and Realignment Act of 1990, and

"(3) any area for which a designation as an empowerment zone or renewal community is in effect.

"SEC. 1400U–2. RECOVERY ZONE ECONOMIC DEVELOPMENT BONDS.

"(a) IN GENERAL.—In the case of a recovery zone economic development bond—

"(1) such bond shall be treated as a qualified bond for purposes of section 6431, and

"(2) subsection (b) of such section shall be applied by substituting '45 percent' for '35 percent'. Applicability.

"(b) RECOVERY ZONE ECONOMIC DEVELOPMENT BOND.—

"(1) IN GENERAL.—For purposes of this section, the term 'recovery zone economic development bond' means any build America bond (as defined in section 54AA(d)) issued before January 1, 2011, as part of issue if—

"(A) 100 percent of the excess of—

"(i) the available project proceeds (as defined in section 54A) of such issue, over

"(ii) the amounts in a reasonably required reserve (within the meaning of section 150(a)(3)) with respect to such issue,

are to be used for one or more qualified economic development purposes, and

"(B) the issuer designates such bond for purposes of this section.

"(2) LIMITATION ON AMOUNT OF BONDS DESIGNATED.—The maximum aggregate face amount of bonds which may be designated by any issuer under paragraph (1) shall not exceed

the amount of the recovery zone economic development bond limitation allocated to such issuer under section 1400U–1.

"(c) QUALIFIED ECONOMIC DEVELOPMENT PURPOSE.—For purposes of this section, the term 'qualified economic development purpose' means expenditures for purposes of promoting development or other economic activity in a recovery zone, including—

"(1) capital expenditures paid or incurred with respect to property located in such zone,

"(2) expenditures for public infrastructure and construction of public facilities, and

"(3) expenditures for job training and educational programs.

"SEC. 1400U–3. RECOVERY ZONE FACILITY BONDS.

"(a) IN GENERAL.—For purposes of part IV of subchapter B (relating to tax exemption requirements for State and local bonds), the term 'exempt facility bond' includes any recovery zone facility bond.

"(b) RECOVERY ZONE FACILITY BOND.—

"(1) IN GENERAL.—For purposes of this section, the term 'recovery zone facility bond' means any bond issued as part of an issue if—

"(A) 95 percent or more of the net proceeds (as defined in section 150(a)(3)) of such issue are to be used for recovery zone property,

"(B) such bond is issued before January 1, 2011, and

"(C) the issuer designates such bond for purposes of this section.

"(2) LIMITATION ON AMOUNT OF BONDS DESIGNATED.—The maximum aggregate face amount of bonds which may be designated by any issuer under paragraph (1) shall not exceed the amount of recovery zone facility bond limitation allocated to such issuer under section 1400U–1.

"(c) RECOVERY ZONE PROPERTY.—For purposes of this section—

"(1) IN GENERAL.—The term 'recovery zone property' means any property to which section 168 applies (or would apply but for section 179) if—

"(A) such property was constructed, reconstructed, renovated, or acquired by purchase (as defined in section 179(d)(2)) by the taxpayer after the date on which the designation of the recovery zone took effect,

"(B) the original use of which in the recovery zone commences with the taxpayer, and

"(C) substantially all of the use of which is in the recovery zone and is in the active conduct of a qualified business by the taxpayer in such zone.

"(2) QUALIFIED BUSINESS.—The term 'qualified business' means any trade or business except that—

"(A) the rental to others of real property located in a recovery zone shall be treated as a qualified business only if the property is not residential rental property (as defined in section 168(e)(2)), and

"(B) such term shall not include any trade or business consisting of the operation of any facility described in section 144(c)(6)(B).

Applicability.

"(3) SPECIAL RULES FOR SUBSTANTIAL RENOVATIONS AND SALE-LEASEBACK.—Rules similar to the rules of subsections

(a)(2) and (b) of section 1397D shall apply for purposes of this subsection.

"(d) NONAPPLICATION OF CERTAIN RULES.—Sections 146 (relating to volume cap) and 147(d) (relating to acquisition of existing property not permitted) shall not apply to any recovery zone facility bond.".

(b) CLERICAL AMENDMENT.—The table of parts for subchapter Y of chapter 1 of such Code is amended by adding at the end the following new item:

"PART III. RECOVERY ZONE BONDS.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to obligations issued after the date of the enactment of this Act. 26 USC 1400U–1 note.

SEC. 1402. TRIBAL ECONOMIC DEVELOPMENT BONDS.

(a) IN GENERAL.—Section 7871 is amended by adding at the end the following new subsection: 26 USC 7871.

"(f) TRIBAL ECONOMIC DEVELOPMENT BONDS.—

"(1) ALLOCATION OF LIMITATION.—

"(A) IN GENERAL.—The Secretary shall allocate the national tribal economic development bond limitation among the Indian tribal governments in such manner as the Secretary, in consultation with the Secretary of the Interior, determines appropriate.

"(B) NATIONAL LIMITATION.—There is a national tribal economic development bond limitation of $2,000,000,000.

"(2) BONDS TREATED AS EXEMPT FROM TAX.—In the case of a tribal economic development bond—

"(A) notwithstanding subsection (c), such bond shall be treated for purposes of this title in the same manner as if such bond were issued by a State,

"(B) the Indian tribal government issuing such bond and any instrumentality of such Indian tribal government shall be treated as a State for purposes of section 141, and

"(C) section 146 shall not apply.

"(3) TRIBAL ECONOMIC DEVELOPMENT BOND.—

"(A) IN GENERAL.—For purposes of this section, the term 'tribal economic development bond' means any bond issued by an Indian tribal government—

"(i) the interest on which would be exempt from tax under section 103 if issued by a State or local government, and

"(ii) which is designated by the Indian tribal government as a tribal economic development bond for purposes of this subsection.

"(B) EXCEPTIONS.—Such term shall not include any bond issued as part of an issue if any portion of the proceeds of such issue are used to finance—

"(i) any portion of a building in which class II or class III gaming (as defined in section 4 of the Indian Gaming Regulatory Act) is conducted or housed or any other property actually used in the conduct of such gaming, or

"(ii) any facility located outside the Indian reservation (as defined in section 168(j)(6)).

"(C) LIMITATION ON AMOUNT OF BONDS DESIGNATED.—The maximum aggregate face amount of bonds which may be designated by any Indian tribal government under subparagraph (A) shall not exceed the amount of national tribal economic development bond limitation allocated to such government under paragraph (1).".

(b) STUDY.—The Secretary of the Treasury, or the Secretary's delegate, shall conduct a study of the effects of the amendment made by subsection (a). Not later than 1 year after the date of the enactment of this Act, the Secretary of the Treasury, or the Secretary's delegate, shall report to Congress on the results of the study conducted under this paragraph, including the Secretary's recommendations regarding such amendment.

Deadline. Reports.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to obligations issued after the date of the enactment of this Act.

26 USC 7871 note.

SEC. 1403. INCREASE IN NEW MARKETS TAX CREDIT.

(a) IN GENERAL.—Section 45D(f)(1) is amended—

26 USC 45.

(1) by striking "and" at the end of subparagraph (C),

(2) by striking ", 2007, 2008, and 2009." in subparagraph (D), and inserting "and 2007,", and

(3) by adding at the end the following new subparagraphs:

"(E) $5,000,000,000 for 2008, and

"(F) $5,000,000,000 for 2009.".

(b) SPECIAL RULE FOR ALLOCATION OF INCREASED 2008 LIMITATION.—The amount of the increase in the new markets tax credit limitation for calendar year 2008 by reason of the amendments made by subsection (a) shall be allocated in accordance with section 45D(f)(2) of the Internal Revenue Code of 1986 to qualified community development entities (as defined in section 45D(c) of such Code) which—

26 USC 45D note.

(1) submitted an allocation application with respect to calendar year 2008, and

(2)(A) did not receive an allocation for such calendar year, or

(B) received an allocation for such calendar year in an amount less than the amount requested in the allocation application.

SEC. 1404. COORDINATION OF LOW-INCOME HOUSING CREDIT AND LOW-INCOME HOUSING GRANTS.

Subsection (i) of section 42 is amended by adding at the end the following new paragraph:

"(9) COORDINATION WITH LOW-INCOME HOUSING GRANTS.—

"(A) REDUCTION IN STATE HOUSING CREDIT CEILING FOR LOW-INCOME HOUSING GRANTS RECEIVED IN 2009.—For purposes of this section, the amounts described in clauses (i) through (iv) of subsection (h)(3)(C) with respect to any State for 2009 shall each be reduced by so much of such amount as is taken into account in determining the amount of any grant to such State under section 1602 of the American Recovery and Reinvestment Tax Act of 2009.

"(B) SPECIAL RULE FOR BASIS.—Basis of a qualified low-income building shall not be reduced by the amount of any grant described in subparagraph (A).".

Subtitle F—Infrastructure Financing Tools

PART I—IMPROVED MARKETABILITY FOR TAX-EXEMPT BONDS

SEC. 1501. DE MINIMIS SAFE HARBOR EXCEPTION FOR TAX-EXEMPT INTEREST EXPENSE OF FINANCIAL INSTITUTIONS.

(a) IN GENERAL.—Subsection (b) of section 265 is amended by adding at the end the following new paragraph: 26 USC 265.

"(7) DE MINIMIS EXCEPTION FOR BONDS ISSUED DURING 2009 OR 2010.—

"(A) IN GENERAL.—In applying paragraph (2)(A), there shall not be taken into account tax-exempt obligations issued during 2009 or 2010.

"(B) LIMITATION.—The amount of tax-exempt obligations not taken into account by reason of subparagraph (A) shall not exceed 2 percent of the amount determined under paragraph (2)(B).

"(C) REFUNDINGS.—For purposes of this paragraph, a refunding bond (whether a current or advance refunding) shall be treated as issued on the date of the issuance of the refunded bond (or in the case of a series of refundings, the original bond).".

(b) TREATMENT AS FINANCIAL INSTITUTION PREFERENCE ITEM.—Clause (iv) of section 291(e)(1)(B) is amended by adding at the end the following: "That portion of any obligation not taken into account under paragraph (2)(A) of section 265(b) by reason of paragraph (7) of such section shall be treated for purposes of this section as having been acquired on August 7, 1986.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to obligations issued after December 31, 2008. 26 USC 265 note.

SEC. 1502. MODIFICATION OF SMALL ISSUER EXCEPTION TO TAX-EXEMPT INTEREST EXPENSE ALLOCATION RULES FOR FINANCIAL INSTITUTIONS.

(a) IN GENERAL.—Paragraph (3) of section 265(b) (relating to exception for certain tax-exempt obligations) is amended by adding at the end the following new subparagraph:

"(G) SPECIAL RULES FOR OBLIGATIONS ISSUED DURING 2009 AND 2010.—

"(i) INCREASE IN LIMITATION.—In the case of obligations issued during 2009 or 2010, subparagraphs (C)(i), (D)(i), and (D)(iii)(II) shall each be applied by substituting '$30,000,000' for '$10,000,000'. Applicability.

"(ii) QUALIFIED 501(C)(3) BONDS TREATED AS ISSUED BY EXEMPT ORGANIZATION.—In the case of a qualified 501(c)(3) bond (as defined in section 145) issued during 2009 or 2010, this paragraph shall be applied by treating the 501(c)(3) organization for whose benefit such bond was issued as the issuer. Applicability.

"(iii) SPECIAL RULE FOR QUALIFIED FINANCINGS.—In the case of a qualified financing issue issued during 2009 or 2010—

"(I) subparagraph (F) shall not apply, and

"(II) any obligation issued as a part of such issue shall be treated as a qualified tax-exempt

obligation if the requirements of this paragraph are met with respect to each qualified portion of the issue (determined by treating each qualified portion as a separate issue which is issued by the qualified borrower with respect to which such portion relates).

"(iv) QUALIFIED FINANCING ISSUE.—For purposes of this subparagraph, the term 'qualified financing issue' means any composite, pooled, or other conduit financing issue the proceeds of which are used directly or indirectly to make or finance loans to 1 or more ultimate borrowers each of whom is a qualified borrower.

"(v) QUALIFIED PORTION.—For purposes of this subparagraph, the term 'qualified portion' means that portion of the proceeds which are used with respect to each qualified borrower under the issue.

"(vi) QUALIFIED BORROWER.—For purposes of this subparagraph, the term 'qualified borrower' means a borrower which is a State or political subdivision thereof or an organization described in section 501(c)(3) and exempt from taxation under section 501(a).".

26 USC 265 note.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to obligations issued after December 31, 2008.

SEC. 1503. TEMPORARY MODIFICATION OF ALTERNATIVE MINIMUM TAX LIMITATIONS ON TAX-EXEMPT BONDS.

26 USC 57.

(a) INTEREST ON PRIVATE ACTIVITY BONDS ISSUED DURING 2009 AND 2010 NOT TREATED AS TAX PREFERENCE ITEM.—Subparagraph (C) of section 57(a)(5) is amended by adding at the end a new clause:

"(vi) EXCEPTION FOR BONDS ISSUED IN 2009 AND 2010.—

"(I) IN GENERAL.—For purposes of clause (i), the term 'private activity bond' shall not include any bond issued after December 31, 2008, and before January 1, 2011.

"(II) TREATMENT OF REFUNDING BONDS.—For purposes of subclause (I), a refunding bond (whether a current or advance refunding) shall be treated as issued on the date of the issuance of the refunded bond (or in the case of a series of refundings, the original bond).

"(III) EXCEPTION FOR CERTAIN REFUNDING BONDS.—Subclause (II) shall not apply to any refunding bond which is issued to refund any bond which was issued after December 31, 2003, and before January 1, 2009.".

(b) NO ADJUSTMENT TO ADJUSTED CURRENT EARNINGS FOR INTEREST ON TAX-EXEMPT BONDS ISSUED DURING 2009 AND 2010.—Subparagraph (B) of section 56(g)(4) is amended by adding at the end the following new clause:

"(iv) TAX EXEMPT INTEREST ON BONDS ISSUED IN 2009 AND 2010.—

"(I) IN GENERAL.—Clause (i) shall not apply in the case of any interest on a bond issued after December 31, 2008, and before January 1, 2011.

"(II) TREATMENT OF REFUNDING BONDS.—For purposes of subclause (I), a refunding bond (whether a current or advance refunding) shall be treated as issued on the date of the issuance of the refunded bond (or in the case of a series of refundings, the original bond).

"(III) EXCEPTION FOR CERTAIN REFUNDING BONDS.—Subclause (II) shall not apply to any refunding bond which is issued to refund any bond which was issued after December 31, 2003, and before January 1, 2009.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to obligations issued after December 31, 2008. 26 USC 56 note.

SEC. 1504. MODIFICATION TO HIGH SPEED INTERCITY RAIL FACILITY BONDS.

(a) IN GENERAL.—Paragraph (1) of section 142(i) is amended by striking "operate at speeds in excess of" and inserting "be capable of attaining a maximum speed in excess of". 26 USC 142.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to obligations issued after the date of the enactment of this Act. 26 USC 142 note.

PART II—DELAY IN APPLICATION OF WITHHOLDING TAX ON GOVERNMENT CONTRACTORS

SEC. 1511. DELAY IN APPLICATION OF WITHHOLDING TAX ON GOVERNMENT CONTRACTORS. 26 USC 3402 note.

Subsection (b) of section 511 of the Tax Increase Prevention and Reconciliation Act of 2005 is amended by striking "December 31, 2010" and inserting "December 31, 2011". 26 USC 3402.

PART III—TAX CREDIT BONDS FOR SCHOOLS

SEC. 1521. QUALIFIED SCHOOL CONSTRUCTION BONDS.

(a) IN GENERAL.—Subpart I of part IV of subchapter A of chapter 1 is amended by adding at the end the following new section:

"SEC. 54F. QUALIFIED SCHOOL CONSTRUCTION BONDS.

"(a) QUALIFIED SCHOOL CONSTRUCTION BOND.—For purposes of this subchapter, the term 'qualified school construction bond' means any bond issued as part of an issue if—

"(1) 100 percent of the available project proceeds of such issue are to be used for the construction, rehabilitation, or repair of a public school facility or for the acquisition of land on which such a facility is to be constructed with part of the proceeds of such issue,

"(2) the bond is issued by a State or local government within the jurisdiction of which such school is located, and

"(3) the issuer designates such bond for purposes of this section.

"(b) LIMITATION ON AMOUNT OF BONDS DESIGNATED.—The maximum aggregate face amount of bonds issued during any calendar year which may be designated under subsection (a) by any issuer

shall not exceed the limitation amount allocated under subsection (d) for such calendar year to such issuer.

"(c) NATIONAL LIMITATION ON AMOUNT OF BONDS DESIGNATED.—There is a national qualified school construction bond limitation for each calendar year. Such limitation is—

"(1) $11,000,000,000 for 2009,

"(2) $11,000,000,000 for 2010, and

"(3) except as provided in subsection (e), zero after 2010.

"(d) ALLOCATION OF LIMITATION.—

"(1) ALLOCATION AMONG STATES.—Except as provided in paragraph (2)(C), the limitation applicable under subsection (c) for any calendar year shall be allocated by the Secretary among the States in proportion to the respective amounts each such State is eligible to receive under section 1124 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6333) for the most recent fiscal year ending before such calendar year. The limitation amount allocated to a State under the preceding sentence shall be allocated by the State to issuers within such State.

"(2) 40 PERCENT OF LIMITATION ALLOCATED AMONG LARGEST SCHOOL DISTRICTS.—

"(A) IN GENERAL.—40 percent of the limitation applicable under subsection (c) for any calendar year shall be allocated under subparagraph (B) by the Secretary among local educational agencies which are large local educational agencies for such year.

"(B) ALLOCATION FORMULA.—The amount to be allocated under subparagraph (A) for any calendar year shall be allocated among large local educational agencies in proportion to the respective amounts each such agency received under section 1124 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6333) for the most recent fiscal year ending before such calendar year.

"(C) REDUCTION IN STATE ALLOCATION.—The allocation to any State under paragraph (1) shall be reduced by the aggregate amount of the allocations under this paragraph to large local educational agencies within such State.

"(D) ALLOCATION OF UNUSED LIMITATION TO STATE.—The amount allocated under this paragraph to a large local educational agency for any calendar year may be reallocated by such agency to the State in which such agency is located for such calendar year. Any amount reallocated to a State under the preceding sentence may be allocated as provided in paragraph (1).

"(E) LARGE LOCAL EDUCATIONAL AGENCY.—For purposes of this paragraph, the term 'large local educational agency' means, with respect to a calendar year, any local educational agency if such agency is—

"(i) among the 100 local educational agencies with the largest numbers of children aged 5 through 17 from families living below the poverty level, as determined by the Secretary using the most recent data available from the Department of Commerce that are satisfactory to the Secretary, or

"(ii) 1 of not more than 25 local educational agencies (other than those described in clause (i)) that the Secretary of Education determines (based on the

most recent data available satisfactory to the Secretary) are in particular need of assistance, based on a low level of resources for school construction, a high level of enrollment growth, or such other factors as the Secretary deems appropriate.

"(3) ALLOCATIONS TO CERTAIN POSSESSIONS.—The amount to be allocated under paragraph (1) to any possession of the United States other than Puerto Rico shall be the amount which would have been allocated if all allocations under paragraph (1) were made on the basis of respective populations of individuals below the poverty line (as defined by the Office of Management and Budget). In making other allocations, the amount to be allocated under paragraph (1) shall be reduced by the aggregate amount allocated under this paragraph to possessions of the United States.

"(4) ALLOCATIONS FOR INDIAN SCHOOLS.—In addition to the amounts otherwise allocated under this subsection, $200,000,000 for calendar year 2009, and $200,000,000 for calendar year 2010, shall be allocated by the Secretary of the Interior for purposes of the construction, rehabilitation, and repair of schools funded by the Bureau of Indian Affairs. In the case of amounts allocated under the preceding sentence, Indian tribal governments (as defined in section 7701(a)(40)) shall be treated as qualified issuers for purposes of this subchapter.

"(e) CARRYOVER OF UNUSED LIMITATION.—If for any calendar year—

"(1) the amount allocated under subsection (d) to any State, exceeds

"(2) the amount of bonds issued during such year which are designated under subsection (a) pursuant to such allocation, the limitation amount under such subsection for such State for the following calendar year shall be increased by the amount of such excess. A similar rule shall apply to the amounts allocated under subsection (d)(4).". Applicability.

(b) CONFORMING AMENDMENTS.—

(1) Paragraph (1) of section 54A(d) is amended by striking "or" at the end of subparagraph (C), by inserting "or" at the end of subparagraph (D), and by inserting after subparagraph (D) the following new subparagraph: 26 USC 54.

"(E) a qualified school construction bond,".

(2) Subparagraph (C) of section 54A(d)(2) is amended by striking "and" at the end of clause (iii), by striking the period at the end of clause (iv) and inserting ", and", and by adding at the end the following new clause:

"(v) in the case of a qualified school construction bond, a purpose specified in section 54F(a)(1).".

(3) The table of sections for subpart I of part IV of subchapter A of chapter 1 is amended by adding at the end the following new item:

"Sec. 54F. Qualified school construction bonds.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to obligations issued after the date of the enactment of this Act. 26 USC 54A note.

SEC. 1522. EXTENSION AND EXPANSION OF QUALIFIED ZONE ACADEMY BONDS.

26 USC 54.

(a) IN GENERAL.—Section 54E(c)(1) is amended by striking "and 2009" and inserting "and $1,400,000,000 for 2009 and 2010".

26 USC 54E note.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to obligations issued after December 31, 2008.

PART IV—BUILD AMERICA BONDS

SEC. 1531. BUILD AMERICA BONDS.

(a) IN GENERAL.—Part IV of subchapter A of chapter 1 is amended by adding at the end the following new subpart:

"Subpart J—Build America Bonds

"Sec. 54AA. Build America bonds.

"SEC. 54AA. BUILD AMERICA BONDS.

"(a) IN GENERAL.—If a taxpayer holds a build America bond on one or more interest payment dates of the bond during any taxable year, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to the sum of the credits determined under subsection (b) with respect to such dates.

"(b) AMOUNT OF CREDIT.—The amount of the credit determined under this subsection with respect to any interest payment date for a build America bond is 35 percent of the amount of interest payable by the issuer with respect to such date .

"(c) LIMITATION BASED ON AMOUNT OF TAX.—

"(1) IN GENERAL.—The credit allowed under subsection (a) for any taxable year shall not exceed the excess of—

"(A) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

"(B) the sum of the credits allowable under this part (other than subpart C and this subpart).

"(2) CARRYOVER OF UNUSED CREDIT.—If the credit allowable under subsection (a) exceeds the limitation imposed by paragraph (1) for such taxable year, such excess shall be carried to the succeeding taxable year and added to the credit allowable under subsection (a) for such taxable year (determined before the application of paragraph (1) for such succeeding taxable year).

"(d) BUILD AMERICA BOND.—

"(1) IN GENERAL.—For purposes of this section, the term 'build America bond' means any obligation (other than a private activity bond) if—

"(A) the interest on such obligation would (but for this section) be excludable from gross income under section 103,

"(B) such obligation is issued before January 1, 2011, and

"(C) the issuer makes an irrevocable election to have this section apply.

"(2) APPLICABLE RULES.—For purposes of applying paragraph (1)—

"(A) for purposes of section 149(b), a build America bond shall not be treated as federally guaranteed by reason of the credit allowed under subsection (a) or section 6431,

"(B) for purposes of section 148, the yield on a build America bond shall be determined without regard to the credit allowed under subsection (a), and

"(C) a bond shall not be treated as a build America bond if the issue price has more than a de minimis amount (determined under rules similar to the rules of section 1273(a)(3)) of premium over the stated principal amount of the bond.

"(e) INTEREST PAYMENT DATE.—For purposes of this section, the term 'interest payment date' means any date on which the holder of record of the build America bond is entitled to a payment of interest under such bond.

"(f) SPECIAL RULES.—

"(1) INTEREST ON BUILD AMERICA BONDS INCLUDIBLE IN GROSS INCOME FOR FEDERAL INCOME TAX PURPOSES.—For purposes of this title, interest on any build America bond shall be includible in gross income.

"(2) APPLICATION OF CERTAIN RULES.—Rules similar to the rules of subsections (f), (g), (h), and (i) of section 54A shall apply for purposes of the credit allowed under subsection (a).

"(g) SPECIAL RULE FOR QUALIFIED BONDS ISSUED BEFORE 2011.—In the case of a qualified bond issued before January 1, 2011—

"(1) ISSUER ALLOWED REFUNDABLE CREDIT.—In lieu of any credit allowed under this section with respect to such bond, the issuer of such bond shall be allowed a credit as provided in section 6431.

"(2) QUALIFIED BOND.—For purposes of this subsection, the term 'qualified bond' means any build America bond issued as part of an issue if—

"(A) 100 percent of the excess of—

"(i) the available project proceeds (as defined in section 54A) of such issue, over

"(ii) the amounts in a reasonably required reserve (within the meaning of section 150(a)(3)) with respect to such issue,

are to be used for capital expenditures, and

"(B) the issuer makes an irrevocable election to have this subsection apply.

"(h) REGULATIONS.—The Secretary may prescribe such regulations and other guidance as may be necessary or appropriate to carry out this section and section 6431.".

(b) CREDIT FOR QUALIFIED BONDS ISSUED BEFORE 2011.—Subchapter B of chapter 65 is amended by adding at the end the following new section:

"SEC. 6431. CREDIT FOR QUALIFIED BONDS ALLOWED TO ISSUER.

"(a) IN GENERAL.—In the case of a qualified bond issued before January 1, 2011, the issuer of such bond shall be allowed a credit with respect to each interest payment under such bond which shall be payable by the Secretary as provided in subsection (b).

"(b) PAYMENT OF CREDIT.—The Secretary shall pay (contemporaneously with each interest payment date under such bond) to the issuer of such bond (or to any person who makes such

interest payments on behalf of the issuer) 35 percent of the interest payable under such bond on such date.

"(c) APPLICATION OF ARBITRAGE RULES.—For purposes of section 148, the yield on a qualified bond shall be reduced by the credit allowed under this section.

"(d) INTEREST PAYMENT DATE.—For purposes of this subsection, the term 'interest payment date' means each date on which interest is payable by the issuer under the terms of the bond.

"(e) QUALIFIED BOND.—For purposes of this subsection, the term 'qualified bond' has the meaning given such term in section 54AA(g).".

(c) CONFORMING AMENDMENTS.—

(1) Section 1324(b)(2) of title 31, United States Code, is amended by striking "or 6428" and inserting "6428, or 6431,".

26 USC 54.

(2) Section 54A(c)(1)(B) is amended by striking "subpart C" and inserting "subparts C and J".

(3) Sections 54(c)(2), 1397E(c)(2), and 1400N(l)(3)(B) are each amended by striking "and I" and inserting ", I, and J".

(4) Section 6211(b)(4)(A) is amended by striking "and 6428" and inserting "6428, and 6431".

(5) Section 6401(b)(1) is amended by striking "and I" and inserting "I, and J".

(6) The table of subparts for part IV of subchapter A of chapter 1 is amended by adding at the end the following new item:

"SUBPART J. BUILD AMERICA BONDS.".

(7) The table of section for subchapter B of chapter 65 is amended by adding at the end the following new item:

"Sec. 6431. Credit for qualified bonds allowed to issuer.".

26 USC 54AA note.

(d) TRANSITIONAL COORDINATION WITH STATE LAW.—Except as otherwise provided by a State after the date of the enactment of this Act, the interest on any build America bond (as defined in section 54AA of the Internal Revenue Code of 1986, as added by this section) and the amount of any credit determined under such section with respect to such bond shall be treated for purposes of the income tax laws of such State as being exempt from Federal income tax.

26 USC 54 note.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to obligations issued after the date of the enactment of this Act.

PART V—REGULATED INVESTMENT COMPANIES ALLOWED TO PASS-THRU TAX CREDIT BOND CREDITS

SEC. 1541. REGULATED INVESTMENT COMPANIES ALLOWED TO PASS-THRU TAX CREDIT BOND CREDITS.

(a) IN GENERAL.—Part I of subchapter M of chapter 1 is amended by inserting after section 853 the following new section:

"SEC. 853A. CREDITS FROM TAX CREDIT BONDS ALLOWED TO SHAREHOLDERS.

"(a) GENERAL RULE.—A regulated investment company—

"(1) which holds (directly or indirectly) one or more tax credit bonds on one or more applicable dates during the taxable year, and

"(2) which meets the requirements of section 852(a) for the taxable year,

may elect the application of this section with respect to credits allowable to the investment company during such taxable year with respect to such bonds.

"(b) EFFECT OF ELECTION.—If the election provided in subsection (a) is in effect for any taxable year—

"(1) the regulated investment company shall not be allowed any credits to which subsection (a) applies for such taxable year,

"(2) the regulated investment company shall—

"(A) include in gross income (as interest) for such taxable year an amount equal to the amount that such investment company would have included in gross income with respect to such credits if this section did not apply, and

"(B) increase the amount of the dividends paid deduction for such taxable year by the amount of such income, and

"(3) each shareholder of such investment company shall—

"(A) include in gross income an amount equal to such shareholder's proportionate share of the interest income attributable to such credits, and

"(B) be allowed the shareholder's proportionate share of such credits against the tax imposed by this chapter.

"(c) NOTICE TO SHAREHOLDERS.—For purposes of subsection (b)(3), the shareholder's proportionate share of— Deadline.

"(1) credits described in subsection (a), and

"(2) gross income in respect of such credits,

shall not exceed the amounts so designated by the regulated investment company in a written notice mailed to its shareholders not later than 60 days after the close of its taxable year.

"(d) MANNER OF MAKING ELECTION AND NOTIFYING SHAREHOLDERS.—The election provided in subsection (a) and the notice to shareholders required by subsection (c) shall be made in such manner as the Secretary may prescribe.

"(e) DEFINITIONS AND SPECIAL RULES.—

"(1) DEFINITIONS.—For purposes of this subsection—

"(A) TAX CREDIT BOND.—The term 'tax credit bond' means—

"(i) a qualified tax credit bond (as defined in section 54A(d)),

"(ii) a build America bond (as defined in section 54AA(d)), and

"(iii) any bond for which a credit is allowable under subpart H of part IV of subchapter A of this chapter.

"(B) APPLICABLE DATE.—The term 'applicable date' means—

"(i) in the case of a qualified tax credit bond or a bond described in subparagraph (A)(iii), any credit allowance date (as defined in section 54A(e)(1)), and

"(ii) in the case of a build America bond (as defined in section 54AA(d)), any interest payment date (as defined in section 54AA(e)).

"(2) STRIPPED TAX CREDIT BONDS.—If the ownership of a tax credit bond is separated from the credit with respect to such bond, subsection (a) shall be applied by reference to the Applicability.

instruments evidencing the entitlement to the credit rather than the tax credit bond.

"(f) REGULATIONS, ETC.—The Secretary shall prescribe such regulations or other guidance as may be necessary or appropriate to carry out the purposes of this section, including methods for determining a shareholder's proportionate share of credits.".

(b) CONFORMING AMENDMENTS.—

26 USC 54.

(1) Section 54(l) is amended by striking paragraph (4) and by redesignating paragraphs (5) and (6) as paragraphs (4) and (5), respectively.

(2) Section 54A(h) is amended to read as follows:

Procedures.

"(h) BONDS HELD BY REAL ESTATE INVESTMENT TRUSTS.—If any qualified tax credit bond is held by a real estate investment trust, the credit determined under subsection (a) shall be allowed to beneficiaries of such trust (and any gross income included under subsection (f) with respect to such credit shall be distributed to such beneficiaries) under procedures prescribed by the Secretary.".

(3) The table of sections for part I of subchapter M of chapter 1 is amended by inserting after the item relating to section 853 the following new item:

"Sec. 853A. Credits from tax credit bonds allowed to shareholders.".

26 USC 54 note.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years ending after the date of the enactment of this Act.

Subtitle G—Other Provisions

26 USC 54C note.

SEC. 1601. APPLICATION OF CERTAIN LABOR STANDARDS TO PROJECTS FINANCED WITH CERTAIN TAX-FAVORED BONDS.

Subchapter IV of chapter 31 of the title 40, United States Code, shall apply to projects financed with the proceeds of—

(1) any new clean renewable energy bond (as defined in section 54C of the Internal Revenue Code of 1986) issued after the date of the enactment of this Act,

(2) any qualified energy conservation bond (as defined in section 54D of the Internal Revenue Code of 1986) issued after the date of the enactment of this Act,

(3) any qualified zone academy bond (as defined in section 54E of the Internal Revenue Code of 1986) issued after the date of the enactment of this Act,

(4) any qualified school construction bond (as defined in section 54F of the Internal Revenue Code of 1986), and

(5) any recovery zone economic development bond (as defined in section 1400U–2 of the Internal Revenue Code of 1986).

26 USC 42 note.

SEC. 1602. GRANTS TO STATES FOR LOW-INCOME HOUSING PROJECTS IN LIEU OF LOW-INCOME HOUSING CREDIT ALLOCATIONS FOR 2009.

(a) IN GENERAL.—The Secretary of the Treasury shall make a grant to the housing credit agency of each State in an amount equal to such State's low-income housing grant election amount.

(b) LOW-INCOME HOUSING GRANT ELECTION AMOUNT.—For purposes of this section, the term "low-income housing grant election amount" means, with respect to any State, such amount as the

State may elect which does not exceed 85 percent of the product of—

(1) the sum of—

(A) 100 percent of the State housing credit ceiling for 2009 which is attributable to amounts described in clauses (i) and (iii) of section 42(h)(3)(C) of the Internal Revenue Code of 1986, and

(B) 40 percent of the State housing credit ceiling for 2009 which is attributable to amounts described in clauses (ii) and (iv) of such section, multiplied by

(2) 10.

(c) SUBAWARDS FOR LOW-INCOME BUILDINGS.—

(1) IN GENERAL.—A State housing credit agency receiving a grant under this section shall use such grant to make subawards to finance the construction or acquisition and rehabilitation of qualified low-income buildings. A subaward under this section may be made to finance a qualified low-income building with or without an allocation under section 42 of the Internal Revenue Code of 1986, except that a State housing credit agency may make subawards to finance qualified low-income buildings without an allocation only if it makes a determination that such use will increase the total funds available to the State to build and rehabilitate affordable housing. In complying with such determination requirement, a State housing credit agency shall establish a process in which applicants that are allocated credits are required to demonstrate good faith efforts to obtain investment commitments for such credits before the agency makes such subawards.

Procedures.

(2) SUBAWARDS SUBJECT TO SAME REQUIREMENTS AS LOW-INCOME HOUSING CREDIT ALLOCATIONS.—Any such subaward with respect to any qualified low-income building shall be made in the same manner and shall be subject to the same limitations (including rent, income, and use restrictions on such building) as an allocation of housing credit dollar amount allocated by such State housing credit agency under section 42 of the Internal Revenue Code of 1986, except that such subawards shall not be limited by, or otherwise affect (except as provided in subsection (h)(3)(J) of such section), the State housing credit ceiling applicable to such agency.

(3) COMPLIANCE AND ASSET MANAGEMENT.—The State housing credit agency shall perform asset management functions to ensure compliance with section 42 of the Internal Revenue Code of 1986 and the long-term viability of buildings funded by any subaward under this section. The State housing credit agency may collect reasonable fees from a subaward recipient to cover expenses associated with the performance of its duties under this paragraph. The State housing credit agency may retain an agent or other private contractor to satisfy the requirements of this paragraph.

(4) RECAPTURE.—The State housing credit agency shall impose conditions or restrictions, including a requirement providing for recapture, on any subaward under this section so as to assure that the building with respect to which such subaward is made remains a qualified low-income building during the compliance period. Any such recapture shall be payable to the Secretary of the Treasury for deposit in the general fund of the Treasury and may be enforced by means

of liens or such other methods as the Secretary of the Treasury determines appropriate.

Deadline.

(d) RETURN OF UNUSED GRANT FUNDS.—Any grant funds not used to make subawards under this section before January 1, 2011, shall be returned to the Secretary of the Treasury on such date. Any subawards returned to the State housing credit agency on or after such date shall be promptly returned to the Secretary of the Treasury. Any amounts returned to the Secretary of the Treasury under this subsection shall be deposited in the general fund of the Treasury.

(e) DEFINITIONS.—Any term used in this section which is also used in section 42 of the Internal Revenue Code of 1986 shall have the same meaning for purposes of this section as when used in such section 42. Any reference in this section to the Secretary of the Treasury shall be treated as including the Secretary's delegate.

(f) APPROPRIATIONS.—There is hereby appropriated to the Secretary of the Treasury such sums as may be necessary to carry out this section.

26 USC 48 note.

SEC. 1603. GRANTS FOR SPECIFIED ENERGY PROPERTY IN LIEU OF TAX CREDITS.

(a) IN GENERAL.—Upon application, the Secretary of the Treasury shall, subject to the requirements of this section, provide a grant to each person who places in service specified energy property to reimburse such person for a portion of the expense of such property as provided in subsection (b). No grant shall be made under this section with respect to any property unless such property—

(1) is placed in service during 2009 or 2010, or

(2) is placed in service after 2010 and before the credit termination date with respect to such property, but only if the construction of such property began during 2009 or 2010.

(b) GRANT AMOUNT.—

(1) IN GENERAL.—The amount of the grant under subsection (a) with respect to any specified energy property shall be the applicable percentage of the basis of such property.

(2) APPLICABLE PERCENTAGE.—For purposes of paragraph (1), the term "applicable percentage" means—

(A) 30 percent in the case of any property described in paragraphs (1) through (4) of subsection (d), and

(B) 10 percent in the case of any other property.

(3) DOLLAR LIMITATIONS.—In the case of property described in paragraph (2), (6), or (7) of subsection (d), the amount of any grant under this section with respect to such property shall not exceed the limitation described in section 48(c)(1)(B), 48(c)(2)(B), or 48(c)(3)(B) of the Internal Revenue Code of 1986, respectively, with respect to such property.

(c) TIME FOR PAYMENT OF GRANT.—The Secretary of the Treasury shall make payment of any grant under subsection (a) during the 60-day period beginning on the later of—

(1) the date of the application for such grant, or

(2) the date the specified energy property for which the grant is being made is placed in service.

(d) SPECIFIED ENERGY PROPERTY.—For purposes of this section, the term "specified energy property" means any of the following:

(1) QUALIFIED FACILITIES.—Any qualified property (as defined in section 48(a)(5)(D) of the Internal Revenue Code of 1986) which is part of a qualified facility (within the meaning of section 45 of such Code) described in paragraph (1), (2), (3), (4), (6), (7), (9), or (11) of section 45(d) of such Code.

(2) QUALIFIED FUEL CELL PROPERTY.—Any qualified fuel cell property (as defined in section 48(c)(1) of such Code).

(3) SOLAR PROPERTY.—Any property described in clause (i) or (ii) of section 48(a)(3)(A) of such Code.

(4) QUALIFIED SMALL WIND ENERGY PROPERTY.—Any qualified small wind energy property (as defined in section 48(c)(4) of such Code).

(5) GEOTHERMAL PROPERTY.—Any property described in clause (iii) of section 48(a)(3)(A) of such Code.

(6) QUALIFIED MICROTURBINE PROPERTY.—Any qualified microturbine property (as defined in section 48(c)(2) of such Code).

(7) COMBINED HEAT AND POWER SYSTEM PROPERTY.—Any combined heat and power system property (as defined in section 48(c)(3) of such Code).

(8) GEOTHERMAL HEAT PUMP PROPERTY.—Any property described in clause (vii) of section 48(a)(3)(A) of such Code.

Such term shall not include any property unless depreciation (or amortization in lieu of depreciation) is allowable with respect to such property.

(e) CREDIT TERMINATION DATE.—For purposes of this section, the term "credit termination date" means—

(1) in the case of any specified energy property which is part of a facility described in paragraph (1) of section 45(d) of the Internal Revenue Code of 1986, January 1, 2013,

(2) in the case of any specified energy property which is part of a facility described in paragraph (2), (3), (4), (6), (7), (9), or (11) of section 45(d) of such Code, January 1, 2014, and

(3) in the case of any specified energy property described in section 48 of such Code, January 1, 2017.

Applicability.

In the case of any property which is described in paragraph (3) and also in another paragraph of this subsection, paragraph (3) shall apply with respect to such property.

(f) APPLICATION OF CERTAIN RULES.—In making grants under this section, the Secretary of the Treasury shall apply rules similar to the rules of section 50 of the Internal Revenue Code of 1986. In applying such rules, if the property is disposed of, or otherwise ceases to be specified energy property, the Secretary of the Treasury shall provide for the recapture of the appropriate percentage of the grant amount in such manner as the Secretary of the Treasury determines appropriate.

(g) EXCEPTION FOR CERTAIN NON-TAXPAYERS.—The Secretary of the Treasury shall not make any grant under this section to—

(1) any Federal, State, or local government (or any political subdivision, agency, or instrumentality thereof),

(2) any organization described in section 501(c) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code,

(3) any entity referred to in paragraph (4) of section 54(j) of such Code, or

(4) any partnership or other pass-thru entity any partner (or other holder of an equity or profits interest) of which is described in paragraph (1), (2) or (3).

(h) DEFINITIONS.—Terms used in this section which are also used in section 45 or 48 of the Internal Revenue Code of 1986 shall have the same meaning for purposes of this section as when used in such section 45 or 48. Any reference in this section to the Secretary of the Treasury shall be treated as including the Secretary's delegate.

(i) APPROPRIATIONS.—There is hereby appropriated to the Secretary of the Treasury such sums as may be necessary to carry out this section.

Deadline.

(j) TERMINATION.—The Secretary of the Treasury shall not make any grant to any person under this section unless the application of such person for such grant is received before October 1, 2011.

31 USC 3101.

SEC. 1604. INCREASE IN PUBLIC DEBT LIMIT.

Subsection (b) of section 3101 of title 31, United States Code, is amended by striking out the dollar limitation contained in such subsection and inserting "$12,104,000,000,000".

Subtitle H—Prohibition on Collection of Certain Payments Made Under the Continued Dumping and Subsidy Offset Act of 2000

19 USC 1675c note.

SEC. 1701. PROHIBITION ON COLLECTION OF CERTAIN PAYMENTS MADE UNDER THE CONTINUED DUMPING AND SUBSIDY OFFSET ACT OF 2000.

(a) IN GENERAL.—Notwithstanding any other provision of law, neither the Secretary of Homeland Security nor any other person may—

(1) require repayment of, or attempt in any other way to recoup, any payments described in subsection (b); or

(2) offset any past, current, or future distributions of antidumping or countervailing duties assessed with respect to imports from countries that are not parties to the North American Free Trade Agreement in an attempt to recoup any payments described in subsection (b).

(b) PAYMENTS DESCRIBED.—Payments described in this subsection are payments of antidumping or countervailing duties made pursuant to the Continued Dumping and Subsidy Offset Act of 2000 (section 754 of the Tariff Act of 1930 (19 U.S.C. 1675c; repealed by subtitle F of title VII of the Deficit Reduction Act of 2005 (Public Law 109–171; 120 Stat. 154))) that were—

(1) assessed and paid on imports of goods from countries that are parties to the North American Free Trade Agreement; and

(2) distributed on or after January 1, 2001, and before January 1, 2006.

Deadline.

(c) PAYMENT OF FUNDS COLLECTED OR WITHHELD.—Not later than the date that is 60 days after the date of the enactment of this Act, the Secretary of Homeland Security shall—

(1) refund any repayments, or any other recoupment, of payments described in subsection (b); and

(2) fully distribute any antidumping or countervailing duties that the U.S. Customs and Border Protection is withholding as an offset as described in subsection (a)(2).

(d) LIMITATION.—Nothing in this section shall be construed to prevent the Secretary of Homeland Security, or any other person, from requiring repayment of, or attempting to otherwise recoup, any payments described in subsection (b) as a result of—

(1) a finding of false statements or other misconduct by a recipient of such a payment; or

(2) the reliquidation of an entry with respect to which such a payment was made.

Subtitle I—Trade Adjustment Assistance

Trade and Globalization Adjustment Assistance Act of 2009. 19 USC 2101 note.

SEC. 1800. SHORT TITLE.

This subtitle may be cited as the "Trade and Globalization Adjustment Assistance Act of 2009".

PART I—TRADE ADJUSTMENT ASSISTANCE FOR WORKERS

Subpart A—Trade Adjustment Assistance for Service Sector Workers

SEC. 1801. EXTENSION OF TRADE ADJUSTMENT ASSISTANCE TO SERVICE SECTOR AND PUBLIC AGENCY WORKERS; SHIFTS IN PRODUCTION.

(a) DEFINITIONS.—Section 247 of the Trade Act of 1974 (19 U.S.C. 2319) is amended—

(1) in paragraph (1)—

(A) by striking "or appropriate subdivision of a firm"; and

(B) by striking "or subdivision";

(2) in paragraph (2), by striking "employment—" and all that follows and inserting "employment, has been totally or partially separated from such employment.";

(3) by inserting after paragraph (2) the following:

"(3) Subject to section 222(d)(5), the term 'firm' means—

"(A) a firm, including an agricultural firm, service sector firm, or public agency; or

"(B) an appropriate subdivision thereof.";

(4) by inserting after paragraph (6) the following:

"(7) The term 'public agency' means a department or agency of a State or local government or of the Federal Government, or a subdivision thereof.";

(5) in paragraph (11), by striking ", or in a subdivision of which,"; and

(6) by adding at the end the following:

"(18) The term 'service sector firm' means a firm engaged in the business of supplying services.".

(b) GROUP ELIGIBILITY REQUIREMENTS.—Section 222 of the Trade Act of 1974 (19 U.S.C. 2272) is amended—

(1) in subsection (a)(2)—

(A) by amending subparagraph (A)(ii) to read as follows:

"(ii)(I) imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

"(II) imports of articles like or directly competitive with articles—

"(aa) into which one or more component parts produced by such firm are directly incorporated, or

"(bb) which are produced directly using services supplied by such firm,

have increased; or

"(III) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased; and"; and

(B) by amending subparagraph (B) to read as follows:

"(B)(i)(I) there has been a shift by such workers' firm to a foreign country in the production of articles or the supply of services like or directly competitive with articles which are produced or services which are supplied by such firm; or

"(II) such workers' firm has acquired from a foreign country articles or services that are like or directly competitive with articles which are produced or services which are supplied by such firm; and

"(ii) the shift described in clause (i)(I) or the acquisition of articles or services described in clause (i)(II) contributed importantly to such workers' separation or threat of separation.";

(2) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(3) by inserting after subsection (a) the following:

"(b) ADVERSELY AFFECTED WORKERS IN PUBLIC AGENCIES.—A group of workers in a public agency shall be certified by the Secretary as eligible to apply for adjustment assistance under this chapter pursuant to a petition filed under section 221 if the Secretary determines that—

Certification.

"(1) a significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

"(2) the public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

"(3) the acquisition of services described in paragraph (2) contributed importantly to such workers' separation or threat of separation.".

(c) BASIS FOR SECRETARY'S DETERMINATIONS.—Section 222 of the Trade Act of 1974 (19 U.S.C. 2272), as amended, is further amended by adding at the end the following:

"(e) BASIS FOR SECRETARY'S DETERMINATIONS.—

"(1) IN GENERAL.—The Secretary shall, in determining whether to certify a group of workers under section 223, obtain from the workers' firm, or a customer of the workers' firm, information the Secretary determines to be necessary to make the certification, through questionnaires and in such other manner as the Secretary determines appropriate.

"(2) ADDITIONAL INFORMATION.—The Secretary may seek additional information to determine whether to certify a group of workers under subsection (a), (b), or (c)—

"(A) by contacting—

"(i) officials or employees of the workers' firm;

"(ii) officials of customers of the workers' firm;

"(iii) officials of certified or recognized unions or other duly authorized representatives of the group of workers; or

"(iv) one-stop operators or one-stop partners (as defined in section 101 of the Workforce Investment Act of 1998 (29 U.S.C. 2801)); or

"(B) by using other available sources of information.

"(3) VERIFICATION OF INFORMATION.—

"(A) CERTIFICATION.—The Secretary shall require a firm or customer to certify—

"(i) all information obtained under paragraph (1) from the firm or customer (as the case may be) through questionnaires; and

"(ii) all other information obtained under paragraph (1) from the firm or customer (as the case may be) on which the Secretary relies in making a determination under section 223, unless the Secretary has a reasonable basis for determining that such information is accurate and complete without being certified.

"(B) USE OF SUBPOENAS.—The Secretary shall require the workers' firm or a customer of the workers' firm to provide information requested by the Secretary under paragraph (1) by subpoena pursuant to section 249 if the firm or customer (as the case may be) fails to provide the information within 20 days after the date of the Secretary's request, unless the firm or customer (as the case may be) demonstrates to the satisfaction of the Secretary that the firm or customer (as the case may be) will provide the information within a reasonable period of time. Deadline.

"(C) PROTECTION OF CONFIDENTIAL INFORMATION.—The Secretary may not release information obtained under paragraph (1) that the Secretary considers to be confidential business information unless the firm or customer (as the case may be) submitting the confidential business information had notice, at the time of submission, that the information would be released by the Secretary, or the firm or customer (as the case may be) subsequently consents to the release of the information. Nothing in this subparagraph shall be construed to prohibit the Secretary from providing such confidential business information to a court in camera or to another party under a protective order issued by a court.".

(d) PENALTIES.—Section 244 of the Trade Act of 1974 (19 U.S.C. 2316) is amended to read as follows:

"SEC. 244. PENALTIES.

"Any person who—

"(1) makes a false statement of a material fact knowing it to be false, or knowingly fails to disclose a material fact, for the purpose of obtaining or increasing for that person or for any other person any payment authorized to be furnished

under this chapter or pursuant to an agreement under section 239, or

"(2) makes a false statement of a material fact knowing it to be false, or knowingly fails to disclose a material fact, when providing information to the Secretary during an investigation of a petition under section 221,

shall be imprisoned for not more than one year, or fined under title 18, United States Code, or both.".

(e) CONFORMING AMENDMENTS.—

(1) Section 221(a) of the Trade Act of 1974 (19 U.S.C. 2271(a)) is amended—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "Secretary" and inserting "Secretary of Labor"; and

(II) by striking "or subdivision" and inserting "(as defined in section 247)"; and

(ii) in subparagraph (A), by striking "(including workers in an agricultural firm or subdivision of any agricultural firm)";

(B) in paragraph (2)(A), by striking "rapid response assistance" and inserting "rapid response activities"; and

(C) in paragraph (3), by inserting "and on the website of the Department of Labor" after "Federal Register".

(2) Section 222 of the Trade Act of 1974 (19 U.S.C. 2272), as amended, is further amended—

(A) by striking "(including workers in any agricultural firm or subdivision of an agricultural firm)" each place it appears;

(B) in subsection (a)—

(i) in paragraph (1), by striking ", or an appropriate subdivision of the firm,"; and

(ii) in paragraph (2), by striking "or subdivision" each place it appears;

(C) in subsection (c) (as redesignated)—

(i) in paragraph (2)—

(I) by striking "(or subdivision)" each place it appears;

(II) by inserting "or service" after "the article"; and

(III) by striking "(c) (3)" and inserting "(d) (3)"; and

(ii) in paragraph (3), by striking "(or subdivision)" each place it appears; and

(D) in subsection (d) (as redesignated)—

(i) by striking "For purposes" and inserting "DEFINITIONS.—For purposes";

(ii) in paragraph (2), by striking ", or appropriate subdivision of a firm," each place it appears;

(iii) by amending paragraph (3) to read as follows:

"(3) DOWNSTREAM PRODUCER.—

"(A) IN GENERAL.—The term 'downstream producer' means a firm that performs additional, value-added production processes or services directly for another firm for articles or services with respect to which a group of workers in such other firm has been certified under subsection (a).

"(B) VALUE-ADDED PRODUCTION PROCESSES OR SERVICES.—For purposes of subparagraph (A), value-added production processes or services include final assembly, finishing, testing, packaging, or maintenance or transportation services.";

(iv) in paragraph (4)—

(I) by striking "(or subdivision)"; and

(II) by inserting ", or services, used in the production of articles or in the supply of services, as the case may be," after "for articles"; and

(v) by adding at the end the following:

"(5) REFERENCE TO FIRM.—For purposes of subsection (a), the term 'firm' does not include a public agency.".

(3) Section 231(a)(2) of the Trade Act of 1974 (19 U.S.C. 2291(a)(2)) is amended—

(A) in the matter preceding subparagraph (A), by striking "or subdivision of a firm"; and

(B) in subparagraph (C), by striking "or subdivision".

SEC. 1802. SEPARATE BASIS FOR CERTIFICATION.

Section 222 of the Trade Act of 1974 (19 U.S.C. 2272), as amended, is further amended by adding at the end the following:

"(f) FIRMS IDENTIFIED BY THE INTERNATIONAL TRADE COMMISSION.—Notwithstanding any other provision of this chapter, a group of workers covered by a petition filed under section 221 shall be certified under subsection (a) as eligible to apply for adjustment assistance under this chapter if—

"(1) the workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

"(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1);

"(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1); or

"(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

"(2) the petition is filed during the one-year period beginning on the date on which—

Time period.
Notice.
Federal Register, publication.

"(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the Federal Register under section 202(f)(3); or

"(B) notice of an affirmative determination described in subparagraph (B) or (C) of paragraph (1) is published in the Federal Register; and

"(3) the workers have become totally or partially separated from the workers' firm within—

"(A) the one-year period described in paragraph (2); or

"(B) notwithstanding section 223(b), the one-year period preceding the one-year period described in paragraph (2).".

SEC. 1803. DETERMINATIONS BY SECRETARY OF LABOR.

Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) is amended—

(1) in subsection (b), by striking "or appropriate subdivision of the firm before his application" and all that follows and inserting "before the worker's application under section 231 occurred more than one year before the date of the petition on which such certification was granted.";

(2) in subsection (c), by striking "together with his reasons" and inserting "and on the website of the Department of Labor, together with the Secretary's reasons";

(3) in subsection (d)—

(A) by striking "or subdivision of the firm" and all that follows through "he shall" and inserting ", that total or partial separations from such firm are no longer attributable to the conditions specified in section 222, the Secretary shall"; and

(B) by striking "together with his reasons" and inserting "and on the website of the Department of Labor, together with the Secretary's reasons"; and

(4) by adding at the end the following:

"(e) STANDARDS FOR INVESTIGATIONS AND DETERMINATIONS.—

Criteria.

"(1) IN GENERAL.—The Secretary shall establish standards, including data requirements, for investigations of petitions filed under section 221 and criteria for making determinations under subsection (a).

Deadline.

"(2) CONSULTATIONS.—Not less than 90 days before issuing a final rule with respect to the standards required under paragraph (1), the Secretary shall consult with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives with respect to such rule.".

SEC. 1804. MONITORING AND REPORTING RELATING TO SERVICE SECTOR.

(a) IN GENERAL.—Section 282 of the Trade Act of 1974 (19 U.S.C. 2393) is amended—

(1) in the heading, by striking "**SYSTEM**" and inserting "**AND DATA COLLECTION**";

(2) in the first sentence—

(A) by striking "The Secretary" and inserting "(a) MONITORING PROGRAMS.—The Secretary";

(B) by inserting "and services" after "imports of articles";

(C) by inserting "and domestic supply of services" after "domestic production";

(D) by inserting "or supplying services" after "producing articles"; and

(E) by inserting ", or supply of services," after "changes in production"; and

(3) by adding at the end the following:

"(b) COLLECTION OF DATA AND REPORTS ON SERVICE SECTOR.—

System.

"(1) SECRETARY OF LABOR.—Not later than 90 days after the date of the enactment of this subsection, the Secretary of Labor shall implement a system to collect data on adversely affected workers employed in the service sector that includes the number of workers by State and industry, and by the

cause of the dislocation of each worker, as identified in the certification.

"(2) SECRETARY OF COMMERCE.—Not later than 1 year after such date of enactment, the Secretary of Commerce shall, in consultation with the Secretary of Labor, conduct a study and submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report on ways to improve the timeliness and coverage of data on trade in services, including methods to identify increased imports due to the relocation of United States firms to foreign countries, and increased imports due to United States firms acquiring services from firms in foreign countries.". Study.

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by striking the item relating to section 282 and inserting the following:

"Sec. 282. Trade monitoring and data collection.".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act. 19 USC 2393 note.

Subpart B—Industry Notifications Following Certain Affirmative Determinations

SEC. 1811. NOTIFICATIONS FOLLOWING CERTAIN AFFIRMATIVE DETERMINATIONS.

(a) IN GENERAL.—Section 224 of the Trade Act of 1974 (19 U.S.C. 2274) is amended—

(1) by amending the heading to read as follows:

"SEC. 224. STUDY AND NOTIFICATIONS REGARDING CERTAIN AFFIRMATIVE DETERMINATIONS; INDUSTRY NOTIFICATION OF ASSISTANCE.";

(2) in subsection (a), by striking "Whenever" and inserting "STUDY OF DOMESTIC INDUSTRY.—Whenever";

(3) in subsection (b)—

(A) by striking "The report" and inserting "REPORT BY THE SECRETARY.—The report"; and

(B) by inserting "and on the website of the Department of Labor" after "Federal Register"; and

(4) by adding at the end the following:

"(c) NOTIFICATIONS FOLLOWING AFFIRMATIVE GLOBAL SAFEGUARD DETERMINATIONS.—Upon making an affirmative determination under section 202(b)(1), the Commission shall promptly notify the Secretary of Labor and the Secretary of Commerce and, in the case of a determination with respect to an agricultural commodity, the Secretary of Agriculture, of the determination.

"(d) NOTIFICATIONS FOLLOWING AFFIRMATIVE BILATERAL OR PLURILATERAL SAFEGUARD DETERMINATIONS.—

"(1) NOTIFICATIONS OF DETERMINATIONS OF MARKET DISRUPTION.—Upon making an affirmative determination under section 421(b)(1), the Commission shall promptly notify the Secretary of Labor and the Secretary of Commerce and, in the case of a determination with respect to an agricultural commodity, the Secretary of Agriculture, of the determination.

"(2) NOTIFICATIONS REGARDING TRADE AGREEMENT SAFEGUARDS.—Upon making an affirmative determination in a proceeding initiated under an applicable safeguard provision (other than a provision described in paragraph (3)) that is enacted

to implement a trade agreement to which the United States is a party, the Commission shall promptly notify the Secretary of Labor and the Secretary of Commerce and, in the case of a determination with respect to an agricultural commodity, the Secretary of Agriculture, of the determination.

"(3) NOTIFICATIONS REGARDING TEXTILE AND APPAREL SAFEGUARDS.—Upon making an affirmative determination in a proceeding initiated under any safeguard provision relating to textile and apparel articles that is enacted to implement a trade agreement to which the United States is a party, the President shall promptly notify the Secretary of Labor and the Secretary of Commerce of the determination.

"(e) NOTIFICATIONS FOLLOWING CERTAIN AFFIRMATIVE DETERMINATIONS UNDER TITLE VII OF THE TARIFF ACT OF 1930.—Upon making an affirmative determination under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A)), the Commission shall promptly notify the Secretary of Labor and the Secretary of Commerce and, in the case of a determination with respect to an agricultural commodity, the Secretary of Agriculture, of the determination.

"(f) INDUSTRY NOTIFICATION OF ASSISTANCE.—Upon receiving a notification of a determination under subsection (c), (d), or (e) with respect to a domestic industry—

"(1) the Secretary of Labor shall—

"(A) notify the representatives of the domestic industry affected by the determination, firms publicly identified by name during the course of the proceeding relating to the determination, and any certified or recognized union or, to the extent practicable, other duly authorized representative of workers employed by such representatives of the domestic industry, of—

"(i) the allowances, training, employment services, and other benefits available under this chapter;

"(ii) the manner in which to file a petition and apply for such benefits; and

"(iii) the availability of assistance in filing such petitions;

"(B) notify the Governor of each State in which one or more firms in the industry described in subparagraph (A) are located of the Commission's determination and the identity of the firms; and

"(C) upon request, provide any assistance that is necessary to file a petition under section 221;

"(2) the Secretary of Commerce shall—

"(A) notify the representatives of the domestic industry affected by the determination and any firms publicly identified by name during the course of the proceeding relating to the determination of—

"(i) the benefits available under chapter 3;

"(ii) the manner in which to file a petition and apply for such benefits; and

"(iii) the availability of assistance in filing such petitions; and

"(B) upon request, provide any assistance that is necessary to file a petition under section 251; and

"(3) in the case of an affirmative determination based upon imports of an agricultural commodity, the Secretary of Agriculture shall—

"(A) notify representatives of the domestic industry affected by the determination and any agricultural commodity producers publicly identified by name during the course of the proceeding relating to the determination of—

"(i) the benefits available under chapter 6;

"(ii) the manner in which to file a petition and apply for such benefits; and

"(iii) the availability of assistance in filing such petitions; and

"(B) upon request, provide any assistance that is necessary to file a petition under section 292.

"(g) REPRESENTATIVES OF THE DOMESTIC INDUSTRY.—For purposes of subsection (f), the term 'representatives of the domestic industry' means the persons that petitioned for relief in connection with—

"(1) a proceeding under section 202 or 421 of this Act;

"(2) a proceeding under section 702(b) or 732(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)); or

"(3) any safeguard investigation described in subsection (d)(2) or (d)(3).".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by striking the item relating to section 224 and inserting the following:

"Sec. 224. Study and notifications regarding certain affirmative determinations; industry notification of assistance.".

SEC. 1812. NOTIFICATION TO SECRETARY OF COMMERCE.

Section 225 of the Trade Act of 1974 (19 U.S.C. 2275) is amended by adding at the end the following:

"(c) Upon issuing a certification under section 223, the Secretary shall notify the Secretary of Commerce of the identity of each firm covered by the certification.".

Subpart C—Program Benefits

SEC. 1821. QUALIFYING REQUIREMENTS FOR WORKERS.

(a) IN GENERAL.—Section 231(a)(5)(A)(ii) of the Trade Act of 1974 (19 U.S.C. 2291 (a)(5)(A)(ii)) is amended—

(1) by striking subclauses (I) and (II) and inserting the following: Certification.

"(I) in the case of a worker whose most recent total separation from adversely affected employment that meets the requirements of paragraphs (1) and (2) occurs after the date on which the Secretary issues a certification covering the worker, the last day of the 26th week after such total separation,

"(II) in the case of a worker whose most recent total separation from adversely affected employment that meets the requirements of paragraphs (1) and (2) occurs before the date on which the Secretary issues a certification covering the worker, the last day of the 26th week after the date of such certification,";

(2) in subclause (III)—

(A) by striking "later of the dates specified in subclause (I) or (II)" and inserting "date specified in subclause (I) or (II), as the case may be"; and

(B) by striking "or" at the end;

(3) by redesignating subclause (IV) as subclause (V); and

(4) by inserting after subclause (III) the following:

"(IV) in the case of a worker who fails to enroll by the date required by subclause (I), (II), or (III), as the case may be, due to the failure to provide the worker with timely information regarding the date specified in such subclause, the last day of a period determined by the Secretary, or".

(b) WAIVERS OF TRAINING REQUIREMENTS.—Section 231(c) of the Trade Act of 1974 (19 U.S.C. 2291(c)) is amended—

(1) in paragraph (1)(B)—

(A) by striking "The worker possesses" and inserting the following:

"(i) IN GENERAL.—The worker possesses"; and

(B) by adding at the end the following:

"(ii) MARKETABLE SKILLS DEFINED.—For purposes of clause (i), the term 'marketable skills' may include the possession of a postgraduate degree from an institution of higher education (as defined in section 102 of the Higher Education Act of 1965 (20 U.S.C. 1002)) or an equivalent institution, or the possession of an equivalent postgraduate certification in a specialized field.";

(2) in paragraph (2)(A), by striking "A waiver" and inserting "Except as provided in paragraph (3)(B), a waiver"; and

(3) in paragraph (3)—

(A) in subparagraph (A), by striking "Pursuant to an agreement under section 239, the Secretary may authorize a" and inserting "An agreement under section 239 shall authorize a";

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

Deadlines.

"(B) REVIEW OF WAIVERS.—An agreement under section 239 shall require a cooperating State to review each waiver issued by the State under subparagraph (A), (B), (D), (E), or (F) of paragraph (1)—

"(i) 3 months after the date on which the State issues the waiver; and

"(ii) on a monthly basis thereafter.".

(c) CONFORMING AMENDMENTS.—

(1) Section 231 of the Trade Act of 1974 (19 U.S.C. 2291), as amended, is further amended—

(A) in subsection (a), in the matter preceding paragraph (1), by striking "more than 60 days" and all that follows through "section 221" and inserting "on or after the date of such certification"; and

(B) in subsection (b)—

(i) by striking paragraph (2); and

(ii) in paragraph (1)—

(I) by striking "(1)";

(II) by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively;

(III) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively; and

(IV) by redesignating subclauses (I) and (II) as clauses (i) and (ii), respectively.

(2) Section 233 of the Trade Act of 1974 (19 U.S.C. 2293) is amended—

(A) by striking subsection (b); and

(B) by redesignating subsections (c) through (g) as subsections (b) through (f), respectively.

SEC. 1822. WEEKLY AMOUNTS.

Section 232 of the Trade Act of 1974 (19 U.S.C. 2292) is amended—

(1) in subsection (a)—

(A) by striking "subsections (b) and (c)" and inserting "subsections (b), (c), and (d)";

(B) by striking "total unemployment" the first place it appears and inserting "unemployment"; and

(C) in paragraph (2), by inserting before the period the following: ", except that in the case of an adversely affected worker who is participating in training under this chapter, such income shall not include earnings from work for such week that are equal to or less than the most recent weekly benefit amount of the unemployment insurance payable to the worker for a week of total unemployment preceding the worker's first exhaustion of unemployment insurance (as determined for purposes of section 231(a)(3)(B))"; and

(2) by adding at the end the following:

"(d) ELECTION OF TRADE READJUSTMENT ALLOWANCE OR UNEMPLOYMENT INSURANCE.—Notwithstanding section 231(a)(3)(B), an adversely affected worker may elect to receive a trade readjustment allowance instead of unemployment insurance during any week with respect to which the worker—

"(1) is entitled to receive unemployment insurance as a result of the establishment by the worker of a new benefit year under State law, based in whole or in part upon part-time or short-term employment in which the worker engaged after the worker's most recent total separation from adversely affected employment; and

"(2) is otherwise entitled to a trade readjustment allowance.".

SEC. 1823. LIMITATIONS ON TRADE READJUSTMENT ALLOWANCES; ALLOWANCES FOR EXTENDED TRAINING AND BREAKS IN TRAINING.

Section 233(a) of the Trade Act of 1974 (19 U.S.C. 2293(a)) is amended—

(1) in paragraph (2), by inserting "under paragraph (1)" after "trade readjustment allowance"; and

(2) in paragraph (3)—

(A) in the matter preceding subparagraph (A)—

(i) by striking "training approved for him" and inserting "a training program approved for the worker";

(ii) by striking "52 additional weeks" and inserting "78 additional weeks"; and

(iii) by striking "52-week" and inserting "91-week"; and

(B) in the matter following subparagraph (B), by striking "52-week" and inserting "91-week".

SEC. 1824. SPECIAL RULES FOR CALCULATION OF ELIGIBILITY PERIOD.

Section 233 of the Trade Act of 1974 (19 U.S.C. 2293), as amended, is further amended by adding at the end the following:

"(g) SPECIAL RULE FOR CALCULATING SEPARATION.—Notwithstanding any other provision of this chapter, any period during which a judicial or administrative appeal is pending with respect to the denial by the Secretary of a petition under section 223 shall not be counted for purposes of calculating the period of separation under subsection (a)(2).

"(h) SPECIAL RULE FOR JUSTIFIABLE CAUSE.—If the Secretary determines that there is justifiable cause, the Secretary may extend the period during which trade readjustment allowances are payable to an adversely affected worker under paragraphs (2) and (3) of subsection (a) (but not the maximum amounts of such allowances that are payable under this section).

"(i) SPECIAL RULE WITH RESPECT TO MILITARY SERVICE.—

Waiver authority.

"(1) IN GENERAL.—Notwithstanding any other provision of this chapter, the Secretary may waive any requirement of this chapter that the Secretary determines is necessary to ensure that an adversely affected worker who is a member of a reserve component of the Armed Forces and serves a period of duty described in paragraph (2) is eligible to receive a trade readjustment allowance, training, and other benefits under this chapter in the same manner and to the same extent as if the worker had not served the period of duty.

"(2) PERIOD OF DUTY DESCRIBED.—An adversely affected worker serves a period of duty described in this paragraph if, before completing training under section 236, the worker—

"(A) serves on active duty for a period of more than 30 days under a call or order to active duty of more than 30 days; or

"(B) in the case of a member of the Army National Guard of the United States or Air National Guard of the United States, performs full-time National Guard duty under section 502(f) of title 32, United States Code, for 30 consecutive days or more when authorized by the President or the Secretary of Defense for the purpose of responding to a national emergency declared by the President and supported by Federal funds.".

SEC. 1825. APPLICATION OF STATE LAWS AND REGULATIONS ON GOOD CAUSE FOR WAIVER OF TIME LIMITS OR LATE FILING OF CLAIMS.

Section 234 of the Trade Act of 1974 (19 U.S.C. 2294) is amended—

(1) by striking "Except where inconsistent" and inserting "(a) IN GENERAL.—Except where inconsistent"; and

(2) by adding at the end the following:

"(b) SPECIAL RULE WITH RESPECT TO STATE LAWS AND REGULATIONS ON GOOD CAUSE FOR WAIVER OF TIME LIMITS OR LATE FILING OF CLAIMS.—Any law, regulation, policy, or practice of a cooperating State that allows for a waiver for good cause of any time limitation relating to the administration of the State unemployment insurance law shall, in the administration of the program under this chapter

Applicability.

by the State, apply to any time limitation with respect to an application for a trade readjustment allowance or enrollment in training under this chapter.".

SEC. 1826. EMPLOYMENT AND CASE MANAGEMENT SERVICES.

(a) IN GENERAL.—Section 235 of the Trade Act of 1974 (19 U.S.C. 2295) is amended to read as follows:

"SEC. 235. EMPLOYMENT AND CASE MANAGEMENT SERVICES.

Contracts.

"The Secretary shall make available, directly or through agreements with States under section 239, to adversely affected workers and adversely affected incumbent workers covered by a certification under subchapter A of this chapter the following employment and case management services:

"(1) Comprehensive and specialized assessment of skill levels and service needs, including through—

"(A) diagnostic testing and use of other assessment tools; and

"(B) in-depth interviewing and evaluation to identify employment barriers and appropriate employment goals.

"(2) Development of an individual employment plan to identify employment goals and objectives, and appropriate training to achieve those goals and objectives.

"(3) Information on training available in local and regional areas, information on individual counseling to determine which training is suitable training, and information on how to apply for such training.

"(4) Information on how to apply for financial aid, including referring workers to educational opportunity centers described in section 402F of the Higher Education Act of 1965 (20 U.S.C. 1070a–16), where applicable, and notifying workers that the workers may request financial aid administrators at institutions of higher education (as defined in section 102 of such Act (20 U.S.C. 1002)) to use the administrators' discretion under section 479A of such Act (20 U.S.C. 1087tt) to use current year income data, rather than preceding year income data, for determining the amount of need of the workers for Federal financial assistance under title IV of such Act (20 U.S.C. 1070 et seq.).

"(5) Short-term prevocational services, including development of learning skills, communications skills, interviewing skills, punctuality, personal maintenance skills, and professional conduct to prepare individuals for employment or training.

"(6) Individual career counseling, including job search and placement counseling, during the period in which the individual is receiving a trade adjustment allowance or training under this chapter, and after receiving such training for purposes of job placement.

"(7) Provision of employment statistics information, including the provision of accurate information relating to local, regional, and national labor market areas, including—

"(A) job vacancy listings in such labor market areas;

"(B) information on jobs skills necessary to obtain jobs identified in job vacancy listings described in subparagraph (A);

"(C) information relating to local occupations that are in demand and earnings potential of such occupations; and

"(D) skills requirements for local occupations described in subparagraph (C).

"(8) Information relating to the availability of supportive services, including services relating to child care, transportation, dependent care, housing assistance, and need-related payments that are necessary to enable an individual to participate in training.".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by striking the item relating to section 235 and inserting the following:

"235. Employment and case management services.".

SEC. 1827. ADMINISTRATIVE EXPENSES AND EMPLOYMENT AND CASE MANAGEMENT SERVICES.

(a) IN GENERAL.—Part II of subchapter B of chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2295 et seq.) is amended by inserting after section 235 the following:

19 USC 2295a.

"SEC. 235A. FUNDING FOR ADMINISTRATIVE EXPENSES AND EMPLOYMENT AND CASE MANAGEMENT SERVICES.

"(a) FUNDING FOR ADMINISTRATIVE EXPENSES AND EMPLOYMENT AND CASE MANAGEMENT SERVICES.—

"(1) IN GENERAL.—In addition to any funds made available to a State to carry out section 236 for a fiscal year, the State shall receive for the fiscal year a payment in an amount that is equal to 15 percent of the amount of such funds.

"(2) USE OF FUNDS.—A State that receives a payment under paragraph (1) shall—

"(A) use not more than ⅔ of such payment for the administration of the trade adjustment assistance for workers program under this chapter, including for—

"(i) processing waivers of training requirements under section 231;

"(ii) collecting, validating, and reporting data required under this chapter; and

"(iii) providing reemployment trade adjustment assistance under section 246; and

"(B) use not less than ⅓ of such payment for employment and case management services under section 235.

"(b) ADDITIONAL FUNDING FOR EMPLOYMENT AND CASE MANAGEMENT SERVICES.—

"(1) IN GENERAL.—In addition to any funds made available to a State to carry out section 236 and the payment under subsection (a)(1) for a fiscal year, the Secretary shall provide to the State for the fiscal year a payment in the amount of $350,000.

"(2) USE OF FUNDS.—A State that receives a payment under paragraph (1) shall use such payment for the purpose of providing employment and case management services under section 235.

"(3) VOLUNTARY RETURN OF FUNDS.—A State that receives a payment under paragraph (1) may decline or otherwise return such payment to the Secretary.".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by inserting after the item relating to section 235 the following:

"Sec. 235A. Funding for administrative expenses and employment and case management services.".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act. 19 USC 2295a note.

SEC. 1828. TRAINING FUNDING.

(a) IN GENERAL.—Section 236(a)(2) of the Trade Act of 1974 (19 U.S.C. 2296(a)(2)) is amended to read as follows:

"(2)(A) The total amount of payments that may be made under paragraph (1) shall not exceed—

"(i) for each of the fiscal years 2009 and 2010, $575,000,000; and

"(ii) for the period beginning October 1, 2010, and ending December 31, 2010, $143,750,000. Time period.

"(B)(i) The Secretary shall, as soon as practicable after the beginning of each fiscal year, make an initial distribution of the funds made available to carry out this section, in accordance with the requirements of subparagraph (C).

"(ii) The Secretary shall ensure that not less than 90 percent of the funds made available to carry out this section for a fiscal year are distributed to the States by not later than July 15 of that fiscal year. Deadline.

"(C)(i) In making the initial distribution of funds pursuant to subparagraph (B)(i) for a fiscal year, the Secretary shall hold in reserve 35 percent of the funds made available to carry out this section for that fiscal year for additional distributions during the remainder of the fiscal year.

"(ii) Subject to clause (iii), in determining how to apportion the initial distribution of funds pursuant to subparagraph (B)(i) in a fiscal year, the Secretary shall take into account, with respect to each State—

"(I) the trend in the number of workers covered by certifications of eligibility under this chapter during the most recent 4 consecutive calendar quarters for which data are available;

"(II) the trend in the number of workers participating in training under this section during the most recent 4 consecutive calendar quarters for which data are available;

"(III) the number of workers estimated to be participating in training under this section during the fiscal year;

"(IV) the amount of funding estimated to be necessary to provide training approved under this section to such workers during the fiscal year; and

"(V) such other factors as the Secretary considers appropriate relating to the provision of training under this section.

"(iii) In no case may the amount of the initial distribution to a State pursuant to subparagraph (B)(i) in a fiscal year be less than 25 percent of the initial distribution to the State in the preceding fiscal year.

"(D) The Secretary shall establish procedures for the distribution of the funds that remain available for the fiscal year after the initial distribution required under subparagraph (B)(i). Such procedures may include the distribution of funds pursuant to requests submitted by States in need of such funds. Procedures.

"(E) If, during a fiscal year, the Secretary estimates that the amount of funds necessary to pay the costs of training approved under this section will exceed the dollar amount limitation specified in subparagraph (A), the Secretary shall decide how the amount of funds made available to carry out this section that have not been distributed at the time of the estimate will be apportioned among the States for the remainder of the fiscal year.".

(b) DETERMINATIONS REGARDING TRAINING.—Section 236(a)(9) of the Trade Act of 1974 (19 U.S.C. 2296(a)(9)) is amended—

(1) by striking "The Secretary" and inserting "(A) Subject to subparagraph (B), the Secretary"; and

(2) by adding at the end the following:

"(B)(i) In determining under paragraph (1)(E) whether a worker is qualified to undertake and complete training, the Secretary may approve training for a period longer than the worker's period of eligibility for trade readjustment allowances under part I if the worker demonstrates a financial ability to complete the training after the expiration of the worker's period of eligibility for such trade readjustment allowances.

"(ii) In determining the reasonable cost of training under paragraph (1)(F) with respect to a worker, the Secretary may consider whether other public or private funds are reasonably available to the worker, except that the Secretary may not require a worker to obtain such funds as a condition of approval of training under paragraph (1).".

(c) REGULATIONS.—Section 236 of the Trade Act of 1974 (19 U.S.C. 2296) is amended by adding at the end the following:

Deadlines.

"(g) REGULATIONS WITH RESPECT TO APPORTIONMENT OF TRAINING FUNDS TO STATES.—

"(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this subsection, the Secretary shall issue such regulations as may be necessary to carry out the provisions of subsection (a)(2).

"(2) CONSULTATIONS.—The Secretary shall consult with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives not less than 90 days before issuing any regulation pursuant to paragraph (1).".

19 USC 2296 note.

(d) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act, except that—

(1) subparagraph (A) of section 236(a)(2) of the Trade Act of 1974, as amended by subsection (a) of this section, shall take effect on the date of the enactment of this Act; and

(2) subparagraphs (B), (C), and (D) of such section 236(a)(2) shall take effect on October 1, 2009.

SEC. 1829. PREREQUISITE EDUCATION; APPROVED TRAINING PROGRAMS.

(a) IN GENERAL.—Section 236(a)(5) of the Trade Act of 1974 (19 U.S.C. 2296(a)(5)) is amended—

(1) in subparagraph (A)—

(A) by striking "and" at the end of clause (i);

(B) by adding "and" at the end of clause (ii); and

(C) by inserting after clause (ii) the following:

"(iii) apprenticeship programs registered under the Act of August 16, 1937 (commonly known as the 'National Apprenticeship Act'; 50 Stat. 664, chapter 663; 29 U.S.C. 50 et seq.),";

(2) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively;

(3) by inserting after subparagraph (D) the following:

"(E) any program of prerequisite education or coursework required to enroll in training that may be approved under this section,";

(4) in subparagraph (F)(ii), as redesignated by paragraph (2), by striking "and" at the end;

(5) in subparagraph (G), as redesignated by paragraph (2), by striking the period at the end and inserting ", and"; and

(6) by adding at the end the following:

"(H) any training program or coursework at an accredited institution of higher education (described in section 102 of the Higher Education Act of 1965 (20 U.S.C. 1002)), including a training program or coursework for the purpose of—

"(i) obtaining a degree or certification; or

"(ii) completing a degree or certification that the worker had previously begun at an accredited institution of higher education.

The Secretary may not limit approval of a training program under paragraph (1) to a program provided pursuant to title I of the Workforce Investment Act of 1998 (29 U.S.C. 2801 et seq.).".

(b) CONFORMING AMENDMENTS.—Section 233 of the Trade Act of 1974 (19 U.S.C. 2293) is amended—

(1) in subsection (a)(2), by inserting "prerequisite education or" after "requires a program of"; and

(2) in subsection (f) (as redesignated by section 1821(c) of this subtitle), by inserting "prerequisite education or" after "includes a program of".

(c) TECHNICAL CORRECTIONS.—Section 236 of the Trade Act of 1974 (19 U.S.C. 2296) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the flush text, by striking "his behalf" and inserting "the worker's behalf"; and

(B) in paragraph (3), by striking "this paragraph (1)" and inserting "paragraph (1)"; and

(2) in subsection (b)(2), by striking ", and" and inserting a period.

SEC. 1830. PRE-LAYOFF AND PART-TIME TRAINING.

(a) PRE-LAYOFF TRAINING.—

(1) IN GENERAL.—Section 236(a) of the Trade Act of 1974 (19 U.S.C. 2296(a)) is amended—

(A) in paragraph (1), by inserting after "determines" the following: ", with respect to an adversely affected worker or an adversely affected incumbent worker,";

(B) in paragraph (4)—

(i) in subparagraphs (A) and (B), by inserting "or an adversely affected incumbent worker" after "an adversely affected worker" each place it appears; and

(ii) in subparagraph (C), by inserting "or adversely affected incumbent worker" after "adversely affected worker" each place it appears;

(C) in paragraph (5), in the matter preceding subparagraph (A), by striking "The training programs" and inserting "Except as provided in paragraph (10), the training programs";

(D) in paragraph (6)(B), by inserting "or adversely affected incumbent worker" after "adversely affected worker";

(E) in paragraph (7)(B), by inserting "or adversely affected incumbent worker" after "adversely affected worker"; and

(F) by inserting after paragraph (9) the following:

"(10) In the case of an adversely affected incumbent worker, the Secretary may not approve—

"(A) on-the-job training under paragraph (5)(A)(i); or

"(B) customized training under paragraph (5)(A)(ii), unless such training is for a position other than the worker's adversely affected employment.

"(11) If the Secretary determines that an adversely affected incumbent worker for whom the Secretary approved training under this section is no longer threatened with a total or partial separation, the Secretary shall terminate the approval of such training.".

(2) DEFINITIONS.—Section 247 of the Trade Act of 1974 (19 U.S.C. 2319), as amended, is further amended by adding at the end the following:

"(19) The term 'adversely affected incumbent worker' means a worker who—

"(A) is a member of a group of workers who have been certified as eligible to apply for adjustment assistance under subchapter A;

"(B) has not been totally or partially separated from adversely affected employment; and

"(C) the Secretary determines, on an individual basis, is threatened with total or partial separation.".

(b) PART-TIME TRAINING.—Section 236 of the Trade Act of 1974 (19 U.S.C. 2296), as amended, is further amended by adding at the end the following:

"(h) PART-TIME TRAINING.—

"(1) IN GENERAL.—The Secretary may approve full-time or part-time training for a worker under subsection (a).

"(2) LIMITATION.—Notwithstanding paragraph (1), a worker participating in part-time training approved under subsection (a) may not receive a trade readjustment allowance under section 231.".

SEC. 1831. ON-THE-JOB TRAINING.

(a) IN GENERAL.—Section 236(c) of the Trade Act of 1974 (19 U.S.C. 2296(c)) is amended—

(1) by redesignating paragraphs (1) through (10) as subparagraphs (A) through (J) and moving such subparagraphs 2 ems to the right;

(2) by striking "(c) The Secretary shall" and all that follows through "such costs," and inserting the following:

"(c) ON-THE-JOB TRAINING REQUIREMENTS.—

"(1) IN GENERAL.—The Secretary may approve on-the-job training for any adversely affected worker if—

"(A) the worker meets the requirements for training to be approved under subsection (a)(1);

"(B) the Secretary determines that on-the-job training—

"(i) can reasonably be expected to lead to suitable employment with the employer offering the on-the-job training;

"(ii) is compatible with the skills of the worker;

"(iii) includes a curriculum through which the worker will gain the knowledge or skills to become proficient in the job for which the worker is being trained; and

"(iv) can be measured by benchmarks that indicate that the worker is gaining such knowledge or skills; and

"(C) the State determines that the on-the-job training program meets the requirements of clauses (iii) and (iv) of subparagraph (B).

"(2) MONTHLY PAYMENTS.—The Secretary shall pay the costs of on-the-job training approved under paragraph (1) in monthly installments.

"(3) CONTRACTS FOR ON-THE-JOB TRAINING.—

"(A) IN GENERAL.—The Secretary shall ensure, in entering into a contract with an employer to provide on-the-job training to a worker under this subsection, that the skill requirements of the job for which the worker is being trained, the academic and occupational skill level of the worker, and the work experience of the worker are taken into consideration.

"(B) TERM OF CONTRACT.—Training under any such contract shall be limited to the period of time required for the worker receiving on-the-job training to become proficient in the job for which the worker is being trained, but may not exceed 104 weeks in any case.

"(4) EXCLUSION OF CERTAIN EMPLOYERS.—The Secretary shall not enter into a contract for on-the-job training with an employer that exhibits a pattern of failing to provide workers receiving on-the-job training from the employer with—

"(A) continued, long-term employment as regular employees; and

"(B) wages, benefits, and working conditions that are equivalent to the wages, benefits, and working conditions provided to regular employees who have worked a similar period of time and are doing the same type of work as workers receiving on-the-job training from the employer.

"(5) LABOR STANDARDS.—The Secretary may pay the costs of on-the-job training,"; and

(3) in paragraph (5), as redesignated—

(A) in subparagraph (I), as redesignated by paragraph (1) of this section, by striking "paragraphs (1), (2), (3), (4), (5), and (6)" and inserting "subparagraphs (A), (B), (C), (D), (E), and (F)"; and

(B) in subparagraph (J), as redesignated by paragraph (1) of this section, by striking "paragraph (8)" and inserting "subparagraph (H)".

(b) REPEAL OF PREFERENCE FOR TRAINING ON THE JOB.—Section 236(a)(1) of the Trade Act of 1974 (19 U.S.C. 2296(a)(1)) is amended by striking the last sentence.

SEC. 1832. ELIGIBILITY FOR UNEMPLOYMENT INSURANCE AND PROGRAM BENEFITS WHILE IN TRAINING.

Section 236(d) of the Trade Act of 1974 (19 U.S.C. 2296(d)) is amended to read as follows:

"(d) ELIGIBILITY.—An adversely affected worker may not be determined to be ineligible or disqualified for unemployment insurance or program benefits under this subchapter—

"(1) because the worker—

"(A) is enrolled in training approved under subsection (a);

"(B) left work—

"(i) that was not suitable employment in order to enroll in such training; or

"(ii) that the worker engaged in on a temporary basis during a break in such training or a delay in the commencement of such training; or

Deadline.

"(C) left on-the-job training not later than 30 days after commencing such training because the training did not meet the requirements of subsection (c)(1)(B); or

"(2) because of the application to any such week in training of the provisions of State law or Federal unemployment insurance law relating to availability for work, active search for work, or refusal to accept work.".

SEC. 1833. JOB SEARCH AND RELOCATION ALLOWANCES.

(a) JOB SEARCH ALLOWANCES.—Section 237 of the Trade Act of 1974 (19 U.S.C. 2297) is amended—

(1) in subsection (a)(2)(C)(ii), by striking ", unless the worker received a waiver under section 231(c)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "90 percent of the cost of" and inserting "all"; and

(B) in paragraph (2), by striking "$1,250" and inserting "$1,500".

(b) RELOCATION ALLOWANCES.—Section 238 of the Trade Act of 1974 (19 U.S.C. 2298) is amended—

(1) in subsection (a)(2)(E)(ii), by striking ", unless the worker received a waiver under section 231(c)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "90 percent of the" and inserting "all"; and

(B) in paragraph (2), by striking "$1,250" and inserting "$1,500".

Subpart D—Reemployment Trade Adjustment Assistance Program

SEC. 1841. REEMPLOYMENT TRADE ADJUSTMENT ASSISTANCE PROGRAM.

(a) IN GENERAL.—Section 246 of the Trade Act of 1974 (19 U.S.C. 2318) is amended—

(1) by amending the heading to read as follows:

"SEC. 246. REEMPLOYMENT TRADE ADJUSTMENT ASSISTANCE PROGRAM.";

(2) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "Not later than" and all that follows through "2002, the Secretary" and inserting "The Secretary"; and

(ii) by striking "an alternative trade adjustment assistance program for older workers" and inserting "a reemployment trade adjustment assistance program";

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i), by striking "for a period not to exceed 2 years" and inserting "for the eligibility period under subparagraph (A) or (B) of paragraph (4) (as the case may be)"; and

(II) by striking clauses (i) and (ii) and inserting the following:

"(i) the wages received by the worker at the time of separation; and

"(ii) the wages received by the worker from reemployment.";

(ii) in subparagraph (B)—

(I) by striking "for a period not to exceed 2 years" and inserting "for the eligibility period under subparagraph (A) or (B) of paragraph (4) (as the case may be)"; and

(II) by striking ", as added by section 201 of the Trade Act of 2002"; and

(iii) by adding at the end the following:

"(C) TRAINING AND OTHER SERVICES.—A worker described in paragraph (3)(B) participating in the program established under paragraph (1) is eligible to receive training approved under section 236 and employment and case management services under section 235."; and

(C) by striking paragraphs (3) through (5) and inserting the following:

"(3) ELIGIBILITY.—

"(A) IN GENERAL.—A group of workers certified under subchapter A as eligible for adjustment assistance under subchapter A is eligible for benefits described in paragraph (2) under the program established under paragraph (1).

"(B) INDIVIDUAL ELIGIBILITY.—A worker in a group of workers described in subparagraph (A) may elect to receive benefits described in paragraph (2) under the program established under paragraph (1) if the worker—

"(i) is at least 50 years of age;

"(ii) earns not more than $55,000 each year in wages from reemployment;

"(iii)(I) is employed on a full-time basis as defined by the law of the State in which the worker is employed and is not enrolled in a training program approved under section 236; or

"(II) is employed at least 20 hours per week and is enrolled in a training program approved under section 236; and

"(iv) is not employed at the firm from which the worker was separated.

"(4) ELIGIBILITY PERIOD FOR PAYMENTS.—

Effective date.

"(A) WORKER WHO HAS NOT RECEIVED TRADE READJUSTMENT ALLOWANCE.—In the case of a worker described in paragraph (3)(B) who has not received a trade readjustment allowance under part I of subchapter B pursuant to the certification described in paragraph (3)(A), the worker may receive benefits described in paragraph (2) for a period not to exceed 2 years beginning on the earlier of—

"(i) the date on which the worker exhausts all rights to unemployment insurance based on the separation of the worker from the adversely affected employment that is the basis of the certification; or

"(ii) the date on which the worker obtains reemployment described in paragraph (3)(B).

"(B) WORKER WHO HAS RECEIVED TRADE READJUSTMENT ALLOWANCE.—In the case of a worker described in paragraph (3)(B) who has received a trade readjustment allowance under part I of subchapter B pursuant to the certification described in paragraph (3)(A), the worker may receive benefits described in paragraph (2) for a period of 104 weeks beginning on the date on which the worker obtains reemployment described in paragraph (3)(B), reduced by the total number of weeks for which the worker received such trade readjustment allowance.

"(5) TOTAL AMOUNT OF PAYMENTS.—

"(A) IN GENERAL.—The payments described in paragraph (2)(A) made to a worker may not exceed—

"(i) $12,000 per worker during the eligibility period under paragraph (4)(A); or

"(ii) the amount described in subparagraph (B) per worker during the eligibility period under paragraph (4)(B).

"(B) AMOUNT DESCRIBED.—The amount described in this subparagraph is the amount equal to the product of—

"(i) $12,000, and

"(ii) the ratio of—

"(I) the total number of weeks in the eligibility period under paragraph (4)(B) with respect to the worker, to

"(II) 104 weeks.

"(6) CALCULATION OF AMOUNT OF PAYMENTS FOR CERTAIN WORKERS.—

Applicability.

"(A) IN GENERAL.—In the case of a worker described in paragraph (3)(B)(iii)(II), paragraph (2)(A) shall be applied by substituting the percentage described in subparagraph (B) for '50 percent'.

"(B) PERCENTAGE DESCRIBED.—The percentage described in this subparagraph is the percentage—

"(i) equal to ½ of the ratio of—

"(I) the number of weekly hours of employment of the worker referred to in paragraph (3)(B)(iii)(II), to

"(II) the number of weekly hours of employment of the worker at the time of separation, but

"(ii) in no case more than 50 percent.

"(7) LIMITATION ON OTHER BENEFITS.—A worker described in paragraph (3)(B) may not receive a trade readjustment allowance under part I of subchapter B pursuant to the certification described in paragraph (3)(A) during any week for which the worker receives a payment described in paragraph (2)(A).";

and

(3) in subsection (b)(2), by striking "subsection (a)(3)(B)" and inserting "subsection (a)(3)".

(b) EXTENSION OF PROGRAM.—Section 246(b)(1) of the Trade Act of 1974 (19 U.S.C. 2318(b)(1)) is amended by striking "the date that is 5 years" and all that follows through the end period and inserting "December 31, 2010.".

(c) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by striking the item relating to section 246 and inserting the following:

"Sec. 246. Reemployment trade adjustment assistance program.".

Subpart E—Other Matters

SEC. 1851. OFFICE OF TRADE ADJUSTMENT ASSISTANCE.

(a) IN GENERAL.—Subchapter C of chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2311 et seq.) is amended by adding at the end the following:

"SEC. 249A. OFFICE OF TRADE ADJUSTMENT ASSISTANCE. 19 USC 2322.

"(a) ESTABLISHMENT.—There is established in the Department of Labor an office to be known as the Office of Trade Adjustment Assistance (in this section referred to as the 'Office').

"(b) HEAD OF OFFICE.—The head of the Office shall be an administrator, who shall report directly to the Deputy Assistant Secretary for Employment and Training.

"(c) PRINCIPAL FUNCTIONS.—The principal functions of the administrator of the Office shall be—

"(1) to oversee and implement the administration of trade adjustment assistance program under this chapter; and

"(2) to carry out functions delegated to the Secretary of Labor under this chapter, including—

"(A) making determinations under section 223;

"(B) providing information under section 225 about trade adjustment assistance to workers and assisting such workers to prepare petitions or applications for program benefits;

"(C) providing assistance to employers of groups of workers that have filed petitions under section 221 in submitting information required by the Secretary relating to the petitions;

"(D) ensuring workers covered by a certification of eligibility under subchapter A receive the employment and case management services described in section 235;

"(E) ensuring that States fully comply with agreements entered into under section 239;

"(F) advocating for workers applying for benefits available under this chapter;

"(G) establishing and overseeing a hotline that workers, employers, and other entities may call to obtain information regarding eligibility criteria, procedural requirements, and benefits available under this chapter; and

"(H) carrying out such other duties with respect to this chapter as the Secretary specifies for purposes of this section.

"(d) ADMINISTRATION.—

"(1) DESIGNATION.—The administrator shall designate an employee of the Department of Labor with appropriate experience and expertise to carry out the duties described in paragraph (2).

"(2) DUTIES.—The employee designated under paragraph (1) shall—

"(A) receive complaints and requests for assistance related to the trade adjustment assistance program under this chapter;

"(B) resolve such complaints and requests for assistance, in coordination with other employees of the Office;

"(C) compile basic information concerning such complaints and requests for assistance; and

"(D) carry out such other duties with respect to this chapter as the Secretary specifies for purposes of this section.".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by inserting after the item relating to section 249 the following:

"Sec. 249A. Office of Trade Adjustment Assistance.".

SEC. 1852. ACCOUNTABILITY OF STATE AGENCIES; COLLECTION AND PUBLICATION OF PROGRAM DATA; AGREEMENTS WITH STATES.

(a) IN GENERAL.—Section 239(a) of the Trade Act of 1974 (19 U.S.C. 2311(a)) is amended—

(1) by amending clause (2) to read as follows: "(2) in accordance with subsection (f), shall make available to adversely affected workers and adversely affected incumbent workers covered by a certification under subchapter A the employment and case management services described in section 235,"; and

(2) by striking "will" each place it appears and inserting "shall".

(b) FORM AND MANNER OF DATA.—Section 239 of the Trade Act of 1974 (19 U.S.C. 2311) is amended—

(1) by redesignating subsections (c) through (g) as subsections (d) through (h), respectively; and

(2) by inserting after subsection (b) the following:

"(c) FORM AND MANNER OF DATA.—Each agreement under this subchapter shall—

"(1) provide the Secretary with the authority to collect any data the Secretary determines necessary to meet the requirements of this chapter; and

"(2) specify the form and manner in which any such data requested by the Secretary shall be reported.".

(c) STATE ACTIVITIES.—Section 239(g) of the Trade Act of 1974 (as redesignated) is amended—

(1) in paragraph (3), by striking "and" at the end;

(2) by amending paragraph (4) to read as follows:

"(4) perform outreach to, intake of, and orientation for adversely affected workers and adversely affected incumbent workers covered by a certification under subchapter A with respect to assistance and benefits available under this chapter, and"; and

(3) by adding at the end the following:

"(5) make employment and case management services described in section 235 available to adversely affected workers and adversely affected incumbent workers covered by a certification under subchapter A and, if funds provided to carry out this chapter are insufficient to make such services available, make arrangements to make such services available through other Federal programs.".

(d) REPORTING REQUIREMENT.—Section 239(h) of the Trade Act of 1974 (as redesignated) is amended by striking "1998." and inserting "1998 (29 U.S.C. 2822(b)) and a description of the State's rapid response activities under section 221(a)(2)(A).".

(e) CONTROL MEASURES.—Section 239 of the Trade Act of 1974 (19 U.S.C. 2311), as amended, is further amended by adding at the end the following:

"(i) CONTROL MEASURES.—

"(1) IN GENERAL.—The Secretary shall require each cooperating State and cooperating State agency to implement effective control measures and to effectively oversee the operation and administration of the trade adjustment assistance program under this chapter, including by means of monitoring the operation of control measures to improve the accuracy and timeliness of the data being collected and reported. Requirements.

"(2) DEFINITION.—For purposes of paragraph (1), the term 'control measures' means measures that—

"(A) are internal to a system used by a State to collect data; and

"(B) are designed to ensure the accuracy and verifiability of such data.

"(j) DATA REPORTING.—

"(1) IN GENERAL.—Any agreement entered into under this section shall require the cooperating State or cooperating State agency to report to the Secretary on a quarterly basis comprehensive performance accountability data, to consist of—

"(A) the core indicators of performance described in paragraph (2)(A);

"(B) the additional indicators of performance described in paragraph (2)(B), if any; and

"(C) a description of efforts made to improve outcomes for workers under the trade adjustment assistance program.

"(2) CORE INDICATORS DESCRIBED.—

"(A) IN GENERAL.—The core indicators of performance described in this paragraph are—

"(i) the percentage of workers receiving benefits under this chapter who are employed during the second calendar quarter following the calendar quarter in which the workers cease receiving such benefits;

"(ii) the percentage of such workers who are employed in each of the third and fourth calendar quarters following the calendar quarter in which the workers cease receiving such benefits; and

"(iii) the earnings of such workers in each of the third and fourth calendar quarters following the calendar quarter in which the workers cease receiving such benefits.

"(B) ADDITIONAL INDICATORS.—The Secretary and a cooperating State or cooperating State agency may agree upon additional indicators of performance for the trade adjustment assistance program under this chapter, as appropriate.

Procedures.

"(3) STANDARDS WITH RESPECT TO RELIABILITY OF DATA.—In preparing the quarterly report required by paragraph (1), each cooperating State or cooperating State agency shall establish procedures that are consistent with guidelines to be issued by the Secretary to ensure that the data reported are valid and reliable.".

Immigration.

SEC. 1853. VERIFICATION OF ELIGIBILITY FOR PROGRAM BENEFITS.

Section 239 of the Trade Act of 1974 (19 U.S.C. 2311), as amended, is further amended by adding at the end the following:

"(k) VERIFICATION OF ELIGIBILITY FOR PROGRAM BENEFITS.—

"(1) IN GENERAL.—An agreement under this subchapter shall provide that the State shall periodically redetermine that a worker receiving benefits under this subchapter who is not a citizen or national of the United States remains in a satisfactory immigration status. Once satisfactory immigration status has been initially verified through the immigration status verification system described in section 1137(d) of the Social Security Act (42 U.S.C. 1320b-7(d)) for purposes of establishing a worker's eligibility for unemployment compensation, the State shall reverify the worker's immigration status if the documentation provided during initial verification will expire during the period in which that worker is potentially eligible to receive benefits under this subchapter. The State shall conduct such redetermination in a timely manner, utilizing the immigration status verification system described in section 1137(d) of the Social Security Act (42 U.S.C. 1320b-7(d)).

"(2) PROCEDURES.—The Secretary shall establish procedures to ensure the uniform application by the States of the requirements of this subsection.".

SEC. 1854. COLLECTION OF DATA AND REPORTS; INFORMATION TO WORKERS.

(a) IN GENERAL.—Subchapter C of chapter 2 of title II of the Trade Act of 1974 (19 U.S.C. 2311 et seq.), as amended, is further amended by adding at the end the following:

19 USC 2323.

"SEC. 249B. COLLECTION AND PUBLICATION OF DATA AND REPORTS; INFORMATION TO WORKERS.

System.

"(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall implement a system to collect and report the data described in subsection (b), as well as any other information that the Secretary considers appropriate to effectively carry out this chapter.

"(b) DATA TO BE INCLUDED.—The system required under subsection (a) shall include collection of and reporting on the following data for each fiscal year:

"(1) DATA ON PETITIONS FILED, CERTIFIED, AND DENIED.—

"(A) The number of petitions filed, certified, and denied under this chapter.

"(B) The number of workers covered by petitions filed, certified, and denied.

"(C) The number of petitions, classified by—

"(i) the basis for certification, including increased imports, shifts in production, and other bases of eligibility; and

"(ii) congressional district of the United States.

"(D) The average time for processing such petitions.

"(2) DATA ON BENEFITS RECEIVED.—

"(A) The number of workers receiving benefits under this chapter.

"(B) The number of workers receiving each type of benefit, including training, trade readjustment allowances, employment and case management services, and relocation and job search allowances, and, to the extent feasible, credits for health insurance costs under section 35 of the Internal Revenue Code of 1986.

"(C) The average time during which such workers receive each such type of benefit.

"(3) DATA ON TRAINING.—

"(A) The number of workers enrolled in training approved under section 236, classified by major types of training, including classroom training, training through distance learning, on-the-job training, and customized training.

"(B) The number of workers enrolled in full-time training and part-time training.

"(C) The average duration of training.

"(D) The number of training waivers granted under section 231(c), classified by type of waiver.

"(E) The number of workers who complete training and the duration of such training.

"(F) The number of workers who do not complete training.

"(4) DATA ON OUTCOMES.—

"(A) A summary of the quarterly reports required under section 239(j).

"(B) The sectors in which workers are employed after receiving benefits under this chapter.

"(5) DATA ON RAPID RESPONSE ACTIVITIES.—Whether rapid response activities were provided with respect to each petition filed under section 221.

"(c) CLASSIFICATION OF DATA.—To the extent possible, in collecting and reporting the data described in subsection (b), the Secretary shall classify the data by industry, State, and national totals.

"(d) REPORT.—Not later than December 15 of each year, the Secretary shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report that includes—

"(1) a summary of the information collected under this section for the preceding fiscal year;

"(2) information on the distribution of funds to each State pursuant to section 236(a)(2); and

"(3) any recommendations of the Secretary with respect to changes in eligibility requirements, benefits, or training funding under this chapter based on the data collected under this section.

"(e) AVAILABILITY OF DATA.—

Web posting.

"(1) IN GENERAL.—The Secretary shall make available to the public, by publishing on the website of the Department of Labor and by other means, as appropriate—

"(A) the report required under subsection (d);

"(B) the data collected under this section, in a searchable format; and

"(C) a list of cooperating States and cooperating State agencies that failed to submit the data required by this section to the Secretary in a timely manner.

Deadline.

"(2) UPDATES.—The Secretary shall update the data under paragraph (1) on a quarterly basis.".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by inserting after the item relating to section 249A the following:

"Sec. 249B. Collection and publication of data and reports; information to workers.".

19 USC 2323 note.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act.

SEC. 1855. FRAUD AND RECOVERY OF OVERPAYMENTS.

Section 243(a)(1) of the Trade Act of 1974 (19 U.S.C. 2315(a)(1)) is amended—

(1) in the matter preceding subparagraph (A)—

(A) by striking "may waive" and inserting "shall waive"; and

(B) by striking ", in accordance with guidelines prescribed by the Secretary,"; and

(2) in subparagraph (B), by striking "would be contrary to equity and good conscience" and inserting "would cause a financial hardship for the individual (or the individual's household, if applicable) when taking into consideration the income and resources reasonably available to the individual (or household) and other ordinary living expenses of the individual (or household)".

SEC. 1856. SENSE OF CONGRESS ON APPLICATION OF TRADE ADJUSTMENT ASSISTANCE.

(a) IN GENERAL.—Chapter 5 of title II of the Trade Act of 1974 (19 U.S.C. 2391 et seq.) is amended by adding at the end the following:

19 USC 2397a.

"SEC. 288. SENSE OF CONGRESS.

"It is the sense of Congress that the Secretaries of Labor, Commerce, and Agriculture should apply the provisions of chapter 2 (relating to adjustment assistance for workers), chapter 3 (relating to adjustment assistance for firms), chapter 4 (relating to adjustment assistance for communities), and chapter 6 (relating to adjustment assistance for farmers), respectively, with the utmost regard

for the interests of workers, firms, communities, and farmers petitioning for benefits under such chapters.".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by inserting after the item relating to section 287 the following:

"Sec. 288. Sense of Congress.".

SEC. 1857. CONSULTATIONS IN PROMULGATION OF REGULATIONS.

Section 248 of the Trade Act of 1974 (19 U.S.C. 2320) is amended—

(1) by striking "The Secretary shall" and inserting the following:

"(a) IN GENERAL.—The Secretary shall"; and

(2) by adding at the end the following:

"(b) CONSULTATIONS.—Not later than 90 days before issuing a regulation under subsection (a), the Secretary shall consult with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives with respect to the regulation.". Deadline.

SEC. 1858. TECHNICAL CORRECTIONS.

(a) DETERMINATIONS BY SECRETARY OF LABOR.—Section 223(c) of the Trade Act of 1974 (19 U.S.C. 2273(c)) is amended by striking "his determination" and inserting "a determination".

(b) QUALIFYING REQUIREMENTS FOR WORKERS.—Section 231(a) of the Trade Act of 1974 (19 U.S.C. 2291(a)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "his application" and inserting "the worker's application"; and

(B) in subparagraph (A), by striking "he is covered" and inserting "the worker is covered";

(2) in paragraph (2)—

(A) in subparagraph (A), by striking the period and inserting a comma; and

(B) in subparagraph (D), by striking "5 U.S.C. 8521(a)(1)" and inserting "section 8521(a)(1) of title 5, United States Code"; and

(3) in paragraph (3)—

(A) by striking "he" each place it appears and inserting "the worker"; and

(B) in subparagraph (C), by striking "him" and inserting "the worker".

(c) SUBPOENA POWER.—Section 249 of the Trade Act of 1974 (19 U.S.C. 2321) is amended—

(1) in the section heading, by striking "**SUBPENA**" and inserting "**SUBPOENA**";

(2) by striking "subpena" and inserting "subpoena" each place it appears; and

(3) in subsection (a), by striking "him" and inserting "the Secretary".

(d) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by striking the item relating to section 249 and inserting the following:

"Sec. 249. Subpoena power.".

PART II—TRADE ADJUSTMENT ASSISTANCE FOR FIRMS

SEC. 1861. EXPANSION TO SERVICE SECTOR FIRMS.

(a) IN GENERAL.—Section 251 of the Trade Act of 1974 (19 U.S.C. 2341) is amended by inserting "or service sector firm" after "agricultural firm" each place it appears.

(b) DEFINITION OF SERVICE SECTOR FIRM.—Section 261 of the Trade Act of 1974 (19 U.S.C. 2351) is amended—

(1) by striking "chapter," and inserting "chapter:";

(2) by striking "the term 'firm'" and inserting the following:

"(1) FIRM.—The term 'firm'"; and

(3) by adding at the end the following:

"(2) SERVICE SECTOR FIRM.—The term 'service sector firm' means a firm engaged in the business of supplying services.".

(c) CONFORMING AMENDMENTS.—

(1) Section 251(c)(1)(C) of the Trade Act of 1974 (19 U.S.C. 2341(c)(1)(C)) is amended—

(A) by inserting "or services" after "articles" the first place it appears; and

(B) by inserting "or services which are supplied" after "produced".

(2) Section 251(c)(2)(B)(ii) of such Act is amended to read as follows:

"(ii) Any firm that engages in exploration or drilling for oil or natural gas, or otherwise produces oil or natural gas, shall be considered to be producing articles directly competitive with imports of oil and with imports of natural gas.".

SEC. 1862. MODIFICATION OF REQUIREMENTS FOR CERTIFICATION.

Section 251(c)(1)(B) of the Trade Act of 1974 (19 U.S.C. 2341(c)(1)(B)) is amended to read as follows:

"(B) that—

"(i) sales or production, or both, of the firm have decreased absolutely,

"(ii) sales or production, or both, of an article or service that accounted for not less than 25 percent of the total sales or production of the firm during the 12-month period preceding the most recent 12-month period for which date are available have decreased absolutely,

"(iii) sales or production, or both, of the firm during the most recent 12-month period for which data are available have decreased compared to—

"(I) the average annual sales or production for the firm during the 24-month period preceding that 12-month period, or

"(II) the average annual sales or production for the firm during the 36-month period preceding that 12-month period, and

"(iv) sales or production, or both, of an article or service that accounted for not less than 25 percent of the total sales or production of the firm during the most recent 12-month period for which data are available have decreased compared to—

"(I) the average annual sales or production for the article or service during the 24-month period preceding that 12-month period, or

"(II) the average annual sales or production for the article or service during the 36-month period preceding that 12-month period, and".

SEC. 1863. BASIS FOR DETERMINATIONS.

Section 251 of the Trade Act of 1974 (19 U.S.C. 2341), as amended, is further amended by adding at the end the following:

"(e) BASIS FOR SECRETARY'S DETERMINATIONS.—For purposes of subsection (c)(1)(C), the Secretary may determine that there are increased imports of like or directly competitive articles or services, if customers accounting for a significant percentage of the decrease in the sales or production of the firm certify to the Secretary that such customers have increased their imports of such articles or services from a foreign country, either absolutely or relative to their acquisition of such articles or services from suppliers located in the United States. Certification.

"(f) NOTIFICATION TO FIRMS OF AVAILABILITY OF BENEFITS.—Upon receiving notice from the Secretary of Labor under section 225 of the identity of a firm that is covered by a certification issued under section 223, the Secretary of Commerce shall notify the firm of the availability of adjustment assistance under this chapter.".

SEC. 1864. OVERSIGHT AND ADMINISTRATION; AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Chapter 3 of title II of the Trade Act of 1974 (19 U.S.C. 2341 et seq.) is amended—

(1) by striking sections 254, 255, 256, and 257; 19 USC 2344–2347.

(2) by redesignating sections 258, 259, 260, 261, 262, 264, and 265, as sections 256, 257, 258, 259, 260, 261, and 262, respectively; and 19 USC 2348–2352, 2354, 2355.

(3) by inserting after section 253 the following:

"SEC. 254. OVERSIGHT AND ADMINISTRATION. 19 USC 2344.

"(a) IN GENERAL.—The Secretary shall, to such extent and in such amounts as are provided in appropriations Acts, provide grants to intermediary organizations (referred to in section 253(b)(1)) throughout the United States pursuant to agreements with such intermediary organizations. Each such agreement shall require the intermediary organization to provide benefits to firms certified under section 251. The Secretary shall, to the maximum extent practicable, provide by October 1, 2010, that contracts entered into with intermediary organizations be for a 12-month period and that all such contracts have the same beginning date and the same ending date. Grants. Deadline. Contracts.

"(b) DISTRIBUTION OF FUNDS.—

"(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this subsection, the Secretary shall develop a methodology for the distribution of funds among the intermediary organizations described in subsection (a). Deadline. Methodology.

"(2) PROMPT INITIAL DISTRIBUTION.—The methodology described in paragraph (1) shall ensure the prompt initial distribution of funds and establish additional criteria governing the apportionment and distribution of the remainder of such funds among the intermediary organizations. Criteria.

"(3) CRITERIA.—The methodology described in paragraph (1) shall include criteria based on the data in the annual report on the trade adjustment assistance for firms program

described in section 1866 of the Trade and Globalization Adjustment Assistance Act of 2009.

Guidelines.

"(c) REQUIREMENTS FOR CONTRACTS.—An agreement with an intermediary organization described in subsection (a) shall require the intermediary organization to contract for the supply of services to carry out grants under this chapter in accordance with terms and conditions that are consistent with guidelines established by the Secretary.

Deadlines.

"(d) CONSULTATIONS.—

"(1) CONSULTATIONS REGARDING METHODOLOGY.—The Secretary shall consult with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives—

"(A) not less than 30 days before finalizing the methodology described in subsection (b); and

"(B) not less than 60 days before adopting any changes to such methodology.

"(2) CONSULTATIONS REGARDING GUIDELINES.—The Secretary shall consult with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives not less than 60 days before finalizing the guidelines described in subsection (c) or adopting any subsequent changes to such guidelines.

19 USC 2345.

"SEC. 255. AUTHORIZATION OF APPROPRIATIONS.

Time period.

"(a) IN GENERAL.—There are authorized to be appropriated to the Secretary $50,000,000 for each of the fiscal years 2009 through 2010, and $12,501,000 for the period beginning October 1, 2010, and ending December 31, 2010, to carry out the provisions of this chapter. Amounts appropriated pursuant to this subsection shall—

Deadline.

"(1) be available to provide adjustment assistance to firms that file a petition for such assistance pursuant to this chapter on or before December 31, 2010; and

"(2) otherwise remain available until expended.

"(b) PERSONNEL.—Of the amounts appropriated pursuant to this section for each fiscal year, $350,000 shall be available for full-time positions in the Department of Commerce to administer the provisions of this chapter. Of such funds the Secretary shall make available to the Economic Development Administration such sums as may be necessary to establish the position of Director of Adjustment Assistance for Firms and such other full-time positions as may be appropriate to administer the provisions of this chapter.".

Establishment.

19 USC 2344 note.

(b) RESIDUAL AUTHORITY.—The Secretary of Commerce shall have the authority to modify, terminate, resolve, liquidate, or take any other action with respect to a loan, guarantee, contract, or any other financial assistance that was extended under section 254, 255, 256, or 257 of the Trade Act of 1974 (19 U.S.C. 2344, 2345, 2346, and 2347), as in effect on the day before the effective date set forth in section 1891.

(c) CONFORMING AMENDMENTS.—

19 USC 2348.

(1) Section 256 of the Trade Act of 1974, as redesignated by subsection (a) of this section, is amended by striking subsection (d).

19 USC 2350.

(2) Section 258 of the Trade Act of 1974, as redesignated by subsection (a) of this section, is amended—

(A) in the first sentence, by striking "and financial"; and

(B) in the last sentence—

(i) by striking "sections 253 and 254" and inserting "section 253"; and

(ii) by striking "title 28 of the United States Code" and inserting "title 28, United States Code".

(d) CLERICAL AMENDMENTS.—The table of contents of the Trade Act of 1974 is amended by striking the items relating to sections 254, 255, 256, 257, 258, 259, 260, 261, 262, 264, and 265, and inserting the following:

"Sec. 254. Oversight and administration.
"Sec. 255. Authorization of appropriations.
"Sec. 256. Protective provisions.
"Sec. 257. Penalties.
"Sec. 258. Civil actions.
"Sec. 259. Definitions.
"Sec. 260. Regulations.
"Sec. 261. Study by Secretary of Commerce when International Trade Commission begins investigation; action where there is affirmative finding.
"Sec. 262. Assistance to industries.".

(e) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act, except that subsections (b) and (d) of section 254 of the Trade Act of 1974 (as added by subsection (a) of this section) shall take effect on such date of enactment. 19 USC 2344 note.

SEC. 1865. INCREASED PENALTIES FOR FALSE STATEMENTS.

Section 257 of the Trade Act of 1974, as redesignated by section 1864(a), is amended to read as follows: 19 USC 2349.

"SEC. 257. PENALTIES.

"Any person who—

"(1) makes a false statement of a material fact knowing it to be false, or knowingly fails to disclose a material fact, or willfully overvalues any security, for the purpose of influencing in any way a determination under this chapter, or for the purpose of obtaining money, property, or anything of value under this chapter, or

"(2) makes a false statement of a material fact knowing it to be false, or knowingly fails to disclose a material fact, when providing information to the Secretary during an investigation of a petition under this chapter,

shall be imprisoned for not more than 2 years, or fined under title 18, United States Code, or both.".

SEC. 1866. ANNUAL REPORT ON TRADE ADJUSTMENT ASSISTANCE FOR FIRMS. 19 USC 2356.

(a) IN GENERAL.—Not later than December 15, 2009, and each year thereafter, the Secretary of Commerce shall prepare a report containing data regarding the trade adjustment assistance for firms program provided for in chapter 3 of title II of the Trade Act of 1974 (19 U.S.C. 2341 et seq.) for the preceding fiscal year. The data shall include the following:

(1) The number of firms that inquired about the program.

(2) The number of petitions filed under section 251.

(3) The number of petitions certified and denied.

(4) The average time for processing petitions.

(5) The number of petitions filed and firms certified for each congressional district of the United States.

(6) The number of firms that received assistance in preparing their petitions.

(7) The number of firms that received assistance developing business recovery plans.

(8) The number of business recovery plans approved and denied by the Secretary of Commerce.

(9) Sales, employment, and productivity at each firm participating in the program at the time of certification.

(10) Sales, employment, and productivity at each firm upon completion of the program and each year for the 2-year period following completion.

(11) The financial assistance received by each firm participating in the program.

(12) The financial contribution made by each firm participating in the program.

(13) The types of technical assistance included in the business recovery plans of firms participating in the program.

(14) The number of firms leaving the program before completing the project or projects in their business recovery plans and the reason the project was not completed.

(b) CLASSIFICATION OF DATA.—To the extent possible, in collecting and reporting the data described in subsection (a), the Secretary shall classify the data by intermediary organization, State, and national totals.

(c) REPORT TO CONGRESS; PUBLICATION.—The Secretary of Commerce shall—

(1) submit the report described in subsection (a) to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives; and

Federal Register, publication.

(2) publish the report in the Federal Register and on the website of the Department of Commerce.

(d) PROTECTION OF CONFIDENTIAL INFORMATION.—The Secretary of Commerce may not release information described in subsection (a) that the Secretary considers to be confidential business information unless the person submitting the confidential business information had notice, at the time of submission, that such information would be released by the Secretary, or such person subsequently consents to the release of the information. Nothing in this subsection shall be construed to prohibit the Secretary from providing such confidential business information to a court in camera or to another party under a protective order issued by a court.

SEC. 1867. TECHNICAL CORRECTIONS.

(a) IN GENERAL.—Section 251 of the Trade Act of 1974 (19 U.S.C. 2341), as amended, is further amended—

(1) in subsection (a), by striking "he has" and inserting "the Secretary has"; and

(2) in subsection (d), by striking "60 days" and inserting "40 days".

(b) TECHNICAL ASSISTANCE.—Section 253(a)(3) of the Trade Act of 1974 (19 U.S.C. 2343(a)(3)) is amended by striking "of a certified firm" and inserting "to a certified firm".

PART III—TRADE ADJUSTMENT ASSISTANCE FOR COMMUNITIES

SEC. 1871. PURPOSE. 19 USC 2371 note.

The purpose of the amendments made by this part is to assist communities impacted by trade with economic adjustment through the coordination of Federal, State, and local resources, the creation of community-based development strategies, and the development and provision of programs that meet the training needs of workers covered by certifications under section 223.

SEC. 1872. TRADE ADJUSTMENT ASSISTANCE FOR COMMUNITIES.

(a) IN GENERAL.—Chapter 4 of title II of the Trade Act of 1974 (19 U.S.C. 2371 et seq.) is amended to read as follows:

"CHAPTER 4—TRADE ADJUSTMENT ASSISTANCE FOR COMMUNITIES

"Subchapter A—Trade Adjustment Assistance for Communities

"SEC. 271. DEFINITIONS. 19 USC 2371.

"In this subchapter:

"(1) AGRICULTURAL COMMODITY PRODUCER.—The term 'agricultural commodity producer' has the meaning given that term in section 291.

"(2) COMMUNITY.—The term 'community' means a city, county, or other political subdivision of a State or a consortium of political subdivisions of a State.

"(3) COMMUNITY IMPACTED BY TRADE.—The term 'community impacted by trade' means a community described in section 273(b)(2).

"(4) ELIGIBLE COMMUNITY.—The term 'eligible community' means a community that the Secretary has determined under section 273(b)(1) is eligible to apply for assistance under this subchapter.

"(5) SECRETARY.—The term 'Secretary' means the Secretary of Commerce.

"SEC. 272. ESTABLISHMENT OF TRADE ADJUSTMENT ASSISTANCE FOR COMMUNITIES PROGRAM. 19 USC 2371a.

"Not later than August 1, 2009, the Secretary shall establish a trade adjustment assistance for communities program at the Department of Commerce under which the Secretary shall— Deadline.

"(1) provide technical assistance under section 274 to communities impacted by trade to facilitate the economic adjustment of those communities; and

"(2) award grants to communities impacted by trade to carry out strategic plans developed under section 276. Grants.

"SEC. 273. ELIGIBILITY; NOTIFICATION. 19 USC 2371b.

"(a) PETITION.— Deadlines.

"(1) IN GENERAL.—A community may submit a petition to the Secretary for an affirmative determination under subsection (b)(1) that the community is eligible to apply for assistance under this subchapter if—

"(A) on or after August 1, 2009, one or more certifications described in subsection (b)(3) are made with respect to the community; and

"(B) the community submits the petition not later than 180 days after the date of the most recent certification.

Time period.

"(2) SPECIAL RULE WITH RESPECT TO CERTAIN COMMUNITIES.—In the case of a community with respect to which one or more certifications described in subsection (b)(3) were made on or after January 1, 2007, and before August 1, 2009, the community may submit not later than February 1, 2010, a petition to the Secretary for an affirmative determination under subsection (b)(1).

"(b) AFFIRMATIVE DETERMINATION.—

"(1) IN GENERAL.—The Secretary shall make an affirmative determination that a community is eligible to apply for assistance under this subchapter if the Secretary determines that the community is a community impacted by trade.

"(2) COMMUNITY IMPACTED BY TRADE.—A community is a community impacted by trade if—

"(A) one or more certifications described in paragraph (3) are made with respect to the community; and

"(B) the Secretary determines that the community is significantly affected by the threat to, or the loss of, jobs associated with any such certification.

"(3) CERTIFICATION DESCRIBED.—A certification described in this paragraph is a certification—

"(A) by the Secretary of Labor that a group of workers in the community is eligible to apply for assistance under section 223;

"(B) by the Secretary of Commerce that a firm located in the community is eligible to apply for adjustment assistance under section 251; or

"(C) by the Secretary of Agriculture that a group of agricultural commodity producers in the community is eligible to apply for adjustment assistance under section 293.

"(c) NOTIFICATIONS.—

"(1) NOTIFICATION TO THE GOVERNOR.—The Governor of a State shall be notified promptly—

"(A) by the Secretary of Labor, upon making a determination that a group of workers in the State is eligible for assistance under section 223;

"(B) by the Secretary of Commerce, upon making a determination that a firm in the State is eligible for assistance under section 251; and

"(C) by the Secretary of Agriculture, upon making a determination that a group of agricultural commodity producers in the State is eligible for assistance under section 293.

"(2) NOTIFICATION TO COMMUNITY.—Upon making an affirmative determination under subsection (b)(1) that a community is eligible to apply for assistance under this subchapter, the Secretary shall promptly notify the community and the Governor of the State in which the community is located—

"(A) of the affirmative determination;

"(B) of the applicable provisions of this subchapter; and

"(C) of the means for obtaining assistance under this subchapter and other appropriate economic assistance that may be available to the community.

"SEC. 274. TECHNICAL ASSISTANCE. 19 USC 2371c.

"(a) IN GENERAL.—The Secretary shall provide comprehensive technical assistance to an eligible community to assist the community to—

"(1) diversify and strengthen the economy in the community;

"(2) identify significant impediments to economic development that result from the impact of trade on the community; and

"(3) develop a strategic plan under section 276 to address economic adjustment and workforce dislocation in the community, including unemployment among agricultural commodity producers.

"(b) COORDINATION OF FEDERAL RESPONSE.—The Secretary shall coordinate the Federal response to an eligible community by—

"(1) identifying Federal, State, and local resources that are available to assist the community in responding to economic distress; and

"(2) assisting the community in accessing available Federal assistance and ensuring that such assistance is provided in a targeted, integrated manner.

"(c) INTERAGENCY COMMUNITY ASSISTANCE WORKING GROUP.—

"(1) IN GENERAL.—The Secretary shall establish an interagency Community Assistance Working Group, to be chaired by the Secretary or the Secretary's designee, which shall assist the Secretary with the coordination of the Federal response pursuant to subsection (b). Establishment.

"(2) MEMBERSHIP.—The Working Group shall consist of representatives of any Federal department or agency with responsibility for providing economic adjustment assistance, including the Department of Agriculture, the Department of Defense, the Department of Education, the Department of Labor, the Department of Housing and Urban Development, the Department of Health and Human Services, the Small Business Administration, the Department of the Treasury, and any other Federal, State, or regional public department or agency the Secretary determines to be appropriate.

"SEC. 275. GRANTS FOR ELIGIBLE COMMUNITIES. 19 USC 2371d.

"(a) IN GENERAL.—The Secretary may award a grant under this section to an eligible community to assist the community in carrying out any project or program that is included in a strategic plan developed by the community under section 276.

"(b) APPLICATION.—

"(1) IN GENERAL.—An eligible community seeking to receive a grant under this section shall submit a grant application to the Secretary that contains—

"(A) the strategic plan developed by the community under section 276(a)(1)(A) and approved by the Secretary under section 276(a)(1)(B); and

"(B) a description of the project or program included in the strategic plan with respect to which the community seeks the grant.

"(2) COORDINATION AMONG GRANT PROGRAMS.—If an entity in an eligible community is seeking or plans to seek a Community College and Career Training Grant under section 278 or a Sector Partnership Grant under section 279A while the eligible community is seeking a grant under this section, the eligible community shall include in the grant application a description of how the eligible community will integrate any projects or programs carried out using a grant under this section with any projects or programs that may be carried out using such other grants.

"(c) LIMITATION.—An eligible community may not be awarded more than $5,000,000 under this section.

"(d) COST-SHARING.—

"(1) FEDERAL SHARE.—The Federal share of a project or program for which a grant is awarded under this section may not exceed 95 percent of the cost of such project or program.

"(2) COMMUNITY SHARE.—The Secretary shall require, as a condition of awarding a grant to an eligible community under this section, that the eligible community contribute not less than an amount equal to 5 percent of the amount of the grant toward the cost of the project or program for which the grant is awarded.

"(e) GRANTS TO SMALL- AND MEDIUM-SIZED COMMUNITIES.—The Secretary shall give priority to grant applications submitted under this section by eligible communities that are small- and medium-sized communities.

"(f) ANNUAL REPORT.—Not later than December 15 in each of the calendar years 2009 through 2011, the Secretary shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report—

"(1) describing each grant awarded under this section during the preceding fiscal year; and

"(2) assessing the impact on the eligible community of each such grant awarded in a fiscal year before the fiscal year referred to in paragraph (1).

19 USC 2371e.

"SEC. 276. STRATEGIC PLANS.

"(a) IN GENERAL.—

"(1) DEVELOPMENT.—An eligible community that intends to apply for a grant under section 275 shall—

"(A) develop a strategic plan for the community's economic adjustment to the impact of trade; and

"(B) submit the plan to the Secretary for evaluation and approval.

"(2) INVOLVEMENT OF PRIVATE AND PUBLIC ENTITIES.—

"(A) IN GENERAL.—To the extent practicable, an eligible community shall consult with entities described in subparagraph (B) in developing a strategic plan under paragraph (1).

"(B) ENTITIES DESCRIBED.—Entities described in this subparagraph are public and private entities within the eligible community, including—

"(i) local, county, or State government agencies serving the community;

"(ii) firms, including small- and medium-sized firms, within the community;

"(iii) local workforce investment boards established under section 117 of the Workforce Investment Act of 1998 (29 U.S.C. 2832);

"(iv) labor organizations, including State labor federations and labor-management initiatives, representing workers in the community; and

"(v) educational institutions, local educational agencies, or other training providers serving the community.

"(b) CONTENTS.—The strategic plan shall, at a minimum, contain the following:

"(1) A description and analysis of the capacity of the eligible community to achieve economic adjustment to the impact of trade.

"(2) An analysis of the economic development challenges and opportunities facing the community as well as the strengths and weaknesses of the economy of the community.

"(3) An assessment of the commitment of the eligible community to the strategic plan over the long term and the participation and input of members of the community affected by economic dislocation.

"(4) A description of the role and the participation of the entities described in subsection (a)(2)(B) in developing the strategic plan.

"(5) A description of the projects to be undertaken by the eligible community under the strategic plan.

"(6) A description of how the strategic plan and the projects to be undertaken by the eligible community will facilitate the community's economic adjustment.

"(7) A description of the educational and training programs available to workers in the eligible community and the future employment needs of the community.

"(8) An assessment of the cost of implementing the strategic plan, the timing of funding required by the eligible community to implement the strategic plan, and the method of financing to be used to implement the strategic plan.

"(9) A strategy for continuing the economic adjustment of the eligible community after the completion of the projects described in paragraph (5).

"(c) GRANTS TO DEVELOP STRATEGIC PLANS.—

"(1) IN GENERAL.—The Secretary, upon receipt of an application from an eligible community, may award a grant to the community to assist the community in developing a strategic plan under subsection (a)(1). A grant awarded under this paragraph shall not exceed 75 percent of the cost of developing the strategic plan.

Time period.

"(2) FUNDS TO BE USED.—Of the funds appropriated pursuant to section 277(c), the Secretary may make available not more than $25,000,000 for each of the fiscal years 2009 and 2010, and $6,250,000 for the period beginning October 1, 2010, and ending December 31, 2010, to provide grants to eligible communities under paragraph (1).

"SEC. 277. GENERAL PROVISIONS.

19 USC 2371f.

"(a) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall prescribe such regulations as are necessary to carry out the provisions of this subchapter, including—

"(A) establishing specific guidelines for the submission and evaluation of strategic plans under section 276;

"(B) establishing specific guidelines for the submission and evaluation of grant applications under section 275; and

"(C) administering the grant programs established under sections 275 and 276.

Deadline.

"(2) CONSULTATIONS.—The Secretary shall consult with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives not less than 90 days prior to promulgating any final rule or regulation pursuant to paragraph (1).

Designation.

"(b) PERSONNEL.—The Secretary shall designate such staff as may be necessary to carry out the responsibilities described in this subchapter.

"(c) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—There are authorized to be appropriated to the Secretary $150,000,000 for each of the fiscal years 2009 and 2010, and $37,500,000 for the period beginning October 1, 2010, and ending December 31, 2010, to carry out this subchapter.

"(2) AVAILABILITY.—Amounts appropriated pursuant to this subchapter—

"(A) shall be available to provide adjustment assistance to communities that have been approved for assistance pursuant to this chapter on or before December 31, 2010; and

"(B) shall otherwise remain available until expended.

"(3) SUPPLEMENT NOT SUPPLANT.—Funds appropriated pursuant to this subchapter shall be used to supplement and not supplant other Federal, State, and local public funds expended to provide economic development assistance for communities.

"Subchapter B—Community College and Career Training Grant Program

19 USC 2372.

"SEC. 278. COMMUNITY COLLEGE AND CAREER TRAINING GRANT PROGRAM.

"(a) GRANTS AUTHORIZED.—

Effective date.

"(1) IN GENERAL.—Beginning August 1, 2009, the Secretary may award Community College and Career Training Grants to eligible institutions for the purpose of developing, offering, or improving educational or career training programs for workers eligible for training under section 236.

"(2) LIMITATIONS.—An eligible institution may not be awarded—

"(A) more than one grant under this section; or

"(B) a grant under this section in excess of $1,000,000.

"(b) DEFINITIONS.—In this section:

"(1) ELIGIBLE INSTITUTION.—The term 'eligible institution' means an institution of higher education (as defined in section 102 of the Higher Education Act of 1965 (20 U.S.C. 1002)),

but only with respect to a program offered by the institution that can be completed in not more than 2 years.

"(2) SECRETARY.—The term 'Secretary' means the Secretary of Labor.

"(c) GRANT PROPOSALS.—

"(1) IN GENERAL.—An eligible institution seeking to receive a grant under this section shall submit a grant proposal to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

"(2) GUIDELINES.—Not later than June 1, 2009, the Secretary shall— Deadline.

"(A) promulgate guidelines for the submission of grant proposals under this section; and

"(B) publish and maintain such guidelines on the website of the Department of Labor. Web posting.

"(3) ASSISTANCE.—The Secretary shall offer assistance in preparing a grant proposal to any eligible institution that requests such assistance.

"(4) GENERAL REQUIREMENTS FOR GRANT PROPOSALS.—

"(A) IN GENERAL.—A grant proposal submitted to the Secretary under this section shall include a detailed description of—

"(i) the specific project for which the grant proposal is submitted, including the manner in which the grant will be used to develop, offer, or improve an educational or career training program that is suited to workers eligible for training under section 236;

"(ii) the extent to which the project for which the grant proposal is submitted will meet the educational or career training needs of workers in the community served by the eligible institution who are eligible for training under section 236;

"(iii) the extent to which the project for which the grant proposal is submitted fits within any overall strategic plan developed by an eligible community under section 276;

"(iv) the extent to which the project for which the grant proposal is submitted relates to any project funded by a Sector Partnership Grant awarded under section 279A; and

"(v) any previous experience of the eligible institution in providing educational or career training programs to workers eligible for training under section 236.

"(B) ABSENCE OF EXPERIENCE.—The absence of any previous experience in providing educational or career training programs described in subparagraph (A)(v) shall not automatically disqualify an eligible institution from receiving a grant under this section.

"(5) COMMUNITY OUTREACH REQUIRED.—In order to be considered by the Secretary, a grant proposal submitted by an eligible institution under this section shall—

"(A) demonstrate that the eligible institution—

"(i) reached out to employers, and other entities described in section 276(a)(2)(B) to identify—

"(I) any shortcomings in existing educational and career training opportunities available to workers in the community; and

"(II) any future employment opportunities within the community and the educational and career training skills required for workers to meet the future employment demand;

"(ii) reached out to other similarly situated institutions in an effort to benefit from any best practices that may be shared with respect to providing educational or career training programs to workers eligible for training under section 236; and

"(iii) reached out to any eligible partnership in the community that has sought or received a Sector Partnership Grant under section 279A to enhance the effectiveness of each grant and avoid duplication of efforts; and

"(B) include a detailed description of—

"(i) the extent and outcome of the outreach conducted under subparagraph (A);

"(ii) the extent to which the project for which the grant proposal is submitted will contribute to meeting any shortcomings identified under subparagraph (A)(i)(I) or any educational or career training needs identified under subparagraph (A)(i)(II); and

"(iii) the extent to which employers, including small- and medium-sized firms within the community, have demonstrated a commitment to employing workers who would benefit from the project for which the grant proposal is submitted.

"(d) CRITERIA FOR AWARD OF GRANTS.—

"(1) IN GENERAL.—Subject to the appropriation of funds, the Secretary shall award a grant under this section based on—

"(A) a determination of the merits of the grant proposal submitted by the eligible institution to develop, offer, or improve educational or career training programs to be made available to workers eligible for training under section 236;

"(B) an evaluation of the likely employment opportunities available to workers who complete an educational or career training program that the eligible institution proposes to develop, offer, or improve; and

"(C) an evaluation of prior demand for training programs by workers eligible for training under section 236 in the community served by the eligible institution, as well as the availability and capacity of existing training programs to meet future demand for training programs.

"(2) PRIORITY FOR CERTAIN COMMUNITIES.—In awarding grants under this section, the Secretary shall give priority to an eligible institution that serves a community that the Secretary of Commerce has determined under section 273 is eligible to apply for assistance under subchapter A within the 5-year period preceding the date on which the grant proposal is submitted to the Secretary under this section.

"(3) MATCHING REQUIREMENTS.—A grant awarded under this section may not be used to satisfy any private matching requirement under any other provision of law.

"(e) ANNUAL REPORT.—Not later than December 15 in each of the calendar years 2009 through 2011, the Secretary shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report—

"(1) describing each grant awarded under this section during the preceding fiscal year; and

"(2) assessing the impact of each award of a grant under this section in a fiscal year preceding the fiscal year referred to in paragraph (1) on workers receiving training under section 236.

"SEC. 279. AUTHORIZATION OF APPROPRIATIONS. 19 USC 2372a.

"(a) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Labor $40,000,000 for each of the fiscal years 2009 and 2010, and $10,000,000 for the period beginning October 1, 2010, and ending December 31, 2010, to fund the Community College and Career Training Grant Program. Funds appropriated pursuant to this section shall remain available until expended. Time period.

"(b) SUPPLEMENT NOT SUPPLANT.—Funds appropriated pursuant to this section shall be used to supplement and not supplant other Federal, State, and local public funds expended to support community college and career training programs.

"Subchapter C—Industry or Sector Partnership Grant Program for Communities Impacted by Trade

"SEC. 279A. INDUSTRY OR SECTOR PARTNERSHIP GRANT PROGRAM FOR COMMUNITIES IMPACTED BY TRADE. 19 USC 2373.

"(a) PURPOSE.—The purpose of this subchapter is to facilitate efforts by industry or sector partnerships to strengthen and revitalize industries and create employment opportunities for workers in communities impacted by trade.

"(b) DEFINITIONS.—In this subchapter:

"(1) COMMUNITY IMPACTED BY TRADE.—The term 'community impacted by trade' has the meaning given that term in section 271.

"(2) DISLOCATED WORKER.—The term 'dislocated worker' means a worker who has been totally or partially separated, or is threatened with total or partial separation, from employment in an industry or sector in a community impacted by trade.

"(3) ELIGIBLE PARTNERSHIP.—The term 'eligible partnership' means a voluntary partnership composed of public and private persons, firms, or other entities within a community impacted by trade, that shall include representatives of—

"(A) an industry or sector within the community, including an industry association;

"(B) local, county, or State government;

"(C) multiple firms in the industry or sector, including small- and medium-sized firms, within the community;

"(D) local workforce investment boards established under section 117 of the Workforce Investment Act of 1998 (29 U.S.C. 2832);

"(E) labor organizations, including State labor federations and labor-management initiatives, representing workers in the community; and

"(F) educational institutions, local educational agencies, or other training providers serving the community.

"(4) LEAD ENTITY.—The term 'lead entity' means—

"(A) an entity designated by the eligible partnership to be responsible for submitting a grant proposal under subsection (e) and serving as the eligible partnership's fiscal agent in expending any Sector Partnership Grant awarded under this section; or

"(B) a State agency designated by the Governor of the State to carry out the responsibilities described in subparagraph (A).

"(5) SECRETARY.—The term 'Secretary' means the Secretary of Labor.

"(6) TARGETED INDUSTRY OR SECTOR.—The term 'targeted industry or sector' means the industry or sector represented by an eligible partnership.

Effective date.

"(c) SECTOR PARTNERSHIP GRANTS AUTHORIZED.—Beginning on August 1, 2009, and subject to the appropriation of funds, the Secretary shall award Sector Partnership Grants to eligible partnerships to assist the eligible partnerships in carrying out projects, over periods of not more than 3 years, to strengthen and revitalize industries and sectors and create employment opportunities for dislocated workers.

"(d) USE OF SECTOR PARTNERSHIP GRANTS.—An eligible partnership may use a Sector Partnership Grant to carry out any project that the Secretary determines will further the purpose of this subchapter, which may include—

"(1) identifying the skill needs of the targeted industry or sector and any gaps in the available supply of skilled workers in the community impacted by trade, and developing strategies for filling the gaps, including by—

"(A) developing systems to better link firms in the targeted industry or sector to available skilled workers;

"(B) helping firms in the targeted industry or sector to obtain access to new sources of qualified job applicants;

"(C) retraining dislocated and incumbent workers; or

"(D) facilitating the training of new skilled workers by aligning the instruction provided by local suppliers of education and training services with the needs of the targeted industry or sector;

"(2) analyzing the skills and education levels of dislocated and incumbent workers and developing training to address skill gaps that prevent such workers from obtaining jobs in the targeted industry or sector;

"(3) helping firms, especially small- and medium-sized firms, in the targeted industry or sector increase their productivity and the productivity of their workers;

"(4) helping such firms retain incumbent workers;

"(5) developing learning consortia of small- and medium-sized firms in the targeted industry or sector with similar training needs to enable the firms to combine their purchases of training services, and thereby lower their training costs;

"(6) providing information and outreach activities to firms in the targeted industry or sector regarding the activities of

the eligible partnership and other local service suppliers that could assist the firms in meeting needs for skilled workers;

"(7) seeking, applying, and disseminating best practices learned from similarly situated communities impacted by trade in the development and implementation of economic growth and revitalization strategies; and

"(8) identifying additional public and private resources to support the activities described in this subsection, which may include the option to apply for a community grant under section 275 or a Community College and Career Training Grant under section 278 (subject to meeting any additional requirements of those sections).

"(e) GRANT PROPOSALS.—

"(1) IN GENERAL.—The lead entity of an eligible partnership seeking to receive a Sector Partnership Grant under this section shall submit a grant proposal to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

"(2) GENERAL REQUIREMENTS OF GRANT PROPOSALS.—A grant proposal submitted under paragraph (1) shall, at a minimum—

"(A) identify the members of the eligible partnership;

"(B) identify the targeted industry or sector for which the eligible partnership intends to carry out projects using the Sector Partnership Grant;

"(C) describe the goals that the eligible partnership intends to achieve to promote the targeted industry or sector;

"(D) describe the projects that the eligible partnership will undertake to achieve such goals;

"(E) demonstrate that the eligible partnership has the organizational capacity to carry out the projects described in subparagraph (D);

"(F) explain—

"(i) whether—

"(I) the community impacted by trade has sought or received a community grant under section 275;

"(II) an eligible institution in the community has sought or received a Community College and Career Training Grant under section 278; or

"(III) any other entity in the community has received funds pursuant to any other federally funded training project; and

"(ii) how the eligible partnership will coordinate its use of a Sector Partnership Grant with the use of such other grants or funds in order to enhance the effectiveness of each grant and any such funds and avoid duplication of efforts; and

"(G) include performance measures, developed based on the performance measures issued by the Secretary under subsection (g)(2), and a timeline for measuring progress toward achieving the goals described in subparagraph (C).

"(f) AWARD OF GRANTS.—

"(1) IN GENERAL.—Upon application by the lead entity of an eligible partnership, the Secretary may award a Sector Partnership Grant to the eligible partnership to assist the

partnership in carrying out any of the projects in the grant proposal that the Secretary determines will further the purposes of this subchapter.

"(2) LIMITATIONS.—An eligible partnership may not be awarded—

"(A) more than one Sector Partnership Grant; or

"(B) a total grant award under this subchapter in excess of—

"(i) except as provided in clause (ii), $2,500,000; or

"(ii) in the case of an eligible partnership located within a community impacted by trade that is not served by an institution receiving a Community College and Career Training Grant under section 278, $3,000,000.

"(g) ADMINISTRATION BY THE SECRETARY.—

"(1) TECHNICAL ASSISTANCE AND OVERSIGHT.—

"(A) IN GENERAL.—The Secretary shall provide technical assistance to, and oversight of, the lead entity of an eligible partnership in applying for and administering Sector Partnership Grants awarded under this section.

"(B) TECHNICAL ASSISTANCE.—Technical assistance provided under subparagraph (A) shall include providing conferences and such other methods of collecting and disseminating information on best practices developed by eligible partnerships as the Secretary determines appropriate.

"(C) GRANTS OR CONTRACTS FOR TECHNICAL ASSISTANCE.—The Secretary may award a grant or contract to one or more national or State organizations to provide technical assistance to foster the planning, formation, and implementation of eligible partnerships.

"(2) PERFORMANCE MEASURES.—The Secretary shall issue a range of performance measures, with quantifiable benchmarks, and methodologies that eligible partnerships may use to measure progress toward the goals described in subsection (e). In developing such measures, the Secretary shall consider the benefits of the eligible partnership and its activities for workers, firms, industries, and communities.

"(h) REPORTS.—

"(1) PROGRESS REPORT.—Not later than 1 year after receiving a Sector Partnership Grant, and 3 years thereafter, the lead entity shall submit to the Secretary, on behalf of the eligible partnership, a report containing—

"(A) a detailed description of the progress made toward achieving the goals described in subsection (e)(2)(C), using the performance measures required under subsection (e)(2)(G);

"(B) a detailed evaluation of the impact of the grant award on workers and employers in the community impacted by trade; and

"(C) a detailed description of all expenditures of funds awarded to the eligible partnership under the Sector Partnership Grant approved by the Secretary under this subchapter.

"(2) ANNUAL REPORT.—Not later than December 15 in each of the calendar years 2009 through 2011, the Secretary shall submit to the Committee on Finance of the Senate and the

Committee on Ways and Means of the House of Representatives a report—

"(A) describing each Sector Partnership Grant awarded to an eligible partnership during the preceding fiscal year; and

"(B) assessing the impact of each Sector Partnership Grant awarded in a fiscal year preceding the fiscal year referred to in subparagraph (A) on workers and employers in communities impacted by trade.

"SEC. 279B. AUTHORIZATION OF APPROPRIATIONS. 19 USC 2373a.

"(a) IN GENERAL.—There are authorized to be appropriated to the Secretary of Labor $40,000,000 for each of the fiscal years 2009 and 2010, and $10,000,000 for the period beginning October 1, 2010, and ending December 31, 2010, to carry out the Sector Partnership Grant program under section 279A. Funds appropriated pursuant to this section shall remain available until expended. Time period.

"(b) SUPPLEMENT NOT SUPPLANT.—Funds appropriated pursuant to this section shall be used to supplement and not supplant other Federal, State, and local public funds expended to support the economic development of local communities.

"(c) ADMINISTRATIVE COSTS.—The Secretary may retain not more than 5 percent of the funds appropriated pursuant to this section for each fiscal year to administer the Sector Partnership Grant program under section 279A.

"Subchapter D—General Provisions

"SEC. 279C. RULE OF CONSTRUCTION. 19 USC 2374.

"Nothing in this chapter prevents a worker from receiving trade adjustment assistance under chapter 2 of this title at the same time the worker is receiving assistance in any manner from—

"(1) a community receiving a community grant under subchapter A;

"(2) an eligible institution receiving a Community College and Career Training Grant under subchapter B; or

"(3) an eligible partnership receiving a Sector Partnership Grant under subchapter C.".

SEC. 1873. CONFORMING AMENDMENTS.

(a) TABLE OF CONTENTS.—The table of contents of the Trade Act of 1974 is amended by striking the items relating to chapter 4 of title II and inserting the following:

"CHAPTER 4—TRADE ADJUSTMENT ASSISTANCE FOR COMMUNITIES

"Subchapter A—Trade Adjustment Assistance for Communities

"Sec. 271. Definitions.
"Sec. 272. Establishment of trade adjustment assistance for communities program.
"Sec. 273. Eligibility; notification.
"Sec. 274. Technical assistance.
"Sec. 275. Grants for eligible communities.
"Sec. 276. Strategic plans.
"Sec. 277. General provisions.

"Subchapter B—Community College and Career Training Grant Program

"Sec. 278. Community college and career training grant program.
"Sec. 279. Authorization of appropriations.

"Subchapter C—Industry or Sector Partnership Grant Program for Communities Impacted by Trade

"Sec. 279A. Industry or sector partnership grant program for communities impacted by trade.
"Sec. 279B. Authorization of appropriations.

"Subchapter D—General Provisions

"Sec. 279C. Rule of construction."

(b) JUDICIAL REVIEW.—

(1) Section 284(a) of the Trade Act of 1974 (19 U.S.C. 2395(a)) is amended—

(A) by inserting "or 296" after "section 293";

(B) by striking "or any other interested domestic party" and inserting "or authorized representative of a community"; and

(C) by striking "section 271" and inserting "section 273".

(2) Section 1581(d) of title 28, United States Code, is amended—

(A) in paragraph (2), by striking "; and" and inserting a semicolon;

(B) in paragraph (3)—

(i) by striking "271" and inserting "273"; and

(ii) by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(4) any final determination of the Secretary of Agriculture under section 293 or 296 of the Trade Act of 1974 (19 U.S.C. 2401b) with respect to the eligibility of a group of agricultural commodity producers for adjustment assistance under such Act.".

PART IV—TRADE ADJUSTMENT ASSISTANCE FOR FARMERS

SEC. 1881. DEFINITIONS.

Section 291 of the Trade Act of 1974 (19 U.S.C. 2401) is amended—

(1) by amending paragraph (1) to read as follows:

"(1) AGRICULTURAL COMMODITY.—The term 'agricultural commodity' includes—

"(A) any agricultural commodity (including livestock) in its raw or natural state;

"(B) any class of goods within an agricultural commodity; and

"(C) in the case of an agricultural commodity producer described in paragraph (2)(B), wild-caught aquatic species.";

(2) by amending paragraph (2) to read as follows:

"(2) AGRICULTURAL COMMODITY PRODUCER.—The term 'agricultural commodity producer' means—

"(A) a person that shares in the risk of producing an agricultural commodity and that is entitled to a share of the commodity for marketing, including an operator, a sharecropper, or a person that owns or rents the land on which the commodity is produced; or

"(B) a person that reports gain or loss from the trade or business of fishing on the person's annual Federal income tax return for the taxable year that most closely

corresponds to the marketing year with respect to which a petition is filed under section 292."; and

(3) by adding at the end the following:

"(7) MARKETING YEAR.—The term 'marketing year' means—

"(A) a marketing year designated by the Secretary with respect to an agricultural commodity; or

"(B) in the case of an agricultural commodity with respect to which the Secretary does not designate a marketing year, a calendar year.".

SEC. 1882. ELIGIBILITY.

(a) IN GENERAL.—Section 292 of the Trade Act of 1974 (19 U.S.C. 2401a) is amended by striking subsections (c) through (e) and inserting the following:

"(c) GROUP ELIGIBILITY REQUIREMENTS.—The Secretary shall certify a group of agricultural commodity producers as eligible to apply for adjustment assistance under this chapter if the Secretary determines that— Certification.

"(1)(A) the national average price of the agricultural commodity produced by the group during the most recent marketing year for which data are available is less than 85 percent of the average of the national average price for the commodity in the 3 marketing years preceding such marketing year;

"(B) the quantity of production of the agricultural commodity produced by the group during such marketing year is less than 85 percent of the average of the quantity of production of the commodity produced by the group in the 3 marketing years preceding such marketing year;

"(C) the value of production of the agricultural commodity produced by the group during such marketing year is less than 85 percent of the average value of production of the commodity produced by the group in the 3 marketing years preceding such marketing year; or

"(D) the cash receipts for the agricultural commodity produced by the group during such marketing year are less than 85 percent of the average of the cash receipts for the commodity produced by the group in the 3 marketing years preceding such marketing year;

"(2) the volume of imports of articles like or directly competitive with the agricultural commodity produced by the group in the marketing year with respect to which the group files the petition increased compared to the average volume of such imports during the 3 marketing years preceding such marketing year; and

"(3) the increase in such imports contributed importantly to the decrease in the national average price, quantity of production, or value of production of, or cash receipts for, the agricultural commodity, as described in paragraph (1).

"(d) ELIGIBILITY OF CERTAIN OTHER PRODUCERS.—An agricultural commodity producer or group of producers that resides outside of the State or region identified in the petition filed under subsection (a) may file a request to become a party to that petition not later than 15 days after the date the notice is published in the Federal Register under subsection (a) with respect to that petition. Deadline. Notice. Federal Register, publication.

"(e) TREATMENT OF CLASSES OF GOODS WITHIN A COMMODITY.—In any case in which there are separate classes of goods within

an agricultural commodity, the Secretary shall treat each class as a separate commodity in determining under subsection (c)—

"(1) group eligibility;

"(2) the national average price, quantity of production, or value of production, or cash receipts; and

"(3) the volume of imports.".

(b) CONFORMING AMENDMENTS.—Section 293 of the Trade Act of 1974 (19 U.S.C. 2401b) is amended—

(1) in subsection (a), by striking "section 292 (c) or (d), as the case may be," and inserting "section 292(c)"; and

(2) in subsection (c), by striking "decline in price for" and inserting "decrease in the national average price, quantity of production, or value of production of, or cash receipts for,".

SEC. 1883. BENEFITS.

(a) IN GENERAL.—Section 296 of the Trade Act of 1974 (19 U.S.C. 2401e) is amended to read as follows:

"SEC. 296. QUALIFYING REQUIREMENTS AND BENEFITS FOR AGRICULTURAL COMMODITY PRODUCERS.

"(a) IN GENERAL.—

"(1) REQUIREMENTS.—

Deadline.

"(A) IN GENERAL.—Benefits under this chapter shall be available to an agricultural commodity producer covered by a certification under this chapter who files an application for such benefits not later than 90 days after the date on which the Secretary makes a determination and issues a certification of eligibility under section 293, if the producer submits to the Secretary sufficient information to establish that—

"(i) the producer produced the agricultural commodity covered by the application filed under this subsection in the marketing year with respect to which the petition is filed and in at least 1 of the 3 marketing years preceding that marketing year;

"(ii)(I) the quantity of the agricultural commodity that was produced by the producer in the marketing year with respect to which the petition is filed has decreased compared to the most recent marketing year preceding that marketing year for which data are available; or

"(II)(aa) the price received for the agricultural commodity by the producer during the marketing year with respect to which the petition is filed has decreased compared to the average price for the commodity received by the producer in the 3 marketing years preceding that marketing year; or

"(bb) the county level price maintained by the Secretary for the agricultural commodity on the date on which the petition is filed has decreased compared to the average county level price for the commodity in the 3 marketing years preceding the date on which the petition is filed; and

"(iii) the producer is not receiving—

"(I) cash benefits under chapter 2 or 3; or

"(II) benefits based on the production of an agricultural commodity covered by another petition filed under this chapter.

"(B) SPECIAL RULE WITH RESPECT TO CROPS NOT GROWN EVERY YEAR.—For purposes of subparagraph (A)(ii)(II)(aa), if a petition is filed with respect to an agricultural commodity that is not produced by the producer every year, an agricultural commodity producer producing that commodity may establish the average price received for the commodity by the producer in the 3 marketing years preceding the year with respect to which the petition is filed by using average price data for the 3 most recent marketing years in which the producer produced the commodity and for which data are available.

"(2) LIMITATIONS BASED ON ADJUSTED GROSS INCOME.—

"(A) IN GENERAL.—Notwithstanding any other provision of this chapter, an agricultural commodity producer shall not be eligible for assistance under this chapter in any year in which the average adjusted gross income (as defined in section 1001D(a) of the Food Security Act of 1985 (7 U.S.C. 1308–3a(a))) of the producer exceeds the level set forth in subparagraph (A) or (B) of section 1001D(b)(1) of the Food Security Act of 1985 (7 U.S.C. 1308–3a(b)(1)), whichever is applicable.

"(B) DEMONSTRATION OF COMPLIANCE.—An agricultural commodity producer shall provide to the Secretary such information as the Secretary determines necessary to demonstrate that the producer is in compliance with the limitation under subparagraph (A).

"(C) COUNTER-CYCLICAL AND ACRE PAYMENTS.—The total amount of payments made to an agricultural commodity producer under this chapter during any crop year may not exceed the limitations on payments set forth in subsections (b)(2), (b)(3), (c)(2), and (c)(3) of section 1001 of the Food Security Act of 1985 (7 U.S.C. 1308).

"(b) TECHNICAL ASSISTANCE.—

"(1) INITIAL TECHNICAL ASSISTANCE.—

"(A) IN GENERAL.—An agricultural commodity producer that files an application and meets the requirements under subsection (a)(1) shall be entitled to receive initial technical assistance designed to improve the competitiveness of the production and marketing of the agricultural commodity with respect to which the producer was certified under this chapter. Such assistance shall include information regarding—

"(i) improving the yield and marketing of that agricultural commodity; and

"(ii) the feasibility and desirability of substituting one or more alternative agricultural commodities for that agricultural commodity.

"(B) TRANSPORTATION AND SUBSISTENCE EXPENSES.—

"(i) IN GENERAL.—The Secretary may authorize supplemental assistance necessary to defray reasonable transportation and subsistence expenses incurred by an agricultural commodity producer in connection with initial technical assistance under subparagraph (A) if such assistance is provided at facilities that are not within normal commuting distance of the regular place of residence of the producer.

"(ii) EXCEPTIONS.—The Secretary may not authorize payments to an agricultural commodity producer under clause (i)—

"(I) for subsistence expenses that exceed the lesser of—

"(aa) the actual per diem expenses for subsistence incurred by the producer; or

"(bb) the prevailing per diem allowance rate authorized under Federal travel regulations; or

"(II) for travel expenses that exceed the prevailing mileage rate authorized under the Federal travel regulations.

"(2) INTENSIVE TECHNICAL ASSISTANCE.—A producer that has completed initial technical assistance under paragraph (1) shall be eligible to participate in intensive technical assistance. Such assistance shall consist of—

"(A) a series of courses to further assist the producer in improving the competitiveness of the producer in producing—

"(i) the agricultural commodity with respect to which the producer was certified under this chapter; or

"(ii) another agricultural commodity; and

"(B) assistance in developing an initial business plan based on the courses completed under subparagraph (A).

"(3) INITIAL BUSINESS PLAN.—

"(A) APPROVAL BY SECRETARY.—The Secretary shall approve an initial business plan developed under paragraph (2)(B) if the plan—

"(i) reflects the skills gained by the producer through the courses described in paragraph (2)(A); and

"(ii) demonstrates how the producer will apply those skills to the circumstances of the producer.

"(B) FINANCIAL ASSISTANCE FOR IMPLEMENTING INITIAL BUSINESS PLAN.—Upon approval of the producer's initial business plan by the Secretary under subparagraph (A), a producer shall be entitled to an amount not to exceed $4,000 to—

"(i) implement the initial business plan; or

"(ii) develop a long-term business adjustment plan under paragraph (4).

"(4) LONG-TERM BUSINESS ADJUSTMENT PLAN.—

"(A) IN GENERAL.—A producer that has completed intensive technical assistance under paragraph (2) and whose initial business plan has been approved under paragraph (3)(A) shall be eligible for, in addition to the amount under subparagraph (C), assistance in developing a long-term business adjustment plan.

"(B) APPROVAL OF LONG-TERM BUSINESS ADJUSTMENT PLANS.—The Secretary shall approve a long-term business adjustment plan developed under subparagraph (A) if the Secretary determines that the plan—

"(i) includes steps reasonably calculated to materially contribute to the economic adjustment of the producer to changing market conditions;

"(ii) takes into consideration the interests of the workers employed by the producer; and

"(iii) demonstrates that the producer will have sufficient resources to implement the business plan.

"(C) PLAN IMPLEMENTATION.—Upon approval of the producer's long-term business adjustment plan under subparagraph (B), a producer shall be entitled to an amount not to exceed $8,000 to implement the long-term business adjustment plan.

"(c) MAXIMUM AMOUNT OF ASSISTANCE.—An agricultural commodity producer may receive not more than $12,000 under paragraphs (3) and (4) of subsection (b) in the 36-month period following certification under section 293.

"(d) LIMITATIONS ON OTHER ASSISTANCE.—An agricultural commodity producer that receives benefits under this chapter (other than initial technical assistance under subsection (b)(1)) shall not be eligible for cash benefits under chapter 2 or 3.".

(b) CLERICAL AMENDMENT.—The table of contents of the Trade Act of 1974 is amended by striking the item relating to section 296 and inserting the following:

"Sec. 296. Qualifying requirements and benefits for agricultural commodity producers.".

SEC. 1884. REPORT.

Section 293 of the Trade Act of 1974 (19 U.S.C. 2401b) is amended by adding at the end the following:

"(d) REPORT BY THE SECRETARY.—Not later than January 30, 2010, and annually thereafter, the Secretary of Agriculture shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report containing the following information with respect to adjustment assistance provided under this chapter during the preceding fiscal year:

"(1) A list of the agricultural commodities covered by a certification under this chapter.

"(2) The States or regions in which such commodities are produced and the aggregate amount of such commodities produced in each such State or region.

"(3) The total number of agricultural commodity producers, by congressional district, receiving benefits under this chapter.

"(4) The total number of agricultural commodity producers, by congressional district, receiving technical assistance under this chapter.".

SEC. 1885. FRAUD AND RECOVERY OF OVERPAYMENTS.

Section 297(a)(1) of the Trade Act of 1974 (19 U.S.C. 2401f(a)(1)) is amended by inserting "or has expended funds received under this chapter for a purpose that was not approved by the Secretary," after "entitled,".

SEC. 1886. DETERMINATION OF INCREASES OF IMPORTS FOR CERTAIN FISHERMEN.

19 USC 2271 note.

For purposes of chapters 2 and 6 of title II of the Trade Act of 1974 (19 U.S.C. 2251 et seq.), in the case of an agricultural commodity producer that—

(1) is a fisherman or aquaculture producer, and

(2) is otherwise eligible for adjustment assistance under chapter 2 or 6, as the case may be,

the increase in imports of articles like or directly competitive with the agricultural commodity produced by such producer may be based on imports of wild-caught seafood, farm-raised seafood, or both.

SEC. 1887. EXTENSION OF TRADE ADJUSTMENT ASSISTANCE FOR FARMERS.

Section 298(a) of the Trade Act of 1974 (19 U.S.C. 2401g(a)) is amended by striking "fiscal years 2003 through 2007" and all that follows through the end period and inserting "fiscal years 2009 and 2010, and $22,500,000 for the period beginning October 1, 2010, and ending December 31, 2010, to carry out the purposes of this chapter, including administrative costs, and salaries and expenses of employees of the Department of Agriculture.".

PART V—GENERAL PROVISIONS

19 USC 2271 note.

SEC. 1891. EFFECTIVE DATE.

(a) IN GENERAL.—Except as otherwise provided in this subtitle, and subsection (b) of this section, this subtitle and the amendments made by this subtitle—

(1) shall take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act; and

Applicability.

(2) shall apply to—

(A) petitions for certification filed under chapter 2, 3, or 6 of title II of the Trade Act of 1974 on or after the effective date described in paragraph (1); and

(B) petitions for assistance and proposals for grants filed under chapter 4 of title II of the Trade Act of 1974 on or after such effective date.

(b) CERTIFICATIONS MADE BEFORE EFFECTIVE DATE.—Notwithstanding subsection (a)—

(1) a worker shall continue to receive (or be eligible to receive) trade adjustment assistance and other benefits under subchapter B of chapter 2 of title II of the Trade Act of 1974, as in effect on the day before the effective date described in subsection (a)(1), for any week for which the worker meets the eligibility requirements of such chapter 2 as in effect on the day before such effective date, if the worker—

(A) is certified as eligible for trade adjustment assistance benefits under such chapter 2 pursuant to a petition filed under section 221 of the Trade Act of 1974 on or before such effective date; and

(B) would otherwise be eligible to receive trade adjustment assistance benefits under such chapter as in effect on the day before such effective date;

(2) a worker shall continue to receive (or be eligible to receive) benefits under section 246(a)(2) of the Trade Act of 1974, as in effect on the day before the effective date described in subsection (a)(1), for such period for which the worker meets the eligibility requirements of section 246 of that Act as in effect on the day before such effective date, if the worker—

(A) is certified as eligible for benefits under such section 246 pursuant to a petition filed under section 221 of the Trade Act of 1974 on or before such effective date; and

(B) would otherwise be eligible to receive benefits under such section 246(a)(2) as in effect on the day before such effective date; and

(3) a firm shall continue to receive (or be eligible to receive) adjustment assistance under chapter 3 of title II of the Trade Act of 1974, as in effect on the day before the effective date described in subsection (a)(1), for such period for which the firm meets the eligibility requirements of such chapter 3 as in effect on the day before such effective date, if the firm—

(A) is certified as eligible for benefits under such chapter 3 pursuant to a petition filed under section 251 of the Trade Act of 1974 on or before such effective date; and

(B) would otherwise be eligible to receive benefits under such chapter 3 as in effect on the day before such effective date.

SEC. 1892. EXTENSION OF TRADE ADJUSTMENT ASSISTANCE PROGRAMS.

(a) FOR WORKERS.—Section 245(a) of the Trade Act of 1974 (19 U.S.C. 2317(a)) is amended by striking "December 31, 2007" and inserting "December 31, 2010".

(b) TERMINATION.—Section 285 of the Trade Act of 1974 (19 U.S.C. 2271 note prec.) is amended—

(1) in subsection (a), by striking "December 31, 2007" each place it appears and inserting "December 31, 2010"; and

(2) by amending subsection (b) to read as follows:

"(b) OTHER ASSISTANCE.—

"(1) ASSISTANCE FOR FIRMS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), technical assistance and grants may not be provided under chapter 3 after December 31, 2010.

"(B) EXCEPTION.—Notwithstanding subparagraph (A), any technical assistance or grant approved under chapter 3 on or before December 31, 2010, may be provided—

"(i) to the extent funds are available pursuant to such chapter for such purpose; and

"(ii) to the extent the recipient of the technical assistance or grant is otherwise eligible to receive such technical assistance or grant, as the case may be.

"(2) FARMERS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), technical assistance and financial assistance may not be provided under chapter 6 after December 31, 2010.

"(B) EXCEPTION.—Notwithstanding subparagraph (A), any technical or financial assistance approved under chapter 6 on or before December 31, 2010, may be provided—

"(i) to the extent funds are available pursuant to such chapter for such purpose; and

"(ii) to the extent the recipient of the technical or financial assistance is otherwise eligible to receive such technical or financial assistance, as the case may be.

"(3) ASSISTANCE FOR COMMUNITIES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), technical assistance and grants may not be provided under chapter 4 after December 31, 2010.

"(B) EXCEPTION.—Notwithstanding subparagraph (A), any technical assistance or grant approved under chapter 4 on or before December 31, 2010, may be provided—

"(i) to the extent funds are available pursuant to such chapter for such purpose; and

"(ii) to the extent the recipient of the technical assistance or grant is otherwise eligible to receive such technical assistance or grant, as the case may be.".

19 USC 2271 note prec.

SEC. 1893. TERMINATION; RELATED PROVISIONS.

(a) SUNSET.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this subtitle to chapters 2, 3, 4, 5, and 6 of title II of the Trade Act of 1974 (19 U.S.C. 2271 et seq.) shall not apply on or after January 1, 2011.

(2) EXCEPTION.—The amendments made by this subtitle to section 285 of the Trade Act of 1974 shall continue to apply on and after January 1, 2011, with respect to—

(A) workers certified as eligible for trade adjustment assistance benefits under chapter 2 of title II of that Act pursuant to petitions filed under section 221 of that Act before January 1, 2011;

(B) firms certified as eligible for technical assistance or grants under chapter 3 of title II of that Act pursuant to petitions filed under section 251 of that Act before January 1, 2011;

(C) recipients approved for technical assistance or grants under chapter 4 of title II of that Act pursuant to petitions for assistance or proposals for grants (as the case may be) filed pursuant to such chapter before January 1, 2011; and

(D) agricultural commodity producers certified as eligible for technical or financial assistance under chapter 6 of title II of that Act pursuant to petitions filed under section 292 of that Act before January 1, 2011.

Effective date.

(b) APPLICATION OF PRIOR LAW.—Chapters 2, 3, 4, 5, and 6 of title II of the Trade Act of 1974 (19 U.S.C. 2271 et seq.) shall be applied and administered beginning January 1, 2011, as if the amendments made by this subtitle (other than part VI) had never been enacted, except that in applying and administering such chapters—

(1) section 245 of that Act shall be applied and administered by substituting "2011" for "2007";

(2) section 246(b) of that Act shall be applied and administered by substituting "December 31, 2011" for "the date that is 5 years" and all that follows through "State";

(3) section 256(b) of that Act shall be applied and administered by substituting "the 1-year period beginning January 1, 2011" for "each of fiscal years 2003 through 2007, and $4,000,000 for the 3-month period beginning October 1, 2007";

(4) section 298(a) of that Act shall be applied and administered by substituting "the 1-year period beginning January 1, 2011" for "each of the fiscal years" and all that follows through "October 1, 2007"; and

(5) subject to subsection (a)(2), section 285 of that Act shall be applied and administered—

(A) in subsection (a), by substituting "2011" for "2007" each place it appears; and

(B) by applying and administering subsection (b) as if it read as follows:

"(b) OTHER ASSISTANCE.—

"(1) ASSISTANCE FOR FIRMS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), assistance may not be provided under chapter 3 after December 31, 2011.

"(B) EXCEPTION.—Notwithstanding subparagraph (A), any assistance approved under chapter 3 on or before December 31, 2011, may be provided—

"(i) to the extent funds are available pursuant to such chapter for such purpose; and

"(ii) to the extent the recipient of the assistance is otherwise eligible to receive such assistance.

"(2) FARMERS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), assistance may not be provided under chapter 6 after December 31, 2011.

"(B) EXCEPTION.—Notwithstanding subparagraph (A), any assistance approved under chapter 6 on or before December 31, 2011, may be provided—

"(i) to the extent funds are available pursuant to such chapter for such purpose; and

"(ii) to the extent the recipient of the assistance is otherwise eligible to receive such assistance.".

SEC. 1894. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

Not later than September 30, 2012, the Comptroller General of the United States shall prepare and submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a comprehensive report on the operation and effectiveness of the amendments made by this subtitle to chapters 2, 3, 4, and 6 of the Trade Act of 1974.

SEC. 1895. EMERGENCY DESIGNATION.

Amounts appropriated pursuant to this subtitle are designated as an emergency requirement and necessary to meet emergency needs pursuant to section 204(a) of S. Con. Res. 21 (110th Congress) and section 301(b)(2) of S. Con. Res. 70 (110th Congress), the concurrent resolutions on the budget for fiscal years 2008 and 2009.

PART VI—HEALTH COVERAGE IMPROVEMENT

TAA Health Coverage Improvement Act of 2009.
26 USC 1 note.

SEC. 1899. SHORT TITLE.

This part may be cited as the "TAA Health Coverage Improvement Act of 2009".

SEC. 1899A. IMPROVEMENT OF THE AFFORDABILITY OF THE CREDIT.

(a) IMPROVEMENT OF AFFORDABILITY.—

(1) IN GENERAL.—Section 35(a) of the Internal Revenue Code of 1986 (relating to credit for health insurance costs of eligible individuals) is amended by inserting "(80 percent

26 USC 35.

in the case of eligible coverage months beginning before January 1, 2011)" after "65 percent".

(2) CONFORMING AMENDMENT.—Section 7527(b) of such Code (relating to advance payment of credit for health insurance costs of eligible individuals) is amended by inserting "(80 percent in the case of eligible coverage months beginning before January 1, 2011)" after "65 percent".

26 USC 7527.

26 USC 35 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to coverage months beginning on or after the first day of the first month beginning 60 days after the date of the enactment of this Act.

SEC. 1899B. PAYMENT FOR MONTHLY PREMIUMS PAID PRIOR TO COMMENCEMENT OF ADVANCE PAYMENTS OF CREDIT.

(a) PAYMENT FOR PREMIUMS DUE PRIOR TO COMMENCEMENT OF ADVANCE PAYMENTS OF CREDIT.—Section 7527 of the Internal Revenue Code of 1986 (relating to advance payment of credit for health insurance costs of eligible individuals) is amended by adding at the end the following new subsection:

"(e) PAYMENT FOR PREMIUMS DUE PRIOR TO COMMENCEMENT OF ADVANCE PAYMENTS.—In the case of eligible coverage months beginning before January 1, 2011—

"(1) IN GENERAL.—The program established under subsection (a) shall provide that the Secretary shall make 1 or more retroactive payments on behalf of a certified individual in an aggregate amount equal to 80 percent of the premiums for coverage of the taxpayer and qualifying family members under qualified health insurance for eligible coverage months (as defined in section 35(b)) occurring prior to the first month for which an advance payment is made on behalf of such individual under subsection (a).

"(2) REDUCTION OF PAYMENT FOR AMOUNTS RECEIVED UNDER NATIONAL EMERGENCY GRANTS.—The amount of any payment determined under paragraph (1) shall be reduced by the amount of any payment made to the taxpayer for the purchase of qualified health insurance under a national emergency grant pursuant to section 173(f) of the Workforce Investment Act of 1998 for a taxable year including the eligible coverage months described in paragraph (1).".

26 USC 7527 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to coverage months beginning after December 31, 2008.

26 USC 7527 note.

(c) TRANSITIONAL RULE.—The Secretary of the Treasury shall not be required to make any payments under section 7527(e) of the Internal Revenue Code of 1986, as added by this section, until after the date that is 6 months after the date of the enactment of this Act.

SEC. 1899C. TAA RECIPIENTS NOT ENROLLED IN TRAINING PROGRAMS ELIGIBLE FOR CREDIT.

(a) IN GENERAL.—Paragraph (2) of section 35(c) of the Internal Revenue Code of 1986 (defining eligible TAA recipient) is amended to read as follows:

"(2) ELIGIBLE TAA RECIPIENT.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'eligible TAA recipient' means, with respect to any month, any individual who is receiving for any day of such month a trade readjustment allowance under chapter 2 of title II of the Trade Act of 1974 or who

would be eligible to receive such allowance if section 231 of such Act were applied without regard to subsection (a)(3)(B) of such section. An individual shall continue to be treated as an eligible TAA recipient during the first month that such individual would otherwise cease to be an eligible TAA recipient by reason of the preceding sentence.

"(B) SPECIAL RULE.—In the case of any eligible coverage month beginning after the date of the enactment of this paragraph and before January 1, 2011, the term 'eligible TAA recipient' means, with respect to any month, any individual who—

"(i) is receiving for any day of such month a trade readjustment allowance under chapter 2 of title II of the Trade Act of 1974,

"(ii) would be eligible to receive such allowance except that such individual is in a break in training provided under a training program approved under section 236 of such Act that exceeds the period specified in section 233(e) of such Act, but is within the period for receiving such allowances provided under section 233(a) of such Act, or

"(iii) is receiving unemployment compensation (as defined in section 85(b)) for any day of such month and who would be eligible to receive such allowance for such month if section 231 of such Act were applied without regard to subsections (a)(3)(B) and (a)(5) thereof.

An individual shall continue to be treated as an eligible TAA recipient during the first month that such individual would otherwise cease to be an eligible TAA recipient by reason of the preceding sentence.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to coverage months beginning after the date of the enactment of this Act. 26 USC 35 note.

SEC. 1899D. TAA PRE-CERTIFICATION PERIOD RULE FOR PURPOSES OF DETERMINING WHETHER THERE IS A 63-DAY LAPSE IN CREDITABLE COVERAGE.

(a) IRC AMENDMENT.—Section 9801(c)(2) of the Internal Revenue Code of 1986 (relating to not counting periods before significant breaks in creditable coverage) is amended by adding at the end the following new subparagraph: 26 USC 9801.

"(D) TAA-ELIGIBLE INDIVIDUALS.—In the case of plan years beginning before January 1, 2011—

"(i) TAA PRE-CERTIFICATION PERIOD RULE.—In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date which is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified health insurance costs credit eligibility certificate for such individual for purposes of section 7527 shall not be taken into account in determining the continuous period under subparagraph (A).

"(ii) DEFINITIONS.—The terms 'TAA-eligible individual' and 'TAA-related loss of coverage' have the

meanings given such terms in section 4980B(f)(5)(C)(iv).".

(b) ERISA AMENDMENT.—Section 701(c)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181(c)(2)) is amended by adding at the end the following new subparagraph:

"(C) TAA-ELIGIBLE INDIVIDUALS.—In the case of plan years beginning before January 1, 2011—

"(i) TAA PRE-CERTIFICATION PERIOD RULE.—In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date that is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified health insurance costs credit eligibility certificate for such individual for purposes of section 7527 of the Internal Revenue Code of 1986 shall not be taken into account in determining the continuous period under subparagraph (A).

"(ii) DEFINITIONS.—The terms 'TAA-eligible individual' and 'TAA-related loss of coverage' have the meanings given such terms in section 605(b)(4).".

(c) PHSA AMENDMENT.—Section 2701(c)(2) of the Public Health Service Act (42 U.S.C. 300gg(c)(2)) is amended by adding at the end the following new subparagraph:

"(C) TAA-ELIGIBLE INDIVIDUALS.—In the case of plan years beginning before January 1, 2011—

"(i) TAA PRE-CERTIFICATION PERIOD RULE.—In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date that is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified health insurance costs credit eligibility certificate for such individual for purposes of section 7527 of the Internal Revenue Code of 1986 shall not be taken into account in determining the continuous period under subparagraph (A).

"(ii) DEFINITIONS.—The terms 'TAA-eligible individual' and 'TAA-related loss of coverage' have the meanings given such terms in section 2205(b)(4).".

26 USC 9801 note.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to plan years beginning after the date of the enactment of this Act.

SEC. 1899E. CONTINUED QUALIFICATION OF FAMILY MEMBERS AFTER CERTAIN EVENTS.

26 USC 35.

(a) IN GENERAL.—Subsection (g) of section 35 of such Code is amended by redesignating paragraph (9) as paragraph (10) and inserting after paragraph (8) the following new paragraph:

"(9) CONTINUED QUALIFICATION OF FAMILY MEMBERS AFTER CERTAIN EVENTS.—In the case of eligible coverage months beginning before January 1, 2011—

"(A) MEDICARE ELIGIBILITY.—In the case of any month which would be an eligible coverage month with respect to an eligible individual but for subsection (f)(2)(A), such month shall be treated as an eligible coverage month with respect to such eligible individual solely for purposes of

determining the amount of the credit under this section with respect to any qualifying family members of such individual (and any advance payment of such credit under section 7527). This subparagraph shall only apply with respect to the first 24 months after such eligible individual is first entitled to the benefits described in subsection (f)(2)(A).

"(B) DIVORCE.—In the case of the finalization of a divorce between an eligible individual and such individual's spouse, such spouse shall be treated as an eligible individual for purposes of this section and section 7527 for a period of 24 months beginning with the date of such finalization, except that the only qualifying family members who may be taken into account with respect to such spouse are those individuals who were qualifying family members immediately before such finalization.

"(C) DEATH.—In the case of the death of an eligible individual—

"(i) any spouse of such individual (determined at the time of such death) shall be treated as an eligible individual for purposes of this section and section 7527 for a period of 24 months beginning with the date of such death, except that the only qualifying family members who may be taken into account with respect to such spouse are those individuals who were qualifying family members immediately before such death, and

"(ii) any individual who was a qualifying family member of the decedent immediately before such death (or, in the case of an individual to whom paragraph (4) applies, the taxpayer to whom the deduction under section 151 is allowable) shall be treated as an eligible individual for purposes of this section and section 7527 for a period of 24 months beginning with the date of such death, except that in determining the amount of such credit only such qualifying family member may be taken into account.".

(b) CONFORMING AMENDMENT.—Section 173(f) of the Workforce Investment Act of 1998 (29 U.S.C. 2918(f)) is amended by adding at the end the following:

"(8) CONTINUED QUALIFICATION OF FAMILY MEMBERS AFTER CERTAIN EVENTS.—In the case of eligible coverage months beginning before January 1, 2011—

"(A) MEDICARE ELIGIBILITY.—In the case of any month which would be an eligible coverage month with respect to an eligible individual but for paragraph (7)(B)(i), such month shall be treated as an eligible coverage month with respect to such eligible individual solely for purposes of determining the eligibility of qualifying family members of such individual under this subsection. This subparagraph shall only apply with respect to the first 24 months after such eligible individual is first entitled to the benefits described in paragraph (7)(B)(i). Applicability.

"(B) DIVORCE.—In the case of the finalization of a divorce between an eligible individual and such individual's spouse, such spouse shall be treated as an eligible individual for purposes of this subsection for a period of 24

months beginning with the date of such finalization, except that the only qualifying family members who may be taken into account with respect to such spouse are those individuals who were qualifying family members immediately before such finalization.

"(C) DEATH.—In the case of the death of an eligible individual—

"(i) any spouse of such individual (determined at the time of such death) shall be treated as an eligible individual for purposes of this subsection for a period of 24 months beginning with the date of such death, except that the only qualifying family members who may be taken into account with respect to such spouse are those individuals who were qualifying family members immediately before such death, and

"(ii) any individual who was a qualifying family member of the decedent immediately before such death shall be treated as an eligible individual for purposes this subsection for a period of 24 months beginning with the date of such death, except that no qualifying family members may be taken into account with respect to such individual.".

26 USC 35 note.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to months beginning after December 31, 2009.

SEC. 1899F. EXTENSION OF COBRA BENEFITS FOR CERTAIN TAA-ELIGIBLE INDIVIDUALS AND PBGC RECIPIENTS.

(a) ERISA AMENDMENTS.—Section 602(2)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1162(2)(A)) is amended—

(1) by moving clause (v) to after clause (iv) and before the flush left sentence beginning with "In the case of a qualified beneficiary";

(2) by striking "In the case of a qualified beneficiary" and inserting the following:

"(vi) SPECIAL RULE FOR DISABILITY.—In the case of a qualified beneficiary"; and

(3) by redesignating clauses (v) and (vi), as amended by paragraphs (1) and (2), as clauses (vii) and (viii), respectively, and by inserting after clause (iv) the following new clauses:

"(v) SPECIAL RULE FOR PBGC RECIPIENTS.—In the case of a qualifying event described in section 603(2) with respect to a covered employee who (as of such qualifying event) has a nonforfeitable right to a benefit any portion of which is to be paid by the Pension Benefit Guaranty Corporation under title IV, notwithstanding clause (i) or (ii), the date of the death of the covered employee, or in the case of the surviving spouse or dependent children of the covered employee, 24 months after the date of the death of the covered employee. The preceding sentence shall not require any period of coverage to extend beyond December 31, 2010.

"(vi) SPECIAL RULE FOR TAA-ELIGIBLE INDIVIDUALS.—In the case of a qualifying event described in section 603(2) with respect to a covered employee who is (as of the date that the period of coverage would,

but for this clause or clause (vii), otherwise terminate under clause (i) or (ii)) a TAA-eligible individual (as defined in section 605(b)(4)(B)), the period of coverage shall not terminate by reason of clause (i) or (ii), as the case may be, before the later of the date specified in such clause or the date on which such individual ceases to be such a TAA-eligible individual. The preceding sentence shall not require any period of coverage to extend beyond December 31, 2010.".

(b) IRC AMENDMENTS.—Clause (i) of section 4980B(f)(2)(B) of the Internal Revenue Code of 1986 is amended— 26 USC 4980B.

(1) by striking "In the case of a qualified beneficiary" and inserting the following:

"(VI) SPECIAL RULE FOR DISABILITY.—In the case of a qualified beneficiary", and

(2) by redesignating subclauses (V) and (VI), as amended by paragraph (1), as subclauses (VII) and (VIII), respectively, and by inserting after clause (IV) the following new subclauses:

"(V) SPECIAL RULE FOR PBGC RECIPIENTS.—In the case of a qualifying event described in paragraph (3)(B) with respect to a covered employee who (as of such qualifying event) has a nonforfeitable right to a benefit any portion of which is to be paid by the Pension Benefit Guaranty Corporation under title IV of the Employee Retirement Income Security Act of 1974, notwithstanding subclause (I) or (II), the date of the death of the covered employee, or in the case of the surviving spouse or dependent children of the covered employee, 24 months after the date of the death of the covered employee. The preceding sentence shall not require any period of coverage to extend beyond December 31, 2010.

"(VI) SPECIAL RULE FOR TAA-ELIGIBLE INDIVIDUALS.—In the case of a qualifying event described in paragraph (3)(B) with respect to a covered employee who is (as of the date that the period of coverage would, but for this subclause or subclause (VII), otherwise terminate under subclause (I) or (II)) a TAA-eligible individual (as defined in paragraph (5)(C)(iv)(II)), the period of coverage shall not terminate by reason of subclause (I) or (II), as the case may be, before the later of the date specified in such subclause or the date on which such individual ceases to be such a TAA-eligible individual. The preceding sentence shall not require any period of coverage to extend beyond December 31, 2010.".

(c) PHSA AMENDMENTS.—Section 2202(2)(A) of the Public Health Service Act (42 U.S.C. 300bb-2(2)(A)) is amended—

(1) by striking "In the case of a qualified beneficiary" and inserting the following:

"(v) SPECIAL RULE FOR DISABILITY.—In the case of a qualified beneficiary"; and

(2) by redesignating clauses (iv) and (v), as amended by paragraph (1), as clauses (v) and (vi), respectively, and by inserting after clause (iii) the following new clause:

"(iv) SPECIAL RULE FOR TAA-ELIGIBLE INDIVIDUALS.—In the case of a qualifying event described in section 2203(2) with respect to a covered employee who is (as of the date that the period of coverage would, but for this clause or clause (v), otherwise terminate under clause (i) or (ii)) a TAA-eligible individual (as defined in section 2205(b)(4)(B)), the period of coverage shall not terminate by reason of clause (i) or (ii), as the case may be, before the later of the date specified in such clause or the date on which such individual ceases to be such a TAA-eligible individual. The preceding sentence shall not require any period of coverage to extend beyond December 31, 2010.".

26 USC 4980B note.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to periods of coverage which would (without regard to the amendments made by this section) end on or after the date of the enactment of this Act.

SEC. 1899G. ADDITION OF COVERAGE THROUGH VOLUNTARY EMPLOYEES' BENEFICIARY ASSOCIATIONS.

26 USC 35.

(a) IN GENERAL.—Paragraph (1) of section 35(e) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

"(K) In the case of eligible coverage months beginning before January 1, 2011, coverage under an employee benefit plan funded by a voluntary employees' beneficiary association (as defined in section 501(c)(9)) established pursuant to an order of a bankruptcy court, or by agreement with an authorized representative, as provided in section 1114 of title 11, United States Code.".

26 USC 35 note.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to coverage months beginning after the date of the enactment of this Act.

SEC. 1899H. NOTICE REQUIREMENTS.

(a) IN GENERAL.—Subsection (d) of section 7527 of the Internal Revenue Code of 1986 (relating to qualified health insurance costs credit eligibility certificate) is amended to read as follows:

"(d) QUALIFIED HEALTH INSURANCE COSTS ELIGIBILITY CERTIFICATE.—

"(1) IN GENERAL.—For purposes of this section, the term 'qualified health insurance costs eligibility certificate' means any written statement that an individual is an eligible individual (as defined in section 35(c)) if such statement provides such information as the Secretary may require for purposes of this section and—

"(A) in the case of an eligible TAA recipient (as defined in section 35(c)(2)) or an eligible alternative TAA recipient (as defined in section 35(c)(3)), is certified by the Secretary of Labor (or by any other person or entity designated by the Secretary), or

"(B) in the case of an eligible PBGC pension recipient (as defined in section 35(c)(4)), is certified by the Pension Benefit Guaranty Corporation (or by any other person or entity designated by the Secretary).

"(2) INCLUSION OF CERTAIN INFORMATION.—In the case of any statement described in paragraph (1) which is issued before January 1, 2011, such statement shall not be treated as a

qualified health insurance costs credit eligibility certificate unless such statement includes—

"(A) the name, address, and telephone number of the State office or offices responsible for providing the individual with assistance with enrollment in qualified health insurance (as defined in section 35(e)),

"(B) a list of the coverage options that are treated as qualified health insurance (as so defined) by the State in which the individual resides, and

"(C) in the case of a TAA-eligible individual (as defined in section 4980B(f)(5)(C)(iv)(II)), a statement informing the individual that the individual has 63 days from the date that is 7 days after the date of the issuance of such certificate to enroll in such insurance without a lapse in creditable coverage (as defined in section 9801(c)).".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to certificates issued after the date that is 6 months after the date of the enactment of this Act. 26 USC 7527 note.

SEC. 1899I. SURVEY AND REPORT ON ENHANCED HEALTH COVERAGE TAX CREDIT PROGRAM. 26 USC 35 note.

(a) SURVEY.—

(1) IN GENERAL.—The Secretary of the Treasury shall conduct a biennial survey of eligible individuals (as defined in section 35(c) of the Internal Revenue Code of 1986) relating to the health coverage tax credit under section 35 of the Internal Revenue Code of 1986 (hereinafter in this section referred to as the "health coverage tax credit").

(2) INFORMATION OBTAINED.—The survey conducted under subsection (a) shall obtain the following information:

(A) HCTC PARTICIPANTS.—In the case of eligible individuals receiving the health coverage tax credit (including individuals participating in the health coverage tax credit program under section 7527 of such Code, hereinafter in this section referred to as the "HCTC program")—

(i) demographic information of such individuals, including income and education levels,

(ii) satisfaction of such individuals with the enrollment process in the HCTC program,

(iii) satisfaction of such individuals with available health coverage options under the credit, including level of premiums, benefits, deductibles, cost-sharing requirements, and the adequacy of provider networks, and

(iv) any other information that the Secretary determines is appropriate.

(B) NON-HCTC PARTICIPANTS.—In the case of eligible individuals not receiving the health coverage tax credit—

(i) demographic information of each individual, including income and education levels,

(ii) whether the individual was aware of the health coverage tax credit or the HCTC program,

(iii) the reasons the individual has not enrolled in the HCTC program, including whether such reasons include the burden of the process of enrollment and the affordability of coverage,

(iv) whether the individual has health insurance coverage, and, if so, the source of such coverage, and

(v) any other information that the Secretary determines is appropriate.

(3) REPORT.—Not later than December 31 of each year in which a survey is conducted under paragraph (1) (beginning in 2010), the Secretary of the Treasury shall report to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means, the Committee on Education and Labor, and the Committee on Energy and Commerce of the House of Representatives the findings of the most recent survey conducted under paragraph (1).

(b) REPORT.—Not later than October 1 of each year (beginning in 2010), the Secretary of the Treasury (after consultation with the Secretary of Health and Human Services, and, in the case of the information required under paragraph (7), the Secretary of Labor) shall report to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means, the Committee on Education and Labor, and the Committee on Energy and Commerce of the House of Representatives the following information with respect to the most recent taxable year ending before such date:

(1) In each State and nationally—

(A) the total number of eligible individuals (as defined in section 35(c) of the Internal Revenue Code of 1986) and the number of eligible individuals receiving the health coverage tax credit,

(B) the total number of such eligible individuals who receive an advance payment of the health coverage tax credit through the HCTC program,

(C) the average length of the time period of the participation of eligible individuals in the HCTC program, and

(D) the total number of participating eligible individuals in the HCTC program who are enrolled in each category of coverage as described in section 35(e)(1) of such Code,

with respect to each category of eligible individuals described in section 35(c)(1) of such Code.

(2) In each State and nationally, an analysis of—

(A) the range of monthly health insurance premiums, for self-only coverage and for family coverage, for individuals receiving the health coverage tax credit, and

(B) the average and median monthly health insurance premiums, for self-only coverage and for family coverage, for individuals receiving the health coverage tax credit,

with respect to each category of coverage as described in section 35(e)(1) of such Code.

(3) In each State and nationally, an analysis of the following information with respect to the health insurance coverage of individuals receiving the health coverage tax credit who are enrolled in coverage described in subparagraphs (B) through (H) of section 35(e)(1) of such Code:

(A) Deductible amounts.

(B) Other out-of-pocket cost-sharing amounts.

(C) A description of any annual or lifetime limits on coverage or any other significant limits on coverage services, or benefits.

The information required under this paragraph shall be reported with respect to each category of coverage described in such subparagraphs.

(4) In each State and nationally, the gender and average age of eligible individuals (as defined in section 35(c) of such Code) who receive the health coverage tax credit, in each category of coverage described in section 35(e)(1) of such Code, with respect to each category of eligible individuals described in such section.

(5) The steps taken by the Secretary of the Treasury to increase the participation rates in the HCTC program among eligible individuals, including outreach and enrollment activities.

(6) The cost of administering the HCTC program by function, including the cost of subcontractors, and recommendations on ways to reduce administrative costs, including recommended statutory changes.

(7) The number of States applying for and receiving national emergency grants under section 173(f) of the Workforce Investment Act of 1998 (29 U.S.C. 2918(f)), the activities funded by such grants on a State-by-State basis, and the time necessary for application approval of such grants.

SEC. 1899J. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated $80,000,000 for the period of fiscal years 2009 through 2010 to implement the amendments made by, and the provisions of, sections 1899 through 1899I of this part.

SEC. 1899K. EXTENSION OF NATIONAL EMERGENCY GRANTS.

(a) IN GENERAL.—Section 173(f) of the Workforce Investment Act of 1998 (29 U.S.C. 2918(f)), as amended by this Act, is amended—

(1) by striking paragraph (1) and inserting the following new paragraph:

"(1) USE OF FUNDS.—

"(A) HEALTH INSURANCE COVERAGE FOR ELIGIBLE INDIVIDUALS IN ORDER TO OBTAIN QUALIFIED HEALTH INSURANCE THAT HAS GUARANTEED ISSUE AND OTHER CONSUMER PROTECTIONS.—Funds made available to a State or entity under paragraph (4)(A) of subsection (a) may be used to provide an eligible individual described in paragraph (4)(C) and such individual's qualifying family members with health insurance coverage for the 3-month period that immediately precedes the first eligible coverage month (as defined in section 35(b) of the Internal Revenue Code of 1986) in which such eligible individual and such individual's qualifying family members are covered by qualified health insurance that meets the requirements described in clauses (i) through (v) of section 35(e)(2)(A) of the Internal Revenue Code of 1986 (or such longer minimum period as is necessary in order for such eligible individual and such individual's qualifying family members to be covered by qualified health insurance that meets such requirements).

"(B) ADDITIONAL USES.—Funds made available to a State or entity under paragraph (4)(A) of subsection (a) may be used by the State or entity for the following:

"(i) HEALTH INSURANCE COVERAGE.—To assist an eligible individual and such individual's qualifying family members with enrolling in health insurance coverage and qualified health insurance or paying premiums for such coverage or insurance.

"(ii) ADMINISTRATIVE EXPENSES AND START-UP EXPENSES TO ESTABLISH GROUP HEALTH PLAN COVERAGE OPTIONS FOR QUALIFIED HEALTH INSURANCE.—To pay the administrative expenses related to the enrollment of eligible individuals and such individuals' qualifying family members in health insurance coverage and qualified health insurance, including—

"(I) eligibility verification activities;

"(II) the notification of eligible individuals of available health insurance and qualified health insurance options;

"(III) processing qualified health insurance costs credit eligibility certificates provided for under section 7527 of the Internal Revenue Code of 1986;

"(IV) providing assistance to eligible individuals in enrolling in health insurance coverage and qualified health insurance;

"(V) the development or installation of necessary data management systems; and

"(VI) any other expenses determined appropriate by the Secretary, including start-up costs and on going administrative expenses, in order for the State to treat the coverage described in subparagraphs (C) through (H) of section 35(e)(1) of the Internal Revenue Code of 1986 as qualified health insurance under that section.

"(iii) OUTREACH.—To pay for outreach to eligible individuals to inform such individuals of available health insurance and qualified health insurance options, including outreach consisting of notice to eligible individuals of such options made available after the date of enactment of this clause and direct assistance to help potentially eligible individuals and such individual's qualifying family members qualify and remain eligible for the credit established under section 35 of the Internal Revenue Code of 1986 and advance payment of such credit under section 7527 of such Code.

"(iv) BRIDGE FUNDING.—To assist potentially eligible individuals to purchase qualified health insurance coverage prior to issuance of a qualified health insurance costs credit eligibility certificate under section 7527 of the Internal Revenue Code of 1986 and commencement of advance payment, and receipt of expedited payment, under subsections (a) and (e), respectively, of that section.

"(C) RULE OF CONSTRUCTION.—The inclusion of a permitted use under this paragraph shall not be construed

as prohibiting a similar use of funds permitted under subsection (g).”; and

(2) by striking paragraph (2) and inserting the following new paragraph:

“(2) QUALIFIED HEALTH INSURANCE.—For purposes of this subsection and subsection (g), the term ‘qualified health insurance’ has the meaning given that term in section 35(e) of the Internal Revenue Code of 1986.”.

(b) FUNDING.—Section 174(c)(1) of the Workforce Investment Act of 1998 (29 U.S.C. 2919(c)(1)) is amended—

(1) in the paragraph heading, by striking “AUTHORIZATION AND APPROPRIATION FOR FISCAL YEAR 2002” and inserting “APPROPRIATIONS”; and

(2) by striking subparagraph (A) and inserting the following new subparagraph:

“(A) to carry out subsection (a)(4)(A) of section 173—

“(i) $10,000,000 for fiscal year 2002; and

“(ii) $150,000,000 for the period of fiscal years 2009 through 2010; and”.

SEC. 1899L. GAO STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study regarding the health insurance tax credit allowed under section 35 of the Internal Revenue Code of 1986.

(b) REPORT.—Not later than March 1, 2010, the Comptroller General shall submit a report to Congress regarding the results of the study conducted under subsection (a). Such report shall include an analysis of—

(1) the administrative costs—

(A) of the Federal Government with respect to such credit and the advance payment of such credit under section 7527 of such Code, and

(B) of providers of qualified health insurance with respect to providing such insurance to eligible individuals and their qualifying family members,

(2) the health status and relative risk status of eligible individuals and qualifying family members covered under such insurance,

(3) participation in such credit and the advance payment of such credit by eligible individuals and their qualifying family members, including the reasons why such individuals did or did not participate and the effect of the amendments made by this part on such participation, and

(4) the extent to which eligible individuals and their qualifying family members—

(A) obtained health insurance other than qualifying health insurance, or

(B) went without health insurance coverage.

(c) ACCESS TO RECORDS.—For purposes of conducting the study required under this section, the Comptroller General and any of his duly authorized representatives shall have access to, and the right to examine and copy, all documents, records, and other recorded information—

(1) within the possession or control of providers of qualified health insurance, and

(2) determined by the Comptroller General (or any such representative) to be relevant to the study.

The Comptroller General shall not disclose the identity of any provider of qualified health insurance or any eligible individual in making any information obtained under this section available to the public.

(d) DEFINITIONS.—Any term which is defined in section 35 of the Internal Revenue Code of 1986 shall have the same meaning when used in this section.

Assistance for Unemployed Workers and Struggling Families Act.

TITLE II—ASSISTANCE FOR UNEMPLOYED WORKERS AND STRUGGLING FAMILIES

SEC. 2000. SHORT TITLE; TABLE OF CONTENTS OF TITLE.'

26 USC 1 note.

(a) SHORT TITLE.—This title may be cited as the "Assistance for Unemployed Workers and Struggling Families Act".

(b) TABLE OF CONTENTS OF TITLE.—The table of contents of this title is as follows:

TITLE II—ASSISTANCE FOR UNEMPLOYED WORKERS AND STRUGGLING FAMILIES

Sec. 2000. Short title; table of contents of title.

Subtitle A—Unemployment Insurance

Sec. 2001. Extension of emergency unemployment compensation program.
Sec. 2002. Increase in unemployment compensation benefits.
Sec. 2003. Special transfers for unemployment compensation modernization.
Sec. 2004. Temporary assistance for states with advances.
Sec. 2005. Full Federal funding of extended unemployment compensation for a limited period.
Sec. 2006. Temporary increase in extended unemployment benefits under the Railroad Unemployment Insurance Act.

Subtitle B—Assistance for Vulnerable Individuals

Sec. 2101. Emergency fund for TANF program.
Sec. 2102. Extension of TANF supplemental grants.
Sec. 2103. Clarification of authority of States to use TANF funds carried over from prior years to provide TANF benefits and services.
Sec. 2104. Temporary resumption of prior child support law.

Subtitle C—Economic Recovery Payments to Certain Individuals

Sec. 2201. Economic recovery payment to recipients of social security, supplemental security income, railroad retirement benefits, and veterans disability compensation or pension benefits.
Sec. 2202. Special credit for certain government retirees.

Subtitle A—Unemployment Insurance

SEC. 2001. EXTENSION OF EMERGENCY UNEMPLOYMENT COMPENSATION PROGRAM.

(a) IN GENERAL.—Section 4007 of the Supplemental Appropriations Act, 2008 (Public Law 110–252; 26 U.S.C. 3304 note), as amended by section 4 of the Unemployment Compensation Extension Act of 2008 (Public Law 110–449; 122 Stat. 5015), is amended—

(1) by striking "March 31, 2009" each place it appears and inserting "December 31, 2009";

(2) in the heading for subsection (b)(2), by striking "MARCH 31, 2009" and inserting "DECEMBER 31, 2009"; and

(3) in subsection (b)(3), by striking "August 27, 2009" and inserting "May 31, 2010".

(b) FINANCING PROVISIONS.—Section 4004 of such Act is amended by adding at the end the following: 26 USC 3304 note.

"(e) TRANSFER OF FUNDS.—Notwithstanding any other provision of law, the Secretary of the Treasury shall transfer from the general fund of the Treasury (from funds not otherwise appropriated)—

"(1) to the extended unemployment compensation account (as established by section 905 of the Social Security Act) such sums as the Secretary of Labor estimates to be necessary to make payments to States under this title by reason of the amendments made by section 2001(a) of the Assistance for Unemployed Workers and Struggling Families Act; and

"(2) to the employment security administration account (as established by section 901 of the Social Security Act) such sums as the Secretary of Labor estimates to be necessary for purposes of assisting States in meeting administrative costs by reason of the amendments referred to in paragraph (1).

There are appropriated from the general fund of the Treasury, without fiscal year limitation, the sums referred to in the preceding sentence and such sums shall not be required to be repaid.".

SEC. 2002. INCREASE IN UNEMPLOYMENT COMPENSATION BENEFITS. 26 USC 3304 note.

(a) FEDERAL-STATE AGREEMENTS.—Any State which desires to do so may enter into and participate in an agreement under this section with the Secretary of Labor (hereinafter in this section referred to as the "Secretary"). Any State which is a party to an agreement under this section may, upon providing 30 days' written notice to the Secretary, terminate such agreement. Notification.

(b) PROVISIONS OF AGREEMENT.—

(1) ADDITIONAL COMPENSATION.—Any agreement under this section shall provide that the State agency of the State will make payments of regular compensation to individuals in amounts and to the extent that they would be determined if the State law of the State were applied, with respect to any week for which the individual is (disregarding this section) otherwise entitled under the State law to receive regular compensation, as if such State law had been modified in a manner such that the amount of regular compensation (including dependents' allowances) payable for any week shall be equal to the amount determined under the State law (before the application of this paragraph) plus an additional $25.

(2) ALLOWABLE METHODS OF PAYMENT.—Any additional compensation provided for in accordance with paragraph (1) shall be payable either—

(A) as an amount which is paid at the same time and in the same manner as any regular compensation otherwise payable for the week involved; or

(B) at the option of the State, by payments which are made separately from, but on the same weekly basis as, any regular compensation otherwise payable.

(c) NONREDUCTION RULE.—An agreement under this section shall not apply (or shall cease to apply) with respect to a State upon a determination by the Secretary that the method governing the computation of regular compensation under the State law of that State has been modified in a manner such that—

(1) the average weekly benefit amount of regular compensation which will be payable during the period of the agreement (determined disregarding any additional amounts attributable

to the modification described in subsection (b)(1)) will be less than

(2) the average weekly benefit amount of regular compensation which would otherwise have been payable during such period under the State law, as in effect on December 31, 2008.

(d) PAYMENTS TO STATES.—

(1) IN GENERAL.—

(A) FULL REIMBURSEMENT.—There shall be paid to each State which has entered into an agreement under this section an amount equal to 100 percent of—

(i) the total amount of additional compensation (as described in subsection (b)(1)) paid to individuals by the State pursuant to such agreement; and

(ii) any additional administrative expenses incurred by the State by reason of such agreement (as determined by the Secretary).

(B) TERMS OF PAYMENTS.—Sums payable to any State by reason of such State's having an agreement under this section shall be payable, either in advance or by way of reimbursement (as determined by the Secretary), in such amounts as the Secretary estimates the State will be entitled to receive under this section for each calendar month, reduced or increased, as the case may be, by any amount by which the Secretary finds that his estimates for any prior calendar month were greater or less than the amounts which should have been paid to the State. Such estimates may be made on the basis of such statistical, sampling, or other method as may be agreed upon by the Secretary and the State agency of the State involved.

(2) CERTIFICATIONS.—The Secretary shall from time to time certify to the Secretary of the Treasury for payment to each State the sums payable to such State under this section.

(3) APPROPRIATION.—There are appropriated from the general fund of the Treasury, without fiscal year limitation, such sums as may be necessary for purposes of this subsection.

(e) APPLICABILITY.—

Time period.

(1) IN GENERAL.—An agreement entered into under this section shall apply to weeks of unemployment—

(A) beginning after the date on which such agreement is entered into; and

(B) ending before January 1, 2010.

(2) TRANSITION RULE FOR INDIVIDUALS REMAINING ENTITLED TO REGULAR COMPENSATION AS OF JANUARY 1, 2010.—In the case of any individual who, as of the date specified in paragraph (1)(B), has not yet exhausted all rights to regular compensation under the State law of a State with respect to a benefit year that began before such date, additional compensation (as described in subsection (b)(1)) shall continue to be payable to such individual for any week beginning on or after such date for which the individual is otherwise eligible for regular compensation with respect to such benefit year.

(3) TERMINATION.—Notwithstanding any other provision of this subsection, no additional compensation (as described in subsection (b)(1)) shall be payable for any week beginning after June 30, 2010.

Applicability.

(f) FRAUD AND OVERPAYMENTS.—The provisions of section 4005 of the Supplemental Appropriations Act, 2008 (Public Law 110–

252; 122 Stat. 2356) shall apply with respect to additional compensation (as described in subsection (b)(1)) to the same extent and in the same manner as in the case of emergency unemployment compensation.

(g) APPLICATION TO OTHER UNEMPLOYMENT BENEFITS.—

(1) IN GENERAL.—Each agreement under this section shall include provisions to provide that the purposes of the preceding provisions of this section shall be applied with respect to unemployment benefits described in subsection (i)(3) to the same extent and in the same manner as if those benefits were regular compensation.

(2) ELIGIBILITY AND TERMINATION RULES.—Additional compensation (as described in subsection (b)(1))—

(A) shall not be payable, pursuant to this subsection, with respect to any unemployment benefits described in subsection (i)(3) for any week beginning on or after the date specified in subsection (e)(1)(B), except in the case of an individual who was eligible to receive additional compensation (as so described) in connection with any regular compensation or any unemployment benefits described in subsection (i)(3) for any period of unemployment ending before such date; and

(B) shall in no event be payable for any week beginning after the date specified in subsection (e)(3).

(h) DISREGARD OF ADDITIONAL COMPENSATION FOR PURPOSES OF MEDICAID AND SCHIP.—The monthly equivalent of any additional compensation paid under this section shall be disregarded in considering the amount of income of an individual for any purposes under title XIX and title XXI of the Social Security Act.

(i) DEFINITIONS.—For purposes of this section—

(1) the terms "compensation", "regular compensation", "benefit year", "State", "State agency", "State law", and "week" have the respective meanings given such terms under section 205 of the Federal-State Extended Unemployment Compensation Act of 1970 (26 U.S.C. 3304 note);

(2) the term "emergency unemployment compensation" means emergency unemployment compensation under title IV of the Supplemental Appropriations Act, 2008 (Public Law 110–252; 122 Stat. 2353); and

(3) any reference to unemployment benefits described in this paragraph shall be considered to refer to—

(A) extended compensation (as defined by section 205 of the Federal-State Extended Unemployment Compensation Act of 1970); and

(B) unemployment compensation (as defined by section 85(b) of the Internal Revenue Code of 1986) provided under any program administered by a State under an agreement with the Secretary.

SEC. 2003. SPECIAL TRANSFERS FOR UNEMPLOYMENT COMPENSATION MODERNIZATION.

(a) IN GENERAL.—Section 903 of the Social Security Act (42 U.S.C. 1103) is amended by adding at the end the following:

"Special Transfers in Fiscal Years 2009, 2010, and 2011 for Modernization

"(f)(1)(A) In addition to any other amounts, the Secretary of Labor shall provide for the making of unemployment compensation modernization incentive payments (hereinafter 'incentive payments') to the accounts of the States in the Unemployment Trust Fund, by transfer from amounts reserved for that purpose in the Federal unemployment account, in accordance with succeeding provisions of this subsection.

"(B) The maximum incentive payment allowable under this subsection with respect to any State shall, as determined by the Secretary of Labor, be equal to the amount obtained by multiplying $7,000,000,000 by the same ratio as would apply under subsection (a)(2)(B) for purposes of determining such State's share of any excess amount (as described in subsection (a)(1)) that would have been subject to transfer to State accounts, as of October 1, 2008, under the provisions of subsection (a).

"(C) Of the maximum incentive payment determined under subparagraph (B) with respect to a State—

"(i) one-third shall be transferred to the account of such State upon a certification under paragraph (4)(B) that the State law of such State meets the requirements of paragraph (2); and

"(ii) the remainder shall be transferred to the account of such State upon a certification under paragraph (4)(B) that the State law of such State meets the requirements of paragraph (3).

"(2) The State law of a State meets the requirements of this paragraph if such State law—

"(A) uses a base period that includes the most recently completed calendar quarter before the start of the benefit year for purposes of determining eligibility for unemployment compensation; or

"(B) provides that, in the case of an individual who would not otherwise be eligible for unemployment compensation under the State law because of the use of a base period that does not include the most recently completed calendar quarter before the start of the benefit year, eligibility shall be determined using a base period that includes such calendar quarter.

"(3) The State law of a State meets the requirements of this paragraph if such State law includes provisions to carry out at least 2 of the following subparagraphs:

"(A) An individual shall not be denied regular unemployment compensation under any State law provisions relating to availability for work, active search for work, or refusal to accept work, solely because such individual is seeking only part-time work (as defined by the Secretary of Labor), except that the State law provisions carrying out this subparagraph may exclude an individual if a majority of the weeks of work in such individual's base period do not include part-time work (as so defined).

"(B) An individual shall not be disqualified from regular unemployment compensation for separating from employment if that separation is for any compelling family reason. For purposes of this subparagraph, the term 'compelling family reason' means the following:

"(i) Domestic violence, verified by such reasonable and confidential documentation as the State law may require, which causes the individual reasonably to believe that such individual's continued employment would jeopardize the safety of the individual or of any member of the individual's immediate family (as defined by the Secretary of Labor).

"(ii) The illness or disability of a member of the individual's immediate family (as those terms are defined by the Secretary of Labor).

"(iii) The need for the individual to accompany such individual's spouse—

"(I) to a place from which it is impractical for such individual to commute; and

"(II) due to a change in location of the spouse's employment.

"(C)(i) Weekly unemployment compensation is payable under this subparagraph to any individual who is unemployed (as determined under the State unemployment compensation law), has exhausted all rights to regular unemployment compensation under the State law, and is enrolled and making satisfactory progress in a State-approved training program or in a job training program authorized under the Workforce Investment Act of 1998, except that such compensation is not required to be paid to an individual who is receiving similar stipends or other training allowances for non-training costs.

"(ii) Each State-approved training program or job training program referred to in clause (i) shall prepare individuals who have been separated from a declining occupation, or who have been involuntarily and indefinitely separated from employment as a result of a permanent reduction of operations at the individual's place of employment, for entry into a high-demand occupation.

"(iii) The amount of unemployment compensation payable under this subparagraph to an individual for a week of unemployment shall be equal to—

"(I) the individual's average weekly benefit amount (including dependents' allowances) for the most recent benefit year, less

"(II) any deductible income, as determined under State law.

The total amount of unemployment compensation payable under this subparagraph to any individual shall be equal to at least 26 times the individual's average weekly benefit amount (including dependents' allowances) for the most recent benefit year.

"(D) Dependents' allowances are provided, in the case of any individual who is entitled to receive regular unemployment compensation and who has any dependents (as defined by State law), in an amount equal to at least $15 per dependent per week, subject to any aggregate limitation on such allowances which the State law may establish (but which aggregate limitation on the total allowance for dependents paid to an individual may not be less than $50 for each week of unemployment or 50 percent of the individual's weekly benefit amount for the benefit year, whichever is less), except that a State law may provide for a reasonable reduction in the amount of any such allowance for a week of less than total unemployment.

Application.
Deadline.

"(4)(A) Any State seeking an incentive payment under this subsection shall submit an application therefor at such time, in such manner, and complete with such information as the Secretary of Labor may within 60 days after the date of the enactment of this subsection prescribe (whether by regulation or otherwise), including information relating to compliance with the requirements of paragraph (2) or (3), as well as how the State intends to use the incentive payment to improve or strengthen the State's unemployment compensation program. The Secretary of Labor shall, within 30 days after receiving a complete application, notify the State agency of the State of the Secretary's findings with respect to the requirements of paragraph (2) or (3) (or both).

Deadline.
Notification.

Certifications.

"(B)(i) If the Secretary of Labor finds that the State law provisions (disregarding any State law provisions which are not then currently in effect as permanent law or which are subject to discontinuation) meet the requirements of paragraph (2) or (3), as the case may be, the Secretary of Labor shall thereupon make a certification to that effect to the Secretary of the Treasury, together with a certification as to the amount of the incentive payment to be transferred to the State account pursuant to that finding. The Secretary of the Treasury shall make the appropriate transfer within 7 days after receiving such certification.

Deadline.

Effective date.

"(ii) For purposes of clause (i), State law provisions which are to take effect within 12 months after the date of their certification under this subparagraph shall be considered to be in effect as of the date of such certification.

"(C)(i) No certification of compliance with the requirements of paragraph (2) or (3) may be made with respect to any State whose State law is not otherwise eligible for certification under section 303 or approvable under section 3304 of the Federal Unemployment Tax Act.

"(ii) No certification of compliance with the requirements of paragraph (3) may be made with respect to any State whose State law is not in compliance with the requirements of paragraph (2).

Deadline.

"(iii) No application under subparagraph (A) may be considered if submitted before the date of the enactment of this subsection or after the latest date necessary (as specified by the Secretary of Labor) to ensure that all incentive payments under this subsection are made before October 1, 2011.

"(5)(A) Except as provided in subparagraph (B), any amount transferred to the account of a State under this subsection may be used by such State only in the payment of cash benefits to individuals with respect to their unemployment (including for dependents' allowances and for unemployment compensation under paragraph (3)(C)), exclusive of expenses of administration.

"(B) A State may, subject to the same conditions as set forth in subsection (c)(2) (excluding subparagraph (B) thereof, and deeming the reference to 'subsections (a) and (b)' in subparagraph (D) thereof to include this subsection), use any amount transferred to the account of such State under this subsection for the administration of its unemployment compensation law and public employment offices.

"(6) Out of any money in the Federal unemployment account not otherwise appropriated, the Secretary of the Treasury shall reserve $7,000,000,000 for incentive payments under this subsection. Any amount so reserved shall not be taken into account for purposes of any determination under section 902, 910, or 1203

of the amount in the Federal unemployment account as of any given time. Any amount so reserved for which the Secretary of the Treasury has not received a certification under paragraph (4)(B) by the deadline described in paragraph (4)(C)(iii) shall, upon the close of fiscal year 2011, become unrestricted as to use as part of the Federal unemployment account.

"(7) For purposes of this subsection, the terms 'benefit year', 'base period', and 'week' have the respective meanings given such terms under section 205 of the Federal-State Extended Unemployment Compensation Act of 1970 (26 U.S.C. 3304 note).

"Special Transfer in Fiscal Year 2009 for Administration

"(g)(1) In addition to any other amounts, the Secretary of the Treasury shall transfer from the employment security administration account to the account of each State in the Unemployment Trust Fund, within 30 days after the date of the enactment of this subsection, the amount determined with respect to such State under paragraph (2). Deadline.

"(2) The amount to be transferred under this subsection to a State account shall (as determined by the Secretary of Labor and certified by such Secretary to the Secretary of the Treasury) be equal to the amount obtained by multiplying $500,000,000 by the same ratio as determined under subsection (f)(1)(B) with respect to such State.

"(3) Any amount transferred to the account of a State as a result of the enactment of this subsection may be used by the State agency of such State only in the payment of expenses incurred by it for—

"(A) the administration of the provisions of its State law carrying out the purposes of subsection (f)(2) or any subparagraph of subsection (f)(3);

"(B) improved outreach to individuals who might be eligible for regular unemployment compensation by virtue of any provisions of the State law which are described in subparagraph (A);

"(C) the improvement of unemployment benefit and unemployment tax operations, including responding to increased demand for unemployment compensation; and

"(D) staff-assisted reemployment services for unemployment compensation claimants.".

(b) REGULATIONS.—The Secretary of Labor may prescribe any regulations, operating instructions, or other guidance necessary to carry out the amendment made by subsection (a). 42 USC 1103 note.

SEC. 2004. TEMPORARY ASSISTANCE FOR STATES WITH ADVANCES.

Section 1202(b) of the Social Security Act (42 U.S.C. 1322(b)) is amended by adding at the end the following new paragraph:

"(10)(A) With respect to the period beginning on the date of enactment of this paragraph and ending on December 31, 2010— Time period.

"(i) any interest payment otherwise due from a State under this subsection during such period shall be deemed to have been made by the State; and

"(ii) no interest shall accrue during such period on any advance or advances made under section 1201 to a State.

"(B) The provisions of subparagraph (A) shall have no effect on the requirement for interest payments under this subsection

after the period described in such subparagraph or on the accrual of interest under this subsection after such period.".

26 USC 3304 note.

SEC. 2005. FULL FEDERAL FUNDING OF EXTENDED UNEMPLOYMENT COMPENSATION FOR A LIMITED PERIOD.

Applicability.

(a) IN GENERAL.—In the case of sharable extended compensation and sharable regular compensation paid for weeks of unemployment beginning after the date of the enactment of this section and before January 1, 2010, section 204(a)(1) of the Federal-State Extended Unemployment Compensation Act of 1970 (26 U.S.C. 3304 note) shall be applied by substituting "100 percent of" for "one-half of".

(b) SPECIAL RULE.—At the option of a State, for any weeks of unemployment beginning after the date of the enactment of this section and before January 1, 2010, an individual's eligibility period (as described in section 203(c) of the Federal-State Extended Unemployment Compensation Act of 1970) shall, for purposes of any determination of eligibility for extended compensation under the State law of such State, be considered to include any week which begins—

(1) after the date as of which such individual exhausts all rights to emergency unemployment compensation; and

(2) during an extended benefit period that began on or before the date described in paragraph (1).

Applicability.

(c) LIMITED EXTENSION.—In the case of an individual who receives extended compensation with respect to 1 or more weeks of unemployment beginning after the date of the enactment of this Act and before January 1, 2010, the provisions of subsections (a) and (b) shall, at the option of a State, be applied by substituting "ending before June 1, 2010" for "before January 1, 2010".

(d) EXTENSION OF TEMPORARY FEDERAL MATCHING FOR THE FIRST WEEK OF EXTENDED BENEFITS FOR STATES WITH NO WAITING WEEK.—

26 USC 3304 note.

(1) IN GENERAL.—Section 5 of the Unemployment Compensation Extension Act of 2008 (Public Law 110–449) is amended by striking "December 8, 2009" and inserting "May 30, 2010".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in the enactment of the Unemployment Compensation Extension Act of 2008 (Public Law 110–449).

(e) DEFINITIONS.—For purposes of this section—

(1) the terms "sharable extended compensation" and "sharable regular compensation" have the respective meanings given such terms under section 204 of the Federal-State Extended Unemployment Compensation Act of 1970;

(2) the terms "extended compensation", "State", "State law", and "week" have the respective meanings given such terms under section 205 of the Federal-State Extended Unemployment Compensation Act of 1970;

(3) the term "emergency unemployment compensation" means benefits payable to individuals under title IV of the Supplemental Appropriations Act, 2008 with respect to their unemployment; and

(4) the term "extended benefit period" means an extended benefit period as determined in accordance with applicable

provisions of the Federal-State Extended Unemployment Compensation Act of 1970.

(f) REGULATIONS.—The Secretary of Labor may prescribe any operating instructions or regulations necessary to carry out this section.

SEC. 2006. TEMPORARY INCREASE IN EXTENDED UNEMPLOYMENT BENEFITS UNDER THE RAILROAD UNEMPLOYMENT INSURANCE ACT.

(a) IN GENERAL.—Section 2(c)(2) of the Railroad Unemployment Insurance Act (45 U.S.C. 352(c)(2)) is amended by adding at the end the following:

Applicability.

"(D) TEMPORARY INCREASE IN EXTENDED UNEMPLOYMENT BENEFITS.—

"(i) EMPLOYEES WITH 10 OR MORE YEARS OF SERVICE.—Subject to clause (iii), in the case of an employee who has 10 or more years of service (as so defined), with respect to extended unemployment benefits—

"(I) subparagraph (A) shall be applied by substituting '130 days of unemployment' for '65 days of unemployment'; and

"(II) subparagraph (B) shall be applied by inserting '(or, in the case of unemployment benefits, 13 consecutive 14-day periods)' after '7 consecutive 14-day periods'.

"(ii) EMPLOYEES WITH LESS THAN 10 YEARS OF SERVICE.—Subject to clause (iii), in the case of an employee who has less than 10 years of service (as so defined), with respect to extended unemployment benefits, this paragraph shall apply to such an employee in the same manner as this paragraph would apply to an employee described in clause (i) if such clause had not been enacted.

Time period.
Deadline.

"(iii) APPLICATION.—The provisions of clauses (i) and (ii) shall apply to an employee who received normal benefits for days of unemployment under this Act during the period beginning July 1, 2008, and ending on June 30, 2009, except that no extended benefit period under this paragraph shall begin after December 31, 2009. Notwithstanding the preceding sentence, no benefits shall be payable under this subparagraph and clauses (i) and (ii) shall no longer be applicable upon the exhaustion of the funds appropriated under clause (iv) for payment of benefits under this subparagraph.

"(iv) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated $20,000,000 to cover the cost of additional extended unemployment benefits provided under this subparagraph, to remain available until expended.".

(b) FUNDING FOR ADMINISTRATION.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Railroad Retirement Board $80,000 to cover the administrative expenses associated with the payment of additional extended unemployment benefits under section 2(c)(2)(D) of the Railroad

Unemployment Insurance Act, as added by subsection (a), to remain available until expended.

Subtitle B—Assistance for Vulnerable Individuals

SEC. 2101. EMERGENCY FUND FOR TANF PROGRAM.

(a) TEMPORARY FUND.—

(1) IN GENERAL.—Section 403 of the Social Security Act (42 U.S.C. 603) is amended by adding at the end the following:

"(c) EMERGENCY FUND.—

"(1) ESTABLISHMENT.—There is established in the Treasury of the United States a fund which shall be known as the 'Emergency Contingency Fund for State Temporary Assistance for Needy Families Programs' (in this subsection referred to as the 'Emergency Fund').

"(2) DEPOSITS INTO FUND.—

"(A) IN GENERAL.—Out of any money in the Treasury of the United States not otherwise appropriated, there are appropriated for fiscal year 2009, $5,000,000,000 for payment to the Emergency Fund.

"(B) AVAILABILITY AND USE OF FUNDS.—The amounts appropriated to the Emergency Fund under subparagraph (A) shall remain available through fiscal year 2010 and shall be used to make grants to States in each of fiscal years 2009 and 2010 in accordance with the requirements of paragraph (3).

"(C) LIMITATION.—In no case may the Secretary make a grant from the Emergency Fund for a fiscal year after fiscal year 2010.

"(3) GRANTS.—

"(A) GRANT RELATED TO CASELOAD INCREASES.—

"(i) IN GENERAL.—For each calendar quarter in fiscal year 2009 or 2010, the Secretary shall make a grant from the Emergency Fund to each State that—

"(I) requests a grant under this subparagraph for the quarter; and

"(II) meets the requirement of clause (ii) for the quarter.

"(ii) CASELOAD INCREASE REQUIREMENT.—A State meets the requirement of this clause for a quarter if the average monthly assistance caseload of the State for the quarter exceeds the average monthly assistance caseload of the State for the corresponding quarter in the emergency fund base year of the State.

"(iii) AMOUNT OF GRANT.—Subject to paragraph (5), the amount of the grant to be made to a State under this subparagraph for a quarter shall be an amount equal to 80 percent of the amount (if any) by which the total expenditures of the State for basic assistance (as defined by the Secretary) in the quarter, whether under the State program funded under this part or as qualified State expenditures, exceeds the total expenditures of the State for such assistance for the corresponding quarter in the emergency fund base year of the State.

"(B) GRANT RELATED TO INCREASED EXPENDITURES FOR NON-RECURRENT SHORT TERM BENEFITS.—

"(i) IN GENERAL.—For each calendar quarter in fiscal year 2009 or 2010, the Secretary shall make a grant from the Emergency Fund to each State that—

"(I) requests a grant under this subparagraph for the quarter; and

"(II) meets the requirement of clause (ii) for the quarter.

"(ii) NON-RECURRENT SHORT TERM EXPENDITURE REQUIREMENT.—A State meets the requirement of this clause for a quarter if the total expenditures of the State for non-recurrent short term benefits in the quarter, whether under the State program funded under this part or as qualified State expenditures, exceeds the total expenditures of the State for non-recurrent short term benefits in the corresponding quarter in the emergency fund base year of the State.

"(iii) AMOUNT OF GRANT.—Subject to paragraph (5), the amount of the grant to be made to a State under this subparagraph for a quarter shall be an amount equal to 80 percent of the excess described in clause (ii).

"(C) GRANT RELATED TO INCREASED EXPENDITURES FOR SUBSIDIZED EMPLOYMENT.—

"(i) IN GENERAL.—For each calendar quarter in fiscal year 2009 or 2010, the Secretary shall make a grant from the Emergency Fund to each State that—

"(I) requests a grant under this subparagraph for the quarter; and

"(II) meets the requirement of clause (ii) for the quarter.

"(ii) SUBSIDIZED EMPLOYMENT EXPENDITURE REQUIREMENT.—A State meets the requirement of this clause for a quarter if the total expenditures of the State for subsidized employment in the quarter, whether under the State program funded under this part or as qualified State expenditures, exceeds the total such expenditures of the State in the corresponding quarter in the emergency fund base year of the State.

"(iii) AMOUNT OF GRANT.—Subject to paragraph (5), the amount of the grant to be made to a State under this subparagraph for a quarter shall be an amount equal to 80 percent of the excess described in clause (ii).

"(4) AUTHORITY TO MAKE NECESSARY ADJUSTMENTS TO DATA AND COLLECT NEEDED DATA.—In determining the size of the caseload of a State and the expenditures of a State for basic assistance, non-recurrent short-term benefits, and subsidized employment, during any period for which the State requests funds under this subsection, and during the emergency fund base year of the State, the Secretary may make appropriate adjustments to the data, on a State-by-State basis, to ensure that the data are comparable with respect to the groups of families served and the types of aid provided. The Secretary may develop a mechanism for collecting expenditure data,

including procedures which allow States to make reasonable estimates, and may set deadlines for making revisions to the data.

"(5) LIMITATION.—The total amount payable to a single State under subsection (b) and this subsection for fiscal years 2009 and 2010 combined shall not exceed 50 percent of the annual State family assistance grant.

"(6) LIMITATIONS ON USE OF FUNDS.—A State to which an amount is paid under this subsection may use the amount only as authorized by section 404.

"(7) TIMING OF IMPLEMENTATION.—The Secretary shall implement this subsection as quickly as reasonably possible, pursuant to appropriate guidance to States.

"(8) APPLICATION TO INDIAN TRIBES.—This subsection shall apply to an Indian tribe with an approved tribal family assistance plan under section 412 in the same manner as this subsection applies to a State.

"(9) DEFINITIONS.—In this subsection:

"(A) AVERAGE MONTHLY ASSISTANCE CASELOAD DEFINED.—The term 'average monthly assistance caseload' means, with respect to a State and a quarter, the number of families receiving assistance during the quarter under the State program funded under this part or as qualified State expenditures, subject to adjustment under paragraph (4).

"(B) EMERGENCY FUND BASE YEAR.—

"(i) IN GENERAL.—The term 'emergency fund base year' means, with respect to a State and a category described in clause (ii), whichever of fiscal year 2007 or 2008 is the fiscal year in which the amount described by the category with respect to the State is the lesser.

"(ii) CATEGORIES DESCRIBED.—The categories described in this clause are the following:

"(I) The average monthly assistance caseload of the State.

"(II) The total expenditures of the State for non-recurrent short term benefits, whether under the State program funded under this part or as qualified State expenditures.

"(III) The total expenditures of the State for subsidized employment, whether under the State program funded under this part or as qualified State expenditures.

"(C) QUALIFIED STATE EXPENDITURES.—The term 'qualified State expenditures' has the meaning given the term in section 409(a)(7).".

Effective dates.

(2) REPEAL.—Effective October 1, 2010, subsection (c) of section 403 of the Social Security Act (42 U.S.C. 603) (as added by paragraph (1)) is repealed, except that paragraph (9) of such subsection shall remain in effect until October 1, 2011, but only with respect to section 407(b)(3)(A)(i) of such Act.

(b) TEMPORARY MODIFICATION OF CASELOAD REDUCTION CREDIT.—Section 407(b)(3)(A)(i) of such Act (42 U.S.C. 607(b)(3)(A)(i)) is amended by inserting "(or if the immediately preceding fiscal year is fiscal year 2008, 2009, or 2010, then, at State option, during the emergency fund base year of the State

with respect to the average monthly assistance caseload of the State (within the meaning of section 403(c)(9)), except that, if a State elects such option for fiscal year 2008, the emergency fund base year of the State with respect to such caseload shall be fiscal year 2007))" before "under the State".

(c) DISREGARD FROM LIMITATION ON TOTAL PAYMENTS TO TERRITORIES.—Section 1108(a)(2) of the Social Security Act (42 U.S.C. 1308(a)(2)) is amended by inserting "403(c)(3)," after "403(a)(5),".

(d) SUNSET OF OTHER TEMPORARY PROVISIONS.— Effective dates.

(1) DISREGARD FROM LIMITATION ON TOTAL PAYMENTS TO TERRITORIES.—Effective October 1, 2010, section 1108(a)(2) of the Social Security Act (42 U.S.C. 1308(a)(2)) is amended by striking "403(c)(3)," (as added by subsection (c)).

(2) CASELOAD REDUCTION CREDIT.—Effective October 1, 2011, section 407(b)(3)(A)(i) of such Act (42 U.S.C. 607(b)(3)(A)(i)) is amended by striking "(or if the immediately preceding fiscal year is fiscal year 2008, 2009, or 2010, then, at State option, during the emergency fund base year of the State with respect to the average monthly assistance caseload of the State (within the meaning of section 403(c)(9)), except that, if a State elects such option for fiscal year 2008, the emergency fund base year of the State with respect to such caseload shall be fiscal year 2007))" (as added by subsection (b)).

SEC. 2102. EXTENSION OF TANF SUPPLEMENTAL GRANTS.

(a) EXTENSION THROUGH FISCAL YEAR 2010.—Section 7101(a) of the Deficit Reduction Act of 2005 (Public Law 109–171; 120 Stat. 135), as amended by section 301(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), is amended by striking "fiscal year 2009" and inserting "fiscal year 2010".

(b) CONFORMING AMENDMENT.—Section 403(a)(3)(H)(ii) of the Social Security Act (42 U.S.C. 603(a)(3)(H)(ii)) is amended to read as follows:

"(ii) subparagraph (G) shall be applied as if 'fiscal year 2010' were substituted for 'fiscal year 2001'; and".

SEC. 2103. CLARIFICATION OF AUTHORITY OF STATES TO USE TANF FUNDS CARRIED OVER FROM PRIOR YEARS TO PROVIDE TANF BENEFITS AND SERVICES.

Section 404(e) of the Social Security Act (42 U.S.C. 604(e)) is amended to read as follows:

"(e) AUTHORITY TO CARRY OVER CERTAIN AMOUNTS FOR BENEFITS OR SERVICES OR FOR FUTURE CONTINGENCIES.—A State or tribe may use a grant made to the State or tribe under this part for any fiscal year to provide, without fiscal year limitation, any benefit or service that may be provided under the State or tribal program funded under this part.".

SEC. 2104. TEMPORARY RESUMPTION OF PRIOR CHILD SUPPORT LAW.

During the period that begins on October 1, 2008, and ends on September 30, 2010, section 455(a)(1) of the Social Security Act (42 U.S.C. 655(a)(1)) shall be applied and administered as if the phrase "from amounts paid to the State under section 458 or" does not appear in such section. Time period. Applicability. 42 USC 655 note.

Subtitle C—Economic Recovery Payments to Certain Individuals

26 USC 6428 note.

SEC. 2201. ECONOMIC RECOVERY PAYMENT TO RECIPIENTS OF SOCIAL SECURITY, SUPPLEMENTAL SECURITY INCOME, RAILROAD RETIREMENT BENEFITS, AND VETERANS DISABILITY COMPENSATION OR PENSION BENEFITS.

(a) AUTHORITY TO MAKE PAYMENTS.—

(1) ELIGIBILITY.—

(A) IN GENERAL.—Subject to paragraph (5)(B), the Secretary of the Treasury shall disburse a $250 payment to each individual who, for any month during the 3-month period ending with the month which ends prior to the month that includes the date of the enactment of this Act, is entitled to a benefit payment described in clause (i), (ii), or (iii) of subparagraph (B) or is eligible for a SSI cash benefit described in subparagraph (C).

(B) BENEFIT PAYMENT DESCRIBED.—For purposes of subparagraph (A):

(i) TITLE II BENEFIT.—A benefit payment described in this clause is a monthly insurance benefit payable (without regard to sections 202(j)(1) and 223(b) of the Social Security Act (42 U.S.C. 402(j)(1), 423(b)) under—

(I) section 202(a) of such Act (42 U.S.C. 402(a));

(II) section 202(b) of such Act (42 U.S.C. 402(b));

(III) section 202(c) of such Act (42 U.S.C. 402(c));

(IV) section 202(d)(1)(B)(ii) of such Act (42 U.S.C. 402(d)(1)(B)(ii));

(V) section 202(e) of such Act (42 U.S.C. 402(e));

(VI) section 202(f) of such Act (42 U.S.C. 402(f));

(VII) section 202(g) of such Act (42 U.S.C. 402(g));

(VIII) section 202(h) of such Act (42 U.S.C. 402(h));

(IX) section 223(a) of such Act (42 U.S.C. 423(a));

(X) section 227 of such Act (42 U.S.C. 427); or

(XI) section 228 of such Act (42 U.S.C. 428).

(ii) RAILROAD RETIREMENT BENEFIT.—A benefit payment described in this clause is a monthly annuity or pension payment payable (without regard to section 5(a)(ii) of the Railroad Retirement Act of 1974 (45 U.S.C. 231d(a)(ii))) under—

(I) section 2(a)(1) of such Act (45 U.S.C. 231a(a)(1));

(II) section 2(c) of such Act (45 U.S.C. 231a(c));

(III) section 2(d)(1)(i) of such Act (45 U.S.C. 231a(d)(1)(i));

(IV) section 2(d)(1)(ii) of such Act (45 U.S.C. 231a(d)(1)(ii));

(V) section 2(d)(1)(iii)(C) of such Act to an adult disabled child (45 U.S.C. 231a(d)(1)(iii)(C));

(VI) section 2(d)(1)(iv) of such Act (45 U.S.C. 231a(d)(1)(iv));

(VII) section 2(d)(1)(v) of such Act (45 U.S.C. 231a(d)(1)(v)); or

(VIII) section 7(b)(2) of such Act (45 U.S.C. 231f(b)(2)) with respect to any of the benefit payments described in clause (i) of this subparagraph.

(iii) VETERANS BENEFIT.—A benefit payment described in this clause is a compensation or pension payment payable under—

(I) section 1110, 1117, 1121, 1131, 1141, or 1151 of title 38, United States Code;

(II) section 1310, 1312, 1313, 1315, 1316, or 1318 of title 38, United States Code;

(III) section 1513, 1521, 1533, 1536, 1537, 1541, 1542, or 1562 of title 38, United States Code; or

(IV) section 1805, 1815, or 1821 of title 38, United States Code,

to a veteran, surviving spouse, child, or parent as described in paragraph (2), (3), (4)(A)(ii), or (5) of section 101, title 38, United States Code, who received that benefit during any month within the 3 month period ending with the month which ends prior to the month that includes the date of the enactment of this Act.

(C) SSI CASH BENEFIT DESCRIBED.—A SSI cash benefit described in this subparagraph is a cash benefit payable under section 1611 (other than under subsection (e)(1)(B) of such section) or 1619(a) of the Social Security Act (42 U.S.C. 1382, 1382h).

(2) REQUIREMENT.—A payment shall be made under paragraph (1) only to individuals who reside in 1 of the 50 States, the District of Columbia, Puerto Rico, Guam, the United States Virgin Islands, American Samoa, or the Northern Mariana Islands. For purposes of the preceding sentence, the determination of the individual's residence shall be based on the current address of record under a program specified in paragraph (1).

(3) NO DOUBLE PAYMENTS.—An individual shall be paid only 1 payment under this section, regardless of whether the individual is entitled to, or eligible for, more than 1 benefit or cash payment described in paragraph (1).

(4) LIMITATION.—A payment under this section shall not be made—

(A) in the case of an individual entitled to a benefit specified in paragraph (1)(B)(i) or paragraph (1)(B)(ii)(VIII) if, for the most recent month of such individual's entitlement in the 3-month period described in paragraph (1), such individual's benefit under such paragraph was not payable by reason of subsection (x) or (y) of section 202 the Social Security Act (42 U.S.C. 402) or section 1129A of such Act (42 U.S.C. 1320a-8a);

(B) in the case of an individual entitled to a benefit specified in paragraph (1)(B)(iii) if, for the most recent month of such individual's entitlement in the 3 month

period described in paragraph (1), such individual's benefit under such paragraph was not payable, or was reduced, by reason of section 1505, 5313, or 5313B of title 38, United States Code;

(C) in the case of an individual entitled to a benefit specified in paragraph (1)(C) if, for such most recent month, such individual's benefit under such paragraph was not payable by reason of subsection (e)(1)(A) or (e)(4) of section 1611 (42 U.S.C. 1382) or section 1129A of such Act (42 U.S.C. 1320a-8a); or

(D) in the case of any individual whose date of death occurs before the date on which the individual is certified under subsection (b) to receive a payment under this section.

(5) TIMING AND MANNER OF PAYMENTS.—

Deadline.

(A) IN GENERAL.—The Secretary of the Treasury shall commence disbursing payments under this section at the earliest practicable date but in no event later than 120 days after the date of enactment of this Act. The Secretary of the Treasury may disburse any payment electronically to an individual in such manner as if such payment was a benefit payment or cash benefit to such individual under the applicable program described in subparagraph (B) or (C) of paragraph (1).

(B) DEADLINE.—No payments shall be disbursed under this section after December 31, 2010, regardless of any determinations of entitlement to, or eligibility for, such payments made after such date.

Certification.

(b) IDENTIFICATION OF RECIPIENTS.—The Commissioner of Social Security, the Railroad Retirement Board, and the Secretary of Veterans Affairs shall certify the individuals entitled to receive payments under this section and provide the Secretary of the Treasury with the information needed to disburse such payments. A certification of an individual shall be unaffected by any subsequent determination or redetermination of the individual's entitlement to, or eligibility for, a benefit specified in subparagraph (B) or (C) of subsection (a)(1).

(c) TREATMENT OF PAYMENTS.—

Time period.

(1) PAYMENT TO BE DISREGARDED FOR PURPOSES OF ALL FEDERAL AND FEDERALLY ASSISTED PROGRAMS.—A payment under subsection (a) shall not be regarded as income and shall not be regarded as a resource for the month of receipt and the following 9 months, for purposes of determining the eligibility of the recipient (or the recipient's spouse or family) for benefits or assistance, or the amount or extent of benefits or assistance, under any Federal program or under any State or local program financed in whole or in part with Federal funds.

(2) PAYMENT NOT CONSIDERED INCOME FOR PURPOSES OF TAXATION.—A payment under subsection (a) shall not be considered as gross income for purposes of the Internal Revenue Code of 1986.

Applicability.

(3) PAYMENTS PROTECTED FROM ASSIGNMENT.—The provisions of sections 207 and 1631(d)(1) of the Social Security Act (42 U.S.C. 407, 1383(d)(1)), section 14(a) of the Railroad Retirement Act of 1974 (45 U.S.C. 231m(a)), and section 5301 of title 38, United States Code, shall apply to any payment

made under subsection (a) as if such payment was a benefit payment or cash benefit to such individual under the applicable program described in subparagraph (B) or (C) of subsection (a)(1).

(4) PAYMENTS SUBJECT TO OFFSET.—Notwithstanding paragraph (3), for purposes of section 3716 of title 31, United States Code, any payment made under this section shall not be considered a benefit payment or cash benefit made under the applicable program described in subparagraph (B) or (C) of subsection (a)(1) and all amounts paid shall be subject to offset to collect delinquent debts.

(d) PAYMENT TO REPRESENTATIVE PAYEES AND FIDUCIARIES.—

(1) IN GENERAL.—In any case in which an individual who is entitled to a payment under subsection (a) and whose benefit payment or cash benefit described in paragraph (1) of that subsection is paid to a representative payee or fiduciary, the payment under subsection (a) shall be made to the individual's representative payee or fiduciary and the entire payment shall be used only for the benefit of the individual who is entitled to the payment.

(2) APPLICABILITY.—

(A) PAYMENT ON THE BASIS OF A TITLE II OR SSI BENEFIT.—Section 1129(a)(3) of the Social Security Act (42 U.S.C. 1320a–8(a)(3)) shall apply to any payment made on the basis of an entitlement to a benefit specified in paragraph (1)(B)(i) or (1)(C) of subsection (a) in the same manner as such section applies to a payment under title II or XVI of such Act.

(B) PAYMENT ON THE BASIS OF A RAILROAD RETIREMENT BENEFIT.—Section 13 of the Railroad Retirement Act (45 U.S.C. 231l) shall apply to any payment made on the basis of an entitlement to a benefit specified in paragraph (1)(B)(ii) of subsection (a) in the same manner as such section applies to a payment under such Act.

(C) PAYMENT ON THE BASIS OF A VETERANS BENEFIT.—Sections 5502, 6106, and 6108 of title 38, United States Code, shall apply to any payment made on the basis of an entitlement to a benefit specified in paragraph (1)(B)(iii) of subsection (a) in the same manner as those sections apply to a payment under that title.

(e) APPROPRIATION.—Out of any sums in the Treasury of the United States not otherwise appropriated, the following sums are appropriated for the period of fiscal years 2009 through 2011, to remain available until expended, to carry out this section:

(1) For the Secretary of the Treasury, $131,000,000 for administrative costs incurred in carrying out this section, section 2202, section 36A of the Internal Revenue Code of 1986 (as added by this Act), and other provisions of this Act or the amendments made by this Act relating to the Internal Revenue Code of 1986.

(2) For the Commissioner of Social Security—

(A) such sums as may be necessary for payments to individuals certified by the Commissioner of Social Security as entitled to receive a payment under this section; and

(B) $90,000,000 for the Social Security Administration's Limitation on Administrative Expenses for costs incurred in carrying out this section.

(3) For the Railroad Retirement Board—

(A) such sums as may be necessary for payments to individuals certified by the Railroad Retirement Board as entitled to receive a payment under this section; and

(B) $1,400,000 to the Railroad Retirement Board's Limitation on Administration for administrative costs incurred in carrying out this section.

(4)(A) For the Secretary of Veterans Affairs—

(i) such sums as may be necessary for the Compensation and Pensions account, for payments to individuals certified by the Secretary of Veterans Affairs as entitled to receive a payment under this section; and

(ii) $100,000 for the Information Systems Technology account and $7,100,000 for the General Operating Expenses account for administrative costs incurred in carrying out this section.

(B) The Department of Veterans Affairs Compensation and Pensions account shall hereinafter be available for payments authorized under subsection (a)(1)(A) to individuals entitled to a benefit payment described in subsection (a)(1)(B)(iii).

26 USC 6428 note.

SEC. 2202. SPECIAL CREDIT FOR CERTAIN GOVERNMENT RETIREES.

(a) IN GENERAL.—In the case of an eligible individual, there shall be allowed as a credit against the tax imposed by subtitle A of the Internal Revenue Code of 1986 for the first taxable year beginning in 2009 an amount equal $250 ($500 in the case of a joint return where both spouses are eligible individuals).

(b) ELIGIBLE INDIVIDUAL.—For purposes of this section—

(1) IN GENERAL.—The term "eligible individual" means any individual—

(A) who receives during the first taxable year beginning in 2009 any amount as a pension or annuity for service performed in the employ of the United States or any State, or any instrumentality thereof, which is not considered employment for purposes of chapter 21 of the Internal Revenue Code of 1986, and

(B) who does not receive a payment under section 2201 during such taxable year.

(2) IDENTIFICATION NUMBER REQUIREMENT.—Such term shall not include any individual who does not include on the return of tax for the taxable year—

(A) such individual's social security account number, and

(B) in the case of a joint return, the social security account number of one of the taxpayers on such return.

For purposes of the preceding sentence, the social security account number shall not include a TIN (as defined in section 7701(a)(41) of the Internal Revenue Code of 1986) issued by the Internal Revenue Service. Any omission of a correct social security account number required under this subparagraph shall be treated as a mathematical or clerical error for purposes of applying section 6213(g)(2) of such Code to such omission.

(c) TREATMENT OF CREDIT.—

(1) REFUNDABLE CREDIT.—

(A) IN GENERAL.—The credit allowed by subsection (a) shall be treated as allowed by subpart C of part IV of

subchapter A of chapter 1 of the Internal Revenue Code of 1986.

(B) APPROPRIATIONS.—For purposes of section 1324(b)(2) of title 31, United States Code, the credit allowed by subsection (a) shall be treated in the same manner a refund from the credit allowed under section 36A of the Internal Revenue Code of 1986 (as added by this Act).

(2) DEFICIENCY RULES.—For purposes of section 6211(b)(4)(A) of the Internal Revenue Code of 1986, the credit allowable by subsection (a) shall be treated in the same manner as the credit allowable under section 36A of the Internal Revenue Code of 1986 (as added by this Act).

(d) REFUNDS DISREGARDED IN THE ADMINISTRATION OF FEDERAL PROGRAMS AND FEDERALLY ASSISTED PROGRAMS.—Any credit or refund allowed or made to any individual by reason of this section shall not be taken into account as income and shall not be taken into account as resources for the month of receipt and the following 2 months, for purposes of determining the eligibility of such individual or any other individual for benefits or assistance, or the amount or extent of benefits or assistance, under any Federal program or under any State or local program financed in whole or in part with Federal funds. Time period.

TITLE III—PREMIUM ASSISTANCE FOR COBRA BENEFITS

SEC. 3000. TABLE OF CONTENTS.

The table of contents of this title is as follows:

TITLE III—PREMIUM ASSISTANCE FOR COBRA BENEFITS

Sec. 3000. Table of contents.
Sec. 3001. Premium assistance for COBRA benefits.

SEC. 3001. PREMIUM ASSISTANCE FOR COBRA BENEFITS. 26 USC 6432 note.

(a) PREMIUM ASSISTANCE FOR COBRA CONTINUATION COVERAGE FOR INDIVIDUALS AND THEIR FAMILIES.—

(1) PROVISION OF PREMIUM ASSISTANCE.—

(A) REDUCTION OF PREMIUMS PAYABLE.—In the case of any premium for a period of coverage beginning on or after the date of the enactment of this Act for COBRA continuation coverage with respect to any assistance eligible individual, such individual shall be treated for purposes of any COBRA continuation provision as having paid the amount of such premium if such individual pays (or a person other than such individual's employer pays on behalf of such individual) 35 percent of the amount of such premium (as determined without regard to this subsection).

(B) PLAN ENROLLMENT OPTION.—

(i) IN GENERAL.—Notwithstanding the COBRA continuation provisions, an assistance eligible individual may, not later than 90 days after the date of notice of the plan enrollment option described in this subparagraph, elect to enroll in coverage under a plan offered by the employer involved, or the employee organization involved (including, for this purpose, a joint board of trustees of a multiemployer trust Deadline.

affiliated with one or more multiemployer plans), that is different than coverage under the plan in which such individual was enrolled at the time the qualifying event occurred, and such coverage shall be treated as COBRA continuation coverage for purposes of the applicable COBRA continuation coverage provision.

(ii) REQUIREMENTS.—An assistance eligible individual may elect to enroll in different coverage as described in clause (i) only if—

(I) the employer involved has made a determination that such employer will permit assistance eligible individuals to enroll in different coverage as provided for this subparagraph;

(II) the premium for such different coverage does not exceed the premium for coverage in which the individual was enrolled at the time the qualifying event occurred;

(III) the different coverage in which the individual elects to enroll is coverage that is also offered to the active employees of the employer at the time at which such election is made; and

(IV) the different coverage is not—

(aa) coverage that provides only dental, vision, counseling, or referral services (or a combination of such services);

(bb) a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code of 1986); or

(cc) coverage that provides coverage for services or treatments furnished in an on-site medical facility maintained by the employer and that consists primarily of first-aid services, prevention and wellness care, or similar care (or a combination of such care).

(C) PREMIUM REIMBURSEMENT.—For provisions providing the balance of such premium, see section 6432 of the Internal Revenue Code of 1986, as added by paragraph (12).

(2) LIMITATION OF PERIOD OF PREMIUM ASSISTANCE.—

(A) IN GENERAL.—Paragraph (1)(A) shall not apply with respect to any assistance eligible individual for months of coverage beginning on or after the earlier of—

(i) the first date that such individual is eligible for coverage under any other group health plan (other than coverage consisting of only dental, vision, counseling, or referral services (or a combination thereof), coverage under a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code of 1986), or coverage of treatment that is furnished in an on-site medical facility maintained by the employer and that consists primarily of first-aid services, prevention and wellness care, or similar care (or a combination thereof)) or is eligible for benefits under title XVIII of the Social Security Act, or

(ii) the earliest of—

(I) the date which is 9 months after the first day of the first month that paragraph (1)(A) applies with respect to such individual,

(II) the date following the expiration of the maximum period of continuation coverage required under the applicable COBRA continuation coverage provision, or

(III) the date following the expiration of the period of continuation coverage allowed under paragraph (4)(B)(ii).

(B) TIMING OF ELIGIBILITY FOR ADDITIONAL COVERAGE.—For purposes of subparagraph (A)(i), an individual shall not be treated as eligible for coverage under a group health plan before the first date on which such individual could be covered under such plan.

(C) NOTIFICATION REQUIREMENT.—An assistance eligible individual shall notify in writing the group health plan with respect to which paragraph (1)(A) applies if such paragraph ceases to apply by reason of subparagraph (A)(i). Such notice shall be provided to the group health plan in such time and manner as may be specified by the Secretary of Labor.

(3) ASSISTANCE ELIGIBLE INDIVIDUAL.—For purposes of this section, the term "assistance eligible individual" means any qualified beneficiary if— Definition. Time period.

(A) at any time during the period that begins with September 1, 2008, and ends with December 31, 2009, such qualified beneficiary is eligible for COBRA continuation coverage,

(B) such qualified beneficiary elects such coverage, and

(C) the qualifying event with respect to the COBRA continuation coverage consists of the involuntary termination of the covered employee's employment and occurred during such period.

(4) EXTENSION OF ELECTION PERIOD AND EFFECT ON COVERAGE.—

(A) IN GENERAL.—For purposes of applying section 605(a) of the Employee Retirement Income Security Act of 1974, section 4980B(f)(5)(A) of the Internal Revenue Code of 1986, section 2205(a) of the Public Health Service Act, and section 8905a(c)(2) of title 5, United States Code, in the case of an individual who does not have an election of COBRA continuation coverage in effect on the date of the enactment of this Act but who would be an assistance eligible individual if such election were so in effect, such individual may elect the COBRA continuation coverage under the COBRA continuation coverage provisions containing such sections during the period beginning on the date of the enactment of this Act and ending 60 days after the date on which the notification required under paragraph (7)(C) is provided to such individual.

(B) COMMENCEMENT OF COVERAGE; NO REACH-BACK.—Any COBRA continuation coverage elected by a qualified beneficiary during an extended election period under subparagraph (A)—

(i) shall commence with the first period of coverage beginning on or after the date of the enactment of this Act, and

(ii) shall not extend beyond the period of COBRA continuation coverage that would have been required under the applicable COBRA continuation coverage provision if the coverage had been elected as required under such provision.

(C) PREEXISTING CONDITIONS.—With respect to a qualified beneficiary who elects COBRA continuation coverage pursuant to subparagraph (A), the period—

(i) beginning on the date of the qualifying event, and

(ii) ending with the beginning of the period described in subparagraph (B)(i),

shall be disregarded for purposes of determining the 63-day periods referred to in section 701(c)(2) of the Employee Retirement Income Security Act of 1974, section 9801(c)(2) of the Internal Revenue Code of 1986, and section 2701(c)(2) of the Public Health Service Act.

(5) EXPEDITED REVIEW OF DENIALS OF PREMIUM ASSISTANCE.—In any case in which an individual requests treatment as an assistance eligible individual and is denied such treatment by the group health plan, the Secretary of Labor (or the Secretary of Health and Human Services in connection with COBRA continuation coverage which is provided other than pursuant to part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974), in consultation with the Secretary of the Treasury, shall provide for expedited review of such denial. An individual shall be entitled to such review upon application to such Secretary in such form and manner as shall be provided by such Secretary. Such Secretary shall make a determination regarding such individual's eligibility within 15 business days after receipt of such individual's application for review under this paragraph. Either Secretary's determination upon review of the denial shall be de novo and shall be the final determination of such Secretary. A reviewing court shall grant deference to such Secretary's determination. The provisions of this paragraph, paragraphs (1) through (4), and paragraph (7) shall be treated as provisions of title I of the Employee Retirement Income Security Act of 1974 for purposes of part 5 of subtitle B of such title.

Application.

Determination. Deadline.

Courts.

(6) DISREGARD OF SUBSIDIES FOR PURPOSES OF FEDERAL AND STATE PROGRAMS.—Notwithstanding any other provision of law, any premium reduction with respect to an assistance eligible individual under this subsection shall not be considered income or resources in determining eligibility for, or the amount of assistance or benefits provided under, any other public benefit provided under Federal law or the law of any State or political subdivision thereof.

(7) NOTICES TO INDIVIDUALS.—

(A) GENERAL NOTICE.—

(i) IN GENERAL.—In the case of notices provided under section 606(a)(4) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1166(4)), section 4980B(f)(6)(D) of the Internal Revenue Code of 1986, section 2206(4) of the Public Health Service Act (42

U.S.C. 300bb-6(4)), or section 8905a(f)(2)(A) of title 5, United States Code, with respect to individuals who, during the period described in paragraph (3)(A), become entitled to elect COBRA continuation coverage, the requirements of such sections shall not be treated as met unless such notices include an additional notification to the recipient of—

(I) the availability of premium reduction with respect to such coverage under this subsection, and

(II) the option to enroll in different coverage if the employer permits assistance eligible individuals to elect enrollment in different coverage (as described in paragraph (1)(B)).

(ii) ALTERNATIVE NOTICE.—In the case of COBRA continuation coverage to which the notice provision under such sections does not apply, the Secretary of Labor, in consultation with the Secretary of the Treasury and the Secretary of Health and Human Services, shall, in consultation with administrators of the group health plans (or other entities) that provide or administer the COBRA continuation coverage involved, provide rules requiring the provision of such notice. Regulations.

(iii) FORM.—The requirement of the additional notification under this subparagraph may be met by amendment of existing notice forms or by inclusion of a separate document with the notice otherwise required.

(B) SPECIFIC REQUIREMENTS.—Each additional notification under subparagraph (A) shall include—

(i) the forms necessary for establishing eligibility for premium reduction under this subsection,

(ii) the name, address, and telephone number necessary to contact the plan administrator and any other person maintaining relevant information in connection with such premium reduction,

(iii) a description of the extended election period provided for in paragraph (4)(A),

(iv) a description of the obligation of the qualified beneficiary under paragraph (2)(C) to notify the plan providing continuation coverage of eligibility for subsequent coverage under another group health plan or eligibility for benefits under title XVIII of the Social Security Act and the penalty provided under section 6720C of the Internal Revenue Code of 1986 for failure to so notify the plan,

(v) a description, displayed in a prominent manner, of the qualified beneficiary's right to a reduced premium and any conditions on entitlement to the reduced premium, and

(vi) a description of the option of the qualified beneficiary to enroll in different coverage if the employer permits such beneficiary to elect to enroll in such different coverage under paragraph (1)(B).

(C) NOTICE IN CONNECTION WITH EXTENDED ELECTION PERIODS.—In the case of any assistance eligible individual Deadline.

(or any individual described in paragraph (4)(A)) who became entitled to elect COBRA continuation coverage before the date of the enactment of this Act, the administrator of the group health plan (or other entity) involved shall provide (within 60 days after the date of enactment of this Act) for the additional notification required to be provided under subparagraph (A) and failure to provide such notice shall be treated as a failure to meet the notice requirements under the applicable COBRA continuation provision.

Deadline.

(D) MODEL NOTICES.—Not later than 30 days after the date of enactment of this Act—

(i) the Secretary of the Labor, in consultation with the Secretary of the Treasury and the Secretary of Health and Human Services, shall prescribe models for the additional notification required under this paragraph (other than the additional notification described in clause (ii)), and

(ii) in the case of any additional notification provided pursuant to subparagraph (A) under section 8905a(f)(2)(A) of title 5, United States Code, the Office of Personnel Management shall prescribe a model for such additional notification.

(8) REGULATIONS.—The Secretary of the Treasury may prescribe such regulations or other guidance as may be necessary or appropriate to carry out the provisions of this subsection, including the prevention of fraud and abuse under this subsection, except that the Secretary of Labor and the Secretary of Health and Human Services may prescribe such regulations (including interim final regulations) or other guidance as may be necessary or appropriate to carry out the provisions of paragraphs (5), (7), and (9).

(9) OUTREACH.—The Secretary of Labor, in consultation with the Secretary of the Treasury and the Secretary of Health and Human Services, shall provide outreach consisting of public education and enrollment assistance relating to premium reduction provided under this subsection. Such outreach shall target employers, group health plan administrators, public assistance programs, States, insurers, and other entities as determined appropriate by such Secretaries. Such outreach shall include an initial focus on those individuals electing continuation coverage who are referred to in paragraph (7)(C). Information on such premium reduction, including enrollment, shall also be made available on websites of the Departments of Labor, Treasury, and Health and Human Services.

Web posting.

(10) DEFINITIONS.—For purposes of this section—

(A) ADMINISTRATOR.—The term "administrator" has the meaning given such term in section 3(16)(A) of the Employee Retirement Income Security Act of 1974.

(B) COBRA CONTINUATION COVERAGE.—The term "COBRA continuation coverage" means continuation coverage provided pursuant to part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (other than under section 609), title XXII of the Public Health Service Act, section 4980B of the Internal Revenue Code of 1986 (other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines), or section 8905a

of title 5, United States Code, or under a State program that provides comparable continuation coverage. Such term does not include coverage under a health flexible spending arrangement under a cafeteria plan within the meaning of section 125 of the Internal Revenue Code of 1986.

(C) COBRA CONTINUATION PROVISION.—The term "COBRA continuation provision" means the provisions of law described in subparagraph (B).

(D) COVERED EMPLOYEE.—The term "covered employee" has the meaning given such term in section 607(2) of the Employee Retirement Income Security Act of 1974.

(E) QUALIFIED BENEFICIARY.—The term "qualified beneficiary" has the meaning given such term in section 607(3) of the Employee Retirement Income Security Act of 1974.

(F) GROUP HEALTH PLAN.—The term "group health plan" has the meaning given such term in section 607(1) of the Employee Retirement Income Security Act of 1974.

(G) STATE.—The term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(H) PERIOD OF COVERAGE.—Any reference in this subsection to a period of coverage shall be treated as a reference to a monthly or shorter period of coverage with respect to which premiums are charged with respect to such coverage.

(11) REPORTS.—

(A) INTERIM REPORT.—The Secretary of the Treasury shall submit an interim report to the Committee on Education and Labor, the Committee on Ways and Means, and the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate regarding the premium reduction provided under this subsection that includes—

(i) the number of individuals provided such assistance as of the date of the report; and

(ii) the total amount of expenditures incurred (with administrative expenditures noted separately) in connection with such assistance as of the date of the report.

(B) FINAL REPORT.—As soon as practicable after the last period of COBRA continuation coverage for which premium reduction is provided under this section, the Secretary of the Treasury shall submit a final report to each Committee referred to in subparagraph (A) that includes—

(i) the number of individuals provided premium reduction under this section;

(ii) the average dollar amount (monthly and annually) of premium reductions provided to such individuals; and

(iii) the total amount of expenditures incurred (with administrative expenditures noted separately) in connection with premium reduction under this section.

(12) COBRA PREMIUM ASSISTANCE.—

(A) IN GENERAL.—Subchapter B of chapter 65 of the Internal Revenue Code of 1986, as amended by this Act, is amended by adding at the end the following new section:

26 USC 6432.

"SEC. 6432. COBRA PREMIUM ASSISTANCE.

"(a) IN GENERAL.—The person to whom premiums are payable under COBRA continuation coverage shall be reimbursed as provided in subsection (c) for the amount of premiums not paid by assistance eligible individuals by reason of section 3002(a) of the Health Insurance Assistance for the Unemployed Act of 2009.

"(b) PERSON ENTITLED TO REIMBURSEMENT.—For purposes of subsection (a), except as otherwise provided by the Secretary, the person to whom premiums are payable under COBRA continuation coverage shall be treated as being—

"(1) in the case of any group health plan which is a multiemployer plan (as defined in section 3(37) of the Employee Retirement Income Security Act of 1974), the plan,

"(2) in the case of any group health plan not described in paragraph (1)—

"(A) which is subject to the COBRA continuation provisions contained in—

"(i) the Internal Revenue Code of 1986,

"(ii) the Employee Retirement Income Security Act of 1974,

"(iii) the Public Health Service Act, or

"(iv) title 5, United States Code, or

"(B) under which some or all of the coverage is not provided by insurance,

the employer maintaining the plan, and

"(3) in the case of any group health plan not described in paragraph (1) or (2), the insurer providing the coverage under the group health plan.

"(c) METHOD OF REIMBURSEMENT.—Except as otherwise provided by the Secretary—

"(1) TREATMENT AS PAYMENT OF PAYROLL TAXES.—Each person entitled to reimbursement under subsection (a) (and filing a claim for such reimbursement at such time and in such manner as the Secretary may require) shall be treated for purposes of this title and section 1324(b)(2) of title 31, United States Code, as having paid to the Secretary, on the date that the assistance eligible individual's premium payment is received, payroll taxes in an amount equal to the portion of such reimbursement which relates to such premium. To the extent that the amount treated as paid under the preceding sentence exceeds the amount of such person's liability for such taxes, the Secretary shall credit or refund such excess in the same manner as if it were an overpayment of such taxes.

"(2) OVERSTATEMENTS.—Any overstatement of the reimbursement to which a person is entitled under this section (and any amount paid by the Secretary as a result of such overstatement) shall be treated as an underpayment of payroll taxes by such person and may be assessed and collected by the Secretary in the same manner as payroll taxes.

"(3) REIMBURSEMENT CONTINGENT ON PAYMENT OF REMAINING PREMIUM.—No reimbursement may be made under this section to a person with respect to any assistance eligible individual until after the reduced premium required under

section 3002(a)(1)(A) of such Act with respect to such individual has been received.

"(d) DEFINITIONS.—For purposes of this section—

"(1) PAYROLL TAXES.—The term 'payroll taxes' means—

"(A) amounts required to be deducted and withheld for the payroll period under section 3402 (relating to wage withholding),

"(B) amounts required to be deducted for the payroll period under section 3102 (relating to FICA employee taxes), and

"(C) amounts of the taxes imposed for the payroll period under section 3111 (relating to FICA employer taxes).

"(2) PERSON.—The term 'person' includes any governmental entity.

"(e) REPORTING.—Each person entitled to reimbursement under subsection (a) for any period shall submit such reports (at such time and in such manner) as the Secretary may require, including—

"(1) an attestation of involuntary termination of employment for each covered employee on the basis of whose termination entitlement to reimbursement is claimed under subsection (a),

"(2) a report of the amount of payroll taxes offset under subsection (a) for the reporting period and the estimated offsets of such taxes for the subsequent reporting period in connection with reimbursements under subsection (a), and

"(3) a report containing the TINs of all covered employees, the amount of subsidy reimbursed with respect to each covered employee and qualified beneficiaries, and a designation with respect to each covered employee as to whether the subsidy reimbursement is for coverage of 1 individual or 2 or more individuals.

"(f) REGULATIONS.—The Secretary shall issue such regulations or other guidance as may be necessary or appropriate to carry out this section, including—

"(1) the requirement to report information or the establishment of other methods for verifying the correct amounts of reimbursements under this section, and

"(2) the application of this section to group health plans that are multiemployer plans (as defined in section 3(37) of the Employee Retirement Income Security Act of 1974).".

(B) SOCIAL SECURITY TRUST FUNDS HELD HARMLESS.—In determining any amount transferred or appropriated to any fund under the Social Security Act, section 6432 of the Internal Revenue Code of 1986 shall not be taken into account.

(C) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 65 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

"Sec. 6432. COBRA premium assistance.".

(D) EFFECTIVE DATE.—The amendments made by this paragraph shall apply to premiums to which subsection (a)(1)(A) applies.

(E) SPECIAL RULE.—

(i) IN GENERAL.—In the case of an assistance eligible individual who pays, with respect to the first

period of COBRA continuation coverage to which subsection (a)(1)(A) applies or the immediately subsequent period, the full premium amount for such coverage, the person to whom such payment is payable shall—

(I) make a reimbursement payment to such individual for the amount of such premium paid in excess of the amount required to be paid under subsection (a)(1)(A); or

(II) provide credit to the individual for such amount in a manner that reduces one or more subsequent premium payments that the individual is required to pay under such subsection for the coverage involved.

(ii) REIMBURSING EMPLOYER.—A person to which clause (i) applies shall be reimbursed as provided for in section 6432 of the Internal Revenue Code of 1986 for any payment made, or credit provided, to the employee under such clause.

Time period.
Deadlines.

(iii) PAYMENT OR CREDITS.—Unless it is reasonable to believe that the credit for the excess payment in clause (i)(II) will be used by the assistance eligible individual within 180 days of the date on which the person receives from the individual the payment of the full premium amount, a person to which clause (i) applies shall make the payment required under such clause to the individual within 60 days of such payment of the full premium amount. If, as of any day within the 180-day period, it is no longer reasonable to believe that the credit will be used during that period, payment equal to the remainder of the credit outstanding shall be made to the individual within 60 days of such day.

(13) PENALTY FOR FAILURE TO NOTIFY HEALTH PLAN OF CESSATION OF ELIGIBILITY FOR PREMIUM ASSISTANCE.—

(A) IN GENERAL.—Part I of subchapter B of chapter 68 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

26 USC 6720C.

"SEC. 6720C. PENALTY FOR FAILURE TO NOTIFY HEALTH PLAN OF CESSATION OF ELIGIBILITY FOR COBRA PREMIUM ASSISTANCE.

"(a) IN GENERAL.—Any person required to notify a group health plan under section 3002(a)(2)(C)) of the Health Insurance Assistance for the Unemployed Act of 2009 who fails to make such a notification at such time and in such manner as the Secretary of Labor may require shall pay a penalty of 110 percent of the premium reduction provided under such section after termination of eligibility under such subsection.

"(b) REASONABLE CAUSE EXCEPTION.—No penalty shall be imposed under subsection (a) with respect to any failure if it is shown that such failure is due to reasonable cause and not to willful neglect.".

(B) CLERICAL AMENDMENT.—The table of sections of part I of subchapter B of chapter 68 of such Code is amended by adding at the end the following new item:

"Sec. 6720C. Penalty for failure to notify health plan of cessation of eligibility for COBRA premium assistance.".

(C) EFFECTIVE DATE.—The amendments made by this paragraph shall apply to failures occurring after the date of the enactment of this Act.

(14) COORDINATION WITH HCTC.—

(A) IN GENERAL.—Subsection (g) of section 35 of the Internal Revenue Code of 1986 is amended by redesignating paragraph (9) as paragraph (10) and inserting after paragraph (8) the following new paragraph: 26 USC 35.

"(9) COBRA PREMIUM ASSISTANCE.—In the case of an assistance eligible individual who receives premium reduction for COBRA continuation coverage under section 3002(a) of the Health Insurance Assistance for the Unemployed Act of 2009 for any month during the taxable year, such individual shall not be treated as an eligible individual, a certified individual, or a qualifying family member for purposes of this section or section 7527 with respect to such month.".

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall apply to taxable years ending after the date of the enactment of this Act.

(15) EXCLUSION OF COBRA PREMIUM ASSISTANCE FROM GROSS INCOME.—

(A) IN GENERAL.—Part III of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 139B the following new section:

"SEC. 139C. COBRA PREMIUM ASSISTANCE. 26 USC 139C.

"In the case of an assistance eligible individual (as defined in section 3002 of the Health Insurance Assistance for the Unemployed Act of 2009), gross income does not include any premium reduction provided under subsection (a) of such section.".

(B) CLERICAL AMENDMENT.—The table of sections for part III of subchapter B of chapter 1 of such Code is amended by inserting after the item relating to section 139B the following new item:

"Sec. 139C. COBRA premium assistance.".

(C) EFFECTIVE DATE.—The amendments made by this paragraph shall apply to taxable years ending after the date of the enactment of this Act.

(b) ELIMINATION OF PREMIUM SUBSIDY FOR HIGH-INCOME INDIVIDUALS.—

(1) RECAPTURE OF SUBSIDY FOR HIGH-INCOME INDIVIDUALS.—If—

(A) premium assistance is provided under this section with respect to any COBRA continuation coverage which covers the taxpayer, the taxpayer's spouse, or any dependent (within the meaning of section 152 of the Internal Revenue Code of 1986, determined without regard to subsections (b)(1), (b)(2), and (d)(1)(B) thereof) of the taxpayer during any portion of the taxable year, and

(B) the taxpayer's modified adjusted gross income for such taxable year exceeds $125,000 ($250,000 in the case of a joint return),

then the tax imposed by chapter 1 of such Code with respect to the taxpayer for such taxable year shall be increased by the amount of such assistance.

(2) PHASE-IN OF RECAPTURE.—

(A) IN GENERAL.—In the case of a taxpayer whose modified adjusted gross income for the taxable year does not exceed $145,000 ($290,000 in the case of a joint return), the increase in the tax imposed under paragraph (1) shall not exceed the phase-in percentage of such increase (determined without regard to this paragraph).

(B) PHASE-IN PERCENTAGE.—For purposes of this subsection, the term "phase-in percentage" means the ratio (expressed as a percentage) obtained by dividing—

(i) the excess of described in subparagraph (B) of paragraph (1), by

(ii) $20,000 ($40,000 in the case of a joint return).

(3) OPTION FOR HIGH-INCOME INDIVIDUALS TO WAIVE ASSISTANCE AND AVOID RECAPTURE.—Notwithstanding subsection (a)(3), an individual shall not be treated as an assistance eligible individual for purposes of this section and section 6432 of the Internal Revenue Code of 1986 if such individual—

(A) makes a permanent election (at such time and in such form and manner as the Secretary of the Treasury may prescribe) to waive the right to the premium assistance provided under this section, and

(B) notifies the entity to whom premiums are reimbursed under section 6432(a) of such Code of such election.

(4) MODIFIED ADJUSTED GROSS INCOME.—For purposes of this subsection, the term "modified adjusted gross income" means the adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986) of the taxpayer for the taxable year increased by any amount excluded from gross income under section 911, 931, or 933 of such Code.

(5) CREDITS NOT ALLOWED AGAINST TAX, ETC.—For purposes determining regular tax liability under section 26(b) of such Code, the increase in tax under this subsection shall not be treated as a tax imposed under chapter 1 of such Code.

(6) REGULATIONS.—The Secretary of the Treasury shall issue such regulations or other guidance as are necessary or appropriate to carry out this subsection, including requirements that the entity to whom premiums are reimbursed under section 6432(a) of the Internal Revenue Code of 1986 report to the Secretary, and to each assistance eligible individual, the amount of premium assistance provided under subsection (a) with respect to each such individual.

(7) EFFECTIVE DATE.—The provisions of this subsection shall apply to taxable years ending after the date of the enactment of this Act.

TITLE IV—MEDICARE AND MEDICAID HEALTH INFORMATION TECHNOLOGY; MISCELLANEOUS MEDICARE PROVISIONS

Health Information Technology for Economic and Clinical Health Act.

SEC. 4001. TABLE OF CONTENTS OF TITLE.

The table of contents of this title is as follows:

TITLE IV—MEDICARE AND MEDICAID HEALTH INFORMATION TECHNOLOGY; MISCELLANEOUS MEDICARE PROVISIONS

Sec. 4001. Table of contents of title.

Subtitle A—Medicare Incentives

Sec. 4101. Incentives for eligible professionals.
Sec. 4102. Incentives for hospitals.
Sec. 4103. Treatment of payments and savings; implementation funding.
Sec. 4104. Studies and reports on health information technology.

Subtitle B—Medicaid Incentives

Sec. 4201. Medicaid provider HIT adoption and operation payments; implementation funding.

Subtitle C—Miscellaneous Medicare Provisions

Sec. 4301. Moratoria on certain Medicare regulations.
Sec. 4302. Long-term care hospital technical corrections.

Subtitle A—Medicare Incentives

SEC. 4101. INCENTIVES FOR ELIGIBLE PROFESSIONALS.

(a) INCENTIVE PAYMENTS.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended by adding at the end the following new subsection:

"(o) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

"(1) INCENTIVE PAYMENTS.—

"(A) IN GENERAL.—

"(i) IN GENERAL.—Subject to the succeeding subparagraphs of this paragraph, with respect to covered professional services furnished by an eligible professional during a payment year (as defined in subparagraph (E)), if the eligible professional is a meaningful EHR user (as determined under paragraph (2)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)), from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 an amount equal to 75 percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the payment year) of the allowed charges under this part for all such covered professional services furnished by the eligible professional during such year.

Deadline.

"(ii) NO INCENTIVE PAYMENTS WITH RESPECT TO YEARS AFTER 2016.—No incentive payments may be

made under this subsection with respect to a year after 2016.

"(B) LIMITATIONS ON AMOUNTS OF INCENTIVE PAYMENTS.—

"(i) IN GENERAL.—In no case shall the amount of the incentive payment provided under this paragraph for an eligible professional for a payment year exceed the applicable amount specified under this subparagraph with respect to such eligible professional and such year.

"(ii) AMOUNT.—Subject to clauses (iii) through (v), the applicable amount specified in this subparagraph for an eligible professional is as follows:

"(I) For the first payment year for such professional, $15,000 (or, if the first payment year for such eligible professional is 2011 or 2012, $18,000).

"(II) For the second payment year for such professional, $12,000.

"(III) For the third payment year for such professional, $8,000.

"(IV) For the fourth payment year for such professional, $4,000.

"(V) For the fifth payment year for such professional, $2,000.

"(VI) For any succeeding payment year for such professional, $0.

"(iii) PHASE DOWN FOR ELIGIBLE PROFESSIONALS FIRST ADOPTING EHR AFTER 2013.—If the first payment year for an eligible professional is after 2013, then the amount specified in this subparagraph for a payment year for such professional is the same as the amount specified in clause (ii) for such payment year for an eligible professional whose first payment year is 2013.

"(iv) INCREASE FOR CERTAIN ELIGIBLE PROFESSIONALS.—In the case of an eligible professional who predominantly furnishes services under this part in an area that is designated by the Secretary (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area, the amount that would otherwise apply for a payment year for such professional under subclauses (I) through (V) of clause (ii) shall be increased by 10 percent. In implementing the preceding sentence, the Secretary may, as determined appropriate, apply provisions of subsections (m) and (u) of section 1833 in a similar manner as such provisions apply under such subsection.

"(v) NO INCENTIVE PAYMENT IF FIRST ADOPTING AFTER 2014.—If the first payment year for an eligible professional is after 2014 then the applicable amount specified in this subparagraph for such professional for such year and any subsequent year shall be $0.

"(C) NON-APPLICATION TO HOSPITAL-BASED ELIGIBLE PROFESSIONALS.—

"(i) IN GENERAL.—No incentive payment may be made under this paragraph in the case of a hospital-based eligible professional.

"(ii) HOSPITAL-BASED ELIGIBLE PROFESSIONAL.—For purposes of clause (i), the term 'hospital-based eligible professional' means, with respect to covered professional services furnished by an eligible professional during the EHR reporting period for a payment year, an eligible professional, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of such services in a hospital setting (whether inpatient or outpatient) and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

"(D) PAYMENT.—

"(i) FORM OF PAYMENT.—The payment under this paragraph may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

"(ii) COORDINATION OF APPLICATION OF LIMITATION FOR PROFESSIONALS IN DIFFERENT PRACTICES.—In the case of an eligible professional furnishing covered professional services in more than one practice (as specified by the Secretary), the Secretary shall establish rules to coordinate the incentive payments, including the application of the limitation on amounts of such incentive payments under this paragraph, among such practices. Regulations.

"(iii) COORDINATION WITH MEDICAID.—The Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XIX. The Secretary may also adjust the reporting periods under such title and such subsections in order to carry out this clause.

"(E) PAYMENT YEAR DEFINED.—

"(i) IN GENERAL.—For purposes of this subsection, the term 'payment year' means a year beginning with 2011.

"(ii) FIRST, SECOND, ETC. PAYMENT YEAR.—The term 'first payment year' means, with respect to covered professional services furnished by an eligible professional, the first year for which an incentive payment is made for such services under this subsection. The terms 'second payment year', 'third payment year', 'fourth payment year', and 'fifth payment year' mean, with respect to covered professional services furnished by such eligible professional, each successive year immediately following the first payment year for such professional.

"(2) MEANINGFUL EHR USER.—

"(A) IN GENERAL.—For purposes of paragraph (1), an eligible professional shall be treated as a meaningful EHR

user for an EHR reporting period for a payment year (or, for purposes of subsection (a)(7), for an EHR reporting period under such subsection for a year) if each of the following requirements is met:

"(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary.

"(ii) INFORMATION EXCHANGE.—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

"(iii) REPORTING ON MEASURES USING EHR.—Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible professional submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary may provide for the use of alternative means for meeting the requirements of clauses (i), (ii), and (iii) in the case of an eligible professional furnishing covered professional services in a group practice (as defined by the Secretary). The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

"(B) REPORTING ON MEASURES.—

"(i) SELECTION.—The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

"(I) The Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

Federal Register, publication.

"(II) Prior to any measure being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

"(ii) LIMITATION.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

"(iii) COORDINATION OF REPORTING OF INFORMATION.—In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid

redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C).

"(C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—

"(i) IN GENERAL.—A professional may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

"(I) an attestation;

"(II) the submission of claims with appropriate coding (such as a code indicating that a patient encounter was documented using certified EHR technology);

"(III) a survey response;

"(IV) reporting under subparagraph (A)(iii); and

"(V) other means specified by the Secretary.

"(ii) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (A).

"(3) APPLICATION.—

"(A) PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

"(B) COORDINATION WITH OTHER PAYMENTS.—The provisions of this subsection shall not be taken into account in applying the provisions of subsection (m) of this section and of section 1833(m) and any payment under such provisions shall not be taken into account in computing allowable charges under this subsection.

"(C) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (a)(7)(A), including the limitation under paragraph (1)(B) and coordination under clauses (ii) and (iii) of paragraph (1)(D);

"(ii) the methodology and standards for determining a meaningful EHR user under paragraph (2), including selection of measures under paragraph (2)(B), specification of the means of demonstrating meaningful EHR use under paragraph (2)(C), and the hardship exception under subsection (a)(7)(B);

"(iii) the methodology and standards for determining a hospital-based eligible professional under paragraph (1)(C); and

"(iv) the specification of reporting periods under paragraph (5) and the selection of the form of payment under paragraph (1)(D)(i).

"(D) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone

numbers of the eligible professionals who are meaningful EHR users and, as determined appropriate by the Secretary, of group practices receiving incentive payments under paragraph (1).

"(4) CERTIFIED EHR TECHNOLOGY DEFINED.—For purposes of this section, the term 'certified EHR technology' means a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

"(5) DEFINITIONS.—For purposes of this subsection:

"(A) COVERED PROFESSIONAL SERVICES.—The term 'covered professional services' has the meaning given such term in subsection (k)(3).

"(B) EHR REPORTING PERIOD.—The term 'EHR reporting period' means, with respect to a payment year, any period (or periods) as specified by the Secretary.

"(C) ELIGIBLE PROFESSIONAL.—The term 'eligible professional' means a physician, as defined in section 1861(r).".

(b) INCENTIVE PAYMENT ADJUSTMENT.—Section 1848(a) of the Social Security Act (42 U.S.C. 1395w–4(a)) is amended by adding at the end the following new paragraph:

"(7) INCENTIVES FOR MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

"(A) ADJUSTMENT.—

"(i) IN GENERAL.—Subject to subparagraphs (B) and (D), with respect to covered professional services furnished by an eligible professional during 2015 or any subsequent payment year, if the eligible professional is not a meaningful EHR user (as determined under subsection (o)(2)) for an EHR reporting period for the year, the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

"(ii) APPLICABLE PERCENT.—Subject to clause (iii), for purposes of clause (i), the term 'applicable percent' means—

"(I) for 2015, 99 percent (or, in the case of an eligible professional who was subject to the application of the payment adjustment under section 1848(a)(5) for 2014, 98 percent);

"(II) for 2016, 98 percent; and

"(III) for 2017 and each subsequent year, 97 percent.

"(iii) AUTHORITY TO DECREASE APPLICABLE PERCENTAGE FOR 2018 AND SUBSEQUENT YEARS.—For 2018 and each subsequent year, if the Secretary finds

that the proportion of eligible professionals who are meaningful EHR users (as determined under subsection (o)(2)) is less than 75 percent, the applicable percent shall be decreased by 1 percentage point from the applicable percent in the preceding year, but in no case shall the applicable percent be less than 95 percent.

"(B) SIGNIFICANT HARDSHIP EXCEPTION.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access. In no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.

"(C) APPLICATION OF PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

"(D) NON-APPLICATION TO HOSPITAL-BASED ELIGIBLE PROFESSIONALS.—No payment adjustment may be made under subparagraph (A) in the case of hospital-based eligible professionals (as defined in subsection (o)(1)(C)(ii)).

"(E) DEFINITIONS.—For purposes of this paragraph:

"(i) COVERED PROFESSIONAL SERVICES.—The term 'covered professional services' has the meaning given such term in subsection (k)(3).

"(ii) EHR REPORTING PERIOD.—The term 'EHR reporting period' means, with respect to a year, a period (or periods) specified by the Secretary.

"(iii) ELIGIBLE PROFESSIONAL.—The term 'eligible professional' means a physician, as defined in section 1861(r).".

(c) APPLICATION TO CERTAIN MA-AFFILIATED ELIGIBLE PROFESSIONALS.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

"(l) APPLICATION OF ELIGIBLE PROFESSIONAL INCENTIVES FOR CERTAIN MA ORGANIZATIONS FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

"(1) IN GENERAL.—Subject to paragraphs (3) and (4), in the case of a qualifying MA organization, the provisions of sections 1848(o) and 1848(a)(7) shall apply with respect to eligible professionals described in paragraph (2) of the organization who the organization attests under paragraph (6) to be meaningful EHR users in a similar manner as they apply to eligible professionals under such sections. Incentive payments under paragraph (3) shall be made to and payment adjustments under paragraph (4) shall apply to such qualifying organizations.

"(2) ELIGIBLE PROFESSIONAL DESCRIBED.—With respect to a qualifying MA organization, an eligible professional described in this paragraph is an eligible professional (as defined for purposes of section 1848(o)) who—

"(A)(i) is employed by the organization; or

"(ii)(I) is employed by, or is a partner of, an entity that through contract with the organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of such organization; and

"(II) furnishes at least 80 percent of the professional services of the eligible professional covered under this title to enrollees of the organization; and

"(B) furnishes, on average, at least 20 hours per week of patient care services.

"(3) ELIGIBLE PROFESSIONAL INCENTIVE PAYMENTS.—

"(A) IN GENERAL.—In applying section 1848(o) under paragraph (1), instead of the additional payment amount under section 1848(o)(1)(A) and subject to subparagraph (B), the Secretary may substitute an amount determined by the Secretary to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable if payment for services furnished by such professionals was payable under part B instead of this part.

"(B) AVOIDING DUPLICATION OF PAYMENTS.—

"(i) IN GENERAL.—In the case of an eligible professional described in paragraph (2)—

"(I) that is eligible for the maximum incentive payment under section 1848(o)(1)(A) for the same payment period, the payment incentive shall be made only under such section and not under this subsection; and

"(II) that is eligible for less than such maximum incentive payment for the same payment period, the payment incentive shall be made only under this subsection and not under section 1848(o)(1)(A).

"(ii) METHODS.—In the case of an eligible professional described in paragraph (2) who is eligible for an incentive payment under section 1848(o)(1)(A) but is not described in clause (i) for the same payment period, the Secretary shall develop a process—

"(I) to ensure that duplicate payments are not made with respect to an eligible professional both under this subsection and under section 1848(o)(1)(A); and

"(II) to collect data from Medicare Advantage organizations to ensure against such duplicate payments.

"(C) FIXED SCHEDULE FOR APPLICATION OF LIMITATION ON INCENTIVE PAYMENTS FOR ALL ELIGIBLE PROFESSIONALS.—In applying section 1848(o)(1)(B)(ii) under subparagraph (A), in accordance with rules specified by the Secretary, a qualifying MA organization shall specify a year (not earlier than 2011) that shall be treated as the first payment year for all eligible professionals with respect to such organization.

Deadline.

"(4) PAYMENT ADJUSTMENT.—

"(A) IN GENERAL.—In applying section 1848(a)(7) under paragraph (1), instead of the payment adjustment being an applicable percent of the fee schedule amount for a year under such section, subject to subparagraph (D), the

payment adjustment under paragraph (1) shall be equal to the percent specified in subparagraph (B) for such year of the payment amount otherwise provided under this section for such year.

"(B) SPECIFIED PERCENT.—The percent specified under this subparagraph for a year is 100 percent minus a number of percentage points equal to the product of—

"(i) the number of percentage points by which the applicable percent (under section 1848(a)(7)(A)(ii)) for the year is less than 100 percent; and

"(ii) the Medicare physician expenditure proportion specified in subparagraph (C) for the year.

"(C) MEDICARE PHYSICIAN EXPENDITURE PROPORTION.—The Medicare physician expenditure proportion under this subparagraph for a year is the Secretary's estimate of the proportion, of the expenditures under parts A and B that are not attributable to this part, that are attributable to expenditures for physicians' services.

"(D) APPLICATION OF PAYMENT ADJUSTMENT.—In the case that a qualifying MA organization attests that not all eligible professionals of the organization are meaningful EHR users with respect to a year, the Secretary shall apply the payment adjustment under this paragraph based on the proportion of all such eligible professionals of the organization that are not meaningful EHR users for such year.

"(5) QUALIFYING MA ORGANIZATION DEFINED.—In this subsection and subsection (m), the term 'qualifying MA organization' means a Medicare Advantage organization that is organized as a health maintenance organization (as defined in section 2791(b)(3) of the Public Health Service Act).

Attestation.

"(6) MEANINGFUL EHR USER ATTESTATION.—For purposes of this subsection and subsection (m), a qualifying MA organization shall submit an attestation, in a form and manner specified by the Secretary which may include the submission of such attestation as part of submission of the initial bid under section 1854(a)(1)(A)(iv), identifying—

"(A) whether each eligible professional described in paragraph (2), with respect to such organization is a meaningful EHR user (as defined in section 1848(o)(2)) for a year specified by the Secretary; and

"(B) whether each eligible hospital described in subsection (m)(1), with respect to such organization, is a meaningful EHR user (as defined in section 1886(n)(3)) for an applicable period specified by the Secretary.

"(7) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone numbers of—

"(A) each qualifying MA organization receiving an incentive payment under this subsection for eligible professionals of the organization; and

"(B) the eligible professionals of such organization for which such incentive payment is based.

"(8) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(A) the methodology and standards for determining payment amounts and payment adjustments under this subsection, including avoiding duplication of payments under paragraph (3)(B) and the specification of rules for the fixed schedule for application of limitation on incentive payments for all eligible professionals under paragraph (3)(C);

"(B) the methodology and standards for determining eligible professionals under paragraph (2); and

"(C) the methodology and standards for determining a meaningful EHR user under section 1848(o)(2), including specification of the means of demonstrating meaningful EHR use under section 1848(o)(3)(C) and selection of measures under section 1848(o)(3)(B).".

(d) STUDY AND REPORT RELATING TO MA ORGANIZATIONS.—

(1) STUDY.—The Secretary of Health and Human Services shall conduct a study on the extent to which and manner in which payment incentives and adjustments (such as under sections 1848(o) and 1848(a)(7) of the Social Security Act) could be made available to professionals, as defined in 1861(r), who are not eligible for HIT incentive payments under section 1848(o) and receive payments for Medicare patient services nearly-exclusively through contractual arrangements with one or more Medicare Advantage organizations, or an intermediary organization or organizations with contracts with Medicare Advantage organizations. Such study shall assess approaches for measuring meaningful use of qualified EHR technology among such professionals and mechanisms for delivering incentives and adjustments to those professionals, including through incentive payments and adjustments through Medicare Advantage organizations or intermediary organizations.

(2) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the findings and the conclusions of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

(e) CONFORMING AMENDMENTS.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (a)(1)(A), by striking "and (i)" and inserting "(i), and (l)";

(2) in subsection (c)—

(A) in paragraph (1)(D)(i), by striking "section 1886(h)" and inserting "sections 1848(o) and 1886(h)"; and

(B) in paragraph (6)(A), by inserting after "under part B," the following: "excluding expenditures attributable to subsections (a)(7) and (o) of section 1848,"; and

(3) in subsection (f), by inserting "and for payments under subsection (l)" after "with the organization".

(f) CONFORMING AMENDMENTS TO E-PRESCRIBING.—

(1) Section 1848(a)(5)(A) of the Social Security Act (42 U.S.C. 1395w–4(a)(5)(A)) is amended—

(A) in clause (i), by striking "or any subsequent year" and inserting ", 2013 or 2014"; and

(B) in clause (ii), by striking "and each subsequent year".

(2) Section 1848(m)(2) of such Act (42 U.S.C. 1395w–4(m)(2)) is amended—

(A) in subparagraph (A), by striking "For 2009" and inserting "Subject to subparagraph (D), for 2009"; and

(B) by adding at the end the following new subparagraph:

"(D) LIMITATION WITH RESPECT TO EHR INCENTIVE PAYMENTS.—The provisions of this paragraph shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the EHR reporting period the eligible professional (or group practice) receives an incentive payment under subsection (o)(1)(A) with respect to a certified EHR technology (as defined in subsection (o)(4)) that has the capability of electronic prescribing.".

SEC. 4102. INCENTIVES FOR HOSPITALS.

(a) INCENTIVE PAYMENT.—

(1) IN GENERAL.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

"(n) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, with respect to inpatient hospital services furnished by an eligible hospital during a payment year (as defined in paragraph (2)(G)), if the eligible hospital is a meaningful EHR user (as determined under paragraph (3)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this section, there also shall be paid to the eligible hospital, from the Federal Hospital Insurance Trust Fund established under section 1817, an amount equal to the applicable amount specified in paragraph (2)(A) for the hospital for such payment year.

"(2) PAYMENT AMOUNT.—

"(A) IN GENERAL.—Subject to the succeeding subparagraphs of this paragraph, the applicable amount specified in this subparagraph for an eligible hospital for a payment year is equal to the product of the following:

"(i) INITIAL AMOUNT.—The sum of—

"(I) the base amount specified in subparagraph (B); plus

"(II) the discharge related amount specified in subparagraph (C) for a 12-month period selected by the Secretary with respect to such payment year.

"(ii) MEDICARE SHARE.—The Medicare share as specified in subparagraph (D) for the eligible hospital for a period selected by the Secretary with respect to such payment year.

"(iii) TRANSITION FACTOR.—The transition factor specified in subparagraph (E) for the eligible hospital for the payment year.

"(B) BASE AMOUNT.—The base amount specified in this subparagraph is $2,000,000.

"(C) DISCHARGE RELATED AMOUNT.—The discharge related amount specified in this subparagraph for a 12-

month period selected by the Secretary shall be determined as the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

"(i) For the first through 1,149th discharge, $0.

"(ii) For the 1,150th through the 23,000th discharge, $200.

"(iii) For any discharge greater than the 23,000th, $0.

"(D) MEDICARE SHARE.—The Medicare share specified under this subparagraph for an eligible hospital for a period selected by the Secretary for a payment year is equal to the fraction—

"(i) the numerator of which is the sum (for such period and with respect to the eligible hospital) of—

"(I) the estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and

"(II) the estimated number of inpatient-bed-days (as so established) which are attributable to individuals who are enrolled with a Medicare Advantage organization under part C; and

"(ii) the denominator of which is the product of—

"(I) the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

"(II) the estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under this title), divided by the estimated total amount of the hospital's charges during such period.

Data.

Insofar as the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II), the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary, with respect to a hospital, for the Secretary to compute the amount described in clause (ii)(II), the amount under such clause shall be deemed to be 1. In the absence of data, with respect to a hospital, necessary to compute the amount described in clause (i)(II), the amount under such clause shall be deemed to be 0.

"(E) TRANSITION FACTOR SPECIFIED.—

"(i) IN GENERAL.—Subject to clause (ii), the transition factor specified in this subparagraph for an eligible hospital for a payment year is as follows:

"(I) For the first payment year for such hospital, 1.

"(II) For the second payment year for such hospital, ¾.

"(III) For the third payment year for such hospital, ½.

"(IV) For the fourth payment year for such hospital, ¼.

"(V) For any succeeding payment year for such hospital, 0.

"(ii) PHASE DOWN FOR ELIGIBLE HOSPITALS FIRST ADOPTING EHR AFTER 2013.—If the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013. If the first payment year for an eligible hospital is after 2015 then the transition factor specified in this subparagraph for such hospital and for such year and any subsequent year shall be 0.

"(F) FORM OF PAYMENT.—The payment under this subsection for a payment year may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

"(G) PAYMENT YEAR DEFINED.—

"(i) IN GENERAL.—For purposes of this subsection, the term 'payment year' means a fiscal year beginning with fiscal year 2011.

"(ii) FIRST, SECOND, ETC. PAYMENT YEAR.—The term 'first payment year' means, with respect to inpatient hospital services furnished by an eligible hospital, the first fiscal year for which an incentive payment is made for such services under this subsection. The terms 'second payment year', 'third payment year', and 'fourth payment year' mean, with respect to an eligible hospital, each successive year immediately following the first payment year for that hospital.

"(3) MEANINGFUL EHR USER.—

"(A) IN GENERAL.—For purposes of paragraph (1), an eligible hospital shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (b)(3)(B)(ix), for an EHR reporting period under such subsection for a fiscal year) if each of the following requirements are met:

"(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the hospital is using certified EHR technology in a meaningful manner.

"(ii) INFORMATION EXCHANGE.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

"(iii) REPORTING ON MEASURES USING EHR.—Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible hospital submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

"(B) REPORTING ON MEASURES.—

"(i) SELECTION.—The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

"(I) The Secretary shall provide preference to clinical quality measures that have been selected for purposes of applying subsection (b)(3)(B)(viii) or that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

Federal Register, publication.

"(II) Prior to any measure (other than a clinical quality measure that has been selected for purposes of applying subsection (b)(3)(B)(viii)) being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

"(ii) LIMITATIONS.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

"(iii) COORDINATION OF REPORTING OF INFORMATION.—In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under subsection (b)(3)(B)(viii).

"(C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—

"(i) IN GENERAL.—An eligible hospital may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

"(I) an attestation;

"(II) the submission of claims with appropriate coding (such as a code indicating that inpatient care was documented using certified EHR technology);

"(III) a survey response;

"(IV) reporting under subparagraph (A)(iii); and

"(V) other means specified by the Secretary.

"(ii) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (A).

"(4) APPLICATION.—

"(A) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (b)(3)(B)(ix), including selection of periods under paragraph (2) for determining, and making estimates or using proxies of, discharges under paragraph (2)(C) and inpatient-bed-days, hospital charges, charity charges, and Medicare share under paragraph (2)(D);

"(ii) the methodology and standards for determining a meaningful EHR user under paragraph (3), including selection of measures under paragraph (3)(B), specification of the means of demonstrating meaningful EHR use under paragraph (3)(C), and the hardship exception under subsection (b)(3)(B)(ix)(II); and

"(iii) the specification of EHR reporting periods under paragraph (6)(B) and the selection of the form of payment under paragraph (2)(F).

"(B) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the eligible hospitals that are meaningful EHR users under this subsection or subsection (b)(3)(B)(ix) (and a list of the names of critical access hospitals to which paragraph (3) or (4) of section 1814(l) applies), and other relevant data as determined appropriate by the Secretary. The Secretary shall ensure that an eligible hospital (or critical access hospital) has the opportunity to review the other relevant data that are to be made public with respect to the hospital (or critical access hospital) prior to such data being made public.

"(5) CERTIFIED EHR TECHNOLOGY DEFINED.—The term 'certified EHR technology' has the meaning given such term in section 1848(o)(4).

"(6) DEFINITIONS.—For purposes of this subsection:

"(A) EHR REPORTING PERIOD.—The term 'EHR reporting period' means, with respect to a payment year, any period (or periods) as specified by the Secretary.

"(B) ELIGIBLE HOSPITAL.—The term 'eligible hospital' means a subsection (d) hospital.".

(2) CRITICAL ACCESS HOSPITALS.—Section 1814(l) of the Social Security Act (42 U.S.C. 1395f(l)) is amended—

(A) in paragraph (1), by striking "paragraph (2)" and inserting "the subsequent paragraphs of this subsection"; and

(B) by adding at the end the following new paragraph:

Regulations. Applicability.

"(3)(A) The following rules shall apply in determining payment and reasonable costs under paragraph (1) for costs described in subparagraph (C) for a critical access hospital that would be a

meaningful EHR user (as would be determined under paragraph (3) of section 1886(n)) for an EHR reporting period for a cost reporting period beginning during a payment year if such critical access hospital was treated as an eligible hospital under such section:

"(i) The Secretary shall compute reasonable costs by expensing such costs in a single payment year and not depreciating such costs over a period of years (and shall include as costs with respect to cost reporting periods beginning during a payment year costs from previous cost reporting periods to the extent they have not been fully depreciated as of the period involved).

"(ii) There shall be substituted for the Medicare share that would otherwise be applied under paragraph (1) a percent (not to exceed 100 percent) equal to the sum of—

"(I) the Medicare share (as would be specified under paragraph (2)(D) of section 1886(n)) for such critical access hospital if such critical access hospital was treated as an eligible hospital under such section; and

"(II) 20 percentage points.

"(B) The payment under this paragraph with respect to a critical access hospital shall be paid through a prompt interim payment (subject to reconciliation) after submission and review of such information (as specified by the Secretary) necessary to make such payment, including information necessary to apply this paragraph. In no case may payment under this paragraph be made with respect to a cost reporting period beginning during a payment year after 2015 and in no case may a critical access hospital receive payment under this paragraph with respect to more than 4 consecutive payment years.

"(C) The costs described in this subparagraph are costs for the purchase of certified EHR technology to which purchase depreciation (excluding interest) would apply if payment was made under paragraph (1) and not under this paragraph.

"(D) For purposes of this paragraph, paragraph (4), and paragraph (5), the terms 'certified EHR technology', 'eligible hospital', 'EHR reporting period', and 'payment year' have the meanings given such terms in sections 1886(n).".

(b) INCENTIVE MARKET BASKET ADJUSTMENT.—

(1) IN GENERAL.—Section 1886(b)(3)(B) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)) is amended—

(A) in clause (viii)(I), by inserting "(or, beginning with fiscal year 2015, by one-quarter)" after "2.0 percentage points"; and

(B) by adding at the end the following new clause:

"(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(A)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period for such fiscal year, three-quarters of the applicable percentage increase otherwise applicable under clause (i) for such fiscal year shall be reduced by 33⅓ percent for fiscal year 2015, 66⅔ percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

Applicability.

"(II) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. In no case may a hospital be granted an exemption under this subclause for more than 5 years.

"(III) For fiscal year 2015 and each subsequent fiscal year, a State in which hospitals are paid for services under section 1814(b)(3) shall adjust the payments to each subsection (d) hospital in the State that is not a meaningful EHR user (as defined in subsection (n)(3)) in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each subsection (d) hospital in the State in a manner comparable to the reduction under the previous provisions of this clause. The State shall report to the Secretary the methodology it will use to make the payment adjustment under the previous sentence. Reports.

"(IV) For purposes of this clause, the term 'EHR reporting period' means, with respect to a fiscal year, any period (or periods) as specified by the Secretary.".

(2) CRITICAL ACCESS HOSPITALS.—Section 1814(l) of the Social Security Act (42 U.S.C. 1395f(l)), as amended by subsection (a)(2), is further amended by adding at the end the following new paragraphs:

"(4)(A) Subject to subparagraph (C), for cost reporting periods beginning in fiscal year 2015 or a subsequent fiscal year, in the case of a critical access hospital that is not a meaningful EHR user (as would be determined under paragraph (3) of section 1886(n) if such critical access hospital was treated as an eligible hospital under such section) for an EHR reporting period with respect to such fiscal year, paragraph (1) shall be applied by substituting the applicable percent under subparagraph (B) for the percent described in such paragraph (1). Applicability.

"(B) The percent described in this subparagraph is— Applicability.

"(i) for fiscal year 2015, 100.66 percent;

"(ii) for fiscal year 2016, 100.33 percent; and

"(iii) for fiscal year 2017 and each subsequent fiscal year, 100 percent.

"(C) The provisions of subclause (II) of section 1886(b)(3)(B)(ix) shall apply with respect to subparagraph (A) for a critical access hospital with respect to a cost reporting period beginning in a fiscal year in the same manner as such subclause applies with respect to subclause (I) of such section for a subsection (d) hospital with respect to such fiscal year.

"(5) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(A) the methodology and standards for determining the amount of payment and reasonable cost under paragraph (3) and payment adjustments under paragraph (4), including selection of periods under section 1886(n)(2) for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and Medicare share under subparagraph (D) of section 1886(n)(2);

"(B) the methodology and standards for determining a meaningful EHR user under section 1886(n)(3) as would apply if the hospital was treated as an eligible hospital under section 1886(n), and the hardship exception under paragraph (4)(C);

"(C) the specification of EHR reporting periods under section 1886(n)(6)(B) as applied under paragraphs (3) and (4); and

"(D) the identification of costs for purposes of paragraph (3)(C).".

(c) APPLICATION TO CERTAIN MA-AFFILIATED ELIGIBLE HOSPITALS.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23), as amended by section 4101(c), is further amended by adding at the end the following new subsection:

"(m) APPLICATION OF ELIGIBLE HOSPITAL INCENTIVES FOR CERTAIN MA ORGANIZATIONS FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

"(1) APPLICATION.—Subject to paragraphs (3) and (4), in the case of a qualifying MA organization, the provisions of sections 1886(n) and 1886(b)(3)(B)(ix) shall apply with respect to eligible hospitals described in paragraph (2) of the organization which the organization attests under subsection (l)(6) to be meaningful EHR users in a similar manner as they apply to eligible hospitals under such sections. Incentive payments under paragraph (3) shall be made to and payment adjustments under paragraph (4) shall apply to such qualifying organizations.

"(2) ELIGIBLE HOSPITAL DESCRIBED.—With respect to a qualifying MA organization, an eligible hospital described in this paragraph is an eligible hospital (as defined in section 1886(n)(6)(A)) that is under common corporate governance with such organization and serves individuals enrolled under an MA plan offered by such organization.

"(3) ELIGIBLE HOSPITAL INCENTIVE PAYMENTS.—

"(A) IN GENERAL.—In applying section 1886(n)(2) under paragraph (1), instead of the additional payment amount under section 1886(n)(2), there shall be substituted an amount determined by the Secretary to be similar to the estimated amount in the aggregate that would be payable if payment for services furnished by such hospitals was payable under part A instead of this part. In implementing the previous sentence, the Secretary—

"(i) shall, insofar as data to determine the discharge related amount under section 1886(n)(2)(C) for an eligible hospital are not available to the Secretary, use such alternative data and methodology to estimate such discharge related amount as the Secretary determines appropriate; and

"(ii) shall, insofar as data to determine the medicare share described in section 1886(n)(2)(D) for an eligible hospital are not available to the Secretary, use such alternative data and methodology to estimate such share, which data and methodology may include use of the inpatient-bed-days (or discharges) with respect to an eligible hospital during the appropriate period which are attributable to both individuals for

whom payment may be made under part A or individuals enrolled in an MA plan under a Medicare Advantage organization under this part as a proportion of the estimated total number of patient-bed-days (or discharges) with respect to such hospital during such period.

"(B) AVOIDING DUPLICATION OF PAYMENTS.—

"(i) IN GENERAL.—In the case of a hospital that for a payment year is an eligible hospital described in paragraph (2) and for which at least one-third of their discharges (or bed-days) of Medicare patients for the year are covered under part A, payment for the payment year shall be made only under section 1886(n) and not under this subsection.

"(ii) METHODS.—In the case of a hospital that is an eligible hospital described in paragraph (2) and also is eligible for an incentive payment under section 1886(n) but is not described in clause (i) for the same payment period, the Secretary shall develop a process—

"(I) to ensure that duplicate payments are not made with respect to an eligible hospital both under this subsection and under section 1886(n); and

"(II) to collect data from Medicare Advantage organizations to ensure against such duplicate payments.

"(4) PAYMENT ADJUSTMENT.—

"(A) Subject to paragraph (3), in the case of a qualifying MA organization (as defined in section 1853(l)(5)), if, according to the attestation of the organization submitted under subsection (l)(6) for an applicable period, one or more eligible hospitals (as defined in section 1886(n)(6)(A)) that are under common corporate governance with such organization and that serve individuals enrolled under a plan offered by such organization are not meaningful EHR users (as defined in section 1886(n)(3)) with respect to a period, the payment amount payable under this section for such organization for such period shall be the percent specified in subparagraph (B) for such period of the payment amount otherwise provided under this section for such period.

"(B) SPECIFIED PERCENT.—The percent specified under this subparagraph for a year is 100 percent minus a number of percentage points equal to the product of—

"(i) the number of the percentage point reduction effected under section 1886(b)(3)(B)(ix)(I) for the period; and

"(ii) the Medicare hospital expenditure proportion specified in subparagraph (C) for the year.

"(C) MEDICARE HOSPITAL EXPENDITURE PROPORTION.—The Medicare hospital expenditure proportion under this subparagraph for a year is the Secretary's estimate of the proportion, of the expenditures under parts A and B that are not attributable to this part, that are attributable to expenditures for inpatient hospital services.

"(D) APPLICATION OF PAYMENT ADJUSTMENT.—In the case that a qualifying MA organization attests that not all eligible hospitals are meaningful EHR users with respect to an applicable period, the Secretary shall apply the payment adjustment under this paragraph based on a methodology specified by the Secretary, taking into account the proportion of such eligible hospitals, or discharges from such hospitals, that are not meaningful EHR users for such period.

"(5) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format—

"(A) a list of the names, business addresses, and business phone numbers of each qualifying MA organization receiving an incentive payment under this subsection for eligible hospitals described in paragraph (2); and

"(B) a list of the names of the eligible hospitals for which such incentive payment is based.

"(6) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(A) the methodology and standards for determining payment amounts and payment adjustments under this subsection, including avoiding duplication of payments under paragraph (3)(B);

"(B) the methodology and standards for determining eligible hospitals under paragraph (2); and

"(C) the methodology and standards for determining a meaningful EHR user under section 1886(n)(3), including specification of the means of demonstrating meaningful EHR use under subparagraph (C) of such section and selection of measures under subparagraph (B) of such section.".

(d) CONFORMING AMENDMENTS.—

(1) Section 1814(b) of the Social Security Act (42 U.S.C. 1395f(b)) is amended—

(A) in paragraph (3), in the matter preceding subparagraph (A), by inserting ", subject to section 1886(d)(3)(B)(ix)(III)," after "then"; and

(B) by adding at the end the following: "For purposes of applying paragraph (3), there shall be taken into account incentive payments, and payment adjustments under subsection (b)(3)(B)(ix) or (n) of section 1886.".

(2) Section 1851(i)(1) of the Social Security Act (42 U.S.C. 1395w–21(i)(1)) is amended by striking "and 1886(h)(3)(D)" and inserting "1886(h)(3)(D), and 1853(m)".

(3) Section 1853 of the Social Security Act (42 U.S.C. 1395w–23), as amended by section 4101(d), is amended—

(A) in subsection (c)—

(i) in paragraph (1)(D)(i), by striking "1848(o)" and inserting ", 1848(o), and 1886(n)"; and

(ii) in paragraph (6)(A), by inserting "and subsections (b)(3)(B)(ix) and (n) of section 1886" after "section 1848"; and

(B) in subsection (f), by inserting "and subsection (m)" after "under subsection (l)".

SEC. 4103. TREATMENT OF PAYMENTS AND SAVINGS; IMPLEMENTATION FUNDING.

(a) PREMIUM HOLD HARMLESS.—

(1) IN GENERAL.—Section 1839(a)(1) of the Social Security Act (42 U.S.C. 1395r(a)(1)) is amended by adding at the end the following: "In applying this paragraph there shall not be taken into account additional payments under section 1848(o) and section 1853(l)(3) and the Government contribution under section 1844(a)(3).".

(2) PAYMENT.—Section 1844(a) of such Act (42 U.S.C. 1395w(a)) is amended—

(A) in paragraph (2), by striking the period at the end and inserting "; plus"; and

(B) by adding at the end the following new paragraph:

"(3) a Government contribution equal to the amount of payment incentives payable under sections 1848(o) and 1853(l)(3).".

(b) MEDICARE IMPROVEMENT FUND.—Section 1898 of the Social Security Act (42 U.S.C. 1395iii), as added by section 7002(a) of the Supplemental Appropriations Act, 2008 (Public Law 110–252) and as amended by section 188(a)(2) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275; 122 Stat. 2589) and by section 6 of the QI Program Supplemental Funding Act of 2008, is amended—

(1) in subsection (a)—

(A) by inserting "medicare" before "fee-for-service"; and

(B) by inserting before the period at the end the following: "including, but not limited to, an increase in the conversion factor under section 1848(d) to address, in whole or in part, any projected shortfall in the conversion factor for 2014 relative to the conversion factor for 2008 and adjustments to payments for items and services furnished by providers of services and suppliers under such original medicare fee-for-service program"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "during fiscal year 2014," and all that follows and inserting the following: "during—

"(A) fiscal year 2014, $22,290,000,000; and

"(B) fiscal year 2020 and each subsequent fiscal year, the Secretary's estimate, as of July 1 of the fiscal year, of the aggregate reduction in expenditures under this title during the preceding fiscal year directly resulting from the reduction in payment amounts under sections 1848(a)(7), 1853(l)(4), 1853(m)(4), and 1886(b)(3)(B)(ix).";

and

(B) by adding at the end the following new paragraph:

"(4) NO EFFECT ON PAYMENTS IN SUBSEQUENT YEARS.—In the case that expenditures from the Fund are applied to, or otherwise affect, a payment rate for an item or service under this title for a year, the payment rate for such item or service shall be computed for a subsequent year as if such application or effect had never occurred.".

(c) IMPLEMENTATION FUNDING.—In addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services for the Center for Medicare & Medicaid Services

Program Management Account, $100,000,000 for each of fiscal years 2009 through 2015 and $45,000,000 for fiscal year 2016, which shall be available for purposes of carrying out the provisions of (and amendments made by) this subtitle. Amounts appropriated under this subsection for a fiscal year shall be available until expended.

SEC. 4104. STUDIES AND REPORTS ON HEALTH INFORMATION TECHNOLOGY.

(a) STUDY AND REPORT ON APPLICATION OF EHR PAYMENT INCENTIVES FOR PROVIDERS NOT RECEIVING OTHER INCENTIVE PAYMENTS.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study to determine the extent to which and manner in which payment incentives (such as under title XVIII or XIX of the Social Security Act) and other funding for purposes of implementing and using certified EHR technology (as defined in section 1848(o)(4) of the Social Security Act, as added by section 4101(a)) should be made available to health care providers who are receiving minimal or no payment incentives or other funding under this Act, under title XIII of division A, under title XVIII or XIX of such Act, or otherwise, for such purposes.

(B) DETAILS OF STUDY.—Such study shall include an examination of—

(i) the adoption rates of certified EHR technology by such health care providers;

(ii) the clinical utility of such technology by such health care providers;

(iii) whether the services furnished by such health care providers are appropriate for or would benefit from the use of such technology;

(iv) the extent to which such health care providers work in settings that might otherwise receive an incentive payment or other funding under this Act, under title XIII of division A, under title XVIII or XIX of the Social Security Act, or otherwise;

(v) the potential costs and the potential benefits of making payment incentives and other funding available to such health care providers; and

(vi) any other issues the Secretary deems to be appropriate.

(2) REPORT.—Not later than June 30, 2010, the Secretary shall submit to Congress a report on the findings and conclusions of the study conducted under paragraph (1).

(b) STUDY AND REPORT ON AVAILABILITY OF OPEN SOURCE HEALTH INFORMATION TECHNOLOGY SYSTEMS.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall, in consultation with the Under Secretary for Health of the Veterans Health Administration, the Director of the Indian Health Service, the Secretary of Defense, the Director of the Agency for Healthcare Research and Quality, the Administrator of the Health Resources and Services Administration, and the Chairman

of the Federal Communications Commission, conduct a study on—

(i) the current availability of open source health information technology systems to Federal safety net providers (including small, rural providers);

(ii) the total cost of ownership of such systems in comparison to the cost of proprietary commercial products available;

(iii) the ability of such systems to respond to the needs of, and be applied to, various populations (including children and disabled individuals); and

(iv) the capacity of such systems to facilitate interoperability.

(B) CONSIDERATIONS.—In conducting the study under subparagraph (A), the Secretary of Health and Human Services shall take into account the circumstances of smaller health care providers, health care providers located in rural or other medically underserved areas, and safety net providers that deliver a significant level of health care to uninsured individuals, Medicaid beneficiaries, SCHIP beneficiaries, and other vulnerable individuals.

(2) REPORT.—Not later than October 1, 2010, the Secretary of Health and Human Services shall submit to Congress a report on the findings and the conclusions of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

Subtitle B—Medicaid Incentives

SEC. 4201. MEDICAID PROVIDER HIT ADOPTION AND OPERATION PAYMENTS; IMPLEMENTATION FUNDING.

(a) IN GENERAL.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(1) in subsection (a)(3)—

(A) by striking "and" at the end of subparagraph (D);

(B) by striking "plus" at the end of subparagraph (E) and inserting "and"; and

(C) by adding at the end the following new subparagraph:

"(F)(i) 100 percent of so much of the sums expended during such quarter as are attributable to payments to Medicaid providers described in subsection (t)(1) to encourage the adoption and use of certified EHR technology; and

"(ii) 90 percent of so much of the sums expended during such quarter as are attributable to payments for reasonable administrative expenses related to the administration of payments described in clause (i) if the State meets the condition described in subsection (t)(9); plus"; and

(2) by inserting after subsection (s) the following new subsection:

"(t)(1) For purposes of subsection (a)(3)(F), the payments described in this paragraph to encourage the adoption and use of certified EHR technology are payments made by the State in accordance with this subsection —

"(A) to Medicaid providers described in paragraph (2)(A) not in excess of 85 percent of net average allowable costs (as defined in paragraph (3)(E)) for certified EHR technology (and support services including maintenance and training that is for, or is necessary for the adoption and operation of, such technology) with respect to such providers; and

"(B) to Medicaid providers described in paragraph (2)(B) not in excess of the maximum amount permitted under paragraph (5) for the provider involved.

Definition.

"(2) In this subsection and subsection (a)(3)(F), the term 'Medicaid provider' means—

"(A) an eligible professional (as defined in paragraph (3)(B))—

"(i) who is not hospital-based and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title;

"(ii) who is not described in clause (i), who is a pediatrician, who is not hospital-based, and who has at least 20 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title; and

"(iii) who practices predominantly in a Federally qualified health center or rural health clinic and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to needy individuals (as defined in paragraph (3)(F)); and

"(B)(i) a children's hospital, or

"(ii) an acute-care hospital that is not described in clause (i) and that has at least 10 percent of the hospital's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title.

An eligible professional shall not qualify as a Medicaid provider under this subsection unless any right to payment under sections 1848(o) and 1853(l) with respect to the eligible professional has been waived in a manner specified by the Secretary. For purposes of calculating patient volume under subparagraph (A)(iii), insofar as it is related to uncompensated care, the Secretary may require the adjustment of such uncompensated care data so that it would be an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care.

Applicability.

In applying subparagraphs (A) and (B)(ii), the methodology established by the Secretary for patient volume shall include individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

Definitions.

"(3) In this subsection and subsection (a)(3)(F):

"(A) The term 'certified EHR technology' means a qualified electronic health record (as defined in 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an

ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

"(B) The term 'eligible professional' means a—

"(i) physician;

"(ii) dentist;

"(iii) certified nurse mid-wife;

"(iv) nurse practitioner; and

"(v) physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led.

"(C) The term 'average allowable costs' means, with respect to certified EHR technology of Medicaid providers described in paragraph (2)(A) for—

"(i) the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology) for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C); and

"(ii) a subsequent year of payment with respect to such a provider, the average costs not described in clause (i) relating to the operation, maintenance, and use of such technology for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C).

"(D) The term 'hospital-based' means, with respect to an eligible professional, a professional (such as a pathologist, anesthesiologist, or emergency physician) who furnishes substantially all of the individual's professional services in a hospital setting (whether inpatient or outpatient) and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

"(E) The term 'net average allowable costs' means, with respect to a Medicaid provider described in paragraph (2)(A), average allowable costs reduced by any payment that is made to such Medicaid provider from any other source (other than under this subsection or by a State or local government) that is directly attributable to payment for certified EHR technology or support services described in subparagraph (C).

"(F) The term 'needy individual' means, with respect to a Medicaid provider, an individual—

"(i) who is receiving assistance under this title;

"(ii) who is receiving assistance under title XXI;

"(iii) who is furnished uncompensated care by the provider; or

"(iv) for whom charges are reduced by the provider on a sliding scale basis based on an individual's ability to pay.

"(4)(A) With respect to a Medicaid provider described in paragraph (2)(A), subject to subparagraph (B), in no case shall—

"(i) the net average allowable costs under this subsection for the first year of payment (which may not be later than 2016), which is intended to cover the costs described in paragraph (3)(C)(i), exceed $25,000 (or such lesser amount as the Secretary determines based on studies conducted under subparagraph (C));

"(ii) the net average allowable costs under this subsection for a subsequent year of payment, which is intended to cover costs described in paragraph (3)(C)(ii), exceed $10,000; and

"(iii) payments be made for costs described in clause (ii) after 2021 or over a period of longer than 5 years.

"(B) In the case of Medicaid provider described in paragraph (2)(A)(ii), the dollar amounts specified in subparagraph (A) shall be ⅔ of the dollar amounts otherwise specified.

Study.

"(C) For the purposes of determining average allowable costs under this subsection, the Secretary shall study the average costs to Medicaid providers described in paragraph (2)(A) of purchase and initial implementation and upgrade of certified EHR technology described in paragraph (3)(C)(i) and the average costs to such providers of operations, maintenance, and use of such technology described in paragraph (3)(C)(ii). In determining such costs for such providers, the Secretary may utilize studies of such amounts submitted by States.

"(5)(A) In no case shall the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) exceed—

"(i) in the aggregate the product of—

"(I) the overall hospital EHR amount for the provider computed under subparagraph (B); and

"(II) the Medicaid share for such provider computed under subparagraph (C);

"(ii) in any year 50 percent of the product described in clause (i); and

"(iii) in any 2-year period 90 percent of such product.

"(B) For purposes of this paragraph, the overall hospital EHR amount, with respect to a Medicaid provider, is the sum of the applicable amounts specified in section 1886(n)(2)(A) for such provider for the first 4 payment years (as estimated by the Secretary) determined as if the Medicare share specified in clause (ii) of such section were 1. The Secretary shall establish, in consultation with the State, the overall hospital EHR amount for each such Medicaid provider eligible for payments under paragraph (1)(B). For purposes of this subparagraph in computing the amounts under section 1886(n)(2)(C) for payment years after the first payment year, the Secretary shall assume that in subsequent payment years discharges increase at the average annual rate of growth of the most recent 3 years for which discharge data are available per year.

"(C) The Medicaid share computed under this subparagraph, for a Medicaid provider for a period specified by the Secretary, shall be calculated in the same manner as the Medicare share under section 1886(n)(2)(D) for such a hospital and period, except that there shall be substituted for the numerator under clause (i) of such section the amount that is equal to the number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals who are receiving medical assistance

under this title and who are not described in section 1886(n)(2)(D)(i). In computing inpatient-bed-days under the previous sentence, the Secretary shall take into account inpatient-bed-days attributable to inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

"(D) In no case may the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) be paid—

"(i) for any year beginning after 2016 unless the provider has been provided payment under paragraph (1)(B) for the previous year; and

"(ii) over a period of more than 6 years of payment.

"(6) Payments described in paragraph (1) are not in accordance with this subsection unless the following requirements are met:

"(A)(i) The State provides assurances satisfactory to the Secretary that amounts received under subsection (a)(3)(F) with respect to payments to a Medicaid provider are paid, subject to clause (ii), directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

"(ii) Amounts described in clause (i) may also be paid to an entity promoting the adoption of certified EHR technology, as designated by the State, if participation in such a payment arrangement is voluntary for the eligible professional involved and if such entity does not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

"(B) A Medicaid provider described in paragraph (2)(A) is responsible for payment of the remaining 15 percent of the net average allowable cost.

"(C)(i) Subject to clause (ii), with respect to payments to a Medicaid provider—

"(I) for the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates that it is engaged in efforts to adopt, implement, or upgrade certified EHR technology; and

"(II) for a year of payment, other than the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n).

"(ii) In the case of a Medicaid provider who has completed adopting, implementing, or upgrading such technology prior to the first year of payment to the Medicaid provider under this subsection, clause (i)(I) shall not apply and clause (i)(II) shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.

"(D) To the extent specified by the Secretary, the certified EHR technology is compatible with State or Federal administrative management systems.

For purposes of subparagraph (B), a Medicaid provider described in paragraph (2)(A) may accept payments for the costs described

in such subparagraph from a State or local government. For purposes of subparagraph (C), in establishing the means described in such subparagraph, which may include clinical quality reporting to the State, the State shall ensure that populations with unique needs, such as children, are appropriately addressed.

"(7) With respect to Medicaid providers described in paragraph (2)(A), the Secretary shall ensure coordination of payment with respect to such providers under sections 1848(o) and 1853(l) and under this subsection to assure no duplication of funding. Such coordination shall include, to the extent practicable, a data matching process between State Medicaid agencies and the Centers for Medicare & Medicaid Services using national provider identifiers. For such purposes, the Secretary may require the submission of such data relating to payments to such Medicaid providers as the Secretary may specify.

"(8) In carrying out paragraph (6)(C), the State and Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XVIII. In doing so, the Secretary may deem satisfaction of requirements for such meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under this subsection. The Secretary may also specify the reporting periods under this subsection in order to carry out this paragraph.

"(9) In order to be provided Federal financial participation under subsection (a)(3)(F)(ii), a State must demonstrate to the satisfaction of the Secretary, that the State—

"(A) is using the funds provided for the purposes of administering payments under this subsection, including tracking of meaningful use by Medicaid providers;

"(B) is conducting adequate oversight of the program under this subsection, including routine tracking of meaningful use attestations and reporting mechanisms; and

"(C) is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.

Reports.

"(10) The Secretary shall periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on status, progress, and oversight of payments described in paragraph (1), including steps taken to carry out paragraph (7). Such reports shall also describe the extent of adoption of certified EHR technology among Medicaid providers resulting from the provisions of this subsection and any improvements in health outcomes, clinical quality, or efficiency resulting from such adoption.".

(b) IMPLEMENTATION FUNDING.—In addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services for the Centers for Medicare & Medicaid Services Program Management Account, $40,000,000 for each of fiscal years 2009 through 2015 and $20,000,000 for fiscal year 2016, which shall be available for purposes of carrying out the provisions of (and the amendments made by) this section. Amounts appropriated under this subsection for a fiscal year shall be available until expended.

Subtitle C—Miscellaneous Medicare Provisions

SEC. 4301. MORATORIA ON CERTAIN MEDICARE REGULATIONS.

(a) DELAY IN PHASE OUT OF MEDICARE HOSPICE BUDGET NEUTRALITY ADJUSTMENT FACTOR DURING FISCAL YEAR 2009.—Notwithstanding any other provision of law, including the final rule published on August 8, 2008, 73 Federal Register 46464 et seq., relating to Medicare Program; Hospice Wage Index for Fiscal Year 2009, the Secretary of Health and Human Services shall not phase out or eliminate the budget neutrality adjustment factor in the Medicare hospice wage index before October 1, 2009, and the Secretary shall recompute and apply the final Medicare hospice wage index for fiscal year 2009 as if there had been no reduction in the budget neutrality adjustment factor.

(b) NON-APPLICATION OF PHASED-OUT INDIRECT MEDICAL EDUCATION (IME) ADJUSTMENT FACTOR FOR FISCAL YEAR 2009.—

Applicability.

(1) IN GENERAL.—Section 412.322 of title 42, Code of Federal Regulations, shall be applied without regard to paragraph (c) of such section, and the Secretary of Health and Human Services shall recompute payments for discharges occurring on or after October 1, 2008, as if such paragraph had never been in effect.

(2) NO EFFECT ON SUBSEQUENT YEARS.—Nothing in paragraph (1) shall be construed as having any effect on the application of paragraph (d) of section 412.322 of title 42, Code of Federal Regulations.

(c) FUNDING FOR IMPLEMENTATION.—In addition to funds otherwise available, for purposes of implementing the provisions of subsections (a) and (b), including costs incurred in reprocessing claims in carrying out such provisions, the Secretary of Health and Human Services shall provide for the transfer from the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i) to the Centers for Medicare & Medicaid Services Program Management Account of $2,000,000 for fiscal year 2009.

SEC. 4302. LONG-TERM CARE HOSPITAL TECHNICAL CORRECTIONS.

(a) PAYMENT.—Subsection (c) of section 114 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173) is amended—

42 USC 1395ww note.

(1) in paragraph (1)—

(A) by amending the heading to read as follows: "DELAY IN APPLICATION OF 25 PERCENT PATIENT THRESHOLD PAYMENT ADJUSTMENT";

(B) by striking "the date of the enactment of this Act" and inserting "July 1, 2007,"; and

(C) in subparagraph (A), by inserting "or to a long-term care hospital, or satellite facility, that as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Social Security Act at the off-campus location" after "freestanding long-term care hospitals"; and

(2) in paragraph (2)—

(A) in subparagraph (B)(ii), by inserting "or that is described in section 412.22(h)(3)(i) of such title" before the period; and

(B) in subparagraph (C), by striking "the date of the enactment of this Act" and inserting "October 1, 2007 (or July 1, 2007, in the case of a satellite facility described in section 412.22(h)(3)(i) of title 42, Code of Federal Regulations)".

(b) MORATORIUM.—Subsection (d)(3)(A) of such section is amended by striking "if the hospital or facility" and inserting "if the hospital or facility obtained a certificate of need for an increase in beds that is in a State for which such certificate of need is required and that was issued on or after April 1, 2005, and before December 29, 2007, or if the hospital or facility".

42 USC 1395ww note.

(c) EFFECTIVE DATE.—The amendments made by this section shall be effective and apply as if included in the enactment of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173).

TITLE V—STATE FISCAL RELIEF

SEC. 5000. PURPOSES; TABLE OF CONTENTS.

42 USC 1396a note.

(a) PURPOSES.—The purposes of this title are as follows:

(1) To provide fiscal relief to States in a period of economic downturn.

(2) To protect and maintain State Medicaid programs during a period of economic downturn, including by helping to avert cuts to provider payment rates and benefits or services, and to prevent constrictions of income eligibility requirements for such programs, but not to promote increases in such requirements.

(b) TABLE OF CONTENTS.—The table of contents for this title is as follows:

TITLE V—STATE FISCAL RELIEF

Sec. 5000. Purposes; table of contents.
Sec. 5001. Temporary increase of Medicaid FMAP.
Sec. 5002. Temporary increase in DSH allotments during recession.
Sec. 5003. Extension of moratoria on certain Medicaid final regulations.
Sec. 5004. Extension of transitional medical assistance (TMA).
Sec. 5005. Extension of the qualifying individual (QI) program.
Sec. 5006. Protections for Indians under Medicaid and CHIP.
Sec. 5007. Funding for oversight and implementation.
Sec. 5008. GAO study and report regarding State needs during periods of national economic downturn.

42 USC 1396d note.

SEC. 5001. TEMPORARY INCREASE OF MEDICAID FMAP.

(a) PERMITTING MAINTENANCE OF FMAP.—Subject to subsections (e), (f), and (g), if the FMAP determined without regard to this section for a State for—

(1) fiscal year 2009 is less than the FMAP as so determined for fiscal year 2008, the FMAP for the State for fiscal year 2008 shall be substituted for the State's FMAP for fiscal year 2009, before the application of this section;

(2) fiscal year 2010 is less than the FMAP as so determined for fiscal year 2008 or fiscal year 2009 (after the application of paragraph (1)), the greater of such FMAP for the State for fiscal year 2008 or fiscal year 2009 shall be substituted

for the State's FMAP for fiscal year 2010, before the application of this section; and

(3) fiscal year 2011 is less than the FMAP as so determined for fiscal year 2008, fiscal year 2009 (after the application of paragraph (1)), or fiscal year 2010 (after the application of paragraph (2)), the greatest of such FMAP for the State for fiscal year 2008, fiscal year 2009, or fiscal year 2010 shall be substituted for the State's FMAP for fiscal year 2011, before the application of this section, but only for the first calendar quarter in fiscal year 2011.

(b) GENERAL 6.2 PERCENTAGE POINT INCREASE.—

(1) IN GENERAL.—Subject to subsections (e), (f), and (g) and paragraph (2), for each State for calendar quarters during the recession adjustment period (as defined in subsection (h)(3)), the FMAP (after the application of subsection (a)) shall be increased (without regard to any limitation otherwise specified in section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b))) by 6.2 percentage points.

Applicability.

(2) SPECIAL ELECTION FOR TERRITORIES.—In the case of a State that is not one of the 50 States or the District of Columbia, paragraph (1) shall only apply if the State makes a one-time election, in a form and manner specified by the Secretary and for the entire recession adjustment period, to apply the increase in FMAP under paragraph (1) and a 15 percent increase under subsection (d) instead of applying a 30 percent increase under subsection (d).

(c) ADDITIONAL RELIEF BASED ON INCREASE IN UNEMPLOYMENT.—

(1) IN GENERAL.—Subject to subsections (e), (f), and (g), if a State is a qualifying State under paragraph (2) for a calendar quarter occurring during the recession adjustment period, the FMAP for the State shall be further increased by the number of percentage points equal to the product of—

(A) the State percentage applicable for the State under section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) after the application of subsection (a) and after the application of ½ of the increase under subsection (b); and

(B) the applicable percent determined in paragraph (3) for the calendar quarter (or, if greater, for a previous such calendar quarter).

(2) QUALIFYING CRITERIA.—

(A) IN GENERAL.—For purposes of paragraph (1), a State qualifies for additional relief under this subsection for a calendar quarter occurring during the recession adjustment period if the State is 1 of the 50 States or the District of Columbia and the State satisfies any of the following criteria for the quarter:

(i) The State unemployment increase percentage (as defined in paragraph (4)) for the quarter is at least 1.5 percentage points but less than 2.5 percentage points.

(ii) The State unemployment increase percentage for the quarter is at least 2.5 percentage points but less than 3.5 percentage points.

(iii) The State unemployment increase percentage for the quarter is at least 3.5 percentage points.

(B) MAINTENANCE OF STATUS.—If a State qualifies for additional relief under this subsection for a calendar quarter, it shall be deemed to have qualified for such relief for each subsequent calendar quarter ending before July 1, 2010.

(3) APPLICABLE PERCENT.—

(A) IN GENERAL.—For purposes of paragraph (1), subject to subparagraph (B), the applicable percent is—

(i) 5.5 percent, if the State satisfies the criteria described in paragraph (2)(A)(i) for the calendar quarter;

(ii) 8.5 percent if the State satisfies the criteria described in paragraph (2)(A)(ii) for the calendar quarter; and

(iii) 11.5 percent if the State satisfies the criteria described in paragraph (2)(A)(iii) for the calendar quarter.

(B) MAINTENANCE OF HIGHER APPLICABLE PERCENT.—

(i) HOLD HARMLESS PERIOD.—If the percent applied to a State under subparagraph (A) for any calendar quarter in the recession adjustment period beginning on or after January 1, 2009, and ending before July 1, 2010, (determined without regard to this subparagraph) is less than the percent applied for the preceding quarter (as so determined), the higher applicable percent shall continue in effect for each subsequent calendar quarter ending before July 1, 2010.

Deadline.

(ii) NOTICE OF LOWER APPLICABLE PERCENT.—The Secretary shall notify a State at least 60 days prior to applying any lower applicable percent to the State under this paragraph.

(4) COMPUTATION OF STATE UNEMPLOYMENT INCREASE PERCENTAGE.—

(A) IN GENERAL.—In this subsection, the "State unemployment increase percentage" for a State for a calendar quarter is equal to the number of percentage points (if any) by which—

(i) the average monthly unemployment rate for the State for months in the most recent previous 3-consecutive-month period for which data are available, subject to subparagraph (C); exceeds

(ii) the lowest average monthly unemployment rate for the State for any 3-consecutive-month period preceding the period described in clause (i) and beginning on or after January 1, 2006.

(B) AVERAGE MONTHLY UNEMPLOYMENT RATE DEFINED.—In this paragraph, the term "average monthly unemployment rate" means the average of the monthly number unemployed, divided by the average of the monthly civilian labor force, seasonally adjusted, as determined based on the most recent monthly publications of the Bureau of Labor Statistics of the Department of Labor.

(C) SPECIAL RULE.—With respect to—

(i) the first 2 calendar quarters of the recession adjustment period, the most recent previous 3-consecutive-month period described in subparagraph (A)(i)

shall be the 3-consecutive-month period beginning with October 2008; and

(ii) the last 2 calendar quarters of the recession adjustment period, the most recent previous 3-consecutive-month period described in such subparagraph shall be the 3-consecutive-month period beginning with December 2009, or, if it results in a higher applicable percent under paragraph (3), the 3-consecutive-month period beginning with January 2010.

(d) INCREASE IN CAP ON MEDICAID PAYMENTS TO TERRITORIES.—Subject to subsections (f) and (g), with respect to entire fiscal years occurring during the recession adjustment period and with respect to fiscal years only a portion of which occurs during such period (and in proportion to the portion of the fiscal year that occurs during such period), the amounts otherwise determined for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under subsections (f) and (g) of section 1108 of the Social Security Act (42 6 U.S.C. 1308) shall each be increased by 30 percent (or, in the case of an election under subsection (b)(2), 15 percent). In the case of such an election by a territory, subsection (a)(1) of such section shall be applied without regard to any increase in payment made to the territory under part E of title IV of such Act that is attributable to the increase in FMAP effected under subsection (b) for the territory.

Applicability.

(e) SCOPE OF APPLICATION.—The increases in the FMAP for a State under this section shall apply for purposes of title XIX of the Social Security Act and shall not apply with respect to—

(1) disproportionate share hospital payments described in section 1923 of such Act (42 U.S.C. 1396r–4);

(2) payments under title IV of such Act (42 U.S.C. 601 et seq.) (except that the increases under subsections (a) and (b) shall apply to payments under part E of title IV of such Act (42 U.S.C. 670 et seq.) and, for purposes of the application of this section to the District of Columbia, payments under such part shall be deemed to be made on the basis of the FMAP applied with respect to such District for purposes of title XIX and as increased under subsection (b));

(3) payments under title XXI of such Act (42 U.S.C. 1397aa et seq.);

(4) any payments under title XIX of such Act that are based on the enhanced FMAP described in section 2105(b) of such Act (42 U.S.C. 1397ee(b)); or

(5) any payments under title XIX of such Act that are attributable to expenditures for medical assistance provided to individuals made eligible under a State plan under title XIX of the Social Security Act (including under any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)) because of income standards (expressed as a percentage of the poverty line) for eligibility for medical assistance that are higher than the income standards (as so expressed) for such eligibility as in effect on July 1, 2008, (including as such standards were proposed to be in effect under a State law enacted but not effective as of such date or a State plan amendment or waiver request under title XIX of such Act that was pending approval on such date).

(f) STATE INELIGIBILITY; LIMITATION; SPECIAL RULES.—

(1) MAINTENANCE OF ELIGIBILITY REQUIREMENTS.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), a State is not eligible for an increase in its FMAP under subsection (a), (b), or (c), or an increase in a cap amount under subsection (d), if eligibility standards, methodologies, or procedures under its State plan under title XIX of the Social Security Act (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)) are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on July 1, 2008.

(B) STATE REINSTATEMENT OF ELIGIBILITY PERMITTED.—Subject to subparagraph (C), a State that has restricted eligibility standards, methodologies, or procedures under its State plan under title XIX of the Social Security Act (including any waiver under such title or under section 1115 of such Act (42 U.S.C. 1315)) after July 1, 2008, is no longer ineligible under subparagraph (A) beginning with the first calendar quarter in which the State has reinstated eligibility standards, methodologies, or procedures that are no more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on July 1, 2008.

(C) SPECIAL RULES.—A State shall not be ineligible under subparagraph (A)—

(i) for the calendar quarters before July 1, 2009, on the basis of a restriction that was applied after July 1, 2008, and before the date of the enactment of this Act, if the State prior to July 1, 2009, has reinstated eligibility standards, methodologies, or procedures that are no more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on July 1, 2008; or

(ii) on the basis of a restriction that was directed to be made under State law as in effect on July 1, 2008, and would have been in effect as of such date, but for a delay in the effective date of a waiver under section 1115 of such Act with respect to such restriction.

(2) COMPLIANCE WITH PROMPT PAY REQUIREMENTS.—

(A) APPLICATION TO PRACTITIONERS.—

(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, no State shall be eligible for an increased FMAP rate as provided under this section for any claim received by a State from a practitioner subject to the terms of section 1902(a)(37)(A) of the Social Security Act (42 U.S.C. 1396a(a)(37)(A)) for such days during any period in which that State has failed to pay claims in accordance with such section as applied under title XIX of such Act.

(ii) REPORTING REQUIREMENT.—Each State shall report to the Secretary, on a quarterly basis, its compliance with the requirements of clause (i) as such requirements pertain to claims made for covered services during each month of the preceding quarter.

(iii) WAIVER AUTHORITY.—The Secretary may waive the application of clause (i) to a State, or the

reporting requirement imposed under clause (ii), during any period in which there are exigent circumstances, including natural disasters, that prevent the timely processing of claims or the submission of such a report.

(iv) APPLICATION TO CLAIMS.—Clauses (i) and (ii) shall only apply to claims made for covered services after the date of enactment of this Act.

(B) APPLICATION TO NURSING FACILITIES AND HOSPITALS.—

(i) IN GENERAL.—Subject to clause (ii), the provisions of subparagraph (A) shall apply with respect to a nursing facility or hospital, insofar as it is paid under title XIX of the Social Security Act on the basis of submission of claims, in the same or similar manner (but within the same timeframe) as such provisions apply to practitioners described in such subparagraph.

(ii) GRACE PERIOD.—Notwithstanding clause (i), no period of ineligibility shall be imposed against a State prior to June 1, 2009, on the basis of the State failing to pay a claim in accordance with such clause.

(3) STATE'S APPLICATION TOWARD RAINY DAY FUND.—A State is not eligible for an increase in its FMAP under subsection (b) or (c), or an increase in a cap amount under subsection (d), if any amounts attributable (directly or indirectly) to such increase are deposited or credited into any reserve or rainy day fund of the State.

(4) NO WAIVER AUTHORITY.—Except as provided in paragraph (2)(A)(iii), the Secretary may not waive the application of this subsection or subsection (g) under section 1115 of the Social Security Act or otherwise.

(5) LIMITATION OF FMAP TO 100 PERCENT.—In no case shall an increase in FMAP under this section result in an FMAP that exceeds 100 percent.

Time period.

(6) TREATMENT OF CERTAIN EXPENDITURES.—With respect to expenditures described in section 2105(a)(1)(B) of the Social Security Act (42 U.S.C. 1397ee(a)(1)(B)), as in effect before April 1, 2009, that are made during the period beginning on October 1, 2008, and ending on March 31, 2009, any additional Federal funds that are paid to a State as a result of this section that are attributable to such expenditures shall not be counted against any allotment under section 2104 of such Act (42 U.S.C. 1397dd).

(g) REQUIREMENTS.—

(1) STATE REPORTS.—Each State that is paid additional Federal funds as a result of this section shall, not later than September 30, 2011, submit a report to the Secretary, in such form and such manner as the Secretary shall determine, regarding how the additional Federal funds were expended.

(2) ADDITIONAL REQUIREMENT FOR CERTAIN STATES.—In the case of a State that requires political subdivisions within the State to contribute toward the non-Federal share of expenditures under the State Medicaid plan required under section 1902(a)(2) of the Social Security Act (42 U.S.C. 1396a(a)(2)), the State is not eligible for an increase in its FMAP under subsection (b) or (c), or an increase in a cap amount under subsection (d), if it requires that such political subdivisions

pay for quarters during the recession adjustment period a greater percentage of the non-Federal share of such expenditures, or a greater percentage of the non-Federal share of payments under section 1923, than the respective percentage that would have been required by the State under such plan on September 30, 2008, prior to application of this section.

(h) DEFINITIONS.—In this section, except as otherwise provided:

(1) FMAP.—The term "FMAP" means the Federal medical assistance percentage, as defined in section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)), as determined without regard to this section except as otherwise specified.

(2) POVERTY LINE.—The term "poverty line" has the meaning given such term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

(3) RECESSION ADJUSTMENT PERIOD.—The term "recession adjustment period" means the period beginning on October 1, 2008, and ending on December 31, 2010.

(4) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(5) STATE.—The term "State" has the meaning given such term in section 1101(a)(1) of the Social Security Act (42 U.S.C. 1301(a)(1)) for purposes of title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(i) SUNSET.—This section shall not apply to items and services furnished after the end of the recession adjustment period.

(j) LIMITATION ON FMAP CHANGE.—The increase in FMAP effected under section 614 of the Children's Health Insurance Program Reauthorization Act of 2009 shall not apply in the computation of the enhanced FMAP under title XXI or XIX of the Social Security Act for any period (notwithstanding subsection (i)).

SEC. 5002. TEMPORARY INCREASE IN DSH ALLOTMENTS DURING RECESSION.

Section 1923(f)(3) of the Social Security Act (42 U.S.C. 1396r–4(f)(3)) is amended—

(1) in subparagraph (A), by striking "paragraph (6)" and inserting "paragraph (6) and subparagraph (E)"; and

(2) by adding at the end the following new subparagraph:

"(E) TEMPORARY INCREASE IN ALLOTMENTS DURING RECESSION.—

"(i) IN GENERAL.—Subject to clause (ii), the DSH allotment for any State—

"(I) for fiscal year 2009 is equal to 102.5 percent of the DSH allotment that would be determined under this paragraph for the State for fiscal year 2009 without application of this subparagraph, notwithstanding subparagraphs (B) and (C);

"(II) for fiscal year 2010 is equal to 102.5 percent of the DSH allotment for the State for fiscal year 2009, as determined under subclause (I); and

"(III) for each succeeding fiscal year is equal to the DSH allotment for the State under this paragraph determined without applying subclauses (I) and (II).

"(ii) APPLICATION.—Clause (i) shall not apply to a State for a year in the case that the DSH allotment for such State for such year under this paragraph determined without applying clause (i) would grow higher than the DSH allotment specified under clause (i) for the State for such year.".

SEC. 5003. EXTENSION OF MORATORIA ON CERTAIN MEDICAID FINAL REGULATIONS.

(a) FINAL REGULATIONS RELATING TO OPTIONAL CASE MANAGEMENT SERVICES AND ALLOWABLE PROVIDER TAXES.—Section 7001(a)(3)(A) of the Supplemental Appropriations Act, 2008 (Public Law 110–252) is amended by striking "April 1, 2009" and inserting "July 1, 2009".

(b) FINAL REGULATION RELATING TO SCHOOL-BASED ADMINISTRATION AND SCHOOL-BASED TRANSPORTATION.—Section 206 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173), as amended by section 7001(a)(2) of the Supplemental Appropriations Act, 2008 (Public Law 110–252), is amended by inserting "(July 1, 2009, in the case of the final regulation relating to school-based administration and school-based transportation)" after "April 1, 2009,".

(c) FINAL REGULATION RELATING TO OUTPATIENT HOSPITAL FACILITY SERVICES.—Notwithstanding any other provision of law, with respect to expenditures for services furnished during the period beginning on December 8, 2008, and ending on June 30, 2009, the Secretary of Health and Human Services shall not take any action (through promulgation of regulation, issuance of regulatory guidance, use of Federal payment audit procedures, or other administrative action, policy, or practice, including a Medical Assistance Manual transmittal or letter to State Medicaid directors) to implement the final regulation relating to clarification of the definition of outpatient hospital facility services under the Medicaid program published on November 7, 2008 (73 Federal Register 66187). Time period.

(d) SENSE OF CONGRESS.—It is the sense of Congress that the Secretary of Health and Human Services should not promulgate as final regulations any of the following proposed Medicaid regulations:

(1) COST LIMITS FOR CERTAIN PROVIDERS.—The proposed regulation published on January 18, 2007, (72 Federal Register 2236) (and the purported final regulation published on May 29, 2007 (72 Federal Register 29748) and determined by the United States District Court for the District of Columbia to have been "improperly promulgated", *Alameda County Medical Center, et al., v. Leavitt, et al.,* Civil Action No. 08-0422, Mem. at 4 (D.D.C. May 23, 2008)).

(2) PAYMENTS FOR GRADUATE MEDICAL EDUCATION.—The proposed regulation published on May 23, 2007 (72 Federal Register 28930).

(3) REHABILITATIVE SERVICES.—The proposed regulation published on August 13, 2007 (72 Federal Register 45201).

SEC. 5004. EXTENSION OF TRANSITIONAL MEDICAL ASSISTANCE (TMA).

(a) 18-MONTH EXTENSION.—

(1) IN GENERAL.—Sections 1902(e)(1)(B) and 1925(f) of the Social Security Act (42 U.S.C. 1396a(e)(1)(B), 1396r–6(f)) are

each amended by striking "September 30, 2003" and inserting "December 31, 2010".

42 USC 1396a note.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on July 1, 2009.

(b) STATE OPTION OF INITIAL 12-MONTH ELIGIBILITY.—Section 1925 of the Social Security Act (42 U.S.C. 1396r–6) is amended—

(1) in subsection (a)(1), by inserting "but subject to paragraph (5)" after "Notwithstanding any other provision of this title";

(2) by adding at the end of subsection (a) the following:

"(5) OPTION OF 12-MONTH INITIAL ELIGIBILITY PERIOD.—A State may elect to treat any reference in this subsection to a 6-month period (or 6 months) as a reference to a 12-month period (or 12 months). In the case of such an election, subsection (b) shall not apply."; and

(3) in subsection (b)(1), by inserting "but subject to subsection (a)(5)" after "Notwithstanding any other provision of this title".

(c) REMOVAL OF REQUIREMENT FOR PREVIOUS RECEIPT OF MEDICAL ASSISTANCE.—Section 1925(a)(1) of such Act (42 U.S.C. 1396r–6(a)(1)), as amended by subsection (b)(1), is further amended—

(1) by inserting "subparagraph (B) and" before "paragraph (5)";

(2) by redesignating the matter after "REQUIREMENT.—" as a subparagraph (A) with the heading "IN GENERAL.—" and with the same indentation as subparagraph (B) (as added by paragraph (3)); and

(3) by adding at the end the following:

"(B) STATE OPTION TO WAIVE REQUIREMENT FOR 3 MONTHS BEFORE RECEIPT OF MEDICAL ASSISTANCE.—A State may, at its option, elect also to apply subparagraph (A) in the case of a family that was receiving such aid for fewer than three months or that had applied for and was eligible for such aid for fewer than 3 months during the 6 immediately preceding months described in such subparagraph.".

(d) CMS REPORT ON ENROLLMENT AND PARTICIPATION RATES UNDER TMA.—Section 1925 of such Act (42 U.S.C. 1396r–6), as amended by this section, is further amended by adding at the end the following new subsection:

"(g) COLLECTION AND REPORTING OF PARTICIPATION INFORMATION.—

"(1) COLLECTION OF INFORMATION FROM STATES.—Each State shall collect and submit to the Secretary (and make publicly available), in a format specified by the Secretary, information on average monthly enrollment and average monthly participation rates for adults and children under this section and of the number and percentage of children who become ineligible for medical assistance under this section whose medical assistance is continued under another eligibility category or who are enrolled under the State's child health plan under title XXI. Such information shall be submitted at the same time and frequency in which other enrollment information under this title is submitted to the Secretary.

"(2) ANNUAL REPORTS TO CONGRESS.—Using the information submitted under paragraph (1), the Secretary shall submit

to Congress annual reports concerning enrollment and participation rates described in such paragraph.".

(e) EFFECTIVE DATE.—The amendments made by subsections (b) through (d) shall take effect on July 1, 2009. 42 USC 1396r–6 note.

SEC. 5005. EXTENSION OF THE QUALIFYING INDIVIDUAL (QI) PROGRAM.

(a) EXTENSION.—Section 1902(a)(10)(E)(iv) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)(iv)) is amended by striking "December 2009" and inserting "December 2010".

(b) EXTENDING TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—Section 1933(g) of such Act (42 U.S.C. 1396u–3(g)) is amended—

(1) in paragraph (2)—

(A) by striking "and" at the end of subparagraph (K);

(B) in subparagraph (L), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new subparagraphs:

"(M) for the period that begins on January 1, 2010, and ends on September 30, 2010, the total allocation amount is $412,500,000; and Time period.

"(N) for the period that begins on October 1, 2010, and ends on December 31, 2010, the total allocation amount is $150,000,000."; and Time period.

(2) in paragraph (3), in the matter preceding subparagraph (A), by striking "or (L)" and inserting "(L), or (N)".

SEC. 5006. PROTECTIONS FOR INDIANS UNDER MEDICAID AND CHIP.

(a) PREMIUMS AND COST SHARING PROTECTION UNDER MEDICAID.—

(1) IN GENERAL.—Section 1916 of the Social Security Act (42 U.S.C. 1396o) is amended—

(A) in subsection (a), in the matter preceding paragraph (1), by striking "and (i)" and inserting ", (i), and (j)"; and

(B) by adding at the end the following new subsection:

"(j) NO PREMIUMS OR COST SHARING FOR INDIANS FURNISHED ITEMS OR SERVICES DIRECTLY BY INDIAN HEALTH PROGRAMS OR THROUGH REFERRAL UNDER CONTRACT HEALTH SERVICES.—

"(1) NO COST SHARING FOR ITEMS OR SERVICES FURNISHED TO INDIANS THROUGH INDIAN HEALTH PROGRAMS.—

"(A) IN GENERAL.—No enrollment fee, premium, or similar charge, and no deduction, copayment, cost sharing, or similar charge shall be imposed against an Indian who is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization or through referral under contract health services for which payment may be made under this title.

"(B) NO REDUCTION IN AMOUNT OF PAYMENT TO INDIAN HEALTH PROVIDERS.—Payment due under this title to the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or a health care provider through referral under contract health services for the furnishing of an item or service to an Indian who is eligible for assistance under such title, may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deduction, copayment, cost

sharing, or similar charge that would be due from the Indian but for the operation of subparagraph (A).

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as restricting the application of any other limitations on the imposition of premiums or cost sharing that may apply to an individual receiving medical assistance under this title who is an Indian.".

(2) CONFORMING AMENDMENT.—Section 1916A(b)(3) of such Act (42 U.S.C. 1396o–1(b)(3)) is amended—

(A) in subparagraph (A), by adding at the end the following new clause:

"(vii) An Indian who is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization or Urban Indian Organization or through referral under contract health services."; and

(B) in subparagraph (B), by adding at the end the following new clause:

"(x) Items and services furnished to an Indian directly by the Indian Health Service, an Indian Tribe, Tribal Organization or Urban Indian Organization or through referral under contract health services.".

(b) TREATMENT OF CERTAIN PROPERTY FROM RESOURCES FOR MEDICAID AND CHIP ELIGIBILITY.—

(1) MEDICAID.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by sections 203(c) and 211(a)(1)(A)(ii) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3), is amended by adding at the end the following new subsection:

"(ff) Notwithstanding any other requirement of this title or any other provision of Federal or State law, a State shall disregard the following property from resources for purposes of determining the eligibility of an individual who is an Indian for medical assistance under this title:

"(1) Property, including real property and improvements, that is held in trust, subject to Federal restrictions, or otherwise under the supervision of the Secretary of the Interior, located on a reservation, including any federally recognized Indian Tribe's reservation, pueblo, or colony, including former reservations in Oklahoma, Alaska Native regions established by the Alaska Native Claims Settlement Act, and Indian allotments on or near a reservation as designated and approved by the Bureau of Indian Affairs of the Department of the Interior.

"(2) For any federally recognized Tribe not described in paragraph (1), property located within the most recent boundaries of a prior Federal reservation.

"(3) Ownership interests in rents, leases, royalties, or usage rights related to natural resources (including extraction of natural resources or harvesting of timber, other plants and plant products, animals, fish, and shellfish) resulting from the exercise of federally protected rights.

"(4) Ownership interests in or usage rights to items not covered by paragraphs (1) through (3) that have unique religious, spiritual, traditional, or cultural significance or rights that support subsistence or a traditional lifestyle according to applicable tribal law or custom.".

(2) APPLICATION TO CHIP.—Section 2107(e)(1) of such Act (42 U.S.C. 1397gg(e)(1)), as amended by sections 203(a)(2),

203(d)(2), 214(b), 501(d)(2), and 503(a)(1) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3), is amended—

(A) by redesignating subparagraphs (C) through (I), as subparagraphs (D) through (J), respectively; and

(B) by inserting after subparagraph (B), the following new subparagraph:

"(C) Section 1902(ff) (relating to disregard of certain property for purposes of making eligibility determinations).".

(c) CONTINUATION OF CURRENT LAW PROTECTIONS OF CERTAIN INDIAN PROPERTY FROM MEDICAID ESTATE RECOVERY.—Section 1917(b)(3) of the Social Security Act (42 U.S.C. 1396p(b)(3)) is amended—

(1) by inserting "(A)" after "(3)"; and

(2) by adding at the end the following new subparagraph:

"(B) The standards specified by the Secretary under subparagraph (A) shall require that the procedures established by the State agency under subparagraph (A) exempt income, resources, and property that are exempt from the application of this subsection as of April 1, 2003, under manual instructions issued to carry out this subsection (as in effect on such date) because of the Federal responsibility for Indian Tribes and Alaska Native Villages. Nothing in this subparagraph shall be construed as preventing the Secretary from providing additional estate recovery exemptions under this title for Indians.".

(d) RULES APPLICABLE UNDER MEDICAID AND CHIP TO MANAGED CARE ENTITIES WITH RESPECT TO INDIAN ENROLLEES AND INDIAN HEALTH CARE PROVIDERS AND INDIAN MANAGED CARE ENTITIES.—

(1) IN GENERAL.—Section 1932 of the Social Security Act (42 U.S.C. 1396u–2) is amended by adding at the end the following new subsection:

"(h) SPECIAL RULES WITH RESPECT TO INDIAN ENROLLEES, INDIAN HEALTH CARE PROVIDERS, AND INDIAN MANAGED CARE ENTITIES.—

"(1) ENROLLEE OPTION TO SELECT AN INDIAN HEALTH CARE PROVIDER AS PRIMARY CARE PROVIDER.—In the case of a non-Indian Medicaid managed care entity that—

"(A) has an Indian enrolled with the entity; and

"(B) has an Indian health care provider that is participating as a primary care provider within the network of the entity,

insofar as the Indian is otherwise eligible to receive services from such Indian health care provider and the Indian health care provider has the capacity to provide primary care services to such Indian, the contract with the entity under section 1903(m) or under section 1905(t)(3) shall require, as a condition of receiving payment under such contract, that the Indian shall be allowed to choose such Indian health care provider as the Indian's primary care provider under the entity.

"(2) ASSURANCE OF PAYMENT TO INDIAN HEALTH CARE PROVIDERS FOR PROVISION OF COVERED SERVICES.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall require any such entity, as a condition of receiving payment under such contract, to satisfy the following requirements:

"(A) DEMONSTRATION OF ACCESS TO INDIAN HEALTH CARE PROVIDERS AND APPLICATION OF ALTERNATIVE PAYMENT ARRANGEMENTS.—Subject to subparagraph (C), to—

"(i) demonstrate that the number of Indian health care providers that are participating providers with respect to such entity are sufficient to ensure timely access to covered Medicaid managed care services for those Indian enrollees who are eligible to receive services from such providers; and

"(ii) agree to pay Indian health care providers, whether such providers are participating or nonparticipating providers with respect to the entity, for covered Medicaid managed care services provided to those Indian enrollees who are eligible to receive services from such providers at a rate equal to the rate negotiated between such entity and the provider involved or, if such a rate has not been negotiated, at a rate that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a participating provider which is not an Indian health care provider.

Procedures.

The Secretary shall establish procedures for applying the requirements of clause (i) in States where there are no or few Indian health providers.

"(B) PROMPT PAYMENT.—To agree to make prompt payment (consistent with rule for prompt payment of providers under section 1932(f)) to Indian health care providers that are participating providers with respect to such entity or, in the case of an entity to which subparagraph (A)(ii) or (C) applies, that the entity is required to pay in accordance with that subparagraph.

"(C) APPLICATION OF SPECIAL PAYMENT REQUIREMENTS FOR FEDERALLY-QUALIFIED HEALTH CENTERS AND FOR SERVICES PROVIDED BY CERTAIN INDIAN HEALTH CARE PROVIDERS.—

"(i) FEDERALLY-QUALIFIED HEALTH CENTERS.—

"(I) MANAGED CARE ENTITY PAYMENT REQUIREMENT.—To agree to pay any Indian health care provider that is a federally-qualified health center under this title but not a participating provider with respect to the entity, for the provision of covered Medicaid managed care services by such provider to an Indian enrollee of the entity at a rate equal to the amount of payment that the entity would pay a federally-qualified health center that is a participating provider with respect to the entity but is not an Indian health care provider for such services.

"(II) CONTINUED APPLICATION OF STATE REQUIREMENT TO MAKE SUPPLEMENTAL PAYMENT.—Nothing in subclause (I) or subparagraph (A) or (B) shall be construed as waiving the application of section 1902(bb)(5) regarding the State plan requirement to make any supplemental payment due under such section to a federally-qualified health center for services furnished by such center to an enrollee of a managed care entity (regardless

of whether the federally-qualified health center is or is not a participating provider with the entity).

"(ii) PAYMENT RATE FOR SERVICES PROVIDED BY CERTAIN INDIAN HEALTH CARE PROVIDERS.—If the amount paid by a managed care entity to an Indian health care provider that is not a federally-qualified health center for services provided by the provider to an Indian enrollee with the managed care entity is less than the rate that applies to the provision of such services by the provider under the State plan, the plan shall provide for payment to the Indian health care provider, whether the provider is a participating or nonparticipating provider with respect to the entity, of the difference between such applicable rate and the amount paid by the managed care entity to the provider for such services.

"(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as waiving the application of section 1902(a)(30)(A) (relating to application of standards to assure that payments are consistent with efficiency, economy, and quality of care).

"(3) SPECIAL RULE FOR ENROLLMENT FOR INDIAN MANAGED CARE ENTITIES.—Regarding the application of a Medicaid managed care program to Indian Medicaid managed care entities, an Indian Medicaid managed care entity may restrict enrollment under such program to Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians.

"(4) DEFINITIONS.—For purposes of this subsection:

"(A) INDIAN HEALTH CARE PROVIDER.—The term 'Indian health care provider' means an Indian Health Program or an Urban Indian Organization.

"(B) INDIAN MEDICAID MANAGED CARE ENTITY.—The term 'Indian Medicaid managed care entity' means a managed care entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C)) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of 1 or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

"(C) NON-INDIAN MEDICAID MANAGED CARE ENTITY.—The term 'non-Indian Medicaid managed care entity' means a managed care entity that is not an Indian Medicaid managed care entity.

"(D) COVERED MEDICAID MANAGED CARE SERVICES.—The term 'covered Medicaid managed care services' means, with respect to an individual enrolled with a managed care entity, items and services for which benefits are available with respect to the individual under the contract between the entity and the State involved.

"(E) MEDICAID MANAGED CARE PROGRAM.—The term 'Medicaid managed care program' means a program under sections 1903(m), 1905(t), and 1932 and includes a managed care program operating under a waiver under section 1915(b) or 1115 or otherwise.".

(2) APPLICATION TO CHIP.—Section 2107(e)(1) of such Act (42 U.S.C. 1397gg(1)), as amended by subsection (b)(2), is amended—

(A) by redesignating subparagraph (J) as subparagraph (K); and

(B) by inserting after subparagraph (I) the following new subparagraph:

"(J) Subsections (a)(2)(C) and (h) of section 1932.".

42 USC 1320b–24.

(e) CONSULTATION ON MEDICAID, CHIP, AND OTHER HEALTH CARE PROGRAMS FUNDED UNDER THE SOCIAL SECURITY ACT INVOLVING INDIAN HEALTH PROGRAMS AND URBAN INDIAN ORGANIZATIONS.—

Establishment.

(1) CONSULTATION WITH TRIBAL TECHNICAL ADVISORY GROUP (TTAG).—The Secretary of Health and Human Services shall maintain within the Centers for Medicaid & Medicare Services (CMS) a Tribal Technical Advisory Group (TTAG), which was first established in accordance with requirements of the charter dated September 30, 2003, and the Secretary of Health and Human Services shall include in such Group a representative of a national urban Indian health organization and a representative of the Indian Health Service. The inclusion of a representative of a national urban Indian health organization in such Group shall not affect the nonapplication of the Federal Advisory Committee Act (5 U.S.C. App.) to such Group.

(2) SOLICITATION OF ADVICE UNDER MEDICAID AND CHIP.—

(A) MEDICAID STATE PLAN AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 501(d)(1) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3), (42 U.S.C. 1396a(a)) is amended—

(i) in paragraph (71), by striking "and" at the end;

(ii) in paragraph (72), by striking the period at the end and inserting "; and"; and

(iii) by inserting after paragraph (72), the following new paragraph:

"(73) in the case of any State in which 1 or more Indian Health Programs or Urban Indian Organizations furnishes health care services, provide for a process under which the State seeks advice on a regular, ongoing basis from designees of such Indian Health Programs and Urban Indian Organizations on matters relating to the application of this title that are likely to have a direct effect on such Indian Health Programs and Urban Indian Organizations and that—

"(A) shall include solicitation of advice prior to submission of any plan amendments, waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations; and

"(B) may include appointment of an advisory committee and of a designee of such Indian Health Programs and Urban Indian Organizations to the medical care advisory committee advising the State on its State plan under this title.".

(B) APPLICATION TO CHIP.—Section 2107(e)(1) of such Act (42 U.S.C. 1397gg(1)), as amended by subsections (b)(2) and (d) (2), is amended—

(i) by redesignating subparagraphs (B), (C), (D), (E), (F), (G), (H), (I), (J), and (K) as subparagraphs (D), (F), (B), (E), (G), (I), (H), (J), (K), and (L), respectively;

(ii) by moving such subparagraphs so as to appear in alphabetical order; and

(iii) by inserting after subparagraph (B) (as so redesiganted and moved) the following new subparagraph:

"(C) Section 1902(a)(73) (relating to requiring certain States to seek advice from designees of Indian Health Programs and Urban Indian Organizations).".

(3) RULE OF CONSTRUCTION.—Nothing in the amendments made by this subsection shall be construed as superseding existing advisory committees, working groups, guidance, or other advisory procedures established by the Secretary of Health and Human Services or by any State with respect to the provision of health care to Indians.

42 USC 1396a note.

(f) EFFECTIVE DATE.—The amendments made by this section shall take effect on July 1, 2009.

42 USC 1396a note.

SEC. 5007. FUNDING FOR OVERSIGHT AND IMPLEMENTATION.

(a) OVERSIGHT.—For purposes of ensuring the proper expenditure of Federal funds under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), there is appropriated to the Office of the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated and without further appropriation, $31,250,000 for fiscal year 2009, which shall remain available for expenditure until September 30, 2011, and shall be in addition to any other amounts appropriated or made available to such Office for such purposes.

(b) IMPLEMENTATION OF INCREASED FMAP.—For purposes of carrying out section 5001, there is appropriated to the Secretary of Health and Human Services, out of any money in the Treasury not otherwise appropriated and without further appropriation, $5,000,000 for fiscal year 2009, which shall remain available for expenditure until September 30, 2011, and shall be in addition to any other amounts appropriated or made available to such Secretary for such purposes.

SEC. 5008. GAO STUDY AND REPORT REGARDING STATE NEEDS DURING PERIODS OF NATIONAL ECONOMIC DOWNTURN.

(a) IN GENERAL.—The Comptroller General of the United States shall study the period of national economic downturn in effect on the date of enactment of this Act, as well as previous periods of national economic downturn since 1974, for the purpose of developing recommendations for addressing the needs of States during such periods. As part of such analysis, the Comptroller General shall study the past and projected effects of temporary increases in the Federal medical assistance percentage under the Medicaid program with respect to such periods.

(b) REPORT.—Not later than April 1, 2011, the Comptroller General of the United States shall submit a report to the appropriate committees of Congress on the results of the study conducted under paragraph (1). Such report shall include the following:

(1) Such recommendations as the Comptroller General determines appropriate for modifying the national economic downturn assistance formula for temporary adjustment of the

Federal medical assistance percentage under Medicaid (also referred to as a "countercyclical FMAP") described in GAO report number GAO–07–97 to improve the effectiveness of the application of such percentage in addressing the needs of States during periods of national economic downturn, including recommendations for—

(A) improvements to the factors that would begin and end the application of such percentage;

(B) how the determination of the amount of such percentage could be adjusted to address State and regional economic variations during such periods; and

(C) how the determination of the amount of such percentage could be adjusted to be more responsive to actual Medicaid costs incurred by States during such periods.

(2) An analysis of the impact on States during such periods of—

(A) declines in private health benefits coverage;

(B) declines in State revenues; and

(C) caseload maintenance and growth under Medicaid, the Children's Health Insurance Program, or any other publicly-funded programs to provide health benefits coverage for State residents.

(3) Identification of, and recommendations for addressing, the effects on States of any other specific economic indicators that the Comptroller General determines appropriate.

TITLE VI—BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM

SEC. 6000. TABLE OF CONTENTS.

The table of contents of this title is as follows:

TITLE VI—BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM

Sec. 6000. Table of contents.
Sec. 6001. Broadband Technology Opportunities Program.

47 USC 1305.

SEC. 6001. BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM.

(a) The Assistant Secretary of Commerce for Communications and Information (Assistant Secretary), in consultation with the Federal Communications Commission (Commission), shall establish a national broadband service development and expansion program in conjunction with the technology opportunities program, which shall be referred to as the Broadband Technology Opportunities Program. The Assistant Secretary shall ensure that the program complements and enhances and does not conflict with other Federal broadband initiatives and programs.

(b) The purposes of the program are to—

(1) provide access to broadband service to consumers residing in unserved areas of the United States;

(2) provide improved access to broadband service to consumers residing in underserved areas of the United States;

(3) provide broadband education, awareness, training, access, equipment, and support to—

(A) schools, libraries, medical and healthcare providers, community colleges and other institutions of higher education, and other community support organizations and

entities to facilitate greater use of broadband service by or through these organizations;

(B) organizations and agencies that provide outreach, access, equipment, and support services to facilitate greater use of broadband service by low-income, unemployed, aged, and otherwise vulnerable populations; and

(C) job-creating strategic facilities located within a State-designated economic zone, Economic Development District designated by the Department of Commerce, Renewal Community or Empowerment Zone designated by the Department of Housing and Urban Development, or Enterprise Community designated by the Department of Agriculture;

(4) improve access to, and use of, broadband service by public safety agencies; and

(5) stimulate the demand for broadband, economic growth, and job creation.

(c) The Assistant Secretary may consult a State, the District of Columbia, or territory or possession of the United States with respect to—

(1) the identification of areas described in subsection (b)(1) or (2) located in that State; and

(2) the allocation of grant funds within that State for projects in or affecting the State.

(d) The Assistant Secretary shall—

(1) establish and implement the grant program as expeditiously as practicable; Grants.

(2) ensure that all awards are made before the end of fiscal year 2010; Deadline.

(3) seek such assurances as may be necessary or appropriate from grantees under the program that they will substantially complete projects supported by the program in accordance with project timelines, not to exceed 2 years following an award; and

(4) report on the status of the program to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Commerce, Science, and Transportation of the Senate, every 90 days. Reports. Deadlines.

(e) To be eligible for a grant under the program, an applicant shall—

(1)(A) be a State or political subdivision thereof, the District of Columbia, a territory or possession of the United States, an Indian tribe (as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450(b)) or native Hawaiian organization;

(B) a nonprofit—

(i) foundation,

(ii) corporation,

(iii) institution, or

(iv) association; or

(C) any other entity, including a broadband service or infrastructure provider, that the Assistant Secretary finds by rule to be in the public interest. In establishing such rule, the Assistant Secretary shall to the extent practicable promote the purposes of this section in a technologically neutral manner;

(2) submit an application, at such time, in such form, and containing such information as the Assistant Secretary may require;

(3) provide a detailed explanation of how any amount received under the program will be used to carry out the purposes of this section in an efficient and expeditious manner, including a showing that the project would not have been implemented during the grant period without Federal grant assistance;

(4) demonstrate, to the satisfaction of the Assistant Secretary, that it is capable of carrying out the project or function to which the application relates in a competent manner in compliance with all applicable Federal, State, and local laws;

(5) demonstrate, to the satisfaction of the Assistant Secretary, that it will appropriate (if the applicant is a State or local government agency) or otherwise unconditionally obligate, from non-Federal sources, funds required to meet the requirements of subsection (f);

(6) disclose to the Assistant Secretary the source and amount of other Federal or State funding sources from which the applicant receives, or has applied for, funding for activities or projects to which the application relates; and

(7) provide such assurances and procedures as the Assistant Secretary may require to ensure that grant funds are used and accounted for in an appropriate manner.

(f) The Federal share of any project may not exceed 80 percent, except that the Assistant Secretary may increase the Federal share of a project above 80 percent if—

(1) the applicant petitions the Assistant Secretary for a waiver; and

(2) the Assistant Secretary determines that the petition demonstrates financial need.

(g) The Assistant Secretary may make competitive grants under the program to—

(1) acquire equipment, instrumentation, networking capability, hardware and software, digital network technology, and infrastructure for broadband services;

(2) construct and deploy broadband service related infrastructure;

(3) ensure access to broadband service by community anchor institutions;

(4) facilitate access to broadband service by low-income, unemployed, aged, and otherwise vulnerable populations in order to provide educational and employment opportunities to members of such populations;

(5) construct and deploy broadband facilities that improve public safety broadband communications services; and

(6) undertake such other projects and activities as the Assistant Secretary finds to be consistent with the purposes for which the program is established.

(h) The Assistant Secretary, in awarding grants under this section, shall, to the extent practical—

(1) award not less than 1 grant in each State;

(2) consider whether an application to deploy infrastructure in an area—

(A) will, if approved, increase the affordability of, and subscribership to, service to the greatest population of users in the area;

(B) will, if approved, provide the greatest broadband speed possible to the greatest population of users in the area;

(C) will, if approved, enhance service for health care delivery, education, or children to the greatest population of users in the area; and

(D) will, if approved, not result in unjust enrichment as a result of support for non-recurring costs through another Federal program for service in the area; and

(3) consider whether the applicant is a socially and economically disadvantaged small business concern as defined under section 8(a) of the Small Business Act (15 U.S.C. 637).

(i) The Assistant Secretary—

Reports. Deadlines. Public information.

(1) shall require any entity receiving a grant pursuant to this section to report quarterly, in a format specified by the Assistant Secretary, on such entity's use of the assistance and progress fulfilling the objectives for which such funds were granted, and the Assistant Secretary shall make these reports available to the public;

(2) may establish additional reporting and information requirements for any recipient of any assistance made available pursuant to this section;

(3) shall establish appropriate mechanisms to ensure appropriate use and compliance with all terms of any use of funds made available pursuant to this section;

(4) may, in addition to other authority under applicable law, deobligate awards to grantees that demonstrate an insufficient level of performance, or wasteful or fraudulent spending, as defined in advance by the Assistant Secretary, and award these funds competitively to new or existing applicants consistent with this section; and

Database. Web site. Records.

(5) shall create and maintain a fully searchable database, accessible on the Internet at no cost to the public, that contains at least a list of each entity that has applied for a grant under this section, a description of each application, the status of each such application, the name of each entity receiving funds made available pursuant to this section, the purpose for which such entity is receiving such funds, each quarterly report submitted by the entity pursuant to this section, and such other information sufficient to allow the public to understand and monitor grants awarded under the program.

Publication.

(j) Concurrent with the issuance of the Request for Proposal for grant applications pursuant to this section, the Assistant Secretary shall, in coordination with the Commission, publish the non-discrimination and network interconnection obligations that shall be contractual conditions of grants awarded under this section, including, at a minimum, adherence to the principles contained in the Commission's broadband policy statement (FCC 05-15, adopted August 5, 2005).

Deadline. Reports. Broadband plan.

(k)(1) Not later than 1 year after the date of enactment of this section, the Commission shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate, a report containing a national broadband plan.

(2) The national broadband plan required by this section shall seek to ensure that all people of the United States have access to broadband capability and shall establish benchmarks for meeting that goal. The plan shall also include—

(A) an analysis of the most effective and efficient mechanisms for ensuring broadband access by all people of the United States;

(B) a detailed strategy for achieving affordability of such service and maximum utilization of broadband infrastructure and service by the public;

(C) an evaluation of the status of deployment of broadband service, including progress of projects supported by the grants made pursuant to this section; and

(D) a plan for use of broadband infrastructure and services in advancing consumer welfare, civic participation, public safety and homeland security, community development, health care delivery, energy independence and efficiency, education, worker training, private sector investment, entrepreneurial activity, job creation and economic growth, and other national purposes.

(3) In developing the plan, the Commission shall have access to data provided to other Government agencies under the Broadband Data Improvement Act (47 U.S.C. 1301 note).

Broadband map.

(l) The Assistant Secretary shall develop and maintain a comprehensive nationwide inventory map of existing broadband service capability and availability in the United States that depicts the geographic extent to which broadband service capability is deployed and available from a commercial provider or public provider throughout each State. Not later than 2 years after the date of the enactment of this Act, the Assistant Secretary shall make the broadband inventory map developed and maintained pursuant to this section accessible by the public on a World Wide Web site of the National Telecommunications and Information Administration in a form that is interactive and searchable.

Deadline. Web posting. Public information.

Regulations.

(m) The Assistant Secretary shall have the authority to prescribe such rules as are necessary to carry out the purposes of this section.

TITLE VII—LIMITS ON EXECUTIVE COMPENSATION

SEC. 7000. TABLE OF CONTENTS.

The table of contents of this title is as follows:

TITLE VII—LIMITS ON EXECUTIVE COMPENSATION

Sec. 7000. Table of contents.
Sec. 7001. Executive compensation and corporate governance.
Sec. 7002. Applicability with respect to loan modifications.

SEC. 7001. EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE.

Section 111 of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221) is amended to read as follows:

"SEC. 111. EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE.

"(a) DEFINITIONS.—For purposes of this section, the following definitions shall apply:

"(1) SENIOR EXECUTIVE OFFICER.—The term 'senior executive officer' means an individual who is 1 of the top 5 most highly paid executives of a public company, whose compensation is required to be disclosed pursuant to the Securities Exchange Act of 1934, and any regulations issued thereunder, and non-public company counterparts.

"(2) GOLDEN PARACHUTE PAYMENT.—The term 'golden parachute payment' means any payment to a senior executive officer for departure from a company for any reason, except for payments for services performed or benefits accrued.

"(3) TARP RECIPIENT.—The term 'TARP recipient' means any entity that has received or will receive financial assistance under the financial assistance provided under the TARP.

"(4) COMMISSION.—The term 'Commission' means the Securities and Exchange Commission.

"(5) PERIOD IN WHICH OBLIGATION IS OUTSTANDING; RULE OF CONSTRUCTION.—For purposes of this section, the period in which any obligation arising from financial assistance provided under the TARP remains outstanding does not include any period during which the Federal Government only holds warrants to purchase common stock of the TARP recipient.

"(b) EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE.—

"(1) ESTABLISHMENT OF STANDARDS.—During the period in which any obligation arising from financial assistance provided under the TARP remains outstanding, each TARP recipient shall be subject to—

"(A) the standards established by the Secretary under this section; and

"(B) the provisions of section 162(m)(5) of the Internal Revenue Code of 1986, as applicable.

"(2) STANDARDS REQUIRED.—The Secretary shall require each TARP recipient to meet appropriate standards for executive compensation and corporate governance.

"(3) SPECIFIC REQUIREMENTS.—The standards established under paragraph (2) shall include the following:

"(A) Limits on compensation that exclude incentives for senior executive officers of the TARP recipient to take unnecessary and excessive risks that threaten the value of such recipient during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding.

"(B) A provision for the recovery by such TARP recipient of any bonus, retention award, or incentive compensation paid to a senior executive officer and any of the next 20 most highly-compensated employees of the TARP recipient based on statements of earnings, revenues, gains, or other criteria that are later found to be materially inaccurate.

"(C) A prohibition on such TARP recipient making any golden parachute payment to a senior executive officer or any of the next 5 most highly-compensated employees of the TARP recipient during the period in which any

obligation arising from financial assistance provided under the TARP remains outstanding.

"(D)(i) A prohibition on such TARP recipient paying or accruing any bonus, retention award, or incentive compensation during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding, except that any prohibition developed under this paragraph shall not apply to the payment of long-term restricted stock by such TARP recipient, provided that such long-term restricted stock—

"(I) does not fully vest during the period in which any obligation arising from financial assistance provided to that TARP recipient remains outstanding;

"(II) has a value in an amount that is not greater than ⅓ of the total amount of annual compensation of the employee receiving the stock; and

"(III) is subject to such other terms and conditions as the Secretary may determine is in the public interest.

Applicability.

"(ii) The prohibition required under clause (i) shall apply as follows:

"(I) For any financial institution that received financial assistance provided under the TARP equal to less than $25,000,000, the prohibition shall apply only to the most highly compensated employee of the financial institution.

"(II) For any financial institution that received financial assistance provided under the TARP equal to at least $25,000,000, but less than $250,000,000, the prohibition shall apply to at least the 5 most highly-compensated employees of the financial institution, or such higher number as the Secretary may determine is in the public interest with respect to any TARP recipient.

"(III) For any financial institution that received financial assistance provided under the TARP equal to at least$250,000,000, but less than $500,000,000, the prohibition shall apply to the senior executive officers and at least the 10 next most highly-compensated employees, or such higher number as the Secretary may determine is in the public interest with respect to any TARP recipient.

"(IV) For any financial institution that received financial assistance provided under the TARP equal to $500,000,000 or more, the prohibition shall apply to the senior executive officers and at least the 20 next most highly-compensated employees, or such higher number as the Secretary may determine is in the public interest with respect to any TARP recipient.

"(iii) The prohibition required under clause (i) shall not be construed to prohibit any bonus payment required to be paid pursuant to a written employment contract executed on or before February 11, 2009, as such valid employment contracts are determined by the Secretary or the designee of the Secretary.

"(E) A prohibition on any compensation plan that would encourage manipulation of the reported earnings of such

TARP recipient to enhance the compensation of any of its employees.

"(F) A requirement for the establishment of a Board Compensation Committee that meets the requirements of subsection (c).

"(4) CERTIFICATION OF COMPLIANCE.—The chief executive officer and chief financial officer (or the equivalents thereof) of each TARP recipient shall provide a written certification of compliance by the TARP recipient with the requirements of this section—

"(A) in the case of a TARP recipient, the securities of which are publicly traded, to the Securities and Exchange Commission, together with annual filings required under the securities laws; and

"(B) in the case of a TARP recipient that is not a publicly traded company, to the Secretary.

"(c) BOARD COMPENSATION COMMITTEE.—

"(1) ESTABLISHMENT OF BOARD REQUIRED.—Each TARP recipient shall establish a Board Compensation Committee, comprised entirely of independent directors, for the purpose of reviewing employee compensation plans.

"(2) MEETINGS.—The Board Compensation Committee of each TARP recipient shall meet at least semiannually to discuss and evaluate employee compensation plans in light of an assessment of any risk posed to the TARP recipient from such plans.

"(3) COMPLIANCE BY NON-SEC REGISTRANTS.—In the case of any TARP recipient, the common or preferred stock of which is not registered pursuant to the Securities Exchange Act of 1934, and that has received $25,000,000 or less of TARP assistance, the duties of the Board Compensation Committee under this subsection shall be carried out by the board of directors of such TARP recipient.

"(d) LIMITATION ON LUXURY EXPENDITURES.—The board of directors of any TARP recipient shall have in place a company-wide policy regarding excessive or luxury expenditures, as identified by the Secretary, which may include excessive expenditures on—

"(1) entertainment or events;

"(2) office and facility renovations;

"(3) aviation or other transportation services; or

"(4) other activities or events that are not reasonable expenditures for staff development, reasonable performance incentives, or other similar measures conducted in the normal course of the business operations of the TARP recipient.

"(e) SHAREHOLDER APPROVAL OF EXECUTIVE COMPENSATION.—

"(1) ANNUAL SHAREHOLDER APPROVAL OF EXECUTIVE COMPENSATION.—Any proxy or consent or authorization for an annual or other meeting of the shareholders of any TARP recipient during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding shall permit a separate shareholder vote to approve the compensation of executives, as disclosed pursuant to the compensation disclosure rules of the Commission (which disclosure shall include the compensation discussion and analysis, the compensation tables, and any related material).

"(2) NONBINDING VOTE.—A shareholder vote described in paragraph (1) shall not be binding on the board of directors of a TARP recipient, and may not be construed as overruling

a decision by such board, nor to create or imply any additional fiduciary duty by such board, nor shall such vote be construed to restrict or limit the ability of shareholders to make proposals for inclusion in proxy materials related to executive compensation.

"(3) DEADLINE FOR RULEMAKING.—Not later than 1 year after the date of enactment of the American Recovery and Reinvestment Act of 2009, the Commission shall issue any final rules and regulations required by this subsection.

"(f) REVIEW OF PRIOR PAYMENTS TO EXECUTIVES.—

"(1) IN GENERAL.—The Secretary shall review bonuses, retention awards, and other compensation paid to the senior executive officers and the next 20 most highly-compensated employees of each entity receiving TARP assistance before the date of enactment of the American Recovery and Reinvestment Act of 2009, to determine whether any such payments were inconsistent with the purposes of this section or the TARP or were otherwise contrary to the public interest.

"(2) NEGOTIATIONS FOR REIMBURSEMENT.—If the Secretary makes a determination described in paragraph (1), the Secretary shall seek to negotiate with the TARP recipient and the subject employee for appropriate reimbursements to the Federal Government with respect to compensation or bonuses.

"(g) NO IMPEDIMENT TO WITHDRAWAL BY TARP RECIPIENTS.—Subject to consultation with the appropriate Federal banking agency (as that term is defined in section 3 of the Federal Deposit Insurance Act), if any, the Secretary shall permit a TARP recipient to repay any assistance previously provided under the TARP to such financial institution, without regard to whether the financial institution has replaced such funds from any other source or to any waiting period, and when such assistance is repaid, the Secretary shall liquidate warrants associated with such assistance at the current market price.

"(h) REGULATIONS.—The Secretary shall promulgate regulations to implement this section.".

SEC. 7002. APPLICABILITY WITH RESPECT TO LOAN MODIFICATIONS.

Section 109(a) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5219(a)) is amended—

(1) by striking "To the extent" and inserting the following: "(1) IN GENERAL.—To the extent"; and

(2) by adding at the end the following:

"(2) WAIVER OF CERTAIN PROVISIONS IN CONNECTION WITH LOAN MODIFICATIONS.—The Secretary shall not be required to apply executive compensation restrictions under section 111, or to receive warrants or debt instruments under section 113, solely in connection with any loan modification under this section.".

Approved February 17, 2009.

LEGISLATIVE HISTORY—H.R. 1 (S. 336) (S. 350):

SENATE REPORTS: No. 111–3 accompanying S. 336 (Comm. on Appropriations).
CONGRESSIONAL RECORD, Vol. 155 (2009):
Jan. 27, 28, considered and passed House.
Feb. 2–7, 9, 10, considered and passed Senate, amended.
Feb. 13, House and Senate agreed to conference report.
DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2009):
Feb. 17, Presidential remarks and statement.

○

Public Law 107–347
107th Congress

An Act

To enhance the management and promotion of electronic Government services and processes by establishing a Federal Chief Information Officer within the Office of Management and Budget, and by establishing a broad framework of measures that require using Internet-based information technology to enhance citizen access to Government information and services, and for other purposes.

Dec. 17, 2002
[H.R. 2458]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

E-Government Act of 2002.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

44 USC 101 note.

(a) SHORT TITLE.—This Act may be cited as the "E-Government Act of 2002".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings and purposes.

TITLE I—OFFICE OF MANAGEMENT AND BUDGET ELECTRONIC GOVERNMENT SERVICES

Sec. 101. Management and promotion of electronic government services.
Sec. 102. Conforming amendments.

TITLE II—FEDERAL MANAGEMENT AND PROMOTION OF ELECTRONIC GOVERNMENT SERVICES

Sec. 201. Definitions.
Sec. 202. Federal agency responsibilities.
Sec. 203. Compatibility of executive agency methods for use and acceptance of electronic signatures.
Sec. 204. Federal Internet portal.
Sec. 205. Federal courts.
Sec. 206. Regulatory agencies.
Sec. 207. Accessibility, usability, and preservation of government information.
Sec. 208. Privacy provisions.
Sec. 209. Federal information technology workforce development.
Sec. 210. Share-in-savings initiatives.
Sec. 211. Authorization for acquisition of information technology by State and local governments through Federal supply schedules.
Sec. 212. Integrated reporting study and pilot projects.
Sec. 213. Community technology centers.
Sec. 214. Enhancing crisis management through advanced information technology.
Sec. 215. Disparities in access to the Internet.
Sec. 216. Common protocols for geographic information systems.

TITLE III—INFORMATION SECURITY

Sec. 301. Information security.
Sec. 302. Management of information technology.
Sec. 303. National Institute of Standards and Technology.
Sec. 304. Information Security and Privacy Advisory Board.
Sec. 305. Technical and conforming amendments.

TITLE IV—AUTHORIZATION OF APPROPRIATIONS AND EFFECTIVE DATES

Sec. 401. Authorization of appropriations.

Sec. 402. Effective dates.

TITLE V—CONFIDENTIAL INFORMATION PROTECTION AND STATISTICAL EFFICIENCY

Sec. 501. Short title.
Sec. 502. Definitions.
Sec. 503. Coordination and oversight of policies.
Sec. 504. Effect on other laws.

Subtitle A—Confidential Information Protection

Sec. 511. Findings and purposes.
Sec. 512. Limitations on use and disclosure of data and information.
Sec. 513. Fines and penalties.

Subtitle B—Statistical Efficiency

Sec. 521. Findings and purposes.
Sec. 522. Designation of statistical agencies.
Sec. 523. Responsibilities of designated statistical agencies.
Sec. 524. Sharing of business data among designated statistical agencies.
Sec. 525. Limitations on use of business data provided by designated statistical agencies.
Sec. 526. Conforming amendments.

44 USC 3601 note.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) The use of computers and the Internet is rapidly transforming societal interactions and the relationships among citizens, private businesses, and the Government.

(2) The Federal Government has had uneven success in applying advances in information technology to enhance governmental functions and services, achieve more efficient performance, increase access to Government information, and increase citizen participation in Government.

(3) Most Internet-based services of the Federal Government are developed and presented separately, according to the jurisdictional boundaries of an individual department or agency, rather than being integrated cooperatively according to function or topic.

(4) Internet-based Government services involving interagency cooperation are especially difficult to develop and promote, in part because of a lack of sufficient funding mechanisms to support such interagency cooperation.

(5) Electronic Government has its impact through improved Government performance and outcomes within and across agencies.

(6) Electronic Government is a critical element in the management of Government, to be implemented as part of a management framework that also addresses finance, procurement, human capital, and other challenges to improve the performance of Government.

(7) To take full advantage of the improved Government performance that can be achieved through the use of Internet-based technology requires strong leadership, better organization, improved interagency collaboration, and more focused oversight of agency compliance with statutes related to information resource management.

(b) PURPOSES.—The purposes of this Act are the following:

(1) To provide effective leadership of Federal Government efforts to develop and promote electronic Government services and processes by establishing an Administrator of a new Office of Electronic Government within the Office of Management and Budget.

(2) To promote use of the Internet and other information technologies to provide increased opportunities for citizen participation in Government.

(3) To promote interagency collaboration in providing electronic Government services, where this collaboration would improve the service to citizens by integrating related functions, and in the use of internal electronic Government processes, where this collaboration would improve the efficiency and effectiveness of the processes.

(4) To improve the ability of the Government to achieve agency missions and program performance goals.

(5) To promote the use of the Internet and emerging technologies within and across Government agencies to provide citizen-centric Government information and services.

(6) To reduce costs and burdens for businesses and other Government entities.

(7) To promote better informed decisionmaking by policy makers.

(8) To promote access to high quality Government information and services across multiple channels.

(9) To make the Federal Government more transparent and accountable.

(10) To transform agency operations by utilizing, where appropriate, best practices from public and private sector organizations.

(11) To provide enhanced access to Government information and services in a manner consistent with laws regarding protection of personal privacy, national security, records retention, access for persons with disabilities, and other relevant laws.

TITLE I—OFFICE OF MANAGEMENT AND BUDGET ELECTRONIC GOVERNMENT SERVICES

SEC. 101. MANAGEMENT AND PROMOTION OF ELECTRONIC GOVERNMENT SERVICES.

(a) IN GENERAL.—Title 44, United States Code, is amended by inserting after chapter 35 the following:

"CHAPTER 36—MANAGEMENT AND PROMOTION OF ELECTRONIC GOVERNMENT SERVICES

"Sec.
"3601. Definitions.
"3602. Office of Electronic Government.
"3603. Chief Information Officers Council.
"3604. E-Government Fund.
"3605. Program to encourage innovative solutions to enhance electronic Government services and processes.
"3606. E-Government report.

"§ 3601. Definitions

"In this chapter, the definitions under section 3502 shall apply, and the term—

"(1) 'Administrator' means the Administrator of the Office of Electronic Government established under section 3602;

"(2) 'Council' means the Chief Information Officers Council established under section 3603;

"(3) 'electronic Government' means the use by the Government of web-based Internet applications and other information technologies, combined with processes that implement these technologies, to—

"(A) enhance the access to and delivery of Government information and services to the public, other agencies, and other Government entities; or

"(B) bring about improvements in Government operations that may include effectiveness, efficiency, service quality, or transformation;

"(4) 'enterprise architecture'—

"(A) means—

"(i) a strategic information asset base, which defines the mission;

"(ii) the information necessary to perform the mission;

"(iii) the technologies necessary to perform the mission; and

"(iv) the transitional processes for implementing new technologies in response to changing mission needs; and

"(B) includes—

"(i) a baseline architecture;

"(ii) a target architecture; and

"(iii) a sequencing plan;

"(5) 'Fund' means the E-Government Fund established under section 3604;

"(6) 'interoperability' means the ability of different operating and software systems, applications, and services to communicate and exchange data in an accurate, effective, and consistent manner;

"(7) 'integrated service delivery' means the provision of Internet-based Federal Government information or services integrated according to function or topic rather than separated according to the boundaries of agency jurisdiction; and

"(8) 'tribal government' means—

"(A) the governing body of any Indian tribe, band, nation, or other organized group or community located in the continental United States (excluding the State of Alaska) that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians, and

"(B) any Alaska Native regional or village corporation established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 et seq.).

"§ 3602. Office of Electronic Government

Establishment. Government organization. President.

"(a) There is established in the Office of Management and Budget an Office of Electronic Government.

"(b) There shall be at the head of the Office an Administrator who shall be appointed by the President.

"(c) The Administrator shall assist the Director in carrying out—

"(1) all functions under this chapter;

"(2) all of the functions assigned to the Director under title II of the E-Government Act of 2002; and

"(3) other electronic government initiatives, consistent with other statutes.

"(d) The Administrator shall assist the Director and the Deputy Director for Management and work with the Administrator of the Office of Information and Regulatory Affairs in setting strategic direction for implementing electronic Government, under relevant statutes, including—

"(1) chapter 35;

"(2) subtitle III of title 40, United States Code;

"(3) section 552a of title 5 (commonly referred to as the 'Privacy Act');

"(4) the Government Paperwork Elimination Act (44 U.S.C. 3504 note); and

"(5) the Federal Information Security Management Act of 2002.

"(e) The Administrator shall work with the Administrator of the Office of Information and Regulatory Affairs and with other offices within the Office of Management and Budget to oversee implementation of electronic Government under this chapter, chapter 35, the E-Government Act of 2002, and other relevant statutes, in a manner consistent with law, relating to—

"(1) capital planning and investment control for information technology;

"(2) the development of enterprise architectures;

"(3) information security;

"(4) privacy;

"(5) access to, dissemination of, and preservation of Government information;

"(6) accessibility of information technology for persons with disabilities; and

"(7) other areas of electronic Government.

"(f) Subject to requirements of this chapter, the Administrator shall assist the Director by performing electronic Government functions as follows:

"(1) Advise the Director on the resources required to develop and effectively administer electronic Government initiatives.

"(2) Recommend to the Director changes relating to Governmentwide strategies and priorities for electronic Government.

"(3) Provide overall leadership and direction to the executive branch on electronic Government.

"(4) Promote innovative uses of information technology by agencies, particularly initiatives involving multiagency collaboration, through support of pilot projects, research, experimentation, and the use of innovative technologies.

"(5) Oversee the distribution of funds from, and ensure appropriate administration and coordination of, the E-Government Fund established under section 3604.

"(6) Coordinate with the Administrator of General Services regarding programs undertaken by the General Services Administration to promote electronic government and the efficient use of information technologies by agencies.

"(7) Lead the activities of the Chief Information Officers Council established under section 3603 on behalf of the Deputy Director for Management, who shall chair the council.

"(8) Assist the Director in establishing policies which shall set the framework for information technology standards for the Federal Government developed by the National Institute of Standards and Technology and promulgated by the Secretary of Commerce under section 11331 of title 40, taking into account, if appropriate, recommendations of the Chief Information Officers Council, experts, and interested parties from the private and nonprofit sectors and State, local, and tribal governments, and maximizing the use of commercial standards as appropriate, including the following:

"(A) Standards and guidelines for interconnectivity and interoperability as described under section 3504.

"(B) Consistent with the process under section 207(d) of the E-Government Act of 2002, standards and guidelines for categorizing Federal Government electronic information to enable efficient use of technologies, such as through the use of extensible markup language.

"(C) Standards and guidelines for Federal Government computer system efficiency and security.

"(9) Sponsor ongoing dialogue that—

"(A) shall be conducted among Federal, State, local, and tribal government leaders on electronic Government in the executive, legislative, and judicial branches, as well as leaders in the private and nonprofit sectors, to encourage collaboration and enhance understanding of best practices and innovative approaches in acquiring, using, and managing information resources;

"(B) is intended to improve the performance of governments in collaborating on the use of information technology to improve the delivery of Government information and services; and

"(C) may include—

"(i) development of innovative models—

"(I) for electronic Government management and Government information technology contracts; and

"(II) that may be developed through focused discussions or using separately sponsored research;

"(ii) identification of opportunities for public-private collaboration in using Internet-based technology to increase the efficiency of Government-to-business transactions;

"(iii) identification of mechanisms for providing incentives to program managers and other Government employees to develop and implement innovative uses of information technologies; and

"(iv) identification of opportunities for public, private, and intergovernmental collaboration in addressing the disparities in access to the Internet and information technology.

"(10) Sponsor activities to engage the general public in the development and implementation of policies and programs, particularly activities aimed at fulfilling the goal of using the most effective citizen-centered strategies and those activities

which engage multiple agencies providing similar or related information and services.

"(11) Oversee the work of the General Services Administration and other agencies in developing the integrated Internet-based system under section 204 of the E-Government Act of 2002.

"(12) Coordinate with the Administrator for Federal Procurement Policy to ensure effective implementation of electronic procurement initiatives.

"(13) Assist Federal agencies, including the General Services Administration, the Department of Justice, and the United States Access Board in—

"(A) implementing accessibility standards under section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d); and

"(B) ensuring compliance with those standards through the budget review process and other means.

"(14) Oversee the development of enterprise architectures within and across agencies.

"(15) Assist the Director and the Deputy Director for Management in overseeing agency efforts to ensure that electronic Government activities incorporate adequate, risk-based, and cost-effective security compatible with business processes.

"(16) Administer the Office of Electronic Government established under this section.

"(17) Assist the Director in preparing the E-Government report established under section 3606.

"(g) The Director shall ensure that the Office of Management and Budget, including the Office of Electronic Government, the Office of Information and Regulatory Affairs, and other relevant offices, have adequate staff and resources to properly fulfill all functions under the E-Government Act of 2002.

"§ 3603. Chief Information Officers Council

Establishment.

"(a) There is established in the executive branch a Chief Information Officers Council.

"(b) The members of the Council shall be as follows:

"(1) The Deputy Director for Management of the Office of Management and Budget, who shall act as chairperson of the Council.

"(2) The Administrator of the Office of Electronic Government.

"(3) The Administrator of the Office of Information and Regulatory Affairs.

"(4) The chief information officer of each agency described under section 901(b) of title 31.

"(5) The chief information officer of the Central Intelligence Agency.

"(6) The chief information officer of the Department of the Army, the Department of the Navy, and the Department of the Air Force, if chief information officers have been designated for such departments under section 3506(a)(2)(B).

"(7) Any other officer or employee of the United States designated by the chairperson.

"(c)(1) The Administrator of the Office of Electronic Government shall lead the activities of the Council on behalf of the Deputy Director for Management.

"(2)(A) The Vice Chairman of the Council shall be selected by the Council from among its members.

"(B) The Vice Chairman shall serve a 1-year term, and may serve multiple terms.

"(3) The Administrator of General Services shall provide administrative and other support for the Council.

"(d) The Council is designated the principal interagency forum for improving agency practices related to the design, acquisition, development, modernization, use, operation, sharing, and performance of Federal Government information resources.

"(e) In performing its duties, the Council shall consult regularly with representatives of State, local, and tribal governments.

"(f) The Council shall perform functions that include the following:

"(1) Develop recommendations for the Director on Government information resources management policies and requirements.

"(2) Share experiences, ideas, best practices, and innovative approaches related to information resources management.

"(3) Assist the Administrator in the identification, development, and coordination of multiagency projects and other innovative initiatives to improve Government performance through the use of information technology.

"(4) Promote the development and use of common performance measures for agency information resources management under this chapter and title II of the E-Government Act of 2002.

"(5) Work as appropriate with the National Institute of Standards and Technology and the Administrator to develop recommendations on information technology standards developed under section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3) and promulgated under section 11331 of title 40, and maximize the use of commercial standards as appropriate, including the following:

"(A) Standards and guidelines for interconnectivity and interoperability as described under section 3504.

"(B) Consistent with the process under section 207(d) of the E-Government Act of 2002, standards and guidelines for categorizing Federal Government electronic information to enable efficient use of technologies, such as through the use of extensible markup language.

"(C) Standards and guidelines for Federal Government computer system efficiency and security.

"(6) Work with the Office of Personnel Management to assess and address the hiring, training, classification, and professional development needs of the Government related to information resources management.

"(7) Work with the Archivist of the United States to assess how the Federal Records Act can be addressed effectively by Federal information resources management activities.

"§ 3604. E-Government Fund

"(a)(1) There is established in the Treasury of the United States the E-Government Fund.

"(2) The Fund shall be administered by the Administrator of the General Services Administration to support projects approved by the Director, assisted by the Administrator of the Office of

Electronic Government, that enable the Federal Government to expand its ability, through the development and implementation of innovative uses of the Internet or other electronic methods, to conduct activities electronically.

"(3) Projects under this subsection may include efforts to—

"(A) make Federal Government information and services more readily available to members of the public (including individuals, businesses, grantees, and State and local governments);

"(B) make it easier for the public to apply for benefits, receive services, pursue business opportunities, submit information, and otherwise conduct transactions with the Federal Government; and

"(C) enable Federal agencies to take advantage of information technology in sharing information and conducting transactions with each other and with State and local governments.

"(b)(1) The Administrator shall—

"(A) establish procedures for accepting and reviewing proposals for funding; Procedures.

"(B) consult with interagency councils, including the Chief Information Officers Council, the Chief Financial Officers Council, and other interagency management councils, in establishing procedures and reviewing proposals; and

"(C) assist the Director in coordinating resources that agencies receive from the Fund with other resources available to agencies for similar purposes.

"(2) When reviewing proposals and managing the Fund, the Administrator shall observe and incorporate the following procedures:

"(A) A project requiring substantial involvement or funding from an agency shall be approved by a senior official with agencywide authority on behalf of the head of the agency, who shall report directly to the head of the agency.

"(B) Projects shall adhere to fundamental capital planning and investment control processes.

"(C) Agencies shall identify in their proposals resource commitments from the agencies involved and how these resources would be coordinated with support from the Fund, and include plans for potential continuation of projects after all funds made available from the Fund are expended.

"(D) After considering the recommendations of the interagency councils, the Director, assisted by the Administrator, shall have final authority to determine which of the candidate projects shall be funded from the Fund.

"(E) Agencies shall assess the results of funded projects.

"(c) In determining which proposals to recommend for funding, the Administrator—

"(1) shall consider criteria that include whether a proposal—

"(A) identifies the group to be served, including citizens, businesses, the Federal Government, or other governments;

"(B) indicates what service or information the project will provide that meets needs of groups identified under subparagraph (A);

"(C) ensures proper security and protects privacy;

"(D) is interagency in scope, including projects implemented by a primary or single agency that—

"(i) could confer benefits on multiple agencies; and

"(ii) have the support of other agencies; and

"(E) has performance objectives that tie to agency missions and strategic goals, and interim results that relate to the objectives; and

"(2) may also rank proposals based on criteria that include whether a proposal—

"(A) has Governmentwide application or implications;

"(B) has demonstrated support by the public to be served;

"(C) integrates Federal with State, local, or tribal approaches to service delivery;

"(D) identifies resource commitments from nongovernmental sectors;

"(E) identifies resource commitments from the agencies involved;

"(F) uses web-based technologies to achieve objectives;

"(G) identifies records management and records access strategies;

"(H) supports more effective citizen participation in and interaction with agency activities that further progress toward a more citizen-centered Government;

"(I) directly delivers Government information and services to the public or provides the infrastructure for delivery;

"(J) supports integrated service delivery;

"(K) describes how business processes across agencies will reflect appropriate transformation simultaneous to technology implementation; and

"(L) is new or innovative and does not supplant existing funding streams within agencies.

"(d) The Fund may be used to fund the integrated Internet-based system under section 204 of the E-Government Act of 2002.

Notification.

"(e) None of the funds provided from the Fund may be transferred to any agency until 15 days after the Administrator of the General Services Administration has submitted to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Governmental Affairs of the Senate, the Committee on Government Reform of the House of Representatives, and the appropriate authorizing committees of the Senate and the House of Representatives, a notification and description of how the funds are to be allocated and how the expenditure will further the purposes of this chapter.

Reports.

"(f)(1) The Director shall report annually to Congress on the operation of the Fund, through the report established under section 3606.

"(2) The report under paragraph (1) shall describe—

"(A) all projects which the Director has approved for funding from the Fund; and

"(B) the results that have been achieved to date for these funded projects.

"(g)(1) There are authorized to be appropriated to the Fund—

"(A) $45,000,000 for fiscal year 2003;

"(B) $50,000,000 for fiscal year 2004;

"(C) $100,000,000 for fiscal year 2005;

"(D) $150,000,000 for fiscal year 2006; and

"(E) such sums as are necessary for fiscal year 2007.

"(2) Funds appropriated under this subsection shall remain available until expended.

"§ 3605. Program to encourage innovative solutions to enhance electronic Government services and processes

"(a) ESTABLISHMENT OF PROGRAM.—The Administrator shall establish and promote a Governmentwide program to encourage contractor innovation and excellence in facilitating the development and enhancement of electronic Government services and processes.

"(b) ISSUANCE OF ANNOUNCEMENTS SEEKING INNOVATIVE SOLUTIONS.—Under the program, the Administrator, in consultation with the Council and the Administrator for Federal Procurement Policy, shall issue announcements seeking unique and innovative solutions to facilitate the development and enhancement of electronic Government services and processes.

"(c) MULTIAGENCY TECHNICAL ASSISTANCE TEAM.—(1) The Administrator, in consultation with the Council and the Administrator for Federal Procurement Policy, shall convene a multiagency technical assistance team to assist in screening proposals submitted to the Administrator to provide unique and innovative solutions to facilitate the development and enhancement of electronic Government services and processes. The team shall be composed of employees of the agencies represented on the Council who have expertise in scientific and technical disciplines that would facilitate the assessment of the feasibility of the proposals.

"(2) The technical assistance team shall—

"(A) assess the feasibility, scientific and technical merits, and estimated cost of each proposal; and

"(B) submit each proposal, and the assessment of the proposal, to the Administrator.

"(3) The technical assistance team shall not consider or evaluate proposals submitted in response to a solicitation for offers for a pending procurement or for a specific agency requirement.

"(4) After receiving proposals and assessments from the technical assistance team, the Administrator shall consider recommending appropriate proposals for funding under the E-Government Fund established under section 3604 or, if appropriate, forward the proposal and the assessment of it to the executive agency whose mission most coincides with the subject matter of the proposal.

"§ 3606. E-Government report

"(a) Not later than March 1 of each year, the Director shall submit an E-Government status report to the Committee on Governmental Affairs of the Senate and the Committee on Government Reform of the House of Representatives. Deadline.

"(b) The report under subsection (a) shall contain—

"(1) a summary of the information reported by agencies under section 202(f) of the E-Government Act of 2002;

"(2) the information required to be reported by section 3604(f); and

"(3) a description of compliance by the Federal Government with other goals and provisions of the E-Government Act of 2002.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of chapters for title 44, United States Code, is amended by inserting after the item relating to chapter 35 the following:

"36. Management and Promotion of Electronic Government Services 3601".

SEC. 102. CONFORMING AMENDMENTS.

(a) ELECTRONIC GOVERNMENT AND INFORMATION TECHNOLOGIES.—

(1) IN GENERAL.—Chapter 3 of title 40, United States Code, is amended by inserting after section 304 the following new section:

"§ 305. Electronic Government and information technologies

"The Administrator of General Services shall consult with the Administrator of the Office of Electronic Government on programs undertaken by the General Services Administration to promote electronic Government and the efficient use of information technologies by Federal agencies.".

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 3 of such title is amended by inserting after the item relating to section 304 the following:

"305. Electronic Government and information technologies.".

(b) MODIFICATION OF DEPUTY DIRECTOR FOR MANAGEMENT FUNCTIONS.—Section 503(b) of title 31, United States Code, is amended—

(1) by redesignating paragraphs (5), (6), (7), (8), and (9), as paragraphs (6), (7), (8), (9), and (10), respectively; and

(2) by inserting after paragraph (4) the following:

"(5) Chair the Chief Information Officers Council established under section 3603 of title 44.".

(c) OFFICE OF ELECTRONIC GOVERNMENT.—

(1) IN GENERAL.—Chapter 5 of title 31, United States Code, is amended by inserting after section 506 the following:

"§ 507. Office of Electronic Government

"The Office of Electronic Government, established under section 3602 of title 44, is an office in the Office of Management and Budget.".

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 5 of title 31, United States Code, is amended by inserting after the item relating to section 506 the following:

"507. Office of Electronic Government.".

TITLE II—FEDERAL MANAGEMENT AND PROMOTION OF ELECTRONIC GOVERNMENT SERVICES

44 USC 3501 note.

SEC. 201. DEFINITIONS.

Except as otherwise provided, in this title the definitions under sections 3502 and 3601 of title 44, United States Code, shall apply.

SEC. 202. FEDERAL AGENCY RESPONSIBILITIES.

44 USC 3501 note.

(a) IN GENERAL.—The head of each agency shall be responsible for—

(1) complying with the requirements of this Act (including the amendments made by this Act), the related information resource management policies and guidance established by the Director of the Office of Management and Budget, and the related information technology standards promulgated by the Secretary of Commerce;

(2) ensuring that the information resource management policies and guidance established under this Act by the Director, and the related information technology standards promulgated by the Secretary of Commerce are communicated promptly and effectively to all relevant officials within their agency; and

(3) supporting the efforts of the Director and the Administrator of the General Services Administration to develop, maintain, and promote an integrated Internet-based system of delivering Federal Government information and services to the public under section 204.

(b) PERFORMANCE INTEGRATION.—

(1) Agencies shall develop performance measures that demonstrate how electronic government enables progress toward agency objectives, strategic goals, and statutory mandates.

(2) In measuring performance under this section, agencies shall rely on existing data collections to the extent practicable.

(3) Areas of performance measurement that agencies should consider include—

(A) customer service;

(B) agency productivity; and

(C) adoption of innovative information technology, including the appropriate use of commercial best practices.

(4) Agencies shall link their performance goals, as appropriate, to key groups, including citizens, businesses, and other governments, and to internal Federal Government operations.

(5) As appropriate, agencies shall work collectively in linking their performance goals to groups identified under paragraph (4) and shall use information technology in delivering Government information and services to those groups.

(c) AVOIDING DIMINISHED ACCESS.—When promulgating policies and implementing programs regarding the provision of Government information and services over the Internet, agency heads shall consider the impact on persons without access to the Internet, and shall, to the extent practicable—

(1) ensure that the availability of Government information and services has not been diminished for individuals who lack access to the Internet; and

(2) pursue alternate modes of delivery that make Government information and services more accessible to individuals who do not own computers or lack access to the Internet.

(d) ACCESSIBILITY TO PEOPLE WITH DISABILITIES.—All actions taken by Federal departments and agencies under this Act shall be in compliance with section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d).

(e) SPONSORED ACTIVITIES.—Agencies shall sponsor activities that use information technology to engage the public in the development and implementation of policies and programs.

(f) CHIEF INFORMATION OFFICERS.—The Chief Information Officer of each of the agencies designated under chapter 36 of title 44, United States Code (as added by this Act) shall be responsible for—

(1) participating in the functions of the Chief Information Officers Council; and

(2) monitoring the implementation, within their respective agencies, of information technology standards promulgated by the Secretary of Commerce, including common standards for interconnectivity and interoperability, categorization of Federal Government electronic information, and computer system efficiency and security.

(g) E-GOVERNMENT STATUS REPORT.—

(1) IN GENERAL.—Each agency shall compile and submit to the Director an annual E-Government Status Report on—

(A) the status of the implementation by the agency of electronic government initiatives;

(B) compliance by the agency with this Act; and

(C) how electronic Government initiatives of the agency improve performance in delivering programs to constituencies.

(2) SUBMISSION.—Each agency shall submit an annual report under this subsection—

(A) to the Director at such time and in such manner as the Director requires;

(B) consistent with related reporting requirements; and

(C) which addresses any section in this title relevant to that agency.

(h) USE OF TECHNOLOGY.—Nothing in this Act supersedes the responsibility of an agency to use or manage information technology to deliver Government information and services that fulfill the statutory mission and programs of the agency.

(i) NATIONAL SECURITY SYSTEMS.—

(1) INAPPLICABILITY.—Except as provided under paragraph (2), this title does not apply to national security systems as defined in section 11103 of title 40, United States Code.

(2) APPLICABILITY.—This section, section 203, and section 214 do apply to national security systems to the extent practicable and consistent with law.

44 USC 3501 note.

SEC. 203. COMPATIBILITY OF EXECUTIVE AGENCY METHODS FOR USE AND ACCEPTANCE OF ELECTRONIC SIGNATURES.

(a) PURPOSE.—The purpose of this section is to achieve interoperable implementation of electronic signatures for appropriately secure electronic transactions with Government.

(b) ELECTRONIC SIGNATURES.—In order to fulfill the objectives of the Government Paperwork Elimination Act (Public Law 105–277; 112 Stat. 2681–749 through 2681–751), each Executive agency (as defined under section 105 of title 5, United States Code) shall ensure that its methods for use and acceptance of electronic signatures are compatible with the relevant policies and procedures issued by the Director.

(c) AUTHORITY FOR ELECTRONIC SIGNATURES.—The Administrator of General Services shall support the Director by establishing a framework to allow efficient interoperability among Executive agencies when using electronic signatures, including processing of digital signatures.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the General Services Administration, to ensure the development and operation of a Federal bridge certification authority for digital signature compatibility, and for other activities consistent with this section, $8,000,000 or such sums as are necessary in fiscal year 2003, and such sums as are necessary for each fiscal year thereafter.

SEC. 204. FEDERAL INTERNET PORTAL.

44 USC 3501 note.

(a) IN GENERAL.—

(1) PUBLIC ACCESS.—The Director shall work with the Administrator of the General Services Administration and other agencies to maintain and promote an integrated Internet-based system of providing the public with access to Government information and services.

(2) CRITERIA.—To the extent practicable, the integrated system shall be designed and operated according to the following criteria:

(A) The provision of Internet-based Government information and services directed to key groups, including citizens, business, and other governments, and integrated according to function or topic rather than separated according to the boundaries of agency jurisdiction.

(B) An ongoing effort to ensure that Internet-based Government services relevant to a given citizen activity are available from a single point.

(C) Access to Federal Government information and services consolidated, as appropriate, with Internet-based information and services provided by State, local, and tribal governments.

(D) Access to Federal Government information held by 1 or more agencies shall be made available in a manner that protects privacy, consistent with law.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the General Services Administration $15,000,000 for the maintenance, improvement, and promotion of the integrated Internet-based system for fiscal year 2003, and such sums as are necessary for fiscal years 2004 through 2007.

SEC. 205. FEDERAL COURTS.

44 USC 3501 note.

(a) INDIVIDUAL COURT WEBSITES.—The Chief Justice of the United States, the chief judge of each circuit and district and of the Court of Federal Claims, and the chief bankruptcy judge of each district shall cause to be established and maintained, for the court of which the judge is chief justice or judge, a website that contains the following information or links to websites with the following information:

(1) Location and contact information for the courthouse, including the telephone numbers and contact names for the clerk's office and justices' or judges' chambers.

(2) Local rules and standing or general orders of the court.

(3) Individual rules, if in existence, of each justice or judge in that court.

(4) Access to docket information for each case.

(5) Access to the substance of all written opinions issued by the court, regardless of whether such opinions are to be published in the official court reporter, in a text searchable format.

(6) Access to documents filed with the courthouse in electronic form, to the extent provided under subsection (c).

(7) Any other information (including forms in a format that can be downloaded) that the court determines useful to the public.

(b) MAINTENANCE OF DATA ONLINE.—

(1) UPDATE OF INFORMATION.—The information and rules on each website shall be updated regularly and kept reasonably current.

(2) CLOSED CASES.—Electronic files and docket information for cases closed for more than 1 year are not required to be made available online, except all written opinions with a date of issuance after the effective date of this section shall remain available online.

(c) ELECTRONIC FILINGS.—

Public information.

(1) IN GENERAL.—Except as provided under paragraph (2) or in the rules prescribed under paragraph (3), each court shall make any document that is filed electronically publicly available online. A court may convert any document that is filed in paper form to electronic form. To the extent such conversions are made, all such electronic versions of the document shall be made available online.

(2) EXCEPTIONS.—Documents that are filed that are not otherwise available to the public, such as documents filed under seal, shall not be made available online.

Regulations.

(3) PRIVACY AND SECURITY CONCERNS.—(A)(i) The Supreme Court shall prescribe rules, in accordance with sections 2072 and 2075 of title 28, United States Code, to protect privacy and security concerns relating to electronic filing of documents and the public availability under this subsection of documents filed electronically.

(ii) Such rules shall provide to the extent practicable for uniform treatment of privacy and security issues throughout the Federal courts.

(iii) Such rules shall take into consideration best practices in Federal and State courts to protect private information or otherwise maintain necessary information security.

(iv) To the extent that such rules provide for the redaction of certain categories of information in order to protect privacy and security concerns, such rules shall provide that a party that wishes to file an otherwise proper document containing such information may file an unredacted document under seal, which shall be retained by the court as part of the record, and which, at the discretion of the court and subject to any applicable rules issued in accordance with chapter 131 of title 28, United States Code, shall be either in lieu of, or in addition, to, a redacted copy in the public file.

(B)(i) Subject to clause (ii), the Judicial Conference of the United States may issue interim rules, and interpretive statements relating to the application of such rules, which conform to the requirements of this paragraph and which shall cease to have effect upon the effective date of the rules required under subparagraph (A).

(ii) Pending issuance of the rules required under subparagraph (A), any rule or order of any court, or of the Judicial Conference, providing for the redaction of certain categories of information in order to protect privacy and security concerns

arising from electronic filing shall comply with, and be construed in conformity with, subparagraph (A)(iv).

(C) Not later than 1 year after the rules prescribed under subparagraph (A) take effect, and every 2 years thereafter, the Judicial Conference shall submit to Congress a report on the adequacy of those rules to protect privacy and security. Deadlines. Reports.

(d) DOCKETS WITH LINKS TO DOCUMENTS.—The Judicial Conference of the United States shall explore the feasibility of technology to post online dockets with links allowing all filings, decisions, and rulings in each case to be obtained from the docket sheet of that case.

(e) COST OF PROVIDING ELECTRONIC DOCKETING INFORMATION.—Section 303(a) of the Judiciary Appropriations Act, 1992 (28 U.S.C. 1913 note) is amended in the first sentence by striking "shall hereafter" and inserting "may, only to the extent necessary,".

(f) TIME REQUIREMENTS.—Not later than 2 years after the effective date of this title, the websites under subsection (a) shall be established, except that access to documents filed in electronic form shall be established not later than 4 years after that effective date. Deadlines.

(g) DEFERRAL.—

(1) IN GENERAL.—

(A) ELECTION.—

(i) NOTIFICATION.—The Chief Justice of the United States, a chief judge, or chief bankruptcy judge may submit a notification to the Administrative Office of the United States Courts to defer compliance with any requirement of this section with respect to the Supreme Court, a court of appeals, district, or the bankruptcy court of a district.

(ii) CONTENTS.—A notification submitted under this subparagraph shall state—

(I) the reasons for the deferral; and

(II) the online methods, if any, or any alternative methods, such court or district is using to provide greater public access to information.

(B) EXCEPTION.—To the extent that the Supreme Court, a court of appeals, district, or bankruptcy court of a district maintains a website under subsection (a), the Supreme Court or that court of appeals or district shall comply with subsection (b)(1).

(2) REPORT.—Not later than 1 year after the effective date of this title, and every year thereafter, the Judicial Conference of the United States shall submit a report to the Committees on Governmental Affairs and the Judiciary of the Senate and the Committees on Government Reform and the Judiciary of the House of Representatives that— Deadline.

(A) contains all notifications submitted to the Administrative Office of the United States Courts under this subsection; and

(B) summarizes and evaluates all notifications.

SEC. 206. REGULATORY AGENCIES. 44 USC 3501 note.

(a) PURPOSES.—The purposes of this section are to—

(1) improve performance in the development and issuance of agency regulations by using information technology to increase access, accountability, and transparency; and

(2) enhance public participation in Government by electronic means, consistent with requirements under subchapter II of chapter 5 of title 5, United States Code, (commonly referred to as the "Administrative Procedures Act").

(b) INFORMATION PROVIDED BY AGENCIES ONLINE.—To the extent practicable as determined by the agency in consultation with the Director, each agency (as defined under section 551 of title 5, United States Code) shall ensure that a publicly accessible Federal Government website includes all information about that agency required to be published in the Federal Register under paragraphs (1) and (2) of section 552(a) of title 5, United States Code.

(c) SUBMISSIONS BY ELECTRONIC MEANS.—To the extent practicable, agencies shall accept submissions under section 553(c) of title 5, United States Code, by electronic means.

(d) ELECTRONIC DOCKETING.—

(1) IN GENERAL.—To the extent practicable, as determined by the agency in consultation with the Director, agencies shall ensure that a publicly accessible Federal Government website contains electronic dockets for rulemakings under section 553 of title 5, United States Code.

(2) INFORMATION AVAILABLE.—Agency electronic dockets shall make publicly available online to the extent practicable, as determined by the agency in consultation with the Director—

(A) all submissions under section 553(c) of title 5, United States Code; and

(B) other materials that by agency rule or practice are included in the rulemaking docket under section 553(c) of title 5, United States Code, whether or not submitted electronically.

(e) TIME LIMITATION.—Agencies shall implement the requirements of this section consistent with a timetable established by the Director and reported to Congress in the first annual report under section 3606 of title 44 (as added by this Act).

44 USC 3501 note.

SEC. 207. ACCESSIBILITY, USABILITY, AND PRESERVATION OF GOVERNMENT INFORMATION.

(a) PURPOSE.—The purpose of this section is to improve the methods by which Government information, including information on the Internet, is organized, preserved, and made accessible to the public.

(b) DEFINITIONS.—In this section, the term—

(1) "Committee" means the Interagency Committee on Government Information established under subsection (c); and

(2) "directory" means a taxonomy of subjects linked to websites that—

(A) organizes Government information on the Internet according to subject matter; and

(B) may be created with the participation of human editors.

(c) INTERAGENCY COMMITTEE.—

Deadline.

(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of this title, the Director shall establish the Interagency Committee on Government Information.

(2) MEMBERSHIP.—The Committee shall be chaired by the Director or the designee of the Director and—

(A) shall include representatives from—

(i) the National Archives and Records Administration;

(ii) the offices of the Chief Information Officers from Federal agencies; and

(iii) other relevant officers from the executive branch; and

(B) may include representatives from the Federal legislative and judicial branches.

(3) FUNCTIONS.—The Committee shall—

(A) engage in public consultation to the maximum extent feasible, including consultation with interested communities such as public advocacy organizations;

(B) conduct studies and submit recommendations, as provided under this section, to the Director and Congress; and

(C) share effective practices for access to, dissemination of, and retention of Federal information.

(4) TERMINATION.—The Committee may be terminated on a date determined by the Director, except the Committee may not terminate before the Committee submits all recommendations required under this section.

(d) CATEGORIZING OF INFORMATION.—

(1) COMMITTEE FUNCTIONS.—Not later than 2 years after the date of enactment of this Act, the Committee shall submit recommendations to the Director on— Deadline.

(A) the adoption of standards, which are open to the maximum extent feasible, to enable the organization and categorization of Government information—

(i) in a way that is searchable electronically, including by searchable identifiers; and

(ii) in ways that are interoperable across agencies;

(B) the definition of categories of Government information which should be classified under the standards; and

(C) determining priorities and developing schedules for the initial implementation of the standards by agencies.

(2) FUNCTIONS OF THE DIRECTOR.—Not later than 1 year after the submission of recommendations under paragraph (1), the Director shall issue policies— Deadline. Policies.

(A) requiring that agencies use standards, which are open to the maximum extent feasible, to enable the organization and categorization of Government information—

(i) in a way that is searchable electronically, including by searchable identifiers;

(ii) in ways that are interoperable across agencies; and

(iii) that are, as appropriate, consistent with the provisions under section 3602(f)(8) of title 44, United States Code;

(B) defining categories of Government information which shall be required to be classified under the standards; and

(C) determining priorities and developing schedules for the initial implementation of the standards by agencies.

(3) MODIFICATION OF POLICIES.—After the submission of agency reports under paragraph (4), the Director shall modify

the policies, as needed, in consultation with the Committee and interested parties.

Reports.

(4) AGENCY FUNCTIONS.—Each agency shall report annually to the Director, in the report established under section 202(g), on compliance of that agency with the policies issued under paragraph (2)(A).

(e) PUBLIC ACCESS TO ELECTRONIC INFORMATION.—

Deadline.

(1) COMMITTEE FUNCTIONS.—Not later than 2 years after the date of enactment of this Act, the Committee shall submit recommendations to the Director and the Archivist of the United States on—

(A) the adoption by agencies of policies and procedures to ensure that chapters 21, 25, 27, 29, and 31 of title 44, United States Code, are applied effectively and comprehensively to Government information on the Internet and to other electronic records; and

(B) the imposition of timetables for the implementation of the policies and procedures by agencies.

Deadline.
Policies.

(2) FUNCTIONS OF THE ARCHIVIST.—Not later than 1 year after the submission of recommendations by the Committee under paragraph (1), the Archivist of the United States shall issue policies—

(A) requiring the adoption by agencies of policies and procedures to ensure that chapters 21, 25, 27, 29, and 31 of title 44, United States Code, are applied effectively and comprehensively to Government information on the Internet and to other electronic records; and

(B) imposing timetables for the implementation of the policies, procedures, and technologies by agencies.

(3) MODIFICATION OF POLICIES.—After the submission of agency reports under paragraph (4), the Archivist of the United States shall modify the policies, as needed, in consultation with the Committee and interested parties.

Reports.

(4) AGENCY FUNCTIONS.—Each agency shall report annually to the Director, in the report established under section 202(g), on compliance of that agency with the policies issued under paragraph (2)(A).

(f) AGENCY WEBSITES.—

Deadline.
Guidelines.

(1) STANDARDS FOR AGENCY WEBSITES.—Not later than 2 years after the effective date of this title, the Director shall promulgate guidance for agency websites that includes—

(A) requirements that websites include direct links to—

(i) descriptions of the mission and statutory authority of the agency;

(ii) information made available to the public under subsections (a)(1) and (b) of section 552 of title 5, United States Code (commonly referred to as the "Freedom of Information Act");

(iii) information about the organizational structure of the agency; and

(iv) the strategic plan of the agency developed under section 306 of title 5, United States Code; and

(B) minimum agency goals to assist public users to navigate agency websites, including—

(i) speed of retrieval of search results;

(ii) the relevance of the results;

(iii) tools to aggregate and disaggregate data; and

(iv) security protocols to protect information.

(2) AGENCY REQUIREMENTS.—(A) Not later than 2 years after the date of enactment of this Act, each agency shall— Deadline.

(i) consult with the Committee and solicit public comment;

(ii) establish a process for determining which Government information the agency intends to make available and accessible to the public on the Internet and by other means;

(iii) develop priorities and schedules for making Government information available and accessible;

(iv) make such final determinations, priorities, and schedules available for public comment;

(v) post such final determinations, priorities, and schedules on the Internet; and

(vi) submit such final determinations, priorities, and schedules to the Director, in the report established under section 202(g).

(B) Each agency shall update determinations, priorities, and schedules of the agency, as needed, after consulting with the Committee and soliciting public comment, if appropriate.

(3) PUBLIC DOMAIN DIRECTORY OF PUBLIC FEDERAL GOVERNMENT WEBSITES.—

(A) ESTABLISHMENT.—Not later than 2 years after the effective date of this title, the Director and each agency shall— Deadline.

(i) develop and establish a public domain directory of public Federal Government websites; and

(ii) post the directory on the Internet with a link to the integrated Internet-based system established under section 204.

(B) DEVELOPMENT.—With the assistance of each agency, the Director shall—

(i) direct the development of the directory through a collaborative effort, including input from—

(I) agency librarians;

(II) information technology managers;

(III) program managers;

(IV) records managers;

(V) Federal depository librarians; and

(VI) other interested parties; and

(ii) develop a public domain taxonomy of subjects used to review and categorize public Federal Government websites.

(C) UPDATE.—With the assistance of each agency, the Administrator of the Office of Electronic Government shall—

(i) update the directory as necessary, but not less than every 6 months; and Deadline.

(ii) solicit interested persons for improvements to the directory.

(g) ACCESS TO FEDERALLY FUNDED RESEARCH AND DEVELOPMENT.—

(1) DEVELOPMENT AND MAINTENANCE OF GOVERNMENTWIDE REPOSITORY AND WEBSITE.—

(A) REPOSITORY AND WEBSITE.—The Director of the Office of Management and Budget (or the Director's delegate), in consultation with the Director of the Office of Science and Technology Policy and other relevant agencies, shall ensure the development and maintenance of—

(i) a repository that fully integrates, to the maximum extent feasible, information about research and development funded by the Federal Government, and the repository shall—

(I) include information about research and development funded by the Federal Government, consistent with any relevant protections for the information under section 552 of title 5, United States Code, and performed by—

(aa) institutions not a part of the Federal Government, including State, local, and foreign governments; industrial firms; educational institutions; not-for-profit organizations; federally funded research and development centers; and private individuals; and

(bb) entities of the Federal Government, including research and development laboratories, centers, and offices; and

(II) integrate information about each separate research and development task or award, including—

(aa) the dates upon which the task or award is expected to start and end;

(bb) a brief summary describing the objective and the scientific and technical focus of the task or award;

(cc) the entity or institution performing the task or award and its contact information;

(dd) the total amount of Federal funds expected to be provided to the task or award over its lifetime and the amount of funds expected to be provided in each fiscal year in which the work of the task or award is ongoing;

(ee) any restrictions attached to the task or award that would prevent the sharing with the general public of any or all of the information required by this subsection, and the reasons for such restrictions; and

(ff) such other information as may be determined to be appropriate; and

Public information.

(ii) 1 or more websites upon which all or part of the repository of Federal research and development shall be made available to and searchable by Federal agencies and non-Federal entities, including the general public, to facilitate—

(I) the coordination of Federal research and development activities;

(II) collaboration among those conducting Federal research and development;

(III) the transfer of technology among Federal agencies and between Federal agencies and non-Federal entities; and

(IV) access by policymakers and the public to information concerning Federal research and development activities.

(B) OVERSIGHT.—The Director of the Office of Management and Budget shall issue any guidance determined necessary to ensure that agencies provide all information requested under this subsection. Guidelines.

(2) AGENCY FUNCTIONS.—Any agency that funds Federal research and development under this subsection shall provide the information required to populate the repository in the manner prescribed by the Director of the Office of Management and Budget.

(3) COMMITTEE FUNCTIONS.—Not later than 18 months after the date of enactment of this Act, working with the Director of the Office of Science and Technology Policy, and after consultation with interested parties, the Committee shall submit recommendations to the Director on— Deadline.

(A) policies to improve agency reporting of information for the repository established under this subsection; and

(B) policies to improve dissemination of the results of research performed by Federal agencies and federally funded research and development centers.

(4) FUNCTIONS OF THE DIRECTOR.—After submission of recommendations by the Committee under paragraph (3), the Director shall report on the recommendations of the Committee and Director to Congress, in the E-Government report under section 3606 of title 44 (as added by this Act). Reports.

(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the development, maintenance, and operation of the Governmentwide repository and website under this subsection—

(A) $2,000,000 in each of the fiscal years 2003 through 2005; and

(B) such sums as are necessary in each of the fiscal years 2006 and 2007.

SEC. 208. PRIVACY PROVISIONS. 44 USC 3501 note.

(a) PURPOSE.—The purpose of this section is to ensure sufficient protections for the privacy of personal information as agencies implement citizen-centered electronic Government.

(b) PRIVACY IMPACT ASSESSMENTS.—

(1) RESPONSIBILITIES OF AGENCIES.—

(A) IN GENERAL.—An agency shall take actions described under subparagraph (B) before—

(i) developing or procuring information technology that collects, maintains, or disseminates information that is in an identifiable form; or

(ii) initiating a new collection of information that—

(I) will be collected, maintained, or disseminated using information technology; and

(II) includes any information in an identifiable form permitting the physical or online contacting of a specific individual, if identical questions have been posed to, or identical reporting requirements

imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the Federal Government.

(B) AGENCY ACTIVITIES.—To the extent required under subparagraph (A), each agency shall—

(i) conduct a privacy impact assessment;

(ii) ensure the review of the privacy impact assessment by the Chief Information Officer, or equivalent official, as determined by the head of the agency; and

Public information. Federal Register, publication.

(iii) if practicable, after completion of the review under clause (ii), make the privacy impact assessment publicly available through the website of the agency, publication in the Federal Register, or other means.

(C) SENSITIVE INFORMATION.—Subparagraph (B)(iii) may be modified or waived for security reasons, or to protect classified, sensitive, or private information contained in an assessment.

(D) COPY TO DIRECTOR.—Agencies shall provide the Director with a copy of the privacy impact assessment for each system for which funding is requested.

(2) CONTENTS OF A PRIVACY IMPACT ASSESSMENT.—

(A) IN GENERAL.—The Director shall issue guidance to agencies specifying the required contents of a privacy impact assessment.

(B) GUIDANCE.—The guidance shall—

(i) ensure that a privacy impact assessment is commensurate with the size of the information system being assessed, the sensitivity of information that is in an identifiable form in that system, and the risk of harm from unauthorized release of that information; and

(ii) require that a privacy impact assessment address—

(I) what information is to be collected;

(II) why the information is being collected;

(III) the intended use of the agency of the information;

(IV) with whom the information will be shared;

(V) what notice or opportunities for consent would be provided to individuals regarding what information is collected and how that information is shared;

(VI) how the information will be secured; and

(VII) whether a system of records is being created under section 552a of title 5, United States Code, (commonly referred to as the "Privacy Act").

(3) RESPONSIBILITIES OF THE DIRECTOR.—The Director shall—

Guidelines.

(A) develop policies and guidelines for agencies on the conduct of privacy impact assessments;

(B) oversee the implementation of the privacy impact assessment process throughout the Government; and

(C) require agencies to conduct privacy impact assessments of existing information systems or ongoing collections of information that is in an identifiable form as the Director determines appropriate.

(c) PRIVACY PROTECTIONS ON AGENCY WEBSITES.—

(1) PRIVACY POLICIES ON WEBSITES.—

(A) GUIDELINES FOR NOTICES.—The Director shall develop guidance for privacy notices on agency websites used by the public.

(B) CONTENTS.—The guidance shall require that a privacy notice address, consistent with section 552a of title 5, United States Code—

(i) what information is to be collected;

(ii) why the information is being collected;

(iii) the intended use of the agency of the information;

(iv) with whom the information will be shared;

(v) what notice or opportunities for consent would be provided to individuals regarding what information is collected and how that information is shared;

(vi) how the information will be secured; and

(vii) the rights of the individual under section 552a of title 5, United States Code (commonly referred to as the "Privacy Act"), and other laws relevant to the protection of the privacy of an individual.

(2) PRIVACY POLICIES IN MACHINE-READABLE FORMATS.—The Director shall issue guidance requiring agencies to translate privacy policies into a standardized machine-readable format. Guidelines.

(d) DEFINITION.—In this section, the term "identifiable form" means any representation of information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means.

SEC. 209. FEDERAL INFORMATION TECHNOLOGY WORKFORCE DEVELOPMENT. 44 USC 3501 note.

(a) PURPOSE.—The purpose of this section is to improve the skills of the Federal workforce in using information technology to deliver Government information and services.

(b) WORKFORCE DEVELOPMENT.—

(1) IN GENERAL.—In consultation with the Director of the Office of Management and Budget, the Chief Information Officers Council, and the Administrator of General Services, the Director of the Office of Personnel Management shall—

(A) analyze, on an ongoing basis, the personnel needs of the Federal Government related to information technology and information resource management;

(B) identify where current information technology and information resource management training do not satisfy the personnel needs described in subparagraph (A);

(C) oversee the development of curricula, training methods, and training priorities that correspond to the projected personnel needs of the Federal Government related to information technology and information resource management; and

(D) assess the training of Federal employees in information technology disciplines in order to ensure that the information resource management needs of the Federal Government are addressed.

(2) INFORMATION TECHNOLOGY TRAINING PROGRAMS.—The head of each Executive agency, after consultation with the Director of the Office of Personnel Management, the Chief

Information Officers Council, and the Administrator of General Services, shall establish and operate information technology training programs consistent with the requirements of this subsection. Such programs shall—

(A) have curricula covering a broad range of information technology disciplines corresponding to the specific information technology and information resource management needs of the agency involved;

(B) be developed and applied according to rigorous standards; and

(C) be designed to maximize efficiency, through the use of self-paced courses, online courses, on-the-job training, and the use of remote instructors, wherever such features can be applied without reducing the effectiveness of the training or negatively impacting academic standards.

(3) GOVERNMENTWIDE POLICIES AND EVALUATION.—The Director of the Office of Personnel Management, in coordination with the Director of the Office of Management and Budget, shall issue policies to promote the development of performance standards for training and uniform implementation of this subsection by Executive agencies, with due regard for differences in program requirements among agencies that may be appropriate and warranted in view of the agency mission. The Director of the Office of Personnel Management shall evaluate the implementation of the provisions of this subsection by Executive agencies.

(4) CHIEF INFORMATION OFFICER AUTHORITIES AND RESPONSIBILITIES.—Subject to the authority, direction, and control of the head of an Executive agency, the chief information officer of such agency shall carry out all powers, functions, and duties of the head of the agency with respect to implementation of this subsection. The chief information officer shall ensure that the policies of the agency head established in accordance with this subsection are implemented throughout the agency.

Records.

(5) INFORMATION TECHNOLOGY TRAINING REPORTING.—The Director of the Office of Management and Budget shall ensure that the heads of Executive agencies collect and maintain standardized information on the information technology and information resources management workforce related to the implementation of this subsection.

(6) AUTHORITY TO DETAIL EMPLOYEES TO NON-FEDERAL EMPLOYERS.—In carrying out the preceding provisions of this subsection, the Director of the Office of Personnel Management may provide for a program under which a Federal employee may be detailed to a non-Federal employer. The Director of the Office of Personnel Management shall prescribe regulations for such program, including the conditions for service and duties as the Director considers necessary.

Regulations.

(7) COORDINATION PROVISION.—An assignment described in section 3703 of title 5, United States Code, may not be made unless a program under paragraph (6) is established, and the assignment is made in accordance with the requirements of such program.

(8) EMPLOYEE PARTICIPATION.—Subject to information resource management needs and the limitations imposed by resource needs in other occupational areas, and consistent with their overall workforce development strategies, agencies shall

encourage employees to participate in occupational information technology training.

(9) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Office of Personnel Management for the implementation of this subsection, $15,000,000 in fiscal year 2003, and such sums as are necessary for each fiscal year thereafter.

(10) EXECUTIVE AGENCY DEFINED.—For purposes of this subsection, the term "Executive agency" has the meaning given the term "agency" under section 3701 of title 5, United States Code (as added by subsection (c)).

(c) INFORMATION TECHNOLOGY EXCHANGE PROGRAM.—

(1) IN GENERAL.—Subpart B of part III of title 5, United States Code, is amended by adding at the end the following:

"CHAPTER 37—INFORMATION TECHNOLOGY EXCHANGE PROGRAM

"Sec.
"3701. Definitions.
"3702. General provisions.
"3703. Assignment of employees to private sector organizations.
"3704. Assignment of employees from private sector organizations.
"3705. Application to Office of the Chief Technology Officer of the District of Columbia.
"3706. Reporting requirement.
"3707. Regulations.

"§ 3701. Definitions

"For purposes of this chapter—

"(1) the term 'agency' means an Executive agency, but does not include the General Accounting Office; and

"(2) the term 'detail' means—

"(A) the assignment or loan of an employee of an agency to a private sector organization without a change of position from the agency that employs the individual, or

"(B) the assignment or loan of an employee of a private sector organization to an agency without a change of position from the private sector organization that employs the individual,

whichever is appropriate in the context in which such term is used.

"§ 3702. General provisions

"(a) ASSIGNMENT AUTHORITY.—On request from or with the agreement of a private sector organization, and with the consent of the employee concerned, the head of an agency may arrange for the assignment of an employee of the agency to a private sector organization or an employee of a private sector organization to the agency. An eligible employee is an individual who—

"(1) works in the field of information technology management;

"(2) is considered an exceptional performer by the individual's current employer; and

"(3) is expected to assume increased information technology management responsibilities in the future.

Eligibility.

An employee of an agency shall be eligible to participate in this program only if the employee is employed at the GS–11 level

or above (or equivalent) and is serving under a career or career-conditional appointment or an appointment of equivalent tenure in the excepted service, and applicable requirements of section 209(b) of the E-Government Act of 2002 are met with respect to the proposed assignment of such employee.

"(b) AGREEMENTS.—Each agency that exercises its authority under this chapter shall provide for a written agreement between the agency and the employee concerned regarding the terms and conditions of the employee's assignment. In the case of an employee of the agency, the agreement shall—

"(1) require the employee to serve in the civil service, upon completion of the assignment, for a period equal to the length of the assignment; and

"(2) provide that, in the event the employee fails to carry out the agreement (except for good and sufficient reason, as determined by the head of the agency from which assigned) the employee shall be liable to the United States for payment of all expenses of the assignment.

An amount under paragraph (2) shall be treated as a debt due the United States.

"(c) TERMINATION.—Assignments may be terminated by the agency or private sector organization concerned for any reason at any time.

"(d) DURATION.—Assignments under this chapter shall be for a period of between 3 months and 1 year, and may be extended in 3-month increments for a total of not more than 1 additional year, except that no assignment under this chapter may commence after the end of the 5-year period beginning on the date of the enactment of this chapter.

"(e) ASSISTANCE.—The Chief Information Officers Council, by agreement with the Office of Personnel Management, may assist in the administration of this chapter, including by maintaining lists of potential candidates for assignment under this chapter, establishing mentoring relationships for the benefit of individuals who are given assignments under this chapter, and publicizing the program.

"(f) CONSIDERATIONS.—In exercising any authority under this chapter, an agency shall take into consideration—

"(1) the need to ensure that small business concerns are appropriately represented with respect to the assignments described in sections 3703 and 3704, respectively; and

"(2) how assignments described in section 3703 might best be used to help meet the needs of the agency for the training of employees in information technology management.

"§ 3703. Assignment of employees to private sector organizations

"(a) IN GENERAL.—An employee of an agency assigned to a private sector organization under this chapter is deemed, during the period of the assignment, to be on detail to a regular work assignment in his agency.

"(b) COORDINATION WITH CHAPTER 81.—Notwithstanding any other provision of law, an employee of an agency assigned to a private sector organization under this chapter is entitled to retain coverage, rights, and benefits under subchapter I of chapter 81, and employment during the assignment is deemed employment by the United States, except that, if the employee or the employee's

dependents receive from the private sector organization any payment under an insurance policy for which the premium is wholly paid by the private sector organization, or other benefit of any kind on account of the same injury or death, then, the amount of such payment or benefit shall be credited against any compensation otherwise payable under subchapter I of chapter 81.

"(c) REIMBURSEMENTS.—The assignment of an employee to a private sector organization under this chapter may be made with or without reimbursement by the private sector organization for the travel and transportation expenses to or from the place of assignment, subject to the same terms and conditions as apply with respect to an employee of a Federal agency or a State or local government under section 3375, and for the pay, or a part thereof, of the employee during assignment. Any reimbursements shall be credited to the appropriation of the agency used for paying the travel and transportation expenses or pay.

"(d) TORT LIABILITY; SUPERVISION.—The Federal Tort Claims Act and any other Federal tort liability statute apply to an employee of an agency assigned to a private sector organization under this chapter. The supervision of the duties of an employee of an agency so assigned to a private sector organization may be governed by an agreement between the agency and the organization.

"(e) SMALL BUSINESS CONCERNS.—

"(1) IN GENERAL.—The head of each agency shall take such actions as may be necessary to ensure that, of the assignments made under this chapter from such agency to private sector organizations in each year, at least 20 percent are to small business concerns.

"(2) DEFINITIONS.—For purposes of this subsection—

"(A) the term 'small business concern' means a business concern that satisfies the definitions and standards specified by the Administrator of the Small Business Administration under section 3(a)(2) of the Small Business Act (as from time to time amended by the Administrator);

"(B) the term 'year' refers to the 12-month period beginning on the date of the enactment of this chapter, and each succeeding 12-month period in which any assignments under this chapter may be made; and

"(C) the assignments 'made' in a year are those commencing in such year.

"(3) REPORTING REQUIREMENT.—An agency which fails to comply with paragraph (1) in a year shall, within 90 days after the end of such year, submit a report to the Committees on Government Reform and Small Business of the House of Representatives and the Committees on Governmental Affairs and Small Business of the Senate. The report shall include— Deadline.

"(A) the total number of assignments made under this chapter from such agency to private sector organizations in the year;

"(B) of that total number, the number (and percentage) made to small business concerns; and

"(C) the reasons for the agency's noncompliance with paragraph (1).

"(4) EXCLUSION.—This subsection shall not apply to an agency in any year in which it makes fewer than 5 assignments under this chapter to private sector organizations.

"§ 3704. Assignment of employees from private sector organizations

"(a) IN GENERAL.—An employee of a private sector organization assigned to an agency under this chapter is deemed, during the period of the assignment, to be on detail to such agency.

"(b) TERMS AND CONDITIONS.—An employee of a private sector organization assigned to an agency under this chapter—

"(1) may continue to receive pay and benefits from the private sector organization from which he is assigned;

"(2) is deemed, notwithstanding subsection (a), to be an employee of the agency for the purposes of—

"(A) chapter 73;

"(B) sections 201, 203, 205, 207, 208, 209, 603, 606, 607, 643, 654, 1905, and 1913 of title 18;

"(C) sections 1343, 1344, and 1349(b) of title 31;

"(D) the Federal Tort Claims Act and any other Federal tort liability statute;

"(E) the Ethics in Government Act of 1978;

"(F) section 1043 of the Internal Revenue Code of 1986; and

"(G) section 27 of the Office of Federal Procurement Policy Act;

"(3) may not have access to any trade secrets or to any other nonpublic information which is of commercial value to the private sector organization from which he is assigned; and

"(4) is subject to such regulations as the President may prescribe.

The supervision of an employee of a private sector organization assigned to an agency under this chapter may be governed by agreement between the agency and the private sector organization concerned. Such an assignment may be made with or without reimbursement by the agency for the pay, or a part thereof, of the employee during the period of assignment, or for any contribution of the private sector organization to employee benefit systems.

"(c) COORDINATION WITH CHAPTER 81.—An employee of a private sector organization assigned to an agency under this chapter who suffers disability or dies as a result of personal injury sustained while performing duties during the assignment shall be treated, for the purpose of subchapter I of chapter 81, as an employee as defined by section 8101 who had sustained the injury in the performance of duty, except that, if the employee or the employee's dependents receive from the private sector organization any payment under an insurance policy for which the premium is wholly paid by the private sector organization, or other benefit of any kind on account of the same injury or death, then, the amount of such payment or benefit shall be credited against any compensation otherwise payable under subchapter I of chapter 81.

"(d) PROHIBITION AGAINST CHARGING CERTAIN COSTS TO THE FEDERAL GOVERNMENT.—A private sector organization may not charge the Federal Government, as direct or indirect costs under a Federal contract, the costs of pay or benefits paid by the organization to an employee assigned to an agency under this chapter for the period of the assignment.

"§ 3705. Application to Office of the Chief Technology Officer of the District of Columbia

"(a) IN GENERAL.—The Chief Technology Officer of the District of Columbia may arrange for the assignment of an employee of the Office of the Chief Technology Officer to a private sector organization, or an employee of a private sector organization to such Office, in the same manner as the head of an agency under this chapter.

"(b) TERMS AND CONDITIONS.—An assignment made pursuant to subsection (a) shall be subject to the same terms and conditions as an assignment made by the head of an agency under this chapter, except that in applying such terms and conditions to an assignment made pursuant to subsection (a), any reference in this chapter to a provision of law or regulation of the United States shall be deemed to be a reference to the applicable provision of law or regulation of the District of Columbia, including the applicable provisions of the District of Columbia Government Comprehensive Merit Personnel Act of 1978 (sec. 1–601.01 et seq., D.C. Official Code) and section 601 of the District of Columbia Campaign Finance Reform and Conflict of Interest Act (sec. 1–1106.01, D.C. Official Code).

"(c) DEFINITION.—For purposes of this section, the term 'Office of the Chief Technology Officer' means the office established in the executive branch of the government of the District of Columbia under the Office of the Chief Technology Officer Establishment Act of 1998 (sec. 1–1401 et seq., D.C. Official Code).

"§ 3706. Reporting requirement

"(a) IN GENERAL.—The Office of Personnel Management shall, not later than April 30 and October 31 of each year, prepare and submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate a semiannual report summarizing the operation of this chapter during the immediately preceding 6-month period ending on March 31 and September 30, respectively. Deadline.

"(b) CONTENT.—Each report shall include, with respect to the 6-month period to which such report relates—

"(1) the total number of individuals assigned to, and the total number of individuals assigned from, each agency during such period;

"(2) a brief description of each assignment included under paragraph (1), including—

"(A) the name of the assigned individual, as well as the private sector organization and the agency (including the specific bureau or other agency component) to or from which such individual was assigned;

"(B) the respective positions to and from which the individual was assigned, including the duties and responsibilities and the pay grade or level associated with each; and

"(C) the duration and objectives of the individual's assignment; and

"(3) such other information as the Office considers appropriate.

"(c) PUBLICATION.—A copy of each report submitted under subsection (a)—

"(1) shall be published in the Federal Register; and Federal Register, publication.

Public information.

"(2) shall be made publicly available on the Internet.

"(d) AGENCY COOPERATION.—On request of the Office, agencies shall furnish such information and reports as the Office may require in order to carry out this section.

"§ 3707. Regulations

"The Director of the Office of Personnel Management shall prescribe regulations for the administration of this chapter.".

Deadline.

(2) REPORT.—Not later than 4 years after the date of the enactment of this Act, the General Accounting Office shall prepare and submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate a report on the operation of chapter 37 of title 5, United States Code (as added by this subsection). Such report shall include—

(A) an evaluation of the effectiveness of the program established by such chapter; and

(B) a recommendation as to whether such program should be continued (with or without modification) or allowed to lapse.

(3) CLERICAL AMENDMENT.—The analysis for part III of title 5, United States Code, is amended by inserting after the item relating to chapter 35 the following:

"37. Information Technology Exchange Program ..... 3701".

(d) ETHICS PROVISIONS.—

(1) ONE-YEAR RESTRICTION ON CERTAIN COMMUNICATIONS.—Section 207(c)(2)(A) of title 18, United States Code, is amended—

(A) by striking "or" at the end of clause (iii);

(B) by striking the period at the end of clause (iv) and inserting "; or"; and

(C) by adding at the end the following:

"(v) assigned from a private sector organization to an agency under chapter 37 of title 5.".

(2) DISCLOSURE OF CONFIDENTIAL INFORMATION.—Section 1905 of title 18, United States Code, is amended by inserting "or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5," after "(15 U.S.C. 1311–1314),".

(3) CONTRACT ADVICE.—Section 207 of title 18, United States Code, is amended by adding at the end the following:

"(l) CONTRACT ADVICE BY FORMER DETAILS.—Whoever, being an employee of a private sector organization assigned to an agency under chapter 37 of title 5, within one year after the end of that assignment, knowingly represents or aids, counsels, or assists in representing any other person (except the United States) in connection with any contract with that agency shall be punished as provided in section 216 of this title.".

(4) RESTRICTION ON DISCLOSURE OF PROCUREMENT INFORMATION.—Section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423) is amended in subsection (a)(1) by adding at the end the following new sentence: "In the case of an employee of a private sector organization assigned to an agency under chapter 37 of title 5, United States Code, in addition to the restriction in the preceding sentence, such employee shall not, other than as provided by law, knowingly disclose contractor bid or proposal information or source selection

information during the three-year period after the end of the assignment of such employee.".

(e) REPORT ON EXISTING EXCHANGE PROGRAMS.—

(1) EXCHANGE PROGRAM DEFINED.—For purposes of this subsection, the term "exchange program" means an executive exchange program, the program under subchapter VI of chapter 33 of title 5, United States Code, and any other program which allows for—

(A) the assignment of employees of the Federal Government to non-Federal employers;

(B) the assignment of employees of non-Federal employers to the Federal Government; or

(C) both.

(2) REPORTING REQUIREMENT.—Not later than 1 year after the date of the enactment of this Act, the Office of Personnel Management shall prepare and submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate a report identifying all existing exchange programs. Deadline.

(3) SPECIFIC INFORMATION.—The report shall, for each such program, include—

(A) a brief description of the program, including its size, eligibility requirements, and terms or conditions for participation;

(B) specific citation to the law or other authority under which the program is established;

(C) the names of persons to contact for more information, and how they may be reached; and

(D) any other information which the Office considers appropriate.

(f) REPORT ON THE ESTABLISHMENT OF A GOVERNMENTWIDE INFORMATION TECHNOLOGY TRAINING PROGRAM.—

(1) IN GENERAL.—Not later January 1, 2003, the Office of Personnel Management, in consultation with the Chief Information Officers Council and the Administrator of General Services, shall review and submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate a written report on the following: Deadline.

(A) The adequacy of any existing information technology training programs available to Federal employees on a Governmentwide basis.

(B)(i) If one or more such programs already exist, recommendations as to how they might be improved.

(ii) If no such program yet exists, recommendations as to how such a program might be designed and established.

(C) With respect to any recommendations under subparagraph (B), how the program under chapter 37 of title 5, United States Code, might be used to help carry them out.

(2) COST ESTIMATE.—The report shall, for any recommended program (or improvements) under paragraph (1)(B), include the estimated costs associated with the implementation and operation of such program as so established (or estimated difference in costs of any such program as so improved).

(g) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) AMENDMENTS TO TITLE 5, UNITED STATES CODE.—Title 5, United States Code, is amended—

(A) in section 3111, by adding at the end the following:

"(d) Notwithstanding section 1342 of title 31, the head of an agency may accept voluntary service for the United States under chapter 37 of this title and regulations of the Office of Personnel Management.";

(B) in section 4108, by striking subsection (d); and

(C) in section 7353(b), by adding at the end the following:

"(4) Nothing in this section precludes an employee of a private sector organization, while assigned to an agency under chapter 37, from continuing to receive pay and benefits from such organization in accordance with such chapter.".

(2) AMENDMENT TO TITLE 18, UNITED STATES CODE.—Section 209 of title 18, United States Code, is amended by adding at the end the following:

"(g)(1) This section does not prohibit an employee of a private sector organization, while assigned to an agency under chapter 37 of title 5, from continuing to receive pay and benefits from such organization in accordance with such chapter.

"(2) For purposes of this subsection, the term 'agency' means an agency (as defined by section 3701 of title 5) and the Office of the Chief Technology Officer of the District of Columbia.".

(3) OTHER AMENDMENTS.—Section 125(c)(1) of Public Law 100–238 (5 U.S.C. 8432 note) is amended—

(A) in subparagraph (B), by striking "or" at the end;

(B) in subparagraph (C), by striking "and" at the end and inserting "or"; and

(C) by adding at the end the following:

"(D) an individual assigned from a Federal agency to a private sector organization under chapter 37 of title 5, United States Code; and".

44 USC 3501 note.

SEC. 210. SHARE-IN-SAVINGS INITIATIVES.

(a) DEFENSE CONTRACTS.—(1) Chapter 137 of title 10, United States Code, is amended by adding at the end the following new section:

"§ 2332. Share-in-savings contracts

"(a) AUTHORITY TO ENTER INTO SHARE-IN-SAVINGS CONTRACTS.—(1) The head of an agency may enter into a share-in-savings contract for information technology (as defined in section 11101(6) of title 40) in which the Government awards a contract to improve mission-related or administrative processes or to accelerate the achievement of its mission and share with the contractor in savings achieved through contract performance.

"(2)(A) Except as provided in subparagraph (B), a share-in-savings contract shall be awarded for a period of not more than five years.

"(B) A share-in-savings contract may be awarded for a period greater than five years, but not more than 10 years, if the head of the agency determines in writing prior to award of the contract that—

"(i) the level of risk to be assumed and the investment to be undertaken by the contractor is likely to inhibit the government from obtaining the needed information technology

competitively at a fair and reasonable price if the contract is limited in duration to a period of five years or less; and

"(ii) usage of the information technology to be acquired is likely to continue for a period of time sufficient to generate reasonable benefit for the government.

"(3) Contracts awarded pursuant to the authority of this section shall, to the maximum extent practicable, be performance-based contracts that identify objective outcomes and contain performance standards that will be used to measure achievement and milestones that must be met before payment is made.

"(4) Contracts awarded pursuant to the authority of this section shall include a provision containing a quantifiable baseline that is to be the basis upon which a savings share ratio is established that governs the amount of payment a contractor is to receive under the contract. Before commencement of performance of such a contract, the senior procurement executive of the agency shall determine in writing that the terms of the provision are quantifiable and will likely yield value to the Government.

"(5)(A) The head of the agency may retain savings realized through the use of a share-in-savings contract under this section that are in excess of the total amount of savings paid to the contractor under the contract, but may not retain any portion of such savings that is attributable to a decrease in the number of civilian employees of the Federal Government performing the function. Except as provided in subparagraph (B), savings shall be credited to the appropriation or fund against which charges were made to carry out the contract and shall be used for information technology.

"(B) Amounts retained by the agency under this subsection shall—

"(i) without further appropriation, remain available until expended; and

"(ii) be applied first to fund any contingent liabilities associated with share-in-savings procurements that are not fully funded.

"(b) CANCELLATION AND TERMINATION.—(1) If funds are not made available for the continuation of a share-in-savings contract entered into under this section in a subsequent fiscal year, the contract shall be canceled or terminated. The costs of cancellation or termination may be paid out of—

"(A) appropriations available for the performance of the contract;

"(B) appropriations available for acquisition of the information technology procured under the contract, and not otherwise obligated; or

"(C) funds subsequently appropriated for payments of costs of cancellation or termination, subject to the limitations in paragraph (3).

"(2) The amount payable in the event of cancellation or termination of a share-in-savings contract shall be negotiated with the contractor at the time the contract is entered into.

"(3)(A) Subject to subparagraph (B), the head of an agency may enter into share-in-savings contracts under this section in any given fiscal year even if funds are not made specifically available for the full costs of cancellation or termination of the contract if funds are available and sufficient to make payments with respect to the first fiscal year of the contract and the following conditions

are met regarding the funding of cancellation and termination liability:

"(i) The amount of unfunded contingent liability for the contract does not exceed the lesser of—

"(I) 25 percent of the estimated costs of a cancellation or termination; or

"(II) $5,000,000.

"(ii) Unfunded contingent liability in excess of $1,000,000 has been approved by the Director of the Office of Management and Budget or the Director's designee.

"(B) The aggregate number of share-in-savings contracts that may be entered into under subparagraph (A) by all agencies to which this chapter applies in a fiscal year may not exceed 5 in each of fiscal years 2003, 2004, and 2005.

"(c) DEFINITIONS.—In this section:

"(1) The term 'contractor' means a private entity that enters into a contract with an agency.

"(2) The term 'savings' means—

"(A) monetary savings to an agency; or

"(B) savings in time or other benefits realized by the agency, including enhanced revenues (other than enhanced revenues from the collection of fees, taxes, debts, claims, or other amounts owed the Federal Government).

"(3) The term 'share-in-savings contract' means a contract under which—

"(A) a contractor provides solutions for—

"(i) improving the agency's mission-related or administrative processes; or

"(ii) accelerating the achievement of agency missions; and

"(B) the head of the agency pays the contractor an amount equal to a portion of the savings derived by the agency from—

"(i) any improvements in mission-related or administrative processes that result from implementation of the solution; or

"(ii) acceleration of achievement of agency missions.

"(d) TERMINATION.—No share-in-savings contracts may be entered into under this section after September 30, 2005.".

(2) The table of sections at the beginning of such chapter is amended by adding at the end of the following new item:

"2332. Share-in-savings contracts.".

(b) OTHER CONTRACTS.—Title III of the Federal Property and Administrative Services Act of 1949 is amended by adding at the end the following:

41 USC 266a.

"SEC. 317. SHARE-IN-SAVINGS CONTRACTS.

"(a) AUTHORITY TO ENTER INTO SHARE-IN-SAVINGS CONTRACTS.—(1) The head of an executive agency may enter into a share-in-savings contract for information technology (as defined in section 11101(6) of title 40, United States Code) in which the Government awards a contract to improve mission-related or administrative processes or to accelerate the achievement of its mission and share with the contractor in savings achieved through contract performance.

"(2)(A) Except as provided in subparagraph (B), a share-in-savings contract shall be awarded for a period of not more than five years.

"(B) A share-in-savings contract may be awarded for a period greater than five years, but not more than 10 years, if the head of the agency determines in writing prior to award of the contract that—

"(i) the level of risk to be assumed and the investment to be undertaken by the contractor is likely to inhibit the government from obtaining the needed information technology competitively at a fair and reasonable price if the contract is limited in duration to a period of five years or less; and

"(ii) usage of the information technology to be acquired is likely to continue for a period of time sufficient to generate reasonable benefit for the government.

"(3) Contracts awarded pursuant to the authority of this section shall, to the maximum extent practicable, be performance-based contracts that identify objective outcomes and contain performance standards that will be used to measure achievement and milestones that must be met before payment is made.

"(4) Contracts awarded pursuant to the authority of this section shall include a provision containing a quantifiable baseline that is to be the basis upon which a savings share ratio is established that governs the amount of payment a contractor is to receive under the contract. Before commencement of performance of such a contract, the senior procurement executive of the agency shall determine in writing that the terms of the provision are quantifiable and will likely yield value to the Government.

"(5)(A) The head of the agency may retain savings realized through the use of a share-in-savings contract under this section that are in excess of the total amount of savings paid to the contractor under the contract, but may not retain any portion of such savings that is attributable to a decrease in the number of civilian employees of the Federal Government performing the function. Except as provided in subparagraph (B), savings shall be credited to the appropriation or fund against which charges were made to carry out the contract and shall be used for information technology.

"(B) Amounts retained by the agency under this subsection shall—

"(i) without further appropriation, remain available until expended; and

"(ii) be applied first to fund any contingent liabilities associated with share-in-savings procurements that are not fully funded.

"(b) CANCELLATION AND TERMINATION.—(1) If funds are not made available for the continuation of a share-in-savings contract entered into under this section in a subsequent fiscal year, the contract shall be canceled or terminated. The costs of cancellation or termination may be paid out of—

"(A) appropriations available for the performance of the contract;

"(B) appropriations available for acquisition of the information technology procured under the contract, and not otherwise obligated; or

"(C) funds subsequently appropriated for payments of costs of cancellation or termination, subject to the limitations in paragraph (3).

"(2) The amount payable in the event of cancellation or termination of a share-in-savings contract shall be negotiated with the contractor at the time the contract is entered into.

"(3)(A) Subject to subparagraph (B), the head of an executive agency may enter into share-in-savings contracts under this section in any given fiscal year even if funds are not made specifically available for the full costs of cancellation or termination of the contract if funds are available and sufficient to make payments with respect to the first fiscal year of the contract and the following conditions are met regarding the funding of cancellation and termination liability:

"(i) The amount of unfunded contingent liability for the contract does not exceed the lesser of—

"(I) 25 percent of the estimated costs of a cancellation or termination; or

"(II) $5,000,000.

"(ii) Unfunded contingent liability in excess of $1,000,000 has been approved by the Director of the Office of Management and Budget or the Director's designee.

"(B) The aggregate number of share-in-savings contracts that may be entered into under subparagraph (A) by all executive agencies to which this chapter applies in a fiscal year may not exceed 5 in each of fiscal years 2003, 2004, and 2005.

"(c) DEFINITIONS.—In this section:

"(1) The term 'contractor' means a private entity that enters into a contract with an agency.

"(2) The term 'savings' means—

"(A) monetary savings to an agency; or

"(B) savings in time or other benefits realized by the agency, including enhanced revenues (other than enhanced revenues from the collection of fees, taxes, debts, claims, or other amounts owed the Federal Government).

"(3) The term 'share-in-savings contract' means a contract under which—

"(A) a contractor provides solutions for—

"(i) improving the agency's mission-related or administrative processes; or

"(ii) accelerating the achievement of agency missions; and

"(B) the head of the agency pays the contractor an amount equal to a portion of the savings derived by the agency from—

"(i) any improvements in mission-related or administrative processes that result from implementation of the solution; or

"(ii) acceleration of achievement of agency missions.

"(d) TERMINATION.—No share-in-savings contracts may be entered into under this section after September 30, 2005.".

(c) DEVELOPMENT OF INCENTIVES.—The Director of the Office of Management and Budget shall, in consultation with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform of the House of Representatives, and executive agencies, develop techniques to permit an executive agency to retain

a portion of the savings (after payment of the contractor's share of the savings) derived from share-in-savings contracts as funds are appropriated to the agency in future fiscal years.

(d) REGULATIONS.—Not later than 270 days after the date of the enactment of this Act, the Federal Acquisition Regulation shall be revised to implement the provisions enacted by this section. Such revisions shall— Deadline.

(1) provide for the use of competitive procedures in the selection and award of share-in-savings contracts to—

(A) ensure the contractor's share of savings reflects the risk involved and market conditions; and

(B) otherwise yield greatest value to the government; and

(2) allow appropriate regulatory flexibility to facilitate the use of share-in-savings contracts by executive agencies, including the use of innovative provisions for technology refreshment and nonstandard Federal Acquisition Regulation contract clauses.

(e) ADDITIONAL GUIDANCE.—The Administrator of General Services shall—

(1) identify potential opportunities for the use of share-in-savings contracts; and

(2) in consultation with the Director of the Office of Management and Budget, provide guidance to executive agencies for determining mutually beneficial savings share ratios and baselines from which savings may be measured.

(f) OMB REPORT TO CONGRESS.—In consultation with executive agencies, the Director of the Office of Management and Budget shall, not later than 2 years after the date of the enactment of this Act, submit to Congress a report containing— Deadline.

(1) a description of the number of share-in-savings contracts entered into by each executive agency under by this section and the amendments made by this section, and, for each contract identified—

(A) the information technology acquired;

(B) the total amount of payments made to the contractor; and

(C) the total amount of savings or other measurable benefits realized;

(2) a description of the ability of agencies to determine the baseline costs of a project against which savings can be measured; and

(3) any recommendations, as the Director deems appropriate, regarding additional changes in law that may be necessary to ensure effective use of share-in-savings contracts by executive agencies.

(g) GAO REPORT TO CONGRESS.—The Comptroller General shall, not later than 6 months after the report required under subsection (f) is submitted to Congress, conduct a review of that report and submit to Congress a report containing— Deadline.

(1) the results of the review;

(2) an independent assessment by the Comptroller General of the effectiveness of the use of share-in-savings contracts in improving the mission-related and administrative processes of the executive agencies and the achievement of agency missions; and

(3) a recommendation on whether the authority to enter into share-in-savings contracts should be continued.

(h) REPEAL OF SHARE-IN-SAVINGS PILOT PROGRAM.—

(1) REPEAL.—Section 11521 of title 40, United States Code, is repealed.

(2) CONFORMING AMENDMENTS TO PILOT PROGRAM AUTHORITY.—

(A) Section 11501 of title 40, United States Code, is amended—

(i) in the section heading, by striking "**PROGRAMS**" and inserting "**PROGRAM**";

(ii) in subsection (a)(1), by striking "conduct pilot programs" and inserting "conduct a pilot program pursuant to the requirements of section 11521 of this title";

(iii) in subsection (a)(2), by striking "each pilot program" and inserting "the pilot program";

(iv) in subsection (b), by striking "LIMITATIONS.—" and all that follows through "$750,000,000." and inserting the following: "LIMITATION ON AMOUNT.—The total amount obligated for contracts entered into under the pilot program conducted under this chapter may not exceed $375,000,000."; and

(v) in subsection (c)(1), by striking "a pilot" and inserting "the pilot".

(B) The following provisions of chapter 115 of such title are each amended by striking "a pilot" each place it appears and inserting "the pilot":

(i) Section 11502(a).

(ii) Section 11502(b).

(iii) Section 11503(a).

(iv) Section 11504.

(C) Section 11505 of such chapter is amended by striking "programs" and inserting "program".

(3) ADDITIONAL CONFORMING AMENDMENTS.—

(A) Section 11522 of title 40, United States Code, is redesignated as section 11521.

(B) The chapter heading for chapter 115 of such title is amended by striking "**PROGRAMS**" and inserting "**PROGRAM**".

(C) The subchapter heading for subchapter I and for subchapter II of such chapter are each amended by striking "PROGRAMS" and inserting "PROGRAM".

(D) The item relating to subchapter I in the table of sections at the beginning of such chapter is amended to read as follows:

"SUBCHAPTER I—CONDUCT OF PILOT PROGRAM".

(E) The item relating to subchapter II in the table of sections at the beginning of such chapter is amended to read as follows:

"SUBCHAPTER II—SPECIFIC PILOT PROGRAM".

(F) The item relating to section 11501 in the table of sections at the beginning of such is amended by striking "programs" and inserting "program".

(G) The table of sections at the beginning of such chapter is amended by striking the item relating to section 11521 and redesignating the item relating to section 11522 as section 11521.

(H) The item relating to chapter 115 in the table of chapters for subtitle III of title 40, United States Code, is amended to read as follows:

"115. INFORMATION TECHNOLOGY ACQUISITION PILOT PROGRAM ....11501".

(i) DEFINITIONS.—In this section, the terms "contractor", "savings", and "share-in-savings contract" have the meanings given those terms in section 317 of the Federal Property and Administrative Services Act of 1949 (as added by subsection (b)).

SEC. 211. AUTHORIZATION FOR ACQUISITION OF INFORMATION TECHNOLOGY BY STATE AND LOCAL GOVERNMENTS THROUGH FEDERAL SUPPLY SCHEDULES.

44 USC 3501 note.

(a) AUTHORITY TO USE CERTAIN SUPPLY SCHEDULES.—Section 502 of title 40, United States Code, is amended by adding at the end the following new subsection:

"(c) USE OF CERTAIN SUPPLY SCHEDULES.—

"(1) IN GENERAL.—The Administrator may provide for the use by State or local governments of Federal supply schedules of the General Services Administration for automated data processing equipment (including firmware), software, supplies, support equipment, and services (as contained in Federal supply classification code group 70).

"(2) VOLUNTARY USE.—In any case of the use by a State or local government of a Federal supply schedule pursuant to paragraph (1), participation by a firm that sells to the Federal Government through the supply schedule shall be voluntary with respect to a sale to the State or local government through such supply schedule.

"(3) DEFINITIONS.—In this subsection:

"(A) The term 'State or local government' includes any State, local, regional, or tribal government, or any instrumentality thereof (including any local educational agency or institution of higher education).

"(B) The term 'tribal government' means—

"(i) the governing body of any Indian tribe, band, nation, or other organized group or community located in the continental United States (excluding the State of Alaska) that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians, and

"(ii) any Alaska Native regional or village corporation established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 et seq.).

"(C) The term 'local educational agency' has the meaning given that term in section 8013 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7713).

"(D) The term 'institution of higher education' has the meaning given that term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).".

(b) PROCEDURES.—Not later than 30 days after the date of the enactment of this Act, the Administrator of General Services shall establish procedures to implement section 501(c) of title 40, United States Code (as added by subsection (a)).

Deadline.

Deadline.

(c) REPORT.—Not later than December 31, 2004, the Administrator shall submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate a report on the implementation and effects of the amendment made by subsection (a).

44 USC 3501 note.

SEC. 212. INTEGRATED REPORTING STUDY AND PILOT PROJECTS.

(a) PURPOSES.—The purposes of this section are to—

(1) enhance the interoperability of Federal information systems;

(2) assist the public, including the regulated community, in electronically submitting information to agencies under Federal requirements, by reducing the burden of duplicate collection and ensuring the accuracy of submitted information; and

(3) enable any person to integrate and obtain similar information held by 1 or more agencies under 1 or more Federal requirements without violating the privacy rights of an individual.

(b) DEFINITIONS.—In this section, the term—

(1) "agency" means an Executive agency as defined under section 105 of title 5, United States Code; and

(2) "person" means any individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, interstate body, or agency or component of the Federal Government.

(c) REPORT.—

Deadline.

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Director shall oversee a study, in consultation with agencies, the regulated community, public interest organizations, and the public, and submit a report to the Committee on Governmental Affairs of the Senate and the Committee on Government Reform of the House of Representatives on progress toward integrating Federal information systems across agencies.

(2) CONTENTS.—The report under this section shall—

(A) address the integration of data elements used in the electronic collection of information within databases established under Federal statute without reducing the quality, accessibility, scope, or utility of the information contained in each database;

(B) address the feasibility of developing, or enabling the development of, software, including Internet-based tools, for use by reporting persons in assembling, documenting, and validating the accuracy of information electronically submitted to agencies under nonvoluntary, statutory, and regulatory requirements;

(C) address the feasibility of developing a distributed information system involving, on a voluntary basis, at least 2 agencies, that—

(i) provides consistent, dependable, and timely public access to the information holdings of 1 or more agencies, or some portion of such holdings, without requiring public users to know which agency holds the information; and

(ii) allows the integration of public information held by the participating agencies;

(D) address the feasibility of incorporating other elements related to the purposes of this section at the discretion of the Director; and

(E) make any recommendations that the Director deems appropriate on the use of integrated reporting and information systems, to reduce the burden on reporting and strengthen public access to databases within and across agencies.

(d) PILOT PROJECTS TO ENCOURAGE INTEGRATED COLLECTION AND MANAGEMENT OF DATA AND INTEROPERABILITY OF FEDERAL INFORMATION SYSTEMS.—

(1) IN GENERAL.—In order to provide input to the study under subsection (c), the Director shall designate, in consultation with agencies, a series of no more than 5 pilot projects that integrate data elements. The Director shall consult with agencies, the regulated community, public interest organizations, and the public on the implementation of the pilot projects.

(2) GOALS OF PILOT PROJECTS.—

(A) IN GENERAL.—Each goal described under subparagraph (B) shall be addressed by at least 1 pilot project each.

(B) GOALS.—The goals under this paragraph are to—

(i) reduce information collection burdens by eliminating duplicative data elements within 2 or more reporting requirements;

(ii) create interoperability between or among public databases managed by 2 or more agencies using technologies and techniques that facilitate public access; and

(iii) develop, or enable the development of, software to reduce errors in electronically submitted information.

(3) INPUT.—Each pilot project shall seek input from users on the utility of the pilot project and areas for improvement. To the extent practicable, the Director shall consult with relevant agencies and State, tribal, and local governments in carrying out the report and pilot projects under this section.

(e) PROTECTIONS.—The activities authorized under this section shall afford protections for—

(1) confidential business information consistent with section 552(b)(4) of title 5, United States Code, and other relevant law;

(2) personal privacy information under sections 552(b) (6) and (7)(C) and 552a of title 5, United States Code, and other relevant law;

(3) other information consistent with section 552(b)(3) of title 5, United States Code, and other relevant law; and

(4) confidential statistical information collected under a confidentiality pledge, solely for statistical purposes, consistent with the Office of Management and Budget's Federal Statistical Confidentiality Order, and other relevant law.

SEC. 213. COMMUNITY TECHNOLOGY CENTERS.

44 USC 3501 note.

(a) PURPOSES.—The purposes of this section are to—

(1) study and enhance the effectiveness of community technology centers, public libraries, and other institutions that provide computer and Internet access to the public; and

(2) promote awareness of the availability of on-line government information and services, to users of community technology centers, public libraries, and other public facilities that provide access to computer technology and Internet access to the public.

Deadline.

(b) STUDY AND REPORT.—Not later than 2 years after the effective date of this title, the Administrator shall—

(1) ensure that a study is conducted to evaluate the best practices of community technology centers that have received Federal funds; and

(2) submit a report on the study to—

(A) the Committee on Governmental Affairs of the Senate;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) the Committee on Government Reform of the House of Representatives; and

(D) the Committee on Education and the Workforce of the House of Representatives.

(c) CONTENTS.—The report under subsection (b) may consider—

(1) an evaluation of the best practices being used by successful community technology centers;

(2) a strategy for—

(A) continuing the evaluation of best practices used by community technology centers; and

(B) establishing a network to share information and resources as community technology centers evolve;

(3) the identification of methods to expand the use of best practices to assist community technology centers, public libraries, and other institutions that provide computer and Internet access to the public;

(4) a database of all community technology centers that have received Federal funds, including—

(A) each center's name, location, services provided, director, other points of contact, number of individuals served; and

(B) other relevant information;

(5) an analysis of whether community technology centers have been deployed effectively in urban and rural areas throughout the Nation; and

(6) recommendations of how to—

(A) enhance the development of community technology centers; and

(B) establish a network to share information and resources.

(d) COOPERATION.—All agencies that fund community technology centers shall provide to the Administrator any information and assistance necessary for the completion of the study and the report under this section.

(e) ASSISTANCE.—

(1) IN GENERAL.—The Administrator, in consultation with the Secretary of Education, shall work with other relevant Federal agencies, and other interested persons in the private and nonprofit sectors to—

(A) assist in the implementation of recommendations; and

(B) identify other ways to assist community technology centers, public libraries, and other institutions that provide computer and Internet access to the public.

(2) TYPES OF ASSISTANCE.—Assistance under this subsection may include—

(A) contribution of funds;

(B) donations of equipment, and training in the use and maintenance of the equipment; and

(C) the provision of basic instruction or training material in computer skills and Internet usage.

(f) ONLINE TUTORIAL.—

(1) IN GENERAL.—The Administrator, in consultation with the Secretary of Education, the Director of the Institute of Museum and Library Services, other relevant agencies, and the public, shall develop an online tutorial that—

(A) explains how to access Government information and services on the Internet; and

(B) provides a guide to available online resources.

(2) DISTRIBUTION.—The Administrator, with assistance from the Secretary of Education, shall distribute information on the tutorial to community technology centers, public libraries, and other institutions that afford Internet access to the public.

(g) PROMOTION OF COMMUNITY TECHNOLOGY CENTERS.—The Administrator, with assistance from the Department of Education and in consultation with other agencies and organizations, shall promote the availability of community technology centers to raise awareness within each community where such a center is located.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the study of best practices at community technology centers, for the development and dissemination of the online tutorial, and for the promotion of community technology centers under this section—

(1) $2,000,000 in fiscal year 2003;

(2) $2,000,000 in fiscal year 2004; and

(3) such sums as are necessary in fiscal years 2005 through 2007.

SEC. 214. ENHANCING CRISIS MANAGEMENT THROUGH ADVANCED INFORMATION TECHNOLOGY.

44 USC 3501 note.

(a) PURPOSE.—The purpose of this section is to improve how information technology is used in coordinating and facilitating information on disaster preparedness, response, and recovery, while ensuring the availability of such information across multiple access channels.

(b) IN GENERAL.—

(1) STUDY ON ENHANCEMENT OF CRISIS RESPONSE.—Not later than 90 days after the date of enactment of this Act, the Administrator, in consultation with the Federal Emergency Management Agency, shall ensure that a study is conducted on using information technology to enhance crisis preparedness, response, and consequence management of natural and man-made disasters.

Deadline.

(2) CONTENTS.—The study under this subsection shall address—

(A) a research and implementation strategy for effective use of information technology in crisis response and

consequence management, including the more effective use of technologies, management of information technology research initiatives, and incorporation of research advances into the information and communications systems of—

(i) the Federal Emergency Management Agency; and

(ii) other Federal, State, and local agencies responsible for crisis preparedness, response, and consequence management; and

(B) opportunities for research and development on enhanced technologies into areas of potential improvement as determined during the course of the study.

Deadline.

(3) REPORT.—Not later than 2 years after the date on which a contract is entered into under paragraph (1), the Administrator shall submit a report on the study, including findings and recommendations to—

(A) the Committee on Governmental Affairs of the Senate; and

(B) the Committee on Government Reform of the House of Representatives.

(4) INTERAGENCY COOPERATION.—Other Federal departments and agencies with responsibility for disaster relief and emergency assistance shall fully cooperate with the Administrator in carrying out this section.

(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for research under this subsection, such sums as are necessary for fiscal year 2003.

(c) PILOT PROJECTS.—Based on the results of the research conducted under subsection (b), the Administrator, in consultation with the Federal Emergency Management Agency, shall initiate pilot projects or report to Congress on other activities that further the goal of maximizing the utility of information technology in disaster management. The Administrator shall cooperate with other relevant agencies, and, if appropriate, State, local, and tribal governments, in initiating such pilot projects.

44 USC 3501 note.
Deadlines.

SEC. 215. DISPARITIES IN ACCESS TO THE INTERNET.

(a) STUDY AND REPORT.—

(1) STUDY.—Not later than 90 days after the date of enactment of this Act, the Administrator of General Services shall request that the National Academy of Sciences, acting through the National Research Council, enter into a contract to conduct a study on disparities in Internet access for online Government services.

(2) REPORT.—Not later than 2 years after the date of enactment of this Act, the Administrator of General Services shall submit to the Committee on Governmental Affairs of the Senate and the Committee on Government Reform of the House of Representatives a final report of the study under this section, which shall set forth the findings, conclusions, and recommendations of the National Research Council.

(b) CONTENTS.—The report under subsection (a) shall include a study of—

(1) how disparities in Internet access influence the effectiveness of online Government services, including a review of—

(A) the nature of disparities in Internet access;

(B) the affordability of Internet service;

(C) the incidence of disparities among different groups within the population; and

(D) changes in the nature of personal and public Internet access that may alleviate or aggravate effective access to online Government services;

(2) how the increase in online Government services is influencing the disparities in Internet access and how technology development or diffusion trends may offset such adverse influences; and

(3) related societal effects arising from the interplay of disparities in Internet access and the increase in online Government services.

(c) RECOMMENDATIONS.—The report shall include recommendations on actions to ensure that online Government initiatives shall not have the unintended result of increasing any deficiency in public access to Government services.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $950,000 in fiscal year 2003 to carry out this section.

SEC. 216. COMMON PROTOCOLS FOR GEOGRAPHIC INFORMATION SYSTEMS.

44 USC 3501 note.

(a) PURPOSES.—The purposes of this section are to—

(1) reduce redundant data collection and information; and

(2) promote collaboration and use of standards for government geographic information.

(b) DEFINITION.—In this section, the term "geographic information" means information systems that involve locational data, such as maps or other geospatial information resources.

(c) IN GENERAL.—

(1) COMMON PROTOCOLS.—The Administrator, in consultation with the Secretary of the Interior, working with the Director and through an interagency group, and working with private sector experts, State, local, and tribal governments, commercial and international standards groups, and other interested parties, shall facilitate the development of common protocols for the development, acquisition, maintenance, distribution, and application of geographic information. If practicable, the Administrator shall incorporate intergovernmental and public private geographic information partnerships into efforts under this subsection.

(2) INTERAGENCY GROUP.—The interagency group referred to under paragraph (1) shall include representatives of the National Institute of Standards and Technology and other agencies.

(d) DIRECTOR.—The Director shall oversee—

(1) the interagency initiative to develop common protocols;

(2) the coordination with State, local, and tribal governments, public private partnerships, and other interested persons on effective and efficient ways to align geographic information and develop common protocols; and

(3) the adoption of common standards relating to the protocols.

(e) COMMON PROTOCOLS.—The common protocols shall be designed to—

(1) maximize the degree to which unclassified geographic information from various sources can be made electronically compatible and accessible; and

(2) promote the development of interoperable geographic information systems technologies that shall—

(A) allow widespread, low-cost use and sharing of geographic data by Federal agencies, State, local, and tribal governments, and the public; and

(B) enable the enhancement of services using geographic data.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section, for each of the fiscal years 2003 through 2007.

Federal Information Security Management Act of 2002.

TITLE III—INFORMATION SECURITY

SEC. 301. INFORMATION SECURITY.

44 USC 101 note.

(a) SHORT TITLE.—This title may be cited as the "Federal Information Security Management Act of 2002".

(b) INFORMATION SECURITY.—

(1) IN GENERAL.—Chapter 35 of title 44, United States Code, is amended by adding at the end the following new subchapter:

"SUBCHAPTER III—INFORMATION SECURITY

"§ 3541. Purposes

"The purposes of this subchapter are to—

"(1) provide a comprehensive framework for ensuring the effectiveness of information security controls over information resources that support Federal operations and assets;

"(2) recognize the highly networked nature of the current Federal computing environment and provide effective governmentwide management and oversight of the related information security risks, including coordination of information security efforts throughout the civilian, national security, and law enforcement communities;

"(3) provide for development and maintenance of minimum controls required to protect Federal information and information systems;

"(4) provide a mechanism for improved oversight of Federal agency information security programs;

"(5) acknowledge that commercially developed information security products offer advanced, dynamic, robust, and effective information security solutions, reflecting market solutions for the protection of critical information infrastructures important to the national defense and economic security of the nation that are designed, built, and operated by the private sector; and

"(6) recognize that the selection of specific technical hardware and software information security solutions should be left to individual agencies from among commercially developed products.

"§ 3542. Definitions

"(a) IN GENERAL.—Except as provided under subsection (b), the definitions under section 3502 shall apply to this subchapter.

"(b) ADDITIONAL DEFINITIONS.—As used in this subchapter:

"(1) The term 'information security' means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

"(A) integrity, which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

"(B) confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

"(C) availability, which means ensuring timely and reliable access to and use of information.

"(2)(A) The term 'national security system' means any information system (including any telecommunications system) used or operated by an agency or by a contractor of an agency, or other organization on behalf of an agency—

"(i) the function, operation, or use of which—

"(I) involves intelligence activities;

"(II) involves cryptologic activities related to national security;

"(III) involves command and control of military forces;

"(IV) involves equipment that is an integral part of a weapon or weapons system; or

"(V) subject to subparagraph (B), is critical to the direct fulfillment of military or intelligence missions; or

"(ii) is protected at all times by procedures established for information that have been specifically authorized under criteria established by an Executive order or an Act of Congress to be kept classified in the interest of national defense or foreign policy.

"(B) Subparagraph (A)(i)(V) does not include a system that is to be used for routine administrative and business applications (including payroll, finance, logistics, and personnel management applications).

"(3) The term 'information technology' has the meaning given that term in section 11101 of title 40.

"§ 3543. Authority and functions of the Director

"(a) IN GENERAL.—The Director shall oversee agency information security policies and practices, including—

"(1) developing and overseeing the implementation of policies, principles, standards, and guidelines on information security, including through ensuring timely agency adoption of and compliance with standards promulgated under section 11331 of title 40;

"(2) requiring agencies, consistent with the standards promulgated under such section 11331 and the requirements of this subchapter, to identify and provide information security protections commensurate with the risk and magnitude of the

harm resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of—

"(A) information collected or maintained by or on behalf of an agency; or

"(B) information systems used or operated by an agency or by a contractor of an agency or other organization on behalf of an agency;

"(3) coordinating the development of standards and guidelines under section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3) with agencies and offices operating or exercising control of national security systems (including the National Security Agency) to assure, to the maximum extent feasible, that such standards and guidelines are complementary with standards and guidelines developed for national security systems;

"(4) overseeing agency compliance with the requirements of this subchapter, including through any authorized action under section 11303 of title 40, to enforce accountability for compliance with such requirements;

"(5) reviewing at least annually, and approving or disapproving, agency information security programs required under section 3544(b);

"(6) coordinating information security policies and procedures with related information resources management policies and procedures;

"(7) overseeing the operation of the Federal information security incident center required under section 3546; and

"(8) reporting to Congress no later than March 1 of each year on agency compliance with the requirements of this subchapter, including—

"(A) a summary of the findings of evaluations required by section 3545;

"(B) an assessment of the development, promulgation, and adoption of, and compliance with, standards developed under section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g-3) and promulgated under section 11331 of title 40;

"(C) significant deficiencies in agency information security practices;

"(D) planned remedial action to address such deficiencies; and

"(E) a summary of, and the views of the Director on, the report prepared by the National Institute of Standards and Technology under section 20(d)(10) of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3).

"(b) NATIONAL SECURITY SYSTEMS.—Except for the authorities described in paragraphs (4) and (8) of subsection (a), the authorities of the Director under this section shall not apply to national security systems.

"(c) DEPARTMENT OF DEFENSE AND CENTRAL INTELLIGENCE AGENCY SYSTEMS.—(1) The authorities of the Director described in paragraphs (1) and (2) of subsection (a) shall be delegated to the Secretary of Defense in the case of systems described in paragraph (2) and to the Director of Central Intelligence in the case of systems described in paragraph (3).

"(2) The systems described in this paragraph are systems that are operated by the Department of Defense, a contractor of the Department of Defense, or another entity on behalf of the Department of Defense that processes any information the unauthorized access, use, disclosure, disruption, modification, or destruction of which would have a debilitating impact on the mission of the Department of Defense.

"(3) The systems described in this paragraph are systems that are operated by the Central Intelligence Agency, a contractor of the Central Intelligence Agency, or another entity on behalf of the Central Intelligence Agency that processes any information the unauthorized access, use, disclosure, disruption, modification, or destruction of which would have a debilitating impact on the mission of the Central Intelligence Agency.

"§ 3544. Federal agency responsibilities

"(a) IN GENERAL.—The head of each agency shall—

"(1) be responsible for—

"(A) providing information security protections commensurate with the risk and magnitude of the harm resulting from unauthorized access, use, disclosure, disruption, modification, or destruction of—

"(i) information collected or maintained by or on behalf of the agency; and

"(ii) information systems used or operated by an agency or by a contractor of an agency or other organization on behalf of an agency;

"(B) complying with the requirements of this subchapter and related policies, procedures, standards, and guidelines, including—

"(i) information security standards promulgated under section 11331 of title 40; and

"(ii) information security standards and guidelines for national security systems issued in accordance with law and as directed by the President; and

"(C) ensuring that information security management processes are integrated with agency strategic and operational planning processes;

"(2) ensure that senior agency officials provide information security for the information and information systems that support the operations and assets under their control, including through—

"(A) assessing the risk and magnitude of the harm that could result from the unauthorized access, use, disclosure, disruption, modification, or destruction of such information or information systems;

"(B) determining the levels of information security appropriate to protect such information and information systems in accordance with standards promulgated under section 11331 of title 40, for information security classifications and related requirements;

"(C) implementing policies and procedures to cost-effectively reduce risks to an acceptable level; and

"(D) periodically testing and evaluating information security controls and techniques to ensure that they are effectively implemented;

"(3) delegate to the agency Chief Information Officer established under section 3506 (or comparable official in an agency not covered by such section) the authority to ensure compliance with the requirements imposed on the agency under this subchapter, including—

"(A) designating a senior agency information security officer who shall—

"(i) carry out the Chief Information Officer's responsibilities under this section;

"(ii) possess professional qualifications, including training and experience, required to administer the functions described under this section;

"(iii) have information security duties as that official's primary duty; and

"(iv) head an office with the mission and resources to assist in ensuring agency compliance with this section;

"(B) developing and maintaining an agencywide information security program as required by subsection (b);

"(C) developing and maintaining information security policies, procedures, and control techniques to address all applicable requirements, including those issued under section 3543 of this title, and section 11331 of title 40;

"(D) training and overseeing personnel with significant responsibilities for information security with respect to such responsibilities; and

"(E) assisting senior agency officials concerning their responsibilities under paragraph (2);

"(4) ensure that the agency has trained personnel sufficient to assist the agency in complying with the requirements of this subchapter and related policies, procedures, standards, and guidelines; and

"(5) ensure that the agency Chief Information Officer, in coordination with other senior agency officials, reports annually to the agency head on the effectiveness of the agency information security program, including progress of remedial actions.

"(b) AGENCY PROGRAM.—Each agency shall develop, document, and implement an agencywide information security program, approved by the Director under section 3543(a)(5), to provide information security for the information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor, or other source, that includes—

"(1) periodic assessments of the risk and magnitude of the harm that could result from the unauthorized access, use, disclosure, disruption, modification, or destruction of information and information systems that support the operations and assets of the agency;

"(2) policies and procedures that—

"(A) are based on the risk assessments required by paragraph (1);

"(B) cost-effectively reduce information security risks to an acceptable level;

"(C) ensure that information security is addressed throughout the life cycle of each agency information system; and

"(D) ensure compliance with—

"(i) the requirements of this subchapter;

"(ii) policies and procedures as may be prescribed by the Director, and information security standards promulgated under section 11331 of title 40;

"(iii) minimally acceptable system configuration requirements, as determined by the agency; and

"(iv) any other applicable requirements, including standards and guidelines for national security systems issued in accordance with law and as directed by the President;

"(3) subordinate plans for providing adequate information security for networks, facilities, and systems or groups of information systems, as appropriate;

"(4) security awareness training to inform personnel, including contractors and other users of information systems that support the operations and assets of the agency, of—

"(A) information security risks associated with their activities; and

"(B) their responsibilities in complying with agency policies and procedures designed to reduce these risks;

"(5) periodic testing and evaluation of the effectiveness of information security policies, procedures, and practices, to be performed with a frequency depending on risk, but no less than annually, of which such testing—

"(A) shall include testing of management, operational, and technical controls of every information system identified in the inventory required under section 3505(c); and

"(B) may include testing relied on in a evaluation under section 3545;

"(6) a process for planning, implementing, evaluating, and documenting remedial action to address any deficiencies in the information security policies, procedures, and practices of the agency;

"(7) procedures for detecting, reporting, and responding to security incidents, consistent with standards and guidelines issued pursuant to section 3546(b), including—

"(A) mitigating risks associated with such incidents before substantial damage is done;

"(B) notifying and consulting with the Federal information security incident center referred to in section 3546; and

"(C) notifying and consulting with, as appropriate—

"(i) law enforcement agencies and relevant Offices of Inspector General;

"(ii) an office designated by the President for any incident involving a national security system; and

"(iii) any other agency or office, in accordance with law or as directed by the President; and

"(8) plans and procedures to ensure continuity of operations for information systems that support the operations and assets of the agency.

"(c) AGENCY REPORTING.—Each agency shall—

"(1) report annually to the Director, the Committees on Government Reform and Science of the House of Representatives, the Committees on Governmental Affairs and Commerce, Science, and Transportation of the Senate, the appropriate

authorization and appropriations committees of Congress, and the Comptroller General on the adequacy and effectiveness of information security policies, procedures, and practices, and compliance with the requirements of this subchapter, including compliance with each requirement of subsection (b);

"(2) address the adequacy and effectiveness of information security policies, procedures, and practices in plans and reports relating to—

"(A) annual agency budgets;

"(B) information resources management under subchapter 1 of this chapter;

"(C) information technology management under subtitle III of title 40;

"(D) program performance under sections 1105 and 1115 through 1119 of title 31, and sections 2801 and 2805 of title 39;

"(E) financial management under chapter 9 of title 31, and the Chief Financial Officers Act of 1990 (31 U.S.C. 501 note; Public Law 101–576) (and the amendments made by that Act);

"(F) financial management systems under the Federal Financial Management Improvement Act (31 U.S.C. 3512 note); and

"(G) internal accounting and administrative controls under section 3512 of title 31, (known as the 'Federal Managers Financial Integrity Act'); and

"(3) report any significant deficiency in a policy, procedure, or practice identified under paragraph (1) or (2)—

"(A) as a material weakness in reporting under section 3512 of title 31; and

"(B) if relating to financial management systems, as an instance of a lack of substantial compliance under the Federal Financial Management Improvement Act (31 U.S.C. 3512 note).

"(d) PERFORMANCE PLAN.—(1) In addition to the requirements of subsection (c), each agency, in consultation with the Director, shall include as part of the performance plan required under section 1115 of title 31 a description of—

"(A) the time periods, and

"(B) the resources, including budget, staffing, and training, that are necessary to implement the program required under subsection (b).

"(2) The description under paragraph (1) shall be based on the risk assessments required under subsection (b)(2)(1).

"(e) PUBLIC NOTICE AND COMMENT.—Each agency shall provide the public with timely notice and opportunities for comment on proposed information security policies and procedures to the extent that such policies and procedures affect communication with the public.

"§ 3545. Annual independent evaluation

"(a) IN GENERAL.—(1) Each year each agency shall have performed an independent evaluation of the information security program and practices of that agency to determine the effectiveness of such program and practices.

"(2) Each evaluation under this section shall include—

"(A) testing of the effectiveness of information security policies, procedures, and practices of a representative subset of the agency's information systems;

"(B) an assessment (made on the basis of the results of the testing) of compliance with—

"(i) the requirements of this subchapter; and

"(ii) related information security policies, procedures, standards, and guidelines; and

"(C) separate presentations, as appropriate, regarding information security relating to national security systems.

"(b) INDEPENDENT AUDITOR.—Subject to subsection (c)—

"(1) for each agency with an Inspector General appointed under the Inspector General Act of 1978, the annual evaluation required by this section shall be performed by the Inspector General or by an independent external auditor, as determined by the Inspector General of the agency; and

"(2) for each agency to which paragraph (1) does not apply, the head of the agency shall engage an independent external auditor to perform the evaluation.

"(c) NATIONAL SECURITY SYSTEMS.—For each agency operating or exercising control of a national security system, that portion of the evaluation required by this section directly relating to a national security system shall be performed—

"(1) only by an entity designated by the agency head; and

"(2) in such a manner as to ensure appropriate protection for information associated with any information security vulnerability in such system commensurate with the risk and in accordance with all applicable laws.

"(d) EXISTING EVALUATIONS.—The evaluation required by this section may be based in whole or in part on an audit, evaluation, or report relating to programs or practices of the applicable agency.

"(e) AGENCY REPORTING.—(1) Each year, not later than such date established by the Director, the head of each agency shall submit to the Director the results of the evaluation required under this section. Deadline.

"(2) To the extent an evaluation required under this section directly relates to a national security system, the evaluation results submitted to the Director shall contain only a summary and assessment of that portion of the evaluation directly relating to a national security system.

"(f) PROTECTION OF INFORMATION.—Agencies and evaluators shall take appropriate steps to ensure the protection of information which, if disclosed, may adversely affect information security. Such protections shall be commensurate with the risk and comply with all applicable laws and regulations.

"(g) OMB REPORTS TO CONGRESS.—(1) The Director shall summarize the results of the evaluations conducted under this section in the report to Congress required under section 3543(a)(8).

"(2) The Director's report to Congress under this subsection shall summarize information regarding information security relating to national security systems in such a manner as to ensure appropriate protection for information associated with any information security vulnerability in such system commensurate with the risk and in accordance with all applicable laws.

"(3) Evaluations and any other descriptions of information systems under the authority and control of the Director of Central

Intelligence or of National Foreign Intelligence Programs systems under the authority and control of the Secretary of Defense shall be made available to Congress only through the appropriate oversight committees of Congress, in accordance with applicable laws.

Reports.

"(h) COMPTROLLER GENERAL.—The Comptroller General shall periodically evaluate and report to Congress on—

"(1) the adequacy and effectiveness of agency information security policies and practices; and

"(2) implementation of the requirements of this subchapter.

"§ 3546. Federal information security incident center

"(a) IN GENERAL.—The Director shall ensure the operation of a central Federal information security incident center to—

"(1) provide timely technical assistance to operators of agency information systems regarding security incidents, including guidance on detecting and handling information security incidents;

"(2) compile and analyze information about incidents that threaten information security;

"(3) inform operators of agency information systems about current and potential information security threats, and vulnerabilities; and

"(4) consult with the National Institute of Standards and Technology, agencies or offices operating or exercising control of national security systems (including the National Security Agency), and such other agencies or offices in accordance with law and as directed by the President regarding information security incidents and related matters.

"(b) NATIONAL SECURITY SYSTEMS.—Each agency operating or exercising control of a national security system shall share information about information security incidents, threats, and vulnerabilities with the Federal information security incident center to the extent consistent with standards and guidelines for national security systems, issued in accordance with law and as directed by the President.

"§ 3547. National security systems

"The head of each agency operating or exercising control of a national security system shall be responsible for ensuring that the agency—

"(1) provides information security protections commensurate with the risk and magnitude of the harm resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of the information contained in such system;

"(2) implements information security policies and practices as required by standards and guidelines for national security systems, issued in accordance with law and as directed by the President; and

"(3) complies with the requirements of this subchapter.

"§ 3548. Authorization of appropriations

"There are authorized to be appropriated to carry out the provisions of this subchapter such sums as may be necessary for each of fiscal years 2003 through 2007.

"§ 3549. Effect on existing law

"Nothing in this subchapter, section 11331 of title 40, or section 20 of the National Standards and Technology Act (15 U.S.C. 278g–3) may be construed as affecting the authority of the President, the Office of Management and Budget or the Director thereof, the National Institute of Standards and Technology, or the head of any agency, with respect to the authorized use or disclosure of information, including with regard to the protection of personal privacy under section 552a of title 5, the disclosure of information under section 552 of title 5, the management and disposition of records under chapters 29, 31, or 33 of title 44, the management of information resources under subchapter I of chapter 35 of this title, or the disclosure of information to the Congress or the Comptroller General of the United States. While this subchapter is in effect, subchapter II of this chapter shall not apply.".

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter 35 is amended by adding at the end the following:

"SUBCHAPTER III—INFORMATION SECURITY

"Sec.
"3541. Purposes.
"3542. Definitions.
"3543. Authority and functions of the Director.
"3544. Federal agency responsibilities.
"3545. Annual independent evaluation.
"3546. Federal information security incident center.
"3547. National security systems.
"3548. Authorization of appropriations.
"3549. Effect on existing law.".

(c) INFORMATION SECURITY RESPONSIBILITIES OF CERTAIN AGENCIES.—

(1) NATIONAL SECURITY RESPONSIBILITIES.—(A) Nothing in this Act (including any amendment made by this Act) shall supersede any authority of the Secretary of Defense, the Director of Central Intelligence, or other agency head, as authorized by law and as directed by the President, with regard to the operation, control, or management of national security systems, as defined by section 3542(b)(2) of title 44, United States Code. 44 USC 3501 note.

(B) Section 2224 of title 10, United States Code, is amended—

(i) in subsection (b), by striking "(b) OBJECTIVES AND MINIMUM REQUIREMENTS.—(1)" and inserting "(b) OBJECTIVES OF THE PROGRAM.—";

(ii) in subsection (b), by striking paragraph (2); and

(iii) in subsection (c), in the matter preceding paragraph (1), by inserting ", including through compliance with subchapter III of chapter 35 of title 44" after "infrastructure".

(2) ATOMIC ENERGY ACT OF 1954.—Nothing in this Act shall supersede any requirement made by or under the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.). Restricted data or formerly restricted data shall be handled, protected, classified, downgraded, and declassified in conformity with the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.). 44 USC 3501 note.

SEC. 302. MANAGEMENT OF INFORMATION TECHNOLOGY.

(a) IN GENERAL.—Section 11331 of title 40, United States Code, is amended to read as follows:

"§ 11331. Responsibilities for Federal information systems standards

"(a) STANDARDS AND GUIDELINES.—

"(1) AUTHORITY TO PRESCRIBE.—Except as provided under paragraph (2), the Secretary of Commerce shall, on the basis of standards and guidelines developed by the National Institute of Standards and Technology pursuant to paragraphs (2) and (3) of section 20(a) of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3(a)), prescribe standards and guidelines pertaining to Federal information systems.

"(2) NATIONAL SECURITY SYSTEMS.—Standards and guidelines for national security systems (as defined under this section) shall be developed, prescribed, enforced, and overseen as otherwise authorized by law and as directed by the President.

"(b) MANDATORY REQUIREMENTS.—

"(1) AUTHORITY TO MAKE MANDATORY.—Except as provided under paragraph (2), the Secretary shall make standards prescribed under subsection (a)(1) compulsory and binding to the extent determined necessary by the Secretary to improve the efficiency of operation or security of Federal information systems.

"(2) REQUIRED MANDATORY STANDARDS.—(A) Standards prescribed under subsection (a)(1) shall include information security standards that—

"(i) provide minimum information security requirements as determined under section 20(b) of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3(b)); and

"(ii) are otherwise necessary to improve the security of Federal information and information systems.

"(B) Information security standards described in subparagraph (A) shall be compulsory and binding.

"(c) AUTHORITY TO DISAPPROVE OR MODIFY.—The President may disapprove or modify the standards and guidelines referred to in subsection (a)(1) if the President determines such action to be in the public interest. The President's authority to disapprove or modify such standards and guidelines may not be delegated. Notice of such disapproval or modification shall be published promptly in the Federal Register. Upon receiving notice of such disapproval or modification, the Secretary of Commerce shall immediately rescind or modify such standards or guidelines as directed by the President.

Federal Register, publication.

"(d) EXERCISE OF AUTHORITY.—To ensure fiscal and policy consistency, the Secretary shall exercise the authority conferred by this section subject to direction by the President and in coordination with the Director of the Office of Management and Budget.

"(e) APPLICATION OF MORE STRINGENT STANDARDS.—The head of an executive agency may employ standards for the cost-effective information security for information systems within or under the supervision of that agency that are more stringent than the standards the Secretary prescribes under this section if the more stringent standards—

"(1) contain at least the applicable standards made compulsory and binding by the Secretary; and

"(2) are otherwise consistent with policies and guidelines issued under section 3543 of title 44.

"(f) DECISIONS ON PROMULGATION OF STANDARDS.—The decision by the Secretary regarding the promulgation of any standard under this section shall occur not later than 6 months after the submission of the proposed standard to the Secretary by the National Institute of Standards and Technology, as provided under section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3). Deadline.

"(g) DEFINITIONS.—In this section:

"(1) FEDERAL INFORMATION SYSTEM.—The term 'Federal information system' means an information system used or operated by an executive agency, by a contractor of an executive agency, or by another organization on behalf of an executive agency.

"(2) INFORMATION SECURITY.—The term 'information security' has the meaning given that term in section 3542(b)(1) of title 44.

"(3) NATIONAL SECURITY SYSTEM.—The term 'national security system' has the meaning given that term in section 3542(b)(2) of title 44.".

(b) CLERICAL AMENDMENT.—The item relating to section 11331 in the table of sections at the beginning of chapter 113 of such title is amended to read as follows:

"11331. Responsibilities for Federal information systems standards.".

SEC. 303. NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY.

Section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3), is amended by striking the text and inserting the following:

"(a) IN GENERAL.—The Institute shall—

"(1) have the mission of developing standards, guidelines, and associated methods and techniques for information systems;

"(2) develop standards and guidelines, including minimum requirements, for information systems used or operated by an agency or by a contractor of an agency or other organization on behalf of an agency, other than national security systems (as defined in section 3542(b)(2) of title 44, United States Code); and

"(3) develop standards and guidelines, including minimum requirements, for providing adequate information security for all agency operations and assets, but such standards and guidelines shall not apply to national security systems.

"(b) MINIMUM REQUIREMENTS FOR STANDARDS AND GUIDELINES.—The standards and guidelines required by subsection (a) shall include, at a minimum—

"(1)(A) standards to be used by all agencies to categorize all information and information systems collected or maintained by or on behalf of each agency based on the objectives of providing appropriate levels of information security according to a range of risk levels;

"(B) guidelines recommending the types of information and information systems to be included in each such category; and

"(C) minimum information security requirements for information and information systems in each such category;

"(2) a definition of and guidelines concerning detection and handling of information security incidents; and

"(3) guidelines developed in conjunction with the Department of Defense, including the National Security Agency, for identifying an information system as a national security system consistent with applicable requirements for national security systems, issued in accordance with law and as directed by the President.

"(c) DEVELOPMENT OF STANDARDS AND GUIDELINES.—In developing standards and guidelines required by subsections (a) and (b), the Institute shall—

"(1) consult with other agencies and offices and the private sector (including the Director of the Office of Management and Budget, the Departments of Defense and Energy, the National Security Agency, the General Accounting Office, and the Secretary of Homeland Security) to assure—

"(A) use of appropriate information security policies, procedures, and techniques, in order to improve information security and avoid unnecessary and costly duplication of effort; and

"(B) that such standards and guidelines are complementary with standards and guidelines employed for the protection of national security systems and information contained in such systems;

"(2) provide the public with an opportunity to comment on proposed standards and guidelines;

Deadlines.

"(3) submit to the Secretary of Commerce for promulgation under section 11331 of title 40, United States Code—

"(A) standards, as required under subsection (b)(1)(A), no later than 12 months after the date of the enactment of this section; and

"(B) minimum information security requirements for each category, as required under subsection (b)(1)(C), no later than 36 months after the date of the enactment of this section;

Deadline.

"(4) issue guidelines as required under subsection (b)(1)(B), no later than 18 months after the date of the enactment of this section;

"(5) to the maximum extent practicable, ensure that such standards and guidelines do not require the use or procurement of specific products, including any specific hardware or software;

"(6) to the maximum extent practicable, ensure that such standards and guidelines provide for sufficient flexibility to permit alternative solutions to provide equivalent levels of protection for identified information security risks; and

"(7) to the maximum extent practicable, use flexible, performance-based standards and guidelines that permit the use of off-the-shelf commercially developed information security products.

"(d) INFORMATION SECURITY FUNCTIONS.—The Institute shall—

"(1) submit standards developed pursuant to subsection (a), along with recommendations as to the extent to which these should be made compulsory and binding, to the Secretary of Commerce for promulgation under section 11331 of title 40, United States Code;

"(2) provide technical assistance to agencies, upon request, regarding—

"(A) compliance with the standards and guidelines developed under subsection (a);

"(B) detecting and handling information security incidents; and

"(C) information security policies, procedures, and practices;

"(3) conduct research, as needed, to determine the nature and extent of information security vulnerabilities and techniques for providing cost-effective information security;

"(4) develop and periodically revise performance indicators and measures for agency information security policies and practices;

"(5) evaluate private sector information security policies and practices and commercially available information technologies to assess potential application by agencies to strengthen information security;

"(6) assist the private sector, upon request, in using and applying the results of activities under this section;

"(7) evaluate security policies and practices developed for national security systems to assess potential application by agencies to strengthen information security;

"(8) periodically assess the effectiveness of standards and guidelines developed under this section and undertake revisions as appropriate;

"(9) solicit and consider the recommendations of the Information Security and Privacy Advisory Board, established by section 21, regarding standards and guidelines developed under subsection (a) and submit such recommendations to the Secretary of Commerce with such standards submitted to the Secretary; and

"(10) prepare an annual public report on activities undertaken in the previous year, and planned for the coming year, to carry out responsibilities under this section.

"(e) DEFINITIONS.—As used in this section—

"(1) the term 'agency' has the same meaning as provided in section 3502(1) of title 44, United States Code;

"(2) the term 'information security' has the same meaning as provided in section 3542(b)(1) of such title;

"(3) the term 'information system' has the same meaning as provided in section 3502(8) of such title;

"(4) the term 'information technology' has the same meaning as provided in section 11101 of title 40, United States Code; and

"(5) the term 'national security system' has the same meaning as provided in section 3542(b)(2) of title 44, United States Code.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Commerce $20,000,000 for each of fiscal years 2003, 2004, 2005, 2006, and 2007 to enable the National Institute of Standards and Technology to carry out the provisions of this section.".

SEC. 304. INFORMATION SECURITY AND PRIVACY ADVISORY BOARD.

Section 21 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–4), is amended—

(1) in subsection (a), by striking "Computer System Security and Privacy Advisory Board" and inserting "Information Security and Privacy Advisory Board";

(2) in subsection (a)(1), by striking "computer or telecommunications" and inserting "information technology";

(3) in subsection (a)(2)—

(A) by striking "computer or telecommunications technology" and inserting "information technology"; and

(B) by striking "computer or telecommunications equipment" and inserting "information technology";

(4) in subsection (a)(3)—

(A) by striking "computer systems" and inserting "information system"; and

(B) by striking "computer systems security" and inserting "information security";

(5) in subsection (b)(1) by striking "computer systems security" and inserting "information security";

(6) in subsection (b) by striking paragraph (2) and inserting the following:

"(2) to advise the Institute, the Secretary of Commerce, and the Director of the Office of Management and Budget on information security and privacy issues pertaining to Federal Government information systems, including through review of proposed standards and guidelines developed under section 20; and";

(7) in subsection (b)(3) by inserting "annually" after "report";

(8) by inserting after subsection (e) the following new subsection:

"(f) The Board shall hold meetings at such locations and at such time and place as determined by a majority of the Board.";

(9) by redesignating subsections (f) and (g) as subsections (g) and (h), respectively; and

(10) by striking subsection (h), as redesignated by paragraph (9), and inserting the following:

"(h) As used in this section, the terms 'information system' and 'information technology' have the meanings given in section 20.".

SEC. 305. TECHNICAL AND CONFORMING AMENDMENTS.

(a) COMPUTER SECURITY ACT.—Section 11332 of title 40, United States Code, and the item relating to that section in the table of sections for chapter 113 of such title, are repealed.

(b) FLOYD D. SPENCE NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2001.—The Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (Public Law 106–398) is amended by striking section 1062 (44 U.S.C. 3531 note).

(c) PAPERWORK REDUCTION ACT.—(1) Section 3504(g) of title 44, United States Code, is amended—

(A) by adding "and" at the end of paragraph (1);

(B) in paragraph (2)—

(i) by striking "sections 11331 and 11332(b) and (c) of title 40" and inserting "section 11331 of title 40 and subchapter II of this chapter"; and

(ii) by striking "; and" and inserting a period; and

(C) by striking paragraph (3).

(2) Section 3505 of such title is amended by adding at the end—

"(c) INVENTORY OF MAJOR INFORMATION SYSTEMS.—(1) The head of each agency shall develop and maintain an inventory of major information systems (including major national security systems) operated by or under the control of such agency.

"(2) The identification of information systems in an inventory under this subsection shall include an identification of the interfaces between each such system and all other systems or networks, including those not operated by or under the control of the agency.

"(3) Such inventory shall be—

"(A) updated at least annually;

"(B) made available to the Comptroller General; and

"(C) used to support information resources management, including—

"(i) preparation and maintenance of the inventory of information resources under section 3506(b)(4);

"(ii) information technology planning, budgeting, acquisition, and management under section 3506(h), subtitle III of title 40, and related laws and guidance;

"(iii) monitoring, testing, and evaluation of information security controls under subchapter II;

"(iv) preparation of the index of major information systems required under section 552(g) of title 5, United States Code; and

"(v) preparation of information system inventories required for records management under chapters 21, 29, 31, and 33.

"(4) The Director shall issue guidance for and oversee the implementation of the requirements of this subsection.".

(3) Section 3506(g) of such title is amended—

(A) by adding "and" at the end of paragraph (1);

(B) in paragraph (2)—

(i) by striking "section 11332 of title 40" and inserting "subchapter II of this chapter"; and

(ii) by striking "; and" and inserting a period; and

(C) by striking paragraph (3).

TITLE IV—AUTHORIZATION OF APPROPRIATIONS AND EFFECTIVE DATES

SEC. 401. AUTHORIZATION OF APPROPRIATIONS.

Except for those purposes for which an authorization of appropriations is specifically provided in title I or II, including the amendments made by such titles, there are authorized to be appropriated such sums as are necessary to carry out titles I and II for each of fiscal years 2003 through 2007.

SEC. 402. EFFECTIVE DATES.

44 USC 3601 note.

(a) TITLES I AND II.—

(1) IN GENERAL.—Except as provided under paragraph (2), titles I and II and the amendments made by such titles shall take effect 120 days after the date of enactment of this Act.

(2) IMMEDIATE ENACTMENT.—Sections 207, 214, and 215 shall take effect on the date of enactment of this Act.

44 USC 3541 note.

(b) TITLES III AND IV.—Title III and this title shall take effect on the date of enactment of this Act.

Confidential Information Protection and Statistical Efficiency Act of 2002.

TITLE V—CONFIDENTIAL INFORMATION PROTECTION AND STATISTICAL EFFICIENCY

44 USC 3501 note.

SEC. 501. SHORT TITLE.

This title may be cited as the "Confidential Information Protection and Statistical Efficiency Act of 2002".

44 USC 3501 note.

SEC. 502. DEFINITIONS.

As used in this title:

(1) The term "agency" means any entity that falls within the definition of the term "executive agency" as defined in section 102 of title 31, United States Code, or "agency", as defined in section 3502 of title 44, United States Code.

(2) The term "agent" means an individual—

(A)(i) who is an employee of a private organization or a researcher affiliated with an institution of higher learning (including a person granted special sworn status by the Bureau of the Census under section 23(c) of title 13, United States Code), and with whom a contract or other agreement is executed, on a temporary basis, by an executive agency to perform exclusively statistical activities under the control and supervision of an officer or employee of that agency;

(ii) who is working under the authority of a government entity with which a contract or other agreement is executed by an executive agency to perform exclusively statistical activities under the control of an officer or employee of that agency;

(iii) who is a self-employed researcher, a consultant, a contractor, or an employee of a contractor, and with whom a contract or other agreement is executed by an executive agency to perform a statistical activity under the control of an officer or employee of that agency; or

(iv) who is a contractor or an employee of a contractor, and who is engaged by the agency to design or maintain the systems for handling or storage of data received under this title; and

(B) who agrees in writing to comply with all provisions of law that affect information acquired by that agency.

(3) The term "business data" means operating and financial data and information about businesses, tax-exempt organizations, and government entities.

(4) The term "identifiable form" means any representation of information that permits the identity of the respondent to whom the information applies to be reasonably inferred by either direct or indirect means.

(5) The term "nonstatistical purpose"—

(A) means the use of data in identifiable form for any purpose that is not a statistical purpose, including

any administrative, regulatory, law enforcement, adjudicatory, or other purpose that affects the rights, privileges, or benefits of a particular identifiable respondent; and

(B) includes the disclosure under section 552 of title 5, United States Code (popularly known as the Freedom of Information Act) of data that are acquired for exclusively statistical purposes under a pledge of confidentiality.

(6) The term "respondent" means a person who, or organization that, is requested or required to supply information to an agency, is the subject of information requested or required to be supplied to an agency, or provides that information to an agency.

(7) The term "statistical activities"—

(A) means the collection, compilation, processing, or analysis of data for the purpose of describing or making estimates concerning the whole, or relevant groups or components within, the economy, society, or the natural environment; and

(B) includes the development of methods or resources that support those activities, such as measurement methods, models, statistical classifications, or sampling frames.

(8) The term "statistical agency or unit" means an agency or organizational unit of the executive branch whose activities are predominantly the collection, compilation, processing, or analysis of information for statistical purposes.

(9) The term "statistical purpose"—

(A) means the description, estimation, or analysis of the characteristics of groups, without identifying the individuals or organizations that comprise such groups; and

(B) includes the development, implementation, or maintenance of methods, technical or administrative procedures, or information resources that support the purposes described in subparagraph (A).

SEC. 503. COORDINATION AND OVERSIGHT OF POLICIES.

44 USC 3501 note.

(a) IN GENERAL.—The Director of the Office of Management and Budget shall coordinate and oversee the confidentiality and disclosure policies established by this title. The Director may promulgate rules or provide other guidance to ensure consistent interpretation of this title by the affected agencies.

(b) AGENCY RULES.—Subject to subsection (c), agencies may promulgate rules to implement this title. Rules governing disclosures of information that are authorized by this title shall be promulgated by the agency that originally collected the information.

(c) REVIEW AND APPROVAL OF RULES.—The Director shall review any rules proposed by an agency pursuant to this title for consistency with the provisions of this title and chapter 35 of title 44, United States Code, and such rules shall be subject to the approval of the Director.

(d) REPORTS.—

(1) The head of each agency shall provide to the Director of the Office of Management and Budget such reports and other information as the Director requests.

(2) Each Designated Statistical Agency referred to in section 522 shall report annually to the Director of the Office

of Management and Budget, the Committee on Government Reform of the House of Representatives, and the Committee on Governmental Affairs of the Senate on the actions it has taken to implement sections 523 and 524. The report shall include copies of each written agreement entered into pursuant to section 524(a) for the applicable year.

(3) The Director of the Office of Management and Budget shall include a summary of reports submitted to the Director under paragraph (2) and actions taken by the Director to advance the purposes of this title in the annual report to the Congress on statistical programs prepared under section 3504(e)(2) of title 44, United States Code.

44 USC 3501 note.

SEC. 504. EFFECT ON OTHER LAWS.

(a) TITLE 44, UNITED STATES CODE.—This title, including amendments made by this title, does not diminish the authority under section 3510 of title 44, United States Code, of the Director of the Office of Management and Budget to direct, and of an agency to make, disclosures that are not inconsistent with any applicable law.

(b) TITLE 13 AND TITLE 44, UNITED STATES CODE.—This title, including amendments made by this title, does not diminish the authority of the Bureau of the Census to provide information in accordance with sections 8, 16, 301, and 401 of title 13, United States Code, and section 2108 of title 44, United States Code.

(c) TITLE 13, UNITED STATES CODE.—This title, including amendments made by this title, shall not be construed as authorizing the disclosure for nonstatistical purposes of demographic data or information collected by the Census Bureau pursuant to section 9 of title 13, United States Code.

(d) VARIOUS ENERGY STATUTES.—Data or information acquired by the Energy Information Administration under a pledge of confidentiality and designated by the Energy Information Administration to be used for exclusively statistical purposes shall not be disclosed in identifiable form for nonstatistical purposes under—

(1) section 12, 20, or 59 of the Federal Energy Administration Act of 1974 (15 U.S.C. 771, 779, 790h);

(2) section 11 of the Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 796); or

(3) section 205 or 407 of the Department of the Energy Organization Act of 1977 (42 U.S.C. 7135, 7177).

(e) SECTION 201 OF CONGRESSIONAL BUDGET ACT OF 1974.—This title, including amendments made by this title, shall not be construed to limit any authorities of the Congressional Budget Office to work (consistent with laws governing the confidentiality of information the disclosure of which would be a violation of law) with databases of Designated Statistical Agencies (as defined in section 522), either separately or, for data that may be shared pursuant to section 524 of this title or other authority, jointly in order to improve the general utility of these databases for the statistical purpose of analyzing pension and health care financing issues.

(f) PREEMPTION OF STATE LAW.—Nothing in this title shall preempt applicable State law regarding the confidentiality of data collected by the States.

(g) STATUTES REGARDING FALSE STATEMENTS.—Notwithstanding section 512, information collected by an agency for exclusively statistical purposes under a pledge of confidentiality may be provided by the collecting agency to a law enforcement agency for the prosecution of submissions to the collecting agency of false statistical information under statutes that authorize criminal penalties (such as section 221 of title 13, United States Code) or civil penalties for the provision of false statistical information, unless such disclosure or use would otherwise be prohibited under Federal law.

(h) CONSTRUCTION.—Nothing in this title shall be construed as restricting or diminishing any confidentiality protections or penalties for unauthorized disclosure that otherwise apply to data or information collected for statistical purposes or nonstatistical purposes, including, but not limited to, section 6103 of the Internal Revenue Code of 1986 (26 U.S.C. 6103).

(i) AUTHORITY OF CONGRESS.—Nothing in this title shall be construed to affect the authority of the Congress, including its committees, members, or agents, to obtain data or information for a statistical purpose, including for oversight of an agency's statistical activities.

Subtitle A—Confidential Information Protection

SEC. 511. FINDINGS AND PURPOSES.

44 USC 3501 note.

(a) FINDINGS.—The Congress finds the following:

(1) Individuals, businesses, and other organizations have varying degrees of legal protection when providing information to the agencies for strictly statistical purposes.

(2) Pledges of confidentiality by agencies provide assurances to the public that information about individuals or organizations or provided by individuals or organizations for exclusively statistical purposes will be held in confidence and will not be used against such individuals or organizations in any agency action.

(3) Protecting the confidentiality interests of individuals or organizations who provide information under a pledge of confidentiality for Federal statistical programs serves both the interests of the public and the needs of society.

(4) Declining trust of the public in the protection of information provided under a pledge of confidentiality to the agencies adversely affects both the accuracy and completeness of statistical analyses.

(5) Ensuring that information provided under a pledge of confidentiality for statistical purposes receives protection is essential in continuing public cooperation in statistical programs.

(b) PURPOSES.—The purposes of this subtitle are the following:

(1) To ensure that information supplied by individuals or organizations to an agency for statistical purposes under a pledge of confidentiality is used exclusively for statistical purposes.

(2) To ensure that individuals or organizations who supply information under a pledge of confidentiality to agencies for statistical purposes will neither have that information disclosed

in identifiable form to anyone not authorized by this title nor have that information used for any purpose other than a statistical purpose.

(3) To safeguard the confidentiality of individually identifiable information acquired under a pledge of confidentiality for statistical purposes by controlling access to, and uses made of, such information.

44 USC 3501 note.

SEC. 512. LIMITATIONS ON USE AND DISCLOSURE OF DATA AND INFORMATION.

(a) USE OF STATISTICAL DATA OR INFORMATION.—Data or information acquired by an agency under a pledge of confidentiality and for exclusively statistical purposes shall be used by officers, employees, or agents of the agency exclusively for statistical purposes.

(b) DISCLOSURE OF STATISTICAL DATA OR INFORMATION.—

(1) Data or information acquired by an agency under a pledge of confidentiality for exclusively statistical purposes shall not be disclosed by an agency in identifiable form, for any use other than an exclusively statistical purpose, except with the informed consent of the respondent.

(2) A disclosure pursuant to paragraph (1) is authorized only when the head of the agency approves such disclosure and the disclosure is not prohibited by any other law.

(3) This section does not restrict or diminish any confidentiality protections in law that otherwise apply to data or information acquired by an agency under a pledge of confidentiality for exclusively statistical purposes.

(c) RULE FOR USE OF DATA OR INFORMATION FOR NONSTATISTICAL PURPOSES.—A statistical agency or unit shall clearly distinguish any data or information it collects for nonstatistical purposes (as authorized by law) and provide notice to the public, before the data or information is collected, that the data or information could be used for nonstatistical purposes.

(d) DESIGNATION OF AGENTS.—A statistical agency or unit may designate agents, by contract or by entering into a special agreement containing the provisions required under section 502(2) for treatment as an agent under that section, who may perform exclusively statistical activities, subject to the limitations and penalties described in this title.

44 USC 3501 note.

SEC. 513. FINES AND PENALTIES.

Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both.

Subtitle B—Statistical Efficiency

SEC. 521. FINDINGS AND PURPOSES.

44 USC 3501 note.

(a) FINDINGS.—The Congress finds the following:

(1) Federal statistics are an important source of information for public and private decision-makers such as policymakers, consumers, businesses, investors, and workers.

(2) Federal statistical agencies should continuously seek to improve their efficiency. Statutory constraints limit the ability of these agencies to share data and thus to achieve higher efficiency for Federal statistical programs.

(3) The quality of Federal statistics depends on the willingness of businesses to respond to statistical surveys. Reducing reporting burdens will increase response rates, and therefore lead to more accurate characterizations of the economy.

(4) Enhanced sharing of business data among the Bureau of the Census, the Bureau of Economic Analysis, and the Bureau of Labor Statistics for exclusively statistical purposes will improve their ability to track more accurately the large and rapidly changing nature of United States business. In particular, the statistical agencies will be able to better ensure that businesses are consistently classified in appropriate industries, resolve data anomalies, produce statistical samples that are consistently adjusted for the entry and exit of new businesses in a timely manner, and correct faulty reporting errors quickly and efficiently.

(5) The Congress enacted the International Investment and Trade in Services Act of 1990 that allowed the Bureau of the Census, the Bureau of Economic Analysis, and the Bureau of Labor Statistics to share data on foreign-owned companies. The Act not only expanded detailed industry coverage from 135 industries to over 800 industries with no increase in the data collected from respondents but also demonstrated how data sharing can result in the creation of valuable data products.

(6) With subtitle A of this title, the sharing of business data among the Bureau of the Census, the Bureau of Economic Analysis, and the Bureau of Labor Statistics continues to ensure the highest level of confidentiality for respondents to statistical surveys.

(b) PURPOSES.—The purposes of this subtitle are the following:

(1) To authorize the sharing of business data among the Bureau of the Census, the Bureau of Economic Analysis, and the Bureau of Labor Statistics for exclusively statistical purposes.

(2) To reduce the paperwork burdens imposed on businesses that provide requested information to the Federal Government.

(3) To improve the comparability and accuracy of Federal economic statistics by allowing the Bureau of the Census, the Bureau of Economic Analysis, and the Bureau of Labor Statistics to update sample frames, develop consistent classifications of establishments and companies into industries, improve coverage, and reconcile significant differences in data produced by the three agencies.

(4) To increase understanding of the United States economy, especially for key industry and regional statistics,

to develop more accurate measures of the impact of technology on productivity growth, and to enhance the reliability of the Nation's most important economic indicators, such as the National Income and Product Accounts.

44 USC 3501 note.

SEC. 522. DESIGNATION OF STATISTICAL AGENCIES.

For purposes of this subtitle, the term "Designated Statistical Agency" means each of the following:

(1) The Bureau of the Census of the Department of Commerce.

(2) The Bureau of Economic Analysis of the Department of Commerce.

(3) The Bureau of Labor Statistics of the Department of Labor.

44 USC 3501 note.

SEC. 523. RESPONSIBILITIES OF DESIGNATED STATISTICAL AGENCIES.

The head of each of the Designated Statistical Agencies shall—

(1) identify opportunities to eliminate duplication and otherwise reduce reporting burden and cost imposed on the public in providing information for statistical purposes;

(2) enter into joint statistical projects to improve the quality and reduce the cost of statistical programs; and

(3) protect the confidentiality of individually identifiable information acquired for statistical purposes by adhering to safeguard principles, including—

(A) emphasizing to their officers, employees, and agents the importance of protecting the confidentiality of information in cases where the identity of individual respondents can reasonably be inferred by either direct or indirect means;

(B) training their officers, employees, and agents in their legal obligations to protect the confidentiality of individually identifiable information and in the procedures that must be followed to provide access to such information;

(C) implementing appropriate measures to assure the physical and electronic security of confidential data;

(D) establishing a system of records that identifies individuals accessing confidential data and the project for which the data were required; and

(E) being prepared to document their compliance with safeguard principles to other agencies authorized by law to monitor such compliance.

44 USC 3501 note.

SEC. 524. SHARING OF BUSINESS DATA AMONG DESIGNATED STATISTICAL AGENCIES.

(a) IN GENERAL.—A Designated Statistical Agency may provide business data in an identifiable form to another Designated Statistical Agency under the terms of a written agreement among the agencies sharing the business data that specifies—

(1) the business data to be shared;

(2) the statistical purposes for which the business data are to be used;

(3) the officers, employees, and agents authorized to examine the business data to be shared; and

(4) appropriate security procedures to safeguard the confidentiality of the business data.

(b) RESPONSIBILITIES OF AGENCIES UNDER OTHER LAWS.—The provision of business data by an agency to a Designated Statistical

Agency under this subtitle shall in no way alter the responsibility of the agency providing the data under other statutes (including section 552 of title 5, United States Code (popularly known as the Freedom of Information Act), and section 552b of title 5, United States Code (popularly known as the Privacy Act of 1974)) with respect to the provision or withholding of such information by the agency providing the data.

(c) RESPONSIBILITIES OF OFFICERS, EMPLOYEES, AND AGENTS.—Examination of business data in identifiable form shall be limited to the officers, employees, and agents authorized to examine the individual reports in accordance with written agreements pursuant to this section. Officers, employees, and agents of a Designated Statistical Agency who receive data pursuant to this subtitle shall be subject to all provisions of law, including penalties, that relate—

(1) to the unlawful provision of the business data that would apply to the officers, employees, and agents of the agency that originally obtained the information; and

(2) to the unlawful disclosure of the business data that would apply to officers, employees, and agents of the agency that originally obtained the information.

(d) NOTICE.—Whenever a written agreement concerns data that respondents were required by law to report and the respondents were not informed that the data could be shared among the Designated Statistical Agencies, for exclusively statistical purposes, the terms of such agreement shall be described in a public notice issued by the agency that intends to provide the data. Such notice shall allow a minimum of 60 days for public comment.

Public information.

SEC. 525. LIMITATIONS ON USE OF BUSINESS DATA PROVIDED BY DESIGNATED STATISTICAL AGENCIES.

44 USC 3501 note.

(a) USE, GENERALLY.—Business data provided by a Designated Statistical Agency pursuant to this subtitle shall be used exclusively for statistical purposes.

(b) PUBLICATION.—Publication of business data acquired by a Designated Statistical Agency shall occur in a manner whereby the data furnished by any particular respondent are not in identifiable form.

SEC. 526. CONFORMING AMENDMENTS.

44 USC 3501 note.

(a) DEPARTMENT OF COMMERCE.—Section 1 of the Act of January 27, 1938 (15 U.S.C. 176a) is amended by striking "The" and inserting "Except as provided in the Confidential Information Protection and Statistical Efficiency Act of 2002, the".

(b) TITLE 13.—Chapter 10 of title 13, United States Code, is amended—

(1) by adding after section 401 the following:

"§ 402. Providing business data to Designated Statistical Agencies

"The Bureau of the Census may provide business data to the Bureau of Economic Analysis and the Bureau of Labor Statistics ('Designated Statistical Agencies') if such information is required for an authorized statistical purpose and the provision is the subject of a written agreement with that Designated Statistical Agency, or their successors, as defined in the Confidential Information Protection and Statistical Efficiency Act of 2002."; and

(2) in the table of sections for the chapter by adding after the item relating to section 401 the following:

"402. Providing business data to Designated Statistical Agencies.".

Approved December 17, 2002.

LEGISLATIVE HISTORY—H.R. 2458 (S. 803):

HOUSE REPORTS: No. 107–787, Pt. 1 (Comm. on Government Reform).
SENATE REPORTS: No. 107–174 accompanying S. 803 (Comm. on Governmental Affairs).
CONGRESSIONAL RECORD, Vol. 148 (2002):
Nov. 14, considered and passed House.
Nov. 15, considered and passed Senate.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 38 (2002):
Dec. 17, Presidential statement.

○

Executive Order 13505—Removing Barriers to Responsible Scientific Research Involving Human Stem Cells

March 9, 2009

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

Sec. 2. Research. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

Sec. 3. Guidance. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. Revocations. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.

BARACK OBAMA

The White House,
March 9, 2009.

[Filed with the Office of the Federal Register, 11:15 a.m., March 10, 2009]

NOTE: This Executive order was published in the *Federal Register* on March 11.

Categories: Executive Orders : Human stem cells, removing barriers to research.

Subjects: Science and technology : Stem cell research.

DCPD Number: DCPD200900136.

How to complete your ethics Self-Assessment

Version 1.0
11 July 2014

Disclaimer
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Research and Innovation

IMPORTANT NOTICE

This document aims to assist you in **getting your proposal 'ethics-ready' for Horizon 2020 funding** (i.e. to identify and deal correctly with any ethics issues that may arise from it). It thus provides help both for the 'ethics issues table' in Part A of your proposal and will help you both for completing that table and the ethics self-assessment in Part B of your proposal (see proposal templates on the Participant Portal).

This document is however **no more than a 'how to' guide.** It covers the majority of ethics issues that normally arise in research projects and gives advice on how to deal with classic cases. Cases that are not covered must therefore be dealt with outside this guide.

The **ethics self-assessment** will become part of your **grant agreement** (in Annex 1, as description of the action, ethics requirements, etc.) and may thus lead to binding obligations that may later on be checked **during ethics checks, reviews** and **audits**.

The time that you invest in this self-assessment is therefore not wasted. It will actually improve your research results and:

- your proposed research will be compliant with applicable international, EU and national law
- your proposal will be more rapidly processed during the Horizon 2020 proposal selection procedure
- the results of your research can be more easily published in internationally refereed journals
- you will contribute to the responsible conduct of research, ensuring that society needs and expectations are better taken into account.

Consider that ethics issues arise in many areas of research. Apart from the obvious, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. might involve the voluntary participation of research subjects and the collection of data that might be considered as personal. You must protect your volunteers and also protect yourself (and your researcher colleagues).

Start thinking about ethics while designing your research protocols. Do not wait until the last minute to seek advice or check what is required under national and European legislation.

Ethics also matter for scholarly publication. Major scientific journals in many areas will increasingly require ethics committee approval before publishing research articles. Thus, you should be prepared for ethics procedures even if your research is funded by sources other than Horizon 2020.

Your first source should always be at your institution. We invite you actively to seek advice from colleagues with expertise in the ethics of research: specialised ethics departments, relevant managers in your university/research organisation, hospital research ethics committees, ethics advisors in your company, data protection officers, etc. They will be able to provide you with the necessary information targeted at your specific needs and legal environment.

Consider involving/appointing an ethics adviser/advisory board. An ethics adviser can help you from the beginning of your project to deal with ethical issues and put in place the procedures to handle them appropriately. If your research includes several ethical concerns or involves several significant or complex ethical issues *(such as participation of children from developing countries, NHPs, potential malevolent use or vulnerable populations)* it is suggested to appoint an ethics advisor or ethics advisory board with several experts with varied expertise. This may also be set as an ethics requirement by the Commission/Agency during the selection procedure. For more information on ethics advisers/advisory boards (see section 6).

Other information

This document is limited to the Ethics Issues Table and Ethics Self-Assessment for Horizon 2020 proposals.

For a more general overview of how Horizon 2020 grants work, see the Horizon 2020 Online Manual. For detailed information see the Horizon 2020 Annotated Grant Agreements.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

If you need to, you can also contact the Horizon 2020 Helpdesk.

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1. Human embryos and foetuses

This section refers to research involving human embryonic stem cells (hESC), human embryos or foetuses.

⚠ The following fields of research **cannot be financed** at all under Horizon 2020 (and therefore may not be part of any proposal):

- research activities aiming at human cloning for reproductive purposes
- research activity intended to modify the genetics of human beings that could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed)
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.[1]

⚠ Research on human stem cells (both adult and embryonic) may be financed — depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding will be granted for research activities that are prohibited in all the Member States. No activity will be funded in a Member State where such activity is forbidden.[2]

1.1 Ethics issues checklist

Section 1: HUMAN EMBRYOS/ FOETUSES		YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐			
If **YES:**	- Will they be directly derived from embryos within this project?	☐	☐		*Research cannot be funded.*	*Research cannot be funded.*
	- Are they previously established cells lines?	☐	☐		Origin and line of cells. Details on licensing and control measures by the competent authorities of the Member States involved.	Copies of Ethics Approval. A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines.

[1] *See Article 19(3) of the Horizon 2020 Regulation (EU) No 1291/2013.*
[2] *See also Article 19(4) of the Horizon 2020 Regulation (EU) No 1291/2013.*

						A statement confirming that the 6 specific conditions (see below) for research activities involving human embryonic stem cells are met.
Does your research involve the use of human embryos?		☐	☐		Origin of embryos. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. Confirm that informed consent has been obtained.	Copies of Ethics Approval. Informed Consent Forms + Information Sheets.
Does your research involve the use of human foetal tissues / cells?		☐	☐		Origin of human foetal tissues/cells. Details on informed consent procedures. Confirm that informed consent has been obtained.	Copies of Ethics Approval. Informed Consent Forms + Information Sheets.

1.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the Statement of the Commission related to research activities involving human embryonic stem cells[3]).

For research activities involving human embryonic stem cells (hESC): this implies specifically that you must make sure that:

- cells were not derived from embryos specially created for research or by somatic cell nuclear transfer
- the project only uses existing cultured cell lines
- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation
- informed consent has been obtained for the use of donated embryos for the derivation of the cell lines
- personal data and privacy of donors of embryos for the derivation of the cells are protected
- no financial inducements were provided for the donation of embryos used for derivation of the cell lines.

[3] *See Article 19(1) of the Horizon 2020 Regulation (EU) No 1291/2013.*

⚠ Compliance with these specific conditions must be confirmed in a statement to be provided to the Commission/Agency.

Moreover, under national law, research on human embryonic stem cells (hESC) is normally subject to strict licensing and control.[4]

For research on human embryos: you must obtain free and fully **informed consent** of the donors *(see section 2)*.

1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Statement of the Commission related to research activities involving human embryonic stem cells. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

Recommendations on the ethical review of hESC FP7 research projects (Opinion 22), European Group on Ethics in Science and New Technologies. Available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf

[4] *See also Article 13(2) of the Rules for Participation Regulation (EU) No 1290/2013.*

2. Humans

This section refers to any research involving work with humans ('research or study participants'), regardless of its nature or topic.

Examples: collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites, etc.

2.1 Ethics issues checklist

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human participants?		☐	☐		Confirm that informed consent has been obtained. **plus:**	Informed Consent Forms + Information Sheets (see text box below). **plus:**
If **YES:**	- Are they volunteers for social or human sciences research?	☐	☐		Details on recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of Ethics Approvals (if required).
	- Are they persons unable to give informed consent (including children/minors)?	☐	☐		Details on your procedures to obtain approval from guardian/ legal representative. Details on the measures you intend to take to ensure that there is no coercion on participants.	Copies of Ethics Approvals.
	- Are they vulnerable individuals or groups?	☐	☐		Details on the type of vulnerability. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.	Copies of Ethics Approvals.
	- Are they	☐	☐		Details on the age	Copies of Ethics

	children/minors?				range. Details on your children/minors assent procedures and parental consent. Details on the measures you intend to take to ensure welfare of the child/minor.	Approvals.
	- Are they patients?	☐	☐		Details on the nature of disease/condition/disability. Details on recruitment, inclusion and exclusion criteria and informed consent procedures Details on your policy for incidental findings.	Copies of Ethics Approvals.
	- Are they healthy volunteers for medical studies?	☐	☐			Copies of Ethics Approvals.
Does your research also involve physical interventions on the study participants?		☐	☐			
If **YES:**	- Does it involve invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)*?	☐	☐		Risk assessment for each technique and as a whole	Copies of Ethics Approvals.
	- Does it involve collection of biological samples?	☐	☐		Details on the type of samples to be collected. Details on your procedures for collection of biological samples.	Copies of Ethics Approvals.
For research involving processing of genetic information, see also section 4.						

2.3 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law.

This implies that you must ensure respect for people and for human **dignity,** fair distribution of **research benefits** and burden and protecting the **values**, **rights** and **interests** of the research participants.

Moreover, you must obtain:

- the necessary **ethics approvals** (if required)
- free and fully **informed consent** of the research participants.

Informed consent

Participation of persons must be entirely voluntary and you must obtain (and clearly document) their informed consent in advance.

⚠ No consent is required if national law provides for an exception (e.g. in the public interest).

Participants must be provided with an '**informed consent form**' and detailed '**information sheets**' that:

- are in a language and in terms fully understandable to them
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might be involved
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- indicate how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
- indicate what procedures will be implemented in the event of unexpected or incidental findings (in particular, if the participants have the right to know, or not to know, of any such findings).

You must ensure that the potential participant has fully understood the information and does not feel pressured or forced to give consent.

Consent must normally be given in writing (e.g. by signing the 'informed consent form' and 'information sheets').

If the consent cannot be given in writing, for example because of illiteracy, the non-written consent must be formally documented and independently witnessed.

Specific cases:

Research involving children (or other persons unable to give consent, *e.g. certain elderly populations, persons judged as lacking mental capacity*) — You must obtain informed consent from the legally authorised representative and ensure that they have sufficient information to enable them to provide this on behalf and in the best interests of the participants. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents or legal representatives. If necessary, re-consent must be asked by the participants at the age of maturity. Dissent should be respected.

In **social sciences and humanities research**, there may be situations where standard procedures for obtaining written informed consent are harmful or offensive to the participants (rather than providing them with protection). In such cases, explain how alternative consent will be gained *(e.g. orally)*. If deception is to be used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred by both researchers and participants.

For **medical and human research** you must follow the procedures for informed consent that are described in the Declaration of Helsinki and the Oviedo Bioethics Convention *(see below)*.

What do you need to provide?

Informed Consent Forms + Information Sheets (⚠ It is sufficient if you provide examples of the different types of Forms and Information Sheets you will use (one example per type)).

You must also ensure that your research methodologies do not result in discriminatory practices or unfair treatment. ⚠ As a general principle, benefits should be maximised and harm/risks minimised.

In addition, when conducting surveys, interviews or focus groups where personal information is gathered and stored, you must also pay attention to privacy, data protection, data management *(see also section 4)* and the health and safety of participants *(see section 10)*.

Specific cases:

Research involving children (or other persons unable to give consent) should be carried out only if:

- studies with consenting adults would not be effective
- there is only a minimal risk and burden to the participants and
- the results of the research will benefit the individual or the group represented by the participant.

Social sciences and humanities research — Research in this field often involves working with human participants and particular methodological tools *(e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and whether these include physical interventions)*.

You must therefore clarify the ethical implications of the chosen methodologies.

Example:

You should describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable, as a consequence of the methodology, describe any action to be taken to mitigate them.

For your grant proposal, you should also provide an assessment of risks, stating explicitly what kinds of harm *(psychological, social, legal, economic, environmental, etc.)* might occur, the likelihood of subjects actually incurring such harm, and the procedures that you will take to minimise them.

Research entailing more than minimal risk involve typically:

- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation

- deception
- risks to researcher safety or
- seeking respondents through the internet/social media *(e.g. using identifiable visual images or where sensitive issues are discussed)*.

Particular attention must be paid to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc.

If your research involves children or other persons unable to make decisions for themselves, you must maintain an active relationship with their legal guardians and/or carers; you must not only seek their consent, but also allow them to monitor the research.

⚠ Ensure that data are kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity.

In rare cases, there may be a need to override agreements on confidentiality and anonymity *(e.g. if maintaining confidentiality facilitates illegal behaviour such as drug dealing, child abuse, etc. that has come to light in the course of the research)*. In such circumstances, you must carefully consider disclosure to the appropriate authorities. Insofar as it does not undermine disclosure, you must inform the participants or their guardians of your intentions and the reasons for disclosure. You should also consider the technical aspects of how the data for your research will be collected and stored.

Data collection using electronic encoding tools (digital recorders or cameras) should be given special attention *(see also section 4)*. You should also discuss these issues with your organisation's data protection officer.

Medical studies — Medical research is specifically addressed by the Declaration of Helsinki.

Your grant proposal must also comply with:

- the principles enshrined in the Oviedo Bioethics Convention and
- EU Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

2.4 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Medical research

WMA Declaration of Helsinki. Available at http://www.wma.net/en/30publications/10policies/b3/

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997) (Oviedo Bioethics Convention). Available at http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use as well as the requirements for authorization of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC (OJ L158, 27/5/2014).

Social science research

http://ec.europa.eu/programmes/horizon2020/en/area/social-sciences-humanities

3. Human cells/tissues

This section refers to research using, producing or collecting human cells or tissues.

Such cells or tissues may:

- be obtained from commercial sources
- originate from another laboratory, institution or biobank
- be produced or collected by you during previous research activities or
- be produced or collected by you as part of this research project.

3.1 Ethics issues checklist

Section 3: HUMAN CELLS / TISSUES		YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, *see section 1*)?		☐	☐		Details of the cells/ tissue types. **plus:**	Copies of relevant Ethics Approvals. Copies of accreditation/designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required), **plus:**
If **YES:**	- Are they obtained from commercial sources?	☐	☐		Details on provider (company or other).	Copies of import licences (if relevant).
	- Do they originate from another laboratory/institution/biobank	☐	☐		Name of the laboratory/institution/biobank. Country in which the laboratory/institution/biobank is located. Details of the legislation under which material is stored. Confirm that material is fully anonymised or that consent for secondary use has been obtained.	Copies of import licences (if relevant). Statement of laboratory/institution /biobank that informed consent has been obtained.
	- Were they produced or collected by you from previous research	☐	☐		Country in which the material is stored. Details on the	

	activities?				legislation under which material is stored. Details on the duration of storage and what you will do with the material at the end of the research. project.	
	- Are they produced or collected by you as part of this project?	☐	☐		Details on the source of the material, the amount to be collected and the procedure for collection. Details on the duration of storage and what you will do with the material at the end of the research. Confirm that informed consent has been obtained.	Informed Consent Forms + Information Sheets.

3.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2004/23/EC).

  Under this Directive, the handling of cells and tissues is subject to specific rules (in particular, concerning donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries).

The main obligations are to:

- keep track of the **origin** of the cells and tissues you use, produce or collect

and to obtain:

- the necessary **accreditation/designation/authorisation/licensing** for using, producing or collecting the cells or tissues
- free and fully **informed consent** of the donors *(see section 2)*.

Specific cases:

Cells or tissues from clinical practice (secondary use) — For human cells or tissues derived by you or others from clinical practice *(e.g. waste material from surgery or other operations*) provide evidence *(e.g.*

copies of examples of informed consent documentation) that the donors have given informed consent *(see section 2)* for the use of their waste cells or tissues (either specifically for the research or generally, for any secondary use).

If, for the purposes of your research, you intend to collect more **additional material** than would normally be collected during the standard clinical procedure *(e.g. a larger than normal tissue sample or a sample that includes some additional adjacent material)*, you must ensure informed consent also about the collection of additional material. You must also explain the need for obtaining the additional material in your grant proposal and show that you obtained appropriate ethics approvals.

Secondary use for future research — If you will store the material for future use in other projects, you must confirm that you have obtained the donor's consent to such secondary use, state the legislation under which the material will be stored, and provide information on the duration of storage and what you will do with the material at the end of the research.

Biobanking — Biobanks raise significant ethical issues concerning informed consent and data privacy.

'Biobanks' are repositories for the storage of biological samples (usually human) and play a significant role in biomedical research. These 'libraries' provide researchers with access to large numbers of tissue samples, genetic material and associated data.

If your project has the aim or effect of setting up a biobank, you must ensure that there is strict compliance with appropriate European and national ethical standards (in particular, regarding data privacy; *see section 4*).

You must confirm that informed consent has been obtained and show that you have obtained all necessary ethics approvals (or that you are exempted under national law).

⚠ No samples/data may be placed in the biobank before all appropriate consents and ethics approvals have been obtained

You will need to provide a report on key aspects of the biobank's activities, including in particular:

- information on which donors will be excluded/included (e.*g. competent adults, children and minors, adults unable to provide informed consent, individuals in an emergency setting, etc*.)
- details on the material that will be 'banked', including:
  - personal (coded or fully identifiable) biosamples
  - personal information associated with a sample *(e.g. name/code, gender, age, etc.)*
  - personal data resulting from analysis of a sample *(e.g. analysis of genetic material or a genome)*
  - anonymised biosamples
  - anonymised data resulting from analysis of a sample (from which individuals could be identified) and
  - epidemiological (population level) data
- information on the standard procedures for:
  - accepting material into the biobank,
  - processes and standards on sample-quality assurance and ensuring accuracy of data and information
  - handling requests for release of samples/data from the biobank (including fair and just financial arrangements and benefit-sharing for third countries).

Genetic testing — For using or storing human cells or tissues for genetic testing, you must obtain informed consent *(see section 2)* of the donor on the genetic testing, and show that you obtained approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from third countries — If your research project involves the transfer of cells and tissues from/to third countries, you must comply with the specific provisions on import/export under Directive 2004/23/EC *(see also section 6)*.

Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to third countries *(see section 4)*.

3.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p.48).

4. Personal data

This section concerns research which involves collecting or processing of personal data, regardless of the method by which they are/were collected *(e.g. through interviews, questionnaires, direct online retrieval etc.)*.

'Personal data' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of EU Directive 95/46/EC).

> ***Examples:*** *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Completely anonymised data does not fall under the data privacy rules (as from the moment is has been completely anonymised).

'Processing of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection (digital audio recording, digital video caption, etc.)
- recording
- organisation and storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, appification, etc.)
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)
- alignment or combination
- blocking, deleting or destruction.

> ***Examples:*** *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

⚠ Processing covers normally any action that uses data for research purposes (including if interviewees, human volunteers, patients, etc. are *not* actively included in the research).

Data may come from any type of research activity (ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.), lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking and domicile information, etc.).

4.1 Ethics issues checklist

Section 4: PROTECTION OF PERSONAL DATA	YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve personal data collection and/or processing?	☐	☐		Details on your procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.). Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that informed consent has been obtained. Details on data transfers to third countries (type of data transferred and country to which it is transferred; for US/Canada: information if recipient is 'safe harbour recipient'). **plus:**	Copies of notifications/authorisations for the collection and/or processing of the personal data (if required). Informed Consent Forms + Information Sheets + Other consent documents (opt in processes, etc.) (if relevant). Copy of authorisation for data transfer to third country (if required) For US/Canada: print-out from safe harbour list **plus:**

If **YES:**	- Does it involve the collection or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*?	☐	☐			Copy of notification/authorisation for processing of sensitive data (if required)
	- Does it involve processing of genetic information?	☐	☐			
	- Does it involve tracking or observation of participants *(e.g. surveillance or localization data, and Wan data, such as IP address, MACs, cookies etc.)?*	☐	☐		Details on methods used for tracking or observing participants.	Copy of notification/authorisation for tracking or observation (if required)
Does your research involve further processing of previously collected personal data ('secondary use') *(including use of pre-existing data sets or sources, merging existing data sets, sharing data with non-EU member states)***?**		☐	☐		Details on the database used or of the source of the data. Details on your procedures for data processing. Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that data is openly and publicly accessible or that consent for secondary use has been obtained (and details on how this consent was obtained (automatic opt in, etc.)). Confirm permissions by the owner/manager of the data sets.	Evidence of open public access *(e.g. print screen from website)*. Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.). Copies of permissions (if required).

4.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 95/46/EC).

  Under this Directive, personal data must be processed according to certain principles and conditions that aim to limit the impact on the persons concerned and ensure data quality and confidentiality. Certain categories of data are more 'sensitive' than others *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)* and these may only be processed according to specific rules.

  ⚠ The Directive is currently under revision. Any changes in the legislation will have an effect on your research, and must therefore be monitored.

You may collect and process data only if and insofar as it is really **necessary** for your research.

Collecting personal data *(for example, on religion, sexual orientation, race, ethnicity, etc.)* that is not essential to your research may moreover expose you to allegations of 'hidden objectives' or 'mission creep' — i.e. information being collected with permission for one purpose and being used or made available, including online, for another reason, without additional permission.

You must moreover obtain:

- the necessary **notifications/authorisations** for collecting and processing the data (including specific authorisations, if applicable)
- free and fully **informed consent** of the persons concerned ('data subjects') *(see section 2)*.

Specific cases:

Secondary use — If you use secondary data in your research, it must originate from a public source or be authorised for use in your research (either specifically for your research or generally for any secondary use).

Recording of information — Recorded information (audio and/or visual) will need special consideration by your data controller, to ensure that privacy and personal identities are protected.

Sensitive data — If you collect or process sensitive data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*, you may require a specific authorisation by the national data protection authority.

If you collect or process **health data**, you should refer to the processes recommended in the Ilves report on e-health.

Genetic information is currently not considered sensitive data, unless used in the context of health data.

Tracking or observing of participants may require a specific authorisation from the national data protection authority.

Data transfer within EU/EEA countries — Data transfers within the EU/EEA are not subject to specific requirements (i.e. specific authorisations or other restrictions). You only need to comply with the general requirements of Directive 95/46/EC.

Data transfer to third countries — Data transfers to third countries are normally subject to the following rules:

- for third countries on the Commission list of countries offering adequate protection: no additional requirements

  Currently (April 2014) this list covers: Andorra, Argentina, Australia, Canada (⚠ only private (commercial) sector, not public sector), Switzerland, the Faroe Islands, Guernsey, Israel, the Isle of Man, Jersey, New Zealand, Uruguay.

- for US: no additional requirements if recipient is 'safe harbour recipient' (see US Department of Commerce safe harbour list)

  'Safe Harbour' is a set of rules on privacy and data protection established by the US Department of Commerce, to which US organisations and companies can commit on a voluntary basis. If they do, they are entered in the 'safe harbour list'.

  ⚠ Following recent public debate, the safe harbour concept is under discussion and the European Parliament is considering its suspension. You must therefore monitor possible changes and take them into account for your research (for instance via the DG Justice data protection news room).

- for other third countries: you must make a data transfer agreement with the recipient and obtain a specific authorisation by the national data protection authority (of the Member State from which you are sending the data).

Electronic data

Regarding the processing of personal data and the protection of privacy in the electronic communications sector, as well as the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks (e.g. cloud, big data, open data, cookies etc.) your research must comply with the relevant legislation (in particular EU Directive 2002/58/EC and 2006/24/EC).

4.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

Examples:

If you are collecting personal information, interviewing, observing or tracking people, or recording data or audio/visual information, you need fully informed consent (see section 2) from your research subjects and provide a clear description of the procedures that you will use for data control and anonymisation.

DOCUMENTS AND LINKS

General

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31)

News on the revision of Directive 95/46/EC. Available at http://ec.europa.eu/justice/data-protection/index_en.htm.

Article 29 Working Party Documentation. Available at http://ec.europa.eu/justice/data-protection/article-29/documentation/index_en.htm.

Health data

e-Health task force report ('Ilves report on e-health'). Available at http://www.president.ee/images/stories/pdf/ehtf-report2012.pdf

Transfer to third countries

Commission list of countries offering adequate protection. Available at http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index_en.htm#h2-5

US Department of Commerce safe harbour list. Available at https://safeharbor.export.gov/list.aspx.

Electronic communications

Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).

Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks.

5. Animals

This section refers to research involving animals.

5.1 Ethics issues checklist

Section 5: ANIMALS		YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve animals?		☐	☐		Details on species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used. **plus:**	
Does your research involve research procedures that may cause pain, suffering, distress or lasting harm to live non-human vertebrate animals *(including independently feeding larval forms, foetal forms of mammals in the last trimester of their normal development and cephalopods)***?**		☐	☐		Details on implementation of the Three Rs (Replacement, Reduction and Refinement). Details on measures you intend to apply to ensure animal welfare during their lifetime and during the experiment and how its impact will be minimised. Details on fate of animals (method of killing with minimum pain, suffering, distress). Details on severity classification and justification. **plus:**	Copies of authorisations for the supply of animals and the animal experiments. Copies of training certificates/ personnel licences of the staff involved in animal experiments. Personal history file of cats, dogs **plus:**
If **YES:**	- Are they vertebrates or live cephalopods?	☐	☐			

	- Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc)?	☐	☐		Explanation why NHPs are the only suitable research subjects to achieve the scientific objectives. Details on the purpose of the animal testing. Details on provenance of the animals.	Personal history file of NHP
	- Are they genetically modified?	☐	☐		Details of the phenotype and any inherent suffering expected. Details on scientific justification for producing such animals. Details on measures you intend to apply to minimise suffering in the breeding, maintenance of the colony and use of the GM animals.	Copies of GMO authorisations.
	- Are they cloned farm animals?	☐	☐		Details of the phenotype and any inherent suffering expected. Details on scientific justification for producing such animals. Details on measures you intend to apply to minimise suffering in the breeding, maintenance of the colony and use of the GM animals.	Copies of authorisations for cloning (if required).
	- Are they an endangered species?	☐	☐		Details on why there is no alternative to the use of this species. Details on the purpose of the research.	Copies of authorisations for supply of endangered animal species (including CITES).

5.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2010/63/EU).

  This Directive aims at limiting the use of animal testing for scientific purposes and provides for common standards for the welfare of animals that are used (including authorisations, restrictions for the use of certain kinds of animals, standards for procedures, minimum requirements for personnel, recording and traceability, care and accommodation).

  ⚠ Some EU Member States have stricter rules.

This means that you must favour alternatives to animal use and implement the principles of **replacement**, **reduction** and **refinement** (‘**three Rs**’).

‘Replacement’ means replacing animal use by an alternative method or testing strategy (without use of live animals).

Examples:

‘Higher' animals can be replaced with 'lower' animals: Microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals.

Live animals may be replaced with non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audio-visual aids, or in vitro modelling.

‘Reduction’ means to reduce the number of animals used.

‘Refinement’ means to improve breeding, accommodation and care of animals and methods used, in order to minimise pain, suffering, distress or lasting harm to the animals.

Moreover, you must obtain:

- the necessary **authorisations** for the supply of animals and the animal experiments (and other specific authorisations, if applicable).

⚠ All relevant national authorisations must be in place before use of animals can commence.

Specific cases:

Non-human primates (NHPs) — Being so close to human beings, the use of non-human primates for experiments raises particular ethics concerns. Directive 2010/63/EU sets strict limits to their use: They may only be used for specific research purposes (of primary importance) and only if there is no alternative.[5] Moreover, only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used.[6]

⚠ The use of great apes requires very exceptional justification and must be specifically authorised by the Commission/Agency.

[5] *See Article 8 of Directive 2010/63/EU.*
[6] *See Article 10 of Directive 2010/63/EU.*

Endangered species — Endangered species cannot be used, except for very important research purposes and where there is no alternative non-endangered species that will meet the scientific objective.[7]

In this case, you should follow agreed international practices (CITES).

5.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

General

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

The ARRIVE Guidelines — Animal Research: Reporting In Vivo Experiments. Available at http://www.nc3rs.org.uk/page.asp?id=1357.

Festing MFW, Overend P, Gaines Das R, Cortina Borja M, Berdoy M (2002), *The design of animal experiments: reducing the number of animals in research through better experimental design*, Laboratory Animal Handbooks Series, 14. London: Royal Society of Medicine Press.

Hooijmans C. *et al*. (2010), *A gold standard publication checklist to improve the quality of animal studies, to fully integrate the Three Rs, and to make a systematic review more feasible*, ATLA 38: 167-182.

For alternatives to animal testing, refer to the following websites:
http://ecvam.jrc.it/, http://www.nc3rs.org.uk/category.asp?catID=3
http://www.vet.uu.nl/nca/links/databases_of_3r_models

Endangered species

CITES (http://www.cites.org/).

[7] *See Article 7 of Directive 2010/63/EU.*

6. Third countries

This section concerns research that involves third countries (i.e. non EU Member States).

This is the case where:

- (parts of) research activities are carried out in a third country
- participants or resources come from a third country
- material is imported/exported from/to a third country.

Being outside the reach of European laws and standards, such research can raise specific ethical issues (particularly in developing countries), in particular:

- exploitation of research participants
- exploitation of local resources
- risks for researchers and staff
- research that is prohibited in the EU.

⚠ Horizon 2020 funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States.[8]

6.1 Ethics issues checklist

Section 6: THIRD COUNTRIES	YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve third countries?	☐	☐		Risk-benefit analysis. **plus:**	
Are research activities going to be carried out in a third country? *Specify the countries involved:*	☐	☐		Details on activities carried out in non-EU countries.	Copies of Ethics Approvals and other Authorisations or Notifications (if required). Confirmation that the activity could have been legally carried out in an EU Member States (for instance, by submitting an 'opinion' of an appropriate ethics structure in an EU Member State).
Do you plan to use local resources *(e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of*	☐	☐		Details on type of local resources to be used and modalities	For human resources: copies of Ethics Approvals.

[8] *See Article 19(4) of the Horizon 2020 Regulation (EU) No 1291/2013.*

*historical value, endangered fauna or flora samples, traditional knowledge, etc.)***?**				for their use.	For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the *UN Convention on Biological Diversity* (e.g. access permit and benefit sharing agreement)
Do you plan to import any material from third countries into the EU? *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.*	☐	☐		Details on type of materials to be imported.	Copies of import licences.
If **YES:** *Specify the materials and countries involved*					
Do you plan to export any material from the EU to third countries? *For data exports, see section 4.*	☐	☐		Details on type of materials to be exported.	Copies of export licences.
If **YES**: *Specify material and countries involved:*					
If your research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?	☐	☐		Details on benefit sharing measures. Details on responsiveness to local research needs. Details on procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the research at risk?	☐	☐		Details on safety measures you intend to apply, including personnel training and insurance cover.	

6.2 How to deal with the issues?

Specific cases:

Research carried out in a third country — For research activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of the third country; you must also:

- confirm that the research is compatible with EU and international law
- show that it could have been legally conducted in (at least) one of the EU Member States[9].

  This can be done by submitting the approval of a European ethics committee *(e.g. the ethics committee of the institution hosting the researcher(s) that conduct the activity)*.

  ⚠ Getting such approval is mandatory when there is no competent structure in the third country. In this case, you must moreover implement other safeguards *(e.g. appoint an independent **ethics adviser** from the third country or an **ethics advisory board**)*.

Ethics advisers/advisory boards

A suitably experienced *ethics adviser* can help you to deal with ethical issues and putting into place the procedures to handle these appropriately if your research includes several ethical concerns.

If your research involves several significant or complex ethical issues, you should appoint an *ethics advisory board* with several experts with varied expertise.

If you appoint an ethics adviser/advisory board, it is important that they are:

- external to the project and to the host institution
- totally independent and
- free from any conflict of interest.

Your university or institution (or members of your consortium) may have experience with an ethics adviser or members of an ethics advisory board and may be in a position to suggest potential candidates.

The ethics adviser or ethics advisory board should maintain an overview of the work throughout the whole course of your project and help you to think ahead about possible problems that might arise and how they can be addressed. Their experience will help you check for compliance with ethical standards within the relevant research fields. They will also be responsible for reporting to you and to the Commission, on a regular basis, on ethics concerns as they arise and the continuing probity of your studies.

If you appoint an ethics adviser or set up an ethics advisory board, you should work with them on a regular basis throughout your project. Their oversight role should be fully integrated into your research activities and they should work closely with you and your colleagues so they are fully aware of all the developments as your research progresses. Your ethics advisers/ethics advisory board should be an essential element in your project management structure.

[9] *See Article 19 of the H2020 Regulation (EU) No 1291/2013.*

What do you need to provide?

You must provide:

- the name and contact information for persons suggested
- the terms of reference for their involvement and the deliverables expected
- their declarations of no conflict of interest.

Resources from a third country — Any use of local resources (especially animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples) must show respect to cultural traditions and share benefits (i.e. also benefit local participants and their communities, involve local researchers – as equal partners – and respond also to local research needs).

This is particularly important for **low income and lower-middle income countries** *(see Convention on Biological Diversity and Declaration of Helsinki)*.

For access to **genetic resources**, you must also comply with the Nagoya Protocol on Access and Benefit Sharing and EU Regulation (EU) No 511/2014 which implements this Protocol.

Import/export of material — If genetic resources are transferred across borders, the law of the provider country may provide for the need to obtain an authorisationfor the transfer. In addition, an agreement must be provided which describes the conditions for the export and the terms of utilisation and, if applicable, relevant benefit-sharing measures.

ⓘ For transfers of human cells or tissues, see section 3.

ⓘ For data transfers, see section 4.

Sending researchers to a third country — Third countries are not necessarily less safe than EU countries. Nevertheless, a risk assessment must be undertaken when sending researchers abroad and appropriate safety measures must be taken. These may include insurance cover or health and safety measures, *such as no lone working, contact points via phone, counselling support, etc. (see also section 7)*.

6.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Human resources

Declaration of Helsinki. Available at http://www.wma.net/en/30publications/10policies/b3/

Flora and fauna

Convention on Biological Diversity. Available at http://www.cbd.int/

Genetic resources

Nagoya Protocol on Access and Benefit Sharing. Available at http://www.cbd.int/abs

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing of benefits arising from their utilization in the Union.

7. Environment & Health and Safety

This section concerns research that may have a negative impact on:

- the environment or
- the health and safety of the researchers involved.

This may be due to any of the following:

- the experimental design of the research itself
- undesirable side-effects of the technologies used.

7.1 Environment

7.1.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH AND SAFETY	YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve the use of elements that may cause harm to the environment, animals or plants? *For research involving animal experiments, see section 5.*	☐	☐		Risk-benefit analysis. Show how you apply the precautionary principle (if relevant). Details on safety measures you intend to apply. **plus:**	Safety classification of laboratory. Copy of GMO and other authorisations (if required) **plus:**
Does your research deal with endangered fauna and/or flora /protected areas?	☐	☐			Specific authorisations (if required).

7.1.2 How to deal with the issues?

Your research must comply with:

- ethical principles

– applicable international, EU and national law (in particular, the precautionary principle and the legislation on nature conservation and pollution control).

The precautionary principle requires that — where scientific evidence suggests that serious risks are plausible — you must prove that a new technology will not harm the environment.

The legislation on nature conservation and pollution control includes the Habitats Directive 92/43/EEC, the Wild Birds Directive 79/409/EEC, Regulation (EC) No 338/97 on protection of wild fauna, the GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety.

This means that you must assess potential risks to the environment and to avoid or minimise such risks.

Moreover, you must obtain:

– the necessary environmental **authorisations** (if applicable).

⚠ All relevant national authorisations must be in place before your research can commence.

7.1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

7.2 Health and Safety

The health and safety of all human participants in research, either as subjects, as investigators or as unconcerned third parties, must be a priority in all research studies.

The kinds of risk to researcher safety will vary according to the nature of the discipline, the topic and the research site. Only the 'researcher in the field' will be fully able to assess safety concerns and/or their willingness to tolerate risks.

However, both research in familiar and unfamiliar settings can hold added safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks.

Moreover, in certain types of research, the risk of harm to the researcher is caused by the topic of study or by the actions of the researchers themselves. Lack of caution or failure to obey standard procedures may lead to physical or psychological harm.

⚠ Improved safety practices may impose additional cost burdens which can be included as an element in the estimated budget for your proposal.

7.2.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH AND SAFETY	YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve the use of elements that may cause harm to humans, including research staff?	☐	☐		Details on health and safety procedures you intend to apply.	Safety classification of laboratory. **plus:**

For research involving human participants, see section 2.					**plus:**	
If **YES:**	Does your research involve harmful biological agents (pathogenic organisms) or GMOs of Risk Class 2 or higher?	☐	☐		Risk-assessment	Copies of GMO and other authorisations (if required).
	Does your research involve harmful chemical and explosive agents?	☐	☐		Risk-assessment	Copies of authorisations for possession of toxic substances and for the handling and transfer of explosives (if required).
	Does your research involve harmful radioactive agents?	☐	☐		Risk-assessment	Copies of authorisations of use of radioactive material. Copy of authorisation of release of radioactive material into the environment.
	Does your research involve other harmful materials or equipment *(e.g. high-powered laser systems)*?	☐	☐		Risk-assessment	Copies of authorisations (if required).

7.2.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the legislation on public-health control *(e.g. regulating conduct in animal epidemics, food imports, consumer protection, etc.)* and safety at work *(e.g. Directive 2006/25/EC)*).

This means that you must warn, advise and even remove researchers from dangerous situations.

Moreover you should establish and follow a set of safety checks and procedures (or a more in-depth risk assessment) for each project they conduct.

You also must obtain:

- the necessary health and safety **authorisations** (if applicable).

Specific cases:

T**oxic chemicals** and/or **explosives** — Staff should have adequate training in storing, handling and disposing of such substances. If new substances and/or formulations *(e.g. nanomaterials)* are developed, you must provide adequate risk assessments.

Radioactive material — Clear legislation exists in all EU countries on the storage, handling and disposal of radioactive materials.

> The release of radioactive material into the environment is anticipated, is only admitted if you can show that use of alternatives (e.g. non-radioactive stable isotopes, simulants etc.) is not possible.

Research 'in the field' — Establish and follow recognised procedures to help keep researchers and subjects safe. These should include:

- keeping careful notes of all research engagements
- ensuring projects are adequately staffed
- using mobile phones to keep in touch with the research base
- conducting full risk assessments of fieldwork sites
- formally notifying authorities of research being conducted in an area
- carrying authorised identification
- researcher preparation and training covering techniques for handling conflict, threats, abuse or compromising situations
- debriefing after field research with an assessment of fieldwork safety and
- reporting any health and safety incidents.

7.2.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

General Environment

Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7)

Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (OJ L 103, 25.4.1979, p.1)

Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 103, 25.4.1979, p.1)

Cartagena Protocol on Biosafety. Available at http://bch.cbd.int/protocol/.

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration

Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)

GMO

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms

Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75)

Public health and consumer protection

For further guidance, please see: http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm

Health and safety at work

Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of the workers to risks arising from physical agents (OJ L 114, 27.4.2006, p.38)

A Code of Practice for the Safety of Social Researchers. Available at http://the-sra.org.uk/wp-content/uploads/safety_code_of_practice.pdf

8. Dual use

This section concerns research that has the potential also for military applications.

⚠ Only research that has an exclusive focus on civil applications can be funded.[10]

However, this does not rule out the participation by military partners or the application of military technologies for civil uses, provided that the research itself is clearly focused on civil applications.

8.1 Ethics issues checklist

Section 8: DUAL USE		YES/NO		Page	Information to be provided	Documents to be provided
Does your research have the potential for military applications?		☐	☐			
If **YES:**	Does your research have an exclusive civilian application focus?	☐	☐		Explanations on the exclusive civilian focus of the research. Justify inclusion of military partners or military technologies (i.e. explain how they relate to civilian applications, e.*g. in the context of law enforcement activities*).	
	Will your research use or produce goods or information that will require export licenses in accordance with legislation on dual use items?	☐	☐		Details on what goods and information used and produced in your research will need export licences.	Copies of export licences.
	Does your research affect current standards in military ethics *(e.g. global ban on weapons of mass destruction, issues of proportionality, discrimination of combatants and accountability in drone and autonomous robotics developments, incendiary or laser weapons)*?	☐	☐		Details on how the research might affect current standards in military ethics. Details on measures you intend to apply to avoid negative implications on military ethics standards (including training of researchers).	

[10] *See Article 19(2) of the Horizon 2020 Regulation (EU) No 1291/2013.*

8.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, Regulation (EC) No 428/2009).

  ⚠ Your research must follow national legislation for *civil* research and not rely on legal exceptions for military research.

Specific cases:

Cross-border transfers — For cross-border transfers of dual-use materials, technologies and information, you must observe EU export control Regulation (EC) No 428/2009. If you have any doubts, you should consult the relevant national export control authority to clarify whether transfer licences are needed.

Research that may affect military ethics standards — If your research may be concerned by international non-proliferation laws or international humanitarian laws on military ethics *(e.g. pathogen-related research, development of autonomous robotics, drones and certain laser technologies, etc.)* you must comply with the international legislation in this area (in particular, the Biological and Toxin Weapons Convention).

⚠ You may also want to appoint an independent ethics adviser/ethics board, with relevant ethics and security expertise, to carry out a risk-benefit analysis of the intended research and to suggest appropriate safeguards to cover security risks (during, and beyond, the lifetime of the project) and training for researchers.

8.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p.1)

EU Charter of Fundamental Rights (OJ C 364, 18.12.2000, p.1)

Biological and Toxin Weapons Convention. Available at
http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument

UN Security Council Resolution 1540. Available at
http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540(2004)

9. Misuse

This section concerns research that could potentially be misused.

9.1 Ethics issues checklist

Section 9: MISUSE		YES/NO		Page	Information to be provided	Documents to be provided
Does your research have the potential for malevolent/criminal/terrorist abuse?		☐	☐		Risk-assessment. **plus:**	
If **YES:**	Does your research involve information on/or the use of biological-, chemical-, nuclear/radiological-security sensitive materials and explosives, or means of their delivery? *For research involving dual items, see section 8.*	☐	☐		Details on the applicable legal requirements. Details on the measures you intend to take to prevent abuse (including training of personnel).	Copies of Authorisations (if required). Copies of personnel security clearances, (if applicable).
	Does your research involve the development of technologies or the creation of information that could have severe negative impacts on human rights standards *(e.g. privacy, stigmatization, discrimination)*, if misapplied?	☐	☐		Details on how your research could affect human rights Details on the measures you intend to take to prevent abuse.	Copies of Ethics Approvals (if applicable).
	Does your research have other potential for terrorist or criminal abuse *(e.g. infrastructural vulnerability studies, cyber-security related research)*?	☐	☐		Details on the measures you intend to take to prevent abuse.	Copies of Ethics Approvals (if required). Copies of personnel security clearances, (if applicable).

9.2 How to deal with the issues?

You must make a risk-assessment and take appropriate measures to avoid abuse.

Moreover, you must comply with the numerous international, EU and national laws that address concerns relating to potential misuse of materials, technologies and information (see below).

Specific cases:

Biological, chemical, radiological and nuclear security sensitive materials and explosives (CBRNE) — Key elements to avoid abuses include appropriate measures to ensure adequate security for the facility used, personnel, transfer, and information. Including security expertise in your research (such as the appointment of an independent adviser) and appropriate training of all personnel, provides further possible safeguards.

In many cases, overlaps between safety and security measures will exist but gaps need to be identified and addressed. The most frequently encountered issue relates to research involving pathogens and the need to implement adequate biosecurity measures.

Research that could impact on human rights — Concerns in this field are primarily related to research on surveillance technologies, new data-gathering and data-merging technologies *(e.g. in the context of big data)*. However, social or genetic research that could lead to discrimination or stigmatisation is also affected.

Risk mitigation measures may include:

- a human rights impact assessment
- involving human rights experts in your research
- training of personnel and/or technological safeguards and
- caution when publishing or otherwise disseminating results, (e.g. through privacy by design).

Research that has other potential for terrorist or criminal abuse — Although anything could ultimately be used for malevolent purposes, research in this category is that which provides terrorists or criminals with information or technologies that would have *substantial direct impacts* on the security of individuals, groups or states.

Examples: infrastructural vulnerability studies, cyber-security related research

In many cases, researchers outside the security domain are not familiar with security safeguards. In such situations, researchers should consult with experts familiar with security ethics and/or human rights. If security or human rights abuse concerns exist, you should arrange for:

- training on this issue and
- the appointment of an ethics adviser/ethics advisory board.

9.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Council Common Position 2003/805/CFSP of 17 November 2003 on the universalisation and reinforcement of multilateral agreements in the field of non-proliferation of weapons of mass destruction and means of delivery

Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items

Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction; Available at http://disarmament.un.org/treaties/t/bwc/text

UN Security Council Resolution 1540 Available at http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540(2004)

Treaty on the Non-Proliferation of Nuclear Weapons (NPT) Available at http://www.un.org/disarmament/WMD/Nuclear/NPTtext.shtml

Chemical Weapons Convention Available at http://www.opcw.org/chemical-weapons-convention

Responsible life sciences research for global health security: A guidance document. Available at http://whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.2_eng.pdf

Biorisk management: Laboratory biosecurity guidance. Available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

10. Other ethics issues

Ethics issues checklist

Section 10: OTHER ETHICS ISSUES	YES/ NO		Page	Information to be provided	Documents to be provided
Are there any other ethics issues that should be taken into consideration? *Please specify:*	☐	☐		Any relevant information.	Any relevant document.

Other ethics issues?

Since Horizon 2020 intends to support ground-breaking and innovative research, it may be that your research raises **new ethical issues and concerns** that are currently not covered by the Ethics Issue Table *(e.g. new developments in the fields of neurobiology, man-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, etc.)*. If you know of any such other ethically relevant issues that apply to your project, describe them in this section and explain how you intend to address them.

This allows you to alert the Commission in time and get appropriate assistance for addressing them. It also avoids the problems you would have if such issues were found out only later (in the context of an audit or investigation).

⚠ If, ethical issues arise **unexpectedly during your research**, contact the Commission/Agency immediately and provide detailed information on the issue and how you intend to handle it. We will ensure that you receive appropriate help and guidance.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 March 2014
EMA/199793/2011

EU Clinical Trials Register – FAQs

Questions and answers relating to practical and technical aspects of the EU Clinical Trials Register

IMPORTANT: Refer to the How to Search EU Clinical Trials Register guide (under 'About here for more information' on the EU CTR Search page) for detailed guidance on using the search functionality.

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Q.1. What is the EU Clinical Trials Register?

A. The EU Clinical Trials Register is part of EudraPharm. EudraPharm is the community database of authorised medicinal products. The website provides public access to information extracted from the EU clinical trials database, EudraCT.

The EU Clinical Trials Register contains information on clinical trials with investigator sites in the EEA. Clinical trials where the investigator sites are outside the EEA are only included if they are marketing authorisation holder-sponsored and involve the use in the paediatric population of a medicinal product covered by an EU marketing authorisation (Article 46 of Regulation (EC) No 1901/2006), or if they form part of an agreed PIP (Paediatric Investigation Plan). The register offers users the ability to search for information on any paediatric clinical trial, and any Phase II-IV adult clinical trial recorded in EudraCT.

In addition to the above trials, the register also provides summary information about any paediatric trials that were completed by 26 January 2007 in respect of products covered by an EU marketing authorisation (Article 45 of Regulation (EC) No 1901/2006). These trials are presented in a dedicated tab in the user interface.

Q.2. Why has the EU Clinical Trials Register been launched?

A. The EU Clinical Trials Register website provides the public with information held in the EU clinical trials database, EudraCT. EudraCT is used by national competent authorities to support supervision of clinical trials and was established as a confidential database, in accordance with article 11 of Directive 2001/20/EC. EU pharmaceutical legislation requires the European Medicines Agency (EMA), which maintains the EudraCT database on behalf of EU member states to provide information held in EudraCT to the public. This is described in article 57 of Regulation (EC) No 726/2004 and article 41 of the Paediatric Regulation (EC) No 1901/2006. Together, they established that data on clinical trials conducted in adults and in paediatric populations be made public. The EU Clinical Trials Register website puts these requirements into practice.

Q.3. What information can I find in the EU Clinical Trials Register?

A. The EU Clinical Trials Register website has:

- The description of **any phase II-IV adult clinical trial** where the investigator sites are in the European Union or the European Economic Area.
- The description of **any paediatric clinical trial** with investigator sites **in the European Union**.
- The description of **any paediatric clinical trial** that is **marketing authorisation holder-sponsored** and involves the use in the paediatric population of a medicinal product covered by an **EU marketing authorisation** (**Article 46** of Regulation (EC) No 1901/2006), including those where the investigator sites are **outside the European Union**.

- The description of **any trials which form part of an agreed paediatric investigation plan (PIP)** including those where the investigator sites are **outside the European Union**.
- Summaries of **results** of the clinical trials mentioned above (if results have been posted by the sponsor or marketing authorisation holder).

- Summaries of **results** (with a reduced set of data fields) of **paediatric trials** that were **completed by 26 January 2007** in respect of products covered by an EU marketing authorisation (**Article 45** of Regulation (EC) No 1901/2006) [These trials are presented in a dedicated tab in the user interface.]

  The EU Clinical Trials Register website **does not**:

  - Provide information on **non-interventional clinical trials** of medicines (observational studies on authorised medicines).
  - Provide access to the **authorisation document** from the national medicine regulatory authority or the **opinion document** from the relevant ethics committee.
  - Provide information on clinical trials for **surgical procedures, medical devices or psychotherapeutic procedures**.
  - Manage **the process for joining** any clinical trial published on the website.
  - Provide navigation and web content in languages other than **English.**

    *Information on non-interventional post authorisation safety studies can be found on the electronic ENCePP register of studies which provides a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.

    http://www.encepp.eu/encepp/studiesDatabase.jsp

Q.4. What information is available?

A. Information on the design of each clinical trial, its sponsor(s), the investigational medicinal product(s) and therapeutic area(s) involved and its trial status (authorised, ongoing, complete, etc.) is available. Users can search all available data using the free text search and the advanced search filters..

- Clinical trials in the register are those which have been authorised by the national medicine regulatory authority and have a positive opinion of the ethics committee for clinical trials in the Member State where they have been run. Additionally, clinical trials including the paediatric population that have received a negative ethics committee opinion are also made public.
- Phase 1 clinical trials in adults are not being made public unless they form part of an agreed Paediatric Investigation Plan (PIP). These criteria are those established by the guidelines published by the European Commission.

Q.5. How do I find the EU Clinical Trials Register?

A. The EU Clinical Trials Register is part of EudraPharm and can be accessed from the EudraPharm homepage

The homepage of the EU Clinical Trial Register is: http://www.clinicaltrialsregister.eu

Q.6. Who provides the information?

A. Protocol information on any clinical trial conducted in the EU Member States is provided, in electronic format, to the national medicine regulatory authorities by the trial sponsor as part of the sponsor's application for authorisation to conduct a trial. It is entered into the database by the national competent authority which adds the authorisation, the ethics committee opinion, and later completes the end-of-trial information.

The information on third-country clinical trials is supplied by the third country data providers (i.e. Paediatric-Investigation-Plan (PIP) addressees or Article 46 data providers) who enter the information directly to the system.

Result related information is entered by sponsors, marketing authorisation holders and PIP addressees directly to the system.

Q.7 Data displayed for some clinical trials is incomplete. How will data quality improve?

A. National competent authorities and the Agency are working to develop, where possible, a more complete data set for historical trials (May 2004-March 2011) entered in the EudraCT database. Furthermore, it aims to improve the quality of the new records through enhanced automated checking, quality control and through the increased use of standardised data.

Data quality and historical information:

Information on clinical trials entered into the database between May 2004 and March 2011 is referred to as historical data. It may be incomplete or contain inconsistencies. For instance, the end date of a trial may not have been entered, so the trial may appear to have a trial status of 'Ongoing' when in fact it has been completed. Member states implemented the Directive and started using EudraCT at different times between 2004 and 2006 and the links with the ethics committees needed to be established. The validation rules applying to the data have been upgraded and the EMA is working with national competent authorities to ensure key data on the status of existing trials is complete

Q.8 Where can I get more information about a specific trial?

A. In order to obtain additional information on a particular trial of interest address your request directly to the sponsor of the trial. To contact the sponsor, please refer to the contact point in the clinical trial record. Furthermore, a sponsor contact information list is accessible here and is also provided on the Clinical Trial Sponsors page of the EU Clinical Trials Register website to facilitate communication between stakeholders.

Please note that the sponsor contact information list is not exhaustive The Agency will add new contact information as it is provided by sponsors. Sponsors should send contact information to euctr@ema.europa.eu.

Note that the requirement to provide public contact information was only introduced in March 2011. As a consequence this information is not available for trial records uploaded prior to that date.

If you cannot find the sponsor contact details information in the clinical trial record or the list provided, look for information from your patient or professional association, your healthcare provider, or other sources.

Q.9 What if I want to join a trial?

A. If you believe that there is a trial that could be of interest to you, it is recommended that you discuss this with your healthcare professional, where possible.

To contact the sponsor for further information, please refer to the contact point in the clinical trial record or the Clinical Trials Sponsors page of the EU Clinical Trials Register.

Patients should not interpret the information provided in the register as a recommendation to use the medicine or to participate in the trial. Patients should consult their treating physician or the trial investigator to discuss appropriate treatment options.

Q.10 The clinical trial I am interested in is not listed on the EU Clinical Trials Register website? Why is that?

A. There can be different explanations for this:

- The clinical trial does not have a site in the EEA and it is not part of an agreed PIP (Paediatric Investigation Plan).
- The trial started before the implementation of the Clinical Trial Directive 2001/20/EC in 2004.
- The clinical trial is part of historical data not yet publicly available.
- The trial does not meet the rules for publication, e.g. it is a phase I clinical trial conducted in adults, or it is not a clinical trial of medicines but of a medical device, or other therapeutic procedure.

Q.11 Why do some protocol related data fields read 'Information not present in EudraCT'?

A: Possible reasons for this are:

- Historical records provide less information, due to less stringent requirements for data completion, or absence of some fields in earlier versions of EudraCT.
- The information has not been entered by the sponsor.
- Some fields may not be relevant for some clinical trial designs, or the medicines being tested.

Q.12 What is RSS?

A: RSS stands for Really Simple Syndication. RSS allows you to receive updates to content from websites which provide a web feed (called an 'RSS feed'). To do this you subscribe to the web feed. The web feed is then gathered in your browser's RSS reader for you to view at your convenience. Different browsers support web feeds in different ways; search your browser's help for information on its particular implementation.

The EU Clinical Trials Register provides customised RSS feeds for any search you might make regularly on the website.

For example, if you are interested in clinical trials concerning 'bowel cancer', you can tailor your search within the EU Clinical Trials Register search page and simply subscribe to the RSS feed for your search by clicking the RSS link: Subscribe to this Search

Once subscribed, you will be able to see when your search returns additional results via your RSS reader. (Note that this feature is not available in Internet Explorer 6.)

Q.13 When I select United Kingdom with the status 'Ongoing', why do the search results return clinical trials with the status for United Kingdom 'Completed'?**A:** Such a search returns a list of clinical trials for which the values 'GB' and 'Ongoing' are present. It should be noted that this does not mean that the status 'Ongoing' is necessarily associated with the country 'GB', but rather that it is associated with the clinical trial itself which may have multiple trial statuses across all participating countries.

Q.14 Why is for example the sum of returned trial records of a search for United Kingdom phase II ongoing trials commenced in 2011 and that of United Kingdom phase II completed trials commenced in 2011 not the same as the sum of returned trial records of United Kingdom phase II ongoing and completed trials commenced in 2011?

A: Both trial statuses of 'Completed' and 'Ongoing' may be present for a single clinical trial, because trials frequently take place in multiple countries. For example, a clinical trial taking place in the United Kingdom and France might, at some point in time, have a trial status of 'Completed' in France and 'Ongoing' in the United Kingdom.

Such clinical trials therefore belong to the intersection between the two sets of search results, since they fulfil search criteria (i.e. **UK Phase II ongoing trials commenced in 2011** and **UK Phase II completed trials commenced in 2011**) as the following Venn diagram illustrates:

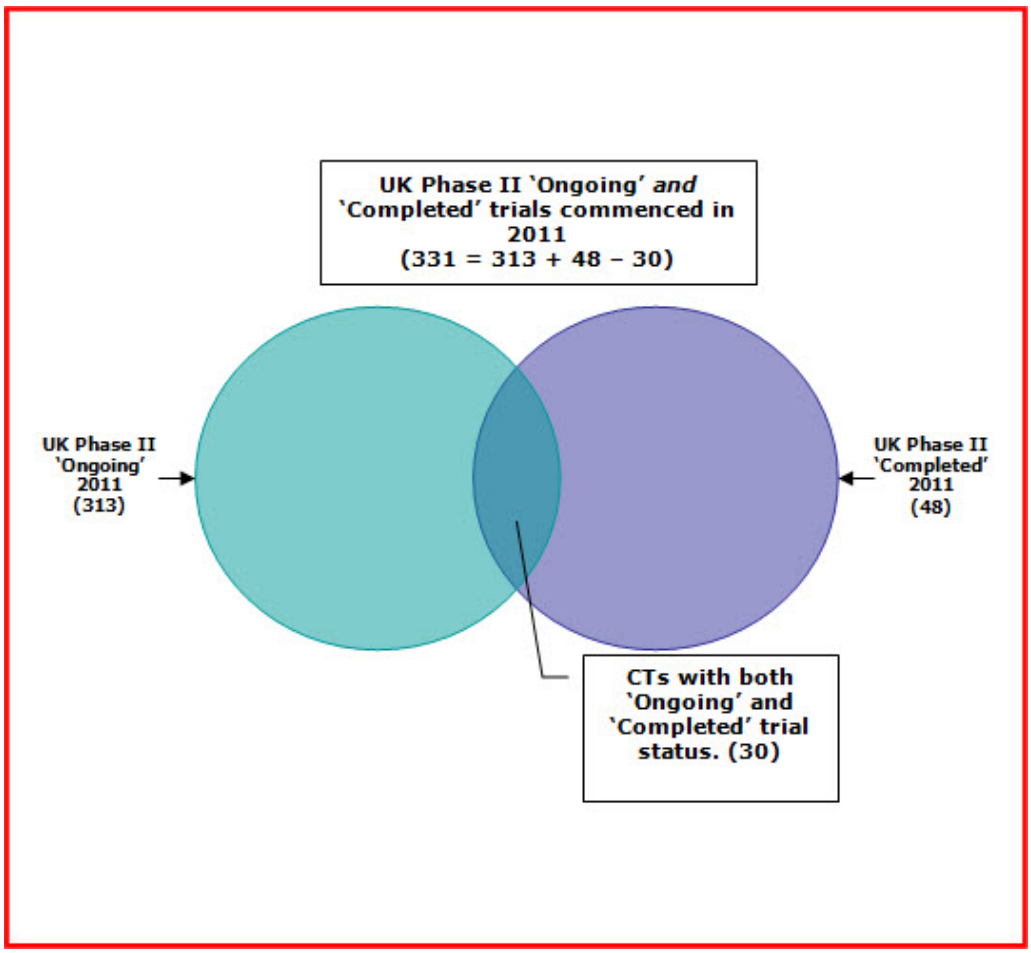

Simply adding up the numbers of set 1 (UK Phase II 'Ongoing' 2011 (313)) and set 2 (UK Phase II 'Completed' 2011 (48)) would result in double counting 30 clinical trials in the intersection, so these must be subtracted to reach an accurate total.

Q.15 What should I do if my question is not answered here?

A: If your question regarding the EU Clinical Trials Register is not answered here, or in the How to Search EU Clinical Trials Register guide, please send your question to euctr@ema.europa.eu.

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

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COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

(OJ L 169, 12.7.1993, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998	L 331	1	7.12.1998
►M2	Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000	L 313	22	13.12.2000
►M3	Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001	L 6	50	10.1.2002
►M4	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
►M5	Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007	L 247	21	21.9.2007

▼B

COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ([1]),

In cooperation with the European Parliament ([2]),

Having regard to the opinion of the Economic and Social Committee ([3]),

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;

Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market;

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

Whereas certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products ([4]); whereas, in such cases, the placing on the market of the medical device as a general rule is governed by the present Directive and the placing on the market of the medicinal product is governed by Directive 65/65/EEC; whereas if, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product shall be governed by Directive 65/65/EEC; whereas a distinction must be drawn between the abovementioned devices and medical devices incorporating, *inter alia*, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC; whereas in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by

([1]) OJ No C 237, 12.9.1991 and OJ No C 251, 28.9.1992, p. 40.
([2]) OJ No C 150, 31.5.1993 and OJ No C 176, 28.6.1993.
([3]) OJ No C 79, 30.3.1992, p. 1.
([4]) OJ No 22, 9.6.1965, p. 369/65. Directive as last amended by Directive 92/27/EEC (OJ No L 113, 30.4.1992, p. 8).

▼B

this Directive; whereas, in this context, the safety, quality and usefulness of the substances must be verified by analogy with the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products ([1]);

Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;

Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization ([2]), rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discretion to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

Whereas Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([3]) is the first case of application of the new approach to the field of medical devices; whereas in the interest of uniform Community rules applicable to all medical devices, this Directive is based largely on the provisions of Directive 90/385/EEC; whereas for the same reasons Directive 90/385/EEC must be amended to insert the general provisions laid down in this Directive;

Whereas the electromagnetic compatibility aspects form an integral part of the safety of medical devices; whereas this Directive should contain specific rules on this subject with regard to Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility ([4]);

Whereas this Directive should include requirements regarding the design and manufacture of devices emitting ionizing radiation; whereas this Directive does not affect the authorization required by Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation ([5]), nor application of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment ([6]); whereas Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([7]) and the specific directives on the same subject should continue to apply;

Whereas, in order to demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices;

([1]) OJ No L 147, 9.6.1975, p. 1. Directive as last amended by Directive 91/507/EEC (OJ No L 270, 26.9.1991, p. 32).
([2]) OJ No C 136, 4.6.1985, p. 1.
([3]) OJ No L 189, 20.7.1990, p. 17.
([4]) OJ No L 139, 23.5.1989, p. 19. Directive as last amended by Directive 92/31/EEC (OJ No L 126, 12.5.1992, p. 11).
([5]) OJ No L 246, 17.9.1980, p. 1. Directive as last amended by Directive 84/467/Euratom (OJ No L 265, 5.10.1984, p. 4).
([6]) OJ No L 265, 5.10.1984, p. 1.
([7]) OJ No L 183, 29.6.1989, p. 1.

▼B

whereas such harmonized European standards are drawn up by private-law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on cooperation between the Commission and these two bodies signed on 13 November 1984;

Whereas, for the purpose of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted, on a mandate from the Commission, by either or both of these bodies in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations ([1]), and pursuant to the abovementioned general guidelines; whereas with regard to possible amendment of the harmonized standards, the Commission should be assisted by the Committee set up pursuant to Directive 83/189/EEC; whereas the measures to be taken must be defined in line with procedure I, as laid down in Council Decision 87/373/EEC ([2]); whereas, for specific fields, what already exists in the form of European *Pharmacopoeia* monographs should be incorporated within the framework of this Directive; whereas, therefore, several European *Pharmacopoeia* monographs may be considered equal to the abovementioned harmonized standards;

Whereas, in Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives ([3]), the Council has laid down harmonized conformity assessment procedures; whereas the application of these modules to medical devices enables the responsibility of manufacturers and notified bodies to be determined during conformity assessment procedures on the basis of the type of devices concerned; whereas the details added to these modules are justified by the nature of the verification required for medical devices;

Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes; whereas the classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices; whereas the conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; whereas, for Class IIa devices, the intervention of a notified body should be compulsory at the production stage; whereas, for devices falling within Classes IIb and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market;

Whereas in cases where the conformity of the devices can be assessed under the responsibility of the manufacturer the competent authorities must be able, particularly in emergencies, to contact a person responsible for placing the device on the market and established in the Community, whether the manufacturer or another person established in the Community and designated by the manufacturer for the purpose;

Whereas medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of this Directive to enable

([1]) OJ No L 109, 26.4.1983, p. 8. Directive as last amended by Commission Decision 92/400/EEC (OJ No L 221, 6.8.1992, p. 55).
([2]) OJ No L 197, 18.7.1987, p. 33.
([3]) OJ No L 147, 9.6.1975, p. 1. Directive as last amended by Directive 91/507/EEC (OJ No L 270, 26.9.1991, p. 32).

▼B

them to move freely within the Community and to be put into service in accordance with their intended purpose;

Whereas, in the fight against AIDS and in the light of the conclusions of the Council adopted on 16 May 1989 regarding future activities on AIDS prevention and control at Community level ([1]), medical devices used for protection against the HIV virus must afford a high level of protection; whereas the design and manufacture of such products should be verified by a notified body;

Whereas the classification rules generally enable medical devices to be appropriately classified; whereas, in view of the diverse nature of the devices and technological progress in this field, steps must be taken to include amongst the implementing powers conferred on the Commission the decisions to be taken with regard to the proper classification or reclassification of the devices or, where appropriate, the adjustment of the classification rules themselves; whereas since these issues are closely connected with the protection of health, it is appropriate that these decisions should come under procedure IIIa, as provided for in Directive 87/373/EEC;

Whereas the confirmation of complicance with the essential requirements may mean that clinical investigations have to be carried out under the responsibility of the manufacturer; whereas, for the purpose of carrying out the clinical investigations, appropriate means have to be specified for the protection of public health and public order;

Whereas the protection of health and the associated controls may be made more effective by means of medical device vigilance systems which are integrated at Community level;

Whereas this Directive covers the medical devices referred to in Council Directive 76/764/EEC of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers ([2]); whereas the abovementioned Directive must therefore be repealed; whereas for the same reasons Council Directive 84/539/EEC on 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine ([3]) must be amended,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions, scope

1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) ►M5 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: ◄

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

([1]) OJ No C 185, 22.7.1989, p. 8.
([2]) OJ No L 262, 27.9.1976, p. 139. Directive as last amended by Directive 84/414/EEC (OJ No L 228, 25.8.1984, p. 25).
([3]) OJ No L 300, 19.11.1984, p. 179. Directive as amended by the Act of Accession of Spain and Portugal.

▼B

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

▼M1

(c) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations,

derived from the human body, solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or

— concerning a congenital abnormality, or

— to determine the safety and compatibility with potential recipients, or

— to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

▼B

(d) 'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user ►M5 shall not be ◄ considered to be custom-made devices;

(e) 'device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of Annex X in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

▼B

(f) ‘manufacturer’ means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

(g) ‘intended purpose’ means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

(h) ‘placing on the market’ means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

▼M1

(i) ‘putting into service’ means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;

(j) ‘authorised representative’ means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;

▼M5

(k) ‘clinical data’ means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

— clinical investigation(s) of the device concerned; or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or

— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

(l) ‘device subcategory’ means a set of devices having common areas of intended use or common technology;

(m) ‘generic device group’ means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(n) ‘single use device’ means a device intended to be used once only for a single patient.

3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC [1], that

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).

▼M5

device shall be governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to this Directive shall apply as far as safety and performance-related device features are concerned.

▼B

4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive ►M5 2001/83/EC ◄ and which is liable to act upon the body with action ancillary to that of the device, ►M5 that device shall ◄ be assessed and authorized in accordance with this Directive.

▼M2

4 a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive ►M5 2001/83/EC ◄ and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a 'human blood derivative', ►M5 that device shall ◄ be assessed and authorised in accordance with this Directive.

▼B

5. ►M5 This Directive shall not apply to: ◄

(a) *in vitro* diagnostic devices;

(b) active implantable devices covered by Directive 90/385/EEC;

▼M5

(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product;

▼B

(d) cosmetic products covered by Directive 76/768/EEC ([1]);

▼M3

(e) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in paragraph 4a;

▼M5

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4a;

▼B

(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

([1]) OJ No L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 92/86/EEC (OJ No L 325, 11.11.1992, p. 18).

▼M5

6. Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC [1] and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.

7. This Directive is a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC of the European Parliament and of the Council [2].

8. This Directive shall not affect the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation [3], nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure [4].

▼M1

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.

▼B

Article 3

Essential requirements

The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

▼M5

Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery [5] shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.

▼B

Article 4

Free movement, devices intended for special purposes

1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate

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(1) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(2) Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 390, 31.12.2004, p. 24).

(3) OJ L 159, 29.6.1996, p. 1.

(4) OJ L 180, 9.7.1997, p. 22.

(5) OJ L 157, 9.6.2006, p. 24.

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that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.

2. Member States shall not create any obstacle to:

— devices intended for clinical investigation being made available to medical practitioners or authorized persons for that purpose if they meet the conditions laid down in Article 15 and in Annex VIII,

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— custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII, which shall be available to the particular patient identified by name, an acronym or a numerical code.

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These devices shall not bear the CE marking.

3. At trade fairs, exhibitions, demonstrations, etc. Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.

4. Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another Community language, when a device reaches the final user, regardless of whether it is for professional or other use.

5. Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices also fulfil the provisions of the other Directives.

However, should one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the devices fulfil the provisions only of those directives applied by the manufacturer. In this case, the particulars of these directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the directives and accompanying such devices.

Article 5

Reference to standards

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the *Official Journal of the European Communities*; Member States shall publish the references of such national standards.

2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European *Pharmacopoeia* notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the *Official Journal of the European Communities*.

3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in

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paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2).

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Article 6

Committee on Standards and Technical Regulations

1. The Commission shall be assisted by the Committee set up by Article 5 of Directive ►M5 98/34/EC [1] ◄, hereinafter referred to as 'the Committee'.

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC [2] shall apply, having regard to the provisions of Article 8 thereof.

3. The Committee shall adopt its rules of procedure.

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Article 7

1. The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC, hereinafter referred to as 'the Committee'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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Article 8

Safeguard clause

1. Where a Member State ascertains that the devices referred to in Article 4 (1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3;

(b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;

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[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.

[2] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

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(c) shortcomings in the standards themselves.

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2. The Commission shall enter into consultation with the Parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

(a) the measures are justified:

(i) it shall immediately so inform the Member State which took the measures and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the Parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the advisory procedure referred to in Article 6(2);

(ii) when necessary in the interests of public health, appropriate measures designed to amend non-essential elements of this Directive relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4);

(b) the measures are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorised representative.

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3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 9

Classification

1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.

2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject.

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3. Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it may submit a duly substantiated request to the Commission and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Directive relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

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Article 10

Information on incidents occuring following placing of devices on the market

1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally:

(a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative ►M5 ———— ◄, is also informed of the incident.

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3. After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents.

4. Any appropriate measures to adopt procedures to implement this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).

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Article 11

Conformity assessment procedures

1. In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV;

or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).

2. In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:

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(a) the procedure relating to the EC verification set out in Annex IV;

or

(b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance);

or

(c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Instead of applying these procedures, the manufacturer may also follow the procedure referred to in paragraph 3 (a).

3. In the case of devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable; or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV;

or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance);

or

(iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

4. The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10 (1), Article 15 (1), in particular in respect of Class I and Class IIa devices, and on the operation of the provisions referred to in Annex II, Section 4.3 second and third subparagraphs and in Annex III, Section 5 second and third subparagraphs to this Directive, accompanied, if necessary, by appropriate proposals.

5. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.

6. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.

Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.

7. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

8. The manufacturer may instruct his authorized representative ►M5 ———— ◄ to initiate the procedures provided for in Annexes III, IV, VII and VIII.

9. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized repre-

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sentative ►M5 ——————— ◄, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

10. The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

11. Decisions taken by the notified bodies in accordance with ►M5 Annexes II, III, V and VI ◄ shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, ►M5 for further periods of a maximum length of five years ◄.

12. The records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.

13. By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health.

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14. The measures designed to amend non-essential elements of this Directive, by supplementing it, relating to the means by which, in the light of technical progress and considering the intended users of the devices concerned, the information laid down in Annex I Section 13.1 may be set out, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

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Article 12

►M5 Particular procedure for systems and procedure packs and procedure for sterilisation ◄

1. By way of derogation from Article 11 this Article shall apply to systems and procedure packs.

2. Any natural or legal person who puts devices bearing the CE marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

(a) he has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and

(b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and

(c) the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure pursuant to Article 11.

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3. Any natural or legal person who sterilises, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other CE-marked medical devices designed by their

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manufacturers to be sterilised before use, shall, at his choice, follow one of the procedures referred to in Annex II or V. The application of the abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions.

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4. The products referred to in paragraphs 2 and 3 themselves shall not bear an additional CE marking. They shall be accompanied by the information referred to in point 13 of Annex I which includes, where appropriate, the information supplied by the manufacturers of the devices which have been put together. ►M5 The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the competent authorities for a period of five years. ◄

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Article 12a

Reprocessing of medical devices

The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community.

In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection.

Article 13

Decisions with regard to classification and derogation clause

1. A Member State shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations:

(a) that Member State considers that the application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices;

(b) that Member State considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX, be classified in another class;

(c) that Member State considers that the conformity of a device or family of devices should, by way of derogation from Article 11, be established by applying solely one of the given procedures chosen from among those referred to in Article 11;

(d) that Member State considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1(2)(a) to (e).

The measures referred to in the first subparagraph of this paragraph shall, as appropriate, be adopted in accordance with the procedure referred to in Article 7(2).

2. The Commission shall inform the Member States of the measures taken.

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Article 14

Registration of persons responsible for placing devices on the market

1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 11 (5) and (6) and any other natural or legal person engaged in the activities referred to in Article 12 shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned.

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For all medical devices of ►M5 classes IIa, IIb and III ◄, Member States may request to be informed of all data allowing for identification of such devices together with the label and the instructions for use when such devices are put into service within their territory.

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2. Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union. For devices referred to in the first subparagraph of paragraph 1, the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of the details referred to in paragraph 1.

3. The Member States shall on request inform the other Member States and the Commission of the details referred to in the first subparagraph of paragraph 1 given by the manufacturer or authorised representative.

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Article 14a

European databank

1. Regulatory data in accordance with this Directive shall be stored in a European database accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis.

The databank shall contain the following:

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(a) data relating to registration of manufacturers and authorised representatives and devices in accordance with Article 14 excluding data related to custom-made devices;

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(b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes II to VII;

(c) data obtained in accordance with the vigilance procedure as defined in Article 10;

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(d) data relating to clinical investigations referred to in Article 15.

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2. Data shall be forwarded in a standardised format.

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3. The measures necessary for the implementation of paragraphs 1 and 2 of this Article, in particular paragraph 1(d), shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).

4. The provisions of this Article shall be implemented no later than 5 September 2012. The Commission shall, no later than 11 October 2012, evaluate the operational functioning and the added value of the

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databank. On the basis of this evaluation, the Commission shall, if appropriate, present proposals to the European Parliament and the Council or present draft measures in accordance with paragraph 3.

Article 14b

Particular health monitoring measures

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures.

The Member State shall then inform the Commission and all other Member States, giving the reasons for its decision.

The Commission shall, whenever possible, consult the interested Parties and the Member States.

The Commission shall adopt its opinion, indicating whether the national measures are justified or not. The Commission shall inform all the Member States and the consulted interested Parties thereof.

When appropriate, the necessary measures designed to amend non-essential elements of this Directive, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4).

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Article 15

Clinical investigation

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1. In the case of devices intended for clinical investigations, the manufacturer or the authorised representative, established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted by means of the statement mentioned in Section 2.2 of Annex VIII.

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy.

Member States may however authorise manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question, including its review of the clinical investigation plan.

3. In the case of devices other than those referred to in paragraph 2, Member States may authorise manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has issued a favourable opinion on the programme of investigation in question including its review of the clinical investigation plan.

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4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3, may be made subject to authorization from the competent authority.

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5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The measures designed to amend non-essential elements of this Directive, inter alia by supplementing it, relating to the provisions on clinical investigation in Annex X shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken.

7. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in Section 2.3.7 of Annex X at the disposal of the competent authorities.

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8. The provisions of paragraphs 1 and 2 do not apply where the clinical investigations are conducted using devices which are authorized in accordance with Article 11 to bear the CE marking unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Annex X remain applicable.

Article 16

Notified bodies

1. The Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 11 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as ‘notified bodies’.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the *Official Journal of the European Communities*. It shall ensure that the list is kept up to date.

2. Member States shall apply the criteria set out in Annex XI for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria.

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When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).

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3. A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria

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referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof.

4. The notified body and the manufacturer, or his authorized representative ►M5 ———— ◄, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes II to VI.

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5. The notified body shall inform its competent authority about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Directive about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.

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6. Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State shall inform the other Member States and the Commission.

7. The notified body shall, on request, supply all relevant information and documents including budgetary documents, required to enable the Member State to verify compliance with Annex XI requirements.

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Article 17

CE marking

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.

2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging.

It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.

Article 18

Wrongly affixed CE marking

Without prejudice to Article 8:

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(a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the Directive, the manufacturer or his authorised representative shall be obliged to end the infringement under conditions imposed by the Member State;

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(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

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Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.

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Article 19

Decision in respect of refusal or restriction

1. Any decision taken pursuant to this Directive:

(a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

or

(b) to withdraw devices from the market,

shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative ►M5 ——————— ◄, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.

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Article 20

Confidentiality

1. Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the Parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:

(a) information on the registration of persons responsible for placing devices on the market in accordance with Article 14;

(b) information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure according to Article 10(3);

(c) information contained in certificates issued, modified, supplemented, suspended or withdrawn.

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3. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to determination of the conditions under which other information may be made publicly available, and in particular for Class IIb and Class III devices to any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

Article 20a

Cooperation

Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

Without prejudice to the provisions of this Directive, cooperation may be part of initiatives developed at an international level.

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Article 21

Repeal and amendment of Directives

1. Directive 76/764/EEC is hereby repealed with effect from 1 January 1995.

2. In the title and Article 1 of Directive 84/539/EEC, 'human or' is deleted.

In Article 2 of Directive 84/539/EEC, the following subparagraph is added to paragraph 1:

'If the appliance is at the same time a medical device within the meaning of Directive 93/42/EEC (*) and if it satisfies the essential requirements laid down therein for that device, the device shall be deemed to be in conformity with the requirements of this Directive.

(*) OJ No L 169, 12.7.1993, p. 1.'

3. Directive 90/385/EEC is hereby amended as follows:

1. in Article 1 (2) the following two subparagraphs are added:

'(h) "placing on the market" means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) "manufacturer" means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph

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does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;'

2. in Article 9 the following paragraphs are added:

'5. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

6. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

7. The notified body may require, where duly justified, any information or data which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

8. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years.

9. By derogation from paragraphs 1 and 2 the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 and 2 have not been carried out and the use of which is in the interest of protection of health.';

3. the following Article 9a is inserted after Article 9:

'Article 9a

1. Where a Member State considers that the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 9, by applying solely one of the given procedures chosen from among those referred to in Article 9, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7 (2) of Directive 93/42/EEC (*).

2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the *Official Journal of the European Communities*.

(*) OJ No L 169, 12.7.1993, p. 1.'

4. Article 10 shall be amended as follows:

— the following subparagraph shall be added to paragraph 2:

'Member States may however authorize manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the Ethical Committee concerned has delivered a favourable opinion with respect to the investigation programme in question.',

— the following paragraph shall be inserted:

'2a. The authorization referred to in the second subparagraph of paragraph 2 may be subject to approval by the competent authority.';

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5. the following is added to Article 14:

‘In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measures to be taken.’

Article 22

Implementation, transitional provisions

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1994. They shall immediately inform the Commission thereof.

The Standing Committee referred to in Article 7 may assume its tasks from the date of notification [1] of this Directive. The Member States may take the measures referred to in Article 16 on notification of this Directive.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Member States shall apply these provisions with effect from 1 January 1995.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 11 (1) to (5) for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

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4. Member States shall accept:

— devices which conform to the rules in force in their territory on 31 December 1994 being placed on the market during a period of five years following the adoption of this Directive, and

— the aforementioned devices being put into service until 30 June 2001 at the latest.

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In the case of devices which have been subjected to EEC pattern approval in accordance with Directive 76/764/EEC, Member States shall accept their being placed on the market and put into service during the period up to 30 June 2004.

Article 23

This Directive is addressed to the Member States.

[1] This Directive was notified to the Member States on 29 June 1993.

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ANNEX I

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

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1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

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2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

— eliminate or reduce risks as far as possible (inherently safe design and construction),

— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

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6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

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II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

7. **Chemical, physical and biological properties**

7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the ‘General requirements’. Particular attention must be paid to:

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— the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,

— the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,

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— where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

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7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.

7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

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7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 [1] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.

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order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]).

If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

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7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

8. **Infection and microbial contamination**

8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Notified bodies shall retain information on the geographical origin of the animals.

Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other ►M5 transmissible ◄ agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

([1]) OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

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8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.

8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.

8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

9. **Construction and environmental properties**

9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

— the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,

— risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,

— the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,

— risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

10. **Devices with a measuring function**

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC ([1]).

11. **Protection against radiation**

11.1. *General*

11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

([1]) OJ No L 39, 15.2.1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7.12.1989, p. 28).

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11.2. *Intended radiation*

11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3. *Unintended radiation*

11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

11.4. *Instructions*

11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5. *Ionizing radiation*

11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.

11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.

12. **Requirements for medical devices connected to or equipped with an energy source**

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

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12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

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12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.

12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.

12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

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12.6. *Protection against electrical risks*

Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.

12.7. *Protection against mechanical and thermal risks*

12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.

12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.

12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.

12.8. *Protection against the risks posed to the patient by energy supplies or substances*

12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

12.9. *The function of the controls and indicators must be clearly specified on the devices.*

Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13. **Information supplied by the manufacturer**

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13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

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This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.

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13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

13.3. *The label* must bear the following particulars:

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(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;

(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;

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(c) where appropriate, the word ‘STERILE’;

(d) where appropriate, the batch code, preceded by the word ‘LOT’, or the serial number;

(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

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(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;

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(g) if the device is costum-made, the words ‘custom-made device’;

(h) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;

(i) any special storage and/or handling conditions;

(j) any special operating instructions;

(k) any warnings and/or precautions to take;

(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;

(m) where applicable, method of sterilization;

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(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.

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13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

13.6. Where appropriate, the instructions for use must contain the following particulars:

(a) the details referred to in Section 13.3, with the exception of (d) and (e);

(b) the performances referred to in Section 3 and any undesirable side-effects;

(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

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(d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

(e) where appropriate, information to avoid certain risks in connection with implantation of the device;

(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.

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If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;

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(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

(k) precautions to be taken in the event of changes in the performance of the device;

(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

(m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

(n) precautions to be taken against any special, unusual risks related to the disposal of the device;

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(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;

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(p) degree of accuracy claimed for devices with a measuring function;

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(q) date of issue or the latest revision of the instructions for use.

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ANNEX II

EC DECLARATION OF CONFORMITY

(Full quality assurance system)

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 4 and to Community surveillance as specified in Section 5.

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2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

   The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.

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3. **Quality system**

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

— the name and address of the manufacturer and any additional manufacturing site covered by the quality system,

— all the relevant information on the product or product category covered by the procedure,

— a written declaration that no application has been lodged with any other notified body for the same product-related quality system,

— the documentation on the quality system,

— an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,

— an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,

— ►M5 an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: ◄

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

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It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).

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It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,

— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,

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— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

— a general description of the product, including any variants planned, and its intended use(s),

— the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,

— the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,

— if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC ([1]),

— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Annex X,

— the draft label and, where appropriate, instructions for use.

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(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

([1]) Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (OJ L 105, 26.4.2003, p. 18).

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(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

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The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

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The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. **Examination of the design of the product**

4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in Section 3.1.

4.2. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this Directive, as referred to in Section 3.2 (c).

4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of this Directive, issue the application with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the product.

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In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

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4.4. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. The applicant shall inform the notified body which issued the EC design-examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the EC design-examination certificate.

5. **Surveillance**

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2. The manufacturer must authorize the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

— the documentation on the quality system,

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— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted as referred to in Annex I, Chapter I, Section 2, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc.,

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— the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. **Administrative provisions**

6.1. ►M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the national authorities: ◄

— the declaration of conformity,

— the documentation referred to in the fourth indent of Section 3.1 ►M5 and in particular the documentation, data and records referred to in the second paragraph of Section 3.2 ◄,

— the changes referred to in Section 3.4,

— the documentation referred to in Section 4.2, and

— the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.

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7. **Application to devices in Classes IIa and IIb.**

7.1. In line with Article 11(2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply.

7.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

7.3. For devices in Class IIb the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in

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Section 3.2(c) for at least one representative sample for each generic device group for compliance with the provisions of this Directive.

7.4. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

7.5. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 5.

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8. **Application to the devices referred to Article 1(4a)**

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with ►M5 Article 114(2) of Directive 2001/83/EC ◄.

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ANNEX III

EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Directive.

2. The application includes:

— the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative,

— the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Directive. The applicant must make a 'type' available to the notified body. The notified body may request other samples as necessary,

— a written declaration that no application has been lodged with any other notified body for the same type.

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3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

— a general description of the type, including any variants planned, and its intended use(s),

— design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,

— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,

— the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,

— a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in Section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,

— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Annex X,

— the draft label and, where appropriate, instructions for use.

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4. The notified body must:

4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it

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conforms to the essential requirements when connected to any such device (s) having the characteristics specified by the manufacturer;

4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. agree with the applicant on the place where the necessary inspections and tests will be caried out.

5. If the type conforms to the provisions of this Directive, the notified body issues the applicant with an EC type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body.

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In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

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6. The applicant must inform the notified body which issued the EC type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval must, where appropriate, take the form of a supplement to the initial EC type-examination certificate.

7. **Administrative provisions**

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7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed.

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7.3. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured.

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ANNEX IV

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his authorized representative ►M5 ——————— ◄ ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.

2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 17 and draw up a declaration of conformity.

   In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, Sections 3 and 4.

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3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

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   (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

   (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

   The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. **Verification by examination and testing of every product**

5.1. Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out in order to verify, where appropriate, the conformity of the products with the EC type described in the type-examination certificate and with the requirements of the Directive which apply to them.

5.2. The notified body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. **Statistical verification**

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

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6.2. A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.

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6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.

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6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

7. **Administrative provisions**

►M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: ◄

— the declaration of conformity,

— the documentation referred to in Section 2,

— the certificates referred to in Sections 5.2 and 6.4,

— where appropriate, the type-examination certificate referred to in Annex III.

8. **Application to devices in Class IIa**

In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following ►M5 ———————— ◄:

8.1. in derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them;

8.2. in derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class IIa with the technical documentation referred to in Section 3 of Annex VII.

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9. **Application to devices referred to in Article 1(4a)**

In the case of section 5, upon completing the manufacture of each batch of devices referred to in Article 1(4a), and in the case of verification under section 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with ►M5 Article 114(2) of Directive 2001/83/EC ◄.

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ANNEX V

EC DECLARATION OF CONFORMITY

(Production quality assurance)

1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and is subject to the Community surveillance referred to in Section 4.

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2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.

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3. **Quality system**

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

— the name and address of the manufacturer,

— all the relevant information on the product or product category covered by the procedure,

— a written declaration that no application has been lodged with any other notified body for the same products,

— the documentation on the quality system,

— an undertaking to fulfil the obligations imposed by the quality system is approved,

— an undertaking to maintain the practicability and effectiveness of the approved quality system,

— where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,

— ►M5 an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: ◄

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the

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quality policy and procedures such as quality programmes, plans, manuals and records.

It must include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,

— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform,

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— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

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(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision must be notified to the manufacturer after the final inspection and contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2.

After the abovementioned information has been received the decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

4. **Surveillance**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer authorizes the notified body to carry out all the necessary inspections and must supply it with all relevant information, in particular:

— the documentation on the quality system,

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— the technical documentation,

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— the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. **Administrative provisions**

5.1. ►M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: ◄

— the declaration of conformity,

— the documentation referred to in the fourth indent of Section 3.1,

— the changes referred to in Section 3.4,

— the documentation referred to in the seventh indent of Section 3.1,

— the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4,

— where appropriate, the type-examination certificate referred to in Annex III.

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6. **Application to devices in Class IIa**

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.

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7. **Application to devices referred to in Article 1(4a)**

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with ►M5 Article 114(2) of Directive 2001/83/EC ◄.

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ANNEX VI

EC DECLARATION OF CONFORMITY

(Product quality assurance)

1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in Section 3 and must be subject to the surveillance referred to in Section 4.

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, Sections 3 and 4.

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2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer affixes the CE marking in accordance with Article 17 and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.

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3. **Quality system**

3.1. The manufacturer lodges an application for assessment of his quality system with a notified body.

The application must include:

— the name and address of the manufacturer,

— all the relevant information on the product or product category covered by the procedure,

— a written declaration specifying that no application has been lodged with any other notified body for the same products,

— the documentation on the quality system,

— an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,

— an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,

— where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,

— ►M5 an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: ◄

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (i) leading to a systematic recall of devices of the same type by the manufacturer.

3.2. Under the quality system, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standard

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(s) referred to in Article 5 or equivalent tests are carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the provisions of this Directive which apply to them. All the elements, requirements and provisionsadopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.

It must include in particular an adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality,

— the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the test equipment adequately,

— the methods of monitoring the efficient operation of the quality system,

— the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.,

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— where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.

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The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

3.3. The notified body audits the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2.

After receiving the abovementioned information it must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. **Surveillance**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage locations and supply it with all relevant information, in particular:

— the documentation on the quality system,

— the technical documentation,

— the quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and must supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary,

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carry out or ask for tests in order to check that the quality system is working properly and that the production conforms to the requirements of the Directive which apply to it. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out. Where one or more of the samples fails to conform, the notified body must take the appropriate measures.

It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. **Administrative provisions**

5.1. ►M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: ◄

— the declaration of conformity,

— the documentation referred to in the seventh indent of Section 3.1,

— the changes referred to in Section 3.4,

— the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4,

— where appropriate, the certificate of conformity referred to in Annex III.

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6. **Application to devices in Class IIa**

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.

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ANNEX VII

EC DECLARATION OF CONFORMITY

▼M5

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured.

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3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:

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— a general description of the product, including any variants planned and its intended use(s),

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— design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operations of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full,

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— in the case of products placed on the market in a sterile condition, description of the methods used and the validation report,

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— the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,

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— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation in accordance with Annex X,

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— the label and instructions for use.

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4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:

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(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

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(ii) any technical or medical reason connected with the characteristics on the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

5. With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in ►M5 Annex II, IV, V or VI ◄. Application of the abovementioned Annexes and the intervention by the notified body is limited to:

— in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,

— in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Section 6.1. of this Annex is applicable.

6. **Application to devices in Class IIa**

In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following derogation:

6.1. where this Annex is applied in conjunction with the procedure referred to in Annex IV, V or VI, the declaration of conformity referred to in the abovementioned Annexes forms a single declaration. As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the provisions of this Directive which apply to it.

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ANNEX VIII

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative ►M5 ——————— ◄ must draw up the statement containing the information stipulated in Section 2.

2. The statement must contain the following information:

2.1. for custom-made devices:

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— the name and address of the manufacturer,

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— data allowing identification of the device in question,

— a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,

— the name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned,

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— the specific characteristics of the product as indicated by the prescription,

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— a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds;

2.2. for devices intended for the clinical investigations covered by Annex X:

— data allowing identification of the device in question,

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— the clinical investigation plan,

— the investigator's brochure,

— the confirmation of insurance of subjects,

— the documents used to obtain informed consent,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,

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— the opinion of the ethics committee concerned and details of the aspects covered by its opinion,

— the name of the medical practitioner or other authorized person and of the institution responsible for the investigations,

— the place, starting date and scheduled duration for the investigations,

— a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer must also undertake to keep available for the competent national authorities:

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3.1. For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive.

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The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;

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3.2. For devices intended for clinical investigations, the documentation must contain:

— a general description of the product and its intended use,

— design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operation of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied,

— if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— if the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the risk management measures in this connection which have been applied to reduce the risk of infection,

— the results of the design calculations, and of the inspections and technical tests carried out, etc.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in the first paragraph of this Section.

The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures.

4. The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years.

5. For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

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ANNEX IX

CLASSIFICATION CRITERIA

I. DEFINITIONS

1. **Definitions for the classification rules**

1.1. *Duration*

Transient

Normally intended for continuous use for less than 60 minutes.

Short term

Normally intended for continuous use for not more than 30 days.

Long term

Normally intended for continuous use for more than 30 days.

1.2. *Invasive devices*

Invasive device

A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device

An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device

Any device which is intended:

— to be totally introduced into the human body or,

— to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

1.3. *Reusable surgical instrument*

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. *Active medical device*

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. ►**M5** Stand alone software is considered to be an active medical device. ◄

1.5. *Active therapeutical device*

Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

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1.6. *Active device for diagnosis*

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

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1.7. *Central circulatory system*

For the purposes of this Directive, 'central circulatory system' means the following vessels:

arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

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1.8. *Central nervous system*

For the purposes of this Directive, 'central nervous system' means brain, meninges and spinal cord.

II. IMPLEMENTING RULES

2. **Implementing rules**

2.1. Application of the classification rules shall be governed by the intended purpose of the devices.

2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

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2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means 'an uninterrupted actual use of the device for the intended purpose'. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.

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III. CLASSIFICATION

1. **Non-invasive devices**

1.1. *Rule 1*

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

1.2. *Rule 2*

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

— if they may be connected to an active medical device in Class IIa or a higher class,

— if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues,

in all other cases they are in Class I.

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1.3. *Rule 3*

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

1.4. *Rule 4*

All non-invasive devices which come into contact with injured skin:

— are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

— are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,

— are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

2. **Invasive devices**

2.1. *Rule 5*

►M5 All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: ◄

— are in Class I if they are intended for transient use,

— are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,

— are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

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2.2. *Rule 6*

All surgically invasive devices intended for transient use are in Class IIa unless they are:

— intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— reusable surgical instruments, in which case they are in Class I,

— intended specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— intended to supply energy in the form of ionising radiation in which case they are in Class IIb,

— intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,

— intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.

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2.3. *Rule 7*

All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:

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— either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

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— or specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— or to supply energy in the form of ionizing radiation in which case they are in Class IIb,

— or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.

2.4. *Rule 8*

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

— to be placed in the teeth, in which case they are in Class IIa,

— to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,

— to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

3. **Additional rules applicable to active devices**

3.1. *Rule 9*

All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

3.2. *Rule 10*

Active devices intended for diagnosis are in Class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,

— if they are intended to image *in vivo* distribution of radiopharmaceuticals,

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

Rule 11

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

— that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

3.3. *Rule 12*

All other active devices are in Class I.

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4. **Special Rules**

4.1. *Rule 13*

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive ►M5 2001/83/EC ◄, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

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All devices incorporating, as an integral part, a human blood derivative are in Class III.

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4.2. *Rule 14*

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.

4.3. *Rule 15*

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb.

All devices intended specifically to be used for disinfecting medical devices are in Class IIa. ►M5 Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb. ◄

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

4.4. *Rule 16*

►M5 Devices ◄ specifically intended for recording of X-ray diagnostic images are in Class IIa.

4.5. *Rule 17*

All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.

5. **Rule 18**

By derogation from other rules, blood bags are in Class IIb.

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ANNEX X

CLINICAL EVALUATION

1. **General provisions**

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1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as 'clinical evaluation', where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:

— there is demonstration of equivalence of the device to the device to which the data relates, and

— the data adequately demonstrate compliance with the relevant essential requirements.

1.1.2. Or a critical evaluation of the results of all clinical investigations made.

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.

1.1a In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.1c The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

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1.2. All the data must remain confidential, in accordance with the provisions of Article 20.

2. **Clinical investigations**

2.1. *Objectives*

The objectives of clinical investigation are:

— to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and

— to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

2.2. *Ethical considerations*

►M5 Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly. ◄ It is mandatory that all measures relating to the protection

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of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

2.3. *Methods*

2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.

2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.

2.3.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined.

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2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed.

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2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment.

The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device.

2.3.7. The written report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.

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ANNEX XI

CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.

   Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Directive and, in particular, of this Annex. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Directive.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes II to VI and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. ►**M1** This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I. ◄ It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

   — sound vocational training covering all the assessment and verification operations for which the body has been designated,

   — satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,

   — the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the notified body must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except *vis-à-vis* the competent administrative authorities of the State in which their activities are carried out) pursuant to this Directive or any provision of national law putting it into effect.

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ANNEX XII

CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials ‘CE’ taking the following form:

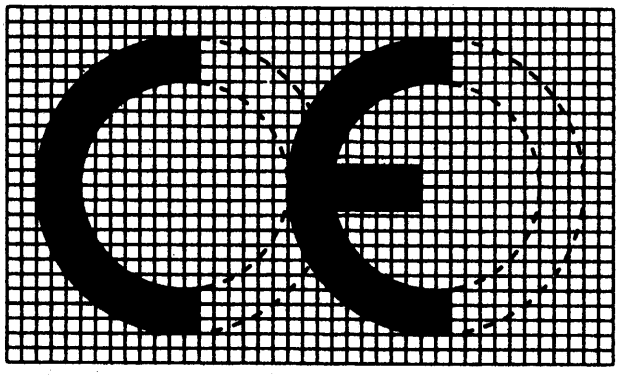

— If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale devices.

DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 September 2007

amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) Council Directive 93/42/EEC ([3]) requires the Commission to submit a report to the Council, no later than five years from the date of implementation of that Directive, concerning: (i) information on incidents occurring following the placing of devices on the market, (ii) clinical investigation carried out in accordance with the procedure set out in Annex VIII to Directive 93/42/EEC, and (iii) design examination and EC type examination of medical devices that incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([4]) and which is liable to act upon the body with action ancillary to that of the device.

(2) The Commission brought forward the conclusions of that report in its Communication to the Council and the European Parliament on medical devices which, at the request of the Member States, was expanded to cover all aspects of the Community regulatory framework for medical devices.

(3) This Communication was welcomed by the Council in its Conclusions on medical devices of 2 December 2003 ([5]). It was also discussed by the European Parliament which on 3 June 2003 adopted a resolution on the health implications of Directive 93/42/EEC ([6]).

(4) Following from the conclusions drawn in that Communication it is necessary and appropriate to amend Council Directive 90/385/EEC ([7]), Directive 93/42/EEC and Directive 98/8/EC of the European Parliament and of the Council ([8]).

(5) To ensure consistency of interpretation and implementation between Directives 93/42/EEC and 90/385/EEC the legal framework related to issues such as authorised representative, the European databank, health protection measures, and the application of Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma, as introduced by Directive 2000/70/EC ([9]), should be extended to Directive 90/385/EEC. The application of the provisions on medical devices incorporating stable derivates of human blood or human plasma includes application of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC ([10]).

(6) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.

(7) Particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients' safety or health. It is therefore necessary to provide clarification on the definition of the term 'single use', as well as to make provision for uniform labelling and

([1]) OJ C 195, 18.8.2006, p. 14.
([2]) Opinion of the European Parliament of 29 March 2007 (not yet published in the Official Journal) and Council Decision of 23 July 2007.
([3]) OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).
([4]) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ L 378, 27.12.2006, p. 1).
([5]) OJ C 20, 24.1.2004, p. 1.
([6]) OJ C 68 E, 18.3.2004, p. 85.
([7]) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003.
([8]) OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2007/20/EC (OJ L 94, 4.4.2007, p. 23).
([9]) Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (OJ L 313, 13.12.2000, p. 22).
([10]) OJ L 33, 8.2.2003, p. 30.

instructions for use. Moreover, the Commission should engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients.

(8) In the light of technical innovation and the development of initiatives at the international level it is necessary to enhance the provisions on clinical evaluation, including clarification that clinical data is generally required for all devices regardless of classification and the possibility to centralise data on clinical investigations in the European databank.

(9) In order to provide clearer evidence of the compliance of custom-made device manufacturers, an explicit requirement for a post market production review system involving incident reporting to authorities should be introduced, as is already in place for other devices, and to enhance patient information, a requirement should be introduced that the 'Statement' under Annex VIII to Directive 93/42/EEC should be available to the patient and that it should contain the name of the manufacturer.

(10) In the light of technical progress in information technology and medical devices, a process should be provided to allow information supplied by the manufacturer to be available by other means.

(11) Manufacturers of Class I sterile and/or measuring medical devices should be given the option of using the full quality assurance conformity assessment module in order to provide them with more flexibility in the choice of compliance modules.

(12) In order to support market surveillance activities by Member States it is necessary and appropriate, in the case of implantable devices, to increase the time period for the retention of documents for administrative purposes to at least 15 years.

(13) For the appropriate and efficient functioning of Directive 93/42/EEC as regards regulatory advice on classification issues arising at national level, in particular on whether or not a product falls under the definition of a medical device, it is in the interest of national market surveillance and the health and safety of humans to establish a procedure for decisions on whether or not a product falls under the medical device definition.

(14) To ensure that, where a manufacturer does not have a registered place of business in the Community, authorities have a single individual person authorised by the manufacturer whom they can address in matters relating to the compliance of the devices with the Directives it is necessary to introduce an obligation for such manufacturers to designate an authorised representative for a device. This designation should be effective at least for all devices of the same model.

(15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures. Particular care should be taken to ensure that, when in use, the products do not endanger patients' health or safety.

(16) In support of transparency in Community legislation, certain information related to medical devices and their conformity with Directive 93/42/EEC, in particular information on registration, on vigilance reports and on certificates, should be available to any interested party and the general public.

(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC, the Member States should cooperate with each other and at international level.

(18) As design for patient safety initiatives play an increasing role in public health policy, it is necessary to expressly set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, should be further emphasised within the essential requirements. The manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.

(19) In the light of experience gained regarding activities of both the notified bodies and the authorities in the assessment of devices which require intervention of the appropriate authorities for medicines and human blood derivatives their duties and tasks should be clarified.

(20) Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement.

(21) In the light of the increased use of third Parties to carry out the design and manufacture of devices on behalf of the manufacturer, it is important that the manufacturer demonstrates that he applies adequate controls to the third party to continue to ensure the efficient operating of the quality system.

(22) The classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices. Explicit prior authorisation with regard to conformity, including an assessment of the design documentation, is required for Class III devices to be placed on the market. In performing its duties under the quality assurance and verification conformity assessment modules for all other classes of devices, it is essential and necessary for a notified body, in order to be assured of the

compliance of the manufacturer with Directive 93/42/EEC, to review the design documentation for the medical device. The depth and extent of this review should be commensurate with the classification of the device, the novelty of the intended treatment, the degree of intervention, the novelty of the technology or construction materials, and the complexity of the design and/or technology. This review can be achieved by taking a representative example of design documentation of one or more type(s) of devices from those being manufactured. Further review(s), and in particular the assessment of changes to the design that could affect conformity with the essential requirements, should be part of the surveillance activities of the notified body.

(23) It is necessary to remove the incoherence in the classification rules as a result of which invasive devices with respect to body orifices intended for connection to an active Class I medical device were not classified.

(24) The measures necessary for the implementation of Directive 90/385/EEC and Directive 93/42/EEC should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(25) In particular, power should be conferred on the Commission to adapt classification rules for medical devices, to adapt the means by which the information needed to use medical devices safely and properly may be set out, to determine conditions for making certain information publicly available, to adapt the provisions on clinical investigations set out in certain Annexes, to adopt particular requirements for placing certain medical devices on the market or putting them into service, and to take decisions to withdraw such devices from the market for reasons of protection of health or safety. Since those measures are of general scope and are designed to amend or supplement Directive 90/385/EEC and Directive 93/42/EEC by the modification or addition of non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(26) When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for taking decisions on withdrawal of certain medical devices from the market and for the adoption of particular requirements for placing such devices on the market or putting them into service for reasons of protection of health or safety.

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(27) The Commission should give a mandate to CEN and/or Cenelec to specify technical requirements and a suitable specific label for phthalate-containing devices within 12 months after entry into force of this Directive.

(28) Many Member States have established recommendations with the aim of reducing or limiting the use of medical devices containing critical phthalates on children, pregnant and nursing women and other patients at risk. To enable medical professionals to avoid such risks, devices which possibly release phthalates to the body of the patient should be labelled accordingly.

(29) In accordance with the essential requirements on the design and manufacture of medical devices, manufacturers should avoid the use of substances that may possibly compromise the health of patients, in particular of substances which are carcinogenic, mutagenic or toxic to reproduction, and should, as appropriate, strive to develop alternative substances or products with a lower risk potential.

(30) It should be clarified that alongside Directives 90/385/EEC and 93/42/EEC, in vitro diagnostic medical devices, which are the subject of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ([2]), should also be excluded from the scope of Directive 98/8/EC.

(31) In accordance with point 34 of the Interinstitutional agreement on better law-making ([3]), Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(32) Directives 90/385/EEC, 93/42/EEC and 98/8/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/385/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

   (a) paragraph 2 shall be amended as follows:

      (i) point (a) shall be replaced by the following:

         ‘(a) “medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its

([2]) OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

([3]) OJ C 321, 31.12.2003, p. 1.

manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;'

(ii) points (d), (e) and (f) shall be replaced by the following:

'(d) "custom-made device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;

(e) "device intended for clinical investigation" means any device intended for use by a duly qualified medical practitioner when conducting clinical investigations as referred to in Section 2.1 of Annex 7 in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorised to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

(f) "intended purpose" means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional material;'

(iii) the following points shall be added:

'(j) "authorised representative" means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;

(k) "clinical data" means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

— clinical investigation(s) of the device concerned, or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, or

— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.';

(b) paragraph 3 shall be replaced by the following:

'3. Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of Article 1 of Directive 2001/83/EC (*), that device shall be governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

(*) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1)'

(c) paragraph 4 shall be replaced by the following:

'4. Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the

human body with action that is ancillary to that of the device, that device shall be evaluated and authorised in accordance with this Directive.';

(d) the following paragraph shall be inserted:

'4a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the human body with action that is ancillary to that of the device, hereinafter referred to as a "human blood derivative", that device shall be assessed and authorised in accordance with this Directive.';

(e) paragraph 5 shall be replaced by the following:

'5. This Directive constitutes a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC (*).

(*) Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 390, 31.12.2004, p. 24).';

(f) the following paragraph shall be added:

'6. This Directive shall not apply to:

(a) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product;

(b) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells with the exception of devices referred to in paragraph 4a;

(c) transplants or tissues or cells of human origin or to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4a;

(d) transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.';

2. Article 2 shall be replaced by the following:

'Article 2

Member States shall take all necessary steps to ensure that the devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied, properly implanted and/or properly installed, maintained and used in accordance with their intended purposes.';

3. Article 3 shall be replaced by the following:

'Article 3

The active implantable medical devices referred to in Article 1(2)(c), (d) and (e), hereinafter referred to as "devices", shall satisfy the essential requirements set out in Annex 1 which apply to them, account being taken of the intended purpose of the devices concerned.

Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (*) shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex 1 to this Directive.

(*) OJ L 157, 9.6.2006, p. 24.';

4. in Article 4, paragraphs 1, 2 and 3 shall be replaced by the following:

'1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices complying with the provisions of this Directive and bearing the CE marking provided for in Article 12, which indicates that they have been the subject of an assessment of their conformity in accordance with Article 9.

2. Member States shall not create any obstacles to:

— devices intended for clinical investigations being made available to duly qualified medical practitioners or authorised persons for that purpose if they satisfy the conditions laid down in Article 10 and in Annex 6,

— custom-made devices being placed on the market and put into service if they satisfy the conditions laid down in Annex 6 and are accompanied by the statement, which shall be available to the particular identified patient, referred to in that Annex.

These devices shall not bear the CE marking.

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices do not conform and cannot be marketed or put into service until they have been made to comply by the manufacturer or his authorised representative.';

5. Article 5 shall be replaced by the following:

'Article 5

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the Official Journal of the European Union; Member States shall publish the references of such national standards.

2. For the purposes of this Directive, reference to harmonised standards also includes the monographs of the European Pharmacopoeia notably on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the *Official Journal of the European Union*.';

6. Article 6 shall be amended as follows:

(a) in paragraph 1 the reference '83/189/EEC' shall be replaced by the reference

'98/34/EC (*)

(*) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.';

(b) paragraph 2 shall be replaced by the following:

'2. The Commission shall be assisted by a standing committee (hereinafter referred to as the Committee).

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

7. Article 8 shall be replaced by the following:

'Article 8

1. Member States shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralised manner:

(a) any malfunction of or deterioration in the characteristics and performances of a device, as well as any inadequacy in the labelling or in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performances of a device for the reasons referred to in point (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 7, immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents.

4. The measures necessary for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).';

8. Article 9 shall be amended as follows:

(a) paragraph 8 shall be replaced by the following:

'8. Decisions taken by the notified bodies in accordance with Annexes 2, 3 and 5 shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both Parties, for further periods of a maximum length of five years.';

(b) the following paragraph shall be added:

'10. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to the means by which, in the light of

technical progress and considering the intended users of the devices concerned, the information laid down in Annex 1 Section 15 may be set out shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4).';

9. Article 9a shall be replaced by the following:

'Article 9a

1. A Member State shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations:

— that Member State considers that the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 9, by applying solely one of the given procedures chosen from among those referred to in Article 9,

— that Member State considers that a decision is required as to whether a particular product or product group falls within the definition of Article 1(2)(a), (c), (d) or (e).

Where measures are deemed necessary pursuant to the first subparagraph of this paragraph they shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).

2. The Commission shall inform the Member States of the measures taken.';

10. Article 10 shall be amended as follows:

(a) in paragraph 1, the word 'his' shall be replaced by the word 'the'.

(b) the second subparagraph of paragraph 2 shall be replaced by the following:

'Member States may, however, authorise manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the ethics committee concerned has issued a favourable opinion with respect to the investigation programme in question including its review of the clinical investigation plan.';

(c) paragraph 3 shall be replaced by the following:

'3. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken.';

(d) the following paragraphs shall be added:

'4. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in point 2.3.7 of Annex 7 at the disposal of the competent authorities.

5. Clinical investigations shall be conducted in accordance with the provisions of Annex 7. The measures designed to amend non-essential elements of this Directive relating to the provisions on clinical investigation in Annex 7 shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4).';

11. the following Articles shall be inserted:

'Article 10a

1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedure referred to in Article 9(2) shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned.

Member States may request to be informed of all data allowing for the devices to be identified together with the label and the instructions for use when the devices are put into service within their territory.

2. Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union.

For devices referred to in the first subparagraph of paragraph 1 the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of all details as referred to in paragraph 1.

3. The Member States shall on request inform the other Member States and the Commission of the details referred to in the first subparagraph of paragraph 1 given by the manufacturer or authorised representative.

Article 10b

1. Regulatory data in accordance with this Directive shall be stored in a European databank accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis.

The databank shall contain the following:

(a) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures as laid down in Annexes 2 to 5;

(b) data obtained in accordance with the vigilance procedure as defined in Article 8;

(c) data relating to clinical investigations referred to in Article 10.

2. Data shall be forwarded in a standardised format.

3. The measures necessary for the implementation of paragraphs 1 and 2 of this Article, in particular paragraph 1 (c), shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).

Article 10c

Where a Member State considers in relation to a given product or group of products that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures.

The Member State shall then inform the Commission and all the other Member States of the transitional measures, giving the reasons for its decision.

The Commission shall, whenever possible, consult the interested Parties and the Member States. The Commission shall adopt its opinion, indicating whether the national measures are justified or not. The Commission shall inform all the Member States and the consulted interested Parties.

When appropriate, the necessary measures designed to amend non-essential elements of this Directive, by supplementing it, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements therefor, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 6(5).';

12. Article 11 shall be amended as follows:

(a) in paragraph 2, the following subparagraph shall be added: 'When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex 8 to this Directive for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).';

(b) in paragraph 4, the words 'agent established in the Community' shall be replaced by the words 'authorised representative';

(c) the following paragraphs shall be added:

'5. The notified body shall inform its competent authority about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Directive about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.

6. Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or that a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof.

The Member State shall inform the other Member States and the Commission.

7. The notified body shall, on request, supply all relevant information and documents, including budgetary documents, required to enable the Member State to verify compliance with the criteria laid down in Annex 8.';

13. Article 13 shall be replaced by the following:

'Article 13

Without prejudice to Article 7

(a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of this Directive, the manufacturer or his authorised representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the device in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.

Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.';

14. Article 14 shall be amended as follows:

(a) the first paragraph shall be replaced by the following:

'Any decision taken pursuant to this Directive

(a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

or

(b) to withdraw devices from the market

shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.';

(b) in the second paragraph the words 'established in the Community' shall be deleted;

15. Article 15 shall be replaced by the following:

'Article 15

1. Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the Parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:

(a) information on the registration of persons responsible for placing devices on the market in accordance with Article 10a;

(b) information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure in accordance with Article 8;

(c) information contained in certificates issued, modified, supplemented, suspended or withdrawn.

3. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to the determination of the conditions under which information other than that referred to in paragraph 2, and in particular concerning any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, may be made publicly available shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6 (4).';

16. the following Article shall be inserted:

'Article 15a

Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

Without prejudice to the provisions of this Directive, cooperation may be part of initiatives developed at an international level.';

17. Annexes 1 to 7 shall be amended in accordance with Annex I to this Directive.

Article 2

Directive 93/42/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

(i) in point (a) the introductory phrase shall be replaced by the following:

'"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:';

(ii) in the third paragraph of point (d) the words 'are not' shall be replaced by the words 'shall not be';

(iii) the following points shall be added:

'(k) "clinical data" means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

— clinical investigation(s) of the device concerned; or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or

— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

(l) "device subcategory" means a set of devices having common areas of intended use or common technology;

(m) "generic device group" means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(n) "single use device" means a device intended to be used once only for a single patient.';

(b) paragraph 3 shall be replaced by the following:

'3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC (*), that device shall be governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to this Directive shall apply as far as safety and performance-related device features are concerned.

(*) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).';

(c) in paragraph 4:

(i) the reference '65/65/EEC' shall be replaced by the reference '2001/83/EC';

(ii) the words 'that device must' shall be replaced by the words 'that device shall';

(d) in paragraph 4a:

(i) the reference '89/381/EEC' shall be replaced by the reference '2001/83/EC';

(ii) the words 'that device must' shall be replaced by the words 'that device shall';

(e) paragraph 5 shall be amended as follows:

(i) The introductory phrase shall be replaced by the following:

'This Directive shall not apply to:';

(ii) point (c) shall be replaced by the following:

'(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product;';

(iii) point (f) shall be replaced by the following:

'(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4a.';

(f) paragraph 6 shall be replaced by the following:

'6. Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive

89/686/EEC (*) and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.

(*) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).'

(g) paragraphs 7 and 8 shall be replaced by the following:

'7. This Directive is a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC of the European Parliament and of the Council (*).

8. This Directive shall not affect the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (**), nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (***).

(*) Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 390, 31.12.2004, p. 24).
(**) OJ L 159, 29.6.1996, p. 1.
(***) OJ L 180, 9.7.1997, p. 22.'

2. in Article 3 the following paragraph shall be added:

'Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (*) shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.

(*) OJ L 157, 9.6.2006, p. 24.'

3. the second indent of Article 4(2) shall be replaced by the following:

'— custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII, which shall be available to the particular patient identified by name, an acronym or a numerical code.';

4. in Article 6(1) the reference '83/189/EEC' shall be replaced by the reference '98/34/EC (*)

(*) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.'

5. Article 7 shall be replaced by the following:

'Article 7

1. The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC, hereinafter referred to as "the Committee".

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a (1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

6. In Article 8 paragraph 2 shall be replaced by the following:

'2. The Commission shall enter into consultation with the Parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

(a) the measures are justified:

(i) it shall immediately so inform the Member State which took the measures and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the Parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the advisory procedure referred to in Article 6(2);

(ii) when necessary in the interests of public health, appropriate measures designed to amend non-essential elements of this Directive relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market, shall be adopted in

accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7 (4);

(b) the measures are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorised representative.';

7. In Article 9 paragraph 3 shall be replaced by the following:

'3. Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it may submit a duly substantiated request to the Commission and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Directive relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).';

8. Article 10 shall be amended as follows:

(a) in paragraph 2, the words 'established in the Community' shall be deleted;

(b) paragraph 3 shall be replaced by the following:

'3. After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents.';

(c) the following paragraph shall be added:

'4. Any appropriate measures to adopt procedures to implement this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).';

9. Article 11 shall be amended as follows:

(a) in paragraphs 8 and 9 the words 'established in the Community' shall be deleted;

(b) in paragraph 11, the words 'Annexes II and III' shall be replaced by the words 'Annexes II, III, V and VI' and the words 'for further periods of five years' shall be replaced by the words 'for further periods of a maximum length of five years';

(c) the following paragraph shall be added:

'14. The measures designed to amend non-essential elements of this Directive, by supplementing it, relating to the means by which, in the light of technical progress and considering the intended users of the devices concerned, the information laid down in Annex I Section 13.1 may be set out, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).';

10. Article 12 shall be amended as follows:

(a) the title shall be replaced by 'Particular procedure for systems and procedure packs and procedure for sterilisation';

(b) paragraph 3 shall be replaced by the following:

'3. Any natural or legal person who sterilises, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other CE-marked medical devices designed by their manufacturers to be sterilised before use, shall, at his choice, follow one of the procedures referred to in Annex II or V. The application of the abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions.';

(c) in paragraph 4, the third sentence shall be replaced by the following:

'The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the competent authorities for a period of five years.';

11. The following Article shall be inserted:

'Article 12a

Reprocessing of medical devices

The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community.

In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection.'

12. Article 13 shall be replaced by the following:

'Article 13

Decisions with regard to classification and derogation clause

1. A Member State shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations:

(a) that Member State considers that the application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices;

(b) that Member State considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX, be classified in another class;

(c) that Member State considers that the conformity of a device or family of devices should, by way of derogation from Article 11, be established by applying solely one of the given procedures chosen from among those referred to in Article 11;

(d) that Member State considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1(2)(a) to (e).

The measures referred to in the first subparagraph of this paragraph shall, as appropriate, be adopted in accordance with the procedure referred to in Article 7(2).

2. The Commission shall inform the Member States of the measures taken.';

13. Article 14 shall be amended as follows:

(a) in the second subparagraph of paragraph 1, the words 'Classes IIb and III' shall be replaced by the words 'Classes IIa, IIb and III';

(b) paragraph 2 shall be replaced by the following:

'2. Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union. For devices referred to in the first subparagraph of paragraph 1, the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of the details referred to in paragraph 1.';

(c) paragraph 3 shall be replaced by the following:

'3. The Member States shall on request inform the other Member States and the Commission of the details referred to in the first subparagraph of paragraph 1 given by the manufacturer or authorised representative.';

14. Article 14a shall be amended as follows:

(a) the second subparagraph of paragraph 1 shall be amended as follows:

(i) point (a) shall be replaced by the following:

'(a) data relating to registration of manufacturers and authorised representatives and devices in accordance with Article 14 excluding data related to custom-made devices;';

(ii) the following point shall be added:

'(d) data relating to clinical investigations referred to in Article 15;';

(b) paragraph 3 shall be replaced by the following:

'3. The measures necessary for the implementation of paragraphs 1 and 2 of this Article, in particular paragraph 1(d), shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).'

(c) the following paragraph shall be added:

'4. The provisions of this Article shall be implemented no later than 5 September 2012. The Commission shall, no later than 11 October 2012, evaluate the operational functioning and the added value of the databank. On the basis of this evaluation, the Commission shall, if appropriate, present proposals to the European Parliament and the Council or present draft measures in accordance with paragraph 3.';

15. Article 14b shall be replaced by the following:

'Article 14b

Particular health monitoring measures

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures.

The Member State shall then inform the Commission and all other Member States, giving the reasons for its decision.

The Commission shall, whenever possible, consult the interested Parties and the Member States.

The Commission shall adopt its opinion, indicating whether the national measures are justified or not. The Commission shall inform all the Member States and the consulted interested Parties thereof.

When appropriate, the necessary measures designed to amend non-essential elements of this Directive, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7 (3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4).';

16. Article 15 shall be amended as follows:

(a) paragraphs 1, 2 and 3 shall be replaced by the following:

'1. In the case of devices intended for clinical investigations, the manufacturer or the authorised representative, established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted by means of the statement mentioned in Section 2.2 of Annex VIII.

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy.

Member States may however authorise manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question, including its review of the clinical investigation plan.

3. In the case of devices other than those referred to in paragraph 2, Member States may authorise manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has issued a favourable opinion on the programme of investigation in question including its review of the clinical investigation plan.';

(b) paragraphs 5, 6 and 7 shall be replaced by the following:

'5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The measures designed to amend non-essential elements of this Directive, inter alia by supplementing it, relating to the provisions on clinical investigation in Annex X shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken.

7. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in Section 2.3.7 of Annex X at the disposal of the competent authorities.';

17. Article 16 shall be amended as follows:

(a) the following subparagraph shall be added to paragraph 2:

'When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).';

(b) in paragraph 4, the words 'established in the Community' shall be deleted;

(c) paragraph 5 shall be replaced by the following:

'5. The notified body shall inform its competent authority about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Directive about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.';

18. in Article 18 point (a) shall be replaced by the following:

'(a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the Directive, the manufacturer or his authorised representative shall be obliged to end the infringement under conditions imposed by the Member State;';

19. in Article 19(2), the words 'established in the Community' shall be deleted;

20. Article 20 shall be replaced by the following:

'Article 20

Confidentiality

1. Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the Parties involved in the application

of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:

(a) information on the registration of persons responsible for placing devices on the market in accordance with Article 14;

(b) information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure according to Article 10(3);

(c) information contained in certificates issued, modified, supplemented, suspended or withdrawn.

3. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to determination of the conditions under which other information may be made publicly available, and in particular for Class IIb and Class III devices to any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).';

21. the following Article shall be inserted:

'*Article 20a*

Cooperation

Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

Without prejudice to the provisions of this Directive, cooperation may be part of initiatives developed at an international level.';

22. Annexes I to X shall be amended in accordance with Annex II to this Directive.

Article 3

In Article 1(2) of Directive 98/8/EC the following point shall be added:

'(s) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (*).

(*) OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).'

Article 4

1. Member States shall adopt and publish by 21 December 2008 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those measures.

They shall apply those measures from 21 March 2010.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Strasbourg, 5 September 2007.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	M. LOBO ANTUNES

ANNEX I

Annexes 1 to 7 to Directive 90/385/EEC shall be amended as follows:

1. Annex 1 shall be amended as follows:

(a) the following Section shall be inserted:

'5a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 7.';

(b) in Section 8, the fifth indent shall be replaced by the following:

'— risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (*) and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (**).

(*) OJ L 159, 29.6.1996, p. 1.
(**) OJ L 180, 9.7.1997, p. 22.';

(c) in Section 9, seventh indent, the following phrase shall be added:

'For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.';

(d) Section 10 shall be replaced by the following:

'10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (*) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, it shall provide the notified body with advice,

whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

(*) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.';

(e) Section 14.2 shall be amended as follows:

(i) the first indent shall be replaced by the following:

'— the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,';

(ii) the following indent shall be added:

'— in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.';

(f) the following indent shall be added to the second paragraph of Section 15:

'— date of issue or the latest revision of the instructions for use.';

2. Annex 2 shall be amended as follows:

(a) in Section 2, the third paragraph shall be replaced by the following:

'This declaration shall cover one or more clearly identified devices by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.';

(b) in the second paragraph of Section 3.1, the first sentence of the fifth indent shall be replaced by the following:

'— an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7.';

(c) Section 3.2 shall be amended as follows:

(i) the following sentence shall be added to the second subparagraph:

'It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).';

(ii) the following indent shall be added to point (b):

'— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.';

(iii) the following indents shall be added to point (c):

'— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Annex 7.';

(d) in Section 3.3, the last sentence of the second subparagraph shall be replaced by the following:

'The evaluation procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.';

(e) Section 4.2 shall be amended as follows:

(i) the first paragraph shall be replaced by the following:

'The application shall describe the design, manufacture and performances of the product in question, and it must include the documents needed to assess whether the product conforms to the requirements of this Directive, and in particular Annex 2, Section 3.2, third paragraph, points (c) and (d).';

(ii) in the fourth indent of the second paragraph, the word 'data' shall be replaced by the word 'evaluation';

(f) in Section 4.3, the following paragraphs shall be added:

'In the case of devices referred to in Annex 1, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex 1, Section 10, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.';

(g) in Section 5.2, the second indent shall be replaced by the following:

'— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc.';

(h) Section 6.1 shall be replaced by the following:

'6.1. For at least 15 years from the last date of manufacture of the product, the manufacturer or his authorised representative shall keep available for the national authorities:

— the declaration of conformity,

— the documentation referred to in the second indent of Section 3.1, and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,

— the amendments referred to in Section 3.4,

— the documentation referred to in Section 4.2,

— the decisions and reports of the notified body referred to in Sections 3.4, 4.3, 5.3 and 5.4.';

(i) Section 6.3 shall be deleted;

(j) the following Section shall be added:

'7. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate

concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.';

3. Annex 3 shall be amended as follows:

(a) Section 3 shall be amended as follows:

(i) the first indent shall be replaced by the following:

'— a general description of the type, including any variants planned, and its intended use(s),';

(ii) the fifth to eighth indents shall be replaced by the following:

'— the results of design calculations, risk analysis, investigations and technical tests carried out, etc.,

— a declaration stating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Annex 7,

— the draft instruction leaflet.';

(b) the following paragraphs shall be added to Section 5:

'In the case of devices referred to in Annex 1, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex 1, Section 10, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.';

(c) in Section 7.3, the words 'five years from the manufacture of the last appliance' shall be replaced by the words '15 years from the manufacture of the last product';

(d) Section 7.4 shall be deleted;

4. Annex 4 shall be amended as follows:

(a) in Section 4, the words 'post-marketing surveillance system' shall be replaced by the words 'post-marketing surveillance system including the provisions referred to in Annex 7';

(b) Section 6.3 shall be replaced by the following:

'6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.';

(c) the following Section shall be added:

'7. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.';

5. Annex 5 shall be amended as follows:

(a) in Section 2, second paragraph, the words 'identified specimens of the product and shall be kept by the manufacturer' shall be replaced by the words 'devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer';

(b) in the sixth indent of Section 3.1, the words 'post-marketing surveillance system' shall be replaced by the words 'post-marketing surveillance system including the provisions referred to in Annex 7';

(c) in Section 3.2(b), the following indent shall be added:

'— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.';

(d) in Section 4.2, the following indent shall be inserted after the first indent:

'— the technical documentation,';

(e) the following Section shall be added:

'6. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.';

6. Annex 6 shall be amended as follows:

(a) Section 2.1 shall be amended as follows:

(i) the first indent shall be replaced by the following two indents:

'— the name and address of the manufacturer,

— the information necessary for the identification of the product in question,';

(ii) in the third indent, the word 'doctor' shall be replaced by the words 'duly qualified medical practitioner';

(iii) the fourth indent shall be replaced by the following:

'— the specific characteristics of the product revealed by the prescription,';

(b) Section 2.2 shall be replaced by the following:

'2.2. For devices intended for clinical investigations covered in Annex 7:

— data allowing the devices in question to be identified,

— the clinical investigation plan,

— the investigator's brochure,

— the confirmation of insurance of subjects,

— the documents used to obtain informed consent,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1,

— the opinion of the ethics committee concerned and details of the aspects covered by its opinion,

— the name of the duly qualified medical practitioner or other authorised person and of the institution responsible for the investigations,

— the place, date of commencement and duration scheduled for the investigations,

— a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.';

(c) in Section 3.1, the first paragraph shall be replaced by the following:

'For custom-made devices, documentation, indicating manufacturing site(s) and enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirements of this Directive to be assessed.';

(d) in Section 3.2, the first paragraph shall be amended as follows:

(i) the first indent shall be replaced by the following:

'— a general description of the product and its intended use,';

(ii) in the fourth indent, the words 'a list of the standards' shall be replaced by the words 'the results of the risk analysis and a list of the standards';

(iii) the following indent shall be inserted after the fourth indent:

'— if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,';

(e) the following two sections shall be added:

'4. The information included in the declarations covered by this Annex shall be kept for a period of at least 15 years from the date of manufacture of the last product.

5. For custom-made devices, the manufacturer must undertake to review and to document experience gained in the post-production phase, including the provisions referred to in Annex 7, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in point (i) leading to systematic recall of devices of the same type by the manufacturer.';

7. Annex 7 shall be amended as follows:

(a) Section 1 shall be replaced by the following:

'1. **General provisions**

1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 2 of Annex 1 under the normal conditions of use of the device and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 5 of Annex 1, must be based on clinical data. The evaluation of this data (hereinafter referred to as clinical evaluation), where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device where:

— there is demonstration of equivalence of the device to the device to which the data relates and,

— the data adequately demonstrate compliance with the relevant essential requirements;

1.1.2. Or a critical evaluation of the results of all the clinical investigations made,

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.

1.2. Clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.3. The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.4. The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.5. Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

1.6. All data must remain confidential unless it is deemed essential that they be divulged.'

(b) Section 2.3.5 shall be replaced by the following:

'2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed.'

(c) In Section 2.3.6, the words 'appropriately qualified medical specialist' shall be replaced by the words 'duly qualified medical practitioner or authorised person'.

ANNEX II

Annexes I to X to Directive 93/42/EEC shall be amended as follows:

1. Annex I shall be amended as follows:

(a) Section 1 shall be replaced by the following:

'1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).';

(b) the following Section shall be inserted:

'6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.';

(c) in Section 7.1, the following indent shall be added:

'— where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.';

(d) Section 7.4. shall be replaced by the following:

'7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (*) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into

account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

(*) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.'

(e) Section 7.5 shall be replaced by the following:

'7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (*).

If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

(*) OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).'

(f) in Section 8.2, the word 'transferable' shall be replaced by the word 'transmissible';

(g) the following Section shall be inserted:

'12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.';

(h) in Section 13.1, the first paragraph shall be replaced by the following:

'13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.';

(i) Section 13.3 shall be amended as follows:

(i) point (a) shall be replaced by the following:

'(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;'

(ii) point (b) shall be replaced by the following:

'(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;'

(iii) point (f) shall be replaced by the following:

'(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;'

(j) Section 13.6 shall be amended as follows:

(i) the following subparagraph shall be added to point (h):

'If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;'

(ii) point (o) shall be replaced by the following:

'(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;'

(iii) the following point shall be added:

'(q) date of issue or the latest revision of the instructions for use.';

(k) Section 14 shall be deleted.

2. Annex II shall be amended as follows:

(a) Section 2 shall be replaced by the following:

'2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.';

(b) in Section 3.1, second paragraph, the introductory part of the seventh indent shall be replaced by the following:

'— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:';

(c) Section 3.2 shall be amended as follows:

(i) the following paragraph shall be inserted after the first paragraph:

'It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).';

(ii) in point (b), the following indent shall be added:

'— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;'

(iii) point (c) shall be replaced by the following:

'(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

— a general description of the product, including any variants planned, and its intended use(s),

— the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,

— the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,

— if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device (s) having the characteristics specified by the manufacturer,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC (*),

— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Annex X,

— the draft label and, where appropriate, instructions for use.

(*) Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (OJ L 105, 26.4.2003, p. 18).'

(d) the second paragraph of Section 3.3 shall be replaced by the following:

'The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.';

(e) in Section 4.3, the second and third paragraphs shall be replaced by the following:

'In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.';

(f) in Section 5.2, the second indent shall be replaced by the following:

'— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted as referred to in Annex I, Chapter I, Section 2, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc.,';

(g) Section 6.1 shall be amended as follows:

(i) the introductory part shall be replaced by the following:

'The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the national authorities:';

(ii) the following phrase shall be added to the second indent:

'and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,';

(h) Section 6.3 shall be deleted;

(i) Section 7 shall be replaced by the following:

'7. Application to devices in Classes IIa and IIb.

7.1. In line with Article 11(2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply.

7.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

7.3. For devices in Class IIb the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each generic device group for compliance with the provisions of this Directive.

7.4. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

7.5. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 5.';

(j) in Section 8, the words 'Article 4(3) of Directive 89/381/EEC' shall be replaced by the words 'Article 114(2) of Directive 2001/83/EC';

3. Annex III shall be amended as follows:

(a) Section 3 shall be replaced by the following:

'3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

— a general description of the type, including any variants planned, and its intended use(s),

— design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,

— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,

— the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,

— a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in Section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,

— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,

— the clinical evaluation referred to in Annex X,

— the draft label and, where appropriate, instructions for use.';

(b) in Section 5, the second and third paragraphs shall be replaced by the following:

'In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.';

(c) Section 7.3 shall be replaced by the following:

'7.3. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured.';

(d) Section 7.4 shall be deleted;

4. Annex IV shall be amended as follows:

(a) in Section 1, the words 'established in the Community' shall be deleted;

(b) in Section 3, the first paragraph shall be replaced by the following:

'3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in

Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:';

(c) Section 6.3 shall be replaced by the following:

'6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.';

(d) in Section 7, the introductory part shall be replaced by the following:

'The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:';

(e) in the introductory part of Section 8 the word 'exemptions' shall be deleted;

(f) in Section 9, the words 'Article 4(3) of Directive 89/381/EEC' shall be replaced by the words 'Article 114(2) of Directive 2001/83/EC';

5. Annex V shall be amended as follows:

(a) Section 2 shall be replaced by the following:

'2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.';

(b) in the eighth indent of the second paragraph of Section 3.1, the introductory part shall be replaced by the following:

'— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them;';

(c) in point (b) of the third paragraph of Section 3.2, the following indent shall be added:

'— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;'

(d) in Section 4.2, the following indent shall be inserted after the first indent:

'— the technical documentation,';

(e) in Section 5.1, the introductory part shall be replaced by the following:

'The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:';

(f) Section 6 shall be replaced by the following:

'6. **Application to devices in Class IIa**

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.';

(g) in Section 7, the words 'Article 4(3) of Directive 89/381/EEC' shall be replaced by the words 'Article 114(2) of Directive 2001/83/EC';

6. Annex VI shall be amended as follows:

(a) Section 2 shall be replaced by the following:

'2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer affixes the CE marking in accordance with Article 17 and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.';

(b) in the eighth indent of the second paragraph of Section 3.1, the introductory part shall be replaced by the following:

'— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:';

(c) in Section 3.2, the following indent shall be added:

'— where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;'

(d) in Section 5.1, the introductory part shall be replaced by the following:

'The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:';

(e) Section 6 shall be replaced by the following:

'6. **Application to devices in Class IIa**

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.';

7. Annex VII shall be amended as follows:

(a) Sections 1 and 2 shall be replaced by the following:

'1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured.';

(b) Section 3 shall be amended as follows:

(i) the first indent shall be replaced by the following:

'— a general description of the product, including any variants planned and its intended use(s),';

(ii) the fifth indent shall be replaced by the following:

'— in the case of products placed on the market in a sterile condition, description of the methods used and the validation report,';

(iii) the seventh indent shall be replaced by the following indents:

'— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,';

(iv) the following indent shall be inserted after the seventh indent:

'— the clinical evaluation in accordance with Annex X,';

(c) in Section 4, the introductory part shall be replaced by the following:

'4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:';

(d) in Section 5, the words 'Annex IV, V or VI' shall be replaced by the words 'Annex II, IV, V or VI';

8. Annex VIII shall be amended as follows:

(a) in Section 1, the words 'established in the Community' shall be deleted;

(b) Section 2.1 shall be amended as follows:

(i) the following indent shall be inserted after the introductory phrase:

'— the name and address of the manufacturer,';

(ii) the fourth indent shall be replaced by the following:

'— the specific characteristics of the product as indicated by the prescription,';

(c) Section 2.2 shall be amended as follows:

(i) the second indent shall be replaced by the following:

'— the clinical investigation plan,';

(ii) the following indents shall be inserted after the second indent:

'— the investigator's brochure,

— the confirmation of insurance of subjects,

— the documents used to obtain informed consent,

— a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I,

— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,';

(d) in Section 3.1, the first paragraph shall be replaced by the following:

'3.1. For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive.';

(e) Section 3.2 shall be replaced by the following:

'3.2. For devices intended for clinical investigations, the documentation must contain:

— a general description of the product and its intended use,

— design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied,

— if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

— if the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the risk management measures in this connection which have been applied to reduce the risk of infection,

— the results of the design calculations, and of the inspections and technical tests carried out, etc.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in the first paragraph of this Section.

The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures.';

(f) Section 4 shall be replaced by the following:

'4. The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years.';

(g) the following section shall be added:

'5. For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.';

9. Annex IX shall be amended as follows:

(a) Chapter I shall be amended as follows:

(i) in Section 1.4, the following sentence shall be added:

'Stand alone software is considered to be an active medical device.';

(ii) Section 1.7 shall be replaced by the following:

'1.7. **Central circulatory system**

For the purposes of this Directive, "central circulatory system" means the following vessels:

arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.';

(b) in Chapter II, Section 2, the following section shall be added:

'2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means "an uninterrupted actual use of the device for the intended purpose". However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.';

(c) Chapter III shall be amended as follows:

(i) the introductory phrase of the first paragraph of Section 2.1 shall be replaced by the following:

'All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:';

(ii) Section 2.2 shall be replaced by the following:

'2.2. **Rule 6**

All surgically invasive devices intended for transient use are in Class IIa unless they are:

— intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— reusable surgical instruments, in which case they are in Class I,

— intended specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— intended to supply energy in the form of ionising radiation in which case they are in Class IIb,

— intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,

— intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.';

(iii) in Section 2.3, the first indent shall be replaced by the following:

'— either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,';

(iv) in Section 4.1, first paragraph, the reference '65/65/EEC' shall be replaced by the reference '2001/83/EC';

(v) in Section 4.1, the second paragraph shall be replaced by the following:

'All devices incorporating, as an integral part, a human blood derivative are in Class III.';

(vi) in Section 4.3, second paragraph, the following phrase shall be added:

'unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.';

(vii) in Section 4.4, the words 'Non-active devices' shall be replaced by the word 'Devices';

10. Annex X shall be amended as follows:

(a) Section 1.1 shall be replaced by the following:

'1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as "clinical evaluation", where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:

— there is demonstration of equivalence of the device to the device to which the data relates, and

— the data adequately demonstrate compliance with the relevant essential requirements.

1.1.2. Or a critical evaluation of the results of all clinical investigations made.

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.'

(b) The following Sections shall be inserted:

'1.1a In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.1c The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.';

(c) in Section 2.2, the first sentence shall be replaced by the following:

'Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly.';

(d) Section 2.3.5 shall be replaced by the following:

'2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed.'.

STATEMENTS BY THE COMMISSION

Re Article 6

For the 7th Framework Programme, the European Commission proposes to continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 6th Framework Programme.

The European Commission proposes the continuation of this ethical framework because it has developed, based on experience, a responsible approach for an area of science which holds much promise and that has proven to work satisfactorily in the context of a research programme in which researchers participate from many countries with very diverse regulatory situations.

(1) The decision on the 7th Framework Programme explicitly excludes three fields of research from Community funding:

— research activities aiming at human cloning for reproductive purposes;

— research activities intended to modify the genetic heritage of human beings which could make such changes heritable;

— research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

(2) No activity will be funded that is forbidden in all Member States. No activity will be funded in a Member State where such activity is forbidden.

(3) The decision on FP7 and the provisions for the ethical framework governing the Community funding of human embryonic stem cell research entail in no way a value judgement on the regulatory or ethical framework governing such research in Member States.

(4) In calling for proposals, the European Commission does not explicitly solicit the use of human embryonic stem cells. The use of human stem cells, be they adult or embryonic, if any, depends on the judgement of the scientists in view of the objectives they want to achieve. In practice, by far the largest part of Community funds for stem cell research is devoted to the use of adult stem cells. There is no reason why this would substantially change in FP7.

(5) Each project proposing to use human embryonic stem cells must successfully pass a scientific evaluation during which the necessity of using such stem cells to achieve the scientific objectives is assessed by independent scientific experts.

(6) Proposals which successfully pass the scientific evaluation are then subject to a stringent ethical review organised by the European Commission. In this ethical review, account is taken of principles reflected in the EU Charter of Fundamental Rights and relevant international conventions such as the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997 and its additional protocols and the Universal Declaration on the Human Genome and the Human Rights adopted by UNESCO. The ethical review also serves to check that the proposals respect the rules of the countries where the research will be carried out.

(7) In particular cases, an ethical review may be carried out during the lifetime of the project.

(8) Each project proposing to use human embryonic stem cells must seek the approval of the relevant national or local ethics committee prior to the start of the project. All national rules and procedures must be respected, including on such issues as parental consent, absence of financial inducement, etc. Checks will be made on whether the project includes references to licensing and control measures to be taken by the competent authorities of the Member State where the research will be carried out.

(9) A proposal that successfully passes the scientific evaluation, the national or local ethical reviews and the European ethical review will be presented for approval, on a case by case basis, to the Member States, meeting as a Regulatory Committee. No project involving the use of human embryonic stem cells will be funded that does not obtain approval from the Member States.

(10) The European Commission will continue to work to make the results from Community funded stem cell research widely accessible to all researchers, for the ultimate benefit of patients in all countries.

(11) The European Commission will support actions and initiatives that contribute to a coordination and rationalisation of HESC research within a responsible ethical approach. In particular, the Commission will support a European registry of human embryonic stem cell lines. Support for such a registry will allow a monitoring of existing human embryonic stem cells in Europe, will contribute to maximise their use by scientists and may help to avoid unnecessary derivations of new stem cell lines.

(12) The European Commission will continue with the current practice and will not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells.

Re the Energy theme

The ten themes of the Cooperation Programme include research needed to underpin the formulation, implementation and assessment of Community policies to which the Commission attaches a central role. It appreciates the importance that the European Parliament attaches to energy policy in general and to the promotion of energy efficiency and renewable energy sources in particular. In order to allow the Parliament to follow the implementation of the Programme, the Commission intends to continue the policy of transparency and provision of information. Appropriate information on projects funded by the FP will be fully available to the public through the internet. Particular attention will be given to ensuring, at least every two years, a comprehensive presentation of projects related to rational and efficient use of energy and the role of renewable energy sources.

Re Ideas

In the context of the progress report referred to in Article 7(2) and preceding the interim evaluation, the Commission will present to the European Parliament and the Council by mid-2008 a Communication on the methodology and terms of reference to be used for the review to be carried out by independent experts concerning the ERC's structures and mechanisms. If necessary the Commission will present a proposal for the adaptation of the Framework Programme.

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 2 December 2015

DH-BIO/INF (2015) 13
FINAL

COMMITTEE ON BIOETHICS
(DH-BIO)

8th meeting
1-4 December 2015
Strasbourg

Statement on genome editing technologies

adopted by the DH-BIO

- The development of new genome editing technologies, such as CRISPR-Cas9, has given rise to important reaction in particular within the scientific community. Gene modification methods are not new and have been used for several decades playing an essential role in biomedical research. The new genome editing technologies have made possible simple and precise modifications in a wide variety of species.

- There is strong support for the better understanding of the causes of diseases and for future treatment and these technologies have considerable potential for research in this field and to improve human health. However, the application of genome editing technologies to human gametes or embryos raises many ethical, social and safety issues, particularly from any modification of the human genome which could be passed on to future generations.

- These developments have led eminent experts and institutions within and outside the biomedical field worldwide to call for an in-depth analysis of potential risks of genome editing and for international and regional debate on its implications for the human being.

- In this context, the Committee on Bioethics (DH-BIO), representing 47 European states, wishes to recall the work carried out at the level of the Council of Europe on developments in the biomedical field and its implications for human being, and to underline the relevance of the framework provided by the Convention on Human Rights and Biomedicine (ETS N° 164, 1997), hereinafter referred to as "the Oviedo Convention" – the only international legally binding instrument addressing human rights in the biomedical field.

- The Convention represents the outcome of an in-depth discussion at European level, on developments in the biomedical field, in particular in the field of genetics. This work was guided by the acknowledgement of the positive perspectives of genetic modification with the development of knowledge of the human genome; but also by the greater possibility to intervene on and control genetic characteristics of human beings, raising concern about possible misuse and abuses, in particular the intentional modification of human genome so as to produce individuals or groups endowed with particular characteristics and required qualities.

- Article 13[1] of the Oviedo Convention addresses these concerns about genetic enhancement or germline genetic engineering by limiting the purposes of any intervention on the human genome, including in the field of research, to prevention, diagnosis or therapy. Furthermore, it prohibits any intervention with the aim of introducing a modification in the genome of any descendants.

- These expectations and concerns remain both very relevant today with regard to those new genome editing technologies.

The Committee on Bioethics (DH-BIO):

- **is convinced that the Oviedo Convention provides principles that could be used as reference for the debate called for at international level on the fundamental questions raised by these recent technological developments; and recalls that the need for such debates was foreseen by the Convention in its Article 28[2];**

- **agrees, as part of its mandate, to examine the ethical and legal challenges raised by these emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention.**

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[1] Article 13 - Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

[2] Article 28 – Public debate

Parties to this Convention shall see to it that the fundamental questions raised by the developments in biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 April 2016

on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) The protection of natural persons in relation to the processing of personal data is a fundamental right. Article 8(1) of the Charter of Fundamental Rights of the European Union (the 'Charter') and Article 16(1) of the Treaty on the Functioning of the European Union (TFEU) provide that everyone has the right to the protection of personal data concerning him or her.

(2) The principles of, and rules on the protection of natural persons with regard to the processing of their personal data should, whatever their nationality or residence, respect their fundamental rights and freedoms, in particular their right to the protection of personal data. This Regulation is intended to contribute to the accomplishment of an area of freedom, security and justice and of an economic union, to economic and social progress, to the strengthening and the convergence of the economies within the internal market, and to the well-being of natural persons.

(3) Directive 95/46/EC of the European Parliament and of the Council ([4]) seeks to harmonise the protection of fundamental rights and freedoms of natural persons in respect of processing activities and to ensure the free flow of personal data between Member States.

([1]) OJ C 229, 31.7.2012, p. 90.
([2]) OJ C 391, 18.12.2012, p. 127.
([3]) Position of the European Parliament of 12 March 2014 (not yet published in the Official Journal) and position of the Council at first reading of 8 April 2016 (not yet published in the Official Journal). Position of the European Parliament of 14 April 2016.
([4]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

(4) The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality. This Regulation respects all fundamental rights and observes the freedoms and principles recognised in the Charter as enshrined in the Treaties, in particular the respect for private and family life, home and communications, the protection of personal data, freedom of thought, conscience and religion, freedom of expression and information, freedom to conduct a business, the right to an effective remedy and to a fair trial, and cultural, religious and linguistic diversity.

(5) The economic and social integration resulting from the functioning of the internal market has led to a substantial increase in cross-border flows of personal data. The exchange of personal data between public and private actors, including natural persons, associations and undertakings across the Union has increased. National authorities in the Member States are being called upon by Union law to cooperate and exchange personal data so as to be able to perform their duties or carry out tasks on behalf of an authority in another Member State.

(6) Rapid technological developments and globalisation have brought new challenges for the protection of personal data. The scale of the collection and sharing of personal data has increased significantly. Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities. Natural persons increasingly make personal information available publicly and globally. Technology has transformed both the economy and social life, and should further facilitate the free flow of personal data within the Union and the transfer to third countries and international organisations, while ensuring a high level of the protection of personal data.

(7) Those developments require a strong and more coherent data protection framework in the Union, backed by strong enforcement, given the importance of creating the trust that will allow the digital economy to develop across the internal market. Natural persons should have control of their own personal data. Legal and practical certainty for natural persons, economic operators and public authorities should be enhanced.

(8) Where this Regulation provides for specifications or restrictions of its rules by Member State law, Member States may, as far as necessary for coherence and for making the national provisions comprehensible to the persons to whom they apply, incorporate elements of this Regulation into their national law.

(9) The objectives and principles of Directive 95/46/EC remain sound, but it has not prevented fragmentation in the implementation of data protection across the Union, legal uncertainty or a widespread public perception that there are significant risks to the protection of natural persons, in particular with regard to online activity. Differences in the level of protection of the rights and freedoms of natural persons, in particular the right to the protection of personal data, with regard to the processing of personal data in the Member States may prevent the free flow of personal data throughout the Union. Those differences may therefore constitute an obstacle to the pursuit of economic activities at the level of the Union, distort competition and impede authorities in the discharge of their responsibilities under Union law. Such a difference in levels of protection is due to the existence of differences in the implementation and application of Directive 95/46/EC.

(10) In order to ensure a consistent and high level of protection of natural persons and to remove the obstacles to flows of personal data within the Union, the level of protection of the rights and freedoms of natural persons with regard to the processing of such data should be equivalent in all Member States. Consistent and homogenous application of the rules for the protection of the fundamental rights and freedoms of natural persons with regard to the processing of personal data should be ensured throughout the Union. Regarding the processing of personal data for compliance with a legal obligation, for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, Member States should be allowed to maintain or introduce national provisions to further specify the application of the rules of this Regulation. In conjunction with the general and horizontal law on data protection implementing Directive 95/46/EC, Member States have several sector-specific laws in areas that need more specific provisions. This Regulation also provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data ('sensitive data'). To that extent, this Regulation does not exclude Member State law that sets out the circumstances for specific processing situations, including determining more precisely the conditions under which the processing of personal data is lawful.

(11) Effective protection of personal data throughout the Union requires the strengthening and setting out in detail of the rights of data subjects and the obligations of those who process and determine the processing of personal data, as well as equivalent powers for monitoring and ensuring compliance with the rules for the protection of personal data and equivalent sanctions for infringements in the Member States.

(12) Article 16(2) TFEU mandates the European Parliament and the Council to lay down the rules relating to the protection of natural persons with regard to the processing of personal data and the rules relating to the free movement of personal data.

(13) In order to ensure a consistent level of protection for natural persons throughout the Union and to prevent divergences hampering the free movement of personal data within the internal market, a Regulation is necessary to provide legal certainty and transparency for economic operators, including micro, small and medium-sized enterprises, and to provide natural persons in all Member States with the same level of legally enforceable rights and obligations and responsibilities for controllers and processors, to ensure consistent monitoring of the processing of personal data, and equivalent sanctions in all Member States as well as effective cooperation between the supervisory authorities of different Member States. The proper functioning of the internal market requires that the free movement of personal data within the Union is not restricted or prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data. To take account of the specific situation of micro, small and medium-sized enterprises, this Regulation includes a derogation for organisations with fewer than 250 employees with regard to record-keeping. In addition, the Union institutions and bodies, and Member States and their supervisory authorities, are encouraged to take account of the specific needs of micro, small and medium-sized enterprises in the application of this Regulation. The notion of micro, small and medium-sized enterprises should draw from Article 2 of the Annex to Commission Recommendation 2003/361/EC ([1]).

(14) The protection afforded by this Regulation should apply to natural persons, whatever their nationality or place of residence, in relation to the processing of their personal data. This Regulation does not cover the processing of personal data which concerns legal persons and in particular undertakings established as legal persons, including the name and the form of the legal person and the contact details of the legal person.

(15) In order to prevent creating a serious risk of circumvention, the protection of natural persons should be technologically neutral and should not depend on the techniques used. The protection of natural persons should apply to the processing of personal data by automated means, as well as to manual processing, if the personal data are contained or are intended to be contained in a filing system. Files or sets of files, as well as their cover pages, which are not structured according to specific criteria should not fall within the scope of this Regulation.

(16) This Regulation does not apply to issues of protection of fundamental rights and freedoms or the free flow of personal data related to activities which fall outside the scope of Union law, such as activities concerning national security. This Regulation does not apply to the processing of personal data by the Member States when carrying out activities in relation to the common foreign and security policy of the Union.

(17) Regulation (EC) No 45/2001 of the European Parliament and of the Council ([2]) applies to the processing of personal data by the Union institutions, bodies, offices and agencies. Regulation (EC) No 45/2001 and other Union legal acts applicable to such processing of personal data should be adapted to the principles and rules established in this Regulation and applied in the light of this Regulation. In order to provide a strong and coherent data protection framework in the Union, the necessary adaptations of Regulation (EC) No 45/2001 should follow after the adoption of this Regulation, in order to allow application at the same time as this Regulation.

(18) This Regulation does not apply to the processing of personal data by a natural person in the course of a purely personal or household activity and thus with no connection to a professional or commercial activity. Personal or

([1]) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (C(2003) 1422) (OJ L 124, 20.5.2003, p. 36).

([2]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

household activities could include correspondence and the holding of addresses, or social networking and online activity undertaken within the context of such activities. However, this Regulation applies to controllers or processors which provide the means for processing personal data for such personal or household activities.

(19) The protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security and the free movement of such data, is the subject of a specific Union legal act. This Regulation should not, therefore, apply to processing activities for those purposes. However, personal data processed by public authorities under this Regulation should, when used for those purposes, be governed by a more specific Union legal act, namely Directive (EU) 2016/680 of the European Parliament and of the Council ([1]). Member States may entrust competent authorities within the meaning of Directive (EU) 2016/680 with tasks which are not necessarily carried out for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and prevention of threats to public security, so that the processing of personal data for those other purposes, in so far as it is within the scope of Union law, falls within the scope of this Regulation.

With regard to the processing of personal data by those competent authorities for purposes falling within scope of this Regulation, Member States should be able to maintain or introduce more specific provisions to adapt the application of the rules of this Regulation. Such provisions may determine more precisely specific requirements for the processing of personal data by those competent authorities for those other purposes, taking into account the constitutional, organisational and administrative structure of the respective Member State. When the processing of personal data by private bodies falls within the scope of this Regulation, this Regulation should provide for the possibility for Member States under specific conditions to restrict by law certain obligations and rights when such a restriction constitutes a necessary and proportionate measure in a democratic society to safeguard specific important interests including public security and the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security. This is relevant for instance in the framework of anti-money laundering or the activities of forensic laboratories.

(20) While this Regulation applies, inter alia, to the activities of courts and other judicial authorities, Union or Member State law could specify the processing operations and processing procedures in relation to the processing of personal data by courts and other judicial authorities. The competence of the supervisory authorities should not cover the processing of personal data when courts are acting in their judicial capacity, in order to safeguard the independence of the judiciary in the performance of its judicial tasks, including decision-making. It should be possible to entrust supervision of such data processing operations to specific bodies within the judicial system of the Member State, which should, in particular ensure compliance with the rules of this Regulation, enhance awareness among members of the judiciary of their obligations under this Regulation and handle complaints in relation to such data processing operations.

(21) This Regulation is without prejudice to the application of Directive 2000/31/EC of the European Parliament and of the Council ([2]), in particular of the liability rules of intermediary service providers in Articles 12 to 15 of that Directive. That Directive seeks to contribute to the proper functioning of the internal market by ensuring the free movement of information society services between Member States.

(22) Any processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union should be carried out in accordance with this Regulation, regardless of whether the processing itself takes place within the Union. Establishment implies the effective and real exercise of activity through stable arrangements. The legal form of such arrangements, whether through a branch or a subsidiary with a legal personality, is not the determining factor in that respect.

([1]) Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data and repealing Council Framework Decision 2008/977/JHA (see page 89 of this Official Journal).

([2]) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

(23) In order to ensure that natural persons are not deprived of the protection to which they are entitled under this Regulation, the processing of personal data of data subjects who are in the Union by a controller or a processor not established in the Union should be subject to this Regulation where the processing activities are related to offering goods or services to such data subjects irrespective of whether connected to a payment. In order to determine whether such a controller or processor is offering goods or services to data subjects who are in the Union, it should be ascertained whether it is apparent that the controller or processor envisages offering services to data subjects in one or more Member States in the Union. Whereas the mere accessibility of the controller's, processor's or an intermediary's website in the Union, of an email address or of other contact details, or the use of a language generally used in the third country where the controller is established, is insufficient to ascertain such intention, factors such as the use of a language or a currency generally used in one or more Member States with the possibility of ordering goods and services in that other language, or the mentioning of customers or users who are in the Union, may make it apparent that the controller envisages offering goods or services to data subjects in the Union.

(24) The processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union should also be subject to this Regulation when it is related to the monitoring of the behaviour of such data subjects in so far as their behaviour takes place within the Union. In order to determine whether a processing activity can be considered to monitor the behaviour of data subjects, it should be ascertained whether natural persons are tracked on the internet including potential subsequent use of personal data processing techniques which consist of profiling a natural person, particularly in order to take decisions concerning her or him or for analysing or predicting her or his personal preferences, behaviours and attitudes.

(25) Where Member State law applies by virtue of public international law, this Regulation should also apply to a controller not established in the Union, such as in a Member State's diplomatic mission or consular post.

(26) The principles of data protection should apply to any information concerning an identified or identifiable natural person. Personal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person. To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments. The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes.

(27) This Regulation does not apply to the personal data of deceased persons. Member States may provide for rules regarding the processing of personal data of deceased persons.

(28) The application of pseudonymisation to personal data can reduce the risks to the data subjects concerned and help controllers and processors to meet their data-protection obligations. The explicit introduction of 'pseudonymisation' in this Regulation is not intended to preclude any other measures of data protection.

(29) In order to create incentives to apply pseudonymisation when processing personal data, measures of pseudonymisation should, whilst allowing general analysis, be possible within the same controller when that controller has taken technical and organisational measures necessary to ensure, for the processing concerned, that this Regulation is implemented, and that additional information for attributing the personal data to a specific data subject is kept separately. The controller processing the personal data should indicate the authorised persons within the same controller.

(30) Natural persons may be associated with online identifiers provided by their devices, applications, tools and protocols, such as internet protocol addresses, cookie identifiers or other identifiers such as radio frequency identification tags. This may leave traces which, in particular when combined with unique identifiers and other information received by the servers, may be used to create profiles of the natural persons and identify them.

(31) Public authorities to which personal data are disclosed in accordance with a legal obligation for the exercise of their official mission, such as tax and customs authorities, financial investigation units, independent administrative authorities, or financial market authorities responsible for the regulation and supervision of securities markets should not be regarded as recipients if they receive personal data which are necessary to carry out a particular inquiry in the general interest, in accordance with Union or Member State law. The requests for disclosure sent by the public authorities should always be in writing, reasoned and occasional and should not concern the entirety of a filing system or lead to the interconnection of filing systems. The processing of personal data by those public authorities should comply with the applicable data-protection rules according to the purposes of the processing.

(32) Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject's consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.

(33) It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

(34) Genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained.

(35) Personal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council ([1]) to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.

(36) The main establishment of a controller in the Union should be the place of its central administration in the Union, unless the decisions on the purposes and means of the processing of personal data are taken in another establishment of the controller in the Union, in which case that other establishment should be considered to be

([1]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

the main establishment. The main establishment of a controller in the Union should be determined according to objective criteria and should imply the effective and real exercise of management activities determining the main decisions as to the purposes and means of processing through stable arrangements. That criterion should not depend on whether the processing of personal data is carried out at that location. The presence and use of technical means and technologies for processing personal data or processing activities do not, in themselves, constitute a main establishment and are therefore not determining criteria for a main establishment. The main establishment of the processor should be the place of its central administration in the Union or, if it has no central administration in the Union, the place where the main processing activities take place in the Union. In cases involving both the controller and the processor, the competent lead supervisory authority should remain the supervisory authority of the Member State where the controller has its main establishment, but the supervisory authority of the processor should be considered to be a supervisory authority concerned and that supervisory authority should participate in the cooperation procedure provided for by this Regulation. In any case, the supervisory authorities of the Member State or Member States where the processor has one or more establishments should not be considered to be supervisory authorities concerned where the draft decision concerns only the controller. Where the processing is carried out by a group of undertakings, the main establishment of the controlling undertaking should be considered to be the main establishment of the group of undertakings, except where the purposes and means of processing are determined by another undertaking.

(37) A group of undertakings should cover a controlling undertaking and its controlled undertakings, whereby the controlling undertaking should be the undertaking which can exert a dominant influence over the other undertakings by virtue, for example, of ownership, financial participation or the rules which govern it or the power to have personal data protection rules implemented. An undertaking which controls the processing of personal data in undertakings affiliated to it should be regarded, together with those undertakings, as a group of undertakings.

(38) Children merit specific protection with regard to their personal data, as they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data. Such specific protection should, in particular, apply to the use of personal data of children for the purposes of marketing or creating personality or user profiles and the collection of personal data with regard to children when using services offered directly to a child. The consent of the holder of parental responsibility should not be necessary in the context of preventive or counselling services offered directly to a child.

(39) Any processing of personal data should be lawful and fair. It should be transparent to natural persons that personal data concerning them are collected, used, consulted or otherwise processed and to what extent the personal data are or will be processed. The principle of transparency requires that any information and communication relating to the processing of those personal data be easily accessible and easy to understand, and that clear and plain language be used. That principle concerns, in particular, information to the data subjects on the identity of the controller and the purposes of the processing and further information to ensure fair and transparent processing in respect of the natural persons concerned and their right to obtain confirmation and communication of personal data concerning them which are being processed. Natural persons should be made aware of risks, rules, safeguards and rights in relation to the processing of personal data and how to exercise their rights in relation to such processing. In particular, the specific purposes for which personal data are processed should be explicit and legitimate and determined at the time of the collection of the personal data. The personal data should be adequate, relevant and limited to what is necessary for the purposes for which they are processed. This requires, in particular, ensuring that the period for which the personal data are stored is limited to a strict minimum. Personal data should be processed only if the purpose of the processing could not reasonably be fulfilled by other means. In order to ensure that the personal data are not kept longer than necessary, time limits should be established by the controller for erasure or for a periodic review. Every reasonable step should be taken to ensure that personal data which are inaccurate are rectified or deleted. Personal data should be processed in a manner that ensures appropriate security and confidentiality of the personal data, including for preventing unauthorised access to or use of personal data and the equipment used for the processing.

(40) In order for processing to be lawful, personal data should be processed on the basis of the consent of the data subject concerned or some other legitimate basis, laid down by law, either in this Regulation or in other Union or

Member State law as referred to in this Regulation, including the necessity for compliance with the legal obligation to which the controller is subject or the necessity for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract.

(41) Where this Regulation refers to a legal basis or a legislative measure, this does not necessarily require a legislative act adopted by a parliament, without prejudice to requirements pursuant to the constitutional order of the Member State concerned. However, such a legal basis or legislative measure should be clear and precise and its application should be foreseeable to persons subject to it, in accordance with the case-law of the Court of Justice of the European Union (the 'Court of Justice') and the European Court of Human Rights.

(42) Where processing is based on the data subject's consent, the controller should be able to demonstrate that the data subject has given consent to the processing operation. In particular in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware of the fact that and the extent to which consent is given. In accordance with Council Directive 93/13/EEC ([1]) a declaration of consent pre-formulated by the controller should be provided in an intelligible and easily accessible form, using clear and plain language and it should not contain unfair terms. For consent to be informed, the data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended. Consent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment.

(43) In order to ensure that consent is freely given, consent should not provide a valid legal ground for the processing of personal data in a specific case where there is a clear imbalance between the data subject and the controller, in particular where the controller is a public authority and it is therefore unlikely that consent was freely given in all the circumstances of that specific situation. Consent is presumed not to be freely given if it does not allow separate consent to be given to different personal data processing operations despite it being appropriate in the individual case, or if the performance of a contract, including the provision of a service, is dependent on the consent despite such consent not being necessary for such performance.

(44) Processing should be lawful where it is necessary in the context of a contract or the intention to enter into a contract.

(45) Where processing is carried out in accordance with a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority, the processing should have a basis in Union or Member State law. This Regulation does not require a specific law for each individual processing. A law as a basis for several processing operations based on a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of an official authority may be sufficient. It should also be for Union or Member State law to determine the purpose of processing. Furthermore, that law could specify the general conditions of this Regulation governing the lawfulness of personal data processing, establish specifications for determining the controller, the type of personal data which are subject to the processing, the data subjects concerned, the entities to which the personal data may be disclosed, the purpose limitations, the storage period and other measures to ensure lawful and fair processing. It should also be for Union or Member State law to determine whether the controller performing a task carried out in the public interest or in the exercise of official authority should be a public authority or another natural or legal person governed by public law, or, where it is in the public interest to do so, including for health purposes such as public health and social protection and the management of health care services, by private law, such as a professional association.

(46) The processing of personal data should also be regarded to be lawful where it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal data

([1]) Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ L 95, 21.4.1993, p. 29).

based on the vital interest of another natural person should in principle take place only where the processing cannot be manifestly based on another legal basis. Some types of processing may serve both important grounds of public interest and the vital interests of the data subject as for instance when processing is necessary for humanitarian purposes, including for monitoring epidemics and their spread or in situations of humanitarian emergencies, in particular in situations of natural and man-made disasters.

(47) The legitimate interests of a controller, including those of a controller to which the personal data may be disclosed, or of a third party, may provide a legal basis for processing, provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, taking into consideration the reasonable expectations of data subjects based on their relationship with the controller. Such legitimate interest could exist for example where there is a relevant and appropriate relationship between the data subject and the controller in situations such as where the data subject is a client or in the service of the controller. At any rate the existence of a legitimate interest would need careful assessment including whether a data subject can reasonably expect at the time and in the context of the collection of the personal data that processing for that purpose may take place. The interests and fundamental rights of the data subject could in particular override the interest of the data controller where personal data are processed in circumstances where data subjects do not reasonably expect further processing. Given that it is for the legislator to provide by law for the legal basis for public authorities to process personal data, that legal basis should not apply to the processing by public authorities in the performance of their tasks. The processing of personal data strictly necessary for the purposes of preventing fraud also constitutes a legitimate interest of the data controller concerned. The processing of personal data for direct marketing purposes may be regarded as carried out for a legitimate interest.

(48) Controllers that are part of a group of undertakings or institutions affiliated to a central body may have a legitimate interest in transmitting personal data within the group of undertakings for internal administrative purposes, including the processing of clients' or employees' personal data. The general principles for the transfer of personal data, within a group of undertakings, to an undertaking located in a third country remain unaffected.

(49) The processing of personal data to the extent strictly necessary and proportionate for the purposes of ensuring network and information security, i.e. the ability of a network or an information system to resist, at a given level of confidence, accidental events or unlawful or malicious actions that compromise the availability, authenticity, integrity and confidentiality of stored or transmitted personal data, and the security of the related services offered by, or accessible via, those networks and systems, by public authorities, by computer emergency response teams (CERTs), computer security incident response teams (CSIRTs), by providers of electronic communications networks and services and by providers of security technologies and services, constitutes a legitimate interest of the data controller concerned. This could, for example, include preventing unauthorised access to electronic communications networks and malicious code distribution and stopping 'denial of service' attacks and damage to computer and electronic communication systems.

(50) The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required. If the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, Union or Member State law may determine and specify the tasks and purposes for which the further processing should be regarded as compatible and lawful. Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations. The legal basis provided by Union or Member State law for the processing of personal data may also provide a legal basis for further processing. In order to ascertain whether a purpose of further processing is compatible with the purpose for which the personal data are initially collected, the controller, after having met all the requirements for the lawfulness of the original processing, should take into account, inter alia: any link between those purposes and the purposes of the intended further processing; the context in which the personal data have been collected, in particular the reasonable expectations of data subjects based on their relationship with the controller as to their

further use; the nature of the personal data; the consequences of the intended further processing for data subjects; and the existence of appropriate safeguards in both the original and intended further processing operations.

Where the data subject has given consent or the processing is based on Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard, in particular, important objectives of general public interest, the controller should be allowed to further process the personal data irrespective of the compatibility of the purposes. In any case, the application of the principles set out in this Regulation and in particular the information of the data subject on those other purposes and on his or her rights including the right to object, should be ensured. Indicating possible criminal acts or threats to public security by the controller and transmitting the relevant personal data in individual cases or in several cases relating to the same criminal act or threats to public security to a competent authority should be regarded as being in the legitimate interest pursued by the controller. However, such transmission in the legitimate interest of the controller or further processing of personal data should be prohibited if the processing is not compatible with a legal, professional or other binding obligation of secrecy.

(51) Personal data which are, by their nature, particularly sensitive in relation to fundamental rights and freedoms merit specific protection as the context of their processing could create significant risks to the fundamental rights and freedoms. Those personal data should include personal data revealing racial or ethnic origin, whereby the use of the term 'racial origin' in this Regulation does not imply an acceptance by the Union of theories which attempt to determine the existence of separate human races. The processing of photographs should not systematically be considered to be processing of special categories of personal data as they are covered by the definition of biometric data only when processed through a specific technical means allowing the unique identification or authentication of a natural person. Such personal data should not be processed, unless processing is allowed in specific cases set out in this Regulation, taking into account that Member States law may lay down specific provisions on data protection in order to adapt the application of the rules of this Regulation for compliance with a legal obligation or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. In addition to the specific requirements for such processing, the general principles and other rules of this Regulation should apply, in particular as regards the conditions for lawful processing. Derogations from the general prohibition for processing such special categories of personal data should be explicitly provided, inter alia, where the data subject gives his or her explicit consent or in respect of specific needs in particular where the processing is carried out in the course of legitimate activities by certain associations or foundations the purpose of which is to permit the exercise of fundamental freedoms.

(52) Derogating from the prohibition on processing special categories of personal data should also be allowed when provided for in Union or Member State law and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where it is in the public interest to do so, in particular processing personal data in the field of employment law, social protection law including pensions and for health security, monitoring and alert purposes, the prevention or control of communicable diseases and other serious threats to health. Such a derogation may be made for health purposes, including public health and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. A derogation should also allow the processing of such personal data where necessary for the establishment, exercise or defence of legal claims, whether in court proceedings or in an administrative or out-of-court procedure.

(53) Special categories of personal data which merit higher protection should be processed for health-related purposes only where necessary to achieve those purposes for the benefit of natural persons and society as a whole, in particular in the context of the management of health or social care services and systems, including processing by the management and central national health authorities of such data for the purpose of quality control, management information and the general national and local supervision of the health or social care system, and ensuring continuity of health or social care and cross-border healthcare or health security, monitoring and alert purposes, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, based on Union or Member State law which has to meet an objective of public interest, as well as for studies conducted in the public interest in the area of public health. Therefore, this Regulation should provide for harmonised conditions for the processing of special categories of personal data concerning health, in respect of specific needs, in particular where the processing of such data is carried out for certain health-related purposes

by persons subject to a legal obligation of professional secrecy. Union or Member State law should provide for specific and suitable measures so as to protect the fundamental rights and the personal data of natural persons. Member States should be allowed to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. However, this should not hamper the free flow of personal data within the Union when those conditions apply to cross-border processing of such data.

(54) The processing of special categories of personal data may be necessary for reasons of public interest in the areas of public health without consent of the data subject. Such processing should be subject to suitable and specific measures so as to protect the rights and freedoms of natural persons. In that context, 'public health' should be interpreted as defined in Regulation (EC) No 1338/2008 of the European Parliament and of the Council ([1]), namely all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality. Such processing of data concerning health for reasons of public interest should not result in personal data being processed for other purposes by third parties such as employers or insurance and banking companies.

(55) Moreover, the processing of personal data by official authorities for the purpose of achieving the aims, laid down by constitutional law or by international public law, of officially recognised religious associations, is carried out on grounds of public interest.

(56) Where in the course of electoral activities, the operation of the democratic system in a Member State requires that political parties compile personal data on people's political opinions, the processing of such data may be permitted for reasons of public interest, provided that appropriate safeguards are established.

(57) If the personal data processed by a controller do not permit the controller to identify a natural person, the data controller should not be obliged to acquire additional information in order to identify the data subject for the sole purpose of complying with any provision of this Regulation. However, the controller should not refuse to take additional information provided by the data subject in order to support the exercise of his or her rights. Identification should include the digital identification of a data subject, for example through authentication mechanism such as the same credentials, used by the data subject to log-in to the on-line service offered by the data controller.

(58) The principle of transparency requires that any information addressed to the public or to the data subject be concise, easily accessible and easy to understand, and that clear and plain language and, additionally, where appropriate, visualisation be used. Such information could be provided in electronic form, for example, when addressed to the public, through a website. This is of particular relevance in situations where the proliferation of actors and the technological complexity of practice make it difficult for the data subject to know and understand whether, by whom and for what purpose personal data relating to him or her are being collected, such as in the case of online advertising. Given that children merit specific protection, any information and communication, where processing is addressed to a child, should be in such a clear and plain language that the child can easily understand.

(59) Modalities should be provided for facilitating the exercise of the data subject's rights under this Regulation, including mechanisms to request and, if applicable, obtain, free of charge, in particular, access to and rectification or erasure of personal data and the exercise of the right to object. The controller should also provide means for requests to be made electronically, especially where personal data are processed by electronic means. The controller should be obliged to respond to requests from the data subject without undue delay and at the latest within one month and to give reasons where the controller does not intend to comply with any such requests.

([1]) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work (OJ L 354, 31.12.2008, p. 70).

(60) The principles of fair and transparent processing require that the data subject be informed of the existence of the processing operation and its purposes. The controller should provide the data subject with any further information necessary to ensure fair and transparent processing taking into account the specific circumstances and context in which the personal data are processed. Furthermore, the data subject should be informed of the existence of profiling and the consequences of such profiling. Where the personal data are collected from the data subject, the data subject should also be informed whether he or she is obliged to provide the personal data and of the consequences, where he or she does not provide such data. That information may be provided in combination with standardised icons in order to give in an easily visible, intelligible and clearly legible manner, a meaningful overview of the intended processing. Where the icons are presented electronically, they should be machine-readable.

(61) The information in relation to the processing of personal data relating to the data subject should be given to him or her at the time of collection from the data subject, or, where the personal data are obtained from another source, within a reasonable period, depending on the circumstances of the case. Where personal data can be legitimately disclosed to another recipient, the data subject should be informed when the personal data are first disclosed to the recipient. Where the controller intends to process the personal data for a purpose other than that for which they were collected, the controller should provide the data subject prior to that further processing with information on that other purpose and other necessary information. Where the origin of the personal data cannot be provided to the data subject because various sources have been used, general information should be provided.

(62) However, it is not necessary to impose the obligation to provide information where the data subject already possesses the information, where the recording or disclosure of the personal data is expressly laid down by law or where the provision of information to the data subject proves to be impossible or would involve a disproportionate effort. The latter could in particular be the case where processing is carried out for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. In that regard, the number of data subjects, the age of the data and any appropriate safeguards adopted should be taken into consideration.

(63) A data subject should have the right of access to personal data which have been collected concerning him or her, and to exercise that right easily and at reasonable intervals, in order to be aware of, and verify, the lawfulness of the processing. This includes the right for data subjects to have access to data concerning their health, for example the data in their medical records containing information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided. Every data subject should therefore have the right to know and obtain communication in particular with regard to the purposes for which the personal data are processed, where possible the period for which the personal data are processed, the recipients of the personal data, the logic involved in any automatic personal data processing and, at least when based on profiling, the consequences of such processing. Where possible, the controller should be able to provide remote access to a secure system which would provide the data subject with direct access to his or her personal data. That right should not adversely affect the rights or freedoms of others, including trade secrets or intellectual property and in particular the copyright protecting the software. However, the result of those considerations should not be a refusal to provide all information to the data subject. Where the controller processes a large quantity of information concerning the data subject, the controller should be able to request that, before the information is delivered, the data subject specify the information or processing activities to which the request relates.

(64) The controller should use all reasonable measures to verify the identity of a data subject who requests access, in particular in the context of online services and online identifiers. A controller should not retain personal data for the sole purpose of being able to react to potential requests.

(65) A data subject should have the right to have personal data concerning him or her rectified and a 'right to be forgotten' where the retention of such data infringes this Regulation or Union or Member State law to which the controller is subject. In particular, a data subject should have the right to have his or her personal data erased and no longer processed where the personal data are no longer necessary in relation to the purposes for which they are collected or otherwise processed, where a data subject has withdrawn his or her consent or objects to the processing of personal data concerning him or her, or where the processing of his or her personal data does not otherwise comply with this Regulation. That right is relevant in particular where the data subject has given

his or her consent as a child and is not fully aware of the risks involved by the processing, and later wants to remove such personal data, especially on the internet. The data subject should be able to exercise that right notwithstanding the fact that he or she is no longer a child. However, the further retention of the personal data should be lawful where it is necessary, for exercising the right of freedom of expression and information, for compliance with a legal obligation, for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, on the grounds of public interest in the area of public health, for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, or for the establishment, exercise or defence of legal claims.

(66) To strengthen the right to be forgotten in the online environment, the right to erasure should also be extended in such a way that a controller who has made the personal data public should be obliged to inform the controllers which are processing such personal data to erase any links to, or copies or replications of those personal data. In doing so, that controller should take reasonable steps, taking into account available technology and the means available to the controller, including technical measures, to inform the controllers which are processing the personal data of the data subject's request.

(67) Methods by which to restrict the processing of personal data could include, inter alia, temporarily moving the selected data to another processing system, making the selected personal data unavailable to users, or temporarily removing published data from a website. In automated filing systems, the restriction of processing should in principle be ensured by technical means in such a manner that the personal data are not subject to further processing operations and cannot be changed. The fact that the processing of personal data is restricted should be clearly indicated in the system.

(68) To further strengthen the control over his or her own data, where the processing of personal data is carried out by automated means, the data subject should also be allowed to receive personal data concerning him or her which he or she has provided to a controller in a structured, commonly used, machine-readable and interoperable format, and to transmit it to another controller. Data controllers should be encouraged to develop interoperable formats that enable data portability. That right should apply where the data subject provided the personal data on the basis of his or her consent or the processing is necessary for the performance of a contract. It should not apply where processing is based on a legal ground other than consent or contract. By its very nature, that right should not be exercised against controllers processing personal data in the exercise of their public duties. It should therefore not apply where the processing of the personal data is necessary for compliance with a legal obligation to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of an official authority vested in the controller. The data subject's right to transmit or receive personal data concerning him or her should not create an obligation for the controllers to adopt or maintain processing systems which are technically compatible. Where, in a certain set of personal data, more than one data subject is concerned, the right to receive the personal data should be without prejudice to the rights and freedoms of other data subjects in accordance with this Regulation. Furthermore, that right should not prejudice the right of the data subject to obtain the erasure of personal data and the limitations of that right as set out in this Regulation and should, in particular, not imply the erasure of personal data concerning the data subject which have been provided by him or her for the performance of a contract to the extent that and for as long as the personal data are necessary for the performance of that contract. Where technically feasible, the data subject should have the right to have the personal data transmitted directly from one controller to another.

(69) Where personal data might lawfully be processed because processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, or on grounds of the legitimate interests of a controller or a third party, a data subject should, nevertheless, be entitled to object to the processing of any personal data relating to his or her particular situation. It should be for the controller to demonstrate that its compelling legitimate interest overrides the interests or the fundamental rights and freedoms of the data subject.

(70) Where personal data are processed for the purposes of direct marketing, the data subject should have the right to object to such processing, including profiling to the extent that it is related to such direct marketing, whether with regard to initial or further processing, at any time and free of charge. That right should be explicitly brought to the attention of the data subject and presented clearly and separately from any other information.

(71) The data subject should have the right not to be subject to a decision, which may include a measure, evaluating personal aspects relating to him or her which is based solely on automated processing and which produces legal effects concerning him or her or similarly significantly affects him or her, such as automatic refusal of an online credit application or e-recruiting practices without any human intervention. Such processing includes 'profiling' that consists of any form of automated processing of personal data evaluating the personal aspects relating to a natural person, in particular to analyse or predict aspects concerning the data subject's performance at work, economic situation, health, personal preferences or interests, reliability or behaviour, location or movements, where it produces legal effects concerning him or her or similarly significantly affects him or her. However, decision-making based on such processing, including profiling, should be allowed where expressly authorised by Union or Member State law to which the controller is subject, including for fraud and tax-evasion monitoring and prevention purposes conducted in accordance with the regulations, standards and recommendations of Union institutions or national oversight bodies and to ensure the security and reliability of a service provided by the controller, or necessary for the entering or performance of a contract between the data subject and a controller, or when the data subject has given his or her explicit consent. In any case, such processing should be subject to suitable safeguards, which should include specific information to the data subject and the right to obtain human intervention, to express his or her point of view, to obtain an explanation of the decision reached after such assessment and to challenge the decision. Such measure should not concern a child.

In order to ensure fair and transparent processing in respect of the data subject, taking into account the specific circumstances and context in which the personal data are processed, the controller should use appropriate mathematical or statistical procedures for the profiling, implement technical and organisational measures appropriate to ensure, in particular, that factors which result in inaccuracies in personal data are corrected and the risk of errors is minimised, secure personal data in a manner that takes account of the potential risks involved for the interests and rights of the data subject and that prevents, inter alia, discriminatory effects on natural persons on the basis of racial or ethnic origin, political opinion, religion or beliefs, trade union membership, genetic or health status or sexual orientation, or that result in measures having such an effect. Automated decision-making and profiling based on special categories of personal data should be allowed only under specific conditions.

(72) Profiling is subject to the rules of this Regulation governing the processing of personal data, such as the legal grounds for processing or data protection principles. The European Data Protection Board established by this Regulation (the 'Board') should be able to issue guidance in that context.

(73) Restrictions concerning specific principles and the rights of information, access to and rectification or erasure of personal data, the right to data portability, the right to object, decisions based on profiling, as well as the communication of a personal data breach to a data subject and certain related obligations of the controllers may be imposed by Union or Member State law, as far as necessary and proportionate in a democratic society to safeguard public security, including the protection of human life especially in response to natural or manmade disasters, the prevention, investigation and prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, or of breaches of ethics for regulated professions, other important objectives of general public interest of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, the keeping of public registers kept for reasons of general public interest, further processing of archived personal data to provide specific information related to the political behaviour under former totalitarian state regimes or the protection of the data subject or the rights and freedoms of others, including social protection, public health and humanitarian purposes. Those restrictions should be in accordance with the requirements set out in the Charter and in the European Convention for the Protection of Human Rights and Fundamental Freedoms.

(74) The responsibility and liability of the controller for any processing of personal data carried out by the controller or on the controller's behalf should be established. In particular, the controller should be obliged to implement appropriate and effective measures and be able to demonstrate the compliance of processing activities with this Regulation, including the effectiveness of the measures. Those measures should take into account the nature, scope, context and purposes of the processing and the risk to the rights and freedoms of natural persons.

(75) The risk to the rights and freedoms of natural persons, of varying likelihood and severity, may result from personal data processing which could lead to physical, material or non-material damage, in particular: where the processing may give rise to discrimination, identity theft or fraud, financial loss, damage to the reputation, loss of confidentiality of personal data protected by professional secrecy, unauthorised reversal of pseudonymisation, or any other significant economic or social disadvantage; where data subjects might be deprived of their rights and freedoms or prevented from exercising control over their personal data; where personal data are processed which reveal racial or ethnic origin, political opinions, religion or philosophical beliefs, trade union membership, and the processing of genetic data, data concerning health or data concerning sex life or criminal convictions and offences or related security measures; where personal aspects are evaluated, in particular analysing or predicting aspects concerning performance at work, economic situation, health, personal preferences or interests, reliability or behaviour, location or movements, in order to create or use personal profiles; where personal data of vulnerable natural persons, in particular of children, are processed; or where processing involves a large amount of personal data and affects a large number of data subjects.

(76) The likelihood and severity of the risk to the rights and freedoms of the data subject should be determined by reference to the nature, scope, context and purposes of the processing. Risk should be evaluated on the basis of an objective assessment, by which it is established whether data processing operations involve a risk or a high risk.

(77) Guidance on the implementation of appropriate measures and on the demonstration of compliance by the controller or the processor, especially as regards the identification of the risk related to the processing, their assessment in terms of origin, nature, likelihood and severity, and the identification of best practices to mitigate the risk, could be provided in particular by means of approved codes of conduct, approved certifications, guidelines provided by the Board or indications provided by a data protection officer. The Board may also issue guidelines on processing operations that are considered to be unlikely to result in a high risk to the rights and freedoms of natural persons and indicate what measures may be sufficient in such cases to address such risk.

(78) The protection of the rights and freedoms of natural persons with regard to the processing of personal data require that appropriate technical and organisational measures be taken to ensure that the requirements of this Regulation are met. In order to be able to demonstrate compliance with this Regulation, the controller should adopt internal policies and implement measures which meet in particular the principles of data protection by design and data protection by default. Such measures could consist, inter alia, of minimising the processing of personal data, pseudonymising personal data as soon as possible, transparency with regard to the functions and processing of personal data, enabling the data subject to monitor the data processing, enabling the controller to create and improve security features. When developing, designing, selecting and using applications, services and products that are based on the processing of personal data or process personal data to fulfil their task, producers of the products, services and applications should be encouraged to take into account the right to data protection when developing and designing such products, services and applications and, with due regard to the state of the art, to make sure that controllers and processors are able to fulfil their data protection obligations. The principles of data protection by design and by default should also be taken into consideration in the context of public tenders.

(79) The protection of the rights and freedoms of data subjects as well as the responsibility and liability of controllers and processors, also in relation to the monitoring by and measures of supervisory authorities, requires a clear allocation of the responsibilities under this Regulation, including where a controller determines the purposes and means of the processing jointly with other controllers or where a processing operation is carried out on behalf of a controller.

(80) Where a controller or a processor not established in the Union is processing personal data of data subjects who are in the Union whose processing activities are related to the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union, or to the monitoring of their behaviour as far as their behaviour takes place within the Union, the controller or the processor should designate a representative, unless the processing is occasional, does not include processing, on a large scale, of special categories of personal data or the processing of personal data relating to criminal convictions and offences, and is unlikely to result in a risk to the rights and freedoms of natural persons, taking into account the

nature, context, scope and purposes of the processing or if the controller is a public authority or body. The representative should act on behalf of the controller or the processor and may be addressed by any supervisory authority. The representative should be explicitly designated by a written mandate of the controller or of the processor to act on its behalf with regard to its obligations under this Regulation. The designation of such a representative does not affect the responsibility or liability of the controller or of the processor under this Regulation. Such a representative should perform its tasks according to the mandate received from the controller or processor, including cooperating with the competent supervisory authorities with regard to any action taken to ensure compliance with this Regulation. The designated representative should be subject to enforcement proceedings in the event of non-compliance by the controller or processor.

(81) To ensure compliance with the requirements of this Regulation in respect of the processing to be carried out by the processor on behalf of the controller, when entrusting a processor with processing activities, the controller should use only processors providing sufficient guarantees, in particular in terms of expert knowledge, reliability and resources, to implement technical and organisational measures which will meet the requirements of this Regulation, including for the security of processing. The adherence of the processor to an approved code of conduct or an approved certification mechanism may be used as an element to demonstrate compliance with the obligations of the controller. The carrying-out of processing by a processor should be governed by a contract or other legal act under Union or Member State law, binding the processor to the controller, setting out the subject-matter and duration of the processing, the nature and purposes of the processing, the type of personal data and categories of data subjects, taking into account the specific tasks and responsibilities of the processor in the context of the processing to be carried out and the risk to the rights and freedoms of the data subject. The controller and processor may choose to use an individual contract or standard contractual clauses which are adopted either directly by the Commission or by a supervisory authority in accordance with the consistency mechanism and then adopted by the Commission. After the completion of the processing on behalf of the controller, the processor should, at the choice of the controller, return or delete the personal data, unless there is a requirement to store the personal data under Union or Member State law to which the processor is subject.

(82) In order to demonstrate compliance with this Regulation, the controller or processor should maintain records of processing activities under its responsibility. Each controller and processor should be obliged to cooperate with the supervisory authority and make those records, on request, available to it, so that it might serve for monitoring those processing operations.

(83) In order to maintain security and to prevent processing in infringement of this Regulation, the controller or processor should evaluate the risks inherent in the processing and implement measures to mitigate those risks, such as encryption. Those measures should ensure an appropriate level of security, including confidentiality, taking into account the state of the art and the costs of implementation in relation to the risks and the nature of the personal data to be protected. In assessing data security risk, consideration should be given to the risks that are presented by personal data processing, such as accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed which may in particular lead to physical, material or non-material damage.

(84) In order to enhance compliance with this Regulation where processing operations are likely to result in a high risk to the rights and freedoms of natural persons, the controller should be responsible for the carrying-out of a data protection impact assessment to evaluate, in particular, the origin, nature, particularity and severity of that risk. The outcome of the assessment should be taken into account when determining the appropriate measures to be taken in order to demonstrate that the processing of personal data complies with this Regulation. Where a data-protection impact assessment indicates that processing operations involve a high risk which the controller cannot mitigate by appropriate measures in terms of available technology and costs of implementation, a consultation of the supervisory authority should take place prior to the processing.

(85) A personal data breach may, if not addressed in an appropriate and timely manner, result in physical, material or non-material damage to natural persons such as loss of control over their personal data or limitation of their rights, discrimination, identity theft or fraud, financial loss, unauthorised reversal of pseudonymisation, damage to reputation, loss of confidentiality of personal data protected by professional secrecy or any other significant economic or social disadvantage to the natural person concerned. Therefore, as soon as the controller becomes

aware that a personal data breach has occurred, the controller should notify the personal data breach to the supervisory authority without undue delay and, where feasible, not later than 72 hours after having become aware of it, unless the controller is able to demonstrate, in accordance with the accountability principle, that the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. Where such notification cannot be achieved within 72 hours, the reasons for the delay should accompany the notification and information may be provided in phases without undue further delay.

(86) The controller should communicate to the data subject a personal data breach, without undue delay, where that personal data breach is likely to result in a high risk to the rights and freedoms of the natural person in order to allow him or her to take the necessary precautions. The communication should describe the nature of the personal data breach as well as recommendations for the natural person concerned to mitigate potential adverse effects. Such communications to data subjects should be made as soon as reasonably feasible and in close cooperation with the supervisory authority, respecting guidance provided by it or by other relevant authorities such as law-enforcement authorities. For example, the need to mitigate an immediate risk of damage would call for prompt communication with data subjects whereas the need to implement appropriate measures against continuing or similar personal data breaches may justify more time for communication.

(87) It should be ascertained whether all appropriate technological protection and organisational measures have been implemented to establish immediately whether a personal data breach has taken place and to inform promptly the supervisory authority and the data subject. The fact that the notification was made without undue delay should be established taking into account in particular the nature and gravity of the personal data breach and its consequences and adverse effects for the data subject. Such notification may result in an intervention of the supervisory authority in accordance with its tasks and powers laid down in this Regulation.

(88) In setting detailed rules concerning the format and procedures applicable to the notification of personal data breaches, due consideration should be given to the circumstances of that breach, including whether or not personal data had been protected by appropriate technical protection measures, effectively limiting the likelihood of identity fraud or other forms of misuse. Moreover, such rules and procedures should take into account the legitimate interests of law-enforcement authorities where early disclosure could unnecessarily hamper the investigation of the circumstances of a personal data breach.

(89) Directive 95/46/EC provided for a general obligation to notify the processing of personal data to the supervisory authorities. While that obligation produces administrative and financial burdens, it did not in all cases contribute to improving the protection of personal data. Such indiscriminate general notification obligations should therefore be abolished, and replaced by effective procedures and mechanisms which focus instead on those types of processing operations which are likely to result in a high risk to the rights and freedoms of natural persons by virtue of their nature, scope, context and purposes. Such types of processing operations may be those which in, particular, involve using new technologies, or are of a new kind and where no data protection impact assessment has been carried out before by the controller, or where they become necessary in the light of the time that has elapsed since the initial processing.

(90) In such cases, a data protection impact assessment should be carried out by the controller prior to the processing in order to assess the particular likelihood and severity of the high risk, taking into account the nature, scope, context and purposes of the processing and the sources of the risk. That impact assessment should include, in particular, the measures, safeguards and mechanisms envisaged for mitigating that risk, ensuring the protection of personal data and demonstrating compliance with this Regulation.

(91) This should in particular apply to large-scale processing operations which aim to process a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects and which are likely to result in a high risk, for example, on account of their sensitivity, where in accordance with the achieved state of technological knowledge a new technology is used on a large scale as well as to other processing operations which result in a high risk to the rights and freedoms of data subjects, in particular where those operations render it more difficult for data subjects to exercise their rights. A data

protection impact assessment should also be made where personal data are processed for taking decisions regarding specific natural persons following any systematic and extensive evaluation of personal aspects relating to natural persons based on profiling those data or following the processing of special categories of personal data, biometric data, or data on criminal convictions and offences or related security measures. A data protection impact assessment is equally required for monitoring publicly accessible areas on a large scale, especially when using optic-electronic devices or for any other operations where the competent supervisory authority considers that the processing is likely to result in a high risk to the rights and freedoms of data subjects, in particular because they prevent data subjects from exercising a right or using a service or a contract, or because they are carried out systematically on a large scale. The processing of personal data should not be considered to be on a large scale if the processing concerns personal data from patients or clients by an individual physician, other health care professional or lawyer. In such cases, a data protection impact assessment should not be mandatory.

(92) There are circumstances under which it may be reasonable and economical for the subject of a data protection impact assessment to be broader than a single project, for example where public authorities or bodies intend to establish a common application or processing platform or where several controllers plan to introduce a common application or processing environment across an industry sector or segment or for a widely used horizontal activity.

(93) In the context of the adoption of the Member State law on which the performance of the tasks of the public authority or public body is based and which regulates the specific processing operation or set of operations in question, Member States may deem it necessary to carry out such assessment prior to the processing activities.

(94) Where a data protection impact assessment indicates that the processing would, in the absence of safeguards, security measures and mechanisms to mitigate the risk, result in a high risk to the rights and freedoms of natural persons and the controller is of the opinion that the risk cannot be mitigated by reasonable means in terms of available technologies and costs of implementation, the supervisory authority should be consulted prior to the start of processing activities. Such high risk is likely to result from certain types of processing and the extent and frequency of processing, which may result also in a realisation of damage or interference with the rights and freedoms of the natural person. The supervisory authority should respond to the request for consultation within a specified period. However, the absence of a reaction of the supervisory authority within that period should be without prejudice to any intervention of the supervisory authority in accordance with its tasks and powers laid down in this Regulation, including the power to prohibit processing operations. As part of that consultation process, the outcome of a data protection impact assessment carried out with regard to the processing at issue may be submitted to the supervisory authority, in particular the measures envisaged to mitigate the risk to the rights and freedoms of natural persons.

(95) The processor should assist the controller, where necessary and upon request, in ensuring compliance with the obligations deriving from the carrying out of data protection impact assessments and from prior consultation of the supervisory authority.

(96) A consultation of the supervisory authority should also take place in the course of the preparation of a legislative or regulatory measure which provides for the processing of personal data, in order to ensure compliance of the intended processing with this Regulation and in particular to mitigate the risk involved for the data subject.

(97) Where the processing is carried out by a public authority, except for courts or independent judicial authorities when acting in their judicial capacity, where, in the private sector, processing is carried out by a controller whose core activities consist of processing operations that require regular and systematic monitoring of the data subjects on a large scale, or where the core activities of the controller or the processor consist of processing on a large scale of special categories of personal data and data relating to criminal convictions and offences, a person with expert knowledge of data protection law and practices should assist the controller or processor to monitor internal compliance with this Regulation. In the private sector, the core activities of a controller relate to its primary activities and do not relate to the processing of personal data as ancillary activities. The necessary level of expert knowledge should be determined in particular according to the data processing operations carried out

and the protection required for the personal data processed by the controller or the processor. Such data protection officers, whether or not they are an employee of the controller, should be in a position to perform their duties and tasks in an independent manner.

(98) Associations or other bodies representing categories of controllers or processors should be encouraged to draw up codes of conduct, within the limits of this Regulation, so as to facilitate the effective application of this Regulation, taking account of the specific characteristics of the processing carried out in certain sectors and the specific needs of micro, small and medium enterprises. In particular, such codes of conduct could calibrate the obligations of controllers and processors, taking into account the risk likely to result from the processing for the rights and freedoms of natural persons.

(99) When drawing up a code of conduct, or when amending or extending such a code, associations and other bodies representing categories of controllers or processors should consult relevant stakeholders, including data subjects where feasible, and have regard to submissions received and views expressed in response to such consultations.

(100) In order to enhance transparency and compliance with this Regulation, the establishment of certification mechanisms and data protection seals and marks should be encouraged, allowing data subjects to quickly assess the level of data protection of relevant products and services.

(101) Flows of personal data to and from countries outside the Union and international organisations are necessary for the expansion of international trade and international cooperation. The increase in such flows has raised new challenges and concerns with regard to the protection of personal data. However, when personal data are transferred from the Union to controllers, processors or other recipients in third countries or to international organisations, the level of protection of natural persons ensured in the Union by this Regulation should not be undermined, including in cases of onward transfers of personal data from the third country or international organisation to controllers, processors in the same or another third country or international organisation. In any event, transfers to third countries and international organisations may only be carried out in full compliance with this Regulation. A transfer could take place only if, subject to the other provisions of this Regulation, the conditions laid down in the provisions of this Regulation relating to the transfer of personal data to third countries or international organisations are complied with by the controller or processor.

(102) This Regulation is without prejudice to international agreements concluded between the Union and third countries regulating the transfer of personal data including appropriate safeguards for the data subjects. Member States may conclude international agreements which involve the transfer of personal data to third countries or international organisations, as far as such agreements do not affect this Regulation or any other provisions of Union law and include an appropriate level of protection for the fundamental rights of the data subjects.

(103) The Commission may decide with effect for the entire Union that a third country, a territory or specified sector within a third country, or an international organisation, offers an adequate level of data protection, thus providing legal certainty and uniformity throughout the Union as regards the third country or international organisation which is considered to provide such level of protection. In such cases, transfers of personal data to that third country or international organisation may take place without the need to obtain any further authorisation. The Commission may also decide, having given notice and a full statement setting out the reasons to the third country or international organisation, to revoke such a decision.

(104) In line with the fundamental values on which the Union is founded, in particular the protection of human rights, the Commission should, in its assessment of the third country, or of a territory or specified sector within a third country, take into account how a particular third country respects the rule of law, access to justice as well as international human rights norms and standards and its general and sectoral law, including legislation concerning public security, defence and national security as well as public order and criminal law. The adoption of an adequacy decision with regard to a territory or a specified sector in a third country should take into account clear and objective criteria, such as specific processing activities and the scope of applicable legal standards and legislation in force in the third country. The third country should offer guarantees ensuring an adequate level of

protection essentially equivalent to that ensured within the Union, in particular where personal data are processed in one or several specific sectors. In particular, the third country should ensure effective independent data protection supervision and should provide for cooperation mechanisms with the Member States' data protection authorities, and the data subjects should be provided with effective and enforceable rights and effective administrative and judicial redress.

(105) Apart from the international commitments the third country or international organisation has entered into, the Commission should take account of obligations arising from the third country's or international organisation's participation in multilateral or regional systems in particular in relation to the protection of personal data, as well as the implementation of such obligations. In particular, the third country's accession to the Council of Europe Convention of 28 January 1981 for the Protection of Individuals with regard to the Automatic Processing of Personal Data and its Additional Protocol should be taken into account. The Commission should consult the Board when assessing the level of protection in third countries or international organisations.

(106) The Commission should monitor the functioning of decisions on the level of protection in a third country, a territory or specified sector within a third country, or an international organisation, and monitor the functioning of decisions adopted on the basis of Article 25(6) or Article 26(4) of Directive 95/46/EC. In its adequacy decisions, the Commission should provide for a periodic review mechanism of their functioning. That periodic review should be conducted in consultation with the third country or international organisation in question and take into account all relevant developments in the third country or international organisation. For the purposes of monitoring and of carrying out the periodic reviews, the Commission should take into consideration the views and findings of the European Parliament and of the Council as well as of other relevant bodies and sources. The Commission should evaluate, within a reasonable time, the functioning of the latter decisions and report any relevant findings to the Committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council ([1]) as established under this Regulation, to the European Parliament and to the Council.

(107) The Commission may recognise that a third country, a territory or a specified sector within a third country, or an international organisation no longer ensures an adequate level of data protection. Consequently the transfer of personal data to that third country or international organisation should be prohibited, unless the requirements in this Regulation relating to transfers subject to appropriate safeguards, including binding corporate rules, and derogations for specific situations are fulfilled. In that case, provision should be made for consultations between the Commission and such third countries or international organisations. The Commission should, in a timely manner, inform the third country or international organisation of the reasons and enter into consultations with it in order to remedy the situation.

(108) In the absence of an adequacy decision, the controller or processor should take measures to compensate for the lack of data protection in a third country by way of appropriate safeguards for the data subject. Such appropriate safeguards may consist of making use of binding corporate rules, standard data protection clauses adopted by the Commission, standard data protection clauses adopted by a supervisory authority or contractual clauses authorised by a supervisory authority. Those safeguards should ensure compliance with data protection requirements and the rights of the data subjects appropriate to processing within the Union, including the availability of enforceable data subject rights and of effective legal remedies, including to obtain effective administrative or judicial redress and to claim compensation, in the Union or in a third country. They should relate in particular to compliance with the general principles relating to personal data processing, the principles of data protection by design and by default. Transfers may also be carried out by public authorities or bodies with public authorities or bodies in third countries or with international organisations with corresponding duties or functions, including on the basis of provisions to be inserted into administrative arrangements, such as a memorandum of understanding, providing for enforceable and effective rights for data subjects. Authorisation by the competent supervisory authority should be obtained when the safeguards are provided for in administrative arrangements that are not legally binding.

(109) The possibility for the controller or processor to use standard data-protection clauses adopted by the Commission or by a supervisory authority should prevent controllers or processors neither from including the

([1]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

standard data-protection clauses in a wider contract, such as a contract between the processor and another processor, nor from adding other clauses or additional safeguards provided that they do not contradict, directly or indirectly, the standard contractual clauses adopted by the Commission or by a supervisory authority or prejudice the fundamental rights or freedoms of the data subjects. Controllers and processors should be encouraged to provide additional safeguards via contractual commitments that supplement standard protection clauses.

(110) A group of undertakings, or a group of enterprises engaged in a joint economic activity, should be able to make use of approved binding corporate rules for its international transfers from the Union to organisations within the same group of undertakings, or group of enterprises engaged in a joint economic activity, provided that such corporate rules include all essential principles and enforceable rights to ensure appropriate safeguards for transfers or categories of transfers of personal data.

(111) Provisions should be made for the possibility for transfers in certain circumstances where the data subject has given his or her explicit consent, where the transfer is occasional and necessary in relation to a contract or a legal claim, regardless of whether in a judicial procedure or whether in an administrative or any out-of-court procedure, including procedures before regulatory bodies. Provision should also be made for the possibility for transfers where important grounds of public interest laid down by Union or Member State law so require or where the transfer is made from a register established by law and intended for consultation by the public or persons having a legitimate interest. In the latter case, such a transfer should not involve the entirety of the personal data or entire categories of the data contained in the register and, when the register is intended for consultation by persons having a legitimate interest, the transfer should be made only at the request of those persons or, if they are to be the recipients, taking into full account the interests and fundamental rights of the data subject.

(112) Those derogations should in particular apply to data transfers required and necessary for important reasons of public interest, for example in cases of international data exchange between competition authorities, tax or customs administrations, between financial supervisory authorities, between services competent for social security matters, or for public health, for example in the case of contact tracing for contagious diseases or in order to reduce and/or eliminate doping in sport. A transfer of personal data should also be regarded as lawful where it is necessary to protect an interest which is essential for the data subject's or another person's vital interests, including physical integrity or life, if the data subject is incapable of giving consent. In the absence of an adequacy decision, Union or Member State law may, for important reasons of public interest, expressly set limits to the transfer of specific categories of data to a third country or an international organisation. Member States should notify such provisions to the Commission. Any transfer to an international humanitarian organisation of personal data of a data subject who is physically or legally incapable of giving consent, with a view to accomplishing a task incumbent under the Geneva Conventions or to complying with international humanitarian law applicable in armed conflicts, could be considered to be necessary for an important reason of public interest or because it is in the vital interest of the data subject.

(113) Transfers which can be qualified as not repetitive and that only concern a limited number of data subjects, could also be possible for the purposes of the compelling legitimate interests pursued by the controller, when those interests are not overridden by the interests or rights and freedoms of the data subject and when the controller has assessed all the circumstances surrounding the data transfer. The controller should give particular consideration to the nature of the personal data, the purpose and duration of the proposed processing operation or operations, as well as the situation in the country of origin, the third country and the country of final destination, and should provide suitable safeguards to protect fundamental rights and freedoms of natural persons with regard to the processing of their personal data. Such transfers should be possible only in residual cases where none of the other grounds for transfer are applicable. For scientific or historical research purposes or statistical purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration. The controller should inform the supervisory authority and the data subject about the transfer.

(114) In any case, where the Commission has taken no decision on the adequate level of data protection in a third country, the controller or processor should make use of solutions that provide data subjects with enforceable and effective rights as regards the processing of their data in the Union once those data have been transferred so that that they will continue to benefit from fundamental rights and safeguards.

(115) Some third countries adopt laws, regulations and other legal acts which purport to directly regulate the processing activities of natural and legal persons under the jurisdiction of the Member States. This may include judgments of courts or tribunals or decisions of administrative authorities in third countries requiring a controller or processor to transfer or disclose personal data, and which are not based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or a Member State. The extraterritorial application of those laws, regulations and other legal acts may be in breach of international law and may impede the attainment of the protection of natural persons ensured in the Union by this Regulation. Transfers should only be allowed where the conditions of this Regulation for a transfer to third countries are met. This may be the case, inter alia, where disclosure is necessary for an important ground of public interest recognised in Union or Member State law to which the controller is subject.

(116) When personal data moves across borders outside the Union it may put at increased risk the ability of natural persons to exercise data protection rights in particular to protect themselves from the unlawful use or disclosure of that information. At the same time, supervisory authorities may find that they are unable to pursue complaints or conduct investigations relating to the activities outside their borders. Their efforts to work together in the cross-border context may also be hampered by insufficient preventative or remedial powers, inconsistent legal regimes, and practical obstacles like resource constraints. Therefore, there is a need to promote closer cooperation among data protection supervisory authorities to help them exchange information and carry out investigations with their international counterparts. For the purposes of developing international cooperation mechanisms to facilitate and provide international mutual assistance for the enforcement of legislation for the protection of personal data, the Commission and the supervisory authorities should exchange information and cooperate in activities related to the exercise of their powers with competent authorities in third countries, based on reciprocity and in accordance with this Regulation.

(117) The establishment of supervisory authorities in Member States, empowered to perform their tasks and exercise their powers with complete independence, is an essential component of the protection of natural persons with regard to the processing of their personal data. Member States should be able to establish more than one supervisory authority, to reflect their constitutional, organisational and administrative structure.

(118) The independence of supervisory authorities should not mean that the supervisory authorities cannot be subject to control or monitoring mechanisms regarding their financial expenditure or to judicial review.

(119) Where a Member State establishes several supervisory authorities, it should establish by law mechanisms for ensuring the effective participation of those supervisory authorities in the consistency mechanism. That Member State should in particular designate the supervisory authority which functions as a single contact point for the effective participation of those authorities in the mechanism, to ensure swift and smooth cooperation with other supervisory authorities, the Board and the Commission.

(120) Each supervisory authority should be provided with the financial and human resources, premises and infrastructure necessary for the effective performance of their tasks, including those related to mutual assistance and cooperation with other supervisory authorities throughout the Union. Each supervisory authority should have a separate, public annual budget, which may be part of the overall state or national budget.

(121) The general conditions for the member or members of the supervisory authority should be laid down by law in each Member State and should in particular provide that those members are to be appointed, by means of a transparent procedure, either by the parliament, government or the head of State of the Member State on the basis of a proposal from the government, a member of the government, the parliament or a chamber of the parliament, or by an independent body entrusted under Member State law. In order to ensure the independence of the supervisory authority, the member or members should act with integrity, refrain from any action that is incompatible with their duties and should not, during their term of office, engage in any incompatible occupation, whether gainful or not. The supervisory authority should have its own staff, chosen by the supervisory authority or an independent body established by Member State law, which should be subject to the exclusive direction of the member or members of the supervisory authority.

(122) Each supervisory authority should be competent on the territory of its own Member State to exercise the powers and to perform the tasks conferred on it in accordance with this Regulation. This should cover in particular the

processing in the context of the activities of an establishment of the controller or processor on the territory of its own Member State, the processing of personal data carried out by public authorities or private bodies acting in the public interest, processing affecting data subjects on its territory or processing carried out by a controller or processor not established in the Union when targeting data subjects residing on its territory. This should include handling complaints lodged by a data subject, conducting investigations on the application of this Regulation and promoting public awareness of the risks, rules, safeguards and rights in relation to the processing of personal data.

(123) The supervisory authorities should monitor the application of the provisions pursuant to this Regulation and contribute to its consistent application throughout the Union, in order to protect natural persons in relation to the processing of their personal data and to facilitate the free flow of personal data within the internal market. For that purpose, the supervisory authorities should cooperate with each other and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation.

(124) Where the processing of personal data takes place in the context of the activities of an establishment of a controller or a processor in the Union and the controller or processor is established in more than one Member State, or where processing taking place in the context of the activities of a single establishment of a controller or processor in the Union substantially affects or is likely to substantially affect data subjects in more than one Member State, the supervisory authority for the main establishment of the controller or processor or for the single establishment of the controller or processor should act as lead authority. It should cooperate with the other authorities concerned, because the controller or processor has an establishment on the territory of their Member State, because data subjects residing on their territory are substantially affected, or because a complaint has been lodged with them. Also where a data subject not residing in that Member State has lodged a complaint, the supervisory authority with which such complaint has been lodged should also be a supervisory authority concerned. Within its tasks to issue guidelines on any question covering the application of this Regulation, the Board should be able to issue guidelines in particular on the criteria to be taken into account in order to ascertain whether the processing in question substantially affects data subjects in more than one Member State and on what constitutes a relevant and reasoned objection.

(125) The lead authority should be competent to adopt binding decisions regarding measures applying the powers conferred on it in accordance with this Regulation. In its capacity as lead authority, the supervisory authority should closely involve and coordinate the supervisory authorities concerned in the decision-making process. Where the decision is to reject the complaint by the data subject in whole or in part, that decision should be adopted by the supervisory authority with which the complaint has been lodged.

(126) The decision should be agreed jointly by the lead supervisory authority and the supervisory authorities concerned and should be directed towards the main or single establishment of the controller or processor and be binding on the controller and processor. The controller or processor should take the necessary measures to ensure compliance with this Regulation and the implementation of the decision notified by the lead supervisory authority to the main establishment of the controller or processor as regards the processing activities in the Union.

(127) Each supervisory authority not acting as the lead supervisory authority should be competent to handle local cases where the controller or processor is established in more than one Member State, but the subject matter of the specific processing concerns only processing carried out in a single Member State and involves only data subjects in that single Member State, for example, where the subject matter concerns the processing of employees' personal data in the specific employment context of a Member State. In such cases, the supervisory authority should inform the lead supervisory authority without delay about the matter. After being informed, the lead supervisory authority should decide, whether it will handle the case pursuant to the provision on cooperation between the lead supervisory authority and other supervisory authorities concerned ('one-stop-shop mechanism'), or whether the supervisory authority which informed it should handle the case at local level. When deciding whether it will handle the case, the lead supervisory authority should take into account whether there is an establishment of the controller or processor in the Member State of the supervisory authority which informed it in order to ensure effective enforcement of a decision *vis-à-vis* the controller or processor. Where the lead supervisory authority decides to handle the case, the supervisory authority which informed it should have the

possibility to submit a draft for a decision, of which the lead supervisory authority should take utmost account when preparing its draft decision in that one-stop-shop mechanism.

(128) The rules on the lead supervisory authority and the one-stop-shop mechanism should not apply where the processing is carried out by public authorities or private bodies in the public interest. In such cases the only supervisory authority competent to exercise the powers conferred to it in accordance with this Regulation should be the supervisory authority of the Member State where the public authority or private body is established.

(129) In order to ensure consistent monitoring and enforcement of this Regulation throughout the Union, the supervisory authorities should have in each Member State the same tasks and effective powers, including powers of investigation, corrective powers and sanctions, and authorisation and advisory powers, in particular in cases of complaints from natural persons, and without prejudice to the powers of prosecutorial authorities under Member State law, to bring infringements of this Regulation to the attention of the judicial authorities and engage in legal proceedings. Such powers should also include the power to impose a temporary or definitive limitation, including a ban, on processing. Member States may specify other tasks related to the protection of personal data under this Regulation. The powers of supervisory authorities should be exercised in accordance with appropriate procedural safeguards set out in Union and Member State law, impartially, fairly and within a reasonable time. In particular each measure should be appropriate, necessary and proportionate in view of ensuring compliance with this Regulation, taking into account the circumstances of each individual case, respect the right of every person to be heard before any individual measure which would affect him or her adversely is taken and avoid superfluous costs and excessive inconveniences for the persons concerned. Investigatory powers as regards access to premises should be exercised in accordance with specific requirements in Member State procedural law, such as the requirement to obtain a prior judicial authorisation. Each legally binding measure of the supervisory authority should be in writing, be clear and unambiguous, indicate the supervisory authority which has issued the measure, the date of issue of the measure, bear the signature of the head, or a member of the supervisory authority authorised by him or her, give the reasons for the measure, and refer to the right of an effective remedy. This should not preclude additional requirements pursuant to Member State procedural law. The adoption of a legally binding decision implies that it may give rise to judicial review in the Member State of the supervisory authority that adopted the decision.

(130) Where the supervisory authority with which the complaint has been lodged is not the lead supervisory authority, the lead supervisory authority should closely cooperate with the supervisory authority with which the complaint has been lodged in accordance with the provisions on cooperation and consistency laid down in this Regulation. In such cases, the lead supervisory authority should, when taking measures intended to produce legal effects, including the imposition of administrative fines, take utmost account of the view of the supervisory authority with which the complaint has been lodged and which should remain competent to carry out any investigation on the territory of its own Member State in liaison with the competent supervisory authority.

(131) Where another supervisory authority should act as a lead supervisory authority for the processing activities of the controller or processor but the concrete subject matter of a complaint or the possible infringement concerns only processing activities of the controller or processor in the Member State where the complaint has been lodged or the possible infringement detected and the matter does not substantially affect or is not likely to substantially affect data subjects in other Member States, the supervisory authority receiving a complaint or detecting or being informed otherwise of situations that entail possible infringements of this Regulation should seek an amicable settlement with the controller and, if this proves unsuccessful, exercise its full range of powers. This should include: specific processing carried out in the territory of the Member State of the supervisory authority or with regard to data subjects on the territory of that Member State; processing that is carried out in the context of an offer of goods or services specifically aimed at data subjects in the territory of the Member State of the supervisory authority; or processing that has to be assessed taking into account relevant legal obligations under Member State law.

(132) Awareness-raising activities by supervisory authorities addressed to the public should include specific measures directed at controllers and processors, including micro, small and medium-sized enterprises, as well as natural persons in particular in the educational context.

(133) The supervisory authorities should assist each other in performing their tasks and provide mutual assistance, so as to ensure the consistent application and enforcement of this Regulation in the internal market. A supervisory authority requesting mutual assistance may adopt a provisional measure if it receives no response to a request for mutual assistance within one month of the receipt of that request by the other supervisory authority.

(134) Each supervisory authority should, where appropriate, participate in joint operations with other supervisory authorities. The requested supervisory authority should be obliged to respond to the request within a specified time period.

(135) In order to ensure the consistent application of this Regulation throughout the Union, a consistency mechanism for cooperation between the supervisory authorities should be established. That mechanism should in particular apply where a supervisory authority intends to adopt a measure intended to produce legal effects as regards processing operations which substantially affect a significant number of data subjects in several Member States. It should also apply where any supervisory authority concerned or the Commission requests that such matter should be handled in the consistency mechanism. That mechanism should be without prejudice to any measures that the Commission may take in the exercise of its powers under the Treaties.

(136) In applying the consistency mechanism, the Board should, within a determined period of time, issue an opinion, if a majority of its members so decides or if so requested by any supervisory authority concerned or the Commission. The Board should also be empowered to adopt legally binding decisions where there are disputes between supervisory authorities. For that purpose, it should issue, in principle by a two-thirds majority of its members, legally binding decisions in clearly specified cases where there are conflicting views among supervisory authorities, in particular in the cooperation mechanism between the lead supervisory authority and supervisory authorities concerned on the merits of the case, in particular whether there is an infringement of this Regulation.

(137) There may be an urgent need to act in order to protect the rights and freedoms of data subjects, in particular when the danger exists that the enforcement of a right of a data subject could be considerably impeded. A supervisory authority should therefore be able to adopt duly justified provisional measures on its territory with a specified period of validity which should not exceed three months.

(138) The application of such mechanism should be a condition for the lawfulness of a measure intended to produce legal effects by a supervisory authority in those cases where its application is mandatory. In other cases of cross-border relevance, the cooperation mechanism between the lead supervisory authority and supervisory authorities concerned should be applied and mutual assistance and joint operations might be carried out between the supervisory authorities concerned on a bilateral or multilateral basis without triggering the consistency mechanism.

(139) In order to promote the consistent application of this Regulation, the Board should be set up as an independent body of the Union. To fulfil its objectives, the Board should have legal personality. The Board should be represented by its Chair. It should replace the Working Party on the Protection of Individuals with Regard to the Processing of Personal Data established by Directive 95/46/EC. It should consist of the head of a supervisory authority of each Member State and the European Data Protection Supervisor or their respective representatives. The Commission should participate in the Board's activities without voting rights and the European Data Protection Supervisor should have specific voting rights. The Board should contribute to the consistent application of this Regulation throughout the Union, including by advising the Commission, in particular on the level of protection in third countries or international organisations, and promoting cooperation of the supervisory authorities throughout the Union. The Board should act independently when performing its tasks.

(140) The Board should be assisted by a secretariat provided by the European Data Protection Supervisor. The staff of the European Data Protection Supervisor involved in carrying out the tasks conferred on the Board by this Regulation should perform its tasks exclusively under the instructions of, and report to, the Chair of the Board.

(141) Every data subject should have the right to lodge a complaint with a single supervisory authority, in particular in the Member State of his or her habitual residence, and the right to an effective judicial remedy in accordance

with Article 47 of the Charter if the data subject considers that his or her rights under this Regulation are infringed or where the supervisory authority does not act on a complaint, partially or wholly rejects or dismisses a complaint or does not act where such action is necessary to protect the rights of the data subject. The investigation following a complaint should be carried out, subject to judicial review, to the extent that is appropriate in the specific case. The supervisory authority should inform the data subject of the progress and the outcome of the complaint within a reasonable period. If the case requires further investigation or coordination with another supervisory authority, intermediate information should be given to the data subject. In order to facilitate the submission of complaints, each supervisory authority should take measures such as providing a complaint submission form which can also be completed electronically, without excluding other means of communication.

(142) Where a data subject considers that his or her rights under this Regulation are infringed, he or she should have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal data to lodge a complaint on his or her behalf with a supervisory authority, exercise the right to a judicial remedy on behalf of data subjects or, if provided for in Member State law, exercise the right to receive compensation on behalf of data subjects. A Member State may provide for such a body, organisation or association to have the right to lodge a complaint in that Member State, independently of a data subject's mandate, and the right to an effective judicial remedy where it has reasons to consider that the rights of a data subject have been infringed as a result of the processing of personal data which infringes this Regulation. That body, organisation or association may not be allowed to claim compensation on a data subject's behalf independently of the data subject's mandate.

(143) Any natural or legal person has the right to bring an action for annulment of decisions of the Board before the Court of Justice under the conditions provided for in Article 263 TFEU. As addressees of such decisions, the supervisory authorities concerned which wish to challenge them have to bring action within two months of being notified of them, in accordance with Article 263 TFEU. Where decisions of the Board are of direct and individual concern to a controller, processor or complainant, the latter may bring an action for annulment against those decisions within two months of their publication on the website of the Board, in accordance with Article 263 TFEU. Without prejudice to this right under Article 263 TFEU, each natural or legal person should have an effective judicial remedy before the competent national court against a decision of a supervisory authority which produces legal effects concerning that person. Such a decision concerns in particular the exercise of investigative, corrective and authorisation powers by the supervisory authority or the dismissal or rejection of complaints. However, the right to an effective judicial remedy does not encompass measures taken by supervisory authorities which are not legally binding, such as opinions issued by or advice provided by the supervisory authority. Proceedings against a supervisory authority should be brought before the courts of the Member State where the supervisory authority is established and should be conducted in accordance with that Member State's procedural law. Those courts should exercise full jurisdiction, which should include jurisdiction to examine all questions of fact and law relevant to the dispute before them.

Where a complaint has been rejected or dismissed by a supervisory authority, the complainant may bring proceedings before the courts in the same Member State. In the context of judicial remedies relating to the application of this Regulation, national courts which consider a decision on the question necessary to enable them to give judgment, may, or in the case provided for in Article 267 TFEU, must, request the Court of Justice to give a preliminary ruling on the interpretation of Union law, including this Regulation. Furthermore, where a decision of a supervisory authority implementing a decision of the Board is challenged before a national court and the validity of the decision of the Board is at issue, that national court does not have the power to declare the Board's decision invalid but must refer the question of validity to the Court of Justice in accordance with Article 267 TFEU as interpreted by the Court of Justice, where it considers the decision invalid. However, a national court may not refer a question on the validity of the decision of the Board at the request of a natural or legal person which had the opportunity to bring an action for annulment of that decision, in particular if it was directly and individually concerned by that decision, but had not done so within the period laid down in Article 263 TFEU.

(144) Where a court seized of proceedings against a decision by a supervisory authority has reason to believe that proceedings concerning the same processing, such as the same subject matter as regards processing by the same controller or processor, or the same cause of action, are brought before a competent court in another Member State, it should contact that court in order to confirm the existence of such related proceedings. If related proceedings are pending before a court in another Member State, any court other than the court first

seized may stay its proceedings or may, on request of one of the parties, decline jurisdiction in favour of the court first seized if that court has jurisdiction over the proceedings in question and its law permits the consolidation of such related proceedings. Proceedings are deemed to be related where they are so closely connected that it is expedient to hear and determine them together in order to avoid the risk of irreconcilable judgments resulting from separate proceedings.

(145) For proceedings against a controller or processor, the plaintiff should have the choice to bring the action before the courts of the Member States where the controller or processor has an establishment or where the data subject resides, unless the controller is a public authority of a Member State acting in the exercise of its public powers.

(146) The controller or processor should compensate any damage which a person may suffer as a result of processing that infringes this Regulation. The controller or processor should be exempt from liability if it proves that it is not in any way responsible for the damage. The concept of damage should be broadly interpreted in the light of the case-law of the Court of Justice in a manner which fully reflects the objectives of this Regulation. This is without prejudice to any claims for damage deriving from the violation of other rules in Union or Member State law. Processing that infringes this Regulation also includes processing that infringes delegated and implementing acts adopted in accordance with this Regulation and Member State law specifying rules of this Regulation. Data subjects should receive full and effective compensation for the damage they have suffered. Where controllers or processors are involved in the same processing, each controller or processor should be held liable for the entire damage. However, where they are joined to the same judicial proceedings, in accordance with Member State law, compensation may be apportioned according to the responsibility of each controller or processor for the damage caused by the processing, provided that full and effective compensation of the data subject who suffered the damage is ensured. Any controller or processor which has paid full compensation may subsequently institute recourse proceedings against other controllers or processors involved in the same processing.

(147) Where specific rules on jurisdiction are contained in this Regulation, in particular as regards proceedings seeking a judicial remedy including compensation, against a controller or processor, general jurisdiction rules such as those of Regulation (EU) No 1215/2012 of the European Parliament and of the Council ([1]) should not prejudice the application of such specific rules.

(148) In order to strengthen the enforcement of the rules of this Regulation, penalties including administrative fines should be imposed for any infringement of this Regulation, in addition to, or instead of appropriate measures imposed by the supervisory authority pursuant to this Regulation. In a case of a minor infringement or if the fine likely to be imposed would constitute a disproportionate burden to a natural person, a reprimand may be issued instead of a fine. Due regard should however be given to the nature, gravity and duration of the infringement, the intentional character of the infringement, actions taken to mitigate the damage suffered, degree of responsibility or any relevant previous infringements, the manner in which the infringement became known to the supervisory authority, compliance with measures ordered against the controller or processor, adherence to a code of conduct and any other aggravating or mitigating factor. The imposition of penalties including administrative fines should be subject to appropriate procedural safeguards in accordance with the general principles of Union law and the Charter, including effective judicial protection and due process.

(149) Member States should be able to lay down the rules on criminal penalties for infringements of this Regulation, including for infringements of national rules adopted pursuant to and within the limits of this Regulation. Those criminal penalties may also allow for the deprivation of the profits obtained through infringements of this Regulation. However, the imposition of criminal penalties for infringements of such national rules and of administrative penalties should not lead to a breach of the principle of *ne bis in idem*, as interpreted by the Court of Justice.

(150) In order to strengthen and harmonise administrative penalties for infringements of this Regulation, each supervisory authority should have the power to impose administrative fines. This Regulation should indicate

([1]) Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 351, 20.12.2012, p. 1).

infringements and the upper limit and criteria for setting the related administrative fines, which should be determined by the competent supervisory authority in each individual case, taking into account all relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of its consequences and the measures taken to ensure compliance with the obligations under this Regulation and to prevent or mitigate the consequences of the infringement. Where administrative fines are imposed on an undertaking, an undertaking should be understood to be an undertaking in accordance with Articles 101 and 102 TFEU for those purposes. Where administrative fines are imposed on persons that are not an undertaking, the supervisory authority should take account of the general level of income in the Member State as well as the economic situation of the person in considering the appropriate amount of the fine. The consistency mechanism may also be used to promote a consistent application of administrative fines. It should be for the Member States to determine whether and to which extent public authorities should be subject to administrative fines. Imposing an administrative fine or giving a warning does not affect the application of other powers of the supervisory authorities or of other penalties under this Regulation.

(151) The legal systems of Denmark and Estonia do not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark the fine is imposed by competent national courts as a criminal penalty and in Estonia the fine is imposed by the supervisory authority in the framework of a misdemeanour procedure, provided that such an application of the rules in those Member States has an equivalent effect to administrative fines imposed by supervisory authorities. Therefore the competent national courts should take into account the recommendation by the supervisory authority initiating the fine. In any event, the fines imposed should be effective, proportionate and dissuasive.

(152) Where this Regulation does not harmonise administrative penalties or where necessary in other cases, for example in cases of serious infringements of this Regulation, Member States should implement a system which provides for effective, proportionate and dissuasive penalties. The nature of such penalties, criminal or administrative, should be determined by Member State law.

(153) Member States law should reconcile the rules governing freedom of expression and information, including journalistic, academic, artistic and or literary expression with the right to the protection of personal data pursuant to this Regulation. The processing of personal data solely for journalistic purposes, or for the purposes of academic, artistic or literary expression should be subject to derogations or exemptions from certain provisions of this Regulation if necessary to reconcile the right to the protection of personal data with the right to freedom of expression and information, as enshrined in Article 11 of the Charter. This should apply in particular to the processing of personal data in the audiovisual field and in news archives and press libraries. Therefore, Member States should adopt legislative measures which lay down the exemptions and derogations necessary for the purpose of balancing those fundamental rights. Member States should adopt such exemptions and derogations on general principles, the rights of the data subject, the controller and the processor, the transfer of personal data to third countries or international organisations, the independent supervisory authorities, cooperation and consistency, and specific data-processing situations. Where such exemptions or derogations differ from one Member State to another, the law of the Member State to which the controller is subject should apply. In order to take account of the importance of the right to freedom of expression in every democratic society, it is necessary to interpret notions relating to that freedom, such as journalism, broadly.

(154) This Regulation allows the principle of public access to official documents to be taken into account when applying this Regulation. Public access to official documents may be considered to be in the public interest. Personal data in documents held by a public authority or a public body should be able to be publicly disclosed by that authority or body if the disclosure is provided for by Union or Member State law to which the public authority or public body is subject. Such laws should reconcile public access to official documents and the reuse of public sector information with the right to the protection of personal data and may therefore provide for the necessary reconciliation with the right to the protection of personal data pursuant to this Regulation. The reference to public authorities and bodies should in that context include all authorities or other bodies covered by Member State law on public access to documents. Directive 2003/98/EC of the European Parliament and of the Council ([1]) leaves intact and in no way affects the level of protection of natural persons with regard to the

([1]) Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information (OJ L 345, 31.12.2003, p. 90).

processing of personal data under the provisions of Union and Member State law, and in particular does not alter the obligations and rights set out in this Regulation. In particular, that Directive should not apply to documents to which access is excluded or restricted by virtue of the access regimes on the grounds of protection of personal data, and parts of documents accessible by virtue of those regimes which contain personal data the re-use of which has been provided for by law as being incompatible with the law concerning the protection of natural persons with regard to the processing of personal data.

(155) Member State law or collective agreements, including 'works agreements', may provide for specific rules on the processing of employees' personal data in the employment context, in particular for the conditions under which personal data in the employment context may be processed on the basis of the consent of the employee, the purposes of the recruitment, the performance of the contract of employment, including discharge of obligations laid down by law or by collective agreements, management, planning and organisation of work, equality and diversity in the workplace, health and safety at work, and for the purposes of the exercise and enjoyment, on an individual or collective basis, of rights and benefits related to employment, and for the purpose of the termination of the employment relationship.

(156) The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. Those safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation. The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data). Member States should provide for appropriate safeguards for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. Member States should be authorised to provide, under specific conditions and subject to appropriate safeguards for data subjects, specifications and derogations with regard to the information requirements and rights to rectification, to erasure, to be forgotten, to restriction of processing, to data portability, and to object when processing personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific processing along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles. The processing of personal data for scientific purposes should also comply with other relevant legislation such as on clinical trials.

(157) By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

(158) Where personal data are processed for archiving purposes, this Regulation should also apply to that processing, bearing in mind that this Regulation should not apply to deceased persons. Public authorities or public or private bodies that hold records of public interest should be services which, pursuant to Union or Member State law, have a legal obligation to acquire, preserve, appraise, arrange, describe, communicate, promote, disseminate and provide access to records of enduring value for general public interest. Member States should also be authorised to provide for the further processing of personal data for archiving purposes, for example with a view to providing specific information related to the political behaviour under former totalitarian state regimes, genocide, crimes against humanity, in particular the Holocaust, or war crimes.

(159) Where personal data are processed for scientific research purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179(1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health. To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific research purposes. If the result of scientific research in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures.

(160) Where personal data are processed for historical research purposes, this Regulation should also apply to that processing. This should also include historical research and research for genealogical purposes, bearing in mind that this Regulation should not apply to deceased persons.

(161) For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council ([1]) should apply.

(162) Where personal data are processed for statistical purposes, this Regulation should apply to that processing. Union or Member State law should, within the limits of this Regulation, determine statistical content, control of access, specifications for the processing of personal data for statistical purposes and appropriate measures to safeguard the rights and freedoms of the data subject and for ensuring statistical confidentiality. Statistical purposes mean any operation of collection and the processing of personal data necessary for statistical surveys or for the production of statistical results. Those statistical results may further be used for different purposes, including a scientific research purpose. The statistical purpose implies that the result of processing for statistical purposes is not personal data, but aggregate data, and that this result or the personal data are not used in support of measures or decisions regarding any particular natural person.

(163) The confidential information which the Union and national statistical authorities collect for the production of official European and official national statistics should be protected. European statistics should be developed, produced and disseminated in accordance with the statistical principles as set out in Article 338(2) TFEU, while national statistics should also comply with Member State law. Regulation (EC) No 223/2009 of the European Parliament and of the Council ([2]) provides further specifications on statistical confidentiality for European statistics.

(164) As regards the powers of the supervisory authorities to obtain from the controller or processor access to personal data and access to their premises, Member States may adopt by law, within the limits of this Regulation, specific rules in order to safeguard the professional or other equivalent secrecy obligations, in so far as necessary to reconcile the right to the protection of personal data with an obligation of professional secrecy. This is without prejudice to existing Member State obligations to adopt rules on professional secrecy where required by Union law.

(165) This Regulation respects and does not prejudice the status under existing constitutional law of churches and religious associations or communities in the Member States, as recognised in Article 17 TFEU.

(166) In order to fulfil the objectives of this Regulation, namely to protect the fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data and to ensure the free movement

([1]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

([2]) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

of personal data within the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. In particular, delegated acts should be adopted in respect of criteria and requirements for certification mechanisms, information to be presented by standardised icons and procedures for providing such icons. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(167) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission when provided for by this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. In that context, the Commission should consider specific measures for micro, small and medium-sized enterprises.

(168) The examination procedure should be used for the adoption of implementing acts on standard contractual clauses between controllers and processors and between processors; codes of conduct; technical standards and mechanisms for certification; the adequate level of protection afforded by a third country, a territory or a specified sector within that third country, or an international organisation; standard protection clauses; formats and procedures for the exchange of information by electronic means between controllers, processors and supervisory authorities for binding corporate rules; mutual assistance; and arrangements for the exchange of information by electronic means between supervisory authorities, and between supervisory authorities and the Board.

(169) The Commission should adopt immediately applicable implementing acts where available evidence reveals that a third country, a territory or a specified sector within that third country, or an international organisation does not ensure an adequate level of protection, and imperative grounds of urgency so require.

(170) Since the objective of this Regulation, namely to ensure an equivalent level of protection of natural persons and the free flow of personal data throughout the Union, cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union (TEU). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(171) Directive 95/46/EC should be repealed by this Regulation. Processing already under way on the date of application of this Regulation should be brought into conformity with this Regulation within the period of two years after which this Regulation enters into force. Where processing is based on consent pursuant to Directive 95/46/EC, it is not necessary for the data subject to give his or her consent again if the manner in which the consent has been given is in line with the conditions of this Regulation, so as to allow the controller to continue such processing after the date of application of this Regulation. Commission decisions adopted and authorisations by supervisory authorities based on Directive 95/46/EC remain in force until amended, replaced or repealed.

(172) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 7 March 2012 ([1]).

(173) This Regulation should apply to all matters concerning the protection of fundamental rights and freedoms *vis-à-vis* the processing of personal data which are not subject to specific obligations with the same objective set out in Directive 2002/58/EC of the European Parliament and of the Council ([2]), including the obligations on the controller and the rights of natural persons. In order to clarify the relationship between this Regulation and Directive 2002/58/EC, that Directive should be amended accordingly. Once this Regulation is adopted, Directive 2002/58/EC should be reviewed in particular in order to ensure consistency with this Regulation,

([1]) OJ C 192, 30.6.2012, p. 7.
([2]) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject-matter and objectives

1. This Regulation lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data.

2. This Regulation protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data.

3. The free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data.

Article 2

Material scope

1. This Regulation applies to the processing of personal data wholly or partly by automated means and to the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system.

2. This Regulation does not apply to the processing of personal data:

(a) in the course of an activity which falls outside the scope of Union law;

(b) by the Member States when carrying out activities which fall within the scope of Chapter 2 of Title V of the TEU;

(c) by a natural person in the course of a purely personal or household activity;

(d) by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security.

3. For the processing of personal data by the Union institutions, bodies, offices and agencies, Regulation (EC) No 45/2001 applies. Regulation (EC) No 45/2001 and other Union legal acts applicable to such processing of personal data shall be adapted to the principles and rules of this Regulation in accordance with Article 98.

4. This Regulation shall be without prejudice to the application of Directive 2000/31/EC, in particular of the liability rules of intermediary service providers in Articles 12 to 15 of that Directive.

Article 3

Territorial scope

1. This Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not.

2. This Regulation applies to the processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union, where the processing activities are related to:

(a) the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or

(b) the monitoring of their behaviour as far as their behaviour takes place within the Union.

3. This Regulation applies to the processing of personal data by a controller not established in the Union, but in a place where Member State law applies by virtue of public international law.

Article 4

Definitions

For the purposes of this Regulation:

(1) 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

(2) 'processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

(3) 'restriction of processing' means the marking of stored personal data with the aim of limiting their processing in the future;

(4) 'profiling' means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements;

(5) 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person;

(6) 'filing system' means any structured set of personal data which are accessible according to specific criteria, whether centralised, decentralised or dispersed on a functional or geographical basis;

(7) 'controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;

(8) 'processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

(9) 'recipient' means a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the

framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing;

(10) 'third party' means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data;

(11) 'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;

(12) 'personal data breach' means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed;

(13) 'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question;

(14) 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data;

(15) 'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status;

(16) 'main establishment' means:

(a) as regards a controller with establishments in more than one Member State, the place of its central administration in the Union, unless the decisions on the purposes and means of the processing of personal data are taken in another establishment of the controller in the Union and the latter establishment has the power to have such decisions implemented, in which case the establishment having taken such decisions is to be considered to be the main establishment;

(b) as regards a processor with establishments in more than one Member State, the place of its central administration in the Union, or, if the processor has no central administration in the Union, the establishment of the processor in the Union where the main processing activities in the context of the activities of an establishment of the processor take place to the extent that the processor is subject to specific obligations under this Regulation;

(17) 'representative' means a natural or legal person established in the Union who, designated by the controller or processor in writing pursuant to Article 27, represents the controller or processor with regard to their respective obligations under this Regulation;

(18) 'enterprise' means a natural or legal person engaged in an economic activity, irrespective of its legal form, including partnerships or associations regularly engaged in an economic activity;

(19) 'group of undertakings' means a controlling undertaking and its controlled undertakings;

(20) 'binding corporate rules' means personal data protection policies which are adhered to by a controller or processor established on the territory of a Member State for transfers or a set of transfers of personal data to a controller or processor in one or more third countries within a group of undertakings, or group of enterprises engaged in a joint economic activity;

(21) 'supervisory authority' means an independent public authority which is established by a Member State pursuant to Article 51;

(22) 'supervisory authority concerned' means a supervisory authority which is concerned by the processing of personal data because:

(a) the controller or processor is established on the territory of the Member State of that supervisory authority;

(b) data subjects residing in the Member State of that supervisory authority are substantially affected or likely to be substantially affected by the processing; or

(c) a complaint has been lodged with that supervisory authority;

(23) 'cross-border processing' means either:

(a) processing of personal data which takes place in the context of the activities of establishments in more than one Member State of a controller or processor in the Union where the controller or processor is established in more than one Member State; or

(b) processing of personal data which takes place in the context of the activities of a single establishment of a controller or processor in the Union but which substantially affects or is likely to substantially affect data subjects in more than one Member State.

(24) 'relevant and reasoned objection' means an objection to a draft decision as to whether there is an infringement of this Regulation, or whether envisaged action in relation to the controller or processor complies with this Regulation, which clearly demonstrates the significance of the risks posed by the draft decision as regards the fundamental rights and freedoms of data subjects and, where applicable, the free flow of personal data within the Union;

(25) 'information society service' means a service as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council ([1]);

(26) 'international organisation' means an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries.

CHAPTER II

Principles

Article 5

Principles relating to processing of personal data

1. Personal data shall be:

(a) processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');

(b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation');

(c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation');

(d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy');

([1]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation');

(f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality').

2. The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 ('accountability').

Article 6

Lawfulness of processing

1. Processing shall be lawful only if and to the extent that at least one of the following applies:

(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

(b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

(c) processing is necessary for compliance with a legal obligation to which the controller is subject;

(d) processing is necessary in order to protect the vital interests of the data subject or of another natural person;

(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

(f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Point (f) of the first subparagraph shall not apply to processing carried out by public authorities in the performance of their tasks.

2. Member States may maintain or introduce more specific provisions to adapt the application of the rules of this Regulation with regard to processing for compliance with points (c) and (e) of paragraph 1 by determining more precisely specific requirements for the processing and other measures to ensure lawful and fair processing including for other specific processing situations as provided for in Chapter IX.

3. The basis for the processing referred to in point (c) and (e) of paragraph 1 shall be laid down by:

(a) Union law; or

(b) Member State law to which the controller is subject.

The purpose of the processing shall be determined in that legal basis or, as regards the processing referred to in point (e) of paragraph 1, shall be necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. That legal basis may contain specific provisions to adapt the application of rules of this Regulation, inter alia: the general conditions governing the lawfulness of processing by the controller; the types of data which are subject to the processing; the data subjects concerned; the entities to, and the purposes for which, the personal data may be disclosed; the purpose limitation; storage periods; and processing operations and processing procedures, including measures to ensure lawful and fair processing such as those for other specific

processing situations as provided for in Chapter IX. The Union or the Member State law shall meet an objective of public interest and be proportionate to the legitimate aim pursued.

4. Where the processing for a purpose other than that for which the personal data have been collected is not based on the data subject's consent or on a Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1), the controller shall, in order to ascertain whether processing for another purpose is compatible with the purpose for which the personal data are initially collected, take into account, inter alia:

(a) any link between the purposes for which the personal data have been collected and the purposes of the intended further processing;

(b) the context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller;

(c) the nature of the personal data, in particular whether special categories of personal data are processed, pursuant to Article 9, or whether personal data related to criminal convictions and offences are processed, pursuant to Article 10;

(d) the possible consequences of the intended further processing for data subjects;

(e) the existence of appropriate safeguards, which may include encryption or pseudonymisation.

Article 7

Conditions for consent

1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.

2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.

3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.

4. When assessing whether consent is freely given, utmost account shall be taken of whether, *inter alia*, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

Article 8

Conditions applicable to child's consent in relation to information society services

1. Where point (a) of Article 6(1) applies, in relation to the offer of information society services directly to a child, the processing of the personal data of a child shall be lawful where the child is at least 16 years old. Where the child is below the age of 16 years, such processing shall be lawful only if and to the extent that consent is given or authorised by the holder of parental responsibility over the child.

Member States may provide by law for a lower age for those purposes provided that such lower age is not below 13 years.

2. The controller shall make reasonable efforts to verify in such cases that consent is given or authorised by the holder of parental responsibility over the child, taking into consideration available technology.

3. Paragraph 1 shall not affect the general contract law of Member States such as the rules on the validity, formation or effect of a contract in relation to a child.

Article 9

Processing of special categories of personal data

1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

2. Paragraph 1 shall not apply if one of the following applies:

(a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;

(b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;

(c) processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;

(e) processing relates to personal data which are manifestly made public by the data subject;

(f) processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity;

(g) processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject;

(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;

(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

3. Personal data referred to in paragraph 1 may be processed for the purposes referred to in point (h) of paragraph 2 when those data are processed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies.

4. Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

Article 10

Processing of personal data relating to criminal convictions and offences

Processing of personal data relating to criminal convictions and offences or related security measures based on Article 6(1) shall be carried out only under the control of official authority or when the processing is authorised by Union or Member State law providing for appropriate safeguards for the rights and freedoms of data subjects. Any comprehensive register of criminal convictions shall be kept only under the control of official authority.

Article 11

Processing which does not require identification

1. If the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this Regulation.

2. Where, in cases referred to in paragraph 1 of this Article, the controller is able to demonstrate that it is not in a position to identify the data subject, the controller shall inform the data subject accordingly, if possible. In such cases, Articles 15 to 20 shall not apply except where the data subject, for the purpose of exercising his or her rights under those articles, provides additional information enabling his or her identification.

CHAPTER III

Rights of the data subject

Section 1

Transparency and modalities

Article 12

Transparent information, communication and modalities for the exercise of the rights of the data subject

1. The controller shall take appropriate measures to provide any information referred to in Articles 13 and 14 and any communication under Articles 15 to 22 and 34 relating to processing to the data subject in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child. The information shall be provided in writing, or by other means, including, where appropriate, by electronic means. When requested by the data subject, the information may be provided orally, provided that the identity of the data subject is proven by other means.

2. The controller shall facilitate the exercise of data subject rights under Articles 15 to 22. In the cases referred to in Article 11(2), the controller shall not refuse to act on the request of the data subject for exercising his or her rights under Articles 15 to 22, unless the controller demonstrates that it is not in a position to identify the data subject.

3. The controller shall provide information on action taken on a request under Articles 15 to 22 to the data subject without undue delay and in any event within one month of receipt of the request. That period may be extended by two further months where necessary, taking into account the complexity and number of the requests. The controller shall inform the data subject of any such extension within one month of receipt of the request, together with the reasons for the delay. Where the data subject makes the request by electronic form means, the information shall be provided by electronic means where possible, unless otherwise requested by the data subject.

4. If the controller does not take action on the request of the data subject, the controller shall inform the data subject without delay and at the latest within one month of receipt of the request of the reasons for not taking action and on the possibility of lodging a complaint with a supervisory authority and seeking a judicial remedy.

5. Information provided under Articles 13 and 14 and any communication and any actions taken under Articles 15 to 22 and 34 shall be provided free of charge. Where requests from a data subject are manifestly unfounded or excessive, in particular because of their repetitive character, the controller may either:

(a) charge a reasonable fee taking into account the administrative costs of providing the information or communication or taking the action requested; or

(b) refuse to act on the request.

The controller shall bear the burden of demonstrating the manifestly unfounded or excessive character of the request.

6. Without prejudice to Article 11, where the controller has reasonable doubts concerning the identity of the natural person making the request referred to in Articles 15 to 21, the controller may request the provision of additional information necessary to confirm the identity of the data subject.

7. The information to be provided to data subjects pursuant to Articles 13 and 14 may be provided in combination with standardised icons in order to give in an easily visible, intelligible and clearly legible manner a meaningful overview of the intended processing. Where the icons are presented electronically they shall be machine-readable.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 92 for the purpose of determining the information to be presented by the icons and the procedures for providing standardised icons.

Section 2

Information and access to personal data

Article 13

Information to be provided where personal data are collected from the data subject

1. Where personal data relating to a data subject are collected from the data subject, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information:

(a) the identity and the contact details of the controller and, where applicable, of the controller's representative;

(b) the contact details of the data protection officer, where applicable;

(c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;

(d) where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;

(e) the recipients or categories of recipients of the personal data, if any;

(f) where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available.

2. In addition to the information referred to in paragraph 1, the controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing:

(a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;

(b) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;

(c) where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;

(d) the right to lodge a complaint with a supervisory authority;

(e) whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;

(f) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

3. Where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information as referred to in paragraph 2.

4. Paragraphs 1, 2 and 3 shall not apply where and insofar as the data subject already has the information.

Article 14

Information to be provided where personal data have not been obtained from the data subject

1. Where personal data have not been obtained from the data subject, the controller shall provide the data subject with the following information:

(a) the identity and the contact details of the controller and, where applicable, of the controller's representative;

(b) the contact details of the data protection officer, where applicable;

(c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;

(d) the categories of personal data concerned;

(e) the recipients or categories of recipients of the personal data, if any;

(f) where applicable, that the controller intends to transfer personal data to a recipient in a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means to obtain a copy of them or where they have been made available.

2. In addition to the information referred to in paragraph 1, the controller shall provide the data subject with the following information necessary to ensure fair and transparent processing in respect of the data subject:

(a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;

(b) where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;

(c) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject and to object to processing as well as the right to data portability;

(d) where processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;

(e) the right to lodge a complaint with a supervisory authority;

(f) from which source the personal data originate, and if applicable, whether it came from publicly accessible sources;

(g) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

3. The controller shall provide the information referred to in paragraphs 1 and 2:

(a) within a reasonable period after obtaining the personal data, but at the latest within one month, having regard to the specific circumstances in which the personal data are processed;

(b) if the personal data are to be used for communication with the data subject, at the latest at the time of the first communication to that data subject; or

(c) if a disclosure to another recipient is envisaged, at the latest when the personal data are first disclosed.

4. Where the controller intends to further process the personal data for a purpose other than that for which the personal data were obtained, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information as referred to in paragraph 2.

5. Paragraphs 1 to 4 shall not apply where and insofar as:

(a) the data subject already has the information;

(b) the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available;

(c) obtaining or disclosure is expressly laid down by Union or Member State law to which the controller is subject and which provides appropriate measures to protect the data subject's legitimate interests; or

(d) where the personal data must remain confidential subject to an obligation of professional secrecy regulated by Union or Member State law, including a statutory obligation of secrecy.

Article 15

Right of access by the data subject

1. The data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the following information:

(a) the purposes of the processing;

(b) the categories of personal data concerned;

(c) the recipients or categories of recipient to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organisations;

(d) where possible, the envisaged period for which the personal data will be stored, or, if not possible, the criteria used to determine that period;

(e) the existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data concerning the data subject or to object to such processing;

(f) the right to lodge a complaint with a supervisory authority;

(g) where the personal data are not collected from the data subject, any available information as to their source;

(h) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

2. Where personal data are transferred to a third country or to an international organisation, the data subject shall have the right to be informed of the appropriate safeguards pursuant to Article 46 relating to the transfer.

3. The controller shall provide a copy of the personal data undergoing processing. For any further copies requested by the data subject, the controller may charge a reasonable fee based on administrative costs. Where the data subject makes the request by electronic means, and unless otherwise requested by the data subject, the information shall be provided in a commonly used electronic form.

4. The right to obtain a copy referred to in paragraph 3 shall not adversely affect the rights and freedoms of others.

Section 3

Rectification and erasure

Article 16

Right to rectification

The data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her. Taking into account the purposes of the processing, the data subject shall have the right to have incomplete personal data completed, including by means of providing a supplementary statement.

Article 17

Right to erasure ('right to be forgotten')

1. The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay where one of the following grounds applies:

(a) the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;

(b) the data subject withdraws consent on which the processing is based according to point (a) of Article 6(1), or point (a) of Article 9(2), and where there is no other legal ground for the processing;

(c) the data subject objects to the processing pursuant to Article 21(1) and there are no overriding legitimate grounds for the processing, or the data subject objects to the processing pursuant to Article 21(2);

(d) the personal data have been unlawfully processed;

(e) the personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject;

(f) the personal data have been collected in relation to the offer of information society services referred to in Article 8(1).

2. Where the controller has made the personal data public and is obliged pursuant to paragraph 1 to erase the personal data, the controller, taking account of available technology and the cost of implementation, shall take reasonable steps, including technical measures, to inform controllers which are processing the personal data that the data subject has requested the erasure by such controllers of any links to, or copy or replication of, those personal data.

3. Paragraphs 1 and 2 shall not apply to the extent that processing is necessary:

(a) for exercising the right of freedom of expression and information;

(b) for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

(c) for reasons of public interest in the area of public health in accordance with points (h) and (i) of Article 9(2) as well as Article 9(3);

(d) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing; or

(e) for the establishment, exercise or defence of legal claims.

Article 18

Right to restriction of processing

1. The data subject shall have the right to obtain from the controller restriction of processing where one of the following applies:

(a) the accuracy of the personal data is contested by the data subject, for a period enabling the controller to verify the accuracy of the personal data;

(b) the processing is unlawful and the data subject opposes the erasure of the personal data and requests the restriction of their use instead;

(c) the controller no longer needs the personal data for the purposes of the processing, but they are required by the data subject for the establishment, exercise or defence of legal claims;

(d) the data subject has objected to processing pursuant to Article 21(1) pending the verification whether the legitimate grounds of the controller override those of the data subject.

2. Where processing has been restricted under paragraph 1, such personal data shall, with the exception of storage, only be processed with the data subject's consent or for the establishment, exercise or defence of legal claims or for the protection of the rights of another natural or legal person or for reasons of important public interest of the Union or of a Member State.

3. A data subject who has obtained restriction of processing pursuant to paragraph 1 shall be informed by the controller before the restriction of processing is lifted.

Article 19

Notification obligation regarding rectification or erasure of personal data or restriction of processing

The controller shall communicate any rectification or erasure of personal data or restriction of processing carried out in accordance with Article 16, Article 17(1) and Article 18 to each recipient to whom the personal data have been disclosed, unless this proves impossible or involves disproportionate effort. The controller shall inform the data subject about those recipients if the data subject requests it.

Article 20

Right to data portability

1. The data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided, where:

(a) the processing is based on consent pursuant to point (a) of Article 6(1) or point (a) of Article 9(2) or on a contract pursuant to point (b) of Article 6(1); and

(b) the processing is carried out by automated means.

2. In exercising his or her right to data portability pursuant to paragraph 1, the data subject shall have the right to have the personal data transmitted directly from one controller to another, where technically feasible.

3. The exercise of the right referred to in paragraph 1 of this Article shall be without prejudice to Article 17. That right shall not apply to processing necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

4. The right referred to in paragraph 1 shall not adversely affect the rights and freedoms of others.

Section 4

Right to object and automated individual decision-making

Article 21

Right to object

1. The data subject shall have the right to object, on grounds relating to his or her particular situation, at any time to processing of personal data concerning him or her which is based on point (e) or (f) of Article 6(1), including profiling based on those provisions. The controller shall no longer process the personal data unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defence of legal claims.

2. Where personal data are processed for direct marketing purposes, the data subject shall have the right to object at any time to processing of personal data concerning him or her for such marketing, which includes profiling to the extent that it is related to such direct marketing.

3. Where the data subject objects to processing for direct marketing purposes, the personal data shall no longer be processed for such purposes.

4. At the latest at the time of the first communication with the data subject, the right referred to in paragraphs 1 and 2 shall be explicitly brought to the attention of the data subject and shall be presented clearly and separately from any other information.

5. In the context of the use of information society services, and notwithstanding Directive 2002/58/EC, the data subject may exercise his or her right to object by automated means using technical specifications.

6. Where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Article 89(1), the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data concerning him or her, unless the processing is necessary for the performance of a task carried out for reasons of public interest.

Article 22

Automated individual decision-making, including profiling

1. The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.

2. Paragraph 1 shall not apply if the decision:

(a) is necessary for entering into, or performance of, a contract between the data subject and a data controller;

(b) is authorised by Union or Member State law to which the controller is subject and which also lays down suitable measures to safeguard the data subject's rights and freedoms and legitimate interests; or

(c) is based on the data subject's explicit consent.

3. In the cases referred to in points (a) and (c) of paragraph 2, the data controller shall implement suitable measures to safeguard the data subject's rights and freedoms and legitimate interests, at least the right to obtain human intervention on the part of the controller, to express his or her point of view and to contest the decision.

4. Decisions referred to in paragraph 2 shall not be based on special categories of personal data referred to in Article 9(1), unless point (a) or (g) of Article 9(2) applies and suitable measures to safeguard the data subject's rights and freedoms and legitimate interests are in place.

Section 5

Restrictions

Article 23

Restrictions

1. Union or Member State law to which the data controller or processor is subject may restrict by way of a legislative measure the scope of the obligations and rights provided for in Articles 12 to 22 and Article 34, as well as Article 5 in so far as its provisions correspond to the rights and obligations provided for in Articles 12 to 22, when such a restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society to safeguard:

(a) national security;

(b) defence;

(c) public security;

(d) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(e) other important objectives of general public interest of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, including monetary, budgetary and taxation a matters, public health and social security;

(f) the protection of judicial independence and judicial proceedings;

(g) the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;

(h) a monitoring, inspection or regulatory function connected, even occasionally, to the exercise of official authority in the cases referred to in points (a) to (e) and (g);

(i) the protection of the data subject or the rights and freedoms of others;

(j) the enforcement of civil law claims.

2. In particular, any legislative measure referred to in paragraph 1 shall contain specific provisions at least, where relevant, as to:

(a) the purposes of the processing or categories of processing;

(b) the categories of personal data;

(c) the scope of the restrictions introduced;

(d) the safeguards to prevent abuse or unlawful access or transfer;

(e) the specification of the controller or categories of controllers;

(f) the storage periods and the applicable safeguards taking into account the nature, scope and purposes of the processing or categories of processing;

(g) the risks to the rights and freedoms of data subjects; and

(h) the right of data subjects to be informed about the restriction, unless that may be prejudicial to the purpose of the restriction.

CHAPTER IV

Controller and processor

Section 1

General obligations

Article 24

Responsibility of the controller

1. Taking into account the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons, the controller shall implement appropriate technical and organisational measures to ensure and to be able to demonstrate that processing is performed in accordance with this Regulation. Those measures shall be reviewed and updated where necessary.

2. Where proportionate in relation to processing activities, the measures referred to in paragraph 1 shall include the implementation of appropriate data protection policies by the controller.

3. Adherence to approved codes of conduct as referred to in Article 40 or approved certification mechanisms as referred to in Article 42 may be used as an element by which to demonstrate compliance with the obligations of the controller.

Article 25

Data protection by design and by default

1. Taking into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of natural persons posed by the processing, the controller shall, both at the time of the determination of the means for processing and at the time of the processing itself, implement appropriate technical and organisational measures, such as pseudonymisation, which are designed to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements of this Regulation and protect the rights of data subjects.

2. The controller shall implement appropriate technical and organisational measures for ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed. That obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility. In particular, such measures shall ensure that by default personal data are not made accessible without the individual's intervention to an indefinite number of natural persons.

3. An approved certification mechanism pursuant to Article 42 may be used as an element to demonstrate compliance with the requirements set out in paragraphs 1 and 2 of this Article.

Article 26

Joint controllers

1. Where two or more controllers jointly determine the purposes and means of processing, they shall be joint controllers. They shall in a transparent manner determine their respective responsibilities for compliance with the obligations under this Regulation, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in Articles 13 and 14, by means of an arrangement between them unless, and in so far as, the respective responsibilities of the controllers are determined by Union or Member State law to which the controllers are subject. The arrangement may designate a contact point for data subjects.

2. The arrangement referred to in paragraph 1 shall duly reflect the respective roles and relationships of the joint controllers *vis-à-vis* the data subjects. The essence of the arrangement shall be made available to the data subject.

3. Irrespective of the terms of the arrangement referred to in paragraph 1, the data subject may exercise his or her rights under this Regulation in respect of and against each of the controllers.

Article 27

Representatives of controllers or processors not established in the Union

1. Where Article 3(2) applies, the controller or the processor shall designate in writing a representative in the Union.

2. The obligation laid down in paragraph 1 of this Article shall not apply to:

(a) processing which is occasional, does not include, on a large scale, processing of special categories of data as referred to in Article 9(1) or processing of personal data relating to criminal convictions and offences referred to in Article 10, and is unlikely to result in a risk to the rights and freedoms of natural persons, taking into account the nature, context, scope and purposes of the processing; or

(b) a public authority or body.

3. The representative shall be established in one of the Member States where the data subjects, whose personal data are processed in relation to the offering of goods or services to them, or whose behaviour is monitored, are.

4. The representative shall be mandated by the controller or processor to be addressed in addition to or instead of the controller or the processor by, in particular, supervisory authorities and data subjects, on all issues related to processing, for the purposes of ensuring compliance with this Regulation.

5. The designation of a representative by the controller or processor shall be without prejudice to legal actions which could be initiated against the controller or the processor themselves.

Article 28

Processor

1. Where processing is to be carried out on behalf of a controller, the controller shall use only processors providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing will meet the requirements of this Regulation and ensure the protection of the rights of the data subject.

2. The processor shall not engage another processor without prior specific or general written authorisation of the controller. In the case of general written authorisation, the processor shall inform the controller of any intended changes concerning the addition or replacement of other processors, thereby giving the controller the opportunity to object to such changes.

3. Processing by a processor shall be governed by a contract or other legal act under Union or Member State law, that is binding on the processor with regard to the controller and that sets out the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller. That contract or other legal act shall stipulate, in particular, that the processor:

(a) processes the personal data only on documented instructions from the controller, including with regard to transfers of personal data to a third country or an international organisation, unless required to do so by Union or Member State law to which the processor is subject; in such a case, the processor shall inform the controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest;

(b) ensures that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;

(c) takes all measures required pursuant to Article 32;

(d) respects the conditions referred to in paragraphs 2 and 4 for engaging another processor;

(e) taking into account the nature of the processing, assists the controller by appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the controller's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III;

(f) assists the controller in ensuring compliance with the obligations pursuant to Articles 32 to 36 taking into account the nature of processing and the information available to the processor;

(g) at the choice of the controller, deletes or returns all the personal data to the controller after the end of the provision of services relating to processing, and deletes existing copies unless Union or Member State law requires storage of the personal data;

(h) makes available to the controller all information necessary to demonstrate compliance with the obligations laid down in this Article and allow for and contribute to audits, including inspections, conducted by the controller or another auditor mandated by the controller.

With regard to point (h) of the first subparagraph, the processor shall immediately inform the controller if, in its opinion, an instruction infringes this Regulation or other Union or Member State data protection provisions.

4. Where a processor engages another processor for carrying out specific processing activities on behalf of the controller, the same data protection obligations as set out in the contract or other legal act between the controller and the processor as referred to in paragraph 3 shall be imposed on that other processor by way of a contract or other legal act under Union or Member State law, in particular providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of this Regulation. Where that other processor fails to fulfil its data protection obligations, the initial processor shall remain fully liable to the controller for the performance of that other processor's obligations.

5. Adherence of a processor to an approved code of conduct as referred to in Article 40 or an approved certification mechanism as referred to in Article 42 may be used as an element by which to demonstrate sufficient guarantees as referred to in paragraphs 1 and 4 of this Article.

6. Without prejudice to an individual contract between the controller and the processor, the contract or the other legal act referred to in paragraphs 3 and 4 of this Article may be based, in whole or in part, on standard contractual clauses referred to in paragraphs 7 and 8 of this Article, including when they are part of a certification granted to the controller or processor pursuant to Articles 42 and 43.

7. The Commission may lay down standard contractual clauses for the matters referred to in paragraph 3 and 4 of this Article and in accordance with the examination procedure referred to in Article 93(2).

8. A supervisory authority may adopt standard contractual clauses for the matters referred to in paragraph 3 and 4 of this Article and in accordance with the consistency mechanism referred to in Article 63.

9. The contract or the other legal act referred to in paragraphs 3 and 4 shall be in writing, including in electronic form.

10. Without prejudice to Articles 82, 83 and 84, if a processor infringes this Regulation by determining the purposes and means of processing, the processor shall be considered to be a controller in respect of that processing.

Article 29

Processing under the authority of the controller or processor

The processor and any person acting under the authority of the controller or of the processor, who has access to personal data, shall not process those data except on instructions from the controller, unless required to do so by Union or Member State law.

Article 30

Records of processing activities

1. Each controller and, where applicable, the controller's representative, shall maintain a record of processing activities under its responsibility. That record shall contain all of the following information:

(a) the name and contact details of the controller and, where applicable, the joint controller, the controller's representative and the data protection officer;

(b) the purposes of the processing;

(c) a description of the categories of data subjects and of the categories of personal data;

(d) the categories of recipients to whom the personal data have been or will be disclosed including recipients in third countries or international organisations;

(e) where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1), the documentation of suitable safeguards;

(f) where possible, the envisaged time limits for erasure of the different categories of data;

(g) where possible, a general description of the technical and organisational security measures referred to in Article 32(1).

2. Each processor and, where applicable, the processor's representative shall maintain a record of all categories of processing activities carried out on behalf of a controller, containing:

(a) the name and contact details of the processor or processors and of each controller on behalf of which the processor is acting, and, where applicable, of the controller's or the processor's representative, and the data protection officer;

(b) the categories of processing carried out on behalf of each controller;

(c) where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1), the documentation of suitable safeguards;

(d) where possible, a general description of the technical and organisational security measures referred to in Article 32(1).

3. The records referred to in paragraphs 1 and 2 shall be in writing, including in electronic form.

4. The controller or the processor and, where applicable, the controller's or the processor's representative, shall make the record available to the supervisory authority on request.

5. The obligations referred to in paragraphs 1 and 2 shall not apply to an enterprise or an organisation employing fewer than 250 persons unless the processing it carries out is likely to result in a risk to the rights and freedoms of data subjects, the processing is not occasional, or the processing includes special categories of data as referred to in Article 9(1) or personal data relating to criminal convictions and offences referred to in Article 10.

Article 31

Cooperation with the supervisory authority

The controller and the processor and, where applicable, their representatives, shall cooperate, on request, with the supervisory authority in the performance of its tasks.

Section 2

Security of personal data

Article 32

Security of processing

1. Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, the controller and the processor shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk, including inter alia as appropriate:

(a) the pseudonymisation and encryption of personal data;

(b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;

(c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;

(d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

2. In assessing the appropriate level of security account shall be taken in particular of the risks that are presented by processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed.

3. Adherence to an approved code of conduct as referred to in Article 40 or an approved certification mechanism as referred to in Article 42 may be used as an element by which to demonstrate compliance with the requirements set out in paragraph 1 of this Article.

4. The controller and processor shall take steps to ensure that any natural person acting under the authority of the controller or the processor who has access to personal data does not process them except on instructions from the controller, unless he or she is required to do so by Union or Member State law.

Article 33

Notification of a personal data breach to the supervisory authority

1. In the case of a personal data breach, the controller shall without undue delay and, where feasible, not later than 72 hours after having become aware of it, notify the personal data breach to the supervisory authority competent in accordance with Article 55, unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. Where the notification to the supervisory authority is not made within 72 hours, it shall be accompanied by reasons for the delay.

2. The processor shall notify the controller without undue delay after becoming aware of a personal data breach.

3. The notification referred to in paragraph 1 shall at least:

(a) describe the nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;

(b) communicate the name and contact details of the data protection officer or other contact point where more information can be obtained;

(c) describe the likely consequences of the personal data breach;

(d) describe the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

4. Where, and in so far as, it is not possible to provide the information at the same time, the information may be provided in phases without undue further delay.

5. The controller shall document any personal data breaches, comprising the facts relating to the personal data breach, its effects and the remedial action taken. That documentation shall enable the supervisory authority to verify compliance with this Article.

Article 34

Communication of a personal data breach to the data subject

1. When the personal data breach is likely to result in a high risk to the rights and freedoms of natural persons, the controller shall communicate the personal data breach to the data subject without undue delay.

2. The communication to the data subject referred to in paragraph 1 of this Article shall describe in clear and plain language the nature of the personal data breach and contain at least the information and measures referred to in points (b), (c) and (d) of Article 33(3).

3. The communication to the data subject referred to in paragraph 1 shall not be required if any of the following conditions are met:

(a) the controller has implemented appropriate technical and organisational protection measures, and those measures were applied to the personal data affected by the personal data breach, in particular those that render the personal data unintelligible to any person who is not authorised to access it, such as encryption;

(b) the controller has taken subsequent measures which ensure that the high risk to the rights and freedoms of data subjects referred to in paragraph 1 is no longer likely to materialise;

(c) it would involve disproportionate effort. In such a case, there shall instead be a public communication or similar measure whereby the data subjects are informed in an equally effective manner.

4. If the controller has not already communicated the personal data breach to the data subject, the supervisory authority, having considered the likelihood of the personal data breach resulting in a high risk, may require it to do so or may decide that any of the conditions referred to in paragraph 3 are met.

Section 3

Data protection impact assessment and prior consultation

Article 35

Data protection impact assessment

1. Where a type of processing in particular using new technologies, and taking into account the nature, scope, context and purposes of the processing, is likely to result in a high risk to the rights and freedoms of natural persons, the controller shall, prior to the processing, carry out an assessment of the impact of the envisaged processing operations on the protection of personal data. A single assessment may address a set of similar processing operations that present similar high risks.

2. The controller shall seek the advice of the data protection officer, where designated, when carrying out a data protection impact assessment.

3. A data protection impact assessment referred to in paragraph 1 shall in particular be required in the case of:

(a) a systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing, including profiling, and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person;

(b) processing on a large scale of special categories of data referred to in Article 9(1), or of personal data relating to criminal convictions and offences referred to in Article 10; or

(c) a systematic monitoring of a publicly accessible area on a large scale.

4. The supervisory authority shall establish and make public a list of the kind of processing operations which are subject to the requirement for a data protection impact assessment pursuant to paragraph 1. The supervisory authority shall communicate those lists to the Board referred to in Article 68.

5. The supervisory authority may also establish and make public a list of the kind of processing operations for which no data protection impact assessment is required. The supervisory authority shall communicate those lists to the Board.

6. Prior to the adoption of the lists referred to in paragraphs 4 and 5, the competent supervisory authority shall apply the consistency mechanism referred to in Article 63 where such lists involve processing activities which are related to the offering of goods or services to data subjects or to the monitoring of their behaviour in several Member States, or may substantially affect the free movement of personal data within the Union.

7. The assessment shall contain at least:

(a) a systematic description of the envisaged processing operations and the purposes of the processing, including, where applicable, the legitimate interest pursued by the controller;

(b) an assessment of the necessity and proportionality of the processing operations in relation to the purposes;

(c) an assessment of the risks to the rights and freedoms of data subjects referred to in paragraph 1; and

(d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data and to demonstrate compliance with this Regulation taking into account the rights and legitimate interests of data subjects and other persons concerned.

8. Compliance with approved codes of conduct referred to in Article 40 by the relevant controllers or processors shall be taken into due account in assessing the impact of the processing operations performed by such controllers or processors, in particular for the purposes of a data protection impact assessment.

9. Where appropriate, the controller shall seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of processing operations.

10. Where processing pursuant to point (c) or (e) of Article 6(1) has a legal basis in Union law or in the law of the Member State to which the controller is subject, that law regulates the specific processing operation or set of operations in question, and a data protection impact assessment has already been carried out as part of a general impact assessment in the context of the adoption of that legal basis, paragraphs 1 to 7 shall not apply unless Member States deem it to be necessary to carry out such an assessment prior to processing activities.

11. Where necessary, the controller shall carry out a review to assess if processing is performed in accordance with the data protection impact assessment at least when there is a change of the risk represented by processing operations.

Article 36

Prior consultation

1. The controller shall consult the supervisory authority prior to processing where a data protection impact assessment under Article 35 indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk.

2. Where the supervisory authority is of the opinion that the intended processing referred to in paragraph 1 would infringe this Regulation, in particular where the controller has insufficiently identified or mitigated the risk, the supervisory authority shall, within period of up to eight weeks of receipt of the request for consultation, provide written advice to the controller and, where applicable to the processor, and may use any of its powers referred to in Article 58. That period may be extended by six weeks, taking into account the complexity of the intended processing. The supervisory authority shall inform the controller and, where applicable, the processor, of any such extension within one month of receipt of the request for consultation together with the reasons for the delay. Those periods may be suspended until the supervisory authority has obtained information it has requested for the purposes of the consultation.

3. When consulting the supervisory authority pursuant to paragraph 1, the controller shall provide the supervisory authority with:

(a) where applicable, the respective responsibilities of the controller, joint controllers and processors involved in the processing, in particular for processing within a group of undertakings;

(b) the purposes and means of the intended processing;

(c) the measures and safeguards provided to protect the rights and freedoms of data subjects pursuant to this Regulation;

(d) where applicable, the contact details of the data protection officer;

(e) the data protection impact assessment provided for in Article 35; and

(f) any other information requested by the supervisory authority.

4. Member States shall consult the supervisory authority during the preparation of a proposal for a legislative measure to be adopted by a national parliament, or of a regulatory measure based on such a legislative measure, which relates to processing.

5. Notwithstanding paragraph 1, Member State law may require controllers to consult with, and obtain prior authorisation from, the supervisory authority in relation to processing by a controller for the performance of a task carried out by the controller in the public interest, including processing in relation to social protection and public health.

Section 4

Data protection officer

Article 37

Designation of the data protection officer

1. The controller and the processor shall designate a data protection officer in any case where:

(a) the processing is carried out by a public authority or body, except for courts acting in their judicial capacity;

(b) the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or

(c) the core activities of the controller or the processor consist of processing on a large scale of special categories of data pursuant to Article 9 and personal data relating to criminal convictions and offences referred to in Article 10.

2. A group of undertakings may appoint a single data protection officer provided that a data protection officer is easily accessible from each establishment.

3. Where the controller or the processor is a public authority or body, a single data protection officer may be designated for several such authorities or bodies, taking account of their organisational structure and size.

4. In cases other than those referred to in paragraph 1, the controller or processor or associations and other bodies representing categories of controllers or processors may or, where required by Union or Member State law shall, designate a data protection officer. The data protection officer may act for such associations and other bodies representing controllers or processors.

5. The data protection officer shall be designated on the basis of professional qualities and, in particular, expert knowledge of data protection law and practices and the ability to fulfil the tasks referred to in Article 39.

6. The data protection officer may be a staff member of the controller or processor, or fulfil the tasks on the basis of a service contract.

7. The controller or the processor shall publish the contact details of the data protection officer and communicate them to the supervisory authority.

Article 38

Position of the data protection officer

1. The controller and the processor shall ensure that the data protection officer is involved, properly and in a timely manner, in all issues which relate to the protection of personal data.

2. The controller and processor shall support the data protection officer in performing the tasks referred to in Article 39 by providing resources necessary to carry out those tasks and access to personal data and processing operations, and to maintain his or her expert knowledge.

3. The controller and processor shall ensure that the data protection officer does not receive any instructions regarding the exercise of those tasks. He or she shall not be dismissed or penalised by the controller or the processor for performing his tasks. The data protection officer shall directly report to the highest management level of the controller or the processor.

4. Data subjects may contact the data protection officer with regard to all issues related to processing of their personal data and to the exercise of their rights under this Regulation.

5. The data protection officer shall be bound by secrecy or confidentiality concerning the performance of his or her tasks, in accordance with Union or Member State law.

6. The data protection officer may fulfil other tasks and duties. The controller or processor shall ensure that any such tasks and duties do not result in a conflict of interests.

Article 39

Tasks of the data protection officer

1. The data protection officer shall have at least the following tasks:

(a) to inform and advise the controller or the processor and the employees who carry out processing of their obligations pursuant to this Regulation and to other Union or Member State data protection provisions;

(b) to monitor compliance with this Regulation, with other Union or Member State data protection provisions and with the policies of the controller or processor in relation to the protection of personal data, including the assignment of responsibilities, awareness-raising and training of staff involved in processing operations, and the related audits;

(c) to provide advice where requested as regards the data protection impact assessment and monitor its performance pursuant to Article 35;

(d) to cooperate with the supervisory authority;

(e) to act as the contact point for the supervisory authority on issues relating to processing, including the prior consultation referred to in Article 36, and to consult, where appropriate, with regard to any other matter.

2. The data protection officer shall in the performance of his or her tasks have due regard to the risk associated with processing operations, taking into account the nature, scope, context and purposes of processing.

Section 5

Codes of conduct and certification

Article 40

Codes of conduct

1. The Member States, the supervisory authorities, the Board and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper application of this Regulation, taking account of the specific features of the various processing sectors and the specific needs of micro, small and medium-sized enterprises.

2. Associations and other bodies representing categories of controllers or processors may prepare codes of conduct, or amend or extend such codes, for the purpose of specifying the application of this Regulation, such as with regard to:

(a) fair and transparent processing;

(b) the legitimate interests pursued by controllers in specific contexts;

(c) the collection of personal data;

(d) the pseudonymisation of personal data;

(e) the information provided to the public and to data subjects;

(f) the exercise of the rights of data subjects;

(g) the information provided to, and the protection of, children, and the manner in which the consent of the holders of parental responsibility over children is to be obtained;

(h) the measures and procedures referred to in Articles 24 and 25 and the measures to ensure security of processing referred to in Article 32;

(i) the notification of personal data breaches to supervisory authorities and the communication of such personal data breaches to data subjects;

(j) the transfer of personal data to third countries or international organisations; or

(k) out-of-court proceedings and other dispute resolution procedures for resolving disputes between controllers and data subjects with regard to processing, without prejudice to the rights of data subjects pursuant to Articles 77 and 79.

3. In addition to adherence by controllers or processors subject to this Regulation, codes of conduct approved pursuant to paragraph 5 of this Article and having general validity pursuant to paragraph 9 of this Article may also be adhered to by controllers or processors that are not subject to this Regulation pursuant to Article 3 in order to provide appropriate safeguards within the framework of personal data transfers to third countries or international organisations under the terms referred to in point (e) of Article 46(2). Such controllers or processors shall make binding and enforceable commitments, via contractual or other legally binding instruments, to apply those appropriate safeguards including with regard to the rights of data subjects.

4. A code of conduct referred to in paragraph 2 of this Article shall contain mechanisms which enable the body referred to in Article 41(1) to carry out the mandatory monitoring of compliance with its provisions by the controllers or processors which undertake to apply it, without prejudice to the tasks and powers of supervisory authorities competent pursuant to Article 55 or 56.

5. Associations and other bodies referred to in paragraph 2 of this Article which intend to prepare a code of conduct or to amend or extend an existing code shall submit the draft code, amendment or extension to the supervisory authority which is competent pursuant to Article 55. The supervisory authority shall provide an opinion on whether the draft code, amendment or extension complies with this Regulation and shall approve that draft code, amendment or extension if it finds that it provides sufficient appropriate safeguards.

6. Where the draft code, or amendment or extension is approved in accordance with paragraph 5, and where the code of conduct concerned does not relate to processing activities in several Member States, the supervisory authority shall register and publish the code.

7. Where a draft code of conduct relates to processing activities in several Member States, the supervisory authority which is competent pursuant to Article 55 shall, before approving the draft code, amendment or extension, submit it in the procedure referred to in Article 63 to the Board which shall provide an opinion on whether the draft code, amendment or extension complies with this Regulation or, in the situation referred to in paragraph 3 of this Article, provides appropriate safeguards.

8. Where the opinion referred to in paragraph 7 confirms that the draft code, amendment or extension complies with this Regulation, or, in the situation referred to in paragraph 3, provides appropriate safeguards, the Board shall submit its opinion to the Commission.

9. The Commission may, by way of implementing acts, decide that the approved code of conduct, amendment or extension submitted to it pursuant to paragraph 8 of this Article have general validity within the Union. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 93(2).

10. The Commission shall ensure appropriate publicity for the approved codes which have been decided as having general validity in accordance with paragraph 9.

11. The Board shall collate all approved codes of conduct, amendments and extensions in a register and shall make them publicly available by way of appropriate means.

Article 41

Monitoring of approved codes of conduct

1. Without prejudice to the tasks and powers of the competent supervisory authority under Articles 57 and 58, the monitoring of compliance with a code of conduct pursuant to Article 40 may be carried out by a body which has an appropriate level of expertise in relation to the subject-matter of the code and is accredited for that purpose by the competent supervisory authority.

2. A body as referred to in paragraph 1 may be accredited to monitor compliance with a code of conduct where that body has:

(a) demonstrated its independence and expertise in relation to the subject-matter of the code to the satisfaction of the competent supervisory authority;

(b) established procedures which allow it to assess the eligibility of controllers and processors concerned to apply the code, to monitor their compliance with its provisions and to periodically review its operation;

(c) established procedures and structures to handle complaints about infringements of the code or the manner in which the code has been, or is being, implemented by a controller or processor, and to make those procedures and structures transparent to data subjects and the public; and

(d) demonstrated to the satisfaction of the competent supervisory authority that its tasks and duties do not result in a conflict of interests.

3. The competent supervisory authority shall submit the draft criteria for accreditation of a body as referred to in paragraph 1 of this Article to the Board pursuant to the consistency mechanism referred to in Article 63.

4. Without prejudice to the tasks and powers of the competent supervisory authority and the provisions of Chapter VIII, a body as referred to in paragraph 1 of this Article shall, subject to appropriate safeguards, take appropriate action in cases of infringement of the code by a controller or processor, including suspension or exclusion of the controller or processor concerned from the code. It shall inform the competent supervisory authority of such actions and the reasons for taking them.

5. The competent supervisory authority shall revoke the accreditation of a body as referred to in paragraph 1 if the conditions for accreditation are not, or are no longer, met or where actions taken by the body infringe this Regulation.

6. This Article shall not apply to processing carried out by public authorities and bodies.

Article 42

Certification

1. The Member States, the supervisory authorities, the Board and the Commission shall encourage, in particular at Union level, the establishment of data protection certification mechanisms and of data protection seals and marks, for the purpose of demonstrating compliance with this Regulation of processing operations by controllers and processors. The specific needs of micro, small and medium-sized enterprises shall be taken into account.

2. In addition to adherence by controllers or processors subject to this Regulation, data protection certification mechanisms, seals or marks approved pursuant to paragraph 5 of this Article may be established for the purpose of demonstrating the existence of appropriate safeguards provided by controllers or processors that are not subject to this Regulation pursuant to Article 3 within the framework of personal data transfers to third countries or international organisations under the terms referred to in point (f) of Article 46(2). Such controllers or processors shall make binding and enforceable commitments, via contractual or other legally binding instruments, to apply those appropriate safeguards, including with regard to the rights of data subjects.

3. The certification shall be voluntary and available via a process that is transparent.

4. A certification pursuant to this Article does not reduce the responsibility of the controller or the processor for compliance with this Regulation and is without prejudice to the tasks and powers of the supervisory authorities which are competent pursuant to Article 55 or 56.

5. A certification pursuant to this Article shall be issued by the certification bodies referred to in Article 43 or by the competent supervisory authority, on the basis of criteria approved by that competent supervisory authority pursuant to Article 58(3) or by the Board pursuant to Article 63. Where the criteria are approved by the Board, this may result in a common certification, the European Data Protection Seal.

6. The controller or processor which submits its processing to the certification mechanism shall provide the certification body referred to in Article 43, or where applicable, the competent supervisory authority, with all information and access to its processing activities which are necessary to conduct the certification procedure.

7. Certification shall be issued to a controller or processor for a maximum period of three years and may be renewed, under the same conditions, provided that the relevant requirements continue to be met. Certification shall be withdrawn, as applicable, by the certification bodies referred to in Article 43 or by the competent supervisory authority where the requirements for the certification are not or are no longer met.

8. The Board shall collate all certification mechanisms and data protection seals and marks in a register and shall make them publicly available by any appropriate means.

Article 43

Certification bodies

1. Without prejudice to the tasks and powers of the competent supervisory authority under Articles 57 and 58, certification bodies which have an appropriate level of expertise in relation to data protection shall, after informing the supervisory authority in order to allow it to exercise its powers pursuant to point (h) of Article 58(2) where necessary, issue and renew certification. Member States shall ensure that those certification bodies are accredited by one or both of the following:

(a) the supervisory authority which is competent pursuant to Article 55 or 56;

(b) the national accreditation body named in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ([1]) in accordance with EN-ISO/IEC 17065/2012 and with the additional requirements established by the supervisory authority which is competent pursuant to Article 55 or 56.

2. Certification bodies referred to in paragraph 1 shall be accredited in accordance with that paragraph only where they have:

(a) demonstrated their independence and expertise in relation to the subject-matter of the certification to the satisfaction of the competent supervisory authority;

([1]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(b) undertaken to respect the criteria referred to in Article 42(5) and approved by the supervisory authority which is competent pursuant to Article 55 or 56 or by the Board pursuant to Article 63;

(c) established procedures for the issuing, periodic review and withdrawal of data protection certification, seals and marks;

(d) established procedures and structures to handle complaints about infringements of the certification or the manner in which the certification has been, or is being, implemented by the controller or processor, and to make those procedures and structures transparent to data subjects and the public; and

(e) demonstrated, to the satisfaction of the competent supervisory authority, that their tasks and duties do not result in a conflict of interests.

3. The accreditation of certification bodies as referred to in paragraphs 1 and 2 of this Article shall take place on the basis of criteria approved by the supervisory authority which is competent pursuant to Article 55 or 56 or by the Board pursuant to Article 63. In the case of accreditation pursuant to point (b) of paragraph 1 of this Article, those requirements shall complement those envisaged in Regulation (EC) No 765/2008 and the technical rules that describe the methods and procedures of the certification bodies.

4. The certification bodies referred to in paragraph 1 shall be responsible for the proper assessment leading to the certification or the withdrawal of such certification without prejudice to the responsibility of the controller or processor for compliance with this Regulation. The accreditation shall be issued for a maximum period of five years and may be renewed on the same conditions provided that the certification body meets the requirements set out in this Article.

5. The certification bodies referred to in paragraph 1 shall provide the competent supervisory authorities with the reasons for granting or withdrawing the requested certification.

6. The requirements referred to in paragraph 3 of this Article and the criteria referred to in Article 42(5) shall be made public by the supervisory authority in an easily accessible form. The supervisory authorities shall also transmit those requirements and criteria to the Board. The Board shall collate all certification mechanisms and data protection seals in a register and shall make them publicly available by any appropriate means.

7. Without prejudice to Chapter VIII, the competent supervisory authority or the national accreditation body shall revoke an accreditation of a certification body pursuant to paragraph 1 of this Article where the conditions for the accreditation are not, or are no longer, met or where actions taken by a certification body infringe this Regulation.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 92 for the purpose of specifying the requirements to be taken into account for the data protection certification mechanisms referred to in Article 42(1).

9. The Commission may adopt implementing acts laying down technical standards for certification mechanisms and data protection seals and marks, and mechanisms to promote and recognise those certification mechanisms, seals and marks. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 93(2).

CHAPTER V

Transfers of personal data to third countries or international organisations

Article 44

General principle for transfers

Any transfer of personal data which are undergoing processing or are intended for processing after transfer to a third country or to an international organisation shall take place only if, subject to the other provisions of this Regulation, the conditions laid down in this Chapter are complied with by the controller and processor, including for onward transfers of personal data from the third country or an international organisation to another third country or to another international organisation. All provisions in this Chapter shall be applied in order to ensure that the level of protection of natural persons guaranteed by this Regulation is not undermined.

Article 45

Transfers on the basis of an adequacy decision

1. A transfer of personal data to a third country or an international organisation may take place where the Commission has decided that the third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection. Such a transfer shall not require any specific authorisation.

2. When assessing the adequacy of the level of protection, the Commission shall, in particular, take account of the following elements:

(a) the rule of law, respect for human rights and fundamental freedoms, relevant legislation, both general and sectoral, including concerning public security, defence, national security and criminal law and the access of public authorities to personal data, as well as the implementation of such legislation, data protection rules, professional rules and security measures, including rules for the onward transfer of personal data to another third country or international organisation which are complied with in that country or international organisation, case-law, as well as effective and enforceable data subject rights and effective administrative and judicial redress for the data subjects whose personal data are being transferred;

(b) the existence and effective functioning of one or more independent supervisory authorities in the third country or to which an international organisation is subject, with responsibility for ensuring and enforcing compliance with the data protection rules, including adequate enforcement powers, for assisting and advising the data subjects in exercising their rights and for cooperation with the supervisory authorities of the Member States; and

(c) the international commitments the third country or international organisation concerned has entered into, or other obligations arising from legally binding conventions or instruments as well as from its participation in multilateral or regional systems, in particular in relation to the protection of personal data.

3. The Commission, after assessing the adequacy of the level of protection, may decide, by means of implementing act, that a third country, a territory or one or more specified sectors within a third country, or an international organisation ensures an adequate level of protection within the meaning of paragraph 2 of this Article. The implementing act shall provide for a mechanism for a periodic review, at least every four years, which shall take into account all relevant developments in the third country or international organisation. The implementing act shall specify its territorial and sectoral application and, where applicable, identify the supervisory authority or authorities referred to in point (b) of paragraph 2 of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 93(2).

4. The Commission shall, on an ongoing basis, monitor developments in third countries and international organisations that could affect the functioning of decisions adopted pursuant to paragraph 3 of this Article and decisions adopted on the basis of Article 25(6) of Directive 95/46/EC.

5. The Commission shall, where available information reveals, in particular following the review referred to in paragraph 3 of this Article, that a third country, a territory or one or more specified sectors within a third country, or an international organisation no longer ensures an adequate level of protection within the meaning of paragraph 2 of this Article, to the extent necessary, repeal, amend or suspend the decision referred to in paragraph 3 of this Article by means of implementing acts without retro-active effect. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 93(2).

On duly justified imperative grounds of urgency, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 93(3).

6. The Commission shall enter into consultations with the third country or international organisation with a view to remedying the situation giving rise to the decision made pursuant to paragraph 5.

7. A decision pursuant to paragraph 5 of this Article is without prejudice to transfers of personal data to the third country, a territory or one or more specified sectors within that third country, or the international organisation in question pursuant to Articles 46 to 49.

8. The Commission shall publish in the *Official Journal of the European Union* and on its website a list of the third countries, territories and specified sectors within a third country and international organisations for which it has decided that an adequate level of protection is or is no longer ensured.

9. Decisions adopted by the Commission on the basis of Article 25(6) of Directive 95/46/EC shall remain in force until amended, replaced or repealed by a Commission Decision adopted in accordance with paragraph 3 or 5 of this Article.

Article 46

Transfers subject to appropriate safeguards

1. In the absence of a decision pursuant to Article 45(3), a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available.

2. The appropriate safeguards referred to in paragraph 1 may be provided for, without requiring any specific authorisation from a supervisory authority, by:

(a) a legally binding and enforceable instrument between public authorities or bodies;

(b) binding corporate rules in accordance with Article 47;

(c) standard data protection clauses adopted by the Commission in accordance with the examination procedure referred to in Article 93(2);

(d) standard data protection clauses adopted by a supervisory authority and approved by the Commission pursuant to the examination procedure referred to in Article 93(2);

(e) an approved code of conduct pursuant to Article 40 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights; or

(f) an approved certification mechanism pursuant to Article 42 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.

3. Subject to the authorisation from the competent supervisory authority, the appropriate safeguards referred to in paragraph 1 may also be provided for, in particular, by:

(a) contractual clauses between the controller or processor and the controller, processor or the recipient of the personal data in the third country or international organisation; or

(b) provisions to be inserted into administrative arrangements between public authorities or bodies which include enforceable and effective data subject rights.

4. The supervisory authority shall apply the consistency mechanism referred to in Article 63 in the cases referred to in paragraph 3 of this Article.

5. Authorisations by a Member State or supervisory authority on the basis of Article 26(2) of Directive 95/46/EC shall remain valid until amended, replaced or repealed, if necessary, by that supervisory authority. Decisions adopted by the Commission on the basis of Article 26(4) of Directive 95/46/EC shall remain in force until amended, replaced or repealed, if necessary, by a Commission Decision adopted in accordance with paragraph 2 of this Article.

Article 47

Binding corporate rules

1. The competent supervisory authority shall approve binding corporate rules in accordance with the consistency mechanism set out in Article 63, provided that they:

(a) are legally binding and apply to and are enforced by every member concerned of the group of undertakings, or group of enterprises engaged in a joint economic activity, including their employees;

(b) expressly confer enforceable rights on data subjects with regard to the processing of their personal data; and

(c) fulfil the requirements laid down in paragraph 2.

2. The binding corporate rules referred to in paragraph 1 shall specify at least:

(a) the structure and contact details of the group of undertakings, or group of enterprises engaged in a joint economic activity and of each of its members;

(b) the data transfers or set of transfers, including the categories of personal data, the type of processing and its purposes, the type of data subjects affected and the identification of the third country or countries in question;

(c) their legally binding nature, both internally and externally;

(d) the application of the general data protection principles, in particular purpose limitation, data minimisation, limited storage periods, data quality, data protection by design and by default, legal basis for processing, processing of special categories of personal data, measures to ensure data security, and the requirements in respect of onward transfers to bodies not bound by the binding corporate rules;

(e) the rights of data subjects in regard to processing and the means to exercise those rights, including the right not to be subject to decisions based solely on automated processing, including profiling in accordance with Article 22, the right to lodge a complaint with the competent supervisory authority and before the competent courts of the Member States in accordance with Article 79, and to obtain redress and, where appropriate, compensation for a breach of the binding corporate rules;

(f) the acceptance by the controller or processor established on the territory of a Member State of liability for any breaches of the binding corporate rules by any member concerned not established in the Union; the controller or the processor shall be exempt from that liability, in whole or in part, only if it proves that that member is not responsible for the event giving rise to the damage;

(g) how the information on the binding corporate rules, in particular on the provisions referred to in points (d), (e) and (f) of this paragraph is provided to the data subjects in addition to Articles 13 and 14;

(h) the tasks of any data protection officer designated in accordance with Article 37 or any other person or entity in charge of the monitoring compliance with the binding corporate rules within the group of undertakings, or group of enterprises engaged in a joint economic activity, as well as monitoring training and complaint-handling;

(i) the complaint procedures;

(j) the mechanisms within the group of undertakings, or group of enterprises engaged in a joint economic activity for ensuring the verification of compliance with the binding corporate rules. Such mechanisms shall include data protection audits and methods for ensuring corrective actions to protect the rights of the data subject. Results of such verification should be communicated to the person or entity referred to in point (h) and to the board of the controlling undertaking of a group of undertakings, or of the group of enterprises engaged in a joint economic activity, and should be available upon request to the competent supervisory authority;

(k) the mechanisms for reporting and recording changes to the rules and reporting those changes to the supervisory authority;

(l) the cooperation mechanism with the supervisory authority to ensure compliance by any member of the group of undertakings, or group of enterprises engaged in a joint economic activity, in particular by making available to the supervisory authority the results of verifications of the measures referred to in point (j);

(m) the mechanisms for reporting to the competent supervisory authority any legal requirements to which a member of the group of undertakings, or group of enterprises engaged in a joint economic activity is subject in a third country which are likely to have a substantial adverse effect on the guarantees provided by the binding corporate rules; and

(n) the appropriate data protection training to personnel having permanent or regular access to personal data.

3. The Commission may specify the format and procedures for the exchange of information between controllers, processors and supervisory authorities for binding corporate rules within the meaning of this Article. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 93(2).

Article 48

Transfers or disclosures not authorised by Union law

Any judgment of a court or tribunal and any decision of an administrative authority of a third country requiring a controller or processor to transfer or disclose personal data may only be recognised or enforceable in any manner if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or a Member State, without prejudice to other grounds for transfer pursuant to this Chapter.

Article 49

Derogations for specific situations

1. In the absence of an adequacy decision pursuant to Article 45(3), or of appropriate safeguards pursuant to Article 46, including binding corporate rules, a transfer or a set of transfers of personal data to a third country or an international organisation shall take place only on one of the following conditions:

(a) the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards;

(b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of pre-contractual measures taken at the data subject's request;

(c) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and another natural or legal person;

(d) the transfer is necessary for important reasons of public interest;

(e) the transfer is necessary for the establishment, exercise or defence of legal claims;

(f) the transfer is necessary in order to protect the vital interests of the data subject or of other persons, where the data subject is physically or legally incapable of giving consent;

(g) the transfer is made from a register which according to Union or Member State law is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down by Union or Member State law for consultation are fulfilled in the particular case.

Where a transfer could not be based on a provision in Article 45 or 46, including the provisions on binding corporate rules, and none of the derogations for a specific situation referred to in the first subparagraph of this paragraph is applicable, a transfer to a third country or an international organisation may take place only if the transfer is not repetitive, concerns only a limited number of data subjects, is necessary for the purposes of compelling legitimate interests pursued by the controller which are not overridden by the interests or rights and freedoms of the data subject, and the controller has assessed all the circumstances surrounding the data transfer and has on the basis of that assessment provided suitable safeguards with regard to the protection of personal data. The controller shall inform the supervisory authority of the transfer. The controller shall, in addition to providing the information referred to in Articles 13 and 14, inform the data subject of the transfer and on the compelling legitimate interests pursued.

2. A transfer pursuant to point (g) of the first subparagraph of paragraph 1 shall not involve the entirety of the personal data or entire categories of the personal data contained in the register. Where the register is intended for consultation by persons having a legitimate interest, the transfer shall be made only at the request of those persons or if they are to be the recipients.

3. Points (a), (b) and (c) of the first subparagraph of paragraph 1 and the second subparagraph thereof shall not apply to activities carried out by public authorities in the exercise of their public powers.

4. The public interest referred to in point (d) of the first subparagraph of paragraph 1 shall be recognised in Union law or in the law of the Member State to which the controller is subject.

5. In the absence of an adequacy decision, Union or Member State law may, for important reasons of public interest, expressly set limits to the transfer of specific categories of personal data to a third country or an international organisation. Member States shall notify such provisions to the Commission.

6. The controller or processor shall document the assessment as well as the suitable safeguards referred to in the second subparagraph of paragraph 1 of this Article in the records referred to in Article 30.

Article 50

International cooperation for the protection of personal data

In relation to third countries and international organisations, the Commission and supervisory authorities shall take appropriate steps to:

(a) develop international cooperation mechanisms to facilitate the effective enforcement of legislation for the protection of personal data;

(b) provide international mutual assistance in the enforcement of legislation for the protection of personal data, including through notification, complaint referral, investigative assistance and information exchange, subject to appropriate safeguards for the protection of personal data and other fundamental rights and freedoms;

(c) engage relevant stakeholders in discussion and activities aimed at furthering international cooperation in the enforcement of legislation for the protection of personal data;

(d) promote the exchange and documentation of personal data protection legislation and practice, including on jurisdictional conflicts with third countries.

CHAPTER VI

Independent supervisory authorities

Section 1

Independent status

Article 51

Supervisory authority

1. Each Member State shall provide for one or more independent public authorities to be responsible for monitoring the application of this Regulation, in order to protect the fundamental rights and freedoms of natural persons in relation to processing and to facilitate the free flow of personal data within the Union ('supervisory authority').

2. Each supervisory authority shall contribute to the consistent application of this Regulation throughout the Union. For that purpose, the supervisory authorities shall cooperate with each other and the Commission in accordance with Chapter VII.

3. Where more than one supervisory authority is established in a Member State, that Member State shall designate the supervisory authority which is to represent those authorities in the Board and shall set out the mechanism to ensure compliance by the other authorities with the rules relating to the consistency mechanism referred to in Article 63.

4. Each Member State shall notify to the Commission the provisions of its law which it adopts pursuant to this Chapter, by 25 May 2018 and, without delay, any subsequent amendment affecting them.

Article 52

Independence

1. Each supervisory authority shall act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation.

2. The member or members of each supervisory authority shall, in the performance of their tasks and exercise of their powers in accordance with this Regulation, remain free from external influence, whether direct or indirect, and shall neither seek nor take instructions from anybody.

3. Member or members of each supervisory authority shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.

4. Each Member State shall ensure that each supervisory authority is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers, including those to be carried out in the context of mutual assistance, cooperation and participation in the Board.

5. Each Member State shall ensure that each supervisory authority chooses and has its own staff which shall be subject to the exclusive direction of the member or members of the supervisory authority concerned.

6. Each Member State shall ensure that each supervisory authority is subject to financial control which does not affect its independence and that it has separate, public annual budgets, which may be part of the overall state or national budget.

Article 53

General conditions for the members of the supervisory authority

1. Member States shall provide for each member of their supervisory authorities to be appointed by means of a transparent procedure by:

— their parliament;

— their government;

— their head of State; or

— an independent body entrusted with the appointment under Member State law.

2. Each member shall have the qualifications, experience and skills, in particular in the area of the protection of personal data, required to perform its duties and exercise its powers.

3. The duties of a member shall end in the event of the expiry of the term of office, resignation or compulsory retirement, in accordance with the law of the Member State concerned.

4. A member shall be dismissed only in cases of serious misconduct or if the member no longer fulfils the conditions required for the performance of the duties.

Article 54

Rules on the establishment of the supervisory authority

1. Each Member State shall provide by law for all of the following:

(a) the establishment of each supervisory authority;

(b) the qualifications and eligibility conditions required to be appointed as member of each supervisory authority;

(c) the rules and procedures for the appointment of the member or members of each supervisory authority;

(d) the duration of the term of the member or members of each supervisory authority of no less than four years, except for the first appointment after 24 May 2016, part of which may take place for a shorter period where that is necessary to protect the independence of the supervisory authority by means of a staggered appointment procedure;

(e) whether and, if so, for how many terms the member or members of each supervisory authority is eligible for reappointment;

(f) the conditions governing the obligations of the member or members and staff of each supervisory authority, prohibitions on actions, occupations and benefits incompatible therewith during and after the term of office and rules governing the cessation of employment.

2. The member or members and the staff of each supervisory authority shall, in accordance with Union or Member State law, be subject to a duty of professional secrecy both during and after their term of office, with regard to any confidential information which has come to their knowledge in the course of the performance of their tasks or exercise of their powers. During their term of office, that duty of professional secrecy shall in particular apply to reporting by natural persons of infringements of this Regulation.

Section 2

Competence, tasks and powers

Article 55

Competence

1. Each supervisory authority shall be competent for the performance of the tasks assigned to and the exercise of the powers conferred on it in accordance with this Regulation on the territory of its own Member State.

2. Where processing is carried out by public authorities or private bodies acting on the basis of point (c) or (e) of Article 6(1), the supervisory authority of the Member State concerned shall be competent. In such cases Article 56 does not apply.

3. Supervisory authorities shall not be competent to supervise processing operations of courts acting in their judicial capacity.

Article 56

Competence of the lead supervisory authority

1. Without prejudice to Article 55, the supervisory authority of the main establishment or of the single establishment of the controller or processor shall be competent to act as lead supervisory authority for the cross-border processing carried out by that controller or processor in accordance with the procedure provided in Article 60.

2. By derogation from paragraph 1, each supervisory authority shall be competent to handle a complaint lodged with it or a possible infringement of this Regulation, if the subject matter relates only to an establishment in its Member State or substantially affects data subjects only in its Member State.

3. In the cases referred to in paragraph 2 of this Article, the supervisory authority shall inform the lead supervisory authority without delay on that matter. Within a period of three weeks after being informed the lead supervisory authority shall decide whether or not it will handle the case in accordance with the procedure provided in Article 60, taking into account whether or not there is an establishment of the controller or processor in the Member State of which the supervisory authority informed it.

4. Where the lead supervisory authority decides to handle the case, the procedure provided in Article 60 shall apply. The supervisory authority which informed the lead supervisory authority may submit to the lead supervisory authority a draft for a decision. The lead supervisory authority shall take utmost account of that draft when preparing the draft decision referred to in Article 60(3).

5. Where the lead supervisory authority decides not to handle the case, the supervisory authority which informed the lead supervisory authority shall handle it according to Articles 61 and 62.

6. The lead supervisory authority shall be the sole interlocutor of the controller or processor for the cross-border processing carried out by that controller or processor.

Article 57

Tasks

1. Without prejudice to other tasks set out under this Regulation, each supervisory authority shall on its territory:

(a) monitor and enforce the application of this Regulation;

(b) promote public awareness and understanding of the risks, rules, safeguards and rights in relation to processing. Activities addressed specifically to children shall receive specific attention;

(c) advise, in accordance with Member State law, the national parliament, the government, and other institutions and bodies on legislative and administrative measures relating to the protection of natural persons' rights and freedoms with regard to processing;

(d) promote the awareness of controllers and processors of their obligations under this Regulation;

(e) upon request, provide information to any data subject concerning the exercise of their rights under this Regulation and, if appropriate, cooperate with the supervisory authorities in other Member States to that end;

(f) handle complaints lodged by a data subject, or by a body, organisation or association in accordance with Article 80, and investigate, to the extent appropriate, the subject matter of the complaint and inform the complainant of the progress and the outcome of the investigation within a reasonable period, in particular if further investigation or coordination with another supervisory authority is necessary;

(g) cooperate with, including sharing information and provide mutual assistance to, other supervisory authorities with a view to ensuring the consistency of application and enforcement of this Regulation;

(h) conduct investigations on the application of this Regulation, including on the basis of information received from another supervisory authority or other public authority;

(i) monitor relevant developments, insofar as they have an impact on the protection of personal data, in particular the development of information and communication technologies and commercial practices;

(j) adopt standard contractual clauses referred to in Article 28(8) and in point (d) of Article 46(2);

(k) establish and maintain a list in relation to the requirement for data protection impact assessment pursuant to Article 35(4);

(l) give advice on the processing operations referred to in Article 36(2);

(m) encourage the drawing up of codes of conduct pursuant to Article 40(1) and provide an opinion and approve such codes of conduct which provide sufficient safeguards, pursuant to Article 40(5);

(n) encourage the establishment of data protection certification mechanisms and of data protection seals and marks pursuant to Article 42(1), and approve the criteria of certification pursuant to Article 42(5);

(o) where applicable, carry out a periodic review of certifications issued in accordance with Article 42(7);

(p) draft and publish the criteria for accreditation of a body for monitoring codes of conduct pursuant to Article 41 and of a certification body pursuant to Article 43;

(q) conduct the accreditation of a body for monitoring codes of conduct pursuant to Article 41 and of a certification body pursuant to Article 43;

(r) authorise contractual clauses and provisions referred to in Article 46(3);

(s) approve binding corporate rules pursuant to Article 47;

(t) contribute to the activities of the Board;

(u) keep internal records of infringements of this Regulation and of measures taken in accordance with Article 58(2); and

(v) fulfil any other tasks related to the protection of personal data.

2. Each supervisory authority shall facilitate the submission of complaints referred to in point (f) of paragraph 1 by measures such as a complaint submission form which can also be completed electronically, without excluding other means of communication.

3. The performance of the tasks of each supervisory authority shall be free of charge for the data subject and, where applicable, for the data protection officer.

4. Where requests are manifestly unfounded or excessive, in particular because of their repetitive character, the supervisory authority may charge a reasonable fee based on administrative costs, or refuse to act on the request. The supervisory authority shall bear the burden of demonstrating the manifestly unfounded or excessive character of the request.

Article 58

Powers

1. Each supervisory authority shall have all of the following investigative powers:

(a) to order the controller and the processor, and, where applicable, the controller's or the processor's representative to provide any information it requires for the performance of its tasks;

(b) to carry out investigations in the form of data protection audits;

(c) to carry out a review on certifications issued pursuant to Article 42(7);

(d) to notify the controller or the processor of an alleged infringement of this Regulation;

(e) to obtain, from the controller and the processor, access to all personal data and to all information necessary for the performance of its tasks;

(f) to obtain access to any premises of the controller and the processor, including to any data processing equipment and means, in accordance with Union or Member State procedural law.

2. Each supervisory authority shall have all of the following corrective powers:

(a) to issue warnings to a controller or processor that intended processing operations are likely to infringe provisions of this Regulation;

(b) to issue reprimands to a controller or a processor where processing operations have infringed provisions of this Regulation;

(c) to order the controller or the processor to comply with the data subject's requests to exercise his or her rights pursuant to this Regulation;

(d) to order the controller or processor to bring processing operations into compliance with the provisions of this Regulation, where appropriate, in a specified manner and within a specified period;

(e) to order the controller to communicate a personal data breach to the data subject;

(f) to impose a temporary or definitive limitation including a ban on processing;

(g) to order the rectification or erasure of personal data or restriction of processing pursuant to Articles 16, 17 and 18 and the notification of such actions to recipients to whom the personal data have been disclosed pursuant to Article 17(2) and Article 19;

(h) to withdraw a certification or to order the certification body to withdraw a certification issued pursuant to Articles 42 and 43, or to order the certification body not to issue certification if the requirements for the certification are not or are no longer met;

(i) to impose an administrative fine pursuant to Article 83, in addition to, or instead of measures referred to in this paragraph, depending on the circumstances of each individual case;

(j) to order the suspension of data flows to a recipient in a third country or to an international organisation.

3. Each supervisory authority shall have all of the following authorisation and advisory powers:

(a) to advise the controller in accordance with the prior consultation procedure referred to in Article 36;

(b) to issue, on its own initiative or on request, opinions to the national parliament, the Member State government or, in accordance with Member State law, to other institutions and bodies as well as to the public on any issue related to the protection of personal data;

(c) to authorise processing referred to in Article 36(5), if the law of the Member State requires such prior authorisation;

(d) to issue an opinion and approve draft codes of conduct pursuant to Article 40(5);

(e) to accredit certification bodies pursuant to Article 43;

(f) to issue certifications and approve criteria of certification in accordance with Article 42(5);

(g) to adopt standard data protection clauses referred to in Article 28(8) and in point (d) of Article 46(2);

(h) to authorise contractual clauses referred to in point (a) of Article 46(3);

(i) to authorise administrative arrangements referred to in point (b) of Article 46(3);

(j) to approve binding corporate rules pursuant to Article 47.

4. The exercise of the powers conferred on the supervisory authority pursuant to this Article shall be subject to appropriate safeguards, including effective judicial remedy and due process, set out in Union and Member State law in accordance with the Charter.

5. Each Member State shall provide by law that its supervisory authority shall have the power to bring infringements of this Regulation to the attention of the judicial authorities and where appropriate, to commence or engage otherwise in legal proceedings, in order to enforce the provisions of this Regulation.

6. Each Member State may provide by law that its supervisory authority shall have additional powers to those referred to in paragraphs 1, 2 and 3. The exercise of those powers shall not impair the effective operation of Chapter VII.

Article 59

Activity reports

Each supervisory authority shall draw up an annual report on its activities, which may include a list of types of infringement notified and types of measures taken in accordance with Article 58(2). Those reports shall be transmitted to the national parliament, the government and other authorities as designated by Member State law. They shall be made available to the public, to the Commission and to the Board.

CHAPTER VII

Cooperation and consistency

Section 1

Cooperation

Article 60

Cooperation between the lead supervisory authority and the other supervisory authorities concerned

1. The lead supervisory authority shall cooperate with the other supervisory authorities concerned in accordance with this Article in an endeavour to reach consensus. The lead supervisory authority and the supervisory authorities concerned shall exchange all relevant information with each other.

2. The lead supervisory authority may request at any time other supervisory authorities concerned to provide mutual assistance pursuant to Article 61 and may conduct joint operations pursuant to Article 62, in particular for carrying out investigations or for monitoring the implementation of a measure concerning a controller or processor established in another Member State.

3. The lead supervisory authority shall, without delay, communicate the relevant information on the matter to the other supervisory authorities concerned. It shall without delay submit a draft decision to the other supervisory authorities concerned for their opinion and take due account of their views.

4. Where any of the other supervisory authorities concerned within a period of four weeks after having been consulted in accordance with paragraph 3 of this Article, expresses a relevant and reasoned objection to the draft decision, the lead supervisory authority shall, if it does not follow the relevant and reasoned objection or is of the opinion that the objection is not relevant or reasoned, submit the matter to the consistency mechanism referred to in Article 63.

5. Where the lead supervisory authority intends to follow the relevant and reasoned objection made, it shall submit to the other supervisory authorities concerned a revised draft decision for their opinion. That revised draft decision shall be subject to the procedure referred to in paragraph 4 within a period of two weeks.

6. Where none of the other supervisory authorities concerned has objected to the draft decision submitted by the lead supervisory authority within the period referred to in paragraphs 4 and 5, the lead supervisory authority and the supervisory authorities concerned shall be deemed to be in agreement with that draft decision and shall be bound by it.

7. The lead supervisory authority shall adopt and notify the decision to the main establishment or single establishment of the controller or processor, as the case may be and inform the other supervisory authorities concerned and the Board of the decision in question, including a summary of the relevant facts and grounds. The supervisory authority with which a complaint has been lodged shall inform the complainant on the decision.

8. By derogation from paragraph 7, where a complaint is dismissed or rejected, the supervisory authority with which the complaint was lodged shall adopt the decision and notify it to the complainant and shall inform the controller thereof.

9. Where the lead supervisory authority and the supervisory authorities concerned agree to dismiss or reject parts of a complaint and to act on other parts of that complaint, a separate decision shall be adopted for each of those parts of the matter. The lead supervisory authority shall adopt the decision for the part concerning actions in relation to the controller, shall notify it to the main establishment or single establishment of the controller or processor on the territory of its Member State and shall inform the complainant thereof, while the supervisory authority of the complainant shall adopt the decision for the part concerning dismissal or rejection of that complaint, and shall notify it to that complainant and shall inform the controller or processor thereof.

10. After being notified of the decision of the lead supervisory authority pursuant to paragraphs 7 and 9, the controller or processor shall take the necessary measures to ensure compliance with the decision as regards processing activities in the context of all its establishments in the Union. The controller or processor shall notify the measures taken for complying with the decision to the lead supervisory authority, which shall inform the other supervisory authorities concerned.

11. Where, in exceptional circumstances, a supervisory authority concerned has reasons to consider that there is an urgent need to act in order to protect the interests of data subjects, the urgency procedure referred to in Article 66 shall apply.

12. The lead supervisory authority and the other supervisory authorities concerned shall supply the information required under this Article to each other by electronic means, using a standardised format.

Article 61

Mutual assistance

1. Supervisory authorities shall provide each other with relevant information and mutual assistance in order to implement and apply this Regulation in a consistent manner, and shall put in place measures for effective cooperation with one another. Mutual assistance shall cover, in particular, information requests and supervisory measures, such as requests to carry out prior authorisations and consultations, inspections and investigations.

2. Each supervisory authority shall take all appropriate measures required to reply to a request of another supervisory authority without undue delay and no later than one month after receiving the request. Such measures may include, in particular, the transmission of relevant information on the conduct of an investigation.

3. Requests for assistance shall contain all the necessary information, including the purpose of and reasons for the request. Information exchanged shall be used only for the purpose for which it was requested.

4. The requested supervisory authority shall not refuse to comply with the request unless:

(a) it is not competent for the subject-matter of the request or for the measures it is requested to execute; or

(b) compliance with the request would infringe this Regulation or Union or Member State law to which the supervisory authority receiving the request is subject.

5. The requested supervisory authority shall inform the requesting supervisory authority of the results or, as the case may be, of the progress of the measures taken in order to respond to the request. The requested supervisory authority shall provide reasons for any refusal to comply with a request pursuant to paragraph 4.

6. Requested supervisory authorities shall, as a rule, supply the information requested by other supervisory authorities by electronic means, using a standardised format.

7. Requested supervisory authorities shall not charge a fee for any action taken by them pursuant to a request for mutual assistance. Supervisory authorities may agree on rules to indemnify each other for specific expenditure arising from the provision of mutual assistance in exceptional circumstances.

8. Where a supervisory authority does not provide the information referred to in paragraph 5 of this Article within one month of receiving the request of another supervisory authority, the requesting supervisory authority may adopt a provisional measure on the territory of its Member State in accordance with Article 55(1). In that case, the urgent need to act under Article 66(1) shall be presumed to be met and require an urgent binding decision from the Board pursuant to Article 66(2).

9. The Commission may, by means of implementing acts, specify the format and procedures for mutual assistance referred to in this Article and the arrangements for the exchange of information by electronic means between supervisory authorities, and between supervisory authorities and the Board, in particular the standardised format referred to in paragraph 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 93(2).

Article 62

Joint operations of supervisory authorities

1. The supervisory authorities shall, where appropriate, conduct joint operations including joint investigations and joint enforcement measures in which members or staff of the supervisory authorities of other Member States are involved.

2. Where the controller or processor has establishments in several Member States or where a significant number of data subjects in more than one Member State are likely to be substantially affected by processing operations, a supervisory authority of each of those Member States shall have the right to participate in joint operations. The supervisory authority which is competent pursuant to Article 56(1) or (4) shall invite the supervisory authority of each of those Member States to take part in the joint operations and shall respond without delay to the request of a supervisory authority to participate.

3. A supervisory authority may, in accordance with Member State law, and with the seconding supervisory authority's authorisation, confer powers, including investigative powers on the seconding supervisory authority's members or staff involved in joint operations or, in so far as the law of the Member State of the host supervisory authority permits, allow the seconding supervisory authority's members or staff to exercise their investigative powers in accordance with the law of the Member State of the seconding supervisory authority. Such investigative powers may be exercised only under the guidance and in the presence of members or staff of the host supervisory authority. The seconding supervisory authority's members or staff shall be subject to the Member State law of the host supervisory authority.

4. Where, in accordance with paragraph 1, staff of a seconding supervisory authority operate in another Member State, the Member State of the host supervisory authority shall assume responsibility for their actions, including liability, for any damage caused by them during their operations, in accordance with the law of the Member State in whose territory they are operating.

5. The Member State in whose territory the damage was caused shall make good such damage under the conditions applicable to damage caused by its own staff. The Member State of the seconding supervisory authority whose staff has caused damage to any person in the territory of another Member State shall reimburse that other Member State in full any sums it has paid to the persons entitled on their behalf.

6. Without prejudice to the exercise of its rights *vis-à-vis* third parties and with the exception of paragraph 5, each Member State shall refrain, in the case provided for in paragraph 1, from requesting reimbursement from another Member State in relation to damage referred to in paragraph 4.

7. Where a joint operation is intended and a supervisory authority does not, within one month, comply with the obligation laid down in the second sentence of paragraph 2 of this Article, the other supervisory authorities may adopt a provisional measure on the territory of its Member State in accordance with Article 55. In that case, the urgent need to act under Article 66(1) shall be presumed to be met and require an opinion or an urgent binding decision from the Board pursuant to Article 66(2).

Section 2

Consistency

Article 63

Consistency mechanism

In order to contribute to the consistent application of this Regulation throughout the Union, the supervisory authorities shall cooperate with each other and, where relevant, with the Commission, through the consistency mechanism as set out in this Section.

Article 64

Opinion of the Board

1. The Board shall issue an opinion where a competent supervisory authority intends to adopt any of the measures below. To that end, the competent supervisory authority shall communicate the draft decision to the Board, when it:

(a) aims to adopt a list of the processing operations subject to the requirement for a data protection impact assessment pursuant to Article 35(4);

(b) concerns a matter pursuant to Article 40(7) whether a draft code of conduct or an amendment or extension to a code of conduct complies with this Regulation;

(c) aims to approve the criteria for accreditation of a body pursuant to Article 41(3) or a certification body pursuant to Article 43(3);

(d) aims to determine standard data protection clauses referred to in point (d) of Article 46(2) and in Article 28(8);

(e) aims to authorise contractual clauses referred to in point (a) of Article 46(3); or

(f) aims to approve binding corporate rules within the meaning of Article 47.

2. Any supervisory authority, the Chair of the Board or the Commission may request that any matter of general application or producing effects in more than one Member State be examined by the Board with a view to obtaining an opinion, in particular where a competent supervisory authority does not comply with the obligations for mutual assistance in accordance with Article 61 or for joint operations in accordance with Article 62.

3. In the cases referred to in paragraphs 1 and 2, the Board shall issue an opinion on the matter submitted to it provided that it has not already issued an opinion on the same matter. That opinion shall be adopted within eight weeks by simple majority of the members of the Board. That period may be extended by a further six weeks, taking into account the complexity of the subject matter. Regarding the draft decision referred to in paragraph 1 circulated to the members of the Board in accordance with paragraph 5, a member which has not objected within a reasonable period indicated by the Chair, shall be deemed to be in agreement with the draft decision.

4. Supervisory authorities and the Commission shall, without undue delay, communicate by electronic means to the Board, using a standardised format any relevant information, including as the case may be a summary of the facts, the draft decision, the grounds which make the enactment of such measure necessary, and the views of other supervisory authorities concerned.

5. The Chair of the Board shall, without undue, delay inform by electronic means:

(a) the members of the Board and the Commission of any relevant information which has been communicated to it using a standardised format. The secretariat of the Board shall, where necessary, provide translations of relevant information; and

(b) the supervisory authority referred to, as the case may be, in paragraphs 1 and 2, and the Commission of the opinion and make it public.

6. The competent supervisory authority shall not adopt its draft decision referred to in paragraph 1 within the period referred to in paragraph 3.

7. The supervisory authority referred to in paragraph 1 shall take utmost account of the opinion of the Board and shall, within two weeks after receiving the opinion, communicate to the Chair of the Board by electronic means whether it will maintain or amend its draft decision and, if any, the amended draft decision, using a standardised format.

8. Where the supervisory authority concerned informs the Chair of the Board within the period referred to in paragraph 7 of this Article that it does not intend to follow the opinion of the Board, in whole or in part, providing the relevant grounds, Article 65(1) shall apply.

Article 65

Dispute resolution by the Board

1. In order to ensure the correct and consistent application of this Regulation in individual cases, the Board shall adopt a binding decision in the following cases:

(a) where, in a case referred to in Article 60(4), a supervisory authority concerned has raised a relevant and reasoned objection to a draft decision of the lead authority or the lead authority has rejected such an objection as being not relevant or reasoned. The binding decision shall concern all the matters which are the subject of the relevant and reasoned objection, in particular whether there is an infringement of this Regulation;

(b) where there are conflicting views on which of the supervisory authorities concerned is competent for the main establishment;

(c) where a competent supervisory authority does not request the opinion of the Board in the cases referred to in Article 64(1), or does not follow the opinion of the Board issued under Article 64. In that case, any supervisory authority concerned or the Commission may communicate the matter to the Board.

2. The decision referred to in paragraph 1 shall be adopted within one month from the referral of the subject-matter by a two-thirds majority of the members of the Board. That period may be extended by a further month on account of the complexity of the subject-matter. The decision referred to in paragraph 1 shall be reasoned and addressed to the lead supervisory authority and all the supervisory authorities concerned and binding on them.

3. Where the Board has been unable to adopt a decision within the periods referred to in paragraph 2, it shall adopt its decision within two weeks following the expiration of the second month referred to in paragraph 2 by a simple majority of the members of the Board. Where the members of the Board are split, the decision shall by adopted by the vote of its Chair.

4. The supervisory authorities concerned shall not adopt a decision on the subject matter submitted to the Board under paragraph 1 during the periods referred to in paragraphs 2 and 3.

5. The Chair of the Board shall notify, without undue delay, the decision referred to in paragraph 1 to the supervisory authorities concerned. It shall inform the Commission thereof. The decision shall be published on the website of the Board without delay after the supervisory authority has notified the final decision referred to in paragraph 6.

6. The lead supervisory authority or, as the case may be, the supervisory authority with which the complaint has been lodged shall adopt its final decision on the basis of the decision referred to in paragraph 1 of this Article, without undue delay and at the latest by one month after the Board has notified its decision. The lead supervisory authority or, as the case may be, the supervisory authority with which the complaint has been lodged, shall inform the Board of the date when its final decision is notified respectively to the controller or the processor and to the data subject. The final decision of the supervisory authorities concerned shall be adopted under the terms of Article 60(7), (8) and (9). The final decision shall refer to the decision referred to in paragraph 1 of this Article and shall specify that the decision referred to in that paragraph will be published on the website of the Board in accordance with paragraph 5 of this Article. The final decision shall attach the decision referred to in paragraph 1 of this Article.

Article 66

Urgency procedure

1. In exceptional circumstances, where a supervisory authority concerned considers that there is an urgent need to act in order to protect the rights and freedoms of data subjects, it may, by way of derogation from the consistency mechanism referred to in Articles 63, 64 and 65 or the procedure referred to in Article 60, immediately adopt provisional measures intended to produce legal effects on its own territory with a specified period of validity which shall not exceed three months. The supervisory authority shall, without delay, communicate those measures and the reasons for adopting them to the other supervisory authorities concerned, to the Board and to the Commission.

2. Where a supervisory authority has taken a measure pursuant to paragraph 1 and considers that final measures need urgently be adopted, it may request an urgent opinion or an urgent binding decision from the Board, giving reasons for requesting such opinion or decision.

3. Any supervisory authority may request an urgent opinion or an urgent binding decision, as the case may be, from the Board where a competent supervisory authority has not taken an appropriate measure in a situation where there is an urgent need to act, in order to protect the rights and freedoms of data subjects, giving reasons for requesting such opinion or decision, including for the urgent need to act.

4. By derogation from Article 64(3) and Article 65(2), an urgent opinion or an urgent binding decision referred to in paragraphs 2 and 3 of this Article shall be adopted within two weeks by simple majority of the members of the Board.

Article 67

Exchange of information

The Commission may adopt implementing acts of general scope in order to specify the arrangements for the exchange of information by electronic means between supervisory authorities, and between supervisory authorities and the Board, in particular the standardised format referred to in Article 64.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 93(2).

Section 3

European data protection board

Article 68

European Data Protection Board

1. The European Data Protection Board (the 'Board') is hereby established as a body of the Union and shall have legal personality.

2. The Board shall be represented by its Chair.

3. The Board shall be composed of the head of one supervisory authority of each Member State and of the European Data Protection Supervisor, or their respective representatives.

4. Where in a Member State more than one supervisory authority is responsible for monitoring the application of the provisions pursuant to this Regulation, a joint representative shall be appointed in accordance with that Member State's law.

5. The Commission shall have the right to participate in the activities and meetings of the Board without voting right. The Commission shall designate a representative. The Chair of the Board shall communicate to the Commission the activities of the Board.

6. In the cases referred to in Article 65, the European Data Protection Supervisor shall have voting rights only on decisions which concern principles and rules applicable to the Union institutions, bodies, offices and agencies which correspond in substance to those of this Regulation.

Article 69

Independence

1. The Board shall act independently when performing its tasks or exercising its powers pursuant to Articles 70 and 71.

2. Without prejudice to requests by the Commission referred to in point (b) of Article 70(1) and in Article 70(2), the Board shall, in the performance of its tasks or the exercise of its powers, neither seek nor take instructions from anybody.

Article 70

Tasks of the Board

1. The Board shall ensure the consistent application of this Regulation. To that end, the Board shall, on its own initiative or, where relevant, at the request of the Commission, in particular:

(a) monitor and ensure the correct application of this Regulation in the cases provided for in Articles 64 and 65 without prejudice to the tasks of national supervisory authorities;

(b) advise the Commission on any issue related to the protection of personal data in the Union, including on any proposed amendment of this Regulation;

(c) advise the Commission on the format and procedures for the exchange of information between controllers, processors and supervisory authorities for binding corporate rules;

(d) issue guidelines, recommendations, and best practices on procedures for erasing links, copies or replications of personal data from publicly available communication services as referred to in Article 17(2);

(e) examine, on its own initiative, on request of one of its members or on request of the Commission, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation;

(f) issue guidelines, recommendations and best practices in accordance with point (e) of this paragraph for further specifying the criteria and conditions for decisions based on profiling pursuant to Article 22(2);

(g) issue guidelines, recommendations and best practices in accordance with point (e) of this paragraph for establishing the personal data breaches and determining the undue delay referred to in Article 33(1) and (2) and for the particular circumstances in which a controller or a processor is required to notify the personal data breach;

(h) issue guidelines, recommendations and best practices in accordance with point (e) of this paragraph as to the circumstances in which a personal data breach is likely to result in a high risk to the rights and freedoms of the natural persons referred to in Article 34(1).

(i) issue guidelines, recommendations and best practices in accordance with point (e) of this paragraph for the purpose of further specifying the criteria and requirements for personal data transfers based on binding corporate rules adhered to by controllers and binding corporate rules adhered to by processors and on further necessary requirements to ensure the protection of personal data of the data subjects concerned referred to in Article 47;

(j) issue guidelines, recommendations and best practices in accordance with point (e) of this paragraph for the purpose of further specifying the criteria and requirements for the personal data transfers on the basis of Article 49(1);

(k) draw up guidelines for supervisory authorities concerning the application of measures referred to in Article 58(1), (2) and (3) and the setting of administrative fines pursuant to Article 83;

(l) review the practical application of the guidelines, recommendations and best practices referred to in points (e) and (f);

(m) issue guidelines, recommendations and best practices in accordance with point (e) of this paragraph for establishing common procedures for reporting by natural persons of infringements of this Regulation pursuant to Article 54(2);

(n) encourage the drawing-up of codes of conduct and the establishment of data protection certification mechanisms and data protection seals and marks pursuant to Articles 40 and 42;

(o) carry out the accreditation of certification bodies and its periodic review pursuant to Article 43 and maintain a public register of accredited bodies pursuant to Article 43(6) and of the accredited controllers or processors established in third countries pursuant to Article 42(7);

(p) specify the requirements referred to in Article 43(3) with a view to the accreditation of certification bodies under Article 42;

(q) provide the Commission with an opinion on the certification requirements referred to in Article 43(8);

(r) provide the Commission with an opinion on the icons referred to in Article 12(7);

(s) provide the Commission with an opinion for the assessment of the adequacy of the level of protection in a third country or international organisation, including for the assessment whether a third country, a territory or one or more specified sectors within that third country, or an international organisation no longer ensures an adequate level of protection. To that end, the Commission shall provide the Board with all necessary documentation, including correspondence with the government of the third country, with regard to that third country, territory or specified sector, or with the international organisation.

(t) issue opinions on draft decisions of supervisory authorities pursuant to the consistency mechanism referred to in Article 64(1), on matters submitted pursuant to Article 64(2) and to issue binding decisions pursuant to Article 65, including in cases referred to in Article 66;

(u) promote the cooperation and the effective bilateral and multilateral exchange of information and best practices between the supervisory authorities;

(v) promote common training programmes and facilitate personnel exchanges between the supervisory authorities and, where appropriate, with the supervisory authorities of third countries or with international organisations;

(w) promote the exchange of knowledge and documentation on data protection legislation and practice with data protection supervisory authorities worldwide.

(x) issue opinions on codes of conduct drawn up at Union level pursuant to Article 40(9); and

(y) maintain a publicly accessible electronic register of decisions taken by supervisory authorities and courts on issues handled in the consistency mechanism.

2. Where the Commission requests advice from the Board, it may indicate a time limit, taking into account the urgency of the matter.

3. The Board shall forward its opinions, guidelines, recommendations, and best practices to the Commission and to the committee referred to in Article 93 and make them public.

4. The Board shall, where appropriate, consult interested parties and give them the opportunity to comment within a reasonable period. The Board shall, without prejudice to Article 76, make the results of the consultation procedure publicly available.

Article 71

Reports

1. The Board shall draw up an annual report regarding the protection of natural persons with regard to processing in the Union and, where relevant, in third countries and international organisations. The report shall be made public and be transmitted to the European Parliament, to the Council and to the Commission.

2. The annual report shall include a review of the practical application of the guidelines, recommendations and best practices referred to in point (l) of Article 70(1) as well as of the binding decisions referred to in Article 65.

Article 72

Procedure

1. The Board shall take decisions by a simple majority of its members, unless otherwise provided for in this Regulation.

2. The Board shall adopt its own rules of procedure by a two-thirds majority of its members and organise its own operational arrangements.

Article 73

Chair

1. The Board shall elect a chair and two deputy chairs from amongst its members by simple majority.

2. The term of office of the Chair and of the deputy chairs shall be five years and be renewable once.

Article 74

Tasks of the Chair

1. The Chair shall have the following tasks:

(a) to convene the meetings of the Board and prepare its agenda;

(b) to notify decisions adopted by the Board pursuant to Article 65 to the lead supervisory authority and the supervisory authorities concerned;

(c) to ensure the timely performance of the tasks of the Board, in particular in relation to the consistency mechanism referred to in Article 63.

2. The Board shall lay down the allocation of tasks between the Chair and the deputy chairs in its rules of procedure.

Article 75

Secretariat

1. The Board shall have a secretariat, which shall be provided by the European Data Protection Supervisor.

2. The secretariat shall perform its tasks exclusively under the instructions of the Chair of the Board.

3. The staff of the European Data Protection Supervisor involved in carrying out the tasks conferred on the Board by this Regulation shall be subject to separate reporting lines from the staff involved in carrying out tasks conferred on the European Data Protection Supervisor.

4. Where appropriate, the Board and the European Data Protection Supervisor shall establish and publish a Memorandum of Understanding implementing this Article, determining the terms of their cooperation, and applicable to the staff of the European Data Protection Supervisor involved in carrying out the tasks conferred on the Board by this Regulation.

5. The secretariat shall provide analytical, administrative and logistical support to the Board.

6. The secretariat shall be responsible in particular for:

(a) the day-to-day business of the Board;

(b) communication between the members of the Board, its Chair and the Commission;

(c) communication with other institutions and the public;

(d) the use of electronic means for the internal and external communication;

(e) the translation of relevant information;

(f) the preparation and follow-up of the meetings of the Board;

(g) the preparation, drafting and publication of opinions, decisions on the settlement of disputes between supervisory authorities and other texts adopted by the Board.

Article 76

Confidentiality

1. The discussions of the Board shall be confidential where the Board deems it necessary, as provided for in its rules of procedure.

2. Access to documents submitted to members of the Board, experts and representatives of third parties shall be governed by Regulation (EC) No 1049/2001 of the European Parliament and of the Council [1].

CHAPTER VIII

Remedies, liability and penalties

Article 77

Right to lodge a complaint with a supervisory authority

1. Without prejudice to any other administrative or judicial remedy, every data subject shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the data subject considers that the processing of personal data relating to him or her infringes this Regulation.

2. The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy pursuant to Article 78.

Article 78

Right to an effective judicial remedy against a supervisory authority

1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a supervisory authority concerning them.

2. Without prejudice to any other administrative or non-judicial remedy, each data subject shall have the right to a an effective judicial remedy where the supervisory authority which is competent pursuant to Articles 55 and 56 does not handle a complaint or does not inform the data subject within three months on the progress or outcome of the complaint lodged pursuant to Article 77.

3. Proceedings against a supervisory authority shall be brought before the courts of the Member State where the supervisory authority is established.

4. Where proceedings are brought against a decision of a supervisory authority which was preceded by an opinion or a decision of the Board in the consistency mechanism, the supervisory authority shall forward that opinion or decision to the court.

Article 79

Right to an effective judicial remedy against a controller or processor

1. Without prejudice to any available administrative or non-judicial remedy, including the right to lodge a complaint with a supervisory authority pursuant to Article 77, each data subject shall have the right to an effective judicial remedy where he or she considers that his or her rights under this Regulation have been infringed as a result of the processing of his or her personal data in non-compliance with this Regulation.

2. Proceedings against a controller or a processor shall be brought before the courts of the Member State where the controller or processor has an establishment. Alternatively, such proceedings may be brought before the courts of the Member State where the data subject has his or her habitual residence, unless the controller or processor is a public authority of a Member State acting in the exercise of its public powers.

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Article 80

Representation of data subjects

1. The data subject shall have the right to mandate a not-for-profit body, organisation or association which has been properly constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest, and is active in the field of the protection of data subjects' rights and freedoms with regard to the protection of their personal data to lodge the complaint on his or her behalf, to exercise the rights referred to in Articles 77, 78 and 79 on his or her behalf, and to exercise the right to receive compensation referred to in Article 82 on his or her behalf where provided for by Member State law.

2. Member States may provide that any body, organisation or association referred to in paragraph 1 of this Article, independently of a data subject's mandate, has the right to lodge, in that Member State, a complaint with the supervisory authority which is competent pursuant to Article 77 and to exercise the rights referred to in Articles 78 and 79 if it considers that the rights of a data subject under this Regulation have been infringed as a result of the processing.

Article 81

Suspension of proceedings

1. Where a competent court of a Member State has information on proceedings, concerning the same subject matter as regards processing by the same controller or processor, that are pending in a court in another Member State, it shall contact that court in the other Member State to confirm the existence of such proceedings.

2. Where proceedings concerning the same subject matter as regards processing of the same controller or processor are pending in a court in another Member State, any competent court other than the court first seized may suspend its proceedings.

3. Where those proceedings are pending at first instance, any court other than the court first seized may also, on the application of one of the parties, decline jurisdiction if the court first seized has jurisdiction over the actions in question and its law permits the consolidation thereof.

Article 82

Right to compensation and liability

1. Any person who has suffered material or non-material damage as a result of an infringement of this Regulation shall have the right to receive compensation from the controller or processor for the damage suffered.

2. Any controller involved in processing shall be liable for the damage caused by processing which infringes this Regulation. A processor shall be liable for the damage caused by processing only where it has not complied with obligations of this Regulation specifically directed to processors or where it has acted outside or contrary to lawful instructions of the controller.

3. A controller or processor shall be exempt from liability under paragraph 2 if it proves that it is not in any way responsible for the event giving rise to the damage.

4. Where more than one controller or processor, or both a controller and a processor, are involved in the same processing and where they are, under paragraphs 2 and 3, responsible for any damage caused by processing, each controller or processor shall be held liable for the entire damage in order to ensure effective compensation of the data subject.

5. Where a controller or processor has, in accordance with paragraph 4, paid full compensation for the damage suffered, that controller or processor shall be entitled to claim back from the other controllers or processors involved in the same processing that part of the compensation corresponding to their part of responsibility for the damage, in accordance with the conditions set out in paragraph 2.

6. Court proceedings for exercising the right to receive compensation shall be brought before the courts competent under the law of the Member State referred to in Article 79(2).

Article 83

General conditions for imposing administrative fines

1. Each supervisory authority shall ensure that the imposition of administrative fines pursuant to this Article in respect of infringements of this Regulation referred to in paragraphs 4, 5 and 6 shall in each individual case be effective, proportionate and dissuasive.

2. Administrative fines shall, depending on the circumstances of each individual case, be imposed in addition to, or instead of, measures referred to in points (a) to (h) and (j) of Article 58(2). When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case due regard shall be given to the following:

(a) the nature, gravity and duration of the infringement taking into account the nature scope or purpose of the processing concerned as well as the number of data subjects affected and the level of damage suffered by them;

(b) the intentional or negligent character of the infringement;

(c) any action taken by the controller or processor to mitigate the damage suffered by data subjects;

(d) the degree of responsibility of the controller or processor taking into account technical and organisational measures implemented by them pursuant to Articles 25 and 32;

(e) any relevant previous infringements by the controller or processor;

(f) the degree of cooperation with the supervisory authority, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

(g) the categories of personal data affected by the infringement;

(h) the manner in which the infringement became known to the supervisory authority, in particular whether, and if so to what extent, the controller or processor notified the infringement;

(i) where measures referred to in Article 58(2) have previously been ordered against the controller or processor concerned with regard to the same subject-matter, compliance with those measures;

(j) adherence to approved codes of conduct pursuant to Article 40 or approved certification mechanisms pursuant to Article 42; and

(k) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.

3. If a controller or processor intentionally or negligently, for the same or linked processing operations, infringes several provisions of this Regulation, the total amount of the administrative fine shall not exceed the amount specified for the gravest infringement.

4. Infringements of the following provisions shall, in accordance with paragraph 2, be subject to administrative fines up to 10 000 000 EUR, or in the case of an undertaking, up to 2 % of the total worldwide annual turnover of the preceding financial year, whichever is higher:

(a) the obligations of the controller and the processor pursuant to Articles 8, 11, 25 to 39 and 42 and 43;

(b) the obligations of the certification body pursuant to Articles 42 and 43;

(c) the obligations of the monitoring body pursuant to Article 41(4).

5. Infringements of the following provisions shall, in accordance with paragraph 2, be subject to administrative fines up to 20 000 000 EUR, or in the case of an undertaking, up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher:

(a) the basic principles for processing, including conditions for consent, pursuant to Articles 5, 6, 7 and 9;

(b) the data subjects' rights pursuant to Articles 12 to 22;

(c) the transfers of personal data to a recipient in a third country or an international organisation pursuant to Articles 44 to 49;

(d) any obligations pursuant to Member State law adopted under Chapter IX;

(e) non-compliance with an order or a temporary or definitive limitation on processing or the suspension of data flows by the supervisory authority pursuant to Article 58(2) or failure to provide access in violation of Article 58(1).

6. Non-compliance with an order by the supervisory authority as referred to in Article 58(2) shall, in accordance with paragraph 2 of this Article, be subject to administrative fines up to 20 000 000 EUR, or in the case of an undertaking, up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.

7. Without prejudice to the corrective powers of supervisory authorities pursuant to Article 58(2), each Member State may lay down the rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.

8. The exercise by the supervisory authority of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedy and due process.

9. Where the legal system of the Member State does not provide for administrative fines, this Article may be applied in such a manner that the fine is initiated by the competent supervisory authority and imposed by competent national courts, while ensuring that those legal remedies are effective and have an equivalent effect to the administrative fines imposed by supervisory authorities. In any event, the fines imposed shall be effective, proportionate and dissuasive. Those Member States shall notify to the Commission the provisions of their laws which they adopt pursuant to this paragraph by 25 May 2018 and, without delay, any subsequent amendment law or amendment affecting them.

Article 84

Penalties

1. Member States shall lay down the rules on other penalties applicable to infringements of this Regulation in particular for infringements which are not subject to administrative fines pursuant to Article 83, and shall take all measures necessary to ensure that they are implemented. Such penalties shall be effective, proportionate and dissuasive.

2. Each Member State shall notify to the Commission the provisions of its law which it adopts pursuant to paragraph 1, by 25 May 2018 and, without delay, any subsequent amendment affecting them.

CHAPTER IX

Provisions relating to specific processing situations

Article 85

Processing and freedom of expression and information

1. Member States shall by law reconcile the right to the protection of personal data pursuant to this Regulation with the right to freedom of expression and information, including processing for journalistic purposes and the purposes of academic, artistic or literary expression.

2. For processing carried out for journalistic purposes or the purpose of academic artistic or literary expression, Member States shall provide for exemptions or derogations from Chapter II (principles), Chapter III (rights of the data subject), Chapter IV (controller and processor), Chapter V (transfer of personal data to third countries or international organisations), Chapter VI (independent supervisory authorities), Chapter VII (cooperation and consistency) and Chapter IX (specific data processing situations) if they are necessary to reconcile the right to the protection of personal data with the freedom of expression and information.

3. Each Member State shall notify to the Commission the provisions of its law which it has adopted pursuant to paragraph 2 and, without delay, any subsequent amendment law or amendment affecting them.

Article 86

Processing and public access to official documents

Personal data in official documents held by a public authority or a public body or a private body for the performance of a task carried out in the public interest may be disclosed by the authority or body in accordance with Union or Member State law to which the public authority or body is subject in order to reconcile public access to official documents with the right to the protection of personal data pursuant to this Regulation.

Article 87

Processing of the national identification number

Member States may further determine the specific conditions for the processing of a national identification number or any other identifier of general application. In that case the national identification number or any other identifier of general application shall be used only under appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation.

Article 88

Processing in the context of employment

1. Member States may, by law or by collective agreements, provide for more specific rules to ensure the protection of the rights and freedoms in respect of the processing of employees' personal data in the employment context, in particular for the purposes of the recruitment, the performance of the contract of employment, including discharge of obligations laid down by law or by collective agreements, management, planning and organisation of work, equality and diversity in the workplace, health and safety at work, protection of employer's or customer's property and for the purposes of the exercise and enjoyment, on an individual or collective basis, of rights and benefits related to employment, and for the purpose of the termination of the employment relationship.

2. Those rules shall include suitable and specific measures to safeguard the data subject's human dignity, legitimate interests and fundamental rights, with particular regard to the transparency of processing, the transfer of personal data within a group of undertakings, or a group of enterprises engaged in a joint economic activity and monitoring systems at the work place.

3. Each Member State shall notify to the Commission those provisions of its law which it adopts pursuant to paragraph 1, by 25 May 2018 and, without delay, any subsequent amendment affecting them.

Article 89

Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes

1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in

order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.

2. Where personal data are processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

3. Where personal data are processed for archiving purposes in the public interest, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18, 19, 20 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

4. Where processing referred to in paragraphs 2 and 3 serves at the same time another purpose, the derogations shall apply only to processing for the purposes referred to in those paragraphs.

Article 90

Obligations of secrecy

1. Member States may adopt specific rules to set out the powers of the supervisory authorities laid down in points (e) and (f) of Article 58(1) in relation to controllers or processors that are subject, under Union or Member State law or rules established by national competent bodies, to an obligation of professional secrecy or other equivalent obligations of secrecy where this is necessary and proportionate to reconcile the right of the protection of personal data with the obligation of secrecy. Those rules shall apply only with regard to personal data which the controller or processor has received as a result of or has obtained in an activity covered by that obligation of secrecy.

2. Each Member State shall notify to the Commission the rules adopted pursuant to paragraph 1, by 25 May 2018 and, without delay, any subsequent amendment affecting them.

Article 91

Existing data protection rules of churches and religious associations

1. Where in a Member State, churches and religious associations or communities apply, at the time of entry into force of this Regulation, comprehensive rules relating to the protection of natural persons with regard to processing, such rules may continue to apply, provided that they are brought into line with this Regulation.

2. Churches and religious associations which apply comprehensive rules in accordance with paragraph 1 of this Article shall be subject to the supervision of an independent supervisory authority, which may be specific, provided that it fulfils the conditions laid down in Chapter VI of this Regulation.

CHAPTER X

Delegated acts and implementing acts

Article 92

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 12(8) and Article 43(8) shall be conferred on the Commission for an indeterminate period of time from 24 May 2016.

3. The delegation of power referred to in Article 12(8) and Article 43(8) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 12(8) and Article 43(8) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 93

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER XI

Final provisions

Article 94

Repeal of Directive 95/46/EC

1. Directive 95/46/EC is repealed with effect from 25 May 2018.

2. References to the repealed Directive shall be construed as references to this Regulation. References to the Working Party on the Protection of Individuals with regard to the Processing of Personal Data established by Article 29 of Directive 95/46/EC shall be construed as references to the European Data Protection Board established by this Regulation.

Article 95

Relationship with Directive 2002/58/EC

This Regulation shall not impose additional obligations on natural or legal persons in relation to processing in connection with the provision of publicly available electronic communications services in public communication networks in the Union in relation to matters for which they are subject to specific obligations with the same objective set out in Directive 2002/58/EC.

Article 96

Relationship with previously concluded Agreements

International agreements involving the transfer of personal data to third countries or international organisations which were concluded by Member States prior to 24 May 2016, and which comply with Union law as applicable prior to that date, shall remain in force until amended, replaced or revoked.

Article 97

Commission reports

1. By 25 May 2020 and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

2. In the context of the evaluations and reviews referred to in paragraph 1, the Commission shall examine, in particular, the application and functioning of:

(a) Chapter V on the transfer of personal data to third countries or international organisations with particular regard to decisions adopted pursuant to Article 45(3) of this Regulation and decisions adopted on the basis of Article 25(6) of Directive 95/46/EC;

(b) Chapter VII on cooperation and consistency.

3. For the purpose of paragraph 1, the Commission may request information from Member States and supervisory authorities.

4. In carrying out the evaluations and reviews referred to in paragraphs 1 and 2, the Commission shall take into account the positions and findings of the European Parliament, of the Council, and of other relevant bodies or sources.

5. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account of developments in information technology and in the light of the state of progress in the information society.

Article 98

Review of other Union legal acts on data protection

The Commission shall, if appropriate, submit legislative proposals with a view to amending other Union legal acts on the protection of personal data, in order to ensure uniform and consistent protection of natural persons with regard to processing. This shall in particular concern the rules relating to the protection of natural persons with regard to processing by Union institutions, bodies, offices and agencies and on the free movement of such data.

Article 99

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from 25 May 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 April 2016.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	J.A. HENNIS-PLASSCHAERT

Bundesgesetz über die Organisation der Universitäten und ihre Studien (Universitätsgesetz 2002 – UG)

StF: BGBl. I Nr. 120/2002 (NR: GP XXI RV 1134 AB 1224 S. 111. BR: 6697 AB 6717 S. 690.)

Änderung

BGBl. I Nr. 21/2004 (VfGH)

BGBl. I Nr. 96/2004 (NR: GP XXII IA 414/A AB 603 S. 73 BR: 7085 AB 7107 S. 712.)

BGBl. I Nr. 116/2004 (VfGH)

BGBl. I Nr. 77/2005 (NR: GP XXII AB 1045 S. 117. BR: 7336 AB 7359 S. 724.)

BGBl. I Nr. 74/2006 (NR: GP XXII IA 752/A AB 1308 S. 139. Einspr. d. BR: 1439 AB 1449 S. 150. BR: 7475 AB 7501 S. 733.)

BGBl. I Nr. 24/2007 (NR: GP XXIII RV 43 AB 67 S. 20. BR: 7681 AB 7682 S. 745.) [CELEX-Nr.: 32003L0096, 32006L0048, 32006L0098, 32006L0112, 32006L0141]

BGBl. I Nr. 87/2007 (NR: GP XXIII RV 241 AB 276 S. 37. BR: AB 7787 S. 750.)

BGBl. I Nr. 134/2008 (NR: GP XXIII IA 890/A S. 72. BR: 8017 AB 8027 S. 760.)

BGBl. I Nr. 81/2009 (NR: GP XXIV RV 225 AB 308 S. 31. BR: 8138 AB 8159 S. 774.)

BGBl. I Nr. 111/2010 (NR: GP XXIV RV 981 AB 1026 S. 90. BR: 8437 AB 8439 S. 792.) [CELEX-Nr.: 32010L0012]

BGBl. I Nr. 13/2011 (NR: GP XXIV RV 1054 AB 1079 S. 96. BR: AB 8459 S. 794.)

BGBl. I Nr. 45/2011 (VfGH)

BGBl. I Nr. 35/2012 (NR: GP XXIV RV 1685 AB 1708 S. 148. BR: 8686 AB 8688 S. 806.)

BGBl. I Nr. 47/2012 (NR: GP XXIV RV 1710 AB 1741 S. 153. BR: AB 8722 S. 808.) ersetzt durch BGBl. I Nr. 52/2012

BGBl. I Nr. 52/2012 (NR: GP XXIV RV 1710 AB 1741 S. 153. BR: AB 8722 S. 808.)

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Federal Act on the Organisation of Universities and their Studies (Universities Act 2002 – UG)

⇐ Original version

as amended by:

(list of amendments published in the Federal Law Gazette [F. L. G. = BGBl.])

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BGBl. I Nr. 79/2013 (NR: GP XXIV RV 2164 AB 2282 S. 199. BR: 8945 AB 8957 S. 820.)
BGBl. I Nr. 124/2013 (NR: GP XXIV RV 2348 AB 2397 S. 206. BR: 9006 AB 9012 S. 822.)
BGBl. I Nr. 168/2013 (VfGH)
BGBl. I Nr. 176/2013 (NR: GP XXIV RV 2435 AB 2452 S. 216. BR: 9056 AB 9119 S. 823.)
BGBl. I Nr. 16/2014 (NR: GP XXV AB 35 S. 12. BR: AB 9144 S. 827.)
BGBl. I Nr. 45/2014 (NR: GP XXV RV 136 AB 171 S. 30. BR: 9189 AB 9192 S. 831.)
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BGBl. I Nr. 56/2018 (NR: GP XXVI RV 189 AB 207 S. 36. BR: 9998 AB 10020 S. 883.) [CELEX-Nr. 32016L0801]
BGBl. I Nr. 3/2019 (NR: GP XXVI RV 378 AB 442 S. 55. BR: AB 10106 S. 888.)
BGBl. I Nr. 135/2020 (NR: GP XXVII RV 408 AB 440 S. 62. BR: 10438 AB 10443 S. 915.)
BGBl. I Nr. 20/2021 (NR: GP XXVII RV 479 AB 571 S. 71. BR: AB 10468 S. 917.)
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BGBl. I Nr. 25/2025 (NR: GP XXVIII RV 69 und Zu 69 AB 100 S. 30. BR: 11643 AB 11645 S. 979.)
BGBl. I Nr. 28/2025 (NR: GP XXVIII RV 96 AB 103 S. 30. BR: AB 11648 S. 979.)
BGBl. I Nr. 50/2025 (NR: GP XXVIII RV 129 AB 151 S. 35. BR: 11651 AB 11654 S. 980.)
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Click here for checking the up-to-date list of amendments
in the Austrian Legal Information System.

Disclaimer: This translation has been done with great care. In case of discrepancies or contradictions between the German original text and the translated version, only the German version is considered authentic and legally binding.

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I. Teil
Organisationsrecht

1. Abschnitt
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1. Unterabschnitt
Grundsätze, Aufgaben und Geltungsbereich

Ziele

§ 1. Die Universitäten sind berufen, der wissenschaftlichen Forschung und Lehre, der Entwicklung und der Erschließung der Künste sowie der Lehre der Kunst zu dienen und hiedurch auch verantwortlich zur Lösung der Probleme des Menschen sowie zur gedeihlichen Entwicklung der Gesellschaft und der natürlichen Umwelt beizutragen. Universitäten sind Bildungseinrichtungen des öffentlichen Rechts, die in Forschung und in forschungsgeleiteter akademischer Lehre auf die Hervorbringung neuer wissenschaftlicher Erkenntnisse sowie auf die Erschließung neuer Zugänge zu den Künsten ausgerichtet sind. Im gemeinsamen Wirken von Lehrenden und Studierenden wird in einer aufgeklärten Wissensgesellschaft das Streben nach Bildung und Autonomie des Individuums durch Wissenschaft vollzogen. Die Förderung des wissenschaftlichen Nachwuchses geht mit der Erarbeitung von Fähigkeiten und Qualifikationen sowohl im Bereich der wissenschaftlichen und künstlerischen Inhalte als auch im Bereich der methodischen Fertigkeiten mit dem Ziel einher, zur Bewältigung der gesellschaftlichen Herausforderungen in einer sich wandelnden humanen und geschlechtergerechten Gesellschaft beizutragen. Um den sich ständig wandelnden Erfordernissen organisatorisch, studien- und personalrechtlich Rechnung zu tragen, konstituieren sich die Universitäten und ihre Organe in größtmöglicher Autonomie und Selbstverwaltung.

Leitende Grundsätze

§ 2. Die leitenden Grundsätze für die Universitäten bei der Erfüllung ihrer Aufgaben sind:

1. Freiheit der Wissenschaften und ihrer Lehre (Art. 17 des Staatsgrundgesetzes über die allgemeinen Rechte der Staatsbürger, RGBl.

Part I
Organisational Law

Chapter 1
General Provisions

Sub-Chapter 1
Principles, Responsibilities and Scope of Application

Objectives

§ 1. The mission of the universities is to serve academic research and teaching and the advancement, appreciation and teaching of the arts, and thereby to contribute to the personal development of the individual and to the welfare of society and the environment. Universities are public educational institutions which, in their research and research-based teaching, are directed towards the advancement of knowledge and the development of new approaches to the arts. Through the common efforts of teachers and students, working in an enlightened knowledge society, they assist individuals in their striving for the education and autonomy through science. They promote the advancement of junior academics, which goes hand in hand with the acquisition of scientific and artistic abilities and qualifications, and methodological skills, with the goal of helping a society in transition to master the challenges it faces in a humane and gender-equal fashion. To enable them to respond to the constantly changing demands made on them in terms of organisation, study laws and employment laws, the universities and their governing bodies shall constitute themselves under conditions of the greatest possible autonomy and self-administration.

Guiding Principles

§ 2. The guiding principles to be observed by the universities in pursuance of their objects are:

1. freedom of sciences and their teaching (Art 17 of the Basic Law on the General Rights of Nationals, Imperial Legal Gazette No 142/1867) and

Nr. 142/1867) und Freiheit des wissenschaftlichen und des künstlerischen Schaffens, der Vermittlung von Kunst und ihrer Lehre (Art. 17a des Staatsgrundgesetzes über die allgemeinen Rechte der Staatsbürger);

2. Verbindung von Forschung und Lehre, Verbindung der Entwicklung und Erschließung der Künste und ihrer Lehre sowie Verbindung von Wissenschaft und Kunst;
3. Vielfalt wissenschaftlicher und künstlerischer Theorien, Methoden und Lehrmeinungen;

3a. ~~Sicherstellung guter wissenschaftlicher Praxis und akademischer~~ Integrität im wissenschaftlichen und künstlerischen Studien-, Lehr- und Forschungsbetrieb;

4. Lernfreiheit;
5. Berücksichtigung der Erfordernisse der Berufszugänge, insbesondere für das Lehramt an Schulen bzw. Berufstätigkeiten an elementarpädagogischen Bildungseinrichtungen;
6. Mitsprache der Studierenden, insbesondere bei Studienangelegenheiten und bei der Qualitätssicherung der Lehre;
7. nationale und internationale Mobilität der Studierenden, der Absolventinnen und Absolventen sowie des wissenschaftlichen und künstlerischen Universitätspersonals;
8. Zusammenwirken der Universitätsangehörigen;
9. Gleichstellung der Geschlechter;
10. soziale Chancengleichheit;
11. besondere Berücksichtigung der Erfordernisse von behinderten Menschen;
12. Wirtschaftlichkeit, Sparsamkeit und Zweckmäßigkeit der Gebarung;
13. Vereinbarkeit von Studium oder Beruf mit Betreuungspflichten für Kinder und pflegebedürftige Angehörige;
14. Nachhaltige Nutzung von Ressourcen.

Aufgaben

§ 3. Die Universitäten erfüllen im Rahmen ihres Wirkungsbereichs folgende Aufgaben:

1. Entwicklung der Wissenschaften (Forschung und Lehre), Entwicklung und Erschließung der Kunst sowie Lehre der Kunst;
2. Bildung durch Wissenschaft und durch die Entwicklung und Erschließung der Künste;

freedom of scientific and artistic activity, the dissemination of the arts and their teaching (Art 17a of the Basic Law on the General Rights of Nationals);

2. interaction between research and teaching, the advancement, appreciation and teaching of the arts, and science and art;
3. diversity of scientific and artistic theories, methods and doctrines;

3a. ensuring good scientific practice and academic integrity;

4. freedom of study;
5. attention to the requirements for entry to professional careers, in particular for teaching at schools or at elementary educational institutions;
6. student co-determination, particularly in respect of matters relating to studies and quality assurance of teaching;
7. national and international mobility of students, graduates, and university scientific and artistic staff;
8. collaborative relationships between members of the university;
9. gender equality;
10. equality of social opportunity;
11. special attention to the needs of the handicapped;
12. efficient, economical and expedient management of finances;
13. compatibility of studies or career and responsibilities for the care of children and family members requiring care;
14. sustainable use of resources.

Tasks

§ 3. Within their sphere of action, the universities fulfil the following tasks:

1. advancement of sciences (research and teaching), and the advancement, appreciation and teaching of the arts;
2. education through science and the advancement and appreciation of the arts;

3. wissenschaftliche, künstlerische, künstlerisch-pädagogische und künstlerisch-wissenschaftliche Berufsvorbildung, Qualifizierung für berufliche Tätigkeiten, die eine Anwendung wissenschaftlicher Erkenntnisse und Methoden erfordern, sowie Ausbildung der künstlerischen und wissenschaftlichen Fähigkeiten bis zur höchsten Stufe;
4. Entwicklung und Förderung geeigneter Karrieremodelle für den höchstqualifizierten wissenschaftlichen und künstlerischen Nachwuchs;
5. Weiterbildung;
6. Koordinierung der wissenschaftlichen Forschung (Entwicklung und Erschließung der Künste) und der Lehre innerhalb der Universität;
7. Unterstützung der nationalen und internationalen Zusammenarbeit im Bereich der wissenschaftlichen Forschung und Lehre sowie der Kunst;
8. Unterstützung der Nutzung und Umsetzung ihrer Forschungsergebnisse in der Praxis und Unterstützung der gesellschaftlichen Einbindung von Ergebnissen der Entwicklung und Erschließung der Künste;
9. Gleichstellung der Geschlechter sowie Frauenförderung;
10. Pflege der Kontakte zu den Absolventinnen und Absolventen;
11. Information der Öffentlichkeit über die Erfüllung der Aufgaben der Universitäten.;
12. Sicherstellung der Integrität im wissenschaftlichen und künstlerischen Studien-, Lehr- und Forschungsbetrieb, insbesondere durch Vermittlung entsprechender Regeln.

Rechtsform

§ 4. Die Universitäten sind juristische Personen des öffentlichen Rechts.

Weisungsfreiheit und Satzungsfreiheit

§ 5. Die Universitäten erfüllen ihre Aufgaben gemäß § 3 im Rahmen der Gesetze und Verordnungen weisungsfrei und geben sich ihre Satzung im Rahmen der Gesetze nach Maßgabe des Art. 81c Abs. 1 des Bundes-Verfassungsgesetzes (B-VG), BGBl. Nr. 1/1930, in der Fassung des Bundesgesetzes BGBl. I Nr. 2/2008.

Geltungsbereich

§ 6. (1) Dieses Bundesgesetz gilt für folgende Universitäten:

1. Universität Wien;
2. Universität Graz;
3. Universität Innsbruck;

3. scientific, artistic, artistic-pedagogical and artistic-scientific training, qualification for professional activities requiring the application of scientific knowledge and methods, as well as teaching artistic and scientific skills at the highest level;
4. development and promotion of suitable career models for the highest qualified junior academics and young artists;
5. continuing education;
6. internal co-ordination of scientific research (and the advancement and appreciation of the arts) and teaching at universities;
7. promotion of domestic and international co-operation in research and teaching, and the arts;
8. promotion of the use and practical application of their research findings, and of community involvement in efforts to promote the advancement and appreciation of the arts;
9. gender equality and the advancement of women;
10. maintenance of contacts with graduates;
11. provision of public information on the performance of the tasks of the universities.

Legal Nature

§ 4. The universities are legal entities under public law.

Immunity from Ministerial Instructions and Freedom to Adopt Statutes

§ 5. The universities shall perform their tasks under § 3 within the limits of the law and decrees without restriction by ministerial instructions and adopt their statutes within the limits of the law according to Art 81c para 1 Federal Constitutional Law, F. L. G. No 1/1930, as amended by the Federal Act F. L. G. I No 2/2008.

Scope of Application

§ 6. (1) The following universities shall be subject to this Act:

1. University of Vienna;
2. University of Graz;
3. University of Innsbruck;

4. Medizinische Universität Wien;
5. Medizinische Universität Graz;
6. Medizinische Universität Innsbruck;
7. Universität Salzburg;
8. Technische Universität Wien;
9. Technische Universität Graz;
10. Montanuniversität Leoben;
11. Universität für Bodenkultur Wien;
12. Veterinärmedizinische Universität Wien;
13. Wirtschaftsuniversität Wien;
14. Universität Linz;
15. Universität Klagenfurt;
16. Universität für angewandte Kunst Wien;
17. Universität für Musik und darstellende Kunst Wien;
18. Universität Mozarteum Salzburg;
19. Universität für Musik und darstellende Kunst Graz;
20. Universität für künstlerische und industrielle Gestaltung Linz;
21. Akademie der bildenden Künste Wien;
22. Universität für Weiterbildung Krems.

(2) Universitäten werden durch Bundesgesetz errichtet und aufgelassen.

(3) Zwei oder mehrere Universitäten können durch Bundesgesetz vereinigt werden.

(4) Eine Initiative zu einer Vereinigung kann auch von zwei oder mehreren Universitäten ausgehen. Auf Basis übereinstimmender Beschlüsse der beteiligten Universitätsräte und Rektorate sowie nach Stellungnahme der jeweiligen Senate kann die Bundesministerin oder der Bundesminister einen entsprechenden Vorschlag zur Änderung des Abs. 1 sowie zur Festlegung der notwendigen weiteren gesetzlichen Regelungen (Vereinigungsrahmenbestimmungen) vorlegen. Eine Vereinigung kann nur mit Beginn einer neuen Leistungsvereinbarungsperiode wirksam werden.

(5) Die Beschlüsse für eine Initiative zu einer Vereinigung haben jedenfalls zu enthalten:

4. Medical University of Vienna;
5. Medical University of Graz;
6. Medical University of Innsbruck;
7. University of Salzburg;
8. Vienna University of Technology;
9. Graz University of Technology;
10. University of Mining Leoben;
11. University of Natural Resources and Life Sciences, Vienna;
12. University of Veterinary Medicine Vienna;
13. Vienna University of Economics and Business;
14. University of Linz;
15. University of Klagenfurt;
16. University of Applied Arts Vienna;
17. University of Music and Performing Arts Vienna;
18. Mozarteum University „Salzburg;
19. University of Music and Performing Arts Graz;
20. University of Art and Design Linz;
21. Academy of Fine Arts Vienna;
22. University of Continuing Education Krems.

(2) Universities shall be established and dissolved by federal law.

(3) Two or more universities may be merged by federal law.

(4) The initiative for a merger may also be taken by two or more universities. Based on the decisions by the university councils and rectorates of the universities involved and after hearing the opinions of the respective senates, the Federal Minister shall have the right to present a proposal for the amendment of para 1 as well as for the adoption of necessary further legal regulations (merger framework regulations). A merger shall only become effective at the beginning of a new performance agreement period.

(5) The decision to initiate a merger shall contain the following:

1. einen Vorschlag zur Regelung der Rechtsnachfolge sowie zum gewünschten künftigen Namen der Universität;
2. den gewünschten Zeitpunkt des Wirksamwerdens der Vereinigung;
3. einen vorläufigen gemeinsamen Organisations- sowie Entwicklungsplan, der unter Berücksichtigung der Organisations- und Entwicklungspläne der beteiligten Universitäten erstellt wurde;
4. für den Fall der Beteiligung einer Medizinischen Universität einen Vorschlag für Regelungen im Organisationsplan, die sicherstellen, dass den der medizinischen Organisationseinheit zugehörigen Instituten, Kliniken etc. die zur Erfüllung ihrer Aufgaben erforderlichen Ressourcen zugewiesen werden;
5. einen Vorschlag für Übergangsregelungen betreffend die obersten Leitungsorgane längstens innerhalb eines Jahres nach dem Wirksamwerden der Vereinigung und die gesetzlich eingerichteten Kollegialorgane sowie
6. einen Vorschlag für Übergangsregelungen betreffend die gemäß Organisationsplan der beteiligten Universitäten eingerichteten Organe und Gremien.

(6) Liegt eine Initiative zu einer Vereinigung gemäß Abs. 4 einschließlich der Beilagen gemäß Abs. 5 vor, so hat die Bundesministerin oder der Bundesminister die Zweckmäßigkeit der Vereinigung hinsichtlich der Ziele, der leitenden Grundsätze und der Aufgaben der Universitäten (§§ 1 bis 3) zu prüfen und darüber der Bundesregierung zu berichten. Eine Initiative zu einer Vereinigung von Universitäten kann im verfassungsrechtlich vorgesehenen Weg der Bundesgesetzgebung aber auch von der Bundesministerin oder dem Bundesminister selbst ausgehen.

(7) Soweit dieses Bundesgesetz keine abweichenden Bestimmungen enthält, sind der 1. und 2. Abschnitt des Forschungsorganisationsgesetzes (FOG), BGBl. Nr. 341/1981, auch im Anwendungsbereich dieses Bundesgesetzes anzuwenden.

(~~7~~8) Die §§ 88, 116 und 116a beziehen sich auf alle Bildungseinrichtungen gemäß § 51 Abs. 2 Z 1.

(9) Hinsichtlich der Verarbeitung personenbezogener Daten durch die Universität und der universitären Organe ist die Universität Verantwortlicher im Sinne des Art. 4 Z 7 der Verordnung (EU) 2016/679 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten, zum freien Datenverkehr und zur Aufhebung der Richtlinie 95/46/EG [Datenschutz-Grundverordnung], ABl. Nr. L 119 vom 04.05.2016 S. 1, [im Folgenden: DSGVO].

1. a proposal for arrangements for the legal succession as well as for the desired future name of the university;
2. the desired date at which the merger shall enter into full effect;
3. a preliminary common organisation plan and development plan that have been prepared taking into account the organisation plans and development plans of the universities involved;
4. if a medical university is involved, a proposal for provisions in the organisation plan that ensure that the institutes, clinics etc. that are part of the medical organisational unit receive the resources necessary for the fulfilment of their tasks;
5. a proposal for transitional provisions pertaining to the governing positions within a maximum of one year after the merger has entered into full effect and to the legally mandated collegial bodies, and
6. a proposal for transitional provisions pertaining to the bodies, boards and committees established at the universities involved according to their organisation plans.

(6) If the initiative for a merger according to para 4, including the documents stipulated in para 5, has been taken, the Federal Minister shall assess the reasonability of the merger regarding the objectives, guiding principles and tasks of the universities involved (§§ 1 to 3) and shall report to the Federal Government on this. The initiative for a merger of universities may be taken in conformity with the constitutionally mandated procedures of federal legislation, but may also be taken by the Federal Minister.

(7) Unless this Federal Act does not contain differing provisions, sections 1 and 2 of the Research Organisation Act (Forschungsorganisationsgesetz – FOG), F. L. G. No 341/1981, shall apply also in the scope of this Federal Act.

(7) §§ 88, 116 and 116a refer to all educational institutions in the meaning of § 51 para 2 subpara 1.

Wirkungsbereich der Universitäten

§ 7. (1) Der Wirkungsbereich der Universitäten gemäß § 6 Abs. 1 Z 1 bis 3 und 7 bis 21 ergibt sich, soweit nicht Abs. 2 anderes bestimmt, aus den am Tag vor dem In-Kraft-Treten dieses Bundesgesetzes an den gleichnamigen Universitäten eingerichteten Studien und Forschungseinrichtungen.

(2) Der Wirkungsbereich der Medizinischen Universitäten Wien, Graz und Innsbruck ergibt sich aus den am Tag vor dem In-Kraft-Treten dieses Bundesgesetzes an den Medizinischen Fakultäten der Universitäten Wien, Graz und Innsbruck eingerichteten Studien und Forschungseinrichtungen.

(3) Änderungen der Wirkungsbereiche der Universitäten sind nur im Wege der Leistungsvereinbarungen gemäß § 13 oder durch Verordnung der Bundesregierung gemäß § 8 zulässig.

Sicherung von Forschungs- und Lehrbereichen

§ 8. Die Bundesregierung kann auf Vorschlag der Bundesministerin oder des Bundesministers einer Universität oder mehreren Universitäten durch Verordnung die Einrichtung eines Studiums auftragen, wenn dies aus übergeordneten bildungspolitischen oder wissenschaftspolitischen Gründen erforderlich ist und keine diesbezügliche Einigung im Rahmen einer Leistungsvereinbarung erfolgt.

Rechtsaufsicht

§ 9. Die Universitäten, die von ihnen gemäß § 10 Abs. 1 gegründeten Gesellschaften, Stiftungen und Vereine sowie jene Gesellschaften, deren Geschäftsanteile die Universität mittelbar oder unmittelbar zu ~~mehr als~~mindestens 50 vH hält, unterliegen der Aufsicht des Bundes. Diese umfasst die Aufsicht über die Einhaltung der Gesetze und Verordnungen einschließlich der Satzung (Rechtsaufsicht).

Gesellschaften, Stiftungen, Vereine

§ 10. (1) Jede Universität ist berechtigt, Gesellschaften, Stiftungen und Vereine zu gründen sowie sich an Gesellschaften zu beteiligen und Mitglied in Vereinen zu sein, sofern diese Gründung, Beteiligung oder Mitgliedschaft der Erfüllung der Aufgaben der Universität dient und insbesondere die Forschung (Entwicklung und Erschließung der Künste) und die Lehre dadurch nicht beeinträchtigt werden.

(2) Jede Universität ist überdies berechtigt, sonstige Vermögenswerte – unbeschadet §§ 26 und 27 – insbesondere auch in Form von Spenden, Schenkungen und Sponsoring einzuwerben.

Sphere of Action of the Universities

§ 7. (1) The sphere of action of the universities named in § 6 para 1 subparas 1–3 and 7–21 of this Act, unless otherwise provided for by para 2, shall correspond to the study programmes and research institutions at the above universities as constituted on the day before the entry into force of this Act.

(2) The sphere of action of the Medical Universities of Vienna, Graz and Innsbruck shall correspond to the study programmes and research institutions at the Faculties of Medicine of the Universities of Vienna, Graz and Innsbruck as constituted on the day before the entry into force of this Act.

(3) Modifications to the spheres of action of the universities are only permissible by way of the performance agreements according to § 13 or by decrees of the Federal Government according to § 8.

Safeguarding Fields of Research and Teaching

§ 8. On the recommendation of the Federal Minister, the Federal Government may, by decree, direct one or more universities to establish a programme of study if this is necessary for overriding educational or scientific policy reasons and no performance agreement to this effect is reached.

Legal Supervision

§ 9. The universities as well as the companies, foundations and associations they have founded under § 10 para 1, and those companies of which the university holds a direct or indirect share of more than 50%, are subject to supervision by the Federal Government. This shall comprise monitoring of compliance with the acts, decrees and the universities' statutes (legal supervision).

Companies, Foundations and Associations

§ 10. (1) Each university shall be entitled to form companies, foundations and associations and to invest therein and to be a member of associations, provided that such formation, investment or membership is in furtherance of the performance of such university's tasks and, in particular, that it does not obstruct its research (advancement and appreciation of the arts) and teaching.

(2) Each university shall also have the right to acquire other assets – without prejudice to §§ 26 and 27 – in particular in the form of donations, gifts, and sponsoring.

Universitätsbericht

§ 11. Die Bundesministerin oder der Bundesminister hat dem Nationalrat ab dem Jahr 2005 auf der Grundlage der Wissensbilanzen der Universitäten mindestens alle drei Jahre einen Bericht über die bisherige Entwicklung und die künftige Ausrichtung der Universitäten vorzulegen. Dabei ist unter anderem auch auf die Nachwuchsförderung, auf die Entwicklung der Personalstruktur der Universitäten und auf die Lage der Studierenden einzugehen.

2. Unterabschnitt
Finanzierung, Leistungsvereinbarung und Qualitätssicherung

Universitätsfinanzierung aus Bundesmitteln

§ 12. (1) Die Universitäten sind vom Bund zu finanzieren. Dabei sind die finanziellen Leistungsmöglichkeiten des Bundes, seine Anforderungen an die Universitäten und die Aufgabenerfüllung der Universitäten zu berücksichtigen.

(2) Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen bis spätestens 31. Oktober des zweiten Jahres jeder Leistungsvereinbarungsperiode gemäß § 13 unter Berücksichtigung der zu erwartenden Studierendenzahlen und der Betreuungsverhältnisse den für die nächste Leistungsvereinbarungsperiode zur Finanzierung der Universitäten zur Verfügung stehenden Gesamtbetrag und dessen Aufteilung auf Budgetsäulen für die universitären Leistungsbereiche

1. Lehre („Budgetsäule Lehre“),
2. Forschung bzw. Entwicklung und Erschließung der Künste („Budgetsäule Forschung bzw. EEK“) und
3. Infrastruktur und strategische Entwicklung („Budgetsäule Infrastruktur und strategische Entwicklung“)

festzusetzen und darüber das Einvernehmen gemäß § 60 des Bundeshaushaltsgesetzes 2013 (BHG 2013), BGBl. I Nr. 139/2009, in der Fassung des Bundesgesetzes BGBl. I Nr. 53/2017, herzustellen.

(3) Im Zusammenhang mit den Verhandlungen zu den Leistungsvereinbarungen kann eine Verschiebung zwischen den Budgetsäulen gemäß Abs. 2 erfolgen. Von den Budgetsäulen Lehre und Forschung bzw. EEK darf jedoch nur ein Anteil von jeweils bis zu 2 vH der Budgetsäule Infrastruktur und strategische Entwicklung zugeschlagen werden. Im Einvernehmen mit der Bundesministerin oder dem

University Report

§ 11. Starting in 2005, the Federal Minister shall submit to the National Council at the minimum every three years a report on the universities' previous development and future strategy based on the universities' intellectual capital reports. Such ministerial reports shall contain, inter alia, a discussion of the advancement of junior academics, developments with regard to universities’ staffing, and the situation of students.

Sub-Chapter 2
Financing, Performance Agreement and Quality Assurance

Federal Funding of Universities

§ 12. (1) The universities shall be funded by the Federal Government, having regard to its financial resources, the requirements imposed by it on the universities and the fulfilment of their tasks.

(2) Pursuant to § 13, the Federal Minister shall, in consultation with the Federal Minister of Finance, taking into account the by 31 October of the second year of each performance agreement period establish the total amount dedicated to university funding in the next performance agreement period and its division into the budget columns for the university performance areas

1. teaching (“budget column ‘teaching’”),
2. research, and the advancement and appreciation of the arts (“budget column ‘research and AAA’”), and
3. infrastructure and strategic development (“budget column ‘infrastructure and strategic development’”),

and shall reach agreement thereto in accordance with § 60 of the Federal Budget Act 2013 (BHG 2013), F. L. G. I No 139/2009, as amended by F. L. G. I No 53/2017.

(3) In connection with the negotiations of the performance agreements, a shifting of amounts between the budget columns according to para 2 may take place. However, only up to 2% of each of the budget columns “teaching and research” or AAA may be shifted to the budget column “infrastructure and strategic development”. In consultation with the Federal Minister of Finance, it may also be

Bundesminister für Finanzen kann auch ein höherer Anteil der Budgetsäule Infrastruktur und strategische Entwicklung zugeschlagen werden.

(4) Die Budgetsäulen Lehre, Forschung bzw. EEK sowie Infrastruktur und strategische Entwicklung gemäß Abs. 2 setzen sich jeweils aus den folgenden Beträgen zusammen:

1. Budgetsäule Lehre gemäß Abs. 2 Z 1:
   a) Betrag für alle österreichweit in den einzelnen Fächergruppen mindestens anzubietenden Studienplätze. Die Festlegung der Anzahl der Studienplätze in den einzelnen Fächergruppen erfolgt anhand des Basisindikators 1 „Ordentliche Bachelor-, Master- und Diplomstudien, die mit mindestens 16 ECTS-Anrechnungspunkten oder 8 positiv beurteilten Semesterstunden pro Studienjahr prüfungsaktiv betrieben werden“;
   b) Betrag, welcher anhand von mindestens einem wettbewerbsorientierten Indikator berechnet wird und höchstens 20 vH der Budgetsäule Lehre betragen darf.
2. Budgetsäule Forschung bzw. EEK gemäß Abs. 2 Z 2:
   a) Betrag für die österreichweit in den einzelnen Fächergruppen mindestens zu beschäftigenden Personen (in Vollzeitäquivalenten) in ausgewählten Verwendungsgruppen. Die Festlegung der Anzahl der zu beschäftigenden Personen (Vollzeitäquivalente) in den einzelnen Fächergruppen erfolgt anhand des Basisindikators 2 „Personal in ausgewählten Verwendungen in Vollzeitäquivalenten pro Kalenderjahr“;
   b) Betrag für die Universitäten gemäß § 6 Abs. 1 Z 1 bis 15 („wissenschaftliche Universitäten“), welcher anhand von mindestens einem wettbewerbsorientierten Indikator berechnet wird;
   c) Betrag für die Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 („künstlerische Universitäten“), welcher anhand von mindestens einem wettbewerbsorientierten Indikator berechnet wird,

wobei die Beträge gemäß lit. b und c gemeinsam höchstens 20 vH der Säule Forschung bzw. EEK betragen dürfen.

3. Die Budgetsäule Infrastruktur und strategische Entwicklung gemäß Abs. 2 Z 3 umfasst die Beträge für die von den Universitäten genutzten Gebäude, für den Klinischen Mehraufwand gemäß § 55 Z 2 des Bundesgesetzes über Krankenanstalten und Kuranstalten (KAKuG), BGBl. Nr. 1/1957, in der Fassung des Bundesgesetzes BGBl. I Nr. 59/2017 (Medizinische

permissible to shift a higher percentage to the budget column “infrastructure and strategic development”.

(4) The budget columns “teaching”, “research or AAA” as well as “infrastructure and strategic development” according to para 2 are composed of the following amounts:

1. Budget column “teaching” according to para 2 subpara 1:
   a) Amount allocated for covering the costs of the minimum number of all study places to be offered in each group of disciplines throughout Austria. The amount of study places to be offered in each group of disciplines shall be determined based on the basic indicator 1 “Students actively taking examinations amounting to at least 16 ECTS credits or 8 semester hours per academic year in bachelor's, master's and diploma degree programmes”;
   b) Amount which is calculated on the basis of at least one competition indicator and may not exceed 20% of the budget column “teaching”.
2. Budget column “research or AAA” according to para 2 subpara 2:
   a) Amount allocated for covering the costs of the minimum number of persons (full-time equivalents) to be employed in each group of disciplines throughout Austria in selected job groups. The amount of persons (full-time equivalents) to be employed in each group of disciplines shall be determined based on the basic indicator 2 “Staff in selected job groups in full-time equivalents per calendar year”;
   b) Amount allocated to the universities according to § 6 para 1 subparas 1 to 15 (“scientific universities”) which is calculated based on at least one competition indicator;
   c) Amount allocated to the universities according to § 6 para 1 subparas 16 to 21 (“artistic universities”) which is calculated based on at least one competition indicator;

However, together the amounts pursuant to lit b and c shall not exceed 20% of the column research or AAA.

3. The budget column “infrastructure and strategic development” according to para 2 subpara 3 comprises the amounts for the buildings used by the universities and for the clinical overheads according to § 55 subpara 2 of the Hospitals and Health Resorts Act (KAKuG), F. L. G. No 1/1957, as amended by the Federal Act F. L. G. I No 59/2017 (Medical Universities), a

Universitäten), einen strategischen Betrag für Lehre, Forschung bzw. Entwicklung und Erschließung der Künste sowie für sonstige Maßnahmen. Seine Höhe wird insbesondere nach Maßgabe des sachlich gerechtfertigten Bedarfs gemäß § 13 Abs. 2 Z 1 ermittelt und dient auch der wirtschaftlichen Absicherung der Universitäten unter Berücksichtigung der aktuellen Entwicklungen im Universitätsbereich, der hochschulpolitischen Schwerpunktsetzungen und der erforderlichen strukturellen Veränderungen.

(5) Die einzelnen Fächergruppen in den Budgetsäulen Lehre und Forschung bzw. EEK werden gewichtet, wobei insbesondere folgende Kriterien zu berücksichtigen sind:

1. der Gesamtbetrag gemäß Abs. 2 und dessen Aufteilung auf die Budgetsäulen Lehre und Forschung bzw. EEK,
2. die unterschiedlichen Ausstattungsnotwendigkeiten der einzelnen Fächergruppen sowie
3. die tatsächlichen Kostenstrukturen.

(6) Für die Verteilung der Mittel gemäß Abs. 4 Z 1 lit. a und Z 2 lit. a werden Finanzierungssätze ermittelt. Die Ermittlung der Finanzierungssätze Lehre erfolgt auf Basis der Budgetsäule Lehre sowie unter Berücksichtigung der Anzahl der österreichweit in den einzelnen Fächergruppen mindestens anzubietenden Studienplätze und den entsprechenden Fächergruppengewichtungen. Die Ermittlung der Finanzierungssätze Forschung bzw. Entwicklung und Erschließung der Künste erfolgt auf Basis der Budgetsäule Forschung bzw. EEK sowie unter Berücksichtigung der Anzahl der österreichweit in ausgewählten Verwendungsgruppen in den einzelnen Fächergruppen mindestens zu beschäftigenden Personen (Vollzeitäquivalente) und den entsprechenden Fächergruppengewichtungen.

(7) Durch Verordnung der Bundesministerin oder des Bundesministers ist im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen Folgendes festzulegen:

1. Anteilige Aufteilung der Budgetsäulen Lehre und Forschung bzw. EEK in die Beträge gemäß Abs. 4 Z 1 lit. a und b und Z 2 lit. a bis c,
2. Definition und Datengrundlage der Basisindikatoren 1 und 2 und der wettbewerbsorientierten Indikatoren gemäß Abs. 4 Z 1 lit. b und Z 2 lit. b und c und deren Gewichtung gemäß Abs. 5,

strategic amount for teaching, research or the advancement and appreciation of the arts as well as for other measures. The amount is determined, in particular, in accordance with the objectively justifiable demand according to § 13 para 2 subpara 1, and shall also serve as an economic security for the universities in consideration of the current developments in the university sector, the focus areas in higher education policy and the necessary structural changes.

(5) Each of the groups of disciplines in the budget columns “teaching” and “research or AAA” shall be weighted, taking into account especially the following criteria:

1. the total amount set out in para 2 and its division into the budget columns “teaching” and “research or AAA”,
2. the different equipment needs for each group of disciplines, as well as
3. the actual cost structures.

(6) Funding rates shall be determined for the allocation of the resources according to para 4 subpara 1 lit a and subpara 2 lit a. The funding rates for teaching shall be determined on the basis of the budget column “teaching” as well as in consideration of the minimum number of study places to be offered throughout Austria in each group of disciplines and the corresponding weighting of the groups of disciplines. The funding rates for research or the advancement and appreciation of the arts shall be determined on the basis of the budget column “research or AAA” as well as in consideration of the minimum number of persons (full-time equivalents) to be employed throughout Austria in each group of disciplines in selected job groups and the corresponding weighting of the groups of disciplines.

(7) In consultation with the Federal Minister of Finance, the Federal Minister shall, by decree, determine the following:

1. proportionate division of the budget columns “teaching” and “research or AAA” into the amounts set out in para 4 subpara 1 lit a and b and subpara 2 lit a to c,
2. definition and data basis for the basic indicators 1 and 2 and the competition indicators according to para 4 subpara 1 lit b and subpara 2 lit b and c and their weighting according to para 5,

3. Ermittlung der Finanzierungssätze für die Budgetsäulen Lehre sowie Forschung bzw. EEK gemäß Abs. 6 sowie
4. Zuordnung der von den Universitäten angebotenen Studienfelder zu den Fächergruppen.

(8) Der Gesamtbetrag gemäß Abs. 2 erhöht sich um die in den einzelnen Jahren der jeweiligen Leistungsvereinbarungsperiode anfallenden Aufwendungen der Universitäten aus den allgemeinen Bezugserhöhungen für das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an den Universitäten vorhandene Bundespersonal, soweit es in diesem Zeitraum in einem Arbeitsverhältnis zur Universität oder in einem Bundesdienstverhältnis, in einem besonderen öffentlich-rechtlichen Rechtsverhältnis als wissenschaftliche (künstlerische) Mitarbeiterin oder als wissenschaftlicher (künstlerischer) Mitarbeiter (in Ausbildung) (§ 132) steht und der Universität zugewiesen ist. Die Erhöhung wird von der Bundesministerin oder dem Bundesminister im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen für jede Leistungsvereinbarungsperiode gemeinsam mit dem Gesamtbetrag gemäß Abs. 2 festgelegt.

(9) Die Erhöhung gemäß Abs. 8 ist mit jenem Betrag begrenzt, der erforderlich wäre, wenn das von dieser Bestimmung erfasste Universitätspersonal noch in einem Dienst- oder besonderen öffentlich-rechtlichen Rechtsverhältnis als wissenschaftliche (künstlerische) Mitarbeiterin oder als wissenschaftlicher (künstlerischer) Mitarbeiter (in Ausbildung) (§ 132) zum Bund stünde.

(10) Die Bundesministerin oder der Bundesminister kann bis zu 2 vH des Gesamtbetrags gemäß Abs. 2 für besondere Finanzierungserfordernisse sowie zur Ergänzung von Leistungsvereinbarungen gemäß § 13 einbehalten. Die einbehaltenen Mittel müssen den Universitäten in voller Höhe zur Verfügung gestellt werden.

(11) Erlöse aus Drittmitteln und Erträge, die Universitäten aus Veranlagungen erzielen, sind auszuweisen. Sie verbleiben in der Verfügung der Universitäten und reduzieren nicht die Höhe der staatlichen Zuweisungen.

(12) Die Zuteilungen der Mittel erfolgen monatlich aliquot. Die monatlichen Zuweisungen können entsprechend den universitären Erfordernissen im Rahmen der zur Verfügung stehenden Globalbudgets verändert werden.

(13) Die Bundesministerin oder der Bundesminister kann im Falle der drohenden oder eingetretenen Zahlungsunfähigkeit der Universität ein Sanierungskonzept als verbindlichen Rahmen für ihre Wirtschaftsführung vorgeben, welches dem Ziel dient, im Rahmen einer geordneten Gebarung die künftige, dauerhafte Leistungsfähigkeit der Universität zu erreichen. Das Sanierungskonzept

3. determination of the funding rates for the budget columns “teaching” as well as “research or AAA” according to para 6, as well as
4. assignment of the fields of education offered at the universities to the groups of disciplines.

(8) The total amount shall, in accordance with the arrangements set out in para 2, be increased by that of the universities’ expenditure incurred as a result of general salary increases payable in each year of the current performance agreement period to federal employees present at universities on the day before the entry of this Act into full effect, insofar as during the periods in question such staff are employed by universities or under public law, or assigned to universities under special contracts as academic (artistic) staff or as junior academic (artistic) staff (§ 132). Together with the total amount set out in para 2, the increase shall be determined for each performance agreement period by the Federal Minister in consultation with the Federal Minister of Finance.

(9) The increase under para 8 shall be limited to the amount that would be required, if the university staff subject to this provision still had employment or special contracts as academic (artistic) staff or as junior academic (artistic) staff (§ 132) with the Federal Government.

(10) The Federal Minister may retain 2% of the total amount set out in para 2 for the basic budgets for special funding requirements and for supplementary performance agreements under § 13. The universities shall have the right to use these retained funds in full.

(11) The universities shall report their receipts from third-party funds and investment income. These shall remain at the disposal of the universities and shall not reduce state allocations.

(12) Resources shall be allocated monthly, on a pro rata basis. Universities’ monthly allocations may, within the limits of the global budgets available to them, be adapted to their requirements.

(13) The Federal Minister may, in the event of an imminent or actual insolvency of the university, enact a restructuring plan as a binding framework for its financial management, which shall fulfil the objective of ensuring the university's long-lasting solid performance in the future with sound financial management. As part of the restructuring plan, one or several university trustees may be appointed.

kann die Bestellung einer Universitätskuratorin, eines Universitätskurators oder von mehreren Universitätskuratorinnen oder Universitätskuratoren beinhalten.

Festlegung der Globalbudgets der Universitäten

§ 12a. (1) Die Universitäten erhalten jeweils ein in der Leistungsvereinbarung festgelegtes Globalbudget. Die Universitäten können im Rahmen ihrer Aufgaben und der Leistungsvereinbarungen frei über den Einsatz der Globalbudgets verfügen.

(2) Das in der Leistungsvereinbarung festgelegte Globalbudget setzt sich aus folgenden Teilbeträgen, deren Höhe unter Berücksichtigung des in § 12 Abs. 2 genannten Gesamtbetrags sowie der Budgetsäulen Lehre, Forschung bzw. EEK und Infrastruktur und strategische Entwicklung festgelegt wird, sowie unter Berücksichtigung der §§ 2 und 3 zusammen:

1. Teilbetrag für Lehre:
   a) Die Universität erhält für jeden in der Leistungsvereinbarung vereinbarten von der Universität mindestens anzubietenden Studienplatz für Bachelor-, Master- und Diplomstudien einen nach Fächergruppen gewichteten Finanzierungssatz Lehre.
   b) Dazu kommt ein Betrag, welcher anhand von mindestens einem wettbewerbsorientierten Indikator berechnet wird. Jede Universität erhält jenen Anteil aus diesem Betrag, der ihrem Anteil am Indikatorwert aller Universitäten entspricht.
2. Teilbetrag für Forschung bzw. EEK:
   a) Die Universität erhält für jede in der Leistungsvereinbarung vereinbarte von der Universität mindestens zu beschäftigende Person (in Vollzeitäquivalenten) in ausgewählten Verwendungen nach Fächergruppen einen Finanzierungssatz Forschung bzw. Entwicklung und Erschließung der Künste.
   b) Dazu kommt jeweils ein Betrag für die Universitäten gemäß § 6 Abs. 1 Z 1 bis 15 („wissenschaftliche Universitäten“) sowie für die Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 („künstlerische Universitäten“), welcher anhand von mindestens einem wettbewerbsorientierten Indikator berechnet wird. Jede Universität gemäß § 6 Abs. 1 Z 1 bis 15 erhält jenen Anteil aus diesem Betrag, der ihrem Anteil am Indikatorwert aller Universitäten gemäß § 6 Abs. 1 Z 1 bis 15 entspricht. Jede Universität gemäß § 6 Abs. 1 Z 16 bis 21 erhält jenen Anteil aus diesem Betrag, der ihrem Anteil am Indikatorwert aller Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 entspricht.

Determining the Universities' Global Budgets

§ 12a. (1) Each university shall receive a global budget as specified in the performance agreement. The universities shall be free, within the limits of their tasks and the performance agreements, to use their global budgets as they see fit.

(2) The global budget as specified in the performance agreement consists of the following components, the amount of which shall be determined, taking into account the total amount named in § 12 para 2, the budget columns “teaching”, “research or AAA”, and “infrastructure and strategic development” as well as in consideration of §§ 2 and 3:

1. Component for “teaching”:
   a) For each study place for bachelor's, master's or diploma programmes to be offered by the university as stipulated in the performance agreement, the university shall receive a “financing rate teaching” weighted according to groups of disciplines.
   b) In addition, the university shall receive an amount which is calculated based on at least one competition indicator. Each university shall receive a portion of this amount corresponding to its share of the indicator value of all universities.
2. Component for “research or AAA”:
   a) For each person (full-time equivalent) to be employed in selected job groups as stipulated in the performance agreement, the university shall receive a “financing rate research or advancement and appreciation of the arts” by group of disciplines.
   b) In addition, they shall receive an amount allocated to universities according to § 6 para 1 subparas 1 to 15 (“scientific universities”) as well as to universities according to § 6 para 1 subparas 16 to 21 (“artistic universities”) which is calculated based on at least one competition indicator. Each university according to § 6 para 1 subparas 1 to 15 shall receive a proportion of this amount corresponding to its share of the indicator value of all universities according to § 6 para 1 subparas 1 to 15. Each university according to § 6 para 1 subparas 16 to 21 shall receive a proportion of this amount corresponding to its share of the indicator value of all universities according to § 6 para 1 subparas 16 to 21.

3. Teilbetrag für Infrastruktur und strategische Entwicklung:

Der Teilbetrag umfasst die Beträge für die von den Universitäten genutzten Gebäude, für den Klinischen Mehraufwand gemäß § 55 Z 2 KAKuG (Medizinische Universitäten) sowie einen Betrag für strategische Maßnahmen für Lehre, Forschung bzw. Entwicklung und Erschließung der Künste sowie für sonstige Maßnahmen. Dieser Teilbetrag dient auch der wirtschaftlichen Absicherung der Universität unter Berücksichtigung der aktuellen Entwicklungen im Universitätsbereich, der hochschulpolitischen Schwerpunktsetzungen und der erforderlichen strukturellen Veränderungen. Jede Universität erhält den auf sie entfallenden Anteil nach Maßgabe des sachlich gerechtfertigten Bedarfs.

(3) Die Höhe des Globalbudgets sowie die Höhe der Teilbeträge wird mit Ausnahme jener Beträge, die aufgrund der wettbewerbsorientierten Indikatoren vergeben werden, im Voraus für die dreijährige Leistungsvereinbarungsperiode festgelegt. Die Höhe jener Beträge, die aufgrund der wettbewerbsorientierten Indikatoren vergeben werden, wird jährlich ermittelt und auf die einzelnen Universitäten aufgeteilt. Eine allfällige Reduktion des Globalbudgets einer Universität beträgt im ersten Jahr der dreijährigen Leistungsvereinbarungsperiode höchstens 2 vH, im zweiten Jahr höchstens 4 vH und im dritten Jahr höchstens 6 vH eines Drittels des für die vorangegangene dreijährige Periode festgesetzten Globalbudgets.

(4) Zur Sicherstellung der Umsetzung der Maßnahmen zur sozialen Dimension in der Lehre sowie zur Einbeziehung von unterrepräsentierten Gruppen in die Hochschulbildung gemäß § 13 Abs. 2 Z 1 lit. g kann die Bundesministerin oder der Bundesminister bis zu 0,5 vH des Globalbudgets einbehalten. Der einbehaltene Betrag wird bei Nachweis der Umsetzung der in der Leistungsvereinbarung vereinbarten Maßnahmen ausbezahlt.

Gesamtösterreichischer Universitätsentwicklungsplan

§ 12b. (1) Die Entwicklungsplanung für das öffentliche Universitätswesen ist eine Aufgabe, die von der Bundesministerin oder dem Bundesminister und von den Universitäten in der Gesamtverantwortung des Bundes gemeinsam wahrgenommen wird. Hierbei dient der gesamtösterreichische Universitätsentwicklungsplan als Planungsinstrument für die Entwicklung eines überregional abgestimmten und regional ausgewogenen Leistungsangebots, einer für das österreichische Wissenschaftssystem adäquaten und ausgewogenen Fächervielfalt, der Lenkung von Studienangebot bzw. Studiennachfrage, der Auslastung der Kapazitäten sowie der Forschung. Dabei werden auf allen Stufen des Entwicklungsprozesses die Belange

3. Component for “infrastructure and strategic development”:

The component consists of the amounts allocated for covering the costs of the buildings used by the universities, the clinical overheads according to § 55 para 2 KAKuG (Medical Universities) as well as an amount for strategic measures regarding teaching, research or the advancement and appreciation of the arts and other measures. This component also serves as an economic security for the universities in consideration of the current developments in the university sector, the focus areas in higher education policy and the necessary structural changes. Each university also receives the proportion attributable to them on the basis of objectively justified requirements.

(3) With the exception of those amounts allocated on the basis of competition indicators, the amount of the global budget as well as that of the components are determined in advance for the three-year performance agreement period. Those amounts allocated on the basis of competition indicators shall be calculated on a yearly basis and allocated to each of the universities. Any reduction in the global budget of a university may not exceed 2% of a third of the global budget determined for the preceding three-year period in the first year of the three-year performance agreement period, 4% in the second year and 6% in the third year.

(4) In order to ensure that the measures aiming to promote the social dimension in teaching and to include underrepresented groups in higher education according to § 13 para 2 subpara 1 lit g are realised, the Federal Minister may retain up to 0.5% of the global budget. The retained amount shall be paid if evidence of the implementation of the measures agreed upon in the performance agreement can be given.

Austrian National Development Plan for Public Universities

§ 12b. (1) Development planning for the public university sector is a task which is performed jointly by the Federal Minister and the universities within the overall responsibility of the Federal Government. The Austrian National Development Plan for Public Universities serves as a planning instrument for the development of a nationwide coordinated and regionally balanced range of services, a balanced subject diversity which is adequate for the Austrian research system, furthermore for the management of the range of and demand for study programmes, the capacity utilisation as well as research. The interests of the universities, in particular the

der Universitäten, insbesondere die universitätseigenen Entwicklungspläne, berücksichtigt („Gegenstromprinzip“).

(2) Die Entwicklungspläne der Universitäten gemäß § 13b haben sich inhaltlich an den Zielsetzungen des gesamtösterreichischen Universitätsentwicklungsplans zu orientieren.

(3) Der gesamtösterreichische Universitätsentwicklungsplan wird ~~nach vorheriger Anhörung des Wissenschaftsrats~~ bis spätestens Ende des ersten Jahres jeder Leistungsvereinbarungsperiode für die zwei kommenden Leistungsvereinbarungsperioden erstellt und bis spätestens 31. Oktober des zweiten Jahres jeder Leistungsvereinbarungsperiode, insbesondere hinsichtlich der Statistiken zu Entwicklungen und Prognosen in der Lehre, Forschung bzw. Entwicklung und Erschließung der Künste sowie zum Universitätspersonal, aktualisiert.

Leistungsvereinbarung

§ 13. (1) Die Leistungsvereinbarung ist ein öffentlich-rechtlicher Vertrag. Sie ist zwischen den einzelnen Universitäten und dem Bund im Rahmen der Gesetze für jeweils drei Jahre abzuschließen.

(2) Inhalt der Leistungsvereinbarung ist insbesondere:

1. die von der Universität zu erbringenden Leistungen, die entsprechend den Zielen, leitenden Grundsätzen und Aufgaben der Universität in folgenden Bereichen festzulegen sind:

   a) strategische Ziele, Profilbildung, Universitäts- und Personalentwicklung:

   Die langfristigen und die innerhalb der Leistungsvereinbarungsperiode zu erreichenden Ziele sind festzulegen. Die Universität hat ihre besonderen Schwerpunkte und Stärken und den daraus abgeleiteten und zur Zielerreichung vorgesehenen Ressourceneinsatz bekannt zu geben. Es ist anzugeben, welche Fördermaßnahmen und Anreize zur Erreichung der Ziele in der Personalentwicklung erforderlich sind und welche Beiträge die Angehörigen der Universität leisten sollen. Im Rahmen der Personalentwicklung sind jedenfalls Maßnahmen zur Verbesserung der Vereinbarkeit von Kinderbetreuung und wissenschaftlicher Karriere zu berücksichtigen. Die Universität hat weiters anzugeben, welche Maßnahmen sie zur Verstetigung von Beschäftigungsverhältnissen der Lehrbeauftragten und zur attraktiven Ausgestaltung von Karrierewegen

universities' own development plans, shall be taken into consideration at all levels of this development process (“principle of countervailing influence”).

(2) The content of the universities' development plans according to § 13b shall be based on the objectives of the Austrian National Development Plan for Public Universities.

(3) After prior consultation of the Science Council, the Austrian National Development Plan for Public Universities shall be drawn up for two performance agreement periods by the end of the first year of each performance agreement period at the latest and updated by 31 October of the second year of each performance agreement period, in particular with regard to statistics on developments and forecasts in the field of teaching, research or the advancement and appreciation of the arts as well as on the university staff.

Performance Agreement

§ 13. (1) Performance agreements are contracts under public law. They shall be concluded by the individual universities and the Federal Government, within the limits of the law, for periods of three years.

(2) Performance agreements shall, in particular, contain:

1. the services to be provided by the university in question, which shall, in accordance with the objectives, guiding principles and tasks of such university, cover the following areas:

   a) strategic objectives, academic profiles, and university and human resources development:

   The long-term objectives and those to be attained within the performance agreement period shall be specified. The university shall set out its special priorities and strengths, and the resources allocated to the attainment of the objectives derived out of it. It shall also state which human resources development measures and incentives are required in order to attain the objectives, and what contributions the university’s members are to make thereto. As part of human resource development, measures for improving the compatibility of child care and an academic career shall be taken into consideration. The university shall furthermore indicate measures to ensure permanence of employment relationships for external lecturers and to make career paths attractive for junior academics and young artists who are funded by excellence programmes.

für den wissenschaftlichen und künstlerischen Nachwuchs, der aus Exzellenzprogrammen gefördert wird, setzt.

b) Forschung sowie Entwicklung und Erschließung der Künste:

Die Universität hat insbesondere die geplanten und die weiterzuführenden Forschungsprojekte und Forschungsprogramme sowie die Vorhaben zur Entwicklung und Erschließung der Künste bekannt zu geben. Weiters ist die mindestens zu erbringende Forschungsbasis-leistung/Basisleistung in der Entwicklung und Erschließung der Künste in den einzelnen Fächergruppen anhand der Anzahl von Vollzeitäquivalenten des Personals in ausgewählten Verwendungen nach Fächergruppen pro Kalenderjahr festzulegen.

c) Studien und Weiterbildung:

Die Angaben zum Studienbetrieb und zu den Weiterbildungsaktivitäten sind durch entsprechende Statistiken über die quantitative Entwicklung in diesen Bereichen und mittels der Ergebnisse der Auswertung der Lehrveranstaltungsbeurteilungen nach Studien zu belegen. Auf dieser Basis sind die Vorhaben im Studien- und Weiterbildungsbereich zu bezeichnen und allfällige Änderungen der Lehr- und Lernorganisation zu definieren, mit denen den anzustrebenden Qualifikationsprofilen der Studierenden und der Forscherinnen und Forscher entsprochen werden soll. Weiters ist die Anzahl der in den einzelnen Fächergruppen mindestens anzubietenden Studienplätze für ordentliche Bachelor-, Master- und Diplomstudien pro Studienjahr sowie die Anzahl der Studienplätze für Studienanfängerinnen und -anfänger für Bachelor- und Diplomstudien gemäß § 71b pro Studienjahr festzulegen.

d) Maßnahmen zur Verringerung der Zahl der Studienabbrecherinnen und Studienabbrecher:

Die Universität hat Erhebungen über die Ursachen von Studienabbrüchen vorzunehmen und Aktivitäten zur Verbesserung der Abschlussquoten bekanntzugeben. Weiters hat die Universität Maßnahmen zum Ausbau der Studierendenberatung, zum Coaching und Mentoring in der Studieneingangs- und Orientierungsphase sowie zum Ausbau der Betreuungsangebote für Studierende mit Kindern zu entwickeln.

e) Verbesserung der Betreuungsrelationen:

Es ist insbesondere unter Berücksichtigung der Bedürfnisse des jeweiligen wissenschaftlichen oder künstlerischen Faches eine

b) research, and the advancement and appreciation of the arts:

The university shall, in particular, make known its planned research projects and programmes, and those to be continued during the period in question, as well as its projects for the advancement and appreciation of the arts. Furthermore, the minimum basic research performance/basic performance in the advancement and appreciation of the arts in each group of disciplines shall be determined based on the number of full-time equivalents of staff in selected job groups by group of disciplines per calendar year.

c) study programmes and continuing education:

The information on programmes and continuing education activities shall be supported by appropriate statistics relating to quantitative trends in these areas and by the results of analysis of student course evaluations, broken down by programmes. The university shall set out its plans for its degree and continuing education programmes, and shall specify any changes in the organisation of teaching and study aimed at aligning it to the desired qualification profiles of students and research staff. Furthermore, the minimum number of study places to be offered for bachelor's, master's and diploma degree programmes per academic year in each group of disciplines as well as the number of study places for first-year students in bachelor's and diploma programmes according to § 71b per academic year shall be determined.

d) measures to reduce the number of students dropping out:

The university shall examine the reasons for drop-outs and shall announce measures aimed at increasing the proportion of those graduating. Furthermore, the university shall devise measures for extended student counselling, for coaching and mentoring in the orientation period as well as for a greater availability of child care facilities for students with children.

e) improvement of student-teacher ratios:

Taking in particular the requirements of the respective academic or artistic subject into account, an improvement in the student-teacher ratio

Verbesserung der Betreuungsrelation mit dem Ziel anzustreben, internationale Standards in der Betreuung von Studierenden zu erreichen.

f) Angebote für berufstätige Studierende:

Dazu zählt jedenfalls die Schaffung von berufsbegleitend organisierten Studienangeboten sowie von Teilzeitstudienangeboten auch unter Berücksichtigung von blended learning.

g) gesellschaftliche Zielsetzungen:

Die Universität hat ihren Beitrag zur Entwicklung der Gesellschaft zu formulieren. Dazu zählen jedenfalls Maßnahmen zur besseren sozialen Durchlässigkeit, zur Erhöhung des Frauenanteils in leitenden Funktionen der Universität sowie zur gezielten Förderung von Nachwuchsforscherinnen, der Ausbau von gesellschaftlich relevanten Kunst-, Kultur- und Forschungsbereichen sowie der Wissens- und Technologietransfer. Weiters hat die Universität Maßnahmen zur sozialen Dimension in der Lehre sowie zur Einbeziehung von unterrepräsentierten Gruppen in die Hochschulbildung zu entwickeln.

h) Erhöhung der Internationalität und Mobilität:

Aktivitäten und Vorhaben in diesem Bereich beziehen sich insbesondere auf mehrjährige internationale Kooperationen mit Universitäten, mit anderen Forschungseinrichtungen und Institutionen aus dem Kunst- und Kulturbereich, auf gemeinsame Studien- und Austauschprogramme für Studierende, für das wissenschaftliche und künstlerische Personal sowie auf die Erhöhung des Anteils der ausländischen Studierenden und Postgraduierten.

i) interuniversitäre Kooperationen und Kooperationen mit anderen postsekundären Bildungseinrichtungen: Dabei hat die Universität insbesondere ihre Aktivitäten zur gemeinsamen Nutzung von Organisationseinheiten und Leistungsangeboten mit anderen postsekundären Bildungseinrichtungen zu bestimmen. Es sind Informationen über die Bereiche, das Ausmaß und die Auswirkungen der Kooperationen zu liefern.

j) Festlegung von Indikatoren:

Es sind Indikatoren festzulegen, anhand derer die Erreichung von bestimmten Leistungsvereinbarungszielen gemessen werden kann; die betreffenden Indikatoren sind in die Wissensbilanz der Universität aufzunehmen.

shall be aimed at, with a view to student-teacher ratios that are common by international standards.

f) offerings for working students:

This includes the creation of part-time study programmes, which should also include blended learning.

g) social goals:

The university shall formulate its contribution to social progress. This includes measures to improve social permeability, to increase the proportion of women in leadership positions at universities, the promotion of female junior researchers in a targeted manner, the advancement of socially relevant areas of art, culture and research, and knowledge and technology transfers. Furthermore, the university shall develop measures aiming to promote the social dimension in teaching and to include underrepresented groups in higher education.

h) increase in internationality and mobility:

Activities and projects in this area relate, in particular, to multi-year international co-operation agreements with other universities, research institutions and artistic or cultural institutions, to joint programmes and exchange programmes for students as well as for the scientific and artistic staff, and to an increase in the proportion of foreign undergraduates and postgraduates in the student body.

i) inter-university co-operation and co-operation with other post-secondary educational institutions: In that, the university shall give an account of its efforts to promote the common use of organisational units and services with other post-secondary educational institutions. This shall include information on the areas, extent and effects of the co-operation with other Austrian universities.

j) establishment of indicators:

Indicators shall be established which serve to measure the attainment of particular objectives of the performance agreement; the indicators chosen shall be included in the intellectual capital report of the the university.

k) in Bezug auf Studien für das Lehramt an Schulen bzw. Berufstätigkeiten an elementarpädagogischen Bildungseinrichtungen: Grundlage der Leistungsvereinbarung ist bei neu eingerichteten Studien eine positive Stellungnahme des Qualitätssicherungsrates für Pädagoginnen- und Pädagogenbildung.

2. die Leistungsverpflichtung des Bundes: Zuteilung des Globalbudgets aufgegliedert in die Teilbeträge gemäß § 12a Abs. 2 Z 1 bis 3 mit Ausnahme jener Beträge, die aufgrund der wettbewerbsorientierten Indikatoren vergeben werden. Letztere werden für die jeweilige Leistungsvereinbarungsperiode vorabgeschätzt, die Zuteilung der endgültigen Beträge erfolgt jährlich im Nachhinein;
3. Inhalt, Ausmaß und Umfang der Ziele sowie Zeitpunkt der Zielerreichung;

(Anm.: Z 4 aufgehoben durch BGBl. I Nr. 8/2018)

5. Maßnahmen im Falle der Nichterfüllung der Leistungsvereinbarung;
6. Berichtswesen und Rechenschaftslegung.

(3) Die Leistungsvereinbarung kann bei gravierenden Veränderungen der ihr zugrunde liegenden Rahmenbedingungen sowie für besondere Finanzierungserfordernisse, zB für bestimmte Vorhaben zur Schaffung oder Unterstützung eines nationalen Hochschulraumes, einvernehmlich abgeändert werden. Kommt es zu keiner einvernehmlichen Abänderung, kann die Schlichtungskommission (§ 13a) angerufen werden. Liegt eine gravierende Veränderung der zugrunde liegenden Rahmenbedingungen vor, hat die Schlichtungskommission unter sinngemäßer Anwendung des Abs. 8 eine abgeänderte Leistungsvereinbarung zu erlassen.

(Anm.: Abs. 4 aufgehoben BGBl. *I Nr. 8/2018)*

(Anm.: Abs. 5 aufgehoben BGBl. I Nr. 81/2009)

(6) Das Rektorat hat dem Universitätsrat bis 30. April jeden Jahres eine Wissensbilanz über das abgelaufene Kalenderjahr vorzulegen. Der Universitätsrat hat die Wissensbilanz innerhalb von vier Wochen zu genehmigen und an die Bundesministerin oder den Bundesminister weiterzuleiten. Erfolgt bis zu diesem Zeitpunkt keine Genehmigung, ist die Wissensbilanz mit einer entsprechenden Stellungnahme dennoch weiterzuleiten. In der Wissensbilanz sind zumindest gesondert darzustellen:

1. der Wirkungsbereich, gesellschaftliche Zielsetzungen sowie selbst definierte Ziele und Strategien;

k) for teacher training programmes for schools or elementary educational institutions: Performance agreements for newly established programmes shall be subject to approval by the Quality Assurance Council for Teacher Training.

2. undertakings made by the federal government: allocation of the global budget, broken down into the components according to § 12a para 2 subparas 1 to 3, with the exception of those amounts allocated on the basis of competition indicators. The latter are pre-estimated for the respective performance agreement period. An ex-post allocation of the final amounts shall take place every year;
3. content, extent and scope of the objectives and the timing of goal attainment;
4. *[removed]*
5. measures in the case of non-fulfilment of the performance agreement;
6. reporting and accounting.

(3) The performance agreement may be amended in the case of significant changes in the circumstances on which they are based, or for specific financial requirements, e.g. for certain projects for creating or supporting of a national higher education area. In case that amendments cannot be made by mutual agreement, the arbitration commission (§ 13a) may be invoked. In the case of significant changes in the circumstances on which a performance agreement is based, the arbitration committee shall enact an amended agreement, applying para 8 by analogy.

(4) [removed]

(5) [removed]

(6) The rectorate shall submit by 30 April of each year an intellectual capital report for the past calendar year to the university council. The university council shall approve the intellectual capital report within four weeks and shall forward it to the Federal Minister. In the absence of such approval within the appointed period, the intellectual capital report shall nevertheless be forwarded together with an explanatory statement. The intellectual capital report shall, as a minimum, present in itemised form:

1. the sphere of action, social goals and self-imposed objectives and strategies;

2. das intellektuelle Vermögen, differenziert in Human-, Struktur- und Beziehungskapital;
3. die in der Leistungsvereinbarung definierten Leistungsprozesse mit ihren Outputgrößen und Wirkungen.

Die Wissensbilanz hat einen Berichtsteil zu enthalten, der auf der Basis der Leistungsvereinbarung zu erstellen ist. Nach dem zweiten Budgetjahr ist überdies eine Prognose über die zu erwartenden Leistungsergebnisse aufzunehmen. Die Bundesministerin oder der Bundesminister hat durch Verordnung Richtlinien für den Aufbau und die Gestaltung der Wissensbilanz einschließlich des durch das Bundesministerium für ~~Bildung~~Frauen, Wissenschaft und Forschung durchzuführenden Datenclearingprozesses zu erlassen.

(7) Im dritten Jahr einer Leistungsperiode hat die Universität der Bundesministerin oder dem Bundesminister bis 30. April einen Entwurf für die nächste Leistungsvereinbarung vorzulegen. Die Bundesministerin oder der Bundesminister hat bis 31. August dazu Stellung zu nehmen. Die Verhandlungen über die Leistungsvereinbarung sind bis 31. Dezember abzuschließen.

(7a) Spätestens bis 31. Dezember des zweiten Jahres jeder Leistungsvereinbarungsperiode haben die Universitäten der Bundesministerin oder dem Bundesminister zum Zweck der Vorbereitungen der Verhandlungen der jeweiligen Leistungsvereinbarungen gemäß Abs. 1 eine Planungsübersicht, basierend auf dem jeweiligen Entwicklungsplan, insbesondere hinsichtlich der gemäß § 13b Abs. 3 enthaltenen Entwicklungsziele und Strategien, vorzulegen. Darüber hinaus sind darin die Stellen gemäß § 13b Abs. 3 Z 7 bis 11 in tabellarischer Form anzuführen. Das Rektorat hat die Planungsübersicht zu erstellen sowie nach Information des Senats und des Universitätsrats an die Bundesministerin oder den Bundesminister weiterzuleiten. Die Bundesministerin oder der Bundesminister hat eine Verordnung zur Gestaltung der Planungsübersicht zu erlassen, die insbesondere deren Struktur sowie das Vorlageprozedere regelt.

(8) Kommt eine Leistungsvereinbarung nicht rechtzeitig zustande, bestimmt die Schlichtungskommission (§ 13a) auf Antrag der Bundesministerin oder des Bundesministers oder der betreffenden Universität im Rahmen der Bestimmungen dieses Bundesgesetzes unter Abwägung der wechselseitigen Interessen und auf der Grundlage des bisherigen Verhandlungsstandes den Inhalt der Leistungsvereinbarung durch Bescheid. Bis zur Rechtskraft dieses Bescheides gilt die Leistungsvereinbarung der vorhergehenden Leistungsperiode provisorisch weiter. Der Bescheid der Schlichtungskommission ersetzt die zu treffende Vereinbarung. Er steht dem späteren einvernehmlichen Abschluss einer

2. its intellectual capital, broken down into human, structural and relationship capital;
3. the performance processes set out in the performance agreement, including their outputs and impacts.

The intellectual capital report shall contain a report section, which shall be based on the performance agreement. After the second budget year, it shall also contain a forecast of the performance outcomes. The Federal Minister shall, by decree, issue regulations for the structure and organisation of intellectual capital reports including the data clearing process to be implemented by the Federal Ministry of Education, Science and Research.

(7) The university shall submit a draft for the next performance agreements to the Federal Minister by 30 April of the third year of the term of the current performance agreement. The Federal Minister shall respond to this draft by 31 August. Negotiations on the performance agreement shall be concluded by December 31.

(8) In case that a performance agreement is not concluded by the appointed date, the arbitration committee (§ 13a) shall, upon application of the Federal Minister or of the university concerned, subject to the provisions of this Act and having regard to the interests of both parties, determine the contents of the performance agreement by official notification on the basis of the position reached by the negotiations up to that point. Until such official notification enters into effect the performance agreement for the previous period shall remain in force on a provisional basis. The official notification of the arbitration committee shall apply instead of the agreement to be concluded. It shall not preclude the subsequent conclusion by mutual consent

Leistungsvereinbarung nach Abs. 1 nicht entgegen und tritt mit dem Abschluss einer solchen Vereinbarung außer Kraft.

(9) Die Bundesministerin oder der Bundesminister stellt von Amts wegen oder auf Antrag jener Universität, die Vertragspartner einer Leistungsvereinbarung nach Abs. 1 ist, durch Bescheid die Gültigkeit oder allfällige Ungültigkeit dieser Leistungsvereinbarung fest. Dies gilt nicht für jene Leistungsvereinbarungen, die durch Bescheid der Schlichtungskommission errichtet wurden. Die Universität hat in diesem Verfahren Parteistellung sowie das Recht, gegen den das Verfahren abschließenden Bescheid vor dem Bundesverwaltungsgericht Beschwerde zu führen.

(10) Die Bundesministerin oder der Bundesminister stellt von Amts wegen oder auf Antrag bescheidmäßig die aus einer Leistungsvereinbarung nach Abs. 1 oder Abs. 8 folgenden Verpflichtungen fest. Die Universität hat in diesem Verfahren Parteistellung sowie das Recht, gegen den das Verfahren abschließenden Bescheid vor dem Verwaltungsgerichtshof Beschwerde zu führen.

Schlichtungskommission

§ 13a. (1) Zur Entscheidung über Anträge nach § 13 Abs. 8 ist eine Schlichtungskommission beim Bundesministerium für ~~Bildung~~Frauen, Wissenschaft und Forschung zu errichten.

(2) Die Schlichtungskommission besteht aus einer Richterin oder einem Richter des Aktivstands als Vorsitzender oder Vorsitzendem und vier Beisitzern. Die oder der Vorsitzende und eine Stellvertreterin oder ein Stellvertreter für den Fall der Verhinderung sind von der Bundesministerin oder dem Bundesminister auf Vorschlag der Präsidentin oder des Präsidenten des Obersten Gerichtshofes für die Dauer einer Funktionsperiode von fünf Jahren zu bestellen. Eine Wiederbestellung ist zulässig. Je zwei Beisitzer werden im Einzelfall vom Rektorat im Einvernehmen mit dem Universitätsrat der beteiligten Universität und von der Bundesministerin oder dem Bundesminister über Aufforderung der oder des Vorsitzenden für die Dauer des laufenden Verfahrens entsendet. Die Schlichtungskommission ist beschlussfähig, wenn alle Mitglieder anwesend sind. Sie fasst ihre Beschlüsse mit Stimmenmehrheit; eine Stimmenthaltung ist nicht zulässig.

(3) Die Beisitzer müssen eine entsprechende Tätigkeit in der wissenschaftlichen Lehre und Forschung oder im Universitätsmanagement aufweisen, die zur sachkundigen Beurteilung von Fragen der Steuerung und Finanzierung von Universitäten qualifiziert. Die Mitglieder der Schlichtungskommission dürfen keine Mitarbeiterinnen oder Mitarbeiter des für die Angelegenheiten der Universitäten zuständigen Bundesministeriums und keine Universitätsangehörigen gemäß § 94 der

of a performance agreement under para 1, and shall cease to have effect upon the conclusion of such agreement.

(9) The Federal Minister shall, acting proprio motu or upon application of the university that is party to a performance agreement under para 1, determine the validity or invalidity of such performance agreement by official notification. This shall not apply to performance agreements created by official notification of the arbitration committee. The university shall be entitled to be a party to this procedure, and to appeal to the Federal Administrative Court against the official notification issued upon conclusion of the procedure.

(10) The Federal Minister shall, by official notification, acting proprio motu or upon application, determine the duties arising from a performance agreement under paras 1 or 8. The university shall be entitled to be a party to this procedure and to appeal to the Federal Administrative Court against the official notification issued upon conclusion of the procedure.

Arbitration Committee

§ 13a. (1) An arbitration committee shall be established at the Federal Ministry of Education, Science and Research to hear applications according to § 13 para 8.

(2) The arbitration committee shall consist of a serving judge as chairperson and four lay members. The Federal Minister shall appoint the chairperson and a deputy chairperson to serve in the case of the chairperson's indisposition, for a term of five years on the recommendation of the President of the Supreme Court of Justice. Re-election is permissible. Two lay members shall be delegated by the rectorate in consultation with the university council of the university in question, and two by the Federal Minister on request of the chairperson, for the duration of the current proceeding. The arbitration committee shall require the presence of all members for a quorum. It shall resolve by a simple majority of the votes cast; abstention is prohibited.

(3) The lay members must hold respective positions in academic teaching or research, or university management that qualify them to make informed judgements on university management and finance issues. The arbitrators may not be employees of the federal ministry in charge of higher education matters, and may not be members, in the meaning of § 94, of the university concerned. They may not be members of the federal or provincial governments, the National Council, the Federal

beteiligten Universität sein. Sie dürfen nicht Mitglieder der Bundesregierung oder einer Landesregierung, Mitglieder des Nationalrats, des Bundesrats oder eines sonstigen allgemeinen Vertretungskörpers und Funktionäre einer politischen Partei sowie Personen, die eine dieser Funktionen in den letzten vier Jahren ausgeübt haben, sein. Ferner müssen sie die Gewähr der Unabhängigkeit und Unparteilichkeit gegenüber den Parteien des Verfahrens erfüllen.

(4) Die Schlichtungskommission hat auf das Verfahren das Allgemeine Verwaltungsverfahrensgesetz 1991 – AVG, BGBl. Nr. 51/1991, anzuwenden, sofern dieses Bundesgesetz nicht anderes anordnet. Der Schlichtungskommission sind von den Parteien alle sachdienlichen Informationen (personenbezogene Daten gemäß Art. 4 Nr. ~~1 der Verordnung (EU) 2016/679 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten, zum freien Datenverkehr und zur Aufhebung der Richtlinie 95/46/EG [Datenschutz-Grundverordnung], ABl. Nr. L 119 vom 04.05.2016 S. 1, [im Folgenden: DSGVO]~~1 DSGVO und sonstige Informationen) zugänglich zu machen. Sie kann ferner bei Bedarf geeignete Personen als Sachverständige heranziehen. Im Übrigen ist die Geschäftsordnung der Schlichtungskommission von der Bundesministerin oder vom Bundesminister nach Anhörung der oder des Vorsitzenden durch Verordnung zu regeln. Vor der Erlassung eines Bescheides hat die Schlichtungskommission auf den Abschluss oder die einvernehmliche Abänderung einer Leistungsvereinbarung innerhalb einer vierwöchigen Frist ab Antragstellung hinzuwirken.

(5) Die Bundesministerin oder der Bundesminister hat die Vorsitzende oder den Vorsitzenden oder deren Stellvertreter mit Bescheid des Amtes zu entheben, wenn sich ergibt, dass die Voraussetzungen für die Bestellung nicht gegeben waren oder sie sich einer groben Verletzung oder dauernden Vernachlässigung ihrer Amtspflichten schuldig gemacht haben. Wird die Vorsitzende oder der Vorsitzende enthoben, ist die Stellvertreterin oder der Stellvertreter für die Dauer der laufenden Verfahren heranzuziehen, bis eine neue Vorsitzende oder ein neuer Vorsitzender bestellt wird.

(6) Die Mitglieder der Schlichtungskommission sind in Ausübung ihres Amtes unabhängig und an keine Weisungen gebunden. Entscheidungen der Schlichtungskommission unterliegen weder der Aufhebung noch der Abänderung im Verwaltungsweg. Gegen die Entscheidung ist die Anrufung des Bundesverwaltungsgerichts durch jede der beiden Parteien zulässig.

(7) Die Mitglieder der Schlichtungskommission haben Anspruch auf Ersatz der angemessenen Reisekosten und Barauslagen sowie auf eine dem Zeit- und Arbeitsaufwand entsprechende Vergütung, die von der Bundesministerin oder vom

Council or any other popular representative body, or officers of political parties or persons who have exercised such functions within the past four years. They must, further, be in a position to maintain independence and impartiality with regard to the parties to the proceeding.

(4) The arbitration committee shall apply the General Administrative Procedure Act 1991 (Allgemeines Verwaltungsverfahrensgesetz – AVG), F. L. G. No 51/1991, to the procedure, unless otherwise specified by this Act. The parties shall furnish the arbitration committee with all information (personal data according to Art 4 No 1 of the Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC [General Data Protection Regulation], OJ No L 119 of 04.05.2016 p. 1, [subsequently referred to as GDPR] and other information) as is required for its deliberations. The committee may, as required, call suitable persons as expert witnesses. The rules of procedure of the arbitration committee shall be determined by the Federal Minister by decree following consultation of the chairperson. Prior to the enactment of an official notification the committee shall make best efforts to achieve the conclusion or amendment of a performance agreement by mutual consent within four weeks of the application.

(5) The Federal Minister shall, by official notification, dismiss the chairperson or deputy chairperson if circumstances arise which disqualify such persons from holding office, or in the case of a gross violation or persistent neglect of their duties. If the chairperson is dismissed, the deputy chairperson shall perform the chairperson's duties for the duration of the current proceeding or until such time as a new chairperson is appointed.

(6) The members of the arbitration committee shall perform their duties independently, and shall not be bound by any instructions. Decisions of the arbitration committee may not be annulled or amended by administrative decisions. Both parties may appeal to the Federal Administrative Court against the committee's decision.

(7) The members of the arbitration committee are entitled to reasonable travel and out-of-pocket expenses, and to compensation commensurate with the time and work devoted to their duties. Such compensation shall be determined by decree of

Bundesminister durch Verordnung unter Bedachtnahme auf die Bedeutung und den Umfang der zu besorgenden Aufgaben festzusetzen ist.

Entwicklungsplan

§ 13b. (1) Der Entwicklungsplan ist das strategische Planungsinstrument der Universität und bildet eine wesentliche Grundlage für die Leistungsvereinbarung. Das Rektorat hat den Entwicklungsplan ~~bis spätestens 31. Dezember des zweiten Jahres jeder Leistungsvereinbarungsperiode mittels rollierender Planung für die folgenden zwei Leistungsvereinbarungsperioden~~ zu erstellen sowie nach Befassung des Senats (§ 25 Abs. 1 Z 2) und nach Genehmigung durch den Universitätsrat im Mitteilungsblatt zu verlautbaren und an die Bundesministerin oder den Bundesminister weiterzuleiten.

(2) Der Entwicklungsplan ~~hat sich an~~ist jedenfalls alle sechs Jahre zu erstellen und jeweils spätestens bis 31. Dezember des zweiten Jahres jeder zweiten Leistungsvereinbarungsperiode der ~~Struktur~~Bundesministerin oder dem Bundesminister vorzulegen.

(3) Der Entwicklungsplan hat die Entwicklungsziele und Strategien der Universität zumindest für die folgenden zwei Leistungsvereinbarungsperioden zu beschreiben und dabei insbesondere zu enthalten:

1. Befassung mit den Inhalten der Leistungsvereinbarung gemäß § 13 Abs. 2 Z 1 ~~zu orientieren. Er beinhaltet die fachliche Widmung der für~~;
2. Konkretisierung der Zielsetzungen des gesamtösterreichischen Universitätsentwicklungsplans gemäß § 12b Abs. 2;
3. beabsichtigte Einführung von neuen und die beabsichtigte Auflassung von bestehenden ordentlichen Studien;
4. langfristige Entwicklung der Standortstrategie im Hinblick auf den Raumbedarf;

the Federal Minister, having regard to the importance and scope of the duties to be performed.

Development Plan

§ 13b. (1) The development plan is the university's strategic planning instrument and shall constitute an important basis for the performance agreements. The rectorate shall prepare the development plan by 31 December of the second year of each performance agreement period based on rolling forecasts for the following two performance agreement periods and after hearing the opinion of the senate (§ 25 para 1 (2)) and shall publish it in the university gazette, after approval has been given by the university council, and forward it to the Federal Minister.

(2) The development plan shall be aligned with the structure of the performance agreement under § 13 para 2 (1). It shall specify the specific field of the positions allocated to university professors according to § 98 para 1, including the allocation of positions for university professors in the clinical and non-clinical departments according to § 123b para 1. The development plan shall contain a description of the human- resource strategy as well as the number of university professors according to §§ 98 and 99, provided that they have been appointed for at least three years. It shall specify the specific field of positions for university professors according to § 123b para 1. The development plan shall also contain an outline of human-resource development. This shall also include the envisioned workplace quality at all career stages, but particularly that of junior academic staff. In addition, plans to launch new degree programmes and to discontinue degree programmes shall be laid out.

(3) The development plan shall also specify the number of positions for which a qualification agreement in the meaning of § 27 para 1 of the collective contract concluded according to § 108 para 3 in the version effective on 1 October 2015 can be made.

5. Strategien zur Beförderung von Nachhaltigkeit in allen universitären Leistungsbereichen und im eigenen Wirkungsbereich, insbesondere auch hinsichtlich der nachhaltigen Immobilienbewirtschaftung;
6. Beschreibung der Personalstrategie und der Personalentwicklung. Diese umfasst die angestrebte Qualität eines Arbeitsplatzes auf allen Karrierestufen, insbesondere jedoch jene des wissenschaftlichen und künstlerischen Nachwuchses und eine Darstellung zur Verringerung der Zahl befristeter Arbeitsverhältnisse (Entfristungsmodelle);
7. Anzahl der Stellen der Universitätsprofessorinnen und Universitätsprofessoren gemäß § 98 Abs. ~~1 vorgesehenen~~1 sowie fachliche Widmung dieser Stellen einschließlich der Stellenwidmungen für Universitätsprofessorinnen und Universitätsprofessoren im Klinischen und Nichtklinischen Bereich gemäß § 123b Abs. ~~1. Der Entwicklungsplan hat eine Beschreibung der Personalstrategie sowie die Zahl~~1;
8. Anzahl der Stellen der Universitätsprofessorinnen und Universitätsprofessoren gemäß §§ 98 und 99, soweit sie für mindestens drei Jahre bestellt sind~~, zu beinhalten. Er beinhaltet die fachliche Widmung der Stellen für Universitätsprofessorinnen und Universitätsprofessoren gemäß § 123b Abs. 1. Der Entwicklungsplan hat weiters eine Beschreibung der Personalentwicklung zu beinhalten. Diese umfasst auch die angestrebte Qualität eines Arbeitsplatzes auf allen Karrierestufen, insbesondere jedoch jene des wissenschaftlichen Nachwuchses. Außerdem sind die beabsichtigte Einführung von neuen ordentlichen Studien und die beabsichtigte Auflassung von ordentlichen Studien darzustellen.~~;
9. Anzahl der Stellen gemäß § 99 Abs. 4, für welche vereinfachte Berufungsverfahren für Universitätsprofessorinnen oder Universitätsprofessoren durchgeführt werden können;
10. Anzahl der Stellen für Universitätsprofessorinnen und Universitätsprofessoren gemäß § 99a;
11. Anzahl jener Stellen, die im Sinne des § 27 Abs. 1 des gemäß § 108 Abs. 3 abgeschlossenen Kollektivvertrages in der am 1. Oktober 2015 geltenden Fassung für eine Qualifizierungsvereinbarung in Betracht kommen~~, auszuweisen~~.

Evaluierung und Qualitätssicherung

§ 14. (1) Die Universitäten haben zur Qualitäts- und Leistungssicherung ein eigenes Qualitätsmanagementsystem aufzubauen, das die Aufgaben und das gesamte

Evaluation and Quality Assurance

§ 14. (1) The universities shall develop their own quality management system to assure the quality and the attainment of their performance objectives which covers

Leistungsspektrum der Universität umfasst. Das Qualitätsmanagementsystem sieht regelmäßige Evaluierungen des Leistungsspektrums gemäß den in der Satzung zu erlassenden Bestimmungen vor.

(2) Im Rahmen der Qualitätssicherung der Lehre sind Instrumente und Verfahren zu etablieren, die die angemessene Verteilung der ECTS-Anrechnungspunkte in den Curricula insbesondere bei deren Erstellung evaluieren.

(3) Evaluierungen haben nach fachbezogenen internationalen Evaluierungsstandards zu erfolgen. Die zu evaluierenden Bereiche des universitären Leistungsspektrums sind für jene Evaluierungen, die sich nur auf eine Universität beziehen, in der Leistungsvereinbarung festzulegen.

(4) Universitätsinterne Evaluierungen sind nach Maßgabe der Satzung kontinuierlich durchzuführen.

(5) Externe Evaluierungen sind, wenn sie

1. eine einzelne Universität betreffen, auf Veranlassung des Universitätsrats, des Rektorats oder der Bundesministerin oder des Bundesministers,
2. mehrere Universitäten betreffen, auf Veranlassung der Universitätsräte, der Rektorate der betreffenden Universitäten oder der Bundesministerin oder des Bundesministers

durchzuführen.

(6) Die betreffenden Universitäten und ihre Organe haben die für die Evaluierungen erforderlichen Daten und Informationen (personenbezogene Daten gemäß Art. 4 Nr. 1 DSGVO und sonstige Informationen) zur Verfügung zu stellen und sind zur Mitwirkung verpflichtet.

(7) Die Leistungen der Universitätsprofessorinnen und Universitätsprofessoren sowie der Universitätsdozentinnen und Universitätsdozenten und der wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb sind regelmäßig, zumindest aber alle fünf Jahre, zu evaluieren. Die näheren Bestimmungen trifft die Satzung.

(8) Die Ergebnisse aller Evaluierungen sind den Entscheidungen der Universitätsorgane zugrunde zu legen. Die Beurteilung der Lehre durch die Studierenden ist bei den Leistungsvereinbarungen zu berücksichtigen.

(9) Der Aufwand für von der Bundesministerin oder vom Bundesminister veranlasste Evaluierungen ist vom Bund zu tragen.

all tasks and the whole spectrum of their services. The quality management system shall provide for regular evaluations of their range of services in accordance with the provisions to be laid down in the statutes.

(2) Within the framework of assuring the quality of teaching, instruments and procedures shall be established to evaluate a fair allocation of ECTS credits within the curricula, in particular during the process of its development.

(3) Evaluations shall be conducted in accordance with subject-based international evaluation standards. The areas of university services to be evaluated shall, in the case of evaluations relating to single universities, be established by the respective performance agreement.

(4) The universities shall carry out internal evaluations on an ongoing basis, in accordance with their statutes.

(5) External evaluations shall take place:

1. on the initiative of the university council or rectorate of the university in question or the Federal Minister where they relate to individual universities;
2. on the initiative of the university councils or rectorates of the universities in question or the Federal Minister where more than one university is concerned.

(6) The universities concerned and their governing bodies shall be obliged to provide the necessary data and information (personal data according to Art 4 No 1 GDPR and other information) for evaluations, and to contribute to it.

(7) The performance of university professors, associate professors, and other research, artistic and teaching staff shall be regularly evaluated, at least once every five years. The detailed arrangements shall be established by university statutes.

(8) The consequences of all evaluations shall be for the decision of the governing bodies of the universities. Performance agreements shall include arrangements for student evaluation of teaching.

(9) The cost of evaluations ordered by the Federal Minister shall be borne by the Federal Government.

3. Unterabschnitt
Gebarung und Rechnungswesen

Gebarung

§ 15. (1) Das Rektorat hat die Gebarung der Universität nach den Grundsätzen der Rechtmäßigkeit, Wirtschaftlichkeit, Zweckmäßigkeit, Sparsamkeit und Transparenz zu gestalten und den Haushalt der Universität mit entsprechender Sorgfalt zu führen.

(2) Die Universitäten können über ihre Einnahmen frei verfügen, sofern gesetzlich nicht anderes bestimmt ist. Allfällige Zweckwidmungen sind zu berücksichtigen.

(3) Die Gebarung der Universitäten erfolgt im eigenen Namen und auf eigene Rechnung.

(4) Die Begründung von Verbindlichkeiten, die über die laufende Geschäftstätigkeit der Universität hinausgehen, bedarf der Zustimmung des Universitätsrats. Dieser kann das Rektorat ermächtigen, Verbindlichkeiten bis zu einer bestimmten Höhe ohne seine vorherige Zustimmung einzugehen.

(4a) Die Universitäten haben unbeschadet von Abs. 4 vor dem Eingehen von Haftungen oder vor der Aufnahme von Krediten ab einer Betragsgrenze von 10 Millionen Euro die Zustimmung der Bundes-ministerin oder des Bundesministers einzuholen. Die Bundesministerin oder der Bundesminister hat binnen vier Monaten mit Bescheid zu entscheiden. Vor Erteilung der Zustimmung ist der Bundesministerin oder dem Bundesminister für Finanzen die Möglichkeit einer Stellungnahme einzuräumen. Die Zustimmung kann mit Bescheid verweigert werden, wenn das Eingehen der Haftung oder die Aufnahme des Kredits die finanzielle Leistungsfähigkeit der Universität überschreitet oder gefährdet. Gegen den Bescheid kann Beschwerde an das Bundesverwaltungsgericht erhoben werden. Durch Verordnung der Bundesministerin oder des Bundesministers kann für Gruppen von Universitäten unter Berücksichtigung des jeder Universität gemäß § 12 Abs. 6 zur Verfügung gestellten Globalbudgets eine höhere Betragsgrenze festgelegt werden.

(5) Für Verbindlichkeiten der Universitäten trifft den Bund keine Haftung, sofern gesetzlich nicht anderes bestimmt ist.

Sub-Chapter 3
Financial Management and Accounting

Financial Management

§ 15. (1) The rectorate shall conduct the financial affairs of the university in accordance with the law, and with the principles of efficiency, expediency, frugality and transparency, and shall manage the universities' budget with due care.

(2) The universities shall be free to use their income as they see fit, except insofar as the law provides otherwise, and having regard to the purposes of any tied funds.

(3) The universities shall manage their financial affairs in their own name and for their own account.

(4) The assumption of non-current liabilities shall require the approval of the university council. This may empower the rectorate to assume liabilities up to a given amount without its prior consent.

(4a) Notwithstanding para 4, the universities shall seek the approval of the Federal Minister, before entering into liabilities or taking out loans exceeding 10 million €. The Federal Minister shall take a decision within four months by official notification. Prior to this approval, the Federal Minister of Finance shall have the opportunity to give her/his opinion. The approval can be denied by official notification, if entering into liabilities or taking out a loan exceeds or endangers the university's financial capacity. An appeal against the official notification can be lodged with the Federal Administrative Court. The Federal Minister shall have the right to determine, by decree, a higher limit for groups of universities, taking into account the global budget that each university has been allocated under § 12 para 6.

(5) The Federal Government shall not be liable for the universities' debts except insofar as the law provides otherwise.

(6) Die Gebarung der Universitäten, der von ihnen gemäß § 10 Abs. 1 gegründeten Gesellschaften, Stiftungen und Vereine sowie die Gebarung jener Gesellschaften, deren Geschäftsanteile die Universität mittelbar oder unmittelbar zu ~~mehr als~~mindestens 50 vH hält, unterliegt der Prüfung durch den Rechnungshof.

(7) Die Universitäten unterliegen dem Beteiligungs- und Finanzcontrolling gemäß § 67 BHG 2013.

Rechnungswesen und Berichte

§ 16. (1) An jeder Universität ist unter der Verantwortung und Leitung des Rektorats ein Rechnungswesen, einschließlich einer Kosten- und Leistungsrechnung, sowie ein Berichtswesen einzurichten, die den Aufgaben der Universität entsprechen. Für das Rechnungswesen ist der erste Abschnitt des dritten Buches des Unternehmensgesetzbuches – UGB, dRGBl. S 219/1897, sinngemäß anzuwenden.

(2) Jede Universität kann darüber hinaus weitere Abschnitte des dritten Buches des UGB anwenden, um damit ihrer Verpflichtung zur Rechnungslegung bei Wahrung der Vergleichbarkeit mit den anderen Universitäten nachzukommen. Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen durch Verordnung die erforderlichen Regelungen, Anpassungen und Ergänzungen für die Gliederung des Rechnungsabschlusses, bestehend aus Bilanz sowie Gewinn- und Verlustrechnung, für die Bewertung der Vermögensgegenstände und Schulden, für die Anwendung von Bewertungsvereinfachungsverfahren, für die Prüfung des Rechnungsabschlusses, für die Aufnahme entsprechender Erläuterungen und für eine einheitliche Anwendung dieser Grundsätze festzulegen.

(2a) Die Bundesministerin oder der Bundesminister hat nach Anhörung der Universitäten im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen durch Verordnung einheitliche Standards für die Kosten- und Leistungsrechnung gemäß Abs. 1 sicherzustellen.

(3) Das Rechnungsjahr der Universitäten entspricht dem Kalenderjahr, soweit nicht in der Verordnung gemäß Abs. 2 etwas anderes angeordnet wird.

(4) Das Rektorat hat dem Universitätsrat bis 30. April einen Rechnungsabschluss über das abgelaufene Rechnungsjahr zusammen mit einem Bericht einer Abschlussprüferin oder eines Abschlussprüfers vorzulegen. Die Abschlussprüferin oder der Abschlussprüfer ist vom Universitätsrat längstens sechs Monate vor Ablauf des Rechnungsjahres mit der Prüfung des Rechnungswesens und

(6) The universities' financial management as well as that of the companies, foundations and associations they have founded under § 10 para 1 and the financial management of those companies of which the university holds a direct or indirect share of more than 50%, shall be examined by the Court of Audit.

(7) The universities are subject to share and finance controlling according to § 67 BHG 2013 (Federal Budget Act).

Accounting and Reporting

§ 16. (1) Every university shall install an accounting system, including income and expenditure accounting, and a reporting system, appropriate to its duties, which shall fall under the responsibility and management of the rectorate. The first chapter of the third volume of the Corporate Code (Unternehmensgesetzbuch – UGB), Law Gazette of the German Reich p. 219/1897, shall apply by analogy to such accounting system.

(2) Any university may, in addition, apply further chapters of the third volume of the UGB in order to comply with its obligation to present financial statements comparable with those of other universities. The Federal Minister shall, by decree, in consultation with the Federal Minister of Finance, make such regulations for, and adjustments and additions to the format of the financial statements – which shall consist of a balance sheet and a profit and loss account – as are necessary for measurement of a university's assets and liabilities, the use of simplified valuation methods, auditing of the statements, the preparation of appropriate notes and uniform application of these principles.

(2a) The Federal Minister shall by decree, after hearing the opinion of the universities and in consultation with the Federal Minister of Finance, ensure that uniform principles for income and expenditure accounting under para 1 are in place.

(3) The universities' financial year shall correspond to the calendar year, unless otherwise provided for by the decree under para 3.

(4) The rectorate shall submit annual financial statements, together with an auditor's report, to the university council by 30 April of each year. The auditor shall be appointed by the university council to audit the books of account and the financial statements not later than six months before the end of the current financial year. The

des Rechnungsabschlusses zu beauftragen. Die Abschlussprüferin oder der Abschlussprüfer muss eine von der Universität unabhängige beeidete Wirtschaftsprüferin und Steuerberaterin oder ein von der Universität unabhängiger beeideter Wirtschaftsprüfer und Steuerberater oder eine Wirtschaftsprüfungs- und Steuerberatungsgesellschaft sein.

(5) Der Universitätsrat hat den vom Rektorat vorgelegten Rechnungsabschluss innerhalb von vier Wochen zu genehmigen und an die Bundesministerin oder den Bundesminister weiterzuleiten. Erfolgt bis zu diesem Zeitpunkt keine Genehmigung, ist der Rechnungsabschluss mit einer entsprechenden Stellungnahme dennoch weiterzuleiten.

(6) Die Bundesministerin oder der Bundesminister kann durch Verordnung festlegen, dass die Universitäten ihr oder ihm laufend automationsunterstützt und in technisch geeigneter Form den Zugang zu den für die Planung, die Steuerung und die Statistik benötigten standardisierten personenbezogenen Daten (Art. 4 Nr. 1 DSGVO) und sonstigen Informationen, insbesondere für die Berechnung der Indikatoren gemäß § 12 Abs. 8, ermöglichen.

Inanspruchnahme von Dienstleistungen

§ 17. (1) Die Bundesrechenzentrum GmbH hat die Universitäten auf deren Verlangen und gegen Entgelt bei der Einrichtung, Fortentwicklung und beim Betrieb der IT-Verfahren zu unterstützen, die für ein Rechnungswesen gemäß § 16 und eine Personalverwaltung gemäß §§ 125 ff erforderlich sind.

(2) Für die Personalverrechnung der Beamtinnen und Beamten sind die von der Bundesrechenzentrum GmbH betriebenen diesbezüglichen IT-Verfahren jedenfalls in Anspruch zu nehmen. Aufgrund der Verarbeitung personenbezogener Daten wird die Bundesrechenzentrum GmbH dabei als Auftragsverarbeiter im Sinne des Art. 28 DSGVO tätig.

Gewerbe- und abgabenrechtliche Stellung der Universitäten

§ 18. (1) Bei der Erfüllung ihrer Aufgaben unterliegen die Universitäten nicht den Bestimmungen der Gewerbeordnung 1994 (GewO 1994), BGBl. Nr. 194/1994.

(2) Alle dem Bund auf Grund bundesgesetzlicher Bestimmungen eingeräumten abgaben- und gebührenrechtlichen Begünstigungen finden auch auf die Universitäten Anwendung, soweit diese in Erfüllung ihrer gesetzlichen Aufgaben tätig werden.

auditor must be a registered auditor and chartered accountant or an auditing and accounting firm independent of the university.

(5) The university council shall approve the financial statements submitted by the rectorate within four weeks and forward them to the Federal Minister. In the absence of such approval within the appointed period the financial statements shall nevertheless be forwarded to the Federal Minister, together with an opinion thereon.

(6) The Federal Minister may, by decree, determine the universities' duty to provide him/her with ongoing, automated access in an appropriate technical form to such standardised personal data (Art 4 No 1 GDPR) and other information as are necessary for the planning, control and statistics, and in particular for the calculation of indicators in accordance with § 12 para 8.

Use of External Services

§ 17. (1) At their request, Federal Computer Centre shall, for consideration, assist the universities with the installation, development and operation of the IT applications necessary for accounting systems as required by § 16 and personnel management systems as required by §§ 125 ff.

(2) The universities shall, in all events, make use of the IT applications operated by Federal Computer Centre for their payroll computations in respect of permanent civil servants. Because of the processing of personal data, Federal Computer Centre shall act as processor in the meaning of Art 28 GDPR.

Trade and Tax Law Position of the Universities

§ 18. (1) In the fulfilment of their tasks, the universities shall not be subject to the provisions of the Trade Code 1994, F. L. G. No 194/1994.

(2) In the performance of their statutory tasks the universities shall be eligible for all exemptions from taxes and duties accorded to the Federal Government under federal legislation.

2. Abschnitt
Leitung und innerer Aufbau der Universität

1. Unterabschnitt
Bestimmungen für alle Universitäten

Satzung

§ 19. (1) Jede Universität erlässt durch Verordnung (Satzung) die erforderlichen Ordnungsvorschriften im Rahmen der Gesetze und Verordnungen selbst. Die Satzung ist vom Senat auf Vorschlag des Rektorats mit einfacher Mehrheit zu beschließen und zu ändern.

(2) In der Satzung sind insbesondere folgende Angelegenheiten zu regeln:

1. Wahlordnung für die Wahl der Mitglieder des Universitätsrats, des Senats und anderer Organe;
2. Einrichtung eines für die Vollziehung der studienrechtlichen Bestimmungen zuständigen monokratischen Organs und Festlegung von Rahmenbedingungen für eine etwaige Delegation von Aufgaben;
3. generelle Richtlinien für die Durchführung, Veröffentlichung und Umsetzung von Evaluierungen;
4. studienrechtliche Bestimmungen nach Maßgabe des II. Teils dieses Bundesgesetzes;
5. Zusammensetzung des Arbeitskreises für Gleichbehandlungsfragen (§ 42 Abs. 2);
6. Frauenförderungsplan und Gleichstellungsplan (§ 20b);
7. Einrichtung einer Organisationseinheit zur Koordination der Aufgaben der Gleichstellung, der Frauenförderung sowie der Geschlechterforschung;
8. Richtlinien für akademische Ehrungen;
9. Art und Ausmaß der Einbindung der Absolventinnen und Absolventen der Universität.

~~(2a) In die Satzung können Bestimmungen betreffend Maßnahmen bei Plagiaten oder anderem Vortäuschen von wissenschaftlichen oder künstlerischen Leistungen insbesondere im Rahmen von schriftlichen Seminar- und Prüfungsarbeiten,~~

Chapter 2
University Governance and Internal Structures

Sub-Chapter 1
Provisions Applicable to all Universities

Statute

§ 19. (1) Every university shall, within the limits of the law and decrees, itself enact by decree (statute) the rules of procedure necessary for its governance. The statute shall be proposed by the rector for approval by the senate, and shall require a simple majority for its adoption and amendment.

(2) The statute shall, in particular, contain arrangements governing:

1. rules for the election of the university council, senate and other governing bodies;
2. appointment of an officer to administrate matters concerning the enforcement of study law, and specification of frame conditions for a possible delegation of tasks;
3. general guidelines for the conduct and publication of evaluations, and the implementation of their findings;
4. provisions of study law in accordance with Part II of this Act;
5. composition of the working group on equal opportunities (§ 42 para 2);
6. career advancement plan for women and equal opportunities plan (§ 20b);
7. establishment of an organisational unit responsible for the co-ordination of activities relating to equal opportunities, the advancement of women and gender research;
8. guidelines for academic honours;
9. form and extent of graduates’ involvement in university life.

(2a) The statute may contain provisions concerning measures taken in cases of plagiarism or other forms of academic dishonesty in written term papers and exams, bachelor's papers, as well as academic theses and artistic submissions. In addition,

~~Bachelorarbeiten sowie wissenschaftlichen und künstlerischen Arbeiten aufgenommen werden. Darüber hinaus kann das Rektorat über einen allfälligen Ausschluss vom Studium in der Dauer von höchstens zwei Semestern bei schwerwiegendem und vorsätzlichem Plagiieren oder schwerwiegendem und vorsätzlichem anderen Vortäuschen von wissenschaftlichen oder künstlerischen Leistungen im Rahmen von Abschlussarbeiten (Bachelorarbeiten sowie wissenschaftliche und künstlerische Arbeiten) mit Bescheid entscheiden.~~

(Anm.: Abs. 2a aufgehoben durch Art. 1 Z 14, BGBl. I Nr. 50/2024)

(2b) In die Satzung können Bestimmungen über die Verwendung von Fremdsprachen bei der Abhaltung von Lehrveranstaltungen und Prüfungen und bei der Abfassung von wissenschaftlichen Arbeiten aufgenommen werden. Für gemeinsame Studienprogramme, die zu einem joint degree führen, kann bei Bedarf die Abfassung von Urkunden über die Verleihung akademischer Grade und akademischer Bezeichnungen sowie die Ausstellung von Zeugnissen und Abgangsbescheinigungen in englischer Sprache in der Satzung vorgesehen werden.

(3) Wahlen sind geheim durchzuführen, das Wahlrecht ist persönlich und unmittelbar auszuüben.

Leitung und innere Organisation

§ 20. (1) Die obersten Organe der Universität sind der Universitätsrat, das Rektorat, die Rektorin oder der Rektor und der Senat.

(2) Die Mitgliedschaft in mehr als einem der obersten Organe der Universität ist unzulässig.

(3) Die Mitglieder von Kollegialorganen sind bei der Ausübung dieser Funktion an keine Weisungen oder Aufträge gebunden (Art. 81c Abs. 1 B-VG). Sie haben mit einfacher Stimmenmehrheit eine Vorsitzende oder einen Vorsitzenden zu wählen. Kommt eine zur Wahl, Entsendung oder Nominierung von Vertreterinnen und Vertretern in ein Kollegialorgan der Universität berufene Personengruppe dieser Verpflichtung nicht zeitgerecht nach, hat der Universitätsrat dieser Personengruppe eine einmalige Nachfrist zur Nachholung der Wahl, Entsendung oder Nominierung zu setzen. Kommt der Senat seiner Verpflichtung zur Wahl der Mitglieder des Universitätsrats gemäß § 21 Abs. 6 Z 1 oder Abs. 7 nicht zeitgerecht nach, hat die Bundesministerin oder der Bundesminister dem Senat eine einmalige Nachfrist zur Nachholung der Wahl zu setzen. Verstreicht diese Frist ergebnislos, gilt das Kollegialorgan auch ohne Vertreterinnen und Vertreter dieser Personengruppe als gesetzmäßig zusammengesetzt.

the rectorate may decide, by official notification, on a suspension from the studies for up to two semesters in cases of severe and deliberate plagiarism or severe and deliberate forms of academic dishonesty (bachelor's papers, as well as academic theses and artistic submissions).

(2b) The statute may contain certain provisions concerning the use of foreign languages in courses and examinations as well as for writing academic theses.

(3) Elections shall be by secret ballot, and the right to vote must be exercised in person.

Management and Internal Organisation

§ 20. (1) The senior governing bodies of the university shall be the university council, the rectorate, the rector and the senate.

(2) Membership of more than one of these senior bodies is impermissible.

(3) The members of collegial boards shall not be bound by any instructions in the exercise of this function (Art 81c para 1 Federal Constitutional Law). They shall elect a chairperson by a simple majority. In case that the group of persons responsible for electing, appointing or nominating representatives to a collegial board of a university fails to do so within the appointed time, the university council shall grant such group of persons a one-time extension for such election, appointment or nomination. In case that the senate fails to comply with its obligation to elect the members of the university council in accordance with § 21 para 6 subpara 1 or para 7 within the appointed time, the Federal Minister shall grant a one-time extension for such election. If this extension period passes without result, the collegial board shall be deemed to be legally constituted without representatives of such group of persons.

(3a) Die Nutzung von Mitteln der elektronischen Kommunikation für Sitzungen von Kollegialorganen ist zulässig. Näheres ist in der Geschäftsordnung des Kollegialorgans zu regeln, wobei insbesondere die sichere Identifizierung der Mitglieder und zuverlässige Feststellung der Erfüllung von Beschlusserfordernissen sicherzustellen sind. Personen, die mit Mitteln der elektronischen Kommunikation an der Sitzung des Kollegialorgans teilnehmen, gelten als persönlich anwesend. Für die vom Senat gemäß § 25 Abs. 7 und 8 eingerichteten Kollegialorgane sind in der Satzung Rahmenbedingungen für die Nutzung von Mitteln der elektronischen Kommunikation festzulegen.

(3a) The use of electronic communication tools for the meetings of collegial bodies is permissible. Detailed provisions shall be laid down in the collegial body's rules of procedure. In particular, secure identification of the members and reliable determination of the fulfilment of resolution requirements shall be ensured. Persons participating in a meeting of the collegial body by means of an electronic communication tool, are considered to be personally present. Framework conditions for the use of electronic communication tools shall be defined for the collegial bodies established by the senate pursuant to § 25 paras 7 and 8.

(4) Das Rektorat hat nach Stellungnahme des Senats einen Organisationsplan zu erstellen, der der Genehmigung des Universitätsrats bedarf. Bei der Einrichtung von Organisationseinheiten (Departments, Fakultäten, Institute oder andere Organisationseinheiten) ist auf eine zweckmäßige Zusammenfassung nach den Gesichtspunkten von Forschung, Entwicklung und Erschließung der Künste, Lehre und Lernen sowie Verwaltung zu achten. Das Rektorat hat sicherzustellen, dass den Organisationseinheiten die zur Erfüllung ihrer Aufgaben erforderlichen Ressourcen zugewiesen werden.

(4) The rectorate shall, having received the opinion of the senate, prepare an organisation plan which shall require the approval of the university council. When establishing organisational units (departments, faculties, institutes or other organisational units) attention shall be paid to combining units in the interests of efficient research (and advancement and appreciation of the arts), teaching, study and administration. The rectorate shall ensure that sufficient resources are allocated to such organisational units to enable them to fulfil their tasks.

(5) Zur Leiterin oder zum Leiter einer Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst ist vom Rektorat auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren der betreffenden Organisationseinheit eine entsprechend qualifizierte Person mit einem aufrechten Dienstverhältnis zum Bund, die der Universität zur Dienstleistung zugewiesen ist, oder einem aufrechten Arbeitsverhältnis zur Universität zu bestellen. Diese Leiterinnen und Leiter haben mit den der betreffenden Organisationseinheit zugeordneten Angehörigen der Universität Zielvereinbarungen über die Leistungen in Forschung oder Entwicklung und Erschließung der Künste sowie in der Lehre abzuschließen, die von diesen Angehörigen zu erbringen sind. Dabei ist auf die Freiheit der Wissenschaft und der Künste und auf einen entsprechenden Freiraum der einzelnen Wissenschafterinnen und Wissenschafter sowie Künstlerinnen und Künstler in der Forschung oder bei der Entwicklung und Erschließung der Künste sowie in der Lehre Bedacht zu nehmen. Nähere Bestimmungen sind in der Satzung festzulegen.

(5) The rectorate shall, on the basis of nominations from the university professors of the organisational unit concerned, appoint a person with relevant qualifications – who is employed by the Federal Government and assigned to the university or is employed by the university – as the head of an organisational unit responsible for research and teaching or the advancement and appreciation of the arts and teaching. Such unit heads shall conclude target agreements with the university members assigned to the respective organisational units specifying the services to be rendered by such members in respect of research, the advancement and appreciation of the arts, and teaching. In so doing, they shall have regard for scientific and artistic freedom, and for the need to leave sufficient scope for scientists and artists to pursue their research, artistic and teaching activities. The detailed arrangements shall be established by the statute.

(5a) Die Leiterin oder der Leiter einer Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst kann vom Rektorat wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder gesundheitlicher Eignung oder

(5a) The rectorate may, by way of official notification, dismiss the head of an organisational unit with research and teaching responsibilities or responsibilities with regard to the advancement and appreciation of the arts and art teaching because of severe misconduct, conviction of a criminal offence, mental incapacity or health impairment, or loss of confidence on reasonable grounds.

wegen eines begründeten Vertrauensverlustes von ihrer oder seiner Funktion durch Bescheid abberufen werden.

(6) Jede Universität hat ein Mitteilungsblatt herauszugeben und im Internet auf der Homepage der Universität öffentlich zugänglich zu machen. Im Mitteilungsblatt sind insbesondere kundzumachen:

1. Satzung, Entwicklungsplan und Organisationsplan einschließlich der Personalzuordnung;
2. Eröffnungsbilanz;
3. Leistungsvereinbarung unverzüglich nach deren Abschluss, Rechnungsabschluss und Wissensbilanz unverzüglich nach deren Weiterleitung an die Bundesministerin oder den Bundesminister;
4. Verordnungen und Geschäftsordnungen von Organen;
5. Richtlinien der Leitungsorgane;
6. Curricula;
7. von der Universität zu verleihende akademische Grade sowie Bezeichnungen für die Absolventinnen und Absolventen von Universitätslehrgängen;
8. Mitteilungen an die Studierenden sowie sonstige Verlautbarungen von allgemeinem Interesse;
9. Ausschreibung und Ergebnisse von Wahlen;
10. Ausschreibung von Stellen und Leitungsfunktionen;
11. Mitglieder der Leitungsorgane;
12. Verleihung von Lehrbefugnissen;
13. Berechtigungen und erteilte Bevollmächtigungen;

(Anm.: Z 14 aufgehoben durch Art. 1 Z 4, BGBl. I Nr. 177/2021)

15. Vergütung für die Mitglieder des Universitätsrats.

(7) Personen ohne österreichische Staatsbürgerschaft können – unbeschadet anderer in diesem Bundesgesetz geregelter Voraussetzungen – Organfunktionen im Rahmen von monokratischen und kollegialen Universitätsorganen übernehmen.

Geschlechtergerechte Zusammensetzung von Kollegialorganen

§ 20a. (1) § 20a gilt für alle gemäß diesem Bundesgesetz sowie durch den Organisationsplan und die Satzung der Universität eingerichteten Kollegialorgane, sofern in diesem Bundesgesetz nichts anderes bestimmt ist. Prüfungskommissionen sind von der Anwendung dieser Bestimmung ausgenommen.

(6) Every university shall publish a university gazette and provide public access to the same on its website. The university gazette shall, in particular, be used to publish:

1. statute, development plan and an organisation plan including the assignments of personnel;
2. opening balance sheet;
3. performance agreement immediately upon its conclusion, financial statements and intellectual capital report immediately after they have been forwarded to the Federal Minister;
4. decrees enacted by, and rules of procedure of governing bodies;
5. directives issued by management bodies:
6. curricula;
7. academic degrees to be awarded by the university as well as titles for graduates of certificate university programmes for further education;
8. announcements to students and other announcements of general interest;
9. advertisements and results of elections;
10. advertisements of posts and management positions;
11. members of the management bodies;
12. award of habilitation degrees (venia docendi);
13. authorisations;

14. [removed]

15. remuneration for the members of the university council.

(7) Persons without Austrian citizenship may – irrespective of other requirements laid down hereunder – accept functions in monocratic and collegial university governing bodies.

Gender-Balanced Composition of Collegial Bodies

§ 20a. (1) § 20a shall apply to all collegial bodies established hereunder as well as under the organisation plan and the statute of the university, unless otherwise provided hereunder. Examination boards shall be excluded from this provision.

(2) Jedem Kollegialorgan gemäß Abs. 1 haben mindestens 50 vH Frauen anzugehören. Bei Kollegialorganen mit einer ungeraden Anzahl von Mitgliedern erfolgt die Berechnung, indem die Anzahl der Mitglieder rechnerisch um ein Mitglied zu reduzieren ist und der erforderliche Frauenanteil von dieser Anzahl zu bestimmen ist.

(3) Sowohl der Senat als auch die Bundesregierung haben bei der Wahl bzw. Bestellung der Mitglieder des Universitätsrats Abs. 2 zu beachten.

(4) Die Erstellung der Liste der Kandidatinnen und Kandidaten als Teil der Wahlvorschläge für die zu wählenden Vertreterinnen und Vertreter der Gruppen gemäß § 25 Abs. 4 Z 1, 2 und 3 hat so zu erfolgen, dass mindestens 50 vH Frauen an wählbarer Stelle zu reihen sind. Dies gilt auch für die zu wählenden Ersatzmitglieder. Abs. 2 zweiter Satz ist anzuwenden. Erhebt der Arbeitskreis für Gleichbehandlungsfragen keine Einreden der Mangelhaftigkeit der Wahlvorschläge gemäß § 42 Abs. 8d, gilt der auf Grund dieser Wahlvorschläge gewählte Senat jedenfalls im Hinblick auf Abs. 2 als richtig zusammengesetzt.

Frauenförderungsplan und Gleichstellungsplan

§ 20b. (1) Der Frauenförderungsplan und der Gleichstellungsplan sind Teil der Satzung (§ 19 Abs. 2 Z 6). Das Recht auf Vorschlag des Frauenförderungsplanes und des Gleichstellungsplans sowie das Recht auf Vorschlag einer Änderung des Frauenförderungsplanes und des Gleichstellungsplanes an das Rektorat stehen dem Arbeitskreis für Gleichbehandlungsfragen zu (§ 44). Ein Abgehen vom Vorschlag des Arbeitskreises für Gleichbehandlungsfragen durch das Rektorat ist nur mit einer entsprechenden Begründung an den Arbeitskreis für Gleichbehandlungsfragen möglich. Über den Frauenförderungsplan und der Gleichstellungsplan ist innerhalb von sechs Monaten ab Vorlage des Vorschlages des Rektorats vom Senat ein Beschluss zu fassen.

(2) Der Frauenförderungsplan und der Gleichstellungsplan dienen der Umsetzung der verfassungsrechtlichen Vorgaben zur tatsächlichen Gleichstellung gemäß Art. 7 Abs. 2 und 3 B-VG sowie des Bundes-Gleichbehandlungsgesetzes – B-GlBG, BGBl. Nr. 100/1993, im Hinblick auf die Universitäten und die Bestimmungen dieses Bundesgesetzes zur Gleichstellung und Gleichbehandlung von Frauen und Männern. Zusätzlich zum Frauenförderungsplan gemäß § 11a B-GlBG sind in einem eigenen Gleichstellungsplan insbesondere die Bereiche Vereinbarkeit (§ 2 Z 13) sowie Antidiskriminierung (2. Hauptstück des I. Teils B-GlBG) zu regeln.

(2) All collegial bodies under para 1 shall consist of at least 50% women. For collegial bodies with an unequal number of members, this proportion shall be calculated by reducing the total number of members by one and calculating the required proportion of women from this number.

(3) Both the senate and the Federal Government shall give regard to para 2 when electing or appointing members of the university council.

(4) The list of candidates included in the election proposals for the representatives to be elected for the groups under § 25 para 4 subparas 1, 2 and 3 shall be prepared in a way that at least 50% women are in electable positions. This shall also apply to the election of substitute members. Para 2, second sentence, shall apply. If the working group on equal opportunities does not raise objections against the inadequacy of the election proposals according to § 42 para 8d, the senate elected on the basis of these election proposals shall be deemed to be correct with respect to para 2.

Career Advancement Plan for Women and Equal Opportunities Plan

§ 20b. (1) The career advancement plan for women and the equal opportunities plan shall be components of the statute (§ 19 para. 2 subpara. 6). The working group on equal opportunities shall be entitled to prepare a draft career advancement plan for women and a draft equal opportunities plan as well as to propose changes to the career advancement plan for women and the equal opportunities plan to the rectorate (§ 44). The rectorate may only depart from the draft plans prepared by the working group on equal opportunities when providing adequate justification to the working group on equal opportunities. The senate shall resolve on the career advancement plan for women and the equal opportunities plan within six months after the rectorate has submitted the draft plans.

(2) The career advancement plan for women and the equal opportunities plan shall facilitate the implementation of the provisions under constitutional law for the actual gender equality according to § 7 paras. 2 and 3 of the Federal Constitutional Law (Bundes-Verfassungsgesetz, B-VG) and the Federal Equal Opportunities Act (Bundes-Gleichbehandlungsgesetz, B-GlBG), F. L. G. No. 100/1993, with regard to the universities and the provisions hereunder regarding gender equality and equal opportunities for women and men. In addition to the career advancement plan for women under § 11a of the Federal Equal Opportunities Act, in particular matters of compatibility (§ 2 subpara. 13) and anti-discrimination (Chapter 2 of Part I of the Federal Equal Opportunities Act) shall be laid down in the equal opportunities plan.

Interuniversitäre Organisationseinheiten

§ 20c. (1) Zur Durchführung von Kooperationen in der Lehre, in der Forschung bzw. Entwicklung und Erschließung der Künste oder in der Verwaltung können durch übereinstimmende Regelungen in den Organisationsplänen zweier oder mehrerer Universitäten interuniversitäre Organisationseinheiten eingerichtet und deren Aufgabenbereiche geregelt werden. Änderungen und Erweiterungen des Wirkungsbereiches der jeweiligen Universität setzen eine entsprechende Festlegung in der Leistungsvereinbarung voraus (§ 7 Abs. 3). Die Auflassung von interuniversitären Organisationseinheiten erfolgt ebenfalls durch übereinstimmende Regelungen in den Organisationsplänen der beteiligten Universitäten.

(2) Zur Leiterin oder zum Leiter der interuniversitären Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst ist für eine Dauer von vier Jahren durch übereinstimmende Beschlüsse der Rektorate der beteiligten Universitäten auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren der interuniversitären Organisationseinheit eine entsprechend qualifizierte Person mit einem aufrechten Dienstverhältnis zum Bund, die einer der beteiligten Universitäten zur Dienstleistung zugewiesen ist, oder mit einem aufrechten Arbeitsverhältnis zu einer der beteiligten Universitäten zu bestellen.

(3) Zur Leiterin oder zum Leiter der interuniversitären Organisationseinheit mit Verwaltungsaufgaben ist durch übereinstimmende Beschlüsse der Rektorate der beteiligten Universitäten eine entsprechend qualifizierte Person zu bestellen.

(4) Die Leiterin oder der Leiter der interuniversitären Organisationseinheit kann durch übereinstimmende Beschlüsse der Rektorate der beteiligten Universitäten wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder gesundheitlicher Eignung oder wegen eines begründeten Vertrauensverlustes von ihrer oder seiner Funktion mittels Bescheid jenes Rektorats, mit dem die Leiterin oder der Leiter in einem aufrechten Arbeitsverhältnis steht, abberufen werden.

(5) Durch übereinstimmende Regelungen in den Organisationsplänen der beteiligten Universitäten ist überdies insbesondere zu regeln:

1. Abschluss der Zielvereinbarung zwischen dem Rektorat und der Leiterin oder dem Leiter der interuniversitären Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst,

Inter-university organisational units

§ 20c. (1) In order to realise cooperation projects in teaching, research or the advancement and appreciation of the arts or at an administrative level, inter-university organisational units may be established and their areas of competence governed by way of concordant regulations in the organisation plans of two or more universities. Amendments and an extension of the sphere of action of the respective university must be laid down accordingly in the performance agreement (§ 7 para 3). The dissolution of an inter-university organisational unit shall also be initiated by way of concordant regulations in the organisation plans of the universities involved.

(2) The rectorates of the universities involved shall, on the basis of nominations from the university professors of the inter-university organisational unit and by way of concordant resolutions, appoint a person – with relevant qualifications who is employed by the Federal Government and assigned to one of the universities involved or is employed by the university – as the head of the inter-university organisational unit responsible for research and teaching or the advancement and appreciation of the arts and art teaching for a duration of four years.

(3) The rectorates of the universities involved shall, by way of concordant resolutions, appoint a person with relevant qualifications as the head of the inter-university organisational unit responsible for administrative tasks.

(4) In case of severe misconduct, conviction of a criminal offence, mental incapacity or health impairment, or loss of confidence on reasonable grounds, the rectorates of the universities involved may recall from his/her office the head of the inter-university organisational unit by way of concordant resolutions and by official notification of the rectorate of the university at which he/she is in a valid employment relationship.

(5) Concordant regulations on the following shall be made in the organisation plans of the universities involved:

1. Conclusion of target agreements between the rectorate and the head of the inter-university organisational unit responsible for research and teaching or the advancement and appreciation of the arts and art teaching,

2. Abschluss der Zielvereinbarungen zwischen der Leiterin oder dem Leiter und dem der betreffenden interuniversitären Organisationseinheit zugeordneten wissenschaftlichen und künstlerischen Personal,
3. Zuordnung des erforderlichen Personals zur interuniversitären Organisationseinheit; die betreffenden Personen bleiben Angehörige der Universität, mit der sie bereits einen Arbeitsvertrag abgeschlossen haben,
4. Dienst- und Fachaufsicht über das der interuniversitären Organisationseinheit zugeordnete Personal.

(6) Durch schriftliche Vereinbarung zwischen den Rektoraten der beteiligten Universitäten ist insbesondere zu regeln:

1. Ausgestaltung der arbeitsrechtlichen Beziehungen des der interuniversitären Organisationseinheit zugeordneten Personals,
2. Regelungen für die wirtschaftliche Gebarung,
3. Nutzung der Infrastruktur,
4. Anschaffung von erforderlichen Sachmitteln,
5. Durchführung von Vorhaben gemäß §§ 26 und 27 unter sinngemäßer Anwendung dieser Bestimmungen,
6. Aufteilung der auf Grund von Tätigkeiten gemäß §§ 26 und 27 eingeworbenen Drittmittel sowie des geistigen Eigentums an den Forschungsergebnissen auf die beteiligten Universitäten und die Zuordnung sonstiger Leistungen der interuniversitären Organisationseinheit.

(7) Für Kooperationen in der Lehre sind die Bestimmungen über die gemeinsam eingerichteten Studien oder gemeinsamen Studienprogramme anzuwenden.

Interhochschulische Organisationseinheiten

§ 20d. (1) Zur Durchführung von Kooperationen in der Lehre, in der Forschung bzw. Entwicklung und Erschließung der Künste oder in der Verwaltung können durch übereinstimmende Regelungen in den Satzungen zweier oder mehrerer Hochschulen, jedenfalls unter Beteiligung einer Universität, interhochschulische Organisationseinheiten eingerichtet und deren Aufgabenbereiche geregelt werden. Änderungen und Erweiterungen des Wirkungsbereiches der jeweiligen Universität setzen eine entsprechende Festlegung in der Leistungsvereinbarung voraus (§ 7 Abs. 3). Die Kooperationsvereinbarung bedarf der Genehmigung des Universitätsrats. Die Auflassung von interhochschulischen Organisationseinheiten erfolgt ebenfalls durch übereinstimmende Regelungen in den Satzungen der beteiligten Hochschulen.

2. conclusion of target agreements between the head of the respective inter-university organisational unit and scientific and artistic staff assigned to the inter-university organisational unit,
3. assignment of the required staff to the inter-university organisational unit; the respective persons remain members of the university with which they have already concluded an employment contract,
4. staff and functional supervision of the staff assigned to the inter-university organisational unit.

(6) Written agreements between the rectorates of the universities involved shall include regulations of the following, in particularly:

1. structure of labour-law relationships of the staff assigned to the inter-university organisational unit,
2. regulations regarding financial management,
3. use of infrastructure,
4. purchasing of required equipment,
5. implementation of projects according to §§ 26 and 27, applying these provisions by analogy,
6. distribution of the third-party funds raised with activities under §§ 26 and 27 and the intellectual property rights to the research findings to the universities involved and assignment of other services/benefits of the inter-university organisational unit.

(7) The regulations pertaining to jointly offered study programmes or joint programmes shall apply to cooperation projects in teaching.

(2) Zur Leiterin oder zum Leiter der interhochschulischen Organisationseinheit ist für eine Dauer von vier Jahren durch übereinstimmende Beschlüsse der Leitungen der beteiligten Universitäten und der entscheidungsbefugten Organe der beteiligten Hochschulen eine entsprechend qualifizierte Person mit einem aufrechten Arbeitsverhältnis zu einer der beteiligten Hochschulen zu bestellen.

(3) Die Leiterin oder der Leiter der interhochschulischen Organisationseinheit kann durch übereinstimmende Beschlüsse der Rektorate der beteiligten Universitäten und der entscheidungsbefugten Organe der beteiligten Hochschulen wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder gesundheitlicher Eignung oder wegen eines begründeten Vertrauensverlustes von ihrer oder seiner Funktion abberufen werden.

(4) Durch schriftliche Vereinbarung zwischen den Rektoraten der Universitäten und zuständigen Organen der beteiligten Hochschulen ist insbesondere zu regeln:

1. Zuordnung des erforderlichen Personals zur interhochschulischen Organisationseinheit; die betreffenden Personen bleiben Angehörige der Hochschule, mit der sie bereits einen Arbeitsvertrag abgeschlossen haben;
2. Dienst- und Fachaufsicht über das der interhochschulischen Organisationseinheit zugeordnete Personal;
3. Ausgestaltung der arbeitsrechtlichen Beziehungen des der interhochschulischen Organisationseinheit zugeordneten Personals;
4. Regelungen für die wirtschaftliche Gebarung;
5. Nutzung der Infrastruktur;
6. Anschaffung von erforderlichen Sachmitteln;
7. Durchführung von Vorhaben gemäß §§ 26 und 27 unter sinngemäßer Anwendung dieser Bestimmungen;
8. Aufteilung der auf Grund von Tätigkeiten gemäß §§ 26 und 27 eingeworbenen Drittmittel sowie des geistigen Eigentums an den Forschungsergebnissen auf die beteiligten Hochschulen und die Zuordnung sonstiger Leistungen der interhochschulischen Organisationseinheit.

(5) Geldwerte Leistungen für interhochschulische Organisationseinheiten, die nach Maßgabe der Leistungsvereinbarung im Interesse des Bundes eingerichtet wurden, unterliegen nicht § 6 Abs. 1 PrivHG.

Universitätsrat

§ 21. (1) Der Universitätsrat hat in seiner Funktion als begleitend und vorausschauend tätiges Aufsichtsorgan folgende Aufgaben:

1. Genehmigung des Entwicklungsplans, des Organisationsplans, des Entwurfs der Leistungsvereinbarung sowie der Geschäftsordnung des Rektorats;
2. Ausschreibung der Funktion der Rektorin oder des Rektors ~~spätestens acht Monate vor dem voraussichtlichen Freiwerden dieser Funktion bzw. innerhalb von drei Monaten ab dem Zeitpunkt der Abberufung oder des Rücktritts~~;
3. Erlassung der Bestimmungen für die Wahl der Rektorin oder des Rektors nach Einholung einer Stellungnahme des Senates, die dieser innerhalb von vier Wochen nach Vorlage abzugeben hat;
4. Wahl der Rektorin oder des Rektors aus dem Dreiervorschlag des Senats innerhalb von vier Wochen ab Vorlage des Vorschlags;
5. Wahl der Vizerektorinnen und Vizerektoren auf Grund eines Vorschlags der Rektorin oder des Rektors und nach Stellungnahme des Senats;
6. Abschluss der Zielvereinbarungen mit der Rektorin oder dem Rektor und dem Rektorat;

6a. Abschluss der Arbeitsverträge mit der Rektorin oder dem Rektor und den Vizerektorinnen und Vizerektoren;

7. Abberufung der Rektorin oder des Rektors und der Vizerektorinnen und Vizerektoren;
8. Nominierung eines weiblichen und eines männlichen Mitglieds für die Schiedskommission;
9. Genehmigung der Gründung von Gesellschaften und Stiftungen sowie der Beteiligung an Gesellschaften;
10. Genehmigung der Richtlinien für die Gebarung sowie Genehmigung des Rechnungsabschlusses und der Wissensbilanz des Rektorats und Weiterleitung an die Bundesministerin oder den Bundesminister;
11. Bestellung einer Abschlussprüferin oder eines Abschlussprüfers zur Prüfung des Rechnungsabschlusses der Universität;
12. Zustimmung zur Begründung von Verbindlichkeiten, die über die laufende Geschäftstätigkeit der Universität hinausgehen, sowie Ermächtigung des Rektorats, solche Verbindlichkeiten bis zu einer bestimmten Höhe ohne vorherige Einholung der Zustimmung des Universitätsrats einzugehen;

University Council

§ 21. (1) In its guiding and proactive role as a supervisory body, the university council shall have the following duties:

1. approving the development plan, the organisation plan, the draft performance agreement as well as the rules of procedure of the rectorate;
2. advertising the post of the rector eight months prior to the expected availability of the post at the latest or within three months after dismissal or resignation;
3. enacting regulations for the election of the rector after receiving the senate's opinion thereon, which shall be submitted within four weeks upon receipt;
4. electing the rector from a shortlist of three candidates nominated by the senate within four weeks upon receipt of the shortlist;
5. electing the vice-rectors on the basis of nominations made by the rector after receiving the senate's opinion thereon;
6. concluding the performance agreements with the rector and the rectorate;

6a. concluding the service agreements with the rector and the vice-rectors;

7. dismissing the rector and the vice-rectors;
8. nominating one female and one male member of the arbitration board;
9. approving the establishment of companies and foundations as well as shareholding in companies;
10. approving the guidelines for financial management, the financial statements and the intellectual capital report of the rectorate and forwarding the same to the Federal Minister;
11. appointing an auditor to audit the financial statements of the university;
12. approving the assumption of non-current liabilities, and empowering the rectorate to assume such liabilities up to a certain limit without seeking the prior approval of the university council;

13. Pflicht zur unverzüglichen Berichterstattung an die Bundesministerin oder den Bundesminister bei schwerwiegenden Rechtsverstößen von Universitätsorganen, Gefahr eines schweren wirtschaftlichen Schadens, Vorliegen von für die strategische Ausrichtung der jeweiligen Universität wesentlichen Entwicklungen sowie Vorliegen von Umständen, welche die Universitätsleitung gravierend beeinträchtigen;
14. Zustimmung zum Budgetvoranschlag innerhalb von vier Wochen ab Vorlage durch das Rektorat; verweigert der Universitätsrat innerhalb von vier Wochen ab Vorlage die Zustimmung, hat das Rektorat unverzüglich einen neuen Budgetvoranschlag vorzulegen; stimmt der Universitätsrat nicht fristgerecht zu, gilt der Budgetvoranschlag als genehmigt;
15. Stellungnahme zur Leistungsvereinbarung vor Abschluss durch die Rektorin oder den Rektor innerhalb von drei Wochen;
16. Erlassung der Geschäftsordnung des Universitätsrats~~.~~;
17. Genehmigung einer interhochschulischen Organisationseinheit gemäß § 20d Abs. 1.

(2) Der Universitätsrat oder jeweils mindestens zwei Mitglieder des Universitätsrats gemeinsam sind berechtigt, sich über alle Angelegenheiten der Universität zu informieren. Die Stellungnahme hat an den Universitätsrat zu ergehen und ist in der nächstfolgenden Sitzung des Universitätsrats zu behandeln. Die Universitätsorgane sind verpflichtet, dem Universitätsrat alle zweckdienlichen Auskünfte zu erteilen, Geschäftsstücke und Unterlagen über die vom Universitätsrat bezeichneten Gegenstände vorzulegen, von ihm angeordnete Erhebungen anzustellen und Überprüfungen an Ort und Stelle vornehmen zu lassen. Dies kann allenfalls auch personenbezogene Daten (Art. 4 Nr. 1 DSGVO) umfassen.

(3) Der Universitätsrat besteht aus fünf, sieben oder neun Mitgliedern, die in verantwortungsvollen Positionen in der Gesellschaft, insbesondere der Wissenschaft, Kultur oder Wirtschaft, tätig sind oder waren und auf Grund ihrer hervorragenden Kenntnisse und Erfahrungen einen Beitrag zur Erreichung der Ziele und Aufgaben der Universität leisten können. Über eine Änderung der Größe des Universitätsrats entscheidet der Senat mit Zweidrittelmehrheit.

(4) Dem Universitätsrat dürfen Mitglieder der Bundesregierung, Staatssekretärinnen und Staatssekretäre, Mitglieder einer Landesregierung, Mitglieder des Nationalrats, des Bundesrats oder eines sonstigen allgemeinen Vertretungskörpers und Funktionäre einer politischen Partei sowie Personen nicht angehören, die eine dieser Funktionen in den letzten vier Jahren ausgeübt haben oder

13. reporting obligation to the Federal Minister without delay for serious breaches of the law by university governing bodies or the danger of serious financial loss, substantial developments for the strategic orientation of the respective university as well as any circumstances which may severely impair the university leadership;
14. approving the proposed budget within four weeks upon receipt from the rectorate; if the university council refuses acceptance within four weeks upon receipt, the rectorate shall submit a new proposal without delay; if the university council fails to accept it within the period stipulated, the proposed budget shall be deemed to be approved;
15. preparing an opinion on the performance agreement prior to its conclusion by the rector within three weeks;
16. enacting rules of procedure for the university council.

(2) The university council or at least two members of the university council together shall be entitled to request information on all and any matters concerning the university. The statement shall be forwarded to the university council and shall be dealt with in the next meeting of the university council. The university governing bodies shall be obliged to provide the university council with all relevant information, to submit all documents relating to matters specified by it, to undertake investigations required by it, and to initiate investigations in situ. This can, if need be, comprise also personal data (Art 4 No 1 GDPR).

(3) The university council shall consist of five, seven or nine members, who shall be past or present holders of responsible positions, especially in academic, cultural or business life, and whose exceptional knowledge and experience are such as to enable them to contribute to the attainment of the objectives and the fulfilment of the tasks of the university. Any change in the size of the university council shall be for resolution of the senate and shall require a two-thirds majority.

(4) Members of the federal government, state secretaries, members of a provincial government, members of the National Council, the Federal Council or any other popular representative body, and officers of political parties or persons who have exercised such functions within the past four years or who were members of the

die an der betreffenden Universität in den letzten vier Jahren Mitglied des Rektorats waren.

(5) Die Mitglieder des Universitätsrats dürfen keine Universitätsangehörigen gemäß §§ 125, 132 und 133, keine Arbeitnehmerinnen und Arbeitnehmer der Universität, keine Mitglieder oder Ersatzmitglieder der Schiedskommission der Universität, keine Mitglieder eines obersten Organs einer anderen Universität und keine Mitarbeiterinnen oder Mitarbeiter des für die Angelegenheiten der Universitäten zuständigen Bundesministeriums sein. Die Mitgliedschaft in mehr als einem Universitätsrat ist unzulässig. Geschäftsbeziehungen zwischen einem Mitglied des Universitätsrats und der Universität bedürfen der Genehmigung durch den Universitätsrat, die nur dann erteilt werden darf, wenn keine Befangenheit vorliegt. Mögliche Interessenkonflikte haben die Mitglieder dem Universitätsrat unverzüglich zu melden. Ein Mitglied eines Universitätsrats darf nicht in einem Weisungs- oder Kontrollverhältnis zu einem anderen Mitglied desselben Universitätsrats stehen.

(6) Dem Universitätsrat gehören nach Maßgabe des Abs. 3 folgende fünf, sieben oder neun Mitglieder an:

1. zwei, drei oder vier Mitglieder, die vom Senat gewählt werden;
2. zwei, drei oder vier Mitglieder, die von der Bundesregierung auf Vorschlag der Bundesministerin oder des Bundesministers bestellt werden;
3. ein weiteres Mitglied, das von den unter Z 1 und 2 genannten Mitgliedern einvernehmlich bestellt wird.

Der Senat und die Bundesregierung haben gleich viele Mitglieder zu bestellen, die Bestellung der Mitglieder gemäß Z 2 hat nach der Wahl der Mitglieder gemäß Z 1 zu erfolgen. Die Bundesministerin oder der Bundesminister hat ihre oder seine Vorschläge für die von der Bundesregierung zu bestellenden Mitglieder zu begründen. Vorschläge für die durch den Senat zu wählenden Mitglieder an den Senat sind ebenfalls zu begründen.

(Anm.: Abs. 6a aufgehoben durch BGBl. I Nr. 21/2015)

(7) Kommt es bis zum 30. April des betreffenden Jahres zu keiner einvernehmlichen Bestellung des weiteren Mitglieds gemäß Abs. 6 Z 3, hat die Bundesministerin oder der Bundesminister eine angemessene Nachfrist zu setzen. Verstreicht diese ergebnislos, ist dieses Mitglied des Universitätsrats vom Senat aus einem Dreiervorschlag des Präsidiums der Österreichischen Akademie der Wissenschaften auszuwählen. Das Präsidium der Österreichischen Akademie der

rectorate at the respective university in the past four years shall be excluded from membership in the university council.

(5) Members of the university council shall not be members of the university in the meaning of §§ 125, 132 and 133, employees of the university, members or substitute members of the arbitration board of the university, members of the highest university governing bodies of another university, or employees of the federal ministry in charge of higher education. Membership of more than one university council shall not be permissible. Business relations between a member of the university council and the university shall be subject to approval by the university council, which may only be given in the absence of a conflict of interest. The members shall report possible conflicts of interest immediately to the university council. A member of a university council shall not be in a relationship of authority or control with another member of the same university council.

(6) The membership of the university council shall, pursuant to para 3, comprise five, seven or nine members, namely:

1. two, three or four members elected by the senate;
2. two, three or four members appointed by the Federal Government on the recommendation of the Federal Minister;
3. an additional member appointed by the members named in para 6 subparas 1 and 2 by mutual agreement.

The senate and the Federal Government shall each appoint equal numbers of members; the appointment of the members according to subpara 2 shall be carried out following the election of the members according to subpara 1. The Federal Minister shall justify his/her proposals for the members to be appointed by the Federal Government. Proposals submitted to the senate for members to be elected by the senate shall also be justified.

(6a) [removed]

(7) In case that by 30 April of the respective year no additional member under para 6 subpara 3 has been appointed by mutual agreement, the Federal Minister shall grant a reasonable extension. In case that this passes without result, such member of the university council shall be selected by the senate from a shortlist of three candidates prepared by the presiding committee of the Austrian Academy of Sciences. The presiding committee of the Austrian Academy of Sciences shall submit

Wissenschaften hat den Dreiervorschlag binnen einem Monat nach Befassung durch die Bundesministerin oder den Bundesminister vorzulegen.

(8) Die Funktionsperiode der Mitglieder beträgt fünf Jahre und beginnt mit dem 1. März des betreffenden Jahres. Die Einladung zur ersten Sitzung des Universitätsrats erfolgt durch die Vorsitzende oder den Vorsitzenden der vorhergegangenen Funktionsperiode, allenfalls durch die Rektorin oder den Rektor. Der Universitätsrat hat sich unverzüglich zu konstituieren und längstens bis 30. April des betreffenden Jahres das weitere Mitglied (Abs. 6 Z 3) zu bestellen. Die Wahl der oder des Vorsitzenden hat bis zum 30. April des betreffenden Jahres zu erfolgen. Eine Wiederwahl oder Wiederbestellung eines Mitgliedes ist zulässig, sofern nicht insgesamt eine Amtszeit von zehn Jahren überschritten wird. Bei vorzeitigem Ausscheiden eines Mitglieds des Universitätsrats ist für den Rest der Funktionsperiode ein neues Mitglied auf dieselbe Art wie das ausgeschiedene Mitglied zu wählen oder zu bestellen.

(9) Die oder der Vorsitzende des Universitätsrats wird vom Universitätsrat aus dem Kreis der Mitglieder mit einfacher Mehrheit gewählt.

(10) Die Mitglieder des Universitätsrats sind bei ihrer Tätigkeit zu entsprechender Sorgfalt verpflichtet.

(11) Die Mitglieder des Universitätsrats erhalten für ihre Tätigkeit eine Vergütung des Zeit- und Arbeitsaufwandes, die vom Universitätsrat festzusetzen ist. Die Bundesministerin oder der Bundesminister hat insbesondere unter Berücksichtigung der Größe der Universität und des daraus resultierenden Zeit- und Arbeitsaufwandes durch Verordnung Obergrenzen für die Vergütung festzusetzen, wobei für Gruppen von Universitäten unterschiedliche Obergrenzen festgelegt werden können. Die Höhe der Vergütung ist im Mitteilungsblatt zu veröffentlichen.

(12) Der Universitätsrat ist beschlussfähig, wenn wenigstens die Hälfte der gemäß Abs. 3 festgelegten Anzahl der Mitglieder persönlich anwesend ist. Stimmübertragungen sind unzulässig. Der Universitätsrat entscheidet mit Stimmenmehrheit, sofern in diesem Bundesgesetz nicht anderes bestimmt ist. Dies gilt auch, wenn ein Mitglied oder mehrere Mitglieder vorzeitig aus dem Universitätsrat ausscheiden oder das neue Mitglied oder die neuen Mitglieder noch nicht gewählt oder bestellt wurden oder das zusätzliche Mitglied noch nicht bestellt worden ist.

(13) Die Mitgliedschaft im Universitätsrat endet

1. durch Ablauf der Funktionsperiode;
2. durch Verzicht;

the shortlist of three candidates within one month after the Federal Minister has dealt with the matter.

(8) The members' term of office shall be five years and shall commence on 1 March of the respective year. The invitation to the first meeting of the university council shall be extended by the chairperson of the previous term of office or, if need be, by the rector. The university council shall constitute itself without delay and appoint the additional members (para 3 subpara 30) by 6 April of the respective year. The election of the chairperson shall take place by 30 April of the respective year. Re-election or reappointment of a member is permissible, provided that the term of office does not exceed ten years in total. In the case of the premature termination of the service of a member of the university council, a replacement member shall be elected or appointed in the same manner as the departing member for the remainder of his/her term of office.

(9) The chairperson of the university council shall be elected by the council from among its members by a simply majority of the votes cast.

(10) The members of the university council shall be obliged to fulfil their tasks with due care.

(11) The members of the university council shall receive compensation for the time and effort dedicated to their activities in an amount to be determined by the university council. The Federal Minister shall, by decree, determine upper limits for the compensation, taking into account in particular the size of the university and the time requirements and workload resulting therefrom, and may determine different upper limits for groups of universities. The compensation shall be published in the university gazette.

(12) The university council shall have a quorum when at least half of the number of members stipulated under para 3 are present. Voting by proxy is impermissible. The university council shall resolve by simple majority, except insofar as this Act provides otherwise. This shall also apply if one member or several members terminate their membership prematurely or the new member or the new members have not been elected or appointed or the additional member has not been appointed yet.

(13) Membership of the university council may be terminated by:

1. expiry of the term of office;
2. resignation;

3. durch Abberufung;
4. durch Tod;
5. durch Ablauf der zehnjährigen Amtszeit.

(14) Die Bundesministerin oder der Bundesminister kann ein Mitglied des Universitätsrats wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung oder wegen mangelnder gesundheitlicher Eignung mit Bescheid von seiner Funktion abberufen. Eine Abberufung setzt übereinstimmende Beschlüsse des Senats und des Rektorats voraus, die beide einer Zweidrittelmehrheit bedürfen.

(15) Das Rektorat, die oder der Vorsitzende des Senats, die oder der Vorsitzende des Arbeitskreises für Gleichbehandlungsfragen und die oder der Vorsitzende der Hochschülerinnen- und Hochschülerschaft an der betreffenden Universität haben das Recht, in den Sitzungen des Universitätsrats zu Tagesordnungspunkten angehört zu werden, die ihren Aufgabenbereich betreffen. Die Vorsitzenden der beiden Betriebsräte gemäß § 135 Abs. 3 sind einzuladen und haben jeweils das Recht, an den Sitzungen teilzunehmen, Anträge zu allen Tagesordnungspunkten zu stellen sowie zusätzliche Punkte auf die Tagesordnung setzen zu lassen, die mit der Ausübung ihrer Funktion als Betriebsrat im Rahmen ihrer innerbetrieblichen Interessenwahrnehmungskompetenz nach dem Arbeitsverfassungsgesetz (ArbVG), BGBl. Nr. 22/1974, unmittelbar in Zusammenhang stehen und in die Zuständigkeit des Universitätsrats fallen. Sie sind bei diesen Punkten stimmberechtigt, wobei diesbezügliche Beschlüsse der Zweidrittelmehrheit der Anwesenden bedürfen. Den Vorsitzenden der beiden Betriebsräte ist unverzüglich jeweils eine Abschrift der Protokolle der Sitzungen des Universitätsrats zu übermitteln.

(16) Das Rektorat hat dem Universitätsrat die für die Erfüllung seiner Aufgaben entsprechenden Personal- und Sachressourcen sowie die erforderlichen Räume zur Verfügung zu stellen.

Rektorat

§ 22. (1) Das Rektorat leitet die Universität und vertritt diese nach außen. Es hat alle Aufgaben wahrzunehmen, die durch dieses Bundesgesetz nicht einem anderen Organ zugewiesen sind. Zu seinen Aufgaben zählen insbesondere:

1. Erstellung eines Entwurfs der Satzung sowie von Entwürfen von Satzungsänderungen zur Vorlage an den Senat;
2. Erstellung eines Entwicklungsplans der Universität zur Vorlage an den Senat und an den Universitätsrat;

3. dismissal;
4. death;
5. expiry of the ten-year term of office.

(14) The Federal Minister may, by order, dismiss a member of the university council because of severe misconduct, conviction of a criminal offence, or mental incapacity or health impairment. Such dismissal shall be subject to consonant resolutions of the senate and rectorate, in both cases requiring a two-thirds majority.

(15) The rectorate, the chairperson of the senate, the chairperson of the working group on equal opportunities and the chairperson of the Austrian Students' Union at the university in question shall be entitled to a hearing on agenda items relating to their functions at meetings of the university council. The chairpersons of the two employee's councils under § 135 para 3 shall be invited to all meetings of the university council and shall be entitled to participate in the meetings, to file an application for all agenda items, and to request any additional items to be added to the agenda that are directly related to their duties as employees' councils under the Labour Relations Act, F. L. G. No 22/1974, and that fall within the responsibility of the university council. They shall have the right to vote on these items, but decisions on them shall be subject to a two-thirds majority vote of the members present. The chairpersons of the two employee's councils shall receive a copy of the minutes of the meetings of the university council without delay.

(16) The rectorate shall provide the university council with the staff and equipment as well as the premises necessary for the performance of its tasks.

Rectorate

§ 22. (1) The rectorate shall manage the university and shall represent it. It shall be responsible for all matters not assigned to other governing bodies by this Act. Its tasks shall, in particular, include:

1. preparing a draft statute as well as drafts of changes to the statute for submission to the senate;
2. preparing a university development plan for submission to the senate and the university council;

3. Erstellung eines Organisationsplans der Universität zur Vorlage an den Senat und an den Universitätsrat;
4. Erstellung eines Entwurfs der Leistungsvereinbarung zur Vorlage an den Universitätsrat;
5. Bestellung und Abberufung der Leiterinnen und Leiter von Organisationseinheiten;
6. Abschluss von Zielvereinbarungen mit den Leiterinnen und Leitern der Organisationseinheiten;
7. Zuordnung der Universitätsangehörigen (§ 94 Abs. 1 Z 2 bis 6) zu den einzelnen Organisationseinheiten;
8. Aufnahme der Studierenden;
9. Einhebung der Studienbeiträge in der gesetzlich festgelegten Höhe;

9a. Festlegung der Lehrgangsbeiträge gemäß § 56 Abs. 5;

10. Veranlassung von Evaluierungen und der Veröffentlichung von Evaluierungsergebnissen;
11. Erteilung der Lehrbefugnis (venia docendi);
12. Initiierung der Erlassung und Änderung von Curricula und Information des Senats; das zuständige vom Senat eingesetzte Kollegialorgan für Studienangelegenheiten gemäß § 25 Abs. 8 Z 3 hat die Vorschläge des Rektorats innerhalb von sechs Monaten zu behandeln und den Senat und das Rektorat über das Ergebnis seiner Beratungen zu informieren;

12a. Erlassung von Richtlinien zur strukturellen Gestaltung von Curricula nach Stellungnahme des Senates;

12b. Einrichtung und Auflassung von Studien, Stellungnahme zu den Curricula, Untersagung von Curricula oder deren Änderungen, wenn diese dem Entwicklungsplan oder den Richtlinien gemäß Z 12a widersprechen oder wenn diese nicht bedeckbar sind, oder, wenn ein vom Rektorat in Auftrag gegebenes nach international anerkannten wissenschaftlichen Kriterien erstelltes Gutachten zu dem Schluss kommt, dass der Inhalt des Curriculums in Hinblick auf die wissenschaftliche und künstlerische Berufsvorbildung und die Qualifizierung für berufliche Tätigkeiten, welche die Anwendung wissenschaftlicher und künstlerischer Erkenntnisse und Methoden erfordern, nicht ausreichend ist; bei der Auflassung eines Studiums oder Untersagung eines Curriculums oder dessen Änderung sowie der Beauftragung eines Gutachtens ist nach Möglichkeit das Einvernehmen mit dem Senat herzustellen;

3. preparing a university organisation plan for submission to the senate and the university council;
4. preparing a draft performance agreement for submission to the university council;
5. appointing and dismissing the heads of organisational units;
6. concluding target agreements with the heads of organisational units;
7. assigning university members (§ 94 para 1 subparas 2 to 6) to organisational units;
8. admitting students;
9. collecting tuition fees in the amount provided for by statute;

9a. determining the course fees under § 56 para 5;

10. initiating evaluations and publication of the results thereof;
11. awarding habilitation degrees (venia docendi);
12. initiating the enactment and amendment of curricula and informing the senate; the competent collegial body for study related matters established by the senate pursuant to § 25 para 8 subpara 3 shall deal with the proposals of the rectorate within six months and inform the senate and the rectorate of the outcome of their deliberations;

12a. enacting guidelines on the structural design of curricula after hearing the opinion of the senate;

12b. establishing and discontinuing study programmes, giving opinions on curricula, prohibiting curricula or changes thereto, if they do not comply with the development plan or the guidelines laid out in subpara 12a or if they are not feasible, or, if an expert opinion which has been commissioned by the rectorate and prepared based on internationally recognised scientific criteria concludes that the content of the curriculum is not sufficient regarding the scientific and artistic training and the qualification for professions that require the application of scientific and artistic knowledge and methods; discontinuing a study programme or prohibiting a curriculum or changes thereto and commissioning an expert opinion shall take place in consultation with the senate, wherever possible;

13. Einrichtung eines Rechnungs- und Berichtswesens;
14. Erstellung des Budgetvoranschlages zur Vorlage an den Universitätsrat und Budgetzuteilung;
14a. Übermittlung des Budgetvoranschlages an den Senat zur Information;
15. Erstellung des Rechnungsabschlusses und der Wissensbilanz;
16. Erlassung von Richtlinien für die Bevollmächtigung von Arbeitnehmerinnen und Arbeitnehmern der Universität gemäß § 28 Abs. 1;
17. die Errichtung eines Planungs- und Berichterstattungssystems, das die Erfüllung der Berichterstattungspflichten durch die Universitäten nach den gesetzlichen Vorschriften und den Vorgaben der Bundesministerin oder des Bundesministers für Finanzen hinsichtlich der Einrichtung eines Beteiligungs- und Finanzcontrolling gewährleistet.

(2) Dem Rektorat unterstehen alle Einrichtungen der Universität. Das Rektorat kann Entscheidungen anderer Organe mit Ausnahme der Beschlüsse des Universitätsrats zurückverweisen, wenn diese Entscheidungen nach Auffassung des Rektorats im Widerspruch zu Gesetzen und Verordnungen einschließlich der Satzung stehen. Der Universitätsrat ist in schwerwiegenden Fällen zu informieren.

(3) Das Rektorat besteht aus der Rektorin oder dem Rektor und bis zu vier Vizerektorinnen oder Vizerektoren. Bei der Zusammensetzung des Rektorats ist sicherzustellen, dass dieses über entsprechende Kompetenzen im Bereich der Wissenschaft sowie Management- und Verwaltungsführungskompetenzen verfügt. Ist gemäß dem Organisationsplan der Universität eine Medizinische Fakultät eingerichtet, so ist jedenfalls eine Vizerektorin oder ein Vizerektor für den medizinischen Bereich vorzusehen, wodurch sich abweichend vom ersten Satz die Anzahl der Mitglieder des Rektorats entsprechend erhöhen kann. Die Vizerektorin oder der Vizerektor für den medizinischen Bereich ist gleichzeitig Leiterin oder Leiter der Medizinischen Fakultät.

(Anm.: Abs. 3a aufgehoben durch BGBl. I Nr. 21/2015)

(4) Die Rektorin oder der Rektor ist Vorsitzende oder Vorsitzender des Rektorats und dessen Sprecherin oder Sprecher.

(5) Das Rektorat entscheidet mit Stimmenmehrheit, sofern in der Geschäftsordnung nicht anderes bestimmt ist. Bei Stimmengleichheit gibt die Stimme der Rektorin oder des Rektors den Ausschlag.

(6) Das Rektorat hat eine Geschäftsordnung zu erlassen, die der Genehmigung des Universitätsrats bedarf und im Mitteilungsblatt zu verlautbaren ist. In der

13. establishing an accounting and reporting system;
14. preparing a draft budget for submission to the university council and allocating budgets;
14a. forwarding the draft budget to the senate for its information:
15. preparing the financial statements and the intellectual capital report;
16. enacting regulations for the granting of authorisations to employees of the university according to § 28 para 1;
17. establishing a planning and reporting system which guarantees the fulfilment of the reporting obligations of the universities according to the legal provisions and the directives of the Federal Minister of Finance on the establishment of a share and finance controlling.

(2) The rectorate shall superintend all organisational units of the university. The rectorate may remit decisions by other governing bodies with the exception of the university council if in its opinion such decisions are in conflict with the law or decrees including the university statute. In cases of major importance, the rectorate shall inform the university council.

(3) The rectorate shall consist of the rector and up to four vice-rectors. In determining the composition of the rectorate, care shall be taken to ensure that its members possess the necessary scientific, managerial and administrative capabilities. If a faculty of medicine has been established according to the organisation plan of the university, a vice rector for the clinical department shall be appointed, which can mean an increase in the number of members of the rectorate, notwithstanding the first sentence. The vice rector for the clinical department shall also be the dean of the faculty of medicine.

(3a) [removed]

(4) The rector shall be the chairperson and spokesperson of the rectorate.

(5) The rectorate shall resolve by simple majority, except insofar as its rules of procedure provide otherwise. In the case of a tie, the rector shall have the casting vote.

(6) The rectorate shall enact rules of procedure which shall require the approval of the university council and shall be published in the university gazette. Such rules

Geschäftsordnung ist festzulegen, welche Agenden gemäß Abs. 1 den einzelnen Mitgliedern des Rektorats allein zukommen, welche Agenden von zwei Mitgliedern des Rektorats und welche von allen Mitgliedern gemeinsam wahrzunehmen sind. Entscheidungen in wirtschaftlichen Angelegenheiten sind jedenfalls von mindestens zwei Mitgliedern des Rektorats zu treffen. In der Geschäftsordnung ist auch die Vertretungsbefugnis festzulegen.

(7) Die Mitglieder des Rektorats sind in dieser Funktion an keine Weisungen oder Aufträge gebunden (Art. 81c Abs. 1 B-VG); die Vizerektorinnen und Vizerektoren sind in dieser Funktion auch an keine Weisungen oder Aufträge der Rektorin oder des Rektors gebunden. Die Mitglieder des Rektorats sind bei ihrer Tätigkeit zu entsprechender Sorgfalt verpflichtet.

Rektorin oder Rektor

§ 23. (1) Die Rektorin oder der Rektor hat folgende Aufgaben:

1. Vorsitzende oder Vorsitzender sowie Sprecherin oder Sprecher des Rektorats;
2. Erstellung eines Vorschlags für die Wahl der Vizerektorinnen und Vizerektoren;
3. Leitung des Amts der Universität;
4. Verhandlung und Abschluss der Leistungsvereinbarungen mit der Bundesministerin oder dem Bundesminister und unverzügliche Information über das Ergebnis an den Universitätsrat;
5. Ausübung der Funktion der oder des obersten Vorgesetzten des gesamten Universitätspersonals;

(Anm.: Z 6 aufgehoben durch BGBl. I Nr. 81/2009)

7. Auswahlentscheidung aus Besetzungsvorschlägen der Berufungskommissionen für Universitätsprofessorinnen und Universitätsprofessoren;
8. Führung von Berufungsverhandlungen;
9. Abschluss von Arbeits- und Werkverträgen;
10. Erteilung von Vollmachten gemäß § 28 Abs. 1.

(2) Die Funktion der Rektorin oder des Rektors ist vom Universitätsrat nach Zustimmung des Senats, spätestens zehn Monate vor dem voraussichtlichen Freiwerden der Funktion bzw. innerhalb von ~~drei~~zwei Monaten ab dem Zeitpunkt der Abberufung oder ~~des Rücktritts~~der Rücktrittserklärung, öffentlich auszuschreiben. Zur Rektorin oder zum Rektor kann nur eine Person mit

of procedure shall establish the responsibilities under para 1 to be assumed by individual members, by two members and collectively by all members of the rectorate. Decisions relating to financial matters must be taken by at least two members of the rectorate. The rules of procedure shall also determine the right to represent the university.

(7) The members of the rectorate shall not be bound by any instructions in the exercise of their tasks (Art 81c para 1 Federal Constitutional Law), neither shall the vice-rectors be bound by any instructions of the rector. The rectorate shall be obliged to perform its tasks with due care.

Rector

§ 23. (1) The rector shall have the following duties:

1. presiding over the meetings of the rectorate and acting as its spokesperson;
2. nominating candidates for election as vice-rector;
3. managing the university office;
4. negotiating and concluding performance agreements with the Federal Minister and informing the university council about the results without delay;
5. acting as the superior of all university staff;
6. *[removed]*
7. selecting professors from shortlists drawn up by the appointments committees;
8. conducting appointment negotiations;
9. concluding employment and service contracts;
10. awarding authorisations according to § 28 para 1.

(2) The university council shall publicly advertise the post of the rector upon approval by the senate, no later than ten months prior to the expected availability of the post or within three months after dismissal or resignation. Only persons with international experience, knowledge of the Austrian and European university system

internationaler Erfahrung, Kenntnissen des österreichischen und europäischen Universitätssystems und der Fähigkeit zur organisatorischen und wirtschaftlichen Leitung einer Universität gewählt werden.

(3) Die Rektorin oder der Rektor ist vom Universitätsrat aus einem Dreiervorschlag des Senats für eine Funktionsperiode von vier Jahren zu wählen. Stehen dem Universitätsrat weniger als drei geeignete Kandidatinnen bzw. Kandidaten für seine Auswahlentscheidung zur Verfügung, kann der Universitätsrat eine Neuausschreibung vornehmen. Die zweimalige unmittelbar aufeinanderfolgende Wiederwahl ist zulässig.

(4) Der Arbeitsvertrag und die Zielvereinbarung mit der Rektorin oder dem Rektor wird vom Universitätsrat abgeschlossen.

(5) Die Rektorin oder der Rektor kann vom Universitätsrat wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder gesundheitlicher Eignung oder wegen eines begründeten Vertrauensverlusts durch Bescheid von der Funktion abberufen werden. Die Abberufung kann auf Antrag des Senats oder von Amts wegen durch den Universitätsrat erfolgen. Im ersten Fall ist in beiden Organen jeweils die einfache Mehrheit aller Mitglieder erforderlich; im zweiten Fall bedarf der Beschluss im Universitätsrat der Zweidrittelmehrheit aller Mitglieder, der Senat ist anzuhören. Mit der Wirksamkeit der Abberufung endet das Arbeitsverhältnis der Rektorin oder des Rektors zur Universität.

Findungskommission

§ 23a. (1) Zur Wahl der Rektorin oder des Rektors ist spätestens vier Wochen nach der Ausschreibung eine Findungskommission einzurichten. Der Findungskommission gehören folgende fünf Mitglieder an:

1. die oder der Vorsitzende des Universitätsrats sowie ein weiteres vom Universitätsrat zu bestellendes Mitglied des Universitätsrats,
2. die oder der Vorsitzende des Senats sowie ein weiteres vom Senat zu bestellendes Mitglied des Senats,
3. eine weitere Person, die von den Mitgliedern gemäß Z 1 und 2 als Mitglied einvernehmlich bestellt wird.

§ 20a Abs. 1 und 2 ist anzuwenden. Für das Mitglied gemäß Z 3 ist § 21 Abs. 4 sinngemäß anzuwenden. Einigen sich die Mitglieder gemäß Z 1 und 2 nicht innerhalb von zwei Wochen ab Einrichtung der Findungskommission auf das Mitglied gemäß Z 3, ist § 21 Abs. 7 sinngemäß anzuwenden.

and the necessary abilities to manage a university's organisation and finances may be selected as rector.

(3) The rector shall be selected from a shortlist of three candidates proposed by the senate, and shall be appointed for a term of four years. Re-election is permissible twice in immediate succession.

(4) The rector's employment contract and target agreement shall be concluded with the university council.

(5) The university council may, by official notification, dismiss the rector because of severe misconduct, conviction of a criminal offence, mental incapacity or health impairment or loss of confidence on reasonable grounds. Such dismissal may be effected on application of the senate or by the university council acting ex officio. In the former case, a simple majority of all members of both bodies shall be required, and in the latter a resolution of the university council passed by a two-thirds majority of all members, whereby the opinion of the senate must be heard. Upon the entry into effect of the dismissal the employment contract of the rector with the university shall be terminated.

Search Committee

§ 23a. (1) For the election of the rector, a search committee shall be established no more than four weeks after the advertisement of the post. The search committee shall be composed of the following five members:

1. the chairperson of the university council as well as another member of the university council to be appointed by the university council,
2. the chairperson of the senate as well as another member of the senate to be appointed by the senate,
3. another person to be appointed by the members under subparas 1 and 2 by mutual consent.

§ 20a paras 1 and 2 shall apply. With regard to the members under subpara 3, § 21 para 4 shall apply by analogy. If the members under subparas 1 and 2 cannot reach consent within two weeks following the establishment of the search committee for the member under subpara 3, § 21 para 7 shall apply by analogy.

(2) Aufgaben der Findungskommission sind:

1. Überprüfung der eingelangten Bewerbungen für die Funktion der Rektorin oder des Rektors;
2. Aktive Suche nach Kandidatinnen und Kandidaten für die Funktion der Rektorin oder des Rektors;
3. Erstellung eines Vorschlages für die Wahl der Rektorin oder des Rektors an den Senat innerhalb von längstens vier Monaten ab der Ausschreibung. Der Vorschlag hat die drei für die Besetzung der Funktion am besten geeigneten Kandidatinnen und Kandidaten zu enthalten; die Findungskommission ist berechtigt, auch Kandidatinnen und Kandidaten, die sich nicht beworben haben, mit deren Zustimmung in den Vorschlag aufzunehmen.

(3) Der von der Findungskommission erstellte Dreiervorschlag ist nicht bindend.

(4) Bei der Erstellung des Vorschlages gemäß Abs. 2 Z 3 ist das Diskriminierungsverbot gemäß B-GlBG zu beachten.

(5) Die Findungskommission entscheidet mit Zweidrittelmehrheit.

(6) Ist die Findungskommission im Sinne des Abs. 2 Z 3 säumig, hat der Universitätsrat innerhalb von vier Wochen die Ersatzvornahme vorzunehmen. Der vom Universitätsrat im Rahmen der Ersatzvornahme erstellte Dreiervorschlag ist nicht bindend.

Wiederbestellung der Rektorin oder des Rektors

§ 23b. (1) Gibt die amtierende Rektorin oder der amtierende Rektor rechtzeitig vor der Ausschreibung der Funktion ihr oder sein Interesse bekannt, die Funktion für eine zweite Funktionsperiode auszuüben, kann eine Wiederbestellung ohne Ausschreibung erfolgen, wenn der Senat und der Universitätsrat dies mit jeweils einfacher Mehrheit beschließen.

(2) Gibt die amtierende Rektorin oder der amtierende Rektor rechtzeitig vor der Ausschreibung der Funktion ihr oder sein Interesse bekannt, diese Funktion für eine dritte Funktionsperiode auszuüben, kann eine Wiederbestellung ohne Ausschreibung erfolgen, wenn der Senat und der Universitätsrat jeweils mit Zweidrittelmehrheit zustimmen, wobei der Senat zuerst abzustimmen hat.

(2) The search committee shall have the following duties:

1. examining the applications received for the post of the rector;
2. actively searching for candidates for the post of the rector;
3. drawing up a shortlist for the election of the rector and forwarding it to the senate within no more than four months after the advertisement. The shortlist shall include the three candidates most suitable for the post; the search committee shall be entitled to include also candidates in the shortlist who did not apply, provided that they agree.

(3) The shortlist of three candidates prepared by the search committee shall not be binding.

(4) When drawing up the shortlist under para 2 subpara 3, regard shall be given to the principle of non-discrimination under B-GlBG.

(5) The search committee shall resolve by a two-thirds majority.

(6) If the search committee is in delay in the meaning of para 2 subpara 3, the university council shall make the substitute performance within four weeks. The shortlist of three candidates drawn up by the university council as a result of the substitute performance shall not be binding.

Reappointment of the Rector

§ 23b. (1) If, in good time prior to the advertisement of the post, the rector in office expresses her/his interest in serving in this function for a second term, a re-appointment without advertising the post shall be permissible, if both the senate and the university council accept this with a simple majority.

(2) If, in good time prior to the advertisement of the post, the rector in office expresses his/her interest in serving in this function for a third term, a re-appointment without advertising the post shall be permissible, if both the senate and the university council accept this with a two-thirds majority. The senate shall vote first.

Vizerektorinnen und Vizerektoren

§ 24. (1) Die Rektorin oder der Rektor bestimmt die Zahl und das Beschäftigungsausmaß der Vizerektorinnen und Vizerektoren. Dem Senat kommt ein Recht zur Stellungnahme zu.

(2) Die Vizerektorinnen und Vizerektoren sind vom Universitätsrat auf Vorschlag der Rektorin oder des Rektors und nach Anhörung des Senats für eine Funktionsperiode zu wählen, die jener der Rektorin oder des Rektors entspricht. Die Wiederwahl ist zulässig.

(3) Scheidet die Rektorin oder der Rektor vor Ablauf der Funktionsperiode aus dem Amt aus oder ist zum Zeitpunkt des Ablaufes der Funktionsperiode noch keine neue Rektorin oder kein neuer Rektor gewählt, endet die Funktion der Vizerektorinnen und Vizerektoren mit dem Zeitpunkt des Amtsantritts der auf Vorschlag der neuen Rektorin oder des neuen Rektors gewählten Vizerektorinnen und Vizerektoren.

(4) Eine Vizerektorin oder ein Vizerektor kann vom Universitätsrat wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder gesundheitlicher Eignung oder wegen eines begründeten Vertrauensverlusts von der Funktion abberufen werden. Die Rektorin oder der Rektor kann die Abberufung einer Vizerektorin oder eines Vizerektors beim Universitätsrat anregen. Die Abberufung bedarf der Zweidrittelmehrheit aller Mitglieder des Universitätsrats, der Senat ist anzuhören. Mit der Wirksamkeit der Abberufung endet das Arbeitsverhältnis der Vizerektorin oder des Vizerektors zur Universität.

Senat

§ 25. (1) Der Senat hat folgende Aufgaben:

1. Erlassung und Änderung der Satzung auf Vorschlag des Rektorates;
2. Zustimmung zu dem vom Rektorat erstellten Entwurf des Entwicklungsplans innerhalb von zwei Monaten; stimmt der Senat nicht fristgerecht zu, ist der Entwicklungsplan dennoch an den Universitätsrat weiterzuleiten;
3. Zustimmung zu dem vom Rektorat beschlossenen Entwurf des Organisationsplans innerhalb von zwei Monaten; stimmt der Senat nicht fristgerecht zu, ist der Organisationsplan dennoch an den Universitätsrat weiterzuleiten;

Vice-rectors

§ 24. (1) The rector shall determine the number and extent of employment of the vice-rectors. The senate shall be entitled to express an opinion thereon.

(2) The vice-rectors shall be selected by the university council from a shortlist of candidates nominated by the rector, after hearing the opinion of the senate, for a term of office corresponding to that of the rector. A re-election is permissible.

(3) In case that the rector leaves office before expiry of his/her term or no new rector has been elected when the term of office expires, the term of office of the vice-rectors shall end when the vice-rectors elected on the recommendation of the new rector take up their functions.

(4) The university council may dismiss a vice-rector because of severe misconduct, conviction of a criminal offence, or mental incapacity or health impairment, or loss of confidence on reasonable grounds. The rector may initiate the dismissal of a vice-rector by the university council. Such dismissal shall require a two-thirds majority of all members of the university council, whereby the opinion of the senate must be heard. Upon the entry into effect of the dismissal the employment contract of a vice-rector with the university shall be terminated.

Senate

§ 25. (1) The senate shall have the following duties:

1. enacting and amending the statute as proposed by the rectorate;
2. approving the draft development plan prepared by the rectorate within two months; if the senate fails to give approval within the appointed period, the development plan shall nevertheless be forwarded to the university council;
3. approving the draft organisation plan prepared by the rectorate within two months; if the senate fails to give approval within the appointed period, the organisation plan shall nevertheless be forwarded to the university council;

4. Änderung der Größe des Universitätsrats und Wahl von Mitgliedern des Universitätsrats (§ 21 Abs. 6 Z 1, Abs. 6a und Abs. 7);
5. Zustimmung zur Ausschreibung für die Funktion der Rektorin oder des Rektors innerhalb von zwei Wochen ab Vorlage durch den Universitätsrat; verweigert der Senat innerhalb von zwei Wochen die Zustimmung, hat der Universitätsrat unverzüglich einen neuen Ausschreibungstext vorzulegen; stimmt der Senat neuerlich fristgerecht nicht zu, so geht die Zuständigkeit zur Ausschreibung auf die Bundesministerin oder den Bundesminister über. Trifft der Senat innerhalb von zwei Wochen keine Entscheidung, ist die Ausschreibung dennoch durchzuführen;

5a. Erstellung eines Dreiervorschlages an den Universitätsrat für die Wahl der Rektorin oder des Rektors unter Berücksichtigung des Vorschlages der Findungskommission innerhalb von längstens vier Wochen ab Vorlage des Vorschlages. Weicht der Senat vom Vorschlag der Findungskommission ab, hat er dem Dreiervorschlag an den Universitätsrat eine schriftliche Begründung für seine Entscheidung anzuschließen. Bei der Erstellung des Dreiervorschlages ist das Diskriminierungsverbot gemäß B-GlBG zu beachten;

6. Stellungnahme zu den Vorschlägen der Rektorin oder des Rektors bezüglich der Vizerektorinnen und Vizerektoren (Anzahl, Beschäftigungsausmaß und Wahlvorschlag);
7. Mitwirkung bei der Abberufung von Mitgliedern des Universitätsrats, der Rektorin oder des Rektors sowie von Vizerektorinnen und Vizerektoren;
8. Mitwirkung an Habilitationsverfahren;
9. Mitwirkung an Berufungsverfahren;
10. Stellungnahme an das Rektorat zu den Richtlinien zur strukturellen Gestaltung von Curricula;

10a. Erlassung und Änderung der Curricula für Studien (§§ 56 und 58) nach Maßgabe der §§ 22 Abs. 1 Z 12 und 54d Abs. 2;

11. Festlegung von akademischen Graden und Bezeichnungen für die Absolventinnen und Absolventen von Universitätslehrgängen;
12. Abgabe von Gutachten im Beschwerdevorentscheidungsverfahren gemäß § 14 des Verwaltungsgerichtsverfahrensgesetzes – VwGVG, BGBl. I Nr. 33/2013 bei Beschwerden in Studienangelegenheiten;

(Anm.: Z 13 aufgehoben durch Art. 5 Z 8, BGBl. I Nr. 129/2017)

4. changing the size of the university council and electing its members (§ 21 para 6 subpara 1, para 6a and para 7);
5. approving the advertisement for the post of the rector within two weeks upon receipt from the university council; if the senate refuses acceptance within two weeks, the university council shall submit a new advertisement without delay; if the senate again fails to approve it within the period stipulated, the responsibility for the advertisement shall be transferred to the Federal Minister. If the senate fails to take a decision within two weeks, the post shall nevertheless be advertised;

5a. drawing up a shortlist of three candidates for the election of the rector by the university council, taking into account the shortlist of the search committee within a maximum of four weeks upon receipt of the shortlist. If the senate does not comply with the shortlist of the search committee, an explanatory statement in writing for its decision shall be forwarded to the university council together with the shortlist of three candidates. Regard shall be given to the principle of non-discrimination under B-GlBG when drawing up the shortlist of three candidates;

6. expressing an opinion on the rector's recommendations with regard to the vice-rectors (number, extent of employment and shortlist);
7. participating in procedures for the dismissal of members of the university council, the rector or vice-rectors;
8. participating in procedures for the awarding habilitation degrees;
9. participating in procedures for the appointment of professors;
10. opinion to the rectorate on the guidelines on the structural design of curricula;

10a. enacting and changing the curricula for study programmes (§§ 56 and 58) according to § 22 para 1 subpara 12 and § 54d para 2;

11. prescription of the academic degrees and titles for graduates of certificate university programmes for further education;
12. Preparing reports as part of the procedure for preliminary rulings on appeals pursuant to § 14 of the Administrative Court Act (VwGVG), F. L. G. I No 33/2013, for appeals in matters relating to studies;

13. [removed]

14. Einsetzung von Kollegialorganen mit und ohne Entscheidungsbefugnis (Abs. 7 und 8);
15. Erlassung von Richtlinien für die Tätigkeit von Kollegialorganen;
16. Genehmigung der Durchführung von Beschlüssen der entscheidungsbefugten Kollegialorgane;
17. Stellungnahme an das Rektorat vor der Zuordnung von Personen zu den einzelnen Organisationseinheiten durch das Rektorat;
18. Einrichtung eines Arbeitskreises für Gleichbehandlungsfragen;
19. Nominierung eines weiblichen und eines männlichen Mitglieds für die Schiedskommission.

(Anm.: Z 20 aufgehoben durch BGBl. I Nr. 81/2009)

(2) Der Senat besteht aus achtzehn oder sechsundzwanzig Mitgliedern. Über eine Änderung der Größe des Senats entscheidet der Senat mit Zweidrittelmehrheit.

(3) Dem Senat gehören Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren, einschließlich der Leiterinnen und Leiter von Organisationseinheiten mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst, die keine Universitätsprofessorinnen und Universitätsprofessoren sind, der im § 94 Abs. 2 Z 2 und Z 3 genannten Gruppen, des allgemeinen Universitätspersonals und der Studierenden an.

(3a) Die Anzahl der Vertreterinnen und Vertreter dieser Gruppen ist folgendermaßen festgelegt:

1. gehören dem Senat achtzehn Mitglieder an:
   - Neun Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren einschließlich der Leiterinnen und Leiter von Organisationseinheiten mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst, die keine Universitätsprofessorinnen und Universitätsprofessoren sind;
   - Vier Vertreterinnen und Vertreter der Gruppe der Universitätsdozentinnen und Universitätsdozenten sowie der wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb einschließlich der Ärztinnen und Ärzte in Facharztausbildung;

14. appointing collegial bodies with or without decision-making power (paras 7 and 8);
15. enacting directives on the activities of collegial bodies;
16. approving the implementation of decisions by collegial bodies with decision-making power;
17. opinions to the rectorate prior to the assignment by it of persons to given organisational units;
18. establishing a working group on equal opportunities;
19. nominating one female and one male member of the arbitration board.

20. [removed]

(2) The senate shall consist of eighteen or twenty-six members. Any change in the size of the senate shall be for resolution of the senate and shall require a two-thirds majority.

(3) The senate shall consist of representatives of the professors, including heads of organisational units with research and teaching responsibilities or responsibilities with regard to the advancement and appreciation of the arts and art teaching who are not university professors, the group of persons named in § 94 para 2 subparas 2 and 3, the non-academic university staff, and students.

(3a) The number of representatives of these groups shall be determined as follows:

1. if the senate consists of eighteen members:
   - nine representatives of the professors including heads of organisational units with research and teaching responsibilities or responsibilities with regard to the advancement and appreciation of the arts and art teaching who are not professors;
   - four representatives of the group of associate professors as well as the other scientific, artistic and teaching staff including physicians in specialists' training;

– Vier Vertreterinnen und Vertreter der Studierenden;
– Eine Vertreterin oder ein Vertreter des allgemeinen Universitätspersonals.

2. gehören dem Senat sechsundzwanzig Mitglieder an:
   – Dreizehn Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren einschließlich der Leiterinnen und Leiter von Organisationseinheiten mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst, die keine Universitätsprofessorinnen und Universitätsprofessoren sind;
   – Sechs Vertreterinnen und Vertreter der Gruppe der Universitätsdozentinnen und Universitätsdozenten sowie der wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb einschließlich der Ärztinnen und Ärzte in Facharztausbildung;
   – Sechs Vertreterinnen und Vertreter der Studierenden;
   – Eine Vertreterin oder ein Vertreter des allgemeinen Universitätspersonals.

(4) Die Mitglieder und Ersatzmitglieder des Senats sind folgendermaßen zu wählen bzw. zu entsenden:

1. Die Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren sind von allen Universitätsprofessorinnen und Universitätsprofessoren (§ 97) und den Leiterinnen und Leitern von Organisationseinheiten mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst, die keine Universitätsprofessorinnen und Universitätsprofessoren sind, zu wählen.
2. Die Vertreterinnen und Vertreter der in den § 94 Abs. 2 Z 2 und 3 genannten Gruppen sind von allen Universitätsdozentinnen und Universitätsdozenten (§ 122 Abs. 3) sowie den wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeitern im Forschungs-, Kunst- und Lehrbetrieb (§ 100) sowie den Ärztinnen und Ärzten in Facharztausbildung (§ 96) zu wählen. An den Universitäten gemäß § 6 Abs. 1 Z 1 bis 15 und 22 muss den Gewählten zumindest eine Person mit Lehrbefugnis (venia docendi) angehören.

– four representatives of the students;
– one representative of the non-academic university staff.

2. if the senate consists of twenty-six members:
   – thirteen representatives of the professors including heads of organisational units with research and teaching responsibilities or responsibilities with regard to the advancement and appreciation of the arts and art teaching who are not professors;
   – six representatives of the group of associate professors as well as the other scientific, artistic and teaching staff including physicians in specialists' training;
   – six representatives of the students;
   – one representative of the non-academic university staff.

(4) The members and substitute members of the senate shall be elected or delegated as follows:

1. The representatives of the professors shall be elected by all the professors (§ 97) and heads of organisational units with research and teaching responsibilities or responsibilities with regard to the advancement and appreciation of the arts and art teaching who are not professors,
2. The representatives of the group under § 94 para 2 subparas 2 and 3 shall be elected by all associate professors (§ 122 para 3) and the other scientific and artistic staff as well as research, artistic and teaching staff (§ 100) and physicians in specialists' training (§ 96). At the universities named in § 6 para 1 subparas 1 to 15 and 22, those elected shall include at least one person with a habilitation degree (venia docendi).

3. Die Vertreterinnen und Vertreter des allgemeinen Universitätspersonals sind von allen Angehörigen des allgemeinen Universitätspersonals zu wählen.
4. Die Vertreterinnen und Vertreter der Studierenden sind zu entsenden (§ 32 Abs. 1 des Hochschülerinnen- und Hochschülerschaftsgesetzes 2014 – HSG 2014, BGBl. I Nr. 45/2014).

Die Wahlen gemäß Z 1, 2 und 3 können als Briefwahl durchgeführt werden. Näheres ist in der Wahlordnung (§ 19 Abs. 2 Z 1) festzulegen. Die Mitglieder gemäß Z 1 bis 3 dürfen für höchstens vier unmittelbar aufeinanderfolgende Funktionsperioden gewählt werden.

(Anm.: Abs. 4a aufgehoben durch BGBl. I Nr. 21/2015)

(5) Die Funktionsperiode des Senats beträgt drei Jahre und beginnt mit dem 1. Oktober des betreffenden Jahres.

(6) Der Senat ist beschlussfähig, wenn wenigstens die Hälfte der Mitglieder anwesend ist. Er entscheidet mit Stimmenmehrheit, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(7) Vom Senat können zur Beratung oder Entscheidung einzelner seiner Aufgaben Kollegialorgane eingerichtet werden.

(Anm.: Abs. 7a aufgehoben durch BGBl. I Nr. 21/2015)

(8) Für folgende Angelegenheiten sind entscheidungsbefugte Kollegialorgane einzusetzen:

1. Habilitationsverfahren (§ 103),
2. Berufungsverfahren (§ 98),
3. Studienangelegenheiten gemäß § 25 Abs. 1 Z ~~10~~10a.

Für die Beschlussfassung über die Einsetzung eines Kollegialorgans gemäß Z 1 und 2 ist neben den sonstigen Beschusserfordernissen eine Mehrheit der anwesenden Mitglieder der Gruppe gemäß Abs. 4 Z 1 einschließlich der sonstigen Mitglieder des Senats mit venia docendi erforderlich.

(9) Die Zahl der Mitglieder der Kollegialorgane gemäß Abs. 8 darf die Hälfte der Zahl der Senatsmitglieder nicht überschreiten. In den Kollegialorganen gemäß Abs. 8 Z 3 stellen die Studierenden mindestens ein Viertel der Mitglieder. Die Kollegialorgane gemäß Abs. 7 haben in ihrer Zusammensetzung der Relation der Vertreterinnen und Vertreter der einzelnen Gruppen im Senat zu entsprechen.

(10) Die Kollegialorgane gemäß Abs. 7 und Abs. 8 Z 3 sind längstens für die Dauer der Funktionsperiode des Senats einzurichten. Diese Kollegialorgane sind an

3. The representatives of the non-academic university staff shall be elected by all non-academic university staff.
4 . The student representatives shall be appointed (§ 32 para 1 of the Students' Union Act 2014, F. L. G. I No 45/2014).

The elections under subparas 1, 2 and 3 may be conducted as a postal vote. Further details shall be laid down in the electoral regulations (§ 19 para 2 subpara 1). The members under subparas 1 to 3 may be elected for a maximum of four consecutive terms of office.

4a. [removed]

(5) The term of office of the senate shall be three years and shall commence on 1 October of the respective year.

(6) The senate shall have a quorum when at least half of the members are present. It shall resolve by simple majority, except insofar as this Act provides otherwise.

(7) The senate may establish collegial bodies to advise it on matters forming part of its tasks.

(7a) [removed]

(8) Collegial bodies with decision-making power shall be appointed to deal with the following matters:

1. procedures for the awarding habilitation degrees (§ 103);
2. procedures for the appointment of professors (§ 98);
3. study related matters in the meaning of § 25 para 1 subpara 10.

Decisions on the appointment of a collegial body under subparas 1 and 2 shall, in addition to the other decision-making requirements, be subject to a majority vote of the present members of the group under para 4 subpara 1, including other members of the senate with a habilitation degree.

(9) The size of the collegial bodies under para 8 may not exceed half of that of the senate. At least one quarter of the members of the collegial bodies under para 8 subpara 3 shall be students. The composition of the collegial bodies under para 7 shall, with regard to the proportions accounted for by representatives of the various groups, correspond to that of the senate.

(10) The collegial bodies under paras 7 and 8 subpara 3 shall be established for not longer than the term of the senate. These collegial bodies shall be bound by the

die Richtlinien des Senats gebunden und entscheiden in dessen Namen. Der Senat kann eine gemäß Abs. 7 erteilte Entscheidungsvollmacht jederzeit widerrufen. Die Beschlüsse der Kollegialorgane gemäß Abs. 7 und Abs. 8 Z 3 bedürfen der Genehmigung des Senats.

(Anm.: Abs. 11 aufgehoben durch Art. 5 Z 9, BGBl. I Nr. 129/2017)

instructions of the senate and shall take their decisions in its name. The senate may at any time revoke authorisations to take decisions granted under para 7. The decisions of the collegial bodies under paras 7 and 8 subpara 3 shall require the approval of the senate.

(11) [removed]

2. Unterabschnitt
Forschungsförderung, Auftragsforschung und Vollmachten

Forschungsförderung und Auftragsforschung

§ 26. (1) Die Angehörigen des wissenschaftlichen und künstlerischen Universitätspersonals sind berechtigt, in ihrem Fach auch Forschungsvorhaben oder künstlerische Arbeiten an der Universität einzuwerben und durchzuführen, die nicht aus dem Budget der Universität, sondern aus Forschungsaufträgen Dritter, aus Mitteln der Forschungsförderung oder aus anderen Zuwendungen Dritter finanziert werden. Die Durchführung solcher Vorhaben zählt zur Universitätsforschung bzw. zur universitären Entwicklung und Erschließung der Künste.

(2) Voraussetzung für die Durchführung eines Vorhabens gemäß Abs. 1 an der Universität ist, dass

1. die Erfüllung der Pflichten aus dem Arbeitsverhältnis,
2. die Erfüllung der Aufgaben der betreffenden Organisationseinheit der Universität in der Forschung oder in der Entwicklung und Erschließung der Künste sowie im Lehrbetrieb und
3. die Rechte und Pflichten anderer Universitätsangehöriger

nicht beeinträchtigt werden.

(3) Für die Inanspruchnahme von Personal und Sachmitteln der Universität zur Durchführung von Forschungsaufträgen oder künstlerischen Arbeiten im Auftrag Dritter ist voller Kostenersatz an die Universität zu leisten. Über die Verwendung dieses Kostenersatzes entscheidet das Rektorat.

(4) Ein Vorhaben gemäß Abs. 1 ist dem Rektorat von der Projektleiterin oder vom Projektleiter vor der beabsichtigten Übernahme und Durchführung zu melden. Es ist nur zu untersagen, wenn die Voraussetzungen des Abs. 2 nicht erfüllt sind oder keine Vereinbarung über den vollen Kostenersatz vorliegt.

Sub-Chapter 2
Research Promotion, Commissioned Research and Authorisations

Research Promotion and Commissioned Research

§ 26. (1) University scientific and artistic staff shall be entitled to procure and undertake research or artistic projects, in their fields and at their universities, which are financed not from the university budget, but by third-party research contracts, research promotion or other allocations by third parties. Such projects shall be deemed to be university research or advancement and appreciation of the arts at universities.

(2) The acceptance of a project in the meaning of para 1 at a university shall be conditional on:

1. fulfilment of the duties arising from the employment contracts of the staff members concerned;
2. fulfilment of the tasks of the university organisational unit concerned with regard to research or the advancement and appreciation of the arts, and teaching;
3. respect for the rights and duties of other university members.

(3) The cost of the use of university staff and physical resources for research contracts or artistic projects commissioned by third parties shall be reimbursed to the university in full. The application of such reimbursed money shall be at the discretion of the rectorate.

(4) A project in the meaning of para 1 shall be notified to the rectorate by the project leader prior to acceptance and implementation. The project shall not be prohibited unless the conditions set out in para 2 are not met or no agreement on full reimbursement of costs has been concluded.

(5) Über die Verwendung der Projektmittel entscheidet die Projektleiterin oder der Projektleiter. Die Mittel für Vorhaben gemäß Abs. 1 sind von der Universität zu verwalten und ausschließlich auf Anweisung der Projektleiterin oder des Projektleiters zu verwenden.

(6) Mitarbeiterinnen und Mitarbeiter an einem Vorhaben gemäß Abs. 1 sind auf Vorschlag der oder des Universitätsangehörigen, die oder der dieses Vorhaben durchführt, gegen Ersatz der Personalkosten in ein zeitlich befristetes Arbeitsverhältnis zur Universität aufzunehmen.

Vollmachten

§ 27. (1) Jede Leiterin und jeder Leiter einer Organisationseinheit ist berechtigt, im Namen der Universität und im Zusammenhang mit deren Aufgaben

1. durch unentgeltliche Rechtsgeschäfte sowie Spenden und Sponsoring Vermögen einzuwerben und Rechte zu erwerben;
2. Förderungen anderer Rechtsträger entgegenzunehmen;
3. Mittel für die Durchführung wissenschaftlicher oder künstlerischer Arbeiten sowie für Untersuchungen und Befundungen im Auftrag Dritter einzuwerben und damit im Zusammenhang stehende Verträge abzuschließen, soweit sie der wissenschaftlichen Forschung oder der Entwicklung und Erschließung der Künste dienen;
4. staatlich autorisierte technische Prüf- und Gutachtertätigkeiten durchzuführen, sofern die betreffende Universitätseinrichtung als staatlich autorisierte Prüfanstalt anerkannt ist;
5. von Vermögen und Rechten, die aus Rechtsgeschäften gemäß Z 1 bis 4 erworben werden, zur Erfüllung der Zwecke der Organisationseinheit Gebrauch zu machen.

Bei Missbrauch kann diese Berechtigung vom Rektorat entzogen werden.

(2) Jede oder jeder mit der Erfüllung von Verträgen gemäß Abs. 1 Z 3 verantwortlich betraute Universitätsangehörige (Projektleiterin oder Projektleiter) ist zum Abschluss der für die Vertragserfüllung erforderlichen Rechtsgeschäfte und zur Verfügung über die Geldmittel im Rahmen der Einnahmen aus diesem Vertrag zu ermächtigen. Diese Bevollmächtigungen sind im Mitteilungsblatt der Universität zu verlautbaren.

(3) Für die Inanspruchnahme von Personal und Sachmitteln der Universität zur Durchführung von Aufträgen Dritter (Abs. 1 Z 3 und 4) ist voller Kostenersatz an die

(5) The application of project funds shall be at the discretion of the project leader. The funds received for projects in the meaning of para 1 shall be administered by the university and shall only be used as instructed by the project leader.

(6) Staff engaged in a project in the meaning of para 1 shall be employed by the university under limited term contracts on the recommendation of the university member conducting the project in return for reimbursement of the resultant staff costs.

Authorisations

§ 27. (1) All heads of organisational units shall be entitled, on behalf of the university and in connection with its tasks:

1. to acquire assets and rights by way of non-remunerative legal transactions as well as through donations and sponsoring;
2. to accept funding from other legal entities;
3. to acquire funding for the performance of scientific or artistic work and for investigations and reports on behalf of third parties and to make contracts in connection therewith, insofar as this serves the purpose of scientific research or the advancement and appreciation of the arts;
4. to perform state-certified technical testing and prepare assessment reports provided that the university facility in question is recognized as a state-certified test laboratory;
5. to employ assets and rights acquired by way of legal transactions in the meaning of paras 1 to 4 to fulfil the objects of the organisational unit in question.

In the case of abuse, this entitlement may be withdrawn by the rectorate.

(2) All university members (project leaders) entrusted with the fulfilment of contracts in the meaning of para 1 subpara 3 shall be authorised to make the legal transactions required for such fulfilment and to use the funds accruing from such contracts. Such authorisations shall be announced in the university gazette.

(3) The cost of the use of university staff and physical resources for third-party contracts and commissions (para 1 subpara 3 and 4) shall be reimbursed to the

Universität zu leisten. Über die Verwendung dieses Kostenersatzes entscheidet das Rektorat.

(4) Die der Universität auf Grund von Tätigkeiten gemäß Abs. 1 zufließenden Drittmittel sind, sofern keine Zweckwidmung vorliegt, für Zwecke jener Organisationseinheit zu verwenden, der die zeichnungsbefugte Arbeitnehmerin oder der zeichnungsbefugte Arbeitnehmer der Universität zugeordnet ist. Zur Erfüllung von Verpflichtungen der Universität auf Grund von Rechtsgeschäften gemäß Abs. 1 sind zunächst die Mittel heranzuziehen, die für die betreffende Organisationseinheit zweckgewidmet sind.

(5) Die gemäß Abs. 1 berechtigten oder gemäß Abs. 2 bevollmächtigten Universitätsangehörigen haben dem Rektorat über die Durchführung der von ihnen abgeschlossenen Rechtsgeschäfte zu berichten.

§ 28. (1) Die Rektorin oder der Rektor kann unter Beachtung der vom Rektorat erlassenen Richtlinien festlegen, welche Arbeitnehmerinnen und Arbeitnehmer der Universität Rechtsgeschäfte im Namen der Universität abschließen dürfen. Diese Bevollmächtigungen sind im Mitteilungsblatt der Universität zu verlautbaren.

(2) § 27 Abs. 4 und 5 gelten sinngemäß.

3. Unterabschnitt

Sonderbestimmungen für die Klinischen Bereiche der Medizinischen Universitäten bzw. der Universitäten, an denen eine Medizinische Fakultät eingerichtet ist

Organisation

§ 29. (1) Die Medizinischen Universitäten gemäß § 6 Abs. 1 Z 4 bis 6 bzw. die Universitäten, an denen eine Medizinische Fakultät eingerichtet ist, erfüllen ihre Forschungs- und Lehraufgaben im Klinischen Bereich auch im Zusammenwirken mit öffentlichen Krankenanstalten.

(2) Die organisatorische Gliederung des Klinischen Bereichs der Medizinischen Universität bzw. der Medizinischen Fakultät und der Krankenanstalt sind aufeinander abzustimmen. Dabei sind auch jene Einrichtungen der Medizinischen Universität bzw. der Medizinischen Fakultät festzulegen, die zur Unterstützung der Lehr- und Forschungsaufgaben des Klinischen Bereichs erforderlich sind. Vor der Erstellung des Organisationsplans für den Klinischen Bereich hat das Rektorat daher das Einvernehmen mit dem Träger der Krankenanstalt herzustellen. Der

university in full. The application of such reimbursed money shall be at the discretion of the rectorate.

(4) Third-party funds accruing to a university as a result of activities in the meaning of para 1 shall, to the extent that they are not tied, be employed for the objects of the organisational unit to which the university's authorised signatory is assigned. For the fulfilment of the university's obligations under legal transactions in the meaning of para 1, in the first instance funds shall be applied which are earmarked for the organisational unit concerned.

(5) University members authorised under paras 1 or 2 shall report to the rectorate on the legal transactions made by them.

§ 28. (1) The rector may, having regard to the regulations enacted by the rectorate, determine which employees of the university may make legal transactions on its behalf. Such authorisations shall be announced in the university gazette.

(2) § 27 paras 4 and 5 shall apply by analogy.

Sub-Chapter 3

Special Provisions for the Clinical Departments of Medical Universities and Universities with a Faculty of Medicine

Organisation

§ 29. (1) The medical university under § 6 para 1 subparas 4 to 6 or the universities at which a faculty of medicine has been established shall perform their clinical research and teaching tasks in cooperation with public hospitals.

(2) The organisational structures of the clinical departments of medical universities or faculties of medicine and the attached hospitals shall be coordinated with each other. In doing so, the organisational units of medical universities or faculties of medicine required to support the teaching and research activities of clinical departments shall be determined. Prior to the preparation of the organisation plan for a clinical department, the rectorate shall, therefore, reach agreement with the

Organisationsplan für den Klinischen Bereich bedarf der Zustimmung der Bundesministerin oder des Bundesministers.

(3) Die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, ist berechtigt, sich an einer Gesellschaft zur Führung des Betriebs der Krankenanstalt zu beteiligen.

(4) Die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, hat folgende Verpflichtungen:

1. Sie hat ihre in ärztlicher oder zahnärztlicher Verwendung stehenden Arbeitnehmerinnen und Arbeitnehmer mit der Mitwirkung an der Erfüllung der Aufgaben der Organisationseinheiten des Klinischen Bereichs als Einrichtungen der Krankenanstalt zu beauftragen. Diese Mitwirkung ist dem Rechtsträger dieser Krankenanstalt und nicht der Medizinischen Universität bzw. der Universität, an der eine Medizinische Fakultät eingerichtet ist, zuzurechnen und gilt als Überlassung im Sinne des § 9 ArbeitnehmerInnenschutzgesetz – ASchG, BGBl. Nr. 450/1994. Ein Arbeitsverhältnis zum Rechtsträger der Krankenanstalt, eine Arbeitskräfteüberlassung gemäß Arbeitskräfteüberlassungsgesetz – AÜG, BGBl. Nr. 196/1988 oder eine Überlassung nach anderen gesetzlichen Regelungen wird dadurch nicht begründet.
2. Sie hat die notwendigen personenbezogenen Daten (Art. 4 Nr. 1 DSGVO) und sonstigen Informationen aller Organisationseinheiten über die Erfordernisse von Forschung und Lehre zur Ermittlung und Abwicklung des Klinischen Mehraufwandes nach betriebswirtschaftlichen Kriterien zu erheben, zu dokumentieren und zu bewerten. Die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, hat ab 1. Jänner 2007 das Ergebnis ihrer Ermittlung der Leistung des Kostenersatzes gemäß § 55 KAKuG zu Grunde zu legen, sofern nicht in einer Verordnung gemäß § 56 KAKuG oder in einer Vereinbarung gemäß Abs. 5 eine andere Regelung getroffen wird.
3. Sie hat eine mittelfristige Planung für sämtliche Anlagen zu erstellen, die ganz oder teilweise dem Bedarf von Forschung und Lehre dienen und zu Mehrkosten im Sinne des § 55 KAKuG führen. Diese Planung sowie Neuanschaffungen sind nach Maßgabe des Bedarfs für Forschung und Lehre unter Beachtung der Grundsätze der Sparsamkeit, Wirtschaftlichkeit und Zweckmäßigkeit sowie in Abstimmung mit den sonstigen Einrichtungen und Anschaffungen der Krankenanstalt vorzunehmen.

maintaining body of the attached hospital. The organisation plan for a clinical department shall require the Federal Minister's approval.

(3) The medical university or the university at which a faculty of medicine has been established shall be entitled to acquire interests in companies charged with the operation of the attached hospitals.

(4) The medical universities or the university at which a faculty of medicine has been established shall have the following obligations:

1. It shall charge the medical and dental staff employed with assisting in the fulfilment of the tasks of the organisational units of the clinical department in their functions as hospital units. The cost of such assistance shall not be borne by the medical university or the university at which a faculty of medicine has been established but by the maintaining body of the hospital. This is considered to be a transfer within the meaning of § 9 of the Employee Protection Act (ArbeitnehmerInnenschutzgesetz – ASchG), F. L. G. No 450/1994. This shall not, however, result in employment of the staff concerned by the maintaining body of the hospital, in temporary work as stipulated in the Temporary Work Act (Arbeitskräfteüberlassungsgesetz – AÜG), F. L. G. No 196/1988 or a transfer pursuant to other legal regulations.
2. It shall acquire from all organisational units the required personal data (Art 4 No 1 GDPR) and information on their research and teaching requirements needed to identify and manage the additional clinical overhead in accordance with business management criteria, and to document and assess them. From 1 January 2007 onwards, the medical university or the university at which a faculty of medicine has been established shall calculate such expenses on a cost replacement basis under § 55 KAKuG, unless other arrangements are made under an order pursuant to § 56 KAKuG or an agreement under para 5.
3. To prepare a medium-term budget for all facilities partly or wholly devoted to research and teaching and giving rise to additional costs in the meaning of § 55 of the Hospitals and Health Resorts Act. Such budgeting and the procurement of new equipment shall be undertaken in accordance with the research and teaching needs of the university, having regard to the principles of economy, efficiency and expediency, and shall be coordinated with the hospital's other units and purchases.

(5) Die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, hat mit dem Rechtsträger der Krankenanstalt nach Zustimmung der Bundesministerin oder des Bundesministers unter Bedachtnahme auf die Leistungsvereinbarung gemäß § 13 eine Vereinbarung über die Zusammenarbeit beim Betrieb der einzelnen zum Klinischen Bereich der Medizinischen Universität bzw. Medizinischen Fakultät gehörenden und gleichzeitig einen Teil der öffentlichen Krankenanstalt bildenden Organisationseinheiten zu treffen, die auch die wechselseitigen Leistungen und deren Bewertung enthält. In dieser Vereinbarung über die Zusammenarbeit ist auch festzulegen, dass Universitätsangehörige gemäß § 94 Abs. 1 Z 4 in ärztlicher oder zahnärztlicher Verwendung, mit Ausnahme der Ärztinnen und Ärzte in Facharztausbildung gemäß § 94 Abs. 2 Z 3, die mit der Mitwirkung an der Erfüllung der Aufgaben der Organisationseinheiten des Klinischen Bereichs als Einrichtungen der Krankenanstalt beauftragt sind, in einem Durchrechnungszeitraum von 26 Wochen mindestens 30vH der Normalarbeitszeit dieser Universitätsangehörigen, bezogen auf die Gesamtheit der Organisationseinheiten im Klinischen Bereich, für universitäre Lehre und Forschung verwenden.

(6) Den Organisationseinheiten einer Medizinischen Universität bzw. einer Medizinischen Fakultät können gegen Ersatz der Kosten auch Aufgaben des öffentlichen Gesundheitswesens übertragen werden. Die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, ist unbeschadet von § 27 berechtigt, Untersuchungen und Befundungen an Organisationseinheiten des Nichtklinischen Bereichs mittelbar für Patientinnen und Patienten durchzuführen, soweit sie der wissenschaftlichen Forschung dienen. Bei der Erfüllung dieser Aufgaben unterliegt die Universität nicht den Bestimmungen des KAKuG.

(7) Die Leiterin oder der Leiter der Universitätsklinik für Zahn-, Mund- und Kieferheilkunde der Medizinischen Universität Wien ist berechtigt, im Namen der Medizinischen Universität Wien Verträge über die Erbringung zahnärztlicher Leistungen abzuschließen.

(8) Die Wahrnehmung der Aufgaben im Rahmen einer öffentlichen Krankenanstalt und der allfälligen Aufgaben im Rahmen des Gesundheitswesens ist von der autonomen Besorgung durch die Medizinische Universität bzw. durch die Universität, an der eine Medizinische Fakultät eingerichtet ist, ausgenommen.

(9) Die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, kann sich zur Erfüllung ihrer Aufgaben nach Abs. 1 auch

(5) Subject to approval by the Federal Minister and having regard to the performance agreements according to § 13, the medical universities or the universities at which a faculty of medicine has been established shall conclude agreements with the maintaining bodies of the attached hospitals on the joint operation of those organisational units that belong to the clinical department of the medical university or the faculty of medicine and at the same time form part of the public hospital involved; such agreements shall include the reciprocal services and the pricing thereof. This agreement on the joint operation shall also lay down that university members named in § 94 para 1 (4), working as physicians or dentists, with the exception of physicians in specialists' training according to § 94 para 2 (3), who are charged with assisting in the fulfilment of the tasks of the organisational units of the clinical department in their functions as hospital units, shall use at least 30% of their normal working time within a reference period of 26 weeks, relating to the respective organisational units of the clinical department, for university teaching and research.

(6) Responsibilities of the public health service may be transferred to the organisational units of a medical university or a faculty of medicine on a cost replacement basis. Notwithstanding § 27, the medical university or the university at which a faculty of medicine has been established shall be entitled to perform examinations and prepare reports indirectly for patients in organisational units of non-clinical departments as far as they serve scientific research. In the fulfilment of these tasks, the university shall not be subject to the KAKuG.

(7) The director of the Vienna University Clinic of Dentistry shall be entitled to conclude contracts for the provision of dental services on behalf of the Medical University of Vienna.

(8) The fulfilment of tasks on behalf of public hospitals and any duties forming part of the public health service are excluded from the autonomous health care provision of the universities or the universities at which a faculty of medicine has been established.

(9) The medical university or the university at which a faculty of medicine has been established may, for the fulfilment of its tasks under para 1, call upon employees

der Bediensteten des Rechtsträgers der Krankenanstalt bedienen. Diesbezüglich ist nach Zustimmung der Bundesministerin oder des Bundesministers durch die Medizinische Universität bzw. die Universität, an der eine Medizinische Fakultät eingerichtet ist, unter Bedachtnahme auf die Leistungsvereinbarungen gemäß § 13 mit dem Rechtsträger der Krankenanstalt eine Vereinbarung zu treffen, die insbesondere sowohl die Eignung der Bediensteten, als auch das Ausmaß der Tätigkeit in Lehre und Forschung, den dafür notwendigen Kostenersatz und Ausführungen über das Weisungsrecht der Rektorin oder des Rektors hinsichtlich der für Aufgaben der Universität konkret betrauten Bediensteten des Rechtsträgers der Krankenanstalt enthält. Der Bedarf der Medizinischen Universität bzw. der Universität, an der eine Medizinische Fakultät eingerichtet ist, und die Qualifikation der Bediensteten sind zu berücksichtigen. Für die Tätigkeit dieser Bediensteten im Rahmen von Forschung und Lehre ist § 2 Z 1 bis 3 anzuwenden. Die konkrete Betrauung der oder des Bediensteten erfolgt durch die Rektorin oder den Rektor auf Basis der Qualifikation der betreffenden Person in Forschung und Lehre. Ein Arbeitsverhältnis zur Medizinischen Universität bzw. der Universität, an der eine Medizinische Fakultät eingerichtet ist, wird dadurch nichtbegründet. Die von der Rektorin oder dem Rektor konkret mit wissenschaftlichen Aufgaben betrauten Bediensteten des Rechtsträgers der Krankenanstalt sind den Angehörigen der Universität gemäß § 94 Abs. 2 Z 2 gleichgestellt. Vor Vorlage der Vereinbarung an die Bundesministerin oder den Bundesminister ist eine Stellungnahme des Senates einzuholen.

of the maintaining body of the attached hospital. For this purpose and upon approval by the Federal Minister, the medical university or the university at which a faculty of medicine has been established shall, taking the performance agreements according to § 13 into consideration, conclude an agreement with the maintaining body of the attached hospital pertaining to, in particular, the qualifications of the employees, the extent of their teaching and research activities, the required reimbursement of costs, and details on the rector's right to give instructions to the employees of the maintaining body of the attached hospital who have been entrusted with tasks of the university. The demand of the medical university or the university at which a faculty of medicine has been established and the employees' qualifications shall be taken into account. § 2 (1) to (3) shall apply to the research and teaching activities of these employees. The rector shall entrust these employees based on their qualifications regarding research and teaching. This shall not constitute a contract of employment with the medical university or the university at which a faculty of medicine has been established. The employees of the maintaining body of the attached hospital who the rector has entrusted with scientific tasks shall be accorded equal status to employees at the university according to § 94 para 2 (2). Before the agreement is submitted to the Federal Minister, the senate shall give its opinion.

Ethikkommission

§ 30. (1) An jeder Medizinischen Universität bzw. an jeder Universität, an der eine Medizinische Fakultät eingerichtet ist, ist vom Senat zur Beurteilung klinischer Prüfungen von Arzneimitteln und Medizinprodukten, der Anwendung neuer medizinischer Methoden und angewandter medizinischer Forschung an Menschen eine Ethikkommission einzurichten.

(2) Die Ethikkommissionen haben jedenfalls den Erfordernissen des § 8c Abs. 1 bis 5 und 7 KAKuG zu entsprechen. In Abweichung von § 8c Abs. 4 KAKuG haben den Ethikkommissionen mindestens 50 vH Frauen anzugehören (§ 20a).

(3) Die Ethikkommission hat sich eine Geschäftsordnung zu geben. Diese ist dem Universitätsrat und dem Rechtsträger der Krankenanstalt im Wege der Rektorin oder des Rektors zur Kenntnis zu bringen.

Ethics Committee

§ 30. (1) The senate of every medical university or every university at which a faculty of medicine has been established shall appoint an ethics committee to assess clinical tests of drugs and medical products, the application of new medical methods and applied medical research involving human subjects.

(2) The ethics committees shall, as a minimum, meet the requirements of § 8c paras 1 to 5 and 7 of the Hospitals and Health Resorts Act (KAKuG). Notwithstanding § 8c para 4 of the Hospitals and Health Resorts Act, the ethics committees shall consist of at least 50% women (§ 20a).

(3) The ethics committee shall adopt rules of procedure. These shall be communicated to the university council and the maintaining body of the attached hospital by way of the rector.

(4) Die Mitglieder der Ethikkommission unterliegen in dieser Funktion weder Weisungen der Organe der Krankenanstalt noch Weisungen der Organe der Universität.

(4) The members of the ethics committee shall not, in this capacity, be bound by instructions of the governing bodies of the hospital or the university.

Gliederung des Klinischen Bereichs

§ 31. (1) Der Klinische Bereich einer Medizinischen Universität bzw. einer Medizinischen Fakultät umfasst jene Einrichtungen, die funktionell gleichzeitig Organisationseinheiten einer öffentlichen Krankenanstalt sind.

(2) Die Organisationseinheiten einer Medizinischen Universität bzw. einer Medizinischen Fakultät, in denen im Rahmen einer Krankenanstalt neben Forschungs- und Lehraufgaben auch ärztliche oder zahnärztliche Leistungen unmittelbar am Menschen erbracht werden, führen die Bezeichnung „Universitätsklinik“.

(3) Die Organisationseinheiten einer Medizinischen Universität bzw. einer Medizinischen Fakultät, in denen im Rahmen einer Krankenanstalt neben Forschungs- und Lehraufgaben auch ärztliche Leistungen mittelbar für den Menschen erbracht werden, führen die Bezeichnung „Klinisches Institut“.

(4) Die Universitätskliniken und Klinischen Institute können in „Klinische Abteilungen“ gegliedert werden. In diesem Fall obliegt der Leiterin oder dem Leiter der Klinischen Abteilung die Verantwortung für die zu erfüllenden ärztlichen Aufgaben gemäß § 7b Abs. 1 KAKuG.

Structure of the Clinical Department

§ 31. (1) The clinical department of a medical university or a faculty of medicine shall comprise those units that simultaneously function as organisational units of a public hospital.

(2) The organisational units of a medical university or a faculty of medicine that, within a hospital, apart from their research and teaching tasks, directly provide patients with medical and dental care shall be designated as “university clinics”.

(3) Those organisational units of a medical university or a faculty of medicine that, within a hospital, apart from their research and teaching tasks, indirectly provide patients with medical care shall be designated as “clinical institutes”.

(4) The university clinics and clinical institutes may be structured into “clinical sections”. Where this occurs, the head of the clinical section shall be responsible for the performance of medical tasks according § 7b para 1 of the Hospitals and Health Resorts Act.

Leitungsfunktionen im Klinischen Bereich

§ 32. (1) Die Leiterin oder der Leiter einer Organisationseinheit oder einer Klinischen Abteilung einer Medizinischen Universität bzw. einer Medizinischen Fakultät, die gleichzeitig die Funktion einer Krankenabteilung oder einer gleichzuwertenden Einrichtung einer öffentlichen Krankenanstalt (§ 7 Abs. 4, § 7a Abs. 1 sowie § 7b Abs. 1 und 2 KAKuG) hat, ist vom Rektorat zu bestellen. Zur Leiterin oder zum Leiter ist eine entsprechend qualifizierte Person mit einem aufrechten Dienstverhältnis zum Bund, die der Universität zur Dienstleistung zugewiesen ist, oder mit einem aufrechten Arbeitsverhältnis zur Universität oder eine entsprechend qualifizierte Person mit einschlägiger Facharzt- oder Zahnarztbefugnis, die in ein Arbeitsverhältnis zur Universität aufgenommen werden soll, zu bestellen. Die Bestellung hat nach Anhörung der Universitätsprofessorinnen und Universitätsprofessoren der betreffenden Organisationseinheit zu erfolgen. Zur Stellvertreterin oder zum Stellvertreter der Leiterin oder des Leiters darf nur eine Universitätsangehörige oder ein Universitätsangehöriger mit entsprechender

Governing Positions in the Clinical Department

§ 32. (1) The rectorate shall appoint the head of an organisational unit or a clinical section of a medical university or a faculty of medicine which simultaneously fulfils the function of a clinical department or other equivalent unit of a public hospital (§ 7 para 4, § 7a para 1 as well as § 7b paras 1 and 2 KAKuG). The person to be appointed as the head shall have relevant qualifications and shall be employed by the Federal Government and assigned to the university, or employed by the university; Furthermore, a suitably skilled person with relevant medical specialist or dental qualifications who is to be accepted into an employment relationship with the university may be appointed. The appointment shall be made after hearing the university professors of the respective organisational unit. Only university members with relevant qualifications as a medical specialist or dentist may be appointed as deputy head. Prior to the appointment, the maintaining body of the attached hospital shall have the opportunity to give its opinion.

Qualifikation als Fachärztin oder Facharzt oder als Zahnärztin oder Zahnarzt bestellt werden. Vor der Bestellung ist dem Rechtsträger der Krankenanstalt Gelegenheit zur Stellungnahme zu geben.

(1a) Die Leiterin oder der Leiter einer Organisationseinheit oder einer Klinischen Abteilung einer Medizinischen Universität bzw. einer Medizinischen Fakultät, die gleichzeitig die Funktion einer Krankenabteilung oder einer gleichzuwertenden Einrichtung einer öffentlichen Krankenanstalt (§ 7 Abs. 4, § 7a Abs. 1 sowie § 7b Abs. 1 und 2 KAKuG) hat, kann vom Rektorat wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder gesundheitlicher Eignung oder wegen eines begründeten Vertrauensverlustes von ihrer oder seiner Funktion abberufen werden. Vor der Abberufung ist dem Rechtsträger der Krankenanstalt Gelegenheit zur Stellungnahme zu geben.

(2) Die Bestellung zur Leiterin oder zum Leiter sowie zur Stellvertreterin oder zum Stellvertreter der Leiterin oder des Leiters einer im Abs. 1 genannten Organisationseinheit oder einer Klinischen Abteilung hat zunächst zeitlich befristet zu erfolgen.

(3) Die erstmalige Einbeziehung von Organisationseinheiten einer Krankenanstalt in den Klinischen Bereich einer Medizinischen Universität bzw. einer Universität, an der eine Medizinische Fakultät eingerichtet ist, wird jeweils erst zeitgleich mit der Bestellung einer Universitätsprofessorin oder eines Universitätsprofessors gemäß § 98 zur Leiterin oder zum Leiter der betreffenden Organisationseinheit (Universitätsklinik, Klinisches Institut, Klinische Abteilung) gemäß Abs. 1 wirksam.

Kostenersatz an den Krankenanstaltenträger

§ 33. Die Medizinischen Universitäten bzw. die Universitäten, an denen eine Medizinische Fakultät eingerichtet ist, sind verpflichtet, die Kostenersätze gemäß § 55 KAKuG namens des Bundes an den jeweiligen Rechtsträger der Krankenanstalt zu leisten. Ausgenommen davon sind die Kostenersätze des Bundes für Klinikneubauten und Klinikumbauten sowie für die Ersteinrichtung dieser Gebäude.

Vertreterinnen und Vertreter der Ärzte und Zahnärzte

§ 34. Die im Klinischen Bereich einer Medizinischen Universität bzw. einer Medizinischen Fakultät tätigen Ärztinnen und Ärzte sowie Zahnärztinnen und Zahnärzte mit Ausnahme der Leiterinnen und Leiter von Organisationseinheiten

(1a) The head of an organisational unit or a clinical section at a medical university or a faculty of medicine that simultaneously fulfils the function of a ward or like unit of a public hospital (§ 7 para 4, § 7a para 1 and § 7b paras 1 and 2 of the Hospitals and Health Resorts Act) may be dismissed by the rectorate due to severe misconduct, conviction of a criminal offence, health impairment, or loss of confidence on reasonable grounds. Prior to the dismissal, the maintaining body of the attached hospital shall have the opportunity to give its opinion.

(2) Appointments as the head or deputy head of an organisational unit or a clinical section under para 1 shall initially be for a limited term.

(3) The initial inclusion of organisational units of a hospital into the clinical department of a medical university or a university at which a faculty of medicine has been established shall become effective together with the appointment of a university professor under § 98 as the head of the respective organisational unit (university clinic, clinical institute, clinical section) under para 1.

Reimbursement of Hospital Maintaining Bodies' Costs

§ 33. The medical universities or the universities at which a faculty of medicine has been established shall be obliged to reimburse the costs under § 55 of the Hospitals and Health Resorts Act to the maintaining body of the attached hospital on behalf of the Federal Government. The reimbursement by the Federal Government of the costs of new clinic buildings and alterations to clinic buildings as well as the costs of the initial furnishings of such buildings shall be exempt from these arrangements.

Doctors' and Dentists' Representatives

§ 34. The doctors and dentists working in the clinical department of a medical university or a faculty of medicine, excluding the heads of organisational units (§ 32), shall elect five representatives from among their number to perform the duties

(§ 32) haben zur Wahrnehmung der Aufgaben gemäß § 3 Abs. 3 des Krankenanstalten-Arbeitszeitgesetzes, BGBl. I Nr. 8/1997, aus ihrer Mitte fünf Vertreterinnen oder Vertreter zu wählen.

Lehreinrichtungen

§ 35. (1) Krankenanstalten oder Einrichtungen von Krankenanstalten, die nicht zum Klinischen Bereich einer Medizinischen Universität bzw. einer Medizinischen Fakultät gehören, können von den Medizinischen Universitäten bzw. den Universitäten, an denen eine Medizinische Fakultät eingerichtet ist, mit Zustimmung des Rechtsträgers der Krankenanstalt zur Verbesserung und Intensivierung des praktisch-medizinischen Unterrichts herangezogen werden. Diesen Krankenanstalten kann von der betreffenden Medizinischen Universität bzw. von der betreffenden Universität, an der eine Medizinische Fakultät eingerichtet ist, die Bezeichnung „Lehrkrankenhaus“ verliehen werden.

(2) Ärztliche Einrichtungen im niedergelassenen Bereich können von den Medizinischen Universitäten bzw. den Universitäten, an denen eine Medizinische Fakultät eingerichtet ist, mit deren Zustimmung zur Verbesserung und Intensivierung des praktisch-medizinischen Unterrichts herangezogen werden. Diesen Einrichtungen kann von der betreffenden Medizinischen Universität bzw. von der betreffenden Universität, an der eine Medizinische Fakultät eingerichtet ist, die Bezeichnung „Lehrordination“ verliehen werden.

Klinisch-Praktisches Jahr

§ 35a. (1) Das Klinisch-Praktische Jahr ist Teil des Studiums der Humanmedizin und dient dem Erwerb und der Vertiefung ärztlicher Fertigkeiten, insbesondere im Bereich des praktisch-medizinischen Unterrichts.

(2) Die aktive Teilnahme an der Betreuung von Patientinnen und Patienten ist nach Maßgabe der Vorschriften des Ärztegesetzes 1998, BGBl. I Nr. 169/1998, möglich. Diese Teilnahme an der Betreuung von Patientinnen und Patienten ist dem Rechtsträger der Lehreinrichtung und nicht der Medizinischen Universität bzw. der Universität, an der eine Medizinische Fakultät eingerichtet ist, oder den in Ausbildung stehenden Studierenden zuzurechnen. Ein Dienst- oder Arbeitsverhältnis zum Rechtsträger der Lehreinrichtung wird dadurch nicht begründet.

(3) Bloße Unterstützungsleistungen zur Lebensführung der Studierenden durch den Rechtsträger der Lehreinrichtung begründen kein Dienst- oder Arbeitsverhältnis.

stipulated in § 3 para 3 of the Hospital Working Hours Act (KA-AZG), Federal Law Gazette I No. 8/1997.

Training Units

§ 35. (1) Subject to approval by the maintaining body of the attached hospital, hospitals or hospital units that are not part of the clinical department of a medical university or a faculty of medicine may be called upon by the medical universities or those universities at which a faculty of medicine has been established for the purpose of improving and intensifying practical medical training. This hospital may be awarded the title of “training hospital” by the medical university in question or the university in question at which a faculty of medicine has been established.

(2) Medical facilities in the private practice area may, subject to their approval, be called upon by the medical universities or those universities at which a faculty of medicine has been established, for the purpose of improving and intensifying practical medical training. These facilities may be awarded the title of “training practice” by the medical university in question or the university in question at which a faculty of medicine has been established.

Clinical Internship Year

§ 35a. (1) The clinical internship year shall be a part of the studies in human medicine and shall serve the purpose of acquiring and refining medical skills, particularly in the area of practical clinical training.

(2) The active involvement in the care of patients shall be permissible in accordance with the provisions of the Physicians Act 1998, F. L. G. I No 169/1998. This involvement in the care of patients shall be in the sphere of the maintaining body of the attached training unit and not the medical university or the university at which a faculty of medicine has been established or the students undergoing training. This shall not give rise to an employment contract with the maintaining body of the attached training unit.

(3) Support provided by the maintaining body of the attached training unit to assist students with their cost of living shall not give rise to an employment contract.

Zahnmedizinisch-Klinisches Praktikum

§ 35b. (1) Das Zahnmedizinisch-Klinische Praktikum ist Teil des Studiums der Zahnmedizin und dient dem Erwerb und der Vertiefung von zahnärztlichen Fertigkeiten, insbesondere im Bereich des praktisch-medizinischen Unterrichts.

(2) Die aktive Teilnahme an der Betreuung von Patientinnen und Patienten ist nach Maßgabe der Vorschriften des Zahnärztegesetzes, BGBl. I Nr. 126/2005, möglich. Diese Teilnahme an der Betreuung von Patientinnen und Patienten ist dem Rechtsträger der Lehreinrichtung und nicht der Medizinischen Universität oder den in Ausbildung stehenden Studierenden zuzurechnen. Ein Dienst- oder Arbeitsverhältnis zum Rechtsträger der Lehreinrichtung wird dadurch nicht begründet.

(3) Bloße Unterstützungsleistungen zur Lebensführung der Studierenden durch den Rechtsträger der Lehreinrichtung begründen kein Dienst- oder Arbeitsverhältnis.

4. Unterabschnitt
Sonderbestimmungen für die Veterinärmedizinische Universität Wien

Tierspital

§ 36. (1) Die Organisationseinheiten der Veterinärmedizinischen Universität Wien, die neben ihren Lehr- und Forschungsaufgaben auch tierärztliche Leistungen unmittelbar an lebenden Tieren zu erbringen haben, führen die Bezeichnung „Universitätsklinik“ und bilden gemeinsam organisatorisch das „Tierspital“.

(2) Für das Tierspital ist vom Rektorat durch Verordnung eine Anstaltsordnung zu erlassen, die der Genehmigung des Universitätsrats bedarf.

(3) Zu Leiterinnen und Leitern der Organisationseinheiten des Tierspitals dürfen nur Personen mit facheinschlägiger Qualifikation bestellt werden.

(4) Das den Organisationseinheiten des Tierspitals zugeordnete Personal hat an der Erfüllung der Aufgaben mitzuwirken, die dem Tierspital im Rahmen der Untersuchung und Behandlung von Tieren obliegen.

(5) Die Leiterinnen und Leiter der Organisationseinheiten des Tierspitals sind berechtigt, im Namen der Veterinärmedizinischen Universität Wien Verträge über die Erbringung tierärztlicher Leistungen abzuschließen.

Dental-Clinical Internship

§ 35b. (1) The dental-clinical internship shall be a part of the studies in dental medicine and shall serve the purpose of acquiring and refining skills, particularly in the area of practical medical training.

(2) The active involvement in the care of patients shall be permissible in accordance with the provisions of the Dentists Act, F. L. G. I No 126/2005. This involvement in the care of patients shall be in the sphere of the maintaining body of the attached training unit and not of the medical university or the students undergoing training. This shall not give rise to an employment contract with the maintaining body of the attached training unit.

(3) Support provided by the maintaining body of the attached training unit to assist students with their cost of living shall not give rise to an employment contract.

Sub-Chapter 4
Special Provisions for the University of Veterinary Medicine Vienna

Veterinary Hospital

§ 36. (1) The organisational units of the University of Veterinary Medicine Vienna which, apart from their teaching and research tasks, also directly provide veterinary care for live animals shall bear the title “university clinic” and shall, in organisational terms, collectively constitute the “veterinary hospital”.

(2) The rectorate shall, by decree, enact hospital regulations for the animal hospital which shall require the approval of the university council.

(3) Appointments as heads of organisational units of the veterinary hospital shall be restricted to persons with relevant qualifications.

(4) Staff assigned to the organisational units of the veterinary hospital shall assist in the fulfilment of the hospital’s tasks in respect of the examination and treatment of animals.

(5) The heads of organisational units of the veterinary hospital shall be entitled to make agreements for the provision of veterinary services on behalf of the University of Veterinary Medicine Vienna.

(6) Die Wahrnehmung der tierärztlichen Aufgaben im Rahmen des Tierspitals ist von der autonomen Besorgung durch die Universität gemäß § 5 ausgenommen (§ 70 Abs. 4 UOG 1993).

Veterinärmedizinische Lehrinstitute und Organisationseinheit für Wildtierkunde und Ökologie

§ 37. (1) Tierkliniken, die nicht zur Veterinärmedizinischen Universität Wien gehören, und Tierarztpraxen können vom Rektorat mit Zustimmung der Betreiberin oder des Betreibers der Tierklinik oder der Tierarztpraxis zur Verbesserung und Intensivierung des praktisch-veterinärmedizinischen Unterrichts herangezogen werden. Wird eine Tierklinik oder eine Tierarztpraxis ständig zu diesem Zweck herangezogen, kann dieser die Bezeichnung „Veterinärmedizinisches Lehrinstitut“ verliehen werden.

(2) An der Veterinärmedizinischen Universität Wien ist eine Organisationseinheit mit der Bezeichnung „Forschungsinstitut für Wildtierkunde und Ökologie“ einzurichten.

(3) Die im Abs. 2 genannte Organisationseinheit ist in der Leistungsvereinbarung und im Rechnungsabschluss gesondert auszuweisen.

5. Unterabschnitt

Sonderbestimmungen für die Katholische und die Evangelische Theologie

§ 38. (1) Die Universitäten, deren Wirkungsbereich sich auch auf Studien der Katholischen Theologie erstreckt, haben bei der Gestaltung ihrer inneren Organisation und der Studienvorschriften sowie bei der Sicherstellung des Lehr- und Forschungsbetriebs das Konkordat zwischen dem Heiligen Stuhle und der Republik Österreich, BGBl. II Nr. 2/1934, zu beachten. Die Verpflichtung zur Einholung der Zustimmung gemäß Art. V § 3 und zu einer allfälligen Enthebung von der Ausübung der Lehrbefugnis gemäß Art. V § 4 obliegt der Rektorin oder dem Rektor.

(2) Die Universität, deren Wirkungsbereich sich auch auf Studien der Evangelischen Theologie erstreckt, hat bei der Gestaltung ihrer internen Organisation und der Studienvorschriften sowie bei der Sicherstellung des Lehr- und Forschungsbetriebs § 15 des Bundesgesetzes über äußere Rechtsverhältnisse der Evangelischen Kirche, BGBl. Nr. 182/1961, zu beachten. Die Verpflichtung, gemäß § 15 Abs. 4 des Bundesgesetzes über äußere Rechtsverhältnisse der Evangelischen Kirche vor der Auswahl aus dem Besetzungsvorschlag mit der Evangelischen Kirche Kontakt aufzunehmen, obliegt der Rektorin oder dem Rektor.

(6) The fulfilment of veterinary tasks of the veterinary hospital is excepted from the autonomous provision of veterinary services by the University according to § 5 (§ 70 para 4 University Organisation Act 1993).

Veterinary Teaching Institutes and the Organisational Unit for Wildlife Ecology

§ 37. (1) The rectorate may enlist the assistance of veterinary clinics not forming part of the University of Veterinary Medicine Vienna, and veterinary practices to improve and intensify practical veterinary training, subject to the agreement of the operators of such clinics or practices. If a veterinary clinic or practice is permanently employed for such purposes it may be awarded the title of “veterinary teaching institute”.

(2) An organisational unit entitled “Research Institute of Wildlife Ecology” shall be established at the University of Veterinary Medicine Vienna.

(3) The organisational unit named in para 2 shall be separately presented in the performance agreement and financial statements.

Sub-Chapter 5

Special Provisions for Catholic and Protestant Theology

§ 38. (1) Universities whose activities include the teaching of Catholic theology shall, in the design of their internal organisation and study regulations, and in securing such teaching and research, observe the Concordat between the Holy See and the Republic of Austria, Federal Law Gazette II No. 2/1934. The rector shall be responsible for seeking Church approval of appointments under Art V § 3 and for withdrawing authorisations to teach under Art V § 4.

(2) Universities whose activities include the teaching of Protestant theology shall, in the design of their internal organisation and study regulations, and in securing such teaching and research, observe § 15 of the Legal Relations with the Protestant Church Act, F. L. G. No 182/1961. The rector shall be responsible for fulfilling the obligation according to § 15 para 4 of the Legal Relations with the Protestant Church Act to consult the Protestant Church prior to the selection of shortlisted candidates for appointments.

6. Unterabschnitt
Sonderbestimmungen für die Akademie der bildenden Künste Wien

Gemäldegalerie und Kupferstichkabinett

§ 39. (1) An der Akademie der bildenden Künste Wien sind folgende Organisationseinheiten einzurichten:

1. die „Gemäldegalerie der Akademie der bildenden Künste Wien“, der eine Glyptothek eingegliedert ist;
2. das „Kupferstichkabinett“.

Bei der Organisation dieser beiden Einrichtungen sind die Aufgaben und die besondere Stellung dieser Einrichtungen zu berücksichtigen.

(2) Die Gemäldegalerie ist eine durch eine Stiftung geschaffene Einrichtung. Sie hat die Aufgaben der gleichnamigen Einrichtung gemäß § 46 des Bundesgesetzes über die Organisation der Universitäten der Künste (KUOG) weiterzuführen. Sie hat durch ständige Schausammlungen und zusätzliche Ausstellungen für eine Darbietung ausgewählter Objekte ihrer Sammlungen für die Öffentlichkeit zu sorgen.

(3) Das Kupferstichkabinett hat die Aufgaben der gleichnamigen Einrichtung gemäß § 65 KUOG weiterzuführen. Es hat ausgewählte Objekte seiner Sammlung der Öffentlichkeit darzubieten.

(4) Zur gemeinsamen Leiterin oder zum gemeinsamen Leiter der Gemäldegalerie und des Kupferstichkabinetts darf nur eine Person mit einschlägiger Ausbildung und entsprechend hoher fachlicher Qualifikation bestellt werden. Die Bestellung hat zunächst auf fünf Jahre befristet zu erfolgen. Eine Wiederbestellung ist möglich. Die Leiterin oder der Leiter der Gemäldegalerie und des Kupferstichkabinetts trägt die Funktionsbezeichnung „Direktorin“ oder „Direktor“.

(5) Die Gemäldegalerie und das Kupferstichkabinett sind in der Leistungsvereinbarung und im Rechnungsabschluss der Akademie der bildenden Künste Wien gesondert auszuweisen.

Sub-Chapter 6
Special Provisions for the Academy of Fine Arts Vienna

Art Gallery and Collection of Copperplate Engravings

§ 39. (1) The following organisational units shall be established at the Academy of Fine Arts Vienna:

1. the Art Gallery of the Academy of Fine Arts Vienna, which incorporates a collection of glyptic art;
2. the Collection of Copperplate Engravings.

The organisation of these units shall take account of their functions and their special importance.

(2) The Art Gallery shall be established by a foundation. It shall assume the responsibilities under the § 46 of the Universities of the Arts Organisation Act hitherto performed by the institution of the same name. It shall secure that selected objects from its collections are exhibited to the public by means of permanent and additional exhibitions.

(3) The Collection of Copperplate Engravings shall assume the responsibilities of the institution of that name according to § 65 Universities of the Arts Organisation Act. It shall exhibit selected objects from its collection to the public.

(4) The appointment as the joint director of the Art Gallery and of the Collection of Copperplate Engravings shall be restricted to a person with relevant training and correspondingly high professional qualifications. The initial appointment shall be limited to five years. A re-appointment is permissible. The head of the Art Gallery and of the Collection of Copperplate Engravings shall bear the title of “Director”.

(5) The Art Gallery and the Collection of Copperplate Engravings shall be separately presented in the performance agreement and financial statements of the Academy of Fine Arts Vienna.

7. Unterabschnitt

Universitäts-Sportinstitute

§ 40. (1) An den Universitäten gemäß § 6 Abs. 1 Z 1, 2, 3, 7, 10, 14, 15 und 22 sind Universitäts-Sportinstitute eingerichtet, die den Studierenden bis zwei Semester

Sub-Chapter 7

University Sports Centres

§ 40. (1) At the universities named according to § 6 para 1 subparas 1, 2, 3, 7, 10, 14, 15 and 22 university sports centres shall be established which shall be open

nach Studienabschluss und Mitarbeiterinnen und Mitarbeitern der Universitäten, der Pädagogischen Hochschulen, der Fachhochschulen und der Privatuniversitäten des Universitätsstandortes für sportliche Tätigkeiten und Wettkämpfe zur Verfügung stehen.

(2) Die Universitäts-Sportinstitute sind in der Leistungsvereinbarung und im Rechnungsabschluss, sowie in der Wissensbilanz der betreffenden Universität gesondert auszuweisen.

(3) Mittel, die dem Universitäts-Sportinstitut aus dem freiwilligen Hochschulsport, sowie aus dem Betrieb von Universitätssportanlagen zufließen, sind für die Zwecke des Universitäts-Sportinstituts zu verwenden.

(4) Zur Leiterin oder zum Leiter eines Universitäts-Sportinstituts darf nur eine Person mit einschlägiger Ausbildung und entsprechender fachlicher Qualifikation bestellt werden.

(5) Das Rektorat einer Universität mit Universitäts-Sportinstitut kann Richtlinien zur Aufnahme von sonstigen Personengruppen in den Teilnehmerinnen- und Teilnehmerkreis des Universitäts-Sportinstituts der Universität zu marktüblichen Preisen erlassen.

8. Unterabschnitt
Sonderbestimmungen für die Universität Wien

Institut für Österreichische Geschichtsforschung

§ 40a. (1) An der Universität Wien ist eine Organisationseinheit mit der Bezeichnung „Institut für Österreichische Geschichtsforschung“ einzurichten. Bei der Organisation dieser Einrichtung sind die Aufgaben in Forschung und Lehre und die besondere Stellung des Instituts für Österreichische Geschichtsforschung im Kontext der Geschichtswissenschaften und des Archivwesens auf nationaler und internationaler Ebene zu berücksichtigen.

(2) Die Aufgaben des Instituts für Österreichische Geschichtsforschung umfassen im Hinblick auf seine Bedeutung im Bereich der Geschichtswissenschaften insbesondere die Planung und Durchführung von Forschungsvorhaben auf dem Gebiet der europäischen Geschichte des Mittelalters und der Neuzeit sowie der österreichischen Geschichte mit einem Schwerpunkt auf den Historischen Hilfswissenschaften, der Quellenedition und Quellenerschließung auf der Grundlage anerkannter internationaler Standards und deren Dokumentation und Publikation.

to students up to two semesters after graduation, staff of universities, university colleges of teacher education, universities of applied sciences and private universities for sporting activities and competitions.

(2) The university sports centres shall be separately presented in the performance agreements, the financial statements and the intellectual capital report of the universities concerned.

(3) Funds accruing to a university sports centre from voluntary university sporting activities and the operation of university sports facilities shall be employed for the purpose of the university sports centre.

(4) Appointments as the head of a university sports centre shall be restricted to persons with relevant training and appropriate professional qualifications.

(5) The rectorate of a university with a university sports centre may adopt guidelines on the admission of other groups of persons to the circle of participants of the university sports centre of the university at market rates.

Sub-Chapter 8
Special Provisions for the University of Vienna

Austrian Institute of Historical Research

§ 40a. (1) At the University of Vienna, an organisational unit with the designation “Austrian Institute of Historical Research“ shall be established. The organisation of this unit shall take into account the duties in research and teaching and the particular position of the Austrian Institute of Historical Research in the context of historical research and archive management nationally and internationally.

(2) In view of its significance in the field of historical research, the tasks of the Austrian Institute of Historical Research shall encompass in particular the planning and completion of research projects in the area of European medieval and modern history as well as Austrian history, with an emphasis on auxiliary sciences of history, primary-source editions, and locating and indexing sources on the basis of recognized international standards, and their documentation and publication.

(3) Zur Leiterin oder zum Leiter des Instituts für Österreichische Geschichtsforschung darf nur eine Person mit einschlägiger Ausbildung und entsprechend hoher fachlicher Qualifikation bestellt werden. Die Leiterin oder der Leiter des Instituts für Österreichische Geschichtsforschung trägt die Funktionsbezeichnung „Direktorin“ oder „Direktor“.

(4) Das Institut für Österreichische Geschichtsforschung ist in der Leistungsvereinbarung und im Rechnungsabschluss der Universität Wien gesondert auszuweisen.

9. Unterabschnitt
Sonderbestimmungen für die Universität für Weiterbildung Krems

Geltungsbereich

§ 40b. (1) Die Universität für Weiterbildung Krems gemäß § 6 Abs. 1 Z 22 ist Gesamtrechtsnachfolgerin der Universität gemäß § 2 des Bundesgesetzes über die Universität für Weiterbildung Krems (UWK-Gesetz – UWKG), BGBl. I Nr. 22/2004, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 31/2018.

(2) Der Wirkungsbereich der Universität für Weiterbildung Krems ergibt sich aus den am 31. Dezember 2021 an dieser Universität eingerichteten Studien und Forschungseinrichtungen.

(3) Änderungen des Wirkungsbereiches sind nur im Wege der Leistungsvereinbarung gemäß § 13 oder durch Verordnung der Bundesregierung gemäß § 8 zulässig und haben unter Berücksichtigung der Vereinbarung gemäß Art. 15a B-VG zwischen dem Bund und dem Land Niederösterreich über die Errichtung und den Betrieb des Universitätszentrums für Weiterbildung (Donau-Universität Krems), BGBl. Nr. 501/1994, Abschnitt V, der Vereinbarung gemäß Art. 15a B-VG zwischen dem Bund und dem Land Niederösterreich über den Ausbau des Universitätszentrums für Weiterbildung (Donau-Universität Krems) samt Anlage, BGBl. I Nr. 81/2004, sowie der Vereinbarung gemäß Art. 15a B-VG zwischen dem Bund und dem Land Niederösterreich über die weitere Entwicklung der Universität für Weiterbildung Krems, BGBl. I Nr. 9/2019, zu erfolgen.

(3) Only a person with a relevant education and appropriate professional qualifications can be appointed as the head of the Austrian Institute of Historical Research. The head of the Austrian Institute of Historical Research shall be designated as “director”.

(4) The Austrian Institute of Historical Research shall be accounted for separately in the performance agreement and the accounts of the University of Vienna.

Sub-Chapter 9
Special Provisions for the University for Continuing Education Krems

Scope of Application

§ 40b. (1) The University for Continuing Education Krems according to § 6 para 1 subpara 22 shall be the universal successor of the university in the meaning of § 2 of the Federal Act on the University for Continuing Education Krems (Bundesgesetz über die Universität für Weiterbildung Krems – UWKG), F. L. G. I No 22/2004, last amended by the Federal Act published in F. L. G. I No 31/2018.

(2) The sphere of action of the University for Continuing Education Krems shall correspond to the study programmes and research institutions at this university as constituted on 31 December 2021.

(3) Modifications to the spheres of action are only permissible by way of the performance agreement according to § 13 or by decree of the Federal Government according to § 8 and shall take into account the agreement according to Art 15a B-VG between the Federal Government and the Provincial Government of Lower Austria on the Establishment and the Maintenance of the University Center for Further Studies (Danube University Krems) together with its Appendix, F. L. G. No 501/1994, Chapter V, the agreement according to Art 15a B-VG between the Federal Government and the Provincial Government of Lower Austria on the Extension of the University Center for Further Studies (Danube University Krems) together with its Appendix, F. L. G. I No 81/2014, as well as the agreement according to Art. 15a B-VG between the Federal Government and the Provincial Government of Lower Austria on the Further Development of the University for Continuing Education Krems, F. L. G. I No 9/2019.

Aufgaben

§ 40c. (1) Die Universität für Weiterbildung Krems ist berufen, der im Zusammenhang mit Weiterbildung stehenden wissenschaftlichen Lehre und Forschung zu dienen.

(2) Die Universität für Weiterbildung Krems hat im Rahmen dieses Wirkungsbereiches insbesondere folgende Aufgaben zu erfüllen:

1. Entwicklung und Durchführung von Universitätslehrgängen;
2. wissenschaftliche Forschung zur Unterstützung der Lehre in den Universitätslehrgängen;
3. Entwicklung zu einem Kompetenzzentrum für Weiterbildung;
4. Berücksichtigung neuer Lehr- und Lernformen, insbesondere auch der Fernlehre;
5. Weiterentwicklung des Qualitätsmanagementsystems zur Qualitäts- und Leistungssicherung;
6. Heranbildung und Förderung des wissenschaftlichen Nachwuchses, insbesondere durch Doktoratsstudien gemäß § 40d Abs. 1 ~~und 2~~.

Studien und Organisation

§ 40d. (1) Die Universität für Weiterbildung Krems ist berechtigt, Universitätslehrgänge, das ordentliche Masterstudium Psychotherapie und Doktoratsstudien ~~gemäß Abs. 2~~ anzubieten.

~~(2) Die Einrichtung eines Doktoratsstudiums bedarf einer Studiengangsakkreditierung gemäß den §§ 18 ff und 24 ff des Hochschul-Qualitätssicherungsgesetzes (HS-QSG), BGBl.~~ *(Anm.: Abs. 2 aufgehoben durch Art. 1 Z 21, BGBl. I Nr. 50/2024)*

(3) Die Bestimmungen dieses Bundesgesetzes über die Bestellung der Mitglieder des Universitätsrates durch die Bundesregierung gelten mit der Maßgabe, dass die Bundesministerin oder der Bundesminister ein Mitglied auf Vorschlag der Niederösterreichischen Landesregierung der Bundesregierung zur Bestellung vorzuschlagen hat.

Finanzierung

§ 40e. (1) Die Finanzierung der Universität für Weiterbildung Krems erfolgt gemäß der Vereinbarung zwischen dem Bund und dem Land Niederösterreich über die Errichtung und den Betrieb des Universitätszentrums für Weiterbildung (Donau-Universität Krems) samt Anlage, BGBl. Nr. 501/1994, der Vereinbarung gemäß

Tasks

§ 40c. (1) The mission of the University for Continuing Education Krems is to serve academic teaching and research in connection with continuing education.

(2) Within its sphere of action, the University for Continuing Education Krems shall fulfil the following tasks, in particular:

1. developing and implementing continuing education university programmes;
2. academic research to support teaching in the continuing education university programmes;
3. developing into a competence centre for continuing education;
4. taking into account new forms of teaching and learning, in particular distance learning;
5. further advancing the quality management system to assure the quality and the attainment of their performance objectives;
6. training and career promotion of junior academics, in particular by offering doctoral programmes in the meaning of § 40d paras 1 and 2.

Study programmes and organisation

§ 40d. (1) The University for Continuing Education Krems shall be entitled to offer continuing education university programmes and doctoral programmes in the meaning of para 2.

(2) The establishment of a doctoral programme shall require a programme accreditation according to §§ 18ff and 24ff of the Act on Quality Assurance in Higher Education (Hochschul-Qualitätssicherungsgesetz – HS-QSG), F. L. G I No 74/2011.

(3) The provisions of this Act on the appointment of members of the university council by the Federal Government shall apply, providing that the Federal Minister shall nominate a member on the recommendation of the Provincial Government of Lower Austria to be appointed by the Federal Government.

Funding

§ 40e. (1) The funding of the University for Continuing Education Krems shall be subject to the agreement between the Federal Government and the Provincial Government of Lower Austria on the Establishment and the Maintenance of the University Center for Further Studies (Danube University Krems) together with its

Art. 15a B-VG zwischen dem Bund und dem Land Niederösterreich über den Ausbau des Universitätszentrums für Weiterbildung (Donau-Universität Krems) samt Anlage, BGBl. I Nr. 81/2004, sowie der Vereinbarung gemäß Art. 15a B-VG zwischen dem Bund und dem Land Niederösterreich über die weitere Entwicklung der Universität für Weiterbildung Krems, BGBl. I Nr. 9/2019.

(2) Die §§ 12 und 12a sind auf die Finanzierung der Universität für Weiterbildung Krems gemäß Abs. 1 nicht anzuwenden.

(3) § 13 ist unter Berücksichtigung der besonderen Aufgabenstellung der Universität für Weiterbildung Krems sinngemäß anzuwenden. § 13 Abs. 2 Z 2 ist mit der Maßgabe anzuwenden, dass eine Gliederung in Teilbeträge gemäß § 12a Abs. 2 Z 1 bis 3 nicht zu erfolgen hat.

(4) Abweichend von § 56 Abs. 3 ist der Lehrgangsbeitrag für die an der Universität für Weiterbildung Krems angebotenen Universitätslehrgänge kostendeckend festzulegen, wobei die Kostendeckung in der Gesamtheit der angebotenen Universitätslehrgänge an der Universität für Weiterbildung Krems zu erreichen ist. Als Kosten in diesem Sinn gelten die angebotsabhängigen variablen Lehrgangskosten.

3. Abschnitt
Gleichstellung der Geschlechter und Frauenförderung

Frauenfördergebot

§ 41. Alle Organe der Universität haben darauf hinzuwirken, dass in allen universitären Arbeitsbereichen ein ausgewogenes Zahlenverhältnis zwischen den an der Universität tätigen Frauen und Männern erreicht wird. Die Erreichung dieses Ziels ist durch geeignete Maßnahmen, insbesondere durch die Erlassung und Umsetzung eines Frauenförderungsplans, anzustreben.

Arbeitskreis für Gleichbehandlungsfragen

§ 42. (1) An jeder Universität ist vom Senat ein Arbeitskreis für Gleichbehandlungsfragen einzurichten, dessen Aufgabe es ist, Diskriminierungen durch Universitätsorgane auf Grund des Geschlechts sowie auf Grund der ethnischen Zugehörigkeit, der Religion oder Weltanschauung, des Alters oder der sexuellen

Appendix, F. L. G. No 501/1994, the agreement according to Art 15a B-VG between the Federal Government and the Provincial Government of Lower Austria on the Extension of the University Center for Further Studies (Danube University Krems) together with its Appendix, F. L. G. I No 81/2014, as well as the agreement according to Art. 15a B-VG between the Federal Government and the Provincial Government of Lower Austria on the Further Development of the University for Continuing Education Krems, F. L. G. I No 9/2019.

(2) According to para 1, §§ 12 and 12a shall not apply to the funding of the University for Continuing Education Krems.

(3) § 13 shall apply by analogy, taking into account the special tasks of the University for Continuing Education Krems. § 13 para 2 subpara 2 shall apply, providing that a breakdown into the components according to § 12a para 2 subpara 1 does not have to be made.

(4) Notwithstanding § 56 para 3, the programme fees as determined for the continuing education university programmes offered at the University for Continuing Education Krems shall cover the costs; cost coverage shall be achieved in the totality of the continuing education university programmes offered at the University for Continuing Education Krems. Costs in this sense are the supply-dependent variable programme fees.

Chapter 3
Gender Equality and Career Advancement for Women

Duty of Career Advancement for Women

§ 41. All university bodies shall make efforts to achieve a balanced representation of men and women at work in all areas of university activities. Appropriate action shall be taken to attain this goal, particularly by means of the adoption and implementation of a career advancement plan for women.

Working Group on Equal Opportunities

§ 42. (1) The senate of each university shall establish a working group on equal opportunities responsible for combating gender discrimination as well as discrimination on the basis of ethnicity, religion or conviction, age, or sexual orientation by university governing bodies and for advising and supporting the university’s members and governing bodies in connection with these issues.

Orientierung entgegenzuwirken und die Angehörigen und Organe der Universität in diesen Angelegenheiten zu beraten und zu unterstützen.

(2) Die Anzahl der Mitglieder des Arbeitskreises für Gleichbehandlungsfragen ist in der Satzung festzulegen. Die im Senat vertretenen Gruppen von Universitätsangehörigen sind berechtigt, Mitglieder in einem in der Satzung festgelegten Verhältnis in den Arbeitskreis zu entsenden. Aus dem Kreis der Mitglieder des Arbeitskreises ist eine Vorsitzende oder ein Vorsitzender sowie zumindest ein Stellvertreter oder eine Stellvertreterin zu wählen. Die Funktionsperiode des Arbeitskreises für Gleichbehandlungsfragen beträgt drei Jahre und beginnt mit dem 1. Oktober des betreffenden Jahres. Die Mitglieder des Arbeitskreises für Gleichbehandlungsfragen dürfen für höchstens vier unmittelbar aufeinanderfolgende Funktionsperioden entsendet werden. Die gleichzeitige Mitgliedschaft im Senat und im Arbeitskreis für Gleichbehandlungsfragen ist unzulässig. Bis zur Konstituierung des Arbeitskreises für Gleichbehandlungsfragen, die längstens bis zu dem auf den Beginn der Funktionsperiode folgenden 1. März zu erfolgen hat, verlängert sich die Funktionsperiode des bis dahin eingerichteten Arbeitskreises für Gleichbehandlungsfragen.

(3) Die Mitglieder des Arbeitskreises für Gleichbehandlungsfragen sind bei der Ausübung ihrer Funktion an keine Weisungen oder Aufträge gebunden (Art. 81c B-VG). Sie dürfen bei der Ausübung ihrer Befugnisse nicht behindert und wegen dieser Tätigkeit in ihrem beruflichen Fortkommen nicht benachteiligt werden.

(4) Den Mitgliedern des Arbeitskreises ist vom Rektorat in allen inneruniversitären Angelegenheiten Auskunft zu erteilen sowie Einsicht in die Geschäftsstücke, Unterlagen und in die automationsunterstützt verarbeiteten Daten über das Personal der Universität zu geben, deren Kenntnis zur Erfüllung der Aufgaben des Arbeitskreises erforderlich ist. Auf Verlangen ist die Herstellung von Fotokopien dieser Unterlagen zu gestatten. Einsicht in die Personalakten ist nur mit Einwilligung der betroffenen Personen zulässig.

(5) Werden vom Arbeitskreis für Gleichbehandlungsfragen zur Vorbereitung seiner Beschlüsse Gutachten und Stellungnahmen facheinschlägiger Expertinnen oder Experten sowie Auskünfte eingeholt, dürfen diesen Expertinnen oder Experten die dafür erforderlichen Unterlagen zur Verfügung gestellt werden. Diese Expertinnen oder Experten sind zur Verschwiegenheit verpflichtet.

(6) Dem Arbeitskreis für Gleichbehandlungsfragen sind insbesondere unverzüglich zur Kenntnis zu bringen:

(2) The number of the members of the working group on equal opportunities shall be established by the statute. The groups of university members represented in the senate shall be entitled to delegate members to the working group in proportions established by the statute. The working group shall elect a chairperson from among its number as well as a minimum of one deputy chairperson. The term of office of the working group on equal opportunities shall be three years and shall commence on 1 October of the respective year. The members of the working group on equal opportunities may be delegated for a maximum of four consecutive terms of office. It shall not be permissible to be a member of the senate and of the working group on equal opportunities at the same time. Until the constitution of the working group on equal opportunities, which shall take place at the latest by 1 March following the beginning of the term of office, the term of office of the former working group on equal opportunities is extended.

(3) The members of the working group on equal opportunities shall not be bound by any instructions in the fulfilment of their tasks (Art 81c Federal Constitutional Law). They may not be obstructed in the fulfilment of their tasks, and shall not be disadvantaged in their career promotion as a result of these activities.

(4) The rectorate shall provide the working group on equal opportunities with information on all internal university matters, and shall grant it access to all documents and electronic data relating to the university's personnel, knowledge of which is necessary for the exercise of its tasks. Photocopying of such documents shall be permitted on request. Access to employees' files shall be subject to the consent of the persons concerned.

(5) In case that the working group on equal opportunities seeks reports, opinions or information from experts as a basis for its decisions, such experts shall be furnished with the necessary documentation. These experts shall be obliged to observe confidentiality.

(6) The following shall, in particular, be submitted to the working group on equal opportunities:

1. alle Ausschreibungstexte für die Besetzung von Stellen und Funktionen vor erfolgter Ausschreibung. Der Arbeitskreis hat das Recht, innerhalb von zwei Wochen ab Zustellung zur Ausschreibung Stellung zu nehmen;
2. die Liste der eingelangten Bewerbungen einschließlich der Bewerbungsunterlagen, sofern der Arbeitskreis für Gleichbehandlungsfragen nicht darauf verzichtet;
3. die Liste der zu Aufnahmegesprächen eingeladenen Bewerberinnen und Bewerber.

(7) Das Rektorat hat gleichzeitig mit der Information des zuständigen Betriebsrats den Arbeitskreis für Gleichbehandlungsfragen darüber in Kenntnis zu setzen, mit welcher Bewerberin oder mit welchem Bewerber ein Arbeitsvertrag abgeschlossen werden soll. Arbeitsverträge, die ohne vorherige Verständigung des Arbeitskreises oder vor Ablauf der Frist gemäß Abs. 8 abgeschlossen werden, sind unwirksam.

(8) Hat der Arbeitskreis für Gleichbehandlungsfragen Grund zur Annahme, dass die Entscheidung eines Universitätsorgans eine Diskriminierung von Personen auf Grund ihres Geschlechts oder auf Grund der ethnischen Zugehörigkeit, der Religion oder Weltanschauung, des Alters oder der sexuellen Orientierung oder einen Verstoß gegen das Frauenförderungsgebot oder gegen den Frauenförderungs- und Gleichstellungsplan der Universität darstellt, ist er berechtigt, innerhalb von drei Wochen die Schiedskommission anzurufen.

(8a) Das jeweilige Kollegialorgan hat den Arbeitskreis für Gleichbehandlungsfragen unverzüglich über seine Zusammensetzung zu informieren. Ist der Frauenanteil von mindestens 50 vH gemäß § 20a Abs. 2 nicht ausreichend gewahrt, so kann der Arbeitskreis für Gleichbehandlungsfragen binnen vier Wochen die Einrede der unrichtigen Zusammensetzung an die Schiedskommission erheben. Die Einrede der unrichtigen Zusammensetzung hat zu unterbleiben, wenn sachliche Gründe vorliegen. Ist das Kollegialorgan unrichtig zusammengesetzt, und erhebt der Arbeitskreis für Gleichbehandlungsfragen Einrede, sind die Beschlüsse des Kollegialorgans nichtig. Erhebt der Arbeitskreis für Gleichbehandlungsfragen nicht fristgerecht die Einrede der unrichtigen Zusammensetzung, gilt das Kollegialorgan im Hinblick auf § 20a Abs. 2 als richtig zusammengesetzt.

(8b) Der Senat hat den Arbeitskreis für Gleichbehandlungsfragen unverzüglich über das Ergebnis der Wahl der Mitglieder des Universitätsrats gemäß § 21 Abs. 6 Z 1 zu informieren. Bei Verletzung des § 20a Abs. 3 kann der Arbeitskreis für

1. texts of all advertisements for posts and functions prior to their publication. The working group shall be entitled to give its opinion on the advertisement within two weeks upon receipt;
2. a list of applications received, including the application documents, unless waived by the working group on equal opportunities;
3. a list of candidates invited for interviews.

(7) The rectorate shall, when notifying the responsible employee's council of the candidate with whom an employment contract is to be concluded, simultaneously inform the working group on equal opportunities. Employment contracts concluded without prior notification of the working group or before expiry of the period prescribed by para 8 shall be null and void.

(8) If the working group on equal opportunities has reason to believe that a decision made by a university governing body constitutes a discrimination against a person on the basis of gender, ethnicity, religion or conviction, age, or sexual orientation or a violation of the duty of career advancement for women or of the university's career advancement plan for women and the equal opportunities plan, it shall have the right to invoke the arbitration board within three weeks.

(8a) Each collegial body shall inform the working group on equal opportunities of its composition without delay. If the quota of at least 50% women according to § 20a para 2 in the collegial body is not met, the working group on equal opportunities may raise an objection against the incorrect composition to the arbitration board within four weeks. The objection against the incorrect composition shall not be raised when objective reasons exist. If the composition of the collegial body is incorrect and if the working group on equal opportunities raises an objection, its decisions shall be void. If the working group on equal opportunities does not raise an objection against the incorrect composition of the collegial body within the period stipulated, the composition of the collegial body shall be deemed to be correct in this respect with regard to § 20a para 2.

(8b) The senate shall inform the working group on equal opportunities without delay about the election results regarding the members of the university council according to § 21 para 6 subpara 1. If § 20a para 3 is violated, the working group on

Gleichbehandlungsfragen binnen vier Wochen die Einrede der unrichtigen Zusammensetzung des Universitätsrats an die Schiedskommission erheben. Die Einrede der unrichtigen Zusammensetzung hat zu unterbleiben, wenn sachliche Gründe vorliegen.

(8c) Die Findungskommission und der Senat haben dem Arbeitskreis für Gleichbehandlungsfragen ihren jeweiligen Vorschlag für die Bestellung der Rektorin oder des Rektors vorzulegen. Liegt der Verdacht der Diskriminierung auf Grund des Geschlechts einer Bewerberin vor, so hat der Arbeitskreis für Gleichbehandlungsfragen binnen einer Woche Beschwerde an die Schiedskommission zu erheben.

(8d) Sämtliche von der Wahlkommission zugelassenen Wahlvorschläge für die Wahlen zum Senat einschließlich der Vorschläge für die Ersatzmitglieder sind im Hinblick auf die Einhaltung der Reihung von mindestens 50 vH Frauen an wählbarer Stelle gemäß § 20a Abs. 4 dem Arbeitskreis für Gleichbehandlungsfragen vorzulegen. Dieser hat binnen einer Woche zu entscheiden, ob der Wahlvorschlag § 20a Abs. 4 entspricht. Entscheidet der Arbeitskreis für Gleichbehandlungsfragen, dass nicht ausreichend Frauen auf dem Wahlvorschlag enthalten sind, hat er die Einrede der Mangelhaftigkeit des Wahlvorschlages an die Schiedskommission zu erheben. Die Einrede hat zu unterbleiben, wenn sachliche Gründe vorliegen. Entscheidet die Schiedskommission, dass die Einrede zu Recht erhoben wurde, hat die Wahlkommission den Wahlvorschlag an die wahlwerbende Gruppe zur Verbesserung zurückzuverweisen.

(8e) Der Arbeitskreis für Gleichbehandlungsfragen hat unverzüglich an die Bundesministerin oder den Bundesminister zu berichten, wenn er

1. eine Einrede der unrichtigen Zusammensetzung eines Kollegialorgans an die Schiedskommission gemäß Abs. 8a,
2. eine Einrede der unrichtigen Zusammensetzung des Universitätsrats gemäß Abs. 8b,
3. eine Beschwerde wegen Diskriminierung im Zusammenhang mit der Wahl der Rektorin oder des Rektors gemäß Abs. 8c oder
4. eine Einrede der Mangelhaftigkeit des Wahlvorschlages gemäß Abs. 8d

erhebt.

(8f) Die Bundesministerin oder der Bundesminister hat in geeigneter Form auf der Homepage des Bundesministeriums für ~~Bildung~~Frauen, Wissenschaft und Forschung eine auf Grund der Wissensbilanzen der Universitäten gemäß der

equal opportunities may raise an objection against the incorrect composition of the university council to the arbitration board within four weeks. The objection against the incorrect composition shall not be raised when objective reasons exist.

(8c) The search committee and the senate shall submit their shortlists for the election of the rector to the working group on equal opportunities. If discrimination on the basis of gender against a female applicant is suspected, the working group on equal opportunities shall lodge a complaint with the arbitration board within a week.

(8d) All election proposals accepted by the election committee for the election of the senate, including proposals for substitute members, shall be submitted to the working group on equal opportunities for review as to compliance with the requirement of including at least 50% women in electable positions according to § 20a para 4. The working group on equal opportunities shall decide within one week, whether the election proposal is in accordance with § 20a para 4. If the working group on equal opportunities decides that the election proposal does not include a sufficient number of women, it shall raise an objection against the inadequacy of the election proposal to the arbitration board. The objection shall not be raised, when objective reasons exist. If the arbitration board decides that the objection was rightly raised, the election committee shall return the election proposal to the candidate group for improvement.

(8e) The working group on equal opportunities shall report, without delay, to the Federal Minister, when it

1. raises an objection against the incorrect composition of a collegial body to the arbitration board under para 8a,
2. raises an objection against the incorrect composition of the university council under para 8b,
3. lodges a complaint because of discrimination in connection with the election of the rector under para 8c or
4. raises an objection against the inadequacy of an election proposal under para 8d.

(8f) The Federal Minister shall publish on the website of the Federal Ministry of Education, Science and Research in an appropriate format a statement based on the intellectual capital reports of the universities in the meaning of the Decree on

Wissensbilanz-Verordnung 2016 – WBV 2016~~)~~, BGBl. II Nr. 97/2016, in der jeweils geltenden Fassung~~ der Verordnung BGBl. II Nr. 307/2019~~ erstellte Darstellung der Umsetzung der geschlechtergerechten Zusammensetzung von Kollegialorganen gemäß § 20a an allen Universitäten zu veröffentlichen.

(9) Erhebt der Arbeitskreis für Gleichbehandlungsfragen Beschwerde an die Schiedskommission, ist die Vollziehung der Entscheidung des Universitätsorgans bis zur Entscheidung der Schiedskommission unzulässig.

(10) Dem Universitätsrat und dem Rektorat ist jährlich ein Tätigkeitsbericht des Arbeitskreises zu übermitteln.

(11) Das Rektorat hat dem Arbeitskreis für Gleichbehandlungsfragen die für die Erfüllung seiner Aufgaben entsprechenden Personal- und Sachressourcen sowie die erforderlichen Räume nach Maßgabe der budgetären Möglichkeiten zur Verfügung zu stellen.

Schiedskommission

§ 43. (1) An jeder Universität ist eine Schiedskommission einzurichten. Zu ihren Aufgaben zählen:

1. die Vermittlung in Streitfällen von Angehörigen der Universität;
2. die Entscheidung über Beschwerden des Arbeitskreises für Gleichbehandlungsfragen wegen einer Diskriminierung auf Grund des Geschlechts oder auf Grund der ethnischen Zugehörigkeit, der Religion oder Weltanschauung, des Alters oder der sexuellen Orientierung oder auf Grund eines Verstoßes gegen das Frauenförderungsgebot oder gegen den Frauenförderungs- und Gleichstellungsplan der Universität durch die Entscheidung eines Universitätsorgans;
3. Entscheidung über Einreden der unrichtigen Zusammensetzung des Arbeitskreises für Gleichbehandlungsfragen binnen vier Wochen;
4. Entscheidung über Einreden der Mangelhaftigkeit des Wahlvorschlages des Arbeitskreises für Gleichbehandlungsfragen binnen 14 Tagen.

(2) Angelegenheiten, die einem Rechtszug unterliegen, und Leistungsbeurteilungen sind von der Prüfung durch die Schiedskommission ausgenommen.

(3) Die Schiedskommission soll bei der Erfüllung ihrer Aufgaben möglichst auf ein Einvernehmen zwischen den Beteiligten hinwirken.

(4) Alle Organe und Angehörigen der Universität sind verpflichtet, den Mitgliedern der Schiedskommission Auskünfte, insbesondere auch über

Intellectual Capital Reports 2016 (Wissensbilanz-Verordnung 2016 – WBV 2016), F. L. G. II No 97/2016, as amended in the decree published in F. L. G. II No 307/2019, on the implementation of the gender-balanced composition of collegial bodies according to § 20a at all universities.

(9) If the working group on equal opportunities lodges a complaint with the arbitration board, the entry into effect of the university governing body's decision shall be impermissible until the arbitration board has ruled on the matter.

(10) The working group shall submit annual reports on its activities to the university council and the rectorate.

(11) The rectorate shall, contingent upon budgetary considerations, allocate the required personnel and equipment as well as the necessary rooms to the working group on equal opportunities for the performance of its duties.

Arbitration Board

§ 43. (1) An arbitration board shall be established at every university. Its duties shall include:

1. mediating in disputes between university members;
2. ruling on complaints by the working group on equal opportunities with regard to discrimination on the basis of gender, ethnicity, religion or conviction, age, or sexual orientation or due to a violation of the duty of career advancement for women or of the university's career advancement plan for women and the equal opportunities plan through the decision of a university governing body;
3. deciding on objections against the incorrect composition by the working group on equal opportunities within four weeks;
4. deciding on objections against the inadequacy of the election proposal by the working group on equal opportunities within fourteen days.

(2) Matters which are the subject of legal proceedings, and performance evaluations shall be excluded from investigation by the arbitration board.

(3) In the performance of its duties, the arbitration board shall try to reach an agreement between the parties to disputes.

(4) All university bodies and members shall be obliged to furnish the arbitration board with information on matters investigated by it, especially on personal data

personenbezogene Daten (Art. 4 Nr. 1 DSGVO) und sonstige Informationen, in der Sache zu erteilen und an Kontaktgesprächen teilzunehmen.

(5) Die Schiedskommission hat in den Angelegenheiten gemäß Abs. 1 Z 2 innerhalb von drei Monaten mit Bescheid darüber abzusprechen, ob durch die Entscheidung des Universitätsorgans eine Diskriminierung auf Grund eines oder mehrerer der in Abs. 1 Z 2 genannten Gründe vorliegt. Betrifft die Beschwerde den Vorschlag der Findungskommission oder den Vorschlag des Senates zur Bestellung der Rektorin oder des Rektors, so hat die Schiedskommission binnen 14 Tagen zu entscheiden.

(6) Bejaht die Schiedskommission in den Fällen des Abs. 1 Z 2 das Vorliegen einer Diskriminierung auf Grund eines oder mehrerer der in Abs. 1 Z 2 genannten Grundes oder Gründe, hat das Universitätsorgan eine neue Personalentscheidung unter Beachtung der Rechtsauffassung der Schiedskommission zu treffen. Betrifft die Diskriminierung den Vorschlag der Findungskommission oder des Senates zur Bestellung der Rektorin oder des Rektors, ist der Vorschlag an die Findungskommission oder den Senat zurückzustellen. Die Findungskommission und der Senat sind in diesem Fall verpflichtet, den der Rechtsanschauung der Schiedskommission entsprechenden Rechtszustand unverzüglich herzustellen.

(7) Der Arbeitskreis für Gleichbehandlungsfragen und das betroffene Universitätsorgan haben das Recht, gegen den das Verfahren abschließenden Bescheid vor dem Bundesverwaltungsgericht Beschwerde zu führen.

(8) Arbeitsverträge, die von der Rektorin oder vom Rektor während eines anhängigen Verfahrens vor der Schiedskommission oder trotz eines negativen Bescheids der Schiedskommission abgeschlossen werden, sind unwirksam.

(9) Die Schiedskommission besteht aus sechs Mitgliedern, die keine Angehörigen der betreffenden Universität sein müssen. Je ein männliches und ein weibliches Mitglied sind vom Senat, vom Universitätsrat und vom Arbeitskreis für Gleichbehandlungsfragen für eine Funktionsperiode von zwei Jahren zu nominieren. Zwei der Mitglieder müssen rechtskundig sein. Vom Senat, vom Universitätsrat und vom Arbeitskreis für Gleichbehandlungsfragen sind jeweils ein weibliches und ein männliches Ersatzmitglied zu nominieren. Personen, die in einer Geschäftsbeziehung mit dem Rektorat, dem Universitätsrat oder dem Senat stehen, dürfen der Schiedskommission nicht angehören. Mögliche Interessenkonflikte haben die Mitglieder der Schiedskommission unverzüglich zu melden.

(10) Die Mitglieder der Schiedskommission sind bei der Ausübung dieser Funktion an keine Weisungen oder Aufträge gebunden (Art. 81c B-VG).

(Art 4 No 1 DSGVO) and other information, and take part in communication dialogues.

(5) The arbitration board shall issue an official notification on the matters under para 1 subpara 2 within three months, specifying whether the decision by the university governing body discriminates on the basis of one or more reasons named in para 1 subpara 2. If the complaint concerns the shortlist drawn up by the search committee or the shortlist drawn up by the senate for the election of the rector, the arbitration board shall decide within fourteen days.

(6) If the arbitration board finds that discrimination on the basis of one or more reasons named in para 1 subara 2 in cases under para 1 subpara 2 has occurred, the university governing body shall be obliged to make a new personnel decision having regard to the legal opinion of the arbitration board. If the discrimination concerns the shortlist submitted by the search committee or the senate for the election of the rector, the shortlist shall be returned to the search committee or the senate. The search committee and the senate are in this case obliged to, without delay, bring about the legal situation which accords with the legal opinion of the arbitration board.

(7) The working group on equal opportunities and the university governing body concerned shall however have the right to appeal to the Federal Administrative Court against the official notification concluding an arbitration procedure.

(8) Employment contracts concluded by the rector during a pending arbitration procedure or in the face of a negative ruling of the arbitration board shall be null and void.

(9) The arbitration board shall consist of six members, none of whom may be members of the university concerned. The senate, university council and working group on equal opportunities shall each nominate one male and one female member of the commission for a term of office of two years. Two of the members must have legal education. The senate, the university council, and the working group on equal opportunities shall each nominate one woman and one man as substitute members. Persons in a business relationship with the rectorate, the university council or the senate shall be excluded from being member of the arbitration board. Members shall report possible conflicts of interest immediately to the arbitration board.

(10) The members of the arbitration board shall not be bound by any instructions in the fulfilment of their tasks (art. 81c B-VG).

(11) Die Schiedskommission entscheidet mit einfacher Mehrheit. Bei Stimmengleichheit gibt die Stimme der oder des Vorsitzenden den Ausschlag.

(12) Dem Universitätsrat und dem Rektorat ist jährlich ein Tätigkeitsbericht der Schiedskommission zu übermitteln.

Anwendung des Bundes-Gleichbehandlungsgesetzes

§ 44. Auf alle Angehörigen der Universität sowie auf die Bewerberinnen und Bewerber um Aufnahme in ein Arbeitsverhältnis zur Universität oder um Aufnahme als Studierende ist das B-GlBG mit Ausnahme des dritten und vierten Abschnitts des ersten Hauptstücks des zweiten Teils und der §§ 12 und 12a mit der Maßgabe anzuwenden, dass die Universität als Dienststelle und als Zentralstelle (§ 2 Abs. 1 und 2 B-GlBG) gilt und sie die Pflicht zur Leistung von Schadenersatz gemäß §§ 17 bis 19b B-GlBG trifft. Das Recht zur Erstellung eines Vorschlags für den Frauenförderungsplan (§ 11a Abs. 1 B-GlBG) steht dem Arbeitskreis für Gleichbehandlungsfragen zu.

4. Abschnitt
Verfahren

Aufsicht

§ 45. (1) Die Universitäten, die von ihnen gemäß § 10 Abs. 1 gegründeten Gesellschaften, Stiftungen und Vereine sowie jene Gesellschaften, deren Geschäftsanteile die Universität mittelbar oder unmittelbar zu ~~mehr als~~mindestens 50 vH hält, unterliegen der Aufsicht des Bundes. Diese umfasst die Einhaltung der Gesetze und Verordnungen einschließlich der Satzung (Rechtsaufsicht).

(2) Die zuständigen Organe der Universität haben der Bundesministerin oder dem Bundesminister im Wege des Universitätsrats auf Verlangen unverzüglich alle zur Erfüllung ihrer oder seiner Aufgaben erforderlichen Auskünfte zu erteilen und alle erforderlichen Unterlagen zu übermitteln. Dies kann allenfalls auch personenbezogene Daten (Art. 4 Nr. 1 DSGVO) umfassen.

(3) Die Bundesministerin oder der Bundesminister hat mit Verordnung Verordnungen und mit Bescheid Entscheidungen von Universitätsorganen aufzuheben, wenn die betreffende Verordnung oder Entscheidung im Widerspruch zu geltenden Gesetzen oder Verordnungen einschließlich der Satzung steht. Im Falle einer Verletzung von Verfahrensvorschriften hat eine Aufhebung nur dann zu

(11) The arbitration board shall reach its decisions by simple majority. In the case of a tie, the chairperson shall have the casting vote.

(12) The arbitration board shall submit annual reports on its activities to the university council and the rectorate.

Application of the Federal Equal Opportunities Act

§ 44. The Federal Equal Opportunities Act shall apply to all members of a university as well as applicants for employment thereat or for admission as a student, with the exception of Sub-Chapters 3 and 4 of Chapter 1 of Part II and with the exception of §§ 12 and 12a, insofar as the university is deemed to be an administrative unit and a central unit (§ 2 paras 1 and 2 of the Federal Equal Opportunities Act) and is subject to the obligation to pay compensation according to §§ 17 to 19b of the Federal Equal Opportunities Act. The working group on equal opportunities shall be entitled to prepare a draft career advancement plan for women (§ 11a para 1 of the Federal Equal Opportunities Act).

Chapter 4
Procedure

Supervision

§ 45. (1) The universities as well as the companies, foundations and associations they have founded under § 10 para 1, and those companies of which the university holds a direct or indirect share of more than 50%, are subject to supervision by the Federal Government. This shall comprise monitoring of compliance with the acts and decrees, including the statute (legal supervision).

(2) The responsible university governing bodies shall, at the Federal Minister's request, furnish him/her with any information and documentation required for the performance of his/her tasks without delay, via the university council. This can, if need be, comprise also personal data (Art 4 No 1 GDPR).

(3) The Federal Minister shall annul decrees of university governing bodies with decrees and decisions of university governing bodies by official notification, if the respective decrees or decisions are in conflict with acts and decrees in force including the statute. In the case of an infringement of procedural regulations, decisions may not be annulled unless compliance with such regulations would have resulted in a different decision.

erfolgen, wenn das Organ bei deren Einhaltung zu einem anderen Ergebnis hätte kommen können.

(4) Die Bundesministerin oder der Bundesminister hat mit Bescheid Wahlen, die im Widerspruch zu geltenden Gesetzen oder Verordnungen einschließlich der Satzung stehen, aufzuheben.

(5) Ab der formellen Einleitung eines aufsichtsbehördlichen Verfahrens durch die Bundesministerin oder den Bundesminister ist die Durchführung der diesem Verfahren zu Grunde liegenden Beschlüsse bis zum Abschluss des Verfahrens unzulässig. Ein in diesem Zeitraum oder nach der aufsichtsbehördlichen Aufhebung des betreffenden Beschlusses dennoch ergangener Bescheid leidet an einem gemäß § 68 Abs. 4 Z 4 AVG mit Nichtigkeit bedrohten Fehler. Hebt die Bundesministerin oder der Bundesminister eine Entscheidung eines Universitätsorganes mit Bescheid auf, so enden Arbeitsverhältnisse, die auf der aufgehobenen Entscheidung beruhen, mit Eintritt der Rechtskraft des Bescheides.

(6) Die Universitätsorgane sind im Fall der Abs. 3 und 4 verpflichtet, den der Rechtsanschauung der Bundesministerin oder des Bundesministers entsprechenden Rechtszustand unverzüglich herzustellen.

(7) Im aufsichtsbehördlichen Verfahren haben die Universitätsorgane Parteistellung sowie das Recht, gegen den das Verfahren abschließenden Bescheid vor dem Bundesverwaltungsgericht Beschwerde zu führen.

Verfahren in behördlichen Angelegenheiten

§ 46. (1) Die Universitätsorgane haben in allen behördlichen Angelegenheiten das AVG anzuwenden.

(2) Beschwerden in Studienangelegenheiten sind bei dem Organ einzubringen, das den Bescheid erlassen hat. Dieses hat, wenn die Beschwerde nicht unzulässig oder verspätet ist, die Beschwerde mit dem gesamten Akt unverzüglich dem Senat vorzulegen. Der Senat kann ein Gutachten zur Beschwerde erstellen. Liegt ein derartiges Gutachten vor, so hat die Beschwerdevorentscheidung unter Beachtung dieses Gutachtens zu erfolgen. Wird die Beschwerde dem Bundesverwaltungsgericht vorgelegt, so ist das Gutachten des Senats anzuschließen. Abweichend von § 14 Abs. 1 VwGVG hat das zuständige Organ innerhalb von vier Monaten zu entscheiden.

(4) The Federal Minister shall, by official notification, annul elections which are in conflict with acts and decrees, including the statute.

(5) Upon the formal initiation of a supervisory procedure by the Federal Minister implementation of the decisions which are the subject thereof is impermissible until the procedure has been concluded. An official notification made during this period or subsequent to the annulment of the decision in question by the supervisory authority shall risk nullity due to a procedural defect in the meaning of § 68 para 4 subpara 4 AVG. If the Federal Minister annuls a decision taken by a university governing body by official notification, employment contracts which are governed by the decision annulled shall end when the official notification enters into force.

(6) In the circumstances set out in paras 3 or 4 the university governing bodies shall, without delay, bring about the legal situation which accords with the Federal Minister's legal opinion.

(7) In case that supervisory procedures are initiated, the university governing bodies shall have the right to be parties thereto and to appeal to the Federal Administrative Court against the official notification marking the conclusion of the procedure.

Official Procedure

§ 46. (1) University governing bodies shall apply the General Administrative Procedure Act.

(2) Appeals in matters relating to studies shall be submitted to the university governing body that has issued the official notification. The university governing body shall forward the appeal together with all relevant documents to the senate without delay, unless the appeal is inadmissible or was made too late. The senate shall have the right to prepare a report on the appeal. If such a report has been prepared, the preliminary ruling on the appeal shall take into account this report. If the appeal is submitted to the Federal Administrative Court, the report prepared by the senate shall be enclosed. Notwithstanding § 14 para 1 of the Administrative Court Act, the competent university governing body shall take a decision within four months.

(3) In Studienangelegenheiten sind auch die Organe der gesetzlichen Vertretung der Studierenden nach Maßgabe der **§§** 4 Abs. 1a und 12 Abs. 2a HSG 2014 zur Einbringung von Rechtsmitteln berechtigt.

(4) Universitätsorganen, denen gemäß Art. 132 Abs. 5 B-VG das Recht der Beschwerde an das Bundesverwaltungsgericht eingeräumt ist, steht das Recht zu, gegen Erkenntnisse dieses Gerichts Revision gemäß Art. 133 B-VG zu erheben.

(5) Studienwerberinnen und Studienwerber sowie Studierende, die das 16. Lebensjahr vollendet haben, sind in studienrechtlichen Verfahren verfahrensfähig.

(6) Die Universitäten haben den Verwaltungs- und Strafvollzugsbehörden, den Gerichten sowie den anderen Universitäten und Pädagogischen Hochschulen auf deren Ersuchen die zur Feststellung des Sachverhaltes erforderlichen Auskünfte zu erteilen sowie die dafür notwendigen Unterlagen zu übermitteln.

Säumnis von Organen

§ 47. (1) Kommt ein nicht zu den Leitungsorganen zählendes Organ einer Universität einer ihm nach diesem Bundesgesetz obliegenden Aufgabe nicht innerhalb angemessener Zeit nach, hat das Rektorat auf Antrag einer oder eines davon betroffenen Angehörigen der Universität oder von Amts wegen eine Frist von vier Wochen zu setzen, innerhalb der das säumige Organ die zu erfüllende Aufgabe nachzuholen hat. Lässt dieses die Frist verstreichen, ist die zu erfüllende Aufgabe vom Rektorat durchzuführen (Ersatzvornahme). Dies gilt nicht im Anwendungsbereich des § 73 AVG.

(2) Ist der Senat, das Rektorat oder die Rektorin oder der Rektor im Sinne des Abs. 1 säumig, hat der Universitätsrat auf Antrag einer oder eines davon betroffenen Angehörigen der Universität oder von Amts wegen die Maßnahmen gemäß Abs. 1 zu setzen.

(3) Ist der Universitätsrat im Sinne des Abs. 2 oder in einer Angelegenheit des § 21 Abs. 1 säumig, hat die Bundesministerin oder der Bundesminister die Ersatzvornahme vorzunehmen.

~~**Verschwiegenheitspflicht**~~

Zugang zu Informationen und proaktive Veröffentlichungspflicht

§ 48. (1) Die Universitäten unterliegen der Informationspflicht nach Art. 22a B-VG und haben Informationen von allgemeinem Interesse in einer für jedermann

(3) In study related matters the official student representatives shall be entitled to take legal action according to § 4 para 1a and § 12 para 2a HSG 2014.

(4) University bodies which, according to Art 132 para 5 Federal Constitutional Law, have been accorded the right to raise a complaint before the Federal Administration Court shall have the right to raise final complaints against the decision of this Court according to Art 133 Federal Constitutional Law.

(5) Applicants as well as students who are at least 16 years of age have the capacity to sue and be sued in procedures under study law.

(6) The universities shall, at the request of the administrative agencies and law enforcement authorities, of the courts as well as other universities and university colleges of teacher education, submit all information and documents needed for establishing the facts.

Dilatoriness of Bodies

§ 47. (1) If a university body not forming part of the university management fails to fulfil a duty incumbent upon it by virtue of this Act within a reasonable period, the rectorate may, on application of a university member affected thereby or acting ex officio, grant an extension of four weeks, within which the body which is in delay must fulfil such task (substitute performance). If this period expires without action being taken, the rectorate shall itself perform the task in question. This shall not apply to the area of application of § 73 AVG.

(2) If the senate, rectorate or rector is in delay in the meaning of para 1, the university council shall, on application of a university member affected thereby or acting ex officio, take action in accordance with para 1.

(3) If the university council is in delay under para 2 or in respect of a task according to § 21 para 1, the Federal Minister shall him-/herself make the substitute performance.

Duty of Secrecy

§ 48. Members of collegial bodies and other university bodies shall be subject to official secrecy (Art 20 para of the 3 Federal Constitutional Law).

zugänglichen Art und Weise zu veröffentlichen, soweit und solange diese nicht gemäß Abs. 3 geheim zu halten sind.

(2) Der Zugang zu Informationen ist darüber hinaus auf Antrag zu gewähren. Die Antragstellerinnen und Antragsteller haben die Informationen möglichst präzise zu bezeichnen (§ 7 des Informationsfreiheitsgesetzes – IFG, BGBl. I Nr. 5/2024).

(3) Die Mitglieder von gemäß diesem Bundesgesetz sowie durch den Organisationsplan und die Satzung der Universität eingerichteten Kollegialorganen ~~und~~sowie andere Universitätsorgane sind zur ~~Amtsverschwiegenheit~~Geheimhaltung verpflichtet ~~(Art. 20 Abs. 3 B-VG).~~, soweit und solange dies aus den Gründen des Art. 22a Abs. 2 B-VG erforderlich und gesetzlich nicht anderes bestimmt ist. Insbesondere sind Informationen geheim zu halten, die gemäß § 6 Abs. 1 IFG nicht zur Veröffentlichung bestimmt und auch nicht auf Antrag zugänglich zu machen sind.

Haftung

§ 49. (1) Die Universität kann für sich Rechte und Pflichten begründen. Für Verbindlichkeiten, die daraus entstehen, trifft den Bund keine Haftung. Die Rechte und Pflichten für die Obsorge für die ordnungsgemäße Instandhaltung, Instandsetzung und Abwendung von Schäden ergeben sich aus den einschlägigen gesetzlichen Bestimmungen, sofern im Mietvertrag nichts anderes geregelt ist. Insbesondere ist hier auf §§ 1319 und 1319a des Allgemeinen bürgerlichen Gesetzbuches (ABGB), JGS Nr. 946/1811, zu verweisen.

(2) Für den von Organen oder Arbeitnehmerinnen oder Arbeitnehmern der Universität oder von anderen Personen im Auftrag der Universität auf Grund dieses Bundesgesetzes in Wahrnehmung der hoheitlichen Aufgaben wem immer schuldhaft zugefügten Schaden haftet der Bund nach den Bestimmungen des Amtshaftungsgesetzes, BGBl. Nr. 20/1949. Der Bund hat in diesem Fall derjenigen oder demjenigen, die oder den sie für den Rückersatzanspruch für haftbar erachtet, den Streit zu verkünden (§ 21 Zivilprozessordnung, RGBl. Nr. 113/1895). Diese oder dieser kann dem Rechtsstreit als Nebenintervenientin oder Nebenintervenient beitreten (§ 17 Zivilprozessordnung). Die Universität und diejenige oder derjenige, die oder der den Schaden zugefügt hat, haften der oder dem Geschädigten nicht.

(3) Hat der Bund der oder dem Geschädigten gemäß Abs. 2 den Schaden ersetzt, ist er berechtigt, nach Maßgabe der §§ 3, 5 und 6 Abs. 2 des Amtshaftungsgesetzes von derjenigen oder demjenigen, die oder den sie für den Rückersatzanspruch für haftbar erachtet, Rückersatz zu fordern. In diesem Verfahren sind die zum Rückersatz herangezogenen Personen von der Verschwiegenheitspflicht befreit.

Liability

§ 49. (1) Universities may acquire rights and enter into obligations. The Federal Government shall not be liable for any liabilities arising therefrom. The rights and obligations with regard to the responsibility for the orderly maintenance, repair and prevention of damage shall arise from the applicable legal provisions, unless otherwise provided in the lease contract. In particular, §§ 1319 and 1319a of the General Code of Civil Law, JGS No 946/1811 shall be mentioned.

(2) The Federal Government shall be liable for any damage culpably inflicted upon any person whosoever by the bodies or employees of a university or other persons acting on its behalf in the fulfilment of public tasks under this Act, under the Public Bodies' Liability Act, F. L. G. No 20/1949. In such cases, the Federal Government shall give notice of claim against that/those person(s) it holds liable for the damage (§ 21 of the Code of Civil Procedure, Imperial Legal Gazette No 113/1895). The aggrieved party may intervene in the proceedings (§ 17 of the Code of Civil Procedure). The university and that person/those persons who have caused the damage shall not be liable to the aggrieved party.

(3) In case that the Federal Government indemnifies the aggrieved party in accordance with para 2, it shall be entitled according to §§ 3, 5 and 6 para 2 of the Liability of Public Bodies' Act to claim damages from that person/those persons it holds liable for the claim. In such proceedings the defendant(s) shall be released from the duty of secrecy.

(4) Für die von Organen oder Arbeitnehmerinnen oder Arbeitnehmern der Universität oder von anderen Personen im Auftrag der Universität in Wahrnehmung der hoheitlichen Aufgaben dem Bund schuldhaft unmittelbar zugefügten Schäden haften diese Organe dem Bund nach den Bestimmungen des Organhaftpflichtgesetzes, BGBl. Nr. 181/1967, mit der Maßgabe, dass die zur Haftung herangezogenen Personen von der Verschwiegenheitspflicht befreit sind.

Rechtsvertretung

§ 50. Die Universität sowie Gesellschaften, deren Geschäftsanteile die Universität mittelbar oder unmittelbar zu ~~mehr als~~mindestens 50 vH hält, sind berechtigt, sich von der Finanzprokuratur gemäß dem Prokuraturgesetz, StGBl. Nr. 172/1945, gegen Entgelt rechtlich beraten und vertreten zu lassen.

II. Teil
Studienrecht

1. Abschnitt
Allgemeine Bestimmungen

Begriffsbestimmungen

§ 51. (1) In Vollziehung der Studienvorschriften werden die Universitäten im Rahmen der Hoheitsverwaltung tätig.

(2) Im Geltungsbereich dieses Bundesgesetzes gelten folgende Begriffsbestimmungen:

1. Anerkannte postsekundäre Bildungseinrichtungen sind die Bildungseinrichtungen, die Studien im Ausmaß von mindestens sechs Semestern durchführen, bei denen die Zulassung die allgemeine Universitätsreife im Sinne dieses Bundesgesetzes oder bei künstlerischen Studien den Nachweis der künstlerischen Eignung voraussetzt, und die auf Grund der Rechtsvorschriften des Staates, in dem sie ihren Sitz haben, als Bildungseinrichtungen im Sinne dieser Begriffsbestimmung anerkannt sind.
2. Ordentliche Studien sind die Diplomstudien, die Bachelorstudien, die Masterstudien, die Doktoratsstudien, die kombinierten Master- und Doktoratsstudien sowie die Erweiterungsstudien.

(4) University bodies or employees of a university shall be liable to the Federal Government for damage directly and culpably inflicted on the Federal Government by themselves or university employees or other persons acting on behalf of the university in the performance of public duties, under the Public Organs Liability Act, F. L. G. No 181/1967; the defendants shall be released from their duty of secrecy.

Legal Representation

§ 50. Universities and companies in which they hold direct or indirect majority interests shall be entitled to fee-paying legal advice and representation by the Finanzprokuratur under the Prokuratur Act, State Legal Gazette No 172/1945.

Part II
Study Law

Chapter 1
General Provisions

Definitions

§ 51. (1) In the implementation of the study regulations, the universities shall act with public power.

(2) In the meaning of this Act the following definitions shall apply:

1. “Recognized post-secondary educational institutions” mean educational institutions which offers study programmes lasting for at least six semesters for which admission requires the general university entrance qualification in terms of the present Federal Act and which is accredited as a post-secondary educational institution according to the legal rules of the country in which it is domiciled.
2. “Degree programmes” mean diploma, bachelor's, master's, and doctoral programmes, combined master’s and doctoral programmes as well as extension programmes.

3. Diplomstudien sind die ordentlichen Studien, die sowohl der wissenschaftlichen und künstlerischen Berufsvorbildung und der Qualifizierung für berufliche Tätigkeiten, welche die Anwendung wissenschaftlicher und künstlerischer Erkenntnisse und Methoden erfordern, als auch deren Vertiefung und Ergänzung dienen. Diese Studien erfüllen die Anforderungen des Art. 11 lit. e der Richtlinie 2005/36/EG über die Anerkennung von Berufsqualifikationen, ABl. Nr. L 255 vom 30.09.2005 S. 22, zuletzt geändert durch die Richtlinie 2013/55/EU, ABl. Nr. L 354 vom 28.12.2013 S. 132, in der Fassung der Berichtigung ABl. Nr. L 305 vom 24.10.2014 S. 115.
4. Bachelorstudien sind die ordentlichen Studien, die der wissenschaftlichen und künstlerischen Berufsvorbildung oder Berufsausbildung und der Qualifizierung für berufliche Tätigkeiten dienen, welche die Anwendung wissenschaftlicher und künstlerischer Erkenntnisse und Methoden erfordern. Diese Studien erfüllen die Anforderungen des Art. 11 lit. d der Richtlinie 2005/36/EG. Sie sind nicht in Studienabschnitte gegliedert.
5. Masterstudien sind die ordentlichen Studien, die der Vertiefung und Ergänzung der wissenschaftlichen und künstlerischen Berufsvorbildung oder Berufsausbildung auf der Grundlage von Bachelorstudien dienen. Diese Studien erfüllen die Anforderungen des Art. 11 lit. e der Richtlinie 2005/36/EG. Sie sind nicht in Studienabschnitte gegliedert.

5a. Erweiterungsstudien sind ordentliche Studien, die dem Zweck dienen, die in einem ordentlichen Studium erworbenen Kompetenzen um zusätzliche Kompetenzen zu erweitern.

5b. ~~ein~~Ein Unterrichtsfach entspricht einem Unterrichtsgegenstand oder einem Fachbereich oder zwei einander überschneidenden Unterrichtsgegenständen oder Fachbereichen an Sekundarschulen.

5c. ~~eine~~Eine Spezialisierung im Lehramtsstudium Sekundarstufe (Allgemeinbildung) ist die Ausrichtung auf ein von einem Unterrichtsfach der Sekundarstufe verschiedenes, in den Curricula näher zu umschreibendes Fachgebiet, in welchem die oder der Studierende vertiefende Kenntnisse erlangt.

5d. ~~ein kohärentes~~Ein Fächerbündel (Allgemeinbildung) im Lehramtsstudium Sekundarstufe (Allgemeinbildung) entspricht mehr als zwei einander ~~inhaltlich~~ überschneidenden Unterrichtsfächern oder zwei einander überschneidenden Unterrichtsfächern und einer Spezialisierung.

3. "Diploma programmes" mean degree programmes which provide pre-vocational scientific or artistic vocational education and qualify students for occupations requiring the application of scientific and artistic knowledge and methods, as well as deepening and extending such knowledge. These programmes fulfil the requirements of Art 11 lit e of the directive 2005/36/EC on the recognition of professional qualifications, OJ No L 255 of 30/09/2005 p. 22, last amended by directive 2013/55/EU, OJ No L 354 of 28/12/2013 p. 132, as amended by the corrigendum in OJ No L 305 of 24/10/2014 p. 115.

4. "Bachelor's programmes" mean degree programmes which provide pre-vocational or vocational scientific or artistic education and qualify students for occupations requiring the application of scientific and artistic knowledge and methods. These programmes fulfil the requirements of Art 11 lit d of the directive 2005/36/EC. They are not divided into stages.

5. "Master's programmes" mean degree programmes which serve to deepen and extend pre-vocational or vocational scientific or artistic education, building on the basis provided by a bachelor's programme. These programmes fulfil the requirements of Art 11 lit d of the directive 2005/36/EC. They are not divided into stages.

5a. "Extension programmes" mean degree programmes which serve the purpose of adding additional competences to those acquired in a degree programme.

5b. A subject corresponds to a teaching subject or a discipline at secondary schools.

5c. A specialisation in the teacher training programmes for secondary schools (general education) is the focus on a field – different than the secondary school subject –, to be further defined in the curricula, in which the student shall gain in-depth knowledge.

5d. A combination of related subjects in the teacher training programme for secondary schools (general education) corresponds to more than two overlapping subjects.

5e. Pädagogisch-praktische Studien bestehen aus begleiteten Praktika vornehmlich an Schulen sowie den jeweiligen Begleitlehrveranstaltungen und fokussieren vorrangig auf die Planung, Durchführung, systematische Reflexion und Weiterentwicklung von Unterricht. Sie stellen fachwissenschaftliche, fachdidaktische und bildungswissenschaftliche Bezüge her und initiieren auf Basis einer forschenden Grundhaltung Verknüpfungen und Reflexionsprozesse mit dem Ziel, Studierende in ihrer professionellen Weiterentwicklung sowie bei der Realisierung der Praktika zu unterstützen.

5f. Ein professionsbegleitendes Lehramtsstudium ist ein solches, das in einer den Beruf der Lehrerin oder des Lehrers begleitenden Studienform und in enger Abstimmung mit den zuständigen Schulbehörden angeboten wird.

6. Studieneingangs- und Orientierungsphase ist das Angebot von Lehrveranstaltungen aus den das jeweilige Diplom- oder Bachelorstudium besonders kennzeichnenden Fächern, das der Information und der Orientierung der Studienanfängerinnen und Studienanfänger dient.

7. Bachelorarbeiten sind die im Bachelorstudium anzufertigenden eigenständigen schriftlichen oder künstlerischen Arbeiten, die im Rahmen von Lehrveranstaltungen abzufassen sind.

8. Diplom- und Masterarbeiten sind die wissenschaftlichen Arbeiten in den Diplom- und Masterstudien, die dem Nachweis der Befähigung dienen, wissenschaftliche Themen selbstständig sowie inhaltlich und methodisch vertretbar zu bearbeiten.

9. Künstlerische Diplom- und Masterarbeiten sind künstlerische Arbeiten, die dem Nachweis der Befähigung dienen, im Hinblick auf das Studienziel des Studiums selbstständig und wissenschaftlich fundiert künstlerisch zu arbeiten.

10. Bachelorgrade sind die akademischen Grade, die nach dem Abschluss der ordentlichen Bachelorstudien verliehen werden. Sie lauten „Bachelor“ mit einem im Curriculum festzulegenden Zusatz, wobei auch eine Abkürzung festzulegen ist. Bachelorstudien für das Lehramt schließen mit dem akademischen Grad „Bachelor of Education“ („BEd“) ab.

11. Mastergrade sind die akademischen Grade, die nach dem Abschluss der ordentlichen Masterstudien verliehen werden. Sie lauten „Master“ mit einem im Curriculum festzulegenden Zusatz, wobei auch eine Abkürzung festzulegen ist, bzw. „Diplom-Ingenieurin/Diplom-Ingenieur“, abgekürzt „Dipl.-Ing.“ oder „DI“; für den Abschluss des humanmedizinischen

5e. Pedagogic-practical studies consist of supervised practical training, mainly at schools, as well as of the respective accompanying courses, focussing primarily on the planning, implementation, systematic reflection on and development of lessons. They create subject-specific, subject-didactic and educational references and, on the basis of an exploratory attitude, initiate links and reflectional processes with the goal to support students in their professional development as well as in the realisation of their practical training.

6. “Study starting and orientation period” means the phase during which courses on subjects of particular significance for a given diploma or bachelor's programme are offered to provide first-year students with information and guidance.

7. “Bachelor’s papers” mean independently prepared papers forming part of bachelor's programmes which must be written or fulfilled artistically in connection with courses.

8. “Diploma and master’s theses” mean academic theses forming part of diploma and master's programmes which serve to demonstrate students’ ability to achieve adequate standards of content and methodology when independently addressing scientific topics.

9. “Artistic diploma and master degree submissions” mean works of art which serve to demonstrate students’ ability to work independently towards the goal of their study, and to perform artistic work on a sound academic basis.

10. “Bachelor’s degrees” mean the academic degrees awarded on successful completion of a bachelor's degree programme. The title is “Bachelor”, followed by a supplement designated by the curriculum, together with an abbreviation. Bachelor's programmes for teacher training end up with the academic degree “Bachelor of Education” (“BEd”).

11. “Master's degrees” mean the degrees awarded on successful completion of a master's degree programme. Their domination is “Master” together with a supplement designated by the curriculum and a designated abbreviation or “Diplom-Ingenieurin/Diplom-Ingenieur”, abbreviated as “Dipl.-Ing.” or “DI”; for the successful completion of the master's programme in human

Masterstudiums kann der Mastergrad „Doctor medicinae universae“, abgekürzt „Dr. med. univ.“, für den Abschluss des Zahnmedizinischen Masterstudiums kann der Mastergrad „Doctor medicinae dentalis“, abgekürzt „Dr. med. dent.“, und für den Abschluss des Masterstudiums der Pharmazie kann der akademische Grad „Magistra pharmaciae“ oder „Magister pharmaciae“, jeweils abgekürzt „Mag. pharm.“, verliehen werden. Masterstudien für das Lehramt schließen mit dem akademischen Grad „Master of Education“ („MEd“) ab.

12. Doktoratsstudien (einschließlich der Doctor of Philosophy-Doktoratsstudien) sind die ordentlichen Studien, die der Weiterentwicklung der Befähigung zu selbstständiger wissenschaftlicher Arbeit sowie der Heranbildung und Förderung des wissenschaftlichen Nachwuchses auf der Grundlage von Diplom- und Masterstudien dienen. Sie sind nicht in Studienabschnitte gegliedert.

12a. Künstlerische Doktoratsstudien sind die ordentlichen Studien, die der Weiterentwicklung der Befähigung zu selbstständiger künstlerischer Arbeit sowie der Heranbildung und Förderung des künstlerischen Nachwuchses auf der Grundlage von künstlerischen Diplom- und Masterstudien dienen. Sie stellen eine über ein künstlerisches Diplom- bzw. Masterstudium hinausgehende künstlerische Qualifikation dar und streben eine künstlerisch vertiefende Auseinandersetzung mit künstlerischen Fragestellungen an. Neben der Entwicklung der künstlerischen Dissertation gemäß Z 13a beinhalten künstlerische Doktoratsstudien begleitende Lehrveranstaltungen künstlerischer, wissenschaftlich-künstlerischer und wissenschaftlicher Ausrichtung. Künstlerische Doktoratsstudien sind nicht in Studienabschnitte gegliedert.

12b. Kombinierte Master- und Doktoratsstudien sind ordentliche Studien, die sowohl der Vertiefung und Ergänzung der wissenschaftlichen und künstlerischen Berufsvorbildung oder der Berufsausbildung auf der Grundlage von Bachelorstudien als auch der Weiterentwicklung der Befähigung zu selbstständiger wissenschaftlicher oder künstlerischen Arbeit mit einem spezifischen wissenschaftlichen oder künstlerischen Forschungsschwerpunkt sowie der Heranbildung und Förderung des wissenschaftlichen und künstlerischen Nachwuchses dienen.

medicine the master's degree “Doctor medicinae universae”, abbreviated “Dr. med. univ.”, can be awarded, for the successful completion of the master's programme in dental medicine the master's degree “Doctor medicinae dentalis”, abbreviated “Dr. med. dent.”, can be awarded, and for the successful completion of the master's programme in pharmacology the master's degree “Magistra pharmaciae” or “Magister pharmaciae”, abbreviated “Mag. pharm.”, can be awarded. Master's programmes for teacher training end up with the academic degree “Master of Education” (“MEd”).

12. “Doctoral programmes” (including doctoral programmes concluding with the award of a Doctor of Philosophy) mean degree programmes which develop students’ ability to undertake independent scientific work, and promote the training and career promotion of junior academic staff, building on the basis provided by diploma and master's programmes. They are not divided into stages.

12a. “Artistic doctoral programmes” mean degree programmes which develop students’ ability to undertake independent artistic work and further the training of junior artistic staff, building on the basis provided by diploma and master's programmes. They provide an artistic qualification beyond the artistic diploma and master's programme and are aimed at the in-depth study of artistic questions. In addition to the preparation of the artistic doctoral thesis according to (13a), artistic doctoral programmes shall include accompanying courses with an artistic, scientific-artistic and scientific focus. Artistic doctoral programmes are not divided into stages.

12b. “Combined master's and doctoral programmes” mean degree programmes which serve to deepen and extend pre-vocational or vocational scientific or artistic education on the basis of bachelor's programmes as well as to further develop the student's ability to undertake independent scientific or artistic work for the defined scientific or artistic research priorities as well as to train and promote junior academics and young artists.

13. Dissertationen sind die wissenschaftlichen Arbeiten, die anders als die Diplom- und Masterarbeiten dem Nachweis der Befähigung zur selbstständigen Bewältigung wissenschaftlicher Fragestellungen dienen.

13a. Künstlerische Dissertationen beinhalten unter Erprobung von künstlerischen Methoden und Techniken die Entwicklung eines künstlerischen, originären, konkreten Rechercheprojekts, das zu einem eigenständigen und autonom entwickelten künstlerischen Werk führt.

14. Doktorgrade sind die akademischen Grade, die nach dem Abschluss der Doktoratsstudien verliehen werden. Sie lauten „Doktorin“ oder „Doktor“, abgekürzt „Dr.“, mit einem im Curriculum festzulegenden Zusatz, oder nach Abschluss eines Doctor of Philosophy- Doktoratsstudiums „Doctor of Philosophy“, abgekürzt „PhD“.

14a. Studienwerberinnen und -werber sind jene Personen, die an der betreffenden Universität die Zulassung zu einem bestimmten Studium beantragen.

14b. Studienanfängerinnen und -anfänger sind jene Studienwerberinnen und -werber, die nach allfälliger Absolvierung eines Aufnahme- oder Auswahlverfahrens tatsächlich zum Studium zugelassen werden.

14c. Studierende sind die nach den Bestimmungen dieses Bundesgesetzes durch das Rektorat zum Studium an der Universität zugelassenen Personen.

14d. Studienplätze für Studienanfängerinnen und -anfänger sind jene Studienplätze, welche von den Universitäten österreichweit bzw. von einer Universität für Studienanfängerinnen und -anfänger pro Studienjahr und Studienfeld bzw. pro Studienjahr und Studium zur Verfügung gestellt werden.

14e. Nicht-traditionelle Studienwerberinnen und -werber umfassen: Studienwerberinnen und -werber mit Behinderung, berufstätige Personen, Personen mit Betreuungsverpflichtungen, Personen mit verzögertem Studienbeginn, Personen mit alternativem Universitätszugang sowie Personen im Ruhestand oder in Pension.

14f. Betreuungsrichtwert ist ein aus Verhältniszahlen von Studierenden zu Lehrpersonal abgeleiteter Maßstab für die zumutbare Inanspruchnahme des wissenschaftlichen und künstlerischen Personals durch Lehre. Die Festlegung des Betreuungsrichtwerts erfolgt in der Verordnung gemäß § 71d Abs. 1.

14g. Studienfeld entspricht grundsätzlich dem Kriterium „detailed field“ der ISCED Fields of Education and Training 2013 der UNESCO. Studienfelder

13. “Doctoral theses” mean academic theses which, unlike diploma and master’s theses, serve to demonstrate students’ ability to master scientific topics independently.

13a. Drawing on artistic methods and techniques, artistic doctoral theses shall include the development of an artistic, original, concrete research project that results in an independently and autonomously produced artistic creation.

14. “Doctoral degrees” mean the degrees awarded on successful completion of a doctoral programme. Their denomination is “Doctor”, abbreviated as “Dr.”, followed by a supplement designated by the curriculum, or following the completion of a Doctor of Philosophy programme “Doctor of Philosophy”, abbreviated as “PhD”.

14a. “Applicants” mean those persons who apply for admission to a particular study programme at a university.

14b. “First-year students” mean those applicants who have been admitted to a programme after, where applicable, successfully completing an admission or selection procedure.

14c. “Students” mean persons admitted by the rectorate to study at a university according to the provisions of this act.

14d. “Study places for first-year students” mean those study places that shall be offered by all universities in Austria or by one university, respectively, for first-year students in each academic year and field of education or study programme, respectively.

14e. “Non-traditional applicants” refers to: applicants with disabilities, working persons, persons with care responsibilities, persons who have delayed the beginning of their studies, persons who have chosen an alternative route to university, and retired persons.

14f. The “reference value for the student-teacher ratio” is a scale which is derived from figures on the reasonable use of scientific and artistic staff for teaching and is determined by decree according to § 71d para 1.

14g. “Field of education” basically corresponds to the UNESCO ISCED Fields of Education and Training 2013 criterion “detailed field”. With the

im Sinne der kapazitätsorientierten, studierendenbezogenen Universitätsfinanzierung sind – mit Ausnahme von § 71d – fachliche Zuordnungen der Studien nach der ISCED Fields of Education and Training 1999.

15. Ordentliche Studierende sind die Studierenden, die zu den ordentlichen Studien zugelassen sind.
16. Allgemeine Universitätsreife ist jener Ausbildungsstand, der einer Person die Fähigkeit und das Recht vermittelt, bei Erfüllung allfälliger ergänzender studienspezifischer Erfordernisse zu einem ordentlichen Studium an einer Universität zugelassen zu werden.
17. Besondere Universitätsreife ist die Erfüllung ergänzender studienspezifischer Voraussetzungen für die Zulassung zu einem bestimmten ordentlichen Studium.
18. Ergänzungsprüfungen sind die Prüfungen zur Erlangung der allgemeinen oder besonderen Universitätsreife oder für den Nachweis der Kenntnis der deutschen Sprache.
19. Zulassungsprüfungen sind die Prüfungen, die unter Berücksichtigung der Vorbildungsmöglichkeiten dem Nachweis der künstlerischen Eignung für die künstlerischen Studien und für die Lehramtsstudien in diesen Fächern oder dem Nachweis der sportlichen Eignung für sportwissenschaftliche Studien und für die Lehramtsstudien in diesen Fächern dienen.
20. Außerordentliche Studien sind die Universitätslehrgänge und der Besuch einzelner Lehrveranstaltungen aus wissenschaftlichen Fächern sowie Studien zur Herstellung der Gleichwertigkeit gemäß § 90 Abs. 4.
21. Universitätslehrgänge dienen der Fort- oder Weiterbildung. Die Einrichtung von Universitätslehrgängen zur Vorbereitung auf ein künstlerisches Bachelor- oder Diplomstudium ist zulässig.
22. Außerordentliche Studierende sind die Studierenden, die zu den außerordentlichen Studien zugelassen sind.
23. Bachelorgrade in Universitätslehrgängen sind die akademischen Grade, die gemäß § 87 Abs. 2 nach dem Abschluss eines außerordentlichen Bachelorstudiums verliehen werden. Sie lauten „Bachelor of Arts (Continuing Education)“, abgekürzt „BA (CE)“, „Bachelor of Science (Continuing Education)“, abgekürzt „BSc (CE)“, „Bachelor of Engineering

exception of § 71d, fields of education in the context of the capacity-oriented, student-based funding of universities mean the bundling of programmes pursuant to the ISCED Fields of Education and Training 1999.

15. “Degree students” mean students admitted to degree programmes.
16. “General university entrance qualification” means a qualification providing evidence that a person has reached a level of educational attainment conferring the ability and the right to be admitted to a degree programme at a university, subject to the fulfilment of any additional subject-specific requirements.
17. “Special university entrance qualification” means a qualification fulfilling additional, subject-specific requirements for admission to a given degree programme.
18. “Supplementary examinations” mean examinations for obtaining the general or the special university entrance qualification, or examinations required to demonstrate proficiency in the German language or physical-motor aptitude.
19. “Admission examinations” mean examinations which, taking the sitter’s previous educational opportunities into account, serve to demonstrate artistic aptitude for art and the teacher training programmes in these subjects, or sportive aptitude for studies in sports sciences and the teacher training programmes in these subjects.
20. “Non-degree programmes” mean certificate university programmes for further education and individual courses in scientific subjects as well as studies for establishing the equivalency in the meaning of § 90 para 4.
21. “Certificate university programmes for further education” mean courses providing further and continuing education. The establishment of certificate university programmes for further education to prepare students for bachelor's or diploma programmes in the fine and applied arts is permissible.
22. “Non-degree seeking students” mean students admitted to non-degree programmes.
23. Bachelor's degrees in continuing education university programmes are academic degrees awarded pursuant to § 87 para 2 following the completion of a continuing education bachelor's programme. Their denomination is “Bachelor of Arts (Continuing Education)”, abbreviated “BA (CE)”, “Bachelor of Science (Continuing Education)”, abbreviated “BSc (CE)” or “Bachelor Professional”, abbreviated “BPr”.

(Continuing Education)“, abgekürzt „BEng (CE)“, oder „Bachelor Professional“, abgekürzt „BPr“.

23a. Mastergrade in Universitätslehrgängen sind die akademischen Grade, die gemäß § 87 Abs. 2 nach dem Abschluss eines außerordentlichen Masterstudiums verliehen werden. Sie lauten „Master of Arts (Continuing Education)“, abgekürzt „MA (CE)“, „Master of Science (Continuing Education)“, abgekürzt „MSc (CE)“, „Master of Engineering (Continuing Education)“, abgekürzt „MEng (CE)“, „Master Professional“, abgekürzt „MPr“, „Master of Laws“, abgekürzt „LL.M.“, „Master of Business Administration“, abgekürzt „MBA“, oder „Executive Master of Business Administration“, abgekürzt „EMBA“.

24. Curriculum ist die Verordnung, mit der das Qualifikationsprofil, der Inhalt und der Aufbau eines Studiums und die Prüfungsordnung festgelegt werden. Nähere Bestimmungen sind in der Satzung zu erlassen.

25. Prüfungsordnung ist der Teil des Curriculums, der die Arten der Prüfungen, die Festlegung der Prüfungsmethode und nähere Bestimmungen für das Prüfungsverfahren enthält.

26. Gemeinsame Studienprogramme (joint programmes) sind Studien, die auf Grund von Vereinbarungen zwischen zwei oder mehreren Universitäten, Pädagogischen Hochschulen, Fachhochschulen, Privathochschulen, Privatuniversitäten oder ausländischen anerkannten postsekundären Bildungseinrichtungen durchgeführt und abgeschlossen werden. Ein gemeinsames Studienprogramm kann zu einem joint degree führen, wobei eine gemeinsame Urkunde über die Verleihung des gemeinsamen akademischen Grades auszustellen ist. Ein gemeinsames Studienprogramm kann zu einem double degree führen, wobei zwei Urkunden über die Verleihung der akademischen Grade auszustellen sind. Ein gemeinsames Studienprogramm kann zu einem multiple degree führen, wobei mehrere Urkunden über die Verleihung der akademischen Grade auszustellen sind. Universitätslehrgänge können ebenfalls in der Form von gemeinsamen Studienprogrammen durchgeführt werden.

27. Gemeinsam eingerichtete Studien sind Studien, die auf Grund von Vereinbarungen zwischen einer oder mehreren österreichischen Universitäten, Pädagogischen Hochschulen, Erhaltern von Fachhochschul-Studiengängen oder Privatuniversitäten durchgeführt werden, wobei ein gleichlautendes Curriculum zu erlassen ist. Universitätslehrgänge können

23a. Master's degrees in continuing education university programmes are the academic degrees awarded pursuant to § 87 para 2 following the completion of a continuing education master's programme. Their denomination is “Master of Arts (Continuing Education)”, abbreviated “MA (CE)”, “Master of Science (Continuing Education)”, abbreviated “MSc (CE)”, “Master Professional”, abbreviated “MPr”,“Master of Laws”, abbreviated “LL.M.”, “Master of Business Administration”, abbreviated “MBA” or “Executive Master of Business Administration”, abbreviated “EMBA”.

24. “Curriculum” means the decree which sets out the qualification profile, contents and structure of a programme, and the examination regulations. The detailed arrangements shall be established by the statute.

25. “Examination regulations” mean that part of the curriculum which sets out the nature and method of the examinations, and detailed provisions governing examination procedures.

26. “Joint programmes” mean study programmes which are offered and completed jointly on the basis of agreements between two or several universities, university colleges of teacher education, universities of applied sciences, private university colleges, private universities or foreign recognised post-secondary educational institutions. Following the completion of a joint programme, a joint degree may be awarded. In that case, a joint awarding document shall be issued attesting to the award of the joint academic degree. Following the completion of a joint programme, a double degree may be awarded. In that case, two awarding documents shall be issued attesting to the award of the academic degrees. Following the completion of a joint programme, a multiple degree may be awarded. In that case, several awarding documents shall be issued attesting to the award of the academic degrees. Continuing education university programmes may also be run as a joint programme.

27. “Jointly offered study programmes” mean study programmes which are offered jointly on the basis of agreements between one or several universities, university colleges of teacher education, providers of university of applied sciences programmes or private universities, in that an identical curriculum shall be enacted. Continuing education university programmes may also be run as jointly offered study programmes.

ebenfalls in der Form von gemeinsam eingerichteten Studien durchgeführt werden.

28. Nostrifizierung ist die Anerkennung eines ausländischen Studienabschlusses als Abschluss eines inländischen ordentlichen Studiums.
29. Qualifikationsprofil ist jener Teil des Curriculums, der beschreibt, welche wissenschaftlichen, künstlerischen und beruflichen Qualifikationen die Studierenden durch die Absolvierung des betreffenden Studiums erwerben.
31. ~~Ein Plagiat liegt jedenfalls dann vor, wenn Texte, Inhalte oder Ideen übernommen und als eigene ausgegeben werden. Dies umfasst insbesondere die Aneignung und Verwendung von Textpassagen, Theorien, Hypothesen, Erkenntnissen oder Daten durch direkte, paraphrasierte oder übersetzte Übernahme ohne entsprechende Kenntlichmachung und Zitierung der Quelle und der Urheberin oder des Urhebers.~~
32. ~~Vortäuschen von wissenschaftlichen oder künstlerischen Leistungen liegt jedenfalls dann vor, wenn jemand unerlaubte Hilfsmittel benutzt oder sich bei der Verfassung einer schriftlichen Arbeit oder Ablegung einer Prüfung oder bei der Erstellung einer künstlerischen Arbeit unerlaubter Weise einer anderen Person bedient (insbesondere Inanspruchnahme einer von einer dritten Person erstellten Auftragsarbeit) oder wenn Daten und Ergebnisse erfunden oder gefälscht werden.~~
33. ~~Gute wissenschaftliche Praxis bedeutet, im Rahmen der Aufgaben und Ziele der jeweiligen Einrichtung die rechtlichen Regelungen, ethischen Normen und den aktuellen Erkenntnisstand des jeweiligen Faches einzuhalten.~~

(Anm.: Z 31 bis 33 aufgehoben durch Art. 1 Z 32, BGBl. I Nr. 50/2024)

34. Lernergebnisse sind diejenigen Kenntnisse, Fertigkeiten und Kompetenzen, die im Rahmen eines Studiums, in einer Aus-, Fort- oder Weiterbildung, im Arbeitsprozess oder in einem nicht geregelten Lernprozess erworben werden und im Hinblick auf eine berufliche Tätigkeit oder eine weitere Ausbildung eingesetzt werden können. Im Rahmen eines Studiums erworbene Lernergebnisse werden insbesondere im Qualifikationsprofil zu diesem Studium beschrieben.
35. Bildungsniveau ist die Gesamtheit aller Bildungsqualifikationen, die nach Ausbildungen erworben wurden, welche auf Grund gesetzlicher Bestimmungen dasselbe Zugangsniveau haben und akademische bzw. berufliche Berechtigungen auf derselben Stufe vermitteln.
36. Validierung ist ein Verfahren, welches jedenfalls die Verfahrensschritte Identifizierung, Dokumentation und Bewertung von bereits erworbenen

28. "Nostrification" means the recognition of a foreign degree as a domestic one.
29. A qualification profile is that part of the curriculum that describes which scientific and professional qualifications the students acquire in the course of the degree programme.
31. An act of plagiarism is in any case committed, when text, content, or ideas are used and presented as one's own. This encompasses in particular the appropriation and use of text, theories, hypotheses, findings or data by directly quoting, paraphrasing or translating them without appropriate acknowledgement and reference to the source and the original author.
32. Academic or artistic dishonesty has been unquestionably committed when unauthorised aids have been used, unauthorised use has been made of another person (especially, the use of a commissioned work prepared by a third person) in writing a scientific thesis, taking an examination or preparing an artistic submission, or data and results have been fabricated or falsified.
33. "Good scientific practice" means to comply with the legal regulations, ethical standards and the state of knowledge of the respective field within the framework of the respective institution's mission and objectives.
34. "Learning outcomes" mean the knowledge, skills and competences which are acquired within the framework of a study programme, in training, further or continuing education, in the work process or as a result of a non-regulated learning process and may be used with regard to professional activities or further training. Learning outcomes acquired within the framework of a study programme are described more specifically within the qualification profile of this study programme.
35. "Educational level" means the entirety of all educational qualifications acquired after trainings which, due to statutory provisions, have the same access level and impart academic as well as professional qualifications at the same level.
36. "Validation" means a procedure, comprising the following procedural steps, as a minimum: identification, documentation and assessment of acquired

Lernergebnissen zum Zweck der Anerkennung als Prüfungen oder andere Studienleistungen umfasst.

37. Kurzzeitmobilität von Studierenden ist der Besuch einzelner Lehrveranstaltungen in physischer bzw. virtueller Form bis zu insgesamt 15 ECTS-Anrechnungspunkten, die den Studierenden eine internationale Lernerfahrung im Rahmen des Programms Erasmus+ (zB Blended Intensive Programmes), der „European Universities"-Allianzen oder der Absolvierung von Microcredentials ermöglichen.

Einteilung des Studienjahres

§ 52. (1) Das Studienjahr beginnt am 1. Oktober und endet am 30. September des Folgejahres. Es besteht aus dem Wintersemester, das am 1. Oktober beginnt und am 28. bzw. 29. Februar endet, und dem Sommersemester, das am 1. März beginnt und am 30. September endet, jeweils einschließlich der lehrveranstaltungsfreien Zeiten. Der Senat hat nähere Bestimmungen über Beginn und Ende der lehrveranstaltungsfreien Zeiten zu erlassen.

(2) An den Medizinischen Universitäten bzw. an den Universitäten, an denen eine Medizinische Fakultät eingerichtet ist, kann der Senat nähere Bestimmungen über Beginn und Ende des Klinisch-Praktischen Jahres im Rahmen des Studiums der Humanmedizin (§ 35a) erlassen, wobei während der Dauer des Klinisch-Praktischen Jahres keine lehrveranstaltungsfreie Zeit möglich ist.

(3) An den Medizinischen Universitäten kann der Senat nähere Bestimmungen über Beginn und Ende des Zahnmedizinisch-Klinischen Praktikums im Rahmen des Studiums der Zahnmedizin (§ 35b) erlassen, wobei während der Dauer des Zahnmedizinisch-Klinischen Praktikums keine lehrveranstaltungsfreie Zeit möglich ist.

Aufbewahrung von universitätsspezifischen Daten

§ 53. Folgende Prüfungsdaten gemäß § 9 Z 15 des Bildungsdokumentationsgesetzes 2020 – BilDokG 2020, BGBl. I Nr. 20/2021 müssen mindestens 80 Jahre in geeigneter Form aufbewahrt werden:

1. die Bezeichnung von Prüfungen oder das Thema der wissenschaftlichen oder künstlerischen Arbeiten,
2. die vergebenen ECTS-Anrechnungspunkte,
3. die Beurteilung,

learning outcomes for the purpose of their recognition as examinations or other academic achievements.

Structure of the Academic Year

§ 52. (1) The academic year shall commence on 1 October and end on 30 September of the following year. It consists of the winter semester, which commences on 1 October and ends on 28 or 29 February, and the summer semester, which commences on 1 March and ends on 30 September, each including the recess periods. The senate shall enact detailed regulations on the commencement and end of the periods during which courses are not held.

(2) At the medical universities or the universities at which a faculty of medicine has been established, the senate shall have the right to enact more detailed provisions regarding the beginning and the end of the clinical internship year as part of the programme in human medicine (§ 35a), yet no period of recess is permissible in the course of the clinical internship year.

(3) At the medical universities the senate shall have the right to enact more detailed provisions regarding the beginning and the end of the dental-clinical internship as part of the programme in dentistry (§ 35b), yet no period of recess is permissible in the course of the dental-clinical internship.

Storage of University-Specific Data

§ 53. The following examination data according to § 9 subpara 15 of the Education Documentation Act 2020 (Bildungsdokumentationsgesetzes 2020 – BilDokG 2020), F. L. G. I No 20/2021) shall be preserved in a suitable form for at least 80 years:

1. the titles of examinations or the topics of scientific theses or artistic submissions,
2. the number of ECTS credits awarded,
3. the grade,

4. die Namen der Prüferinnen und Prüfer oder der Beurteilerinnen und Beurteiler,
5. das Datum der Prüfung oder der Beurteilung sowie
6. der Name und die Matrikelnummer der oder des Studierenden.

2. Abschnitt
Studien

Ordentliche Studien

§ 54. (1) Die Universitäten sind berechtigt, Diplomstudien, Bachelorstudien, Masterstudien, Doktoratsstudien, kombinierte Master- und Doktoratsstudien sowie Erweiterungsstudien einzurichten. Dabei sind die Studien einer der folgenden Gruppen zuzuordnen:

1. Geistes- und kulturwissenschaftliche Studien;
2. Ingenieurwissenschaftliche Studien;
3. Künstlerische Studien;
4. Veterinärmedizinische Studien;
5. Naturwissenschaftliche Studien;
6. Rechtswissenschaftliche Studien;
7. Sozial- und wirtschaftswissenschaftliche Studien;
8. Theologische Studien;
9. Medizinische Studien;
10. Lehramtsstudien;
11. Interdisziplinäre Studien.

(2) Neu einzurichtende Studien dürfen nur als Bachelorstudien, Masterstudien, Doktoratsstudien, kombinierte Master- und Doktoratsstudien oder Erweiterungsstudien eingerichtet werden. Der Umfang der Studien mit Ausnahme der Doktoratsstudien ist im Sinne des Europäischen Systems zur Anrechnung von Studienleistungen (European Credit Transfer System – ECTS, 253/2000/EG, Amtsblatt Nr. L 28 vom 3. Februar 2000) in ECTS-Anrechnungspunkten anzugeben. Mit diesen Anrechnungspunkten ist der relative Anteil des mit den einzelnen Studienleistungen verbundenen Arbeitspensums zu bestimmen, wobei das Arbeitspensum eines Jahres 1 500 Echtstunden zu betragen hat und diesem Arbeitspensum 60 Anrechnungspunkte zugeteilt werden.

4. the names of the examiners or the assessors,
5. the date of the examination or the results, as well as
6. the name and the matriculation number of the student.

Chapter 2
Study Programmes

Degree Programmes

§ 54. (1) Universities shall be entitled to offer diploma, bachelor’s, master’s and doctoral programmes, combined master’s and doctoral programmes as well as extension programmes. In that, the study programmes shall be assigned to one of the following groups:

1. Studies in Arts and Humanities;
2. Studies in Engineering Sciences;
3. Art studies;
4. Studies in Veterinary Medicine;
5. Studies in Natural Science;
6. Law studies;
7. Studies in Social and Economic Sciences;
8. Theological studies;
9. Medical studies;
10. Teacher training studies;
11. Interdisciplinary studies.

(2) New programmes may only be instituted as bachelor's, master's or doctoral programmes, combined master's and doctoral programmes or extension programmes. The extent of programmes, with the exception of doctoral programmes, shall be defined in accordance with the European Credit Transfer System (ECTS, Decision No 253/2000/EC of the European Parliament and of the Council, Official Journal No L 28, 3 February 2000) and shall be expressed in ECTS credits. With these credits the share of the workload of the students related to the individual academic achievements shall be determined in relation to the entire programme, with an amount of 1,500 hours for one year of studies and 60 credits being assigned to this workload.

(3) Der Arbeitsaufwand für Bachelorstudien hat 180 ECTS-Anrechnungspunkte und für Masterstudien mindestens 120 ECTS-Anrechnungspunkte zu betragen. Der Arbeitsaufwand für ein Bachelorstudium kann in Ausnahmefällen, wenn dies zur Erlangung der Beschäftigungsfähigkeit zwingend erforderlich ist und diese Studiendauer international vergleichbar ist, bis zu 240 ECTS-Anrechnungspunkte betragen. Zur Beschäftigungsfähigkeit ist die Vorlage eines nach international anerkannten wissenschaftlichen Kriterien erstellten Gutachtens erforderlich. In den Humanmedizinischen und Zahnmedizinischen Studien kann der Arbeitsaufwand für das Bachelor- und das Masterstudium insgesamt 360 ECTS-Anrechnungspunkte betragen. Die Berufsberechtigung für den Beruf der Ärztin oder des Arztes und der Zahnärztin oder des Zahnarztes, für sonstige Gesundheitsberufe sowie für den Beruf der Apothekerin oder des Apothekers richtet sich ausschließlich nach den jeweiligen berufsrechtlichen Regelungen, insbesondere nach der Richtlinie 2005/36/EG. Der Arbeitsaufwand für Masterstudien hat mindestens 60 ECTS-Anrechnungspunkte zu betragen, wenn das gemäß § 64 Abs. 3 zu Grunde liegende Bachelorstudium 240 ECTS-Anrechnungspunkte betragen hat. Für das Bachelorstudium für das Lehramt beträgt der Arbeitsaufwand ~~240~~180 ECTS-Anrechnungspunkte und es ist kein Gutachten zur Beschäftigungsfähigkeit zu erstellen. Masterstudien für das Lehramt Sekundarstufe (Allgemeinbildung) und für das Lehramt Sekundarstufe (Allgemeinbildung) für Absolventinnen und Absolventen eines Lehramtsstudiums für das Lehramt Primarstufe haben mindestens 90 ECTS-Anrechnungspunkte zu umfassen. Die im Schulorganisationsgesetz, BGBl. Nr. 242/1962, genannten Aufgaben der Schularten sind entsprechend zu berücksichtigen.

(4) Die Dauer von Doktoratsstudien (einschließlich der Doctor of Philosophy-Doktoratsstudien) beträgt mindestens drei Jahre.

(4a) Die Dauer von kombinierten Master- und Doktoratsstudien beträgt mindestens fünf Jahre. Der Arbeitsaufwand für einen (Zwischen-)Abschluss dieses Studiums mit einem Mastergrad hat mindestens 120 ECTS-Anrechnungspunkte zu betragen.

(5) In Lehramtsstudien Sekundarstufe (Allgemeinbildung) kann anstelle eines Unterrichtsfachs eine Spezialisierung gewählt werden. ~~Inklusive Pädagogik ist jedenfalls als Spezialisierung anzubieten~~Inklusive Pädagogik und Deutsch als Zweitsprache und sprachliche Bildung sind jedenfalls als Spezialisierungen anzubieten. Der Umfang eines Bachelorstudiums für die Sekundarstufe (Allgemeinbildung), in welchem anstelle zweier Unterrichtsfächer oder einem Unterrichtsfach und einer Spezialisierung ein Fächerbündel (Allgemeinbildung) angeboten wird, hat 210 ECTS-Anrechnungspunkte zu betragen. Das Masterstudium

(3) The workload associated with bachelor's programmes shall amount to 180 ECTS credits, and that associated with master's programmes to at least 120 ECTS credits. The workload associated with a bachelor's programme may, in exceptional cases, amount to up to 240 ECTS credits, if this is vital for guaranteeing employability and if the duration of the studies is comparable to that in other countries. As regards employability, an expert opinion based on internationally recognised scientific criteria shall be presented. In the studies of human and dental medicine, the workload associated with the bachelor's programme and the master's programme may amount to a total of 360 ECTS credits. The professional authorisation of physicians and dentists, of other medical professions, and of pharmacists shall solely be governed by the respective vocational regulations, in particular directive 2005/36/EC. The workload associated with master's programmes shall amount to at least 60 ECTS credits, provided that the bachelor's programme completed beforehand according to § 64 para 3 amounted to 240 ECTS credits. The workload associated with the bachelor's programme for teacher training shall amount to 240 ECTS credits, and no expert opinion on employability shall be needed. The workload associated with master's programmes for teacher training for secondary schools (general education) as well as for teacher training for secondary schools (general education) for graduates of a teacher training programme for primary schools shall amount to at least 90 ECTS credits. The tasks for the types of schools named in the School Organisation Act, F. L. G. No 242/1962, shall be taken into account adequately.

(4) The duration of doctoral programmes (including Doctor of Philosophy programmes) is at least three years.

(4a) The duration of combined master's and doctoral programmes is at least five years. The workload associated with the award of an (interim) master's degree following the completion of this study programme shall amount to at least 120 ECTS credits.

(5) In teacher training programmes for secondary schools (general education) it is possible to select a specialization instead of a subject. Inclusive education shall in any case be offered as a specialization.

für das Lehramt Sekundarstufe (Allgemeinbildung) kann auch als professionsbegleitendes Lehramtsstudium angeboten werden.

(Anm.: Abs. 6 aufgehoben durch Art. 1 Z 15, BGBl. I Nr. 177/2021)

(7) Studien dürfen auch als gemeinsam eingerichtete Studien (§ 54e) oder als gemeinsame Studienprogramme (§ 54d) angeboten werden.

(8) Angebote von Bachelor- und Masterstudien zur Erlangung eines Lehramtes für Volksschulen, Sonderschulen, Polytechnische Schulen, Hauptschulen, Neue Mittelschulen oder für den Bereich der Berufsbildung können nur in Form eines mit einer (oder mehreren) Pädagogischen Hochschulen gemeinsam eingerichteten Studiums angeboten und geführt werden.

Erweiterungsstudien

§ 54a. (1) Die Zulassung zu einem und die Meldung der Fortsetzung eines Erweiterungsstudiums setzt die Zulassung zu einem oder den bereits erfolgten Abschluss eines ordentlichen Studiums, dessen Erweiterung es dient, voraus. Erlischt die Zulassung zu dem ordentlichen Studium, dessen Erweiterung es dient, aufgrund des § 68 Abs. 1 Z 1, 2, 3, 4, 5, 7~~,~~ oder 8, Abs. 2 oder 2a~~„~~ erlischt auch ~~gleichzeitig~~ die Zulassung zum Erweiterungsstudium. Der Abschluss des Erweiterungsstudiums setzt den Abschluss des ordentlichen Studiums, dessen Erweiterung es dient, voraus. Näheres ist im Curriculum zu regeln.

(2) Der Arbeitsaufwand für ein Erweiterungsstudium hat mindestens 30 ECTS-Anrechnungspunkte zu betragen. Zur Dokumentation des Abschlusses eines Erweiterungsstudiums wird ein Zeugnis ausgestellt. Mit dem Abschluss eines Erweiterungsstudiums wird kein Recht auf Verleihung eines akademischen Grades erworben.

(3) Die Einrichtung von Erweiterungsstudien zur Erweiterung eines Doktoratsstudiums sowie eines kombinierten Master- und Doktoratsstudiums ist nicht zulässig.

Erweiterungsstudien zur Erweiterung von Lehramtsstudien

§ 54b. (1) Erweiterungsstudien zur Erweiterung eines Lehramtsstudiums dienen dem Zweck, ein Lehramtsstudium um ein oder mehrere Unterrichtsfächer, Spezialisierungen, Schwerpunkte oder ~~kohärente~~ Fächerbündel (Allgemeinbildung) zu erweitern. Dabei hat sich der Arbeitsaufwand am Arbeitsaufwand für das Unterrichtsfach, die Spezialisierung oder das ~~kohärente~~ Fächerbündel (Allgemeinbildung) zu orientieren.

(6) [removed]

(7) Study programmes may be run as jointly offered study programmes (§ 54e) or as joint programmes (§ 54d).

(8) Bachelor's and master's programmes that provide teacher training for elementary schools, special needs schools, polytechnical schools, secondary schools, “new middle schools” or for teaching in the area of vocational training may only be offered as joint programmes together with one (or several) university colleges of teacher education.

Extension Programmes

§ 54a. (1) The admission to and registration for the continuation of an extension programme requires the admission to or completion of a degree programme to which it shall serve as an extension. If the admission to the degree programme to which it shall serve as an extension expires on the basis of § 68 para 1 subparas 1, 2, 3, 4, 5, 7, 8, paras 2 or 2a, the admission to the extension programme also shall expire at the same time. The completion of the extension programme requires the completion of a degree programme to which it shall serve as an extension. Further details shall be regulated in the curriculum.

(2) The workload associated with an extension programme shall amount to at least 30 ECTS credits. For the purpose of documentation of the completion of an extension programme, a certificate shall be issued. The completion of an extension programme does not entitle the student to be awarded an academic degree.

(3) The establishment of extension programmes which shall serve the extension of doctoral programmes as well as of a combined master’s and doctoral programme is not permissible.

Extension Programmes extending a Teacher Training Programme

§ 54b. (1) Extension programmes extending a teacher training programme shall serve the purpose of adding one or more subjects, specialisations or combinations of related subjects to a teacher training programme. The workload shall be aligned to the workload for the subject, the specialisations or the combination of related subjects.

(2) Die Zulassung und die Meldung der Fortsetzung eines Erweiterungsstudiums zur Erweiterung eines Bachelorstudiums für das Lehramt setzt die Zulassung zu einem oder den bereits erfolgten Abschluss eines mindestens ~~achtsemestrigen~~sechssemestrigen Lehramtsstudiums voraus.

(3) Die Zulassung und die Meldung der Fortsetzung eines Erweiterungsstudiums zur Erweiterung eines Masterstudiums für das Lehramt setzt neben der Absolvierung eines Erweiterungsstudiums zur Erweiterung eines Bachelorstudiums für das Lehramt gemäß Abs. 2 die Zulassung oder den bereits erfolgten Abschluss eines Masterstudiums für das Lehramt oder den Abschluss eines Diplomstudiums für das Lehramt an einer Universität, dessen Erweiterung es dient, voraus. Es ist keine Masterarbeit zu verfassen.

(4) Für Erweiterungsstudien zur Erweiterung eines Lehramtsstudiums sind abweichend von §§ 54a Abs. 1 und 58 Abs. 1 keine gesonderten Curricula zu erlassen, sofern die Inhalte und Anforderungen in dem dem Unterrichtsfach, der Spezialisierung oder dem ~~kohärentem~~ Fächerbündel (Allgemeinbildung) zugrunde liegenden Curriculum gekennzeichnet sind.

~~Erweiterungsstudien für Absolventinnen und Absolventen sechssemestriger Lehramtsstudien~~

~~**§ 54c.** (1) Absolventinnen und Absolventen sechssemestriger Bachelorstudien für das Lehramt an Pädagogischen Hochschulen haben vor der Zulassung zum Masterstudium für das Lehramt ein Erweiterungsstudium zu absolvieren. Dieses umfasst 60 bis 90 ECTS-Anrechnungspunkte, welche im Curriculum für das Bachelorstudium für das Lehramt oder in einem eigenen Curriculum auszuweisen sind. Im Bereich der Sekundarstufe (Allgemeinbildung) sind dieselben Unterrichtsfächer zu wählen wie im sechssemestrigen Bachelorstudium.~~

~~(2) Für Erweiterungsstudien für Absolventinnen und Absolventen sechssemestriger Bachelorstudien an Pädagogischen Hochschulen sind abweichend von §§ 54a Abs. 1 und 58 Abs. 1 keine gesonderten Curricula zu erlassen, sofern die Inhalte und Anforderungen im zugrunde liegenden Curriculum des Bachelorstudiums für das Lehramt gekennzeichnet sind.~~

~~(3) Absolventinnen und Absolventen eines sechssemestrigen Lehramtsstudiums können dieses Lehramtsstudium abweichend von Abs. 1 um ein oder mehrere Unterrichtsfächer, Spezialisierungen oder kohärente Fächerbündel gemäß § 54b Abs. 2 erweitern.~~

(2) The admission to and registration for the continuation of an extension programme extending a bachelor's programme for teacher training requires the admission to or completion of at least an eight-semester teacher training programme.

(3) In addition to the admission to an extension programme extending a bachelor's programme for teacher training according to para 2, the admission to and registration for the continuation of an extension programme extending a master's programme for teacher training requires the admission to or the completion of a master's programme for teacher training or the completion of a diploma programme for teacher training at a university to which it shall serve as an extension. It is not required to prepare a master's thesis.

(4) Notwithstanding §§ 54a para 1 and 58 para 1, it is not necessary to enact a separate curriculum for extension programmes extending a teacher training programme if the contents and requirements are marked in the curriculum on which the subject, the specialisation or the combination of related subjects is based.

Extension Programmes for Graduates of Six-Semester Teacher Training Programmes

§ 54c. (1) Prior to their admission to a master's programme for teacher training, graduates of six-semester bachelor's programmes for teacher training at university colleges of teacher education shall complete an extension programme amounting to 60 to 90 ECTS credits which shall be specified in the curriculum for the bachelor's programme for teacher training or in a separate curriculum. For secondary school teaching (general education) the same subjects shall be chosen as in the six-semester bachelor's programme.

(2) Notwithstanding §§ 54a para 1 and 58 para 1, it is not necessary to enact a separate curriculum for extension programmes for graduates of a six-semester bachelor's programme at a university college of teacher education if the contents and requirements are marked in the curriculum on which the bachelor's programme for teacher training is based.

(3) Notwithstanding para 1, graduates of a six-semester teacher training programme may extend this teacher training programme by adding one or more subjects, specialisations or combinations of related subjects according to § 54b para 2.

Gemeinsame Studienprogramme

§ 54d. (1) Bei gemeinsamen Studienprogrammen haben die beteiligten Bildungseinrichtungen Vereinbarungen über die Durchführung, insbesondere über die Festlegung der Leistungen, die die betreffenden Studierenden an den beteiligten Bildungseinrichtungen zu erbringen haben, und die Finanzierung zu schließen. Dabei können bei Bedarf, unter Beachtung der §§ 2 (leitende Grundsätze) und 59 (Rechte und Pflichten der Studierenden) sowie der Regelungen der Satzung, von diesem Bundesgesetz abweichende Regelungen getroffen werden, sofern das gemeinsame Studienprogramm nicht nur von Universitäten gemäß § 6 Abs. 1 und Pädagogischen Hochschulen gemäß § 1 Abs. 1 und 2 des Hochschulgesetzes 2005 – HG, BGBl. I Nr. 30/2006, durchgeführt wird.

(2) Bei Vorliegen einer Vereinbarung gemäß Abs. 1 hat der Senat im Sinne des § 25 Abs. 1 Z 10 binnen angemessener Frist ein entsprechendes Curriculum zu erlassen.

(3) Wenn die beteiligten Bildungseinrichtungen beschließen, die Durchführung eines gemeinsamen Studienprogrammes zu beenden, haben sie Vorsorge zu treffen, dass Studierenden der Abschluss des Studiums innerhalb einer angemessenen Frist, die jedenfalls die Studiendauer zuzüglich zweier Semester zu umfassen hat, möglich ist.

Gemeinsam eingerichtete Studien

§ 54e. (1) Bei gemeinsam eingerichteten Studien haben die beteiligten österreichischen postsekundären Bildungseinrichtungen eine Vereinbarung insbesondere über die Durchführung sowie die Arbeits- und die Ressourcenaufteilung zu schließen.

(2) In dem von den zuständigen Organen der beteiligten österreichischen postsekundären Bildungseinrichtungen gleichlautend zu erlassenden Curriculum ist die Zuordnung der Fächer zu der jeweiligen Bildungseinrichtung ersichtlich zu machen.

(3) In den von den Rektoraten der beteiligten Universitäten und öffentlichen Pädagogischen Hochschulen gleichlautend zu erlassenden Verordnungen bzw. von den zuständigen Organen von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten zu veröffentlichenden gleichlautenden Vereinbarungen sind Regelungen betreffend die Zuständigkeiten zur Vollziehung der studienrechtlichen Bestimmungen festzulegen. Weiters ist festzulegen, welche studienrechtlichen

Joint Study Programmes

§ 54d. (1) In the case of joint programmes, the educational institutions involved shall conclude agreements specifying the implementation, in particular on the performance which the students shall be committed to at the educational institutions concerned, and funding. In this context, if required and having regard to §§ 2 (guiding principles) and 59 (rights and duties of students) as well as the provisions laid down in the statutes, other arrangements than those specified in this Act may be made if the joint programme is offered not only by universities according to § 6 para 1 and university colleges of teacher education according to § 1 paras 1 and 2 of the Teacher Education Act 2005 (Hochschulgesetz – HG), F. L. G. I No 30/2006.

(2) Upon the existence of an agreement according to para 1, the senate shall enact a curriculum in the meaning of § 25 para 1 subpara 10 in due time.

(3) If the participating educational institutions decide to discontinue a joint programme, they shall make arrangements so that students of the respective programme have the possibility to complete their studies within a reasonable period, which shall at least comprise the duration of the studies plus two semesters.

Jointly Offered Study Programmes

§ 54e. (1) In the case of jointly offered study programmes, the participating Austrian post-secondary educational institutions shall conclude agreements, in particular on the implementation as well as the distribution of the tasks and the resources.

(2) The curriculum to be enacted identically by the competent bodies of the participating Austrian post-secondary educational institutions shall indicate the division of subjects among the educational institutions.

(3) The decrees to be enacted identically by the rectorates of the participating universities and public university colleges of teacher education or the agreements to be published identically by the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences programmes, and private universities, respectively, shall contain provisions on the competences for the implementation of the provisions of study law. Moreover, it shall

Satzungsbestimmungen welcher beteiligten Bildungseinrichtungen jeweils zur Anwendung kommen.

(4) Die Zulassung zu einem gemeinsam eingerichteten Studium darf nur an einer der beteiligten Bildungseinrichtungen nach Wahl der oder des Studierenden erfolgen. Die Rektorate der beteiligten Universitäten und öffentlichen Pädagogischen Hochschulen können durch gleichlautend zu erlassende Verordnungen bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten können durch zu veröffentlichende gleichlautende Vereinbarungen jene Bildungseinrichtung bestimmen, welche die Zulassung durchzuführen hat. Mit der Zulassung wird die oder der Studierende auch Angehörige oder Angehöriger aller am gemeinsam eingerichteten Studium beteiligten Bildungseinrichtungen.

(5) Die zulassende Bildungseinrichtung hat die Fortsetzungsmeldungen durchzuführen, die das Studium betreffenden Bestätigungen, Bescheinigungen und Nachweise sowie die abschließenden Zeugnisse auszustellen und den vorgesehenen akademischen Grad oder die vorgesehene akademische Bezeichnung zu verleihen sowie den Anhang zum Diplom auszustellen.

(6) Im Falle der Beteiligung von Fachhochschulen oder Privatuniversitäten an einem gemeinsam eingerichteten Studium finden die studienrechtlichen Bestimmungen dieses II. Teils Anwendung. Gegen Entscheidungen ist eine Beschwerde an das Bundesverwaltungsgericht zulässig.

(7) Wird ein Studium zur Erlangung eines Lehramtes im Bereich der Primarstufe oder der Sekundarstufe (Berufsbildung) gemeinsam mit einer Pädagogischen Hochschule eingerichtet, sind die einschlägigen Bestimmungen des Hochschulgesetzes 2005 – HG, BGBl. I Nr. 30/2006, anzuwenden.

(8) Wird ein Studium gemeinsam mit einer Pädagogischen Hochschule eingerichtet, können die Rektorate der beteiligten Bildungseinrichtungen für den Fall, dass aus Platzgründen nicht alle Studienwerberinnen und Studienwerber zugelassen werden können, durch gleichlautende Verordnungen eine den Kapazitäten entsprechende Anzahl von Studienanfängerinnen und -anfängern sowie für alle in gleicher Weise geltende Zulassungskriterien festlegen.

(9) Wenn die beteiligten Bildungseinrichtungen beschließen, die Durchführung eines gemeinsam eingerichteten Studiums zu beenden, haben sie Vorsorge zu treffen, dass Studierenden der Abschluss des Studiums innerhalb einer angemessenen Frist,

be stated which provisions of study law in the statutes of which participating educational institution shall apply.

(4) Admission to a jointly offered study programme may be granted only at one of the participating educational institutions to be chosen by the student. The rectorates of the participating universities and public university colleges of teacher education may, by decrees to be enacted identically, or the competent bodies of recognized private university colleges of teacher education, institutions offering university of applied sciences programmes, and private universities may, by agreements to be published identically, indicate the educational institution which shall implement the admission. By the admission, the student shall become a member of all educational institutions participating in the jointly offered study programme.

(5) The institution which has admitted the student shall implement the registration for the continuation of studies, issue the confirmations, certifications and pieces of evidence regarding the studies and the final certificates, award the prescribed academic degree or the prescribed academic designation, respectively, as well as issue the diploma supplement.

(6) In the case of participation of universities of applied sciences or private universities in a jointly offered study programme, the study law provisions of this Part II shall apply. Appeals to the Federal Administrative Court against such decisions shall be permissible.

(7) If a teacher training programme for primary school teaching and for secondary school teaching (vocational training) is offered jointly with a university college of teacher education, the respective provisions of the Teacher Education Act 2005 – HG, F. L. G. I No 30/2006, shall apply.

(8) If a programme is offered jointly with a university college of teacher education, the rectorates of the participating educational institutions may, in the case that not all applicants can be admitted for reasons of study places, by decrees to be enacted identically, determine a number of first-year students which corresponds to the capacities available as well as admission criteria which shall apply to all applicants in the same way.

(9) If the participating educational institutions decide to discontinue a jointly offered study programme, they shall make arrangements so that students of the respective programme have the possibility to complete their studies within a

die jedenfalls die Studiendauer zuzüglich zweier Semester zu umfassen hat, möglich ist.

Studien im Ausland

§ 54f. Die Universitäten sind berechtigt, Studien zur Gänze oder zum Teil im Ausland durchzuführen, sofern der Lehr- und Forschungsbetrieb der betreffenden Universität hierdurch nicht beeinträchtigt wird und dies in der Leistungsvereinbarung festgelegt wurde.

Individuelles Studium

§ 55. (1) Fächer aus verschiedenen Diplom-, Bachelor- oder Masterstudien dürfen zu einem individuellen Bachelor- oder Masterstudium verbunden werden. Der Antrag auf Zulassung zu einem individuellen Studium ist an jener Universität einzubringen, an welcher der Schwerpunkt des geplanten Studiums liegen soll.

(2) Der Antrag hat jedenfalls zu enthalten:

1. die Bezeichnung des Studiums;
2. ein Curriculum einschließlich Qualifikationsprofil;
3. den Umfang in ECTS-Anrechnungspunkten;
4. wenn das Studium an mehreren Universitäten durchgeführt werden soll, die Zuordnung der Fächer zu den beteiligten Universitäten.

(3) Der Antrag ist vom für die Organisation der Studien zuständigen Organ bescheidmäßig zu genehmigen, wenn das beantragte Studium einem facheinschlägigen Studium gleichwertig ist. In der Genehmigung ist der Zeitpunkt der Zulassung zum individuellen Studium festzulegen.

(4) Absolventinnen und Absolventen individueller Bachelorstudien ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ jener Universität, an welcher der Schwerpunkt des Studiums gelegen ist, der akademische Grad „Bachelor“, abgekürzt, „BA“, Absolventinnen und Absolventen individueller Diplomstudien ist der akademische Grad „Magistra“ bzw. „Magister“, abgekürzt, jeweils „Mag.“ zu verleihen, Absolventinnen und Absolventen individueller Masterstudien ist der akademische Grad „Master“, abgekürzt, „MA“ zu verleihen. Überwiegen in einem individuellen Diplom- oder Masterstudium die Fächer aus ingenieurwissenschaftlichen Studien, ist den Absolventinnen und Absolventen der akademische Grad „Diplom-Ingenieurin“ bzw. „Diplom-Ingenieur“, abgekürzt, jeweils „Dipl.-Ing.“ oder „DI“ zu verleihen.

reasonable period, which shall at least comprise the duration of the studies plus two semesters.

Study Programmes Carried Out Abroad

§ 54f. The universities shall be entitled to carry out studies entirely or partially abroad, provided that the teaching and research activities of the university concerned are not limited thereby and that it has been set out in the performance agreement.

Individually Designed Degree Programmes

§ 55. (1) Subjects forming part of different diploma, bachelor’s or master’s programmes may be combined in individual bachelor’s or master’s programmes. Applications for admission to an individual programme shall be made to the university at which will be the main focus of the planned studies.

(2) Such applications shall, at the least, contain:

1. the designation of the programme;
2. a curriculum including the qualification profile;
3. the number of ECTS credits conferred; and
4. if the programme of study is to be undertaken at more than one university, the universities at which given subjects are to be studied.

(3) Applications shall, by official notification, be approved by the governing bodies responsible for the programmes if the programme applied for is of equivalent standing to a programme relevant to such subjects. Such approval shall include the date of admission to individual programmes.

(4) Persons who have successfully completed individual bachelor's programmes shall be granted the academic degree of “Bachelor”, abbreviated as “BA”, by the responsible governing body at the university at which the main focus of their studies lay. Persons who have successfully completed individual diploma programmes shall be awarded the academic degree of “Magistra” or “Magister”, abbreviated as “Mag.”. Persons who have successfully completed individual master's programmes shall be awarded the title of “Master”, abbreviated as “MA”. If subjects related to engineering sciences predominate in an individual diploma or master's programme, the graduates in question shall be awarded the title of “Diplom-Ingenieurin” or “Diplom-Ingenieur”, abbreviated as “Dipl.-Ing.” or “DI”.

Universitätslehrgänge

§ 56. (1) Die Universitäten sind berechtigt, in ihrem Wirkungsbereich Universitätslehrgänge einzurichten. Diese sind in die hochschulinterne Qualitätssicherung und -entwicklung einzubinden. Die Qualität der Lehre ist durch wissenschaftlich, wissenschaftlich-künstlerisch, künstlerisch oder berufspraktisch und didaktisch entsprechend qualifiziertes Lehrpersonal sicherzustellen.

(2) Universitätslehrgänge können auch als außerordentliche Bachelorstudien und außerordentliche Masterstudien eingerichtet werden. Diese Universitätslehrgänge sind ordentlichen Bachelorstudien gemäß § 51 Abs. 2 Z 4 und ordentlichen Masterstudien gemäß § 51 Abs. 2 Z 5 gleichwertig und berechtigen nach Maßgabe der weiteren gesetzlichen Bestimmungen zur Zulassung zu ordentlichen Masterstudien und Doktoratsstudien. Der Arbeitsaufwand für außerordentliche Bachelorstudien hat 180 ECTS-Anrechnungspunkte und für außerordentliche Masterstudien 120 ECTS-Anrechnungspunkte zu betragen. Der Arbeitsaufwand für ein außerordentliches Masterstudium kann in Ausnahmefällen weniger ECTS-Anrechnungspunkte betragen, wenn dieses in Umfang und Anforderungen mit mehreren fachlich in Frage kommenden ausländischen Masterstudien vergleichbar ist.

(3) Universitätslehrgänge können auch als gemeinsame Studienprogramme (§ 54d) oder als gemeinsam eingerichtete Studien (§ 54e) und während der lehrveranstaltungsfreien Zeit angeboten und durchgeführt werden.

(4) Universitätslehrgänge können zur wirtschaftlichen und organisatorischen Unterstützung in Zusammenarbeit mit einem außerhochschulischen Rechtsträger angeboten und durchgeführt werden. Abweichend davon ist für Universitätslehrgänge, in denen der akademische Grad „Bachelor Professional“ oder „Master Professional“ verliehen werden soll, eine erweiterte Zusammenarbeit mit einer außerhochschulischen Bildungseinrichtung erforderlich. In diesem Fall sind Verträge insbesondere über die Festlegungen der Leistungen, die die beteiligten Einrichtungen zu erbringen haben, die Durchführung und die Finanzierung zu schließen. Diese Verträge sind ohne Personenbezug sowie die Angabe von privaten Finanzierungsquellen und von Betriebs- und Geschäftsgeheimissen auf den Webseiten der beteiligten Einrichtungen zu veröffentlichen.

(5) Für den Besuch von Universitätslehrgängen haben die Teilnehmerinnen und Teilnehmer einen Lehrgangsbeitrag zu entrichten. Dieser ist unter Berücksichtigung der tatsächlichen Kosten des Universitätslehrgangs vom Rektorat festzusetzen. Teilnehmerinnen und Teilnehmern, die gleichzeitig ein ordentliches Studium an

Continuing Education University Programmes

§ 56. (1) The universities shall be entitled, in their sphere of action, to establish continuing education university programmes. These shall be integrated into the internal quality assurance and quality enhancement processes. The quality of teaching shall be assured by scientifically, scientifically-artistically, artistically or professionally and didactically appropriately qualified teaching staff.

(2) Continuing education university programmes may also be run as continuing education bachelor's programmes and continuing education master's programmes. These continuing education university programmes shall be equivalent to bachelor's degree programmes according to § 51 para 2 subpara 4 and master's degree programmes according to § 51 para 2 subpara 5 which, in accordance with the further statutory provisions, shall entitle the graduates to be admitted to master's and doctoral degree programmes. The workload associated with continuing education bachelor's programmes shall amount to 180 ECTS credits, and that associated with continuing education master's programmes to 120 ECTS credits. In exceptional cases, the workload for a continuing education master's programme may amount to less ECTS credits if this is comparable to the scope and requirements of several related foreign master's programmes.

(3) Continuing education university programmes may be run as joint programmes (§ 54d) or as jointly offered programmes (§ 54e) and may also be conducted during the recess periods.

(4) Continuing education university programmes may be offered and conducted in co-operation with legal entities outside the higher education area for the purpose of financial and organisational support. As an exception to this rule, extended cooperation with educational institutions outside higher education is required for continuing education university programmes upon completion of which the academic degree “Bachelor Professional” or “Master Professional” shall be awarded. In this case, agreements shall be concluded, in particular, on the performance which the institutions concerned shall be committed to, on the execution and on the funding. These agreements shall be published without any personal references on the websites of the institutions concerned, excluding the disclosure of private funding sources as well as of operational and business secrets.

(5) Students attending continuing education university programmes shall pay programme fees. These shall be set by the rectorate at levels reflecting actual course costs. Participants who at the same time are enrolled in a degree programme at the same university at which they receive student grants, shall, on application, be

derselben Universität belegen und die eine Studienbeihilfe beziehen, ist auf Antrag unter Bedachtnahme auf ihre Leistungsfähigkeit eine Ermäßigung oder Erlassung des Lehrgangsbeitrags zu gewähren.

(6) Die Teilnahme an Universitätslehrgängen der Fort- und Weiterbildung für Lehrerinnen und Lehrer, die im öffentlich-rechtlichen Bildungsauftrag durchgeführt werden, ist für die Teilnehmerinnen und Teilnehmer frei von Lehrgangsbeiträgen.

(7) Im Curriculum eines Universitätslehrgangs kann eine Höchststudiendauer vorgesehen werden, die mindestens die vorgesehene Studienzeit zuzüglich zwei Semester umfasst.

Vorbereitungslehrgänge

§ 57. Die Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 sind berechtigt, Vorbereitungslehrgänge zur Vorbereitung auf ein künstlerisches Bachelor- oder Diplomstudium einzurichten. Für Vorbereitungslehrgänge ist kein Lehrgangsbeitrag und kein Studienbeitrag einzuheben.

Curricula

§ 58. (1) An den Universitäten sind für die einzelnen Studien nach Maßgabe ~~der §§~~des § 54b Abs. 4~~ und 54c Abs. 2~~ Curricula zu erlassen.

(2) Die Curricula haben ein Qualifikationsprofil (§ 51 Abs. 2 Z 29) zu enthalten.

(3) Die Curricula von Lehramtsstudien haben kompetenzorientiert nach Maßgabe der Anlage des Hochschul-Qualitätssicherungsgesetzes – HS-QSG, BGBl. I Nr. 74/2011, gestaltet zu sein.

(4) In den Curricula von Bachelorstudien für das Lehramt sind gegebenenfalls fachspezifische Kriterien für die Feststellung der fachlichen Eignung festzulegen. In den Curricula von künstlerischen Studien und von sportwissenschaftlichen Studien sowie für die Lehramtsstudien in diesen Fächern ist festzulegen, in welcher Weise im Rahmen der Überprüfung der fachlichen Eignung Zulassungsprüfungen gemäß § 51 Abs. 2 Z 19 und § 75 durchgeführt werden.

(5) Curricula und deren Änderungen sind vor der Beschlussfassung dem Rektorat, Curricula theologischer Studien auch den zuständigen kirchlichen Stellen sowie Curricula für Lehramtsstudien auch dem Qualitätssicherungsrat für Pädagoginnen- und Pädagogenbildung zur Stellungnahme zuzuleiten.

(6) Curricula von ordentlichen Studien und deren Änderungen treten bei Veröffentlichung im Mitteilungsblatt vor dem 1. Juli mit dem 1. Oktober desselben

accorded a reduction or waiver of the programme fees having regard to their financial circumstances.

(6) Teachers attending certificate university programmes for continuing and further education offered within the educational mission under public law shall be free of programme fees.

(7) The curriculum of a continuing education university programme may determine a maximal duration of studies, which shall comprise at least the requested duration of studies plus two semesters.

Preparatory Courses

§ 57. The universities named in § 6 para 1 subparas 16 to 21 shall be entitled to establish certificate university programmes for further education to prepare students for artistic bachelor or diploma programmes. For preparatory courses neither course fees nor tuition fees shall be levied.

Curricula

§ 58. (1) At the universities curricula shall be enacted for the single study programmes within the limits of §§ 54b para 4 and 54c para 2.

(2) The curricula shall contain a qualification profile (§ 51 para 2 subpara 29).

(3) The curricula for teacher training programmes shall be designed in a competence-oriented way within the limits of the annexe to the Act on Quality Assurance in Higher Education – HS-QSG, F. L. G. No 74/2011.

(4) In the curricula for teacher training bachelor's programmes subject-specific criteria for ascertaining the subject-related capacity shall be defined. In the curricula for artistic subjects and for sports science as well as for teacher training programmes in these subjects shall be laid down in which kind within ascertaining the subject-related capacity admission examinations under § 51 para 2 subpara 19 and § 75 shall take place.

(5) Curricula and changes thereto shall be submitted to the rectorate for its opinion prior to decision-making, curricula of theological programmes shall also be submitted to the competent ecclesiastical institutions, and curricula for training programs for teaching at schools shall also be submitted to the Quality Assurance Council for Teacher Training.

(6) Curricula and changes thereto shall enter into force on 1 October of the same year, if published in the university gazette prior to 1 July; if published after 30 June,

Jahres in Kraft; bei Veröffentlichung nach dem 30. Juni treten sie mit 1. Oktober des nächsten Jahres in Kraft. Werden Studien aufgelassen, treten Curricula bei Veröffentlichung im Mitteilungsblatt vor dem 1. Juli mit Ablauf des 30. September desselben Jahres außer Kraft; bei Veröffentlichung nach dem 30. Juni treten Curricula mit 30. September des nächsten Jahres außer Kraft.

(7) Im Curriculum darf als Voraussetzung für die Anmeldung zu Lehrveranstaltungen, für deren Verständnis besondere Vorkenntnisse erforderlich sind, der Nachweis dieser Vorkenntnisse durch die positive Beurteilung einer oder mehrerer Prüfungen oder in anderer zweckmäßiger Form festgelegt werden. Diese Festlegungen gelten auch für Studierende, die sich zu der betreffenden Lehrveranstaltung im Rahmen der Nutzung des Lehrangebotes oder eines individuellen Studiums anmelden.

(8) Im Curriculum sind für Lehrveranstaltungen mit einer beschränkten Zahl von Teilnehmerinnen und Teilnehmern die Anzahl der möglichen Teilnehmerinnen und Teilnehmer sowie das Verfahren zur Vergabe der Plätze festzulegen. Dabei ist darauf zu achten, dass den bei einer Anmeldung zurückgestellten Studierenden daraus keine Verlängerung der Studienzeit erwächst. Im Bedarfsfall sind überdies Parallellehrveranstaltungen, allenfalls auch während der lehrveranstaltungsfreien Zeit, anzubieten.

(9) Curricula von Bachelor- und Masterstudien sind so zu gestalten, dass die Erbringung von Studienleistungen auch an ausländischen postsekundären Bildungseinrichtungen möglich ist. Dabei ist darauf zu achten, dass dies ohne Verlust von Studienzeiten möglich ist.

(10) Die Curricula haben die Zielsetzungen von Art. 24 der UN-Behindertenrechtskonvention zu beachten.

(11) Für Studierende mit einer Behinderung im Sinne des § 3 des Bundes-Behindertengleichstellungsgesetzes, BGBl. I Nr. 82/2005, sind die Anforderungen der Curricula – allenfalls unter Bedachtnahme auf gemäß § 59 Abs. 1 Z 12 beantragte abweichende Prüfungsmethoden – durch Bescheid des studienrechtlichen Organs zu modifizieren, wobei das Ausbildungsziel des gewählten Studiums erreichbar sein muss.

(12) Curricula sind so zu gestalten, dass die Verteilung der ECTS-Anrechnungspunkte dem tatsächlichen Arbeitsaufwand entspricht.

they shall enter into force on 1 October of the following year. In the case of expiry of study programmes, curricula shall expire with 30 September of the same year, if published in the university gazette prior to 1 July; if published after 30 June, they shall expire with 30 September of the following year.

(7) For courses requiring special types of prior knowledge, the curriculum may require evidence of such knowledge in the form of one or more examinations passed or another expedient form as a condition for registration. These conditions shall also apply to students registering for the courses in question in connection with the use of the range of courses or within an individual study programme.

(8) In the case of courses which can only be attended by a limited number of students, the curriculum shall state the maximum number of persons who can be accepted and the procedure for awarding places, whereby care shall be taken to ensure that the studies of students whose applications do not receive priority are not prolonged as a result. If necessary, parallel courses shall be offered, and these may also be held during the recess period.

(9) The curricula of bachelor's and master's programmes shall be designed in a way that studies at foreign recognized post-secondary educational institutions are possible, whereby care shall be taken to ensure that this is possible without loss of study time.

(10) In the curricula regard shall be given to the objectives stipulated in Art 24 of the UN Convention on the Rights of Persons with Disabilities.

(11) For students with disabilities in the meaning of § 3 of the Federal Act on the Equalization of Persons with Disabilities, F. L. G. I No 82/2005, the requirements stipulated in the curricula – if need be with regard to examinations according to alternative methods pursuant to § 59 para 1 subpara 12 applied for – shall be modified by official notification of the body responsible for study law, making the educational goal of the chosen programme attainable.

(12) The curricula shall be designed in a way that the allocation of the ECTS credits correspond to the actual workload.

3. Abschnitt
Studierende

Rechte und Pflichten der Studierenden

§ 59. (1) Den Studierenden steht nach Maßgabe der gesetzlichen Bestimmungen Lernfreiheit zu. Sie umfasst insbesondere das Recht,

1. sowohl an der Universität, an der sie zum Studium zugelassen wurden, als auch an anderen Universitäten die Zulassung für andere Studien zu erlangen;
2. nach Maßgabe des Lehrangebotes und der Vorgaben des Curriculums aus Lehrveranstaltungen auszuwählen;
3. neben einem ordentlichen Studium an der Universität der Zulassung oder nach Maßgabe des § 63 Abs. 9 an anderen Universitäten oder bei gemeinsam eingerichteten Studien mit Pädagogischen Hochschulen an diesen das Lehrangebot zu nutzen, für welches die Studierenden die in den Curricula festgelegten Anmeldungsvoraussetzungen erfüllen;
4. die facheinschlägigen Lehr- und Forschungseinrichtungen und die Bibliotheken an allen Bildungseinrichtungen, deren Angehörige sie sind, nach Maßgabe der Benützungsordnungen zu benützen;
5. als ordentliche Studierende eines Diplom- oder Masterstudiums das Thema und die Betreuerin oder den Betreuer ihrer Diplom- oder Masterarbeit oder das Thema ihrer künstlerischen Diplom- oder Masterarbeit, als ordentliche Studierende eines Doktoratsstudiums das Thema ihrer Dissertation und als ordentliche Studierende eines kombinierten Master- und Doktoratsstudiums, wenn eine Masterarbeit vorgesehen ist, das Thema und die Betreuerin oder den Betreuer ihrer Masterarbeit sowie ihrer Dissertation nach Maßgabe der universitären Regelungen sowie nach vorheriger Befassung der Betreuerin oder des Betreuers vorzuschlagen oder aus einer Anzahl von Vorschlägen auszuwählen;

(Anm.: Z 6 aufgehoben durch Art. 1 Z 82, BGBl. I Nr. 93/2021)

7. wissenschaftliche oder künstlerische Arbeiten in einer Fremdsprache abzufassen, wenn die Betreuerin oder der Betreuer zustimmt;
8. als ordentliche Studierende nach Maßgabe der universitären Regelungen Prüfungen abzulegen;
9. nach Erbringung der in den Curricula vorgeschriebenen Leistungen akademische Grade verliehen zu erhalten;

Chapter 3
Students

Rights and Duties of Students

§ 59. (1) Within the limits of the law, students are entitled to freedom of study. This shall, in particular, include the right,

1. to be accepted for other programmes both at the university to which they have been admitted and at other universities;
2. within the limits of the range of courses and the provisions of the curriculum, to choose between courses;
3. beyond a degree programme at the university which has admitted them or, in accordance with § 63 para 9, at other universities or, in programmes offered jointly with university colleges of teacher education, at those, to take advantage of range of courses for which they fulfil the registration requirements set out in the curricula;
4. to make use of the teaching and research facilities relevant to their subject, and the libraries at all educational institutions from which they are members, in accordance with the regulations pertaining thereto;
5. if they are degree students in a diploma or master's degree programme, to propose or select from a number of suggestions the supervisor and the topic of their diploma or master’s thesis or that of their artistic diploma or master’s submission, subject to the university regulations, or if they are degree students in a doctoral programme to select the topic of their doctoral thesis and if they are degree students in a combined master's and doctoral programme – provided that a master's thesis is part of the curriculum – to select the topic and a supervisor for their master's thesis as well as their doctoral thesis in accordance with the university regulations and following prior consultation of the supervisor;
6. *[removed]*
7. to prepare academic or artistic theses in a foreign language, subject to the agreement of their supervisor;
8. if they are degree students, to take examinations in accordance with the university regulations;
9. having met the requirements prescribed by the curriculum, to be awarded a degree;

10. als außerordentliche Studierende an den betreffenden Universitätslehrgängen teilzunehmen und die darin vorgeschriebenen Prüfungen abzulegen;
11. als außerordentliche Studierende, die nur zum Besuch von Lehrveranstaltungen zugelassen sind, Lehrveranstaltungen zu besuchen, für welche sie die in den Curricula festgelegten Anmeldungsvoraussetzungen erfüllen, sowie nach Maßgabe der universitären Regelungen Prüfungen abzulegen;
12. auf eine abweichende Prüfungsmethode, wenn die oder der Studierende eine Behinderung nachweist, die ihr oder ihm die Ablegung der Prüfung in der vorgeschriebenen Methode unmöglich macht, und der Inhalt und die Anforderungen der Prüfung durch eine abweichende Methode nicht beeinträchtigt werden;
13. auf Anträge hinsichtlich der Person der Prüferinnen oder Prüfer. Diese Anträge sind nach Möglichkeit zu berücksichtigen. Bei der zweiten Wiederholung einer Prüfung oder der Wiederholung eines im Curriculum gekennzeichneten Praktikums im Rahmen der pädagogisch-praktischen Studien ist dem Antrag auf eine bestimmte Prüferin oder einen bestimmten Prüfer der Universität der Zulassung zum Studium, in dem die Prüfung abzulegen ist, jedenfalls zu entsprechen, sofern diese oder dieser zur Abhaltung der Prüfung berechtigt ist. Bei gemeinsam eingerichteten Studien ist bei der zweiten Wiederholung einer Prüfung oder der Wiederholung eines im Curriculum gekennzeichneten Praktikums im Rahmen der pädagogisch-praktischen Studien dem Antrag auf eine bestimmte Prüferin oder einen bestimmten Prüfer der beteiligten Bildungseinrichtungen jedenfalls zu entsprechen.

(1a) Die Bundesministerin oder der Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung hat durch Verordnung Personengruppen festzulegen, die auf Grund deren besonderer persönlicher Nahebeziehungen zur Republik Österreich oder deren Tätigkeit im Auftrag der Republik Österreich, entweder wie österreichische Staatsangehörige (§§ 61 Abs. 3 Z 4, 63 Abs. 3 Z 4, 64a Abs. 4 Z 2 und 91 Abs. 1) oder wie Inhaberinnen und Inhaber von in Österreich ausgestellten Reifezeugnissen (§ 71c Abs. 5) zu behandeln sind (Personengruppenverordnung).

(2) Studierende haben die Pflicht, ihren Studienfortschritt eigenverantwortlich im Sinne eines raschen Studienabschlusses zu gestalten. Sie haben darüber hinaus insbesondere

10. if they are non-degree seeking students, to attend the relevant certificate university programmes for further education and take the examinations prescribed therefore;
11. if they are non-degree seeking students, admitted only for the attendance of individual courses, to attend courses for which they meet the registration requirements specified by the curricula, and to take examinations, subject to the university regulations;
12. to be examined according to an alternative method if they suffer from a disability which makes it impossible for them to take an examination in the prescribed manner and the other method does not limit the content and standards of the examination;
13. to make requests regarding the identity of the examiners. Such applications shall be acceded to wherever possible. In the case of a second resit, or the resit of an internship in the framework of the pedagogic-practical studies, indicated by the curriculum, to automatic acceptance of a request for a specific examiner at the university to which they have been admitted and where the examination is to be sat, provided that the examiner is entitled to take the examination. In jointly offered programmes, in the case of a second resit, or the resit of an internship in the framework of the pedagogic-practical studies, indicated by the curriculum, the request for a specific examiner at the educational institutions concerned has to be accepted in any case.

(1a) The Federal Minister of Education, Science and Research shall designate, by decree, groups of persons, who, on grounds of their close personal relationships with the Republic of Austria or their activities on behalf of the Republic of Austria, shall be treated as Austrian citizens (§§ 61 para 3 subpara 4, 63 para 3 subpara 4, 64a para 4 subpara 2 and 91 para 1) or as persons with secondary-school leaving certificates issued in Austria (§ 71c para 5) (Decree on Groups of Persons – Personengruppenverordnung).

(2) Students shall have an obligation to autonomously organise their progress of studies with the aim of finishing their studies rapidly. In addition they shall

1. der Universität, an der eine Zulassung zum Studium besteht, Namens- und Adressenänderungen unverzüglich bekannt zu geben,
2. die Fortsetzung des Studiums der Universität, an der die Zulassung zu einem Studium besteht, gemäß § 62 Abs. 1 zu melden,
3. sich bei vorhersehbarer Studieninaktivität zeitgerecht vom Studium abzumelden,
4. sich zu den Prüfungen fristgerecht an- und abzumelden und
5. anlässlich der Verleihung des akademischen Grades je ein Exemplar ihrer wissenschaftlichen oder künstlerischen Arbeit oder eine Dokumentation ihrer künstlerischen Arbeit an die Universitätsbibliothek und je ein Exemplar der Dissertation oder eine Dokumentation der künstlerischen Dissertation an die Österreichische Nationalbibliothek abzuliefern.

(3) Die berufstätigen Studierenden und die Studierenden mit Kinderbetreuungspflichten oder anderen gleichartigen Betreuungspflichten, die somit nicht Vollzeit studieren, sondern nur einen Teil ihrer Zeit dem Studium widmen können, sind berechtigt zu melden, zu welchen Tageszeiten sie einen besonderen Bedarf nach Lehr- und Prüfungsangeboten haben. Die Universitäten haben diesen besonderen Bedarf auf Grund der Meldeergebnisse bei der Gestaltung ihres Lehr- und Prüfungsangebotes nach Möglichkeit zu berücksichtigen. Bereits anlässlich der Zulassung zu einem Studium hat die Studienwerberin oder der Studienwerber das Recht, diesen Bedarf zu melden.

(4) Den Studierenden sollen nach Maßgabe der budgetären Möglichkeiten ausreichend zusätzliche Studienangebote oder Lehrveranstaltungen im selben oder spätestens im nächstfolgenden Semester angeboten werden, wenn der oder dem Studierenden eine Verlängerung der Studienzeit zu erwachsen droht, deren Ursache alleine oder überwiegend der Universität zuzurechnen ist, insbesondere im Zusammenhang mit zu geringen Lehrveranstaltungsangeboten der Universität. Der Universität zurechenbar ist eine Verlängerung der Studienzeit insbesondere dann, wenn diese durch Rückstellung bei der Anmeldung zu einer Lehrveranstaltung erfolgt.

(5) Das Recht, als Vertreterin oder als Vertreter der Studierenden in Kollegialorganen tätig zu werden, richtet sich nach den Bestimmungen des HSG 2014. Für Entsendungen in Kollegialorgane des Senates gemäß § 25 Abs. 8 Z 1 bis 3 kann die Universität in der Satzung festlegen, dass fachlich in Frage kommende

1. inform the university which has admitted them of changes of name and address without delay,
2. notify the university which has admitted them of the continuation of their studies, pursuant to § 62 para 1,
3. to deregister from their programme in a timely manner in case that it is apparent that they are unlikely to continue their studies,
4. to register for and deregister from examinations within the appointed periods and
5. to deliver a copy of their academic thesis or artistic submission or a related written component thereof to the university library and a copy of their doctoral thesis or a related written component of their artistic doctoral thesis to the Austrian National Library upon the award of their degree.

(3) Working students and students who are unable to study full time due to child care or similar care commitments and can thus only devote part of their time to their studies shall be entitled to notify the university of the times at which they have special needs in respect of courses and examinations. Wherever possible, universities shall take into account such special needs in their course and examination timetabling, on the basis of the information supplied to them by such students. Applicants shall be entitled to notify such needs when applying for admission.

(4) The students shall be offered, contingent on budgetary considerations, sufficient courses in the same or the following semester at the latest, if the prolongation of a student's duration of studies appears to be imminent, for which the university is solely or mainly responsible, in particular because the university has offered too few courses. The university shall be responsible for a prolonged period of study in particular, if the prolongation is caused, because the student was not given a place in a course s/he wanted to register for.

(5) The right to act as a representative of students in collegial bodies is determined by the provisions of HSG 2014. With regard to the appointment of representatives to a collegial body of the senate according to § 25 para 8 subparas 1 to 3, the university may determine in its statutes that proof of related knowledge amounting to a maximum of 60 ECTS credits must be submitted.

Kenntnisse im Ausmaß von bis zu 60 ECTS-Anrechnungspunkten nachgewiesen werden müssen.

Mindeststudienleistung

§ 59a. (1) In Bachelor- und Diplomstudien sind die Studierenden verpflichtet, in jedem Studium, zu dem eine Zulassung besteht, in den ersten vier Semestern insgesamt eine Studienleistung im Umfang von mindestens 16 ECTS-Anrechnungspunkten zu erbringen. Anerkennungen gemäß § 78 sind nur dann auf die Mindeststudienleistung anzurechnen, wenn die der Anerkennung zugrundeliegende Prüfung, andere Studienleistung, Tätigkeit und ~~Qualifikation~~Kompetenz während der betreffenden Semester erbracht wurde.

(2) ECTS-Anrechnungspunkte für das Erreichen der Mindeststudienleistung nach vier Semestern gemäß Abs. 1 können im Wintersemester bis zum 31. Oktober und im Sommersemester bis zum 31. März erbracht werden. Für die Berechnung der Zahl der ECTS-Anrechnungspunkte ist der Zeitpunkt der Absolvierung der Leistung maßgeblich.

(3) Semester, für die eine Beurlaubung vorliegt, sind in die in Abs. 1 festgelegten vier Semester nicht einzurechnen.

(4) Gemäß § 68 Abs. 1 Z 2a erlischt die Zulassung zum Studium mit 1. November bzw. mit 1. April, wenn die oder der Studierende die Mindeststudienleistung gemäß Abs. 1 nicht erbracht hat.

(5) Diese Bestimmung gilt nicht für Studierende mit einer Behinderung gemäß § 3 BGStG.

Unterstützungsleistungen seitens der Universität

§ 59b. (1) Die Universität hat Studierende, die in den ersten beiden Semestern nicht mindestens 12 ECTS-Anrechnungspunkte absolviert haben, darüber zu informieren, dass die Zulassung zum Studium erlischt, wenn sie nach Beenden des vierten Semesters die Mindeststudienleistung gemäß § 59a Abs. 1 nicht erbracht haben.

(2) Die Universität hat jedenfalls im Zusammenhang mit der Information über das Erlöschen der Zulassung auf die bestehenden Möglichkeiten einer Studienberatung sowie von Unterstützungsleistungen hinzuweisen.

(3) Die Universität kann Studierenden, die in einem Diplom- oder Bachelorstudium mindestens 120 ECTS-Anrechnungspunkte absolviert haben, bei Prüfungsinaktivität der Studierenden im vorangegangenen Studienjahr eine „Vereinbarung über die Studienleistung“ für dieses Studium anbieten. Näheres ist in

Minimum Requirement of Study Progress

§ 59a. (1) In bachelor's and diploma programmes, students shall be required to submit proof of academic achievements amounting to a total of at least 16 ECTS credits within the first four semesters. This shall apply to each study programme they have been admitted to. Recognitions according to § 78 shall be counted towards this minimum requirement of study progress only if the examination, other academic achievement, activity and qualification on which the recognition is based was successfully completed during the relevant semesters.

(2) The ECTS credits for the achievement of the minimum requirement of study progress after four semesters according to para 1 may be acquired by 31 October in the winter semester and by 31 March in the summer semester. The time of successful completion of the achievement is decisive for the calculation of the ECTS credits.

(3) Semesters for which an academic leave has been granted shall not be counted into the four semesters as determined in para 1.

(4) According to § 68 para 1 subpara 2a, admission to a study programme shall expire on 1 November or 1 April, respectively, if the student fails to achieve the minimum amount of ECTS credits according to para 1.

(5) These provisions shall not apply to students with disabilities in the meaning of § 3 BGStG.

Support Provided by the University

§ 59b. (1) The university shall inform students who have failed to achieve a minimum of 12 ECTS credits within the first two semesters that their admission to the study programme will expire if they cannot submit proof of the minimum requirement of study progress according to § 59a para 1 following completion of the fourth semester.

(2) In connection with the information on the expiry of admission, the university shall, in any case, point out existing student counselling services as well as other support provided.

(3) In the case of student inactivity with regard to examinations throughout the preceding academic year, the university may offer students who have achieved a minimum of 120 ECTS credits in a diploma or bachelor's programme an “Agreement on Academic Achievements”. Further details shall be regulated in the statutes. The

der Satzung zu regeln. Die Vereinbarung ist zwischen der oder dem Studierenden und dem Rektorat abzuschließen und hat jedenfalls folgende Mindestinhalte zu umfassen:

1. Unterstützungsmaßnahmen für die Studierenden seitens der Universität (insbesondere durch Anspruch auf Absolvierung bestimmter Lehrveranstaltungen und Prüfungen, Aufnahme in Lehrveranstaltungen mit einer beschränkten Zahl von Teilnehmerinnen und Teilnehmern, Rückerstattung des Studienbeitrages, etc.),
2. Verpflichtungen der Studierenden (insbesondere zur Absolvierung bestimmter Lehrveranstaltungen und Prüfungen, etc.),
3. Sanktionen bei Nichterfüllung der Vereinbarung (insbesondere keine Rückerstattung des Studienbeitrages, etc.).

Zulassung zum Studium

§ 60. (1) Das Rektorat hat Personen, welche die Zulassungsvoraussetzungen erfüllen, auf Grund ihres Antrages mit Bescheid zum jeweiligen Studium zuzulassen. Das Rektorat ist berechtigt, die höchstzulässige Anzahl der Anträge auf Zulassung zum Studium innerhalb einer Zulassungsfrist pro Studienwerberin bzw. Studienwerber festzulegen, wobei die Zulassung für bis zu fünf Studien sicherzustellen ist.

(1a) Für Studien, für die die Eignung gemäß § 63 Abs. 1 Z 4 und 5 und Abs. 1a nachzuweisen ist, können Bescheide über eine bedingte Zulassung erlassen werden, wenn zum Zeitpunkt der Zulassung das Eignungsverfahren noch nicht abgeschlossen ist.

(1b) Zur studienvorbereitenden und studienbegleitenden Beratung sind anlässlich der Zulassung zum Diplom- oder Bachelorstudium Orientierungsveranstaltungen abzuhalten und Orientierungsinformationen zur Verfügung zu stellen, in deren Rahmen

1. die Studierenden in geeigneter Form über
   a) die wesentlichen Bestimmungen des Universitätsrechts und des Studienförderungsrechts,
   b) die studentische Mitbestimmung in den Organen der Universität,
   c) die Rechtsgrundlagen der Frauenförderung,
   d) den gesetzlichen Diskriminierungsschutz,
   e) das Curriculum,
   f) das Qualifikationsprofil der Absolventinnen und der Absolventen,

agreement shall be concluded between the student and the rectorate and shall include the following, as a minimum:

1. support measures for students provided by the university (in particular, by entitling them to complete certain courses and examinations, by admitting them to courses with a limited number of participants, by reimbursing the tuition fees etc.)
2. obligations of the students (in particular, the successful completion of certain courses and examinations etc.),
3. penalties in the case of non-fulfilment of the agreement (in particular, no reimbursement of the tuition fees etc.).

Admission to Studies

§ 60. (1) The rectorate shall, on application by persons fulfilling the requirements for admission to a programme of study, admit such persons to such studies.

(1a) For programmes for which proof of aptitude shall be provided under § 63 para 1 subparas 4 and 5, and para 1a, official notifications of the conditional admission can be issued, provided that at the date of admission the procedure for the proof of aptitude has not been completed yet.

(1b) On admission to diploma or bachelor's programmes, orientation tutorials shall be held and orientation information be offered as study-preparatory and study-accompanying guidance, as part of which

1. the students shall receive, in a suitable format, information on
   a) the main provisions of university law and student grants legislation,
   b) the student representation on the governing bodies of the university,
   c) the legal basis of arrangements for the advancement of women,
   d) the statutory protection against discrimination,
   e) the curriculum,
   f) the qualification profiles of graduates,

g) die Studieneingangs- und Orientierungsphase,
h) das empfohlene Lehrangebot in den ersten beiden Semestern,
i) die Vereinbarkeit von Studium und Beruf,
j) die Zahl der Studierenden im Studium, die durchschnittliche Studiendauer, die Studienerfolgsstatistik und die Beschäftigungsstatistik,
k) studienbezogene Auslandsaufenthalte,
l) die Vertretungseinrichtungen der Studierenden, somit insbesondere die Österreichische Hochschülerinnen- und Hochschülerschaft, die jeweilige Hochschülerinnen- und Hochschülerschaft sowie
m) die Ombudsstelle für Studierende

zu informieren sind, und

2. eine Einführung in die gute wissenschaftliche oder künstlerische Praxis zu geben ist.

Es ist zulässig, die Orientierungsveranstaltungen oder die Orientierungsinformationen auch im Zusammenwirken mit anderen Rechtsträgern, insbesondere mit der Österreichischen Hochschülerinnen- und Hochschülerschaft, zu veranstalten bzw. zur Verfügung zu stellen.

(1c) Zur studienbegleitenden Beratung sind Anfängerinnen- und Anfängertutorien einzurichten, welche die Studierenden bei der Bewältigung der leistungsmäßigen, organisatorischen und sozialen Anforderungen des ersten Studienjahres unterstützen sollen und von den Studierenden besucht werden können. Es ist zulässig, diese Anfängerinnen- und Anfängertutorien auch im Zusammenwirken mit anderen Rechtsträgern, insbesondere mit der Österreichischen Hochschülerinnen- und Hochschülerschaft zu veranstalten.

(2) Soweit zur Beurteilung der Erfüllung der Zulassungsvoraussetzungen fremdsprachige Urkunden vorgelegt werden, sind dem Antrag durch allgemein beeidete und gerichtlich zertifizierte Dolmetscherinnen oder Dolmetscher angefertigte Übersetzungen anzuschließen.

(3) Das Rektorat ist berechtigt, die Verpflichtung zur Vorlage einzelner Unterlagen nachzusehen, wenn glaubhaft gemacht wird, dass deren Beibringung innerhalb einer angemessenen Frist unmöglich oder mit unverhältnismäßig großen Schwierigkeiten verbunden ist und die vorgelegten Unterlagen für eine Entscheidung ausreichen.

g) the orientation period,
h) the recommended courses for the first two semesters,
i) the compatibility of studies with work,
j) the number of students enrolled in the programme, the average duration of studies, the pass rates, the employment statistics,
k) study-related stays abroad,
l) the institutions for representation fo students, i.e. the Austrian Students' Union and the respective Students' Union, and
m) the Austrian Student Ombudsman,

and

2. an introduction to good scientific practice shall be provided.

It shall be permissible to hold the orientation tutorials and to offer the orientation information together with other legal entities, particularly the Austrian Students' Union.

(1c) Provision shall be made for tutorials that offer first-year students on-going support in meeting the academic, organisational and social challenges presented by their first year of study. It is permissible to organise these tutorials for students who begin their studies in conjunction with other legal entities, particularly the Austrian Students' Union.

(2) If supporting documents in foreign languages are required to determine whether the admission requirements are met, the application shall be fitted with translations which have be done by generally sworn and jurisdictionally certified translators.

(3) The rectorate shall be entitled to waive the obligation to submit some documents if it is satisfied that it would be impossible or excessively difficult to furnish them within a reasonable period, and that the supporting documentation submitted is a sufficient basis for a decision. The representation of foreign study applicants by persons who are not admitted to a professional representation of parties in Austria or not empowered for representations by law, is not allowed. Applications which are not in line with these requirements shall be rejected.

(3a) Bestehen Zweifel an der Echtheit der Urkunden, mit denen die Erfüllung der Zulassungsvoraussetzungen nachgewiesen wird, oder an deren inhaltlicher Richtigkeit oder reichen diese für eine Entscheidung nicht aus, kann das Rektorat die Überprüfung der Unterlagen oder der Kenntnisse vornehmen oder durch vom Rektorat bestellte Sachverständige vornehmen lassen. Dafür kann vom Rektorat eine Kaution in der Höhe von höchstens 500 Euro eingehoben werden, welche der Studienwerberin oder dem Studienwerber rückzuerstatten ist, wenn die Überprüfung die Echtheit und Richtigkeit der Unterlagen ergeben hat und diese oder dieser zu einem Studium zugelassen worden ist.

(3b) Bestehen Zweifel an der Wertigkeit von ausländischen Qualifikationen für den Universitätszugang gemäß § 64 Abs. 2, kann das Rektorat vor der Zulassung eine Bewertung der für den Universitätszugang erforderlichen Bildungsdokumente durch Sachverständige oder durch auf Bewertungen im Hinblick auf das österreichische Hochschulsystem spezialisierte Stellen vornehmen lassen. Nähere Regelungen sind in der Satzung zu treffen.

(4) Mit der Zulassung wird die Studienwerberin oder der Studienwerber als ordentliche oder außerordentliche Studierende oder ordentlicher oder außerordentlicher Studierender Angehörige oder Angehöriger dieser Universität. Dies ist durch die Ausstellung eines Studierendenausweises ~~zu beurkunden~~, der als Lichtbildausweis ausgestaltet sein kann~~. Der Ausweis hat zumindest Namen, Geburtsdatum und Matrikelnummer der oder des Studierenden und die Gültigkeitsdauer zu enthalten.~~, bzw. eines digitalen Studierendenausweises gemäß § 11a BilDokG 2020 zu beurkunden. Der Studierendenausweis bzw. der digitale Studierendenausweis kann ~~über ein Speichermedium~~ mit weiteren Funktionalitäten ausgestattet sein.

(5) Einer Studienwerberin oder einem Studienwerber, die oder der noch an keiner Universität, Pädagogischen Hochschule, Einrichtung zur Durchführung von Fachhochschul-Studiengängen oder Privatuniversität zugelassen war, hat die Universität anlässlich der erstmaligen Zulassung eine Matrikelnummer zuzuordnen. Diese ist für alle weiteren Studienzulassungen der oder des betreffenden Studierenden beizubehalten. Die näheren Bestimmungen über Bildung und Vergabe von Matrikelnummern sind durch eine Verordnung der Bundesministerin oder des Bundesministers für ~~Bildung~~Frauen, Wissenschaft und Forschung zu treffen.

(6) Universitäten gemäß § 6 Abs. 1 Z 1 bis 15 und 22 haben ausländischen Studienwerberinnen und Studienwerbern, die zur sichtvermerksfreien Einreise berechtigt sind oder über einen gültigen Aufenthaltstitel verfügen, den

(3a) If there are any doubts about the authenticity of the documents furnishing proof of the fulfilment of the admission requirements, or the correctness of their contents, or if they are not sufficient to make a decision, the rectorate may carry out or call suitable persons for an evaluation of the documents or a test of the applicant's knowledge. For this purpose, the rectorate may collect a deposit of a maximum of 500 € which shall be refunded to the applicant in case the evaluation has revealed the authenticity and correctness of the documents and he or she has been admitted to a study programme.

(4) Upon admission the applicant shall become a member of the university in question, as a degree or non-degree seeking student. This shall be evidenced by the issue of a student’s pass, which may take the form of a photographic identity document. The pass shall, as a minimum, bear the student’s name, date of birth and matriculation number, as well as the expiry date. The pass may be fitted with other functionalities by a storage medium.

(5) On initial admission, an applicant who has not yet been admitted to a university, a university college of teacher education, an institution for the execution of university of applied sciences degree programmes, or a private university shall be assigned a matriculation number by the university. These shall be retained by the students concerned for all further admissions. The Federal Minister of Education, Science and Research shall by decree enact detailed regulations on the generation and assignment of matriculation numbers.

(6) The universities named in § 6 para 1 subparas 1 to 15 and 22 shall deliver admission confirmations directly to foreign applicants entitled to visa-free entry to Austria or in possession of valid residence permits. If applications from other foreign

Zulassungsbescheid direkt zuzustellen. Langen an österreichischen Berufsvertretungsbehörden Anträge anderer ausländischer Studienwerberinnen und Studienwerber auf Zulassung zum Studium zur Weiterleitung an die zuständige Universität ein, können die Berufsvertretungsbehörden auf die Vollständigkeit und Schlüssigkeit des Antrags sowie darauf hinwirken, dass die Zulassung zum Studium und der Erstaufenthaltstitel zeitgleich zugestellt werden können. Hierbei ist der Studienwerberin oder dem Studienwerber Gelegenheit zu geben, auf ihre oder seine Kosten Ergänzungen und Klarstellungen vorzunehmen. Die Vertretung ausländischer Studienwerberinnen und -werber durch Personen, die nicht zur berufsmäßigen Parteienvertretung in Österreich zugelassen oder nicht durch Gesetz zur Vertretung berechtigt sind, ist nicht zulässig. Anträge, die diesen Anforderungen nicht entsprechen, sind zurückzuweisen.

Zulassungsfristen

§ 61. (1) Das Rektorat hat nach Anhörung des Senates für jedes Semester die allgemeine Zulassungsfrist festzulegen. Dies ist der Zeitraum, in dem die Studierenden ihre Anträge auf Zulassung zum Studium einzubringen, die Studierendenbeiträge samt allfälliger Sonderbeiträge und bei Bestehen einer Studienbeitragspflicht gemäß § 91 Abs. 2 und 3 den Studienbeitrag zu entrichten haben. Die allgemeine Zulassungsfrist hat für das Wintersemester mindestens acht Wochen und für das Sommersemester mindestens vier Wochen zu betragen. Für Zulassungen zu Bachelor- oder Diplomstudien endet die allgemeine Zulassungsfrist im Wintersemester am 5. September und im Sommersemester am 5. Februar. Die Zulassung zu Master- und Doktoratsstudien sowie kombinierten Master- und Doktoratsstudien kann auch außerhalb der allgemeinen Zulassungsfrist erfolgen. Für Zulassungen zu Studien, für die besondere Zulassungs-, Aufnahme- oder Eignungsverfahren vorgesehen sind, können vom Rektorat nach Anhörung des Senats abweichende allgemeine Zulassungsfristen festgelegt werden.

(2) Die Zulassung zu einem Bachelor- oder Diplomstudium darf in den folgenden Ausnahmefällen im Wintersemester bis längstens 31. Oktober und im Sommersemester bis längstens 31. März erfolgen:

1. Nichtbestehen eines Aufnahme- oder Zulassungsverfahrens oder der Studieneingangs- und Orientierungsphase in einem anderen Studium, sofern das Ergebnis für das Wintersemester erst nach dem 31. August, für das Sommersemester erst nach dem 31. Jänner vorliegt;
2. Erlangung der allgemeinen Universitätsreife für das Wintersemester erst nach dem 31. August, für das Sommersemester erst nach dem 31. Jänner;

applicants for admission to programmes of study are received by Austrian official representations for forwarding to the responsible universities, the official representations may ensure that the applications are complete and the details therein consistent, and take steps to ensure that the admission confirmations and initial residential permits are delivered at the same time. Applicants shall be given an opportunity to clarify or add to the information contained in applications at their own expense. The representation of foreign study applicants by persons who are not admitted to a professional representation of parties in Austria or not empowered for representations by law, is not allowed. Applications which are not in line with these requirements shall be rejected.

Admission Periods

§ 61. (1) After consulting the senate, the rectorate shall establish the general admission period for each semester. This is the period during which the students shall apply for admission to the study programme, pay the student's union fees, including any extraordinary contributions and, in the event of an obligation to pay tuition fees pursuant to § 91 paras 2 and 3, pay the tuition fees. The general admission period shall last at least eight weeks for the winter semester and at least four weeks for the summer semester. For bachelor's and diploma programmes the general admission period shall end on 5 September in the winter semester and on 5 February in the summer semester. Admission to master’s and doctoral programmes as well as combined master’s and doctoral programmes may also be granted outside of the general admission period. A different general admission period may be stipulated by the rectorate for the admission to those study programmes that are subject to a special admission or selection procedure or procedure for the proof of aptitude after hearing the opinion of the senate.

(2) In the following exceptional cases, admission to a bachelor's or diploma programme may be granted no longer than until 31 October in the winter semester and 31 March in the summer semester:

1. failure to pass an admission procedure or successfully complete an introductory and orientation period in another degree programme, provided that the results for the winter semester are available only after 31 August and for the summer semester after 31 January;
2. obtaining the general university entrance qualification for the winter semester after 31 August and for the summer semester after 31 January;

3. nicht rechtzeitige Ausstellung einer Aufenthaltsberechtigung für Studierende gemäß § 64 des Niederlassungs- und Aufenthaltsgesetzes (NAG), BGBl. I Nr. 100/2005, sofern diese daran kein Verschulden trifft.

Weitere Ausnahmefälle können vom Rektorat nach Anhörung des Senates festgelegt werden.

(3) Die allgemeine Zulassungsfrist gilt für:

1. österreichische Staatsangehörige;
2. Staatsangehörige eines EU- oder EWR-Staates;
3. andere ausländische Staatsangehörige und Staatenlose, die eine auf höchstens zwei Semester befristete Zulassung zum Studium in Österreich entweder auf Grund transnationaler EU-, staatlicher oder universitärer Mobilitätsprogramme, einschließlich gemeinsamer Studienprogramme, oder nach Absolvierung ausländischer Studien in einem der ersten Diplomprüfung des gewählten Diplomstudiums oder einem Bachelorstudium entsprechenden Umfang anstreben;
4. Personengruppen aufgrund der Personengruppenverordnung~~;~~.

(4) Für alle anderen ausländischen Staatsangehörigen und Staatenlosen kann das Rektorat nach Anhörung des Senates eine abweichende besondere Zulassungsfrist festlegen.

Meldung der Fortsetzung des Studiums

§ 62. (1) Das Rektorat hat nach Anhörung des Senates für jedes Semester die Frist für die Meldung der Fortsetzung des Studiums festzulegen. Dies ist der Zeitraum, in dem, mit Ausnahme des ersten Semesters, die Studierenden die Meldung der Fortsetzung ihres Studiums vornehmen und bei Bestehen einer Studienbeitragspflicht gemäß § 91 Abs. 1 bis 3 den Studienbeitrag zu entrichten haben. Die Frist zur Meldung der Fortsetzung hat für das Wintersemester mindestens acht Wochen und für das Sommersemester mindestens vier Wochen zu betragen. Die Studierenden sind verpflichtet, für das Wintersemester bis 31. Oktober und für das Sommersemester bis 31. März der Universität, an der eine Zulassung zum Studium besteht, die Fortsetzung des Studiums zu melden.

(2) Die Meldung der Fortsetzung des Studiums ist unwirksam, solange die Studierendenbeiträge samt allfälliger Sonderbeiträge nach den Bestimmungen des HSG 2014 und die allfälligen Studienbeiträge nicht eingelangt sind.

3. untimely issuance of a residence permit for students under § 64 of the Settlement and Residence Act (Niederlassungs- und Aufenthaltsgesetzes – NAG), F. L. G. I No 100/2005, providing that this was beyond their control.

After hearing the opinion of the senate, the rectorate may stipulate further exceptional cases.

(3) The general admission period shall be applicable to:

1. Austrian citizens;
2. nationals of a EU or EEA country;
3. other foreign nationals and stateless persons seeking admission for studies in Austria for a maximum of two semesters either under transnational EU, state or university mobility programmes including joint diploma programmes or on successful completion of studies abroad equivalent to a pass in the first diploma examination in the diploma programme selected or a bachelor degree;
4. groups of persons designated by decree of the Federal Minister on Groups of Persons;

(4) For all other foreign nationals and stateless persons, the rectorate may, after hearing the opinion of the senate, lay down a divergent special admission period in the statutes.

Registration for the Continuation of Studies

§ 62. (1) After hearing the senate, the rectorate shall establish the registration period for the continuation of studies for each semester, except for the first. This is the period during which the students shall register for the continuation of their studies and, in the event of an obligation to pay tuition fees pursuant to § 91 paras 1 to 3 pay the tuition fees. The registration period for the continuation of studies shall last at least eight weeks for the winter semester and at least four weeks for the summer semester. Students are obliged to register for the continuation of their studies by 31 October in the winter semester and by 31 March in the summer semester at the university at which admission has been granted.

(2) Registration for the continuation of studies shall be invalid if any students' fees and any extraordinary contributions pursuant to the provisions of the HSG 2014 and any tuition fees payable have not been received.

(3) Die Wirkung der Meldung der Fortsetzung des Studiums für das Wintersemester erstreckt sich bis zum 31. März des unmittelbar darauffolgenden Sommersemesters, die Wirkung der Meldung der Fortsetzung des Studiums für das Sommersemester erstreckt sich bis zum 31. Oktober des unmittelbar darauffolgenden Wintersemesters, in beiden Fällen sofern die Zulassung zum Studium noch nicht erloschen ist.

(4) Über die Meldung der Fortsetzung des Studiums hat die Universität den Studierenden Studienbestätigungen auszustellen. Diese müssen jedenfalls Namen, Geburtsdatum, Matrikelnummer und Sozialversicherungsnummer der oder des Studierenden sowie den Studierendenstatus, das Studium und das Semester enthalten.

(5) Die Meldung der Fortsetzung des Studiums ist im Studierendenausweis bzw. im digitalen Studierendenausweis (§ 60 Abs. 4) zu vermerken.

Zulassung zu ordentlichen Studien

§ 63. (1) Die Zulassung zu einem ordentlichen Studium setzt voraus:

1. die allgemeine Universitätsreife,
2. die besondere Universitätsreife für das gewählte Studium,
3. die für den erfolgreichen Studienfortgang notwendigen Kenntnisse der deutschen oder, wenn das Studium in englischer Sprache abgehalten wird, der englischen Sprache; für die Zulassung zu einem Doktoratsstudium die für den erfolgreichen Studienfortgang notwendigen Kenntnisse der Sprache, in welcher das Studium abgehalten wird,
4. die künstlerische Eignung für die Studien an den Universitäten gemäß § 6 Abs. 1 Z 16 bis 21,
5. die sportliche Eignung für sportwissenschaftliche Studien und
6. für die Zulassung zu einem Bachelor- oder Diplomstudium, nach Maßgabe des Vorliegens einer Verordnung des Rektorats für einzelne oder sämtliche Bachelor- oder Diplomstudien, zu deren Zulassung keine besonderen Zugangsregelungen bestehen, den Nachweis, dass die Studienwerberin oder der Studienwerber ein Verfahren zur Eignungsüberprüfung durchlaufen hat. Im Rahmen dieses Verfahrens sind Maßnahmen im Sinne des § 13 Abs. 2 Z 1 lit. g zu treffen, um die Zulassung zum Studium von nicht-traditionellen Studienwerberinnen und -werbern sowie Studienwerberinnen und -werbern aus beim Zugang zur Hochschulbildung unterrepräsentierten Gruppen

(3) Unless admission to the study programme in question has lapsed, registration for the continuation of studies for the winter semester shall remain valid until 31 March of the subsequent summer semester, registration for the continuation of studies for the summer semester shall remain valid until 31 October of the subsequent winter semester.

(4) Universities shall issue students with confirmations of registration for the continuation of studies. These must, as a minimum, bear the student's name, date of birth, matriculation number and social security number, as well as his/her student status, the programme of study and the semester.

(5) The registration for the continuation of studies shall be evidenced in the student's pass (§ 60 para 4).

Admission to Degree Programmes

§ 63. (1) Admission to degree programmes is conditional on:

1. the possession of a general university entrance qualification;
2. the possession of a special university entrance qualification required for the study programme selected;
3. knowledge of the German language or, if the programme is held in English, the English language required for the successful continuation of studies; for the admission to a doctoral programme, the knowledge of the language in which the studies are held required for the successful continuation of studies;
4. artistic aptitude, in the case of studies at the universities named in § 6 para 1 subparas 16 to 21;
5. sportive aptitude, in the case of degree programmes in sports science; and
6. proof that the applicant has passed through an aptitude test procedure, in the case of admission to a bachelor's or diploma programme in accordance with a decree to be issued by the rectorate for some or all bachelor's or diploma programmes which have no special admission regulations. Within the framework of this procedure, measures in the meaning of § 13 para 2 subpara 1 lit g must be taken to especially promote the admission of non-traditional applicants to study programmes as well as applicants from underrepresented groups in access to higher education. Prior to the

besonders zu fördern. Vor der Erlassung der Verordnung ist dem Senat die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben.

(1a) Die Zulassung zu einem Lehramtsstudium oder einem Studium für Berufstätigkeiten an elementarpädagogischen Bildungseinrichtungen setzt abweichend von Abs. 1 voraus:

1. die allgemeine Universitätsreife,
2. die besondere Universitätsreife für das gewählte Studium,
3. die für die Ausübung des jeweiligen Berufes erforderlichen Kenntnisse der deutschen Sprache und
4. die Eignung für das Studium und die jeweilige berufliche Tätigkeit.

(2) Personen, die zu dem Studium, für das die Zulassung beantragt wird, bereits an einer anderen inländischen Universität oder Pädagogischen Hochschule zugelassen waren, haben mit dem Antrag auf Zulassung die Abgangsbescheinigung dieser Universität oder Pädagogischen Hochschule vorzulegen.

(3) Bei Nachweis der allgemeinen und der besonderen Universitätsreife sind unbefristet zuzulassen:

1. österreichische Staatsangehörige;
2. Staatsangehörige eines EU- oder EWR- Staates;
3. andere ausländische Staatsangehörige und Staatenlose, wenn im betreffenden Studium vertretbare Studienbedingungen (Abs. 4) bestehen;
4. Personengruppen aufgrund der Personengruppenverordnung.

(4) Der Senat ist berechtigt, auf Grund der Verhältniszahl zwischen Lehrenden und Studierenden in einem Studium Studienbedingungen festzustellen, die durch die weitere Zulassung von ausländischen Staatsangehörigen und Staatenlosen gemäß Abs. 3 Z 3 unvertretbar würden. In diesem Fall hat der Senat festzulegen, wie viele dieser Personen jedes Semester zugelassen werden können, ohne dass unvertretbare Studienbedingungen entstehen, und nach welchen Kriterien die allenfalls zahlenmäßig beschränkte Zulassung erfolgt. Es ist dabei zulässig, eine bevorzugte Zulassung von Studienwerberinnen und Studienwerbern aus Entwicklungsländern zu beschließen. Diese Festlegungen sind im Mitteilungsblatt der Universität zu verlautbaren.

enactment of the decree, the senate shall have the opportunity to give its opinion within six weeks.

(1a) Notwithstanding para 1, admission to a teacher training programme or a programme for teaching at elementary educational institutions is conditional on:

1. the possession of a general university entrance qualification;
2. the possession of a special university entrance qualification required for the study programme selected;
3. knowledge of the German language required for the practice of the respective profession; and
4. the aptitude for the studies and the respective profession.

(2) Persons applying to study a subject for which they have already been admitted by another Austrian university or university college of teacher education must submit their leaving certificate of this university or university college of teacher education together with the application.

(3) The following shall be admitted for an indefinite period on presentation of proof of possession of a general and a special university entrance qualification:

1. Austrian citizens;
2. nationals of a EU or EEA country;
3. other foreign nationals or stateless persons, provided that the conditions for study of the subject concerned are acceptable in the countries concerned (para 4);
4. groups of persons designated by decree of the Federal Minister on Groups of Persons.

(4) The senate shall be entitled, on the basis of the student-teacher ratio, to determine the point at which study conditions in a programme of study would become unacceptable if additional foreign nationals or stateless persons in the meaning of para 3 subpara 3 were admitted. In such cases, the senate shall determine how many such persons may be admitted per semester without giving rise to unacceptable study conditions, and establish criteria for any limits to admission numbers. It is permissible to accord preferential treatment to applicants from developing countries. Such enactments shall be published in the university gazette.

(5) Bei Nachweis der allgemeinen und der besonderen Universitätsreife sind ohne Berücksichtigung allfälliger Beschlüsse gemäß Abs. 4 befristet zuzulassen:

1. Personen für die Dauer der bewilligten Teilnahme an universitären Mobilitätsprogrammen einschließlich gemeinsamer Studienprogramme,
2. Personen, die ausschließlich Fernstudienangebote auf der Grundlage von Kooperationsverträgen nützen wollen, für höchstens zwei Semester;
3. ausländische Staatsangehörige und Staatenlose gemäß Abs. 3 Z 3, die nach Absolvierung ausländischer Studien in einem der ersten Diplomprüfung des gewählten Diplomstudiums oder einem Bachelorstudium entsprechenden Umfang eine Zulassung zum Studium in Österreich anstreben, für höchstens zwei Semester.

Eine Verlängerung der jeweiligen Befristung ist unzulässig.

(6) Die befristete Zulassung gemäß Abs. 5 Z 1 und 2 setzt voraus, dass ein Kooperationsvertrag zwischen den beteiligten Bildungseinrichtungen besteht, der die Bedingungen für die Zusammenarbeit, den Austausch der Studierenden und die Durchführung näher regelt. Mit der Nominierung durch die Partnerbildungseinrichtungen gelten die allgemeine und die besondere Universitätsreife als nachgewiesen.

(7) Nach dem Erlöschen der Zulassung wegen der negativen Beurteilung bei der letzten zulässigen Wiederholung einer Prüfung ist die neuerliche Zulassung an der Universität oder bei gemeinsam eingerichteten Studien an den beteiligten Bildungseinrichtungen für jene Studien, bei denen die Absolvierung derselben Prüfung verpflichtend vorgesehen ist, nicht zulässig. Beim Lehramtsstudium Sekundarstufe (Allgemeinbildung) ist davon abweichend eine neuerliche Zulassung zum Studium ausschließlich für jene Unterrichtsfächer oder Spezialisierungen zulässig, bei denen die Absolvierung derselben Prüfung nicht verpflichtend vorgesehen ist. Erlischt bei einem Lehramtsstudium die Zulassung aufgrund des § 68 Abs. 1 Z 7, ist eine neuerliche Zulassung zu einem Lehramtsstudium nicht zulässig. Erlischt bei einem Studium die Zulassung aufgrund des § 68 Abs. 1 Z 8, ist eine neuerliche Zulassung zu einem Studium nur möglich, wenn eine Gefährdung nicht mehr festgestellt werden kann. Erlischt bei einem Studium die Zulassung aufgrund des § 68 Abs. 1 Z 2a, ist eine neuerliche Zulassung zu diesem Studium an derselben Universität oder bei gemeinsam eingerichteten Studien an denselben beteiligten Bildungseinrichtungen erst nach Ablauf von zwei Studienjahren zulässig.

(5) The following shall be granted temporary admission upon furnishing proof of possession of a general and a special university entrance qualification, regardless of any enactments under para 4:

1. persons participating in university mobility programmes, including joint programmes, for the duration of authorised participation therein,
2. persons wishing only to make use of distance learning course offerings based on co-operation agreements, for a maximum of two semesters;
3. foreign nationals and stateless persons in the meaning of para 3 subpara 3 seeking admission to study programmes in Austria on successful completion of studies abroad equivalent to the first diploma examination of the diploma programme selected or a bachelor's degree, for a maximum of two semesters.

Extension of these limited terms is impermissible.

(6) Temporary admission under para 5 subparas 1 and 2 shall be conditional on the existence of a co-operation agreement between the universities concerned governing the detailed arrangements for co-operation, student exchange and programme implementation. Nomination by the partner educational institution shall be deemed equivalent to proof of possession of a general and a special university entrance qualification.

(7) Upon expiry of an admission due to failure of the last permissible repetition of an examination, renewed admission to the university or, in the case of jointly offered study programmes, to the universities involved shall be excluded for those study programmes which require the completion of the same examination. In derogation thereof, a renewed admission to the teacher training programme for secondary schools (general education) is permitted only for those subjects or specialisations which do not require the successful completion of the same examination. If the admission to a teacher training programme expires on the basis of § 68 para 1 subpara 7, renewed admission to a teacher training programme shall be excluded. If the admission to a study programme expires on the basis of § 68 para 1 subpara 8, renewed admission to a study programme is only possible if the threat can no longer be detected. If the admission to a study programme expires on the basis of § 68 para 1 subpara 2a, renewed admission to this study programme at the same university or in the case of a jointly offered study programme at the same educational institutions involved is possible only after two academic years have passed.

(8) Die gleichzeitige Zulassung für dasselbe Studium an mehr als einer Universität oder Pädagogischen Hochschule in Österreich ist unzulässig. Weitere Zulassungen für dasselbe Studium an anderen Universitäten oder Pädagogischen Hochschulen leiden im Sinne des § 68 Abs. 4 Z 4 AVG an einem mit Nichtigkeit bedrohten Fehler und sind vom Rektorat von Amts wegen für nichtig zu erklären. Beim Lehramtsstudium Sekundarstufe (Allgemeinbildung) liegt dasselbe Studium vor, wenn ein Unterrichtsfach oder eine Spezialisierung ident ist.

(9) Die Ablegung von Prüfungen und anderen Studienleistungen für ein Studium an einer anderen österreichischen Universität oder Pädagogischen Hochschule als jener ~~oder jene~~ der Zulassung ist nur zulässig, wenn

1. das Curriculum oder das Curriculum eines gemeinsam mit einer anderen Universität oder Pädagogischen Hochschule eingerichteten Studiums dies vorsieht oder
2. das für die studienrechtlichen Angelegenheiten zuständige Organ die Ablegung der Prüfung oder anderen Studienleistung an der anderen Universität oder Pädagogischen Hochschule im Voraus genehmigt, weil die Ablegung der betreffenden Prüfung oder anderen Studienleistung an der Universität oder bei gemeinsam eingerichteten Studien an den beteiligten Universitäten und Pädagogischen Hochschulen nicht möglich ist.

(10) Personen, deren Erstsprache nicht die Sprache ist, in welcher das Studium abgehalten wird, haben die für den erfolgreichen Studienfortgang notwendigen Kenntnisse dieser Sprache nachzuweisen. Die Kenntnis der Sprache wird insbesondere durch ein Reifeprüfungszeugnis auf Grund des Unterrichts in dieser Sprache nachgewiesen. Das Rektorat kann durch Verordnung weitere Nachweise der erforderlichen Sprachkenntnisse festlegen.

(10a) Kann der Nachweis der Kenntnis der deutschen Sprache nicht erbracht werden, hat das Rektorat die Ablegung einer Ergänzungsprüfung vorzuschreiben, die vor der Zulassung abzulegen ist. In den künstlerischen Studien ist die Ergänzungsprüfung nicht vor der Zulassung abzulegen, wenn eine abweichende Regelung gemäß Abs. 11 im Curriculum festgelegt worden ist.

(10b) Die Ergänzungsprüfung für den Nachweis der Kenntnis der deutschen Sprache ist im Rahmen des Besuches eines dafür eingerichteten Universitätslehrganges abzulegen. Die Vorschreibung dieser Ergänzungsprüfung setzt Kenntnisse der deutschen Sprache im Zeitpunkt der Antragstellung für das Studium zumindest im Ausmaß des Niveaus A2 des Gemeinsamen Europäischen Referenzrahmens für Sprachen (GeR) des Europarats voraus. Als Nachweis über

(8) Simultaneous admission to the same studies at more than one university or university college of teacher education in Austria is impermissible. Additional admissions to the same studies at other universities or university colleges of teacher education risk nullity due to a defect in the meaning of § 68 para 4 subpara 4 General Administrative Procedure Act and shall be declared null and void by the rectorate, acting ex officio. In teacher training programmes for secondary schools (general education) the same study shall be assumed if a subject or a specialization is identical.

(9) Taking examinations for a programme of study at a university or university college of teacher education other than that to which a student has been admitted is only permissible if:

1. the home curriculum, or the curriculum of a programme of study offered jointly with another university or university college of teacher education makes provisions therefore; or
2. the officer responsible for study matters approves sitting of the examination at the other university or university college of teacher education because it cannot be taken at the university or, in the case of jointly offered degree programmes, the universities university colleges of teacher education in question.

(10) Persons whose first language is not the language in which the study programme is held shall provide proof of their knowledge of the language as required for the successful continuation of studies, in particular by submitting a secondary school leaving certificate obtained as a result of tuition received in the required language. The rectorate may, by decree, determine further documentary evidence for the required language proficiency.

(10a) In case that proof of knowledge of the German language cannot be furnished, the rectorate shall prescribe a supplementary examination to be taken prior to admission. In artistic study programmes the supplementary examination does not have to be taken prior to admission if other arrangements according to para 11 have been laid down in the curriculum.

(10b) The supplementary examination providing proof of the knowledge of the German language shall be part of a certificate university programme set up for this purpose. This supplementary examination prescribed by the curriculum requires an A2 level in the German language according to the Common European Framework of Reference for Languages (CEFRL) of the Council of Europe at the time of submission of the application for the study programme. Generally recognised

diese Kenntnisse der deutschen Sprache gelten allgemein anerkannte Sprachdiplome, die durch Verordnung des Rektorates festzulegen sind. Aus dem Sprachdiplom muss hervorgehen, dass die Inhaberin oder der Inhaber über Kenntnisse der deutschen Sprache zumindest auf Niveau A2 des Gemeinsamen Europäischen Referenzrahmens für Sprachen verfügt. Das Sprachdiplom darf zum Zeitpunkt der Vorlage nicht älter als zwei Jahre sein. Diese Regelung gilt nicht für künstlerische Studien, wenn durch Verordnung des Rektorats die Durchführung der Ergänzungsprüfung für den Nachweis der Kenntnis der deutschen Sprache in abweichender Form festgelegt worden ist.

(11) In den künstlerischen Studien kann im Curriculum festgelegt werden, dass die Ablegung der Ergänzungsprüfung spätestens vor der Meldung der Fortsetzung des Studiums für das dritte Semester nachzuweisen ist.

Sonderbestimmung für die Zulassung zu Master- und Doktoratsstudien

§ 63a. (1) In den Curricula für Masterstudien können qualitative Zulassungsbedingungen vorgeschrieben werden, die im Zusammenhang mit der erforderlichen Kenntnis jener Fächer, auf denen das jeweilige Masterstudium aufbaut, stehen müssen.

(2) Es ist sicherzustellen, dass die Absolvierung eines Bachelorstudiums an der jeweiligen Universität jedenfalls ohne weitere Voraussetzungen zur Zulassung zu mindestens einem fachlich in Frage kommenden Masterstudium an der Universität oder bei gemeinsam eingerichteten Studien an einer der beteiligten Bildungseinrichtungen berechtigt. Dies gilt auch für Masterstudien gemäß Abs. 8, nicht jedoch für Masterstudien an den Universitäten gemäß § 6 Abs. 1 Z 16 bis 21, für die jedenfalls auch die künstlerische Eignung gemäß § 63 Abs. 1 Z 4 nachzuweisen ist.

(3) Die Zulassung zu einem Masterstudium für das Lehramt Sekundarstufe (Allgemeinbildung) setzt zusätzlich zu § 63 Abs. 1a den Abschluss eines Bachelorstudiums für das Lehramt Sekundarstufe (Allgemeinbildung) gemäß Punkt 2.1 der Anlage zum HS-QSG oder eines facheinschlägigen ausländischen Studiums voraus. Bei einer Zulassung zu einem Masterstudium für das Lehramt Sekundarstufe (Allgemeinbildung) können auch Unterrichtsfächer oder Spezialisierungen gewählt werden, die in Form von Erweiterungsstudien ergänzend zum Bachelorstudium Lehramt absolviert worden sind. Zum Ausgleich wesentlicher fachlicher Unterschiede können Ergänzungsprüfungen vorgeschrieben werden, die während des Masterstudiums abzulegen sind. Das Rektorat kann festlegen, welche

language diplomas, to be specified by decree by the rectorate, shall be regarded as proof of the knowledge of the German language. The language diploma must clearly certify the holder's knowledge of the German language at least at an A2 language level according to the Common European Framework of Reference for Languages. The language diploma must not be older than two years at the time of submission. This regulation shall not apply to artistic study programmes if the rectorate has, by decree, specified another form for the supplementary examination as a proof for the knowledge of the German language.

(11) The curricula of artistic study programmes may require proof that supplementary examinations have been taken prior to registration for the continuation of studies in the third semester, at the latest.

Special Provision relating to the Admission to Master's and Doctoral Programmes

§ 63a. (1) The curricula for master's programmes may prescribe qualitative admission requirements which must be related to the required knowledge of those subjects on which the respective master's programme is based.

(2) In any case, it must be ensured that the completion of a bachelor's programme at the respective university entitles the student, without further requirements, to be admitted to at least one related master's programme at the university or, in jointly offered programmes, at one of the educational institutions involved. This shall also apply to master's programmes according to para 8, not however to master’s programmes at universities according to § 6 para 1 subparas 16 to 21 for which proof of artistic aptitude according to § 63 para 1 subpara 4 must be submitted.

(3) In addition to § 63 para 1a, admission to a master's programme for teaching at secondary schools (general education) requires the completion of a bachelor's programme for teaching at secondary schools (general education) according to item 2.1 of the Appendix to the Act on Quality Assurance in Higher Education or of a relevant foreign study programme. Upon admission to a master's programme for teaching at secondary schools (general education), it is possible to choose subjects or specialisations which have been completed in addition to the bachelor's programme for teacher training in the form of extension programmes. To compensate for substantial differences, it may be specified that supplementary examinations have to be taken during the master's programme. The rectorate shall be entitled to lay down

dieser Ergänzungsprüfungen Voraussetzung für die Ablegung von im Curriculum des Masterstudiums vorgesehenen Prüfungen sind. Dies gilt auch für den Abschluss eines facheinschlägigen sechssemestrigen Lehramtsstudiums an Pädagogischen Hochschulen, das gemäß den Regelungen dieses Bundesgesetzes in der Fassung vor der Novelle BGBl. I Nr. 124/2013 absolviert wurde.

~~(4) Die Zulassung zu einem Masterstudium für das Lehramt Sekundarstufe (Allgemeinbildung) für Absolventinnen und Absolventen sechssemestriger Lehramtsstudien setzt abweichend von § 63 Abs. 1a die Absolvierung eines Erweiterungsstudiums gemäß § 54c voraus.~~

(Anm.: Abs. 4 aufgehoben durch Art. 1 Z 49, BGBl. I Nr. 50/2024)

(5) Die Zulassung zu einem Masterstudium für das Lehramt Sekundarstufe (Allgemeinbildung) für Absolventinnen und Absolventen eines Lehramtsstudiums für das Lehramt Primarstufe setzt abweichend von § 63 Abs. 1a die Absolvierung des Bachelor- und Masterstudiums für das Lehramt Primarstufe gemäß Punkt 1. der Anlage zum HS-QSG voraus.

(Anm.: Abs. 6 aufgehoben durch Art. 1 Z 17, BGBl. I Nr. 177/2021)

(7) Für die Zulassung zu einem Doktoratsstudium können im Curriculum qualitative Zulassungsbedingungen vorgeschrieben werden.

(7a) In den Curricula für kombinierte Master- und Doktoratsstudien sind qualitative Zulassungsbedingungen vorzuschreiben, die den spezifischen Forschungscharakter dieses Studiums berücksichtigen.

(8) Das Rektorat ist berechtigt, in Master- und Doktoratsstudien, die ausschließlich in einer Fremdsprache angeboten werden, eine Anzahl von Studienanfängerinnen und -anfängern festzulegen und den Zugang entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch ein Auswahlverfahren nach der Zulassung zu regeln. Vor der Festlegung des Aufnahme- oder Auswahlverfahrens durch das Rektorat ist dem Senat die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden.

(9) § 71b Abs. 7 ist mit Ausnahme der Z 4 anzuwenden.

Allgemeine Universitätsreife (Universitätszugang)

§ 64. (1) Die allgemeine Universitätsreife ist durch eine der folgenden Urkunden nachzuweisen:

which of these supplementary examinations are prerequisites for sitting examinations which are prescribed in the curriculum of the master's programme.

(4) Notwithstanding § 63 para 1a, admission to a master's programme for teaching at secondary schools (general education) for graduates of six-semester programmes for teacher training requires the completion of an extension programme according to § 54c.

(5) Notwithstanding § 63 para 1a, admission to a master's programme for teaching at secondary schools (general education) for graduates of a programme for teaching at primary schools requires the completion of the bachelor's and master's programme for teaching at primary schools according to item 1 of the Appendix to the Act on Quality Assurance in Higher Education.

(6) [removed]

(7) The curriculum may stipulate qualitative admission requirements for the admission to a doctoral programme.

(7a) The curricula for combined master's and doctoral programmes shall include qualitative admission requirements, taking into account the specific research character of this study programme.

(8) For master's and doctoral programmes which are offered exclusively in a foreign language, the rectorate shall be entitled to determine a number of first-year students and to limit admission either by means of an admission procedure prior to admission or by a selecting procedure after admission. Before the rectorate determines the admission or selection procedure, the senate shall have the opportunity to give its opinion within six weeks. The rectorate's decision shall be taken by 30 April at the latest in order to become effective in the following academic year.

(9) § 71b para 7, with the exception of subpara 4, shall apply.

General University Entrance Qualification

§ 64. (1) Possession of the general university entrance qualification shall be certified by the following documents:

1. ein österreichisches Reifeprüfungszeugnis, ein österreichisches Reife- und Diplomprüfungszeugnis oder ein österreichisches Zeugnis über die Berufsreifeprüfung, sowie diesen durch völkerrechtliche Vereinbarung gleichwertige Zeugnisse,
2. ein österreichisches Zeugnis über die Zuerkennung der Studienberechtigung für eine bestimme Studienrichtungsgruppe an einer Universität, Pädagogischen Hochschule oder Fachhochschule,
3. eine Urkunde über den Abschluss eines mindestens dreijährigen Studiums (auf Vollzeitbasis oder 180 ECTS-Anrechnungspunkte) an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung,
4. eine Bestätigung über die positiv beurteilte Zulassungsprüfung in den künstlerischen Studien,
5. ein „IB Diploma“ nach den Bestimmungen der „International Baccalaureate Organization“ oder
6. ein Europäisches Abiturzeugnis gemäß Art. 5 Abs. 2 der Vereinbarung über die Satzung der Europäischen Schulen, BGBl. III Nr. 173/2005.

(2) Die allgemeine Universitätsreife kann darüber hinaus durch eine ausländische Qualifikation nachgewiesen werden, wenn kein wesentlicher Unterschied zur allgemeinen Universitätsreife gemäß Abs. 1 Z 1 besteht. ~~Ein wesentlicher Unterschied besteht jedenfalls nicht~~Anhaltspunkte für das Fehlen eines wesentlichen Unterschiedes liegen insbesondere vor, wenn

1. die Qualifikation im Ausstellungsstaat Zugang zu allen Sektoren von Hochschulen vermittelt,
2. die Dauer der Schulzeit mindestens zwölf Jahre beträgt und
3. allgemeinbildende Ausbildungsinhalte überwiegen, was durch die Absolvierung von sechs allgemeinbildenden Unterrichtsfächern (zwei Sprachen, Mathematik, ein naturwissenschaftliches, ein geisteswissenschaftliches sowie ein weiteres allgemeinbildendes Unterrichtsfach) in der Sekundarstufe II nachgewiesen wird.

Beträgt die Schulzeit gemäß Z 2 nur elf Jahre oder fehlen Ausbildungsinhalte gemäß Z 3, kann das Rektorat insgesamt bis zu vier Ergänzungsprüfungen vorschreiben, die vor der Zulassung abzulegen sind.

(3) Die allgemeine Universitätsreife für die Zulassung zu einem Masterstudium ist durch den Abschluss eines fachlich in Frage kommenden Bachelorstudiums, eines

1. an Austrian secondary-school leaving certificate, an Austrian secondary-school leaving and diploma certificate, or an Austrian certificate of the TVE Diploma Examination as well as any certificates equivalent to these by agreement under international law;
2. an Austrian certificate testifying the right to study a certain group of studies at a university, a university college of teacher education, or a university of applied sciences,
3. a document certifying the completion of studies of at least three years (on a full-time basis or amounting to 180 ECTS credits) at a recognised domestic or foreign post-secondary educational institution,
4. a confirmation that the applicant has successfully passed the admission examination for art studies,
5. an “IB Diploma” awarded according to the stipulations of the “International Baccalaureate Organization” or
6. a European school-leaving certificate according to Art 5 para 2 of the Convention defining the Statute of the European Schools, F. L. G. III No 173/2005.

(2) The general university entrance qualification may also be established by proof of a foreign qualification if there are no substantial differences to the general university entrance qualification according to para 1 subpara 1. In any case, there is no significant difference if

1. the qualification gives access to all sectors of higher education institutions in the country of issue,
2. the duration of schooling is at least twelve years and
3. general educational contents prevail; this may be established by proof of the successful completion of six general education subjects (two languages, mathematics, one natural sciences subject, one humanities subject as well as another general education subject) at secondary level II.

If the duration of schooling under subpara 2 is only eleven years, or if educational contents under subpara 3 should be missing, the rectorate may prescribe no more than a total of four supplementary examinations to be taken prior to admission.

(3) The general university entrance qualification for admission to a master's programme shall be deemed to be established by proof of successful completion of a

anderen fachlich in Frage kommenden Studiums mindestens desselben hochschulischen Bildungsniveaus an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung oder eines im Curriculum des Masterstudiums definierten Studiums nachzuweisen. Zum Ausgleich wesentlicher fachlicher Unterschiede können Ergänzungsprüfungen vorgeschrieben werden, die bis zum Ende des zweiten Semesters des Masterstudiums abzulegen sind. Das Rektorat kann festlegen, welche dieser Ergänzungsprüfungen Voraussetzung für die Ablegung von im Curriculum des Masterstudiums vorgesehenen Prüfungen sind.

(4) Die allgemeine Universitätsreife für die Zulassung zu einem Doktoratsstudium ist mit Ausnahme von Abs. 5 durch den Abschluss eines fachlich in Frage kommenden Diplomstudiums oder Masterstudiums oder eines anderen fachlich in Frage kommenden Studiums mindestens desselben hochschulischen Bildungsniveaus an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung nachzuweisen. Zum Ausgleich wesentlicher fachlicher Unterschiede können Ergänzungsprüfungen vorgeschrieben werden, die bis zum Ende des zweiten Semesters des Doktoratsstudiums abzulegen sind. Das Rektorat kann festlegen, welche dieser Ergänzungsprüfungen Voraussetzung für die Ablegung von im Curriculum des Doktoratsstudiums vorgesehenen Prüfungen sind.

(5) Die allgemeine Universitätsreife für die Zulassung zu einem Doktoratsstudium kann auch durch den Abschluss eines fachlich in Frage kommenden Bachelorstudiums nachgewiesen werden, wenn das Bachelorstudium innerhalb der vorgesehenen Studienzeit und mit besonderem Studienerfolg abgeschlossen wurde. Nähere Regelungen hat das Rektorat zu erlassen.

(6) Für die Zulassung zu kombinierten Master- und Doktoratsstudien ist Abs. 3 anzuwenden.

Studienberechtigungsprüfung

§ 64a. (1) Personen ohne Reifeprüfung erlangen nach Maßgabe einer Verordnung des Rektorates durch Ablegung der Studienberechtigungsprüfung die allgemeine Universitätsreife für Bachelorstudien und Diplomstudien einer Studienrichtungsgruppe.

(2) Die Studienberechtigungsprüfung kann entsprechend einer Verordnung des Rektorates für folgende Studienrichtungsgruppen abgelegt werden:

1. Geistes- und kulturwissenschaftliche Studien;
2. Ingenieurwissenschaftliche Studien;

related bachelor's programme, of another related study programme of at least the same academic level at a recognised domestic or foreign post-secondary educational institution or a master's programme as defined in the curriculum. To compensate for substantial differences, it may be specified that supplementary examinations have to be completed by the end of the second semester of the master's programme. The rectorate shall be entitled to lay down which of these supplementary examinations are prerequisites for sitting examinations which are prescribed in the curriculum of the doctoral programme.

(4) The general university entrance qualification for admission to a doctoral programme shall, with the exception of para 5, be deemed to be established by proof of successful completion of a related diploma or master's programme or of another related study programme of at least the same academic level at a recognised domestic or foreign post-secondary educational institution. To compensate for substantial differences, it may be specified that supplementary examinations have to be completed by the end of the second semester of the doctoral programme. The rectorate shall be entitled to lay down which of these supplementary examinations are prerequisites for sitting examinations which are prescribed in the curriculum of the doctoral programme.

(5) The general university entrance qualification for admission to a doctoral programme may also be established by proof of the completion of a related bachelor's programme, if the bachelor's programme has been completed within the prescribed duration of studies and with great success. The rectorate shall enact more detailed regulations.

(6) Para 3 shall apply for admission to combined master's and doctoral programmes.

University Entrance Qualification Examination

§ 64a. (1) Persons who do not possess an Austrian secondary-school leaving certificate shall obtain, in accordance with a decree by the rectorate, the general university entrance qualification for bachelor's programmes and diploma programmes of a group of studies, after having passed the university entrance qualification examination.

(2) The university entrance qualification examination may, according to a decree of the rectorate, be sat for one of the following groups of studies:

1. Studies in Arts and Humanities;
2. Studies in Engineering Sciences;

3. Künstlerische Studien;
4. Naturwissenschaftliche Studien;
5. Rechtswissenschaftliche Studien;
6. Sozial- und wirtschaftswissenschaftliche Studien;
7. Theologische Studien;
8. Medizinische und Veterinärmedizinische Studien;
9. Lehramtsstudien;
10. Studien in allgemeinen pädagogischen Berufsfeldern.

(3) Zur Studienberechtigungsprüfung sind Personen zuzulassen, die die Zulassung zu Studien einer der Studienrichtungsgruppen an einer Universität anstreben, das 20. Lebensjahr vollendet haben und eine eindeutig über die Erfüllung der allgemeinen Schulpflicht hinausgehende erfolgreiche berufliche oder außerberufliche Vorbildung für das angestrebte Studium nachweisen.

(4) Das Ansuchen um Zulassung zur Studienberechtigungsprüfung ist schriftlich beim Rektorat jener Universität einzubringen, bei der ein Studium der angestrebten Studienrichtungsgruppe eingerichtet ist. Das Ansuchen hat zu enthalten:

1. den Namen, das Geburtsdatum, die Adresse sowie – falls vorhanden – die Matrikelnummer;
2. den Nachweis der Staatsangehörigkeit eines EU- oder EWR-Staates oder den Nachweis der Angehörigkeit einer Personengruppe gemäß der Personengruppenverordnung;
3. das angestrebte Studium;
4. den Nachweis der Vorbildung (Abs. 3);
5. das Wahlfach oder die Wahlfächer.

(5) Die Studienberechtigungsprüfung umfasst folgende fünf Prüfungen:

1. eine schriftliche Arbeit über ein allgemeines Thema;
2. zwei oder drei Prüfungen, die im Hinblick auf Vorkenntnisse oder Fertigkeiten für die angestrebte Studienrichtungsgruppe erforderlich sind (Pflichtfächer) und
3. eine oder zwei Prüfungen nach Wahl der Prüfungskandidatin oder des Prüfungskandidaten aus dem Bereich der angestrebten Studienrichtungsgruppe (Wahlfach oder Wahlfächer).

3. Art studies;
4. Studies in Natural Science;
5. Law studies;
6. Studies in Social and Economic Sciences;
7. Theological studies;
8. Medical and Veterinary studies;
9. Teacher training studies;
10. Studies in general educational professional fields.

(3) Persons who seek admission to studies of one of the groups of studies at a university, are at least 20 years of age, and can submit proof of the completion of professional or non-professional prior education that clearly goes beyond compulsory education for the studies aimed for, shall be admitted to the university entrance qualification examination.

(4) The application for admittance to the university entrance qualification examination shall be submitted in writing to the rectorate of the university at which studies in the group of studies aimed for are offered. The application shall contain:

1. Name, date of birth, address and – where available – matriculation number;
2. proof of citizenship of a EU or EEA country, or proof of belonging to a group of persons according to the Decree on Groups of Persons;
3. the studies aimed for;
4. proof of prior education;
5. the elective or electives.

(5) The university entrance qualification examination shall comprise five examinations:

1. a written paper on a general topic;
2. two or three examinations that are required with regard to prior knowledge or skills for the group of studies aimed for (compulsory subjects); and
3. one or two examinations to be chosen by the candidate from the area of the group of studies aimed for (elective or electives).

(6) Mit der schriftlichen Arbeit über ein allgemeines Thema gemäß Abs. 5 Z 1 hat die Prüfungskandidatin oder der Prüfungskandidat nachzuweisen, dass sie oder er sich zu einem vorgegebenen Thema in einwandfreier und gewandter Sprache und mit klarem Gedankengang schriftlich zu äußern vermag.

(7) Die Prüfungsanforderungen und -methoden für Prüfungen gemäß Abs. 5 Z 1 und 2 haben sich am Lehrstoff der 12. bzw. 13. Schulstufe zu orientieren und sind in der Verordnung des Rektorates festzulegen.

(8) Für die Prüfung oder Prüfungen gemäß Abs. 5 Z 3 (Wahlfach oder Wahlfächer) sind die Prüfungsanforderungen und -methoden vom Rektorat zu bestimmen. Auf den studienvorbereitenden Charakter der Studienberechtigungsprüfung ist Bedacht zu nehmen.

(9) Positiv beurteilte Prüfungen, die eine Prüfungskandidatin oder ein Prüfungskandidat an einer Bildungseinrichtung, die auf Grund der Rechtsvorschriften des Staates, in dem sie ihren Sitz hat, als Bildungseinrichtung anerkannt ist, abgelegt haben, sind auf Antrag vom Rektorat anzuerkennen, soweit sie den vorgeschriebenen Prüfungen inhaltlich und umfangmäßig gleichwertig sind. Das Rektorat darf höchstens vier Prüfungen anerkennen. Mindestens eine Prüfung ist an der Universität oder bei gemeinsam eingerichteten Studien an einer der beteiligten Bildungseinrichtungen abzulegen.

(10) Prüfungskandidatinnen und Prüfungskandidaten, die eine Meisterprüfung oder eine Befähigungsprüfung gemäß der Gewerbeordnung, BGBl. Nr. 194/1994, oder dem Land- und forstwirtschaftlichen Berufsausbildungsgesetz, BGBl. Nr. 298/1990, erfolgreich abgelegt haben, sind von der Ablegung der Studienberechtigungsprüfung im Wahlfach oder den Wahlfächern gemäß Abs. 5 Z 3 auf Ansuchen zu befreien.

(11) Das Rektorat hat für Prüfungen, die an einer Universität abgelegt werden, mindestens eine Prüferin oder einen Prüfer zu bestellen.

(12) Die Prüfungskandidatinnen und Prüfungskandidaten sind berechtigt, negativ beurteilte Prüfungen zweimal zu wiederholen. Die letzte zulässige Wiederholung ist in kommissioneller Form durchzuführen. Nach negativer Beurteilung der letzten zulässigen Wiederholung erlischt die Zulassung zur Studienberechtigungsprüfung für diese Studienrichtungsgruppe. Eine neuerliche Zulassung zur Studienberechtigungsprüfung für diese Studienrichtungsgruppe an der betreffenden Universität ist ausgeschlossen. Bei gemeinsam eingerichteten Lehramtsstudien ist eine neuerliche Zulassung zur Studienberechtigungsprüfung für

(6) The written paper on a general topic under para 5 subpara 1, shall serve to prove that the candidate is able to express herself/himself correctly, eloquently and clearly in writing on a given topic.

(7) The standards and methods for examinations under para 5 subparas 1 and 2 shall be aligned with the teaching contents of the 12th or 13th level of education and shall be laid down in the rectorate's decree.

(8) For the examination or examinations under para 5 subpara 3 (elective or electives), the standards and methods shall be determined by the rectorate. The preparatory nature of the university entrance qualification examination shall be taken into account.

(9) Passed examinations which a candidate for the university entrance qualification examination has taken at an educational institution that is recognised as an educational institution based on the legal provisions of the country in which it is located shall, on application, be recognised by the rectorate if they are equivalent to the prescribed examinations in terms of content and scope. The rectorate may recognise a maximum of four examinations. At least one examination shall be taken at the respective university or, in jointly offered degree programmes, at one of the educational institutions concerned.

(10) Candidates for the university entrance qualification examination who have successfully passed a master craftsman's certificate in a skilled trade or a qualifying examination under the Trade Regulation Act, F. L. G No 194/1994, or the Vocational Training Act for Agriculture and Forestry, F. L. G. No 298/1990 shall, on application, be exempt from taking the university entrance qualification examination in the elective or the electives under para 5 subpara 3.

(11) The rectorate shall appoint at least one examiner for examinations taken at a university.

(12) The candidates shall be entitled to repeat failed examinations two times. The final repetition permitted shall be held before a board. After failing the final repetition permitted, the admission to the university entrance qualification examination for the respective group of studies shall expire. A further admission to the university entrance qualification examination for the respective group of studies at the university concerned shall be excluded. In the case of jointly offered teacher training programmes, a further admission to the university entrance qualification examination for the group of studies “teacher training programmes” shall be excluded at all educational institutions concerned.

die Studienrichtungsgruppe Lehramtsstudien an allen beteiligten Bildungseinrichtungen ausgeschlossen.

(13) Die Beurteilung einer Prüfung gemäß Abs. 5 hat mit „bestanden“ oder „nicht bestanden“ zu erfolgen. Die Gesamtbeurteilung hat auf „bestanden“ zu lauten, wenn keine Prüfung mit „nicht bestanden“ beurteilt wurde; in den übrigen Fällen ist sie mit „nicht bestanden“ festzulegen. Die Bestimmungen des § 59 Abs. 1 Z 12 und der §§ 73 und 79 sind sinngemäß anzuwenden.

(14) Über die Ablegung jeder Prüfung ist ein Zeugnis auszustellen. Das Rektorat hat nach Vorliegen aller Prüfungszeugnisse ein Studienberechtigungszeugnis für die jeweilige Studienrichtungsgruppe auszustellen. Dieses Studienberechtigungszeugnis gilt für jede Universität, Pädagogische Hochschule und Fachhochschule, an der ein Studium der jeweiligen Studienrichtungsgruppe eingerichtet ist.

(15) Der erfolgreiche Abschluss der Studienberechtigungsprüfung berechtigt zur Zulassung zu allen Studien jener Studienrichtungsgruppe, für welche die Studienberechtigung erworben wurde.

(16) Die Festlegung der Anzahl der Prüfungen nach Abs. 5 Z 2 und 3 und die Festlegung der Pflichtfächer gemäß Abs. 5 Z 2 für die jeweilige Studienrichtungsgruppe erfolgen durch Verordnung des Rektorates.

Besondere Universitätsreife

§ 65. Zusätzlich zur allgemeinen Universitätsreife sind die in der Universitätsberechtigungsverordnung – UBVO 1998, BGBl. II Nr. 44/1998, festgelegten Zusatzprüfungen zur Reifeprüfung für die darin festgelegten Studien nachzuweisen oder als Ergänzungsprüfungen abzulegen (besondere Universitätsreife).

Eignung für Lehramtsstudien und Studien für Berufstätigkeiten an elementarpädagogischen Bildungseinrichtungen

§ 65a. (1) In Aufnahmeverfahren für Lehramtsstudien oder Studien für Berufstätigkeiten an elementarpädagogischen Bildungseinrichtungen sind die für die berufliche Ausbildung und Tätigkeit der Pädagoginnen und Pädagogen erforderlichen leistungsbezogenen, persönlichen, fachlichen und pädagogischen Kompetenzen zu überprüfen. Die Feststellung der fachlichen Eignung hat sich an den im Curriculum verankerten fachspezifischen Kriterien zu orientieren.

(2) Die Feststellung der Eignung hat wissenschaftliche Kriterien zu berücksichtigen. Informationen zu den berufsspezifischen Anforderungen und

(13) An examination shall be graded as “successfully completed” or “unsuccessfully completed”. The overall grading shall read “successfully completed” if no examination has been graded as “unsuccessfully completed”; in all other cases it shall read “unsuccessfully completed”. The provisions of § 59 para 1 subpara 12 and §§ 73 to 79 shall apply by analogy

(14) A certificate shall be issued for each passed examination. The rectorate shall issue a university entrance qualification certificate for the respective group of studies upon presentation of all certificates. This university entrance qualification certificate shall be valid for all universities, university colleges of teacher education, or universities of applied sciences offering studies in the respective group of studies.

(15) The successful completion of the university entrance qualification examination entitles a person to be admitted to all studies within the group of studies, for which the university entrance qualification has been obtained.

(16) The number of examinations under para 5 subparas 2 and 3 as well as the compulsory subjects under para 5 subpara 2 for the respective group of studies shall be determined by the rectorate by decree.

Special University Entrance Qualification

§ 65. In addition to possession of a general university entrance qualification, proof must be furnished on passing the supplementary examinations for certain study programmes provided for in the University Entrance Qualification Decree (Universitätsberechtigungsverordnung – UBVO) 1998, F. L. G. II No 44/1998, otherwise they shall be taken as additional examinations (special university entrance qualification).

Aptitude for Teacher Training Programmes and Study Programmes for Teaching at Elementary Educational Institutions

§ 65a. (1) The admission procedure for teacher training programmes or study programmes for teaching at elementary educational institutions shall check the performance-based, personal, professional and pedagogical competences required for the professional training for and activity as teachers. Ascertaining the subject-related capacity shall be aligned with the subject-specific criteria laid down in the curriculum.

(2) It shall also take into consideration scientific criteria. The website shall provide information on the professional requirements as well as self-assessment

Selbsterkundungsinstrumentarien sind auf der Website zur Verfügung zu halten. Informationen zur Feststellung der Eignung sind spätestens vier Wochen vor Beginn der Registrierung auf der Website zur Verfügung zu stellen, spätestens jedoch sechs Monate vor Beginn des Studienjahres.

(3) Es ist vom Nachweis jener Eignungskriterien Abstand zu nehmen, die bei Erfüllung der wesentlichen Anforderungen für den angestrebten Beruf aufgrund einer Behinderung im Sinne des BGStG, nicht erfüllt werden können. Bei Bedarf sind im Rahmen des Eignungsfeststellungsverfahrens geeignete Ausgleichsmaßnahmen insbesondere (Sprach-)Assistenz vorzusehen.

(4) Es können für Studienwerberinnen und Studienwerber mit einer anderen Erstsprache als Deutsch bei Bedarf geeignete Vorkehrungen im organisatorischen Ablauf und in der Durchführung der Eignungsprüfung ohne Änderung des Anforderungsniveaus vorgesehen werden.

(5) Die näheren Bestimmungen über das Aufnahmeverfahren einschließlich der Feststellung der Eignung sind durch Verordnung des Rektorats festzulegen. Bei gemeinsam eingerichteten Studien haben die Rektorate der beteiligten Bildungseinrichtungen gleichlautende Verordnungen zu erlassen.

Rechtsschutz bei Aufnahmeverfahren

§ 65b. (1) Der Studienwerberin oder dem Studienwerber ist Einsicht in die Beurteilungsunterlagen und in die Auswertungsprotokolle von Aufnahmeverfahren zu gewähren, wenn sie oder er dies innerhalb von drei Monaten ab Bekanntgabe des Ergebnisses verlangt. Die Beurteilungsunterlagen umfassen auch die bei dem betreffenden Verfahren gestellten Fragen. Im Rahmen der Einsichtnahme ist sicherzustellen, dass auch eine individuelle Rückmeldung zur Beurteilung gegeben werden kann. Die Studienwerberin oder der Studienwerber ist berechtigt, die Beurteilungsunterlagen zu vervielfältigen. Vom Recht auf Einsichtnahme und auf Vervielfältigung sind Fragen betreffend die persönliche Eignung ausgenommen. Vom Recht auf Vervielfältigung sind ebenso Multiple Choice-Fragen einschließlich der jeweiligen Antwortmöglichkeiten ausgenommen.

(2) Aufnahmeverfahren für Studien sind unbeschränkt wiederholbar.

Studieneingangs- und Orientierungsphase

§ 66. (1) Die Studieneingangs- und Orientierungsphase ist als Teil aller Diplom- und Bachelorstudien, (ausgenommen der Bachelorstudien für die Sekundarstufe (Berufsbildung) mit Ausnahme der Bachelorstudien für die Fachbereiche

tools. Information on the ascertaining process of the capacity shall be provided on the website not later than four weeks prior to the beginning of the registration, but at least six months prior to the beginning of the academic year.

(3) In the case of fulfilment of the most important requirements for the desired profession, it shall be refrained from requiring proof of those eligibility criteria which cannot be fulfilled on the grounds of a disability in the meaning of BGStG. If required, appropriate compensatory measures, in particular (language) assistance, shall be provided within the framework of the aptitude test procedure.

(4) Suitable arrangements shall be made in the organisational process and the implementation of the aptitude test for applicants whose first language is not German, without, however, changing the requirement level.

(5) The rectorate shall, by decree, establish detailed regulations for the admission procedure, including the ascertaining process of the capacity. In the case of jointly offered study programmes, the rectorates of the educational institutions involved shall enact identical decrees.

Legal Protection in respect of Admission Procedures

§ 65b. (1) Applicants shall be permitted to have inspection of the assessment documents and the evaluation records of admission procedures, provided that they make such requests within three months of the announcement of the result. The assessment documents shall also include the questions asked during the respective procedure. Within the framework of inspection, it shall be ensured that also individual information on the assessment can be given. The applicant shall be entitled to make photocopies of the assessment documents. Questions regarding the personal aptitude shall be excluded from the right to make photocopies. Furthermore, multiple-choice questions including their answers shall be excluded from the right to make photocopies.

(2) Admission procedures to study programmes may be repeated without limitation.

Study Starting and Orientation Period

§ 66. (1) The orientation period, which is part of all diploma degree and bachelor's programmes, unless they are established at a university under § 6 para 1 subparas 16 to 21, but in any case for jointly offered teacher training programmes,

Information und Kommunikation (Angewandte Digitalisierung), Mode und Design und Ernährung), sofern diese nicht an einer Universität gemäß § 6 Abs. 1 Z 16 bis 21 eingerichtet sind, jedenfalls aber bei gemeinsam eingerichteten Lehramtsstudien so zu gestalten, dass sie der oder dem Studierenden einen Überblick über die wesentlichen Inhalte des jeweiligen Studiums und dessen weiteren Verlauf vermittelt und eine sachliche Entscheidungsgrundlage für die persönliche Beurteilung ihrer oder seiner Studienwahl schafft. Die Studieneingangs- und Orientierungsphase findet im ersten Semester des Studiums statt und besteht aus mehreren Lehrveranstaltungen, die insgesamt mindestens 8 und höchstens 20 ECTS-Anrechnungspunkte umfassen. Auf den Bedarf berufstätiger Studierender ist Bedacht zu nehmen. Für die Studien Humanmedizin, Zahnmedizin, Psychologie und Veterinärmedizin kann durch Verordnung des jeweiligen Rektorats von einer Studieneingangs- und Orientierungsphase abgesehen werden.

shall be designed in such a manner that it provides students with an overview of the most important contents of the study programme and its continuation and that it forms a relevant basis for their own evaluation of their choice of studies. The orientation period shall be part of the first semester of the studies and shall consist of several courses, amounting to a total of at least 8 and no more than 20 ECTS credits. The needs of working students shall be taken into account. For studies in human medicine, dental medicine, psychology and veterinary medicine, an orientation period is not mandatory, if the rectorate decides so by decree.

(2) § 59 sowie die §§ 72 bis 79 gelten auch für die Studieneingangs- und Orientierungsphase. Innerhalb der Studieneingangs- und Orientierungsphase müssen mindestens zwei Prüfungen vorgesehen werden, für die in jedem Semester mindestens zwei Prüfungstermine anzusetzen sind, wobei ein Prüfungstermin auch während der lehrveranstaltungsfreien Zeit abgehalten werden kann. Der positive Erfolg bei allen Lehrveranstaltungen und Prüfungen der Studieneingangs- und Orientierungsphase berechtigt zur Absolvierung der weiteren Lehrveranstaltungen und Prüfungen sowie zum Verfassen der im Curriculum vorgesehenen Bachelor- oder Diplomarbeiten.

(2) § 59 and §§ 72 to 79 shall apply also to the orientation period. The orientation period shall include at least two examinations, for which at least two examination dates shall be offered in each semester, one of which may also take place in the recess period. The successful completion of all courses and examinations of the orientation period shall entitle students to take other courses and examinations as well as to write the bachelor's papers and diploma theses prescribed in the curriculum.

(3) Im Curriculum kann festgelegt werden, dass vor der vollständigen Absolvierung der Studieneingangs- und Orientierungsphase weiterführende Lehrveranstaltungen im Ausmaß von bis zu 22 ECTS-Anrechnungspunkten absolviert werden dürfen, wobei gemäß § 78 anerkannte Prüfungen, andere Studienleistungen, Tätigkeiten und ~~Qualifikationen~~Kompetenzen darin nicht einzurechnen sind.

(3) The curriculum may permit that more advanced courses of up to 22 ECTS credits may be taken prior to the successful completion of the introductory and orientation period. However, examinations, other academic achievements, activities and qualifications recognised pursuant to § 78 shall not be counted.

(3a) Die Universität hat sicherzustellen, dass im ersten Semester des betreffenden Diplom- oder Bachelorstudiums das Erreichen von 30 ECTS-Anrechnungspunkten jedenfalls möglich ist.

(3a) The university shall ensure that the achievement of 30 ECTS credits is possible in any case in the first semester of the respective diploma or bachelor's programme.

(3b) Die Universität hat ein Monitoring der Studieneingangs- und Orientierungsphase durchzuführen, das insbesondere die Prüfungsaktivität in Verbindung mit der Studieneingangs- und Orientierungsphase zum Inhalt hat.

(3b) The university shall carry out a monitoring for the introductory and orientation period, covering, in particular, the activity of students with regard to examinations within the introductory and orientation period.

(4) Die Zulassung zum Studium erlischt, wenn die oder der Studierende bei einer für sie oder ihn im Rahmen der Studieneingangs- und Orientierungsphase

(4) The admission to a study programme shall expire if a student fails the last permissible repetition of an examination prescribed for the orientation period.

vorgeschriebenen Prüfung auch bei der letzten Wiederholung negativ beurteilt wurde.

(5) Die Studieneingangs- und Orientierungsphase dient der Orientierung über die wesentlichen Studieninhalte und nicht als quantitative Zugangsbeschränkung.

(Anm.: § 66 tritt mit Ablauf des 31.12.2027 außer Kraft)

Beurlaubung

§ 67. (1) Studierende sind auf Antrag für ein oder mehrere Semester wegen

1. Leistung eines Präsenz-, Ausbildungs- oder Zivildienstes oder
2. Erkrankung, die nachweislich am Studienfortschritt hindert oder
3. Schwangerschaft oder
4. Kinderbetreuungspflichten oder anderen gleichartigen Betreuungspflichten oder
5. der Ableistung eines freiwilligen sozialen Jahres oder
6. vorübergehende Beeinträchtigung im Zusammenhang mit einer Behinderung

bescheidmäßig zu beurlauben. Weitere Gründe können in der Satzung festgelegt werden.

(2) Bei Beurlaubungen gilt Folgendes:

1. Die Beurlaubung ist bis längstens zum Beginn des jeweiligen Semesters zu beantragen.
2. Bei unvorhergesehenem und unabwendbarem Eintritt eines Beurlaubungsgrundes gemäß Abs. 1 Z 2 bis 4 und 6 kann die Beurlaubung auch während des Semesters beantragt werden.
3. Bis zum Zeitpunkt der Beurlaubung erbrachte Studienleistungen (insbesondere abgeschlossene Lehrveranstaltungen und Prüfungen) bleiben gültig.

(3) Die Beurlaubung wirkt für alle Studien der Bildungseinrichtung, an welcher diese beantragt wurde und bei gemeinsam eingerichteten Studien für alle Studien der beteiligten Bildungseinrichtungen. Während der Beurlaubung bleibt die Zulassung zum Studium aufrecht. Die Teilnahme an Lehrveranstaltungen, die Ablegung von Prüfungen sowie die Einreichung und Beurteilung wissenschaftlicher sowie künstlerischer Arbeiten ist unzulässig.

(5) The goal of the orientation period is the orientation to the most important contents of the studies and not a quantitative admission restriction.

(§ 66 will expire after 31.12.2027)

Academic Leave

§ 67. (1) Students shall, upon application, be permitted by official notification to take a leave of absence because of

1. compulsory military service, training service, or community service, or
2. longer periods of sickness which verifiable impedes the progress of studies, or
3. pregnancy, or
4. care of children or similar kinds of care, or
5. a voluntary year of social service or
6. temporary impairment in connection with a disability

for two or more semesters. Additional exceptions may be laid down in the statutes.

(2) The following applies to academic leave:

1. Academic leave shall be applied for at the beginning of the respective semester at the latest.
2. In the event of the unforeseen and unavoidable occurrence of a reason for academic leave according to para 1 subparas 2 to 4 and 6, it may be applied for even during the semester.
3. Any academic achievements acquired up to the time of academic leave (in particular successfully completed courses and examinations) shall remain valid.

(3) The academic leave shall be effective for all study programmes at the educational institution at which it was applied for and in the case of jointly offered study programmes for all study programmes at the educational institutions involved. The admission to the study programme shall remain valid for the duration of the academic leave. Attendance of courses, taking examinations, and the submission and assessment of scientific theses or artistic submissions shall not be permissible.

Erlöschen der Zulassung zu ordentlichen Studien

§ 68. (1) Die Zulassung zu einem Studium erlischt, wenn die oder der Studierende

1. sich vom Studium abmeldet oder
2. die Meldung der Fortsetzung des Studiums unterlässt oder

2a. die Mindeststudienleistung gemäß § 59a nicht erbringt oder

3. bei einer für ihr oder sein Studium vorgeschriebenen Prüfung auch bei der letzten zulässigen Wiederholung negativ beurteilt wurde und diese Prüfung nicht gemäß § 79 Abs. 1 aufgehoben worden ist, wobei sich die Zahl der zulässigen Wiederholungen nach den Prüfungsantritten an der jeweiligen Universität und bei gemeinsam eingerichteten Studien nach den Prüfungsantritten an den beteiligten Bildungseinrichtungen in allen Studien bemisst oder

(Anm.: Z 4 aufgehoben durch Art. 1 Z 107, BGBl. I Nr. 93/2021)

5. im Falle der befristeten Zulassung das Teilstudium im Befristungsausmaß absolviert hat oder
6. das Studium durch die positive Beurteilung bei der letzten vorgeschriebenen Prüfung abgeschlossen hat oder
7. bei einem Lehramtsstudium in den im Curriculum gekennzeichneten Praktika im Rahmen der pädagogisch-praktischen Studien bei der letzten zulässigen Wiederholung negativ beurteilt wurde und ein allfälliger Antrag gemäß § 77 Abs. 4 zurück- oder abgewiesen wurde, wobei ein Verweis von der Praxisschule einer negativen Beurteilung gleichzuhalten ist, oder
8. aufgrund einer Handlung oder von Handlungen, die eine dauerhafte oder schwer wiegende Gefährdung anderer Universitätsangehöriger oder Dritter im Rahmen des Studiums darstellt oder darstellen, vom Rektorat durch Bescheid vom Studium ausgeschlossen wird, wobei Näheres in der Satzung zu regeln ist.

(2) An den Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 kann in der Satzung vorgesehen werden, dass die Zulassung zum Studium erlischt, wenn mehr als drei Semester während der gesamten Studiendauer das jeweilige Lehrangebot aus dem zentralen künstlerischen Fach nicht besucht wird.

Expiry of Admission to Degree Programmes

§ 68. (1) Admission to a programme of study shall expire if a student:

1. deregisters from the programme; or
2. fails to register for the continuation of studies or

2a. fails to achieve the minimum requirement of study progress according to § 59a or

3. fails the last permissible repetition of an examination prescribed for his/her study programme if it has not been annulled according to § 79 para 1, whereby the permissible number of repetitions is calculated on the basis of the examinations taken in all degree programmes at the respective university and, in jointly offered degree programmes, on the basis of the examinations taken at the educational institutions involved or

4. [removed]

5. in the case of temporary admission, has completed the respective programme component in the appointed period; or
6. has completed his/her studies by passing the last prescribed examination; or
7. receives a negative assessment for the last permissible repetition of an internship within the framework of the pedagogic-practical studies prescribed in the curriculum of a teacher training programme and any application according to § 77 para 4 was rejected or dismissed; the receipt of a reprimand from the partner school shall also be considered as a negative assessment; or
8. is excluded by official notification by the rectorate owing to an act or acts presenting a lasting or serious threat to other university members or to third parties within the framework of their studies. Further details shall be regulated in the statute.

(2) The statutes of the universities named in § 6 para 1 subparas 16 to 21 may provide for an admission to expire if a student has failed to attend the courses relating to the major artistic subject for a total of more than three semesters over the entire duration of his/her studies.

(3) Das Erlöschen der Zulassung in den Fällen des Abs. 1 Z 3~~, 4~~ und ~~7sowie~~7 sowie Abs. 2 ist der oder dem betroffenen Studierenden schriftlich mitzuteilen. Das Rektorat hat auf Antrag der oder des Studierenden einen Feststellungsbescheid zu erlassen.

Abgangsbescheinigung

§ 69. Beendet die oder der Studierende ein Studium, ohne das Studium erfolgreich abgeschlossen zu haben, so ist auf Antrag eine Abgangsbescheinigung auszustellen. Diese hat alle Prüfungen, zu denen die oder der Studierende in diesem Studium angetreten ist, und deren Beurteilungen anzugeben. Hinsichtlich der positiv beurteilten Prüfungen ist nur die positive Beurteilung anzugeben. Zur Unterstützung der internationalen Mobilität der Studierenden ist der Anschluss einer fremdsprachigen Übersetzung zulässig, wobei die Benennung der Universität und des ausstellenden Organs nicht zu übersetzen sind.

Zulassung zu außerordentlichen Studien

§ 70. (1) Die Zulassung zu Universitätslehrgängen setzt den Nachweis der im Curriculum des betreffenden Universitätslehrganges geforderten Voraussetzungen voraus. Wird ein Universitätslehrgang als außerordentliches Bachelor- oder Masterstudium angeboten, sind davon abweichend folgende Voraussetzungen anzuwenden:

1. Voraussetzung für die Zulassung zu einem außerordentlichen Bachelorstudium ist ~~die allgemeine Universitätsreife~~der Nachweis der im Curriculum des betreffenden außerordentlichen Bachelorstudiums geforderten Voraussetzungen und eine mehrjährige einschlägige Berufserfahrung.
2. Voraussetzung für die Zulassung zu einem außerordentlichen Bachelorstudium, in dem der akademische Grad „Bachelor Professional“ verliehen werden soll, ist eine einschlägige berufliche Qualifikation oder eine mehrjährige einschlägige Berufserfahrung. Wenn es das Curriculum erfordert, können weitere Voraussetzungen und Ergänzungsprüfungen vorgesehen werden. Das Rektorat kann festlegen, welche dieser Ergänzungsprüfungen Voraussetzung für die Ablegung von im Curriculum des Universitätslehrganges vorgesehenen Prüfungen sind.
3. Voraussetzung für die Zulassung zu einem außerordentlichen Masterstudium ist der Abschluss eines fachlich in Frage kommenden Bachelorstudiums~~ mit mindestens 180 ECTS-Anrechnungspunkten~~, eines

(3) The expiry of the admission in the cases of para 1 subparas 3, 4 and 7, and para 2 shall be notified to the student in writing. Upon application by the student, the rectorate shall issue a notification of assessment.

Leaving Certificate

§ 69. A leaving certificate shall be issued on application of a student terminating his/her studies without completing it successfully. The leaving certificate shall list all examinations taken by the student during his/her studies, and the assessments awarded. With regard to the examinations passed, only the positive assessments shall be stated. In the interest of international student mobility a translation may be appended, with the name of the university and of the issuing body not having to be translated.

Admission to Non-Degree Programmes

§ 70. (1) Admission to continuing education university programmes is conditional on proof that the applicant fulfils the requirements laid down in the curriculum of the respective continuing education university programme concerned. In derogation thereof, the following requirements shall apply if a continuing education university programme is offered as a continuing education bachelor's or master's programme:

1. Admission to a continuing education bachelor's programme requires the general university entrance qualification and several years of professional experience in a relevant field.
2. Admission to a continuing education bachelor's programme upon completion of which the academic degree “Bachelor Professional” shall be awarded, requires a subject-relevant professional qualification or several years of professional experience in a relevant field. If required by the curriculum, supplementary examinations may be prescribed. The rectorate shall be entitled to determine which of these supplementary examinations are prerequisites for sitting examinations that are prescribed in the curriculum of the continuing education university programme.
3. The admission to a continuing education master's programme shall require the successful completion of a related bachelor's programme amounting to a minimum of 180 ECTS credits, of another related study programme of at

anderen fachlich in Frage kommenden Studiums mindestens desselben hochschulischen Bildungsniveaus an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung oder ein im Curriculum des Universitätslehrganges definiertes Studium mit mindestens 180 ECTS-Anrechnungspunkten und eine mehrjährige einschlägige Berufserfahrung. Wenn es das Curriculum erfordert, können weitere Voraussetzungen vorgesehen werden. Zum Ausgleich wesentlicher fachlicher Unterschiede können Ergänzungsprüfungen vorgeschrieben werden. Das Rektorat kann festlegen, welche dieser Ergänzungsprüfungen Voraussetzung für die Ablegung von im Curriculum des Universitätslehrganges vorgesehenen Prüfungen sind. ~~Abweichend davon kann für Universitätslehrgänge, in denen der akademische Grad „Executive Master of Business Administration“ verliehen wird, im Curriculum auch eine einschlägige berufliche Qualifikation als Zulassungsvoraussetzung festgelegt werden, sofern Zulassungsbedingungen, Umfang und Anforderungen mit Zulassungsbedingungen, Umfang und Anforderungen mehrerer fachlich in Frage kommender ausländischer Masterstudien nachweislich vergleichbar sind.~~

4. Abweichend von Z 3 kann für Universitätslehrgänge, in denen der akademische Grad „Master of Business Administration“ gemäß § 87 Abs. 2 Z 3 oder „Executive Master of Business Administration“ gemäß § 87 Abs. 2 Z 4 verliehen wird, im Curriculum auch eine mehrjährige einschlägige Berufserfahrung als Zugangsvoraussetzung festgelegt werden, sofern Zugangsbedingungen, Umfang und Anforderungen mit Zugangsbedingungen, Umfang und Anforderungen mehrerer fachlich in Frage kommender ausländischer Masterstudien nachweislich vergleichbar sind. Wenn es das Curriculum erfordert, können weitere Voraussetzungen vorgesehen werden. Für diese Universitätslehrgänge kommt § 56 Abs. 2 letzter Satz nicht zur Anwendung.

(2) Die Zulassung zu den Vorbereitungslehrgängen ist längstens bis zur Vollendung des 20. Lebensjahres möglich. Darüber hinaus sind die Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 berechtigt, im Curriculum für einen Vorbereitungslehrgang ein Zulassungsalter bis zur Vollendung des 25. Lebensjahres vorzusehen, wenn dies auf Grund der Studieninhalte erforderlich ist.

(3) Nach dem Erlöschen der Zulassung wegen der negativen Beurteilung bei der letzten zulässigen Wiederholung einer Prüfung ist die neuerliche Zulassung für diesen Universitätslehrgang ausgeschlossen.

least the same academic level at a recognised domestic or foreign post-secondary educational institution or a study programme as defined in the curriculum of the continuing education university programme and several years of professional experience in a relevant field. To compensate for substantial differences, it may be specified that supplementary examinations have to be taken. The rectorate shall be entitled to determine which of these supplementary examinations are prerequisites for sitting examinations that are prescribed in the curriculum of the continuing education university programme. In derogation thereof, the curriculum for continuing education university programmes upon completion of which the academic degree “Executive Master of Business Administration” is awarded, may prescribe a relevant professional qualification as admission requirement, provided that the admission requirements, scope and requirements are demonstrably comparable to those of several related foreign master's programmes.

(2) Eligibility for admission to preparatory continuing education courses shall cease on the applicant’s 21st birthday. The universities named in § 6 para 1 subparas 16 to 21 shall be entitled to provide for admission to preparatory continuing education courses up to the applicant’s 26th birthday if this is necessitated by the course contents.

(3) Upon expiry of an admission due to failure of the last permissible repetition of an examination renewed admission to the certificate university programme for further education concerned shall be excluded.

Erlöschen der Zulassung zu außerordentlichen Studien

§ 71. (1) Die Zulassung erlischt, wenn die oder der Studierende

1. sich vom Studium abmeldet,
2. die Meldung der Fortsetzung des Studiums unterlässt,
3. bei einer für ihr oder sein Studium vorgeschriebenen Prüfung bei der letzten zulässigen Wiederholung negativ beurteilt wurde,
4. bei gemeinsam eingerichteten Universitätslehrgängen gemäß § 39 Abs. 1 HG die Zulassung zum ordentlichen Studium verliert (§ 61 Abs. 1 Z 4 HG),
5. den Universitätslehrgang durch die positive Beurteilung bei der letzten vorgeschriebenen Prüfung abgeschlossen hat,
6. die im Curriculum eines Universitätslehrganges festgelegte Höchststudiendauer überschreitet oder
7. aus dem in § 68 Abs. 1 Z 8 genannten Grund vom außerordentlichen Studium ausgeschlossen wird.

(2) Das Erlöschen der Zulassung ist in den Fällen des Abs. 1 Z 3, 4 und 6 der oder dem betroffenen Studierenden schriftlich mitzuteilen. Das Rektorat hat auf Antrag einen Feststellungsbescheid zu erlassen.

3a. Abschnitt

Zugangsregelungen im Kontext einer kapazitätsorientierten, studierendenbezogenen Universitätsfinanzierung

Ziele

§ 71a. Im Zuge der Implementierung einer kapazitätsorientierten, studierendenbezogenen Universitätsfinanzierung sollen die Anzahl der prüfungsaktiv betriebenen Studien und die Anzahl der abgeschlossenen Studien an den Universitäten gesteigert werden.

(Anm.: § 71a tritt mit Ablauf des 31.12.2027 außer Kraft)

Zulassung zu besonders stark nachgefragten Bachelor- und Diplomstudien

§ 71b. (1) In den österreichweit besonders stark nachgefragten Studienfeldern bzw. Studien wird die österreichweit anzubietende Mindestanzahl an Studienplätzen für Studienanfängerinnen und –anfänger pro Studienjahr und Studienfeld bzw. Studium wie folgt festgelegt:

Expiry of Admission to Non-Degree Programmes

§ 71. (1) Admission shall expire if a student:

1. deregisters from the programme;
2. fails to register for the continuation of studies;
3. fails the last permissible repetition of an examination prescribed for his/her programme of study;
4. in the case of jointly offered university programmes for further education under § 39 para 1 HG has lost the right to admission to the degree programme (§ 61 para 1 subpara 4 HG;
5. has completed the certificate university programme for further education by passing the last prescribed examination;
6. exceeds the maximum duration of a certificate university programme for further education, or
7. is excluded from the non-degree programme for the reason stated in § 68 para 1 subpara 8.

(2) The expiry of the admission in the cases of para 1 subparas 3, 4 and 6 shall be notified to the student in writing. Upon application, the rectorate shall issue a notification of assessment.

Chapter 3a

Admission Regulations in the Context of the Future Capacity-Oriented, Student-Based Funding of Universities Rights and Duties of Students

Objectives

§ 71a. As part of the implementation of a capacity-oriented, student-based funding of universities, the proportion of students who actively take examinations as well as the number of degrees awarded at universities shall be increased.

(§ 71a will expire after 31.12.2027)

Admission to Very Popular Bachelor and Diploma Programmes

§ 71b. (1) For the very popular fields of education or degree programmes throughout Austria, the following number of study places shall be offered for first-year students for each academic year and field of education or degree programme:

Studienfeld/Studium	**Mindestanzahl**
Architektur und Städteplanung*	2.020
Biologie und Biochemie**	3.700
Erziehungswissenschaft	1.460
Fremdsprachen	3.020
Informatik	2.800
Management und Verwaltung / Wirtschaft und Verwaltung, allgemein / Wirtschaftswissenschaft	10.630
Pharmazie	bis zu 1.370
Publizistik und Kommunikationswissenschaft	1.530
Recht	4.300

* ausgenommen sind die Studien an der Universität für angewandte Kunst Wien, an der Universität für künstlerische und industrielle Gestaltung Linz und an der Akademie der bildenden Künste Wien.

** ausgenommen sind Studien, zu denen bereits Zugangsregelungen gemäß § 124b in der Fassung des Bundesgesetzes BGBl. I Nr. 21/2015 bestanden haben sowie gemäß § 71c bestehen.

(2) Die Aufteilung der in Abs. 1 festgelegten Anzahl an Studienplätzen auf die einzelnen Universitäten hat im Rahmen der Leistungsvereinbarungen zu erfolgen.

(3) Sofern eine Universität über standardisierte datenbasierte Evidenzen verfügt, können an dieser Universität bei der Aufteilung der Anzahl der Studienplätze für Studienanfängerinnen und –anfänger für ein Studienfeld bzw. Studium gemäß Abs. 1 und 2 die infrastrukturbezogenen Kapazitäten bzw. physischen Plätze, die Nachfrage am Arbeitsmarkt, Forschungsstärke sowie die bisherigen Zahlen der tatsächlichen Studienanfängerinnen und –anfänger berücksichtigt werden. Durch die Berücksichtigung universitätsspezifischer Faktoren kann die österreichweit anzubietende Mindestanzahl gemäß Abs. 1 insgesamt um bis zu 20 vH erhöht oder verringert werden.

(4) In den von Abs. 1 umfassten Studienfeldern bzw. Studien ist das Rektorat jeder Universität, an der das betreffende Studium eingerichtet ist, berechtigt, die Zulassung zu diesem Studium durch Verordnung entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln, wobei Elemente eines Aufnahmeverfahrens im Sinne einer mehrstufigen Gestaltung auch mit Elementen eines Auswahlverfahrens verbunden werden können. Vor der Festlegung des

Field of education / study programme	Total number
Architecture and town planning *	2,020
Biology and biochemistry**	3,700
Educational science	1,460
Foreign languages	3,020
Computer science	2,800
Management and administration / business and administration, general / economic sciences	10,630
Pharmacology	up to 1,370
Media and communication studies	1,530
Law	4,300

* exempt are degree programmes at the University of Applied Art Vienna, the University of Art and Design Linz, and the Academy of Fine Art Vienna.

** exempt are degree programmes for which admission regulations have been in place according to § 124b, as amended by F. L. G. I No 21/2015, or are already in place according to § 71c.

(2) The distribution of the number of study places under para 1 among the universities shall be determined as part of the performance agreements.

(3) If a university has standardised data-based records, the infrastructure-related capacities or physical places, the demand on the labour market, research performance as well as previous figures on the actual number of first-year students can be taken into consideration for the distribution of the number of study places for first-year students for a field of education or study programme according to paras 1 and 2 at this university. By taking into consideration university-specific factors, the minimum number of study places to be offered throughout Austria according to para 1 may be increased or reduced by up to a total of 20%.

(4) For the fields of education or degree programmes under para 1, the rectorate of each university at which the respective degree programme is offered shall have the right to limit admission to this degree programme by decree either by means of an admission procedure prior to admission or by selecting students no later than one semester after admission, in that elements of an admission procedure may, in the sense of a multi-level design, be combined with elements of a selection procedure. Before the rectorate determines the admission or selection procedure, the senate shall

Aufnahme- oder Auswahlverfahrens durch das Rektorat ist dem Senat die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden.

(5) In den von Abs. 1 umfassten gemeinsam eingerichteten Studien gemäß § 51 Abs. 2 Z 27 sind die Rektorate der beteiligten Universitäten und öffentlichen Pädagogischen Hochschulen berechtigt, durch gleichlautend zu erlassende Verordnungen bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten berechtigt, durch zu veröffentlichende gleichlautende Vereinbarungen die Zulassung zu diesem Studium entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln, wobei Elemente eines Aufnahmeverfahrens im Sinne einer mehrstufigen Gestaltung auch mit Elementen eines Auswahlverfahrens verbunden werden können. Vor der Festlegung bzw. Vereinbarung des Aufnahme- oder Auswahlverfahrens durch das Rektorat bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten ist dem Senat bzw. den zuständigen Organen von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden.

(6) Im Rahmen des Aufnahme- oder Auswahlverfahrens gemäß Abs. 4 und 5 ist innerhalb einer vom Rektorat festzulegenden Frist eine verpflichtende Registrierung der Studienwerberinnen und -werber vorzusehen. Das Verfahren darf nur dann durchgeführt werden, wenn die Anzahl der registrierten Studienwerberinnen und -werber die in der Leistungsvereinbarung gemäß Abs. 2 und 3 festgelegte Anzahl an Studienplätzen für Studienanfängerinnen und -anfänger pro Studium übersteigt. Bleibt die Anzahl der registrierten Studienwerberinnen und -werber unter der in der Leistungsvereinbarung gemäß Abs. 2 und 3 festgelegten Anzahl an Studienplätzen für Studienanfängerinnen und -anfänger pro Studium, so sind diese registrierten Studienwerberinnen und -werber bei Vorliegen der allgemeinen Voraussetzungen gemäß § 63 jedenfalls zuzulassen. Darüber hinaus hat die Universität bis zum

have the opportunity to give its opinion within six weeks. The rectorate's decision shall be taken by 30 April at the latest in order to become effective in the following academic year.

(5) For the jointly offered study programmes according to § 51 para 2 subpara 27 mentioned under para 1, the rectorates of the universities and public university colleges of teacher education involved shall have the right to limit admission to this study programme by decrees to be enacted identically, or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, by agreements to be published identically. Admission may be limited either by means of an admission procedure prior to admission or by selecting students no later than one semester after admission, in that elements of an admission procedure may, in the sense of a multi-level design, be combined with elements of a selection procedure. Before the rectorate determines, or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities agree on the admission or selection procedure, the senate or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, shall have the opportunity to give an opinion within six weeks. The decision of the rectorate, or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, shall be taken by 30 April at the latest in order to become effective in the following academic year.

(6) As part of the admission or selection procedure under paras 4 and 5, the rectorate shall require a mandatory registration of all applicants within a period stipulated. The procedure shall only take place, if the number of registered applicants exceeds the number of places for first-year students for a degree programme stipulated in the performance agreement under paras 2 and 3. If the number of registered applicants does not exceed the number of places for first-year students for a degree programme stipulated in the performance agreement under paras 2 and 3, these registered applicants shall be admitted, if they meet the general requirements under § 63. Furthermore, the university shall also admit applicants who are already registered for a corresponding degree programme at another university, until the number laid down for a degree programme has been reached.

Erreichen der pro Studium festgelegten Anzahl auch Studienwerberinnen und -werber zuzulassen, die für ein entsprechendes Studium bereits an einer anderen Universität registriert sind.

(7) Das Aufnahme- oder Auswahlverfahren gemäß Abs. 4 und 5 ist durch die Universität so zu gestalten, dass insbesondere folgende Vorgaben maßgebend sind:

1. Überprüfung der für das den Ausbildungserfordernissen des jeweiligen Studiums entsprechenden leistungsbezogenen Kriterien;
2. Sicherstellung, dass das Aufnahme- oder Auswahlverfahren zu keinerlei Diskriminierung aufgrund des Geschlechts sowie der sozialen Herkunft führt;
3. rechtzeitige und kostenlose Zurverfügungstellung des Prüfungsstoffes auf der Homepage der Universität (bei Aufnahmeverfahren vor der Zulassung spätestens vier Monate vor dem Prüfungstermin, bei Auswahlverfahren nach der Zulassung spätestens zu Beginn des betreffenden Semesters) und
4. eine mehrstufige Gestaltung der Aufnahme- oder Auswahlverfahren. Allfällige mündliche Komponenten können nur ein Teil der Aufnahme- oder Auswahlverfahren sein und dürfen nicht zu Beginn des Aufnahme- oder Auswahlverfahrens stattfinden. Weiters dürfen die mündlichen Komponenten nicht das alleinige Kriterium für das Bestehen des Aufnahme- oder Auswahlverfahrens sein;
5. Studienwerberinnen und –werber mit einer Behinderung gemäß § 3 BGStG haben das Recht, eine abweichende Prüfungsmethode zu beantragen, wenn die Studienwerberin oder der Studienwerber eine Behinderung nachweist, die ihr oder ihm die Ablegung einer Prüfung im Rahmen des Aufnahme- oder Auswahlverfahrens in der vorgeschriebenen Methode unmöglich macht. Das Ausbildungsziel des gewählten Studiums muss jedoch erreichbar bleiben. Bei Bedarf sind geeignete Unterstützungsmaßnahmen, insbesondere (Sprach-)Assistenz vorzusehen.

Auf die Durchführung der Aufnahme- oder Auswahlverfahren ist § 41 B-GlBG anzuwenden. Die Wiederholung von Prüfungen im Rahmen von Auswahlverfahren kann in der Verordnung des Rektorats gemäß Abs. 4 oder 5 geregelt werden. § 58 Abs. 8 ist nicht anzuwenden.

(7) The university shall design the admission or selection procedure under paras 4 and 5 in a manner that particularly the following criteria are met:

1. Testing performance-based criteria relevant to the educational requirements of the respective degree programme;
2. ensuring that the admission or selection procedure does not discriminate against any persons on the basis of gender or social origin;
3. making the examinable material accessible on the university's website in good time and free of charge (for admission procedures prior to admission no later than four months before the examination date, for selection procedures after admission no later than the beginning of the respective semester); and
4. designing admission or selection procedures that consist of multiple stages. Oral examinations, if applicable, may only be a part of the admission and selection procedure and shall not take place at the beginning of the admission or selection procedure. Furthermore, oral examinations shall not be the sole criterion for successfully completing the admission or selection procedure;
5. Applicants with disabilities in the meaning of § 3 of the Federal Act on the Equalization of Persons with Disabilities (Bundes-Behindertengleichstellungsgesetz, BGStG), F. L. G. I No 82/2005, shall have the right to apply for an alternative examination method if they can submit proof of a disability which will make it impossible for them to take an examination within the framework of the application or selection procedure in the method as prescribed. The educational objective of the chosen degree programme must, however, remain attainable. Suitable support measures, in particular (language) assistance shall be provided as needed.

§ 41 B-GlBG shall apply to the implementation of the admission or selection procedure. Re-sits within the framework of selection procedures may be regulated by decree of the rectorate in accordance with paras 4 or 5. § 58 para 8 shall not apply.

(8) Regelt ein Rektorat einer Universität oder einer öffentlichen Pädagogischen Hochschule bzw. regeln die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten gemäß Abs. 4 und 5 die Zulassung zu einem Studium durch Verordnung oder Vereinbarung entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung, sind nach Möglichkeit die Termine für die Registrierung und die Durchführung des Verfahrens, die Anforderungen und der Ablauf des Verfahrens sowie der für den positiven Abschluss des Verfahrens relevante Prüfungsstoff mit den anderen Universitäten, Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten, an denen dieses Studium eingerichtet ist, abzustimmen.

(9) Wird eine Studienwerberin oder ein Studienwerber nach Durchführung des Aufnahmeverfahrens nicht zum Studium zugelassen, so ist ihr oder ihm auf ihr oder sein Verlangen vom Rektorat ein diesbezüglicher Bescheid auszustellen. Die Studienwerberin oder der Studienwerber hat das Recht, gegen diesen Bescheid vor dem Bundesverwaltungsgericht Beschwerde zu führen. § 46 Abs. 2 zweiter bis vierter Satz sind nicht anzuwenden.

(Anm.: § 71b tritt mit Ablauf des 31.12.2027 außer Kraft)

Ergänzende Bestimmungen für die Zulassung zu den vom deutschen Numerus Clausus betroffenen Studien

§ 71c. (1) Das Rektorat kann in den Bachelor-, Master-, Diplom- und Doktoratsstudien, die von den deutschen ~~bundesweiten~~ Numerus-Clausus-Studien Medizin, Psychologie, Psychotherapie, Tiermedizin und Zahnmedizin betroffen sind, den Zugang entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens zwei Semester nach der Zulassung beschränken, wobei Elemente eines Aufnahmeverfahrens im Sinne einer mehrstufigen Gestaltung auch mit Elementen eines Auswahlverfahrens verbunden werden können. Vor dieser Festlegung ist dem Senat Gelegenheit zu einer Stellungnahme zu geben, die innerhalb einer Frist von sechs Wochen erstattet werden muss. Die Festlegung samt allfälliger Stellungnahme des Senats hat das Rektorat dem Universitätsrat zur Genehmigung vorzulegen. Entscheidet der Universitätsrat nicht innerhalb von vier Wochen ab Vorlage, gilt die Festlegung als genehmigt.

(2) In den Studien Human- und Zahnmedizin, Psychologie, Psychotherapie sowie Veterinärmedizin muss im Sinne einer bedarfsgerechten Studienplatzentwicklung folgende Anzahl an Studienplätzen für

(8) If the rectorate of a university or a public university college of teacher education has, or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, have regulated admission to a study programme according to paras 4 and 5 by decree or agreement, either by an admission procedure prior to admission, or by selecting students no later than one semester after admission, the registration dates and the dates for the procedure, the requirements for and the procedure as such, as well as the examinable material relevant for its successful completion shall, wherever possible, be coordinated with the other universities, university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities offering the same study programme.

(9) If an applicant is not admitted to the study programme after completion of the admission procedure, the rectorate shall, upon request, issue an official notification in this regard. The applicant shall be entitled to appeal to the Federal Administrative Court against this official notification. § 46 para 2, second to fourth sentence, shall not apply.

(§ 71b will expire after 31.12.2027)

Supplementary Provisions Relating to the Admission to Degree Programmes Subject to the German Numerus Clausus

§ 71c. (1) The rectorate may limit admission to bachelor's and master's as well as diploma and doctoral programmes that are subject to German nation-wide numerous-clausus restrictions in medicine, psychology, veterinary medicine and dental medicine by means of either an admission procedure prior to admission or a selection up to two semesters after admission at the latest, in that elements of an admission procedure may, in the sense of a multi-level design, be combined with elements of a selection procedure. Prior to such a decision, the senate shall have the opportunity to give its opinion within a period of six weeks. The rectorate shall submit its decision, together with any opinion expressed by the senate, for approval to the university council. In case that the university council fails to reach a decision within four weeks of submission, the decision shall be deemed to have been approved.

(2) For the degree programmes in human and dental medicine, psychology, and veterinary medicine, the following number of study places for first-year students

Studienanfängerinnen und -anfänger pro Studienjahr und Studium österreichweit ansteigend zur Verfügung gestellt werden:

Studium	Gesamt
Human- und Zahnmedizin	bis zu 2.000
Psychologie	1.300
Veterinärmedizin	bis zu 250
Psychotherapie	bis zu 500 im Masterstudium

(3) In den Studien gemäß Abs. 2 erfolgt in der Leistungsvereinbarung jener Universitäten, an denen die betreffenden Studien angeboten werden, eine Festlegung der Anzahl an Studienplätzen für Studienanfängerinnen und -anfänger im Sinne einer bedarfsgerechten Studienplatzentwicklung und unter Berücksichtigung der bisherigen Studierendenzahlen. Im Studium Humanmedizin und im Masterstudium Psychotherapie ist zusätzlich die Wahrung der in Abs. 5 geregelten Schutzinteressen sicherzustellen.

(4) § 71b Abs. 7 mit Ausnahme der Z 4 sowie Abs. 9 ist anzuwenden. Zur Vorbereitung auf das Aufnahme- oder Auswahlverfahren für die Studien Human- und Zahnmedizin sowie das Masterstudium Psychotherapie hat die Universität kostenlose Unterstützungsangebote zur Verfügung zu stellen.

(5) Im Studium Humanmedizin und im Masterstudium Psychotherapie ist das Recht auf Bildung und Zugang zur Hochschulbildung der Inhaberinnen und Inhaber in Österreich ausgestellter Reifezeugnisse durch erhöhten Zustrom von Inhaberinnen und Inhabern nicht in Österreich ausgestellter Reifezeugnisse stark beschränkt und die öffentliche Gesundheit einschließlich der Wahrung einer ausgewogenen, allen zugänglichen und auf hohem Niveau stehenden ärztlichen und psychotherapeutischen Versorgung der Bevölkerung beeinträchtigt. Unbeschadet der Aufnahmeverfahren gemäß Abs. 1 sind zum Schutz der Homogenität des Bildungssystems im Studium Humanmedizin und im Masterstudium Psychotherapie 95 vH der Gesamtstudienplätze für Studienanfängerinnen und -anfänger den EU-Bürgerinnen und EU-Bürgern und ihnen im Hinblick auf den Studienzugang gleichgestellten Personen vorbehalten. 75 vH der Gesamtstudienplätze für Studienanfängerinnen und -anfänger stehen

1. den Inhaberinnen und Inhabern in Österreich ausgestellter Reifezeugnisse ~~und~~ ,
2. den Angehörigen von Personengruppen ~~aufgrund~~im Sinn der Personengruppenverordnung sowie

shall be offered gradually for each academic year and degree programme nationally with a view to a demand-oriented growth in study places:

Study programme	Total number
Human and dental medicine	Up to 2,000
Psychology	1,300
Veterinary medicine	Up to 250

(3) For the degree programmes under para 2, the performance agreements of those universities offering the respective programmes shall stipulate the number of study places for students beginning their studies with a view to a demand-oriented growth in study places and taking into account the past number of students. In the degree programmes for human medicine and dental medicine, it shall be ensured that the interests under para 5 are also protected.

(4) § 71b para 7, with the exception of subpara 4, and para 9 shall apply. In preparation of the admission or selection procedure for the degree programmes in human and dental medicine, the university shall provide support services free of charge.

(5) For the programme in human medicine, the right to education and to access to higher education of persons with Austrian secondary-school leaving certificates has been substantially curtailed due to the increased influx of persons with foreign secondary-school leaving certificates, and public health including the maintenance of comprehensive and high-quality medical care accessible to the entire population, is affected. Regardless of the admission procedure under para 1, a total of 95% of all places for first-year students in the programme in human medicine shall be reserved for EU citizens and those persons who are accorded the same rights to access to higher education in order to safeguard the homogeneity of the education system. 75% of all places for first-year students are reserved for students with Austrian secondary-school leaving certificates and groups of persons designated by decree of the Federal Minister on Groups of Persons.

3. den Absolventinnen und Absolventen einer fachlich einschlägigen Studienberechtigungsprüfung nach § 64a, sofern diese entweder selbst wenigstens fünf zusammenhängende Jahre unmittelbar vor der Ablegung der Studienberechtigungsprüfung ihren Hauptwohnsitz in Österreich hatten oder mindestens eine gesetzliche Unterhaltspflichtige oder einen gesetzlichen Unterhaltspflichtigen haben, bei der bzw. dem dies der Fall ist,

zur Verfügung.

(5a) In der Leistungsvereinbarung können zeitlich befristet aus den 5 vH der gemäß Abs. 5 verbleibenden Studienplätze eine bestimmte Anzahl an Studienplätzen für Aufgaben im öffentlichen Interesse sowie Kriterien für deren Vergabe festgelegt werden, wobei es zulässig ist, eine zu erbringende Mindestleistung im Aufnahmeverfahren gemäß Abs. 1 zu definieren. Es ist sicherzustellen, dass die Studierenden, die einen solchen Studienplatz erhalten haben, die Aufgaben im öffentlichen Interesse auch tatsächlich erbringen.

(5a) A certain number of study places from the remaining 5% stipulated under para 5 may be determined for tasks in the public interest and criteria for the procedure of awarding these study places defined, whereby it shall be permissible to stipulate a minimum performance which has to be reached in the admission procedure in the meaning of para 1. It must be ensured that the students who have been awarded such a study place actually carry out these tasks in the public interest.

(6) Das Rektorat ist berechtigt, in den sonstigen Medizinischen sowie Veterinärmedizinischen Studien die Zulassung zu diesen Studien durch Verordnung entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln, wobei Elemente eines Aufnahmeverfahrens im Sinne einer mehrstufigen Gestaltung auch mit Elementen eines Auswahlverfahrens verbunden werden können. § 71b Abs. 7 mit Ausnahme der Z 4 sowie Abs. 9 ist anzuwenden.

(6) For the other medical and veterinary programmes, the rectorate shall have the right to limit admission to these programmes by decree by means of either an admission procedure prior to admission or the selection of students up to one semester after admission at the latest, in that elements of an admission procedure may, in the sense of a multi-level design, be combined with elements of a selection procedure. § 71b para 7, with the exception of subpara 4, and para 9 shall apply.

(6a) In der Leistungsvereinbarung können zeitlich befristet 5 vH der gemäß Abs. 2 zu vergebenden Studienplätze der Veterinärmedizin für Aufgaben im öffentlichen Interesse sowie Kriterien für deren Vergabe festgelegt werden, wobei es zulässig ist, eine zu erbringende Mindestleistung im Aufnahme- oder Auswahlverfahren zu definieren. Es ist sicherzustellen, dass die Studierenden, die einen solchen Studienplatz erhalten haben, die Aufgaben im öffentlichen Interesse auch tatsächlich erbringen.

(7) Sofern in den Auswahlverfahren Prüfungen vorgesehen sind, gelten für die Wiederholungen die Bestimmungen dieses Bundesgesetzes. Auch die Wiederholung positiv beurteilter Prüfungen ist zulässig. Prüfungstermine sind grundsätzlich einmal im Semester anzubieten. § 58 Abs. 8 ist nicht anzuwenden.

(7) If the selection procedure is to include examinations, re-sits shall be subject to the provisions of this Act. Examinations that have been passed may be repeated. Examination dates shall be offered once per semester. § 58 para 8 shall not apply.

(Anm.: § 71c tritt mit Ablauf des 31.12.2027 außer Kraft)

(§ 71c will expire after 31.12.2027)

Zulassung zu an einer Universität besonders stark nachgefragten Bachelor- und Diplomstudien

§ 71d. (1) Die Bundesministerin oder der Bundesminister ist ermächtigt, von Amts wegen oder auf Antrag der betroffenen Universität bzw. Universitäten durch Verordnung in Studienfeldern bzw. Studien, die an einer Universität besonders stark nachgefragt sind, eine Anzahl an Studienplätzen für Studienanfängerinnen und –anfänger festzulegen und das Rektorat zu ermächtigen, die Zulassung zu diesem Studium durch Verordnung entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln, wobei Elemente eines Aufnahmeverfahrens im Sinne einer mehrstufigen Gestaltung auch mit Elementen eines Auswahlverfahrens verbunden werden können. Vor der Festlegung des Aufnahme- oder Auswahlverfahrens durch das Rektorat ist dem Senat die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden.

(2) In den von der Verordnung gemäß Abs. 1 umfassten gemeinsam eingerichteten Studien gemäß § 51 Abs. 2 Z 27 sind die Rektorate der beteiligten Universitäten und öffentlichen Pädagogischen Hochschulen berechtigt, durch gleichlautend zu erlassende Verordnungen bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten berechtigt, durch zu veröffentlichende gleichlautende Vereinbarungen die Zulassung zu diesem Studium entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln, wobei Elemente eines Aufnahmeverfahrens im Sinne einer mehrstufigen Gestaltung auch mit Elementen eines Auswahlverfahrens verbunden werden können. Vor der Festlegung bzw. Vereinbarung des Aufnahme- oder Auswahlverfahrens durch das Rektorat bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten ist dem Senat bzw. den zuständigen Organen von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen und Privatuniversitäten die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat bzw. die zuständigen Organe von anerkannten privaten Pädagogischen Hochschulen, Einrichtungen zur Durchführung von Fachhochschul-Studiengängen

Admission to Very Popular Bachelor's and Diploma Programmes at a University

§ 71d. (1) The Federal Minister shall, acting ex officio or on application of the university or universities affected, be entitled to, by decree, determine a number of study places for first-year students in very popular fields of education or study programmes at a university and may empower the rectorate to regulate admission to this study programme by decree, either by means of an admission procedure prior to admission or by selecting students no later than one semester after admission, in that elements of an admission procedure may, in the sense of a multi-level design, be combined with elements of a selection procedure. Before the rectorate determines the admission or selection procedure, the senate shall have the opportunity to give its opinion within six weeks. The rectorate's decision shall be taken by 30 April at the latest in order to become effective in the following academic year.

(2) For the jointly offered study programmes according to § 51 para 2 subpara 27 mentioned under para 1, the rectorates of the universities and public university colleges of teacher education involved or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, shall have the right to limit admission to this study programme by decrees to be enacted identically or by agreements to be published identically, respectively. Admission may be limited either by means of an admission procedure prior to admission or by selecting students no later than one semester after admission, in that elements of an admission procedure may, in the sense of a multi-level design, be combined with elements of a selection procedure. Before the rectorate determines, or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities agree on, the admission or selection procedure, the senate or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, shall have the opportunity to give an opinion within six weeks. The decision of the rectorate, or the competent bodies of recognised private university colleges of teacher education, institutions offering university of applied sciences study programmes, and private universities, respectively, shall be taken by 30 April at the latest in order to become effective in the following academic year.

und Privatuniversitäten hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden.

(3) Besonders stark nachgefragt ist ein Studienfeld bzw. Studium, wenn entweder

1. die durchschnittliche Betreuungsrelation der letzten fünf Studienjahre in dem betreffenden Studienfeld bzw. Studium an dieser Universität das 1,75-Fache des Betreuungsrichtwerts des betreffenden Studienfelds bzw. Studiums übersteigt und in diesem Studienfeld bzw. Studium im Durchschnitt der letzten fünf Studienjahre österreichweit mehr als 500 prüfungsaktive Bachelor-, Master- und Diplomstudien belegt waren oder
2. die Anzahl der Studienanfängerinnen und -anfänger in dem betreffenden Studienfeld bzw. Studium binnen zweier Studienjahre um mehr als 50 vH zunimmt und dabei die absolute Zahl von 200 Studienanfängerinnen und –anfängern überschritten wird, und gleichzeitig die Zahl der prüfungsaktiven Bachelor- und Diplomstudien in dem betreffenden Studienfeld bzw. Studium binnen zweier Studienjahre um mehr als 25 vH zunimmt und dabei die absolute Zahl von 500 prüfungsaktiven Bachelor- und Diplomstudien überschritten wird.

(4) Die Universität hat den Nachweis der Erfordernisse gemäß Abs. 3 auf Basis harmonisierter Daten zu erbringen. Im Zuge dieses Nachweises ist ua darzulegen, dass die Universität in den letzten Jahren Ressourcen hin zum betreffenden Studienfeld bzw. Studium verlagert bzw. etwaige organisatorische Maßnahmen gesetzt hat. Bei Feststellung kritischer Betreuungsverhältnisse oder Kapazitäten in einem Studienfeld bzw. Studium hat die Bundesministerin oder der Bundesminister die Möglichkeit, im Rahmen der Leistungsvereinbarung oder eines Nachtrags zur Leistungsvereinbarung universitäts- oder standortbezogene Lösungen für geeignete Studienplatzzahlen zu erwirken.

(5) Die Anzahl der mindestens anzubietenden Studienplätze für Studienanfängerinnen und –anfänger pro Studienfeld bzw. Studium ist durch die Verordnung gemäß Abs. 1 anhand der Indikatoren „Anzahl der Studienanfängerinnen und –anfänger in Bachelor- und Diplomstudien (ohne Incoming-Studierende)“ (Indikator 1), „Anzahl der prüfungsaktiven Bachelor- und Diplomstudien im ersten Studienjahr“ (Indikator 2) sowie „Anzahl der Studienabschlüsse in Bachelor- und Diplomstudien“ (Indikator 3) festzulegen, wobei der Indikator 1 mit einem Anteil von 25 vH, der Indikator 2 mit einem Anteil von 50 vH sowie der Indikator 3 mit einem Anteil von 25 vH zu gewichten ist.

(3) A field of education or study programme, respectively, is very popular if either

1. the average student-teacher ratio of the past five academic years in the respective field of education or study programme at this university exceeds the reference value for the respective field of education or study programme by 1.75 times, and, on average over the past five academic years, more than 500 students actively taking examinations were enrolled in bachelor's, master's and diploma programmes throughout Austria, or
2. the number of first-year students in the respective field of education or study programme increases by more than 50% within a period of two academic years and exceeds the absolute number of 200 first-year students, and, at the same time, the number of students actively taking examinations in bachelor's and diploma programmes in the respective field of education or study programme increases by more than 25% within a period of two academic years and exceeds the absolute number of 500 students actively taking examinations in bachelor's and diploma programmes.

(4) The university shall provide proof of the needs according to para 3 based on harmonised data. In the course of providing proof, the university shall, i.a., describe the shifting of resources during the last years towards the respective field of education or study programme as well as any organisational measures it has taken. If the student-teacher ratios or capacities in a field of education or study programme are found to be critical, the Federal Minister shall have the option, within the framework of the performance agreement or a supplementary agreement thereto, to effect university- or location-specific solutions for providing adequate numbers of study places.

(5) The minimum number of study places for first-year students to be offered per field of education or study programme shall be determined by decree according to para 1 based on the indicators “Number of first-year students in bachelor's and diploma programmes (excluding incoming students)” (indicator 1), “Number of students actively taking examinations in bachelor's and diploma programmes in the first year of studies” (indicator 2) as well as “Number of graduates in bachelor's and diploma programmes” (indicator 3). In that, indicator 1 shall account for a share of 25%, indicator 2 for 50% and indicator 3 for 25%.

(6) Die Festlegung des Betreuungsrichtwerts gemäß Abs. 3 Z 1, die Definition, Datengrundlage und Berechnung der Betreuungsrelation gemäß Abs. 3 Z 1 in Bachelor-, Master- und Diplomstudien sowie der Anzahl der prüfungsaktiven Bachelor-, Master- und Diplomstudien gemäß Abs. 3 Z 1 und 2 sowie die Definition, Datengrundlage und Berechnung der Indikatoren gemäß Abs. 5 erfolgt in der Verordnung gemäß Abs. 1.

(7) § 71b Abs. 3, 6, 7 und 9 ist anzuwenden.

(Anm.: § 71d tritt mit Ablauf des 31.12.2027 außer Kraft)

Zulassung zu an einer Universität besonders stark nachgefragten Masterstudien

§ 71e. (1) In der Leistungsvereinbarung mit der betroffenen Universität kann evidenzbasiert festgestellt werden, dass einzelne Masterstudien besonders stark nachgefragt sind. In diesen Studien ist das Rektorat berechtigt, die Anzahl der Studienplätze für Studienanfängerinnen und –anfänger nach Maßgabe der Leistungsvereinbarung festzulegen und die Zulassung zu diesen Masterstudien durch Verordnung entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln. Vor der Festlegung des Aufnahme- oder Auswahlverfahrens durch das Rektorat ist dem Senat die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden.

(2) Für die evidenzbasierte Festlegung der besonders starken Nachfrage im Sinne des Abs. 1 sind insbesondere folgende Kriterien heranzuziehen: infrastrukturbezogene Kapazitäten, Personalkapazitäten, Betreuungsrelationen, bisherige Zahlen der tatsächlichen Studienanfängerinnen und –anfänger, der Studienwerberinnen und –werber sowie die Anzahl der Absolventinnen und Absolventen. Die Universität hat standardisierte, datenbasierte Evidenzen vorzulegen, die eine besonders starke Nachfrage belegen.

(3) § 71b Abs. 6, 7 und 9 ist sinngemäß anzuwenden.

(4) Abs. 1 bis 3 gelten nicht für jene Masterstudien, die als Voraussetzung für die Ausübung eines reglementierten Berufes zu absolvieren sind.

(5) Es ist sicherzustellen, dass die Absolvierung eines Bachelorstudiums an der jeweiligen Universität jedenfalls ohne weitere Voraussetzungen zur Zulassung zu mindestens einem fachlich in Frage kommenden Masterstudium an der Universität

(6) The decree according to para 1 shall comprise the determination of the reference value for the teacher-student ratios according to para 3 subpara 1, the definition, data basis, and calculation of the student-teacher ratio according to para 3 subpara 1 in bachelor's, master's and diploma programmes, as well as the number of students actively taking examinations in bachelor's, master's and diploma programmes according to para 3 subparas 1 and 2, and furthermore the definition, data basis and calculation of the indicators according to para 5.

(7) § 71b paras 3, 6, 7 and 9 shall apply.

(§ 71d will expire after 31.12.2027)

oder bei gemeinsam eingerichteten Studien an einer der beteiligten Bildungseinrichtungen im Sinne von § 63a Abs. 2 berechtigt.

4. Abschnitt
Beurteilung des Studienerfolgs und Zeugnisse

Feststellung und Beurteilung des Studienerfolgs

§ 72. (1) Der Studienerfolg ist durch die Prüfungen und die Beurteilung der wissenschaftlichen (Diplomarbeit, Masterarbeit oder Dissertation) oder der künstlerischen Arbeit (künstlerische Diplom-, Masterarbeit oder Dissertation) festzustellen.

(2) Der positive Erfolg von Prüfungen und wissenschaftlichen sowie künstlerischen Arbeiten ist mit „sehr gut“ (1), „gut“ (2), „befriedigend“ (3) oder „genügend“ (4), der negative Erfolg ist mit „nicht genügend“ (5) zu beurteilen. Zwischenbeurteilungen sind unzulässig. Wenn diese Form der Beurteilung unmöglich oder unzweckmäßig ist, hat die positive Beurteilung „mit Erfolg teilgenommen“, die negative Beurteilung „ohne Erfolg teilgenommen“ zu lauten.

(3) Prüfungen, die aus mehreren Fächern oder Teilen bestehen, sind nur dann positiv zu beurteilen, wenn jedes Fach oder jeder Teil positiv beurteilt wurde.

(4) Die Beurteilung der Praktika im Rahmen der pädagogisch-praktischen Studien erfolgt durch die Lehrveranstaltungsleiterin oder den Lehrveranstaltungsleiter auf der Grundlage der schriftlichen Leistungsbeschreibung der Praxislehrerin oder des Praxislehrers~~.~~ oder der Mentorin oder des Mentors. Führt die schriftliche Leistungsbeschreibung voraussichtlich zu einer negativen Beurteilung, hat die oder der Studierende das Recht, eine schriftliche Stellungnahme abzugeben. § 46 Abs. 1 bis 4 sowie § 214 des Beamten-Dienstrechtsgesetzes 1979, BGBl. Nr. 333/1979, gilt für Studierende hinsichtlich im Curriculum verankerter Praktika an Schulen sinngemäß, wobei an die Stelle der Beamtin oder des Beamten bzw. der Lehrerin oder des Lehrers die oder der Studierende tritt und an die Stelle der Dienstbehörde die zuständige Schulbehörde.

Gesamtnote

§ 72a. (1) Auf Antrag der Absolventin oder des Absolventen eines ordentlichen Studiums ist, sofern eine Gesamtnote in Form eines Notendurchschnittes vorzuweisen ist, eine nach ECTS-Anrechnungspunkten gewichtete Gesamtnote zu

Chapter 4
Determination of Academic Success and Certificates

Determination of Academic Success and Academic Assessment

§ 72. (1) Academic success shall be determined by examinations and the assessment of the academic thesis (diploma, master’s or doctoral thesis) or artistic submission (artistic diploma or master's submission or artistic doctoral thesis).

(2) Passes of examinations and positive assessments of academic theses and artistic submissions shall be graded as “excellent” (1), “good” (2), “satisfactory” (3) or “sufficient” (4); fails shall be graded as “insufficient” (5). Intermediate assessments are impermissible. If this form of assessment is impossible or inexpedient the form of words for a pass shall be “successfully completed” and that for a fail shall be “unsuccessfully completed”.

(3) Passes for examinations consisting of a number of subjects or parts shall only be awarded if each subject or part has been passed.

(4) The teachers of courses shall be responsible for the assessment of the internships in the framework of the pedagogic-practical studies on the basis of the written performance description of the practice instructor. If the written performance description is likely to lead to a negative assessment, the student shall have the opportunity to express an opinion in writing. § 46 paras 1 to 4 as well as § 214 of the Civil Service Code 1979 (Beamten-Dienstrechtsgesetz), F. L. G. No 333/1979, shall apply by analogy to students with regard to the internships at schools as laid down in the curriculum; the student shall take the place of the civil servant or teacher and the competent school authority shall take the place of the employing authority.

Overall grade

§ 72a. (1) On application of the graduate of a degree programme and if an overall grade in the form of the grade average must be shown, an overall grade shall be calculated, weighted by the number of ECTS credits and rounded to two digits after the decimal point; the thousandth shall be rounded up if its value is at least 5.

berechnen und auf zwei Kommastellen gerundet darzustellen, wobei aufzurunden ist, wenn die Tausendstelstelle mindestens den Wert 5 hat.

(2) Abweichend von Abs. 1 ist die Gesamtnote gemäß Z 13 des Notenwechsels zwischen der Regierung der Republik Österreich und der Italienischen Republik über die gegenseitige Anerkennung akademischer Grade und Titel samt Anlage, BGBl. III Nr. 45/2001, sowie gemäß Z 12 des Abkommens zwischen der Regierung der Republik Österreich und der Regierung der Italienischen Republik über die gegenseitige Anerkennung akademischer Grade und Titel, BGBl. III Nr. 177/2008, zu ermitteln, indem

1. die Noten aller für das betreffende Studium vorgeschriebenen Prüfungsfächer und gegebenenfalls Bachelorarbeiten sowie die Note der Diplomarbeit bzw. der Masterarbeit addiert werden,
2. der gemäß Z 1 errechnete Wert durch die Anzahl der Prüfungsfächer, im Fall eines Diplom- oder Masterstudiums vermehrt um die Zahl 1, dividiert wird sowie
3. das Ergebnis der Division auf zwei Kommastellen gerundet wird, wobei aufzurunden ist, wenn die Tausendstelstelle mindestens den Wert 5 hat.

Nichtigerklärung von Beurteilungen

§ 73. (1) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat die Beurteilung mit Bescheid für nichtig zu erklären, wenn

1. bei einer Prüfung die Anmeldung zu dieser Prüfung erschlichen wurde oder
2. bei einer Prüfung oder einer wissenschaftlichen oder künstlerischen Arbeit die Beurteilung, insbesondere durch~~, ein Plagiat gemäß § 51 Abs. 2 Z 31 oder durch Vortäuschen von wissenschaftlichen oder künstlerischen Leistungen gemäß § 51 Abs. 2 Z 32~~ schwerwiegendes wissenschaftliches oder künstlerisches Fehlverhalten im Sinne des § 2a Abs. 3 Z 2 bis 5 HS-QSG, erschlichen wurde.

(2) Die Prüfung, deren Beurteilung für nichtig erklärt wurde, ist auf die Gesamtzahl der Wiederholungen anzurechnen.

(3) Prüfungen, die außerhalb des Wirkungsbereiches einer Fortsetzungsmeldung abgelegt wurden, und Beurteilungen wissenschaftlicher sowie künstlerischer Arbeiten, die außerhalb des Wirkungsbereiches einer Fortsetzungsmeldung erfolgten, sind absolut nichtig. Eine Anrechnung auf die Gesamtzahl der Wiederholungen erfolgt nicht.

(2) Notwithstanding para 1, the overall grade under subpara 13 of the exchange of notes between the Federal Government of the Republic of Austria and the Republic of Italy on the mutual recognition of academic degrees and titles, together with its Appendix, F. L. G. III No 45/2001, as well as according to subpara 12 of the exchange of notes between the Federal Government of the Republic of Austria and the Republic of Italy on the mutual recognition of academic degrees and titles, F. L. G. III No 177/2008, shall be calculated by

1. adding up the grades of all subjects prescribed for the study programme concerned, including that of any bachelor's theses, as well as the grade of the diploma thesis or master's thesis,
2. dividing the value calculated according to subpara 1 by the number of subjects, in the case of a diploma or master's programme plus 1, and
3. rounding the result to two digits after the decimal point; the thousandth shall be rounded up if its value is at least 5.

Annulations of Assessments

§ 73. (1) The assessment shall be annulled by an official notification of the officer responsible for study matters if

1. in the case of an examination, the latter was registered for under false pretences;
2. in the case of an examination, academic thesis or artistic submission, the assessment was obtained by fraudulent means, in particular, plagiarism in the meaning of § 51 para 2 subpara 31 or academic or artistic dishonesty in the meaning of § 51 para 2 subpara 32.

(2) An examination, the result of which is annulled, shall count towards the number of repetitions.

(3) The results of examinations taken outside the registered continuation period for studies, and the assessments of academic theses and artistic submissions awarded outside the registered continuation period shall be null and void. Such results or assessments shall not count towards the number of repetitions.

Zeugnisse

§ 74. (1) Die Beurteilung von Prüfungen und wissenschaftlichen sowie künstlerischen Arbeiten ist jeweils durch ein Zeugnis zu beurkunden. Sammelzeugnisse sind zulässig.

(2) Die Zeugnisse sind vom Senat festzulegen und haben jedenfalls folgende Angaben zu enthalten:

1. die ausstellende Universität und die Bezeichnung des Zeugnisses;
2. die Matrikelnummer;
3. den Familiennamen und die Vornamen;
4. das Geburtsdatum;
5. die Bezeichnung des Studiums;
6. die Bezeichnung der Prüfung oder das Fach und die erfolgte Beurteilung sowie die ECTS-Anrechnungspunkte;
7. das Thema der wissenschaftlichen oder künstlerischen Arbeiten und die Beurteilung sowie die ECTS-Anrechnungspunkte;
8. den Namen der Prüferin oder des Prüfers, das Prüfungsdatum und die Beurteilung;
9. den Namen der Ausstellerin oder des Ausstellers.

(3) Zeugnisse über Prüfungen vor Einzelprüferinnen oder Einzelprüfern hat die Prüferin oder der Prüfer, Zeugnisse über die Beurteilung wissenschaftlicher sowie künstlerischer Arbeiten hat die Beurteilerin oder der Beurteiler, Zeugnisse über kommissionelle Prüfungen hat die oder der Vorsitzende der Prüfungskommission, Zeugnisse über Studienabschlüsse hat das für die studienrechtlichen Angelegenheiten zuständige Organ auszustellen.

(4) Die Zeugnisse sind unverzüglich, längstens jedoch innerhalb von vier Wochen nach Erbringung der zu beurteilenden Leistung auszustellen. Zur Unterstützung der internationalen Mobilität der Studierenden ist der Anschluss einer fremdsprachigen Übersetzung zulässig, wobei die Benennung der Universität und des ausstellenden Organs nicht zu übersetzen sind.

(Anm.: Abs. 5 aufgehoben durch Art. 1 Z 115, BGBl. I Nr. 93/2021)

(6) Die Universität hat einer oder einem ausländischen Studierenden ab dem zweiten Studienjahr auf Antrag der oder des Studierenden einen Studienerfolgsnachweis auszustellen, sofern sie oder er im vorausgegangenen

Certificates

§ 74. (1) The results of examinations and assessments of academic theses and artistic submissions shall be evidenced by certificates. Consolidated certificates may be issued.

(2) The certificates awarded shall be determined by the senate, and shall, as a minimum, contain the following information:

1. the awarding university and the designation of the certificate;
2. the matriculation number;
3. the surname and first names;
4. the date of birth;
5. the designation of the programme;
6. the designation of the examination or the subject, the assessment and the ECTS credits;
7. the topic of the academic theses and artistic submissions, the assessment and the ECTS credits;
8. the name of the examiner, the date of the examination and the result(s) awarded;
9. the name of the issuer.

(3) Certificates of examinations held before one examiner shall be issued by the latter, those of assessments of academic theses and artistic submissions by the assessor, and those of examinations held before senates by the chairperson of the examination senate. Graduation certificates shall be issued by the officer responsible for study matters.

(4) Certificates shall be issued without delay, and within four weeks of performance of the work assessed at the latest. In the interest of international student mobility a translation may be appended, with the name of the university and of the issuing body not having to be translated.

(5) [removed]

(6) Universities shall, on application of a foreign student, issue him/her a certificate of successful course completion from the second year of study onwards, if he/she has passed examinations equivalent to at least 16 ECTS credits or 8 semester hours.

Studienjahr positiv beurteilte Prüfungen im Umfang von mindestens 16 ECTS-Anrechnungspunkten oder 8 Semesterwochenstunden abgelegt hat.

(7) Erfolgreich absolvierte Studien gemäß § 58 Abs. 11 sind im studienabschließenden Zeugnis durch einen Hinweis auf die mit Bescheid modifizierten Anforderungen zu kennzeichnen.

4a. Abschnitt

Zulassungs- und Ergänzungsprüfungen, Lehrveranstaltungen und Prüfungen

Zulassungs- und Ergänzungsprüfungen

§ 75. (1) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat fachlich geeignete Prüferinnen oder Prüfer für die Zulassungs- und Ergänzungsprüfungen heranzuziehen, die Prüfungsmethode zu bestimmen und festzulegen, ob diese als Einzelprüfung oder als kommissionelle Prüfung abzulegen ist.

(2) Wird zur Vorbereitung auf eine Ergänzungsprüfung ein Universitätslehrgang eingerichtet, gilt dessen positiver Abschluss als Ergänzungsprüfung.

(3) Zulassungsprüfungen sind unbeschränkt wiederholbar.

Lehrveranstaltungen und Prüfungen

§ 76. (1) Vor Beginn jedes Semesters ist ein elektronisches Verzeichnis der Lehrveranstaltungen zu veröffentlichen, welches Informationen über den Titel, den Namen der Leiterin oder des Leiters, die Art, die Form (gegebenenfalls inklusive Angabe des Ortes der Abhaltung) und die Termine der Lehrveranstaltungen enthält. Dieses ist laufend zu aktualisieren.

(2) Die Leiterinnen und Leiter der Lehrveranstaltungen haben, zusätzlich zum veröffentlichten Verzeichnis gemäß Abs. 1, vor Beginn jedes Semesters die Studierenden in geeigneter Weise über die Ziele, die Form, die Inhalte, die Termine und die Methoden ihrer Lehrveranstaltungen sowie über die Inhalte, die Form, die Methoden, die Termine, die Beurteilungskriterien und die Beurteilungsmaßstäbe der Prüfungen zu informieren.

(3) Für Prüfungen, die in Form eines einzigen Prüfungsvorganges durchgeführt werden, sind Prüfungstermine jedenfalls drei Mal in jedem Semester anzusetzen, wobei die Studierenden vor Beginn jedes Semesters über die Inhalte, die Form, die

(7) Successfully completed study programmes according to § 58 para 11 shall be specified in the graduation certificate by a reference to the requirements modified by official notification.

Chapter 4a

Admission and Supplementary Examinations, Courses and Examinations

Admission and Supplementary Examinations

§ 75. (1) The officer responsible for study matters shall appoint academically qualified examiners for the admission and supplementary examinations; these persons shall determine the method of examination, and determine whether the examination is to be heard by a single examiner or an examination board.

(2) If a university further education course is held to prepare students for a supplementary examination, its successful completion shall be deemed equivalent to such examination.

(3) Admission examinations may be repeated without limitation.

Courses and Examinations

§ 76. (1) Before a new semester begins, a digital index of courses, providing details such as the designation of the course, the name of the course instructor, the type and mode of (including information on the place where it will be held) as well as the fixed dates for the courses, shall be published and updated on a regular basis.

(2) Before each new semester begins, the course instructors shall, in addition to the published digital index in the meaning of para 1, inform the students appropriately of the objectives, the mode, contents, methods and fixed dates of their courses, as well as of the contents, mode, methods, dates, assessment criteria and the standards of assessment for examinations.

(3) For examinations which are executed in a single phase, examination dates must be scheduled to take place at least three times each semester. Before each new semester begins, the students shall be informed of the contents, mode, methods, fixed

Methoden, die Termine, die Beurteilungskriterien und die Beurteilungsmaßstäbe der Prüfungen zu informieren sind. Bei der Festlegung der Prüfungstermine sind nach Maßgabe der Möglichkeiten die zentralen Feiertage der gesetzlich anerkannten Kirchen und Religionsgesellschaften zu berücksichtigen.

(4) Sollten sich die gemäß Abs. 2 und 3 bekannt gegebene Form, die Termine, die Methoden oder die Beurteilungskriterien der Lehrveranstaltung oder der Prüfung während des Semesters aus zwingenden Gründen, welche vom Rektorat festzustellen sind, ändern, sind allfällige Änderungen den Studierenden unverzüglich in geeigneter Weise mitzuteilen. Den Studierenden, die unter den geänderten Rahmenbedingungen nicht mehr teilnehmen wollen, ist jedenfalls das Recht einzuräumen, sich von der betreffenden Lehrveranstaltung oder Prüfung abzumelden, ohne dass eine Anrechnung auf die Gesamtzahl der zulässigen Prüfungsantritte erfolgt.

(5) In den pädagogisch-praktischen Studien ist ein aufbauender Kompetenzerwerb vorzusehen, bei dem die Eigenverantwortlichkeit sowie die Selbständigkeit durch Studierende im Unterricht steigernd erhöht wird und schließlich ein gänzlich eigenverantwortlicher Unterricht durch Studierende zu erfolgen hat. Die Praktika der pädagogisch-praktischen Studien sind zum überwiegenden Teil im Rahmen des Unterrichts an Schulen durchzuführen, wobei nach Verfügbarkeit und Schwerpunkt die Absolvierung an verschiedenen Schularten desselben Altersbereichs zu ermöglichen ist.

Sondervorschrift für die Durchführung von Prüfungen mit Mitteln der elektronischen Kommunikation

§ 76a. Bei Prüfungen mit Mitteln der elektronischen Kommunikation ist eine ordnungsgemäße Durchführung der Prüfung zu gewährleisten, wobei zusätzlich zu den allgemeinen Regelungen zu Prüfungen folgende Mindesterfordernisse einzuhalten sind:

1. Bekanntgabe der Standards vor dem Beginn des Semesters, die die technischen Geräte der Studierenden erfüllen müssen, um an diesen Prüfungen teilnehmen zu können.
2. Zur Gewährleistung der eigenständigen Erbringung der Prüfungsleistung durch die Studierende oder den Studierenden sind technische oder organisatorische Maßnahmen vorzusehen.
3. Bei technischen Problemen, die ohne Verschulden der oder des Studierenden auftreten, ist die Prüfung abzubrechen und nicht auf die zulässige Zahl der Prüfungsantritte anzurechnen.

dates as well as the assessment criteria and standards for the assessment of the examinations. When setting the examinations dates, the most important holidays of the legally recognised churches and religious societies shall be taken into account, whenever possible.

(4) If the mode, fixed dates, methods or assessment criteria pursuant to paras 2 and 3 of the course or examination should change due to unavoidable reasons which are to be determined by the rectorate, the students must be informed appropriately and without delay of any changes. Those students who no longer want to participate under the changed conditions, shall, in any case, shall be granted the right to deregister from the course or examination without it being counted towards the permissible number of resits.

(5) In pedagogic-practical studies, competences should be acquired, building on previous knowledge, in which a student's personal responsibility and autonomy in lessons are promoted increasingly until, finally, the students have to teach entirely on their own responsibility. Practical trainings in pedagogic-practical studies shall be carried out mainly at schools. However, depending on availability and focus areas, it shall be made possible to complete these trainings at different types of schools in the same age range.

Special provision for the use of electronic communication tools in examining

§ 76a. When using electronic communication in examining, it must be ensured that the examination is carried out in an orderly manner. In addition to the general regulations on examinations, the following minimum requirements must be met:

1. Prior to the beginning of the semester the standards must be announced which the students' technical equipment have to fulfil in order to take part in the examination.
2. Technical or organisational measures shall ensure that the students complete the examination themselves.
3. In case of technical problems that may arise without the fault of the student, the examination shall be aborted. The examination shall not be counted towards the permissible number of resits.

Wiederholung von Prüfungen

§ 77. (1) Die Studierenden sind berechtigt, positiv beurteilte Prüfungen bis zwölf Monate nach der Ablegung, jedoch längstens bis zum Abschluss des betreffenden Studienabschnittes oder bis zum Abschluss des betreffenden Studiums einmal zu wiederholen. Die positiv beurteilte Prüfung wird mit dem Antreten zur Wiederholungsprüfung nichtig. Dies gilt auch für die im Curriculum von Lehramtsstudien gekennzeichneten Praktika im Rahmen der pädagogisch-praktischen Studien. An den Universitäten gemäß § 6 Abs. 1 Z 16 bis 21 dürfen zwei positiv beurteilte Lehrveranstaltungsprüfungen aus dem zentralen künstlerischen Fach während der gesamten Studiendauer je einmal wiederholt werden.

(2) Die Studierenden sind berechtigt, negativ beurteilte Prüfungen dreimal zu wiederholen. Auf die Zahl der zulässigen Prüfungsantritte sind alle Antritte für dieselbe Prüfung an derselben Universität und bei gemeinsam eingerichteten Studien an allen beteiligten Bildungseinrichtungen anzurechnen. In der Satzung ist festzulegen, ob und wie viele weitere Prüfungswiederholungen zulässig sind. Bei negativer Beurteilung der letzten Wiederholung der letzten Prüfung des Studiums sind die Studierenden berechtigt, diese ein weiteres Mal zu wiederholen.

(3) Ab der dritten Wiederholung einer Prüfung ist diese kommissionell abzuhalten, wenn die Prüfung in Form eines einzigen Prüfungsvorganges durchgeführt wird. Auf Antrag der oder des Studierenden gilt dies auch ab der zweiten Wiederholung.

(4) Die Studierenden sind berechtigt, im Curriculum gekennzeichnete Praktika im Rahmen der pädagogisch-praktischen Studien bei negativer Beurteilung ein Mal zu wiederholen. Die oder der Studierende ist berechtigt, im Curriculum gekennzeichnete Praktika im Rahmen der pädagogisch-praktischen Studien ein weiteres Mal zu wiederholen, wenn die negative Beurteilung der Wiederholung darauf zurückzuführen ist, dass die oder der Studierende ohne eigenes Verschulden dieses oder Teile davon versäumt hat. Es ist dahingehend beim für die studienrechtlichen Angelegenheiten zuständigen Organ binnen zwei Wochen ab Beurteilung ein Antrag zu stellen und es sind die erforderlichen Nachweise beizubringen.

(5) Die Festlegung von Fristen und die Verpflichtung zur Ablegung von Lehrveranstaltungsprüfungen als Voraussetzung für die Wiederholung von Prüfungen sind unzulässig.

Repetition of Examinations

§ 77. (1) Students shall be entitled to repeat passed examinations up to twelve months after taking them, but not later than the end of the respective stage of the study programme or the programme as a whole. The result of the passed examination shall become null and void when the resit is taken. This shall also apply to internships in the framework of the pedagogic-practical studies, indicated by the curriculum of teacher training programmes. At the universities named in § 6 para 1 subparas 16 to 21 a maximum of two passed course examinations in the major artistic subject may be repeated once throughout the entire duration of studies.

(2) Students shall be entitled to repeat failed examinations three times. All examinations taken in the same subject at the same university and, in jointly offered programmes, at all educational institutions concerned, shall count towards the permissible number of resits. The statute shall state whether further resits are permitted, and if so how many may be taken. In the case of a negative assessment of the last permissible repetition of the last examination of a study programme, the students shall be entitled to repeat it one more time.

(3) Starting with the third repetition of an examination, re-sits must be held before an examination board, if the examination takes the form of a single procedure. On application of the student the same shall apply, starting with the second repetition.

(4) In the case of receiving a negative assessment, students shall be entitled to repeat internships in the framework of the pedagogic-practical studies indicated by the curriculum once. The student is permitted to repeat internships in the framework of the pedagogic-practical studies indicated by the curriculum one more time if the negative assessment of the resit is due to the fact that the student missed (parts of) it without fault of his/her own. An application to that effect shall be submitted to the body responsibly for study matters within two weeks of the assessment. The necessary supporting documents shall be provided.

(5) Setting of deadlines for repetitions of examinations and making them conditional on taking course examinations is impermissible.

Anerkennung von Prüfungen, anderen Studienleistungen, Tätigkeiten und ~~Qualifikationen~~Kompetenzen

§ 78. (1) Positiv beurteilte Prüfungen und andere Studienleistungen sind ~~bis zu dem in Abs. 4 Z 6 festgelegten Höchstausmaß~~ anzuerkennen, wenn

1. keine wesentlichen Unterschiede hinsichtlich der erworbenen Kompetenzen (Lernergebnisse) bestehen und
2. sie an einer der folgenden Bildungseinrichtungen abgelegt wurden:
   a) einer anerkannten postsekundären Bildungseinrichtung gemäß § 51 Abs. 2 Z 1;
   b) einer berufsbildenden höheren Schule in den für die künftige Berufstätigkeit erforderlichen berufsqualifizierenden Fächern;
   c) einer allgemeinbildenden höheren Schule unter besonderer Berücksichtigung der musischen oder der sportlichen Ausbildung in künstlerischen und künstlerisch-wissenschaftlichen sowie in sportlichen und sportlich-wissenschaftlichen Fächern~~.~~;
   d) einem österreichischen Konservatorium mit Öffentlichkeitsrecht.

(2) Folgende wissenschaftliche, künstlerische und berufliche Tätigkeiten sind anzuerkennen, wenn keine wesentlichen Unterschiede hinsichtlich der erworbenen Kompetenzen (Lernergebnisse) bestehen:

1. wissenschaftliche Tätigkeiten oder wissenschafts- oder ausbildungsbezogene Praktika in Betrieben oder Forschungseinrichtungen außerhalb der Universität und bei gemeinsam eingerichteten Studien außerhalb der beteiligten Bildungseinrichtungen, die eine wissenschaftliche Berufsvorbildung vermitteln können;
2. künstlerische Tätigkeiten und kunstbezogene Praktika in Organisationen und Unternehmen außerhalb der Universität und bei gemeinsam eingerichteten Studien außerhalb der beteiligten Bildungseinrichtungen, die eine künstlerische Berufsvorbildung vermitteln können;
3. einschlägige berufliche Tätigkeiten mit pädagogischen Anteilen für Lehramtsstudien sowie instrumental(gesangs-)-, religions- und wirtschaftspädagogische Studien.

(3) Andere berufliche oder außerberufliche ~~Qualifikationen~~Kompetenzen können nach Durchführung einer Validierung der Lernergebnisse bis zu dem in Abs. 4 Z 6 festgelegten Höchstausmaß anerkannt werden. In diesem Fall sind

Recognition of Examinations, other academic achievements, activities and qualifications

§ 78. (1) Passed examinations and other academic achievements shall be recognised up to the maximum amount stipulated in para 4 subpara 6 if

1. there are no substantial differences with regard to the acquired competences (learning outcomes) and
2. they were taken at one of the following educational institutions:
   a) one of the recognised post-secondary educational institutions named in § 51 para 2 subpara 1;
   b) a higher vocational school in those vocational subjects which are required for a future professional activity;
   c) an academic secondary schools with a particular emphasis on music or sports education, in artistic and artistic-scientific subjects as well as in sportive and sportive-scientific subjects.

(2) The following scientific, artistic and professional activities shall be recognised if there are no substantial differences with regard to the acquired competences (learning outcomes):

1. scientific work or internships related to science or training at business establishments or research establishments outside the university and in jointly offered programmes outside the educational institutions concerned, which are capable of providing scientific pre-vocational education.
2. artistic activities and art-related internships at organisations and companies outside the university and in jointly offered programmes outside the educational institutions concerned, which are capable of providing artistic pre-vocational education;
3. relevant professional activities with pedagogic components for teacher training programmes as well as instrumental or vocal, religious and economic educational programmes.

(3) Other vocational or non-vocational qualifications may be recognised up to the maximum number of ECTS credits as laid down in para 4 subpara 6 following the completion of validation of the learning outcomes. In that case, regulations for

Regelungen zum Verfahren zur Validierung der Lernergebnisse gemäß den in der Satzung festgelegten Standards aufzunehmen.

(4) Für Anerkennungen von Prüfungen, anderen Studienleistungen, Tätigkeiten und ~~Qualifikationen~~Kompetenzen gilt Folgendes:

1. Die Anerkennung erfolgt auf Antrag der oder des Studierenden für ein ordentliches oder außerordentliches Studium.
2. ~~Die Anerkennung für bereits vor der Zulassung absolvierte Prüfungen, andere Studienleistungen, Tätigkeiten und Qualifikationen gemäß Abs. 1 bis 3 ist bis spätestens Ende des zweiten Semesters zu beantragen.~~

(Anm.: Z 2 aufgehoben durch Art. 1 Z 68, BGBl. I Nr. 50/2024)

3. Die für die Beurteilung notwendigen Unterlagen sind von der Antragstellerin oder dem Antragsteller dem Antrag anzuschließen. § 60 Abs. 3a ist sinngemäß anzuwenden.
4. Die Anerkennung erfolgt durch Bescheid des für die studienrechtlichen Angelegenheiten zuständigen Organs für ein ordentliches oder außerordentliches Studium. Über Anerkennungsanträge ist abweichend von § 73 AVG spätestens zwei Monate nach Einlangen des Antrages zu entscheiden. Für Beschwerden gegen den Bescheid gilt § 46 Abs. 2. ~~§ 60 Abs. 3a ist sinngemäß anzuwenden.~~
5. Die Anerkennung von Prüfungen und anderen Studienleistungen, die entgegen der Bestimmung des § 63 Abs. 8 und 9 an einer anderen Universität oder Pädagogischen Hochschule abgelegt wurden, ist ausgeschlossen.
6. Die Universität kann absolvierte Prüfungen gemäß Abs. 1 Z 2 lit. b und c bis zu einem Höchstausmaß von 60 ECTS-Anrechnungspunkten sowie berufliche oder außerberufliche ~~Qualifikationen~~Kompetenzen bis zu einem Höchstausmaß von 60 ECTS-Anrechnungspunkten anerkennen. Diese Anerkennungen sind bis zu einem Höchstausmaß von insgesamt 90 ECTS-Anrechnungspunkten zulässig.
7. Die Anerkennung als Prüfung gilt als Prüfungsantritt und positive Beurteilung der entsprechenden im Curriculum vorgeschriebenen Prüfung in dem Studium, für welches die Anerkennung erfolgt.
8. Anerkannte Prüfungen, andere Studienleistungen, Tätigkeiten und ~~Qualifikationen~~Kompetenzen sind mit der Bezeichnung „anerkannt“ einschließlich der Anzahl jener ECTS-Anrechnungspunkte auszuweisen, die

the procedure of validation of the learning outcomes pursuant to the standards laid down in the statutes shall be included.

(4) The following shall apply to the recognition of examinations, other academic achievements, activities and qualifications:

1. Recognition shall be granted on application of the student for a degree or continuing education programme.
2. Recognition of examinations completed prior to admission, other academic achievements, activities and qualifications pursuant to paras. 1 to 3 shall be applied for no later than at the end of the second semester.
3. The applicant shall attach the documents required to assess such equivalence.
4. Recognition shall be granted by official notification by the officer responsible for study matters for a degree or continuing education programme. Notwithstanding § 73 AVG, a decision on an application for recognition shall be made within two months of receipt of the application. For appeals against the official notification, § 46 para 2 shall apply. § 60 para 3a shall apply by analogy.
5. Recognition of examinations taken at another university or university college of teacher education which contravene the provisions of § 63 paras 8 and 9 is excluded.
6. The university may recognise passed examinations pursuant to para 1 subpara 2 lit b and c up to a maximum of 60 ECTS credits as well as professional and non-professional qualifications up to a maximum of 60 ECTS credits. Such recognitions are permissible up to a maximum of 90 ECTS credits.
7. The recognition as an examination shall be deemed equivalent to a pass in the like examination prescribed by the curriculum for the study programme towards which the recognition shall be counted.
8. Recognised examinations, other academic achievements, activities and qualifications shall be shown with the designation “recognised”, including the number of ECTS credits as specified in the curriculum for the recognised examination or other academic achievement.

im Curriculum für die anerkannte Prüfung oder andere Studienleistung vorgesehen ist.

9. Die Anerkennung von Prüfungen kann auch durch Verordnung des für die studienrechtlichen Angelegenheiten zuständigen Organs erfolgen.

(5) Auf Antrag ordentlicher Studierender, die Teile ihres Studiums im Ausland durchführen wollen, ist im Voraus mit Bescheid festzustellen, welche der geplanten Prüfungen und anderen Studienleistungen anerkannt werden.

~~(6) Positiv beurteilte Prüfungen, die außerordentliche Studierende abgelegt haben, sind für ordentliche Studien bei nicht wesentlichen Unterschieden nur insoweit anzuerkennen, als sie~~

~~1. im Rahmen von Universitätslehrgängen oder Hochschullehrgängen,~~

~~2. vor der vollständigen Ablegung der Reifeprüfung oder der Studienberechtigungsprüfung,~~

~~3. vor der Zulassungsprüfung für den Nachweis der sportlichen Eignung für das Studium, für welches die Prüfung anerkannt werden soll,~~

~~4. vor der Zulassungsprüfung für den Nachweis der künstlerischen Eignung für das Studium, für welches die Prüfung anerkannt werden soll, oder~~

~~5. vor der vollständigen Absolvierung der Eignungsfeststellung für das Lehramtsstudium, für welches die Prüfung anerkannt werden soll,~~

~~abgelegt wurden.~~ *(Anm.: Abs. 6 aufgehoben durch Art. 1 Z 70, BGBl. I Nr. 50/2024)*

Rechtsschutz bei Prüfungen

§ 79. (1) Gegen die Beurteilung einer Prüfung ist kein Rechtsmittel zulässig. Wenn die Durchführung einer negativ beurteilten Prüfung einen schweren Mangel aufweist, hat das für die studienrechtlichen Angelegenheiten zuständige Organ diese Prüfung auf Antrag der oder des Studierenden bzw. einer Person, deren Zulassung gemäß § 68 Abs. 1 Z 3 erloschen ist, mit Bescheid aufzuheben. Der Antrag ist innerhalb von vier Wochen ab der Bekanntgabe der Beurteilung einzubringen und der schwere Mangel ist glaubhaft zu machen. Der Antritt zu einer Prüfung, die aufgehoben wurde, ist nicht auf die zulässige Zahl der Prüfungsantritte anzurechnen.

9. The recognition of examinations may also be granted by official notification by the officer responsible for study matters.

(5) In response to a request by a degree student to conduct part of his/her studies abroad, the university shall, by official notice, specify which of the examinations and other academic achievements such student plans to take will be recognised.

(6) If there are no substantial differences, recognition of examinations passed by continuing education students for degree programmes shall only be permissible if they were taken

1. in connection with continuing education university programmes or continuing higher education programmes;
2. prior to passing the secondary-school leaving examination or university entrance qualification examination;
3. prior to passing the supplementary examination providing proof of physical fitness, appropriate to the programme of study for which the examination is to be recognised;
4. prior to passing the supplementary examination providing proof of artistic aptitude, appropriate to the programme of study for which the examination is to be recognised;
5. prior to passing the supplementary examination providing proof of physical fitness, appropriate to the programme of study for which the examination is to be recognised;

Legal Protection in respect of Examinations

§ 79. (1) Appeals against the academic judgment of examiners shall be impermissible. If the manner in which an examination resulting in a negative assessment is conducted exhibits severe defects, the officer responsible for study matters shall, by official notification, annul the examination on application of the student or of a person who's admission has lapsed according to § 68 para 1 subpara 3. The application shall be submitted within four weeks of announcement of the assessment and substantiate the alleged severe defect. Examinations which are annulled shall not be counted towards the permissible number of re-sits.

(2) Mündliche Prüfungen sind öffentlich. Die Prüferin oder der Prüfer oder die oder der Vorsitzende einer Prüfungskommission ist berechtigt, den Zutritt erforderlichenfalls auf eine den räumlichen Verhältnissen entsprechende Anzahl von Personen bzw. bei Durchführung mit Mitteln der elektronischen Kommunikation die Zuschaltung auf eine den technischen Verhältnissen entsprechende Anzahl von Personen zu beschränken. Bei kommissionellen mündlichen Prüfungen hat jedes Mitglied der Prüfungskommission während der gesamten Prüfung anwesend bzw. zugeschaltet zu sein. Das Ergebnis einer mündlichen Prüfung ist unmittelbar nach der Prüfung der oder dem Studierenden bekannt zu geben. Wurde die Prüfung negativ beurteilt, sind die Gründe dafür der oder dem Studierenden zu erläutern.

(3) Wenn die Beurteilungsunterlagen (insbesondere Gutachten, Korrekturen schriftlicher Prüfungen und Prüfungsarbeiten) den Studierenden nicht ausgehändigt werden, ist sicherzustellen, dass diese mindestens sechs Monate ab der Bekanntgabe der Beurteilung aufbewahrt werden.

(4) Die Prüferin oder der Prüfer oder die oder der Vorsitzende einer Prüfungskommission hat für den geordneten Ablauf der Prüfung zu sorgen und das Prüfungsprotokoll zu führen. In das Protokoll sind der Prüfungsgegenstand, der Ort bzw. die Form und der Beginn und das Ende der Prüfung, die Namen der Prüferin oder des Prüfers oder die Namen der Mitglieder der Prüfungskommission, der Name der oder des Studierenden, die gestellten Fragen, die erteilten Beurteilungen, die Gründe für die negative Beurteilung sowie allfällige besondere Vorkommnisse aufzunehmen. Die Gründe für die negative Beurteilung sind der oder dem Studierenden auf Antrag schriftlich mitzuteilen. Das Prüfungsprotokoll ist mindestens sechs Monate ab der Bekanntgabe der Beurteilung aufzubewahren.

(5) Der oder dem Studierenden ist Einsicht in die Beurteilungsunterlagen und in die Prüfungsprotokolle zu gewähren, wenn sie oder er dies innerhalb von sechs Monaten ab Bekanntgabe der Beurteilung verlangt. Die Beurteilungsunterlagen umfassen auch die bei der betreffenden Prüfung gestellten Prüfungsfragen. Die oder der Studierende ist berechtigt, diese Unterlagen zu vervielfältigen. Vom Recht auf Vervielfältigung und einer Einsichtnahme mit Mitteln der elektronischen Kommunikation ausgenommen sind Multiple Choice-Fragen sowie Fragen von strukturierten mündlichen Prüfungen inklusive der jeweiligen Antwortmöglichkeiten.

(2) Oral examinations shall be open to the public. If necessary, the examiners or the chairpersons of examination boards may limit admission to the number of persons that the premises can accommodate or, in the case of use of electronic communication tools, limit the number of persons connected corresponding to the technical conditions. In the case of oral examinations held before examination boards, all members of the board must be present in person or online throughout the examination. The result of an oral examination shall be made known to the student immediately after the examination. In the case of a negative assessment, the reasons shall be explained to the student.

(3) If the assessment documents (in particular, examiners' reports, and corrected written examinations and assessment papers) are not surrendered to the student, steps shall be taken to ensure that they are held in safekeeping for at least six months after announcement of the result.

(4) The examiners or the chairpersons of examination boards shall ensure that examinations are conducted in an orderly manner, and shall make records of examinations. Such records shall include the subject of the examination, the place or mode and the time the examination begins and ends, the name of the examiner or examination board members, the name of the student, the questions asked, the assessment grades awarded, the reasons for a negative assessment and any unusual occurrences. The reasons for a negative assessment shall be communicated to the student in writing on application of the same. The examination record shall be held in safekeeping for at least one year.

(5) Students shall be permitted to have inspection of the assessment documents and the examination records, provided that they make such requests within six months of the announcement of examination results. The assessment documents shall also include the examination questions asked at the respective examination. Students shall be entitled to make photocopies of these documents. Multiple-choice questions including their answers shall be excluded from the right to make photocopies or to inspection using electronic communication tools.

5. Abschnitt
Bachelorarbeiten, Diplom- und Masterarbeiten sowie Dissertationen

Bachelorarbeiten

§ 80. (1) Im Bachelorstudium sind im Rahmen von Lehrveranstaltungen eine Bachelorarbeit oder mehrere Bachelorarbeiten abzufassen. Nähere Bestimmungen über Bachelorarbeiten sind im jeweiligen Curriculum festzulegen.

(2) Bei der Bearbeitung des Themas und der Betreuung der Studierenden sind die Bestimmungen des Urheberrechtsgesetzes, BGBl. Nr. 111/1936, zu beachten.

Diplom- und Masterarbeiten

§ 81. (1) Im Diplom- oder Masterstudium ist eine Diplom- oder Masterarbeit abzufassen. In besonders berufsorientierten Studien mit Ausnahme von Lehramtsstudien ist es zulässig, im Curriculum anstelle der Diplom- oder Masterarbeit einen anderen gleichwertigen Nachweis vorzusehen. Die Abfassung als Klausurarbeit ist unzulässig. Nähere Bestimmungen über Betreuung und Beurteilung von Diplom- oder Masterarbeiten sind in der Satzung, nähere Bestimmungen über das Thema der Diplom- oder Masterarbeit sind im jeweiligen Curriculum festzulegen.

(2) Die Aufgabenstellung der Diplom- oder Masterarbeit ist so zu wählen, dass für eine Studierende oder einen Studierenden die Bearbeitung innerhalb von sechs Monaten möglich und zumutbar ist.

(3) Die gemeinsame Bearbeitung eines Themas durch mehrere Studierende ist zulässig, wenn die Leistungen der einzelnen Studierenden gesondert beurteilbar bleiben. Erfordert die Bearbeitung eines Themas die Verwendung der Geld- oder Sachmittel von Einrichtungen der Universität, so ist die Vergabe nur zulässig, wenn die Leiterin oder der Leiter dieser Einrichtung über die beabsichtigte Vergabe informiert wurde und diese nicht binnen eines Monats wegen einer wesentlichen Beeinträchtigung des Lehr- und Forschungsbetriebes untersagt hat.

(4) § 80 Abs. 2 gilt auch für Diplom- und Masterarbeiten.

Künstlerische Diplom- und Masterarbeiten

§ 82. (1) In künstlerischen Studien ist eine künstlerische Diplom- oder Masterarbeit zu schaffen. Die Studierenden sind berechtigt, anstelle der

Chapter 5
Bachelor's Papers, Diploma, Master's and Doctoral Theses

Bachelor's Papers

§ 80. (1) One or more bachelor's papers shall be prepared as part of bachelor's programmes. Detailed regulations for bachelor's papers shall be established by the respective curricula.

(2) In the treatment of the topic and the supervision of students, regard shall be given to the provisions of the Copyright Act, F. L. G. No 111/1936.

Diploma and Master's Theses

§ 81. (1) The preparation of diploma or master's theses shall form part of diploma or master's programmes. In the case of studies with a particularly strong vocational orientation, except teacher training programmes, it is permissible to provide for another equivalent means of demonstrating proficiency in place of the diploma or master's thesis. This may not take the form of a written examination. Detailed regulations for the supervision and assessment of diploma and master's theses shall be established by the statute, and those governing the topics by the respective curricula.

(2) The assignments for diploma or master's theses shall be so chosen that it is reasonable to expect a student to complete them within six months.

(3) A number of students may jointly address a topic provided that the performance of individual students can be assessed. In case that treatment of a topic requires the use of financial or material resources furnished by a university organisational unit, assignment of the topic is only permissible if notice of the intention to assign it is given to the head of that unit and he/she does not prohibit it within one month because of potential significant interference with the unit's teaching and research activities.

(4) § 80 para 2 shall apply only to diploma and master's theses.

Artistic Diploma and Master's Submissions

§ 82. (1) Artistic diploma or master's submissions shall be completed as part of art study programmes. Students shall be entitled to prepare a diploma or master's

künstlerischen Diplom- oder Masterarbeit eine Diplom- oder Masterarbeit aus einem im Curriculum festgelegten wissenschaftlichen Prüfungsfach zu verfassen.

(2) Die künstlerische Diplom- oder Masterarbeit hat neben einem künstlerischen Teil, der den Schwerpunkt bildet, auch einen schriftlichen Teil zu umfassen. Dieser hat den künstlerischen Teil zu erläutern. Nähere Bestimmungen über Betreuung und Beurteilung von künstlerischen Diplom- und Masterarbeiten sind in der Satzung, nähere Bestimmungen über das Thema der künstlerischen Diplom- und Masterarbeit sind im jeweiligen Curriculum festzulegen.

(3) § 80 Abs. 2 und § 81 Abs. 3 gelten auch für künstlerische Diplom- und Masterarbeiten.

Dissertationen und künstlerische Dissertationen

§ 83. (1) Im Doktoratsstudium und im kombinierten Master- und Doktoratsstudium ist eine wissenschaftliche oder künstlerische Dissertation abzufassen. Nähere Bestimmungen über Betreuung und Beurteilung von Dissertationen und künstlerischen Dissertationen sind in der Satzung, nähere Bestimmungen über das Thema der Dissertation oder künstlerischen Dissertation sind im jeweiligen Curriculum festzulegen.

(2) § 80 Abs. 2 und § 81 Abs. 3 gelten auch für Dissertationen und künstlerische Dissertationen.

Einsicht in die Beurteilungsunterlagen

§ 84. (1) Wenn die Beurteilungsunterlagen (insbesondere Gutachten und Korrekturen) den Studierenden nicht ausgehändigt werden, hat das für die studienrechtlichen Angelegenheiten zuständige Organ sicherzustellen, dass diese mindestens sechs Monate ab der Bekanntgabe der Beurteilung aufbewahrt werden.

(2) Der oder dem Studierenden ist Einsicht in die Beurteilungsunterlagen zu gewähren, wenn sie oder er dies innerhalb von sechs Monaten ab Bekanntgabe der Beurteilung beantragt. Die oder der Studierende ist berechtigt, diese Unterlagen zu vervielfältigen.

Anerkennung von wissenschaftlichen und künstlerischen Arbeiten

§ 85. (1) Die Anerkennung von wissenschaftlichen und künstlerischen Arbeiten ist unbeschadet von Abs. 2 unzulässig.

(2) Positiv beurteilte wissenschaftliche und künstlerische Arbeiten, die Studierende in einem Studium verfasst haben, das sie aus rechtlichen Gründen nicht mehr erfolgreich abschließen können, sind auf Antrag der oder des Studierenden von

thesis on an academic subject specified by the curriculum instead of submitting works of art.

(2) Artistic diploma or master's submissions shall include a written component as well as the artistic component that represents the main focus of the work. This shall comment on the artistic component. Detailed regulations for the supervision and assessment of artistic diploma and master's submissions shall be established by the statute, and those governing the themes by the respective curricula.

(3) § 80 para 2 and § 81 para 3 shall apply also to artistic diploma and master's submissions.

Doctoral Theses and Artistic Doctoral Theses

§ 83. (1) The preparation of a doctoral thesis or an artistic doctoral thesis shall form part of a doctoral programme and a combined master's and doctoral programme. Detailed regulations for the supervision and assessment of doctoral theses and artistic doctoral theses shall be established by the statute, and those governing the topics by the respective curricula.

(2) § 80 para 2 and § 81 para 3 shall also apply to doctoral theses and artistic doctoral theses.

Inspection of Assessment Documents

§ 84. (1) If the assessment documents (in particular, examiners' reports on, and corrected papers) are not surrendered to the student, the officer responsible for study matters shall take steps to ensur e that they are held in safekeeping for at least six months after notification of the result.

(2) Students shall be permitted to inspect the assessment documents provided that they make such requests within six months of notification of the results. Students shall be entitled to make photocopies of these documents.

Recognition of Academic Theses and Artistic Submissions

§ 85. (1) The recognition of academic theses and artistic submissions shall be permissible, notwithstanding para 2.

(2) Accepted academic theses or artistic submissions that students have submitted as part of a programme that they are unable to complete on legal grounds shall be recognized by official notification by the officer responsible for study

dem für die studienrechtlichen Angelegenheiten zuständigen Organ bescheidmäßig anzuerkennen, wenn sie den im Curriculum des Studiums, für das die Arbeit anerkannt werden soll, festgelegten Anforderungen einer wissenschaftlichen oder künstlerischen Arbeit entsprechen. Die Anerkennung derartiger Arbeiten für mehr als ein Studium ist unzulässig.

matters on application of the degree student concerned, provided that they meet the requirements of an academic thesis or artistic submission prescribed shall be recognized in the curriculum of the programme for which the academic thesis or artistic submission shall be recognized. The recognition of such theses or submissions for more than one programme shall not be permissible.

Veröffentlichungspflicht

§ 86. (1) Die Absolventin oder der Absolvent hat vor der Verleihung des akademischen Grades jeweils ein vollständiges Exemplar der positiv beurteilten wissenschaftlichen oder künstlerischen Arbeit oder der Dokumentation der künstlerischen Arbeit durch Übergabe an die Bibliothek der Universität, an welcher der akademische Grad verliehen wird, zu veröffentlichen. Für diese Übergabe kann in der Satzung festgelegt werden, dass diese ausschließlich in elektronischer Form zu erfolgen hat. Weiters kann in der Satzung festgelegt werden, dass die Veröffentlichung elektronisch in einem öffentlich zugänglichen Repositorium erfolgen muss.

(2) Die positiv beurteilte Dissertation oder künstlerische Dissertation oder die Dokumentation der künstlerischen Dissertation ist überdies durch Übergabe an die Österreichische Nationalbibliothek zu veröffentlichen. Für diese Übergabe kann in der Satzung festgelegt werden, dass diese ausschließlich in elektronischer Form zu erfolgen hat. Weiters kann in der Satzung festgelegt werden, dass die Veröffentlichung elektronisch in einem öffentlich zugänglichen Repositorium erfolgen muss.

(3) Von der Veröffentlichungspflicht ausgenommen sind die wissenschaftlichen oder künstlerischen Arbeiten oder deren Teile, die einer Massenvervielfältigung nicht zugänglich sind.

(4) Anlässlich der Übergabe einer wissenschaftlichen oder künstlerischen Arbeit oder der Dokumentation der künstlerischen Arbeit ist die Verfasserin oder der Verfasser berechtigt, den Ausschluss der Benützung der abgelieferten Exemplare für längstens fünf Jahre nach der Übergabe zu beantragen. Dem Antrag ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ stattzugeben, wenn die oder der Studierende glaubhaft macht, dass wichtige rechtliche oder wirtschaftliche Interessen der oder des Studierenden gefährdet sind.

Duty of Publication

§ 86. (1) Before the award of the degree, a graduate shall publish one complete copy of the accepted academic thesis or artistic submission or the documentation of the artistic submission by lodging it with the library of the university where the degree is awarded. The statutes can stipulate that this submission shall be done only electronically. Furthermore the statutes can stipulate that the publication shall be done electronically in a publicly accessible repository.

(2) An accepted doctoral thesis or artistic doctoral thesis or the documentation of the artistic doctoral thesis shall also be published by lodging a copy with the Austrian National Library. The statutes can stipulate that this submission shall be done only electronically. Furthermore the statutes can stipulate that the publication shall be done electronically in a publicly accessible repository.

(3) Academic theses or artistic submissions or related components thereof that are not capable of reproduction shall be exempt from the duty of publication.

(4) On lodging an academic thesis or artistic submission or the documentation of the artistic submission with a library, the author shall be entitled to apply for access to the copies deposited therewith to be withheld for a maximum of five years from the time of delivery. The officer responsible for study matters shall allow such applications, if the student establishes that his/her legal or business interests would be materially endangered by permitting access.

6. Abschnitt
Akademische Grade

Verleihung akademischer Grade

§ 87. (1) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat den Absolventinnen und Absolventen der ordentlichen Studien, mit Ausnahme der Erweiterungsstudien, nach der positiven Beurteilung aller im jeweiligen Curriculum vorgeschriebenen Prüfungen und in den Diplom-, Master- und Doktoratsstudien nach der Ablieferung der positiv beurteilten wissenschaftlichen oder künstlerischen Arbeit oder der Dokumentation der künstlerischen Arbeit, den festgelegten akademischen Grad durch einen schriftlichen Bescheid unverzüglich, jedoch spätestens einen Monat nach der Erfüllung aller Voraussetzungen von Amts wegen zu verleihen.

(1a) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat den Studierenden von kombinierten Master- und Doktoratsstudien nach der positiven Beurteilung aller im Curriculum für einen (Zwischen-)Abschluss dieses Studiums mit einem Mastergrad vorgeschriebenen Prüfungsleistungen den festgelegten Mastergrad sowie nach der positiven Beurteilung aller im Curriculum vorgeschriebenen Prüfungen und nach der Ablieferung der positiv beurteilten Dissertation den festgelegten Doktorgrad durch einen schriftlichen Bescheid unverzüglich, jedoch spätestens einen Monat nach der Erfüllung aller Voraussetzungen von Amts wegen zu verleihen. Das Curriculum hat vorzusehen, dass für einen (Zwischen-)Abschluss des Studiums mit einem Mastergrad insbesondere auch die Abfassung und positive Beurteilung einer Masterarbeit Voraussetzung sind. Das Curriculum kann vorsehen, dass die Masterarbeit und der (Zwischen-)Abschluss des Studiums mit Verleihung eines Mastergrads keine Voraussetzungen für die Verleihung des Doktorgrads darstellen. Das Curriculum kann regeln, inwieweit sich das Thema der Dissertation vom Thema einer allfälligen im selben Studium erbrachten Masterarbeit unterscheiden muss oder nicht.

(2) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat den Absolventinnen und Absolventen von Universitätslehrgängen nach der positiven Beurteilung aller im jeweiligen Curriculum vorgeschriebenen Prüfungen und nach Ablieferung der im Curriculum allenfalls vorgesehenen abschließenden schriftlichen Arbeit die festgelegten akademischen Grade durch einen schriftlichen Bescheid unverzüglich, jedoch spätestens einen Monat nach der Erfüllung aller Voraussetzungen von Amts wegen zu verleihen. Den Absolventinnen und Absolventen

Chapter 6
Academic Degrees

Award of Academic Degrees

§ 87. (1) The officer responsible for study matters shall, acting ex officio, without delay and not later than one month after fulfilment of all requirements, issue to graduates of degree programmes, except extension programmes, an official notification of the award of the designated academic degree upon successful completion of all examinations prescribed by the curriculum and acceptance of the academic thesis or artistic submission or the documentation of the artistic submission required by the diploma, master's or doctoral programme in question.

(1a) The officer responsible for study matters shall, without delay and not later than one month after fulfilment of all requirements, acting ex officio, issue an official notification of the award of the designated master's degree to students of a combined master's and doctoral programme who have successfully completed all examinations prescribed by the curriculum to be awarded an (interim) master's degree for this study programme as well as of the designated doctoral degree after the successful completion of all examinations prescribed by the curriculum and following the submission of the accepted doctoral thesis. The curriculum shall include provisions for writing an accepted master's thesis as a prerequisite for the award of an (interim) master's degree upon successful completion of the study programme. The curriculum may prescribe that the master's thesis and the award of an (interim)master's degree shall not be a prerequisite for the award of the doctoral degree. The curriculum may stipulate to what extent or whether the topic of the doctoral thesis shall differ from the topic of any master's thesis submitted within the same study programme.

(2) The officer responsible for study matters shall, without delay and not later than one month after fulfilment of all requirements, issue to persons who have successfully completed a continuing education university programme, including all the examinations and the possible final thesis prescribed by the curriculum, an official notification of the award of the designated academic degrees. The graduates of

1. von außerordentlichen Bachelorstudien ist der akademische Grad „Bachelor of Arts (Continuing Education)“, abgekürzt „BA (CE)“, „Bachelor of Science (Continuing Education)“, abgekürzt „BSc (CE)“, „Bachelor of Engineering (Continuing Education)“, abgekürzt „BEng (CE)“, oder „Bachelor Professional“, abgekürzt „BPr“, zu verleihen.
2. von außerordentlichen Masterstudien ist der akademische Grad „Master of Arts (Continuing Education)“, abgekürzt „MA (CE)“, „Master of Science (Continuing Education)“, abgekürzt „MSc (CE)“, „Master of Engineering (Continuing Education)“, abgekürzt „MEng (CE)“, oder „Master Professional“, abgekürzt „MPr“, zu verleihen.
3. von außerordentlichen Masterstudien im Bereich „Business Administration“ ist der akademische Grad „Master of Business Administration“, abgekürzt „MBA“, zu verleihen, sofern Zugangsbedingungen, Umfang und Anforderungen mit Zugangsbedingungen, Umfang und Anforderungen mehrerer fachlich in Frage kommender ausländischer MBA-Masterstudien nachweislich vergleichbar sind.
4. von außerordentlichen Masterstudien im Bereich „Business Administration“ ist der akademische Grad „Executive Master of Business Administration“, abgekürzt „EMBA“, zu verleihen, sofern Zugangsbedingungen, Umfang und Anforderungen mit Zugangsbedingungen, Umfang und Anforderungen mehrerer fachlich in Frage kommender ausländischer EMBA-Masterstudien nachweislich vergleichbar sind.
5. von außerordentlichen Masterstudien im Bereich „Recht“ ist der akademische Grad „Master of Laws“, abgekürzt „LL.M.“, zu verleihen, sofern Zugangsbedingungen, Umfang und Anforderungen mit Zugangsbedingungen, Umfang und Anforderungen mehrerer fachlich in Frage kommender ausländischer Masterstudien nachweislich vergleichbar sind.

(3) Zur Unterstützung der internationalen Mobilität der Absolventinnen und Absolventen ist dem Verleihungsbescheid eine englischsprachige Übersetzung anzuschließen, wobei die Benennung der Universität und des ausstellenden Organs sowie der akademische Grad oder die akademische Bezeichnung nicht zu übersetzen sind. Der Verleihungsbescheid hat jedenfalls folgende Angaben zu enthalten:

1. den Familiennamen und die Vornamen, allenfalls den Geburtsnamen,
2. das Geburtsdatum und die Staatsangehörigkeit,
3. das abgeschlossene Studium,

1. continuing education bachelor's programmes shall be awarded the academic degree “Bachelor of Arts (Continuing Education)”, abbreviated “BA (CE)”, “Bachelor of Science (Continuing Education)”, abbreviated “BSc (CE)” or “Bachelor Professional”, abbreviated “BPr”.
2. continuing education master's programmes shall be awarded the academic degree “Master of Arts (Continuing Education)”, abbreviated “MA (CE)”, “Master of Science (Continuing Education)”, abbreviated “MSc (CE)”, “Master Professional”, abbreviated “MPr”.
3. continuing education master's programmes in the field of “Business Administration” shall be awarded the academic degree “Master of Business Administration”, abbreviated “MBA” provided that the scope and qualifications are demonstrably comparable to those of several related foreign master's programmes.
4. continuing education master's programmes in the field of “Business Administration” shall be awarded the academic degree “Executive Master of Business Administration”, abbreviated “EMBA” provided that the access requirements, scope and qualifications are demonstrably comparable to those of several related foreign master's programmes.
5. continuing education master's programmes in the field of “Law” shall be awarded the academic degree “Master of Laws”, abbreviated “LL.M.”, provided that the access requirements, scope and qualifications are demonstrably comparable to those of several related foreign master's programmes.

(3) In order to promote international mobility of graduates, an English translation shall be added to the awarding document, without translating the name of the university and of the issuing body as well as the academic degree or the academic designation. The notification of award shall, as a minimum, contain the following information:

1. surname, first names and maiden name if different;
2. date of birth and nationality;
3. programme of study completed;

4. den verliehenen akademischen Grad oder die akademische Bezeichnung.

(3a) Auf Antrag einer Absolventin oder eines Absolventen ist ein neuer Verleihungsbescheid auszustellen, wenn eine Geschlechtsänderung durch Vorlage einer Personenstandsurkunde nachgewiesen wird.

(4) Werden die Voraussetzungen für einen akademischen Grad mit demselben Wortlaut mehr als einmal erbracht, so ist derselbe akademische Grad auch mehrfach zu verleihen.

(5) Wird ein ordentliches Studium auf Grund eines gemeinsamen Studienprogrammes abgeschlossen, bei dessen Durchführung bei einem Studienumfang von bis zu 120 ECTS-Anrechnungspunkten jeweils mindestens 30 ECTS-Anrechnungspunkte, bei einem Studienumfang von mehr als 120 ECTS-Anrechnungspunkten jeweils mindestens 60 ECTS-Anrechnungspunkte unter der Verantwortung der beteiligten österreichischen Partnerinstitution erbracht wurden, ist es zulässig,

1. gemeinsam einen akademischen Grad (joint degree) zu verleihen oder
2. bei double oder multiple degree programmes einen akademischen Grad zu verleihen, wobei die allenfalls verliehenen akademischen Grade der Partnerinstitutionen auszuweisen sind.

(5a) Bei gemeinsamen Studienprogrammen, die von mindestens drei Partnerinstitutionen und unter Beteiligung ausländischer Partnerinstitutionen durchgeführt werden, kann die beteiligte österreichische Partnerinstitution bei Bedarf vom Mindeststudienumfang gemäß Abs. 5 abweichen.

(6) Bei gemeinsam eingerichteten Studien gemäß §54e hat das für die studienrechtlichen Angelegenheiten zuständige Organ der zulassenden Bildungseinrichtung den akademischen Grad zu verleihen, wobei die weiteren an der Durchführung des Studiums beteiligten Bildungseinrichtungen auszuweisen sind.

(7) Zur Unterstützung der internationalen Mobilität der Studierenden sowie der Absolventinnen und Absolventen ist dem Verleihungsbescheid ein Anhang (Diploma Supplement) gemäß Art. IX.3 des Übereinkommens über die Anerkennung von Qualifikationen im Hochschulbereich in der europäischen Region, BGBl. III Nr. 71/1999, anzuschließen. Die Bundesministerin oder der Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung hat durch eine Verordnung festzulegen, in welcher Form das Diploma Supplement auszustellen ist.

4 . academic degree or academic designation awarded.

(3a) Upon application by a graduate, a new notification of award shall be issued if a gender change is evidenced by presentation of a civil status certificate.

(4) If the requirements for the award of an academic degree with the same wording have been fulfilled more than once, the same academic degree shall be awarded more than once.

(5) If a student successfully completes a joint diploma programme comprising up to 120 ECTS credits of which at least 30 were obtained under the auspices of a partner institution, or more than 120 ECTS credits of which at least 60 ECTS were obtained under the auspices of the Austrian partner institution involved, it shall be permissible to

1. jointly award an academic degree (joint degree) or
2. award an academic degree in the case of double or multiple degree programmes. The academic degrees, if any, awarded by the partner institutions must be shown.

(6) In the case of jointly offered study programmes in the meaning of § 54e, the body responsible for study matters at the educational institution which has admitted the student shall award the academic degree. The other educational institutions involved in the study programme shall be specified in the document.

(7) In the interest of international students and graduate mobility, a Diploma Supplement under Art IX.3 of the Convention on the Recognition of Qualifications Concerning Higher Education in the European Region, F. L. G. III No 71/1999, has to be attached to the official notification of the award. The Federal Minister of Education, Science and Research shall, by decree, determine the manner in which the Diploma Supplement is to be issued.

Festlegung akademischer Bezeichnungen für die Absolventinnen und Absolventen von Universitätslehrgängen

§ 87a. (1) Wenn ein Universitätslehrgang mindestens 60 ECTS-Anrechnungspunkte umfasst, darf die akademische Bezeichnung „Akademische ...“ bzw. „Akademischer ...“ mit einem die Inhalte des jeweiligen Universitätslehrganges charakterisierenden Zusatz festgelegt werden, die den Absolventinnen und Absolventen zu verleihen ist.

(2) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat den Absolventinnen und Absolventen von Universitätslehrgängen gemäß Abs. 1 nach der positiven Beurteilung aller im jeweiligen Curriculum vorgeschriebenen Prüfungen und nach Ablieferung der im Curriculum allenfalls vorgesehenen abschließenden schriftlichen Arbeit die festgelegten akademischen Bezeichnungen durch einen schriftlichen Bescheid unverzüglich, jedoch spätestens einen Monat nach der Erfüllung aller Voraussetzungen von Amts wegen zu verleihen.

(3) Den Urkunden über die Verleihung der Bezeichnung dürfen fremdsprachige Übersetzungen angeschlossen werden, wobei die Benennung der Universität und des ausstellenden Organs sowie die Bezeichnung selbst nicht zu übersetzen sind.

Führung akademischer Grade

§ 88. (1) Personen, denen von einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung ein akademischer Grad verliehen wurde, haben das Recht, diesen in der in der Verleihungsurkunde festgelegten, auch abgekürzten, Form zu führen, wobei der akademische Grad einschließlich eines geschlechtsspezifischen Zusatzes („a“, „in“ oder „x“) geführt werden darf. Dies gilt auch für Personen, denen aufgrund von § 87 Abs. 5 Z 2 mehrere akademische Grade verliehen wurden, mit der Maßgabe, dass lediglich einer der verliehenen akademischen Grade geführt werden darf.

(1a) Personen, denen von einer inländischen postsekundären Bildungseinrichtung, einer anerkannten postsekundären ~~Einrichtung~~Bildungseinrichtung einer anderen, auch ehemaligen Vertragspartei des EU-Beitrittsvertrages oder einer anderen Vertragspartei des Abkommens über den Europäischen Wirtschaftsraum ein akademischer Grad verliehen wurde, haben das Recht, die Eintragung dieses akademischen Grades in abgekürzter Form einschließlich des geschlechtsspezifischen Zusatzes gemäß Abs. 1 in öffentliche Urkunden zu verlangen. Personen, denen aufgrund des § 87 Abs. 5 Z 2 mehrere akademische Grade verliehen wurden, haben das Recht, die Eintragung eines akademischen Grades in abgekürzter Form in öffentliche Urkunden zu verlangen.

Determining Academic Designations for Graduates of Continuing Education University Programmes

§ 87a. (1) If a continuing education university programme comprises at least 60 ECTS credits, the designation “Akademische …” or “Akademischer …” with an addition specifying the contents of the respective continuing education university programme may be laid down, which shall be conferred upon the graduates.

(2) The body responsible for study matters shall, without delay and not later than one month after fulfilment of all requirements, issue ex officio an official notification of the award of the designated academic degrees to graduates of continuing education university programmes in the meaning of para 1 following the successful completion of all examinations prescribed in the respective curriculum and after handing in a possible final thesis.

(3) Translations into foreign languages may be added to the documents on the award of designations. However, the names of the university and of the issuing institution as well as the designation itself shall not be translated.

Use of Academic Degrees

§ 88. (1) Persons who have been awarded an academic degree by a recognised domestic or foreign post-secondary educational institution shall be entitled to use this degree in the form set down in the document of award, also abbreviated, and the academic degree may be used with a gender-inclusive suffix (“a”, “in” or “x”). This shall also apply to persons who, pursuant to § 87 para 5 subpara 2 have been awarded several academic degrees, providing that only one of the awarded academic degrees may be used.

(1a) Persons who have been awarded an academic degree by a recognised domestic post-secondary educational institution, a recognised post-secondary institution in another signatory to the EU Accession Treaty or another signatory to the Agreement on the European Economic Area shall be entitled to request the inclusion of this academic degree in the abbreviated form and including the gender-inclusive suffix according to para 1 in official documents. Persons who have been awarded more than one academic degree based on § 87 para 5 subpara 2 shall be entitled to have one academic degree entered in official documents in abbreviated form.

(2) „Mag.“, „Dr.“ und „Dipl.-Ing.“ („DI“) sind im Falle der Führung dem Namen voranzustellen, die übrigen akademischen Grade sind dem Namen nachzustellen.

Widerruf inländischer akademischer Grade oder akademischer Bezeichnungen

§ 89. (1) Der Verleihungsbescheid ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ aufzuheben und einzuziehen, wenn sich nachträglich ergibt, dass der akademische Grad oder die akademische Bezeichnung insbesondere

a. durch gefälschte Zeugnisse ~~oder~~,

b. durch ~~das Vortäuschen von wissenschaftlichen~~gefälschte Urkunden oder

c. durch schwerwiegendes wissenschaftliches oder ~~künstlerischen Leistungen~~ künstlerisches Fehlverhalten im Sinne des § 2a Abs. 3 Z 2 bis 5 HS-QSG

erschlichen worden ist. Bei Erweiterungsstudien ist das Abschlusszeugnis für nichtig zu erklären und einzuziehen, wenn sich nachträglich ergibt, dass der Abschluss insbesondere ~~durch gefälschte Zeugnisse oder durch das Vortäuschen von wissenschaftlichen oder künstlerischen Leistungen erschlichen worden ist.~~

a. durch gefälschte Zeugnisse,

b. durch gefälschte Urkunden oder

c. durch schwerwiegendes wissenschaftliches oder künstlerisches Fehlverhalten im Sinne des § 2a Abs. 3 Z 2 bis 5 HS-QSG

erschlichen worden ist.

(2) Die Aufhebung und Einziehung des Verleihungsbescheides aufgrund eines Plagiats in einer Bachelor-, Diplom- oder Masterarbeit ist nur im Zeitraum von zehn Jahren ab dem Zeitpunkt der Beurteilung der Bachelor-, Diplom- oder Masterarbeit zulässig.

(2) “Mag.”, “Dr.” and “Dipl.-Ing.” (“DI”) shall precede the name if used, and other academic degrees shall follow it.

Revocation of Domestic Academic Degrees or Academic Designations

§ 89. The body responsible for study matters shall revoke and recall the notification of award if it subsequently transpires that a the academic degree or the academic designation has been obtained by fraudulent means, in particular the use of counterfeit certificates or the pretence of scientific or artistic achievements. In the case of extension programmes, the certificate of completion shall be declared invalid and revoked if it subsequently transpires that the degree has been obtained by counterfeit certificates or academic or artistic dishonest.

7. Abschnitt

Nostrifizierung

§ 90. (1) Die Antragstellung betreffend die Anerkennung eines ausländischen Studienabschlusses als Abschluss eines inländischen ordentlichen Studiums (Nostrifizierung) setzt den Nachweis voraus, dass die Nostrifizierung zwingend für die Berufsausübung oder die Fortsetzung der Ausbildung der Antragstellerin oder des Antragstellers in Österreich erforderlich ist. Nähere Bestimmungen sind in der Satzung festzulegen.

(2) Der Antrag ist an einer Universität oder einer Pädagogischen Hochschule einzubringen, an der das entsprechende inländische Studium eingerichtet ist. Es ist unzulässig, denselben Nostrifizierungsantrag gleichzeitig oder nach der Zurückziehung an einer anderen Universität oder Pädagogischen Hochschule einzubringen.

(3) Die Nostrifizierung ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ mit Bescheid auszusprechen. Im Bescheid ist festzulegen, welchem inländischen Studienabschluss der ausländische Studienabschluss entspricht und welchen inländischen akademischen Grad die Antragstellerin oder der Antragsteller an Stelle des ausländischen akademischen Grades auf Grund der Nostrifizierung zu führen berechtigt ist. Die Nostrifizierung ist auf der Urkunde, die als Nachweis des ausländischen Studienabschlusses vorgelegt wurde, zu vermerken. Über Anträge auf Nostrifizierung ist abweichend von § 73 AVG spätestens drei Monate nach Einlangen der vollständigen Unterlagen bescheidmäßig zu entscheiden.

(4) Wenn die Gleichwertigkeit grundsätzlich gegeben ist und nur einzelne Ergänzungen auf die volle Gleichwertigkeit fehlen, hat das für die studienrechtlichen Angelegenheiten zuständige Organ der Antragstellerin oder dem Antragsteller zur Herstellung der Gleichwertigkeit mit Bescheid die Ablegung der erforderlichen Prüfungen und bzw. oder die Anfertigung einer wissenschaftlichen Arbeit innerhalb einer angemessenen Frist aufzutragen. Zur Erbringung der Ergänzung ist die Antragstellerin oder der Antragsteller als außerordentliche Studierende oder als außerordentlicher Studierender zuzulassen.

(5) Die Nostrifizierung ist bescheidmäßig zu widerrufen, wenn sie insbesondere durch gefälschte Zeugnisse erschlichen worden ist.

Chapter 7

Nostrification

§ 90. (1) Acceptance of requests for the recognition of foreign degrees as domestic ones (nostrification) shall be conditional on the provision of that the nostrification is indispensable in Austria for the practice of the profession or the continuation of the education of the applicant. The detailed arrangements shall be established by the statute.

(2) The application shall be directed to an Austrian university or university college of teacher education offering degrees corresponding to the original qualification. The same application for nostrification may not be submitted to more than one university simultaneously, nor may it be resubmitted to a second university or university college of teacher education after its withdrawal.

(3) Nostrification shall be awarded by the officer responsible for study matters by issuing official notifications thereof. Such official notification shall specify the domestic degree to which the foreign degree corresponds, and the domestic academic degree that the applicant is entitled to use instead of his/her foreign one in consequence of nostrification. A note recording the nostrification shall be put onto the awarding document of the foreign degree submitted. A decision on applications for the recognition of foreign degrees shall be made, notwithstanding § 73 General Administrative Procedure Act, within a maximum of three months of receipt of the application by official notification.

(4) In case that equivalence has been established basically and only certain supplementary qualifications are required for full equivalence, the officer responsible for study matters shall, by official notification, instruct the applicant to take the required examinations and/or write an academic thesis within a reasonable period. For the purpose of submission of the supplementary requirements, the applicant shall be admitted as a non-degree seeking student.

(5) Nostrification shall be revoked if obtained by fraudulent means, in particular the use of counterfeit certificates.

(6) Die Taxe für die Nostrifizierung eines ausländischen Studienabschlusses beträgt 150 Euro. Die Taxe ist im Voraus zu entrichten. Sie verfällt, wenn der Antrag auf Nostrifizierung abgewiesen oder zurückgezogen wird.

8. Abschnitt

Studienbeitragsbestimmungen

Studienbeitrag

§ 91. (1) Ordentliche Studierende mit der Staatsangehörigkeit eines EU- oder EWR-Staates und ordentliche Studierende, denen Österreich auf Grund eines völkerrechtlichen Vertrages dieselben Rechte für den Berufszugang zu gewähren hat wie österreichischen Staatsangehörigen, und ordentliche Studierende, die unter die Personengruppen gemäß der Personengruppenverordnung, fallen, sowie ordentliche Studierende aus Drittstaaten, die über eine andere Aufenthaltsberechtigung als jene für Studierende gemäß § 64 NAG verfügen, haben, wenn sie die vorgesehene Studienzeit

1. eines Bachelor- oder Masterstudiums, wobei 30 ECTS-Anrechnungspunkte einem Semester entsprechen,
2. eines Doktoratsstudiums, eines kombinierten Master- und Doktoratsstudiums oder eines Studienabschnittes eines Diplomstudiums,
3. eines Erweiterungsstudiums gemäß § 54a, wobei 30 ECTS-Anrechnungspunkte einem Semester entsprechen und gegebenenfalls auf ganze Semester aufzurunden ist, oder
4. eines Erweiterungsstudiums gemäß § 54b, wobei die vorgesehene Studienzeit für das Erweiterungsstudium zur Erweiterung des Bachelorstudiums acht Semester und für das Erweiterungsstudium zur Erweiterung des Masterstudiums vier Semester beträgt, ~~oder~~
5. ~~eines Erweiterungsstudiums gemäß § 54c, wobei die vorgesehene Studienzeit acht Semester beträgt,~~

(Anm.: Z 5 aufgehoben durch Art. 1 Z 78, BGBl. I Nr. 50/2024)

um mehr als zwei Semester überschreiten, einen Studienbeitrag von 363,36 Euro für jedes Semester zu entrichten.

(2) Ordentliche Studierende aus Drittstaaten, die nicht unter Abs. 1 fallen und die über eine Aufenthaltsberechtigung für Studierende gemäß § 64 NAG verfügen, haben einen Studienbeitrag von 726,72 Euro für jedes Semester zu entrichten.

(6) The fee for nostrification of a foreign degree shall be 150 €, payable in advance. It shall become forfeited if the application for nostrification is refused or withdrawn.

Chapter 8

Provisions on Tuition Fees

Tuition Fees

§ 91. (1) Degree students who are citizens of EU or EEA member states, degree students to whom Austria is obliged under other international treaties to accord the same rights to access to employment as Austrian citizens, degree students belonging to a group of persons according to the Decree on Groups of Persons, as well as degree students from third countries who have been granted another kind of residence permit than that for students under § 64 NAG, shall pay tuition fees in an amount of 363.36 € per semester, if they exceed the prescribed duration

1. of a bachelor's or master's programme, with 30 ECTS credits corresponding to one semester,
2. of a doctoral programme, a combined master’s and doctoral programme or one stage of a diploma programme,
3. of an extension programme under § 54a, with 30 ECTS credits corresponding to one semester and, where applicable, with rounding to whole semesters,
4. of an extension programme under § 54b, with counting the prescribed duration of an extension programme for extending the bachelor's programme with eight semesters and of an extension programme for extending the master's programme with two semesters, or
5. of an extension programme under § 54c, with counting the prescribed duration of studies with eight semesters,

by more than two semesters.

(2) Degree-programme students from third countries who do not fulfil the requirements under para 1 and who have been granted a residence permit for students under § 64 NAG shall pay tuition fees in an amount of 726.72 € per semester.

(3) Außerordentliche Studierende, die ausschließlich zum Besuch einzelner Lehrveranstaltungen aus wissenschaftlichen Fächern zugelassen sind, haben unabhängig von ihrer Staatsangehörigkeit einen Studienbeitrag von 363,36 Euro für jedes Semester zu entrichten.

(4) Studierende, die zu mehreren Studien, auch an mehreren Universitäten und Pädagogischen Hochschulen, zugelassen sind, haben den Studienbeitrag nur einmal zu entrichten. Dies gilt auch für Studierende, die zu einem gemeinsam mit einer Pädagogischen Hochschule eingerichteten Studium zugelassen sind, wobei die Einhebung des Studienbeitrages durch die zulassende Bildungseinrichtung erfolgt.

(5) Der Studienbeitrag ist für jedes Semester im Voraus zu entrichten. Die Studienbeiträge verbleiben der jeweiligen Universität. Der Studienbeitrag von Studierenden, die ein von mehreren Universitäten und bzw. oder Pädagogischen Hochschulen gemeinsam eingerichtetes Studium betreiben oder die zu mehreren Studien verschiedener Universitäten und bzw. oder Pädagogischen Hochschulen zugelassen sind, ist unter den beteiligten Universitäten und Pädagogischen Hochschulen gemäß einer abzuschließenden Vereinbarung aufzuteilen.

(6) Nähere Bestimmungen zur Einhebung des Studienbeitrages sind durch eine Verordnung der Bundesministerin oder des Bundesministers für ~~Bildung~~Frauen, Wissenschaft und Forschung festzulegen (Studienbeitragsverordnung).

Erlass und Rückerstattung des Studienbeitrages

§ 92. (1) Der Studienbeitrag ist ordentlichen Studierenden insbesondere zu erlassen

1. für die Semester, in denen sie nachweislich Studien oder Praxiszeiten im Rahmen von transnationalen EU-, staatlichen oder universitären Mobilitätsprogrammen absolvieren werden;
2. für die Semester, in denen sie auf Grund verpflichtender Bestimmungen im Curriculum Studien im Ausland absolvieren werden;
3. wenn die von ihnen zuletzt besuchte ausländische postsekundäre Bildungseinrichtung mit der österreichischen Universität ein Partnerschaftsabkommen abgeschlossen hat, welches auch den gegenseitigen Erlass des Studienbeitrages vorsieht;

3a. wenn sie Staatsangehörige von in der Studienbeitragsverordnung festgelegten Staaten sind, wobei sich die Festlegung an den „Least Developed Countries“ gemäß der „DAC List of ODA Recipients“ zu

(3) Non-degree-seeking students who have been admitted exclusively to individual courses in scientific subjects shall pay tuition fees in an amount of 363.36 € per semester irrespective of their nationality.

(4) Students who have been admitted to more than one programme, also at more than one university or university college of teacher education, shall be required to pay the tuition fee only once. This shall also apply to students who have been admitted to a programme offered jointly with a university college of teacher education, whereupon the tuition fees shall be levied by the institution which has admitted the student.

(5) The tuition fee shall be payable every semester in advance. The tuition fees shall be retained by the respective universities. Tuition fees of students who are enrolled in a study programme established jointly by more than one university and/or university colleges of teacher education or who have been admitted to more than one study programme at different universities and/or university colleges of teacher education, shall be divided among the universities and university colleges of teacher education concerned, due to a relevant agreement.

(6) The Federal Minister of Education, Science and Research shall, by decree, enact more detailed provisions for the collection of tuition fees.

Remission and Reimbursement of the Tuition Fees

§ 92. (1) Remission of the tuition fees shall, in particular, be granted to degree-programme students

1. for semesters during which they will demonstrably be studying or acquiring work experience under transnational EU, national or university mobility programmes;
2. for semesters during which they will be studying abroad due to mandatory curriculum requirements;
3. whose most recently attended foreign post-secondary educational institution has concluded a partnership agreement with an Austrian university providing for the reciprocal remission of tuition fees;

3a. who are citizens of states determined in the Decree on the Collection of Tuition Fees. The determination shall be aligned with the “Least Developed Countries” pursuant to the “DAC List of ODA Recipients” which is drawn

orientieren hat, welche vom Ausschuss für Entwicklungshilfe (kurz DAC) der Organisation für wirtschaftliche Zusammenarbeit und Entwicklung (OECD) erstellt wird;

4. welche die Voraussetzungen gemäß § 91 Abs. 1 erfüllen, auch bei Überschreitung des in Abs. 1 festgelegten Zeitraumes für Semester, in denen sie nachweislich mehr als zwei Monate durch Krankheit oder Schwangerschaft bzw. durch Kinderbetreuungspflichten von Kindern bis zum 7. Geburtstag oder einem allfälligen späteren Schuleintritt oder durch andere gleichartige Betreuungspflichten am Studium gehindert waren;

(Anm.: Z 5 aufgehoben durch VfGH, BGBl. I Nr. 11/2017)

6. welche die Voraussetzungen gemäß § 91 Abs. 1 erfüllen, auch bei Überschreitung des in Abs. 1 festgelegten Zeitraumes, wenn eine Behinderung nach bundesgesetzlichen Vorschriften mit mindestens 50 % festgestellt ist;
7. wenn sie im vergangenen Semester Studienbeihilfe gemäß dem Studienförderungsgesetz 1992, BGBl. Nr. 305/1992, bezogen haben oder im laufenden Semester beziehen.

(2) Über den Antrag auf Erlass des Studienbeitrages entscheidet das Rektorat. Dem Antrag sind die für die Entscheidung erforderlichen Nachweise beizufügen.

(2a) Das Rektorat ist berechtigt, Gründe festzulegen, bei deren Vorliegen außerordentlichen Studierenden, die ausschließlich zum Besuch einzelner Lehrveranstaltungen zugelassen sind, der Studienbeitrag auf deren Antrag erlassen werden kann.

(3) Studierende, denen gemäß Abs. 1 Z 1 und 2 der Studienbeitrag erlassen wurde und die in diesem Semester keine Studien oder Praxiszeiten im Sinne dieser Bestimmungen im Ausland absolviert haben, haben den Studienbeitrag nachträglich zu entrichten. Dies hat das Rektorat bescheidmäßig zu verfügen.

(4) Sofern Studierende den Erlass des Studienbeitrages durch unvollständige oder unwahre Angaben maßgebender Tatsachen schuldhaft veranlasst oder erschlichen haben, haben sie unbeschadet strafrechtlicher Verantwortlichkeit den doppelten Studienbeitrag zu entrichten. Dies hat das Rektorat bescheidmäßig zu verfügen.

(5) Studierende, die beurlaubt sind, haben keinen Studienbeitrag zu entrichten. Studierenden, die auf Grund eines unvorhergesehenen und unabwendbaren Eintritts eines Beurlaubungsgrundes während des Semesters beurlaubt wurden, ist auf Antrag

up by the Organisation for Economic Co-Operation and Development's (OECD) Development Assistance Committee (DAC);

4. who fulfil the requirements under § 91 para 1, even when the time period laid down in para 1 is exceeded, for those semesters for which they have documentary evidence of being hindered by illness, pregnancy or care of children and upbringing of a child up to the age of seven or until the child enters first grade, or similar kinds of care, for more than two months;

5. *[removed]*

6. students who fulfil the requirements under § 91 para 1, even when the time period laid down in para 1 is exceeded, if they have a disability of at least 50% as defined by federal law;

7. Students, if they received student grants under the Student Support Act 1992, F. L. G. No 305/1992, in the previous semester or receive them in the current semester.

(2) An application for remission of the tuition fee shall be for the decision of the rectorate. The application for remission shall be accompanied by the necessary supporting documentary evidence.

(2a) The rectorate shall be entitled to determine grounds on the basis of which the tuition fee may be waived, on application, for continuing education students who are admitted to attend only individual courses.

(3) Students granted remission under para 1 subparas 1 and 2 who have undertaken no study or work experience abroad in the meaning of these provisions during the term in question shall be obliged to pay the tuition fee retroactively. The rectorate shall order such payment.

(4) Students obtaining remission of the tuition fee by wilfully providing incomplete or incorrect information with respect to material facts shall pay double the normal tuition fee without prejudice to legal action. The rectorate shall order such payment.

(5) Students who have been granted academic leave shall not be required to pay the tuition fee. Students who, on grounds of an unforeseen and unavoidable occurrence of a reason for academic leave, have been granted academic leave during

ein bereits bezahlter Studienbeitrag rückzuerstatten, sofern der Zeitraum der Beurlaubung mehr als die Hälfte des betreffenden Semesters umfasst, wobei die lehrveranstaltungsfreie Zeit nicht zu berücksichtigen ist.

(5a) Studierenden, welche die in der „Vereinbarung über die Studienleistung“ gemäß § 59b Abs. 3 festgelegten Verpflichtungen für das jeweilige Semester erfüllen, ist auf Antrag ein bereits bezahlter Studienbeitrag für dieses Semester rückzuerstatten, sofern dies in der Vereinbarung festgelegt wurde.

(6) Die Bundesministerin oder der Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung ist berechtigt, entsprechend den Schwerpunktsetzungen Österreichs bei den Maßnahmen zur Unterstützung und Förderung der wirtschaftlichen und sozialen Entwicklung durch eine Verordnung Staaten festzulegen, deren Angehörige von der Entrichtung des Studienbeitrages befreit werden können. Die Befreiung erfolgt im Rahmen der Privatwirtschaftsverwaltung auf Grund von Anträgen der Studierenden. Über die Befreiung hat das Rektorat binnen vier Wochen ab Antragstellung zu entscheiden. Auf die Befreiung besteht kein Rechtsanspruch.

the semester, shall, on application, be refunded their tuition fees they have already paid, provided that the period of academic leave comprises more than half of the semester concerned; recess periods shall not be taken into account.

(5a) Students who have fulfilled the obligations for the respective semester as stipulated in the “Agreement on Academic Achievement” pursuant to § 59b para 3, shall, on application, be refunded their tuition fees they have paid for that semester, provided that this has been stipulated in the agreement.

(6) The Federal Minister of Education, Science and Research shall be entitled to designate by decree countries to whose nationals the tuition fee shall be reimbursed, in accordance with Austria’s priorities with respect to measures for the support and promotion of economic and social development. Reimbursements shall be made within the private sector administration on application of the students concerned. The fee shall be reimbursed within four weeks of application. There shall be no legal entitlement to reimbursement.

9. Abschnitt
Sonderbestimmungen

Sonderbestimmungen für die Katholische Theologie

§ 93. (1) Bei einem Übertritt von Studierenden von einer kirchlichen theologischen Lehranstalt (Art. V § 1 des Konkordates zwischen dem Heiligen Stuhle und der Republik Österreich) an eine Organisationseinheit einer Universität, deren Wirkungsbereich sich auf die Katholische Theologie bezieht, gelten folgende besondere Bestimmungen:

1. Die Prüfungen, die an diesen Lehranstalten abgelegt wurden, sind als Ergänzungsprüfungen anzuerkennen, wenn die von der Lehranstalt namhaft gemachte Prüferin oder der von der Lehranstalt namhaft gemachte Prüfer
   a) die Lehrbefugnis (venia docendi) für das betreffende Fach besitzt oder
   b) von einer Organisationseinheit einer Universität, deren Wirkungsbereich sich auf die Katholische Theologie bezieht, zur Abnahme der Ergänzungsprüfungen für die Dauer von jeweils drei Jahren bevollmächtigt wurde.
2. Die Prüfungen, die an diesen Lehranstalten abgelegt wurden, sind anzuerkennen, wenn sie vor

Chapter 9
Special Provisions

Special Provisions for Catholic Theology

§ 93. (1) The following special provisions shall apply to students transferring from an ecclesiastical School of Theology (Art V § 1 of the Concordat between the Holy See and the Republic of Austria) to an organisational unit of a university, the sphere of action of which relates to Catholic theology:

1. Examinations taken at such schools shall be recognized as supplementary examinations, provided that the examiners appointed by such a school:
   a) are authorised to teach the subject in question (venia docendi); or
   b) have been authorised by an organisational unit of a university, the sphere of action of which relates to Catholic theology, to hear supplementary examinations for a period of three years.
2. Examinations taken at such schools shall be recognized if heard by:

a) einer für ein Fach der Katholischen Theologie hiezu bestellten Universitätsprofessorin oder einem für ein Fach der Katholischen Theologie hiezu bestellten Universitätsprofessor oder

b) einer oder einem sonst von einer Organisationseinheit einer Universität, deren Wirkungsbereich sich auf die Katholische Theologie bezieht, hiezu Bevollmächtigten abgelegt wurden. Zu der in angemessener Frist vorzunehmenden Bevollmächtigung ist der kirchlichen theologischen Lehranstalt Gelegenheit zur Stellungnahme zu geben.

3. Absolventinnen und Absolventen dieser kirchlichen theologischen Lehranstalten ist der jeweilige für das Studium vorgesehene akademische Grad zu verleihen, wenn die abgelegten Prüfungen gemäß den oben genannten Bestimmungen anerkannt wurden und die wissenschaftliche Arbeit von einer für ein Fach der Katholischen Theologie bestellten Universitätsprofessorin oder einem für ein Fach der Katholischen Theologie bestellten Universitätsprofessor positiv beurteilt oder von einer fachzuständigen Person mit Lehrbefugnis (venia docendi) an der betreffenden Lehranstalt betreut und positiv beurteilt wurde.

(2) Für die Verleihung des akademischen Grades ist diesfalls die Zulassung zum Studium an der Universität nicht erforderlich.

Sonderbestimmungen für das gemeinsame Studium der Humanmedizin an der Universität Linz und der Medizinischen Universität Graz

§ 93a. (1) Das Studium der Humanmedizin ist gemäß der Vereinbarung gemäß Art. 15a B-VG zwischen dem Bund und dem Land Oberösterreich über die Errichtung und den Betrieb einer Medizinischen Fakultät und die Einrichtung des Studiums der Humanmedizin an der Universität Linz, BGBl. I Nr. 18/2014, („Art. 15a B-VG-Vereinbarung“) von der Universität Linz gemeinsam mit der Medizinischen Universität Graz als Bachelorstudium und von der Universität Linz als Masterstudium einzurichten und durchzuführen. Näheres zur Durchführung des Bachelorstudiums ist in einer Vereinbarung über die Durchführung des gemeinsamen Studiums der Humanmedizin zwischen der Universität Linz und der Medizinischen Universität Graz zu regeln. § 54e ist sinngemäß anzuwenden.

(2) Die Einrichtung des gemeinsamen Bachelorstudiums der Humanmedizin gemäß Abs. 1 steht abweichend von § 124 Abs. 5 einer weiteren Zulassung zum Diplomstudium Humanmedizin an der Medizinischen Universität Graz nicht entgegen.

a) a university professor for a subject related to Catholic theology, appointed for this purpose; or

b) another person authorised to do so by an organisational unit of a university, the sphere of action of which relates to Catholic theology. Ecclesiastical Schools of Theology shall be enabled to give their opinion on such authorisations, which shall be granted for reasonable periods.

3. Graduates of ecclesiastical Schools of Theology shall be awarded the academic degrees prescribed for their programmes of study if the examinations taken by them have been recognized in accordance with the provisions above, and the theses prepared by them have been accepted by a university professor for a subject related to Catholic theology or supervised and accepted by another person responsible for such subject having a habilitation degree (venia docendi) at the respective school.

(2) For the purpose of the award of the academic degree, admission to study at the university shall not be necessary.

Special Provisions for the Joint Degree Programme in Human Medicine at the University of Linz and the Medical University of Graz

§ 93a. (1) The degree programme in Human Medicine shall be established as a bachelor’s programme by the University of Linz in cooperation with the Medical University of Graz and as a master’s programme by the University of Linz, pursuant to the agreement under para 15a of the Federal Constitutional Act (B-VG) between the Federal Government and the Federal Province of Upper Austria on the establishment and operations of a faculty of Medicine and the establishment of the degree programme in Human Medicine at the University of Linz, Federal Law Gazette I No. 18/2014 (“para 15a Federal Constitutional Act Agreement”). Details on the bachelor's programme shall be specified in an agreement on the joint programme in Human Medicine concluded between the University of Linz and the Medical University of Graz. § 54e shall apply by analogy.

(2) The establishment of the joint bachelor's programme in Human Medicine under para 1 shall, notwithstanding § 124 para 5, not preclude the admission to the diploma programme in Human Medicine at the Medical University of Graz.

III. Teil
Angehörige der Universität

1. Abschnitt
Einteilung

§ 94. (1) Zu den Angehörigen der Universität zählen:
1. die Studierenden (§ 51 Abs. 2 Z 14c);
2. die Forschungsstipendiatinnen und Forschungsstipendiaten;
(Anm.: Z 3 aufgehoben durch BGBl. I Nr. 96/2004)
4. das wissenschaftliche und das künstlerische Universitätspersonal;
5. das allgemeine Universitätspersonal;
6. die Privatdozentinnen und Privatdozenten (§ 102);
7. die emeritierten Universitätsprofessorinnen und Universitätsprofessoren;
8. die Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand.

(2) Zum wissenschaftlichen und künstlerischen Universitätspersonal gehören:
1. die Universitätsprofessorinnen und Universitätsprofessoren;
2. die Universitätsdozentinnen und Universitätsdozenten sowie die wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb;
3. die Ärztinnen und Ärzte in Facharztausbildung.

(3) Zum allgemeinen Universitätspersonal gehören:
1. das administrative Personal;
2. das technische Personal;
3. das Bibliothekspersonal;
4. das Krankenpflegepersonal;
5. die Ärztinnen und Ärzte zur ausschließlichen Erfüllung von Aufgaben im Rahmen einer öffentlichen Krankenanstalt.

Part III
University Members

Chapter 1
Classification

§ 94. (1) The members of a university comprise:
1. the students (§ 51 para 2 subpara 14c);
2. the research fellows;
3. [removed]
4. the scientific and artistic university staff;
5. the non-academic university staff;
6. the non-tenured associate professors (§ 102);
7. the university professors emeriti;
8. the retired university professors.

(2) The scientific and artistic university staff shall comprise:
1. the university professors;
2. the associate professors and the scientific as well as artistic staff in research, art, and teaching;
3. physicians in specialists' training.

(3) The non-academic university staff shall comprise:
1. the administrative staff;
2. the technical staff;
3. the library staff;
4. the nursing staff;
5. physicians exclusively engaged in public hospital duties.

2. Abschnitt

Forschungsstipendiatinnen und Forschungsstipendiaten sowie Ärztinnen und Ärzte in Ausbildung

Forschungsstipendiatinnen und Forschungsstipendiaten

§ 95. Forschungsstipendiatinnen und Forschungsstipendiaten sind Studierende oder Absolventinnen und Absolventen eines Doktoratsstudiums (post docs), die an der Universität im Rahmen eines Stipendiums an einem Forschungsprojekt arbeiten. Durch die Zuerkennung des Stipendiums wird kein Arbeitsverhältnis zur Universität begründet und ein bestehendes Arbeitsverhältnis nicht verändert.

Ärztinnen und Ärzte in Ausbildung

§ 96. (1) Ärztinnen und Ärzte in Ausbildung (§§ 6a, 7 und 8 Ärztegesetz 1998) stehen für die Dauer ihrer Ausbildung in einem zeitlich befristeten Ausbildungsverhältnis zur Universität. Ihre Aufgaben ergeben sich aus den ärzterechtlichen Ausbildungsvorschriften und die Erfüllung der Aufgaben erfolgt in engem Kontakt mit wissenschaftlicher Forschung und Lehre. Die Ärztinnen und Ärzte in Ausbildung sind berechtigt, Aufgaben in Forschung und Lehre wahrzunehmen, soweit die Ausbildung dadurch nicht beeinträchtigt wird.

(2) In Ausbildungsverhältnissen gemäß Abs. 1 verbrachte Zeiten sind für die höchstzulässige Anzahl von Befristungen und die höchstzulässige Gesamtdauer gemäß § 109 nicht zu berücksichtigen.

Chapter 2

Research Fellows and Physicians in Training

Research Fellows

§ 95. Research fellows are doctoral students or doctoral graduates (post docs) in receipt of grants to work on a research project at the university. The award of a grant shall not give rise to an employment contract with the university or alter the beneficiary's existing terms of employment.

Physicians in Training

§ 96. (1) Physicians undergoing training (§§ 6a, 7 and 8 Doctors' Act – Ärztegesetz 1998) shall receive limited-term training contracts at a university for the duration of their training. Their duties shall be determined by the medical training regulations, and they shall perform their duties in close contact with scientific research and teaching. Physicians in training shall have the right to perform tasks in research and teaching, provided that this does not interfere with their training.

(2) Periods spent in training in the meaning of para 1 shall not count towards the maximum number and duration of limitation of terms according to § 109.

3. Abschnitt

Wissenschaftliches und künstlerisches Universitätspersonal

Universitätsprofessorinnen und Universitätsprofessoren

§ 97. (1) Die Universitätsprofessorinnen und Universitätsprofessoren sind für die Forschung oder die Entwicklung und Erschließung der Künste sowie für die Lehre in ihrem Fachgebiet verantwortlich und stehen in einem befristeten oder unbefristeten Arbeitsverhältnis zur Universität. Sie sind Vollzeit- oder Teilzeitbeschäftigte.

(2) Zu Universitätsprofessorinnen und Universitätsprofessoren können in- oder ausländische Wissenschafterinnen und Wissenschafter oder Künstlerinnen und Künstler mit einer entsprechend hohen wissenschaftlichen oder künstlerischen und

Chapter 3

Scientific and Artistic University Staff

University Professors

§ 97. (1) The university professors shall be responsible for research, or the advancement and appreciation of the arts, and for teaching in their field, and shall be employed by the university on a temporary or permanent basis. They shall be full-time or part-time employees.

(2) Both Austrian and foreign researchers or artists whose scientific or artistic and professional credentials qualify them for the subjects related to the positions to be filled may be appointed as university professors.

beruflichen Qualifikation für das Fach bestellt werden, das der zu besetzenden Stelle entspricht.

(3) Universitätsprofessorinnen und Universitätsprofessoren werden von der Rektorin oder vom Rektor nach Durchführung eines Berufungsverfahrens gemäß § 98 oder § 99 bestellt.

Berufungsverfahren für Universitätsprofessorinnen und Universitätsprofessoren

§ 98. (1) Die fachliche Widmung einer unbefristet oder länger als drei Jahre befristet zu besetzenden Stelle einer Universitätsprofessorin oder eines Universitätsprofessors ist im Entwicklungsplan festzulegen.

(2) Jede Stelle ist vom Rektorat im In- und Ausland öffentlich auszuschreiben. Bis zur Übermittlung der Bewerbungen an die Gutachterinnen und Gutachter gemäß Abs. 5 können in das Berufungsverfahren mit ihrer Zustimmung auch Wissenschafterinnen und Wissenschafter oder Künstlerinnen und Künstler, die sich nicht beworben haben, von der Berufungskommission oder von der Rektorin oder dem Rektor als Kandidatinnen und Kandidaten einbezogen werden.

(3) Die im Senat vertretenen Universitätsprofessorinnen und Universitätsprofessoren haben auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs mindestens zwei – davon mindestens eine externe oder einen externen – Gutachterinnen oder Gutachter zu bestellen. Sie können diese Aufgabe aber auch an die Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs und des fachlich nahe stehenden Bereichs übertragen. Die Rektorin oder der Rektor hat das Recht, eine weitere Gutachterin oder einen weiteren Gutachter zu bestellen.

(4) Der Senat hat eine entscheidungsbevollmächtigte Berufungskommission einzusetzen. Die Universitätsprofessorinnen und Universitätsprofessoren stellen mehr als die Hälfte der Mitglieder und die Studierenden mindestens ein Mitglied. Der Berufungskommission können auch Angehörige anderer Universitäten oder postsekundärer Bildungseinrichtungen angehören.

(4a) Die Rektorin oder der Rektor kann mehrere Universitätsprofessorinnen und Universitätsprofessoren aus verschiedenen Fachbereichen oder Personen aus der Universitätsverwaltung mit der Begleitung von Berufungsverfahren beauftragen. Jeweils eine oder einer dieser Universitätsprofessorinnen oder Universitätsprofessoren oder eine Person aus der Universitätsverwaltung (Berufungsbeauftragte oder Berufungsbeauftragter) ist berechtigt, in einem Berufungsverfahren der Berufungskommission als zusätzliches Mitglied ohne

(3) University professors shall be appointed by the rector following an appointment procedure in accordance with §§ 98 or 99.

Appointment Procedure for University Professors

§ 98. (1) The subject allocation of a chair to be filled on a permanent basis or for longer than three years shall be specified by the development plan.

(2) All positions shall be advertised by the rectorate in Austria and abroad. Until the applications have been forwarded to the assessors according to para 5, the appointment committee or the rector may include scientists and artists who have not applied, with their agreement, as candidates in the appointment procedure.

(3) The professorial members of the senate shall appoint at least two assessors, nominated by the university professors in the department in question, of whom at least one shall be external. However, they may also delegate this task to the university professors of the department or of a department in a related field. The rector shall have the right to appoint one additional assessor.

(4) The senate shall appoint an appointment committee with decision-making power. More than half of the members shall be university professors, and at least one shall be a student. Members of the appointment committee can also be members of other universities or post-secondary educational institutions.

(4a) The rector may entrust several university professors from different fields or staff working in university administration with the task of acting as consultants in appointment procedures. One of these university professors or a person working in university administration (appointment officer) shall be entitled to participate as an additional member of the appointment committee without voting rights in the appointment procedure. The appointment officer shall draw up a report on the

Stimmrecht anzugehören. Die Berufungsbeauftragte oder der Berufungsbeauftragte erstellt einen Bericht über das Berufungsverfahren, der dem Besetzungsvorschlag der Berufungskommission an die Rektorin oder den Rektor anzuschließen ist.

(5) Die Berufungskommission hat innerhalb eines Monats nach dem Ende der Bewerbungsfrist zu überprüfen, ob die vorliegenden Bewerbungen die Ausschreibungskriterien erfüllen und jene Bewerbungen, die die Ausschreibungskriterien offensichtlich nicht erfüllen, auszuscheiden. Die übrigen Bewerbungen sind den Gutachterinnen und Gutachtern zu übermitteln, welche die Eignung der Bewerberinnen und Bewerber für die ausgeschriebene Stelle einer Universitätsprofessorin oder eines Universitätsprofessors zu beurteilen haben.

(6) Die Rektorin oder der Rektor ist vor Weiterleitung darüber zu informieren, welche Bewerbungen an die Gutachterinnen und Gutachter weitergeleitet werden. Sollte eine oder mehrere Bewerbungen nicht den Ausschreibungskriterien entsprechen, so ist die Berufungskommission darauf hinzuweisen. Die Rektorin oder der Rektor hat allen geeigneten Kandidatinnen und Kandidaten Gelegenheit zu geben, sich in angemessener Weise zumindest dem Fachbereich und dem fachlich nahe stehenden Bereich zu präsentieren.

(7) Die Berufungskommission erstellt innerhalb von sieben Monaten nach dem Ende der Bewerbungsfrist auf Grund der Gutachten und Stellungnahmen einen begründeten Besetzungsvorschlag, der die drei für die Besetzung der ausgeschriebenen Stelle am besten geeigneten Kandidatinnen und Kandidaten zu enthalten hat. Ein Vorschlag mit weniger als drei Kandidatinnen und Kandidaten ist besonders zu begründen.

(8) Die Rektorin oder der Rektor hat die Auswahlentscheidung aus dem Besetzungsvorschlag unter Berücksichtigung des Berichts der Berufungsbeauftragten oder des Berufungsbeauftragten zu treffen oder den Besetzungsvorschlag an die Berufungskommission zurückzuverweisen, wenn dieser nicht die am besten geeigneten Kandidatinnen und Kandidaten enthält.

(9) Die Rektorin oder der Rektor hat ihre oder seine Auswahlentscheidung dem Arbeitskreis für Gleichbehandlungsfragen vor Aufnahme der Berufungsverhandlungen bekannt zu geben. Der Arbeitskreis hat das Recht, innerhalb von drei Wochen Beschwerde zu erheben. Über diese entscheidet die Schiedskommission mit Bescheid.

(10) Weist die Schiedskommission die Beschwerde ab, kann die Rektorin oder der Rektor die Berufungsverhandlungen aufnehmen. Gibt die Schiedskommission der Beschwerde statt, wird die Auswahlentscheidung unwirksam. Eine neue

appointment procedure to be forwarded to the rector together with the shortlist of the most suitable candidates for appointment.

(5) The appointment committee shall, within one month following the end of the application period, check whether the applications received meet the criteria stipulated in the advertisement and those applications which clearly do not meet these criteria shall be eliminated. The remaining applications shall be forwarded to the assessors who shall assess the aptitude of the applicants for the advertised post of a professor.

(6) Before they are forwarded, the rector shall be informed of which applications will be forwarded to the assessors. The appointment committee shall be informed if one or more applications do not conform with the criteria stipulated in the advertisement. The rector shall offer all suitable candidates appropriate opportunities to introduce themselves at least to the department and the departments in related fields.

(7) The appointment committee shall, within seven months following the end of the application period draw up a shortlist of the three most suitable candidates for the advertised chair on the basis of the reports and opinions received, giving reasons for its decision. It shall state particular reasons in case that the shortlist contains less than three candidates.

(8) The rector shall, in consideration of the appointment officer's report, select a candidate from the shortlist or remit the shortlist to the appointment committee if it does not include the most suitable candidates.

(9) The rector shall notify the working group on equal opportunities of his/her decision prior to the initiation of appointment negotiations. The working group shall be entitled to object to the decision within three weeks of notification. The arbitration board shall rule on such objection.

(10) If the arbitration board dismisses the objection, the rector shall be entitled to initiate appointment negotiations. If the arbitration board upholds the objection the

Auswahlentscheidung ist unter Beachtung der von der Schiedskommission vertretenen Rechtsanschauung zu treffen.

(11) Die Rektorin oder der Rektor führt die Berufungsverhandlungen und schließt mit der ausgewählten Kandidatin oder dem ausgewählten Kandidaten den Arbeitsvertrag.

(12) Die Universitätsprofessorin oder der Universitätsprofessor erwirbt mit dem Abschluss des Arbeitsvertrages mit der Universität die Lehrbefugnis (venia docendi) für das Fach, für das sie oder er berufen ist. Eine allenfalls früher erworbene Lehrbefugnis wird hievon nicht berührt.

(13) Die Lehrbefugnis (venia docendi) einer Universitätsprofessorin oder eines Universitätsprofessors in einem zeitlich befristeten Arbeitsverhältnis erlischt mit dem Ende des Arbeitsverhältnisses.

Abgekürztes Berufungsverfahren für Universitätsprofessorinnen und Universitätsprofessoren

§ 99. (1) Soll eine Universitätsprofessorin oder ein Universitätsprofessor für einen Zeitraum bis zu fünf Jahren aufgenommen werden, ist § 98 Abs. 1 und 3 bis 8 nicht anzuwenden. Eine Verlängerung der Bestellung ist nur nach Durchführung eines Berufungsverfahrens gemäß § 98 zulässig.

(2) Die Rektorin oder der Rektor hat die Kandidatin oder den Kandidaten für die zu besetzende Stelle auf Vorschlag oder nach Anhörung der Universitätsprofessorinnen und Universitätsprofessoren des fachlichen Bereichs der Universität auszuwählen, dem die Stelle zugeordnet ist.

(3) Durch Verordnung des Rektorates, die der Genehmigung des Universitätsrats bedarf, kann einmalig eine Anzahl von Stellen für Universitätsprofessorinnen oder Universitätsprofessoren festgelegt werden, die für einen Zeitraum von bis zu sechs Jahren gewidmet sind und nur für Universitätsdozentinnen und Universitätsdozenten gemäß § 94 Abs. 2 Z 2 vorgesehen sind. Die Anzahl darf bis zu 20 vH der Stellen gemäß § 122 Abs. 2 Z 4 umfassen. § 98 Abs. 1 bis 8 sind nicht anzuwenden. Die Stellen sind im Mitteilungsblatt der Universität auszuschreiben. Die Rektorin oder der Rektor hat die Stellen nach Durchführung eines Auswahlverfahrens, das internationalen kompetitiven Standards entspricht, zu besetzen. Eine unbefristete Verlängerung der Bestellung durch die Rektorin oder den Rektor ist nur nach Durchführung einer Qualifikationsprüfung zulässig. Inhalt der Qualifikationsprüfung ist die Qualität der wissenschaftlichen Leistungen sowie der Leistungen in der Lehre der letzten fünf Jahre. Die Durchführung der Qualifikationsprüfung hat internationalen kompetitiven

selection decision shall be null and void, and a new decision shall be made, having regard to the legal opinion of the arbitration board.

(11) The rector shall conduct the appointment negotiations and conclude the employment contract with the candidate selected.

(12) On conclusion of the employment contract the university professor shall be granted a venia docendi for the subject for which he/she has been appointed. A previously acquired habilitation degree shall not be affected thereby.

(13) The venia docendi of a university professor with a limited term employment contract shall expire upon termination of employment.

Shortened Appointment Procedure for University Professors

§ 99. (1) If a university professor is to be appointed for a period of not more than five years, § 98 paras 1 to 3 shall not apply. Extension of the appointment is only permissible after an appointment procedure in accordance with § 98.

(2) The rector shall appoint the candidate for the post to be filled on the recommendation of, or after hearing opinions of the university professors of the department to which the post is assigned.

(3) By decree of the rectorate, which shall be subject to approval by the university council, once a number of posts for professors may be determined which shall be limited to a period of up to six years and shall be reserved only for associate professors under § 94 para 2 subpara 2. The number may comprise up to 20% of posts under § 122 para 2 subpara 4. § 98 paras 1 to 8 shall not apply. The posts shall be advertised in the university gazette. The rector shall fill the posts after completing a selection procedure that conforms to international, competitive standards. An unlimited extension of the appointment by the rector shall only be permissible after a qualification assessment. The qualification assessment shall focus on the quality of the research performance and the teaching performance of the past five years. The qualification assessment shall conform to international, competitive standards. The application for unlimited extension may be submitted after completion of the fifth year.

Standards zu entsprechen. Der Antrag auf unbefristete Verlängerung kann nach dem vollendeten fünften Jahr gestellt werden.

(4) Im Entwicklungsplan ist jeweils eine Anzahl von Stellen für Universitätsdozentinnen und Universitätsdozenten gemäß § 94 Abs. 2 Z 2 und für Assoziierte Professorinnen und Professoren festzulegen, die in jeweils einem vereinfachten Verfahren zu Universitätsprofessorinnen oder Universitätsprofessoren berufen werden können. Auf diese Verfahren sind § 98 Abs. 1 bis 8 nicht anzuwenden. Diese Stellen sind im Mitteilungsblatt der Universität auszuschreiben. Die Rektorin oder der Rektor hat die Kandidatin oder den Kandidaten für die zu besetzende Stelle nach Anhörung der Universitätsprofessorinnen und Universitätsprofessoren des fachlichen Bereichs der Universität, dem die Stelle zugeordnet ist, sowie des Arbeitskreises für Gleichbehandlungsfragen auszuwählen. Nähere Bestimmungen sind in der Satzung festzulegen.

(5) Das Angebot des Abschlusses einer Qualifizierungsvereinbarung gemäß § 27 des gemäß § 108 Abs. 3 abgeschlossenen Kollektivvertrages, in der am 1. Oktober 2015 geltenden Fassung, setzt die Durchführung eines internationalen kompetitiven Standards entsprechenden Auswahlverfahrens voraus, insbesondere ist die Stelle international auszuschreiben. Zum Ergebnis des Auswahlverfahrens sind die Universitätsprofessorinnen und Universitätsprofessoren des betreffenden Fachbereichs anzuhören. Der Aspekt der Gleichstellung der Geschlechter ist entsprechend zu berücksichtigen. § 42 ist anzuwenden.

(6) Jene Personen, die ein Auswahlverfahren gemäß Abs. 5 durchlaufen und die Qualifikation gemäß § 27 Abs. 5 des gemäß § 108 Abs. 3 abgeschlossenen Kollektivvertrages in der am 1. Oktober 2015 geltenden Fassung entsprechend der getroffenen Vereinbarung erreicht haben (Assoziierte Professorinnen und Professoren), gehören dem wissenschaftlichen und künstlerischen Universitätspersonal gemäß § 94 Abs. 2 Z 1 an.

(7) Die gemäß Abs. 4 und 5 durchgeführten Verfahren sind im Abstand von fünf Jahren einer Evaluierung zu unterziehen. Diese Evaluierung ist durch die Bundesministerin oder den Bundesminister zu veranlassen.

§ 99a. (1) Im Entwicklungsplan kann eine Anzahl von höchstens 5 vH der Stellen für Universitätsprofessorinnen und Universitätsprofessoren gemäß § 98 ohne fachliche Widmung festgelegt werden, die im internationalen Wettbewerb um die besten Wissenschaftlerinnen und Wissenschaftler sowie Künstlerinnen und Künstler zwecks proaktiver Gewinnung wissenschaftlich bzw. künstlerisch herausragender Persönlichkeiten besetzt werden können.

(4) The development plan shall allow for a number of positions for associate professors under § 94 para 2 subpara 2 and for adjunct professors, who can be appointed as university professors in a simplified procedure. § 98 paras 1 to 8 shall not apply to these procedures. These positions shall be advertised in the university gazette of the respective university. The rector shall select the candidate for the position to be filled after hearing the opinion of the university professors of the university's department to which the position is assigned and the working group on equal opportunities. The detailed arrangements shall be established by the statute.

(5) An offer for the conclusion of a qualification agreement according to § 27 of the collective contract concluded under § 108 para 3 in the version effective on 1 October 2015 shall require the completion of a selection procedure according to internationally competitive standards and in particular the international advertisement of the position. The opinion of the university professors of the respective department shall be heard regarding the results of the selection procedure. The aspect of gender equality shall be taken into account as a relevant factor. § 42 shall apply.

(6) Those persons who have gone through a selection procedure under para 5 and have obtained the qualifications according to § 27 para 5 of the collective contract concluded under § 108 para 3 in the version of 1 October 2015 according to the agreement made (adjunct professors) shall be members of the scientific and artistic staff under § 94 para 2 subpara 1.

(7) The procedures carried out under paras 4 and 5 shall be evaluated every five years. This evaluation shall be initiated by the Federal Minister.

§ 99a. (1) The development plan may specify a number of a maximum of 5% of the positions for university professors according to § 98 without subject allocation for the proactive recruitment of outstanding scientific personalities or artists in the international competition for the best scientists or artists.

(2) § 98 Abs. 1 bis 8 ist nicht anzuwenden. Die Rektorin oder der Rektor hat mit der Kandidatin oder dem Kandidaten für die zu besetzende Stelle nach Anhörung der Universitätsprofessorinnen und Universitätsprofessoren des fachlichen Bereichs, dem die Stelle zugeordnet wird, Berufungsverhandlungen zu führen und einen zunächst auf höchstens fünf Jahre befristeten Arbeitsvertrag abzuschließen. In sachlich gerechtfertigten Fällen kann auch sofort ein unbefristeter Arbeitsvertrag abgeschlossen werden. Nähere Bestimmungen über die Besetzungen gemäß Abs. 1 und die Voraussetzungen für die Anhörung der Universitätsprofessorinnen und Universitätsprofessoren sind in der Satzung festzulegen.

(3) Wurde ein befristeter Arbeitsvertrag abgeschlossen, so ist eine unbefristete Verlängerung durch die Rektorin oder den Rektor nur nach Durchführung einer Qualifikationsprüfung zulässig. Inhalt der Qualifikationsprüfung ist die Qualität der wissenschaftlichen, wissenschaftlich-künstlerischen oder künstlerischen Leistungen, der Leistungen in der Lehre sowie der sonstigen Tätigkeiten. Die Durchführung der Qualifikationsprüfung hat internationalen Standards zu entsprechen, wobei die näheren Bestimmungen dafür in der Satzung festzulegen sind. Der Antrag auf unbefristete Verlängerung kann nach dem vollendeten vierten Jahr gestellt werden. Der Arbeitskreis für Gleichbehandlungsfragen ist in das Verfahren einzubeziehen.

Wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb

§ 100. (1) Die wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb müssen eine für die vorgesehene Verwendung in Betracht kommende angemessene Qualifikation aufweisen. Sie haben in ihrem Fach an der Erfüllung der Aufgaben der Universität in der Forschung oder bei der Entwicklung und Erschließung der Künste und in der Lehre mitzuarbeiten. Sie stehen in einem Arbeitsverhältnis zur Universität und sind Vollzeit- oder Teilzeitbeschäftigte.

(2) Die Universität hat die berufliche Weiterbildung der Mitarbeiterinnen und Mitarbeiter gemäß Abs. 1 zu fördern.

(3) Das wissenschaftliche und künstlerische Personal im Forschungs-, Kunst- und Lehrbetrieb besteht aus hauptberuflich und aus nebenberuflich tätigen Personen.

(4) Nebenberuflich tätige Personen sind Personen, die

1. ausschließlich in der Lehre tätig sind und
2. nicht mehr als vier Semesterstunden lehren und

(2) § 98 paras 1 to 8 shall not apply. After hearing the opinion of the university professors of the relevant field to which the position will be assigned, the rector shall conduct the appointment negotiations with the candidate for the position to be filled and conclude an employment contract which shall initially be limited to a maximum of five years. In objectively justified cases, a permanent employment contract can be concluded immediately. Detailed arrangements regarding the recruitments according to para 1 and the conditions for hearing the university professors shall be established by the statute.

(3) If a limited contract was concluded, an unlimited extension by the rector shall only be permissible after a qualification assessment. The qualification assessment shall focus on the quality of the scientific, scientific-artistic or artistic performance, the teaching performance as well as on the other activities. The qualification assessment shall conform to international standards. Detailed arrangements shall be established by the statute. The application for unlimited extension may be submitted after completion of the fourth year. The working group on equal opportunities shall be included in the procedure.

Scientific and Artistic Staff in Research, Art and Teaching

§ 100. (1) The scientific and artistic staff in research, art and teaching must be appropriately qualified for the employment envisaged. They shall, in their subjects, be obliged to contribute to the fulfilment of the university's tasks in respect of research, or the advancement and appreciation of the arts, and teaching. They shall be employed by the university on a full- or part-time basis.

(2) The university shall promote the professional development of staff members under para 1.

(3) The scientific and artistic staff in research, art, and teaching is composed of internal and external faculty members.

(4) External faculty members are persons who

1. work exclusively as teachers and
2. do not teach more than four semester hours and

3. nachweislich einer anderen vollen Sozialversicherungspflicht auf Grund von Einkünften im Ausmaß von mindestens 60 vH der Höchstbeitragsgrundlage gemäß § 108 des Allgemeinen Sozialversicherungsgesetzes – ASVG, BGBl. Nr. 189/1955, unterliegen.

(5) Nebenberufliches Lehrpersonal steht in einem freien Dienstverhältnis zur Universität; es kann sich ohne vorherige Zustimmung der Universität von anderen geeigneten Personen vertreten lassen.

(6) § 98 ArbVG (personelles Informationsrecht) gilt auch für die Gruppe der nebenberuflich tätigen Personen, selbst wenn ein freies Dienstverhältnis oder eine selbständige Tätigkeit vorliegt.

4. Abschnitt

Allgemeines Universitätspersonal

§ 101. (1) Die Angehörigen des allgemeinen Universitätspersonals haben die zur Erfüllung ihrer Aufgaben erforderlichen fachlichen Qualifikationen aufzuweisen. Sie stehen in einem Arbeitsverhältnis zur Universität und sind Vollzeit- oder Teilzeitbeschäftigte.

(2) Die Universität hat die berufliche Weiterbildung der Mitarbeiterinnen und Mitarbeiter gemäß Abs. 1 zu fördern.

(3) Für das Bibliothekspersonal aller Universitäten ist eine einheitliche Ausbildung aus dem Bereich Bibliotheks-, Informations- und Dokumentationswesen vorzusehen.

5. Abschnitt

Privatdozentinnen und Privatdozenten, Habilitation, emeritierte Universitätsprofessorinnen und Universitätsprofessoren sowie Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand

Privatdozentinnen und Privatdozenten

§ 102. Privatdozentinnen und Privatdozenten sind Personen, denen auf Grund ihrer wissenschaftlichen oder künstlerischen Qualifikation von der Universität die Lehrbefugnis (venia docendi) für ein wissenschaftliches oder künstlerisches Fach verliehen wurde. Sie stehen in dieser Funktion in keinem Arbeitsverhältnis zur Universität.

3. can submit proof that they are fully covered by another compulsory social insurance resulting from income amounting to at least 60% of the maximum contribution basis under § 108 General Social Insurance Act, F. L. G. No 189/1955.

(5) External faculty members have concluded freelance contracts with the university; they shall have the right to have other persons with relevant qualifications act as their substitutes without the university's prior approval.

(6) § 98 Labour Constitution Act (personnel information rights) shall also apply to the group of external faculty members, even if they work under freelance contracts or are self-employed.

Chapter 4

Non-Academic University Staff

§ 101. (1) The non-academic university staff must possess appropriate professional qualifications for their duties. They shall be employed by the university on a full- or part-time basis.

(2) The university shall promote the professional development of staff members under para 1.

(3) Provision shall be made for the library staff at all universities to receive a uniform training in librarianship, information science and documentation.

Chapter 5

Non-Tenured Associate Professors, Habilitation, Professors Emeriti and Retired Professors

Non-Tenured Associate Professors

§ 102. Non-tenured associate professors are persons to whom a university awards a habilitation degree for a subject (venia docendi) on the basis of their academic or artistic qualification, but who are with regard to this function not employed by the university. but who are with regard to this function not employed by the university.

Habilitation

§ 103. (1) Das Rektorat hat das Recht, auf Antrag die Lehrbefugnis (venia docendi) für ein ganzes wissenschaftliches oder künstlerisches Fach zu erteilen. Die beantragte Lehrbefugnis muss in den Wirkungsbereich der Universität fallen . Mit der Erteilung der Lehrbefugnis ist das Recht verbunden, die wissenschaftliche oder künstlerische Lehre an dieser Universität mittels deren Einrichtungen frei auszuüben sowie wissenschaftliche oder künstlerische Arbeiten (§§ 81 bis 83, § 124) zu betreuen und zu beurteilen.

(2) Voraussetzung für die Erteilung der Lehrbefugnis ist der Nachweis einer hervorragenden wissenschaftlichen oder künstlerischen Qualifikation und der mehrmaligen Lehrtätigkeit an anerkannten postsekundären Bildungseinrichtungen zum Nachweis der didaktischen Fähigkeiten der Bewerberin oder des Bewerbers.

(3) Die vorgelegten schriftlichen Arbeiten müssen

1. methodisch einwandfrei durchgeführt sein,
2. neue wissenschaftliche Ergebnisse enthalten und
3. die wissenschaftliche Beherrschung des Habilitationsfaches und die Fähigkeit zu seiner Förderung beweisen.

Die vorgelegten künstlerischen Arbeiten müssen die Fähigkeit zur Vertretung des künstlerischen Faches im Umfang der beantragten Lehrbefugnis beweisen.

(4) Der Antrag auf Erteilung der Lehrbefugnis ist an das Rektorat zu richten. Dieses hat den Antrag, sofern er nicht mangels Zuständigkeit der Universität zurückzuweisen ist, an den Senat weiterzuleiten.

(5) Die Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren im Senat haben auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs mindestens zwei Vertreterinnen oder Vertreter des angestrebten Habilitationsfaches, darunter mindestens eine externe oder einen externen, als Gutachterinnen oder Gutachter über die vorgelegten wissenschaftlichen oder künstlerischen Arbeiten zu bestellen. Sie können diese Aufgabe aber auch an die Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs und des fachlich nahe stehenden Bereichs übertragen.

(6) Die Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs und des fachlich nahe stehenden Bereichs haben das Recht, Stellungnahmen zu den Gutachten abzugeben.

Habilitation

§ 103. (1) The rectorate shall, on application, be entitled to award an habilitation degree (venia docendi) for an entire academic or artistic subject. The venia docendi applied for must be within the sphere of action of the university. The habilitation degree shall confer the right to the free exercise thereof at the university in question, using its facilities, and to the supervision and assessment of academic theses or art submissions (§§ 81 to 83 and 124).

(2) The award of a habilitation degree shall be conditional on evidence of outstanding scientific or artistic qualification as well as repeated teaching at recognized post-secondary educational institutions as evidence of the didactic abilities of the applicant.

(3) The habilitation thesis submitted must:

1. be of impeccable methodological quality;
2. contain new scientific insights;
3. demonstrate the candidate’s command of his/her habilitation subject and ability for its advancement.

Art submissions must demonstrate the candidate’s ability to exercise his/her artistic discipline within the full scope of the venia docendi applied for.

(4) An application for a habilitation degree shall be directed to the rectorate. The latter shall forward the application to the senate, unless it must be rejected due to the university’s incompetence to process it.

(5) The representatives of university professors in the senate shall appoint, nominated by the university professors in the department concerned, at least two experts in the habilitation subject, including at least one external, to act as assessors of the academic papers or works of art submitted. However, they may also delegate this task to the university professors of the department or of a department in a related field.

(6) The university professors in the department concerned and departments in related fields shall be entitled to give opinions on the assessors’ reports.

(7) Der Senat hat eine entscheidungsbevollmächtigte Habilitationskommission einzusetzen. Die Universitätsprofessorinnen und Universitätsprofessoren stellen mehr als die Hälfte der Mitglieder der Habilitationskommission, die Studierenden mindestens ein Mitglied.

(8) Die Habilitationskommission entscheidet auf Grund der Gutachten und Stellungnahmen.

(9) Das Rektorat erlässt auf Grund des Beschlusses der Habilitationskommission den Bescheid über den Antrag auf Erteilung der Lehrbefugnis. Gegen diesen Bescheid ist Beschwerde an das Bundesverwaltungsgericht zulässig.

(10) Das Rektorat hat einen Beschluss der Habilitationskommission zurückzuverweisen, wenn wesentliche Grundsätze des Verfahrens verletzt wurden.

(11) Durch die Erteilung der Lehrbefugnis (venia docendi) wird weder ein Arbeitsverhältnis begründet, noch ein bestehendes Arbeitsverhältnis zur Universität verändert (Privatdozentin oder Privatdozent).

Emeritierte Universitätsprofessorinnen und Universitätsprofessoren sowie Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand

§ 104. (1) Emeritierte Universitätsprofessorinnen und Universitätsprofessoren sowie Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand stehen in keinem aktiven Arbeitsverhältnis zum Bund oder zur Universität.

(2) Sie haben das Recht, ihre Lehrbefugnis (venia docendi) an der Universität, an der sie vor ihrer Emeritierung oder vor ihrem Übertritt oder ihrer Versetzung in den Ruhestand in einem aktiven Arbeitsverhältnis tätig waren, weiter auszuüben und im Rahmen ihrer Lehrbefugnis Lehrveranstaltungen und Prüfungen abzuhalten.

6. Abschnitt
Allgemeine Bestimmungen

Gewissensfreiheit und Forschungsfreiheit

§ 105. Keine Universitätsangehörige und kein Universitätsangehöriger darf gegen ihr oder sein Gewissen zur Mitwirkung bei einzelnen wissenschaftlichen oder künstlerischen Arbeiten verhalten werden. Aus einer Weigerung zur Mitwirkung darf ihr oder ihm kein Nachteil erwachsen. Die oder der betroffene

(7) The senate shall appoint a habilitation committee with decision-making power. More than half of the members shall be university professors, and at least one shall be a student.

(8) The habilitation committee shall make its decision on the basis of the reports and opinions received.

(9) The rectorate shall issue an official notification on the application for a habilitation degree, which shall be based on the decision of the habilitation committee. Appeals to the Federal Administrative Court against such an official notification shall be permissible.

(10) The rectorate shall reject a decision by the habilitation committee in case of serious procedural defects.

(11) The award of a habilitation degree (venia docendi) shall neither confer the right to employment nor modify an existing employment contract (non-tenured associate professor).

Professors Emeriti and Retired Professors

§ 104. (1) Professors emeriti and retired professors are not in an active employment status to the Federal Government or the university.

(2) They shall be entitled to retain their habilitation degrees (venia docendi) at the university where they were employed prior to their retirement and to give lectures and hear examinations under such authorisation.

Chapter 6
General Provisions

Freedom of Conscience and Research

§ 105. No member of a university may be required to participate in scientific or artistic work which conflicts with his/her conscience. Refusal to participate in such work shall not result in any disadvantage. However, the university member concerned must inform his/her superior of such refusal in writing.

Universitätsangehörige hat jedoch ihre oder seine Vorgesetzte oder ihren oder seinen Vorgesetzten von ihrer oder seiner Weigerung schriftlich zu informieren.

Verwertung von geistigem Eigentum

§ 106. (1) Jede oder jeder Universitätsangehörige hat das Recht, eigene wissenschaftliche oder künstlerische Arbeiten selbstständig zu veröffentlichen. Bei der Veröffentlichung der Ergebnisse der Forschung oder der Entwicklung und Erschließung der Künste sind Universitätsangehörige, die einen eigenen wissenschaftlichen oder künstlerischen Beitrag zu dieser Arbeit geleistet haben, als Mitautorinnen oder Mitautoren zu nennen.

(2) Auf Diensterfindungen gemäß § 7 Abs. 3 Patentgesetz, BGBl. Nr. 259/1970, die an einer Universität im Rahmen eines öffentlich-rechtlichen oder privatrechtlichen Dienst- oder Ausbildungsverhältnisses zum Bund oder im Rahmen eines Arbeits- oder Ausbildungsverhältnisses zur Universität gemacht werden, ist das Patentgesetz mit der Maßgabe anzuwenden, dass die Universität als Dienstgeber gemäß § 7 Abs. 2 Patentgesetz gilt.

(3) Jede Diensterfindung ist dem Rektorat unverzüglich zur Kenntnis zu bringen. Will die Universität die Diensterfindung zur Gänze oder ein Benützungsrecht daran für sich in Anspruch nehmen, hat das Rektorat dies der Erfinderin oder dem Erfinder innerhalb von drei Monaten mitzuteilen. Andernfalls steht dieses Recht der Erfinderin oder dem Erfinder zu.

Commercial Exploitation of Intellectual Property

§ 106. (1) All university members shall have the right to independent publication of academic papers and artistic work. When research findings or work serving the advancement and appreciation of the arts are published, university members who have contributed to such work shall be named as co-authors.

(2) Inventions in the meaning of § 7 para 3 of the Patents Act, F. L. G. No 259/1970, made at a university in the course of employment or training under federal public law or employment or training by the university, shall be subject to the Patents Act, and the university shall be deemed to be the employer according to § 7 para 2 of the Patents Act.

(3) All inventions shall be promptly reported to the rectorate. The rectorate shall inform the inventor within three months if it intends to claim title to the invention in its entirety or rights to the use thereof. Otherwise the inventor shall be entitled to such rights.

IV. Teil
Personalrecht

Ausschreibung und Aufnahme

§ 107. (1) Alle zur Besetzung offen stehenden Stellen sind vom Rektorat öffentlich auszuschreiben. Stellen für das wissenschaftliche und künstlerische Personal gemäß § 94 Abs. 1 Z 4 sind international, zumindest EU-weit auszuschreiben. Im Rahmen einer Ausschreibung können auch alternative Zuordnungen zu einer Personalgruppe vorgesehen werden. Die Ausschreibungsfrist hat zumindest zehn Tage, für Arbeitsverhältnisse gemäß § 94 Abs. 2 Z 1 jedoch mindestens drei Wochen zu betragen.

(2) In folgenden Fällen kann von einer Ausschreibung abgesehen werden:

1. bei der Besetzung von Stellen, die ausschließlich für Aufgaben in der Lehre und mit geringem Stundenausmaß (Lehrauftrag) vorgesehen sind, und

Part IV
Employment Law

Advertisement of Positions and Appointments

§ 107. (1) All vacant posts shall be advertised by the rectorate. Positions for scientific and artistic university staff under § 94 para 1 subpara 4 shall be advertised internationally, at least in the EU. In the context of an advertisement, it shall be possible to provide for alternative assignments to a category of staff. The application deadline shall be set at least three weeks after the publication of an advertisement.

(2) Advertisement of posts shall not be mandatory in the following cases:

1. posts solely involving teaching duties, and with low teaching loads (part-time temporary lectureships);

2. bei Stellen für zeitlich befristete Drittmittelprojekte, denen ein qualifiziertes Auswahlverfahren vorausgegangen ist, wenn die Bestimmungen des Geldgebers dem nicht entgegenstehen;
3. bei Stellen, die gemäß § 99a besetzt werden.

(3) Arbeitsverträge sind von der Rektorin oder vom Rektor auf Vorschlag oder nach Anhörung der Leiterin oder des Leiters der Organisationseinheit und der oder des unmittelbaren Vorgesetzten, der oder dem die zu besetzende Stelle zugeordnet ist, abzuschließen.

(4) Arbeitsverträge für Mitarbeiterinnen und Mitarbeiter an Vorhaben gemäß § 27 Abs. 1 Z 3 sowie für Mitarbeiterinnen und Mitarbeiter, die aus zweckgebundenen Mitteln der Forschungsförderung finanziert werden, sind von der Rektorin oder vom Rektor auf Vorschlag der oder des unmittelbaren Vorgesetzten, der oder dem die zu besetzende Stelle zugeordnet ist, abzuschließen.

(5) Arbeitsverträge von Universitätsprofessorinnen und Universitätsprofessoren sind von der Rektorin oder vom Rektor nach Durchführung des Berufungsverfahrens gemäß §§ 98 oder 99 abzuschließen.

Rechtsgrundlagen der Arbeitsverhältnisse

§ 108. (1) Auf Arbeitsverhältnisse zur Universität ist, soweit gesetzlich nicht anderes bestimmt ist, das Angestelltengesetz, BGBl. Nr. 292/1921, anzuwenden.

(2) Die Universitäten bilden gemeinsam den Dachverband der Universitäten, in den das Rektorat jeder Universität eine Vertreterin oder einen Vertreter zu entsenden hat. Der Dachverband beschließt eine Geschäftsordnung und wählt mit Stimmenmehrheit eine Vorsitzende oder einen Vorsitzenden.

(3) Der Dachverband ist für die ihm angehörenden Universitäten auf Arbeitgeberseite kollektivvertragsfähig im Sinne des ArbVG. Ein vom Dachverband abgeschlossener Kollektivvertrag gilt für die Arbeitnehmerinnen und Arbeitnehmer der im Dachverband zusammengefassten Universitäten.

(4) Der Kollektivvertragsfähigkeit des Dachverbandes kommt im Verhältnis zur Kollektivvertragsfähigkeit anderer Interessenvertretungen oder Berufsvereinigungen der Arbeitgeberinnen und Arbeitgeber Vorrang zu.

(Anm.: Abs. 5 aufgehoben durch Art. 17 Z 23, BGBl. I Nr. 31/2018)

2. posts relating to limited term projects funded by third parties which have been preceded by a properly conducted selection procedure, provided that this does not conflict with the conditions imposed by the financier;
3. posts to be filled under § 99a.

(3) The rector shall conclude employment contracts on the recommendation of, or after consultation of the head of the organisational unit to which the vacant post in question is assigned, or the appointee's immediate superior.

(4) Employment contracts with staff involved in a project in the meaning of § 27 para 1 subpara 3 and with staff whose employment is paid for by tied research funds shall be concluded by the rector on the recommendation of the appointee's immediate supervisor.

(5) Employment contracts with university professors shall be concluded by the rector following an appointment procedure in accordance with §§ 98 or 99.

Legal Basis of Employments

§ 108. (1) University employment shall, unless otherwise provided for by statute, be governed by the Salaried Employees Act, F. L. G. No 292/1921.

(2) The universities shall form the National University Federation, to which the rectorate of every university shall appoint a representative. The federation shall adopt rules of procedure and shall elect a chairperson by a simple majority.

(3) The federation shall be empowered to negotiate collective contracts in the meaning of the ArbVG, on behalf of member universities. Collective contracts concluded by the federation shall be applicable to the employees of member universities.

(4) The federation's legal capacity to make collective contracts shall take precedence over the capacity of other employers' associations or professional associations to make such contracts.

(5) [Removed]

Gesetzliche Sonderregelung für Angehörige von Einrichtungen für Gerichtliche Medizin

§ 108a. Arbeitnehmerinnen und Arbeitnehmer, die einer Einrichtung für Gerichtliche Medizin zugeordnet sind, haben im Rahmen ihrer Aufgaben an der Erstellung von Gutachten und Befunden im gerichtlichen Verfahren mitzuwirken. Auftraggeberin für die Gutachten und Befunde ist die jeweils zuständige Ermittlungs- oder Justizbehörde.

Dauer der Arbeitsverhältnisse

§ 109. (1) Arbeitsverhältnisse können auf unbestimmte oder bestimmte Zeit abgeschlossen werden. Arbeitsverhältnisse auf bestimmte Zeit sind bei sonstiger Rechtsunwirksamkeit des Arbeitsvertrags einmalig bis zu einer Dauer von höchstens sechs Jahren zu befristen, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(2) Eine zweimalige Verlängerung bzw. ein zweimaliger neuerlicher Abschluss befristeter Arbeitsverhältnisse von Personen, die dem wissenschaftlichen und künstlerischen Universitätspersonal gemäß § 94 Abs. 2 angehören, ist bis zu einer Gesamtdauer von acht Jahren unter Berücksichtigung von Abs. 1 zulässig.

(3) Unbeschadet der zulässigen Gesamtdauer gemäß Abs. 1 und 2 finden Arbeitsverhältnisse, die überwiegend zur Durchführung von Drittmittelprojekten oder Forschungsprojekten abgeschlossen werden, bei der Feststellung der höchstzulässigen Anzahl von befristeten Arbeitsverhältnissen keine Berücksichtigung.

(4) Wechselt eine Arbeitnehmerin oder ein Arbeitnehmer in eine Verwendung gemäß § 94 Abs. 2 Z 1, ist eine einmalige neuerliche Befristung bis zu einer Dauer von sechs Jahren zulässig.

(5) Bei Ersatzkräften ist eine mehrmalige Verlängerung oder ein mehrfacher neuerlicher Abschluss von Arbeitsverhältnissen bis zur Gesamtdauer von sechs Jahren zulässig.

(6) Bei ausschließlich in der Lehre verwendetem Personal ist eine mehrmalige Verlängerung oder ein mehrfacher neuerlicher Abschluss von Arbeitsverhältnissen innerhalb von acht Studienjahren zulässig.

(7) Arbeitsverhältnisse, die auch den Abschluss eines Doktoratsstudiums zum Inhalt haben, bleiben bis zum Ausmaß von bis zu vier Jahren für die höchstzulässige Gesamtdauer und die höchstzulässige Anzahl der Arbeitsverhältnisse unberücksichtigt. Ebenso unberücksichtigt bleiben Arbeitsverhältnisse als studentische Mitarbeiterin oder als studentischer Mitarbeiter.

Special Arrangements for Members of Units of Forensic Medicine

§ 108a. Employees who are assigned to a unit of forensic medicine shall participate in the preparation of assessments and reports in court proceedings as part of their official duties. The contracting body shall be the competent investigative or judicial body.

Term of Employment Contracts

§ 109. (1) Employment contracts may be of unlimited or limited term. A limited employment contract may be concluded once and shall not exceed six years, on pain of invalidity, unless otherwise provided for by this Act.

(2) The extension or renewed conclusion of a temporary employment contract of members of the scientific or artistic university staff under § 94 para 2, shall be permissible twice up a total duration of eight years, taking into account para 1.

(3) Notwithstanding the permissible maximum duration according to paras 1 and 2, employment contracts which are concluded predominantly for the implementation of third-party projects or research projects shall not be taken into account when establishing the maximum number of temporary employment contracts.

(4) If the assignment of an employee in the meaning of § 94 para 2 subpara 1 changes, it shall be permissible to limit the employment contract once more up to a maximum of six years.

(5) A repeated extension or renewed conclusion of an employment contract is permissible up to a maximum duration of six years for staff acting as temporary replacements.

(6) A repeated extension or renewed conclusion of employment contracts within eight academic years shall be permissible for staff which is exclusively used for teaching.

(7) Employment contracts which also include the completion of a doctoral programme up to a maximum of four years shall not be taken into account when establishing the maximum number and duration of employment contracts. Similarly, employment as student assistants shall not be taken into account.

(8) Unberücksichtigt bleiben Zeiten gemäß § 20 Abs. 3 Z 1 des gemäß § 108 Abs. 3 abgeschlossenen Kollektivvertrages für die ArbeitnehmerInnen der Universitäten (KV) in der am 1. Mai 2021 geltenden Fassung.

(9) Bei der Feststellung der höchstzulässigen Gesamtdauer der Arbeitsverhältnisse gemäß Abs. 1, 2, 5 und 6 sind alle Arbeitsverhältnisse zur Universität zu berücksichtigen, unabhängig davon, ob die Arbeitsverhältnisse unmittelbar aufeinanderfolgen.

Gesetzliche Sonderregelungen zur Arbeitszeit und Arbeitsruhe für das wissenschaftliche und künstlerische Universitätspersonal

§ 110. (1) Anstelle der Bestimmungen des Arbeitszeitgesetzes – AZG, BGBl. Nr. 461/1969, und des Arbeitsruhegesetzes – ARG, BGBl. Nr. 144/1983, gelten für das wissenschaftliche und künstlerische Personal der Universitäten die nachfolgenden Bestimmungen. Ausgenommen sind

1. das wissenschaftliche Personal, auf das das Krankenanstalten-Arbeitszeitgesetz anzuwenden ist, wobei im Hinblick auf § 29 Abs. 5 abweichend von § 4 Abs. 4 Z 2 und Abs. 4b Krankenanstalten-Arbeitszeitgesetz im Einvernehmen mit den gemäß § 34 gewählten Vertreterinnen und Vertretern durch Betriebsvereinbarung zugelassen werden kann, dass die durchschnittliche Wochenarbeitszeit 60 Stunden betragen kann, wenn die einzelne Arbeitnehmerin oder der einzelne Arbeitnehmer im Vorhinein schriftlich zugestimmt hat, und die die durchschnittliche Wochenarbeitszeit von 48 Stunden übersteigenden Zeiten ausschließlich für universitäre Aufgaben in Forschung und Lehre in der Normalarbeitszeit gewidmet werden.
2. leitende Angestellte der Universitäten, denen maßgebliche Führungsaufgaben selbstverantwortlich übertragen sind.

(2) Im Sinne dieser Bestimmung ist:

1. Arbeitszeit: die Zeit vom Beginn bis zum Ende der Arbeit ohne die Ruhepausen und die Ruhezeiten, sie umfasst die Normalarbeitszeit und die Überstundenarbeit;
2. Tagesarbeitszeit: die Arbeitszeit innerhalb eines ununterbrochenen Zeitraumes von 24 Stunden;
3. Wochenarbeitszeit: die Arbeitszeit innerhalb des Zeitraumes von Montag bis einschließlich Sonntag;

(8) Periods according to § 20 para 3 subpara 1 of the collective bargaining agreement for university staff (Kollektivvertrag für die ArbeitnehmerInnen der Universitäten – KV) concluded according to § 108 para 3 as amended on 1 May 2021 shall not be taken into account.

(9) When establishing the maximum duration of employment relationships according to paras 1, 2, 5 and 6, all employment contracts concluded with the university shall be taken into account, regardless of whether or not they are directly consecutive.

Special Arrangements for the Hours of Work and Rest Periods of Scientific and Artistic University Staff

§ 110. (1) The following provisions shall apply to scientific and artistic university staff instead of those of the Working Hours Act (Arbeitszeitgesetz – AZG), F. L. G. No. 461/1969, and the Rest Periods Act (Arbeitsruhegesetz – ARG), F. L. G. No. 144/1983. The following shall be excluded:

1. the scientific staff to which the Hospital Working Hours Act shall apply. Notwithstanding § 4 para 4 subpara 2 and para 4b of the Hospital Working Hours Act, in consultation with the representatives elected according to § 34, an employee's council agreement may permit that the average weekly working time may amount to 60 hours if the individual employee has given his/her written consent in advance and the times exceeding the average weekly working time of 48 hours are dedicated exclusively to university tasks in the field of research and teaching in the normal working time.
2. senior university employees entrusted with important managerial responsibilities.

(2) For the purposes of these provisions:

1. “Hours of work” mean the time from the start to the finish of working time, apart from the rest breaks and rest periods, and comprise normal working time and overtime;
2. “Daily working time” means the hours of work within an uninterrupted period of 24 hours;
3. “Weekly working time” means the hours of work within the period from Monday up to and including Sunday;

4. Nacht: der Zeitraum zwischen 22 Uhr und 6 Uhr;
5. Nachtarbeitnehmerin oder Nachtarbeitnehmer: eine Arbeitnehmerin oder ein Arbeitnehmer, die oder der regelmäßig oder, sofern der Kollektivvertrag nichts anderes vorsieht, in mindestens 48 Nächten im Kalenderjahr während der Nacht mindestens drei Stunden arbeitet.

(2a) Die wöchentliche Normalarbeitszeit beträgt 40 Stunden, soweit nicht durch Kollektivvertrag abweichende Regelungen getroffen werden.

(3) Die Tagesarbeitszeit darf 13 Stunden nicht überschreiten. Die Wochenarbeitszeit darf innerhalb eines Durchrechnungszeitraumes von bis zu 17 Wochen im Durchschnitt 48 Stunden und in den einzelnen Wochen des Durchrechnungszeitraumes 60 Stunden nicht überschreiten.

(4) Die Tagesarbeitszeit von Nachtarbeitnehmerinnen und Nachtarbeitnehmern darf innerhalb eines Durchrechnungszeitraumes von 17 Wochen im Durchschnitt acht Stunden nicht überschreiten.

(5) Beträgt die Gesamtdauer der Arbeitszeit mehr als sechs Stunden, ist die Arbeitszeit durch eine Ruhepause von mindestens 30 Minuten zu unterbrechen.

(6) Nach Beendigung der Tagesarbeitszeit ist den Arbeitnehmerinnen und Arbeitnehmern eine ununterbrochene Ruhezeit von mindestens elf Stunden zu gewähren.

(7) Innerhalb eines Zeitraumes von Montag bis einschließlich Sonntag ist den Arbeitnehmerinnen und Arbeitnehmern eine ununterbrochene Ruhezeit von 36 Stunden zu gewähren. Das Ausmaß der wöchentlichen Ruhezeit kann auf 24 Stunden gekürzt werden, wenn der Arbeitnehmerin oder dem Arbeitnehmer innerhalb von 14 Tagen eine durchschnittliche wöchentliche Ruhezeit von 36 Stunden gesichert ist.

(7a) Soweit betriebliche Erfordernisse nicht entgegenstehen, sind Sonntage und gesetzliche Feiertage (§ 7 Abs. 2 und 3 ARG) arbeitsfrei zu halten.

(8) Nachtarbeitnehmerinnen und Nachtarbeitnehmer sind auf ihr Verlangen auf eine Arbeitsstelle mit Tagesarbeit zu versetzen, wenn sie durch die Nachtarbeit nachweislich in ihrer Gesundheit beeinträchtigt sind und eine Versetzung auf eine Arbeitsstelle mit Tagesarbeit aus betrieblichen Gründen möglich ist.

(9) Nachtarbeitnehmerinnen und Nachtarbeitnehmer haben Anspruch auf unentgeltliche Untersuchungen ihres Gesundheitszustands vor Aufnahme der Tätigkeit und danach in regelmäßigen Zeitabständen. Diese Untersuchungen sind besondere Untersuchungen gemäß § 51 des ArbeitnehmerInnenschutzgesetzes (ASchG), BGBl. Nr. 450/1994.

4. “Night” means the period from 10 p.m. until 6 a.m.
5. “Night workers” means workers who work at least three hours during the night either regularly or, unless otherwise provided for by the collective contract, at least 48 nights per calendar year.

(2a) The normal working week is 40 hours unless otherwise provided for by the collective contract.

(3) Daily working time may not exceed 13 hours. Weekly working time may not exceed an average of 48 hours within a reference period of up to 17 weeks or 60 hours in single weeks within the reference period.

(4) The daily working time of night workers may not exceed an average of eight hours within a reference period of 17 weeks.

(5) If the total duration of hours of work amounts to more than six hours, working time shall be interrupted by a rest break of at least 30 minutes.

(6) After daily working time, employees shall be given an uninterrupted rest period of at least 11 hours.

(7) Employees shall be given an uninterrupted rest period of 36 hours within the period from Monday up to and including Sunday. The weekly rest period may be reduced to 24 hours if an employee is assured of an average weekly rest period of 36 hours over a 14 day period.

(7a) Unless precluded by operational requirements, Sundays and statutory holidays (§ 7 paras 2 ARG) shall be kept free.

(8) At their request, night workers shall be transferred to day jobs, if night work is demonstrably detrimental to their health and such transfer is operationally feasible.

(9) Night workers shall be entitled to free health assessments prior to the commencement of their duties and at regular intervals thereafter. Such assessments shall be special assessments according to § 51 of the Employees Protection Act, F. L. G. No 450/1994.

(10) Durch Kollektivvertrag kann die ununterbrochene Ruhezeit gemäß Abs. 6 bis auf acht Stunden verkürzt werden. Solche Verkürzungen der Ruhezeit sind innerhalb der nächsten zwei Wochen durch entsprechende Verlängerung einer anderen täglichen oder wöchentlichen Ruhezeit auszugleichen. Überdies kann durch Kollektivvertrag der Durchrechnungszeitraum für die wöchentliche Arbeitszeit gemäß Abs. 3 bis auf zwölf Monate und für die wöchentliche Ruhezeit gemäß Abs. 7 bis auf zwei Monate ausgedehnt werden. Abweichungen durch Kollektivvertrag sind nur dann zulässig, wenn den betroffenen Arbeitnehmerinnen und Arbeitnehmern gleichwertige Ausgleichruhezeiten gewährt werden.

(11) Der Arbeitgeber ist, sofern die Tat nicht nach anderen Vorschriften einer strengeren Strafe unterliegt, von der Bezirksverwaltungsbehörde mit einer Geldstrafe von 36 Euro bis zu 1 500 Euro zu bestrafen, wenn

1. Arbeitnehmerinnen oder Arbeitnehmer vom Arbeitgeber über die Höchstgrenzen der täglichen oder wöchentlichen Arbeitszeit gemäß Abs. 3 oder 4 hinaus eingesetzt werden,
2. ihnen Ruhepausen gemäß Abs. 5 oder die tägliche oder wöchentliche Ruhezeit gemäß Abs. 6 oder 7 nicht gewährt wird,
3. der Gesundheitszustand von Nachtarbeitnehmerinnen oder Nachtarbeitnehmern nicht entsprechend den Bestimmungen des Abs. 9 untersucht wird.

Gesetzliche Sonderregelungen zur Arbeitsruhe für das allgemeine Universitätspersonal

§ 111. Das allgemeine Universitätspersonal, dessen Mitarbeit zur Unterstützung und Aufrechterhaltung des Lehrbetriebs oder des Forschungs- oder Kunstbetriebs unbedingt erforderlich ist, darf während der Wochenend- und Feiertagsruhe gemäß §§ 3 und 7 ARG beschäftigt werden.

Erweiterter Kündigungs- und Entlassungsschutz

§ 113. Eine Kündigung oder Entlassung einer oder eines Angehörigen des wissenschaftlichen oder künstlerischen Universitätspersonals ist unwirksam, wenn die Kündigung wegen einer von ihr oder ihm in Forschung (Entwicklung und Erschließung der Künste) oder Lehre vertretenen Auffassung oder Methode erfolgt.

Übernahme von öffentlichen Ämtern

§ 114. (1) Die Übernahme eines öffentlichen Amtes bedarf keiner Bewilligung durch die Universität, ist jedoch dem Rektorat unverzüglich zu melden.

(10) The uninterrupted rest period according to para 6 may be reduced to eight hours by a collective contract. Such reductions in rest periods shall be compensated by corresponding extensions of other daily or weekly rest periods within the succeeding two weeks. The reference period for weekly hours of work under para 3 may, further, be extended to 12 months, and that for weekly rest periods under para 7 to two months by a collective contract. Deviations from the statutory provisions by virtue of collective contracts are only permissible if the employees concerned are granted equivalent compensatory rest periods.

(11) Employers shall, unless the offence is subject to a heavier penalty under other enactments, be punishable by the district administrative authority with a fine of between 36 € and 1,500 € if:

1. employees are used beyond the limits for daily or weekly hours of work under paras 3 or 4;
2. they are not granted rest breaks under para 5 or daily or weekly rest periods under paras 6 or 7; or
3. night workers are not provided with health assessments in accordance with the provisions of para 9.

Special Arrangements for the Rest Periods of Non-Academic University Staff

§ 111. Non-academic university staff whose work is essential to support and maintain teaching, research or artistic activities may be employed during week-end and holiday rest periods according to §§ 3 and 7 ARG.

Extended Protection against Dismissal

§ 113. The termination or dismissal of a member of the scientific and artistic university staff shall be null and void if an official notification has been issued as a result of an opinion or method advocated by such staff member in the course of his/her research, artistic or teaching activities.

Acceptance of Public Offices

§ 114. (1) Acceptance of public offices shall not require the permission of the university, but must be reported to the rectorate without delay.

(2) Ist eine Ausübung des öffentlichen Amtes neben der Erfüllung der Pflichten aus dem Arbeitsverhältnis zur Universität nicht möglich, ist die Arbeitnehmerin oder der Arbeitnehmer auf Antrag gänzlich oder teilweise bei entsprechender Kürzung oder Entfall des Entgelts freizustellen.

Pensionskassensystem und betriebliche Kollektivversicherung

§ 115. Durch Kollektivvertrag ist jedenfalls für das wissenschaftliche und künstlerische Universitätspersonal eine Pensionskassenzusage oder die Zusage einer betrieblichen Kollektivversicherung im Sinne des Betriebspensionsgesetzes, BGBl. Nr. 282/1990, vorzusehen. Auch für das allgemeine Universitätspersonal kann eine Pensionskassenzusage oder die Zusage einer betrieblichen Kollektivversicherung im Sinne des Betriebspensionsgesetzes vorgesehen werden. An jeder Universität kann nur jeweils eines der genannten Systeme zur Anwendung kommen.

V. Teil

Strafbestimmungen

§ 116. (1) Wer vorsätzlich

1. eine dem inländischen oder ausländischen Hochschulwesen eigentümliche Bezeichnung oder
2. einen oder mehrere inländische akademische Grade oder
3. eine den inländischen oder ausländischen akademischen Graden oder Titeln gleiche oder ähnliche Bezeichnung ~~unberechtigt verleiht, vermittelt oder führt,~~

unberechtigt verleiht, vermittelt oder führt, begeht, wenn die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet oder nach anderen Verwaltungsbestimmungen mit strengerer Strafe bedroht ist, eine Verwaltungsübertretung, die von der örtlich zuständigen Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 15 000 Euro zu bestrafen ist.

(2) Unberechtigt ist die Verleihung, Vermittlung oder Führung insbesondere dann, wenn der akademische Grad oder die gleiche oder ähnliche Bezeichnung

1. von einer Einrichtung stammt, die einer postsekundären Bildungseinrichtung nicht gleichrangig ist;
2. von einer Einrichtung stammt, die vom Sitzstaat nicht als postsekundäre Bildungseinrichtung anerkannt ist;

(2) In case that the exercise of a public office in addition to the fulfilment of an employee's duties under his/her employment contract is impossible, such employee shall, on application, be partly or entirely released from such duties subject to a corresponding reduction in or suspension of remuneration.

System of Pension Funds and Corporate Collective Insurance

§ 115. A pension fund commitment or the commitment to a corporate collective insurance in the meaning of the Company Pension Act, F. L. G. No 282/1990, shall be made for the scientific and artistic university staff under a collective contract. For the non-academic university staff, a pension fund commitment or a commitment to a corporate collective insurance in the meaning of the Company Pension Act can also be made. At each university, only one of the systems named shall be offered.

Part V

Penal Provisions

§ 116. (1) Anyone who deliberately without authority awards, grants or uses

1. a designation specific to a domestic or foreign higher education system; or
2. one or more domestic academic degrees; or
3. a degree or title identical or similar to domestic or foreign academic degrees or titles,

if the act does not constitute a punishable offence coming under the jurisdiction of a court of law or is not according to other rules of administrative penalty subject to more severe punishment, is committing an administrative offence punishable by the locally competent district administration by a fine of up to 15,000 €.

(2) The award, grant or use of an academic degree or identical or similar designation is, in particular, improper if it:

1. originates from an institution which is not of equivalent status to a post-secondary educational institution;
2. originates from an institution not recognized by its country of domicile as a post-secondary educational institution;

3. nicht auf Grund entsprechender Studien- und Prüfungsleistungen oder wissenschaftlicher oder künstlerischer Leistungen erworben wurde;
4. nicht auf Grund des wegen wissenschaftlicher oder künstlerischer Leistungen hohen Ansehens in Fachkreisen oder wegen hervorragender Verdienste für die wissenschaftlichen oder kulturellen Aufgaben der postsekundären Bildungseinrichtung ehrenhalber verliehen wurde.

(3) Unberechtigt ist die Führung insbesondere dann, wenn der akademische Grad oder die gleiche oder ähnliche Bezeichnung nicht auf Grund entsprechender Studien- und Prüfungsleistungen oder wissenschaftlicher oder künstlerischer Leistungen, sondern aufgrund eines Plagiates erlangt wurde.

Ghostwriting

§ 116a. (1) Wer entgeltlich oder unentgeltlich ein Werk für eine andere Person herstellt oder einer anderen Person zur Verfügung stellt, ist, wenn sie oder er weiß oder nach den Umständen annehmen kann, dass dieses Werk in der Folge teilweise oder zur Gänze als Seminar-, Prüfungs-, oder Abschlussarbeit (Bachelorarbeit, wissenschaftliche oder künstlerische Arbeit) zum Nachweis nicht erbrachter eigenständiger Leistungen verwendet werden soll, mit Geldstrafe bis zu 25.000 Euro zu bestrafen.

(2) Nicht zu bestrafen sind unentgeltliche Hilfestellungen, welche die gedankliche und fachliche Eigenständigkeit der Seminar-, Prüfungs-, oder Abschlussarbeit (Bachelorarbeit, wissenschaftliche oder künstlerische Arbeit) der ausgewiesenen Verfasserin oder des ausgewiesenen Verfassers nicht beeinträchtigen.

(3) Ebenso ist zu bestrafen, wer unter den in Abs. 1 genannten Umständen öffentlich anbietet, ein solches Werk für eine andere Person herzustellen oder einer anderen Person zur Verfügung zu stellen.

(4) Handelt die Täterin oder der Täter mit dem Vorsatz, sich durch die wiederkehrende Begehung solcher Taten laufende Einkünfte zu verschaffen, so ist sie oder er mit Geldstrafe bis zu 60.000 Euro zu bestrafen. Im Wiederholungsfall kann auf Freiheitsstrafe bis zu vier Wochen erkannt werden.

(5) Das empfangene Entgelt oder eine sonstige Zuwendung, die die Täterin oder der Täter empfangen hat, ist für verfallen zu erklären (§ 17 VStG). Handelt es sich beim Entgelt oder bei der Zuwendung nicht um eine körperliche Sache oder besitzt die Täterin oder der Täter das Entgelt oder die Zuwendung nicht mehr, so ist sie oder

3. was not obtained by virtue of appropriate studies and examinations or scientific or artistic achievement;
4. was not awarded on an honorary basis in recognition of the recipient’s high standing in academic circles due to his/her scientific or artistic achievements, or for outstanding services to the scholarly or cultural activities of a post-secondary educational institution.

(3) The use of use of an academic degree or identical or similar designation is improper, in particular if it was not obtained by virtue of appropriate academic achievements and examinations or scientific or artistic achievement, but due to plagiarism.

Ghostwriting

§ 116a. (1) Anyone who produces or provides a piece of work for/to others, be it gratuitous or non-gratuitous, if he/she knows or under the circumstance can assume that this piece of work will subsequently be used in part or entirely for a seminar paper, examination or thesis (bachelor's paper, academic thesis or artistic submission) as a proof of individual achievements not rendered, is committing an offence punishable by a fine of up to 25,000 Euro.

(2) Providing gratuitous support that does not impair the intellectual or professional individuality of the seminar paper, examination or thesis (bachelor's paper, academic thesis or artistic submission) of the designated author shall not be punishable.

(3) A person who publicly offers to produce or provide such work for/to another person under the circumstances named under para 1 shall also be punishable.

(4) If the offender acts with the intention to obtain regular income by recurrent committal of such acts, he/she is committing an offence punishable by a fine of up to 60,000 Euro. In case of recurrence, the offender may be sentenced to imprisonment for up to four weeks.

(5) The payments or other benefits received by the offender shall be declared forfeited (§ 17 VStG). Where the payments or benefits are not tangible things, or if the offender no longer has the payments or benefits, he/she shall be punishable by payment of a further sum, corresponding to the value of the payment or benefits received (forfeiture penalty – Verfallsersatzstrafe).

er mit der Zahlung eines weiteren Geldbetrages zu bestrafen, der dem Wert des Entgelts oder der Zuwendung entspricht (Verfallsersatzstrafe).

(6) Die Strafbarkeit erlischt durch Verjährung. Die Verjährungsfrist beträgt 30 Jahre und beginnt mit dem Zeitpunkt, in dem die strafbare Handlung abgeschlossen wurde oder das strafbare Verhalten aufgehört hat. Ist der zum Tatbestand gehörende Erfolg erst später eingetreten, läuft die Frist erst von diesem Zeitpunkt an.

(7) Wer eine Tat gemäß Abs. 1, 3 oder 4 ausführt, begeht, wenn die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet oder nach anderen Verwaltungsbestimmungen mit strengerer Strafe bedroht ist, eine Verwaltungsübertretung, die von der örtlich zuständigen Bezirksverwaltungsbehörde zu bestrafen ist.

(6) Criminal liability shall expire under the statute of limitations which shall be 30 years and begins at the time at which the punishable offence was completed or the criminal conduct ceased. If the success as part of the corpus delicti falls on a later time, the statute of limitations only begins to run at that date.

(7) Anyone who acts pursuant to paras 1, 3 or 4, if the act does not constitute a punishable offence coming under the jurisdiction of a court of law or is not according to other rules of administrative penalty subject to more severe punishment, is committing an administrative offence punishable by the locally competent district administration.

VI. Teil
Liegenschaften, Bauwerke, Räumlichkeiten

Raumnutzung

§ 117. Die Universitäten sind insbesondere im Rahmen ihrer Mietrechte verpflichtet, für eine optimale Raumnutzung zu universitären Zwecken zu sorgen.

Mietrechte an Objekten der BIG und anderer Eigentümer

§ 118. Von der BIG oder von anderen Dritten angemietete Liegenschaften, Bauwerke und Räumlichkeiten, die kurzfristig nicht zu universitären Zwecken benötigt werden, dürfen an Dritte weitergegeben werden, soweit dies auf Grund des Mietvertrags und des Mietrechtsgesetzes – MRG, BGBl. Nr. 520/1981 zulässig ist.

Immobilienbewirtschaftung der Universitäten

§ 118a. (1) Die Realisierung bzw. Finanzierung sämtlicher universitärer Immobilienprojekte ist zwischen der Bundesministerin oder dem Bundesminister und der betreffenden Universität zu vereinbaren. Immobilienprojekte sind insbesondere Neubauten, Umbauten, (General-)Sanierungen, Adaptierungen und Anmietungen sowie der Erwerb von Immobilien, die von einer Universität genutzt werden, und die von der Universität oder von Dritten für die Universität durchgeführt werden.

(2) Die Bundesministerin oder der Bundesminister hat regionale Bauleitpläne, die in drei getrennte Planungsregionen gegliedert sind, als Planungsinstrument für die Realisierung universitärer Immobilienprojekte zu führen, die den gemeinsamen

Part VI
Properties, Buildings and Rooms

Use of Space

§ 117. The universities shall, particularly with regard to the use of their tenancy rights, ensure that space is efficiently used for university purposes.

Tenancy Rights in respect of Properties Owned by BIG and other Owners

§ 118. Properties, buildings and rooms rented from BIG or other third parties, which are temporarily not required for university use, may be sublet to third parties provided that this is permitted by the tenancy agreement and the Rent Act (Mietrechtsgesetz – MRG), F. L. G. No 520/1981.

Real Estate Management by Universities

§ 118a. (1) The realisation and funding of all university real estate projects shall be agreed upon by the Federal Minister and the university involved. Real estate projects are, in particular, new buildings, the modification, (complete) refurbishment, remodelling and leasing as well as acquisition of buildings used by the university, which are implemented by the university or by third parties for the university.

(2) The Federal Minister shall maintain regional development plans for real estate which are divided into three separate planning regions, as a planning instrument for the realisation of building projects of universities which represent the

Vorschlag der in einer Planungsregion zusammengefassten Universitäten darstellen und alle vom Bund teilweise oder zur Gänze zu finanzierenden Immobilienprojekte der jeweiligen Planungsregion in einer Prioritätenreihung umfasst. Die regionalen Bauleitpläne sind zu veröffentlichen.

(3) Die Universitäten haben ihre geplanten Immobilienprojekte, die teilweise oder zur Gänze vom Bund zu finanzieren sind, der Bundesministerin oder dem Bundesminister im Wege der regionalen Bauleitpläne bekanntzugeben. Die Immobilienprojekte sind unter Berücksichtigung hochschulpolitischer Schwerpunktsetzungen und der Bedarfe der Universitäten, nach Priorität zu reihen. Hierzu hat die Bundesministerin oder der Bundesminister die Universitäten einer Planungsregion einzuladen, gemeinsam einen entsprechenden Vorschlag zu erstellen. Diese Prioritätenreihung ist regelmäßig, wenigstens im Abstand von drei Jahren, zu aktualisieren.

(4) Die Bundesministerin oder der Bundesminister kann nach Maßgabe des aktuellen budgetären Handlungsspielraumes, der Prioritätenreihung der regionalen Bauleitpläne, der Angemessenheit der finanziellen Bewertungen, der hochschulpolitischen Schwerpunktsetzung sowie der allgemeinen volkswirtschaftlichen Lage die Freigaben für einzelne Projekte erteilen.

(5) Für vom Bund teilweise oder zur Gänze zu finanzierende Immobilienprojekte, deren Einmalkosten die Betragsgrenze von 10 Millionen Euro (brutto) bzw. deren laufende Mietkosten 600 000 Euro (netto) pro Jahr übersteigen, ist vor Erteilung der Freigabe das Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen herzustellen.

(6) Nach Freigabe eines Immobilienprojekts durch die Bundesministerin oder den Bundesminister erfolgt die Aufnahme in den gesamtösterreichischen Bauleitplan. Der gesamtösterreichische Bauleitplan enthält alle seitens der Bundesministerin oder des Bundesministers geprüften und freigegebenen Immobilienprojekte der Universitäten, jeweils mit den entsprechenden Einmalkosten sowie laufenden Kosten.

(7) Ebenfalls in den gesamtösterreichischen Bauleitplan aufzunehmen sind gemäß Abs. 1 vereinbarte Immobilienprojekte, die von der Universität zur Gänze eigenfinanziert werden.

(8) Nicht in den gesamtösterreichischen Bauleitplan aufzunehmen sind Projekte, die in Hinblick auf die wirtschaftliche Leistungsfähigkeit der jeweiligen Universität von geringer wirtschaftlicher Bedeutung sind. Für diese Projekte ist zwischen der Bundesministerin oder dem Bundesminister und der betreffenden

joint proposal of the universities that are combined in a planning region and comprise all building projects of the respective planning region that are financed in part or in full by the Federal Government in order of priority. The regional development plans for real estate shall be published.

(3) The universities shall communicate their planned real estate projects which are to be financed in part or in full by the Federal Government to the Federal Minister by means of the regional development plans. The real estate projects shall be priority-ranked, having regard to the focus areas in higher education policy and the needs of universities. To this end, the Federal Minister shall invite the universities located within the same planning region to prepare the proposal jointly. This prioritisation shall be updated periodically, at least every three years.

(4) The Federal Minister may grant the approval of individual projects, contingent upon current budgetary considerations, the priority ranking in the regional development plans for real estate, the adequacy of the valuation, the focus areas in higher education policy, and the general economic situation.

(5) Prior to granting the approval of real estate projects to be financed in part or in full by the Federal Government, with non-recurring costs exceeding the limit of 10 million Euro (gross) or for which the annual running costs of rent exceed 600,000 Euro (net), the Federal Minister shall reach agreement with the Federal Minister of Finance.

(6) Following the approval of a real estate project by the Federal Minister, it shall be included in the Austrian national development plan for buildings. The Austrian national development plan for buildings contains all real estate projects of universities which have been assessed and approved by the Federal Minister, including, in each case, the respective non-recurring costs as well as the running costs.

(7) Real estate projects agreed upon pursuant to para 1 which are self-funded by the university, shall also be included in the Austrian national development plan for buildings.

(8) Projects which are of small importance with regard to the respective university's financial capacity shall not be included in the Austrian national development plan for buildings. For such projects, the Federal Minister and the university in question shall determine a default limit within the framework of the

Universität eine pauschale Obergrenze im Rahmen der Leistungsvereinbarung festzulegen. Diese Projekte sind jedenfalls von der Universität aus dem laufenden Globalbudget einschließlich der Drittmittel zu bedecken.

(9) Die Bundesministerin oder der Bundesminister kann das Verfahren für universitäre Immobilienprojekte im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen durch Verordnung regeln, wobei insbesondere Regelungen über die einzelnen Verfahrensschritte, die in der Projektbeschreibung anzuwendenden Berechnungsgrundlagen, die Aufnahme in die regionalen Bauleitpläne, die Erstellung eines Raum- und Funktionsprogrammes, die Planungsfreigabe, die Baufreigabe, die Berichtspflichten der betreffenden Universität sowie Maßnahmen bei Nichteinhaltung getroffen werden können. Die Bundesministerin oder der Bundesminister kann für Immobilienprojekte, deren Kosten zur Gänze von Dritten bedeckt werden, Ausnahmen von dieser Vorgehensweise genehmigen.

(10) Die Bundesministerin oder der Bundesminister hat mit Bescheid die Rechtswidrigkeit einer Handlung eines Universitätsorgans festzustellen, wenn diese Handlung im Widerspruch zu dieser Bestimmung oder der Verordnung des Bundesministers für Bildung, Wissenschaft und Forschung über das Verfahren zur Planung und Abwicklung von Immobilienprojekten an Universitäten (Universitäten-Immobilienverordnung – Uni-ImmoV) steht oder wenn das Universitätsorgan die Vornahme einer gebotenen Handlung im Sinne der zitierten Bestimmungen unterlassen hat. Im Bescheid kann eine vorzeitige Beendigung oder eine zeitliche Nachreihung des betroffenen Immobilienprojekts oder nachfolgender Immobilienprojekte der Universität bei der Einordnung in den gesamtösterreichischen Bauleitplan angeordnet werden. Frustrierte Aufwendungen sind grundsätzlich von der Universität zu tragen. Bei wesentlichen Änderungen der dem Immobilienprojekt zugrundeliegenden Voraussetzungen kann eine neuerliche Bewertung durch die Bundesministerin oder den Bundesminister erfolgen.

~~VII. Teil~~

~~Wissenschaftsrat~~

~~**§ 119.** (1) Der Wissenschaftsrat ist eine Einrichtung des Bundes. Er unterliegt der Aufsicht durch die Bundesministerin oder den Bundesminister gemäß § 45.~~

~~(2) Die Aufgaben des Wissenschaftsrats sind:~~

~~1. Beratung der Bundesministerin oder des Bundesministers, der gesetzgebenden Körperschaften und der Universitäten in den~~

performance agreement. Such projects shall, in any case, be covered by the university from the current global budget, including third-party funds.

(9) The Federal Minister may, in consultation with the Federal Minister of Finance, lay down, by decree, the procedure for university real estate projects, and, in particular, stipulate provisions pertaining to the individual procedural steps, the valuation standards used in the project description, the inclusion in the regional development plans for real estate, the preparation of a space allocation and function programme, the planning approval, the construction approval, and the reporting duties of the university as well as any non-compliance measures. The Federal Minister may grant exceptions to this procedure for real estate projects that are funded in total by third parties.

Part VII

Science Council

§ 119. (1) The Science Council shall be a federal institution. It shall be subject to ministerial supervision in accordance with § 45.

(2) The functions of the Science Council shall be:

1. advising the Federal Minister, the legislature and the universities on university matters and on questions of science policy and the arts;

~~Angelegenheiten der Universitäten und in Fragen der Wissenschaftspolitik und der Kunst;~~

~~2. Beobachtung und Analyse des österreichischen Universitäts- und Wissenschaftssystems unter Bedachtnahme auf europäische und internationale Entwicklungen sowie Erarbeitung von Vorschlägen zu dessen Weiterentwicklung.~~

~~(3) Die Beschlüsse, Stellungnahmen und Empfehlungen des Wissenschaftsrats sind zu veröffentlichen, wobei personenbezogene Daten (Art. 4 Nr. 1 DSGVO) nur veröffentlicht werden dürfen, wenn:~~

~~1. die betroffenen Personen eingewilligt haben oder~~

~~2. die betroffenen Personen eine öffentliche Funktion ausüben.~~

~~(4) Der Wissenschaftsrat hat dem Nationalrat ab 2004 zumindest alle drei Jahre im Wege der Bundesministerin oder des Bundesministers einen Tätigkeitsbericht vorzulegen. Dieser Bericht hat auch Empfehlungen über die Grundausrichtung der Leistungsvereinbarungen mit den Universitäten unter Bedachtnahme auf die Standortentwicklung zu enthalten.~~

~~(5) Der Wissenschaftsrat besteht aus zwölf Mitgliedern aus unterschiedlichen Bereichen der Gesellschaft, insbesondere der Wissenschaft und der Kunst, die von der Bundesregierung auf Vorschlag der Bundesministerin oder des Bundesministers bestellt werden. Der Wissenschaftsrat erstattet der Bundesministerin oder dem Bundesminister Vorschläge für die Nominierung der Mitglieder. Dabei sind Frauen in entsprechender Anzahl zu berücksichtigen.~~

~~(6) Von der Mitgliedschaft im Wissenschaftsrat ausgeschlossen sind:~~

~~1. akademische Funktionärinnen und Funktionäre der Universitäten gemäß § 6 Abs. 1, der Pädagogischen Hochschulen gemäß § 1 Abs. 1 und 2 HG sowie der in Österreich gemäß §§ 23 und 24 HS-QSG akkreditierten Fachhochschul-Einrichtungen, Fachhochschul-Studiengängen und Privatuniversitäten;~~

~~2. Mitarbeiterinnen und Mitarbeiter der für die Universitäten und Pädagogischen Hochschulen zuständigen Bundesministerien sowie~~

~~3. Mitglieder der Bundesregierung oder einer Landesregierung, Mitglieder des Nationalrats, des Bundesrats oder sonst eines allgemeinen Vertretungskörpers, Funktionäre einer politischen Partei sowie Personen, die eine dieser Funktionen in den letzten vier Jahren ausgeübt haben.~~

~~*(Anm.: Abs. 7 aufgehoben durch BGBl. I Nr. 81/2009)*~~

2. monitoring and analysing the Austrian higher education and research system, having regard to European and international trends, and formulating proposals for its further development.

(3) The resolutions, opinions and recommendations of the Science Council shall be published, in that personal data (Art 4 No 1 GDPR) may only be published if

1. the persons concerned have given their consent, or
2. the persons concerned exercise a public function

(4) From 2004 onwards the Science Council shall submit reports on its activities at least once every three years to the National Council, by way of the Federal Minister. Such reports shall also include recommendations for the strategic alignment of the performance agreements with universities, having regard to the development of university locations.

(5) The Science Council shall consist of 12 members from different spheres of society, particularly science and the arts, who shall be nominated by the Federal Minister and appointed by the Federal Government. The Science Council shall submit suggestions to the Federal Minister for the nomination of its members, having regard to adequate female representation.

(6) The following shall be excluded from membership of the Science Council:

1. officers of the universities named in § 6 para 1, of the university colleges of teacher education named in § 1 paras 1 and 2 HG, and of accredited Austrian universities of applied sciences, university of applied sciences programmes and private universities under §§ 23 and 24 HS-QSG;
2. employees of the federal ministries in charge of the universities and university colleges of teacher education; and
3. members of the federal or provincial governments, the National Council, the Federal Council or any other popular representative body, and officers of political parties or persons who have exercised such functions during the past four years.

*(7) [*removed*]*

~~(8) Die Funktionsperiode der Mitglieder des Wissenschaftsrats ist von der Bundesregierung anlässlich der Bestellung mit drei oder sechs Jahren festzusetzen und beginnt mit der Bestellung. Eine einmalige Wiederbestellung ist zulässig. Bei vorzeitigem Ausscheiden eines Mitglieds des Wissenschaftsrats ist für den Rest der Funktionsperiode des ausgeschiedenen Mitglieds ein neues Mitglied zu bestellen.~~

~~(9) Die Mitgliedschaft im Wissenschaftsrat endet~~

~~1. durch Ablauf der Funktionsperiode,~~

~~2. durch Verzicht,~~

~~3. durch Abberufung,~~

~~4. durch Tod.~~

~~(10) Die Bundesministerin oder der Bundesminister beruft die konstituierende Sitzung des Wissenschaftsrats ein. Die oder der Vorsitzende wird aus dem Kreis der Mitglieder mit Stimmenmehrheit gewählt. Der Wissenschaftsrat gibt sich eine Geschäftsordnung.~~

~~(11) Die Bundesregierung kann ein Mitglied des Wissenschaftsrats auf Antrag der Bundesministerin oder des Bundesministers oder auf Antrag der Mehrheit der Mitglieder des Wissenschaftsrats wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung oder wegen mangelnder gesundheitlicher Eignung mit Bescheid von seiner Funktion abberufen.~~

~~(12) Der Wissenschaftsrat ist beschlussfähig, wenn wenigstens die Hälfte der Mitglieder persönlich anwesend ist. Stimmübertragungen sind unzulässig.~~

~~(13) Der Wissenschaftsrat ist berechtigt, in- und ausländische Expertinnen und Experten zu den Sitzungen einzuladen und Arbeitsgruppen einzurichten.~~

~~(14) Die Mitglieder des Wissenschaftsrats erhalten für ihre Tätigkeit eine Vergütung, die von der Bundesministerin oder vom Bundesminister festzusetzen ist.~~

~~(15) Die Bundesministerin oder der Bundesminister hat dem Wissenschaftsrat die zur Erfüllung seiner Aufgaben erforderliche räumliche, technische und personelle Ausstattung zur Verfügung zu stellen.~~

(8) The term of office of the members of the Science Council shall be determined by the Federal Government as either three or six years when they are appointed and shall commence with the appointment. Reappointment shall be permissible for one term. In case of the premature termination of the service of a member of the Science Council, a replacement shall be appointed for the remainder of the term of office of the departing member.

(9) Membership of the Science Council may be terminated by:

1. expiry of the term of office;
2. resignation;
3. dismissal;
4. death.

(10) The Federal Minister shall convene the constituent meeting of the Science Council. The members shall elect a chairperson from among their number. The Science Council shall adopt rules of procedure.

(11) The Federal Government may, on application of the Federal Minister or of a majority of the members of the Science Council, by official notification, dismiss a member of the Council due to severe misconduct, conviction of a criminal offence, or mental incapacity or health impairment.

(12) The Science Council shall have a quorum when at least half of the members are present. Voting by proxy is impermissible.

(13) The Science Council shall be entitled to invite domestic and foreign experts to its meetings, and to establish working parties.

(14) The members of the Science Council shall receive compensation for their activities in an amount to be determined by the Federal Minister.

(15) The Federal Minister shall provide the Science Council with the premises, equipment and staff necessary for the performance of its tasks.

VIII. Teil
Übergangs- und Schlussbestimmungen

1. Abschnitt
Implementierung der neuen Organisation

Gründungskonvent

§ 120. (1) An jeder der in § 6 Z 1 bis 21 vorgesehenen Universitäten ist unverzüglich nach der Kundmachung dieses Bundesgesetzes ein Gründungskonvent einzurichten, der aus zwölf Mitgliedern besteht.

(2) Dem Gründungskonvent gehören Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren, der im § 94 Abs. 2 Z 2 genannten Gruppe, des allgemeinen Universitätspersonals und der Studierenden der gleichnamigen Universität gemäß UOG 1993 oder KUOG an.

(3) Abweichend von Abs. 2 sind die Angehörigen einer Medizinischen Fakultät nur für den Gründungskonvent jener Medizinischen Universität aktiv und passiv wahlberechtigt oder entsendungsfähig, die gemäß § 136 Abs. 2 die Gesamtrechtsnachfolgerin der betreffenden Medizinischen Fakultät ist.

(4) Angehörige von Interuniversitären Einrichtungen sind für den Gründungskonvent jener Universität aktiv und passiv wahlberechtigt, welche gemäß § 136 Abs. 4 bis 11 die Nachfolgeeinrichtung der jeweiligen Interuniversitären Einrichtung ist.

(5) Die im Amt befindlichen Rektorinnen und Rektoren, Vizerektorinnen und Vizerektoren gemäß UOG 1993 und KUOG sind passiv nicht wahlberechtigt.

(6) Die Bundesministerin oder der Bundesminister hat durch Verordnung eine Wahlordnung für die Gründungskonvente aller Universitäten nach den Grundsätzen des gleichen, unmittelbaren, geheimen und persönlichen Verhältniswahlrechts zu erlassen.

(7) Die Mitglieder und Ersatzmitglieder des Gründungskonvents sind folgendermaßen zu bestellen:

Part VIII
Transitional and Final Provisions

Chapter 1
Implementation of the New Organisational Structure

Constituent Convention

§ 120. (1) A constituent convention consisting of 12 members shall be established at each of the universities named in § 6 subparas 1 to 21 upon publication of this Act.

(2) The constituent convention shall consist of representatives of the professors, the group of persons named in § 94 para 2 subpara 2, the non-academic university staff and the students of the university in the meaning of the University Organisation Act 1993 and the Universities of the Arts Organisation Act.

(3) Notwithstanding para 2, the members of medical faculties shall only be eligible to vote and be elected to the constituent conventions of those medical universities which are the legal successors of the faculties of medicine concerned according to § 136 para 2.

(4) Members of inter-university institutions shall be eligible to vote and be elected to the constituent conventions of those universities which are the legal successors of the respective inter-university institutions according to § 136 paras 4 to 11.

(5) In accordance with the University Organisation Act 1993 and Universities of the Arts Organisation Act, rectors and vice-rectors in office shall not be eligible for election.

(6) The Federal Minister shall, by decree, enact electoral regulations for the constituent conventions of all universities. These shall conform to the principles of equal, direct, secret and personal voting and proportional representation.

(7) The members and substitute members of the constituent convention shall be appointed as follows:

1. Sieben Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren sind von allen Universitätsprofessorinnen und Universitätsprofessoren (§ 97) zu wählen.
2. Zwei Vertreterinnen und Vertreter der im § 94 Abs. 2 Z 2 genannten Gruppe sind von allen Universitätsdozentinnen und Universitätsdozenten (§ 122 Abs. 3) sowie den wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeitern im Forschungs-, Kunst- und Lehrbetrieb zu wählen. Den Gewählten muss zumindest eine Person mit Lehrbefugnis (venia docendi) angehören.
3. Eine Vertreterin oder ein Vertreter des allgemeinen Universitätspersonals ist von allen Angehörigen des allgemeinen Universitätspersonals zu wählen.
4. Zwei Vertreterinnen und Vertreter der Studierenden sind durch die gesetzliche Vertretung der Studierenden zu entsenden.

(8) Die oder der Vorsitzende des Dienststellenausschusses der Universitätslehrer sowie die oder der Vorsitzende des Dienststellenausschusses für die Bediensteten mit Ausnahme der Universitätslehrer, die oder der Vorsitzende des Arbeitskreises für Gleichbehandlungsfragen, die Bibliotheksdirektorin oder der Bibliotheksdirektor, die Universitätsdirektorin oder der Universitätsdirektor, die Leiterin oder der Leiter des zentralen Informatikdienstes sowie die oder der Vorsitzende der Hochschülerschaft an der betreffenden Universität gehören dem Gründungskonvent mit beratender Stimme an.

(9) Der Gründungskonvent ist beschlussfähig, wenn wenigstens die Hälfte der stimmberechtigten Mitglieder persönlich anwesend oder durch ein Ersatzmitglied vertreten ist. Die Beschlüsse werden mit Stimmenmehrheit gefasst, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(10) Die im Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes im Amt befindliche Rektorin oder der im Amt befindliche Rektor hat die Wahlen in den Gründungskonvent auszuschreiben, die konstituierende Sitzung bis längstens 30. November 2002 einzuberufen und bis zur Wahl der oder des Vorsitzenden zu leiten. Für den Gründungskonvent einer Medizinischen Universität kommt diese Aufgabe der Dekanin oder dem Dekan der Medizinischen Fakultät zu, deren Nachfolgeeinrichtung die Medizinische Universität ist.

(11) Der Gründungskonvent hat die im § 121 vorgesehenen Maßnahmen zur Implementierung vorzubereiten und durchzuführen, soweit gesetzlich nicht ausdrücklich anderes bestimmt ist.

1. Seven representatives of the university professors shall be elected by all the university professors (§ 97).
2. Two representatives of the group of persons named in § 94 para 2 subpara 2 shall be elected by all the associate professors (§ 122 para 3) as well as the other research, artistic and teaching staff. Those elected must include at least one person with a habilitation degree (venia docendi).
3. One representative of the non-academic university staff shall be elected by all the non-academic university staff.
4. Two student representatives shall be delegated by the legal student representative organisation.

(8) The chairpersons of the employment committee for university teachers and the employment committee for non-academic university staff, the chairperson of the working group on equal opportunities, the library director, the university director, the head of the central information service and the chairperson of the students' union at the university concerned shall be non-voting members of the constituent convention.

(9) The constituent convention shall have a quorum when at least half of the voting members or their substitutes are present. The constituent convention shall resolve by simple majority, except insofar as this Act provides otherwise.

(10) The rector in office at the time of the entry into force of this Act shall call elections to the constituent convention, call the constituent meeting not later than 30 November 2002, and preside over the meeting until the election of a chairperson. In the case of the constituent convention of a medical university, these tasks shall be performed by the dean of the faculty of medicine of which that university is the successor institution.

(11) The constituent convention shall make preparations for the implementing measures provided for by § 121, insofar as these are not expressively provided for by statute.

(12) Die Funktion des Gründungskonvents endet mit Ablauf des 31. Dezember 2003.

Implementierungsschritte

§ 121. (1) Die Bestimmungen des UOG 1993 und des KUOG sind an den Universitäten und an den Universitäten der Künste bis 31. Dezember 2003 anzuwenden.

(2) Die zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes im Amt befindlichen Rektorinnen und Rektoren, Vizerektorinnen und Vizerektoren üben ihr Amt bis zur Funktionsübernahme des Rektorats nach diesem Bundesgesetz aus.

(3) Der Gründungskonvent hat die Größe des Senats gemäß § 25 Abs. 2 festzulegen, eine provisorische Satzung einschließlich einer Wahlordnung für den Senat zu beschließen und die erforderlichen weiteren Schritte der Überleitung zu veranlassen, soweit hiefür gesetzlich keine anderen Maßnahmen vorgesehen sind. Die Wahlordnung hat den Grundsätzen gemäß § 120 Abs. 6 zu entsprechen.

(4) Der Gründungskonvent hat die Größe des Universitätsrats mit fünf, sieben oder neun Mitgliedern festzulegen und unverzüglich zwei, drei oder vier Mitglieder des Universitätsrats zu wählen. Kommt der Gründungskonvent einer Universität bis 31. Jänner 2003 dieser Aufgabe nicht nach, bestellt die Bundesministerin oder der Bundesminister auch die Mitglieder, die vom Gründungskonvent zu wählen gewesen wären.

(5) Die Bundesregierung hat bis 28. Februar 2003 auf Antrag der Bundesministerin oder des Bundesministers nach Maßgabe des Abs. 4 zwei, drei oder vier Mitglieder für jeden Universitätsrat zu bestellen.

(6) Der Universitätsrat hat sich unverzüglich zu konstituieren und längstens bis 31. März 2003 das weitere Mitglied (§ 21 Abs. 6 Z 3) zu wählen.

(7) Der Gründungskonvent hat unverzüglich die Wahl der Rektorin oder des Rektors auszuschreiben und einen Vorschlag für die Wahl der Rektorin oder des Rektors zu erstellen. Die Wahl der Rektorin oder des Rektors durch den Universitätsrat hat bis spätestens 30. Juni 2003 zu erfolgen.

(8) Die gewählten Rektorinnen oder Rektoren haben nach Anhörung des Gründungskonvents unverzüglich die Zahl der Vizerektorinnen und Vizerektoren sowie deren Beschäftigungsausmaß festzulegen und einen Wahlvorschlag vorzulegen. Die Wahl der Vizerektorinnen und Vizerektoren hat spätestens acht Wochen nach der Rektorswahl stattzufinden.

(12) The term of office of the constituent convention shall expire at the end of 31 December 2003.

Implementation Steps

§ 121. (1) The provisions of the University Organisation Act 1993 and the Universities of the Arts Organisation Act shall continue to apply to the universities and the universities of the arts until 31 December 2003.

(2) The rectors and vice-rectors in office at the time of the entry into force of this Act shall remain in office until the rectorate takes office under this Act.

(3) The constituent convention shall determine the size of the senate in accordance with § 25 para 2, shall adopt a provisional statute including electoral regulations for the senate, and initiate the other necessary transitional arrangements, insofar as other measures are not provided for by statute. The electoral regulations shall conform to the principles named in § 120 para 6.

(4) The constituent convention shall determine the size of the university council, which may have five, seven or nine members, and shall elect two, three or four members to the council without delay. In case that the constituent convention of a university fails to comply with this task by 31 January 2003, the Federal Minister shall appoint the members who would otherwise have been elected by the convention.

(5) The Federal Government shall, on application by the Federal Minister, appoint two, three or four members to each university council, in accordance with para 2003, by 4 February, 28.

(6) The university council shall constitute itself without delay, and shall elect the additional member (§ 21 para 6 subpara 3) not later than 31 March 2003.

(7) The constituent convention shall, without delay, give notice of the election of the rector, and draw up a shortlist of candidates for such election. The election of the rector by the university council shall take place not later than 30 June 2003.

(8) The rectors elected shall determine the number and tasks of the vice-rectors, and nominate candidates after hearing the opinion of the constituent convention. The election of the vice-rectors shall take place not later than eight weeks after the election of the rector.

(9) Die Mitglieder des Rektorats haben am 1. Oktober 2003 ihr Amt anzutreten.

(10) Das Rektorat hat unverzüglich einen provisorischen Organisationsplan zu erlassen und die provisorischen Leiterinnen und Leiter der einzelnen Organisationseinheiten zu bestellen. Dieser provisorische Organisationsplan ist mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität in Kraft zu setzen.

(11) Die Rektorin oder der Rektor hat unverzüglich die Wahlen für den Senat auszuschreiben und die Sitzung bis zur Wahl der oder des Vorsitzenden zu leiten. Die Wahlen zum Senat haben bis 31. Oktober 2003, die konstituierende Sitzung des Senats und die Wahl des Vorsitzenden bis 30. November 2003 stattzufinden.

(12) Die Geschäftsordnung des Rektorats ist bis 31. Oktober 2003 kundzumachen.

(13) Bis spätestens 31. Dezember 2003 ist dem Universitätsrat die endgültige Organisationsform der Universität (Organisationsplan) und dem Senat der Vorschlag für die Satzung zur Beschlussfassung vorzulegen.

(14) Unverzüglich nach der Genehmigung des Organisationsplans sind die Leiterinnen und Leiter der Organisationseinheiten zu bestellen.

(15) Die gemäß UOG 1993 errichteten Universitätskliniken und Klinischen Institute der Medizinischen Fakultäten bleiben bis zum Wirksamwerden eines neuen Organisationsplans der betreffenden Medizinischen Universität bestehen und die bestellten Leiterinnen und Leiter im Amt. Diese Einrichtungen gelten ab 1. Jänner 2004 als Organisationseinheiten des Klinischen Bereichs dieser Medizinischen Universität.

(16) Die Universität hat der Bundesministerin oder dem Bundesminister jeweils bis zum 30. April 2005, 2006 und 2007 zusätzlich zum Rechnungsabschluss einen Tätigkeitsbericht vorzulegen, der sich auf das gesamte Leistungsspektrum der Universität zu beziehen hat.

(17) Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen bis spätestens Ende des Jahres 2005 den für die erste Leistungsvereinbarungsperiode zur Finanzierung der Universitäten zur Verfügung stehenden Gesamtbetrag festzusetzen und darüber das Einvernehmen gemäß § 45 des Bundeshaushaltsgesetzes herzustellen. Die Universität hat der Bundesministerin oder dem Bundesminister bis 30. April 2006 den Entwurf der ersten Leistungsvereinbarung für die Jahre 2007 bis 2009 vorzulegen.

(9) The rectorate shall commence their office on 1 October 2003.

(10) The rectorate shall enact a provisional organisation plan and appoint provisional heads of the various organisational units without delay. This provisional organisation plan shall come into force on the day when this Act enters into full effect at the university.

(11) The rector shall give notice of the elections to the senate without delay, and shall preside over its constituent meeting until the election of a chairperson. The elections to the senate shall be held by 31 October 2003, and the constituent meeting of the senate and election of a chairperson by 30 November 2003.

(12) The rules of procedure of the rectorate shall be published by 31 October 2003.

(13) The rectorate shall submit its plans for the definitive organisational form of the university (organisation plan) to the university council, and submit the proposed university statute for resolution by the senate, not later than 31 December 2003.

(14) Upon approval of the organisation plan the heads of the organisational units shall be appointed without delay.

(15) The university clinics and clinical institutes within faculties of medicine, established under the University Organisation Act 1993, shall continue to exist and the heads thereof remain in office until the entry into effect of new organisation plans at the respective medical universities. From 1 January 2004 these institutions shall be deemed to be organisational units of the clinical departments of these medical universities.

(16) Universities shall, in addition to financial statements, submit to the Federal Minister reports on their activities, covering the entire spectrum of their services, by 30 April 2005, 2006 and 2007.

(17) The Federal Minister shall, not later than the end of 2005, establish a global budget for university funding in the first performance agreement period in consultation with the Federal Minister of Finance, and shall reach agreement thereto in accordance with § 45 of the Federal Budget Act. Universities shall submit drafts of their first performance agreements, for the period from 2007 to 2009, to the Federal Minister by 30 April 2006.

(18) Jede Universität hat bis zum Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes ein Bestandsverzeichnis zu erstellen. Dieses Verzeichnis hat das bisher der Universität gewidmete bewegliche und unbewegliche Vermögen, Verbindlichkeiten der Universität gegenüber Dritten, insbesondere aus Kreditaufnahmen, sowie alle Bankkonten inklusive der Wertpapierbestände und die Drittmittel der Institute (Kliniken) anzuführen. Diesem Verzeichnis ist auch eine Aufstellung des am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität beschäftigten Personals beizufügen.

(19) Die Bundesministerin oder der Bundesminister hat bis 30. September 2006 einen Bericht über die Nachwuchsförderung und die Entwicklung der Personalstruktur der Universitäten vorzulegen.

(20) Der Gründungskonvent jeder Universität hat bis spätestens 31. Dezember 2002 eine Vertreterin oder einen Vertreter in den Dachverband der Universitäten zu entsenden. Die Funktionsperiode dieser Vertreterin oder dieses Vertreters endet mit der Entsendung einer neuen Vertreterin oder eines neuen Vertreters durch das Rektorat der betreffenden Universität (§ 108 Abs. 2).

(21) Die Rektorin oder der Rektor der Universität Wien hat die konstituierende Sitzung des Dachverbandes der Universitäten (§ 108) einzuberufen und diese Sitzung bis zur Wahl der oder des Vorsitzenden zu leiten.

(22) Erfolgen die zur Implementierung erforderlichen Schritte nicht rechtzeitig, können die notwendigen Maßnahmen ohne Setzung einer Nachfrist durch die Bundesministerin oder den Bundesminister im Wege der Ersatzvornahme vorgenommen werden.

(23) Legt eine Universität den Entwurf einer ersten Leistungsvereinbarung der Bundesministerin oder dem Bundesminister nicht rechtzeitig vor, beträgt das Budget für das betreffende Jahr 98 vH des Budgets des Vorjahres.

(24) Die Fakultätsvertretungen gemäß § 15 des Hochschülerschaftsgesetzes 1998 an den Medizinischen Fakultäten der Universitäten Wien, Graz und Innsbruck für die Studienrichtungen Medizin, Humanmedizin, Zahnmedizin und das Doktoratsstudium der medizinischen Wissenschaft üben bezüglich der Vollziehung der Bestimmungen des Universitätsgesetzes 2002 bis 31. Dezember 2003 auch die Funktion der Universitätsvertretungen der Studierenden gemäß § 13 des Hochschülerschaftsgesetzes 1998 an den Medizinischen Universitäten Wien, Graz und Innsbruck aus und gelten ab 1. Jänner 2004 als diese Universitätsvertretungen.

(18) Every university shall prepare an inventory by the time of the entry of this Act into full effect. Such inventory shall set forth the movable and immovable assets with which the university has hitherto been endowed, and its liabilities to third parties, particularly loans; all bank accounts including security accounts; as well as the third-party funds of institutes (or clinics). A schedule listing the staff employed at the university on the day before the entry of this Act into full effect shall be appended to this inventory.

(19) The Federal Minister shall submit to the universities a report on the career advancement for junior academics and future developments with regard to university staffing not later than 30 September 2006.

(20) The constituent convention of each university shall appoint a representative to the national university federation not later than 31 December 2002. The term of office of such representative shall end upon the appointment of a new representative by the rectorate of the university concerned (§ 108 para 2).

(21) The rector of the University of Vienna shall call the constituent meeting of the national university federation (§ 108), and shall preside over this meeting until the election of a chairperson.

(22) In case that the necessary implementing measures are not taken in a timely manner, the Federal Minister may take the necessary action him-/herself by official notification without granting an extension.

(23) If a university fails to submit a draft initial performance agreement to the Federal Minister within the appointed period, the budget of that university for the year in question shall be 98 per cent of its budget for the previous year.

(24) The faculty representatives (§ 15 of the Students' Union Act 1998) of the medical faculties of the Universities of Vienna, Graz and Innsbruck for medicine, human medicine, dental medicine and doctoral studies in medical science shall, in respect of implementation of the provisions of the Universities Act 2002, continue to act as student representatives according to § 13 of the Students' Union Act 1998 at the Medical Universities of Vienna, Graz and Innsbruck until 31 December 2003, and shall be deemed to be the representatives of these universities from 1 January 2004.

(25) Die Bestimmungen dieses Bundesgesetzes werden an den Universitäten mit 1. Jänner 2004 voll wirksam.

2. Abschnitt
Organisation

Überleitung der Universitätsangehörigen gemäß UOG 1993 und KUOG

§ 122. (1) Alle zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes in einem Dienstverhältnis, Arbeitsverhältnis oder in einem sonstigen Rechtsverhältnis stehenden oder im Zeitraum zwischen dem In-Kraft-Treten und dem vollen Wirksamwerden dieses Bundesgesetzes neu in ein Dienst-, Arbeits- oder sonstiges Rechtsverhältnis aufgenommenen Universitätsangehörigen haben Rechte und Aufgaben nach Maßgabe dieses Bundesgesetzes.

(2) Im Übrigen gilt Folgendes:

1. Universitätsprofessorinnen und Universitätsprofessoren gemäß § 21 UOG 1993 oder § 22 KUOG gelten organisationsrechtlich als Universitätsprofessorinnen und Universitätsprofessoren gemäß § 97 dieses Bundesgesetzes;
2. emeritierte Universitätsprofessorinnen und Universitätsprofessoren und Universitätsprofessorinnen oder Universitätsprofessoren im Ruhestand gemäß § 24 UOG 1993 oder § 25 KUOG gelten organisationsrechtlich als emeritierte Universitätsprofessorinnen und Universitätsprofessoren oder Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand gemäß § 104 dieses Bundesgesetzes;
3. Gastprofessorinnen und Gastprofessoren gemäß § 25 UOG 1993 oder § 26 KUOG gelten organisationsrechtlich als Universitätsprofessorinnen und Universitätsprofessoren gemäß § 97 dieses Bundesgesetzes;
4. Universitätsdozentinnen und Universitätsdozenten gemäß § 27 Abs. 3 UOG 1993 oder § 28 Abs. 3 KUOG (Amtstitel: Außerordentliche Universitätsprofessorin oder Außerordentlicher Universitätsprofessor) gelten organisationsrechtlich als Universitätsdozentinnen und Universitätsdozenten gemäß § 94 Abs. 2 Z 2 dieses Bundesgesetzes;
5. Universitätsassistentinnen und Universitätsassistenten gemäß § 29 UOG 1993 oder § 30 KUOG und Ärztinnen und Ärzte in Ausbildung zur

(25) The provisions of this Act shall enter into full effect at the universities on 1 January 2004.

Chapter 2
Organisation

Transitional Arrangements for University Members under the University Organisation Act 1993 and Universities of the Arts Organisation Act

§ 122. (1) All university members with federal, university or other employment contracts at the time of the entry into force of this Act or accepted for service under federal, university or other employment contracts between the entry into force of this Act and its full entry into effect shall have rights and duties in accordance with the provisions of this Act.

(2) In addition, the following shall apply:

1. university professors according to § 21 University Organisation Act 1993 or § 22 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be university professors according to § 97 of this Act;
2. university professors emeriti and retired university professors according to § 24 University Organisation Act 1993 or § 25 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be university professors emeriti or retired university professors according to § 104 of this Act;
3. visiting professors according to § 25 University Organisation Act 1993 or § 26 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be university professors according to § 97 of this Act;
4. associate professors according to § 27 para 3 University Organisation Act 1993 or § 28 para 3 Universities of the Arts Organisation Act with the title of “Außerordentliche/r Universitätsprofessor/in” shall, for organisational purposes, be deemed to be associate professors according to § 94 para 2 subpara 2 of this Act;
5. assistant professors according to § 29 University Organisation Act 1993 or § 30 Universities of the Arts Organisation Act and physicians in specialists’

Fachärztin oder zum Facharzt gemäß § 33 Abs. 1 Z 1 UOG 1993 in Verbindung mit § 19 Abs. 2 Z 1 lit. f UOG 1993 (Universitätsassistenten) gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;

6. Wissenschaftliche Mitarbeiterinnen und Mitarbeiter im Forschungs- und Lehrbetrieb gemäß § 32 UOG 1993 und Mitarbeiterinnen und Mitarbeiter im Kunst-, Forschungs- und Lehrbetrieb gemäß § 33 KUOG gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;
7. Studienassistentinnen und Studienassistenten gemäß § 34 UOG 1993 oder § 34 KUOG gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;
8. Lehrbeauftragte gemäß § 30 UOG 1993 oder § 31 KUOG gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;
9. die Wissenschaftlichen Mitarbeiterinnen und Mitarbeiter im Forschungs- und Lehrbetrieb gemäß § 19 Abs. 2 Z 2 UOG 1993 sind, soweit sie arbeitsrechtlich zur Gruppe der Wissenschaftlichen und Künstlerischen Mitarbeiterinnen und Mitarbeiter (in Ausbildung) gemäß § 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, gehören, organisationsrechtlich den wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeitern im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes gleichgestellt;
10. die Mitarbeiterinnen und Mitarbeiter im Kunst-, Forschungs- und Lehrbetrieb gemäß § 20 Abs. 2 Z 2 KUOG sind, soweit sie arbeitsrechtlich zur Gruppe der Wissenschaftlichen und Künstlerischen Mitarbeiter (in Ausbildung) gemäß § 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, gehören, organisationsrechtlich den wissenschaftlichen und künstlerischen

training according to § 33 para 1 subpara 1 University Organisation Act 1993 in conjunction with § 19 para 2 subpara 1 lit f University Organisation Act 1993 (assistant professors) shall, for organisational purposes, be deemed to be academic or artistic staff engaged in research, the arts or teaching according to § 100 of this Act;

6. scientific staff engaged in research and teaching according to § 32 University Organisation Act 1993 and staff engaged in the arts, research and teaching according to § 33 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be academic or artistic staff engaged in research, the arts or teaching according to § 100 of this Act.
7. teaching assistants according to § 34 University Organisation Act 1993 or § 34 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be scientific or artistic staff engaged in research, the arts or teaching according to § 100 of this Act;
8. external lecturers according to § 30 University Organisation Act 1993 or § 31 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be scientific or artistic staff engaged in research, the arts or teaching according to § 100 of this Act;
9. academic staff engaged in teaching and research according to § 19 para 2 subpara 2 University Organisation Act 1993 shall, if classed as junior academic or artistic staff according to § 6 of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act, F. L. G. No 463/1974, for organisational purposes be accorded equal status to scientific or artistic staff engaged in research, the arts or teaching according to § 100 of this Act;
10. staff engaged in the arts, teaching and research according to § 20 para 2 subpara 2 Universities of the Arts Organisation Act 1993 shall, if classed as trainee scientific or artistic staff according to § 6 of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act, F. L. G. No 463/1974, for organisational purposes be accorded equal status to scientific or artistic staff engaged in research, the arts or teaching according to § 100 of this Act;

Mitarbeiterinnen und Mitarbeitern im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes gleichgestellt;

11. Ärztinnen und Ärzte in Ausbildung zur Fachärztin oder zum Facharzt gelten, soweit sie nicht unter Z 5 oder Z 9 fallen, organisationsrechtlich als Ärztinnen und Ärzte in Facharztausbildung gemäß § 94 Abs. 3 Z 6 dieses Bundesgesetzes;
12. Ärztinnen und Ärzte gemäß § 33 Abs. 2 UOG 1993 gelten organisationsrechtlich als allgemeines Universitätspersonal gemäß § 101 dieses Bundesgesetzes;
13. Allgemeine Universitätsbedienstete gemäß § 35 UOG 1993 oder gemäß § 35 KUOG gelten organisationsrechtlich als allgemeines Universitätspersonal gemäß § 101 dieses Bundesgesetzes;
14. Universitätsdozentinnen und Universitätsdozenten gemäß § 27 UOG 1993 oder gemäß § 28 KUOG, die als solche in keinem Dienstverhältnis (§ 170 BDG 1979, § 55 Vertragsbedienstetengesetz 1948) stehen, gelten organisationsrechtlich als Privatdozentinnen und Privatdozenten gemäß § 102 dieses Bundesgesetzes;
15. Honorarprofessorinnen und Honorarprofessoren gemäß § 26 UOG 1993 oder § 27 KUOG gelten organisationsrechtlich als Privatdozentinnen und Privatdozenten gemäß § 102 dieses Bundesgesetzes.

(3) Universitätsdozentinnen und Universitätsdozenten (Amtstitel: Ao. Universitätsprofessorinnen und Universitätsprofessoren) gemäß Abs. 2 Z 4 bleibt das Recht gewahrt, die wissenschaftliche oder künstlerische Lehre in ihrem Fach an der Universität, die ihnen die Lehrbefugnis (venia docendi) verliehen hat, mittels der Einrichtungen der Universität frei auszuüben, die Einrichtungen dieser Universität für wissenschaftliche oder künstlerische Arbeiten zu benützen und wissenschaftliche oder künstlerische Arbeiten (§§ 81 bis 83, § 124) zu betreuen und zu beurteilen. Darüber hinaus haben sie das Recht, auf dem Gebiet ihrer Lehrbefugnis Lehrveranstaltungen auch an anderen Universitäten, zu deren Wirkungsbereich das Fachgebiet ihrer Lehrbefugnis gehört, anzukündigen und nach Maßgabe der räumlichen Möglichkeiten abzuhalten.

(4) Die im Abs. 3 genannten Universitätsdozentinnen und Universitätsdozenten haben folgende Aufgaben verantwortlich wahrzunehmen:

1. Forschungstätigkeit (Entwicklung und Erschließung der Künste);

11. physicians in specialists' training to the extent that paragraphs 5 or 9 are not applicable to them shall, for organisational purposes, be deemed to be physicians in specialists' training according to § 94 para 3 subpara 6 of this Act;
12. physicians according to § 33 para 2 University Organisation Act 1993 shall, for organisational purposes, be deemed to be non-academic university staff according to § 101 of this Act;
13. non-academic university staff according to § 35 University Organisation Act 1993 or § 35 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be non-academic university staff according to § 101 of this Act;
14. associate professors according to § 27 University Organisation Act 1993 or § 28 Universities of the Arts Organisation Act who are not employed (§ 170 of the Civil Service Code 1979 or § 55 of the Contractual Employees Act 1948) shall, for organisational purposes, be deemed to be non-tenured associate professors according to § 102 of this Act.
15. honorary professors according to § 26 University Organisation Act 1993 or § 27 Universities of the Arts Organisation Act shall, for organisational purposes, be deemed to be non-tenured associate professors according to § 102 of this Act.

(3) Associate professors with the title of "Außerordentliche/r Universitätsprofessor/in" under para 2 subpara 4 shall be entitled to freely exercise their venia docendi for their scientific or artistic subject at the university which has granted it, using that university's facilities, to use the facilities of such university for scientific or artistic work, and to supervise and assess academic theses or art submissions (§§ 81 to 83, § 124). They shall, further, have the right to offer courses in the field covered by their venia docendi at other universities, the activities of which include this subject, and to hold such courses, subject to the availability of premises.

(4) The associate professors referred to in para 3 shall perform the following duties in a responsible manner:

1. conducting research, or advancing the arts and appreciation thereof;

2. Durchführung von Lehrveranstaltungen, insbesondere der Pflichtlehrveranstaltungen, in Vertretung ihres Faches, nach Maßgabe des Bedarfs, unter Berücksichtigung der Studienvorschriften;
3. Durchführung von Prüfungen;
4. Betreuung von Studierenden;
5. Heranbildung und Förderung des wissenschaftlichen oder künstlerischen Nachwuchses;
6. Mitwirkung an Organisations-, Verwaltungs- und Managementaufgaben;
7. Mitwirkung bei Evaluierungsmaßnahmen.

(5) Auf Vorschlag der Mehrheit der Universitätsprofessorinnen und Universitätsprofessoren einer Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst können die im Abs. 3 genannten Universitätsdozentinnen und Universitätsdozenten vom Rektorat abweichend von § 20 Abs. 5 mit der Leitung dieser Organisationseinheit betraut werden.

(6) Hinsichtlich der Wahl in Kollegialorgane gehören die in Abs. 3 genannten Universitätsdozentinnen und Universitätsdozenten zu der im § 94 Abs. 2 Z 2 genannten Gruppe.

(7) Universitätsdozentinnen und Universitätsdozenten gemäß Abs. 2 Z 14 sowie Honorarprofessorinnen und Honorarprofessoren gemäß Abs. 2 Z 15 bleibt das Recht gewahrt, die wissenschaftliche oder künstlerische Lehre in ihrem Fach an der Universität, die ihnen die Lehrbefugnis verliehen hat, mittels der Einrichtungen der Universität frei auszuüben sowie wissenschaftliche oder künstlerische Arbeiten (§§ 81 bis 83, § 124) zu betreuen und zu beurteilen. Darüber hinaus haben sie das Recht, auf dem Gebiet ihrer Lehrbefugnis Lehrveranstaltungen auch an anderen Universitäten, zu deren Wirkungsbereich das Fachgebiet ihrer Lehrbefugnis gehört, anzukündigen und nach Maßgabe der räumlichen Möglichkeiten abzuhalten.

Übergangsbestimmungen für Berufungskommissionen, Habilitationskommissionen und besondere Habilitationskommissionen

§ 123. Berufungskommissionen, Habilitationskommissionen und besondere Habilitationskommissionen, die vor dem vollen Wirksamwerden dieses Bundesgesetzes an der betreffenden Universität oder Universität der Künste konstituiert wurden und ihre Tätigkeit bereits aufgenommen haben, haben das Verfahren in ihrer bisherigen Zusammensetzung und nach den bisherigen Bestimmungen durchzuführen.

2. course teaching in their subject, particularly of required courses, in accordance with teaching needs and having regard to the study regulations;
3. examining;
4. supervising students;
5. training and career promotion of junior academics and young artists;
6. assuming organisational, administrative and managerial responsibilities;
7. participating in evaluation procedures.

(5) On the recommendation of a majority of the university professors in an organisational unit with research and teaching responsibilities, or responsibilities with regard to the advancement and appreciation of the arts and art teaching, the associate professors referred to in para 3 may, notwithstanding § 20 para 5, be entrusted with the management of such organisational unit.

(6) In respect of election to collegial bodies, the associate professors referred to in para 3 shall form part of the group of persons referred to in § 94 para 2 subpara 2.

(7) Associate professors under para 2 subpara 14 and honorary professors under para 2 subpara 15 shall be entitled to freely exercise their venia docendi for their scientific or artistic subject at the university which has granted it, using that university's facilities, to use the facilities of such university for scientific or artistic work, and to supervise and assess academic theses or art submissions (§§ 81 to 83, § 124). They shall, further, have the right to offer courses in the field covered by their venia docendi at other universities, the activities of which include this subject, and to hold such courses, subject to the availability of premises.

Transitional Arrangements for Appointment Committees, Habilitation Committees and Special Habilitation Committees

§ 123. Appointment committees, habilitation committees and special habilitation committees appointed prior to the entry of this Act into full effect and having already taken up their duties shall conduct the procedures in question as previously constituted and in accordance with the previous regulations.

Übergangsbestimmungen für die Errichtung einer Medizinischen Fakultät

§ 123a. Die gemäß § 29 Abs. 9 vorletzter Satz konkret betrauten Bediensteten des Rechtsträgers einer Krankenanstalt sind in den ersten drei Jahren ab dem im Organisationsplan der Universität vorgesehenen Zeitpunkt der Einrichtung einer Medizinischen Fakultät organisationsrechtlich nur dann den Universitätsangehörigen gemäß § 94 Abs. 2 Z 2 gleichgestellt, wenn sie in einem Durchrechnungszeitraum von 26 Wochen mindestens 30 vH der Normalarbeitszeit bezogen auf die jeweilige Organisationseinheit mit Aufgaben der universitären Lehre und Forschung betraut werden. In Ausnahmefällen kann das Rektorat auf Antrag von gemäß § 29 Abs. 9 vorletzter Satz konkret betrauten Bediensteten des Rechtsträgers einer Krankenanstalt in den ersten drei Jahren ab dem im Organisationsplan der Universität vorgesehenen Zeitpunkt der Einrichtung einer Medizinischen Fakultät diesen die Angehörigeneigenschaft zuerkennen, wenn dies im universitären Interesse ist.

§ 123b. (1) Bei Errichtung einer Medizinischen Fakultät hat der Entwicklungsplan die entsprechenden Stellenwidmungen für Universitätsprofessorinnen und Universitätsprofessoren im Klinischen und Nichtklinischen Bereich nach § 98 Abs. 1 vorzusehen.

(2) Vor der Bestellung von Gutachterinnen und Gutachtern gemäß § 98 Abs. 3 haben die im Senat vertretenen Universitätsprofessorinnen und Universitätsprofessoren Vorschläge mindestens zweier Universitätsprofessorinnen oder Universitätsprofessoren des Fachbereichs mindestens zweier anderer Universitäten einzuholen. Es sind mindestens drei externe Gutachterinnen oder Gutachter zu bestellen.

(3) Der Berufungskommission haben Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs mindestens zweier anderer Universitäten anzugehören.

(4) Eine Berufung nach § 99 kann nur in besonders begründeten Ausnahmefällen erfolgen. In solchen Fällen hat die Rektorin oder der Rektor die Universitätsprofessorinnen und die Universitätsprofessoren nach Anhörung mindestens zweier Universitätsprofessorinnen oder Universitätsprofessoren des fachlichen Bereichs mindestens zweier anderer Universitäten, auszuwählen. Die Auswahl der zwei Universitätsprofessorinnen oder Universitätsprofessoren des fachlichen Bereichs mindestens zweier anderer Universitäten durch die Rektorin oder den Rektor erfolgt nach Anhörung des Senats.

(5) Abs. 2 bis 4 sind ab dem Bestehen eines Fachbereiches für die fachliche Widmung der zu besetzenden Stelle nicht mehr anzuwenden.

Transitional Provisions for the Establishment of a Faculty of Medicine

§ 123a. In the first three years after the date set for the establishment of a faculty of medicine in the university's organisation plan, the employees of the maintaining body of the attached hospital under § 29 para 9, penultimate sentence, who have been entrusted with university tasks shall only be accorded equal status to university members according to § 94 para 2 subpara 2, if they are entrusted with university teaching and research for at least 30% of their normal working hours within a reference period of 26 weeks, relating to the respective organisational unit. In exceptional cases, the rectorate may, on application of the employees of the maintaining body of the attached hospital under § 29 para 9, penultimate sentence, who have been entrusted with university tasks, accord equal status to them in the first three years after the date set for the establishment of a faculty of medicine in the university's organisation plan, if this is in the interest of the university.

§ 123b. (1) When establishing a faculty of medicine, the development plan shall provide for the required allocation of positions for university professors in the clinical and non-clinical departments pursuant to § 98 para 1.

(2) Prior to the appointment of assessors under § 98 para 3, the professorial members of the senate shall obtain suggestions from at least two university professors in a relevant field from at least two other universities. At least three external assessors shall be appointed.

(3) The appointment committee shall consist of university professors of the field in question from at least two other universities.

(4) An appointment under § 99 shall only be permissible in exceptional, justified cases. In such cases, the rector shall select the university professors after hearing the opinion of at least two university professors of a relevant field from at least two other universities. The rector shall select university professors of a relevant field from at least two other universities after hearing the opinion of the senate.

(5) Paras 2 to 4 shall no longer apply, once a department has been established for the field of the position to be filled.

(6) Die Abs. 2 und 3 gelten sinngemäß auch für Habilitationsverfahren gemäß § 103, solange an der Medizinischen Fakultät noch kein entsprechender Fachbereich besteht.

3. Abschnitt

Studienrecht

§ 124. (1) Die an den Universitäten am 1. Oktober 2003 eingerichteten Diplom-, Bakkalaureats-, Magister- und Doktoratsstudien bleiben an diesen Universitäten, solange keine entgegenstehenden Entscheidungen gemäß § 54 dieses Bundesgesetzes getroffen werden, weiterhin eingerichtet. Auf diese Studien sind die jeweiligen Studienpläne in der am 1. Oktober 2003 geltenden Fassung weiterhin anzuwenden und diese Studienpläne dürfen gemäß § 25 Abs. 1 Z 10 auch abgeändert werden. An Absolventinnen und Absolventen dieser Diplomstudien sowie dieser Bakkalaureats- oder Magisterstudien sind jeweils jene akademischen Grade zu verleihen, die am 1. Oktober 2003 für die jeweiligen Studien vorgesehen sind. § 80 bis § 80b UniStG sind sinngemäß anzuwenden. Werden an Stelle bestehender Studien gemäß § 54 Abs. 1 Bakkalaureats-, Magister- oder Doktoratsstudien eingerichtet, so sind in den Curricula den § 80 Abs. 2 und § 80a Abs. 2 UniStG entsprechende Übergangsbestimmungen vorzusehen.

(1a) Für angebotene Diplomstudien sind die in Anlage 1 zum UniStG vorgesehenen akademischen Grade zu verleihen. Der Umfang dieser Diplomstudien richtet sich ebenfalls nach Anlage 1 zum UniStG.

(2) Die Studienkommissionen haben bis zum 1. Juli 2003 allen gemäß UniStG erlassenen Studienplänen ECTS-Anrechnungspunkte im Sinne des § 13 Abs. 4 Z 9 und § 19 Abs. 4 UniStG zuzuteilen.

(3) Die an den Universitäten am 31. Dezember 2003 gemäß UniStG eingerichteten Universitätslehrgänge und Vorbereitungslehrgänge bleiben an den Universitäten weiterhin eingerichtet. Auf diese Studien sind die jeweiligen Studienpläne in der am 31. Dezember 2003 geltenden Fassung weiterhin anzuwenden.

(4) § 77 ist ab dem 1. Oktober 2003 anzuwenden. Für die Wiederholung von Prüfungen, die vor dem 1. Oktober 2003 negativ beurteilt wurden, ist statt § 77 dieses Bundesgesetzes der § 58 Abs. 1 bis Abs. 6 UniStG, in der zuletzt geltenden Fassung, anzuwenden.

(6) Paras 2 and 3 shall apply by analogy to procedures for the awarding of licenses to teach under § 103, as long as the respective department at the faculty of medicine has not been established yet.

Chapter 3

Study Law

§ 124. (1) Diploma, bachelor, master and doctoral programmes offered at universities as of 1 October 2003 shall continue to be offered at those universities unless decisions to the contrary according to § 54 of this Act are made. The respective curricula for these programmes in the versions valid as of 1 October 2003 shall continue to apply, but such curricula may be amended according to § 25 para 1 subpara 10. Graduates of such diploma, bachelor's or master's programmes shall be awarded the degrees designated for the respective studies as of 1 October 2003. § 80 to § 80b University Studies Act shall apply by analogy. If new bachelor, master or doctoral programmes are introduced in place of existing programmes according to § 54 para 1, provision shall be made in the curricula for transitional arrangements corresponding to § 80 para 2 and § 80a para 2 University Studies Act.

(1a) For the diploma programmes offered, the academic degrees prescribed in Appendix 1 to the University Studies Act shall be awarded. The scope of these diploma programmes shall also be governed by Appendix 1 to the University Studies Act

(2) Pursuant to § 13 para 4 subpara 9 and § 19 para 4 University Studies Act, curriculum committees shall allocate ECTS credits to all curricula adopted under the University Studies Act.

(3) Certificate university programmes for further education and preparatory continuing education courses introduced under the University Studies Act offered at universities as of 31 December 2003 shall continue to exist. The respective curricula for these programmes in the versions valid as of 31 December 2003 shall continue to apply.

(4) From 1 October 2003, § 77 shall apply. Repetition of examinations failed before 1 October 2003 shall be subject to § 6 paras 77 to 58 University Studies Act, as last amended, instead of § 1 of this Act.

(Anm.: Abs. 5 aufgehoben durch Art. 1 Z 162, BGBl. I Nr. 93/2021)

(6) Auf Anträge gemäß den §§ 27 und 28 UniStG, die vor dem 1. Jänner 2004 anhängig gemacht wurden, sind die §§ 27 und 28 UniStG, in der zuletzt geltenden Fassung, anzuwenden.

(6a) Außeruniversitäre Bildungseinrichtungen, auf die zum Zeitpunkt des Inkrafttretens der Änderung des Universitätsgesetzes 2002 durch das Bundesgesetz BGBl. I Nr. 81/2009 eine Verordnung gemäß §§ 27 und 28 UniStG anzuwenden ist und die im Jahr 2009 diesen Lehrgang anbieten, haben bis zum 30. Juni 2010 das Recht auf Antragstellung um Verlängerung der Gültigkeitsdauer dieser Verordnung. Die Verordnungen sind bis längstens 31. Dezember 2012 zu befristen.

(7) Auf jene Nostrifizierungsverfahren, die an den Universitäten gemäß § 6 Z 16 bis 21 vor dem 1. August 1998 anhängig gemacht wurden, ist statt § 90 dieses Bundesgesetzes § 49 KHStG anzuwenden. Auf jene Nostrifizierungsverfahren, die an den Universitäten gemäß § 6 Z 1 bis 15 vor dem 1. August 1997 anhängig gemacht wurden, ist statt § 90 dieses Bundesgesetzes § 40 AHStG anzuwenden. Auf jene Nostrifizierungsverfahren, die an den Universitäten bis zum 31. Dezember 2003 anhängig gemacht werden, sind statt § 90 dieses Bundesgesetzes die §§ 70 bis 73 UniStG anzuwenden.

(8) Auf ordentliche Studierende, die an den Universitäten vor dem 1. Jänner 2004 zu einem individuellen Diplomstudium zugelassen wurden, ist § 17 UniStG weiterhin anzuwenden.

(9) § 64 Abs. 1 Z 6 und § 78 Abs. 1 sind nur für jene Lehrgänge universitären Charakters anzuwenden, denen die Berechtigung zur Bezeichnung nach dem 1. September 2001 verliehen wurde.

(10) Bisherige Bakkalaureatsstudien und Magisterstudien gelten als Bachelorstudien und Masterstudien gemäß § 51 Abs. 2 Z 4 und 5, bisherige Bakkalaureatsarbeiten und Magisterarbeiten gelten als Bachelorarbeiten und Masterarbeiten gemäß § 51 Abs. 2 Z 7 bis 8.

(11) Bis zur Änderung der akademischen Grade aufgrund des § 51 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 74/2006 in den betreffenden Curricula sind die bisherigen akademischen Grade weiter zu verleihen.

(12) Absolventinnen und Absolventen, die vor In-Kraft-Treten des Bundesgesetzes BGBl. I Nr. 74/2006 das Studium begonnen haben, sind jene akademischen Grade zu verleihen, die zum Zeitpunkt des In-Kraft-Tretens des Bundesgesetzes BGBl. I Nr. 74/2006 für dieses Studium vorgesehen sind. Über

(5) [removed]

(6) §§ 27 and 28 University Studies Act, as last amended, shall apply to applications according to §§ 27 and 28 University Studies Act pending before 1 January 2004.

(6a) Non-university educational institutions to which a decree pursuant to §§ 27 and 28 University Studies Act applies at the time of the entry into force of the amendment to the Universities Act 2002 by F. L. G. I No 81/2009 and which offer this programme in the year 2009 shall have to right, until 30 June 2010, to apply for prolongation of the applicability of this decree. The decrees shall be limited to 31 December 2012 at the latest.

(7) § 49 of the Universities of the Arts Studies Act shall apply instead of § 90 of this Act to nostrification procedures pending before 1 August 1998 at the universities named in § 6 subparas 16 to 21. §40 of the General Higher Education Studies Act shall apply instead of § 90 of this Act to nostrification procedures pending before 1 August 1997 at the universities named in § 6 subparas 1 to 15. §§ 70 to 73 University Studies Act shall apply instead of § 90 of this Act to nostrification procedures at universities pending up to 31 December 2003.

(8) § 17 University Studies Act shall continue to apply to degree students admitted to individual diploma programmes before 1 January 2004.

(9) § 64 para 1 subpara 6 and § 78 para 1 shall only apply to university-level courses recognized as such after 1 September 2001.

(10) Prior bachelor's and master's programmes shall be regarded as bachelor's and master's programmes according to § 51 para 2 subparas 4 and 5, prior bachelor's papers and master's theses shall be regarded as bachelor's papers and master's theses according to § 51 para 2 subparas 7 to 8.

(11) Until the change of the academic degrees according to § 51 para 2 as amended by the Federal Act F. L. G. I No 74/2006, will take place in the relevant curricula, the prior academic degrees shall continue to be awarded.

(12) Graduates who have started their studies before entering into force of the Federal Act, F. L. G. I No 74/2006, shall be awarded those academic degrees which are provided for at the time of entering into force of the Federal Act, F. L. G. I No 74/2006, for the relevant study programme. On demand of the holder, there shall

Antrag sind anstelle dieser akademischen Grade die akademischen Grade „Bachelor ...“, oder „Master ...“, jeweils mit dem im Curriculum festgelegten Zusatz zu verleihen, wenn diese akademischen Grade in den Curricula festgelegt sind.

(13) Absolventinnen und Absolventen, die vor In-Kraft-Treten des Bundesgesetzes BGBl. I Nr. 74/2006 aufgrund eines abgeschlossenen Bakkalaureats- oder Magisterstudiums das Recht zur Führung eines akademischen Grades „Bakkalaurea/Bakkalaureus ...“, oder „Magistra/Magister ...“, jeweils mit einem Zusatz, sowie „Diplom-Ingenieurin/Diplom-Ingenieur“, erworben haben, sind berechtigt, anstelle dieser akademischen Grade die akademischen Grade „Bachelor …“ oder „Master …“, jeweils mit dem im Curriculum festgelegten Zusatz zu führen, wenn diese akademischen Grade in den Curricula festgelegt sind. Auf Antrag hat die Universität, die den akademischen Grad verliehen hat, darüber eine Bestätigung auszustellen.

(14) Auf Anträge auf Anerkennung von Dissertationen gemäß § 85, die vor dem In-Kraft-Treten des § 85 in der Fassung des Bundesgesetzes BGBl. I Nr. 74/2006 anhängig gemacht wurden, ist § 85 in der bis dahin geltenden Fassung anzuwenden.

(15) Ordentliche Studierende, die Doktoratsstudien betreiben, welche mit einem Arbeitsaufwand von mindestens 120 ECTS-Anrechnungspunkten vor dem Inkrafttreten des § 54 Abs. 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 74/2006 eingerichtet wurden, sind berechtigt, diese Studien bis längstens 30. November 2017 nach diesen Vorschriften abzuschließen. Ab dem Studienjahr 2009/10 darf eine Zulassung zu einem Doktoratsstudium, dessen Mindeststudiendauer weniger als drei Jahre beträgt, nicht mehr erfolgen.

4. Abschnitt
Überleitung des Personals

Beamtinnen und Beamte des Bundes

§ 125. (1) Für den Bereich jeder Universität wird ein „Amt der Universität ...“ eingerichtet, das in seiner Bezeichnung den Namen der betreffenden Universität zu führen hat. Das „Amt der Universität ...“ ist der Bundesministerin oder dem Bundesminister unmittelbar nachgeordnet und wird von der Rektorin oder dem Rektor dieser Universität geleitet. Diese oder dieser ist in dieser Funktion an die Weisungen der Bundesministerin oder des Bundesministers gebunden. Das „Amt der Universität ...“ ist die zuständige Dienstbehörde. In Dienstrechtsverfahren hat die

be awarded, instead of these academic degrees, the academic degrees “Bachelor …” or “Master …”, each followed by the suffix designated by the curriculum, provided that these academic degrees are provided for in the curricula.

(13) Graduates who have gained, on the basis of a completed bachelor’s or master’s programme, before entering into force of the Federal Act, F. L. G. I No 74/2006, the right to use an academic degree “Bakkalaurea/Bakkalaureus …”, or “Magistra/Magister …”, each followed by a suffix, as well as “Diplom-Ingenieurin/Diplom-Ingenieur”, shall be entitled to use, instead of these academic degrees, the academic degrees “Bachelor …” or “Master …”, each followed by the suffix designated by the curriculum, provided that these academic degrees are provided for in the curricula. On demand of the holder, the university which has awarded the academic degree shall deliver a confirmation on that.

(14) To applications for the recognition of doctoral theses according to § 85 which have been filed before entering into force of § 85 as amended by the Federal Act F. L. G. I No 74/2006, § 85 in the version which has been in force up to that time shall apply.

(15) Degree students who are enrolled in doctoral programmes which were installed with a minimum workload of 120 ECTS credits before the entry into force of § 54 para 4, as amended by F. L. G. I No 74/2006, shall be entitled to complete their studies by 30 November 2017 at the latest, according to these provisions. From the academic year 2009/10, the admission to a doctoral programme the minimum duration of which is less than three years must not take place any more.

Chapter 4
Transition of University Staff

Permanent Federal Civil Servants

§ 125. (1) For each university, a “university office”, bearing the name of the respective university, shall be established. The university office shall report directly to the Federal Minister, and shall be headed by the rector of the respective university. The rector shall be bound by ministerial instructions in this capacity. The university office shall be the competent employing authority. In matters concerning employment law procedures, the rector in his/her capacity as head of the university office shall apply the Federal Employment Law Procedure Act 1984, F. L. G.

Rektorin oder der Rektor als Leiterin oder Leiter des „Amts der Universität ...“ das Dienstrechtsverfahrensgesetz 1984, BGBl. Nr. 29/1984, anzuwenden. Über Beschwerden gegen Bescheide des „Amts der Universität …“ entscheidet das Bundesverwaltungsgericht.

(2) Beamtinnen oder Beamte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität im Planstellenbereich Universitäten oder Universitäten der Künste ernannt sind, gehören ab dem auf diesen Zeitpunkt folgenden Tag (Stichtag) für die Dauer ihres Dienststandes dem Amt jener Universität an, deren Aufgaben sie überwiegend besorgt haben, und sind dieser Universität zur dauernden Dienstleistung zugewiesen, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(3) Beamtinnen und Beamte, die in einem anderen Planstellenbereich ernannt und der Universität zur Dienstleistung zugewiesen sind, gelten bei entsprechendem Bedarf ab dem Stichtag weiterhin der Universität zur Dienstleistung zugewiesen.

(4) Beamtinnen oder Beamte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität im Planstellenbereich Universitäten ernannt und einer Einrichtung einer Medizinischen Fakultät zugeordnet sind, gehören ab dem auf diesen Zeitpunkt folgenden Tag (Stichtag) für die Dauer ihres Dienststandes dem Amt jener Medizinischen Universität an, welche die Nachfolgeeinrichtung der betreffenden Medizinischen Fakultät ist, und sind dieser Medizinischen Universität zur dauernden Dienstleistung zugewiesen, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(5) Beamtinnen oder Beamte, die zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes einer Interuniversitären Einrichtung zugeordnet sind oder in der Zeit danach zugeordnet werden, gelten mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität, welche die Nachfolgeeinrichtung der betreffenden Interuniversitären Einrichtung ist, als dieser Universität zugeordnet, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(6) Die in den Abs. 2 bis 5 genannten und in einem definitiven Bundesdienstverhältnis stehenden Beamtinnen und Beamten sind den Arbeitnehmerinnen und Arbeitnehmern der Universität in einem unbefristeten Arbeitsverhältnis organisationsrechtlich gleichgestellt.

(7) Die Verwendung der Beamtinnen und Beamten gemäß Abs. 2 bis 5 in einer Gesellschaft, an der die Universität mehrheitlich beteiligt ist, ist unter Beachtung der Art. 17 und 17a StGG zulässig.

No 29/1984. The Federal Administrative Court shall find on appeals against official notifications issued by the university office.

(2) Civil servants with budgeted posts at a university or a university of the arts as of the day before the entry of this Act into full effect shall, from the following day (effective date) and for the duration of their service, be assigned to the office of that university where their duties have predominantly been performed, and shall be permanently assigned to such university unless transferred to another federal post.

(3) Civil servants with other budgeted posts and assigned to service at a university shall be deemed to continue to be assigned to service at such university from the effective date onwards.

(4) Civil servants with budgeted university posts who are assigned to an organisational unit of a faculty of medicine as of the day before the entry of this Act into full effect shall, from the following day (effective date) and for the duration of their service, be assigned to the office of that medical university which is the successor institution of the faculty concerned, and shall be permanently assigned to such medical university unless transferred to another federal post.

(5) Civil servants assigned to inter-university institutions at the time of the entry into force of this Act or thereafter shall, as of the day of the entry of this Act into full effect, be deemed to be assigned to that university which is the successor institution of the inter-university institution concerned unless transferred to another federal post.

(6) Civil servants in the categories referred to in paras 2 to 5 and having permanent federal employment contracts shall have the same organisational rights and duties as university employees with permanent employment contracts.

(7) The assignment of civil servants under paras 2 to 5 to a company in which the university holds a majority interest is permissible, subject to Art 17 and 17a Basic Law on the General Rights of Nationals.

(8) Dem „Amt der Universität ...“ zugewiesene Beamtinnen und Beamte gemäß Abs. 2, 4 und 5 in einem definitiven Dienstverhältnis haben, wenn sie innerhalb von drei Jahren ab dem Stichtag ihren Austritt aus dem Bundesdienst erklären, mit Wirksamkeit von dem auf den Austritt folgenden Monatsersten Anspruch auf Aufnahme in ein Arbeitsverhältnis zur betreffenden Universität zu den zu diesem Zeitpunkt für neu eintretende Arbeitnehmerinnen und Arbeitnehmer geltenden Bestimmungen.

(9) Dem „Amt der Universität ...“ zugewiesene Beamtinnen und Beamte gemäß Abs. 2, 4 und 5, die sich zum Stichtag im provisorischen Dienstverhältnis (§§ 10 und 177 BDG 1979) befinden, haben, wenn sie innerhalb von drei Jahren ab ihrer Definitivstellung ihren Austritt aus dem Bundesdienst erklären, mit Wirksamkeit von dem auf den Austritt folgenden Monatsersten Anspruch auf Aufnahme in ein Arbeitsverhältnis zur betreffenden Universität zu den zu diesem Zeitpunkt für neu eintretende Arbeitnehmerinnen und Arbeitnehmer geltenden Bestimmungen.

(10) Die beim Bund zurückgelegte Dienstzeit ist in den Fällen der Abs. 8 und 9 für alle zeitabhängigen Ansprüche anzurechnen. Forderungen des Bundes gegenüber diesen Bediensteten aus ihrem öffentlich-rechtlichen Dienstverhältnis, die bis zum Austritt entstanden sind, gehen bei Begründung eines Arbeitsverhältnisses zur Universität auf die Universität über und sind von dieser dem Bund zu refundieren.

(11) Eine Beamtin oder ein Beamter, die oder der in ein Arbeitsverhältnis zur Universität übertritt, hat keinen Anspruch auf Abfertigung gemäß § 26 und § 54 des Gehaltsgesetzes 1956, BGBl. Nr. 54. Wird eine Beamtin oder ein Beamter, die oder der gemäß § 21 BDG 1979 in Verbindung mit § 26 Abs. 3 Gehaltsgesetz 1956 aus dem Dienstverhältnis ausgetreten ist, innerhalb von sechs Monaten nach Beendigung dieses Dienstverhältnisses in ein Arbeitsverhältnis zur Universität aufgenommen, hat sie oder er der Universität die anlässlich der Beendigung des bisherigen Dienstverhältnisses gemäß § 26 Abs. 3 Gehaltsgesetz 1956 erhaltene Abfertigung zu erstatten.

(12) Für dem „Amt der Universität ...“ zugewiesene Beamtinnen und Beamten hat die Universität dem Bund den gesamten Aktivitätsaufwand samt Nebenkosten zu ersetzen und einen Beitrag zur Deckung des Pensionsaufwands zu leisten. Dieser Beitrag beträgt 31,8 vH des Aufwandes an Aktivbezügen. Als Aktivbezüge gelten alle Geldleistungen, von denen ein Pensionsbeitrag zu entrichten ist. Die von den Beamtinnen und Beamten einzubehaltenden Pensionsbeiträge sind anzurechnen. Im Falle einer künftigen Änderung der Höhe des Pensionsbeitrages der

(8) Civil servants under paras 2, 4 and 5 with permanent employment contracts who are assigned to a university office and who give note of resignation from the federal civil service within three years of the effective date shall be entitled to employment by the university concerned on the terms and conditions applicable to new employees at that time, with effect from the first day of the month after termination.

(9) Civil servants under paras 2 to 5 who, being assigned to a university office and having provisional employment contracts (§§ 10 and 177 Civil Service Code 1979) as of the effective date, give notice of resignation from the federal civil service within three years of their permanent appointment, shall be entitled to employment by the university concerned on the terms and conditions applicable to new employees at that time, with effect from the first day of the month after termination.

(10) In the circumstances set out in paras 8 and 9 the period of service with the Federal Government shall count towards all service-dependent entitlements. Claims of the Federal Government against such employees arising from their public employment prior to termination shall be assigned to the university concerned upon the commencement of employment by it, and shall be refunded by such university to the Federal Government.

(11) A civil servant who transfers his/her employment to a university shall not be entitled to a severance payment according to §§ 26 and 54 of the Salaries Act 1956, F. L. G. No 54. If a civil servant who has resigned according to § 21 Civil Service Code 1979 in conjunction with § 26 para 3 of the Salaries Act 1956 enters the employment of a university within six months of termination of his/her civil service employment, he/she shall be obliged to remit to the university the severance payment received upon termination of the previous employment according to § 26 para 3 of the Salaries Act.

(12) Universities shall reimburse to the Federal Government the entire salaries and non-salary costs incurred by it in respect of civil servants assigned to university offices, and shall contribute to the pension expense arising from their employment. Such contributions shall represent 31.8 percent of gross salary. A salary shall be deemed to constitute all payments in respect of which a pension contribution is to be paid. Employee pension contributions deducted at source shall be counted towards salary. In the case of a future change in the amount of the pension contributions of

Bundesbeamtinnen und Bundesbeamten gemäß § 22 Gehaltsgesetz 1956 ändert sich der Prozentsatz des Deckungsbeitrages im gleichen Ausmaß. Ab 1. Jänner 2004 geleistete besondere Pensionsbeiträge und Überweisungsbeträge sind umgehend und in voller Höhe an den Bund zu überweisen. Die sonstigen Zahlungen an den Bund sind jeweils am 10. des betreffenden Monats fällig. Sozialversicherungsrechtliche Überweisungsbeträge anlässlich des Ausscheidens aus einem pensionsversicherungsfreien Dienstverhältnis sind von der Universität zu leisten. Die dafür erforderlichen Mittel sind der Universität durch den Bund im Globalbudget zur Verfügung zu stellen.

(13) Für Beamtinnen und Beamte an den Universitäten gilt das ArbeitnehmerInnenschutzgesetz, BGBl. Nr. 450/1994.

(14) Beamtinnen und Beamte, die einer Einrichtung für Gerichtliche Medizin zugeordnet sind, haben im Rahmen ihrer Dienstpflichten an der Erstellung von Gutachten und Befunden in gerichtlichen Verfahren mitzuwirken. Auftraggeberin ist die jeweils zuständige Ermittlungs- oder Justizbehörde.

(15) Soll eine Universitätsdozentin oder ein Universitätsdozent an jener Universität, der sie oder er zur Dienstleistung zugewiesen ist, in ein Arbeitsverhältnis als Universitätsprofessorin oder Universitätsprofessor gemäß §§ 97 ff aufgenommen werden, ist die Anwendung des § 160 BDG 1979 zulässig. Im Falle der Gewährung einer Freistellung unter Beibehaltung der Bezüge gelten aus dem Arbeitsverhältnis gebührende, den fortgezahlten Bezug übersteigende Leistungen als Entgelt.

Vertragsbedienstete des Bundes

§ 126. (1) Bedienstete des Bundes, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität zu Lasten einer Planstelle der Planstellenbereiche Universitäten oder Universitäten der Künste in einem vertraglichen Dienstverhältnis stehen, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer jener Universität, deren Aufgaben sie überwiegend besorgt haben.

(2) Vertragsbedienstete, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an einer Universität zu Lasten einer Planstelle der Planstellenbereiche Universitäten in einem vertraglichen Dienstverhältnis stehen und einer Einrichtung einer Medizinischen Fakultät zugeordnet sind, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer jener Medizinischen Universität, welche die Nachfolgeeinrichtung der Medizinischen Fakultät ist.

civil servants according to § 22 of the Salaries Act 1956, the percentage contribution shall be changed to the same extent. Special pension contributions and other transfer payments made after 1 January 2004 shall be transferred to the Federal Government in full without delay. Other payments to the Federal Government shall be due on the tenth day of the respective month. Amounts to be transferred under social security law upon termination of an employment without a pension scheme shall be borne by the university. Within the framework of the global budget, the Federal Government shall provide the universities with the resources required.

(13) Civil servants at universities shall be subject to the Employees Protection Act, F. L. G. No 450/1994.

(14) Permanent federal civil servants assigned to a unit of forensic medicine shall participate in the preparation of assessments and reports in court proceedings as part of their official duties. The contracting body shall be the competent investigative or judicial body.

(15) If an associate professor is appointed as a university professor under §§ 97 ff at the university at which he or she is assigned to service, the application of § 160 of the Civil Service Code 1979 shall be permissible. If paid leave is granted, benefits resulting from the appointment and exceeding the pay received shall be deemed to be remuneration.

Federal Contractual Employees

§ 126. (1) Federal contractual employees employed at universities or universities of the arts as of the day before the entry of this Act into full effect at the expense of budgeted university posts shall, on the following day (effective date), become employees of that university where their duties have predominantly been performed.

(2) Contractual employees employed at universities and assigned to an organisational unit of a faculty of medicine as of the day before the entry of this Act into full effect at the expense of budgeted university posts shall, on the following day (effective date), become employees of the medical university which is the successor institution of such faculty.

(3) Vertragsbedienstete, die zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes einer Interuniversitären Einrichtung zugeordnet sind oder in der Zeit danach zugeordnet werden, werden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität, welche die Nachfolgeeinrichtung der betreffenden Interuniversitären Einrichtung ist, Arbeitnehmerinnen oder Arbeitnehmer dieser Universität.

(4) Hinsichtlich einer allfälligen zeitlichen Befristung des Arbeitsverhältnisses tritt keine Änderung ein. Die Universität setzt die Rechte und Pflichten des Bundes gegenüber diesen Arbeitnehmerinnen und Arbeitnehmern fort. Das Vertragsbedienstetengesetz 1948, BGBl. Nr. 86, gilt hinsichtlich der ihm zum Stichtag unterliegenden Arbeitnehmerinnen und Arbeitnehmer als Inhalt des Arbeitsvertrags mit der Universität. Der Abschluss von Sonderverträgen gemäß § 36 Vertragsbedienstetengesetz 1948 ist nicht mehr zulässig. Innerhalb von zwei Jahren ab dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität ist eine Kündigung aus einem der im § 32 Abs. 4 des Vertragsbedienstetengesetzes 1948 angeführten Gründe nicht zulässig.

(5) Die Arbeitnehmerinnen und Arbeitnehmer gemäß Abs. 1 bis 3 können innerhalb von drei Jahren nach dem Wirksamwerden des für neu eintretende Arbeitnehmerinnen und Arbeitnehmer abgeschlossenen Kollektivvertrags ihre Bereitschaft zum Übertritt in diesen Kollektivvertrag erklären. Ihre Arbeitsverträge sind mit Wirksamkeit des auf die Erklärung folgenden Monatsersten entsprechend anzupassen.

(6) Auf Vertragsassistentinnen und Vertragsassistenten in einem Dienstverhältnis gemäß § 52a des Vertragsbedienstetengesetzes 1948 ist § 52b des Vertragsbedienstetengesetzes 1948 mit der Maßgabe anzuwenden, dass an die Stelle der Bundesministerin oder des Bundesministers (§ 52b Abs. 1 Z 2) das Rektorat tritt.

(7) Arbeitnehmerinnen und Arbeitnehmer gemäß Abs. 6 können innerhalb von drei Jahren nach dem Wirksamwerden des für neu eintretende Arbeitnehmerinnen und Arbeitnehmer abgeschlossenen Kollektivvertrags, frühestens jedoch nach der Verlängerung des Arbeitsverhältnisses auf unbestimmte Zeit gemäß § 52b des Vertragsbedienstetengesetzes 1948, ihre Bereitschaft zum Übertritt in diesen Kollektivvertrag erklären. Ihre Arbeitsverträge sind mit Wirksamkeit des auf die Erklärung folgenden Monatsersten entsprechend anzupassen.

(8) Aus Anlass des Ausscheidens aus dem Bundesdienstverhältnis gemäß Abs. 1 bis 3 und des Übertritts gemäß Abs. 5 oder 7 gebührt keine Abfertigung gemäß § 35 des Vertragsbedienstetengesetzes 1948. Die im vorangegangenen

(3) Contractual employees assigned to inter-university institutions at the time of the entry into force of this Act or thereafter shall, as of the day of the entry of this Act into full effect, become employees of that university which is the successor institution of the inter-university institution concerned.

(4) There is no change with regard to any limitation of the term of employment. The rights and duties of the Federal Government in respect of these employees shall pass to the universities. The Contractual Employees Act 1948, F. L. G. No 86, shall determine the terms and conditions of the employment contracts with universities of employees subject to it. The conclusion of special contracts according to § 36 of the Contractual Employees Act 1948 is no longer permissible. Termination of employment on any of the reasons set out in § 32 para 4 of the Contractual Employees Act 1948 within two years of the entry of this Act into full effect is impermissible.

(5) New entrants to the service of universities under paras 1 to 3 may, within three years of the entry into effect of the collective contract applicable to them, declare their willingness to transfer to this collective contract. Their employment contracts shall be amended accordingly with effect from the first day of the month after such declaration.

(6) § 52b of the Contractual Employees Act 1948 shall apply to contract assistant professors with employment contracts according to § 52a of that Act, except insofar as the Federal Minister (§ 52b para 1 subpara 2) is substituted by the rectorate.

(7) Employees under para 6 may, within three years of the entry into effect of the collective contract for new entrants to the service of universities, but not earlier than the extension of employment for an indefinite period according to § 52b of the Contractual Employees Act 1948, declare their willingness to transfer to that collective contract. Their employment contracts shall be amended accordingly with effect from the first day of the month after such declaration.

(8) Termination of federal employment under paras 1 to 3 and transfer of employment under paras 5 or 7 shall not give rise to any entitlement to a severance payment according to § 35 of the Contractual Employees Act 1948. The period of

Dienstverhältnis zurückgelegte Dienstzeit ist für alle zeitabhängigen Rechte zu berücksichtigen.

service under the former employment contract shall count towards all service-dependent entitlements.

Lehrlinge des Bundes

§ 127. Hinsichtlich der Rechtsstellung der Lehrlinge des Bundes, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem Ausbildungsverhältnis gemäß Berufsausbildungsgesetz, BGBl. Nr. 142/1969, stehen, tritt nach dem Stichtag keine Änderung ein. Die Universität tritt in die Ausbildungsverpflichtung des Bundes ein.

Federal Apprentices

§ 127. There shall be no change in the legal position of federal apprentices at universities having apprenticeship contracts under the Vocational Training Act, F. L. G. No 142/1969 on the day before the entry of this Act into full effect. The Federal Government's obligation to provide training shall pass to the respective university.

Neuaufnahmen

§ 128. Für ab dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität neu aufgenommene Arbeitnehmerinnen und Arbeitnehmer gilt bis zum In-Kraft-Treten eines Kollektivvertrags gemäß § 108 Abs. 3 das Vertragsbedienstetengesetz 1948 mit Ausnahme der §§ 4, 32 und 34 als Inhalt des Arbeitsvertrags mit der Universität. § 108a ist anzuwenden.

New Entrants

§ 128. The Contractual Employees Act 1948 except for §§ 4, 32 and 34 shall determine the terms and conditions of the employment contracts of new entrants to the service of universities between the entry of this Act into full effect and the entry into force of a collective contract according to § 108 para 3. § 108a shall apply.

Haftungen des Bundes

§ 129. (1) Zur Sicherung der bezugsrechtlichen Ansprüche der Beamtinnen und Beamten, die nach dem Stichtag in ein Arbeitsverhältnis zur Universität überwechseln, und der Vertragsbediensteten sowie der Lehrlinge, die in ein Arbeits- oder Ausbildungsverhältnis zur Universität übergeführt werden, haftet der Bund wie ein Ausfallsbürge (§ 1356 des Allgemeinen Bürgerlichen Gesetzbuches). Die Höhe der Haftung ist mit jenem Betrag begrenzt, der sich am Tag vor dem Ausscheiden der Bediensteten aus dem Bundesdienst aus der für die genannten Bediensteten maßgeblich gewesenen besoldungsrechtlichen Stellung unter Berücksichtigung ihrer Verwendung zu diesem Zeitpunkt ergibt, zuzüglich der nach diesem Zeitpunkt zurückgelegten Dienstzeit, der vorgesehenen regelmäßigen Vorrückungen und der allgemeinen Gehaltserhöhungen.

(2) Anwartschaften auf Abfertigungen und Jubiläumszuwendungen von Arbeitnehmerinnen und Arbeitnehmern gemäß Abs. 1 werden von der Universität übernommen.

Liability of the Federal Government

§ 129. (1) The Federal Government shall, as a deficiency guarantor (§ 1356 of the General Civil Code), guarantee the entitlements to remuneration of civil servants who transfer to employment by a university after the effective date, and of contractual employees and apprentices who are transferred to a university. Such liability shall be limited to the amount arising from the grades of such civil servants on the day before the termination of their federal civil service, taking into account their duties at this time, as well as their length of service after this time, their regular salary increments and general salary increases.

(2) Pursuant to para 1, liability for employees' accrued entitlements to severance payments and jubilee bonuses shall be assumed by universities.

Forderungen des Bundes gegenüber den Bediensteten

§ 130. Die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität bestehenden Forderungen des Bundes aus dem Titel gewährter Vorschüsse sowie allfällige Rückersatzansprüche nach dem Amtshaftungsgesetz, BGBl. Nr. 20/1949, Organhaftpflichtgesetz, BGBl. Nr. 181/1967, oder Dienstnehmerhaftpflichtgesetz, BGBl. Nr. 80/1965, gegenüber Arbeitnehmerinnen

Claims of the Federal Government against Employees

§ 130. Any outstanding claims of the Federal Government against persons transferring from civil service or government contract to university employment, in respect of advances on salaries or of damages under the Liability of Public Bodies' Act, F. L. G. No 20/1949, the Public Officers Liability Act, F. L. G. No 18/1967 or the Employees Liability Act, F. L. G. No 80/1965, as of the day before the entry of

und Arbeitnehmern der Universität, die aus einem Beamtendienstverhältnis in ein Arbeitsverhältnis zur Universität überwechseln oder aus einem Dienstverhältnis als Vertragsbedienstete oder Vertragsbediensteter in ein Arbeitsverhältnis zur Universität übergeführt werden, gehen mit dem Entstehen dieser Arbeitnehmerschaft auf die Universität über und sind von dieser dem Bund zu refundieren.

Übergang der Dienst- und Naturalwohnungen

§ 131. Beamtinnen oder Beamte, die in ein Arbeitsverhältnis zur Universität überwechseln, und Vertragsbedienstete, die in ein Arbeitsverhältnis zur Universität überführt werden, sind hinsichtlich der Nutzung von Dienst- oder Naturalwohnungen so zu behandeln, als ob sie Bundesbedienstete wären. Dadurch wird kein Bestandsverhältnis an der Wohnung begründet, die Bestimmungen des § 80 des Beamten-Dienstrechtsgesetzes 1979, BGBl. Nr. 333, und der §§ 24a bis 24c des Gehaltsgesetzes 1956, BGBl. Nr. 54, finden weiterhin sinngemäß Anwendung. Die Rechte des Dienstgebers im Sinne des § 80 des Beamten-Dienstrechtsgesetzes 1979 nimmt die Bundesministerin oder der Bundesminister wahr.

Wissenschaftliche (Künstlerische) Mitarbeiterinnen und Mitarbeiter (in Ausbildung)

§ 132. (1) Hinsichtlich der Rechtsstellung der Wissenschaftlichen (Künstlerischen) Mitarbeiterinnen und Mitarbeiter (in Ausbildung) (§ 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974), die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem Ausbildungsverhältnis zum Bund stehen, tritt nach dem Stichtag keine Änderung ein. Sie gelten ab dem Stichtag als der Universität oder der Medizinischen Universität zugeordnet, welche die Nachfolgeeinrichtung der Universität oder der Medizinischen Fakultät ist, deren Aufgaben sie überwiegend besorgt haben. Die Universität tritt in die Ausbildungsverpflichtung des Bundes ein. Das Rechtsverhältnis endet aus den im § 6e des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste genannten Gründen oder durch Aufnahme in ein Arbeitsverhältnis zu einer Universität oder einer Medizinischen Universität.

(2) Die §§ 6 bis 6g und 7 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, sind auf die im Abs. 1 genannten Mitarbeiterinnen und Mitarbeiter bis zum Ablauf ihres Ausbildungsverhältnisses weiter anzuwenden.

this Act into full effect, shall be assigned to the university concerned upon the commencement of employment, and the amounts in question refunded by it to the Federal Government.

Transfer of Rented and Rent-Free Tied Accommodation

§ 131. With regard to rented and rent-free tied accommodation, civil servants and government contractual employees transferring to university employment shall be treated as though they remained federal employees. This shall not result in any sitting tenant's rights to continued occupation of the accommodation; the provisions of § 80 of the Civil Service Code 1979, F. L. G. No 333, and §§ 24a to 24c of the Salaries Act 1956, F. L. G. No 54, shall continue to apply by extension. The Federal Minister shall be responsible for exercising the employer's rights according to § 80 of the Civil Service Code 1979.

Junior Scientific and Artistic Staff

§ 132. (1) There shall be no change after the effective date in the legal position of junior academic scientific and artistic staff (§ 6 of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act, F. L. G. No 463/1974) having training contracts with the Federal Government on the day before the entry of this Act into full effect at the universities. As of the effective date they shall be deemed to be assigned to the respective university or the medical university which is the successor of the university or faculty of medicine where their duties have predominantly been performed. The Federal Government's obligation to provide training shall pass to the respective university. The contractual relationship shall be terminated on the reasons named in § 6e of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act or by the commencement of employment by a university or medical university.

(2) §§ 6 to 6g and 7 of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act, F. L. G. No 463/1974, shall continue to apply to the employees named in para 1 until the expiry of their training contracts.

Personen in einem besonderen Rechtsverhältnis zum Bund

§ 133. (1) Hinsichtlich des Rechtsverhältnisses von Personen, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem besonderen Rechtsverhältnis zum Bund (Tutoren gemäß § 1a, Studienassistenten und Demonstratoren gemäß § 1b, Lehrbeauftragte gemäß § 1 Abs. 2 und § 2 sowie Gastprofessorinnen und Gastprofessoren gemäß § 3 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste) stehen, tritt nach dem Stichtag keine Änderung ein. Sie gelten ab dem Stichtag als der Universität oder der Medizinischen Universität zugeordnet, welche die Nachfolgeeinrichtung der Universität oder Medizinischen Fakultät ist, deren Aufgaben sie überwiegend besorgt haben. Das Rechtsverhältnis endet mit Zeitablauf.

(2) Der Abschluss oder die Verlängerung eines solchen besonderen Rechtsverhältnisses zum Bund durch die Universität ist mit Wirksamkeit ab dem Stichtag unzulässig.

(3) Die §§ 1, 1a, 1b, 2, 2a, 3 und 7 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste sind auf die im Abs. 1 genannten Personen bis zum Ablauf ihres besonderen Rechtsverhältnisses weiter anzuwenden.

Angestellte im Rahmen der Teilrechtsfähigkeit

§ 134. (1) Angestellte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem Arbeitsverhältnis zu einer teilrechtsfähigen Einrichtung der Universität stehen, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer dieser Universität. Ab diesem Zeitpunkt setzt die Universität als Arbeitgeberin die Rechte und Pflichten der teilrechtsfähigen Einrichtung der Universität fort. Ein im Rahmen der Teilrechtsfähigkeit befristet abgeschlossenes Arbeitsverhältnis endet mit Zeitablauf.

(2) Angestellte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an einer Medizinischen Fakultät in einem Arbeitsverhältnis zu einer teilrechtsfähigen Einrichtung dieser Medizinischen Fakultät stehen, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer der Medizinischen Universität, welche die Nachfolgeeinrichtung der Medizinischen Fakultät ist. Ab diesem Zeitpunkt setzt die Medizinische Universität als Arbeitgeberin die Rechte und Pflichten der teilrechtsfähigen Einrichtung der Medizinischen Fakultät fort. Ein im Rahmen der Teilrechtsfähigkeit befristet abgeschlossenes Arbeitsverhältnis endet mit Zeitablauf.

Persons with Special Contracts with the Federal Government

§ 133. (1) There shall be no change after the effective date in the legal position of persons with special contracts with the Federal Government (tutors according to § 1a, teaching assistants and demonstrators according to § 1b, external lecturers according to § 1 para 2 and § 2, and visiting professors according to § 3 of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act). As of the effective date they shall be deemed to be assigned to the respective university or the medical university which is the successor of the university or faculty of medicine where their duties have predominantly been performed. The contracts shall terminate upon expiry.

(2) The conclusion or extension of such special contracts with the Federal Government shall be impermissible as of the effective date.

(3) §§ 1, 1a, 1b, 2, 2a, 3 and 7 of the Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act shall continue to apply to the persons named in para 1 until the expiry of their special contracts.

Employees under Restricted Legal Capacity

§ 134. (1) Staff employed by a university organisational unit with restricted legal capacity on the day before the entry of this Act into full effect shall become employees of the respective university on the following day (effective date). From this time on the rights and duties as an employer of the university organisational unit with restricted legal capacity as an employer shall pass to the university. Temporary employment contracts concluded under circumstances of restricted legal capacity shall terminate upon expiry.

(2) Staff employed by a university organisational unit with restricted legal capacity within a faculty of medicine on the day before the entry of this Act into full effect shall, on the following day (effective date), become employees of the medical university which is the successor of that faculty of medicine. From this time on the rights and duties as an employer of the university organisational unit with restricted legal capacity within the faculty of medicine shall pass to the medical university. Temporary employment contracts concluded under circumstances of restricted legal capacity shall terminate upon expiry.

(3) Angestellte, die in einem Arbeitsverhältnis zu einer teilrechtsfähigen Interuniversitären Einrichtung stehen, werden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an jener Universität, welche die Nachfolgeeinrichtung dieser Interuniversitären Einrichtung ist, zu deren Arbeitnehmerinnen oder Arbeitnehmern. Ab diesem Zeitpunkt setzt diese Universität als Arbeitgeberin die Rechte und Pflichten der teilrechtsfähigen Interuniversitären Einrichtung fort. Ein im Rahmen der Teilrechtsfähigkeit befristet abgeschlossenes Arbeitsverhältnis endet mit Zeitablauf.

Interessenvertretung der Arbeitnehmerinnen und Arbeitnehmer der Universität

§ 135. (1) Für alle Arbeitnehmerinnen und Arbeitnehmer der Universität gilt das ArbVG.

(2) Die Universität gilt als Betrieb im Sinne des § 34 ArbVG.

(3) An jeder der in § 6 Abs. 1 Z 1 bis 22 genannten Universitäten ist je ein Betriebsrat für das wissenschaftliche und künstlerische sowie für das allgemeine Universitätspersonal nach den Bestimmungen der §§ 50 ff ArbVG zu wählen. Die Ärztinnen und Ärzte gemäß § 94 Abs. 3 Z 5 sind zum Betriebsrat für das wissenschaftliche und künstlerische Personal aktiv und passiv wahlberechtigt. Gemäß § 22a des Behinderteneinstellungsgesetzes (BEinstG), BGBl. Nr. 92/1970, sind Behindertenvertrauenspersonen zu wählen.

(4) Der am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an den Universitäten gemäß § 6 Abs. 1 Z 1 bis 3 und 7 bis 21 eingerichtete Dienststellenausschuss für die Universitätslehrer bleibt bis zum Ablauf der am Stichtag noch laufenden Funktionsperiode bestehen. Ab dem Stichtag obliegt dem bestehenden Dienststellenausschuss für die Universitätslehrer die Funktion des Betriebsrats für das wissenschaftliche und künstlerische Personal im Sinne des ArbVG.

(5) Der am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an den Universitäten gemäß § 6 Abs. 1 Z 1 bis 3 und 7 bis 21 eingerichtete Dienststellenausschuss für die Bediensteten mit Ausnahme der Universitätslehrer bleibt bis zum Ablauf der am Stichtag noch laufenden Funktionsperiode bestehen. Ab dem Stichtag obliegt dem bestehenden Dienststellenausschuss für die Bediensteten mit Ausnahme der Universitätslehrer die Funktion des Betriebsrats für das allgemeine Universitätspersonal im Sinne des ArbVG.

(3) Staff employed by an inter-university organisational institution with restricted legal capacity shall become employees of the university which is the successor of that inter-university institution on the day when this Act enters into full effect at that university. From this time on the rights and duties as an employer of inter-university organisational institution with restricted legal capacity shall pass to this university. Temporary employment contracts concluded under circumstances of restricted legal capacity shall terminate upon expiry.

Representation of Interests of University Employees

§ 135. (1) All employees shall be subject to the ArbVG.

(2) Universities shall be deemed to be business establishments in the meaning of § 34 of the Labour Relations Act.

(3) Pursuant to the provisions of §§ 50 ff ArbVG, employee's councils shall be elected by the scientific and artistic staff and the non-academic university staff, respectively, at each of the universities named in § 6 para 1 subparas 1 to 22. Physicians according to § 94 para 3 subpara 5 shall be eligible to vote for and be elected to the employee's council for the scientific and artistic staff. Pursuant to § 22a of the Disabled Persons Employment Act (Behinderteneinstellungsgesetz, BEinstG), F. L. G. No 92/1970, representatives of disabled people shall be elected.

(4) The employment committees for university teachers at the universities named in § 6 para 1 subparas 1 to 3 and 7 to 21 in office on the day before the entry of this Act into full effect shall continue to serve until the expiry of their terms of office unless these expire on the effective date. As of the effective date existing employment committees for university teachers shall assume the functions of employee's councils under the ArbVG for the scientific and artistic staff.

(5) The employment committees for employees other than university teachers at the universities named in § 6 para 1 subparas 1 to 3 and 7 to 21 in office on the day before the entry of this Act into full effect shall continue to serve until the expiry of their terms of office unless these expire on the effective date. As of the effective date existing employment committees for employees other than university teachers shall assume the functions of employee's councils under the ArbVG for the non-academic university staff.

(6) Die Dienststellenausschüsse für die Universitätslehrer und die Dienststellenausschüsse für die Bediensteten mit Ausnahme der Universitätslehrer an den Universitäten gemäß § 6 Abs. 1 Z 1 bis 3 haben ab dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes auch die Funktion des entsprechenden Dienststellenausschusses an der Medizinischen Universität desselben Standorts wahrzunehmen.

(7) Die bestehenden Personalvertretungsorgane haben vor Ablauf ihrer Funktionsperiode für die rechtzeitige Ausschreibung von Betriebsratswahlen zu sorgen.

(8) Im Übrigen gelten für die Universitäten die Bestimmungen des ArbVG mit folgender Maßgabe:

1. Eine Unterteilung in Arbeiter- und Angestelltenbetriebsrat findet nicht statt.
2. Für die zur Dienstleistung zugewiesenen Beamtinnen und Beamten hat der Betriebsrat gleichzeitig die Funktion des Dienststellenausschusses im Sinne des § 9 des Bundes-Personalvertretungsgesetzes, BGBl. Nr. 133/1967, wahrzunehmen. Die der Universität zugewiesenen Beamtinnen und Beamten gehören darüber hinaus weiterhin dem Wirkungsbereich des zuständigen Zentralausschusses beim Bundesministerium für ~~Bildung~~Frauen, Wissenschaft und Forschung an.

(9) Der beim Bundesministerium eingerichtete Zentralausschuss für die Universitätslehrer und der Zentralausschuss für die Bediensteten mit Ausnahme der Universitätslehrer bleiben bis zum Ende der am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes laufenden Funktionsperiode bestehen, § 23 Abs. 2 lit. a und c des Bundes-Personalvertretungsgesetzes sind nicht anzuwenden.

(10) Die Vorsitzenden der beiden in Abs. 3 genannten Betriebsräte jeder Universität gemäß § 6 Abs. 1 sind berechtigt, bei Bedarf zum Zweck des Erfahrungs- und Meinungsaustausches über die beruflichen, wirtschaftlichen, sozialen, kulturellen und gesundheitlichen Interessen der von diesen Betriebsräten zu vertretenden Arbeitnehmerinnen bzw. Arbeitnehmer zu einer Konferenz der Vorsitzenden der Betriebsräte für das wissenschaftliche und künstlerische Universitätspersonal bzw. einer Konferenz der Vorsitzenden der Betriebsräte für das allgemeine Universitätspersonal zusammenzutreten. Nähere Regelungen treffen die betreffenden Vorsitzenden jeweils durch eine Geschäftsordnung.

(6) Upon the entry of this Act into full effect the employment committees for university teachers and for employees other than university teachers at the universities named in § 6 para 1 subparas 1 to 3 shall also assume the functions of the corresponding employment committees at the medical universities at the same sites.

(7) The existing personnel representation bodies shall secure that employee's council elections are called up in a timely manner, before expiry of their term of office.

(8) Otherwise, the provisions of the ArbVG shall apply to the universities, subject to the following:

1. No distinction shall be made between employee's councils for workers and employees.
2. For civil servants assigned to a university, the employee's council shall also fulfil the function of the employment committee according to § 9 of the Federal Employees Representation Act, F. L. G. No 133/1967. Civil servants assigned to universities shall also continue to be represented by the central employment committee responsible for them at the Federal Ministry of Education, Science and Research.

(9) The central employment committees for university teachers and for employees other than university teachers at the federal ministry shall remain in existence until the end of its term of office, which shall expire on the day before the entry of this Act into full effect; § 23 para 2 lit a and c of the Federal Employee Representation Act shall not apply.

5. Abschnitt
Übertragung von Rechten und Vermögen

Nachfolgeeinrichtungen

§ 136. (1) Die im § 6 Z 1 bis 3 angeführten Universitäten werden mit dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität Gesamtrechtsnachfolgerinnen der jeweiligen gleichnamigen Universität (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) gemäß § 5 UOG 1993. Diese Universitäten werden einerseits in ihre gleichnamige Nachfolgeuniversität und andererseits in die Medizinische Universität aufgespalten.

(2) Die im § 6 Z 4 bis 6 angeführten Medizinischen Universitäten Wien, Graz und Innsbruck sind Gesamtrechtsnachfolgerinnen der Medizinischen Fakultät (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) der Universität des jeweiligen Standorts.

(3) Die im § 6 Z 7 bis 21 angeführten Universitäten sind Gesamtrechtsnachfolgerinnen der jeweiligen gleichnamigen Universität (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) gemäß § 5 UOG 1993 oder Universität der Künste (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) gemäß § 6 Z 1 bis 6 KUOG.

(4) Die Universität Klagenfurt ist die Gesamtrechtsnachfolgerin des Instituts für Interdisziplinäre Forschung und Fortbildung der Universitäten Klagenfurt, Wien, Innsbruck und Graz – IFF.

(5) Die Universität für Bodenkultur Wien ist die Gesamtrechtsnachfolgerin des Interuniversitären Forschungsinstituts für Agrarbiotechnologie Tulln. Die an dieser Interuniversitären Einrichtung beteiligten Universitäten haben bis spätestens 31. Dezember 2003 basierend auf ihrer Zusammenarbeit und ihren daraus resultierenden Rechten und Pflichten mit Wirksamkeit vom 1. Jänner 2004 einen Vertrag über die weitere Zusammenarbeit auf diesem Fachgebiet abzuschließen. Kommt dieser Vertrag nicht zeitgerecht zustande, ist das Vermögen der Interuniversitären Einrichtung mit 1. Jänner 2004 entsprechend den von den beteiligten Universitäten bis zum 31. Dezember 2003 eingebrachten Ressourcen aufzuteilen.

Chapter 5
Transfer of Rights and Assets

Successor Institutions

§ 136. (1) Upon the entry of this Act into full effect at the universities, those universities named in § 6 subparas 1 to 3 shall become the universal successors of the respective universities of the same names (including their organisational units with restricted legal capacity) referred to in § 5 University Organisation Act 1993. These universities shall be divided into their successors of the same name and the medical universities.

(2) The Medical Universities of Vienna, Graz and Innsbruck (§ 6 subparas 4 to 6) shall be the universal successors of the faculties of medicine (including their organisational units with restricted legal capacity) at the universities at the respective sites.

(3) The universities named in § 6 subparas 7 to 21 shall be the universal successors of the respective universities of the same names (including their organisational units with restricted legal capacity) referred to in § 5 University Organisation Act 1993 or the universities of the arts (including their organisational units with restricted legal capacity) referred to in § 6 subparas 1 to 6 Universities of the Arts Organisation Act.

(4) The University of Klagenfurt shall be the universal successor of the Institute for Interdisciplinary Research and Continuing Education at the Universities of Klagenfurt, Vienna, Innsbruck and Graz.

(5) The University of Natural Resources and Applied Life Sciences Vienna shall be the universal successor of the Institute for Agrobiotechnology Tulln. The universities participating in this inter-university institution have to conclude, by 31 December 2003, an agreement on their continued collaboration in this field with effect from 1 January, 2004, based on their existing collaboration and the rights and duties arising there from. In case that such agreement is not concluded by the appointed day, the assets of the said inter-university institution shall as of 1 January, 2004 be divided among the participating universities in accordance with the resources contributed by them up to 31 December 2003.

(6) Die Universität Linz ist die Gesamtrechtsnachfolgerin des Interuniversitären Instituts für Informationssysteme zur Unterstützung sehgeschädigter Studierender.

(7) Die Technische Universität Wien ist die Gesamtrechtsnachfolgerin des Interuniversitären Instituts für Technologie Management (ITM).

(8) Die Universität Graz ist die Gesamtrechtsnachfolgerin der Interuniversitären Koordinationsstelle für Frauen- und Geschlechterforschung Graz.

(9) Die Universität Wien ist die Gesamtrechtsnachfolgerin der Österreichischen Zentralbibliothek für Physik.

(10) Die Medizinische Universität Wien ist die Gesamtrechtsnachfolgerin der Österreichischen Zentralbibliothek Medizin.

(11) Die Universität Graz ist die Gesamtrechtsnachfolgerin des Interuniversitären Universitäts-Sportinstituts in Graz.

Übergang von Mietrechten an Liegenschaften, Bauwerken und Räumlichkeiten

§ 137. (1) Die Mietrechte an den vom Bund, einer Universität oder einer teilrechtsfähigen Organisationseinheit einer Universität angemieteten Liegenschaften, Bauwerken und Räumlichkeiten gehen mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität (Stichtag) unter Ausschluss der Rechtsfolgen der §§ 12a und 46a des Mietrechtsgesetzes im Wege der Gesamtrechtsnachfolge auf die am Tag vor dem Stichtag nutzende Universität oder Medizinische Fakultät über.

(2) Zu dem im Abs. 1 genannten Stichtag tritt die Universität auch als Verpächterin oder Leihgeberin an Stelle des Bundes in die bestehenden Pacht- und Leihverträge ein.

Rechtsnachfolge bei gemeinsam genutzten Liegenschaften, Bauwerken und Räumlichkeiten

§ 138. Das Mietrecht geht auf jene Universität über, der die Liegenschaft, das Gebäude oder die einzelnen Räumlichkeiten am Tag vor dem Stichtag zur ausschließlichen und dauerhaften Nutzung zugeordnet war oder waren. Ist eine Liegenschaft, ein Bauwerk oder sind einzelne Räumlichkeiten mehreren Universitäten zur gemeinsamen dauerhaften Nutzung überlassen, geht das Mietrecht auf jene Universität über, die das Objekt im Beobachtungszeitraum zwischen 1. Jänner 2001 und 30. September 2003 überwiegend genutzt hat. Für die Medizinischen Universitäten gelten für diesen Beobachtungszeitraum die Nutzungen

(6) The University of Linz shall be the universal successor of the Inter-University Institute for Information Systems supporting visually impaired students.

(7) The Vienna University of Technology shall be the universal successor of the Institute for Technology Management (ITM).

(8) The University of Graz shall be the universal successor of the Inter-University Coordination Centre for Women's Studies and Gender Research, Graz.

(9) The University of Vienna shall be the universal successor of the Austrian Central Library for Physics.

(10) The Medical University of Vienna shall be the universal successor of the Austrian Central Library for Medicine.

(11) The University of Graz shall be the universal successor of the Inter-University University Sports Centre in Graz.

Transfer of Tenancy Rights to Properties, Buildings and Rooms

§ 137. (1) As of the day when this Act enters into full effect (effective date) tenancy rights attaching to properties, buildings and rooms rented by the Federal Government, a university or a university organisational unit with restricted legal capacity shall pass by universal succession to the university or faculty of medicine using them on the day before the effective date. The legal implications of §§ 12a and 46a of the Rent Act shall be excluded.

(2) As of the effective date referred to in para 1 the respective universities shall replace the Federal Government as the lessors or loaners in existing leasehold or loan agreements.

Legal Succession with respect to Shared Properties, Buildings and Rooms

§ 138. The tenancy rights shall pass to the university to which the property, building or individual rooms was/were assigned for exclusive, permanent use on the day before the effective date. If a property, a building or single rooms has/have been assigned to a number of universities for joint permanent use, the tenancy rights shall pass to that university which has predominantly used the property during the reference period between 1 January, 2001 and 30 September, 2003. In the case of the medical universities, the applicable uses during this reference period shall be those by the respective faculty of medicine. If a property, a building or single rooms

der jeweiligen Medizinischen Fakultät. Ist eine Liegenschaft, ein Bauwerk oder sind einzelne Räumlichkeiten mehreren Universitäten zur gemeinsamen dauerhaften Nutzung überlassen, wird jener Universität das Hauptmietrecht eingeräumt, die das Objekt im Beobachtungszeitraum zwischen dem 1. Jänner 2001 und dem 30. September 2003 überwiegend genutzt hat. Die anderen Universitäten erhalten ein Untermietrecht und bezahlen einen Untermietzins in der Höhe des Hauptmietzinses.

Übertragung der im Eigentum des Bundes stehenden Mobilien auf die Universitäten

§ 139. (1) Das Eigentumsrecht an dem beweglichen Vermögen des Bundes, das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes den Universitäten und Universitäten der Künste zur Nutzung überlassen ist, geht einschließlich aller zugehörenden Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem folgenden Tag (Stichtag) im Wege der Gesamtrechtsnachfolge auf die nutzende Universität über. Die Gesamtrechtsnachfolge ist im Mitteilungsblatt der Universität kundzumachen (§ 20 Abs. 6).

(2) Das Eigentumsrecht an dem beweglichen Vermögen des Bundes, das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes einer Medizinischen Fakultät oder einer ihrer Organisationseinheiten zur Nutzung überlassen ist, geht einschließlich aller zugehörenden Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem folgenden Tag (Stichtag) im Wege der Gesamtrechtsnachfolge auf jene Medizinische Universität über, welche die Gesamtrechtsnachfolgerin der Medizinischen Fakultät ist. Die Gesamtrechtsnachfolge ist im Mitteilungsblatt der Universität kundzumachen.

(3) Das Eigentumsrecht an dem beweglichen Vermögen des Bundes, das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes einer Interuniversitären Einrichtung gemäß § 136 Abs. 4 bis 11 zur Nutzung überlassen ist, geht einschließlich aller zugehörenden Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem folgenden Tag (Stichtag) im Wege der Gesamtrechtsnachfolge auf die in diesen Gesetzesstellen jeweils genannte Universität über. Die Gesamtrechtsnachfolge ist im Mitteilungsblatt der Universität kundzumachen. Diese Vermögenswerte sind von den als Nachfolgeeinrichtungen bestimmten Universitäten zur Weiterführung der Aufgaben der bisherigen Interuniversitären Einrichtungen zu verwenden.

(4) Abweichend von Abs. 1 bis 3 verbleiben die Bestände der Universitätsbibliotheken, die aus geschichtlichem, künstlerischem und sonstigem kulturellen oder wissenschaftlichen Zusammenhang ein Ganzes bilden, im Eigentum

has/have been assigned to a number of universities for joint permanent use, the master tenancy rights shall be accorded to that university which has predominantly used the property during the reference period between 1 January 2001 and 30 September 2003. The other universities shall receive subtenancy rights and shall pay subrent in the amount of the master rent.

Transfer of Properties Owned by the Federal Government to the Universities

§ 139. (1) Title to the movable assets owned by the Federal Government assigned to the universities and universities of the arts for their use as of the day before the entry of this Act into full effect, including all associated rights and obligations, claims and debts shall, on the following day (effective date), pass by universal succession to the university using such assets. Such universal succession shall be published in the university gazette (§ 20 para 6).

(2) Title to the movable assets owned by the Federal Government assigned to a faculty of medicine or one of its organisational units for its use as of the day before the entry of this Act into full effect, including all associated rights and obligations, claims and debts shall, on the following day (effective date), pass by universal succession to the medical university which is the universal successor of that faculty of medicine. Such universal succession shall be published in the university gazette.

(3) Title to the movable assets owned by the Federal Government assigned to the inter-university institutions named in § 136 paras 4 to 11 for their use as of the day before the entry of this Act into full effect, including all associated rights and obligations, claims and debts shall, on the following day (effective date), pass by universal succession to the universities named in these provisions. Such universal succession shall be published in the university gazette. These assets shall be used by the universities designated as successor institutions for the continuation of the activities of the former inter-university institutions.

(4) Notwithstanding paras 1 to 3, stocks of university libraries forming a historical, artistic or other cultural or scientific unity shall remain the property of the Federal Government. Movable assets temporarily loaned by the Federal Government

des Bundes. Weiters verbleiben die Mobilien im Eigentum des Bundes, die einzelnen Universitäten insbesondere zu Zwecken zur Repräsentation oder zur künstlerischen Ausgestaltung leihweise vorübergehend zur Nutzung überlassen worden sind. Jede Universität hat bis 30. September 2003 ein Verzeichnis dieser Bestände anzulegen.

(5) Hinsichtlich des Eigentums an den Sammlungen der Gemäldegalerie und des Kupferstichkabinetts der Akademie der bildenden Künste Wien tritt abweichend von Abs. 1 bis 3 keine Änderung ein.

Übertragung der im Eigentum teilrechtsfähiger Einrichtungen der Universitäten und Universitäten der Künste stehenden Immobilien, Mobilien und Rechte auf die Universitäten

§ 140. (1) Das Eigentumsrecht am beweglichen und unbeweglichen Vermögen der teilrechtsfähigen Einrichtungen der Universitäten und Universitäten der Künste geht einschließlich aller zugehörigen Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der betreffenden Universität im Wege der Gesamtrechtsnachfolge auf die jeweilige Universität über.

(2) Das Eigentumsrecht am beweglichen und unbeweglichen Vermögen einer teilrechtsfähigen Medizinischen Fakultät oder einer ihrer teilrechtsfähigen Einrichtungen geht einschließlich aller zugehörigen Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Medizinischen Universität im Wege der Gesamtrechtsnachfolge auf die Medizinische Universität über, welche die Nachfolgeeinrichtung der betreffenden Medizinischen Fakultät ist.

(3) Das Eigentumsrecht am beweglichen und unbeweglichen Vermögen der teilrechtsfähigen Interuniversitären Einrichtungen gemäß § 136 Abs. 4 bis 11 geht einschließlich aller zugehörigen Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes im Wege der Gesamtrechtsnachfolge auf die in diesen Gesetzesstellen jeweils genannte Universität über.

(4) Die Universitäten haben dafür zu sorgen, dass bestehenden Auflagen, Bedingungen und Widmungen bestmöglich entsprochen wird. Eine interne personenbezogene Drittmittel-Zuweisung des damit verbundenen Vermögenswertes ist dadurch nicht ausgeschlossen.

to universities for ceremonial or decorative purposes shall remain the property of the Federal Government. Universities shall have to compile an inventory of such assets by 30 September, 2003.

(5) Notwithstanding paras 1 to 3, there shall be no change in the ownership of the contents of the Art Gallery and the Collection of Copperplate Engravings of the Academy of Fine Arts Vienna.

Transfer to Universities of Properties, Movable Assets and Rights Owned by Organisational Units with Restricted Legal Capacity at Universities and Universities of the Arts

§ 140. (1) Title to the movable assets and immovable assets of organisational units with restricted legal capacity universities and universities of the arts, as well as all associated rights and obligations, claims and debts, shall pass to the respective universities by universal succession on the day when this Act enters into full effect at the universities concerned.

(2) Title to the movable assets and immovable assets of a faculty of medicine with restricted legal capacity or one of its organisational units with restricted legal capacity, as well as all associated rights and obligations, claims and debts, shall pass to the medical university, which is the successor institution of that faculty of medicine by universal succession on the day when this Act enters into full effect at the medical university concerned.

(3) Title to the movable and immovable assets of the inter-university institutions with restricted legal capacity named in § 136 paras 4 to 11 as well as the associated rights and obligations, claims and debts shall pass to the universities named in these provisions by universal succession on the day when this Act enters into full effect.

(4) The universities shall ensure that existing conditions of use and dedications of assets to specific purposes are complied with to the maximum possible extent. Internal ad personam allocation of assets shall not be excluded thereby.

5a. Abschnitt
Vereinigung von Universitäten

Rechtsnachfolge

§ 140a. (1) Zwei oder mehrere Universitäten können durch Bundesgesetz vereinigt werden (§ 6 Abs. 3 bis 6). Die Vereinigungsrahmenbestimmungen gemäß § 6 Abs. 4 haben auch die Rechtsnachfolge festzulegen.

(2) Ist eine an einer Vereinigung beteiligte Medizinische Universität nicht die rechtsnachfolgende Universität, so ist für diesen Bereich von der rechtsnachfolgenden Universität durch den Organisationsplan eine Medizinische Fakultät einzurichten.

(3) Die Rechte und Pflichten aus den Leistungsvereinbarungen der beteiligten Universitäten gehen mit dem Zeitpunkt des Wirksamwerdens der Vereinigung gemäß § 6 Abs. 3 bis 6 auf die rechtsnachfolgende Universität über.

Übergangsbestimmungen für die Satzung, den Organisations- und den Entwicklungsplan

§ 140b. (1) In Abweichung von § 22 Abs. 1 Z 1 haben die Senate der beteiligten Universitäten unter Berücksichtigung der jeweiligen Satzungen bis zum Wirksamwerden der Vereinigung gemäß § 6 Abs. 3 bis 6 eine vorläufige gemeinsame Satzung zu beschließen und im Mitteilungsblatt der beteiligten Universitäten zu verlautbaren.

(2) Bis längstens drei Jahre ab dem Zeitpunkt des Wirksamwerdens der Vereinigung gemäß § 6 Abs. 3 bis 6 sind von den zuständigen Organen der rechtsnachfolgenden Universität eine Satzung, ein Entwicklungs- sowie ein Organisationsplan zu beschließen und im Mitteilungsblatt zu verlautbaren. Die vorläufige gemeinsame Satzung gemäß Abs. 1 sowie der vorläufige Organisations- sowie Entwicklungsplan gemäß § 6 Abs. 5 Z 3 bleiben bis zu diesem Zeitpunkt in Geltung.

Übergang von Mietrechten an Liegenschaften, Bauwerken und Räumlichkeiten

§ 140c. (1) Die Mietrechte an den von den beteiligten Universitäten angemieteten Liegenschaften, Bauwerken und Räumlichkeiten gehen mit dem Tag des Wirksamwerdens der Vereinigung (Stichtag) unter Ausschluss der Rechtsfolgen

Chapter 5a
Merger of Universities

Legal Succession

§ 140a. (1) Two or more universities may be merged by Federal Law (§ 6 paras 3 to 6). The merger framework regulations under § 6 para 4 shall also regulate the legal succession.

(2) If a medical university involved in a merger is not the legal successor of the universities, the legal successor shall establish a faculty of medicine for this area in its organisation plan.

(3) The rights and duties arising from the performance agreements of the universities involved shall be transferred to the legal successor when the merger pursuant to § 6 paras 3 to 6 enters into full effect.

Transitional Provisions for the Statutes, the Organisation Plan and the Development Plan

§ 140b. (1) Notwithstanding § 22 para 1 (1) and taking into account the existing statutes, the senates of the universities involved shall adopt a preliminary common statute that is effective until the merger according to § 6 paras 3 to 6 enters into full effect, and shall publish it in the university gazettes of the universities involved.

(2) No later than three years after the merger according to § 6 paras 3 to 6 has entered into full effect, the competent bodies of the university that is the legal successor shall adopt a statute, a development plan, and an organisation plan and publish it in the university gazette. The preliminary common statute under para 1 as well as the preliminary organisation plan and development plan under § 6 para 5 (3) shall remain in force until then.

Transfer of Tenancy Rights to Properties, Buildings and Rooms

§ 140c. (1) The tenancy rights attached to properties, buildings and rooms rented by the universities involved shall pass by universal succession to the university that is the legal successor on the day the merger enters into full effect (effective date); the legal implications of §§ 12a and 46a of the Rent Act shall be excluded.

der §§ 12a und 46a des Mietrechtsgesetzes im Wege der Gesamtrechtsnachfolge auf die rechtsnachfolgende Universität über.

(2) Zu dem im Abs. 1 genannten Stichtag tritt die rechtsnachfolgende Universität auch als Verpächterin oder Leihgeberin anstelle der beteiligten Universitäten in die bestehenden Pacht- und Leihverträge ein.

Überleitung des Personals

§ 140d. (1) Beamtinnen und Beamte, die am Tag vor dem Wirksamwerden der Vereinigung gemäß § 6 Abs. 3 bis 6 den beteiligten Universitäten im Sinne des § 125 Abs. 2 angehören, gehören ab dem auf diesen Zeitpunkt folgenden Tag für die Dauer des Dienststandes dem Amt der rechtsnachfolgenden Universität an und sind dieser Universität zur dauernden Dienstleistung zugewiesen, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(2) Für die Arbeitnehmerinnen und Arbeitnehmer der beteiligten Universitäten gilt die Vereinigung gemäß § 6 Abs. 3 bis 6 als Betriebsübergang gemäß § 3 des Arbeitsvertragsrechts-Anpassungsgesetz – AVRAG, BGBl. Nr. 459/1993. Auf diese sind das AVRAG sowie die auf den Betriebsübergang bezogenen Bestimmungen der Arbeitsverfassung (Arbeitsverfassungsgesetz – ArbVG), BGBl. Nr. 22/1974, anzuwenden. Auf jene dieser Arbeitnehmerinnen und Arbeitnehmer, die gemäß § 126 Abs. 1 in ein Arbeitsverhältnis zur einer der beteiligten Universitäten übergeleitet wurden und die am Tag vor dem Stichtag der Wirksamkeit der Vereinigung einem Kollektivvertrag gemäß § 108 nicht unterliegen, ist § 126 Abs. 4 weiter anzuwenden.

(3) Eine an einer beteiligten Universität verliehene Lehrbefugnis (§ 103) gilt ab dem Zeitpunkt des Wirksamwerdens der Vereinigung gemäß § 6 Abs. 3 bis 6 als von der rechtsnachfolgenden Universität verliehene Lehrbefugnis.

Übergangsbestimmungen für die Interessenvertretung der Arbeitnehmerinnen und Arbeitnehmer

§ 140e. (1) Ab dem Zeitpunkt des Wirksamwerdens der Vereinigung gemäß § 6 Abs. 3 bis 6 bilden die Betriebsräte gemäß § 135 Abs. 3 der beteiligten Universitäten jeweils einen Betriebsrat. Die Betriebsräte sind längstens binnen eines Jahres ab dem Wirksamwerden der Vereinigung gemäß § 6 Abs. 3 bis 6 neu zu wählen. Die Funktionsperiode der Betriebsräte endet mit der Konstituierung der neugewählten Betriebsräte.

(2) As of the effective date referred to in para 1, the university that is the legal successor shall also enter into existing leasehold agreements or loan agreements as the lessor or loaner instead of the universities involved.

Transition of University Staff

§ 140d. (1) Permanent civil servants who are members of the universities involved within the meaning of § 125 para 2, as of the day before the merger according to § 6 paras 3 to 6 enters into full effect, shall be assigned to the office of the university that is the legal successor from the following day and for the duration of their service and shall be permanently assigned to this university, unless transferred to another federal post.

(2) For the employees of the universities involved, the merger according to § 6 paras 3 to 6 shall be deemed to be a transfer of business according to § 3 of the Employment Contract Law Adaptation Act (AVRAG), F. L. G. No 459/1993. To them, the Employment Contract Law Adaptation Act as well as the provisions pertaining to the transfer of business under the Labour Relations Act (ArbVG), F. L. G. No 22/1974, shall apply. § 126 para 126 shall continue to apply to those employees whose contracts of employment have been converted into contracts of employment with one of the universities involved according to § 4 para 108 and who are not subject to a collective contract according to § 1 on the day before the effective date of the merger.

(3) A habilitation degree (§ 103) awarded by a university involved shall, as of the day when the merger according to § 6 paras 3 to 6 enters into full effect, be deemed to be a habilitation degree awarded by the university that is the legal successor.

Transitional Provisions for the Representation of Employee Interests

§ 140e. (1) As of the day when the merger according to § 6 paras 3 to 6 enters into full effect, the employees' councils according to § 135 para 3 of the universities involved shall establish an employees' council each. The employees' councils shall be re-elected no later than one year after the merger according to § 6 paras 3 to 6 enters into full effect. The term of office of the employees' councils shall end when the newly elected employees' councils constitute themselves.

(2) Hinsichtlich der Betriebsvereinbarungen der beteiligten Universitäten gilt § 31 Abs. 7 ArbVG.

Studienrechtliche Übergangsbestimmungen

§ 140f. Die an den beteiligten Universitäten eingerichteten Diplom-, Bachelor-, Master- und Doktoratsstudien gelten ab dem Wirksamwerden der Vereinigung gemäß § 6 Abs. 3 bis 6 als an der rechtsnachfolgenden Universität eingerichtet. Auf diese Studien sind die jeweiligen Curricula in der zum Zeitpunkt des Wirksamwerdens der Vereinigung geltenden Fassung weiterhin anzuwenden, und diese Studienpläne dürfen gemäß § 25 Abs. 1 Z 10 auch abgeändert werden. An Absolventinnen und Absolventen dieser Studien sind jeweils jene akademischen Grade zu verleihen, die zum Zeitpunkt des Wirksamwerdens der Vereinigung für die jeweiligen Studien vorgesehen sind. § 80 bis § 80b UniStG sind sinngemäß anzuwenden. Werden an Stelle bestehender Studien gemäß § 54 Abs. 1 Bachelor- und Masterstudien eingerichtet, so sind in den Curricula den § 80 Abs. 2 und § 80a Abs. 2 UniStG entsprechende Übergangsbestimmungen vorzusehen.

Sonstige Bestimmungen

§ 140g. Die rechtsnachfolgende Universität und die beteiligten Universitäten gemäß § 6 Abs. 3 bis 6 sind hinsichtlich der Vereinigung von allen dadurch entstehenden Gebühren und Abgaben befreit. Davon ausgenommen sind Gerichts- und Justizverwaltungsgebühren.

§ 140h. Zivilrechtliche Vertragsverhältnisse zwischen der rechtsnachfolgenden Universität und den beteiligten Universitäten erlöschen mit dem Wirksamwerden der Vereinigung (§ 1445 Abs. 1 ABGB).

6. Abschnitt

Budget

§ 141. (1) Die Auswirkungen der Budgetierung der Universitäten aufgrund der §§ 12, 12a, und 13 in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 sind ab der Leistungsvereinbarungsperiode 2019 bis 2021 durch die Bundesministerin oder den Bundesminister in Zusammenarbeit mit der Bundesministerin oder dem Bundesminister für Finanzen begleitend zu evaluieren. Die Evaluierung hat insbesondere die Erbringung der in der Leistungsvereinbarung vereinbarten Leistungen durch die Universität in der Lehre sowie in der Forschung bzw. Entwicklung und Erschließung der Künste anhand der Indikatoren „Anzahl der mit

(2) § 31 para 7 of the Labour Relations Act shall apply to the employees' council agreements of the universities involved.

Transitional Provisions Pertaining to Study Law

§ 140f. The diploma, bachelor, master, and doctoral programmes established at the universities involved shall be deemed to be established at the university that is the legal successor of the university after the merger under § 6 paras 3 to 6 has entered into full effect. The curricula in force when the merger enters into full effect shall continue to apply to these programmes, and these curricula may also be modified according to § 25 para 1 (10). Graduates of these programmes shall be awarded those academic degrees that are designated for the respective programmes when the merger enters into full effect. § 80 to § 80b University Studies Act shall apply by analogy. If bachelor's and master's programmes are established instead of existing programmes according to § 54 para 1, transitional provisions shall be included in the curricula that correspond to § 80 para 2 and § 80a para 2 of the Universities Studies Act.

Other Provisions

§ 140g. The university that is the legal successor and the universities involved pursuant to § 6 paras 3 to 6 shall be exempt from all fees and taxes arising from the merger. Court and legal administrative fees shall be excluded from this exemption.

§ 140h. Contracts under private law between the university that is the legal successor and the universities involved shall become null and void when the merger enters into full effect (§ 1445 para 1 of the General Code of Civil Law - ABGB).

Chapter 6

Budget

§ 141. (1) From the performance agreement period 2019 to 2021, the Federal Minister shall, in cooperation with the Federal Minister of Finance, monitor the effects of the budgeting of the universities on the basis of §§ 12, 12a, and 13 as amended by F. L. G. I No 8/2018. The evaluation shall, in particular, include the university's performance in teaching as well as in research or the advancement and appreciation of the arts agreed on in the performance agreement, based on the indicators “Number of students actively taking examinations amounting to at least 16 ECTS credits or successfully passed examinations comprising 8 semester hours

mindestens 16 ECTS-Anrechnungspunkten oder 8 positiv beurteilten Semesterstunden prüfungsaktiv betriebenen ordentlichen Bachelor-, Diplom- und Masterstudien mit Gewichtung nach Fächergruppen“ sowie „Personal in ausgewählten Verwendungen nach Fächergruppen in Vollzeitäquivalenten“ sowie die praktische Umsetzung der vereinbarten Maßnahmen bei Nichterfüllung der Leistungsvereinbarung zu beinhalten.

(2) Die Universitäten können im Rahmen von Aufnahme- oder Auswahlverfahren von Studienwerberinnen und -werbern bzw. Prüfungsteilnehmerinnen und –teilnehmern personenbezogene Daten gemäß § 18 Abs. 6 BilDokG 2020 erfassen und anonymisiert und aggregiert für statistische Zwecke und Evaluierungszwecke verarbeiten.

(3) Zur Sicherstellung der Umsetzung der Maßnahmen gemäß § 12a Abs. 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 sowie zur Vornahme eines umfassenden personenbezogenen Monitorings zur Verhinderung von Studienabbruch und Erhöhung des Studienfortschritts haben die Universitäten

1. datenbezogene Evidenzen zur sozialen Dimension in der Lehre sowie zur Einbeziehung von unterrepräsentierten Gruppen in die Hochschulbildung gemäß § 13 Abs. 2 Z 1 lit. g in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 zu führen bzw. bestehende Erhebungen in diesem Bereich heranzuziehen und mit
2. Daten zu den Studierenden und deren Studienfortschritt gemäß § 9 BilDokG 2020 zu verknüpfen

und damit die quantitativen Entwicklungen dieser Aspekte zu dokumentieren und nachweisbar zu machen. Zu diesem Zweck ist den Universitäten insbesondere Zugriff auf jene personenbezogenen Daten einzuräumen, die aufgrund des § 18 Abs. 6 BilDokG 2020 anlässlich der Aufnahme der Studierenden sowie des Abgangs der Studierenden erhoben werden.

(Anm.: Abs. 4 aufgehoben durch Art. 1 Z 168, BGBl. I Nr. 93/2021)

(5) Die §§ 12, 12a und 13 in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 sind auf die Budgetierung der an der Universität Linz eingerichteten Medizinischen Fakultät ab dem 1. Jänner 2029 anwendbar. Bis zum Ablauf der Geltungsdauer der Vereinbarung gemäß Art. 15a B-VG zwischen dem Bund und dem Land Oberösterreich über die Errichtung und den Betrieb einer Medizinischen Fakultät und die Einrichtung des Studiums der Humanmedizin an der Universität Linz, BGBl. I Nr. 18/2014, mit 31. Dezember 2028 erfolgt die Budgetierung und

in bachelor's, diploma and master's degree programmes weighted according to the groups of disciplines” as well as “Staff in selected job groups by group of disciplines in full-time equivalents”, as well as the practical implementation of the measures in case of non-fulfilment of the performance agreement.

(2) Within the framework of admission and selection procedures, it shall be permissible for the universities to collect data according to § 18 para 6 BilDokG 2020 on the applicants or examinees, respectively, and to process these data in anonymous and aggregated format for statistical and evaluation purposes.

(3) In order to ensure that the measures according to § 12a para 4, as amended by the Federal Act published in F. L. G. I No 8/2018, are implemented and a comprehensive personal monitoring for the prevention of drop-outs and an increase of the study progress is carried out, the universities shall

1. keep data-related records on the social dimension in teaching as well as on the inclusion of underrepresented groups in higher education according to § 13 para 2 subpara 1 lit g, as amended by the Federal Act published in F. L. G. I No 8/2018, and make use of existing surveys in this field to
2. link them to data on students and their study progress according to § 9 BilDokG 2020,

and thus to document and provide verifiable evidence for the quantitative developments of these aspects. For this purpose, the universities shall be given access, in particular, to those personal data collected on the basis of § 18 para 6 BildDokG 2020 on the occasion of the application of students as well as their leaving.

(4) [removed]

(5) §§ 12, 12a and 13, as amended by the Federal Act F. L. G. I No 8/2018, shall apply from 1 January 2029 to the budgeting of the Faculty of Medicine established at the University of Linz. Until the expiry of the validity of the agreement according to Art 15a Federal Constitutional Law between the Federal Government and the Provincial Government of Upper Austria on the Establishment and the Maintenance of a Faculty of Medicine and the Establishment of the Study Programme in Human Medicine at the University of Linz, F. L. G. I No 18/2014, on 31 December 2028, the budgeting and funding of the Faculty of Medicine established at the University of

Finanzierung der an der Universität Linz eingerichteten Medizinischen Fakultät gemäß der Art. 15a B-VG-Vereinbarung, BGBl. I Nr. 18/2014.

(6) § 12 Abs. 2 ist hinsichtlich der Einvernehmensherstellung mit der Bundesministerin oder dem Bundesminister für Finanzen für die Leistungsvereinbarungsperiode 2019 bis 2021 nicht anzuwenden. Über die Aufteilung des Gesamtbetrags gemäß § 141b auf die drei in § 12 Abs. 2 genannten Budgetsäulen hat die Bundesministerin oder der Bundesminister spätestens bis einen Monat nach Inkrafttreten dieses Bundesgesetzes das Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen herzustellen. Der gemäß § 141b in der Fassung des Bundesgesetzes BGBl. I Nr. 129/2017 zur Finanzierung der Universitäten festgelegte Gesamtbetrag umfasst für die Leistungsvereinbarungsperiode 2019 bis 2021 die Aufwendungen gemäß § 12 Abs. 8 und 9, die für die Finanzierung der Medizinischen Fakultät an der Universität Linz gemäß der Vereinbarung gemäß Art. 15a B-VG, BGBl. I Nr. 18/2014, sowie die für die Finanzierung der Universität für Weiterbildung Krems auf Grund der Vereinbarung gemäß Art. 15a B-VG, BGBl. I Nr. 81/2004, vom Bund zu erbringenden Mittel.

(7) Die der Bundesimmobiliengesellschaft m.b.H. gegenüber den Universitäten insgesamt aufgrund von vertraglichen Vereinbarungen zustehenden Mietforderungen reduzieren sich für die Jahre 2018 bis 2021 um 17.391.000 Euro jährlich. Der gemäß § 12 Abs. 2 festgelegte Gesamtbetrag für die Leistungsvereinbarungsperiode 2016 bis 2018 sowie der gemäß § 141b festgelegte Gesamtbetrag für die Leistungsvereinbarungsperiode 2019 bis 2021 verringern sich im gleichen Ausmaß. Das Rektorat ist verpflichtet, ein Angebot der Bundesimmobiliengesellschaft m.b.H. zur Reduktion der der Bundesimmobiliengesellschaft m.b.H. vertraglich zustehenden Mietforderungen auch unter allfälligen Bedingungen anzunehmen, sofern diese für die Universität wirtschaftlich vertretbar sind. Das zwischen der Bundesministerin oder dem Bundesminister und einer Universität in der Leistungsvereinbarung für die Periode 2016 bis 2018 vereinbarte Globalbudget der Universität verringert sich in jenem Ausmaß, in dem die Bundesimmobiliengesellschaft m.b.H. die ihr gegenüber dieser Universität aufgrund vertraglicher Vereinbarung zustehenden Mietforderungen für das Jahr 2018 reduziert.

Linz shall follow the provisions in Art 15a Federal Constitutional Law Agreement, F. L. G. I No 18/2014.

(6) With regard to reaching an agreement with the Federal Minister of Finance, § 12 para 2 shall not apply for the performance agreement period 2019 to 2021. The Federal Minister shall reach an agreement with the Federal Minister of Finance on the division of the total amount according to § 141b into the three budget columns named in § 12 para 2 no later than one month following the entry into force of this Federal Act. The total amount determined according to § 141b, as amended by the Federal Act published in F. L. G. I No 129/2017, for university funding for the performance agreement period 2019 to 2021 shall comprise expenditures according to § 12 paras 8 and 9, the funds to be provided by the Federal Government for the financing of the Faculty of Medicine at the University of Linz according to the agreement according to Art 15a Federal Constitutional Law, F. L. G. I No 18/2014, as well as for the financing of the University for Continuing Education Krems based on the agreement according to Art 15a Federal Constitutional Law, F. L. G. I No 81/2004.

(7) The rent receivables owed to the Bundesimmobiliengesellschaft m.b.H. by the universities due to contractual agreements shall be reduced by 17,391,000 € per year from 2018 to 2021. The total amount determined for the performance agreement period 2016 to 2018 according to § 12 para 2 as well as the total amount determined for the performance agreement period 2019 to 2021 according to § 141b shall be reduced by the same amount. The rectorate shall be obliged to accept an offer by the Bundesimmobiliengesellschaft m.b.H. for a reduction of the contractually due rent receivables owed to the Bundesimmobiliengesellschaft m.b.H., even under any conditions, where this is economically feasible for the university. The global budget of a university agreed upon by the Federal Minister and the respective university in the performance agreement for the period of 2016 to 2018 shall be reduced in line with the reduction of the rent receivables for the year 2018 owed to the Bundesimmobiliengesellschaft m.b.H. by that university due to the contractual agreement.

6a. Abschnitt

Zukünftige kapazitätsorientierte, studierendenbezogene Universitätsfinanzierung

Leistungsvereinbarungen für den Zeitraum 2019 bis 2021

§ 141b. Der Gesamtbetrag zur Finanzierung der Universitäten (§ 12 Abs. 2) beträgt für die Leistungsvereinbarungsperiode 2019 bis 2021 11 004 600 000 €.

Implementierung der kapazitätsorientierten, studierendenbezogenen Universitätsfinanzierung

§ 141c. Die Bundesregierung hat dem Nationalrat bis zum 31. Jänner 2018 eine Regierungsvorlage zur Neuregelung der Finanzierung der Universitäten im Sinne des § 141a zuzuleiten.

(Anm.: Abs. 2 und 3 aufgehoben durch BGBl. I Nr 8/2018)

7. Abschnitt

In-Kraft-Treten und Vollziehung

Verweisungen

§ 142. (1) Die Bezeichnungen „Bundesministerin“ oder „Bundesminister“ in diesem Bundesgesetz beziehen sich, soweit nicht ausdrücklich anderes angeführt ist, auf die Bundesministerin oder den Bundesminister, die oder der für die Angelegenheiten der Universitäten zuständig ist.

(2) Soweit in diesem Bundesgesetz auf andere Bundesgesetze verwiesen wird, sind diese Bundesgesetze in der jeweils geltenden Fassung anzuwenden.

(3) Wird in anderen Bundesgesetzen auf Bestimmungen verwiesen, an deren Stelle mit dem In-Kraft-Treten dieses Bundesgesetzes neue Bestimmungen wirksam werden, sind diese Verweisungen auf die entsprechenden neuen Bestimmungen zu beziehen.

Inkrafttreten und Außerkrafttreten von Rechtsvorschriften

§ 143. (1) Die Bestimmungen dieses Bundesgesetzes treten mit 1. Oktober 2002 in Kraft, soweit im Folgenden nicht anderes bestimmt ist.

(2) Der II. Teil dieses Bundesgesetzes tritt mit 1. Jänner 2004 in Kraft.

Chapter 6a

Future Capacity-Oriented, Student-Based Funding of Universities

Performance Agreements for the Period 2019 to 2021

§ 141b. The total amount for the financing of the universities (§ 12 para 2) amounts to 11 004 600 000 € for the performance agreement period 2019 to 2021.

Implementation of the Capacity-Oriented, Student-Based Funding of Universities

§ 141c. The Federal Government shall direct a government bill on the reorganisation of the funding of universities in the meaning of § 141a to the National Council by the 31 January 2018.

[Removed]

Chapter 7

Entry into Force and Implementation

References

§ 142. (1) Unless otherwise stated, in this Act “Federal Minister” means the federal minister in charge of higher education.

(2) References in this Act to other federal Acts are references to such Acts as amended.

(3) If reference is made in other federal Acts to provisions in place of which new provisions will take effect upon the entry into force of this Act, such citations refer to the corresponding new provisions.

Entry into Force and Expiration of Legal Provisions

§ 143. (1) The provisions of this Act shall enter into force on 1 October 2002, unless otherwise stated below.

(2) Part II of this Act shall enter into force on 1 January 2004.

(3) Die §§ 120 bis 122 treten mit dem auf die Kundmachung folgenden Tag in Kraft.

(4) Die Bestimmungen des UOG 1993 mit Ausnahme der Verfassungsbestimmungen treten mit Ablauf des 31. Dezember 2003 außer Kraft.

(5) Die Bestimmungen des KUOG mit Ausnahme der Verfassungsbestimmungen treten mit Ablauf des 31. Dezember 2003 außer Kraft.

(6) Das Bundesgesetz über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, tritt, soweit nicht die §§ 132 Abs. 2 und 133 Abs. 3 anderes bestimmen, mit Ablauf des 31. Dezember 2003 außer Kraft.

(7) Das Hochschul-Taxengesetz 1972, BGBl. Nr. 76/1972, tritt mit Ablauf des 31. Dezember 2003 außer Kraft.

(8) § 112 tritt mit 1. Oktober 2018 außer Kraft.

(9) Die Bestimmungen des Universitäts-Studiengesetzes (UniStG) mit Ausnahme der Verfassungsbestimmungen treten mit Ablauf des 31. Dezember 2003 außer Kraft.

(10) Das Inhaltsverzeichnis, § 13 Abs. 1 bis 3 und Abs. 8 bis 10, § 13a, § 31 Abs. 4, § 32 Abs. 1 erster Satz und Abs. 2, § 94 Abs. 1 und 3, § 122 Abs. 2 Z 5, 9, 10 und 11, § 135 Abs. 3 sowie § 141 Abs. 3 und 7 in der Fassung des Bundesgesetzes BGBl. I Nr. 96/2004 treten mit 1. Oktober 2004 in Kraft.

(11) § 124b in der Fassung BGBl. I Nr. 87/2007 tritt mit Ablauf des 30. Juni 2009 außer Kraft.

(12) § 61 Abs. 1 und Abs. 2, § 91 Abs. 1 und Abs. 2 sowie § 92 Abs. 1 Ziffer 4 bis 6, sowie § 141 Abs. 8 und 9 sowie § 143 Abs. 11 des Bundesgesetzes in der Fassung BGBl. I Nr. 134/2008 treten mit 1. Jänner 2009 in Kraft, §124b des Bundesgesetzes in der Fassung BGBl. I Nr. 134/2008 tritt mit 1. Juli 2009 in Kraft.

(12a) Die Überschrift, das Inhaltsverzeichnis, die §§ 5, 9, 10, 11, 12, 13, 15, 16, 19, 20, 21, 22, 23, 23a, 23b, 24, 25, 29, 32, 42, 43, 45, 46, 49, 51, 54 Abs. 3, Abs. 3a, Abs. 5, Abs. 9, Abs. 9a, Abs. 10, Abs. 11 und Abs. 12, 56, 59, 60, 61, 63, 64, 65, 66, 67, 78, 79, 85, 86, 87, 91, 92, 98, 99, 100, 103, 107, 108a, 109, 119, 124, 124b, 125, 128, und 141 in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 treten mit 1. Oktober 2009 in Kraft.

(3) §§ 120 to 122 shall enter into force on the day after publication of this Act.

(4) The provisions of the University Organisation Act 1993, except for the constitutional provisions, shall expire at the end of 31 December 2003.

(5) The provisions of the Universities of the Arts Organisation Act 1993, except for the constitutional provisions, shall expire at the end of 31 December 2003.

(6) The Compensation for Scientific and Artistic Activities at Universities and Universities of the Arts Act, F. L. G. No 463/1974, shall expire at the end of 31 December 2003 except to the extent otherwise provided for by §§ 132 para 2 and 133 para 3.

(7) The Tuition and Fees Act 1972, F. L. G. No 76/1972, shall expire at the end of 31 December 2003.

(8) § 112 shall expire on 1 October 2018.

(9) The provisions of the University Studies Act, except for the constitutional provisions, shall expire at the end of 31 December 2003.

(10) The table of contents, § 13 paras 1 to 3 and 8 to 10, § 13a, § 31 para 4, § 32 para 1 first sentence and para 2, § 94 paras 1 and 3, § 122 para 2 subparas 5, 9, 10 and 11, § 135 para 3 and § 141 paras 3 and 7, as amended by the Federal Act F. L. G. I No 96/2004, shall enter into force on 1 October 2004.

(11) § 124b, as amended by F. L. G. I No 87/2007, shall expire on 30 June 2009.

(12) § 61 para 1 and para 2, § 91 para 1 and para 2 and § 92 para 1 (4)-(6), and § 141 para 8 and 9 and § 143 para 11, as amended by F. L. G. I No 134/2008. shall enter into force on 1 January 2009, §124b of this Federal Act, as amended by F. L. G. I No 134/2008, shall enter into force on 1 July 2009.

(12a) The heading, the table of contents, §§ 5, 9, 10, 11, 12, 13, 15, 16, 19, 20, 21, 22, 23, 23a, 23b, 24, 25, 29, 32, 42, 43, 45, 46, 49, 51, 54 para 3, para 3a, para 5, para 9, para 9a, para 10, para 11 and para 12, 56, 59, 60, 61, 63, 64, 65, 66, 67, 78, 79, 85, 86, 87, 91, 92, 98, 99, 100, 103, 107, 108a, 109, 119, 124, 124b, 125, 128, and 141, as amended by the Federal Act F. L. G. I No 81/2009, shall enter into force on 1 October 2009.

(13) § 64a in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 tritt mit 1. Oktober 2010 in Kraft. Verordnungen aufgrund des § 64a dürfen bereits vor dem 1. Oktober 2010 erlassen werden, sie dürfen aber frühestens mit 1. Oktober 2010 in Kraft treten.

(14) Das Bundesgesetz über die Erlangung studienrichtungsbezogener Studienberechtigungen an Universitäten und Hochschulen künstlerischer Richtung (Studienberechtigungsgesetz – StudBerG), BGBl. Nr. 292/1985, tritt mit Ablauf des 30. September 2010 außer Kraft. Es ist jedoch auf Bewerberinnen und Bewerber, die vor dem 1. Oktober 2010 bereits zur Studienberechtigungsprüfung zugelassen waren, bis zum Ablauf des 30. September 2012 weiterhin anzuwenden.

(15) § 54 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 tritt mit 1. Oktober 2012 in Kraft.

(16) Die Funktionsperiode der am 1. Oktober 2009 bestehenden Universitätsräte endet mit Ablauf des 28. Februar 2013.

(17) Die Funktionsperiode der am 1. Jänner 2010 bestehenden Senate endet mit Ablauf des 30. September 2010. Diese Senate haben die Größe der neuen Senate gemäß § 25 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 rechtzeitig vor Ablauf der Funktionsperiode festzulegen; kommt ein Beschluss nicht zustande, besteht der Senat aus 18 Mitgliedern. Für die Wahlen zum Senat, die im Jahr 2009 stattfinden, sind die am 1. Jänner 2009 gültigen Bestimmungen weiterhin anzuwenden. Für die Konstituierung von Senaten ab dem 1. Jänner 2010, ist § 25 in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 anzuwenden.

(18) Organe und Gremien, die am 1. Oktober 2009 konstituiert sind, gelten in Hinblick auf die sinngemäße Anwendung des Bundes-Gleichbehandlungsgesetzes als gesetzeskonform zusammengesetzt.

(19) Auf Anträge auf Anerkennung von Diplom- und Masterarbeiten bzw. künstlerische Diplom- und Masterarbeiten, die vor dem 1. Jänner 2011 gestellt wurden, ist § 85 in der Fassung des Tages vor dem Inkrafttreten des Bundesgesetzes BGBl. I Nr. 81/2009 weiterhin anzuwenden.

(20) Verfahren für die Wahl der Funktion der Rektorin oder des Rektors, die zum Zeitpunkt des Inkrafttretens des Bundesgesetzes BGBl. I Nr. 81/2009 bereits durch Übermittlung der Ausschreibung an den Universitätsrat zur Stellungnahme eingeleitet wurden, sind nach den Bestimmungen für die Wahl der Rektorin oder des Rektors in der Fassung des Tages vor dem Inkrafttreten des Bundesgesetzes BGBl. I Nr. 81/2009 fortzuführen.

(13) § 64a, as amended by the Federal Act F. L. G. I No 81/2009, shall enter into force on 1 October 2010. Decrees under § 64a may be enacted already before 1 October 2010, but shall enter into force no earlier than 1 October 2010.

(14) The Higher Education Entrance Act, F. L. G. No 292/1985, shall cease to be in force after 30 September 2010. However, it shall continue to apply until after 30 September 2012 to applicants who were already admitted to the university entrance qualification examination before 1 October 2010.

(15) § 54 para 2, as amended by the Federal Act F. L. G. I No 81/2009, shall enter into force on 1 October 2012.

(16) The term of office of university councils in office on 1 October 2009 shall end after 28 February 2013.

(17) The term of office of the senates in office on 1 January 2010 shall end after 30 September 2010. These senates shall determine the size of the new senates under § 25 para 2, as amended by the Federal Act F. L. G. I No 81/2009, in time before the expiry of their term of office; if no decision is taken, the senate shall consist of 18 members. For elections to the senate taking place in 2009, the provisions in force on 1 January 2009 shall continue to apply. For the constitution of senates from 1 January 2010, § 25, as amended by the Federal Act F. L. G. I No 81/2009, shall apply.

(18) Bodies, boards, and committees in office on 1 October 2009 shall be deemed to be constituted in conformity with the law with regard to the application of the Federal Act on Equal Treatment in the Public Service by analogy.

(19) For applications for the recognition of diploma or master's theses or artistic diploma or master's submissions which were submitted before 1 January 2011, § 85, as amended the day before the entry into force of the Federal Act F. L. G. I No 81/2009, shall continue to apply.

(20) Procedures for the election of the rector which at the time of the entry into force of the Federal Act published in the F. L. G. I No 81/2009 have already been opened by forwarding the advertisement to the university council for its opinion shall be continued according to the regulations for the election of the rector, as amended the day before the entry into force of the Federal Act F. L. G. I No 81/2009.

(21) Bis zum 1. Oktober 2013 ist für jedes an der Universität eingerichtete Bachelorstudium im Curriculum ein Qualifikationsprofil zu erstellen und im Mitteilungsblatt zu verlautbaren. Ist der Senat bei der Erlassung des Qualifikationsprofils säumig, hat der Universitätsrat von Amts wegen ein Qualifikationsprofil zu erstellen. Ist der Universitätsrat säumig, hat die Bundesministerin oder der Bundesminister die Ersatzvornahme vorzunehmen.

(Anm.: Abs. 22 aufgehoben durch BGBl. I Nr. 52/2013)

(Anm.: Abs. 23 aufgehoben durch BGBl. I Nr. 131/2015)

(24) § 124b in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 tritt mit 1. Juli 2009 in Kraft und mit Ablauf des 31. Dezember 2015 außer Kraft. Die Bundesministerin oder der Bundesminister hat die Auswirkungen des § 124b auf die Anzahl der Studierenden zu evaluieren und dem Nationalrat spätestens im Dezember 2015 einen Bericht über das Ergebnis der Evaluierung vorzulegen.

(25) § 29 Abs. 5 letzter Satz in der Fassung des Bundesgesetzes BGBl. I Nr. 81/2009 ist nur auf jene Vereinbarungen über die Zusammenarbeit anzuwenden, die nach dem Inkrafttreten dieser Bestimmung abgeschlossen werden.

(26) Personen, die am 30. September 2009 als Universitätsprofessorin oder Universitätsprofessor gemäß § 99 aufgenommen sind, haben das Recht, Anträge auf Verlängerung ihrer Bestellung zu stellen, wobei insgesamt eine Bestellungsdauer von bis zu fünf Jahren zulässig ist.

(27) § 60 Abs. 1b sowie § 66 Abs. 1 und 1a in der Fassung des Bundesgesetzes BGBl. I Nr. 13/2011 sind auf Studierende, die das Studium ab dem Wintersemester 2011/2012 beginnen, anzuwenden.

(Anm.: Abs. 28 aufgehoben durch BGBl. I Nr. 52/2013)

(29) § 12 Abs. 2, Abs. 3 erster Satz und Abs. 5 bis 9 in der Fassung des 2. Stabilitätsgesetzes 2012, BGBl. I Nr. 35/2012, treten mit 1. Jänner 2013 in Kraft, wobei die im Jahr 2012 stattfindenden Verhandlungen für die Leistungsvereinbarungen der Leistungsvereinbarungsperiode 2013 bis 2015 sowie deren Abschlüsse bereits in Hinblick auf die ab 1. Jänner 2013 geltenden Rechtslage erfolgen. Die Verordnung gemäß § 12 Abs. 9 in der Fassung des 2. Stabilitätsgesetzes 2012 kann bereits vor dem 1. Jänner 2013 erlassen werden, sie darf aber frühestens mit 1. Jänner 2013 in Kraft treten.

(29a) § 61 Abs. 1, 2 und 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2012 sind erstmalig für das Wintersemester 2012/2013 anzuwenden. § 90

(21) By 1 October 2013, a qualification profile shall be drawn up in the curriculum for each bachelor's programme established at the university and published in the university gazette. If the senate is in delay in drawing up the qualification profile, the university council shall, acting proprio motu, draw up a qualification profile. If the university council is in delay, the Federal Minister shall make the substitute performance.

(22) [removed]

(23) [removed]

(24) § 124b, as amended by the Federal Act F. L. G. I No 81/2009, shall enter into force on 1 July 2009 and shall cease to be in force after 31 December 2015. The Federal Minister shall evaluate the effects of § 124b on the number of students and submit a report on the results of the evaluation to the National Council by December 2015 at the latest.

(25) § 29 para 5, last sentence, as amended by the Federal Act , F. L. G. I No 81/2009, shall only apply to those agreements on the joint operation that have been concluded after the entry into force of this provision.

(26) Persons who are employed as professors under § 99 on 30 September 2009, shall have the right to apply for an extension of their appointment, with an appointment period of a total of up to five years being permissible.

(27) § 60 para 1b and § 66 paras 1 and 1a, as amended by the Federal Act F. L. G. I No 13/2011, shall apply to students who will be admitted to their studies from the winter semester 2011/2012.

(28) [removed]

(29) § 12 para 2, para 3, first sentence, and paras 5 to 9, as amended by the 2nd Stability Act 2012, F. L. G. I No 35/2012, shall enter into force on 1 January 2013, and the negotiations of the performance agreements for the performance agreement period 2015 to 2012, which take place in 2013, and their conclusion shall be in accordance with the legal regulations in force from 1 January 2013. The decree under § 12 para 9, as amended by the 2nd Stability Act 2012, may be issued prior to 1 January 2013, but shall not enter into force prior to 1 January 2013.

(29a) § 61 paras 1, 2 and 4, as amended by the Federal Act F. L. G. I No 47/2012, shall apply for the first time for the winter semester 2012/2013. § 90

Abs. 3 in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2012 ist auf Nostrifizierungsanträge anzuwenden, die nach dem 1. Mai 2012 gestellt werden.

(30) Studienbeiträge gemäß § 91 Abs. 1 bis 3 in der Fassung BGBl. I Nr. 18/2013 sind ab dem Sommersemester 2013 zu entrichten. Kommt es bis 1. Juni 2014 zu keiner Neuerung der Studienbeitragsregelung, so bleibt die vorliegende Fassung in Geltung.

(31) § 143 Abs. 22 und 28 treten mit Ablauf des 28. Februar 2013 außer Kraft. § 66 Abs. 1, Abs. 1a und Abs. 1b treten mit Ablauf des 31. Dezember 2015 außer Kraft. Die Bundesministerin oder der Bundesminister hat die Auswirkungen der Studieneingangs- und Orientierungsphase in Zusammenarbeit mit den Universitäten zu evaluieren und dem Nationalrat spätestens im Dezember 2015 einen Bericht über das Ergebnis der Evaluierung vorzulegen.

(32) §§ 12 und 13 sind unter Berücksichtigung der §§ 14a bis 14g in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2013 bis spätestens 31. März 2014 zu ändern. Sollte bis zu diesem Zeitpunkt keine entsprechende Änderung der §§ 12 und 13 erfolgt sein, treten die §§ 14a bis 14g mit Ablauf des 31. März 2014 außer Kraft.

(33) §§ 64 und 66 sind unter Berücksichtigung der §§ 14g und 14i in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2013 bis spätestens 31. März 2014 zu ändern. Sollte bis zu diesem Zeitpunkt keine entsprechende Änderung der §§ 64 und 66 erfolgt sein, tritt § 14i mit Ablauf des 31. März 2014 außer Kraft.

(34) § 14h tritt mit 1. Jänner 2013 in Kraft und mit Ablauf des 31. Dezember 2015 außer Kraft. Die Bundesministerin oder der Bundesminister hat die Auswirkungen der Zulassungsvoraussetzungen gemäß § 14h in Zusammenarbeit mit den Universitäten zu evaluieren und dem Nationalrat spätestens im Dezember 2015 einen Bericht über das Ergebnis der Evaluierung vorzulegen. Schwerpunkt der Evaluierung ist die Zusammensetzung der Studienwerberinnen und -werber bzw. der Studierenden in sozialer und kultureller Hinsicht sowie nach Geschlecht und Staatsangehörigkeit.

(35) § 13 Abs. 9 und 10, § 13a Abs. 6, § 25 Abs. 1 Z 12, § 43 Abs. 7, § 45 Abs. 7, § 46 Abs. 1 und 2, § 79 Abs. 1, § 92 Abs. 8, § 103 Abs. 9 und § 125 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 79/2013 treten mit 1. Jänner 2014 in Kraft.

(35a) § 63 Abs. 1 Z 5a und Abs. 12 in der Fassung des Bundesgesetzes BGBl. I Nr. 124/2013 sind auf Studierende, die das Studium ab dem Wintersemester 2014/2015 beginnen, anzuwenden.

para 3, as amended by the Federal Act F. L. G. I No 47/2012, shall apply to applications for recognition of foreign degrees submitted after 1 May 2012.

(30) Tuition fees under § 91 paras 1 to 3, as amended by F. L. G. I No 18/2013, shall be paid from the summer semester 2013. Unless there are amendments to the regulations on tuition fees by 1 June 2014, the present version shall remain in force.

(31) § 143 paras 22 and 28 shall expire on 28 February 2013. § 66 para 1, para 1a and para 1b shall expire on 31 December 2015. The Federal Minister shall evaluate the effects of the orientation period in cooperation with the universities and shall submit a report on the results of the evaluation to the National Council no later than December 2015.

(32) §§ 12 and 13 shall be amended by 31 March 2014, having regard to §§ 14a to 14g, as amended by the Federal Act F. L. G. I No 52/2013. If §§ 12 and 13 have not been amended by then, §§ 14a to 14g shall expire on 31 March 2014.

(33) §§ 64 and 66 shall be amended by 31 March 2014, having regard to §§ 14g and 14i, as amended by the Federal Act F. L. G. I No 52/2013. If §§ 64 and 66 have not been amended by then, § 14i shall expire on 31 March 2014.

(34) § 14h shall enter into force on 1 January 2013 and shall expire on 31 December 2015. The Federal Minister shall evaluate the effects of the admission requirements under § 14h in cooperation with the universities and shall submit a report on the results of the evaluation to the National Council no later than December 2015. The main focus of the evaluation shall be a break-down of applicants and enrolled students according to their social and cultural background as well as according to gender and nationality.

(35) § 13 paras 9 and 10, § 13a para 6, § 25 para 1 (12), § 43 para 7, § 45 para 7, § 46 paras 1 and 2, § 79 para 1, § 92 para 8, § 103 para 9 and § 125 para 1, as amended by the Federal Act F. L. G. I No 79/2013, shall enter into force on 1 January 2014.

(35a) § 63 para 1 (5a) and para 12, as amended by the Federal Act F. L. G. I No 124/2013, shall apply to students who start their studies in the winter semester 2014/2015.

(36) Kollegialorgane und Gremien, die am 1. März 2015 konstituiert sind, gelten bis zum Ende ihrer Funktionsperiode im Hinblick auf § 20a als gesetzeskonform zusammengesetzt.

(37) Das Inhaltsverzeichnis, §§ 2 Z 13 und 14, 7 Abs. 1, 13 Abs. 2 Z 1, 13b samt Überschrift, 15 Abs. 4a, 19 Abs. 2 Z 2, 2a, der Einleitungsteil zu 21 Abs. 1, Abs. 1 Z 13, 4, 5, 11 und 16, die Überschrift zu 23b, 23b Abs. 1, 25 Abs. 4 Z 2, 26 Abs. 1, 29 Abs. 1 und 5, 35a samt Überschrift, 40 Abs. 1, der 8. Unterabschnitt des 2. Abschnitts des I. Teils, 46 Abs. 4, 51 Abs. 2 Z 3, 4, 5, 11, 12a und 13a, 52 Abs. 1 und 2, 54 Abs. 1 Z 10 und 11, 54 Abs. 3, 54 Abs. 9, 56, 57, 59 Abs. 2 Z 5, 60 Abs. 1b und 6, 61 Abs. 2 Z 3, Abs. 3 Z 5, 63 Abs. 1 Z 4, 64 Abs. 1 Z 6 bis 8, 64 Abs. 4, 5 und 6, 66 Abs. 1 bis 6, 67 Abs. 1 und 2, 68 Abs. 2, 70 Abs. 2, der 3a. Abschnitt des II. Teils, 72, 73 Abs. 1, 74 Abs. 2 und 4, 75 Abs. 1 bis 3, 77 Abs. 1, 79 Abs. 5 und 6, 78 Abs. 8, die Überschrift zu 82, 82 Abs. 1 und 2, 84 Abs. 2, 85 samt Überschrift, 86, 87 Abs. 1, 90 Abs. 3, 98 Abs. 4, 99 Abs. 4, 109 Abs. 3 und 4, 115 samt Überschrift, 119 Abs. 6 Z 1, 123a, 123b Abs. 5 und 6, 125 Abs. 1, 135 Abs. 3 bis 6 sowie 143 Abs. 8, 12a, 23, 24, 29a, 35a, 37 bis 44 in der Fassung des Bundesgesetzes BGBl. I Nr. 131/2015 treten mit 1. Jänner 2016 in Kraft. § 99 Abs. 5 bis 7 treten mit 1. Oktober 2016 in Kraft.

(38) § 21 Abs. 4 und 5 in der Fassung des BGBl. I Nr. 131/2015 sind erst auf die Zusammensetzung der Universitätsräte für die mit 1. März 2018 beginnende Funktionsperiode anzuwenden.

(39) § 21 Abs. 11 in der Fassung des Bundesgesetzes BGBl. I Nr. 131/2015 ist ab Beginn der Funktionsperiode für die Universitätsräte am 1. März 2018 anzuwenden.

(40) § 13 Abs. 2 Z 1 lit. k, l und m, § 54 Abs. 6d und § 64 Abs. 6 treten mit Ablauf des 31. Dezember 2015 außer Kraft.

(41) § 66 in der Fassung des Bundesgesetzes BGBl. I Nr. 131/2015 tritt mit 1. Jänner 2016 in Kraft und mit Ablauf des 31. Dezember 2027 außer Kraft. Die Bundesministerin oder der Bundesminister hat die Auswirkungen der Studieneingangs- und Orientierungsphase ab dem Jahr 2022 in Zusammenarbeit mit den Universitäten zu evaluieren und dem Nationalrat spätestens im Dezember 2026 einen Bericht über das Ergebnis der Evaluierung vorzulegen.

(42) Der 3a. Abschnitt des II. Teils samt Überschrift (§§ 71a bis 71d samt Überschriften) tritt mit 1. Jänner 2016 in Kraft und mit Ablauf des 31. Dezember 2027 außer Kraft. Die Bundesministerin oder der Bundesminister hat die Auswirkungen der Zugangsregelungen ab dem Jahr 2022 in Zusammenarbeit mit den

(36) Collegial bodies, boards and committees in office on 1 March 2015 shall be deemed to be constituted in conformity with the law with regard to the application of § 20a until the end of their term of office.

(37) The table of contents, §§ 2 subparas 13 and 14, 7 para 1, 13 para 2 subpara 1, 13b including the heading, 15 para 4a, 19 para 2 subpara 2, 2a, the introduction to 21 para 1, para 1 subpara 13, 4, 5, 11 and 16, the heading of 23b, 23b para 1, 25 para 4 subpara 2, 26 para 1, 29 paras 1 and 5, 35a including the heading, 40 para 1, Sub-Chapter 8 of Chapter 2 of Part I, 46 para 4, 51 paras 2 subpara 3, 4, 5, 11, 12a and 13a, 52 paras 1 and 2, 54 para 1 subparas 10 and 11, 54 para 3, 54 para 9, 56, 57, 59 para 2 subpara 5, 60 paras 1b and 6, 61 para 2 subpara 3, para 3 subpara 5, 63 para 1 subpara 4, 64 para 1 subparas 6 to 8, 64 paras 4, 5 and 6, 66 paras 1 to 6, 67 paras 1 and 2, 68 para 2, 70 para 2, Chapter 3a of Part II, 72, 73 para 1, 74 paras 2 and 4, 75 paras 1 to 3, 77 para 1, 79 paras 5 and 6, 78 para 8, the heading of 82, 82 paras 1 and 2, 84 para 2, 85 including the heading, 86, 87 para 1, 90 para 3, 98 para 4, 99 para 4, 109 paras 3 and 4, 115 including the heading, 119 para 6 subpara 1, 123a, 123b paras 5 and 6, 125 para 1, 135 paras 3 to 6 and 143 paras 8, 12a, 23, 24, 29a, 35a, 37 to 44, as amended by the Federal Act F. L. G. I No 131/2015, shall enter into force on 1 January 2016. § 99 paras 5 to 7 shall enter into force on 1 October 2016.

(38) § 21 paras 4 and 5, as amended by F. L. G. I No 131/2015, shall first apply to the composition of the university councils for the term of office beginning on 1 March 2018.

(39) § 21 para 11, as amended by Federal Act F. L. G. I No 131/2015, shall first apply to the term of office of university councils beginning on 1 March 2018.

(40) § 13 para 2 subpara 1 lit k, l and m, § 54 para 6d and § 64 para 6 shall expire as of 31 December 2015.

(41) § 66, as amended by the Federal Act F. L. G. I No 131/2015, shall enter into force on 1 January 2016 and shall expire as of 31 December 2027. The Federal Minister shall evaluate the ramifications of the introductory and orientation period starting in the year 2022 and following in collaboration with the universities and shall submit a report on the results of the evaluation to the National Council by December 2026 at the latest.

(42) Chapter 3a of Part II including the heading (§§ 71a to 71d including the headings) shall enter into force on 1 January 2016 and shall become invalid as of 31 December 2027. The Federal Minister shall evaluate the ramifications of the admission regulations starting in the year 2022 and following in collaboration with

Universitäten zu evaluieren und dem Nationalrat spätestens im Dezember 2026 einen Bericht über das Ergebnis der Evaluierung vorzulegen. Schwerpunkt der Evaluierung ist die Zusammensetzung der Studienwerberinnen und -werber bzw. der Studierenden sowie jener Personen, die sich für ein Aufnahme- oder Auswahlverfahren angemeldet haben, aber die nicht zur Prüfung erschienen sind, nach soziodemografischen Merkmalen wie zB Geschlecht, Bildungshintergrund der Eltern und Staatsangehörigkeit. Es ist zulässig, von den Studienwerberinnen und -werbern bzw. Prüfungsteilnehmerinnen und -teilnehmern deren Herkunft sowie die Herkunft und Bildungslaufbahn der Eltern im Sinne des § 18 Abs. 6 des Bildungsdokumentationsgesetzes 2020, BGBl. I Nr. 20/2021, zu erfassen und anonymisiert und aggregiert für statistische Zwecke und Evaluierungszwecke zu verarbeiten.

(43) Für die Änderung der Curricula von Studien, die von § 14h in der Fassung des Bundesgesetzes BGBl I Nr. 52/ 2013 umfasst sind, ist bis zum 1. Oktober 2016 § 54 Abs. 5 letzter Satz nicht anzuwenden.

(44) Änderungen der Curricula, die aufgrund von § 66 in der Fassung des Bundesgesetzes BGBl. I Nr. 131/2015 erforderlich sind, sind bis spätestens 30. Juni 2017 zu verlautbaren.

(45) Die Verordnung der Bundesregierung über die Festsetzung einer Zahl an Studienplätzen für Studienanfängerinnen und Studienanfänger und über die Ermächtigung an Rektorate zur Festlegung eines qualitativen Aufnahmeverfahrens, BGBl. II Nr. 133/2010, tritt mit Ablauf des 31. Dezember 2015 außer Kraft.

(46) § 71b Abs. 7 Z 3 in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 ist mit der Maßgabe anzuwenden, dass für die Zulassung zum Studium bis zum Wintersemester 2019/2020 die Zurverfügungstellung des Prüfungsstoffes auf der Homepage der Universität oder in anderer geeigneter Form erfolgen kann.

(47) Die Bestimmungen des Bundesgesetzes BGBl. I Nr. 129/2017 treten mit 1. Oktober 2017 in Kraft. Verordnungen auf Grund des Bundesgesetzes BGBl. I Nr. 129/2017 können bereits ab dem seiner Kundmachung folgenden Tag erlassen werden. Diese Verordnungen sind frühestens gleichzeitig mit dem Inkrafttreten dieses Bundesgesetzes in Kraft zu setzen. Änderungen von Curricula, Satzungen und anderen Verordnungen, die aufgrund des Bundesgesetzes BGBl. I Nr. 129/2017 erforderlich sind, sind bis spätestens 30. Juni 2019 zu verlautbaren. Abschnitt 6a des Teil VIII in der Fassung des Bundesgesetzes BGBl. I Nr. 129/2017 tritt mit 1. August 2017 in Kraft.

the universities and shall submit a report on the results of the evaluation to the National Council by December 2026 at the latest. The focus of the evaluation shall be the composition of applicants, students and those persons who have registered for an admission procedure or selection procedure, but did not sit the examination, according to socio-demographic characteristics, such as gender, educational background of the parents and nationality. It shall be permissible to collect data on the applicants' or examinees' level of education and that of their parents as well as the latter's occupational status in the meaning of § 18 para 6 of the Education Documentation Act 2020, F. L. G. I No 20/2021, and to process these data in an anonymous and aggregated format for statistical purposes and evaluation purposes.

(43) § 54 para 5, last sentence, shall not apply to changes to curricula of programmes that fall under § 14h, as amended by the Federal Act F. L. G. I No 52/2013, before 1 October 2016.

(44) Changes to the curricula that become necessary on the basis of § 66, as amended by the Federal Act F. L. G. I No 131/2015, shall be announced by 30 June 2017 at the latest.

(45) The decree issued by the Federal Government that regulates the number of study places for students beginning their studies and authorises rectorates to implement a qualitative admission procedure, F. L. G. II No 133/2010, shall expire as of 31 December 2015.

(46) § 71c para 6 subpara 3, as amended by the Federal Act F. L. G. I No 8/2018, shall apply, provided that the examinable material can be made accessible on the university's website or in another suitable manner by the winter term 2019/2020 for admission to the programme.

(47) The provisions of the Federal Act published in the F. L. G. I No 129/2017 shall enter into force on 1 October 2017. Decrees based on the Federal Act published in the F. L. G. I No 129/2017 may be issued beginning already on the day following the promulgation of this Act. These decrees shall come into force at the earliest together with the entry into force of this Federal Act. Changes to curricula, statutes and other decrees that become necessary on the basis of the Federal Act published in the F. L. G. I No 129/2017 shall be announced by 30 June 2019 at the latest. Chapter 6a of Part VIII, as amended by the Federal Act published in the F. L. G. I No 129/2017, shall enter into force as of 1 August 2017.

(48) Die Verleihung eines akademischen Bachelorgrades für den Abschluss eines Human- oder Zahnmedizinischen Bachelorstudiums ist ab dem 1. Juni 2017 zulässig.

(49) Das Inhaltsverzeichnis, § 12, §§ 12a und 12b samt Überschriften, § 13 Abs. 2 Z 1 lit. b, c und g, § 13 Abs. 2 Z 2, § 13 Abs. 3, § 20 Abs. 6 Z 15, § 21 Abs. 1 Z 1, § 22 Abs. 1 Z 4, § 23 Abs. 1 Z 4, § 51 Abs. 2 Z 14d bis 14g, § 61 Abs. 4, § 63 Abs. 1 Z 4 bis 6, § 99a, § 107 Abs. 2 Z 2 und 3 sowie § 141 in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 treten mit 1. Februar 2018 in Kraft. Die §§ 12, 12a und 12b, § 13 Abs. 2 Z 1 lit. b, c und g, § 13 Abs. 2 Z 2, § 13 Abs. 3 sowie § 141 in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 sind erstmals auf die Leistungsvereinbarungsperiode 2019 bis 2021 anzuwenden. Auf die Finanzierung der Universitäten für die laufende Leistungsvereinbarungsperiode 2016 bis 2018 sind die §§ 12, 13 sowie 141 in der am 31. Jänner 2018 geltenden Fassung weiterhin anzuwenden. § 13 Abs. 4 tritt mit Ablauf des 31. Jänner 2018 außer Kraft.

(50) § 63a Abs. 9 sowie der 3a. Abschnitt des II. Teils samt Überschrift (§§ 71a bis 71d samt Überschriften) in der Fassung des Bundesgesetzes BGBl. I Nr. 8/2018 treten mit 1. Mai 2018 in Kraft und sind erstmals für die Zulassung zum Studium für das Wintersemester 2019/2020 anzuwenden. Für die Zulassungen für das Wintersemester 2018/2019 sowie für das Sommersemester 2019 sind § 63a Abs. 9 sowie der 3a. Abschnitt des II. Teils samt Überschrift in der am 30. April 2018 geltenden Fassung weiterhin anzuwenden.

(51) § 141a sowie § 141b zweiter Satz treten mit Ablauf des 31. Jänner 2018 außer Kraft. In § 141c entfällt die Absatzbezeichnung „(1)“ und die Abs. 2 und 3 treten mit Ablauf des 31. Jänner 2018 außer Kraft.

(52) § 141 Abs. 7 und § 141b in der Fassung des Bundesgesetzes BGBl. I Nr. 30/2018 treten mit 1. Februar 2018 in Kraft.

(53) Das Inhaltsverzeichnis, § 1, § 13a Abs. 4, § 14 Abs. 6, § 16 Abs. 6, § 17 Abs. 2, § 21 Abs. 2, § 29 Abs. 4 Z 2, § 42 Abs. 4, § 43 Abs. 4, § 45 Abs. 2, § 60 Abs. 5, § 119 Abs. 3 sowie § 143 Abs. 42 in der Fassung des Datenschutz-Anpassungsgesetzes 2018 – Wissenschaft und Forschung, BGBl. I Nr. 31/2018, treten mit 25. Mai 2018 in Kraft.

(54) § 30a und § 108 Abs. 5 treten mit Ablauf des 24. Mai 2018 außer Kraft.

(48) The award of an academic bachelor's degree for the completion of a bachelor's programme in human or dental medicine shall be permissible as of 1 June 2017.

(49) The table of contents, § 12, §§ 12a and 12b including the headings, § 13 para 2 subpara 1 lit b, c and g, § 13 para 2 subpara 2, § 13 para 3, § 20 para 6 subpara 15, § 21 para 1 subpara 1, § 22 para 1 subpara 4, § 23 para 1 subpara 4, § 51 para 2 subparas 14d to 14g, § 61 para 4, § 63 para 1 subparas 4 to 6, § 99a, § 107 para 2 subparas 2 and 3 as well as § 141, as amended by the Federal Act published in the F. L. G. I No 8/2018, shall enter into force on 1 February 2018. §§ 12, 12a and 12b, § 13 para 2 subpara 1 lit b, c and g, § 13 para 2 subpara 2, § 13 para 3 as well as § 141, as amended by the Federal Act F. L. G. I No 8/2018, shall first apply to the performance agreement period 2019 to 2021. §§ 12, 13 as well as 141 in the version valid as of 31 January 2018 shall continue to apply to university funding for the performance agreement period 2016 to 2018. § 13 para 4 shall expire at the end of 31 January 2018.

(50) § 63a para 9 as well as Chapter 3a of Part II including the heading (§§ 71a to 71d including the headings), as amended by the Federal Act F. L. G. I No 8/2018, shall enter into force on 1 May 2018 and shall first apply to the admission to study programmes for the winter semester 2019/2020. For admissions in the winter semester 2018/2019 as well as in the summer semester 2019, § 63a para 9 as well as Chapter 3a of Part II including the heading in the version valid as of 30 April 2018 shall continue to apply.

(51) § 141a as well as § 141b, second sentence, shall expire as of 31 January 2018. In § 141c the following shall be deleted: “(1)”, and paras 2 and 3 shall expire at the end of 31 January 2018.

(52) § 141 para 7 and § 141b, as amended by the Federal Act F. L. G. I No 30/2018, shall enter into force on 1 February 2018.

(53) The table of contents, § 1, § 13a para 4, § 14 para 6, § 16 para 6, § 17 para 2, § 21 para 2, § 29 para 4 subpara 2, § 42 para 4, § 43 para 4, § 45 para 2, § 60 para 5, § 119 para 3 as well as § 143 para 42, as amended by the Data Protection Amendment Act 2018 – Science and Research, F. L. G. I No 31/2018, shall enter into force on 25 May 2018.

(54) § 30a and § 108 para 5 shall expire at the end of 24 May 2018.

(55) Die §§ 60 Abs. 6 und 63 Abs. 1 Z 3, Abs. 10, 10a und 10b in der Fassung des Bundesgesetzes BGBl. I Nr. 56/2018 sind auf Anträge für die Zulassung zu Studien ab dem Sommersemester 2019 anzuwenden.

(56) § 29 Abs. 6, § 35, § 35a Abs. 2 und 3 sowie § 35b in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2018 treten an dem Tag in Kraft, der der Kundmachung folgt. § 52 Abs. 3 in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2018 tritt mit 1. Oktober 2018 in Kraft.

(57) § 125 Abs. 12 in der Fassung des Bundesgesetzes BGBl. I Nr. 52/2018 tritt an dem Tag in Kraft, der der Kundmachung folgt. Allfällige vor Inkrafttreten dieser Regelung durch den Bund geleistete und noch nicht refundierte sozialversicherungsrechtliche Überweisungsbeträge sind dem Bund durch die Universität zu ersetzen.

(58) § 6 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 3/2019 tritt mit 1. Jänner 2019 in Kraft. Für die Universität für Weiterbildung Krems (Donau-Universität Krems) gemäß § 6 Abs. 1 Z 22 ist das Bundesgesetz über die Universität für Weiterbildung Krems (UWK-Gesetz – UWKG), BGBl. I Nr. 22/2004, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 31/2018, anzuwenden.

(59) § 141b in der Fassung des Bundesgesetzes BGBl. I Nr. 135/2021 tritt mit 1. März 2021 in Kraft.

(60) § 53, § 141 Abs. 2 und 3 sowie § 143 Abs. 42 in der Fassung des Bundesgesetzes BGBl. I Nr. 20/2021 treten mit Ablauf des Tages der Kundmachung im Bundesgesetzblatt in Kraft.

(61) Die Änderungen des Inhaltsverzeichnisses mit Ausnahme der Einträge, die die Universität für Weiterbildung Krems betreffen, § 1, § 2 Z 3a und 9, § 3 Z 4 und 9, § 6 Abs. 1 Z 22 und Abs. 7, § 12 Abs. 8, § 13 Abs. 2 Z 1 lit. a, § 13a Abs. 4, § 14 Abs. 1 und 2, § 15 Abs. 7, § 16 Abs. 1 und 2, § 20 Abs. 3a und 5a, § 20b Abs. 2, § 20c, § 21 Abs. 1 Z 13, § 21 Abs. 6, § 22 Abs. 1 Z 12, 12a und 12b, § 23 Abs. 2, 3 und 5, § 23a Abs. 1, 4 und 5, § 23b, § 25 Abs. 1 Z 5a, 10 und 10a, Einleitungssatz zu § 25 Abs. 4, § 25 Abs. 4 Z 2, Schlussteil zu § 25 Abs. 4, § 29 Abs. 4 Z 2, § 32 Abs. 1, § 39 Abs. 4, § 40 Abs. 1, die Überschrift des 3. Abschnitts des I. Teils, § 42 Abs. 2, Abs. 6 Z 2, Abs. 8 und 8f, § 43 Abs. 9, § 45 Abs. 5, § 47 Abs. 1, die Überschrift des 2. Abschnitts des III. Teils, § 96 samt Überschrift, § 98 Abs. 2 zweiter Satz, Abs. 4a bis 9, § 99 Abs. 5, § 99a Abs. 1 bis 3, § 107 Abs. 1, § 108 Abs. 3, § 110 Abs. 1 und 7a, § 116 Abs. 3, § 111, § 116a samt Überschrift, § 118, §§ 118a samt Überschrift und 118b, § 124 Abs. 5, § 126 Abs. 4, § 135 Abs. 1, 3 bis 5 und 8, § 141 Abs. 2 bis 4 und Abs. 6 sowie § 143 Abs. 47 und 60 treten mit 1. Oktober 2021 in Kraft.

(55) §§ 60 para 6 and 63 para 1 subpara 3, paras 10, 10a and 10b, as amended by the Federal Act F. L. G. I No 56/2018, shall apply to applications for the admission to a study programme starting with the summer semester 2019.

(56) § 29 para 6, § 35, § 35a paras 2 and 3 as well as § 35b, as amended by the Federal Act F. L. G. I No 52/2018, shall enter into force on the day following the promulgation. § 52 para 3, as amended by the Federal Act F. L. G. I No 52/2018, shall enter into force on 1 October 2018.

(57) § 125 para 12, as amended by the Federal Act F. L. G. I No 52/2018, shall enter into force on the day following the promulgation. Any amounts to be transferred under social security law which have been paid by the Federal Government but not yet refunded before entry into force of this regulation shall be reimbursed to the Federal Government by the university.

(58) § 6 para 1, as amended by the Federal Act F. L. G. I No 3/2019, shall enter into force on 1 January 2019. The Federal Act on the University for Continuing Education Krems (UWKG), F. L. G. I No 22/2004, as amended by the Federal Act F. L. G. I No 31/2018, shall apply to the University for Continuing Education Krems (Danube University Krems) according to § 6 para 1 subpara 22.

(59) § 141b as amended by the Federal Act F. L. G. I No 135/2021 shall enter into force on 1 March 2021.

(60) § 53, § 141 para 2 and 3 as well as §143 para 42 as amended by the Federal Act F. L. G. I No 20/2021 shall enter into force upon the expiry of the day of promulgation.

(61) The changes in the table of contents, with the exception of the entries pertaining to the University for Continuing Education Krems, § 1, § 2 subparas 3a and 9, § 3 subparas 4 and 9, § 6 para 1 subpara 22 and para 7, § 12 para 8, § 13 para 2 subpara 1 lit a, § 13a para 4, § 14 paras 1 and 2, § 15 para 7, § 16 paras 1 and 2, § 20 paras 3a and 5a, § 20b para 2, § 20c, § 21 para 1 subpara 13, § 21 para 6, § 22 para 1 subparas 12, 12a and 12b, § 23 paras 2, 3 and 5, § 23a paras 1, 4 and 5, § 23b, § 25 para 1 subparas 5a, 10 and 10a, introductory sentence of § 25 para 4, § 25 para 4 subpara 2, final section of § 25 para 4, § 29 para 4 subpara 2, § 32 para 1, § 39 para 4, § 40 para 1, the heading of Chapter 3 of Part I, § 42 para 2, para 6 subpara 2, paras 8 and 8f, § 43 para 9, § 45 para 5, § 47 para 1, the heading of Chapter 2 of Part III, § 96 including the heading, § 98 para 2 second sentence, paras 4a to 9, § 99 para 5, § 99a paras 1 to 3, § 107 para 1, § 108 para 3, § 110 paras 1 and 7a, § 116 para 3, § 111, § 116a including the heading, § 118, §§ 118a including the heading

(62) § 23 Abs. 3 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 ist auf eine am 1. Oktober 2021 bereits laufende Funktionsperiode der Rektorin oder des Rektors der Universität anzuwenden. Vor dem 1. Oktober 2021 abgeschlossene Funktionsperioden bleiben außer Betracht.

(63) § 25 Abs. 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 ist auf eine am 1. Oktober 2021 bereits laufende Funktionsperiode des Senats der Universität anzuwenden. Vor dem 1. Oktober 2021 abgeschlossene Funktionsperioden bleiben außer Betracht.

(64) Die Einträge im Inhaltsverzeichnis, die die Universität für Weiterbildung Krems betreffen, die §§ 40b bis 40e samt Überschrift in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 treten mit 1. Jänner 2022 in Kraft.

(65) Das Bundesgesetz über die Universität für Weiterbildung Krems (UWK-Gesetz – UWKG), BGBl. I Nr. 22/2004, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 31/2018, tritt mit Ablauf des 31. Dezembers 2021 außer Kraft. Wird in anderen Bundesgesetzen auf Bestimmungen verwiesen, an deren Stelle mit Inkrafttreten dieses Bundesgesetzes neue Bestimmungen wirksam werden, sind diese Verweisungen auf die entsprechenden neuen Bestimmungen zu beziehen.

(66) Die gemäß UWKG mit Ablauf des 31. Dezembers 2021 durch dieses Bundesgesetz sowie durch den Organisationsplan und die Satzung der Universität für Weiterbildung Krems eingerichteten monokratischen Organe und Kollegialorgane bleiben weiterhin für die jeweilige Funktionsperiode eingerichtet.

(67) Der an der Universität für Weiterbildung Krems mit Ablauf des 31. Dezembers 2021 geltende Entwicklungsplan, der Organisationsplan sowie die an der Universität für Weiterbildung Krems mit Ablauf des 31. Dezembers 2021 geltende Satzung und die Leistungsvereinbarung bleiben weiterhin in Geltung.

(68) Die an der Universität für Weiterbildung Krems mit Ablauf des 31. Dezember 2021 eingerichteten Universitätslehrgänge und PhD-Studien bleiben weiterhin eingerichtet. Auf diese Studien sind die jeweiligen Curricula in der am 31. Dezember 2021 geltenden Fassung weiterhin anzuwenden.

(69) Acht Jahre nach Einrichtung eines „PhD“-Studiums hat eine Evaluierung hinsichtlich § 40c Abs. 2 Z 6 stattzufinden.

and 118b, § 124 para 5, § 126 para 4, § 135 paras 1, 3 to 5 and 8, § 141 paras 2 to 4 and para 6 as well as § 143 paras 47 and 60 shall enter into force on 1 October 2021.

(62) § 23 para 3 as amended by the Federal Act published in the F. L. G. I No 93/2021 shall apply to a term of office of the rector of the university already running on 1 October 2021. Terms of offices which ended before 1 October 2021 shall not be considered.

(63) § 25 para 4 as amended by the Federal Act published in the F. L. G. I No 93/2021 shall apply to a term of office of the senate of the university already running on 1 October 2021. Terms of offices which ended before 1 October 2021 shall not be considered.

(64) The entries in the table of contents pertaining to the University for Continuing Education Krems, §§ 40b to 40e including the heading as amended by the Federal Act published in the F. L. G. I No 93/2021 shall enter into force on 1 January 2022.

(65) The Federal Act on the University for Continuing Education Krems (Bundesgesetz über die Universität für Weiterbildung Krems – UWKG), F. L. G. I No 22/2004, last amended by the Federal Act published in the F. L. G. I No 31/2018, shall expire at the end of 31 December 2021. If reference is made in other Federal Acts to provisions in place of which new provisions will take effect upon the entry into force of this Act, such citations refer to the corresponding new provisions.

(66) The monocratic administrative and collegial bodies established under UWKG at the end of 31 December 2021 by this Federal Act as well as by the organisation plan and the statutes of the University for Continuing Education Krems shall remain in office for the respective term of office.

(67) The current development plan, the organisation plan as well as the statutes and performance agreement valid as of the end of 31 December 2021 at the University for Continuing Education Krems shall remain in force.

(68) The continuing education university programmes and PhD programmes offered at the University for Continuing Education Krems as of the end of 31 December 2021 shall continue to be offered. The respective curricula for these programmes in the versions valid as of 31 December 2021 shall continue to apply.

(69) Eight years following the establishment of a “PhD” programme, an evaluation in terms of § 40c para 2 subpara 6 shall take place.

(70) Der Betriebsrat für das wissenschaftliche und künstlerische Universitätspersonal sowie der Betriebsrat für das allgemeine Universitätspersonal der Universität für Weiterbildung Krems sind nach den Bestimmungen der §§ 50 ff ArbVG bis längstens 31. Dezember 2022 zu wählen. Die Funktionsperiode des zum Zeitpunkt des Inkrafttretens der Änderung dieses Bundesgesetzes BGBl. I Nr. 93/2021 gewählten Betriebsrats endet mit der Konstituierung der neugewählten Betriebsräte.

(71) § 108 Abs. 2 und 3 ist für die Universität für Weiterbildung Krems insofern ab dem 1. Jänner 2022 anzuwenden, als die Universität für Weiterbildung Krems ab dem 1. Jänner 2022 dem Dachverband der Universitäten angehört.

(72) Arbeitnehmerinnen und Arbeitnehmer, die am 31. Dezember 2021 an der Universität für Weiterbildung Krems in einem vertraglichen Dienstverhältnis stehen, werden mit dem 1. Jänner 2022 Arbeitnehmerinnen oder Arbeitnehmer der Universität für Weiterbildung Krems gemäß § 6 Abs. 1 Z 22 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021.

(73) Die Dienst- und Besoldungsordnung für das Personal des Universitätszentrums für Weiterbildung (Donau-Universität Krems) ist weiterhin anzuwenden.

(74) § 42 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 ist mit dem Beginn der nächsten Funktionsperiode des Senates erstmalig anwendbar. § 42 Abs. 2 vierter Satz in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 ist auf eine am 1. Oktober 2021 bereits laufende Funktionsperiode des Arbeitskreises für Gleichbehandlungsfragen anzuwenden. Vor dem 1. Oktober 2021 abgeschlossene Funktionsperioden bleiben außer Betracht.

(75) § 43 Abs. 9 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 ist ab der auf den 1. Oktober 2021 folgenden Funktionsperiode der Schiedskommission anzuwenden.

(76) Die studienrechtlichen Bestimmungen des Bundesgesetzes BGBl. I Nr. 93/2021, mit Ausnahme der §§ 76, 76a, 79 Abs. 2, 4 und 5, sind ab dem Studienjahr 2022/23 und die dafür durchzuführenden Aufnahme-, Eignungs- und Zulassungsverfahren und die Zulassungen für Studien für das Studienjahr 2022/23 anzuwenden. Bis dahin sind die studienrechtlichen Bestimmungen in der Fassung des Tages vor dem Inkrafttreten des Bundesgesetzes BGBl. I Nr. 93/2021 anzuwenden.

(70) Pursuant to the provisions of §§ 50 ff ArbVG, the employee's council for scientific and artistic staff as well as the employee's council for non-academic staff at the University for Continuing Education Krems shall be elected by 31 December 2022 at the latest. The term of office of the employees' council that was elected at the time of the entry into force of the amendments to this Federal Act published in the F. L. G. I No 93/2021 shall end when the newly elected employees' councils constitute themselves.

(71) § 108 paras 2 and 3 shall apply to the University for Continuing Education Krems as of 1 January 2022 insofar as the University for Continuing Education Krems is part of the national university federation as of 1 January 2022.

(72) Employees who on 31 December 2021 are in a contractual employment relationship with the University for Continuing Education Krems, shall become employees of the University for Continuing Education Krems according to § 6 para 1 subpara 22 as amended by the Federal Act published in the F. L. G. I No 93/2021, as of 1 January 2022.

(73) The service and salary regulations for the staff of the University Center for Further Studies (Danube University Krems) shall further apply.

(74) § 42 para 2 as amended by the Federal Act published in the F. L. G. I No 93/2021 shall first be applicable with the beginning of the next term of office of the senate. § 42 para 2 fourth sentence as amended by the Federal Act published in the F. L. G. I No 93/2021 shall apply to a term of office of the working group on equal opportunities already running on 1 October 2021. Terms of offices which ended before 1 October 2021 shall not be considered.

(75) § 43 para 9 as amended by the Federal Act published in the F. L. G. I No 93/2021 shall apply beginning with the term of office of the arbitration board following 1 October 2021.

(76) The provisions pertaining to study law in the Federal Act published in the F. L. G. I No 93/2021, with the exception of §§ 76, 76a, 79 paras 2, 4 and 5, shall apply from the academic year 2022/23, and the admission procedure and the procedure for the proof of aptitude for the study programmes shall apply from the academic year 2022/23. Until then, the provisions pertaining to study law as amended on the day prior to the entry into force of the Federal Act published in the F. L. G.I No 93/2021, shall apply.

(77) Änderungen von Satzungen und anderen Verordnungen und Regelungen, die aufgrund der Änderung dieses Bundesgesetzes durch das Bundesgesetz BGBl. I Nr. 93/2021 erforderlich sind, sind bis spätestens 1. Oktober 2022 zu verlautbaren. Erforderliche Änderungen von Curricula sind vor dem 1. Juli 2022 im Mitteilungsblatt zu veröffentlichen.

(78) § 59a, § 59b und § 68 Abs. 1 Z 2a in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 sind für jene Studierenden anzuwenden, die ab dem Wintersemester 2022/23 zu einem Bachelor- oder Diplomstudium zugelassen werden.

(79) § 64 Abs. 3 und 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 ist für Studierende anzuwenden, die ab dem Studienjahr 2022/2023 zum Master- bzw. zum Doktoratsstudium zugelassen werden.

(80) Die §§ 76, 76a, 79 Abs. 2, 4 und 5 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 sind für Lehrveranstaltungen und Prüfungen ab dem Wintersemester 2021/22 anzuwenden.

(81) Kollegialorgane und Gremien, die am 1. Oktober 2021 konstituiert sind, gelten bis zum Ende ihrer Funktionsperiode in Hinblick auf § 59 Abs. 5 als gesetzeskonform zusammengesetzt.

(82) Die Bundesministerin oder der Bundesminister hat die Auswirkungen der Mindeststudienleistung sowie der Unterstützungsleistungen seitens der Universität gemäß den §§ 59a und 59b in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 in Zusammenarbeit mit den Universitäten begleitend zu evaluieren und dem Nationalrat spätestens im Dezember 2025 einen Bericht über das Ergebnis der Evaluierung vorzulegen. Schwerpunkt der Evaluierung ist die Zusammensetzung der Studierenden in sozialer Hinsicht sowie nach Geschlecht und Staatsangehörigkeit.

(83) § 109 in der Fassung des Bundesgesetzes BGBl. I Nr. 93/2021 tritt mit 1. Oktober 2021 in Kraft und ist auf Arbeitsverhältnisse anzuwenden, die ab dem 1. Oktober 2021 abgeschlossen werden. Bei der Feststellung der höchstzulässigen Gesamtdauer gemäß § 109 Abs. 9 sind auch Zeiten in Arbeitsverhältnissen zur Universität zu berücksichtigen, die vor dem 1. Oktober 2021 liegen, Zeiten gemäß § 109 Abs. 7 bleiben dabei unberücksichtigt. Im Ausmaß von bis zu vier Jahren bleiben ebenso Zeiten vor dem 1. Oktober 2021 unberücksichtigt, die während eines Doktoratsstudiums an derselben Universität in einem Arbeitsverhältnis verbracht wurden, das in einem untrennbaren inhaltlichen Zusammenhang mit dem Doktoratsstudium stand.

(77) Changes to statutes and other decrees and regulations that become necessary on the basis of the Federal Act published in the F. L. G. I No 93/2021 shall be announced by 1 October 2022 at the latest. Any necessary changes to the curricula shall be published prior to 1 July 2022 in the university gazette.

(78) § 59a, § 59b and § 68 para 1 subpara 2a as amended in the Federal Act published in the F. L. G.I No 93/2021 shall apply to all students who are admitted to a bachelor's or diploma programme from the winter semester 2022/23.

(79) § 64 paras 3 and 4 as amended by the Federal Act published in the F. L. G. I No 93/2021 shall apply to students who are admitted to a master's or doctoral programme from the academic year 2022/2023.

(80) §§ 76, 76a, 79 paras 2, 4 and 5 as amended by the Federal Act published in the F. L. G. I No 93/2021 shall apply to courses and examinations from the winter semester 2021/22.

(81) Collegial bodies, boards and committees in office on 1 October 2021 shall be deemed to be constituted in conformity with the law with regard to the application of § 59 para 5 until the end of their term of office.

(82) The Federal Minister shall monitor the effects of the minimum requirement of study progress as well as the support provided by the university under §§ 59a and 59b as amended by the Federal Act published in F. L. G. I No 93/2021 in cooperation with the universities and shall submit a report on the results of the evaluation to the National Council no later than December 2025. The main focus of the evaluation shall be a break-down of students according to their social background as well as according to gender and nationality.

(83) § 109 as as amended by the Federal Act published in the F. L. G. I No 93/2021 shall enter into force on 1 October 2021 and shall apply to all employment contracts concluded from 1 October 2021. When establishing the maximum duration according to § 109 para 9, also the periods of employment at the university prior to 1 October 2021 shall be taken into account; periods according to § 109 para 7 shall not be taken into account. Also, periods of employment at the same university during a doctoral programme prior to 1 October 2021 up to a total of four years shall not be taken into account if they were inseparably connected with the doctoral programme in terms of content.

(84) Wird ein bestehendes Arbeitsverhältnis ab dem 1. Oktober 2021 ohne Änderung der Verwendung verlängert, ist § 109 in der Fassung des Bundesgesetzes BGBl. I Nr. 20/2021 weiterhin anzuwenden.

(85) Wird ein Arbeitsverhältnis gemäß § 109 Abs. 6 ab dem 1. Oktober 2021 neu abgeschlossen, bleiben Zeiten, die vor dem 1. Oktober 2021 verbracht wurden, unberücksichtigt. Wird ein Arbeitsverhältnis ab dem 1. Oktober 2021 überwiegend zur Durchführung von Drittmittelprojekten oder Forschungsprojekten abgeschlossen, bleiben Zeiten, die vor dem 1. Oktober 2021 in einem solchen Arbeitsverhältnis verbracht wurden, im Ausmaß von bis zu vier Jahren unberücksichtigt.

(86) Das Inhaltsverzeichnis, § 3 Z 5, § 6 Abs. 7, § 20 Abs. 6 Z 14, § 22 Abs. 1 Z 9a, § 25 Abs. 1 Z 10, § 29 Abs. 4 Z 1 zweiter und dritter Satz, § 46 Abs. 6, § 51 Abs. 2 Z 10, 11, 14g, 23, 23a, 26 und 27, § 54 Abs. 3 und 6, § 56, § 63a Abs. 6, § 66 Abs. 3a und 3b, § 70 Abs. 1, § 71b Abs. 1, § 71b Abs. 7 Z 5, § 71c Abs. 4 und 5a, § 76 Abs. 3, die Überschrift zu § 87, § 87 Abs. 2, § 87a samt Überschrift, § 92 Abs. 2a sowie die Überschrift zu § 143 und § 143 Abs. 41, 42 und 77 in der Fassung des Bundesgesetzes BGBl. I Nr. 177/2021 treten mit 1. Oktober 2021 in Kraft.

(87) Universitätslehrgänge gemäß § 56 in der Fassung vor dem 1. Oktober 2021, in denen die Verleihung eines Mastergrades gemäß § 87a Abs. 1 in der Fassung vor dem 1. Oktober 2021 vorgesehen ist, können bis zum 30. September 2023 eingerichtet werden.

(88) Die Zulassung zu einem Universitätslehrgang gemäß Abs. 87 ist bis längstens 30. September 2023 zulässig. Teilnehmerinnen und Teilnehmer, die bis zum 30. September 2023 zu Universitätslehrgängen zugelassen werden, haben den Universitätslehrgang ab dem 1. Oktober 2023 binnen der dreifachen Dauer der im Curriculum festgelegten Studienzeit oder binnen der allenfalls im Curriculum festgelegten Höchststudiendauer abzuschließen. Für diese Teilnehmerinnen und Teilnehmer sind die Bestimmungen dieses Bundesgesetzes in der Fassung vor dem 1. Oktober 2021 weiterhin anzuwenden.

(89) Die Zulassung zu einem Universitätslehrgang gemäß § 56 in der Fassung vor dem 1. Oktober 2021, der im Rahmen des Erasmus Mundus Joint Master Degree Programms finanziert wird, ist auch nach dem 30. September 2023 bis zum Ende der jeweils genehmigten Programmperiode zulässig.

(84) If an existing employment contract is extended from 1 October 2021 without change of assignment, § 109 as amended by the Federal Act published in the F. L. G. I No 20/2021 shall continue to apply.

(85) If an employment contract according to § 109 para 6 is newly concluded from 1 October 2021, any periods of employment prior to 1 October 2021 shall not be taken into account. If, from 1 October 2021, an employment contract is concluded predominantly for the implementation of third-party or research projects, any such employment prior to 1 October 2021 up to four years shall not be taken into account.

(86) The table of contents, § 3 subpara 5, § 6 para 7, § 20 para 6 subpara 14, § 22 para 1 subpara 9a, § 25 para 1 subpara 10, § 29 para 4 subpara 1 second and third sentence, § 46 para 6, § 51 para 2 subparas 10, 11, 14g, 23, 23a, 26 and 27, § 54 paras 3 and 6, § 56, § 63a para 6, § 66 paras 3a and 3b, § 70 para 1, § 71b para 1, § 71b para 7 subpara 5, § 71c paras 4 and 5a, § 76 para 3, the heading of § 87, § 87 para 2, § 87a including the heading, § 92 para 2a as well as the heading of § 143 and § 143 paras 41, 42 and 77 as amended by the Federal Act published in the F. L. G. I No 177/2021 shall enter into force on 1 October 2021.

(87) Certificate university programmes under § 56 as amended before 1 October 2021, upon completion of which a master's degree according to § 87a para 1 as amended before 1 October 2021 is awarded, may be established until 30 September 2023.

(88) Admission to a certificate university programme for further education under para 87 shall be permissible until 30 September 2023. Participants who are admitted until 30 September 2023 to certificate university programmes for further education shall complete the certificate university programme for further education within a period of study of three times the duration specified in the curriculum or within the maximum duration of studies, if specified in the curriculum, following the 1 October 2023. For these participants, the provisions of this Federal Act as amended before 1 October 2021 shall continue to apply.

(89) Admission to a certificate university programme for further education according to § 56 as amended before 1 October 2021, which is funded within the framework of the Erasmus Mundus Joint Master Degree Programme shall be permissible even after 30 September 2023 until the end of the respective programme period as approved.

(90) Masterstudien für das Lehramt Sekundarstufe (Allgemeinbildung) in nur einem Unterrichtsfach gemäß § 54 Abs. 6 in der Fassung dieser Bestimmung vor dem Bundesgesetz BGBl. I Nr. 177/2021 dürfen nur nach Maßgabe des Bedarfs und nur bis zum 30. September 2021 eingerichtet werden.

(91) Studierende, die bis zum 30. September 2029 zu einem Masterstudium gemäß Abs. 90 zugelassen werden, haben ab dem 1. Oktober 2029 dieses Masterstudium binnen der doppelten Dauer der im Curriculum festgelegten Studienzeit abzuschließen. Für die Studienwerberinnen und -werber für dieses Studium sind die Bestimmungen dieses Bundesgesetzes in der Fassung vor dem Bundesgesetz BGBl. I Nr. 177/2021 weiterhin anzuwenden. Eine Zulassung zu einem Masterstudium gemäß Abs. 90 der Fassung vor dem Bundesgesetz BGBl. I Nr. 177/2021 ist nach dem 30. September 2029 nicht mehr zulässig.

(92) Die Rektorate der betreffenden Universitäten sind ermächtigt, in den in dieser Bestimmung genannten Studienfeldern jeweils die angegebene Anzahl an Studienplätzen für Studienanfängerinnen und -anfänger pro Studienjahr durch Verordnung festzulegen sowie die Zulassung zu den betreffenden Studien durch Verordnung entweder durch ein Aufnahmeverfahren vor der Zulassung oder durch die Auswahl der Studierenden bis längstens ein Semester nach der Zulassung zu regeln.

Universität	Studienfeld	Anzahl der Studienplätze für Studienanfängerinnen und -anfänger
Universität Wien	Bildende Kunst	300
	Musik und darstellende Kunst	590
	Muttersprache	520
	Politikwissenschaft und Staatsbürgerkunde	620
	Soziologie und Kulturwissenschaften	830
	Chemie	250
Universität Graz	Umweltschutz, allgemein	380
Universität für	Natürliche Lebensräume und Wildtierschutz	280

(90) Master's programmes for teacher training for secondary schools (general education) in only one subject according to § 54 para 6 in the version of this provision prior to the Federal Act published in F. L. G. I No 177/2021 may only be offered with regard to the need and no longer than until 30 September 2021.

(91) Students who are admitted until 30 September 2029 to a master's programme according to para 9, shall complete this master's programme within a period of study of double the duration specified in the curriculum, following the 1 October 2029. For applicants to this study programme, the provisions of this Federal Act as amended prior to the Federal Act published in F. L. G. I No 177/2021 shall continue to apply. Admission to a master's programme according to para 90 of the version before the Federal Act published in F. L. G. I No 177/2021 shall no longer be permissible after 30 September 2029.

(92) The rectorates of the universities concerned shall be entitled to determine, by official notification, the indicated number of study places for first-year students per academic year in each of the fields of education listed in this provision and, by official notification, to limit admission to the study programmes concerned, either by means of an admission procedure prior to admission or the selection of students no later than one semester after admission.

University	Field of education	Number of study places for first-year students
University of Vienna	Fine Arts	300
	Music and Performing Arts	590
	Mother tongue	520
	Political sciences and Civics	620
	Sociology and Cultural studies	830
	Chemistry	250
University of Graz	Environmental protection, general	380
University of Natural Resources and Life Sciences, Vienna	Natural habitats and wildlife protection	280

Bodenkultur Wien		
Universität Linz	Ausbildung von Lehrkräften in berufsbildenden Fächern	170

Vor der Festlegung des Aufnahme- oder Auswahlverfahrens durch das Rektorat ist dem Senat die Möglichkeit zur Stellungnahme innerhalb von sechs Wochen zu geben. Die Festlegung durch das Rektorat hat bis spätestens 30. April zu erfolgen, um ab dem darauffolgenden Studienjahr wirksam zu werden. Diese Bestimmung tritt mit Ablauf des 31. Dezember 2027 außer Kraft.

(Anm.: Abs. 92 tritt mit Ablauf des 31.12.2027 außer Kraft)

(93) § 12b Abs. 3 in der Fassung des Bundesgesetzes über den Forschungs-, Wissenschafts-, Innovations- und Technologieentwicklungsrat, BGBl. I Nr. 52/2023, tritt mit 1. Juli 2023 in Kraft. Die Einträge im Inhaltsverzeichnis zum VII. Teil und zu § 119, der VII. Teil samt Überschrift sowie § 119 treten mit Ablauf des 30. Juni 2023 außer Kraft.

(94) Für das Inkrafttreten der durch das Bundesgesetz BGBl. I Nr. 50/2024 geänderten oder eingefügten Bestimmungen und das Außerkrafttreten der durch dieses Bundesgesetz entfallenen Bestimmungen sowie für den Übergang zur neuen Rechtslage gilt Folgendes:

1. § 51 Abs. 2 Z 5b, § 58 Abs. 1 sowie § 66 Abs. 1 treten mit Ablauf des Tages der Kundmachung im Bundesgesetzblatt in Kraft;
2. § 51 Abs. 2 Z 5d und 5f, § 54 Abs. 3 siebenter Satz, § 54 Abs. 5, § 54b Abs. 1, 2 und 4, § 63a Abs. 3, § 72 Abs. 4 sowie § 91 Abs. 1 Z 3 und Z 4 treten mit 1. Oktober 2024 in Kraft; gleichzeitig treten die den § 54c betreffende Zeile im Inhaltsverzeichnis sowie § 54c samt Überschrift, § 63a Abs. 4 und § 91 Abs. 1 Z 5 außer Kraft;
3. Auf Lehramtsstudien der Sekundarstufe (Allgemeinbildung) können § 54 Abs. 3 siebenter Satz, § 54 Abs. 5, § 54b Abs. 2 sowie § 54c und die Anlage zum HS-QSG mit Ausnahme des Punktes 1. in der Fassung vor dem Bundesgesetz BGBl. I Nr. 50/2024 bis spätestens 30. September 2026 weiterhin angewendet werden; Änderungen der Curricula, die aufgrund der Änderungen der genannten Bestimmungen in der Fassung des Bundesgesetzes BGBl. I Nr. 50/2024 erforderlich sind, können ab Kundmachung dieses Bundesgesetzes erlassen werden und sind bis 30. Juni 2026 zu erlassen.

University of Linz	Teacher training in vocational subjects	170

Before the rectorate determines the admission or selection procedure, the senate shall have the opportunity to give its opinion within six weeks. The rectorate's decision shall be taken by 30 April at the latest in order to become effective in the following academic year. This provision shall expire at the end of 31 December 2027.

(Para 92 will expire after 31.12.2027)

(95) Für das Inkrafttreten der durch das Bundesgesetz BGBl. I Nr. 50/2024 geänderten oder eingefügten Bestimmungen und das Außerkrafttreten der durch dieses Bundesgesetz entfallenen Bestimmungen sowie für den Übergang zur neuen Rechtslage gilt Folgendes:

1. Das Inhaltsverzeichnis zu § 20d, § 64, § 71e sowie § 78, § 2 Z 3a, § 3 Z 12, § 6 Abs. 8, § 9, § 13 Abs. 7a, § 13b, § 14 Abs. 6a, § 15 Abs. 6, § 20d, § 21 Abs. 1 Z 2 und 4, § 23 Abs. 3, § 25 Abs. 8 Z 3, § 40c Abs. 2 Z 6, § 40d Abs. 1, § 42 Abs. 8f, § 43 Abs. 6, § 45 Abs. 1, § 50, § 51 Abs. 2 Z 5c sowie Z 37, § 54a Abs. 1, § 59a Abs. 1, § 60 Abs. 1 und 1b Z 2 und Abs. 3b, § 63 Abs. 9, § 64 samt Überschrift, § 65, § 65a Abs. 3, § 66 Abs. 3, § 68 Abs. 3, § 71c Abs. 6a, § 71e, § 73 Abs. 1 Z 2, § 78 Abs. 1, 3 und 4 Z 5, 6 und 8 samt Überschrift, § 79 Abs. 5, § 87 Abs. 2 Z 3 und 4, § 88 Abs. 1a, § 89 Abs. 1 und 2, § 107 Abs. 1, § 116 Abs. 1, § 118a Abs. 10 sowie § 135 Abs. 10 treten mit Ablauf des Tages der Kundmachung im Bundesgesetzblatt in Kraft;
2. § 51 Abs. 2 Z 23 und 23a, § 70 Abs. 1 Z 1, 2, 3 und 4, § 87 Abs. 2 Z 1 und Z 2 in der Fassung des BGBl. I Nr. 50/2024 treten mit 1. Juli 2024 in Kraft;
3. § 19 Abs. 2a, § 40d Abs. 2, § 51 Abs. 2 Z 31, 32 und 33 sowie § 78 Abs. 4 Z 2 und Abs. 6 treten mit Ablauf des Tages der Kundmachung im Bundesgesetzblatt außer Kraft.
4. § 71c Abs. 1 in der Fassung des BGBl. I Nr. 50/2024 tritt mit Ablauf des Tages der Kundmachung im Bundesgesetzblatt und § 71c Abs. 2 in der Fassung des BGBl. I Nr. 50/2024 tritt mit dem auf die Kundmachung des Bundesgesetzes BGBl. I Nr. 68/2025 folgenden Tag in Kraft.

(96) Die Zulassung zu einem Universitätslehrgang gemäß § 70 Abs. 1 Z 3 letzter Satz in der Fassung des BGBl. I Nr. 177/2021, ist bis längstens 30. September 2024 zulässig. Teilnehmerinnen und Teilnehmer, die bis zum 30. September 2024 zu diesen Universitätslehrgängen zugelassen werden, haben den Universitätslehrgang ab 1. Oktober 2024 binnen der dreifachen Dauer der im Curriculum festgelegten Studienzeit oder binnen der allenfalls im Curriculum festgelegten Höchststudiendauer abzuschließen. Für diese Teilnehmerinnen und Teilnehmer sind die Bestimmungen dieses Bundesgesetzes in der Fassung vor dem 1. Juli 2024 weiterhin anzuwenden.

(97) Studierende, die ein Bachelor- oder Masterstudium für das Lehramt Sekundarstufe (Allgemeinbildung) gemäß der Rechtslage vor dem Bundesgesetz BGBl. I Nr. 50/2024 begonnen haben, sind berechtigt, dieses Studium

1. nach den Bestimmungen der vor dem Bundesgesetz BGBl. I Nr. 50/2024 geltenden Rechtslage innerhalb einer angemessenen Frist gemäß Abs. 99 fortzusetzen oder
2. nach den Bestimmungen der ab dem Bundesgesetz BGBl. I Nr. 50/2024 geltenden Rechtslage fortzuführen.

(98) Wird das Bachelorstudium für das Lehramt Sekundarstufe (Allgemeinbildung) innerhalb der in Abs. 97 Z 1 genannten Frist beendet bzw. wurde dieses bereits beendet, ist das Masterstudium ab der Änderung bzw. Neuerlassung des Curriculums nach den Bestimmungen der ab dem Bundesgesetz BGBl. I Nr. 50/2024 geltenden Rechtslage zu betreiben. Auf höchstmögliche Anerkennungen von Prüfungen und Studienleistungen aus dem Bachelorstudium ist Bedacht zu nehmen.

(99) Die Fristen gemäß Abs. 97 Z 1 und Abs. 98 sind in den auf Basis des Bundesgesetzes BGBl. I Nr. 50/2024 zu erlassenden Curricula festzulegen und haben jedenfalls die vorgesehene Studiendauer zuzüglich zweier Semester und für Studierende, die die vorgesehene Studiendauer bereits erreicht haben, jedenfalls zwei weitere Semester, zu umfassen. Wird das jeweilige Studium nicht innerhalb der Frist beendet, so findet Abs. 97 Z 2 Anwendung.

(100) Bei einem Wechsel in das auf Basis des Bundesgesetzes BGBl. I Nr. 50/2024 erlassene Curriculum eines Bachelor- oder Masterstudiums für das Lehramt ist auf höchstmögliche Anerkennungsmöglichkeiten Bedacht zu nehmen.

(101) Studierende, die vor dem Studienjahr 2024/25 ein Erweiterungsstudium gemäß § 54c begonnen haben, sind berechtigt, dieses Studium innerhalb einer angemessenen Frist zu abzuschließen. Die Fristen gemäß diesem Absatz sind durch das Rektorat festzulegen und haben jedenfalls die vorgesehene Studiendauer zuzüglich zweier Semester und für Studierende, die die vorgesehene Studiendauer bereits erreicht haben, jedenfalls zwei weitere Semester, zu umfassen.

(102) Die Bundesministerin oder der Bundesminister hat den Gesamtbetrag im Sinn des § 12 Abs. 2 und dessen Aufteilung auf Budgetsäulen für die Leistungsvereinbarungsperiode 2025 bis 2027 im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen erneut festzusetzen und darüber das Einvernehmen gemäß § 60 BHG herzustellen.

(103) § 13 Abs. 6, § 13a Abs. 1, § 42 Abs. 8f, § 59 Abs. 1a, § 60 Abs. 5, § 87 Abs. 7, § 91 Abs. 6, § 92 Abs. 6, § 135 Abs. 8 Z 2, § 143 Abs. 102 sowie § 144 Z 2 bis 7 und 9 in der Fassung des Budgetbegleitgesetzes 2025, BGBl. I Nr. 25/2025, treten mit dem auf die Kundmachung folgenden Tag in Kraft.

(104) Für das Inkrafttreten der durch das Bundesgesetz BGBl. I Nr. 28/2025 geänderten oder eingefügten Bestimmungen sowie für den Übergang zur neuen Rechtslage gilt Folgendes:

1. § 13 Abs. 7a, § 19 Abs. 2b, § 21 Abs. 1 Z 2, § 23 Abs. 2, § 78 Abs. 1 Z 2 lit. d, Abs. 4 Z 3 und 4 sowie § 87 Abs. 5a treten mit Ablauf des Tages der Kundmachung im Bundesgesetzblatt in Kraft;
2. § 60 Abs. 4 und § 62 Abs. 5 treten mit 1. September 2025 in Kraft.

(105) Beim Abschluss von Arbeitsverträgen für Angehörige des wissenschaftlichen und künstlerischen Personals gemäß § 94 Abs. 2 im Zeitraum vom 1. Juli 2025 bis 30. September 2026 mit Personen, deren Mittelpunkt ihrer Forschungs- und Lehrtätigkeit in den vergangenen 24 Monaten vor Abschluss des Arbeitsvertrages in den Vereinigten Staaten von Amerika lag, kann die Rektorin oder der Rektor von der Anwendung der Bestimmungen des § 13b Abs. 3 Z 8, des § 98 Abs. 2 und des § 107 Abs. 1 absehen. Der Abschluss von Arbeitsverträgen gemäß § 99a ist im genannten Zeitraum für die betreffende Personengruppe bis höchstens 10 vH der Stellen der Universitätsprofessorinnen und Universitätsprofessoren gemäß § 98 zulässig, auch wenn eine entsprechende Festlegung im Entwicklungsplan gemäß § 13b Abs. 3 Z 10 nicht erfolgt ist.

(106) Das Inhaltsverzeichnis und § 48 samt Überschrift in der Fassung des Informationsfreiheits-Anpassungsgesetzes, BGBl. I Nr. 50/2025, treten mit 1. September 2025 in Kraft.

(107) § 40d Abs. 1, § 71c Abs. 3, 4 und 5 sowie § 143 Abs. 95 Z 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 68/2025 treten mit dem auf die Kundmachung folgenden Tag in Kraft.

Vollziehung

§ 144. Mit der Vollziehung dieses Bundesgesetzes sind betraut:

1. hinsichtlich des § 17 die Bundesministerin oder der Bundesminister für Finanzen;
2. hinsichtlich der §§ 137 und 139 die Bundesministerin oder der Bundesminister für Finanzen im Einvernehmen mit der Bundesministerin oder dem Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung;
3. hinsichtlich der §§ 12 Abs. 2 und 7, 16 Abs. 2, 121 Abs. 17 und § 141 die Bundesministerin oder der Bundesminister für ~~Bildung~~Frauen,

Implementation

§ 144. The following authorities shall be entrusted with the implementation of this Act:

1. in respect of § 17, the Federal Minister of Finance;
2. in respect of §§ 137 and 139, the Federal Minister of Finance in consultation with the Federal Minister of Education, Science and Research;
3. in respect of §§ 12 paras 2 and 7, 16 para 2, 121 para 17 and 141, the Federal Minister of Education, Science and Research in consultation with the Federal Minister of Finance;

Wissenschaft und Forschung im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen;

4. hinsichtlich des § 18 Abs. 2 die Bundesministerin oder der Bundesminister für ~~Verfassung, Reformen, Deregulierung und~~ Justiz, soweit Gerichts- und Justizverwaltungsgebühren betroffen sind, im Übrigen die Bundesministerin oder der Bundesminister für Finanzen;
5. hinsichtlich des § 29 Abs. 6 die Bundesministerin oder der Bundesminister für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz im Einvernehmen mit der Bundesministerin oder dem Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung;
6. hinsichtlich des § 44 die Bundesministerin oder der Bundesminister für ~~Arbeit, Soziales, Gesundheit und Konsumentenschutz~~Frauen, Wissenschaft und Forschung;
7. hinsichtlich der §§ 106 Abs. 2 und 3, 108 Abs. 1, 3 und 4, 109 bis 113, 115 sowie 135 die Bundesministerin oder der Bundesminister für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz im Einvernehmen mit der Bundesministerin oder dem Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung;
8. hinsichtlich der §§ 8 und 21 Abs. 6 Z 2 die Bundesregierung;
9. im Übrigen die Bundesministerin oder der Bundesminister für ~~Bildung~~Frauen, Wissenschaft und Forschung.

4. in respect of § 18 para 2, the Federal Minister of Constitution, Reforms, Deregulation and Justice, to the extent that court and legal administrative fees are affected, and otherwise the Federal Minister of Finance;
5. in respect of § 29 para 6, the Federal Minister of Labour, Social Security, Health, Family and Consumer Protection in consultation with the Federal Minister of Education, Science and Research;
6. in respect of § 44, the Federal Minister of Labour, Social Security, Health, Family and Consumer Protection;
7. in respect of §§ 106 paras 2 and 3, 108 paras 1, 3 and 4, 109 to 113, 115 and 135, the Minister of Labour, Social Security, Health, Family and Consumer Protection in consultation with the Federal Minister of Education, Science and Research;
8. in respect of §§ 8 and 21 para 6 subpara 2, the Federal Government;
9. and otherwise the Federal Minister of Education, Science and Research.

Übersetzung: Rebecca Fischer, BA MA
Fa. xlation, Wien

Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz – DSG)

StF: BGBl. I Nr. 165/1999 (NR: GP XX RV 1613 AB 2028 S. 179. BR: 5992 AB 6034 S. 657.)
[CELEX-Nr.: 395L0046]

Änderung

BGBl. I Nr. 136/2001 (NR: GP XXI RV 742 AB 824 S. 81. BR: 6458 AB 6459 S. 681.)
BGBl. I Nr. 13/2005 (NR: GP XXII IA 515/A AB 821 S. 96. BR: AB 7228 S. 719.)
BGBl. I Nr. 2/2008 (1. BVRBG) (NR: GP XXIII RV 314 AB 370 S. 41. BR: 7799 AB 7830 S. 751.)
BGBl. I Nr. 133/2009 (NR: GP XXIV RV 472 AB 531 S. 49. BR: 8220 AB 8225 S. 780.)
BGBl. I Nr. 135/2009 (NR: GP XXIV RV 485 AB 558 S. 49. BR: 8217 AB 8228 S. 780.)
BGBl. I Nr. 112/2011 (NR: GP XXIV RV 1494 AB 1500 S. 130. BR: 8602 AB 8603 S. 802.) [CELEX-Nr.: 32009L0133, 32010L0024]
BGBl. I Nr. 51/2012 (NR: GP XXIV RV 1618 AB 1771 S. 155. BR: 8730 AB 8731 S. 809.)
BGBl. I Nr. 57/2013 (NR: GP XXIV RV 2131 AB 2245 S. 194. BR: AB 8940 S. 819.)
BGBl. I Nr. 83/2013 (NR: GP XXIV RV 2168 AB 2268 S. 200. BR: AB 8968 S. 820.) [CELEX-Nr.: 31995L0046]
BGBl. I Nr. 132/2015 (VfGH)
BGBl. I Nr. 120/2017 (NR: GP XXV RV 1664 AB 1761 S. 190. BR: 9824 AB 9856 S. 871.) [CELEX-Nr.: 32016L0680]
BGBl. I Nr. 23/2018 (NR: GP XXVI IA 188/A AB 99 S. 21. BR: AB 9958 S. 879.)
BGBl. I Nr. 24/2018 (NR: GP XXVI IA 189/A AB 98 S. 21. BR: AB 9948 S. 879.)
BGBl. I Nr. 14/2019 (NR: GP XXVI RV 301 AB 463 S. 57. BR: AB 10104 S. 888.)

Federal Act concerning the Protection of Personal Data (DSG)

⇐ Original version

as amended by:
(list of amendments published in the Federal Law Gazette [F. L. G. = BGBl.])

BGBl. I Nr. 148/2021 (NR: GP XXVII RV 937 AB 963 S. 117. BR: AB 10729 S. 929.)
BGBl. I Nr. 2/2023 (VfGH)
BGBl. I Nr. 62/2024 (NR: GP XXVII IA 4031/A AB 2566 S. 266. BR: 11496 AB 11507 S. 968.)
BGBl. I Nr. 70/2024 (NR: GP XXVII AB 2594 S. 268. BR: AB 11514 S. 968.)
BGBl. I Nr. 50/2025 (NR: GP XXVIII RV 129 AB 151 S. 35. BR: 11651 AB 11654 S. 980.)

⇐ amendment entailing the latest update of the present translation

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Artikel 1
(Verfassungsbestimmung)

Grundrecht auf Datenschutz

§ 1. (1) Jedermann hat, insbesondere auch im Hinblick auf die Achtung seines Privat- und Familienlebens, Anspruch auf Geheimhaltung der ihn betreffenden personenbezogenen Daten, soweit ein schutzwürdiges Interesse daran besteht. Das Bestehen eines solchen Interesses ist ausgeschlossen, wenn Daten infolge ihrer allgemeinen Verfügbarkeit oder wegen ihrer mangelnden Rückführbarkeit auf den Betroffenen einem Geheimhaltungsanspruch nicht zugänglich sind.

(2) Soweit die Verwendung von personenbezogenen Daten nicht im lebenswichtigen Interesse des Betroffenen oder mit seiner Zustimmung erfolgt,

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Article 1
(Constitutional provision)

Fundamental right to data protection

§ 1. (1) Every person shall have the right to secrecy of the personal data concerning that person, especially with regard to the respect for his or her private and family life, insofar as that person has an interest which deserves such protection. Such an interest is precluded if data cannot be subject to the right to secrecy due to the data's general availability or because they cannot be traced back to the data subject.

(2) Insofar as personal data are not used in the vital interest of the data subject or with the data subject's consent, restrictions of the right to secrecy are permitted

sind Beschränkungen des Anspruchs auf Geheimhaltung nur zur Wahrung überwiegender berechtigter Interessen eines anderen zulässig, und zwar bei Eingriffen einer staatlichen Behörde nur auf Grund von Gesetzen, die aus den in Art. 8 Abs. 2 der Europäischen Konvention zum Schutze der Menschenrechte und Grundfreiheiten (EMRK), BGBl. Nr. 210/1958, genannten Gründen notwendig sind. Derartige Gesetze dürfen die Verwendung von Daten, die ihrer Art nach besonders schutzwürdig sind, nur zur Wahrung wichtiger öffentlicher Interessen vorsehen und müssen gleichzeitig angemessene Garantien für den Schutz der Geheimhaltungsinteressen der Betroffenen festlegen. Auch im Falle zulässiger Beschränkungen darf der Eingriff in das Grundrecht jeweils nur in der gelindesten, zum Ziel führenden Art vorgenommen werden.

(3) Jedermann hat, soweit ihn betreffende personenbezogene Daten zur automationsunterstützten Verarbeitung oder zur Verarbeitung in manuell, dh. ohne Automationsunterstützung geführten Dateien bestimmt sind, nach Maßgabe gesetzlicher Bestimmungen

1. das Recht auf Auskunft darüber, wer welche Daten über ihn verarbeitet, woher die Daten stammen, und wozu sie verwendet werden, insbesondere auch, an wen sie übermittelt werden;
2. das Recht auf Richtigstellung unrichtiger Daten und das Recht auf Löschung unzulässigerweise verarbeiteter Daten.

(4) Beschränkungen der Rechte nach Abs. 3 sind nur unter den in Abs. 2 genannten Voraussetzungen zulässig.

(Anm.: Abs. 5 aufgehoben durch BGBl. I Nr. 51/2012)

Artikel 2

1. Hauptstück

Durchführung der Datenschutz-Grundverordnung und ergänzende Regelungen

1. Abschnitt

Allgemeine Bestimmungen

Anwendungsbereich und Durchführungsbestimmung

§ 4. (1) Die Bestimmungen der Verordnung (EU) 2016/679 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten, zum freien

only to safeguard overriding legitimate interests of another person, namely in the case of interference by a public authority only on the basis of laws which are necessary for the reasons stated in Article 8 para. 2 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR), Federal Law Gazette No 210/1958. Such laws may provide for the use of data that, due to their nature, deserve special protection only in order to safeguard substantial public interests and, at the same time, shall provide for adequate safeguards for the protection of the data subjects' interests in confidentiality. Even in the case of permitted restrictions, a fundamental right may only be interfered with using the least intrusive of all effective methods.

(3) Insofar as personal data concerning a person are intended for automated processing or processing in files managed manually, i.e. files managed without automated processing, every person shall, as provided for by law, have

1. the right to obtain information as to who processes what data concerning the person, where the data originated from, for which purpose they are used, and in particular to whom the data are transmitted;
2. the right to rectification of incorrect data and the right to erasure of illegally processed data.

(4) Restrictions of the rights according to para. 3 are only permitted under the conditions laid out in para. 2.

(Note: para. 5 repealed by Federal Law Gazette I No 51/2012)

Article 2

Chapter 1

Implementation of the General Data Protection Regulation and supplementary provisions

Part 1

General provisions

Scope of application and implementing provision

§ 4. (1) The provisions of Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of

Datenverkehr und zur Aufhebung der Richtlinie 95/46/EG (Datenschutz-Grundverordnung), ABl. Nr. L 119 vom 4.5.2016 S. 1, (im Folgenden: DSGVO) und dieses Bundesgesetzes gelten für die ganz oder teilweise automatisierte Verarbeitung personenbezogener Daten natürlicher Personen sowie für die nichtautomatisierte Verarbeitung personenbezogener Daten natürlicher Personen, die in einem Dateisystem gespeichert sind oder gespeichert werden sollen, soweit nicht die spezifischeren Bestimmungen des 3. Hauptstücks dieses Bundesgesetzes vorgehen.

(2) Kann die Berichtigung oder Löschung von automationsunterstützt verarbeiteten personenbezogenen Daten nicht unverzüglich erfolgen, weil diese aus wirtschaftlichen oder technischen Gründen nur zu bestimmten Zeitpunkten vorgenommen werden kann, so ist die Verarbeitung der betreffenden personenbezogenen Daten mit der Wirkung nach Art. 18 Abs. 2 DSGVO bis zu diesem Zeitpunkt einzuschränken.

(3) Die Verarbeitung von personenbezogenen Daten über gerichtlich oder verwaltungsbehördlich strafbare Handlungen oder Unterlassungen, insbesondere auch über den Verdacht der Begehung von Straftaten, sowie über strafrechtliche Verurteilungen oder vorbeugende Maßnahmen ist unter Einhaltung der Vorgaben der DSGVO zulässig, wenn

1. eine ausdrückliche gesetzliche Ermächtigung oder Verpflichtung zur Verarbeitung solcher Daten besteht oder
2. sich sonst die Zulässigkeit der Verarbeitung dieser Daten aus gesetzlichen Sorgfaltspflichten ergibt oder die Verarbeitung zur Wahrung der berechtigten Interessen des Verantwortlichen oder eines Dritten gemäß Art. 6 Abs. 1 lit. f DSGVO erforderlich ist, und die Art und Weise, in der die Datenverarbeitung vorgenommen wird, die Wahrung der Interessen der betroffenen Person nach der DSGVO und diesem Bundesgesetz gewährleistet.

(4) Bei einem Angebot von Diensten der Informationsgesellschaft, das einem Kind direkt gemacht wird, ist die Einwilligung gemäß Art. 6 Abs. 1 lit. a DSGVO zur Verarbeitung der personenbezogenen Daten des Kindes rechtmäßig, wenn das Kind das vierzehnte Lebensjahr vollendet hat.

(5) Das Recht auf Auskunft der betroffenen Person gemäß Art. 15 DSGVO besteht gegenüber einem hoheitlich tätigen Verantwortlichen unbeschadet anderer gesetzlicher Beschränkungen dann nicht, wenn durch die Erteilung dieser Auskunft

such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ No L 119 of 4 May 2016, p. 1 (in the following: General Data Protection Regulation) and this federal law shall apply to the processing of personal data of natural persons wholly or partly by automated means and to the processing other than by automated means of personal data of natural persons which form part of a filing system or are intended to form part of a filing system, unless the more specific provisions of Chapter 3 of this federal law prevail.

(2) If personal data processed by automated means cannot be rectified or erased immediately because they can be rectified or erased only at certain times for economic or technical reasons, processing of the personal data concerned shall be restricted until that time, with the effect as stipulated in Article 18 para. 2 of the General Data Protection Regulation.

(3) Processing personal data on acts or omissions punishable by courts or administrative authorities, in particular concerning suspected criminal offences, as well as data on criminal convictions and precautionary measures involving the deprivation of liberty, is permitted if the requirements of the General Data Protection Regulation are met and if

1. an explicit legal authorisation or obligation to process such data exists; or
2. the legitimacy of the processing of such data is otherwise based on statutory duties of diligence, or processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party pursuant to Article 6 para. 1 (f) of the General Data Protection Regulation, and the manner in which the data are processed safeguards the interests of the data subject according the General Data Protection Regulation and this federal law.

(4) In the case of an offer of information society services directly to a child, consent to the processing of the personal data of a child pursuant to Article 6 para. 1 (a) of the General Data Protection Regulation shall be lawful where the child is at least 14 years old.

(5) Without prejudice to other statutory restrictions, data subjects shall not have a right of access pursuant to Article 15 of the General Data Protection Regulation in relation to a controller acting with public authority and powers if granting access put at risk performance of a task delegated to the controller by law.

die Erfüllung einer dem Verantwortlichen gesetzlich übertragenen Aufgabe gefährdet wird.

(6) Das Recht auf Auskunft der betroffenen Person gemäß Art. 15 DSGVO besteht gegenüber einem Verantwortlichen unbeschadet anderer gesetzlicher Beschränkungen in der Regel dann nicht, wenn durch die Erteilung dieser Auskunft ein Geschäfts- oder Betriebsgeheimnis des Verantwortlichen bzw. Dritter gefährdet würde.

(Anm.: Abs. 7 aufgehoben durch Art. 5 Z 3, BGBl. I Nr. 14/2019)

Datenschutzbeauftragter

§ 5. (1) Der Datenschutzbeauftragte und die für ihn tätigen Personen sind unbeschadet sonstiger Verschwiegenheitspflichten bei der Erfüllung der Aufgaben zur Geheimhaltung verpflichtet. Dies gilt insbesondere in Bezug auf die Identität betroffener Personen, die sich an den Datenschutzbeauftragten gewandt haben, sowie über Umstände, die Rückschlüsse auf diese Personen zulassen, es sei denn, es erfolgte eine ausdrückliche Entbindung von der Verschwiegenheit durch die betroffene Person. Der Datenschutzbeauftragte und die für ihn tätigen Personen dürfen die zugänglich gemachten Informationen ausschließlich für die Erfüllung der Aufgaben verwenden und sind auch nach Ende ihrer Tätigkeit zur Geheimhaltung verpflichtet.

(2) Erhält ein Datenschutzbeauftragter bei seiner Tätigkeit Kenntnis von Daten, für die einer der Kontrolle des Datenschutzbeauftragten unterliegenden Stelle beschäftigten Person ein gesetzliches Aussageverweigerungsrecht zusteht, steht dieses Recht auch dem Datenschutzbeauftragten und den für ihn tätigen Personen insoweit zu, als die Person, der das gesetzliche Aussageverweigerungsrecht zusteht, davon Gebrauch gemacht hat. Im Umfang des Aussageverweigerungsrechts des Datenschutzbeauftragten unterliegen seine Akten und andere Schriftstücke einem Sicherstellungs- und Beschlagnahmeverbot.

(3) Der Datenschutzbeauftragte im öffentlichen Bereich (in Formen des öffentlichen Rechts eingerichtet, insbesondere auch als Organ einer Gebietskörperschaft) ist bezüglich der Ausübung seiner Aufgaben weisungsfrei. Das oberste Organ hat das Recht, sich über die Gegenstände der Geschäftsführung beim Datenschutzbeauftragten im öffentlichen Bereich zu unterrichten. Dem ist vom Datenschutzbeauftragten nur insoweit zu entsprechen, als dies nicht der Unabhängigkeit des Datenschutzbeauftragten im Sinne von Art. 38 Abs. 3 DSGVO widerspricht.

(6) Without prejudice to other statutory restrictions, data subjects shall not have a right of access pursuant to Article 15 of the General Data Protection Regulation in relation to a controller if granting access put at risk a trade or business secret of the controller or a third party.

(Note: para. 7 repealed by Article 5 subpara. 3, Federal Law Gazette I No 14/2019)

Data protection officer

§ 5. (1) Without prejudice to other obligations of confidentiality, the data protection officer and the persons working for the data protection officer shall be bound by confidentiality when fulfilling their duties. This shall apply in particular in relation to the identity of data subjects who applied to the data protection officer, and to circumstances that allow identification of these persons, unless the data subject has expressly granted a release from confidentiality. The data protection officer and the persons working for the data protection officer may exclusively use information made available to fulfil their duties and shall be bound by confidentiality even after the end of their activities.

(2) If, during his or her activities, a data protection officer obtains knowledge of data in respect of which a person employed with a body subject to the supervision of the data protection officer has a statutory right to refuse to give evidence, the data protection officer and the persons working for the data protection officers shall also have such a right to the extent to which the person who has the right to refuse to give evidence exercised that right. The files and other documents of the data protection officer are subject to a prohibition of seizure and confiscation to the extent of the right of the data protection officer to refuse to give evidence.

(3) Public-sector data protection officers (established in a form provided by public law, in particular also as an officer of a territorial authority) are not bound by any instructions when exercising their duties. The highest governing bodies or officers have the right to obtain information on matters to be dealt with from a public-sector data protection officer. The data protection officer shall provide information only insofar as the independence of the data protection officer as described in Article 38 para. 3 of the General Data Protection Regulation is not impaired by doing so.

(4) Im Wirkungsbereich jedes Bundesministeriums sind unter Bedachtnahme auf Art und Umfang der Datenverarbeitungen sowie je nach Einrichtung des Bundesministeriums ein oder mehrere Datenschutzbeauftragte vorzusehen. Diese müssen dem jeweiligen Bundesministerium oder der jeweiligen nachgeordneten Dienststelle oder sonstigen Einrichtung angehören.

(5) Die Datenschutzbeauftragten im öffentlichen Bereich gemäß Abs. 4 pflegen einen regelmäßigen Erfahrungsaustausch, insbesondere im Hinblick auf die Gewährleistung eines einheitlichen Datenschutzstandards.

Datengeheimnis

§ 6. (1) Der Verantwortliche, der Auftragsverarbeiter und ihre Mitarbeiter – das sind Arbeitnehmer (Dienstnehmer) und Personen in einem arbeitnehmerähnlichen (dienstnehmerähnlichen) Verhältnis – haben personenbezogene Daten aus Datenverarbeitungen, die ihnen ausschließlich auf Grund ihrer berufsmäßigen Beschäftigung anvertraut wurden oder zugänglich geworden sind, unbeschadet sonstiger gesetzlicher Verschwiegenheitspflichten, geheim zu halten, soweit kein rechtlich zulässiger Grund für eine Übermittlung der anvertrauten oder zugänglich gewordenen personenbezogenen Daten besteht (Datengeheimnis).

(2) Mitarbeiter dürfen personenbezogene Daten nur auf Grund einer ausdrücklichen Anordnung ihres Arbeitgebers (Dienstgebers) übermitteln. Der Verantwortliche und der Auftragsverarbeiter haben, sofern eine solche Verpflichtung ihrer Mitarbeiter nicht schon kraft Gesetzes besteht, diese vertraglich zu verpflichten, personenbezogene Daten aus Datenverarbeitungen nur aufgrund von Anordnungen zu übermitteln und das Datengeheimnis auch nach Beendigung des Arbeitsverhältnisses (Dienstverhältnisses) zum Verantwortlichen oder Auftragsverarbeiter einzuhalten.

(3) Der Verantwortliche und der Auftragsverarbeiter haben die von der Anordnung betroffenen Mitarbeiter über die für sie geltenden Übermittlungsanordnungen und über die Folgen einer Verletzung des Datengeheimnisses zu belehren.

(4) Unbeschadet des verfassungsrechtlichen Weisungsrechts darf einem Mitarbeiter aus der Verweigerung der Befolgung einer Anordnung zur unzulässigen Datenübermittlung kein Nachteil erwachsen.

(4) Considering the type and scope of data processing activities and depending on the facilities of a federal ministry, one or several data protection officers shall be appointed in the sphere of responsibilities of each federal ministry. These data protection officers shall be employed by the relevant federal ministry or the relevant subordinate office or other entity.

(5) Public-sector data protection officers pursuant to para. 4 shall regularly exchange information, in particular with regard to ensuring uniform data protection standards.

Confidentiality of data

§ 6. (1) The controller, the processor and their employees, i.e. employees and persons in a quasi-employee relationship, shall ensure the confidentiality of personal data from data processing activities that have been entrusted or have become accessible to them solely due to their employment, without prejudice to other statutory obligations of confidentiality, unless a legitimate reason for the transmission of the data that have been entrusted or have become accessible to them exists (confidentiality of data).

(2) Employees may transmit personal data only if expressly ordered to do so by their employer. Unless such an obligation of their employees already exists by law, the controller and the processor shall contractually bind their employees to transmit personal data from data processing activities only on the basis of orders and to maintain the confidentiality of data even after the end of their employment with the controller or processor.

(3) The controller and the processor shall inform the employees affected by these orders about the transmission orders applicable to them and about the consequences of a violation of data confidentiality.

(4) Without prejudice to the right to give instructions under constitutional law, an employee must not incur any disadvantage from refusing to comply with an order for a prohibited transmission of data.

(5) Ein zugunsten eines Verantwortlichen bestehendes gesetzliches Aussageverweigerungsrecht darf nicht durch die Inanspruchnahme eines für diesen tätigen Auftragsverarbeiters, insbesondere nicht durch die Sicherstellung oder Beschlagnahme von automationsunterstützt verarbeiteten Dokumenten, umgangen werden.

2. Abschnitt
Datenverarbeitungen zu spezifischen Zwecken

Verarbeitung für im öffentlichen Interesse liegende Archivzwecke, wissenschaftliche oder historische Forschungszwecke oder statistische Zwecke

§ 7. (1) Für im öffentlichen Interesse liegende Archivzwecke, wissenschaftliche oder historische Forschungszwecke oder statistische Zwecke, die keine personenbezogenen Ergebnisse zum Ziel haben, darf der Verantwortliche alle personenbezogenen Daten verarbeiten, die

1. öffentlich zugänglich sind,
2. er für andere Untersuchungen oder auch andere Zwecke zulässigerweise ermittelt hat oder
3. für ihn pseudonymisierte personenbezogene Daten sind und der Verantwortliche die Identität der betroffenen Person mit rechtlich zulässigen Mitteln nicht bestimmen kann.

(2) Bei Datenverarbeitungen für im öffentlichen Interesse liegende Archivzwecke, wissenschaftliche oder historische Forschungszwecke oder statistische Zwecke, die nicht unter Abs. 1 fallen, dürfen personenbezogene Daten nur

1. gemäß besonderen gesetzlichen Vorschriften,
2. mit Einwilligung der betroffenen Person oder
3. mit Genehmigung der Datenschutzbehörde gemäß Abs. 3

verarbeitet werden.

(3) Eine Genehmigung der Datenschutzbehörde für die Verarbeitung von personenbezogenen Daten für im öffentlichen Interesse liegende Archivzwecke, wissenschaftliche oder historische Forschungszwecke oder statistische Zwecke ist auf Antrag des Verantwortlichen der Untersuchung zu erteilen, wenn

(5) The statutory right of a controller to refuse to give evidence shall not be avoided by questioning a processor working for the controller, and in particular not by seizing or confiscating documents processed by automated means.

Part 2
Data processing for specific purposes

Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes

§ 7. (1) For archiving purposes in the public interest, scientific or historical research purposes or statistical purposes whose goal is not to obtain results in a form relating to specific data subjects, the controller may process all personal data that

1. are publicly accessible,
2. the controller has lawfully collected for other research projects or other purposes, or
3. are pseudonymised personal data for the controller, and the controller cannot establish the identity of the data subject by legal means.

(2) In the case of processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes that do not fall under para. 1, personal data may be processed only

1. pursuant to specific legal provisions,
2. with the consent of the data subject, or
3. with a permit of the Data Protection Authority pursuant to para. 3.

(3) A permit of the Data Protection Authority for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall be granted at the request of the controller ordering the research project, if

1. die Einholung der Einwilligung der betroffenen Person mangels ihrer Erreichbarkeit unmöglich ist oder sonst einen unverhältnismäßigen Aufwand bedeutet,
2. ein öffentliches Interesse an der beantragten Verarbeitung besteht und
3. die fachliche Eignung des Verantwortlichen glaubhaft gemacht wird.

Sollen besondere Kategorien personenbezogener Daten (Art. 9 DSGVO) ermittelt werden, muss ein wichtiges öffentliches Interesse an der Untersuchung vorliegen; weiters muss gewährleistet sein, dass die personenbezogenen Daten beim Verantwortlichen der Untersuchung nur von Personen verarbeitet werden, die hinsichtlich des Gegenstandes der Untersuchung einer gesetzlichen Verschwiegenheitspflicht unterliegen oder deren diesbezügliche Verlässlichkeit sonst glaubhaft ist. Die Datenschutzbehörde hat die Genehmigung an die Erfüllung von Bedingungen und Auflagen zu knüpfen, soweit dies zur Wahrung der schutzwürdigen Interessen der betroffenen Person notwendig ist.

(4) Einem Antrag nach Abs. 3 ist jedenfalls eine vom Verfügungsbefugten über die Datenbestände, aus denen die personenbezogenen Daten ermittelt werden sollen, unterfertigte Erklärung anzuschließen, dass er dem Verantwortlichen die Datenbestände für die Untersuchung zur Verfügung stellt. Anstelle dieser Erklärung kann auch ein diese Erklärung ersetzender Exekutionstitel (§ 367 Abs. 1 der Exekutionsordnung – EO, RGBl. Nr. 79/1896) vorgelegt werden.

(5) Auch in jenen Fällen, in welchen die Verarbeitung von personenbezogenen Daten für Zwecke der wissenschaftlichen Forschung oder Statistik in personenbezogener Form zulässig ist, ist der Personenbezug unverzüglich zu verschlüsseln, wenn in einzelnen Phasen der wissenschaftlichen oder statistischen Arbeit mit personenbezogenen Daten gemäß Abs. 1 Z 3 das Auslangen gefunden werden kann. Sofern gesetzlich nicht ausdrücklich anderes vorgesehen ist, ist der Personenbezug der Daten gänzlich zu beseitigen, sobald er für die wissenschaftliche oder statistische Arbeit nicht mehr notwendig ist.

(6) Rechtliche Beschränkungen der Zulässigkeit der Benützung von personenbezogenen Daten aus anderen, insbesondere urheberrechtlichen Gründen, bleiben unberührt.

1. the consent of the data subject is impossible to obtain because the data subject cannot be reached or the effort would otherwise be unreasonable,
2. there is a public interest in the processing for which a permit is sought, and
3. the professional aptitude of the controller has been satisfactorily demonstrated.

If special categories of personal data (Article 9 of the General Data Protection Regulation) are to be collected, an important public interest in the research project must exist; furthermore, it must be ensured that the personal data are processed at the premises of the controller ordering the research project only by persons who are subject to a statutory obligation of confidentiality regarding the subject matter of the research project or whose reliability in this respect is credible. The Data Protection Authority shall issue the permit subject to terms and conditions, insofar as this is necessary to safeguard the data subjects' interests which deserve protection.

(4) A request according to para. 3 must, however, be accompanied by a statement signed by the person authorised to exercise rights in respect of the data files from which the personal data are to be collected, stating that this person is making the data files available for the research project. Instead of this statement, a writ of enforcement (§ 367 para. 1 of the Enforcement Code, Imperial Law Gazette No 79/1896) replacing this statement may be submitted.

(5) Even in cases where the processing of personal data for scientific research purposes or statistical purposes is permitted in a form which allows the identification of data subjects, the data shall be coded without delay so that the data subjects are no longer identifiable if specific phases of scientific or statistical work can be performed with personal data pursuant to para. 1 subpara. 3. Unless otherwise expressly provided for by law, data in a form which allows the identification of data subjects shall be rendered unidentifiable as soon as it is no longer necessary for scientific or statistical work to keep them identifiable.

(6) Legal restrictions on the right to use personal data for other reasons, in particular for copyright reasons, shall not be affected.

Zurverfügungstellung von Adressen zur Benachrichtigung und Befragung von betroffenen Personen

§ 8. (1) Soweit gesetzlich nicht ausdrücklich anderes bestimmt ist, bedarf die Übermittlung von Adressdaten eines bestimmten Kreises von betroffenen Personen zum Zweck ihrer Benachrichtigung oder Befragung der Einwilligung der betroffenen Personen.

(2) Wenn allerdings eine Beeinträchtigung der Geheimhaltungsinteressen der betroffenen Personen angesichts der Auswahlkriterien für den Betroffenenkreis und des Gegenstands der Benachrichtigung oder Befragung unwahrscheinlich ist, bedarf es keiner Einwilligung, wenn

1. Daten desselben Verantwortlichen verarbeitet werden oder
2. bei einer beabsichtigten Übermittlung der Adressdaten an Dritte
   a) an der Benachrichtigung oder Befragung auch ein öffentliches Interesse besteht oder
   b) keine der betroffenen Personen nach entsprechender Information über Anlass und Inhalt der Übermittlung innerhalb angemessener Frist Widerspruch gegen die Übermittlung erhoben hat.

(3) Liegen die Voraussetzungen des Abs. 2 nicht vor und würde die Einholung der Einwilligung der betroffenen Personen gemäß Abs. 1 einen unverhältnismäßigen Aufwand erfordern, ist die Übermittlung der Adressdaten mit Genehmigung der Datenschutzbehörde gemäß Abs. 4 zulässig, falls die Übermittlung an Dritte

1. zum Zweck der Benachrichtigung oder Befragung aus einem wichtigen Interesse der betroffenen Personen selbst,
2. aus einem wichtigen öffentlichen Benachrichtigungs- oder Befragungsinteresse oder
3. zur Befragung der betroffenen Personen für wissenschaftliche oder statistische Zwecke

erfolgen soll.

(4) Die Datenschutzbehörde hat auf Antrag eines Verantwortlichen, der Adressdaten verarbeitet, die Genehmigung zur Übermittlung zu erteilen, wenn der Antragsteller das Vorliegen der in Abs. 3 genannten Voraussetzungen glaubhaft macht und überwiegende schutzwürdige Geheimhaltungsinteressen der betroffenen Personen der Übermittlung nicht entgegenstehen. Die Datenschutzbehörde hat die Genehmigung an die Erfüllung von Bedingungen und

Providing addresses to inform and interview data subjects

§ 8. (1) Unless otherwise expressly provided for by law, providing address data of a certain group of data subjects in order to inform or interview them shall require the consent of the data subjects.

(2) If, however, an infringement of the data subject's interests in confidentiality is unlikely, considering the selection criteria for the group of data subjects and the subject of the information or interview, no consent shall be required

1. if data from the same controller are processed, or
2. in the case of an intended transfer of address data to third parties,
   a) if there is also a public interest in the information or interview, or
   b) if none of the data subjects, after having received appropriate information on the reason and content of the transfer, has objected to the transfer within a reasonable period.

(3) If the requirements of para. 2 are not met and if obtaining the consent of the data subjects pursuant to para. 1 would require a disproportionate effort, the transfer of the address data shall be permissible with a permit of the Data Protection Authority pursuant to para. 4 if the data are to be transferred to third parties

1. for the purpose of information or an interview due to an important interest of the data subject,
2. due to an important public interest in the information or interview, or
3. for an interview of the data subjects for scientific or statistical purposes.

(4) At the request of a controller processing address data, the Data Protection Authority shall grant the permit for their transfer if the controller has satisfactorily demonstrated that the requirements stipulated in para. 3 have been met and no overriding interests in confidentiality which deserve protection on the part of the data subjects represent an obstacle to the transfer. The Data Protection Authority shall

Auflagen zu knüpfen, soweit dies zur Wahrung der schutzwürdigen Interessen der betroffenen Personen notwendig ist.

(5) Die übermittelten Adressdaten dürfen ausschließlich für den genehmigten Zweck verarbeitet werden und sind zu löschen, sobald sie für die Benachrichtigung oder Befragung nicht mehr benötigt werden.

(6) Sofern es gemäß den vorstehenden Bestimmungen zulässig ist, Namen und Adresse von Personen, die einem bestimmten Betroffenenkreis angehören, zu übermitteln, dürfen auch die zum Zweck der Auswahl der zu übermittelnden Adressdaten notwendigen Verarbeitungen vorgenommen werden.

Freiheit der Meinungsäußerung und Informationsfreiheit

§ 9. (1) Für die Verarbeitung personenbezogener Daten durch Medieninhaber, Herausgeber, Medienmitarbeiter und Arbeitnehmer eines Medienunternehmens oder Mediendienstes im Sinne des Mediengesetzes – MedienG, BGBl. Nr. 314/1981, sowie durch sonstige Personen, die in einem Medienunternehmen oder Mediendienst auf Grundlage eines Vertrages an der inhaltlichen Gestaltung eines Mediums oder der inhaltlichen Gestaltung der Mitteilungen eines Mediendienstes journalistisch mitwirken, zu journalistischen Zwecken des Medienunternehmens oder Mediendienstes gelten die Bestimmungen der DSGVO sowie dieses Bundesgesetzes mit folgenden Maßgaben:

1. Der Verantwortliche ist gegenüber der betroffenen Person nicht zur Offenlegung von Informationen verpflichtet, die dem Schutz des Redaktionsgeheimnisses (§ 31 MedienG) unterliegen (datenschutzrechtliches Redaktionsgeheimnis); § 31 Abs. 2 MedienG ist anzuwenden. In Verfahren vor Gerichten und Behörden, die Angelegenheiten des Datenschutzes zum Gegenstand haben, gilt § 31 MedienG mit der Maßgabe, dass der Verantwortliche die Beantwortung von Fragen im Sinne des § 31 Abs. 1 MedienG nicht nur als Zeuge, sondern auch als sonst Verfahrensbeteiligter verweigern darf. § 321 Abs. 1 der Zivilprozessordnung – ZPO, RGBl. Nr. 113/1895, ist sinngemäß anzuwenden. Die Datenschutzbehörde hat bei Ausübung ihrer Befugnisse den Schutz des Redaktionsgeheimnisses zu beachten.
2. Der Verantwortliche ist berechtigt, personenbezogene Daten einschließlich der in Art. 9 Abs. 1 DSGVO genannten besonderen Kategorien personenbezogener Daten sowie personenbezogener Daten über strafrechtliche Verurteilungen und Straftaten oder damit zusammenhängende Sicherungsmaßregeln (Art. 10 DSGVO) zu

issue the permit subject to terms and conditions, insofar as this is necessary to safeguard interests of the data subjects which deserve protection.

(5) The transferred address data shall only be processed for the permitted purpose and shall be erased as soon as they are no longer needed for information or interviews.

(6) If it is lawful pursuant to the aforementioned provisions to transfer the names and addresses of persons belonging to a certain group of data subjects, the processing required for selecting the address data to be transferred shall also be permitted.

Freedom of expression and information

§ 9. (1) The provisions of the General Data Protection Regulation and of this federal law shall apply to the processing of personal data by media owners, editors, copy editors and employees of a media undertaking or a media service as defined in the Media Act, Federal Law Gazette No 314/1981, as well as by other persons who, on the basis of a contract, are engaged as journalists in contributing to editing the contents of a medium or editing the contents of the publications of a media service in a media undertaking or media service for journalistic purposes of the media undertaking or media service with the following reservations:

1. The controller is not required to disclose to the data subject information subject to the protection of editorial confidentiality (editorial confidentiality under data protection law, § 31 of the Media Act); § 31 para. 2 of the Media Act shall be applied. In proceedings before courts and authorities having matters of data protection as their subject matter, § 31 of the Media Act shall apply with the reservation that the controller may refuse to answer questions as referred to in § 31 para. 1 of the Media Act not only as a witnesses but also as any other person involved in the proceedings. § 321 para. 1 of the Code of Civil Procedure, Imperial Law Gazette No 113/1895, shall be applied accordingly. In exercising its powers, the Data Protection Authority shall take into consideration the protection of editorial confidentiality.
2. The controller is entitled to process personal data, including the special categories of personal data referred to in Article 9 para. 1 of the General Data Protection Regulation as well as personal data relating to criminal convictions and offences or related security measures (Article 10 of the General Data Protection Regulation), provided that the processing is carried

verarbeiten, soweit dies für journalistische Zwecke erfolgt. Art. 10 letzter Satz DSGVO bleibt unberührt. Die §§ 12 und 13 dieses Bundesgesetzes sind nicht anwendbar.

3. Art. 5 Abs. 1 lit. a DSGVO gilt in Bezug auf den Grundsatz der Transparenz mit der Maßgabe, dass die Verarbeitung personenbezogener Daten für die betroffene Person nur insoweit nachvollziehbar sein muss, als dadurch die Meinungsäußerungs- und Informationsfreiheit nicht unverhältnismäßig beeinträchtigt wird, und nur insoweit, als die Bestimmungen dieses Absatzes nicht anderes vorsehen.
4. Die Art. 13 und 14 (Informationspflicht) sowie Art. 21 Abs. 1 (Widerspruchsrecht) DSGVO sind nicht anwendbar.
5. Das Auskunftsrecht (Art. 15 DSGVO) ist in Bezug auf personenbezogene Daten, auf deren Grundlage noch keine Veröffentlichung erfolgt ist, nicht anwendbar. Im Übrigen gilt das Auskunftsrecht (Art. 15 DSGVO) mit der Maßgabe, dass die betroffene Person Auskünfte nur in Bezug auf bestimmte, im Antrag auf Auskunft konkret zu bezeichnende Veröffentlichungen verlangen darf und ihre Betroffenheit individuell zu begründen hat und der Verantwortliche abweichend von Art. 12 Abs. 5 erster Satz DSGVO berechtigt ist, für die Bearbeitung von Auskunftsersuchen ein Entgelt von 9 Euro zu verlangen; unterlässt die betroffene Person die konkrete Bezeichnung einer Veröffentlichung, die individuelle Begründung ihrer Betroffenheit oder legt sie keinen Nachweis für die Bezahlung des Entgelts vor, so kann der Verantwortliche sich weigern, aufgrund des Antrags tätig zu werden. Der Verantwortliche ist berechtigt, die Auskunft zu verweigern, soweit dies im Einzelfall zum Schutz der Meinungsäußerungs- und Informationsfreiheit erforderlich und verhältnismäßig ist; in solchen Fällen muss der Verantwortliche bei der Beantwortung des Auskunftsersuchens gegenüber der betroffenen Person nicht offenlegen, ob ihre personenbezogenen Daten verarbeitet werden, soweit dadurch der Zweck der Auskunftsverweigerung unterlaufen würde. Das Recht auf Kopie (Art. 15 Abs. 3 DSGVO) ist ausgeschlossen.
6. Art. 16 (Recht auf Berichtigung), Art. 17 (Recht auf Löschung) und Art. 18 (Recht auf Einschränkung der Verarbeitung) DSGVO sind nicht anzuwenden
   a) in Bezug auf personenbezogene Daten, auf deren Grundlage noch keine Veröffentlichung erfolgt ist;

out for journalistic purposes. Article 10 last sentence of the General Data Protection Regulation shall remain unaffected. § 12 and § 13 of this federal law shall not be applicable.

3. With regard to the principle of transparency, Article 5 para. 1 (a) of the General Data Protection Regulation shall apply with the reservation that the processing of personal data must be transparent for the data subject only insofar as the freedom of expression and information is not unreasonably impaired thereby and only insofar as the provisions of this paragraph do not provide otherwise.
4. Articles 13 and 14 (Information to be provided) and Article 21 para. 1 (Right to object) of the General Data Protection Regulation shall not be applicable.
5. The right of access (Article 15 of the General Data Protection Regulation) shall not be applicable in relation to personal data on the basis of which no publication has yet been made. In all other cases, the right of access (Article 15 of the General Data Protection Regulation) shall apply with the reservation that the data subject may request access only in relation to certain publications that must be specifically named in the request for access, and the data subject must give reasons as to why and how the data subject is affected in each case, and the controller is entitled, by way of derogation from Article 12 para. 5 first sentence of the General Data Protection Regulation, to charge a fee of €9 for processing the request for access; if the data subject does not specifically name a publication, does not give reasons as to why and how the data subject is affected in each case or does not provide evidence of payment of the fee, the controller may refuse to act on the request. The controller is entitled to refuse access insofar as this is required and proportionate in individual cases to protect the freedom of expression and information; in such cases, the controller is not required to disclose to the data subject when answering the request for access whether or not the data subject's personal data have been processed, insofar as this would undermine the purpose of the refusal to provide access. The right to a copy (Article 15 para. 3 of the General Data Protection Regulation) is excluded.
6. Article 16 (Right to rectification), Article 17 (Right to erasure) and Article 18 (Right to restriction of processing) of the General Data Protection Regulation shall not be applied
   a) in relation to personal data on the basis of which no publication has yet been made;

b) in Bezug auf personenbezogene Daten, die in einem Medium im Sinne des § 1 Abs. 1 Z 1 MedienG veröffentlicht wurden;

c) soweit eine konkurrierende Anspruchsgrundlage wegen Verletzung der Persönlichkeitsrechte der betroffenen Person nach bürgerlichem Recht, insbesondere nach § 20 oder § 1330 des Allgemeinen bürgerlichen Gesetzbuches, JGS Nr. 946/1811, oder nach § 78 des Urheberrechtsgesetzes, BGBl. I Nr. 111/1936, besteht.

In allen anderen Fällen ist der Verantwortliche im Falle einer Geltendmachung der in Art. 16 und 18 DSGVO genannten Rechte durch die betroffene Person berechtigt, die Berichtigung oder die Einschränkung der Verarbeitung zu verweigern, soweit dies im Einzelfall zum Schutz der Meinungsäußerungs- und Informationsfreiheit erforderlich und verhältnismäßig ist.

7. In den Fällen der Z 5 zweiter und dritter Satz, Z 6 zweiter Satz und Art. 17 Abs. 3 DSGVO ist die betroffene Person berechtigt, eine Überprüfung der Rechtmäßigkeit der Verweigerung der Auskunft, Berichtigung, Einschränkung der Verarbeitung oder Löschung durch die Datenschutzbehörde zu verlangen. Der Verantwortliche hat die betroffene Person über dieses Recht zu unterrichten. Wird dieses Recht ausgeübt, hat der Verantwortliche das Vorliegen der Voraussetzungen der bezüglichen Einschränkung glaubhaft zu machen. § 25 Abs. 3 ist mit der Maßgabe anzuwenden, dass die Datenschutzbehörde die betroffene Person nur darüber zu unterrichten hat, dass alle erforderlichen Prüfungen oder eine Überprüfung durch die Datenschutzbehörde erfolgt sind, es sei denn, dass die Datenschutzbehörde zum Ergebnis gelangt, dass die betreffende Einschränkung unzulässig war. Die Datenschutzbehörde hat zudem die betroffene Person über ihr Recht zu unterrichten, Beschwerde an das Bundesverwaltungsgericht zu erheben.

8. Zum Schutz des datenschutzrechtlichen Redaktionsgeheimnisses, sowie soweit dies sonst zum Schutz der Meinungsäußerungs- und Informationsfreiheit, insbesondere im Hinblick auf Z 4 sowie Einschränkungen nach Z 5, erforderlich und verhältnismäßig ist, sind Verantwortliche im Sinne des Abs. 1 erster Satz sowie weitere Verantwortliche, die gemeinsam mit diesen personenbezogene Daten zu den in Abs. 1 erster Satz genannten Zwecken verarbeiten, nicht zur Offenlegung gemäß Art. 26 Abs. 2 zweiter Satz DSGVO verpflichtet.

b) in relation to personal data published in a medium as defined in § 1 para. 1 subpara. 1 of the Media Act;

c) to the extent that there is a conflicting basis of a claim on the ground of the infringement of personality rights of the data subject under civil law, in particular pursuant to § 20 or § 1330 of the General Civil Code, Collection of Laws No 946/1811, or pursuant to § 78 of the Copyright Act, Federal Law Gazette I No 111/1936.

In all other cases, the controller is entitled, in case the data subject asserts the rights provided for in Articles 16 and 18 of the General Data Protection Regulation, to refuse rectification or restriction of processing insofar as this is required and proportionate in individual cases to protect the freedom of expression and information.

7. In the cases referred to in subpara. 5 second and third sentences, subpara. 6 second sentence and Article 17 para. 3 of the General Data Protection Regulation, the data subject is entitled to request a review by the Data Protection Authority of the lawfulness of the refusal of access, rectification, restriction of processing or erasure. The controller shall inform the data subject about this right. If this right is exercised, the controller shall satisfactorily demonstrate that the requirements for such restriction have been met. § 25 para. 3 shall be applied with the reservation that the Data Protection Authority shall inform the data subject only about the fact that all necessary verifications or a review by the Data Protection Authority have taken place, unless the Data Protection Authority reaches the conclusion that the relevant restriction was not permitted. In addition, the Data Protection Authority shall inform the data subject about the data subject's right to lodge a complaint with the Federal Administrative Court.

8. To protect editorial confidentiality under data protection law, and insofar as this is required and proportionate to protect the freedom of expression and information, in particular with regard to subpara. 4 as well as to restrictions pursuant to subpara. 5, controllers as referred to in para. 1 first sentence as well as other controllers who, jointly with these controllers, process data for the purposes referred to in para. 1 first sentence, do not have an obligation of disclosure pursuant to Article 26 para. 2 second sentence of the General Data Protection Regulation.

9. Art. 33 DSGVO (Meldung einer Datenschutzverletzung an die Aufsichtsbehörde) ist mit der Maßgabe anzuwenden, dass eine Verletzung des Schutzes personenbezogener Daten nur dann an die Datenschutzbehörde zu melden ist, wenn sie voraussichtlich ein hohes Risiko für die persönlichen Rechte und Freiheiten natürlicher Personen zur Folge hat. Eine Benachrichtigung der von einer Verletzung des Schutzes personenbezogener Daten betroffenen Person gemäß Art. 34 DSGVO ist nur nach Maßgabe einer Anweisung der Datenschutzbehörde gemäß Art. 58 Abs. 2 lit. e DSGVO und, soweit das datenschutzrechtliche Redaktionsgeheimnis dadurch nicht beeinträchtigt wird, erforderlich.
10. Art. 38 DSGVO (Stellung des Datenschutzbeauftragten) gilt mit der Maßgabe, dass der Verantwortliche oder der Auftragsverarbeiter den Zugang des Datenschutzbeauftragten zu personenbezogenen Daten, die zu journalistischen Zwecken verarbeitet werden, einschränken kann, soweit dies zum Schutz der Meinungsäußerungs- und Informationsfreiheit erforderlich und verhältnismäßig ist.
11. Der Verantwortliche und der Auftragsverarbeiter sind nicht zur Einhaltung der Vorschriften des Kapitel V der DSGVO (Übermittlung personenbezogener Daten an Drittländer oder an internationale Organisationen) verpflichtet. Unbeschadet des Art. 24 DSGVO (Verantwortung des für die Verarbeitung Verantwortlichen) haben der Verantwortliche und der Auftragsverarbeiter geeignete Maßnahmen zu treffen, um sicherzustellen, dass die Rechte und Freiheiten der betroffenen Person im Falle einer Übermittlung personenbezogener Daten an Drittländer oder internationale Organisationen nicht unverhältnismäßig beeinträchtigt werden.
12. In Verhaltensregeln gemäß Art. 40 Abs. 2 DSGVO können Einschränkungen gemäß Z 5 dritter Satz und Z 6 zweiter Satz sowie geeignete Maßnahmen im Sinne der Z 11 zweiter Satz dieses Absatzes näher präzisiert werden. Die Datenschutzbehörde hat in Verfahren gemäß Art. 40 Abs. 5 DSGVO eine Stellungnahme der Kommunikationsbehörde Austria („KommAustria“) (§ 1 Abs. 1 KommAustriaG – KOG, BGBl. I Nr. 32/2001) zum Entwurf der Verhaltensregeln bzw. zum Entwurf zu deren Änderung oder Erweiterung einzuholen.

9. Article 33 of the General Data Protection Regulation (Notification of a personal data breach to the supervisory authority) shall be applied with the reservation that the Data Protection Authority must be notified of a personal data breach only if the personal data breach is likely to result in a high risk to the rights and freedoms of natural persons. Communication of a personal data breach to the data subject pursuant to Article 34 of the General Data Protection Regulation is required only in accordance with an order by the Data Protection Authority pursuant to Article 58 para. 1 (e) of the General Data Protection Regulation and provided that editorial confidentiality under data protection law is not adversely affected thereby.
10. Article 38 of the General Data Protection Regulation (Position of the data protection officer) shall apply with the reservation that the controller or the processor may restrict access by the data protection officer to personal data processed for journalistic purposes insofar as this is required and proportionate to protect the freedom of expression and information.
11. The controller and the processor are not required to comply with the provisions of Chapter V of the General Data Protection Regulation (Transfers of personal data to third countries or international organisations). Without prejudice to Article 24 of the General Data Protection Regulation (Responsibility of the controller), the controller and the processor shall take appropriate measures to ensure that the data subject’s rights and freedoms are not unreasonably impaired if personal data are transferred to third countries or international organisations.
12. Codes of conduct pursuant to Article 40 para. 2 of the General Data Protection Regulation may specify more details of restrictions pursuant to subpara. 5 third sentence and subpara. 6 second sentence as well as appropriate measures as referred to in subpara. 11 second sentence of this paragraph. In procedures pursuant to Article 40 para. 5 of the General Data Protection Regulation, the Data Protection Authority shall obtain an opinion by the Austrian Communications Authority (“KommAustria”) (§ 1 para. 1 of the KommAustria Act, Federal Law Gazette I No 32/2001) on a draft code of conduct or on a draft amendment or extension.

13. Art. 56 (Zuständigkeit der federführenden Aufsichtsbehörde) und Kapitel VII der DSGVO (Zusammenarbeit und Kohärenz) sind nicht anwendbar.

(1a) Für die nicht von Abs. 1 erfasste Verarbeitung personenbezogener Daten zu journalistischen Zwecken gilt Abs. 1 Z 1, 4 und 13; Abs. 1 Z 3 gilt mit der Maßgabe, dass sich der Verweis auf die Bestimmungen in Abs. 1 Z 1, 4 und 13 und Abs. 1a bezieht. Der Verantwortliche ist berechtigt, personenbezogene Daten, aus denen politische Meinungen oder religiöse oder weltanschauliche Überzeugungen hervorgehen (Art. 9 Abs. 1 DSGVO), sowie personenbezogene Daten über strafrechtliche Verurteilungen und Straftaten oder damit zusammenhängende Sicherungsmaßregeln (Art. 10 DSGVO) zur Wahrung berechtigter Interessen (Art. 6 Abs. 1 lit. f DSGVO) zu verarbeiten, soweit dies zur Ausübung der Meinungsäußerungs- und Informationsfreiheit erforderlich und verhältnismäßig ist. Art. 10 letzter Satz DSGVO bleibt unberührt. In Bezug auf personenbezogene Daten, die in einem Medium im Sinne des § 1 Abs. 1 Z 1 MedienG veröffentlicht wurden, sind die Art. 16 (Recht auf Berichtigung), 17 (Recht auf Löschung) und 18 (Recht auf Einschränkung der Verarbeitung) DSGVO nicht anzuwenden. Im Übrigen ist der Verantwortliche berechtigt, in Bezug auf zu journalistischen Zwecken verarbeitete personenbezogene Daten, auf deren Grundlage noch keine Veröffentlichung erfolgt ist, im Falle einer Geltendmachung der in den Art. 15 bis 18 DSGVO genannten Rechte durch die betroffene Person die Auskunft, Berichtigung, Löschung oder Einschränkung der Verarbeitung zu verweigern, soweit dies im Einzelfall zum Schutz der Meinungsäußerungs- und Informationsfreiheit erforderlich und verhältnismäßig ist; § 25 Abs. 3 ist anzuwenden. Derartige Einschränkungen können in Verhaltensregeln gemäß Art. 40 Abs. 2 DSGVO näher präzisiert werden. Die Datenschutzbehörde hat in Verfahren gemäß Art. 40 Abs. 5 DSGVO eine Stellungnahme der KommAustria zum Entwurf der Verhaltensregeln bzw. zum Entwurf zu deren Änderung oder Erweiterung einzuholen.

(2) Soweit dies erforderlich ist, um das Recht auf Schutz der personenbezogenen Daten mit der Freiheit der Meinungsäußerung und der Informationsfreiheit in Einklang zu bringen, finden von der DSGVO die Kapitel II (Grundsätze), mit Ausnahme des Art. 5, Kapitel III (Rechte der betroffenen Person), Kapitel IV (Verantwortlicher und Auftragsverarbeiter), mit Ausnahme der Art. 28, 29 und 32, Kapitel V (Übermittlung personenbezogener Daten an Drittländer oder an internationale Organisationen), Kapitel VI (Unabhängige Aufsichtsbehörden), Kapitel VII (Zusammenarbeit und Kohärenz) und Kapitel IX

13. Article 56 (Competence of the lead supervisory authority) and Chapter VII of the General Data Protection Regulation (Cooperation and consistency) shall not be applicable.

(1a) Para. 1 subparas. 1, 4 and 13 shall apply to the processing of personal data for journalistic purposes not covered by para. 1; para. 1 subpara. 3 shall apply with the reservation that the reference refers to the provisions in para. 1 subparas. 1, 4 and 13 and para. 1a. The controller is entitled to process personal data revealing political opinions, or religious or philosophical beliefs (Article 9 para. 1 of the General Data Protection Regulation) as well as personal data relating to criminal convictions and offences or related security measures (Article 10 of the General Data Protection Regulation) for the purposes of legitimate interests (Article 6 para. 1 (f) of the General Data Protection Regulation) insofar as this is required and proportionate to exercise the freedom of expression and information. Article 10 last sentence of the General Data Protection Regulation shall remain unaffected. Articles 16 (Right to rectification), 17 (Right to erasure) and 18 (Right to restriction of processing) of the General Data Protection Regulation shall not be applied in relation to personal data published in a medium as defined in § 1 para. 1 subpara. 1 of the Media Act. In all other cases, the controller is entitled to refuse access, rectification, erasure or restriction of processing in relation to personal data processed for journalistic purposes on the basis of which no publication has yet been made, in case the rights referred to in Articles 15 to 18 of the General Data Protection Regulation are asserted by the data subject, insofar as this is required and proportionate in individual cases to protect the freedom of expression and information; § 25 para. 3 shall be applied. Codes of conduct pursuant to Article 40 para. 2 of the General Data Protection Regulation may specify more details of such restrictions. In procedures pursuant to Article 40 para. 5 of the General Data Protection Regulation, the Data Protection Authority shall obtain an opinion by KommAustria on a draft code of conduct or on a draft amendment or extension.

(2) If it is necessary to reconcile the right to the protection of personal data with the freedom of expression and information, Chapter II (principles), with the exception of Article 5, Chapter III (rights of the data subject), Chapter IV (controller and processor), with the exception of Articles 28, 29 and 32, Chapter V (transfer of personal data to third countries or international organisations), Chapter VI (independent supervisory authorities), Chapter VII (cooperation and consistency) and Chapter IX (specific data processing situations) of the General Data Protection Regulation shall not apply to processing for the purposes of academic, artistic or

(Vorschriften für besondere Verarbeitungssituationen) auf die Verarbeitung, die zu wissenschaftlichen, künstlerischen oder literarischen Zwecken erfolgt, keine Anwendung. Von den Bestimmungen dieses Bundesgesetzes ist in solchen Fällen § 6 (Datengeheimnis) anzuwenden.

literary expression. Of the provisions of this federal law, § 6 (confidentiality of data) shall be applied in such cases.

Verarbeitung personenbezogener Daten im Katastrophenfall

§ 10. (1) Verantwortliche des öffentlichen Bereichs und Hilfsorganisationen sind im Katastrophenfall ermächtigt, personenbezogene Daten gemeinsam zu verarbeiten, soweit dies zur Hilfeleistung für die von der Katastrophe unmittelbar betroffenen Personen, zur Auffindung und Identifizierung von Abgängigen und Verstorbenen und zur Information von Angehörigen notwendig ist.

(2) Wer rechtmäßig über personenbezogene Daten verfügt, darf diese an Verantwortliche des öffentlichen Bereichs und Hilfsorganisationen übermitteln, sofern diese die personenbezogenen Daten zur Bewältigung der Katastrophe für die in Abs. 1 genannten Zwecke benötigen.

(3) Eine Übermittlung von personenbezogenen Daten in das Ausland ist zulässig, soweit dies für die Erfüllung der in Abs. 1 genannten Zwecke unbedingt notwendig ist. Daten, die für sich allein die betroffene Person strafrechtlich belasten, dürfen nicht übermittelt werden, es sei denn, dass diese zur Identifizierung im Einzelfall unbedingt notwendig sind. Die Datenschutzbehörde ist von den veranlassten Übermittlungen und den näheren Umständen des Anlass gebenden Sachverhaltes unverzüglich zu verständigen. Die Datenschutzbehörde hat zum Schutz der Betroffenenrechte weitere Datenübermittlungen zu untersagen, wenn der durch die Datenweitergabe bewirkte Eingriff in das Grundrecht auf Datenschutz durch die besonderen Umstände der Katastrophensituation nicht gerechtfertigt ist.

(4) Auf Grund einer konkreten Anfrage eines nahen Angehörigen einer tatsächlich oder vermutlich von der Katastrophe unmittelbar betroffenen Person sind Verantwortliche ermächtigt, dem Anfragenden personenbezogene Daten zum Aufenthalt der betroffenen Person und dem Stand der Ausforschung zu übermitteln, wenn der Angehörige seine Identität und das Naheverhältnis glaubhaft darlegt.

Besondere Kategorien personenbezogener Daten (Art. 9 DSGVO) dürfen an nahe Angehörige nur übermittelt werden, wenn sie ihre Identität und ihre Angehörigeneigenschaft nachweisen und die Übermittlung zur Wahrung ihrer Rechte oder jener der betroffenen Person erforderlich ist. Die Sozialversicherungsträger und Behörden sind verpflichtet, die Verantwortlichen

Processing of personal data in case of emergency

§ 10. (1) In case of emergency, public-sector controllers and relief organisations shall be authorised to jointly process data to the extent that this is necessary to assist persons directly affected by a disaster, to locate and identify missing or deceased persons and to provide information to their relatives.

(2) Anybody who lawfully possesses personal data shall be permitted to transfer these data to public-sector controllers and relief organisations if these controllers and organisations need this personal data to manage a disaster for the purposes specified in para. 1.

(3) The transfer abroad of personal data is permitted insofar as this is absolutely necessary to fulfil the purposes mentioned in para. 1. Data that by themselves would make the data subject liable to criminal prosecution shall not be transferred unless they are absolutely necessary for identification in a particular case. The Data Protection Authority shall be informed immediately about the data transfers performed and about the circumstances of the motivating incident. The Data Protection Authority shall prohibit further data transfers if the interference with the fundamental right to data protection resulting from the data transfer is not justified by the special circumstances caused by a disaster.

(4) Based on a specific inquiry of a close relative of a person who has actually or presumably been directly affected by a disaster, controllers are authorised to transfer to the inquiring person personal data regarding the whereabouts of the data subject and on the progress of the search, if the relative satisfactorily demonstrates his or her identity and close relationship to the data subject.

Special categories of personal data (Article 9 of the General Data Protection Regulation) may be transferred to close relatives only if they prove their identity and their capacity as a relative and if the transfer is necessary to safeguard their rights or the rights of the data subject. The social insurance agencies and authorities are

des öffentlichen Bereichs und Hilfsorganisationen zu unterstützen, soweit dies zur Überprüfung der Angaben des Anfragenden erforderlich ist.

(5) Als nahe Angehörige im Sinne dieser Bestimmung sind Eltern, Kinder, Ehegatten, eingetragene Partner und Lebensgefährten der betroffenen Personen zu verstehen. Andere Angehörige dürfen die erwähnten Auskünfte unter denselben Voraussetzungen wie nahe Angehörige dann erhalten, wenn sie eine besondere Nahebeziehung zu der von der Katastrophe tatsächlich oder vermutlich unmittelbar betroffenen Person glaubhaft machen.

(6) Die zu Zwecken der Bewältigung des Katastrophenfalles verarbeiteten personenbezogenen Daten sind unverzüglich zu löschen, wenn sie für die Erfüllung des konkreten Zwecks nicht mehr benötigt werden.

Verwarnung durch die Datenschutzbehörde

§ 11. Die Datenschutzbehörde wird den Katalog des Art. 83 Abs. 2 bis 6 DSGVO so zur Anwendung bringen, dass die Verhältnismäßigkeit gewahrt wird. Insbesondere bei erstmaligen Verstößen wird die Datenschutzbehörde im Einklang mit Art. 58 DSGVO von ihren Abhilfebefugnissen insbesondere durch Verwarnen Gebrauch machen.

3. Abschnitt
Bildverarbeitung

Zulässigkeit der Bildaufnahme

§ 12. (1) Eine Bildaufnahme im Sinne dieses Abschnittes bezeichnet die durch Verwendung technischer Einrichtungen zur Bildverarbeitung vorgenommene Feststellung von Ereignissen im öffentlichen oder nicht-öffentlichen Raum zu privaten Zwecken. Zur Bildaufnahme gehören auch dabei mitverarbeitete akustische Informationen. Für eine derartige Bildaufnahme gilt dieser Abschnitt, soweit nicht durch andere Gesetze Besonderes bestimmt ist.

(2) Eine Bildaufnahme ist unter Berücksichtigung der Vorgaben gemäß § 13 zulässig, wenn

1. sie im lebenswichtigen Interesse einer Person erforderlich ist,
2. die betroffene Person zur Verarbeitung ihrer personenbezogenen Daten eingewilligt hat,
3. sie durch besondere gesetzliche Bestimmungen angeordnet oder erlaubt ist, oder

obliged to assist the public-sector controllers and relief organisations if this is necessary to verify the information provided by the inquiring person.

(5) Close relatives pursuant to this provision means parents, children, spouses, registered partners and companions in life of the data subjects. Other relatives may receive the aforementioned information under the same conditions as close relatives if they satisfactorily demonstrate a special close relationship to the person actually or presumably directly affected by a disaster.

(6) The personal data processed for the purposes of managing a disaster shall be deleted immediately if they are no longer required to fulfil the specific purpose.

Reprimand by the Data Protection Authority

§ 11. The Data Protection Authority shall apply the catalogue of Article 83 paras. 2 to 6 of the General Data Protection Regulation in a manner so as to observe proportionality. In the case of first-time infringements, in particular, the Data Protection Authority shall use its corrective powers in accordance with Article 58 of the General Data Protection Regulation, in particular by issuing reprimands.

Part 3
Processing of images

Permissibility of recording images

§ 12. (1) For the purposes of this Part, recording images means observing occurrences in public or non-public space for private purposes, using technical devices for the processing of images. Recording images also includes acoustic information processed together with the images. This Part shall apply to such recording of images unless other laws provide for more specific provisions.

(2) Considering the requirements pursuant to § 13, recording images is permitted if

1. it is necessary in the vital interest of a person,
2. the data subject has consented to the processing of the data subject's personal data,
3. it is ordered or permitted by special statutory provisions, or

4. im Einzelfall überwiegende berechtigte Interessen des Verantwortlichen oder eines Dritten bestehen und die Verhältnismäßigkeit gegeben ist.

(3) Eine Bildaufnahme ist gemäß Abs. 2 Z 4 insbesondere dann zulässig, wenn

1. sie dem vorbeugenden Schutz von Personen oder Sachen auf privaten Liegenschaften, die ausschließlich vom Verantwortlichen genutzt werden, dient, und räumlich nicht über die Liegenschaft hinausreicht, mit Ausnahme einer zur Zweckerreichung allenfalls unvermeidbaren Einbeziehung öffentlicher Verkehrsflächen,
2. sie für den vorbeugenden Schutz von Personen oder Sachen an öffentlich zugänglichen Orten, die dem Hausrecht des Verantwortlichen unterliegen, aufgrund bereits erfolgter Rechtsverletzungen oder eines in der Natur des Ortes liegenden besonderen Gefährdungspotenzials erforderlich ist, oder
3. sie ein privates Dokumentationsinteresse verfolgt, das nicht auf die identifizierende Erfassung unbeteiligter Personen oder die gezielte Erfassung von Objekten, die sich zur mittelbaren Identifizierung solcher Personen eignen, gerichtet ist.

(4) Unzulässig ist

1. eine Bildaufnahme ohne ausdrückliche Einwilligung der betroffenen Person in deren höchstpersönlichen Lebensbereich,
2. eine Bildaufnahme zum Zweck der Kontrolle von Arbeitnehmern,
3. der automationsunterstützte Abgleich von mittels Bildaufnahmen gewonnenen personenbezogenen Daten ohne ausdrückliche Einwilligung und für das Erstellen von Persönlichkeitsprofilen mit anderen personenbezogenen Daten oder
4. die Auswertung von mittels Bildaufnahmen gewonnenen personenbezogenen Daten anhand von besonderen Kategorien personenbezogener Daten (Art. 9 DSGVO) als Auswahlkriterium.

(5) Im Wege einer zulässigen Bildaufnahme ermittelte personenbezogene Daten dürfen im erforderlichen Ausmaß übermittelt werden, wenn für die Übermittlung eine der Voraussetzungen des Abs. 2 Z 1 bis 4 gegeben ist. Abs. 4 gilt sinngemäß.

4. there are overriding legitimate interests of the controller or a third party in a particular case, and proportionality is given.

(3) Recording images pursuant to para. 2 subpara. 4 is permitted, in particular, if

1. it serves the precautionary protection of persons and items on private land exclusively used by the controller and does not reach beyond the boundaries of the piece of land, except when it includes public traffic areas, which may be unavoidable to fulfil the purpose of the image recording.
2. it is required for the precautionary protection of persons or items in publicly accessible places that are subject to the controller's right to undisturbed possession because that right has already been infringed or because the place, by its nature, has a special risk potential, or
3. it serves a private documentary interest and does not aim to record uninvolved persons to identify them or to record, in a targeted manner, items that are appropriate for indirectly identifying such persons.

(4) It is not permitted to:

1. record images in a data subject's most private sphere without the express consent of the data subject,
2. record images to monitor employees,
3. align with other personal data, in an automated manner without express consent and for creating personal profiles, personal data obtained from image recordings, or
4. analyse personal data obtained from image recordings on the basis of special categories of personal data (Article 9 of the General Data Protection Regulation) as selection criteria.

(5) Data collected by means of permitted image recording may be transferred to the extent required, if one of the requirements of para. 2 subparas. 1 to 4 is met. Para. 4 shall apply accordingly.

Besondere Datensicherheitsmaßnahmen und Kennzeichnung

§ 13. (1) Der Verantwortliche hat dem Risiko des Eingriffs angepasste geeignete Datensicherheitsmaßnahmen zu ergreifen und dafür zu sorgen, dass der Zugang zur Bildaufnahme und eine nachträgliche Veränderung derselben durch Unbefugte ausgeschlossen ist.

(2) Der Verantwortliche hat – außer in den Fällen einer Echtzeitüberwachung – jeden Verarbeitungsvorgang zu protokollieren.

(3) Aufgenommene personenbezogene Daten sind vom Verantwortlichen zu löschen, wenn sie für den Zweck, für den sie ermittelt wurden, nicht mehr benötigt werden und keine andere gesetzlich vorgesehene Aufbewahrungspflicht besteht. Eine länger als 72 Stunden andauernde Aufbewahrung muss verhältnismäßig sein und ist gesondert zu protokollieren und zu begründen.

(4) Die Abs. 1 bis 3 finden keine Anwendung auf Bildaufnahmen nach § 12 Abs. 3 Z 3.

(5) Der Verantwortliche einer Bildaufnahme hat diese geeignet zu kennzeichnen. Aus der Kennzeichnung hat jedenfalls der Verantwortliche eindeutig hervorzugehen, es sei denn, dieser ist den betroffenen Personen nach den Umständen des Falles bereits bekannt.

(6) Die Kennzeichnungspflicht gilt nicht in den Fällen des § 12 Abs. 3 Z 3 und für zeitlich strikt zu begrenzende Verarbeitungen im Einzelfall, deren Zweck ausschließlich mittels einer verdeckten Ermittlung erreicht werden kann, unter der Bedingung, dass der Verantwortliche ausreichende Garantien zur Wahrung der Betroffeneninteressen vorsieht, insbesondere durch eine nachträgliche Information der betroffenen Personen.

(7) Werden entgegen Abs. 5 keine ausreichenden Informationen bereitgestellt, kann jeder von einer Verarbeitung potenziell Betroffene vom Eigentümer oder Nutzungsberechtigten einer Liegenschaft oder eines Gebäudes oder sonstigen Objekts, von dem aus eine solche Verarbeitung augenscheinlich ausgeht, Auskunft über die Identität des Verantwortlichen begehren. Die unbegründete Nichterteilung einer derartigen Auskunft ist einer Verweigerung der Auskunft nach Art. 15 DSGVO gleichzuhalten.

Special data security measures and warning sign

§ 13. (1) The controller shall take appropriate measures corresponding to the risk posed by an interference and ensure that unauthorised persons cannot access or subsequently change the image recording.

(2) Except in the case of real-time surveillance, the controller shall keep logs of every processing operation.

(3) The controller shall erase personal data recorded if they are no longer necessary in relation to the purposes for which they were collected and if there is no other statutory obligation to maintain the data. Maintaining data for more than 72 hours must be proportionate; separate logs must kept of these data, and reasons must be stated.

(4) Paras. 1 to 3 shall not be applied to image recordings pursuant to § 12 para. 3 subpara. 3.

(5) The controller of an image recording must appropriately mark the recording. The warning sign shall clearly specify the controller, unless the controller is already known to the data subjects based on the circumstances of the case.

(6) The obligation to warning sign the data shall not apply in the cases referred to in § 12 para. 3 subpara. 3 and, in particular cases, to processing operations that must be strictly limited in terms of time and whose purpose can exclusively be achieved by means of covert investigation, provided that the controller ensures there are sufficient safeguards for the data subjects' interests, in particular by subsequent notification of the data subject.

(7) If, in violation of para. 5, sufficient information is not provided, every data subject potentially affected by a processing operation can request information on the identity of the controller from the owner of, or person authorised to use, the piece of land or building or other property from which the processing operation evidently originates. Failure to provide such information without giving reasons shall be deemed a refusal to provide access pursuant to Article 15 of the General Data Protection Regulation.

2. Hauptstück
Organe

1. Abschnitt
Datenschutzrat

Einrichtung und Aufgaben

§ 14. (1) Beim Bundesministerium für Justiz ist ein Datenschutzrat eingerichtet. Dieser nimmt zu Fragen von grundsätzlicher Bedeutung für den Datenschutz Stellung, fördert die einheitliche Fortentwicklung des Datenschutzes und berät die Bundesregierung in rechtspolitischer Hinsicht bei datenschutzrechtlich relevanten Vorhaben.

(2) Zur Erfüllung seiner Aufgaben nach Abs. 1

1. kann der Datenschutzrat Empfehlungen in datenschutzrechtlicher Hinsicht an die Bundesregierung und die Bundesminister richten;
2. kann der Datenschutzrat Gutachten erstellen oder in Auftrag geben;
3. ist dem Datenschutzrat Gelegenheit zur Stellungnahme zu Gesetzesentwürfen der Bundesministerien, soweit diese datenschutzrechtlich von Bedeutung sind, sowie zu Verordnungen im Vollzugsbereich des Bundes, die wesentliche Fragen des Datenschutzes betreffen, zu geben;
4. hat der Datenschutzrat das Recht, von Verantwortlichen des öffentlichen Bereichs Auskünfte und Berichte zu verlangen, soweit dies zur datenschutzrechtlichen Beurteilung von Vorhaben mit wesentlichen Auswirkungen auf den Datenschutz in Österreich notwendig ist;
5. kann der Datenschutzrat seine Beobachtungen, Bedenken und Anregungen veröffentlichen und den Verantwortlichen des öffentlichen Bereichs zur Kenntnis bringen.

(3) Abs. 2 Z 3 und 4 gilt nicht, soweit innere Angelegenheiten der anerkannten Kirchen und Religionsgesellschaften betroffen sind.

Zusammensetzung

§ 15. (1) Dem Datenschutzrat gehören an:

Chapter 2
Bodies

Part 1
Data Protection Council

Establishment and duties

§ 14. (1) A Data Protection Council has been established at the Federal Ministry of Justice. The Data Protection Council shall comment on questions of fundamental importance for data protection, promote the uniform further development of data protection, and advise the Federal Government on legal policy in the case of projects relevant to data protection.

(2) To fulfil its duties pursuant to para. 1,

1. the Data Protection Council can make recommendations relating to data protection to the Federal Government and the federal ministers;
2. the Data Protection Council can prepare opinions or commission such opinions;
3. the Data Protection Council shall be given the opportunity to comment on draft bills of federal ministries, insofar as these are significant for data protection law, and on regulations to be implemented by the Federal Government concerning essential issues of data protection;
4. the Data Protection Council shall have the right to request information and reports from public-sector controllers insofar as this is necessary to evaluate, from the viewpoint of data protection law, projects of significant impact on data protection in Austria;
5. the Data Protection Council can publish its observations, concerns and suggestions and submit them to the public-sector controllers.

(3) Para. 2 subparas. 3 and 4 shall not apply insofar as internal affairs of recognised churches and religious communities are concerned.

Composition

§ 15. (1) The Data Protection Council shall have the following members:

1. Vertreter der politischen Parteien: Zwölf Mitglieder entsenden die politischen Parteien nach dem System von d'Hondt im Verhältnis ihrer Mandatsstärke im Hauptausschuss des Nationalrates. Jede im Hauptausschuss des Nationalrates vertretene politische Partei hat Anspruch, im Datenschutzrat vertreten zu sein. Eine im Hauptausschuss des Nationalrates vertretene Partei, der nach der obigen Berechnung kein Mitglied zukommt, kann ein Mitglied namhaft machen;
2. je ein Vertreter der Bundeskammer für Arbeiter und Angestellte und der Wirtschaftskammer Österreich;
3. zwei Vertreter der Länder;
4. je ein Vertreter des Gemeindebundes und des Städtebundes;
5. ein von der Bundesministerin für Justiz zu entsendender Vertreter des Bundes;
6. ein von der Bundesregierung zu entsendender Vertreter aus dem Kreis der Datenschutzbeauftragten der Bundesministerien;
7. zwei vom Datenschutzrat nach seiner Konstituierung zu benennende nationale oder internationale Experten aus dem Bereich des Datenschutzes.

(2) Die in Abs. 1 genannten Vertreter sollen Kenntnisse sowie Erfahrungen auf den Gebieten des Datenschutzrechtes, des Unionsrechtes und der Grundrechte haben.

(3) Für jedes Mitglied gemäß Abs. 1 Z 1 bis 6 ist ein Ersatzmitglied zu entsenden, welches bei Verhinderung des Mitgliedes an dessen Stelle tritt. Die Entsendung der Mitglieder und Ersatzmitglieder ist dem Bundesministerium für Justiz schriftlich mitzuteilen.

(4) Nicht angehören können dem Datenschutzrat Mitglieder der Bundesregierung oder einer Landesregierung sowie Staatssekretäre und weiters Personen, die zum Nationalrat nicht wählbar sind.

(5) Die Funktionsperiode der Mitglieder und Ersatzmitglieder gemäß Abs. 1 Z 1 bis 6 beginnt mit deren Entsendung in den Datenschutzrat und endet

1. mit der Abberufung durch die entsendende Stelle (Abs. 1) im Wege einer schriftlichen Mitteilung an das Bundesministerium für Justiz unter

1. representatives of the political parties: The political parties shall delegate twelve members according to the d'Hondt method in proportion to the seats they have in the Main Committee of the National Council. Every political party represented in the Main Committee of the National Council has the right to be represented in the Data Protection Council. A party represented in the Main Committee of the National Council that cannot delegate a member according to the above calculation method can name a member;
2. one representative each of the Federal Chamber of Labour and the Austrian Federal Economic Chamber;
3. two representatives of the provinces;
4. one representative each of the Association of Austrian Municipalities and the Association of Austrian Cities and Towns;
5. one representative of the Federal Government to be delegated by the Federal Minister of Justice;
6. one representative to be delegated by the Federal Government from among the data protection officers of the federal ministries;
7. two national or international experts in data protection to be named by the Data Protection Council after its constitution.

(2) The representatives mentioned in para. 1 should have knowledge of and experience in data protection law, Union law, and fundamental rights.

(3) For each member pursuant to para. 1 subparas. 1 to 6, a substitute member shall be delegated who shall replace the member if the member is incapacitated or unavailable. The Federal Ministry of Justice shall be notified in writing of the delegation of the members and substitute members.

(4) Members of the Federal Government or of a provincial government and state secretaries as well as persons who may not be elected to the National Council cannot be members of the Data Protection Council.

(5) The term of office of the members and substitute members pursuant to para. 1 subparas. 1 to 6 starts when they are delegated to the Data Protection Council and ends

1. when they are dismissed by the entity or body delegating them (para. 1) by means of a written notification to the Federal Ministry of Justice, with a new member or substitute member being named at the same time,

gleichzeitiger Namhaftmachung eines neuen Mitgliedes oder Ersatzmitgliedes,

2. mit der Bekanntgabe des Ausscheidens durch das Mitglied oder Ersatzmitglied im Wege einer schriftlichen Mitteilung an das Bundesministerium für Justiz oder
3. spätestens mit der Neuwahl des Hauptausschusses des Nationalrates nach den §§ 29 und 30 des Geschäftsordnungsgesetzes 1975, BGBl. Nr. 410/1975.

Auf gemäß Abs. 1 Z 7 benannte Mitglieder des Datenschutzrates findet Z 3 Anwendung.

(6) Nach Neuwahl des Hauptausschusses des Nationalrates (Abs. 5 Z 3) führt das bisherige Präsidium gemäß § 17 Abs. 4 die Geschäfte bis zur konstituierenden Sitzung der neubestellten Mitglieder und Ersatzmitglieder fort. Binnen eines Zeitraumes von zwei Wochen ab der Neuwahl des Hauptausschusses des Nationalrates haben die entsendenden Stellen eine dem Abs. 1 entsprechende Anzahl von Mitgliedern und Ersatzmitgliedern dem Bundesministerium für Justiz schriftlich bekannt zu geben. Die Wiederbestellung von Mitgliedern und Ersatzmitgliedern ist zulässig.

(7) Die konstituierende Sitzung des Datenschutzrates hat spätestens sechs Wochen nach der Wahl des Hauptausschusses des Nationalrates stattzufinden und ist vom Bundesministerium für Justiz einzuberufen.

(8) Die Tätigkeit der Mitglieder und Ersatzmitglieder des Datenschutzrates ist ehrenamtlich. Mitglieder und Ersatzmitglieder des Datenschutzrates, die außerhalb von Wien wohnen, haben im Fall der Teilnahme an Sitzungen des Datenschutzrates Anspruch auf Ersatz der angemessenen Reisekosten nach Maßgabe der Reisegebührenvorschriften des Bundes. Die Vergütungen und Erstattungen sind im Nachhinein quartalsweise vom Bundesministerium für Justiz anzuweisen.

Vorsitz und Geschäftsführung

§ 16. (1) Der Datenschutzrat gibt sich mit Beschluss eine Geschäftsordnung.

(2) Der Datenschutzrat hat in der konstituierenden Sitzung aus den vorliegenden Wahlvorschlägen mit einfacher Mehrheit aus seiner Mitte einen Vorsitzenden und zwei stellvertretende Vorsitzende zu wählen. Stichwahlen sind

2. when the member or substitute member announces his or her resignation by means of a written notification to the Federal Ministry of Justice, or
3. no later than when a new Main Committee of the National Council is elected pursuant to § 29 and § 30 of the Rules of Procedure Law of 1975, Federal Law Gazette No 410/1975.

Subpara. 3 shall not apply to members of the Data Protection Council named pursuant to para. 1 subpara. 7.

(6) After the election of the new Main Committee of the National Council (para. 5 subpara. 3), the previous Executive Board pursuant to § 17 para. 4 shall continue to manage the business of the Council until the constitutive meeting of the newly appointed members and substitute members. The entities or bodies delegating the members and substitute members shall notify the Federal Ministry of Justice in writing within a period of two weeks of the election of the new Main Committee of the National Council of the members and substitute members, the number of whom must correspond to para. 1. Reappointment of the members and substitute members is permitted.

(7) The constitutive meeting of the Data Protection Council shall take place no later than six weeks after the election of the Main Committee of the National Council and shall be convened by the Federal Ministry of Justice.

(8) The members and substitute members of the Data Protection Council shall serve in an honorary capacity. Members and substitute members of the Data Protection Council living outside of Vienna shall be entitled to receive compensation for reasonable travel expenses according to the federal regulations on travelling fees if they attend meetings of the Data Protection Council. The Federal Ministry of Justice shall order reimbursements and refunds of the travel expenses to be paid every quarter in arrears.

Chair and management

§ 16. (1) The Data Protection Council shall adopt its rules of procedure by a resolution.

(2) In the constitutive meeting, the Data Protection Council shall elect, by a simple majority, a chair and two deputy chairs from among its members on the basis of the list of candidates proposed for election. Run-off elections are permitted. The

zulässig. Die Wahlvorschläge sind den Mitgliedern und Ersatzmitgliedern gleichzeitig mit der Einladung zur konstituierenden Sitzung bekannt zu geben. Die Wiederwahl ist zulässig.

(3) Die Funktionsperiode des Vorsitzenden und der stellvertretenden Vorsitzenden endet

1. mit Eintritt einer der Voraussetzungen des § 15 Abs. 5 Z 1 bis 3,
2. mit Bekanntgabe der Zurücklegung der Funktion durch den Vorsitzenden oder einen der stellvertretenden Vorsitzenden im Wege einer Erklärung in der Sitzung des Datenschutzrates oder einer schriftlichen Mitteilung an das Bundesministerium für Justiz oder
3. nach Abwahl durch den Datenschutzrat mit einfacher Mehrheit der abgegebenen Stimmen und Anwesenheit von mehr als zwei Drittel seiner Mitglieder oder Ersatzmitglieder.

Nach dem Ende der Funktionsperiode des Vorsitzenden oder eines stellvertretenden Vorsitzenden ist umgehend ein neuer Vorsitzender oder ein neuer stellvertretender Vorsitzender zu wählen.

(4) Der gemäß Abs. 2 gewählte Vorsitzende vertritt den Datenschutzrat nach außen.

(5) Die Geschäftsführung des Datenschutzrates obliegt dem Bundesministerium für Justiz. Die Bundesministerin für Justiz hat das hierfür notwendige Personal zur Verfügung zu stellen. Bei ihrer Tätigkeit für den Datenschutzrat sind die Bediensteten des Bundesministeriums für Justiz fachlich an die Weisungen des Vorsitzenden des Datenschutzrates gebunden.

Sitzungen und Beschlussfassung

§ 17. (1) Die Sitzungen des Datenschutzrates werden vom Vorsitzenden nach Bedarf einberufen. Jedes Mitglied des Datenschutzrates kann schriftlich die Einberufung des Datenschutzrates unter Angabe des gewünschten Verhandlungsgegenstandes begehren. Liegt ein solches Begehren vor, so hat der Vorsitzende die Sitzung so anzuberaumen, dass sie spätestens vier Wochen nach Einlangen des Begehrens stattfindet.

(2) Jedes Mitglied des Datenschutzrates ist – außer im Fall der gerechtfertigten Verhinderung – verpflichtet, an den Sitzungen des Datenschutzrates teilzunehmen. Nur bei Verhinderung des Mitglieds nimmt das Ersatzmitglied an der Sitzung teil.

list of candidates proposed for election shall be made known to the members and substitute members together with the invitation to the constitutive meeting. Re-election is permitted.

(3) The term of office of the chair and the deputy chairs ends

1. when the requirements of § 15 para. 5 subparas. 1 to 3 are met,
2. when the chair or one of the deputy chairs announces his or her resignation from his or her function by means of a declaration in the meeting of the Data Protection Council or a written notification to the Federal Ministry of Justice, or
3. after the chair or one of the deputy chairs has been voted out of office by the Data Protection Council by a simple majority of the votes cast, with more than two thirds of its members or substitute members having to be present at the vote.

After the end of the term of office of the chair or one of the deputy chairs, a new chair or a new deputy chair shall be elected without delay.

(4) The chair elected pursuant to para. 2 shall represent the Data Protection Council vis-á-vis third parties.

(5) The Federal Ministry of Justice shall be responsible for the management of the Data Protection Council. The Federal Minister of Justice shall supply the necessary personnel for that purpose. While working for the Data Protection Council, the employees of the Federal Ministry of Justice shall be bound by the instructions of the chair of the Data Protection Council with regard to their work.

Meetings and resolutions

§ 17. (1) The meetings of the Data Protection Council shall be convened by the chair whenever the need arises. Every member of the Data Protection Council can request in writing that the Data Protection Council be convened, stating the requested topic of discussion. If such a request has been made, the chair shall schedule a meeting that must take place no later than four weeks after receipt of the request.

(2) Every member of the Data Protection Council must attend the meetings of the Data Protection Council unless the member is incapacitated or unavailable for justifiable reasons. A substitute member shall attend a meeting only if a member is incapacitated or unavailable.

(3) Für Beratungen und Beschlussfassung im Datenschutzrat ist die Anwesenheit von mehr als der Hälfte seiner Mitglieder oder Ersatzmitglieder erforderlich. Zur Beschlussfassung genügt die einfache Mehrheit der abgegebenen Stimmen. Bei Stimmengleichheit gibt die Stimme des Vorsitzenden den Ausschlag. Stimmenthaltung ist unzulässig. Minderheitenvoten sind zulässig.

(4) Bei dringlichen Angelegenheiten kann der Vorsitzende die stellvertretenden Vorsitzenden und je einen Vertreter der politischen Parteien (§ 15 Abs. 1 Z 1) zu einer außerordentlichen Sitzung (Präsidium) einladen.

(5) Der Datenschutzrat kann aus seiner Mitte ständige oder nichtständige Arbeitsausschüsse bilden, denen er die Vorbereitung, Begutachtung und Bearbeitung einzelner Angelegenheiten übertragen kann. Er ist auch berechtigt, die Geschäftsführung, Vorbegutachtung und die Bearbeitung einzelner Angelegenheiten einem einzelnen Mitglied (Berichterstatter) zu übertragen.

(6) Der Leiter der Datenschutzbehörde und der Vorsitzende des Parlamentarischen Datenschutzkomitees sind berechtigt, an den Sitzungen des Datenschutzrates oder seiner Arbeitsausschüsse teilzunehmen. Ein Stimmrecht steht ihnen nicht zu.

(7) Der Vorsitzende kann bei Bedarf Sachverständige zu den Sitzungen des Datenschutzrates oder zu Arbeitsausschüssen beiziehen. Auch zur Vorbereitung von Sitzungen des Datenschutzrates oder Arbeitsausschüssen kann der Vorsitzende des Datenschutzrates Experten des jeweiligen Fachgebietes beiziehen, soweit dies zur Klärung von Fragen von besonderer Bedeutung für den Datenschutz erforderlich ist.

(8) Die Beratungen in den Sitzungen des Datenschutzrates sind, soweit er nicht selbst anderes beschließt, nicht öffentlich. Die Mitglieder und Ersatzmitglieder des Datenschutzrates, der Leiter der Datenschutzbehörde sowie sein Stellvertreter, der Vorsitzende des Parlamentarischen Datenschutzkomitees und die zur Sitzung zugezogenen Sachverständigen sind zur Geheimhaltung über alle ihnen ausschließlich aus ihrer Tätigkeit im Datenschutzrat bekanntgewordenen Tatsachen verpflichtet.

(3) Deliberations and resolutions of the Data Protection Council shall require the presence of more than half of its members or substitute members. Resolutions shall be passed by a simple majority of votes cast. In the case of a parity of votes, the chair shall have a casting vote. An abstention from the vote is not permitted. Dissenting opinions are permitted.

(4) In urgent matters, the chair can invite the deputy chairs and one representative of each political party (§ 15 para. 1 subpara. 1) to attend an extraordinary meeting (Executive Board).

(5) The Data Protection Council may establish permanent or non-permanent working groups from among its members which it may entrust with the preparation, appraisal and handling of specific issues. The Data Protection Council may also delegate the management, pre-appraisal and handling of specific issues to an individual member (rapporteur).

(6) The head of the Data Protection Authority and the chair of the Parliamentary Data Protection Committee shall have the right to attend the meetings of the Data Protection Council or its working groups. The head of the Data Protection Authority and the chair of the Parliamentary Data Protection Committee shall not have a voting right.

(7) If required, the chair can ask experts to attend the meetings of the Data Protection Council or the working groups. The chair of the Data Protection Council can also ask experts in the relevant field to assist in preparing meetings of the Data Protection Council or of working groups if this is required to clarify issues of special significance for data protection.

(8) The deliberations of the Data Protection Council shall not be public unless the Data Protection Council itself decides otherwise. The members and substitute members of the Data Protection Council, the head and deputy head of the Data Protection Authority, the chair of the Parliamentary Data Protection Committee and the experts asked to attend meetings are obliged to observe secrecy in relation to all facts that have become known to them exclusively on the basis of their activities in the Data Protection Council.

2. Abschnitt
Datenschutzbehörde

Einrichtung

§ 18. (1) Die Datenschutzbehörde wird als nationale Aufsichtsbehörde gemäß Art. 51 DSGVO eingerichtet.

(2) Der Datenschutzbehörde steht ein Leiter vor. In seiner Abwesenheit leitet sein Stellvertreter die Datenschutzbehörde. Auf ihn finden die Regelungen hinsichtlich des Leiters der Datenschutzbehörde Anwendung.

Unabhängigkeit

§ 19. (1) Die Datenschutzbehörde ist eine Dienstbehörde und Personalstelle.

(2) Der Leiter darf für die Dauer seines Amtes keine Tätigkeit ausüben, die

1. Zweifel an der unabhängigen Ausübung seines Amtes oder seiner Unbefangenheit hervorrufen könnte,
2. ihn bei der Erfüllung seiner dienstlichen Aufgaben behindert oder
3. wesentliche dienstliche Interessen gefährdet.

Er ist verpflichtet, Tätigkeiten, die er neben seiner Tätigkeit als Leiter der Datenschutzbehörde ausübt, unverzüglich der Bundesministerin für Justiz zur Kenntnis zu bringen.

(3) Die Bundesministerin für Justiz kann sich beim Leiter der Datenschutzbehörde über die Gegenstände der Geschäftsführung unterrichten. Dem ist vom Leiter der Datenschutzbehörde nur insoweit zu entsprechen, als dies nicht der völligen Unabhängigkeit der Aufsichtsbehörde im Sinne von Art. 52 DSGVO widerspricht.

Leiter der Datenschutzbehörde

§ 20. (1) Der Leiter der Datenschutzbehörde wird vom Bundespräsidenten auf Vorschlag der Bundesregierung für eine Dauer von fünf Jahren bestellt; die Wiederbestellung ist zulässig. Dem Vorschlag hat eine Ausschreibung zur allgemeinen Bewerbung voranzugehen.

(2) Der Leiter der Datenschutzbehörde hat

1. das Studium der Rechtswissenschaften abgeschlossen zu haben,

Part 2
Data Protection Authority

Establishment

§ 18. (1) The Data Protection Authority is established as a national supervisory authority pursuant to Article 51 of the General Data Protection Regulation.

(2) The Data Protection Authority is managed by its head. If the head is absent, his or her deputy shall manage the Data Protection Authority. The rules regarding the head of the Data Protection Authority shall also apply to the deputy.

Independent status

§ 19. (1) The Data Protection Authority acts as an authority supervising staff and as a human resource department.

(2) During his or her term of office, the head must not exercise any function that

1. could cast doubt on the independent exercise of his or her office or impartiality,
2. prevents him or her from performing their professional duties, or
3. puts essential official interests at risk.

The head is required to report functions that he or she exercises alongside his or her office as the head of the Data Protection Authority to the Federal Minister of Justice without delay.

(3) The Federal Minister of Justice can request information from the head of the Data Protection Authority on matters to be dealt with by the Authority. The head of the Data Protection Authority has to meet this request only insofar as it does not impair the complete independence of the supervisory authority as described in Article 52 of the General Data Protection Regulation.

The head of the Data Protection Authority

§ 20. (1) The head of the Data Protection Authority is appointed for a term of five years by the Federal President on the basis of a proposal by the Federal Government; re-appointment is permitted. The proposal is to be preceded by an advertisement for the position permitting general applications.

(2) The head of the Data Protection Authority must

1. have completed a law degree,

2. die persönliche und fachliche Eignung durch eine entsprechende Vorbildung und einschlägige Berufserfahrung in den von der Datenschutzbehörde zu besorgenden Angelegenheiten aufzuweisen,
3. über ausgezeichnete Kenntnisse des österreichischen Datenschutzrechtes, des Unionsrechtes und der Grundrechte zu verfügen und
4. über eine mindestens fünfjährige juristische Berufserfahrung zu verfügen.

(3) Zum Leiter der Datenschutzbehörde dürfen nicht bestellt werden:

1. Mitglieder der Bundesregierung, Staatssekretäre, Mitglieder einer Landesregierung, Mitglieder des Nationalrates, des Bundesrates oder sonst eines allgemeinen Vertretungskörpers oder des Europäischen Parlaments, ferner Volksanwälte und der Präsident des Rechnungshofes,
2. Personen, die eine in Z 1 genannte Funktion innerhalb der letzten zwei Jahre ausgeübt haben, und
3. Personen, die von der Wählbarkeit in den Nationalrat ausgeschlossen sind.

(4) Die Enthebung des Leiters ist auf Vorschlag der Bundesregierung durch den Bundespräsidenten vorzunehmen.

(5) Der Stellvertreter des Leiters der Datenschutzbehörde wird vom Bundespräsidenten auf Vorschlag der Bundesregierung nach Maßgabe der Abs. 1 bis 3 bestellt. Auf die Enthebung des Stellvertreters findet Abs. 4 Anwendung.

Aufgaben

§ 21. (1) Die Datenschutzbehörde berät die Ausschüsse des Nationalrates und des Bundesrates, die Bundesregierung und die Landesregierungen auf deren Ersuchen über legislative und administrative Maßnahmen. Die Datenschutzbehörde ist vor Erlassung von Bundesgesetzen sowie von Verordnungen im Vollzugsbereich des Bundes, die Fragen des Datenschutzes unmittelbar betreffen, anzuhören.

(2) Die Datenschutzbehörde hat die Listen nach Art. 35 Abs. 4 und 5 DSGVO im Wege einer Verordnung im Bundesgesetzblatt kundzumachen.

(3) Die Datenschutzbehörde hat die nach Art. 57 Abs. 1 lit. p DSGVO festzulegenden Kriterien im Wege einer Verordnung kundzumachen. Sie fungiert

2. have the necessary personal and professional aptitude through relevant prior education and appropriate professional experience in the matters to be handled by the Data Protection Authority,
3. possess excellent knowledge of Austrian data protection law, Union law and fundamental rights, and
4. have at least five years of professional experience in the legal field.

(3) The following persons may not be appointed head of the Data Protection Authority:

1. members of the Federal Government, state secretaries, members of a provincial government, members of the National Council, the Federal Council or any other general representative body or of the European Parliament, as well as members of the Ombudsman Board, and the president of the Court of Audit;
2. persons who have held one of the positions listed in subpara. 1 in the last two years;
3. persons who may not be elected to the National Council.

(4) The head of the Data Protection Authority shall be dismissed by the Federal President on the basis of a proposal by the Federal Government.

(5) The deputy head of the Data Protection Authority is appointed for a term of five years by the Federal President on the basis of a proposal by the Federal Government in accordance with paras. 1 to 3. Para. 4 applies to the dismissal of the deputy.

Tasks

§ 21. (1) At their request, the Data Protection Authority advises the committees of the National Council and the Federal Council, the Federal Government and the provincial governments on legislative and administrative measures. Before federal laws as well as regulations to be implemented by the Federal Government that directly concern issues of data protection law are adopted, the Federal Data Protection Authority shall be consulted.

(2) The Data Protection Authority shall make public, by way of a regulation in the Federal Law Gazette, the lists pursuant to Article 35 paras. 4 and 5 of the General Data Protection Regulation.

(3) The Data Protection Authority shall make public, by way of a regulation, the criteria to be specified pursuant to Article 57 para. 1 (p) of the General Data Protection Regulation. At the same time, the Data Protection Authority shall serve as

zugleich als einzige nationale Akkreditierungsstelle gemäß Art. 43 Abs. 1 lit. a DSGVO.

Befugnisse

§ 22. (1) Die Datenschutzbehörde kann vom Verantwortlichen oder Auftragsverarbeiter der überprüften Datenverarbeitung insbesondere alle notwendigen Aufklärungen verlangen und Einschau in Datenverarbeitungen und diesbezügliche Unterlagen begehren. Der Verantwortliche oder Auftragsverarbeiter hat die notwendige Unterstützung zu leisten. Die Kontrolltätigkeit ist unter möglichster Schonung der Rechte des Verantwortlichen oder des Auftragsverarbeiters und Dritter auszuüben.

(2) Zum Zweck der Einschau ist die Datenschutzbehörde nach Verständigung des Inhabers der Räumlichkeiten und des Verantwortlichen oder des Auftragsverarbeiters berechtigt, Räume, in welchen Datenverarbeitungen vorgenommen werden, zu betreten, Datenverarbeitungsanlagen in Betrieb zu setzen, die zu überprüfenden Verarbeitungen durchzuführen sowie Kopien von Datenträgern in dem für die Ausübung der Kontrollbefugnisse unbedingt erforderlichen Ausmaß herzustellen.

(3) Informationen, die der Datenschutzbehörde oder den von ihr Beauftragten bei der Kontrolltätigkeit zukommen, dürfen ausschließlich für die Kontrolle im Rahmen der Vollziehung datenschutzrechtlicher Vorschriften verwendet werden. Die Pflicht zur Geheimhaltung gilt soweit und solange dies aus den in § 6 Abs. 1 des Informationsfreiheitsgesetzes – IFG, BGBl. I Nr. 5/2024, genannten Gründen erforderlich und verhältnismäßig ist. Im Übrigen besteht die Pflicht zur Geheimhaltung auch gegenüber Gerichten und Verwaltungsbehörden, insbesondere Abgabenbehörden; dies allerdings mit der Maßgabe, dass dann, wenn die Einschau den Verdacht einer strafbaren Handlung nach § 63 dieses Bundesgesetzes oder nach §§ 118a, 119, 119a, 126a bis 126c, 148a oder § 278a des Strafgesetzbuches – StGB, BGBl. Nr. 60/1974, oder eines Verbrechens mit einer Freiheitsstrafe, deren Höchstmaß fünf Jahre übersteigt, ergibt, Anzeige zu erstatten ist und hinsichtlich solcher Verbrechen und Vergehen auch Ersuchen nach § 76 der Strafprozeßordnung – StPO, BGBl. Nr. 631/1975, zu entsprechen ist.

(4) Liegt durch den Betrieb einer Datenverarbeitung eine wesentliche unmittelbare Gefährdung schutzwürdiger Geheimhaltungsinteressen der betroffenen Personen (Gefahr im Verzug) vor, so kann die Datenschutzbehörde die Weiterführung der Datenverarbeitung mit Bescheid gemäß § 57 Abs. 1 des Allgemeinen Verwaltungsverfahrensgesetzes 1991 – AVG, BGBl. Nr. 51/1991,

the only national accreditation body pursuant to Article 43 para. 1 (a) of the General Data Protection Regulation.

Powers

§ 22. (1) The Data Protection Authority can request from the controller or the processor of the examined processing all necessary clarifications and inspect data processing activities and relevant documents. The controller or processor shall render the necessary assistance. Supervisory activities are to be exercised in a way that least interferes with the rights of the controller or processor and third parties.

(2) For purposes of the inspection, the Data Protection Authority shall have the right, after having informed the owner of the premises and the controller or processor, to enter rooms where data processing operations are carried out, put data processing equipment into operation, carry out the processing operations to be examined and make copies of the storage media to the extent strictly necessary to exercise its supervisory powers.

(3) Information acquired by the Data Protection Authority or persons authorised by it during any examination shall be used only for supervisory purposes in the context of the execution of data protection regulations. The obligation of secrecy shall apply to the extent and as long as this is necessary and proportionate for the reasons stated in § 6 para. 1 of the Freedom of Information Act, Federal Law Gazette I No. 5/2024. Incidentally, the obligation of secrecy also exists before courts and administrative authorities, in particular fiscal authorities, with the reservation that, if the inspection leads to the suspicion that a crime pursuant to § 63 of this federal law or pursuant to § 118a, § 119, § 119a, § 126a to § 126c, § 148a or § 278a of the Criminal Code, Federal Law Gazette No 60/1974, or any crime punishable with more than five years of imprisonment has been committed, this shall be reported to the police, and requests pursuant to § 76 of the Code of Criminal Procedure, Federal Law Gazette No 631/1975, regarding such crimes and offences shall also be complied with.

(4) In case a data processing operation causes serious immediate danger to the interests of confidentiality of the data subject which deserve protection (imminent danger), the Data Protection Authority may prohibit the continuation of the data processing operation by an administrative decision pursuant to § 57 para. 1 of the General Administrative Procedure Act 1991, Federal Law Gazette No 51/1991. The

untersagen. Wenn dies technisch möglich, im Hinblick auf den Zweck der Datenverarbeitung sinnvoll und zur Beseitigung der Gefährdung ausreichend scheint, kann die Weiterführung auch nur teilweise untersagt werden. Ebenso kann die Datenschutzbehörde auf Antrag einer betroffenen Person eine Einschränkung der Verarbeitung nach Art. 18 DSGVO mit Bescheid gemäß § 57 Abs. 1 AVG anordnen, wenn der Verantwortliche einer diesbezüglichen Verpflichtung nicht fristgerecht nachkommt. Wird einer Untersagung nicht unverzüglich Folge geleistet, hat die Datenschutzbehörde nach Art. 83 Abs. 5 DSGVO vorzugehen.

(5) Der Datenschutzbehörde obliegt im Rahmen ihrer Zuständigkeit die Verhängung von Geldbußen gegenüber natürlichen und juristischen Personen.

(6) Bestehen im Zuge einer auf § 29 gestützten Klage einer betroffenen Person, die sich von einer Einrichtung, Organisation oder Vereinigung im Sinne des Art. 80 Abs. 1 DSGVO vertreten lässt, Zweifel am Vorliegen der diesbezüglichen Kriterien, trifft die Datenschutzbehörde auf Antrag des Einbringungsgerichtes entsprechende Feststellungen mit Bescheid. Diese Einrichtung, Organisation oder Vereinigung hat im Verfahren Parteistellung. Gegen einen negativen Feststellungsbescheid steht ihr die Beschwerde an das Bundesverwaltungsgericht offen.

Tätigkeitsbericht und Veröffentlichung von Entscheidungen

§ 23. (1) Die Datenschutzbehörde hat bis zum 31. März eines jeden Jahres einen dem Art. 59 DSGVO entsprechenden Tätigkeitsbericht zu erstellen und der Bundesministerin für Justiz vorzulegen. Der Bericht ist von der Bundesministerin für Justiz der Bundesregierung, dem Nationalrat und dem Bundesrat vorzulegen. Die Datenschutzbehörde hat den Bericht der Öffentlichkeit, der Europäischen Kommission, dem Europäischen Datenschutzausschuss (Art. 68 DSGVO) und dem Datenschutzrat zugänglich zu machen.

(2) Entscheidungen der Datenschutzbehörde von grundsätzlicher Bedeutung für die Allgemeinheit sind von der Datenschutzbehörde unter Beachtung der Geheimhaltungsgründe gemäß § 6 Abs. 1 IFG in geeigneter Weise zu veröffentlichen.

continuation may also be prohibited only partially if this seems technically possible, meaningful with regard to the purpose of the data processing operation and sufficient to eliminate the danger. At the request of a data subject, the Data Protection Authority can also order, by an administrative decision pursuant to § 57 para. 1 of the General Administrative Procedure Act, the restriction of processing pursuant to Article 18 of the General Data Protection Regulation if the controller does not comply with an obligation to that effect within the period specified. If prohibition is not complied with immediately, the Data Protection Authority shall proceed pursuant to Article 83 para. 5 of the General Data Protection Regulation.

(5) As part of its responsibilities, the Data Protection Authority is responsible for imposing administrative fines on natural and legal persons.

(6) If, with regard to a claim based on § 29 by a data subject represented by a body, organisation or association as referred to in Article 80 para. 1 of the General Data Protection Regulation, there are doubts whether the relevant criteria have been met, the Data Protection Authority shall, at the request of the court where the claim is filed, make appropriate findings in an administrative decision. Such body, organisation or association shall have the position of a party in the proceedings. It has the right to lodge a complaint against a negative declaratory decision with the Federal Administrative Court.

Activity reports and the publication of decisions

§ 23. (1) The Data Protection Authority shall prepare an activity report complying with Article 59 of the General Data Protection Regulation by 31 March of every year and submit it to the Federal Minister of Justice. The Federal Minister of Justice shall submit the report to the Federal Government, the National Council and the Federal Council. The Data Protection Authority shall make the report accessible to the public, the European Commission, the European Data Protection Board (Article 68 of the General Data Protection Regulation) and the Data Protection Council.

(2) Decisions made by the Data Protection Authority which are of fundamental importance to the general public shall be published by the Data Protection Authority in an appropriate manner while respecting the reasons for confidentiality pursuant to § 6 para. 1 of the Freedom of Information Act.

3. Abschnitt
Rechtsbehelfe, Haftung und Sanktionen

Beschwerde an die Datenschutzbehörde

§ 24. (1) Jede betroffene Person hat das Recht auf Beschwerde bei der Datenschutzbehörde, wenn sie der Ansicht ist, dass die Verarbeitung der sie betreffenden personenbezogenen Daten gegen die DSGVO oder gegen § 1 oder Artikel 2 1. Hauptstück verstößt. Dies gilt nicht, soweit ein Recht auf Beschwerde beim Parlamentarischen Datenschutzkomitee gemäß § 35f Abs. 1 besteht.

(2) Die Beschwerde hat zu enthalten:

1. die Bezeichnung des als verletzt erachteten Rechts,
2. soweit dies zumutbar ist, die Bezeichnung des Rechtsträgers oder Organs, dem die behauptete Rechtsverletzung zugerechnet wird (Beschwerdegegner),
3. den Sachverhalt, aus dem die Rechtsverletzung abgeleitet wird,
4. die Gründe, auf die sich die Behauptung der Rechtswidrigkeit stützt,
5. das Begehren, die behauptete Rechtsverletzung festzustellen und
6. die Angaben, die erforderlich sind, um zu beurteilen, ob die Beschwerde rechtzeitig eingebracht ist.

(3) Einer Beschwerde sind gegebenenfalls der zu Grunde liegende Antrag und eine allfällige Antwort des Beschwerdegegners anzuschließen. Die Datenschutzbehörde hat im Falle einer Beschwerde auf Ersuchen der betroffenen Person weitere Unterstützung zu leisten.

(4) Der Anspruch auf Behandlung einer Beschwerde erlischt, wenn der Einschreiter sie nicht binnen eines Jahres, nachdem er Kenntnis von dem beschwerenden Ereignis erlangt hat, längstens aber binnen drei Jahren, nachdem das Ereignis behaupteter Maßen stattgefunden hat, einbringt. Verspätete Beschwerden sind zurückzuweisen.

(5) Soweit sich eine Beschwerde als berechtigt erweist, ist ihr Folge zu geben. Ist eine Verletzung einem Verantwortlichen des privaten Bereichs zuzurechnen, so ist diesem aufzutragen, den Anträgen des Beschwerdeführers auf Auskunft, Berichtigung, Löschung, Einschränkung oder Datenübertragung in jenem Umfang zu entsprechen, der erforderlich ist, um die festgestellte Rechtsverletzung zu

Part 3
Remedies, liability and penalties

Complaints with the Data Protection Authority

§ 24. (1) Every data subject has the right to lodge a complaint with the Data Protection Authority if the data subject is of the opinion that the processing of the personal data concerning the data subject infringes the General Data Protection Regulation or § 1 or Chapter 1 Article 2. This shall not apply insofar as the data subject has the right to lodge a complaint with the Parliamentary Data Protection Committee pursuant to § 35f para. 1.

(2) The complaint must contain:

1. the description of the right considered to have been infringed,
2. to the extent reasonable, the description of the legal entity or the executive body or officer that is deemed to be responsible for the alleged infringement (respondent to the complaint),
3. the facts from which the infringement is derived,
4. the reasons for which the unlawfulness is alleged,
5. the request to find that the alleged infringement has been committed, and
6. the details which are necessary in order to decide whether the complaint has been lodged in due time.

(3) A complaint must be accompanied by the request on which it is based and the answer of the respondent to the complaint, if any. In the case of a complaint, the Data Protection Authority shall provide further assistance on request of the data subject.

(4) The right to have a complaint dealt with expires if the intervening party does not lodge the complaint within a year after having gained knowledge of the incident that gave rise to the complaint, but no later than within three years after the incident allegedly occurred. Late complaints shall be rejected.

(5) To the extent the complaint is shown to be justified, it is to be granted. If an infringement can be attributed to a private-sector controller, the controller shall be instructed to comply with the complainant's requests for information, rectification, erasure, restriction or data communication to the extent required to eliminate the

beseitigen. Soweit sich die Beschwerde als nicht berechtigt erweist, ist sie abzuweisen.

(6) Ein Beschwerdegegner kann bis zum Abschluss des Verfahrens vor der Datenschutzbehörde die behauptete Rechtsverletzung nachträglich beseitigen, indem er den Anträgen des Beschwerdeführers entspricht. Erscheint der Datenschutzbehörde die Beschwerde insofern als gegenstandslos, so hat sie den Beschwerdeführer dazu zu hören. Gleichzeitig ist er darauf aufmerksam zu machen, dass die Datenschutzbehörde das Verfahren formlos einstellen wird, wenn er nicht innerhalb einer angemessenen Frist begründet, warum er die ursprünglich behauptete Rechtsverletzung zumindest teilweise nach wie vor als nicht beseitigt erachtet. Wird durch eine derartige Äußerung des Beschwerdeführers die Sache ihrem Wesen nach geändert (§ 13 Abs. 8 AVG), so ist von der Zurückziehung der ursprünglichen Beschwerde und der gleichzeitigen Einbringung einer neuen Beschwerde auszugehen. Auch diesfalls ist das ursprüngliche Beschwerdeverfahren formlos einzustellen und der Beschwerdeführer davon zu verständigen. Verspätete Äußerungen sind nicht zu berücksichtigen.

(7) Der Beschwerdeführer wird von der Datenschutzbehörde innerhalb von drei Monaten ab Einbringung der Beschwerde über den Stand und das Ergebnis der Ermittlung unterrichtet.

(8) Jede betroffene Person kann das Bundesverwaltungsgericht befassen, wenn die Datenschutzbehörde sich nicht mit der Beschwerde befasst oder die betroffene Person nicht innerhalb von drei Monaten über den Stand oder das Ergebnis der erhobenen Beschwerde in Kenntnis gesetzt hat.

(9) Die Datenschutzbehörde kann – soweit erforderlich – Amtssachverständige im Verfahren beiziehen.

(10) In die Entscheidungsfrist gemäß § 73 AVG werden nicht eingerechnet:

1. die Zeit, während deren das Verfahren bis zur rechtskräftigen Entscheidung einer Vorfrage ausgesetzt ist;
2. die Zeit während eines Verfahrens nach Art. 56, 60 und 63 DSGVO.

Begleitende Maßnahmen im Beschwerdeverfahren

§ 25. (1) Macht der Beschwerdeführer im Rahmen einer Beschwerde eine wesentliche Beeinträchtigung seiner schutzwürdigen Geheimhaltungsinteressen

infringement that has been found to exist. To the extent that the complaint is not found to be justified, it shall be rejected.

(6) A respondent to the complaint can subsequently eliminate the alleged infringement until the end of the proceedings before the Data Protection Authority by complying with the complainant's requests. If the Data Protection Authority deems the complaint to be settled thereby, it shall hear the complainant on this. Simultaneously, the complainant is to be informed that the Data Protection Authority will informally end the proceedings unless the complainant states reasons, within a reasonable period, why the complainant still considers the originally alleged infringement or at least parts of it as not having been eliminated. If such a statement by the complainant modifies the merits of the case (§ 13 para. 8 of the General Administrative Procedure Act), the original complaint is to be deemed withdrawn and simultaneously a new complaint to be deemed lodged. In this case the original complaint procedure is also to be ended informally and the complainant is to be informed thereof. Late statements are to be ignored.

(7) The data subject shall be informed by the Data Protection Authority of the progress and the outcome of the investigation within three months of filing the complaint.

(8) Each data subject can apply to the Federal Administrative Court if the Data Protection Authority does not handle a complaint or does not inform the data subject within three months of the progress or outcome of the complaint lodged.

(9) To the extent required, the Data Protection Authority can engage official experts to assist in the proceedings.

(10) The term allowed for the decision pursuant to § 73 of the General Administrative Procedure Act shall not include:

1. the time during which proceedings are suspended until a final decision on a preliminary issue has been made;
2. the duration of proceedings pursuant to Articles 56, 60 and 63 of the General Data Protection Regulation.

Accompanying measures in the complaint procedure

§ 25. (1) If, in the context of a complaint, the complainant satisfactorily demonstrates a serious infringement of his or her interests in confidentiality which

durch die Verarbeitung seiner personenbezogenen Daten glaubhaft, kann die Datenschutzbehörde nach § 22 Abs. 4 vorgehen.

(2) Ist in einem Verfahren die Richtigkeit von personenbezogenen Daten strittig, so ist vom Beschwerdegegner bis zum Abschluss des Verfahrens ein Bestreitungsvermerk anzubringen. Erforderlichenfalls hat dies die Datenschutzbehörde auf Antrag des Beschwerdeführers mit Bescheid gemäß § 57 Abs. 1 AVG anzuordnen.

(3) Beruft sich ein Verantwortlicher gegenüber der Datenschutzbehörde auf eine Beschränkung im Sinne des Art. 23 DSGVO, so hat diese die Rechtmäßigkeit der Anwendung der Beschränkungen zu überprüfen. Kommt sie zur Auffassung, dass die Geheimhaltung von verarbeiteten personenbezogenen Daten gegenüber der betroffenen Person nicht gerechtfertigt war, ist die Offenlegung der personenbezogenen Daten mit Bescheid aufzutragen. Wird dem Bescheid der Datenschutzbehörde binnen acht Wochen nicht entsprochen, so hat die Datenschutzbehörde die Offenlegung der personenbezogenen Daten gegenüber der betroffenen Person selbst vorzunehmen und ihr die verlangte Auskunft zu erteilen oder ihr mitzuteilen, welche personenbezogenen Daten bereits berichtigt oder gelöscht wurden.

(4) Bescheide, mit denen Übermittlungen von personenbezogenen Daten ins Ausland genehmigt wurden, sind zu widerrufen, wenn die rechtlichen oder tatsächlichen Voraussetzungen für die Erteilung der Genehmigung nicht mehr bestehen.

Verantwortliche des öffentlichen und des privaten Bereichs

§ 26. (1) Unbeschadet des § 5 Abs. 3 sind Verantwortliche des öffentlichen Bereichs alle Verantwortlichen,

1. die in Formen des öffentlichen Rechts eingerichtet sind, insbesondere auch als Organ einer Gebietskörperschaft, oder
2. soweit sie trotz ihrer Einrichtung in Formen des Privatrechts in Vollziehung der Gesetze tätig sind.

(2) Verantwortliche des öffentlichen Bereichs sind Partei in Verfahren vor der Datenschutzbehörde.

(3) Verantwortliche des öffentlichen Bereichs können Beschwerde an das Bundesverwaltungsgericht und Revision beim Verwaltungsgerichtshof erheben.

(4) Die dem Abs. 1 nicht unterliegenden Verantwortlichen gelten als Verantwortliche des privaten Bereichs im Sinne dieses Bundesgesetzes.

deserve protection due to the processing of the complainant's personal data, the Data Protection Authority may proceed according to § 22 para. 4.

(2) If the correctness of personal data is disputed in proceedings, the respondent to the complaint shall submit, by the end of the proceedings, a note stating that the correctness is disputed. If required, the Data Protection Authority shall order, by an administrative decision pursuant to § 57 para. 1 of the General Administrative Procedure Act, such note to be submitted at the request of the complainant.

(3) If a controller invokes a restriction pursuant to Article 23 of the General Data Protection Regulation in relation to the Data Protection Authority, the Data Protection Authority shall examine the lawfulness of the application of the restrictions. If the Data Protection Authority comes to the conclusion that it was not justified in keeping the processed personal data secret from the data subject, the disclosure of the data shall be ordered by an administrative decision. If the administrative decision by the Data Protection Authority is not complied with within eight weeks, the Data Protection Authority shall disclose the personal data to the data subject and shall communicate to the data subject the desired information or inform the data subject of the personal data that have already been rectified or erased.

(4) Administrative decisions that permit the transfer of data abroad shall be revoked once the legal or factual prerequisites for the issue of the permit no longer apply.

Public-sector and private-sector controllers

§ 26. (1) Without prejudice to § 5 para. 3, public-sector controllers are all controllers

1. that are established in legal structures of public law, in particular also as an executive officer of a territorial authority, or
2. as far as they execute laws despite having been incorporated according to private law.

(2) Public-sector controllers have the status of a party in proceedings before the Data Protection Authority.

(3) Public-sector controllers can lodge complaints with the Federal Administrative Court and final complaints with the Supreme Administrative Court.

(4) Controllers which are not within the scope of para. 1 are considered to be private-sector controllers according to this federal law.

Beschwerde an das Bundesverwaltungsgericht

§ 27. (1) Das Bundesverwaltungsgericht entscheidet durch Senat über Beschwerden gegen Bescheide, wegen der Verletzung der Unterrichtungspflicht gemäß § 24 Abs. 7 und der Entscheidungspflicht der Datenschutzbehörde.

(2) Der Senat besteht aus einem Vorsitzenden und je einem fachkundigen Laienrichter aus dem Kreis der Arbeitgeber und aus dem Kreis der Arbeitnehmer. Die fachkundigen Laienrichter werden auf Vorschlag der Wirtschaftskammer Österreich und der Bundeskammer für Arbeiter und Angestellte bestellt. Es sind entsprechende Vorkehrungen zu treffen, dass zeitgerecht eine hinreichende Anzahl von fachkundigen Laienrichtern zur Verfügung steht.

(3) Die fachkundigen Laienrichter müssen eine mindestens fünfjährige einschlägige Berufserfahrung und besondere Kenntnisse des Datenschutzrechtes besitzen.

(4) Der Vorsitzende hat den fachkundigen Laienrichtern alle entscheidungsrelevanten Dokumente unverzüglich zu übermitteln oder, wenn dies untunlich oder zur Wahrung der Vertraulichkeit von Dokumenten unbedingt erforderlich ist, zur Verfügung zu stellen.

(5) Kommt es zu einem Verfahren gegen den Bescheid der Datenschutzbehörde, der eine Stellungnahme oder ein Beschluss des Europäischen Ausschusses im Rahmen des Kohärenzverfahrens vorangegangen ist, so leitet die Datenschutzbehörde diese Stellungnahme oder diesen Beschluss dem Bundesverwaltungsgericht zu.

Complaints with the Federal Administrative Court

§ 27. (1) The Federal Administrative Court shall decide through a panel of judges on complaints against administrative decisions on the ground of a breach of the duty to provide information pursuant to § 24 para. 7 and the duty to reach a decision of the Data Protection Authority.

(2) The panel of judges shall consist of a chair and one expert lay judge each from among employers and from among employees. The expert lay judges shall be appointed on the basis of a proposal by the Austrian Federal Economic Chamber and the Federal Chamber of Labour. Appropriate arrangements shall be made so that a sufficient number of expert lay judges is available in due time.

(3) The expert lay judges must have at least five years of relevant professional experience and special knowledge of data protection law.

(4) The chair shall provide all documents relevant to the decision to the expert lay judges without delay, or, if this is impractical or strictly necessary to safeguard the confidentiality of the documents, make them available in some other way.

(5) Where proceedings are brought against an administrative decision of the Data Protection Authority which was preceded by an opinion or a decision of the European Data Protection Board in the consistency mechanism, the Data Protection Authority shall forward that opinion or decision to the Federal Administrative Court.

Vertretung von betroffenen Personen

§ 28. Die betroffene Person hat das Recht, eine Einrichtung, Organisation oder Vereinigung ohne Gewinnerzielungsabsicht, die ordnungsgemäß gegründet ist, deren satzungsmäßige Ziele im öffentlichem Interesse liegen und die im Bereich des Schutzes der Rechte und Freiheiten von betroffenen Personen in Bezug auf den Schutz ihrer personenbezogenen Daten tätig ist, zu beauftragen, in ihrem Namen eine Beschwerde einzureichen und in ihrem Namen die in den §§ 24 bis 27 genannten Rechte wahrzunehmen.

Representation of data subjects

§ 28. The data subject shall have the right to mandate a not-for-profit body, organisation or association which has been properly constituted, has statutory objectives which are in the public interest, and is active in the field of the protection of data subjects' rights and freedoms with regard to the protection of their personal data to lodge the complaint on his or her behalf and to exercise the rights referred to in § 24 to § 27 on his or her behalf.

Haftung und Recht auf Schadenersatz

§ 29. (1) Jede Person, der wegen eines Verstoßes gegen die DSGVO oder gegen § 1 oder Artikel 2 1. Hauptstück ein materieller oder immaterieller Schaden entstanden ist, hat Anspruch auf Schadenersatz gegen den Verantwortlichen oder

Right to compensation and liability

§ 29. (1) Pursuant to Article 82 of the General Data Protection Regulation, any person who has suffered material or non-material damage as a result of an infringement of the General Data Protection Regulation or § 1 or Chapter 1 Article 2

gegen den Auftragsverarbeiter nach Art. 82 DSGVO. Im Einzelnen gelten für diesen Schadenersatzanspruch die allgemeinen Bestimmungen des bürgerlichen Rechts.

(2) Für Klagen auf Schadenersatz ist in erster Instanz das mit der Ausübung der Gerichtsbarkeit in bürgerlichen Rechtssachen betraute Landesgericht zuständig, in dessen Sprengel der Kläger (Antragsteller) seinen gewöhnlichen Aufenthalt oder Sitz hat. Klagen (Anträge) können aber auch bei dem Landesgericht erhoben werden, in dessen Sprengel der Beklagte seinen gewöhnlichen Aufenthalt oder Sitz oder eine Niederlassung hat.

Allgemeine Bedingungen für die Verhängung von Geldbußen

§ 30. (1) Die Datenschutzbehörde kann Geldbußen gegen eine juristische Person verhängen, wenn Verstöße gegen Bestimmungen der DSGVO und des § 1 oder Artikel 2 1. Hauptstück durch Personen begangen wurden, die entweder allein oder als Teil eines Organs der juristischen Person gehandelt haben und eine Führungsposition innerhalb der juristischen Person aufgrund

1. der Befugnis zur Vertretung der juristischen Person,
2. der Befugnis, Entscheidungen im Namen der juristischen Person zu treffen, oder
3. einer Kontrollbefugnis innerhalb der juristischen Person

innehaben.

(2) Juristische Personen können wegen Verstößen gegen Bestimmungen der DSGVO und des § 1 oder Artikel 2 1. Hauptstück auch verantwortlich gemacht werden, wenn mangelnde Überwachung oder Kontrolle durch eine in Abs. 1 genannte Person die Begehung dieser Verstöße durch eine für die juristische Person tätige Person ermöglicht hat, sofern die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet.

(3) Die Datenschutzbehörde hat von der Bestrafung eines Verantwortlichen gemäß § 9 des Verwaltungsstrafgesetzes 1991 – VStG, BGBl. Nr. 52/1991, abzusehen, wenn für denselben Verstoß bereits eine Verwaltungsstrafe gegen die juristische Person verhängt wird.

(4) Die gemäß § 22 Abs. 5 verhängten Geldbußen fließen dem Bund zu und sind nach den Bestimmungen über die Eintreibung von gerichtlichen Geldstrafen einzubringen. Rechtskräftige Bescheide der Datenschutzbehörde sind Exekutionstitel. Die Bewilligung und der Vollzug der Exekution ist auf Grund des Exekutionstitels der Datenschutzbehörde bei dem Bezirksgericht, in dessen

shall have the right to receive compensation from the controller or processor for the damage suffered. In detail, the general provisions of civil law shall apply to this right to compensation.

(2) The regional court entrusted with exercising jurisdiction in civil matters in whose judicial district the plaintiff (applicant) has his usual place of residence or registered office shall have first-instance jurisdiction over actions for compensation. Actions (requests) may, however, also be brought before the regional court in whose judicial district the defendant has his usual place of residence or registered office or a branch office.

General conditions for imposing administrative fines

§ 30. (1) The Data Protection Authority can impose administrative fines on a legal person if infringements of provisions of the General Data Protection Regulation and of § 1 or Chapter 1 Article 2 were committed by persons who acted either individually or as part of an executive body of the legal person and have a leading position within the legal person on the basis of:

1. a power of representation of the legal person,
2. the authority to take decisions on behalf of the legal person, or
3. the authority to exercise control within the legal person.

(2) Legal persons may also be held responsible for infringements of provisions of the General Data Protection Regulation and of § 1 or Chapter 1 Article 2 if such infringements by a person acting for the legal person were made possible by a lack of supervision or control by one of the persons referred to in para. 1 unless the act constitutes a criminal offence within the jurisdiction of the courts.

(3) The Data Protection Authority shall refrain from imposing a fine on a responsible party pursuant to § 9 of the Administrative Penal Act 1991, Federal Law Gazette 52/1991, if an administrative penalty has already been imposed on the legal person for the same infringement.

(4) Administrative fines imposed pursuant to § 22 para. 5 shall be received by the Federal Government and shall be collected pursuant to the provisions on the collection of judicial fines. Final administrative decisions by the Data Protection Authority are writs of enforcement. Approval and implementation of enforcement is to be requested on the basis of the writ of enforcement by the Data Protection

Sprengel der Verpflichtete seinen allgemeinen Gerichtsstand in Streitsachen hat (§§ 66, 75 der Jurisdiktionsnorm – JN, RGBl. Nr. 111/1895), oder bei dem in den §§ 18 und 19 EO bezeichneten Exekutionsgericht zu beantragen.

(5) Gegen Behörden und öffentliche Stellen, wie insbesondere in Formen des öffentlichen Rechts sowie des Privatrechts eingerichtete Stellen, die im gesetzlichen Auftrag handeln, und gegen Körperschaften des öffentlichen Rechts können keine Geldbußen verhängt werden.

4. Abschnitt

Aufsichtsbehörde nach der Richtlinie (EU) 2016/680

Datenschutzbehörde

§ 31. (1) Die Datenschutzbehörde wird als nationale Aufsichtsbehörde für den in § 36 Abs. 1 genannten Anwendungsbereich eingerichtet. Die Datenschutzbehörde ist nicht zuständig für die Aufsicht über die von Gerichten im Rahmen ihrer justiziellen Tätigkeit vorgenommenen Verarbeitungen.

(2) Hinsichtlich der Unabhängigkeit, der allgemeinen Bedingungen und der Errichtung der Aufsichtsbehörde finden die Art. 52, 53 und 54 DSGVO sowie der § 18 Abs. 2, §§ 19 und 20 sinngemäß Anwendung.

Aufgaben der Datenschutzbehörde

§ 32. (1) Die Datenschutzbehörde hat im Anwendungsbereich des § 36 Abs. 1

1. die Anwendung des § 1 und der im 3. Hauptstück erlassenen Vorschriften sowie der Durchführungsvorschriften zur Richtlinie (EU) 2016/680 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten durch die zuständigen Behörden zum Zwecke der Verhütung, Ermittlung, Aufdeckung oder Verfolgung von Straftaten oder der Strafvollstreckung sowie zum freien Datenverkehr und zur Aufhebung des Rahmenbeschlusses 2008/977/JI des Rates, ABl. Nr. L 119 vom 4.5.2016 S. 89, zu überwachen und durchzusetzen;
2. die Öffentlichkeit für die Risiken, Vorschriften, Garantien und Rechte im Zusammenhang mit der Verarbeitung zu sensibilisieren und sie darüber aufzuklären;
3. die in Art. 57 Abs. 1 lit. c bis e, g, h und t DSGVO festgelegten Aufgaben im Hinblick auf das 3. Hauptstück zu erfüllen;

Authority from the district court in whose judicial district the obligated party has his or her general place of jurisdiction (§ 66 and § 75 of the Court Jurisdiction Act, Imperial Law Gazette No 111/1895) or from the enforcing court referred to in § 18 and § 19 of the Enforcement Code.

(5) Administrative fines cannot be imposed on authorities and public entities, such as, in particular, entities established in a form provided by public law as well as private law, which act on the basis of a statutory mandate, and on corporations under public law.

Part 4

Supervisory authority pursuant to Directive (EU) 2016/680

Data Protection Authority

§ 31. (1) The Data Protection Authority is established as a national supervisory authority for the scope referred to in § 36 para. 1. The Data Protection Authority shall not be competent to supervise processing operations of courts acting in their judicial capacity.

(2) In respect of independence, general provisions and the establishment of the supervisory authority, Articles 52, 53 and 54 of the General Data Protection Regulation and § 18 para. 2, § 19 and § 20 shall apply accordingly.

Tasks of the Data Protection Authority

§ 32. (1) In the scope of § 36 para. 1, the Data Protection Authority shall

1. monitor and enforce the application of § 1 and of the provisions adopted pursuant to Chapter 3 and the implementing measures regarding Directive (EU) 2016/680 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ No L 119 of 4 May 2016, p. 89;
2. promote public awareness and understanding of the risks, rules, safeguards and rights in relation to processing;
3. perform the tasks specified in Article 57 para. 1 (c) to (e), (g), (h) and (t) of the General Data Protection Regulation with regard to Chapter 3;

4. sich mit Beschwerden einer betroffenen Person oder einer Stelle, einer Organisation oder einer Vereinigung gemäß § 28 zu befassen, den Gegenstand der Beschwerde in angemessenem Umfang zu untersuchen und den Beschwerdeführer innerhalb einer Frist von drei Monaten über den Fortgang und das Ergebnis der Untersuchung zu unterrichten, insbesondere, wenn eine weitere Untersuchung oder Koordinierung mit einer anderen Aufsichtsbehörde notwendig ist;
5. die Rechtmäßigkeit der Verarbeitung gemäß § 42 Abs. 8 zu überprüfen und die betroffene Person innerhalb einer angemessenen Frist über das Ergebnis der Überprüfung gemäß § 42 Abs. 9 zu unterrichten oder ihr die Gründe mitzuteilen, aus denen die Überprüfung nicht vorgenommen wurde;
6. maßgebliche Entwicklungen zu verfolgen, soweit sie sich auf den Schutz personenbezogener Daten auswirken, insbesondere die Entwicklung der Informations- und Kommunikationstechnologie,
7. Beratung in Bezug auf die in § 53 genannten Verarbeitungsvorgänge zu leisten, und
8. die Rechte der betroffenen Person in den Fällen der §§ 43 Abs. 4, 44 Abs. 3 und 45 Abs. 4 auszuüben.

(2) Die Datenschutzbehörde erleichtert das Einreichen von in Abs. 1 Z 4 genannten Beschwerden durch Maßnahmen wie etwa die Bereitstellung eines Beschwerdeformulars, das auch elektronisch ausgefüllt werden kann, ohne dass andere Kommunikationsmittel ausgeschlossen werden.

(3) Art. 57 Abs. 3 und 4 DSGVO finden sinngemäß Anwendung.

Befugnisse der Datenschutzbehörde

§ 33. (1) Die Datenschutzbehörde verfügt im Anwendungsbereich des § 36 Abs. 1 über die zur Vollziehung ihres Aufgabenbereichs erforderlichen wirksamen Untersuchungsbefugnisse. Diese umfassen insbesondere die in § 22 Abs. 2 genannten Befugnisse.

(2) Die Datenschutzbehörde verfügt im Anwendungsbereich des § 36 Abs. 1 über die zur Vollziehung ihres Aufgabenbereichs erforderlichen wirksamen Abhilfebefugnisse. Dazu zählen jedenfalls die Befugnisse, die es ihr gestatten

4. deal with complaints lodged by a data subject, or by a body, organisation or association in accordance with § 28, and investigate, to the extent appropriate, the subject matter of the complaint and inform the complainant of the progress and the outcome of the investigation within a period of three months, in particular if further investigation or coordination with another supervisory authority is necessary;
5. check the lawfulness of processing pursuant to § 42 para. 8, and inform the data subject within a reasonable period of the outcome of the check pursuant to § 42 para. 9 or of the reasons why the check has not been carried out;
6. monitor relevant developments insofar as they have an impact on the protection of personal data, in particular the development of information and communication technologies;
7. provide advice on the processing operations referred to in § 53; and
8. exercise the rights of data subjects in the cases referred to in § 43 para. 4, § 44 para. 3 and § 45 para. 4.

(2) The Data Protection Authority shall facilitate the submission of complaints referred to in para. 1 subpara. 4 by measures such as a complaint submission form which can also be completed electronically, without excluding other means of communication.

(3) Article 57 paras. 3 and 4 of the General Data Protection Regulation shall apply accordingly.

Powers of the Data Protection Authority

§ 33. (1) In the scope of § 36 para. 1, the Data Protection Authority shall have the effective investigative powers required to perform its tasks. Such powers include, in particular, the powers referred to in § 22 para. 2.

(2) In the scope of § 36 para. 1, the Data Protection Authority shall have the effective corrective powers required to perform its tasks. These include the powers to enable the Data Protection Authority

1. einen Verantwortlichen oder einen Auftragsverarbeiter zu warnen, dass beabsichtigte Verarbeitungsvorgänge voraussichtlich gegen die im Anwendungsbereich der Richtlinie (EU) 2016/680 erlassenen Vorschriften verstoßen;
2. den Verantwortlichen oder den Auftragsverarbeiter anzuweisen, Verarbeitungsvorgänge, auf bestimmte Weise und innerhalb eines bestimmten Zeitraums, mit den im Anwendungsbereich der Richtlinie (EU) 2016/680 erlassenen Vorschriften in Einklang zu bringen, insbesondere durch die Anordnung der Berichtigung oder Löschung personenbezogener Daten oder Einschränkung der Verarbeitung gemäß § 45;
3. eine vorübergehende oder endgültige Beschränkung der Verarbeitung, einschließlich eines Verbots, zu verhängen.

(3) Die Datenschutzbehörde verfügt im Anwendungsbereich des § 36 Abs. 1 über die zur Vollziehung erforderlichen wirksamen Beratungsbefugnisse, die es ihr gestatten, gemäß dem Verfahren der vorherigen Konsultation nach § 53 den Verantwortlichen zu beraten und zu allen Fragen, die im Zusammenhang mit dem Schutz personenbezogener Daten stehen, von sich aus oder auf Antrag Stellungnahmen an den Nationalrat oder den Bundesrat, die Bundes- oder Landesregierung oder an sonstige Einrichtungen und Stellen sowie an die Öffentlichkeit zu richten.

(4) Die Ausübung der der Aufsichtsbehörde übertragenen Befugnisse richtet sich im Anwendungsbereich § 36 Abs. 1 sinngemäß nach Art. 58 Abs. 4 DSGVO.

(5) § 22 Abs. 3 2. Satz gilt sinngemäß für Verstöße im Anwendungsbereich des § 36 Abs. 1.

Allgemeine Bestimmungen

§ 34. (1) Verantwortliche haben im Anwendungsbereich des § 36 Abs. 1 wirksame Vorkehrungen zu treffen, um vertrauliche Meldungen über Verstöße zu fördern. In diesem Sinne haben Verantwortliche insbesondere angemessene Verfahren einzurichten, die es ermöglichen, Verstöße gegen die Bestimmungen des 3. Hauptstücks an eine geeignete Stelle zu melden.

(2) Die in Abs. 1 angeführten Vorkehrungen umfassen zumindest

1. spezielle Verfahren für den Empfang der Meldungen über Verstöße und deren Weiterverfolgung;

1. to issue warnings to a controller or processor that intended processing operations are likely to infringe provisions adopted in the scope of Directive (EU) 2016/680;
2. to order the controller or processor to bring processing operations into compliance with the provisions adopted in the scope of Directive (EU) 2016/680 in a specified manner and within a specified period, in particular by ordering the rectification or erasure of personal data or the restriction of processing pursuant to § 45;
3. to impose a temporary or definitive limitation including a ban on processing.

(3) In the scope of § 36 para. 1, the Data Protection Authority has effective advisory powers required for implementation which allow it to advise the controller in accordance with the prior consultation procedure referred to in § 53 and to issue, on its own initiative or on request, opinions to the National Council or the Federal Council, the Federal Government or a provincial government or to other institutions and bodies as well as to the public on any issue related to the protection of personal data.

(4) In the scope of § 36 para. 1, the exercise of the powers conferred on the supervisory authority is based on Article 58 para. 4 of the General Data Protection Regulation.

(5) § 22 para. 3 sentence 2 shall apply accordingly to infringements in the scope of § 36 para. 1

General provisions

§ 34. (1) In the scope of § 36 para. 1, controllers shall put in place effective mechanisms to encourage confidential reporting of infringements. For this purpose, controllers shall, in particular, establish adequate procedures that enable reports of infringements of the provisions of Chapter 3 to an appropriate entity.

(2) The mechanisms referred to in para. 1 shall at least include

1. specific procedures for the receipt of reports on infringements and their follow-up;

2. den Schutz personenbezogener Daten sowohl für die Person, die die Verstöße anzeigt, als auch für die natürliche Person, die mutmaßlich für einen Verstoß verantwortlich ist;
3. klare Regeln, welche die Geheimhaltung der Identität der Person, die die Verstöße anzeigt, gewährleisten, soweit nicht die Offenlegung der Identität im Rahmen eines staatsanwaltschaftlichen, gerichtlichen oder verwaltungsrechtlichen Verfahrens zwingend zu erfolgen hat.

(3) Die Datenschutzbehörde hat im Rahmen des Tätigkeitsberichtes nach § 23 über die Tätigkeiten nach dem 4. und 5. Abschnitt zu berichten. Die Vorgaben des Art. 59 DSGVO und § 23 für den Tätigkeitsbericht und die Veröffentlichung von Entscheidungen finden sinngemäß Anwendung.

(4) Auf die gegenseitige Amtshilfe im Anwendungsbereich des § 36 Abs. 1 findet Art. 61 Abs. 1 bis 7 DSGVO sinngemäß Anwendung.

(5) Im Anwendungsbereich des § 36 Abs. 1 finden die Regelungen des 3. Abschnitts des 2. Hauptstücks – mit Ausnahme des § 30 – sinngemäß Anwendung.

5. Abschnitt
Besondere Befugnisse der Datenschutzbehörde

§ 35. (1) Die Datenschutzbehörde ist nach den näheren Bestimmungen der DSGVO und dieses Bundesgesetzes zur Wahrung des Datenschutzes berufen.

(2) **(Verfassungsbestimmung)** Die Datenschutzbehörde übt ihre Befugnisse auch gegenüber den in Art. 19 B-VG bezeichneten obersten Organen der Vollziehung sowie gegenüber dem Präsidenten des Verwaltungsgerichtshofes im Bereich der diesem zustehenden Verwaltungsangelegenheiten aus.

6. Abschnitt
Parlamentarisches Datenschutzkomitee

Einrichtung

§ 35a. (**Verfassungsbestimmung**) (1) Für den Bereich der Gesetzgebung wird das Parlamentarische Datenschutzkomitee als nationale Aufsichtsbehörde

2. protection of personal data concerning both the person who reports the infringements and the natural person who is presumably responsible for an infringement;
3. clear rules to guarantee that the identity of the person who reported the infringement is not disclosed, unless such disclosure of identity is obligatory in relation to public prosecution, court or administrative proceedings.

(3) In its activity report pursuant to § 23, the Data Protection Authority shall report on its activities pursuant to Parts 4 and 5. The requirements of Article 59 of the General Data Protection Regulation and § 23 for the activity report and the publication of decisions shall apply accordingly.

(4) Article 61 paras. 1 to 7 of the General Data Protection Regulation shall apply accordingly to mutual assistance in the scope of § 36 para. 1.

(5) In the scope of § 36 para. 1, the provisions of Chapter 2 Part 3, with the exception of § 30, shall apply accordingly.

Part 5
Special powers of the Data Protection Authority

§ 35. (1) The Data Protection Authority shall safeguard data protection in accordance with the detailed provisions of the General Data Protection Regulation and this federal law.

(2) **(Constitutional provision)** The Data Protection Authority shall exercise its powers also in relation to the highest governing bodies or officers referred to in Article 19 of the Federal Constitutional Act entrusted with implementing the laws as well as in relation to the president of the Supreme Administrative Court in the administrative matters for which the president is responsible.

Part 6
Parliamentary Data Protection Committee

Establishment

§ 35a. (Constitutional provision) (1) For the legislative sector, the Parliamentary Data Protection Committee is established as the national supervisory

gemäß Art. 51 DSGVO eingerichtet. Es ist zuständig für die Aufsicht über die Verarbeitungen

1. des Nationalrates und des Bundesrates einschließlich deren Mitglieder in Ausübung ihres Mandates sowie der Funktionäre gemäß § 56i Abs. 1 Z 1 bis 3 des Verfassungsgerichtshofgesetzes 1953 – VfGG, BGBl. Nr. 85/1953,
2. des Rechnungshofes und der Volksanwaltschaft,
3. der obersten Organe gemäß Art. 30 Abs. 3 bis 6, 125 und 148h Abs. 1 und 2 B-VG im Bereich der diesen zustehenden Verwaltungsangelegenheiten.

(2) Durch Landesverfassungsgesetz kann die Zuständigkeit des Parlamentarischen Datenschutzkomitees für die Aufsicht über die Verarbeitungen der Landtage einschließlich deren Mitglieder in Ausübung ihres Mandates, der Landesrechnungshöfe und der Landesvolksanwälte vorgesehen werden. Dabei kann auch die Zuständigkeit für die Aufsicht über die Verarbeitungen im Bereich der Verwaltungsangelegenheiten der Landtage, der Landesrechnungshöfe und der Landesvolksanwälte vorgesehen werden.

(3) Das Parlamentarische Datenschutzkomitee ist eine Dienstbehörde und Personalstelle. Die Diensthoheit des Bundes gegenüber den beim Parlamentarischen Datenschutzkomitee Bediensteten wird von dessen Vorsitzenden ausgeübt.

Mitglieder

§ 35b. (1) **(Verfassungsbestimmung)** Die Mitglieder des Parlamentarischen Datenschutzkomitees werden auf Vorschlag des Hauptausschusses vom Nationalrat mit Zustimmung des Bundesrates für eine Funktionsperiode von fünf Jahren gewählt; die Wiederwahl ist zulässig. Die Anzahl der Mitglieder hat mindestens drei und höchstens sechs zu betragen. Dem Vorschlag des Hauptausschusses hat eine Ausschreibung zur allgemeinen Bewerbung durch den Präsidenten des Nationalrates voranzugehen. Der Vorschlag des Hauptausschusses, die Wahl durch den Nationalrat und die Zustimmung des Bundesrates bedürfen jeweils der Anwesenheit von mindestens der Hälfte der Mitglieder und einer Mehrheit von zwei Dritteln der abgegebenen Stimmen. Die Mitglieder des Parlamentarischen Datenschutzkomitees leisten vor Antritt ihres Amtes dem Bundespräsidenten die Angelobung.

(2) Die Mitglieder des Parlamentarischen Datenschutzkomitees haben

authority pursuant to Article 51 of the General Data Protection Regulation. The Committee is responsible for supervising processing operations by

1. the National Council and the Federal Council, including their members in their exercise of their functions as well as the officials referred to in § 56i para. 1 subparas. 1 to 3 of the Constitutional Court Act 1953, Federal Law Gazette No 85/1953,
2. the Court of Audit and the Ombudsman Board,
3. the highest governing bodies or officers pursuant to Article 30 paras. 3 to 6, Article 125 and Article 148h paras. 1 and 2 of the Federal Constitutional Act in the administrative matters for which they are responsible.

(2) Provincial constitutional laws may stipulate that the Parliamentary Data Protection Committee is responsible for supervising processing operations by the provincial parliaments, including their members in their exercise of their functions, the provincial courts of audit and the provincial ombudspersons. Provincial constitutional laws may also stipulate that the Parliamentary Data Protection Committee is responsible for supervising processing operations in administrative matters of the provincial parliaments, the provincial courts of audit and the provincial ombudspersons.

(3) The Provincial Data Protection Committee shall act as an authority supervising staff and as a human resource department. The Federal Government's competence to supervise persons employed with the Parliamentary Data Protection Committee shall be exercised by the chair of the Committee.

Members

§ 35b. (1) **(Constitutional provision)** The members of the Parliamentary Data Protection Committee shall be elected by the National Council on the basis of a proposal by the Main Committee and with the consent of the Federal Council for a term of office of five years; re-election is permitted. The Parliamentary Data Protection Committee shall have at least three and no more than six members. The proposal by the Main Committee is to be preceded by an advertisement for the position permitting general applications issued by the president of the National Council. The proposal by the Main Committee, election by the National Council and consent of the Federal Council shall each require the presence of at least half of the members and a majority of two thirds of the votes cast. Before taking office, the members of the Parliamentary Data Protection Committee shall be sworn into office by the Federal President.

(2) The members of the Parliamentary Data Protection Committee shall

1. über ein abgeschlossenes Studium zu verfügen, wobei es sich bei mindestens der Hälfte der Mitglieder um ein rechtswissenschaftliches Studium handeln muss,
2. die persönliche und fachliche Eignung durch eine entsprechende Vorbildung und mindestens fünfjährige einschlägige Berufserfahrung aufzuweisen und
3. über Kenntnisse des österreichischen und europäischen Datenschutzrechts, der Grundrechte, des Parlamentsrechts und des parlamentarischen Verfahrens zu verfügen.

(3) Zum Mitglied des Parlamentarischen Datenschutzkomitees dürfen nicht bestellt werden:

1. Mitglieder der Bundesregierung, Staatssekretäre, Mitglieder einer Landesregierung, Mitglieder des Nationalrates, des Bundesrates oder sonst eines allgemeinen Vertretungskörpers oder des Europäischen Parlaments, ferner der Präsident des Rechnungshofes und die Mitglieder der Volksanwaltschaft sowie Direktoren der Landesrechnungshöfe und Landesvolksanwälte,
2. Personen, die eine in Z 1 genannte Funktion innerhalb der letzten fünf Jahre ausgeübt haben, und
3. Personen, die von der Wählbarkeit in den Nationalrat ausgeschlossen sind.

(4) **(Verfassungsbestimmung)** Die Enthebung eines Mitglieds des Parlamentarischen Datenschutzkomitees ist auf Vorschlag des Hauptausschusses durch den Nationalrat vorzunehmen, wenn es eine schwere Verfehlung begangen hat oder die Voraussetzungen für die Wahrnehmung seiner Aufgaben nicht mehr erfüllt (Art. 53 Abs. 4 DSGVO). Der Vorschlag des Hauptausschusses und der Beschluss des Nationalrates bedürfen jeweils der Anwesenheit von mindestens der Hälfte der Mitglieder und einer Mehrheit von zwei Dritteln der abgegebenen Stimmen.

(5) Den Mitgliedern des Parlamentarischen Datenschutzkomitees gebührt als Entschädigung für die Erfüllung ihrer Aufgaben für jede begonnene Stunde ein Zehntel der Entschädigung eines Ersatzmitgliedes des Verfassungsgerichtshofes für einen Sitzungstag (§ 4 Abs. 3 VfGG). Für die Vergütung ihrer Reisekosten gelten die Bestimmungen der Reisegebührenvorschrift 1955, BGBl. Nr. 133/1955, sinngemäß.

1. have completed a university degree programme, and at least half of the members shall have completed a law degree,
2. have the necessary personal and professional aptitude through relevant prior education and at least five years' appropriate professional experience, and
3. possess knowledge of Austrian and European data protection law and of fundamental rights, legislation relating to the functioning of parliament and parliamentary procedures.

(3) The following persons may not be appointed members of the Parliamentary Data Protection Committee:

1. members of the Federal Government, state secretaries, members of a provincial government, members of the National Council, the Federal Council or any other general representative body or of the European Parliament as well as the president of the Court of Audit, members of the Ombudsman Board, directors of the provincial courts of audit and the provincial ombudspersons,
2. persons who have held one of the positions listed in subpara. 1 in the last five years, and
3. persons who may not be elected to the National Council.

(4) **(Constitutional provision)** A member of the Parliamentary Data Protection Committee shall be dismissed by the National Council on the basis of a proposal by the Main Committee if the member has committed serious misconduct or if the member no longer fulfils the conditions required for the performance of the member's duties (Article 53 para. 4 of the General Data Protection Regulation). The proposal by the Main Committee and the resolution by the National Council shall each require the presence of at least half of the members and a majority of two thirds of the votes cast.

(5) As remuneration for fulfilling their duties, for each hour or part thereof, the members of the Parliamentary Data Protection Committee are entitled to one tenth of the remuneration of a substitute member of the Constitutional Court for one day of hearing (§ 4 para. 3 of the Constitutional Court Act). The provisions of the Travelling Fees Regulation 1955, Federal Law Gazette No 133/1955, shall apply accordingly to the reimbursement of travelling costs.

Unabhängigkeit

§ 35c. (1) Die Mitglieder des Parlamentarischen Datenschutzkomitees üben dieses Amt neben ihren beruflichen Tätigkeiten aus. Sie dürfen für die Dauer ihres Amtes lediglich keine Tätigkeit ausüben, die

1. Zweifel an der unabhängigen Ausübung ihres Amtes oder ihrer Unbefangenheit hervorrufen könnte, oder
2. sie bei der Erfüllung ihrer Aufgaben als Mitglied des Parlamentarischen Datenschutzkomitees behindert oder wesentliche Interessen dieser Aufgabe gefährdet.

Sie sind verpflichtet, ihre beruflichen Tätigkeiten, die sie neben ihrer Tätigkeit als Mitglied des Parlamentarischen Datenschutzkomitees ausüben, unverzüglich dem Vorsitzenden des Parlamentarischen Datenschutzkomitees zu melden.

(2) Der Vorsitzende des Parlamentarischen Datenschutzkomitees hat seine und die gemäß Abs. 1 gemeldeten beruflichen Tätigkeiten im Internet zu veröffentlichen. Die Veröffentlichungen sind für die Dauer der jeweiligen Funktionsperiode aufrecht zu erhalten.

(3) **(Verfassungsbestimmung)** Der Präsident des Nationalrates kann sich beim Vorsitzenden des Parlamentarischen Datenschutzkomitees über die Gegenstände der Geschäftsführung unterrichten. Dem ist vom Vorsitzenden des Parlamentarischen Datenschutzkomitees nur insoweit zu entsprechen, als dies nicht der völligen Unabhängigkeit der Aufsichtsbehörde im Sinne von Art. 52 DSGVO widerspricht.

Vorsitz und Beschlussfassung

§ 35d. (1) Der Vorsitz des Parlamentarischen Datenschutzkomitees wechselt jährlich zwischen den Mitgliedern. Die Reihenfolge ist in der Geschäftsordnung festzulegen. Bei Bedarf bestimmt das Parlamentarische Datenschutzkomitee aus seiner Mitte eine Stellvertretung, die ebenfalls jährlich wechselt; der Stellvertreter vertritt den Vorsitzenden des Parlamentarischen Datenschutzkomitees in dessen Abwesenheit. Der Vorsitzende des Parlamentarischen Datenschutzkomitees hat dem Präsidenten des Nationalrates rechtzeitig einen Entwurf betreffend die für die Aufgabenerfüllung des Parlamentarischen Datenschutzkomitees erforderlichen Ressourcen als Grundlage für die Erstellung des Voranschlagsentwurfs gemäß § 14 Abs. 2 des Geschäftsordnungsgesetzes 1975 zu unterbreiten.

(2) Das Parlamentarische Datenschutzkomitee ist bei Anwesenheit von mehr als der Hälfte seiner Mitglieder beschlussfähig. Es fasst seine Beschlüsse mit

Independence

§ 35c. (1) The members of the Parliamentary Data Protection Committee shall exercise their office in addition to their professional activities. During their term of office, however, they must not exercise any activities that

1. could cast doubt on the independent exercise of their office or their impartiality, or
2. prevent them from fulfilling their duties as members of the Parliamentary Data Protection Committee or put at risk material interests associated with these duties.

They are required to report the professional activities which they exercise in addition to their activities as members of the Parliamentary Data Protection Committee to the chair of the Parliamentary Data Protection Committee without delay.

(2) The chair of the Parliamentary Data Protection Committee shall publish his or her professional activities and the professional activities reported pursuant to para. 1 on the internet. The activities must be published for the duration of the relevant term of office.

(3) **(Constitutional provision)** The president of the National Council may request information on matters to be dealt with from the chair of the Parliamentary Data Protection Committee. The chair of the Parliamentary Data Protection Committee shall comply with this request only insofar as it does not conflict with the supervisory authority's complete independence as referred to in Article 52 of the General Data Protection Regulation.

Chair and resolutions

§ 35d. (1) The position of chair of the Parliamentary Data Protection Committee shall alternate annually between the members. Succession must be specified in the rules of procedure. If required, the Parliamentary Data Protection Committee shall appoint a deputy from among its members, also alternating annually; the deputy shall represent the chair of the Parliamentary Data Protection Committee if the chair is absent. The chair of the Parliamentary Data Protection Committee shall submit to the president of the National Council, in due time, a draft regarding the resources required for fulfilling the tasks of the Parliamentary Data Protection Committee to serve as the basis for the preparation of the draft federal budget pursuant to § 14 para. 2 of the Rules of Procedure Act of 1975.

(2) The Parliamentary Data Protection Committee is quorate if more than half of its members are present. Resolutions are passed by a simple majority of votes. A

Stimmenmehrheit. Ein befangenes Mitglied hat sich seiner Stimme zu enthalten; ansonsten ist Stimmenthaltung unzulässig.

(3) Die Sitzungen des Parlamentarischen Datenschutzkomitees können auch als Telefon- oder Videokonferenz (auch in hybrider Form) stattfinden. Mitglieder, die durch Telefon- oder Videokonferenz zugeschaltet sind, gelten als anwesend. Eine Beschlussfassung auf schriftlichem oder elektronischem Weg im Umlaufverfahren ist zulässig. Näheres bestimmt die Geschäftsordnung des Parlamentarischen Datenschutzkomitees.

(4) Das Parlamentarische Datenschutzkomitee hat sich durch Beschluss eine Geschäftsordnung zu geben. Die Geschäftsordnung hat insbesondere Regelungen über die Reihenfolge des Vorsitzes und gegebenenfalls der Stellvertretung sowie über die Arbeitsweise des Parlamentarischen Datenschutzkomitees zu enthalten. In der Geschäftsordnung können einzelne Mitglieder mit der Führung der laufenden Geschäfte und bestimmten verfahrensrechtlichen Angelegenheiten betraut werden. Bis zum Beschluss der Geschäftsordnung lädt das an Jahren älteste Mitglied zur Sitzung ein und leitet diese.

Aufgaben, Befugnisse, Tätigkeitsbericht und Veröffentlichung von Entscheidungen

§ 35e. (1) Genehmigungen gemäß § 7 Abs. 2 Z 3 und Abs. 3 sowie § 8 Abs. 3 und 4, soweit dadurch personenbezogene Daten aus Verarbeitungen gemäß § 35a Abs. 1 betroffen sind, obliegen dem Parlamentarischen Datenschutzkomitee. Dies gilt auch in Bezug auf personenbezogene Daten aus Verarbeitungen gemäß § 35a Abs. 2, sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

(2) § 21 Abs. 1, § 22 und § 30 Abs. 5 gelten sinngemäß. Gegenüber den in § 2 des Informationsordnungsgesetzes – InfOG, BGBl. I Nr. 102/2014, genannten Personen bestehen die Untersuchungsbefugnisse gemäß § 22 Abs. 1 und 2 (Art. 58 Abs. 1 lit. e und f DSGVO) jedoch nicht, soweit die Inanspruchnahme der Befugnisse zu einem Verstoß gegen die Geheimhaltungsverpflichtungen dieser Personen führen würde. Gegenüber dem Rechnungshof und der Volksanwaltschaft bestehen die Untersuchungsbefugnisse gemäß § 22 Abs. 1 und 2 (Art. 58 Abs. 1 lit. e und f DSGVO) nicht, soweit die Inanspruchnahme dieser Befugnisse zu einer Verletzung von Geheimhaltungsverpflichtungen des Rechnungshofes oder der Volksanwaltschaft führen würde.

member who has a conflict of interests shall abstain from voting; in all other cases, abstentions are not permitted.

(3) The meetings of the Parliamentary Data Protection Committee may also be held as a telephone or video conference (even in hybrid format). Members who attend by telephone or video link shall be deemed present. Passing resolutions in writing or electronically by circulation is permitted. Detailed provisions shall be laid down in the rules of procedure of the Parliamentary Data Protection Committee.

(4) The Parliamentary Data Protection Committee shall issue rules of procedure by passing a resolution. The rules of procedure must contain, in particular, rules on the succession of the chair and, where applicable, of the deputy as well as on the functioning of the Parliamentary Data Protection Committee. The rules of procedure may entrust individual members with managing regular affairs and certain procedural matters. Until a resolution on the rules of procedure is passed, the member who is most senior in age shall convene and chair the meeting.

Tasks, powers, activity reports and publication of decisions

§ 35e. (1) The Parliamentary Data Protection Committee is responsible for permits pursuant to § 7 para. 2 subpara. 3 and para. 3 as well as § 8 paras. 3 and 4, insofar as they concern personal data from processing operations pursuant to § 35a para. 1. This shall also apply in relation to personal data from processing operations pursuant to § 35a para. 2, provided that a provincial constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

(2) § 21 para. 1, § 22 and § 30 para. 5 shall apply accordingly. The investigative powers pursuant to § 22 paras. 1 and 2 (Article 58 para. 1 (e) and (f) of the General Data Protection Regulation) shall not apply in relation to the persons referred to in § 2 of the Information Rules Act, Federal Law Gazette I No 102/2014, insofar as exercising these powers would result in non-compliance with the obligation to observe secrecy incumbent upon these persons. The investigative powers pursuant to § 22 paras. 1 and 2 (Article 58 para. 1 (e) and (f) of the General Data Protection Regulation) shall not apply in relation to the Court of Audit and the Ombudsman Board insofar as exercising these powers would result in non-compliance with the obligation to observe secrecy incumbent upon the Court of Audit or the Ombudsman Board.

(3) **(Verfassungsbestimmung)** § 23 gilt sinngemäß mit der Maßgabe, dass der Tätigkeitsbericht dem Präsidenten des Nationalrates und von diesem der Bundesregierung, dem Nationalrat, dem Bundesrat und, soweit eine Zuständigkeit des Parlamentarischen Datenschutzkomitees gemäß § 35a Abs. 2 vorgesehen wurde, den Landtagen vorzulegen ist.

Beschwerde an das Parlamentarische Datenschutzkomitee

§ 35f. (1) Jede betroffene Person hat das Recht auf Beschwerde beim Parlamentarischen Datenschutzkomitee, wenn sie der Ansicht ist, dass die Verarbeitung der sie betreffenden personenbezogenen Daten gemäß § 35a Abs. 1 gegen die DSGVO oder gegen § 1 oder Artikel 2 1. Hauptstück verstößt. Dies gilt auch in Bezug auf Verarbeitungen gemäß § 35a Abs. 2, sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

(2) § 24 Abs. 2 bis 9 und Abs. 10 Z 1 sowie § 28 gelten sinngemäß.

Parteistellung, Rechtsmittellegitimation und Geheimhaltungsverpflichtung

§ 35g. (1) **(Verfassungsbestimmung)** Die für die Verarbeitungen gemäß § 35a Abs. 1 Verantwortlichen sind Partei in Verfahren vor dem Parlamentarischen Datenschutzkomitee. Dasselbe gilt für die für Verarbeitungen gemäß § 35a Abs. 2 Verantwortlichen, sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

(2) **(Verfassungsbestimmung)** Die für die Verarbeitungen gemäß § 35a Abs. 1 Verantwortlichen können Beschwerde an das Bundesverwaltungsgericht und Revision beim Verwaltungsgerichtshof erheben. Dasselbe gilt für die für Verarbeitungen gemäß § 35a Abs. 2 Verantwortlichen, sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

(3) Erlangen das Parlamentarische Datenschutzkomitee, das Bundesverwaltungsgericht, der Verwaltungsgerichtshof oder der Verfassungsgerichtshof im Rahmen eines Verfahrens betreffend Verarbeitungen gemäß § 35a Abs. 1 Kenntnis von Informationen, die einer gesetzlichen Geheimhaltungsverpflichtung unterliegen, gilt die Geheimhaltungsverpflichtung auch für diese. Dies gilt auch in Bezug auf Verarbeitungen gemäß § 35a Abs. 2,

(3) **(Constitutional provision)** § 23 shall apply accordingly with the reservation that the activity report is to be submitted to the president of the National Council, and by the president of the National Council to the Federal Government, the National Council, the Federal Council and, insofar as responsibility of the Parliamentary Data Protection Committee pursuant to § 35a para. 2 has been provided for, to the provincial parliaments.

Complaints with the Parliamentary Data Protection Committee

§ 35f. (1) Every data subject has the right to lodge a complaint with the Parliamentary Data Protection Committee if the data subject is of the opinion that the processing of the personal data concerning the data subject pursuant to § 35a para. 1 infringes the General Data Protection Regulation or § 1 or Article 2 Chapter 1. This shall also apply in relation to processing operations pursuant to § 35a para. 2, provided that a provincial constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

(2) § 24 paras. 2 to 9 and para. 10 subpara. 1 and § 28 shall apply accordingly.

Status of a party, right to lodge a complaint, and obligation of secrecy

§ 35g. (1) **(Constitutional provision)** Controllers of processing operations pursuant to § 35a para. 1 shall have the status of a party in proceedings before the Parliamentary Data Protection Committee. The same shall apply to controllers of processing operations pursuant to § 35a para. 2, provided that a provincial constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

(2) **(Constitutional provision)** Controllers of processing operations pursuant to § 35a para. 1 may lodge a complaint with the Federal Administrative Court and a final complaint with the Supreme Administrative Court. The same shall apply to controllers of processing operations pursuant to § 35a para. 2, provided that a provincial constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

(3) If, in the context of proceedings concerning processing operations pursuant to § 35a para. 1, the Parliamentary Data Protection Committee, the Federal Administrative Court, the Supreme Administrative Court or the Constitutional Court obtain knowledge of information that is subject to a statutory obligation of secrecy, the obligation of secrecy shall also apply to them. This shall also apply in relation to processing operations pursuant to § 35a para. 2, provided that a provincial

sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

Beschwerde an das Bundesverwaltungsgericht

§ 35h. § 27 Abs. 1 gilt sinngemäß. § 27 Abs. 2 bis 4 kommt nicht zur Anwendung.

7. Abschnitt

Vertretung im Europäischen Datenschutzausschuss, zentrale Anlaufstelle und Zusammenarbeit der Aufsichtsbehörden in Angelegenheiten der Europäischen Union

Vertretung im Europäischen Datenschutzausschuss, zentrale Anlaufstelle

§ 35i. Gemeinsamer Vertreter im Europäischen Datenschutzausschuss (Art. 68 DSGVO) und zentrale Anlaufstelle ist der Leiter der Datenschutzbehörde.

Zusammenarbeit und Kohärenz

§ 35j. Die Datenschutzbehörde und das Parlamentarische Datenschutzkomitee arbeiten in Angelegenheiten der Europäischen Union mit dem Ziel einer einheitlichen Anwendung der DSGVO zusammen. In Bezug auf den Europäischen Datenschutzausschuss (Kapitel VII. der DSGVO) hat die Datenschutzbehörde das Parlamentarische Datenschutzkomitee über alle Angelegenheiten rechtzeitig zu informieren und jedenfalls einzubinden, wenn dieses von der Angelegenheit betroffen sein könnte.

constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

Complaints with the Federal Administrative Court

§ 35h. § 27 para. 1 shall apply accordingly. § 27 paras. 2 to 4 shall not apply.

Part 7

Representation on the European Data Protection Board, single contact point and cooperation between the supervisory authorities in matters of the European Union

Representation on the European Data Protection Board, single contact point

§ 35i. The head of the Data Protection Authority shall be the joint representative on the European Data Protection Board (Article 68 of the General Data Protection Regulation) and the single contact point.

Cooperation and consistency

§ 35j. The Data Protection Authority and the Parliamentary Data Protection Committee shall cooperate in matters of the European Union with the aim of consistent application of the General Data Protection Regulation. In relation to the European Data Protection Board (Chapter VII of the General Data Protection Regulation), the Data Protection Authority shall inform, in due time, the Parliamentary Data Protection Committee of all matters and involve the Parliamentary Data Protection Committee in any event if the latter could be affected by the matter.

3. Hauptstück

Verarbeitung personenbezogener Daten für Zwecke der Sicherheitspolizei einschließlich des Verfassungsschutzes, des militärischen Eigenschutzes, der Aufklärung und Verfolgung von Straftaten, der Strafvollstreckung und des Maßnahmenvollzugs

1. Abschnitt

Allgemeine Bestimmungen

Anwendungsbereich und Begriffsbestimmungen

§ 36. (1) Die Bestimmungen dieses Hauptstücks gelten für die Verarbeitung personenbezogener Daten durch zuständige Behörden zum Zweck der Verhütung, Ermittlung, Aufdeckung oder Verfolgung von Straftaten oder der Strafvollstreckung, einschließlich des Schutzes vor und der Abwehr von Gefahren für die öffentliche Sicherheit, sowie zum Zweck der nationalen Sicherheit, des Nachrichtendienstes und der militärischen Eigensicherung.

(2) Im Sinne dieses Hauptstücks bezeichnet der Ausdruck:

1. „personenbezogene Daten“ alle Informationen, die sich auf eine identifizierte oder identifizierbare natürliche Person (im Folgenden „betroffene Person“) beziehen; als identifizierbar wird eine natürliche Person angesehen, die direkt oder indirekt, insbesondere mittels Zuordnung zu einer Kennung wie einem Namen, zu einer Kennnummer, zu Standortdaten, zu einer Online-Kennung oder zu einem oder mehreren besonderen Merkmalen, die Ausdruck der physischen, physiologischen, genetischen, psychischen, wirtschaftlichen, kulturellen oder sozialen Identität dieser natürlichen Person sind, identifiziert werden kann;
2. „Verarbeitung“ jeden mit oder ohne Hilfe automatisierter Verfahren ausgeführten Vorgang oder jede solche Vorgangsreihe im Zusammenhang mit personenbezogenen Daten wie das Erheben, das Erfassen, die Organisation, das Ordnen, die Speicherung, die Anpassung oder Veränderung, das Auslesen, das Abfragen, die Verwendung, die Offenlegung durch Übermittlung, Verbreitung oder eine andere Form der Bereitstellung, den Abgleich oder die Verknüpfung, die Einschränkung, das Löschen oder die Vernichtung;

Chapter 3

Processing of personal data for purposes of the security police, including the protection of the constitution, the protection of military facilities by the armed forces, the resolution and prosecution of criminal offences, the enforcement of sentences and the enforcement of precautionary measures involving the deprivation of liberty

Part 1

General provisions

Scope of application, and definitions

§ 36. (1) The provisions of this Chapter apply to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, and for the purposes of national security, intelligence, and the protection of military facilities by the armed forces.

(2) For the purposes of this Chapter:

1. “personal data” means any information relating to an identified or identifiable natural person (“data subject”); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;
2. “processing” means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

3. „Einschränkung der Verarbeitung“ die Markierung gespeicherter personenbezogener Daten mit dem Ziel, ihre künftige Verarbeitung einzuschränken;
4. „Profiling“ jede Art der automatisierten Verarbeitung personenbezogener Daten, die darin besteht, dass diese personenbezogenen Daten verwendet werden, um bestimmte persönliche Aspekte, die sich auf eine natürliche Person beziehen, zu bewerten, insbesondere um Aspekte bezüglich Arbeitsleistung, wirtschaftliche Lage, Gesundheit, persönliche Vorlieben, Interessen, Zuverlässigkeit, Verhalten, Aufenthaltsort oder Ortswechsel dieser natürlichen Person zu analysieren oder vorherzusagen;
5. „Pseudonymisierung“ die Verarbeitung personenbezogener Daten in einer Weise, dass die personenbezogenen Daten ohne Hinzuziehung zusätzlicher Informationen nicht mehr einer spezifischen betroffenen Person zugeordnet werden können, sofern diese zusätzlichen Informationen gesondert aufbewahrt werden und technischen und organisatorischen Maßnahmen unterliegen, die gewährleisten, dass die personenbezogenen Daten nicht einer identifizierten oder identifizierbaren natürlichen Person zugewiesen werden;
6. „Dateisystem“ jede strukturierte Sammlung personenbezogener Daten, die nach bestimmten Kriterien zugänglich sind, unabhängig davon, ob diese Sammlung zentral, dezentral oder nach funktionalen oder geografischen Gesichtspunkten geordnet geführt wird;
7. „zuständige Behörde“
   a) eine staatliche Stelle, die für die Verhütung, Ermittlung, Aufdeckung oder Verfolgung von Straftaten oder die Strafvollstreckung, einschließlich des Schutzes vor und der Abwehr von Gefahren für die öffentliche Sicherheit, die nationale Sicherheit, den Nachrichtendienst oder die militärische Eigensicherung zuständig ist, oder
   b) eine andere Stelle oder Einrichtung, der durch das Recht der Mitgliedstaaten die Ausübung öffentlicher Gewalt und hoheitlicher Befugnisse zur Verhütung, Ermittlung, Aufdeckung oder Verfolgung von Straftaten oder zur Strafvollstreckung, einschließlich des Schutzes vor und der Abwehr von Gefahren für die öffentliche Sicherheit, zum Zweck der nationalen Sicherheit, des Nachrichtendienstes oder der militärischen Eigensicherung übertragen wurde;

3. “restriction of processing” means the marking of stored personal data with the aim of limiting their processing in the future;
4. “profiling” means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person’s performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements;
5. “pseudonymisation” means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person;
6. “filing system” means any structured set of personal data which are accessible according to specific criteria, whether centralised, decentralised or dispersed on a functional or geographical basis;
7. “competent authority” means
   a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, national security, intelligence, or the protection of military facilities by the armed forces; or
   b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, national security, intelligence, or the protection of military facilities by the armed forces;

8. „Verantwortlicher“ die zuständige Behörde, die allein oder gemeinsam mit anderen über die Zwecke und Mittel der Verarbeitung von personenbezogenen Daten entscheidet;
9. „Auftragsverarbeiter“ eine natürliche oder juristische Person, Behörde, Einrichtung oder andere Stelle, die personenbezogene Daten im Auftrag des Verantwortlichen verarbeitet;
10. „Empfänger“ eine natürliche oder juristische Person, Behörde, Einrichtung oder andere Stelle, der personenbezogene Daten offengelegt werden, unabhängig davon, ob es sich bei ihr um einen Dritten handelt oder nicht. Behörden, die im Rahmen eines bestimmten Untersuchungsauftrags aufgrund von Gesetzen möglicherweise personenbezogene Daten erhalten, gelten jedoch nicht als Empfänger; die Verarbeitung dieser Daten durch die genannten Behörden erfolgt im Einklang mit den geltenden Datenschutzvorschriften gemäß den Zwecken der Verarbeitung;
11. „Verletzung des Schutzes personenbezogener Daten“ eine Verletzung der Sicherheit, die zur Vernichtung, zum Verlust oder zur Veränderung, ob unbeabsichtigt oder unrechtmäßig, oder zur unbefugten Offenlegung von beziehungsweise zum unbefugten Zugang zu personenbezogenen Daten führt, die übermittelt, gespeichert oder auf sonstige Weise verarbeitet wurden;
12. „genetische Daten“ personenbezogene Daten zu den ererbten oder erworbenen genetischen Eigenschaften einer natürlichen Person, die eindeutige Informationen über die Physiologie oder die Gesundheit dieser natürlichen Person liefern und insbesondere aus der Analyse einer biologischen Probe der betreffenden natürlichen Person gewonnen wurden;
13. „biometrische Daten“ mit speziellen technischen Verfahren gewonnene personenbezogene Daten zu den physischen, physiologischen oder verhaltenstypischen Merkmalen einer natürlichen Person, die die eindeutige Identifizierung dieser natürlichen Person ermöglichen oder bestätigen, wie Gesichtsbilder oder daktyloskopische Daten;
14. „Gesundheitsdaten“ personenbezogene Daten, die sich auf die körperliche oder geistige Gesundheit einer natürlichen Person, einschließlich der Erbringung von Gesundheitsdienstleistungen, beziehen und aus denen Informationen über deren Gesundheitszustand hervorgehen;
15. „Aufsichtsbehörde“ die Datenschutzbehörde;

8. “controller” means the competent authority which, alone or jointly with others, determines the purposes and means of the processing of personal data;
9. “processor” means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;
10. “recipient” means a natural or legal person, public authority, agency or other body to which the personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the framework of a particular inquiry in accordance with laws shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing;
11. “personal data breach” means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed;
12. “genetic data” means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question;
13. “biometric data” means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data;
14. “data concerning health” means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status;
15. “supervisory authority” means the Data Protection Authority;

16. „internationale Organisation“ eine völkerrechtliche Organisation und ihre nachgeordneten Stellen oder jede sonstige Einrichtung, die durch eine zwischen zwei oder mehr Staaten geschlossene Übereinkunft oder auf der Grundlage einer solchen Übereinkunft geschaffen wurde.

Grundsätze für die Datenverarbeitung, Kategorisierung und Datenqualität

§ 37. (1) Personenbezogene Daten

1. müssen auf rechtmäßige Weise und nach Treu und Glauben verarbeitet werden,
2. müssen für festgelegte, eindeutige und rechtmäßige Zwecke erhoben und dürfen nicht in einer mit diesen Zwecken nicht zu vereinbarenden Weise verarbeitet werden,
3. müssen dem Verarbeitungszweck entsprechen dafür maßgeblich sein und dürfen in Bezug auf die Zwecke, für die sie verarbeitet werden, nicht übermäßig sein,
4. müssen sachlich richtig und erforderlichenfalls auf dem neuesten Stand sein; dabei sind alle angemessenen Maßnahmen zu treffen, damit personenbezogene Daten, die im Hinblick auf die Zwecke ihrer Verarbeitung unrichtig sind, unverzüglich gelöscht oder berichtigt werden,
5. dürfen nicht länger, als es für die Zwecke, für die sie verarbeitet werden, erforderlich ist, in einer Form gespeichert werden, die die Identifizierung der betroffenen Personen ermöglicht,
6. müssen in einer Weise verarbeitet werden, die eine angemessene Sicherheit der personenbezogenen Daten gewährleistet, einschließlich des Schutzes vor unbefugter oder unrechtmäßiger Verarbeitung und vor unbeabsichtigtem Verlust, unbeabsichtigter Zerstörung oder unbeabsichtigter Schädigung durch geeignete technische und organisatorische Maßnahmen.

(2) Für die Verarbeitung für im öffentlichen Interesse liegende Archivzwecke, für wissenschaftliche oder historische Forschungszwecke oder für statistische Zwecke im Anwendungsbereich des § 36 Abs. 1 gilt § 38.

(3) Der Verantwortliche ist für die Einhaltung der Abs. 1 und 2 verantwortlich und muss deren Einhaltung nachweisen können.

(4) Soweit möglich und zumutbar, ist zwischen den personenbezogenen Daten insbesondere folgender Kategorien betroffener Personen zu unterscheiden:

16. “international organisation” means an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries.

Principles for processing, classification and data quality

§ 37. (1) Personal data shall be:

1. processed lawfully and fairly;
2. collected for specified, explicit and legitimate purposes and shall not be processed in a manner that is incompatible with those purposes;
3. adequate, relevant and not excessive in relation to the purposes for which they are processed;
4. accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;
5. kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which they are processed;
6. processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

(2) § 38 shall apply to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in the scope of § 36 para. 1.

(3) The controller shall be responsible for, and be able to demonstrate compliance with, paras. 1 and 2.

(4) As far as possible and reasonable, a clear distinction between personal data of different categories of data subjects, such as the following, shall be made:

1. Personen, die aufgrund bestimmter Tatsachen konkret verdächtig sind, eine strafbare Handlung begangen zu haben,
2. Personen, gegen die aufgrund bestimmter Tatsachen der begründete Verdacht besteht, dass sie in naher Zukunft eine strafbare Handlung begehen werden,
3. verurteilte Straftäter,
4. Opfer einer Straftat oder Personen, bei denen bestimmte Tatsachen die Annahme rechtfertigen, dass sie Opfer einer Straftat sind, und
5. sonstige Personen, die im Zusammenhang mit einer Straftat stehen, insbesondere Personen, die als Zeugen in Betracht kommen, Personen, die Hinweise zur Straftat geben können, oder Personen, die mit den in Z 1 bis 3 genannten Personen in Kontakt oder in Verbindung stehen.

(5) Soweit möglich ist zwischen faktenbasierten und auf persönlichen Einschätzungen beruhenden personenbezogenen Daten zu unterscheiden. Auf persönlichen Einschätzungen beruhende personenbezogene Daten sind entsprechend zu kennzeichnen und können mit einer Begründung versehen werden, welche die Nachvollziehbarkeit der Einschätzung ermöglicht.

(6) Unrichtige, unvollständige, nicht mehr aktuelle oder zu löschende personenbezogene Daten dürfen weder übermittelt noch zum automatisierten Abruf aus Dateisystemen bereitgestellt werden. Die Behörde hat zu diesem Zweck vor einer Übermittlung die Datenqualität soweit möglich entsprechend zu überprüfen. Zum automatisierten Abruf bereit gehaltene personenbezogene Daten sind entsprechend laufend vollständig und aktuell zu halten.

(7) Bei jeder Übermittlung personenbezogener Daten sind soweit möglich die zur Beurteilung der Aktualität, Richtigkeit, Vollständigkeit und Zuverlässigkeit der personenbezogenen Daten durch den Empfänger erforderlichen Informationen beizufügen.

(8) Wird von Amts wegen oder infolge einer Mitteilung eines Betroffenen festgestellt, dass personenbezogene Daten übermittelt worden sind, die nicht den Anforderungen nach Abs. 6 entsprechen, teilt die übermittelnde bzw. dateisystemführende Dienststelle und Behörde dies der empfangenden Stelle oder Behörde unverzüglich mit. Letztere hat unverzüglich die Löschung unrechtmäßig übermittelter Daten, die Berichtigung unrichtiger Daten, die Ergänzung unvollständiger Daten oder eine Einschränkung der Verarbeitung vorzunehmen.

1. persons who, on the basis of certain facts, are specifically suspected of having committed a criminal offence,
2. persons with regard to whom, on the basis of certain facts, there are serious grounds for believing that they are about to commit a criminal offence,
3. persons convicted of a criminal offence;
4. victims of a criminal offence or persons with regard to whom certain facts give rise to reasons for believing that they are the victims of a criminal offence, and
5. other persons connected to a criminal offence, such as persons who might be called on to testify, persons who can provide information on criminal offences, or contacts or associates of one of the persons referred to in subparas. 1 to 3.

(5) Personal data based on facts are to be distinguished, as far as possible, from personal data based on personal assessments. Personal data based on personal assessments must be marked accordingly, and reasons can be added to facilitate the understanding of an assessment.

(6) Incorrect or incomplete personal data, personal data that are no longer current or are to be erased must neither be transferred nor made available for automated retrieval from filing systems. For that purpose, the authority shall check the data quality accordingly as far as possible before a transmission. Personal data kept ready for automated retrieval must be kept complete and up to date at all times.

(7) As far as possible, the information required for the recipient to assess the up-to-dateness, correctness, completeness and reliability of the personal data shall be added in any transmission of personal data.

(8) If it is found ex officio or following notification by a data subject that personal data that do not comply with the requirements of para. 6 have been transmitted, the transmitting administrative office and authority, or the administrative office and authority keeping the filing system shall notify the receiving office or authority thereof without delay. The receiving office or authority shall immediately erase data which have been unlawfully transmitted, rectify incorrect data, complete incomplete data or restrict processing without delay.

(9) Hat die empfangende Dienststelle oder Behörde Grund zur Annahme, dass übermittelte personenbezogene Daten unrichtig oder nicht aktuell sind oder zu löschen oder in der Verarbeitung einzuschränken wären, so unterrichtet sie die übermittelnde Dienststelle oder Behörde unverzüglich hierüber. Letztere ergreift unverzüglich die erforderlichen Maßnahmen.

Rechtmäßigkeit der Verarbeitung

§ 38. Die Verarbeitung personenbezogener Daten ist, soweit sie nicht zur Wahrung lebenswichtiger Interessen einer Person erforderlich ist, nur rechtmäßig, soweit sie gesetzlich oder in unmittelbar anwendbaren Rechtsvorschriften, die innerstaatlich den Rang eines Gesetzes haben, vorgesehen und für die Erfüllung einer Aufgabe erforderlich und verhältnismäßig ist, die von der zuständigen Behörde zu den in § 36 Abs. 1 genannten Zwecken wahrgenommen wird.

Verarbeitung besonderer Kategorien personenbezogener Daten

§ 39. Die Verarbeitung personenbezogener Daten, aus denen die rassische oder ethnische Herkunft, politische Meinungen, religiöse oder weltanschauliche Überzeugungen oder die Gewerkschaftszugehörigkeit hervorgehen, sowie die Verarbeitung von genetischen Daten, biometrischen Daten zur eindeutigen Identifizierung einer natürlichen Person, Gesundheitsdaten oder Daten zum Sexualleben oder der sexuellen Orientierung einer natürlichen Person für die in § 36 Abs. 1 genannten Zwecke ist nur zulässig, wenn die Verarbeitung unbedingt erforderlich ist und wirksame Maßnahmen zum Schutz der Rechte und Freiheiten der betroffenen Personen getroffen werden und

1. die Verarbeitung gemäß § 38 zulässig ist oder
2. sie sich auf Daten bezieht, die die betroffene Person offensichtlich selbst öffentlich gemacht hat.

Verarbeitung für andere Zwecke und Übermittlung

§ 40. (1) Eine Verarbeitung von personenbezogenen Daten nach den Bestimmungen dieses Hauptstücks durch denselben oder einen anderen Verantwortlichen für einen anderen Verarbeitungszweck, als jenen, für den sie erhoben wurden, ist nur zulässig, wenn dieser andere Zweck vom Anwendungsbereich des § 36 Abs. 1 umfasst ist und die Voraussetzungen der §§ 38 und 39 erfüllt sind.

(2) Die Übermittlung von nach den Bestimmungen dieses Hauptstücks verarbeiteten personenbezogenen Daten für einen nicht in § 36 Abs. 1 genannten

(9) If the receiving administrative office or authority has reason to believe that the personal data transmitted are incorrect or not up to date or would have to be erased, or that their processing would have to be restricted, the receiving administrative office or authority shall notify the transmitting administrative office or authority thereof without delay. The latter shall take the required measures without delay.

Lawfulness of processing

§ 38. Unless it is required to protect the vital interests of a person, processing is lawful only to the extent it is provided for by laws or by directly applicable legal provisions that have the status of laws in Austria and is required and proportionate to fulfil a task performed by the competent authority for the purposes referred to in § 36 para. 1.

Processing of special categories of personal data

§ 39. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation for the purposes referred to in § 36 para. 1 shall be allowed only where strictly necessary and if effective measures to protect the rights and freedoms of the data subjects are taken and

1. where authorised pursuant to § 38, or
2. where such processing relates to data which are manifestly made public by the data subject.

Processing for other purposes, and transfer

§ 40. (1) Processing of personal data pursuant to the provisions of this Chapter by the same or another controller for a purpose other than the one for which the data were collected shall be allowed only if this other purpose is covered by the scope of § 36 para. 1 and the requirements of § 38 and § 39 are met.

(2) Transferring personal data processed pursuant to the provisions of this Chapter for a purpose not referred to in § 36 para. 1 shall be allowed only if this is

Zweck ist nur zulässig, wenn dies gesetzlich oder in unmittelbar anwendbaren Rechtsvorschriften, die innerstaatlich den Rang eines Gesetzes haben, ausdrücklich vorgesehen ist und der Empfänger zur Verarbeitung dieser personenbezogenen Daten für diesen anderen Zweck befugt ist.

(3) Unterliegt die Verarbeitung von personenbezogenen Daten besonderen Bedingungen, so hat die übermittelnde zuständige Behörde den Empfänger der personenbezogenen Daten darauf hinzuweisen, dass diese Bedingungen gelten und einzuhalten sind. Die Übermittlung an Empfänger in anderen Mitgliedstaaten oder nach Titel V Kapitel 4 und 5 AEUV errichtete Einrichtungen und sonstige Stellen darf keinen Bedingungen unterworfen werden, die nicht auch für entsprechende Datenübermittlungen im Inland gelten.

Automatisierte Entscheidungsfindung im Einzelfall

§ 41. (1) Ausschließlich auf einer automatischen Verarbeitung beruhende Entscheidungen einschließlich Profiling, die für die betroffene Person nachteilige Rechtsfolgen haben oder sie erheblich beeinträchtigen können, sind nur zulässig, soweit sie gesetzlich oder in unmittelbar anwendbaren Rechtsvorschriften, die innerstaatlich den Rang eines Gesetzes haben, ausdrücklich vorgesehen sind.

(2) Entscheidungen nach Abs. 1 dürfen nur auf besonderen Kategorien personenbezogener Daten nach § 39 beruhen, wenn und soweit wirksame Maßnahmen zum Schutz der Rechte und Freiheiten sowie der berechtigten Interessen der betroffenen Person getroffen wurden.

(3) Entscheidungen nach Abs. 1, die zur Folge haben, dass natürliche Personen auf Grundlage von personenbezogenen Daten, aus denen die rassische oder ethnische Herkunft, politische Meinungen, religiöse oder weltanschauliche Überzeugungen oder die Gewerkschaftszugehörigkeit hervorgehen, genetischen Daten, biometrischen Daten zur eindeutigen Identifizierung, Gesundheitsdaten oder Daten zum Sexualleben oder der sexuellen Orientierung diskriminiert werden, sind verboten.

2. Abschnitt
Rechte der betroffenen Person

Grundsätze

§ 42. (1) Der Verantwortliche hat der betroffenen Person alle Informationen und Mitteilungen gemäß §§ 43 bis 45, die sich auf die Verarbeitung beziehen, in

expressly provided for by laws or by directly applicable legal provisions that have the status of laws in Austria, and the recipient is authorised to process these personal data for such other purpose.

(3) If the processing of personal data is subject to special conditions, the transmitting competent authority shall inform the recipient of the personal data that such conditions apply and must be complied with. Transfers to recipients in other Member States or to bodies, offices and agencies established pursuant to Title V Chapters 4 and 5 of the TFEU must not be subject to conditions that do not apply to domestic data transmissions as well.

Automated individual decision-making

§ 41. (1) Decisions based solely on automated processing, including profiling, which have negative legal consequences for the data subject or can significantly affect the data subject, shall be allowed only to the extent they are expressly provided for by laws or by directly applicable legal provisions that have the status of laws in Austria.

(2) Decisions referred to in para. 1 shall not be based on special categories of personal data referred to in § 39 unless effective measures to safeguard the data subject's rights and freedoms and legitimate interests are in place.

(3) Decisions pursuant to para. 1 that have the consequence that natural persons are discriminated against on the basis of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

Part 2
Rights of the data subject

Principles

§ 42. (1) The controller shall provide any information and make any communication with regard to § 43 to § 45 relating to processing to the data subject

möglichst präziser, verständlicher und leicht zugänglicher Form in einer klaren und einfachen Sprache zu übermitteln. Die Informationen sind in geeigneter Form, im Falle eines Antrags nach Möglichkeit in der gleichen Form wie der Antrag, zu übermitteln.

(2) Der Verantwortliche hat den betroffenen Personen die Ausübung der ihnen gemäß §§ 43 bis 45 zustehenden Rechte zu erleichtern.

(3) Der Verantwortliche hat die betroffene Person unverzüglich schriftlich darüber in Kenntnis zu setzen, wie mit ihrem Antrag verfahren wurde.

(4) Der Verantwortliche stellt der betroffenen Person Informationen über die aufgrund eines Antrags gemäß §§ 44 bis 45 ergriffenen Maßnahmen unverzüglich, in jedem Fall aber innerhalb eines Monats nach Eingang des Antrags zur Verfügung. Diese Frist kann um weitere zwei Monate verlängert werden, wenn dies unter Berücksichtigung der Komplexität und der Anzahl von Anträgen erforderlich ist. Der Verantwortliche unterrichtet die betroffene Person innerhalb eines Monats nach Eingang des Antrags über eine Fristverlängerung, zusammen mit den Gründen für die Verzögerung. Stellt die betroffene Person den Antrag elektronisch, so ist sie nach Möglichkeit auf elektronischem Weg zu unterrichten, sofern sie nichts anderes angibt.

(5) Wird der Verantwortliche auf den Antrag der betroffenen Person hin nicht tätig, so unterrichtet er die betroffene Person ohne Verzögerung, spätestens aber innerhalb eines Monats nach Eingang des Antrags über die Gründe hierfür und über die Möglichkeit, bei einer Aufsichtsbehörde Beschwerde einzulegen oder einen gerichtlichen Rechtsbehelf einzulegen.

(6) Informationen gemäß § 43 sowie alle Mitteilungen und Maßnahmen gemäß den §§ 44 und 45 werden unentgeltlich zur Verfügung gestellt. Bei offenkundig unbegründeten oder – insbesondere im Fall von häufiger Wiederholung – exzessiven Anträgen einer betroffenen Person kann der Verantwortliche entweder

1. ein angemessenes Entgelt verlangen, bei dem die Verwaltungskosten für die Unterrichtung oder die Mitteilung oder die Durchführung der beantragten Maßnahme berücksichtigt werden, oder
2. sich weigern, aufgrund des Antrags tätig zu werden.

Der Verantwortliche hat den Nachweis für den offenkundig unbegründeten oder exzessiven Charakter des Antrags zu erbringen.

in as concise, intelligible and easily accessible a form as possible, using clear and plain language. The information shall be transmitted in an appropriate manner, in the case of a request in the same form as the request, if possible.

(2) The controller shall facilitate the exercise of the rights of the data subject pursuant to § 43 to 45.

(3) The controller shall inform the data subject in writing about the follow-up to his or her request without undue delay.

(4) The controller shall provide the data subject with information on measures taken because of a request pursuant to § 44 to § 45 without delay, but in any event within one month after receipt of the request. That period may be extended by two further months where necessary, taking into account the complexity and number of the requests. The controller shall inform the data subject of any such extension within one month of receipt of the request, together with the reasons for the delay. Where the data subject makes the request by electronic means, the information shall be provided by electronic means where possible, unless otherwise requested by the data subject.

(5) If the controller does not take action on the request of the data subject, the controller shall inform the data subject without delay and at the latest within one month of receipt of the request of the reasons for not taking action and on the possibility of lodging a complaint with a supervisory authority and seeking a judicial remedy.

(6) Information provided under § 43 and any communication and any action taken under § 44 and 45 shall be provided free of charge. Where requests from a data subject are manifestly unfounded or excessive, in particular because of their repetitive character, the controller may either:

1. charge a reasonable fee taking into account the administrative costs of providing the information or communication or taking the action requested, or
2. refuse to act on the request.

The controller shall bear the burden of demonstrating the manifestly unfounded or excessive character of the request.

(7) Der Verantwortliche kann zur Bestätigung der Identität der Person, die einen Antrag gemäß §§ 44 oder 45 gestellt hat, erforderliche zusätzliche Informationen verlangen.

(8) In den Fällen der §§ 43 Abs. 4, 44 Abs. 3 und 45 Abs. 4 ist die betroffene Person berechtigt, eine Überprüfung der Rechtmäßigkeit der bezüglichen Einschränkung ihrer Rechte durch die Datenschutzbehörde zu verlangen. Der Verantwortliche hat die betroffene Person über dieses Recht zu unterrichten.

(9) Wird das in Abs. 8 genannte Recht ausgeübt, hat die Datenschutzbehörde die betroffene Person zumindest darüber zu unterrichten, dass alle erforderlichen Prüfungen oder eine Überprüfung durch die Datenschutzbehörde erfolgt sind. Die Datenschutzbehörde hat zudem die betroffene Person über ihr Recht zu unterrichten, Beschwerde an das Bundesverwaltungsgericht zu erheben.

Information der betroffenen Person

§ 43. (1) Der Verantwortliche hat der betroffenen Person zumindest die folgenden Informationen zur Verfügung zu stellen:

1. den Namen und die Kontaktdaten des Verantwortlichen,
2. gegebenenfalls die Kontaktdaten des Datenschutzbeauftragten,
3. die Zwecke, für die die personenbezogenen Daten verarbeitet werden,
4. das Bestehen eines Beschwerderechts bei der Aufsichtsbehörde sowie deren Kontaktdaten,
5. das Bestehen eines Rechts auf Auskunft und Berichtigung oder Löschung personenbezogener Daten und Einschränkung der Verarbeitung der personenbezogenen Daten der betroffenen Person durch den Verantwortlichen.

(2) Zusätzlich zu den in Abs. 1 genannten Informationen hat der Verantwortliche der betroffenen Person in besonderen Fällen die folgenden zusätzlichen Informationen zu erteilen, um die Ausübung der Rechte der betroffenen Person zu ermöglichen:

1. die Rechtsgrundlage der Verarbeitung,
2. die Dauer, für die die personenbezogenen Daten gespeichert werden oder, falls dies nicht möglich ist, die Kriterien für die Festlegung dieser Dauer,
3. gegebenenfalls die Kategorien von Empfängern der personenbezogenen Daten, auch der Empfänger in Drittländern oder in internationalen Organisationen,

(7) The controller may request the provision of additional information necessary to confirm the identity of the person who submitted a request pursuant to § 44 or § 45.

(8) In the cases referred to in § 43 para. 4, § 44 para. 3 and § 45 para. 4, the data subject is entitled to request verification of the lawfulness of the relevant restriction of the data subject's rights by the Data Protection Authority. The controller shall inform the data subject of this right.

(9) Where the right referred to in para. 8 is exercised, the Data Protection Authority shall inform the data subject at least that all necessary verifications or a review by the Data Protection Authority have taken place. In addition, the Data Protection Authority shall inform the data subject of the data subject's right to lodge complaints with the Federal Administrative Court.

Information of the data subject

§ 43. (1) The controller shall make available to the data subject at least the following information:

1. the identity and the contact details of the controller;
2. the contact details of the data protection officer, where applicable;
3. the purposes of the processing for which the personal data are intended;
4. the right to lodge a complaint with a supervisory authority and the contact details of the supervisory authority;
5. the existence of the right to request from the controller access to and rectification or erasure of personal data and restriction of processing of the personal data concerning the data subject.

(2) In addition to the information referred to in para. 1, the controller shall give to the data subject, in specific cases, the following further information to enable the exercise of his or her rights:

1. the legal basis for the processing;
2. the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;
3. where applicable, the categories of recipients of the personal data, including in third countries or international organisations;

4. erforderlichenfalls weitere Informationen, insbesondere wenn die personenbezogenen Daten ohne Wissen der betroffenen Person erhoben werden.

(3) Im Fall der Erhebung der personenbezogenen Daten bei der betroffenen Person müssen der betroffenen Person die Informationen nach den Vorgaben des Abs. 1 und 2 zum Zeitpunkt der Erhebung vorliegen. In allen übrigen Fällen findet Art. 14 Abs. 3 DSGVO Anwendung. Die Information gemäß Abs. 1 und 2 kann entfallen, wenn die Daten nicht durch Befragung des Betroffenen, sondern durch Übermittlung von Daten aus anderen Aufgabengebieten desselben Verantwortlichen oder aus Anwendungen anderer Verantwortlicher ermittelt und die Datenverarbeitung durch Gesetz vorgesehen ist.

(4) Die Unterrichtung der betroffenen Person gemäß Abs. 2 kann soweit und solange aufgeschoben, eingeschränkt oder unterlassen werden, wie dies im Einzelfall unbedingt erforderlich und verhältnismäßig ist

1. zur Gewährleistung, dass die Verhütung, Aufdeckung, Ermittlung oder Verfolgung von Straftaten oder die Strafvollstreckung nicht beeinträchtigt werden, insbesondere durch die Behinderung behördlicher oder gerichtlicher Untersuchungen, Ermittlungen oder Verfahren,
2. zum Schutz der öffentlichen Sicherheit,
3. zum Schutz der nationalen Sicherheit,
4. zum Schutz der verfassungsmäßigen Einrichtungen der Republik Österreich,
5. zum Schutz der militärischen Eigensicherung oder
6. zum Schutz der Rechte und Freiheiten anderer.

Auskunftsrecht der betroffenen Person

§ 44. (1) Jede betroffene Person hat das Recht, vom Verantwortlichen eine Bestätigung darüber zu erhalten, ob sie betreffende personenbezogene Daten verarbeitet werden; ist dies der Fall, so hat sie das Recht, Auskunft über personenbezogene Daten und zu folgenden Informationen zu erhalten:

1. die Zwecke der Verarbeitung und deren Rechtsgrundlage,
2. die Kategorien personenbezogener Daten, die verarbeitet werden,
3. die Empfänger oder Kategorien von Empfängern, gegenüber denen die personenbezogenen Daten offengelegt worden sind, insbesondere bei Empfängern in Drittländern oder bei internationalen Organisationen,

4. where necessary, further information, in particular where the personal data are collected without the knowledge of the data subject.

(3) Where personal data are collected from the data subject, the data subject must be in possession of the information pursuant to the requirements of paras. 1 and 2 at the time of the collection of the personal data. In all other cases, Article 14 para. 3 of the General Data Protection Regulation shall apply. The information according to paras. 1 and 2 may be omitted where data have not been collected by asking the data subject, but through transmission from another application purpose of the same controller or from a data application of another controller, and where the processing is provided for by law.

(4) The provision of the information to the data subject pursuant to para. 2 can be delayed, restricted or omitted to the extent this is strictly necessary and proportionate in a particular case to

1. avoid prejudicing the prevention, detection, investigation or prosecution of criminal offences or the execution of criminal penalties, in particular by obstructing inquiries, investigations or proceedings of authorities or courts,
2. protect public security,
3. protect national security,
4. protect the constitutional institutions of the Republic of Austria,
5. enable the protection of military facilities by the armed forces, or
6. protect the rights and freedoms of others.

Right of access by the data subject

§ 44. (1) Every data subject has the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the following information:

1. the purposes of and legal basis for the processing,
2. the categories of personal data concerned,
3. the recipients or categories of recipients to whom the personal data have been disclosed, in particular recipients in third countries or international organisations,

4. falls möglich die geplante Dauer, für die die personenbezogenen Daten gespeichert werden oder, falls dies nicht möglich ist, die Kriterien für die Festlegung dieser Dauer,
5. das Bestehen eines Rechts auf Berichtigung oder Löschung personenbezogener Daten oder Einschränkung der Verarbeitung personenbezogener Daten der betroffenen Person durch den Verantwortlichen,
6. das Bestehen eines Beschwerderechts bei der Datenschutzbehörde sowie deren Kontaktdaten und
7. Mitteilung zu den personenbezogenen Daten, die Gegenstand der Verarbeitung sind, sowie alle verfügbaren Informationen über die Herkunft der Daten.

(2) Einschränkungen des Auskunftsrechts sind nur unter den in § 43 Abs. 4 angeführten Voraussetzungen zulässig.

(3) Im Falle einer Nichterteilung der Auskunft gemäß Abs. 2 hat der Verantwortliche die betroffene Person unverzüglich schriftlich über die Verweigerung oder die Einschränkung der Auskunft und die Gründe hierfür zu unterrichten. Dies gilt nicht, wenn die Erteilung dieser Informationen einem der in § 43 Abs. 4 genannten Zwecke zuwiderliefe. Der Verantwortliche hat die betroffene Person über die Möglichkeit zu unterrichten, Beschwerde bei der Datenschutzbehörde einzulegen.

(4) Der Verantwortliche hat die Gründe für die Entscheidung über die Nichterteilung der Auskunft gemäß Abs. 2 zu dokumentieren. Diese Angaben sind der Datenschutzbehörde zur Verfügung zu stellen.

(5) In dem Umfang, in dem eine Datenverarbeitung für eine betroffene Person hinsichtlich der zu ihr verarbeiteten Daten von Gesetzes wegen einsehbar ist, hat diese das Recht auf Auskunft nach Maßgabe der das Einsichtsrecht vorsehenden Bestimmungen. Für das Verfahren der Einsichtnahme (einschließlich deren Verweigerung) gelten die näheren Regelungen des Gesetzes, das das Einsichtsrecht vorsieht. In Abs. 1 genannte Bestandteile einer Auskunft, die vom Einsichtsrecht nicht umfasst sind, können dennoch nach diesem Bundesgesetz geltend gemacht werden.

4. if possible, the period for which the personal data are planned to be stored, or if that is not possible, the criteria used to determine that period,
5. the existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data concerning the data subject,
6. the right to lodge a complaint with the Data Protection Authority and the contact details of the Data Protection Authority, and
7. communication of the personal data undergoing processing and of any available information as to their origin.

(2) Restrictions of the right of access are permitted only on the conditions referred to in § 43 para. 4.

(3) In case access is not granted pursuant to para. 2, the controller shall inform the data subject, without undue delay, in writing of any refusal or restriction of access and of the reasons for the refusal or the restriction. Such information may be omitted where the provision thereof would undermine a purpose under § 43 para. 4. The controller shall inform the data subject of the possibility to lodge a complaint with the Data Protection Authority.

(4) The controller shall document the reasons for the decision not to grant access pursuant to para. 2. That information shall be made available to the Data Protection Authority.

(5) To the extent that a data processing operation is, by law, open to inspection by a data subject with regard to data processed on the data subject, the data subject shall have a right of access in accordance with the provisions granting the right of inspection. The detailed provisions of the law granting the right of inspection shall apply to the procedure of inspection (and its refusal). Parts of information according to para. 1 that are not covered by the right of inspection may, however, be asserted according to this federal law.

Recht auf Berichtigung oder Löschung personenbezogener Daten und auf Einschränkung der Verarbeitung

§ 45. (1) Jede betroffene Person hat das Recht, vom Verantwortlichen unverzüglich die Berichtigung sie betreffender unrichtiger personenbezogener Daten sowie die Vervollständigung unvollständiger personenbezogener Daten zu verlangen. Die Berichtigung oder Vervollständigung kann erforderlichenfalls mittels einer ergänzenden Erklärung erfolgen, soweit eine nachträgliche Änderung mit dem Dokumentationszweck unvereinbar ist. Der Beweis der Richtigkeit der Daten obliegt dem Verantwortlichen, soweit die personenbezogenen Daten nicht ausschließlich aufgrund von Angaben der betroffenen Person ermittelt wurden.

(2) Der Verantwortliche hat personenbezogene Daten aus eigenem oder über Antrag der betroffenen Person unverzüglich zu löschen, wenn

1. die personenbezogenen Daten für die Zwecke, für die sie erhoben oder auf sonstige Weise verarbeitet wurden, nicht mehr notwendig sind,
2. die personenbezogenen Daten unrechtmäßig verarbeitet wurden oder
3. die Löschung der personenbezogenen Daten zur Erfüllung einer rechtlichen Verpflichtung erforderlich ist.

(3) Anstatt die personenbezogenen Daten zu löschen, kann der Verantwortliche deren Verarbeitung einschränken, wenn

1. die betroffene Person die Richtigkeit der personenbezogenen Daten bestreitet und die Richtigkeit oder Unrichtigkeit nicht festgestellt werden kann, oder
2. die personenbezogenen Daten für Beweiszwecke im Rahmen der Wahrnehmung einer ihm gesetzlich übertragenen Aufgabe weiter aufbewahrt werden müssen.

Im Falle einer Einschränkung gemäß Z 1 hat der Verantwortliche die betroffene Person vor einer Aufhebung der Einschränkung zu unterrichten.

(4) Der Verantwortliche hat die betroffene Person schriftlich über eine Verweigerung der Berichtigung oder Löschung personenbezogener Daten oder eine Einschränkung der Verarbeitung und über die Gründe für die Verweigerung zu unterrichten. Der Verantwortliche hat die betroffene Person über die Möglichkeit zu unterrichten, bei der Datenschutzbehörde Beschwerde einzulegen.

(5) Der Verantwortliche hat die Berichtigung von unrichtigen personenbezogenen Daten der zuständigen Behörde, von der die unrichtigen personenbezogenen Daten stammen, mitzuteilen.

Right to rectification or erasure of personal data and to the restriction of processing

§ 45. (1) Every data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her and the completion of incomplete personal data. Where necessary, the personal data can be rectified or completed by means of a supplementary statement if later changes are incompatible with the documentation purpose. It shall be the obligation of the controller to prove that the data are correct unless the personal data have been collected exclusively based on statements made by the data subject.

(2) The controller shall erase the personal data on the controller's own initiative or at the request of the data subject if

1. the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed,
2. the personal data have been unlawfully processed,
3. erasure is necessary for compliance with a legal obligation to which the controller is subject.

(3) Instead of erasure, the controller shall restrict processing where:

1. the accuracy of the personal data is contested by the data subject and their accuracy or inaccuracy cannot be ascertained, or
2. the personal data must be maintained for the purposes of evidence to perform a task delegated to the controller by law.

In the case of a restriction pursuant to subpara. 1, the controller shall inform the data subject before the restriction is lifted.

(4) The controller shall inform the data subject in writing of any refusal of rectification or erasure of personal data or restriction of processing and of the reasons for the refusal. The controller shall inform the data subject of the possibility to lodge a complaint with the Data Protection Authority.

(5) The controller shall communicate the rectification of inaccurate personal data to the competent authority from which the inaccurate personal data originate.

(6) In Fällen der Berichtigung, Löschung oder Einschränkung der Verarbeitung gemäß Abs. 1 bis 3 hat der Verantwortliche alle Empfänger der betroffenen personenbezogenen Daten in Kenntnis zu setzen. Die Empfänger sind verpflichtet, die ihrer Verantwortung unterliegenden personenbezogenen Daten unverzüglich zu berichtigen, löschen oder deren Verarbeitung einschränken.

(Anm.: Abs. 7 aufgehoben durch Z 22, BGBl. I Nr. 24/2018)

3. Abschnitt
Verantwortlicher und Auftragsverarbeiter

Pflichten des Verantwortlichen

§ 46. Der Verantwortliche hat die in Art. 24 Abs. 1 und 2 sowie Art. 25 Abs. 1 und 2 DSGVO angeführten Verpflichtungen in Bezug auf die Übereinstimmung der Verarbeitung mit den Bestimmungen dieses Hauptstücks einzuhalten.

Gemeinsam Verantwortliche

§ 47. Zwei oder mehr Verantwortliche, die gemeinsam die Zwecke und die Mittel zur Verarbeitung festlegen, sind gemeinsam Verantwortliche. Sie haben in einer Vereinbarung in transparenter Form ihre jeweiligen Aufgaben nach diesem Bundesgesetz festzulegen, insbesondere was die Wahrnehmung der Rechte der betroffenen Person angeht, und wer welchen Informationspflichten gemäß § 43 nachkommt, sofern und soweit die jeweiligen Aufgaben der Verantwortlichen nicht gesetzlich festgelegt sind. In der Vereinbarung ist eine Anlaufstelle für die betroffenen Personen anzugeben.

Auftragsverarbeiter und Aufsicht über die Verarbeitung

§ 48. (1) Erfolgt eine Verarbeitung im Auftrag eines Verantwortlichen, so arbeitet dieser nur mit Auftragsverarbeitern, die hinreichend Garantien dafür bieten, dass geeignete technische und organisatorische Maßnahmen so durchgeführt werden, dass die Verarbeitung im Einklang mit den Anforderungen dieses Bundesgesetzes erfolgt und den Schutz der Rechte der betroffenen Person gewährleistet.

(2) Der Auftragsverarbeiter nimmt keinen weiteren Auftragsverarbeiter ohne vorherige gesonderte schriftliche Genehmigung des Verantwortlichen in Anspruch.

(3) Die Verarbeitung durch einen Auftragsverarbeiter erfolgt auf der Grundlage eines Vertrags oder eines anderen Rechtsinstruments nach dem

(6) Where personal data has been rectified or erased or processing has been restricted pursuant to paras. 1 to 3, the controller shall notify all recipients of the personal data concerned. The recipients shall rectify or erase the personal data or restrict processing of the personal data under their responsibility without undue delay.

(Note: para. 7 repealed by subpara. 22, Federal Law Gazette I No 24/2018)

Part 3
Controller and processor

Obligations of the controller

§ 46. The controller shall comply with the obligations referred to in Article 24 paras. 1 and 2 and Article 25 paras. 1 and 2 of the General Data Protection Regulation with regard to the compliance of processing with the provisions of this Chapter.

Joint controllers

§ 47. Two or more controllers who jointly determine the purposes and means of processing shall be joint controllers. They shall, in a transparent manner, determine their respective responsibilities under this federal law, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in § 43, by means of an arrangement between them if, and insofar as, the respective responsibilities of the controllers are not determined by law. The arrangement shall designate a contact point for data subjects.

Processor and the supervision of processing

§ 48. (1) Where processing is carried out on behalf of a controller, the controller shall only use processors providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing will meet the requirements of this federal law and ensure the protection of the rights of the data subject.

(2) The processor shall not engage another processor without prior specific written authorisation of the controller.

(3) Processing by a processor shall be governed by a contract or other legal act under Union law or on the grounds of an explicit legal authorisation that is binding

Unionsrecht oder aufgrund ausdrücklicher gesetzlicher Ermächtigung, der oder das den Auftragsverarbeiter in Bezug auf den Verantwortlichen bindet und in dem Gegenstand und Dauer der Verarbeitung, Art und Zweck der Verarbeitung, die Art der personenbezogenen Daten, die Kategorien betroffener Personen und die Pflichten und Rechte des Verantwortlichen festgelegt sind. Dieser Vertrag oder dieses andere Rechtsinstrument sieht insbesondere vor, dass der Auftragsverarbeiter

1. die personenbezogenen Daten nur auf dokumentierte Weisung des Verantwortlichen – auch in Bezug auf die Übermittlung personenbezogener Daten an ein Drittland oder eine internationale Organisation – verarbeitet, sofern er nicht durch das Unionsrecht oder durch Gesetze, dem der Auftragsverarbeiter unterliegt, hierzu verpflichtet ist; in einem solchen Fall teilt der Auftragsverarbeiter dem Verantwortlichen diese rechtlichen Anforderungen vor der Verarbeitung mit, sofern das betreffende Recht eine solche Mitteilung nicht wegen eines wichtigen öffentlichen Interesses verbietet;
2. gewährleistet, dass sich die zur Verarbeitung der personenbezogenen Daten befugten Personen zur Vertraulichkeit verpflichtet haben oder einer angemessenen gesetzlichen Verschwiegenheitspflicht unterliegen;
3. alle gemäß § 54 erforderlichen Maßnahmen ergreift;
4. die in den Abs. 2 und 4 genannten Bedingungen für die Inanspruchnahme der Dienste eines weiteren Auftragsverarbeiters einhält;
5. angesichts der Art der Verarbeitung den Verantwortlichen nach Möglichkeit mit geeigneten technischen und organisatorischen Maßnahmen dabei unterstützt, seiner Pflicht zur Beantwortung von Anträgen auf Wahrnehmung der in diesem Hauptstück genannten Rechte der betroffenen Person nachzukommen;
6. unter Berücksichtigung der Art der Verarbeitung und der ihm zur Verfügung stehenden Informationen den Verantwortlichen bei der Einhaltung der in den §§ 52 bis 56 genannten Pflichten unterstützt;
7. nach Abschluss der Erbringung der Verarbeitungsleistungen alle personenbezogenen Daten nach Wahl des Verantwortlichen entweder löscht oder zurückgibt, sofern nicht nach dem Unionsrecht oder aufgrund von Gesetzen eine Verpflichtung zur Speicherung der personenbezogenen Daten besteht;
8. dem Verantwortlichen alle erforderlichen Informationen zum Nachweis der Einhaltung der in Abs. 1 bis 6 niedergelegten Pflichten zur Verfügung

on the processor with regard to the controller and that sets out the subject matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller. This contract or other legal act shall stipulate, in particular, that the processor:

1. processes the personal data only on documented instructions from the controller, including with regard to transfers of personal data to a third country or an international organisation, unless required to do so by Union law or by laws to which the processor is subject; in such a case, the processor shall inform the controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
2. ensures that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
3. takes all measures necessary pursuant to § 54;
4. respects the conditions referred to in paras. 2 and 4 for engaging another processor;
5. taking into account the nature of the processing, assists the controller by appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the controller's obligation to respond to requests for exercising the data subject's rights laid down in this Chapter;
6. assists the controller in ensuring compliance with the obligations pursuant to § 52 to § 56, taking into account the nature of processing and the information available to the processor;
7. at the choice of the controller, deletes or returns all the personal data to the controller after the end of the provision of services relating to processing, and deletes existing copies unless Union law or laws require(s) storage of the personal data;
8. makes available to the controller all information necessary to demonstrate compliance with the obligations laid down in paras. 1 to 6 and allows for

stellt und Überprüfungen – einschließlich Inspektionen –, die vom Verantwortlichen oder einem anderen von diesem beauftragten Prüfer durchgeführt werden, ermöglicht und dazu beiträgt.

Im Hinblick auf Z 8 informiert der Auftragsverarbeiter den Verantwortlichen unverzüglich, falls er der Auffassung ist, dass eine Weisung gegen dieses Hauptstücks oder gegen andere Datenschutzbestimmungen der Union oder gesetzliche Datenschutzbestimmungen verstößt.

(4) Nimmt der Auftragsverarbeiter die Dienste eines weiteren Auftragsverarbeiters in Anspruch, um bestimmte Verarbeitungstätigkeiten im Namen des Verantwortlichen auszuführen, so werden diesem weiteren Auftragsverarbeiter im Wege eines Vertrags oder eines anderen Rechtsinstruments nach dem Unionsrecht oder aufgrund von Gesetzen dieselben Datenschutzpflichten auferlegt, die in dem Vertrag oder anderen Rechtsinstrument zwischen dem Verantwortlichen und dem Auftragsverarbeiter gemäß Abs. 3 festgelegt sind, wobei insbesondere hinreichende Garantien dafür geboten werden müssen, dass die geeigneten technischen und organisatorischen Maßnahmen so durchgeführt werden, dass die Verarbeitung entsprechend den Anforderungen dieses Hauptstücks erfolgt. Kommt der weitere Auftragsverarbeiter seinen Datenschutzpflichten nicht nach, so haftet der erste Auftragsverarbeiter gegenüber dem Verantwortlichen für die Einhaltung der Pflichten jenes anderen Auftragsverarbeiters.

(5) Der Vertrag oder das andere Rechtsinstrument im Sinne der Abs. 3 und 4 ist schriftlich abzufassen, was auch in einem elektronischen Format erfolgen kann.

(6) Der Auftragsverarbeiter und jede dem Verantwortlichen oder dem Auftragsverarbeiter unterstellte Person, die Zugang zu personenbezogenen Daten hat, dürfen diese Daten ausschließlich auf Weisung des Verantwortlichen verarbeiten, es sei denn, dass sie nach dem Unionsrecht oder aufgrund von Gesetzen zur Verarbeitung verpflichtet sind.

(7) Ein Auftragsverarbeiter, der unter Verstoß gegen dieses Hauptstück die Zwecke und Mittel der Verarbeitung bestimmt, gilt in Bezug auf diese Verarbeitung als Verantwortlicher.

Verzeichnis von Verarbeitungstätigkeiten

§ 49. (1) Jeder Verantwortliche hat sinngemäß nach Maßgabe des Art. 30 Abs. 1 bis 4 DSGVO ein Verzeichnis von Verarbeitungstätigkeiten zu führen, wobei sich die Verweise in Art. 30 Abs. 1 lit. g und Abs. 2 lit. d DSGVO auf § 54

and contributes to audits, including inspections, conducted by the controller or another auditor mandated by the controller.

With regard to subpara. 8, the processor shall immediately inform the controller if, in its opinion, an instruction infringes this Chapter or other data protection provisions of Union law or statutory data protection provisions.

(4) Where a processor engages another processor for carrying out specific processing activities on behalf of the controller, the same data protection obligations as set out in the contract or other legal act between the controller and the processor as referred to in para. 3 shall be imposed on that other processor by way of a contract or other legal act under Union law or in accordance with laws, in particular providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of this Chapter. Where that other processor fails to fulfil its data protection obligations, the initial processor shall remain fully liable to the controller for the performance of that other processor's obligations.

(5) The contract or the other legal act referred to in paras. 3 and 4 shall be in writing, including in electronic form.

(6) The processor and any person acting under the authority of the controller or of the processor, who has access to personal data, shall not process those data except on instructions from the controller, unless required to do so by Union law or in accordance with laws.

(7) If a processor determines, in infringement of this Chapter, the purposes and means of processing, that processor shall be considered to be a controller in respect of that processing.

Records of processing activities

§ 49. (1) Each controller shall maintain a record of processing activities, applying Article 30 paras. 1 to 4 of the General Data Protection Regulation accordingly; the references in Article 30 para. 1 (g) and para. 2 (d) of the General

beziehen und die Bezugnahme auf einen Vertreter des Verantwortlichen oder des Auftragsverarbeiters gegenstandslos ist.

(2) Das Verzeichnis gemäß Abs. 1 hat auch Angaben zu enthalten über

1. die Verwendung von Profiling, wenn eine solche Verwendung vorgenommen wird, und
2. die Rechtsgrundlage der Verarbeitung, einschließlich der Übermittlungen, für die die personenbezogenen Daten bestimmt sind.

(3) Jeder Auftragsverarbeiter hat ein Verzeichnis zu allen Kategorien von im Auftrag eines Verantwortlichen durchgeführten Verarbeitungstätigkeiten zu führen, das Folgendes enthält:

1. Name und Kontaktdaten des Auftragsverarbeiters oder der Auftragsverarbeiter, jedes Verantwortlichen, in dessen Auftrag der Auftragsverarbeiter tätig ist, sowie eines etwaigen Datenschutzbeauftragten,
2. die Kategorien von Verarbeitungen, die im Auftrag jedes Verantwortlichen durchgeführt werden,
3. gegebenenfalls Übermittlungen von personenbezogenen Daten an ein Drittland oder an eine internationale Organisation, wenn vom Verantwortlichen entsprechend angewiesen, einschließlich der Identifizierung des Drittlandes oder der internationalen Organisation,
4. wenn möglich, eine allgemeine Beschreibung der technischen und organisatorischen Maßnahmen gemäß § 54 Abs. 1.

Protokollierung

§ 50. (1) Jeder Verarbeitungsvorgang ist in geeigneter Weise so zu protokollieren, dass die Zulässigkeit der Verarbeitung nachvollzogen und überprüft werden kann.

(2) In automatisierten Verarbeitungssystemen sind alle Verarbeitungsvorgänge in automatisierter Form zu protokollieren. Aus diesen Protokolldaten müssen zumindest der Zweck, die verarbeiteten Daten, das Datum und die Uhrzeit der Verarbeitung, die Identifizierung der Person, die die personenbezogenen Daten verarbeitet hat, sowie die Identität eines allfälligen Empfängers solcher personenbezogenen Daten hervorgehen.

(3) In nicht automatisierten Verarbeitungssystemen sind zumindest Abfragen und Offenlegungen einschließlich Übermittlungen, Veränderungen sowie Löschungen zu protokollieren. Für diese Protokolldaten gilt Abs. 2 zweiter Satz.

Data Protection Regulation refer to § 54, and the reference to the representative of the controller or the processor shall not apply.

(2) The record referred to in para. 1 shall also contain information on

1. the use of profiling, if profiling is used, and
2. the legal basis for the processing operation, including transfers, for which the personal data are intended.

(3) Each processor shall maintain a record for all categories of processing activities performed on behalf of a controller, containing the following:

1. name and contact details of the processor or processors, each controller on whose behalf the processor is acting, as well as any data protection officer,
2. the categories of processing activities performed on behalf of each controller,
3. where applicable, transfers of personal data to a third country or an international organisation, if ordered accordingly by the controller, including the identification of the third country or the international organisation,
4. if possible, a general description of the technical and organisational measures pursuant to § 54 para. 1.

Logging

§ 50. (1) Every processing operation shall be logged in an appropriate manner so that the legitimacy of processing can be traced and verified.

(2) In automated processing systems, all processing operations shall be logged in an automated manner. These log data shall at least reveal the purpose, the processed data, the date and time of processing, the identification of the person who processed the personal data, and the identity of any recipient of such personal data.

(3) In non-automated processing systems, at least consultations and disclosures, including transmissions, changes and erasures, shall be logged. Para. 2 sentence 2 shall apply to these log data.

(4) Die Protokolle dürfen ausschließlich zur Überprüfung der Rechtmäßigkeit der Datenverarbeitung einschließlich der Eigenüberwachung, der Gewährleistung von Integrität und Sicherheit der personenbezogenen Daten sowie in gerichtlichen Strafverfahren verwendet werden.

(5) Der Verantwortliche und der Auftragsverarbeiter haben der Datenschutzbehörde auf deren Verlangen die Protokolle zur Verfügung zu stellen.

Zusammenarbeit mit der Datenschutzbehörde

§ 51. Der Verantwortliche und der Auftragsverarbeiter sind verpflichtet, über Aufforderung mit der Datenschutzbehörde bei der Erfüllung ihrer Aufgaben zusammenzuarbeiten.

Datenschutz-Folgenabschätzung

§ 52. Der Verantwortliche hat zum Schutz der Rechte und berechtigten Interessen der von der Datenverarbeitung betroffenen Personen und sonstiger Betroffener eine Datenschutz-Folgenabschätzung gemäß Art. 35 Abs. 1, 2, 3, 7 und 11 DSGVO durchzuführen, wobei sich der Nachweis gemäß Art. 35 Abs. 7 lit. d DSGVO auf die Einhaltung der Vorgaben dieses Hauptstücks bezieht.

Vorherige Konsultation der Datenschutzbehörde

§ 53. Der Verantwortliche hat nach Maßgabe des Art. 36 DSGVO vor der Verarbeitung personenbezogener Daten in neu anzulegenden Dateisystemen die Datenschutzbehörde zu konsultieren, wobei sich die Verweise in Art. 36 Abs. 1 und Abs. 3 lit. e DSGVO auf § 52 und der Verweis auf die Bestimmungen hinsichtlich der Befugnisse der Datenschutzbehörde in Art. 36 Abs. 2 DSGVO auf § 33 beziehen und die in Art. 36 Abs. 2 DSGVO angeführten Maßnahmen innerhalb von sechs Wochen mit der Möglichkeit einer Verlängerung um einen weiteren Monat zu treffen sind.

Datensicherheitsmaßnahmen

§ 54. (1) Der Verantwortliche und der Auftragsverarbeiter haben unter Berücksichtigung des Stands der Technik, der Implementierungskosten und der Art, des Umfangs, der Umstände und der Zwecke der Verarbeitung sowie der unterschiedlichen Eintrittswahrscheinlichkeit und Schwere des Risikos für die Rechte und Freiheiten natürlicher Personen, unter Berücksichtigung der unterschiedlichen Kategorien gemäß § 37, geeignete technische und organisatorische Maßnahmen zu treffen, um ein dem Risiko angemessenes

(4) The logs shall exclusively be used to verify the lawfulness of the data processing, including self-monitoring and ensuring the integrity and security of the personal data, and in criminal proceedings in court.

(5) The controller and the processor shall provide the logs to the Data Protection Authority at its request.

Cooperation with the Data Protection Authority

§ 51. The controller and the processor shall cooperate, on request, with the Data Protection Authority in the performance of its tasks.

Data protection impact assessment

§ 52. To protect the rights and legitimate interests of data subjects affected by data processing activities and other persons concerned, the controller shall carry out a data protection impact assessment pursuant to Article 35 paras. 1, 2, 3, 7 and 11 of the General Data Protection Regulation, with demonstration pursuant to Article 35 para. 7 (d) of the General Data Protection Regulation referring to compliance with the requirements of this Chapter.

Prior consultation of the Data Protection Authority

§ 53. In accordance with Article 36 of the General Data Protection Regulation, the controller shall consult the Data Protection Authority prior to processing which will form part of a new filing system to be created; references in Article 36 paras. 1 and 3 (e) of the General Data Protection Regulation refer to § 52, and the reference to the provisions regarding the powers of the Data Protection Authority in Article 36 para. 2 of the General Data Protection Regulation refers to § 33, and the measures referred to in Article 36 para. 2 of the General Data Protection Regulation shall be taken within six weeks, with the possibility to extend that period by an additional month.

Data security measures

§ 54. (1) The controller and the processor, taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of the processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, shall implement appropriate technical and organisational measures, taking into account the different categories pursuant to § 37, to ensure a level of security appropriate to the risk, in particular as regards the processing of special categories of personal data referred to in § 39.

Schutzniveau zu gewährleisten, insbesondere im Hinblick auf die Verarbeitung besonderer Kategorien personenbezogener Daten gemäß § 39.

(2) Der Verantwortliche und der Auftragsverarbeiter haben im Hinblick auf die automatisierte Verarbeitung nach einer Risikobewertung Maßnahmen zu ergreifen, um folgende Zwecke zu erreichen:

1. Verwehrung des Zugangs zu Verarbeitungsanlagen, mit denen die Verarbeitung durchgeführt wird, für Unbefugte (Zugangskontrolle);
2. Verhinderung des unbefugten Lesens, Kopierens, Veränderns oder Entfernens von Datenträgern (Datenträgerkontrolle);
3. Verhinderung der unbefugten Eingabe von personenbezogenen Daten sowie der unbefugten Kenntnisnahme, Veränderung und Löschung von gespeicherten personenbezogenen Daten (Speicherkontrolle);
4. Verhinderung der Nutzung automatisierter Verarbeitungssysteme mit Hilfe von Einrichtungen zur Datenübertragung durch Unbefugte (Benutzerkontrolle);
5. Gewährleistung, dass die zur Benutzung eines automatisierten Verarbeitungssystems Berechtigten ausschließlich zu den ihrer Zugangsberechtigung unterliegenden personenbezogenen Daten Zugang haben (Zugriffskontrolle);
6. Gewährleistung, dass überprüft und festgestellt werden kann, an welche Stellen personenbezogene Daten mit Hilfe von Einrichtungen zur Datenübertragung übermittelt oder zur Verfügung gestellt wurden oder werden können (Übertragungskontrolle);
7. Gewährleistung, dass nachträglich überprüft und festgestellt werden kann, welche personenbezogenen Daten zu welcher Zeit und von wem in automatisierte Verarbeitungssysteme eingegeben worden sind (Eingabekontrolle);
8. Verhinderung, dass bei der Übermittlung personenbezogener Daten sowie beim Transport von Datenträgern die Daten unbefugt gelesen, kopiert, verändert oder gelöscht werden können (Transportkontrolle);
9. Gewährleistung, dass eingesetzte Systeme im Störungsfall wiederhergestellt werden können (Wiederherstellung);
10. Gewährleistung, dass alle Funktionen des Systems zur Verfügung stehen, auftretende Fehlfunktionen gemeldet werden (Zuverlässigkeit) und gespeicherte personenbezogene Daten nicht durch Fehlfunktionen des Systems beschädigt werden können (Datenintegrität).

(2) In respect of automated processing, the controller or processor, following an evaluation of the risks, shall implement measures designed to:

1. deny unauthorised persons access to processing equipment used for processing (‘equipment access control’);
2. prevent the unauthorised reading, copying, modification or removal of data media (‘data media control’);
3. prevent the unauthorised input of personal data and the unauthorised inspection, modification or deletion of stored personal data (‘storage control’);
4. prevent the use of automated processing systems by unauthorised persons using data communication equipment (‘user control’);
5. ensure that persons authorised to use an automated processing system have access only to the personal data covered by their access authorisation (‘data access control’);
6. ensure that it is possible to verify and establish the bodies to which personal data have been or may be transmitted or made available using data communication equipment (‘communication control’);
7. ensure that it is subsequently possible to verify and establish which personal data have been input into automated processing systems and when and by whom the personal data were input (‘input control’);
8. prevent the unauthorised reading, copying, modification or deletion of personal data during transfers of personal data or during transportation of data media (‘transport control’);
9. ensure that installed systems may, in the case of interruption, be restored (‘recovery’);
10. ensure that the functions of the system perform, that the appearance of faults in the functions is reported (‘reliability’) and that stored personal data cannot be corrupted by means of a malfunctioning of the system (‘integrity’).

Meldung von Verletzungen an die Datenschutzbehörde

§ 55. (1) Der Verantwortliche hat nach Maßgabe des Art. 33 DSGVO Verletzungen des Schutzes personenbezogener Daten der Datenschutzbehörde zu melden.

(2) Soweit von der Verletzung des Schutzes personenbezogene Daten betroffen sind, die von dem oder an den Verantwortlichen eines anderen Mitgliedstaates der Europäischen Union übermittelt wurden, sind die in Art. 33 Abs. 3 DSGVO genannten Informationen dem Verantwortlichen jenes Mitgliedstaates der Europäischen Union unverzüglich zu übermitteln.

Benachrichtigung der betroffenen Person von Verletzungen

§ 56. (1) Der Verantwortliche hat nach Maßgabe des Art. 34 DSGVO betroffene Personen von Verletzungen des Schutzes ihrer personenbezogenen Daten zu benachrichtigen.

(2) Die Benachrichtigung gemäß Abs. 1 kann unter den in § 43 Abs. 4 genannten Voraussetzungen aufgeschoben, eingeschränkt oder unterlassen werden.

Benennung, Stellung und Aufgaben des Datenschutzbeauftragten

§ 57. (1) Jeder Verantwortliche hat nach Maßgabe des Art. 37 Abs. 5 und 7 DSGVO einen Datenschutzbeauftragten zu benennen. Gerichte sind im Rahmen ihrer justiziellen Tätigkeit von der Verpflichtung zur Benennung eines Datenschutzbeauftragten ausgenommen. § 5 gilt im Hinblick auf die Bestimmungen dieses Hauptstücks sinngemäß.

(2) Für die Stellung des Datenschutzbeauftragten gilt Art. 38 DSGVO.

(3) Dem Datenschutzbeauftragten obliegen die in Art. 39 DSGVO genannten Aufgaben in Bezug auf die Einhaltung der Bestimmungen dieses Hauptstücks.

(4) Der Verantwortliche hat die Kontaktdaten des Datenschutzbeauftragten zu veröffentlichen und der Datenschutzbehörde mitzuteilen.

Notification of a breach to the Data Protection Authority

§ 55. (1) In accordance with Article 33 of the General Data Protection Regulation, the controller shall notify personal data breaches to the Data Protection Authority.

(2) Where the personal data breach involves personal data that have been transmitted by or to the controller of another Member State of the European Union, the information referred to in Article 33 para. 3 of the General Data Protection Regulation shall be communicated to the controller of that Member State of the European Union without undue delay.

Communication of personal data breaches to data subjects

§ 56. (1) In accordance with Article 34 of the General Data Protection Regulation, the controller shall communicate breaches concerning their personal data to data subjects.

(2) Communication pursuant to para. 1 can be delayed, restricted or omitted under the conditions laid out in § 43 para. 4.

Designation, position and tasks of the data protection officer

§ 57. (1) Every controller shall designate a data protection officer in accordance with Article 37 paras. 5 and 7 of the General Data Protection Regulation. Courts are exempted from the obligation to designate a data protection officer in the context of their judicial activities. § 5 shall apply accordingly with regard to the provisions of this Chapter.

(2) Article 38 of the General Data Protection Regulation shall apply to the position of the data protection officer.

(3) The data protection officer shall have the tasks referred to in Article 39 of the General Data Protection Regulation with regard to compliance with the provisions of this Chapter.

(4) The controller shall publish the contact details of the data protection officer and communicate them to the Data Protection Authority.

4. Abschnitt

Übermittlung personenbezogener Daten an Drittländer oder internationale Organisationen

Allgemeine Grundsätze für die Übermittlung personenbezogener Daten

§ 58. (1) Eine Übermittlung von personenbezogenen Daten, die bereits verarbeitet werden oder nach ihrer Übermittlung an ein Drittland oder eine internationale Organisation verarbeitet werden sollen, durch zuständige Behörden ist nur zulässig, wenn die Bestimmungen dieses Hauptstücks eingehalten werden und

1. die Übermittlung für die in § 36 Abs. 1 genannten Zwecke erforderlich ist,
2. die personenbezogenen Daten an einen Verantwortlichen in einem Drittland oder einer internationalen Organisation, die eine für die in § 36 Abs. 1 genannten Zwecke zuständige Behörde ist, übermittelt werden,
3. in Fällen, in denen personenbezogene Daten aus einem anderen Mitgliedstaat der EU übermittelt oder zur Verfügung gestellt werden, dieser Mitgliedstaat die Übermittlung zuvor genehmigt hat,
4. die Europäische Kommission gemäß § 59 Abs. 1 und 2 einen Angemessenheitsbeschluss gefasst hat oder, wenn kein solcher Beschluss vorliegt, geeignete Garantien im Sinne des § 59 Abs. 3 bis 5 erbracht wurden oder bestehen oder, wenn kein Angemessenheitsbeschluss gemäß § 59 Abs. 1 und 2 vorliegt und keine geeigneten Garantien im Sinne des § 59 Abs. 3 bis 5 vorhanden sind, Ausnahmen für bestimmte Fälle gemäß § 59 Abs. 6 und 7 anwendbar sind und
5. sichergestellt ist, dass eine Weiterübermittlung an ein anderes Drittland oder eine andere internationale Organisation nur aufgrund einer vorherigen Genehmigung der zuständigen Behörde, die die ursprüngliche Übermittlung durchgeführt hat, und unter gebührender Berücksichtigung sämtlicher maßgeblicher Faktoren, einschließlich der Schwere der Straftat, des Zwecks der ursprünglichen Übermittlung personenbezogener Daten und des Schutzniveaus für personenbezogene Daten in dem Drittland oder der internationalen Organisation, an das bzw. die personenbezogene Daten weiterübermittelt werden, zulässig ist.

(2) Eine Übermittlung ohne vorherige Genehmigung gemäß Abs. 1 Z 3 ist nur zulässig, wenn die Übermittlung erforderlich ist, um eine unmittelbare und

Part 4

Transfers of personal data to third countries or international organisations

General principles for transfers of personal data

§ 58. (1) Any transfer by competent authorities of personal data which are undergoing processing or are intended for processing after transfer to a third country or to an international organisation shall take place only if the conditions laid down in this Chapter are complied with and

1. the transfer is necessary for the purposes set out in § 36 para. 1,
2. the personal data are transferred to a controller in a third country or international organisation that is an authority competent for the purposes referred to in § 36 para. 1,
3. where personal data are transmitted or made available from another EU Member State, that Member State has given its prior authorisation to the transfer,
4. the European Commission has adopted an adequacy decision pursuant to § 59 paras. 1 and 2 or, in the absence of such a decision, appropriate safeguards as referred to in § 59 paras. 3 to 5 have been provided or exist, or, in the absence of an adequacy decision pursuant to § 59 paras. 1 and 2 and of appropriate safeguards in accordance with § 59 paras. 3 to 5, derogations for specific situations apply pursuant to § 59 paras. 6 and 7; and
5. it is ensured that an onward transfer to another third country or international organisation is permitted only subject to prior authorisation by the competent authority that carried out the original transfer and after taking into due account all relevant factors, including the seriousness of the criminal offence, the purpose for which the personal data was originally transferred and the level of personal data protection in the third country or an international organisation to which personal data are onward transferred.

(2) Transfers without prior authorisation pursuant to para. 1 subpara. 3 shall be permitted only if the transfer is necessary for the prevention of an immediate and

ernsthafte Gefahr für die öffentliche Sicherheit eines Mitgliedstaats oder eines Drittlandes oder für die wesentlichen Interessen eines Mitgliedstaats abzuwehren, und die vorherige Genehmigung nicht rechtzeitig eingeholt werden kann. Die für die Erteilung der vorherigen Genehmigung zuständige Behörde ist unverzüglich zu unterrichten.

(3) Ersucht eine zuständige Behörde eines anderen Mitgliedstaates der EU um Genehmigung zur Übermittlung von personenbezogenen Daten, die ursprünglich aus dem Inland übermittelt wurden, an ein Drittland oder eine internationale Organisation gemäß Abs. 1 Z 3, so ist zur Erteilung dieser Genehmigung jene zuständige Behörde zuständig, die die personenbezogenen Daten ursprünglich übermittelt hat, soweit nicht gesetzlich anderes angeordnet ist.

Datenübermittlung an Drittländer oder internationale Organisationen

§ 59. (1) Die Übermittlung personenbezogener Daten an ein Drittland oder eine internationale Organisation ist zulässig, wenn die Europäische Kommission gemäß Art. 36 Abs. 3 der Richtlinie (EU) 2016/680 im Wege eines Durchführungsaktes beschlossen hat, dass das betreffende Drittland, ein Gebiet oder ein oder mehrere spezifische Sektoren in diesem Drittland oder die betreffende internationale Organisation ein angemessenes Schutzniveau bietet. Eine solche Datenübermittlung bedarf keiner besonderen Genehmigung. Die Genehmigungspflicht gemäß § 58 Abs. 1 Z 3 bleibt davon unberührt.

(2) Übermittlungen personenbezogener Daten an ein Drittland, an ein Gebiet oder einen oder mehrere spezifischen Sektoren in einem Drittland oder an eine internationale Organisation gemäß den Abs. 3 bis 8 werden durch einen gemäß Art. 36 Abs. 5 der Richtlinie (EU) 2016/680 gefassten Beschluss der Europäischen Kommission zum Widerruf, zur Änderung oder zur Aussetzung eines Beschlusses nach Art. 36 Abs. 3 der Richtlinie (EU) 2016/680 nicht berührt.

(3) Liegt kein Beschluss nach Abs. 1 vor, so ist die Übermittlung personenbezogener Daten an ein Drittland oder eine internationale Organisation zulässig, wenn

1. in einem rechtsverbindlichen Instrument geeignete Garantien für den Schutz personenbezogener Daten vorgesehen sind oder
2. der Verantwortliche auf Grund einer Beurteilung der für die Übermittlung personenbezogener Daten maßgeblichen Umstände zu der Auffassung gelangt ist, dass geeignete Garantien zum Schutz personenbezogener Daten bestehen.

serious threat to public security of a Member State or a third country or to essential interests of a Member State and the prior authorisation cannot be obtained in good time. The authority responsible for giving prior authorisation shall be informed without delay.

(3) If a competent authority of another EU Member State requests authorisation to transfer to a third country or an international organisation pursuant to para. 1 subpara. 3 personal data that have originally been transferred from Austria, the authority that originally transferred the personal data shall be the authority competent for giving the authorisation, unless otherwise provided for by law.

Data transfers to third countries or international organisations

§ 59. (1) The transfer of personal data to a third country or an international organisation shall be permitted where the European Commission has decided pursuant to Article 36 para. 3 of Directive (EU) 2016/680 by way of an implementing act that the third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection. Such a transfer shall not require any specific authorisation. The authorisation obligation pursuant to § 58 para. 1 subpara. 3 shall remain unaffected thereby.

(2) A decision by the European Commission taken pursuant to Article 36 para. 5 of Directive (EU) 2016/680 to revoke, amend or suspend a decision pursuant to Article 36 para. 3 of Directive (EU) 2016/680 shall be without prejudice to transfers of personal data to the third country, the territory or one or more specified sectors within that third country, or the international organisation in question pursuant to paras. 3 to 8.

(3) In the absence of a decision pursuant to para. 1, a transfer of personal data to a third country or an international organisation may take place where

1. appropriate safeguards with regard to the protection of personal data are provided for in a legally binding instrument; or
2. the controller, following an assessment of the circumstances relevant for the transfer of personal data, concludes that appropriate safeguards exist with regard to the protection of personal data.

(4) Bestehen geeignete Garantien gemäß Abs. 3 Z 2 für Kategorien von Übermittlungen, so hat der Verantwortliche die Datenschutzbehörde über diese Kategorien zu unterrichten.

(5) Übermittlungen gemäß Abs. 3 Z 2 sind zu dokumentieren und die Dokumentation einschließlich Datum und Zeitpunkt der Übermittlung, Informationen über die empfangende zuständige Behörde, Begründung der Übermittlung und übermittelte personenbezogenen Daten, der Datenschutzbehörde auf Anforderung zur Verfügung zu stellen.

(6) Wenn weder ein Angemessenheitsbeschluss gemäß Abs. 1 bis 2 vorliegt noch geeignete Garantien gemäß Abs. 3 bis 5 vorhanden sind, so ist nach Maßgabe des Abs. 5 eine Übermittlung personenbezogener Daten an ein Drittland oder an eine internationale Organisation nur zulässig, wenn die Übermittlung erforderlich ist

1. zum Schutz lebenswichtiger Interessen einer Person,
2. wenn dies zur Wahrung berechtigter Interessen der betroffenen Person gesetzlich vorgesehen ist,
3. zur Abwehr einer unmittelbaren und ernsthaften Gefahr für die öffentliche Sicherheit eines Mitgliedstaates der EU oder eines Drittlandes,
4. im Einzelfall für die in § 36 Abs. 1 genannten Zwecke, oder
5. im Einzelfall zur Geltendmachung, Ausübung oder Verteidigung von Rechtsansprüchen im Zusammenhang mit den in § 36 Abs. 1 genannten Zwecken.

(7) In den Fällen des Abs. 6 Z 4 und 5 ist die Übermittlung nur zulässig, wenn keine das öffentliche Interesse an der Übermittlung überwiegenden Grundrechte und Grundfreiheiten der betroffenen Person der Übermittlung entgegenstehen.

4. Hauptstück
Besondere Strafbestimmungen

Verwaltungsstrafbestimmung

§ 62. (1) Sofern die Tat nicht einen Tatbestand nach Art. 83 DSGVO verwirklicht oder nach anderen Verwaltungsstrafbestimmungen mit strengerer Strafe bedroht ist, begeht eine Verwaltungsübertretung, die mit Geldstrafe bis zu 50 000 Euro zu ahnden ist, wer

(4) If appropriate safeguards pursuant to para. 3 subpara. 2 exist for categories of transfers, the controller shall inform the Data Protection Authority of these categories.

(5) Transfers pursuant to para. 3 subpara. 2 shall be documented, and the documentation shall be made available to the Data Protection Authority on request, including the date and time of the transfer, information about the receiving competent authority, the justification for the transfer and the personal data transferred.

(6) In the absence of an adequacy decision pursuant to paras. 1 to 2 or of appropriate safeguards pursuant to paras. 3 to 5, a transfer of personal data to a third country or an international organisation may take place in accordance with para. 5 only on the condition that the transfer is necessary:

1. to protect the vital interests of a person,
2. to safeguard legitimate interests of the data subject, where the law so provides,
3. for the prevention of an immediate and serious threat to the public security of an EU Member State or a third country,
4. in individual cases for the purposes set out in § 36 para. 1, or
5. in an individual case for the establishment, exercise or defence of legal claims relating to the purposes set out in § 36 para. 1.

(7) In the cases referred to in para. 6 subparas. 4 and 5, a transfer is permitted only if no fundamental rights and freedoms of the data subject overriding the public interests in the transfer are an obstacle to the transfer.

Chapter 4
Special penal provisions

Administrative penalties

§ 62. (1) Unless the offence meets the elements of Article 83 of the General Data Protection Regulation or is subject to a more severe punishment according to other administrative penal provisions, an administrative offence punishable by a fine of up to €50,000 is committed by anyone who

1. sich vorsätzlich widerrechtlichen Zugang zu einer Datenverarbeitung verschafft oder einen erkennbar widerrechtlichen Zugang vorsätzlich aufrechterhält,
2. Daten vorsätzlich in Verletzung des Datengeheimnisses (§ 6) übermittelt, insbesondere Daten, die ihm gemäß §§ 7 oder 8 anvertraut wurden, vorsätzlich für andere unzulässige Zwecke verarbeitet,
3. sich unter Vortäuschung falscher Tatsachen vorsätzlich personenbezogene Daten gemäß § 10 verschafft,
4. eine Bildverarbeitung entgegen den Bestimmungen des 3. Abschnittes des 1. Hauptstücks betreibt oder
5. die Einschau gemäß § 22 Abs. 2 verweigert.

(2) Der Versuch ist strafbar.

(3) Gegen juristische Personen können bei Verwaltungsübertretung nach Abs. 1 und 2 Geldbußen nach Maßgabe des § 30 verhängt werden.

(4) Die Strafe des Verfalls von Datenträgern und Programmen sowie Bildübertragungs- und Bildaufzeichnungsgeräten kann ausgesprochen werden (§§ 10, 17 und 18 VStG), wenn diese Gegenstände mit einer Verwaltungsübertretung nach Abs. 1 in Zusammenhang stehen.

(5) Die Datenschutzbehörde ist zuständig für Entscheidungen nach Abs. 1 bis 4.

(6) Das Parlamentarische Datenschutzkomitee ist zuständig für Entscheidungen nach Abs. 1 bis 4, soweit durch die Verwaltungsübertretung personenbezogene Daten aus Verarbeitungen gemäß § 35a Abs. 1 betroffen sind. Dasselbe gilt, soweit personenbezogene Daten aus Verarbeitungen gemäß § 35a Abs. 2 betroffen sind, sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

Datenverarbeitung in Gewinn- oder Schädigungsabsicht

§ 63. Wer mit dem Vorsatz, sich oder einen Dritten dadurch unrechtmäßig zu bereichern, oder mit der Absicht, einen anderen dadurch in seinem von § 1 Abs. 1 gewährleisteten Anspruch zu schädigen, personenbezogene Daten, die ihm ausschließlich auf Grund seiner berufsmäßigen Beschäftigung anvertraut oder zugänglich geworden sind oder die er sich widerrechtlich verschafft hat, selbst benützt, einem anderen zugänglich macht oder veröffentlicht, obwohl der Betroffene an diesen Daten ein schutzwürdiges Geheimhaltungsinteresse hat, ist,

1. intentionally and illegally gains access to data processing or maintains an obviously illegal means of access,
2. transmits data intentionally in violation of the rules on confidentiality (§ 6), in particular intentionally uses data entrusted to him or her according to § 7 or § 8 for other prohibited purposes,
3. by giving incorrect information intentionally obtains personal data according to § 10,
4. processes images contrary to the provisions of Chapter 1, Part 3, or
5. refuses inspection pursuant to § 22 para. 2.

(2) Attempts shall be punishable.

(3) In the case of an administrative offence pursuant to paras. 1 and 2, administrative fines can be imposed on legal persons in accordance with § 30.

(4) Data media and programs as well as apparatus for the transmission and recording of images can be forfeited (§ 10, § 17 and § 18 of the Administrative Penal Act) if they are linked to an administrative offence according to para. 1.

(5) The Data Protection Authority shall be the competent authority for decisions pursuant to paras. 1 to 4.

(6) The Parliamentary Data Protection Committee shall be the competent authority for decisions pursuant to paras. 1 to 4 insofar as the administrative offence concerns personal data from data processing operations pursuant to § 35a para. 1. The same shall apply insofar as personal data from processing operations pursuant to § 35a para. 2 are concerned, provided that a provincial constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

Processing with the intention to make a profit or to cause harm

§ 63. Whoever, with the intention to enrich himself or a third person unlawfully or to harm someone regarding that person's entitlement guaranteed according to § 1 para. 1, deliberately uses personal data that have been entrusted to or have become accessible to him solely because of his professional occupation, or that he has acquired illegally, for himself or makes such data available to another person or publishes such data despite the data subject's interest in confidentiality which deserves protection, shall be punished by a court with imprisonment of up to one year

wenn die Tat nicht nach einer anderen Bestimmung mit strengerer Strafe bedroht ist, vom Gericht mit Freiheitsstrafe bis zu einem Jahr oder mit Geldstrafe bis zu 720 Tagessätzen zu bestrafen.

5. Hauptstück
Schlussbestimmungen

Durchführung und Umsetzung von Rechtsakten der EU

§ 64. (1) Dieses Bundesgesetz dient der Durchführung der Verordnung (EU) 2016/679 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten, zum freien Datenverkehr und zur Aufhebung der Richtlinie 95/46/EG (Datenschutz-Grundverordnung), ABl. Nr. L 119 vom 4.5.2016 S. 1.

(2) Dieses Bundesgesetz dient weiters der Umsetzung der Richtlinie (EU) 2016/680 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten durch die zuständigen Behörden zum Zwecke der Verhütung, Ermittlung, Aufdeckung oder Verfolgung von Straftaten oder der Strafvollstreckung sowie zum freien Datenverkehr und zur Aufhebung des Rahmenbeschlusses 2008/977/JI des Rates, ABl. Nr. L 119 vom 4.5.2016 S. 89.

Sprachliche Gleichbehandlung

§ 65. Soweit in diesem Bundesgesetz auf natürliche Personen bezogene Bezeichnungen nur in männlicher Form angeführt sind, beziehen sie sich auf Frauen und Männer in gleicher Weise. Bei der Anwendung der Bezeichnungen auf bestimmte natürliche Personen ist die jeweils geschlechtsspezifische Form zu verwenden.

Erlassung von Verordnungen

§ 66. Verordnungen auf Grund dieses Bundesgesetzes in seiner jeweiligen Fassung dürfen bereits von dem Tag an erlassen werden, der der Kundmachung der durchzuführenden Gesetzesbestimmungen folgt; sie dürfen jedoch nicht vor den durchzuführenden Gesetzesbestimmungen in Kraft treten.

Verweisungen

§ 67. Soweit in diesem Bundesgesetz auf Bestimmungen anderer Bundesgesetze verwiesen wird, sind diese in ihrer jeweils geltenden Fassung anzuwenden.

or with a fine of up to €720, unless the offence is subject to a more severe punishment pursuant to another provision.

Chapter 5
Final provisions

Execution and implementation of EU legal acts

§ 64. (1) This federal law serves to implement Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ No L 119 of 4 May 2016, p. 1.

(2) Furthermore, this federal law serves to implement Directive (EU) 2016/680 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ No L 119 of 4 May 2016, p. 89.

Gender-neutral use of language

§ 65. Insofar as expressions relating to natural persons in this federal law are given only in the male form, they shall apply to males and females equally. When the expressions are applied to specific natural persons, the form specific to the gender shall be used.

Enactment of regulations

§ 66. Regulations based on this federal law as amended may already be enacted as of the day following the promulgation of the legal provision to be implemented; they shall, however, not enter into force before the statutory provisions which are to be implemented.

References

§ 67. Insofar as provisions of this federal law refer to provisions of other federal laws, these shall be applied as amended from time to time.

Vollziehung

§ 68. (1) Mit der Vollziehung dieses Bundesgesetzes sind, soweit sie nicht der Bundesregierung obliegt, die Bundesministerin für Justiz sowie der Bundeskanzler und die anderen Bundesminister im Rahmen ihres Wirkungsbereichs betraut.

(2) **(Verfassungsbestimmung)** Mit der Vollziehung des 6. Abschnitts des 2. Hauptstücks und des § 62 Abs. 6 ist der Präsident des Nationalrates betraut.

Übergangsbestimmungen

§ 69. (1) Die zum Zeitpunkt des Inkrafttretens dieses Bundesgesetzes laufende Funktionsperiode des Leiters der Datenschutzbehörde wird bis zu deren Ablauf fortgesetzt. Dies gilt auch für dessen Stellvertreter.

(2) Das von der Datenschutzbehörde geführte Datenverarbeitungsregister ist von der Datenschutzbehörde bis zum 31. Dezember 2019 zu Archivzwecken fortzuführen. Es dürfen keine Eintragungen und inhaltliche Änderungen im Datenverarbeitungsregister vorgenommen werden. Registrierungen im Datenverarbeitungsregister werden gegenstandslos. Jedermann kann in das Register Einsicht nehmen. In den Registrierungsakt einschließlich darin allenfalls enthaltener Genehmigungsbescheide ist Einsicht zu gewähren, wenn der Einsichtswerber glaubhaft macht, dass er eine betroffene Person ist, und soweit nicht überwiegende schutzwürdige Geheimhaltungsinteressen des Verantwortlichen (Auftraggebers) oder anderer Personen entgegenstehen.

(3) Gemäß den §§ 17 und 18 Abs. 2 DSG 2000 im Zeitpunkt des Inkrafttretens dieses Bundesgesetzes anhängige Registrierungsverfahren gelten als eingestellt. Im Zeitpunkt des Inkrafttretens dieses Bundesgesetzes anhängige Verfahren nach den §§ 13, 46 und 47 DSG 2000 sind fortzuführen, sofern die Genehmigung nach diesem Bundesgesetz oder der DSGVO erforderlich ist. Anderenfalls gelten sie als eingestellt.

(4) Zum Zeitpunkt des Inkrafttretens dieses Bundesgesetzes bei der Datenschutzbehörde oder bei den ordentlichen Gerichten zum Datenschutzgesetz 2000 anhängige Verfahren sind nach den Bestimmungen dieses Bundesgesetzes und der DSGVO fortzuführen, mit der Maßgabe, dass die Zuständigkeit der ordentlichen Gerichte aufrecht bleibt.

(5) Verletzungen des Datenschutzgesetzes 2000, die zum Zeitpunkt des Inkrafttretens dieses Bundesgesetzes noch nicht anhängig gemacht wurden, sind nach der Rechtslage nach Inkrafttreten dieses Bundesgesetzes zu beurteilen. Ein

Execution

§ 68. (1) The Federal Minister of Justice and the other federal ministers, within their sphere of responsibilities, shall execute this federal law insofar as the execution has not been entrusted to the Federal Government.

(2) **(Constitutional provision)** The president of the National Council shall execute Part 6 of Chapter 2 and § 62 para. 6.

Transitional provisions

§ 69. (1) The current term of office of the head of the Data Protection Authority at the time of the entry into force of this federal law shall continue until the end of the term of office. This shall also apply to the deputy.

(2) The Data Protection Authority shall continue to have the Data Processing Register kept by the Data Protection Authority for archiving purposes until 31 December 2019. No entries and changes to the contents of the Data Processing Register may be made. Registrations in the Data Processing Register shall become void. Any person may inspect the Register. Inspection of the registration file including any authorisations contained therein shall be granted if the person applying for inspection can satisfactorily demonstrate that he or she is a data subject, and as far as no overriding interests in confidentiality which deserve protection on the part of the controller or another person are an obstacle to access.

(3) Any registration procedures pursuant to § 17 and § 18 para. 2 of the Data Protection Act 2000 pending at the time of entry into force of this federal law shall be deemed discontinued. Any registration procedures pursuant to § 13, § 46 and § 47 of the Data Protection Act 2000 pending at the time of entry into force of this federal law shall be continued if authorisation is required pursuant to this federal law or the General Data Protection Regulation. If no authorisation is required, they shall be deemed discontinued.

(4) Proceedings regarding the Data Protection Act 2000 pending before the Data Protection Authority or before courts of law at the time of entry into force of this federal law shall be continued in accordance with the provisions of this federal law and the General Data Protection Regulation with the reservation that courts of law continue to have jurisdiction.

(5) Infringements of the Data Protection Act 2000 that are not yet pending at the time of entry into force of this federal law shall be judged in accordance with the legal situation after entry into force of this federal law. A punishable offence

strafbarer Tatbestand, der vor dem Inkrafttreten dieses Bundesgesetzes verwirklicht wurde, ist nach jener Rechtslage zu beurteilen, die für den Täter in ihrer Gesamtauswirkung günstiger ist; dies gilt auch für das Rechtsmittelverfahren.

(6) Die Eingaben der betroffenen Personen nach den §§ 24 und 35f sind von den Verwaltungsabgaben des Bundes befreit.

(7) Die entsendenden Stellen haben eine dem § 15 Abs. 1 Z 1 bis 6 entsprechende Anzahl von Mitgliedern und Ersatzmitgliedern des Datenschutzrates dem Bundesministerium für Verfassung, Reformen, Deregulierung und Justiz innerhalb von zwei Wochen ab dem 25. Mai 2018 schriftlich bekannt zu geben. Die konstituierende Sitzung des Datenschutzrates hat innerhalb von sechs Wochen ab dem 25. Mai 2018 zu erfolgen. Bis zur Wahl des neuen Vorsitzenden und der beiden stellvertretenden Vorsitzenden bleiben der bisherige Vorsitzende sowie die beiden bisherigen stellvertretenden Vorsitzenden in ihrer Funktion.

(8) Besondere Bestimmungen über die Verarbeitung von personenbezogenen Daten in anderen Bundes- oder Landesgesetzen bleiben unberührt.

(9) Vor Inkrafttreten dieses Bundesgesetzes nach §§ 13, 46 und 47 DSG 2000 rechtskräftig erteilte Genehmigungen der Datenschutzbehörde bleiben unberührt. Nach dem Datenschutzgesetz 2000 erteilte Zustimmungen bleiben aufrecht, sofern sie den Vorgaben der DSGVO entsprechen.

(10) **(Verfassungsbestimmung)** Das Parlamentarische Datenschutzkomitee hat seine Zuständigkeiten nach diesem Bundesgesetz ab 1. Jänner 2025 wahrzunehmen. Zu diesem Zeitpunkt bei der Datenschutzbehörde anhängige Verfahren betreffend Verarbeitungen gemäß § 35a Abs. 1 sind vom Parlamentarischen Datenschutzkomitee fortzuführen, wobei die Entscheidungsfrist neu zu laufen beginnt. In den beim Bundesverwaltungsgericht, beim Verwaltungsgerichtshof oder beim Verfassungsgerichtshof mit Ablauf des 31. Dezember 2024 anhängigen Verfahren betreffend Verarbeitungen gemäß § 35a Abs. 1 tritt das Parlamentarische Datenschutzkomitee an die Stelle der Datenschutzbehörde.

(11) **(Verfassungsbestimmung)** Abs. 10 gilt auch in Bezug auf Verarbeitungen gemäß § 35a Abs. 2, sofern für die Aufsicht über diese Verarbeitungen durch Landesverfassungsgesetz die Zuständigkeit des Parlamentarischen Datenschutzkomitees vorgesehen wurde.

committed before this federal law enters into force shall be judged in accordance with the legal situation that is more favourable for the offender with regard to its overall effects; this shall also apply to appellate proceedings.

(6) Submissions by a data subject pursuant to § 24 and § 35f shall be exempt from federal administrative fees.

(7) The entities or bodies delegating the members and substitute members shall notify the Federal Ministry of Constitutional Affairs, Reforms, Deregulation and Justice in writing within a period of two weeks from 25 May 2018 of the members and substitute members of the Data Protection Council, the number of whom must correspond to § 15 para. 1 subparas. 1 to 6. The constitutive meeting of the Data Protection Council shall take place within six weeks after 25 May 2018. The previous head and the two previous deputy heads shall continue to exercise their functions until the election of the new head and the two deputy heads.

(8) Special provisions on the processing of personal data in other federal or provincial laws shall remain unaffected.

(9) Authorisations pursuant to § 13, § 46 and § 47 of the Data Protection Act 2000 granted by the Data Protection Authority in a final manner shall remain unaffected. Consent given pursuant to the Data Protection Act 2000 shall continue to be valid if it meets the requirements of the General Data Protection Regulation.

(10) **(Constitutional provision)** The Parliamentary Data Protection Committee shall perform its duties under this federal law from 1 January 2025. Proceedings concerning processing operations pursuant to § 35a para. 1 pending with the Data Protection Authority at this time shall be continued by the Parliamentary Data Protection Committee, and the term allowed for a decision shall start anew. In proceedings concerning processing operations pursuant to § 35a para. 1 pending with the Federal Administrative Court, the Supreme Administrative Court or the Constitutional Court as of the end of 31 December 2024, the Parliamentary Data Protection Committee shall replace the Data Protection Authority.

(11) **(Constitutional provision)** Para. 10 shall also apply in relation to processing operations pursuant to § 35a para. 2, provided that a provincial constitutional law has stipulated that the Parliamentary Data Protection Committee is responsible for supervising such processing operations.

Inkrafttreten

§ 70. (1) Die übrigen Bestimmungen dieses Bundesgesetzes treten ebenfalls mit 1. Jänner 2000 in Kraft.

(2) §§ 26 Abs. 6 und 52 Abs. 1 und 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.

(3) § 48a Abs. 5 in der Fassung des Bundesgesetzes BGBl. I Nr. 135/2009 tritt mit 1. Jänner 2010 in Kraft.

(4) Das Inhaltsverzeichnis, § 4 Abs. 1 Z 4, 5, 7 bis 9, 11 und 12, § 8 Abs. 1, 2 und 4, § 12 Abs. 1, die Umnummerierung der Absätze in § 13, § 16 Abs. 1 und 3, § 17 Abs. 1, 1a und 4, § 19 Abs. 1 Z 3a und Abs. 2, die Umnummerierung der Absätze in § 19, die §§ 20 bis 22a samt Überschriften, § 24 Abs. 2a, § 24 Abs. 4, § 26 Abs. 1 bis 8 und 10, § 28 Abs. 3, § 30 Abs. 2a, 5 bis 6a, die §§ 31 und 31a samt Überschriften, § 32 Abs. 1, 4, 6 und 7, § 34 Abs. 1, 3 und 4, § 36 Abs. 3, 3a und 9, § 39 Abs. 5, § 40 Abs. 1 und 2, § 41 Abs. 2 Z 4a, § 42 Abs. 1 Z 1, § 42 Abs. 5, § 46 Abs. 1 Z 2 und 3, Abs. 2 bis 3a, § 47 Abs. 4, § 49 Abs. 3, § 50 Abs. 1 bis 2a, der 9a. Abschnitt, § 51, § 52 Abs. 2 und 4, § 55, § 61 Abs. 6 bis 9 sowie § 64 in der Fassung des Bundesgesetzes BGBl. I Nr. 133/2009 treten mit 1. Jänner 2010 in Kraft. Gleichzeitig treten § 4 Abs. 1 Z 10, § 13 Abs. 3 sowie § 51 Abs. 2 außer Kraft.

(5) § 36 Abs. 6 in der Fassung des Bundesgesetzes BGBl. I Nr. 133/2009 tritt am 1. Juli 2010 in Kraft.

(6) § 37 Abs. 2, § 38 Abs. 2 und § 61 Abs. 9 in der Fassung des Bundesgesetzes BGBl. I Nr. 57/2013 treten mit 1. Mai 2013 in Kraft.

(7) Das Inhaltverzeichnis, § 5 Abs. 4, § 10 Abs. 2, § 12 Abs. 4, § 13 Abs. 1, 2 Z 2, Abs. 3, 4 und 6, § 16 Abs. 1, § 17 Abs. 1, § 18 Abs. 2, § 19 Abs. 1 Z 6 und Abs. 2, § 20 Abs. 2 und 5 Z 2, § 21 Abs. 1 Z 3, § 22 Abs. 2 bis 4, § 22a Abs. 1, 3 bis 5, § 23 Abs. 2, § 26 Abs. 2, 5 und 7, § 27 Abs. 5 und 7, die Überschrift zu § 30, § 30 Abs. 1, 2, 2a, 4 bis 6a, die Überschrift zu § 31, § 31 Abs. 1, 2, 5, 6 und 8, § 31a, § 32 Abs. 5 bis 7, § 34 Abs. 3 und 4, die Überschrift zu § 35, § 35 Abs. 1, §§ 36 bis 40 samt Überschriften, § 41 Abs. 2 Z 1, § 44 Abs. 6 und 8, § 46 Abs. 2 Z 3 und Abs. 3, § 47 Abs. 3 und 4, § 48a Abs. 2, § 50 Abs. 1 und 2, § 50b Abs. 2, § 50c Abs. 1, § 52 Abs. 2 Z 2 und 3 sowie Abs. 5, § 54 Abs. 2 und § 61 Abs. 8 bis 10 in der Fassung des Bundesgesetzes BGBl. I Nr. 83/2013 treten mit 1. Jänner

Entry into force

§ 70. (1) The other provisions of this federal law shall also enter into force on 1 January 2000.

(2) § 26 para. 6 and § 52 paras. 1 and 2 as amended by the federal law promulgated in Federal Law Gazette I No 136/2001 shall enter into force on 1 January 2002.

(3) § 48a para. 5 as amended by the federal law promulgated in Federal Law Gazette I No 135/2009 shall enter into force on 1 January 2010.

(4) The table of contents, § 4 para. 1 subparas. 4, 5, 7 to 9, 11 and 12, § 8 paras. 1, 2 and 4, § 12 para. 1, the re-numbering of the paragraphs in § 13, § 16 paras. 1 and 3, § 17 paras. 1, 1a and 4, § 19 para. 1 subpara. 3a and para. 2, the re-numbering of the paragraphs in § 19, § 20 to § 22a including captions, § 24 para. 2a, § 24 para. 4, § 26 paras. 1 to 8 and 10, § 28 para. 3, § 30 para. 2a, 5 to 6a, § 31 and § 31a including captions, § 32 paras. 1, 4, 6 and 7, § 34 paras. 1, 3 and 4, § 36 paras. 3, 3a and 9, § 39 para. 5, § 40 paras. 1 and 2, § 41 para. 2 subpara. 4a, § 42 para. 1 subpara. 1, § 42 para. 5, § 46 para. 1 subparas. 2 and 3, paras. 2 to 3a, § 47 para. 4, § 49 para. 3, § 50 paras. 1 to 2a, Part 9a, § 51, § 52 paras. 2 and 4, § 55, § 61 paras. 6 to 9 as well as § 64 as amended by the federal law promulgated in Federal Law Gazette I No 133/2009 shall enter into force on 1 January 2010. Simultaneously, § 4 para. 1 subpara. 10, § 13 para. 3 as well as § 51 para. 2 shall become ineffective.

(5) § 36 para. 6 as amended by the federal law promulgated in Federal Law Gazette I No 133/2009 shall enter into force on 1 July 2010.

(6) § 37 para. 2, § 38 para. 2 and § 61 para. 9 as amended by the federal law promulgated in Federal Law Gazette I No 57/2013 shall enter into force on 1 May 2013.

(7) The table of contents, § 5 para. 4, § 10 para. 2, § 12 para. 4, § 13 paras. 1 and 2 subpara. 2, paras. 3, 4 and 6, § 16 para. 1, § 17 para. 1, § 18 para. 2, § 19 para. 1 subpara. 6 and para. 2, § 20 paras. 2 and 5 subpara. 2, § 21 para. 1 subpara. 3, § 22 paras. 2 to 4, § 22a paras. 1, 3 to 5, § 23 para. 2, § 26 paras. 2, 5 and 7, § 27 paras. 5 and 7, the caption of § 30, § 30 paras. 1, 2, 2a, 4 to 6a, the caption of § 31, § 31 paras. 1, 2, 5, 6 and 8, § 31a, § 32 paras. 5 to 7, § 34 para. 3 and 4, the caption of § 35, § 35 para. 1, § 36 to § 40 including the captions, § 41 para. 2 subpara. 1, § 44 paras. 6 and 8, § 46 para. 2 subpara. 3 and para. 3, § 47 paras. 3 and 4, § 48a para. 2, § 50 paras. 1 and 2, § 50b para. 2, § 50c para. 1, § 52 para. 2 subparas. 2 and 3 as well as para. 5, § 54 para. 2 and § 61 paras. 8 to 10 as amended by the federal law

2014 in Kraft. Gleichzeitig treten § 41 Abs. 2 Z 4a und die DSK-Vergütungsverordnung, BGBl. II Nr. 145/2006, außer Kraft. Die für die Bestellung des Leiters der Datenschutzbehörde und seines Stellvertreters notwendigen organisatorischen und personellen Maßnahmen können bereits vor Inkrafttreten des Bundesgesetzes BGBl. I Nr. 83/2013 getroffen werden.

(8) **(Verfassungsbestimmung)** § 2 Abs. 2 und § 35 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 83/2013 treten mit 1. Jänner 2014 in Kraft.

(9) Der Titel, das Inhaltsverzeichnis, das 1. Hauptstück, die Bezeichnung und Überschrift des 2. Hauptstücks, der 1., 2., 3. und 4. Abschnitt, die Überschrift und Bezeichnung des 5. Abschnittes, § 35 Abs. 1, die Bezeichnung und Überschrift des 3. Hauptstücks, der 1., 2. und 3. Abschnitt, die Überschrift und Bezeichnung des 4. Abschnittes, die §§ 58 und 59 samt Überschriften sowie das 4. und 5. Hauptstück in der Fassung des Bundesgesetzes BGBl. I Nr. 120/2017 treten mit 25. Mai 2018 in Kraft. Im Art. 2 treten der 1., 2., 3., 4., 5 und 6. Abschnitt, die Bezeichnung und die Überschrift des 7. Abschnittes, die Überschrift zu § 35, die §§ 36 bis 44 samt Überschriften, der 8., 9., 9a. und 10. Abschnitt, die Bezeichnung und die Überschrift des 11. Abschnittes, die §§ 53 bis 59 samt Überschriften, § 61 Abs. 1 bis 3 und 5 bis 10 sowie die §§ 62 bis 64 samt Überschriften in der Fassung vor der Novelle BGBl. I Nr. 120/2017 mit Ablauf des 24. Mai 2018 außer Kraft.

(10) Die Standard- und Muster-Verordnung 2004 – StMV 2004, BGBl. II Nr. 312/2004, die Datenverarbeitungsregister-Verordnung 2012 – DVRV 2012, BGBl. II Nr. 257/2012, und die Datenschutzangemessenheits-Verordnung – DSAV, BGBl. II Nr. 521/1999, treten mit Ablauf des 24. Mai 2018 außer Kraft.

(11) **(Verfassungsbestimmung)** § 35 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 23/2018 tritt mit 25. Mai 2018 in Kraft.

(12) Das Inhaltsverzeichnis, § 4 Abs. 1, 5 bis 7, § 5 Abs. 3 erster Satz und Abs. 5, § 9 samt Überschrift, § 11 samt Überschrift, § 12 Abs. 3 Z 2 und Abs. 4 Z 3, § 14 Abs. 1, § 15 Abs. 1 Z 5, Abs. 3, Abs. 5 Z 1 und 2, Abs. 6, 7 und 8, § 16 Abs. 3 Z 2 und Abs. 5, § 19 Abs. 2 und 3, § 23 Abs. 1, § 26 Abs. 1, § 28, § 30 Abs. 3 und 5, § 32 Abs. 1 Z 1, § 36 Abs. 1 und 2 Z 7, § 44 Abs. 2, § 49 Abs. 1 und 3, § 56 Abs. 1, § 64 Abs. 2, § 68 sowie § 69 Abs. 5 und 7 in der Fassung des Bundesgesetzes BGBl. I Nr. 24/2018 treten mit 25. Mai 2018 in Kraft. Gleichzeitig tritt § 45 Abs. 7 in der Fassung vor der Novelle BGBl. I Nr. 24/2018 außer Kraft.

promulgated in Federal Law Gazette I No 83/2013 shall enter into force on 1 January 2014. Simultaneously, § 41 para. 2 subpara. 4a and the Data Protection Commission Remuneration Regulation, Federal Law Gazette II No 145/2006, shall become ineffective. All organisational and human resource measures needed to appoint the head of the Data Protection Authority and the deputy may be implemented before the federal law promulgated in Federal Law Gazette I No 83/2013 enters into force.

(8) **(Constitutional provision)** § 2 para. 2 and § 35 para. 2 as amended by the federal law promulgated in Federal Law Gazette I No 83/2013 shall enter into force on 1 January 2014.

(9) The title, the table of contents, Chapter 1, the name and caption of Chapter 2, Parts 1, 2, 3, and 4, the caption and name of Part 5, § 35 para. 1, the name and caption of Chapter 3, Parts 1, 2, and 3, the caption and name of Part 4, § 58 and § 59, including the captions, as well as Chapters 4 and 5 as amended by the federal law promulgated in Federal Law Gazette I No 120/2017 shall enter into force on 25 May 2018. In Article 2, Parts 1, 2, 3, 4, 5 and 6, the name and caption of Part 7, the caption of § 35, § 36 to § 44 including the captions, Parts 8, 9, 9a and 10, the name and the caption of Part 11, § 53 to § 59 including the captions, § 61 paras. 1 to 3 and 5 to 10 as well as § 62 to § 64 including the captions in the version before the amendment by Federal Law Gazette I No 120/2017 shall become ineffective as of the end of 24 May 2018.

(10) The Standards and Models Regulation 2004, Federal Law Gazette II No 312/2004, the Data Processing Register Regulation 2012, Federal Law Gazette II No 257/2012, and the Data Protection Adequacy Regulation, Federal Law Gazette II No 521/1999, shall become ineffective as of the end of 24 May 2018.

(11) **(Constitutional provision)** § 35 para. 2 as amended by the federal law promulgated in Federal Law Gazette I No 23/2018 shall enter into force on 25 May 2018.

(12) The table of contents, § 4 paras. 1, 5 to 7, § 5 para. 3 sentence 1 and para. 5, § 9 including the caption, § 11 including the caption, § 12 para. 3 subpara. 2 and para. 4 subpara. 3, § 14 para. 1, § 15 para. 1 subpara. 5, para. 3, para. 5 subparas. 1 and 2, paras. 6, 7 and 8, § 16 para. 3 subpara. 2 and para. 5, § 19 paras. 2 and 3, § 23 para. 1, § 26 para. 1, § 28, § 30 paras. 3 and 5, § 32 para. 1 subpara. 1, § 36 para. 1 and para. 2 subpara. 7, § 44 para. 2, § 49 paras. 1 and 3, § 56 para. 1, § 64 para. 2, § 68 as well as § 69 para. 5 and 7 as amended by the federal law promulgated in Federal Law Gazette I No 24/2018 shall enter into force on 25 May 2018.

§ 70 Abs. 1 bis 8 in der Fassung des Bundesgesetzes BGBl. I Nr. 24/2018 tritt mit dem auf die Kundmachung folgenden Tag in Kraft. Soweit sich die im Bundesgesetz BGBl. I Nr. 24/2018 getroffenen Anordnungen auf durch das Datenschutz-Anpassungsgesetz 2018, BGBl. I Nr. 120/2017, geschaffene Vorschriften beziehen, gehen die Regelungen des Bundesgesetzes BGBl. I Nr. 24/2018 jenen des Datenschutz-Anpassungsgesetzes 2018, BGBl. I Nr. 120/2017, vor.

(13) § 16 Abs. 5 und § 70 Abs. 6, 7, 9, 10 und 12 in der Fassung des Bundesgesetzes BGBl. I Nr. 14/2019 treten mit Ablauf des Tages der Kundmachung dieses Bundesgesetzes in Kraft; gleichzeitig treten die Einträge zu den §§ 60 und 61 im Inhaltsverzeichnis außer Kraft. Die Einträge zu den §§ 2 und 3 im Inhaltsverzeichnis und § 4 Abs. 7 treten mit 1. Jänner 2020 außer Kraft.

(14) **(Verfassungsbestimmung)** Die §§ 2 und 3 samt Überschriften treten mit Ablauf des 31. Dezember 2019 außer Kraft. § 70 Abs. 8 und 11 in der Fassung des Bundesgesetzes BGBl. I Nr. 14/2019 tritt mit Ablauf des Tages der Kundmachung dieses Bundesgesetzes in Kraft; gleichzeitig tritt § 61 samt Überschrift außer Kraft.

(15) § 9 Abs. 1 und 1a in der Fassung des Bundesgesetzes BGBl. I Nr. 62/2024 tritt mit 1. Juli 2024 in Kraft. § 8 Abs. 2 Z 2 lit. b und Abs. 3 Z 1, § 14 Abs. 1, § 15 Abs. 1 Z 5, Abs. 3, Abs. 5 Z 1 und 2, Abs. 6, 7 und 8, § 16 Abs. 3 Z 2 und Abs. 5, § 19 Abs. 2 und 3, § 23 Abs. 1 erster und zweiter Satz, § 28, § 36 Abs. 2 Z 10 erster Satz und Z 15, § 37 Abs. 1 Z 2 und 3 und § 68 in der Fassung des Bundesgesetzes BGBl. I Nr. 62/2024 treten mit Ablauf des Tages der Kundmachung in Kraft.

(16) In der Fassung des Bundesgesetzes BGBl. I Nr. 70/2024 treten in Kraft:

1. Das Inhaltsverzeichnis, § 17 Abs. 6 und 8, § 24 Abs. 1 zweiter Satz, die Bezeichnung und die Überschrift des 6. Abschnittes des 2. Hauptstücks, die Überschrift zu § 35b, § 35b Abs. 2, 3 und 5, die Überschrift zu § 35c, § 35c Abs. 1 und 2, § 35d samt Überschrift, die Überschrift zu § 35e, § 35e Abs. 1 und 2, § 35f samt Überschrift, die Überschrift zu § 35g, § 35g Abs. 3, § 35h samt Überschrift, die Bezeichnung und die Überschrift des

Simultaneously, § 45 para. 7 in the version before the amendment by Federal Law Gazette I No 24/2018 shall become ineffective. § 70 paras. 1 to 8 as amended by the federal law promulgated in Federal Law Gazette I No 24/2018 shall enter into force on the day following promulgation. To the extent that the instructions given in the federal law promulgated in Federal Law Gazette I No 24/2018 refer to provisions created by the Data Protection Amendment Act 2018, Federal Law Gazette I No 120/2017, the provisions of the federal law promulgated in Federal Law Gazette I No 24/2018 shall prevail over the provisions of the Data Protection Amendment Act 2018, Federal Law Gazette I No 120/2017.

(13) § 16 para. 5 and § 70 paras. 6, 7, 9, 10 and 12 as amended by the federal law promulgated in Federal Law Gazette I No 14/2019 shall enter into force as of the end of the day of promulgation of this federal law; simultaneously, the entries made with regard to § 60 and § 61 in the table of contents shall become ineffective. The entries regarding § 2 and § 3 in the table of contents and § 4 para. 7 shall become ineffective on 1 January 2020.

(14) **(Constitutional provision)** § 2 and § 3 including the captions shall become ineffective as of the end of 31 December 2019. § 70 paras. 8 and 11 as amended by the federal law promulgated in Federal Law Gazette I No 14/2019 shall enter into force as of the end of the day of promulgation of this federal law; simultaneously, § 61 including the caption shall become ineffective.

(15) § 9 paras. 1 and 1a as amended by the federal law promulgated in Federal Law Gazette I No 62/2024 shall enter into force on 1 July 2024. § 8 para. 2 subpara. 2 (b) and para. 3 subpara. 1, § 14 para. 1, § 15 para. 1 subpara. 5, para. 3, para. 5 subparas. 1 and 2, paras. 6, 7 and 8, § 16 para. 3 subpara. 2 and para. 5, § 19 paras. 2 and 3, § 23 para. 1 first and second sentences, § 28, § 36 para. 2 subpara. 10 first sentence and subpara. 15, § 37 para. 1 subparas. 2 and 3 and § 68 as amended by the federal law promulgated in Federal Law Gazette I No 62/2024 shall enter into force as of the end of the day of promulgation.

(16) The following shall enter into force as amended by the federal law promulgated in Federal Law Gazette I No 70/2024:

1. The table of contents, § 17 paras. 6 and 8, § 24 para. 1 second sentence, the name and the caption of Part 6 of Chapter 2, the caption of § 35b, § 35b paras. 2, 3 and 5, the caption of § 35c, § 35c paras. 1 and 2, § 35d including the caption, the caption of § 35e, § 35e paras. 1 and 2, § 35f including the caption, the caption of § 35g, § 35g para. 3, § 35h including the caption, the name and the caption of Part 7 of Chapter 2, § 35i and § 35j including the captions, § 62 para. 6, § 68 para. 1 as well as § 69 para. 6 on 15 July 2024;

7. Abschnittes des 2. Hauptstücks, § 35i und § 35j samt Überschriften, § 62 Abs. 6, § 68 Abs. 1 sowie § 69 Abs. 6 mit 15. Juli 2024;

2. **(Verfassungsbestimmung)** § 35 Abs. 2, § 35a samt Überschrift, § 35b Abs. 1 und 4, § 35c Abs. 3, § 35e Abs. 3, § 35g Abs. 1 und 2, § 68 Abs. 2 sowie § 69 Abs. 10 und 11 mit 15. Juli 2024.

(17) §§ 17 Abs. 8, 22 Abs. 3 und 23 Abs. 2 in der Fassung des Informationsfreiheits-Anpassungsgesetzes, BGBl. I Nr. 50/2025, tritt mit 1. September 2025 in Kraft.

2. **(Constitutional provision)** § 35 para. 2, § 35a including the caption, § 35b paras. 1 and 4, § 35c para. 3, § 35e para. 3, § 35g paras. 1 and 2, § 68 para. 2 as well as § 69 paras. 10 and 11 on 15 July 2024.

(17) § 17 para. 8, § 22 para. 3 and § 23 para. 2 as amended by the Freedom of Information Amendment Act, Federal Law Gazette I No 50/2025, shall enter into force on 1 September 2025.

MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

In force from 13.04.2007

Prom. SG. 31/13 Apr 2007, amend. SG. 19/22 Feb 2008, amend. SG. 65/22 Jul 2008, amend. SG. 71/12 Aug 2008, amend. SG. 10/6 Feb 2009, amend. SG. 23/27 Mar 2009, amend. SG. 41/2 Jun 2009, amend. SG. 88/6 Nov 2009, amend. SG. 102/22 Dec 2009, amend. SG. 59/31 Jul 2010, amend. SG. 98/14 Dec 2010, amend. SG. 9/28 Jan 2011, amend. SG. 12/8 Feb 2011, amend. SG. 60/5 Aug 2011, amend. SG. 61/9 Aug 2011, amend. SG. 38/18 May 2012, amend. SG. 60/7 Aug 2012, amend. SG. 102/21 Dec 2012, amend. SG. 15/15 Feb 2013, amend. SG. 1/3 Jan 2014, amend. SG. 18/4 Mar 2014, amend. SG. 12/13 Feb 2015, amend. and suppl. SG. 48/27 Jun 2015, ***amend. SG. 43/7 Jun 2016***

Chapter one.
GENERAL PROVISIONS

Section I.
GENERAL PROVISIONS

Art. 1. This Act shall provide for the terms and procedure for:

1. authorisation for use or registration of medicinal products designated for the human medicine, which are industrially manufactured or the manufacturing method, which includes industrial process;

2. (amend. – SG, 102, in force from 21.12.2012) authorisation of manufacturing and import of medicinal products;

2a (new – SG, 102/2012, in force from 21.12.2012) manufacturing, import and wholesale trade with active substances;

3. approval and conducting clinical trials;

4. wholesale of and retail trade in medicinal products;

5. parallel import of medicinal products;

5a (new – SG, 102/2012, in force from 21.12.2012) intermediation in the area of medicinal products

5b (new – SG 18/14) export of medicinal products according to the provisions of Chapter Nine

“b”;

6. advertising medicinal products;

7. follow-up of the safety of the medicinal products released on the market;

8. classification of the method of prescribing and dispensing medicinal products;

9. control of the manufacture and import, wholesale and retail trade, conducting clinical trials, advertising, and the system for the follow-up of the safety the medicinal products released on the market;

10. pricing of medicinal products;

11. development of Positive Medicines List.

Art. 2. The purpose of this Act is to create conditions for providing the release on the market of medicinal products, which comply with the requirements relating to quality, safety, and

efficacy.

Art. 3. (1) Medicinal product in human medicine shall be:

1.any substance or combination of substances, which are intended for treatment or prophylactic of diseases in humans, or

2. any substance or combination of substances, which may be used or applied to humans with the aim of:

a) recovery, correction, or modification of physiological functions in humans by means of pharmacological,, immunological or metabolic action, or

b) diagnostic purposes.

(2) Substance is any matter, the origin or which could be:

1. human (human blood, human blood products, and others);

2. animal (microorganisms, animal organs, extracts, secretions, toxins, blood products, and others.);

3. vegetal (microorganisms, plants and parts thereof, plant extracts, secretions, and others.);

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4. chemical (elements, natural chemical materials, synthetic and semi synthetic substances, and others).

Art. 4. Where a product meets simultaneously the characteristics of both medicinal product and another product regulated by other law, the provisions of this Act shall apply.

Art. 5. Medicinal products shall be classified according to the anatomic-therapeutic-chemical classification in accordance with the requirements of the World Health Organisation (WHO).

Art. 6. This Act shall not be applicable to:

1. hermetically closed radionuclides;

2. blood, plasma, or blood cells derived by a method including an industrial process.

Art. 7. (1) Only the manufacture of, import, wholesale and retail trade in, advertising of and treatment, prophylaxis, and diagnosis with medicinal products, which have received marketing authorisation, shall be permitted under terms of:

1. this Act or

2. Regulation (EC) N 726/2004 of the European Parliament and of the Council.

(2) The import of, trade in, treatment, prophylaxis and diagnosis with medicinal products beyond their expiry date shall be prohibited.

(3) Possession of a marketing authorisation or certificate of use, manufacture, and clinical trials of medicinal products issued in accordance with this Act shall not constitute ground for discharge according to the legislation in force.

Art. 8. Marketing authorisation according to this Act shall not be required for:

1. medicinal product prepared according to magisterial recipe in a pharmacy;
2. medicinal product prepared according to pharmacopoeia recipe in a pharmacy;
3. intermediate products designated for industrial processing by a person who has received authorisation for manufacture under the terms of this Act;
4. active and auxiliary substances;
5. medicinal products in the course of development and/or test;
6. medicinal products designated for export.
7. (new - SG 71/2008, in force from 12.08.2008, amend. – SG, 102/2012, in force from 21.12.2012) medicinal product for modern therapy, prepared for a certain patient upon an individual medical prescription, in reference to specific standards for quality and is applied in a medical institution to the explicit professional responsibility of the physician.

Art. 8a (new – SG, 102/2012, in force from 21.12.2012) In manufacture of medicinal products, intended only for export, of intermediate products, active substances and of assisting substances , the relevant provisions of Chapter Five shall apply.

Art. 9. (1) The treatment of a specific patient a medicinal product, which has not been authorised under the terms of chapter three, can be applied according to a special procedure for therapeutic establishment for hospital care under the terms and procedures as set out in an ordinance issued by the Minister of Health.

(2) The manager of the healthcare establishment shall be responsible for the treatment according to para 1.

Art. 10. (1) The Minister of Health can authorise for certain period of time treatment with a medicinal product which has not been authorised according to chapter three, by an order on the basis of reasoned proposal from chief state health inspector coordinated with the director Bulgarian Drug Agency (BDA) wherever there is a declared epidemic in the country caused by pathogenic microorganisms or toxins or there is suspected or confirmed dissemination of chemical agents or nuclear radiation and there is no suitable medicinal product authorised for use.

(2) In the cases under para 1, the marketing authorisation holders, manufacturers, and medical specialists shall not bear civil or administrative and penal

responsibility for the consequences of the use in an unauthorised indication of a medicinal product or of a medicinal product, which has not been authorised according to chapter three.

(3) para 2 does not exclude the responsibility for defective products according to the Consumer Protection Act.

Art. 11. (1) The Minister of Health may, due to reasons relating to the protection of the health of the population, instruct by way of order the Executive Director of the BDA to authorise the use of a medicinal product, which has not been authorised for use on the territory of the Republic of Bulgaria and for which no application for issuing of an authorisation has been submitted but which has been authorised in another Member State.

(2) In the cases under para 1, the director of BDA, or his authorised representative shall:

1. inform the holder of the marketing authorisation for the medicinal product on the

initiation of a procedure for the authorisation of the medicinal product for use;

2. register the person referred to in point 1 as a holder of the issued authorisation;

3. demand from the regulatory body of the Member State that has issued the marketing authorisation a copy of the assessment report and a copy of the marketing authorisation.

(3) (suppl. – SG, 102/2012, in force from 21.12.2012) The Bulgarian Drug Agency shall be obliged to ensure compliance of the label, patient information leaflet, classification, advertising, and follow-up of the safety of the medicinal product released on the market according to Para. 1 with the requirements of this Act. The information on the packing and in the leaflet of the medicinal product under Para. 1 shall not be obligatorily in the Bulgarian language.

(4) The Executive Director of BDA shall inform the European Commission about the authorisation issued according to para 1, the name and address of the authorisation holder, as well as about the date of termination of the validity thereof.

Art. 12. (1) The official pharmacopoeia of the Republic of Bulgaria shall be the European Pharmacopoeia

(2) The official pharmacopoeia may be supplemented with the requirements of the Bulgarian pharmacopoeia.

(3) The Minister of Health shall determine by way of order the dates of entry into effect of the current edition of the official pharmacopoeia and the annexes thereof.

(4) The order according to para 3 shall be promulgated in the State Gazette and published on the internet site of BDA.

Art. 13. (1) The monographs of the European Pharmacopoeia shall be obligatory for all substances, preparations, and pharmaceutical forms contained therein. In the cases where there is no monographs in the European Pharmacopoeia, the requirements of the current editions of the pharmacopoeias of the Member States, the U.S.A, and Japan provided that these are in compliance with the general rules of the European Pharmacopoeia.

(2) Where the specification contained in a monograph of the European Pharmacopoeia or other national pharmacopoeia is insufficient to ensure the quality of the substance or pharmaceutical form, the Bulgarian Drug Agency can require supplementation of the specification by the applicant/marketing authorisation holder.

Chapter two.
MANAGING AND FINANCING BODIES

Section I.
Managing Bodies

Art. 14. (1) The medicinal product policy in the Republic of Bulgaria is part of the State health policy and is implemented by the Minister of Health.

(2) The Minister of Health shall:

1. be the national coordinator for the problems of medicinal product;

2. take part in international bodies and organisations carrying out activities in the domain of the medicinal products;

3. (repealed – SG, 60/2011, in force from 05.08.2011 new – SG, 102/2012, in force from 21.12.2012) organize provision of public information to the patient organisations and to the

consumers organisations about the actions, undertaken against falsification of medicinal products.

4. Carry out other activities set out by a law.

When activities according para 2, point 3 carried out, the Ministry of Health collect taxes in amount, determined in tariff according to Art. 21, para 2.

(3) (repealed – SG, 60/2011, in force from 05.08.2011)

Art. 15. (1) Pharmacopoeia Committee shall be established with the Minister of Health as a consulting body on issues relating to the current pharmacopoeia.

(2) The Minister of Health shall, on the grounds of a proposal of the Executive Director of the BDA determine by an order the composition of the Pharmacopoeia Committee and the expert groups thereto and shall approve the regulation relating to their activity.

(3) The activity of the Pharmacopoeia Committee shall be financed by the budget of the Ministry of Health.

Art. 16. (1) Higher Council of Pharmacy shall be established to the Minister of Health as a consulting body on issues relating to pharmacy. It shall be composed by five representatives appointed by the Minister of Health, five representatives from Bulgarian Pharmaceutical Union, two representatives from National Health Insurance Fund (NHIF) and one representative from Faculty of pharmacy of the high medicinal schools. The Minister of Health is a chairman of the council without right of vote.

(2) The Higher Council of Pharmacy is consultative body, which discuss and provide statements for:

1. Basic approaches and priorities in the pharmaceutical area;
2. Ethical problems of the pharmacy;
3. Projects for normative acts, related with the pharmacy;
4. The scientific priorities in the area of pharmacy;
5. Programs for organisation of social educational campaign in the area of medicinal products.

(3) (repealed – SG, 60/2011, in force from 05.08.2011)

(4) The organisation and the activity of the Higher Council of Pharmacy are settled with ordinance issued by the Minister of Health, after proposal of Higher Council of Pharmacy.

Art. 17. (1) The Bulgarian Drug Agency shall be a specialised body at the Minister of Health for the surveillance on the quality, safety, and efficacy of the medicinal products.

(2) (amend. SG 15/13, in force from 01.01.2014) The Bulgarian Drug Agency shall be a legal entity budget financed with registered office in the city of Sofia with the Minister of Health.

(3) The Bulgarian Drug Agency shall be managed and represented by an Executive Director who shall be appointed under the terms of the Administration Act.

(4) The structure, functions, and work organisation of the Bulgarian Drug Agency shall be regulated by statutes adopted by the Council of Ministers.

(5) The Bulgarian Drug Agency shall:

1. issue manufacture authorisation for medicinal products;
2. issue marketing authorisations and registration certificated for medicinal products;
3. issue authorisations for wholesale of medicinal products;
4. issue authorisations for parallel import of medicinal products;

5. (amend. – SG, 60/2011, in force from 05.08.2011), issue, refuse or terminate authorisations for retail trade with medicinal products;

5a (new – SG, 102/2012, in force from 21.12.2012) enters the producers, importers and wholesale traders with active substances;

5b (new – SG, 102/2012, in force from 21.12.2012) keeps register of the persons, carrying out intermediation activity in the area of the medicinal products;

6. issue authorisations to conduct clinical trials of medicinal products;

7. carry out assessment of the quality, efficacy, safety of medicinal products in relation with their marketing authorisations;

8. issue authorisations for the advertising of medicinal products;

9. exert control on the manufacture, import, storage, wholesale and retail trade, clinical trials, safety, and advertising of medicinal products;

10. carry out laboratory analysis in case of doubt of deviation in the quality, efficacy, and safety of the medicinal products and shall undertake the measures provided by law;

10a (new – SG, 102/2012, in force from 21.12.2012) carries out the functions of a competent body for vigilance medicinal safety;

11. (amend. - SG, 102/2012, in force from 21.12.2012) organize and maintain a system for vigilance the medicinal safety;

12. issue certificates according to the certification system of the World Health Organisation;

12a. (new – SG 18/14) issue certificates of Good Distribution Practice;

13. Issue Good Manufacturing Practice certificates;

14. (amend. – SG 18/14) consult investment projects for the construction of new and/or refurbishing of existing sites relating to the manufacture of medicinal products in accordance with the rules of Good Manufacturing Practice;

15. execute the functions of national coordinator and consulting body on the issues relating to the quality, efficacy, and safety of medicinal products;

16. carry out consulting, scientific, information, and publishing activity in the domain of the medicinal sector;

17. coordinate and participate in activities relating to the European Pharmacopoeia and the development of the Bulgarian Pharmacopoeia;

18. take part in activities in the field of the medicinal products relating to the work of the European Medicines Agency, the European Directorate of the Quality of the Medicinal Products and Healthcare, of international bodies and organisations, as well as relating to the fulfillment of international treaties in which Bulgaria is a party to;

18a (new – SG, 102/2012, in force from 21.12.2012) participate in the international harmonisation and standardisation of the technical measures, referring to vigilance the medicinal safety under the coordination of the European Medicines Agency;

18b (new – SG, 102/2012, in force from 21.12.2012) establish and maintain a national internet portal for medicinal products;

19. carry out other activities provided by a law.

(6) (amend., - SG 98/10, in force from 01.01.2011) The Bulgarian Drug Agency coordinates its activity with the Regional health inspectorates (RHI) in the field of the control on the medicinal products.

(7) (new – SG, 102/2012, in force from 21.12.2012) The implementation of this act measures, related to prevention of entering and dissemination of falsified medicinal products shall be carried out in cooperation between the Bulgarian Drug Agency and the customs authorities.

Art. 17a (New – SG, 60/2011, in force from 05.08. 2011) The Regional health inspectorates shall issue authorisations for registration of drug stores.

Art. 17b. (new – SG 18/14) (1) Expert drug retail trade council shall be set up subordinated to the Managing Director of the BDA including three representatives of Bulgarian Pharmaceutical Association, one representative of every Pharmaceutical department of Higher Medicinal Schools and four representatives of the BDA. The members of the council shall be appointed by an order of the Managing Director of BDA agreed by the Minister of Health.

(2) The council referred to in par. 1 is a consultancy unit, which shall:

1. issue opinions on the submitted to the BDA applications and documents under Art. 228, par. 1 and 5 which they are submitting to the Managing Director of BDA;

2. make justified proposals to the Minister of Health through the Managing Director of BDA for improvement of the access of individuals to drugs.

(3) The organization and the activity of the expert council under par. 1 shall be regulated by regulations issued by the Managing Director of BDA upon council's proposal.

(4) The members of the expert council referred to in par. 1 shall not get paid for the participation in council meetings.

(5) The expert council referred to in par. 1 shall report on their activity on an annual basis to the Minister of Health.

Art. 17c. (new – SG 18/14) Cannot be members of the expert council referred to in Art. 17b, par.1 persons who are:

1. owners, members of managing and supervisory bodies of business companies or sole traders with a scope of business production, import, wholesale or retail trade with drugs;

2. partners or shareholders holding more than 5 per cent of the equity of business companies with a scope of business production, import, wholesale or retail trade with drugs or working under a full time employment agreement in such companies.

Section II.
Registers

Art. 18. (Repealed - SG, 60/2011, in force from 05.08. 2011)

Art. 19. (1) The Bulgarian Drug Agency shall keep registers of:

1. (amend. – SG, 102/2012, in force from 21.12.2012) manufacturers and importers of medicinal products on the territory of the Republic of Bulgaria and qualified persons according to Art. 148, point 2,and Art. 161, Para. 2, p. 1;

2. (amend. – SG, 102/2012, in force from 21.12.2012) the manufacturers, importers and the wholesale traders of active substances;

3. authorised/registered medicinal products on the territory of the Republic of Bulgaria;

4. wholesalers of medicinal products on the territory of the Republic of Bulgaria;

4a (new - SG, 102/2012, in force from 21.12.2012) the intermediation in the area of medicinal products;

5. (amend. - SG, 60/2011, in force from 05.08. 2011).the issued authorisations for retail

trade with medicinal products;

6. authorised clinical trials;

7. issued authorisations for parallel import;

8. (new – SG 18/14) issued permits for the export of drugs subject to compliance with the provisions of Chapter Nine “b”.

(2) The data of the registers according to Para. 1, points 1 to 5 and point 7 shall be published on the internet site of the Bulgarian Drug Agency.

(3) The Bulgarian Drug Agency shall maintain systems for electronic data exchange with the regulatory bodies of other Member States, European Commission, and the European Medicines Agency.

Art. 19a. (New - SG, 60/2011, in force from 05.08. 2011) (1) The relevant Regional health inspectorates (RHI) shall keep and maintain public registers for the issued by them authorisations for registration of drug stores.

(2) Within 7-day term from the issuance of an authorisation for registration of a drug store, the relevant RHI shall submit information to the Ministry of Health about the issued act.

(3) The Ministry of Health shall keep and maintain on its internet site a public national register of the issued authorisations for registration of a drug store.

Section III.
Financing

Art. 20. (1) The activity of the Bulgarian Drug Agency is financed from the budget funds and its own activity.

(2) (amend. SG 15/13, in force from 01.01.2014) Budget funds shall be ensured by a subsidy from the state budget through the budget of the Ministry of Health.

Art. 21. (1) The Bulgarian Drug Agency shall be the administrator of the revenues of its own activity, namely:

1. chemico-pharmaceutical examinations;

2. laboratory analyses and tests;

3. assessment of documentation and issue of authorisations, certificates, and other documents set forth in this Act;

4. evaluation by the renewal, variation and cease of marketing authorisation approval and certificate for registration of medicinal product;

5. maintenance of marketing authorisations of medicinal products;

6. fines and property sanctions imposed by penal ordinances issued for infringements of this Act;

7. consulting, publishing, and research activities in the field of the drug sector;

8. coordination of investment projects for the construction of new and/or refurbishing of existing sites relating to the manufacture of medicinal products;

9. conduct of inspections in connection with assessment of compliance of the manufacturing conditions with the requirements of Good Manufacturing Practice;

10 other sources.

(2) During the execution of the activities according to para 1, points 1 – 5, points 7 – 9 the Bulgarian Drug Agency shall collect fees to the amounts as defined in a tariff adopted by the

Council of Ministers.

(3) (New - SG 71/2008, in force from 12.08.2008) The tariff under para 2 shall have determined lower and various in amount fees for realisation of the procedures on permission for usage, production and import of medicinal products for small and medium enterprises in the pharmaceutical sector in the meaning of the Small- and Medium-Size Enterprises Act.

Art. 22. (1) The funds according to Art. 21 shall be spent for:

1. control activity of the BDA;

2. Payment of the activities according to Art. 21, Para. 1, p. 1 and 2, when The BDA is assigned their execution of another persons by contract;

3. (revoked – SG 38/12, in force from 01.07.2012)

4. establishment and maintenance and update of the registers according to Art. 19, Para. 1;

5. maintenance of systems for electronic data exchange with the regulatory bodies of the other Member States, with the European Commission, with and the European Medicines Agency;

6. (suppl. – SG, 102/2012, in force from 21.12.2012) information and publishing activities relating to the quality, efficacy, and safety of the medicinal products and vigilance medicinal safety;

7. provision of the activity of the specialised commissions according to Art. 47, Par. 1 and 2 and the council according to Art. 251, Para. 3;

8. (revoked – SG 38/12, in force from 01.07.2012)

9. participations in international and national inter-laboratory tests;

10. (amend. – SG. 60/2011, in force from 5. 8. 2011; revoked – SG 38/12, in force from 01.07.2012)

(2) (suppl. SG 71/2008, in force from 12.08.2008; amend. and suppl. – SG 12/11, in force from 08.02. 2011, amend. – SG, 60/2011, in force from 5.8.2011, amend. – SG, 102.2012, in force from 21.12.2012) The funds according to Art. 114, Para. 4, and Art. 259, Para. 5 shall be spent for:

1. (amend. – SG, 60/2011, in force from 5.8.2011).

2. activities of the Pharmacopoeia Committee;

3. (amend. – SG, 60/2011, in force from 5.8.2011, amend. – SG, 102.2012, in force from 21.12.2012)).activities of the Transparency Commission, the Central Commission on Ethics and the Commission on Ethics for Multi-centre Tests;

4. (revoked – SG 38/12, in force from 01.07.2012)

5. (suppl. – SG 71/08, in force from 12.08.2008; amend. – SG 12/11, in force from 08.02.2011, amend. – SG, 60/2011, in force from 5.8.2011; revoked – SG 38/12, in force from 01.07.2012)

Chapter three.
PLACING MEDICINAL PRODUCTS ON THE MARKET

Section I.
General Provisions

Art. 23. (1) An industrially manufactured medicinal product or a medicinal product obtained by a method involving an industrial process may only be placed on the market after a

marketing authorisation or a registration certificate has been issued under the terms of:

1. this Act or

2. Regulation (EC) 726/2004 of the European Parliament and the Council.

(2) A marketing authorisation within the meaning of para 1 shall also be required for a radionuclide generator, radionuclide precursor, or a kit.

(3) Types of procedures according to para 1 shall be:

1. centralised procedure;

2. mutual recognition /decentralised procedure;

3. national procedure.

(4) (New - SG 71/2008, in force from 12.08.2008) On the territory of the Republic of Bulgaria may be placed on the market only medicinal products, whose owner of permission for usage/certificate for registration has been established on the territory of a Member State.

Art. 24. (1) Marketing authorisation shall not be required for radiopharmaceuticals prepared immediately before use from authorised radionuclide generators, radionuclide precursors, or kits in accordance with the manufacturer's instructions.

(2) The products according to para 1 shall be prepared by qualified persons I laboratories or institutes authorised for such activity under the terms of the Safe Use of Nuclear Energy Act.

(3) The preparation, use, and administration of the products according to para 1 shall be performed in compliance with the nuclear medicine standard.

Art. 25. (1) The criteria for the determination of a medicinal product designated for the treatment, prophylaxis, or diagnostics of rare diseases are laid down in Regulation (EC) N 141/2000 of the European Parliament and of the Council.

(2) The conditions and order for granting of a marketing authorisation of the medicinal products according to para 1 are laid down in (EC) N 726/2004 of the European Parliament and of the Council.

Art. 26. (1) A marketing authorisation of a medicinal product, a registration certificate for the authorisation of a homeopathic medicinal product according to Art. 35, or a registration certificate for the authorisation of a traditional herbal medicinal product according to Art. 37 on the territory of the Republic of Bulgaria shall be issued by the executive director BDA to a natural or legal person established on the territory of a Member State or a state member of the European Economic Area.

(2) Where the person according to para 1 is not established on the territory of the Republic of Bulgaria, it shall designate a representative.

(3) The marketing authorisation holder takes responsibility for the medicinal products placed on the territory of the Republic of Bulgaria. The designation of a person according to para 2 shall not release the marketing authorisation holder from responsibility according to the acting legislation in Republic of Bulgaria.

Section II.
Requirements Relating to the Documentation for Granting a Marketing Authorisation

Art. 27. (1) For granting a marketing authorisation of a medicinal product, the person

according to Art. 26, para 1, shall submit to the BDA a formal application accompanied by a dossier in the format of the Common Technical Document, which shall contain:

1. name and address of management and/or permanent address of the applicant according to Art. 26, para 2; where the applicant is a person other than the manufacturer(s) – address of the manufacture sties;

2. name of the medicinal product;

3. qualitative and quantitative particulars of the medicinal product, including its international non-proprietary name (INN) recommended by the WHO, where an INN for the medicinal product exists, or the relevant chemical name;

4. therapeutic indications, contraindications and adverse drug reactions;

5. posology, pharmaceutical form, method and route of administration and expected shelf-life;

6. precautions and safety measures during storage of the medicinal product, its administration to patients and for the disposal of waste products together with an indication of potential risks for the environment;

7. description of the method of manufacture;

8. description of the control methods employed by the manufacturer;

8a (new – SG, 102/2012, in force from 02.01.2013) declaration, that the audit results under Art. 160, Para. 2, conducted by the manufacturer of the medicinal product confirm that the active substance has been produced in compliance with the principles and directives for good production practice; the declaration shall indicate the date on which the audit is conducted;

9. assessment of the potential risks presented by the medicinal product for the environment for every individual case and measures for the limitation thereof;

10. results of:

a) pharmaceutical (physico-chemical, biological or microbiological) tests;

b) preclinical (toxicological and pharmacological) tests;

c) clinical trials;

11. declaration that the ethic principles of the Good Manufacturing Practice have been complied with in the clinical trials conducted outside the territory of the Member States;

12. (amend. – SG, 102/2012, in force from 21.12.2012) a summary of the system

a) for vigilance the medicinal safety, which shall include the following elements:

b) which is to be implemented and, where appropriate, description of the risk management system;

c) name of the qualified person under Art. 191, a CV – education, acquired professional experience in the area of vigilance the medicinal safety and qualification for performing his/her duties under Chapter Eight;

d) each Member state in which the qualified person fulfils his/her duties;

e) address, tel. fax, e-amil address of the person under letter "a";

f) address, at which the basic document is kept of the system for vigilance medicinal safety;

12a. (new - SG, 102/2012, in force from 21.12.2012) declaration by the applicant that he/she has the needed means for fulfilling the obligations under Chapter Eight;

13. (amend. -SG, 102/2012, in force from 21.12.2012) plan for risk management with a description of the system for risk management, which the applicant will introduce for the relevant medicinal product with the plan summary;

14. summary of product characteristics according to Art. 34;

15. mock-up of the immediate and outer packaging of the product and a proposed package leaflet in compliance with the requirements of chapter six;

16. copy of the manufacturing authorisation issued by the regulatory authority of the

country where manufacture is performed accompanied by a Good Manufacturing Practice certificate or a certificate evidencing that the manufacture of the medicinal product and the active substances contained in its composition has been performed in compliance with standards, which are at least equivalent to the standards of the Good Manufacturing Practice;

17. copy of a document evidencing that the medicinal product is designated for treatment, prophylaxis, or diagnostics of rare diseases accompanied by a copy of the opinion of the European Medicines Agency;

18. copies of all marketing authorisations issued in other Member States or in a third state of the medicinal product applied for marketing authorisation;

18a. (new -SG, 102/2012, in force from 21.12.2012) a copy of summary of the safety data, including the data, contained in the periodical updated safety reports and if any – the signals for suspected unacceptable medicinal reactions;

19. list of the Member States where an application for marketing authorisation the medicinal product has been submitted;

20. copy of the summary of product characteristics proposed by the person according to Art. 26, para 1, or a copy of the summary of product characteristics approved by a regulatory authority of a Member State/ states members of the European Economic Area, which has already issued a marketing authorisation;

21. copy of a refusal for a marketing authorisation in a Member State or a third state accompanied by motives; information for temporary suspension or termination of the effect of the marketing authorisation;

22. copy of the proposed package leaflet accompanied by a summary of the results of the assessment of the level of comprehensibility of the contents of the package leaflet by a target patient group selected by the applicant or a copy of a leaflet approved by a regulatory authority in a Member State, which has already issued a marketing authorisation;

23. document of paid fee in amounts up in the tariff according to Art. 21, para 2.

(2) (suppl. – SG 18/14) The documents according to para 1, item 18 and 18a, relating to the Member States, and point 19, respectively, shall only be submitted in the procedures according to section VII.

(3) To radionuclide generators, the following documents shall be added to the data according to para 1:

1. description of the system together with a detailed description of its components, which may affect the composition or quality of the daughter radionuclides;

2. qualitative and quantitative particulars of the eluate or the sublimate.

(4) The documents and data from pharmaceutical tests, preclinical and clinical trials shall be accompanied by summarised reports prepared by experts with the required technical and professional qualification. To the reports a curricula vitae report of the experts shall be applied.

(5) The dossier of the medicinal product shall be submitted in the Bulgarian and/or English language.

(6) (new – SG, 102/2012, in force from 21.12.2012) The risk management system under Para. 1, p. 13 should be proportional to the identified and to the potential risks of the medicinal product and to the need of collecting safety data of post-marketing researches.

(7) (new – SG, 102/2012, in force from 21.12.2012) The holder of the authorisation for use shall update the data of the file under Para. 1. For each change in the file the provisions of Chapter Three Section VI shall apply, where applicable.

Art. 28. (1) The person according to Art. 26, para 1, insofar as he does not infringe industrial and commercial property rights, shall not submit to the BDA the data according to Art.

27, para 1, point 10, letters "b" and "c" provided that he can prove that the medicinal product indicated in the application is generic of a reference medicinal product, which is or has been authorised to market for not less than 8 years in a Member State or in a state member of the European Economic Area.

(2) The marketing authorisation holder of a generic product according to para 1 may not place it to market until 10 years from the initial marketing authorisation of the reference medicinal product have elapsed.

(3) Under observance of the conditions of para 1 and 2, the person according to Art. 26, para 1, may submit to the BDA an application for marketing authorisation of a medicinal product, which is generic of a reference medicinal product, even where the reference product has never had marketing authorisation on the territory of the Republic of Bulgaria.

(4) In the cases according to para 3, the person according to Art. 26, para 1, shall indicate in the application according to Art. 27, para 1, the Member State where the reference product is or has been authorised to market.

(5) In the cases according to para 3, the BDA shall request from the regulatory authority of the Member State indicated in the application according to Art. 27, para 1, a confirmation of the information according to para 4, the qualitative and quantitative composition of the reference product and, if necessary, additional documentation.

(6) At the request of a regulatory authority of a Member State where the application for a medicinal product generic to a referent medicinal product, which is or has been authorised to market on the territory of the Republic of Bulgaria, is submitted, the BDA shall submit the requested information according to para 5 within one month from the request date.

(7) The ten-year period according to para 2 may be extended by maximum one year at the request of the marketing authorisation holder of the reference medicinal product provided that during the first 8 years from the issue of the marketing authorisation of the reference medicinal product its marketing authorisation holder has received authorisation for a new therapeutic indication the significant clinical advantages of which versus the existing therapeutic opportunities are scientifically well-grounded.

(8) (new – SG 12/11, in force from 08.02.2011) Where for a medicinal product an initial marketing authorisation has been issued according to Art. 23, regarding each change of the strength of the active substance, in the pharmaceutical form, of the quantity per package, of the administrative route of the medicinal product, as well as regarding all other changes or extensions of the range of the marketing authorisation, an authorisation according to the requirements of this Act shall be also issued or the initial marketing authorisation shall be supplemented. All these authorisations shall be considered belonging to a general marketing authorisation of the medicinal product for the purposes of application of this Article.

Art. 29. (1) The person according to Art. 26, para 1, shall submit to the BDA the results of the required preclinical and/or clinical trials in the cases where the medicinal product indicated in the application:

1. cannot be defined as generic or
2. the bioavailability tests do not prove bioequivalence, or
3. there is a change in the active substance(s), therapeutic indications, pharmaceutical form, and/or posology compared with the reference medicinal product, or
4. is offered in dosage units, which are different compared with the reference medicinal product.

(2) Where a biological medicinal product indicated in the application as similar to a reference biological medicinal product does not comply with the conditions to be determined as

a generic medicinal product due to different method of manufacture or different starting materials compared with the reference product, or for other reasons, the applicant shall submit to the BDA the results of the required preclinical and/or clinical trials associated with these conditions.

(3) In the cases according to para 1 and 2 the documentation as laid down in the regulation according to Art. 42 shall also be submitted.

Art. 30. (1) The person according to Art. 26, para 1, insofar as he does not infringe the industrial and commercial property, shall not submit to the BDA the data according to Art. 27, para 1, point 10, letters "b" and "c" provided that he can prove that the conditions laid down in the regulation according to Art. 42 to the effect that the active substance included in the composition of the medicinal product applied for marketing authorisation has a well-established use in the medical practice and possesses acknowledged efficacy and acceptable safety level. In these cases, the results from the tests and tests may be replaced by the relevant scientific publications.

(2) The person according to para 1 shall submit the results from the required preclinical and clinical trials in case that the medicinal product containing active substances with well-established use, which have not been used for therapeutic use in the proposed combination. In this case, the documentation relating to each active substance shall not be submitted.

(3) Where an active substance within the meaning of para 1 has a proven new therapeutic indication on the basis of significant preclinical or clinical data associated with the new indication, the next applicant may not refer to the data for the new indication of the active substance more than once in a year.

Art. 31. In case, when medicinal product containing active substances used in the composition of authorised medicinal products but which are not used in the proposed combination for therapeutic purposes, the person according to Art. 26, para 1, shall submit the results of the preclinical trials and clinical trials associated with this combination. In

this case the applicant shall not submit documentation relating to the safety and efficacy of each separate active substance.

Art. 32. The marketing authorisation holder of a medicinal product may authorise the use of the pharmaceutical, preclinical and clinical documentation contained in the dossier of the medicinal product for the assessment of subsequent applications for medicinal products with the same qualitative and quantitative composition with respect to the active substances and with the same pharmaceutical form.

Art. 33. Conducting the necessary studies and tests for the purpose of preparing the documentation for marketing authorisation and the subsequent practical requirements in connection with the authorisation to market of medicinal products according to Art. 28 and Art. 29 shall not be regarded as breach of patent rights or to supplementary protection certificates of medicinal products.

Art. 34. (1) The summary of product characteristics shall contain the following information:

1. name of the medicinal product, quantity of the active substance in a dose unit, and pharmaceutical form;

2. qualitative and quantitative composition in terms of the active substances and constituents of the excipient, the information of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used;

3. pharmaceutical form;

4. clinical particulars:

a) therapeutic indications,

b) posology and method of administration for adults and, where necessary, for children,

c) contra-indications,

d) special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such products and administering them to patients, together with any precautions to be taken by the patient,

e) interaction with other medicinal products and other forms of interactions,

f) use during pregnancy and lactation,

g) effects on ability to drive and to use machines,

h) undesirable effects,

i) overdose (symptoms, antidotes, emergency measures).

5. pharmacological properties:

a) pharmacodynamic properties,

b) pharmacokinetic properties,

c) preclinical safety data.

6. pharmaceutical particulars:

a) list of excipients,

b) major incompatibilities,

c) shelf life, where necessary after reconstitution of the medicinal product or where the immediate packaging is opened for the first time,

d) special precautions for storage,

e) nature and contents of container,

f) special precautions for disposal of unused medicinal product or waste materials from such medicinal product.

7. marketing authorisation holder.

8. registration number.

9. date of the first marketing authorisation or renewal of the marketing authorisation.

10. date of a variation in the summary of product characteristics.

11. for radiopharmaceuticals, full details of internal radiation dosimetry.

12. for radiopharmaceuticals, detailed instructions for extemporaneous preparation and quality control and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform to its specifications.

(2) The summary of product characteristics of medicinal products according to Art. 28-33, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed shall not be included.

(3) The requirements relating to the form and content of the summary of product characteristics shall be laid down in the regulation according to Art. 42.

(4) (new – SG, 102/2012, in force from 21.12.2012) The short characteristics of the medicinal products, included in the list under Art. 23 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures

for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency contains information with the following text: "This medicinal product shall be subject to additional observation". Before the text a sign in black color shall be placed under Art. 23, Para. 5 of Regulation (EC) No 726/2004 of the European Parliament and of the Council, accompanied by an explanatory note.

(5) (new – SG, 102/2012, in force from 21.12.2012) The short characteristics of the medicinal products shall contain a standard text, which shall encourage the medical specialists to report each suspected unwilling medicinal reaction according to the forms under Art. 185, Para. 2, p. 4.

Section III.
Specific Requirements Applicable to Homeopathic Medicinal Products

Art. 35. (1) Certificate for the registration of a homeopathic medicinal product shall be issued according to a simplified procedure provided that it complies with the following conditions:

1. they are administered orally or externally;
2. no specific therapeutic indications appear on the labelling of the medicinal product or in any information relating thereto;
3. there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

(2) For granting a registration certificate of a homeopathic medicinal product the person according to Art. 26, para 1, shall submit to the BDA a formal application, which may cover a series of medicinal products derived from the same homeopathic stock or stocks.

(3) The following documentation shall be included in the application according to para 2 in order to demonstrate the pharmaceutical quality and the batch-t-batch homogeneity of the products concerned:

1. scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms, and degree of dilution to be registered;
2. dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic use, on the basis of an adequate bibliography;
3. manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation;
4. manufacturing authorisation accompanied by a Good Manufacturing Practice certificate or by a certificate evidencing that the product is manufactured under conditions equivalent to the requirements of the Good Manufacturing Practice;
5. copies of any registrations or authorisations obtained for the same medicinal product in other Member States;
6. one or more mock-ups of the outer packaging and the immediate packaging of the medicinal products to be registered;
7. data concerning the stability of the medicinal product.

(4) The requirements relating to the data according to para 3 shall be laid down in the regulation according to Art. 42.

Art. 36. (1) Homeopathic medicinal products other than those referred to in Art. 35, para 1, the provisions of Art. 27 – 32 shall apply.

(2) For the homeopathic medicinal products according to para 1 the person according to Art. 26, para 1, shall not submit results of preclinical and clinical trials provided that it can be proven by bibliographical data from scientific literature that the homeopathic use of the medicinal product or homeopathic stocks involved in its composition have an established safety.

(3) In the cases according to para 2 the following shall be proven from the bibliographical data:

1. the homeopathic character of the uses raw materials and their traditional use in the indication applied for;

2. the innoxiousness of the homeopathic medicinal product with respect to the degree of dilution of each component.

Section IV.
Specific Provisions Applicable to Traditional Herbal Medicinal Products

Art. 37. (1) Registration certificate for a traditional herbal according to a simplified procedure provided that the product complies with the following conditions:

1. the product has indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

2. the product is exclusively administered in accordance with a specified strength and posology;

3. the product is administered orally, by inhalation, or is designated for external use;

4. the period for traditional use according to Art. 38, para 1, point 5, has elapsed;

5. the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

(2) The BDA may apply the procedure according to para 1 to a herbal medicinal product containing vitamins or minerals for the safety of which there is well documented evidence shall not prevent the product from being eligible for registration in accordance with para 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication(s).

Art. 38. (1) For granting a registration certificate for a traditional herbal product the person according to Art. 26, para 1, shall submit to the BDA an application accompanied by the following documentation:

1. the data according to Art. 27, para 1, points 1 – 9 and point 10, letter "a";

2. summary of product characteristics without the data according to Art. 34, para 1, point 4;

3. in case of a herbal medicinal product according to Art. 37, para 2, or of a combined herbal medicinal product – the information according to Art. 37, para 1, point 5 for the combination; where the individual active substances of the combined product are not sufficiently known, data on the traditional use of each shall be provided;

4. a copy of the marketing authorisation or registration certificate of the herbal medicinal product granted by a Member State or a third country and/or a copy of a refusal accompanied by the motives of the decision;

5. bibliographical or expert evidence to the effect that the medicinal product in question or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application including at least 15 years within a Member State or country of the European Economic Area preceding the date the application;

6. bibliographical evidence of the safety the product accompanied by an expert report for the product accompanied by an expert report;

7. a copy of the manufacturing authorisation accompanied by a Good Manufacturing Practice certificate or by a certificate evidencing that the product is manufactured under conditions equivalent to the requirements of the Good Manufacturing Practice.

(2) The BDA may request additional information from the applicant for the assessment of the safety of the medicinal product according to para 1.

(3) The BDA may request an opinion of the Committee for Herbal Medicinal Products at the European Medicines Agency relating to the adequacy of the data according to para 1, point 5, by submitting the necessary parts of the dossier of medicinal product.

(4) The data submitted according to para 1, point 5 shall also be valid in the cases where throughout the period of 30 years of use in the medical practice:

1. the medicinal product, which is similar to the product which is applied for registration, has been marketed without authorisation or registration or

2. where the number of the components or the strength of the medicinal product, which is applied for registration, is decreased.

Art. 39. (1) Where the product has been used in the Community for less than 15 years, but is otherwise eligible for simplified registration Art. 37, para 1, the BDA shall submit the documentation according to Art. 38, para 1, to the Committee on Herbal Medicinal Products for opinion.

(2) The BDA shall make the final decision following the establishment of the monograph of the Committee according to para 1 on the compliance or the product with the criteria for registration for traditional use.

(3) In the cases according to para 1 the term according to Art. 44 shall cease to run.

Art. 40. The BDA may request from the applicant for herbal medicinal product to submit the documentation according to Art. 27 - 32 or according to Art. 35.

Art. 41. (1) The BDA shall publish on its internet site a list of the herbal substances, preparations, or combinations thereof used in the traditional herbal medicinal products established by the Committee on Herbal Medicinal Products of the European Evaluation Agency. The list shall contain therapeutic indications, strength, posology and method of administration as well as other information, which is necessary for the safe use of the herbal substance as a traditional medicinal product.

(2) Where the product proposed in the application for registration for traditional use contains herbal substance, preparation, or combination of products included in the list according to para 1, the applicant shall not submit the data according to Art. 38, para 1, points 4 - 6.

(3) Where the herbal substance, preparation, or combination thereof are excluded from

the list according to para 1, the holder of the registration certificate of a herbal medicinal product must submit to the BDA the full documentation according to Art. 38 within three months from the amendment.

(4) In case the holder of the registration certificate of the herbal medicinal product does not fulfil the obligation according to para 3, the BDA shall cancel the registration certificate of the product.

Section V.
Procedure for Granting Marketing Authorisation of Medicinal Products and Registration of Homeopathic and Traditional Herbal Products

Art. 42. The requirements relating to the dossier data and documentation according to Art. 27 - 32, Art. 35, para 3, Art. 36, para 2, and Art. 38 shall be laid dawn in a regulation of the Minister of Health.

Art. 43. (1) Within 30 of the submission date of the documentation according to Art. 27-32, Art. 35, para 3, or according to Art. 38, the BDA shall review the completeness of the parts of the dossier accompanying the application and their compliance with the requirements for granting a the marketing authorisation or the registration certificate according to this Act.

(2) Where no incompleteness or discrepancies in the documentation according to para 1 are established, the BDA shall, within the term according to para 1 above, notify the applicant in writing that the documentation is valid. This notification shall state the date from which the time limit according to Art. 44 shall start to run.

(3) Where incompleteness and/or discrepancies in the documentation according to para 1 are established, the BDA shall notify the applicant in writing to submit additional information and/or present an oral or written explanation of the established incompleteness and discrepancies within 14 days of the notification date.

(4) Where the requirements according to para 3 have not been satisfied within the said term, the BDA shall notify the applicant in writing that the application is invalid. In such case the BDA shall return the submitted documentation in 14 days period and shall refund 75 percent of the fee paid by the applicant.

(5) Where the requirements according to para 3 have been satisfied within the said term, the BDA shall notify the applicant in writing that the documentation is valid stating in the notification the date from which the term according to Art. 44 shall start to run.

Art. 44. The procedure for granting marketing authorisation or registration certificate of a medicinal product shall start from the date indicated in the notification according to Art. 43, para 2, respectively Art. 43, para 5, and shall end within 210 days.

Art. 45. (1) Where in the BDA has been submitted an application for marketing authorisation or registration of a medicinal product for which, according to Art. 27, para 1, point 18, there is information of a marketing authorisation granted in a Member State, the BDA shall notify the applicant in writing to implement the procedure according to Art. 74.

(2) Where in the BDA has been submitted an application for marketing authorisation or registration of a medicinal product for which, according to Art. 27, para 1, point 19, there is

information that the dossier of the same medicinal product is in a procedure of assessment in a Member State, the BDA shall not review the documentation according to Art. 27-32 or Art. 35, para 3, or according to Art. 38 and shall notify the applicant in writing to implement the procedure according to Art. 75.

(3) For the implementation of the provisions of para 1 and 2, a medicinal product shall be deemed as the same as authorised in another Member State, or as a product in a procedure of assessment of the dossier in another Member State where both medicinal products:

1. have the same qualitative and quantitative composition with respect t the active substance(s) and are offered in the same pharmaceutical form, whereas admissible shall be differences in the excipients provided that this shall not affect the safety and efficacy, and where

2. belong to the same company or the application for the medicinal products is submitted by the same company or group of companies, or where the application for the medicinal products is submitted by persons who have concluded a license or other agreement or conduct joint activities relating to the placing on the market of the respective medicinal product in different Member States.

Art. 46. (1) For the assessment of the documentation the BDA shall:

1. may conduct tests of the final product, intermediate product, or the starting materials of the medicinal product or forward these for tests in a laboratory in a Member State belonging to the system of official medicines control laboratories in order to establish whether the control methods of analysis used by the manufacturer and described in the dossier comply with the requirements;

2. confirm, following inspection on the spot or by documents, whether the manufacturers of medicinal products from third states conduct the manufacture in compliance with the data set out in Art. 27, para 1, point 7, and/or conduct the control in compliance with the methods set out in Art. 27, para 1, point 8;

3. inspect the manufacturing site indicated in the application where the manufacturer(s) has, by way of exception, assigned to another manufacturer to conduct certain stages of the manufacture or control of the medicinal product.

(2) Where the BDA conducts an inspection on the spot of a manufacturing site, the term according to Art. 44 shall cease to run until the establishment of a report of the results of the inspection.

(3) In the cases according to para 1, points 2 and 3, the manufacturers shall pay a fee in amount, determined in the tariff according to Art. 21, para 2.

Art. 47. (1) To the executive director of the BDA with the statute of consulting authorities shall be established following specialised committees

1. Committee for medicinal products;
2. Committee for immunological medicinal products;
3. Committee for homeopathic medicinal products;
4. Committee for herbal medicinal products;
5. Committee for radiopharmaceuticals.
6. (new – SG, 71/2008, in force from 12.08.200) Commission for medicinal products with application in podiatry;
7. (amend. – SG, 71/2008, in force from 12.08.200) Commission for medicinal products for modern therapies;
8. (new - SG, 71/2008, in force from 12.08.200) commission for risk assessment at

pharmaco-vigilance medicinal safety.

(2) In case of necessity, the executive director of the BDA may also establish specialised committees other than those mentioned in para 1.

(3) The specialised committees shall involve medical and other specialists with scientific achievements and practical experience in the respective fields of application of the medicinal products.

(4) External specialists with scientific achievements and practical experience in the field of a specific group of medicinal products may be involved in the standing staff of the committees.

(5) The executive director of the BDA shall appoint by an order the composition of the committees for a period of three years, the amount of their remuneration and shall approve a regulation on the conditions and order of their work.

(6) Not later than 30 January of each year, the executive director of the BDA shall approve lists of the experts outside the composition of the committees according to para 1 after receiving the approval of the Minister of Health.

(7) The executive director of the BDA may ahead of term dismiss a member of a specialised committee on his own request, in case of failure to fulfil his obligations for a period of more than three months, or in case of unconscious conduct of his functions.

(8) The composition of the committees and the list of experts according to para 6 shall be published on the internet site of the BDA.

Art. 48. (1) The members of the specialised committees according to Art. 47, para 1, and the experts according to Art. 47, para 4, shall sign a declaration to the effect of their obligation:

1. not to disclose data and circumstances, which have become known to them during or on the occasion of the conduct of their activities;

2. not to be involved in activities associated with the manufacture of or wholesale or retail trade in medicinal products.

(2) In case the persons according to para 1 have been involved in the stages or preparation of the documentation necessary for the marketing authorisation of a medicinal product, they shall not participate in the sessions of the respective specialised committee according to Art. 47.

(3) The persons according to para 1 shall not vote during making of a decision on issues in which they or members of their families have commercial, financial, or other interests.

Art. 49. (1) (amend. – SG, 102/2012, in force from 21.12.2012) Within 200 days from the receipt of a valid documentation, the BDA, jointly with the respective committee according to Art. 47, Para. 1, shall assess the quality, safety, and efficacy of the medicinal product and shall establish an assessment report, with comments of the result of the pharmaceutical an pre-clinic tests, clinic studies of the system for risk management and of the system for safety vigilance of the relevant medicinal product.

which shall be submitted to the of the. The assessment report shall be updated upon receipt of new information relating to the quality, safety and efficacy of the product. The drawn up assessment report shall be produced to the BDA executive director.

(2)(new – SG, 102/2012, in force from 21.12.2012) The report under Para. 1 shall be updated in case that new information appears, important for the quality assessment, safety and efficiency of the medicinal product.

(3) (former Para. (2) – SG, 102/2012, in force from 21.12.2012) Where a medicinal product contains genetically modified organisms, the BDA shall submit to the Ministry of

Environment and Waters the necessary documentation of the dossier of the medicinal product and request an opinion with respect to the potential risk to the environment established within 60 days. The sixty-day period shall be within the frames of the period according to Para. 1.

(4) (former Para. (3) – SG, 102/2012, in force from 21.12.2012) In the cases of radiopharmaceuticals, the BDA shall submit the necessary documentation of the dossier of the medicinal product to the Nuclear Regulatory Agency request an opinion with respect to the quality and safety of the product established within 60 days. The sixty-day period shall be within the frames of the period according to Para. 1.

(5) (former Para. (4) – SG, 102/2012, in fore rom 21.12.2012) Where the Ministry of Environment and the Nuclear Regulatory Agency do not pass a judgment within the terms according to Para. 3 and 4, it shall be presumed that their opinion is positive.

Art. 50. (1) Where the BDA establishes incompliance of the dossier with the requirements for granting marketing authorisation or registration certificate according to this Act, it shall notify the applicant in writing to submit additional information associated with the documentation according to Art. 27-32 or according to Art. 35, para 3, or according to Art. 38, and or to present an oral or written explanation of the established incompleteness and discrepancies within 180 days of the notification date.

(2) In the cases according to para 1, the term according to Art. 44 shall cease to run as from the notification date until the presentation of the requested information.

(3) The executive director of the BDA shall terminate the procedure for granting a marketing authorisation or authorisation for registration of a medicinal product where:

1. the applicant has not submitted the information according to para 1 within the required time limit;

2. the persons according to Art. 26, para 1, request its termination in writing.

Art. 51. Within 10 days of the establishment of the assessment report according to Art. 49, para 1, the executive director of the BDA shall issue a marketing authorisation/registration certificate of the medicinal product or make a motivated refusal.

Art. 52. (1) (amend. – SG, 102/2012, in force from 21.12.2012) Within 5 days of granting, the marketing authorisation/registration certificate in the register according to Art. 19, Para. 1, point 3, which shall contain the following data for the certificate:

1. registration number;

2. number and date of the marketing authorisation/registration certificate of the medicinal product;

3. name of the medicinal product;

4. international non-proprietary name of any active substance;

5. name and address of the holder of the marketing authorisation/registration certificate;

5a (new - SG, 102/2012, in force from 21.12.2012) the conditions of Art. 55a, 56 and 56a, entered in the authorisation for use/registration certificate;

6. date of variation of the marketing authorisation/registration certificate;

7. date of termination of the marketing authorisation/registration certificate;

8. other data.

(2) The marketing authorisation/registration certificate of the medicinal product shall be delivered to the person according to Art. 26, Para. 1, and shall enter into effect as from the date

of its inscription in the register according to Art. 19, Para. 1, point 3.

Art. 53. (1) (amend. – SG, 102/2012, in force from 21.12.2012) The BDA shall publish on its internet site data according to Art. 52, Para.1 for the marketing authorisation of the medicinal product granted and the approved summary of product characteristics and the datas of the leaflet.

(2) The BDA shall publish o its internet site the assessment report under art. 49, Para. 1 with the motives of the decision taken while deleting the data, representing commercial secret.

(3) The report under Para. 2 shall be accompanied by a summary in understandable by the public language. The summary shall contain a section, related to the conditions for use of the medicinal product.

Art. 54. (1) (amend. – SG 12/11, in force from 08.02.2011) The holder of a marketing authorisation/registration certificate of a medicinal product shall notify the BDA in writing about the date of actual placing on the market of the medicinal product in the Republic of Bulgaria.

(2) (amend. – SG 18/14) The holder of a marketing authorisation/registration certificate of a medicinal product shall notify the BDA in writing within minimum two months prior to any discontinuation of the sales of a medicinal product irrespective temporary or permanent.

(3) (amend. – SG 18/14) The holder of a marketing authorisation/registration certificate of a medicinal product shall indicate the reasons for the discontinuation of the sales subject to compliance with the provision of Art. 68, par. 1, item 6 and shall declare whether the measures under par. 2 undertaken by them are because of any of the grounds referred to in Art. 276 and Art. 277.

(4) (amend. – SG 18/14) In case of discontinuation of the sales of a medicinal product as a result of unforeseen circumstances, the holder of a marketing authorisation/registration certificate of a medicinal product shall notify the BDA in writing within 7 days of the establishment of the circumstances.

Art. 54a. (New – SG, 60/2011, in force from 5. 8. 2011) (1) (amend. – SG 18/14) With receiving a signal at the Executive Agency on Medicines (EAM) for termination of sales of a medicinal product, with the exception of the cases under Art. 54, Para. 2 and 4, the Agency shall perform a check within the term of 30 days after receiving the signal.

(2) While performing the check under Para. 1, the BDA may request information from the holder of the authorisation for use and/or from the person under Art. 26, Para. 2 on termination of the sales of the concrete medicinal product, as well as from the wholesale traders with medicinal products about the available quantities of the products.

(3) The BDA shall publish on its internet site the results from the performed check.

Art. 55. (1) The marketing authorisation/registration certificate of a medicinal product shall be issued by the executive director of the BDA for a period of 5 years.

(2) Upon expiration of the period according to para 1, the marketing authorisation/registration certificate of the medicinal product may be renewed by the BDA on the basis of an assessment of the benefit/risk ratio.

(3) In the case according to para 2, the holder of a marketing authorisation/registration certificate shall submit to the BDA renewal application accompanied by a summarised dossier

relating to the quality, safety, and efficacy the medicinal product including the variations thereof effected during the validity period according to para 1 within 6 months prior to the expiration of the period.

(4) The marketing authorisation/registration certificate shall become timeless upon its renewal.

(5) (amend. – SG, 102/2012, in force from 21.12.2012) In the presence of well-grounded reasons vigilance of the medicinal safety, including because of exposition of the medicinal product on not sufficient number of patients, the BDA may request the holder of a marketing authorisation to submit a renewal application for another 5 years under Art. 59a.

(6) Upon expiration of the term of the marketing authorisation, the medicinal product may be sold until the quantities available in this country are exhausted but for not more than one year of the expiration of the marketing authorisation.

(7) The executive director of The BDA shall revoke by an order the marketing authorisation of a medicinal product provided that:

1. the holder has not placed the medicinal product on the market within three years from the date of granting the marketing authorisation or

2. the sales of the medicinal product have been discontinued for a period of 3 consecutive years after its placing on the Bulgarian market.

(8) The order according to para 7 shall be subject to appeal under the terms of the Administrative Procedure Code.

(9) By way of exception and in the interest of the public health, the provision of para 7 may not be applied provided that the marketing authorisation holder of the medicinal product shall indicate well-grounded reasons. In these cases the executive director of the BDA shall motivate his decision.

(10) The holder of a marketing authorisation shall annually pay a fee as laid down in the tariff according to Art. 21, para 2, for the maintenance of the granted marketing authorisation.

Art. 55a (new – SG, 102/2012, in force from 21.12.2012) (1) The BDA executive director may issue a marketing authorisation/registration certificate of a medicinal product, which shall contain one or more of the following conditions:

1. to be undertaken certain measures for guaranteeing safe use of the medicinal product, which shall be included in the risk management system;

2. to be observed stricter obligations than the ones, indicated in Chapter Eight for registration or reporting of suspected not willing medicinal reactions;

3. to be observed stricter obligations, than the ones, indicated in Chapter Eight for registration or reporting of suspected not willing medicinal reactions;

4. to be observed any other conditions or restrictions in view to safe and efficient use of the medicinal product;

5. existence of an adequate vigilance system of the medicinal safety;

6. to be conucted postmarketing researches for efficiency, where there are doubts, related to efficiency of the medicinal product, which may be permitted only after the medicinal product is placed on the market.

(2) The marketing authorisation/registration certificate shall indicate the terms for fulfillment of the conditions uner Para. 1, where applicable.

(3) The reasons for imposing the condition under Para. 1, p. 6 shall be determined by a delegated act uder Art. 22b of Directive 2001/93/EC, by accounting the scientific irectives, developed in the Manual under Art. 194a.

(4) The requirement for conducting post-marketing researches for efficiency shall be

determined by a Manual, issued by the European Medicines Agency.

Art. 56 (Amend. – SG, 102/2012, in force from 21.12.2012) (1) exceptionally, after conulation with the applicant, the BDA excutive director may issue a marketing authorisation/registration certificate under the condition, where the applicant may prove that he/she has not produced sufficient data about the efficiency and safety of the medicinal product under normal conditions of use because of one of the following reasons:

1. the indications, for which the medicinal prodict is intended, are so rare, that the applicant cannot produce complete evidence material, or

2. the condition of the scientific knowledge at the moment is such, that no complete data may be produced, or

3. collecting similar ata contradicts the commonly adopted principles of the medical ethics.

(2) The marketing authorisation/registration certificate under Para. 1 shall be issued under one of the following conditions:

1. the applicant/holder should fulfill a programme of researches for the term under Para. 3 where the results serve for re-assessment of the correlation benefit – risk;

2. the medicinal product has regime of prescribing only by a doctor's prescription, where in certain cases may be used only under strict doctor's control in a medical establishment for medicinal help and in case of radiopharmaceutical specialist – only under the control of an authorised person;

3. the leaflet, as well as in any medical information, attached to the medicinal product should contain a text, which pays attention to the medicinal specialists, that some of the available data for the medicinal product are subject to further researches.

(3) The marketing authorisation/registration certificate under Para. 1 shall be issued for the term of 1 year and for each following year may be extended on the basis of an assessment of the fulfillment of the conditions under Para. 2.

Art. 56a (new – SG, 102/2012, in force from 21.12.2012) (1) After issuing the marketing authorisation/registration certificate, BDA may olige the holder of the marketing authorisation/registration certificate to conduct:

1. post-marketing safety research, if there are concerns for identified or potential risks or lack of information, related to vigilance the medicinal safety for the relevant medicinal product, where the same risks refer to other medicinal products, after consultations with the Committee for risk assessment in the area of the pharmacologic awareness, established under Art. 56, Para. 1, letter "aa" of Regulation (EC) N 726/2004 of the European Parliament and of the Council, BDA recommends to the relevant holder of marketing authorisation to conduct a mutual safety research with the other concerned holders of authorisation;

2. post-marketing efficiency research, where the knowledge about the illness or the used clinic methodology gives ground for revision of the efficiency assessment, the conclusions about which have been made on the date of issuance of the authorisation.

(2) The BDA shall notify in writing the owner of the marketing authorisation/registration certificate for the obligation under Para. 1, by grounding the reasons and indicating the objectives of the research and the terms for its conducting.

(3) Within 30-day term after receiving the notification under Para. 2, the owner of the marketing authorisation/registration certificate may request from BDA granting a possibility for providing information about the obligations under Para. 1.

(4) After receiving the request under Para. 3, the BDA shall set a term for provision of the information by the authorisation/registration certificate holder.

(5) The BDA after information analysis under Para. 3, may:

1. confirm the obligation under Para. 1, or

2. repeal it.

(6) The BDA shall notify the holder about the decision, taken under Para. 5.

(7) In the cases under Para. 5, p. 1, the BDA executive director shall officially amend the issued marketing authorisation/registration certificate of the medicinal product by including in it the obligation under Para. 1 as a condition.

(8) The grounds for imposing the obligations under Para. 1, p. 2 shall be determined by a delegated instrument under Art. 22b of Directive 2001/83/EC.

Art. 56b (new – SG 102/2012, in force from 21.12.2012) (1) The holder of the marketing authorisation/registration certificate shall include in his/her risk management system all the conditions under Art. 551,56 and 56a.

(2) In the cases under Para. 1 the holder of the marketing authorisation/registration certificate shall submit to BDA a notification about any change in the risk management system.

Art. 56c (new – SG 102/2012, in force from 21.12.2012) The BDA shall submit information to the European Medicines Agency about the issued authorisations under Art. 551, 56 and 56a.

Art. 57. (1) The executive director of The BDA shall refuse to grant a marketing authorisation or registration certificate of a medicinal product where, after assessment of the dossier according to Art. 27 – 32, it shall be established that:

1. the benefit/risk ratio is unfavourable or

2. the efficacy of the medicinal product has not been convincingly defended by he applicant, or

3. the qualitative and quantitative composition of the medicinal product does not comply with those described in the dossier.

(2) The executive director of The BDA shall refuse to grant a marketing authorisation/registration certificate of medicinal product where certain data in the dossier do not comply with the requirements of Art. 27 - 32.

(3) The executive director of the BDA shall refuse registration of a traditional herbal medicinal product where, after assessment of the documentation, it shall be established that the product does not comply with the conditions according to Art. 37, para 1, the data in the dossier do not comply with Art. 38, or:

1. the qualitative and quantitative composition does not comply with those described in the dossier;

2. the medicinal product can be noxious at correct use;

3. the data for the traditional use are insufficient, especially where the pharmacological properties or the efficacy are not proven on the basis long-standing use and the experience acquired;

4. the pharmaceutical quality of the medicinal product is insufficiently grounded.

Art. 58. The marketing authorisation holder takes the responsibility for the completeness and authenticity of the data in the dossier.

Art. 59. (1) The refusal of the executive director of the BDA to grant a marketing authorisation/registration certificate of a medicinal product may be appealed under the terms of the Administrative Procedure Code.

(2) The refusal of the executive director of the BDA and the motives thereof shall be published on the internet site of the Agency.

Art. 59a. (New - SG 71/2008, in force from 12.08.2008) (1) (amend. – SG, 102/2012, in force from 21.12.2012) In the cases under Art. 55, Para. 2 and 5 not later than 6 months before expiry of the term of the authorisation for usage/certificate for registration, its owner shall file to BDA application for renewal, accompanied with a summarised dossier in relation to the quality, safety and efficacy of the medicinal product, including data assessment, contained in the reports for suspected unwilling medicinal reactions and the periodical updated safety reports, submitted under Chapter Eight, and all the approved changes after issuing the authorisation for usage/certificate for registration.

(2) The requirements for the data and the documents of the dossier under para 1 shall be determined by the ordinance under Art. 42.

(3) within 120 days after filing the application and the documentation under para 1, BDA shall assess the quality, safety and efficacy of the medicinal product and shall prepare an assessment report, which shall be submitted to the executive director of BDA

(4) In cases, where incompleteness and/or incompatibilities have been established in the presented documentation under para 1, BDA shall notify in writing the owner of the authorisation for usage/certificate for registration and shall give instructions for their removal. The owner of the authorisation for usage/certificate for registration shall remove the incompleteness and/or incompatibilities in the documentation within the term of 30 days after the date of receiving the notification.

(5) within the term of 10 days after receiving the assessment report under para 3, the executive director of BDA shall issue authorisation for renewal of the authorisation for usage/certificate for registration of the medicinal product or a motivated refusal.

Art. 59b. (New - SG 71/2008, in force from 12.08.2008) (1) The executive director of BDA shall refuse renewal of the authorisation for usage/certificate for registration of the medicinal product, in cases where after the assessment of the dossier under Art. 59a, para 1 it is established, that:

1. the medicinal product is hazardous in correct usage, or
2. there is not therapeutic efficacy, or
3. the relation between usefulness/risk is unfavourable in correct usage, or
4. the quantity and quality composition of the medicinal product do not comply with the one, described in the dossier, or
5. the data in the dossier under. 59a, para 1 are not true, or
6. the control of the medicinal product and/or of the ingredients and of the interim stages of the production process has not been performed or another requirement has not been fulfilled, where the authorisation for production has been issued, or
7. some of the data in the dossier do not comply with the requirements of Art. 59a, para

1 and 2.

(2) The refusal of the executive director of BDA to renew the authorisation for the usage/certificate for registration of the medicinal product may be appealed, as provided by the Administrative Procedure Code.

(3) The refusal of the executive director of BDA and the motives shall be published on the BDA website.

Art. 59c. (New – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 01.04.2013) The BDA shall notify the National council of prices and reimbursement of medicinal products about the terminated and withdrawn authorisations for use, as well as the made refusals for renewal of issued authorisations for use of medicinal products within 7 day term from issuance of the relevant act.

Section VI.
Variations in Granted Marketing Authorisation

Art. 60. (1) (amend. – SG 12/11, in force from 08.02.2011) The holder of a marketing authorisation of the medicinal product shall be obliged to notify the BDA about any change in the conditions under which the permit has been granted.

(2) (amend. – SG 12/11, in force from 08.02.2011)Variations may be of type IA, of type IB, of type II, extension of the marketing authorisation and urgent restricting measures of safety.

(3) (amend. – SG 12/11, in force from 08.02.2011) Terms and criteria of classification of the variation shall be laid down in the regulation envisaged in Art. 42.

(4) (amend. – SG 12/11, in force from 08.02.2011) Any variation, which is not an extension and whose classification is undetermined after application of the terms and criteria stipulated in the envisaged in Art. 42 regulation, shall be considered a variation of type IB by default.

(5) (new – SG 12/11, in force from 08.02.2011) As an exception from Para 4, and whose classification is undetermined after application of the terms and criteria stipulated in the envisaged in Art. 42 regulation, shall be considered, shall be considered a variation of type II in the following cases:

1. upon a request of the holder of the marketing authorisation, entered in the application for variation;

2. where the BDA, after an assessment of the validity of the notification under Art. 63, comes to the opinion that the change could have significant impact on the quality, safety or on the efficacy of the medicinal product.

Art. 61. (amend. – SG 12/11, in force from 08.02.2011) (1) Holder of the marketing authorisation of the medicinal product shall submit separate notifications, respectively applications to the BDA for each variation of type IA, type IB or type II or for extension of the range.

(2) If a concrete variation leads to a change in the data of the summary characteristic of the product, of the labelling or of the leaflet, these changes shall be assumed as a part of the declared variation and about them separate application shall not be submitted.

(3) Holder of the marketing authorisation may arrange the variations in groups, where:

1. notifies simultaneously of one and the same variations of type IA in the conditions of

one or several marketing authorisations;

2. declares simultaneously several variations in the conditions of the marketing authorisations, belonging to a global marketing authorisation for the medicinal products as per Art. 28, Para 8, provided that the envisaged variations fall under one of the following cases:

a) one of the variations in the group constitutes extension of the marketing authorisation;

b) one of the variations in the group constitutes a variation of type II, and all the other variations appear as a consequence of the variation of type II;

c) one of the variations in the group constitutes variation of type IB, and all the other variations appear as a consequence of the variation of IB

d) all variations in the group relate solely to changes of administrative nature to the summary product characteristics, labelling and package leaflet;

e) all variations in the group are changes to the Active Substance Master File, Vaccine Antigen Master File or Plasma Master File;

f) all variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or its active substance(s);

g) all variations in the group are changes affecting the quality of a human pandemic influenza vaccine;

h) all variations in the group are changes to the pharmaco-vigilance system referred to in Chapter Eight;

i) all variations in the group are consequential to a given urgent safety restriction and are submitted in accordance with Art. 66;

k) all variations in the group relate to the implementation of a given class labelling;

l) all variations of the group are consequential to the assessment of a given periodic update report on the safety;

m) all variations in the group are consequential to a given post-authorisation study conducted under the supervision of the holder of the marketing authorisation;

n) all variations in the group are consequential to a specific obligation carried out pursuant to Art. 56;

3. the declared variations to the terms of the same marketing authorisation do not fall within one of the cases specified in item 2, provided that the BDS agrees to subject those variations to the same procedure.

(4) Where variations as per Para 3, items 2 and 3 are grouped, holder of the marketing authorisation shall submit to the BDA:

1. a single notification, where at least one of the variations is a variation of type IB and all variations are of type IA or of type IB;

2. a single application, if the main variation is of type II and none of the rest of variations is an extension of the marketing authorisation;

3. a single application, where the main variation is extension of the marketing authorisation.

(5) Attached to the application, respectively to the notification, the holder of the marketing authorisation shall submit:

1. documentation, related to the variations, as determined by the regulation envisaged in Art. 42;

2. a document, certifying that the fee, in an amount as per Tariff under Art. 21, Para 2, is paid.

(6) The Executive Director of the BDA shall approve form of the application, respectively of notification, envisaged in Para 1 and 4, which shall be published on the Internet site of the BDA.

Art. 62. (amend. – SG 12/11, in force from 08.02.2011) (1) The holder of marketing authorisation shall submit a notification of variations of type IA within 12 months following the implementation of the variation, except for the cases where variations require immediate notification.

(2) Variations of type IA requiring immediate notification shall be specified in the regulation envisaged in Art. 42.

(3) In the cases of Para 2, holder of marketing authorisation shall submit notification for the variation of type IA immediately after its implementation.

(4) Within 30 days following receipt of the notification per Para 1, respectively per Para 3, the BDA shall notify the marketing authorisation holder:

1. if the variation(s) is/are accepted or not; in the cases where the variation(s) concerned is/are not accepted, reasons for that shall be stated; and

2. if variation(s) concerned lead(s) to amendment of the data in the issued marketing authorisation; where amendment of the issued marketing authorisation is needed, Art. 64a shall be applied.

(5) Marketing authorisation holder shall stop implementation of the respective variation(s) of type IA, immediately after a notification of unfavourable opinion under Para 4, item 1 is received.

Art. 63. (amend. – SG 12/11, in force from 08.02.2011)(1) In event that the notification for variation of type IB meets the requirements of Art. 61, the BDA shall inform the holder of marketing authorisation that the notification is valid, and shall state the date from which the term as per Para 2 starts running.

(2) Within 30 days following the receipt of a valid notification, the BDA shall assess the submitted documentation and shall notify the holder of marketing authorisation:

1. whether it accepts or rejects the variation concerned; in the cases where the notification cannot be accepted, the grounds on which its unfavourable opinion is based shall be stated, and

2. if variation concerned leads to change in the data of the issued marketing authorisation; where amendment of the issued marketing authorisation is needed, Art. 64a shall be applied.

(3) Where, within the term laid down in Para 2, the BDA finds that the submitted documentation does not fulfil the requirements of the Law and of the regulation envisaged in Art. 42, it shall notify of this the holder of the marketing authorisation.

(4) Within 30 days, following the receipt of the notification per Para 3, the holder of the marketing authorisation may amend or supplement the notification.

(5) Where, within the term per Para 4, the holder of the marketing authorisation does not submit amended or supplemented documentation, the BDA shall terminate the procedure and notify of this the holder of the marketing authorisation.

(6) Within 30 days from the receipt of the amended documentation envisaged in Para 4, the BDA shall notify the holder of the marketing authorisation:

1. whether it accepts or rejects the variation concerned; in the cases where the notification cannot be accepted, the grounds on which its unfavourable opinion is based shall be stated, and

2. if variation concerned leads to change in the data of the issued marketing authorisation; where amendment of the issued marketing authorisation is needed, Art. 64a shall be applied.

(7) The holder of the marketing authorisation shall apply the approved variation of type IB only after a notification of approval as per Para 2, item 1, respectively notification as per Para 6, item 1 is received.

Art. 64. (amend. – SG 12/11, in force from 08.02.2011)(1) Where the application for variation of type II fulfils the requirements of Art. 61, the BDA shall notify the holder of the marketing authorisation about receipt of a valid application and by stating the date from which the period envisaged in Para 2 starts.

(2) Within 60 days from the receipt of a valid application, BDA shall prepare an assessment report.

(3) The period referred to in Para 2 may be:

1. reduced, having regard to the urgency of the matter of safe use of the medicinal product, or

2. extended to 90 days for variations concerning a change to or addition of therapeutic indications.

(4) In event that the BDA finds that the submitted documentation does not fulfil the requirements of the Law and of the regulation envisaged in Art. 42, it shall notify the holder of the marketing authorisation of this and shall set a time limit within which supplementary information and documentation shall be provided.

(5) In the cases under Para 4, the time period envisaged in Para 2 shall be suspended until the requested supplementary information and documentation has been provided.

(6) Within 15 days following the preparation of the assessment report, the Executive Director of the BDA:

1. shall approve the variation or shall make a grounded rejection and shall notify of this the holder of the authorisation;

2. shall notify the holder of the marketing authorisation if the approved variation leads to amendment of the data in the issued marketing authorisation; where amendment of the issued marketing authorisation is needed, Art. 64a shall be applied.

(7) The holder of the marketing authorisation shall apply the approved variation of type II only after the authorisation for amendment as per Art. 64a is issued.

Art. 64a. (new – SG 12/11, in force from 08.02.2011) Executive Director of the BDA shall issue amendment of the decision granting the marketing authorisation within following time limits:

1.30 days following the issuance of the notification under Art. 62, Para 4, item 4, Art. 63, Para 2, item 2, respectively under Art. 63, Para 6, item 2 and under Art. 64, Para 6, item 2, where the respective variation leads to sex-months extension of the period, envisaged in Art. 13, Paragraphs 1 and 2 of Council Regulation No 1768/92 of 18 June 1992 concerning the provision of supplementary protection certificate as set out in Art. 36 of Regulation (EC) No 1901/2006;

2. 60 days following the issuance of the notification under Art. 62, Para 4, item 2 – in case of variations of type IA, which do not require immediate notification;

3. 60 days following the issuance of the notification under Art. 64, Para 6, item 2 – for variations of type II;

4. 180 days – in all other cases.

Art. 64b. (new – SG 12/11, in force from 08.02.2011) (1) In case of variations concerning

changes to the active substance for the purposes of the annual update of a human influenza vaccine, the holder of marketing authorisation shall submit application, with attached thereto documentation, as specified in the regulation envisaged in Art. 42. Within 7- days period, the BDA shall examine the completeness of the submitted documentation.

(2) If the application concerned fulfils the requirements of Para 1, the BDA shall notify the holder of the marketing authorisation, shall acknowledge the receipt of valid application and state the date, from which the specified time limit in Para 3 starts.

(3) Within 45- days period from the receipt of a valid application, the BDA shall assess the documentation and prepare an assessment report.

(4) The BDA may request the holder of marketing authorisation to provide the clinical data and the stability data of the medicinal product. The holder of marketing authorisation shall submit to the BDA data required within 12 days following the elapse of the time limit stipulated in Para 3.

(5) The BDA shall assess the documentation and take final decision within 10 days term from the receipt of the data referred to in Para1, by issuing authorisation for variation or rejection.

Art. 65. (1) Where the marketing authorisation holder has established a risk for the health from the use of the medicinal product, he shall undertake urgent limiting measures and shall immediately notify the BDA in writing.

(2) The BDA shall pass a judgment regarding the measures within 24 hours of the notification.

(3) Where the BDA has not passed a judgment within the term according to para 2, it shall be presumed that the measures have been approved.

(4) Where the BDA has established that there is a risk for the health of the population from the use of medicinal product, it shall order the marketing authorisation holder to immediately undertake limiting measures.

(5) In the cases according to para 1 and 4, the marketing authorisation holder of the medicinal product shall coordinate the method and term of implementation of the undertaken measures with the BDA.

(6) Marketing authorisation holder of the medicinal product shall submit to the executive director of The BDA a variation application under the terms Art. 64 not later than 15 from the date undertaking the measures.

Art. 66. (1) (amend. – SG 12/11, in force from 08.02.2011) The holder of the marketing authorisation of a medicinal product shall submit an application for enlargement of the scope of the granted marketing authorisation in case of:

1. change of the active substance(s):

a. replacement of a chemical active substance by a different by a different salt/ester, complex/derivative, including the same therapeutic moiety, where the efficacy/safety characteristics are not significantly different.

b. replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer (e.g. racemate with single enantiomer), where the efficacy/safety characteristics are not significantly different;

c. replacement of a biological active substance with one of a slightly different molecular structure where the efficacy/safety characteristics are not significantly different, with the exception of changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza;

d. modification of the vector used to produce the antigen of the source material, including a new master cell bank from a different source, where the efficacy/safety characteristics are not significantly different;

e. a new ligand or coupling mechanism for a radiopharmaceutical, where the efficacy/safety characteristics are not significantly different

f. change to the extraction solvent of the ration of herbal drug to herbal drug preparation where the efficacy/safety characteristics are not significantly different.

2. Changes to strength, pharmaceutical form and route of administration:

a. change of bioavailability;

b. change of pharmacokinetics e.g. change in rate of release;

c. change or addition of a new strength/potency;

d. change or addition of a new pharmaceutical form; e.g. change or addition of a new route of administration– for parenteral application to differentiate between intraarterial, intravenous, intramuscular, subcutaneous and other routs of administration.

(2) The application according to para 1 shall be accompanied by the documentation according to Art. 27, para 1, point 10, associated with variations according to para 1.

(3) The requirements to the documentation according to para 2 shall be laid down in the regulation according to Art. 42.

(4) The name of the medicinal product in the granted authorisation for enlargement of the scope of the initial marketing authorisation shall not be changed.

(5) The granting of an authorisation for enlargement of the scope of a granted marketing authorisation of a medicinal product shall be performed under the conditions and under the terms of Art. 49 - 51.

Art. 67. (1) The marketing authorisation holder of a medicinal product shall submit an application for granting a new marketing authorisation in case of:

1. addition or deletion of one or more active substances including antigenic components in case of vaccines;

2. change in the quality of the active substance indicated in the dossier, which essentially changes the safety and efficacy characteristics of the medicinal product, and the changed substance is defined as a new one;

3. addition of a new or change in an existing therapeutic, prophylactic, or diagnostic indication in another therapeutic field.

(2) (New - SG 71/2008, in force from 12.08.2008) The owner of the authorisation for use of the medicinal product shall file an application for issuing new authorisation for use, where the application for renewal of the authorisation for use was not filed within the term under Art. 59a, para 1.

(3) (Former para 2 - SG 71/2008, in force from 12.08.2008) The application shall be accompanied by the documentation laid down in the regulation according to Art. 42.

(4) (Former para 3 - SG 71/2008, in force from 12.08.2008) The procedure according to Art. 49 – 51 shall be applied in the cases according to para 1 and 2.

Art. 68. (1) (amend. – SG, 102/2012, in force from 21.12.2012)The holder of the marketing authorisation/registration certificate of a medicinal product shall be obliged to:

1. report the achievements of the scientific-technical progress and introduce all the needed changes in the documentation under Art. 27, Para. 1, p. 7 and 8 in view the medicinal product to be produced and controlled under the commonly adopted new methods; the changes

shall be made under Chapters Three and Five;

2. submit immediately to BDA any new information, which may affect the variation in the data and documents according to Art. 27 - 32 and in the summary of product characteristics;

3. inform immediately the BDA about any ban or limitation imposed by regulatory authorities of other states where the medicinal product is placed on the market, about the reasons standing behind those measures, as well as about any other new information, which may affect the benefit and risk assessment if the relevant medicinal product; the information shall include the positive, as well as the negative results from the clinical tests or other researches of all indicators and populations, notwithstanding of the fact whether they are included in the use authorisation, as well as data for use of the medicinal product, where this use is outside the conditions of the use authorisation;

4. keep and update the information about the medicinal product with the current scientific knowledge, including the conclusions from the assessment and recommendations, published in the European internet portal for medicinal products, established under Art. 26 of Regulation (EC) N 726/2004 of the European Parliament and of the Council;

5. disseminate the medicinal product with the last approved short characteristic of the product and a leaflet for the patient.

6. (new – SG 18/14) inform BDA of every action undertaken by them, related to temporary suspension of offering on the market of a specific medicinal product, withdrawal from the market of a particular medicinal product, request for termination of a marketing authorisation or stated intention of non-renewal of the marketing authorisation, and also to indicate the reasons for which this action has been taken; in these cases the marketing authorisation holder declare whether the undertaken by them actions are due to any of the reasons under Art. 276 or Art. 277;

7. (new – SG 18/14) inform BDA, if the actions referred to in item 6 are undertaken in a third country and are due to any of the reasons referred to in Art. 276 or Art. 277;

8. (new – SG 18/14) inform European drug agency where the actions under items 6 and 7 are undertaken on the grounds of Art. 276 and 277;

9. (new – SG 18/14) provide sufficient quantities of medicinal products for satisfying the health care needs of the individuals in the Republic of Bulgaria.

(2) The marketing authorisation/registration certificate holder shall be obliged to submit to the BDA upon request the following:

1. data in support of the positive benefit/risk ratio of the medicinal product;

2. (amend. – SG 18/14) information about the sales volume of the medicinal products and any other information available to the holder of the marketing authorisation regarding the medicinal prescriptions for the product;

3. a copy of the basic documentation of the vigilance system of the medicinal safety.

(3) The marketing authorisation holder shall submit to BDA the documentation under Para. 2, p. 3 within 7 day term after receiving the request.

Art. 69. (1) The marketing authorisation holder of a vaccine or immunological medicinal product designated for immunisation shall be obliged to submit to the BDA the following prior to the placing of any batch of the product on the market:

1. a sample of the finished product and/or a sample of the bulk/not finalised product;

2. protocols of the manufacturing and quality control;

3. document for paid fee as paid down in the tariff according to Art. 21, para 2.

(2) The marketing authorisation holder of new immunological medicinal products or immunological medicinal products manufactured by new or altered technologies or by

technologies, which are new for a given manufacturer, shall fulfil the obligations according to para 1 for a defined period set out in the marketing authorisation.

(3) Within 60 days from the date of submission of the full set of documents, the BDA shall perform an assessment of the manufacturing and quality control protocols of live vaccines, immunological, and new immunological medicinal products and tests of the provided samples in an accredited laboratory in order to establish whether the medicinal products according to para 1 and 2 are manufactured in compliance with the approved specifications.

(4) In case of a positive result from the tests, the BDA shall issue a batch release certificate.

(5) The conditions and order, as well as the requirements to the documentation for granting a batch release certificate for the products according to para 1 and 2 shall be laid down in the regulation of the Minister of Health.

(6) Where the assessment and tests according to para 3 of the respective batch of medicinal products have been conducted in an official laboratory for control of medicinal products in another Member State, the marketing authorisation holder shall submit to the BDA the medicinal products batch release certificate issued by the regulatory bogy of the Member State.

(7) In the cases according to para 6 the BDA shall not conduct the activities according to para 3 and 4.

Art. 70. (1) Prior to the placement on the market of each batch of the product the marketing authorisation of a medicinal product obtained from human blood or human plasma shall submit to the BDA the following:

1. a sample of the finished product and/or a sample of the bulk/ unfinished product;
2. manufacturing and quality control protocols;
3. document for paid fee as laid down in the tariff according to Art. 21, para 2.

(2) Within 60 days of the submission of the full set of documents, the BDA shall perform an assessment of the manufacturing and control protocols of the medicinal product obtained from human blood or human plasma and tests of the submitted samples in an accredited laboratory in order to establish whether the medicinal product according to para 1 is manufactured in compliance with the approved specifications.

(3) In case of a positive result from the tests, the BDA shall issue a batch release certificate.

(4) The conditions and order, as well as the requirements to the documentation for granting a batch release certificate for the products according to para 1 shall be laid down in the regulation according to Art. 69, para 5.

(5) Where the assessment and tests according to para 2 of the respective batch of medicinal products have been conducted in an official laboratory for control of medicinal products in another Member State, the marketing authorisation holder shall submit to the BDA the medicinal products batch release certificate issued by the regulatory authority of the Member State for the respective batch of the medicinal product.

(6) In the cases according to para 6 the BDA shall not conduct the activities according to para 2 and 3.

Art. 71. (1) The marketing authorisation holder shall be obliged to maintain a system for blocking and recall of medicinal products, which do not comply with the requirements relating to quality, safety, and efficacy.

(2) The marketing authorisation holder shall be obliged to block and recall of medicinal products, which do not comply with the requirements relating to quality, safety, and efficacy under the terms in the regulation pursuant to Art. 274, para 1.

Art. 72. (repealed – SG, 102/2012, in force from 21.12.2012)

Art. 73. (1) The marketing authorisation holder may assign the rights over the marketing authorisation of a medicinal product to another legal person or to unions, which are not legal persons established on the territory of the Member States.

(2) The marketing authorisation holder shall submit to the BDA an application appending the documentation laid down in the regulation according to Art. 42 indicating a proposal for the date of assignment.

(3) In case of establishing incompleteness in the documentation according to para 2, the BDA shall notify the marketing authorisation holder in writing to, within 30 days, submit the necessary additional information. The term according to para 5 shall cease to run as from the notification date until submission of the requested information.

(4) if the marketing authorisation holder does not supplement the documentation within the term according to para 3, the procedure of assignment of the marketing authorisation of the medicinal product shall be terminated.

(5) Within 30 days from the date of submission of the application according to para 2, the executive director of the BDA shall issue an authorisation for variation for the transfer. In the variation approval of the assignment stating explicitly the date of assignment of the marketing authorisation is pointed out.

(6) The holder of the marketing authorisation shall wholly assume the rights and obligations of the former marketing authorisation holder.

(7) By the transfer of the marketing authorisation of the medicinal product pursuant to the order of para 1-6 the time limit shall remain unchanged.

Section VII.
Mutual Recognition Procedure and Decentralised Procedure

Art. 74. (1) Where the person according to Art. 26, para 1, has a granted marketing authorisation in another Member State for the same product within the meaning of Art. 45, para 3, for which this person has submitted an application for marketing authorisation to the BDA, this person shall submit a request to the regulatory authority of the state indicated in the application, hereinafter referred to as "Reference Member State", to establish an assessment report or update the existing one.

(2) Together with the application, the person according to para 1 shall submit to the BDA a dossier identical to the one submitted in the reference Member State and in the other Member States indicated in the application, hereinafter referred to as "Concerned Member States".

(3) The BDA and the applicant shall officially receive the assessment report together by the approved summary of product characteristics and the approved packaging mock-up and package leaflet from the regulatory authority of the Reference Member State according to para 1.

(4) The BDA shall review the documents according to para 3 and inform the reference Member State for the decision taken in writing within 90 days from the date of receipt thereof.

(5) Within 30 days of the receipt of a notification for the accomplishment of the procedure from the part of the Reference Member State, the executive director of the BDA shall issue a marketing authorisation of the medicinal product for the territory of the Republic of Bulgaria with the approved summary of product characteristics, packaging mock-up, and package leaflet.

Art. 75. (1) Where the person according to Art. 26, para 1 submits simultaneously to the BDA and in other Member States an application for marketing authorisation of a medicinal product for which there is a granted marketing authorisation on the territory of a Member State, this person shall indicate in the application the regulatory authority of the Member State, hereinafter referred to as "reference member state", which shall establish a draft assessment report, a draft summary of product characteristics and packaging mock-up and package leaflet.

(2) Together with the application the person according to para 1 shall submit to the BDA a dossier identical to the one submitted in all other Member States indicated in the application, hereinafter referred to as "states concerned".

(3) The BDA and the applicant shall officially receive from the regulatory authority of the Reference Member State the draft assessment report, draft summary of product characteristics and draft packaging mock-up and packaging leaflet.

(4) The BDA shall review the documents according to para 3 and inform the Reference Member State for the decision taken in writing within 90 days from the date of receipt thereof.

(5) Within 30 days of the receipt of a notification for the accomplishment of the procedure from the part of the Reference Member State, the executive director of the BDA shall issue a marketing authorisation of the medicinal product for the territory of the Republic of Bulgaria with the approved summary of product characteristics, packaging mock-up, and patient leaflet.

Art. 76. (1) Where the Republic of Bulgaria is a Reference Member State according to Art. 74, the BDA shall:

1. forward the assessment report accompanied by the approved summary of product characteristics and the approved packaging mock-up and package leaflet within 90 days from the submission of a valid documentation;

2. close the procedure and notify the applicant and the Concerned Member States provided that all Concerned Member States have approved it.

(2) Within 30 days of the closure of the procedure according to para 1, point 2, the executive director of the BDA shall issue a marketing authorisation of the medicinal product for the territory of the Republic of Bulgaria with the approved summary of product characteristics, packaging mock-up, and package leaflet.

(3) Where The Republic of Bulgaria is a reference Member State according to Art. 75, the BDA shall:

1. submit to the regulatory authorities of the Concerned Member States and the applicant the draft assessment report, draft summary of product characteristics, and draft packaging mock-up and packaging leaflet within 120 days from the submission date of a valid documentation;

2. close the procedure and notify the applicant and the Concerned Member States provided that all Concerned Member States have approved it.

(4) Within 30 days of the closure of the procedure according to para 3, point 2, the executive director of the BDA shall issue a marketing authorisation of the medicinal product for the territory of the Republic of Bulgaria with the approved summary of product characteristics, packaging mock-up, and package leaflet.

Art. 77. (1) Where the BDA disapproves the submitted documentation according to Art. 74, para 4 or according to Art. 75, para 4, due to considerations of potential serious risk for the population health, it shall establish a detailed report with motives to the Referent Member State, the other Concerned Member States, and the applicant.

(2) Disputable issues according to para 1 shall be considered by the Coordination Group to the European Medicines Agency. The applicant may present his position for consideration in writing or by word of mouth.

(3) The BDA shall participate in the sessions of the Coordination Group according to para 2 until the closure of the procedure by the Reference Member State.

(4) The executive director of the BDA shall issue a marketing authorisation of the medicinal product with the approved summary of product characteristics, packaging mock-up, and package leaflet within 30 days from the receipt of a notification for the closure of the procedure by the Reference Member State.

Art. 78. (1) Where the Member States do not reach agreement before the Coordination Group, pursuant to Art. 22, para 2, the disputable issues shall be considered by the Committee for Medicinal Products for Human Medicine to the European Medicines Agency according to an arbitrage procedure. A copy of the documentation shall be forwarded to the applicant.

(2) The applicant shall submit to the European Medicines Agency the dossier of the medicinal product and the summary of product characteristics.

(3) In the cases according to para 1, provided that the BDA has approved the assessment report, draft summary of product characteristics and packaging mock-up and package leaflet submitted by the Reference Member State, the executive director of the BDA may, upon a request of the applicant, grant a marketing authorisation of the medicinal product prior to the completion of the arbitrage procedure according to para 1.

(4) After the accomplishment of the arbitrage procedure, the executive director of the BDA shall put the granted marketing authorisation according to para 3 into effect in compliance with the decision of the European Commission.

Art. 79. (1) Where the regulatory authorities of one or several Member States have made different decisions with respect to the marketing authorisation of the same medicinal product or with respect to its temporary suspension or revocation, the BDA or the applicant/marketing authorisation holder may refer the issue to the Committee on Medicinal products in Human Medicine to the European Medicines Agency for application of the arbitrage procedure. The Applicant or the marketing authorisation holder may apply the question to the Committee for Human Medicinal Products at the European Evaluation Agency for applying arbitration procedure upon its evaluation.

(2) (repealed – SG, 102/2012, in force from 21.12.2012)

(3) (amend. – SG 18/14) Bulgarian drug agency shall apply the procedure of Chapter Eight, Section IV, where one of the measures referred to in Art. 194s, par. 2 and 3.

(4) (new – SG 18/14) Notwithstanding the provision of par. 1 – 3, where urgent action for the protection of the public health is required at a certain stage of the arbitration procedure, BDA may suspend the effect of the marketing authorisation and to prohibit the use of the respective medicinal product in the Republic of Bulgaria until the adoption of the final decision.

(5) (new- SG 18/14) In cases referred to in par. 4 BDA shall inform the European

commission, the European Drug Agency and the other Member States of the reasons for their decision on the next work day at the latest.

Art. 79a (New – SG, 60/2011, in force from 5. 8. 2011) Depending on the decision of the European Commission after finalisation of the arbitration procedure, the BDA within the term of 30 days from receiving the notification, shall:

1. issue, temporarily stop or terminate an authorisation for use, or

2. request amendments to be made in the issued authorisation for reaching compliance with the decision of the European Commission.

(2) The BDA shall notify the European Commission and the European Agency on Medicines about the issued act under Para. 1.

Art. 79b (new – SG, 102/2012, in force from 21.12.2012) (1) In the cases where interests of the EU have been affected and before decision taking for issuance of a marketing authorisation of a medicinal products, for its temporary termination, or its change, BDA, the applicant or the marketing authorisation holder may refer the issue to the Committee under Art. 79, Para. 1 for applying arbitration procedure.

(2) In the cases under Para. 1, where the reference is as a result of a data assessment, related to vigilance of the medicinal safety of a medicinal product, permitted for use, the issue shall be referred to the committee under Art. 56a, Para. 1, p. 1 and the procedure under Art. 194x or 194y shall be applied.

(3)Where undertaking of urgent actions are needed, the procedure of Chapter Eight, Section V shall be applied.

Art. 80. (amend. – SG 12/11, in force from 08.02.2011) Terms and procedure for effecting variations to authorisations granted under this Section, shall be settled as prescribed by the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ, L 334/7 of 12.12.2008).

Chapter four.
CLINICAL TRIALS

Section I.
General Provisions

Art. 81. Clinical trials of medicinal products in human subjects can be conducted:

1. to reveal and confirm clinical, pharmacological, or pharmacodynamic effects of one or more study medicinal products;

2. to determine the adverse reactions to one or more study medicinal products;

3. to investigate the absorption, distribution, metabolism, and excretion of one or more study medicinal products and/or to establish their safety and/or efficacy.

Art. 82. (1) Clinical trials in human subjects shall be conducted with observation of the

basic principles for the protection of human rights and human dignity in any medico-biological study according to the Helsinki Declaration.

(2) Any clinical test of medicinal products in human subjects including bioavailability and bioequivalence shall be planned, conducted, and reported in compliance with the principles of Good Clinical Practice and in accordance with the requirements of this Act.

(3) The rules of Good Clinical Practice shall be laid down in a regulation issued by the Minister of Health.

Art. 83. (1) The rights, safety, and health of the subjects in the clinical test shall be placed above the interests of science and society.

(2) The available preclinical and/or clinical data about the study medicinal product shall be sufficient to substantiate the conduct of a clinical test.

Art. 84. (1) The clinical test shall be scientifically substantiated and clearly described in detail in the study protocol.

(2) During the development of the documentation and the conduct of the clinical test of a medicinal product, the contracting authority and the researcher shall take into account any available guidelines published by the European Commission and the European Medicine Agency, and the scientific committees thereto.

Art. 85. (1) Any clinical test of a medicinal product in human subjects shall be conducted with observation of the required quality assurance procedures in any aspect of the clinical test.

(2) The whole information from a clinical test shall be recorded and kept in a manner ensuring its accurate reporting, interpretation, and confirmation with protection of the personal data of the subjects.

Art. 86. (1) All persons conducting clinical trials shall possess the respective qualification, training, and experience to perform the study related tasks in compliance with rules for Good Clinical Practice.

(2) A clinical test of a medicinal product shall be conducted under the leadership of a medical doctor or a doctor of dental medicine with acknowledged medical specialty in the respective field and shall be familiar with the available preclinical and/or clinical data about the product and the study risks and procedures.

(3) During a clinical test, responsible for the medical care delivered to a study subject and for the medical decisions taken shall be a medical doctor or a doctor of dental medicine with adequate qualification.

Art. 87. (1) (amend. – SG 59/10, in force from 31.07.2010, amend. – SG, 60/2011, in force from 5. 8. 2011) A clinical test may only be conducted in hospital healthcare establishments, mental health centres, skin and venereal diseases health centre, complex oncologic centres and diagnostic-consulting centres, medical centres, dental centres and medical-dental centres, which have received authorisation for activity/certificate for registration in accordance with the Medical Establishments Act.

(2) A clinical test can only be conducted in healthcare establishments which shall have

an ethics Commission established and inscribed in the register of the BDA in accordance with Art. 103.

(3) The manager of the healthcare establishment, in which a clinical test of a medicinal product is to be conducted, shall give his/her consent as to the participation of the principal researcher in the study, as well as to the conduct of the study.

Art. 88. (1) A clinical test in human subjects shall be conducted with:

1. medicinal products unauthorised for use in the Republic of Bulgaria;

2. medicinal products authorised for use in the Republic of Bulgaria where these are studied for an unauthorised indication, pharmaceutical form different from the authorised one, in a so far unstudied patient group, or for obtaining additional data.

(2) Medicinal products authorised for use in the Republic of Bulgaria within the meaning of para 1 above shall be medicinal products that have received marketing authorisation under the terms of this Act or under the terms of Regulation N 726/2004 (EC) of the European Parliament and of the Council.

Art. 89. (1) A clinical test in human subjects shall be conducted with medicinal products, which are manufactured, maintained, and stored in compliance with the rules for Good Manufacturing Practice for medicinal products under development and research.

(2) The rules for Good Manufacturing Practice for medicinal products under development and research shall be laid down in the regulation according to Art. 152.

(3) A medicinal product can be proposed for a clinical test where pharmacological and toxicological studies have been conducted in accordance with the requirements for Good Laboratory Practice.

Art. 90. The clinical test can be started and conducted provided that:

1. the anticipated therapeutic benefits for the study subjects, for current and future patients and the benefits for the healthcare justify the foreseen risks;

2. the physical and mental immunity of the study subjects, their right of immunity of their private life and the right of personal data protection have been guaranteed pursuant to the Protection of Personal Data Act;

3. insurance or indemnity for covering researcher or contracting authority liability has been provided.

Art. 91. The contracting authority and the principal researcher shall make insurance covering their liability for property or non-property damages to the study subjects caused in or on the occasion of the conduct of the clinical test.

Art. 92. (1) The contracting authority shall be responsible in case of injury of the health or death caused by or in the occasion of the conduct of the clinical test where the clinical test has been conducted in compliance with the requirements and procedures of the study protocol as approved by the ethics committee.

(2) The principal researcher shall be responsible in case of injury of the health or death caused by or in the occasion of the conduct of the clinical test where the clinical test has not

been conducted in compliance with the requirements and procedures of the study protocol as approved by the ethics committee.

Art. 93. (1) Contracting authority of a clinical test shall be a person established on the territory of a Member State.

(2) Contracting authority and researcher can be the same person.

Art. 94. The contracting authority shall gratuitously provide the study medicinal product(s) and any device required for the administration thereof.

Art. 95. (1) The contracting authority shall develop the labelling of the study medicinal product in compliance with the rules for Good Manufacturing Practice for medicinal products under development and research.

(2) The requirements relating to the data on the packaging of medicinal products for a clinical test shall be determined by the regulation according to Art. 170.

Art. 96. (1) A clinical test with medicinal products shall only be allowed in a person who has:

1. been informed in a preliminary conversation with a physician member of the study team about the purposes, risks and inconveniences of the study and about the conditions in which it is to be conducted;

2. been informed about his/her right to withdraw from the study at any time without this having any negative consequences for him/her;

3. personally given written informed consent to participate having been familiarised of the essence, importance, consequences, and eventual risks of the clinical test.

(2) Where the person cannot write, the informed consent to participate in the clinical test shall be given by word of mouth in the presence of at least one independent witness who shall certify in writing that this subject has expressed informed consent to participate in the clinical test in person.

(3) The informed consent according to para 1, point 3, and para 2 can only be given by a capable person who understands the essence, importance, scope, consequences, and eventual risks of the clinical test. Informed consent to participate in a clinical test can be withdrawn at any time.

(4) The informed consent according to para 1, point 3, of an incapable major person shall be given by his/her legal representative. The consent of the legal representative must represent the supposed will of the subject and can be withdrawn at any time without negative consequences for the subject.

(5) In the cases according to Art. 162, para 3 of the Health Act, informed consent shall be given by the person appointed by the court.

(6) An incapable person shall be given information about the clinical test, eventual risks, and benefits in accordance with his/her capability to understand.

(7) The explicit will of an incapable major person to refuse to participate in or to withdraw from the clinical test at any time must be taken into consideration by the researcher or, in case of necessity, by the principal researcher.

Art. 97. (1) A clinical test in a minor person shall be conducted after obtaining written informed consent by both subject's parents or guardians with observation of Art. 96, para 1 and 3.

(2) Parents' or guardians' consent must represent the supposed will of the minor person and can be withdrawn at any time without negative consequences for the minor person.

(3) The express will of the minor person to participate or to at any time withdraw from the clinical test must be taken into consideration by the researcher or, in case of necessity, by the principal researcher.

(4) A clinical test in a minor person shall be conducted after obtaining written informed consent by both parents and the guardian in compliance of Art. 96, para 1 and 3. Where one of the parents is unknown, deceased, or deprived of parental rights or such rights have not been delegated in case of divorce, the written informed consent shall be given by the parent who is exercising the parental rights.

(5) Minor's, parents' and guardian's' consent can be withdrawn at any time without negative consequences for the minor person.

(6) The express will of the minor person to at any time withdraw from the clinical test must be taken into consideration by the researcher or, in case of necessity, by the principal researcher.

(7) The minor or underage person shall be provided information about the clinical test and for the eventual risks and benefits in a manner understandable for that person by a physician with experience with minor or underage persons.

Art. 98. Informed consent to participate in a clinical test shall not be required if immediate decision is imperative to save the patient's life or if at that moment it cannot be obtained. Decision shall be taken by at least two physicians who are not part of the study team.

Art. 99. (1) In the course of the clinical test the study subject shall receive additional information by a person independent from the contracting authority upon request.

(2) The written information provided to the subjects in a clinical test of a medicinal product shall contain contact details of an independent person for additional information.

Section .
Clinical Trials in Vulnerable Patient Groups

Art. 100. A clinical test in minor or underage persons can be undertaken provided that:

1. the study protocol has been approved by the respective ethics committee after discussion of the clinical, moral, and psycho-social aspects of childhood age in which at least two paediatricians have participated;
2. there is an anticipated direct benefit of the clinical test for the patient group, which is to be included;
3. the study is directly associated with the clinical condition from which the minor or underage person is suffering;
4. the study medicinal product is designated for the diagnosis, treatment, or prophylaxis of diseases, which are specific for minor or underage persons;
5. the study is designated to be conducted in minor or underage persons;

6. the study purpose is to check data obtained in clinical trials in persons who are capable of giving informed consent or of data obtained by other research methods;

7. the results obtained from clinical trials in adults and the interpretation thereof cannot be considered also valid for minor or underage persons;

8. the study is planned in a manner that pain, inconvenience, fear, and other disease-associated foreseeable risks are minimised and the risk threshold and physical pain degree have been determined in advance and shall be incessantly controlled throughout the clinical test;

9. the study has been planned and shall be conducted in compliance with the guidelines of the European Medicines Agency;

10. no financial or other incentives shall be given except compensations.

Art. 101. (1) Clinical trials in the persons according to Art. 96, para 4 and 5, who are not capable of giving informed consent, shall be conducted in compliance with the requirements of Art. 90.

(2) Except for the requirements of para 1, inclusion of major persons who are not capable of giving informed consent in clinical trials is permitted provided that:

1. the respective ethics committee with the participation of a specialist competent in the respective disease or in the patient group has approved the study protocol after discussion of the clinical, moral, and psycho-social aspects relating to the respective disease and patient group;

2. it can be anticipated that taking the medicinal product subject to research would result in benefits, which overweigh the risks or the risks are fully eliminated;

3. the study purpose is to check data obtained from clinical trials in persons who are capable of giving informed consent or of data obtained through other research methods;

4. the study is directly associated with a disease, which is life-threatening or resulting in disability, from which the major person who is not capable of giving informed consent is suffering;

5. the clinical trials are planned in such manner that pain, inconvenience, fear, and the other foreseeable risks associated with the disease are minimised and the risk threshold and physical pain degree have been determined in advance and shall be incessantly controlled throughout the clinical test;

6. no financial or other incentives shall be given except compensations.

Art. 102. No clinical test with a medicinal product can be conducted in pregnant women or breastfeeding mothers except if the medicinal product is required for their treatment or cannot be tested in other patient groups.

Section .
Ethics Committee

Art. 103. (1) (amend. – SG, 6/2011, in force from 5. 8. 2011) Ethics Commission for multicentre clinical trials shall be established to the Minister of Health the composition of which shall be determined by an order of the Minister and shall include regular and reserve members. The reserve members shall participate in the Commission meetings and shall have the right to vote in the event of absence of the regular members.

(2) Ethics committees shall be established at the healthcare establishments where clinical trials are to be conducted the composition of which shall be determined by an order of

the manager of the healthcare establishment.

(3) The BDA shall maintain and keep a register of ethics committees.

(4) The register of healthcare establishments where ethics committees have been established shall be published on the internet site of the BDA.

Art. 104. (1) The committees according to Art. 103 para 1 and 2 shall be composed of 7 to 12 persons with qualification and experience to review and assess the scientific, medical, and ethic aspects of the proposed clinical test.

(2) The committees according to para 1 shall include at least two persons of non-medical education, representatives of both genders, who are financially and administratively independent of the healthcare establishment where the clinical test is to be conducted.

(3) The committees according to para 1 can involve external specialists for the needs of their work.

(4) In clinical trials in minor or underage persons the respective ethics committee at the healthcare establishment can involve external experts in order to facilitate its work.

Art. 105. (1) The mandate of the ethics committee members shall have duration of 4 years.

(2) One half of the composition of the ethics committees shall be renewed every 2 years.

(3) A member of an ethics committee cannot be appointed in the same committee for more than two consecutive mandates.

Art. 106. (1) The ethics committees according to Art. 103, para 1 and 2, shall draw written standard operating procedures in compliance with the rules for Good Clinical

Practice, which shall determine the conditions and order for their work within one month from its establishment.

(2) The standard operating procedures of the ethics committees shall be approved by the executive director of the BDA.

(3) The sessions of the ethics committees shall be held in camera. In case of necessity, the chairman of the ethics committee can invite the contracting authority or the principal researcher to participate.

(4) only members of ethics committees who do not participate in a particular clinical test and are administratively and financially independent of the contracting authority and the principal researcher can vote and participate in the discussion.

(5) To certify the circumstances according to para 4, the members of the ethics committees shall sign declarations for conflict of interests.

Art. 107. (1) Central Ethics Committee shall be established to the Council of Ministers.

(2) The Central Ethics Committee shall consist of 9 members, representatives of both genders and shall obligatorily include medical doctors, doctors of dental medicine, a psychologist, a theologian, and a lawyer.

(3) The composition of the committee shall be determined by a decision of the Council of Ministers according to a proposal of the Minister of Health for a period of 4 years.

(4) The Central Ethics Committee shall provide opinions on deontological and ethics issues in the field of clinical trials where it is approached by the ethics committees according to

Art. 103, para 1 and 2, the BDA, or by contracting authorities.

(5) The Central Ethics Committee shall carry out the methodical guidance with respect to the ethics committees according to Art. 103, para 1 and 2.

(6) The sessions of the Central Ethics Committee shall be held in camera. In case of necessity, the chairman of the Central Ethics Committee can invite the contracting authority or the principal researcher to participate.

(7) The Council of Ministers, according to a proposal of the Minister of Health, shall determine the conditions and order for the work of the Central Ethics Committee by a regulation.

Art. 108. (1) A member of the Central Ethics Committee cannot be appointed in the same committee for more than two consecutive mandates. The duration of a mandate shall be 4 years.

(2) Half of the composition of the Central Ethics Committee shall be renewed every 2 years.

Section V.
Authorisation to Conduct a Clinical Test

Art. 109. A clinical test can be started provided that the following conditions have been met:

1. the respective ethics committee has given a positive opinion and

2. the executive director of BDA has issued a written authorisation for the conduct thereof where one of the study medicinal products is either:

a) a medicinal product for gene therapy;

b) a medicinal product for somato-cellular therapy;

c) a medicinal product, which contains genetically modified organisms;

d) a high technology medicinal product described in the Annex to Regulation (EC) 726/2004 of the European Parliament and the Council;

e) a medicinal product, which contains biological substance(s) of human or animal origin or contains biological components of human or animal origin or the manufacturing process of which involves such components, or

3. the contracting authority has not been notified by the BDA in writing that the clinical test cannot be conducted within the time limit as set out by the law; for medicinal products outside those according to 2.

Art. 110. (1) For obtaining opinion, the principal researcher or the coordinating researcher shall submit to the respective ethics committee according to Art. 103 the following documentation:

1. administrative documentation;

2. subject information;

3. documentation about the study protocol;

4. documentation about the study medicinal product(s);

5. documentation about the technical requirements and about the staff;

6. data about the financing and administrative organisation of the clinical test.

(2) The content, form, and requirements to the documentation according to para 1 shall be determined in the regulation according to Art. 82, para 3.

Art. 111. (1) The ethics committee shall establish an opinion taking into consideration the following:

1. importance of the clinical test;

2. positive assessment of the ratio between the anticipated benefits and risks according to Art. 90, para 1, and the motivation of the conclusions;

3. protocol of the clinical test;

4. to what extent the principal researcher and the study team are adequate for the conduct of the clinical test;

5. researcher's brochure;

6. availability of the required equipment and its adequate quality;

7. compliance and completeness of the written information, which is to be given, as well as the procedure for obtaining informed consent and the validity of the clinical test in human subjects incapable of giving informed consent in the cases according to Art. 100 and 101;

8. provided indemnity or recovery in case of injury or death, which could result from the clinical test;

9. insurance covering researcher or contracting authority liability;

10. where necessary, the conditions and order for remuneration or indemnification of study researchers and subjects and the elements of the contract between the contracting authority and the healthcare establishment;

11. conditions and order for subject recruitment.

(2) The ethics committee shall:

1. give positive opinion;

2.. refuse in a motivated manner, or

3. request amendment of a part of the documentation as a condition for obtaining a positive opinion.

Art. 112. (1) Within 60 days from the submission of an application, the ethics committee shall pass resolution with an opinion, which shall be sent to the applicant and the BDA.

(2) Where the clinical test involves a medicinal product for gene therapy or somato-cellular therapy or a medicinal product containing genetically modified organisms, the time limit according to para 1 shall be extended by 30 days.

(3) Where for the review of a clinical test involving a medicinal product for gene therapy or somato-0-cellular therapy or a medicinal product containing genetically modified organisms it shall be imperative to consult a specially established for the purpose expert committee by an order to the director of the BDA, the time limit for drawing an opinion shall be 180 days.

Art. 113. (1) During assessment of the documentation, the ethics committee can once request additional written documentation from the applicant. The time limits according to Art. 112 shall cease to run until submission of the requested documentation.

(2) The review procedure of the study shall be terminated if the applicant should not submit the additional documentation required by the committee within 30 days of the receipt of the request for additional information.

Art. 114. (1) Where the clinical test is to be conducted in more than one centre on the territory of the Republic of Bulgaria, the application shall be submitted to the ethics committee

for multicentre tests according to Art. 103, para 1.

(2) Where the clinical test is to be conducted in only one centre on the territory of the Republic of Bulgaria, the application can be submitted to the ethics committee according to Art. 103, para 1 or 2 at applicant's discretion.

(3) The opinion of the ethics committee according to Art. 103, para 1, shall be valid for all centres on the territory of the Republic of Bulgaria.

(4) (new – SG 12/11, in force from 08.02.2011) For submission of applications to obtain opinion by the Ethics Committee, the Ministry of Health shall collect a fee in amount as determined by the Tariff envisaged in Art. 21. Para 2.

Art. 115. (1) Where the opinion of the respective ethics committee according to Art. 103 is negative, the applicant can appeal before the Central Ethics Committee within 90 days of the date of notification.

(2) Where the negative opinion of the respective ethics committee according to Art. 103 is established without taking into consideration the opinion of the expert commission according to Art. 112, para 3, the contracting authority can, within 14 days of the date of notification, request in writing that the committee revise its opinion.

(3) The expert committee according to Art. 112, para 3, shall, within 60 days of the date of receipt of a written application of the applicant, pass a resolution on the negative opinion of the respective committee and can either challenge or support it, wherefore it shall notify the ethics committee in writing. The ethics committee shall take final decision and send it to the applicant.

(4) Where the expert commission according to Art. 112, para 3, supports the negative opinion, the contracting authority can, within 14 days of the date of notification, appeal against the decision before the Central Ethics Committee.

(5) The opinion of the Central Ethics Committee shall be final and binding on the respective ethics committee.

Art. 116. (1) The applicant shall submit to the BDA an application after the pattern for the conduct of the clinical test.

(2) Where the applicant for the clinical test is not the contracting authority, the application shall be accompanied by documentation certifying that the person has been empowered by the contracting authority.

(3) Where the contracting authority has not been registered as a natural person or legal entity on the territory of Bulgaria, the application shall be accompanied by a document evidencing the data of his empowered representative on the territory of the Republic of Bulgaria.

(4) The following documents shall be appended to the application:

1. administrative documentation;
2. subject information;
3. documentation about the study protocol;
4. documentation about the study medicinal product(s);
5. documentation about the technical requirements and about the staff;
6. data about the financing and administrative organisation of the clinical test.

(5) The content, form, and requirements to the documentation according to para 1 shall be determined in the regulation according to Art. 82, para 3.

Art. 117. (1) During assessment of the documentation, the BDA can once request additional written documentation from the applicant.

(2) The time limits according to Art. 118, 119, and 120 shall cease to run until submission of the requested documentation.

Art. 118. (1) Within 60 days of the date of submission of an application for a clinical test of medicinal products according to Art. 109, point 3, the BDA shall notify the applicant that:

1. the clinical test can be conducted on the territory of the Republic of Bulgaria or
2. the clinical test cannot be conducted indicating the reasons therefore.

(2) In the cases according to para 1, point 2, the contracting authority can submit to the BDA an application amended in accordance with the motives set out or submit the required information in accordance with the requirements of the BDA within 30 days.

(3) Within 30 days of the submission of the amended application according to para 2 or the additional information, the BDA shall notify the applicant in writing that:

1. the clinical test can be conducted on the territory of the Republic of Bulgaria or
2. that it refuses the conduct of the clinical test stating the reasons therefore.

(4) The refusal according to para 3, point 2, shall be subject to appeal under the terms of the Administrative Procedure Code.

(5) The clinical test can be started provided that within the time limit according to para 1 the BDA has not issued a notification with motives of disapproval of the clinical test.

(6) Provided that the applicant does not submit an application according to para 2 within the stipulated time limit, the procedure shall be terminated and the clinical test shall no be conducted.

Art. 119. (1) Within 60 days of the date of submission of an application for a clinical test with the medicinal products according to Art. 109, point 2,, the executive director of the BDA shall:

1. issue authorisation for the conduct of the clinical test, or
2. issue a motivated refusal.

(2) The refusal according to para 1, point 2, shall be subject to appeal under the terms of the Administrative Procedure Code.

Art. 120. (1) In case of medicinal products according to Art. 109, point 2, letters "a" - "c" the time limit according to Art. 119, para 1, for the issue of authorisation by the BDA for the conduct of a clinical test can be extended by 30 days.

(2) Provided that the BDA should consult the expert commission according to Art. 112, para 3, which is to assess the safety of the medicinal products according to para 1, the extended time limit according to para 1 can be extended by another 90 days.

Art. 121. The executive director of the BDA shall refuse to issue authorisation for the conduct of a clinical test of medicinal products for gene therapy where there is a risk of modifying the genome of the reproductive cells of a study subject.

Art. 122. (1) In case of a multicentre clinical test in the Republic of Bulgaria and in a third

state, the BDA shall request the contracting authority to submit a declaration that he shall provide access to representatives of the BDA for inspection aimed at the establishment of compliance with the requirements and principles of Good Clinical Practice and Good Manufacturing Practice.

(2) Provided that the contracting authority should not submit the declaration according to para 1, the BDA shall not review the submitted application.

Art. 123. The contracting authority shall declare that the documentation submitted to the BDA and the ethics committee contains the same information.

Art. 124. (1) The procedures in the ethics committee and in the BDA can be carried out simultaneously or consecutively at the discretion of the contracting authority.

(2) The time limit for documentation review according to Art. 118, para 1, shall not cease to run in case of lack of decision of the ethics committee.

Art. 125. The clinical test shall be conducted in compliance with the study protocol, which has received positive opinion of the respective ethics committee according to Art. 103 and under the conditions set out in the submitted documentation.

Section V.
Amendments

Art. 126. (1) The contracting authority can at any time make amendments in the study protocol different from the essential amendments according to Art. 127, para 2.

(2) In the cases according to para 1 the contracting authority shall keep the documentation relating to the amendments and shall provide it to the BDA and the ethics committee upon request.

Art. 127. (1) Amendment in the conduct of a clinical test can be required by the BDA wherever necessary to guarantee the safety of the subjects, the scientific value of the clinical test, and/or the observation of the rules for Good Clinical Practice.

(2) Essential amendment in the conduct of the clinical test shall be any amendment in the study protocol and/or in the information and the documentation according to Art. 110 and 116, which can affect:

1. the safety or the physical and mental immunity of the study subjects;
2. the scientific value of the clinical test;
3. the conduct or the organisation of the clinical test;
4. the quality or the safety of any study medicinal products.

Art. 128. (1) The contracting authority can also implement planned study essential protocol and documentation amendments according to Art. 110 and 116 wherever:

1. the ethics committee has given a written positive opinion;
2. the executive director of the BDA has issued a written authorisation as to clinical trials with medicinal products according to Art. 109, point 2, or

3. the contracting authority has not been notified by the BDA about refusal of the proposed amendment in the clinical test with medicinal products according to Art. 109, point 3.

(2) The provision of para 1 shall not apply to changes in an approved protocol, which are imperative to protect the subjects from immediate threat in case of occurrence or new information associated with the conduct of the clinical test or the development of the study medicinal product.

(3) In the cases according to para 2, the contracting authority shall immediately notify the ethics committee according to para 1, point 1, and the BDA about the available new information, the measures taken, and the applied changes in the protocol.

Art. 129. (1) While planning essential amendments to the clinical test and the documentation according to Art. 110 and 116, the applicant shall submit a formal written application to the BDA and the respective ethics committee.

(2) The application shall be accompanied by documentation, which is necessary for grounding the amendments and certifies that after the implementation of the amendment the assessment of the benefit/risk ratio according to Art. 90, para 1, shall remain unchanged.

(3) The requirements relating to the application and the documentation for the amendment shall be determined in the regulation according to Art. 82, para 3.

Art. 130. (1) Within 35 days of receipt of an application for amendment, the ethics committee shall notify the contracting authority of its decision by issuing:

1. positive opinion on the requested amendment or

2. motivated refusal of the amendments in the clinical test.

(2) Within 35 days of the date of receipt of an application with positive opinion of the ethics committee, the BDA shall:

1 approve the amendments in a clinical test of medicinal products according to Art. 109, point 2, or

2. disapprove the amendments with explicit motivation.

(3) Provided that within 35 days of the submission of the documentation for amendments in clinical trials of medicinal products according to Art. 109, point 3, the applicant does not receive notification for disapproval of the amendment, the proposed amendments can be implemented.

Art. 131. (1) In the cases according to Art. 130, para 2, point 2, the contracting authority can submit alteration of the proposed amendments consistent with the motives not later than 14 days prior to the implementation of the amendments.

(2) Within 14 days of the date of receipt of the amended documentation according to para 1, the BDA shall issue and amendment of its authorisation for the clinical test of medicinal products according to Art. 109, point 2, or shall issue a refusal, which shall not be subject to appeal.

(3) The refusal according to para 2 shall not be subject to appeal.

Section V.
Cessation of the Clinical Test

Art. 132. (1) The contracting authority or the researcher can undertake urgent measures

to protect the study subjects from suddenly occurred risks for their safety and health.

(2) In the cases according to para 1 the contracting authority shall immediately notify the BDA and the respective ethics committee about the undertaken actions and the reasons, which have raised these.

Art. 133. (1) Where the clinical test is to be conducted under conditions different from those determined at the issue of the authorisation or there is information vitiating the scientific validity of the clinical test or the safety of the study subjects, the BDA can temporarily stop the conduct of the test or put a ban on it.

(2) The ban can be imposed for a specific centre or for all centres in a multicentre clinical test on the territory of the Republic of Bulgaria.

(3) In case of termination of the clinical test in all centres on the territory of the Republic of Bulgaria, the BDA shall, prior to undertaking actions according to para 1, notify the contracting authority and the principal researcher or the coordinating researcher in writing.

(4) Within 7 days of the receipt of the notification the contracting authority and/or the principal researcher can express an opinion on the undertaken measures by the BDA.

(5) The provision of para 3 shall not apply provided that there is an immediate threat for the health and safety of the study subjects.

Art. 134. In the cases according to Art. 133, para 1, the BDA shall immediately notify the respective ethics committee, the regulatory bodies of the Member States, the European Medicines Agency, and the European Commission about the undertaken measures and the reasons therefore.

Section V.
Pharmaco-vigilance

Art. 135. (1) The principal researcher shall immediately report in writing or by word of mouth any serious adverse event that has occurred in the course of the clinical test in a study subject at the centre he is responsible for.

(2) A detailed written report shall be submitted after the report according to para 1.

(3) At the notification according to para 1 and in the report according to para 2 the study subject shall be identified by a unique code number as defined in the study protocol.

(4) The provisions of para 1 and 2 shall not apply provided that the protocol of the clinical test or the researcher's brochure explicitly states that there is no requirement for an urgent report of a specific serious adverse event.

(5) The researcher shall report to the contracting authority any adverse events or laboratory aberrations, which are defined in the study protocol as critical with respect to safety, within the timelines and format as required by the protocol.

Art. 136. Where the outcome of an adverse event during the conduct of a clinical test is death, the researcher shall be obliged to submit to the contracting authority and the ethics committees any information requested additionally.

Art. 137. The contracting authority shall keep detailed records of any serious adverse events provided to him by the researchers and shall present these upon request to the BDA or the regulatory bodies of the Member States where the clinical test is conducted in case of multicentre clinical test.

Art. 138. (1) The contracting authority shall notify the BDA, the regulatory bodies of all Member States where the clinical test is conducted in case of a multicentre test, and the respective ethics committee of any suspected serious adverse drug reaction occurring in the course of the clinical test, which has resulted in death or has been life-threatening not later than 7 days of receipt of information thereof.

(2) The contracting authority shall provide the bodies according to para 1 with additional information on the case within 8 days of the date of the notification sent.

(3) The contracting authority shall notify the bodies according to para 1 of any other suspected unexpected serious drug reactions occurring in the course of the clinical test, which are different from those set out in para 1, not later than 15 days from the date of receipt of the information for their occurrence.

Art. 139. (1) The contracting authority can fulfil his obligations according to Art. 138, para 1 and 3, by entering his reports in the European adverse drug reactions database.

(2) Where the clinical test is also conducted in countries outside the Member States and the European Economic Area, the contracting authority shall enter his reports of suspected unexpected serious adverse drug reactions in the European adverse drug reactions database.

(3) (amend. – SG, 102/2012, in force from 21.12.2012) The format and content of the reports for adverse drug reactions shall be determined by the regulation according to Art. 82, Para. 3.

(4) The contracting authority shall inform the researchers conducting a clinical test with medicinal product about any suspected unexpected serious adverse drug reaction associated with the study medicinal product irrespective of its origin.

Art. 140. (1) The contracting authority shall submit to the BDA and the respective ethics committee a list of all suspected serious adverse drug reactions occurring during the past period and a report about the safety of the study subjects once yearly.

(2) (amend. – SG, 102/2012, in force from 21.12.2012) The format and content of the reports for adverse drug reactions shall be determined by the regulation according to Art. 82, Para. 3.

Art. 141. (1) The BDA shall document any information about suspected unexpected serious adverse drug reactions of the study medicinal products provided under the terms of Art. 138, para 1 and 3.

(2) The BDA shall immediately enter the information according to para 1 in the European adverse drug reactions database.

Section V.
Notification of Clinical Test Closure

Art. 142. (1) The contracting authority shall notify in writing the BDA and the respective ethics committee of the closure of the clinical test on the territory of the Republic of Bulgaria.

(2) The notification shall be submitted within 90 days of the closure of the clinical test in a format as defined by the regulation according to Art. 82, para 3.

(3) Provided that nothing is otherwise stipulated in the protocol as approved by the respective ethics committee, the last subject visit shall be considered as end of study.

(4) Where the study is prematurely terminated, the contracting authority shall notify the BDA and the respective ethics committee within 15 days of taking such decision providing the reasons thereof.

Art. 143. The contracting authority shall submit a final report of the clinical test to the BDA and the respective ethics committee.

Art. 144. (1) The BDA shall enter data of any clinical test conducted on the territory of the Republic of Bulgaria in the European clinical trials database: application submitted, ethics committee decision, authorisation, essential amendments, end of study, and data of any audit conducted.

(2) Upon request by another Member State, the European Medicines Agency or the European Commission, the BDA shall provide additional information besides that entered in the European clinical trials database.

(3) During the fulfilment of its obligations according to para 1, the BDA shall observe the published guidelines of the European Commission.

Chapter four.
NON-INTERVENTIONAL STUDY (NEW, PREVIOUS SECTION IX,"NON-INTERVENTIONAL STUDY" – SG 12/11, IN FORCE FROM 08.02.2011)

Art. 145. (1) (suppl. – SG 12/11, in force from 08.02.2011) A non-interventional study shall be conducted with medicinal products authorised for use in the Republic of Bulgaria where these are studied in order to obtain additional information about the product prescribed in the usual manner in compliance with the conditions determined in the marketing authorisation. No additional diagnostic or monitoring procedures, different from the usual practices shall be applied to the patients in non-interventional studies, and epidemiological methods should be used for the analysis of the collected data.

(2) (amend. – SG 12/11, in force from 08.02.2011, repealed – SG, 102/2012, in force from 21.12.2012)

(3) (repealed – SG, 102/2012, in force from 21.12.2012)

(4) (repealed – SG, 102/2012, in force from 21.12.2012)

(5) (repealed – SG, 102/2012, in force from 21.12.2012)

(6) (repealed – SG, 102/2012, in force from 21.12.2012)

Art. 145a. (new - SG, 102/2012, in force from 21.12.2012) (1) Non-interventional pos-marketing safety studies shall be conducted upon initiative of the marketing authorisation holder or in fulfillment of the conditions of Art. 55a and 56a and are related to data collection of medicinal safety by patiednt and medical specialists.

(2) Where with the study, collection of data is planned by patients, their consent must be received. The personal data of the patients shall be processed while observing the requirements of the Act on Personal Data Protection.

(3) The medical specialists shall not receive financial or other benefits for participation in the non-interventional safety studies, unless compensations for the spent time and means.

Art. 145b. (new – SG, 102/2012, in force from 21.12.2012) (1) During the study under Art. 145c, Para. 1 and Art. 145f, Para. 1 the holder of the marketing authorisation shall carry out monitoring of the obtained data and shall account for their impact over the correlation benefit-risk for the medicinal product.

(2) The marketing authorisation holder shall announce to BDA about each new information, which could influence the correlation benefit-risk for the medicinal product.

(3) The obligation under Para. 2 shall not liberate the marketing authorisation holder from the requirements of Art. 194h for providing the information under Para. 2 and through the periodic updated safety reports.

Art. 145c. (new – SG, 102/2012, in force from 21.12.2012) (1) Where the study is conducted only on the territory of the Republic of Bulgaria in implementation of the obligation under Art. 56a, the holder of the marketing authorisation shall produce a draft protocol of the study to BDA. The draft protocol, with a written consent under Art. 145a, Para. 2 shall be produced also to the commissions under Art. 103, Para. 1 or 2, where applicable.

(2) The BDA executive director, within the term of up to 60 days from the date of receiving the documentation under Para. 1, the marketing authorisation holder shall submit a notification of the study or shall give a grounded refusal.

(3) The BDA executive director shall refuse conducting of the study with one or more of the grounds under Art. 145f, Para. 2, p. 2.

(4) The commission under Art. 103, Para. 1 or the commissions under Art. 103, Para. 2 within the term of up to 60 days from the date of receiving the documentation under Para. 1 shall submit to the marketing authorisation holder a positive or negative opinion.

(5) Conducting of the study may start after receiving approval by BDA and a positive opinion by the commission under Art. 103, Para. 1 or by the commissions under Art. 103, Para. 2.

(6) For assessment of the documentation under Para. 1, BDA shall collect a fee in the amount, determined by the tariff under Art. 21,Para. 2.

Art. 145d. (new – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder shall apply planned substantial changes in the protocol in the cases under Art. 145c, Para. 1 after their prior approval by BDA and by the commission under art. 103, Para. 1, or the commissions under Art. 103, Para. 2.

(2) The marketing authorisation holder shall produce to BDA and to the commission under Art. 103, Para. 1 or the commissions under Art. 103, Para. 2 the documentation, related to the changes and thee motives for that.

(3) The BDA executive director within the term of 30 days after receiving the documentation under Para. 2 shall approve the changed protocol or shall issue a motivated refusal and shall notify the marketing authorisation holder.

(4) The commission under Art. 103, Para. 1 or the commissions under Art. 103, Para. 2

within the term of 30 days from the date of receiving the documentation under Para. 2 shall submit to the marketing authorisation holder a positive or negative opinion.

(5) The BDA executive director shall refuse the changes under Para. 1 with one or more of the grounds, indicated in Art. 145f, Para. 2, p. 2.

(6) The marketing authorisation holder may apply the changes under Para. 1 after receiving an approval by BDA and a positive opinion by the commission under Art. 103, Para. 1 or by the commissions under Art. 103, Para. 2.

(7) BDA shall collect fee in the amount, defined by the tariff under Art. 21, Para. 2 for assessment of the documentation under Para. 1.

Art. 145e. (New – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder shall produce to BDA a final report of the study within the term of up to 12 months after finalisation of the data collecting. The report shall have attached a study result summary.

(2) The marketing authorisation holder may submit a grounded request to BDA for postponing the term under Para. 1 at least 3 months before the date for producing the final report, indicated in the protocol.

(3) The BDA shall approve or refuse grounded the request under Para. 2 and shall notify the marketing authorisation holder.

(4) Where the marketing authorisation holder, based on the report of Para. 1, considers that a change in the marketing authorisation is needed, he/she shall submit to BDA an application for a change under Chapter Three, Section VI.

(5) The BDA executive director by an order shall interrupt the action or shall terminate the marketing authorisation, where BDA on the basis of the report under Para. 1 after consultation with the marketing authorisation holder considers that interruption or termination of marketing authorisation is needed.

Art. 145f. (new – SG, 102/2012, in force from 21.12.2012) (1) Where the study is conducted on the territory of the Republic of Bulgaria, also on the territory of other EU Member States, for medicinal products, permitted under Regulation (EC) N 726.2004 of the European Parliament and of the Council or under Chapter Three, Section VII in implementation of the obligations under Art. 55a or Art. 56a, the marketing authorisation holder shall submit the draft protocol to the committee under Art. 56a, Para. 1, p. 1.

(2) Within the term of up to 60 days from the date of receiving the documentation under Para. 1, the committee under Art. 56a, Para. 1, p. 1. Shall draw up an opinion and shall submit to the marketing authorisation holder:

1. a approval notification, or

2. grounded refusal, where:

a) it finds, that the study conducting encourages the use of the medicinal product, and/or

b) considers, that the design of the study will not achieve the objectives, laid down in the protocol, and/or

c) the study has nature of a clinic study.

(3) In the cases under Para. 2, p. 1 the marketing authorisation holder shall produce the notification to BDA and to the commissions under Art. 103, Para. 1 or 2, where applicable.

(4) The commission under Art. 103, Para. 1 or the commissions under Art. 103, Para. 2, within the term of up to 15 days from the date of receiving the notification under Pra. 3 shall submit to the marketing authorisation holder a positive or negative opinion.

(5) The study conducting may start after receiving a positive opinion by the commission under Art. 103, Para. 1 or a commission under art. 103, Para. 2.

(6) The contents and the form of the protocol under Para. 1 shall be determined by Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmaco-vigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ, L 159/5 of 20 June 2012), called hereinafter "Implementing Regulation (EU) N 520/2012".

Art. 145g. (new – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder in the cases under art. 154f, Para. 1 shall apply planned substantial changes in the study protocol after their prior approval by the committee under Art. 56a, Para. 1, p. 1.

(2) The marketing authorisation holder shall produce to the committee under Art. 56a, Para. 1, p. 1 the documentation, related to the changes and grounds for that.

(3) Where the committee under Art. 56a, Para. 1 approves the protocol changes, the marketing authorisation holder shall notify the BDA and the commission under Art. 103, Para. 1 or the commissions under Art. 103. Para. 2.

(4) The marketing authorisation holder may apply the changes under Para. 1 after receiving a positive opinion by the commission under Art. 103, Para. 1 or the commissions under Art. 103, Para. 2.

Art. 145h. (new – SG, 102/2012, in force from 21.12.2012) The marketing authorisation holder shall submit in electronic way to the committee under Art. 56a, Para. 1, p. 1 a final report, with a study result summary within the term of up to 12 months after finalisation of data collecting.

(2) The marketing authorisation holder may submit a grounded request to the committee under Art. 56.a, Para. 1, p. 1 for postponing the term under Para. 1 at least 3 months before the date for producing the final report, indicated in the protocol.

(3) The committee under Art. 56a, Para. 1, p. 1 shall approve or refuse groundedly the request under Para. 2 and shall notify the marketing authorisation holder.

(4) The contents and form of the report under Para. 1 shall be determined by Implementing Regulation (EU) N 520/2012.

Art. 145i. (new – SG, 102/2012, in force from 21.12.2012) (1) The committee under Art. 56a, Para. 1, p. 1 based on the report under Art. 145h, Para. 1 and after consultation with the marketing authorisation holder shall issue a grounded recommendation about the marketing authorisation of the medicinal product and shall submit it to:

1. The committee of the medicinal product for human use under Art. 5 of Regulation (EC) N 726/2004 of the European Parliament and of the Council or

2. The coordination group under art. 77, Para. 2.

(2) In the cases under Para. 1. P. 2 where the committee under Art. 56a, Para. 1, p. 1 has recommended a change, interruption or termination of the marketing authorisation, the coordination group, represented by the Member States, in which the study has been conducted, shall issue an opinion about the needed actions, to be undertaken in relation to the marketing authorisation, including a schedule for its implementation.

(3) Where the represented member States in the coordination group reach consensus about the opinion under Para. 2, it shall be published on the European internet portal for

medicinal products under Art. 68, Para. 1, p. 4 and shall be submitted to the marketing authorisation holder.

(4) The BDA executive director in compliance with the opinion under Para. 2 shall interrupt or terminate the action of the marketing authorisation.

(5) Where in the opinion under Para. 2 changes have been recommended in the issued marketing authorisation, the marketing authorisation holder within the frames of the determined implementation schedule shall submit to BDA an application for change under Chapter Three, Section VI, including an updated short characteristic of the product and a leaflet.

(6) Where it is impossible an agreement to be reached within the frames of the coordination group, the position of the majority Member States shall be produced to the European Commission, which shall adopt a decision for change, interruption or termination of the marketing authorisation, issued by the relevant regulatory bodies of the Member States.

(7) The decision under Para. 6 shall be published on the European internet portal for medicinal products under Art. 68, Para. 1, p. 4 and shall be submitted to the marketing authorisation holder.

(8) The BDA shall apply the temporary and/or final measures of the decision under Para. 6 and shall inform the European Medicines Agency and the European Commission.

(9) In the cases under Para. 1, the Committee on medicinal products for human use in compliance with the recommendations of the committee under art. 56a, Para. 1, p. 1 shall issue an opinion about storage, change, termination or interruption of the validity of the marketing authorisation, including a schedule for implementation of the opinion. The opinion shall be published on the European internet portal for medicinal products under Art. 68, Para. 1, p. 4 and shall be submitted to the marketing authorisation holder.

(10) Where in the opinion under Para. 9 a position is expressed for undertaking regulatory actions in relation to the marketing authorisations, the European Commission shall undertake a decision for a change, termination or interruption of the marketing authorisation, issued under Regulation (EC) N 726/2004 of the European Parliament and of the Council.

Art. 145j. (new – SG, 102/2012, in force from 21.12.2012) (1) Non-interventional studies on the territory of the Republic of Bulgaria shall be conducted under Art. 145c – 145e.

(2) During conducting non-interventional studies under Para. 1 the financing source shall ne indicated

Chapter five.
MANUFACTURING AND IMPORT OF MEDICINAL PRODUCTS AND ACTIVE SUBSTANCES (TITLE. AMEND. – SG, 102/2012, IN FORCE FROM 02.01.2013)

Section .
Manufacture

Art. 146. (1) (amend. – SG, 102/2012, in force from 02.01.2013)Within the meaning of this Act manufacture of all types of medicinal products and medicinal products intended for clinical trials can only be performed on the territory of the Republic of Bulgaria by natural or legal persons registered as traders on the territory of a Member State which have received manufacturing authorisation issued by the director of the BDA.

(2) Manufacturing authorisation shall also be required in the cases where the products according to para 1 are intended for export only.

(3) Manufacturing authorisation shall also be required for persons who perform simultaneously of separately one of the following activities: packaging, retail packaging, repackaging, labelling of medicinal products, and medicinal products intended for clinical trials.

(4) Manufacturing authorisation shall also be required for persons who perform simultaneously or separately one of the following activities: complete or partial manufacture of active substances intended for the manufacture of medicinal products and various processes of packaging, retail packaging, repackaging, and re-labelling of active substances.

(5) No manufacturing authorisation shall be required where the processes of retail packaging, mixing, or packaging are performed according to magisterial or pharmacopoeia recipe in a pharmacy.

Art. 147. (amend. – SG, 102/2012, in force from 02.01.2013) The BDA shall introduce information about the issued manufacturing authorisations of medicinal products and certificates for good production practice to be entered in the European Union database.

Art. 148. To obtain manufacturing authorisation the person according to Art. 146 must possess:

1. personnel with adequate qualification depending on the specificity of the manufactured types of medicinal products and pharmaceutical forms;

2. always at least one qualified person, who correspond to the condition of Art. 159 at any time;

3. manufacturing, control, and storage facilities for the medicinal products equipped with the required technical equipment and control laboratories.

Art. 149. The managers of manufacture and quality control of medicinal products in the manufacturing enterprises shall be:

1. persons with educational qualification master's degree in pharmacy, chemistry, or biology and at least two-year practical experience in the pharmaceutical manufacture;

2. for the manufacture of radiopharmaceuticals or medicinal products subjected to ionizing radiation – persons who comply with the requirements according to point 1 and have an additionally recognised specialty in radiobiology or radiochemistry.

3. for the manufacture of immunological medicinal products including vaccines, toxins, sera, biotechnological products, and medicinal products obtained from human plasma or human blood – persons with recognised speciality in medical haematology, medical microbiology, virology, or immunology.

Art. 150. (1) The person according to Art. 146 shall submit to the BDA a formal application as approved by the director of the Agency.

(2) Together with the application according to para 1 the applicant shall also submit:

1. diploma, document for acquired speciality, document for length of service, certificate of clean court record, and employment contract for the persons according to Art. 148, point 2, and Art. 149;

2. copies of contracts of assignment of the manufacture and/or control of the products ordered for manufacture – in the cases according to Art. 151;

3.(amend. – SG, 60/2011, in force from 5. 8. 2011) data for the Single identification code

of the trader or cooperation from the Trade register, and for the companies, registered in a EU Member State or in a state – party on the Agreement for the EEA – a document for updated registration under the national legislation, issued by a competent body of the relevant state;

4. (amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 02.01.2013)) a list of the production activities and the medicinal forms, which will be manufactured;

5. schemes of the premises for the manufacture, control, and storage and a dossier of the manufacturing capacity;

6. assessment of the environmental impact during the manufacture of the medicinal products for the cases stipulated in the Environmental Protection Act;

7. authorisation by the Nuclear Regulatory Agency where the application concerns manufacture of radiopharmaceuticals or medicinal products subjected to ionised radiation during their manufacture;

8. authorisation for the use of the premises for manufacture, control, and storage issued according to order of the Spatial Development Act or another substituting document;

9. (amend., - SG 98/10, in force from 01.01.2011, repealed - SG, 60/2011, in force from 5. 8. 2011)

10. document for paid fee, in amount determined in the tariff to Art. 21, para 2.

(3) For the manufacturing of narcotic substances and pharmaceutical forms containing such substances, the requirements of the Control on Drugs and Precursors Act shall be observed.

Art. 151. Where some aspects of the stages of manufacture or control tests within the manufacturing process shall be carried in another site of the territory of Bulgaria or abroad under contract, the persons according to Art. 146 shall be obliged to indicate the location of that site and a copy of the contract determining the responsibilities of the parties thereto with respect to the observation of the requirements of the Good Manufacturing Practice for medicinal products the obligations of the qualified person according to Art. 148, point 2.

Art. 152. (amend. – SG, 102/2012, in force fro 02.01.2013) (1) The principles and requirements for Good Manufacturing Practice for all types of medicinal products, medicinal products for clinical trials, and active substances shall be arranged by a regulation of the Minister of Health and by acts and directives, adopted by the European Commission.

(2) The principles and requirements for official risk assessment in view to establishing Good manufacturing practice for assisting substances shall be determined by the ordinance under Para. 1 and by directives, adopted by the European Commission.

Art. 153. (1) Upon receipt of an application according to Art. 150, the BDA shall assess the submitted documentation and shall conduct inspection on the spot of the location of the sites for manufacture, control, and storage including the cases according to Art. 151 to determine the compliance between the submitted documentation and the conditions for manufacture, control, and storage of the starting manufacturing materials and the finished medicinal products and their compliance with the requirements of the Good Manufacturing Practice.

(2) The expenses for the conduct of an on the spot inspection according to para 1 shall be carried out at the expenses of the applicant.

(3) For conducting of on the spot inspection according to para 1 the applicant shall pay

a fee of the amount as laid down in the tariff under Art. 21, para 2.

Art. 154. (1) Where the BDA finds omissions in the documentation submitted and/or inconsistencies between the content of the submitted documentation and the condition of

the site or the requirements for the qualification of the personnel, it shall notify the applicant in writing and give written instructions.

(2) In the cases according to para 1 the time limit under Art. 155, para 1 shall cease to run until rendering the site or documentation in compliance with the requirements.

Art. 155. (1) Within 90 days of the date of submission of the application according to Art. 150, the executive director of the BDA shall:

1. issue manufacturing authorisation or
2. state it reasoned refusal.

(2) (Amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 02.01.2013) Manufacturing authorisation shall only be issued for manufacturing activities and medical forms, medicinal products intended for clinical trials, indicated in the application and for the premises where manufacture, control, and storage shall be carried out.

(3) The deeds according to para 1 shall be delivered to the applicant.

(4) The manufacturing authorisation shall be timeless.

(5) The refusal according to para 1, point 2, shall be subject to appeal according to order of the Administrative Procedure Code.

Art. 156. (1) The manufacturing authorisation holder shall submit an application in case of change of:

1. the person according to Art. 148, point 2;
2. the persons according to Art. 149;
3. (repealed - SG, 60/2011, in force from 5. 8. 2011)
4. the location or reorganisation of some of the sites for manufacture, control, and storage;
5. (amend. - SG, 60/2011, in force from 5. 8. 2011) the manufacturing activities;
6. (amend. - SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 02.01.2013) the manufactured medicinal forms;
7. (amend. - SG, 60/2011, in force from 5. 8. 2011) the trade registration.

(2) the application according to para 1 shall be accompanied by documents associated with the change, which as laid down in the regulation according to Art. 152.

(3) (New - SG, 60/2011, in force from 5. 8. 2011) Within 14 day term from occurrence of a change of the equipment, the holder of the authorisation for manufacture shall notify the BDA in writing.

(4) (New - SG, 60/2011, in force from 5. 8. 2011) The holder of the authorisation for manufacture shall submit to the BDA a notification at the beginning of the manufacture of each new permitted for use medicinal product.

(5) (former Para. (3), SG, 60/2011, in force from 5. 8. 2011) The manufacturing authorisation shall be cancelled provided that its holder terminates his activity and he shall be obliged to notify the BDA accordingly.

Art. 157. (1) When issuing the authorisation allowing the change, the provisions of Art. 150 and 151 shall apply, whereas the time limit for issuing shall be:

1. 14 days - in the cases under Art. 156, para 1, points 1, 2 and 7 – up to 14 days;

2. (amend. - SG, 60/2011, in force from 5. 8. 2011) 30 days in the cases under Art. 156, para 1, points 4 – 6.

(2) (amend. - SG, 60/2011, in force from 5. 8. 2011) Where the changes according to Art. 156, para 1, points 4 - 6 cannot be assessed according to documents, the BDA shall conduct on the spot inspection. In such cases the term according to para 1, point 2, shall cease to run until the accomplishment of the inspection.

(3) The expenses for the conduct of the inspection on the spot according to para 2 shall be for the account of the applicant.

(4) For the conduct of an inspection on the spot according to para 2, the applicant shall pay a fee to the amount as laid down in the tariff according to Art. 21, para 2.

Art. 158. (1) The BDA shall keep a register according to Art. 19, para 1, point 1, of the issued manufacturing authorisations, which shall contain:

1. number and date of the manufacturing authorisation;

2. name, place of business, and address of administration of the person who has been granted manufacturing authorisation;

3. address of the premises for the manufacture, control, and storage of the medicinal product;

4. (amend. – SG, 102/2012, in force from 02.-1.2013) medicinal products, and forms for which the authorisation has been granted;

5. name of the person according to Art. 148, point 2;

6. names of the persons according to Art. 149;

7. date of deletion from the register of the manufacturing authorisation and the reason therefore.

(2) The data from the register of the issued manufacturing authorisations shall be published on the internet site of the BDA.

(3) Upon request of the European Commission or another regulatory body of a Member State, the BDA shall provide information for an issued manufacturing authorisation.

Art. 159. (1) The manufacturing authorisation holder shall employ on a labour contract at least one qualified person according to Art. 148, point 2, who shall be constantly at his disposal.

(2) The qualified person according to para 1 must meet the following requirements:

1. to be a master of medicine, pharmacy, chemistry, biotechnology, or biology;

2. to have at least two-year practical experience in the pharmaceutical manufacture and in conducting qualitative and/or quantitative analysis of medicinal products and active substances;

(3) Where the manufacturing authorisation holder of a medicinal product complies with the requirements according to para 2, he can perform the obligation of the qualified person.

(4) (new – SG, 102/2012, in force from 21.02.2012) The qualified person shall be responsible for the fact, that on the packing of the medicinal product the safety indicators have been written under Art. 168, Para. 8.

(5) (former Para. 4 - SG, 102/2012, in force from 21.02.2012) The qualified person shall issue a certificate for the release of each batch evidencing that the batch of the medicinal product has been manufactured and controlled in compliance with the requirements of the manufacturing

authorisation according to order of this Act.

(6) (former Para. 5 - SG, 102/2012, in force from 21.02.2012) The qualified person shall issue a certificate of release each batch certifying that the batch of the medicinal product intended for clinical trials has been manufactured and controlled in compliance with the requirements for Good Manufacturing Practice, with the manufacturing dossier of the product, and the information submitted according to Art. 110, Para. 1, point 4.

(7) (former Para. 6 - SG, 102/2012, in force from 21.02.2012) The qualified person shall keep a register of the issued release certificates for each batch of a medicinal product.

(8) (former Para. 7 - SG, 102/2012, in force from 21.02.2012) The data from the register according to Para. 6 shall be kept at least 5 years after the last entry and shall be provided to the control bodies upon request.

(9) (former Para, 8, - SG, 102/2012, in force from 21.02.2012) In case of constitution of an administrative-penal procedure for violations committed during the execution of the obligations of the qualified person, the BDA shall order the manufacturing authorisation holder to temporarily dismiss the qualified person from the position.

(10) (former Para. 9, - SG, 102/2012, in force from 21.02.2012) The criteria and requirements relating to the qualification and training of the persons according to Art. 148, point 2, shall be laid down in the regulation according to Art. 152.

Art. 160. (1) The manufacturing authorisation holder shall:

1. ensure the performance of the manufacturing operations in compliance with the requirements of the Good Manufacturing Practice and in compliance with the information according to Art. 27, Para. 1, points 7 and 8 approved from the BDA, and in the cases of medicinal products for clinical trials – in compliance with the information according to Art. 110, Para. 1, point 4 submitted to the agency by the contracting authority.

2. (amend. – SG, 102/2012, in force from 02.01.2013) use only active substances, which have been manufactured in compliance with the requirements of the Good Manufacturing Practice for active substances;

2a. (new – SG, 102/2012, in force from 02.01.2013) be certain that the assisting substances, put in the medicinal products are manufactured in compliance with the appropriate Good manufacturing practices for assisting substances, determined on the basis of an official risk assessment in compliance with the applicable directives, adopted by the European Commission;

3. ensure on a permanent basis qualified personnel for the production and control according to the requirements the regulation according to Art. 152;

4. (amend. – SG 12/11, in force from 08.02.2011) only dispose of medicinal products, which have marketing authorisation fulfilling the requirements of this Act;

5. (revoked – SG 12/11, in force from 08.02.2011);

6. immediately notify the control bodies in case of substitution of the qualified person according to Art. 148, point 2;

7. ensure access of the control bodies to the premises and the documentation at any time;

8. ensures to the qualified person according to Art. 148, point 2 the required condition to fulfill his obligations.

9. (new – SG, 102/2012, in force from 02.01.2013) inform immediately the BDA and the use authorisation holder, if information is received that the medicinal products, which fall in the scope of hi/her manufacture automation, are falsified or there are suspects for falsification, notwithstanding of the fact whether these medicinal products have been disseminated within the

frames of the legal supply or an illegal way, including through illegal sale through the services of the information society;

10 (new – SG, 102/2012, in force from 02.01.2013) check if the manufacturers, importers or traders, from whom he/she receives active substances have been register by the competent body of the Member state in which they are established;

11. (new – SG, 102/2012, in force from 02.01.2013) check up the authenticity and quality of the active and assisting substances.

(2) (new – SG, 102/2012, in force from 02.01.2013) The manufacturing authorisation holder shall perform audits in the production sites and trade with active substances for observation of the Good manufacturing practice and the Good distribution practice. The manufacture authorisation holder may sign a contract with a third person to carry out the audit on his/her behalf and on his/her account.

(3) (new – SG, 102/2012, in force from 02.01.2013) The manufacturing authorisation holder shall document the undertaken under Para.. 1, p. 2 and 2a measures.

(4) (former Para. 2 – SG, 102/2012, in force from 01.01.2013)The manufacturing authorisation holder shall keep the samples of and the documentation for the manufactured medicinal products, active substances, and medicinal products intended for clinical trials under the conditions and under the terms laid down in the regulation according to Art. 152.

(5) (former Para. 3 – SG, 102/2012, in force from 01.01.2013)The In case of a medicinal product intended for clinical trials, the manufacturing authorisation holder shall guarantee that all manufacturing operations shall be carried out in compliance with the information submitted by the contracting authority to the BDA in accordance with the regulation according to Art. 82, Para. 3.

(6) (former Para. 4 – SG, 102/2012, in force from 01.01.2013)The documentation for any deal made shall be kept for 5 years and shall contain the date, description of the medicinal product, quantity delivered, consignee's name and address, and batch number.

(7) (former Para. 5 – SG, 102/2012, in force from 01.01.2013)The manufacturing authorisation holder shall ensure and maintain a system for blocking and recall of medicinal products, which have shown discrepancies with the requirements relating to quality.

(8) (former Para. 6 – SG, 102/2012, in force from 01.01.2013)The manufacturing authorisation holder shall be obliged to block and recall the medicinal products, which have shown discrepancies with the requirements relating to quality, efficacy, and safety under the terms of the regulation according to Art. 274, Para. 1.

(9) (former Para. 7 – SG, 102/2012, in force from 01.01.2013)The manufacturing authorisation holder shall be obliged to update the manufacturing methods in compliance with the development of new technologies and the development of medicinal products for tests.

(10) (new – SG 12/11, in force from 08.02.2011,former Para. 8, amend. – SG, 102/2012, in force from 01.01.2013)) On the base of the manufacturing authorisation, issued under the procedure of this Section, its holder may perform import of auxiliary substances, needed for the manufacturing of medicinal products, enlisted in the manufacturing authorisation.

Art. 160a. (New – SG, 60/2011, in force from 5. 8. 2011) The executive director of BDA by an order shall withdraw an issued authorisation, where the conditions under Art. 148 are not evident and the requirements of the Good manufacture practice, determined under Art. 152 have not been observed.

(2) The executive director of BDA by an order shall terminate the authorisation for manufacture:

1.upon a written request of its holder;

2. in the event of termination of the activities, for which it was issued;

3.in the event of deleting the registration of the trader;

4. in the event of death of the natural persons – sole trader.

(3) The order under Para. 1 may be appealed under the Administrative – procedure Code, where the appeal shall not stop the implementation.

Section .

Import of Medicinal Products (Title, amend. – SG, 102/2012, in force from 02.01.2013)

Art. 161. (1) amend. – SG, 102/2012, in force from 02.01.2013) Import on the territory of the Republic of Bulgaria from third country of medicinal products and medicinal products intended for clinical trials from a third country within the meaning of this Act can only be carried out by natural or legal persons registered as traders according to the legislation of the Member State who has been granted import authorisation issued by the executive director of the BDA.

(2) To obtain import authorisation, the person according to Para. 1 must:

1. (amend. – SG, 102/2012, in force from 02.01.2013) at any time with at least one qualified person, who meets the requirements of art. 159, Para. 2 and 10;

2. (amend. – SG, 102/2012, in force from 02.01.2013) dispose of a quality control laboratory in compliance with the requirements of the regulation according to Art. 152 and premises for the storage of the medicinal products and medicinal products for clinical trials having the required technical equipment in compliance with the requirements of the regulation according to Art. 198.

Art. 162. (1) To obtain import authorisation, the person according to Art. 161, para 1, shall submit to the BDA a formal application as approved by the executive director of the agency.

(2) The following documents shall be annexed to the application according to para 1:

1. certificate of actual court registration, document for actual court registration respectively;

2. (amend. – SG, 102/2012, in force from 02.01.2013) list of the medicinal products and forms, which are to be imported;

3. copy of the manufacturing authorisation issued by the regulatory body of the exporting country;

4. documents certifying the circumstances according to Art. 159, para 1 and 2 for the qualified person;

5. data about the address of the laboratory on the territory of the Republic of Bulgaria for the conduct of complete quantitative and qualitative analysis at least of the active substances and of any other tests and checks required to prove the quality of any imported batch of a medicinal product in compliance with the requirements of the marketing authorisation under the terms of this Act and the address of the storage premises;

6. a contract, where the responsibilities of the parties are determined there to with respect to the observation of the principles of the Good Manufacturing Practice by the assignee and the method according to which the qualified person according to Art. 161, para 2, point 1, shall fulfil its obligations in the cases where the person according to Art. 161, para 1, does not have a laboratory of his own;

7. document for paid fee to the amount as laid down in the tariff according to Art. 21, para 2.

(3) (New - SG 71/2008, in force from 12.08.2008) In case of received application under

para 1, BDA shall assess the filed documentation and shall perform check up on the spot of the control laboratory and the premises for storage of the medicinal products and of medicinal products, intended for clinical testing, for establishing their compliance with the requirements of the Good Manufacturing Practice and of the Good Distribution Practice.

(4) (Former para 3 - SG 71/2008, in force from 12.08.2008) Where the manufacturing facilities are situated in a third country with which the European Community has a signed agreement for mutual recognition of Good Manufacturing Practice certificates, the persons according to Art. 161, para 1 shall annex to the application the address of any facility manufacturing medicinal products, active substances, or medicinal products intended for clinical trials, name, place of business and address of management of the person who has been granted manufacturing authorisation, certificate evidencing compliance of he manufacturing, control, and storage conditions with standards, which equivalent to the standards approved with the requirements pf the Good Manufacturing Practice, and the name of the qualified person.

(5) (Former para 4 - SG 71/2008, in force from 12.08.2008) In the cases different from 3, the BDA shall perform, if necessary, on the spot inspection to determine the compliance of the documentation with the manufacturing, control, and storage of the medicinal products in the country, exporter. Provided that compliance with the Good Manufacturing Practice has been established, the BDA shall issue a certificate.

(6) (Former para 5 - SG 71/2008, in force from 12.08.2008) The expenses for the conduct of an inspection on the spot according to para 4 shall be for the account of the importer.

(7) (Former para 6 - SG 71/2008, in force from 12.08.2008) For conduction an inspection on the spot according to para 4 the applicant shall pay a fee to the amount as laid down in the tariff according to Art. 21, para 2.

Art. 163. (1) The qualified person according to Art. 161, para 2, point 1, shall issue a certificate of release for each batch evidencing that the batch of a medicinal product imported from a third country has been subjected to complete quantitative and qualitative analysis, at least of the active substances, and all required tests and checks for compliance with the requirements for issuing a marketing authorisation under the terms of this Act have been performed prior to the introduction to the market on the territory of, irrespective whether the product has been manufactured in another Member State or not.

(2) Where the batch of a medicinal product imported from a third country has been subjected to the analyses according to para 1 in another Member State and is accompanied y a certificate of batch release signed by another qualified person, no conduct of control tests on the territory of the Republic of Bulgaria shall be required.

(3) Where the batch of a medicinal product imported from a third country with which the European Community has signed an agreement for mutual recognition of Good Manufacturing Practice certificates, the qualified person shall issue a certificate of batch release based in the documents accompanying the batch without obligation to perform control tests on the territory of the Republic of Bulgaria.

(4) The qualified person according to para 1, shall issue a certificate of release for each imported batch certifying that the batch of the medicinal product on the territory of the Republic of Bulgaria intended for a clinical test has been manufactured and controlled in compliance with standards, which are equivalent to the Good Manufacturing Practice and with the manufacturing dossier of the product and that all required quality analyses and tests in accordance with the information submitted by the contracting authority to the BDA according to the regulation Art. 82, para 3, have been performed.

(5) The qualified person according to Art. 161, para 2, point 1, shall issue a certificate of

release for each batch of a medicinal product used as a comparator in a clinical test conducted on the territory of the Republic of Bulgaria, which is to be imported from a third country and is not accompanied by a document evidencing that the product has been manufactured and controlled in compliance with standards equivalent to the Good Manufacturing Practice including where this medicinal product has an issued marketing authorisation.

(6) No conduct of control tests on the territory of the Republic of Bulgaria shall be required where the requirements according to para 4 or 5 have been fulfilled in another Member State or a country of the European Economic Area and a medicinal product intended for clinical trials is accompanied by a certificate of batch release signed by another qualified person.

(7) The qualified person according to para 1 shall keep the documentation for any imported batch of a medicinal product at least 5 years and shall provide it to the control bodies upon request.

(8) The import authorisation holder shall ensure and maintain a system for blocking and recall of medicinal products, which have shown discrepancies with the quality requirements.

(9) The import authorisation holder shall be obliged to block and recall medicinal products, which have shown discrepancies with the requirements of safety, and efficacy according to the regulation according to Art. 274, para 1.

(10) (amend. – SG 12/11, in force from 08.02.2011) Provisions of Art. 160, Para 1, points 4 and 7, shall also be applied with respect of import authorisation holders.

(11) The import authorisation holder shall ensure to the qualified person according to Art. 161, para 2, point 1, the required condition for the fulfilment of his obligations and shall immediately notify the control bodies of his substitution.

(12) In case of constitution of an administrative-penal procedure for violations committed during the execution of the obligations of the qualified person, the BDA shall order the import authorisation holder to temporarily dismiss the qualified person from the position.

Art. 163a. (new – SG 12/11, in force from 08.02.2011) (1) Where BDA finds incompleteness and imperfections in the submitted documentation, it shall notify in written the applicant and shall give written instructions.

(2) In the cases of Para 1, the term envisaged in Art. 164, Para 1 shall stop running until the documentation is not brought in accordance with the requirements.

Art. 164. (1) The executive director of the BDA shall issue an import authorisation within 30 days of the date of submission of the application according to Art. 162 or make a motivated refusal.

(2) The refusal according to para 1 shall be subject to appeal under the terms of the Administrative Procedure Code.

(3) The import authorisation shall only be issued for the medicinal products, forms thereof, active substances, medicinal products intended for clinical trials indicated in the application and for the premises where control and storage are to be carried out.

(4) The import authorisation is timeless.

Art. 165. (1) The import authorisation holder of a third country shall submit to the BDA in case of change of:

1. the person according to Art. 161, para 2, point 1;

2. (amend. – SG, 102/2012, in force from 02.01.2013) the medicinal products, and forms

he has been issued the import authorisation for;

3. address of the laboratory according to Art. 161, para 2, point 2;

4. trader's court registration.

(2) Documents associated with the change defined in the regulation according to Art. 152 shall be annexed to the application according to para 1.

Art. 166. (1) The provisions of Art. 164 shall be applied at the issue of the authorisation allowing the changes, whereas the terms for the issue thereof are:

1. in the cases according to Art. 165, para 1, point 1, 2, and 4 – up to 14 days;

2. in the cases according to Art. 165, para 1, point 3 – up to 30 days.

(2) Where the change according to Art. 165, para 1, point 3, cannot be assessed by documents, the BDA shall conduct inspections on the spot. In these cases the term according to para 1, point 2, shall cease to run until the accomplishment of the inspection.

(3) The expenses for the conduct of the inspection on the spot according to para 2 shall be for the account of the account of the applicant.

(4) For the conduct of the inspection on the spot according to para 2 the applicant shall pay a fee to the amount as laid down on the tariff according to Art. 21, para 2.

Art. 167. (1) The BDA shall keep a register according to Art. 19, para 1, point 2, of the issued import authorisations, which shall contain:

1. number and date of the import authorisation;

2. name, place of business and address of management of the person, who has been granted import authorisation;

3. address of the premises for the control and storage of the medicinal products;

4. (amend. – SG, 102/2012, in force from 02.01.2013) the medicinal products, and forms for which the authorisation has been obtained;

5. name of the person according to Art. 161, para 2, point 1;

6. date of deletion of the import authorisation from the register and reason thereof.

(2) Data from the register shall be published on the internet site of the BDA.

Section III.
PRODUCTION, IMPORT AND WHOLESALE TRADE WITH ACTIVE SUBSTANCES (NEW – SG, 102/2012, IN FORCE FROM 02.01.2013)

Art. 167a. (new – SG, 102/2012, in force from 02.01.2013) Manufacture, import or wholesale trade with active substance may be carried out by natural or legal persons, registered as traders under the legislation of an EU Member State and entered in to the register under Art. 167.

Art. 167b. (new – SG, 102/2012, in force from 02.01.2013) (1) For entering into the register under Art. 167d, the applicant shall submit to BDA an application according to a form, confirmed by the BDA executive director, which shall contain:

1. name, management central office of the person under Art. 167a;

2. a list of the active substances, which will be imported, manufactured or traded;

3. the activities, which the person under Art. 167a will carry out;

4. Premise addresses for the technical equipment for realizing the activity of the persons under Art. 167a;

(2) The application under Para. 1 shall have attached:

1. data about the single identification code (SIC) of the trader and for the companies, registered in an EU Member State p a document for current registration under the national legislation, issued by a competent body of the relevant state;

2. document for a paid fee under Art. 21, Para. 2.

(3) Within the term of 60 days after the application and the documents under Para. 1 and 2 are received, BDA, on the basis of the risk assessment shall:

1. enter the person under Art. 167a in the register under Art. 167d, for which shall notify, or

2. notify about the date of the inspection, carried out for establishing the compliance of the conditions for the activities under Art. 167a with the requirements of the Good manufacturing practice under Art. 152, Para. 1 and of the Good distribution practices of active substances under Art. 198.

(4) Where as a result of the inspection under Para. 3, p. 2, BDA finds out compliance with the Good manufacturing practice under Art. 152, Para. 1 and of the Good distribution practices of active substances under Art. 198, it shall enter the applicant in the register under art. 167d, for which it shall notify him/her.

(5) The expenses for performing the inspection under Para. 3, p. 2 shall be on the account of the applicant.

(6) For the inspection under Para. 3, p. 2 the applicant shall pay a fee in the amount, determined by the tariff under Art. 21, Para. 2.

(7) In the cases under Para. 3, p. 1 and Para. 4 the applicant may start to carry out his/her activity after registering in the register under Art. 167d.

Art. 167c. (new – SG, 102/2012, in force from 02.01.2013) Where within the term under Art. 167b, Para. 3 BDA fails to notify, that an inspection will be carried out, the applicant may start carrying out the activity.

Art. 167d. (new – SG, 102/2012, in force from 02.01.2013) (1) The BDA shall keep a public register of the importers, manufacturers and wholesale traders with active substances, which shall contain:

1. name management address of the person under Art. 167a;

2. list of the active substances to be imported, manufactured or traded;

3. the activities, which the person under Art. 167a will carry out;

4. 4. Premise address in which the activities will be carried out;

5. 5. Notes on the entered circumstances.

(2) The BDA shall enter in the data base under Art. 147 the information about the registered importers, manufacturers and wholesale traders of active substances.

Art. 167e. (new – SG, 102/2012, in force from 02.01.2013) (1) The person under Art. 167a shall submit to BDA yearly by 31 January a notification about changes in the information, entered in the register under Art. 167d.

(2) In case of changes, which may influence the quality or safety of the active substances, which are manufactured, imported or disseminated, the person under Art. 167a shall notify the

BDA immediately

Art. 167f. (1) (new – SG, 102/2012, in force from 02.01.2013) The manufacture, import and wholesale trade of active substances on the territory of the Republic of Bulgaria, including active substances, intended for export, shall be carried out in compliance with the Good manufacturing practice and the Good dissemination practices for active substances.

(2) The importers may import active substances only if the following conditions have been observed:

1. the active substances are manufactured in compliance with standards for Good manufacturing practice, which are at least equivalent to the ones, established in the European Union and

2. (in force from 02.07.2013) the active substances are accompanied by a written confirmation by the competent body of the state-importer, that:

a) the standards for good manufacturing practice, applicable to the object for manufacture of the exported active substances are at least equivalent to the ones, established by the European Union;

b) The relevant object for manufacture shall be subject to a regular control and in it effectively is applied the Good manufacturing practice, where this includes multiple and immediate inspections in view to guaranteeing protection of the public health, at least equal to the one in the European Union, and

c) in case of a found failure to observe the requirements, the state exporter shall inform immediately the BDA.

(3) (in force from 02.07.2013) The requirement of Para. 2, p. 2 shall not apply if the state exporter is included in the list under Art. 111b of Directive 2001/83/EC

Art. 167g. (new – SG, 102/2012, in force from 02.07.2013) (1) As an exception, where it is needed to be provided availability of medicinal products, the importer may import the active substance without a written confirmation under Art. 167f, Para. 2, p. 2 for the term, not longer than the validity term of the certificate for Good manufacturing practice, where the object for manufacture of an active substance in the state exporter has been inspected by a regular body of a Member State and it has been found, that it observes the principle and directives for Good manufacturing practice.

(2) In the cases of Para. 1, BDA shall notify the European Commission.

Art. 167h. (new – SG, 102/2012, in force from 02.01.2013) manufacturing authorisation holders, including those, who fulfill the activities under Art. 168b, Para. 2 shall be considered as manufacturers in the meaning of § 13, p. 3 of the Additional Provisions of the Act on Consumer Protection and shall bare responsibility for harms, caused by goods defects, provided in it.

Chapter six.
PACKAGING AND LEAFLETS OF MEDICINAL PRODUCTS

Art. 168 (1) Medicinal product packaging consists of primary and/or secondary packaging and patient information leaflet.

(2) (amend. - SG 61/11, in force from 10.11.2011) The secondary packaging of medicinal

products containing substances specified in the list under Art. 3, para 2, item 2 of the Control on Drugs and Precursors Act shall be marked diagonally with two red strips and the secondary packaging of medicinal products containing substances specified in the list under Art. 3, para 2, item 2 of the Control on Drugs and Precursors Act – with two blue strips. The packaging shall obligatorily contain a notice that the medicinal product shall only be dispensed by special medical prescription.

(3) (amend. – SG, 102/2012, in force from 21.12.2012) The leaflet of the medical products, included in the list under Art. 23 of Regulation (EC) N 7262004 of the European Parliament and of the Council contains information with the following text: "This medicinal product is subject to additional observation". Before the text a sign is placed in black cooler under Art. 23, Para. 5 of Regulation (EC) N 7262004 of the European Parliament and of the Council, accompanied by an explanatory note.

(4) (amend. – SG, 102/2012, in force from 21,12,2012) The leaflet of the medicinal products shall included a standard text, by which the patients are invited to report to the medical specialists or directly to BDA about every suspected unwilling medicinal reaction according to the samples in Art. 185, Para. 2, p. 4.

(5) Where a medicinal product is to be authorised for use on the territory of the Republic of Bulgaria, a marking for separate collection and recycling according to the Waste Management Act and the acts for the application thereof shall be placed in its secondary packaging.

(6) Where a medicinal product is to be authorised for use, its name on the secondary packaging, pharmaceutical form, and content of active substance in a single dose shall also be printed in the Braille's alphabet.

(7) The requirements of para 6 are not applied for vaccines and medicinal products in hospital's packages.

(8) (new – SG, 102/2012, in force from 21.12.2012) On the secondary package (if there is no such) on the initial package of the medicinal products, with the exception of radio-pharmaceutics, the following shall be placed:

1. individual identification sign for indicators of safety, which gives opportunity for the wholesale and retail traders to:

a) check up the authenticity of the medicinal product;

b) to identify separate packages.

2. a means, which may check up the package of the medicinal product if it has been faked.

Art. 168a. (new – SG, 102/2012, in force from 21.12.2012) (1). On the package of the medicinal product, which is prescribed by a doctor's prescription, safety indicators shall be placed under Art. 168, Para. 8 with the exception of the cases, in which the medicinal product has been included in the list, determined by the European Commission by a delegated act under Art. 168b.

(2) On the package of a medicinal product, which does not need doctor's prescription, no safety indicators shall be placed under Art. 168, Para. 8, with the exception of the cases, in which the medicinal product is included in the list, determined by the European Commission by a delegated act under Art. 168b, after it has been assessed, that it may be put to a risk to be faked.

(3) The BDA shall notify the European Commission:

1. about medicinal products, which do not need doctor's prescription, for which it has found that there is a risk to be faked;

2. about medicinal products, for which it has found that there is not risk to be fakes, while

accounting the following criteria:

a) price and volume of the sales of the medicinal product;

b) number and frequency of cases of faked medicinal products, registered in the frames of the European Union and in third states and change in the number and frequency of similar cases in historical plan;

c) specific characteristics of the relevant medicinal products;

d) stage of the sicknesses, whose treatment is aimed;

e) other potential risks for public health.

Art. 168b. (new – SG, 102/2012, in force from 21.12.2012) (1) The rules about the safety indicators under Art. 168, Para. 8 shall be determined by the European Commission with the delegated acts under Art. 54a, Para. 2 of Directive 2001/83/EC.

(2) The safety indicators shall not be removed nor closed partially or thoroughly, unless the following conditions have been fulfilled:

1. the manufacturing authorisation holder, before partially or thoroughly removes or closes the safety indicators, shall check whether the relevant medicinal product is authentic or it has been faked;

2. the manufacturing authorisation holder while observing the requirements of Art. 168, Para. 8 may replace the safety indicators with ones, equal to them in relation to the possibility for guaranteeing the authenticity, identification and provision of evidences for faking the medicinal product.

(3) The safety indicators shall be considered as equal, if:

1. they meet the requirements, determined by the delegated acts under Art. 54a, Para. 2 of Directive 2001/83/EC and

2. they are so effected that they allow the check of authenticity and identification of the medicinal products and provide evidences for their being faked.

(4) The replacement under Para. 2, p. 2 shall be made without opening the initial packing of the medicinal product and in compliance with the Good manufacturing practice for medicinal products.

(5) The BDA shall carry out supervision on the replacement of the safety indicators.

Art. 169. (1) The information of the packaging and the medicinal product leaflet must be in full compliance with the data in the summary of product characteristics approved by the BDA upon the issue of the marketing authorisation and must comply with the requirements set out in the regulation according to Art. 170.

(2) The information on the packaging and leaflet can be in several languages but one of these must obligatorily be Bulgarian language. The content of the information in various languages must be identical.

(3) The name of the medicinal product shall obligatorily be written in the Bulgarian language and the international non-proprietary name of the medicinal substance shall be written according to the Anatomic-Chemical-Therapeutic Classification of the WHO. The name and address of the marketing authorisation holder can be written in Latin.

(4) The information of the packaging and leaflet must be in a language comprehensible for the patient and must be readable and indelible.

(5) (new – SG 18/14) The leaflet must be produced so that to be clear and understandable, and to allow the patient to undertake adequate actions, where required, with the assistance of the health care specialists.

Art.170. (1) (former text of Art. 170 – SG, 102/2012, in force from 01.03.2012) The requirements relating to the packaging and leaflets of medicinal products shall be determined by an ordinance of the Minister of Health.

(2) (new - SG, 102/2012, in force from 01.03.2012; suppl. – SG 18/14) Where a medicinal product, permitted for use under this act, is not intended for direct supply to the patient or is not available on the market in the Republic of Bulgaria, BDA may permit its use, where some of the data, determined by the ordinance under Para. 1 has not been placed on the package or in the leaflet.

(3) (new - SG, 102/2012, in force from 01.03.2012) In the cases under Para. 2, the information on the packing and in the leaflets may not be provided in the Bulgarian language.

(4) (new - SG, 102/2012, in force from 01.03.2012) The conditions and procedure for supply of medicinal products under Para. 2 shall be determined by the ordinance under Art. 198.

Chapter seven.
CLASSIFICATION OF MEDICINAL PRODUCTS

Art. 171. (1) Depending on the method of dispensing, the medicinal products shall be classified as follows:

1. medicinal products dispensed on medical prescription;
2. medicinal products dispensed without medical prescription.

(2) The dispensing regime of a medicinal product shall be determined by the BDA in the marketing authorisation/registration certificate.

(3) The person according to Art. 26, para 1, shall indicate the dispensing regime of a medicinal product in the application for marketing authorisation/registration certificate, variation of the marketing authorisation or its renewal.

Art. 172. The medicinal products according to Art. 171, para 1, point 1, shall be divided in the following categories:

1. medicinal products with restricted medical prescription intended only for use in certain specialised fields;
2. medicinal products subject to special medical prescription;
3. medicinal products for multiple or single dispensing on the same medical prescription.

Art.173. Medicinal products, which meet the following requirements, shall be dispensed on medical prescription:

1. medicinal products, which can represent a direct or indirect danger for human health even at correct use if administered without medical observation;
2. medicinal products, which are frequently and very widely administered in a wrong manner and as a result of that can represent a threat for the people's health;
3. medicinal products containing substances the activity and/or adverse drug reactions of which require subsequent additional study;
4. medicinal products, which are usually prescribed by a physician for potential administration.

Art. 174. Medicinal products shall be subject to special medical prescription wherever

these meet one of the following conditions:

1. contain narcotic substances within the meaning of the Control on Drugs and Precursors Act in admissible for use quantities;

2. in case of incorrect use can cause significant risk of misuse, lead to drug addiction, or be used for illegal purposes;

3. contain new medicinal substances the characteristics of which are not sufficiently known and therefore these can be assigned to the group of medicinal products according to point 2.

Art. 175. Medicinal products shall be subject to limited medical prescription wherever these meet one of the following conditions:

1. are limited to administration in hospital conditions only due to limited experience with their use or in the interest of public health;

2. are intended for treatment of pathological conditions, which can only be diagnosed in therapeutic establishments, irrespective that their administration and follow-up in the course of treatment can be carried out in other healthcare establishments;

3. are intended for treatment of out-patients but their use can cause serious adverse drug reactions, which can require specialist prescribing and monitoring in the course of treatment.

Art. 176. (1) The BDA can refuse to approve the dispensing regime of a medicinal product requested by the applicant according to Art. 26, para 1, on the grounds of assessment of:

1. the maximum single dose, maximum daily dose, quantity of the active substance in one dose unit, pharmaceutical form, specific appearance of the primary product packaging, and/or

2. other specific conditions of use.

(2) The BDA can refuse to indicate the exact category of a medicinal product according to Art. 172 but pursuant to the criteria according to Art. 174 and Art. 175 shall determine whether a medicinal product shall be classified as a product dispensed only on medical prescription.

Art. 177. Medicinal products, which do not meet the requirements according to Art. 173, 174, and 175 and the criteria laid down in the regulation according to Art. 178, shall be dispensed without medical prescription.

Art. 178. The criteria for classification of medicinal products and the requirements to the documentation for changing the classification shall be determines by a regulation of the Minister of Health.

Art. 179. (1) The BDA shall draw and publish on its internet site a list of the medicinal products, which shall be dispensed on the territory of the Republic of Bulgaria on medical prescription.

(2) The list according to para 1 shall be updated annually.

Art. 180. Should new data of a medicinal product, which has a marketing authorisation/registration certificate issued, become available, the BDA shall reconsider and if necessary change the classification in accordance with the requirements of Art. 173 and the criteria laid down in the regulation according to Art. 178.

Art. 181. In the cases where a change in the classification of a given medicinal product is authorised on the grounds of significant preclinical and clinical trials, next applicants or marketing authorisation holders cannot refer within one year of the date of authorisation of the change issued by a regulatory body of a member country when submitting an application for a change in the classification of the same substance.

Art. 182. Annually the BDA shall notify the European commission and the regulatory bodies of the other Member States of changes occurred in the list according to Art. 179.

Chapter eight.
PHARMACO-VIGILANCE

Section I.
General Provisions. (new – SG, 102/2012, in force from 21.12.2012)

Art. 183. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall organize and maintain a system for pharmaco-vigilance for implementation of the obligations under this Chapter.

(2) The system under Para. 1 shall be used for collecting information about the risks of medicinal products for the patients' health and for public health. The information shall cover reports for unwilling medicinal reactions in use of a medicinal product in compliance with the confirmed short characteristics, as well as information for misuse and use, which is not in compliance with the confirmed short characteristics of the product, including information for unwilling medicinal reactions, observed while fulfilling professional duties.

(3) The BDA shall valid the process and classify the information under Para. 2, make scientific analysis of the collected data in view to an assessment of the possibilities for decreasing and preventing the risk and shall undertake the needed actions in relation to permit for use of the medicinal product.

(4) The BDA shall carry out audits of the system under Para. 1 and every 2 years shall submit to the European Commission a report with the results from them.

(5) The BDA shall apply an adequate and effective quality system in order to provide compliance of the system under Para. 1 with the requirements of this act. The minimal requirements for the quality system shall be determined by Implementation Regulation (EU) N 520/2012.

Art. 184. (amend. – SG, 102/2012, in force from 21.12.2012) (1) Medical specialists shall be obliged to immediately report to the marketing authorisation holder or to the BDA any suspected serious or unexpected adverse drug reaction and to provide upon request additional information from the vigilance of the case.

(2) The patients may report adverse medicinal reactions at any time to the medical

specialists or to BDA.

(3) In the cases under Para. 1 and 2 where the report refers to biological medicinal product, prescribed, disseminated or sold on the territory of the Republic of Bulgaria, it must be clearly identified by the reporter with its trade name and lot number or this information is provided during the additional vigilance.

Art. 185. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall maintain national internet portal for medicinal products, connected to the European internet portal for medicinal products under Art. 68, Para. 1, p. 4.

(2) The BDA shall provide through the portal under Para. 1 at least the following information:

1. the public assessment reports under Art. 53, Para. 2 and their summaries;
2. the short characteristics of the products and the leaflets;
3. summary of the risk management plans of the medicinal products, permitted for use on the territory of the Republic of Bulgaria;
4. standard forms for reporting of suspected adverse reactions by medical specialists and patients, drawn up with compliance with the requirements of Art. 25 of Regulation (EC) N 726/2004 of the European Parliament and of the Council;
5. updated list of the medicinal products under Art. 23 of Regulation (EC) N 726/2004 of the European Parliament and of the Council;
6. announcements, providing information of the wide public about suspicions about safety of usage of a certain medicinal product;
7. instructions for all ways and forms for announcements of suspected adverse medicinal reactions by medical specialists and patients.

Art. 186. (1) (amend. – SG, 102/2012, in force from 21.12.2012) The BDA shall carry out the following actions for the medicinal products, placed on the market of the Republic of Bulgaria:

1. monitoring of the result of the measures for decreasing the risk for a medical products, contained in the risk management plan;
2. monitoring of the result of implementation of conditions, indicated in Art. 55a, 56, or 56a;
3. assessment of the updating of the risk management system;
4. monitoring of the data base of Eudra Vigilance", created in compliance with Art. 24 of Regulation (EC) N 726/2004 of the European Parliament and of the Council for new risks or for change of already established and for change of the correlation benefit/risk.

Art. 187. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall inform the European Medicines Agency and the marketing authorisation holder at identification of signals for new risks or change of found risks or in case of change of the correlation benefit/risk of a medicinal products.

(2) The committee under Art. 56a, Para. 1, p. 1 shall analyze and prioritize the valid signals for new risks or for change of already found and for change of the correlation benefit/risk.

(3) Where the Committee under Art. 56a, Para. 1, p. 1 recommends follow up actions, the coordination group under Art. 77, Para. 2 or the Committee on Medicinal Products for Human Use shall draw up an opinion for regulatory actions related to the authorisation for use within the

frames of a schedule, drawn up in compliance with the seriousness and level of danger.

(4) The BDA shall apply the recommended in the opinion of the coordination group under Art. 77, Para. 2 or in the decision of the European Commission temporary and/or final measures.

Art. 188. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall inform the European Medicines Agency, the regulatory bodies of the other EU Member States and the European Commission at least 24 hours before the public announcement of the information about suspects, related to vigilance of safety of the medicinal product, unless in the cases, where protection of public health required immediate announcement of the information.

(2) The BDA shall publish information, related to active substances, contained in medicinal products, permitted for use and in other Member States by using harmonised draft announcement and schedule of the publication, proposed by the European Medicines Agency.

(3) In the cases under Para. 1 and 2 the information, containing personal data or trade secret, shall be deleted, unless the publication of this data is needed for protection of public health.

Art. 189. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The BDA may delegate some of the rights and duties under this Chapter to a regulatory body of another Member State by signing an agreement.

(2) In the cases under Para. 1, BDA shall inform the European Commission, the European Medicines Agency and the regulatory bodies of the other Member States for the delegation of the authorisations and shall publish and announcement on the internet portal under Art. 185, Para. 1 or on its internet site.

Art. 190. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder shall be obliged to dispose with a vigilance system of the medicinal safety for fulfilling his/her duty under this Chapter

(2) The marketing authorisation holder by the system of Para. 1 shall make a scientific assessment of the collected information about the safety of the medicinal products, estimate the possibilities for minimizing or preventing the risk and shall undertake the needed actions.

(3) The marketing authorisation holder shall apply adequate and effective system of quality in order to provide compliance of the system under Para. 1 with the requirements of this act. The minimal requirements for the quality system shall be determined by Implementation Regulation (EU) N 520/2012.

(4) The marketing authorisation holder shall carry out a regular audit of the system under Para. 1. Information for the basic findings of the audit shall be entered in the basic documentation of the system and shall serve for preparing a plan for applying appropriate correcting actions. This information may be deleted after the thorough implementation of the correcting actions.

Art. 191. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder shall select a qualified person with an appropriate qualification, responsible for vigilance of the medicinal safety.

(2) The person under Para. 1 shall be established on the territory of a Member State and shall be permanently at disposal of the marketing authorisation holder.

(3) In order to assist the activity of the qualified person, the marketing authorisation

holder shall select a person, established on the territory of the Republic of Bulgaria. The appointment of such a person shall not liberate the qualified person under Para. 1 from his/her responsibilities under this Chapter.

(4) The marketing authorisation holder shall produce to BDA the data under Art. 27, Para. 1, p. 12, letters "a" – "c" for the persons under Para. 1 and 3.

(5) The marketing authorisation holder shall notify BDA in case of every change in the data under Para. 4.

(6) The marketing authorisation holder shall give the data under Para. 4 to the qualified person of the European Medicines Agency.

Art. 192. (amend. – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder shall be obliged to:

1. maintain and produce upon request by the BDA the basic system document for vigilance of the medicinal safety;

2. apply the risk management system for each medicinal product;

3. carry out monitoring of the result from the measures, contained in the risk management plan, or

4. carry out monitoring of the result from fulfillment of the conditions under Art. 551, 56 or 56a;

5.update the risk management system;

6. carry out monitoring of the system data under Art. 190, Para. 1 in order to identify new risks or change of the found risks, as well as define, whether changes have occurred in the correlation benefit/risk for the observed medicinal product.

6. carry out monitoring of the system data under Art. 190, Para. 1 in order to identify new risks or change of the found risks, as well as define whether changes have occurred in the correlation benefit/risk for the observed medicinal product.

(2) The contents and the procedure for maintaining the basic documentation of the pharmaco-vigilance system shall be provided by Implementation Regulation (EU) n 520/2012.

Art. 193. (amend. – SG, 102/2012, in force from 21.12.2012) The marketing authorisation holder shall inform the BDA and the European Medicines Agency in case of identified signals about new risks or change if the found risks, or in case of change of the correlation benefit/risk of the medicinal product.

Art. 194. (amend. – SG, 102/2012, in force from 21,12,2012) (1) The marketing authorisation holder shall simultaneously or before providing for the public new information about concerns, related to pharmaco-vigilance of a certain medicinal product, permitted for use on the territory of the Republic of Bulgaria, shall notify the BDA, the European Medicines Agency and the European Commission.

(2) The information under Para. 1 shall be objective and not misleading.

(3) before disseminating information, related to pharmaco-vigilance, the marketing authorisation holder shall coordinate it in advance with BDA with the exception of the cases under Para. 1.

(4) For carrying out assessment of the information under Para. 3, a fee shall be paid in the amount, determined by the tariff under Art. 21, Para. 2.

Art. 194a. (new – SG, 102/2012, in force from 21.12.2012) (1) The principles and requirements of the Good pahrmaco-vigilance practice shall be defined by a manual, issued by the European Medicines Agency.

(2) While carrying out the pharmaco-vigilance activities, the marketing authorisation holder shall observe the good practice under Para. 1.

Section II.
Collecting and Announcing Information about Suspected Adverse Reactions. (new – SG, 102/2012, in force from 21.12.2012)

Art. 194b. (new – SG, 102/2012, in force from 21.12.2012) The marketing authorisation holder in fulfilling his/her duties under Art. 190, shall be obliged to document all reports for suspected adverse medicinal reactions, observed on the territory of the European Union or in third states, reported spontaneously by medical specialists or patients or occurred in the process of conducting post-marketing studies.

Art. 194c. (new – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder shall submit electronically to the data base "Eudra Vigilance" under Art. 24 of Regulation (EC) N 726/2004 of the European Parliament and of the Council reports about suspected adverse medicinal reactions, occurred on the territory of the EU and in third states within the term of 15 days from the date of receiving the report.

(2) The marketing authorisation holder shall submit electronically to the database "Eudra Vigilance" reports, about all suspected adverse medicinal reactions, different form the ones, indicated in Para. 1, occurred on the territory of the EU within the term of 90 days from the date of receiving the report.

(3) The marketing authorisation holder shall follow the publications in the specialised medicinal literature and shall report in the database "Eudra Vigilance" every described in it suspected adverse medicinal reaction with the exception of suspected adverse medicinal reactions of medicinal products, containing active substances, indicated in the list of Art. 27 of Regulation (EC) N 726/2004 of the European Parliament and of the Council and described in the literature sources of pharmaco-vigilance of the European Medicines Agency.

(5) The form and contents of the reports under Para. 1 – 3 shall be provided by Implementation Regulation (EU) 520/2012.

Art. 194d. (new – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall register in the system under Art. 183 all the reports about suspected adverse medicinal reactions, occurred on the territory of the Republic of Bulgaria, by medical specialists and by patients, and shall require, if needed additional information of the case vigilance.

(2) Where the reports for suspected adverse medicinal reactions on the territory of the Republic of Bulgaria have been reported by the marketing authorisation holder, he/she shall provide additional information of the case vigilance upon request by BDA.

Art. 194e. (new – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall submit electronically to the Eudra Vigilance database reports about all serious suspected adverse

medicinal reactions, occurred on the territory of the Republic of Bulgaria within the term of up to 15 days from the date of their receiving;

(2) The BDA shall submit electronically to the Eudra Vigilance database reports about all serious suspected adverse medicinal reactions, different from the ones, indicated in Para. 1, occurred on the territory of the Republic of Bulgaria within the term of 90 days from the date of receiving the report.

(3) The BDA shall submit electronically to the Eudra Vigilance database reports about suspected adverse medicinal reactions, occurred on the territory of the Republic of Bulgaria as a result of incorrect use of the medicinal product. The BDA shall inform about this fact the Ministry of Health and the professional organisations of the medical specialists.

(4) Each body or institution, to which information has been received about suspected medicinal adverse reaction on the territory of the Republic of Bulgaria, shall inform the BDA about this fact.

(5) The contents and form of the announcements and reports under Para. 1 – 3 shall be provided by the Implementation Regulation (EU) N 520/2012.

Art. 194f. (new – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall receive the submitted information by the marketing authorisation holder about serious suspected adverse medicinal reactions, occurred on the territory of the European Union, or in a third state through the Eudra Vigilance database.

(2) The requirements for monitoring of the information in the Eudra Vigilance database shall be provided by the Implementation Regulation (EU) N 520/2012.

Art. 194g. (new – SG, 102/2012, in force from 21.12.2012). In the process of the information exchange, BDA, the marketing authorisations holders and the European Medicines Agency shall cooperate about finding duplicated reports about suspected adverse medicinal reactions.

Section III.
Periodic updated reports for vigilance. (new – SG, 102/2012, in force from 21.12.2012).

Art. 194h. (new – SG, 102/2012, in force from 21.12.2012). (1) The marketing authorisation holder shall be obliged to provide electronically to the European Medicines agency periodic updated safety reports, which shall contain:

1. summarised data about the relation benefit/risk of the medicinal product, including the results from all studies in view to their potential reflection on the marketing authorisation;

2. scientific assessment of the correlation benefit/risk of the medicinal product; the assessment shall be based on all available data, including data from clinical tests for non-permitted indications and for target groups, which have not been included in the product short characteristics;

3. all the data about the volume of the sales of the medicinal product and any other information, which the marketing authorisation holder has about the volume of the prescriptions, including the approximate number of the persons, having used the medicinal product or exposed to its impact because of some other reason.

(2) The contents and form of the electronic periodic upated vigilance reports shall be provided by the Implementation Regulation (EU) N 520/2012.

(3) The information under Para. 1 shall e collected and stored in a regitr, established under Art. 25a of Regulation (EC) N 726/2004 of the European Parliament an of the Council and shall be accessible for BDA.

Art. 194i. (new – SG, 102/2012, in force from 21.12.2012). The marketing authorisations holders for registration of medicinal products under Art. 28, 30, 35 and 37 shall submit periodic updated vigilance reports in cases, where:

1. submitting a report shall be a conditions under art. 55 or 56, entered in the marketing authorisation or registration certificate, or

2. The BDA or a regulatory body if another Member State shall require this on the basis of safety considerations of the medicinal product or because of a lack o periodic updated safety reports for the active substance, contained in the medicinal product, to which marketing authorisation or registration certificate has been issued.

Art. 194k. (new – SG, 102/2012, in force from 21.12.2012). (1) The marketing authorisation/registration certificate shall determine frequency o submission of the periodic updated safety reports.

(2) The dates of submission of the reports, depending on the frequency under Para. 1 shall be calculated from the date of issuance of the marketing authorisation/registration certificate.

(3)The periodic updated safety reports shall be submitted during time intervals with the exception of the cases, where the frequency of submission of the reports is a condition for issuance of the marketing authorisation/registration certificate or it has been determined in compliance with Art. 194l, 194m and 194n:

1. every 6 months from the date of issuance of the marketing authorisation/registration certificate of a medicinal product till the date of its placement on the market;

2. every 6 months during the first 2 years from the date of placement on the market of the medicinal product;

3. once a year during the following 2 years;

4. once every 3 years after the 4th year from the date of placement on the market of the medicinal product;

(4) Apart from the cases under Para. 3, the periodic updated safety reports shall be submitted immediately upon request of BDA or a regulatory body of a Member State.

Art. 194l. (new – SG, 102/2012, in force from 21.12.2012) Where the medicinal products, which contain one and the same active substance, or combination lf one and the same active substances, have received separate marketing authorisations/ registration certificates, the frequency and the date of submitting of the periodic updated safety reports may be changed and harmonised in view to performing one assessment of these reports.

Art. 194m. (new – SG, 102/2012, in force from 21.12.2012) (1) The dates of submission of the periodic updated safety reports for the medicinal products under art. 194l shall be calculated according to the reference date of the European Union.

(2) The reference date of the EU under Para. 1 is:

1. the ate of the first marketing authorisation in the European Union of the medicinal

product, containing the relevant active substance or the relevant combination of the active substances, or

2.the earliest of the known dates of the marketing authorisations of the medicinal product, containing the relevant active substance or the relevant combination of active substances, if the date, indicated in p. 1 cannot be found.

Art. 194n. (new – SG, 102/2012, in force from 21.12.2012) (1) The marketing authorisation holder of medicinal products under Art. 194l may submit a motivated request to the Committee of Medicinal Products for human use or to the coordination group under Art. 77, Para. 2 for defining the reference date of the EU or for change of the frequency of submitting periodic updated vigilance reports on one of the following grounds:

1. reasons, related to public health;
2. in order to be avoided duplicating of an assessment;
3. in order to be reached international harmonisation.

(2) The Committee on Medicinal Products for human use, or the coordination group under Art. 77, Para. 2 after consultations with the committee under Art. 56a, Para. 1, p. 1 shall approve the request or shall make a motivated refusal.

(3) The frequency of submitting and the reference ate of the EU shall be defined after consultation with the committee under Art. 56a, Para. 1. P. 1 by:

1.The Committee on Medicinal Products for human use – where at least on of the marketing authorisations for medicinal products, containing the relevant active substance has been provided in compliance with the centralised procedure, provided in Title II, Chapter 1 of Regulation (EC) N 726/2004 of the European Parliament and of the Council, or

2. the coordination group under Art. 77, Para. 2 – for cases, different from the ones, indicated in p. 1.

(4) The list with the reference dates of the EU of the medicinal products under Art. 194l and the harmonised frequency for submitting their periodic updated vigilance reports shall be published on the European internet portal under Art. 68, Para. 1, p. 4.

(5) The marketing authorisation holder after publication of the data under Para. 4 shall produce to BDA an application for change of the marketing authorisation of the relevant medicinal product. Each change of the dates of submitting the frequency of submission of the periodic updated safety reports, defined in the marketing authorisation, shall come into force 6 months after the date of their publication.

Art. 194o. (new – SG, 102/2012, in force from 21.12.2012) (1) The BDA shall assess the periodic updated safety reports fpr the medicinal products, in order to define whether there are new risks or change of the established risks or change of the correlation benefit/risk.

(2) The BDA shall carry out single assessment of the periodic updated safety reports of the medicinal products for which the Republic of Bulgaria has fulfilled the functions of a reference state in the meaning of Art. 76 and has been defined by the coordination group under art. 77, Para. 2.

(3) A reporter from the Republic of Bulgaria shall participate in the single assessment of the periodic updated safety reports of medicinal products, where one of the products has been permitted for use under Regulation (EC) N 726/2004 of the European Parliament and of the Council and has been defined as such by the committee under Art. 56a, Para. 1, p. 1.

Art. 194p. (new – SG, 102/2012, in force from 21.12.2012) (1) In the cases under Art. 194o, Para. 2 and 3, BDA or the reporter from the Republic of Bulgaria within the term of 60 days from the date of receiving the periodic updated safety report shall draw up n assessment report and shall submit it electronically to the European Medicines Agency and to the regulatory bodies of the Member States. The marketing authorisation holder shall receive the assessment report from the European Medicines Agency.

(2) Within the term of up to 30 days from receiving the report under Para. 1, the marketing authorisation holder or the regulatory bodies of the Member States may produce their comments to the European medicines Agency and to BDA.

(3) Within the term of up to 15 days from the date of receiving the comments under Para. 2, BDA shall update the assessment report y taking into consideration all produced objections and shall submit it to the committee under Art. 56a, Para. 1, p. 1 for approval and recommendation.

(4) The European Medicines agency shall include the adopted assessment report and the recommendation of the committee under Art. 56a, Para. 1, p. 1 to the register under Art. 194h, Para. 3 and shall submit it to the marketing authorisation holder.

Art. 194q. (new – SG, 102/2012, in force from 21.12.2012). Where the Republic of Bulgaria is not a reporter in the procedure under Art. 194o, Para. 2, BDA may produce comments within the term under Art. 194p, Para. 2 to the European Medicines Agency and to the regulatory body of the Member State, which has drawn up the report.

Art. 194r. (new – SG, 102/2012, in force from 21.12.2012). (1) In case of a single assessment of periodic updated safety reports of medicinal product under Art. 194l and where neither of the marketing authorisations of these products has been issued under Regulation (EC) 726/2004 of the European Parliament and of the Council, the coordination group under Art. 77, Para. 2 within the term of up to 30 days from the date of receiving the recommendation of the committee under Art. 56a, Para. 1, p. 1 shall issue an opinion about keeping, change, termination of the relevant marketing authorisations, including a schedule for implementation of the opinion.

(2) Where the represented Member States in the coordination group under Art. 77, Para. 2 reach agreement about the action to be undertaken, BDA shall fulfill the adopted decision.

(3) Where the opinion under Para. 1 is for interruption or termination of the marketing authorisation, the BDA executive director shall issue the order.

(4) Where the opinion under Para. 1 recommends changes in the issued marketing authorisation, the marketing authorisation holder shall submit to BDA an application for change, including an updated short characteristics of the product and a leaflet, within the frames of the defined implementation schedule.

(5) Where no agreement can be reached in the coordination group under Art. 77, Para. 2, the position of the majority Member States shall be produced to the European Commission, which shall adopt a decision for change, interruption or termination of the marketing authorisation, issued by the relevant regulatory bodies of the Member States.

(6) The BDA shall apply the temporary and/or final measures of the decision under Para. 5.

Art. 194s. (new – SG, 102/2012, in force from 21.12.2012).(1) In case of single assessment of periodic updated safety reports of medicinal products under Art. 194l and where

at least one of the marketing authorisations has been issued under Regulation (EC) N 726/2004 of the European Parliament and of the Council, the Committee of the medicinal products for human use within the term of 30 days from receiving the recommendation of the committee under Art. 56a, Para. 1, p. 1 shall issue an opinion about keeping, changing, termination or interruption of the validity of the relevant marketing authorisations, including a schedule for the opinion implementation.

(2) Where the opinion under Para. 1 expresses a position for undertaking regulatory actions in relation to the marketing authorisations, the European Commission shall:

1. adopt as decision for change, termination or interruption of the marketing authorisations, issue under Regulation (EC) N 726/2004 of the European Parliament and of the Council;

2. adopt decision with a recommendation for change, termination or interruption of the marketing authorisations, issued by the relevant Member States regulatory bodies.

(3) The BDA shall apply the temporary and/or final measures of the decision under Para. 2, p. 2.

Section IV.
Urgent Procedure at European Union Level. (new – SG, 102/2012, in force from 21.12.2012)

Art. 194t. (new – SG, 102/2012, in force from 21.12.2012) (1) Urgent procedure at the level of the European Union may be initiated by the European Commission, by the European Medicines Agency or by a Member State.

(2) (amend. – SG 18/14) The BDA shall initiate an urgent procedure under this section by notification of the regulatory bodies of the other Member States, the European Medicines Agency and the European Commission where upon considerations, related with pharmaco-vigilance considers, that for a certain medicinal product, placed on the Bulgarian market, one of the following measures are needed to be undertaken:

1. termination or interruption of the marketing authorisation;

2. prohibition of distribution of the medicinal product;

3. issuing a refusal for renewing the marketing authorisation.

(3) (amend. – SG 18/14) The BDA shall initiate the procedure under Para. 2 where they are advised by the marketing authorisation holder that, for reasons related to tracing of drug safety, they terminate the distribution of the medicinal product or they have undertaken or they intend to undertake actions for its withdrawal from the market, or will not undertake actions for the renewal of the issued marketing authorisation.

(4) (amend. – SG 18/14) The BDA may initiate the procedure under par. 2 in the cases where they consider that for reasons, related to tracing of drug safety, regarding a particular medicinal product new counter-indications may be added or the recommended dose should be reduced, or the indications shall be limited.

(5) (amend. – SG 18/14) The BDA shall submit to the European Medicines Agency and to the regulatory authorities of the other Member States the entire scientific information, available to them, as well as the performed data assessment and the justifications for the initiation of the procedure pursuant to the provisions of this section.

(6) (amend. – SG 18/14) In the cases referred to par. 2 - 4 the European Medicines Agency shall notify the BDA of the initiation of the procedure, where the concerns regarding safety are related also to other medicinal products, belonging to one and the same therapeutic group or contain the same active substance with the product, indicated in the information under

par. 5 or where this medicinal product is permitted for use also in other Member States.

(7) (amend. – SG 18/14) In the cases under Para. 4, where no urgent measures are required, BDA shall apply the procedure under Art. 77 or Art. 79b.

(8) (new – SG 18/14) BDA shall inform the marketing authorisation holder of the initiation of the procedure under the provisions of this section.

Art. 194u. (new – SG, 102/2-12, in force from 21.12.2012) (1) In the cases under Art. 194s, Para. 2, where BDA considers, that urgent measures are needed to be undertaken for protection of public health, BDA may temporary to terminate the marketing authorisation and to ban the use of the medicinal product on the territory of the Republic of Bulgaria until a final decision is taken under Art. 194x or 194y.

(2) The BDA shall notify the European Medicines Agency, the European Commission and the regulatory bodies of the other Member States about the measures, undertaken under Para. 1 within the term of up to 1 working day after their application and shall indicate the grounds for that.

(3) Where the BDA participates in the procedure under this Section, upon request of the European Commission, BDA shall undertake the recommended temporary measures in relation to the marketing authorisation of the medicinal product, or where the medicinal product is permitted for use under Regulation (EC) N 726/2004 0f the European Parliament and of the Council – in relation to the very product, by the finalisation of the procedure.

Art. 194v. (new – SG, 102/2-12, in force from 21.12.2012) The BDA shall publish an announcement on the national internet portal under art. 185, Para. 1 about the way, in which the interested parties may provide information to the European internet portal under Art. 68, Para. 1,p. 4 about the medicinal product – subject of the procedure under Art. 194s and about the possibility to participate in a public discussion, if such has been announced.

Art. 194w. (new – SG, 102/2-12, in force from 21.12.2012) (1) The Committee under Art. 56a, Para. 1, p. 1 within the term of up to 60 days from the date of announcing the procedure on the European internet portal shall draw up a motivated recommendation.

(2) The marketing authorisation holder may within the term under Para. 1 provide written comments.

(3) The recommendation under Para. 1 shall be published on the European internet portal under Art. 68, Para. 1, p. 4 and shall contain one or more of the following conclusions:

1.it is not needed additional study or undertaking actions at Community level;

2. the marketing authorisation holder shall have to carry out an additional study and data analysis;

3. the marketing authorisation holder shall have to conduct safety post-marketing study with a follow up assessment of the results from it;

4. the Member State or the marketing authorisation holder shall apply measures for decreasing the risk;

5. the marketing authorisation shall have to be terminated, interrupted or a refusal for its renewal has to be issued;

6 the marketing authorisation shall have to be changed.

(4) The concrete measures under Para. 3, p. 4, as well as the conditions and restrictions, which are to be included in the marketing authorisation, shall be indicated in the recommendation.

(5) In the cases under Para. 3, p. 6, where the changes are related to change or addition of information in the short characteristics, on the packing or leaflet of the medicinal product, the recommendation shall contain the formulation of the changes or added information and the place, where it has to be put.

Art. 194x. (new – SG, 102/2012, in force from 21.12.2012) (1) Where in the scope of the procedure under Art. 194t no medicinal product has been included, permitted for use under Regulation (EC) N 726/2004 of the European Parliament and of the Council, the coordination group under Art. 77, Para. 2 on the basis of the recommendation under Art. 194v within the term of up to 30 days from the date of its receiving shall issue an opinion about the keeping, change, termination, interruption of the validity of the relevant decisions for use or refusal of their renewal, including a schedule for implementation of the opinion.

(2) Where the opinion recommends undertaking measures under Art. 194v, Para. 3, p. 5, the BDA executive director shall interrupt by an order the action or shall terminate the marketing authorisation or shall refuse its renewal.

(3) Where the opinion under Para. 1 recommends changes in the issuance of a marketing authorisation, the marketing authorisation holder shall submit an application and a leaflet to BDA for a change, including an updated short characteristics of the product and a leaflet, within the frames of the schedule for implementation.

(4) Where the opinion under Para. 1 recommends undertaking measures under Art. 194v, Para. 3, p. 2 – 4, the marketing authorisation holder shall undertake the needed actions and shall inform BDA and the regulatory bodies of the other Member States.

(5) Where within the frames of the coordination group under Art. 77, Para. 2 no agreement can be reached, the position of the majority of the Member States shall be given to the European Commission, which shall adopt a decision with a recommendation for a change, termination or interruption of the marketing authorisation, issued by the relevant regulatory bodies of the Member States.

(6) The BDA shall apply the temporary or final measures, recommended in the decision.

Art. 194y. (new – SG, 102/2012, in force from 21.12.2012) (1) Where in the scope of the procedure under Art. 194t a medicinal products has been included, permitted for use under Regulation (EC) N 726/2004 of the European Parliament and of the Council, the Committee of the medicinal products for human medicine on the basis of the recommendation under Art. 194v, Para. 3 within the term of 30 days from the date of its receiving, shall issue an opinion about keeping, change, termination, interruption of the validity of the relevant marketing authorisations or refusal for their renewal, including a schedule for implementation of the opinion.

(2) Where the opinion under Para. 1 expresses a position for undertaking regulatory action in relation to the marketing authorisations, the European Commission shall:

1. adopt a decision for change, termination or interruption the validity of the marketing authorisations, issued under Regulation (EC) N 726/2004 of the European Parliament and of the Council;

2. adopt a decision with a recommendation for a change, termination or interruption of the validity of the marketing authorisations, issued by the relevant regulatory bodies of the Member States.

(3) The BDA shall apply the recommended temporary and/or final measures in the decision of the European Commission under Para. 2, p. 2.

Art. 194z. (new – SG, 102/2012, in force from 21.12.2012) The recommendation under Art. 194v, Para. 1, the opinion under Art. 194x, Para. 1 and the decision of the European Commission under Art. 194w, Para. 5 and Art. 194x, Para. 2 shall be published on the European internet portal under Art. 68, Para. 1, p. 4.

Chapter nine.
WHOLESALE TRADE OF MEDICINAL PRODUCTS AND intermediation IN THE AREA OF THE MEDICINAL PRODUCTS (TITLE, AMEND. – SG, 71/2008, IN FORCE FROM 12.08.2008, TITLE, AMEND. – SG, 102/2012, IN FORCE FROM 02.01.2013)

Section .
Wholesale Trade of Medicinal Products

Art. 195. (1) Wholesale of medicinal products can perform natural and legal persons registered as traders pursuant to the national legislation of a Member State and possessing authorisation for such activity issued by a regulatory body of the respective Member State.

(2) Where the person according to para 1 is in possession of warehouse premises on the territory of the Republic of Bulgaria, he can perform wholesale of medicinal products after receipt of authorisation from the executive director of the BDA.

Art. 196. (1) Manufacturer of medicinal products within the meaning of this Act can only perform wholesale of the medicinal products, which he has an issued manufacturing authorisation for.

(2) Importer of medicinal products within the meaning of this Act can only perform wholesale of the medicinal products, which he has an issued import authorisation for.

Art. 197. The persons according to Art. 195 shall dispose of:

1. suitable premises, equipment and outfits, and transport vehicles ensuring correct storage, distribution, and transportation of the medicinal products in compliance with the requirements of the Good Distribution Practice;

2. personnel and responsible master-pharmacist with at least two years length of service in his speciality and whose obligations shall be laid down in the regulation according to Art. 198.

Art. 198. (amend. – SG, 102/2012, in force from 02.01.2013) The principles and requirements for the Good Distribution Practice of medicinal products and of active substances shall be adopted by an ordinance of the Minister of Health and by directives, adopted by the European Commission.

Art. 199. (1) The persons according to Art. 195, para 2, shall submit to the BDA:

1. application containing name, place of business and address of management of the trader; address and description of the premises and equipment for the storage of the medicinal products;

2. (amend. – SG, 60/2011, in force from 5. 8. 2011) data for the Single identification

code of the trader of cooperation from the Trade Register and for the companies, registered in a EU Member State or a state – party on the EEA Agreement – a document for updated registration according to the national legislation, issued by a competent body of the relevant state;

3. name, certificate of clean court record, diploma for higher education and length of service for the responsible master - pharmacist according to Art. 197, point 2, and a copy of his/her employment contract;

4. (repealed - SG, 60/2011, in force from 5. 8. 2011)

5. (repealed - SG, 60/2011, in force from 5. 8. 2011)

6. document certifying the legal grounds for the use of the premises;

7. (amend., - SG 98/10, in force from 01.01.2011) conclusion of the Regional Health Inspectorates after inspection on the spot evidencing that the health requirements in the whole sale premises according to the regulation according to Art. 198.

8. document for paid fee as laid down in the tariff Art. 21, para 2.

(2) The persons according to Art. 195, para 1, shall submit to the BDA an application accompanied by the following documents:

1. copy of the wholesale authorisation issued by a regulatory body of a Member State;

2. name and address of the contact person on the territory of the Republic of Bulgaria;

3. address of the premises for the storage of the medicinal products on the territory of the Member State.

(3) In case of wholesale of narcotic substances, as well as pharmaceutical forms containing such substances, the requirements of the Control on Drugs and Precursors Act shall also be applied.

(4) In case of wholesale of radiopharmaceuticals, an opinion of the Nuclear Regulatory Agency shall also be submitted.

Art. 200. The BDA shall assess the documentation the documentation and conduct an inspection on the spot of the sites mentioned in the application to certify their compliance with the requirements of the Good Distribution Practice.

Art. 201. (1) Provided that the BDA establishes omissions in the submitted documentation, it shall notify the applicant in writing.

(2) In the cases according to para 1 the term according to Art. 202, para 1, shall cease to run.

Art. 202. (1) In a period of 90 days of the date of submission of the application according to Art. 199, para 1, the executive director of the BDA shall issue a wholesale authorisation or make a motivated refusal.

(2) The refusal according to para 1 shall be subject to appeal under the terms of the Administrative Procedure Code.

Art. 203. In a period of 15 days of the date of submission of the documentation according to Art. 199, para 2, the executive director of the BDA shall issue a registration certificate for wholesale on the territory of the Republic of Bulgaria to the person according to Art. 195, para 1.

Art. 204. (1) The wholesale authorisation for medicinal products shall be timeless.

(2) The authorisation according to Art. 202 or the certificate according to Art. 203 shall be cancelled provided that its holder requests so from the executive director of the BDA in writing.

(3) The person according to Art. 195 shall be obliged to notify the BDA in writing within 7 days of the termination of its activities relating the wholesale of medicinal products. In such cases, the executive director of the BDA shall cancel the issued authorisations/certificates for wholesale of medicinal products.

Art. 205. (1) The BDA shall keep a register of the issued authorisations for wholesale of medicinal products according to Art. 202, para 1, which shall contain:

1. authorisation number and date;
2. name, place of business and address of management of the person who has received the authorisation;
3. address of the premises for the storage of the medicinal products;
4. the data of the respective master - pharmacist according to Art. 197, point 2;
5. list of the medicinal products containing narcotic substances, radiopharmaceuticals, immunological medicinal products, and medicinal products obtained from human plasma and human blood;
6. date of deletion of the authorisation from the register and reason therefore;
7. remarks relating to the inscribed circumstances.

(2) The BDA shall keep a register of the issued certificates according to Art. 203 for wholesale of medicinal products, which shall contain:

1. certificate number and date;
2. number of the authorisation for wholesale of medicinal products and the issuing body;
3. name, place of business and address of management of the person who has received the certificate;
4. data for the person according to Art. 199, para 2, p. 2;
5. date of deletion of the certificate from the register and reason therefore;
6. remarks relating to the inscribed circumstances.

(3) Data from the register shall be published on the internet site of the BDA.

(4) (new – SG, 102/2012, in force from 02.01.2013) The BDA shall introduce to the data base under Art. 147 information about the issued authorisations for wholesale trade with medicinal products.

(5) (new – SG, 102/2012, in force from 02.01.2013) Upon request by the European Commission or by a Member State, BDA shall provide information about an issued authorisation for wholesale trade with medicinal products.

Art. 206. (1) In case of change of the circumstances associated with the issued wholesale authorisation, its holder shall summit to the BDA an application under the terms of Art. 199 and append the documentation associated with the change.

(2) The change authorisation shall be issued under the conditions and under the terms of Art. 200-202. In case of change of the premises for storage, the term according to Art. 202 shall apply and for the other cases the term shall be 14 days.

Art. 207. (1) The wholesale authorisation holder who conducts his activity on the territory of the Republic of Bulgaria shall be obliged to:

1. at any time ensure access of the control bodies to the premises for storage of the medicinal products;

2. only trade in medicinal products authorised to the order of this Act;

3. trade in medicinal products, whose packaging and leaflets of which are in compliance with the issued marketing authorisation and under the terms of this Act and the expiry term of which has not elapsed;

4. only supply medicinal products from manufacturers, importers, and wholesalers of medicinal products who have received authorisation to perform such activity under the terms of this Act;

4a (new – SG, 102/2012, in force from 02.01.2013) check whether the received medicinal products from the persons under p. 4 have been falsified by a checkup of the safety indicators on the secondary packing;

5. supply medicinal products to other wholesale authorisation holders, pharmacies, and drugstores, opened under the terms of this Act;

6. supply medicinal products to physicians and physicians in dental medicine where a settlement has no pharmacy under the conditions and order laid down in a regulation of the Minister of Health;

6a (new – SG, 102/2012, in force from 02.01.2013) enter in the documents for supply the lot number of the supplied medicinal products;

6b (new – SG, 102/2012, in force from 02.01.2013) have an action plan in extraordinary situations, which shall contain effective measures for drawing out a medicinal product from the market upon an order of BDA or upon initiative of the manufacturer or the marketing authorisation holder of the relevant medicinal product;

6c (new – SG 18/14) provide for the supply of sufficient quantities of medicinal products for satisfying of health care needs of the individuals of the Republic of Bulgaria;

7. (amend. – SG, 102/2012, in force from 02.01.2013) keep data for each deal with received, supplied or realised by intermediation medicinal products under the form of invoices for buying and selling or in electronic mode or under any other form, as follows:

a) date of receipt and delivery;

b) name of the medicinal product;

c) received, delivered or realised quantity by intermediary;

d) name and address of the person from whom the medicinal product has been received or to whom it has been delivered;

e) batch number and number of the batch release certificate issued by the qualified person according to Art. 148, point 2 or by the qualified person according to Art. 161, Para. 2, point 1, respectively, and number of the batch release certificate issued by the BDA - in the cases according to Art. 69 and 70;

d) received or delivered quantity;

e) name and address of the person whom the medicinal product has been received from or delivered to;

8. keep purchase/sale documentation for all medicinal products;

9. observe the requirements of the Good Distribution Practice laid down in the regulation according to Art. 198.

10. (new – SG, 102/2012, in force from 02.01.2013) maintain a quality system, defining the responsibilities, processes and risk management measures, elated to his/her activity;

11. (new – SG, 102/2012, in force from 02.01.2013) inform immediately BDA and the marketing authorisation holder, where he/she has found or suspects that the medicinal product,

which has been received or offered is falsified;

12. (new – SG, 102/2012, in force from 02.01.2013) check up whether the whole sale trader, from whom has been received the medicinal product, observes the principles and directives for Good distribution practices under Art. 198, as well as if he has authorisation for wholesale trade;

13. (new – SG, 102/2012, in force from 02.01.2013) check up whether the manufacturer or importer, from whom the medicinal product is received, has authorisation for manufacture/import;

14. (new – SG, 102/2012, in force from 02.01.2013) check up whether the intermediary, through whom the medicinal product is received, meets the requirements of this Chapter.

(2) The documentation according to Para. 1, points 7 and 8 shall be kept for at least 5 years and shall be provided to the control bodies upon request.

Art. 208. (amend. – SG, 102/2012, in force from 02.01.2013) The obligations according to Art. 207, Para. 1, point 2, and Art. 209a shall also apply to the wholesalers according to Art. 203, as well as to the importers and manufacturers trading in medicinal products manufactured by them.

Art. 209. The requirements of the special provisions of other laws shall also apply to the wholesale of medicinal products containing narcotic substances or obtained from blood, or immunological products, or radiopharmaceuticals.

Art. 209a. (New - SG 71/2008, in force from 12.08.2008) (1) The wholesale traders with medicinal products may deliver medicinal products to:

1. other wholesale traders with medicinal products;

2. pharmacies and drugstores;

3. the Ministry of Defence and the Ministry of Interior for own needs, with the exception of their medical institutions, as well as the State Reserve and Military time Reserve State Agency;

4. the Ministry of Health with:

a) vaccines, tocsins and serums, needed for implementation of the Immunisation calendar of the Republic of Bulgaria, as well as during emergency epidemical situations;

b) medicinal products, intended for treatment of illnesses, which are paid as provided by the Health Act, as well as for providing the implementation of national programmes in the area of healthcare;

5. (new – SG 60/12, in force from 07.08.2012) outpatient health care institutions which have signed an agreement with the National Health Insurance Fund, with medicinal products required for performance of health activities under Art. 82, para 2, item 3 of the Health Act.

(2) Doctors and Dental doctors in the populated areas, where there are no pharmacies may be supplied with medicinal products by wholesale traders, as provided by the ordinance under Art. 207, para 1, p. 6.

Art. 209b. (new – SG, 102/2012, in force from 02.01.2013) (1) In wholesale trade of medicinal products in third states the requirements of Art. 207, Para. 1, p. 2, 5 and 6 shall not apply, as well as the requirements of Chapter Nine "a".

(2) Where the medicinal product is received directly from a third state, but jas not been imported on the territory of the Republic of Bulgaria, the requirements of Art. 207, Para. 1, p. 4 and 4a shall not apply.

(3) (new – SG 18/14) In cases referred to in par. 1 the wholesalers shall certify by relevant documents that the medicinal products are received from persons holding a permit or have got the right to supply medicinal products subject to compliance with the applicable national laws of the third country.

(4) (new – SG 18/14) Where the wholesalers supply medicinal products to persons in third countries, they certify by relevant documents that the supplies are solely for persons, holding a permit or having got the right to receive medicinal products intended for wholesaling or for supplying to individuals subject to compliance with the applicable national laws of the third country.

(5) (prev. par. 3 – SG 18/14) A wholesale trader, who delivers medicinal products to persons from third states, which have the right under the relevant national legislation to deliver medicinal products to the consumers, shall issue a document ,which shall certify:

1. date of delivery;
2. name and form of the medicinal product;
3. delivered quantity;
4. name and address of the person, to whom the medicinal product has been delivered;
5. lot number.

Art. 210. (Amend. – SG, 60/2011, in force from 5. 8. 2011) (1) The holder of the authorisation for use and the person under Art. 26, Para. 2 may provide samples of authorised medicinal products to:

1. physicians and physicians in dental medicine;
2. higher medical schools and medical colleges;

(2) In the cases according to para 1, the packaging of the medicinal products shall bear an inscription "Sample".

(3) The persons according to para 1, point 1, maid be supplied not more than two pieces of the same pharmaceutical form of a medicinal product in one calendar year in the smallest existing pack of a manufacturer, and the higher medical schools and medical colleges – only in quantities required for the purposes of the education.

(4) The holder of the authorisation for use and the person under Art. 26, Para. 2 shall keep record of all persons whom they have delivered samples to, about the type, quantity, and time of delivery and shall provide this data to the control bodies upon request.

Art. 211. (1) The wholesalers must have a system for blocking and recall of medicinal products, which have shown discrepancies with the requirements relating to quality, safety, and efficacy.

(2) The holder of approval for wholesale is duty to freeze and draw out medicinal product, which showed discrepancies with the requirement for quality, safety and efficacy based on the order, determined in the regulation according Art 274, para 1.

Art. 212. (1) The executive director of the BDA shall notify the European Commission, the regulatory bodies of the other Member States, and the European Medicines Agency for the issued wholesale authorisations, temporarily stopped, or bereaved authorisations and the

reasons therefore.

(2) (amend. – SG, 102/2012, in force from 02.01.2013) Where the executive director of the BDA has established that the person according to Art. 195, Para. 1, does not fulfill its obligations according to Art. 207, Para. 1, points 2-14, he shall notify the regulatory body of the Member State, which has issued the wholesale authorisation, as well as the European Commission.

(3) Where the regulatory body according to para 2 has temporarily stopped or bereaved the wholesale authorisation of the person according to Art. 195, para 1, it shall notify the executive director of the BDA and the European Commission.

Art. 212a (new – SG, 102/2012, in force from 02.01.2013) (1) (amend. – SG 18/14)Intermediation in the area of medicinal products may carry out natural and legal persons, registered as intermediation traders in the meaning of the Commercial Act of the Republic of Bulgaria, who have been registered for carrying out this activity by BDA.

(2) The persons under Para. 1, who wish to be registered as intermediary traders shall submit to BDA a notification according to a form, confirmed by the BDA executive director, which shall contain:

1. name, central office and management address;
2. contact data.

(3) The notification under Para. 2 shall have attached:

1. the SIC;
2. a document for a paid fee in the amount, defined by the tariff under Art. 21, Para. 2

(4) The BDA shall enter in the public register the persons, carrying out intermediation in the area of medicinal products.

(5) The persons under Para. 1 may carry out intermediation in the area of medicinal products after submitting a notification under Para. 2 to BDA.

(6) The persons under Para. 1 shall notify BDA within 7 day term after a change in some of the circumstances under Para. 2.

Art. 212b (new – SG, 102/2012, in force from 02.01.2013) (1) The persons under Art. 212a, Para. 1 shall be obliged to:

1. carry out their activity only with medicinal products, authorised for use;
2. have an action plan in extraordinary situations, which shall contain effective measures for drawing out the medicinal product from the market after a BDA order or upon initiative of the manufacturer or the marketing authorisation holder of the relevant medicinal product;
3. keep data, including the following information about each deal with medicinal product, realised via intermediation:

a) date of the deal;
b) name of the medicinal product;
c) the realised quantity vial intermediation;
d) name and address of the persons, received, and delivered the medicinal product;
e) lot number;

4. observe the requirements of the Good distribution practice, adopted by the ordinance under Art. 198;
5. maintain a quality system, determining the responsibilities, processes and management risk measures, related to his/her activity;
6. immediately inform BDA and the marketing authorisation holder, where he/she has

found or suspects that the medicinal products – subject of the intermediation, has been falsified;

7. check whether the trader holds wholesale authorisation for trade with medicinal products;

8. check up whether the manufacturer or importer holds an authorisation for manufacture/import;

9. keep the data under p. 3 for the term of at least 5 years and provide them upon request of the control bodies.

(2) The requirements to the intermediary activities in the area of the medicinal products shall be determined by the ordinance under Art. 198 and in the European Commission directives.

Section .
Parallel Import of Medicinal Products

Art. 213. Parallel import of medicinal products on the territory of the Republic or Bulgaria can be performed by a natural or legal person registered according to the Commerce Act, the legislation of a Member State, or the legislation of a state party to the Agreement on the European Economic Area after receipt of a parallel import authorisation issued by the executive director of the BDA.

Art. 214. (1) A medicinal product authorised for use in another Member State, can be imported on the territory of the Republic of Bulgaria, provided that it is identical or similar to a medicinal product authorised for use in the Republic of Bulgaria under the terms of this Act.

(2) (Amen. - SG 71/2008, in force from 12.08.2008; amend. – SG 12/11, in force from 08.02.2011) Within the meaning of Para 1, a medicinal product is identical or similar shall be the one, that has identical qualitative and quantitative composition with respect to the active substance(s), is supplied in the same pharmaceutical form, the same primary packaging, with the same graphic design of the packaging

Art. 215. (1) (Amen. And suppl. - SG 71/2008, in force from 12.08.2008) To obtain authorisation to perform parallel import on the territory of the Republic of Bulgaria, the person according to Art. 213, para 1 shall submit to the executive director of BDA an application stating the Member State from which the parallel import of the medicinal product is to be effected from.

(2) The following data and documents shall be appended to the application:

1. name, pharmaceutical form, quantity of the active substance in a dose unit of the medicinal product authorised for use in the Republic of Bulgaria;

2. name, pharmaceutical form, quantity of the active substance in a dose unit of the medicinal product intended for parallel import;

3. (suppl. – SG 12/11, in force from 08.02.2011) name of the marketing authorisation holder and the manufacturer if a person different from the marketing authorisation holder, name of the medicinal product intended for parallel import;

4. number of the marketing authorisation of the medicinal product in the Republic of Bulgaria and number of the marketing authorisation of the medicinal product in the Member State where the parallel import is to be effected from;

5. declaration for establishment of circumstances pursuant 217, issue 1;

6. copy of the patient information leaflet and a sample of the medicinal product in the form in which it is sold in the Member State where the parallel import is to be effected from,

translation of the patient information leaflet in the Bulgarian language accompanied by a declaration that the translation is in compliance with the original of the leaflet;

7. proposal for patient information leaflet of the parallel imported medicinal product accompanied by a declaration that the content of the leaflet is identical with the content of the medicinal product authorised in the Republic of Bulgaria except for the following data:

a) name and address of management of the person effecting the parallel import;

b) name of manufacturer where it is different for both products;

c) stability period where it is different for both products;

d) excipients where these are different in both products;

8. in case of repackaging:

a) sample of the parallel import product;

b) copy of the contract between the person carrying out parallel import and the persons performing partial manufacturing activity – packaging, labelling;

c) certificate of Good Manufacturing Practice where the repackaging processes are performed outside the territory of the Republic of Bulgaria;

d) where repackaging is performed by the person according to Art. 213, para 1, copy of the manufacturing authorisation issued by the regulatory body of the Member State where repackaging is to be performed;

9. document for paid fee, in the amount as laid down in the tariff according to Art. 21, para 2.

(3) (Amen. - SG 71/2008, in force from 12.08.2008) Where there are differences (in the composition of the excipients or other) between the parallel imported medicinal product and the product authorised for use on the territory of the Republic of Bulgaria, the person according to para 1 shall submit evidence that these do not affect the therapeutic qualities of the parallel imported medicinal product.

(4) In the cases according to para 3 the person according to para 1 shall point out the differences on the packaging and in the patient information leaflet of the parallel imported medicinal product.

(5) Where the person according to Art. 213, para 1, is repackaging and/or labelling the medicinal product in the Bulgarian language on the territory of the Republic of Bulgaria, it must possess a manufacturing authorisation issued by the executive director of the BDA.

(6) The parallel imported product shall be used according to the conditions of the issued marketing authorisation for the use of the medicinal product on the territory of the Republic of Bulgaria.

Art. 216. (1) The authorisation for parallel import on the territory of the Republic of Bulgaria shall be issued within 45 days of the date of submission of the documentation to the BDA.

(2) Where the BDA shall request additional documentation from the applicant, the term according to para 1 shall cease to run until receipt of the requested information.

(3) Where the BDA shall require information relating to the issue of the marketing authorisation of the imported medicinal product from the regulatory body of the Member State where the parallel import is to be effected from, the term according to para 1 shall be extended by 45 days.

(4) If the BDA does not receive the requested documentation within the term according to para 3, the procedure for the issue of a parallel import authorisation for the territory of the Republic of Bulgaria shall be terminated.

(5) The issued parallel import authorisations for the territory of the Republic of Bulgaria

shall be published on the internet site of the BDA.

(6) The parallel import authorisation shall be valid for 5 years. New authorisation shall be issued under the terms of Art. 215.

(7) The parallel import authorisation shall not be automatically cancelled where the marketing authorisation holder of the medicinal product launched on the market on the territory of the Republic of Bulgaria would withdraw it for reasons, which are not associated with a threat for the health of the population.

Art. 217. The parallel import authorisation holder shall be obliged to:

1. notify the marketing authorisation holder of the medicinal product launched on the territory of the Republic of Bulgaria of his intention to effect parallel import and provide a sample of the parallel imported medicinal product upon request;

2. keep the following information for 5 years: name and address of the person whom the parallel imported medicinal product is to be delivered to, date of delivery, delivered quantity, and batch number;

3. submit in BDA:

a) actualised patient's leaflet of parallel imported product according with the variations in issued marketing authorisation of the approved medicinal product in Republic of Bulgaria;

b)(Amen. - SG 71/2008, in force from 12.08.2008) declaration that the content of the leaflet according to letter "a" shall be identical with the content of the product leaflet, approved in Republic of Bulgaria except of the data according to Art. 215, para 2, point 7, letters "a" – "d";

4. document and report to the marketing authorisation holder and the BDA all reports of adverse drug reactions of the imported medicinal product.

Chapter nine.
"B" EXPORT OF MEDICINAL PRODUCTS (NEW – SG 18/14)

Art. 217a. (new – SG 18/14) (1) Export of medicinal products from the territory of the Republic of Bulgaria may be done by a natural person or a legal entity holding a permit for wholesale with medicinal products or by a holder of a production license.

(2) Holders of a production license may carry out export only of the medicinal products manufactured by them.

(3) Within the meaning of this Chapter, export shall also be an intra-Community supply within the European Union.

(4) Export of medicinal products included in the Positive Medicines List referred to in Art. 262, par. 1 from the territory of the Republic of Bulgaria shall take place upon notification of BDA in every individual case, where the export is being carried out by the holder of a permit for wholesale of drugs.

Art. 217b. (new – SG 18/14) The notification referred to in Art. 217a, par. 4 shall be send to the Managing Director of BDA and shall contain the following information:

1. name and registered address of the person under Art. 217a, par. 1;

2. name, pharmaceutical form and active substance quantity in a dose unit of the medicinal product intended for export;

3. reference number of the permit for wholesale of medicinal products;

4. number of packages of the medicinal product intended for export;

5. the state of destination of the export.

Art. 217c. (new – SG 18/14; declared anti-constitutional CCD No 1 of 2015 - SG 12/2015) (1) Upon receipt of a notification under Art. 217b, BDA shall request information about the medicinal product intended for export for a period of the last 6 months as from the day of the notification:

1. about the consumption of the respective medicinal product from the National Health Insurance Fund and/or from the Ministry of Health;

2. about the supplied quantities of the respective medicinal product to the Republic of Bulgaria by the holder of the marketing authorisation.

(2) The persons referred to in par. 1 shall provide the information requested by BDA within 15 days after the request.

(3) BDA shall analyze the information about the respective medicinal product, received subject to compliance with the provision of par. 2, and shall compare the information about the used quantities under par. 1, item 1 and the supplier quantities under par. 1, item 2 with the available information obtained pursuant to the provision of Art. 217b, item 4 about the number of packages intended for export.

(4) Where within 30 days as from the date of receipt of the notification under Art. 217b, the Managing Director of BDA does not object in writing the export, it shall be deemed that there is a tacit consent to the export.

(5) The Managing Director of BDA may within the term under par. 4 refuse by a justified order the export, where the analysis carried out pursuant to par. 3 has found out that:

1. the quantities of the respective medicinal product available in the Republic of Bulgaria as of the time of sending of notification under Art. 217b are not sufficient to satisfy health care needs of the people;

2. as a result of the export a temporary shortage of the quantities of the respective medicinal products needed for satisfying health care needs of the people may occur;

3. lack of sufficient quantities of the respective medicinal product for satisfying health care needs of the people may endanger seriously people's lives and health.

(6) The refusal under par. 5 shall be subject to appeal following the provisions of the Code of Administrative Procedure.

(7) Information about the export of medicinal products from the territory of the Republic of Bulgaria are published on the Internet site of BDA.

Art. 217d. (new – SG 18/14) Export of medicinal products shall take place within three months after the expiration of the term referred to in Art. 217c, par. 3.

Chapter ten.
RETAIL TRADE IN MEDICINAL PRODUCTS

Art. 218. Retail trade in medicinal products can only be conducted by pharmacies and drugstores under the terms of this Act except for the cases according to Art. 232, para 2.

Art. 219. (1) (Amend. – SG, 60/2011, in force from 5. 8. 2011) Pharmacy is a health establishment conducting the following activities: storage, preparation, packaging, control, giving out consultations, dispensing medicinal products, medical devices authorised in Republic of Bulgaria on or without medical prescription, as well as food additives, cosmetic, and sanitary-hygienic articles.

(2) (Amend. – SG, 60/2011, in force from 5. 8. 2011) The structure, order, and organisation of work in the pharmacies, the nomenclature of the medicinal products shall be laid down in a regulation of the Minister of Health.

(3) (Amen. - SG 71/2008, in force from 12.08.2008, repealed. - SG 23/2009, in force from 30.03.2009).

Art. 220. (1) The activities according to Art. 219, para 1, shall be conducted by a master - pharmacist.

(2) (Suppl. - SG 71/2008, in force from 12.08.2008) The master - pharmacy shall be obliged to fulfil a given medical prescription including pharmaceutical forms prepared according to magisterial and pharmacopoeia recipe under the terms laid down in the regulation according to Art. 221, para 1.

(3) (amend. – SG, 102/2012, in force from 02.01.2013)The assistant pharmacist can fulfill all activities according to Art. 219, Para. 1 in the presence and under the control of master - pharmacist, excluding: release of medicinal product with a prescription, control and consultancy, related to the medicinal products.

Art. 221. (1) (Former text Art. 221 - SG 71/2008, in force from 12.08.2008). The Minister of Health shall determine in an ordinance the medical specialists who can issue prescriptions, the order for prescribing of medicinal products, the term for fulfilment, as well as the cases and order where the master - pharmacist may refuse to fulfil a medical prescription.

(2) (New - SG 71/2008, in force from 12.08.2008; amend. – SG 9/11) The Bulgarian nationals and foreign nationals, who have permission to stay in the country, during their travel out of the Republic of Bulgaria, may carry or export medicinal products, intended for their treatment, under terms and conditions of the ordinance under para 1.

(3) (New - SG 71/2008, in force from 12.08.2008; amend. – SG 9/11) Foreigners, for who a visa for short-term stay on the territory of the Republic of Bulgaria, may possess medicinal products, intended only for their treatment, in quantities, determined in the ordinance under para 1.

(4) (new - SG 1/14, in force from 03.01.2014) Requirements to medical prescriptions issued upon request of a patient who intends to use them in another Member State, as well as the recognition and fulfillment of those issued in another Member State shall be carried out under the terms and conditions established by the ordinance under para 1.

(5) (new - SG 1/14, in force from 03.01.2014) Reimbursement of costs for medicinal products on medical prescriptions fulfilled in another Member State shall be subject to the terms and conditions set out by the ordinance under Art. 80e, para. 4 of the Health Insurance Act.

Art. 222. (1) (Declared for anticonstitutional by DCC 5 of 2008. - SG 65/2008, amen. - SG 71/2008, in force from 26.07.2008) Entitled to carry out retail with medicinal product, to retail trade with medicinal products shall have natural or legal person, registered as trader according to the Bulgarian legislation or the legislation of a Member State who has signed and employment contract, or a contract for managing a pharmacy with a Master of Pharmacy, and in the cases, provided by the law – with an Assistant of Pharmacy, where on the territory of the Republic of Bulgaria he/she may open not more than 4 pharmacies.

(2) (New - SG 71/2008, in force from 26.07.2008) Where the person under para 1 is Master of Pharmacy and is head of the pharmacy, it shall not be necessary a presentation of an employment contract, or a contract for managing the pharmacy.

(3) (Former para 2, amen. - SG 71/2008, in force from 26.07.2008) A person obtaining Master in pharmacy who has been granted approval for retail trade with medicinal products according to para 1 is manager of the pharmacy and he/she obligatory works in it.

(4) (Former para 3, amen. - SG 71/2008, in force from 26.07.2008) Entitled to retail trade

with medicinal products to cover its own needs provided observation of the requirement of para 1 shall have:

1. therapeutic establishments according to Art. 5 of the Medical Establishments Act that provide hospital care;

2. healthcare establishments for hospital care;

3. (amend. – SG 59/10, in force from 31.07.2010) mental health centres, skin and venereal diseases health centre, complex oncologic centres;

4. hospices with stationary according Art. 10, point 5 from the Medical Establishments Act.

(5) (New – SG, 60/2011, in force from 5. 8. 2011) For satisfying own needs, the medical establishments under Para. 4, which have no open pharmacy, may supply from a pharmacy of a medical establishment, which has received an authorisation for retail trade with medicinal products under terms and conditions, determined by the Ordinance under Art. 219, Para. 2.

(6) (Repealed., former para 4, amen. - SG 71/2008, in force from26.07.2008, former Para. 5, amend. – SG, 60/2011, in force from 5. 8. 2011) Pharmacies of therapeutic establishments for outpatient care at the Ministry of Defence and Ministry of Interior can be managed from assistant pharmacist after proposal by the corresponding administration and after issued approval from the executive director of BDA.

Art. 223. (1) Master - pharmacist and assistant pharmacist can be manager of only one pharmacy and shall obligatorily work in it.

(2) (amend. – SG 12/11, in force from 08.02.2011) Master of pharmacy or assistant pharmacist who is the manager of a pharmacy cannot be hired to work upon agreement with sole trader or trade company having as its objectives manufacture, import, wholesale or retail trade in medicinal products.

(3) The person, envisaged in Para 1, who have received authorisation to retail trade with medicinal products cannot be an owner or participate in trade companies that have as their objectives manufacture, import, or wholesale trade in medicinal products including companies of related persons within the meaning of the Commerce Act.

Art. 224. The manager of a pharmacy must:

1. be a Master in Pharmacy, respectively assistant pharmacist in the cases stipulated by the law;

2. not be deprived of the right to practice the profession;

3. not to be convicted for crimes associated with practicing his profession, for crimes against property and economy, or for intentional crimes against personality;

4. have at least one year practice like the person obtaining a master in pharmacy.

Art. 225. (1). (Amen. - SG 71/2008, in force from 26.07.2008) In settlement on the territory, which does not have another pharmacy, right for retail trade with medicinal products, shall have a person under Art. 222, para 1, who has signed an employment contract or contract for managing of the pharmacy with an Assistant Pharmacist or Master of Pharmacy with less than a year of work experience.

(2) The assistant pharmacist who has authorisation for retail trade with medicinal products according to para 1 is the manager of the pharmacy and he/she shall obligatory work in it.

(3) (New – SG, 60/2011, in force from 5. 8. 2011) Assistant – pharmacist – manager of the pharmacy under Para. 1 may perform the following activities : storage and selling without doctor's prescription permitted for use in the Republic of Bulgaria medicinal products, medical items, diet food for special medical purposes and food for babies and transitional food, as well as food supplements, cosmetic and sanitary-hygienic articles.

Art. 226. (1) Pharmacies for selling medicinal products to citizens can be opened on the territory of healthcare establishments for outpatient care.

(2) Pharmacies for selling medicinal products to citizens cannot be opened on the territory of healthcare establishments to Art. 21, para 2 of the Health Act, therapeutic establishments for hospital care, and healthcare establishments according to Art. 10 of the Medical Establishments Act.

Art. 227. (1) (Prev. text of Art. 227 – SG 102/09, in force from 22.12.2009) The requirements relating to the location and to the premises of the pharmacy shall be laid down in the regulation according to Art. 219, para 2.

(2) (New – SG 102/09, in force from 22.12.2009, amend. – SG, 60/2011, in force from 5. 8. 2011) The requirements to the structure and the premises of pharmacies as per Art. 228, para. 5 shall be set forth in an ordinance mentioned in para. 1.

Art. 228. (Amen. - SG 71/2008, in force from 26.07.2008) (1) (amend. – SG, 60/2011, in force from 5. 8. 2011) Authorisation for retail trade with medicinal product shall be issued by the executive director of BDA, on the grounds of a formal application accompanied with the following documents:

1. (amend. – SG, 60/2011, in force from 5. 8. 2011) data for the Single identification code of the trader or cooperation from the Trade register and for the companies, registered in EU Member State or in a state – party of the EEA Agreement – a document for updated registration according to the national legislation, issued by a competent body of the relevant state of the persons under Art. 222, Para. 1;

2. labour contract or a contract for managing a pharmacy, signed with a Master of Pharmacy or assistant Pharmacist;

3. copy of the act for establishing the persons under Art. 222, para 4;

4. documents, evidencing that the requirements of Art. 224 have been observed;

5. certificate of court record of the Master of Pharmacy, respectively of the assistant pharmacist indicated as manager of the pharmacy;

6. medical certificate of the Master of Pharmacy or the assistant pharmacist, manager of the pharmacy;

7. (suppl. – SG, 60/2011, in force from 5. 8. 2011; revoked - SG 48/15)

7a. (new - SG, 60/2011, in force from 5. 8. 2011) hygiene conclusion, issued by the relevant RHI;

8. document for paid state fee in the amount as laid down in the tariff according to Art. 21, para 2.

(2) (New - SG, 60/2011, in force from 5. 8. 2011) While issuing an authorisation for retail trade with medicinal products a check up shall be performed if the produced diploma of the Master Pharmacist /Assistant Pharmacist has been issued by the relevant competent institution.

(3) (Former Para. 2, amend. - SG, 60/2011, in force from 5. 8. 2011) The pharmacies of

the therapeutic establishments according to Art. 222, para 4 and 6 shall be opened and closed according to the request of the person representing the healthcare establishment;

(4) (Former Para. 3, amend. - SG, 60/2011, in force from 5. 8. 2011) For opening a pharmacy, in which medicinal products containing narcotic substances are sold, the requirements of the Control on Drugs and Precursors Act shall also be applied.

(5) (New – SG 102/09, in force from 22.12.2009, former Para. 4 - SG, 60/2011, in force from 5. 8. 2011) Authorisation for retail trade in medicinal products at a pharmacy, opened in a populated area with not more than 10 000 citizens, shall be issued on the grounds of a submitted request in a form, to which shall be attached the following documents:

1. (amend. - SG, 60/2011, in force from 5. 8. 2011) the documents referred to in para 1, items 1, - 7a and a document issued by the mayor of the respective municipality, certifying the number of citizens in the respective populated area;

2. (amend. – SG, 102/2012, in force from 02.01.20120 document for paid fee amounting to 50% of the fee, defined by the tariff under Art. 21, Para. 2 for issuance of a permit for retail sale with medicinal products under Art. 222, Para. 1.

(6) (prev. text of para 4, suppl. – SG 102/09, in force from 22.12.2009; amend., - SG 98/10, in force from 01.01.2011, former Para. 5, amend. – SG, 60/2011, in force from 5. 8. 2011) The application and the documents under para 1 and 5 shall be filed to the BDA.

(7) (prev. text of para 5, amend. – SG 102/09, in force from 22.12.2009; amend., - SG 98/10, in force from 01.01.2011, former Para. 6, amend. – SG, 60/2011, in force from 5. 8. 2011) The RHI shall issue hygiene resolution up to 14 days from the date of filing the application about this.

submit the documents under para 5 to the Ministry of Health within 3 days from issuing the

Art. 229. (1) (Repealed – SG, 60/2011, in force from 5. 8. 2011).

(2) (amend. – SG 102/09, in force from 22.12.2009, amend. – SG, 60/2011, in force from 5. 8. 2011; suppl. – SG 18/14) Within the term of 1 month after receiving the documentation under Art. 228, Para. 6, the executive director of BDA upon an issued opinion by the Expert Council for Retail Sale of Medicinal Products shall issue authorisation for retail with medicinal products or make a motivated refusal to issue an authorisation. The authorisation or refusal shall be delivered to the person who has submitted the application.

(3) (Amend. - SG, 60/2011, in force from 5. 8. 2011) Where discrepancies with or omissions in the submitted documentation have been established, within 15 day term from filing the documentation under Art. 228, Para. 6, the BDA shall perform a check up of the produced documents and shall notify the candidate in writing about the found discrepancies and omissions. In these cases the term according to para 2 shall cease to run as from the date of the notification till the elimination of the defects.

(4) (New SG. 71/2008, in force from 12. 08. 2008) In case that within 60 day term after the notification date, under para 3, the applicant fails to remove the established irregularities or incompleteness, the procedure for issuing authorisation for retail trade in medicinal products or for change of an issued authorisation shall be terminated.

(5) (Former para 4 – SG 71/2008, in force from 12, 08 2008, amend. – SG, 60/2011, in force from 5. 8. 2011). The refusal of the executive director of the BDA to issue an authorisation shall be subject to appeal under the terms of the Administrative Procedure Code.

Art. 229a. (New – SG. 23/2009, in force from 30. 03. 2009) (1) (amend. and suppl. - SG.

41/2009, in force from 02.06.2009; amend. – SG 98/10, in force from 01.01.2011, amend. – SG, 60/2011, in force from 5. 8. 2011) The BDA shall officially submit to RHI on the location of the relevant pharmacy with an authorisation, issued under Art. 229, para 2, including retail trade with food supplements, dietetic foods for special medical purposes, Infant formulas and transitional foods, copy of the authorisation for registering into the register under Art. 14, para 1 of the Foodstuffs Act.

(2) (Amen. And suppl. – SG. 41/2009, in force from 02.06.2009) The pharmacies which perform retail trade with food supplements, dietetic foods for special medical purposes, Infant formulas and reansitional foods shall be subject to control according to the Foodstuffs Act;

Art. 230. (1) (Amend. – SG, 60/2011, in force from 5. 8. 2011) The BDA shall keep a register of the issued authorisations for retail trade with medicinal products under Art. 229, para 2, which shall contain:

1. authorisation number and date;

2. name, place of business and address of management of the person who has received the authorisation;

3.(amend. – SG 12/11, in force from 08.02.2011) name and UCN of the manager of the pharmacy;

4. address of the pharmacy;

5. activities, which will be conducted in the pharmacy;

6. date of cancelling the authorisation and its deletion from the register and reason therefore;

7. remarks relating to the inscribed circumstances.

(2) (amend. – SG 12/11, in force from 08.02.2011) Data from the register shall be published on the internet site of the BDA.

Art. 231. (1) In case of change of the circumstances inscribed in the register according to Art. 230, para 1, points 2-5, the person who has received authorisation to carry out retail trade with medicinal products shall submit an application under the terms of Art. 228, para 1, and shall append the documents associated with the change.

(2) (New – SG, 60/2011, in force from 5. 8. 2011) In case of a change of the name and type of the trader, address of the pharmacy and manager of the pharmacy, a new application shall be submitted under Art. 228, Para. 1 and the charge for issuance a new authorisation for retail trade with medicinal products in a pharmacy shall be paid, determined by the tariff under Art. 21, Para. 2.

(3) (New – SG, 60/2011, in force from 5. 8. 2011) Any person, who has received an authorisation for retail trade with medicinal products under Art. 228, Para. 5, may make a change under Art. 230, Para. 1, p. 4 only in a populated place with population up to 10 000 citizens.

(4) (New – SG, 60/2011, in force from 5. 8. 2011) Where the person under Para. 3 wishes to make a change under Art. 230, Para. 1, p. 4 in a populated place with population up to 10 000 citizens, he/she shall pay the charge for issuance an authorisation for retail trade with medicinal products in a pharmacy, determined by the tariff under Art. 21, Para. 2.

(5) (Former Para. 2, - SG, 60/2011, in force from 5. 8. 2011) at issuing the authorisation allowing the change according to para 1, the provisions in Art. 229 shall be applied.

Art. 232. (1) Physicians and physicians in dental medicine can keep medicinal products

according to a list determined by the Minister of Health.

(2) Where there is no pharmacy in a settlement, the persons according to para 1 can only keep and sell medicinal products provided that they have received authorisation therefore according to an order laid down in a regulation of the Minister of Health.

Art. 233. The manager of the pharmacy takes the responsibility for the activities according to Art. 219, para 1.

Art. 234. (1) Prohibited shall be the sale of medicinal products through automatic machines except for the medicinal products indicated in a list determined to the regulation according to Art. 219, para 2.

(2) The automatic machines according to para 1 can be possession only on the persons according to Art. 222 and Art. 238, para 2.

(3) The bargain trade with drug products shall be prohibited

(4) The sale of medicinal products dispensed on medical prescription via internet shall be prohibited.

(5) (New – SG, 60/2011, in force from 5. 8. 2011) Medicinal products without doctor's prescription may be sold on internet only by a pharmacy or drug store, which have received authorisation under the terms and conditions of this Act and the ordinance under Art. 219, Para. 2, or Art. 243.

(6) (new – SG, 102/2012, in force from 02.01.2013) The pharmacies and drug stores under Para. 5 shall publish on the internet site, which is for their trade with medicinal products without doctor's prescription a general logo, recognizable for the whole EU.

(7) (new – SG, 102/2012, in force from 02.01.2013) The requirements to the general logo under Para. 6 shall be determined by a delegated act under Art. 85c, Para. 3 of Directive 2001/83/EC.

Art. 234a (new – SG, 102/2012, in force from 02.01.2013) (1) The BDA shall publish and maintain on its internet site:

1. information about the national legislation, applicable for offering medicinal products for sale on internet, including information about the fact, that there may exist differences between the Member States in relation to the classification of the medicinal products and of the conditions for their delivery;

2. information about the purpose of the general logo;

3. list of the persons, offering medicinal products for sale on internet, as well as the addresses of their internet sites;

4. general information about the risks, related to the medicinal products, delivered to the consumers via internet in violation of the ordinance under Art. 234, Para. 5.

(2) The BDA internet site under Para. 1 shall be connected with the internet site of the European Medicines Agency.

Art. 234b (new – SG, 102/2012, in force from 02.01.2013) The BDA shall participate in information campaigns, organised by the European Commission and the European Medicines Agency about the danger of falsified medicinal products.

Art. 235. (1) The authorisation to carry out retail trade with medicinal products shall be cancelled with the termination of the activity of the persons according to Art. 222.

(2) (amend. – SG, 60/2011, in force from 5. 8. 2011) The executive director of BDA shall cancel the authorisation for retail trade with medicinal products:

1. according to an application by the person who has received authorisation for carrying out retail trade with medicinal products:

2. wherever it has been established that the manager of the pharmacy does not comply with the requirements laid down in Art. 224 and 225.

(3) (Amend. – SG, 60/2011, in force from 5. 8. 2011) The persons according to Art. 222 and 225 shall notify the BDA in writing within 14 days of the termination of the activity according to para 1.

Art. 236. (1) The pharmacy cannot be closed for more than 30 days within a calendar year due to the absence of the manager.

(2) (suppl. – SG 71/2008, in force from 12.08.2008; amend. – SG 12/11, in force from 08.02.2011, amend. – SG, 60/2011, in force from 5. 8. 2011) Where the manager of the pharmacy is not in a position to fulfil his obligations due to a leave for temporary incapacity of work due to an illness, pregnancy and birth, or adoption and leave for breeding of a little child, as per Labour Code, the pharmacy can operate under the management of another master of pharmacy, respectively another assistant pharmacist, in the cases to Art. 225 complying with the requirements of Art. 224 for not more than two years. In all these cases a permission of the executive director of BDA shall be issued.

(3) The permission according to 2 shall be issued within 30 days.

Art. 237. Upon termination of the activity of the person who received authorisation to retail trade with medicinal products, the medicinal products can be sold by persons who have received authorisation for wholesale trade in medicinal products.

Art. 238. (1) Products of importance for human health and medicinal products, which are dispensed without medical prescription as laid down in lists of the Minister of Health, can be sold in a drugstore. Also, products and goods of importance for human health may be sold in drugstores, as laid down in the Ordinance under Art. 243, and medical products.

(2) Entitled for carry out retail trade with medicinal products, as opening drugstores shall have all natural or legal person registered according to the Commerce Act or the legislation of a Member State;

(3) The manager of a drugstore must be a medical specialist, who:

1.has not been deprived of the right to exercise his/her profession;

2.has not been convicted for crimes in relation to his/her profession, for crimes against property and undertaking, or for premeditated crimes against the personality;

3. has at least 1 year of professional experience in this field.

Art. 239. (1) (amend. – SG, 60/2011, in force from 5. 8. 2011) Drugstores shall be opened after registration at the relevant RHI.

(2) (amend. – SG, 60/2011, in force from 5. 8. 2011) The persons according to Art. 238,

para 2, shall submit to the RHI a registration application accompanied by the following documents:

1. (amend. – SG, 60/2011, in force from 5. 8. 2011) data for the Single identification code of the trader or cooperation from the Trade register and for the companies, registered in EU Member State or in a state – party of the EEA Agreement – a document for updated registration according to the national legislation, issued by a competent body of the relevant state of the persons under Art. 238, Para. 1;

2. education document and certificate of clean court record or the person appointed as manager of the drugstore;

3. medical certificate of the person according to point 2;

4. (repealed – SG, 60/2011, in force from 5. 8. 2011).

5. (amend., - SG 98/10, in force from 01.01.2011, repealed – SG, 60/2011, in force from 5. 8. 2011).

6. document for paid state fee to the amount as laid down in the tariff according to Art. 21, para 2.

(3) (New – SG, 60/2011, in force from 5. 8. 2011).Within 14 day term from receiving the application under Para. 2, RHI shall perform an inspection on the observation of the requirements of the Ordinance under Art. 243. In the cases, where it is found that the requirements of the Ordinance under Art. 243 have not been observed, within 7 day term after the inspection the RHI shall give instructions and shall determine term for removing them.

(4) (New – SG, 60/2011, in force from 5. 8. 2011). Within 14 day term from receiving the application and the documents under Para. 2, the director of RHI shall notify in writing the persons for finding irregularities in them and shall determine a term for their removal.

(5) (New – SG, 60/2011, in force from 5. 8. 2011). For submitting a registration application for a drug store or for performing a change under Art. 242, the relevant RHI shall collect charges in the amount, determined by the tariff under Art. 21, Para. 2.

Art. 240 (Amend. - SG, 60/2011, in force from 5. 8. 2011). Within 14 day term after the inspection under Art. 239, Para. 3 or after removing the irregularities under Art. 239, Para. 4, the director of the RDA shall issue a registration certificate for a drug store or shall give a grounded refusal for its issuance.

(2) (new – SG, 102. 2012, in force from 2.1.2013) The director of the RDA shall provide grounded refusal to issue a registration certificate to the persons under Art. 238, Para. 2, where:

1. some of the documents under Art. 239, Para. 2 has not been produced;

2. within the term under Art. 239, Para. 4 the applicant has not removed the found incompleteness.

(3) (new – SG, 102. 2012, in force from 21.12.2012) Where within the term under Para. 1 the RDA director has not issued a registration certificate of drug store or has not refused with a ground, it shall be accepted that there is a silent agreement.

(4) (new – SG, 102. 2012, in force from 21.12.2012) IN the cases under Para. 3, the applicant may begin carrying out the actions, applied for while observing Art. 29 of the Act on Restriction of the Administrative Regulation and Administration Control on Economic Activity.

(5) (former Para. 2 – SG, 102. 2012, in force from 21.12.2012) The refusal of the executive director of the RDA under Para. 1, to issue certificate of registration shall be subject to appeal under the terms of the Administrative Procedure Code.

Art. 240a (new - SG, 102. 2012, in force from 21.12.2012) (1) The RDA director shall

terminate by an order the registration of a drug store:

1. upon request of the persons, received a registration certificate for a drug store;

2. with termination of the person's activity under Art. 238, Para. 2, for which he/she shall notify the relevant RDA.

(2) Within 14-day term from termination of the activity under Para. 1, p. 2, the person under Art. 238, Para. 2 shall notify in writing the RDA.

Art. 241. (1) (Amend. - SG, 60/2011, in force from 5. 8. 2011) The relevant RHI shall keep a record of the issued certificates for a drugstore authorisation, which shall contain:

1. number and date of the issued certificate;

2. place of business and address of management of the persons who have received certificates for registration of drugstore;

3. name, personal data, and address of the manager of the drugstore;

4. address of the drugstore;

5. date of cancelling the registration and reason therefore;

6. remarks relating to the inscribed circumstances.

(2) (Amend. - SG, 60/2011, in force from 5. 8. 2011) Data of the register shall be published on the internet site of the relevant RHI.

Art. 241a. (New - SG, 60/2011, in force from 5. 8. 2011) The National register of the issued registration certificates of a drug store under Art. 19a, Para. 3 shall contain:

1. name of the relevant RHI, issued the registration certificate;

2. number and date of the issued certificate;

3. seat and address of the persons, received the registration certificate for a drug store;

4. name of the drug store manager;

5. address of the drug store;

6. date of termination of the registration and ground for that.

Art. 242. In case of change of the address of the drugstore of the manager, the person who has received the authorisation to open the pharmacy shall submit an application under the terms of Art. 239, para 2, and documents associated with the change.

Art. 243. The conditions and order for the organisation of work in a drugstore shall be paid down in a regulation of the Minister of Health.

Chapter eleven.
ADVERTISING MEDICINAL PRODUCTS

Art. 244. (1) Advertising of medicinal products shall be any form of information, provision, promotion, or offers aimed at stimulating the prescribing, sale, or use of a medicinal product and shall include:

1. advertising intended for the population;

2. advertising, intended for medical specialists;

3. visit of a medical trade representative with medical specialists;

4. provision of samples to medicinal products;

5. sponsorship of promotional meetings and scientific congresses visited by medical specialists including taking their travel and stay expenses in the respective country where the event is taking place.

(2) The following shall not be considered advertising of medicinal products:

1. text on the secondary packaging and in the patient information leaflet, which has been approved in the procedure for marketing authorisation;

2. correspondence on the occasion of a specific issue or problems associated with a given medicinal product;

3. informative announcements and instructions as to changes in the packaging, warnings for adverse drug reactions as a part of the overall safety measures for the medicinal product, trade catalogues and pricelists provided that these do not contain data of advertising character with respect to the medicinal product;

4. statements relating to human health or diseases provided that when these do not directly or indirectly bear on treatment, prophylaxis, or diagnostics with medicinal products;

5. campaigns carried out by the Ministry of Health for vaccination of the population where the associated materials do not contain data for a specific medicinal product.

Art. 245. (1) The marketing authorisation holder shall be obliged to establish a scientific unit for the proliferation of information fir the medicinal products for which he has received marketing authorisation under the terms of this Act.

(2) The marketing authorisation holder shall be obliged to:

1. guarantee that the advertising of a medicinal product is presented to the population and medical specialists in an appearance corresponding to the requirements of this chapter and in compliance with the advertising authorisation issued by the BDA;

2. have at his disposal data and materials of all advertising campaigns undertaken within the framework of his activity including information about the groups, which the advertising is intended for, about the method of its realisation, as well as the starting date of the advertising campaign;

3. guarantee the training of the medical trade representatives;

4. accurately and timely fulfil the instructions of the persons responsible for the control of advertising.

(3) The medical trade representatives must report to the scientific units according to para 1 any information about the use of the advertised medicinal products, particularly with respect of the information of adverse drug reactions communicated to them by the medical specialists.

Art. 245a. (New – SG. 71/2008, in force from 12. 08. 2008) Advertisement shall be admitted only of medicinal products, for which an authorisation has been issued under this Act.

Art. 246. (1) The content of the advertising must comply with the data of the approved during the marketing authorisation procedure summary of product characteristics and only present the indications approved therein.

(2) Advertising of a medicinal product must only bear on its correct use by objectively presenting the therapeutic indications of the medicinal product without exaggerating its therapeutic, prophylactic, and diagnostic capacities.

(3) The advertising must not contain misleading information.

(4) (New – SG. 71/2008, in force from 12.08.2008) The advertisement shall not contain proposal and/or promise for a gift and/or another property or non-property benefit.

(5) (New – SG. 71/2008, in force from 12.08.2008) A medical specialist or a person, representing himself/herself as a medical specialist shall not perform direct or indirect advertisement of medicinal products in the printed and/or electronic media, as well as in internet.

Art. 247. Advertising to the population shall only be allowed for medicinal products dispensed without medical prescription.

Art. 248. Besides the cases according to Art. 247, advertising campaigns carried out by marketing authorisation holders in connection with vaccination shall be permitted provided observation of the requirements of Art. 251, and under terms and procedure, provided for in the Ordinance under Art. 249.

Art. 248a. (New – SG. 71/2008, in force from 12.08.2008) Advertising in internet shall be prohibited of medicinal products, which are prescribed by doctor's prescription, with the e exception of advertisement campaigns of vaccination, performed as provided by Art. 248, and approved by the competent authorities.

Art. 249. The requirements to the advertising of medicinal products shall be paid down in a regulation of the Minister of Health.

Art. 250. Application for authorisation of advertising of medicinal product shall be submitted by the marketing authorisation holder of the medicinal product or a duly empowered person.

Art. 251. (1) For advertising authorisation the person according to Art. 250 shall submit to the BDA a formal application as approved by the executive director of the agency accompanied by:

1. design of the advertising;
2. notarised power of attorney issued by the marketing authorisation holder where the application shall be submitted by another person;
3. bibliographical references of the used quotations, tables, or other materials, if any;
4. document for paid fee to the amount as paid down in the tariff according to Art. 21, para 2.

(2) The presented advertising drafts - designs to Art. 1 issue 1 must be clear and if there is text, it must be understandable providing possibility to assess all of its elements - text and illustrations.

(3) Expert Council of Advertising shall be established to the BDA. It shall involve physicians and specialists with practical experience in the field of advertising. The executive director of the BDA shall appoint by an order the composition of the council, where a representatives of the Professional Ethic Commission of the Bulgarian Medical Association, Bulgarian Dental Association and Bulgarian Pharmacists Union, the amount of the remuneration

of its members, and shall approve rules for the condition and order for its work. In the Council representatives of patients organisations may be included.

(4) The council according to para 3 shall prepare examination to the advertising design and shall establish an opinion for the executive director of the BDA.

(5) In case of establishment of discrepancies between the advertising and the requirements of this Act, the BDA shall, within 7 days of the submission of the application according to para 1, give written instructions for their elimination by the applicant within one month of the notification date. This decision term shall cease to run as from the notification date till the elimination of the discrepancies.

(6) If the applicant shall not fulfil the instructions within one month of the notification date according to para 5, the authorisation procedure shall be terminated.

Art. 252. (1) The executive director of the BDA shall authorise or issue a motivated refusal of the advertising by an order within one month of the submission of the documentation according to Art. 251, para 1, on the grounds of the opinion according to Art. 251, para 4, and shall notify the marketing authorisation holder.

(2) (New – SG, 60/2011, in force from 5. 8. 2011) Where within the term under Para. 1 the executive director of BDA does not permit by an order the advertisement or fails to make a grounded refusal, it shall be accepted, that there is a silent agreement with the project of the advertisement under Art. 251, Para. 1, p. 1 and it may be disseminated.

(3) (Former, Para. 2 – SG, 60/2011, in force from 5. 8. 2011) The refusal of the executive director of the BDA shall be subject to appeal under the terms of the Administrative Procedure Code.

Art. 253. (1) The issued advertising authorisation to Art. 252, para 1 shall refer to a concrete medicinal product within the validity of its marketing authorisation.

(2) Where there have been variations in the marketing authorisation of a medicinal product resulting in changes of an authorised advertising of this product, the marketing authorisation holder shall submit to the BDA an application for change.

Art. 254. In case of change in the authorised advertising, the person according to Art. 250 shall submit an application under the terms of Art. 251.

Art. 254a. (New – SG, 60/2011, in force from 5. 8. 2011) (1) The advertisement, intended for the medical specialists shall not be permitted under Art. 250 – 252.

(2) The advertisement under Para. 1 shall be disseminated after submitting a notification to BDA, which shall contain an advertisement draft, while observing the requirements of this Chapter and the Ordinance under Art. 249.

Art. 255. (1) The proliferation of samples of medicinal products containing narcotic substances within the meaning of the Control on Drugs and Precursors Act shall be prohibited.

(2) The direct provision of samples of medicinal products to the population by medical trade representatives according to Art. 244, para 1, point 3 shall be prohibited.

Art. 256. Samples of medicinal products shall be provided to medical specialists under the conditions and order laid down in the regulation according to Art. 249.

Art. 257. (1) The medical trade representatives according to Art. 245, para 2, point 3, must have passed special education organised by the marketing authorisation holder who has employed them and must possess scientific knowledge about the presented medicinal product.

(2) During any visit, the medical trade representatives must dispose of the summary of the product characteristics and price data of the medicinal product and about the conditions of its payment and shall provide these upon request.

(3) While presenting medicinal products before medical specialists, the medical trade representatives cannot offer gifts and other material and immaterial benefits.

Chapter twelve.
REGULATION OF PRICES OF MEDICINAL PRODUCTS (TITLE, AMEND. – SG 102/2012)

Section I.
National Council on Prices and Reimbursement of Medicinal Products (new – SG, 102/2012, in force from 21.12.2012)

Art. 258. (1) (Amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) (amend. – SG 43/16) Under the Minister of Health shall be established National Council on Prices and Reimbursement of medicinal products, called hereinafter "The Council". The Council shall be a legal persons, a second level budget administrator. Its status is of a state commission with a central office in Sofia.

(2) The Council activity shall be funded by the state budget through the budget of the Ministry of Health.

(3) The Council shall be a college body and shall consist of a Chairperson and 6 members of whom 3 shall be medical doctors or Master-Pharmacists, 2 layers and 2 economists, all with at least 5 years professional practical experience. The chairperson and the Council members shall be elected and discharged by a decision of the Council of Ministers upon proposal of the Minister of Health. The chairperson shall direct the Council activity and shall represent it.

(4) The Council members shall not occupy a position or perform activity under Art. 19, Para. 6 of the Administration Act.

(5) The Council activity shall be assisted by an administration, whose structure and operation organisation shall be determined by Rules of procedure, adopted by the Council of Ministers.

Art. 259. (1) (Amend. - SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) The Council shall:

1. confirm, refuse to confirm, changes or delete a price of medicinal products under Art. 261a, Para. 1;

2. confirm, refuse to confirm, change and delete a limit price of medicinal products under Art. 261a, Para. 2;

3. register, refuse to register, change or delete prices of medicinal products, sold without doctor’s prescription under Art. 261a, Para. 3;

4. (amend. - SG 48/15) confirm, withdraw or change pharmaco-therapeutic directories, including criteria for results assessment of the applied therapy, as well as recommendations for algorithms for treatment with medicinal products, proposed by the relevant national consultants, medical scientific companies and expert councils, under terms and procedure, determined by the ordinance under Art. 261a, Para. 5;

5. include, change or exclude medicinal products of the Positive Medicine List;

6. maintain and update the Positive Medicine List;

7. (new - SG 48/15) support the reimbursement status of medicinal products every three years from their inclusion in the Positive Medicine List;

8. (new - SG 48/15) provide assistance in negotiating discounts in the cases under Art. 45 para 10, 13 and 19 of the Health Insurance Act regarding medicinal products for which applications have been submitted to be included in the Positive Medicine List.

(2) The Council shall keep public registers of:

1. the confirmed prices of the medicinal products under Art. 161a, Para. 1;

2. the confirmed limit prices of the medicinal products under Art. 261a, Para. 2;

3. the registered prices of the medicinal products under Art. 261a, Para. 3.

(3) The council shall carry out control on the sale of medicinal products with a confirmed price, limit price and registered price.

(4) The Council shall adopt the written application for confirmation or registration of a price or for including, excluding and changes of medicinal products of the Positive Medicines List under this Chapter, shall carry out checkups and studies on them and shall pronounce grounded decisions.

(5) The Council shall collect charges in the amount, defined by the tariff under Art. 21, Para. 2 for submitting applications for:

1. confirmation, registration or change in a confirmed or registered price of a medicinal product;

2. (amend. - SG 48/15) inclusionq change or maintaining the reimbursement status in a medicinal product included in the List under Art. 262, Para. 1.

Art. 259a. (New – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) The Council meetings shall be regular if more than half of the its members are present.

(2) The Council shall take decisions with a majority more than half of the total number of its members.

(3) At the Council's meetings may be invited to be present the interested parties, which shall be informed about the date and time of the meeting in which the request will be discussed.

Art. 259b. (New – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) The council shall pronounce within the term up to:

1. 60 days, where an application has been submitted for confirmation of a price under Art. 261a, Para. 1 and inclusion of the medicinal product in the Positive medicine list;

2. 30 days where an application has been submitted for a change or deletion of a medicinal product, included in the Positive medicine list;

3. 30 days where an application has been submitted for confirmation, change or deletion of a price under Art. 261a, Para. 2;

4. 30 days, where an application has been submitted for registration, change or deletion of a price under Art. 161a, Para. 3;

5. 30 days for confirmation/registration of a price of medicinal products, for which authorisation for parallel import has been received;

6. (new - SG 48/15) ninety days where an application is filed for inclusion in the Positive Medicine List of a medicinal product with a new international non-proprietary name;

7. (new - SG 48/15) sixty days where an application is filed for maintaining the the reimbursement status of a medicinal products included in the Positive Medicine List.

(2) For the medicinal products under Art. 262, Para. 5, the Council shall pronounce within the term of up to 30 days where an application has been submitted for confirmation of a price under Art. 261a, Para. 1 and including the product in the Positive medicine list.

(3) The terms under Para. 1 and 2 start to run from the date of submitting an application under the ordinance under Art. 261a, Para. 5.

Art. 259c. (New – SG, 60/2011, in force from 5. 8. 2011, repealed – SG, 102/2012, in force from 21.12.2012)

Art. 259d. (New – SG, 60/2011, in force from 5. 8. 2011, repealed – SG, 102/2012, in force from 21.12.2012).

Art. 260. (Amend. - SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) The state bodies, officials and applicants on this Chapter shall be obliged to give assistance to the Council and the employees in it while fulfilling their assigned obligations.

Art. 261. (Amend. - SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) The Council members and its employees shall be obliged not to announce circumstances and facts, known to them during fulfilling their official duties under this act, unless upon a written request by a state body, where this is provided by an act.

(2) In relation to their duties under Para. 1 the persons shall sign a declaration according to a form, confirmed by the Council chairperson.

Section II.
Regulation and registration of prices of medicinal products. Algorithms for treatment with medicinal products (new – SG, 102/2012, in force from 21.12.2012)

Art. 261a (New – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) The council shall regulate the prices of medicinal products, included in the Positive Medicines List under Art. 262, Para. 1 and paid by public means in compliance with the lowest reference prices in the Member States.

(2) The Council shall regulate the limit prices of the medicinal products, which are sold after doctor’s prescription apart from those under Para. 1 in compliance with the lowest reference prices of the Member States.

(3) The Council shall register maximum selling prices for retail trade of the medicinal products, which are sold without doctor’s prescription.

(4) The price, defined under Para. 1 shall also be the limit price of the medicinal products at their retail trade.

(5) The Council of Ministers upon proposal of the Minister of Health shall determine by an ordinance the conditions and rules for regulation of prices of medicinal products under Para. 1 for regulation of the limit prices of medicines, sold after doctor's prescription under Para. 2 at their retail trade, as well as the conditions and procedure for registration for prices of medicinal products, which are sold without doctor's prescription.

Art. 262. (Amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) (amend. SG 15/13, in force from 01.01.2014) The Positive Medicines List shall be drawn up and maintained by the Council and shall include medicinal products dispensed on medical prescription, which are necessary to cover the healthcare needs of the population and are paid by money from the budget of the NHIF, from the state budget outside the scope of the obligatory health insurance, and from the budget of the healthcare establishments according to Art. 5 of the Medical Establishments Act and from the budget of the therapeutic establishments with state and or/municipal participation, according to Art. 9 and 10 of the Medical Establishments Act with state participation.

(2) Positive Medicines List shall include medicinal products classified by pharmacological groups according to the code of the anatomo-therapeutic- chemical classification with the respective international non-proprietary names, the names, attached to them, with the respective defined daily doses/therapeutic course , reference price (value) under Art. 261a, Para. 1, limit price of the medicinal products in their retail sale, referent value for the defined daily dose/therapeutic course, value of the package, calculated on the basis of the reference value/therapeutic course for a defined daily dose and level of payment, needed for their treatment, as well as sicknesses on the international code of sickness (ICS).

(3) For the medicinal products for which there is not defined daily dose, the reference value shall be defined on the basis therapeutic course, concentration or volume.

(4) (suppl. - SG 48/15) The medicinal products in the Positive Medicines List shall be selected according to proof for effectiveness, therapeutic efficiency, safety and analysis of the pharmaco-economic indicators, provided that for medicinal products with new international non-proprietary names shall also be carried out health technology assessment. Health technology assessment shall be carried out under conditions and procedures specified by the Minister of Health

(5) Where on or more medicinal products with the same international non-patent name, medicinal form and concentration of active substance, with the exception of the medicinal products under Art. 29, have already been included in the relevant part of the Positive Medicines List, the assessment under Para. 4 shall not be made.

(6) The Positive Medicines List shall include:

1. medicinal products for treatment of diseases paid under the terms of Health Insurance Act;

2. medicinal products paid by the budget of the healthcare establishments according to Art. 5 of the Medical Establishments Act and by the budget of the therapeutic establishments according to Art. 9 and 10 of the Medical Establishments Act with state and or municipality participation;

3. medicinal products intended for treatment of AIDS, of infection diseases, of treatment of diseases out of range of Health Insurance Act, paid under the terms of Art. 82, Para. 1, point 8 from the Health Act, as well as vaccines for obligatory immunisations and re-immunisations, vaccines on special indicators and in extraordinary circumstances, specific serums, immune globulins;

4. limit price of the medicinal products under Art. 261a, Para. 4 on elements.

(7) The Ministry of Health and NHIF may make grounded proposals to the Council under Art. 258. Para. 1for re-examination of included medicinal products in the Positive Medicines List under the terms and conditions, determined by the Ordinance under Art. 261a, Para. 5.

(8) The NHIF shall pay the medicinal products under Para. 6, p. 1,under the terms and conditions of the Ordinance under Art. 45, Para. 9 of the Health Insurance Act.

(9) (new – SG 18/14; amend. - SG 48/15) The terms and conditions, the rules and the criteria for the inclusion, amendment and/or exclusion of medicinal products from the Positive Medicine List and for maintaining the reimbursement status of medicinal products shall be determined by the ordinance referred to in Art. 261a, par. 5.

(10) (new – SG 48/15) Medicinal products under Art. 45 para 10, 13 and 19 of the Health Insurance Act, regarding which no discounts were settled shall not be included in the Positive Medicine List. Contracts for discounts shall be received by the Council in order determined by the ordinance under Art. 261A, para. 5.

(11) (new – SG 48/15) Medicinal products regarding which positive assessment is not proved in the procedure under Art. 259, para. 1, p. 7 during their inclusion shall be excluded from the Positive medicines list.

Art. 262a. (New – SG, 60/2011, in force from 5. 8. 2011, repealed – SG, 102/2012, in force from 21.12.2012).

Art. 263. (Amend. – SG, 60/2011, in force from 5. 8. 2011; amend. SG 15/13, in force from 01.01.2014) With the funds from the state budget outside the scope of the obligatory health insurance may be paid medicinal products, prescribed by doctors, which have not been included in the list under Art. 262, Para. 1, needed for prophylaxis or treatment during epidemic bursts, epidemics, as well as in supposed or confirmed spreading of chemical or biological agents or nuclear radiation.

Art. 264. (Amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) (1) (suppl. – SG 18/14) With termination of the sales under Art. 54, Para. 3 of the medicinal products from the Positive Medicines List and where within the frames of the relevant international non-patent name there is no other authorised under this act medicinal products, the marketing authorisation holder shall notify in writing the Ministry of Health and the National Council of Medicinal Products Prices and Reimbursement.

(2) (suppl. – SG 18/14) The marketing authorisation holder shall also notify the Ministry of Health and the National Council of Medicinal Products Prices and Reimbursement in the cases of termination of the sale of a medicinal product whose price serves for determining the reference value within the relevant international non-patented name and pharmaceutical form.

(3) When the product under par. 1 and 2 is intended for treatment of diseases to be reimbursed under the Health Insurance Act, the marketing authorisation holder shall inform in writing the National Health Insurance Fund as well within the time periods specified in par. 4.

(4) The marketing authorisation holder shall have the obligation to effect the notification under par. 1 not later than 18 months prior to the date of discontinuation of the sales, and in the cases under par. 2 - not later than three months prior to the date of discontinuation of the sales.

(5) (suppl. - SG No. 18/14) Prior to the discontinuation of the sales under Paragraphs 1 and 2, the marketing authorisation holder shall be obliged to secure sufficient quantities of the respective medicinal product for satisfying the health needs, except for in cases where

discontinuation is based on any of the grounds referred to in Art. 276, or Art. 277 of this Act.

(6) Upon expiration of the terms under par. 4, the marketing authorisation holder shall file an application with the relevant document for deletion of the medicinal product from the Positive Medicines List.

(7) Where after the discontinuation of the sales of the medicinal product the marketing authorisation holder has failed to fulfil his obligation under par. 6, the Council under Art. 258, par. 1 shall delete it ex officio from the Positive Medicines List.

Art. 265. (1) (Suppl. – SG, 60/2011, in force from 5. 8. 2011) The Council of Ministers shall establish a Transparency Commission.

(2) The composition of the Transparency Commission shall be determined by the Council of Ministers according to a proposal by the Minister of Health. In it representatives of the Ministry of Health, the Ministry of Labour and Social Policy, the BDA, the NHIF, the Bulgarian Medical Association, Bulgarian Dental Association, Bulgarian Pharmacists Union, the professional organisation of the pharmacists, and organisations of the patients and the pharmaceutical industry are obligatory included.

(3) (Amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) A person, who is a member of the Transparency Commission shall not be a member of the Council.

(4) The Council of Ministers determines with Rules the condition and the order for work of the Transparency Commission.

Art. 266. (1) (Amend. – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012, in force from 21.12.2012) The Transparency Commission shall be a body before which decisions of the Council may be appealed.

(2) The decisions of the Transparency Commission shall be taken by a majority of two thirds of its members.

(3) The decisions of Para. 2 could be appealed under the terms of the Administrative Procedure Code and the appeal has no suspense effect.

Art. 266a. (New – SG, 60/2011, in force from 5. 8. 2011) (1) Where the treatment of a relevant sickness is without alternative in the country, for a concrete patient may be applied a medicinal products, which is authorised for use in an EU Member State, authorised for use under this Act, but is not sold on the Bulgarian market.

(2) Annually, upon proposal of the medical establishments for hospital assistance after an opinion of the relevant national consultant on the profile of the sickness, the Minister of Health shall confirm a list of the medicinal products under Para. 1, which shall contain the following information:

1. code on the anatomy-therapeutic – chemical classification;
2. international non-patent name, to which the product belongs;
3.sickness according to international code of sicknesses;
4.medicinal form and quantity active substance;
5. additional information.

(3) The list under Para. 2 shall be published on the internet site of the Ministry of Health.

(4) The terms and conditions for inclusion, changes or exclusion of medicinal products in the list under Para. 2 shall be determined by the Ordinance under Art. 9, Para. 1.

(5) The medicinal product under Para. 1 shall be supplied upon a special order of a medical establishment for hospital assistance under terms and conditions, determined by the Ordinance under Art. 9, Para. 1.

(6) The head of the medical establishment under Para. 5 shall bear responsibility for applying the treatment under Para. 1.

Chapter thirteen.
STATE CONTROL ON THE MEDICINAL PRODUCTS

Art. 267. (1) (amend., - SG 98/10, in force from 01.01.2011, suppl. – SG 102/2012, in force from 21.12.2012) The Ministry of Health shall exercise the state control on the medicinal products. The immediate management shall be executed by the chief state health inspector, the Council chairperson under Art. 258, Para. 1, the executive director of the BDA, and the directors of the regional health inspectorates (RHI) who shall be state inspectors for the control of the medicinal products.

(2) (amend., - SG 98/10, in force from 01.01.2011, suppl. – SG 102/2012, in force from 21.12.2012)) Bodies for state control of the medicinal products shall be the Council under Art. 258, Para. 1, BDA and RHI.

(3) (amend., - SG 98/10, in force from 01.01.2011, suppl. – SG 102/2012, in force from 21.12.2012) The immediate control shall be exercised by officials – inspectors and experts appointed by orders of the Council chairpersons under Art. 258, Para. 1 and of the director of the BDA or the director of corresponding RHI depending on their subjection.

(4) For the execution of their control functions, the bodies according to Para. 1 can request the assistance of the bodies of the Ministry of Interior.

Art. 267a (New – SG, 60/2011, in force from 5. 8. 2011, amend. - SG 102/2012, in force from 21.12.2012) The Executive Agency Medical Audit shall perform control for observation of the confirmed phrmaco-therapeutic guides and performing evaluation of the effectiveness of the therapy in compliance with the criteria under art. 259, Para. 1, p. 4.

Art. 268. (1) The BDA shall exercise control on:

1. (suppl. - SG 102/2012, in force from 21.12.2012)the compliance of the premises, equipment, and conditions for manufacture, control, storage, and trade in medicinal products and active substances and for the observation of the Good Manufacturing Practice for medicinal products and the Good Distribution Practice;

2. (amend. - SG 102/2012, in force from 21.12.2012) the activity of the manufacturers, importers, marketing authorisation holders, manufacturers, importers, wholesalers of medicinal products, and active substances of intermediaries in the area of medicinal products, pharmacies, and drugstores;

3. the quality, safety, and efficacy of the medicinal products;

4. the clinical trials with medicinal products and the control of the observation of the requirements of the Good Clinical Practice;

5. drug information associated with marketing and advertising authorisation;

6. (amend. - SG 102/2012, in force from 21.12.2012) the pharmaco-vigilance system of the marketing authorisation holders and for observation of the requirements of the Good practice for pharmaco-vigilance.

(2) (amend., - SG 98/10, in force from 01.01.2011) The regional health inspectorates shall exercise control over the premises, equipment, and conditions for storage of and trade in medicinal products, as well as over the activity of the wholesalers, pharmacies, and drugstores situated on the territory of the respective region.

(3) Investment projects for construction of new and/or refurbishment of existing sites associated with the manufacture of medicinal products in compliance with the rules for Good Manufacturing Practice of medicinal products shall be coordinated with the BDA.

Art. 268a. (New – SG, 60/2011, in force from 5. 8. 2011) (1) Donations of medicinal products from holders authorisation for use, producers, wholesale and retail traders and from the Bulgarian red cross may be done only after coordination of the donator with the BDA through producing an application according to a form, confirmed by the Minister of Health upon proposal of the executive director of BDA.

(2) The donations shall be done while observing the rules for Good donation practice of the World Health Organisation.

(3) Where within 10 day term from receiving the application under Para. 1, BDA fails to respond in writing to the donator, it shall be accepted, that there is a silent agreement for the donation.

(4) The medical establishments and the Bulgarian red cross shall inform BDA for the received donations of medicinal products within 7 day term from their receiving.

(5) At the end of each quarterly, the BDA shall send information to the Ministry of Health about the donations under Para, 4.

(6) For a performed donation of a medicinal product upon request of a medical establishment, intended for treatment of a concrete patient in a lifesaving situation, the donator shall inform the BDA within 7 day term from the donation.

(7) The donations under Para. 6 shall not exceed the quantity, needed for a single course of treatment.

Art. 269. (1) The control according to Art. 267 shall be exercised through inspections and laboratory tests.

(2) The inspections and laboratory tests according to Para. 1 shall be conducted:

1. in connection with issuing marketing, manufacture, and import authorisations and certificates under the terms of this Act;

2. in connection with exercising surveillance on the medicinal products market;

3. in case of application on the part of the European Commission, the European Medicines Agency, or on the part of a competent body of another Member State;

4. in case of application on the part of a manufacturer, importer, or marketing authorisation holder outside the cases according to point 1.

(3) (amend. – SG, 102/2012, in force from 21.12.2012) The BDA shall conduct inspections:

1. of manufacturers of medicinal products, placed on the territory of the Republic of Bulgaria of a Member State or in third states;

2. of importers and wholesale traders of medicinal products;

3. of the manufacturers, importers and wholesale traders of active substances premises, placed on the territory of the Republic of Bulgaria;

4. of premises of manufacturers or wholesale traders of active substances, placed in third states, as well as of manufacturers or importers of auxiliary substances;

5. of premises of marketing authorisation holders of medicinal products and of intermediaries in the area of medicinal products, registered under Art. 212a;

6. as a part of the certification procedure, which in connection with European Pharmacopoeia monographs.

7. of manufacturers of exit materials upon written request of the manufacturer.

(4) The BDA shall conduct inspections of manufacturers of medicinal products established in a third country in connection with a submitted application for receipt of marketing or import authorisation.

(5) (amend. – SG, 102/2012, in force from 21.12.2012) The inspections under Para. 3 and 4 shall be carried out in compliance with directives, adopted by the European Commission.

(6) (amend. – SG, 102/2012, in force from 21.12.2012(The BDA shall participate upon request of the European Commission, the European Medicines Agency or a Member State while carrying out inspections under Para. 3 in the EU or in third states.

(7) (amend. – SG, 102/2012, in force from 21.12.2012) The BDA shall cooperate and exchange information with European Medicines Agency while planning and carrying out the inspections under Para. 3.

(8) (new – SG, 102/2012, in force from 21.12.2012) The BDA shall cooperation with the European Medicines Agency in coordination of inspections in third states.

Art. 269a. (new - SG, 102/2012, in force from 21.12.2012) (1) The officials under Art. 267, Para. 3 shall draw up a report for each carried out inspection under Art. 269, Para. 3 and 4 for observing the principles and directions for Good manufacturing practice or for Good distribution practices or for observation of the requirements of Chapter Eight, as well as the requirements of this act.

(2) The report under Para. 1 shall be given to the checked person, who can provide notes on it.

(3) with receiving a grounded request, BDA shall submit electronically the reports under Para. 1 to the competent body of another Member State or to the European Medicines Agency.

Art. 269b. (new – SG, 102/2012, in force from 21.12.2012) (1) Where as a result of carried out inspections under Art. 269, Para. 3 compliance with the Good manufacturing practice is found, or the Good distribution practices where applicable, BDA shall issue to the manufacturer, importer or wholesale trader a certificate for Good manufacturing practice or certificate for Good distribution practice within the term of 90 days from the inspection.

(2) Where as a result of a carried out inspection under Art. 269, Para. 3 it is found that the manufacturer, importer or wholesale trader of medicinal products or active substances fails to observe the requirements of the act and/or principles and directives of Good manufacturing practice and/or Good distribution practice, BDA shall issue an incompliance opinion.

(3) The BDA shall introduce to the data base under Art. 147 the issued certificates under Para. 1 and information under Para. 2.

Art. 269c. (new – SG, 102/2012, in force from 21.12.2012) (1) Where as a result of an inspection under Art. 270, Para. 1, p. 5 it is found that the marketing authorisation holder fails to observe the requirements of Chapter Eight, BDA shall give prescriptions for removal of the incompliance.

(2) In the cases under Para. 1, BDA shall notify the Member States, the European

medicines Agency and the European Commission.

Art. 270. (1) Within the framework of their competence, the officials according to Art. 267, Para. 3, shall be entitled to:

1. (amend. - SG, 102/2012, in force from 21.12.2012) Access to all documents, connected to the subject of the inspection, as well as documents, connected directly and indirectly with violation of this Act or of legislation of the Member States, implementing requirements of Directive 2001/83/EC of the European Parliament and the Council for approval of the Community code concerning medicinal products for human use, as last amended by Directive 2004/27/EC of the European Parliament and the Council, independently from the form of the document;

2. order of each person to present information for violations according to point 1, which are familiar to him;

2a (new - SG, 102/2012, in force from 21.12.2012) inspect the manufacture and trade sites of manufacturers of medicinal products, active or auxiliary substances, as well as the laboratories, used by manufacture or import authorisation holders;

3. at any time inspect the sites subject to control and require, check, or make copies of all documents relating to the overall activity of the controlled site;

4. take samples of medicinal products, active substances, and percipients for laboratory tests;

5. (amend. - SG, 102/2012, in force from 21.12.2012) inspect the premises, archives, records, and documents and the basic documentation of the pharmaco-vigilance of the marketing authorisation holder or persons, who have been assigned to carry out the activities under Chapter Eight;

6. (new - SG, 102/2012, in force from 21.12.2012) carry out inspection about the observation of confirmed prices, limit prices or registered prices during sale of medicinal products;

7. (former Art. 6 - SG, 102/2012, in force from 21.12.2012) draw up statements of administrative infringements.

(2) (repealed - SG, 102/2012, in force from 21.12.2012).

(3) (amend., - SG 98/10, in force from 01.01.2011) The Executive Director of BDA of the corresponding director of RHI, depending of the administrative person, who determined the violence, has right to:

1. order in written form to the violator to cease the violation according to Para. 1, point 1;

2. requires from the violator to declare that it will cease the violation according to Para. 1, point 1 and when it is necessary to makes the declaration matter publicly available.

3. to order cease or prohibition of each violation according to Para. 1, point 1 and when it is necessary to order for cease or prohibition of violation matter publicly available.

(4) (new - SG, 102/2012, in force from 21.12.2012). The Council chairperson under Art. 258, Para. 1 shall have the right to order in writing to the violator to stop the violation, found during the inspection under Para. 1, p. 6.

Art. 271. (1) (amend., - SG 98/10, in force from 01.01.2011) The regional health inspectorates shall be entitled to:

1. stop construction and issue directions where violations of hygienic norms and requirements have been established in the course of construction; notify the Directorate for

National Construction Control or the municipal technical office in case of illegal construction of sites and equipment for manufacture, storage, and sale of medicinal products shall be established;

2. prohibit the commissioning and stop the operation of sites and equipment in case of violation of the hygienic norms for the manufacture, storage, and sale of medicinal products – until the elimination of the violations;

3. block medicinal products in case of available documented information of discrepancies with the quality requirements; medicinal products imported or manufactured in infringement of this Act; as well as medicinal products, which are offered in packaging non-complying with the requirements of this Act; order the recall of such medicinal products from pharmacies and drugstores, wholesale warehouse, manufacturers, and healthcare establishments in case of necessity and notify for that the Ministry of Health;

4. give conclusions of the compliance of the controlled sites with the legal determined requirements;

5. issue orders, directions, and instructions in the field of their competency, which shall be obligatory for all persons on the territory of the respective district.

(2) ()amend., - SG 98/10, in force from 01.01.2011 The compulsory administrative measures according to para 1 or pursuant to art.270, para 3 shall be imposed by an order of the director of RHI,

(3) The orders according to para 2 shall be subject to appeal under the terms of the Administrative Proceeding Code whereas the appeal shall not stop their execution.

Art. 272. (1) The BDA shall:

1. (suppl. – SG, 102/2012, in force from 02.01.2013) prohibit the commissioning and stop the operation of sites and equipment in case of violation of the rules for Good Manufacturing Practice for medicinal products and of active substances, as well as the Good distribution practices until the elimination of the violations;

2. prohibit the manufacture, import, export and trade with medicinal products, which directly or indirectly threaten the health of the population and shall order destruction, reprocessing or otherwise use of such medicinal products;

2a (new - SG, 102/2012, in force from 02.01.2013) delete from the register the persons, carrying out activity of intermediation with medicinal products not observing the obligations under Art. 212b.

3. temporarily stop the operation of sites for wholesale and retail trade in medicinal products where the conditions under which the respective authorisation has been issued have not been fulfilled;

4. block medicinal products in case of available documented information of discrepancies with the requirements for: quality, efficacy, and safety, medicinal products imported or manufactured in infringement of this Act, as well as medicinal products, which are offered in packaging with leaflets non-complying with the requirements of this Act; order the recall of such medicinal products from pharmacies and drugstores, wholesale warehouse, manufacturers, and healthcare establishments in case of necessity and notify for that the Ministry of Health;

5. stop clinical trials in case of established violation until the elimination thereof or order heir termination;

5a. (New - SG 71/2008, in force from 12.08.2008, amend. – SG, 102/2012, in force from 02.01.2013) order blocking, withdrawal and destruction of false medicinal products and such with unclear origin;

5b.(new – SG, 60/2011, in force from 5. 8. 2011) perform checks of the made donations under Art. 268a, Para. 1;

6. issue orders, directions, and instructions, in the field of its competency, which shall be obligatory to persons.

7. (new – SG, 60/2011, in force from 5. 8. 2011) place under prohibition medicinal products and active substances in case of doubt in their quality by placing establishment signs in the production sites.

(2) The compulsory measures according to Para. 1 shall or pursuant to Art. 270, Para. 3 shall be imposed by an order of the director of the BDA.

(3) The orders according to Para. 2 shall be subject to appeal under the terms the Administrative Procedure Code, whereas the appeal shall not stop their execution.

Art. 272a (new – SG, 102/2012, in force from 02.01.2013) (1) With delegated acts under Para. 52b, Para. 2 of Directive 2001/83/EC the needed measures shall be established for prevention setting in turnover medicinal products, introduced to the EU but intended for placing on the market of the EU for which there are sufficient grounds for suspect that they are falsified.

(2) The BDA shall undertake the needed measures in compliance with the delegated acts under Para. 1 for prevention placing in turnover medicinal products, introduced to EU, but not intended for placing on the EU market, for which there a sufficient suspects that they are falsified.

(3) The customs bodies shall notify BDA about introduction on the territory of the Republic of Bulgaria medicinal products under Para. 1 in view to undertaking measures under Para. 2.

Art. 273. (1) The conditions and order for taking samples, conduct of teats, and payment thereof shall be laid down in a regulation of the Minister of Health.

(2) Repeated tests shall be conducted in case of litigation of the results of conducted laboratory tests. These shall be conducted upon a written request by the interested party made within 7 days of the date of receipt of the results of the initial test.

(3) The repeated tests according to para 2 shall be conducted by experts appointed by the executive director of the BDA who have not participated in the initial test and in the presence of a representative on the interested party.

Art. 274. (1) The conditions and order for blocking and recall of medicinal products, which have shown discrepancies with the requirements to quality, efficacy, and safety shall be paid down in a regulation of the Minister of Health.

(2) The conditions and order for destruction, reprocessing, and otherwise use of medicinal products shall be paid down in a regulation of the Minister of Health.

Art. 275. (1) During exercising control, the BDA shall undertake all necessary measures to ensure correct validation of the processes of manufacture and purification of the medicinal products obtained from human blood or human plasma, consistency of batch quality, and guaranteeing the absence of specific viral contamination in so far as technology allows.

(2) Manufacturers shall notify the BDA of the method used for decreasing or elimination of pathogenic viruses, which can be transmitted through medicinal products obtained from

human blood or human plasma.

(3) The BDA shall test or forward to another official laboratory for control of medicinal products in Republic of Bulgaria or another Member State samples of bulk product and/or medicinal product for a test or in the course of assessment of an application for marketing authorisation according to Art. 46, para 1, point 2, or after issuing a marketing authorisation.

Art. 276. The executive director of the BDA shall temporarily stop, bereave, or amend by an order the marketing authorisation of a medicinal product or its registration where it shall be established that:

1. there is an inadmissible adverse drug reaction during correct use or

2. there is lack of therapeutic efficacy (lack of therapeutic shall be where it has been established that the declared therapeutic results cannot be achieved at its marketing authorisation), or

3. the benefit/risk ratio is unfavourable during correct use, or

4. the quantitative and qualitative composition of a medicinal product does not comply with that declared at the marketing authorisation, or

5. the data in the dossier according to Art. 27 - 32 are untrue, or

6. (Amen. - SG 71/2008, in force from 12.08.2008) the data in the dossier according to Art. 27 - 32 have not been supplemented of amended in compliance with the requirements of Chapter Three, Section six, or

6a (new – SG, 102/2012, in force from 21.12.2012) the conditions under Art. 55a or 56a are not fulfilled, or

6b (new – SG, 102/2012, in force from 21.12.2012) the manufacture of the medicinal product has not been carried out in compliance with the described way of manufacture under Art. 27, Para. 1, p. 7, or

7. (amend. – SG, 102/2012, in force from 21.12.2012) the control tests are not conducted or they have not been conducted in compliance with the methods laid down in Art. 27, Para. 1, p. 8, or

8. the data on the packaging and/or leaflet is not in compliance with those approved at the issuing of the marketing authorisation.

9. (New - SG 71/2008, in force from 12.08.2008) the owner of the authorisation for use has not fulfilled the obligations under Art. 45, para 1 of Regulation (EC) N 1901/2006.

Art. 277. (1) The executive director of the BDA irrespective of the measures according to Art. 276, shall prohibit by an order the supply with the medicinal product and shall order its blocking and recall from the market where:

1. (amend. – SG, 102/2012, in force from 21.12.2012) there is an inadmissible adverse drug reaction or

2. there is lack of therapeutic efficacy, or

3. (amend. – SG, 102/2012, in force from 21.12.2012) the benefit/risk ratio is unfavourable, or

4. the quantitative and qualitative composition of a medicinal product does not comply with that declared at the marketing authorisation, or

5. the control of the medicinal product and/or its ingredients and on the intermediate stages of the manufacturing process has not been done or the requirements under which the manufacture authorisation ahs been granted are not met.

(2) The executive director of the BDA can also impose a ban according to para 1 on

concrete batches of a medicinal product.

Art. 278. (1) The executive director of the BDA shall, by an order, temporarily stop or bereave the marketing authorisation of a group of or all medicinal products, for which the requirements as regards the place manufacture for which the manufacturing authorisation has been granted are not met.

(2) The executive director of the BDA besides the measures according to Art. 276, can, by an order, temporarily stop the import of a group of or all medicinal products from third countries or bereave the issued import authorisation for a group of or all medicinal products where these do not comply with the requirements of chapter five.

(3) The executive director of the BDA besides the measures according to Art. 276, can, by an order, temporarily stop or bereave the manufacturing authorisation for a group of or all medicinal products, which are not in compliance with the requirements of chapter five.

Art. 279. (1) The orders according to Art. 276, 277, or 278 shall be delivered to the marketing authorisation holder, the manufacturer, or importer, respectively.

(2) The orders according to para 1 shall subject to appeal under the terms of the Administrative Procedure Code and the appeal does not stop their execution.

Art. 280. (1) In case that infringement of the provisions of chapter eleventh, respectively of the regulation according to Art. 249 are established, executive director of the BDA shall order termination of the proliferation of advertising.

(2) By the order according to para 1 the executive director of the BDA can oblige the advertiser to publish or proliferate in a manner coordinated with the BDA a disclaimer of the statements in the advertising through the same media and in the same format and volume.

(3) The order according to para 2 shall be subject to appeal under the terms of the Administrative Procedure Code.

Chapter fourteen.
ADMINISTRATIVE PENAL PROVISIONS

Art. 281. (1) 9amend. – SG, 102/2012, in force from 02.01.2013) Whoever manufactures, imports, sells, stores, or provides for use in Republic of Bulgaria medicinal products, which have no marketing authorisation, except for the cases according to Art. 8, 9, and 10, if he/she is not a subject to heavier punishment, shall be penalised with a fine from BGN 25,000 to BGN 50,000, if not subject to more severe penalty.

(2) The same penalty shall also be imposed on the persons who manufacture, import, sell, or permit the use in Republic of Bulgaria of medicinal products, which do not comply with the requirements of the acting pharmacopoeia and the conditions of their marketing authorisation.

(3) Where the infringements according to para 1 and 2 are associated with unauthorised medicinal products containing narcotic substances or in case repeated perpetration the authorisation issued under the terms of this Act shall be bereaved provided that the deed shall not constitute a crime.

(4) Medical specialists who manufacture, sell, or provide for use unauthorised medicinal products shall be deprived of the right to exercise the profession for a term of 6 months to two

years.

(5) The penalty according to para 4 shall be imposed by and order of the Minister of Health according to a proposal by the executive director of the BDA.

Art. 282. (1) Whoever sells medicinal products in packaging or with patient information leaflets, which do not comply with the requirements of this Act, shall be penalised with a fine from BGN 750 to BGN 1,500 and in case of a repeated perpetration of the same infringement - with a fine from BGN 1,500 o BGN 3,000.

(2) Whoever sells medicinal products without patient information leaflets shall be penalised with a fine from BGN 750 to BGN 1,500 and in case of a repeated perpetration of the same infringement - with a fine from BGN 1,500 to BGN 3,000.

Art. 283. (1) Whoever imports, trades with, or provides for same medicinal products with expired validity term shall be penalised with a fine from BGN 10 000 to BGN 20 000.

(2) Whoever breaks the primary/secondary packaging or sells/provides medicinal products with broken primary/secondary packaging shall be penalised with a fine from BGN 750 to BGN 1500 and in case of a repeated infringement with a fine from BGN 1,500 to BGN 3,000.

Art. 284. (1) Whoever manufactures, imports, or conducts wholesale with medicinal products, or sells without respective authorisation or in infringement of an issued authorisation shall be penalised with a fine from BGN 50,000.

(2) amend. – SG, 102/2012, in force from 02.01.2013) Whoever manufactures, imports, or conducts wholesale with medicinal products, or sells without respective authorisation or in infringement, or sell, storage or provides medicinal products, which of uncertain origin, shall be penalised with a fine from BGN 25,000 to BGN 50,000.

(3) In the cases according to Para. 1 the bodies of the state control shall stop the operation of the site by an order.

(4) The order according to Para. 3 shall be subject to appeal under the terms of the Administrative Procedure Code; however, the appeal shall not stop its execution.

Art. 284a (new – SG, 102/2012, in force from 02.01.2013) Anyone, who manufactures, imports, exports, keeps, sells or provides false medicinal products, as well as intermediates in selling and buying falsified medicinal products, shall be punished by a fine of BGN 25 000 to BGN 50 000.

Art. 284b (new – SG, 102/2012, in force from 02.01.2013) Any marketing authorisation holder, who fails to fulfill his/her obligation under Art. 160, shall be punished by a property sanctions of BGN 5000 to 10 000 and in a repeated violation – by a property sanction of BGN 10 000 to 20 000.

Art. 284c (new – SG, 102/2012, in force from 02.01.2013) Any wholesale authorisation holder of medicinal products, who fails to fulfill his/her obligation under Art. 207 shall be punished by a property sanction of BGN 2000 to 5000 and in a repeated deed of the same violation 0 by

a property sanction of BGN 5000 to 10000.

Art. 285. (1) Whoever trades in medicinal products without certificate of batch release shall be penalised with a fine from BGN 5,000 to BGN 10,000 and in case of repeated perpetration of the same infringement – with a fine from BGN 10,000 to BGN 20,000.

(2) (Amend. – SG, 60/2011, in force from 5. 8. 2011) A wholesaler who supplies drugstores with medicinal products upon doctor's prescription, outside the lists approved by the Minister of Health shall be penalised with a property sanction from BGN 2500 to 5000 and in case of repeated infringement with a fine from BGN 5,000 to BGN 10,000.

(3) A qualified person who has permitted sale of batches of medicinal products without certificate of batch release of any separate batch shall be penalised with a fine from BGN 2,500 to BGN 5,000.

Art. 285a. (New – SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012) Holder of an authorisation for use, who fails to notify the Minister of health for termination of the sales under Art. 264 shall be punished by a property sanction of BGN 25 000 to 50 000.

Art. 285b. (new – SG, 102/2012, in force from 21.12.2012) Anyone, who manufactures, imports, exports, sells or keeps active substances in violation of this act, shall be punished by a fine BGN 10 000 to 20 000.

Art. 285c. (new – SG 18/14) A holder of a permit for wholesale of medicinal products failing to notify BDA of carrying out export of medicinal products under Art. 217a, par. 4 shall be punished with a fine, respectively with a proprietary sanction from BGN50 000 to BGN100 000, and in case of repeated the same violation – from BGN100 000 to BGN200 000.

Art. 286. (1) In case of clinical trials conducted in infringement of this Act, provided no crime has been committed, the guilty persons shall be penalised with a fine from BGN 5,000 to BGN 10000 and in case of repeated permission or commitment of the same infringement – with a fine from BGN 10000 to BGN 20000.

(2) Medial specialists who have permitted or committed infringements according to para 1 can be imposed the penalty of "deprived of the right to exercise the profession" for a term from 6 months to two years.

(3) The measure according to para 2 shall be imposed by the Minister of Health according to a proposal by the executive director of the BDA.

Art. 287. (1) (Supl.. - SG 71/2008 in force from 12.08.2008, amend. – SG, 60/2011, in force from 5. 8. 2011) Whoever conducts retail trade in medicinal products without having respective authorisation/certificate, or works in violation of his/her issued authorisation/certificate, shall be penalised by a fine from BGN 5,000 to BGN 10,000.

(2) The penalty according to para 1 shall also be imposed on persons who conduct retail trade in pharmacy or drugstore after the authorisation/certificate has ceased to be in effect.

(3) (Supl. - SG 71/2008 in force from 12.08.2008, amend. – SG, 60/2011, in force from

5. 8. 2011) Whoever sells, or stores in a drug store medicinal products, prescribed by doctor's prescription, or products or goods of human health significance, outside the ones, determined in the ordinance under Art. 243, shall be punished by the fine under para 1, and in repeated perpetration of the infringement the issued registration of the drug store will be deprived of.

(4) In the cases according to para 1 and 2, the bodies of the state control on the medicinal products shall stop the operation of the site by an order.

(5) The order according to para 4 shall be subject to appeal under the terms of the Administrative Procedure Code; however, the appeal shall not stop its execution.

(6) (Repealed - SG 71/2008 in force from 12.08.2008).

Art. 287a. (New - SG 71/2008 in force from 12.08.2008). (1) Medical specialist, who works with persons, performing retail trade with medicinal products, without having authorisation/certificate for this, shall be punished by a fine of BGN 2500 to 5000

(2) The punishment under para 1 shall be imposed on a person under para 1, who works in a pharmacy or a drugstore after termination of the action of the authorisation/certificate.

(3)In case of established more than 2 violations under para 1 and 2, the Minister of Health may deprive the medical specialist of the right to exercise his/her profession for the term of up to 2 years.

Art. 287b. (new – SG, 102/2012, in force from 02.01.2013) Anyone, who carries out trade with medicinal products on internet in violation of this act and the ordinance under Art. 234, Para. 5 shall be punished by a fine of BGN 5000 to 10 000.

Art. 288. (1) A retailer in medicinal products who has permitted an incapable person to exercise activities, pointed out in Art. 219, shall be penalised with a property sanction from BGN 5,000 to BGN 10,000 and in case of repeated perpetration of the infringement the issued retail trade authorisation shall be bereaved.

(2) In the cases according to para 1 the bodies of the state control shall stop the operation of the site by an order.

Art. 289. (1) (prev. text of Art. 289 – SG 60.12, in force from 07.08.2012) Whoever sells medicinal products on prices different from those formed under the terms of this law shall be penalised with a fine from BGN 5,000 to BGN 10,000 and in case of repeated perpetration of the same infringement – with a fine from BGN 6,000 to BGN 12,000.

(2) (new – SG 60.12, in force from 07.08.2012, amend. – SG, 102/2012, in force from 21.12.2012) A marketing authorisation holder who fails to fulfill an obligation set out by the Ordinance under Art. 261a, Para. 5, shall be punishable by property sanction amounting from BGN 5000 to BGN 10 000, and in case of repeated offence – by a property sanction amounting from BGN 10 000 to BGN 20 000.

(3) (new - SG, 102/2012, in force from 21.12.2012). The violations under Para. 1 and 2 shall be found out by acts, drawn up by officials, determined by the Council chairperson under Art. 258, Para. 1, and the penal decrees shall be issued by the Council chairperson under Art. 258, Para. 1 or a council member, authorised by him/her.

Art. 289a. (New – SG, 60/2011, in force from 5. 8. 2011) (1) (amend. – SG, 102/2012, in force from 21.12.2012) whoever works in violation of the confirmed pharmaco-therapeutic guides or performs assessment of the efficiency of the therapy not in the criteria under Art. 259, Para. 1, p. 4, shall be punished by a fine of BGN 1000 to 2000, and in a repeated violation – by a fine of BGN 2000 to 3000.

(2) The violations under Para. 1 shall be established by acts, drawn out by officials, determined by the executive director of the Executive agency Medical Audit, and the penal orders shall be issued by the executive director of the Executive agency Medical Audit

Art. 290. (1) (Amend. - SG 71/2008 in force from 12.08.2008) Whoever advertises medicinal products, which are not authorised under the terms of this Act, shall be penalised by a fine from BGN 10000 to BGN 20000.

(2) (New - SG 71/2008 in force from 12.08.2008) Whoever advertises medicinal products describing and/or directing to properties, related to prophylactics, diagnosis or treatment of human illnesses, shall be penalised by a fine from BGN 10000 to BGN 20000.

(3) (Former para 2 - SG 71/2008 in force from 12.08.2008) Whoever advertises medicinal products in violation of this Act shall be punished by a fine from BGN 10 000 to 20 000.

(4) (Former para 3, amen. - SG 71/2008 in force from 12.08.2008) The penalties according to para 1-3 shall also be imposed on persons who have permitted the emission, publication, and proliferation of the advertisement.

Art. 290a. (New - SG 71/2008 in force from 12.08.2008) Any medical specialist or person representing himself/herself for a medical specialist, who performs direct or indirect advertisement of medicinal products in the printed and/or in electronic media, as well as in the internet, shall be punished by a fine from BGN 1000 to 5000, and in a repeated violation – from BGN 3000 to 10 000.

Art. 290b. (New – SG, 60/2011, in force from 5. 8. 2011) Whoever performs a donation of medicinal products in violation of Art. 268a, Para. 1 shall be punished by a fine of BGN 1000 to 3000, and in repeated violation – by a fine of BGN 3000 to 5000.

Art. 290c. (new – SG, 102/2012, in force from 21.12.2012) Any marketing authorisation holder, who holds non-interventional studies in violation of this act shall be punished by a property sanction of BGN 5000 to 10 000 and in a repeated deed of the same violation – by a property sanction of BGN 10 000 to 20 000.

Art. 290d. (new – SG, 102/2012, in force from 21.12.2012) Any marketing authorisation holder, who fails to fulfill the provision of Art. 55a, 56a and 56b shall be punished by a property sanction of BGN 5000 to 10 000 and in a repeated deed of the same violation – by a property sanction of BGN 10000 to 20000.

Art. 290e. (new – SG, 102/2012, in force from 21.12.2012) Any marketing authorisation holder, who fails to fulfill the obligations under Art. 190 – 192, 194b, 194c, 194h and 194i shall

be punished by a property sanction of BGN 5 000 to 10 000 and in a repeated deed of the same violation 0 by a property sanction of BGN 10 000 to 20 000.

Art. 290f. (new – SG, 102/2012, in force from 21.12.2012) Any marketing authorisation holder, who fails to fulfill the obligation under Art. 193 and 194 shall be punished by a property sanction of BGN 2000 to 5000 and in a repeated deed of the same violation – by a property sanction of BGN 5000 to 10 000.

Art. 291. (1) (Suppl. SG, 60/2011, in force from 5. 8. 2011, amend. – SG, 102/2012 in force from 21.12.2012) Property sanctions shall be imposed in case the infringements according to Art. 281-284a, 285, 285b, Art. 286, Para. 1 and 287b, Art. 289, Para. 1, Art. 289a, Art. 290, 290b, 292 and 294 have been committed by legal persons or sole traders in amount of the property sanction cannot be less than the triple amount of the respective fines and cannot be more than the triple amount of the stipulated maximum amounts of the respective fines.

(2) (suppl. – SG 60.12, in force from 07.08.2012) For infringements according to Art. 289, para 1 the property sanction shall be the nine-fold amount of the overdrawn amount provided that it exceeds the maximum amount of the sanction according to para 1.

(3) The imposing of a property sanction shall not exclude fining of the guilty officials.

(4) The imposing of property sanctions shall not exclude the imposing of the stipulated measures regarding the right of the medical specialists and qualified persons.

Art. 292. (1) Whoever shall not execute an order, directions, or instruction of the bodies of the state control, except in the cases pursuant to Art. 270, para 1, issue 2 and para 3 shall be penalised with a fine from BGN 1,500 to BGN 3,000.

(2) For failure to execute an order, pursuant Art. 270, para 1, issue 2 and 3, the blamed persons shall be penalised with a fine of from BGN 500 to BGN1000.

Art. 293. (1) (amend. – SG, 102/2012, in force from 02.01.2013)In cases according Art. 281, Para. 1-3, Art. 283, Para. 1, as and of non-observance of the condition under which the authorisations to retail trade with medicinal products in a pharmacy, the BDA executive director shall issue an order for the bereavement thereof.

(2) In case of non-observance of the conditions under which the authorisations/certificates for registration of a drug store as well as in the cases under 287, Para. 3, the director of the BDA shall issue an order for the bereavement thereof.

(3) In case of non-observance of the obligation to notify according to Art. 204, Para. 3, for the termination of the activity on the part of a wholesaler of medicinal products, the executive director of the BDA shall issue an order for the bereavement the issued authorisation.

(4) (amend. – SG, 102/2012, in force from 02.01. 2013) In case of non-observance of the obligation to notify according to Art. 235, Para. 3, for the termination of the activity on the part of a holder of an authorisation to retail trade with medicinal products, the BDA executive director shall issue an order for bereavement of the issued authorisation.

(5) The orders according to Para. 1 - 4 shall be subject to appeal under the terms of the Administrative Procedure Code, however, the appeal shall not stop their execution.

Art. 294. Whoever infringes the provisions of this Act or the regulations for its implementation, except for the cases according to Art. 281-293, shall be penalised with a fine from BGN 1,000 to BGN 3,000 and in case of repeated perpetration of the same infringement – with a fine from BGN 3,000 to BGN 5,000.

Art. 295. (1) (amend., - SG 98/10, in force from 01.01.2011) The infringements according to this Act shall be established by virtue of deeds drawn up by state inspectors of the BDA or of the RHI.

(2) The infringements according to Art. 289 shall only be established by officials appointed by the Minister of Health.

(3) (amend., - SG 98/10, in force from 01.01.2011) The penal ordinances shall be issued by the Minister of Health, the chief state health inspector, and the directors of the BDA and RHI depending on the subjection of the official, who has established the infringement.

Art. 296. The drawing of the deeds and the issue, appeal and the execution of penal ordinances shall be made in compliance with the provisions of the Administrative Violations and Penalties Act.

Art. 297. In the cases pursuant Art. 281, 282, 283, 284, 285 and 287 the penalty body enact a bereavement of the medicinal products for state benefit, the subject of the infringement by rules and order, determined in a regulation by the Minister of Health.

Additional provisions

§ 1. Within the meaning of this Act:

1. "Active substance" shall mean any substance (ingredient) intended to be used for manufacturing of medicinal product, which during it production turns in active component of this product, intended for exercising pharmacologic, immunologic or metabolic action with the purpose of restoration, correction or change of physiologic functions or for putting a medical diagnosis.

2. "Bioequivalence" shall be in place where medicinal products are pharmaceutically equivalent or pharmaceutical alternatives and if their bio availabilities after administration of the same molar dose are similar to such extent that their effects with respect to efficacy and safety are essentially similar.

3. "Bioavailability" shall mean the rate and degree at which an active substance or its therapeutically active part is absorbed from the pharmaceutical form and it becomes available at its site of action. Where the medicinal substance is intended to exert a systemic therapeutic effect, bioavailability shall mean the rate and degree at which the medicinal substance or its therapeutically active part is released from the pharmaceutical form and passes into the total circulation.

4. "Researcher’s brochure" shall mean the aggregate of clinical and non clinical data of tests of medicinal product(s), which are relevant to the clinical test of the product(s) in man.

5. "Valid documentation" shall mean any documentation which is compliant with the requirements laid down in a give procedure pursuant to this Act both with respect to content and

completeness.

6. "Substance with well established use in medical practice" shall mean a substance to which the following criteria can be applied:

a) the period for proving the well established use in medical practice is not less than 10 years from the date of the first systematised and documented use of the substance as a medicinal product in the European Union or in the European Economic Area;

b) quantitative aspects of the use of the substance, taking into consideration the degree of use in medical practice, the degree of use on geographical principle, and the degree of follow-up through the pharmaco-vigilance system including pre- and post marketing studies and published scientific literature for epidemiological studies and comparative epidemiological studies in particular;

c) high degree of scientific interest in the use of the substance (number of scientific publications) and coherence in scientific assessments.

7. "Outer packaging" shall mean the packaging, which does not come in immediate contact with the medicinal product.

8. "Contracting authority" shall mean a natural or legal person, institution, or organisation responsible for the start-up, management, and/or financing of a clinical test.

9. "Generic medicinal product" shall mean a medicinal product, which has the same qualitative and quantitative composition as regards the active substances and the same pharmaceutical form as the reference medicinal product and its bioequivalence compared to the reference medicinal product has been proven in adequate bioavailability studies. Various immediate release oral pharmaceutical forms shall be regarded as the same pharmaceutical form. Various salts, esters, ethers, isomers, mixtures of isomers, complexes, or derivatives of an active substance shall be regarded as the same active substance except if these are significantly different in respect of safety and/or efficacy.

10. "Principal researcher" shall mean an appointed by the contracting authority medical doctor or doctor in dental medicine who is managing the overall conduct of a clinical test in compliance with an approved protocol and the rules for Good Clinical Practice and is responsible for the work of the researchers.

11. "Defined daily dose" shall be the mean daily maintenance dose of a given medicinal product, which administered to adults according to the main indication of a medicinal product.

12. "Good clinical practice" shall mean the aggregate of internationally recognised ethical and scientific quality requirement, which shall be observed during the planning, conduct, accounting, and reporting of clinical trials.

13. "Good laboratory practice" shall mean a system of rules in respect if the conditions for planning, processes of organizing, conduct, follow up, and documenting of laboratory tests.

14. "Good manufacturing practice" shall mean a system of rules encompassing all aspects of manufacture: personnel, premises, equipment, materials, documentation, and quality control and has the purpose of ensuring safety, efficacy, and compliance with a specification.

15.. (Suppl. - SG 71/2008 in force from 12.08.2008) "Member State" shall mean a State Member of the European Union, or a State, party of the Agreement of the EEA.

16. "Labeling" shall mean information on the immediate or outer packaging of a medicinal product.

17. "Immunological medicinal product" shall mean a medicinal product, which contains vaccines, toxins, sera, or allergens. Agents used to create active immunity or establish a condition of immunity or invoke passive immunity shall be involved in the scope of vaccines, toxins, and sera. Allergens shall mean medicinal products, which are intended to identify or stimulate specific purposeful change in the immunological response to an allergens agent.

18. "Bioequivalence study" shall mean a clinical test aimed at proving that two medicinal

products are bioequivalent provided that they are pharmaceutically equivalent or pharmaceutical alternatives and provided that their bioavailability after administration of the same molar dose are similar to a degree, which is a condition for equivalence in respect of efficacy and safety.

19. "Bioavailability study" shall mean a clinical test aimed at showing what is the rate and degree which an active substance or a therapeutically significant part of a studied medicinal product reach from the pharmaceutical form to the systemic circulation of the blood.

20. "Study medicinal product" shall mean a pharmaceutical form of an active substance or placebo, which are investigated or used as comparators in a clinical test including products with granted marketing authorisation but are used in an unauthorised indication or with a view of obtaining additional information for an authorised form, or are made up (in a pharmaceutical form or packaged) in a manner, which is different from the authorised form.

21. "Researcher" shall mean an appointed by the contracting authority and the principal researcher medical doctor or doctor in dental medicine who practically conducts a clinical test under the management of a principal researcher in compliance with an approved protocol and the guidelines for Good Clinical Practice in an investigational site for the conduct of a clinical test. If a clinical test is not conducted by a team, the researcher shall be the manager responsible for the team and shall be called principal researcher.

22. "Informed consent" shall mean a decision to participate in a clinical test, which must be in writing, dated and signed and taken freely by any person capable of giving his consent or – where a person is incapable of giving his consent by his legal representative after being duly informed about the essence, importance, consequences and risks of a clinical test and documented in an adequate manner.

23. "Kit" shall mean any substance, which – usually before use – shall be dissolved, suspended, diluted, or combined with radionuclides as a result of which procedure the finished radioactive medicinal product is obtained.

24. "Clinical test of a medicinal product" shall mean any study in man intended for discovering or confirming clinical, pharmacological, and/or other pharmacodynamic effects of one or more study medicinal products, and /or for determination of the adverse reactions to one or more study medicinal products, and/or for studying the absorption, distribution, metabolism, and excretion of one or more study medicinal products with the purpose of establishing their safety and/or efficacy.

25. "Clinical advantage" shall mean a significant therapeutic or diagnostic advantage of a medicinal product compared to a medicinal product, which has already received marketing authorisation.

26. "Coordinating researcher" shall mean a researcher appointed for the purpose of coordinating the researchers or various sites participating in a multicentre test.

27. "Patient information leaflet" shall mean a leaflet accompanying a medicinal product and containing information for the customer.

27a. (New - SG 71/2008 in force from 12.08.2008, amend. – SG, 102/2012, in force from 21.12.2012) "Medicinal product for modern therapy" is a medicinal product, determined in Art. 2 of Regulation (EC) N 1394/2007 of the European Parliament and of the Council of 13 November 2007 on the medicinal products for modern therapy and amending Directive 2001/83/EC and Regulation (EC) № 726/2004.

28. "Medicinal product obtained from human plasma or human blood" shall mean a medicinal product produced from human blood constituents and by a method involving industrial process. The following shall be ascribed to this group: immunoglobulins, coagulating factors and antiproteases, solutions of plasma proteins, and other plasma fractions and combinations thereof.

29. "Medicinal product intended for treatment, prophylaxis, and diagnostics of rare

diseases" shall mean a product, which:

a) is intended for diagnostics, prophylaxis, or treatment of life-threatening diseases or chronic diseases taking progressive course, which affect not more than 5 of 10,000 people on the territory of a state or

b) is intended for diagnostics, prophylaxis, or treatment of life-threatening diseases and severely health damaging chronic disease (diseases with high percentage of disease-related incapacity of work or disability) and are there is evidence appended that the sale of the product does ensure satisfactory return, which can justify the required investment for scientific research and development without having stimuli for the creator of the product, and

c) where the is no satisfactory method of diagnostics, prophylaxis, or treatment of a given condition or where there is such method the proposed medicinal product has significantly more advantages and benefits for the people affected by this condition.

30. "Pharmaceutical form" shall mean an adequate for intake structure containing active substance(s), which can include or cannot include excipients and which is obtained through application of certain technological operations ensuring the desired healing effect and stability at storage within the expiry term.

31.. (Amen. - SG 71/2008 in force from 12.08.2008) "Any person, established on the territory of a Member State shall mean a legal subject registered according to the civil or trade legislation of a Member State or established pursuant to a normative act and having place of business in a Member State or a state - party of the European Economic Area.

32. "Magisterial formula" shall mean a prescription for a medicinal product prepared in a pharmacy according to a prescription of a medical specialist or according to an established recipe and intended for a definite patient.

33. "International non-proprietary name" shall mean a recommended name of an active substance approved and published by the World Health Organisation.

34. "Medical specialists" shall mean medical doctors, doctors in dental medicine, masters of pharmacy, nurses, midwives, medical laboratory assistants, medical auxiliaries and pharmacy assistants.

35. "Medical trade representative" shall mean a person who has passed special training and possessing scientific knowledge for the presentation of accurate and comprehensive information about the medicinal product he is advertising.

35a. (new – SG 1/14, in force from 03.01.2014)”Medical prescription” shall mean a prescription of a medicinal product, issued by a person who exercises a regulated medical profession within the meaning of § 1, item 1 of the Additional Provisions of the Recognition of Professional Qualifications Act and who is legally entitled to do so in the Member State in which the medical prescription is issued.

36. "Multicentre clinical test" shall mean a clinical test, which is conducted according to a single protocol but in more than one site and by more than one researcher. Researcher sites can be situated in the territory of one Member State, more than one Member State, and/or in Member States and third states.

37. "Name of a medicinal product" shall mean the name given to a medicinal product, which can be:

a) a freely selected name (trade name);

b) (amend. – SG 12/11, in force from 08.02.2011) a common name together with the trade mark or the name of the holder of the marketing authorisation;

c) (amend. – SG 12/11, in force from 08.02.2011) scientific name together with the trade mark or the name of the holder of the marketing authorisation.

38. "Scientific literature" shall mean publication(s) of results from scientific research in specialised international scientific editions.

39. "New active substance" shall mean:

a) chemical, biological, or radiopharmaceutical substance, which has not been authorised to market in the European Union as a medicinal product;

b) isomer, mixture of isomers, complex or derivative or salt of a chemical substance, which has been authorised to market in the European Union as a medicinal product but is different with respect to safety and efficacy from a formerly authorised substance;

c) biological substance, which has been authorised to market in the European Union as a medicinal product but has different molecular structure, different origin with respect to the starting material, or has been obtained through a different manufacturing process;

d) radiopharmaceutical substance the radionuclides or molecular bonds (ligands) of which have not been authorised in the European Union as a medicinal product or the mechanism of bonding in a couple of the molecules and radionuclides has not been authorised in the European Union.

40. "Adverse event" shall mean any untoward unfavorable change the health condition observed during the administration of a medicinal product in a patient or a clinical test subject and which has not necessarily a causal relationship with this treatment.

41. (amend. – SG, 102/2012, in force from 21.12.2012) "Adverse drug reaction" shall mean any untoward and unpredicted response to a medicinal product. In case of a clinical test – any untoward and unpredicted response to a study medicinal product irrespective of the administered dose. The types of adverse reactions shall be:

a) "unexpected" – an adverse drug reaction, which has not been mentioned in the summary of product characteristics of the character, severity, and outcome of which do not comply with those mentioned in the summary of product characteristics. In case of a clinical test – an adverse drug reaction the character, severity, and outcome of which do not comply with the information for the study medicinal product mentioned in the researcher's brochure;

b) "suspected" – and adverse drug reaction fore which the reporter or the marketing authorisation holder supposes that there is a possible causal relationship with a taken medicinal product;

c) "serious" – any unfavorable effect on the health condition, which has become the reason for a lethal outcome, immediate threat to life, hospitalisation, or prolongation if hospitalisation, significant or durable injury, disability, and innate anomalies;

d) combination of reactions according to subsections "a", "b", and "c".

42. "Common name" shall mean the international non-proprietary name (INN) of a medicinal substance or excipient recommended by the World Health Organisation; if not any, the name in the European Pharmacopoeia shall be used; if there is no such name there, another pharmacopoeia name shall be used; if there is no pharmacopoeia name, the common name shall be used.

42a (new – SG, 102/2012, in force from 21.12.2012) "Basic documentation of a system of pharmaco-vigilance" is a detail description of the pharmaco-vigilance system, used by the marketing authorisation holder in relation or one or more authorised for use medicinal products.

42b. (new - SG48/15) "Health technology assessment" shall mesn:

a) a form of policy on research that examines the short- and long-term outcomes related to the implementation of health technologies and aims to provide information concerning alternative health strategies;

b) multidisciplinary activity that systematically evaluates technical specifications, safety, clinical efficacy and effectiveness, cost, cost effectiveness, organizational, social, legal and ethical consequences of administration of medicinal products in health care and focuses on value - clinical and economic, provided that the analysis is comparative to existing or best alternative at the time;

43. "Batch" shall mean a definite quantity of a medicinal product manufactured according to an established reproducible technological scheme ensuring the required batch homogeneity with respect to the required quality characteristics.

43a. (new – SG, 102/2012, in force from 21.12.2012) "plan for risk management" is a detailed description of the system for risk management.

44. "Maintenance of a marketing authorisation" shall include all required activities with regard to the maintenance of an updated registration status of a medicinal product including pharmaco-vigilance.

45. "Benefit" shall mean a positive result/therapeutic efficacy of a medicinal product for a definite patient, patient group, or the society. Quantitative assessment of the anticipated benefit shall include approximate calculation of the probability of this positive result.

46. (amend. – SG, 102/2012, in force from 02.01.2013) "Auxiliary substance" is any component of a medicinal product, different for the active substance and the packing material.

47. "Post marketing study" shall mean any study conducted during the use of a medicinal product within the approved summary of product characteristics during the period after the authorisation to market.

47a (new - SG, 102/2012, in force from 02.01.2013) "Mediation in the area of medicinal products" are all the activities, which aim at signing contract for buying or selling of medicinal products with the exception of wholesale trade, which do not include physical keeping and which are expressed in negotiating independent and on behalf of another legal or natural person.

48. "Post marketing safety study" shall mean any study, related to an authorised for use medicinal product, conducted with the purpose of identification, characterisation of defining the risk level in relation of safety, to confirm the safety profile of the medicinal product or to assess the effectiveness of the measures for risk management.

49. "Potential serious risk for the population" shall exist where there is a high probability a medicinal product to cause irremovable, irremediable, and irreversible consequences. The assessment process shall identify the threat of causing damages to the health of the population and its actual exposition during wide use of the product. The serious risk for the health in the context of the use of a given medicinal can be assessed under the following conditions:

a) efficacy – the submitted therapeutic efficacy data with regard to the proposed indication(s), the proposed target group, and the proposed dosage mentioned in the proposed patient information leaflet do not scientifically defend to the full extent the efficacy claims;

b) safety – the assessment of the data for preclinical toxicity/pharmacological safety and clinical safety cannot convincingly defend the conclusion that all potential safety aspects with regard to the target patient group(s) have been accurately and comprehensively reflected in the proposed patient information leaflet or the absolute risk degree is unacceptable;

c) quality – the proposed method of manufacture and control methods cannot guarantee the lack of an essential defect in the quality of the product, which can affect the product safety and/or efficacy;

d) benefit/risk ratio: the assessment of the benefit/risk ratio and the potential benefit for the proposed indication(s) and the patient group(s).

50. "Representative of the person according to Art. 26, Para. 1, or of a marketing authorisation holder" shall mean a person residing on the territory of the Republic of Bulgaria appointed by the person according to Art. 26, Para. 1, or by the marketing authorisation holder to represent them before the regulatory bodies on the territory of the Republic of Bulgaria.

51. "Acceptable safety level" shall be in place where the submitted data shall be accepted as statistically reliable safety according to clinical trials conducted in compliance with the Good Clinical Practice.

52. "Manufacture of a medicinal product" shall mean all operations relating to the supply

of materials, their processing during the manufacturing process including packaging and labeling, quality control, batch release, storage, shipment, and operations control relating there to.

53. "Clinical test protocol" shall mean a document describing the purpose(s), design, methodology, statistical processing, and organisation of a clinical test. The protocol shall also include all subsequent amendments thereto.

54. "Placing on the market" shall mean the distribution of a medicinal product in the trade network on the territory of the Republic of Bulgaria outside the direct control of the marketing authorisation holder.

55. "Immediate packaging" shall mean the packaging, which enters in immediate contact with a product.

56. "Radiopharmaceutical" shall mean a medicinal product, which when in a ready for use form contains one or more radionuclides (radioactive isotopes) included with medical purpose.

57. "Radionuclide generator" shall mean any system, which includes a fixed maternal radionuclide from which a filial radionuclide is obtained, which is separated by elusion or other methods and is used in a radiopharmaceutical.

58. "Radionuclide precursor" shall mean any other radionuclide manufactured for radioactive marking of another substance immediately before its introduction in a patient's body.

59. "Herbal medicinal product" shall mean a medicinal product containing as active ingredient one or more herbal substances or one or more herbal preparations, or one or more herbal substances in a combination with one or more herbal preparations.

60. "Herbal substances" shall basically mean plants or parts of plants, seaweed, mushrooms, and lichens, which are whole, broken, or cut, usually dried or sometimes fresh. Certain exudates, which have not been subjected to specific processing, shall also be assigned to the herbal substances. Herbal substances shall have be accurately defined botanical scientific name of the plant wherefrom they originate according to the binominal system (species, sort, variety, and author).

61. "Herbal preparation" shall mean the product obtained after extraction, distillation, pressing, fractionation, purification, concentration, or fermentation of herbal substance. The herbal preparation can also represent ground or powdered herbal substances, tinctures, extracts, essential oils, and processed herbal liquids/juices.

62. "Rare diseases" shall mean the diseases, which are characterised with incidence of not more than 5 in 10,000 of the population.

63. "Reference medicinal product" shall mean a medicinal product authorised under the terms of Art. 23 in compliance with the requirements of Art. 27.

64. "Reference value of a defined daily dose" on an international non-proprietary name with the corresponding pharmaceutical for according to the anatomo-therapeutic classification of medicinal products shall mean the lowest value of a defined daily dose determined on the basis of the values of a defined daily dose for various medicinal products for the international non-proprietary with the corresponding pharmaceutical form according to the anatomo-therapeutic classification of medicinal products.

65. "Reference value of a therapeutic course" shall be the lowest value of a therapeutic course determined on the basis of the values of a therapeutic course of the medicinal products according to international non-proprietary name with the corresponding pharmaceutical form.

66. "Risk during the use of a medicinal product" shall mean:

a) risk for the health of the patient or risk for the health of the population, which is associated with the quality, safety, or efficacy of a medicinal product;

b) risk of undesirable effects on the environment.

67. "Serious adverse event" shall mean any unfavorable change in the health condition,

which has become the cause of lethal outcome, immediate threat to life, hospitalisation or extension of hospitalisation, significant or durable injury, disability, and innate anomalies.

68. "Batch release certificate" shall mean a document issued for each batch by the qualified person of the manufacturer or importer and shall include the requirements according to the specification, as well as all results from the tests for the release of the batch.

69. "Additional protection certificate" shall mean a document, which shall provide additional patent protection for a medicinal product of maximum 5 years after the lapse date of the main patent.

69a (new – SG, 102/2012, in force from 21.12.2012) "Risk management system" is a system of measures and activities for pharmaco-vigilance, intended for identification, characteristics, prevention or setting to minimum risks, related to the medicinal product, including effectiveness assessment of these activities and measures.

69b (new – SG, 102/2012, in force from 21.12.2012) "Pharmaco-vigilance system" is a system, used by the marketing authorisation holder and BDA for implementation of the tasks and responsibilities under Chapter Eight, intended for observation of vigilance of the permitted for use medicinal products and for finding every change in the benefit/risk ratio.

70. "Urgent limitation safety measures" shall mean temporary changes in the product information with respect of one or more parts of the summary of product characteristics, indications, method of administration, contraindications, and warnings, which result from new information associated with the safe use of a medicinal product.

71. "Spontaneous report" shall mean a voluntarily report for a suspected adverse reaction during the use of a medicinal product forwarded to the marketing authorisation holder, to the bodies for supervision on the medicinal products, or to other organisations, which is not originating from a study or another organised system for data capturing.

72. "Expiry period of a medicinal product" shall mean the interval of time during which, if a medicinal product is stored under the prescribed conditions, it shall comply with the specification developed on the grounds of stability tests of several batches of the finished form.

73. (Amen. - SG 71/2008, in force from 12.08.2008) "Medicinal product equivalent to a herbal medicinal product" shall mean a product containing the same active substances irrespective of the composition of the excipients and which is intended for the same purpose, has equivalent quantity of the medicinal substance, the same dosage and the same or similar method of administration as the product for which an application has been submitted.

74. "Adverse drug reaction reports" shall mean documented information for one or more suspected adverse reactions associated with the use of one or more medicinal products by one patient. Required to recognize the validity of an adverse drug reaction report shall be minimum data for the identification of the reporter (initials or age, or date of birth, or gender) and data about the adverse reaction/event and the suspected medicinal product.

75. "Essential amendment in a clinical test protocol" shall mean any amendment in the protocol and/or in the information of the accompanying documentation, which can affect:

a) the safety or physical and mental validity of the participants;

b) the scientific value of the study;

c) the conduct or the organisation of the study;

d) the quality or the safety of any study medicinal product.

75a (new – SG, 102/2012, in forcefrom 21.12.2012) "Substantial changes in the protocol for non-intervention postmarketing study" are changes. Which influence safety, physical or mental inviolability of patients or the study results and their interpretation.

76. (Amen. - SG 71/2008, in force from 12.08.2008) "Third country" shall mean a state outside the Member States of the European Union, or a state – party of the European Economic Area.

77. "Wholesale distribution" shall mean all activities for the acquisition, storage, supply, import, or export of medicinal products except for the cases of provision of medicinal products directly to the population.

78. "Subject" shall mean a person taking part in a clinical test irrespective whether taking the study medicinal product or a medicinal product used for comparison.

79. "Vulnerable patient groups" shall mean persons whose wish to participate in s clinical test can be affected by the anticipation of benefits or affected by eventual penalty on the part of higher officials in the hierarchical structure associated with the person's participation or refusal to participate in the clinical test. Examples of such group in the hierarchical structures shall be students in medicine, pharmacy, dental medicine or nursing, laboratory personnel, employees in the pharmaceutical industry, members of the armed forces or persons deprived of freedom. Other vulnerable groups shall be patients with incurable diseases, persons in hospices, unemployed and beggars, patients in critical conditions, waifs and strays, under-aged and minors and persons who are unable to give consent.

80. "Pharmacopoeia" shall mean a collection of approved specifications and respective requirements in connection with the manufacture, investigation, storage, and marking of active substances, excipients, pharmaceutical forms, packaging materials, and components of the medicinal products.

81. "Pharmacopoeia recipe" shall mean a prescription for a medicinal product prepared in a pharmacy according to a recipe from an acting pharmacopoeia and intended for provision to the patients in the same pharmacy.

81a. (New - SG 71/2008, in force from 12.08.2008, amend. – SG, 102/2012, in force from 02.01.2013) "False medicinal product" is any medicinal product, in which untrue have been presented:

a) its identity, including the data on the initial or secondary packing, its name or contents in relation to any of its compounds, including the auxiliary substances and the quantity of active substance in a dose unit;

b) its source, including the manufacturer, state, in which it is manufactured, the state in which it is placed on the market or the marketing authorisation holder, or

c) chronology, including records and documents, related to the used delivery chain. Medicinal product shall not be considered as falsified with not intentionally admitted diverse in quality, as well as such, placed on the market in violation of the intellectual property rights.

82. "Homeopathic medicinal product" shall mean a medicinal product prepared from substances called homeopathic source according to the manufacturing procedures of the European Pharmacopoeia and – in the absence of such – according to the national pharmacopoeia of a Member State.

83. "Price calculated on the basis of a referent value" shall be the price formed for any medicinal product included in the Positive Medicines Listcalculated on the basis of the determined reference value for a defined daily dose or therapeutic course.

84. "Site" shall mean a structure in a healthcare establishment where a clinical test is conducted.

85. "Abuse of medicinal products" shall mean permanent or incidental intentional excessive use of medicinal products accompanied by noxious physical or mental effects.

86. (New - SG 41/2009, in force from 02.06.2009) "Sucklings" are children under 12 months of age.

87. (New - SG 41/2009, in force from 02.06.2009) "Infant formulas" are foods, intended for specific feeding use by sucklings in the period of their first months, which are sufficient to satisfy the feeding needs of those sucklings by the moment of introducing appropriate additional food.

88. (New - SG 41/2009, in force from 02.06.2009) "Transitional foods" are foods, intended for specific feeding use by sucklings in introducing of appropriate additional food and which represent the basic liquid of progressively increasing varieties of the foods of these sucklings.

89. (new – SG 12/11, in force from 08.02.2011) "Variation of type IA" means a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;

90. (new – SG 12/11, in force from 08.02.2011) "Variation of type IB" means a variation which is neither variation of type IA nor variation of type II nor extension a marketing authorisation.

91. (new – SG 12/11, in force from 08.02.2011) "Variation of type II" means a variation, which is not a extension of a marketing authorisation and which may have a significant impact on the quality, safety or on the efficacy of the medicinal product concerned.

91 (new – SG, 102/2012, in force from 21.12.2012) "Delegated act" is an act in the meaning of Art. 290 of the Treaty on the European Union.

§ 2. The name of the Executive Drug Agency shall be written in Latin as "Bulgarian Drug Agency".

§ 2. The name of the Executive Drug Agency shall be written in Latin as "Bulgarian Drug Agency".

§ 3. The Council of Ministers shall determine the conditions and order for the supply, storage and renewal of the medicinal products kept in the State Agency "State Reserve and War-time Reserves".

§ 4. (suppl. – SG 18/14) This Act shall implement the provisions of Directive 2001/83/EC of the European Parliament and the Council on the Community code relating to medicinal products for human use subsequently amended by Directive 2004/27/EC of the European Parliament and the Council and of Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012.

§ 5. The data protection periods for reference medicinal products shall be applied according to the provisions of Art. 89 of Regulation (EC) № 726/2004 of the European Parliament and the Council and Art. 2 of Directive 2004/27/EC of the European Parliament and the Council

§ 5a. (New – SG, 60/2011, in force from 5. 8. 2011) (1) (amend. – SG, 102/2012, in force from 21.12.2012) The Ministry of Health, the National Council on prices and reimbursement of medicinal products, the BDA and the Regional health inspectorates shall provide opportunity for giving information and accepting applications and documents under this Act electronically under the terms and conditions of the Electronic Document and Electronic Signature Act and the Electronic Government Act.

(2) Providing information and accepting applications and documents in electronic way

shall be done after providing the relevant technical and organisation conditions, as well as the relevant programme products.

Transitional and concluding provisions

§ 6. The Medicines and Pharmacies in the Human Medicine Act (State Gazette, No 36 from 1995; No 61 from 1996 - Decision No 10 of the Constitutional Court from 1996; amended, State Gazette No 38 from 1998, No 30 from 1999, No 10 from 2000, No 37 from 2000 - Decision No 3 of the Constitutional Court from 2000; amended, State Gazette No 59 from 2000, No 78 from 2000 - Decision № 7 of the Constitutional Court from 2000; amended, State Gazette No 41 from 2001, No 107 and 120 from 2002; amended, State Gazette No 2 from

2003; amended, State Gazette No 56, 71 and 112 from 2003, No 70 and 111 from 2004, No 37, 76, 85, 87, 99 and 105 from 2005, No 30, 31, 34, 75 and 105 from 2006) is repealed, with exception of the Regulation of Art. 10, para 2, which is applied for term to one year since the day of the coming in the force of this Act.

§ 7. (1) The marketing authorisations for medicinal products published before the entering into force of this Act under national procedure, which are authorised also in a Member States under centralised procedure shall cease to be valid as from 1 January 2007.

(2) The marketing authorisations for medicinal products issued up to the entering into force of this Act under national procedure shall be brought into line with the requirements at the date of their renewal.

(3) The marketing authorisations for medicinal products falling within the scope of Regulation (EC) 726/2004 of the European Parliament and the Council and which have issued marketing authorisation under the terms of the repealed Medicines and Pharmacies in Human Medicine Act as materially similar products, but which have no marketing authorisation in European Union under the centralised procedure shall cease to be valid.

(4) The medicinal products which have been issued marketing authorisation in the European Union under the centralised procedure, which national marketing authorisation is ceased under the terms of para 1, can be sold on the territory of Republic of Bulgaria in packages and with leaflets according to the ceased national marketing authorisation for a time limit not longer than one year since the date of its cessation.

§ 8. (1) The setting up of ceiling prices and the registered prices under the terms of the repealed Medicines and Pharmacies in Human Medicine Act of the medicinal product, which have marketing authorisation in the European Union according to the centralised procedure, which national marketing authorisation is suspended under the terms of

§ 7, para 1, remain in force for a time limit of one year from the date of its cessation.

(2) The setting up of ceiling prices and registered prices under the terms of the repealed Medicines and Pharmacies in Human Medicine Act of the medicinal products, other than those according to para 1 remain in force for a time limit expiring on 31 December 2007.

§ 9. (1) The applications for marketing authorisation, renewal, modification of the published authorisation, which are submitted up to the entering into force of this Act are reviewed and closed according to the terms and the conditions provided for herein.

(2) The submitted applications and documentations for marketing authorisation for medicinal products falling within the scope of the procedure provided for in Art. 74 and also according to Art. 75 shall be brought into line with the requirements of this Act within three months from its entering into force.

(3) When in the case provided for in para 2, the application and the documentation under para 2 have not been brought into line with the requirements of this Act, the procedure of their review shall be terminated.

§ 10. (1) The clinical trials which were approved before this Act comes in force shall be finished according to under the conditions prevailing hitherto.

(2) The applications for conduction of the clinical trial on the territory of Republic of Bulgaria are submitted, reviewed and closed according to the terms and conditions of this Act after the regulation according Art. 82, para 3 comes in force.

(3) The applications for amendments in approved clinical trials, which were submitted before this Act comes in force, are reviewed and closed according to the terms and conditions provided for herein.

§ 11. The applications for publishing of the authorisations for manufacture and wholesale with medicinal products, which are submitted before this Act comes in force are reviewed and are reviewed and closed according to the terms and conditions provided for herein.

§ 12. (1) The manufacturers of medicines, which received authorisation for manufacture under the terms of the repealed Medicines and Pharmacies in Human Medicine Act shall put their manufacture activity in compliance with the requirements of this Act according to the requirements of this Act regarding the qualified person according to Art. 148, point 2 within three months of the entering into force of this Act.

(2) The established state manufacturers which shall carry out their activity according to their authorisations, issued under the terms of the repealed Medicines and Pharmacies in Human Medicine Act.

§ 13. (1) The persons, who have been granted authorisation for wholesale with medicines under the terms of the repealed Medicines and Pharmacies in Human Medicine Act shall set their activity according to the requirements of this Act in term of 12 months after it is in force.

(2) Until the publishing of authorisation for wholesale with medicinal products under the terms of this Act, but not later than the expiration of the term according to para 1, the persons according the para 1 shall carry out their activity based on the published authorisation for wholesale with medicines under the terms of the repealed Medicines and Pharmacies in Human Medicine Act.

(3) With the publishing of the authorisation for wholesale with medicinal products, according to this Act, and also with expiration of the term according the para 1, the published authorisation for wholesale with medicines under the terms of the repealed Medicines and

Pharmacies in Human Medicine Act is terminated.

§ 14. (1) The persons, who received authorisation for wholesale with medicines under the terms of the repealed Medicines and Pharmacies in Human Medicine Act may import medicinal products on the territory of Republic of Bulgaria from third countries based on this authorisation till receiving of the authorisation for import under the terms of this Act not more late than 12 months after it comes in force.

(2) In the term of one month since this Act comes in force the persons according to para 1 shall give in BDA the notification for the person who will fulfil the functions of the qualified person according to the Art. 161, para 2, point 1.

§ 15. The term for action of the authorisations for wholesale with medical devices, which are published under the terms of the repealed Medicines and Pharmacies in Human Medicine Act is prolonged officially to 31 December 2007.

§ 16. (1) (Repealed. - SG 71/2008 in force from 12.08.2008)

§ 17. (1) The established state drugstores till the moment when that Act comes in force carry out their activity based on their published authorisations under the terms of the repealed Medicines and Pharmacies in Human Medicine Act.

(2) The applications for publication of the certifications, which are granted before the entering into force of this Act, are reviewed and closed under the terms and conditions provided for herein.

§ 18. (1) (Amen. - SG 71/2008 in force from 14.04.2008, amen. - SG 10/2009 in force from 29.01.2009) The Positive medicinal list under this Act shall be developed under the procedure, provided in it and shall come into force from 31 March, 2009.

(2) (Amen. - SG 71/2008 in force from 14.04.2008) By the time the list under Para 1 comes into force, the acting Positive medicinal list is the one, adopted by the Ordinance on defining the Positive medicinal list in the Republic of Bulgaria (SG 113/ 2003; amen, 18/2004, 4/2005 and 8, 107 and 112/2007).

(3) (New - SG 71/2008 in force from 14.04.2008, amen. - SG 23/2009 in force from 30.03.2009) Within 2 month term after the list under para 1 comes into force, the executors of medicinal help shall prescribe and the NHIF shall pay the medicinal products according to the medicinal list of NHIF, adopted by Decision NRD-US-04-127 of 27 December 2007 for determining the conditions, with which the executors of medicinal help must comply, the procedure for signing the contracts with them and other conditions under Art. 55, para 2, p. 2, 4, 6 and 7 of the Health Insurance Act.

§ 19. (1) Within three months after the entering into force of this Act:

1. The Council of ministers shall amend and supplement the ordinance for the structure of BDA in compliance with this Act.

2. The Minister of Health shall issue regulation, pursuant Art. 82, para 3.

(2) In six month period of time, after the entering into force of this Act, the Council of Minister shall adopt and the Minister of Health shall issue the remaining legislative documents for the implementation of this Act.

§ 20. After the first two years of the mandate of the members of the committees according to Art. 104, 107, 259, and 261 half of the members whose mandate is terminated shall be elected by drawing lots.

§ 21. (Amen. - SG 71/2008 in force from 14.04.2008) Within 2 years of the entering into force of this Act, the BDA shall take the necessary actions for accreditation of the laboratory for control of the medicinal products and active substances by the European Directorate for Quality of Medicines and Healthcare

§ 22. (In force from 14.04.2008) in the Health Insurance Act (promulgated, SG 70 of 1998; amended and supplemented, 93 and 153 of 1998, 62, 65, 67, 69, 110, and 113 of 1999, 1, 31, 64 of 2000, 41 of 2001, 1, 54, 74, 107, 112, 119, and 120 of 2002, 8, 50, 107, and 114 of 2003, 28, 38, 49, 70, 85, and 111 of 2004, 39, 45, 76, 99, 102, 103 and 105 of 2005, and 17, 18, 30, 33, and 34, 59, 95 and 105 from 2006, 11 from 2007, 26 from 2007- Decision № 3 off the Constitution court of 2007):

1. In Art. 45:

a) para 4, 5, 6, and 7 shall be repealed;

b) in para 8 the shall be amended as follows:

(8) The terms and conditions for payment of the medicinal product, included in the Positive Medicines List pursuant to Art. 262 of the Medicinal Product in the Human Medicine Act, of medical devices and of the diet foot for special medical purposes are laid down with a regulation of the Minister of Health.

2. In Art 55, para 2, shall be amended as follow:

7. The lists of the medical devices, diet foots for special medical purposes and the prices, fully or partially paid; condition of prescribing and receiving, medical devices and diet foots for special medical purposes.

§ 23 In the Medical Establishments Act (promulgated, SG 62 of 1999; amended and supplemented, 88, 113 and 114 of 1999, amended 36, 65 and 108 of 2000; Decision № 11 of the Constitutional Court of 2001 – 51 of 2001; amended and supplemented, 28 and 62 of 2002, 83, 102 and 114 of 2003, 70 of 2004, 46, 76, 85, 88 and 105 of 2005. and 30, 34, 59 and 105 of 2006 following amendments are made.

1. In Art. 17 a new para shall be introduced:

"(4) Clinical trials of medicinal products can be conducted in the diagnostic – consultancy centre under the terms of the Medicinal Products in Human Medicine Act."

2. In Art. 26 new para 4 shall be inserted:

(4) In the dispensary clinical trials of medicinal products can be conducted under the terms of the Medicinal Products in Human Medicine Act.

§ 24. In § 14 Of Transitional and Final Provisions in the amended Act on the Branch

organisation of physicians and dentists (SG N. 76 from 2005) following amendments and supplementation shall be made:

1. The text in Art 1 shall be amended as follow:

(1) The individual and group of practices for dental assistance, dentist and medico-dental centres, which are registered as traders under the Commerce Act or as a cooperative under the Cooperatives Act, shall apply their names in compliance according § 2 of that Act and shall inscribe that change in the Commercial Register, Register BULSTAT and in the Regional health centre until 31 of December 2007.

2. New Art. 2, 3 and 4 are inserted:

The individual dental assistance practices, which are nor registered as traders upon the Commerce Act, shall apply their names in compliance with § 2 of that Act and inscribe the change in the BULSTAT register and in the Regional health centre in the period provided in para 1.

(3) The registration of the change of the name of the practices and the centres according to para 1 in the Commercial Register and BULSTAT shall be carried out as follows:

1. until 1 of July 2007 - upon the rules in the Commerce Act, Cooperatives Act, BULSTAT Register Act.

2. until 1 of July 2007 – under the procedures of the Commercial Register

(4) State fees for modification in the registration under para 1 and 2 shall not be required.

§ 25. In the Act on Patents and Registration of Utility Models (promulgated SG 27 from 1993; amended, 83 from 1996, 11 from 1998, 81 from 1999, 45 and 66 from 2002,17, 30 and 64 from 2006) in Art. 20, issue 7 is repealed.

§ 26. In the Act on the society organisation of master of pharmacists SG 75 from 2006, amended 105 from 2006, Art. 5, point 9 shall be amended as follow:

"9. Provides statements for opening of pharmacies, pursuant Art. 228, para 1, issue 9 from the Medicinal Products in Human Medicine Act.

§ 27 In § 1, point 5 of the Additional provisions of the Integration of People with Disabilities Act (promulgated SG N81 from 2004, amended., N. 28, 88, 94, 103 and 105 from 2005, N 18, 30, 33, 37, 63, 95, 97 and 108 from 2006) the second sentence shall be amended as follow "Medical devices are not auxiliary devices, installations and equipment ".

§ 28. In the Excises and Tax Warehouses Act (promulgated, SG No 91 of 2005; amended and supplemented, No 105 of 2005. and No 30 and 34, 63, 81, 105 and 108 from 2006 of 2006) the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".

§ 29. In the Genetically Modified Organisms Act (promulgated, SG 27 of 2005; amended and supplemented, 88 and 99 of 2005 and 30 of 2006) the para 2 in Art. 2, issue 3 the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".

§ 30. In Protection of Customers Act (promulgated, SG No 99 of 2005; amended and supplemented, No 30 and 51, 53, 59, 105 and 108 of 2006) in Art. 186, para 2, issue 4 the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".

§ 31. The following amendments shall be introduced in the Health Act (promulgated, SG 70 of 2004; amended and supplemented, 46, 76, 85, 88, 94 and 103 of 2005 and 18, 30, and 34, 59, 71, 75, 81,95 and 102 of 2006):

1. In Art. 4 the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".
2. In Art. 21, para 3, the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".

§ 32. The following amendments shall be introduced in the Control on Drugs and Precursors Act (promulgated, SG 30 of 1999; amended and supplemented, 63 of 2000, 74, 75, and 120 of 2002, 56 of 2003, 76, 79, and 103 of 2005, and 30,75 and 82 of 2006):

1. In Art. 32, para 3 the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".
2. In Art. 33, para 1, item 1 the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".
3. In Art. 34 after the word "issued" the words "on master of pharmacy" are deleted.
4. In Art. 39, para 2 the words "Art. 55, item 2 of Medicinal Products in Human Medicine Act" shall be replaced by "Art. 197, para 2 of Medicinal Products in Human Medicine Act".
5. In Art. 44 a, para 3 is deleted.
6. In Art. 44b the words master of pharmacy are deleted.
7. In § 1, item 14 of the Additional provision the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".

§ 33. In the Act on Blood, Blood Donation, and Blood Transfusion (promulgated, SG 102 of 2003; amended and supplemented, 70 of 2004 and 30 and 65 of 2006) in Art. 8, para 4, the words "Medicinal Products in Human Medicine Act" shall be replaced by "Medicinal Products in Human Medicine Act".

§ 34. In Art. 140 of Environmental Protection Act (promulgated, SG 91 of 2002; correction, 98 of 2002; amended and supplemented, 86 of 2003, 70 of 2004, 74, 77, 88, 95, and 105 of 2005, and 30,65, 82, 99, 102 and 105 of 2006.) in the Art. 140 after the words "pharmaceutical products and medical devices" the expression "within the meaning of the Medicinal Products in Human Medicine Act" shall be added and the words "within the meaning of § 1, item 40 of the additional provisions of the Medicinal Products in Human Medicine Act and medical devices " shall be deleted.

§ 35. In Foodstuffs Act (promulgated, SG 90 of 1999; amended and supplemented, 102 of 2003, 70 of 2004, 87, 99, and 105 of 2005 and 30, 31, 34, and 51,55 and 96 of 2006) in Art.2,

para 3, issue 4 shall be amended:

"4. medicinal product within the meaning of the "Medicinal Products in Human Medicine Act".

§ 36 Until coming into force of the provisions pursuant to § 19 the issued normative acts for applying the repealed "Medicinal Products in Human Medicine Act" shall be applied, until they shall not contradict to that Act.

§ 37. This Act shall take effect as from the date of is promulgation in State Gazette, except § 22, which shall take effect after one year from the date of the promulgation of this Act.

This Act has been adopted by the 40 National Assembly on 30 of March 2007 and has been sealed with the official seal of the National Assembly.

This Act was adopted by the 40th National Assembly on 30 March 2007 and has been sealed by the official stamp of the National Assembly.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ON MEDICINAL PRODUCTS IN THE HUMANE MEDICINE ACT

(PUBL. - SG 71/2008, IN FORCE FROM 12.08.2008)

§ 65. (1) The issued according to the repealed Act on Medicines and Pharmacies in the Humane Medicine (publ., SG 36/1995; amen., 61/1996, 38/1998, 30/1999, 10, 37, 59 and 78/2000, 41/2001, 107 and 120/2002, 2, 56, 71 and 112/2003, 70 and 111/2004, 37, 76, 85, 87, 99 and 105/ 2005, 30, 31, 34, 75 and 105/2006; repealed 31/2007) permissions for use of medicinal products, falling in the scope of the repealed Council Regulation (EC) № 2309/93 of 22 July 1993, which established the Community procedure for issuing authorisations (licences) and exercising supervision over the medicinal products, used in the human and veterinary medicine and is established European Agency for evaluation of medicinal products, but have not been permitted in the other Member States according to the procedure, established by the repealed Council Directive 87/22/EEC of 22 December 1986 on approximation of the national measures, related to placement on the market of highly technological medicinal products, especially those, received through biotechnology, or by Regulation (EC) № 2309/93, shall be terminated.

(2) The issued after 20 November 2005, as provided by the repealed Act on the Medicines and Pharmacies in the Human Medicine authorisation for use if medicinal products in the scope of Regulation (EC) № 726/2004 of the European Parliament and of the Council, but have not been permitted according to centralised procedure, shall be terminated.

§ 66. (1) Master of Pharmacy and Assistant Pharmacist, who have authorisation for opening a pharmacy as sole traders, the medical establishments, as well as the municipalities, received authorisation for opening a pharmacy, as provided by the Act on the Medicines and Pharmacies in the Human Medicine shall perform their activity as provided by their issued authorisations.

(2) By this Act comes into force, the filed applications for issuing authorisation for retail

trade with medicinal products shall be examined under the terms and conditions, provided by it.

(3) Apart from the cases under para 1, the persons, status quo at the time of this Act comes into force, who have received authorisation for opening a pharmacy, shall comply their activity with its requirements within 1 year after its coming into force.

(4) The persons under para 3 shall file in the Ministry of Health an application for re-registration, which shall contain:

1. application for issuing authorisation for retail trade with medicinal products by the persons under Art. 222, para 1, according to a form, approved by the Minister of Health;

2. updated certificate for listing into the trade register, correspondingly a document for updated registration of the person under Art. 222, para 1;

3. copy of the issued authorisation for opening a pharmacy, as provided by the Act on the Medicines and Pharmacies in the Human Medicine

4. certified copy of the employment contract or a contract for assignment of management of the head of the pharmacy – in the cases, where such is required;

5. declaration of the persons under Art. 222, para 1, that the conditions have been met for issuing the authorisation for retail trade with medicinal products of the persons under para 2;

6. document for a single paid fee in the amount of BGN 100.

§ 67. The persons, who have filed by this Act comes into force application for re-registration as provided by the repealed § 16 of the Transitional and Final Provisions, who will perform their activity as provided by the requirements of this Act, shall file in the Ministry of Health within 3 months after its coming into force, the following documents:

1. application, according to a form, approved by the Minister of Health;

2.updated certificate for listing in the trade register, or a document for updated registration or a certified copy of a similar document according to the national legislation of an EU Member State or the legislation of another Member- State – party of the EEA, under Art. 222, para 1;

3. employment contract or a contract for management of the pharmacy, signed with a Master of Pharmacy of Assistant Pharmacist.

§ 68. (1) Master of Pharmacy of Assistant Pharmacist, who has received authorisation for opening a pharmacy, as provided by the repealed § 16 of the Transitional and Final Provisions may transfer the issued authorisation to a person under Art. 222, para 1.

(2) For performing the transfer, the persons under para 1 shall file in the Ministry of Health an application, which shall contain:

1. an application for issuing authorisation for retail trade with medicinal products by the persons under Art. 222, para 1, according to a form, approved by the Minister of Health;

2. an updated certificate for listing in the trade register, or a document for updated registration of the persons under Art. 22, para 1;

3. copy of the issued, as provided by the Act on the Medicines and Pharmacies in the Human Medicine, authorisation for opening a pharmacy or authorisation for re-registration, as provided by the repealed § 16 of the Transitional and Final Provisions;

4. a certified copy of the employment contract or a contract for management of the head of the pharmacy;

5. a declaration of the persons under Art. 222, para 1 that the conditions, in which the authorisation for retail trade with medicinal products of the persons under para 1 have been met;

(3) The transfer under para 1 may be done within the term of 1 year after this Act comes

into force.

§ 69. The drugstores, status quo at the time of this Act's coming into force shall continue to perform its activity on the basis of the certificates, issued for registration.

§ 70. The Commission on the Positive medicine list, assigned by the time of this Act coming into force shall continue to perform its activity by the assignment of its new staff, in compliance with Art. 261, para 6.

§ 71. The products, falling into the scope of Art. 37 – traditional herbal medicinal products and have been placed on the market in the country before the date of this Act coming into force, shall be complied with its requirements not later than 30 April 2011.

§ 72. (1) By 31 December 2008 the file under Art. 27 for authorisation of use of a medical product on the procedure of mutual recognition or decentralised procedure may be filed in the form of "general technical document".

(2) By 31 December 2009 the file under Art. 27 for authorisation for use of medicinal product upon national procedure may be submitted in the form "General technical document"

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§ 75. This Act shall come into force from the day of its publishing in the State Gazette, with the exception of the provision of § 64, p. 2, which shall come into force from 14 April 2008 and of the provisions of § 9, p. 4, § 41, 42 and 43, which shall come into force from 26 July 2008.

Concluding provisions
TO THE ACT AMENDING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PUBL. - SG 10/2009, IN FORCE FROM 29.01.2009)

§ 2. The Act shall come into force from 29 January 2009.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PUBL. - SG 23/2009, IN FORCE FROM 30.03.2009)

§ 4. Persons, who have received by the time this Act comes into force authorisation under Art. 229, para 2, including performing trade with food supplements, may perform retail trade with dietetic foods for special medical purposes.

§ 5. Within 2 months after this Act comes into force, the Ministry of Health shall officially sent to the relevant RIPCPH of the locality of the pharmacies for listing into the register under

Art. 14, para 1 of the Foodstuffs Act, a copy of the authorisations under Art. 229, para 2, issued by this Act comes into force.

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§ 7. This Act shall come into force from 30 March 2009.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PUBL. - SG 41/2009, IN FORCE FROM 02.06.2009)

§ 92. (1) Persons, who have received by the time this Act comes into force authorisation under Art. 229, para 2 of the Medicinal Products in Human Medicine Act, including performing trade with food supplements, may perform retail trade also with Infant formulas and transitional foods.

(2) Within the term of 2 months after this Act comes into force, the Ministry of Health shall officially submit in the relevant RIPCPH on the locality of the pharmacies, which perform retail trade with Infant formulas and transitional foods under Art. 1 for listing into the register under Art. 14, para 1 of the Foodstuffs Act copy of the authorisations under Art. 229, para 2 of the Medicinal Products in Human Medicine Act issued by the time this Act comes into force.

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§ 96. This Act shall come into force from the day of its publication in the State Gazette, with the exception of:

1. para 3, 5, 6 and 9, which shall come into force from 1 January 2009;
2. para 26, 36, 38, 39, 40, 41, 42, 43, 44, 65, 66, 69, 70, 73, 77, 78, 79, 80, 81, 82, 83, 88, 89 and 90, which shall come into force from 1 July 2009;
3. para 21, which shall come into force from 1 June 2009.

Concluding provisions
TO THE ACT SUPPLEMENTING THE MEDICINAL PRODUCTS IN THE HUMANE MEDICINE ACT

(PUBL. - SG 88/2009 IN FORCE FROM 06.11.2009)

§ 2. The Act shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PROM. - SG 102/09, IN FORCE FROM 22.12.2009)

§ 4. (1) Master-pharmacists and assistant pharmacists who, prior to the entry into force of this Act, have been granted permissions to open a pharmacy in populated areas referred to in Art. 228, para 4 according to the revoked Act on Medicines and Pharmacies for the Human Medicine, and who have not submitted an application for re-registration within the term fixed in

§ 66, para 3 of the Act on Amendment and Supplementation of the Medicinal Products in Human Medicine Act (SG 71/08), shall bring their activity in compliance with the requirements of this Act by 31st of January 2010.

(2) The persons referred to in para 1 shall submit to the Ministry of Health an application for re-registration, to which shall be enclosed the following documents:

1. an application for authorisation for retail trade with medicinal products by the persons under Art. 222, para 1 in a form. Approved by the Minister of Health

2. up-to-date certificate for entry in the commercial register, respectively a document certifying up-to-date registration of the person as per Art. 222, para 1;

3. a copy of the permission to open a pharmacy pursuant to the revoked Medicinal Products in Human Medicine Act;

4. a verified copy of the employment contract with the manager of the pharmacy – where such is required;

5. a declaration by the persons as per Art. 222, para 1 that the requirements under which is granted the authorisation for retail trade in medicinal products to persons under para 1, have been met;

6. a document issued by the mayor of the respective municipality verifying the number of citizens in the respective populated area;

7. a document for paid fee amounting to 100 BGN.

§ 5. Within three months from the entry into force of this Act the Minister of Health shall make the respective amendments in the ordinance as per Art. 219, para 2.

§ 6. The Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS ACT

(PROM. – SG 59/10, IN FORCE FROM 31.07.2010)

§ 77. The Act shall enter into force from the day of its promulgation in the State Gazette, except for:

1. paragraphs 9 (regarding Art. 19, para. 4), 53, 60 and 66 (regarding Art. 98, para 5 and 6), which shall enter into force from 1 January 2011;

2. paragraph 75, which shall enter into force from 30 September 2011.

Transitional and concluding provisions
TO THE ACT ON THE BUDGET OF THE NATIONAL HEALT HINSURANCE FUND FOR YEAR 2011

(PROM. – SG 98/2010, IN FORCE FROM 01.01.2011)

§ 5. (1) In year 2011 activities on diagnosing and treatments of malignant illnesses and of ill of renal insufficiency treated with dialysis, including provision of the medical products and articles, as well as the other medical activities, which in 2010 has been funded through the budget of the Ministry of Health and through the assigned by the state activities to the

municipalities, shall be paid with the funds envisaged in Art. 1, Para 2, line 5.

(2) Activities, medical products and articles envisaged in Para 1 shall be paid under a procedure and method, determined by the Minister of Health.

(3) Funds envisaged in Art.1, Para 2, line 5 shall be transferred monthly the end of the current month.

§ 7. Supervising Board of the National Health Insurance Fund shall be entitled to execute internal compensated changes of the credits between the elements of the expenses and of the transfers envisaged in Art.1, Para 2, which shall be within the frames of the approved budged.

§ 8. Supervising Board of the National Health Insurance Fund, on the grounds of Art. 26, Para 2 of the Health Insurance Act, shall be entitled to spend the funds of the reserve for unexpected and urgent expenditures envisaged in Art.1, Para 2, line 3.

……

§ 15. This Act shall enter into force from 1st of January 2011, except for § 10, which shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PROM. - SG 98/2010, IN FORCE FROM 01.01.2011)

§ 106. In the Medicinal Products in Human Medicine Act (prom. – SG 31/2007; amend. – SG 19/08; decision No. 5 of the Constitutional Court of 2008- SG 65/08; amend. – SG 71/08, 10,23, 41, 88 and 102 of 2009 and SG 59/10), everywhere words "regional inspectorate(s) on/for protection and control of the public health", and "RIPCPH" shall be replaced respectively by "regional health inspectorate(s)" and "RHI".

……..

§ 121. This Act shall enter into force from 1st of January 2011, except for:

1.paragraphs 1, 16, 20, 29, 30, 33, 34, 35, 42, 44, § 56, items 1 and 2, § 65, 68, 70, 76, 80, 81, 90, 92, 96, § 102, items 3,4,7 and 8; § 105, items 1,3, and 5; § 107, items 1,2,3,4,6, letter "a", items 7, 10, 11, 13, and 15, letter "a"; § 109, 110, 112, 113; § 116, items 4 and 6; § 117, items 5 and 7 and § 118, item 1, which shall enter into force from the day of promulgation of the Law in the State Gazette;

2. paragraph 102, items 1,2 and 6, which shall enter into force from 1st of March 2011;

3. paragraphs 22, item1 (regarding Art. 36, Para 1, Sentence Two), § 37, § 48, item2, § 51 and 59, which shall enter into force from 1st of July 2011;

4. paragraph 107, item 15, letter ‘b", which shall enter into force from 30 September 2011.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PROM. – SG 12/2011, IN FROCE FROM 08.02.2011)

§ 24. Lodged before the entering into force of this Act valid applications and notifications for variations to marketing authorisations shall be decided under the existing procedure.

§ 25. Minister of Health shall bring the ordinance envisaged in Art. 42 in accordance with this Act within three-months term from the moment it enters into force.

§ 27. This Act shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PBLISHED – SG, 60/2011, IN FORCE FROM 5. 8. 2011)

§ 66. (1) The producers under § 12, Para. 2 of the Transitional and final provision shall be complied with the relevant requirements of Art. 148 of the Good production practice, determined under Art. 152 within the term of 6 months from the enforcement of this Act.

(2) After expiry of the term of Para. 1, the BDA shall perform an inspection on the compliance with the requirements under Art. 148 and the Good production practice, determined under Art. 152.

(3) Where after the inspection under Para. 2, BDA finds that the conditions for production, control and storage of the out coming materials for production and of the ready medicinal products fail to meet the requirements of this Act, and of the Good production practice, it shall notify the relevant person under Para. 1 and shall give written instructions.

(4) In case that within the term of 60 days from the date of the notification the relevant persons under Para. 1 fails to remove the found non-compliances, the executive director of the BDA shall withdraw the issued under the repealed Act on the Medicines and Pharmacies in the Human Medicine (published, SG, 36/1995; Decision N 10 of the Constitutional court of 1996 - 61/1996; amend., 38 /1998, 30/1999, 10/ 2000; Decision N 3 of the Constitutional court of 2000 – 37/ 2000; amend., 59/2000; Decision N 7 of the Constitutional court of 2000 - 78/2000; amend, 41/2001, 107 and 120 of 2002; corr., 2/2003; amend., 56, 71 and 112/2003, 70 and 111 of 2004, 37, 76, 85, 87, 99 and 105 /2005, 30, 31, 34, 75, 80 and 105/2006.; repealed., 31/2007) permit for production under the conditions of Art. 160a.

(5) Where after the inspection under Para. 2 it is found that the relevant persons under Para. 1 has not complied with the requirements of Art. 148 and of the Good production practice under Art. 152, the BDA shall withdraw the issued authorisation for production under the conditions of Art. 160a.

(6) Where after the inspection under Para. 2 it is found that the relevant persons under Para. 1 has complied with the requirements of Art. 148 and of the Good production practice under Art. 152, the BDA shall issue a new authorisation for production under this Act, after:

1. submitting an application and the documentation under Art. 150 and 151, and

2. producing a document for a paid charge in the amount of BGN 1500.

(7) Where within one month term after finalisation of the inspection under Para. 2, the person under Para. 6 has not submitted an application and the documentation under Art. 150 and 151, the issued permit for production under the repealed Act on the Medicines and Pharmacies in the Human Medicine shall be terminated.

§ 67. (1) The open and non-finalised up to the enforcement of this Act procedures for issuance or changes of authorisations for retail trade with medicinal products shall be examined and finalised under the previous order without producing proposals of the High council of pharmacy.

(2) Within the term of 3 months from the enforcement of this Act, the Ministry of Health shall submit to the BDA with a protocol the archive of the finalised procedures.

(3) Within the term of up to 2 months from the enforcement of this Act, the Ministry of Health shall submit to the BDA with a protocol they kept by the Ministry of Health register of the issued authorisations for retail trade with medicinal products in a pharmacy.

(4) After issuance of an authorisation under Para. 1, the Ministry of Health shall submit within 3 day term officially to the BDA a copy of it for entering into the register of the issued authorisations for retain trade with medicinal products.

(5) After finalisation of the procedures under Para. 1, the Ministry of Health shall submit to the BDA with a protocol their archive.

§ 68. (1) The applications for issuance or changes of registrations certificates for drugstores, submitted before the enforcement of this Act, shall be examined under the terms and conditions, provided by it.

(2) Within the term of 1 month after the enforcement of this Act, the BDA shall submit to the relevant Regional health inspectorate with a protocol the applications and the documentation, submitted for procedures for issuance of registration certificates of drugstores, as well as the archive of the finalised procedures.

(3) Within the term of 1 month after the enforcement of this Act, the BDA shall submit to the Ministry of Health with a protocol the kept in BDA register of the issued registration certificates for a drugstore.

(4) Within the term of 1 month after the submission of the register under Para. 3, the Ministry of Health shall draw up and publish on its website the national register of the issued before the enforcement of this Act registration certificate for drugstores.

§ 69. (1) Within the term of 3 months from the enforcement of this Act, the procedures for conforming or registration of prices of medicinal products shall be done under the current procedure by the Commission of prices of the medicinal products.

(2) After expiry of the term under Para. 1, the Commission of prices of the medicinal products shall submit to the Commission on prices and reimbursement with a protocol the applications and documents. Submitted rot the procedures under Para. 1, as well as the archive of the finalised procedures for confirming or registration of prices of medicinal products.

(3) After expiry of the term under Para. 1, the Commission of prices of the medicinal products shall submit to the Commission on prices and reimbursement with a protocol they kept by the Commission registers of issued authorisations for confirmation or registration of prices of medicinal products.

§ 70. (1) Within the term of 3 months after the enforcement of this Act, the procedures for including, excluding and/or changes of medicinal products in the Positive Medicines List shall be done in the current procedure by the Commission on the Positive Medicines List.

(2) After expiry of the term under Para. 1, the Commission of the Positive Medicines List shall submit to the Commission on prices and reimbursement with a protocol the application and documents, submitted for the procedures under Para. 1, as well as the archive of the finalised procedures for including, excluding and/or changes of medicinal products of the Positive Medicines List.

§ 71. The state charges, paid under the procedures under § 69, Para. 1 and § 70, Para. 1, shall be spend for the administrative procedures, as well as for the activity of the Transparency commission.

§ 72. (1) The prices, determined under Art. 258, Para. 1 of the medicinal products, which at the enforcement of this Act have been included in the Positive Medicines List, shall be considered for their limit prices at their retail sale under Art. 258, Para. 3.

(2) Within the term of 3 months from the enforcement of this Act, the Commission of prices of the medicinal products shall delete from the register of the limit prices they formed limit prices of the medicinal products under Para. 1.

(3) By 31 December 2012 the holders of authorisations for use shall not change the price of a medicinal products with the exception of its lowering for products, which at the enforcement of this Act have has a determined price, but have not been included in the Positive Medicines List.

§ 73. (1) With the enforcement of this Act, the formed limit prices of medicinal products, sold on doctor's prescription and the registered prices of medicinal products, sold without doctor's prescription shall be considered for their registered prices under Art. 158, Para. 2.

(2) Apart from the cases under Para. 1, with the enforcement of this Act the formed limit prices of medicinal products, which belong to an international non-patent name, which has been included in the Positive medicinal list, with the exception of the products, included in Annex N2 of the list, shall be considered for their limit prices at their retail sale and shall not be changed until the adoption of the Ordinance under Art. 258, Para. 5.

(3) Within the term of up to 3 months from the enforcement of this Act, the Commission of prices of the medicinal products shall draw up the register under Art. 261, Para. 3, which shall contain the prices under Para. 1.

§ 74. Within the term of up to 3 months from the enforcement of this Act, the Commission on the Positive Medicines List shall comply the Positive Medicines List with the requirements of Art. 262, Para. 5, p. 1-3.

§ 75. Within the term of up to 3 months from the enforcement of this Act the Council of Ministers shall select a staff of the Commission on prices and reimbursement.

§ 76. Within the term of up to 3 months from the enforcement of this Act:

1. The Minister of Health shall amend and supplement the ordinances under Art. 82, Para. 3, Art. 219, Para. 2 and Art. 243 in compliance with this Act.

2. The Council of Ministers shall adopt the Ordinance under Art. 258, Para. 5 and shall amend the tariff under Art. 21, Para. 2 and the Rules of procedure of the Ministry of Health in compliance with this Act.

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§ 84. This Act shall come into force from the day of its publication in the State Gazette, with the exception of § 65, which shall come into force from 30 September 2011.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE CIVIL SERVANTS ACT

(PROM. - SG 38/12, IN FORCE FROM 01.07.2012)

§ 84. (In force from 18.05.2012) Within one month after the promulgation of this Act in the State Gazette:

1. The Council of Ministers shall adjust the Classified of positions in administration to the provision of this Act;

2. the competent bodies shall adjust the structural acts of the respective administration to the provisions of this Act.

§ 85. (1) The legal relationships with the persons from administrations under the Radio and Television Act, Independent Financial Audit Act, Electronic Communications Act, Financial Supervision Commission Act, Act on Access to and Disclosure of the Documents and Announcing Affiliation of Bulgarian Citizens with the State Security Service and the Intelligence Services of the Bulgarian Popular Army, Act on Seizure in Favour of the State of Property, Acquired through Criminal Activity Act on Prevention and Findings of Conflict of Interests, Code of Social Insurance, Health Insurance Act, Agricultural Producers Assistance Act, Roads Act shall be regulated subject to compliance with the provisions and following the procedure of § 36 of the Transitional and Conclusive Provisions of the Act amending and supplementing the Civil Servants Act (SG 24/06).

(2) By the act of appointment of a civil servant:

1. the minimum rank for the occupied position shall be conferred, as determined in the Classified of positions in the administration, unless the servant hold a higher rank;

2. individual monthly salary shall be fixed.

(3) Additionally required funds for insurance contributions of the persons under par. 2 shall be provided within the cost of salaries, remunerations and insurance contributions within the budgets of the respective administrators of budget credits.

(4) Council of Ministers must make necessary adjustments in the out-of-budget account of State Fund "Agriculture", arising out of this Act.

(5) Managing bodies of National Social Insurance Institute and of National Health Insurance Fund must make necessary adjustments in the respective budgets, arising out of this

Act.

(6) The non-used leaves regulated in the employment agreement shall be kept and shall not be compensated with a financial benefit.

§ 86. (1) Within one month after entering of this Act into force the individual basic monthly salary of the employee shall be determined in such a way that the salary after the due tax and the obligatory insurance contributions chargeable to the insured person, where they have been payable, shall not be less than the gross monthly salary received by that time after the due obligatory insurance contributions chargeable to the insured person, where they have been payable, and the due tax.

(2) The gross salary under par. 1 shall include:

1. the basic monthly salary or the basic monthly remuneration;

2. additional payments payable permanently together with the payable basic monthly salary or basic monthly remuneration and depend solely on the hours worked.

§ 87. The law shall enter into force from 1 July 2012, except for § 84, which shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH INSURANCE ACT

(PROM. - SG 60/12, IN FORCE FROM 07.08.2012)

§ 44. The Act shall enter into force from the day of its promulgation in the State Gazette.

Additional provisions
S TO THE ACT, AMENDING AND SUPPLEMENTING THE ACT ON MEDICINAL PRODUCTS IN HUMANE MEDICINE

(PUBL. – SG, 102/2012, IN FORCE FROM 21.12.2012)

§ 118. This act shall introduce the provisions of Directive 2012/84/EU on the European Parliament and of the Council of 15 December 2012 amending, as regards pharmaco-vigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ, L 348/74 of 31 December 2010) and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ, L 174/74 of 1 July 2011).

Transitional and concluding provisions
TO THE ACT, AMENDING AND SUPPLEMENTING THE ACT ON MEDICINAL PRODUCTS IN HUMANE MEDICINE

(PUBL. – SG, 102/2012, IN FORCE FROM 21.12.2012)

§ 119. (1) After 2 January 2013, the manufacturers, importers and wholesale traders of active substances shall submit to BDA within the term of up to 2. March 2013 an application and entry documents under Art. 167b.

(2)The manufacturers and importers, who have manufactured or imported active substances on the basis of their issued authorisations for manufacture/import by 2 January 2013, shall not pay fee for their entry into the register under Art. 167.

(3) By 2 March 2013 the persons under Para. 2 shall carry out activities of manufacture and import of active substances, based on their issued authorisations for manufacture/import.

§ 120. Persons, who carry out intermediation in the area of medicinal products and have started their activity before 2 January 2013, shall be registered under the conditions and procedure of Art. 212a within the term of up to 2 March 2013.

§ 121. The started marketing authorisation procedures by the enforcement of this act shall be finalised under the terms and procedure, provided by it.

§ 122. (1) The marketing authorisations holders shall not apply a system for risk management under Art. 192, Para. 1, p. 2 for medicinal products, who have been issued marketing authorisations before 21, July 2012, apart from the cases under Para. 2.

(2) The BDA may impose obligations of the marketing authorisation holder to establish and apply a risk management system, where he/she considers, that for a certain medicinal products there are suspects, which may influence the benefit/risk ratio. In this case BDA shall require from the marketing authorisation holder to produce a detailed description of the risk management system, which he/she intends to introduce for the relevant medicinal product.

(3) In the cases under Para. 2, BDA shall notify in writing the marketing authorisation holder by pointing out the motives for imposing the obligation and the term for producing a detailed description of the risk management system.

(4) Within 30-day term after receiving the notification under Para. 3, the marketing authorisation holder may request from BDA providing an opportunity for producing information about the imposed obligation under Para. 2.

(5) After receiving the request under Para. 4, BDA shall determine and term for producing the information by the marketing authorisation holder.

(6) Based on the produced information, BDA may confirm the imposed obligation under Para. 2 or withdraw it.

(7) The BDA shall notify the holder about the decision, taken under Para. 6.

(8) Where BDA confirms the obligation, the executive director shall issue officially a change of the marketing authorisation by including in it a condition for the imposed obligation under Para. 2.

§ 123. The marketing authorisation holders of medicinal products, issued before 21 June 2012, shall fulfill the obligation under Art. 192, Para. 1, p. 1 starting from 21 July 2015 or from the date of renewal of the marketing authorisation of the relevant medicinal product, depending on which of the two dates will come first.

§ 124. The started non-interventional studies before the enforcement of this act shall be finalised under the current procedure.

§ 125. (1) By occurrence of the conditions and term under Art. 2, p. 3 of Directive 2010/84/EU the marketing authorisation holders shall submit the notifications for serious reverse medicinal reactions, occurred on the territory of the Republic of Bulgaria to BDA and to the European Medicines Agency within the term of up to 15 days from their receiving.

(2) The BDA shall check the fulfillment of the obligation under Para. 1.

(3) Where the notification refers a serious reverse medicinal reaction, occurred on the territory of a third state, the marketing authorisation holders within the term under Para. 1 shall notify the European Medicines Agency.

§ 126. (1) The marketing authorisation holders shall submit to BDA periodic updated safety reports in compliance with the time intervals under Art. 194k, Para. 3 for the medicinal products, which have issued marketing authorisations before 21 June 2012 and for which the frequency and the dates a of submitting the periodic updated safety reports have not been entered as conditions in the marketing authorisations.

(2) The provision of Para. 1 shall apply by determination of another frequency or other dates for submitting the reports in the marketing authorisation or by determining dates and frequency under Art. 194l-194n.

§ 127. (1) The marketing authorisation holders shall provide periodic updated safety reports under Art. 194h, Para. 1 in the register under Art. 194h, Para. 3 after expiry of 12 months from the date on which the European Medicines Agency announces its functioning.

(2) By the time the term under Para. 1 comes, the marketing authorisation holders shall produce periodic updated safety reports to BDA and to the regulatory bodies if the other Member States, in which the relevant medicinal products is permitted for use.

§ 128. The wholesale trade authorisation/certificate holders of medicinal products in a pharmacy or drug store under Art. 234, Para. 5 shall place on the internet site the logo under Art. 234, Para. 6 within the term of up to 1 year from the date of publication of the act under Art. 85a, Para. 3 of Directive 2001/83/EC.

§ 129. The BDA shall carry out the first audit of the system under Art. 183, Para. 1 and shall submit to the European Commission a report with the results from it by 21, September 2013 latest.

§ 130. (1) By 20 March 2013 the initiated and not finalised procedures before the Commission on Prices and Reimbursement shall be finalised by it under the current procedure.

(2) After 1 April 2013 not finalised procedure before the Commission on Prices and Reimbursement shall be finalised by the National council on prices and reimbursement of medicinal products under the terms and procedure of this act.

(3) Within the term of up to 31 March 2013 the Commission on Prices and

Reimbursement shall produce to the National council on prices and reimbursement of medicinal products by a record protocol the applications and documents, submitted for the procedures under Para. 1 as well as the archive of the finalised procedures.

(4) Within the term of up to 31 March 2013 Commission on Prices and Reimbursement shall produce to the National council on prices and reimbursement of medicinal products by a record protocol the kept registers by the Commission.

§ 131. (1) By 20 March 2013 the fees for submitting an application for confirmation of process / limit prices, registration of process of medicinal products, for inclusion, exclusion or changes of medicinal products in the Positive Medicines List shall be collected by the Ministry of Health within the sizes, provided by the tariff under Art. 21, Para. 2.

(2) The collected by 20 March 2013 financial means under Para. 1 shall be spent for the activity of the Commission on Prices and Reimbursement and the Transparency Commission.

§ 132. Within the term of up to 3 months from the enforcement of this act, the Council of Ministers upon proposal of the Minister of Health shall:

1. select the chairperson and the members of the National council on prices and reimbursement of medicinal products;

2. adopt rules of procedure of National council on prices and reimbursement of medicinal products.

§ 133. (1) Within the term of 2 months from the enforcement of this act, the Counsel of Ministers shall amend the tariff under Art. 21, Para. 2.

(2) Within the term of up to 1 April 2013 the Council of Ministers shall adopt the ordinance under Art. 261a, Para. 5.

§ 134. The obligations under Art. 159, Para. 4, Art. 168, Para. 8, Art. 168a and 168b shall begin to be implemented 3 years after the date of publication of the delegated acts under Art. 54a of Directive 2001/83/EC in Official Journal of the EU.

§ 138. This act shall come into force from the day of its publication in the State Gazette with the exception of:

1. Para. 9, p. 1, letter a, § 29 – 36, § 38-43, § 44 about Art. 167a, 167b. 167c, 167d, Art. Q67f, Para. 1 and Para. 2, p. 1 and Art. 167h, § 65-76, § 98, p. 1 and 2, § 101, p.1, letters a and b, § 102, 103, 106-108, 111, § 117, p. 1 letters a, f, g and l, which shall come into force from 2 January 2013;

2. Para. 20 and 117, p. 2, which shall come into force from 1 April 2013;

3. Para. 44 about Art. 167, Para. 2, p. 2 and Para. 3 and Art. 167g, which shall come into force from 2 July 2013.

Transitional and concluding provisions
TO THE PUBLIC FINANCE ACT

(PROM. SG 15/13, IN FORCE FROM 01.01.2014)

§ 123. This Act shall enter into force on 1 January 2014 with the exception of § 115, which enters into force on January 1, 2013, and § 18, § 114, § 120, § 121 and § 122, which came into force on 1 February in 2013.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PROM. SG 1/14, IN FORCE FROM 03.01.2014)

§ 18. Within one month from entry into force of this Act the Minister of Health shall bring the ordinance under Art. 221, para 1 of the Medicinal Products in Human Medicine Act in compliance therewith.

§ 19. This Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENING AND SUPPLEMENTING THE HEALTH INSURANCE ACT

(PROM. - SG 48/15)

§ 46. (1) Within three months from entry into force of this Act, medical scientific societies shall provide the National Council on Prices and Reimbursement of Medicinal Products with manuals and algorithms under Art. 259, para 1, item 4 of the Medicinal Products in Human Medicine Act.

(2) Where medical scientific societies fail to provide guidelines and algorithms under Art. 259, para. 1, item 4 of the Medicinal Products in Human Medicine Act within the time limits under para 1, the National Council on Prices and Reimbursement of Medicinal Products shall organize their preparation by national consultants or other medical professionals who have experience in the field.

(3) The National Council on Prices and Reimbursement of Medicinal Products shall approve the manuals and algorithms under Art. 259, para 1, item 4 of the Medicinal Products in Human Medicine Act within three months from expiry of the time limit set under para 1.

§ 47. (1) Within three months from entry into force of this Act, the Minister of Health shall issue an ordinance under Art. 262, para 4 of the Medicinal Products in Human Medicine Act.

(2) Within 6 months from entry into force of this Act in the Positive Medicines List may be included medicines with new international non-proprietary names without health technology assessment.

Relevant legislative Documents from the European Legislation:

Directive 2001/83/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 6 November 2001 on the Community code relating to medicinal product for human use

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

DIRECTIVE OF COUNCIL 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications.

COUNCIL DIRECTIVE FROM 14 OF JUNE 1989 extending the scope of application of the Directive 65/65/EEC and (89/381/EEC) and 75/319/EEC for the approximation of the laws, regulations and administrative provisions regarding the medicinal products and establishing specific provisions for the medicinal products derived from human blood and plasma

COUNCIL DIRECTIVE 87/18/EEC OF 18 DECEMBER 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for trials on chemical substances.

COUNCIL DIRECTIVE 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy

SECOND COUNCIL DIRECTIVE 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products

DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

REGULATION (EC) NO 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

COMMISSION REGULATION (EC) NO 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

REGULATION (EC) NO 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999 on orphan medicinal products.

COMMISSION REGULATION (EC) NO 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ, L 334/7 of 12.12.2008).

НАРЕДБА № 31 от 12.08.2007 г. за определяне на правилата за Добра клинична практика

Издадена от министъра на здравеопазването, обн., ДВ, бр. 67 от 17.08.2007 г., изм. и доп., бр. 14 от 17.02.2012 г.

Раздел I
Общи положения

Чл. 1. (1) С тази наредба се определят правилата на Добрата клинична практика (ДКП) съгласно приложение № 1 и се урежда контролът по изпълнението им.

(2) С наредбата се определят и изискванията към съдържанието и формата на документацията, която се представя за разрешаване на клинично изпитване и неинтервенционално проучване, при промяна и при прекратяване на клинично изпитване и неинтервенционално проучване.

Раздел II
Изисквания към документацията за разрешение за провеждане на клинични изпитвания
(Загл. изм. - ДВ, бр. 14 от 2012 г.)

Чл. 2. Административната документация по чл. 110, ал. 1, т. 1 от Закона за лекарствените продукти в хуманната медицина (ЗЛПХМ) съдържа:

1. придружително писмо;

2. заявление по образец;

3. потвърждение за получен номер от Европейската база данни за клинични изпитвания;

4. списък на регулаторните органи и комисии по етика, до които е подадено заявление, и решението им;

5. списък на всички планирани центрове, главни изследователи и изследователски екипи за територията на Република България;

6. копие от препоръките на научен комитет на Европейската агенция по лекарствата по консултация по планиране на изпитвания, при преминала процедура;

7. възлагателно писмо или договор за упълномощаване на лицето, което подава

заявлението от името на възложителя, когато заявителят не е възложител;

8. (доп. - ДВ, бр. 14 от 2012 г.) документ за актуална регистрация, издаден от компетентен орган, на възложителя и заявителя на територията на Европейския съюз; когато възложителят или заявителят е физическо лице, се представят данни - имена, адрес, телефон, факс;

9. декларацията по чл. 122 ЗЛПХМ.

Чл. 3. Информацията за участник по чл. 110, ал. 1, т. 2 ЗЛПХМ съдържа:

1. информация за пациента/участника;

2. форма за информирано съгласие;

3. описание на процедурите за набиране на пациенти/участници;

4. описание на процедурите за получаване на информирано съгласие от законен представител, когато се предвижда;

5. етична обосновка в случай на набиране на участници, които не са в състояние да дадат информирано съгласие, съгласно чл. 98 ЗЛПХМ;

6. копие от всяка друга информация, която ще бъде използвана за набиране на участници и/или предоставяна на участник преди или по време на клиничното изпитване.

Чл. 4. (1) Документацията за протокола на изпитването по чл. 110, ал. 1, т. 3 ЗЛПХМ съдържа:

1. протокол на изпитването с всички актуални промени;

2. обобщение на протокола на български език;

3. оценка на научната стойност на изпитването от специалист в съответната област, когато е налична;

4. етична оценка на протокола от главния или координиращия изследовател, когато не е част от протокола.

(2) Протоколът се изготвя в съответствие с правилата за ДКП и съдържа минимум следното:

1. оценка на очакваните ползи и рискове съгласно чл. 90, т. 1 ЗЛПХМ;

2. определяне на включващите и изключващите критерии;

3. обосновка на избора на пациенти, особено в случай на предвидено включване на

пациенти, които не са в състояние да дадат лично информирано съгласие, и други уязвими групи пациенти;

4. описание на процедурите за набиране на пациенти и получаване на информирано съгласие, когато се предвижда включване на пациенти, които временно или постоянно не са в състояние да дадат лично информирано съгласие, и когато се предвижда получаване на съгласие от независим свидетел;

5. описание на плана и процедурите за осигуряване на допълнителни медицински грижи на участниците след края на проучването;

6. процедури за извършване на мониториране;

7. план за публикуване на данните.

(3) Протоколът трябва да бъде подписан от възложителя и главния изследовател за всеки от предлаганите центрове.

Чл. 5. (1) Документацията за изпитвания лекарствен продукт по чл. 110, ал. 1, т. 4 ЗЛПХМ съдържа:

1. брошура на изследователя;

2. обобщение на всички текущи клинични изпитвания с лекарствения продукт.

(2) Когато изпитваният лекарствен продукт е разрешен за употреба в държава - членка на Европейския съюз, и изпитването предвижда употребата му в съответствие с условията, определени в разрешението за употреба, вместо документа по чл. 1, т. 1 може да се представи кратка характеристика на продукта.

(3) Брошурата на изследователя и всяка нейна актуализация трябва да представя научно аргументирана и пълна информация за продукта, която е необходима за обективна преценка на съотношението риск/полза на предложеното клинично изпитване.

(4) Възложителят преоценява брошурата на изследователя и я допълва с нови данни при наличие на такива най-малко веднъж годишно.

Чл. 6. (1) Документацията за техническите изисквания и персонала по чл. 110, ал. 1, т. 5 ЗЛПХМ съдържа:

1. описание на необходимото оборудване и/или технически изисквания за изпълнение на протокола;

2. документи, удостоверяващи наличните технически възможности за изпълнение на протокола, за всеки от предлаганите центрове, включително документи за сертификация, акредитация и установен качествен контрол и/или външна оценка на качеството;

3. автобиография и/или други документи, удостоверяващи образованието и квалификацията на членовете на изследователския екип и спазването на изискванията на чл. 86, ал. 2 ЗЛПХМ;

4. документи, удостоверяващи обстоятелствата по чл. 87, ал. 1 ЗЛПХМ.

(2) Документите по т. 2 се изготвят от специализирана независима организация и/или ръководителя на лечебното заведение и/или структура, в която е планирано извършването на всяка процедура, изискваща специфично оборудване, описана в протокола.

(3) Документите по т. 4 се представят за координиращ изследовател, главен изследовател, за всеки от предлаганите центрове. При изискване от комисията по етика документите по т. 4 се представят и за другите лица от изследователския колектив.

Чл. 7. Данните за финансиране и административна организация на проучването по чл. 110, ал. 1, т. 6 ЗЛПХМ съдържат:

1. застраховка, покриваща отговорността на възложителя и главния/те изследовател/и за причинените при или по повод на провеждането на клиничното изпитване неимуществени и имуществени вреди на участниците;

2. информация за предвидените обезщетения и компенсации в случай на смърт или на увреждане на здравето на участника при провеждане на клиничното изпитване;

3. договор между възложителя и участниците в изпитването, който определя и възнаграждението за участие, когато се предвижда такова;

4. договор между възложителя и изследователя;

5. договор между възложителя и лечебното заведение - център на клинично изпитване;

6. писмено съгласие по чл. 87, ал. 3 ЗЛПХМ;

7. данни за източника на финансиране на проучването, когато възложителят е юридическо лице с нестопанска цел;

8. документ за платена такса.

Чл. 8. (1) За клинично изпитване на лекарствен продукт по чл. 88 ЗЛПХМ възложителят или упълномощено от него лице представя в Изпълнителната агенция по лекарствата заявление за провеждане на клинично изпитване по образец.

(2) Към заявлението се прилагат документите по чл. 2 , 3 , 4, 5, 6, 7, 9 и чл. 19, ал. 3 , както и декларациите по чл. 122 и 123 ЗЛПХМ.

(3) (Отм. - ДВ, бр. 14 от 2012 г.).

Чл. 9. Възложителят или упълномощеното от него лице представя в Изпълнителната агенция по лекарствата и следната документация по чл. 116, ал. 4, т. 4 ЗЛПХМ:

1. досие на изпитвания лекарствен продукт;

2. документация, удостоверяваща производството на изпитваните продукти при условията на Добра производствена практика;

3. аналитичен сертификат на изпитвания продукт, когато примесите не са обосновани в спецификацията или когато се установят неохарактеризирани примеси;

4. резултати от изпитвания за вирусна безопасност;

5. сертификат за отсъствие на причинители на преносима спонгиформна енцефалопатия;

6. макети на етикета на български език;

7. становище от Министерството на околната среда и водите по отношение на потенциалния риск за околната среда, когато изпитваният лекарствен продукт съдържа генетично модифицирани организми.

Чл. 10. (1) Досието на изпитвания лекарствен продукт се изготвя в съответствие с публикуваните ръководства на Европейската комисия във формат и съдържание съгласно приложение № 2.

(2) Когато изпитваният лекарствен продукт се произвежда на територията на Европейския съюз и няма разрешение за употреба, вместо документа по чл. 9, т. 2 се представя копие от разрешение за производство за лекарствени продукти в процес на разработване и изследване, издадено от държава - членка на Европейския съюз.

(3) Когато изпитваният лекарствен продукт не се произвежда на територията на Европейския съюз и няма разрешение за употреба, се представят следните документи за производство:

1. документ от квалифицираното лице на физическо или юридическо лице, притежаващо разрешение за внос на територията на Европейския съюз, удостоверяващ съответствието на условията за производство, контрол и съхранение със стандарти, еквивалентни на изискванията на Добрата производствена практика за лекарствени продукти в процес на разработване и изследване, валидни за територията на Европейския съюз;

2. копие от разрешението за внос за територията на Европейския съюз;

3. сертификат за Добра производствена практика за активните вещества от биологичен произход.

(4) Когато изпитваният лекарствен продукт се произвежда на територията на Европейския съюз и има разрешение за употреба, вместо документа по чл. 9, т. 2 се представя декларация от производителя за произход на продукта от стандартни партиди, произведени при условията на разрешението за употреба, в място на производство, включено в разрешението за употреба на територията на държава - членка на Европейския съюз.

(5) Когато изпитваният лекарствен продукт има разрешение за употреба в държава - членка на Европейския съюз, и/или разрешено клинично изпитване в Република България, по чл. 9, т. 1 се представя съкратено досие на изпитвания лекарствен продукт.

Чл. 11. (Отм. - ДВ, бр. 14 от 2012 г.).

Раздел III
Изисквания към документацията за промяна на разрешение за провеждане на клинични изпитвания
(Загл. изм. - ДВ, бр. 14 от 2012 г.)

Чл. 12. Съществена промяна по чл. 127, ал. 2 ЗЛПХМ е налице, когато има промяна в данните, посочени в приложение № 3.

Чл. 13. (1) При планиране на съществени промени в клиничното изпитване и в документацията по чл. 110 ЗЛПХМ възложителят или упълномощено от него лице подава писмено заявление по образец до комисията по етика по чл. 103 ЗЛПХМ.

(2) Заявлението се придружава от следната документация:

1. придружително писмо;

2. обобщение на планираната промяна;

3. списък на актуализираните документи;

4. актуализираната документация по чл. 2, 3, 4, 5, 6 и 7, отразяваща промените;

5. страници от документацията с маркирани промени, сравняващи актуалните и предлаганите нови текстове;

6. обосновка на промените;

7. копие на заявлението за провеждане на клинично изпитване по чл. 2 с маркирани промени, на електронен и хартиен носител;

8. документ за платена такса.

Чл. 14. (1) При планиране на съществени промени в клиничното изпитване и в документацията по чл. 116 ЗЛПХМ възложителят или упълномощено от него лице подава в Изпълнителната агенция по лекарствата писмено заявление за промяна по образец.

(2) Заявлението се придружава от документацията по чл. 13, ал. 2, т. 1, 2, 3, 4, 5, 6 и 8 , декларацията по чл. 123 ЗЛПХМ и копие от положителното становище на комисията по етика, когато стане налично.

(3) Представя се и заявлението по чл. 8, ал. 1 , попълнено с актуализирана информация, отразяваща предлаганата промяна, както и копие с маркирани промени, на електронен и хартиен носител.

(4) При промени по чл. 127, ал. 1 ЗЛПХМ заявление се подава в срок до 14 дни от получаване на уведомление от Изпълнителната агенция по лекарствата за необходимата промяна.

Чл. 15. (Отм. - ДВ, бр. 14 от 2012 г.).

Раздел IIIA
(Нов - ДВ, бр. 14 от 2012 г.)
Изисквания към документацията за провеждане на неинтервенционално проучване и промени в него

Чл. 15а. (Нов - ДВ, бр. 14 от 2012 г.) За неинтервенционално проучване на лекарствен продукт по чл. 145 ЗЛПХМ възложителят или упълномощеното лице представя в Изпълнителната агенция по лекарствата и в комисията по етика по чл. 103 ЗЛПХМ заявление по образец за провеждане на неинтервенционално проучване.

Чл. 15б. (Нов - ДВ, бр. 14 от 2012 г.) Административната документация за проучванията по чл. 145 ЗЛПХМ съдържа:

1. придружително писмо;

2. заявление по образец;

3. списък на всички планирани центрове и главни изследователи за територията на Република България;

4. копие от препоръките на научен комитет на Европейската агенция по лекарствата по консултация по планиране на проучвания, при преминала процедура;

5. възлагателно писмо или договор за упълномощаване на лицето, което подава заявлението от името на възложителя, когато заявителят не е възложител;

6. документ за актуална регистрация, издаден от компетентен орган, на възложителя и заявителя на територията на Европейския съюз; когато възложителят или заявителят е физическо лице, се представят данни - имена, адрес, телефон, факс;

7. декларация, че подадената до ИАЛ и до комисията по етика документация съдържа една и съща информация.

Чл. 15в. (Нов - ДВ, бр. 14 от 2012 г.) Информацията за участник в неинтервенционално проучване съдържа:

1. информация за пациента/участника;

2. форма за информирано съгласие, с изключение на случаите, когато се обработва ретроспективно и анонимно медицинска информация;

3. описание на процедурите за набиране на пациенти/участници;

4. описание на процедурите за получаване на информирано съгласие от законен представител, когато се предвижда;

5. етична обосновка в случай на набиране на пациенти/участници, които не са в състояние да дадат информирано съгласие съгласно чл. 98 ЗЛПХМ;

6. копие от всяка друга информация, която ще бъде използвана за набиране на пациенти/участници и/или предоставяна на пациент/участник преди или по време на неинтервенционалното проучване.

Чл. 15г. (Нов - ДВ, бр. 14 от 2012 г.) (1) Документацията за протокола на неинтервенционалното проучване или ръководството за извършване на неинтервенционално проучване с ретроспективно и анонимно обработване на медицинска информация съдържа:

1. протокол или ръководство за извършване на неинтервенционалното проучване с всички актуални промени;

2. обобщение на протокола или ръководството за извършване на проучването на български език;

3. план за публикуване на данните.

(2) Протоколът, съответно ръководството, трябва да бъде подписан от възложителя и от главния изследовател за всеки от предлаганите центрове.

Чл. 15д. (Нов - ДВ, бр. 14 от 2012 г.) Документацията за наблюдавания/те лекарствен/и продукт/и за неинтервенционално проучване съдържа актуалната кратка характеристика на лекарствения продукт.

Чл. 15е. (Нов - ДВ, бр. 14 от 2012 г.) Документацията за техническите изисквания съдържа:

1. описание на необходимото оборудване и/или технически изисквания за изпълнение на протокола или ръководството за извършване на неинтервенционалното проучване, когато е приложимо съгласно съответния медицински стандарт;

2. документи, удостоверяващи наличните технически възможности за изпълнение на протокола или ръководството, за всеки от предлаганите центрове, включително документи за сертификация, акредитация и установен качествен контрол и/или външна оценка на качеството, когато е приложимо;

3. разрешение за осъществяване на лечебна дейност по чл. 47, ал. 1/ удостоверение за регистрация по чл. 40, ал. 1 от Закона за лечебните заведения за лечебното заведение - център на неинтервенционалното проучване.

Чл. 15ж. (Нов - ДВ, бр. 14 от 2012 г.) Данните за финансиране и административна организация за неинтервенционално проучване съдържат:

1. застраховка, покриваща отговорността на възложителя и главния/те изследовател/и за причинените при или по повод на провеждането на неинтервенционалното проучване неимуществени и имуществени вреди на участниците, с изключение на случаите на неинтервенционално проучване, в което се обработва ретроспективно и анонимно медицинска информация;

2. договор между възложителя и изследователя;

3. договор между възложителя и участниците в изпитването, който определя и възнаграждението за участие, когато се предвижда такова;

4. данни за източника на финансиране на проучването, когато възложителят е юридическо лице с нестопанска цел;

5. документ за платена държавна такса.

Чл. 15з. (Нов - ДВ, бр. 14 от 2012 г.) (1) При планиране на съществени промени в неинтервенционално проучване по чл. 145 ЗЛПХМ възложителят или упълномощеното лице подава в Изпълнителната агенция по лекарствата и в комисията по етика по чл. 103 ЗЛПХМ писмено заявление за промяна по образец.

(2) Към заявлението по ал. 1 се прилага следната документация:

1. придружително писмо;

2. обобщение и обосновка на планираните промени;

3. списък на актуализираните документи;

4. актуализираната документация по чл. 15б - 15ж, отразяваща промените;

5. страници от документацията с маркирани промени, сравняващи актуалните и предлаганите нови текстове;

6. декларация, че подадената до Изпълнителната агенция по лекарствата и до комисията по етика документация съдържа една и съща информация;

7. документ за платена държавна такса.

(3) Възложителят може да приложи планирана промяна в неинтервенционално проучване по чл. 145 ЗЛПХМ, ако в едномесечен срок от подаване на заявлението за промяна не получи изричен отказ от директора на Изпълнителната агенция по лекарствата, съответно отрицателно становище от комисията по етика по чл. 103 ЗЛПХМ.

Раздел IV
Изисквания към документацията за уведомление за приключване на изпитване

Чл. 16. (1) Уведомлението по чл. 142, ал. 2 ЗЛПХМ се представя във формат, утвърден от изпълнителния директор на Изпълнителната агенция по лекарствата, на хартиен и електронен носител.

(2) Когато проучването се прекратява преди посоченото в протокола условие за приключване на изпитването, уведомлението съдържа следните допълнителни данни:

1. обосновка за прекратяването;

2. брой на участниците, получаващи изпитваните продукти в центровете на територията на Република България, и план за медицинските грижи за тях след прекратяване на проучването;

3. влиянието на прекратяването върху оценката на данните и съотношението риск/полза на изпитвания лекарствен продукт;

4. значение на данните, довели до прекратяване на изпитването, за други разрешени клинични изпитвания на територията на Република България.

Чл. 17. Всички документи, представяни на комисията по етика по чл. 103 ЗЛПХМ и Изпълнителната агенция по лекарствата, носят най-малко следните идентификационни елементи:

1. номер на изпитването от Европейската база данни за клинични изпитвания;

2. код на протокола;

3. версия и дата на документа.

Чл. 18. (1) Документацията за разрешаване, промяна и прекратяване на клинично изпитване се представя на български и/или английски език.

(2) (Изм. - ДВ, бр. 14 от 2012 г.) Документацията по чл. 2, т. 1, 2 и 5 , чл. 3, т. 1, 2 и 6 , чл. 4, ал. 1, т. 2 , чл. 6, ал. 1, т. 1, 3 и 4 , чл. 7, т. 1, 2, 3, 5 и 6 , чл. 8, ал. 1 и 3 , чл. 9, т. 6 , чл. 13, ал. 1 и ал. 2, т. 1 и 2, чл. 14, ал. 1 , чл. 15б, т. 1, 2 и 3, чл. 15в, т. 1, 2 и 6, чл. 15г, ал. 1, т. 2, чл. 15е, т. 1, чл. 15ж, т. 1, 2 и 3, чл. 15з, ал. 1 и ал. 2, т. 1 и 3 и чл. 16, ал. 1 се предоставя задължително и на български език.

(3) (Изм. - ДВ, бр. 14 от 2012 г.) Документацията по чл. 8, ал. 1 , чл. 14, ал. 1 и 3 , чл. 15а, чл. 15з, ал. 1, чл. 16, ал. 1 се предоставя задължително и на английски език.

Чл. 19. (1) (Изм. - ДВ, бр. 14 от 2012 г.) Изпълнителният директор на Изпълнителната агенция по лекарствата утвърждава със заповед образци на заявленията по чл. 2 , 8 , 13, 14, 15а и 15з, ал. 1 и уведомлението по чл. 16 .

(2) Заявленията се представят в един екземпляр, на хартиен и електронен носител.

(3) Заявленията на електронен носител се подават във формат, съвместим с изискванията за въвеждане в Европейската база данни за клинични изпитвания.

(4) Възложителят или упълномощеното лице декларира, че заявленията на електронен и хартиен носител съдържат идентична информация.

Раздел V
Контрол

Чл. 20. (1) Контролът върху клиничните изпитвания, провеждани в Република България, се осъществява от определените по чл. 267, ал. 3 ЗЛПХМ държавни инспектори.

(2) Контролът върху клиничните изпитвания, провеждани в Република България, може да се осъществява и от длъжностни лица на държавите - членки на Европейския съюз, и определени от Европейската агенция по лекарствата и научните й комитети.

(3) При нужда инспекторите могат да се съпътстват и подпомагат от експерти, определени от изпълнителния директор на Изпълнителната агенция по лекарствата.

(4) Контролът, провеждан от държавните инспектори, се извършва:

1. като предварителен, текущ и последващ при клинично изпитване на лекарствен продукт;

2. в хода на процедура по разрешаване за употреба;

3. като проследяващи мерки след разрешение за употреба.

(5) На контрол подлежат възложителят, главният изследовател и изследователите, договорната изследователска организация, комисиите по етика, центърът на изпитването, местата на производство и контрол на изпитвания лекарствен продукт, лабораториите и всяко място и съоръжение, използвано в хода на изпитването, както и цялата документация по клиничното изпитване.

Чл. 21. (1) Контролът върху клиничните изпитвания се провежда в съответствие със стандартни оперативни процедури, утвърдени от изпълнителния директор на Изпълнителната агенция по лекарствата. Стандартните оперативни процедури се разработват в съответствие с ръководните документи на Европейската комисия.

(2) Всяка проверка във връзка с клинично изпитване на лекарствен продукт завършва с доклад, който се предоставя на възложителя.

(3) Доклад от проверка на клинично изпитване може да бъде предоставен на изследователите, комисията по етика по чл. 103 ЗЛПХМ, другите държави - членки на Европейския съюз, и Европейската агенция по лекарствата.

Чл. 22. При констатиране на несъответствия, които налагат временно спиране или прекратяване на проучване, Изпълнителната агенция по лекарствата информира Европейската агенция по лекарствата, държавите членки, в които се провежда изпитването, Европейската комисия и комисията по етика по чл. 103 ЗЛПХМ.

Чл. 23. Изпълнителната агенция по лекарствата въвежда в Европейската база данни за клинични изпитвания информация за планираните и извършени проверки на клинични изпитвания.

ПРЕХОДНИ И ЗАКЛЮЧИТЕЛНИ РАЗПОРЕДБИ

§ 1. Тази наредба въвежда разпоредбите на Директива 2005/28/ЕО на Комисията от 8 април 2005 г. относно определяне на принципи и подробни насоки за добра клинична практика по отношение на лекарствените продукти за хуманна употреба, предназначени за изследване, както и изискванията относно издаването на разрешително за производството или вноса на такива продукти.

§ 2. Към подадените до влизането в сила на наредбата заявления за съществени промени в разрешение за провеждане на клинично изпитване на лекарствен продукт на територията на Република България възложителите представят в срок три месеца документацията, предвидена в наредбата.

§ 3. Тази наредба се издава на основание чл. 82, ал. 3, чл. 110, ал. 2, чл. 116, ал. 5, чл. 129, ал. 3, чл. 142, ал. 2 и чл. 145, ал. 2 ЗЛПХМ и отменя Наредба № 14 от 2000 г. за

условията и реда за провеждане на клинични изпитвания на лекарства върху хора (ДВ, бр. 73 от 2000 г.).

Приложение № 1
към чл. 1, ал. 1
(Изм. - ДВ, бр. 14 от 2012 г.)

ПРАВИЛА ЗА ДОБРА КЛИНИЧНА ПРАКТИКА

Въведение

Добра клинична практика е съвкупността от международно признати етични и научни изисквания за качество, които се спазват при планирането, провеждането, отчитането и докладването на клинични изпитвания.

Спазването на тези изисквания осигурява публично обезпечаване и защита на правата, безопасността и здравето на участниците в изпитването в съответствие с принципите, залегнали в Декларацията от Хелзинки, както и научната стойност и възпроизводимост на данните от клиничното изпитване.

Целта на правилата за ДКП е да се осигури единен стандарт за Европейската общност, Япония и САЩ с цел облекчаване на взаимното признаване на данни от клинични изпитвания от подвластните им регулаторни органи.

Правилата за ДКП са разработени, като са взети под внимание текущите добри клинични практики на Европейската общност, Япония и САЩ, както и тези на Австралия, Канада, скандинавските страни и Световната здравна организация.

Тези правила трябва да бъдат спазвани, когато се генерират данни от клинични изпитвания, които ще бъдат представяни пред регулаторните органи.

Принципите, заложени в тези правила, също така могат да бъдат прилагани по отношение на други клинични изследвания, които биха могли да имат въздействие върху безопасността и здравето на хората.

1. Определения

1.1. Нежелана лекарствена реакция (НЛР)

"Нежелана лекарствена реакция" е всеки нежелан и непредвиден отговор към лекарствен продукт, който се проявява при приложение на продукта в дози, нормално използвани за лечение, профилактика или диагностика на заболяване при хора или за възстановяване, корекция или модифициране на физиологична функция. В случай на клинично изпитване - всеки нежелан и непредвиден отговор към изпитван лекарствен продукт, независимо от приложената доза. Фразата "отговори към един лекарствен продукт" означава, че причинно-следствената връзка между лекарственото средство и нежеланата реакция е поне разумна възможност, т. е. връзката не може да се отхвърли.

1.2. Нежелано събитие

Нежелано събитие е всяка неблагоприятна промяна в здравното състояние, наблюдавана при прилагане на лекарствен продукт на пациент или участник в клинично изпитване, която не е непременно причинно свързана с това лечение.

Нежелано събитие следователно може да бъде всяка неблагоприятна и непреднамерена физикална находка (вкл. лабораторно отклонение), симптом или заболяване, свързано във времето с употреба на (изпитван) лекарствен

продукт, независимо дали е или не е причинно свързано с продукта.

1.3. Приложими изисквания

Всички нормативни изисквания, отнасящи се до провеждане на клинични изпитвания с лекарствени продукти.

1.4. Одобрение от комисията по етика

Положително становище на комисията по етика в потвърждение, че клиничното изпитване е оценено и може да бъде провеждано в учредения център при условията, определени от комисията по етика, лечебното заведение, ДКП и приложимите изисквания.

1.5. Независима проверка (одит)

Систематична и независима оценка на свързаните с изпитването задължения и документи за преценяване дали са извършени тези задължения, дали данните са записани, анализирани, внимателно докладвани, съгласно протокола, стандартните оперативни процедури (СОП) на възложителя, ДКП и приложимите нормативни изисквания.

1.6. Сертификат от проверка

Документ от проверяващия в потвърждение, че е извършена проверка.

1.7. Доклад от проверка

Писмена оценка на проверяващите от страна на възложителя за резултатите от проверката.

1.8. Следа за проверка

Документация, даваща възможност да се проследи последователността на събитията.

1.9. Заслепяване/маскиране

Процедура, при която една или повече от страните остават незапознати с назначеното лечение по тяхно предварително съгласие. Единично слепи обикновено са изпитванията, при които пациентите остават незапознати, а двойно слепи са изпитванията, при които пациентите, изследователите, лицата, извършващи мониториране, и понякога лицата, извършващи анализ на данните, остават незапознати с назначеното лечение.

1.10. Клинична карта на пациента (ККП)

Печатен, оптичен или електронен носител, изготвен за записване на цялата изисквана от плана информация за докладване на възложителя за всеки отделен участник.

1.11. Клинично изпитване/проучване

Клинично изпитване на лекарствен продукт е всяко проучване при човека, предназначено да се открият или потвърдят клиничните, фармакологичните и/или други фармакодинамични ефекти на един или повече изпитвани лекарствени продукти, и/или да се определят нежеланите реакции към един или повече изпитвани лекарствени продукти, и/или да се изследва абсорбцията, разпределението, метаболизма и екскрецията на един или повече изпитвани лекарствени продукти с цел да се установи тяхната безопасност и/или ефикасност.

Определенията клинично изпитване и клинично проучване са синоними.

Неинтервенционално проучване е проучване, при което лекарственият продукт(и) се предписва(т) по обичайния начин в съответствие с условията, определени в разрешението за употреба. Назначаването на пациента към определена терапевтична стратегия не се определя предварително чрез протокол

за изпитване, а попада в установената практика и решението за предписване на
лекарствения продукт е ясно разграничено от решението да се включи пациентът
в изпитването. По отношение на пациентите не трябва да се прилагат никакви
допълнителни процедури за диагностика или наблюдение и епидемиологичните
методи се използват за анализ на събраните данни.

1.12. Доклад от клинично изпитване/проучване

Писмено описание на всяко изпитване/проучване на терапевтично,
профилактично или диагностично средство, приложено върху хора, в което са
включени пълни клинични и статистически резултати, описания и анализи,
интегрирани в единен доклад.

1.13. Лекарствен продукт за сравнение

Изпитван или разрешен за употреба лекарствен продукт (т. нар. активен
контрол) или плацебо, използвани за сравнение по време на клинично изпитване.

1.14. Съответствие (по отношение на изпитването)

Спазване на всички изисквания - свързани с изпитването, изисквания на
ДКП и приложимите нормативни изисквания.

1.15. Поверителност

Недопускане на разкриване от външни лица, с изключение на
упълномощените лица, на информация, която принадлежи на възложителя, или
информация за самоличността на участниците.

1.16. Договор

Писмено, датирано и подписано споразумение между две или повече страни,
с което са определени всички мерки по възлагане, разпределение на задачи и
задължения и ако е приложимо, финансови въпроси. Протоколът може да служи за
основа на договор.

1.17. Координираща комисия

Комисия, която може да се назначи от възложителя, за координиране на
действията при провеждането на многоцентрови клинични изпитвания.

1.18. Координиращ изследовател

Изследовател, назначен с цел координиране на изследователите от
различните центрове, участващи в многоцентрово изпитване.

1.19. Договорна изследователска организация (ДИО)

Физическо и юридическо лице или научна организация, сключила договор с
възложителя за изпълнение на една или повече от свързаните с изпитването
функции и задължения на възложителя.

1.20. Директен достъп

Разрешение за изследване, анализиране, проверка и възпроизвеждане на
всички записи и доклади, които са важни за оценка на едно клинично изпитване
след разрешение. Всяка страна (напр. местните или чуждите регулаторни
органи, мониториращите на възложителя и проверяващите) с директен достъп
взима всички необходими предпазни мерки съгласно приложимите нормативни
изисквания за запазване на поверителността относно самоличността на
участниците и притежаваната от възложителя информация.

1.21. Документация

Всички записи във всякаква форма (вкл., без да се ограничава до,
писмени, електронни, магнитни, оптични записи, електроенцефалографии,
рентгенографии, електрокардиограми, хроматограми), описващи или записващи
метода, провеждането и/или резултата от изпитването, факторите, влияещи на
изпитването и предприетите действия.

1.22. Основно досие на клинично изпитване

Основното досие на клинично изпитване се състои от основни документи, които самостоятелно или заедно позволяват оценка на провеждането на клиничното изпитване и качеството на получените резултати.

1.23. Основни документи

Документи, които самостоятелно или заедно позволяват оценка на провеждането на клиничното изпитване и качеството на получените резултати.

1.24. Добра клинична практика (ДКП)

Съвкупността от международно признати етични и научни изисквания за качество, които се спазват при планирането, провеждането, отчитането и докладването на клинични изпитвания, които дават гаранция, че данните и докладваните резултати са правдоподобни и точни и че са запазени правата, неприкосновеността и поверителността на участниците.

1.25. Независима комисия за оценка на резултатите

Независима комисия за оценка на резултатите, която може да се създаде от възложителя за оценка през определени интервали от време на прогреса на едно клинично изпитване, данните за безопасност, основните параметри на ефикасност и за формиране на препоръки към възложителя дали да продължи, промени или да прекрати изпитването.

1.26. Независим свидетел

Лице, което: не участва и няма интерес от клиничното изпитване; не може да бъде повлияно от страна на участниците в изпитването; присъства на подписването на информираното съгласие, ако участникът или неговият законен представител не могат да четат, и прочита формата за информирано съгласие и всякаква друга писмена информация, предоставяна на участниците.

1.27. Комисия по етика

Независима структура (институционална, регионална, национална или наднационална комисия или комитет), съставена от медицински/научни специалисти и немедицински/ненаучни членове. Основната отговорност на комисията по етика е да се запазят правата и безопасността на хората, участващи в изпитването, и да се представи публично уверение на тази защита.

Защитата се реализира чрез разглеждане и даване на становище по протокола на клиничното изпитване и материалите за получаване и документиране на информирано съгласие на участниците и оценка дали изследователите, условията, методите за провеждане на изпитването са подходящи.

1.28. Информирано съгласие

Информирано съгласие е волеизявление, което трябва да бъде писмено, лично датирано и подписано, за участие в клинично изпитване, взето напълно свободно след надлежно уведомяване относно неговото естество, значимост, последствия и рискове и подходящо документирано от всяко лице, което е способно да даде съгласието си, или когато лицето не е способно да даде съгласието си - от неговия законен представител.

1.29. Инспекция

Официална проверка на контролните органи върху документи, условия, архив и всички други източници на данни, които се приемат от тях за свързани с клиничното изпитване и могат да се съхраняват в мястото на провеждане на клиничното изпитване, офиса на възложителя/ДИО или други места, които тези контролни органи приемат за подходящи.

1.30. Институция (медицинска)

Лечебни заведения, в които се провеждат клинични изпитвания.

1.31. Междинен доклад за клинично изпитване

Доклад за временните резултати от проучването и тяхната оценка въз

основа на анализи, направени по време на провеждането на клиничното изпитване.

1.32. Изпитван лекарствен продукт

Изпитван лекарствен продукт е лекарствена форма на активно вещество или плацебо, което се изпитва или използва като сравнение в клинично изпитване, включително продукти, за които има издадено разрешение за употреба, но се използват за неразрешено показание или с оглед получаване на допълнителна информация за разрешената форма, или са комплектувани (в лекарствена форма или опаковани) по начин, различен от разрешената форма.

1.33. Главен изследовател

Главен изследовател е определеният от възложителя лекар или лекар по дентална медицина, който ръководи цялостното провеждане на клиничното изпитване в центъра в съответствие с одобрения протокол и ръководството за ДКП и отговаря за работата на изследователите.

1.34. Изследовател

Изследовател е определеният от възложителя и от главния изследовател лекар или лекар по дентална медицина, който практически провежда клиничното изпитване под ръководството на главния изследовател съгласно одобрения протокол и ръководството за ДКП в изследователския център за провеждането на клиничното изпитване. Ако клиничното изпитване се провежда от екип, изследователят е ръководителят, който отговаря за екипа, и се нарича главен изследовател.

1.35. Брошура на изследователя

Документ, съдържащ всички клинични и неклинични данни за изследвания/те лекарствен/и продукт/и, които се отнасят за прилагането на изпитваните лекарствени продукти върху хора.

1.36. Законен представител

Физическо лице, което съгласно действащото законодателство е законен представител и може да даде съгласие за участието на бъдещия участник в клиничното изпитване от негово име.

1.37. Мониториране

Действие за наблюдение на развитието на клиничното изпитване и гарантиране, че то се провежда, записва и докладва в съответствие с протокола, СОП, ДКП и приложимите нормативни изисквания.

1.38. Доклад от мониториране

Писмен доклад от лицето, извършващо мониториране, до възложителя след всяко посещение на мястото на провеждане и/или всяка свързана с изпитването комуникация съгласно СОП на възложителя.

1.39. Многоцентрово изпитване

Клинично изпитване, което се провежда по един протокол, но в повече от един център и от повече от един изследовател. Изследователските центрове могат да бъдат разположени на територията на една държава членка, на повече от една държава членка и/или в държави членки и в трети държави.

1.40. Неклинично изпитване

Биомедицинско изпитване, което не се провежда върху хора.

1.41. Протокол

Протокол на клинично изпитване е документ, който описва целта/целите, проекта, методологията, статистическата обработка и организацията на

изпитването. Протоколът включва и всички последващи изменения и допълнения в
него.

1.42. Промяна на протокол

Писмено описание на изменение/я или официално пояснение на протокол.

1.43. Осигуряване на качеството

Всички планирани и систематични действия, които са установени с цел да
се осигури, че данните са получени, документирани (записани) и докладвани и
че изпитването се провежда в съответствие с ДКП и приложимите нормативни
изисквания.

1.44. Качествен контрол

Работни техники и действия, предприети в рамките на системата за
осигуряване на качеството, с цел проверка дали са изпълнени изискванията за
качество на свързаните с изпитването дейности.

1.45. Рандомизация

Процес за разпределяне на участниците в изпитването или контролните
групи, като се използва елемент на случайност с цел избягване на отклонения.

1.46. Регулаторни органи

Национални компетентни органи за контрол на качеството, ефективността и
безопасността на лекарствените продукти, както и органите, които оценяват
подадената клинична документация и провеждат инспекции.

1.47. Сериозно нежелано събитие (СНС) или сериозна нежелана лекарствена
реакция (СНЛР)

Всеки неблагоприятен ефект или промяна в здравното състояние, който е
станал причина за смъртен изход, непосредствена опасност за живота,
хоспитализация или удължаване на срока на хоспитализация, значителни или
трайни увреждания, инвалидизация и вродени аномалии.

1.48. Изходни данни

Цялата информация в оригиналните записи и заверените копия на
оригиналните записи на клинични находки, наблюдения и други дейности в едно
клинично изпитване, необходими за пресъздаване и оценка на изпитването.

1.49. Изходни документи (документи - източници)

Оригинални документи и записи, в които данните се записват за първи път
след получаването им (напр. болнични записи, клинични и служебни схеми,
лабораторни записки, бележки, дневници на пациентите или списъци за
проверка, записи за раздаване на лекарствени продукти от аптеката, записи от
автоматични уреди, заверени копия от записи след потвърждение, че са точни
копия, микрофишове, фотографски негативи, микрофилми и магнетофонни записи,
рентгенови снимки, файловете на участниците, записи, съхранявани в аптеката,
в лабораторията и медицинско-технически служби, включени в изпитването).

1.50. Възложител

Физическо или юридическо лице, институция или организация, която
отговаря за започването, управлението и/или финансирането на клиничното
изпитване.

1.51. Възложител-изследовател

Физическо лице, което едновременно започва и провежда едно клинично

изпитване, самостоятелно или с други лица, и под чието непосредствено ръководство изследваният лекарствен продукт се прилага, раздава или употребява от пациент. Определението не включва юридически лица и научни организации. Задълженията на възложителя-изследовател са едновременно тези на възложителя и на изследователя.

1.52. Стандартни оперативни процедури (СОП)

Писмени детайлни инструкции за постигане на еднаквост в извършването на специфична функция.

1.53. Съизследовател

Всяко лице, член на клиничния изследователски екип, назначено и ръководено от главния изследовател в мястото на провеждане на клинично изпитване за извършване основни във връзка с изпитването действия и/или да взима важни решения (напр. сътрудници, специализанти, докторанти).

1.54. Участник в изпитване

Лице, което е включено в клинично изпитване, като получава изпитван лекарствен продукт или участва като контролиращ.

1.55. Разпознавателен код на участниците

Уникален разпознавателен код за означаване на всеки участник в клинично изпитване от изследователя с цел запазване на неговата самоличност и използван вместо името на участника при докладване на нежелани събития и/или други свързани с изпитването данни.

1.56. Център на клинично изпитване

Мястото/местата, където се извършват свързани с проучването дейности.

1.57. Неочаквана нежелана лекарствена реакция

За неразрешени за употреба продукти - нежелана лекарствена реакция, чийто характер, тежест или изход не съответстват на информацията за изпитания лекарствен продукт, посочена в брошурата на изследователя. За разрешени са употреба продукти - нежелана лекарствена реакция, която не е посочена в кратката характеристика на продукта или чийто характер, тежест или изход не отговарят на посочените в кратката характеристика на продукта данни.

1.58. Уязвими групи

Лица, чието желание за участие в едно клинично изпитване може да бъде повлияно от очакването на ползите или от положението им спрямо по-висши служители в йерархията, свързани с участието или отказ от участие, например: студенти по медицина, дентална медицина, фармация или медицински сестри, служители във фармацевтичната индустрия, служещи в армията и лица, лишени от свобода.

Други застрашени участници са пациенти с неизлечими заболявания, лица в старчески домове, безработни или просещи, пациенти в спешни състояния, групи от етнически малцинства, безпризорни, скитници, непълнолетни и такива, които са неспособни да дадат съгласие.

1.59. Благополучие (на участниците в клинични изпитвания)

Физическата и психическата неприкосновеност на участниците в клиничното изпитване

2. Принципи на ДКП

2.1. Клиничните изпитвания се провеждат в съответствие с етичните принципи, които са заложени в Декларацията от Хелзинки и съответстват на ДКП

и приложимите нормативни изисквания.

2.2. Преди да е започнало едно изпитване, се сравняват всички предвидими рискове с очакваната полза индивидуално за участника и за обществото. Едно клинично изпитване може да започне и да продължи само ако предвидимите ползи оправдават рисковете.

2.3. Правата, безопасността и благополучието на участниците в изпитването са от първостепенно значение и стоят над интересите на науката и обществото.

2.4. Наличната неклинична и клинична информация за изпитвания лекарствен продукт трябва да е достатъчна в подкрепа на предложеното клинично изпитване.

2.5. Клиничните изпитвания трябва да са научно значими и описани в ясен и детайлизиран протокол.

2.6. Едно клинично изпитване се провежда в съответствие с протокол, който е предварително одобрен от комисията по етика.

2.7. Медицинското наблюдение и медицинските решения, по отношение на участниците, се вземат от лекар или когато е необходимо - от лекар по дентална медицина.

2.8. Всяко лице, натоварено с провеждане на клинично изпитване, притежава образование, квалификация и опит за изпълнение на съответните свързани с изпитването задължения.

2.9. Преди включване в клинично изпитване от всеки участник се получава свободно дадено информирано съгласие.

2.10. Цялата информация за клиничното проучване трябва да е записана, поддържана и съхранявана по начин, позволяващ нейното точно докладване, интерпретация и проверка.

2.11. Поверителността на документите, които могат да разкрият самоличността на участниците, се запазва, като се спазват и приложимите нормативни изисквания за тайна и поверителност.

2.12. Изпитваните лекарствени продукти се произвеждат, поддържат и съхраняват в съответствие с приложимата ДПП. Те се използват в съответствие с одобрения протокол.

2.13. Във всички етапи на клиничното изпитване се въвеждат процедури, осигуряващи качеството на всеки етап от провеждане на проучването.

3. Комисия по етика

3.1. Задължения

3.1.1. Всяка комисия по етика защитава правата, безопасността и благополучието на всички участници в клиничното изпитване. Специално внимание се отделя на клинични изпитвания, които включват уязвими групи пациенти.

3.1.2. Комисията по етика получава следните документи: протокол на клиничното изпитване/промени, форма за писмено информирано съгласие и промени в тези форми, които изследователят предлага да се използват в клиничното изпитване, процедури за набиране на пациенти (напр. обяви), писмена информация за участниците, брошура на изследователя, наличната информация за безопасност, информация за заплащане и компенсация на пациентите, застраховка за пациентите/доброволците и изследователите, актуална автобиография на изследователя/ите и/или други документи за доказване на квалификацията им и други допълнителни документи, които комисията може да изиска за осъществяване на функциите си.

Тя разглежда предложеното клинично изпитване в определения от закона срок и документира своето становище в писмен вид с ясно посочени тема на клиничното изпитване и прегледаните документи и датирано по отношение на

следното:

3.1.2.1. положително становище;

3.1.2.2. изискани преди положително становище изменения;

3.1.2.3. отрицателно становище;

3.1.2.4. промяна на вече издадено положително становище.

3.1.3. Комисията по етика преценява квалификацията на изследователя за предложеното клинично изпитване от представената актуална автобиография на изследователя и/или други съответни документи, които може да изиска.

3.1.4. Комисията по етика провежда текущ надзор над всяко провеждащо се клинично изпитване на интервали, съответстващи на риска за хората, но не по-малко от веднъж годишно.

3.1.5. По своя преценка комисията по етика може да изиска представянето на повече информация от описаната в т. 4.8.10, когато това допълнение има значение за запазване на правата и безопасността и/или здравето на пациентите.

3.1.6. В случаите по т. 4.8.12 и 4.8.14, когато за провеждането на нетерапевтично изпитване е необходимо съгласието на законен представител на участника, комисията по етика се произнася по въпроса, дали предложеният протокол и/или други документи съвпадат с етичните норми и дали отговарят на приложимите нормативни изисквания за такъв тип изпитвания.

3.1.7. В случаите по т. 4.8.15, когато протоколът на клинично изпитване позволява включване на пациент, без да е възможно неговото непосредствено писмено съгласие или съгласието на неговия законен представител, комисията по етика се произнася по въпроса, дали предложеният план и/или други документи съвпадат с етичните норми и дали отговарят на приложимите нормативни изисквания за такъв тип изпитвания.

3.1.8. Комисията по етика преценява доколко размерът и методът за заплащане на здравите доброволци/пациентите влияят на съгласието им за участие и дали решението им ще бъде взето свободно. Заплащанията на един участник трябва да бъдат разпределени пропорционално и да не зависят изцяло от завършването на изпитването от участника.

3.1.9. Комисията по етика осигурява включването във формата за писмено информирано съгласие и във всяка друга писмена информация за участника на информацията по отношение на заплащането на здравите доброволци/пациентите, вкл. количество, метод на заплащане и периодичност. Начинът, по който плащането ще бъде разпределено, трябва да бъде посочен.

3.2. Състав, функции и действия

3.2.1. Комисията по етика се състои от членове, които като колектив имат достатъчно квалификация и опит да разгледат и оценят научните, медицинските и етичните аспекти на предложеното клинично изпитване. Комисията по етика включва най-малко 7 членове, от които най-малко двама с немедицинско образование, финансово и административно независими от мястото на провеждане на клиничното изпитване.

По време на заседанията могат да гласуват и да изразяват мнение само тези членове, които са независими от главния изследовател и възложителя.

Комисията по етика съхранява списък с членовете и техните квалификации,

както и официалните документи за създаването й.

3.2.2. Комисията по етика извършва функциите си в съответствие с писмени стандартни оперативни процедури, с ДКП и приложимите нормативни изисквания и съхранява документи за дейностите си и протоколи от заседанията.

3.2.3. Комисията по етика взима решенията си на предварително обявени заседания при наличието на кворум, определен в стандартните оперативни процедури.

3.2.4. Да гласуват/изразяват мнение могат само членовете на комисията по етика, които са участвали в обсъжданията и прегледа на документацията по проучването.

3.2.5. Изследователят може да представя информация във всякакъв аспект по отношение на клиничното изпитване, но не може да участва в разискванията или да дава мнение/да гласува по време на заседанията на комисията по етика.

3.2.6. Комисията по етика може да покани експерти в различни специалности за съдействие.

3.3. Процедури

Комисията по етика разработва, писмено документира и спазва стандартни оперативни процедури, които включват следното:

3.3.1. определяне на състава (имена и длъжности на членовете) и основание за назначаването;

3.3.2. планиране на заседанията, уведомяване на членовете и провеждане на заседанията;

3.3.3. извършване на първоначална и последваща оценка на проучвания;

3.3.4. определяне на честотата на периодична последваща преоценка на проучвания;

3.3.5. осигуряване на ускорена оценка на минимални промени за клинични изпитвания в ход, които вече са одобрени, в съответствие с нормативните изисквания;

3.3.6. потвърждение, че нито един участник не може да бъде включен в клинично изпитване, преди комисията по етика да издаде положително становище;

3.3.7. потвърждение, че в протокола не могат да се приложат никакви отклонения или промени преди непосредственото писмено положително становище за съответната промяна, с изключение на случаите, когато е необходимо избягване на непосредствени рискове за участниците или когато промените засягат логистични и административни аспекти на изпитването (напр. промяна на лицето, извършващо мониториране, телефонни номера), съгласно задълженията на изследователя по т. 4.5.2;

3.3.8. изискване, че изследователят веднага уведомява комисията по етика за отклонения или промени в протокола, когато е необходимо избягване на непосредствени рискове за участниците, съгласно т. 3.3.7 и задълженията на изследователя по т. 4.5.2 и 4.5.4; промени, увеличаващи риска за участниците и/или значително влияещи върху провеждането на клиничното изпитване (вж. 4.10.2); всички нежелани лекарствени реакции, които са и сериозни, и неочаквани; нова информация, която може да засегне неправилно безопасността на лицата или провеждането на клиничното изпитване;

3.3.9. изискване, че комисията по етика незабавно ще уведоми писмено

изследователя/институцията за свързаните с клиничното изпитване решения/мнения; причините за решенията/становищата си и процедурите за обжалване на решенията/становищата на комисията по етика.

3.4. Документи

Комисията по етика съхранява всички съответни документи (напр. писмени стандартни оперативни процедури, списъци с членове, заповеди за назначаване, списъци с длъжности на членовете, декларации за конфликт на интереси и конфиденциалност, представени документи, протоколи от заседания и кореспонденция) за период не по-малко от три години след прекратяване на клиничното изпитване и ги предоставя при поискване на регулаторните органи.

Комисията по етика предоставя на изследователя, възложителя или регулаторните органи писмените си процедури и заповеди, определящи списъка с членове, при поискване.

4. Изследовател

4.1. Квалификация и задължения на изследователя

4.1.1. Изследователят/ите притежава съответното образование, квалификация и опит, за да прецени отговорността за правилното провеждане на клиничното изпитване; отговаря на всички изисквания, определени от регулаторните органи, и представя доказателство за квалификацията си чрез актуална автобиография и/или други документи, изискани от възложителя, комисията по етика и/или регулаторните органи.

4.1.2. Изследователят е запознат с правилната употреба на изпитвания лекарствен продукт, както е посочено в протокола, актуалната брошура на изследователя, информацията за продукта и всички други източници на информация, предоставени от възложителя.

4.1.3. Изследователят познава и спазва изискванията на ДКП и приложимите нормативни изисквания.

4.1.4. Изследователят позволява извършването на мониториране, проверка от страна на възложителя и инспекция от съответните регулаторни органи.

4.1.5. Изследователят съхранява списък с лица с необходимата квалификация, на които е делегирал отговорни задължения, свързани с клиничното изпитване.

4.2. Възможности за изпълнение на изпитването

4.2.1. Изследователят трябва да може да покаже възможности за набиране на необходимия брой подходящи пациенти в договорения срок (напр. като се базира на ретроспективни данни).

4.2.2. Изследователят има достатъчно време за провеждане и завършване на клиничното изпитване в договорения срок.

4.2.3. Изследователят разполага с необходимия брой квалифициран персонал и съответно оборудване за предвидената продължителност на клиничното изпитване с цел правилно и безопасно провеждане.

4.2.4. Изследователят гарантира, че всички лица, участващи в клиничното изпитване, са достатъчно информирани за протокола, изпитвания лекарствен продукт/и и свързаните им с клиничното изпитване задължения и функции.

4.3. Медицински грижи за лицата участници

4.3.1. Отговорността за всички свързани с клиничното изпитване медицински решения се носи от квалифициран лекар, или където е необходимо - от лекар по дентална медицина, който е изследовател или съизследовател в

клиничното изпитване.

4.3.2. По време и след участието на лицата в клиничното изпитване изследователят гарантира за предоставянето на достатъчно медицинско наблюдение върху лицата участници по отношение на всяко нежелано събитие, вкл. клинично важни лабораторни резултати, свързани с изпитването. Изследователят уведомява пациента за необходимостта от медицинско наблюдение по повод на допълнителното заболяване, което той е установил.

4.3.3. Ако лицето участник има личен лекар и ако се е съгласило личният му лекар да бъде уведомен, изследователят го информира за участието на пациента в клиничното изпитване.

4.3.4. Въпреки че участникът не е задължен да обясни причините за оттеглянето си от клиничното изпитване, изследователят може да положи усилия, за да установи тези причини, спазвайки изцяло правата на пациента.

4.4. Кореспонденция с комисията по етика

4.4.1. Преди започване на клиничното изпитване изследователят трябва да има писменото датирано положително становище от комисията по етика за протокола на клиничното изпитване, формата за писмено информирано съгласие, промени във формата за съгласие, процедурите за набиране на пациенти (напр. обяви) и всяка друга писмена информация, която ще бъде предоставена на участника.

4.4.2. Изследователят представя на комисията по етика копие от актуалната брошура на лекаря изследовател като приложение на писмената молба до комисията по етика за становище. Ако по време на клиничното изпитване настъпят промени в брошурата, изследователят представя в комисията по етика ново копие, включващо промените.

4.4.3. По време на клиничното изпитване изследователят предоставя на комисията по етика за преразглеждане всички документи, касаещи участниците.

4.5. Съответствие с протокола

4.5.1. Изследователят провежда клиничното изпитване в съответствие с протокол, който предварително е одобрен от възложителя и регулаторния орган и който е получил положително становище от комисията по етика. Изследователят и възложителят подписват протокола или допълнителен договор, с който изследователят потвърждава съгласието си за спазването му.

4.5.2. Изследователят не може да прави никакви отклонения или промени в протокола без съгласието на възложителя и предварителното разглеждане и документирано положително становище за промените от комисията по етика. Отклонения от изискванията на плана може да се правят само когато има сериозни основания, че са застрашени животът, здравето и правата на изследваните лица или когато промените включват само организационни или административни аспекти на клиничното изпитване (напр. смяна на лицето, извършващо мониториране, смяна на телефонните номера).

4.5.3. Изследователят или упълномощено от него лице документира и обяснява всяко отклонение от одобрения протокол.

4.5.4. Изследователят може да направи отклонение или промяна в

протокола за избягването на непосредствена заплаха за пациентите без непосредственото положително становище на комисията по етика. Направеното отклонение, промяна или планът с предложените промени се представят възможно най-бързо на комисията по етика за оценка и становище, на възложителя за съгласие и на регулаторните органи за разрешение.

4.6. Изпитван лекарствен продукт

4.6.1. Отговорност за отчетността на изпитвания лекарствен продукт в мястото на провеждане на клиничното изпитване се носи от изследователя.

4.6.2. Изследователят може да предостави някои или всички свои задължения за отчетността в мястото/местата на провеждане на фармацевт или на друго подходящо лице, което е под ръководството на изследователя, когато това е допустимо или се изисква.

4.6.3. Изследователят и/или фармацевтът или друго лице, определено от изследователя, съхранява документите за получените в мястото на провеждане лекарствени продукти, опис на продуктите в центъра, използваните количества от всеки участник и върнатите на възложителя количества или на допълнително място. Тези документи съдържат дати, количества, партиди и номера, срок на годност (където е възможно) и уникалните кодови номера, с които са означени лекарствените продукти и участниците. Изследователите съхраняват документи, в които е отбелязано, че участниците са получили съответните дози, определени в плана, и потвърждение и отчетност за всички получени от възложителя лекарствени продукти.

4.6.4. Изпитваният/те лекарствен/и продукт/и се съхраняват по начин, определен от възложителя, съгласно т. 5.13.2 и т. 5.14.3, и в съответствие с приложимите нормативни изисквания.

4.6.5. Изследователят потвърждава, че изпитваните лекарствени продукти се използват само в съответствие с одобрения протокол.

4.6.6. Изследователят или определено от него лице обяснява правилната употреба на изпитвания лекарствен продукт на всеки отделен участник и на подходящи интервали и проверява дали всеки участник спазва правилно инструкциите.

4.7. Процедури за рандомизиране и разкриване

Изследователят трябва да спазва рандомизационните процедури на клиничното изпитване, ако съществуват такива, и трябва да потвърди, че разкриването на кода се прави само в съответствие с протокола. Ако клиничното изпитване е заслепено, изследователят документира и обяснява на възложителя всяко преждевременно разкриване на кода (напр. случайно разкриване, разкриване в резултат на възникнало сериозно нежелано събитие) на изпитвания лекарствен продукт/и.

4.8. Информирано съгласие на участниците

4.8.1. По време на получаването и документирането на информираното съгласие изследователят спазва приложимите нормативни изисквания, принципите на ДКП и етичните принципи, залегнали в Декларацията от Хелзинки. За започване на клиничното изпитване изследователят трябва да притежава писменото положително становище на комисията по етика на формата за писменото информирано съгласие и всяка друга писмена информация, която ще бъде предоставена на участниците.

4.8.2. Формата за писменото информирано съгласие и всяка друга

писмена
информация, предоставяна на участниците, се актуализира, когато стане известна важна нова информация, която може да повлияе тяхното съгласие. Всяка актуализирана форма за писменото информирано съгласие и писмена информация трябва да има положителното становище на комисията по етика преди прилагането й. Участникът или неговият законен представител своевременно се уведомяват, когато стане известна важна нова информация, която може да повлияе на тяхното желание да продължат да участват в клиничното изпитване.

Комуникациите по отношение на новата информация се документират своевременно.

4.8.3. Нито главният изследовател, нито изследователският персонал могат да принуждават или да подвеждат лицето да участва или да продължи участието си в клиничното изпитване.

4.8.4. Нито една устна или писмена информация, касаеща клиничното изпитване, включително формата за писмено информирано съгласие, не може да съдържа думи и изрази, с които принуждава или звучат като принуда за участника или неговия законен представител да се откаже от някое свое законно право или да освобождава или да внушава освобождаване от отговорност за небрежност на изследователя, възложителя, институцията или техни представители.

4.8.5. Изследователят или упълномощеното от него лице информира участника или в случай че не може да даде своето съгласие, неговия законен представител за всички аспекти на клиничното изпитване, включително и за предоставянето на писмена информация и положителното становище от комисията по етика.

4.8.6. Езикът, използван в устната или писмената информация за клиничното изпитване, включително формата за писмено информирано съгласие, трябва да бъде без медицински термини и достатъчно достъпен, за да бъде разбран от участника или неговия законен представител и където е необходимо, от независимия свидетел.

4.8.7. Преди да е получено писменото информирано съгласие, главният изследовател или упълномощено от него лице са задължени да предоставят на участника или на неговия законен представител достатъчно време и възможност за обсъждане на детайлите по клиничното изпитване и да решат дали да участва или не. На всички въпроси, зададени от участника или на неговия законен представител, трябва да се отговори изчерпателно.

4.8.8. Преди включването на участника писменото информирано съгласие трябва да се подпише лично и лично да се постави датата от участника или от неговия законен представител и от лицето, провело разговора за информиране на участника.

4.8.9. В случай че участникът или неговият законен представител не може да чете по време на обсъждането на информираното съгласие, се осигурява присъствие на независим свидетел. Свидетелят подписва и лично поставя дата на формата за писмено информирано съгласие, след като тя, както и всяка друга писмена информация, е представена, прочетена и обяснена на участниците или на техните законни представители и след като те устно са потвърдили

участието си в клиничното изпитване и (ако са способни) са подписали и лично поставили дата. Чрез подписа си свидетелят потвърждава, че формата за писмено информирано съгласие, както и всяка друга писмена информация, е била точно обяснена и разбрана от участниците или техните законни представители и съгласието е дадено от самите участници или техните законни представители.

4.8.10. Формата за писменото информирано съгласие и всяка друга писмена информация, предоставяна на участниците, съдържа обяснения за следното:

4.8.10.1. че клиничното изпитване представлява процес на научно проучване;

4.8.10.2. целта на клиничното изпитване;

4.8.10.3. изпитваното лечение/я и вероятността за случайно назначаване на всяко лечение;

4.8.10.4. процедурите, които ще се извършат по време на клиничното изпитване, включително и инвазивните манипулации;

4.8.10.5. задълженията на участниците;

4.8.10.6. тези аспекти от клиничното изпитване, които са експериментални;

4.8.10.7. разумно предвидими рискове или неудобства за участниците, а също и за ембрион, плод или кърмаче, когато е необходимо;

4.8.10.8. разумно очакваните ползи; участниците се уведомяват за случаите, когато не се очакват клинични ползи;

4.8.10.9. алтернативните процедури и курсове на лечение, които са възможни за участниците, и важни техни потенциални рискове и ползи;

4.8.10.10. компенсацията и/или възможното лечение за участниците в случай на свързано с клиничното изпитване увреждане;

4.8.10.11. предвиденото, пропорционално на участието във времето, заплащане за доброволците/пациентите за участието им в клиничното изпитване, ако съществува такова;

4.8.10.12. предвидените разходи за участниците за участието им в клиничното изпитване;

4.8.10.13. обяснение, че участието в клиничното изпитване е доброволно и че участникът може да откаже да участва или да се оттегли по всяко време, без да се налага наказание или пропускане на ползи, които участникът може да получи по друг начин;

4.8.10.14. да бъде посочено, че на мониториращите, проверяващите, комисията по етика и на регулаторните органи е осигурен достъп до оригиналните медицински документи на участника за проверка на процедурите по клиничното изпитване и/или на данните, при което се осигурява защита на личните данни на пациента съгласно приложимите закони и наредби, и чрез подписването на формата за писмено информирано съгласие участникът или неговият законен представител дава съгласието си за такъв достъп;

4.8.10.15. че документите, удостоверяващи самоличността на участника, ще се запазят поверителни и данните от тях няма да бъдат разгласявани, съгласно приложимите закони и наредби; в случай на публикуване на резултатите от клиничното изпитване самоличността на участниците ще остане поверителна;

4.8.10.16. обяснение, че участникът или неговият законен представител

своевременно ще бъде уведомен, ако възникне нова информация, която може да повлияе на желанието им за продължаване участието в клиничното изпитване;

4.8.10.17. лицата за контакт за допълнителна информация по отношение на клиничното изпитване, лицата за контакт за информация за правата на участниците и лицата, отговорни в случай на свързано с клиничното изпитване увреждане;

4.8.10.18. предвидимите обстоятелства и/или причини, при които участието може да бъде прекратено;

4.8.10.19. очакваната продължителност на участието на пациента/здравия доброволец в клиничното изпитване;

4.8.10.20. приблизителния брой участници.

4.8.11. Преди участието в клиничното изпитване всеки участник или неговият законен представител получава копие на подписаната и датирана форма за писмено информирано съгласие, както и всяка друга информация, предоставяна на участниците. По време на клиничното изпитване всеки участник или неговият законен представител получава копие от променената форма за писмено информирано съгласие, както и промените във всяка друга писмена информация, предоставяна на участниците.

4.8.12. Когато едно клинично изпитване (терапевтично или нетерапевтично) изисква включването на участници само чрез съгласието на техните законни представители, участниците се информират за клиничното изпитване на ниво в съответствие с тяхната способност за разбиране и лично подписват и поставят дата на писменото информирано съгласие (ако са в състояние).

4.8.13. С изключение на посоченото в т. 4.8.14 едно нетерапевтично изпитване (т. е. изпитване, в което не се предвижда директна клинична полза за участниците) се провежда върху лица, които лично са подписали и поставили дата на формата за писмено информирано съгласие.

4.8.14. Нетерапевтичните изпитвания могат да се провеждат върху лица чрез съгласието на законни техни представители само в случаите, когато:

4.8.14.1. целите на изпитването не могат да бъдат постигнати с изпитване върху участници, които могат лично да дадат информирано съгласие;

4.8.14.2. предвидимите рискове за лицата са малки;

4.8.14.3. негативното въздействие върху участниците е минимално и ниско;

4.8.14.4. клиничното изпитване не е забранено от закон;

4.8.14.5. в разрешението/положителното становище на комисията по етика е посочено изрично включването на точно такива лица и писменото разрешение/положително становище покрива този аспект.

Такива изпитвания (дотолкова, доколкото изключението е оправдано) се провеждат върху пациенти, страдащи от заболяване или състояние, за които е предвиден изпитваният лекарствен продукт. Участниците в тези изпитвания стриктно се наблюдават и се изтеглят в случай на излишно увреждане.

4.8.15. В спешни ситуации, когато непосредственото съгласие на участника не е възможно, се изисква съгласието на неговия законен представител, ако присъства такъв. Когато непосредственото съгласие на участника и на законния му представител не е възможно да бъде получено, включване може да се осъществи, ако се налага незабавно решение, за да се

спаси животът на пациента, съгласно изискванията, посочени в протокола и/или
на друго място, чрез писменото положително становище на комисията по етика,
с цел запазване правата, безопасността и благополучието на лицето и
осигуряване на съответствие с приложимите нормативни изисквания. Лицето или
неговият законен представител се информират възможно най-бързо за клиничното
изпитване и следва да бъдат помолени да документират съгласието си за
продължаване участието си в клиничното изпитване по реда на т. 4.8.10.

4.9. Документи и доклади

4.9.1. Изследователят осигурява точността, пълнотата, четливостта и навременното докладване на данните на възложителя в клиничните карти на пациентите (ККП), както и във всички изисквани доклади.

4.9.2. Данните, които се получават от документи-източници и се записват
в ККП, се съдържат в тези документи-източници, а несъответствията се обясняват.

4.9.3. Всяка промяна или корекция в ККП се датира, поставят се инициали
и (ако е необходимо) се обяснява и не трябва да внася съмнение за оригиналното вписване (т. е. съхранява се следата за проверка). Това се прилага както за писмените, така и за електронните корекции съгласно т. 5.18.4.14. Възложителят снабдява изследователя и/или определеното от изследователя лице за извършване на такива корекции с указания. Възложителите притежават писмени процедури, удостоверяващи, че направените промени или корекции в ККП от възложителя или упълномощени от него лица са били необходими, документирани са и са подписани от изследователя. Изследователят съхранява записи за промените и поправките в ККП.

4.9.4. (Изм. - ДВ, бр. 14 от 2012 г.)
Изследователят/институцията съхранява документацията съгласно одобрения план, болничната документация и подписаните форми за информирано съгласие, както и документите по т. 8 "Основни документи за провеждане на клинично изпитване", както е посочено в приложимите нормативни актове.

Изследователят взема мерки за предотвратяване на случайното или преждевременното унищожаване на тези документи.

След приключване на проучването изследователят предоставя на възложителя частта от документацията на клиничното изпитване според посоченото в протокола и/или друг договор с възложителя.

4.9.5. Основните документи се съхраняват за най-дългия от посочените срокове:

4.9.5.1. петнадесет години след приключване на клиничното проучване;

4.9.5.2. две години след последното разрешение за употреба в регион, обхванат от Международната конференция по хармонизация, или докато не е приключила процедура или няма намерение за получаване на разрешение за употреба в региона, обхванат от Международната конференция по хармонизация;

4.9.5.3. две години от официалното приключване на клиничното разработване на изпитвания продукт.

Сроковете за съхранение може да са по-дълги, ако това се изисква от други приложими нормативни изисквания или ако това е договорено с възложителя. Възложителят уведомява писмено изследователя кога документите не е необходимо да се съхраняват повече съгласно т. 5.5.12.

4.9.6. Финансовите въпроси по клиничното изпитване се документират чрез

договор между възложителя и изследователя.

4.9.7. При молба от страна на лицето, извършващо мониториране, одитора/проверяващия, комисията по етика или регулаторните органи, изследователят осигурява директен достъп до всички свързани с клиничното изпитване документи.

4.10. Доклади за прогреса на клиничното изпитване

4.10.1. Изследователят представя писмени отчети за напредъка на клиничното изпитване пред комисията по етика веднъж годишно или по-често, ако комисията по етика изисква това.

4.10.2. Изследователят своевременно представя писмени отчети на възложителя, на комисията по етика и на регулаторните органи за всички промени, значително въздействащи върху провеждането на клиничното изпитване и/или повишаващи риска за участниците.

4.11. Доклади за безопасност

4.11.1. Всички сериозни нежелани събития се докладват незабавно на възложителя, с изключение на тези, за които според протокола или друг документ (напр. наръчника на изследователя) не е необходимо незабавно докладване. Незабавното докладване се следва от подробни писмени доклади. Незабавните и последващите доклади идентифицират лицата чрез уникални кодови номера, с които са означени участниците в клиничното изпитване, вместо с техните имена, личните идентификационни номера и/или адреси.

Изследователят спазва приложимите нормативни изисквания, отнасящи се до докладването на неочакваните сериозни нежелани лекарствени реакции на регулаторните органи и комисията по етика.

4.11.2. Нежеланите събития и/или лабораторни резултати извън референтните граници, определени в протокола като критични за оценка на безопасността, се докладват на възложителя в съответствие с изискванията и в сроковете, определени от възложителя в протокола.

Изследователят оценява всяко нежелано събитие по отношение на причинно-следствена връзка и сериозност.

4.11.3. В случай на докладвана смърт изследователят представя на възложителя и на комисията по етика всяка допълнителна информация (напр. протокол от аутопсия и заключителен медицински доклад).

4.12. Преждевременно завършване или прекратяване на изпитване

Ако изпитването е прекратено преждевременно или е преустановено по някаква причина, изследователят е длъжен незабавно да уведоми участниците в изпитването и да им осигури съответно лечение и проследяване и, когато се изисква от приложимите нормативни изисквания, да уведоми регулаторните органи.

4.12.1. Ако изследователят прекрати или приключи клинично изпитване без предшестващо съгласие на възложителя, е длъжен да уведоми лечебното заведение, възложителя и комисията по етика, регулаторния орган на страната, където се намира центърът на проучването, като им представи подробно писмено обяснение за прекратяването или приключването.

4.12.2. Ако възложителят приключи или преустанови едно изпитване, изследователят своевременно информира лечебното заведение, комисията по етика и регулаторния орган на страната, където се намира центърът на проучването, като им представи подробно писмено обяснение за преустановяването или приключването.

4.12.3. Ако комисията по етика оттегли или прекрати своето

положително становище за дадено изпитване, съгласно т. 3.1.2.4. и 3.3.8 изследователят уведомява съответното лечебно заведение и възложителя, като им представя подробно писмено обяснение за прекратяването или оттеглянето.

4.13. Окончателни доклади от изследователя

След завършването на клиничното изпитване изследователят уведомява лечебното заведение, представя на комисията по етика обобщение на резултатите от изпитването и всички доклади, които се изискват, на регулаторните органи.

5. Възложител

5.1. Осигуряване на качеството и контрол

5.1.1. Възложителят е отговорен за въвеждането и поддържането на системи за качеството и контрол чрез писмени стандартни оперативни процедури с цел да се осигури, че клиничното изпитване се провежда и данните се набират, документират (записват) и докладват в съответствие с плана, ДКП и приложимите нормативни изисквания.

5.1.2. Възложителят е отговорен за осигуряване на споразумение между изследователите, Договорна изследователска организация (ДИО) и регулаторните органи за получаване на директен достъп до всички места на провеждане на клиничното изпитване, източниците/документите на информация и доклади от извършено мониториране и проверки от възложителя, както и на инспекции от местни или чужди регулаторни органи.

5.1.3. На всеки етап на обработка на данните се прилага качествен контрол с цел да се потвърди, че всички данни са надеждни и са обработени правилно.

5.1.4. Договорите, сключени между възложителя и изследователя и всяка друга страна по клиничното изпитване, са писмени, като част от плана или в допълнително споразумение.

5.2. Договорна изследователска организация

5.2.1. Възложителят може да прехвърли всички или част от задълженията си на други физически и/или юридически лица, които се означават като ДИО. Независимо от прехвърлянето на задължения на други лица възложителят носи цялостната отговорност за провеждането на проучването в съответствие с ДКП и валидността на получените данни.

Договорната изследователска организация е задължена да въведе процедури за качествен контрол и осигуряване на качеството.

5.2.2. Всички договори между възложителя и други лица, участници в клиничното изпитване, са писмени и са част от плана или друга отделна част.

Всяко прехвърляне на свързани с клиничното изпитване задължение и функция на ДИО се документира писмено.

5.2.3. Всички свързани с клиничното изпитване задължение и функция, които не са прехвърлени специфично, остават на възложителя.

5.2.4. Всички указания за възложителя в това ръководство се отнасят и за ДИО до степен, до каквато ДИО е приела свързаните с клиничното изпитване задължения и функции от възложителя.

5.3. Медицинска експертиза

Възложителят назначава квалифициран медицински персонал, който е на разположение за консултация по свързани с клиничното изпитване медицински проблеми и въпроси. За тази цел, ако е необходимо, могат да се назначат външни консултанти.

5.4. Дизайн на изпитване

5.4.1. Възложителят използва квалифицирани лица (напр. биостатистици, клинични фармаколози и лекари) по време на всички етапи на провеждане на клиничното изпитване от съставянето на протокола и ККП и планирането на анализите до анализиране и подготовката на междинните и окончателните доклади на клиничното изпитване.

5.4.2. Протоколът се изготвя в съответствие с т. 6 и с издадените от Международната конференция за хармонизация, Европейската комисия и Европейската агенция по лекарствата ръководства за структурата и съдържанието на протокола, докладите от клинични изпитвания, дизайна и провеждането на клинични изпитвания.

5.5. Ръководене на клинично изпитване, обработване на данни и съхранение на документация

5.5.1. Възложителят използва лица със съответната квалификация за надзор над цялостното провеждане на клиничното изпитване, за обработването и проверяването на данните, за извършване на статистическите анализи и за подготвянето на докладите.

5.5.2. Възложителят може да назначи независима комисия за оценка на резултатите с цел проследяване на хода на едно клинично изпитване, вкл. данните за безопасност и критичните параметри за ефикасност на определени интервали, и която да препоръчва на възложителя да продължи, промени или да прекрати клиничното изпитване. Комисията трябва да разполага с и да следва писмени стандартни оперативни процедури за работата си и да съхранява писмени протоколи от всички свои заседания.

5.5.3. В случай на използване на електронна поддръжка на документите по клиничното изпитване и/или дистанционни електронни системи за данни възложителят:

5.5.3.1. гарантира и документира, че електронните системи за обработка на данни съответстват с утвърдените изисквания на възложителя за пълнота, точност, надеждност и са валидирани;

5.5.3.2. поддържа СОП за използване на тези системи;

5.5.3.3. гарантира, че системите са изготвени да позволяват промяна в данните по начин, по който промените се документират, и не е възможно изтриване на въведените данни (т. е. поддържа се следа за проверка на данните и за редактиране);

5.5.3.4. поддържа система за сигурност, непозволяваща неупълномощен достъп до данните;

5.5.3.5. поддържа списък с упълномощени лица, имащи право да правят промени в данните по т. 4.1.5 и 4.9.3;

5.5.3.6. поддържа адекватна поддръжка и съхранение на резервни копия на данните;

5.5.3.7. поддържа система, предпазваща от разкриване на кода.

5.5.4. В случай на трансформиране на данните по време на тяхната обработка е необходимо винаги да бъде възможно сравняването и наблюдението на оригиналните данни с обработените данни.

5.5.5. Възложителят използва недвусмислен разпознавателен код за участниците съгласно т. 1.55, който позволява разпознаване на всички докладвани данни за всеки отделен участник.

5.5.6. Възложителят или друг притежател на данните съхранява всички специфични основни документи, отнасящи се до клиничното изпитване, посочени в т. 8 "Основни документи за провеждане на клинично изпитване".

Възложителят осигурява подходящи условия на съхранение, които да гарантират запазване на документацията в определените срокове непроменена.

Възложителят определя писмено лица, отговорни за архивирането. Достъпът до архивираната документация е ограничен освен за посочените лица.

5.5.7. Възложителят съхранява цялата оригинална документация на клиничното изпитване, посочена в т. 8, и разпознавателните кодове на пациентите за не по-малко от 15 години след приключване или прекратяване на изпитването.

Възложителят съхранява всички специфични основни документи и в съответствие с приложимите нормативни изисквания на държавата/ите, в която лекарственият продукт е разрешен за употреба и/или където възложителят има намерение да кандидатства за разрешение/я.

5.5.8. При прекратяване на програмата за проучване на изпитвания лекарствен продукт възложителят съхранява документацията не по-малко от две години след прекратяване на последното проучване с изпитвания продукт.

Тези документи се съхраняват за по-дълъг период, ако това се изисква от други нормативни документи или от възложителя.

5.5.9. Ако възложителят прекрати клиничното развитие на изследвания лекарствен продукт, той е задължен да уведоми всички изследователи по клиничното изпитване и всички регулаторни органи.

5.5.10. Всяко прехвърляне на притежанието на данните се документира и докладва на съответните регулаторни органи и както е посочено в приложимите нормативни изисквания. Новият притежател на данните отговаря за съхранението и архивирането на документацията съгласно т. 5.5.7, 5.5.8 и 5.5.9.

5.5.11. При включване на данните в документация за разрешение за употреба възложителят съхранява документацията не по-малко от две години след получаване на последното разрешение за употреба на територията на Европейския съюз.

Специфичните основни документи на възложителя се съхраняват най-малко две години след последното разрешение за употреба или след изтичането на най-малко две години след официалното прекратяване на клиничното развитие на изследвания лекарствен продукт. Тези документи се съхраняват за по-дълъг период, ако това се изисква от други нормативни изисквания или от възложителя.

5.5.12. Възложителят информира писмено главния изследовател и лечебното заведение, в което се провежда клинично изпитване, за срока на съхранение на документацията.

Възложителят информира писмено главния изследовател и лечебното заведение за момента на отпадане на необходимостта от съхранение на документацията.

5.6. Избор на изследовател

5.6.1. Възложителят е отговорен за избор на изследовател и място на провеждане на клиничното изпитване. Необходимо е всеки изследовател да бъде квалифициран чрез обучение и опит и да разполага с подходящи условия съгласно т. 4.1 и 4.2 за правилното провеждане на клиничното изпитване, за което е избран. В случай на използване на организация с координираща комисия и/или координиращ изследовател в многоцентрови изпитвания възложителят е

отговорен за тяхното организиране и/или избор.

5.6.2. Преди влизането в договорни отношения с изследователя за провеждане на изпитване възложителят предоставя на изследователя протокола и актуалната брошура на изследователя и достатъчно време за тяхното разглеждане.

5.6.3. Възложителят задължително получава съгласие от изследователя за:

5.6.3.1. провеждане на клиничното изпитване в съответствие с ДКП, с приложимите нормативни изисквания, с одобрения от възложителя и комисията по етика протокол;

5.6.3.2. спазване на процедурите за записване и докладване на данните;

5.6.3.3. разрешаване на мониториране, проверка и инспекция;

5.6.3.4. съхраняване на свързаните с клиничното изпитване основни документи, докато възложителят уведоми изследователя, че тези документи повече не са необходими.

Възложителят и изследователят подписват протокола и/или друг документ, за да потвърдят това споразумение.

5.7. Разпределение на задълженията и функциите

Преди започване на клиничното изпитване възложителят определя, установява и разпределя всички свързани с клиничното изпитване задължения и функции.

5.8. Компенсации за участниците и изследователите

5.8.1. Възложителят застрахова или осигурява (чрез юридическо и финансово покритие) изследователите срещу искове за щети, възникващи във връзка с клиничното изпитване, с изключение на щетите, възникващи в резултат на незаконни действия и/или небрежност.

5.8.2. Вътрешнофирмените процедури на възложителя трябва да описват покриването на разходи по лечението на участници в случай на свързани с клиничното изпитване увреждания. Тези процедури трябва да са в съответствие с приложимите нормативни изисквания.

5.8.3. Методът и размерът на компенсациите, получени от участниците в клиничното изпитване, съответстват на приложимите нормативни изисквания.

5.9. Финансиране

Финансовите взаимоотношения между възложителя и изследователя се документират чрез договор.

5.10. Уведомяване/заявление до регулаторните органи

Преди започване на клиничното изпитване възложителят представя документацията, която се изисква от регулаторните органи за оценка, одобрение и/или разрешение за започване на клиничното изпитване. Всяко уведомление/заявление съдържа дата и достатъчно информация за идентификация на протокола.

Възложителят уведомява писмено ИАЛ и съответната комисия по етика по чл. 103 ЗЛПХМ при включване на първи пациент в изпитването на територията на Република България.

В случай на многоцентрово проучване възложителят уведомява писмено ИАЛ и съответната комисия по етика по чл. 103 ЗЛПХМ при преустановяване на участието в проучването на някой от одобрените с първоначалното

положително
становище центрове на проучването.
5.11. Потвърждение за разглеждане от комисия по етика
5.11.1. Възложителят набавя от изследователя следните данни и документи: име и адрес на съответната комисия по етика, становище от комисията по етика, че тя е съставена и действа в съответствие с ДКП и приложимите закони и подзаконови нормативни актове; документирано положително становище от комисията по етика за актуалната версия на протокола, форма на писмено информирано съгласие и всяка друга информация, която ще се предоставя на участниците, процедурите за набиране на пациенти, документи, свързани със заплащането и компенсацията на участниците и други документи, които комисията е изискала.
5.11.2. Ако комисията по етика дава положително становище при условие, че бъдат направени промени в някакъв аспект на клиничното изпитване (напр. промяна на протокола, формата на писмено информирано съгласие и всяка друга информация, която ще се предоставя на участниците и/или други процедури), възложителят набавя от изследователя копие на направеното изменение и датата на издаване на положително становище от комисията по етика.
5.11.3. Възложителят набавя от изследователя документи и дати на всички нови положителни становища за промени, както и на всяко оттегляне или прекратяване на дадено положително становище.
5.12. Информация за изпитвания лекарствен продукт
5.12.1. Когато планира клинично изпитване, възложителят гарантира, че са налични достатъчно данни, доказващи безопасност и ефикасност от неклинични и/или клинични изпитвания на продукта в подкрепа на прилагането му върху хора по път, дозировка, продължителност и изпитвана група пациенти, които ще се проучват.
5.12.2. Възложителят актуализира брошурата на изследователя, когато нова и значима информация стане достъпна.
5.13. Производство, опаковане, етикетиране и кодиране на изпитвания лекарствен продукт
5.13.1. Възложителят гарантира, че изпитваният лекарствен продукт (включително лекарствен продукт за сравнение и плацебо, ако се използва) е охарактеризиран в съответствие от етапа от разработка на лекарствения продукт, че се произвежда в съответствие с приложима ДПП и е кодиран и етикетиран по начин, който запазва заслепяването, ако има такова. Възложителят изготвя етикетировка на изпитвания лекарствен продукт в съответствие с изискванията на правилата на Добра производствена практика за лекарствени продукти в процес на разработване и изследване и приложимите нормативни изисквания.
5.13.2. Възложителят определя температура и условия на съхранение (напр. предпазване от светлина), срок за съхранение, течности за разтваряне и процедури, както и изделия за вливане на лекарствения продукт, ако има такива. Възложителят уведомява всички включени в клиничното изпитване страни (т.е. мониториращи, изследователи, фармацевти, отговорници по съхранението) за определените условия.
5.13.3. Необходимо е опаковката на изпитвания лекарствен продукт да

предпазва от замърсяване и неприемливо влошаване на качеството по време на транспорта и съхранението.

5.13.4. В слепите изпитвания кодиращата система за изпитвания лекарствен продукт задължително включва механизъм за незабавно разкриване на лекарствения продукт в случай на спешност, но непозволяващ незабележимо разкриване на кода.

5.13.5. В случай че по време на клиничното изпитване са направени значителни промени в състава на изпитвания лекарствен продукт или на лекарствения продукт за сравнение, резултатите от всички допълнителни изпитвания на лекарствените продукти с нов състав (т.е. тест за стабилност, профил на разтворимост, бионаличност) трябва да бъдат налични преди използването на продуктите в клинично изпитване, за да се прецени дали промените повлияват значително фармакокинетичния профил на лекарствения продукт.

5.14. Доставка и боравене с изпитвания лекарствен продукт

5.14.1. Възложителят е отговорен за снабдяването на изследователя с изпитвания лекарствен продукт. Възложителят предоставя на участниците безвъзмездно изпитвания лекарствен продукт/продукти и всяко изделие, необходимо за прилагането му.

В случай че възложителят е организация с нестопанска цел, клинично изпитване може да се проведе с продукти, които не са предоставени от възложителя, при изричното съгласие на физическото/юридическото лице, финансиращо лечението.

В случай на неинтервенционално проучване проучването може да се проведе с продукти, които не са предоставени от възложителя.

5.14.2. Възложителят не доставя изпитвания лекарствен продукт на изследователя, докато не се набавят всички необходими документи (т.е. положително становище на комисия по етика и регулаторните органи).

5.14.3. Възложителят гарантира, че на изследователя са доставени писмени процедури, включващи инструкции, които той е задължен да следва при боравене и съхранение на изпитвания лекарствен продукт и документацията към него. Процедурите включват адекватно и безопасно получаване, боравене, съхранение, раздаване, събиране на неизползваните количества от пациентите и връщане обратно на възложителя на неизползваните количества от изпитвания лекарствен продукт (или унищожаване или усвояване по друг начин, ако това е разрешено от възложителя и е в съответствие с приложимите нормативни изисквания).

5.14.4. Възложителят:

5.14.4.1. гарантира за навременната доставка на изпитвания лекарствен продукт на изследователите;

5.14.4.2. съхранява записи, документиращи изпращането, получаването, разпределението, връщането и унищожаването на изпитвания лекарствен продукт съгласно т. 8;

5.14.4.3. поддържа система за възстановяване на изпитваните лекарствени продукти и документиране на това възстановяване (т.е. за недостатъчно връщане на лекарствен продукт, обратно получаване след завършване на клиничното изпитване, изтичане на срок за обратното получаване);

5.14.4.4. поддържа система за унищожаване/предаване на други лица на

неупотребеното количество и документация за това унищожаване/предаване.

5.14.5. Възложителят:

5.14.5.1. гарантира, че лекарственият продукт ще бъде стабилен през цялото време на употреба;

5.14.5.2. съхранява достатъчни количества от изпитвания лекарствен продукт, използван по време на клиничното изпитване, за да препотвърди спецификациите, ако това стане необходимо, и съхранява документация от анализа и характеристики на пробната партида;

5.14.5.3. съхранява пробите до степен, която стабилността позволява, до завършване на анализите на данните от клиничното изпитване или за по-дълъг период, ако това се изисква от други приложими нормативни изисквания.

5.15. Достъп до документацията

5.15.1. Възложителят документира в протокола или с друг писмен договор, че главният изследовател/лечебното заведение, център на проучването, ще предоставят директен достъп до източниците на данни/документи, свързани с клиничното изпитване за мониториране, проверки, разглеждане от комисия по етика и инспекция от регулаторните органи.

5.15.2. Възложителят проверява дали всички участници са дали писмено съгласието си за директния достъп до техните оригинални медицински досиета при провеждане на свързани с клиничното изпитване мониториране, проверки, разглеждане от комисия по етика и инспекция от регулаторните органи.

5.16. Информация за безопасност

5.16.1. Възложителят е отговорен за непрекъснатата оценка на безопасността на изпитвания лекарствен продукт.

5.16.2. Възложителят информира ИАЛ, комисията по етика и изследователите за всяка нова информация, която може да представлява заплаха за здравето и благополучието на пациентите, да повлияе на хода на проучването или да промени разрешението на ИАЛ за провеждане на проучването и/или да промени положителното становище на комисия по етика за продължение на клиничното изпитване.

5.16.3. Възложителят съхранява подробни записи за всички съобщения за подозирани нежелани събития, настъпили при употребата на изпитвания лекарствен продукт, за които е информиран от изследователите или от друг източник на информация.

5.16.4. Възложителят оценява нежеланите събития по отношение на сериозност, очакваност и причинно-следствена връзка. Възложителят разработва и прилага процедури за оценка на нежеланите събития за сериозност, очакваност и причинно-следствена връзка в съответствие с публикуваните ръководства на Международната конференция по хармонизация, Европейската комисия и Европейската агенция по лекарствата.

5.16.5. Възложителят събира активно всяка допълнителна информация, която е необходима за оценка на индивидуалните съобщения за нежелани събития.

5.1.6.6. Всички нежелани събития, оценени от изследователя или възложителя като най-малко вероятно свързани с изпитвания продукт, се обработват и докладват като нежелани лекарствени реакции.

5.17. Докладване на нежелани лекарствени реакции

5.17.1. Доклади за подозирани сериозни и неочаквани нежелани реакции по чл. 138 ЗЛПХМ се подават от възложителя на клиничното изпитване.

Възложителят е отговорен за подаване на съобщенията за сериозни неочаквани нежелани реакции, включително когато реакциите са към разрешен за употреба изпитван лекарствен продукт, използван в изпитването като продукт за сравнение, за който възложителят не е притежател на разрешението за употреба. В тези случаи възложителят информира притежателя на разрешение за употреба на продукта за територията на България за реакцията и за подаването на информацията до ИАЛ.

Когато изпитваният лекарствен продукт не е разрешен за употреба, възложителят уведомява ИАЛ и комисията по етика в допълнение към съобщенията по чл. 138, ал. 1 и 3 ЗЛПХМ и за всички подозирани сериозни и неочаквани нежелани реакции при употребата на изпитвания лекарствен продукт независимо от произхода им.

Доклади за сериозни и неочаквани нежелани реакции се подават в Изпълнителната агенция по лекарствата и комисията по етика незабавно и не по-късно от 15 дни от получаването на информация за настъпването им. При изрично писмено съгласие на комисията по етика докладите за подозирани сериозни и неочаквани нежелани реакции могат да се подават на по-големи интервали, но не по-рядко от веднъж на шест месеца.

Възложителят е отговорен за изпращането на доклади до всички заинтересувани изследователи, комисия по етика и регулаторни органи за всички нежелани лекарствени реакции, които са сериозни и неочаквани.

5.17.2. Докладите за сериозни и неочаквани нежелани реакции трябва да съответстват на приложимите нормативни изисквания и ръководството на Международната конференция по хармонизация за обработка на данните за безопасност от клинични изпитвания - "Дефиниции и стандарти за спешно докладване" (ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

5.17.3. Възложителят представя на регулаторните органи всички актуализации на данните за безопасност и периодичните доклади. Възложителят предоставя веднъж годишно на Изпълнителната агенция по лекарствата и на Комисията по етика списък на всички подозирани сериозни нежелани лекарствени реакции, които са възникнали през изминалия период, и доклад за безопасността на участниците в изпитването.

5.17.4. Годишният доклад за безопасност съдържа обобщени данни за безопасността на изпитвания лекарствен продукт за последния едногодишен период, считано от датата на първото разрешение за провеждане на клинично изпитване с изпитвания продукт на територията на Европейския съюз.

Възложителят подава годишния доклад за безопасност в ИАЛ и комисията по етика в срок до 60 календарни дни след края на периода, който обхваща докладът.

За клинични изпитвания с продължителност под една година годишен доклад за безопасност се подава в срок до 90 дни след приключване на изпитването с уведомлението по чл. 142, ал. 2 ЗЛПХМ.

Когато провежда повече от едно клинично изпитване с един и същи изпитван продукт, възложителят подава общ годишен доклад за безопасност. В тези случаи докладът съдържа данни за профила на безопасност на изпитвания

продукт и годишните доклади за безопасност по всяко от провежданите в България клинични изпитвания.

5.17.5. Възложителят предоставя годишен доклад за безопасност и извън посочения срок при поискване от ИАЛ и/или комисията по етика.

5.18. Мониториране

5.18.1. Цел на мониторирането е да се провери дали са запазени правата и благополучието на хората; докладваните данни са точни, пълни и съответстват на оригиналните документи; провеждането на клиничното изпитване е в съответствие с одобрения план и промените, ДКП и приложимите нормативни изисквания.

5.18.2. Избор и квалификация на лицата, извършващи мониториране

5.18.2.1. Лицата, извършващи мониториране, се назначават от възложителя.

5.18.2.2. Лицата, извършващи мониториране, са обучени и притежават нужните научни и/или медицински познания, за да мониторират клиничното изпитване правилно. Квалификацията на лицата, извършващи мониториране, се документира.

5.18.2.3. Лицата, извършващи мониториране, трябва изцяло да бъдат запознати с изпитвания лекарствен продукт, протокола, с формата за писмено информирано съгласие и всяка друга писмена информация, която ще се предоставя на участниците, СОП на възложителя, ДКП и приложимите нормативни изисквания.

5.18.3. Обхват и естество на мониторирането

Възложителят гарантира, че изпитванията се мониторират по подходящ начин. Възложителят е задължен да определи обхвата и начина на мониториране, вземайки предвид целта, дизайна, сложността, заслепяването, размера и крайните точки на клиничното изпитване. В цялост мониториране в мястото на провеждане се извършва преди, по време и след клиничното изпитване. По изключение възложителят може да определи, че централно мониториране, включващо процедури, като обучение и срещи на изследователите и ползване на разширени писмени ръководства, осигурява провеждане на клиничното изпитване в съответствие с ДКП. Приемлив метод за избор на данни за проверка е методът на статистически контролирани проби.

5.18.4. Задължения на лицата, извършващи мониториране

В съответствие с изискванията на възложителя лицето, извършващо мониториране, гарантира, че клиничното изпитване се провежда и документира правилно чрез извършването на следното:

5.18.4.1. действа като основната връзка за кореспонденция между възложителя и изследователя;

5.18.4.2. установява дали изследователят притежава съответна квалификация и ресурси, които ще останат подходящи през цялото изпитване, че условията, включващи лабораторията, оборудването и персонала, са подходящи и че ще останат такива през целия период на клиничното изпитване за неговото безопасно и правилно провеждане;

5.18.4.3. установява, че по отношение на изпитвания лекарствен продукт:

5.18.4.3.1. времето и условията за съхранение са подходящи и

доставките
са достатъчни за цялото изпитване;
5.18.4.3.2. изпитваният лекарствен продукт е доставен само на участниците, които са подходящи за получаването му в доза, определена от протокола;
5.18.4.3.3. членовете на изследователския екип са снабдени с необходимите инструкции за правилната употреба, боравене, съхранение и връщане на изпитвания лекарствен продукт;
5.18.4.3.4. получаването, употребата и връщането на изпитвания лекарствен продукт в местата на провеждане на клинично изпитване се контролират и документират правилно;
5.18.4.3.5. боравенето с неизползваните количества от изпитвания лекарствен продукт съответства на приложимите нормативни изисквания и е съгласувано с възложителя;
5.18.4.4. установява дали изследователят следва одобрения протокол и всички одобрени изменения, ако има такива;
5.18.4.5. установява дали е получено писмено информирано съгласие от всеки участник преди включването му в клиничното изпитване;
5.18.4.6. гарантира, че изследователят получава актуалната брошура на изследователя, всички документи и всички консумативи за клиничното изпитване, необходими за неговото правилно провеждане и в съответствие с приложимите нормативни изисквания;
5.18.4.7. гарантира, че изследователят и неговият екип са достатъчно добре запознати с клиничното изпитване;
5.18.4.8. проверява дали изследователят и неговият екип извършват определените дейности по клиничното изпитване в съответствие с протокола и всички други писмени договори между възложителя и изследователя и че не са прехвърлили тези дейности на други неупълномощени лица;
5.18.4.9. проверява дали изследователят включва само подходящи лица;
5.18.4.10. докладва статуса на включване на участниците;
5.18.4.11. проверява дали оригиналните документи, както и другите документи по клиничното изпитване са точни, пълни и актуални и се съхраняват;
5.18.4.12. проверява дали изследователят предоставя всички изисквани доклади, уведомления и молби и дали тези документи са точни, пълни, навременни, четливи, с дата и идентифицират проучването;
5.18.4.13. проверява и сравнява точността и пълнотата на записаните в клиничната карта на пациента данни, оригиналните документи и други свързани
с клиничното изпитване документи едни с други; лицето, извършващо мониториране, задължително проверява дали:
5.18.4.13.1. данните, изисквани от протокола, са точно докладвани в ККП
и съответстват на оригиналните документи;
5.18.4.13.2. всяка промяна на дозата и/или лечението за всеки отделен участник са добре документирани;
5.18.4.13.3. нежеланите събития, придружаващото лечение и допълнителните заболявания са докладвани в ККП в съответствие с протокола;
5.18.4.13.4. визитите, които участниците не са могли да направят, и изследванията, които не са направени, са ясно докладвани като такива в ККП;
5.18.4.13.5. всички отпаднали и изключени участници от клиничното изпитване са докладвани и обяснени в ККП;
5.18.4.14. уведомява изследователя за всички грешни попълвания на ККП,
пропуски или нечетливости; лицето, извършващо мониториране, гарантира, че корекциите, допълненията или изтриванията са направени с дата и обяснени

(ако е необходимо) и с поставени инициали от изследователя или от член на екипа на изследователя, който е упълномощен да поставя инициалите си върху промените в ККП за изследователя; пълномощното се документира;

5.18.4.15. установява дали всички нежелани събития са докладвани в сроковете, изисквани от ДКП, протокола и приложимите нормативни изисквания;

5.18.4.16. установява дали изследователят съхранява основните документи;

5.18.4.17. обръща внимание на изследователя за отклоненията от протокола, СОП, ДКП и приложимите нормативни изисквания и предприема необходимите мерки за недопускане на нови такива отклонения.

5.18.5. Процедури за мониториране

За мониториране на специфичното изпитване лицето, извършващо мониториране, спазва установените от възложителя писмени СОП, както и онези процедури, които са определени от възложителя за конкретното клинично проучване.

5.18.6. Доклад от мониториране

5.18.6.1. Лицето, извършващо мониториране, представя на възложителя писмен доклад след всяка визита в центъра на клиничното изпитване и след всяка свързана с клиничното изпитване комуникация.

5.18.6.2. Докладите включват датата, името на центъра, името на лицето, извършващо мониториране, името на изследователя или на други лица, с които е контактувал.

5.18.6.3. Докладите трябва да включват резюме за това, което е прегледано от лицето, извършващо мониториране, и неговите становища по отношение на важни факти, отклонения и непълноти, заключенията и действия, които са предприети или ще бъдат предприети, и/или препоръчани действия за осигуряване на съответствие.

5.18.6.4. Прегледът и проследяването на действията след доклад от мониториране от възложителя се документират от упълномощено от възложителя лице.

5.19. Проверка

При проверка като част от осигуряване на качеството възложителят е задължен да има предвид следното:

5.19.1. Цел

Целта на проверката на възложителя, която е независима и отделна от рутинните функции на лицето, извършващо мониториране, или функциите за качествен контрол трябва да бъде оценка на провеждането на клиничното изпитване и съответствието с протокола, СОП, ДКП и приложимите нормативни изисквания.

5.19.2. Избор и квалификации на проверяващите

5.19.2.1. За извършване на проверки възложителят назначава лица, които са независими от клиничните изпитвания/системи.

5.19.2.2. Възложителят трябва да гарантира, че проверяващите са квалифицирани по отношение на обучение и опит за правилното провеждане на проверки. Квалификацията на проверяващите се документира.

5.19.3. Процедури за проверка

5.19.3.1. Възложителят гарантира, че проверяването на клинични изпитвания/системи се провежда в съответствие с писмени процедури на възложителя за това, какво и как да се проверява, честота на проверката, форма и съдържание на докладите от проверката.

5.19.3.2. Планът и процедурите за проверка на едно клинично изпитване от възложителя се ръководят от важността на клиничното изпитване, броя на

участниците в клиничното изпитване, вида и сложността на клиничното изпитване, степента на риск за участниците и всички установени проблеми.

5.19.3.3. Наблюденията и находките на проверяващия/ите се документират.

5.19.3.4. Регулаторните органи могат да изискат достъп до доклад от проверка за всеки конкретен случай, когато има данни за съществуващо сериозно несъответствие с ДКП или в административни или съдебни процедури.

5.19.3.5. Когато се изисква от приложимия закон или наредба, възложителят представя сертификат от проверка.

5.20. Нарушение

5.20.1. В случай на нарушение от страна на изследователя или на член(ове) на изследователския екип по отношение на протокола, СОП, ДКП и/или приложимите нормативни изисквания възложителят предприема незабавна намеса за запазване на съответствие с тях.

5.20.2. Ако по време на мониториране и/или проверка се установи, че е извършено съществено нарушение по вина на изследователя, възложителят прекратява участието му в клиничното изпитване и своевременно уведомява регулаторните органи, когато нарушението води до прекратяване участието на изследователя.

5.21. Преждевременно прекратяване или преустановяване на изпитване

В случай че едно изпитване е преждевременно прекратено или преустановено, възложителят е задължен своевременно да уведоми изследователя и регулаторните органи за прекратяването или преустановяването и причините за това. Изследователят или възложителят в съответствие с приложимите нормативни изисквания своевременно уведомяват комисия по етика, като се представят причините за прекратяването или преустановяването.

5.22. Доклади за клинично изпитване/проучване

В случай че едно изпитване е приключило или е преждевременно прекратено или преустановено, възложителят гарантира подготвянето и представянето пред регулаторните органи и Комисията по етика на докладите от клиничното изпитване според приложимите нормативни изисквания. Възложителят гарантира и съответствието на докладите от тези изпитвания, приложени към заявлението за разрешаване за употреба със стандартите, заложени в ръководството на Международната конференция по хармонизация за структурата и съдържанието на доклади от клинични изпитвания.

5.23. Многоцентрови изпитвания

В случай на многоцентрови изпитвания възложителят гарантира, че:

5.23.1. Всички изследователи провеждат клиничното изпитване в стриктно съответствие с одобрения от възложителя протокол и след дадено положително становище от комисия по етика, ако това се изисква от регулаторните органи.

5.23.2. Клиничните карти на пациентите са съставени така, че да обхващат данните от всички центрове на многоцентровото изпитване. Тези изследователи, които събират допълнителни данни, се снабдяват с допълнителни ККП, съставени така, че да обхващат тези допълнителни данни.

5.23.3. Отговорностите на координиращия изследовател и на участващите изследователи са документирани непосредствено преди започване на клиничното изпитване.

5.23.4. На всички изследователи са раздадени инструкции за спазване на протокола, за спазване на определените от възложителя стандарти за оценка на клинични и лабораторни находки и за попълване на клиничната карта на пациента.

5.23.5. Комуникацията между изследователите е улеснена.

6. Протокол на клинично изпитване и промени в протокола

Протоколът на клинично изпитване трябва основно да съдържа изброените данни. Специфичната информация, която е приложима само за отделни центрове на клиничното изпитване, може да бъде включена в отделна страница/страници или да бъде включена в отделно споразумение. Част от данните, изброени по-долу, може да се съдържат в други, свързани с протокола документи, например брошурата на изследователя.

6.1. Обща информация

6.1.1. Заглавие на протокола, идентификационен код и дата. Всяка промяна/промени включва номер и дата.

6.1.2. Име и адрес на възложителя и лицето, извършващо мониториране, и договорната изследователска организация, ако е включена в клиничното изпитване.

6.1.3. Име и длъжност на лицето/лицата, упълномощено да подписва протокола и промяната/промените в него от името на възложителя.

6.1.4. Име, длъжност, адрес и телефонен номер/а на медицинския експерт от страна на възложителя (или лекар по дентална медицина) за клиничното изпитване.

6.1.5. Име и длъжност на изследователя/ите, който е отговорен за провеждане на клиничното изпитване, както и адресите и телефонните номера на центъра/центровете на клиничното изпитване.

6.1.6. Име, длъжност, адрес и телефонен номер/а на лекаря или лекаря по дентална медицина, който е отговорен за всички свързани с клиничното изпитване медицински (или дентални) решения (ако е различен от изследователя).

6.1.7. Име/на и адрес/и на клиничната лаборатория/и и други здравни и/или технически отделения и/или институции, включени в клиничното изпитване.

6.2. Основна информация

6.2.1. Име и описание на изпитвания/ите продукт/и.

6.2.2. Обобщение на данните от неклиничните проучвания, които могат да имат клинично значение, и от клинични изпитвания, които са свързани с настоящото.

6.2.3. Обобщение на установени и възможни рискове и ползи, ако има такива, за хората.

6.2.4. Описание и обосновка за пътя на въвеждане, дозата, дозовия режим и лечебния период.

6.2.5. Становище, че клиничното изпитване ще се проведе в съответствие с протокола, ДКП и приложимите нормативни изисквания.

6.2.6. Описание на категорията лица, върху която ще се проведе клиничното изпитване.

6.2.7. Използвана литература и данни, които са свързани с клиничното изпитване и представляват основа за клиничното изпитване.

6.3. Задачи и цел

Детайлно описание на задачите и целта на клиничното изпитване.

6.4. Дизайн на изпитване

Научната стойност на клиничното изпитване и достоверността на данните съществено зависят от дизайна на клиничното изпитване. Описанието на дизайна включва:

6.4.1. Изрично посочване на първичните и вторичните крайни точки, които ще се използват като показатели за ефективност и безопасност, които ще бъдат оценени по време на клиничното изпитване.

6.4.2. Описание на типа/дизайна на клиничното изпитване, което ще се проведе (напр. двойно-сляпо, плацебо-контролирано, с успореден дизайн) и схематична диаграма на дизайна, процедурите и етапите на клиничното изпитване.

6.4.3. Описание на взетите мерки за намаление/избягване на отклоненията, вкл. рандомизация и заслепяване.

6.4.4. Описание на изпитваното лечение/я, дозата и дозовия режим на изпитвания лекарствен продукт; включва се описание на дозовата форма, опаковката и етикетирането на изпитвания продукт.

6.4.5. Очакваната продължителност на участието на лицата, както и описание на последователността и продължителността на всички периоди на клиничното изпитване, включително проследяване, ако има такова.

6.4.6. Описание на "спиращите правила" и "критериите за отстраняване" за определени лица в етапи от клиничното изпитване и в цялото изпитване.

6.4.7. Процедури за отчетност на изпитвания продукт, включително плацебото и лекарствения продукт за сравнение, ако има такива.

6.4.8. Съхраняване на рандомизационните кодове и процедурите за разкриване на кодовете на лечението в клиничното изпитване.

6.4.9. Посочване на всички данни, които директно ще бъдат записвани в ККП (т.е. без непосредствено писмено или електронно записване) и които се приемат за оригинални данни.

6.5. Избор и отстраняване на участниците

6.5.1. Критерии за включване на участниците.

6.5.2. Критерии за изключване на участниците.

6.5.3. Критерии за отстраняване на участниците (т.е. прекратяване на лечението с изпитвания продукт/изпитваното лечение) и процедури, определящи:

6.5.3.1. кога и как ще бъдат изключвани участници от изпитваното лечение/лечението с изпитвания продукт;

6.5.3.2. вида на данните и периода, за който ще бъдат събирани данни за отстранените участници;

6.5.3.3. дали и как ще бъдат замествани отпадналите участници;

6.5.3.4. проследяване на отпадналите участници от изпитваното лечение/лечението с изпитвания продукт.

6.6. Лечение на участниците

6.6.1. Назначеното/ите лечение/я, включително имената на всички продукти, доза/и, дозови схеми, пътища/начини на приложения, периоди на лечение, включително проследяващи периоди за участниците за всяко изпитвано лечение/лечение с изпитвания продукт, група/рамо от клиничното изпитване.

6.6.2. Разрешен(и) лекарствен(и) продукт(и)/лечение(я) (вкл. и животоспасяващи), както и неразрешени преди и/или по време на клиничното изпитване.

6.6.3. Процедури за наблюдение на съдействието на участниците по

отношение на лечението.

6.7. Оценка на ефикасността

6.7.1. Определение на параметрите за ефикасност.

6.7.2. Методи и време за оценка, записване и анализиране на параметрите за ефикасност.

6.8. Оценка на безопасността

6.8.1. Определение на параметрите на безопасност.

6.8.2. Методи и време за оценка, записване и анализиране на параметрите за безопасност.

6.8.3. Процедури за набавяне на доклади и за записване и докладване на нежелани събития и съпътстващи заболявания.

6.8.4. Видът и продължението на проследяването на участниците след нежелани събития.

6.9. Статистика

6.9.1. Описание на статистическите методи, които ще бъдат използвани, вкл. всички планирани във времето междинни анализи.

6.9.2. Брой на лицата, които се предвижда да бъдат включени. В случай на многоцентрово изпитване се посочва предвижданият брой на лицата за всеки отделен център. Причина за избор на големина на извадката, включително отражение върху (или изчисление на) мощността на клиничното изпитване и основание за провеждането му.

6.9.3. Използвано ниво на значимост.

6.9.4. Критерии за прекратяване на клиничното изпитване.

6.9.5. Процедури за отчитане на липсващи, неизползвани или неверни данни.

6.9.6. Процедури за докладване на всички отклонения от оригиналния статистически план (необходимо е всички отклонения от оригиналния статистически план да са описани и обосновани в протокола и/или в окончателния доклад).

6.9.7. Изборът на участниците, които ще бъдат включени в анализа (напр. всички рандомизирани участници, всички лица, получили доза, всички подходящи участници, участници, които могат да се оценят).

6.10. Директен достъп до оригиналните данни/документи

Възложителят гарантира, че в протокола или в друго писмено споразумение е посочено, че изследователят ще разреши мониториране, проверки, разглеждане от Комисията по етика и инспекция от регулаторните органи чрез осигуряване на директен достъп до оригиналните документи/данни.

6.11. Контрол на качеството и осигуряване на качеството

6.12. Етика

Описание на етичните аспекти, отнасящи се към клиничното изпитване.

6.13. Поддържане на данни и съхранение на документация

6.14. Начин на финансиране и застраховка

Посочват се, ако не са изложени в отделен договор.

6.15. План за публикуване на данни

Посочва се, ако не са изложени в отделен договор.

6.16. Приложения

7. Брошура на изследователя

7.1. Въведение

Брошурата на изследователя е съвкупност от клинични и неклинични

данни
за изпитвания продукт, които са приложими в процеса на изпитване на лекарствени продукти върху хора. Целта е да се представи информация на изследователите и на други лица, включени в клиничното изпитване, за да се улесни разбирането на мотивите за проучването, да се осигури спазването с основните характеристики на протокола, каквито са дозата, дозовата честота/интервал, пътят на приложение на продукта и процедурите за наблюдение на безопасността. Брошурата на изследователя предоставя и информация в подкрепа на клиничното поведение спрямо лицата - участници в хода на клиничното изпитване. Информацията се представя в кратка, опростена, балансирана и нерекламна форма по начин, който дава възможност на лекаря или на потенциалния изследовател да разбере и да може да направи лична преценка за предназначението на предложеното изпитване, която да бъде точна по отношение на риск - полза. В издаването на брошурата на изследователя участва лице с медицинска квалификация, а одобрението на съдържанието се извършва от специалисти по съответните медицински специалности, които са съставили описаните данни.

Видът и обемът на информацията могат да варират в зависимост от етапа на развитие на изпитвания продукт. Когато изпитваният продукт е разрешен за употреба и лекарите са широко запознати с неговата фармакология, не е необходима подробна брошура на изследователя. Възможно е като алтернатива да се представят брошура с основна информация за продукта или кратка характеристика на продукта, като се посочи, че те съдържат съвременна, пълна и детайлна информация за всички аспекти на изпитвания продукт и могат да са от значение за изследователя. В случай че се изпитва ново приложение (напр. нова индикация) на продукт, имащ разрешение за употреба, се подготвя брошура на изследователя, специфична за тази нова употреба. Брошурата на изследователя се преглежда веднъж годишно и се променя, когато е необходимо, в съответствие с писмените процедури на възложителя. По-чести промени могат да се правят в зависимост от етапа на развитие на продукта и вида на съответната нова информация. Съответната нова информация, в съответствие с добрата клинична практика, може да бъде от такава важност, че да е необходимо тя да се обсъди с изследователите и по възможност в комисията по етика и/или регулаторните органи, преди да бъде включена в брошура на изследователя.

Възложителят е отговорен за гарантиране на това, че изследователите са запознати с актуализираната брошура на изследователя, а изследователите са задължени да представят новата брошура на изследователя на съответните комисии по етика. В случай на изпитване, възложено от изследовател, възложителят-изследовател е задължен да представи уверение, че брошура на изследователя може да се набави от производителя. Ако изпитваният продукт се произвежда от изследователя, то той е задължен да представи необходимата информация пред екипа на изпитването. В случай че подготовката на официална

брошура на изследователя е невъзможна, като замяна възложителят-изследовател представя в протокола подробна основна информационна част, съдържаща минимум актуални данни, описани в това приложение.

7.2. Основни съображения

Брошурата на изследователя включва:

7.2.1. Заглавна страница

Тя включва: име на възложителя, характеристика на всеки изпитван продукт, т.е. изследователски код, химично или одобрено генерично име и търговско име (ако има), дата на издаване, номера на изданието и справка за номера и датата на изданието, което замества. Образец:

ЗАГЛАВНА СТРАНИЦА
ИМЕ НА ВЪЗЛОЖИТЕЛЯ
Лекарствен продукт:
Номер на изпитване:
Име (имена): Химично, INN (ако е одобрено):
Търговско име
Брошура на изследователя

Номер на издание:
Дата на издание:
Замества предишен номер на издание:
Дата:

7.2.2. Становище за поверителност

Възложителят може да включи становище, даващо инструкция на изследователя/получателите да приемат брошурата на изследователя като поверителен документ по отношение на цялата информация и използване от екипа на изследователя и от комисията по етика/регулаторния орган.

7.3. Съдържание на брошурата на изследователя

Брошурата на изследователя съдържа следните раздели, всеки от които има, по възможност, съответната литературна справка:

7.3.1. Таблица със съдържание:

Становище за поверителност
Страница за подписи
1. Съдържание
2. Обобщение
3. Увод
4. Физични, химични и фармацевтични свойства и формула
5. Неклинични изпитвания
5.1. Неклинична фармакология
5.2. Фармакокинетика и метаболизъм на продукта при животни
5.3. Токсикология
6. Ефекти при хора
6.1. Фармакокинетика и метаболизъм на продукта при хора
6.2. Безопасност и ефикасност
6.3. Опит след разрешение за употреба
7. Обобщение на данните и препоръки към изследователя
Препратки към:
1. Публикации
2. Доклади
Приложения (ако има такива)

7.3.2. Обобщение

Дава се кратко обобщение (ненадвишаващо две страници), посочващо важна налична физична, химична, фармацевтична, фармакологична, токсикологична,

фармакокинетична, метаболитна и клинична информация, която съответства на етапа на клинично разработване на изпитвания продукт.

7.3.3. Въведение

Включва се кратко въвеждащо описание, съдържащо химичното име (както и генеричното и търговското име, когато са одобрени) на изпитвания(ите) продукт(и), всички активни съставки, фармакологичния клас и очакваното място в този клас (напр. преимущества), обосновка за провеждане на проучването и очакваните(ата) индикации(я) за профилактика, терапия или диагностика. Най-накрая въвеждащото описание, включващо основния подход, който ще се следва при оценката на изпитвания продукт(и).

7.3.4. Химични, физични, фармацевтични свойства и състав

Представя се описание на веществото/ата (вкл. химична и/или структурна формула/и) и кратко обобщение на съответните химични, физични, фармацевтични свойства.

Представя се и се коментира (ако е клинично значимо) описание на състава/ите, които ще се използват, включително и помощни вещества с цел предприемане на подходящи мерки за безопасност. Дават се инструкции за съхранение и употреба на дозовите форми. Споменават се всички структурни сходства с други известни вещества.

7.3.5. Неклинични изпитвания

Под формата на обобщение се представят резултати от всички значими неклинични фармакологични, токсикологични, фармакокинетични изпитвания и изпитвания за установяване на метаболизма на изпитвания продукт. Това обобщение описва използваната методология, резултатите и обсъждане на значимостта на откритията за изпитвания продукт и възможните неблагоприятни и нежелани ефекти при хората.

Представената информация включва тестуваните видове; брой и пол на животните във всяка група; дозови единици (напр. милиграм/килограм, mg/kg); дозов интервал; начин на приложение; продължителност на дозиране; информация за системно разпределение; продължителност на проследяване след прилагане; резултати, включващи следните аспекти: естество и честота на фармакологичните или токсичните ефекти; тежест и интензивност на фармакологичните или токсичните ефекти; време за възникване на ефектите; продължителност на ефектите; дозов отговор.

Табличен формат или списък може да се използва, за да се подобри яснотата на представеното.

В следващите раздели на брошурата на изследователя се представят най-важните открития от изпитванията, включително дозовият отговор на наблюдаваните ефекти, значимостта за хората и всички ефекти, които ще бъдат проучвани върху хора. Ако е възможно, се сравняват ефективната и нетоксичната доза в животни от един и същи вид (т.е. необходимо е да се представи терапевтичният индекс). Представя се значимостта на тази информация към предложената дозировка при хора. Когато е възможно, се правят сравнения по отношение на кръвно-тъканните нива вместо на база mg/kg.

7.3.5.1. Неклинична фармакология

В раздела се включва обобщение на фармакологичните аспекти на изпитвания продукт, а където е необходимо - и на неговите важни метаболитни

проучвания у животни. Такова обобщение включва проучвания, които оценяват потенциалната терапевтична активност (напр. модели за ефективност, свързване с рецепторите и специфичност), както такива, оценяващи безопасността (напр. специални изпитвания за оценка на фармакологичните действия, различни от предложените терапевтични ефекти).

7.3.5.2. Фармакокинетика и метаболизъм на продукта у животни

Представя се обобщение на фармакокинетиката и биологичната трансформация и диспозиция на изпитвания лекарствен продукт във всички изследвани видове. Коментарът на находките включва абсорбцията, локалната и системната бионаличност на изпитвания лекарствен продукт и неговите метаболити и тяхната връзка с фармакологичните и токсикологичните открития в животинските видове.

7.3.5.3. Токсикология

Представя се обобщение на токсикологичните ефекти, открити в съответни изпитвания, проведени върху различни животински видове, което да включва следното: токсичност при единична доза; токсичност при многократно дозиране; карциногенност; специални изпитвания (напр. дразнимост и чувствителност); репродуктивна токсичност; генотоксичност (мутагенност).

7.3.6. Ефекти при хора

Представя се пълно описание на познатите ефекти на изпитвания(ите) продукт(и) върху хора, включващ информация за фармакокинетиката, метаболизма, фармакодинамиката, дозовия отговор, безопасност, ефикасност и други фармакологични действия. Когато е възможно, се представя обобщение на всяко завършено клинично изпитване, както и информация по отношение на резултатите от всяка употреба на изпитвания лекарствен продукт, която се различава от тази в клиничните изпитвания (например - от опит след пускането на пазара).

7.3.6.1. Фармакокинетика и метаболизъм на продукта у хора

Представя се обобщение на информацията за фармакокинетиката на изпитвания лекарствен продукт, която, ако е възможно, включва следното: фармакокинетика (вкл. метаболизъм и абсорбция, свързване с плазмените протеини, разпределение и елиминиране); бионаличност (където е възможно абсолютна и/или относителна), като се използва дозова форма за сравнение; подгрупи на популацията (напр. пол, възраст и увредена функция на орган); взаимодействия (напр. взаимодействия продукт - продукт или ефекти на храна); други фармакокинетични данни (напр. резултати от изпитвания върху популации, проведени по време на клинични изпитвания).

7.3.6.2. Безопасност и ефикасност

Представя се обобщение на информацията, получена от предишни клинични изпитвания върху хора (здрави доброволци и/или пациенти) за безопасността, фармакодинамиката, ефикасността и дозовия отговор на изпитвания/ите продукт/и (и на техните метаболити, където е необходимо). Коментират се заключенията от тази информация. В случаите, когато са завършени голям брой клинични изпитвания, използването на обобщения за безопасност и ефикасност от многократни изпитвания по индикации в подгрупи може да бъде представително за данните. Обобщенията могат да се представят и в табличен

вид за нежеланите лекарствени реакции за всички клинични изпитвания (вкл. и тези за всички изследвани показания). Коментират се важни различия в тенденциите/честотата на поява на нежеланите лекарствени реакции срещу индикациите или подгрупите.

Представя се описание на предвижданията по отношение на потенциалните рискове и нежеланите лекарствени реакции въз основа на непосредствения опит с изпитвания лекарствен продукт и със свързаните с него продукти, както и на предпазните мерки или специалните наблюдения, които да се извършат по време на изпитваната употреба на лекарствения продукт/продукти.

7.3.6.3. Опит след разрешаване за употреба

Посочват се страните, в които изпитваният лекарствен продукт има разрешение за употреба. Коментира се всяка важна информация, получена от употребата след разрешение (напр. формули, дози, пътища на въвеждане или нежелани лекарствени реакции). Посочват се и страните, в които изпитваният лекарствен продукт не е получил разрешение за употреба или е бил изтеглен от пазара.

7.3.7. Обобщение на данните и препоръки към изследователя

В този раздел, по възможност, се съдържа цялостен коментар по отношение на неклиничните и клиничните данни и се обобщава информацията от различни източници за различни аспекти на изпитвания продукт. По този начин изследователят може да бъде запознат с най-информативната интерпретация на достъпните данни и с оценка на заключенията по информацията за бъдещи клинични изпитвания.

Коментират се публикувани доклади за съответстващи лекарствени продукти с цел помагане на изследователя да предвиди нежеланите лекарствени реакции или други проблеми в клиничните изпитвания.

Основната цел на раздела е да представи на изследователя едно ясно разбиране на възможните рискове, нежелани реакции и на специфичните тестове, наблюдения и предпазни мерки, които могат да се наложат за клинично изпитване. Необходимо е това разбиране да се основава на достъпната физична, химична, фармацевтична, фармакологична, токсикологична и клинична информация за изпитвания/ите лекарствен/и продукт/и. На лекаря-изследовател се представя също ръководство за установяване и лечение на възможно предозиране и нежелана лекарствена реакция, което да се базира на предишния опит върху хора и на фармакологията на изпитвания лекарствен продукт.

8. Основни документи за провеждане на клинично изпитване

8.1. Увод

Основните документи са онези документи, които индивидуално и колективно позволяват оценка на провеждането на едно изпитване и качеството на получените данни и съставляват основното досие на клиничното изпитване. Тези документи служат за демонстриране на спазването от изследователя, възложителя и лицето, извършващо мониториране, на стандартите на Добрата клинична практика и на всички приложими нормативни изисквания.

Основните документи служат също и за няколко други важни цели.

Навременното попълване на основните документи в центъра на изследователя и възложителя може значително да допринесе за успешното провеждане на едно изпитване от изследователя, възложителя и лицето, извършващо мониториране. Тези документи подлежат на независима проверка (одит) от независимия одитор на възложителя и се инспектират от регулаторните органи като част от процеса за потвърждаване на валидността на провеждането на едно изпитване и пълнотата на получените данни.
Списъкът с минималния набор основни документи е изложен по-долу.
Различните документи са групирани в три разделя в зависимост от етапа на клиничното изпитване, по време на които те обикновено се съставят: 1. преди започване на клиничната фаза на клиничното изпитване; 2. по време на провеждането на клиничното изпитване, и 3. след завършване или прекратяване на клиничното изпитване. Представено е описание на всеки отделен документ и къде е необходимо да се съхранява - при изследователя, при възложителя или и при двамата. Приемливо е да се комбинират някои от документите по такъв начин, че отделните елементи да могат лесно да се разпознаят.
Необходимо е основно досие на клиничното изпитване да се съставя в началото на клиничното изпитване както в центъра на изследователя, така и в офиса на възложителя. Окончателното приключване на едно клинично изпитване става едва когато лицето, извършващо мониториране, е прегледало основното досие на изпитването на изследователя и основното досие на изпитването на възложителя и е установило, че всички необходими документи са налични в съответните досиета.
Някои или всички описани документи могат да бъдат обект на проверка от страна на възложителя и на инспекция от страна на регулаторните органи, като за тази цел те трябва да бъдат достъпни.
8.2. Преди започване на клиничната фаза на клиничното изпитване
По време на планирането на този етап и преди формалното начало на клиничното изпитване е необходимо да се съставят и да се съхраняват следните документи:

Документ	Цел	Съхр в докумен изследовател
1	2	3
Брошура на изследователя	Да се документира, че съответната и актуална научна информация за изпитвания продукт е представена на изследователя.	X
Подписан протокол и промени (ако има) и образец от клиничната карта на пациента	Да се документира договорът между изследователя и възложителя за протокола/промените и ККП.	X

Информация, дадена на лицата в клиничното изпитване		
Форма за информирано съгласие (вкл. приложими преводи)	Да се документира информираното съгласие на участниците.	X
Всяка друга писмена информация	Да се документира, че на участниците ще бъде представена подходяща информация (като съдържание и стил).	X
Обява за набиране на пациенти (ако има)	Да се документира, че мерките за набиране на пациенти са подходящи и непринудителни.	X
Финансови аспекти на клиничното изпитване	Да се документират финансовите договори между изследователя и възложителя за клиничното изпитване.	X
Застрахователна полица	Да се документира, че в случай на свързано с клиничното изпитване увреждане лицата ще бъдат компенсирани.	X
Подписан договор между страните участници	Да се документират договорите.	
между изследователя и възложителя/ договорна изследователска организация;		X
между възложителя и лечебното заведение—център на проучването;		X
между възложителя и договорна изследователска организация		0
Датирано, документирано разрешение/положително становище на КЕ за следното:	Да се документира, че клиничното изпитване е било разгледано от комисия по етика и е получило положително становище. За идентифициране на номера и датата на версията на документите.	X
Протокол и промени		
ККП		
Форма за информирано съгласие		

Всяка друга информация, представяна на участниците		
Обява за набиране на участници (ако се използва)		
Компенсации за участниците		
Всички други документи, подлежащи на одобрение/становище		
Състав на комисията по етика/ заповед за назначаването	Да се документира, че комисията по етика е съставена в съответствие с ДКП.	x
Разрешение/уведомление на регулаторните органи	Да се документира, че разрешението е получено/срокът за уведомяването е изтекъл преди започване на клиничното изпитване и в съответствие с приложимите нормативни изисквания.	x
Автобиография и/или друг документ, доказващ квалификациите на главния изследовател и изследователите	Да се документират квалификациите и надеждността за провеждане на клиничното изпитване и/или за оказване на медицинско наблюдение на участниците.	x
Референтни стойности/граници за медицински/лабораторни/технически процедури и/или тестове, включени в протокол	Да се документират нормалните стойности и/или граници за тестовете.	x
Медицински/лабораторни/технически процедури/тестове: сертификат; акредитация; установен качествен контрол и/или външна оценка на качеството; друга валидация	Да се документират компетентността на лабораториите за провеждане на необходимите тестове и поддържане на надеждността на резултатите.	x
Образец на етикета/етикетите, приложени към опаковката на изпитвания продукт	Да се документира съответствие с приложимите наредби за етикетиране и че инструкциите, представени на участниците, са подходящи.	0
Инструкции за боравене с изпитвания продукт и свързаните с клиничното изпитване материали (ако не са включени в брошурата на изследователя)	Да се документират инструкциите, необходими за съхраняване, опаковане, разпространяване и раздаване на изпитвания продукт и на свързаните с клиничното изпитване материали.	X
Документи за изпращане и доставка на изпитвания продукт и свързаните с	Да се документират датите на пратките, номерата на партидите на изпитвания продукт и начинът на изпращане.	X

клиничното изпитване материали	Позволява проследяване на партидата на продукта, на условията на доставка и на отчетността.	
Сертификат за анализ на изпитвания продукт	Да се документират идентичността, чистотата и силата на продукта, който ще се използва в клиничното изпитване.	0
Процедури за разпознаване в слепи изпитвания	Да се документира как, в случай на спешност, идентичността на маскирания продукт ще се разпознае, без да се разкрива маскирането на лечението за останалите участници.	X
Основен списък за рандомизация	Да се документира методът за рандомизиране на участниците в клиничното изпитване.	0
Доклад от лицето, извършващо мониториране преди клиничното изпитване	Да се документира, че центърът е подходящ за клиничното изпитване (може да се комбинира с т. 8.2.20)	0
Доклад от лицето, извършващо мониториране, за стартиране на клиничното изпитване	Да се документира, че процедурите по клиничното изпитване са коментирани с изследователя и с неговия екип (може да се комбинира с т. 8.2.19)	X

реме на клиничното провеждане на изпитването

нение на горепосочените документи е необходимо следващите документи също да се съхраняват по време на клини
елство, всяка нова съответстваща информация е документирана, след като стане достъпна.

Документ	Цел	Съхр към докум изследовател
1	2	3
Актуализации на брошура на изследователя	Да се документира, че съответната информация е своевременно представена на изследователя.	X
Всички промени на протокола/ промените и ККП; формата за писмено информирано съгласие; всяка друга писмена информация, представяна на участниците; обява за набиране на пациенти (ако се използва)	Да се документират промените в тези, свързани с клиничното изпитване и влияещи на клиничното изпитване, документи.	X

Датирано, документирано положително становище на комисия по етика за следното: Промени в протокола Промени във форма за информирано съгласие Промени във всяка друга информация, представяна на участниците Промени в обява за набиране на участници (ако се използва) Промени във всички други документи, изискващи положително становище Промени в продължителния надзор на клиничното изпитване	Да се документира, че промените и/или преработките са били разгледани в комисия по етика и са получили положително становище. Да се идентифицират номерът и датата на версията.	X
Разрешение/уведомяване на регулаторните органи за промени	Да се документира, че разрешението е получено/срокът от подаване на уведомяването е изтекъл преди прилагане на промените в клиничното изпитване и в съответствие с приложимите нормативни изисквания.	X
Автобиография на нов главен изследовател и/или изследователи	Да се документират квалификациите и надеждността за провеждане на клиничното изпитване и/или за оказване на медицинско наблюдение на участниците.	X
Промени в нормалните стойности/граници за медицински/лабораторни/технически процедури и/или тестове, включени в плана	Да се документират промените в нормалните стойности и/или граници за тестовете.	X
Промени в медицински/лабораторни/технически процедури/тестове: сертификат; акредитация; установен качествен контрол и/или външна оценка на качеството; всяка друга валидация	Да се документира, че тестовете остават приложими по време на целия период на клиничното изпитване.	X
Документи за изпращане на изпитвания продукт и свързаните с клиничното изпитване материали	Съгласно т. 8.2.15	X
Сертификат за анализ на нови партиди от изпитвания продукт	Съгласно т. 8.2.16	0

Доклади от посещения на лицето, извършващо мониториране	Да се документират посещенията и находките на лицето, извършващо мониториране.	0
Допълнителна кореспонденция, различна от посещенията в центъра: писма, доклади от срещи, записки от телефонни разговори	Да се документират всички споразумения или значими коментари по отношение на администрация, протокол, нарушения, провеждане на клиничното изпитване и докладване на нежелани събития.	X
Подписани форми на информирано съгласие	Да се документира, че съгласието е получено в съответствие с ДКП и плана и е датирано непосредствено преди участието на всеки участник в клиничното изпитване. Да се документира и разрешение за директен достъп (т. 8.2.3).	X
Изходни документи	Да се документира съществуването на лицето и да се потвърди пълнотата на получените данни. Да се включат оригинални документи, свързани с клиничното изпитване, медицинското лечение и историята на заболяването.	X
Подписани, датирани и попълнени клинични карти на пациентите (ККП)	Да се документира, че изследователят или упълномощен член на екипа потвърждава записаните наблюдения.	X (копие)
Документиране на корекциите в ККП	Да се документират всички промени/допълнения или корекции, направени в ККП след попълване на първоначални данни.	X (копие)
Уведомяване на възложителя от изследователя за сериозни нежелани събития и съответни доклади	Уведомяване на възложителя от изследователя за сериозни нежелани събития и съответни доклади в съответствие с т. 4, 11.	X
Уведомяване от възложителя и/или от изследователя на регулаторните органи и комисия по етика за неочаквани и сериозни нежелани лекарствени реакции и за друга информация за безопасност	Уведомяване от възложителя и/или от изследователя, когато е приложимо, на регулаторните органи и комисия по етика за неочаквани и сериозни нежелани лекарствени реакции в съответствие с т. 5.17 и 4.11.1 и за друга информация за безопасност в съответствие с т. 5.16.2 и 4.11.2.	0
Уведомяване от възложителя на изследователя за информация по безопасността	Уведомяване от възложителя на изследователя за информация по безопасността в съответствие с т. 5.16.2.	X
Временни или годишни доклади до комисията по етика и властите	Временни или годишни доклади до комисията по етика в съответствие с т. 4.10 и властите в съответствие с т. 5.17.3.	X

Таблица на скринираните лица	Да се документира самоличността на лицата, които са преминали скрининг преди клиничното изпитване.	X
Списък с кодове за разпознаване на лицата	Да се документира, че изследователят/институцията съхраняват поверителен списък на имената на всички участници, които са означени с номера при включването им в клиничното изпитване.	X
Таблица за включване на лицата	Да се документира включването и означаването с номера на клиничното изпитване на участниците по хронологичен ред.	X
Отчетност на изпитвания продукт в центъра	Да се документира, че изпитваният продукт е прилаган в съответствие с плана.	X
Лист с подписи	Да се документират подписите и инициалите на всички лица, упълномощени да попълват и да правят корекции в ККП.	X
Документ за запазени проби човешки течности и тъкани (ако има)	Да се документира местонахождението и идентификацията на запазените проби, ако са необходими допълнителни анализи.	X

д завършване на клиничното изпитване

вършване или прекратяване на клиничното изпитване всички документи, изброени в т. 8.2 и 8.3, е необходимо да б
се добавят и следните:

Документ	Цел	Съхр към докум изследовател
Отчетност на изпитвания продукт в центъра	Да се документира, че изпитваният продукт е прилаган в съответствие с плана. Да се документира окончателното преброяване на изпитвания продукт, който е бил получен в центъра, раздаден на участниците, върнат от лицата и върнат на възложителя.	X
Документи за унищожаване на изпитвания продукт	Да се документира унищожаването на неизползваното количество от изпитвания продукт от възложителя или в центъра	X Ако е унищожен в

		центъра
Попълнен списък с кодове за разпознаване на лицата	За да стане възможно разпознаването на всички включени в клиничното изпитване лица, в случай че е необходимо проследяване. Списъкът трябва да се съхранява поверително и в договорения срок.	X
Сертификат от проверка (ако е наличен)	За да се документира, че е направена проверка.	0
Окончателен доклад от лицето, извършващо мониториране за закриване на центъра	За да се документира, че са извършени всички необходими дейности по закриването на центъра и че копия от основните документи се съхраняват към съответната документация.	0
Разпределение на лечението и документи за декодиране	За да се документира, че са върнати на възложителя, в случай, че е възникнало някакво декодиране.	X (когато лечението е известно на изследователс ия екип)
Окончателен доклад от изследователя до комисия по етика и регулаторните органи, в случай че това се изисква	За да се документира завършването на клиничното изпитване.	X
Доклад от клиничното изпитване	За да се документират резултатите и интерпретиране на клиничното изпитване.	0

Приложение № 2
към чл. 10, ал. 1

Съдържание и формат на досие на изпитван лекарствен продукт

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2.3.3. Приложение върху хора

2.4. Оценка на ползите и рисковете

3. Списък на фигурите (препоръчително е да се приложи списък с фигурите с техните заглавия и номер на страницата)

4. Списък на таблиците

Приложение № 3
към чл. 12

Промени в данните, които водят до съществена промяна

1. Промени, свързани с протокола

1.1. Промяна в целта на проучването.

1.2. Промяна в дизайна и/или методологията на проучването или в предварителната информация, на която се основава научната му стойност.

1.3. Промени в следните документи по проучването:

1.3.1. информирано съгласие;

1.3.2. информация за участника;

1.3.3. информация за законния представител и/или лицето, което полага грижи за участника;

1.3.4. въпросници, писма за покана, писма до лекуващия лекар и други изследователи.

1.4. Промяна в процедурата за набиране на пациенти.

1.5. Промяна в показателите за ефективност.

1.6. Промяна в плана за вземане на биологични материали за изследване.

1.7. Добавяне или премахване на изследвания и/или тестове.

1.8. Промяна на възрастовите граници за участие.

1.9. Промяна във включващите и изключващите критерии.

1.10. Промяна в процедурите за проследяване на безопасността.

1.11. Промяна в продължителността на употреба на изпитвания продукт.

1.12. Промяна в начина на употреба на изпитвания продукт.

1.13. Промяна на лекарството за сравнение.

1.14. Промяна в статистическия план.

1.15. Всяка промяна, отнасяща се до безопасността и физическата и/или интелектуалната неприкосновеност на участниците или съотношението риск/полза за проучването.

1.16. Промяна в определението за край на проучването.

2. Промени в административната организация на проучването:

2.3. Промяна на спонсора и/или упълномощения му представител.

2.4. Промяна на одобрен изследователски център.

2.5. Определяне на нов главен изследовател или друг съществен член на изследователския екип.

2.6. Включване на нов изследователски център.

2.7. Определяне на нов главен изследовател в одобрен изследователски център.

2.8. Промяна в условията на застраховката или реда за обезщетяване на участниците в проучването.

2.9. Други значителни промени в протокола и/или съпътстващата заявлението първоначална документация.

3. Промени, касаещи качеството на изпитвания лекарствен продукт:

3.3. Промяна на името на изпитвания продукт от код на възложителя на международно непатентно наименование.

3.4. Промени в материалите за първично опаковане.

3.5. Смяна на вносителя за лекарствени продукти, произведени извън територията на ЕС.

3.6. Смяна на производителя на лекарственото вещество.

3.7. Промяна в производствения процес на лекарственото вещество.

3.8. Промяна в спецификацията на лекарственото вещество, когато включва разширяване на приемливите граници и/или отпадане на тестове.

3.9. Значителни промени в производствения процес на изпитвания продукт.

3.10. Промяна в спецификацията на изпитвания продукт, когато включва разширяване на приемливите граници и/или отпадане на тестове.

3.11. Промяна в спецификацията за помощни вещества, когато могат до повлияят свойствата на продукта.

3.12. Значителна промяна в производствения рецептурен състав.

3.13. Ограничаване на условията на съхранение.

3.14. Намаляване на срока на годност след отваряне или разтваряне.

3.15. Промяна в процедурите за тестване на активното вещество при добавяне на нов тест метод.

3.16. Промяна в процедурите за тестване на изпитвания продукт при добавяне на нов тест метод.

3.17. Промяна в процедурите за тестване на нефармакопейни помощни вещества при добавяне на нов тест метод.

4. Всички промени в неклиничните данни за изпитвания продукт, които могат да променят съотношението риск/полза

5. Всички промени в клиничните данни за изпитвания продукт, които могат да променят съотношението риск/полза

MEDICAL DEVICES ACT

In force from 12.06.2007

Prom. SG. 46/12 Jun 2007, amend. SG. 110/30 Dec 2008, amend. SG. 41/2 Jun 2009, amend. SG. 82/16 Oct 2009, amend. SG. 98/14 Dec 2010, amend. SG. 39/20 May 2011, amend. SG. 60/5 Aug 2011, amend. SG. 54/17 Jul 2012, suppl. SG. 84/2 Nov 2012, amend. SG. 14/20 Feb 2015, amend. and suppl. SG. 38/26 May 2015, ***amend. SG. 14/19 Feb 2016***

Chapter one.
GENERAL PROVISIONS

Section I.
General Provisions

Art. 1. (1) The present Act shall regulate:

1. the terms and procedures for putting on the market and/or putting into service of medical devices;

2. the obligations of manufacturers, their authorized representatives and those of importers of medical devices;

3. (amend. - SG 38/15, in force from 26.05.2015) the terms and procedures for designation and supervision of notified bodies;

4. the terms and procedures for conducting clinical investigations on medical devices;

5. (amend. – SG 54/12) the terms and procedures for trade in medical devices;

6. the surveillance of the medical devices market;

7. the notification and assessment system regarding incidents/potential incidents related to medical devices.

(2) (amend. - SG 38/15, in force from 26.05.2015) This Act aims at:

1. ensuring the putting on the market and/or putting into service medical devices which do not threaten life and health of patients, medical experts or third persons when the devices are used according to their purpose and are being stored, distributed, installed, implanted and maintained according to the instructions manufacturers;

2. ensuring the implementation of Commission Regulation (EU) № 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under the Council Directive 90/385/EEC on active implantable medical devices and the Council Directive 93/42/EEC on medical devices (OJ, L 253/8 of 25 September 2013), hereinafter referred to as "Implementing Regulation (EU) № 920/2013.

Art. 2. (1) Depending on the operation intended by the manufacturer, medical devices shall be categorised as follows:

1. in-vitro diagnostic medical devices;

2. active implantable medical devices;

3. medical devices other than the ones specified in items 1 and 2.

(2) Medical devices under para.1, item 1 are classified in List A, List B and self-testing devices, as well as in other groups determined in the ordinances as per Art.18, depending on the potential risk related to them.

(3) Depending on the potential risk related to them the medical devices under para.1, item 3 are

grouped into class I, IIa, IIb and III according to classification rules set out in the ordinances under Art.18.

(4) (amend. – SG 110/08, in force from 21.03.2010) In case the manufacturer and the notified authority determined pursuant to Chapter IV have different opinions regarding the implementation of the classification rules under para.3, the Bulgarian Drug Agency (BDA) shall take a decision. When it deems it appropriate and when the conditions under Art. 6a, item 1 or 2 are present, the BDA shall prepare a justified request to the European Commission for undertaking relevant measures.

(5) (amend. – SG 110/08, in force from 21.03.2010) In case this is explicitly required, the classification rules under para.3 to be brought in compliance with new technologies development and/or with information received according to Chapter VII, BDA shall work out a reasoned request for undertaking the necessary measures which is to be submitted to the European Commission.

Art. 3. The requirements for medical devices provided for in the present Act also apply to:

1. accessories to the devices;

2. devices including as an integral part a substance which, if used separately, may be considered to be a medicinal product within the meaning of the Medicinal Products in Human Medicine Act and which has an auxiliary effect on the organism with regards to the principal intended action of the device;

3. devices including as an integral part a substance obtained from human blood or plasma which, if used individually, may be considered a component of a medicinal product or a medicinal product under the Medicinal Products in Human Medicine Act and which has an auxiliary effect on the organism with regards to the principal intended action of the device;

4. devices with the use of which medicinal products are being applied;

Art. 4. (1) In case certain product comes within the purview of this Act and the ordinance as per Art.7 of the Technical Requirements to Products Act, regarding personal protection devices, introducing Directive EEC 89/686 of the Council, the relevant general safety requirements set out in the ordinance shall apply to the said product.

(2) (In force from 29.12.2009; amend. – SG 110/08, in force from 21.03.2010) In case the medical device comes also within the purview of the ordinance under Art. 7 of the Technical Requirements to Products Act, introducing Directive EU 2006/42 of the European Parliament and of the Council of 17 May 2007 regarding the machines and amending the Directive 95/16/EC and there is a risk of its application, the relevant essential safety requirements set out in it shall apply to it, provided that these requirements are more specific than the ones provided for in the ordinance as per Art.18.

(3) (new – SG, 84/2012, in force from 02.01.2013) Where a medical device under Art. 2, Para. 1, p. 1 and 3 falls in the application scope of Chapter Five “a” of the Act on Protection of the Dangerous Impact of Chemical Substances and Mixtures, to it shall apply also the requirements for restriction of the use of dangerous substances, determined by the ordinance under Art. 21e, Para. 1 of the same act.

(4) (new – SG, 84/2012, in force from 02.01.2013) The requirements of Para. 3 shall apply also to cable or spare parts for the repair for second use, of updating of the characteristics or for raising the capacity of this device.

Art. 5. (1) This Act shall not apply to:

1. (suppl. – SG 110/08) medicinal products under the Medicinal Products in Human Medicine Act. The assessment whether a particular product falls within the scope of application of this Act or in the scope of application of the Medicinal Products in Human Medicine Act shall be carried out on the grounds of the product main purpose of use;

2. medical devices which are an integral part of medicinal products and are intended for single use only in this form by the manufacturer;

3. cosmetic products under the Health Act;

4. (suppl. – SG 110/08) organs, tissues and cells of human origin intended for transplantation, as well as products containing or obtained from tissues and cells of human origin under the Transplantation of Organs, Tissues, and Cells Act, except for the medical devices under Art. 3, item 3;

5. organs, tissues and cells of animal origin intended for transplantation, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue;

6. blood, blood ingredients of human origin within the meaning of the Blood, as well as devices which incorporate at the time of placing on the market such blood products, plasma or cells, except for medical devices under Art.3, item 3;

7. medical devices under Art.2, para.1, item 1 which are not intended for placing on the market, which are used at the production site and, if used at sites in the immediate vicinity, the ownership on them is not transferred to another legal entity.

(2) In the cases referred to in para.1, item 2 the device must meet the requirements of the Medicinal Products in Human Medicine Act. The essential requirements provided for by this Act shall be applied only with regards to the particular features referring to the safe operation of the device.

Art. 6. While exercising its powers under this Act, BDA shall:

1. (amend. – SG 110/08) arrange registration under the terms and procedures of Chapter II;

2. (new - SG 38/15, in force from 26.05.2015) issue conformity assessment authorizations for medical devices under Chapter Four;

3. (prev. text of item 2 - SG 38/15, in force from 26.05.2015) issue authorizations for carrying out clinical investigations of medicinal products;

4. (amend. – SG 54/12; prev. text of item 3 - SG 38/15, in force from 26.05.2015) issue authorizations for wholesale trade in medical devices;

5. (prev. text of item 4 - SG 38/15, in force from 26.05.2015) supervise the medical devices that have been placed on the market and/or put into service;

6. (amend. – SG 54/12; prev. text of item 5 - SG 38/15, in force from 26.05.2015) exercise control over the storage, trade, clinical investigations and safety of medical devices;

7. (prev. text of item 6 - SG 38/15, in force from 26.05.2015) keep a system for registration and analysis of reports on incidents with medical devices and undertake the necessary measures;

8. (prev. text of item 7 - SG 38/15, in force from 26.05.2015) have its representatives in the Central Ethics Committee, established under the Medicinal Products in Human Medicine Act;

9. (prev. text of item 8 - SG 38/15, in force from 26.05.2015) provide information concerning medical devices that have been placed on the market and/or put into service to the European Database;

10. (prev. text of item 9 - SG 38/15, in force from 26.05.2015) take part in actions in the medical devices field related to the activity of international authorities, organizations and agreements to which the Republic of Bulgaria is a party, together with the regulatory and control bodies of other countries and the organizations carrying out activity in the sphere of medical devices regulation;

11. (amend. – SG 110/08; prev. text of item 10, suppl. - SG 38/15, in force from 26.05.2015) create and keep the registers under Art. 31, par. 2, Art. 58, par. 1, Art. 67, para 1 and Art. 81;

12. (prev. text of item 11 - SG 38/15, in force from 26.05.2015) carry out other activities specified in this Act.

Art. 6a (new – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency shall draw

up a justified request to the European Commission for undertaking necessary measures, whenever it considers, that:

1. the application of the classification rules of Art. 2, par. 3 requires taking a decision for classification of a particular medical device or category of devices of Art. 2, par. 1, item 3;

2. a particular medical device or a group of devices of Art. 2, par. 1, item 3, regardless the classification rules of Art. 2, par. 3 may be classified under a different class of devices;

3. the conformity of a particular medical device or of a group of devices of Art. 2, par. 1, item 2 or 3 must be assessed by applying only one single procedure provided in the ordinances of Art. 18;

4. taking a decision is necessary, whether a particular product or a group of products falls into the scope of application of this Act.

Art. 7. (1) For the purpose of registration and issue of registration certificates, issue of authorization and certificates according to this Act, as well as for entering amendments therein, shall be paid fees the amount of which is specified in a tariff, approved by the Council of Ministers.

(2) (amend. - SG 38/15, in force from 26.05.2015) The amounts of fees under para.1 and of fines and property sanctions enforced on natural and legal persons according to this Act shall be deposited as budget revenue of BDA.

Section II.
Placing on the market and/or putting into service of medical devices

Art. 8. (1) Medical devices shall be released on the market and/or put into service provided that they meet the requirements of this Act and the acts relating to its implementation.

(2) Medical devices, except for custom-made ones, shall be placed on the market and/or put into service if they bear the CE marking under Art.15 certifying that the compliance of the devices with the essential requirements has been assessed by means of the applicable conformity assessment procedures.

Art. 9. (1) The Executive Director of BDA shall issue an order for temporary suspension or prohibition of placing on the market and/or putting into service and for withdrawal from the market of medical devices with CE marking as per Art.15, as well as of custom-made devices, which can threaten the health and safety of patients, medical experts or third persons, when they are correctly installed, maintained and used.

(2) The Bulgarian Drug Agency shall notify immediately the European Commission of the order under para.1 and the measures taken, stating the reasons for the medical devices non-conformity with the requirements of this Act and the acts for its implementation, due to:

1. failure to meet the essential requirements referred to in the ordinances as per Art.18;

2. incorrect application of the standards referred to in Art.13, para.1;

3. shortcomings in standards under Art.13, para.1.

Art. 10. (1) The manufacturer is the person in charge of placing on the market and/or putting into service of medical devices.

(2) (amend. – SG 110/08) In case the manufacturer is not established on the territory of a Member State or a state from the European Economic Area, they shall authorize in writing their representative, hereafter referred to as "authorized representative". For a medical device or a device of

the same model, launched on the Community market, the manufacturer shall authorize only one person.

Art. 11. (1) (suppl. – SG, 84/2012, in force from 02.01.2013) Manufacturers of medical devices shall be obliged to design, develop, produce, package and label them according to the essential requirements set out in the ordinances as per Art.18 and this act and/or of Chapter Five "a" and of the ordinance under Art. 21e, Para. 1 of the Act on Protection of Dangerous Impact of Chemical Substances and Mixtures, and to ensure assessment of their conformity by means of applicable procedures.

(2) (amend. – SG 110/08) Conformity assessment under para.1 shall be carried out by the manufacturer.

(3) (new – SG 110/08, suppl. – SG, 84/2012, in force from 02.01.2013) The manufacturer may assign to his authorized representative to apply the conformity assessment procedures, laid down in the ordinances of Art. 18 of this act and/or Chapter Five "a" and of the ordinance under Art. 21e, Para. 1 of the Act on Protection of Dangerous Impact of Chemical Substances and Mixtures.

(4) (prev. par. 3, amend. – SG 110/08; amend. - SG 38/15, in force from 26.05.2015) In case the procedures provided for by the ordinances as per Art.18 require the interference of a notified authority under Art.63, para.4, the manufacturer or his/her authorized representative in the cases of par. 3 shall assign the carrying out of the procedures applicable to the device type to a notified authority of their choice within its competence.

(5) (suppl. – SG 110/08) In those cases where medical devices under Art. 2, par. 1, item 3 have been produced utilizing non-viable animal tissue or non-viable product derived from animal tissues, prior to their conformity assessment under para.1 the manufacturer shall carry out risk analysis and management, observing the requirements set out in the ordinances as per Art.18 Art. 18.

(6) (prev. par. 4, amend. – SG 110/08) The manufacturer or his/her authorized representative and the notified authority referred to in para.4 shall enter into an agreement concerning the terms and conditions of performing conformity assessment of medical devices.

Art. 12. (1) (suppl. – SG 41/09, in force from 02.06.2009, amend., - SG 98/10, in force from 01.01.2011; amend. - SG 38/15, in force from 26.05.2015) As an exception, to the benefit of public health, the Minister of Health or an official authorized by him/her, may authorize the putting into service of a medical device, which does not meet the requirements of Art. 8, upon reasoned request by the Regional Health Inspectorate, of the National Centre of Public Health and Amalyses or of a medical establishment and provided that the Executive Director of BDA has expressed a positive opinion.

(2) The terms and procedures for putting into service of medical devices under para.1 shall be determined by an ordinance by the Minister of Health.

Art. 13. (1) (suppl. - – SG, 84/2012, in force from 02.01.2013) Where medical devices have been designed and manufactured according to national standards introducing the harmonized European standards, they shall be presumed to meet the essential requirements determined by the ordinances under Art.18 of this act and/or Chapter Five "a" and of the ordinance under Art. 21e, Para. 1 of the Act on Protection of Dangerous Impact of Chemical Substances and Mixtures.

(2) (amend. – SG 110/08, in force from 21.03.2010) Where medical devices under Art.2, para.1, item 2 and 3 have been designed and manufactured in conformity with the official pharmacopoeia in the Republic of Bulgaria determined in Art.12 of the Medicinal Products in Human Medicine Act, they shall be presumed to meet the essential requirements set out in the ordinances as per Art.18.

(3) In case the medical devices referred to in Art.2, para.1, item 1 from List A, and where

necessary, from List B, have been designed and manufactured in compliance with general technical specifications, they shall be presumed to meet the essential requirements set out in the ordinances as per Art.18.

(4) In case a manufacturer is unable to observe the requirements under para.3, the latter shall approve technical decisions in order to achieve equivalent results.

(5) In case BDA considers that standards under para.1 do not entirely meet the essential requirements set out in the ordinances as per Art.18, it shall work out and harmonize an official state stand which is to be presented to the European Commission.

Art. 14. (1) (suppl. – SG, 84/2012, in force from 02.01.2013) Manufacturers of medical devices shall prepare technical documentation the contents of which is determined in the relevant ordinances as per Art.18 of this act and/or of the ordinance under Art. 21e, Para. 1 of the Act on Protection of Dangerous Impact of Chemical Substances and Mixtures.

(2) Manufacturers or their authorized representatives shall work out a declaration on the medical devices conformity following implementation of the applicable conformity assessment procedures.

(3) Manufacturers or their authorized representatives shall be obliged to keep available the technical documentation under para.1 and the conformity declaration under para.2 for at least 5 years from the date of the suspension of the medical device manufacture and, upon request, to present to the persons referred to in Art.86, para.2 for inspection.

Art. 15. (1) The CE marking with graphic image according to the Appendix that is affixed on the medical device prior to its placing on the market and/or putting into service must be easy to read and impossible to efface without leaving traces.

(2) The CE marking shall be placed on a visible spot on the device, in the instructions for use and on its sterile packing, if there is such. Where possible, it shall appear on the sales packaging.

(3) The CE marking shall be at least 5 mm high, unless otherwise provided for in the relevant ordinance as per Art.18. If the CE marking size is being decreased or increased, the graphic scale proportions shall be adhered to.

(4) (amend. – SG 110/08) The CE marking shall be accompanied by the identification number placed next to it of the notified body in the cases referred to in Art.11, para.4, where the procedures, contained in the ordinances of Art. 18 require its displaying.

(5) The CE marking and the identification number under para.4 shall not be placed on a device only if the size and form of the device do not allow it.

(6) It is prohibited to affix any other marks on the device, its packing and/or its instructions for which are likely to mislead users – medical experts or patients with regard to the marking under para 1, provided that the visibility and legibility of the CE marking is not thereby reduced.

(7) As regards to devices that are placed on the market in a sterile packing, the CE marking shall be affixed on both the sterile and user packing of the device.

(8) In the case of overall processing of the device which can affect its safe use, the CE marking shall be affixed following a repeated assessment of the device in accordance with the applicable procedures set out in the ordinances as per Art.18.

(9) (suppl. – SG, 84/2012, in force from 02.01.2013) Where a medical device falls within the application field of the ordinances as per Art.7 of the =Technical Requirements to Products Act and/or Chapter Five “a” and of the ordinance under Art. 21e, Para. 1 of the Act on Protection against the Harmful Impact Of Chemical Substances And Mixtures, subject to CE marking, the marking certifies the compliance of the device with the requirements of each of the ordinances, unless otherwise

stipulated therein.

(10) At exhibitions, trade fairs, demonstrations, promotions, scientific and technical conferences can be presented medical devices without affixed CE marking.

(11) In the cases referred to in para.10 manufacturers shall place a visible sign clearly indicating that such devices are not intended for placing on the market and/or putting into service.

Art. 16 (1) Manufacturers of medical devices shall be obliged to specify their name, headquarters and business address on the device, its packing and instructions for use. Instruction for use is not required for devices under Art.2, para.1, item 3 from class I and IIa which, in the manufacturer's opinion can be used safely without instructions for use.

(2) The name and address of the authorized representative and of the importer are additionally specified on the packing and in the instructions for use of devices which are imported from third countries on the territory of the European Union or on the territory of the European Economic Area.

(3) The instruction for use shall also be written in Bulgarian language.

Art. 17. Manufacturers or their authorized representatives shall be obliged to ensure that medical devices are installed in a safe manner on the territory of the Republic of Bulgaria, where necessary due to their specific character according to the instruction for use, and to guarantee their maintenance.

Art. 18. (amend. – SG 82/09, in force from 16.10.2009; amend. – SG, 14/15) Upon proposal by the Minister of Health and the Minister of Economy, the Council of Ministers shall determine by way of ordinance the following issues concerning medical devices referred to in Art.2. para.1:

1. essential requirements;
2. assessment conformity procedures regarding the essential requirements and the contents of the technical documentation;
3. rules for classification of medical devices referred to in Art.2, para.1, item 3;
4. the lists specifying the scope of groups of in-vitro diagnostic medical devices;
5. requirements for carrying out risk analysis and management with regards to medical devices as per Art.11, para.5.

Section III.
Putting on the market and/or putting into service of custom-made medical devices

Art. 19. (1) (amend. – SG 110/08, in force from 21.03.2010) Prior to placing on the market and/or putting into service of a custom-made medical device under Art.2, para.1, item 2 or 3, the manufacturer or their authorized representative shall prepare documentation containing:

1. the manufacturer's name and address;
2. device identification data;
3. a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient;
4. the name of the medical practitioner or of the dentist who made out the prescription for the device, where applicable, the name of the medical establishment concerned;
5. specific features of the device as specified in the relevant medical prescription

the characteristics of the medical device according to the specification:

6. a statement that the device in question conforms to the essential requirements.

(2) (amend. – SG 110/08, in force from 21.03.2010) In those cases where the device does not meet any of the applicable essential requirements, the non-conformity shall be provided with reasons in the statement under para.1, item 6.

(3) (suppl. – SG 110/08, in force from 21.03.2010) The documentation under para.1 shall be kept by the manufacturer or their authorized representative for a minimum of 5 year-period and in case of implantable medical devices of Art. 2, par. 1, item 3 and of devices of Art. 2, par. 1, item 2 – for a period of minimum 15 years.

(4) (new– SG 110/08, in force from 21.03.2010) The documentation of par. 1, attached to the devices of Art. 2, par. 1, item 2 and the devices of Art. 2, par. 1, item 3 of classes IIa, IIb and III shall be submitted to the particular patient, identified by name, acronym or digital code.

(5) (prev. par. 4, amend. – SG 110/08, in force from 21.03.2010) The manufacturer of custom-made medical devices under Art. 2, para.1, item 2 and 3, shall provide, upon request by BDA, a list of the devices which have been put into service on the territory of the Republic of Bulgaria.

Art. 20. (1) (amend. – SG 110/08) The manufacturer shall prepare documentation including a description of engineering, of production and of the effect of the device, including the expected effect, allowing assessment of product conformity with the requirements of this Act and of the provisions of Art. 18. The documentation shall indicate also the address of the production premises.

(2) Manufacturer shall be obliged to take the measures necessary to ensure by production process the conformity of the devices under Art.19 with the documentation as per para.1.

(3) (new – SG 110/08) The manufacturer shall provide the documentation of par. 1 for review upon request by the persons of Art. 86, par. 2.

Section IV.
Placing on the market of systems or sets of medical devices

Art. 21. (1) A natural or legal person who makes into sets medical devices referred to in Art. 2, para.1, item 3 with CE marking shall, prior to placing them on the market as a system or set, prepare a declaration stating that:

1. they have completed the system or set according to the purpose of the separate devices and the restrictions on their use determined by the manufacturers;

2. they have checked the conformity of the individual medical devices and have carried out the assembling procedures according to the instructions of manufacturers;

3. they have packed the system or set and they have provided the users with the necessary information including the respective manufacturers' instructions;

4. their activity is subject to internal control and surveillance procedures.

(2) In case any of the requirements of para.1 has not been met, the system or set shall be subject to conformity assessment regarding the essential requirements set out in the ordinances as per Art. 18.

Art. 22. (1) A natural or legal person who sterilizes systems or sets of medical devices as per Art. 21 and/or medical devices referred to in Art. 2, para.1, item 3 with CE marking, which manufacturers have intended for sterilization before use, must assess their conformity by way of procedures set out in the respective ordinance as per Art.18.

(2) (suppl. – SG 110/08) The implementation of the procedures set out in para.1 and the actions of the notified authority shall be restricted to meeting the sterility requirements up to the time of

damaging of the integrity of device package.

(3) The person referred to in para.1 shall draw up a declaration in accordance with the requirements set out in the respective ordinance, stating that sterilization has been carried out according to the manufacturers' instructions.

Art. 23. (amend. – SG 110/08) The persons under Art. 21, para.1 and Art. 22, para.1 shall keep the declarations for a period of 5 years and shall present them to the persons referred to in Art. 86, para.2, upon request, in order to be reviewed.

Art. 24. The systems or sets of medical devices under Art. 21, the sterilized systems or sets and the medical devices as per Art. 2, para.1, item 3 with CE marking, intended by the manufacturer for sterilization before use, shall be placed on the market without additional CE marking and shall be accompanied by instructions for use containing, where necessary, the information provided by the manufacturer of the individual devices in the system or set, the requirements for which are determined in the respective ordinance as per Art. 18.

Section V.
Performance evaluation of in-vitro diagnostic medical devices

Art. 25. (1) The conformity assessment of in-vitro diagnostic medical devices regarding their specific purpose under conditions of use specified by the manufacturer shall be carried out by way of performance evaluation on the grounds of:

1. collective data from scientific literature relating to the purpose of the device, and a critical analysis of this data, and/or
2. the results from performance evaluation trials or other appropriate tests.

(2) Manufacturers or their authorized representatives, prior to providing in-vitro diagnostic medical devices for performance evaluation to an accredited laboratory, shall prepare documentation containing the following:

1. data allowing identification of the device in question;
2. an evaluation plan stating in particular the purpose, scientific, technical or medical grounds, scope of the evaluation and number of devices concerned
3. a list of accredited laboratories taking part in the evaluation study;
4. the starting date and scheduled duration for the evaluations and, in the case of devices for self-testing, the location and number of lay persons involved;
5. in the case of self-testing devices – location and number of persons who have no medical qualification and will take part in the study;
6. a statement that the device in question conforms to the applicable essential requirements apart from the aspects covered by the evaluation and apart from those specifically itemised in the statement, and that every precaution has been taken to protect the health and safety of the patients, medical experts and other persons.

Art. 26. (1) Manufacturers shall undertake to keep technical documentation as per Art.14, para.1 and shall provide it to the persons referred to in Art. 86, para.2, upon their request, for inspection.

(2) Manufacturers shall be obliged to take all measures necessary for the manufacturing process to ensure the conformity of in-vitro diagnostic medical devices for performance evaluation with the

documentation mentioned in para.1.

Chapter two.
REGISTRATION OF PERSONS LAUNCHING MEDICAL DEVICES ON THE MARKET
(TITLE AMEND. – SG 110/08)

Art. 27. (1) (amend. – SG 110/08, in force from 21.03.2010) Where manufacturers of medical devices as per Art. 2, para 1, item 3 from class I, manufacturers of custom-made devices under Art. 2, para 1, items 2 and 3, as well as natural or legal persons referred to in Art. 21, para 1 and Art. 22, para 1 are registered under the Commerce Act they shall submit an application for registration to the Executive Director of BDA within14 days from placing the device on the market and/or putting into service on the territory of the Republic of Bulgaria.

(2) The following documents shall be appended to the registration form under para 1:

1. (amend. - SG 60/11, in force from 05.08.2011) a unified identity code of the company;

2. name and description of the device;

3. document certifying paid fee to the amount fixed in the tariff as per Art. 7, para 1.

(3) (amend. – SG 110/08, in force from 21.03.2010) The persons referred to in para 1 are obliged to notify the Executive Director of BDA of any change in their headquarters address within 14 days. In case of change in the information under para 2, item 2, the bodies under para 1 shall submit an application as per para 1 to the Executive Director of BDA, with documents concerning the change attached to it and a document certifying paid fee to the amount fixed in the tariff as per Art. 7, para 1.

Art. 28. (1) Where a manufacturer of devices referred to in Art. 2, para 1, item 1 places on the market and/or puts into service the said devices on the territory of the Republic of Bulgaria and is registered under the Commerce Act, he/she shall submit an application for registration to the Executive Director of BDA.

(2) The following documents shall be attached to the registration form under para 1:

1. (amend. - SG 60/11, in force from 05.08.2011) a unified identity code of the company;

2. information relating to the reagents, reagent products and calibration and control materials in terms of common technological and/or analytical characteristics;

3. in case of devices from list A, list B and self-testing devices - name, type and model of the device, analytical and, if necessary, diagnostic features according to the essential requirements indicated in regulations under Art.18, results of in-vitro medical device performance evaluation.

4. instruction for use in Bulgarian language;

5. document for paid fee in amount fixed by the tariff as per Art. 7, para 1.

(3) (amend. – SG 110/08) Manufacturers who place on the market and/or put into service a new in-vitro diagnostic medical device within the territory of the Republic of Bulgaria, in case he/they are registered under the Commerce Act, shall submit to BDA the documents set out in para 2 as well as indication that the device is new.

(4) (amend. – SG 110/08) An in-vitro diagnostic medical device is new if on the market of a Member State or a state from the European Economic Area during the last three years:

1. there has been no such device continuously available for the relevant analyte or other parameter, or

2. the analytical technology used in connection with a given analyte or other parameter has not been available.

(5) (revoked – SG 110/08, in force from 21.03.2010).

(6) (amend. – SG 110/08, in force from 21.03.2010) The application form for registration under

paras 1 and 3 shall be submitted within 14 days from the date of placing on the market and/or putting into service of devices referred to in Art. 2, para 1, item 1.

(7) (amend. – SG 110/08, in force from 21.03.2010) The persons referred to in paras 1 and 3 are obliged to notify within 14 days the Executive Director of BDA in case of:

1. change in the headquarters address;
2. significant changes in the information as per para 2, items 2 and 3;
3. (revoked – SG 110/08, in force from 21.03.2010);
4. withdrawal of the device from the market.

Art. 29. (amend. – SG 110/08, in force from 21.03.2010) (1) In cases of Art. 10, par. 2 where the authorized representative is registered under the Commerce Act, shall submit an application form to BDA with the attached documentation for the devices under Art. 27, par. 1 and/or under Art. 28, par. 1 or 3.

(2) The authorized representative under Art. 1 shall notify BDA about any change of his/her headquarters address.

Art. 30. (amend. – SG 110/08, in force from 21.03.2010) For all devices under Art. 2, par. 1, item 2 and under Art. 2, par. 1, item 3 of classes IIa, IIb or III, put into service in the territory of the Republic of Bulgaria the BDA may request data, identifying the product, label and operation instructions.

Art. 30a. (new. – SG 110/08; amend. - SG 39/11, in force from 01.01.2012) (1) The Executive Agency for Medicines shall maintain on its internet site a list of the medical devices that may be paid with funds from the budget of the National Health Insurance Fund, of the republican budget, through the budget of the Ministry of Labour and Social Policy, from the budget of the medical establishments referred to in Art. 5 of the Medical Establishments Act, as well as by funds of the medical establishments with state and/or municipal share under Art. 9 and 10 of theMedical Establishments Act.

(2) The list referred to in Para 1 shall contain:

1. general identification data and characteristics of the medical establishment;
2. certification and registration status of the medical device;
3. trade information, including retail price of the medical device, as well as about the manufacturer/authorised representative or the trader of the medical device;
4. value as referred to in Art. 30b, Para 1.

(3) The conditions and order for entry into the list referred to in Para 1 and for its maintenance shall be determined in an ordinance of the Council of Ministers adopted upon proposal of the Minister of the Health and the Minister of Labour and Social Policy.

(4) The medical devices outside the list referred to in Para 1 shall not be paid from the funds referred to in Para 1.

Art. 30b. (new - SG 39/11, in force from 01.01.2012) (1) Every year the state shall determine the value up to which shall be paid the medical devices referred to in the list under Art. 30a, Para 1.

(2) The conditions and order for determining the value of the medical devices under Para 1 shall be determined in the ordinance referred to in Art. 30a, Para 3.

Art. 31. (1) (revoked – SG 110/08, in force from 21.03.2010).

(2) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency shall maintain a register containing:

1. number and registration date;

2. name, type and class of the medical device;

3. name and business address of the applicant under Art. 27, par. 1, Art. 28, par. 1 and 3 and Art. 29, par. 1;

4. date of deletion of the medical device from the register and the reason for this;

5. remarks on documented circumstances.

(3) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency presents registration data for the devices under Art. 27, par. 1, Art. 28, par. 1 and 3 and under Art. 29, par. 1 upon request by the regulatory authorities of other Member States or regulating authorities or the states of the European Economic Area and by the European Commission.

Chapter three.
CLINICAL INVESTIGATION OF MEDICAL DEVICES

Section I.
General Provisions

Art. 32. (amend. – SG 110/08, in force from 21.03.2010) Clinical testing with medical devices under Art. 2, par. 1, item 2 and 3 shall be carried out in order to:

1. confirm that under normal conditions of use the device performs one or more of its functions, determined by the manufacturer;

2. identify adverse side effects under normal conditions of use of the device;

3. assess to what extend the indentified adverse side effects are within the acceptable risk assessed in comparison to the benefit of the intended purpose of use of the device.

Art. 32a (new – SG 110/08, in force from 21.03.2010) The assessment of clinical testing data shall be carried out under the conditions, set out in the ordinance under Art. 48, par. 2.

Art. 33. A clinical investigation shall be carried out in a medical establishment in accordance with the Medical Establishments Act.

Art. 34. (1) Clinical investigations of devices referred to in Art. 32 shall be carried out according to the main principles of the protection of human rights, safety and human dignity of the clinical trial subjects according to the Declaration of Helsinki for the ethical principles of clinical trials with human subjects.

(2) The rights, safety, and health of the subjects in the clinical test shall always prevail over those the interests of science and society.

the interests of the patient always prevail over those of science and society

(3) Clinical investigations shall be initiated and carried out provided that the estimated benefits for the subject and the society justify the risks.

(4) Clinical trials shall be designed to minimise discomfort, pain, fear and any other foreseeable risks in relation to the disease and both the risk threshold and the degree of distress have to be defined in

advance and constantly monitored throughout the investigation.

(5) No financial or other incentives shall be given to clinical trial subjects except compensations (travel and daily costs, etc.).

Art. 35. (revoked – SG 110/08, in force from 21.03.2010)

Art. 36. (1) The whole information from a clinical investigation shall be recorded, processed and kept in such a manner as to ensure its precise reporting, interpretation, and confirmation. Personal data of the clinical trial subjects shall be preserved pursuant to the Protection of Personal Data Act.

(2) The documentation under para 1 shall be stored by the principal or coordinating investigator for a period of 20 years from the end date of the clinical trial and shall be presented to the relevant Ethics Committee(s) and to BDA upon request.

Art. 37. (1) A clinical trial of the devices referred to in Art. 32 shall only be admitted on a person who:

1. has been provided in advance with written information about the nature, importance, consequences and potential risks of the investigation and has been informed in a prior interview by a doctor or dentist – member of the investigation team, about the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted;

2. has been informed of his/her right to withdraw from the investigation at any time without this having any negative consequences for him/her;

3. has personally expressed written informed consent to take part in the investigation.

(2) If the individual is unable to write, oral consent in the presence of at least one witness may be given. The witness shall certify in writing that the person has expressed informed consent to take part in the clinical trial in person.

(3) The informed consent pursuant to para 1, item 3, and para 2 can only be given by a capable person who understands the nature, significance, scope, consequences, and potential risks of the clinical trial. Informed consent to participate in a clinical investigation can be withdrawn at any time without negative consequences for the person.

(4) Clinical investigation of partially capable majors shall be carried out after they and their legal representative have expressed written informed consent. A partially capable person shall be provided with information under para 1, item 1 according to his/her capacity of understanding. The explicit wish of the person to be withdrawn at any time is considered by the investigator or, where appropriate, by the principal investigator.

(5) Informed consent of an incapable major person shall be given by his/her legal representative.

(6) In cases referred to in Art. 162, para 3 of the Health Act, informed consent shall be given by a person assigned by the court.

Art. 38. (1) A clinical trial on a minor person shall be carried out after obtaining written informed consent by his/her legal representatives - both subject's parents or the guardian pursuant to Art. 37, para 1, item 1 and 2 and para 3. Where one of the parents is unknown, deceased, or deprived of parental rights or such rights have not been delegated in case of divorce, written informed consent shall be given by the parent who exercises parental rights.

(2) A clinical trial on an underage person shall be conducted after obtaining written informed

consent by the subject and his/her legal representatives - both subject's parents or the guardian according to Art. 37, para 1, item 1 and 2 and para 3. Where one of the parents is unknown, deceased, or deprived of parental rights or such rights have not been delegated in case of divorce, written informed consent shall be expressed by the parent who is exercising parental rights.

(3) Minors or underage persons shall be provided with information about the nature, significance, consequences and eventual risks and benefits of the clinical trial in a manner understandable for that person by a paediatrician or children's psychologist.

(4) The consent of the parents or the guardian must represent the minor's presumed will and may be revoked at any time, without detriment to the minor and/or to them.

(5) The consent of an underage person, his/her parents and guardian can be withdrawn at any time without negative consequences for them.

Art. 39. Where it is not possible to take urgent informed consent by the parent(s) or respectively by the guardian and the direct purpose to save the life of a minor, underage person, incapable or partially capable major, the decision to take part in a clinical investigation of any of the said persons shall be taken by at least two doctors, independent from the assignor and from the principal and coordinating investigator.

Art. 40. (1) Clinical trials on pregnant women can be conducted according to the requirements as per Art. 37 only in those cases where there are no other alternative diagnostics or treatment methods and if it does not threaten the pregnant woman's life and health and the fetus vitality.

(2) Decision for involvement in a clinical investigation in the cases referred to in para 1 shall be taken by a committee of physicians, independent from the assignor and the principal and coordinating investigator.

Art. 41. (1) Subjects shall be provided with further information throughout the clinical investigation by a person independent from the assignor upon request.

(2) The written information provided to the subject during the clinical trial contains contact data of the independent person under para 1.

Art. 42. (1) In those cases where an assignor who is not established on the territory of EU or on the territory of a state from the European Economic Area carries out one-site or multi-centre clinical trial on the territory of the Republic of Bulgaria, the latter shall authorize his/her representative established on the Republic of Bulgaria.

(2) (amend. – SG 110/08, in force from 21.03.2010) In those cases where an assignor who is not established on the territory of the Republic of Bulgaria and on the territory of another Member State(s) and/or on the territory of a state/states from the European Economic Area and/or on the territory of a third country, he/she shall authorize a representative established on the territory of a state from EU or European Economic Area.

(3) The authorized representative under para 1 and para 2 bears the responsibility for conducting clinical trials on the territory of the Republic of Bulgaria according to the legislation in force.

(4) (revoked – SG 110/08, in force from 21.03.2010).

(5) (revoked – SG 110/08, in force from 21.03.2010).

(6) (revoked – SG 110/08, in force from 21.03.2010).

(7) (revoked – SG 110/08, in force from 21.03.2010).

Art. 43. (amend. – SG 110/08, in force from 21.03.2010) (1) The clinical test shall be carried out under the management of a researcher.

(2) The control over the clinical test shall be carried out by the assignor or by his/her authorized representative under Art. 42, par. 1 or 2 or by an appointed by him/her person-supervisor.

(3) During the clinical test a doctor, respectively a doctor in dental medicine shall follow up the health condition of the participant and, if relevant, he/she shall undertake appropriate medical measures.

(4) The requirements to the assignor, the general or the coordinating researcher and to the supervisor and their obligations during the clinical testing shall be determined by the ordinance of Art. 48, par. 2.

Art. 44. (1) The assignor and principal or coordinating investigator shall conclude insurance agreements, covering their liability for material and non-material damages to the trial subjects.

(2) The assignor shall be responsible in case of damage to health or death caused during or in the occasion of the conduct of the clinical investigation where the said trial has been carried out in compliance with the requirements and procedures of the plan as approved by the ethics committee.

(3) The principal or coordinating investigator shall be responsible in case of health damage or death caused during or in the occasion of clinical trial where the said trial has not been carried out in compliance with the requirements and procedures of the plan as approved by the ethics committee.

Section II.
Clinical Trial Authorizations

Art. 45. (1) Clinical trials of medical devices referred to in Art. 2, para 1, item 3 from class III, of implantable medical devices and invasive medical devices for long-term use as per Art. 2, para 1, item 3 from class IIa or IIb and of devices under Art. 2, para 1, item 2, which take place on the territory of the Republic of Bulgaria can commence upon receiving a positive stand of the Multi-centre Research Ethics Committee or the ethics committee at the respective medical establishment, and an authorization by the Executive Director of the Bulgarian Drug Agency (BDA).

(2) Clinical trials of medical devices other than the ones referred to in para 1 which take place on the territory of the Republic of Bulgaria can commence upon notification to the Executive Director of BDA, if the relevant ethics committee under para 1 has given a favourable opinion.

(3) The provisions of para 1 and para 2 shall also apply to medical devices with applied "CE" marking in case the clinical trials are conducted with the purpose of change in their intended purpose.

Art. 46. The assignor or the principal/coordinating investigator can submit an application form for notification or authorization for conducting a clinical trial to the relevant ethics committee and to BDA simultaneously or consequently.

Art. 47. (1) In the case of multi-centre clinical trial on the territory of the Republic of Bulgaria persons as per Art. 46 shall submit an application form to the Multi-centre Research Ethics Committee.

(2) In the case of one-site clinical trial on the territory of the Republic of Bulgaria persons referred to in Art. 46 shall submit an application form to the Multi-centre Research Ethics Committee or

to the ethics committee at the respective medical establishment.

Art. 48. (1) In order to obtain a stand by the relevant ethics committee, the principal, respectively the coordinating investigator or the assigner, shall provide:

1. administrative documentation;
2. information about the subject;
3. documents related to the study plan;
4. documentation on the medical device being investigated;
5. documents related to the technical specifications of the medical establishment and qualifications of the personnel;
6. information about the financing source and trial administrative organization.

(2) The contents of documentation under para 1 is determined in an ordinance of the Minister of Health.

(3) Where the ethics committee establishes that documentation under para 1 is incomplete it shall notify the applicant within 14 days and shall fix a deadline for completing the documentation.

(4) Within 30 days after submission of the valid documentation the ethics committee passes a stand which shall be presented to the applicant and BDA.

Art. 49. (1) If the opinion of the ethics committee as per Art. 48 is negative, the applicant can appeal before the Central Ethics Committee established under the Medicinal Products in Human Medicine Act within 14 days from the date of notification.

(2) The Central Ethics Committee passes a stand within 14 days from the receipt date of the written request by the applicant.

(3) The decision of the Central Ethics Committee shall be final and binding on the respective ethics committee.

Art. 50. (1) (amend. – SG 110/08, in force from 21.03.2010) In order to get an authorization to conduct clinical test as per Art. 45, para 1, the applicant shall submit an application form to BDA with the following documentation attached:

1. identification data of the medical device on paper and electronic medium;
2. plan of clinical test;
3. researcher's brochure;
4. documentation for obtaining of an informed consent;
5. manufacturer's declaration whether the respective device may be determined as a device under Art. 3, item 2, 3 or 4;
6. manufacturer's declaration whether for the production of the device under Art. 2, par. 1, item 3 non-viable animal tissue or non-viable products, produced from animal tissues, have been used;
7. the names of the researchers, of the general researcher or researchers or of the coordinating researcher, as well as the name and the address of the medical establishments, where the clinical testing is being carried out;
8. starting, closing date and schedule of the implemented tests;
9. positive reference of the ethics commission, where the applicant has submitted subsequent applications under Art. 46;
10. a declaration, that the medical device conforms with the applicable essential requirements, except those, which are subject to clinical testing, and that all preventive measures, required for protection of the health and safety of the participants in the testing and of the research team have been

provided;

11. an insurance contract, covering the researcher's and the applicant's responsibility for caused proprietary and non-proprietary damages to the participants in the testing during or with reference to the implementation of the clinical testing;

12. a draft contract between the applicant and the medical establishment;

13. a document certifying paid fee to the amount determined in the tariff as per Art.7, para 1;

(2) (revoked – SG 110/08, in force from 21.03.2010).

(3) (amend. – SG 110/08, in force from 21.03.2010) In case of application forms as per Art. 46 submitted simultaneously, the applicant can present his/her opinion under para 1, item 9 after its obtaining, but not later than the term fixed under Art. 51, para 1.

(4) (amend. – SG 110/08, in force from 21.03.2010) The applicant shall declare that the information, provided in the documents submitted to BDA and to the ethics commission is identical.

(5) (new – SG 110/08, in force from 21.03.2010) The content of the documentation of par. 1 shall be determined by the ordinance of Art. 48, par. 2.

Art. 51. (1) The Bulgarian Drug Agency assesses the provided documents as per Art. 50 within 60-days from the date of their submission.

(2) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency may request additional information about the documents referred to in Art. 50, para 1.

(3) In the cases referred to in para 2, the 60-day term shall stop running until the submission of the requested documentation.

(4) Within the period under para 1, the Executive Director of BDA shall notify in writing the applicant that:

1. they issue an authorization to conduct the clinical trial or,

2. the trial may not be carried out, stating the reasons for refusal.

(5) In the cases referred to in para 4, item 2, within 30 days from the date of notification, the applicant can submit to BDA an application amended in accordance with the reasons stated for refusal to conduct the clinical trial.

(6) Within 30 days from the date of submission of the amended application under para 5, BDA shall inform the applicant in writing that:

1. they approve the conduct of the clinical trial, or

2. the trial cannot be carried out, stating the reasons for refusal.

(7) A copy of the clinical trial authorization shall be sent to the medical establishment pointed out in the application under Art. 50, para 1.

(8) In case BDA has not pronounced in the term fixed as per para 1, the applicant can start the investigation immediately.

Art. 52. (1) The Executive director of BDA shall pass a well-grounded refusal to conduct a clinical trial on the territory of the Republic of Bulgaria in those cases where:

1. there has not been provided enough evidence for the anticipated scientific and medical benefits from the use of the medical device in question;

2. there has not been provided enough for the safety of the trial subjects and/or the investigation team;

3. the provided information regarding clinical trial safety assessment is insufficient;

4. the operation of the device does not comply with its intended use defined by the manufacturer.

(2) Refusals under para 1 shall be subject to appeal under the terms of the Administrative

Procedure Code.

(3) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency shall notify the regulatory authorities of the other member States, the regulatory authorities of the states of the European Economic Area and the European Commission of the refusal under para 1 and presents its reasons therefore.

Art. 53. (1) Applicant can make amendments in the investigation plan, other than essential ones, at any time.

(2) In cases referred to in para 1 the applicant shall keep the documentation relating to the amendments and shall provide it to the BDA and the ethics committee upon request.

Art. 54. (1) The assignor can implement planned essential amendments in the clinical trial plan.

(2) In the cases referred to in para 1, the applicant shall submit an application form along with the documents regarding the amendments, to the respective ethics committee and to BDA.

(3) The ethics committee passes a stand within 15 days from receiving the application under para 2 and presents it to the assignor and BDA.

(4) Within 15 days from the date of receiving the stand by the respective ethics committee, the Executive Director of BDA shall:

1. issue an amendment to the clinical trial authorization, approving the change in the trial plan, or

2. pass a well-grounded refusal for the substantial amendment referred to in para 1.

(5) The refusal under para 4, item 2 shall not be subject to appeal.

(6) If within the term under para 4 the applicant does not receive a refusal by BDA, he/she can carry out the clinical investigation according to the amended plan.

(7) (new – SG 110/08, in force from 21.03.2010) In the cases of par. 4, item 2 in case of multi-center testing the BDA shall notify the regulatory authorities of the affected member States or the regulatory authorities of the states of the European Economic Area of the refusal and presents its reasons therefore.

Art. 55. (1) Upon occurrence of any new event that is likely to affect the safety of the clinical trial subjects during its conduct, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against any immediate hazard.

(2) (amend. – SG 110/08) In the cases referred to in para 1, the assignor can:

1. make amendments in the clinical testing plan;

2. terminate the clinical testing prior to the scheduled in the clinical testing plan term.

(3) (amend. – SG 110/08) The assignor shall inform immediately the respective ethics committee and BDA:

1. of the undertaken measures, the reasons for them and the amendments made in the plan;

2. of the termination of the clinical testing prior to the scheduled in the clinical testing plan term.

(4) (new – SG 110/08) In the cases under Art. 3, item 1 the BDA shall notify the regulating bodies of the affected member States or the regulatory authorities of the states of the European Economic Area, participating in the testing, of the undertaken measures and of the amendments of the plan and shall present the justifications thereof.

(5) (new – SG 110/08) In the cases under Art. 3, item 2 the BDA shall notify the regulating bodies of the other member States, the regulatory authorities of the states of the European Economic

Area and the European Commission of the premature termination of the clinical testing and shall present the justifications thereof.

Art. 56. (1) (amend. – SG 110/08, in force from 21.03.2010) The assignor of the clinical testing is obliged to present to BDA upon request documentation containing:

general description of the device and of its purpose of use;

2. design drawings, production methods, including the ones related to sterilization, diagrams of components and details, ways of connection, etc.;

3. description and explanations of the drawings and diagrams and the operation of the medical device;

4. results from the risk analysis and a list of the applied fully or partially standards as per Art. 13, para 1 and a description of the adopted technical decisions for ensuring essential requirements conformity, where these standards have not been applied;

5. results of tests, carried out by a regulatory body of a Member State or by the European Medicines Agency for assessment of the quality and safety of the substance in the meaning of Art. 3, item 2, 3 or 4, as well as for assessment of its benefit in terms of device purpose of use;

6. the undertaken measures for reduction of the risk of infections, included in the risk management system in case of a device as per Art. 2, par. 1, item 3, for the manufacturing of which non-viable animal tissue or non-viable products, produced from animal tissues have been used;

7. the results of the engineering calculations and the accomplished inspections and technical tests.

(2) (amend. – SG 110/08, in force from 21.03.2010) The assignor of the clinical test is obliged to keep the documentation of par. 1 for a period of 15 years after the accomplishment of the clinical test – for the devices under Art. 2, para 1, item 2, and for implantable devices under Art. 2, para 1, item 3, and 5 years for the devices of Art. 2, par. 1, item 1.

(3) (amend. – SG 110/08, in force from 21.03.2010) The manufacturer is obliged to ensure a production process whereby the medical devices intended for clinical trials are produced in accordance with the documentation of par. 1.

Art. 57. (1) Within 90 days from completion of the clinical trial, the assignor presents to BDA and the respective ethics committee a final report containing a description of methodology and organization, critical assessment and statistical analysis of received data.

(2) The report under para 1 shall be signed by the assignor and by all investigators. If one of the investigators refuses to sign it, he/she shall enclose his/her reasons in writing.

(3) The report under para 1 shall summarize data received from all medical institutions and from all subjects in the trial.

(4) Personal data of the trial subjects which are included in the report under para 1 shall be coded.

Art. 58. (1) Bulgarian Drug Agency keeps a register of the issued and withdrawn clinical trial authorizations.

(2) Bulgarian Drug Agency shall organize and establish a system for registration, analysis and summary of all incidents related to medical devices that have occurred in the course of clinical trials.

(3) The medical devices pharmacovigilance procedure in the course of the clinical trial is provided in the as per under Art. 48, para 2.

Art. 59. (1) The Executive Director of BDA can temporary suspend the trial being carried out or terminate it by an order, provided that:

1. the trial is conducted under conditions other than the ones stated in the authorization;

2. there is information raising doubts about violating the scientific validity of the trial;

3. there is a risk for the safety of the subjects.

(2) Prior to undertaking any actions under para 1, BDA shall notify of their intentions:

1. the assignor and coordinating investigator, responsible for carrying out the trial at all sites, or,

2. the assignor and principal investigator, who is in charge of the relevant medical institution where the trial shall be terminated.

(3) Within 7 days after notification under para 2 the assignor and the principal and coordinating investigator can present written explanations to BDA.

(4) Para 2 shall not apply if there is imminent risk for the health and safety of the trial subjects.

(5) The order under para 1 can be subject to appeal under the terms of the Administrative Procedure Code, provided that the appeal does not suspend its enforcement.

(6) The principal or coordinating investigator notifies the clinical trial subjects of the order under para 1.

Art. 60. (amend. – SG 110/08) (1) In case of termination of clinical testing the Executive Director of BDA shall notify immediately the regulatory authorities of the Member States of the regulatory bodies of the states of the European Economic Area and the European Commission of the order referred to in Art. 59, par. 1 and shall present justifications thereof.

(2) In case of temporary suspension of the clinical testing the Executive Director of BDA shall notify immediately the regulatory authorities of the affected Member States or of the states of the European Economic Area, participating in the testing, of the ordinance referred to in Art. 59, par. 1 and shall present justifications thereof.

Chapter four.
NOTIFIED BODIES

Art. 61. (amend. - SG 38/15, in force from 26.05.2015)

(1) A conformity assessment authorization for medical devices, including clinical data assessment, shall be granted by the Executive Director of BDA to a natural or legal person, registered under the Commerce Act.

(2) The Bulgarian Drug Agency shall be a designating authority for the purposes of Art. 1 letter "e" of Implementing Regulation (EU) № 920/2013.

(3) A person applying for conformity assessment authorization of medical devices shall submit to BDA an application form on electronic media in accordance with Annex II of Implementing Regulation (EU) № 920/2013, stating the products and procedures applied for, areas of competence and the subdivisions of these areas - using the codes of the European Commission information system NANDO (New Approach Notified and Designated Organisations) and the annexes to the application referred to in Annex II of Implementing Regulation (EU) № 920/2013.

(4) The applicant shall pay a fee for conformity assessment authorization of medical devices in the amount specified in the tariff under Art. 7, para. 1.

Art. 62. (amend. - SG 38/15, in force from 26.05.2015) (1) The evaluation of a person applying for conformity assessment authorization of medical devices shall be carried out by an expert commission assigned by an order of the Executive Director of BDA. If necessary, in the commission may also be involved external experts who have knowledge and practical experience in the relevant medical devices.

(2) Where a person applying for conformity assessment authorization for medical devices has stated medical devices under Art. 2 para. 1, item 1 in the application under Art. 61, para. 3, BDA shall perform assessment pursuant to Art. 62a.

(3) Where a person applying for conformity assessment authorization for medical devices has stated medical devices under Art. 2 para. 1, item 2 or 3 in the application under Art. 61, para. 3, BDA shall perform the assessment pursuant to Art. 62a of this Act and Implementing Regulation (EU) № 920/2013.

(4) The Bulgarian Drug Agency shall apply the assessment criteria under para 2 pr 3 for the respective person according to Annex I of Implementing Regulation (EU) № 920/2013.

Art. 62a. (new – SG 38/15, in force from 26.05.2015) (1) The submitted documentation shall reviewed by the expert commission under Art. 62, para 1, or, where applicable, by a committee of representatives of the governing bodies of another two Member States and a representative of the European Commission.

(2) Where any omissions or inconsistencies with the requirements of documentation are established, the Executive Director of BDA shall notify the applicant in writing and set a two-month deadline for their removal. The term under Art. 63 para. 1 or 2 shall be suspended until the said omissions or inconsistencies are removed.

(3) Where the applicant fails to remove the omissions or inconsistencies within the time limit set under para 2, the proceedings shall be terminated.

(4) Within 75 days from the date of submission of valid documentation under Art. 61, para. 3 the Commission, respectively the committees under para 1, shall perform on-site inspection to establish the competence of the applicant and the ability to meet the stated conformity assessment procedures, including on-site inspection of the subcontractor. A fee fixed by the tariff under Art. 7, para. 1 shall be charged for each on-site inspection carried out.

(5) Where during the inspection are found any inconsistencies between the submitted documentation and the conformity assessment requirements, defined in the ordinances under Art. 18, the Executive Director of BDA shall notify the applicant in writing and shall set a two-months term for removal thereof. The term under Art. 63 para. 1 or 2 shall be suspended until the said inconsistencies are removed.

(6) Where the applicant does not remove the inconsistencies in the time limit specified under para 5, the Executive Director of BDA shall refuse to grant authorization by a reasoned order.

(7) Within 45 days after the on-site inspection the Commission or respectively the committees shall prepare a final assessment report, which shall be announced in the database of NANDO information system.

Art. 63. (amend. - SG 38/15, in force from 26.05.2015) (1) In the cases referred to in Art. 62, para 2 and 4, based on the report under Art. 62a, para 7, the Executive Director of BDA shall notify the applicant that the latter is authorized for notification or shall issue a reasoned order for refusal thereof within 4-months term from submission of the documentation under Art. 61, para 3.

(2) In the cases referred to in Art. 62, para 3, based on the report under Art. 62a, para 7, the Executive Director of BDA shall notify the applicant that the latter is authorized for notification or shall issue a reasoned order for refusal thereof within 6-months term from submission of the documentation under Art. 61, para 3.

(3) Within 3 days from the notification under para 1 or para 2 the Executive Director of BDA announce the authorized through the NANDO system.

(4) The identification number of the approved and notified to the European Commission

conformity assessment authority, hereinafter referred to as "Notified Body", shall be determined by the European Commission.

(5) The Executive Director of BDA shall issue a conformity assessment authorization to the Notified Body under para 4.

(6) The authorization under para 5 shall have a maximum validity term of 5 years. Renewal of the said authorization shall be carried out pursuant to Art. 62, para 2 or para 3.

Art. 64. (amend. - SG 38/15, in force from 26.05.2015) (1) When the person applying for conformity assessment authorization produces a certificate of accreditation according to the requirements specified in the ordinance under Art. 18, it shall be assumed that the said person has a functioning quality system, complies with the criteria of independence, impartiality and confidentiality and possesses the competence required.

(2) In the cases referred to in para 1 the person shall not produce other documents certifying their conformity with the criteria under para 1.

Art. 65. (amend. - SG 38/15, in force from 26.05.2015) Conformity assessment procedures stated in the Ordinance under Art. 18, may also be performed by Notified bodies from other Member States.

Art. 66. (amend. - SG 38/15, in force from 26.05.2015) The authorization to conduct conformity assessment shall contain:

1.(amend. - SG 38/15, in force from 26.05.2015) name of the designating body;

2. name/company name, headquarters, business address and representative office of the notified body;

3. medical devices and conformity assessment procedures;

4. date of authorization issue;

5. (amend. - SG 38/15, in force from 26.05.2015) identification number of the notified body.

Art. 67. (amend. - SG 38/15, in force from 26.05.2015) (1) Bulgarian Drug Agency shall keep a the register, containing the following:

1. the data under Art. 66;

2. date of authorization suspension and the reason for it.

(2) (amend. - SG 38/15, in force from 26.05.2015) Data under para 1 shall be published in the official website of BDA.

Art. 67a. (new – SG 38/15, in force from 26.05.2015) (1) Expansion of the authorization scope and renewal of the authorization to expand the scope of the conformity assessment authorization shall be carried out pursuant to Art. 62, para 2 or 3.

(2) The Executive Director of BDA shall grant an addition to the authorization under Art. 63, para 5 by an order.

Art. 68. (1) (amend. - SG 38/15, in force from 26.05.2015) The notified bodies are obliged to notify BDA in case of:

1. (amend. - SG 38/15, in force from 26.05.2015) changes in the legal status and the organizational structure;

2. (new - SG 38/15, in force from 26.05.2015) changes in the scope of activity except in the cases referred to in Art. 67a, para 1 and changes in the conformity assessment procedures;

3. (prev. text of item 2 - SG 38/15, in force from 26.05.2015) changes in the quality system, management or staff that affect the performance of the conformity assessment procedures;

4. (prev. text of item 3 - SG 38/15, in force from 26.05.2015) change of the subcontractors;

5. (prev. text of item 4 - SG 38/15, in force from 26.05.2015) changes in the circumstances

related to the insurance as per Art. 61, para 3, item 7.

(2) (amend. - SG 38/15, in force from 26.05.2015) The bodies under para 1 shall submit to the BDA the documents concerning the changes and a shall pay a fee to the amount specified in the tariff under Art.7, para 1.

(3) (amend. - SG 38/15, in force from 26.05.2015) Within one month term from the submission of the documents as per para 2, the committee of experts under Art. 62, para 1 shall draft an assessment report to the Executive Director of BDA to approve the changes.

(4) (amend. - SG 38/15, in force from 26.05.2015) In those cases where changes under para 1 require on-site inspection, the committee under Art. 62, para 1 shall draft an assessment report to the Executive Director of BDA for approving the changes.

(5) (amend. - SG 38/15, in force from 26.05.2015) On the grounds of the report under para 3 and para 4, the Executive Director of BDA shall issue a supplement to the authorization as per Art. 63, para 5 by an order.

(6) In case during the inspection of the documentation of para 2 or upon on-site inspection non-conformities and shortcomings regarding the requirements of the ordinances as per Art.18 are found, the committee under Art. 62, para 1 shall issue instructions and a deadline for their removing. The terms under para 3 and 4 cease running until the instructions are implemented.

(7) (amend. - SG 38/15, in force from 26.05.2015) If the notified bodies fail to implement the instructions under para 6, the Executive Director of BDA shall refuse to issue supplement to the authorization by an order.

(8) (new - SG 38/15, in force from 26.05.2015) In the cases under Art. 62, para. 2 the evaluation of the documentation under par. 2 and on-site inspection under para 4 may also be carried out, where applicable, by representatives of the two other two Member States and the European Commission representative, who participated in the assessment procedure under Art. 62 a.

Art. 69. (revoked - SG 38/15, in force from 26.05.2015)

Art. 70. (1) (amend.- SG 38/15, in force from 26.05.2015) The notified bodies are obliged to present to the BDA an annual report on their activity including information about conducted conformity assessments of medical devices, claims, complaints and measures undertaken by 31 January of the following year.

(2) (revoked - SG 38/15, in force from 26.05.2015)

Art. 71. (1) (amend. - SG 38/15, in force from 26.05.2015) The committees appointed by an order of the Executive Director of BDA, shall inspect the operation of notified bodies, including their subcontractors, by carrying out planned inspections in accordance with Art. 5, para 1, letter "a" and "b" of Implementing Regulation (EU) № 920/2013.

(2) The committees under para 1 shall perform exceptional on-site inspections upon receiving signals, complaints and claims of default of notified bodies or deviation from normal or best practices.

(3) When during inspections are found omissions in the work of the notified bodies, the Executive Director of BDA shall issue instructions containing a deadline for removing them.

(4) The Executive Director of BDA shall issue an order to restrict or temporarily suspend the authorization removing the omissions under para 3within the set time limit under par. 3

Art. 72. (1) (amend. - SG 38/15, in force from 26.05.2015) The the Executive Director of BDA shall withdraw the authorization to conduct conformity assessment by an order if during the inspections it has been found that the notified body:

1. no longer complies with some of the conditions under which the authorization has been issued;

2. is no longer able to proceed with the conformity assessment procedures;

3. does not carry out the conformity assessment procedures in compliance with the requirements of the relevant ordinances as per Art. 18;

4. has not undertaken measures for removing the omissions referred to in Art. 71, para 3 within

the fixed term.

(2) (revoked - SG 38/15, in force from 26.05.2015)

Art. 73. (amend. - SG 38/15, in force from 26.05.2015) The Bulgarian Drug Agency shall notify the European Commission, the other Member States, the countries - parties to the Agreement on the European Economic Area and Swiss Confederation of the authorizations withdrawn as per Art. 72 of the changes made according to Art. 67a, para 1 and Art. 68, para 1.

Art. 74. (1) (amend. - SG 38/15, in force from 26.05.2015) The person who has been refused issue of an authorization as per Art. 63, para 2, can submit a new application for authorization not earlier than 6 months from the date of handing the order for refusal.

(2) The notified body whose authorization under Art. 72, para 1 has been withdrawn can submit an application for new authorization not earlier than one year from the date of handling the order for authorization withdrawal.

Art. 75. (amend. - SG 38/15, in force from 26.05.2015) The refusal to issue a conformity assessment authorization as well as the order for authorization withdrawal can be subject to appeal under the terms of the Administrative Procedure Code.

Art. 76. (1) (suppl. - SG 38/15, in force from 26.05.2015)The notified body issues a certificate verifying the essential requirements conformity applicable to the device, with validity specified therein, however of not more than 5 years, or makes a reasoned refusal.

(2) (amend. – SG 110/08) In case the notified body ascertains that a manufacturer has not fulfilled or has stopped fulfilling the requirements defined in the ordinances as per Art. 18, or the conditions, under which the certificate has been granted have changed, and in consideration of the level of unconformity it withdraws the certificate or suspends temporarily its validity, or restricts its scope, until the manufacturer undertakes appropriate corrective measures and provides the required conformity.

(3) (amend. – SG 110/08; amend. - SG 38/15, in force from 26.05.2015) The notified body shall inform BDA in cases of refusal to grant a certificate or temporary suspension of certificate validity, of withdrawal or imposition of restrictions or of amended or supplemented certificates.

(4) (new - SG 38/15, in force from 26.05.2015) In the cases under par. 3 the notified body shall provide additional information upon request by the BDA and the documents requested by BDA.

(5) (amend. – SG 110/08; prev. text of para 4, amend. - SG 38/15, in force from 26.05.2015) The Bulgarian Drug Agency shall inform the regulatory authorities of the other Member States, the regulatory authorities of the states - parties to the Agreement on the European Economic Area and of Swiss Confederation and the European Commission of the cases under par. 3.

Art. 76a. (new – SG 110/08; amend. - SG 38/15, in force from 26.05.2015) The Notified bodies shall be obliged to provide to notified bodies, determined by other Member States, information on refused certificates, on certificates the validity of which has been suspended temporarily, on withdrawn certificates and, upon request, on issued certificates.

Chapter five.
TRADE IN MEDICAL DEVICES (TITLE AMEND. - SG 60/11, IN FORCE FROM 05.08.2011)

Art. 77. (amend. – SG 54/12) (1) Wholesale trade in medical devices on the territory of the

Republic of Bulgaria may be carried out by natural or legal persons registered as traders under Commerce Act or the legislation of a Member State or a contracting state of the Agreement on the European Economic Area, or the Swiss Confederation, holding an authorisation for wholesale trade in medical devices issued by BDA or another document certifying the right to trade in medical devices, issued by a competent authority of the respective state.

(2) The manufacturers located in the territory of the Republic of Bulgaria may carry out commercial transaction with devices manufactured by them without the document referred to in Para 1.

Art. 78. (amend. – SG 54/12) (1) Natural and legal persons registered under the Commerce Act or the legislation of a Member State or a contracting state to the Agreement on the European Economic Area, or the Swiss Confederation, wishing to obtain an authorisation for wholesale trade in medical devices shall file an application with BDA in a form approved by the executive director of BDA, accompanied by:

1. information of UIC of the persons registered under the Commerce Act and of the persons registered in a Member State or a contracting state to the Agreement on the European Economic Area, or the Swiss Confederation – information certifying their commercial registration;

2. a list of the categories medical devices according to the nomenclature system BDS EN ISO 15225 on the categorisation of the medical devices and their respective manufacturers on paper or magnetic career;

3. a document of paid fee in amount determined in the tariff referred to in Art. 7, Para 1.

(2) If they have available premises for storage of medical devices on the territory of the Republic of Bulgaria, the persons under para 1 shall specify their address in the application. In this case the following documents shall also be enclosed to the documentation under para 1:

1. a statement that:

a) the premises meet the requirements for storage of medical devices from the register under Para 1, Item 2 depending on their specifics and instructions of the manufacturer determined in the usage directions, and

b) own or possess transportation means allowing their proper storage during distribution and transportation;

2. information of the name, permanent address and address for correspondence with the person determined to be responsible for the premises for storage and trade in medical devices and a copy of the contract by virtue of which have risen his legal relations with the applicant.

Art. 78a. (new – SG 54/12) Where the persons referred to in Art. 77 hold a document certifying their right to wholesale trade in medical devices issued by a competent authority of a Member State or a contracting state to the Agreement on the European Economic Area, or the Swiss Confederation, and have premises for storage of medical devices on the territory of the Republic of Bulgaria, they shall file with BDA:

1. a notification form in a form approved by the executive director of BDA;

2. a copy of the document attesting their right to wholesale trade, accompanied by a translation in Bulgarian;

3. a list of the categories medical devices according to the nomenclature system BDS EN ISO 15225 for categorisation of the medical devices and their respective manufacturers on paper and magnetic career;

4. the documentation referred to in Art. 78, Para 2.

Art. 79. (amend. – SG 54/12) (1) The Bulgarian Drug Agency shall check the documentation under Art. 78 and 78a. In cases of deficiencies in the documentation BDA shall notify the applicant in writing and shall provide a time limit for their remedy.

(2) Within 30 days from the date of submission of the documentation under Art. 78 the executive director of BDA shall issue an authorisation for wholesale trade in medical devices to the persons under Art. 78, Para 1, and the information of their premises for storage and trading and the list of the categories of medical devices shall be recorded in the register under Art. 81.

(3) The time limit under Para 2 shall be suspended from the date of the notification under Para 1 until the remedy of the deficiencies.

(4) Within 7 days from the notification under Art. 78a the Bulgarian Drug Agency shall record in the register under Art. 81 the information of the notification.

Art. 80. (amend. – SG 54/12) (1) In case of change of the address of the premises for storage and trade in medical devices on the territory of the Republic of Bulgaria the persons referred to in Art. 78 shall file with BDA an application for amendment of the authorization under Art. 79, Para 2, and the persons referred to in Art. 78a – a notification of the change. The application or the notification shall be accompanied by the documentation related to the change and a document of paid fees, in the case of the persons referred to in Art. 78a, in amount determined in the tariff under Art. 7, Para 1.

(2) (new - SG 60/11, in force from 05.08.2011) The wholesale traders of medical devices shall file with EAM a notification accompanied by the change-related documents in cases of the following changes:

1. the legal status, seat and/or business address of the trader;
2. the list of types of medical devices being traded and their respective manufacturers;
3. the name and/or address of the authorized representative as per Art. 78, para 5.

(3) (suppl. – SG 110/08; prev. text of Para 02 - SG 60/11, in force from 05.08.2011) To the application form under para 1 shall also be appended the documents related to the change and a document of a collected fee of the amount, determined by the tariff under Art. 7, par. 1.

(4) (prev. text of Para 03 - SG 60/11, in force from 05.08.2011) Amendment certificates or authorizations shall be issued by the Executive Director of BDA within 15 days from the submission of application form under para 1. In case of change in the address of the premises for storage and wholesale trade in medical devices, the term shall be prolonged by 15 days.

(5) (prev. text of Para 04 - SG 60/11, in force from 05.08.2011) The persons under para 1 are obliged, within 10 days after termination of their activities relating to wholesale trade in medical devices, to notify in writing the Executive Director of BDA.

(6) (prev. text of Para 05 - SG 60/11, in force from 05.08.2011) In the cases referred to in para 4, the Executive Director of BDA shall terminate the effect of the issued authorization or invalidate the issued certificate for wholesale trade by an order.

Art. 80a. (new – SG 54/12) (1) Within 10 days from termination of their activity related to the trade in medical devices on the territory of the Republic of Bulgaria the persons referred to in Art. 78 and 78a shall notify in writing the executive director of BDA.

(2) In the cases of Para 1 the executive director of BDA shall issue an order for terminating the validity of the issued authorization under Art. 79, Para 2. Within 7 days from the issue of the order for termination of the authorization the Bulgarian Drug Agency shall record into the register under Art. 81 the date of termination of the authorization of the trader under Art. 78.

(3) The Bulgarian Drug Agency shall record into the register under Art. 81 the date of termination of the activity of the persons under Art. 78a.

Art. 81. (amend. – SG 54/12) The Bulgarian Drug Agency keeps a register of the persons referred to in Art. 78 and 78a, containing:

1. (amend. – SG 54/12) number and date of the certificates or authorizations for wholesale trade in medical devices to the persons under Art. 78;

2. (amend. – SG 54/12) name, headquarters and registered address of the persons under Art. 78 and 78a;

3. (amend. – SG 54/12) termination date of authorizations under Art. 79, Para 2;

4. (amend. – SG 54/12) address of the premises for storage of medical devices;

5. (amend. – SG 54/12) name and address of the persons referred to in Art. 78, para 2, item 2;

6. (amend. – SG 54/12) a list of the categories of traded medical devices;

7. (new – SG 54/12) changes of the recorded circumstances.

Art. 82. (1) (amend. – SG 54/12) The traders in medical devices, trading on the territory of the Republic of Bulgaria, are obliged to trade only in medical devices the shelf life of which has not expired and which have:

1. affixed CE marking according to the requirements of Art. 15;

1a. (new – SG 54/12) affixed batch/serial number on the packaging, where applicable;

2. (amend. – SG 110/08; amend. - SG 38/15, in force from 26.05.2015) affixed identification number of the notified body as per Art. 63, para 4, where the procedures, determined in the provisions of Art. 18 require its displaying;

3. affixed name and registered address of the manufacturer and/or their authorized representative and the importer;

4. instructions for use, except for devices that the present Act does not cover.

(2) (amend. – SG 54/12) The persons under para 1 are obliged to maintain the premises for storage of medical devices, where available, in conformity with the requirements for storage of the respective type of device, determined by the manufacturer.

(3) (amend. – SG 54/12) The wholesale traders of medical devices shall provide and maintain a documented system for tracing the safety of medical devices placed on the market and for blocking and withdrawing from the market of medical devices which have revealed non-conformity with the safety requirements within the meaning of Chapter VII.

(4) (amend. – SG 54/12) Together with the documentation under para 3, shall be stored the batch certificates of medical devices for a period of 5 years and shall be presented upon request to the officials referred to in Art. 86.

(5) (amend. – SG 54/12) The persons referred to in Para 1 shall be obliged to store the medical devices with expired term of validity, the blocked and/or withdrawn medical devices in a place designated for such purpose with permanent marking until their delivery to the manufacturer or their destruction.

Art. 83. (amend. – SG 54/12) (1) The persons referred to in Art. 77 may carry out business transactions with medical devices, adhering to storage and distribution restrictions, with:

1. other wholesale traders within the meaning of this Act;

2. (amend. - SG 14/16, in force from 19.02.2016) medical establishments under the Medical Establishments Act and veterinary medical centers under the Veterinary Practice Act;

3. health institutions under Art. 21, Para 2, Items 1, 3 and 4 and Para 3 of the Health Act;

4. veterinary medical pharmacies;

5. drugstores;

6. persons carrying out activities of provision of aiding devices, accessories and equipment and medical devices to persons with disabilities under the Integration of Persons with Disabilities Act;

7. persons owning commercial sites where medical devices are offered as determined in an order of the Minister of Health or a deputy minister authorised by him;

8. municipalities, state authorities and state institution conducting public procurement procedures for supply of medical devices;

9. education institutions;

10. persons in a procedure for building and equipping future medical and health establishments following the receipt of a construction permit as set out in the Spatial Planning Act.

(2) The Minister of Health shall determine in an order the medical devices, which may be sold in the commercial sites referred to in Para 1, Item 7.

Art. 83b. (new – SG 54/12) (1) The persons referred to in Art. 78 and 78a shall keep information and store documentation of:

1. purchased and sold quantities of types of medical devices, the date of purchase and sale, warehouse availability, batch number and term of usability;

2. the name and address of management of the persons, from whom they have purchased or to whom they have sold the medical devices;

3. number and date of issue of the document, certifying the right to wholesale trade of the persons under Art. 77, and data identifying the issuing authority.

(2) The persons referred to in Art. 83, Para 1, Items 3 – 5 and Items 7 – 10 shall keep information of:

1. purchased quantities of the types of medical devices, date of the purchase and sale, warehouse availability, batch number and term of usability;

2. the name and address of management of the person under Art. 77, from whom they have purchased the medical devices, and the data under Para 1, Item 3.

(3) The persons referred to in Art. 83, Para 1, Items 2 and 6 shall keep information of:

1. purchased quantities of the types of medical devices, date of the purchase, warehouse availability, batch number and term of usability;

2. the name and address of management of the person under Art. 77, from whom they have purchased the medical devices, and the data under Para 1, Item 3;

3. a person, to whom they have provided/applied the medical device/devices.

Art. 84. (amend. – SG 54/12) (1) The officials referred to in Art. 86, para 2 shall carry out planned and unexpected inspections at the premises for storage and trade in medical devices.

(2) The officials referred to in para 1 may require, inspect and make copies of the documents under Art. 82, paras 3 and under Art. 83b, and take samples and specimens of the devices under the terms of Art. 93, para 3.

(3) In case during the inspection it is established that medical devices do not comply with the requirements set out in Art. 82, para 1, items 1, 2 and 3, or that their shelf life has expired, the Executive Director of BDA shall order the devices to be blocked and withdrawn from the market and/or their destruction.

(4) In case it is established that the premises for storage and trade do not meet the requirements determined by the manufacturer regarding certain device, the officials under para 1 shall give instructions and fix a term for eliminating these non-conformities.

(5) In case the inspection ascertains that there are shortcomings or imperfections in the system

as per Art. 82, para 3 or in the documentation of Art. 83b, the officials referred to in para 1 shall give instructions and fix a term for eliminating them.

(6) In case the non-conformities, shortcomings and imperfections are not eliminated within the terms under para 4 and 5, the officials referred to in para 1 shall present a statement to the Executive Director of BDA, including a proposal to withdraw the authorization for wholesale trade, and in respect of the persons referred to in Art. 78a – removal from the register under Art. 81 and closing of their premises for storage and trading.

(7) The orders of the Executive Director of BDA under para 3 and 6 may be appealed under the terms of the Administrative Procedure Code, and the appeal shall not suspend their implementation.

Art. 85. (amend. – SG 54/12) The Bulgarian Drug Agency shall notify the regulatory authority of the other Member State or contracting state to the Agreement on the European Economic Area, or of the Swiss Confederation, that has issued the document certifying the right to wholesale trade in medical devices, of any violations related to wholesale trade in medical devices on the territory of the Republic of Bulgaria and shall provide information at the request of the persons under Art. 78.

Chapter six.
MARKET SUPERVISION

Art. 86. (1) (suppl. – SG, 84/2012, in force from 02.01.2013) Market supervision is exercised to ensure that the medical devices placed on the market and/or put into service meet the requirements of the Act and the ordinances as per Art. 18 of this act and/or Chapter Five “a” and of the ordinance under Art. 21e, Para. 1 of the Act on Protection of the Dangerous Impact of Chemical Substances and Mixtures.

(2) Market supervision on the territory of the Republic of Bulgaria is carried out by BDA through inspectors and experts appointed by an order of the Executive Director.

Art. 87. (1) Market control is carried out by means of:

1. inspections of devices placed on the market and/or put into service;
2. taking samples and specimens of the devices and testing.

(2) Trials of medical devices may not be carried out by the notified bodies involved in the conformity assessment of the same devices.

Art. 88. Inspections of medical devices placed on the market and/or put into service shall be carried out according to:

1. approved in advance annual market supervision plan by groups of medical devices, respectively by the Executive Director of BDA, and
2. signals from other authorities and identified written signals from citizens.

Art. 89. (amend. – SG 54/12) Persons referred to in Art. 86, para 2 shall conduct inspections at sites as per Art. 83, para 1, items 2 – 7, as well as at the production premises and the premises for storage and trade in medical devices under Art. 78, Para 2 and Art. 78a.

Art. 90. (1) (prev. Art. 20 – SG 110/08) Persons referred to in Art. 86, para 2 shall carry out inspections for:

1. availability of "CE" marking and for its compliance with the requirements of the Act;

2. (amend. – SG 110/08; amend. - SG 38/15, in force from 26.05.2015) identification number of the notified body as per Art. 63, para 4, where the procedures, determined in the provisions of Art. 18, require its displaying;

3. availability of instructions for use and conformity of its content with the requirements of ordinances as per Art.18, exclusive of the devices referred to in Art. 2, para 1, item 3 which fall in class I and class IIa, if they can be safely used without instructions for use;

4. (amend. – SG 110/08) presence of a label and conformity of its content with the requirements contained in the provisions of Art. 18;

5. presence of name and headquarters of manufacturer, or their authorized representative, or the importer on the medical device;

6. shelf life of the medical device;

7. (revoked – SG 110/08).

(2) (new – SG 110/08) The persons of Art. 86, par. 2 shall inspect the fulfillment of the requirement of Art. 27, par. 1 and Art. 28, par. 1 and 6.

Art. 91. (1) Where during inspection the persons as per Art. 86, para 2 establish that the medical devices are placed on the market and/or put into service without "CE" marking or with expired shelf life, they shall pass a stand to the Executive Director of BDA with a proposal for issuing an order to block and withdraw the device from the market.

(2) (amend. – SG 110/08) If upon inspection the persons referred to in Art. 86, para 2 establish that medical devices are placed on the market and/or put into service without instructions for use and/or without a label or the content of the label does not comply with the requirements of the ordinances under Art. 18, and/or manufacturer's name and place of business or those of his/her authorized representative and of the importer are not displayed on the device, they shall give instructions to the manufacturer or his/her authorized representative with a deadline for removing the breach that has been ascertained.

(3) In case the breach under para 2 is not eliminated within the deadline the persons as per Art. 86, para 2 shall pass a statement to the Executive Director of BDA along with a proposal for issuing an order to block and withdraw the device from the market.

(4) (amend. – SG 110/08) Where the requirement of Art. 90, item 2 has not been met or the affixed marking does not comply with the requirements of Art. 15, or there is a doubt that the CE marking has been affixed unjustified, the persons referred to in Art. 86, para 2 shall require from the manufacturer or his/her legal representative or from the importer to present within 10 days after the date of notification:

1. conformity declaration;

2. technical documentation as per Art. 14, para 1.

Art. 92. (1) Persons as per Art. 86, para 2 pass a statement to the Executive Director of BDA who shall issue an order to block and ban on the distribution of devices, if within the term under Art. 91, para 4 the conformity declaration and technical documentation have not been submitted, except for the cases when the term under Art. 14, para 3 has expired.

(2) Within 30 days from the date of handling the order under para 1, the manufacturer, his/her authorized representative or the importer are obliged to withdraw the device from the market.

Art. 93. (1) (amend. – SG 110/08, suppl. – SG, 84/2012, in force from 02.01.2013) When upon inspection of the technical documentation under Art. 14, para 1 and of the conformity declaration of Art. 91, par. 4, item 1 doubts arise that the device does not meet the essential requirements, set in the ordinances under Art. 18 of this act and/or Chapter Five “a” and of the ordinance under Art. 21e, Para. 1 of the Act on Protection of the Dangerous Impact of Chemical Substances and Mixtures, the persons under Art. 86, para 2 shall take samples or specimens of the device to be tested.

(2) The investigation is carried out in a laboratory accredited by the Executive Agency "Bulgarian Accreditation Service" or in laboratory accredited by an authority of a Member State or a state from the European Economic Area.

(3) (amend. – SG 82/09, in force from 16.10.2009; amend. – SG, 14/15) The terms and the manner of taking samples and specimens of medical devices for testing are determined with an ordinance by the Minister of Health and by the Minister of Economy.

(4) In case of the results of the conducted laboratory tests are disputed, within 7 days from the date of receiving the results from the initial test, the manufacturer or his/her authorized representative submits to BDA a written request for conducting a second test.

(5) The second test under para 4 shall be carried out by experts who have not participated in the initial test.

Art. 94. (1) In the cases referred to in Art. 93 the Executive Director of BDA shall issue an order for temporary ban on the distribution or use of the device in question.

(2) Copy of the order under para 1 shall be given to the manufacturer or his/her authorized representative or the importer.

Art. 95. Where persons as per Art. 86, para 2 find that the nonconformity with the essential requirements can be eliminated, they pass a statement to the Executive Director of BDA and give instructions with a deadline, coordinated with the manufacturer or his/her authorized representative, for carrying out the required corrective actions or for complete conformity assessment of the device with the essential requirements.

Art. 96. (1) If the persons referred to in Art. 86, para 2 establish that the nonconformity with the essential requirements can not be elimeinated; they shall pass a statement to the Executive Director of BDA.

(2) On the grounds of the statement under para 1, the Executive Director of BDA issues an order for block and ban on the distribution or use of the device and arranges its withdrawal from the market within 30 days from the date of handling the order to the manufacturer or his/her authorized representative or the importer.

(3) BDA notifies the regulatory authority of the Member State where the manufacturer or his/her authorized representative and the importer are established of the order under para 2.

Art. 97. The orders as per Art. 92, para 1, Art. 94, Art. 96, para 2 and Art. 99, para 1 are subject to appeal under the terms of the Administrative Procedure Code, provided that the appeal does not stop their enforcement.

Art. 98. (1) In case during the trial under Art. 93 it is established that the medical devices do not

comply with the essential requirements, the expenses for taking samples or specimens for testing are on the account of the manufacturer, his/her authorized representative or the importer.

(2) In case during the test under Art. 93 it is ascertained that the medical devices comply with the essential requirements, the expenses for taking samples or specimens for testing are on the account of BDA.

Art. 99. (1) (amend. – SG 110/08; suppl. – SG 41/09, in force from 02.06.2009) Upon a justified proposal by the Executive Director of BDA, where this is in public health interest and/or is required for the implementation of the national health policy, the Minister of Health or a deputy minister authorized by the latter may temporary by an ordinance:

1. prohibit launching on the market and/or putting into operation, or
2. prohibit the distribution, or
3. limit the scope of operation or
4. impose additional requirements for placing on the market and/or putting into service of a device or group of devices.

(2) (suppl. – SG 110/08) In the cases referred to in para 1 BDA shall notify the European Commission and regulatory authorities of the Member States and regulatory authorities of the states of the European Economic Area of the order, the reasons for it and the measures that have been undertaken.

Art. 100. (1) Persons referred to in Art. 86, para 2 shall be insured at the expense of BDA budget against accidents which can occur during or on occasion of fulfillment of their official duties.

(2) (amend., - SG 98/10, in force from 01.01.2011) Upon inspections persons under Art.86, para 2 can ask for cooperation the Regional Health Inspectorate, the bodies of the Ministry of Inferior and the competent authorities of local self-government.

Art. 101. BDA publishes on its web site information about the devices for which there is an order issued as per Art. 91, para 1, Art. 92, para 1, Art. 94 and Art. 96, para 2.

Art. 102. Persons referred to in Art. 86, para 2 are obliged:

1. not to disclose facts and circumstances that have become known to them during or in relation to their official duties.
2. to use the documents and information obtained only for the purposes of market control;
3. to present their identity papers during inspections.

Chapter seven.
INCIDENTS NOTIFICATION AND EVALUATION SYSTEM

Art. 103. (1) Manufacturers shall be obliged to create and maintain a documented system for tracing the safety of medical devices manufactured by them and placed on the market/put into service on the territory of Member States, of states from the European Economic Area and third countries, as well as to have at their disposal the mechanisms for implementation of the necessary corrective actions.

(2) The system under para 1 shall be applied to medical devices which:

1. have CE marking;

2. do not have CE marking in case the incident or the potential incident relating to them under Art. 106, para 1 and 2 requires performance of corrective actions applicable to devices as per item 1.

(3) The system shall not apply to devices intended for clinical trials and devices for operation assessment.

(4) The system under para 1 includes examination of safety of devices under para 2 that have been placed on the market and/or put into service by way of:

1. collecting, documenting and analyzing reports for events under Art. 105 by medical experts, patients, persons installing, maintaining and calibrating the devices, and BDA;

2. analysis of results from additional tests on the devices carried out by the manufacturer;

3. collecting, recording and analyzing data from scientific literature.

Art. 104. (1) (prev. Art. 104 – amend. SG 110/08; amend. – SG 54/12) Doctors, dentists other medical experts, as well as persons installing, maintaining and calibrating the devices are obliged to inform immediately the BDA about events as per Art. 105 at the sites under Art. 83, para 1, items 2 regarding the medical establishments under the Medical Establishments Act.

(2) (new – SG 110/08) The Bulgarian Drug Agency shall provide to the manufacturer or to his/her authorized representative the information under par. 1 within three days after its receipt.

Art. 105. (1) The manufacturer shall inform BDA of any trouble or deterioration in the characteristics of the device manufactured by him/her, and/or in its operation, as well as of incomplete or inaccurate information on its label or instructions for use, which has caused death or serious health damage, or which is likely to cause death or serious health damage to a patient, medical expert or third persons on the territory of the Republic of Bulgaria.

(2) Manufacturers shall also inform BDA of any technical or medical cause related to the device's characteristics or operation, which leads to regular withdrawal from the market of the same type of devices due to the reasons specified in para 1.

Art. 106. (1) The manufacturer shall provide BDA with an advance report within 10 days of receipt of information about an event as per Art. 105 which has caused death or serious health damage, and hereafter referred to as incident.

(2) The manufacturer shall submit to BDA an advance report within 30 days of receipt of information about an event under Art. 105 which could have caused death or serious health damage that were averted due to favourable circumstances or medical intervention, and hereafter referred to as potential incident.

(3) (amend. - SG 38/15, in force from 26.05.2015) In case the incident or potential incident concerns devices of class IIa, Iib or III, or in vitro diagnostic medical devices from List A and List B, or self-testing devices, and has occurred in a third state, the manufacturer shall submit to BDA, within the term under para 1 or 2, an advance report in those cases where a notified body as per Art. 63, para 4 has carried out conformity assessment of the device related to the incident.

(4) In case the incident or potential incident concerns devices of class I or in vitro diagnostic medical devices that are not from List A and List B and are not for self-testing, and has occurred in a third state, the manufacturer shall submit to BDA, within the term under para 1 or 2, an advance report in those cases where the manufacturer or their authorized representative is registered at BDA according to Chapter II.

Art. 107. When the incident or potential incident is a result of combined use of two or more individual devices and/or accessories produced by different manufacturers, each manufacturer shall provide BDA with an individual report under Art. 106.

Art. 108. Immediately upon receiving information for an incident or potential incident, manufacturers shall notify their authorized representative as per Art. 10, para 2, the wholesale trader, and the notified body that carried out the assessment of the device's conformity with essential requirements.

Art. 109. (1) The Bulgarian Drug Agency maintains a system for registration, analysis and summarizing of incidents or potential incidents related to medical devices.

(2) The Bulgarian Drug Agency publishes on its web page the manuals for tracing the safety of medical devices, issued by the European Commission and the European Medicines Agency.

Art. 110. (1) The Bulgarian Drug Agency registers in the system under Art. 109, para 1 the data from the advance report of the manufacturer and assesses the provided information.

(2) The Bulgarian Drug Agency carries out supervision on the manufacturer's procedures regarding the investigation of the incident or potential incident and may issue directions and instructions.

(3) During the investigation of the incident or potential incident BDA assists the manufacturer, where necessary, to contact:

1. the notified body that has performed conformity assessment;

2. regulatory authorities of other affected Member States or states from the European Economic Area;

3. regulatory authorities of Member States or states from the European Economic Area for medical devices in the case of incidents or potential incidents with devices as per Art. 3, item 2, 3 and 4;

4. other manufacturers in the cases referred to in Art. 107;

5. users of the device or third persons.

Art. 111. In case the advance report as per Art. 106 indicates corrective actions, or contains the conclusion that the incident threatens the safety of patients, medical experts or third persons however corrective actions have not been defined yet, BDA sends a report to the regulatory authorities of Member States, states from the European Economic Area, and the European Commission.

Art. 112. (1) Within three months from the submission of the report as per Art. 106, the manufacturer draws in and presents to BDA a final report in a form approved by the Executive Director.

(2) The report under para 1 may contain one of the following conclusions:

1. it is not necessary to take any measures;

2. (amend. – SG 54/12) additional tracing of the device or batch of devices that have been put into service at the sites as per Art. 83, para 1, item 2 regarding the medical establishments under the Medical Establishments Act;

3. distribution of information to medical experts at sites under item 2 and at pharmacies and drugstores in the form of written recommendation prepared by the manufacturer;

4. corrective actions in the course of future production;

5. corrective actions on the device put into service at sites as per item 2;

6. withdrawal of the device or batch of devices that have been placed on the market and/or put into service.

Art. 113. (1) In the cases referred to in Art. 112, para 2, item 2, BDA shall exercise control over the manufacturer's activity on the territory of the Republic of Bulgaria.

(2) In the cases of Art. 112, para 2, item 3, BDA shall assess the contents of the written recommendation and discuss with the manufacturer the addressees of the recommendation and its way of distribution.

(3) In the cases referred to in Art. 112, para 2, item 5, BDA can carry out an inspection on the spot.

(4) The Executive Director of BDA shall issue an order that the manufacturer blocks or withdraws the device or batch of devices with which the incident or potential incident has happened, in case it is ascertained that the manufacturer has not:

1. carried out corrective actions within the term specified by him/her in the report under Art. 112;

2. withdrawn the device or batch of devices from the market within the term specified by him/her in the report as per Art. 112;

(5) The terms and procedures for blocking, withdrawal and/or destruction of devices which do not meet the requirements of this Act shall be determined by an ordinance of the Minister of Health.

Art. 114. (1) The Bulgarian Drug Agency shall publish on its web site a list of the devices included in the ordinance under Art. 113, para 4.

(2) In those cases where the devices under para 1 are being sold at sites as per Art. 83, para 2, BDA informs the public through BTA and the mass media.

(3) The Executive Director of BDA issues a report on the incident that has occurred or the potential incident in cases referred to in Art. 112 and forwards a copy to the European Commission and the regulatory authorities of the Member States.

Art. 115 (1) Any direct notice to BDA regarding an incident or potential incident with medical device on the territory of the Republic of Bulgaria, handed by an identified person in writing, shall be documented in the system under Art.109.

(2) Within three days after receiving the notice for the incident or potential incident under para 1 BDA informs the manufacturer so that he/she undertakes the necessary measures defined under Art.106 - 108 and Art.112.

Art. 116. BDA can be coordinating regulatory authority:

1. in the case of incident or potential incident which has occurred on the territory of more than one Member State or a state from the European Economic Area, and

2. in the event that the incident or the potential incident is registered for the first time on the territory of the Republic of Bulgaria, or

3. where the body which has carried out the conformity assessment of the device with the essential requirements has obtained an authorization under Chapter IV, if the incident or the potential incident has occurred with devices from class IIa, IIb or class III, or in-vitro diagnostic medical devices from list A or list B, or self-testing devices, or

4. in case the manufacturer or their authorized representative is registered at BDA under the terms of Chapter II, if the incident or the potential incident has occurred with devices from class I or in-vitro diagnostic medical devices which are not included in list A and list B and are not for self-testing ones.

Art. 117. Personal data of the source of notice shall be stored by BDA according to the requirements of the Personal Data Protection Act.

Chapter eight.
EUROPEAN DATABASE

Art. 118. Immediately upon receipt, the Executive Director of BDA presents to the European database the following information in a standard format:

1. (amend. – SG 110/08) data regarding the registration of the manufacturers or the authorized representatives of Art. 29 and the devices under Chapter II, except for the devices, which are customized;

2. data obtained from clinical studies of medical devices under the terms of Chapter III;

3. data obtained upon tracing the safety of medical devices placed on the market and/or put into service on the territory of the Republic of Bulgaria under Chapter VII;

4. data regarding the issue, change, supplement, temporary termination, withdrawal or refusal of certificates by the notified bodies according to the procedures specified in the ordinances under Art. 18.

Chapter eight.
"A" CONFIDENTIALITY (NEW – SG 110/08, IN FORCE FROM 21.03.2010)

Art. 118a. (new – SG 110/08, in force from 21.03.2010) (1) The officials and the persons, applying this Act and the secondary legislative documents related to its application, shall be obliged not to disclose any information, obtained for and with regard to fulfillment of their obligations.

(2) The provision of par. 1 shall not apply with regard to:

1. exchange of information between officials, between notified bodies and between officials and notified bodies;

2. disclosure of information which has as an objective to provide humans safety and health;

3. provision of information in case of prosecution proceedings.

(3) Shall not be confidential the information:

1. about the registration of the persons, launching medical devices on the market pursuant to the provisions of Chapter two;

2. which is provided to the users by the manufacturer, by his/her authorized representative or by the wholesaler concerning the measures undertaken according to the provisions of Chapter seven;

3. is contained in the granted, modified, supplemented and withdrawn certificates and in the certificates, the validity of which is temporarily suspended.

Chapter nine.
ADMINISTRATIVE PUNITIVE PROVISIONS

Art. 119. Whoever places on the market and/or puts into service medical devices, the

conformity of which has not been assessed in accordance with this Act and the acts for its implementation, shall be imposed with a fine from 10 000 to 20 000 BGN.

Art. 120. Whoever draws up or uses declaration of conformity with contents that does not meet the requirements set out in Art. 18, shall be imposed with a fine from 3000 to 8000 BGN, unless the act is a crime.

Art. 121. Whoever places on the market and/or puts into service medical devices, whose CE marking violates the requirements under para 15, shall be imposed with a fine from 5000 to 1000 BGN.

Art. 122. Whoever places on the market and/or puts into service medical devices with CE marking without having assessed their conformity with the essential requirements, set out by the ordinances as per Art. 18, shall be imposed with a fine from 10 000 to 20 000 BGN.

Art. 123. Persons who present medical devices at exhibitions, trade fairs, demonstrations, promotions, scientific and technical conferences in violation of Art. 15, para 11 shall be punished by a fine amounting from 500 to 1000 BGN.

Art. 124. Whoever places on the market and/or puts into service medical devices in violation of the provision of Art. 16, shall be punished by a fine amounting from 5000 to 10 000 BGN.

Art. 125. Whoever places on the market and/or puts into service medical devices without instructions for use, except for the devices referred to in Art. 2, 1, item 3 falling in class II and class Iia, in case such may be utilized safely without instructions for use, shall be punished by a fine amounting from 3000 to 5000 BGN.

Art. 126. Whoever places on the market and/or puts into service systems and/or sets of medical devices intended by the manufacturer for sterilization before use in violation of the requirements of this Act and the acts related to its implementation, shall be punished by a fine amounting from 10 000 to 15 000 BGN.

Art. 127. Whoever places on the market and/or puts into service custom-made medical devices in violation of the requirements of this Act, shall be punished by a fine amounting from 5000 to 10 000 BGN.

Art. 128. Whoever carries out trade in medical devices without CE marking affixed, shall be punished by a fine amounting to 10 000 BGN.

Art. 129. (1) A manager of a medical establishment who allows use of medical devices without

affixed CE marking , except for the custom-made devices, and the ones which have been put into service before the entry into force of this Act, as well as the devices referred to in Art. 12, para 1, shall be punished by a fine amounting from 2000 to 10 000 BGN.

(2) The same punishment shall be imposed on a manager of a medical or health institution who allows utilization of devices without instructions for use or devices whose shelf life has expired.

(3) (new – SG 54/12) A head of a medical or health establishment purchasing medical devices from persons without authorisation or another document certifying the right to trade in medical devices issued by a competent authority of a Member State or another contracting state to the Agreement on the European Economic Area, or of the Swiss Confederation, shall be imposed a fine amounting to BGN 10 000.

Art. 130. Whoever carries out wholesale trade in medical devices whose shelf life has expired, shall be punished by a fine amounting to 10 000 BGN.

Art. 131. (amend. – SG 54/12) A trader of medical devices, who breaches the requirements referred to in Art. 82, para 2, shall be punished by a propriety sanction amounting to 5000 BGN.

Art. 132. (amend. – SG 54/12) A trader of medical devices, who breaches the requirements referred to in Art. 82, para 3, 4 or 5 shall be punished by a propriety sanction amounting to 1000 BGN.

Art. 133. A wholesale trader of medical devices, who breaches the requirements referred to in Art. 82, para 1, items 2, 3 or 4 shall be punished by a propriety sanction amounting to 5000 BGN.

Art. 134. (amend. – SG 54/12) Whoever carries out wholesale trade in medical devices without holding a document certifying his right to carry out such activity, shall be punished by a property sanction amounting to 10 000 BGN.

Art. 134a. (new – SG 54/12) A wholesale trader in medical devices failing to perform their obligation under Art. 78a shall be imposed a property sanction amounting to BGN 10 000.

Art. 135. (suppl. – SG 54/12) A wholesale trader who breaches the regulation of Art. 80, para 1 or 3 shall be punished by a propriety sanction amounting to 3000 BGN.

Art. 136. (amend. - SG 60/11, in force from 05.08.2011; amend. – SG 54/12) A wholesale trader who breaches the regulation of Art. 80a, para 1 shall be punished by a propriety sanction amounting to 1000 BGN.

Art. 137. Whoever carries out retail trade in medical devices without CE marking affixed, or in medical devices whose shelf life has expired, shall be punished by a fine amounting to 10 000 BGN.

Art. 138. (amend. – SG 54/12) Whoever carries out retail trade in medical devices outside health establishments under Art. 21, Para 2, Item 4 and Para 3 of the Health Act and/or outside the sites under Art. 83, para 1, item 4 - 7, shall be imposed a fine or a property sanction amounting to BGN 10 000.

Art. 138a. (new – SG 54/12) A trader in medical devices violating the requirements of Art. 83b shall be imposed a property sanction amounting to BGN 1000.

Art. 139. (amend. – SG 110/08) Whoever places on the market and/or puts into service medical devices on the territory of the Republic of Bulgaria without being registered within the prescribed term, shall be punished by a fine amounting to 5000 BGN.

Art. 140. (amend. – SG 110/08, in force from 21.03.2010) Whoever violates the requirements of Art. 27, para 3, Art. 28, para 7, Art. 29, para 2 and Art. 30 shall be punished by a fine amounting to 3000 BGN.

Art. 141. (1) Whoever breaches the requirements for carrying out clinical trials, if this does not constitute a crime, shall be punished by a fine amounting from 5000 to 10 000 BGN, and in the event of repeated violation - a fine amounting from 10 000 to 20 000 BGN.

(2) A medical expert who has committed violations under para 1 may be punished with deprivation of right to exercise the profession for a period from six months to two years.

(3) The punishment under para 2 shall be imposed by the Minister of Health upon proposal by the executive director of BDA.

Art. 142. A notified body, which fails to meet the requirement as per Art. 68, para 1, shall be punished by a sanction amounting from 2000 to 5000 BGN.

Art. 143. A notified body, which fails to meet the requirement as per Art. 70, para 1, shall be punished by a propriety sanction amounting to a maximum of 5000 BGN.

Art. 143a. (new – SG 110/08; amend. - SG 38/15, in force from 26.05.2015)A notified body, which fails to meet the requirement as per Art. 76, para 3 and 4, shall be punished by a propriety sanction amounting to a maximum of 5000 BGN.

Art. 144. Whoever impedes the persons as per Art. 86, para 2 to fulfill their official duties according to the provisions of Chapter VI, shall be punished by a fine amounting from 6000 to 10 000 BGN.

Art. 145. A manufacturer of medical devices who violates the provision of Art. 103, para 1

shall be punished by a propriety sanction amounting from 5000 to 10 000 BGN.

Art. 146. A manufacturer of medical devices who violates the provision of Art. 107, shall be punished by a propriety sanction amounting from 10 000 to 20 000 BGN

Art. 147. Whoever does not inform about an incident or a potential incident related to a medical device according to Art. 104, shall be punished by a fine amounting from 1000 to 2000 BGN.

Art. 148. Whoever does not follow an order of the Executive director of BDA under Art. 113, para 4 shall be punished by a fine amounting from 10 000 to 20 000 BGN.

Art. 149. Whoever breaches the provisions of this Act or the acts related to its implementation, apart from the cases referred to in Art. 119 through Art. 148, shall be punished by a fine amounting from 3000 to 5000 BGN.

Art. 150. Whoever does not follow an order or instruction of BDA shall be punished by a fine amounting from 1000 to 3000 BGN.

Art. 151. (1) Where the breaches referred to in Art. 119 through 150 are committed by legal entities or sole traders, property sanctions shall be imposed. The amount of the propriety sanctions imposed may not be less than the double size of the minimum amount of the respective fines and may not exceed the double amount of the minimum amount of the respective fines fixed.

(2) Imposing propriety sanctions on the officials who have been found guilty does not exclude imposing fines on them.

Art. 152. (amend. - SG 38/15, in force from 26.05.2015) (1) Breaches of this Act shall be established by acts compiled by inspectors and experts, appointed by an order of the Executive director of BDA.

(2) Penal decrees shall be issued by the Executive director of BDA or by empowered by him/her officials.

Art. 153. The drawing up of the acts, the issue, the appeal and the execution of the penal decrees shall be carried out pursuant to the Administrative Violations and Penalties Act.

Additional provisions

§ 1. Within the meaning of this Act:

1. "Active implantable medical device" means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical

intervention into a natural orifice, and which is intended to remain in the body after the procedure.

2. "Active medical device" means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3. "Valid documentation" means documentation which meets the requirements in terms of contents and completeness provided for in the respective procedure under this Act.

4. "Importer" means natural or legal person established on the territory of a Member State or a state from the European Economic Area, who imports medical devices on the European Union market from third countries.

5. "Assignor of clinical investigation" is the manufacturer or their authorized representative in charge of initiation, management and/or financing of a clinical trial.

6. "Principal investigator" is the leader of the investigation team, carrying out clinical trial.

7. "Good clinical practice" means the entirety of internationally acknowledged ethical and scientific quality requirements which are to be met when planning, conducting, accounting and reporting of clinical trials.

8. "Member State" means a Member State of the European.

9. "Data allowing identification of the device" includes:

a) information about the manufacturer, model and type number of the device, including software and appliances;

b) intended use determined by the manufacturer, including clinical indications and contraindications during use and identification of the groups of patients for whom it has been designated;

c) description of the device – description of materials that come into contact with human tissues or liquids, whether the devices comprises a medicinal product, human and/or animal tissues or derivatives, or biologically active substances;

d) instructions for installation and use of the device, in case there are any special terms of preservation or function requirements – preliminary preparation before use – sterilization in cases of repeated use, safety check, measures that should be undertaken before use;

e) recommended training and experience required for use of the device;

f) description of the required medical and surgical procedures related to the use of the device;

10. "Device for self-testing" means any in-vitro diagnostic medical device intended by the manufacturer to be able to be used by lay persons in a home environment.

11. "Invasive medical device for continuous use" means any active medical device which is intended to be totally or partially introduced to the human body through a natural orifice or it surface, and which is intended to remain for more than 30 days.

12. "In-vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

a) concerning a physiological or pathological state, or

b) concerning a congenital abnormality, or

c) to determine the safety and compatibility with potential recipients, or

d) to monitor therapeutic measures.

In vitro diagnostic medical devices are also considered to be the devices for self-testing, specimen receptacles, except for the products for general laboratory use unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examinations.

13. "In vitro diagnostic device for performance evaluation" means any in vitro diagnostic device intended by the manufacturer to be subject to one or more performance evaluation studies in

laboratories for medical analyses or in other appropriate environments outside production premises;

14. "Informed consent" means a decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases.

15. "Calibrator and control material" refer to any substance, material or Art. intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.

15a. (new – SG 110/08, in force from 21.03.2010) "Clinical data" is the information, gathered in the course of device usage concerning its safety and/or its functioning. Clinical data shall be obtained from:

a) the results, obtained in the course of carrying out of clinical testing or the tested medical device, or

b) data of clinical test/tests or data from other studies, published in the research papers, on similar medical device, the equivalency or which with the tested device can be proven, or

c) published and/or non-published reports of another clinical examination of the tested device or of a similar medical device, the equivalency of which with the tested device can be proven.

16. "Coordinating investigator" is the person who coordinates the investigators during multi-centre clinical trials.

17. "Corrective actions" may include withdrawal of the device which has been put into service; issue of recommendations in writing specifying the measures that shall be undertaken; further tracing or modification of the device that has been put into service with the purpose of characteristics and performance improvement; amendment of the project; change of individual components of the device or change in the production process in the event of future manufacturing of such Art.s; amendment of the contents of the label or the instruction for use, etc.

14. "Critical analysis" means:

a) short description of the medical device – intended operation, type, characteristics;

b) analysis of the relevant literature and all the information available;

c) critical analysis of the damages identified while using the device, the related risks and suitable safety measures as regards to patients, medical personnel and third parties;

d) selection methods regarding the literature sources used, the statistics analysis methods, assessment methods applied, the investigation type and duration, heterogeneity and the population included in the investigation;

e) final assessment of the benefit from the use of the device compared to the risk, taking into account the modern scientific achievements and the medical practice;

f) conclusion pointing out whether the purposes set out in the tasks have been fulfilled, identification of shortcomings in the conformity assessment of the device with the essential requirements regarding safety and intended clinical effect, and, where necessary, reasons for conducting clinical trials – goals and plan of the investigation.

19. "A person, established on the territory of a Member State or a state from the European Economic Area" means a person registered according to the civil or trade legislation of a Member State or a state from the European Economic Area, or an entity established by a legislation act, having a business and registered office in a Member State or a state from the European Economic Area.

20. "Personal protective equipment" shall mean any equipment or device designed to protect a person against one or more hazards likely to endanger his safety and health. Personal protective equipment shall also be considered the following:

a) entirety of equipment or devices or means interrelated by the manufacturer for the purpose of protecting a person from one or numerous hazards which may occur at the same time;

b) protective equipment or device connected with a personal device with no protective function in a manner allowing or not separation, utilized by a person for a certain activity.

c) replaceable compounds of a personal protective device, which are essential for its proper functioning and which are being used solely for the same personal device.

21. (amend. – SG 110/08, in force from 21.03.2010) "Medical device" means any instrument, apparatus, appliance, software, material or other device, whether used alone or in combination, including software, designated by the manufacturer to be used specifically for diagnostic and/or therapeutic purposes and required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means and which is intended by the manufacturer to be used for human beings for the purpose of:

a) diagnosis, prevention, monitoring, treatment or alleviation of diseases;

b) diagnosis, monitoring, treatment, alleviation or compensation of trauma or disability;

c) investigation, replacement or modification of the anatomy or of a physiological process;

d) control of conception process.

22. (amend. – SG 110/08, in force from 21.03.2010) "Device intended for clinical testing" means any medical device referred to in Art. 2, para 1, items 2 and 3, intended to be used by a medical specialist of by another specialist, having relevant for the testing purposes qualification, for conducting clinical testing in the medical establishment in order to achieve the objective referred to in Art. 32.

23. (amend. – SG 110/08) "Custom-made device" e means any medical device referred to in Art. 2, para 1, items 2 or 3, specifically made in accordance with a written prescription by a medical expert or a person with relevant professional qualification, which gives, under his/her responsibility, specific design characteristics of the device and is intended to be used only for an individual named patient.

Mass-produced devices, adapted in order to meet the specific requirements of the medical practitioner or of any other trained user are not considered to be custom-made devices.

24. "Multi-centre clinical trial" means a clinical trial conducted according to a single trial plan but at more than one investigation centre/medical establishment, and therefore by more than one investigator. The investigation centres may be located in the territory of a single Member State, in a number of Member States and/or in Member States and third countries;

25. "Observer" means a person, appointed by the assignor, monitoring whether the clinical investigation at each of its stages is being conducted, recorded and reported according to the protocol, the standard operative procedures, the Good Clinical Practice an the applicable control requirements.

26. "A person independent from the assignor" is a natural person acquainted with the characteristics and the operation of the medical device – subject to a clinical investigation, and with the methodology of conducting such, and who is financially independent from the assignor.

27. "Clinical trial plan" is a document providing information on the purposes, design, methodology, statistical methods and organization of a clinical investigation.

28. "Intended purpose" means the use for which a medical device has been designated according to the data provided by the manufacturer on its label, the instructions for use and/or the advertisement notices.

29. "Accessory" means an Art. which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to in vitro diagnostic medical devices;

30. "Manufacturer" means the natural or legal person who:

a) is responsible for the design, manufacture, packaging and labelling of a device before it is

placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;

b) (amend. – SG 11/08) assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name.

Natural or legal persons who assembles or adapts devices already on the market to their intended purpose for an individual patient shall not be considered manufacturers within the meaning of this Act.

31. "Putting into service" means the stage at which a device has been made available to the final user as being ready for use in a Member State or a state from the European Economic Area for the first time for its intended purpose. of An active implantable medical device shall be considered put into service when made available to a qualified expert for implanting.

32. "Placing on the market" means the first making available in return for payment or free of charge of a device, other than a medical device for clinical trial and a device intended for performance evaluation, with a view to distribution and/or use on the territory of the European Union or the European Economic Area, regardless of whether it is new or fully refurbished.

33. "Serious health damage" means:

1. life-threatening condition, illness or harm;

2. lasting harm to the life functions or to a human organ or tissue;

3. a condition which requires medical or surgical intervention in order to prevent the damages under item 2;

34. "Human specimen receptacles" are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

35. "Essential amendment in the clinical trial plan" means any amendment in the plan and/or the information contained in the documentation that goes along with it, which affects:

a) the safety or the physical and mental integrity of the persons involved;

b) the scientific value of the investigation;

c) the conducting or organization of the trial.

35a. (new - SG 38/15, in force from 26.05.2015) "Third country" shall mean any which is not an EU member or not a state - party to the Agreement on the European Economic Area or Swiss Confederation.

36. (amend. – SG 54/12) "Retail trade" are all activities related to acquisition, storage and sale of medical devices to the population.

37. (amend. – SG 54/12) "Wholesale trade" are all activities related to acquisition, storage, supply, import or export of medical devices intended for sale, except the cases of providing medical devices directly to the population.

38. (amend. – SG 110/08) "Authorised representative" means any natural or legal person established on the territory of a Member State or a state from the European Economic Area who, explicitly authorized by the manufacturer to act on his/her behalf and for his/her account before regulatory bodies of the Member States or the regulatory bodies of the states of the European Economic Area for the fulfillment of manufacturer's obligations under this Act.

§ 2. (amend. – SG 110/08, in force from 21.03.2010) This Act introduces the requirements of Directive 90/385/EEC of the Council of 20 July 1990 on the approximation of the legislation of Member States relating to active implantable medical devices, last amended with Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending the Directive 90/385/EEC of the Council on the approximation of the legislation of Member States relating to active implantable

medical devices, of Directive 93/42/EEC of the Council concerning the medical devices and of Directive 98/8/EC concerning the placing on the market of biocidal products (OJ, L 247/21 of 21 September 2007), of Directive 93/42/EEC of the Council of 14 June 1993 of medical devices, last amended by Directive 2007/47/EC of the European Parliament and of the Council and of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, last amended by Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to the Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Art. 251 of the EC Treaty.

§ 3. (1) Names and registration numbers of harmonized European standards and the monographs of the European pharmacopoeia for medical devices are published in the Official Journal of EU.

(2) Harmonized European Standards are introduced identically through publishing the text of the standard in Bulgarian language or confirming their application as a Bulgarian Standard pursuant to the National Standardisation Act.

(3) Names and registration numbers of the Bulgarian standards introducing the harmonized European standards are published in the official bulletin of the State Agency for Metrology and Technical Surveillance and upon publishing it is obligatory that reference to the relevant regulation under Art. 18 is indicated.

§ 4. (1) The general technical specifications determine the requirements for assessment and re-assessment of service, placing on the market and/or putting into service of batches, referent methods and referent materials regarding in-vitro diagnostic medical devices.

(2) The general technical specifications are published in the Official Journal of the EU.

§ 4a. (new - SG 38/15, in force from 26.05.2015) The Executive Director of BDA may delegate his or her powers under this Act to the Deputy Executive Director of BDA.

Transitional and concluding provisions

§ 5. (1) Traders, who have been authorized to carry out wholesale trade in medicines - medical devices, the authorization being issued after December 29, 2002 pursuant to the repealed Act on Medicines and Pharmacies in Human Medicine, shall, within three months from the entry into force of the Act, submit an application form for entry ex officio in the register as per Art. 81, to which shall be attached the documents under Art. 78, para 1, items 1 and 2, para 2, items 3 and 4, as well as a statement that there is a change in the address of the storage and trade premises.

(2) Within 30 days from the submission of the documentation under para 1 the executive director of BDA shall issue an authorization for wholesale trade in medical devices.

(3) By granting the authorization under para 2 the wholesale trade permission issued pursuant to the repealed Act on Medicines and Pharmacies in Human Medicine shall be considered annulled.

§ 6. Traders, who have obtained authorization for wholesale trade in medicines without time limit, issued after December 29, 2002 pursuant to the repealed Act on Medicines and Pharmacies in

Human Medicine, shall submit an application along with the required documents for obtaining authorization for wholesale trade in medical products pursuant to the present Act by 31 December 2007.

§ 7. Traders, who have obtained authorization for wholesale trade in medicines without time limit, issued after December 29, 2002 pursuant to the repealed Act on Medicines and Pharmacies in Human Medicine, shall submit an application along with the required documents for obtaining authorization for wholesale trade in medical products pursuant to the present Act by 31 December 2007.

§ 8. Applications for granting authorization for wholesale trade in medical devices, which have been submitted before the entry into force of this Act shall be considered and completed under the terms and following the procedure provided by it.

§ 9. (1) Authorizations for use issued pursuant to the repealed Act on Medicines And Pharmacies in Human Medicine, shall be considered annulled from the date of entry into force of the present Act.

(2) Manufacturers of medical devices as per Art. 29, paras 1 and 2, whose authorizations have been annulled according to para 1, shall submit notifications in a form to the executive director of BDA within three months from entry into force of this Act.

§ 10. The quantities of medical devices available, whose conformity with the essential requirements as per Directives 90/385/EEC, 93/42/ EC и 98/79/EC at wholesale trade warehouses, pharmacies, drugstores, optics and other commercial sites can be sold for one-year period from the entry into force of the present Act.

§ 11. Medical devices shall be manufactured, stored and renewed as a state reserve and war-time reserves under the terms and following the procedure of the State Reserve and War-Time Stocks Act and the acts for its implementation.

§ 12. The Council of Ministers shall make amendments in the structural regulations of BDA and the State Agency for Metrology and Technical Surveillance in three-months term from the promulgation of this Act in the State Gazette.

§ 13. By-laws related to implementation of the Act shall be issued within six months from the date of promulgation of this Act in the State Gazette.

§ 16. The Act shall enter into force from the date of its promulgation in the State Gazette, except for the provisions of Art. 4, para 2, which shall enter into force from 29 December 2009.

This Act has been passed by the 40th National Assembly on 29 May 2007 and has been affixed by the official seal of the National Assembly.

Concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE MEDICAL DEVICES ACT

(PROM. – SG 110/08)

§ 51. The Council of Ministers within 6 months after entering of this Act into force shall adopt the ordinance referred to in Art. 30a, par. 2.

§ 52. The Minister of Health within two months after entering of this Act into force shall adopt the ordinance referred to in Art. 32a.

…….

§ 54. The provisions of § 1, item 1, § 2, 5, 8, 10, 15, § 16 , item 3, 4 and 5, § 17, 18, 20, 21, 22, 23, 24, 25, 26, 27, 31, 45, 47 and § 50, item 1, items "a", "b", "c" and item 2 shall enter into force from 21 March 2010.

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE HEALTH ACT

(PROM. – SG 41/09, IN FORCE FROM 02.06.2009).

§ 96. The Act shall enter into force from the date of its promulgation in the State Gazette, except for:

1. paragraphs 3, 5, 6 and 9, which shall enter into force from January the 1st 2009;
2. paragraphs 26, 36, 38, 39, 40, 41, 42, 43, 44, 65, 66, 69, 70, 73, 77, 78, 79, 80, 81, 82, 83, 88, 89 and 90, which shall enter into force from July 1st 2009;
3. paragraph 21, which shall enter into force from June 1st 2010.

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE TOURISM ACT

(PROM. – SG 82/03, IN FORCE FROM 16.10.2009)

§ 59. This Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE MEDICAL DEVICES ACT

(PROM. – SG 39/11, IN FORCE FROM 01.01.2012)

§ 4. Within two months from entry into force of this Act the Council of Ministers shall adopt an ordinance under Art. 30a, Para 3.

§ 5. This Act shall enter into force from 1 January 2012.

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE MEDICINAL PRODUCTS IN UMAN MEDICINE ACT

(PROM. – SG 60/11, IN FORCE FROM 05.08.2011)

§ 84. This Act shall enter into force from the day of its promulgation in the State Gazette, except for § 65, which shall enter into force from 30 September 2011.

Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE MEDICAL DEVICES ACT

(PROM. – SG 54/12)

§ 28. The applications for issue of authorisations or certificates for wholesale trade in medical devices filed before entry into force of this Act shall be processed under the conditions and order stipulated therein.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON PROTECTION FROM THE DANGEROUS IMPACT OF CHEMICAL SUBSTANCES AND MIXTURES

(PUBL. – SG 84/2012, IN FORCE FROM 02.01.2013)

§13. The electric and electronic equipment (EEE) which does not fall in the scope of Annexes N 1 and 2 in the Ordinance on requirements for placing on the market EEE and treatment and transportation of EEE wastes (publ. SG, 36/2006; amend. 57/2006, 53/2008, 5/2009 and 29/2011) but does not comply with the requirements of Chapter Five “a” and the ordinance under Art. 21e, Para. 1, may continue to be provided on the market by 22 July 2019, if this is in compliance with § 12, p. 1 – 5.

§ 14. The council of Ministers shall adopt the ordinance under Art. 21e, Para. 1 within 3 month term from the publication of this act in the State Gazette.

§ 15. This act shall come into force from 2 January 2013.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTATING THE ACT ON PROHIBITION OF CHEMICAL WEAPONS AND ON CONTROL OF TOXIC CHEMICAL AGENTS AND THEIR PRECURSORS

(PROM. – SG, 14/2015)

§ 20. In the Medical Devices Act the words "the Minister of Economy, Energy and Tourism" shall be replaced by "the Minister of Economy" and "the Ministry of Economy" everywhere.

Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL DEVICES ACT

(PROM. - SG 38/15, IN FORCE FROM 26.05.2015)

§ 32. The Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE VETERINARY PRACTICE ACT

(PROM. - SG 14/16, IN FORCE FROM 19.02.2016)

§ 103. This Act shall enter into force from the day of its promulgation in the State Gazette with exception of § 24 in connection with Art. 118, Para 2 and 3, which shall enter into force from January 1st 2018.

Appendix to Art. 15, para 1

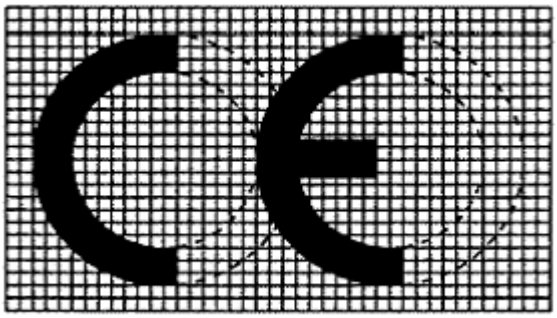

Translation from Bulgarian

ORDINANCE № 10 OF 2008 ON THE DOCUMENTS REQUIRED FROM THE PRINCIPAL/COORDINATING INVESTIGATOR OR SPONSOR FOR OBTAINING AN ETHICS COMMITTEE STATEMENT AND ON THE PROCEDURE FOR SAFETY MONITORING OF MEDICAL DEVICES DURING CLINICAL INVESTIGATIONS AND ASSESSMENT OF THE CLINICAL DATA COLLECTED DURING SUCH INVESTIGATIONS (TITLE AMENDED IN STATE GAZETTE, ISSUE 31 OF 2009, EFFECTIVE AS OF 21 MARCH 2010)

Issued by the Ministry of Health

Promulgated in SG, issue 46 of 16 May 2008, amended in SG, issue 31 of 24 April 2009

Section I
General Provisions

Article 1 (Supplemented SG issue 31 of 2009, effective as of 21 March 2010). This ordinance defines the contents of the documents required for obtaining an Ethics Committee statement pursuant to Article 47 of the Law on Medical Devices (LMD) and the procedure for safety monitoring of medical devices during clinical investigations and assessment of the clinical data collected during such investigations.

Section II
Required documents for obtaining a clinical investigation authorization

Article 2. To obtain a statement from the Ethics Committee, the person referred to in Article 46 of LMD has to submit the following administrative documents in accordance with Article 48, paragraph 1 (1) of LMD:

1. A valid request;

2. A list of all Competent Authorities and Ethics Committees to which an authorization/ statement request/notice has been submitted;

3. A list of all planned medical centres, investigators and investigating teams in Bulgaria;

4. Name and address of the clinical investigation monitor;

5. A written authorization letter for the person submitting the application on behalf of the sponsor, if the applicant is not the sponsor of the clinical investigation;

6. A certificate of current registration of the sponsor and applicant within the European Union, issued by a Competent Authority.

Article 3. Pursuant to Article 48, paragraph 1 (2) of LMD, the information about the subjects of the clinical investigation has to include:

1. The information specified in Article 37, paragraph 1 (1) and (2) of LMD, intended for the subject;

2. A written informed consent form signed by the subject of the clinical investigation;

3. Description of the procedures for recruiting subjects for the clinical investigations;

4. Description of the procedures for obtaining an informed consent from a legal representative in the cases specified in Articles 37, 38 and 39 of LMD;

5. An ethical justification for the recruitment of subjects who are incapable of giving an informed consent as in the cases specified in Article 39 and 40 of LMD;

6. A copy of any other information which will be used in the recruitment of subjects and/or will be provided to subjects before or during the clinical investigation.

Article 4. (1) The documents related to the clinical investigation protocol as specified in Article 48, paragraph 1 (3) of LMD, have to include:

1. A clinical investigation protocol, as last amended;

2. A summary of the protocol in Bulgarian;

3. An assessment of the scientific value of the investigation by an expert in the field, if available, and justification of the clinical investigation project and the proposed protocol;

4. An ethical evaluation of the protocol by the principal or coordinating investigator of the potential risks for the health of subjects when using a medical device not included in the protocol.

(2) The clinical investigation protocol has to contain:

1. Assessment of the expected benefits and the potential risks under Article 34 (3) of LMD, as well as methods and ways of eliminating or reducing risks, if they cannot be prevented;

2. A list of inclusion and exclusion criteria;

3. Justification of the choice of subjects, especially in the cases when these subjects are incapable of giving their informed consent or belong to other vulnerable patient groups;

4. Description of the procedures for recruiting subjects and obtaining an informed consent from subjects who are temporarily or permanently incapable of giving their informed consent, or when consent is to be obtained from an independent witness;

5. Description of the protocol and procedures for providing further medical care for the subjects after the end of the investigation;

6. Procedures for supervision of the investigation;

7. The protocol for publication of collected data;

8. Description of procedures ensuring confidentiality;

9. Document(s) containing codes identifying the subjects and information on any further treatment or measures that have to be undertaken in case of emergency;

10. A report form provided during the investigation, and a final report form in accordance with Article 57, paragraph 1 of LMD;

11. A report form for reporting incidents/potential incidents related to the device, which occurred during the clinical investigation.

(3) The protocol has to be signed by the sponsor and the principal investigator of

each of the proposed medical centres.

Article 5. (1) Pursuant to Article 48, paragraph1 (4) of LMD, the documents related to the tested device have to contain:

1. Investigator's brochure containing full and scientifically justified information on the product, which is required for an objective evaluation of the risk-benefit ratio associated with the proposed clinical investigation;

2. A summary of all clinical investigations conducted so far with the medical device in question;

3. Summarized information from existing literature and an expert evaluation supporting the justification of the intended use of the device and the clinical investigation design;

4. A general description of the device and its components;

5. A description of the materials used in the composition and manufacturing of the device;

6. A description of the operation of the device, including information from scientific literature, instructions for use and assembly of the device, potential risks, counter indications, warnings, etc.;

7. A description of the intended use of the medical device;

8. A summary and assessment of in vitro and/or ex vivo data, including preclinical data, such as biological tests, non-clinical laboratory tests and tests on animals;

9. A summary of the clinical experience with the device or with other devices with similar intended use;

10. A list of the fully or partially applied standards and a description of the solutions adopted to ensure conformity to the essential requirements, when these standards are not applied or are only partially applied;

11. Risk analysis results.

(2) The sponsor has to keep the investigator's brochure up to date by modifying it each time new information is supplied during the clinical investigation and provide it to the investigators.

Article 6. (1) The documents on the technical possibilities of the medical centre and the professional qualification of the investigators under Article 48, paragraph 1 (5) of LMD, have to include:

1. A description of the required equipment and/or technical requirements for implementing the protocol;

2. Documents proving the technical possibilities of the proposed medical centre to implement the protocol;

3. (Amended SG issue 31 of 2009, effective as of 21 March 2010) A curriculum vitae and/or other documents certifying the training and qualification of the members of the investigating team.

(2) The documents specified in paragraph 2 above have to be drawn up by the head of the medical centre in which the procedure described in the protocol and requiring specific equipment is planned to take place.

Article 7. The documents related to the administrative organization and funding of the investigation referred to in Article 48, paragraph 1 (6) of LMD have to contain:

1. An insurance agreement covering the liability of the sponsor and of the principal/coordinating investigator for any material or non-material damages caused to the subjects during or in relation to the clinical investigation;

2. Information on indemnity and compensation in case of death or injury of a subject during the clinical investigation;

3. A contract signed by the sponsor and the subjects in the clinical investigation specifying the compensation (travel and subsistence costs) when such is provided for in accordance with Article 34, paragraph 5 of LMD;

4. A contract signed by the sponsor and the investigator(s);

5. A contract signed by the sponsor and the medical centre(s);

6. Information on the funding source of the study when the sponsor is a non-profit entity.

Section III

Required documents for amendment of clinical investigation authorization

Article 8. (Amended in SG issue 31 of 2009, effective as of 21 March 2010) A substantial amendment under Article 54, paragraph 1 of LMD means a change in the details specified in Annex I.

Article 9. (1) When planning substantial amendments to the clinical investigation and the documents under Article 48, paragraph 1 of LMD, the sponsor, or a duly authorized representative, has to submit a written request to the Ethics Committee as provided for in Article 54 of LMD.

(2) This request has to be accompanied by the following documents:

1. A cover letter;
2. A summary of the proposed amendments;
3. A list of updated documents;
4. Updated documents under Article 2 - 7, specifying the amendments;
5. Pages of the documents with highlighted changes for comparison of the current texts and the proposed amended texts;
6. A justification of the amendments;
7. A copy of the clinical investigation request under Article 2 with highlighted changes both in electronic format and on paper.

Article 10. (1) (Amended SG issue 31 of 2009, effective as of 21 March 2010) When planning substantial amendments to the clinical investigation and the documents referred to in Article 50, paragraph 1 of LMD, the sponsor, or a duly authorized representative, has to submit a written request for the said amendments to the Bulgarian Drug Agency (BDA).

(2) This request has to be supported by the documents specified in Article 9, paragraph 2 (1 – 7), the declaration specified in Article 50, paragraph 4 of LMD, and a copy of the Ethics Committee statement when it becomes available.

(3) Another document that has to be submitted is the request specified in Article 50, paragraph 1 of LMD, containing updated information reflecting the proposed amendments, and a copy with highlighted changes both in electronic format and on paper.

Article 11. (1) The documents for obtaining authorization or amending a clinical investigation have to be submitted in Bulgarian and/or English.

(2) The documents specified in Article 2, paragraphs 1 and 2, Article 3, paragraphs 1, 2 and 6, Article 4, paragraph 1 (2), Article 6, paragraph 1, (1), (2) and (3), Article 7, Article 10, paragraph 1, and Article 18 have to be submitted in Bulgarian as well.

(3) The request under Article 10, paragraphs 1 and 3 has to be submitted in English as well.

Article 12. (1) The Executive Director of the Bulgarian Drug Agency (BDA) has to issue an order for the approval of the requests specified in Articles 2, 9 and 10.

(2) These requests have to be submitted in electronic format and on paper.

(3) The electronic copies must be submitted in the format established for clinical investigations that need to be entered in the European database.

(4) The sponsor, or a duly authorized representative, has to certify that the electronic and paper copies of the requests contain identical information.

Section IV

Procedure for safety monitoring of medical devices during clinical investigations and assessment of clinical data collected during such investigations (Title amended in SG, issue 31 of 2009, effective as of 21 March 2010)

Article 13. The sponsor has to collect and conduct continuous assessment of the safety of the tested medical devices, taking into consideration:

1. Any additional information on the risks for the medical device which may pose a risk to the health or safety of the subjects in the clinical investigation, or information that might lead to an amendment to the clinical investigation protocol;

2. The investigator's reports and assessment of any adverse effect or event in terms of the cause and effect relationship and the seriousness of such effects;

3. Each serious adverse event assessed by the investigator as possibly related to the tested device must be properly handled and reported.

Article 13a (New SG issue 31 of 2009, effective as of 21 March 2010) (1) The assessment of the clinical data collected during a clinical investigation of devices referred to in Article 2, paragraph 1 (3) of LMD, has to be carried out in compliance with Annex II.

(2) The assessment of the clinical data collected during a clinical investigation of active implantable devices has to be carried out in compliance with Annex III.

Article 13b (New SG issue 31 of 2009, effective as of 21 March 2010) (1) The clinical investigation has to be supervised by an investigator who is:

1. A medical doctor or a dentist qualified to use the tested device and specially trained to work with it;

2. Familiar with the methods and requirements for conducting the clinical investigation;

3. Familiar with the principles and requirements for obtaining an informed consent.

(2) The investigating team has to be properly qualified and experienced, and to have undergone special training for completing the operations involved in the investigation.

(3) Supervision of the clinical investigation is performed by the sponsor or a duly authorized representative as specified in Article 42, paragraph 1 or 2 of LMD, or by a monitor appointed by the sponsor.

(4) During the clinical investigation, the medical doctor or dentist has to monitor the health of the subject and to take any medical measures that may be required.

(5) The sponsor is liable for any damages to the health of a patient or a patient's

death caused during or in relation to the clinical investigation, when the investigation is carried out in compliance with the requirements and procedures specified in the protocol approved by the Ethics Committee.

(6) The principal or the coordinating investigator are liable for any damages to the health of the patient or the patient's death caused during or in relation to the clinical investigation, when the requirements and procedures specified in the protocol approved by the Ethics Committee have not been observed.

Article 14. (1) The sponsor or investigator has to undertake urgent action for protecting the subjects in the clinical investigation in case of unexpected risks for their safety or health.

(2) If such emergency as described in paragraph 1 occurs, the sponsor has to notify immediately BDA and the Ethics Committee of any action which has been taken and of any reasons which are known to have caused the emergency.

Article 15. (1) The principal investigator has to notify immediately the sponsor, either in writing or orally, of any serious adverse events which occur during the clinical investigation.

(2) After notifying the person specified in paragraph 1 above, the investigator has to submit a detailed report in writing in the format and within the terms set forth in the clinical investigation protocol, where the subject is identified by means of a code as specified in the protocol.

(3) The investigator has to report to the sponsor any adverse events defined in the protocol as critical in relation to safety, in the format and within the terms set forth in the clinical investigation protocol.

(4) In multi-centre investigations, the sponsor has to inform all investigators conducting the specific clinical investigation about the reported serious adverse events related to the tested medical device.

Article 16. When the outcome of such adverse events is death, the investigator has to supply the sponsor and the Ethics Committees with any further information that

they may require.

Article 17. The sponsor has to keep detailed records of any serious adverse events reported by the investigators, and to provide them upon request to BDA or the Competent Authorities of the member states in the cases of multi-centre clinical investigations.

Article 18. (1) The sponsor has to submit a report to BDA, the Competent Authorities of all member states in which the clinical investigation takes place, and to the specific Ethics Committee, on any unexpected serious adverse events which occur during the clinical investigation and cause the death or a serious injury or damage to the health of a subject, hereinafter referred to as 'incident', within 7 days of receiving information about it.

(2) The sponsor has to notify the authorities specified in paragraph 1 above of any further information on the case within 8 days of the date of the report.

(3) The sponsor has to submit a report to the authorities specified in paragraph 1 above on any other adverse events which occur during the clinical investigation, other than those specified in paragraph 1 above, hereinafter referred to as potential incidents, within 15 days of receiving information about them.

Article 19. (1) The sponsor has to submit a report to BDA on incidents with medical devices bearing the CE marking, which are applied in combination with the tested medical device during the clinical investigation.

(2) In the cases specified in paragraph 1 above, the sponsor has to notify the manufacturer, or the duly authorized representative, of the incident and of the information submitted to BDA.

(3) In the cases specified in paragraph 2 above, the manufacturer or the duly authorized representative does not have to submit reports on the incidents to BDA.

Article 20. Once a year, the sponsor has to submit to BDA and the respective Ethics Committee a list of all incidents / potential incidents which have occurred during

the past period, as well as a report on the safety of the subjects.

Article 21. (1) The reports on incidents / potential incidents during a clinical investigation have to contain at least the following:

1. Administrative information on the clinical investigation;

2. Information about the sponsor;

3. Information about the duly authorized representative;

4. Information about the source of the details presented in the report;

5. Identification of the medical device;

6. The diagnosis which the device was indicated for and any other concurrent diseases of the subject;

7. The condition of the subject during the clinical investigation and a plan for monitoring his/her health status;

8. Information about the incident/potential incident

(2) The report specified in paragraph 1 above has to be signed by the investigator.

Article 22. (1) The Bulgarian Drug Agency has to record, analyse, and summarize any information provided under Article 20 about any incidents / potential incidents involving medical devices, which occurred during the clinical investigations, and has to take specific measures in compliance with Article 59 of LMD.

(2) The Bulgarian Drug Agency has to submit information on any incidents with medical devices which occurred during clinical investigations, as well as any other information other than the information entered in the European database, whenever such is requested by another member state or by the European Commission.

(3) By completing its obligations under paragraph 1 above, BDA complies with the guidelines published by the European Commission.

Section V

Supervision

Article 23. (1) The clinical investigations conducted in Bulgaria are supervised by inspectors and experts defined in specific orders issued by the Executive Director of BDA.

(2) The supervision covers preliminary inspections, ongoing control and follow-ups.

(3) The sponsor, the principal investigator and the other investigators, the medical centres, the Ethics Committees, the facilities where the tested device is manufactured and inspected, the laboratories, and any documents related to the clinical investigation, are subject to supervision.

Article 24. (1) Supervision of the clinical investigations is carried out in compliance with the standard operating procedures approved by the Executive Director of BDA. These standard operating procedures are drawn up in compliance with the guidelines set by the European Commission.

(2) Each inspection related to a clinical investigation of a medical device has to end with a report which is submitted to the sponsor.

(3) In case of any deficiencies, the clinical investigation is suspended until the moment when the deficiency is remedied or the investigation is terminated.

(4) A report on the inspection of a clinical investigation may be submitted to the investigators, the Ethics Committee in case of multi-centre investigations, the other EU member states and the European Commission.

Additional Provisions

§ 1. For the purposes of this ordinance the following words and phrases shall have the following meanings:

1. 'Adverse effect' is any untoward and unexpected response to the medical device when used in compliance with the manufacturer's instructions, including as a result of inadequacies or deficiencies in the instructions for use or as a result of the user's fault.

2. 'Unexpected deterioration': a case of deteriorating health is considered as

unexpected if the circumstances that led to the event were not accounted for in the risk analysis made by the manufacturer.

3. 'Adverse event' is any untoward event involving a subject in the clinical investigation, which does not necessarily have a causal relationship with the tested medical device.

4. 'Serious adverse event' is an untoward event leading to:

1. Death;

2. Serious damages to the health of the subject in the investigation;

3. Damages to an embryo, death of an embryo, or congenital anomalies or birth defects;

5. 'Serious damages to the health' are:

1. Life-threatening conditions or diseases, or injuries;

2. Persistent disability or loss of a vital function or damage to the structure of the body;

3. Conditions requiring hospitalization or significant prolongation of existing hospitalization;

4. Conditions requiring medical care or surgical intervention to prevent damaged as the ones specified in (2) above.

6. 'Incident' is any malfunction or deterioration in the characteristics and/or performance of a device, as well as any incomplete or inadequate information on the label or in the instructions for use which caused the death or serious damages to the health of the patient, user, or to other people.

7. 'Potential incident' is any malfunction or deterioration in the characteristics and/or performance of a device, as well as any incomplete or inadequate information on the label or in the instructions for use, which could directly or indirectly cause the death or serious damages to the health of a person, but which have been prevented thanks to favourable circumstances or medical intervention.

§ 1a. (New – SG issue 31 of 2009, effective as of 21 March 2010) This ordinance introduces the provisions from Directive 90/385/EEA of the Council on the approximation of the laws of the member states related to active implantable medical

devices (promulgated in the Official Journal, Special Issue 2007, chapter 13, volume 9), last amended by Directive 2007/47/EC (promulgated in OJ, L 247 of 21 September 2007, p. 21 - 55), and from Directive 93/42/EEA of the Council, concerning the medical products (promulgated in OJ, Special issue 2007, chapter 13, volume 11), last amended by Directive 2007/47/EC.

Final Provisions

§ 2. (Supplemented in SG issue 31 of 2009, effective as of 21 March 2010) This ordinance is issued pursuant to Article 32a, Article 48, paragraph 2 and Article 58, paragraph 3 of the Law on Medical Devices.

Final Provisions

OF THE ORDINANCE AMENDING AND SUPPLEMENTING ORDINANCE № 10 OF 2008 ON THE DOCUMENTS REQUIRED FROM THE PRINCIPAL/COORDINATING INVESTOGATOR OR SPONSOR FOR OBTAINING AN ETHICS COMMITTEE STATEMENT AND ON THE PROCEDURE FOR SAFETY MONITORING OF MEDICAL DEVICES DURING CLINICAL INVESTIGATIONS

(Promulgated in SG issue 31 of 2009, effective as of 21 March 2010)

§ 12. This ordinance becomes effective on 21 March 2010.

Annex I to Article 8

(Previous Annex to Article 8 - SG issue 31 of 2009, effective as of 21 March 2010)

Amendment of details leading to substantial changes:

1. Amendments to the protocol:

1.1. Amendments to the purpose of the investigation.

1.2. Amendments to the design and/or methods of the investigation, or to the preliminary information on which its scientific value is based.

1.3. Amendments to the following documents required for the investigation:

1.3.1. Informed consent;

1.3.2. Information about the subject;

1.3.3. Information about the legal representative and/or the person who takes care of the subject;

1.3.4. Questionnaires, invitations, letters to the attending physician or other investigators;

1.4. Amendments to the procedure for recruitment of subjects;

1.5. Amendments to the effectiveness indicators;

1.6. Amendments to the protocol for obtaining biological materials for testing;

1.7. Inclusion or exclusion of tests;

1.8. Amendments to the age range for participation;

1.9. Amendments to the inclusion and exclusion criteria.

1.10. Amendments to the procedure for safety monitoring;

1.11. Amendments to the duration of use of the tested product;

1.12. Amendments to the way in which the tested product is used;

1.13. Amendments to the statistical plan;

1.14. Any amendment concerning the safety and the physical and/or mental integrity of the subjects, or the risk/benefit ratio associated with the investigation;

1.15. Amendments to the definition for termination of an investigation;

2. Amendments to the administrative organization of the investigation:

2.1. Change of the sponsor and/or the duly authorized representative;

2.2. Change of the approved medical centre;

2.3. Appointment of a new principal investigator or another major member of the investigating team;

2.4. Inclusion of another medical centre;

2.5. Appointment of a new principal investigator in an approved medical centre;

2.6. Amendments to the terms and conditions of the insurance or the procedures for indemnifying the subjects in the investigation;

2.7. Other significant amendments to the protocol and/or the original documentation submitted with the request;

3. Amendments concerning the quality of the tested medical device:

3.1. Change of the name of the tested product;

3.2. Change of the materials used as primary package;

3.3. Change of the importer of products manufactured outside the European Union;

3.4. Change of manufacturer;

3.5. Amendments to the manufacturing process of any component of the product;

3.6. Major changes of the manufacturing process of the tested product;

3.7. Changes of the characteristics of the tested product when this involves expansion of the acceptable limits and/or exclusion of tests;

3.8. Change of the characteristics of substances which can affect the properties of the product.

3.9. A major change of the composition.

3.10. Limitations on the storage conditions;

3.11. Shortening of the expiration period;

3.12. Amendments to the procedures for testing the product when a new testing method is introduced;

3.13. Amendments to the procedures for testing non-pharmacopoeia substances when a new testing method is introduced;

4. Any changes in the non-clinical data about the tested medical device which may affect the risk/benefit ratio;

5. Any changes in the clinical data about the tested medical device which may affect the risk/benefit ratio.

Annex II to Article 13a, paragraph 1

(New – SG issue 31 of 2009, effective as of 21 March 2010)

Assessment of the clinical data collected during the investigations of devices under Article 2, paragraph 1 (3) of LMD.

1. General provisions

1.1. The statement and conformity to the requirements refer to the characteristics and the performance of the medical devices according to chapter two of the Ordinance on the essential requirements and procedures for assessment of compliance with the essential requirements for medical products under Article 2, paragraph 1 (3) of LMD, adopted by resolution № 186 of 2007 of the Council of Ministers (promulgated in SG issue 65 of 2007; amended and supplemented in issue 106 of 2008). They are defined for normal conditions of use of the products with further assessment of the side effects and the acceptability of the risk/benefit ratio under the terms of Article 15 of the Ordinance on the essential requirements and procedures for assessment of conformity to the essential requirements for medical products under Article 2, paragraph 1 (3) of LMD. The assessment of this information hereinafter referred to as 'clinical assessment' is carried out in compliance with a specific methodologically relevant procedure, taking account of all applicable harmonized standards. The clinical assessment is based on one or more of the following criteria:

1.1.1. Critical assessment of the specific scientific literature on the safety, performance, design characteristics and the intended use of the product when:

a) The product in question and the product for which the information refers are identical;

b) The information indicates clearly and accurately conformity to the specific essential requirements;

1.1.2. Critical assessment of the results from the clinical investigations;

1.1.3. Critical assessment of the general clinical information under paragraphs

1.1.1 and 1.1.2.

1.2. The information which is generated and used during the clinical assessment has to be kept in compliance with Chapter 8a of LMD.

1.3. Clinical investigations of implantable devices and Class III devices need not be conducted, if there is sufficient proof that the existing clinical data is reliable.

1.4. The clinical investigation and its results have to be recorded. These records have to be included and/or described in detail in the technical characteristics of the product.

1.5. The clinical assessment and the documents related to it have to be regularly updated in compliance with the information received from the monitoring after the product is placed on the market. A clinical monitoring need not necessarily be conducted as part of the protocol after the product is placed on the market, but this has to be properly justified and documented.

1.6. When it is not suitable to prove conformity to the essential requirements on the basis of clinical data, this has to be justified in a document containing the results of the risk management and taking account of the specific nature of the interaction of the device with the human body, to the indicated clinical investigations and the requirements of the manufacturer. The adequacy of the proofs of conformity to the essential requirements by assessment of the work, bench testing, and preclinical assessment, has to be duly justified.

2. Clinical investigations

2.1. Goals

The goals of the clinical investigations are:

- to test if under normal conditions of use the performance of the device will comply with that specified in Article 12 of the Ordinance on the essential requirements and procedures for assessment of conformity to the essential requirements for medical products under Article 2, paragraph 1 (3) of LMD;

- to detect any and all adverse side effects under normal conditions of use and to determine whether they pose a threat by interfering with the expected performance of the device.

2.2. Ethical considerations

The clinical investigations have to be carried out in compliance with the Declaration of Helsinki concerning the ethical principles during clinical investigations on human subjects. All measures concerning human protection have to be taken as provided for in the Declaration of Helsinki, and they are mandatory. This refers to each stage of the clinical investigation, from its conception and justification to the publication of the final results.

2.3. Methods

2.3.1. The clinical investigations have to be conducted in compliance with an appropriate clinical investigation protocol consistent with the latest scientific and technical achievements. They are intended to either validate or refute the manufacturer's claims about the product; these investigations have to include a sufficient number of observations so that they can underpin the scientific validity of their conclusions.

2.3.2. The procedure for conducting such an investigation has to be suitable for the specific product.

2.3.3. The clinical investigations have to be carried out under conditions which are similar to the normal conditions of use of the product.

2.3.4. All relevant characteristics, including those related to the safety, performance, and effects of the product on the patients have to be properly investigated.

2.3.5. The Bulgarian Drug Agency has to provide to the Competent Authorities of the other member states detailed information about any serious adverse events which occur during a clinical investigation conducted in Bulgaria.

2.3.6. The investigations have to be carried out under the supervision of an active practitioner, who is a medical doctor or a dentist, or of another authorized qualified person in a suitable environment.

The medical doctor/dentist or authorized person has to be provided access to the technical and clinical information on the product.

2.3.7. The written report signed by the medical doctor/dentist, or the responsible authorized person, has to contain critical assessment of all data collected during the clinical investigation.

Annex III to Article 13a, paragraph 2

(New – SG issue 31 of 2009, effective as of 21 March 2010)

Assessment of the clinical data collected during the testing of active implantable medical devices

1. General provisions

1.1. The statement and conformity to the requirements refer to the characteristics and the performance of the medical devices according to chapter two of the Ordinance on the essential requirements and procedures for assessment of the conformity to the essential requirements for active implantable medical devices, adopted by resolution № 185 of 2007 of the Council of Ministers (promulgated in SG issue 65 of 2007; amended and supplemented in issue 106 of 2008). They are defined for normal conditions of use of the products with further evaluation of the side effects and the acceptability of the risk/benefit ratio under the terms of Article 13 of the Ordinance on the essential requirements and procedures for assessment of the conformity to the essential requirements for active implantable medical devices. The assessment of this information hereinafter referred to as 'clinical assessment' is carried out in compliance with a specific methodologically relevant procedure, with consideration of all applicable harmonized standards. The clinical assessment is based on one or more of the following criteria:

1.1.1. Critical assessment of the specific scientific literature on the safety, operation, design characteristics and the intended use of the product when:

- The product in question and the product for which the information refers are identical; and

- The information indicates clearly and accurately conformity to the specific essential requirements;

1.1.2. Critical assessment of the results from all clinical investigations;

1.1.3. Critical assessment of the general clinical information under paragraphs 1.1.1 and 1.1.2.

1.2. Clinical investigations need not be conducted, if it is duly verified that the existing clinical data is reliable.

1.3. The clinical investigation and the results from it have to be recorded. These records have to be included and/or described in detail in the technical characteristics of the product.

1.4. The clinical assessment and the documents related to it have to be regularly updated in compliance with the information received from the monitoring after the product is placed on the market. A clinical monitoring need not necessarily be conducted as part of the protocol after the product is placed on the market, but this has to be properly justified and documented.

1.5. When it is not suitable to prove conformity to the essential requirements on the basis of clinical data, this has to be justified in a document containing the results of the risk management and with consideration to the specific nature of the interaction of the device with the human body, to the indicated clinical investigations and the requirements of the manufacturer. The adequacy of the proofs of conformity to the essential requirements by assessment of the work, bench testing, and preclinical assessment, has to be duly justified.

1.6. The information which is generated and used in the course of the clinical assessment has to be stored in compliance with Chapter 8a of LMD.

2. Clinical investigations

2.1. Goals

The goals of the clinical investigations are:

- to test if under normal conditions of use the performance of the device will comply with that specified in Article 10 of the Ordinance on the essential requirements and procedures for assessment of conformity to the essential requirements for active implantable medical products;

- to detect any and all adverse side effects under normal conditions of use and to determine whether they pose a threat by interfering with the expected performance of the device.

2.2. Ethical considerations

The clinical investigations have to be carried out in compliance with the

Declaration of Helsinki concerning the ethical principles during clinical investigations on human subjects. All measures concerning human protection have to be taken as provided for in the Declaration of Helsinki, and are mandatory. This is valid for each stage of the clinical investigation, from its very conception and justification to the publication of the final results.

2.3. Methods

2.3.1. The clinical investigations have to be conducted according to the stages of the clinical investigation protocol which are intended to either validate or refute the manufacturer's claims about the product. These investigations have to include a sufficient number of observations which can underpin the scientific validity of their conclusions.

2.3.2. The procedure for conducting such an investigation has to be suitable for the specific product.

2.3.3. The clinical investigations have to be carried out under conditions which are similar to the normal conditions of use of the product.

2.3.4. All relevant characteristics, including those related to the safety, performance, and effects of the product on the patients have to be properly investigated.

2.3.5. The Bulgarian Drug Agency has to provide to the Competent Authorities of the other member states detailed information about any serious adverse events which occur during a clinical investigation conducted in Bulgaria.

2.3.6. The investigations have to be carried out under the supervision of a qualified medical practitioner or an authorized person in a suitable environment. The medical doctor has to be given access to the technical information on the product.

2.3.7. The written report signed by the respective practitioner has to contain critical assessment of all data collected during the clinical investigation.

ZAKON
O OBVEZNOM ZDRAVSTVENOM OSIGURANJU

Interni pročišćeni tekst obuhvaća Zakon o obveznom zdravstvenom osiguranju ("Narodne novine" broj 80/13.), te njegove izmjene i dopune objavljene u "Narodnim novinama" broj 137/13. u kojima je naznačeno vrijeme njihovog stupanja na snagu

I. OPĆE ODREDBE

Članak 1.

(1) Ovim Zakonom uređuje se obvezno zdravstveno osiguranje u Republici Hrvatskoj, opseg prava na zdravstvenu zaštitu i druga prava i obveze osoba obvezno osiguranih prema ovome Zakonu, uvjeti i način njihova ostvarivanja i financiranja, kao i prava i obveze nositelja obveznoga zdravstvenog osiguranja, uključujući prava i obveze ugovornih subjekata nositelja za provedbu zdravstvene zaštite iz obveznoga zdravstvenog osiguranja.

(2) Izrazi koji se koriste u ovom Zakonu, a koji imaju rodno značenje, bez obzira na to jesu li korišteni u muškom ili ženskom rodu, obuhvaćaju na jednak način muški i ženski rod.

Članak 2.

Ovim se Zakonom u pravni poredak Republike Hrvatske prenosi Direktiva 2011/24/EU Europskog parlamenta i Vijeća od 9. ožujka 2011. o primjeni prava pacijenata u prekograničnoj zdravstvenoj zaštiti (SL L 88, 4. 4. 2011.) – u daljnjem tekstu: Direktiva 2011/24/EU.

Članak 3.

(1) Obvezno zdravstveno osiguranje provodi Hrvatski zavod za zdravstveno osiguranje (u daljnjem tekstu: Zavod).

(2) Obveznim zdravstvenim osiguranjem osiguravaju se svim osiguranim osobama Zavoda (u daljnjem tekstu: osigurana osoba) prava i obveze iz obveznoga zdravstvenog osiguranja na načelima uzajamnosti, solidarnosti i jednakosti, na način i pod uvjetima utvrđenim Uredbom (EZ) br. 883/2004 kako je posljednji put izmijenjena Uredbom EU br. 1224/2012 (u daljnjem tekstu: propisi Europske unije), Direktivom 2011/24/EU, ovim Zakonom, posebnim zakonom te propisima donesenim na temelju ovoga Zakona.

(3) U okviru prava iz obveznoga zdravstvenog osiguranja osiguravaju se i prava za slučaj ozljede na radu i profesionalne bolesti koje obuhvaćaju i mjere za provođenje specifične zdravstvene zaštite radnika te dijagnostičke postupke kod sumnje na profesionalnu bolest sukladno Zakonu o zdravstvenoj zaštiti i posebnim zakonima te pravilnicima donesenim na temelju tih zakona.

(4) Opseg prava iz obveznoga zdravstvenog osiguranja, koji se pod jednakim uvjetima osigurava svim osiguranim osobama, utvrđen je odredbama ovoga Zakona i propisima donesenim na temelju ovoga Zakona.

II. OBVEZNO ZDRAVSTVENO OSIGURANJE

Članak 4.

(1) Na obvezno zdravstveno osiguranje prema jednoj od osnova osiguranja utvrđenih ovim Zakonom obvezne su se osigurati sve osobe s prebivalištem u Republici Hrvatskoj i stranci s odobrenim stalnim boravkom u Republici Hrvatskoj, ako međunarodnim ugovorom, odnosno posebnim zakonom nije drukčije određeno.

(2) Osiguranim osobama kojima se osiguravaju prava i obveze iz obveznoga zdravstvenog osiguranja u smislu ovoga Zakona smatraju se osiguranici, djeca do navršene 18. godine života, članovi obitelji osiguranika i druge osigurane osobe obvezno zdravstveno osigurane u određenim okolnostima.

Članak 5.

Na obvezno zdravstveno osiguranje prema odredbama ovoga Zakona obvezno se osiguravaju i državljani drugih država članica Europske unije (u daljnjem tekstu: države članice) te državljani države koja nije država članica (u daljnjem tekstu: treća država) s odobrenim privremenim boravkom u Republici Hrvatskoj, a na temelju radnog odnosa kod poslodavca sa sjedištem u Republici Hrvatskoj, odnosno na temelju obavljanja gospodarske, odnosno profesionalne djelatnosti u Republici Hrvatskoj, ako su ispunjeni uvjeti prema posebnim propisima koji uređuju pitanje boravka i rada stranaca u Republici Hrvatskoj i ako propisima Europske unije, odnosno međunarodnim ugovorom nije drukčije određeno.

Članak 6.

(1) Prava i obveze koje pripadaju osiguranim osobama iz članka 4. stavka 2. ovoga Zakona i propisima donesenim na temelju ovoga Zakona ne mogu se prenositi na druge osobe niti se mogu nasljeđivati.

(2) Iznimno od odredbe stavka 1. ovoga članka, nasljeđivati se mogu prava na novčana primanja koja su dospjela za isplatu, a ostala su neisplaćena zbog smrti osigurane osobe.

III. OSIGURANE OSOBE

1. Osiguranici

Članak 7.

(1) Na obvezno zdravstveno osiguranje prema ovom Zakonu obvezno se osiguravaju i stječu status osiguranika:

1. osobe u radnom odnosu kod pravne ili fizičke osobe sa sjedištem u Republici Hrvatskoj,

2. osobe koje su izabrane ili imenovane na stalne dužnosti u određenim tijelima državne vlasti, odnosno jedinicama lokalne i područne (regionalne) samouprave, ako za taj rad primaju plaću,

3. osobe s prebivalištem ili odobrenim stalnim boravkom u Republici Hrvatskoj zaposlene u drugoj državi članici ili trećoj državi koje nemaju zdravstveno osiguranje nositelja zdravstvenog osiguranja države članice ili treće države, odnosno koje nisu obvezno zdravstveno osigurane prema propisima države rada na način kako je to određeno propisima Europske unije, odnosno međunarodnim ugovorom,

4. članovi uprave trgovačkih društava i izvršni direktori trgovačkih društava, ako nisu obvezno zdravstveno osigurani po osnovi rada kod druge pravne ili fizičke osobe u Republici Hrvatskoj ili drugoj državi članici,

5. osobe koje se stručno osposobljavaju za rad bez zasnivanja radnog odnosa, odnosno koje se stručno osposobljavaju za rad uz mogućnost korištenja mjera aktivne politike zapošljavanja, sukladno posebnim propisima,

6. osobe koje na području Republike Hrvatske obavljaju gospodarsku djelatnost obrta i s obrtom izjednačenih djelatnosti, osobe koje samostalno u obliku slobodnog zanimanja obavljaju profesionalnu djelatnost te osobe koje u Republici Hrvatskoj obavljaju djelatnost poljoprivrede i šumarstva kao jedino ili glavno zanimanje, ako su obveznici poreza na dohodak ili poreza na dobit i ako nisu osigurane po osnovi rada ili su korisnici prava na mirovinu,

7. poljoprivrednici koji u Republici Hrvatskoj obavljaju poljoprivrednu djelatnost kao jedino ili glavno zanimanje ako su vlasnici, posjednici ili zakupci te ako nisu obveznici poreza na dohodak ili poreza na dobit i ako nisu osigurani po osnovi rada ili su korisnici prava na mirovinu,

8. osobe koje obavljaju poljoprivrednu djelatnost kao jedino ili glavno zanimanje, a upisani su u upisnik obiteljskog poljoprivrednog gospodarstva u svojstvu nositelja ili člana obiteljskog poljoprivrednog gospodarstva, ako nisu zdravstveno osigurani po osnovi rada ili su korisnici prava na mirovinu ili se nalaze na redovitom školovanju,

9. svećenici i drugi vjerski službenici vjerske zajednice koja je upisana u evidenciju vjerskih zajednica koju vodi nadležno državno tijelo, ako nisu osigurani po osnovi rada,

10. korisnici prava na mirovinu prema propisima o mirovinskom osiguranju Republike Hrvatske, ako imaju prebivalište ili odobren stalni boravak u Republici Hrvatskoj,

11. korisnici prava na profesionalnu rehabilitaciju po propisima o mirovinskom osiguranju Republike Hrvatske, ako imaju prebivalište ili odobren stalni boravak u Republici Hrvatskoj,

12. korisnici mirovine i invalidnine koji to pravo ostvaruju isključivo od stranog nositelja mirovinskog i invalidskog osiguranja, ako propisima Europske unije, odnosno međunarodnim ugovorom nije drukčije određeno, ako imaju prebivalište ili odobren stalni boravak u Republici Hrvatskoj,

13. osobe s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj koje nisu obvezno zdravstveno osigurane po drugoj osnovi i koje su se prijavile Zavodu u roku od:

a) 30 dana od dana prestanka radnog odnosa, odnosno obavljanja djelatnosti ili od dana prestanka primanja naknade plaće na koju imaju pravo prema ovom Zakonu ili prema propisima donesenim na temelju ovoga Zakona,

b) 30 dana od dana prijevremenog prestanka služenja vojnog roka, odnosno dragovoljnog služenja vojnog roka, odnosno od dana isteka propisanog roka za služenje vojnog roka, odnosno dragovoljnog služenja vojnog roka,

c) 30 dana od dana otpuštanja iz ustanove za izvršenje kaznenih i prekršajnih sankcija, iz zdravstvene ili druge specijalizirane ustanove, ako je bila primijenjena sigurnosna mjera obveznoga psihijatrijskog liječenja ili obveznoga liječenja od ovisnosti u zdravstvenoj ustanovi,

d) 30 dana od dana navršenih 18 godina života, ako nisu zdravstveno osigurane po drugoj osnovi,

e) 90 dana od dana isteka školske godine u kojoj su završile redovito školovanje prema propisima o redovitom školovanju u Republici Hrvatskoj ili drugoj državi članici, odnosno u roku od 30 dana od dana položenog završnog ispita,

14. redoviti učenici srednjih škola i redoviti studenti visokih učilišta iznad 18 godina života koji su državljani Republike Hrvatske i imaju prebivalište ili boravište u Republici Hrvatskoj, odnosno državljani Republike Hrvatske s prebivalištem u drugoj državi članici koji u Republici Hrvatskoj imaju odobren privremeni boravak, pod uvjetom da nisu obvezno zdravstveno osigurani u drugoj državi članici, te stranci s odobrenim stalnim boravkom u Republici Hrvatskoj, s tim da to pravo mogu koristiti najduže do isteka školske godine, odnosno završetka akademske godine u kojoj su završili redovito školovanje, a najduže u trajanju od ukupno osam godina po toj osnovi, ako pravo na obvezno zdravstveno osiguranje ne ostvaruju po drugoj osnovi

15. redoviti učenici srednjih škola i redoviti studenti visokih učilišta u drugim državama članicama iznad 18 godina života, koji su državljani Republike Hrvatske i imaju prebivalište u Republici Hrvatskoj, te stranci s odobrenim stalnim boravkom u Republici Hrvatskoj, s tim da to pravo mogu koristiti najduže do isteka školske godine, odnosno završetka akademske godine u kojoj su završili redovito školovanje prema propisima države školovanja, a najduže u trajanju od ukupno osam godina po toj osnovi, ako pravo na obvezno zdravstveno osiguranje ne ostvaruju po drugoj osnovi

16. osobe s prebivalištem ili odobrenim stalnim boravkom u Republici Hrvatskoj iznad 18 godina života, koje su prema propisima o školovanju u Republici Hrvatskoj ili u drugoj državi članici izgubile status redovitog učenika, odnosno redovitog studenta ako su se prijavile Zavodu u roku od 30 dana od dana gubitka statusa redovitog učenika ili redovitog studenta i ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi,

17. supružnik umrlog osiguranika koji nakon smrti supružnika nije stekao pravo na obiteljsku mirovinu, ako se Zavodu prijavio u roku od 30 dana od dana smrti supružnika, a pravo na obvezno zdravstveno osiguranje ne može ostvariti po drugoj osnovi,

18. osobe s prebivalištem te stranci s odobrenim stalnim boravkom u Republici Hrvatskoj kojima je priznato svojstvo ratnog vojnog ili civilnog invalida rata i mirnodopskog vojnog

invalida, odnosno status korisnika obiteljske invalidnine sukladno Zakonu o zaštiti vojnih i civilnih invalida rata, ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi,

19. hrvatski branitelji iz Domovinskog rata, ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi,

20. osobe koje pružaju njegu i pomoć hrvatskom ratnom vojnom invalidu Domovinskog rata prema propisima o pravima hrvatskih branitelja iz Domovinskog rata i članova njihovih obitelji, ako pravo na obvezno zdravstveno osiguranje ne ostvaruju po drugoj osnovi,

21. osobe na odsluženju vojnog roka, odnosno dragovoljnom odsluženju vojnog roka (ročnici), kadeti te pričuvnici za vrijeme obavljanja službe u Oružanim snagama Republike Hrvatske, ako pravo na obvezno zdravstveno osiguranje ne ostvaruju po drugoj osnovi,

22. osobe koje su prekinule rad zbog toga što ih je pravna ili fizička osoba uputila na obrazovanje ili stručno usavršavanje, dok traje obrazovanje, odnosno stručno usavršavanje,

23. osobe koje je pravna ili fizička osoba prije stupanja u radni odnos uputila kao svoje stipendiste na praktičan rad u drugu pravnu osobu ili kod druge fizičke osobe radi stručnog osposobljavanja ili usavršavanja, dok traje praktični rad,

24. osobe upućene u drugu državu članicu ili treću državu u sklopu međunarodne tehničko-prosvjetne i kulturne suradnje, dok se tamo nalaze po toj osnovi,

25. osobe kojima je priznato pravo na status roditelja njegovatelja prema posebnom zakonu,

26. članovi obitelji smrtno stradalog, zatočenoga ili nestaloga hrvatskog branitelja za vrijeme primanja novčane naknade u skladu s propisima o pravima hrvatskih branitelja iz Domovinskog rata i članova njihovih obitelji, ako pravo na obvezno zdravstveno osiguranje ne ostvaruju po drugoj osnovi,

27. članovi obitelji smrtno stradalog, zatočenog ili nestalog hrvatskog branitelja koji imaju prebivalište ili odobren stalni boravak u Republici Hrvatskoj, ako su se Zavodu prijavili u roku od 30 dana od dana prestanka primanja novčane naknade u skladu s propisima o pravima hrvatskih branitelja iz Domovinskog rata i članova njihovih obitelji, ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi,

28. osobe s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj kojima je odlukom nadležnog suda oduzeta sloboda i nalaze se u ustrojstvenim jedinicama Ministarstva pravosuđa, prema prijavi Ministarstva pravosuđa.

(2) Pod radnim odnosom sukladno stavku 1. točki 1. ovoga članka podrazumijeva se odnos poslodavca i radnika prema propisima o radu i drugim propisima koji uređuju pitanja zapošljavanja.

(3) Djelatnosti osoba iz stavka 1. točke 6. ovoga članka su: registrirana djelatnost obrta, poljoprivrede i šumarstva, slobodnog zanimanja (profesionalna djelatnost) i ostale samostalne djelatnosti za čije je obavljanje odobrenje izdalo nadležno tijelo za samostalno obavljanje djelatnosti fizičke osobe, upisane u odgovarajući registar toga tijela te djelatnost s obilježjem

samostalnosti, trajnosti i namjere stvaranja stalnog izvora prihoda poreznog obveznika upisanog u registar obveznika poreza na dohodak, sukladno propisima o porezu na dohodak kada se radi o samostalnoj djelatnosti za čije obavljanje nije propisano izdavanje odobrenja ili obveza registracije te djelatnosti.

(4) Osiguranici iz stavka 1. točaka 1. do 6., 8., 9., 20. i 25. ovoga članka obvezno se osiguravaju i za slučaj ozljede na radu i profesionalne bolesti.

(5) Za osobe iz stavka 1. točaka 13., 16., 17. i 19. ovoga članka i osobe iz članka 11. stavka 1. točke 3. ovoga Zakona Zavod i Hrvatski zavod za zapošljavanje međusobno će razmjenjivati podatke o nezaposlenim osobama koje se vode u evidenciji Hrvatskog zavoda za zapošljavanje.

(6) Za osobe iz stavka 5. ovoga članka koje se ne vode u evidenciji Hrvatskog zavoda za zapošljavanje kao nezaposlene osobe status osiguranika utvrđivat će se prijavom Zavodu.

(7) Uvjete i način stjecanja statusa osiguranika sukladno stavku 1. ovoga članka Zavod će pobliže utvrditi općim aktom.

Članak 8.

(1) Prava iz obveznoga zdravstvenog osiguranja u opsegu u kojem pripadaju osiguranicima, ako ovim Zakonom nije drukčije određeno, imaju i osobe s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj kojima je po osnovi primitaka od kojih se, prema propisima o porezu na dohodak, utvrđuje drugi dohodak, a sukladno propisima o doprinosima za obvezna osiguranja uplaćen jednokratno ili višekratnim uplatama u posljednjih pet godina doprinos za obvezno zdravstveno osiguranje najmanje u visini doprinosa obračunatog na najnižu osnovicu za obračun doprinosa za obvezno zdravstveno osiguranje za razdoblje od šest mjeseci, ako ne ostvaruju pravo na obvezno zdravstveno osiguranje po drugoj osnovi.

(2) Osobe iz stavka 1. ovoga članka zadržavaju status osiguranika Zavoda za sve vrijeme dok na temelju uplaćenih doprinosa na druge primitke imaju mjesečno uplaćen doprinos za obvezno zdravstveno osiguranje najmanje na najnižu osnovicu za obračun doprinosa.

2. Djeca do 18. godine života i članovi obitelji osiguranika

Članak 9.

Djeca do navršene 18. godine života s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj osiguravaju se na obvezno zdravstveno osiguranje te stječu status osigurane osobe.

Članak 10.

(1) Prema ovom Zakonu, status osigurane osobe – člana obitelji osiguranika, kao nositelja obveznoga zdravstvenog osiguranja, mogu steći:

1. supružnik (bračni i izvanbračni, sukladno propisima o obiteljskim odnosima),

2. djeca (rođena u braku, izvan braka ili posvojena, pastorčad) te druga djeca bez roditelja, ako ih osiguranik uzdržava, na zahtjev osiguranika,

3. roditelji (otac, majka, očuh, maćeha i posvojitelj), ako su nesposobni za samostalan život i rad, ako nemaju sredstava za uzdržavanje i ako ih osiguranik uzdržava,

4. unuci, braća, sestre, djed i baka, ako su nesposobni za samostalan život i rad, ako nemaju sredstava za uzdržavanje i ako ih osiguranik uzdržava.

(2) Članovi obitelji osiguranika iz stavka 1. ovoga članka stječu status osigurane osobe u skladu sa stavkom 1. ovoga članka pod uvjetom da status u obveznom zdravstvenom osiguranju ne mogu ostvariti po nekoj od osnova osiguranja iz članka 7. ovoga Zakona te da imaju prebivalište, odnosno odobren stalni boravak u Republici Hrvatskoj, ako propisima Europske unije, odnosno međunarodnim ugovorom nije drukčije određeno.

(3) Zavod će općim aktom utvrditi uvjete pod kojima se smatra da je osoba iz stavka 1. ovoga članka nesposobna za samostalan život i rad i da nema vlastitih sredstava za uzdržavanje te da je osiguranik uzdržava.

Članak 11.

(1) Supružnik razvodom braka zadržava status osigurane osobe Zavoda kao član obitelji supružnika od kojeg se razveo:

1. ako je sudskom odlukom stekao pravo na uzdržavanje, dok traje uzdržavanje,

2. ako je u vrijeme razvoda braka bio potpuno i trajno nesposoban za rad sukladno propisima o mirovinskom osiguranju,

3. ako su mu sudskom odlukom o razvodu braka djeca povjerena na čuvanje i odgoj, pod uvjetom da se prijavi Zavodu u roku od 30 dana od dana pravomoćnosti sudske odluke, ako pravo na obvezno zdravstveno osiguranje ne može ostvariti po drugoj osnovi.

(2) Osobe iz stavka 1. točke 1. ovoga članka zadržavaju status osigurane osobe kao članovi obitelji i po prestanku uzdržavanja pod uvjetom da se prijave Zavodu u roku od 30 dana od dana pravomoćnosti sudske odluke, ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi.

Članak 12.

(1) Djeca osiguranika iz članka 10. stavka 1. točke 2. ovoga Zakona koja su status osigurane osobe stekle kao članovi obitelji osiguranika mogu taj status zadržati najduže do navršene 18. godine života.

(2) Djeca osiguranika iz stavka 1. ovoga članka koja postanu potpuno i trajno nesposobna za samostalan život i rad, sukladno posebnim propisima, prije navršene 18. godine života, zadržavaju status osigurane osobe kao članovi obitelji osiguranika za sve vrijeme trajanja te nesposobnosti, ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi.

(3) Pravo na obvezno zdravstveno osiguranje kao članovi obitelji osiguranika mogu steći i djeca osiguranika koja su nakon navršene 18. godine života postala potpuno i trajno nesposobna za samostalan život i rad, sukladno posebnim propisima, ako ih osiguranik uzdržava i ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi.

3. Druge osigurane osobe

Članak 13.

(1) Osobe s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj koje pravo na obvezno zdravstveno osiguranje ne mogu ostvariti prema jednoj od osnova osiguranja utvrđenih člancima 7. do 12. i člancima 14. i 15. ovoga Zakona obvezne su se osigurati na obvezno zdravstveno osiguranje kao osigurane osobe.

(2) Osobe iz stavka 1. ovoga članka prava i obveze iz obveznoga zdravstvenog osiguranja stječu pod uvjetom da su prethodno jednokratno uplatile doprinos za obvezno zdravstveno osiguranje na najnižu osnovicu za obračun doprinosa za obvezno zdravstveno osiguranje od dana prestanka ranijeg statusa osigurane osobe, a najdulje za razdoblje od 12 mjeseci.

Članak 14.

Nositelji obveznoga zdravstvenog osiguranja iz članka 10. stavka 1. ovoga Zakona koji se nalaze na radu u trećim državama s kojima Republika Hrvatska nema sklopljen međunarodni ugovor ili sklopljenim međunarodnim ugovorom nije uređeno pitanje zdravstvenog osiguranja obvezni su osigurati na obvezno zdravstveno osiguranje i uplaćivati propisani doprinos za obvezno zdravstveno osiguranje za svakog člana svoje obitelji s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj koji nije zdravstveno osiguran kod nositelja zdravstvenog osiguranja u državi rada nositelja osiguranja a bio je prije njegova odlaska na rad u treću državu obvezno zdravstveno osiguran u Republici Hrvatskoj kao član njegove obitelji sukladno članku 10. ovoga Zakona.

Članak 15.

(1) Osobe s prebivalištem, odnosno odobrenim stalnim boravkom u Republici Hrvatskoj koje su nesposobne za samostalan život i rad i nemaju sredstava za uzdržavanje imaju pravo na obvezno zdravstveno osiguranje kao osigurane osobe osnovom rješenja koje donosi ured državne uprave nadležan za poslove socijalne skrbi, ako pravo na obvezno zdravstveno osiguranje ne mogu ostvariti po drugoj osnovi.

(2) Mjerila za utvrđivanje nesposobnosti za samostalan život i rad i nedostatka sredstava za uzdržavanje iz stavka 1. ovoga članka propisat će pravilnikom ministar nadležan za poslove socijalne skrbi.

(3) Pravo na obvezno zdravstveno osiguranje prema osnovi osiguranja utvrđenoj odredbom stavka 1. ovoga članka traje za sve vrijeme dok se ne promijene okolnosti na osnovi kojih je osobi to pravo priznato.

Članak 16.

(1) Na obvezno zdravstveno osiguranje prema ovome Zakonu za slučaj ozljede na radu i profesionalne bolesti, osim osiguranika iz članka 7. stavka 4. ovoga Zakona, obvezno se osiguravaju i sljedeće osigurane osobe:

1. učenici i studenti na redovitom školovanju prema propisima o redovitom školovanju u Republici Hrvatskoj za vrijeme praktične nastave, za vrijeme stručne prakse, stručnih putovanja, odnosno za vrijeme rada putem posrednika pri zapošljavanju učenika i studenata,

2. osobe koje je Hrvatski zavod za zapošljavanje uputio na obrazovanje koje organizira, odnosno za koje troškove snosi Hrvatski zavod za zapošljavanje,

3. djeca sa smetnjama u tjelesnom i duševnom razvoju na praktičnoj nastavi ili na obveznom praktičnom radu u pravnoj osobi za osposobljavanje,

4. osobe koje pomažu redarstvenim službama u obavljanju poslova iz njihove nadležnosti,

5. osobe koje sudjeluju u akcijama spašavanja ili u zaštiti i spašavanju u slučaju prirodnih i drugih nepogoda,

6. osobe koje na poziv državnih i drugih ovlaštenih tijela obavljaju dužnosti u interesu Republike Hrvatske,

7. sportaši, treneri ili organizatori u sklopu organizirane amaterske sportske aktivnosti,

8. osobe koje kao pripadnici Hrvatske gorske službe spašavanja ili ronioci obavljaju zadatke spašavanja života ili otklanjanja, odnosno sprječavanja opasnosti koje neposredno ugrožavaju život ili imovinu građana,

9. osobe koje kao članovi terenskih sastava sudjeluju u spašavanju i zdravstvenoj zaštiti u prirodnim i drugim nepogodama i nesrećama (poplave, potresi i sl.),

10. osobe na odsluženju vojnog roka, odnosno dragovoljnom služenju vojnog roka (ročnici), kadeti te pričuvnici za vrijeme obavljanja službe u Oružanim snagama Republike Hrvatske,

11. osobe koje sudjeluju u organiziranim javnim radovima u Republici Hrvatskoj,

12. osobe koje ispunjavaju obvezu sudjelovanja u civilnoj zaštiti ili obvezu sudjelovanja u službi motrenja i obavješćivanja,

13. osobe koje kao članovi operativnih sastava dobrovoljnih vatrogasnih organizacija obavljaju zadatke gašenja požara, zaštite i spašavanja u slučaju drugih nepogoda, osiguravanja mjesta gdje postoji požarna opasnost, educiranja građana u protupožarnoj zaštiti, a na javnim priredbama obavljaju zadatke u sklopu javnih nastupa i demonstracija s prikazom vježbi,

14. korisnici prava na mirovinu iz članka 7. stavka 1. točaka 10. i 12. ovoga Zakona koji se po posebnom zakonu zapošljavaju na privremenim, odnosno povremenim sezonskim poslovima u poljoprivredi,

15. osobe iz članka 7. stavka 1. točaka 13., 16., 17. i 19. ovoga Zakona koje se po posebnom zakonu zapošljavaju na privremenim, odnosno povremenim sezonskim poslovima u

poljoprivredi pod uvjetom da se vode u evidenciji nezaposlenih osoba kod Hrvatskog zavoda za zapošljavanje,

16. osobe koje izvršavaju rad za opće dobro sukladno Zakonu o probaciji i osobe koje su raspoređene na poslove tijekom izdržavanja kazne zatvora, mjere istražnog zatvora ili odgojne mjere upućivanja u odgojni zavod.

(2) Pravne i fizičke osobe, odnosno tijela državne vlasti obvezni su osigurati na obvezno zdravstveno osiguranje za slučaj ozljede na radu i profesionalne bolesti osobe iz stavka 1. ovoga članka.

IV. PRAVA IZ OBVEZNOGA ZDRAVSTVENOG OSIGURANJA

Članak 17.

Prava iz obveznoga zdravstvenog osiguranja, uključujući i prava za slučaj ozljede na radu i profesionalne bolesti, prema ovome Zakonu obuhvaćaju:

1. pravo na zdravstvenu zaštitu,

2. pravo na novčane naknade.

1. PRAVO NA ZDRAVSTVENU ZAŠTITU

Članak 18.

(1) Pravo na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja iz članka 17. točke 1. ovoga Zakona u opsegu utvrđenom ovim Zakonom i propisima donesenim na temelju ovoga Zakona obuhvaća pravo na:

1. primarnu zdravstvenu zaštitu,

2. specijalističko-konzilijarnu zdravstvenu zaštitu,

3. bolničku zdravstvenu zaštitu,

4. pravo na lijekove koji su utvrđeni osnovnom i dopunskom listom lijekova Zavoda,

5. dentalna pomagala koja su utvrđena osnovnom i dodatnom listom dentalnih pomagala Zavoda,

6. ortopedska i druga pomagala koja su utvrđena osnovnom i dodatnom listom ortopedskih i drugih pomagala Zavoda,

7. zdravstvenu zaštitu u drugim državama članicama i trećim državama.

(2) Pravo osiguranih osoba na zdravstvenu zaštitu iz stavka 1. točaka 1. do 6. ovoga članka osigurava se provedbom mjera zdravstvene zaštite.

(3) Mjere zdravstvene zaštite iz stavka 2. ovoga članka utvrđuju se na temelju plana i programa mjera zdravstvene zaštite koje donosi ministar nadležan za zdravlje na prijedlog Zavoda i Hrvatskog zavoda za javno zdravstvo, uz prethodno pribavljeno mišljenje nadležnih komora, a sukladno osiguranim financijskim sredstvima te raspoloživim zdravstvenim kapacitetima.

(4) Osigurane osobe zdravstvenu zaštitu iz stavka 1. točaka 1. do 5. ovoga članka mogu, na teret sredstava Zavoda, ostvariti u zdravstvenim ustanovama i kod privatnih zdravstvenih radnika s kojima je Zavod sklopio ugovor o provođenju zdravstvene zaštite (u daljnjem tekstu: ugovorni subjekti Zavoda) na način i pod uvjetima koji su utvrđeni ovim Zakonom i općim aktima Zavoda.

(5) Osigurane osobe zdravstvenu zaštitu iz stavka 1. točke 6. ovoga članka na teret sredstava Zavoda ostvaruju kod pravnih ili fizičkih osoba koje imaju odobrenje za proizvodnju, odnosno promet na malo ortopedskim i drugim pomagalima u skladu s posebnim propisom te u ljekarnama s kojima je Zavod, u skladu s uvjetima i na način utvrđen općim aktom Zavoda, sklopio ugovor o isporuci ortopedskih i drugih pomagala osiguranim osobama (u daljnjem tekstu: ugovorni isporučitelji pomagala).

Članak 19.

(1) Pravo na zdravstvenu zaštitu iz članka 18. ovoga Zakona osigurava se pod jednakim uvjetima za sve osigurane osobe.

(2) Osiguranim osobama u ostvarivanju prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja iz članka 18. ovoga Zakona Zavod osigurava plaćanje zdravstvenih usluga u cijelosti za:

1. cjelokupnu zdravstvenu zaštitu djece do navršene 18. godine života, osiguranih osoba iz članka 12. stavaka 2. i 3. te članka 15. ovoga Zakona,

2. preventivnu i specifičnu zdravstvenu zaštitu školske djece i studenata,

3. preventivnu zdravstvenu zaštitu žena,

4. zdravstvenu zaštitu žena u vezi s praćenjem trudnoće i poroda,

5. zdravstvenu zaštitu u vezi s medicinski potpomognutom oplodnjom, sukladno posebnom zakonu,

6. preventivnu zdravstvenu zaštitu osoba starijih od 65 godina života,

7. preventivnu zdravstvenu zaštitu osoba s invaliditetom iz registra osoba s invaliditetom utvrđenog posebnim propisom,

8. cjelokupnu zdravstvenu zaštitu u vezi s HIV infekcijama i ostalim zaraznim bolestima za koje je zakonom određeno provođenje mjera za sprečavanje njihova širenja,

9. obvezno cijepljenje, imunoprofilaksu i kemoprofilaksu,

10. cjelokupno liječenje kroničnih psihijatrijskih bolesti,

11. cjelokupno liječenje zloćudnih bolesti,

12. cjelokupno liječenje koje je posljedica priznate ozljede na radu, odnosno profesionalne bolesti,

13. hemodijalizu i peritonejsku dijalizu,

14. zdravstvenu zaštitu u vezi s uzimanjem i presađivanjem dijelova ljudskoga tijela u svrhu liječenja,

15. izvanbolničku hitnu medicinsku pomoć u djelatnosti hitne medicine koja uključuje hitni prijevoz (kopnenim, vodenim i zračnim putem), sukladno pravilniku ministra nadležnog za zdravlje,

16. kućne posjete i kućno liječenje,

17. patronažnu zdravstvenu zaštitu,

18. sanitetski prijevoz za posebne kategorije bolesnika, sukladno pravilniku ministra nadležnog za zdravlje,

19. lijekove s osnovne liste lijekova Zavoda propisane na recept,

20. zdravstvenu njegu u kući osigurane osobe,

21. laboratorijsku dijagnostiku na razini primarne zdravstvene zaštite,

22. palijativnu zdravstvenu zaštitu.

(3) Osigurane osobe obvezne su sudjelovati u troškovima zdravstvene zaštite u visini od 20% pune cijene zdravstvene zaštite, a koji iznos ne može biti manji od postotaka proračunske osnovice utvrđenih točkama 1. do 8. ovoga stavka za:

1. specijalističko-konzilijarnu zdravstvenu zaštitu, uključujući dnevnu bolnicu i kirurške zahvate u dnevnoj bolnici, osim ambulantne fizikalne medicine i rehabilitacije – 0,75% proračunske osnovice,

2. specijalističku dijagnostiku koja nije na razini primarne zdravstvene zaštite – 1,50% proračunske osnovice,

3. ortopedska i druga pomagala utvrđena osnovnom listom ortopedskih i drugih pomagala – 1,50% proračunske osnovice,

4. specijalističko-konzilijarnu zdravstvenu zaštitu u ambulantnoj fizikalnoj medicini i rehabilitaciji i za fizikalnu medicinu i rehabilitaciju u kući – 0,75% proračunske osnovice po danu,

5. liječenje u drugim državama članicama i trećim državama sukladno propisima Europske unije, međunarodnom ugovoru, Direktivi 2011/24/EU, ovom Zakonu i općem aktu Zavoda, ako propisima Europske unije, odnosno međunarodnim ugovorom nije drukčije određeno,

6. troškove bolničke zdravstvene zaštite – 3,01% proračunske osnovice po danu,

7. dentalna pomagala utvrđena osnovnom listom dentalnih pomagala za odrasle osobe od 18 do 65 godina starosti – 30,07% proračunske osnovice,

8. dentalna pomagala utvrđena osnovnom listom dentalnih pomagala za odrasle osobe starije od 65 godina – 15,03% proračunske osnovice.

4) Osigurane osobe obvezne su sudjelovati u visini od 0,30% proračunske osnovice za:

1. zdravstvenu zaštitu pruženu kod izabranog doktora primarne zdravstvene zaštite: obiteljske (opće) medicine, ginekologije i dentalne medicine, sukladno općem aktu Zavoda,

2. izdavanje lijeka po receptu.

(5) Najviši iznos sudjelovanja u troškovima zdravstvene zaštite iz stavaka 3. i 4. ovoga članka koji je obvezna snositi osigurana osoba može po jednom ispostavljenom računu za izvršenu zdravstvenu zaštitu iznositi najviše 60,13% proračunske osnovice.

(6) Popis vrsta i broja terapijskih i dijagnostičkih postupaka koji se osiguravaju osiguranim osobama u okviru zdravstvene zaštite iz stavaka 2., 3. i 4. ovoga članka utvrđuje općim aktom Zavod iz članka 33. ovoga Zakona.

1. Lijekovi

Članak 20.

(1) Osnovna i dopunska lista lijekova Zavoda iz članka 18. stavka 1. točke 4. ovoga Zakona sadrži lijekove koji imaju odobrenje za stavljanje u promet u Republici Hrvatskoj.

(2) Liste lijekova Zavoda iz stavka 1. ovoga članka sadrže lijekove prema šifri anatomsko-terapijsko-kemijske (ATK) klasifikacije lijekova Svjetske zdravstvene organizacije, uobičajenom (nezaštićenom) nazivu lijeka, (zaštićenom) nazivu lijeka, nazivu proizvođača, nazivu nositelja odobrenja za stavljanje lijeka u promet, obliku lijeka i načinu primjene, cijeni lijeka za definiranu dnevnu dozu, cijeni pakiranja i jediničnog oblika lijeka te pravila propisivanja lijekova koji se mogu primjenjivati u liječenju u okviru zdravstvene zaštite iz obveznoga zdravstvenog osiguranja.

(3) Osnovna lista lijekova Zavoda sadrži medikoekonomski najsvrhovitije lijekove za liječenje svih bolesti.

(4) Dopunska lista lijekova sadrži lijekove s višom razinom cijene u odnosu na cijene iz osnovne liste lijekova, pri čemu Zavod osigurava pokriće troškova u visini najniže cijene ekvivalentnog lijeka utvrđenog osnovnom listom lijekova.

(5) Dopunska lista lijekova Zavoda, osim pune cijene lijeka, obvezno sadrži iznos sudjelovanja u cijeni lijeka koju osigurava osigurana osoba Zavoda neposredno ili putem dopunskoga zdravstvenog osiguranja sukladno Zakonu o dobrovoljnom zdravstvenom osiguranju.

(6) Način uvrštenja lijekova na osnovnu i dopunsku listu lijekova te način utvrđivanja cijene lijekova propisuje pravilnikom ministar nadležan za zdravlje, sukladno posebnom zakonu.

(7) Osnovnu i dopunsku listu lijekova, uz prethodno pribavljeno mišljenje Hrvatske liječničke komore, donosi Upravno vijeće Zavoda.

(8) Ako komora iz stavka 7. ovoga članka u roku od 8 dana, od dana kada je zaprimila zahtjev za mišljenjem, Zavodu ne dostavi mišljenje o osnovnoj, odnosno dopunskoj listi lijekova, smatra se da je dano pozitivno mišljenje.

(9) Oblik i sadržaj recepata za lijekove s osnovne i dopunske liste lijekova Zavoda utvrdit će općim aktom Zavod u skladu s pravilnikom ministra nadležnog za zdravlje.

Članak 21.

(1) Osigurana osoba u okviru prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja ima pravo na teret sredstava Zavoda ostvariti lijekove koji su utvrđeni osnovnom i dopunskom listom lijekova Zavoda, pod uvjetima i na način utvrđen općim aktima Zavoda.

(2) Iznimno, osigurana osoba kod koje liječenje iz medicinskih razloga nije moguće provoditi lijekovima utvrđenim osnovnom i dopunskom listom lijekova Zavoda može ostvariti pravo na lijek koji nije utvrđen tim listama lijekova, pod uvjetom da je potrebu korištenja lijeka odobrilo povjerenstvo za lijekove bolničke zdravstvene ustanove u kojoj se osigurana osoba liječi i to na teret sredstava bolničke zdravstvene ustanove koja je obvezna osigurati nabavu lijeka.

(3) Pod uvjetima i na način utvrđen stavkom 2. ovoga članka osigurana osoba može ostvariti i pravo na lijek koji je utvrđen osnovnom i dopunskom listom lijekova Zavoda, ali za ostvarivanje kojeg osigurana osoba ne ispunjava medicinske indikacije utvrđene listama lijekova iz stavka 1. ovoga članka.

(4) Doktor specijalist bolničke zdravstvene ustanove koji je osiguranoj osobi predložio liječenje lijekom iz stavka 2. i 3. ovoga članka obvezan je uputiti prijedlog povjerenstvu za lijekove bolničke zdravstvene ustanove.

2. Ortopedska i druga pomagala te dentalna pomagala

Članak 22.

(1) Osigurana osoba u okviru prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja ima pravo na ortopedska i druga pomagala (u daljnjem tekstu: pomagala) koja su utvrđena osnovnom i dodatnom listom ortopedskih i drugih pomagala Zavoda.

(2) Osnovna i dodatna lista pomagala Zavoda sadrži pomagala koja su namijenjena omogućavanju poboljšanja oštećenih funkcija, odnosno ublažavanju ili otklanjanju tjelesnog

oštećenja ili nedostatka organa i sustava organa ili nadomještanju anatomskih ili fizioloških funkcija organa, koji su nastali kao posljedica bolesti ili ozljede.

(3) Način uvrštenja pomagala na osnovnu i dodatnu listu pomagala Zavoda te način utvrđivanja cijena pomagala propisuje pravilnom ministar nadležan za zdravlje, sukladno posebnom zakonu.

(4) Dodatna lista pomagala sadrži pomagala s višom razinom cijene u odnosu na cijene iz osnovne liste pomagala pri čemu Zavod na teret sredstava obveznoga zdravstvenog osiguranja osigurava pokriće troškova u visini cijene ekvivalentnog pomagala s osnovne liste pomagala, umanjene za iznos sudjelovanja u cijeni pomagala s osnovne liste pomagala koju osigurava osigurana osoba neposredno ili putem dopunskoga zdravstvenog osiguranja sukladno Zakonu o dobrovoljnom zdravstvenom osiguranju.

(5) Za razliku u cijeni pomagala s dodatne liste pomagala u odnosu na cijenu ekvivalentnog pomagala s osnovne liste pomagala osigurana osoba se može dodatno zdravstveno osigurati sukladno Zakonu o dobrovoljnom zdravstvenom osiguranju.

Članak 23.

(1) Osigurana osoba u okviru prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja ima pravo na dentalna pomagala koja su utvrđena osnovnom i dodatnom listom dentalnih pomagala Zavoda.

(2) Osnovna i dodatna lista dentalnih pomagala Zavoda sadrži dentalna pomagala koja su namijenjena omogućavanju dentalno-protetske, kirurško-protetske, ortodontske i parodontološke rehabilitacije.

(3) Način uvrštenja dentalnih pomagala na osnovnu i dodatnu listu dentalnih pomagala Zavoda te način utvrđivanja cijena dentalnih pomagala utvrđuje Zavod općim aktom u skladu s člankom 19. stavkom 6., člankom 33. i člankom 88. ovoga Zakona.

(4) Dodatna lista dentalnih pomagala sadrži dentalna pomagala s višom razinom cijene u odnosu na cijene iz osnovne liste dentalnih pomagala pri čemu Zavod na teret sredstava obveznoga zdravstvenog osiguranja osigurava pokriće troškova u visini cijene ekvivalentnog dentalnog pomagala s osnovne liste dentalnih pomagala, umanjene za iznos sudjelovanja u cijeni dentalnih pomagala s osnovne liste dentalnih pomagala koju osigurava osigurana osoba neposredno ili putem dopunskoga zdravstvenog osiguranja sukladno Zakonu o dobrovoljnom zdravstvenom osiguranju.

(5) Za razliku u cijeni dentalnog pomagala s dodatne liste dentalnih pomagala u odnosu na cijenu ekvivalentnog dentalnog pomagala s osnovne liste dentalnih pomagala osigurana osoba se može dodatno zdravstveno osigurati sukladno Zakonu o dobrovoljnom zdravstvenom osiguranju.

Članak 24.

(1) Osigurane osobe imaju pravo na pomagala iz članka 22. ovoga Zakona i dentalna pomagala iz članka 23. ovoga Zakona ako ispunjavaju uvjet prethodnoga obveznoga

zdravstvenog osiguranja u Zavodu u trajanju od najmanje devet mjeseci neprekidno, odnosno 12 mjeseci s prekidima u posljednje dvije godine prije nastupa osiguranog slučaja.

(2) Odredba stavka 1. ovoga članka ne odnosi se na osigurane osobe mlađe od 18 godina, osigurane osobe iz članka 12. stavaka 2. i 3. ovoga Zakona i druge osigurane osobe potpuno i trajno nesposobne za samostalan život i rad prema rješenju nadležnog tijela te na osigurane osobe kojima je ta zdravstvena zaštita potrebna zbog priznate ozljede na radu, odnosno profesionalne bolesti.

(3) Osigurane osobe zdravstvenu zaštitu iz članaka 22. i 23. ovoga Zakona ostvaruju sukladno općem aktu Zavoda.

Članak 25.

Oblik i sadržaj potvrda za pomagala i dentalna pomagala iz članaka 22. i 23. ovoga Zakona utvrdit će općim aktom Zavod.

3. Prekogranična zdravstvena zaštita

Članak 26.

(1) Osigurana osoba ima pravo na teret sredstava obveznoga zdravstvenog osiguranja koristiti zdravstvenu zaštitu u drugim državama članicama i trećim državama.

(2) Pod zdravstvenom zaštitom iz stavka 1. ovoga članka podrazumijeva se pravo na upućivanje na liječenje, pravo na korištenje zdravstvene zaštite za vrijeme privremenog boravka u državama iz stavka 1. ovog članka te pravo na drugu zdravstvenu zaštitu u skladu s odredbama propisa Europske unije, Direktive 2011/24/EU, ovoga Zakona međunarodnih ugovora te općih akata Zavoda.

(3) Pravo na upućivanje na liječenje osigurana osoba može ostvariti samo ako se radi o potrebi liječenja koje se ne provodi u ugovornim zdravstvenim ustanovama u Republici Hrvatskoj, a može se uspješno provesti u državama iz stavka 1. ovoga članka.

(4) Prava, uvjete i način korištenja zdravstvene zaštite iz stavaka 2. i 3. ovoga članka utvrdit će općim aktom Zavod, uz suglasnost ministra nadležnog za zdravlje.

Članak 27.

(1) Osigurane osobe, u skladu s ovim Zakonom, ostvaruju pravo na prekograničnu zdravstvenu zaštitu koja podrazumijeva zdravstvenu zaštitu koja se osiguranoj osobi osigurava u okviru prava iz obveznoga zdravstvenog osiguranja u ugovornim zdravstvenim ustanovama u Republici Hrvatskoj, a koju je osigurana osoba ostvarila kod ugovornih ili privatnih pružatelja zdravstvene zaštite na području drugih država članica.

(2) Zdravstvena zaštita iz stavka 1. ovoga članka podrazumijeva planiranu zdravstvenu zaštitu za koju osigurana osoba mora pribaviti prethodno odobrenje Zavoda, planiranu specijalističko-konzilijarnu zdravstvenu zaštitu za koju nije potrebno pribaviti prethodno odobrenje Zavoda i neodgodivu zdravstvenu zaštitu.

Članak 28.

(1) Pod planiranom zdravstvenom zaštitom u drugoj državi članici, za korištenje koje je osigurana osoba obvezna pribaviti prethodno odobrenje Zavoda, podrazumijeva se zdravstvena zaštita koja je uvjetovana:

– smještajem osigurane osobe u bolničkoj zdravstvenoj ustanovi preko noći u trajanju od najmanje jedne noći ili

– uporabom visokospecijalizirane i skupe medicinske infrastrukture ili medicinske opreme.

(2) Prethodno odobrenje iz stavka 1. ovoga članka potrebno je zatražiti i u slučaju korištenja prekogranične zdravstvene zaštite:

– koja se sastoji od postupaka liječenja koji predstavljaju poseban rizik za osiguranu osobu ili stanovništvo ili

– koju pruža pružatelj zdravstvene zaštite koji bi, ovisno o pojedinom slučaju, mogao dati povoda za ozbiljnu i posebnu zabrinutost u vezi s kvalitetom ili sigurnošću te zdravstvene zaštite, uz iznimku zdravstvene zaštite koja podliježe zakonodavstvu Europske unije kojim se osigurava minimalna razina sigurnosti i kvalitete na njezinu području.

(3) Popis vrsta zdravstvene zaštite iz stavaka 1. i 2. ovoga članka, kao i popis visokospecijalizirane i skupe medicinske infrastrukture ili medicinske opreme iz stavka 1. podstavka 2. ovoga članka utvrđuje općim aktom Zavod.

(4) Tijekom provođenja postupka po zahtjevu osigurane osobe za prethodnim odobrenjem ovlaštena osoba Zavoda, koja provodi postupak, obvezna je provjeriti da li podnositelj zahtjeva udovoljava uvjetima za davanje prethodnoga odobrenja sukladno propisima Europske unije te ako su zadovoljeni uvjeti iz propisa Europske unije prethodno odobrenje daje se prema tim propisima, osim ako osigurana osoba ne zahtijeva drukčije.

(5) O zahtjevu osigurane osobe za prethodnim odobrenjem Zavod odlučuje rješenjem.

Članak 29.

Zavod ima pravo uskratiti prethodno odobrenje za prekograničnu zdravstvenu zaštiti ako:

– će osigurana osoba prema kliničkoj procjeni nedvosmisleno biti izložena riziku u pogledu sigurnosti koji se ne može smatrati prihvatljivim, uzimajući u obzir potencijalnu dobrobit tražene prekogranične zdravstvene zaštite za osiguranu osobu,

– će građani Republike Hrvatske nedvosmisleno biti izloženi velikom sigurnosnom riziku zbog predmetne prekogranične zdravstvene zaštite,

– se ta zdravstvena zaštita može pružiti kod ugovornih subjekata Zavoda u roku koji je medicinski opravdan, uzimajući u obzir sadašnje zdravstveno stanje i vjerojatni tijek bolesti kod osigurane osobe.

Članak 30.

(1) Planiranu specijalističko-konzilijarnu zdravstvenu zaštitu koja nije obuhvaćena člancima 28. i 29. ovoga Zakona osigurana osoba može ostvariti u drugim državama članicama bez prethodnog odobrenja Zavoda.

(2) Na način utvrđen stavkom 1. ovoga članka osigurana osoba može ostvariti i zdravstvenu zaštitu koja je s medicinskog stajališta nužna i ne može se odgoditi do planiranog povratka u Republiku Hrvatsku (nužna zdravstvena zaštita).

Članak 31.

(1) Osigurana osoba koja je koristila zdravstvenu zaštitu sukladno člancima 27., 28. i 30. ovoga Zakona ima pravo na naknadu osobno plaćenih troškova te zdravstvene zaštite.

(2) Naknada troškova iz stavka 1. ovoga članka ne može iznositi više od iznosa koji je općim aktom Zavoda za tu zdravstvenu zaštitu utvrđen za ugovorne subjekte Zavoda iz članka 18. ovoga Zakona.

(3) O pravu na naknadu troškova zdravstvene zaštite iz stavka 1. ovoga članka Zavod odlučuje rješenjem.

(4) Osigurana osoba koja je koristila zdravstvenu zaštitu iz stavka 1. ovoga članka nema pravo na teret sredstava obveznoga zdravstvenog osiguranja ostvariti pravo na naknadu troškova prijevoza kao niti pravo na druge troškove vezane uz korištenje te zdravstvene zaštite.

Članak 32.

Zavod je Nacionalna kontaktna točka za pružanje informacija o pravima osiguranih osoba na zdravstvenu zaštitu u drugoj državi članici u skladu s propisima Europske unije i Direktivom 2011/24/EU.

4. Standardi i normativi zdravstvene zaštite

Članak 33.

Standarde i normative zdravstvene zaštite iz obveznoga zdravstvenog osiguranja, uključujući popis vrsta i broja terapijskih i dijagnostičkih postupaka po osiguranoj osobi na godišnjoj razini, iznos potrebnih sredstava u skladu s osiguranim sredstvima, kao i način ostvarivanja prava osiguranih osoba na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja, u pravilu, za svaku kalendarsku godinu donosi Upravno vijeće Zavoda, uz suglasnost ministra nadležnog za zdravlje, po prethodno pribavljenom mišljenju nadležnih komora.

5. Zdravstvena zaštita koju ne osigurava obvezno zdravstveno osiguranje

Članak 34.

Osiguranim osobama Zavoda u okviru prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja ne osigurava se plaćanje troškova zdravstvenih usluga koje su pružene na način i po postupku koji nije propisan propisima Europske unije, Direktivom 2011/24/EU, međunarodnim ugovorom, ovim Zakonom, odnosno podzakonskim propisima donesenim na temelju ovoga Zakona, kao i za:

1. razliku za povećane troškove liječenja koji su posljedica osobne želje osigurane osobe zbog njezina vjerskog, drugog uvjerenja ili bilo kojeg drugog razloga, a koje predstavlja liječenje izvan utvrđenog standarda prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja koji se osigurava svim osiguranim osobama pod jednakim uvjetima,

2. eksperimentalno liječenje, eksperimentalne medicinske proizvode, pomagala, dentalna pomagala i lijekove koji su u fazi kliničkih ispitivanja,

3. terapijske i dijagnostičke postupke te lijekove koji su provedeni, odnosno primijenjeni na zahtjev osigurane osobe u okolnostima kada ti postupci i lijekovi nisu određeni od strane ugovorne zdravstvene ustanove ili ugovornog zdravstvenog radnika privatne prakse u sklopu korištenja prava iz obveznoga zdravstvenog osiguranja ili po svojoj vrsti i količini nisu pravo iz obveznoga zdravstvenog osiguranja,

4. estetske zahvate, osim za estetsku rekonstrukciju kongenitalnih anomalija, rekonstrukciju dojke nakon mastektomije, estetsku rekonstrukciju nakon teških ozljeđivanja,

5. liječenje dobrovoljno stečenog steriliteta,

6. zdravstvenu zaštitu korištenu mimoilazeći utvrđenu listu naručivanja u okviru standarda zdravstvene zaštite iz obveznoga zdravstvenog osiguranja prema osobnoj želji osigurane osobe, na osnovi njezine pisane izjave,

7. kirurško liječenje pretilosti, osim u slučaju patološke pretilosti kada indeks tjelesne mase (BMI) prelazi 40, odnosno kada BMI prelazi 35, uz uvjet da osigurana osoba boluje i od drugih pridruženih bolesti,

8. liječenje medicinskih komplikacija koje nastaju kao posljedica korištenja zdravstvene zaštite izvan obveznoga zdravstvenoga osiguranja,

9. zdravstvenu zaštitu koju na temelju zakona i drugih propisa osiguravaju poslodavci, Republika Hrvatska ili jedinice lokalne i područne (regionalne) samouprave.

6. Sudjelovanje u troškovima zdravstvene zaštite

Članak 35.

(1) Osigurane osobe obvezne su sudjelovati u troškovima zdravstvene zaštite iz članka 19. stavaka 3. i 4., članka 20. stavka 5., članka 22. stavka 4. i članka 23. stavka 4. ovoga Zakona.

(2) Osigurana osoba troškove zdravstvene zaštite iz stavka 1. ovoga članka plaća osobno prilikom korištenja zdravstvene zaštite, odnosno putem dopunskoga zdravstvenog osiguranja, sukladno Zakonu o dobrovoljnom zdravstvenom osiguranju.

(3) Sredstva ostvarena sudjelovanjem osigurane osobe u troškovima zdravstvene zaštite iz članka 19. stavka 3., članka 20. stavka 5., članka 22. stavka 4. i članka 23. stavka 4. ovoga Zakona prihod su ugovornih subjekata Zavoda, ugovornih isporučitelja pomagala, odnosno zdravstvenih ustanova u drugim državama članicama, odnosno trećim državama u kojima su osigurane osobe koristile zdravstvenu zaštitu u skladu s člankom 26. ovoga Zakona, a sredstva iz članka 19. stavka 4. prihod su Zavoda.

(4) U troškovima zdravstvene zaštite iz članka 19. stavaka 3. i 4., članka 22. stavka 4. i članka 23. stavka 4. ovoga Zakona nisu obvezna sudjelovati djeca do navršene 18. godine života i osigurane osobe iz članka 12. stavaka 2. i 3. te članka 15. ovoga Zakona.

2. PRAVO NA NOVČANE NAKNADE

Članak 36.

(1) Osiguranici u okviru prava iz obveznoga zdravstvenog osiguranja imaju pravo na:

1. naknadu plaće za vrijeme privremene nesposobnosti, odnosno spriječenosti za rad zbog korištenja zdravstvene zaštite, odnosno drugih okolnosti iz članka 39. ovoga Zakona (u daljnjem tekstu: naknada plaće),

2. novčanu naknadu zbog nemogućnosti obavljanja poslova na temelju kojih se ostvaruju drugi primici od kojih se utvrđuju drugi dohoci, sukladno propisima o doprinosima za obvezna osiguranja,

3. naknadu za troškove prijevoza u vezi s korištenjem zdravstvene zaštite iz obveznoga zdravstvenog osiguranja,

4. naknadu za troškove smještaja jednom od roditelja ili osobi koja se skrbi o djetetu za vrijeme bolničkog liječenja djeteta, u iznosu i pod uvjetima utvrđenim općim aktom Zavoda,

(2) Pravo iz stavka 1. točaka 3. i 4. ovoga članka pripada i drugim osiguranim osobama.

(3) Novčane naknade iz stavka 1. ovog članka, kao i novčane naknade na ime povrata troškova za prava iz obveznoga zdravstvenog osiguranja koje je osigurana osoba ostvarila temeljem rješenja Zavoda izuzete su od ovrhe.

Članak 37.

(1) Pravo na novčane naknade za slučaj priznate ozljede na radu, odnosno profesionalne bolesti obuhvaća:

1. naknadu plaće za vrijeme privremene nesposobnosti za rad uzrokovane priznatom ozljedom na radu, odnosno profesionalnom bolešću,

2. naknadu za troškove prijevoza u vezi s korištenjem zdravstvene zaštite iz obveznoga zdravstvenog osiguranja koja je posljedica priznate ozljede na radu, odnosno profesionalne bolesti,

3. naknadu za troškove pogreba u slučaju smrti osigurane osobe, ako je smrt neposredna posljedica priznate ozljede na radu, odnosno profesionalne bolesti.

(2) Pravo na naknadu plaće iz stavka 1. točke 1. ovoga članka ostvaruju osiguranici iz članka 7. stavka 1. točaka 1. do 4. te točaka 6., 8., 9., 20. i 25. ovoga Zakona.

(3) Pravo na naknadu za troškove prijevoza i naknadu za troškove pogreba iz stavka 1. točaka 2. i 3. ovoga članka ostvaruju osiguranici iz stavka 2. ovoga članka te osigurane osobe iz članka 16. i osiguranici iz članka 69. ovoga Zakona.

1. Pravo na naknadu plaće

Članak 38.

(1) Pravo na naknadu plaće zbog privremene nesposobnosti, odnosno spriječenosti za rad radi korištenja zdravstvene zaštite, odnosno drugih okolnosti iz članka 39. ovoga Zakona (u daljnjem tekstu: privremena nesposobnost) pripada osiguranicima iz članka 7. stavka 1. točaka 1. do 4. te točaka 6., 8., 9., 20. i 25. ovoga Zakona, ako posebnim propisom nije drukčije utvrđeno.

(2) Pod privremenom nesposobnošću iz stavka 1. ovoga članka, za vrijeme kojeg osiguraniku pripada pravo na naknadu plaće u smislu ovoga Zakona, smatra se odsutnost s rada zbog bolesti ili ozljede, odnosno drugih okolnosti utvrđenih člankom 39. ovoga Zakona zbog kojih je osiguranik spriječen izvršavati svoju obvezu rada u skladu s ugovorom o radu, drugim ugovorom ili aktom.

(3) Razdoblje privremene nesposobnosti iz stavka 2. ovoga članka, za koje osiguraniku pripada pravo na naknadu plaće u skladu s ovim Zakonom, dokazuje se izvješćem o privremenoj nesposobnosti za rad koju izdaje izabrani doktor medicine primarne zdravstvene zaštite u zdravstvenoj ustanovi, odnosno u privatnoj praksi (u daljnjem tekstu: izabrani doktor).

(4) Razdoblje privremene nesposobnosti za koje osiguranik, u skladu s odredbama ovoga Zakona, nema pravo na naknadu plaće izabrani doktor je obvezan označiti u posebnoj rubrici izvješća o privremenoj nesposobnosti za rad.

(5) Sadržaj i oblik tiskanice izvješća o privremenoj nesposobnosti za rad iz stavka 3. ovoga članka utvrđuje općim aktom Zavod.

Članak 39.

Pravo na naknadu plaće pripada osiguraniku u vezi s korištenjem zdravstvene zaštite iz obveznoga zdravstvenog osiguranja, odnosno drugih okolnosti utvrđenih ovim Zakonom, ako je:

1. privremeno nesposoban za rad zbog bolesti ili ozljede, odnosno ako je radi liječenja ili medicinskih ispitivanja smješten u zdravstvenu ustanovu,

2. privremeno spriječen obavljati rad zbog određenog liječenja ili medicinskog ispitivanja koje se ne može obaviti izvan radnog vremena osiguranika,

3. izoliran kao kliconoša ili zbog pojave zaraze u njegovoj okolini, odnosno privremeno nesposoban za rad zbog transplantacije živog tkiva i organa u korist druge osigurane osobe Zavoda,

4. određen za pratitelja osigurane osobe upućene na liječenje ili liječnički pregled ugovornom subjektu Zavoda izvan mjesta prebivališta, odnosno boravišta osigurane osobe koja se upućuje,

5. određen da njeguje oboljelog člana uže obitelji (dijete i supružnika) uz uvjete propisane ovim Zakonom,

6. privremeno nesposobna za rad zbog bolesti i komplikacija u vezi s trudnoćom i porodom,

7. privremeno spriječen za rad zbog korištenja rodiljnog dopusta i prava na rad u polovici punoga radnog vremena, sukladno propisima o rodiljnim i roditeljskim potporama,

8. privremeno nesposoban za rad zbog korištenja dopusta za slučaj smrti djeteta, u slučaju mrtvorođenog djeteta ili smrti djeteta za vrijeme korištenja rodiljnog dopusta,

9. privremeno nesposoban za rad zbog rane, ozljede ili bolesti koja je neposredna posljedica sudjelovanja u Domovinskom ratu.

10. privremeno nesposoban za rad zbog priznate ozljede na radu, odnosno profesionalne bolesti.

Članak 40.

Naknadu plaće u vezi s korištenjem zdravstvene zaštite iz članka 39. točaka 1. i 2. ovoga Zakona isplaćuje osiguraniku iz svojih sredstava:

1. pravna ili fizička osoba – poslodavac za prva 42 dana privremene nesposobnosti, kao i za sve vrijeme dok se osiguranik nalazi na radu u trećoj državi na koji ga je uputila pravna ili fizička osoba ili je sam zaposlen u trećoj državi.

2. pravna osoba za profesionalnu rehabilitaciju i zapošljavanje osoba s invaliditetom, odnosno pravna ili fizička osoba – poslodavac za osiguranika radnika – invalida rada za prvih sedam dana privremene nesposobnosti.

Članak 41.

(1) Naknada plaće za vrijeme privremene nesposobnosti iz članka 39. točaka 3. do 8. i točke 10. ovoga Zakona isplaćuje se osiguraniku na teret sredstava Zavoda od prvog dana korištenja prava.

(2) Naknadu plaće iz članka 39. točke 9. ovoga Zakona Zavod isplaćuje osiguraniku na teret sredstava državnog proračuna.

(3) Naknadu plaće za vrijeme privremene nesposobnosti iz članka 39. točaka 1. i 2. ovoga Zakona od 43. dana, odnosno osam dana privremene nesposobnosti obračunava i isplaćuje pravna, odnosno fizička osoba – poslodavac, s tim da je Zavod obvezan vratiti isplaćenu naknadu plaće u roku od 45 dana od dana primitka zahtjeva za povrat.

(4) Naknadu plaće za vrijeme privremene nesposobnosti iz članka 39. točaka 4., 5. i 10. ovoga Zakona od prvoga dana privremene nesposobnosti obračunava i isplaćuje pravna, odnosno

fizička osoba – poslodavac, s tim da je Zavod obvezan vratiti isplaćenu naknadu plaće u slučaju iz članka 39. točaka 4. i 5. ovoga Zakona, u roku od 30 dana, a u slučaju iz članka 39. točke 10. ovoga Zakona u roku od 45 dana od dana primitka zahtjeva za povrat.

(5) Ako Zavod nakon zaprimanja zahtjeva iz stavaka 3. i 4. ovoga članka utvrdi da osiguranik, kojem je izvršena isplata naknade plaće od strane pravne, odnosno fizičke osobe – poslodavca, nema pravo na naknadu plaće prema odredbama ovoga Zakona, o tome će pisanim putem odmah izvijestiti poslodavca i vratiti mu zahtjev.

(6) U slučaju kada pravna, odnosno fizička osoba – poslodavac nije u mogućnosti, iz razloga nelikvidnosti, isplatiti plaću, odnosno naknadu plaće u trajanju od najmanje dva kalendarska mjeseca, isplatu naknade plaće iz stavaka 3. i 4. ovog članka, koja tereti sredstva Zavoda, odnosno državnog proračuna, osiguraniku će izvršiti Zavod.

(7) Način ostvarivanja prava na naknadu plaće pobliže će utvrditi općim aktom Zavod.

Članak 42.

U slučaju stečajnog postupka poslodavca naknadu plaće zbog privremene nesposobnosti iz članka 39. točaka 1. i 2. te točaka 4., 5. i 10. ovoga Zakona, kada se naknada plaće isplaćuje na teret sredstava Zavoda, osiguraniku isplaćuje Zavod.

Članak 43.

(1) U slučaju kada osiguraniku pravna, odnosno fizička osoba – poslodavac nije utvrdila naknadu plaće na način i u visini utvrđenoj ovim Zakonom i provedbenim propisom donesenim na temelju ovoga Zakona u roku od 30 dana od dana dospijeća isplate plaće kod poslodavca, osiguranik ima pravo podnijeti Zavodu zahtjev za obračun pripadajuće naknade plaće.

(2) Po zaprimanju zahtjeva iz stavka 1. ovoga članka Zavod će obračunati naknadu plaće i obračun dostaviti osiguraniku i poslodavcu najkasnije u roku od 15 dana od dana zaprimanja zahtjeva.

(3) Poslodavac je obvezan osiguraniku isplatiti naknadu plaće sukladno obračunu koji je dostavio Zavod najkasnije u roku od 15 dana od dana zaprimanja obračuna naknade plaće.

Članak 44.

(1) Naknada plaće za vrijeme privremene nesposobnosti pripada osiguraniku za sve vrijeme privremene nesposobnosti, a najduže u trajanju propisanom ovim Zakonom.

(2) Naknada plaće pripada osiguraniku samo za dane, odnosno sate za koje bi osiguranik imao pravo na plaću da radi prema propisima o radu, ako ovim Zakonom nije drukčije propisano.

Članak 45.

(1) Osiguranik iz članka 39. točke 5. ovoga Zakona ima pravo na naknadu plaće za vrijeme privremene spriječenosti za rad radi njege osigurane osobe – djeteta do navršene sedme

godine života u trajanju najviše do 60 dana za svaku utvrđenu bolest, a za dijete od sedam do 18. godine života najviše do 40 dana.

(2) Iznimno od stavka 1. ovoga članka, ako je prema ocjeni doktora medicine primarne zdravstvene zaštite zdravstveno stanje člana obitelji – djeteta do 18. godine života takvo da duljina trajanja njege određena u stavku 1. ovoga članka neće biti dovoljna, potrebno trajanje njege određuje liječničko povjerenstvo Zavoda.

(3) Pod djetetom iz stavaka 1. i 2. ovoga članka smatra se osim vlastitog djeteta i posvojeno dijete, pastorče, te dijete koje je na osnovi rješenja nadležnog tijela osiguraniku povjereno na čuvanje i odgoj.

(4) Pravo na naknadu plaće za vrijeme privremene spriječenosti za rad radi njege osigurane osobe – djeteta iznad 18 godina života ili supružnika osiguranik ima za svaku utvrđenu bolest najviše do 20 dana.

(5) Njega člana obitelji iz stavka 4. ovoga članka može se odobriti samo u slučaju teškog zdravstvenog stanja člana obitelji uzrokovanog bolešću, odnosno ozljedom.

(6) Zdravstveno stanje člana obitelji iz stavka 5. ovoga članka, za kojeg se može odobriti njega osiguraniku, pobliže će utvrditi Zavod općim aktom, uz suglasnost ministra nadležnog za zdravlje.

(7) Pravo iz stavaka 1. i 2. ovoga članka osiguranik može ostvariti pod uvjetom da drugi roditelj nije nezaposlen, odnosno ako živi sam s djetetom (npr. samohrani ili razvedeni roditelj), da istodobno ne koristi to pravo za drugo dijete te da za dijete kojemu je potrebna njega nema priznato pravo roditelja njegovatelja.

(8) Osiguranik ima pravo privremenu spriječenost za rad radi njege člana obitelji koristiti i kao rad u polovici punog radnog vremena.

Članak 46.

(1) Početak i dužinu trajanja privremene nesposobnosti utvrđuje izabrani doktor.

(2) Izabrani doktor utvrđuje dužinu trajanja privremene nesposobnosti osiguranika ovisno o vrsti bolesti koja utječe na privremenu nesposobnost osiguranika u skladu sa medicinskom indikacijom i smjernicama koje pravilnikom propisuje ministar nadležan za zdravlje, po prethodno pribavljenom mišljenju stručnih društava Hrvatskog liječničkog zbora, odnosno ovisno o drugim razlozima privremene spriječenosti za rad utvrđene odredbom članka 39. ovoga Zakona.

(3) Kada izabrani doktor utvrdi da se zdravstveno stanje osiguranika, čija privremena nesposobnost traje neprekidno najmanje šest mjeseci, poboljšalo i da bi rad u polovici punog radnog vremena bio koristan za brže uspostavljanje pune radne sposobnosti osiguranika, izabrani doktor može odrediti da osiguranik određeno vrijeme radi polovicu punog radnog vremena, ali ne duže od 60 dana.

(4) Izabrani doktor obvezan je utvrditi prestanak privremene nesposobnosti osiguraniku, kod kojega je nalazom i mišljenjem nadležnog tijela vještačenja mirovinskog osiguranja utvrđena

invalidnost zbog opće nesposobnosti za rad ili profesionalne nesposobnosti za rad, s danom zaprimanja obavijesti nadležnog tijela mirovinskog osiguranja iz članka 48. stavka 2. ovoga Zakona, a osiguranik pravo na naknadu plaće za vrijeme te privremene nesposobnosti ostvaruje u skladu s člankom 48. stavkom 1. ovoga Zakona.

(5) Izabrani doktor nakon što je utvrdio prestanak privremene nesposobnosti u skladu sa stavkom 4. ovoga članka može privremenu nesposobnost ponovno utvrditi samo osiguraniku kod kojeg je utvrđena invalidnost zbog profesionalne nesposobnosti za rad i to u slučaju pogoršanja bolesti osnovom koje mu je utvrđena invalidnost ili pojavom bolesti osnovom druge dijagnoze bolesti.

(6) Nadzor nad korištenjem privremene nesposobnosti osiguranika, odnosno utvrđivanja postojanja medicinskih indikacija ili drugih razloga za privremenu nesposobnost, sukladno odredbama ovoga Zakona i propisa donesenih na temelju ovoga Zakona, obavlja Zavod.

(7) Nadzor nad korištenjem privremene nesposobnosti obuhvaća kontrolu u ordinaciji izabranog doktora te neposrednu kontrolu osiguranika u ili izvan ordinacije izabranog doktora, uključujući i kućni posjet.

(8) Poslodavac osiguranika može zahtijevati od Zavoda kontrolu opravdanosti privremene nesposobnosti za sve vrijeme trajanja privremene nesposobnosti osiguranika.

(9) Pravilnik o kontroli privremene nesposobnosti za rad osiguranika donosi ministar nadležan za zdravlje.

Članak 47.

(1) Osiguraniku nezadovoljnom odlukom izabranog doktora o utvrđivanju prestanka privremene nesposobnosti, radi zaštite prava iz obveznoga zdravstvenog osiguranja, izdat će se na njegov zahtjev rješenje u upravnom postupku, a na osnovi prethodno pribavljenog obrazloženog nalaza, mišljenja i ocjene liječničkog povjerenstva Zavoda, koje je obvezno prije donošenja nalaza, mišljenja i ocjene izvršiti pregled osiguranika.

(2) Zahtjev iz stavka 1. ovoga članka rješava se po hitnom postupku.

Članak 48.

(1) Osiguranik za vrijeme privremene nesposobnosti iz članka 39. točaka 1. do 6. te točaka 9. i 10. ovoga Zakona ima pravo na naknadu plaće na teret sredstava Zavoda, odnosno državnog proračuna dok izabrani doktor ne utvrdi da je sposoban za rad ili dok nije nalazom i mišljenjem nadležnog tijela vještačenja mirovinskog osiguranja kod osiguranika utvrđena invalidnost zbog opće nesposobnosti za rad ili profesionalne nesposobnosti za rad.

(2) Kada je prema ocjeni izabranog doktora, a nakon provedenog liječenja i medicinske rehabilitacije zdravstveno stanje osiguranika takvo da se daljnjim liječenjem ne može poboljšati te je kod osiguranika nastupila trajna nesposobnost za rad na poslovima koje osiguranik obavlja, kao i u slučaju kada privremena nesposobnost osiguranika traje neprekidno 12 mjeseci zbog iste dijagnoze bolesti, izabrani doktor je obvezan obraditi osiguranika za upućivanje na ocjenu radne sposobnosti i invalidnosti te ga sa svom propisanom dokumentacijom uputiti nadležnom tijelu vještačenja mirovinskog osiguranja

koje je obvezno donijeti nalaz i mišljenje o radnoj sposobnosti i invalidnosti osiguranika najkasnije u roku od 60 dana od dana zaprimanja prijedloga izabranog doktora i o istome obavijestiti izabranog doktora, poslodavca osiguranika i Zavod u roku od osam dana od dana donošenja nalaza i mišljenja.

(3) Kada nadležno tijelo vještačenja mirovinskog osiguranja utvrdi da je kod osiguranika nastupila profesionalna nesposobnost za rad, odnosno neposredna opasnost od nastanka invalidnosti, obvezno je u nalazu i mišljenju navesti poslove i radne zadatke koje osiguranik s obzirom na preostalu radnu sposobnost može obavljati, odnosno koje poslove i radne zadatke ne može obavljati.

(4) Ako nadležno tijelo vještačenja mirovinskog osiguranja ne donese nalaz i mišljenje te ne izvijesti izabranog doktora, poslodavca osiguranika i Zavod u roku iz stavka 2. ovoga članka naknada plaće za tog osiguranika od prvoga idućeg dana, nakon isteka roka od 60 dana iz stavka 2. ovoga članka, tereti sredstva Hrvatskog zavoda za mirovinsko osiguranje.

(5) Obrada osiguranika za upućivanje na ocjenu radne sposobnosti i invalidnosti tereti sredstva Zavoda samo u slučajevima kada je izabrani doktor uputio osiguranika na ocjenu radne sposobnosti i invalidnosti u skladu sa stavkom 2. ovoga članka.

Članak 49.

(1) Za vrijeme ponovno utvrđene privremene nesposobnosti osiguranika kojem je nalazom i mišljenjem nadležnog tijela vještačenja mirovinskog osiguranja utvrđena invalidnost zbog profesionalne nesposobnosti za rad, neovisno o tome radi li se o privremenoj nesposobnosti koja je posljedica pogoršanja bolesti osnovom koje mu je utvrđena invalidnost ili pojavom bolesti zbog druge dijagnoze bolesti, a kojem poslodavac nije ponudio i s njim sklopio ugovor o radu u pisanom obliku za obavljanje poslova za koje je sposoban u skladu s propisima o radu, naknadu plaće osiguraniku isplaćuje poslodavac iz svojih sredstava.

(2) Naknada plaće za vrijeme privremene nesposobnosti tereti sredstva poslodavca i u slučaju kada je osiguraniku utvrđena neposredna opasnost od nastanka invalidnosti, a poslodavac nije osiguraniku u skladu s propisima o radu ponudio i s njim sklopio ugovor o radu u pisanom obliku za obavljanje poslova za koje je sposoban, i to od dana utvrđene neposredne opasnosti od nastanka invalidnosti. Naknada plaće tereti sredstva poslodavca sve do dana sklapanja pisanog ugovora o radu za obavljanje poslova za koje je sposoban.

(3) Osiguranik koji ne prihvati ponudu poslodavca iz stavaka 1. i 2. ovoga članka i s poslodavcem ne sklopi ugovor o radu za obavljanje poslova za koje je sposoban nema pravo na naknadu plaće prema ovome Zakonu za vrijeme privremene nesposobnosti od dana zaprimanja ponude poslodavca.

(4) Osiguranik iz članka 7. stavka 1. točaka 6., 8. i 9. ovoga Zakona kod kojeg je nalazom i mišljenjem nadležnog tijela vještačenja mirovinskog osiguranja utvrđena invalidnost zbog profesionalne nesposobnosti za rad, odnosno neposredna opasnost od nastanka invalidnosti nema pravo na naknadu plaće na teret sredstava obveznoga zdravstvenog osiguranja od dana utvrđene invalidnosti, odnosno utvrđene neposredne opasnosti od nastanka invalidnosti.

Članak 50.

Osiguranik koji je navršio 65 godina života i 15 godina mirovinskog staža osiguranja na temelju nesamostalnog ili samostalnog rada nema pravo na naknadu plaće na teret sredstava obveznoga zdravstvenog osiguranja za vrijeme privremene nesposobnosti, već na teret sredstava poslodavca, odnosno na teret sredstava osiguranika obveznika uplate doprinosa.

Članak 51.

(1) Osiguraniku kojem je za vrijeme trajanja privremene nesposobnosti prestao radni odnos, odnosno obavljanje djelatnosti osobnim radom naknada plaće pripada još najviše 30 dana računajući od dana prestanka radnog odnosa, odnosno obavljanja djelatnosti osobnim radom i to pod uvjetom da mu je izabrani doktor privremenu nesposobnost utvrdio najmanje osam dana prije dana prestanka radnog odnosa, odnosno obavljanja djelatnosti osobnim radom te da je u vrijeme prestanka radnog odnosa, odnosno obavljanja djelatnosti osobnim radom imao pravo na naknadu plaće u skladu s odredbama ovoga Zakona.

(2) Iznimno, pod uvjetima iz stavka 1. ovoga članka, osiguraniku kojem je za vrijeme privremene nesposobnosti koja je neposredna posljedica sudjelovanja u Domovinskom ratu, odnosno posljedica priznate ozljede na radu ili profesionalne bolesti prestao radni odnos, odnosno obavljanje djelatnosti osobnim radom pripada pravo na naknada plaće i nakon prestanka radnog odnosa, odnosno obavljanja djelatnosti osobnim radom sve dok ponovno ne bude radno sposoban, odnosno dok mu nalazom i mišljenjem nadležnog tijela vještačenja mirovinskog osiguranja ne bude utvrđena invalidnost u skladu s člankom 48. ovoga Zakona.

(3) Za vrijeme privremene nesposobnosti za rad zbog bolesti i komplikacija u vezi s trudnoćom i porodom iz članka 39. točke 6. ovoga Zakona, korištenja prava na rodiljni dopust i prava na rad u polovici punoga radnog vremena iz članka 39. točke 7. ovoga Zakona te prava na dopust za slučaj smrti djeteta iz članka 39. točke 8. ovoga Zakona osiguraniku koji koristi jedno od navedenih prava pripada pravo na naknadu plaće i nakon prestanka radnog odnosa, odnosno obavljanja djelatnosti osobnim radom do isteka korištenja istog prava.

(4) Osiguraniku koji je tijekom korištenja prava iz stavaka 1., 2. i 3. ovoga članka zasnovao radni odnos s punim ili nepunim radnim vremenom ili je počeo obavljati djelatnost osobnim radom prestaje pravo na naknadu plaće ostvarene sukladno ovom članku.

Članak 52.

(1) Osiguranik ima pravo na teret sredstava Zavoda, odnosno državnog proračuna ostvariti pravo na naknadu plaće za vrijeme privremene nesposobnosti iz članka 39. točaka 1. do 5. te točaka 9. i 10. ovoga Zakona u maksimalnom trajanju od 18 mjeseci po istoj dijagnozi bolesti, bez prekida, u visini utvrđenoj u skladu s ovim Zakonom i općim aktima Zavoda.

(2) Nakon isteka roka iz stavka 1. ovoga članka osiguranik ostvaruje pravo na naknadu plaće u iznosu 50% zadnje isplaćene naknade plaće na ime te privremene nesposobnosti dok za privremenu nesposobnost postoji medicinska indikacija.

(3) Odredba stavka 2. ovoga članka ne odnosi se na osiguranika kojem je utvrđena privremena nesposobnost zbog liječenja zloćudnih bolesti, osiguranika kojem je odobrena njega člana obitelji – djeteta oboljelog od zloćudne bolesti, osiguranika čija je privremena nesposobnost u vezi s provođenjem hemodijalize ili peritonejske dijalize te čija je privremena nesposobnost u vezi s uzimanjem i presađivanjem dijelova ljudskog tijela.

Članak 53.

(1) Osiguranik nema pravo na naknadu plaće ako:

1. je svjesno prouzročio privremenu nesposobnost,

2. ne izvijesti izabranog doktora da je obolio u roku od tri dana od dana početka bolesti, odnosno u roku od tri dana od dana prestanka razloga koji ga je u tome onemogućio,

3. namjerno sprječava ozdravljenje, odnosno osposobljavanje za rad,

4. za vrijeme privremene nesposobnosti radi, odnosno obavlja poslove osnovom kojih je obvezno zdravstveno osiguran, obavlja ugovorene poslove temeljem ugovora o djelu te bilo koje druge poslove (npr. poljoprivredni radovi i sl.),

5. se bez opravdanog razloga ne odazove na poziv za liječnički pregled izabranog doktora, odnosno doktora kontrolora Zavoda ili tijela Zavoda ovlaštenog za kontrolu privremene nesposobnosti,

6. izabrani doktor, doktor kontrolor ili tijelo Zavoda ovlašteno za kontrolu privremene nesposobnosti utvrde da se ne pridržava uputa za liječenje, odnosno bez suglasnosti izabranog doktora otputuje iz mjesta prebivališta, odnosno boravišta ili zlorabi privremenu nesposobnost na neki drugi način.

(2) U slučajevima iz stavka 1. ovoga članka osiguranik nema pravo na naknadu plaće od dana nastanka tih slučajeva do dana njihova prestanka, odnosno prestanka posljedica njima uzrokovanih.

Članak 54.

(1) Naknada plaće određuje se od osnovice za naknadu koju čini prosječni iznos plaće koja je osiguraniku isplaćena u posljednjih šest mjeseci prije mjeseca u kojem je nastupio slučaj na osnovi kojeg se stječe pravo na naknadu plaće, neovisno o tome na čiji se teret isplaćuje, osim u slučaju kada je posebnim zakonom drukčije propisano.

(2) Pod plaćom na osnovi koje se utvrđuje osnovica za naknadu plaće podrazumijeva se, u smislu ovoga Zakona, redovita mjesečna plaća osiguranika utvrđena u skladu s odredbama propisa o radu te naknada plaće isplaćena za vrijeme odsutnosti s rada (godišnji odmor, plaćeni dopust i privremena nesposobnost) koja se isplaćuje na teret pravne ili fizičke osobe kod koje je osiguranik zaposlen.

(3) Za osiguranika iz članka 7. stavka 1. točaka 3., 4., 6., 8. i 9. ovoga Zakona osnovica za naknadu plaće jest mjesečna osnovica osiguranja za obračun i uplatu doprinosa za obvezno zdravstveno osiguranje za posljednjih šest mjeseci prije mjeseca u kojem je nastupio osigurani slučaj na osnovi kojeg se stječe pravo na naknadu plaće, umanjena za zakonom propisane obvezne doprinose, poreze i prireze.

(4) Iznimno, osiguranicima koji pravo na naknadu plaće za vrijeme privremene nesposobnosti ostvaruju na teret sredstava Zavoda ili državnog proračuna u osnovicu za naknadu plaće iz stavka 1. ovoga članka uračunavaju se i drugi dohoci ostvareni prema primicima od kojih se,

prema propisima o porezu na dohodak, utvrđuje drugi dohodak, a sukladno propisima o doprinosima za obvezna osiguranja pod uvjetom da su isplaćeni u šestomjesečnom razdoblju na temelju kojih se utvrđuje osnovica za naknadu te da imaju ostvaren staž osiguranja u Zavodu propisan člankom 56. stavkom 1. ovoga Zakona.

(5) U slučaju kad se osnovica za naknadu plaće ne može utvrditi prema stavku 1. ovoga članka, osnovicu za naknadu plaće čini plaća isplaćena do dana nastanka slučaja na osnovi kojeg se stječe pravo na naknadu plaće, odnosno pripadajuća plaća za mjesec za koji se određuje naknada plaće, s tim da tako određena osnovica, kada se naknada isplaćuje na teret sredstava Zavoda, ne može biti veća od najniže osnovice osiguranja koja služi za obračun doprinosa za obvezno zdravstveno osiguranje, važeće za mjesec koji prethodi mjesecu u kojem je nastupio osigurani slučaj.

(6) Iznimno od stavka 5. ovoga članka, kada se osnovica za naknadu plaće, koja pripada osiguraniku u slučaju privremene nesposobnosti zbog priznate ozljede na radu ili profesionalne bolesti, ne može utvrditi prema stavku 1. ovoga članka, osnovicu za naknadu plaće čini pripadajuća plaća za mjesec za koji se određuje naknada plaće.

(7) Kada osiguranik prima naknadu plaće neprekidno dulje od tri mjeseca, osnovica za utvrđivanje naknade iz stavka 1. ovoga članka povećava se sukladno porastu plaće zaposlenih u Republici Hrvatskoj, ako je taj porast veći od 5%.

(8) Naknada plaće prema stavku 7. ovoga članka pripada osiguraniku od prvoga dana idućeg mjeseca po isteku tri mjeseca neprekidne privremene nesposobnosti, ako je ispunjen uvjet za povećanje naknade plaće.

(9) Zavod će općim aktom utvrditi način utvrđivanja osnovice za naknadu plaće iz stavka 3. ovoga članka.

Članak 55.

(1) Naknada plaće ne može biti niža od 70% osnovice za naknadu plaće, ako ovim Zakonom nije drukčije propisano, s time da kao mjesečni iznos za puno radno vrijeme ne može biti niža od 25% proračunske osnovice.

(2) Naknada plaće iznosi 100% od osnovice za naknadu plaće za vrijeme:

1. privremene nesposobnosti zbog rane, ozljede ili bolesti koja je neposredna posljedica sudjelovanja u Domovinskom ratu,

2. privremene nesposobnosti zbog bolesti i komplikacija u vezi s trudnoćom i porodom,

3. korištenja rodiljnog dopusta i prava na rad u polovici punoga radnog vremena iz članka 39. točke 7. ovoga Zakona,

4. korištenja dopusta za slučaj smrti djeteta iz članka 39. točke 8. ovoga Zakona,

5. njege oboljelog djeteta mlađeg od tri godine života,

6. privremene nesposobnosti zbog transplantacije živog tkiva i organa u korist druge osobe,

7. dok je osiguranik izoliran kao kliconoša ili zbog pojave zaraze u njegovoj okolini,

8. privremene nesposobnosti zbog priznate ozljede na radu, odnosno profesionalne bolesti.

(3) Visinu naknade plaće koja se isplaćuje na teret sredstava Zavoda utvrđuje Zavod, s time da najviši mjesečni iznos naknade plaće, obračunate prema odredbama ovoga Zakona i propisa donesenih na temelju ovoga Zakona, ne može za puno radno vrijeme iznositi više od proračunske osnovice uvećane za 28%, osim naknade plaće iz stavka 2. točaka 3., 4. i 8. ovoga članka.

(4) Pod punim radnim vremenom u smislu ovoga Zakona smatra se rad od 40 sati tjedno, ako posebnim propisom, pravilnikom o radu, kolektivnim ugovorom, sporazumom sklopljenim između radničkog vijeća i poslodavca ili ugovorom o radu nije drukčije utvrđeno.

Članak 56.

(1) Naknada plaće koja se isplaćuje na teret sredstava Zavoda pripada osiguraniku u visini propisanoj ovim Zakonom, odnosno propisima i općim aktima donesenim na temelju ovoga Zakona pod uvjetom da prije dana nastanka osiguranog slučaja na osnovi kojeg se stječe pravo na naknadu plaće ima ostvaren staž osiguranja u Zavodu na temelju radnog odnosa, obavljanja gospodarske djelatnosti ili obavljanja profesionalne djelatnosti samostalno u obliku zanimanja, odnosno na temelju primanja naknade plaće nakon prestanka radnog odnosa, odnosno prestanka obavljanja djelatnosti osobnim radom ostvarene prema ovom Zakonu od najmanje devet mjeseci neprekidno ili 12 mjeseci s prekidima u posljednje dvije godine (prethodno osiguranje), ako posebnim zakonom nije drukčije utvrđeno.

(2) Odredbe stavka 1. ovoga članka ne primjenjuju se na naknadu plaće za slučaj priznate ozljede na radu, odnosno profesionalne bolesti.

(3) Osiguraniku, koji ne ispunjava uvjet prethodnog osiguranja iz stavka 1. ovoga članka, naknada plaće, za sve vrijeme trajanja privremene nesposobnosti, pripada u iznosu od 25% proračunske osnovice za puno radno vrijeme.

2. Novčana naknada zbog nemogućnosti obavljanja poslova na temelju kojih se ostvaruju primici od kojih se utvrđuje drugi dohodak sukladno propisima o doprinosima za obvezna osiguranja

Članak 57.

(1) Novčana naknada zbog nemogućnosti obavljanja poslova na temelju kojih se ostvaruju primici od kojih se utvrđuje drugi dohodak sukladno propisima o doprinosima za obvezna osiguranja određuje se od prosječne osnovice za uplatu doprinosa za obvezno zdravstveno osiguranje.

(2) Pod prosječnom osnovicom iz stavka 1. ovoga članka podrazumijeva se prosjek osnovica osiguranja na koji je uplaćen doprinos za obvezno zdravstveno osiguranje u posljednjih šest mjeseci prije mjeseca u kojem je nastupila nemogućnost osiguranika za obavljanje poslova na temelju kojih se ostvaruju primici od kojih se utvrđuje drugi dohodak.

Članak 58.

Novčana naknada iz članka 57. stavka 1. ovoga Zakona iznosi 70% od prosječne osnovice s time da mjesečni iznos naknade ne može biti viši od najvišeg iznosa naknade plaće iz članka 55. stavka 3. ovoga Zakona, a isplaćuje se od prvog dana korištenja prava na teret sredstava Zavoda, u trajanju najdulje šest mjeseci neprekidno.

Članak 59.

Osiguranik ostvaruje novčanu naknadu iz članka 57. stavka 1. ovoga Zakona pod uvjetom da je privremeno nesposoban za obavljanje ugovorenih poslova zbog bolesti, što utvrđuje liječničko povjerenstvo Zavoda.

Članak 60.

Osiguraniku koji ostvaruje novčanu naknadu zbog nemogućnosti obavljanja poslova na temelju kojih se ostvaruju primici od kojih se utvrđuje drugi dohodak sukladno propisima o doprinosima za obvezna osiguranja, a kojem je prestao status osiguranika sukladno članku 8. stavku 2. ovoga Zakona, ostvaruje pravo na novčanu naknadu još najviše 30 dana od dana prestanka statusa osiguranika, pod uvjetom da je liječničko povjerenstvo Zavoda utvrdilo da zbog zdravstvenog stanja nije u mogućnosti obavljati ugovorene poslove najmanje osam dana prije dana prestanka statusa osiguranika.

Članak 61.

Opći akt o načinu ostvarivanja prava na novčanu naknadu zbog nemogućnosti obavljanja poslova na temelju kojih se ostvaruju primici od kojih se utvrđuje drugi dohodak sukladno propisima o doprinosima za obvezna osiguranja donijet će Zavod.

3. Naknada za troškove prijevoza u vezi s korištenjem prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja

Članak 62.

(1) Osigurana osoba radi ostvarivanja prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja ima pravo na naknadu za troškove prijevoza pod uvjetom da je radi korištenja zdravstvene zaštite upućena izvan mjesta prebivališta, odnosno boravišta te da ne ispunjava uvjete za korištenje sanitetskog prijevoza propisane pravilnikom ministra nadležnog za zdravlje iz članka 19. stavka 2. točke 18. ovoga Zakona i utvrđene općim aktom Zavoda.

(2) Osigurana osoba iz stavka 1. ovoga članka ima pravo na naknadu za troškove prijevoza ako je radi korištenja zdravstvene zaštite upućena u ugovornu zdravstvenu ustanovu, odnosno ordinaciju ugovornog doktora privatne prakse ili ugovornom isporučitelju pomagala u mjesto koje je udaljeno 50 i više kilometara od mjesta njezina prebivališta, odnosno boravišta jer odgovarajuću zdravstvenu zaštitu, sukladno svom zdravstvenom stanju ne može ostvariti u bližoj ugovornoj zdravstvenoj ustanovi, odnosno ordinaciji ugovornog doktora privatne prakse s ugovorenom djelatnošću za tu vrstu zdravstvene zaštite ili kod bližeg ugovornog isporučitelja pomagala.

(3) Pod uvjetom iz stavka 2. ovoga članka, koji se odnosi na udaljenost, pravo na naknadu za troškove prijevoza ima i osigurana osoba koja je pozvana od strane Zavoda u predmetu utvrđivanja prava iz obveznoga zdravstvenog osiguranja.

(4) Pravo na naknadu za troškove prijevoza, neovisno o udaljenosti iz stavka 2. ovoga članka, ima osigurana osoba do 18. godine života, osigurana osoba iz članka 12. stavaka 2. i 3. ovoga Zakona, osigurana osoba u vezi korištenja radioterapije i kemoterapije te hemodijalize kao kronični bubrežni bolesnik, osigurana osoba u vezi korištenja zdravstvene zaštite zbog priznate ozljede na radu, odnosno profesionalne bolesti, osigurana osoba darivatelj organa, tkiva ili stanica koja zdravstvenu zaštitu koristi u vezi s darivanjem organa, tkiva ili stanica, te osigurana osoba upućena na liječenje u drugu državu članicu ili treću državu sukladno ovome Zakonu i općem aktu Zavoda.

(5) Pravo na naknadu za troškove prijevoza, sukladno stavku 2. ovoga članka, ima i osigurana osoba koja je radi smanjivanja liste čekanja prihvatila korištenje zdravstvene zaštite u ugovornoj zdravstvenoj ustanovi, odnosno ordinaciji ugovornog doktora privatne prakse koja nije u mjestu, odnosno nije najbliža mjestu njezina prebivališta, odnosno boravišta.

(6) Osigurana osoba koja zdravstvenu zaštitu želi koristiti u drugoj ugovornoj zdravstvenoj ustanovi, odnosno ordinaciji ugovornog doktora privatne prakse ili kod drugog ugovornog isporučitelja pomagala na području Republike Hrvatske, a ne tamo gdje je upućena ima pravo ostvariti tu zdravstvenu zaštitu na teret sredstava obveznoga zdravstvenog osiguranja, ali bez prava na naknadu za troškove prijevoza i prava na sanitetski prijevoz.

Članak 63.

(1) Zavod snosi stvarne troškove prijevoza posmrtnih ostataka osigurane osobe koja je bila upućena na liječenje izvan mjesta prebivališta, odnosno boravka u skladu sa člankom 62. ovoga Zakona.

(2) Zavod snosi troškove prijevoza posmrtnih ostataka osigurane osobe do mjesta njezina prebivališta, odnosno boravišta ako je toj osobi izvršena eksplantacija organa u svrhu transplantacije u ugovornoj zdravstvenoj ustanovi izvan mjesta njezina prebivališta, odnosno boravišta.

(3) Pravo na naknadu troškova prijevoza iz stavaka 1. i 2. ovoga članka isplaćuje se pravnoj ili fizičkoj osobi koja je snosila troškove prijevoza na osnovi njezina zahtjeva i dokaza o plaćenom prijevozu.

Članak 64.

(1) Pravo na naknadu za troškove prijevoza ima i jedna osoba određena za pratitelja osigurane osobe iz članka 62. ovoga Zakona pod uvjetom da je izabrani doktor primarne zdravstvene zaštite utvrdio potrebu pratnje te da osigurana osoba kojoj je određen pratitelj ne ispunjava uvjete za korištenje sanitetskog prijevoza propisane pravilnikom ministra nadležnog za zdravlje iz članka 19. stavka 2. točke 18. ovoga Zakona i utvrđene općim aktom Zavoda.

(2) Smatra se da je djeci do 18. godine života, kao i osiguranim osobama iz članka 12. stavaka 2. i 3. ovoga Zakona potrebna pratnja neovisno o tome ispunjavaju li uvjete za korištenje sanitetskog prijevoza.

Članak 65.

(1) Pod naknadom za troškove prijevoza iz članka 62. ovoga Zakona podrazumijeva se naknada za troškove prijevoza javnim prijevoznim sredstvima po najnižoj cijeni i prema najkraćoj relaciji prema službenom daljinomjeru javnog prijevoznika.

(2) Iznimno od stavka 1. ovoga članka, osiguranoj osobi se zbog njezina zdravstvenog stanja, prema prethodnom odobrenju liječničkog povjerenstva Zavoda, a na prijedlog izabranog doktora može odobriti korištenje skupljeg javnog prijevoznog sredstva (spavaća kola u vlaku, zrakoplov).

(3) Osigurana osoba kojoj je u skladu sa stavkom 2. ovoga članka ili rješenjem Zavoda o upućivanju na liječenje u drugu državu članicu, odnosno treću državu u skladu s člankom 26. stavkom 3. ovoga Zakona, a na osnovi nalaza, mišljenja i ocjene liječničkog povjerenstva Zavoda, zbog zdravstvenog stanja odobren prijevoz zrakoplovom, ima pravo na naknadu za troškove prijevoza u visini najniže cijene zrakoplovne karte za ekonomsku klasu.

(4) Pravo na naknadu za troškove prijevoza osigurana osoba ostvaruje na osnovi tiskanice putnog naloga koji izdaje izabrani doktor medicine primarne zdravstvene zaštite ili izabrani doktor dentalne medicine, odnosno ovlašteni radnik Zavoda kada je osigurana osoba pozvana od strane Zavoda radi ostvarivanja prava iz obveznoga zdravstvenog osiguranja te na osnovi rješenja Zavoda o upućivanju na liječenje sukladno članku 26. stavku 3. ovoga Zakona, odnosno na osnovi potvrde zdravstvene ustanove o provedenim hemodijalizama.

(5) Sadržaj i oblik tiskanice putnog naloga iz stavka 4. ovog članka utvrđuje općim aktom Zavod.

V. OZLJEDA NA RADU I PROFESIONALNA BOLEST

Članak 66.

Ozljedom na radu prema ovome Zakonu smatra se:

1. ozljeda izazvana neposrednim i kratkotrajnim mehaničkim, fizikalnim ili kemijskim djelovanjem te ozljeda prouzročena naglim promjenama položaja tijela, iznenadnim opterećenjem tijela ili drugim promjenama fiziološkog stanja organizma, ako je uzročno vezana uz obavljanje poslova, odnosno djelatnosti na osnovi koje je ozlijeđena osoba osigurana u obveznom zdravstvenom osiguranju, kao i ozljeda nastala tijekom obveznoga kondicijskog treninga vezanog uz održavanje psihofizičke spremnosti za obavljanje određenih poslova, sukladno posebnim propisima,

2. bolest koja je nastala izravno i isključivo kao posljedica nesretnog slučaja ili više sile za vrijeme rada, odnosno obavljanja djelatnosti ili u vezi s obavljanjem te djelatnosti na osnovi koje je osigurana osoba osigurana u obveznom zdravstvenom osiguranju,

3. ozljeda nastala na način iz točke 1. ovoga članka koju osigurana osoba zadobije na redovitom putu od stana do mjesta rada i obratno te na putu poduzetom radi stupanja na posao koji joj je osiguran, odnosno na posao na osnovi kojeg je osigurana u obveznom zdravstvenom osiguranju,

4. ozljeda, odnosno bolest iz točaka 1. i 2. ovoga članka koja nastane kod osigurane osobe u okolnostima iz članka 16. ovoga Zakona.

Članak 67.

Ozljedom na radu, u smislu ovoga Zakona, ne smatra se ozljeda, odnosno bolest do koje je došlo zbog:

1. skrivljenog, nesavjesnog ili neodgovornog ponašanja na radnome mjestu, odnosno pri obavljanju djelatnosti, kao i na redovitom putu od stana do mjesta rada i obrnuto (npr. tučnjava na radnom mjestu ili u vremenu dnevnog odmora, namjerno nanošenje povrede sebi ili drugome, obavljanje poslova pod utjecajem alkohola ili opojnih droga, upravljanje vozilom pod utjecajem alkohola ili opojnih droga i sl.),

2. aktivnosti koje nisu u vezi s obavljanjem radnih aktivnosti (npr. radni odmor koji nije korišten u propisano vrijeme, radni odmor koji nije korišten u cilju obnove psihofizičke i radne sposobnosti nužno potrebne za nastavak radnog procesa, fizičke aktivnosti koje nisu u vezi s radnim odnosom i sl.),

3. namjernog nanošenja ozljede od strane druge osobe izazvanog osobnim odnosom s osiguranom osobom koje se ne može dovesti u kontekst radno-pravne aktivnosti,

4. atake kronične bolesti,

5. urođene ili stečene predispozicije zdravstvenog stanja koje mogu imati za posljedicu bolest.

Članak 68.

(1) Profesionalne bolesti prema ovome Zakonu su bolesti izazvane dužim neposrednim utjecajem procesa rada i uvjeta rada na određenim poslovima.

(2) Lista profesionalnih bolesti i poslova na kojima se te bolesti javljaju i uvjeti pod kojima se smatraju profesionalnim bolestima utvrđuju se posebnim zakonom.

Članak 69.

(1) Osiguranicima iz članka 7. stavka 1. točke 10. ovoga Zakona te osiguranicima iz članka 7. stavka 1. točaka 13., 16., 17. i 19. ovoga Zakona prava iz obveznoga zdravstvenog osiguranja osiguravaju se i u slučaju profesionalne bolesti ako su bili izloženi fibrogenim prašinama ili karcinogenima kao radnici kod pravnih ili fizičkih osoba s registriranom djelatnošću u Republici Hrvatskoj.

(2) Osiguranicima iz stavka 1. ovoga članka, u okviru prava iz obveznoga zdravstvenog osiguranja, osiguravaju se zdravstveni pregledi i nakon prestanka rada u slučaju izloženosti fibrogenim prašinama ili karcinogenima.

1. Pravo na naknadu za pogrebne troškove

Članak 70.

(1) U slučaju smrti osiguranika iz članka 7. stavka 1. točaka 1. do 6., 8., 9., 20. i 25. te osigurane osobe iz članka 16. i osiguranika iz članka 69. ovoga Zakona, osigurava se pravo na

naknadu za pogrebne troškove ako je smrt osiguranika, odnosno osigurane osobe neposredna posljedica priznate ozljede na radu, odnosno profesionalne bolesti.

(2) Naknadu za pogrebne troškove u visini iznosa jedne proračunske osnovice može ostvariti pravna ili fizička osoba koja je snosila troškove pokopa osigurane osobe iz stavka 1. ovoga članka.

2. Specifična zdravstvena zaštita

Članak 71.

Osim prava iz obveznoga zdravstvenog osiguranja za slučaj priznate ozljede na radu i profesionalne bolesti utvrđenih člankom 17. ovoga Zakona osiguranicima iz članka 7. točaka 1. do 6. te točaka 8., 9., 20. i 25. ovoga Zakona osiguravaju se i mjere specifične zdravstvene zaštite radnika koje provode doktori specijalisti medicine rada, sukladno Zakonu o zdravstvenoj zaštiti i posebnim zakonima te pravilnicima donesenim na temelju tih zakona.

VI. FINANCIRANJE OBVEZNOGA ZDRAVSTVENOG OSIGURANJA

1. Izvori sredstava

Članak 72.

(1) Prihodi obveznoga zdravstvenog osiguranja su:

1. doprinosi za obvezno zdravstveno osiguranje,

2. doprinosi za obvezno zdravstveno osiguranje za slučaj ozljede na radu i profesionalne bolesti,

3. doprinosi za obvezno zdravstveno osiguranje nezaposlenih osoba iz članka 7. stavka 1. točaka 13., 16., 17. i 19. i članka 11. stavka 1. točke 3. ovoga Zakona koje se vode u evidenciji nezaposlenih osoba prema propisima o zapošljavanju,

4. doprinosi za obvezno zdravstveno osiguranje osiguranih osoba kojima je odlukom nadležnoga suda oduzeta sloboda iz članka 7. stavka 1. točke 28. ovoga Zakona,

5. doprinosi za obvezno zdravstveno osiguranje drugih obveznika plaćanja doprinosa utvrđenih ovim i drugim zakonom,

6. posebni doprinos za korištenje zdravstvene zaštite u inozemstvu,

7. prihodi iz državnog proračuna,

8. prihodi od sudjelovanja u troškovima zdravstvene zaštite osiguranih osoba, odnosno njihovih osiguravatelja u dopunskom zdravstvenom osiguranju,

9. prihodi od dividendi, kamata i drugih prihoda,

10. prihodi od posebnog poreza na duhanske prerađevine,

11. prihodi od obveznoga osiguranja od automobilske odgovornosti.

(2) Prihod iz stavka 1. točke 10. ovoga članka u visini od 32% od ukupnog prihoda od posebnog poreza na duhanske prerađevine doznačuje se iz državnog proračuna na račun Zavoda do petog dana u mjesecu za prethodni mjesec.

(3) Prihod iz stavka 1. točke 11. ovoga članka uplaćuju društva za osiguranje u visini od 4% naplaćene funkcionalne premije osiguranja od obveznoga osiguranja od automobilske odgovornosti. Navedeni iznos predstavlja predujam naknade prouzročene štete Zavodu u slučajevima iz članka 140. ovoga Zakona koju su prouzročili vlasnici, odnosno korisnici osiguranoga motornog vozila.

(4) Društva za osiguranje obvezna su sredstva na ime prihoda iz stavka 1. točke 11. ovoga članka na način propisan stavkom 3. ovoga članka uplatiti do 10. dana u mjesecu za prethodni mjesec na ukupan iznos naplaćene funkcionalne premije osiguranja od obveznoga osiguranja od automobilske odgovornosti u korist računa Zavoda.

(5) Društva za osiguranje obvezna su za svako obračunsko razdoblje (mjesec) podnijeti izvješće o obračunatim i uplaćenim mjesečnim sredstvima na ime prihoda iz stavka 1. točke 11. ovoga članka do 15. u mjesecu za prethodni mjesec.

(6) Društva za osiguranje i Zavod obvezni su izvršiti konačan obračun uplaćenih sredstava i stvarnih troškova iz stavka 3. ovoga članka i godišnje izvješće o izvršenom konačnom obračunu uplaćenih sredstava i stvarnih troškova iz stavka 3. ovoga članka podnijeti ministarstvu nadležnom za financije do 30. travnja tekuće kalendarske godine za prethodnu kalendarsku godinu.

(7) Ako društva za osiguranje i Zavod ne izvrše konačni obračun uplate sredstava i stvarnih troškova u roku utvrđenom u stavku 6. ovoga članka, Ministarstvo financija – Porezna uprava (u daljnjem tekstu: Porezna uprava) rješenjem će utvrditi obvezu uplate sredstava od strane društava za osiguranje Zavodu, odnosno povrata uplaćenih sredstava društvima za osiguranje od strane Zavoda na osnovi podataka Zavoda o stvarnim troškovima.

(8) Način plaćanja, obračunavanja i izvješćivanja, način izrade godišnjeg obračuna i izvješća uplaćenih sredstava i stvarnih troškova, kao i postupak te ovlaštenje za nadzor nad provedbom odredbi stavaka 4., 5., 6. i 7. ovoga članka utvrdit će pravilnikom ministar nadležan za financije.

(9) Na obračun zatezne kamate, zastaru prava na utvrđivanje i naplatu prihoda od obveznoga osiguranja od automobilske odgovornosti, povrat više uplaćenih sredstava, postupak nadzora, vođenje drugostupanjskog i prekršajnog postupka primjenjuju se odredbe Općeg poreznog zakona.

(10) Nadzor nad provedbom ovoga Zakona u dijelu kojim se uređuje prihod obveznoga zdravstvenog osiguranja po osnovi prihoda od obveznoga osiguranja od automobilske odgovornosti provodi Porezna uprava Ministarstva financija.

(11) Doprinosi i ostali prihodi obveznoga zdravstvenog osiguranja utvrđeni u stavku 1. ovoga članka uplaćuju se u korist računa Zavoda i prihod su Zavoda.

Članak 73.

Izdaci obveznoga zdravstvenog osiguranja obuhvaćaju izdatke za:

1. zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja,

2. specifičnu zdravstvenu zaštitu iz članka 71. ovoga Zakona,

3. naknade plaća za vrijeme privremene nesposobnosti,

4. novčane naknade zbog nemogućnosti obavljanja poslova na temelju kojih se ostvaruju primici od kojih se utvrđuje drugi dohodak sukladno propisima o doprinosima za obvezna osiguranja,

5. naknade za troškove prijevoza u vezi s korištenjem zdravstvene zaštite iz obveznoga zdravstvenog osiguranja,

6. naknade za troškove smještaja iz članka 36. stavka 1. točke 4. ovoga Zakona,

7. naknade za pogrebne troškove iz članka 70. ovoga Zakona,

8. provedbu obveznoga zdravstvenog osiguranja,

9. rad tijela upravljanja Zavodom,

10. ostale izdatke.

Članak 74.

Izdaci obveznoga zdravstvenog osiguranja u jednoj kalendarskoj godini pokrivaju se prihodima u istoj kalendarskoj godini.

2. Doprinosi i obveznici doprinosa

Članak 75.

(1) Osnovice i stope, način obračuna i rokovi plaćanja, visina, te obveznici obračunavanja i plaćanja doprinosa za obvezno zdravstveno osiguranje i obvezno zdravstveno osiguranje za slučaj ozljede na radu i profesionalne bolesti uređuju se posebnim zakonom, ako ovim Zakonom nije drukčije propisano.

(2) Porezna uprava obvezna je do 20. dana u mjesecu za prethodni mjesec dostaviti Zavodu sve evidencije koje se odnose na uplatu doprinosa i ostalih prihoda obveznoga zdravstvenog osiguranja i obveznoga zdravstvenog osiguranja za slučaj ozljede na radu i profesionalne bolesti za koje je nadležna i za koje vodi evidenciju.

(3) Stope doprinosa za obvezno zdravstveno osiguranje i obvezno zdravstveno osiguranje za slučaj ozljede na radu i profesionalne bolesti, a prema podacima Zavoda, utvrđuju se na način da se očekivanim prihodima od doprinosa i drugim prihodima pokriju očekivani izdaci.

Članak 76.

Ako ovim ili posebnim zakonom nije drukčije propisano, osnovice, način obračuna i plaćanja, visinu, te obveznike obračunavanja i plaćanja doprinosa za obvezno zdravstveno osiguranje i obvezno zdravstveno osiguranje za slučaj ozljede na radu i profesionalne bolesti utvrdit će općim aktom Zavod.

Članak 77.

Sredstva za obvezno zdravstveno osiguranje članova obitelji osiguranika iz članka 10. ovoga Zakona, osiguravaju se iz istih izvora sredstava iz kojih se osiguravaju sredstva za obvezno zdravstveno osiguranje osiguranika, osim ako ovim Zakonom ili posebnim zakonom nije drukčije propisano.

Članak 78.

Poljoprivrednik iz članka 7. stavka 1. točke 7. ovoga Zakona koji je navršio 65 godina života oslobađa se plaćanja doprinosa za obvezno zdravstveno osiguranje ako ispunjava uvjete koje pravilnikom utvrđuje ministar nadležan za zdravlje, uz suglasnost ministra nadležnog za poslove socijalne skrbi.

Članak 79.

(1) Obveznici plaćanja posebnog doprinosa za korištenje zdravstvene zaštite u inozemstvu utvrđeni prema posebnom zakonu mogu biti oslobođeni plaćanja tog doprinosa za osiguranika koji nije osiguran kod nositelja zdravstvenog osiguranja u zemlji rada pod uvjetom da djelatnost obavljaju u trećoj državi s kojom Republika Hrvatska nema zaključen međunarodni ugovor ili je međunarodnim ugovorom drukčije određeno, ako su zdravstvenu zaštitu u zemlji rada osigurali o svojem trošku.

(2) Na zahtjev obveznika uplate doprinosa iz stavka 1. ovoga članka oslobađanje plaćanja doprinosa utvrđuje Zavod rješenjem.

(3) Osigurana osoba koja po privatnom poslu putuje u treće države s kojima Republika Hrvatska nema sklopljen međunarodni ugovor ili sklopljenim međunarodnim ugovorom nije uređeno pitanje zdravstvene zaštite, može podnijeti Zavodu prijavu boravka u trećoj državi te uplatiti poseban doprinos za korištenje zdravstvene zaštite u trećim državama na teret sredstava Zavoda.

(4) Osigurana osoba iz stavka 3. ovoga članka koja ne podnese Zavodu prijavu boravka u trećoj državi i prethodno ne uplati poseban doprinos za korištenje zdravstvene zaštite u trećoj državi za sve vrijeme planiranog boravka u trećoj državi, ako općim aktom Zavoda nije drukčije propisano, nema pravo na teret sredstava obveznoga zdravstvenog osiguranja ostvariti naknadu troškova te zdravstvene zaštite.

(5) Osnovicu i stopu te način obračuna i uplate posebnog doprinosa za korištenje zdravstvene zaštite u trećoj državi za osigurane osobe koje po privatnom poslu borave u trećoj državi utvrđuje Zavod općim aktom, ako posebnim zakonom nije drugačije utvrđeno.

Članak 80.

(1) Radi utvrđivanja točnosti podataka i činjenica o kojima ovisi ostvarivanje prava iz obveznoga zdravstvenog osiguranja Zavod ima pravo kontrole poslovnih knjiga, financijske dokumentacije i drugih evidencija obveznika uplate doprinosa.

(2) Porezna uprava, Središnji registar osiguranika, tijela državne vlasti i druga nadležna tijela obvezni su Zavodu dostavljati podatke kojima raspolažu i o kojima vode službene evidencije potrebne za ostvarivanje prava iz obveznoga zdravstvenog osiguranja.

(3) Ako Zavod u postupku provjere iz stavka 1. ovoga članka utvrdi nepravilnosti, o tome sastavlja zapisnik koji dostavlja Poreznoj upravi na nadležno postupanje utvrđeno propisom ministra nadležnog za financije.

(4) Način kontrole iz stavka 1. ovoga članka utvrđuje Zavod općim aktom.

Članak 81.

(1) Osiguranicima iz članka 7. stavka 1. točaka 3., 4., 6., 7., 8. i 9. ovoga Zakona, korisnicima mirovine i invalidnine koji to pravo ostvaruju isključivo od stranog nositelja mirovinskog i invalidskog osiguranja iz članka 7. stavka 1. točke 12. ovoga Zakona, osiguranicima iz članka 13. ovoga Zakona te drugim osiguranicima osiguranim na obvezno zdravstveno osiguranje sukladno posebnom zakonu – obveznicima obračunavanja i plaćanja doprinosa za obvezno zdravstveno osiguranje, a koji nisu uplatili doprinos za najmanje 30 dana prava iz obveznoga zdravstvenog osiguranja ograničavaju se na pravo na hitnu medicinsku pomoć.

(2) Pod hitnom medicinskom pomoći podrazumijeva se pružanje dijagnostičkih i terapijskih postupaka koji su nužni u otklanjanju neposredne opasnosti za život i zdravlje.

(3) Puni opseg prava iz stavka 1. ovoga članka uspostavlja se unaprijed, od dana podmirenja dužnog iznosa doprinosa s pripadajućim kamatama.

3. Osiguranje sredstava u državnom proračunu

Članak 82.

(1) Republika Hrvatska osigurava u državnom proračunu posebna sredstva za prava iz obveznoga zdravstvenog osiguranja, i to za:

1. sredstva za naknadu plaće za vrijeme privremene nesposobnosti iz članka 39. točke 9. i članka 52. stavka 2. ovoga Zakona,

2. troškove zdravstvene zaštite za:

a. osiguranike iz članka 7. stavka 1. točaka 13., 16., 17. i 19. te članka 11. stavka 1. točke 3. ovoga Zakona, za koje se doprinos ne uplaćuje u skladu s člankom 72. stavkom 1. točkom 3. ovoga Zakona, te za osiguranike iz članka 7. stavka 1. točaka 14., 15., 18., 20., 21., 25., 26. i 27. ovoga Zakona,

b. osigurane osobe iz članka 15. ovoga Zakona,

c. osigurane osobe iz članka 78. ovoga Zakona,

d. preventivnu i specifičnu zdravstvenu zaštitu školske djece i studenata,

e. preventivnu zdravstvena zaštita osiguranih osoba starijih od 65 godina života,

f. preventivnu zdravstvena zaštita osiguranih osoba s invaliditetom iz registra utvrđenog posebnim propisom,

g. razliku u troškovima organizacije primarne zdravstvene zaštite iznad propisanih normativa izazvane demografskim karakteristikama (otoci, gustoća naseljenosti),

h. razliku u troškovima zdravstvene zaštite koja se ugovara i plaća prema broju stanovnika, a ne prema broju osiguranih osoba (hitna medicina, patronažna zdravstvena zaštita, higijensko-epidemiološka zdravstvena zaštita),

i. provođenje zdravstvene zaštite osnovom međunarodnih ugovora o socijalnom osiguranju.

(2) Sredstva iz stavka 1. ovoga članka uplaćuju se na račun Zavoda do 10. dana u mjesecu za prethodni mjesec i prihod su Zavoda.

Članak 83.

Zavod ima poslovne fondove za:

1. prava iz obveznoga zdravstvenog osiguranja,

2. prava iz obveznoga zdravstvenog osiguranja za slučaj ozljede na radu i profesionalne bolesti,

3. dopunsko zdravstveno osiguranje sukladno posebnom zakonu,

4. dodatno zdravstveno osiguranje sukladno posebnom zakonu.

Članak 84.

(1) Zavod ima pričuvu za provedbu prava iz obveznoga zdravstvenog osiguranja.

(2) Ako se po završnom računu utvrdi višak prihoda, taj se višak unosi u pričuvu izdvajanjem najmanje 50% viška prihoda.

(3) Nadzor nad korištenjem pričuve obavlja Upravno vijeće Zavoda.

Članak 85.

(1) Pričuva iz članka 84. ovoga Zakona može iznositi najviše jednu dvanaestinu planiranih rashoda u tekućoj godini za provedbu utvrđenog opsega prava iz obveznoga zdravstvenog osiguranja.

(2) Tijekom godine pričuva se može koristiti kao obrtno sredstvo za podmirivanje tekućih obveza Zavoda te kao pozajmica uz obvezu vraćanja najkasnije do kraja iduće godine uz kamatu.

(3) Pričuva služi za pokrivanje viška rashoda nad prihodima i sanaciju gubitaka Zavoda.

Članak 86.

(1) U svrhu osiguravanja podataka potrebnih za provođenje obveznoga zdravstvenog osiguranja te nadzor nad ostvarivanjem prava iz obveznoga zdravstvenog osiguranja u Zavodu se vode evidencije.

(2) Opće akte o načinu i mjestu vođenja, obliku, sadržaju i rokovima evidencije te obveznicima vođenja evidencija donijet će Upravno vijeće Zavoda.

VII. ODNOS ZAVODA I ZDRAVSTVENIH USTANOVA, ZDRAVSTVENIH RADNIKA U PRIVATNOJ PRAKSI I ISPORUČITELJA POMAGALA

1. Ugovaranje zdravstvene zaštite

Članak 87.

(1) Zavod općim aktom uz suglasnost ministra nadležnog za zdravlje, po prethodno pribavljenom mišljenju nadležnih komora, u skladu s utvrđenim opsegom prava na zdravstvenu zaštitu iz članaka 19., 20. i 23. ovoga Zakona te s utvrđenim standardima i normativima zdravstvene zaštite iz obveznoga zdravstvenog osiguranja sukladno članku 33. ovoga Zakona, utvrđuje način provođenja zdravstvene zaštite, elemente i kriterije za raspisivanje natječaja i osnove za sklapanje ugovora sa zdravstvenim ustanovama i privatnim zdravstvenim radnicima koji su uključeni u mrežu javne zdravstvene službe, mrežu hitne medicine i mrežu ugovornih subjekata medicine rada, punu cijenu pojedine zdravstvene usluge iz obveznoga zdravstvenog osiguranja, maksimalni godišnji iznos sredstava za provođenje ugovorene bolničke zdravstvene zaštite te način i rokove plaćanja računa za pruženu zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja.

(2) Zavod općim aktom uz suglasnost ministra nadležnog za zdravlje, u skladu s utvrđenim opsegom prava na zdravstvenu zaštitu iz članaka 19., 20. i 22. ovoga Zakona, te utvrđenim standardom prava na ortopedska i druga pomagala sukladno općem aktu Zavoda, utvrđuje osnove za sklapanje ugovora s isporučiteljima ortopedskih i drugih pomagala koji ispunjavaju uvjete za proizvodnju, odnosno isporuku pomagala sukladno posebnom zakonu te cijene pomagala, način i rokove plaćanja računa za isporučena pomagala.

(3) Općim aktom iz stavaka 1. i 2. ovoga članka obvezno se utvrđuje početak i kraj ugovornog razdoblja za koje se raspisuje natječaj za prikupljanje ponuda za sklapanje ugovora o provođenju zdravstvene zaštite iz obveznoga zdravstvenog osiguranja.

Članak 88.

(1) Sukladno aktu iz članka 87. stavka 1. ovoga Zakona, Zavod u skladu s utvrđenim potrebama za popunu mreže javne zdravstvene službe, mreže hitne medicine i mreže ugovornih subjekata medicine rada, u pravilu, svake treće godine, ako općim aktom iz članka 87. stavka 1. ovoga Zakona nije drukčije određeno, objavljuje natječaj za sklapanje ugovora sa zdravstvenim ustanovama i privatnim zdravstvenim radnicima za provođenje zdravstvene zaštite iz obveznoga zdravstvenog osiguranja u zdravstvenim djelatnostima na primarnoj,

sekundarnoj i tercijarnoj razini zdravstvene djelatnosti te na razini zdravstvenih zavoda, ako posebnim zakonom nije drukčije utvrđeno.

(2) Sukladno aktu iz članka 87. stavka 2. ovoga Zakona, Zavod u pravilu svake treće godine, ako općim aktom iz članka 87. stavka 2. ovoga Zakona nije drukčije određeno, objavljuje natječaj za sklapanje ugovora s isporučiteljima ortopedskih i drugih pomagala.

(3) Na temelju ponuda za provođenje zdravstvene zaštite prema objavljenom natječaju iz stavaka 1. i 2. ovoga članka Zavod, uz suglasnost ministra nadležnog za zdravlje, donosi odluku o izboru najpovoljnijih ponuditelja.

(4) Ponuditelj čija ponuda na natječaj iz stavaka 1. i 2. ovoga članka nije prihvaćena ima pravo uložiti žalbu ministru nadležnom za zdravlje u roku od 15 dana od dana zaprimanja obavijesti o neprihvaćanju ponude.

(5) O žalbi iz stavka 4. ovoga članka odlučuje se rješenjem protiv kojega se može pokrenuti upravni spor.

Članak 89.

Sukladno odluci iz članka 88. stavka 3. ovoga Zakona, odnosno sukladno rješenju iz članka 88. stavka 5. ovoga Zakona, kojim je usvojena žalba i prihvaćena ponuda, Zavod sklapa ugovore za provođenje utvrđenog opsega prava na zdravstvenu zaštitu iz članka 87. stavaka 1. i 2. ovoga Zakona.

Članak 90.

(1) Ugovorom iz članka 89. ovoga Zakona određuje se vrsta, opseg i kvaliteta zdravstvene zaštite iz obveznoga zdravstvenog osiguranja prema standardima i normativima za pojedine djelatnosti, rokovi u kojima se ugovorena zdravstvena zaštita mora pružiti osiguranoj osobi na primarnoj, sekundarnoj i tercijarnoj razini zdravstvene djelatnosti te na razini zdravstvenih zavoda u skladu s pravilnikom ministra nadležnog za zdravlje o određivanju medicinski opravdanog roka u kojem se mora pružiti potrebna zdravstvena zaštita, cijene po kojima ugovorni subjekt Zavoda ispostavlja račune za ugovorenu i pruženu zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja, način obračuna, rokovi ispostavljanja računa i rokovi plaćanja računa za pruženu zdravstvenu zaštitu, nadzor nad izvršavanjem ugovornih obveza, ugovorne kazne i druge mjere zbog neizvršavanja ugovornih obveza, uvjeti pod kojima dolazi do raskida ugovora, kao i druga međusobna prava i obveze ugovornih strana.

(2) Odredbe stavka 1. ovoga članka na odgovarajući način primjenjuju se i na ugovor o isporuci ortopedskih i drugih pomagala.

Članak 91.

Ugovori iz članka 89. ovoga Zakona sklapaju se najkasnije u roku od 60 dana od dana stupanja na snagu odluke iz članka 88. stavka 3. ovoga Zakona, odnosno u roku od 60 dana od dana kada je rješenje iz članka 88. stavka 5. ovoga Zakona postalo izvršno.

Članak 92.

Ugovori iz članka 89. ovoga Zakona sklapaju se unaprijed, a vrijede najduže do isteka roka utvrđenog člankom 91. ovoga Zakona.

Članak 93.

Ravnatelj ugovorne zdravstvene ustanove, odnosno ugovorni zdravstveni radnik privatne prakse te voditelj ustrojstvene jedinice u zdravstvenoj ustanovi, svatko iz svoje nadležnosti, obvezni su u okviru ugovorenih sredstava osigurati osiguranim osobama zdravstvenu zaštitu koju su sa Zavodom ugovorili te odgovaraju za nenamjensko trošenje sredstava osiguranih za provođenje zdravstvene zaštite iz obveznoga zdravstvenog osiguranja.

2. Nadzor nad izvršavanjem ugovornih obveza ugovornih subjekata Zavoda

Članak 94.

(1) Tijekom ugovornog razdoblja Zavod je obvezan kontinuirano nadzirati izvršavanje ugovornih obveza zdravstvenih ustanova, privatnih zdravstvenih radnika i ugovornih isporučitelja pomagala.

(2) Nadzor iz stavka 1. ovoga članka provodi se sukladno odredbama ovoga Zakona i općih akata Zavoda:

1. pregledom i provjerom financijske, medicinske i druge dokumentacije u zdravstvenoj ustanovi i kod privatnog zdravstvenog radnika, odnosno ugovornog isporučitelja pomagala,

2. pregledom i provjerom dostavljene dokumentacije u ustrojstvenim jedinicama Zavoda.

(3) Postupkom nadzora iz stavka 1. ovoga članka posebno se nadzire da li izabrani doktor medicine, odnosno dentalne medicine, zdravstveni radnik zaposlenik zdravstvene ustanove ili privatni zdravstveni radnik:

1. provodi mjere zdravstvene zaštite iz obveznoga zdravstvenog osiguranja na svojoj razini zdravstvene djelatnosti utvrđene opsegom prava na zdravstvenu zaštitu iz članaka 19., 20., 22. i 23. ovoga Zakona,

2. primjenjuje pravila struke, a kod propisivanja terapije preporuke glede farmakoterapije, kliničke smjernice te načela farmakoekonomike vodeći računa o interakcijama i kontraindikacijama za pojedini slučaj,

3. postupa protivno odredbama ovoga Zakona, Zakona o zdravstvenoj zaštiti, drugih zakona, posebnih propisa, podzakonskih akata te općih akata Zavoda,

4. namjenski koristi sredstva ostvarena temeljem ugovora sa Zavodom o provođenju zdravstvene zaštite iz obveznoga zdravstvenog osiguranja,

5. utvrđuje privremenu nesposobnost osiguranika sukladno odredbama članka 46. ovoga Zakona, odnosno da li se prilikom utvrđivanja dijagnoza bolesti osiguranika pridržava odredbe članka 52. stavka 1. Zakona.

(4) Ako se kontrolom iz stavka 3. točaka 4. i 5. ovoga članka utvrdi da ugovorni subjekt Zavoda nenamjenski koristi sredstva ostvarena za provođenje zdravstvene zaštite iz obveznoga zdravstvenog osiguranja, odnosno da izabrani doktor utvrđuje privremenu nesposobnost osiguranika protivno odredbama članka 46. ovoga Zakona, kao i da mijenjanjem dijagnoza bolesti osiguranika te neopravdanim zaključivanjem privremene nesposobnosti postupa protivno odredbama članka 52. ovoga Zakona radi izbjegavanja primjene stavka 2. istog članka Zakona, Zavod može pokrenuti postupak raskida ugovora s tim ugovornim subjektom.

Članak 95.

Radi provedbe nadzora nad izvršavanjem ugovornih obveza, ugovorni subjekti Zavoda obvezni su dostavljati izvješća o poslovanju sukladno općem aktu Zavoda iz članka 87. ovoga Zakona.

Članak 96.

Način provođenja nadzora nad izvršavanjem ugovornih obveza zdravstvenih ustanova i privatnih zdravstvenih radnika te ugovornih isporučitelja pomagala Zavod će utvrditi posebnim aktom, odnosno samim ugovorom.

VIII. HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE

Članak 97.

(1) Poslove provedbe prava iz obveznoga zdravstvenog osiguranja utvrđena ovim Zakonom obavlja Hrvatski zavod za zdravstveno osiguranje.

(2) Zavod jest javna ustanova na koju se primjenjuju propisi o ustanovama, ako ovim Zakonom nije drukčije utvrđeno.

(3) Zavod ima svojstvo pravne osobe s pravima, obvezama te odgovornošću utvrđenom ovim Zakonom i Statutom.

(4) U rješavanju o pravima i obvezama osiguranih osoba iz obveznoga zdravstvenog osiguranja Zavod ima javne ovlasti.

(5) Sjedište Zavoda je u Zagrebu.

Članak 98.

(1) U provedbi prava iz obveznoga zdravstvenog osiguranja Zavod obavlja osobito sljedeće poslove:

1. provodi politiku razvoja i unapređivanja zdravstvene zaštite iz obveznoga zdravstvenog osiguranja,

2. obavlja poslove u vezi s ostvarivanjem prava osiguranih osoba, brine se o zakonitom ostvarivanju tih prava te im pruža stručnu pomoć u ostvarivanju prava i zaštiti njihovih interesa,

3. planira novčana sredstva obveznoga zdravstvenog osiguranja te plaća usluge ugovornim subjektima Zavoda na temelju ispostavljenih računa i povijesti bolesti, otpusnih pisama, odnosno druge odgovarajuće dokumentacije,

4. predlaže ministru nadležnom za zdravlje opseg prava na zdravstvenu zaštitu iz članaka 19., 20., 22. i 23. ovoga Zakona,

5. daje prijedlog ministru nadležnom za zdravlje za izradu plana i programa mjera zdravstvene zaštite iz obveznoga zdravstvenog osiguranja te plana i programa mjera specifične zdravstvene zaštite,

6. daje mišljenje osnivaču zdravstvene ustanove o opravdanosti osnivanja zdravstvene ustanove u mreži javne zdravstvene službe te daje mišljenje zdravstvenom radniku o opravdanosti osnivanja privatne prakse u mreži javne zdravstvene službe,

7. obavlja poslove ugovaranja s provoditeljima zdravstvene zaštite,

8. utvrđuje cijenu zdravstvene zaštite u ukupnom iznosu za punu vrijednost pojedine zdravstvene usluge iz obveznoga zdravstvenog osiguranja, uz suglasnost ministra nadležnog za zdravlje,

9. osigurava provedbu propisa Europske unije i međunarodnih ugovora u dijelu koji se odnosi na obvezno zdravstveno osiguranje,

10. obavlja nadzor nad ispunjavanjem ugovornih obveza ugovornih subjekata Zavoda sukladno ovome Zakonu, propisima donesenim na temelju ovoga Zakona, općim aktima Zavoda i sklopljenom ugovoru,

11. provodi istraživanja, statističke obrade i izrađuje izvješća u vezi ostvarivanja prava iz obveznoga zdravstvenog osiguranja,

12. uređuje ostala pitanja vezana uz ostvarivanje prava iz obveznoga zdravstvenog osiguranja.

(2) Uz poslove iz stavka 1. ovoga članka Zavod obavlja i pojedine poslove vezane uz održavanje informacijskog sustava za potrebe provođenja zdravstvene zaštite prema posebnom nalogu ministra nadležnog za zdravlje.

1. Ustrojstvo Hrvatskog zavoda za zdravstveno osiguranje

Članak 99.

(1) Zavod obavlja poslove iz svoje djelatnosti u sljedećim ustrojstvenim jedinicama:

1. središnjoj ustrojstvenoj jedinici,

2. regionalnim ustrojstvenim jedinicama.

(2) Ustrojstvene jedinice Zavoda obavljaju poslove iz djelatnosti Zavoda pod nazivom Zavoda i svojim nazivom, pri čemu moraju navesti sjedište Zavoda i svoje sjedište.

Članak 100.

(1) Središnja ustrojstvena jedinica Zavoda jest Direkcija, sa sjedištem u Zagrebu.

(2) Regionalne ustrojstvene jedinice Zavoda su regionalni uredi Zavoda.

Članak 101.

Statutom Zavoda utvrđuje se djelokrug ustrojstvenih jedinica, nazivi unutarnjih ustrojstvenih jedinica, kao i druga pitanja značajna za obavljanje poslova u Zavodu.

2. Tijela Zavoda

Članak 102.

(1) Zavodom upravlja Upravno vijeće.

(2) Upravno vijeće čini devet članova, koje imenuje Vlada Republike Hrvatske na prijedlog ministra nadležnog za zdravlje, i to:

a) 2 predstavnika osiguranih osoba Zavoda,

b) 2 predstavnika pružatelja zdravstvenih usluga – zdravstvena radnika,

c) 3 predstavnika Gospodarsko-socijalnog vijeća,

d) 1 predstavnik ministarstva nadležnog za zdravlje,

e) 1 predstavnik radnika Zavoda, imenovan ili izabran u skladu s propisima o radu.

(3) Predsjednika Upravnog vijeća biraju članovi Upravnog vijeća.

(4) Mandat članova Upravnog vijeća traje četiri godine.

(5) Upravno vijeće donosi odluke natpolovičnom većinom od ukupnog broja članova.

(6) Djelokrug, ovlasti i odgovornosti Upravnog vijeća utvrđuju se statutom.

Članak 103.

(1) Upravno vijeće Zavoda obavlja sljedeće poslove:

1. donosi statut Zavoda,

2. donosi financijski plan i završni račun Zavoda,

3. donosi mjere za uravnoteženje prihoda i rashoda kada je u poslovanju Zavoda u tromjesečnom razdoblju iskazan višak rashoda nad prihodima,

4. donosi odluke i opće akte, te obavlja i druge poslove određene ovim Zakonom i statutom Zavoda.

(2) Na statut Zavoda suglasnost daje Vlada Republike Hrvatske.

Članak 104.

(1) Statutom Zavoda utvrđuje se osobito: ustrojstvo Zavoda, djelokrug ustrojstvenih jedinica, nazivi unutarnjih ustrojstvenih jedinica, prava, obveze i odgovornosti tijela Zavoda, javnost rada Zavoda i njegovih tijela, način obavljanja administrativno-stručnih i drugih poslova, kao i druga pitanja od značenja za rad Zavoda.

(2) Statut i opći akti Zavoda kojima se uređuju prava i obveze osiguranih osoba iz obveznoga zdravstvenog osiguranja objavljuju se u »Narodnim novinama«.

Članak 105.

(1) Radom Zavoda rukovodi ravnatelj.

(2) Ravnatelj mora imati završen diplomski sveučilišni studij i najmanje pet godina radnog iskustva na poslovima upravljanja.

(3) Ravnatelj Zavoda ima zamjenika i pomoćnike.

Članak 106.

(1) Ravnatelj Zavoda imenuje se na temelju javnog natječaja.

(2) Ravnatelja Zavoda imenuje i razrješuje Vlada Republike Hrvatske, na prijedlog ministra nadležnog za zdravlje.

(3) Ravnatelj Zavoda imenuje se na vrijeme od četiri godine.

Članak 107.

(1) Ravnatelj Zavoda odgovoran je za financijsko poslovanje Zavoda.

(2) Ravnatelj Zavoda odgovoran je za uravnoteženost rashoda s prihodima Zavoda te je obvezan ministru nadležnom za zdravlje i ministru nadležnom za financije dostavljati tromjesečno izvješće o financijskom poslovanju Zavoda.

Članak 108.

(1) Ravnatelj Zavoda može biti razriješen i prije isteka vremena na koje je imenovan.

(2) Prijedlog za razrješenje ravnatelja prije isteka vremena na koje je imenovan Vladi Republike Hrvatske može podnijeti najmanje jedna trećina članova Upravnog vijeća i ministar nadležan za zdravlje.

Članak 109.

(1) Upravno vijeće Zavoda je dužno predložiti ministru nadležnom za zdravlje i Vladi Republike Hrvatske razrješenje ravnatelja i prije isteka mandata za koji je izabran ako:

1. ravnatelj to osobno zahtijeva,

2. nastane neki od razloga koji po posebnim propisima ili propisima kojima se uređuju radni odnosi dovode do prestanka ugovora o radu,

3. je u poslovanju Zavoda u šestomjesečnom razdoblju iskazan višak rashoda nad prihodima,

4. svojim nesavjesnim ili nezakonitim radom prouzroči Zavodu veću štetu, zanemaruje ili nemarno obavlja svoju dužnost tako da su nastale ili mogu nastati veće smetnje u obavljanju djelatnosti Zavoda, u svojem radu krši odredbe ovoga Zakona i propisa donesenih temeljem ovoga Zakona, drugih zakonskih i pod zakonskih propisa te općih akata Zavoda ili neopravdano ne izvršava odluke Upravnog vijeća Zavoda, odnosno postupa u suprotnosti s njima.

(2) Upravno vijeće Zavoda mora prije donošenja odluke o prijedlogu za razrješenje obavijestiti ravnatelja o razlozima za razrješenje i dati mu mogućnost da se o njima pisano izjasni.

Članak 110.

(1) Zamjenik ravnatelja mora imati završen diplomski sveučilišni studij i najmanje pet godina radnog iskustva na poslovima upravljanja.

(2) Zamjenik ravnatelja Zavoda imenuje se na temelju javnog natječaja.

(3) Zamjenika ravnatelja Zavoda imenuje i razrješuje Vlada Republike Hrvatske, na prijedlog ministra nadležnog za zdravlje.

(4) Zamjenik ravnatelja Zavoda imenuje se na vrijeme od četiri godine.

Članak 111.

(1) Zamjenik ravnatelja Zavoda može biti razriješen i prije isteka vremena na koje je imenovan iz razloga utvrđenih člankom 109. stavkom 1. ovoga Zakona.

(2) Prijedlog za razrješenje zamjenika ravnatelja prije isteka vremena na koje je imenovan Vladi Republike Hrvatske može podnijeti ministar nadležan za zdravlje, najmanje jedna trećina članova Upravnog vijeća Zavoda i ravnatelj Zavoda.

Članak 112.

(1) Upravno vijeće Zavoda dužno je predložiti ministru nadležnom za zdravlje i Vladi Republike Hrvatske razrješenje zamjenika ravnatelja i prije isteka mandata za koji je izabran zbog razloga iz članka 109. ovoga Zakona.

(2) Upravno vijeće Zavoda mora prije donošenja odluke o prijedlogu za razrješenje obavijestiti zamjenika ravnatelja o razlozima za razrješenje i dati mu mogućnost da se o njima pisano izjasni.

Članak 113.

(1) Broj pomoćnika ravnatelja i uvjeti koje moraju ispunjavati utvrđuju se statutom Zavoda.

(2) Pomoćnike ravnatelja imenuje i razrješuje Vlada Republike Hrvatske na prijedlog ravnatelja Zavoda.

Članak 114.

Način imenovanja i razrješenja voditelja regionalnog ureda Zavoda uređuje se statutom Zavoda.

Članak 115.

Djelokrug, ovlaštenja i odgovornost ravnatelja, zamjenika ravnatelja, pomoćnika ravnatelja Zavoda i voditelja regionalnog ureda Zavoda utvrđuju se statutom Zavoda.

3. Nadzor nad radom Zavoda

Članak 116.

(1) Nadzor nad zakonitošću rada i općih akata Zavoda obavlja ministarstvo nadležno za zdravlje.

(2) U provođenju nadzora iz stavka 1. ovoga članka ministarstvo nadležno za zdravlje može:

1. zahtijevati izvješća, podatke i druge obavijesti o obavljanju poslova,

2. predložiti Vladi Republike Hrvatske pokretanje postupka pred Ustavnim sudom Republike Hrvatske za ocjenu suglasnosti općih akata Zavoda sa zakonom i Ustavom,

3. izvršiti uvid u ustrojstvo i način poslovanja te predložiti mjere radi izvršenja pojedinih poslova,

4. poduzeti i druge mjere propisane ovim Zakonom ili drugim propisima.

Članak 117.

Ravnatelj Zavoda obvezan je ministru nadležnom za zdravlje i Vladi Republike Hrvatske podnijeti godišnje izvješće o poslovanju Zavoda najkasnije do 1. ožujka tekuće godine za prethodnu godinu, a mjesečno izvješće o izvršenju ugovornih obveza ugovornih subjekata Zavoda do 15. u mjesecu za prethodni mjesec.

Članak 118.

Ako Vlada Republike Hrvatske utvrdi da su gubici Zavoda u provođenju obveznoga zdravstvenog osiguranja nastali zbog objektivnih okolnosti, sanacija gubitaka pokriva se iz državnog proračuna.

IX. OSTVARIVANJE PRAVA I OBVEZA IZ OBVEZNOGA ZDRAVSTVENOG OSIGURANJA

Članak 119.

(1) Pravo na obvezno zdravstveno osiguranje utvrđuje se priznavanjem statusa osigurane osobe u Zavodu.

(2) Osiguranoj osobi prestaje status osigurane osobe prestankom okolnosti na temelju kojih je stekla taj status.

(3) Status osigurane osobe dokazuje se iskaznicom zdravstveno osigurane osobe ili ovjerenom kopijom prijave na obvezno zdravstveno osiguranje.

(4) Status osigurane osobe u prekograničnoj zdravstvenoj zaštiti dokazuje se europskom karticom zdravstvenog osiguranja ili certifikatom koji privremeno zamjenjuje europsku karticu zdravstvenog osiguranja, odnosno drugom odgovarajućom potvrdom u skladu s propisima Europske unije.

(5) Ispravu iz stavka 4. ovoga članka izdaje Zavod na zahtjev osigurane osobe.

(6) Opći akt o sadržaju, obliku i naknadi za troškove izdavanja isprava iz stavka 3. ovoga članka, kao i načinu njezina izdavanja te uvjetima i načinu izdavanja isprava iz stavka 4. ovoga članka donijet će Zavod.

Članak 120.

(1) Status osigurane osobe utvrđuje Zavod na osnovi prijave na obvezno zdravstveno osiguranje koju prema odredbama ovoga Zakona podnosi obveznik plaćanja doprinosa, osigurana osoba kada je ona obveznik plaćanja doprinosa, odnosno pravna ili fizička osoba za osiguranu osobu.

(2) Status osigurane osobe Zavod može utvrđivati po službenoj dužnosti na osnovi podataka dostavljenih od nadležnog tijela koje ima ovlasti prikupljanja i dostave podataka radi prijave na obvezno zdravstveno osiguranje.

(3) Prijava na obvezno zdravstveno osiguranje, prijava promjene u obveznom zdravstvenom osiguranju te odjava s obveznoga zdravstvenog osiguranja podnose se u roku od osam dana od dana nastanka, promjene ili prestanka okolnosti na osnovi kojih se stječe ili prestaje status osigurane osobe.

(4) Osobi za koju obveznik plaćanja doprinosa ne podnese prijavu, odnosno odjavu s obveznoga zdravstvenog osiguranja Zavod će rješenjem utvrditi status, odnosno prestanak statusa osigurane osobe po službenoj dužnosti.

Članak 121.

(1) Podnositelj prijave obvezan je dostaviti Zavodu sve podatke u vezi s prijavom, promjenom i odjavom osiguranih osoba, a radi ostvarivanja prava i obveza iz obveznoga zdravstvenog osiguranja i izdavanja isprave iz članka 119. stavka 3. ovoga Zakona.

(2) Ako podnositelj prijave iz stavka 1. ovoga članka u roku od 30 dana od dana nastanka okolnosti koja je osnova za stjecanje statusa osigurane osobe ne podnese prijavu na obvezno zdravstveno osiguranje Zavod će po službenoj dužnosti donijeti rješenje o priznavanju statusa osiguranika, odnosno osigurane osobe Zavoda.

Članak 122.

(1) Zavod ima pravo i obvezu po zaprimanju prijave na obvezno zdravstveno osiguranje, kao i za sve vrijeme trajanja statusa osigurane osobe provjeravati postojanje okolnosti na osnovi kojih je prijava podnesena, odnosno na osnovi kojih je osobi priznao taj status.

(2) Pravne i fizičke osobe, podnositelji prijave na obvezno zdravstveno osiguranje i osigurana osoba obvezni su na traženje Zavoda predočiti sve činjenice i dokaze kojima se dokazuje osnovanost prijave na obvezno zdravstveno osiguranje, odnosno valjanost važećeg statusa osigurane osobe.

(3) Ako Zavod ne prihvati podnesenu prijavu ili utvrdi status osigurane osobe po nekoj drugoj osnovi, odnosno ospori status osiguranoj osobi u obveznom zdravstvenom osiguranju zbog nepostojanja okolnosti na osnovi kojih joj je taj status utvrđen, o tome donosi rješenje koje dostavlja podnositelju prijave i zainteresiranoj osobi.

(4) U slučaju sumnje da se podnesena prijava, odnosno utvrđen status osiguranika osnovom zaključenog ugovora o radu ne temelji na istinitom činjeničnom stanju i postojanju stvarnih okolnosti koje su osnova za stjecanje statusa u obveznom zdravstvenom osiguranju, odnosno da svrha zaključenog ugovora o radu nije bila obavljanje poslova u skladu s tim ugovorom već isključivo ostvarivanje prava iz obveznoga zdravstvenog osiguranja, Zavod ima pravo i obvezu, na temelju provedene provjere iz stavka 1. ovog članka i prikupljenih dokaza pokrenuti postupak pred nadležnim sudom za osporavanje tako zaključenog ugovora o radu.

(5) Opći akt o obveznicima podnošenja prijave i odjave osigurane osobe, načinu prijavljivanja i odjavljivanja osigurane osobe u obveznom zdravstvenom osiguranju, utvrđivanju statusa osigurane osobe, datumu početka i prestanka statusa osigurane osobe, datumu početka i datumu prestanka ostvarivanja prava i obveza iz obveznoga zdravstvenog osiguranja, te načinu utvrđivanja i provjere okolnosti koje su osnova za stjecanje, odnosno gubitak statusa osigurane osobe u obveznom zdravstvenom osiguranju te dokumentaciji kojom se dokazuje zakonska osnova osiguranja donijet će Zavod.

Članak 123.

(1) Prava iz obveznoga zdravstvenog osiguranja iz članka 17. ovoga Zakona se, u pravilu, ostvaruju bez donošenja rješenja, a na temelju odgovarajuće dokumentacije utvrđene ovim Zakonom i općim aktima Zavoda donesenim na temelju ovoga Zakona.

(2) O pravima iz obveznoga zdravstvenog osiguranja odlučuje se rješenjem na zahtjev osigurane osobe, osim ako ovim Zakonom nije drukčije propisano.

(3) U postupcima iz stavka 2. ovog članka Zavod odlučuje primjenjujući odredbe Zakona o općem upravnom postupku.

Članak 124.

(1) Radi zaštite prava iz ovoga Zakona, osiguranim osobama se u Zavodu osigurava dvostupanjsko rješavanje u postupku koji je pokrenula osigurana osoba.

(2) Protiv drugostupanjskog rješenja Zavoda nije dopuštena žalba, već se protiv njega može pokrenuti upravni spor.

Članak 125.

(1) O pravima iz obveznoga zdravstvenog osiguranja rješava:

1. u prvom stupnju – ustrojstvena jedinica regionalnog ureda Zavoda nadležna prema mjestu prebivališta, odnosno boravišta osigurane osobe,

2. u drugom stupnju – Direkcija Zavoda.

(2) Žalba protiv rješenja donesenog u prvom stupnju ne odgađa izvršenje rješenja.

Članak 126.

(1) Pri ostvarivanju prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja prema odredbama ovoga Zakona osigurana osoba ima pravo na slobodan izbor doktora medicine i doktora dentalne medicine primarne zdravstvene zaštite.

(2) Osigurana osoba bira doktora medicine i doktora dentalne medicine primarne zdravstvene zaštite za razdoblje od najmanje jedne godine.

(3) Način ostvarivanja prava na slobodan izbor doktora medicine i doktora dentalne medicine primarne zdravstvene zaštite iz stavka 1. ovoga članka te način izbora doktora specijaliste medicine rada za provođenje specifične zdravstvene zaštite utvrdit će Zavod općim aktom.

Članak 127.

(1) U postupcima o pravima iz obveznoga zdravstvenog osiguranja sudjeluju liječnička povjerenstva Zavoda.

(2) Liječnička povjerenstva iz stavka 1. ovoga članka provode stručno-medicinsko vještačenje o pravu osigurane osobe iz obveznoga zdravstvenog osiguranja te donose odluku u obliku nalaza, mišljenja i ocjene.

(3) Ovlasti i način rada liječničkih povjerenstava, područje njihove nadležnosti te izgled i sadržaj tiskanice nalaza, mišljenja i ocjene utvrđuje općim aktom Zavod uz suglasnost ministra nadležnog za zdravlje.

Članak 128.

(1) Postupak utvrđivanja i priznavanja ozljede ili bolesti za ozljedu na radu, odnosno profesionalnu bolest pokreće pravna ili fizička osoba te tijelo državne vlasti kao poslodavac, organizator određenih poslova i aktivnosti iz članka 16. ovoga Zakona, odnosno osoba koja samostalno osobnim radom obavlja djelatnost podnošenjem prijave o ozljedi na radu, odnosno profesionalnoj bolesti.

(2) Prijavu iz stavka 1. ovog članka pravna ili fizička osoba, odnosno tijelo državne vlasti kao poslodavac te organizator određenih poslova i aktivnosti obvezni su podnijeti po službenoj dužnosti ili na traženje ozlijeđenog ili oboljelog radnika, odnosno osigurane osobe kojoj se prema ovome Zakonu osiguravaju prava za slučaj ozljede na radu, odnosno profesionalne bolesti.

(3) Ako poslodavac, odnosno organizator određenih aktivnosti i poslova ne postupe u skladu sa stavkom 2. ovoga članka, prijavu je obvezan podnijeti izabrani doktor opće/obiteljske medicine prema zahtjevu ozlijeđene ili oboljele osigurane osobe ili prema prijedlogu nadležnog doktora specijaliste medicine rada s kojim Zavod ima sklopljen ugovor o provođenju specifične zdravstvene zaštite radnika, a koji je u skladu s općim aktom Zavoda nadležan za provođenje specifične zdravstvene zaštite radnika prema sjedištu poslodavca, odnosno organizatora određenih aktivnosti i poslova.

(4) Sadržaj i oblik tiskanice prijave o ozljedi na radu, odnosno profesionalnoj bolesti utvrdit će općim aktom Zavod.

Članak 129.

(1) O priznavanju ozljede na radu, odnosno profesionalne bolesti Zavod odlučuje, u pravilu, bez donošenja pisanog rješenja, ovjerom tiskanice prijave o ozljedi na radu, odnosno profesionalnoj bolesti.

(2) Iznimno od stavka 1. ovoga članka, Zavod obvezno donosi rješenje u slučaju nepriznavanja ozljede, odnosno bolesti kao ozljede na radu, odnosno profesionalne bolesti te kada odlučuje o priznavanju ozljede na radu, odnosno profesionalne bolesti na osnovi zahtjeva osigurane osobe, odnosno člana obitelji osigurane osobe u slučaju smrti osigurane osobe.

Članak 130.

(1) Prijava o ozljedi na radu, odnosno profesionalnoj bolesti podnosi se:

1. za slučaj ozljede na radu – u roku od osam dana od dana nastanka ozljede na radu,

2. za profesionalnu bolest – u roku od osam dana od dana kada je osigurana osoba primila ispravu zdravstvene ustanove, odnosno ordinacije doktora specijaliste medicine rada u privatnoj praksi uključenih u mrežu ugovornih subjekata medicine rada, kojom joj je dijagnosticirana profesionalna bolest.

(2) Osigurana osoba za koju Zavodu nije podnesena prijava o ozljedi na radu, odnosno profesionalnoj bolesti u roku od tri godine od isteka rokova iz stavka 1. ovoga članka gubi pravo na pokretanje postupka utvrđivanja i priznavanja ozljede na radu, odnosno profesionalne bolesti od strane Zavoda.

Članak 131.

Prava i obveze iz obveznoga zdravstvenog osiguranja za slučaj ozljede na radu i profesionalne bolesti koje obuhvaćaju i mjere specifične zdravstvene zaštite radnika, postupak utvrđivanja i priznavanja ozljede na radu, odnosno profesionalne bolesti, kao i opseg prava, uvjete i način njihovog ostvarivanja Zavod će pobliže utvrditi općim aktom, uz suglasnost ministra nadležnog za zdravlje.

Dospijeće prava i rokovi

Članak 132.

(1) Osiguraniku zaposlenom pri pravnoj, odnosno fizičkoj osobi – poslodavcu zahtjev za isplatu naknade plaće dospijeva danom kojim dospijeva isplata plaće kod poslodavca za odnosni mjesec.

(2) Osiguraniku iz stavka 1. ovog članka zahtjev za isplatu pripadajućeg dijela naknade plaće ostvarene osnovom primitaka od kojih se prema propisima o porezu na dohodak utvrđuje drugi dohodak dospijeva 30. dana od dana podnošenja zahtjeva poslodavca za povrat isplaćenih naknada plaće iz članka 41. stavaka 3. i 4. ovoga Zakona.

(3) Osiguraniku iz članka 7. stavka 1. točaka 3., 4., 6., 8., 9., 20. i 25. i članka 51. ovoga Zakona zahtjev za isplatu naknade plaće dospijeva 15. dana u mjesecu za prethodni mjesec.

(4) Osiguraniku iz članka 8. ovoga Zakona zahtjev za isplatu novčane naknade iz članka 57. ovoga Zakona dospijeva 60. dana od dana podnošenja zahtjeva.

Članak 133.

(1) Zahtjev za isplatu drugih novčanih naknada utvrđenih ovim Zakonom dospijeva 60. dana od dana zaprimanja zahtjeva osigurane osobe u Zavodu, odnosno druge osobe koja ostvaruje prava na novčanu naknadu u skladu s odredbama ovoga Zakona.

(2) Iznimno, u slučaju kad je osigurana osoba podnijela zahtjev za isplatu novčanih naknada iz stavka 1. ovog članka koje u skladu s odredbama ovoga Zakona mogu biti predmet nasljeđivanja, a smrt osigurane osobe je nastupila prije isteka roka dospijeća, smatrat će se da je zahtjev za isplatu dospio istekom roka iz stavka 1. ovoga članka.

Članak 134.

(1) Zahtjev za ostvarivanje prava na novčane naknade utvrđene ovim Zakonom zastarijeva istekom roka od tri godine od dana nastanka troška za osiguranu osobu, odnosno od dana stjecanja prava iz obveznoga zdravstvenog osiguranja prema odredbama ovoga Zakona.

(2) Zahtjev za povrat isplaćene naknade plaće iz članka 41. stavaka 3. i 4. ovoga Zakona zastarijeva istekom roka od tri godine od dana dospijeća naknade plaće iz članka 132. stavka 1. ovoga Zakona.

X. NAKNADA ŠTETE

Članak 135.

(1) Osigurana osoba dužna je Zavodu prijaviti svaku promjenu, u roku od osam dana od dana nastanka okolnosti koja utječe na korištenje priznatog prava po ovom Zakonu.

(2) Osigurana osoba obvezna je Zavodu, odnosno državnom proračunu naknaditi štetu:

1. ako je ostvarila primanje iz sredstava Zavoda, odnosno državnog proračuna uslijed toga što nije, u skladu sa stavkom 1. ovoga članka, prijavila promjenu koja utječe na gubitak ili opseg prava iz obveznoga zdravstvenog osiguranja, a znala je ili je morala znati za tu promjenu,

2. ako je ostvarila primanje iz sredstava Zavoda, odnosno sredstava državnog proračuna na osnovi neistinitih ili netočnih podataka za koje je znala ili je morala znati da su neistiniti, odnosno netočni ili je primanje ostvarila na drugi protupravni način, odnosno u većem opsegu nego što joj pripada.

Članak 136.

(1) Zavod je obvezan zahtijevati naknadu prouzročene štete od osobe koja je prouzročila bolest, ozljedu ili smrt osigurane osobe.

(2) Za štetu koju je Zavodu u slučajevima iz stavka 1. ovoga članka počinio radnik na radu ili u vezi s radom odgovara pravna ili fizička osoba – poslodavac.

(3) Zavod je obvezan u slučajevima iz stavka 2. ovoga članka zahtijevati naknadu štete i neposredno od radnika ako je šteta prouzročena namjerno ili grubom nepažnjom.

(4) Kada Zavod zahtijeva naknadu štete od pravne osobe, odnosno fizičke osobe te od radnika oni odgovaraju za štetu solidarno.

Članak 137.

Osigurana osoba kojoj je iz sredstava Zavoda, odnosno državnog proračuna isplaćen novčani iznos na koji nije imala pravo, obvezna je vratiti primljeni iznos uvećan za zakonsku zateznu kamatu te ga uplatiti na račun Zavoda, odnosno državnog proračuna u roku od osam dana od dana zaprimljene pisane obavijesti Zavoda o utvrđenim okolnostima.

Članak 138.

(1) Zavod je obvezan zahtijevati naknadu prouzročene štete od pravne, odnosno fizičke osobe:

1. ako je šteta nastala zato što nisu dani podaci ili što su dani neistiniti ili netočni podaci o činjenicama o kojima ovisi stjecanje ili opseg prava iz obveznoga zdravstvenog osiguranja,

2. ako je isplata izvršena na temelju neistinitih ili netočnih podataka navedenih u prijavi o stupanju radnika na rad,

3. ako je isplata izvršena stoga što nije podnesena prijava o promjenama koje utječu na gubitak ili na opseg prava radnika, odnosno prijava o istupanju radnika s rada ili ako je prijava podnesena poslije propisanog roka,

4. ako je šteta nastala podnošenjem prijave na obvezno zdravstveno osiguranje na temelju zaključenog ugovora o radu čija svrha nije bila obavljanje poslova u skladu s tim ugovorom, već isključivo ostvarivanje prava iz obveznoga zdravstvenog osiguranja.

(2) Osigurane osobe koje su obvezne same podnositi prijave ili davati određene podatke u vezi sa svojim pravima i obvezama obvezne su u slučajevima iz stavka 1. ovoga članka same Zavodu naknaditi štetu koja je nastala jer prijava nije podnesena ili su dani neistiniti podaci.

(3) Za štetu u slučajevima iz stavka 1. ovoga članka pravna i fizička osoba odgovaraju bez obzira na krivnju, a osigurane osobe u slučajevima iz stavka 2. ovoga članka odgovaraju za štetu ako su znale ili morale znati da su dani podaci neistiniti ili netočni, odnosno ako su znale ili morale znati za promjene koje utječu na gubitak ili opseg prava, a te promjene nisu prijavile.

Članak 139.

(1) Zavod je obvezan zahtijevati naknadu prouzročene štete od pravne ili fizičke osobe ako su bolest, povreda ili smrt osigurane osobe nastale zbog toga što nisu provedene mjere zaštite na radu ili druge mjere za zaštitu građana.

(2) Zavod je obvezan zahtijevati naknadu prouzročene štete od pravne ili fizičke osobe i kada je šteta nastala jer je radnik stupio na rad bez propisanoga prethodnoga zdravstvenog pregleda, a poslije se zdravstvenim pregledom utvrdi da ta osoba prema zdravstvenom stanju nije bila sposobna za rad na određenim poslovima.

Članak 140.

Zavod je obvezan zahtijevati naknadu prouzročene štete u slučajevima iz članka 136. ovoga Zakona i neposredno od osiguravatelja kod koje su ove osobe osigurane od odgovornosti za štetu uzrokovanu trećim osobama, prema propisima o obveznom osiguranju ovog rizika.

Članak 141.

(1) Zavod je obvezan zahtijevati naknadu štete prouzročenu na području Republike Hrvatske uporabom vozila registriranih u drugoj državi članici ili trećoj državi koje ima valjanu međunarodnu ispravu o osiguranju od automobilske odgovornosti izravno od Hrvatskog ureda za osiguranje.

(2) Zavod je obvezan zahtijevati naknadu štete i kad je šteta nastala u drugoj državi članici ili trećoj državi u skladu s odredbama Zakona o osiguranju i međunarodnih ugovora.

Članak 142.

Zavod je obvezan zahtijevati naknadu štete u slučajevima predviđenim ovim Zakonom, bez obzira na to što je šteta nastala isplatom davanja koja kao pravo pripadaju osiguranoj osobi iz sredstava obveznoga zdravstvenog osiguranja, odnosno državnog proračuna.

Članak 143.

Naknada štete koju Zavod ima pravo zahtijevati u slučajevima iz članaka 135. i 136. te članaka 138. do 142. ovoga Zakona obuhvaća troškove za zdravstvene i druge usluge te iznose novčanih naknada i drugih davanja koje plaća Zavod.

Članak 144.

Zdravstvena ustanova, privatni zdravstveni radnik i ugovorni isporučitelj pomagala, odgovoran je Zavodu za štetu koju je prouzročio pri obavljanju ili u vezi s obavljanjem svoje djelatnosti u skladu s odredbama Zakona o obveznim odnosima.

Članak 145.

Zavod je obvezan zahtijevati naknadu prouzročene štete od:

1. doktora primarne zdravstvene zaštite ako je osiguraniku utvrdio privremenu nesposobnost protivno odredbama članka 46. ovoga Zakona ili je neopravdano prekidao privremenu nesposobnost, odnosno neopravdano mijenjao dijagnozu bolesti kako ne bi došlo do primjene članka 52. stavka 2. ovoga Zakona, a čime je osiguraniku omogućio ostvarivanje naknade plaće na koju nije imao pravo ili na naknadu plaće u višem iznosu suprotno odredbama ovoga Zakona,

2. zdravstvene ustanove čiji je doktor specijalist postupio protivno odredbi članka 21. stavka 4. ovoga Zakona, a Zavod je osiguranoj osobi rješenjem utvrdio pravo na naknadu troškova kupljenog lijeka preporučenog od tog specijaliste.

Članak 146.

Pri utvrđivanju prava na naknadu štete prouzročene Zavodu, odnosno državnom proračunu primjenjuju se odgovarajuće odredbe Zakona o obveznim odnosima, kao i posebni propisi o naknadi štete.

Članak 147.

(1) Tražbine naknade štete, u smislu odredbi ovoga Zakona, zastarijevaju istekom rokova određenih Zakonom o obveznim odnosima.

(2) Rokovi zastare tražbina naknade štete u smislu odredbi ovoga Zakona počinju teći:

1. u slučajevima iz članka 135. i članka 138. stavka 1. ovoga Zakona, od dana pravomoćnosti rješenja kojim je utvrđeno da isplaćeno primanje nije pripadalo ili je pripadalo u manjem opsegu,

2. u slučajevima iz članaka 137. i 139. ovoga Zakona, od dana kada je postalo ovršnim rješenje kojim je priznato pravo na primanje iz sredstava Zavoda,

3. u ostalim slučajevima kada se zahtijeva naknada za pojedina isplaćena davanja iz članka 142. ovoga Zakona, od dana izvršene isplate svakog pojedinog davanja.

(3) Iznimno od stavka 2. ovoga članka, na pitanja zastare za štete prouzročene kaznenim djelom primjenjuju se rokovi predviđeni Zakonom o obveznim odnosima.

Članak 148.

(1) Kada se utvrdi da je nastala šteta, Zavod će uz navođenje dokaza pozvati osiguranu osobu, pravnu ili fizičku osobu, pravnu osobu za osiguranje imovine i osoba ili drugu osobu koja je dužna naknaditi štetu, da u određenom roku naknadi štetu.

(2) Ako šteta ne bude naknađena u određenom roku, Zavod tražbinu ostvaruje tužbom kod nadležnog suda.

(3) Zavod ima pravo na zateznu kamatu po stopi propisanoj Zakonom o zateznim kamatama, od dana nastale štete.

(4) Zavod nema pravo bez izričitog pristanka osigurane osobe ostvariti naknadu štete obustavom isplate ili ustezanjem od novčane naknade na koju osigurana osoba ima pravo u vezi s korištenjem prava iz obveznoga zdravstvenog osiguranja.

XI. PREKRŠAJNE ODREDBE

Članak 149.

(1) Novčanom kaznom u iznosu od 500.000,00 do 1.000.000,00 kuna kaznit će se za prekršaj društvo za osiguranje koje u propisanom roku ne uplati prihod u visini od 4% na ukupan iznos naplaćene funkcionalne premije osiguranja od obveznog osiguranja od automobilske odgovornosti (članak 72. stavci 3. i 4.).

(2) Novčanom kaznom u iznosu od 30.000,00 do 50.000,00 kuna za prekršaj iz stavka 1. ovoga članka kaznit će se i odgovorna osoba u društvu za osiguranje.

(3) Novčanom kaznom u iznosu od 5.000,00 do 100.000,00 kuna kaznit će se za prekršaj društvo za osiguranje koje u propisanom roku ne dostavi mjesečno izvješće iz članka 72. stavka 5. ovoga Zakona.

(4) Novčanom kaznom u iznosu od 5.000,00 do 100.000,00 kuna kaznit će se za prekršaj društvo za osiguranje koje u propisanom roku ne dostavi godišnje izvješće iz članka 72. stavka 6. ovoga Zakona.

(5) Novčanom kaznom u iznosu od 5.000,00 do 20.000,00 kuna za prekršaj iz stavaka 3. i 4. ovoga članka kaznit će se i odgovorna osoba u društvu za osiguranje.

Članak 150.

(1) Novčanom kaznom u iznosu od 70.000,00 do 100.000,00 kuna kaznit će se za prekršaj pravna osoba koja Zavodu u propisanom roku ne dostavi prijavu na obvezno zdravstveno osiguranje (članak 120. stavak 3.).

(2) Novčanom kaznom iz stavka 1. ovoga članka kaznit će se za prekršaj pravna osoba koja podnese prijavu na obvezno zdravstveno osiguranje na temelju zaključenog ugovora o radu čija svrha nije bila obavljanje poslova u skladu s tim ugovorom već isključivo ostvarivanje prava iz obveznoga zdravstvenog osiguranja (članak 122. stavak 4.).

(3) Novčanom kaznom u iznosu od 8.000,00 do 15.000,00 kuna kaznit će se i odgovorna osoba u pravnoj osobi i fizička osoba za prekršaj iz stavaka 1. i 2. ovoga članka.

(4) Za prekršaj iz stavka 1. ovoga članka pravnoj ili fizičkoj osobi može se uz novčanu kaznu izreći i mjera zabrane obavljanja djelatnosti.

Članak 151.

(1) Novčanom kaznom u iznosu od 10.000,00 do 15.000,00 kuna kaznit će se za prekršaj pravna osoba, koja u propisanom roku ne dostavi Zavodu sve podatke u vezi s prijavom i odjavom osigurane osobe, radi ostvarivanja prava i obveza iz obveznoga zdravstvenog osiguranja (članak 122. stavak 2.).

(2) Novčanom kaznom u iznosu od 8.000,00 do 13.000,00 kuna kaznit će se za prekršaj iz stavka 1. ovoga članka fizička osoba obveznik podnošenja prijave na obvezno zdravstveno osiguranje

(3) Za prekršaj iz stavka 1. ovoga članka kaznit će se novčanom kaznom u iznosu od 3.000,00 do 5.000,00 kuna i odgovorna osoba u pravnoj osobi.

Članak 152.

(1) Novčanom kaznom u iznosu od 50.000,00 do 250.000,00 kuna kaznit će se za prekršaj ugovorna zdravstvena ustanova koja nenamjenski koristi sredstva ostvarena za provođenje zdravstvene zaštite iz obveznoga zdravstvenog osiguranja (članak 94. stavak 3. točka 4.).

(2) Za prekršaj iz stavka 1. ovoga članka kaznit će se novčanom kaznom u iznosu od 10.000,00 do 50.000,00 kuna i odgovorna osoba u zdravstvenoj ustanovi te ugovorni zdravstveni radnik privatne prakse, odnosno izabrani doktor medicine, odnosno dentalne medicine primarne zdravstvene zaštite (članak 93. i članak 94. stavak 3. točka 4.).

(3) Novčanom kaznom u iznosu od 5.000,00 do 20.000,00 kuna kaznit će se za prekršaj izabrani doktor koji utvrđuje privremenu nesposobnost osiguranika protivno odredbama članka 46. ovoga Zakona, odnosno koji mijenjanjem dijagnoza bolesti osiguranika te neopravdanim zaključivanjem privremene nesposobnosti postupa protivno odredbama članka 52. ovoga Zakona radi izbjegavanja primjene stavka 2. istog članka Zakona (članak 46. stavci 2. i 4. i članak 52. stavak 1.)

(4) Novčanom kaznom u iznosu od 5.000,00 do 15.000,00 kuna kaznit će se za prekršaj doktor specijalist u ugovornoj zdravstvenoj ustanovi koji nije uputio prijedlog za liječenje lijekom bolničkom povjerenstvu za lijekove bolničke zdravstvene ustanove (članka 21. stavak 4.).

Članak 153.

Novčanom kaznom u iznosu od 8.000,00 do 15.000,00 kuna kaznit će se za prekršaj osigurana osoba:

1. ako je svjesno prouzročila privremenu nesposobnost, ako u roku od tri dana nakon početka bolesti ne izvijesti izabranog doktora medicine primarne zdravstvene zaštite da je oboljela,

odnosno u roku od tri dana od dana prestanka razloga koji ju je u tome onemogućio, ako namjerno sprječava ozdravljenje, odnosno osposobljavanje, ako za vrijeme privremene nesposobnosti radi, ako se bez opravdanog razloga ne odazove na poziv za liječnički pregled izabranog doktora, odnosno doktora kontrolora ili tijela Zavoda ovlaštenog za kontrolu privremene nesposobnosti, ako se ne pridržava uputa za liječenje, odnosno bez suglasnosti izabranog doktora otputuje iz mjesta prebivališta, odnosno boravišta ili ako zlorabi pravo na korištenje privremene nesposobnosti na neki drugi način (članak 53.),

2. ako je ostvarila pravo na naknadu za troškove prijevoza u vezi s korištenjem prava na zdravstvenu zaštitu iz obveznoga zdravstvenog osiguranja, a nije za to imala pravne osnove (članak 62.),

3. ako koristi ispravu kojom se dokazuje status osigurane osobe na način protivan odredbama ovoga Zakona i propisa donesenih na temelju ovoga Zakona, odnosno zdravstvenu zaštitu ostvaruje koristeći tuđu ispravu (članak 119. stavci 3. i 6.).

XII. PRIJELAZNE I ZAVRŠNE ODREDBE

Članak 154.

(1) Ministar nadležan za zdravlje donijet će pravilnike iz članka 19. stavka 2. točaka 15. i 18., članka 46. stavaka 2. i 9., članka 78 i članka 90. stavka 1. ovoga Zakona u roku od 90 dana od dana stupanja na snagu ovoga Zakona.

(2) Ministar nadležan za poslove socijalne skrbi donijet će pravilnike iz članka 15. stavka 2. ovoga Zakona u roku od 90 dana od dana stupanja na snagu ovoga Zakona.

(3) Ministar nadležan za financije donijet će pravilnik iz članka 72. stavka 8. ovoga Zakona u roku od 90 dana od dana stupanja na snagu ovoga Zakona.

Članak 155.

(1) Zavod će opće akte iz članka 19. stavka 4., članka 36. stavka 1. točke 4., članka 38. stavka 3., članka 41. stavka 7., članka 45. stavka 6., članka 54. stavka 9., članka 61., članka 79. stavka 5., članka 119. stavka 6., članka 122. stavka 5., članka 126. stavka. 3., članka 127. stavka 3., članka 128. stavka 4. i članka 131. ovoga Zakona donijeti u roku od 90 dana od dana stupanja na snagu ovoga Zakona.

(2) Zavod će opće akte iz članka 7. stavka 7., članka 10. stavka 3., članka 19. stavka 6., članka 20. stavaka 7. i 9., članka 33., članka 76., članka 86. stavka 2., članka 87. stavaka 1. i 2. ovoga Zakona donijeti u roku od 180 dana od dana stupanja na snagu ovoga Zakona, te u istom roku uskladiti ostale opće akte s odredbama ovoga Zakona.

(3) Zavod će opće akte iz članka 26. stavka 4. i članka 28. stavka 3. ovoga Zakona donijeti najkasnije do 25. listopada 2013.

(4) Zavod će opće akte iz članka 23. stavka 3., članka 24. stavka 3. i članka 25. ovoga Zakona donijeti najkasnije do 1. siječnja 2014.

Članak 156.

Sadržaj i oblik recepata iz članka 20. stavka 9., izvješća o privremenoj nesposobnosti za rad iz članka 38. stavka 5. i putnog naloga iz članka 65. stavka 5. ovoga Zakona Zavod će utvrditi općim aktom u roku od 90 dana od dana stupanja na snagu ovoga Zakona.

Članak 157.

Do stupanja na snagu pravilnika i općih akata iz članaka 154., 155. i 156. ovoga Zakona ostaju na snazi u dijelu u kojem nisu u suprotnosti s odredbama ovoga Zakona:

1. Pravilnik o pravima, uvjetima i načinu ostvarivanja prava iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 67/09., 116/09., 4/10., 13/10., 88/10., 131/10., 01/11., 16/11., 87/11., 137/11., 39/12., 69/12., 126/12. i 38/13.),

2. Pravilnik o pravima, uvjetima i načinu ostvarivanja prava iz obveznog zdravstvenog osiguranja u slučaju ozljede na radu i profesionalne bolesti (»Narodne novine«, br. 1/11., 153/11., 51/12., 126/12., 147/12., 38/13. i 67/13.),

3. Pravilnik o načinu ostvarivanja prava na slobodan izbor doktora medicine i doktora stomatologije primarne zdravstvene zaštite (»Narodne novine«, br. 41/07., 4/10., 13/10., 41/12. i 50/13.),

4. Pravilnik o načinu i postupku izbora doktora specijaliste medicine rada (»Narodne novine«, br. 48/11., 51/12. i 147/12.),

5. Pravilnik o uvjetima i načinu ostvarivanja prava iz obveznog zdravstvenog osiguranja za bolničko liječenje medicinskom rehabilitacijom i fizikalnom terapijom u kući (»Narodne novine«, br. 26/96., 79/97., 31/99., 51/99., 73/99., 40/07., 46/07. – pročišćeni tekst, 64/08., 91/09. i 118/09.),

6. Pravilnik o ovlastima i načinu rada ovlaštenih doktora i liječničkih povjerenstava Hrvatskog zavoda za zdravstveno osiguranje (»Narodne novine«, br. 113/09., 126/09., 4/10., 88/10., 1/11., 50/11. i 87/211.),

7. Pravilnik o načinu propisivanja i izdavanja lijekova na recept (»Narodne novine«, br. 17/09., 46/09., 4/10., 110/10., 131/10., 1/11. i 52/11.),

8. Pravilnik o ortopedskim i drugim pomagalima (»Narodne novine«, br. 7/12., 14/12., 23/12., 25/12., 45/12., 69/12., 85/12., 92/12., 119/12., 147/12., 21/13. i 38/13.),

9. Pravilnik o dentalnoj zdravstvenoj zaštiti iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 38/13. i 49/13.),

10. Pravilnik o pravima, uvjetima i načinu korištenja zdravstvene zaštite u inozemstvu (»Narodne novine«, br. 50/09., 118/09., 4/10., 13/10., 14/10., 1/11., 16/11., 31/11., 93/11., 145/11., 41/12., 76/12. i 129/12.)

11. Pravilnik o načinu prijavljivanja i odjavljivanja te stjecanju statusa osigurane osobe u obveznom zdravstvenom osiguranju (»Narodne novine«, br. 31/07., 56/07., 96/07., 130/07., 33/08., 91/09., 4/10., 69/10., 1/11. i 48/11.),

12. Pravilnik o uvjetima i načinu ostvarivanja prava iz obveznog zdravstvenog osiguranja na zdravstvenu njegu u kući osigurane osobe (»Narodne novine«, br. 88/10., 1/11., 87/11., 38/13. i 49/13.),

13. Pravilnik o rokovima najduljeg trajanja bolovanja ovisno o vrsti bolesti (»Narodne novine«, br. 153/09.),

14. Pravilnik o ovlastima i načinu rada kontrolora Hrvatskog zavoda za zdravstveno osiguranje (»Narodne novine«, br. 59/09. i 48/11.),

15. Pravilnik o mjerilima i postupku za utvrđivanje nesposobnosti za samostalan život i rad i nedostatak sredstava za uzdržavanje za osobe s prebivalištem u Republici Hrvatskoj kojima se zdravstvena zaštita ne osigurava po drugoj osnovi (»Narodne novine«, br. 39/02.),

16. Pravilnik o uvjetima za oslobađanje od plaćanja doprinosa za osnovno zdravstveno osiguranje poljoprivrednika starijih od 65 godine (»Narodne novine«, br. 122/02.),

17. Pravilnik o kontroli bolovanja (»Narodne novine«, br. 123/11.),

18. Pravilnik o sanitetskom prijevozu (»Narodne novine«, br. 123/09.),

19. Pravilnik o europskoj kartici zdravstvenog osiguranja (»Narodne novine«, br. 153/11.),

20. Odluka o utvrđivanju Osnovne liste lijekova Hrvatskog zavoda za zdravstveno osiguranje (»Narodne novine«, br. 47/13., 49/13., 50/13. i 54/13.),

21. Odluka o utvrđivanju Dopunske liste lijekova Hrvatskog zavoda za zdravstveno osiguranje (»Narodne novine«, br. 47/13. i 49/13.),

22. Odluka o utvrđivanju popisa posebno skupih lijekova utvrđenih Odlukom o utvrđivanju Osnovne liste lijekova Hrvatskog zavoda za zdravstveno osiguranje (»Narodne novine«, broj 67/13.),

23. Odluka o sadržaju i obliku isprave kojom se dokazuje status osigurane osobe Hrvatskog zavoda za zdravstveno osiguranje (»Narodne novine«, br. 4/07., 91/09., 113/09., 140/09, 4/10., 13/10., 43/10. i 29/11.),

24. Odluka o utvrđivanju visine naknade za troškove izdavanja iskaznice zdravstveno osigurane osobe iz obveznog zdravstvenog osiguranja (Isprava 2) (»Narodne novine«, br. 113/09.),

25. Odluka o osnovama za sklapanje ugovora o provođenju zdravstvene zaštite iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 23/13., 38/13., 50/13. i 51/13.),

26. Odluka o posebnim standardima i mjerilima njihove primjene u provođenju primarne zdravstvene zaštite iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 38/13.),

27. Opći uvjeti ugovora o provođenju primarne zdravstvene zaštite iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 34/13.),

28. Opći uvjeti ugovora o provođenju specijalističko-konzilijarne zdravstvene zaštite iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 34/13.),

29. Opći uvjeti ugovora o provođenju bolničke zdravstvene zaštite iz obveznog zdravstvenog osiguranja (»Narodne novine«, br. 34/13.),

30. Odluka o utvrđivanju Popisa dijagnostičkih i terapijskih postupaka u zdravstvenim djelatnostima – vremenski i kadrovski normativi (»Narodne novine«, br. 15/92., 29/93., 65/93., 31/95., 73/99., 3/00., 18/00., 118/01., 44/02., 76/02., 85/02., 92/02., 130/02., 151/02., 11/03., 32/03., 43/03., 203/03., 30/05., 88/05., 136/06., 16/07., 40/07., 57/07., 80/07., 84/07., 98/07., 111/07., 130/07., 54/08., 85/08., 133/08., 2/09., 10/09., 17/09., 110/10., 49/13. i 65/13.),

31. Odluka o standardima i normativima prava na zdravstvenu zaštitu iz obveznog zdravstvenog osiguranja za slučaj ozljede na radu i profesionalne bolesti s osnovama za sklapanje ugovora (»Narodne novine«, br. 1/211., 6/211., 31/211., 78/11, 153/11., 38/12., 61/12., 118/12., 147/12. i 38/13.),

32. Odluka o posebnom standardu i mjerilima njegove primjene u provođenju specifične zdravstvene zaštite (»Narodne novine«, br. 126/12. i 38/13.),

33. Odluka o osnovici i stopi posebnog doprinosa za korištenje zdravstvene zaštite u inozemstvu osiguranih osoba Hrvatskog zavoda za zdravstveno osiguranje koje u inozemstvu borave radi privatnog posla (»Narodne novine«, br. 93/11.).

Članak 158.

Zavod je obvezan svoje poslovanje uskladiti s odredbama ovoga Zakona u roku od 180 dana od dana stupanja na snagu ovoga Zakona.

Članak 159

Sve pravne i fizičke osobe u ostvarivanju prava i obveza iz obveznoga zdravstvenog osiguranja dužne su svoje poslovanje uskladiti s odredbama ovoga Zakona u roku od 180 dana od dana stupanja na snagu ovoga Zakona.

Članak 160.

(1) Osigurane osobe koje su započele ostvarivati prava iz obveznoga zdravstvenog osiguranja prema odredbama Zakona o obveznom zdravstvenom osiguranju (»Narodne novine«, br. 150/08., 94/09., 153/09., 71/10., 139/10., 49/11., 22/12., 57/12., 90/12. – Odluka Ustavnog suda Republike Hrvatske, 123/12. i 144/12.), od dana stupanja na snagu ovog Zakona prava iz obveznog zdravstvenoga osiguranja nastavljaju koristiti prema njegovim odredbama.

(2) Osigurane osobe koje na dan stupanja na snagu ovoga Zakona imaju utvrđen status člana obitelji osiguranika prema članku 10. stavku 1. Zakona o obveznom zdravstvenom osiguranju (»Narodne novine«, br. 150/08., 94/09., 153/09., 71/10., 139/10., 49/11., 22/12., 57/12., 90/12. – Odluka Ustavnog suda Republike Hrvatske, 123/12. i 144/12.), zadržavaju taj status do završetka tekuće školske, odnosno akademske godine.

Članak 161.

Osiguranicima kojima je privremena nesposobnost utvrđena od dana stupanja na snagu Zakona o obveznom zdravstvenom osiguranju (»Narodne novine«, br. 150/08., 94/09., 153/09., 71/10., 139/10., 49/11., 22/12., 57/12., 90/12. – Odluka Ustavnog suda Republike Hrvatske, 123/12. i 144/12.), te kojima je do dana stupanja na snagu ovoga Zakona utvrđena invalidnost zbog opće, odnosno profesionalne nesposobnosti za rad, izabrani doktor utvrditi će prestanak privremene nesposobnosti od dana stupanja na snagu ovoga Zakona.

Članak 162.

Upravni postupci pokrenuti do dana stupanja na snagu ovoga Zakona dovršit će se prema odredbama Zakona o obveznom zdravstvenom osiguranju (»Narodne novine«, br. 150/08., 94/09., 153/09., 71/10., 139/10., 49/11., 22/12., 57/12., 90/12. – Odluka Ustavnog suda Republike Hrvatske, 123/12. i 144/12.) te propisa i općih akata donesenih na temelju toga Zakona.

Članak 163.

Doprinosi i ostali prihodi obveznoga zdravstvenog osiguranja utvrđeni u odredbi članka 72. stavka 1. ovoga Zakona, te sredstva iz članka 137. ovoga Zakona, uplaćuju se u korist državnog proračuna Republike Hrvatske do 31. prosinca 2014., a od 1. siječnja 2015. uplaćuju se u korist računa Zavoda i prihod su Zavoda.

Članak 164.

Danom stupanja na snagu ovoga Zakona prestaje važiti Zakon o obveznom zdravstvenom osiguranju (»Narodne novine«, br. 150/08., 94/09., 153/09., 71/10., 139/10., 49/11., 22/12., 57/12., 90/12. – Odluka Ustavnog suda Republike Hrvatske, 123/12. i 144/12.).

Članak 165.

Ovaj Zakon objavljuje se u »Narodnim novinama«, a stupa na snagu danom pristupanja Republike Hrvatske Europskoj uniji, osim odredbi:

– članaka 2. i 3. i članka 34., u dijelu koji se odnosi na primjenu Direktive 2011/24/EU i članaka 26. do 32., koji stupaju na snagu 25. listopada 2013.,

– članka 18. točaka 5. i 6., te članaka 19., 22., 23. i 25., u dijelu koji se odnosi na osnovnu i dodatnu listu ortopedskih i drugih pomagala, te dentalnih pomagala, koji stupaju na snagu 1. siječnja 2014.,

– članka 82. stavka 2. koji stupa na snagu 1. siječnja 2015.

Zakon o izmjenama i dopuni Zakona o obveznom zdravstvenom osiguranju („NN“ br.137/13.)

Članak 9.

Redoviti studenti koji su na dan stupanja na snagu ovoga Zakona imali utvrđen status osiguranika u obveznom zdravstvenom osiguranju po osnovi statusa redovitog studenta, od dana stupanja na snagu ovoga Zakona nastavljaju koristiti to pravo prema njegovim odredbama.

Članak 10.

Redoviti studenti koji su do dana stupanja na snagu ovoga Zakona navršili 26 godina života pravo na obvezno zdravstveno osiguranje mogu steći prema odredbama ovoga Zakona pod uvjetom da nisu iskoristili trajanje statusa osiguranika po osnovi redovitog studiranja u trajanju utvrđenom u članku 2. ovoga Zakona.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Council Directive 90/385/EEC ([3]) and Council Directive 93/42/EEC ([4]) constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

([1]) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
([2]) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
([3]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
([4]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of medical devices after they have already been put into service such as in the context of second-hand sales.

(4) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety.

(5) To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations.

(6) For historical reasons, active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.

(7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as *in vitro* diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council ([1]) should be amended to exclude medical devices from its scope.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification decisions in that regard across all Member States, particularly with regard to borderline cases, the Commission should be allowed to, on its own initiative or at the duly substantiated request of a Member State, having consulted the Medical Device Coordination Group ('MDCG'), decide on a case-by-case basis whether or not a specific product, category or group of products falls within the scope of this Regulation. When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility of taking a Union-wide decision regarding the regulatory status of a product should also be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council ([2]).

(10) Products which combine a medicinal product or substance and a medical device are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council. ([3]) The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products. Directive 2001/83/EC should therefore be amended.

([1]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([2]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

([3]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(11) Union legislation, in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council ([1]) and Directive 2004/23/EC of the European Parliament and of the Council ([2]), is incomplete in respect of certain products manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable. Such products should come under the scope of this Regulation, provided they comply with the definition of a medical device or are covered by this Regulation.

(12) Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate the conformity of such products, the Commission should adopt common specifications at least with regard to application of risk management and, where necessary, clinical evaluation regarding safety. Such common specifications should be developed specifically for a group of products without an intended medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose. Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.

(13) As is the case for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain or consist of viable biological materials or viable organisms of another origin in order to achieve or support the intended purpose of those products are not covered by this Regulation either.

(14) The requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council ([3]) should continue to apply.

(15) There is scientific uncertainty about the risks and benefits of nanomaterials used for devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU ([4]), with the necessary flexibility to adapt that definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of devices, manufacturers should take special care when using nanoparticles for which there is a high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures. In preparation of implementing acts regulating the practical and uniform application of the corresponding requirements laid down in this Regulation, the relevant scientific opinions of the relevant scientific committees should be taken into account.

(16) Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council ([5]) are an integral part of the general safety and performance requirements laid down in this Regulation for devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.

(17) This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom ([6]) which pursues other objectives.

(18) This Regulation should include requirements for devices' design, safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

([1]) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

([2]) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

([3]) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (OJ L 33, 8.2.2003, p. 30).

([4]) Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

([5]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014. p. 79).

([6]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

(19) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

(20) The definitions in this Regulation, regarding devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical investigations and clinical evaluations, post-market surveillance, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice in the field at Union and international level in order to enhance legal certainty.

(21) It should be made clear that it is essential that devices offered to persons in the Union by means of information society services within the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council ([1]) and devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union comply with the requirements of this Regulation, where the product in question is placed on the market or the service is provided in the Union.

(22) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([2]) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

(23) Directive 98/79/EC of the European Parliament and of the Council ([3]) allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are insufficient, the Commission should be empowered to lay down common specifications which provide a means of complying with the general safety and performance requirements, and the requirements for clinical investigations and clinical evaluation and/or post-market clinical follow-up, laid down in this Regulation.

(24) Common specifications ('CS') should be developed after consulting the relevant stakeholders and taking account of European and international standards.

(25) The rules applicable to devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([4]) and Decision No 768/2008/EC of the European Parliament and of the Council ([5]).

(26) The rules on Union market surveillance and control of products entering the Union market laid down in Regulation (EC) No 765/2008 apply to devices covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(27) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the various parts of this Regulation, to enhance understanding of the requirements laid down in this Regulation and thus to improve regulatory compliance by the relevant operators.

([1]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

([2]) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

([3]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

([4]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

([5]) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(28) For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices.

(29) Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting, that were set out only in the Annexes to Directives 90/385/EEC and 93/42/EEC, should be incorporated into the enacting provisions of this Regulation to facilitate its application.

(30) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby address, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. In that context, it is appropriate to provide that certain rules of this Regulation, as regards medical devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the healthcare system and/or address patient needs, but which do not treat or care for patients directly, should not apply, since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the concept of 'health institution' does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to such establishments.

(31) In view of the fact that natural or legal persons can claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC ([1]). Such measures should be proportionate to the risk class, type of device and the size of the enterprise. In this context, it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

(32) To ensure that devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of the devices they manufacture is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the device in question. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.

(33) The risk management system should be carefully aligned with and reflected in the clinical evaluation for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated.

(34) It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

(35) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC, and accordingly the authorised representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

([1]) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

(36) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a device.

(37) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations arising from the need for protection of health and safety and from the need for protection of intellectual property rights provided for under Article 36 TFEU. Application of the principle of parallel trade is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the Court of Justice ([1]) in other relevant sectors and existing good practice in the field of medical devices.

(38) The reprocessing and further use of single-use devices should only take place where permitted by national law and while complying with the requirements laid down in this Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers under this Regulation. Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution or by an external reprocessor acting on its behalf may differ from the obligations on a manufacturer described in this Regulation. In principle, such divergence should only be permitted where reprocessing and reuse of single-use devices within a health institution or by an external reprocessor are compliant with CS that have been adopted, or, in the absence of such CS, with relevant harmonised standards and national provisions. The reprocessing of such devices should ensure an equivalent level of safety and performance to that of the corresponding initial single-use device.

(39) Patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, including any necessary health risk warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

(40) Devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.

(41) The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

(42) The UDI system should apply to all devices placed on the market except custom-made devices, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation.

(43) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

(44) One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified

([1]) Judgment of 28 July 2011 in Orifarm and Paranova, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.

bodies, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between Member States and to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission. Within the internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices set up by Commission Decision 2010/227/EU ([1]).

(45) To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

(46) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as a tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of the evaluation of such incidents and events by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(47) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council ([2]) applies to the processing of personal data carried out in the Member States, under the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council ([3]) applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(48) For implantable devices and for class III devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.

(49) The summary of safety and clinical performance for a device should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of that device when compared to the diagnostic or therapeutic alternatives and the specific conditions under which that device and its alternatives can be considered.

(50) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

(51) Notified bodies' assessments of manufacturers' technical documentation, in particular documentation on clinical evaluation, should be critically evaluated by the authority responsible for notified bodies. That evaluation should be part of the risk-based approach to the oversight and monitoring activities of notified bodies and should be based on sampling of the relevant documentation.

(52) The position of notified bodies vis-à-vis manufacturers should be strengthened, including with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification.

([1]) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices (OJ L 102, 23.4.2010, p. 45).
([2]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).
([3]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(53) To increase transparency with regard to the oversight of notified bodies by national authorities, the authorities responsible for notified bodies should publish information on the national measures governing the assessment, designation and monitoring of notified bodies. In accordance with good administrative practice, this information should be kept up to date by those authorities in particular to reflect relevant, significant or substantive changes to the procedures in question.

(54) The Member State in which a notified body is established should be responsible for enforcing the requirements of this Regulation with regard to that notified body.

(55) In view, in particular, of the responsibility of Member States for the organisation and delivery of health services and medical care, they should be allowed to lay down additional requirements on notified bodies designated for the conformity assessment of devices and established on their territory as far as issues that are not regulated in this Regulation are concerned. Any such additional requirements laid down should not affect more specific horizontal Union legislation on notified bodies and equal treatment of notified bodies.

(56) For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, notified bodies should, except in certain cases, be obliged to request expert panels to scrutinise their clinical evaluation assessment report. Competent authorities should be informed about devices that have been granted a certificate following a conformity assessment procedure involving an expert panel. The consultation of expert panels in relation to the clinical evaluation should lead to a harmonised evaluation of high-risk medical devices by sharing expertise on clinical aspects and developing CS on categories of devices that have undergone that consultation process.

(57) For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.

(58) It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body, should take into account the potential risks associated with the technical design and manufacture of the devices. To maintain the same level of safety as provided by Directive 90/385/EEC, active implantable devices should be in the highest risk class.

(59) Rules under the old regime applied to invasive devices do not sufficiently take account of the level of invasiveness and potential toxicity of certain devices which are introduced into the human body. In order to obtain a suitable risk-based classification of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, it is necessary to introduce specific classification rules for such devices. The classification rules should take into account the place where the device performs its action in or on the human body, where it is introduced or applied, and whether a systemic absorption of the substances of which the device is composed, or of the products of metabolism in the human body of those substances occurs.

(60) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. For class IIa, class IIb and class III devices, an appropriate level of involvement of a notified body should be compulsory.

(61) The conformity assessment procedures for devices should be further strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(62) It is appropriate that certificates of free sale contain information that makes it possible to use Eudamed in order to obtain information on the device, in particular with regard to whether it is on the market, withdrawn from the market or recalled, and on any certificate on its conformity.

(63) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

(64) The rules on clinical investigations should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of clinical investigations conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of clinical investigations conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

(65) It should be left to the Member State where a clinical investigation is to be conducted to determine the appropriate authority to be involved in the assessment of the application to conduct a clinical investigation and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical investigation as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. In that context, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

(66) Where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.

(67) An electronic system should be set up at Union level to ensure that every clinical investigation is recorded and reported in a publicly accessible database. To protect the right to the protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union ('the Charter'), no personal data of subjects participating in a clinical investigation should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(68) Where a clinical investigation is to be conducted in more than one Member State, the sponsor should have the possibility of submitting a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety-related aspects of the investigational device and of the scientific design of that clinical investigation, the procedure for the assessment of such single application should be coordinated between the Member States under the direction of a coordinating Member State. Such coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent. For an initial period of seven years from the date of application of this Regulation, Member States should be able to participate on a voluntary basis in the coordinated assessment. After that period, all Member States should be obliged to participate in the coordinated assessment. The Commission, based on the experience gained from the voluntary coordination between Member States, should draw up a report on the application of the relevant provisions regarding the coordinated assessment procedure. In the event that the findings of the report are negative, the Commission should submit a proposal to extend the period of participation on a voluntary basis in the coordinated assessment procedure.

(69) Sponsors should report certain adverse events and device deficiencies that occur during clinical investigations to the Member States in which those clinical investigations are being conducted. Member States should have the possibility of terminating or suspending the investigations or revoking the authorisation for those investigations, if considered necessary to ensure a high level of protection of the subjects participating in a clinical investigation. Such information should be communicated to the other Member States.

(70) The sponsor of a clinical investigation should submit a summary of results of the clinical investigation that is easily understandable for the intended user together with the clinical investigation report, where applicable, within the timelines laid down in this Regulation. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results will be submitted.

(71) This Regulation should cover clinical investigations intended to gather clinical evidence for the purpose of demonstrating conformity of devices and should also lay down basic requirements regarding ethical and scientific assessments for other types of clinical investigations of medical devices.

(72) Incapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures. However, it should be left to Member States to determine the legally designated representatives of incapacitated subjects and minors.

(73) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and of the Council ([1]) should be observed. In particular, the unnecessary duplication of tests and studies should be avoided.

(74) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.

(75) In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

(76) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be encouraged and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers of any suspected serious incidents and, where a manufacturer confirms that such an incident has occurred, the authorities concerned should ensure that appropriate follow-up action is taken in order to minimise recurrence of such incidents.

(77) The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

(78) In the context of the investigation of incidents, the competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

(79) The reporting of serious adverse events or device deficiencies during clinical investigations and the reporting of serious incidents occurring after a device has been placed on the market should be clearly distinguished to avoid double reporting.

(80) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

(81) Any statistically significant increase in the number or severity of incidents that are not serious or in expected side-effects that could have a significant impact on the benefit-risk analysis and which could lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

(82) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices including *in vitro* diagnostic medical devices, should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) 2017/746 of the European Parliament and of the Council ([2]), to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to have access to necessary in-depth

([1]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

([2]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (see page 176 of this Official Journal).

technical expertise in the field of medical devices including *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices.

(83) Expert panels and expert laboratories should be designated by the Commission on the basis of their up-to-date clinical, scientific or technical expertise, with the aim of providing scientific, technical and clinical assistance to the Commission, the MDCG, manufacturers and notified bodies in relation to the implementation of this Regulation. Moreover, expert panels should fulfil the tasks of providing an opinion on clinical evaluation assessment reports of notified bodies in the case of certain high-risk devices.

(84) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is essential for ensuring a consistently high level of health and safety protection within the internal market, in particular in the areas of clinical investigations and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as the designation of notified bodies and should be encouraged in the area of market surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.

(85) The Commission should provide scientific, technical and corresponding logistical support to coordinating national authorities and ensure that the regulatory system for devices is effectively and uniformly implemented at Union level based on sound scientific evidence.

(86) The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of medical devices to facilitate the exchange of safety-related information regarding medical devices and to foster the further development of international regulatory guidelines that promote the adoption in other jurisdictions of regulations that lead to a level of health and safety protection equivalent to that set by this Regulation.

(87) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.

(88) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should, in order to ensure transparency, inform the Commission and the other Member States before they decide on the level and structure of such fees. In order to further ensure transparency, the structure and level of the fees should be publicly available on request.

(89) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

(90) The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in order to amend certain non-essential provisions of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.

(91) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([2]).

([1]) OJ L 123, 12.5.2016, p. 1.
([2]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(92) The advisory procedure should be used for implementing acts that set out the form and presentation of the data elements of manufacturers' summaries of safety and clinical performance, and that establish the model for certificates of free sale, given that such implementing acts are of a procedural nature and do not directly have an impact on health and safety at Union level.

(93) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures, imperative grounds of urgency so require.

(94) In order to enable it to designate issuing entities, expert panels and expert laboratories, implementing powers should be conferred on the Commission.

(95) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements that are to be made. However, certain parts of the Regulation that directly affect Member States and the Commission should be implemented as soon as possible. It is also particularly important that, by the date of application of this Regulation, a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of medical devices on the market. Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directives 90/385/EEC and 93/42/EEC and to their capacity to continue issuing valid certificates under those two Directives until the date of application of this Regulation.

(96) In order to ensure a smooth transition to the new rules for registration of devices and of certificates, the obligation to submit the relevant information to the electronic systems set up at Union level pursuant to this Regulation should, in the event that the corresponding IT systems are developed according to plan, only become fully effective from 18 months after the date of application of this Regulation. During this transitional period, certain provisions of Directives 90/385/EEC and 93/42/EEC should remain in force. However, in order to avoid multiple registrations, economic operators and notified bodies who register in the relevant electronic systems set up at Union level pursuant to this Regulation should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions.

(97) In order to provide for a smooth introduction of the UDI system, the moment of application of the obligation to place the UDI carrier on the label of the device should vary from one to five years after the date of application of this Regulation depending upon the class of the device concerned.

(98) Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation. Manufacturers' obligations as regards the making available of documentation regarding devices they placed on the market and manufacturers' and Member States' obligations as regards vigilance activities for devices placed on the market pursuant to those Directives should however continue to apply. While it should be left to Member States to decide how to organise vigilance activities, it is desirable for them to have the possibility of reporting incidents related to devices placed on the market pursuant to the Directives using the same tools as those for reporting on devices placed on the market pursuant to this Regulation. It is furthermore appropriate, in order to ensure a smooth transition from the old regime to the new regime, to provide that Commission Regulation (EU) No 207/2012 ([1]) and Commission Regulation (EU) No 722/2012 ([2]) should remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

([1]) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

([2]) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3).

Decision 2010/227/EU adopted in implementation of those Directives and Directive 98/79/EC should also remain in force and continue to apply until the date when Eudamed becomes fully functional. Conversely, no such maintenance in force is required for Commission Directives 2003/12/EC [1] and 2005/50/EC [2] and Commission Implementing Regulation (EU) No 920/2013 [3].

(99) The requirements of this Regulation should be applicable to all devices placed on the market or put into service from the date of application of this Regulation. However, in order to provide for a smooth transition it should be possible, for a limited period of time from that date, for devices to be placed on the market or put into service by virtue of a valid certificate issued pursuant to Directive 90/385/EEC or pursuant to Directive 93/42/EEC.

(100) The European Data Protection Supervisor has given an opinion [4] pursuant to Article 28(2) of Regulation (EC) No 45/2001.

(101) Since the objectives of this Regulation, namely to ensure the smooth functioning of the internal market as regards medical devices and to ensure high standards of quality and safety for medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

2. This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. The common specifications for each of the groups of products listed in Annex XVI shall address, at least, application of risk management as set out in Annex I for the group of products in question and, where necessary, clinical evaluation regarding safety.

The necessary common specifications shall be adopted by 26 May 2020. They shall apply as from six months after the date of their entry into force or from 26 May 2020, whichever is the latest.

Notwithstanding Article 122, Member States' measures regarding the qualification of the products covered by Annex XVI as medical devices pursuant to Directive 93/42/EEC shall remain valid until the date of application, as referred to in the first subparagraph, of the relevant common specifications for that group of products.

This Regulation also applies to clinical investigations conducted in the Union concerning the products referred to in the first subparagraph.

3. Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.

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[1] Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).

[2] Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).

[3] Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).

[4] OJ C 358, 7.12.2013, p. 10.

4. For the purposes of this Regulation, medical devices, accessories for medical devices, and products listed in Annex XVI to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as 'devices'.

5. Where justified on account of the similarity between a device with an intended medical purpose placed on the market and a product without an intended medical purpose in respect of their characteristics and risks, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list in Annex XVI, by adding new groups of products, in order to protect the health and safety of users or other persons or other aspects of public health.

6. This Regulation does not apply to:

(a) *in vitro* diagnostic medical devices covered by Regulation (EU) 2017/746;

(b) medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product;

(c) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;

(d) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells, except for devices referred to in paragraph 8 of this Article;

(e) cosmetic products covered by Regulation (EC) No 1223/2009;

(f) transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable;

(g) transplants, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;

(h) products, other than those referred to in points (d), (f) and (g), that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria, fungi or viruses in order to achieve or support the intended purpose of the product;

(i) food covered by Regulation (EC) No 178/2002.

7. Any device which, when placed on the market or put into service, incorporates as an integral part an *in vitro* diagnostic medical device as defined in point 2 of Article 2 of Regulation (EU) 2017/746, shall be governed by this Regulation. The requirements of Regulation (EU) 2017/746 shall apply to the *in vitro* diagnostic medical device part of the device.

8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the device, shall be assessed and authorised in accordance with this Regulation.

However, if the action of that substance is principal and not ancillary to that of the device, the integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

9. Any device which is intended to administer a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC shall be governed by this Regulation, without prejudice to the provisions of that Directive and of Regulation (EC) No 726/2004 with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned.

([1]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

10. Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device shall be assessed and authorised in accordance with this Regulation. In that case, the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.

However, if the action of those tissues or cells or their derivatives is principal and not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

11. This Regulation is specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

12. Devices that are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council ([1]) shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.

13. This Regulation shall not affect the application of Directive 2013/59/Euratom.

14. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

15. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or healthcare institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

16. Nothing in this Regulation shall restrict the freedom of the press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter of Fundamental Rights of the European Union.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

([1]) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

(4) 'active device' means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Software shall also be deemed to be an active device;

(5) 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended:

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;

(6) 'invasive device' means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;

(7) 'generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(8) 'single-use device' means a device that is intended to be used on one individual during a single procedure;

(9) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

(10) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;

(11) 'system' means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose;

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

(13) 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

(15) 'Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

(16) 'non-viable' means having no potential for metabolism or multiplication;

(17) 'derivative' means a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues;

(18) 'nanomaterial' means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials;

(19) 'particle', for the purposes of the definition of nanomaterial in point (18), means a minute piece of matter with defined physical boundaries;

(20) 'agglomerate', for the purposes of the definition of nanomaterial in point (18), means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(21) 'aggregate', for the purposes of the definition of nanomaterial in point (18), means a particle comprising of strongly bound or fused particles;

(22) 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer;

(23) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(24) 'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

(25) 'compatibility' is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

(a) perform without losing or compromising the ability to perform as intended, and/or

(b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

(c) be used together without conflict/interference or adverse reaction.

(26) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:

(a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or

(b) communicate with each other, and/or

(c) work together as intended.

(27) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

(29) 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(30) 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

(31) 'fully refurbishing', for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(32) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(33) 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;

(34) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(35) 'economic operator' means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

(36) 'health institution' means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

(37) 'user' means any healthcare professional or lay person who uses a device;

(38) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

(39) 'reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device;

(40) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

(41) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(42) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

(44) 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

(45) 'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

(46) 'investigational device' means a device that is assessed in a clinical investigation;

(47) 'clinical investigation plan' means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation;

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

(49) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation;

(50) 'subject' means an individual who participates in a clinical investigation;

(51) 'clinical evidence' means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

(52) 'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

(53) 'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

(54) 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;

(55) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;

(56) 'ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

(57) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;

(58) 'serious adverse event' means any adverse event that led to any of the following:

(a) death,

(b) serious deterioration in the health of the subject, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or prolongation of patient hospitalisation,

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

(v) chronic disease,

(c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

(59) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

(60) 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

(61) 'market surveillance' means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

(62) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

(63) 'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market;

(64) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

(65) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat;

(66) 'serious public health threat' means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

(67) 'corrective action' means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

(68) 'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(69) 'field safety notice' means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

(70) 'harmonised standard' means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;

(71) 'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

Article 3

Amendment of certain definitions

The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of nanomaterial set out in point (18) and the related definitions in points (19), (20) and (21) of Article 2 in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.

Article 4

Regulatory status of products

1. Without prejudice to Article 2(2) of Directive 2001/83/EC, upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of this Regulation ('MDCG'), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3) of this Regulation.

2. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

3. The Commission shall ensure that Member States share expertise in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products.

4. When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), as relevant.

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity,

(b) manufacture and use of the devices occur under appropriate quality management systems,

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(e) the health institution draws up a declaration which it shall make publicly available, including:

  (i) the name and address of the manufacturing health institution;

  (ii) the details necessary to identify the devices;

  (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

(f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

6. In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 6

Distance sales

1. A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.

2. Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.

3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.

4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity.

Article 7

Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Article 8

Use of harmonised standards

1. Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up ('PMCF').

References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the *Official Journal of the European Union*.

2. References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, in particular on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided that references to those monographs have been published in the *Official Journal of the European Union*.

Article 9

Common specifications

1. Without prejudice to Article 1(2) and 17(5) and the deadline laid down in those provisions, where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2. Devices that are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or the relevant parts of those CS.

3. Manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.

4. Notwithstanding paragraph 3, manufacturers of products listed in Annex XVI shall comply with the relevant CS for those products.

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.

4. Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.

5. Manufacturers of custom-made devices shall draw up, keep up to date and keep available for competent authorities documentation in accordance with Section 2 of Annex XIII.

6. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.

7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.

8. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

9. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors;

(e) risk management as set out in in Section 3 of Annex I;

(f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

10. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.

11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

12. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly.

Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.

13. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88.

14. Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until the manufacturer cooperates or provides complete and correct information.

If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights.

The competent authority need not comply with the obligation laid down in the third subparagraph where disclosure of the information and documentation referred to in the first subparagraph is ordinarily dealt with in the context of legal proceedings.

15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).

16. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Article 11

Authorised representative

1. Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

3. The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

(c) comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29;

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

4. The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).

5. Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

6. An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

7. Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.

Article 12

Change of authorised representative

The detailed arrangements for a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement shall address at least the following aspects:

(a) the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative.

Article 13

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. In order to place a device on the market, importers shall verify that:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;

(c) the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

(d) where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.

3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall verify that the device is registered in the electronic system in accordance with Article 29. Importers shall add their details to the registration in accordance with Article 31.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.

6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.

9. Importers shall, for the period referred to in Article 10(8), keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56.

10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

Article 14

General obligations of distributors

1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

Article 15

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.

2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC ([1]) shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

([1]) Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

3. The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the post-market surveillance obligations are complied with in accordance with Article 10(10);

(d) the reporting obligations referred to in Articles 87 to 91 are fulfilled;

(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.

4. If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

5. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Article 16

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (30) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

Article 17

Single-use devices and their reprocessing

1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.

3. By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;

(b) the reprocessing is performed in accordance with CS detailing the requirements concerning:

— risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,

— the validation of procedures for the entire process, including cleaning steps,

— the product release and performance testing,

— the quality management system,

— the reporting of incidents involving devices that have been reprocessed, and

— the traceability of reprocessed devices.

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

4. Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.

5. The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.

6. Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2020 in accordance with Directive 93/42/EEC, may be reprocessed.

7. Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.

8. The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Article 18

Implant card and information to be supplied to the patient with an implanted device

1. The manufacturer of an implantable device shall provide together with the device the following:

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(c) any information about the expected lifetime of the device and any necessary follow-up;

(d) any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device.

2. Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identity.

3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.

Article 19

EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

Article 20

CE marking of conformity

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

Article 21

Devices for special purposes

1. Member States shall not create obstacles to:

(a) investigational devices being supplied to an investigator for the purpose of a clinical investigation if they meet the conditions laid down in Articles 62 to 80 and Article 82, in the implementing acts adopted pursuant to Article 81 and in Annex XV;

(b) custom-made devices being made available on the market if Article 52(8) and Annex XIII have been complied with.

The devices referred to in the first subparagraph shall not bear the CE marking, with the exception of the devices referred to in Article 74.

2. Custom-made devices shall be accompanied by the statement referred to in Section 1 of Annex XIII, which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.

Article 22

Systems and procedure packs

1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

(a) other devices bearing the CE marking;

(b) *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;

(c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

2. In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that:

(a) they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52. The natural or legal person shall assume the obligations incumbent on manufacturers.

5. The systems or procedure packs referred to in paragraph 1 of this Article shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraphs 1 and 3 of this Article as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable under Article 10(8) to the devices that have been combined. Where those periods differ, the longest period shall apply.

Article 23

Parts and components

1. Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

2. An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation.

Article 24

Free movement

Except where otherwise provided for in this Regulation, Member States shall not refuse, prohibit or restrict the making available on the market or putting into service within their territory of devices which comply with the requirements of this Regulation.

CHAPTER III

IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

Article 25

Identification within the supply chain

1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8):

(a) any economic operator to whom they have directly supplied a device;

(b) any economic operator who has directly supplied them with a device;

(c) any health institution or healthcare professional to which they have directly supplied a device.

Article 26

Medical devices nomenclature

To facilitate the functioning of the European database on medical devices ('Eudamed') as referred to in Article 33, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Article 27

Unique Device Identification system

1. The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices, and shall consist of the following:

(a) production of a UDI that comprises the following:

(i) a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex VI;

(ii) a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

(b) placing of the UDI on the label of the device or on its packaging;

(c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs 8 and 9 of this Article respectively;

(d) establishment of an electronic system for Unique Device Identification ('UDI database') in accordance with Article 28.

2. The Commission shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation ('issuing entity'). That entity or those entities shall satisfy all of the following criteria:

(a) the entity is an organisation with legal personality;

(b) its system for the assignment of UDIs is adequate to identify a device throughout its distribution and use in accordance with the requirements of this Regulation;

(c) its system for the assignment of UDIs conforms to the relevant international standards;

(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;

(e) the entity undertakes to do the following:

(i) operate its system for the assignment of UDIs for at least 10 years after its designation;

(ii) make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

(iii) remain in compliance with the criteria for designation and the terms of designation.

When designating issuing entities, the Commission shall endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are universally readable regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators and health institutions.

3. Before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.

Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer shall ensure that the information referred to in Part B of Annex VI of the device in question are correctly submitted and transferred to the UDI database referred to in Article 28.

4. UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.

5. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.

6. The Basic UDI-DI, as defined in Part C of Annex VI, of the device shall appear on the EU declaration of conformity referred to in Article 19.

7. As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

8. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to:

— class III implantable devices;

— the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.

9. Health institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices.

For devices other than class III implantable devices, Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

Member States shall encourage, and may require, healthcare professionals to store and keep preferably by electronic means, the UDI of the devices with which they have been supplied with.

10. The Commission is empowered to adopt delegated acts in accordance with Article 115:

(a) amending the list of information set out in Part B of Annex VI in the light of technical progress; and

(b) amending Annex VI in the light of international developments and technical progress in the field of Unique Device Identification.

11. The Commission may, by means of implementing acts, specify the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application in relation to any of the following:

(a) determining the devices, categories or groups of devices to which the obligation laid down in paragraph 8 is to apply;

(b) specifying the data to be included in the UDI-PI of specific devices or device groups;

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

12. When adopting the measures referred to in paragraph 11, the Commission shall take into account all of the following:

(a) confidentiality and data protection as referred to in Articles 109 and 110 respectively;

(b) the risk-based approach;

(c) the cost-effectiveness of the measures;

(d) the convergence of UDI systems developed at international level;

(e) the need to avoid duplications in the UDI system;

(f) the needs of the healthcare systems of the Member States, and where possible, compatibility with other medical device identification systems that are used by stakeholders.

Article 28

UDI database

1. The Commission, after consulting the MDCG shall set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Annex VI.

2. When designing the UDI database, the Commission shall take into account the general principles set out in Section 5 of Part C of Annex VI. The UDI database shall be designed in particular such that no UDI-PIs and no commercially confidential product information can be included therein.

3. The core data elements to be provided to the UDI database, referred to in Part B of Annex VI, shall be accessible to the public free of charge.

4. The technical design of the UDI database shall ensure maximum accessibility to information stored therein, including multi-user access and automatic uploads and downloads of that information. The Commission shall provide for technical and administrative support to manufacturers and other users of the UDI database.

Article 29

Registration of devices

1. Before placing a device, other than a custom-made device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 27(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

2. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), that is not a custom-made device, the natural or legal person responsible shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack.

3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in the second and third subparagraphs of Article 52(4), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.

For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Chapter I of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

4. Before placing a device on the market, other than a custom-made device, the manufacturer shall enter or if, already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and shall thereafter keep the information updated.

Article 30

Electronic system for registration of economic operators

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI.

2. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory.

3. Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1.

Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.

Article 31

Registration of manufacturers, authorised representatives and importers

1. Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. After having verified the data entered pursuant to paragraph 1, the competent authority shall obtain a single registration number ('SRN') from the electronic system referred to in Article 30 and issue it to the manufacturer, the authorised representative or the importer.

3. The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 29.

4. Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 30.

5. Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation.

6. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex VI.

7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 shall be accessible to the public.

8. The competent authority may use the data to charge the manufacturer, the authorised representative or the importer a fee pursuant to Article 111.

Article 32

Summary of safety and clinical performance

1. For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and clinical performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contraindications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) possible diagnostic or therapeutic alternatives;

(e) reference to any harmonised standards and CS applied;

(f) the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

Article 33

European database on medical devices

1. The Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes:

(a) to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators;

(b) to enable unique identification of devices within the internal market and to facilitate their traceability;

(c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81;

(d) to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91;

(e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following electronic systems:

(a) the electronic system for registration of devices referred to in Article 29(4);

(b) the UDI-database referred to in Article 28;

(c) the electronic system on registration of economic operators referred to in Article 30;

(d) the electronic system on notified bodies and on certificates referred to in Article 57;

(e) the electronic system on clinical investigations referred to in Article 73;

(f) the electronic system on vigilance and post-market surveillance referred to in Article 92;

(g) the electronic system on market surveillance referred to in Article 100.

3. When designing Eudamed the Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.

4. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed.

5. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified in the provisions on the electronic systems referred to in paragraph 2.

The Commission shall ensure that public parts of Eudamed are presented in a user-friendly and easily-searchable format.

6. Eudamed shall contain personal data only insofar as necessary for the electronic systems referred to in paragraph 2 of this Article to collate and process information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).

7. The Commission and the Member States shall ensure that data subjects may effectively exercise their rights to information, of access, to rectification and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall also ensure that data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days after a request is made by a data subject.

8. The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). When adopting those implementing acts, the Commission shall ensure that, as far as possible, the system is developed in such a way as to avoid having to enter the same information twice within the same module or in different modules of the system.

9. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered to be the controller of Eudamed and its electronic systems.

Article 34

Functionality of Eudamed

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met.

2. The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that Eudamed has achieved full functionality and Eudamed meets the functional specifications drawn up pursuant to paragraph 1.

3. The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the *Official Journal of the European Union*.

CHAPTER IV

NOTIFIED BODIES

Article 35

Authorities responsible for notified bodies

1. Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority ('authority responsible for notified bodies'), which may consist of separate constituent entities under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

2. The authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

3. The authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.

4. The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

5. The authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on notified bodies with other Member States, the Commission and, when required, with other regulatory authorities.

6. The authority responsible for notified bodies shall have a sufficient number of competent personnel permanently available for the proper performance of its tasks.

Where the authority responsible for notified bodies is a different authority from the national competent authority for medical devices, it shall ensure that the national authority responsible for medical devices is consulted on relevant matters.

7. Member States shall make publicly available general information on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

8. The authority responsible for notified bodies shall participate in the peer-review activities provided for in Article 48.

Article 36

Requirements relating to notified bodies

1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil those tasks. In particular, notified bodies shall comply with Annex VII.

In order to meet the requirements referred to in the first subparagraph, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.

The personnel referred to in Sections 3.2.3 and 3.2.7 of Annex VII shall be employed by the notified body itself and shall not be external experts or subcontractors.

2. Notified bodies shall make available and submit upon request all relevant documentation, including the manufacturer's documentation, to the authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.

3. In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 37

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VII and shall inform the authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Notified bodies shall make publicly available a list of their subsidiaries.

4. Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

5. Notified bodies shall keep at the disposal of the authority responsible for notified bodies all relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 38

Application by conformity assessment bodies for designation

1. Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies.

2. The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body is applying to be designated, and shall be supported by documentation demonstrating compliance with Annex VII.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 39. However, the applicant shall make available all the documentation referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

3. The notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VII.

Article 39

Assessment of the application

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete that authority shall send it to the Commission.

The authority responsible for notified bodies shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2. The authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the MDCG.

3. Within 14 days of the submission referred to in paragraph 2 of this Article, the Commission, in conjunction with the MDCG, shall appoint a joint assessment team made up of three experts, unless the specific circumstances require a different number of experts, chosen from the list referred to in Article 40(2). One of the experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from Member States other than the one in which the applicant conformity assessment body is established.

The joint assessment team shall be comprised of experts who are competent to assess the conformity assessment activities and the types of devices which are the subject of the application or, in particular when the assessment procedure is initiated in accordance with Article 47(3), to ensure that the specific concern can be appropriately assessed.

4. Within 90 days of its appointment, the joint assessment team shall review the documentation submitted with the application in accordance with Article 38. The joint assessment team may provide feedback to, or require clarification from, the authority responsible for notified bodies on the application and on the planned on-site assessment.

The authority responsible for notified bodies together with the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process.

The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

5. Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VII shall be raised during the assessment process and discussed between the authority responsible for notified bodies and the joint assessment team with a view to reaching consensus and resolving any diverging opinions, with respect to the assessment of the application.

At the end of the on-site assessment, the authority responsible for notified bodies shall list for the applicant conformity assessment body the non-compliances resulting from the assessment and summarise the assessment by the joint assessment team.

Within a specified timeframe, the applicant conformity assessment body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

6. The joint assessment team shall document any remaining diverging opinions with respect to the assessment within 30 days of completion of the on-site assessment and send them to the authority responsible for notified bodies.

7. The authority responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

The authority responsible for notified bodies shall having confirmed the corrective and preventive action plan forward it and its opinion thereon to the joint assessment team. The joint assessment team may request of the authority responsible for notified bodies further clarification and modifications.

The authority responsible for notified bodies shall draw up its final assessment report which shall include:

— the result of the assessment,

— confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,

— any remaining diverging opinion with the joint assessment team, and, where applicable,

— the recommended scope of designation.

8. The authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.

9. The joint assessment team shall provide a final opinion regarding the assessment report prepared by the authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission, which shall immediately submit that final opinion to the MDCG. Within 42 days of receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation, which the authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.

10. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements specifying procedures and reports for the application for designation referred to in Article 38 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 40

Nomination of experts for joint assessment of applications for notification

1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the activities referred to in Articles 39 and 48.

2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 57.

Article 41

Language requirements

All documents required pursuant to Articles 38 and 39 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

Member States, in applying the first paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documentation concerned.

The Commission shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 39(3).

Article 42

Designation and notification procedure

1. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 39 was completed and which comply with Annex VII.

2. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).

3. The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation and the types of devices which the notified body is authorised to assess and, without prejudice to Article 44, any conditions associated with the designation.

4. The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 39(9) and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

5. The notifying Member State shall, without prejudice to Article 44, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VII.

6. Within 28 days of the notification referred to in paragraph 2, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.

7. When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.

8. Where the MDCG, after having been consulted in accordance with paragraph 7, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.

9. Where the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.

10. When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and responses referred to in paragraphs 7 and 8 of this Article.

11. The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

12. The conformity assessment body concerned may perform the activities of a notified body only after the designation has become valid in accordance with paragraph 11.

13. The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission, after consulting the MDCG, may update this list based, *inter alia*, on information arising from the coordination activities described in Article 48.

Article 43

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 42(11). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this Regulation, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them pursuant to those Directives.

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in NANDO. It shall also make this list available on the electronic system referred to in Article 57. The Commission shall ensure that the list is kept up to date.

Article 44

Monitoring and re-assessment of notified bodies

1. Notified bodies shall, without delay, and at the latest within 15 days, inform the authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VII or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

2. The authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance.

3. Where the Commission or the authority of a Member State submits a request to a notified body established on the territory of another Member State relating to a conformity assessment carried out by that notified body, it shall send a copy of that request to the authority responsible for notified bodies of that other Member State. The notified body concerned shall respond without delay and within 15 days at the latest to the request. The authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved by the notified body unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.

4. At least once a year, the authorities responsible for notified bodies shall re-assess whether the notified bodies established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in Annex VII. That review shall include an on-site audit of each notified body and, where necessary, of its subsidiaries and subcontractors.

The authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. That plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.

5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel is in the process of conducting quality management system assessments at a manufacturer's facility.

6. The monitoring of notified bodies conducted by the authority responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance to help guide its activities.

The authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

7. The authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.

8. The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the clinical evaluation documentation as further outlined in Article 45.

9. The authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VII and shall monitor the timely implementation of corrective and preventive actions.

10. Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team appointed for the purpose of the procedure described in Articles 38 and 39.

11. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend paragraph 10 to modify the frequency at which the complete re-assessment referred to in that paragraph is to be carried out.

12. The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring and on-site assessment activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. The report shall provide details of the outcome of those activities, including activities pursuant to paragraph 7, and shall be treated as confidential by the MDCG and the Commission; however it shall contain a summary which shall be made publicly available.

The summary of the report shall be uploaded to the electronic system referred to in Article 57.

Article 45

Review of notified body assessment of technical documentation and clinical evaluation documentation

1. The authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies, shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the clinical evaluation documentation as referred to in points (c) and (d) of Section 6.1 of Annex II to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. The reviews by the authority responsible for notified bodies shall be conducted both off-site and on-site.

2. The sampling of files to be reviewed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body, in particular high-risk devices, and be appropriately justified and documented in a sampling plan, which shall be made available by the authority responsible for notified bodies to the MDCG upon request.

3. The authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment. Such reviews shall be conducted utilising CS.

4. Those reviews shall also form part of the re-assessment of notified bodies in accordance with Article 44(10) and the joint assessment activities referred to in Article 47(3). The reviews shall be conducted utilising appropriate expertise.

5. Based on the reports of the reviews and assessments by the authority responsible for notified bodies or joint assessment teams, on input from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, on the continuous monitoring of technical progress, or on the identification of concerns and emerging issues concerning the safety and performance of devices, the MDCG may recommend that the sampling, carried out under this Article, cover a greater or lesser proportion of the technical documentation and clinical evaluation documentation assessed by a notified body.

6. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation and clinical evaluation documentation, as referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 46

Changes to designations and notifications

1. The authority responsible for notified bodies shall notify the Commission and the other Member States of any relevant changes to the designation of a notified body.

The procedures described in Article 39 and in Article 42 shall apply to extensions of the scope of the designation.

For changes to the designation other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.

2. The Commission shall immediately publish the amended notification in NANDO. The Commission shall immediately enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.

3. Where a notified body decides to cease its conformity assessment activities it shall inform the authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates. The new notified body shall complete a full assessment of the devices affected by the end of that period before issuing new certificates for those devices. Where the notified body has ceased its activity, the authority responsible for notified bodies shall withdraw the designation.

4. Where a authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VII, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.

The authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a designation.

5. Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.

6. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to authorities in other Member States responsible for notified bodies and to authorities responsible for market surveillance at their request.

7. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:

(a) assess the impact on the certificates issued by the notified body;

(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;

(d) enter into the electronic system referred to in Article 57 information in relation to certificates of which it has required their suspension or withdrawal;

(e) inform the competent authority for medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 57 of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

8. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

(a) the authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction, and the authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction; or

(b) the authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide, to the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

9. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:

(a) where the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business has confirmed that there is no safety issue associated with the devices in question; and

(b) another notified body has confirmed in writing that it will assume immediate responsibilities for those devices and will have completed assessment of them within twelve months of the withdrawal of the designation.

In the circumstances referred to in the first subparagraph, the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.

The authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Article 47

Challenge to the competence of notified bodies

1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VII or the obligations to which they are subject. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the designation of the notified body concerned.

3. The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment procedure described in Article 39(3) and (4), where there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VII and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 39. Alternatively, depending on the severity of the issue, the Commission, in conjunction with the MDCG, may request that the authority responsible for notified bodies allow the participation of up to two experts from the list established pursuant to Article 40 in an on-site assessment as part of the planned monitoring and assessment activities in accordance with Article 44 and as outlined in the annual assessment plan described in Article 44(4).

4. Where the Commission ascertains that a notified body no longer meets the requirements for its designation, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). It shall notify the Member State concerned of its decision and update NANDO and the electronic system referred to in Article 57.

5. The Commission shall ensure that all confidential information obtained in the course of its investigations is treated accordingly.

Article 48

Peer review and exchange of experience between authorities responsible for notified bodies

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the authorities responsible for notified bodies. Such exchange shall cover elements including:

(a) development of best practice documents relating to the activities of the authorities responsible for notified bodies;

(b) development of guidance documents for notified bodies in relation to the implementation of this Regulation;

(c) training and qualification of the experts referred to in Article 40;

(d) monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;

(e) monitoring of the application and applicability of scope codes referred to in Article 42(13);

(f) development of a mechanism for peer reviews between authorities and the Commission;

(g) methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies.

2. The authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to paragraph 1 of this Article. Such reviews shall normally be conducted in parallel with the on-site joint assessments described in Article 39. Alternatively, an authority may make the choice of having such reviews take place as part of its monitoring activities referred to in Article 44.

3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.

4. The Commission shall compile an annual summary report of the peer review activities, which shall be made publicly available.

5. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements and related documents for the peer review mechanism and training and qualification as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 49

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices. This group shall meet on a regular basis and at least annually.

The bodies notified under this Regulation shall participate in the work of that group.

The Commission may establish the specific arrangements for the functioning of the coordination group of notified bodies.

Article 50

List of standard fees

Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available.

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

SECTION 1

Classification

Article 51

Classification of devices

1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2 of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3. At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

5. In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).

SECTION 2

Conformity assessment

Article 52

Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2. Prior to putting into service a device that is not placed on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

3. Manufacturers of class III devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.

5. Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the second subparagraph of paragraph 4 of this Article, being used in other class IIb implantable devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend that list by adding other types of class IIb implantable devices to that list or removing devices therefrom.

6. Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices.

Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.

7. Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited:

(a) in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;

(b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;

(c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

8. Manufacturers of custom-made devices shall follow the procedure set out in Annex XIII and draw up the statement set out in Section 1 of that Annex before placing such devices on the market.

In addition to the procedure applicable pursuant to the first subparagraph, manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment as specified in Chapter I of Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Part A of Annex XI.

9. In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices referred to in the first subparagraph of Article 1(8), the procedure specified in Section 5.2 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

10. In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices that are covered by this Regulation in accordance with point (f) or (g) of Article 1(6) and with the first subparagraph of Article 1(10), the procedure specified in Section 5.3 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

11. In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7, in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the procedure specified in Section 5.4 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

12. The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 7 and 9 to 11 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13. Investigational devices shall be subject to the requirements set out in Articles 62 to 81.

14. The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

(a) the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in the third paragraph of Section 2.3 and in Section 3.5 of Annex IX in the case of class IIa and class IIb devices, and in Section 10.2 of Annex XI in the case of class IIa devices;

(b) the minimum frequency of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX, Section 3 of Annex X and Section 15 of Annex XI.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 53

Involvement of notified bodies in conformity assessment procedures

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2. The notified body concerned shall, by means of the electronic system referred to in Article 57, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3. When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4. The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 54

Clinical evaluation consultation procedure for certain class III and class IIb devices

1. In addition to the procedures applicable pursuant to Article 52, a notified body shall also follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of the following devices:

(a) class III implantable devices, and

(b) class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12).

2. The procedure referred to in paragraph 1 shall not be required for the devices referred to therein:

(a) in the case of renewal of a certificate issued under this Regulation;

(b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device; or

(c) where the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device.

3. The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report.

4. The Commission shall draw up an annual overview of devices which have been subject to the procedure specified in Section 5.1 of Annex IX and referred to in Section 6 of Annex X. The annual overview shall include the notifications in accordance with paragraph 3 of this Article and point (e) of Section 5.1 of Annex IX and a listing of the cases where the notified body did not follow the advice from the expert panel. The Commission shall submit this overview to the European Parliament, to the Council and to the MDCG.

5. The Commission shall by 27 May 2025 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. The report shall take into account the annual overviews and any available relevant recommendations from the MDCG. On the basis of that report the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Article 55

Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

1. A notified body shall notify the competent authorities of certificates it has granted to devices for which the conformity assessment has been performed pursuant to Article 54(1). Such notification shall take place through the electronic system referred to in Article 57 and shall include the summary of safety and clinical performance pursuant to Article 32, the assessment report by the notified body, the instructions for use referred to in Section 23.4 of Annex I, and, where applicable, the scientific opinion of the expert panels referred to in Section 5.1 of Annex IX or Section 6 of Annex X, as applicable. In the case of divergent views between the notified body and the expert panels, a full justification shall also be included.

2. A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 44, 45, 46, 47 or 94 and, where deemed necessary, take appropriate measures in accordance with Articles 95 and 97.

3. The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.

Article 56

Certificates of conformity

1. The certificates issued by the notified bodies in accordance with Annexes IX, X and XI shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates shall be as set out in Annex XII.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMCF studies pursuant to Part B of Annex XIV.

4. Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

5. The notified body shall enter in the electronic system referred to in Article 57 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public.

6. In the light of technical progress, the Commission is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the certificates set out in Annex XII.

Article 57

Electronic system on notified bodies and on certificates of conformity

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to collate and process the following information:

(a) the list of subsidiaries referred to in Article 37(3);

(b) the list of experts referred to in Article 40(2);

(c) the information relating to the notification referred to in Article 42(10) and the amended notifications referred to in Article 46(2);

(d) the list of notified bodies referred to in Article 43(2);

(e) the summary of the report referred to in Article 44(12);

(f) the notifications for conformity assessments and certificates referred to in Articles 54(3) and 55(1);

(g) withdrawal or refusals of applications for the certificates as referred to in Article 53(2) and Section 4.3 of Annex VII;

(h) the information regarding certificates referred to in Article 56(5);

(i) the summary of safety and clinical performance referred to in Article 32.

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, where appropriate to the notified bodies and where provided elsewhere in this regulation or in Regulation (EU) 2017/746 to the public.

Article 58

Voluntary change of notified body

1. In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. That agreement shall cover at least the following aspects:

(a) the date on which the certificates issued by the outgoing notified body become invalid;

(b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body;

(e) the last serial number or lot number for which the outgoing notified body is responsible.

2. The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid.

Article 59

Derogation from the conformity assessment procedures

1. By way of derogation from Article 52, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

Article 60

Certificate of free sale

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 29. Where a notified body has issued a certificate pursuant to Article 56, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

CHAPTER VI

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Article 61

Clinical evaluation

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and Part A of Annex XIV.

2. For all class III devices and for the class IIb devices referred to in point (b) of Article 54(1), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report referred to in paragraph 12 of this Article.

The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure.

3. A clinical evaluation shall follow a defined and methodologically sound procedure based on the following:

(a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied:

— it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with Section 3 of Annex XIV, and

— the data adequately demonstrate compliance with the relevant general safety and performance requirements;

(b) a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under Articles 62 to 80, any acts adopted pursuant to Article 81, and Annex XV; and

(c) a consideration of currently available alternative treatment options for that purpose, if any.

4. In the case of implantable devices and class III devices, clinical investigations shall be performed, except if:

— the device has been designed by modifications of a device already marketed by the same manufacturer,

— the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and

— the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

In this case, the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

In addition, clinical investigations need not be performed in the cases referred to in paragraph 6.

5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

— the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and

— the original clinical evaluation has been performed in compliance with the requirements of this Regulation,

and the manufacturer of the second device provides clear evidence thereof to the notified body.

6. The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

(a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation:

— is based on sufficient clinical data, and

— is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or

(b) that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

7. Cases in which paragraph 4 is not applied by virtue of paragraph 6 shall be justified in the clinical evaluation report by the manufacturer and in the clinical evaluation assessment report by the notified body.

8. Where justified in view of well-established technologies, similar to those used in the exempted devices listed in point (b) of paragraph 6 of this Article, being used in other devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list of exempted devices referred to in the second subparagraph of Article 52(4) and in point (b) of paragraph 6 of this Article, by adding other types of implantable or class III devices to that list or removing devices therefrom.

9. In the case of the products without an intended medical purpose listed in Annex XVI, the requirement to demonstrate a clinical benefit in accordance with this Chapter and Annexes XIV and XV shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and, where applicable, specific clinical investigation. Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified.

10. Without prejudice to paragraph 4, where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

11. The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84.

For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.

12. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

13. Where necessary to ensure the uniform application of Annex XIV, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 62

General requirements regarding clinical investigations conducted to demonstrate conformity of devices

1. Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of this Article and of Articles 63 to 80, the acts adopted pursuant to Article 81, and Annex XV, where carried out as part of the clinical evaluation for conformity assessment purposes, for one or more of the following purposes:

(a) to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2, and achieves the performance intended as specified by its manufacturer;

(b) to establish and verify the clinical benefits of a device as specified by its manufacturer;

(c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

2. Where the sponsor of a clinical investigation is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication with that legal representative shall be deemed to be a communication with the sponsor.

Member States may choose not to apply the first subparagraph to clinical investigations to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical investigation who shall be the addressee for all communications with the sponsor provided for in this Regulation.

3. Clinical investigations shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests and the clinical data generated are scientifically valid, reliable and robust.

Clinical investigations shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with national law. Member States shall ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a clinical investigation. At least one lay person shall participate in the ethical review.

4. A clinical investigation as referred to in paragraph 1 may be conducted only where all of the following conditions are met:

(a) the clinical investigation is the subject of an authorisation by the Member State(s) in which the clinical investigation is to be conducted, in accordance with this Regulation, unless otherwise stated;

(b) an ethics committee, set up in accordance with national law, has not issued a negative opinion in relation to the clinical investigation, which is valid for that entire Member State under its national law;

(c) the sponsor, or its legal representative or a contact person pursuant to paragraph 2, is established in the Union;

(d) vulnerable populations and subjects are appropriately protected in accordance with Articles 64 to 68;

(e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;

(f) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent in accordance with Article 63;

(g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

(h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;

(i) the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the clinical investigation plan and constantly monitored;

(j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner or any other person entitled by national law to provide the relevant patient care under clinical investigation conditions;

(k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the clinical investigation;

(l) the investigational device(s) in question conform(s) to the applicable general safety and performance requirements set out in Annex I apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;

(m) the requirements of Annex XV are fulfilled.

5. Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

6. The investigator shall be a person exercising a profession which is recognised in the Member State concerned as qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care. Other personnel involved in conducting a clinical investigation shall be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

7. The facilities where the clinical investigation is to be conducted shall be suitable for the clinical investigation and shall be similar to the facilities where the device is intended to be used.

Article 63

Informed consent

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document or the record, as appropriate, by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the clinical investigation.

2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:

(a) enable the subject or his or her legally designated representative to understand:

(i) the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigations;

(ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate in and the right to withdraw from the clinical investigation at any time without any resulting detriment and without having to provide any justification;

(iii) the conditions under which the clinical investigations is to be conducted, including the expected duration of the subject's participation in the clinical investigation; and

(iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical investigation is discontinued;

(b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified under national law;

(d) include information about the applicable damage compensation system referred to in Article 69; and

(e) include the Union-wide unique single identification number of the clinical investigation referred to in Article 70(1) and information about the availability of the clinical investigation results in accordance with paragraph 6 of this Article.

3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.

4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.

5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.

6. The subject shall be informed that a clinical investigation report and a summary presented in terms understandable to the intended user will be made available pursuant to Article 77(5) in the electronic system on clinical investigations referred to in Article 73 irrespective of the outcome of the clinical investigation, and shall be informed, to the extent possible, when they have become available.

7. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical investigation.

Article 64

Clinical investigations on incapacitated subjects

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical investigation may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the incapacitated subjects have received the information referred to in Article 63(2) in a way that is adequate in view of their capacity to understand it;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 63(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) the clinical investigation is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical investigations on persons able to give informed consent, or by other research methods;

(f) the clinical investigation relates directly to a medical condition from which the subject suffers;

(g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the incapacitated subject outweighing the risks and burdens involved.

2. The subject shall as far as possible take part in the informed consent procedure.

Article 65

Clinical investigations on minors

A clinical investigation on minors may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the minors have received the information referred to in Article 63(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 63(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) the clinical investigation is intended to investigate treatments for a medical condition that only occurs in minors or the clinical investigation is essential with respect to minors to validate data obtained in clinical investigations on persons able to give informed consent or by other research methods;

(f) the clinical investigation either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

(g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the minor subject outweighing the risks and burdens involved;

(h) the minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;

(i) if during a clinical investigation the minor reaches the age of legal competence to give informed consent as defined in national law, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical investigation.

Article 66

Clinical investigations on pregnant or breastfeeding women

A clinical investigation on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;

(b) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

(c) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.

Article 67

Additional national measures

Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in clinical investigations, or persons in residential care institutions.

Article 68

Clinical investigations in emergency situations

1. By way of derogation from point (f) of Article 62(4), from points (a) and (b) of Article 64(1) and from points (a) and (b) of Article 65, informed consent to participate in a clinical investigation may be obtained, and information on the clinical investigation may be given, after the decision to include the subject in the clinical investigation, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical investigation plan for that clinical investigation and that all of the following conditions are fulfilled:

(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical investigation;

(b) there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;

(d) the investigator certifies that he or she is not aware of any objections to participate in the clinical investigation previously expressed by the subject;

(e) the clinical investigation relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical investigation is of such a nature that it may be conducted exclusively in emergency situations;

(f) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. Following an intervention pursuant to paragraph 1 of this Article, informed consent in accordance with Article 63 shall be sought to continue the participation of the subject in the clinical investigation, and information on the clinical investigation shall be given, in accordance with the following requirements:

(a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 63(2) shall be given as soon as possible to the subject and to his or her legally designated representative;

(b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever can be done sooner, and the information referred to in Article 63(2) shall be given as soon as possible to the subject or his or her legally designated representative, as applicable.

For the purposes of point (b) where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical investigation shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the clinical investigation.

Article 69

Damage compensation

1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State in which the clinical investigation is conducted.

Article 70

Application for clinical investigations

1. The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the clinical investigation is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Chapter II of Annex XV.

The application shall be submitted by means of the electronic system referred to in Article 73, which shall generate a Union-wide unique single identification number for the clinical investigation, which shall be used for all relevant communication in relation to that clinical investigation. Within 10 days of it receiving the application, the Member State concerned shall notify the sponsor as to whether the clinical investigation falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter II of Annex XV.

2. Within one week of any change occurring in relation to the documentation referred to in Chapter II of Annex XV, the sponsor shall update the relevant data in the electronic system referred to in Article 73 and make that change to the documentation clearly identifiable. The Member State concerned shall be notified of the update by means of that electronic system.

3. Where the Member State concerned finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application dossier is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete the application by means of the electronic system referred to in Article 73. The Member State concerned may extend this period by a maximum of 20 days where appropriate.

Where the sponsor has not provided comments nor completed the application within the time limit referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers the application does fall under the scope of this Regulation and/or is complete but the Member State concerned does not, the application shall be considered to have been rejected. The Member State concerned shall provide for an appeal procedure in respect of such refusal.

The Member State concerned shall notify the sponsor within five days of receipt of the comments or of the requested additional information, whether the clinical investigation is considered as falling within the scope of this Regulation and the application is complete.

4. The Member State concerned may also extend the period referred to in paragraph 1 and 3 each by a further five days.

5. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the periods referred to in paragraphs 1, 3 and 4 respectively.

6. During the period when the application is being assessed, the Member State may request additional information from the sponsor. The expiry of the period laid down in point (b) of paragraph 7 shall be suspended from the date of the first request until such time as the additional information has been received.

7. The sponsor may start the clinical investigation in the following circumstances:

(a) in the case of investigational class I devices or in the case of non-invasive class IIa and class IIb devices, unless otherwise stated by national law, immediately after the validation date of the application pursuant to paragraph 5, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation;

(b) in the case of investigational devices, other than those referred to in point (a), as soon as the Member State concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.

8. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress and global regulatory developments, the requirements laid down in Chapter II of Annex XV.

9. In order to ensure the uniform application of the requirements laid down in Chapter II of Annex XV, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 71

Assessment by Member States

1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of natural or legal persons financing the clinical investigation, as well as free of any other undue influence.

2. Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.

3. Member States shall assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall, while taking into account applicable CS or harmonised standards, examine in particular:

(a) the demonstration of compliance of the investigational device(s) with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;

(b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by harmonised standards;

(c) whether the measures planned for the safe installation, putting into service and maintenance of the investigational device are adequate;

(d) the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects, including sample size, comparator and endpoints;

(e) whether the requirements of Annex XV are met;

(f) in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which have to be conducted by the investigation site;

(g) the demonstration of the safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products in accordance with Directive 2001/83/EC.

4. Member States shall refuse the authorisation of the clinical investigation if:

(a) the application dossier submitted pursuant to Article 70(1) remains incomplete;

(b) the device or the submitted documents, especially the investigation plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients,

(c) the requirements of Article 62 are not met, or

(d) any assessment under paragraph 3 is negative.

Member States shall provide for an appeal procedure in respect of a refusal pursuant to the first subparagraph.

Article 72

Conduct of a clinical investigation

1. The sponsor and the investigator shall ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.

2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical investigation is in compliance with the requirements of this Regulation, the sponsor shall ensure adequate monitoring of the conduct of a clinical investigation. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the clinical investigation including the following:

(a) the objective and methodology of the clinical investigation; and

(b) the degree of deviation of the intervention from normal clinical practice.

3. All clinical investigation information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

5. Member States shall inspect, at an appropriate level, investigation site(s) to check that clinical investigations are conducted in accordance with the requirements of this Regulation and with the approved investigation plan.

6. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

Article 73

Electronic system on clinical investigations

1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:

(a) to create the single identification numbers for clinical investigations referred to in Article 70(1);

(b) to be used as an entry point for the submission of all applications or notifications for clinical investigations referred to in Articles 70, 74, 75 and 78 and for all other submission of data, or processing of data in this context;

(c) for the exchange of information relating to clinical investigations in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in Articles 70 and 76;

(d) for information to be provided by the sponsor in accordance with Article 77, including the clinical investigation report and its summary as required in paragraph 5 of that Article;

(e) for reporting on serious adverse events and device deficiencies and related updates referred to in Article 80.

2. When setting up the electronic system referred in paragraph 1 of this Article, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council ([1]) as concerns combined clinical investigations of devices with a clinical trial under that Regulation.

3. The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

(a) protection of personal data in accordance with Regulation (EC) No 45/2001;

(b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;

(c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.

4. No personal data of subjects shall be publicly available.

5. The user interface of the electronic system referred to in paragraph 1 shall be available in all official languages of the Union.

([1]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Article 74

Clinical investigations regarding devices bearing the CE marking

1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), ('PMCF investigation'), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II of Annex XV as part of the notification. Points (b) to (k) and (m) of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions of Annex XV shall apply to PMCF investigations.

2. Where a clinical investigation is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), Articles 62 to 81 shall apply.

Article 75

Substantial modifications to clinical investigations

1. If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, it shall notify, within one week, by means of the electronic system referred to in Article 73 the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Chapter II of Annex XV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. The Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.

3. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after the notification referred to in that paragraph, unless:

(a) the Member State in which the clinical investigation is being or is to be conducted has notified the sponsor of its refusal based on the grounds referred to in Article 71(4) or on considerations of public health, subject and user safety or health, of public policy, or

(b) an ethics committee in that Member State has issued a negative opinion in relation to the substantial modification to the clinical investigation, which, in accordance with national law, is valid for that entire Member State.

4. The Member State(s) concerned may extend the period referred to in paragraph 3 by a further seven days, for the purpose of consulting with experts.

Article 76

Corrective measures to be taken by Member States and information exchange between Member States

1. Where a Member State in which a clinical investigation is being or is to be conducted has grounds for considering that the requirements set out in this Regulation are not met, it may take at least any of the following measures on its territory:

(a) revoke the authorisation for the clinical investigation;

(b) suspend or terminate the clinical investigation;

(c) require the sponsor to modify any aspect of the clinical investigation.

2. Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor or the investigator or both for their opinion. That opinion shall be delivered within seven days.

3. Where a Member State has taken a measure referred to in paragraph 1 of this Article or has refused a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 73.

4. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 73 to all Member States and the Commission.

Article 77

Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

1. If the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, it shall inform within 15 days the Member State in which that clinical investigation has been temporarily halted or terminated early, through the electronic system referred to in Article 73, of the temporary halt or early termination, providing a justification. In the event that the sponsor has temporarily halted or terminated early the clinical investigation on safety grounds, it shall inform all Member States in which that clinical investigation is being conducted thereof within 24 hours.

2. The end of a clinical investigation shall be deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the clinical investigation plan.

3. The sponsor shall notify each Member State in which a clinical investigation was being conducted of the end of that clinical investigation in that Member State. That notification shall be made within 15 days of the end of the clinical investigation in relation to that Member State.

4. If an investigation is conducted in more than one Member State, the sponsor shall notify all Member States in which that clinical investigation was conducted of the end of the clinical investigation in all Member States. That notification shall be made within 15 days of that end of the clinical investigation.

5. Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV.

The clinical investigation report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 73.

Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be submitted as soon as it is available. In such case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV shall specify when the results of the clinical investigation are going to be available, together with a justification.

6. The Commission shall issue guidelines regarding the content and structure of the summary of the clinical investigation report.

In addition, the Commission may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of clinical investigations.

7. The summary and the clinical investigation report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 73, at the latest when the device is registered in accordance with Article 29 and before it is placed on the market. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission.

If the device is not registered in accordance with Article 29 within one year of the summary and the report having been entered into the electronic system pursuant to paragraph 5 of this Article, they shall become publicly accessible at that point in time.

Article 78

Coordinated assessment procedure for clinical investigations

1. By means of the electronic system referred to in Article 73, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 70, a single application that, upon receipt, is transmitted electronically to all Member States in which the clinical investigation is to be conducted.

2. The sponsor shall propose in the single application referred to in paragraph 1 that one of the Member States in which the clinical investigation is to be conducted acts as coordinating Member State. The Member States in which the clinical investigation is to be conducted shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the coordinating Member State proposed by the sponsor shall assume that role.

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation referred to in Chapter II of Annex XV.

However, the completeness of the documentation referred to in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV shall be assessed separately by each Member State concerned in accordance with Article 70(1) to (5).

4. With regard to documentation other than that referred to in the second subparagraph of paragraph 3, the coordinating Member State shall:

(a) within six days of receipt of the single application, notify the sponsor that it is the coordinating Member State ('notification date');

(b) for the purpose of the validation of the application, take into account any considerations submitted within seven days of the notification date by any Member State concerned;

(c) within 10 days of the notification date, assess whether the clinical investigation falls within the scope of this Regulation and whether the application is complete, and shall notify the sponsor accordingly. Article 70(1) and (3) to (5) shall apply to the coordinating Member State in relation to that assessment;

(d) establish the results of its assessment in a draft assessment report to be transmitted within 26 days of the validation date to the Member States concerned. By day 38 after the validation date, the other Member States concerned shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State which shall take due account of those comments and proposals in its finalisation of the final assessment report, to be transmitted within 45 days of the validation date to the sponsor and the other Member States concerned.

The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with Article 70(7).

5. As regards the assessment of the documentation referred to in the second subparagraph of paragraph 3, each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed 12 days from the receipt of the request. The expiry of the last deadline pursuant to point (d) of paragraph 4 shall be suspended from the date of the request until such time as the additional information has been received.

6. For class IIb and class III devices, the coordinating Member State may also extend the periods referred to in paragraph 4 by a further 50 days, for the purpose of consulting with experts.

7. The Commission may, by means of implementing acts, further specify the procedures and timescales for coordinated assessments to be taken into account by Member States concerned when deciding on the sponsor's application. Such implementing acts may also set out the procedures and timescales for coordinated assessment in the case of substantial modifications pursuant to paragraph 12 of this Article, in the case of reporting of adverse events pursuant to Article 80(4) and in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

8. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the clinical investigation is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member States concerned.

Notwithstanding the first subparagraph, a Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds:

(a) when it considers that participation in the clinical investigation would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned;

(b) infringement of national law; or

(c) considerations as regards subject safety and data reliability and robustness submitted under point (b) of paragraph 4.

Where one of the Member States concerned disagrees with the conclusion on the basis of the second subparagraph of this paragraph, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 73, to the Commission, to all other Member States concerned and to the sponsor.

9. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the clinical investigation is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

10. A Member State concerned shall refuse to authorise a clinical investigation if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 8, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV are not complied with, or where an ethics committee has issued a negative opinion in relation to that clinical investigation, which is valid, in accordance with national law, for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

11. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 73 as to whether the clinical investigation is authorised, whether it is authorised subject to conditions, or whether authorisation has been refused. Notification shall be done by way of one single decision within five days of the transmission, pursuant to point (d) of paragraph 4, by the coordinating Member State of the final assessment report. Where an authorisation of a clinical investigation is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation.

12. Any substantial modifications as referred to in Article 75 shall be notified to the Member States concerned by means of the electronic system referred to in Article 73. Any assessment as to whether there are grounds for disagreement as referred to in the second subparagraph of paragraph 8 of this Article shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV, which shall be assessed separately by each Member State concerned.

13. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks under this Chapter.

14. The procedure set out in this Article shall, until 27 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. After 27 May 2027, all Member States shall be required to apply that procedure.

Article 79

Review of coordinated assessment procedure

By 27 May 2026, the Commission shall submit to the European Parliament and to the Council a report on experience gained from the application of Article 78 and, if necessary, propose a review of Article 78(14) and point (h) of Article 123(3).

Article 80

Recording and reporting of adverse events that occur during clinical investigations

1. The sponsor shall fully record all of the following:

(a) any adverse event of a type identified in the clinical investigation plan as being critical to the evaluation of the results of that clinical investigation;

(b) any serious adverse event;

(c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) any new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report, without delay to all Member States in which the clinical investigation is being conducted, all of the following by means of the electronic system referred to in Article 73:

(a) any serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;

(b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) any new findings in relation to any event referred to in points (a) and (b).

The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

Upon request by any Member State in which the clinical investigation is being conducted, the sponsor shall provide all information referred to in paragraph 1.

3. The sponsor shall also report to the Member States in which the clinical investigation is being conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation by means of the electronic system referred to in Article 73.

4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 78, the sponsor shall report any event as referred to in paragraph 2 of this Article by means of the electronic system referred to in Article 73. Upon receipt, this report shall be transmitted electronically to all Member States in which the clinical investigation is being conducted.

Under the direction of the coordinating Member State referred to in Article 78(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the clinical investigation or whether to revoke the authorisation for that clinical investigation.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of PMCF investigations referred to in Article 74(1), the provisions on vigilance laid down in Articles 87 to 90 and in the acts adopted pursuant to Article 91 shall apply instead of this Article.

6. Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.

Article 81

Implementing acts

The Commission may, by means of implementing acts, establish the detailed arrangements and procedural aspects necessary for the implementation of this Chapter as regards the following:

(a) harmonised electronic forms for the application for clinical investigations and their assessment as referred to in Articles 70 and 78, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 73;

(c) harmonised electronic forms for the notification of PMCF investigations as referred to in Article 74(1), and of substantial modifications as referred to in Article 75;

(d) the exchange of information between Member States as referred to in Article 76;

(e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 80;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 80;

(g) uniform application of the requirements regarding the clinical evidence or data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 82

Requirements regarding other clinical investigations

1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1), shall comply with the provisions of Article 62 (2) and (3), points (b), (c), (d), (f), (h), and (l) of Article 62(4) and Article 62(6).

2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1), each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

SECTION 1

Post-market surveillance

Article 83

Post-market surveillance system of the manufacturer

1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the clinical evaluation;

(d) to update the summary of safety and clinical performance referred to in Article 32;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 88.

The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

Article 84

Post-market surveillance plan

The post-market surveillance system referred to in Article 83 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III. For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II.

Article 85

Post-market surveillance report

Manufacturers of class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

Article 86

Periodic safety update report

1. Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF; and

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

2. For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

SECTION 2

Vigilance

Article 87

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

(a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.

2. As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the serious incident.

3. Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 15 days after they become aware of the incident.

4. Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5. Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8. Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1 in advance of the field safety corrective action being undertaken.

9. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 89(9), in consultation with the competent authorities referred to in point (a) of Article 92(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 92(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10. The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11. Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 89.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting in accordance with Article 88, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 89.

Article 88

Trend reporting

1. Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.

The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in Article 84.

2. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. Each competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.

Article 89

Analysis of serious incidents and field safety corrective actions

1. Following the reporting of a serious incident pursuant to Article 87(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in paragraph 3 of this Article as appropriate.

The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

3. In the context of the evaluation referred to in paragraph 2, the competent authority shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Annex I.

Upon request by the national competent authority, manufacturers shall provide all documents necessary for the risk assessment.

4. The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.

5. The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 92. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6. In the case of devices referred to in the first subparagraph of Article 1(8) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, inform the national competent authority or the EMA, depending on which issued the scientific opinion on that substance under Article 52(9), of that serious incident or field safety corrective action.

In the case of devices covered by this Regulation in accordance with point (g) of Article 1(6) and where the serious incident or field safety corrective action may be related to the derivatives of tissues or cells of human origin utilised for the manufacture of the device, and in the case of devices falling under this Regulation pursuant to Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for human tissues and cells that was consulted by the notified body in accordance with Article 52(10).

7. After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.

8. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in the cases referred to in paragraph 9, to the coordinating competent authority to allow it to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The field safety notice shall allow the correct identification of the device or devices involved, in particular by including the relevant UDIs, and the correct identification, in particular, by including the SRN, if already issued, of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons, and shall clearly indicate all the actions to be taken by users.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 92 through which that notice shall be accessible to the public.

9. The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 in the following cases:

(a) where there is concern regarding a particular serious incident or cluster of serious incidents relating to the same device or type of device of the same manufacturer in more than one Member State;

(b) where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

That coordinated procedure shall cover the following:

— designation of a coordinating competent authority on a case by case basis, when required;

— defining the coordinated assessment process, including the tasks and responsibilities of the coordinating competent authority and the involvement of other competent authorities.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the competent authority of the Member State in which the manufacturer has its registered place of business.

The coordinating competent authority shall, through the electronic system referred to in Article 92, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

10. The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

11. The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 90

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 92, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.

Article 91

Implementing acts

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 85 to 90 and 92 as regards the following:

(a) the typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision of periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 85, 86, 87, 88 and 89 respectively;

(c) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;

(d) timelines for the reporting of field safety corrective actions, and for the provision by manufacturers of periodic summary reports and trend reports, taking into account the severity of the incident to be reported as referred to in Article 87;

(e) harmonised forms for the exchange of information between competent authorities as referred to in Article 89;

(f) procedures for the designation of a coordinating competent authority; the coordinated evaluation process, including tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 92

Electronic system on vigilance and on post-market surveillance

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 87(1) and Article 89(5);

(b) the periodic summary reports by manufacturers referred to in Article 87(9);

(c) the reports by manufacturers on trends referred to in Article 88;

(d) the PSURs referred to in Article 86;

(e) the field safety notices by manufacturers referred to in Article 89(8);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 89(7) and (9).

That electronic system shall include relevant links to the UDI database.

2. The information referred to in paragraph 1 of this Article shall be made available through the electronic system to the competent authorities of the Member States and to the Commission. The notified bodies shall also have access to that information to the extent that it relates to devices for which they issued a certificate in accordance with Article 53.

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system referred to in paragraph 1.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the electronic system referred to in paragraph 1 at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents referred to in point (a) of Article 87(1) shall be automatically transmitted, upon receipt, via the electronic system referred to in paragraph 1 of this Article, to the competent authority of the Member State in which the incident occurred.

6. The trend reports referred to in Article 88(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the Member State in which the incidents occurred.

7. The reports on field safety corrective actions referred to in point (b) of Article 87(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the following Member States:

(a) the Member States in which the field safety corrective action is being or is to be undertaken;

(b) the Member State in which the manufacturer has its registered place of business.

8. The periodic summary reports referred to in Article 87(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

(a) the Member State or Member States participating in the coordination procedure in accordance with Article 89(9) and which have agreed on the periodic summary report;

(b) the Member State in which the manufacturer has its registered place of business.

9. The information referred to in paragraphs 5 to 8 of this Article shall be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of this Article, to the notified body that issued the certificate for the device in question in accordance with Article 56.

SECTION 3

Market surveillance

Article 93

Market surveillance activities

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

2. The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities taking into account the European market surveillance programme developed by the MDCG pursuant to Article 105 and local circumstances.

3. In order to fulfil the obligations laid down in paragraph 1, the competent authorities:

(a) may require economic operators to, *inter alia*, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and

(b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

4. The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 100.

5. The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where they deem it necessary to do so in the interests of the protection of public health.

6. Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.

7. The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the final report, the competent authority shall give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 100.

8. The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 100.

9. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

10. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

11. Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

Article 94

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

(a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or

(b) otherwise does not comply with the requirements laid down in this Regulation,

they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device.

The relevant economic operators shall cooperate with the competent authorities.

Article 95

Procedure for dealing with devices presenting an unacceptable risk to health and safety

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 56 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 100.

3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

4. Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.

The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 100.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 100, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.

In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 100.

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

Article 96

Procedure for evaluating national measures at Union level

1. Where, within two months of receipt of the notification referred to in Article 95(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2. Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 95(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 95(4), the national measure shall be considered to be justified.

3. Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 97

Other non-compliance

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.

3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 98

Preventive health protection measures

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices, considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.

2. The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 100.

3. The Commission, in consultation with the MDCG and, where necessary, the economic operators concerned, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months of their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

4. Where the assessment referred to in paragraph 3 of this Article demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts to take the necessary and duly justified measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 99

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 95 to 98 shall state the exact grounds on which it is based. Where such a measure is addressed to a specific economic operator, the competent authority shall notify without delay the economic operator concerned of that measure, and shall at the same time inform that economic operator of the remedies available under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general applicability, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted.

Where action has been taken without the economic operator having had the opportunity to make submissions as referred to in the first subparagraph, it shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that it has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.

4. Where a measure adopted pursuant to Articles 95 to 98 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 100 inform the relevant notified body and the authority responsible for the notified body of the measure taken.

Article 100

Electronic system on market surveillance

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:

(a) summaries of the results of the surveillance activities referred to in Article 93(4);

(b) the final inspection report referred to in Article 93(7);

(c) information in relation to devices presenting an unacceptable risk to health and safety as referred to in Article 95(2), (4) and (6);

(d) information in relation to non-compliance of products as referred to in Article 97(2);

(e) information in relation to the preventive health protection measures referred to in Article 98(2);

(f) summaries of the results of the reviews and assessments of the market surveillance activities of the Member States referred to in 93(8).

2. The information referred to in paragraph 1 of this Article shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 56 for the device concerned and be accessible to the Member States and to the Commission.

3. Information exchanged between Member States shall not be made public where to do so might impair market surveillance activities and co-operation between Member States.

CHAPTER VIII

COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS

Article 101

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

Article 102

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.

2. Member States shall, with the support of the Commission, participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 103

Medical Device Coordination Group

1. A Medical Device Coordination Group ('MDCG') is hereby established.

2. Each Member State shall appoint to the MDCG, for a three-year term which may be renewed, one member and one alternate each with expertise in the field of medical devices, and one member and one alternate with expertise in the field of *in vitro* diagnostic medical devices. A Member State may choose to appoint only one member and one alternate, each with expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

The alternates shall represent and vote for the members in their absence.

3. The MDCG shall meet at regular intervals and, where the situation requires, upon request by the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of medical devices, or by the members appointed for their expertise in the field of *in vitro* diagnostic medical devices, or by the members appointed for their expertise in both fields, or their alternates, as appropriate.

4. The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the MDCG's position.

5. The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.

7. The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to such sub-groups in the capacity of observers.

8. The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

— the adoption of opinions or recommendations or other positions, including in cases of urgency;

— the delegation of tasks to reporting and co-reporting members;

— the implementation of Article 107 regarding conflict of interests;

— the functioning of sub-groups.

9. The MDCG shall have the tasks laid down in Article 105 of this Regulation and Article 99 of Regulation (EU) 2017/746.

Article 104

Support by the Commission

The Commission shall support the functioning of the cooperation between national competent authorities. It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

Article 105

Tasks of the MDCG

Under this Regulation, the MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices;

(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States.

Article 106

Provision of scientific, technical and clinical opinions and advice

1. The Commission shall, by means of implementing acts and in consultation with the MDCG, make provision for expert panels to be designated for the assessment of the clinical evaluation in relevant medical fields as referred to in paragraph 9 of this Article and to provide views in accordance with Article 48(6) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, observing the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 7 of this Article.

2. Expert panels and expert laboratories may be designated in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.

3. Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission shall determine the number of members of each panel in accordance with the requisite needs.

The members of expert panels shall perform their tasks with impartiality and objectivity. They shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests, which shall be made publicly available.

The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions.

5. The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the *Official Journal of the European Union* and on the Commission website following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.

6. The Commission, following consultation with the MDCG, may include advisors on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panel as needed. That list shall be published on the Commission website.

7. The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in:

— physico-chemical characterisation, or

— microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing

of specific devices, categories or groups of devices.

The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

8. Expert laboratories shall satisfy the following criteria:

(a) have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the devices for which they are designated;

(b) possess the necessary equipment to carry out the tasks assigned to them;

(c) have the necessary knowledge of international standards and best practices;

(d) have an appropriate administrative organisation and structure;

(e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks.

9. Expert panels appointed for clinical evaluation in relevant medical fields shall fulfil the tasks provided for in Article 54(1) and Article 61(2) and Section 5.1 of Annex IX or Section 6 of Annex X, as applicable.

10. Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:

(a) to provide scientific, technical and clinical assistance to the Commission and the MDCG in relation to the implementation of this Regulation;

(b) to contribute to the development and maintenance of appropriate guidance and CS for:

— clinical investigations,

— clinical evaluation and PMCF,

— performance studies,

— performance evaluation and post-market performance follow-up,

— physico-chemical characterisation, and

— microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing

for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;

(c) to develop and review clinical evaluation guidance and performance evaluation guidance for performance of conformity assessment in line with the state of the art with regard to clinical evaluation, performance evaluation, physico-chemical characterisation, and microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;

(d) to contribute to the development of standards at international level, ensuring that such standards reflect the state of the art;

(e) to provide opinions in response to consultations by manufacturers in accordance with Article 61(2), notified bodies and Member States in accordance with paragraphs 11 to 13 of this Article.

(f) to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;

(g) to provide views in accordance with Article 48(4) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices.

11. The Commission, shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, *inter alia*, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for clinical evaluation, with regard to physico-chemical characterisation, and with regard to microbiological, biocompatibility, mechanical, electrical, electronic and non-clinical toxicological testing.

12. When adopting its scientific opinion in accordance with paragraph 9, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.

The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 9 and 11 of this Article, ensuring consideration of aspects of confidentiality as set out in Article 109. The clinical evaluation guidance referred to in point (c) of paragraph 10 shall be published following consultation with the MDCG.

13. The Commission may require manufacturers and notified bodies to pay fees for the advice provided by expert panels and expert laboratories. The structure and the level of fees as well as the scale and structure of recoverable costs shall be adopted by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

14. The fees payable to the Commission in accordance with the procedure under paragraph 13 of this Article shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with point (c) of Section 5.1 of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.

15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the tasks of expert panels and expert laboratories referred to in paragraph 10 of this Article.

Article 107

Conflict of interests

1. Members of the MDCG, its sub-groups, and members of expert panels and expert laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct or indirect interests they may have in the medical device industry and update that declaration whenever a relevant change occurs. The declaration of interests shall be made publicly available on the Commission website. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2. Experts and other third parties invited by the MDCG on a case-by-case basis shall declare any interests they may have in the issue in question.

Article 108

Device registers and databanks

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices, or the traceability of implantable devices, or all of such characteristics.

CHAPTER IX

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

Article 109

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data, in accordance with Article 110;

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights; unless disclosure is in the public interest;

(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 110

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 111

Levying of fees

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.

2. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be made publicly available on request.

Article 112

Funding of activities related to designation and monitoring of notified bodies

The costs associated with joint assessment activities shall be covered by the Commission. The Commission shall, by means of implementing acts, lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 113

Penalties

The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2020 and shall notify it, without delay, of any subsequent amendment affecting them.

CHAPTER X

FINAL PROVISIONS

Article 114

Committee procedure

1. The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or 5 thereof, as appropriate, shall apply.

Article 115

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall be conferred on the Commission for a period of five years from 25 May 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 116

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 117

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (*), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.

(*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'.

Article 118

Amendment to Regulation (EC) No 178/2002

In the third paragraph of Article 2 of Regulation (EC) No 178/2002, the following point is added:

'(i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council (*).

(*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'.

Article 119

Amendment to Regulation (EC) No 1223/2009

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

'4. The Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition 'cosmetic product'. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).'.

Article 120

Transitional provisions

1. From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.

5. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.

6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior 26 May 2020. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.

7. As regards devices subject to the consultation procedure laid down in Article 54, paragraph 5 of this Article shall apply provided that the necessary appointments to the MDCG and expert panels have been made.

8. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to point (d) of Article 123(3) and ending 18 months later, comply with Article 29(4) and Article 56(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Decision 2010/227/EU.

9. Authorisations granted by the competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.

10. Devices falling within the scope of this Regulation in accordance with points (f) and (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2020 may continue to be placed on the market and put into service in the Member States concerned.

11. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2020 may continue to be conducted. As of 26 May 2020, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

12. Until the Commission has designated, pursuant to Article 27(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

Article 121

Evaluation

By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation. Special attention shall be given to the traceability of medical devices through the storage, pursuant to Article 27, of the UDI by economic operators, health institutions and health professionals.

Article 122

Repeal

Without prejudice to Articles 120(3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2020, with the exception of:

— Articles 8 and 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation;

— Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation;

— Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation; and

— Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation.

As regards the devices referred to in Article 120 (3) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Notwithstanding the first paragraph, Regulations (EU) No 207/2012 and (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

References to the repealed Directives shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVII to this Regulation.

Article 123

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from 26 May 2020.

3. By way of derogation from paragraph 2:

(a) Articles 35 to 50 shall apply from 26 November 2017. However, from that date until 26 May 2020, the obligations on notified bodies pursuant to Articles 35 to 50 shall apply only to those bodies which submit an application for designation in accordance with Article 38;

(b) Articles 101 and 103 shall apply from 26 November 2017;

(c) Article 102 shall apply from 26 May 2018;

(d) without prejudice to the obligations on the Commission pursuant to Article 34, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1), Eudamed is not fully functional on 26 May 2020, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3). The provisions referred to in the preceding sentence are:

— Article 29,

— Article 31,

— Article 32,

— Article 33(4),

— the second sentence of Article 40(2),

— Article 42(10),

— Article 43(2),

— the second subparagraph of Article 44(12),

— points (d) and (e) of Article 46(7),

— Article 53(2),

— Article 54(3),

— Article 55(1),

— Articles 70 to 77,

— paragraphs 1 to 13 of Article 78,

— Articles 79 to 82,

— Article 86(2),

— Articles 87 and 88,

— Article 89(5) and (7), and the third subparagraph of Article 89(8),

— Article 90,

— Article 93(4), (7) and (8),

— Article 95(2) and (4),

— the last sentence of Article 97(2),

— Article 99(4),

— the second sentence of the first subparagraph of Article 120(3).

Until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications.

(e) Article 29(4) and Article 56(5) shall apply from 18 months after the later of the dates referred to in point (d);

(f) for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;

(g) for reusable devices that shall bear the UDI carrier on the device itself, Article 27(4) shall apply from two years after the date referred to in point (f) of this paragraph for the respective class of devices in that point;

(h) The procedure set out in Article 78 shall apply from 26 May 2027, without prejudice to Article 78(14);

(i) Article 120(12) shall apply from 26 May 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 5 April 2017.

For the European Parliament
The President
A. TAJANI

For the Council
The President
I. BORG

ANNEXES

I General safety and performance requirements

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ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3. Manufacturers shall establish, implement, document and maintain a risk management system.

   Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

   (a) establish and document a risk management plan for each device;

   (b) identify and analyse the known and foreseeable hazards associated with each device;

   (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

   (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

   (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

   (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

   (a) eliminate or reduce risks as far as possible through safe design and manufacture;

   (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

   (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

   Manufacturers shall inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer shall:

   (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

   (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

9. For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

CHAPTER II

REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

10. Chemical, physical and biological properties

10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:

(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;

(b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;

(c) the compatibility between the different parts of a device which consists of more than one implantable part;

(d) the impact of processes on material properties;

(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;

(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;

(g) surface properties; and

(h) the confirmation that the device meets any defined chemical and/or physical specifications.

10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.

10.4. Substances

10.4.1. Design and manufacture of devices

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

Devices, or those parts thereof or those materials used therein that:

— are invasive and come into direct contact with the human body,

— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

(a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]), or

(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council ([3]), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances

The justification for the presence of such substances shall be based upon:

(a) an analysis and estimation of potential patient or user exposure to the substance;

(b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;

(c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and

(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.

10.4.3. Guidelines on phthalates

For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.

([1]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).

([3]) Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

10.4.4. Guidelines on other CMR and endocrine-disrupting substances

Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.

10.4.5. Labelling

Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.

10.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.

11. Infection and microbial contamination

11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

(a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,

(b) allow easy and safe handling,

(c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and

(d) prevent microbial contamination of the device or its content such as specimens or fluids.

11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.

11.3. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.

11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.

11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.

12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.

12.2. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.

13. Devices incorporating materials of biological origin

13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:

(a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;

(b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;

(c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.

13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:

(a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;

(b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;

(c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.

13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

14. Construction of devices and interaction with their environment

14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.

14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

(e) the risks of accidental ingress of substances into the device;

(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and

(g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

15. Devices with a diagnostic or measuring function

15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.

15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC ([1]).

([1]) Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

16. Protection against radiation

16.1. General

(a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

16.2. Intended radiation

(a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

(b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.

16.4. Ionising radiation

(a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

(b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment.

(c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.

(d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.

17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

18. Active devices and devices connected to them

18.1. For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.

18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.

18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.

18.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.

19. Particular requirements for active implantable devices

19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:

(a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

(b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and

(c) risks which may arise where maintenance and calibration are impossible, including:

— excessive increase of leakage currents,

— ageing of the materials used,

— excess heat generated by the device,

— decreased accuracy of any measuring or control mechanism.

19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure

— if applicable, the compatibility of the devices with the substances they are intended to administer, and

— the reliability of the source of energy.

19.3. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.

19.4. Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.

20. Protection against mechanical and thermal risks

20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

20.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

20.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.

20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

20.6. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

21. Protection against the risks posed to the patient or user by devices supplying energy or substances

21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.

21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

21.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:

— ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,

— reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and

— reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:

— can verify that, at the time of use, the device will perform as intended by the manufacturer, and

— if applicable, is warned if the device has failed to provide a valid result.

CHAPTER III

REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

23. Label and instructions for use

23.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.

(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.

(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

23.2. Information on the label

The label shall bear all of the following particulars:

(a) the name or trade name of the device;

(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;

(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;

(e) where applicable, an indication that the device contains or incorporates:

— a medicinal substance, including a human blood or plasma derivative, or

— tissues or cells, or their derivatives, of human origin, or

— tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;

(f) where applicable, information labelled in accordance with Section 10.4.5.;

(g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;

(i) an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;

(j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

(k) an indication of any special storage and/or handling condition that applies;

(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method;

(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

(n) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;

(p) if the device is custom-made, the words 'custom-made device';

(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';

(r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;

(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.

23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

The following particulars shall appear on the sterile packaging:

(a) an indication permitting the sterile packaging to be recognised as such,

(b) a declaration that the device is in a sterile condition,

(c) the method of sterilisation,

(d) the name and address of the manufacturer,

(e) a description of the device,

(f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',

(g) if the device is custom-made, the words 'custom-made device',

(h) the month and year of manufacture,

(i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and

(j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

23.4. Information in the instructions for use

The instructions for use shall contain all of the following particulars:

(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;

(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;

(c) where applicable, a specification of the clinical benefits to be expected.

(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32;

(e) the performance characteristics of the device;

(f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;

(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;

(h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;

(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;

(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;

(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

— details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,

— identification of any consumable components and how to replace them,

— information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and

— methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;

(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;

(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;

(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;

(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;

(p) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;

(q) for devices intended for use together with other devices and/or general purpose equipment:

— information to identify such devices or equipment, in order to obtain a safe combination, and/or

— information on any known restrictions to combinations of devices and equipment;

(r) if the device emits radiation for medical purposes:

— detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,

— the means of protecting the patient, user, or other person from unintended radiation during use of the device;

(s) information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:

— warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,

— warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro-magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

— warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

— if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,

— warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and

— precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;

(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;

(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;

(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:

— infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and

— physical hazards such as from sharps.

If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;

(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;

(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;

(y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;

(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

(aa) information to be supplied to the patient with an implanted device in accordance with Article 18;

(ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(a) product or trade name and a general description of the device including its intended purpose and intended users;

(b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;

(d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary;

(e) the rationale for the qualification of the product as a device;

(f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;

(g) an explanation of any novel features;

(h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;

(i) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

(j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

(l) technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.

1.2. Reference to previous and similar generations of the device

(a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

(b) an overview of identified similar devices available on the Union or international markets, where such devices exist.

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

A complete set of:

— the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and

— the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

3. DESIGN AND MANUFACTURING INFORMATION

(a) information to allow the design stages applied to the device to be understood;

(b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

(c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards, CS or other solutions applied; and

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1. Pre-clinical and clinical data

(a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

— the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;

— physical, chemical and microbiological characterisation;

— electrical safety and electromagnetic compatibility;

— software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

— stability, including shelf life; and

— performance and safety.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council ([1]) shall be demonstrated.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service;

(c) the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV;

(d) the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable.

6.2. Additional information required in specific cases

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

(b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), a statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I.

(c) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

— absorption, distribution, metabolism and excretion;

— possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;

— local tolerance; and

— toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.

In the absence of such studies, a justification shall be provided.

(d) In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex.

([1]) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

(e) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(f) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1.1. The post-market surveillance plan drawn up in accordance with Article 84.

The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83.

(a) The post-market surveillance plan shall address the collection and utilization of available information, in particular:

— information concerning serious incidents, including information from PSURs, and field safety corrective actions;

— records referring to non-serious incidents and data on any undesirable side-effects;

— information from trend reporting;

— relevant specialist or technical literature, databases and/or registers;

— information, including feedbacks and complaints, provided by users, distributors and importers; and

— publicly available information about similar medical devices.

(b) The post-market surveillance plan shall cover at least:

— a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

— effective and appropriate methods and processes to assess the collected data;

— suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;

— effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;

— methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

— methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;

— reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86;

— systematic procedures to identify and initiate appropriate measures including corrective actions;

— effective tools to trace and identify devices for which corrective actions might be necessary; and

— a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.

1.2. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85.

ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain all of the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The Basic UDI-DI as referred to in Part C of Annex VI;

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

5. Risk class of the device in accordance with the rules set out in Annex VIII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

7. References to any CS used and in relation to which conformity is declared;

8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

9. Where applicable, additional information;

10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

ANNEX V

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking the following form:

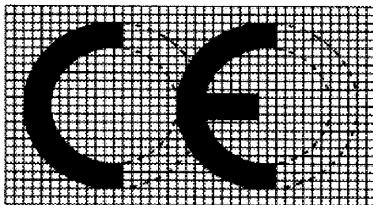

2. If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX VI

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM

PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party.

1. Information relating to the economic operator

1.1. type of economic operator(manufacturer, authorised representative, or importer),

1.2. name, address and contact details of the economic operator,

1.3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details of that person,

1.4. name address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15.

2. Information relating to the device

2.1. Basic UDI-DI,

2.2. type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,

2.3. Member State in which the device is to or has been placed on the market in the Union,

2.4. in the case of class IIa, class IIb or class III devices: Member States where the device is or is to be made available,

2.5. risk class of the device,

2.6. reprocessed single-use device (y/n),

2.7. presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance,

2.8. presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance,

2.9. presence of tissues or cells of human origin, or their derivatives (y/n),

2.10. presence of tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 (y/n),

2.11. where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations,

2.12. in the case of devices listed in Annex XVI, specification as to whether the intended purpose of the device is other than a medical purpose,

2.13. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that legal or natural person,

2.14. in the case of class III or implantable devices, the summary of safety and clinical performance,

2.15. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29

The manufacturer shall provide to the UDI database the UDI-DI and all of the following information relating to the manufacturer and the device:

1. quantity per package configuration,
2. the Basic UDI-DI as referred to in Article 29 and any additional UDI-DIs,
3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),
4. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
6. the SRN issued in accordance with Article 31(2),
7. if applicable, name and address of the authorised representative (as indicated on the label),
8. the medical device nomenclature code as provided for in Article 26,
9. risk class of the device,
10. if applicable, name or trade name,
11. if applicable, device model, reference, or catalogue number,
12. if applicable, clinical size (including volume, length, gauge, diameter),
13. additional product description (optional),
14. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
15. if applicable, additional trade names of the device,
16. labelled as a single-use device (y/n),
17. if applicable, the maximum number of reuses,
18. device labelled sterile (y/n),
19. need for sterilisation before use (y/n),
20. containing latex (y/n),
21. where applicable, information labelled in accordance with Section 10.4.5 of Annex I,
22. URL for additional information, such as electronic instructions for use (optional),
23. if applicable, critical warnings or contra-indications,
24. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

PART C

THE UDI SYSTEM

1. Definitions

Automatic identification and data capture ('AIDC')

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unit of Use DI

The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

Configurable device

A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configurable devices include computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological Monitoring systems, radiology information systems (RIS).

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customized to meet specific needs.

Configurations include *inter alia*:

— gantries, tubes, tables, consoles and other items of equipment that can be configured/combined to deliver an intended function in computed tomography.

— ventilators, breathing circuits, vaporizers combined to deliver an intended function in anaesthesia.

UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

Human Readable Interpretation ('HRI')

HRI is a legible interpretation of the data characters encoded in the UDI carrier.

Packaging levels

Packaging levels means the various levels of device packaging that contain a defined quantity of devices, such as a carton or case.

UDI-PI

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

Radio Frequency Identification RFID

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

Shipping containers

A shipping container is a container in relation to which traceability is controlled by a process specific to logistics systems.

Unique Device Identifier ('UDI')

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

The word 'Unique' does not imply serialisation of individual production units.

UDI carrier

The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, its HRI.

UDI carriers include, *inter alia*, ID/linear bar code, 2D/Matrix bar code, RFID.

2. General requirements

2.1. The affixing of the UDI is an additional requirement — it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.

2.2. The manufacturer shall assign and maintain unique UDIs for its devices.

2.3. Only the manufacturer may place the UDI on the device or its packaging.

2.4. Only coding standards provided by issuing entities designated by the Commission pursuant to Article 27(2) may be used.

3. The UDI

3.1. A UDI shall be assigned to the device itself or its packaging. Higher levels of packaging shall have their own UDI.

3.2. Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

3.3. The UDI shall contain two parts: a UDI-DI and a UDI-PI.

3.4. The UDI-DI shall be unique at each level of device packaging.

3.5. If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.

3.6. Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

3.7. Systems and procedure packs as referred to in Article 22 shall be assigned and bear their own UDI.

3.8. The manufacturer shall assign the UDI to a device following the relevant coding standard.

3.9. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability; in particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(a) name or trade name,

(b) device version or model,

(c) labelled as single use,

(d) packaged sterile,

(e) need for sterilization before use,

(f) quantity of devices provided in a package,

(g) critical warnings or contra-indications: e.g. containing latex or DEHP.

3.10. Manufacturers that repackage and/or relabel devices, with their own label shall retain a record of the original device manufacturer's UDI.

4. UDI carrier

4.1. The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.

4.2. In the event of there being significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.

4.3. For single-use devices of classes I and IIa packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging, e.g. a carton containing several individually packaged devices. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging of the individual device.

4.4. For devices exclusively intended for retail point of sale the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

4.5. When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.

4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC.

4.8. The HRI format shall follow the rules of the UDI code-issuing entity.

4.9. If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device. The requirement of this Section shall not apply to devices in the following circumstances:

(a) any type of direct marking would interfere with the safety or performance of the device;

(b) the device cannot be directly marked because it is not technologically feasible.

4.11. The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

4.12. If the UDI carrier is readily readable or, in the case of AIDC, scannable, through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.

4.13. In the case of single finished devices made up of multiple parts that must be assembled before their first use, it shall be sufficient to place the UDI carrier on only one part of each device.

4.14. The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage.

4.15. Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

5. General principles of the UDI database

5.1. The UDI database shall support the use of all core UDI database data elements referred to in Part B of this Annex.

5.2. Manufacturers shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

5.3. Appropriate methods/procedures for validation of the data provided shall be implemented.

5.4. Manufacturers shall periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

5.5. The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with this Regulation.

5.6. The database shall allow for the linking of all the packaging levels of the device.

5.7. The data for new UDI-DIs shall be available at the time the device is placed on the market.

5.8. Manufacturers shall update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

5.9. Internationally-accepted standards for data submission and updates shall, wherever possible, be used by the UDI database.

5.10. The user interface of the UDI database shall be available in all official languages of the Union. The use of free-text fields shall, however, be minimized in order to reduce translations.

5.11. Data relating to devices that are no longer available on the market shall be retained in the UDI database.

6. Rules for specific device types

6.1. Implantable devices:

6.1.1. Implantable devices shall, at their lowest level of packaging ('unit packs'), be identified, or marked using AIDC, with a UDI (UDI-DI + UDI-PI);

6.1.2. The UDI-PI shall have at least the following characteristics:

(a) the serial number for active implantable devices,

(b) the serial number or lot number for other implantable devices.

6.1.3. The UDI of the implantable device shall be identifiable prior to implantation.

6.2. Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses

6.2.1. The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use.

6.2.2. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

6.3. Systems and procedure packs as referred to in Article 22

6.3.1. The natural or legal person referred to in Article 22 shall be responsible for identifying the system or procedure pack with a UDI including both UDI-DI and UDI-PI.

6.3.2. Device contents of system or procedure packs shall bear a UDI carrier on their packaging or on the device itself.

Exemptions:

(a) individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier;

(b) devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.

6.3.3. Placement of the UDI carrier on systems or procedure packs

(a) The system or procedure pack UDI carrier shall as a general rule be affixed to the outside of the packaging.

(b) The UDI carrier shall be readable, or, in the case of AIDC, scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent packaging.

6.4. Configurable devices:

6.4.1. A UDI shall be assigned to the configurable device in its entirety and shall be called the configurable device UDI.

6.4.2. The configurable device UDI-DI shall be assigned to groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given device as described in the technical documentation.

6.4.3. A configurable device UDI-PI shall be assigned to each individual configurable device.

6.4.4. The carrier of the configurable device UDI shall be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and shall be identified as the configurable device UDI.

6.4.5. Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI.

6.5. Device Software

6.5.1. UDI assignment Criteria

The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.

The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.5.2. A new UDI-DI shall be required whenever there is a modification that changes:

(a) the original performance;

(b) the safety or the intended use of the software;

(c) interpretation of data.

Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.5.3. Minor software revisions shall require a new UDI-PI and not a new UDI-DI.

Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.5.4. UDI placement criteria for software

(a) where the software is delivered on a physical medium, e.g. CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;

(b) the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format, such as an 'about' file, or included on the start-up screen;

(c) software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);

(d) only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays, such as 'about' menu, splash screen etc.;

(e) the human readable format of the UDI for the software shall include the Application Identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

ANNEX VII

REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. Legal status and organisational structure

1.1.1. Each notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect. Its legal personality and status shall be fully documented. Such documentation shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the organisation to which it belongs.

1.1.3. If a notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities under this Regulation shall be subject to the applicable requirements of this Regulation.

1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that they ensure that there is confidence in the performance by the notified body and in the results of the conformity assessment activities it conducts.

1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance by the notified body and upon the results of its conformity assessment activities.

1.1.6. The notified body shall identify the persons in top-level management that have overall authority and responsibility for each of the following:

— the provision of adequate resources for conformity assessment activities;

— the development of procedures and policies for the operation of the notified body;

— the supervision of implementation of the procedures, policies and quality management systems of the notified body;

— the supervision of the notified body's finances;

— the activities and decisions taken by the notified body, including contractual agreements;

— the delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities;

— the interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the device in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer. This does not preclude the notified body from carrying out conformity assessment activities for competing manufacturers.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. Such procedures shall provide for the identification, investigation and resolution of any case in which a conflict of interest may arise, including involvement in consultancy services in the field of devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;

(b) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities;

(c) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;

(d) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, and

(e) be linked to any organisation which itself provides consultancy services as referred to in point (d). Such restriction does not preclude general training activities that are not client specific and that relate to regulation of devices or to related standards.

1.2.4. Involvement in consultancy services in the field of devices prior to taking up employment with a notified body shall be fully documented at the time of employment and potential conflicts of interest shall be monitored and resolved in accordance with this Annex. Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client prior to taking up employment with a notified body, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of three years.

1.2.5. The impartiality of notified bodies, of their top-level management and of the assessment personnel shall be guaranteed. The level of the remuneration of the top-level management and assessment personnel of a notified body and subcontractors, involved in assessment activities shall not depend on the results of the assessments. Notified bodies shall make publicly available the declarations of interest of their top-level management.

1.2.6. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interest shall be ensured and documented between, on the one hand, the authority responsible for notified bodies and/or the competent authority and, on the other hand, the notified body.

1.2.7. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, including the activities of its owners do not affect its independence, impartiality or the objectivity of its conformity assessment activities.

1.2.8. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to fees.

1.2.9. The requirements laid down in this Section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment.

1.3. Confidentiality

1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of conformity assessment activities, except when disclosure is required by law.

1.3.2. The personnel of a notified body shall observe professional secrecy in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the authorities responsible for notified bodies, competent authorities for medical devices in the Member States or the Commission. Proprietary rights shall be protected. The notified body shall have documented procedures in place in respect of the requirements of this Section.

1.4. Liability

1.4.1. The notified body shall take out appropriate liability insurance for its conformity assessment activities, unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for the conformity assessment.

1.4.2. The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its long-term economic viability, taking into account, where relevant, any specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of, any relevant standardisation activities and in the activities of the notified body coordination group referred to in Article 49 and that its assessment and decision-making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.2. The notified body shall take into consideration guidance and best practice documents.

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the consistent fulfilment of the requirements of this Regulation.

2.2. The quality management system of the notified body shall address at least the following:

— management system structure and documentation, including policies and objectives for its activities;

— policies for assignment of activities and responsibilities to personnel;

— assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management;

— the planning, conduct, evaluation and, if necessary, adaptation of its conformity assessment procedures;

— control of documents;

— control of records;

— management reviews;

— internal audits;

— corrective and preventive actions;

— complaints and appeals; and

— continuous training.

Where documents are used in various languages, the notified body shall ensure and control that they have the same content.

2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.

2.4. The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. That commitment shall cover aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel shall be required to complete written statements indicating their compliance with confidentiality, independence and impartiality principles.

3. RESOURCE REQUIREMENTS

3.1. General

3.1.1. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

In particular, notified bodies shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which they have been designated.

Such requirement presupposes at all times and for each conformity assessment procedure and each type of devices in relation to which they have been designated, that the notified body has permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. Such personnel shall be in sufficient numbers to ensure that the notified body in question can perform the conformity assessment tasks, including the assessment of the medical functionality, clinical evaluations and the performance and safety of devices, for which it has been designated, having regard to the requirements of this Regulation, in particular, those set out in Annex I.

A notified body's cumulative competences shall be such as to enable it to assess the types of devices for which it is designated. The notified body shall have sufficient internal competence to critically evaluate assessments conducted by external expertise. Tasks which a notified body is precluded from subcontracting are set out in Section 4.1.

Personnel involved in the management of the operation of a notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of assessment and verification staff, for verification of their competence, for authorisation and allocation of their tasks, for organisation of their initial and ongoing training and for the assignment of their duties and the monitoring of those staff, in order to ensure that personnel who carry out and perform assessment and verification operations are competent to fulfil the tasks required of them.

The notified body shall identify at least one individual within its top-level management as having overall responsibility for all conformity assessment activities in relation to devices.

3.1.2. The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.

3.1.3. The notified body shall clearly document the extent and limits of duties and responsibilities and the level of authorisation of the personnel, including any subcontractors and external experts, involved in conformity assessment activities and inform those personnel accordingly.

3.2. Qualification criteria in relation to personnel

3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities, including as regards knowledge, experience and other competence required, and the required initial and ongoing training. The qualification criteria shall address the various functions within the conformity assessment process, such as auditing, product evaluation or testing, technical documentation review and decision-making, as well as the devices, technologies and areas, such as biocompatibility, sterilisation, tissues and cells of human and animal origin and clinical evaluation, covered by the scope of designation.

3.2.2. The qualification criteria referred to in Section 3.2.1 shall refer to the scope of a notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 42(3), providing a sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined at least for the assessment of:

— the pre-clinical evaluation,

— clinical evaluation,

— tissues and cells of human and animal origin,

— functional safety,

— software,

— packaging,

— devices that incorporate as an integral part a medicinal product,

— devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body and

— the different types of sterilisation processes.

3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be external experts or subcontracted. They shall have proven knowledge and experience in all of the following:

— Union devices legislation and relevant guidance documents;

— the conformity assessment procedures provided for in this Regulation;

— a broad base of knowledge of device technologies and the design and manufacture of devices;

— the notified body's quality management system, related procedures and the required qualification criteria;

— training relevant to personnel involved in conformity assessment activities in relation to devices;

— adequate experience in conformity assessments under this Regulation or previously applicable law within a notified body.

3.2.4. The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

— identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

— appropriately train external clinical experts in the relevant requirements of this Regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implications of their assessment and the advice they provide;

— be able to review and scientifically challenge the clinical data contained within the clinical evaluation, and any associated clinical investigations, and appropriately guide external clinical experts in the assessment of the clinical evaluation presented by the manufacturer;

— be able to scientifically evaluate and, if necessary, challenge the clinical evaluation presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

— be able to ascertain the comparability and consistency of the assessments of clinical evaluations conducted by clinical experts;

— be able to make an assessment of the manufacturer's clinical evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker; and

— be able to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.5. The personnel responsible for carrying out product-related reviews (product reviewers), such as technical documentation reviews or type examination, including aspects such as clinical evaluation, biological safety, sterilisation and software validation, shall have all of the following proven qualifications:

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;

— knowledge of device legislation, including the general safety and performance requirements set out in Annex I;

— appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge and experience of clinical evaluation;

— appropriate knowledge of the devices which they are assessing;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those assessments;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system (site auditors) shall have all of the following proven qualifications:

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the area of quality management;

— appropriate knowledge of devices legislation as well as related harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge of quality management systems and related standards and guidance documents;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those audits;

— training in auditing techniques enabling them to challenge quality management systems;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.7. The personnel with overall responsibility for final reviews and decision-making on certification shall be employed by the notified body itself and shall not be external experts or be subcontracted. Those personnel shall, as a group, have proven knowledge and comprehensive experience of all of the following:

— devices legislation and relevant guidance documents;

— the device conformity assessments relevant to this Regulation;

— the types of qualifications, experience and expertise relevant to device conformity assessment;

— a broad base of knowledge of device technologies, including sufficient experience of conformity assessment of devices being reviewed for certification, the device industry and the design and manufacture of devices;

— the notified body's quality management system, related procedures and the required qualifications for personnel involved;

— the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

3.3. Documentation of qualification, training and authorisation of personnel

3.3.1. The notified body shall have a procedure in place to fully document the qualification of each member of personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2. cannot be fully demonstrated, the notified body shall justify to the authority responsible for notified bodies the authorisation of those members of personnel to carry out specific conformity assessment activities.

3.3.2. For all of its personnel referred to in Sections 3.2.3 to 3.2.7, the notified body shall establish and maintain up to date:

— a matrix detailing the authorisations and responsibilities of the personnel in respect of conformity assessment activities; and

— records attesting to the required knowledge and experience for the conformity assessment activity for which they are authorised. The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.

3.4. Subcontractors and external experts

3.4.1. Notified bodies may, without prejudice to Section 3.2, subcontract certain clearly defined component parts of a conformity assessment activity.

The subcontracting of the auditing of quality management systems or of product related reviews as a whole shall not be permitted; nevertheless parts of those activities may be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body in question shall retain full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf.

The following activities may not be subcontracted by notified bodies:

— review of the qualifications and monitoring of the performance of external experts;

— auditing and certification activities where the subcontracting in question is to auditing or certification organisations;

— allocation of work to external experts for specific conformity assessment activities; and

— final review and decision making functions.

3.4.2. Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:

— the subcontractor meets the relevant requirements of this Annex;

— subcontractors and external experts do not further subcontract work to organisations or personnel; and

— the natural or legal person that applied for conformity assessment has been informed of the requirements referred to in the first and second indent.

Any subcontracting or consultation of external personnel shall be properly documented, shall not involve any intermediaries and shall be subject to a written agreement covering, among other things, confidentiality and conflicts of interest. The notified body in question shall take full responsibility for the tasks performed by subcontractors.

3.4.3. Where subcontractors or external experts are used in the context of a conformity assessment, in particular regarding novel, invasive and implantable devices or technologies, the notified body in question shall have internal competence in each product area for which it is designated that is adequate for the purpose of leading the overall conformity assessment, verifying the appropriateness and validity of expert opinions and making decisions on certification.

3.5. Monitoring of competences, training and exchange of experience

3.5.1. The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel, and subcontractors, involved in conformity assessment activities.

3.5.2. Notified bodies shall review at regular intervals, the competence of their personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel. That review shall at a minimum, verify that personnel:

— are aware of Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities referred to in Section 1.6; and

— take part in the internal exchange of experience and the continuous training and education programme referred to in Section 3.1.2.

4. PROCESS REQUIREMENTS

4.1. General

The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities up to decision making and surveillance and taking into account, when necessary, the respective specificities of the devices.

The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall be fulfilled as part of the internal activities of notified bodies and shall not be subcontracted.

4.2. Notified body quotations and pre-application activities

The notified body shall:

(a) publish a publicly available description of the application procedure by which manufacturers can obtain certification from it. That description shall include which languages are acceptable for submission of documentation and for any related correspondence;

(b) have documented procedures relating to, and documented details about, fees charged for specific conformity assessment activities and any other financial conditions relating to notified bodies' assessment activities for devices;

(c) have documented procedures in relation to advertising of their conformity assessment services. Those procedures shall ensure that advertising or promotional activities in no way imply or are capable of leading to an inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than that of other notified bodies;

(d) have documented procedures requiring the review of pre-application information, including the preliminary verification that the product is covered by this Regulation and its classification, prior to issuing any quotation to the manufacturer relating to a specific conformity assessment; and

(e) ensure that all contracts relating to the conformity assessment activities covered by this Regulation are concluded directly between the manufacturer and the notified body and not with any other organisation.

4.3. Application review and contract

The notified body shall require a formal application signed by a manufacturer or an authorised representative containing all of the information and the manufacturer's declarations required by the relevant conformity assessment as referred to in Annexes IX to XI.

The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.

The notified body shall have documented procedures to review applications, addressing:

(a) the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex, under which approval has been sought,

(b) the verification of the qualification of products covered by those applications as devices and their respective classifications,

(c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation,

(d) the ability of the notified body to assess the application based on its designation, and

(e) the availability of sufficient and appropriate resources.

The outcome of each review of an application shall be documented. Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 57 and shall be accessible to other notified bodies.

4.4. Allocation of resources

The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and related documentation that are subject to conformity assessment.

For each application, the notified body shall determine the resources needed and identify one individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment. The allocation of tasks required to be carried out as part of the conformity assessment and any changes subsequently made to this allocation shall be documented.

4.5. Conformity assessment activities

4.5.1. General

The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.

The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements:

— appropriately plan the conduct of each individual project,

— ensure that the composition of the assessment teams is such that there is sufficient experience in relation to the technology concerned, and that there is continuous objectivity and independence, and to provide for rotation of the members of the assessment team at appropriate intervals,

— specify the rationale for fixing time limits for completion of conformity assessment activities,

— assess the manufacturer's technical documentation and the solutions adopted to meet the requirements laid down in Annex I,

— review the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects,

— review the manufacturer's procedures and documentation relating to clinical evaluation,

— address the interface between the manufacturer's risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I,

— carry out the specific procedures referred to in Sections 5.2 to 5.4 of Annex IX,

— in the case of class IIa or class IIb devices, assess the technical documentation of devices selected on a representative basis,

— plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,

— relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,

— evaluate and verify a manufacturer's compliance with relevant Annexes.

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

4.5.2. Quality management system auditing

(a) As part of the assessment of the quality management system, a notified body shall prior to an audit and in accordance with its documented procedures:

— assess the documentation submitted in accordance with the relevant conformity assessment Annex, and draw up an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,

— identify links between, and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both,

— clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit, and draw up an audit plan that adequately addresses and takes account of the specific requirements for the devices, technologies and processes involved,

— draw up and keep up to date, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and

— select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.

(b) Based on the audit programme it has drawn up, the notified body shall, in accordance with its documented procedures:

— audit the manufacturer's quality management system, in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions of this Regulation which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of this Regulation are met,

— based on relevant technical documentation and in order to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment Annex, review and audit the manufacturer's processes and subsystems, in particular for:

— design and development,

— production and process controls,

— product documentation,

— purchasing controls including verification of purchased devices,

— corrective and preventive actions, including for post-market surveillance, and

— PMCF,

and review and audit requirements and provisions adopted by the manufacturer, including those in relation to fulfilling the general safety and performance requirements set out in Annex I.

The documentation shall be sampled in such a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information,

— if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,

— conduct assessments of the technical documentation based on its sampling plan and taking account of Sections 4.5.4. and 4.5.5. for pre-clinical and clinical evaluations, and

— the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards, or with best practice documents developed or adopted by the MDCG.

4.5.3. Product verification

Assessment of the technical documentation

For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX, notified bodies shall have sufficient expertise, facilities and documented procedures for:

— the allocation of appropriately qualified and authorised personnel for the examination of individual aspects such as use of the device, biocompatibility, clinical evaluation, risk management, and sterilisation, and

— the assessment of conformity of the design with this Regulation, and for taking account of Sections 4.5.4. to 4.5.6. That assessment shall include examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof. If further tests or other evidence is required for the assessment of conformity with the requirements of this Regulation, the notified body in question shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Type-examinations

The notified body shall have documented procedures, sufficient expertise and facilities for the type-examination of devices in accordance with Annex X including the capacity to:

— examine and assess the technical documentation taking account of Sections 4.5.4. to 4.5.6., and verify that the type has been manufactured in conformity with that documentation;

— establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility;

— document its rationale for the selection of those parameters;

— carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements set out in Annex I. Such examinations and tests shall include all tests necessary to verify that the manufacturer has in fact applied the relevant standards it has opted to use;

— agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body; and

— assume full responsibility for test results. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

Verification by examination and testing of every product

The notified body shall:

(a) have documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product in accordance with Part B of Annex XI;

(b) establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:

— verify, for class IIb devices, the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to those devices,

— confirm, for class IIa devices, the conformity with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to those devices;

(c) document its rationale for the selection of the parameters referred to in point (b);

(d) have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation by examining and testing every product as specified in Section 15 of Annex XI;

(e) have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed; and

(f) assume full responsibility for test results in accordance with documented procedures; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

4.5.4. Pre-clinical evaluation assessment

The notified body shall have documented procedures in place for the review of the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:

(a) the planning, conduct, assessment, reporting and, where appropriate, updating of the pre-clinical evaluation, in particular of

— the scientific pre-clinical literature search, and

— the pre-clinical testing, for example laboratory testing, simulated use testing, computer modelling, the use of animal models,

(b) the nature and duration of body contact and the specific associated biological risks,

(c) the interface with the risk management process, and

(d) the appraisal and analysis of the available pre-clinical data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I.

The notified body's assessment of pre-clinical evaluation procedures and documentation shall address the results of literature searches and all validation, verification and testing performed and conclusions drawn, and shall typically include considering the use of alternative materials and substances and take account of the packaging, stability, including shelf life, of the finished device. Where no new testing has been undertaken by a manufacturer or where there are deviations from procedures, the notified body in question shall critically examine the justification presented by the manufacturer.

4.5.5. Clinical evaluation assessment

The notified body shall have documented procedures in place relating to the assessment of a manufacturer's procedures and documentation relating to clinical evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that manufacturers' procedures and documentation adequately address:

— the planning, conduct, assessment, reporting and updating of the clinical evaluation as referred to in Annex XIV,

— post-market surveillance and PMCF,

— the interface with the risk management process,

— the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I, and

— the conclusions drawn with regard to the clinical evidence and drawing up of the clinical evaluation report.

These procedures referred to in the first paragraph shall take into consideration available CS, guidance and best practice documents.

The notified body's assessment of clinical evaluations as referred to in Annex XIV shall cover:

— the intended use specified by the manufacturer and claims for the device defined by it,

— the planning of the clinical evaluation,

— the methodology for the literature search,

— relevant documentation from the literature search,

— the clinical investigation,

— validity of equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

— post-market surveillance and PMCF,

— the clinical evaluation report, and

— justifications in relation to non-performance of clinical investigations or PMCF.

In relation to clinical data from clinical investigations included within the clinical evaluation, the notified body in question shall ensure that the conclusions drawn by the manufacturer are valid in the light of the approved clinical investigation plan.

The notified body shall ensure that the clinical evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements, that it is conducted in accordance with Annex XIV and that it is appropriately reflected in the information provided relating to the device.

4.5.6. Specific Procedures

The notified body shall have documented procedures, sufficient expertise and facilities for the procedures referred to in Sections 5 and 6 of Annex IX, Section 6 of Annex X and Section 16 of Annex XI, for which they are designated.

In the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, such as from TSE susceptible species, as referred to in Regulation (EU) No 722/2012, the notified body shall have documented procedures in place that fulfil the requirements laid down in that Regulation, including for the preparation of a summary evaluation report for the relevant competent authority.

4.6. Reporting

The notified body shall:

— ensure that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can represent objective evidence of such compliance to persons that are not themselves involved in the assessment, for example personnel in designating authorities,

— ensure that records that are sufficient to provide a discernible audit trail are available for quality management system audits,

— clearly document the conclusions of its assessment of clinical evaluation in a clinical evaluation assessment report, and

— for each specific project, provide a detailed report which shall be based on a standard format containing a minimum set of elements determined by the MDCG.

The report of the notified body shall:

— clearly document the outcome of its assessment and draw clear conclusions from the verification of the manufacturer's conformity with the requirements of this Regulation,

— make a recommendation for a final review and for a final decision to be taken by the notified body; this recommendation shall be signed off by the member of personnel responsible in the notified body, and

— be provided to the manufacturer in question.

4.7. Final review

The notified body shall prior to making a final decision:

— ensure that the personnel assigned for the final review and decision-making on specific projects are appropriately authorised and are different from the personnel who have conducted the assessments,

— verify that the report or reports and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and

— verify whether there are any unresolved non-conformities preventing issuance of a certificate.

4.8. Decisions and Certifications

The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:

— decide, based on the assessment documentation and additional information available, whether the requirements of this Regulation are fulfilled,

— decide, based on the results of its assessment of the clinical evaluation and risk management, whether the post-market surveillance plan, including the PMCF plan, is adequate,

— decide on specific milestones for further review by the notified body of the up to date clinical evaluation,

— decide whether specific conditions or provisions need to be defined for the certification,

— decide, based on the novelty, risk classification, clinical evaluation and conclusions from the risk analysis of the device, on a period of certification not exceeding five years,

— clearly document decision making and approval steps including approval by signature of the members of personnel responsible,

— clearly document responsibilities and mechanisms for communication of decisions, in particular, where the final signatory of a certificate differs from the decision maker or decision makers or does not fulfil the requirements laid down in Section 3.2.7,

— issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification,

— issue a certificate or certificates for the applicant alone and shall not issue certificates covering multiple entities, and

— ensure that the manufacturer is notified of the outcome of the assessment and the resultant decision and that they are entered into the electronic system referred to in Article 57.

4.9. Changes and modifications

The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the manufacturers' information obligations and the assessment of changes to:

— the approved quality management system or systems or to the product-range covered,

— the approved design of a device,

— the intended use of or claims made for the device,

— the approved type of a device, and

— any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6.

The procedures and contractual arrangements referred to in the first paragraph shall include measures for checking the significance of the changes referred to in the first paragraph.

In accordance with its documented procedures, the notified body in question shall:

— ensure that manufacturers submit for prior approval plans for changes as referred to in the first paragraph and relevant information relating to such changes,

— assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of this Regulation, and

— notify the manufacturer of its decision and provide a report or as applicable a supplementary report, which shall contain the justified conclusions of its assessment.

4.10. Surveillance activities and post-certification monitoring

The notified body shall have documented procedures:

— defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,

— for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. Such information shall be taken into account in the planning and conduct of surveillance activities, and

— to review vigilance data to which they have access under Article 92(2) in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

The notified body in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide which of the following options to apply:

— not to take action on the basis that the vigilance case is clearly not related to the certification granted,

— observe the manufacturer's and competent authority's activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,

— perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, where it is likely that the certification granted is at risk,

— increase the frequency of surveillance audits,

— review specific products or processes on the occasion of the next audit of the manufacturer, or

— take any other relevant measure.

In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:

— conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5,

— ensure adequate assessment of the manufacturer's documentation on, and application of the provisions on, vigilance, the post-market surveillance, and PMCF,

— sample and test devices and technical documentation, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,

— ensure that the manufacturer complies with the documentation and information obligations laid down in the relevant Annexes and that its procedures take into account best practices in the implementation of quality management systems,

— ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,

— gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,

— ask the manufacturer, if non-conformities are detected, for corrections, corrective actions and, where applicable, preventive actions, and

— where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw it.

The notified body shall, if listed as part of the conditions for certification:

— conduct an in-depth review of the clinical evaluation as most recently updated by the manufacturer based on the manufacturer's post-market surveillance, on its PMCF and on clinical literature relevant to the condition being treated with the device or on clinical literature relevant to similar devices,

— clearly document the outcome of the in-depth review and address any specific concerns to the manufacturer or impose any specific conditions on it, and

— ensure that the clinical evaluation as most recently updated, is appropriately reflected in the instructions for use and, where applicable, the summary of safety and performance.

4.11. Re-certification

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device, including changes not yet notified,

(b) experience gained from post-market surveillance,

(c) experience from risk management,

(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

(e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,

(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

(g) changes to applied or new harmonised standards, CS or equivalent documents, and

(h) changes in medical, scientific and technical knowledge, such as:

— new treatments,

— changes in test methods,

— new scientific findings on materials and components, including findings on their biocompatibility,

— experience from studies on comparable devices,

— data from registers and registries,

— experience from clinical investigations with comparable devices.

The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports.

For the decision on re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps taken for certification such as application and application review.

ANNEX VIII

CLASSIFICATION RULES

CHAPTER I

DEFINITIONS SPECIFIC TO CLASSIFICATION RULES

1. DURATION OF USE

1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.

1.2. 'Short term' means normally intended for continuous use for between 60 minutes and 30 days.

1.3. 'Long term' means normally intended for continuous use for more than 30 days.

2. INVASIVE AND ACTIVE DEVICES

2.1. 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

2.2. 'Surgically invasive device' means:

(a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and

(b) a device which produces penetration other than through a body orifice.

2.3. 'Reusable surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

2.4. 'Active therapeutic device' means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

2.5. 'Active device intended for diagnosis and monitoring' means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

2.6. 'Central circulatory system' means the following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens* to the *bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior* and *vena cava inferior*.

2.7. 'Central nervous system' means the brain, meninges and spinal cord.

2.8. 'Injured skin or mucous membrane' means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

CHAPTER II

IMPLEMENTING RULES

3.1. Application of the classification rules shall be governed by the intended purpose of the devices.

3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.

3.3. Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

If the software is independent of any other device, it shall be classified in its own right.

3.4. If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

3.5. If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.

3.6. In calculating the duration referred to in Section 1, continuous use shall mean:

(a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and

(b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

3.7. A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

CHAPTER III

CLASSIFICATION RULES

4. NON-INVASIVE DEVICES

4.1. Rule 1

All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

4.2. Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

— if they may be connected to a class IIa, class IIb or class III active device; or

— if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.

In all other cases, such devices are classified as class I.

4.3. Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.

All non-invasive devices consisting of a substance or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body are classified as class III.

4.4. Rule 4

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

— class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

— class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;

— class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and

— class IIa in all other cases.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.

5. INVASIVE DEVICES

5.1. Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:

— class I if they are intended for transient use;

— class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and

— class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

5.2. Rule 6

All surgically invasive devices intended for transient use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are reusable surgical instruments, in which case they are classified as class I;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or

— are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

5.3. Rule 7

All surgically invasive devices intended for short-term use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or

— are intended to administer medicines, in which case they are classified as class IIb.

5.4. Rule 8

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

— are intended to be placed in the teeth, in which case they are classified as class IIa;

— are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;

— have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

— are intended to administer medicinal products, in which case they are classified as class III;

— are active implantable devices or their accessories, in which cases they are classified as class III;

— are breast implants or surgical meshes, in which cases they are classified as class III;

— are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or

— are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

6. ACTIVE DEVICES

6.1. Rule 9

All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

6.2. Rule 10

Active devices intended for diagnosis and monitoring are classified as class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;

— if they are intended to image *in vivo* distribution of radiopharmaceuticals; or

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

6.3. Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

— death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

6.4. Rule 12

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

6.5. Rule 13

All other active devices are classified as class I.

7. SPECIAL RULES

7.1. Rule 14

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.

7.2. Rule 15

All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

7.3. Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

7.4. Rule 17

Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

7.5. Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

7.6. Rule 19

All devices incorporating or consisting of nanomaterial are classified as:

— class III if they present a high or medium potential for internal exposure;

— class IIb if they present a low potential for internal exposure; and

— class IIa if they present a negligible potential for internal exposure.

7.7. Rule 20

All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as class IIb.

7.8. Rule 21

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

— class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;

— class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

— class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and

— class IIb in all other cases.

7.9. Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2 and shall be subject to audit, as laid down in Sections 2.3 and 2.4, and to surveillance as specified in Section 3.

2. Quality management system assessment

2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business,

— all relevant information on the device or group of devices covered by the quality management system,

— a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,

— a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,

— the documentation on the manufacturer's quality management system,

— a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures,

— a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

— the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,

— a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,

— documentation on the clinical evaluation plan, and

— a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

2.2. Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

— the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,

— the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,

— where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party, and

— where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:

— the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,

— identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account,

— risk management as referred to in Section 3 of Annex I,

— the clinical evaluation, pursuant to Article 61 and Annex XIV, including post-market clinical follow-up,

— solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,

— solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,

— the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and

— management of design or quality management system changes; and

(d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents; and

(e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

2.3. Audit

The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiates not doing so.

The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing representative samples, the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 105 and in particular the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.

If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.

2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

3. Surveillance assessment applicable to class IIa, class IIb and class III devices

3.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system.

3.2. The manufacturer shall give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

— the documentation on its quality management system,

— documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 87 to 92,

— the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I, and

— the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, sampling referred to in the second paragraph, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer in question with an on-site audit report which shall include, if applicable, the result of the sample test.

3.5. In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.

In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

3.6. The notified body shall ensure that the composition of the assessment team is such that there is sufficient experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall neither lead nor attend audits for more than three consecutive years in respect of the same manufacturer.

3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation applicable to class III devices and to the class IIb devices referred to in the second subparagraph of Article 52(4)

4.1. In addition to the obligations laid down in Section 2, the manufacturer shall lodge with the notified body an application for assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

4.3. The notified body shall examine the application by using staff, employed by it, with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

4.4. The notified body shall review the clinical evidence presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilised, for the purposes of that review.

4.5. The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess to what extent specific claims are supported by specific pre-clinical and clinical data and risk analysis.

4.6. The notified body shall verify that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable.

4.7. Based on its assessment of the clinical evidence, the notified body shall consider the clinical evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMCF data.

4.8. The notified body shall clearly document the outcome of its assessment in the clinical evaluation assessment report.

4.9. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a clinical evaluation assessment report. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the technical documentation assessment, the conditions of the certificate's validity, the data needed for identification of the approved design, and, where appropriate, a description of the intended purpose of the device.

4.10. Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

5. Specific additional procedures

5.1. Assessment procedure for certain class III and class IIb devices

(a) For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12), the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV.

The notified body shall transmit its clinical evaluation assessment report, along with the manufacturer's clinical evaluation documentation, referred to in points (c) and (d) of Section 6.1 of Annex II, to the Commission.

The Commission shall immediately transmit those documents to the relevant expert panel referred to in Article 106.

(b) The notified body may be requested to present its conclusions as referred to in point (a) to the expert panel concerned.

(c) The expert panel shall decide, under the supervision of the Commission, on the basis of all of the following criteria:

(i) the novelty of the device or of the related clinical procedure involved, and the possible major clinical or health impact thereof;

(ii) a significantly adverse change in the benefit-risk profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure of the device;

(iii) a significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices,

whether to provide a scientific opinion on the clinical evaluation assessment report of the notified body based on the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the medical indication or indications and the PMCF plan. That scientific opinion shall be provided within a period of 60 days, starting on the day of receipt of the documents from the Commission as referred to in point (a). The reasons for the decision to provide a scientific opinion on the basis of the criteria in points (i), (ii) and (iii) shall be included in the scientific opinion. Where the information submitted is not sufficient for the expert panel to reach a conclusion, this shall be stated in the scientific opinion.

(d) The expert panel may decide, under the supervision of the Commission, on the basis of the criteria laid down in point (c) not to provide a scientific opinion, in which case it shall inform the notified body as soon as possible and in any event within 21 days of receipt of the documents as referred to in point (a) from the Commission. The expert panel shall within that time limit provide the notified body and the Commission with the reasons for its decision, whereupon the notified body may proceed with the certification procedure of that device.

(e) The expert panel shall within 21 days of receipt of the documents from the Commission notify the Commission, through Eudamed whether it intends to provide a scientific opinion, pursuant to point (c), or whether it intends not to provide a scientific opinion, pursuant to point (d).

(f) Where no opinion has been delivered within a period of 60 days, the notified body may proceed with the certification procedure of the device in question.

(g) The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. Where the expert panel finds that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s), and with the PMCF plan, the notified body shall, if necessary, advise the manufacturer to restrict the intended purpose of the device to certain groups of patients or certain medical indications and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and performance, or to impose other restrictions in its conformity assessment report, as appropriate. The notified body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report and the Commission shall without prejudice to Article 109 make both the scientific opinion of the expert panel and the written justification provided by the notified body publicly available via Eudamed.

(h) The Commission, after consultation with the Member States and relevant scientific experts shall provide guidance for expert panels for consistent interpretation of the criteria in point (c) before 26 May 2020.

5.2. Procedure in the case of devices incorporating a medicinal substance

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma and that has an action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(b) Before issuing an EU technical documentation assessment certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately, may be considered to be a medicinal product falling exclusively within the scope of the Annex to Regulation (EC) No 726/2004, the notified body shall seek the opinion of the EMA.

(c) When issuing its opinion, the medicinal products authority consulted shall take into account the manufacturing process and the data relating to the usefulness of incorporation of the substance into the device as determined by the notified body.

(d) The medicinal products authority consulted shall provide its opinion to the notified body within 210 days of receipt of all the necessary documentation.

(e) The scientific opinion of the medicinal products authority consulted, and any possible update of that opinion, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable and shall convey its final decision to the medicinal products authority consulted.

(f) Before any change is made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes. That notified body shall seek the opinion of the medicinal products authority consulted, in order to confirm that the quality and safety of the ancillary substance remain unchanged. The medicinal products authority consulted shall take into account the data relating to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the risk or benefit previously established concerning the incorporation of the substance into the device. The medicinal products authority consulted shall provide its opinion within 60 days after receipt of all the necessary documentation regarding the changes. The notified body shall not deliver the supplement to the EU technical documentation assessment certificate if the scientific opinion provided by the medicinal products authority consulted is unfavourable. The notified body shall convey its final decision to the medicinal products authority consulted.

(g) Where the medicinal products authority consulted obtains information on the ancillary substance, which could have an impact on the risk or benefit previously established concerning the incorporation of the substance into the device, it shall advise the notified body as to whether this information has an impact on the risk or benefit previously established concerning the incorporation of the substance into the device. The notified body shall take that advice into account in reconsidering its assessment of the conformity assessment procedure.

5.3. Procedure in the case of devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

5.3.1. Tissues or cells of human origin or their derivatives

(a) For devices manufactured utilising derivatives of tissues or cells of human origin that are covered by this Regulation in accordance with point (g) of Article 1(6) and for devices that incorporate, as an integral part, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, that have an action ancillary to that of the device, the notified body shall, prior to issuing an EU technical documentation assessment certificate, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2004/23/EC ('human tissues and cells competent authority') on the aspects relating to the donation, procurement and testing of tissues or cells of human origin or their derivatives. The notified body shall submit a summary of the preliminary conformity assessment which provides, among other things, information about the non-viability of the human tissues or cells in question, their donation, procurement and testing and the risk or benefit of the incorporation of the tissues or cells of human origin or their derivatives into the device.

(b) Within 120 days of receipt of all the necessary documentation, the human tissues and cells competent authority shall provide to the notified body its opinion.

(c) The scientific opinion of the human tissues and cells competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the human tissues and cells competent authority when making its decision. The notified body shall not deliver the certificate if that scientific opinion is unfavourable. It shall convey its final decision to the human tissues and cells competent authority concerned.

(d) Before any change is made with respect to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing or procurement, the manufacturer shall inform the notified body of the intended changes. The notified body shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the tissues or cells of human origin or their derivatives incorporated in the device are maintained. The human tissues and cells competent authority concerned shall take into account the data relating to the usefulness of incorporation of the tissues or cells of human origin or their derivatives into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit-risk ratio of the addition of the tissues or cells of human origin or their derivatives in the device. It shall provide its opinion within 60 days of receipt of all the necessary documentation regarding the intended changes. The notified body shall not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable and shall convey its final decision to the human tissues and cells competent authority concerned.

5.3.2. Tissues or cells of animal origin or their derivatives

In the case of devices manufactured utilising animal tissue which is rendered non-viable or utilising non-viable products derived from animal tissue, as referred to in Regulation (EU) No 722/2012, the notified body shall apply the relevant requirements laid down in that Regulation.

5.4. Procedure in the case of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

(a) The quality and safety of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by, or locally dispersed in, the human body, shall be verified where applicable and only in respect of the requirements not covered by this Regulation, in accordance with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.

(b) In addition, for devices, or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, the notified body shall seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, on the compliance of the device with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

(c) The opinion of the medicinal products authority consulted shall be drawn up within 150 days of receipt of all the necessary documentation.

(d) The scientific opinion of the medicinal products authority consulted, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision and shall convey its final decision to the medicinal products authority consulted.

6. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in Article 1(8)

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood

or human plasma as referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

CHAPTER III

ADMINISTRATIVE PROVISIONS

7. The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1 and in particular the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2,

— information on the changes referred to in Section 2.4,

— the documentation referred to in Section 4.2, and

— the decisions and reports from the notified body as referred to in this Annex.

8. Each Member State shall require that the documentation referred to in Section 7 is kept at the disposal of competent authorities for the period indicated in that Section in case a manufacturer, or its authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of that period.

ANNEX X

CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.

2. Application

The manufacturer shall lodge an application for assessment with a notified body. The application shall include:

— the name of the manufacturer and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business,

— the technical documentation referred to in Annexes II and III. The applicant shall make a representative sample of the device production envisaged ('type') available to the notified body. The notified body may request other samples as necessary, and

— a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

3. Assessment

The notified body shall:

(a) examine the application by using staff with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests;

(b) examine and assess the technical documentation for conformity with the requirements of this Regulation that are applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable standards referred to in Article 8 or with applicable CS, and record the items not designed on the basis of the relevant standards referred to in Article 8 or of the relevant CS;

(c) review the clinical evidence presented by the manufacturer in the clinical evaluation report in accordance with Section 4 of Annex XIV. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or to the clinical condition in which it is utilised, for the purposes of that review;

(d) in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity;

(e) clearly document the outcome of its assessment in a pre-clinical and clinical evaluation assessment report as part of the EU type examination report referred to in point (i);

(f) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements laid down in this Regulation, in the event that the standards referred to in Article 8 or the CS have not been applied. Where the device has to be connected to another device or devices in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device or devices having the characteristics specified by the manufacturer;

(g) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, in the event that the manufacturer has chosen to apply the relevant harmonised standards, those standards have actually been applied;

(h) agree with the applicant on the place where the necessary assessments and tests are to be carried out; and

(i) draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g).

4. Certificate

If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the type examination assessment, the conditions of the certificate's validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XII. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

5.2. Changes to the approved device including limitations of its intended purpose and conditions of use shall require approval from the notified body which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate.

5.3. Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall necessitate a new application for a conformity assessment.

6. Specific additional procedures

Section 5 of Annex IX shall apply with the proviso that any reference to an EU technical documentation assessment certificate shall be understood as a reference to an EU type-examination certificate.

7. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the documentation referred to in the second indent of Section 2,

— information on the changes referred to in Section 5, and

— copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Section 8 of Annex IX shall apply.

ANNEX XI

CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued, and that they meet the provisions of this Regulation which apply to them.

2. Where an EU type-examination certificate has been issued in accordance with Annex X, the manufacturer may either apply the procedure set out in Part A (production quality assurance) or the procedure set out in Part B (product verification) of this Annex.

3. By way of derogation from Sections 1 and 2 above, the procedures in this Annex coupled with the drawing up of technical documentation as set out in Annexes II and III may also be applied by manufacturers of class IIa devices.

PART A

PRODUCTION QUALITY ASSURANCE

4. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out a final verification, as specified in Section 6, and shall be subject to the surveillance referred to in Section 7.

5. When the manufacturer fulfils the obligations laid down in Section 4, it shall draw up and keep an EU declaration of conformity in accordance with Article 19 and Annex IV for the device covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure and to declare that the device concerned conforms to the type described in the EU type-examination certificate and meets the requirements of this Regulation which apply to the device.

6. Quality management system

6.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— all elements listed in Section 2.1 of Annex IX,

— the technical documentation referred to in Annexes II and III for the types approved, and

— a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

6.2. Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

That documentation shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 2.2 of Annex IX.

6.3. The first and second paragraph of Section 2.3 of Annex IX shall apply.

If the quality management system is such that it ensures that the devices conform to the type described in the EU type-examination certificate and that it conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. That decision shall contain the conclusions of the notified body's audit and a reasoned assessment.

6.4. Section 2.4 of Annex IX shall apply.

7. Surveillance

Section 3.1, the first, second and fourth indents of Section 3.2, Sections 3.3, 3.4, 3.6 and 3.7 of Annex IX shall apply.

In the case of class III devices, surveillance shall also include a check that the quantities of produced or purchased raw material or crucial components approved for the type and correspond to the quantities of finished devices.

8. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

9. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1 of Annex IX,

— the documentation referred to in the eighth indent of Section 2.1 of Annex IX, including the EU type-examination certificate referred to in Annex X,

— information on the changes referred to in Section 2.4 of Annex IX, and

— the decisions and reports from the notified body as referred to in Sections 2.3, 3.3 and 3.4 of Annex IX.

Section 8 of Annex IX shall apply.

10. Application to class IIa devices

10.1. By way of derogation from Section 5, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10.2. For class IIa devices the notified body shall assess, as part of the assessment referred to in Section 6.3, whether the technical documentation as referred to in Annexes II and III for the devices selected on a representative basis is compliant with this Regulation.

In choosing a representative sample or samples of devices, the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical, biological or clinical properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample or samples of devices taken.

10.3. Where the assessment under Section 10.2. confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

10.4. Samples additional to those taken for the initial conformity assessment of devices shall be assessed by the notified body as part of the surveillance assessment referred to in Section 7.

10.5. By way of derogation from Section 6, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the technical documentation referred to in Annexes II and III, and

— the certificate referred to in Section 10.3.

Section 8 of Annex IX shall apply.

PART B

PRODUCT VERIFICATION

11. Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing an EU declaration of conformity in accordance with Article 19 and Annex IV, shall be deemed to ensure and to declare that the devices which have been subject to the procedure set out in Sections 14 and 15 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them.

12. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Prior to the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all routine, pre-established procedures to be implemented to ensure homogeneous production and, where appropriate, conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 6 and 7.

13. The manufacturer shall undertake to institute and keep up to date a post-market surveillance plan, including a PMCF plan, and the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in Chapter VII.

14. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 15.

The examinations and tests referred to in the first paragraph of this Section shall not apply to aspects of the manufacturing process designed to secure sterility.

15. Verification by examination and testing of every product

15.1. Every device shall be examined individually and the appropriate physical or laboratory tests as defined in the relevant standard or standards referred to in Article 8, or equivalent tests and assessments, shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

15.2. The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests and assessments carried out.

16. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

17. Administrative provisions

The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in Section 12,

— the certificate referred to in Section 15.2, and

— the EU type-examination certificate referred to in Annex X.

Section 8 of Annex IX shall apply.

18. Application to class IIa devices

18.1. By way of derogation from Section 11, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

18.2. The verification conducted by the notified body in accordance with Section 14 is intended to confirm the conformity of the class IIa devices in question with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to them.

18.3. If the verification referred to in Section 18.2 confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

18.4. By way of derogation from Section 17, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the technical documentation referred to in Annexes II and III, and

— the certificate referred to in Section 18.3.

Section 8 of Annex IX shall apply.

ANNEX XII

CERTIFICATES ISSUED BY A NOTIFIED BODY

CHAPTER I

GENERAL REQUIREMENTS

1. Certificates shall be drawn up in one of the official languages of the Union.

2. Each certificate shall refer to only one conformity assessment procedure.

3. Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 30.

4. The scope of the certificates shall unambiguously identify the device or devices covered:

   (a) EU technical documentation assessment certificates, EU type-examination certificates and EU product verification certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose, as included by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure, risk classification and the Basic UDI-DI as referred to in Article 27(6);

   (b) EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and, for class IIb devices, the intended purpose.

5. The notified body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The notified body shall set up a system that enables the determination of the devices, including their classification, covered by the certificate.

6. Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7. EU quality management system certificates and EU quality assurance certificates for class I devices for which the involvement of a notified body is required pursuant to Article 52(7) shall include a statement that the audit by the notified body of the quality management system was limited to the aspects required under that paragraph.

8. Where a certificate is supplemented, modified or re-issued, the new certificate shall contain a reference to the preceding certificate and its date of issue with identification of the changes.

CHAPTER II

MINIMUM CONTENT OF THE CERTIFICATES

1. name, address and identification number of the notified body;

2. name and address of the manufacturer and, if applicable, of the authorised representative;

3. unique number identifying the certificate;

4. if already issued, the SRN of the manufacturer referred to in to Article 31(2);

5. date of issue;

6. date of expiry;

7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Part I;

8. if applicable, reference to any previous certificate as specified in Section 8 of Chapter I;

9. reference to this Regulation and the relevant Annex in accordance with which the conformity assessment has been carried out;

10. examinations and tests performed, e.g. reference to relevant CS, harmonised standards, test reports and audit report(s);

11. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered;

12. if applicable, information about the surveillance by the notified body;

13. conclusions of the notified body's conformity assessment with regard to the relevant Annex;

14. conditions for or limitations to the validity of the certificate;

15. legally binding signature of the notified body in accordance with the applicable national law.

ANNEX XIII

PROCEDURE FOR CUSTOM-MADE DEVICES

1. For custom-made devices, the manufacturer or its authorised representative shall draw up a statement containing all of the following information:

   — the name and address of the manufacturer, and of all manufacturing sites,

   — if applicable, the name and address of the authorised representative,

   — data allowing identification of the device in question,

   — a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,

   — the name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so, and, where applicable, the name of the health institution concerned,

   — the specific characteristics of the product as indicated by the prescription,

   — a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,

   — where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012.

2. The manufacturer shall undertake to keep available for the competent national authorities documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of this Regulation.

3. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in Section 2.

4. The statement referred to in the introductory part of Section 1 shall be kept for a period of at least 10 years after the device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

   Section 8 of Annex IX shall apply.

5. The manufacturer shall review and document experience gained in the post-production phase, including from PMCF as referred to in Part B of Annex XIV, and implement appropriate means to apply any necessary corrective action, In that context, it shall report in accordance with Article 87(1) to the competent authorities any serious incidents or field safety corrective actions or both as soon as it learns of them.

ANNEX XIV

CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

PART A

CLINICAL EVALUATION

1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

   (a) establish and update a clinical evaluation plan, which shall include at least:

   — an identification of the general safety and performance requirements that require support from relevant clinical data;

   — a specification of the intended purpose of the device;

   — a clear specification of intended target groups with clear indications and contra-indications;

   — a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;

   — a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;

   — an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;

   — an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed; and

   — a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;

   (b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;

   (c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

   (d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and

   (e) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

2. The clinical evaluation shall be thorough and objective, and take into account both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's claims in respect of the device.

3. A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

   — Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

   — Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

— Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

4. The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device.

The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation for the device in question.

Both favourable and unfavourable data considered in the clinical evaluation shall be included in the technical documentation.

PART B

POST-MARKET CLINICAL FOLLOW-UP

5. PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

6. PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.

6.1. The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

(a) confirming the safety and performance of the device throughout its expected lifetime,

(b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,

(c) identifying and analysing emergent risks on the basis of factual evidence,

(d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and

(e) identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

6.2. The PMCF plan shall include at least:

(a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

(b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I;

(e) the specific objectives to be addressed by the PMCF;

(f) an evaluation of the clinical data relating to equivalent or similar devices;

(g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and

(h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.

7. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.

8. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

ANNEX XV

CLINICAL INVESTIGATIONS

CHAPTER I

GENERAL REQUIREMENTS

1. Ethical principles

Each step in the clinical investigation, from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

2. Methods

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims regarding the safety, performance and aspects relating to benefit-risk of devices as referred to in Article 62(1); the clinical investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions. The rationale for the design and chosen statistical methodology shall be presented as further described in Section 3.6 of Chapter II of this Annex.

2.2. The procedures used to perform the clinical investigation shall be appropriate to the device under investigation.

2.3. The research methodologies used to perform the clinical investigation shall be appropriate to the device under investigation.

2.4. Clinical investigations shall be performed in accordance with the clinical investigation plan by a sufficient number of intended users and in a clinical environment that is representative of the intended normal conditions of use of the device in the target patient population. Clinical investigations shall be in line with the clinical evaluation plan as referred to in Part A of Annex XIV.

2.5. All the appropriate technical and functional features of the device, in particular those involving safety and performance, and their expected clinical outcomes shall be appropriately addressed in the investigational design. A list of the technical and functional features of the device and the related expected clinical outcomes shall be provided.

2.6. The endpoints of the clinical investigation shall address the intended purpose, clinical benefits, performance and safety of the device. The endpoints shall be determined and assessed using scientifically valid methodologies. The primary endpoint shall be appropriate to the device and clinically relevant.

2.7. Investigators shall have access to the technical and clinical data regarding the device. Personnel involved in the conduct of an investigation shall be adequately instructed and trained in the proper use of the investigational device, and as regards the clinical investigation plan and good clinical practice. This training shall be verified and where necessary arranged by the sponsor and documented appropriately.

2.8. The clinical investigation report, signed by the investigator, shall contain a critical evaluation of all the data collected during the clinical investigation, and shall include any negative findings.

CHAPTER II

DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION

For investigational devices covered by Article 62, the sponsor shall draw up and submit the application in accordance with Article 70 accompanied by the following documents:

1. Application form

The application form shall be duly filled in, containing information regarding:

1.1. name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with Article 62(2) established in the Union;

1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of its authorised representative;

1.3. title of the clinical investigation;

1.4. status of the clinical investigation application (i.e. first submission, resubmission, significant amendment);

1.5. details and/or reference to the clinical evaluation plan;

1.6. If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;

1.7. if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial;

1.8. identification of the Member States and third countries in which the clinical investigation is to be conducted as part of a multicentre or multinational study at the time of application;

1.9. a brief description of the investigational device, its classification and other information necessary for the identification of the device and device type;

1.10. information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives;

1.11. summary of the clinical investigation plan including the objective or objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation;

1.12. if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;

1.13. evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical investigation in accordance with the clinical investigation plan;

1.14. details of the anticipated start date and duration of the investigation;

1.15. details to identify the notified body, if already involved at the stage of application for a clinical investigation;

1.16. confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application; and

1.17. the statement referred to in Section 4.1.

2. Investigator's Brochure

The investigator's brochure (IB) shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application. Any updates to the IB or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Annex VIII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed on the label, and instructions for use to be provided with the device when placed on the market. In addition, information relating to any relevant training required.

2.3. Pre-clinical evaluation based on relevant pre-clinical testing and experimental data, in particular regarding in-design calculations, *in vitro* tests, *ex vivo* tests, animal tests, mechanical or electrical tests, reliability tests, sterilisation validation, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, as applicable.

2.4. Existing clinical data, in particular:

— from relevant scientific literature available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of the device and/or of equivalent or similar devices;

— other relevant clinical data available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, clinical benefit and safety-related issues and any corrective actions taken.

2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings.

2.6. In the case of devices that incorporate a medicinal substance, including a human blood or plasma derivative or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues, cells or their derivatives, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues, cells or their derivatives, as well as evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device.

2.7. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking.

2.8. A detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice.

3. Clinical Investigation Plan

The clinical investigation plan (CIP) shall set out the rationale, objectives, design methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation. It shall contain in particular the information as laid down in this Annex. If part of this information is submitted in a separate document, it shall be referenced in the CIP.

3.1. General

3.1.1. Single identification number of the clinical investigation, as referred to in Article 70(1).

3.1.2. Identification of the sponsor — name, address and contact details of the sponsor and, where applicable, the name, address and contact details of the sponsor's contact person or legal representative in accordance with Article 62(2) established in the Union.

3.1.3. Information on the principal investigator at each investigational site, the coordinating investigator for the investigation, the address details for each investigational site and the emergency contact details for the principal investigator at each site. The roles, responsibilities and qualifications of the various kinds of investigators shall be specified in the CIP.

3.1.4. A brief description of how the clinical investigation is financed and a brief description of the agreement between the sponsor and the site.

3.1.5. Overall synopsis of the clinical investigation, in an official Union language determined by the Member State concerned.

3.2. Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use, background literature review, the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device.

3.3. Risks and clinical benefits of the device to be examined, with justification of the corresponding expected clinical outcomes in the clinical investigation plan.

3.4. Description of the relevance of the clinical investigation in the context of the state of the art of clinical practice.

3.5. Objectives and hypotheses of the clinical investigation.

3.6. Design of the clinical investigation with evidence of its scientific robustness and validity.

3.6.1. General information such as type of investigation with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation plan.

3.6.2. Information on the investigational device, on any comparator and on any other device or medication to be used in the clinical investigation.

3.6.3. Information on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immuno-compromised or, elderly subjects.

3.6.4. Details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors.

3.6.5. Description of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice.

3.6.6. Monitoring plan.

3.7. Statistical considerations, with justification, including a power calculation for the sample size, if applicable.

3.8. Data management.

3.9. Information about any amendments to the CIP.

3.10. Policy regarding follow-up and management of any deviations from the CIP at the investigational site and clear prohibition of use of waivers from the CIP.

3.11. Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices.

3.12. Statement of compliance with the recognised ethical principles for medical research involving humans, and the principles of good clinical practice in the field of clinical investigations of devices, as well as with the applicable regulatory requirements.

3.13. Description of the Informed consent process.

3.14. Safety reporting, including definitions of adverse events and serious adverse events, device deficiencies, procedures and timelines for reporting.

3.15. Criteria and procedures for follow-up of subjects following the end, temporary halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow-up. Such procedures shall for implantable devices, cover as a minimum traceability.

3.16. A description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question.

3.17. Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.

3.18. List of the technical and functional features of the device, with specific mention of those covered by the investigation.

3.19. Bibliography.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. Where applicable according to national law, copy of the opinion or opinions of the ethics committee or committees concerned. Where according to national law the opinion or opinions of the ethics committee or committees is not required at the time of the submission of the application, a copy of the opinion or opinions shall be submitted as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, pursuant to Article 69 and the corresponding national law.

4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

4.5. Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

— organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;

— a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects; and

— a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports, shall, upon request, be submitted to the competent authority reviewing an application.

CHAPTER III

OTHER OBLIGATIONS OF THE SPONSOR

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter II of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the investigational device, that obligation may be fulfilled by that person on behalf of the sponsor.

2. The Sponsor shall have an agreement in place to ensure that any serious adverse events or any other event as referred to in Article 80(2) are reported by the investigator or investigators to the sponsor in a timely manner.

3. The documentation mentioned in this Annex shall be kept for a period of at least 10 years after the clinical investigation with the device in question has ended, or, in the event that the device is subsequently placed on the market, at least 10 years after the last device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

   Each Member State shall require that this documentation is kept at the disposal of the competent authorities for the period referred to in the first subparagraph in case the sponsor, or its contact person or legal representative as referred to in Article 62(2) established within its territory, goes bankrupt or ceases its activity prior to the end of this period.

4. The Sponsor shall appoint a monitor that is independent from the investigational site to ensure that the investigation is conducted in accordance with the CIP, the principles of good clinical practice and this Regulation.

5. The Sponsor shall complete the follow-up of investigation subjects.

6. The Sponsor shall provide evidence that the investigation is being conducted in line with good clinical practice, for instance through internal or external inspection.

7. The Sponsor shall prepare a clinical investigation report which includes at least the following:

   — Cover/introductory page or pages indicating the title of the investigation, the investigational device, the single identification number, the CIP number and the details with signatures of the coordinating investigators and the principal investigators from each investigational site.

   — Details of the author and date of the report.

   — A summary of the investigation covering the title, purpose of the investigation, description of the investigation, investigational design and methods used, the results of the investigation and conclusion of the investigation. The completion date of the investigation, and in particular details of early termination, temporary halts or suspensions of investigations.

   — Investigational device description, in particular clearly defined intended purpose.

   — A summary of the clinical investigation plan covering objectives, design, ethical aspects, monitoring and quality measures, selection criteria, target patient populations, sample size, treatment schedules, follow-up duration, concomitant treatments, statistical plan, including hypothesis, sample size calculation and analysis methods, as well as a justification.

   — Results of the clinical investigation covering, with rationale and justification, subject demographics, analysis of results related to chosen endpoints, details of subgroup analysis, as well as compliance with the CIP, and covering follow-up of missing data and of patients withdrawing from the clinical investigation, or lost to follow-up.

   — Summary of serious adverse events, adverse device effects, device deficiencies and any relevant corrective actions.

   — Discussion and overall conclusions covering safety and performance results, assessment of risks and clinical benefits, discussion of clinical relevance in accordance with clinical state of the art, any specific precautions for specific patient populations, implications for the investigational device, limitations of the investigation.

ANNEX XVI

LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

1. Contact lenses or other items intended to be introduced into or onto the eye.

2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

ANNEX XVII

CORRELATION TABLE

Council Directive 90/385/EEC	Council Directive 93/42/EEC	This Regulation
Article 1(1)	Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)	Article 2
Article 1(3)	Article 1(3) first subparagraph	Article 1(9) first subparagraph
—	Article 1(3) second subparagraph	Article 1(9) second subparagraph
Article 1(4) and (4a)	Article 1(4) and (4a)	Article 1(8) first subparagraph
Article 1(5)	Article 1(7)	Article 1(11)
Article 1(6)	Article 1(5)	Article 1(6)
—	Article 1(6)	—
—	Article 1(8)	Article 1(13)
Article 2	Article 2	Article 5(1)
Article 3 first paragraph	Article 3 first paragraph	Article 5(2)
Article 3 second paragraph	Article 3 second paragraph	Article 1(12)
Article 4(1)	Article 4(1)	Article 24
Article 4(2)	Article 4(2)	Article 21(1) and (2)
Article 4(3)	Article 4(3)	Article 21(3)
Article 4(4)	Article 4(4)	Article 10(11)
Article 4(5)(a)	Article 4(5) first subparagraph	Article 20(6)
Article 4(5)(b)	Article 4(5) second subparagraph	—
Article 5(1)	Article 5(1)	Article 8(1)
Article 5(2)	Article 5(2)	Article 8(2)
Article 6(1)	Articles 5(3) and 6	—
Article 6(2)	Article 7(1)	Article 114
Article 7	Article 8	Articles 94 to 97
—	Article 9	Article 51
Article 8(1)	Article 10(1)	Articles 87(1) and 89 (2)
Article 8(2)	Article 10(2)	Article 87(10) and Article 87(11) first subparagraph
Article 8(3)	Article 10(3)	Article 89(7)
Article 8(4)	Article 10(4)	Article 91
Article 9(1)	Article 11(1)	Article 52(3)
—	Article 11(2)	Article 52(6)
—	Article 11(3)	Article 52(4) and (5)
—	Article 11(4)	—
—	Article 11(5)	Article 52(7)

Council Directive 90/385/EEC	Council Directive 93/42/EEC	This Regulation
Article 9(2)	Article 11 (6)	Article 52(8)
Article 9(3)	Article 11(8)	Article 11(3)
Article 9(4)	Article 11(12)	Article 52(12)
Article 9(5)	Article 11(7)	—
Article 9(6)	Article 11(9)	Article 53(1)
Article 9(7)	Article 11(10)	Article 53(4)
Article 9(8)	Article 11(11)	Article 56(2)
Article 9(9)	Article 11(13)	Article 59
Article 9(10)	Article 11(14)	Article 4(5) and Article 122 third paragraph
—	Article 12	Article 22
—	Article 12a	Article 17
Article 9a(1) first indent	Article 13(1)(c)	—
Article 9a(1) second indent	Article 13(1)(d)	Article 4(1)
—	Article 13(1)(a)	Article 51(3)(a) and Article 51(6)
—	Article 13(1)(b)	Article 51(3)(b) and Article 51(6)
Article 10	Article 15	Articles 62 to 82
Article 10a(1), second sentence of Article 10a(2) and Article 10a(3)	Article 14(1), second sentence of Article 14(2) and Article 14(3)	Articles 29(4), 30 and 31
Article 10a(2), first sentence	Article 14(2) first sentence	Article 11(1)
Article 10b	Article 14a	Articles 33 and 34
Article 10c	Article 14b	Article 98
Article 11(1)	Article 16(1)	Articles 42 and 43
Article 11(2)	Article 16(2)	Article 36
Article 11(3)	Article 16(3)	Article 46(4)
Article 11(4)	Article 16(4)	—
Article 11(5)	Article 16(5)	Article 56(5)
Article 11(6)	Article 16(6)	Article 56(4)
Article 11(7)	Article 16(7)	Articles 38(2) and 44(2)
Article 12	Article 17	Article 20
Article 13	Article 18	Articles 94 to 97
Article 14	Article 19	Article 99
Article 15	Article 20	Article 109
Article 15a	Article 20a	Article 102
Article 16	Article 22	—
Article 17	Article 23	—
—	Article 21	—

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Directive 98/79/EC of the European Parliament and of the Council ([3]) constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for *in vitro* diagnostic medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of *in vitro* diagnostic medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices by ensuring, among other things, that data generated in performance studies are reliable and robust and that the safety of subjects participating in performance studies is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of *in vitro* diagnostic medical devices after they have already been put into service, such as in the context of second-hand sales.

(4) Key elements of the existing regulatory approach, such as the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced, to improve health and safety.

(5) To the extent possible, guidance developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Harmonization Task Force and its follow-up initiative, the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of

([1]) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
([2]) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
([3]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical evidence.

(6) There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.

(7) The scope of application of this Regulation should be clearly delimited from other legislation concerning products, such as medical devices, general laboratory products and products for research use only.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification decisions in that regard across all Member States, particularly with regard to borderline cases, the Commission should be allowed to, on its own initiative or at the duly substantiated request of a Member State, having consulted the Medical Device Coordination Group ('MDCG'), decide on a case-by-case basis whether or not a specific product, category or group of products falls within the scope of this Regulation. When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) It appears that it is possible that divergent national rules regarding the provision of information and counselling in relation to genetic testing might only have an impact on the smooth functioning of the internal market to a limited extent. Therefore, it is appropriate to lay down only limited requirements in this regard in this Regulation, having regard to the need to ensure constant respect of the principles of proportionality and subsidiarity.

(10) It should be made clear that all tests that provide information on the predisposition to a medical condition or a disease, such as genetic tests, and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are *in vitro* diagnostic medical devices.

(11) Companion diagnostics are essential for defining patients' eligibility for specific treatment with a medicinal product through the quantitative or qualitative determination of specific markers identifying subjects at a higher risk of developing an adverse reaction to the medicinal product in question or identifying patients in the population for whom the therapeutic product has been adequately studied, and found safe and effective. Such biomarker or biomarkers can be present in healthy subjects and/or in patients.

(12) Devices that are used with a view to monitoring treatment with a medicinal product in order to ensure that the concentration of relevant substances in the human body is within the therapeutic window are not considered to be companion diagnostics.

(13) The requirement to reduce risks as far as possible should be fulfilled taking into account the generally acknowledged state of the art in the field of medicine.

(14) Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council ([1]) are an integral part of the general safety and performance requirements laid down in this Regulation for devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.

(15) This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom ([2]) which pursues other objectives.

(16) This Regulation should include requirements for devices' safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

([1]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).

([2]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

(17) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an *in vitro* diagnostic medical device, qualifies as an *in vitro* diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being purposes is not an *in vitro* diagnostic medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

(18) The definitions in this Regulation regarding the devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical evidence, post-market surveillance, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice in the field at Union and international level in order to enhance legal certainty.

(19) It should be made clear that it is essential that devices offered to persons in the Union by means of information society services within the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council ([1]) and devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union comply with the requirements of this Regulation, where the product in question is placed on the market or the service is provided in the Union.

(20) To recognise the important role of standardisation in the field of *in vitro* diagnostic medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([2]) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

(21) Directive 98/79/EC allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are insufficient, the Commission should be empowered to lay down common specifications which provide a means of complying with the general safety and performance requirements and the requirements for performance studies and performance evaluation and/or post-market follow-up, laid down in this Regulation.

(22) Common specifications ('CS') should be developed after consulting the relevant stakeholders and taking account of the European and international standards.

(23) The rules applicable to devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([3]) and Decision No 768/2008/EC of the European Parliament and of the Council ([4]).

(24) The rules on Union market surveillance and control of products entering the Union market laid down in Regulation (EC) No 765/2008 apply to devices covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(25) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the various parts of this Regulation, to enhance understanding of the requirements laid down in this Regulation and thus to improve regulatory compliance by the relevant operators.

(26) For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices.

([1]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

([2]) Regulation (EU) No 1025/2012 of 25 October 2012 of the European Parliament and of the Council on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

([3]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

([4]) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(27) Several of the obligations on manufacturers, such as performance evaluation or vigilance reporting, that were set out only in the Annexes to Directive 98/79/EC, should be incorporated into the enacting provisions of this Regulation to facilitate its application.

(28) To ensure the highest level of health protection, the rules governing *in vitro* diagnostic medical devices, manufactured and used within a single health institution only, should be clarified and strengthened. That use should be understood to include measurement and delivery of results.

(29) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. In that context, it is appropriate to provide that certain rules of this Regulation, as regards devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the health care system and/or address patient needs, but which do not treat or care for patients directly, should not apply, since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the concept of 'health institution' does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to such establishments.

(30) In view of the fact that natural or legal persons can claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC ([1]). Such measures should be proportionate to the risk class, type of device and the size of the enterprise. In this context, it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

(31) To ensure that devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of the devices they manufacture is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the device in question. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting incidents and field safety corrective actions.

(32) The risk management system should be carefully aligned with and reflected in the performance evaluation process for the device, including the clinical risks to be addressed as part of performance studies, performance evaluation and post-market performance follow-up. The risk management and performance evaluation processes should be inter-dependent and should be regularly updated.

(33) It should be ensured that supervision and control of the manufacture of devices, as well as post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

(34) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC, and accordingly the authorised representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

([1]) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

(35) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a device.

(36) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations arising from the need for protection of health and safety and from the need for protection of intellectual property rights provided for under Article 36 TFEU. Application of the principle of parallel trade is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the Court of Justice ([1]) in other relevant sectors and existing good practice in the field of *in vitro* diagnostic medical devices.

(37) Devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.

(38) The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

(39) The UDI system should apply to all devices placed on the market except devices for performance studies, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation and in Regulation (EU) 2017/745 of the European Parliament and of the Council ([2]).

(40) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

(41) One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, performance studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between Member States and to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission. Within the internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices set up by Commission Decision 2010/227/EU ([3]).

(42) To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

([1]) Judgment of 28 July 2011 in Orifarm and Paranova, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.
([2]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (see page 1 of this Official Journal).
([3]) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices (OJ L 102, 23.4.2010, p. 45).

(43) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on performance studies should serve as a tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of the evaluation of such incidents and events by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(44) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council ([1]) applies to the processing of personal data carried out in the Member States, under the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council ([2]) applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(45) For class C and D devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the performance evaluation in a document that should be publicly available.

(46) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

(47) Notified bodies' assessments of manufacturers' technical documentation, in particular documentation on performance evaluation, should be critically evaluated by the authority responsible for notified bodies. That evaluation should be part of the risk-based approach to the oversight and monitoring activities of notified bodies and should be based on sampling of the relevant documentation.

(48) The position of notified bodies vis-à-vis manufacturers should be strengthened, including with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification.

(49) To increase transparency with regard to the oversight of notified bodies by national authorities, the authorities responsible for notified bodies should publish information on the national measures governing the assessment, designation and monitoring of notified bodies. In accordance with good administrative practice, this information should be kept up to date by those authorities in particular to reflect relevant, significant or substantive changes to the procedures in question.

(50) The Member State in which a notified body is established should be responsible for enforcing the requirements of this Regulation with regard to that notified body.

(51) In view, in particular, of the responsibility of Member States for the organisation and delivery of health services and medical care, they should be allowed to lay down additional requirements on notified bodies designated for the conformity assessment of devices and established on their territory as far as issues that are not regulated in this Regulation are concerned. Any such additional requirements laid down should not affect more specific horizontal Union legislation on notified bodies and equal treatment of notified bodies.

(52) For class D devices, competent authorities should be informed about certificates granted by notified bodies and be given the right to scrutinise the assessment conducted by notified bodies.

([1]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

([2]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(53) For class D devices for which no CS exist it is appropriate to provide that where it is the first certification for that specific type of device and there is no similar device on the market having the same intended purpose and based on similar technology, notified bodies should, in addition to the laboratory testing of the performance claimed by the manufacturer and the compliance of the device by the EU reference laboratories, be obliged to request expert panels to scrutinise their performance evaluation assessment reports. The consultation of expert panels in relation to the performance evaluation should lead to a harmonised evaluation of high-risk *in vitro* diagnostic medical devices by sharing expertise on performance aspects and developing CS on categories of devices that have undergone that consultation process.

(54) To enhance patient safety and to take due account of technological progress, the current classification system for devices set out in Directive 98/79/EC should be fundamentally changed, in line with international practice, and the corresponding conformity assessment procedures should be accordingly adapted.

(55) It is necessary, in particular for the purpose of the conformity assessment procedures, to classify devices in four risk classes and to establish a set of robust risk-based classification rules, in line with international practice.

(56) The conformity assessment procedure for class A devices should be carried out, as a general rule, under the sole responsibility of manufacturers, since such devices pose a low risk to patients. For class B, class C and class D devices, an appropriate level of involvement of a notified body should be compulsory.

(57) The conformity assessment procedures for devices should be further strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(58) It is appropriate that certificates of free sale contain information that makes it possible to use Eudamed in order to obtain information on the device, in particular with regard to whether it is on the market, withdrawn from the market or recalled, and on any certificate on its conformity.

(59) It is necessary to clarify the requirements regarding batch release verification for the highest risk devices.

(60) EU reference laboratories should be enabled to verify by laboratory testing the performance claimed by the manufacturer and the compliance of devices presenting the highest risk with the applicable CS, when such CS are available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

(61) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical evidence. It is necessary to clarify the requirements for the demonstration of the clinical evidence, that is based on data on scientific validity, and the analytical performance and clinical performance of the device. To allow for a structured and transparent process, generating reliable and robust data, sourcing and assessment of available scientific information and data generated in performance studies should be based on a performance evaluation plan.

(62) As a general rule, clinical evidence should be sourced from performance studies that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the performance study.

(63) It is necessary to ensure that the clinical evidence of devices is updated throughout their lifecycle. Such updating entails the planned monitoring of scientific developments and changes in medical practice by the manufacturer. Relevant new information should then trigger a reassessment of the clinical evidence of the device thus ensuring safety and performance through a continuous process of performance evaluation.

(64) It should be recognised that the concept of clinical benefit for *in vitro* diagnostic medical devices is fundamentally different from that which applies in the case of pharmaceuticals or of therapeutic medical devices, since the benefit of *in vitro* diagnostic medical devices lies in providing accurate medical information on patients, where appropriate, assessed against medical information obtained through the use of other diagnostic options and technologies, whereas the final clinical outcome for the patient is dependent on further diagnostic and/or therapeutic options which could be available.

(65) Where specific devices have no analytical or clinical performance or specific performance requirements are not applicable, it is appropriate to justify in the performance evaluation plan, and related reports, omissions relating to such requirements.

(66) The rules on performance studies should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of performance studies conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of performance studies conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

(67) It should be left to the Member State where a performance study is to be conducted to determine the appropriate authority to be involved in the assessment of the application to conduct a performance study and to organise the involvement of ethics committees within the timelines for the authorisation of that performance study as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. In that context, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

(68) An electronic system should be set up at Union level to ensure that every interventional clinical performance study and other performance study involving risks for the subjects of the studies is recorded and reported in a publicly accessible database. To protect the right to protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union ('the Charter'), no personal data of subjects participating in a performance study should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on performance studies should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(69) Where an interventional clinical performance study or another performance study involving risks for the subjects is to be conducted in more than one Member State, the sponsor should have the possibility of submitting a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety-related aspects of the device for performance study and of the scientific design of that performance study, the procedure for the assessment of such single application should be coordinated between the Member States under the direction of a coordinating Member State. Such coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a performance study, including informed consent. For an initial period of seven years from the date of application of this Regulation, Member States should be able to participate on a voluntary basis in the coordinated assessment. After that period, all Member States should be obliged to participate in the coordinated assessment. The Commission, based on the experience gained from the voluntary coordination between Member States, should draw up a report on the application of the relevant provisions regarding the coordinated assessment procedure. In the event that the findings of the report are negative, the Commission should submit a proposal to extend the period of participation on a voluntary basis in the coordinated assessment procedure.

(70) Sponsors should report certain adverse events and device deficiencies that occur during interventional clinical performance studies and other performance studies involving risks for the subjects to the Member States in which those studies are being conducted. Member States should have the possibility of terminating or suspending the studies or revoking the authorisation for those studies, if considered necessary to ensure a high level of protection of the subjects participating in such studies. Such information should be communicated to the other Member States.

(71) The sponsor of a performance study should submit a summary of results of the performance study that is easily understandable for the intended user together with the performance study report, where applicable, within the timelines laid down in this Regulation. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results will be submitted.

(72) With exemption of some general requirements, this Regulation should only cover performance studies intended to gather scientific data for the purpose of demonstrating conformity of devices.

(73) It is necessary to clarify that performance studies using left-over specimens need not be authorised. Nevertheless, the general requirements and other additional requirements with regard to data protection and the requirements applicable to procedures that are performed in accordance with national law such as ethical review should continue to apply to all performance studies, including when using left-over specimens.

(74) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and the Council ([1]) should be observed. In particular, the unnecessary duplication of tests and studies should be avoided.

(75) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To that end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and performance evaluation, and should also serve the purposes of transparency.

(76) In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

(77) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be encouraged and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers of any suspected serious incident and, where a manufacturer confirms that such an incident might have occurred, the authorities concerned should ensure that appropriate follow-up action is taken in order to minimise recurrence of such incidents.

(78) The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

(79) In the context of the investigation of incidents, the competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

(80) The reporting of serious adverse events or device deficiencies during interventional clinical performance studies and other performance studies involving risks for the subjects, and the reporting of serious incidents occurring after a device has been placed on the market should be clearly distinguished to avoid double reporting.

(81) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

(82) Any statistically significant increase in the number or severity of incidents that are not serious or in expected erroneous results that could have a significant impact on the benefit-risk analysis and which could lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

(83) An expert committee, the MDCG, composed of persons designated by the Member States based on their role and expertise in the field of medical devices including *in vitro* diagnostic medical devices, should be established in

([1]) Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010. p. 33).

accordance with the conditions and modalities defined in Regulation (EU) 2017/745 to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) 2017/745, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to have access to necessary in-depth technical expertise in the field of medical devices including *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices.

(84) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is essential for ensuring a uniform high level of health and safety protection within the internal market, in particular in the areas of performance studies and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as the designation of notified bodies and should be encouraged in the area of market surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.

(85) The Commission should provide scientific, technical and corresponding logistical support to coordinating national authorities and ensure that the regulatory system for devices is effectively and uniformly implemented at Union level based on sound scientific evidence.

(86) The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of devices to facilitate the exchange of safety-related information regarding devices and foster the further development of international regulatory guidelines that promote the adoption in other jurisdictions of regulations that lead to a level of health and safety protection equivalent to that set by this Regulation.

(87) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.

(88) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should, in order to ensure transparency, inform the Commission and the other Member States before they decide on the level and structure of such fees. In order to further ensure transparency, the structure and level of the fees should be publicly available on request.

(89) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

(90) The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in order to amend certain non-essential provisions of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.

(91) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([2]).

([1]) OJ L 123, 12.5.2016, p. 1.
([2]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(92) The advisory procedure should be used for implementing acts that set out the form and presentation of the data elements of manufacturers' summaries of safety and performance, and that establish the model for certificates of free sale, given that such implementing acts are of a procedural nature and do not directly have an impact on health and safety at Union level.

(93) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures, imperative grounds of urgency so require.

(94) In order to enable it to designate issuing entities and EU reference laboratories, implementing powers should be conferred on the Commission.

(95) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements that are to be made. However, certain parts of the Regulation that directly affect Member States and the Commission should be implemented as soon as possible. It is also particularly important that, by the date of application of this Regulation, a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of devices on the market. Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directive 98/79/EC and to their capacity to continue issuing valid certificates under that Directive until the date of application of this Regulation.

(96) In order to ensure a smooth transition to the new rules for registration of devices and of certificates, the obligation to submit the relevant information to the electronic systems set up at Union level pursuant to this Regulation should, in the event that the corresponding IT systems are developed according to plan, only become fully effective from 18 months after the date of application of this Regulation. During this transitional period, certain provisions of Directive 98/79/EC should remain in force. However, in order to avoid multiple registrations, economic operators and notified bodies who register in the relevant electronic systems set up at Union level pursuant to this Regulation should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions.

(97) In order to provide for a smooth introduction of the UDI system, the moment of application of the obligation to place the UDI carrier on the label of the device should vary from one to five years after the date of application of this Regulation depending upon the class of the device concerned.

(98) Directive 98/79/EC should be repealed to ensure that only one set of rules applies to the placing of *in vitro* diagnostic medical devices on the market and the related aspects covered by this Regulation. Manufacturers' obligations as regards the making available of documentation regarding devices they placed on the market and manufacturers' and Member States' obligations as regards vigilance activities for devices placed on the market pursuant to that Directive should however continue to apply. While it should be left to Member States to decide how to organise vigilance activities, it is desirable for them to have the possibility of reporting adverse incidents related to devices placed on the market pursuant to that Directive using the same tools as those for reporting on devices placed on the market pursuant to this Regulation. However, Decision 2010/227/EU adopted in implementation of that Directive and Council Directives 90/385/EEC ([1]) and 93/42/EEC ([2]) should also be repealed as from the date when Eudamed becomes fully functional.

(99) The requirements of this Regulation should be applicable to all devices placed on the market or put into service from the date of application of this Regulation. However, in order to provide for a smooth transition it should be possible, for a limited period of time from that date, for devices to be placed on the market or put into service by virtue of a valid certificate issued pursuant to Directive 98/79/EC.

(100) The European Data Protection Supervisor has given an opinion ([3]) pursuant to Article 28(2) of Regulation (EC) No 45/2001.

([1]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17)
([2]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)
([3]) OJ C 358, 7.12.2013, p. 10.

(101) Since the objectives of this Regulation, namely to ensure the smooth functioning of the internal market as regards medical devices and to ensure high standards of quality and safety for *in vitro* diagnostic medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

INTRODUCTORY PROVISIONS

Section 1

Scope and definitions

Article 1

Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices for human use and accessories for such devices in the Union. This Regulation also applies to performance studies concerning such *in vitro* diagnostic medical devices and accessories conducted in the Union.

2. For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories for *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.

3. This Regulation does not apply to:

(a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

(b) invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;

(c) internationally certified reference materials;

(d) materials used for external quality assessment schemes.

4. Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in point 1 of Article 2 of Regulation (EU) 2017/745 shall be governed by that Regulation. The requirements of this Regulation shall apply to the *in vitro* diagnostic medical device part.

5. This Regulation is specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

6. Devices which are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council [1] shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.

7. This Regulation shall not affect the application of Directive 2013/59/Euratom.

8. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

[1] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (OJ L 157, 9.6.2006, p. 24).

9. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

10. Nothing in this Regulation shall restrict the freedom of the press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter of Fundamental Rights of the European Union.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means 'medical device' as defined in point (1) of Article 2 of Regulation (EU) 2017/745;

(2) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices;

(3) 'specimen receptacle' means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination;

(4) 'accessory for an *in vitro* diagnostic medical device' means an article which, whilst not being itself an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the *in vitro* diagnostic medical device(s) in terms of its/their intended purpose(s);

(5) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;

(6) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional;

(7) 'companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to:

(a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or

(b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;

(8) 'generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(9) 'single-use device' means a device that is intended to be used during a single procedure;

(10) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

(11) 'kit' means a set of components that are packaged together and intended to be used to perform a specific *in vitro* diagnostic examination, or a part thereof;

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation;

(13) 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

(15) 'Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

(16) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(17) 'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

(18) 'compatibility' is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

(a) perform without losing or compromising the ability to perform as intended, and/or

(b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

(c) be used together without conflict/interference or adverse reaction;

(19) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:

(a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or

(b) communicate with each other, and/or

(c) work together as intended;

(20) 'making available on the market' means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(21) 'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market;

(22) 'putting into service' means the stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(23) 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark;

(24) 'fully refurbishing', for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(25) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(26) 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;

(27) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(28) 'economic operator' means a manufacturer, an authorised representative, an importer or a distributor;

(29) 'health institution' means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

(30) 'user' means any healthcare professional or lay person who uses a device;

(31) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

(32) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

(33) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(34) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(35) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

(36) 'clinical evidence' means clinical data and performance evaluation results, pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

(37) 'clinical benefit' means the positive impact of a device related to its function, such as that of screening, monitoring, diagnosis or aid to diagnosis of patients, or a positive impact on patient management or public health;

(38) 'scientific validity of an analyte' means the association of an analyte with a clinical condition or a physiological state;

(39) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting that intended purpose;

(40) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;

(41) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user;

(42) 'performance study' means a study undertaken to establish or confirm the analytical or clinical performance of a device;

(43) 'performance study plan' means a document that describes the rationale, objectives, design methodology, monitoring, statistical considerations, organisation and conduct of a performance study;

(44) 'performance evaluation' means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;

(45) 'device for performance study' means a device intended by the manufacturer to be used in a performance study.

A device intended to be used for research purposes, without any medical objective, shall not be deemed to be a device for performance study;

(46) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;

(47) 'subject' means an individual who participates in a performance study and whose specimen(s) undergo *in vitro* examination by a device for performance study and/or by a device used for control purposes;

(48) 'investigator' means an individual responsible for the conduct of a performance study at a performance study site;

(49) 'diagnostic specificity' means the ability of a device to recognise the absence of a target marker associated with a particular disease or condition;

(50) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

(51) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

(52) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

(53) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

(54) 'likelihood ratio' means the likelihood of a given result arising in an individual with the target clinical condition or physiological state compared to the likelihood of the same result arising in an individual without that clinical condition or physiological state;

(55) 'calibrator' means a measurement reference material used in the calibration of a device;

(56) 'control material' means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;

(57) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the performance study;

(58) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular performance study, after having been informed of all aspects of the performance study that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance study;

(59) 'ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

(60) 'adverse event' means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a performance study, whether or not related to the device for performance study;

(61) 'serious adverse event' means any adverse event that led to any of the following:

(a) a patient management decision resulting in death or an imminent life-threatening situation for the individual being tested, or in the death of the individual's offspring,

(b) death,

(c) serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or prolongation of patient hospitalisation,

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

(v) chronic disease,

(d) foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

(62) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of a device for performance study, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

(63) 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

(64) 'market surveillance' means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

(65) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

(66) 'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market;

(67) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device;

(68) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat;

(69) 'serious public health threat' means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

(70) 'corrective action' means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

(71) 'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(72) 'field safety notice' means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

(73) 'harmonised standard' means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;

(74) 'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

Section 2

Regulatory status of products and counselling

Article 3

Regulatory status of products

1. Upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of Regulation (EU) 2017/745 (MDCG), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of '*in vitro* diagnostic medical device' or 'accessory for an *in vitro* diagnostic medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3) of this Regulation.

2. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

3. The Commission shall ensure that Member States share expertise in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products.

4. When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as relevant.

Article 4

Genetic information, counselling and informed consent

1. Member States shall ensure that where a genetic test is used on individuals, in the context of healthcare as defined in point (a) of Article 3 of Directive 2011/24/EU of the European Parliament and of the Council ([1]) and for the medical purposes of diagnostics, improvement of treatment, predictive or prenatal testing, the individual being tested or, where applicable, his or her legally designated representative is provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate.

2. In the context of the obligations referred to in paragraph 1, Member States shall, in particular, ensure that there is appropriate access to counselling in the case of the use of genetic tests that provide information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable according to the state of science and technology.

3. Paragraph 2 shall not apply in cases where a diagnosis of a medical condition and/or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used.

4. Nothing in this Article shall prevent Member States from adopting or maintaining measures at national level which are more protective of patients, more specific or which deal with informed consent.

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, CE MARKING, FREE MOVEMENT

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

([1]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 56.

4. Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, shall be considered as having been put into service.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity;

(b) manufacture and use of the devices occur under appropriate quality management systems;

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;

(d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

(e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(f) the health institution draws up a declaration which it shall make publicly available, including:

    (i) the name and address of the manufacturing health institution,

    (ii) the details necessary to identify the devices,

    (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;

(g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII;

(h) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g); and

(i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

6. In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 6

Distance sales

1. A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.

2. Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.

3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.

4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity.

Article 7

Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Article 8

Use of harmonised standards

1. Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up ('PMPF').

References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the *Official Journal of the European Union*.

2. References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, provided that references to those monographs have been published in the *Official Journal of the European Union*.

Article 9

Common specifications

1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the performance evaluation and PMPF set out in Annex XIII or the requirements regarding performance studies set out in Annex XIII. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2. Devices that are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or the relevant parts of those CS.

3. Manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.

Article 10

General obligations of manufacturers

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. Manufacturers shall conduct a performance evaluation in accordance with the requirements set out in Article 56 and Annex XIII, including a PMPF.

4. Manufacturers shall draw up and keep up to date the technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

The Commission is empowered to adopt delegated acts in accordance with Article 108 amending, in the light of technical progress, the Annexes II and III.

5. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance study, shall draw up an EU declaration of conformity in accordance with Article 17, and affix the CE marking of conformity in accordance with Article 18.

6. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 24 and with the registration obligations referred to in Article 26 and 28.

7. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

8. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a product is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than devices for performance study, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors;

(e) risk management as set out in Section 3 of Annex I;

(f) performance evaluation, in accordance with Article 56 and Annex XIII, including PMPF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 24(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 26;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 78;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

9. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 78.

10. Manufacturers shall ensure that the device is accompanied by the information set out in Section 20 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

The information supplied in accordance with Section 20 of Annex I with devices for self-testing or near-patient testing shall be easily understandable and provided in the official Union language(s) determined by the Member State in which the device is made available to the user or patient.

11. Manufacturers that consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly.

Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 51, in particular, of the non-compliance and of any corrective action taken.

12. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 82 and 83.

13. Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until the manufacturer cooperates or provides complete and correct information.

If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights.

The competent authority need not comply with the obligation laid down in the third subparagraph where disclosure of the information and documentation referred to in the first subparagraph is ordinarily dealt with in the context of legal proceedings.

14. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 27(1).

15. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Article 11

Authorised representative

1. Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

3. The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51, at the disposal of competent authorities for the period referred to in Article 10(7);

(c) comply with the registration obligations laid down in Article 28 and verify that the manufacturer has complied with the registration obligations laid down in Article 26;

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

4. The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (5), (6), (8), (9), (10) and (11).

5. Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

6. An authorised representative who terminates its mandate on the grounds referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

7. Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.

Article 12

Change of authorised representative

The detailed arrangements for a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement shall address at least the following aspects:

(a) the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative.

Article 13

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. In order to place a device on the market, importers shall verify that:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;

(c) the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

(d) where applicable, a UDI has been assigned by the manufacturer in accordance with Article 24.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.

3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall verify that the device is registered in the electronic system in accordance with Article 26. Importers shall add their details to the registration in accordance with Article 28.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.

6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it, is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 51 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.

9. Importers shall, for the period referred to in Article 10(7), keep a copy of the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51.

10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

Article 14

General obligations of distributors

1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) the device has been CE marked and the EU declaration of conformity of the device has been drawn up;

(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(10);

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

Article 15

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of *in vitro* diagnostic medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC ([1]) shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

3. The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

([1]) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the post-market surveillance obligations are complied with in accordance with Article 10(9);

(d) the reporting obligations referred to in Articles 82 to 86 are fulfilled;

(e) in the case of devices for performance studies intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects, the statement referred to in Section 4.1 of Annex XIV is issued.

4. If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

5. The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

Article 16

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) makes available on the market a device under its own name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (23) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 20 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

Article 17

EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission is empowered to adopt delegated acts in accordance with Article 108 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

Article 18

CE marking of conformity

1. Devices, other than devices for performance studies, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 48. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

Article 19

Devices for special purposes

1. Member States shall not create obstacles to devices for performance study being supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 57 to 76, and in the implementing acts adopted pursuant to Article 77.

2. The devices referred to in paragraph 1 shall not bear the CE marking, with the exception of the devices referred to in Article 70.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided that a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.

Article 20

Parts and components

1. Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

2. An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation.

Article 21

Free movement

Except where otherwise provided for in this Regulation, Member States shall not refuse, prohibit or restrict the making available on the market or putting into service within their territory of devices which comply with the requirements of this Regulation.

CHAPTER III

IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

Article 22

Identification within the supply chain

1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(7):

(a) any economic operator to whom they have directly supplied a device;

(b) any economic operator who has directly supplied them with a device;

(c) any health institution or healthcare professional to which they have directly supplied a device.

Article 23

Medical devices nomenclature

To facilitate the functioning of the European database on medical devices (Eudamed) as referred to in Article 33 of Regulation (EU) 2017/745, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Article 24

Unique Device Identification system

1. The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than devices for performance studies, and shall consist of the following:

(a) production of a UDI that comprises the following:

  (i) a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex VI;

  (ii) a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

(b) placing of the UDI on the label of the device or on its packaging;

(c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs 8 and 9 respectively;

(d) establishment of an electronic system for Unique Device Identification ('UDI database') in accordance with Article 28 of Regulation (EU) 2017/745.

2. The Commission shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation ('issuing entity'). That entity or those entities shall satisfy all of the following criteria:

(a) the entity is an organisation with legal personality;

(b) its system for the assignment of UDIs is adequate to identify a device throughout its distribution and use in accordance with the requirements of this Regulation;

(c) its system for the assignment of UDIs conforms to the relevant international standards;

(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;

(e) the entity undertakes to do the following:

  (i) operate its system for the assignment of UDIs for at least 10 years after its designation;

  (ii) make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

  (iii) remain in compliance with the criteria for designation and the terms of designation.

When designating issuing entities, the Commission shall endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are universally readable regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators, health institutions and healthcare professionals.

3. Before placing a device, other than a device for performance study, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.

Before a device, other than a device for performance study, is placed on the market the manufacturer must ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database referred to in Article 25.

4. UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.

5. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 82.

6. The Basic UDI-DI, as defined in Part C of Annex VI of the device shall appear on the EU declaration of conformity referred to in Article 17.

7. As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

8. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.

9. Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

Member States shall encourage, and may require, health care professionals to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied with.

10. The Commission is empowered to adopt delegated acts in accordance with Article 108:

(a) amending the list of information set out in Part B of Annex VI in the light of technical progress; and

(b) amending Annex VI in the light of international developments and technical progress in the field of Unique Device Identification.

11. The Commission may, by means of implementing acts, specify the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application in relation to any of the following:

(a) determining the devices, categories or groups of devices to which the obligation laid down in paragraph 8 is to apply;

(b) specifying the data to be included in the UDI-PI of specific devices or device groups.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

12. When adopting the measures referred to in paragraph 11, the Commission shall take into account all of the following:

(a) confidentiality and data protection as referred to in Articles 102 and 103 respectively;

(b) the risk-based approach;

(c) the cost-effectiveness of the measures;

(d) the convergence of UDI systems developed at international level;

(e) the need to avoid duplications in the UDI system;

(f) the needs of the health care systems of the Member States, and where possible, compatibility with other medical device identification systems that are used by stakeholders.

Article 25

UDI database

The Commission, after consulting the MDCG, shall set up and manage a UDI database in accordance with the conditions and detailed arrangements provided for in Article 28 of Regulation (EU) 2017/745.

Article 26

Registration of devices

1. Before placing a device on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 24(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), the second subparagraph of Article 48(7), Article 48(8) and the second subparagraph of Article 48(9), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.

For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

3. Before placing a device on the market, the manufacturer shall enter or, if already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and thereafter shall keep the information updated.

Article 27

Electronic system for registration of economic operators

1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 28(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI.

2. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory.

3. Within two weeks of placing a device on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1.

Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.

Article 28

Registration of manufacturers, authorised representatives and importers

1. Before placing a device on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 48, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. After having verified the data entered pursuant to paragraph 1, the competent authority shall obtain a single registration number ('SRN') from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer.

3. The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 26.

4. Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 27.

5. Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation.

6. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex VI.

7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 27 shall be accessible to the public.

8. The competent authority may use the data to charge the manufacturer, the authorised representative or the importer a fee pursuant to Article 104.

Article 29

Summary of safety and performance

1. For class C and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

The summary of safety and performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contra-indications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) reference to any harmonised standards and CS applied;

(e) the summary of the performance evaluation as referred to in Annex XIII, and relevant information on the PMPF;

(f) the metrological traceability of assigned values;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 107(2).

Article 30

European database on medical devices

1. The Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices ('Eudamed') in accordance with the conditions and detailed arrangements established by Articles 33 and 34 of Regulation (EU) 2017/745.

2. Eudamed shall include the following electronic systems:

(a) the electronic system for registration of devices referred to in Article 26;

(b) the UDI database referred to in Article 25;

(c) the electronic system on registration of economic operators referred to in Article 27;

(d) the electronic system on notified bodies and on certificates referred to in Article 52;

(e) the electronic system on performance studies referred to in Article 69,

(f) the electronic system on vigilance and post-market surveillance referred to in Article 87;

(g) the electronic system on market surveillance referred to in Article 95.

CHAPTER IV

NOTIFIED BODIES

Article 31

Authorities responsible for notified bodies

1. Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority (the 'authority responsible for notified bodies'), which may consist of separate constituent entities under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

2. The authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

3. The authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.

4. The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

5. The authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on notified bodies with other Member States, the Commission and, when required, with other regulatory authorities.

6. The authority responsible for notified bodies shall have a sufficient number of competent personnel permanently available for the proper performance of its tasks.

Where the authority responsible for notified bodies is a different authority from the national competent authority for *in vitro* diagnostic medical devices, it shall ensure that the national authority responsible for *in vitro* diagnostic medical devices is consulted on relevant matters.

7. Member States shall make publicly available general information on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

8. The authority responsible for notified bodies shall participate in peer-review activities provided for in Article 44.

Article 32

Requirements relating to notified bodies

1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil those tasks. In particular, notified bodies shall comply with Annex VII.

In order to meet the requirements referred to in the first subparagraph, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII, and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.

The personnel referred to in Sections 3.2.3 and 3.2.7 of Annex VII shall be employed by the notified body itself and shall not be external experts or subcontractors.

2. Notified bodies shall make available and submit upon request all relevant documentation, including the manufacturer's documentation, to the authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.

3. In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 33

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VII and shall inform the authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Notified bodies shall make publicly available a list of their subsidiaries.

4. Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

5. Notified bodies shall keep at the disposal of the authority responsible for notified bodies all relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 34

Application by conformity assessment bodies for designation

1. Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies.

2. The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body is applying to be designated, and shall be supported by documentation demonstrating compliance with Annex VII.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 35. However, the applicant shall make available all the documentation referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

3. The notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VII.

Article 35

Assessment of the application

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 34 is complete and shall request the applicant to provide any missing information. Once the application is complete that national authority shall send it to the Commission.

The authority responsible for notified bodies shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2. The authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the MDCG.

3. Within 14 days of the submission referred to in paragraph 2 of this Article, the Commission, in conjunction with the MDCG, shall appoint a joint assessment team made up of three experts, unless the specific circumstances require a different number of experts, chosen from the list referred to in Article 36. One of the experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from Member States other than the one in which the applicant conformity assessment body is established.

The joint assessment team shall be comprised of competent experts who are competent to assess the conformity assessment activities and the types of devices which are the subject of the application or, in particular when the assessment procedure is initiated in accordance with Article 43(3) to ensure that the specific concern can be appropriately assessed.

4. Within 90 days of its appointment, the joint assessment team shall review the documentation submitted with the application in accordance with Article 34. The joint assessment team may provide feedback to, or require clarification from, the authority responsible for notified bodies on the application and on the planned on-site assessment.

The authority responsible for notified bodies together with the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process.

The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

5. Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VII shall be raised during the assessment process and discussed between the authority responsible for notified bodies and the joint assessment team with a view to reaching consensus and resolving any diverging opinions, with respect to the assessment of the application.

At the end of the on-site assessment, the authority responsible for notified bodies shall list for the applicant conformity assessment body the non-compliances resulting from the assessment and summarise of the assessment by the joint assessment team.

Within a specified timeframe, the applicant conformity assessment body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

6. The joint assessment team shall document any remaining diverging opinions with respect to the assessment within 30 days of completion of the on-site assessment and send them to the authority responsible for notified bodies.

7. The authority responsible for notified bodies shall, following receipt of a corrective and preventive action plan from the applicant body, assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

The authority responsible for notified bodies shall, having confirmed the corrective and preventive action plan, forward it and its opinion thereon to the joint assessment team. The joint assessment team may request of the authority responsible for notified bodies further clarification and modifications.

The authority responsible for notified bodies shall draw up its final assessment report which shall include:

— the result of the assessment,

— confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,

— any remaining diverging opinion with the joint assessment team, and, where applicable,

— the recommended scope of designation.

8. The authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.

9. The joint assessment team shall provide a final opinion regarding the assessment report prepared by the authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission which shall immediately submit that final opinion to the MDCG. Within 42 days of receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation, which the authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.

10. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements specifying procedures and reports for the application for designation referred to in Article 34 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 36

Nomination of experts for joint assessment of applications for notification

1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of *in vitro* diagnostic medical devices to participate in the activities referred to in Articles 35 and 44.

2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 52.

Article 37

Language requirements

All documents required pursuant to Articles 34 and 35 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

Member States, in applying the first paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documentation concerned.

The Commission shall provide translations of the documentation pursuant to Articles 34 and 35, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 35(3).

Article 38

Designation and notification procedure

1. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 35 was completed and which comply with Annex VII.

2. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).

3. The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation, and the types of devices which the notified body is authorised to assess and, without prejudice to Article 40, any conditions associated with the designation.

4. The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 35(9) and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

5. The notifying Member State shall, without prejudice to Article 40, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VII.

6. Within 28 days of the notification referred to in paragraph 2, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.

7. When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.

8. Where the MDCG, after having been consulted in accordance with paragraph 7, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.

9. Where the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.

10. When publishing the notification in NANDO, the Commission shall add to the electronic system referred to in Article 52 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and response referred to in paragraphs 7 and 8 of this Article.

11. The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

12. The conformity assessment body concerned may perform the activities of a notified body only after the designation has become valid in accordance with paragraph 11.

13 The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3). The Commission, after consulting the MDCG, may update this list based, inter alia, on information arising from the coordination activities described in Article 44.

Article 39

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 38(11). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this Regulation, bodies notified pursuant to Directive 98/79/EC shall retain the identification number assigned to them pursuant to that Directive.

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in NANDO. It shall also make this list available on the electronic system referred to in Article 52. The Commission shall ensure that the list is kept up to date.

Article 40

Monitoring and re-assessment of notified bodies

1. Notified bodies shall, without delay, and at the latest within 15 days, inform the authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VII or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

2. The authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance.

3. Where the Commission or the authority of a Member State submits a request to a notified body established on the territory of another Member State relating to a conformity assessment carried out by that notified body, it shall send a copy of that request to the authority responsible for notified bodies of that other Member State. The notified body concerned shall respond without delay and within 15 days at the latest to the request. The authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved by the notified body unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.

4. At least once a year, the authorities responsible for notified bodies shall re-assess whether the notified bodies established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in Annex VII. That review shall include an on-site audit of each notified body and, where necessary, of its subsidiaries and subcontractors.

The authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. That plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.

5. The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel in the process of conducting quality management system assessments at a manufacturer's facility.

6. The monitoring of notified bodies conducted by the authority responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance to help guide its activities.

The authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

7. The authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.

8. The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the performance evaluation documentation as further outlined in Article 41.

9. The authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VII and shall monitor the timely implementation of corrective and preventive actions.

10. Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team appointed for the purpose of the procedure described in Articles 34 and 35.

11. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend paragraph 10 of this Article to modify the frequency at which the complete re-assessment referred to in that paragraph is to be carried out.

12. The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring and on-site assessment activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. The report shall provide details of the outcome of those activities, including activities pursuant to paragraph 7, and shall be treated as confidential by the MDCG and the Commission; however, it shall contain a summary which shall be made publicly available.

The summary of the report shall be uploaded to the electronic system referred to in Article 52.

Article 41

Review of notified body assessment of technical documentation and performance evaluation documentation

1. The authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies, shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the performance evaluation documentation to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. The reviews by the authority responsible for notified bodies shall be conducted both off-site and on-site.

2. The sampling of files to be reviewed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body, in particular high-risk devices, and be appropriately justified and documented in a sampling plan, which shall be made available by the authority responsible for notified bodies to the MDCG upon request.

3. The authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and performance evaluation documentation of the manufacturer upon which the notified body has based its assessment. Such reviews shall be conducted utilising CS.

4. Those reviews shall also form part of the re-assessment of notified bodies in accordance with Article 40(10) and the joint assessment activities referred to in Article 43(3). The reviews shall be conducted utilising appropriate expertise.

5. Based on the reports of the reviews and assessments by the authority responsible for notified bodies or joint assessment teams, on input from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, or on the continuous monitoring of technical progress, or on the identification of concerns and emerging issues concerning the safety and performance of devices, the MDCG may recommend that the sampling carried out under this Article cover a greater or lesser proportion of the technical documentation and performance evaluation documentation assessed by a notified body.

6. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation and performance evaluation documentation, as referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 42

Changes to designations and notifications

1. The authority responsible for notified bodies shall notify the Commission and the other Member States of any relevant changes to the designation of a notified body.

The procedures described in Article 35 and in Article 38 shall apply to extensions of the scope of the designation.

For changes to the designation other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.

2. The Commission shall immediately publish the amended notification in NANDO. The Commission shall immediately enter information on the changes to the designation of the notified body in the electronic system referred to in Article 52.

3. Where a notified body decides to cease its conformity assessment activities it shall inform the authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates. The new notified body shall complete a full assessment of the devices affected by the end of that period before issuing new certificates for those devices. Where the notified body has ceased its activity, the authority responsible for notified bodies shall withdraw the designation.

4. Where a authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VII, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.

The authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a designation.

5. Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.

6. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to authorities in other Member States responsible for notified bodies and to authorities responsible for market surveillance at their request.

7 In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:

(a) assess the impact on the certificates issued by the notified body;

(b) submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

(c) require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;

(d) enter in the electronic system referred to in Article 52 information in relation to certificates of which it has required their suspension or withdrawal;

(e) inform the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 52 of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

8. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

(a) the authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction and the authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction; or

(b) the authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor, and remain responsible for, existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide, to the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

9. With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:

(a) where the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business has confirmed that there is no safety issue associated with the devices in question; and

(b) another notified body has confirmed in writing that it will assume immediate responsibilities for those devices and will have completed assessment of them within twelve months of the withdrawal of the designation.

In the circumstances referred to in the first subparagraph, the national competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.

The authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Article 43

Challenge to the competence of notified bodies

1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VII or the obligations to which they are subject. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the designation of the notified body concerned.

3. The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment procedure described in Article 35(3) and (5) where there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VII and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 35. Alternatively, depending on the severity of the issue, the Commission, in conjunction with the MDCG, may request that the authority responsible for notified bodies allow the participation of up to two experts from the list established pursuant to Article 36 in an on-site assessment as part of the planned monitoring and assessment activities in accordance with Article 40 and as outlined in the annual assessment plan described in Article 40(4) therein.

4. Where the Commission ascertains that a notified body no longer meets the requirements for its designation, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3). It shall notify the Member State concerned of its decision and update NANDO and the electronic system referred to in Article 52.

5. The Commission shall ensure that all confidential information obtained in the course of its investigations is treated accordingly.

Article 44

Peer review and exchange of experience between authorities responsible for notified bodies

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the authorities responsible for notified bodies. Such exchange shall cover elements including:

(a) development of best practice documents relating to the activities of the authorities responsible for notified bodies;

(b) development of guidance documents for notified bodies in relation to the implementation of this Regulation;

(c) training and qualification of the experts referred to in Article 36;

(d) monitoring of trends relating to changes to notified body designations and notifications, and trends in certificate withdrawals and transfers between notified bodies;

(e) monitoring of the application and applicability of scope codes referred to in Article 38(13);

(f) development of a mechanism for peer reviews between authorities and the Commission;

(g) methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies.

2. The authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to paragraph 1 of this Article. Such reviews shall normally be conducted in parallel with the on-site joint assessments described in Article 35. Alternatively, a national authority may make the choice of having such reviews take place as part of its monitoring activities referred to in Article 40.

3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.

4. The Commission shall compile an annual summary report of the peer review activities, which shall be made publicly available.

5. The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements and related documents for the peer review mechanisms and training and qualification as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 45

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies, as referred to in Article 49 of Regulation (EU) 2017/745.

The bodies notified under this Regulation shall participate in the work of that group.

Article 46

List of standard fees

Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available.

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

Section 1

Classification

Article 47

Classification of devices

1. Devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2. of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3. At the request of a Member State, the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

5. In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6. The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Section 2

Conformity assessment

Article 48

Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2. Prior to putting into service a device that is not placed on the market, with the exception of in-house devices manufactured pursuant to Article 5(5), manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

3. Manufacturers of class D devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I, II except for Section 5, and in Chapter III of Annex IX.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 5.1 of Annex IX.

In addition to the procedures referred to in the first and second subparagraphs, for companion diagnostics, the notified body shall consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([1]) or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX.

4. Manufacturers of class D devices, other than devices for performance study, may, instead of the conformity assessment procedure applicable pursuant to paragraph 3, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

For companion diagnostics, the notified body shall in particular consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in point (k) of Section 3 of Annex X.

5. In particular, and without prejudice to any of the obligations pursuant to the other procedures referred to in paragraphs 3 and 4, for devices for which one or more EU reference laboratories have been designated in accordance with Article 100, the notified body performing the conformity assessment shall request one of the EU reference laboratories to verify by laboratory testing the performance claimed by the manufacturer and the compliance of the device with the applicable CS, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 4.9 of Annex IX and in point (j) of Section 3 of Annex X. Laboratory tests performed by an EU reference laboratory shall in particular focus on analytical and diagnostic sensitivity using the best available reference materials.

6. In addition to the procedure applicable pursuant to paragraphs 3 and 4, where no CS are available for class D devices and where it is also the first certification for that type of device, the notified body shall consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 on the performance evaluation report of the manufacturer. To that end, the notified body shall provide the performance evaluation report of the manufacturer to the expert panel within five days of receiving it from the manufacturer. The relevant experts shall, under the supervision of the Commission, provide their views, in accordance with Section 4.9 of Annex IX or point (j) of Section 3 of Annex X, as applicable, to the notified body within the deadline for delivery of the scientific opinion by the EU reference laboratory as specified therein.

7. Manufacturers of class C devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex of at least one representative device per generic device group.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 5.1 of Annex IX.

In addition to the procedures referred to in the first and second subparagraphs, for companion diagnostics the notified body shall for every device follow the procedure for technical documentation assessment laid down in Section 5.2 of Annex IX, and shall apply the procedure for technical documentation assessment laid down in Sections 4.1 to 4.8 of Annex IX and shall consult the competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX.

([1]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

8. Manufacturers of class C devices, other than devices for performance study, may, instead of the conformity assessment procedure pursuant to paragraph 7, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI except its Section 5.

For companion diagnostics the notified body shall in particular for every device consult a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, as applicable, in accordance with the procedure set out in point (k) of Section 3 of Annex X.

9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Sections 4.4 to 4.8 of that Annex for at least one representative device per category of devices.

In addition to the procedures referred to in the first subparagraph, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 5.1 of Annex IX.

10. Manufacturers of class A devices, other than devices for performance study, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17, after drawing up the technical documentation set out in Annexes II and III.

However, if those devices are placed on the market in sterile condition, the manufacturer shall apply the procedures set out in Annex IX or in Annex XI. Involvement of the notified body shall be limited to the aspects relating to establishing, securing and maintaining sterile conditions.

11. Devices for performance studies shall be subject to the requirements set out in Articles 57 to 77.

12. The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 10 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13. The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:

(a) the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in third paragraph of Section 2.3. and in Section 3.5 of Annex IX, in the case of class C devices;

(b) the minimum frequency of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the frequency of samples of the manufactured devices or batches of class D devices to be sent to an EU reference laboratory designated under Article 100 in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI; or

(d) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX and points (f) and (g) of Section 3. of Annex X.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 49

Involvement of notified bodies in conformity assessment procedures

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2. The notified body concerned shall, by means of the electronic system referred to in Article 52, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3. When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4. The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 50

Mechanism for scrutiny of conformity assessments of class D devices

1. A notified body shall notify the competent authority of certificates it has granted for class D devices, with the exception of applications to supplement or renew existing certificates. Such notification shall take place through the electronic system referred to in Article 52 and shall include the instructions for use referred to in Section 20.4 of Annex I, the summary of safety and performance referred to in Article 29, the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the EU reference laboratory pursuant to the second subparagraph of Article 48(3), and where applicable the views expressed in accordance with Article 48(4) by the experts referred to in Article 106 of Regulation (EU) 2017/745. In the case of divergent views between the notified body and the experts, a full justification shall also be included.

2. A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 40, 41, 42, 43 or 89 and, where deemed necessary, take appropriate measures in accordance with to Articles 90 and 92.

3. The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.

Article 51

Certificates of conformity

1. The certificates issued by the notified bodies in accordance with Annexes IX, X and XI shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates shall be as set out in Annex XII.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or users or require manufacturers to undertake specific PMPF studies pursuant to Part B of Annex XIII.

4. Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

5. The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public.

6. In the light of technical progress, the Commission is empowered to adopt delegated acts in accordance with Article 108 amending the minimum content of the certificates set out in Annex XII.

Article 52

Electronic system on notified bodies and on certificates of conformity

For the purposes of this Regulation, the following information shall be collated and processed pursuant to Article 57 of Regulation (EU) 2017/745 in the electronic system set up in accordance with that Article:

(a) the list of subsidiaries referred to in Article 33(2);

(b) the list of experts referred to in Article 36(2);

(c) the information relating to the notification referred to in Article 38(10) and the amended notifications referred to in Article 42(2);

(d) the list of notified bodies referred to in Article 39(2);

(e) the summary of the report referred to in Article 40(12);

(f) the notifications for conformity assessments and certificates referred to in Article 50(1);

(g) withdrawal or refusals of applications for the certificates as referred to in Article 49(2) and Section 4.3 of Annex VII;

(h) the information regarding certificates referred to in Article 51(5);

(i) the summary of safety and performance referred to in Article 29.

Article 53

Voluntary change of notified body

1. In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. That agreement shall cover at least the following aspects:

(a) the date on which the certificates issued by the outgoing notified body become invalid;

(b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body;

(e) the last serial number or lot number for which the outgoing notified body is responsible.

2. The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid.

Article 54

Derogation from the conformity assessment procedures

1. By way of derogation from Article 48, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

Article 55

Certificate of free sale

1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 26. Where a notified body has issued a certificate pursuant to Article 51, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 107(2).

CHAPTER VI

CLINICAL EVIDENCE, PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

Article 56

Performance evaluation and clinical evidence

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I, in particular those concerning the performance characteristics referred to in Chapter I and Section 9 of Annex I, under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I, shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XIII.

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.

3. A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this Article and with Part A of Annex XIII:

(a) scientific validity;

(b) analytical performance;

(c) clinical performance.

The data and conclusions drawn from the assessment of those elements shall constitute the clinical evidence for the device. The clinical evidence shall be such as to scientifically demonstrate, by reference to the state of the art in medicine, that the intended clinical benefit(s) will be achieved and that the device is safe. The clinical evidence derived from the performance evaluation shall provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Annex I, are fulfilled, under normal conditions of use.

4. Clinical performance studies in accordance with Section 2 of Part A of Annex XIII shall be carried out unless it is duly justified to rely on other sources of clinical performance data.

5. The scientific validity data, the analytical performance data and the clinical performance data, their assessment and the clinical evidence derived therefrom, shall be documented in the performance evaluation report referred to in Section 1.3.2 of Part A of Annex XIII. The performance evaluation report shall be part of the technical documentation, referred to in Annex II, relating to the device concerned.

6. The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's PMPF plan in accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79.

The performance evaluation report for class C and D devices shall be updated when necessary, but at least annually, with the data referred to in the first subparagraph. The summary of safety and performance referred to in Article 29(1) shall be updated as soon as possible, where necessary.

7. Where necessary to ensure the uniform application of Annex XIII, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 57

General requirements regarding performance studies

1. The manufacturer shall ensure that a device for performance study complies with the general safety and performance requirements set out in Annex I apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

2. Where appropriate, performance studies shall be performed in circumstances similar to the normal conditions of use of the device.

3. Performance studies shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are scientifically valid, reliable and robust.

Performance studies, including performance studies that use left-over samples, shall be conducted in accordance with applicable law on data protection.

Article 58

Additional requirements for certain performance studies

1. Any performance study:

(a) in which surgically invasive sample-taking is done only for the purpose of the performance study;

(b) that is an interventional clinical performance study as defined in point (46) of Article 2; or

(c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies,

shall, in addition to meeting the requirements set out in Article 57 and Annex XIII, be designed, authorised, conducted, recorded and reported in accordance with this Article and Articles 59 to 77 and Annex XIV.

2. Performance studies involving companion diagnostics shall be subject to the same requirements as the performance studies listed in paragraph 1. This does not apply to performance studies involving companion diagnostics using only left-over samples. Such studies shall however be notified to the competent authority.

3. Performance studies shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with national law. Member States shall ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a performance study. At least one lay person shall participate in the ethical review.

4. Where the sponsor of a performance study is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication with that legal representative shall be deemed to be a communication with the sponsor.

Member States may choose not to apply the first subparagraph to performance studies to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that performance study who shall be the addressee for all communications with the sponsor provided for in this Regulation.

5. A performance study as referred to in paragraph 1 may be conducted only where all of the following conditions are met:

(a) the performance study is the subject of an authorisation by the Member State(s) in which the performance study is to be conducted, in accordance with this Regulation, unless otherwise stated;

(b) an ethics committee, set up in accordance with national law, has not issued a negative opinion in relation to the performance study, which is valid for that entire Member State under its national law;

(c) the sponsor or its legal representative or a contact person pursuant to paragraph 4 is established in the Union;

(d) vulnerable populations and subjects are appropriately protected in accordance with Articles 59 to 64;

(e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;

(f) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, in accordance with Article 59;

(g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

(h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;

(i) the performance study has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the performance study plan and constantly monitored;

(j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, any other person entitled by national law to provide the relevant patient care under performance study conditions;

(k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the performance study;

(l) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;

(m) in the case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;

(n) in the case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into consideration the state of the art. Where, for companion diagnostics, the scientific validity is not established, the scientific rationale for the use of the biomarker shall be provided;

(o) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;

(p) the requirements of Annex XIV are fulfilled.

6. Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the performance study at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

7. The investigator shall be a person exercising a profession which is recognised in the Member State concerned, as qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care or laboratory medicine. Other personnel involved in conducting a performance study shall be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

8. Where appropriate, the facilities where the performance study involving subjects is to be conducted shall be suitable for the performance study and shall be similar to the facilities where the device is intended to be used.

Article 59

Informed consent

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document or the record, as appropriate, by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the performance study.

2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:

(a) enable the subject or his or her legally designated representative to understand:

(i) the nature, objectives, benefits, implications, risks and inconveniences of the performance study;

(ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate in and the right to withdraw from the performance study at any time without any resulting detriment and without having to provide any justification;

(iii) the conditions under which the performance study is to be conducted, including the expected duration of the subject's participation in the performance study; and

(iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the performance study is discontinued;

(b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified under national law; and

(d) include information about the applicable damage compensation system referred to in Article 65;

(e) include the Union-wide unique single identification number for the performance study referred to in Article 66(1) and information about the availability of the performance study results in accordance with paragraph 6 of this Article.

3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.

4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.

5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.

6. The subject shall be informed that a report of the performance study and a summary presented in terms understandable to the intended user will be made available pursuant to Article 73(5) in the electronic system on performance studies referred to in Article 69, irrespective of the outcome of the performance study, and shall be informed, to the extent possible, when they have become available.

7. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a performance study.

Article 60

Performance studies on incapacitated subjects

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a performance study may be conducted only where, in addition to the conditions set out in Article 58(5), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the incapacitated subjects have received the information referred to in Article 59(2) in a way that is adequate in view of their capacity to understand it;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 59(2) to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;

(e) the performance study is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in performance studies on persons able to give informed consent, or by other research methods;

(f) the performance study relates directly to a medical condition from which the subject suffers;

(g) there are scientific grounds for expecting that participation in the performance study will produce:

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or

(ii) some benefit for the population represented by the incapacitated subject concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

2. The subject shall as far as possible take part in the informed consent procedure.

3. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those performance studies on incapacitated subjects, where there are no scientific grounds to expect that participation in the performance study will produce a direct benefit to the subject outweighing the risks and burdens involved.

Article 61

Performance studies on minors

1. A performance study on minors may be conducted only where, in addition to the conditions set out in Article 58 (5), all of the following conditions are met:

(a) the informed consent of their legally designated representative has been obtained;

(b) the minors have received the information referred to in Article 59(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 59(2) to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;

(e) the performance study is intended to investigate treatments for a medical condition that only occurs in minors or the performance study is essential with respect to minors to validate data obtained in performance studies on persons able to give informed consent or by other research methods;

(f) the performance study either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

(g) there are scientific grounds for expecting that participation in the performance study will produce:

(i) a direct benefit to the minor subject outweighing the risks and burdens involved; or

(ii) some benefit for the population represented by the minor concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition;

(h) the minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;

(i) if during a performance study the minor reaches the age of legal competence to give informed consent as defined in the national law, his or her express informed consent shall be obtained before that subject can continue to participate in the performance study.

2. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those performance studies on minors, where there are no scientific grounds to expect that participation in the performance study will produce a direct benefit to the subject outweighing the risks and burdens involved.

Article 62

Performance studies on pregnant or breastfeeding women

A performance study on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 58(5), all of the following conditions are met:

(a) the performance study has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;

(b) if such a performance study has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if:

  (i) a performance study of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

  (ii) the performance study contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children; and

  (iii) the performance study poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;

(c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

(d) no incentives or financial inducements are given to subjects, except for compensation for expenses and loss of earnings directly related to the participation in the performance study.

Article 63

Additional national measures

Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in performance studies, or persons in residential care institutions.

Article 64

Performance studies in emergency situations

1. By way of derogation from point (f) of Article 58(5), from points (a) and (b) of Article 60(1) and from points (a) and (b) of Article 61(1), informed consent to participate in a performance study may be obtained, and information on the performance studies may be given, after the decision to include the subject in the performance study, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical performance study plan for that performance study and that all of the following conditions are fulfilled:

(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the performance study;

(b) there are scientific grounds to expect that participation of the subject in the performance study will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;

(d) the investigator certifies that he or she is not aware of any objections to participate in the performance study previously expressed by the subject;

(e) the performance study relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the performance study is of such a nature that it may be conducted exclusively in emergency situations;

(f) the performance study poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. Following an intervention pursuant to paragraph 1 of this Article, informed consent in accordance with Article 59 shall be sought to continue the participation of the subject in the performance study, and information on the performance study shall be given, in accordance with the following requirements:

(a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 59(2) shall be given as soon as possible to the subject and to his or her legally designated representative;

(b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever can be done sooner, and the information referred to in Article 59(2) shall be given as soon as possible to the subject or his or her legally designated representative, as applicable.

For the purposes of point (b) where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the performance study shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the performance study.

Article 65

Damage compensation

1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a performance study conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State in which the performance study is conducted.

Article 66

Application for performance studies

1. The sponsor of a performance study referred to in Article 58(1) and (2) shall enter and submit an application to the Member State(s) in which the performance study is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Sections 2 and 3 of Annex XIII and in Annex XIV.

The application shall be submitted by means of the electronic system referred to in Article 69, which shall generate a Union-wide unique single identification number for the performance study which shall be used for all relevant communication in relation to that performance study. Within 10 days of receiving the application, the Member State concerned shall notify the sponsor as to whether the performance study falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter I of Annex XIV.

2. Within one week of any change occurring in relation to the documentation referred to in Chapter I of Annex XIV, the sponsor shall update the relevant data in the electronic system referred to in Article 69 and make that change to the documentation clearly identifiable. The Member State concerned shall be notified of the update by means of that electronic system.

3. Where the Member State concerned finds that the performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete the application by means of the electronic system referred to in Article 69. The Member State concerned may extend this period by a maximum of 20 days where appropriate.

Where the sponsor has not provided comments nor completed the application within the time limit referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers that the application falls under the scope of this Regulation and/or is complete but the Member State concerned does not agree, the application shall be considered to have been rejected. The Member State concerned shall provide for an appeal procedure in respect of such refusal.

The Member State concerned shall notify the sponsor within five days of receipt of the comments or of the requested additional information, whether the performance study is considered as falling within the scope of this Regulation and the application is complete.

4. The Member State concerned may also extend the period referred to in paragraphs 1 and 3 each by a further five days.

5. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the periods referred to in paragraphs 1, 3 and 4 respectively.

6. During the period when the application is being assessed the Member State may request additional information from the sponsor. The expiry of the deadline pursuant to the point (b) of paragraph 7 shall be suspended from the date of the first request until such time as the additional information has been received.

7. The sponsor may start the performance study in the following circumstances:

(a) in the case of performance studies carried out pursuant to point (a) of Article 58(1) and where the specimen collection does not represent a major clinical risk to the subject of the study, unless otherwise stated by national law, immediately after the validation date of application described in paragraph 5 of this Article, provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study;

(b) in the case of performance studies carried out pursuant to points (b) and (c) of Article 58(1) and Article 58(2) or performance studies other than those referred to in point (a) of this paragraph, as soon as the Member State concerned has notified the sponsor of its authorisation and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date of the application referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.

8. The Commission is empowered to adopt delegated acts in accordance with Article 108 amending, in the light of technical progress and global regulatory developments, the requirements laid down in Chapter I of Annex XIV.

9. In order to assure the uniform application of the requirements laid down in Chapter I of Annex XIV, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 67

Assessment by Member States

1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of natural or legal persons financing the performance study, as well as free of any other undue influence.

2. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.

3. Member States shall assess whether the performance study is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall, while taking into account applicable CS or harmonised standards, examine in particular:

(a) the demonstration of compliance of the device(s) for performance study with the applicable general safety and performance requirements, apart from the aspects covered by the performance study, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, in case of performance studies, the evaluation of the analytical performance, and in case of interventional clinical performance studies, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art;

(b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by harmonised standards;

(c) whether the measures planned for the safe installation, putting into service and maintenance of the device for performance study are adequate;

(d) the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the performance study and methodological aspects, including sample size, comparator and endpoints;

(e) whether the requirements of Annex XIV are met.

4. Member States shall refuse the authorisation of the performance study if:

(a) the application dossier submitted pursuant to Article 66(3) remains incomplete;

(b) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the performance study, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients;

(c) the requirements of Article 58 are not met; or

(d) any assessment under paragraph 3 is negative.

Member States shall provide for an appeal procedure in respect of a refusal pursuant to the first subparagraph.

Article 68

Conduct of a performance study

1. The sponsor and the investigator shall ensure that the performance study is conducted in accordance with the approved performance study plan.

2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the performance study is in compliance with the requirements of this Regulation, the sponsor shall ensure adequate monitoring of the conduct of a performance study. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the performance study including the following:

(a) the objective and methodology of the performance study; and

(b) the degree of deviation of the intervention from normal clinical practice.

3. All performance study information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

5. Member States shall inspect, at an appropriate level, performance study site(s) to check that performance studies are conducted in accordance with the requirements of this Regulation and with the approved investigation plan.

6. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the study.

Article 69

Electronic system on performance studies

1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:

(a) to create the single identification numbers for performance studies referred to in Article 66(1);

(b) to be used as an entry point for the submission of all applications or notifications for performance studies referred to in Articles 66, 70, 71 and 74 and for all other submission of data, or processing of data in this context;

(c) for the exchange of information relating to performance studies in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in to Articles 72 and 74;

(d) for information to be provided by the sponsor in accordance with Article 73, including the performance study report and its summary as required in paragraph 5 of that Article;

(e) for reporting on serious adverse events and device deficiencies, and related updates referred to in Article 76.

2. When setting up the electronic system referred to in paragraph 1 of this Article, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council ([1]) as concerns performance studies of companion diagnostics.

3. The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

(a) protection of personal data in accordance with Regulation (EC) No 45/2001;

(b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;

(c) effective supervision of the conduct of the performance study by the Member State(s) concerned.

4. No personal data of subjects shall be publicly available.

5. The user interface of the electronic system referred to in paragraph 1 shall be available in all official languages of the Union.

Article 70

Performance studies regarding devices bearing the CE marking

1. Where a performance study is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 18(1) ('PMPF study'), and where the performance study would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 69. The sponsor shall include the documentation referred to in Section 2 of Part A of Annex XIII and in Annex XIV. Points (b) to (l) and (p) of Article 58(5), and Articles 71, 72 and 73 Article 76(5) and the relevant provisions of Annexes XIII and XIV shall apply to PMPF studies.

2. Where a performance study is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 18(1), Articles 58 to 77 shall apply.

([1]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Article 71

Substantial modifications to performance studies

1. If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, it shall notify, within one week, by means of the electronic system referred to in Article 69, the Member State(s) in which the performance study is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Annex XIV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. The Member State shall assess any substantial modification to the performance study in accordance with the procedure laid down in Article 67.

3. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after the notification referred to in paragraph 1, unless:

(a) the Member State in which the performance study is being or is to be conducted has notified the sponsor of its refusal based on the grounds referred to in Article 67(4) or on considerations of public health, of subject and user safety or health, or of public policy; or

(b) an ethics committee in that Member State has issued a negative opinion in relation to the substantial modification to the performance study, which, in accordance with national law, is valid for that entire Member State.

4. The Member State(s) concerned may extend the period referred to in paragraph 3 by a further seven days, for the purpose of consulting with experts.

Article 72

Corrective measures to be taken by Member States and information exchange between Member States on performance studies

1. Where a Member State in which a performance study is being or is to be conducted has grounds for considering that the requirements set out in this Regulation are not met, it may take at least any of the following measures on its territory:

(a) revoke the authorisation for the performance study;

(b) suspend or terminate the performance study;

(c) require the sponsor to modify any aspect of the performance study.

2. Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor or the investigator or both for their opinion. That opinion shall be delivered within seven days.

3. Where a Member State has taken a measure referred to in paragraph 1 of this Article, or has refused a performance study, or has been notified by the sponsor of the early termination of a performance study on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 69.

4. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 69 to all Member States and the Commission.

Article 73

Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination

1. If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall inform within 15 days the Member States in which that performance study has been temporarily halted or terminated early, through the electronic system referred to in Article 69, of the temporary halt or early termination. In the event that the sponsor has temporarily halted or terminated early the performance study on safety grounds, it shall inform all Member States in which that performance study is being conducted thereof within 24 hours.

2. The end of a performance study shall be deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the performance study plan.

3. The sponsor shall notify each Member State in which that performance study was being conducted of the end of that performance study in that Member State. That notification shall be made within 15 days of the end of the performance study in relation to that Member State.

4. If a study is conducted in more than one Member State, the sponsor shall notify all Member States in which that performance study was conducted of the end of the performance study in all Member States. That notification shall be made within 15 days of that end of the performance study.

5. Irrespective of the outcome of the performance study, within one year of the end of the performance study or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a performance study was conducted a performance study report as referred to in Section 2.3.3. of Part A of Annex XIII.

The performance study report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 69.

Where, for scientific reasons, it is not possible to submit the performance study report within one year of the end of the study, it shall be submitted as soon as it is available. In such case, the clinical performance study plan referred to in Section 2.3.2. of Part A of Annex XIII shall specify when the results of the performance study are going to be available, together with a justification.

6. The Commission shall issue guidelines regarding the content and structure of the summary of the performance study report.

In addition, the Commission may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of performance studies.

7. The summary and the performance study report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 69, at the latest when the device is registered in accordance with Article 26 and before it is placed on the market. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission.

If the device is not registered in accordance with Article 26 within one year of the summary and the performance study report having been entered into the electronic system pursuant to paragraph 5 of this Article, they shall become publicly accessible at that point in time.

Article 74

Coordinated assessment procedure for performance studies

1. By means of the electronic system referred to in Article 69, the sponsor of a performance study to be conducted in more than one Member State may submit, for the purpose of Article 66, a single application that, upon receipt, is transmitted electronically to all Member States in which the performance study is to be conducted.

2. The sponsor shall propose in the single application referred to in paragraph 1 that one of the Member States in which the performance study is to be conducted acts as coordinating Member State. The Member States in which the performance study is to be conducted shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the coordinating Member State proposed by the sponsor shall assume that role.

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation referred to in Chapter I of Annex XIV.

However, the completeness of the documentation referred to in Sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV and point (c) of Section 2.3.2. of Part A of Annex XIII shall be assessed separately by each Member State concerned in accordance with Article 66(1) to (5).

4. With regard to documentation other than that referred to in the second subparagraph of paragraph 3, the coordinating Member State shall:

(a) within six days of receipt of the single application, notify the sponsor that it is the coordinating Member State ('notification date');

(b) for the purpose of the validation of the application, take into account any considerations submitted within seven days of the notification date by any Member State concerned;

(c) within 10 days of the notification date, assess whether the performance study falls within the scope of this Regulation and whether the application is complete and shall notify the sponsor accordingly. Article 66(1) and (3) to (5) shall apply to the coordinating Member State in relation to that assessment;

(d) establish the results of its assessment in a draft assessment report to be transmitted within 26 days of the validation date to the Member States concerned. By day 38 after the validation date, the other Member States concerned shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State which shall take due account of those comments and proposals in its finalisation of the final assessment report, to be transmitted within 45 days of the validation date to the sponsor and the other Member States concerned.

The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with Article 66(7).

5. As regards the assessment of the documentation referred to in the second subparagraph of paragraph 3, each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed 12 days from the receipt of the request. The expiry of the last deadline pursuant to point (d) of paragraph 4 shall be suspended from the date of the request until such time as the additional information has been received.

6. For class C and D devices, the coordinating Member State may also extend the periods referred to in paragraph 4 by a further 50 days, for the purpose of consulting with experts.

7. The Commission may, by means of implementing acts, further specify the procedures and timescales for coordinated assessments to be taken into account by Member States concerned when deciding on the sponsor's application. Such implementing acts may also set out the procedures and timescales for coordinated assessment in the case of substantial modifications pursuant to paragraph 12 of this Article and in the case of reporting of adverse events pursuant to Article 76(4) and in the case of performance studies involving companion diagnostics, where the medicinal products are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

8. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member State(s) concerned.

Notwithstanding the first subparagraph, a Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds:

(a) when it considers that participation in the performance study would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned;

(b) infringement of national law; or

(c) considerations as regards subject safety and data reliability and robustness submitted under point (d) of paragraph 4.

Where one of the Member States concerned disagrees with the conclusion on the basis of the second subparagraph of this paragraph, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 69 to the Commission, to all other Member States concerned, and to the sponsor.

9. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the performance study is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

10. A Member State concerned shall refuse to authorise a performance study if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 8, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV are not complied with, or where an ethics committee has issued a negative opinion in relation to that performance study which is valid in accordance with national law for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

11. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 69 as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation has been refused. Notification shall be done by way of one single decision within five days of the transmission, pursuant to point (d) of paragraph 4 of this Article, by the coordinating Member State of the final assessment report. Where an authorisation of a performance study is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation.

12. Any substantial modifications as referred to in Article 71 shall be notified to the Member States concerned by means of the electronic system referred to in Article 69. Any assessment as to whether there are grounds for disagreement as referred to in the second subparagraph of paragraph 8 of this Article shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV and point (c) of Section 2.3.2 of Part A of Annex XIII, which shall be assessed separately by each Member State concerned.

13. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks under this Chapter.

14. The procedure set out in this Article shall, until 27 May 2029, be applied only by those of the Member States in which the performance studies are to be conducted which have agreed to apply it. After 27 May 2029, all Member States shall be required to apply that procedure.

Article 75

Review of the coordinated assessment procedure

By 27 May 2028, the Commission shall submit to the European Parliament and to the Council a report on the experience gained from the application of Article 74 and, if necessary, propose a review of Article 74(14) and point (g) of Article 113(3).

Article 76

Recording and reporting of adverse events that occur during performance studies

1. The sponsor shall fully record all of the following:

(a) any adverse event of a type identified in the performance study plan as being critical to the evaluation of the results of that performance study;

(b) any serious adverse event;

(c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) any new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report without delay to all Member States in which a performance study is being conducted all of the following by means of the electronic system referred to in Article 69:

(a) any serious adverse event that has a causal relationship with the device, the comparator or the study procedure or where such causal relationship is reasonably possible;

(b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) any new findings in relation to any event referred to in points (a) and (b).

The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

Upon request by any Member State in which the performance study is being conducted, the sponsor shall provide all information referred to in paragraph 1.

3. The sponsor shall also report to the Member States in which the performance study is being conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a performance study is performed under the same clinical performance study plan as the one applying to a performance study covered by this Regulation by means of the electronic system referred to in Article 69.

4. In the case of a performance study for which the sponsor has used the single application referred to in Article 74, the sponsor shall report any event as referred to in paragraph 2 of this Article by means of the electronic system referred to in Article 69. Upon receipt, this report shall be transmitted electronically to all Member States in which the performance study is being conducted.

Under the direction of the coordinating Member State referred to in Article 74(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the performance study or whether to revoke the authorisation for that performance study.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of PMPF studies referred to in Article 70(1), the provisions on vigilance laid down in Articles 82 to 85 and in the implementing acts adopted pursuant to Article 86 shall apply instead of this Article.

6. Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding performance study has been established.

Article 77

Implementing acts

The Commission may, by means of implementing acts, establish the detailed arrangements and procedural aspects necessary for the implementation of this Chapter, as regards the following:

(a) harmonised electronic forms for the application for performance studies and their assessment as referred to in Articles 66 and 74, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 69;

(c) harmonised electronic forms for the notification of PMPF studies as referred to in Article 70(1), and of substantial modifications as referred to in Article 71;

(d) the exchange of information between Member States as referred to in Article 72;

(e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 76;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 76;

(g) uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Section 1

Post-market surveillance

Article 78

Post-market surveillance system of the manufacturer

1. For each device manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(8).

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the performance evaluation;

(d) to update the summary of safety and performance referred to in Article 29;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 83.

The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 82.

Article 79

Post-market surveillance plan

The post-market surveillance system referred to in Article 78 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1 of Annex III. The post-market surveillance plan shall be part of the technical documentation specified in Annex II.

Article 80

Post-market surveillance report

Manufacturers of class A and B devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the notified body and the competent authority upon request.

Article 81

Periodic safety update report

1. Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMPF; and

(c) the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class C and D devices shall update the PSUR at least annually. That PSUR shall be part of the technical documentation as specified in Annexes II and III.

2. Manufacturers of class D devices shall submit PSUR by means of the electronic system referred to in Article 87 to the notified body involved in the conformity assessment of such devices in accordance with Article 48. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSUR and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. For class C devices, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

Section 2

Vigilance

Article 82

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices, made available on the Union market, other than devices for performance study, shall report, to the relevant competent authorities, in accordance with Articles 87(5) and (7), the following:

(a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 83;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 87.

2. As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the serious incident.

3. Manufacturers shall report any serious incident as referred to in point (a) immediately after they have established a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 15 days after they become aware of the incident.

4. Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5. Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8. Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1, in advance of the field safety corrective action being undertaken.

9. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 84(9), in consultation with the competent authorities referred to in points (a) and (b) of Article 87(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 87(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10. The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11. Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 84.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is to be treated as an increase in expected erroneous results, which will be covered by trend reporting in accordance with to Article 83, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 84.

Article 83

Trend reporting

1. Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in points (a) and (b) of Section 9.1 of Annex I and specified in the technical documentation and product information.

The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such events or change in performance, as well as the observation period, in the post-market surveillance plan referred to in Article 79.

2. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. Each competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.

Article 84

Analysis of serious incidents and field safety corrective actions

1. Following the reporting of a serious incident pursuant to Article 82(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include risk assessment of the incident and field safety corrective action taking into account the criteria as referred to in paragraph 3 of this Article as appropriate.

The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 82 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

3. In the context of the evaluation referred to in paragraph 2, the competent authority shall evaluate the risks arising from the reported serious incident and evaluate any field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and the population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Annex I.

Upon request by the national competent authority, manufacturers shall provide for all documents necessary for the risk assessment.

4. The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.

5. The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 87. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6. In the case of companion diagnostic, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, depending on whether the relevant competent authority of the Member State that authorised the medicinal products or the EMA was consulted by the notified body in accordance with the procedures set out in Section 5.2 of Annex IX and Section 3.11 of Annex X, inform that national competent authority or the EMA, as appropriate.

7. After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 87, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying serious incidents and the outcome of its assessment.

8. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in the cases referred to in paragraph 9, to the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The field safety notice shall allow the correct identification of the device or devices involved, in particular by including the relevant UDIs, and the correct identification, in particular by including the SRN, if already issued, of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons and shall clearly indicate all the actions to be taken by users.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 87 through which that notice shall be accessible to the public.

9. The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 in the following cases:

(a) where there is concern regarding a particular serious incident or cluster of serious incidents relating to the same device or type of device of the same manufacturer in more than one Member State;

(b) where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

That coordinated procedure shall cover the following:

— designation of a coordinating competent authority on a case by case basis, when required;

— defining the coordinated assessment process, including the tasks and responsibilities of the coordinating competent authority and the involvement of other competent authorities.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the competent authority of the Member State in which the manufacturer has its registered place of business.

The coordinating competent authority shall, through the electronic system referred to in Article 87, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

10. The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

11. The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 85

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 87, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.

Article 86

Implementing acts

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 80 to 85 and 87 as regards the following:

(a) the typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision of periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 80, 81, 82, 83 and 84 respectively;

(c) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;

(d) timelines for the reporting of field safety corrective actions, and for the provision by manufacturers of periodic summary reports and trend reports, taking into account the severity of the incident to be reported as referred to in Article 82;

(e) harmonised forms for the exchange of information between competent authorities as referred to in Article 84;

(f) procedures for the designation of a coordinating competent authority; the coordinated evaluation process, including tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 87

Electronic system on vigilance and post-market surveillance

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 82(1) and Article 84(5);

(b) the periodic summary reports by manufacturers referred to in Article 82(9);

(c) the reports by manufacturers on trends referred to in Article 83;

(d) the PSURs referred to in Article 81;

(e) the field safety notices by manufacturers referred to in Article 84(8);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 84(7) and (9).

That electronic system shall include relevant links to the UDI database.

2. The information referred to in paragraph 1 of this Article shall be made available through the electronic system to the competent authorities of the Member States and to the Commission. The notified bodies shall also have access to that information to the extent that it relates to devices for which they issued a certificate in accordance with Article 49.

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system referred to in paragraph 1.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the electronic system referred to in paragraph 1 at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents referred to in point (a) of Article 82(1), shall be automatically transmitted, upon receipt, via the electronic system referred to in paragraph 1 of this Article, to the competent authority of the Member State in which the incident occurred.

6. The trend reports referred to in Article 83(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the Member States in which the incidents occurred.

7. The reports on field safety corrective actions referred to in point (b) of Article 82(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the following Member States:

(a) the Member State in which the field safety corrective action is being or is to be undertaken;

(b) the Member State in which the manufacturer has its registered place of business.

8. The periodic summary reports referred to in Article 82(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

(a) the Member State or Member States participating in the coordination procedure in accordance with Article 84(9) and which have agreed on the periodic summary report;

(b) the Member State in which the manufacturer has its registered place of business.

9. The information referred to in paragraphs 5 to 8 of this Article shall be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of this Article, to the notified body that issued the certificate for the device in question in accordance with Article 51.

Section 3

Market surveillance

Article 88

Market surveillance activities

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

2. The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities taking into account the European market surveillance programme developed by the MDCG pursuant to Article 99 and local circumstances.

3. In order to fulfil the obligations laid down in paragraph 1, the competent authorities:

(a) may require economic operators to, *inter alia*, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and

(b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

4. The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 95.

5. The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where they deem it necessary to do so in the interests of the protection of public health.

6. Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.

7. The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the final report, the competent authority shall give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 95.

8. The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 95.

9. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

10. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

11. Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

Article 89

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

(a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or

(b) otherwise does not comply with the requirements laid down in this Regulation,

they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device.

The relevant economic operators shall cooperate with the competent authorities.

Article 90

Procedure for dealing with devices presenting an unacceptable risk to health and safety

1. Where, having performed an evaluation pursuant to Article 89, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 51 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 95.

3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

4. Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.

The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 95.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 95, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.

In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 95.

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified. In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

Article 91

Procedure for evaluating national measures at Union level

1. Where, within two months of receipt of the notification referred to in Article 90(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2. Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 90(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 90(4), the national measure shall be considered to be justified.

3. Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 92

Other non-compliance

1. Where, having performed an evaluation pursuant to Article 89, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall without delay take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 95.

3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 93

Preventive health protection measures

1. Where a Member State, after having performed an evaluation, which indicates a potential risk related to a device or a specific category or group of devices considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.

2. The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 95.

3. The Commission, in consultation with the MDCG and, where necessary, the economic operators concerned, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months of their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

4. Where the assessment referred to in paragraph 3 of this Article demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts) to take the necessary and duly justified measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 94

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 90 to 93 shall state the exact grounds on which it is based. Where such a measure is addressed to a specific economic operator, the competent authority shall notify without delay the economic operator concerned of that measure, and shall at the same time inform that economic operator of the remedies available under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general applicability, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted.

Where action has been taken without the economic operator having had the opportunity to make submissions as referred to in the first subparagraph, it shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that it has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.

4. Where a measure adopted pursuant to Articles 90 to 93 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 95 inform the relevant notified body and the authority responsible for the notified body of the measure taken.

Article 95

Electronic system on market surveillance

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:

(a) summaries of the results of the surveillance activities referred to in Article 88(4);

(b) the final inspection report as referred to in Article 88(7);

(c) information in relation to devices presenting an unacceptable risk to health and safety as referred to in Article 90(2), (4) and (6);

(d) information in relation to non-compliance of products as referred to in Article 92(2);

(e) information in relation to the preventive health protection measures referred to in Article 93(2);

(f) summaries of the results of the reviews and assessments of the market surveillance activities of the Member States referred to in Article 88(8).

2. The information referred to in paragraph 1 of this Article shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 51 for the device concerned and be accessible to the Member States and to the Commission.

3. Information exchanged between Member States shall not be made public where to do so might impair market surveillance activities and co-operation between Member States.

CHAPTER VIII

COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EU REFERENCE LABORATORIES AND DEVICE REGISTERS

Article 96

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

Article 97

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.

2. Member States shall with the support of the Commission participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 98

Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and detailed arrangements referred to in Article 103 and 107 of Regulation (EU) 2017/745 shall carry out, with the support of the Commission as provided in Article 104 of Regulation (EU) 2017/745, the tasks conferred on it under this Regulation as well as those under Regulation (EU) 2017/745.

Article 99

Tasks of the MDCG

Under this Regulation, the MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 45;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of performance evaluations by manufacturers, assessment by notified bodies and vigilance activities;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/745 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards and of CS;

(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, performance studies, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 88;

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States.

Article 100

The European Union reference laboratories

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories (the 'EU reference laboratories'), that satisfy the criteria set out in paragraph 4. The Commission shall only designate the EU reference laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.

2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:

(a) to verify the performance claimed by the manufacturer and the compliance of class D devices with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the third subparagraph of Article 48(3);

(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 4.12 of Annex IX and in Section 5.1 of Annex XI;

(c) to provide scientific and technical assistance to the Commission, the MDCG, the Member States and notified bodies in relation to the implementation of this Regulation;

(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

(e) to set up and manage a network of national reference laboratories after consulting with the national authorities and publish a list of the participating national reference laboratories and their respective tasks;

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;

(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;

(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;

(i) to contribute to the development of CS and of international standards;

(j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation and publish them by electronic means having considered national provisions on confidentiality.

3. At the request of a Member State, the Commission may also designate the EU reference laboratories where that Member State wishes to have recourse to such laboratories to ensure the verification of the performance claimed by the manufacturer and the compliance of class C devices with the applicable CS when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

4. The EU reference laboratories shall satisfy the following criteria:

(a) have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the *in vitro* diagnostic medical devices for which they are designated;

(b) possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) have the necessary knowledge of international standards and best practices;

(d) have an appropriate administrative organisation and structure;

(e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks;

(f) act in the public interest and in an independent manner;

(g) ensure that their staff do not have financial or other interests in the *in vitro* diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the *in vitro* diagnostic medical device industry and update this declaration whenever a relevant change occurs.

5. The EU reference laboratories shall form a network in order to coordinate and harmonise their working methods as regards testing and assessment. That coordination and harmonisation shall involve:

(a) applying coordinated methods, procedures and processes;

(b) agreeing on the use of same reference materials and common test samples and seroconversion panels;

(c) establishing common assessment and interpretation criteria;

(d) using common testing protocols and assessing the test results using standardised and coordinated evaluation methods;

(e) using standardised and coordinated test reports;

(f) developing, applying and maintaining a peer review system;

(g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results);

(h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures;

(i) coordinating the introduction of testing methods for new technologies and according to new or amended CS;

(j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by a Member State or by the Commission.

6. The EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the detailed arrangements and the amount of a Union financial contribution to the EU reference laboratories, taking into account the objectives of health and safety protection, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

7. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to predetermined and transparent terms and conditions.

8. The Commission shall specify by means of implementing acts:

(a) detailed rules to facilitate the application of paragraph 2 of this Article and detailed rules to ensure compliance with the criteria referred to in paragraph 4 of this Article.

(b) the structure and the level of the fees referred to in paragraph 7 of this Article which may be levied by an EU reference laboratory for providing scientific opinions in response to consultations by notified bodies and Member States in accordance with this Regulation, taking into account the objectives of human health and safety protection, support of innovation and cost-effectiveness.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

9. The EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If those controls find that an EU reference laboratory is not complying with the requirements for which it has been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the restriction, suspension or withdrawal of the designation.

10. The provisions in Article 107(1) of Regulation (EU) 2017/745 shall apply to the staff of the EU reference laboratories.

Article 101

Device registers and databanks

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices.

CHAPTER IX

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

Article 102

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data in accordance with Article 103;

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights unless disclosure is in the public interest;

(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 103

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 104

Levying of fees

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.

2. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be made publicly available on request.

Article 105

Funding of activities related to designation and monitoring of notified bodies

The costs associated with joint assessment activities shall be covered by the Commission. The Commission shall, by means of implementing acts, lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 106

Penalties

The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2022 and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER X

FINAL PROVISIONS

Article 107

Committee procedure

1. The Commission shall be assisted by the Committee on Medical Devices established by Article 114 of Regulation (EU) 2017/745. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or 5 thereof, as appropriate, shall apply.

Article 108

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 10(4), 17(4), 24(10), 51(6) and 66(8) shall be conferred on the Commission for a period of five years from 25 May 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 10(4), 17(4), 24(10), 51(6) and 66(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 10(4), 17(4), 24(10), 51(6) and 66(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 109

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 110

Transitional provisions

1. From 26 May 2022, any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.

2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI to Directive 98/79/EC which shall become void at the latest on 27 May 2024.

Certificates issued by notified bodies in accordance with Directive 98/79/EC from 25 May 2017 shall become void by 27 May 2024.

3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with that Directive, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply and replace the corresponding requirements in that Directive.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all applicable requirements relating to the devices it has certified.

4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market 26 May 2022 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.

5. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before 26 May 2022.

6. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2022. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2022.

7. As regards devices subject to the procedures laid down in Article 48(3) and (4), paragraph 5 of this Article applies provided that the necessary appointments to the MDCG and expert panels and of EU reference laboratories have been made.

8. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (f) of Article 113(3) and ending 18 months later, comply with Article 27(3) and Article 28(1) and Article 51(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Decision 2010/227/EU.

9. Authorisations granted by the competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.

10. Until the Commission has designated, pursuant to Article 24(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

Article 111

Evaluation

By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation. Special attention shall be given to the traceability of devices through the storage, pursuant to Article 24, of the UDI by economic operators, health institutions and health professionals. The evaluation shall also include a review on the functioning of Article 4.

Article 112

Repeal

Without prejudice to Articles 110 (3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and the obligations of manufacturers as regards the making available of documentation, under Directive 98/79/EC, that Directive is repealed with effect from 26 May 2022 with the exception of:

(a) Article 11, point (c) of Article 12(1) and Article 12(2) and (3) of Directive 98/79/EC, and the obligations relating to vigilance and performance studies provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation; and

(b) Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, and the obligations relating to registration of devices and economic operators, and certificate notifications provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

References to the repealed Directive shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XV.

Article 113

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from 26 May 2022.

3. By way of derogation from paragraph 2:

(a) Article 27(3) and Article 51(5) shall apply from 27 November 2023;

(b) Articles 31 to 46 and Article 96 shall apply from 26 November 2017. However, from that date until 26 May 2022 the obligations on notified bodies pursuant to Articles 31 to 46 shall apply only to those bodies which submit an application for designation in accordance with Article 34;

(c) Article 97 shall apply from 26 May 2018;

(d) Article 100 shall apply from 25 November 2020;

(e) for class D devices, Article 24(4) shall apply from 26 May 2023. For class B and class C devices Article 24(4) shall apply from 26 May 2025. For class A devices Article 24(4) shall apply from 26 May 2027;

(f) without prejudice to the obligations on the Commission pursuant to Article 34 of Regulation (EU) 2017/745, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1) of that Regulation, Eudamed is not fully functional on 26 May 2022, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3) of that Regulation. The provisions referred to in the preceding sentence are:

— Article 26,

— Article 28,

— Article 29,

— the second sentence of Article 36(2),

— Article 38(10),

— Article 39(2),

— the second subparagraph of Article 40(12),

— points (d) and (e) of Article 42(7),

— Article 49(2),

— Article 50(1),

— Articles 66 to 73,

— paragraphs 1 to 13 of Article 74,

— Articles 75 to 77,

— Article 81(2),

— Articles 82 and 83,

— Article 84(5) and (7) and the third subparagraph of Article 84(8),

— Article 85,

— Article 88(4), (7) and (8),

— Article 90(2) and (4),

— the last sentence of Article 92(2),

— Article 94(4),

— the second sentence of the first subparagraph of Article 110(3).

Until Eudamed is fully functional the corresponding provisions of Directive 98/79/EC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding performance studies, vigilance reporting, registration of devices and economic operators, and certificate notifications.

(g) The procedure set out in Article 74 shall, apply from 26 May 2027 without prejudice to Article 74(14).

(h) Article 110(10) shall apply from 26 May 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 5 April 2017.

For the European Parliament	*For the Council*
The President	*The President*
A. TAJANI	I. BORG

ANNEXES

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ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3. Manufacturers shall establish, implement, document and maintain a risk management system.

   Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

   (a) establish and document a risk management plan for each device;

   (b) identify and analyse the known and foreseeable hazards associated with each device;

   (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

   (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

   (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability; and

   (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

   (a) eliminate or reduce risks as far as possible through safe design and manufacture;

   (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

   (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

   Manufacturers shall inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer shall:

   (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

   (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.

CHAPTER II

REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE

9. Performance characteristics

9.1. Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:

(a) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and

(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.

9.2. The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.

9.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.

9.4. The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions:

(a) for devices for self-testing, performances obtained by laypersons;

(b) for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).

10. Chemical, physical and biological properties

10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.

Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.

10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

10.3. Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]), and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]).

10.4. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.

11. Infection and microbial contamination

11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall:

(a) allow easy and safe handling;

(b) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use;

and, where necessary

(c) prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.

11.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.

11.3. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

11.4. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.

11.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

11.6. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

12. Devices incorporating materials of biological origin

Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.

([1]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).

In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

13. Construction of devices and interaction with their environment

13.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.

13.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

(e) the risks of accidental ingress of substances into the device;

(f) the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;

(g) the risks of any foreseeable interference with other devices.

13.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

13.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

13.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

13.6. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

13.7 The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14. Devices with a measuring function

14.1. Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.

14.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC [1].

15. Protection against radiation

15.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.

15.2. When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be:

(a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and

(b) fitted with visual displays and/or audible warnings of such emissions.

15.3. The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

16. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

16.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

16.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

16.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

16.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

17. Devices connected to or equipped with an energy source

17.1. For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.

17.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.

17.3. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

17.4. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

[1] Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

17.5. Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

18. Protection against mechanical and thermal risks

18.1. Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.

18.2. Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.

18.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.

Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

18.4. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

18.5. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

18.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.

18.7. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

18.8. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

19. Protection against the risks posed by devices intended for self-testing or near-patient testing

19.1. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.

19.2. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to:

(a) ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and

(b) reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

19.3. Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user:

(a) can verify that, at the time of use, the device will perform as intended by the manufacturer; and

(b) be warned if the device has failed to provide a valid result.

CHAPTER III

REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE

20. Label and instructions for use

20.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.

(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.

(d) Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.

(e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

(f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.

(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

(i) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.

(j) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use.

20.2. Information on the label

The label shall bear all of the following particulars:

(a) the name or trade name of the device;

(b) the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;

(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

(d) if the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative;

(e) an indication that the device is an *in vitro* diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;

(f) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

(g) the UDI carrier as referred to in Article 24 and Part C of Annex VI;

(h) an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;

(i) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

(j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;

(k) an indication of any special storage and/or handling condition that applies;

(l) where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;

(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

(n) if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;

(o) where applicable, any particular operating instructions;

(p) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

(q) if the device is intended for self-testing or near-patient testing, an indication of that fact;

(r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;

(s) where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;

(t) the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;

(u) the label for devices for self-testing shall bear the following particulars:

(i) the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);

(ii) the need for additional materials for the test to function properly;

(iii) contact details for further advice and assistance.

The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.

20.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging'):

The following particulars shall appear on the sterile packaging:

(a) an indication permitting the sterile packaging to be recognised as such,

(b) a declaration that the device is in a sterile condition,

(c) the method of sterilisation,

(d) the name and address of the manufacturer,

(e) a description of the device,

(f) the month and year of manufacture,

(g) an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,

(h) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

20.4. Information in the instructions for use

20.4.1. The instructions for use shall contain all of the following particulars:

(a) the name or trade name of the device;

(b) the details strictly necessary for the user to uniquely identify the device;

(c) the device's intended purpose:

(i) what is detected and/or measured;

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);

(iii) the specific information that is intended to be provided in the context of:

— a physiological or pathological state;

— congenital physical or mental impairments;

— the predisposition to a medical condition or a disease;

— the determination of the safety and compatibility with potential recipients;

— the prediction of treatment response or reactions;

— the definition or monitoring of therapeutic measures;

(iv) whether it is automated or not;

(v) whether it is qualitative, semi-quantitative or quantitative;

(vi) the type of specimen(s) required;

(vii) where applicable, the testing population; and

(viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.

(d) an indication that the device is an *in vitro* diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;

(e) the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);

(f) the test principle;

(g) a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);

(h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;

(i) a list of materials provided and a list of special materials required but not provided;

(j) for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:

— information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or

— information on any known restrictions to combinations of devices and equipment.

(k) an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;

(l) in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;

(m) if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;

(n) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate:

(i) warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,

(ii) warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

(iii) warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

(iv) precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,

(v) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union,

(vi) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses;

(o) any warnings and/or precautions related to potentially infectious material that is included in the device;

(p) where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;

(q) conditions for collection, handling, and preparation of the specimen;

(r) details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;

(s) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

— details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;

— identification of any consumable components and how to replace them;

— information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;

— methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.

(t) where applicable, recommendations for quality control procedures;

(u) the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;

(v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;

(w) analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;

(x) clinical performance characteristics as defined in Section 9.1 of this Annex;

(y) the mathematical approach upon which the calculation of the analytical result is made;

(z) where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;

(aa) where relevant, reference intervals in normal and affected populations;

(ab) information on interfering substances or limitations (*e.g.* visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;

(ac) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:

(i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;

(ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);

(iii) physical hazards such as explosion.

(ad) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;

(ae) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;

(af) a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;

(ag) where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;

(ah) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

20.4.2 In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:

(a) details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;

(b) specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;

(c) the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;

(d) the results shall be expressed and presented in a way that is readily understood by the intended user;

(e) information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;

(f) the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;

(g) for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(a) product or trade name and a general description of the device including its intended purpose and intended users;

(b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended purpose of the device which may include information on:

(i) what is to be detected and/or measured;

(ii) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;

(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

(iv) whether it is automated or not;

(v) whether it is qualitative, semi-quantitative or quantitative;

(vi) the type of specimen(s) required;

(vii) where applicable, the testing population;

(viii) the intended user;

(ix) in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s).

(d) the description of the principle of the assay method or the principles of operation of the instrument;

(e) the rationale for the qualification of the product as a device;

(f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;

(g) the description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers;

and where applicable:

(h) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;

(i) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;

(j) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;

(k) a description of any software to be used with the device;

(l) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

(m) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.

1.2. Reference to previous and similar generations of the device

(a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

(b) an overview of identified similar devices available on the Union or international markets, where such devices exist.

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

A complete set of

(a) the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;

(b) the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

3. DESIGN AND MANUFACTURING INFORMATION

3.1. Design information

Information to allow the design stages applied to the device to be understood shall include:

(a) a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;

(b) for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;

(c) for instruments and software, an overview of the entire system;

(d) for software, a description of the data interpretation methodology, namely the algorithm;

(e) for devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self-testing or near-patient testing.

3.2. Manufacturing information

(a) information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures;

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall also include:

(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards, CS or other solutions applied;

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. BENFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

This includes:

6.1. Information on analytical performance of the device

6.1.1. Specimen type

This Section shall describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such *as* duration, temperature limits and freeze/thaw cycles.

6.1.2. Analytical performance characteristics

6.1.2.1. Accuracy of measurement

(a) Trueness of measurement

This Section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow an assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a certified reference material or certified reference method is available.

(b) Precision of measurement

This Section shall describe repeatability and reproducibility studies.

6.1.2.2. Analytical sensitivity

This Section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.

6.1.2.3. Analytical specificity

This Section shall describe interference and cross reactivity studies performed to determine the analytical specificity in the presence of other substances/agents in the specimen.

Information shall be provided on the evaluation of potentially interfering and cross-reacting substances or agents on the assay, on the tested substance or agent type and its concentration, specimen type, analyte test concentration, and results.

Interferents and cross-reacting substances or agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

(a) substances used for patient treatment such as medicinal products;

(b) substances ingested by the patient such as alcohol, foods;

(c) substances added during specimen preparation such as preservatives, stabilisers;

(d) substances encountered in specific specimen types such as haemoglobin, lipids, bilirubin, proteins;

(e) analytes of similar structure such as precursors, metabolites or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that can mimic the test condition.

6.1.2.4. Metrological traceability of calibrator and control material values

6.1.2.5. Measuring range of the assay

This Section shall include information on the measuring range regardless of whether the measuring systems are linear or non-linear, including the limit of detection and describe information on how the range and detection limit were established.

This information shall include a description of specimen type, number of specimens, number of replicates, and specimen preparation including information on the matrix, analyte levels and how levels were established. If applicable, a description of any high dose hook effect and the data supporting the mitigation such as dilution steps shall be added.

6.1.2.6. Definition of assay cut-off

This Section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, such as:

(a) the population(s) studied: demographics, selection, inclusion and exclusion criteria, number of individuals included;

(b) method or mode of characterisation of specimens; and

(c) statistical methods such as Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

6.1.3. The analytical performance report referred to in Annex XIII.

6.2. Information on clinical performance and clinical evidence. Performance Evaluation Report

The documentation shall contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, as referred to in Annex XIII, together with an assessment of those reports.

The clinical performance study documents referred to in Section 2 of Part A of Annex XIII shall be included and/or fully referenced in the technical documentation.

6.3. Stability (excluding specimen stability)

This Section shall describe claimed shelf life, in use stability and shipping stability studies.

6.3.1. Claimed shelf-life

This Section shall provide information on stability testing studies to support the shelf life that is claimed for the device. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions. The three lots do not need to be consecutive. Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claims but shall be followed up with real time stability studies.

Such detailed information shall include:

(a) the study report including the protocol, number of lots, acceptance criteria and testing intervals;

(b) where accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described;

(c) the conclusions and claimed shelf life.

6.3.2. In-use stability

This Section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device, regardless of whether real or simulated. This may include open vial stability and/or, for automated instruments, on board stability.

In the case of automated instrumentation, if calibration stability is claimed, supporting data shall be included.

Such detailed information shall include:

(a) the study report (including the protocol, acceptance criteria and testing intervals);

(b) the conclusions and claimed in-use stability.

6.3.3. Shipping stability

This Section shall provide information on shipping stability studies for one lot of devices to evaluate the tolerance of devices to the anticipated shipping conditions.

Shipping studies may be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold.

Such information shall describe:

(a) the study report (including the protocol, acceptance criteria);

(b) the method used for simulated conditions;

(c) the conclusion and recommended shipping conditions.

6.4. Software verification and validation

The documentation shall contain evidence of the validation of the software, as it is used in the finished device. Such information shall typically include the summary results of all verification, validation and testing performed in-house and applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

6.5. Additional information required in specific cases

(a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with regard to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected.

(c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(d) If the device is to be connected to other equipment in order to operate as intended, a description of the resulting combination including proof that it conforms to the general safety and performance requirements set out in Annex I when connected to any such equipment having regard to the characteristics specified by the manufacturer.

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 78 to 81 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1. The post-market surveillance plan drawn up in accordance with Article 79.

   The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 78.

   (a) The post-market surveillance plan shall address the collection and utilisation of available information, in particular:

   — information concerning serious incidents, including information from PSURs, and field safety corrective actions,

   — records referring to non-serious incidents and data on any undesirable side-effects,

   — information from trend reporting,

   — relevant specialist or technical literature, databases and/or registers,

   — information, including feedbacks and complaints, provided by users, distributors and importers, and

   — publicly-available information about similar medical devices.

   (b) The post-market surveillance plan shall cover at least:

   — a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

   — effective and appropriate methods and processes to assess the collected data;

   — suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;

   — effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;

   — methods and protocols to manage the events subject to the trend report as provided for in Article 83, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

   — methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;

   — reference to procedures to fulfil the manufacturers obligations laid down in Articles 78, 79 and 81;

   — systematic procedures to identify and initiate appropriate measures including corrective actions;

   — effective tools to trace and identify devices for which corrective actions might be necessary; and

   — a PMPF plan as referred to in Part B of Annex XIII, or a justification as to why a PMPF is not applicable.

2. The PSUR referred to in Article 81 and the post-market surveillance report referred to in Article 80.

ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN referred to in Article 28 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The Basic UDI-DI as referred to in Part C of Annex VI;

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

5. Risk class of the device in accordance with the rules set out in Annex VIII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

7. References to any CS used and in relation to which conformity is declared;

8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

9. Where applicable, additional information;

10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

ANNEX V

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking the following form:

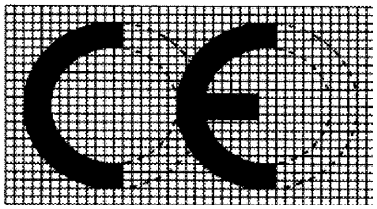

2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX VI

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26 AND THE UDI SYSTEM

PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party.

1. Information relating to the economic operator

1.1. type of economic operator (manufacturer, authorised representative, or importer),

1.2. name, address and contact details of the economic operator,

1.3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details of that person,

1.4. name address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15,

2. Information relating to the device

2.1. Basic UDI-DI,

2.2. type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,

2.3. Member State in which the device shall or has been placed on the market in the Union,

2.4. in the case of class B, class C or class D devices: Member States where the device is or is to be made available,

2.5. presence of tissues, cells, or, their derivatives, of human origin (y/n),

2.6. presence of tissues, cells or their derivatives of animal origin as referred to in Regulation (EU) No 722/2012(y/n),

2.7. presence of cells or substances of microbial origin (y/n),

2.8. risk class of the device,

2.9. where applicable, the single identification number of the performance study,

2.10. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), the name, address and contact details of that legal or natural person,

2.11. in the case of class C or D devices, the summary of safety and performance,

2.12. status of the device (on the market, no longer placed on the market, recalled, field safety corrective Action initiated),

2.13. indication as to whether the device is a ‘new’ device.

A device shall be considered to be ‘new’ if:

(a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;

(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.

2.14. indication as to whether the device is intended for self-testing or near-patient testing.

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26

The manufacturer shall provide to the UDI database the UDI-DI and the following information relating to the manufacturer and the device:

1. quantity per package configuration,

2. the Basic UDI-DI as referred to in Article 24(6) and any additional UDI-DIs,

3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),

4. if applicable, the 'unit of use' UDI-DI (where a UDI is not labelled on the device at the level of its 'unit of use', a 'unit of use' UDI-DI shall be assigned so as to associate the use of a device with a patient),

5. name and address of the manufacturer, as indicated on the label,

6. the SRN issued in accordance with Article 28(2),

7. if applicable, name and address of the authorised representative (as indicated on the label),

8. the medical device nomenclature code as provided for in Article 23,

9. risk class of the device,

10. if applicable, name or trade name,

11. if applicable, device model, reference, or catalogue number,

12. additional product description (optional),

13. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

14. if applicable, additional trade names of the device,

15. labelled as a single use device (y/n),

16. if applicable, the maximum number of reuses,

17. device labelled sterile (y/n),

18. need for sterilisation before use (y/n),

19. URL for additional information, such as electronic instructions for use (optional),

20. if applicable, critical warnings or contra-indications,

21. status of the device (on the market, no longer placed on the market, recalled, field safety action initiated).

PART C

THE UDI SYSTEM

1. Definitions

Automatic identification and data capture ('AIDC')

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unit of Use DI

The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

Configurable device

A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customised to meet specific needs.

UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

Human Readable Interpretation (HRI)

HRI is a legible interpretation of the data characters encoded in the UDI carrier.

Packaging levels

Packaging levels means the various levels of device packaging that contain a fixed quantity of devices, such as a carton or case.

Production Identifier (UDI-PI)

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

The different types of UDI-PI(s) include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

Radio Frequency Identification ('RFID')

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

Shipping containers

A shipping container is a container in relation to which traceability is controlled by a process specific to logistics systems.

Unique Device Identifier ('UDI')

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

The word 'Unique' does not imply serialisation of individual production units.

UDI carrier

The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, its HRI.

UDI carriers include, *inter alia*, ID/linear bar code, 2D/Matrix bar code, RFID.

2. General requirements

2.1. The affixing of the UDI is an additional requirement — it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.

2.2. The manufacturer shall assign and maintain unique UDIs for its devices.

2.3. Only the manufacturer may place the UDI on the device or its packaging.

2.4. Only coding standards provided by issuing entities designated by the Commission pursuant to Article 24(2) may be used.

3. The UDI

3.1. A UDI shall be assigned to the device itself or its packaging. Higher levels of packaging shall have their own UDI.

3.2. Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

3.3. The UDI shall contain two parts: a UDI-DI and a UDI-PI.

3.4. The UDI-DI shall be unique at each level of device packaging.

3.5. If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.

3.6. Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

3.7. Kits shall be assigned and bear their own UDI.

3.8. The manufacturer shall assign the UDI to a device following the relevant coding standard.

3.9. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. In particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(a) Name or trade name,

(b) device version or model,

(c) labelled as single use,

(d) packaged sterile,

(e) need for sterilization before use,

(f) quantity of devices provided in a package,

(g) critical warnings or contra-indications.

3.10. Manufacturers that repackage or relabel devices with their own label shall retain a record of the original device manufacturer's UDI.

4. UDI carrier

4.1. The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label and on all higher levels of device packaging. Higher levels do not include shipping containers.

4.2. In the event of there being significant space constraints on the unit of use packaging the UDI carrier may be placed on the next higher packaging level.

4.3. For single use class A and class B devices packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging e.g. a carton containing several packages. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging.

4.4. For devices exclusively intended for retail point of sale, the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

4.5. When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.

4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC.

4.8. The HRI format shall follow the rules of the UDI code-issuing entity.

4.9. If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

4.11. The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

4.12. If the UDI carrier is readily readable or scannable through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.

4.13. In the case of single finished devices made up of multiple parts that must be assembled before first use, it shall be sufficient to place the UDI carrier on only one part of each device.

4.14. The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage.

4.15. Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

5. General principles of the UDI database

5.1. The UDI database shall support the use of all core UDI database data elements referred to in Part B of this Annex.

5.2. Manufacturers shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

5.3. Appropriate methods/procedures for validation of the data provided shall be implemented.

5.4. Manufacturers shall periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

5.5. The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with this Regulation.

5.6. The database shall allow for the linking of all the packaging levels of the device.

5.7. The data for new UDI-DIs shall be available at the time the device is placed on the market.

5.8. Manufacturers shall update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

5.9. Internationally accepted standards for data submission and updates shall, wherever possible, be used by the UDI database.

5.10. The user interface of the UDI database shall be available in all official languages of the Union. The use of free-text fields shall, however, be minimised in order to reduce translations.

5.11. Data relating to devices that are no longer available on the market shall be retained in the UDI database.

6. Rules for specific device types

6.1. Reusable devices that are part of kits and that require cleaning, disinfection, sterilisation or refurbishing between uses

6.1.1. The UDI of such devices shall be placed on the device and shall be readable after each procedure to make the device ready for the next use;

6.1.2. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

6.2. Device software

6.2.1. UDI assignment Criteria

The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.

The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.2.2. A new UDI-DI shall be required whenever there is a modification that changes:

(a) the original performance,

(b) the safety or the intended use of the software.

(c) interpretation of data.

Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.2.3. Minor software revisions shall require a new UDI-PI and not a new UDI-DI:

Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.2.4. UDI placement criteria for software

(a) where the software is delivered on a physical medium, for example via *a* CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;

(b) the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format such as an 'about' file, or included on the start-up screen;

(c) software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);

(d) only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays such as 'about' menu, splash screen, etc.;

(e) the human readable format of the UDI for the software shall include the application identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

ANNEX VII

REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. Legal status and organisational structure

1.1.1. Each notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect. Its legal personality and status shall be fully documented. Such documentation shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the organisation to which it belongs.

1.1.3. If a notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities under this Regulation shall be subject to the applicable requirements of this Regulation.

1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that they ensure that there is confidence in the performance by the notified body and in the results of the conformity assessment activities it conducts.

1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance by the notified body upon the results of its conformity assessment activities.

1.1.6. The notified body shall identify the persons in top-level management that have overall authority and responsibility for each of the following:

(a) provision of adequate resources for conformity assessment activities;

(b) development of procedures and policies for the operation of the notified body;

(c) supervision of implementation of the procedures, policies and quality management systems of the notified body;

(d) supervision of the notified body's finances;

(e) activities and decisions taken by the notified body, including contractual agreements;

(f) delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities;

(g) interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the device in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer. This does not preclude the notified body from carrying out conformity assessment activities for competing manufacturers.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. Such procedures shall provide for the identification, investigation and resolution of any case in which a conflict of interest may arise including involvement in consultancy services in the field of devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;

(b) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities;

(c) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;

(d) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the devices or processes under assessment; and

(e) be linked to any organisation which itself provides consultancy services as referred to in the point (d). Such restriction shall not preclude general training activities that are not client specific and that relate to regulation of devices s or to related standards.

1.2.4. Involvement in consultancy services in the field of devices prior to taking up employment with a notified body shall be fully documented at the time of employment, and potential conflicts of interests shall be monitored and resolved in accordance with this Annex. Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client prior to taking up employment with a notified body, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of three years.

1.2.5. The impartiality of notified bodies, of their top-level management and of the assessment personnel shall be guaranteed. The level of the remuneration of the top-level management and assessment personnel of a notified body and subcontractors involved in assessment activities shall not depend on the results of the assessments. Notified bodies shall make publicly available the declarations of interest of their top-level management.

1.2.6. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the authority responsible for notified bodies and/or the competent authority and, on the other hand, the notified body.

1.2.7. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors or of any associated body, including the activities of its owners do not affect its independence, impartiality or the objectivity of its conformity assessment activities.

1.2.8. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to fees.

1.2.9. The requirements laid down in this Section shall in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment.

1.3. Confidentiality

1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of the conformity assessment activities, except when disclosure is required by law.

1.3.2. The personnel of a notified body shall observe professional secrecy in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the authorities responsible for notified bodies, competent authorities for devices in the Member States or the Commission. Proprietary rights shall be protected. The notified body shall have documented procedures in place in respect of the requirement of this Section.

1.4. Liability

1.4.1. The notified body shall take out appropriate liability insurance for its conformity assessment activities, unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for their conformity assessment.

1.4.2. The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its long-term economic viability, taking into account, where relevant, any specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of any relevant standardisation activities and in the activities of the notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745 and that its assessment and decision-making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.2. The notified body shall take into consideration guidance and best practice documents.

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the consistent fulfilment of the requirements of this Regulation.

2.2. The quality management system of the notified body shall address at least the following:

(a) management system structure and documentation, including policies and objectives for its activities;

(b) policies for assignment of activities and responsibilities to personnel;

(c) assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management;

(d) the planning, conduct, evaluation and, if necessary, adaptation of its conformity assessment procedures;

(e) control of documents;

(f) control of records;

(g) management reviews;

(h) internal audits;

(i) corrective and preventive actions;

(j) complaints and appeals;

(k) continuous training.

Where documents are used in various languages, the notified body shall ensure and control that they have the same content.

2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.

2.4. The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. That commitment shall cover aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel shall be required to complete written statements indicating their compliance with confidentiality, independence and impartiality principles.

3. RESOURCE REQUIREMENTS

3.1. General

3.1.1. Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, notified bodies shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which they have been designated. Such requirement presupposes at all times and for each conformity assessment procedure and each type of devices in relation to which they have been designated, that the notified body has permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. Such personnel shall be in sufficient numbers to ensure that the notified body in question can perform the conformity assessment tasks, including the assessment of the medical functionality, performance evaluations and the performance and safety of devices, for which it has been designated, having regard to the requirements of this Regulation, in particular those set out in Annex I.

A notified body's cumulative competences shall be such as to enable it to assess the types of devices for which it is designated. The notified body shall have sufficient internal competence to critically evaluate assessments conducted by external expertise. Tasks which a notified body is precluded from subcontracting are set out in Section 4.1.

Personnel involved in the management of the operation of a notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of assessment and verification staff, for verification of their competence, for authorisation and allocation of their tasks, for organisation of their initial and ongoing training, and for their assignment of their duties and monitoring of those staff, in order to ensure that personnel who carry out and perform assessment and verification operations are competent to fulfil the tasks required of them.

The notified body shall identify at least one individual within its top-level management as having overall responsibility for all conformity assessment activities in relation to devices.

3.1.2. The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.

3.1.3. The notified body shall clearly document the extent and limits of duties and responsibilities and the level of authorisation of to the personnel, including any subcontractors and external experts involved in conformity assessment activities and inform those personnel accordingly.

3.2. Qualification criteria in relation to personnel

3.2.1. The notified body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities, including as regards knowledge, experience and other competence required, and the required initial and ongoing training. The qualification criteria shall address the various functions within the conformity assessment process, such as auditing, product evaluation or testing, technical documentation review, decision-making, and batch release, as well as the devices, technologies and areas, such as biocompatibility, sterilisation, self and near patient-testing, companion diagnostics and performance evaluation, covered by the scope of designation.

3.2.2. The qualification criteria referred to in Section 3.2.1 shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 38(3), providing a sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined at least for the assessment of:

— biological safety,

— performance evaluation,

— devices for self and near patient testing,

— companion diagnostics,

— functional safety,

— software,

— packaging, and

— the different types of sterilisation processes.

3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be external experts or subcontracted. They shall have proven knowledge and experience in all of the following:

— Union devices legislation and relevant guidance documents;

— the conformity assessment procedures provided for in this Regulation;

— a broad base of knowledge of device technologies and the design and manufacture of devices;

— the notified body's quality management system, related procedures and the required qualification criteria;

— training relevant to personnel involved in conformity assessment activities in relation to devices;

— adequate experience in conformity assessments under this Regulation or previously applicable law within a notified body.

3.2.4. The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

— identify when specialist input is required for the assessment of the performance evaluation conducted by the manufacturer and identify appropriately qualified experts;

— appropriately train external clinical experts in the relevant requirements of this Regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implications of their assessment and the advice they provide;

— be able to review and scientifically challenge the clinical data contained within the performance evaluation, and any associated performance study, and appropriately guide external clinical experts in the assessment of the performance evaluation presented by the manufacturer;

— be able to scientifically evaluate and, if necessary, challenge the performance evaluation presented, and the results of the external clinical experts' assessment of the manufacturer's performance evaluation;

— be able to ascertain the comparability and consistency of the assessments of performance evaluation conducted by clinical experts;

— be able to make an assessment of the manufacturer's performance evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker; and

— be able to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.5. The personnel responsible for carrying out product-related reviews, (product reviewers), such as technical documentation reviews or type examination, including aspects such as performance evaluation, biological safety, sterilisation and software validation, shall have all the following proven qualifications:

— successful completion of a university or a technical college degree or an equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing, or research, of which two years shall be in the design, manufacture, testing or use of devices or technology to be assessed or related to the scientific aspects to be assessed;

— knowledge of device legislation, including the general safety and performance requirements set out in Annex I;

— appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge and experience of performance evaluation;

— appropriate knowledge of the devices which they are assessing;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those assessments;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system (site auditors) shall have all of the following proven qualifications:

— successful completion of a university or a technical college degree or equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;

— four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the area of quality management;

— appropriate knowledge of devices legislation as well as related harmonised standards, CS and guidance documents;

— appropriate knowledge and experience of risk management and related device standards and guidance documents;

— appropriate knowledge of quality management systems and related l devices standards and guidance documents;

— appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those audits;

— training in auditing techniques enabling them to challenge quality management systems;

— the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.7. The personnel with overall responsibility for final reviews and decision-making on certification shall be employed by the notified body itself and shall not be external experts or be subcontracted. Those personnel, as a group, shall have proven knowledge and comprehensive experience of all of the following:

— devices legislation and relevant guidance documents;

— device conformity assessments relevant to this Regulation;

— the types of qualifications, experience and expertise relevant to device conformity assessment;

— a broad base of knowledge of device technologies, including sufficient experience of the conformity assessment of devices being reviewed for certification, the device industry and the design and manufacture of devices;

— the notified body's quality system, related procedures and the required qualifications for personnel involved;

— the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

3.3. Documentation of qualification, training and authorisation of personnel

3.3.1. The notified body shall have a procedure in place to fully document the qualification of each member of personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where, in exceptional circumstances, the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall justify to the authority responsible for notified bodies the authorisation of those members of personnel to carry out specific conformity assessment activities.

3.3.2. For all of its personnel referred to in Sections 3.2.3 to 3.2.7, the notified body shall establish and maintain up to date:

— a matrix detailing the authorisations and responsibilities of the personnel in respect of conformity assessment activities;

— records attesting to the required knowledge and experience for the conformity assessment activity for which they are authorised. The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.

3.4. Subcontractors and external experts

3.4.1. Notified bodies may, without prejudice to Section 3.2, subcontract certain clearly defined component parts of a conformity assessment activity.

The subcontracting of the auditing of quality management systems or of product-related reviews as a whole shall not be permitted, nevertheless parts of those activities may be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body in question shall retain full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf.

The following activities may not be subcontracted by notified bodies:

— review of the qualifications and monitoring of the performance of external experts;

— auditing and certification activities where the subcontracting in question is to auditing or certification organisations;

— allocation of work to external experts for specific conformity assessment activities;

— final review and decision-making functions.

3.4.2. Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:

— the subcontractor meets the relevant requirements of this Annex;

— subcontractors and external experts do not further subcontract work to organisations or personnel;

— the natural or legal person that applied for conformity assessment has been informed of the requirements referred to in the first and second indent.

Any subcontracting or consultation of external personnel shall be properly documented, shall not involve any intermediaries, and shall be subject to a written agreement covering, among other things, confidentiality and conflicts of interest. The notified body in question shall take full responsibility for the tasks performed by subcontractors.

3.4.3. Where subcontractors or external experts are used in the context of a conformity assessment, in particular regarding novel devices or technologies, the notified body in question shall have adequate internal competence in each product area for which it is designated that is adequate for the purpose of leading the overall conformity assessment, verifying the appropriateness and validity of expert opinions and making decisions on certification.

3.5. Monitoring of competences, training and exchange of experience

3.5.1. The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel and subcontractors, involved in conformity assessment activities.

3.5.2. Notified bodies shall review at regular intervals, the competence of their personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel. That review shall as a minimum, verify that personnel:

— are aware of the Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities referred to in Section 1.6;

— take part in the internal exchange of experience and the continuous training and education programme referred to in Section 3.1.2.

4. PROCESS REQUIREMENTS

4.1. General

The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities up to decision making and surveillance and taking into account, when necessary, the respective specificities of the devices.

The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall be fulfilled as part of the internal activities of notified bodies and shall not be subcontracted.

4.2. Notified body quotations and pre-application activities

The notified body shall

(a) publish a publicly available description of the application procedure by which manufacturers can obtain certification from it. That description shall include which languages are acceptable for submission of documentation and for any related correspondence;

(b) have documented procedures relating to, and documented details about, fees charged for specific conformity assessment activities and any other financial conditions relating to notified bodies' assessment activities for devices;,

(c) have documented procedures in relation to advertising of its conformity assessment services. Those procedures shall ensure that advertising or promotional activities in no way imply or are capable of leading to an inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than that of other notified bodies;

(d) have documented procedures requiring the review of pre-application information including the preliminary verification that the product is covered by this Regulation and its classification prior to issuing any quotation to the manufacturer relating to a specific conformity assessment;

(e) ensure that all contracts relating to the conformity assessment activities covered by this Regulation are concluded directly between the manufacturer and the notified body and not with any other organisation.

4.3. Application review and contract

The notified body shall require a formal application signed by a manufacturer or an authorised representative containing all of the information and the manufacturer's declarations required by the relevant conformity assessment as referred to in Annexes IX to XI.

The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.

The notified body shall have documented procedures to review applications, addressing:

(a) the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex, under which approval has been sought,

(b) the verification of the qualification of products covered by those applications as devices and their respective classifications,

(c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation,

(d) the ability of the notified body to assess the application based on its designation, and

(e) the availability of sufficient and appropriate resources.

The outcome of each review of an application shall be documented. Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 52 and shall be accessible to other notified bodies.

4.4. Allocation of resources

The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and related documentation that are subject to conformity assessment.

For each application, the notified body shall determine the resources needed and identify one individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment. The allocation of tasks required to be carried out as part of the conformity assessment and any changes subsequently made to this allocation shall be documented.

4.5. Conformity assessment activities

4.5.1. General

The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.

The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI and in particular the following requirements:

— to appropriately plan the conduct of each individual project,

— to ensure that the composition of the assessment teams is such that there is sufficient experience in relation to the technology concerned, and that there is continuous objectivity and independence, and to provide for rotation of the members of the assessment team at appropriate intervals,

— to specify the rationale for fixing time limits for completion of conformity assessment activities,

— to assess the manufacturer's technical documentation and the solutions adopted to meet the requirements laid down in Annex I,

— to review the manufacturer's procedures and documentation relating to performance evaluation,

— to address the interface between the manufacturer's risk management process and its appraisal and analysis of the performance evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I,

— to carry out the 'specific procedures' referred to in Section 5 of Annex IX,

— in the case of class B or C devices, to assess the technical documentation of devices selected on a representative basis,

— to plan and periodically carry out appropriate surveillance audits and assessments, to carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,

— relating to the sampling of devices verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,

— to evaluate and verify a manufacturer's compliance with relevant Annexes.

The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

4.5.2. Quality management system auditing

(a) As part of the assessment of the quality management system a, a notified body shall prior to an audit and in accordance with its documented procedures:

— assess the documentation submitted in accordance with the relevant conformity assessment Annex, and draw up an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,

— identify links between and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both,

— clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit, and draw up an audit plan that adequately addresses and takes account of the specific requirements for the devices, technologies and processes involved,

— draw up and keep up to date, for class B and class C devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate,

— select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.

(b) Based on the audit programme it has drawn up, the notified body shall, in accordance with its documented procedures:

— audit the manufacturer's quality management system in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions of this Regulation which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of this Regulation are met,

— based on relevant technical documentation, and in order to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment Annex, review and audit the manufacturer's processes and subsystems,– in particular for:

— design and development,

— production and process controls,

— product documentation,

— purchasing controls including verification of purchased devices,

— corrective and preventive actions including for post-market surveillance, and

— PMPF,

— and review and audit requirements and provisions adopted by the manufacturer, including those in relation to fulfilling the general safety and performance requirements set out in Annex I,

— the documentation shall be sampled in such as a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information,

— if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,

— conduct assessments of the technical documentation based on its sampling plan and taking account of Section 4.5.4. for performance evaluation,

— the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards, or with best practice documents developed or adopted by the MDCG.

4.5.3. Product verification

Assessment of the technical documentation

For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX, notified bodies shall have sufficient expertise, facilities and documented procedures for:

— the allocation of appropriately qualified and authorised personnel for the examination of individual aspects, such as use of the device, biocompatibility, performance evaluation, risk management and sterilisation, and

— the assessment of conformity of the design with this Regulation, and taking account of Sections 4.5.4. and 4.5.5. This assessment shall include the examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof. If further tests or other evidence is required for the assessment of conformity with the requirements of this Regulation, the notified body in question shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Type-examinations

The notified body shall have documented procedures, sufficient expertise and facilities for the type-examination of devices in accordance with Annex X including the capacity to:

— examine and assess the technical documentation, taking account of Sections 4.5.4. and 4.5.5, and verify that the type has been manufactured in conformity with that documentation;

— establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility;

— document its rationale for the selection of those parameters;

— carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements set out in Annex I. Such examinations and tests shall include all tests necessary to verify that the manufacturer has in fact applied the relevant standards it has opted to use;

— agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body;

— assume full responsibility for test results. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

Verification by examination and testing of every product batch

The notified body shall:

(a) have documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product batch in accordance with Annexes IX and XI;

(b) establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:

— verify, for class C devices, the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to those devices,

— confirm, for class B devices, the conformity with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to those devices,

(c) document its rationale for the selection of the parameters referred to in point (b);

(d) have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation by examining and testing every product batch as specified in Section 5 of Annex XI;

(e) have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed;

(f) assume full responsibility for test results in accordance with documented procedures; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

4.5.4. Performance evaluation assessment

The assessment by notified bodies of procedures and documentation shall address the results of literature searches and all validation, verification and testing performed and conclusions drawn, and shall typically include considering the use of alternative materials and substances and take account of the packaging, stability including shelf life of the finished device. Where no new testing has been undertaken by a manufacturer or where there have been deviations from procedures, the notified body in question shall critically examine the justification presented by the manufacturer.

The notified body shall have documented procedures in place relating to the assessment of a manufacturer's procedures and documentation relating to performance evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:

(a) the planning, conduct, assessment, reporting and updating of the performance evaluation as referred to in Annex XIII,

(b) post-market surveillance and post-market performance follow up,

(c) the interface with the risk management process,

(d) the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I,

(e) the conclusions drawn with regard to the clinical evidence and drawing up of the performance evaluation report.

The procedures referred to in the second paragraph shall take into consideration available CS, guidance and best practice documents.

The notified body's assessment of performance evaluations as referred to in Annex XIII shall cover:

— the intended use specified by the manufacturer and claims for the device defined by it,

— the planning of the performance evaluation,

— the methodology for the literature search,

— relevant documentation from the literature search,

— the performance studies,

— post-market surveillance and post-market performance follow up,

— validity of equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

— the performance evaluation report,

— justifications in relation to non-performance of performance studies or PMPF.

In relation to data from performance studies included within the performance evaluation, the notified body in question shall ensure that the conclusions drawn by the manufacturer are valid in the light of the approved performance study plan.

The notified body shall ensure that the performance evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements and that it is conducted in accordance with Annex XIII and that it is appropriately reflected in the information provided relating to the device.

4.5.5. Specific Procedures

The notified body shall have documented procedures, sufficient expertise and facilities for the procedures referred to in Section 5 of Annex IX, for which they are designated.

In the case of companion diagnostics, the notified body shall have documented procedures in place that aim to fulfil the requirements of this Regulation in relation to consultation of the EMA or a medicinal products competent authority during its assessment of such types of device.

4.6. Reporting

The notified body shall:

— ensure that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can represent objective evidence of such compliance to persons that are not themselves involved in the assessment, for example personnel in designating authorities,

— ensure that records that are sufficient to provide a discernible audit trail are available for quality management system audits,

— clearly document the conclusions of its assessment of performance evaluation in a performance evaluation assessment report,

— for each specific project, provide a detailed report which shall be based on a standard format containing a minimum set of elements determined by the MDCG.

The report of the notified body shall:

— clearly document the outcome of its assessment and draw clear conclusions from the verification of the manufacturer's conformity with the requirements of this Regulation,

— make a recommendation for a final review and for a final decision to be taken by the notified body; this recommendation shall be signed off by the member of personnel responsible in the notified body,

— be provided to the manufacturer in question.

4.7. Final review

The notified body shall prior to making a final decision:

— ensure that the personnel assigned for the final review and decision making on specific projects are appropriately authorised and are different from the personnel who have conducted the assessments,

— verify that the report or reports and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and

— verify whether there are any unresolved non-conformities preventing issuance of a certificate.

4.8. Decisions and certifications

The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:

— decide, based on the assessment documentation and additional information available whether the requirements of this Regulation are fulfilled,

— decide, based on the results of its assessment of the performance evaluation and risk management whether the post-market surveillance plan, including the PMPF plan, is adequate,

— decide on specific milestones for further review by the notified body of the up to date performance evaluation,

— decide whether specific conditions or provisions need to be defined for the certification,

— decide, based on the novelty, risk classification, performance evaluation and conclusions from the risk analysis of the device, on a period of certification not exceeding five years,

— clearly document decision making and approval steps including approval by signature of the members of personnel responsible,

— clearly document responsibilities and mechanisms for communication of decisions, in particular, where the final signatory of a certificate differs from the decision maker or decision makers or does not fulfil the requirements laid down in Section 3.2.7.,

— issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification,

— issue a certificate or certificates for the applicant alone and shall not issue certificates covering multiple entities,

— ensure that the manufacturer is notified of the outcome of the assessment and the resultant decision and that they are entered into the electronic system referred to in Article 52.

4.9. Changes and modifications

The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the manufacturers' information obligations and the assessment of changes to:

— the approved quality management system or systems or to the product-range covered,

— the approved design of a device,

— the approved type of a device,

— any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.5.

The procedures and contractual arrangements referred to in the first paragraph shall include measures for checking the significance of the changes referred to in the first paragraph.

In accordance with its documented procedures, the notified body in question shall:

— ensure that manufacturers submit for prior approval plans for changes as referred to in the first paragraph and relevant information relating to such changes,

— assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of this Regulation,

— notify the manufacturer of its decision and provide a report or, as applicable, a supplementary report, which shall contain the justified conclusions of its assessment.

4.10. Surveillance activities and post-certification monitoring

The notified body shall have documented procedures:

— defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,

— for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. Such information shall be taken into account in the planning and conduct of surveillance activities,

— to review vigilance data to which they have access under to Article 87 in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

The notified body in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide on which of the following options to apply:

— not to take action on the basis that the vigilance case is clearly not related to the certification granted,

— observe the manufacturer's and competent authorities' activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,

— perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, where it is likely that the certification granted is at risk,

— increase the frequency of surveillance audits,

— review specific products or processes on the occasion of the next audit of the manufacturer, or

— take any other relevant measure.

In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:

— conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5.,

— ensure that it adequately assesses the manufacturer's documentation on, and application of, the provisions on vigilance, the post-market surveillance and PMPF,

— sample and test devices and technical documentation, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,

— ensure that the manufacturer complies with the documentation and information obligations laid down in the relevant Annexes and that its procedures take into account best practices in the implementation of quality management systems,

— ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,

— gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,

— ask the manufacturer, if non-conformities are detected, for corrections, corrective actions, and where applicable preventive actions, and

— where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw it.

The notified body shall, if listed as part of the conditions for certification:

— conduct an in-depth review of the performance evaluation as most recently updated by the manufacturer based on the manufacturer's post-market surveillance, on its PMPF and on clinical literature relevant to the condition being treated with the device or on clinical literature relevant to similar devices,

— clearly document the outcome of the in-depth review and address any specific concerns to the manufacturer or impose any specific conditions on it,

— ensure that the performance evaluation as most recently updated is appropriately reflected in the instructions for use and, where applicable, the summary of safety and performance.

4.11. Re-certification

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device, including changes not yet notified,

(b) experience gained from post-market surveillance,

(c) experience from risk-management,

(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

(e) experience from reviews of the performance evaluation, including the results of any performance studies and PMPF,

(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

(g) changes to applied or new harmonised standards, CS or equivalent documents, and

(h) changes in medical, scientific and technical knowledge, such as:

— new treatments,

— changes in test methods,

— new scientific findings on materials and components, including findings on their biocompatibility,

— experience from studies on comparable devices,

— data from registers and registries,

— experience from performance studies with comparable devices.

The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMPF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' performance evaluation reports.

For the decision on the re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps to be taken for certification, such as application and application review.

ANNEX VIII

CLASSIFICATION RULES

1. IMPLEMENTING RULES

1.1. Application of the classification rules shall be governed by the intended purpose of the devices.

1.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

1.3. Accessories for an *in vitro* diagnostic medical device shall be classified in their own right separately from the device with which they are used.

1.4. Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

If the software is independent of any other device, it shall be classified in its own right.

1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.

1.6. Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.

1.7. The manufacturer shall take into consideration all classification and implementation rules in order to establish the proper classification for the device.

1.8. Where a manufacturer states multiple intended purposes for a device, and as a result the device falls into more than one class, it shall be classified in the higher class.

1.9. If several classification rules apply to the same device, the rule resulting in the higher classification shall apply.

1.10. Each of the classification rules shall apply to first line assays, confirmatory assays and supplemental assays.

2. CLASSIFICATION RULES

2.1. Rule 1

Devices intended to be used for the following purposes are classified as class D:

— detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;

— detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;

— determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

2.2. Rule 2

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C, except when intended to determine any of the following markers:

— ABO system [A (ABO1), B (ABO2), AB (ABO3)];

— Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];

— Kell system [Kel1 (K)];

— Kidd system [JK1 (Jka), JK2 (Jkb)];

— Duffy system [FY1 (Fya), FY2 (Fyb)];

in which case they are classified as class D.

2.3. Rule 3

Devices are classified as class C if they are intended:

(a) for detecting the presence of, or exposure to, a sexually transmitted agent;

(b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;

(c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;

(d) for pre-natal screening of women in order to determine their immune status towards transmissible agents;

(e) for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(f) to be used as companion diagnostics;

(g) to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(h) to be used in screening, diagnosis, or staging of cancer;

(i) for human genetic testing;

(j) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

(k) for management of patients suffering from a life-threatening disease or condition;

(l) for screening for congenital disorders in the embryo or foetus;

(m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

2.4. Rule 4

(a) Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, *erythrocytes*, *leucocytes* and bacteria in urine, which are classified as class B.

(b) Devices intended for near-patient testing are classified in their own right.

2.5. Rule 5

The following devices are classified as class A:

(a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures relating to a specific examination;

(b) instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures;

(c) specimen receptacles.

2.6. Rule 6

Devices not covered by the above-mentioned classification rules are classified as class B.

2.7. Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as class B.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system, as described in Article 10(8), and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2, and shall be subject to audit as laid down in Sections 2.3 and 2.4 and to surveillance as specified in Section 3.

2. Quality management system assessment

2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative the name of the authorised representative and the address of the authorised representative's registered place of business,

— all relevant information on the device or group of devices covered by the quality management system,

— a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,

— a draft of an EU declaration of conformity in accordance with Article 17 and Annex IV for the device model covered by the conformity assessment procedure,

— the documentation on the manufacturer's quality management system,

— a documented description of the procedures in place to fulfil the obligations arising from by the quality management system and required under this Regulation and of the undertaking by the manufacturer in question to apply those procedures,

— a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

— the documentation on the manufacturer's post-market surveillance system, and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87,

— a description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87, as well as the undertaking by the manufacturer to apply those procedures,

— documentation on the performance evaluation plan, and

— a description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art.

2.2. Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

— the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,

— the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,

— where the design, manufacture, and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,

— where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:

— the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of, and compliance with, conformity assessment procedures,

— identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS into account and, where opted for, harmonised standards,

— risk management as referred to in Section 3 of Annex I,

— the performance evaluation, pursuant to Article 56 and Annex XIII, including PMPF,

— solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,

— solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,

— the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and

— management of design or quality management system changes;

(d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation, and the relevant documents, and

(e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

2.3. Audit

The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiate not doing so.

The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing representative samples the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 99 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.

If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of tits decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.

2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether, after those changes, the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

3. Surveillance assessment applicable to class C and class D devices

3.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system.

3.2. The manufacturer shall give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

— the documentation on its quality management system,

— the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 82 to 87,

— the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I,

— the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3 or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation. Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, sampling referred to in the second paragraph, notified bodies shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer in question with an on-site audit report which shall include, if applicable, the result of the sample test.

3.5. In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.

3.6. Notified bodies shall ensure that the composition of the assessment team is such that there is sufficient experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall neither lead nor attend audits for more than three consecutive years in respect of the same manufacturer.

3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation of class B, C and D devices and batch verification applicable to class D devices

4.1. In addition to the obligation laid down in Section 2, the manufacturer of devices shall lodge with the notified body an application for the assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in point (b) of Section 5.1.

4.3. The notified body shall examine the application by using staff, employed by it, with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

4.4. The notified body shall review the clinical evidence presented by the manufacturer in the performance evaluation report and the related performance evaluation that was conducted. The notified body shall use employed device reviewers with sufficient clinical expertise and including external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review.

4.5. The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity.

4.6. The notified body shall verify that the clinical evidence and the performance evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMPF plan proposed, where applicable.

4.7. Based on its assessment of the clinical evidence, the notified body shall consider the performance evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMPF data.

4.8. The notified body shall clearly document the outcome of its assessment in the performance evaluation assessment report.

4.9. Before issuing an EU technical documentation assessment certificate, the notified body shall request an EU reference laboratory, where designated in accordance with Article 100, to verify the performance claimed by the manufacturer and the compliance of the device with the CS, where available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the EU reference laboratory as referred to in Article 48(5).

In addition, the notified body shall, in the cases referred to in Article 48(6) of this Regulation, consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 in accordance with the procedure laid down in Article 48(6) of this Regulation on the performance evaluation report of the manufacturer.

The EU reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the EU reference laboratory and, where applicable, the views of the experts consulted, pursuant to the procedure laid down in Article 48(6), and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall, when making its decision, give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, and, where applicable, to the views expressed by the experts consulted pursuant to Article 48(6). The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable.

4.10. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a performance evaluation assessment report. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the technical documentation assessment, the conditions of the certificate's validity, the data needed for identification of the approved device, and, where appropriate, a description of the intended purpose of the device.

4.11. Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

Where the changes could affect compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU technical documentation assessment certificate, the notified body shall consult the EU reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS or with other solutions chosen by the manufacturer, to ensure a level of safety and performance that is at least equivalent, is maintained.

The EU reference laboratory shall provide a scientific opinion within 60 days.

4.12. To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings.

4.13. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

5. Assessment of the technical documentation of specific types of devices

5.1. Assessment of the technical documentation of class B, C and D devices for self-testing and near-patient testing

(a) The manufacturer of class B, C and D devices for self-testing and near-patient testing shall lodge with the notified body an application for the assessment of the technical documentation.

(b) The application shall enable the design of the device characteristics and performance(s) to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed. It shall include:

(i) test reports, including results of studies carried out with intended users;

(ii) where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment;

(iii) data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing;

(iv) the information to be provided with the device on its label and its instructions for use.

The notified body may require the application to be completed by carrying out further tests or by providing further proof to allow assessment of conformity with the requirements of this Regulation.

(c) The notified body shall verify the compliance of the device with the relevant requirements set out in Annex I of this Regulation.

(d) The notified body shall assess the application, by using staff, employed by it, with proven knowledge and experience regarding the technology concerned and the intended purpose of the device and provide the manufacturer with a technical documentation assessment report.

(e) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of its validity, the data needed for the identification of the approved devices and, where appropriate, a description of the intended purpose of the device.

(f) Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes, it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

5.2. Assessment of the technical documentation of companion diagnostics

(a) The manufacturer of a companion diagnostic shall lodge with the notified body an application for the assessment of the technical documentation. The notified body shall assess that application in accordance with the procedure laid down in Sections 4.1 to 4.8 of this Annex.

(b) The application shall enable the characteristics and performance of the device to be understood, and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.

(c) The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex to Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), the notified body shall seek the opinion of the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products authority, or the EMA, that is responsible for the authorisation.

(d) The medicinal products authority consulted shall provide its opinion, within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion and any possible update shall be included in the documentation of the notified body concerning the device.

(e) The notified body shall give due consideration to the scientific opinion referred to in point (d) when making its decision. The notified body shall convey its final decision to the medicinal products authority consulted. The EU technical documentation assessment certificate shall be delivered in accordance with point (e) of Section 5.1.

([1]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

(f) Before changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes and seek the opinion of the medicinal products authority consulted. The medicinal products authority consulted shall give its opinion within 30 days of receipt of the all the necessary documentation regarding the changes. A supplement to the EU technical documentation assessment certificate shall be issued in accordance with point (f) of Section 5.1.

CHAPTER III

ADMINISTRATIVE PROVISIONS

6. The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, it's authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1. and, in particular, the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2.,

— information on the changes referred to in Section 2.4.,

— the documentation referred to in Sections 4.2. and point (b) of Section 5.1., and

— the decisions and reports from the notified body as referred to in this Annex.

7. Each Member State shall require that the documentation referred to in Section 6 is kept at the disposal of competent authorities for the period indicated in that Section in case a manufacturer, or its authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of that period.

ANNEX X

CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.

2. Application

The manufacturer shall lodge an application for assessment with a notified body. The application shall include:

— the name of the manufacturer and the address of its registered place of business and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business,

— the technical documentation referred to in Annexes II and III. The applicant shall make a representative sample of the device production envisaged ('type') available to the notified body. The notified body may request other samples as necessary,

— in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in relation to its intended purpose for self-testing or near patient-testing,

— where practicable, an example of the device. If required, the device shall be returned on completion of the technical documentation assessment;

— data showing the suitability of the device in relation to its intended purpose for self-testing or near-patient testing,

— the information to be provided with the device on its label and its instructions for use, and

— a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

3. Assessment

The notified body shall:

(a) examine the application, by using staff with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests;

(b) examine and assess the technical documentation for conformity with the requirements of this Regulation that are applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable standards referred to in Article 8 or with applicable CS, and record items not designed on the basis of the relevant standards referred to in Article 8 or of the relevant CS;

(c) review the clinical evidence presented by the manufacturer in the performance evaluation report in accordance with Section 1.3.2 of Annex XIII. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review;

(d) in circumstances in which the clinical evidence is partly or totally based on data from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity;

(e) clearly document the outcome of its assessment in the performance evaluation assessment report referred to in Section 4.8 of Annex IX;

(f) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements laid down in this Regulation in the event that the standards referred to in Article 8 or the CS have not been applied. Where the device has to be connected to another device or devices in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device or devices having the characteristics specified by the manufacturer;

(g) carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, in the event that the manufacturer has chosen to apply the relevant harmonised standards, those standards have actually been applied;

(h) agree with the applicant on the place where the necessary assessments and tests are to be carried out;

(i) draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g);

(j) in the case of class D devices, request the EU reference laboratory, where designated in accordance with Article 100, to verify the performance claimed by the manufacturer and the compliance of the device with the CS, where available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the EU reference laboratory in accordance with Article 48(5).

In addition, the notified body shall, in the cases referred to in Article 48(6) of this Regulation, consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 following the procedure laid down in Article 48(6) of this Regulation on the performance evaluation report of the manufacturer.

The EU reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the EU reference laboratory and, where the procedure laid down in Article 48(6) is applicable, the views of the experts consulted, and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, and, where applicable, to the views expressed by the experts consulted in accordance with Article 48(6), when making its decision. The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable;

(k) for companion diagnostics, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMA (either of which to be hereinafter referred to as 'the medicinal products authority consulted' depending on which has been consulted under this point) on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products competent authority, or the EMA, that is responsible for the authorisation. The medicinal products authority consulted shall deliver its opinion within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion of the medicinal products authority consulted and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion expressed by the medicinal products authority consulted when making its decision. It shall convey its final decision to the medicinal products authority consulted; and

(l) draw up an EU type-examination report on the results of the assessments and tests carried out, and scientific opinions provided under, points (a) to (k), including a performance evaluation assessment report for class C or class D devices or covered by the third indent of Section 2.

4. Certificate

If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the type examination assessment, the conditions of certificate's validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XII. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

5.2. Changes to the approved device including limitations of its intended purpose and conditions of use shall require further approval from the notified body which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate.

5.3. Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall necessitate a new application for a conformity assessment.

5.4. Where the changes could affect the performance claimed by the manufacturer or compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the EU reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.

The EU reference laboratory shall provide a scientific opinion within 60 days.

5.5. Where the changes affect the performance or the intended use of a companion diagnostic approved through the EU type-examination certificate or its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products authority consulted shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

6. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the documentation referred to in the second indent of Section 2,

— information on the changes referred to in Section 5,

— copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Section 7 of Annex IX shall apply.

ANNEX XI

CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out final verification, as specified in Section 3, and shall be subject to the surveillance referred to in Section 4.

2. When the manufacturer fulfils the obligations laid down in Section 1, it shall draw up and keep an EU declaration of conformity in accordance with Article 17 and Annex IV for the device covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure, and to declare, that the device concerned meets the requirements of this Regulation which apply to the device, and in the case of class C and class D devices that undergo a type examination, conforms to the type described in the EU type-examination certificate.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body.

The application shall include:

— all elements listed in Section 2.1 of Annex IX,

— the technical documentation referred to in Annexes II and III for the types approved,

— a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

3.2. Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

That documentation shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 2.2. of Annex IX.

3.3. The first and second paragraphs of Section 2.3 of Annex IX shall apply.

If the quality management system is such that it ensures that the devices conform to the type described in the EU type-examination certificate and conform to the relevant provisions of this Regulation, the notified body shall issue an EU production quality assurance certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. That decision shall contain the conclusions of the notified body's audit and a reasoned assessment.

3.4. Section 2.4 of Annex IX shall apply.

4. Surveillance

Section 3.1, the first, second and fourth indents of Section 3.2, Sections 3.3, 3.4, 3.6 and 3.7 of Annex IX shall apply.

5. Verification of manufactured class D devices

5.1. In the case of class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body without delay the relevant reports on

those tests. Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer, shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests. The EU reference laboratory shall inform the notified body about its findings.

5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

6. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1 of Annex IX,

— the documentation referred to in the eighth indent of Section 2.1 of Annex IX, including the EU type-examination certificate referred to in Annex X,

— information on the changes referred to in Section 2.4 of Annex IX, and

— the decisions and reports from the notified body as referred to in Sections 2.3., 3.3. and 3.4. of Annex IX.

Section 7 of Annex IX shall apply.

ANNEX XII

CERTIFICATES ISSUED BY A NOTIFIED BODY

CHAPTER I

GENERAL REQUIREMENTS

1. Certificates shall be drawn up in one of the official languages of the Union.

2. Each certificate shall refer to only one conformity assessment procedure.

3. Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 27.

4. The scope of the certificates shall unambiguously describe the device or devices covered:

   (a) EU technical documentation assessment certificates and EU type-examination certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose as indicated by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure, risk classification and the Basic UDI-DI as referred to in Article 24(6).

   (b) EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification and the intended purpose.

5. The notified body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The notified body shall set up a system that enables the determination of the devices, including their classification, covered by the certificate.

6. Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7. EU quality management system certificates and EU production quality assurance certificates for class A sterile devices shall include a statement that the audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions.

8. Where a certificate is supplemented, modified or re-issued, the new certificate shall contain a reference to the preceding certificate and its date of issue with identification of the changes.

CHAPTER II

MINIMUM CONTENT OF THE CERTIFICATES

1. name, address and identification number of the notified body;

2. name and address of the manufacturer and, if applicable, of the authorised representative;

3. unique number identifying the certificate;

4. if already issued, the SRN of the manufacturer referred to in Article 28(2);

5. date of issue;

6. date of expiry;

7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of this Annex;

8. if applicable, reference to any previous certificate as specified in Section 8 of Chapter I;

9. reference to this Regulation and the relevant Annex in accordance with which the conformity assessment has been carried out;

10. examinations and tests performed, e.g. reference to relevant CS, harmonised standards, test reports and audit report(s);

11. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered;

12. if applicable, information about the surveillance by the notified body;

13. conclusions of the notified body's conformity assessment with regard to the relevant Annex;

14. conditions for or limitations to the validity of the certificate;

15. legally binding signature of the notified body in accordance with the applicable national law.

ANNEX XIII

PERFORMANCE EVALUATION, PERFORMANCE STUDIES AND POST-MARKET PERFORMANCE FOLLOW-UP

PART A

PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

1. PERFORMANCE EVALUATION

Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer. To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan. The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.

The performance evaluation shall be thorough and objective, considering both favourable and unfavourable data.

Its depth and extent shall be proportionate and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.

1.1. Performance evaluation plan

As a general rule, the performance evaluation plan shall include at least:

— a specification of the intended purpose of the device;

— a specification of the characteristics of the device as described in Section 9 of Chapter II of Annex I and in point (c) of Section 20.4.1. of Chapter III of Annex I;

— a specification of the analyte or marker to be determined by the device;

— a specification of the intended use of the device;

— identification of certified reference materials or reference measurement procedures to allow for metrological traceability;

— a clear identification of specified target patient groups with clear indications, limitations and contra-indications;

— an identification of the general safety and performance requirements as laid down in Sections 1 to 9 of Annex I that require support from relevant scientific validity and analytical and clinical performance data;

— a specification of methods, including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it;

— a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents;

— an indication and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the intended purpose or purposes and for the analytical and clinical performance of the device;

— for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making;

— an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria;

— the PMPF planning as referred to in Part B of this Annex.

Where any of the above mentioned elements are not deemed appropriate in the Performance Evaluation Plan due to the specific device characteristics a justification shall be provided in the plan.

1.2. Demonstration of the scientific validity and the analytical and clinical performance:

As a general methodological principle the manufacturer shall:

— identify through a systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;

— appraise all relevant data by evaluating their suitability for establishing the safety and performance of the device;

— generate any new or additional data necessary to address outstanding issues.

1.2.1. Demonstration of the scientific validity

The manufacturer shall demonstrate the scientific validity based on one or a combination of the following sources:

— relevant information on the scientific validity of devices measuring the same analyte or marker;

— scientific (peer-reviewed) literature;

— consensus expert opinions/positions from relevant professional associations;

— results from proof of concept studies;

— results from clinical performance studies.

The scientific validity of the analyte or marker shall be demonstrated and documented in the scientific validity report.

1.2.2. Demonstration of the analytical performance

The manufacturer shall demonstrate the analytical performance of the device in relation to all the parameters described in point (a) of Section 9.1 of Annex I, unless any omission can be justified as not applicable.

As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

For novel markers or other markers without available certified reference materials or reference measurement procedures, it may not be possible to demonstrate trueness. If there are no comparative methods, different approaches may be used if demonstrated to be appropriate, such as comparison to some other well-documented methods or the composite reference standard. In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

Analytical performance shall be demonstrated and documented in the analytical performance report.

1.2.3. Demonstration of the clinical performance

The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable.

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

— clinical performance studies;

— scientific peer-reviewed literature;

— published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in the clinical performance report.

1.3. Clinical evidence and performance evaluation report

1.3.1. The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of its device with the general safety and performance requirements as referred to in Annex I. The amount and quality of that data shall allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit or benefits and safety, when used as intended by the manufacturer. The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit or benefits and safety will be achieved according to the state of the art in medicine.

1.3.2. Performance evaluation report

The clinical evidence shall be documented in a performance evaluation report. This report shall include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of those reports allowing demonstration of the clinical evidence.

The performance evaluation report shall in particular include:

— the justification for the approach taken to gather the clinical evidence;

— the literature search methodology and the literature search protocol and literature search report of a literature review;

— the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety;

— the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated;

— the clinical evidence as the acceptable performances against the state of the art in medicine;

— any new conclusions derived from PMPF reports in accordance with Part B of this Annex.

1.3.3. The clinical evidence and its assessment in the performance evaluation report shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's PMPF plan in accordance with Part B of this Annex, as part of the performance evaluation and the post-market surveillance system referred to in Article 10(9). The performance evaluation report shall be part of the technical documentation. Both favourable and unfavourable data considered in the performance evaluation shall be included in the technical documentation.

2. CLINICAL PERFORMANCE STUDIES

2.1. Purpose of clinical performance studies

The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine

diagnostic testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device.

2.2. Ethical considerations for clinical performance studies

Each step in the clinical performance study, from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

2.3. Methods for clinical performance studies

2.3.1. Clinical performance study design type

Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential bias.

2.3.2. Clinical performance study plan

Clinical performance studies shall be performed on the basis of a clinical performance study plan (CPSP).

The CPSP shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study. It shall contain in particular the following information:

(a) the single identification number of the clinical performance study, as referred to in Article 66(1);

(b) identification of the sponsor, including the name, address of the registered place of business and contact details of the sponsor and, if applicable, the name, address of the registered place of business and contact details of its contact person or legal representative pursuant to Article 58(4) established in the Union;

(c) information on the investigator or investigators, namely principal, coordinating or other investigator; qualifications; contact details, and investigation site or sites, such as number, qualification, contact details and, in the case of devices for self-testing, the location and number of lay persons involved;

(d) the starting date and scheduled duration for the clinical performance study;

(e) identification and description of the device, its intended purpose, the analyte or analytes or marker or markers, the metrological traceability, and the manufacturer;

(f) information about the type of specimens under investigation;

(g) overall synopsis of the clinical performance study, its design type, such as observational, interventional, together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis and/or medicine;

(h) a description of the expected risks and benefits of the device and of the clinical performance study in the context of the state of the art in clinical practice, and with the exception of studies using left-over samples, the medical procedures involved and patient management;

(i) the instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other articles to be included or excluded and the specifications on any comparator or comparative method used as reference;

(j) description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors;

(k) the analytical performance in accordance with point (a) of Section 9.1 of Chapter I of Annex I with justification for any omission;

(l) parameters of clinical performance in accordance with point (b) of Section 9.1 of Annex I to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions;

(m) information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity of target population and, if applicable, information on vulnerable subjects involved, such as children, pregnant women, immuno-compromised or elderly subjects;

(n) information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens;

(o) monitoring plan;

(p) data management;

(q) decision algorithms;

(r) policy regarding any amendments, including those in accordance with Article 71, to or deviations from the CPSP, with a clear prohibition of use of waivers from the CPSP;

(s) accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices;

(t) statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements;

(u) description of the informed consent process, including a copy of the patient information sheet and consent forms;

(v) procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting;

(w) criteria and procedures for suspension or early termination of the clinical performance study;

(x) criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up;

(y) procedures for communication of test results outside the study, including communication of test results to the performance study subjects;

(z) policy as regards the establishment of the clinical performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 2.2;

(aa) list of the technical and functional features of the device indicating those that are covered by the performance study;

(ab) bibliography.

If part of the information referred to in the second paragraph is submitted in a separate document, it shall be referenced in the CPSP. For studies using left-over samples, points (u), (x), (y) and (z) shall not apply.

Where any of the elements referred to in the second paragraph are not deemed appropriate for inclusion in the CPSP due to the specific study design chosen, such as use of left-over samples versus interventional clinical performance studies, a justification shall be provided.

2.3.3. Clinical performance study report

A clinical performance study report, signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

3. OTHER PERFORMANCE STUDIES

By analogy, the performance study plan referred to in Section 2.3.2, and the performance study report, referred to in Section 2.3.3, shall be documented for other performance studies than clinical performance studies.

PART B

POST-MARKET PERFORMANCE FOLLOW-UP

4. PMPF shall be understood to be a continuous process that updates the performance evaluation referred to in Article 56 and Part A of this Annex and shall be specifically addressed in the manufacturer's post-market surveillance plan. When conducting PMPF, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, of ensuring the continued acceptability of the benefit-risk ratio and of detecting emerging risks on the basis of factual evidence.

5. PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.

5.1. The PMPF plan shall specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of:

(a) confirming the safety and performance of the device throughout its expected lifetime,

(b) identifying previously unknown risks or limits to performance and contra-indications,

(c) identifying and analysing emergent risks on the basis of factual evidence,

(d) ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio referred to in Sections 1 and 8 of Chapter I of Annex I, and

(e) identifying possible systematic misuse.

5.2. The PMPF plan shall include at least:

(a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;

(b) the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies;

(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) a reference to the relevant parts of the performance evaluation report referred to in Section 1.3 of this Annex and to the risk management referred to in Section 3 of Annex I;

(e) the specific objectives to be addressed by the PMPF;

(f) an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art;

(g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMPF, and;

(h) a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer.

6. The manufacturer shall analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the performance evaluation report and be part of the technical documentation.

7. The conclusions of the PMPF evaluation report shall be taken into account for the performance evaluation referred to in Article 56 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMPF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

8. If PMPF is not deemed appropriate for a specific device then a justification shall be provided and documented within the performance evaluation report.

ANNEX XIV

INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND CERTAIN OTHER PERFORMANCE STUDIES

CHAPTER I

DOCUMENTATION REGARDING THE APPLICATION FOR INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES

For devices intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects of the studies, the sponsor shall draw up and submit the application in accordance with Article 58 accompanied by the following documents:

1. Application form

The application form shall be duly filled in, containing the following information:

1.1. name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with Article 58(4) established in the Union;

1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of its authorised representative;

1.3. title of the performance study;

1.4. single identification number in accordance with Article 66(1);

1.5. status of the performance study, such as. the first submission, resubmission, significant amendment;

1.6. details and/ or reference to the performance study plan, such as including details of the design phase of the performance study;

1.7. if the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;

1.8. if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial;

1.9. identification of the Member States and third countries in which the clinical performance study is to be conducted as part of a multicentre or multinational study at the time of application;

1.10. brief description of the device for performance study, its classification and other information necessary for the identification of the device and device type;

1.11. summary of the performance study plan;

1.12. if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;

1.13. evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical performance study in accordance with the performance study plan;

1.14. details of the anticipated start date and duration of the performance study;

1.15. details to identify the notified body, if already involved at the stage of application for the performance study;

1.16. confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application;

1.17. the statement referred to in Section 4.1.

2. Investigator's brochure

The investigator's brochure (IB) shall contain the information on the device for performance study that is relevant for the study and available at the time of application. Any updates to the IB or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Annex VIII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed the label, and instructions for use to be provided with the device when placed on the market. In addition, information relating to any relevant training required.

2.3. Analytical performance.

2.4. Existing clinical data, in particular:

— from relevant peer-reviewed scientific literature and available consensus expert opinions or positions from relevant professional associations relating to the safety, performance, clinical benefits to patients, design characteristics, scientific validity, clinical performance and intended purpose of the device and/or of equivalent or similar devices;

— other relevant clinical data available relating to the safety, scientific validity, clinical performance, clinical benefits to patients, design characteristics and intended purpose of similar devices, including details of their similarities and differences with the device in question.

2.5. Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks and warnings.

2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to those tissues, cells and substances.

2.7. A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking.

2.8. A detailed description of the clinical procedures and diagnostic tests used in the course of the performance study and in particular information on any deviation from normal clinical practice.

3. Performance study plan as referred to in Sections 2 and 3 of Annex XIII.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance study that the device in question conforms to the general safety and performance requirements laid down in Annex I apart from the aspects covered by the clinical performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. Where applicable according to national law, a copy of the opinion or opinions of the ethics committee or committees concerned. Where under national law the opinion or opinions of the ethics committee or committees is not required at the time of the submission of the application, a copy of the opinion or opinions shall be submitted as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, pursuant to Article 65 and the corresponding national law.

4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

— organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;

— a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects;

— a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports shall be submitted to the competent authority reviewing an application upon request.

CHAPTER II

OTHER OBLIGATIONS OF THE SPONSOR

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance study, that obligation may be fulfilled by that person on behalf of the sponsor.

2. The sponsor shall have an agreement in place to ensure that any serious adverse events or any other event as referred to in Article 76(2) are reported by the investigator or investigators to the sponsor in a timely manner.

3. The documentation mentioned in this Annex shall be kept for a period of time of at least 10 years after the clinical performance study with the device in question has ended, or, in the event that the device is subsequently placed on the market, for at least 10 years after the last device has been placed on the market.

Each Member State shall require that the documentation referred to in this Annex is kept at the disposal of the competent authorities for the period indicated in the first subparagraph in case the sponsor, or his contact person, established within its territory, goes bankrupt or ceases its activity prior to the end of this period.

4. The sponsor shall appoint a monitor that is independent of the investigation site to ensure that the clinical performance study is conducted in accordance with the Clinical Performance Study Plan, the principles of good clinical practice and this Regulation.

5. The sponsor shall complete the follow-up of investigation subjects.

ANNEX XV

CORRELATION TABLE

Directive 98/79/EC	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	Article 2
Article 1(3)	points (54) and (55) of Article 2
Article 1(4)	—
Article 1(5)	Article 5(4) and (5)
Article 1(6)	Article 1(9)
Article 1(7)	Article 1(5)
Article 2	Article 5(1)
Article 3	Article 5(2)
Article 4(1)	Article 21
Article 4(2)	Article 19(1) and (2)
Article 4(3)	Article 19(3)
Article 4(4)	Article 10(10)
Article 4(5)	Article 18(6)
Article 5(1)	Article 8(1)
Article 5(2)	—
Article 5(3)	Article 9
Article 6	—
Article 7	Article 107
Article 8	Articles 89 and 92
Article 9(1) first subparagraph	Article 48(10) first subparagraph
Article 9(1) second subparagraph	Article 48(3) second subparagraph, Article 48(7) second subparagraph and Article 48(9) second subparagraph
Article 9(2)	Article 48(3) to (6)
Article 9(3)	Article 48(3) to (9)
Article 9(4)	Article 5(6)
Article 9(5)	—
Article 9(6)	Article 11(3) and (4)
Article 9(7)	Article 10(7)
Article 9(8)	Article 49(1)
Article 9(9)	Article 49(4)

Directive 98/79/EC	This Regulation
Article 9(10)	Article 51(2)
Article 9(11)	Article 48(12)
Article 9(12)	Article 54(1)
Article 9(13)	Article 48(2)
Article 10(1) and (2), second sentence of Article 10(3) and Article 10(4)	Articles 26(3), 27 and 28
Article 10(3), first sentence	Article 11(1)
Article 11(1)	Articles 82(1) and 84(2)
Article 11(2)	Article 82(10) and Article 82(11) first subparagraph
Article 11(3)	Article 84(7)
Article 11(4)	—
Article 11(5)	Article 86
Article 12	Article 30
Article 13	Article 93
Article 14(1)(a)	—
Article 14(1)(b)	Article 47(3) and (6)
Article 14(2)	—
Article 14(3)	—
Article 15(1)	Article 38 and Article 39
Article 15(2)	Article 32
Article 15(3)	Article 40(2) and (4)
Article 15(4)	—
Article 15(5)	Article 51(5)
Article 15(6)	Article 51(4)
Article 15(7)	Article 34(2) and Article 40(2)
Article 16	Article 18
Article 17	Articles 89 to 92
Article 18	Article 94
Article 19	Article 102
Article 20	Article 97
Article 21	—
Article 22	—
Article 23	—
Article 24	—

Ethical principles of research in the humanities and social and behavioural sciences and proposals for ethical review

National Advisory Board on Research Ethics

Helsinki 2009

THE NATIONAL ADVISORY BOARD ON RESEARCH ETHICS' PROPOSALS

1 Ethical review and its organizational framework in the humanities and social and behavioural sciences[1]

Science should be practiced primarily with the help of the scientific community's own critical review and joint ethical rules. The National Advisory Board on Research Ethics proposes an ethical review system for the humanities and social and behavioural sciences. The review system would follow the same principles as the guidelines published by the National Advisory Board on Research Ethics entitled "Good scientific practice and procedures for handling misconduct and fraud in science" (2002). The scientific community (universities, research institutions, universities of applied sciences and funding agencies) has broadly made a commitment to comply with those guidelines.

With the new proposal, this commitment would also include the obligation to arrange ethical review in the manner proposed by the National Advisory Board, and applying the ethical principles published by it. The commitment model provides a flexible possibility to alter the ethical review system and ethical guidelines on the basis of experience if this is necessary.

2 Establishment of ethics committees

The National Advisory Board on Research Ethics proposes that universities and research organizations that have made a commitment to comply with the guidelines arrange ethical review in the way they consider best. If no organs exist to deal with ethical issues, ethics committees can be established within the organization or through regional cooperation. Cooperation can also be based on language (Finnish or Swedish).

The National Advisory Board on Research Ethics recommends the establishment of regional committees particularly if, in addition to a university, smaller research organizations or universities of applied sciences operate in the region. The initiative to establish regional ethics committees should be taken by university rectors.

Since ethical review examines a study's research methods, committees' composition should ensure familiarity with the content of research fields and broad expertise in research methods as opposed to electing representatives of every possible subject in the humanities and social and behavioural sciences. If necessary, the committee can ask for an expert in a particular field to evaluate an application if it considers its own expertise inadequate for risk evaluation.

The National Advisory Board on Research Ethics considers it important that no fee should be charged for an ethical review. However, committee work requires time and money. The National Advisory Board on Research Ethics was not asked to propose a financing model for the system. It should be noted that some secretaries of ethics committees established on the basis of the Medical Research Act are employed full-time, for example.

The ethics committee can request an ethical review from an outside expert if a planned study will intervene in a subject's personal integrity and if it considers its own expertise inadequate for risk evaluation.

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[1] This also includes nursing science, health sciences and other sciences insofar as they use social and behavioural science research methods.

3 Scope of ethical review

The National Advisory Board on Research Ethics considers that researchers must submit their research plan to ethical review if a study contains any of the following features:

1. The study involves an intervention in the physical integrity of subjects,
2. The study deviates from the principle of informed consent (ethical review is not required if the research is based on public documents, registries or archived data),
3. The subjects are children under the age of 15, and the study is not part of the normal activities of a school or an institution of early childhood education and care, and the data are collected without parental consent and without providing the parents or guardians the opportunity to prevent the child from taking part in the study,
4. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example, studies containing violence or pornography),
5. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life,
6. The study can signify a security risk to subjects (for example, studies concerning domestic violence).

A researcher can also request an ethical review if the research subject, the funding agency or a cooperation partner so requires or if the results are to be published in a scientific journal which requires ethical review. The reason for requesting an ethical review must always be specified.

Ethical review does not mean transferring the ethical responsibility for the conduction and implementation of the study from the researcher to the ethics committee. Which ethics committee will conduct the review will depend on the location of the organization where the researcher works.

The National Advisory Board on Research Ethics proposes that the ethics committees to be established should also evaluate studies that are conducted in health-care institutions that do not fall within the category of medical research as defined in the Act on Medical Research.

The guidelines for ethical review are intended to cover post-graduate research. Thesis supervisors are responsible for ensuring that thesis work complies with the ethical principles. If the planned thesis research includes any of the features requiring ethical review, the student, together with his/her supervisor, must ask the ethics committee for an ethical review.

4 Ethics committees' work

The evaluation carried out by the ethics committees should be based on the ethical principles prepared by the National Advisory Board on Research Ethics.

Ethics committees will give a statement on the ethical acceptability of a planned study. The permission to actually conduct the study will be given by the organization/research target

where the research is conducted, and individual research subjects will give their consent to participate in the study.

A researcher can ask for a statement on an ethics committee's statement from the National Advisory Board on Research Ethics if he/she does not approve the changes recommended by the ethics committee.

The National Advisory Board on Research Ethics considers it important that the work of ethics committees should be as transparent as possible within the framework of the Act on the Openness of Government Activities. This will prevent major policy differences between regional committees. The board recommends that requests for ethical reviews received by the committees and the statements they issue should be published on the websites of the committees.

The National Advisory Board on Research Ethics will prepare a sample statement form for committees.

In addition to ethical review, ethics committees can also handle other tasks that they deem necessary, such as the coordination of education in research ethics.

5 The National Advisory Board on Research Ethics' other proposals

1. A proposal to take measures to amend the Act on Medical Research so that it would cover all health research that involves an intervention in the physical integrity of subjects and so that the person in charge of the study could also be a scientifically qualified expert in some other field than medicine or dentistry.

2. A proposal to take measures to amend legislation so that the right guaranteed to children in the Constitution of Finland and in the UN Convention on the Rights of the Child to influence matters pertaining to themselves to a degree corresponding to their level of development is also implemented in matters regarding participation in research.[2]

3. The National Advisory Board on Research Ethics recommends that education in research ethics be promoted and given a permanent place in undergraduate and post-graduate education. The importance of ethics education has repeatedly come up in the Advisory Board’s own discussions, in the feedback from the scientific community to the Advisory Board, and in articles and seminar presentations on ethical review. Ethical issues in the humanities and social and behavioural sciences also essentially concern the research relationship and the possible consequences of research publications. Therefore, in addition to separate courses, ethics education in these fields should form an integral part of methodology training and research supervision. Since ethical issues in the humanities and social and behavioural sciences research cannot always be predicted and depend on the situation, graduate schools in particular should make sure that researchers are given opportunities to discuss any problematic situations with experienced researchers and with other post-graduate students.

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[2] See also Liisa Nieminen, Lapset tutkimuskohteena: Kuka päättää lapsen osallistumisesta tutkimukseen? Lakimies 2/2009, pp. 226-253.

4. The National Advisory Board on Research Ethics considers it important that the functionality of the proposed new system and the ethical review guidelines, as well as any problems that may arise, are evaluated by the end of 2011. For this purpose, information should be collected on the composition and activities of the ethics committees. Basic information on requests for ethical review should be collected 1) by discipline, 2) according to the reasons for requests, 3) according to the main data collection method and 4) on applications that have to be reconsidered and changes recommended by the committee along with the reasons for suggested alterations. The National Advisory Board on Research Ethics will draft a form for collecting information.

ETHICAL PRINCIPLES OF RESEARCH IN THE HUMANITIES AND SOCIAL AND BEHAVIOURAL SCIENCES

All research must comply with the guidelines prepared by the National Advisory Board on Research Ethics entitled "Good scientific practice and procedures for handling misconduct and fraud in science" (2002).

Ethical principles of research in the humanities and social and behavioural sciences are divided into three areas:
1. Respecting the autonomy of research subjects,
2. Avoiding harm and
3. Privacy and data protection.

1 THE AUTONOMY OF RESEARCH SUBJECTS

1.1 Voluntary participation

Participation in research should be voluntary and based on informed consent. An exception from the principle of voluntary consent can be made when research is conducted on published and public information and archived materials. Research concerning official registries and documents and carried out without the consent of research subjects is governed by legislation.

Research subjects can give consent orally or in writing, or their behaviour can otherwise be interpreted to mean that they have given consent to participate. For example, assenting to a polite request for an interview or responding to a questionnaire or request for a written response indicates that the subject has consented to be studied.

In institutional settings (prisons, child protection institutions, hospitals, homes for the elderly etc) it is important to make sure that consent is given voluntarily by each and every subject. In evaluating the matter, attention must also be paid to the nature of the study, i.e. the degree to which personal matters are dealt with (need to protect privacy). If the research intervenes in personal integrity, it is particularly important to ensure the the genuineness of consent. On the whole, researchers should always take into account the constitutional rights guaranteed to each individual.

If research intervenes in the physical integrity of subjects, consent must always be given in writing or in some other certifiable way, unless this is contrary to the interests of subjects.

For example, a person with AIDS may not want his or her name registered on a written consent.

Consent can be specific or general. General consent applies to research use in general. General consent can include conditions regarding the form in which data are recorded and archived and conditions set for the use of data in secondary research.

If information obtained from subjects is combined with information in official registers, subjects must be given detailed information on the registers that will be used.

Specific consent concerns the use of information in a particular study. Specific consent with regard to the use of data may be justified on the grounds that data cannot be anonymized and that archiving the data with identifiers for secondary research would in all likelihood be harmful to subjects.

Subjects have the right to withdraw from a study at any stage, but this does not mean, however, that their prior input (interviews etc) cannot be used in the study.

1.2 Autonomy and research involving minors

According to section 6 paragraph 3 of the Constitution of Finland, children must be treated equally and as individuals and must be allowed to influence matters pertaining to themselves to a degree corresponding to their level of development. The same right is also ensured in Article 12 of the UN Convention on the Rights of the Child. On the other hand, according to section 4 paragraph 1 of the Child Custody and Right of Access Act (361/1983), a guardian has the right to decide on a child's personal matters. Balancing this right and the above-mentioned principles in the Constitution and the UN Convention on the Rights of the Child is not always easy. Consequently, the National Advisory Board on Research Ethics has called for legislation to be clarified in this respect.

In practice, it cannot be assumed that researchers should always request separate consent from a guardian when research involves minors. First, according to the above-mentioned principles children should be able to influence matters pertaining to themselves to a degree corresponding to their level of development. Second, there are situations where there may be differences in values and interests between a guardian and a minor, and requesting the guardian's consent may endanger the collection of comprehensive research data on the conditions and behaviour of minors, thus restricting the freedom of science, which is guaranteed by the Constitution. Third, there are studies which do not include risks and where requesting consent from the guardian would be difficult.

1.3 Autonomy and age limits

Many studies that are conducted in schools and institutions of early childhood education and care can be carried out as part of the normal work of the institution or school. It is not necessary to request a guardian's permission if the director of an institution of early childhood education and care or the head teacher of a school has evaluated that the study would produce useful information for the institution or school and can be carried out as part of the normal activities of the institution or school. For example, observations, broad questionnaires and open interviews which do not collect directly identifying information

(names, ID’s, addresses) for research purposes can be carried out without the consent of parents or some other guardian. In other cases they must be informed of the study.

When studying minors outside an institution of early childhood education and care or school, researchers must themselves evaluate when it is necessary to ask for a guardian's separate consent or inform a guardian of the study so that the guardian can forbid the child from participating in the study. A study involving children under the age of 15 can be conducted without a guardian's separate consent or informing a guardian if this is justified from the viewpoint of 1) the age and development level of subjects, 2) the subject and research method or 3) the need for information. If a study is to be conducted without a guardian's separate consent or informing a guardian, an ethical review must be requested for studies involving subjects under the age of 15.

Researchers must always respect a minor's autonomy and the principle of voluntary participation, regardless of whether a guardian's consent has been obtained or not.

1.4 Information for subjects

The information that must be provided to research subjects depends on the nature of data collection methods. In studies based on observation, interviews or questionnaires, subjects must be told what the study is about and what participating in the study means in concrete terms and how long it will take.

Information regarding a study should include at least the following: 1) the researcher's contact information, 2) the research topic, 3) the method of collecting data and the estimated time required, 4) the purpose for which data will be collected, how it will be archived for secondary use, and 5) the voluntary nature of participation.

Subjects may ask for additional information regarding the study and researchers should prepare for this in advance. Additional information can concern, for example, 1) a study's scientific or doctrinal orientation, 2) how confidential data will be protected and where data will be archived after the study, 3) how and when the results of the study will be published.

In experimental studies sufficient information must be provided concerning the design of the experiment. Experimental designs vary considerably from one field to another. Determining the adequacy of information is always up to the researcher according to the guidelines in the particular field.

If a study intervenes in the physical integrity of subjects, the information given to subjects must comply with the guidelines issued on the basis of the Act on Medical Research as far as these apply.

Regardless of how data are collected, requests by the subjects for additional information must be answered truthfully. Research personnel should be trained to answer questions. In some studies, such as studies based on participant observation, the research relation deepens over time, and it is natural to provide increasingly detailed information on the objectives and content of the study along the way.

1.5 Exceptions from informed consent: an ethical review must be requested from the ethics committee

If a study deviates from the principle of informed consent, an ethical review from the research ethics committee is always required.

An exception from the principle of informed consent can be made if advance information would distort the results of the study. As a matter of principle, studies on the use of power should be allowed without the consent of those in power. There are also groups and subcultures that researchers cannot approach without using an assumed identity for the sake of their own safety.

Data collection can deviate from the principle of informed consent in a number of ways:

1. Research subjects may be given all the relevant information but participation is not voluntary (e.g., a study based on participant observation of military conscripts or the observation of work processes where the organization's management has given permission for the research).
2. Research subjects may be given insufficient or misleading information about the role of the researcher. For example, the researcher may not identify him/herself as a researcher but does not give misleading information (e.g., observational data collected from an emergency room or riding with a police squad) or the researcher may work under a covert role (e.g., to mislead research subjects in a field study of discrimination).
3. The researcher identifies him/herself but gives misleading information about the content of the study.

Observing subjects in a public place does not require their consent or an ethical review from the ethics committee. Technical recording equipment can be used in a public place provided the principles regarding privacy and data protection are observed in the use, storage and archiving of data.

2 AVOIDING HARM

An important task of historical and social research is to produce information on the improper functioning of social institutions and problems regarding the use of power.

Possible harm resulting from research can stem from the collection of data, the storage of data and consequences following the publication of studies.

2.1 Avoiding mental harm

Avoiding mental harm includes treating subjects with respect and reporting findings in a respectful way in research publications.

How sensitive a subject matter is and what the limits of privacy are depend primarily on the research subjects themselves. If the subjects know what matters will be dealt with on the basis of the information that is supplied to them, by giving consent they have demonstrated their willingness to participate in the study while being aware of the study's scope and methods. If subjects participate in a study by writing about their experiences or answering a questionnaire, they regulate their own participation by avoiding matters and questions that they consider damaging or harmful.

People experience things in different ways. The same research questions or topics can arouse different reactions in different people. Research situations can and may include the same kind of mental strain and feelings (disappointment, joy, sadness, hate, shame, frustration etc) as in everyday life in dealing with different aspects of human life.

If a study includes interaction with subjects (participant observation, experimental study, interviews), subjects must be treated politely and with respect for their human dignity.

A researcher must make sure that the principle of voluntary participation is also observed in situations where there is interaction with subjects. A subject's annoyance, embarrassment, fearfulness or physical fatigue can be sufficient grounds for the researcher to discontinue the study as far as the subject is concerned, even if the subject does not expressly refuse to continue. It is essential to ensure that subjects are participating voluntarily when studying people in institutional settings (hospitals, prisons, child protection institutions, homes for the elderly etc). Unnecessary mental strain can be avoided by testing in advance how much time subjects' participation will take.

2.2 Avoiding financial and social harm

Financial and social harm to subjects is more likely if a study does not observe the ethical principles concerning privacy and data protection. According to the principles, systematic care must be shown in handling and storing confidential information. Furthermore, the duty of confidentiality must be observed regarding subjects' private matters (see ethical principles regarding privacy and data protection).

Research publications can have harmful consequences for subjects. The risk of harm is greatest if results are presented judgmentally, in a prejudiced way or disrespectfully. Harm can also be caused by publishing results giving a negative picture that are not based on comprehensive data or the systematic analysis of data.

Researchers should avoid any damage or harm to subjects that may be caused by research publications. However, this principle should not prevent the publication of research findings that may not be pleasing to subjects in all respects. A researcher's task is to produce new information without having to fear the reaction of authorities or other research subjects. Particularly research concerning the use of power and the functioning of social institutions must not be restricted on the grounds that results can have negative effects for subjects. The best way to ensure freedom of research is to conduct research carefully and systematically and to publish results with proper arguments and shedding light on different perspectives in a balanced manner. Researchers and editors are responsible for compliance with ethical principles in research publications.

2.3 Studies containing risks of harm: an ethical review must be requested from the ethics committee

Studies entailing possible risks that cannot be evaluated by research subjects themselves, and studies with potential to cause harm beyond the limits of normal life, must be evaluated in advance. This includes studies that 1) intervene in the physical integrity of subjects or 2) in which subjects undergo exceptionally strong stimuli and evaluating possible harm requires special expertise (for example, studies containing violence or pornography). In addition, studies in which the researcher is aware that there is a risk of causing long-term mental

harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life or studies that can signify a security risk to subjects (for example, studies concerning family violence) must be evaluated in advance.

3 PRIVACY AND DATA PROTECTION

The protection of privacy is a right protected by the Constitution of Finland. It is also an established and important principle in research ethics. Data protection forms the most important area of privacy protection regarding the collection and processing of research data and the publication of results.
Research ethics principles concerning the protection of privacy fall into three categories: 1) protecting research data and confidentiality, 2) storing or disposing of research data and 3) research publications. The goal is to find a balance between confidentiality and the openness of science and research.

Principles concerning the protection of privacy do not apply to materials that are in the public domain or to published data, which can concern individuals and their activities in the fields of politics, business, official activities and culture. Guidelines concerning privacy and principles concerning data protection must be observed with regard to court sessions and court decisions, however.

The Personal Data Act (523/1999) contains provisions on the processing of personal data. According to section 3, personal data means "any information on a private individual and any information on his/her personal characteristics or personal circumstances, where these are identifiable as concerning him/her or the members of his/her family or household".[3]

According to the main principle in the Act, personal data can be processed with the consent of the subject. A basic principle regarding the collection and storage of personal data is the need for personal data in a study. Personal data may not be collected and stored unnecessarily. If research data can be reasonably analysed without direct identifiers and there are no research grounds for storing identifiers, only data from which identifiers have been removed may be produced for research purposes and stored for secondary research.

Data with identifiers can be collected and used when this is appropriate from the viewpoint of that particular research. With the consent of the subject data can also be stored for secondary research with identifiers. Research in the humanities and social and behavioural sciences may require the processing and storage of identifiers. This may be based on the need to analyse data, later contacts with subjects or the historical and cultural significance of data. All contemporary data may also have historical and cultural significance.

3.1 Protecting research data and confidentiality

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[3] With regard to identifiability the most significant thing is whether a particular individual can be identified from data easily and without unreasonable costs. Identifiers in research data have traditionally been divided into direct and indirect identifiers. Direct identifiers are name, address, data of birth and a person's voice and picture. Indirect identifiers are, for example, place of residence, neighbourhood, education, job and family composition.

The protection of data with identifiers must be carefully planned. The protection of subjects' privacy may not be jeopardized by the careless storage of data or unprotected electronic data transfers.

Data security solutions for data with identifiers include decisions regarding where paper materials containing identifiers will be stored, at what stage unnecessary data will be destroyed or how their storage and archiving will be arranged for secondary research. Decisions must also be made regarding how electronic data containing identifiers will be protected (back-up copies, user names, processing if necessary on computers not linked to a network), and to what extent identifiers will be deleted or stored in connection with the data to be analysed.

If necessary, researchers or other research personnel handling data with identifiers can be required to sign a pledge of confidentiality. The research director or the principal investigator is responsible for written pledges. The confidentiality of data containing identifiers also applies to anyone using data, even if written pledges are not used.

If subjects' personal data are not needed for data analysis, and there are no research grounds for storing them, paper materials containing identifiers must be destroyed, and identifiers must be removed from electronic files or else recoded, categorised or otherwise masked. Identifiers that are stored for the purpose of further contacts with subjects must be protected and stored separately from analysed data.

If research data have been collected from official documents and registers without asking for subjects' consent, both identifiers and sensitive information must be destroyed as soon as they are unnecessary for conducting the research.

The confidentiality of research data relies on restrictions on the processing, use and storage of data. Research data may not be used or handed over for other uses besides research. It is particularly unacceptable to reveal information on research data or hand over data in such a way that it could influence the evaluation, treatment or position of individual subjects. Research data may not be handed over to the media or for commercial purposes.

Protecting privacy as a constitutional right protects citizens particularly against measures taken by public authorities. A researcher's task is to produce scientific information to help understand social problems or society and culture in general. This task does not include revealing information about individual subjects to authorities. For example, information concerning crimes is considered to be sensitive information that is subject to and restricted by the researcher's obligation of confidentiality. Information regarding individual subjects in research data may not be revealed to tax authorities, social welfare authorities or the police.

An exception to the obligation of confidentiality is every citizen's obligation to report an imminent *serious* offence that can still be prevented.[4] The deciding factor is the possibility to

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[4] Chapter 15 section 10 of the Penal Code (563/1998): "A person who knows of imminent genocide, preparation of genocide, breach of the prohibition of chemical weapons, breach of the prohibition of biological weapons, compromising of the sovereignty of Finland, treason, aggravated treason, espionage, aggravated espionage, high treason, aggravated high treason, rape, aggravated rape, aggravated sexual abuse of a child, murder, manslaughter, killing, aggravated assault, robbery, aggravated robbery, kidnapping, hostage taking, aggravated criminal mischief, aggravated

prevent an offence. A researcher does not have an obligation to reveal information regarding crimes that have already been committed, unless revealing information helps to prevent an imminent serious crime.

According to section 25 of the Child Welfare Act (417/2007), the obligation to confidentiality can be inapplicable if in the course of work a researcher discovers that "there is a child for whom it is necessary to investigate the need for child welfare on account of the child's need for care, circumstances endangering the child's development, or the child's behaviour".[5] The primary starting point in a researcher's work is to ensure confidentiality and remain in the role of researcher. In studying children and young people one must respect their own opinion if they are mature enough to form an opinion. If a researcher decides on the basis of the Child Welfare Act to make a report, it is good practice to inform the subjects in question of this intention.

3.2 Storing or destroying research data

Research in the humanities and social and behavioural sciences is not always repeatable, but the scientific community should have the possibility, if necessary, to verify research findings from the data analysed in a study. Openness is a key characteristic of science and also a precondition for testing the validity of scientific information, critically evaluating information and advancing science.

Data that are carefully archived for secondary research reduce the need to collect research data containing identifiers. Archiving also reduces the research pressure on small population groups. It is particularly important to archive for secondary research data that have cultural, historical and/or scientific value.

When necessary, the protection of privacy should be ensured through anonymisation measures and through the regulation of access to data for secondary research.

If it is necessary to remove identifiers from data stored for secondary use, the goal of the anonymisation measures undertaken should be that secondary users of data cannot immediately identify individual subjects. In addition to direct identifiers (name, address, ID), indirect identifiers (workplace, school, place of residence, age, profession etc) can be removed from archived data or be recoded, categorised or otherwise masked.

The protection of subjects' privacy should be ensured by setting strict conditions on the secondary use of data. Data can only be used for research purposes. In addition, secondary users of data should be requested to sign an agreement on the conditions set for secondary research and if needed also a pledge of confidentiality.

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endangerment of health, nuclear device offence, hijacking, an offence committed with terrorist intent referred to in chapter 34 a, section 1(1)(3), aggravated impairment of the environment or aggravated narcotics offence, and fails to report it to the authorities or the endangered person in time to prevent the offence, shall be sentenced, if the offence or a punishable attempt is committed, for a failure to report a serious offence to a fine or to imprisonment for at most six months."

[5] In this connection cf. the judgement of the European Court of Human Rights, 2.12.2008 (*Juppala v. Finland*).

If data containing identifiers are sensitive, and cannot be anonymized, and research subjects have not been asked to give permission to store the data, the datasets should be destroyed after the study has been completed. If data are of scientific value or historically unique, a request for permission to archive data can be submitted to the National Archives.

3.3 Protecting privacy in research publications

Unlike research data, research publications are in the public domain. The need to protect privacy in publications must be evaluated on a case-by-case basis.

For most studies, there is no need to present subjects in an identifiable way in published findings. The results of quantitative research are reported statistically, which means that there is no risk of identification even when the publication is based on data containing identifiers.

In the case of qualitative data, the risk of identification must always be evaluated before any samples/quotations from the data are published: what indirect identifiers (workplace, school, place of residence, age, profession etc) will be left in the sample as such, what will be masked and what will be omitted altogether.

In studying organizations or other social actors (institutions, associations, work communities, public bodies etc), the identifiability of the organization and its individual representatives must be evaluated separately in each case. Subjects generally participate in a study as individual representatives of their social or professional role. Anonymity in research publications does not necessarily prevent identification among those who are familiar with the unit or organization in question, however. Subjects should not be promised complete anonymity unless it can reasonably be guaranteed. Research publications should strive to treat individual subjects and the research target in a respectful manner. Critical findings regarding the research target should be explained analytically, avoiding a labelling attitude.

In research, particularly in the humanities but also in the social sciences, it may be justifiable for research purposes and also ethically to present subjects by name in research publications. For example, a study based on interviews with experts can be published without removing the names of subjects or other identifiers. Agreement about this must be reached with research subjects in advance.

If research concerns archived materials, the identifiability or non-identifiability of subjects in research publications depends on the conditions the distributing archive has set on the use of the data.

4 ETHICAL REVIEW

In preparing a request for an ethical review and in evaluating the possible negative effects and risks of a study, the point of departure should be the ethical principles in the humanities and social and behavioural sciences (the autonomy of research subjects, avoiding harm, privacy and data protection). Evaluation never shifts responsibility for research ethics to the committee. In research in the humanities and social and behavioural sciences, ethical questions focus on the encounter between the researcher and the subject, which can include unanticipated factors. The researcher is always responsible for the ethical and moral solutions in a study.

Researchers must submit their research plan to ethical review if a study contains any of the following features:
1. The study involves an intervention in the physical integrity of subjects.
2. The study deviates from the principle of informed consent (ethical review is not required if the research is based on public documents, registries or archived data).
3. The subjects are children under the age of 15 and the study is not part of the normal activities of a school or an institution of early childhood education and care and the data are collected without parental consent and without providing the parents or guardians the opportunity to forbid the child from taking part in the study.
4. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example studies containing violence or pornography).
5. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life.
6. The study can signify a security risk to subjects (for example studies concerning domestic violence).

A researcher can also request an ethical review if the research subject, the funding agency or a cooperation partner so requires or if the results are to be published in a scientific journal which requires ethical review. The reason for requesting an ethical review must always be specified.

For example, according to the guidelines issued by the Academy of Finland, it is sufficient if a review is submitted after a positive funding decision.

4.1 Guidelines for reviewing studies

An ethical review examines the plan for collecting data, how the study will be carried out, the information that will be given to subjects and the plan for processing and storing data from the perspective of avoiding risks and harm. *The review weighs possible negative effects or harm to subjects resulting from participation in the study in relation to the intended scientific value of the study.* The starting point is always the ethical principles in the humanities and social and behavioural sciences (the autonomy of research subjects, avoiding harm, privacy and data protection).

If necessary, ethical guidelines in the particular research field should also be applied.[6]

In the humanities and social and behavioural sciences, evaluating scientific value and risks is not a utilitarian cost-benefit analysis but rather a question of normative evaluation of values that are in themselves incommensurable. Evaluation ensures that a study does not contain unnecessary risks that could be avoided without reducing the scientific value of the study. Next, one must decide whether risks on the whole are morally acceptable. Research which entails higher risks may be morally acceptable if the scientific value of the study is very high, and the study does not cause harm to subjects (studies that are not based on informed

[6] There are separate ethic codes in psychology and economics, for example. In addition research institutions keeping statutory registers have ethical guidelines concerning register data.

consent), or the people participating in the study can evaluate possible harm themselves on the basis of the information that is supplied to them.

If a study does not have the features listed above (1-6) and does not present a risk of causing long-term mental harm beyond the risks encountered in normal life, this should be mentioned in the request for an ethical review. In this case, the committee will primarily evaluate the information supplied to subjects as well as matters concerning privacy and data protection. If a study entails any of the features listed above (1-6), the ethics committees must also evaluate the proposed research methods in relation to research questions and the value of the new information that the study is intending to provide.

Information for subjects

The committee will check that the informing of research subjects is planned appropriately. Information regarding a study includes at least the following: 1) the researcher's contact information, 2) the research topic, 3) the method of collecting data and the estimated time required, 4) the purpose for which data will be collected, used in secondary research and archived, and 5) the voluntary nature of participation.

In experimental studies, sufficient information must be provided concerning the design of the experiment. Experimental designs vary considerably from one research field to another. Ethics committees will determine whether the proposed level of information is adequate.

If a study intervenes in the physical integrity of subjects, the information given to subjects must comply with the guidelines issued on the basis of the Act on Medical Research, as far as these apply.

Privacy and data protection

An ethical review examines a study's data management plan and ensures that technical data security solutions have been planned. The data management plan must describe 1) how data containing identifiers will be protected or identifiers removed, 2) whether signing a pledge of confidentiality will be required from persons using or processing the personal data and 3) the plan for archiving the data for secondary research or alternatively destroying personal data after the study has been completed.

Ethics committees do not review the protection of privacy in research publications. Researchers and editors are responsible for compliance with ethical principles in research publications.

4.2 Special review guidelines regarding different research designs:

a. The study involves an intervention in the physical integrity of subjects

The ethical guidelines for medical research can be applied in planning and reviewing studies that involve an intervention in the physical integrity of subjects (see http://www.etene.org/tukija/dokumentit/Muistlco.pdf). The committee will evaluate anticipated negative effects (risks, harm and their probability) in relation to the intended scientific value of the study. Studies must be conducted in a manner that minimizes any negative effects and risks to subjects.

Evaluating physical risks requires expertise and background information based on empirical studies. The ethics committee can if necessary request an ethical review from an outside expert if it considers its own expertise inadequate for risk evaluation.

b. The study deviates from the principle of informed consent

With regard to a study that deviates from the principle of informed consent, the ethics committee will evaluate whether conducting the study is ethically acceptable. Conducting the study is ethically acceptable if the following preconditions are met:
1. the research is justified, and it would not be possible to conduct the research if subjects were informed of the study and their consent asked for,
2. the data collection does not involve risks to participants,
3. if possible, research subjects will be informed afterwards of the nature and purpose of the research,
4. adequate attention is paid to the privacy of the research subjects and data protection issues.

c. The subjects are children under the age of 15, and the study is not part of the normal activities of a school or an institution of early childhood education and care, and the data are collected without parental consent and without providing the parents or guardians the opportunity to forbid the child from taking part in the study

A study involving children aged under 15 can be conducted without the consent of a parent or other guardian and without informing the parent or guardian if it does not involve risks to subjects, and the research design is justified by one or more of the following preconditions:

1) On the basis of subjects' age and level of development:

The minors who are intended subjects are able to understand the research topic and what participating in the study requires of them in concrete terms.

2) On the basis of the research area and method:

The research topic is not sensitive and asking for a parent's or guardian's consent is difficult in practice (for example, studies of youth clubs or school pupils' voluntary clubs etc).

3) From the viewpoint of the need for information:

The subject matter of the study will prevent the collection of comprehensive data if parents' consent must be requested for children's participation (for example, domestic violence, social problems etc), or the research covers issues which minors may not want their parents to know about (for example, use of intoxicating substances, sexual orientation etc).

d. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example studies containing violence or pornography).

e. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life.

f. The study can entail a security risk to subjects (for example studies concerning domestic violence).

The researcher must describe possible negative effects and risks so that the ethics committee can evaluate whether the study is ethical, weighing possible risks to subjects against the intended scientific value of the study. Studies must be conducted so as to minimize any negative effects and risks to subjects.

The intended scientific value will be weighed against possible negative effects and the measures that are taken to reduce negative effects to subjects during or after the study (physical and mental harm) or to prevent them altogether (data protection). The evaluation must take into consideration subjects' free will and autonomy. After all, subjects themselves are always able to evaluate to some extent their own risks of participating in a study.

In evaluating experimental studies, the ethical guidelines in the particular field can be applied in a supplementary manner.

Deutsche Gesellschaft
für Chirurgie

Leitfaden der Deutschen Gesellschaft für Chirurgie zur Guten Fachlichen Praxis (GFP) für die Entnahme von menschlichen Geweben und Zellen zur Herstellung eines Arzneimittels

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Deutsche Gesellschaft für Gefäßchirurgie (DGG), Deutsche Gesellschaft für Kinderchirurgie (DGKCH), Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC), Deutsche Gesellschaft der Plastischen, Rekonstruktiven und Ästhetischen Chirurgen (DGPRÄC), Deutsche Gesellschaft für Thoraxchirurgie (DGT), Deutsche Gesellschaft für Thorax-, Herz- und Gefäßchirurgie (DGTHG), Deutsche Gesellschaft für Unfallchirurgie (DGU), Deutsche Gesellschaft für Viszeralchirurgie e.V. (DGVC), Deutsche Gesellschaft für Neurochirurgie (DGNC).

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1. Vorwort

Im vorliegenden Handlungsleitfaden der Deutschen Gesellschaft für Chirurgie (DGCH) zur Guten Fachlichen Praxis (GFP) werden Anforderungen an Entnahmeeinrichtungen – also für Einrichtungen, die zur Verwendung bei Menschen bestimmte Gewebe i. S. d. § 1a Nr. 4 des Transplantationsgesetzes (TPG) gewinnen (§ 20b Abs. 1 Satz 2 Arzneimittelgesetz (AMG) [1]) – beschrieben und erforderliche Voraussetzungen und Maßnahmen zur Qualitätssicherung (QS) sowie zur lückenlosen Rückverfolgbarkeit einer Gewebeentnahme festgelegt.

Der Leitfaden berücksichtigt dabei das unterschiedliche Risikopotential, das nach dem derzeitigen Stand von medizinischer Wissenschaft und Technik mit der Gewinnung verschiedener Gewebe für Spender und Empfänger verbunden ist. Er geht auf spezielle bauliche, räumliche, personelle, organisatorische und technische Voraussetzungen ein und beschreibt unter Berücksichtigung der einschlägigen Bestimmungen des deutschen und europäischen Gesetzgebers (insbesondere die der EG-Geweberichtlinie 2004/23/EG des Europäischen Parlaments und des Rates vom 31. März 2004 zur Festlegung von Qualitäts- und Sicherheitsstandards für die Spende, Beschaffung, Testung, Konservierung, Lagerung und Verteilung von menschlichen Geweben und Zellen [2] und ihrer Durchführungsrichtlinie 2006/17/EG vom 8. Februar 2006 zu den technischen Vorschriften für die Spende, Beschaffung und Testung [3]) die allgemeinen und besonderen Bedingungen für die autologe und allogene Spende sowie für die Entnahme von Gewebe bei lebenden und verstorbenen Spendern.

Der Begriff "Stand der medizinischen Wissenschaft und Technik" wird im Leitfaden wiederholt verwendet, um herauszustellen, dass er in erster Linie und überwiegend medizinische oder die Ärzteschaft betreffende Sachverhalte regelt. Sie werden ausgefüllt und definiert durch die Erkenntnisse der medizinischen Wissenschaft und Technik. Diese ergeben sich für die Gewinnung von Gewebe und Zellen auch nach der Konzeption des Gewebegesetzes (§ 16b TPG) als allgemein anerkannter Standard in der Regel aus den Richtlinien der Bundesärztekammer, bei deren Erarbeitung die angemessene Beteiligung von Sachverständigen der betroffenen Fach- und Verkehrskreise sicherzustellen ist [4]. Einen Baustein hierzu bilden Empfehlungen von medizinischen Fachgesellschaften wie der vorliegende GFP-Leitfaden der DGCH.

Mit den Richtlinien der Bundesärztekammer werden die Anforderungen nach dem Stand der medizinischen Wissenschaft und Technik an die Entnahme und Untersuchung von Gewebe (und damit auch von Zellen) durch Gewebeeinrichtungen nach § 8d TPG – deren Einhaltung zur Erteilung der Erlaubnis gemäß § 20b Abs. 1 Satz 3 Nr. 4 AMG erforderlich ist – ergänzend unter anderem zu der noch ausstehenden Verordnung des Bundesministeriums für Gesundheit nach § 16a TPG konkretisiert [5].

Der GFP-Leitfaden soll Entnahmeeinrichtungen bei der Erstellung eines Systems zur Qualitätssicherung behilflich sein und den zuständigen Behörden die Bewertung von Anträgen auf eine Erlaubniserteilung einschließlich der Inspektion von Entnahmeeinrichtungen erleichtern. Der Leitfaden befasst sich nicht mit speziellen Arbeitsschutzmaßnahmen für Mitarbeiter und für anderes Personal einer Entnahmeeinrichtung. Die hierzu einschlägigen gesetzlichen Bestimmungen und Vorgaben bleiben von ihm unberührt.

In seinem Aufbau ist der GFP-Leitfaden in verschiedene Themenbereiche unterteilt, denen jeweils eine wesentliche Bedeutung für die Qualitätssicherung einer Gewebeentnahme für Spender oder Empfänger zukommt. Zu den einzelnen Bereichen werden die Grundsätze und die Zielsetzung der Qualitätssicherung dargestellt und die erforderlichen Maßnahmen beschrieben mit denen dieses Ziel erreicht werden kann. Die Erläuterungen sind dabei ausführlich genug, um auf die jeweils wesentlichen Aspekte der Qualitätssicherung hinzuweisen. Die Auslegung wichtiger und gängiger Fachbegriffe – gemäß der Definition des Gesetzgebers – wird zum besseren Verständnis des Leitfadens in einem Glossar dargestellt.

Neben den im vorliegenden Leitfaden beschriebenen, gibt es sicherlich auch andere Methoden, mit denen die Einhaltung der Grundsätze der Qualitätssicherung möglich ist. Der Leitfaden will keinesfalls die Entwicklung neuer validierter Konzepte oder Verfahren einschränken oder behindern, die eine Qualitätssicherung gewährleisten und die den nachfolgend beschriebenen Methoden mindestens gleichwertig sind.

Der Leitfaden zur Guten Fachlichen Praxis wird in regelmäßigen Abständen überprüft und gegebenenfalls dem Stand von Wissenschaft und Technik angepasst.

2. Geltungs- und Anwendungsbereich

Der Geltungsbereich des GFP-Leitfadens beschränkt sich auf das Gebiet der Bundesrepublik Deutschland. Anders als der EG-GMP-Leitfaden, der gemeinschaftsweit in der Europäischen Union (EU) der einheitlichen Auslegung der Grundsätze und Leitlinien der Guten Herstellungspraxis (GMP, Good Manufacturing Practice [6]) dient, hat er keine gemeinschaftsweite Bedeutung [7].

Der vorliegende GFP-Leitfaden findet Anwendung auf Entnahmeeinrichtungen i. S. d. § 20b Abs. 1 Satz 1 AMG. Das sind Einrichtungen i. S. d. § 1a Nr. 8 TPG (wie z.B. Krankenhäuser, Kliniken, Arztpraxen, Gewebebanken), bei denen menschliche Gewebe (und Zellen) i. S. d. § 1a Nr. 4 TPG zum Zwecke der Verwendung oder Anwendung bei Menschen und damit auch zum Zweck der Herstellung von Arzneimitteln (auch in Form von Prüfpräparaten gemäß § 3 Abs. 3 der GCP-Verordnung [8]) entnommen, gelagert und verteilt werden. Er sollte aber auch berücksichtigt werden, sofern aufgrund der Ausnahmetatbestände des § 4a Satz 1 Nr. 3 oder Nr. 4 AMG die Anwendbarkeit des AMG ausgeschlossen ist.

Die über die Gewinnung i. S. d. § 20b Abs. 1 Satz 1 und 2 AMG hinausgehende Herstellung von Arzneimitteln aus entnommenem Gewebe sowie die klinische Anwendung dieser Arzneimittel unterliegen nicht diesem GFP-Leitfaden.

Ferner betrifft der Leitfaden nicht die forschungsbedingte Nutzung menschlicher Gewebe und Zellen, wenn diese z.B. für andere Zwecke genutzt werden als für die Verwendung im oder am menschlichen Körper, wie bei der In-vitro-Forschung oder in Tiermodellen. Er gilt auch nicht für die Gewinnung und Herstellung von Blutprodukten oder Blutbestandteilen im Sinne von § 2 Nr. 3 des Transfusionsgesetzes (TFG), die der Guten Herstellungspraxis (GMP) unterliegen.

Die Auslegungen der GMP-Richtlinien (Gute Herstellungspraxis) finden bei der Gewinnung von menschlichen Geweben und Zellen zur Herstellung eines Arzneimittels keine Anwendung, sofern die Entnahme nach den Regeln der Guten Fachlichen Praxis erfolgt.

3. Qualitätssicherung und Verantwortungsabgrenzung

3.1. Verantwortliche ärztliche Person der Entnahmeeinrichtung

Nach § 8d Abs. 1 TPG darf eine Einrichtung, die Gewebe entnimmt oder untersucht, unbeschadet der Vorschriften des Arzneimittelrechts nur betrieben werden, wenn sie einen Arzt (in § 20b Abs. 1 Satz 3 Nr. 1 AMG „ärztliche Person“ genannt) bestellt hat, die die erforderliche Sachkunde nach dem Stand der medizinischen Wissenschaft besitzt.

Für jede Entnahmeeinrichtung ist im Lichte des Art. 17 Abs. 2 lit. a) der EG-Geweberichtlinie 2004/23/EG eine leitende, d.h. verantwortliche ärztliche Person zu benennen, die für die Einhaltung der im Hinblick auf die Gewinnung einschlägigen Gesetze, Verordnungen, Richtlinien, Leitlinien und Empfehlungen Sorge zu tragen hat. Diese Person (nachfolgend als „verantwortliche ärztliche Person“ bezeichnet) ist für die Erstellung und Einführung eines Qualitätssicherungssystems (QS-System) sowie für die Umsetzung, Verwaltung, Pflege und Einhaltung der hiermit verbundenen Qualitäts- und Sicherheitsmaßnahmen verantwortlich, sofern die Entnahmeeinrichtung nicht unter vertraglicher Bindung mit einem Hersteller mit Herstellungserlaubnis nach § 13 AMG oder einem Be- oder Verarbeiter mit Erlaubnis nach § 20c AMG tätig wird, in dessen QS-System sie eingebunden ist.

Die Stelle der verantwortlichen ärztlichen Person, die die "medizinische" Verantwortung für die Entnahmeeinrichtung trägt, muss mit einem approbierten Arzt (Arzt bedeutet im GFP-Leitfaden immer auch Ärztin) besetzt werden, wobei dieser eine auf die Anforderungen der Gewebeentnahme ausgerichtete Sachkunde besitzen muss. Im Regelfall wird es sich hierbei um einen erfahrenen Facharzt handeln.

Die verantwortliche ärztliche Person ist für die Ablauforganisation und Kommunikation der Entnahmeeinrichtung zuständig und legt die Verantwortungsbereiche von Mitarbeitern sowie Freigabeprozeduren für entnommene Gewebe und Zellen fest, sodass die Einhaltung der notwendigen Qualitäts- und Sicherheitsvorgaben für deren Entnahme, Testung, Lagerung und Verteilung an Hersteller (§ 13 AMG) bzw. Be- oder Verarbeiter (§ 20c AMG) im gesamten Arbeitsablauf gewährleistet ist.

Sie hat sicherzustellen, dass zur Entnahme berechtigte Ärzte oder anderweitig hierfür qualifizierte Personen und deren assistierendes Personal über eine ausreichende Ausbildung verfügen, damit sämtliche an sie gestellte Aufgaben fach- und sachkundig in sicherer und zuverlässiger Art und Weise wahrgenommen werden können. Des Weiteren hat sie dafür Sorge zu tragen, dass das Wissen der Mitarbeiter durch Fortbildungsmaßnahmen aufrechterhalten und weiterentwickelt wird. Für die Entnahme geschulte und autorisierte Ärzte oder Personen werden von der verantwortlichen ärztlichen Person in einer Liste mit Datum der Autorisierung und Unterschrift geführt.

Auch in Entnahmeeinrichtungen mit nur einem Arzt können Gewebe gewonnen werden, sofern die gesetzlichen Bestimmungen und die Vorgaben des GFP-Leitfadens erfüllt werden. Der entnehmende Arzt ist dann zugleich die verantwortliche ärztliche Person.

3.2. Kurze Darstellung des QS-Systems für Entnahmeeinrichtungen

Qualitätssicherung (QS) ist Aufgabe der Leitung der jeweiligen Entnahmeeinrichtung, d.h. der verantwortlichen ärztlichen Person, die die Zuständigkeiten und Verantwortlichkeiten festlegt, die erforderliche Qualitätssicherung inhaltlich definiert und geeignete Maßnahmen zur Verwirklichung und Prüfung veranlasst. Das System zur Qualitätssicherung muss der Art und dem Umfang der durchgeführten Gewebe- oder Zellentnahme gerecht werden, damit für Spender und Empfänger größtmögliche Sicherheit und Nutzen entsteht.

Das QS-System ist in das bestehende Qualitätsmanagement-System (QM-System) der Einrichtung zu integrieren und muss die aktive Beteiligung der Leitung der Einrichtung und des Personals der betroffenen Bereiche vorsehen. Die Voraussetzungen dazu sind durch den Träger der Entnahmeeinrichtung zu schaffen.

Qualitätssicherung umfasst dabei die Gesamtheit aller personellen, organisatorischen, technischen und normativen Maßnahmen, die geeignet sind, die Qualität und Sicherheit für die Versorgung der Patienten zu gewährleisten, zu verbessern und gemäß dem medizinisch-wissenschaftlichen Kenntnisstand weiter zu entwickeln (s. insb. auch §§ 135a, 136 und 137 SGB V).

Das Erreichen der solchen Standards entsprechenden Qualitätsziele auf der Grundlage dieser Richtlinien und deren Einhaltung muss durch regelmäßige Überprüfung anhand von definierten Qualitätskriterien kontrolliert und mit Hilfe geeigneter Steuerungsmaßnahmen sichergestellt werden.

Es ist zu empfehlen, die Qualitätssicherung mit Hilfe von Standardarbeitsanweisungen (SOPs) in einem Qualitätshandbuch festzulegen, das die einzelnen, abgrenzbaren Arbeitsschritte beschreibt. Die schriftlich fixierten Anweisungen müssen alle zur Anwendung kommenden Methoden und Verfahrensschritte berücksichtigen und allen beteiligten Personen und autorisierten Stellen zugänglich sein.

Die Qualitätssicherung der Gewebe entnehmenden Stelle muss auf der Grundlage der nationalen rechtlichen Vorgaben insbesondere den nachfolgenden Ansprüchen gerecht werden:

- Name, Stellenbeschreibung und Qualifikation des Leiters und seines Stellvertreters
- Kriterien und Untersuchungsmethoden zur Bestimmung der Spendereignung
- Aufklärung von Spendern oder deren Angehörigen
- Anforderungen an Entnahmeräumlichkeiten und Entnahmeverfahren
- Anforderungen an OP-Instrumente für die Gewebeentnahme
- Anforderungen an Fach- und assistierendes Personal
- Schulung und Ausbildung von Fach- und assistierendem Personal
- Hygienemaßnahmen (Hygieneplan, mit allen technischen und betrieblich-organisatorischen Maßnahmen)
- Kodierung, d.h. Kennzeichnung, Rückverfolgbarkeit und Verwechslungsvermeidung von entnommenen Geweben (evtl. auch von diagnostischen Blutproben)
- Freigabeverfahren
- Verpackung, Lagerung, Verteilung und Transport des entnommenen Gewebes
- Maßnahmen bei Auftreten oder Verdacht schwerwiegender Zwischenfälle oder schwerwiegend unerwünschter Reaktionen
- Meldepflichten
- Dokumentation

Sämtliche Anweisungen sind in regelmäßigen Abständen zu überprüfen und vor in Kraft treten von den Verantwortlichen zu genehmigen. Bei Verfahrensänderungen sind alte Anweisungen einzuziehen und zu vernichten. Das Original wird ungültig gestempelt und archiviert. Es ist zu empfehlen, ein Dokumentenkontrollverfahren für die Chronologie der Dokumentenüberprüfungen und -änderungen einzurichten, das sicherstellt, dass nur die aktuellen Fassungen der Dokumente verwendet werden. Ein adäquates QS-System setzt auch für die Erstellung, Veränderung und das Austauschen von Verfahrensanweisungen eine überprüfbare und vollständige Dokumentation voraus.

3.3. Verantwortungsabgrenzung

Hersteller mit einer Herstellungserlaubnis nach § 13 AMG bzw. Be- oder Verarbeiter mit einer Erlaubnis nach § 20c AMG können Teile der Qualitätssicherung, z.B. in Form von zur Verfügung gestellten Standardarbeitsanweisungen, für die Gewebeentnahme übernehmen. Die Entnahmeeinrichtung kann auch in das QS-System des Herstellers bzw. Be- oder Verarbeiters integriert werden, mit dem sie unter vertraglicher Bindung Gewebe gewinnt. Wichtig ist dabei jedoch stets, dass die Verantwortlichkeiten in den verschiedenen Teilbereichen klar definiert sind und schriftlich fixiert werden.

Sollten die Entnahmeeinrichtung und der Hersteller bzw. Be- oder Verarbeiter nicht personenidentisch (im Sinne einer juristischen Person) sein, müssen die jeweiligen Zuständigkeitsbereiche durch einen Verantwortungsabgrenzungsvertrag (VAV) festgelegt werden.

Vereinbarungen zwischen Entnahmeeinrichtungen und Herstellern bzw. Be- oder Verarbeitern und anderen Dritten müssen § 9 der Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV) entsprechen und sich dabei an den Vorgaben des Art. 24 der Richtlinie 2004/23/EG orientieren. Dementsprechend müssen in der Vereinbarung die Verantwortlichkeiten sowie die genauen Verfahren vertraglich festgelegt werden. Dies gilt insbesondere für Spenderauswahlkriterien, das Entnahmeverfahren und die Spenderdokumentation.

Eine Entnahmeeinrichtung kann auch Verträge mit Dritten abschließen, die ausschließlich Transport oder Analytik, d.h. keine Herstellung für sie betreiben. Auch in diesen Fällen sind die Verträge in Übereinstimmung mit § 9 AMWHV so zu gestalten, dass zwischen Auftraggeber und Auftragnehmer eine klare Abgrenzung der Verantwortung besteht.

Ferner hat eine Entnahmeeinrichtung darauf zu achten, dass ein von ihr beauftragtes Untersuchungslabor die Fähigkeit zur Erledigung der beauftragten Tätigkeiten besitzt, was durch eine dem Untersuchungslabor erteilte Erlaubnis gemäß § 20b Abs. 1 AMG belegt wird. Es ist alternativ möglich, die Tätigkeit des Untersuchungslabors über die vertragliche Bindung mit dem Hersteller bzw. dem Be- oder Verarbeiter mit Erlaubnis nach § 13 bzw. nach § 20c AMG abzusichern (§ 20b Abs. 2 AMG). Der Auftragnehmer muss durch den Auftraggeber auditiert werden. Von der Entnahmeeinrichtung beauftragte Unternehmen sind im QS-System der Entnahmeeinrichtung zu benennen.

4. Dokumentation

4.1. Allgemeine Anforderungen

Der gesamte Ablauf von der Spenderauswahl, über die Entnahme und Weiterverarbeitung von Geweben oder Zellen bis hin zu ihrer therapeutischen Anwendung beim Empfänger muss lückenlos dokumentiert werden (vgl. Art. 8 Richtlinie 2004/23/EG). Der Entnahmeeinrichtung kommt dabei die Dokumentation aller Abläufe ihres Handlungs- und Zuständigkeitsbereichs zu, wobei in diesem Zusammenhang insbesondere auch die Bestimmungen der §§ 14 und 15 TPG zu berücksichtigen sind.

In Verantwortung des autorisierten und durchführenden Arztes muss die Dokumentation parallel zu jedem Arbeitsschritt erstellt werden. Sämtliche Aufzeichnungen sind gewissenhaft, vollständig und gegenüber Unberechtigten vertraulich zu führen. Die Vertraulichkeitsvorschriften des Art. 14 der Richtlinie 2004/23/EG und die deutschen Datenschutzvorschriften sind einzuhalten.

Die Dokumentation muss alle Arbeitsschritte, Maßnahmen und insbesondere auch die Freigabe des Gewebes zur therapeutischen Anwendung oder zur Weitergabe an den Hersteller bzw. den Be- oder Verarbeiter mit Angabe des Datums und des jeweils durchführenden, d.h. für die Entnahme verantwortlichen Arztes, einschließlich dessen Unterschrift, festhalten. Die Einträge müssen leserlich und dürfen nicht löschbar sein.

Korrekturen oder nachträgliche Ergänzungen in der Dokumentation dürfen nur von autorisierten Personen durchgeführt werden und sind ebenfalls mit Angabe des Datums und mit Unterschrift der durchführenden Person zu versehen. Sie sind derart vorzunehmen, dass Originaleintragungen lesbar bleiben.

Alle im Rahmen der Dokumentation erstellten Aufzeichnungen, Unterlagen und Dokumente müssen von der Entnahmeeinrichtung für 30 Jahre nach Ablauf des Verfalldatums des Gewebes archiviert werden, sofern sich aus § 15 TPG nicht eine geringere Dokumentationsfrist ergibt. Nach Ablauf von 30 Jahren sind die Daten zu löschen oder zu anonymisieren.

4.2. Spezielle Anforderungen

Das Dokumentationssystem muss jederzeit den Zugriff auf alle relevanten Daten zur Gewebespende ermöglichen und eine lückenlose Datensicherung gewährleisten. Die Erfassung und Archivierung der Daten kann schriftlich oder auch elektronisch erfolgen (vgl. Art. 8 Abs. 4 Richtlinie 2004/23/EG). Bei elektronischer Datenerfassung und Archivierung muss ein validiertes Verfahren verwendet werden, um Datenverlust ausschließen zu können. Das für die Dokumentation verwendete Archiv muss ggf. von der zuständigen Behörde genehmigt werden (vgl. Anhang IV, Nr. 1.4.4. zur Richtlinie 2006/17/EG).

Unabhängig von der Form der Datenerfassung und Archivierung muss grundsätzlich sichergestellt werden, dass die zum Zwecke der Rückverfolgbarkeit erforderlichen Daten in einwandfreier, d.h. in unbeschädigter und leserlicher Form die gesetzliche Archivierungsdauer von 30 Jahren überstehen.

Die vollständige Spenderdokumentation wird gemäß § 8d Abs. 2 TPG in der Entnahmeeinrichtung und zudem mindestens in Form eines Entnahmeberichts (siehe hierzu auch Punkt 11 des GFP-Leitfadens) auch beim Hersteller bzw. Be- oder Verarbeiter aufbewahrt.

Die Archivierung muss unter Einhaltung der datenschutzrechtlichen Anforderungen aus § 14 TPG in einem geeigneten Bereich der von der Genehmigung nach § 20b AMG erfassten Räume erfolgen.

Für den Fall der Schließung einer Entnahmeeinrichtung, in der die Aufbewahrung der Dokumentation erfolgt, müssen geeignete Maßnahmen getroffen werden, um sicherzustellen, dass die Dokumentation in der gesetzlich vorgeschriebenen Aufbewahrungszeit erhalten und verfügbar bleibt.

5. Räumliche Ausstattung und Einrichtung von Entnahmeeinrichtungen

5.1. Vorbemerkungen

Das wesentliche Ziel aller Maßnahmen hinsichtlich der räumlichen, technischen und hygienischen Anforderungen an Entnahmeeinrichtungen ist der Schutz von Spender und Empfänger, aber auch von Personal, vor Infektionen und anderen schädlichen Einflüssen. Zu diesem Schutz tragen betrieblich-organisatorische, funktionell-bauliche und apparativ-technische Präventivmaßnahmen bei [9,10].

Deren wechselseitige Gewichtung für eine Gewebe- oder Zellspende wird wesentlich durch das Ausmaß, d.h. die Invasivität des Eingriffs, den Kontaminationsgrad der Körperregion, aus der die Spende entnommen werden soll und durch die jeweiligen örtlichen Bedingungen der Entnahmeeinrichtung bestimmt.

Von weiterer Bedeutung ist, ob es sich beim Spender um eine lebende oder tote Person handelt. Die notwendigen Anforderungen an die oben genannten Präventionsmaßnahmen können daher für die Gewinnung verschiedener Gewebe oder Zellen unterschiedlich sein und müssen sich nach der jeweiligen Aufgabenstellung, d.h. der Art und Weise der Spende, richten.

Grundsätzlich ist jedoch sicherzustellen, dass unabhängig von der Invasivität des Eingriffs, dem Kontaminationsgrad der Entnahmeregion und anderen Einflussgrößen sowohl bei lebenden und toten Spendern hygienisch einwandfreies Arbeiten unter Berücksichtigung der jeweiligen medizintechnischen Ausrüstung und des Personalaufwands möglich ist.

Als grundlegende Vorgaben sind in diesem Zusammenhang die Empfehlungen der Kommission für Krankenhaushygiene und Infektionsprävention am Robert-Koch-Institut (RKI) aus dem Jahr 2000 – zu den Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen [11] – zu beachten. Hierdurch wird auch deutlich, dass der vorliegende GFP-Leitfaden für eine Gewebeentnahme keine zusätzlichen Ansprüche an Hygiene und räumliche Ausstattung stellt, sondern dass er lediglich die bereits bestehenden Sicherheitsvorgaben und Schutzmassnahmen des RKI zu Operationen und anderen invasiven Eingriffen berücksichtigt, die eben auch für die operative Gewinnung von Geweben beim Menschen und somit für Entnahmeeinrichtungen gelten.

Bestehen von Seiten des Herstellers bzw. des Be- oder Verarbeiters, an den das entnommene Gewebe zur Aufbereitung weitergereicht werden soll, weitere und begründete Auflagen oder spezielle Anforderungen an die räumliche, technische und hygienische Ausstattung einer Entnahmeeinrichtung, sind auch diese Vorgaben von der Entnahmeeinrichtung zu berücksichtigen.

5.2. Benennung und Festlegung der Räume, in denen die Entnahme stattfindet

Die Betriebsräume (Operations-, Eingriffs-, Behandlungsräume, Sektionssaal oder andere zweckentsprechende Räume) in denen Gewebe gewonnen wird, müssen benannt sein und innerhalb eines Lageplans eindeutig zugeordnet werden können. Der Lageplan ist den zuständigen Arzneimittel überwachenden Behörden auf Anfrage zur Verfügung zu stellen.

Einer Benennung der Räume, in denen die Entnahme stattfindet, bedarf es nicht zwingend für den Fall der Gewebeentnahme bei toten Spendern. Falls eine Gewebeentnahme bei verstorbenen Spendern nicht innerhalb der von der Erlaubnis erfassten Räume erfolgt, sind diese im Entnahmeprotokoll anzugeben (vgl. Anhang IV, Nr. 1.3.4. zur Richtlinie 2006/17/EG). Die Eignung der Entnahmeräumlichkeiten ist durch den für die Entnahme verantwortlichen Arzt zu bewerten und ebenfalls zu dokumentieren.

Entnahmeräumlichkeiten gelten grundsätzlich als geeignet, sofern die Gewebeentnahme in jeweils für den speziellen Eingriff tauglichen Betriebsräumen unter Einhaltung der üblichen Anforderungen, einschließlich der notwendigen Hygienemaßnahmen, durchgeführt wird. Maßgeblich sind dafür die Vorgaben des RKI zu den „Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen“ [11].

Bei der Festlegung der zur Gewebeentnahme vorgesehenen Räume ist der Kontaminationsgrad der betroffenen Körperregion zu berücksichtigen, die in nicht kontaminierte (aseptische, d. h. physiologisch keimfreie) Regionen, potenziell kontaminierte (bedingt aseptische) Regionen und kontaminierte (physiologisch besiedelte) Regionen eingeteilt werden. Zu unterscheiden ist ferner, ob es sich um eine Gewebeentnahme beim lebenden oder beim toten Spender handelt.

Aus infizierten Regionen – diese sind zu unterscheiden von physiologisch besiedelten Regionen – bzw. bei Vorliegen einer systemischen Infektion muss eine Gewebeentnahme unterbleiben. Bei Spendern von Augenhornhaut mit bakterieller Sepsis sind die Ausnahmeregeln dieser Bestimmung zu beachten (siehe Anhang I, Nr. 1.1.5. zur Richtlinie 2006/17/EG).

5.3. Ausstattung und Einrichtung

Die Betriebsräume, deren Ausrüstung und Einrichtungsgegenstände müssen leicht und wirksam zu reinigen und zu desinfizieren sein. Eine Gewebeentnahme ist in sauberen Räumen durchzuführen. Das Ziel, Kreuzkontaminationen zu verhindern, wird durch sterile Einmalinstrumente wesentlich erleichtert.

Zur Entnahme verwendete Instrumente und Bestecke müssen qualitativ hochwertig sein. Sie sind gemäß Art. 2 Abs. 7 der Richtlinie 2006/17/EG zu qualifizieren oder speziell zu zertifizieren.

Werden aus praktischen Erwägungen heraus wiederverwendbare Instrumente oder Instrumentensets benutzt, müssen diese zur Entfernung von Infektionserregern oder von anderen schädlichen Einflüssen mit einem normgerechten, in seinen Einzelschritten validierten und dokumentierten Aufbereitungsverfahren gereinigt und sterilisiert werden (vgl. Anhang IV, Nr. 1.3.9. zur Richtlinie 2006/17/EG).

Wiederverwendbare Bestecke sind regelmäßig für die Entnahme von Geweben zu inspizieren und instand zu halten (siehe hierzu auch Punkt 5.5. des GFP-Leitfadens). Instrumente und Hilfsmittel, die bei der Gewebeentnahme in direkten Kontakt mit dem entnommenen Gewebe treten, sollten in eine Einrichtungsliste aufgenommen werden. Wo immer möglich, werden mit CE-Kennzeichen versehene medizinische Instrumente und Geräte genutzt. Beteiligtes Personal ist auf geeignete Weise im Umgang mit diesen Geräten zu schulen (vgl. Anhang IV, Nr. 1.3.10. zur Richtlinie 2006/17/EG).

Bei der Entnahme von Gewebe, bei dem die Möglichkeit der Übertragung von TSE-Erregern besteht, sind bevorzugt sterile Einmalinstrumente zu verwenden. Ist dies nicht möglich, müssen die verwendeten Instrumente nach den Empfehlungen des Robert-Koch-Instituts zur Vorgehensweise bei möglicher Creutzfeldt-Jakob-Krankheit aufbereitet werden [12]. Grundsätzlich müssen in diesem Zusammenhang auch die Spenderausschlusskriterien nach Anhang I, Nr. 1.1.4. zur Richtlinie 2006/17/EG zur Vermeidung der Krankheitsübertragung durch Prionen berücksichtigt werden.

5.4. Raumlufttechnische Anforderungen an die Entnahmestellen

Die raumlufttechnischen Anforderungen an die Entnahmeeinrichtungen orientieren sich am Ausmaß der Invasivität, d.h. am Gefährdungsgrad des Eingriffs (bei Lebendspendern) sowie am Kontaminationsgrad der Körperregion (gilt auch bei toten Spendern) aus der die Gewebeentnahme erfolgen soll.

Für die zur Entnahme von Gewebe aus physiologisch keimfreien und potentiell kontaminierten Regionen beim Lebendspender bestimmten Räumlichkeiten gelten die gleichen Anforderungen wie für Operationsräume (Raumklasse I nach DIN 1946, Teil 4 [11]). Gleiche Bedingungen sind für die Gewebeentnahme aus physiologisch keimfreien Regionen eines verstorbenen Spenders zum Infektionsschutz des gespendeten Gewebes zu empfehlen.

Unter Anwendung aseptischer Entnahmetechniken kann bei einer Gewebeentnahme aus physiologisch keimfreien Regionen von postmortalen Spendern auch auf eine raumlufttechnische Anlage verzichtet werden, sofern im Anschluss die Keimfreiheit des entnommenen Gewebes durch ein validiertes Prüfverfahren nachgewiesen werden kann, oder bei hierfür geeignetem Gewebe, wie z.B. Knochen, Keimfreiheit durch ein validiertes Inaktivierungsverfahren hergestellt wird, dessen korrekte Durchführung im Einzelfall zu dokumentieren ist.

Im Zusammenhang mit der Anwendung von Verfahren zur Untersuchung der Sterilität bzw. Keimbelastung von entnommenen Geweben ist zu beachten, dass insbesondere bei großvolumigen Gewebestücken ausschließliche Abstrich- oder Abklatschuntersuchungen an deren Oberfläche nicht ausreichend sicher sind [13]. Soweit möglich, sind in diesen Fällen daher Spül- bzw. Durchspüluntersuchungen oder Anreicherungsverfahren anzuwenden. Vor der Anwendung von Inaktivierungsverfahren ist ggf. auch eine Bestimmung der Eingangskeimbelastung (Bioburden) erforderlich, um sicherzustellen, dass die Kapazität des vorgesehenen Verfahrens zur Inaktivierung nicht überschritten wird.

Für die Gewebeentnahme aus physiologisch besiedelten Arealen von toten Spendern ist aus infektionspräventiver Sicht keine raumlufttechnische Anlage erforderlich. Gleiches gilt unter diesen Bedingungen beim Lebendspender, sofern sich hieraus, nach dem jeweils aktuellen Kenntnisstand der medizinischen Wissenschaft und Technik, kein erhöhtes Entnahme- bzw. Infektionsrisiko für ihn ergibt.

5.5. Inbetriebnahme, Wartung und Instandsetzung

Die Qualifizierung, d.h. die technische und hygienische Abnahmeprüfung, raumlufttechnischer Anlagen in OP-Sälen und anderen Betriebsräumen zur Gewebeentnahme muss vor deren Inbetriebnahme anhand einer Musterlastanordnung unter Berücksichtigung der einschlägigen Richtlinien (DIN 1946, Teil 4 oder ggf. VDI 2167-1) durchgeführt werden. Filterdichtsitz, Lecktest und Requalifizierungen sollten regelmäßig, mindestens aber alle zwei Jahre bzw. nach Eingriffen an der Endfilterstufe wiederholt werden.

Geräte, Instrumente oder andere Ausrüstungsgegenstände einer Entnahmeeinrichtung, die für die sichere Durchführung einer Gewebeentnahme kritisch sind, müssen nach den Anweisungen des Herstellers vorbeugend und regelmäßig gewartet werden (vgl. Anhang IV, Nr. 1.3.8. zur Richtlinie 2006/17/EG). Aus Gründen der Qualitätssicherung und Nachverfolgbarkeit ist daher zu empfehlen, diese Ausrüstungsgegenstände in einen Wartungsplan aufzunehmen. Aus einem geeigneten Wartungsplan muss ersichtlich werden, wie häufig, zu welchen Zeitpunkten und durch wen die Wartungen durchzuführen sind. Empfindliche und häufig benutzte Geräte (z.B. Autoklaven für die Sterilisation von OP-Instrumenten) sollten engeren Wartungszeiträumen unterworfen werden. Ausrüstungen mit einer kritischen Messfunktion sind zu kalibrieren. Wartungen sind von qualifizierten Fachkräften auszuführen.

Falls bestimmte Wartungen nicht von hierfür qualifiziertem Personal der Entnahmeeinrichtung durchgeführt werden können, sind Wartungsverträge mit Fachfirmen abzuschließen. Die beauftragende Entnahmeeinrichtung sollte sich von der Qualifikation des Personals überzeugen. Zeitintervalle und Wartungsumfang sollten im Wartungsvertrag festgelegt werden. Die Dokumentation der Wartung ist zu archivieren. Die Überwachung und Einhaltung von Wartungsplänen obliegt der verantwortlichen ärztlichen Person der Entnahmeeinrichtung.

Anlagen, Geräte und OP-Instrumente sowie andere für die Sicherheit und Qualität der Entnahme kritischen Instrumente, Bestecke oder Ausrüstungsgegenstände die nicht mehr funktionstüchtig sind, müssen Instand gesetzt oder ausgetauscht werden. Neue und in Stand gesetzte, für eine Gewebeentnahme kritische Ausrüstungsgegenstände sind bei der Installation zu testen bzw. vor ihrer (Wieder)Inbetriebnahme auf ihre sachgemäße Funktion zu prüfen oder zu (re)validieren.

6. Hygiene

6.1. Hygienemaßnahmen und Hygieneplan der Entnahmeeinrichtungen

Nach dem Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz – IfSG) muss in Krankenhäusern und Einrichtungen für stationäres oder ambulantes Operieren ein Hygieneplan bestehen (Hygieneplan nach § 36 Abs. 1 IfSG bzw. Unfallverhütungsvorschrift Gesundheitsdienst (UVV), BGV C8 (bisherige VBG 103) (Anhang 2)) [14]. Entsprechend dieser Bestimmung müssen auch Entnahmeeinrichtungen über einen regelmäßig aktualisierten Hygieneplan verfügen.

Der erforderliche Hygieneplan richtet sich nach den Empfehlungen des Robert-Koch-Instituts (RKI) und setzt sich aus einzelnen fach- und tätigkeitsbezogenen Hygieneanleitungen zusammen (entsprechende Vorgaben hierzu, wie z.B. zur Infektionsprävention in Pflege, Diagnostik und Therapie, zur Reinigung, Desinfektion, Sterilisation und zur Betriebsorganisation in speziellen Bereichen, finden sich auf der Homepage des RKI (www.rki.de) unter: Infektionsschutz ➧ Krankenhaushaushygiene ➧ Empfehlungen der Kommission für Krankenhaushygiene und Infektionsprävention), die sowohl zum Schutz des Spenders (bei Lebendspendern), zum Schutz des entnommenen Gewebes (gilt auch bei verstorbenen Spendern) als auch zum Schutz des Personals schriftlich festzulegen und zu beachten sind. Anforderungen an die Hygiene bei ambulant oder stationär durchgeführten invasiven Eingriffen (und damit auch an eine ambulant oder stationär durchgeführte Gewebeentnahme) unterscheiden sich im Übrigen nicht [11].

Ein geeigneter Hygieneplan berücksichtigt alle erforderlichen technischen und betrieblich-organisatorischen Maßnahmen. Ziel ist auch hier die Verhinderung von Infektionen durch Mikroorganismen sowie von schädigenden Einflüssen durch erforderliche Reinigungs-, Desinfektions-, Sterilisations-, Ver- und Entsorgungsmaßnahmen einschließlich der regelmäßigen Anleitung von Personal zu hygienegerechtem Verhalten.

Die entsprechend erforderlichen Hygienemaßnahmen sind je Tätigkeitsbereich zu beschreiben. Im Hygieneplan ist festzulegen, wann welche Maßnahmen wie und von wem durchzuführen sind und welcher Mitarbeiter der Entnahmeeinrichtung ggf. für die Einhaltung einzelner Maßnahmen verantwortlich ist.

Der zu regelnde Bereich umfasst sowohl die Personalhygiene, die Hygienemaßnahmen an der entnehmenden Stelle, einschließlich mikrobiologischer Überwachungen und die speziellen hygienischen Anforderungen an die jeweilige Gewebeentnahme. Spezielle Anforderungen an einen Hygieneplan werden ggf. auch mit dem Hersteller bzw. dem Be- oder Verarbeiter festgelegt.

Die Durchführung der Hygienemaßnahmen – insbesondere die der arbeitstäglichen Reinigung und Desinfektion der Entnahmeräumlichkeiten – ist in angemessener Form zu dokumentieren.

Die Überwachung und Einhaltung des Hygieneplans in einer klinischen Einrichtung unterliegt in der Regel einem hygienebeauftragten Arzt in Abstimmung mit dem zuständigen Fachpersonal (Hygienefachkraft, Krankenhaushygieniker). Für die Einhaltung aller notwendigen hygienischen Maßnahmen in einer Entnahmeeinrichtung, die nicht über diese personelle Ausstattung verfügt, ist die verantwortliche ärztliche Person zuständig.

6.2. Spezielle hygienische Maßnahmen von Entnahmepersonal und für Spender vor, während und nach der Spende

Auch hier gelten die Empfehlungen des RKI, die in den Mitteilungen der Kommission für Krankenhaushygiene und Infektionsprävention beschrieben sind [11]. Sie beinhalten detaillierte Anforderungen an die durchzuführenden hygienischen Maßnahmen.

Erfolgt die Gewebeentnahme aus sterilen oder bedingt kontaminierten Bereichen so gelten die gleichen Bedingungen wie für Operationen (Bereichskleidung, präoperative Händedesinfektion, sterile Handschuhe und Operationskleidung einschließlich Mund-Nasen-Schutz, Kopfbedeckung, Schuhe, gründliche Desinfektion/Antiseptik der Haut der Entnahmestelle).

Erfolgt die Entnahme aus physiologisch besiedelten Arealen, so muss diese mit sterilem Instrumentarium und (mindestens) mit sterilen Handschuhen und Mund-Nasen-Schutz vorgenommen werden. Gleiche Bedingungen gelten für die Gewebeentnahme bei verstorbenen Spendern, wobei auch hier der operative Zugang auf den Ort der Entnahme zu beschränken ist. Es ist ein lokal steriler Bereich mit sterilem Abdeckmaterial vorzubereiten (vgl. Anhang IV, Nr. 1.3.3. zur Richtlinie 2006/17EG).

Vor Haut und Schleimhaut durchdringenden Eingriffen ist eine Desinfektion/Antiseptik des Entnahmegebiets erforderlich. Dieselben Anforderungen gelten für die Entnahme von Haut- oder Schleimhautzellen.

Darüber hinaus müssen vor dem Hintergrund des Anhangs IV, Nr. 1.3.7. zur Richtlinie 2006/17/EG Verfahren und Protokolle vorhanden sein, die das Risiko einer Kontaminierung der Gewebe bzw. Zellen durch möglicherweise mit einer übertragbaren Krankheit infiziertes Personal minimieren. Es sind daher regelmäßige Gesundheitskontrollen für beteiligtes Entnahmepersonal zu empfehlen. Die verantwortliche ärztliche Person der Entnahmeeinrichtung muss entscheiden, welche Maßnahmen in Bezug auf Mitarbeiter ergriffen werden müssen, von denen ein nicht vertretbares mikrobiologisches Risiko ausgehen könnte.

7. Personelle Ausstattung

7.1. Personal in Schlüsselstellung und assistierendes Personal

Beim lebenden Spender darf die Entnahme von menschlichem Gewebe zur Herstellung eines Arzneimittels – einschließlich eines zur Verwendung in einer klinischen Prüfung bestimmten Prüfpräparats (§ 3 Abs. 3 GCP-V) – gemäß § 8 Abs. 1 Satz 1 Nr. 4 TPG nur von einem Arzt vorgenommen werden. Abweichend hiervon kann die Entnahme bei verstorbenen Spendern gemäß § 3 Abs. 1 Satz 2 TPG auch durch anderes hierfür qualifiziertes Personal unter der Verantwortung und nach fachlicher Weisung eines Arztes durchgeführt werden.

Treten bei einer Gewebeentnahme unerwartete Probleme auf (z.B. bei verstorbenen Spendern mit vorher nicht bekannten Darmverletzungen), muss der für die Entnahme verantwortliche Arzt die weitere Spendereignung feststellen.

Assistierendes Personal muss entsprechend des jeweiligen Entnahmevorgangs mit angemessener Qualifizierung und in ausreichender Zahl vorhanden sein, um einen sicheren und reibungslosen Entnahmevorgang zu ermöglichen. Auch für diesen Personenkreis müssen klare, dokumentierte und aktuelle Aufgabenbeschreibungen bestehen, die, z.B. in Form von SOPs, im zugehörigen Qualitätshandbuch hinterlegt werden. Die jeweils zugeordneten Aufgaben, Zuständigkeiten und Verantwortlichkeiten müssen für assistierendes Personal verständlich sein.

7.2. Schulung und Schulungsnachweise beteiligter Personen

Personen die Gewebe entnehmen, müssen vor ihrer ersten selbstständigen Entnahme eine für diesen Zweck absolvierte Schulung erhalten. Die Schulung kann entweder durch einen autorisierten Ausbilder des Herstellers mit einer Herstellungserlaubnis nach § 13 AMG bzw. des Be- oder Verarbeiters mit einer Erlaubnis nach § 20c AMG oder durch einen – für das jeweilige Verfahren und die Technik der Entnahme – bereits geschulten, qualifizierten ärztlichen Mitarbeiter der Entnahmeeinrichtung durchgeführt werden (vgl. Art. 2 Abs. 2 der Richtlinie 2006/17/EG).

Ausgehend von der Spenderauswahl, der Spenderaufklärung, der Entnahmetechnik bis hin zur Kennzeichnung, Verpackung, Lagerung und Rückverfolgbarkeit des entnommenen Gewebes muss die Schulung alle theoretischen und praktischen Aspekte berücksichtigen. Hierzu gehören auch alle relevanten Sicherheits-, Hygiene, Gesundheits- und Dokumentationsvorschriften sowie entsprechende ethische, rechtliche und gesetzliche Bestimmungen.

Operations- und Entnahmetechniken sollten ausführlich erläutert und demonstriert werden und wenn nötig vom Auszubildenden an unbedenklichen Simulationsobjekten geübt werden. Notwendige Hilfsmittel und Unterrichtsunterlagen sind dem Schulungsteilnehmer bereitzustellen.

Soweit erforderlich, sind auch für Personen, die Gewebe entnehmen (d.h. Ärzte oder im Fall der Entnahme beim toten Spender ggf. anderweitig hierfür qualifizierte Personen), regelmäßige Weiterbildungsmaßnahmen durchzuführen. Dies gilt insbesondere bei Änderungen von Entnahmetechniken und -verfahren sowie im Zuge neuer wissenschaftlicher Erkenntnisse zu Ein- und Ausschlusskriterien für Gewebespender und zur Hygiene.

Assistierendes Personal für die Entnahme muss in regelmäßigen Abständen geschult werden, wobei die Schulung auch hier alle relevanten Aspekte des Qualitätssicherungssystems berücksichtigen muss. Die Schulung von assistierendem Personal obliegt dem Zuständigkeitsbereich der verantwortlichen ärztlichen Person. Schulungen müssen mit Angabe des Datums und durch Unterschrift des Ausbilders dokumentiert und archiviert werden.

7.3. Fremd- und Zusatzpersonal

Wird für bestimmte Tätigkeiten oder Aufgaben einer Entnahmeeinrichtung Fremdpersonal eingesetzt, z.B. für Reinigungs- und Desinfektionsarbeiten der Betriebsräume, muss sichergestellt werden, dass dieses Personal für die durchzuführenden Arbeiten geeignet ist. Mit den Leistungserbringern sind entsprechende Verträge abzuschließen. Auch Zusatz- oder Fremdpersonal muss regelmäßig geschult werden, dies gilt insbesondere hinsichtlich der hygienischen Anforderungen der Entnahmeeinrichtung.

8. Inspektionen und Audits

8.1. Selbstinspektionen

Einer Entnahmeeinrichtung sind regelmäßige Selbstinspektionen zu empfehlen. Sie sollten mindestens alle zwei Jahre durchgeführt werden. Es ist ein Selbstinspektionsplan zu erstellen. Das Ergebnis einer Inspektion ist schriftlich zu fixieren. Gefundene Missstände müssen schriftlich festgehalten und zeitnah behoben werden. Entnahmeeinrichtungen können die Selbstinspektion auch von einem beauftragten und hierfür qualifizierten Unternehmen durchführen lassen. In diesem Fall sind unter Beachtung der Vorgaben des § 9 AMWHV entsprechende schriftliche Verträge abzuschließen.

8.2. Auditierung durch Hersteller bzw. Be- oder Verarbeiter

Entnahmeeinrichtungen können von einem Hersteller bzw. Be- oder Verarbeiter im Vorfeld der Beantragung oder im Rahmen einer bereits bestehenden Erlaubniserteilung zur Gewebeentnahme auditiert werden. In der Regel wird der Entnahmeeinrichtung ein Fragebogen übersandt, der beantwortet werden muss. Eine praktische Überprüfung vor Ort kann angeschlossen werden, um die schriftlichen Aussagen der Entnahmeeinrichtung zu verifizieren.

8.3. Behördliche Inspektionen

Behördeninspektionen können angekündigt oder auch unangekündigt erfolgen. Im angekündigten Fall werden die wesentlichen Dokumente der Entnahmeeinrichtung zur Qualitätssicherung von der Behörde in der Regel vorab überprüft. Eine örtliche Begehung der Entnahmeeinrichtung kann sich anschließen und liegt im Ermessen der Behörde.

Es liegt ebenso im Ermessen der Behörde, von einer Besichtigung der Entnahmeeinrichtung vor der Erlaubniserteilung abzusehen (§ 20b Abs. 1 Satz 4 AMG). Über die Durchführung einer Inspektion wird ein Bericht erstellt und der Einrichtung übersandt (§ 4 Abs. 7 AMGVwV). Gefundene Mängel müssen entsprechend der behördlichen Aufforderung behoben werden.

9. Voraussetzungen zur Entnahme von menschlichen Geweben oder Zellen

9.1. Gesetzliche Bestimmungen

Menschliche Gewebe i. S. d. § 1a Nr. 4 TPG und damit auch einzelne Zellen zur Verwendung bei Menschen, wozu auch der Zweck der Herstellung eines Arzneimittels einschließlich eines Prüfpräparats zählt, können sowohl von postmortalen Spendern (z.B. Augenhornhäute, Haut, Knochen, Gefäße oder Herzklappen) als auch von Lebendspendern (z.B. Knochenmark, Femurköpfe bei Implantation einer primären Hüftendoprothese oder Knorpelgewebe für die autologe Chondrozyten-Transplantation) für eine gerichtete oder ungerichtete Spende (bezogen auf den Empfänger) gewonnen werden.

Diesbezügliche europarechtliche Vorgaben sind in Art. 2 der Richtlinie 2006/17/EG enthalten. Die in deren Umsetzung erlassenen nationalen Bestimmungen zu den Voraussetzungen für die Gewebeentnahme bei toten Spendern sind in Abschnitt 2 des TPG in den §§ 3 bis 7 TPG und für Lebensspender im Abschnitt 3 des TPG in den §§ 8 bis 8c TPG enthalten. Darüber hinaus müssen die Vorgaben des § 8d TPG sowie die Bestimmungen des § 9 TPG erfüllt werden.

Nach § 8d TPG ist die Entnahmeeinrichtung dazu verpflichtet:

(1) die Anforderungen an die Entnahme von Geweben nach dem Stand der medizinischen Wissenschaft und Technik einzuhalten, insbesondere an die Spenderidentifikation, das Entnahmeverfahren und die Spenderdokumentation

(2) sicherzustellen, dass nur Gewebe von Spendern entnommen werden, bei denen eine ärztliche Beurteilung nach dem Stand der medizinischen Wissenschaft und Technik ergeben hat, dass der Spender dafür medizinisch geeignet ist

(3) sicherzustellen, dass die für Spender nach dem Stand der medizinischen Wissenschaft und Technik erforderlichen Laboruntersuchungen in einem Untersuchungslabor nach § 8e TPG durchgeführt werden

(4) sicherzustellen, dass die Gewebe für die Aufbereitung, Be- oder Verarbeitung, Konservierung oder Aufbewahrung nur freigegeben werden, wenn die ärztliche Beurteilung nach Nummer 2 und die Laboruntersuchung nach Nummer 3 ergeben haben, dass die Gewebe für diese Zwecke geeignet sind

(5) bei lebenden Spendern vor und nach der Entnahme Maßnahmen für eine erforderliche medizinische Versorgung sicherzustellen

(6) eine Qualitätssicherung für die Maßnahmen nach den Nummern 2 bis 5 sicherzustellen

Gemäß § 9 Abs. 2 TPG hat die mögliche Entnahme und Übertragung eines vermittlungspflichtigen Organs Vorrang vor der Entnahme von Geweben. Sie darf durch eine Gewebeentnahme nicht beeinträchtigt werden. Die Entnahme von Geweben bei einem möglichen Spender vermittlungspflichtiger Organe nach § 11 Abs. 4 Satz 2 TPG ist erst dann zulässig, wenn eine von der Koordinierungsstelle beauftragte Person dokumentiert hat, dass die Entnahme oder Übertragung von vermittlungspflichtigen Organen nicht möglich ist oder durch die Gewebeentnahme nicht beeinträchtigt wird (siehe hierzu auch § 11 Abs. 4 Satz 3 und 4 TPG).

9.2. Allgemeine und spezielle Auswahlkriterien für Gewebespender

Geeignete Ein- und Ausschlusskriterien für Gewebespender müssen sowohl den Sicherheitsanforderungen für Spender als auch den Sicherheits- und Qualitätsanforderungen für Empfänger gerecht werden. Das bedeutet, dass bei Lebendspendern durch die Gewebeentnahme kein Leben oder Gesundheit beeinträchtigender Schaden entstehen darf und dass die entnommenen Gewebe oder deren Zubereitungen nach Übertragung beim Empfänger die therapeutisch gewünschte Wirkung ohne unverhältnismäßige Nebenwirkungen erzielen können (siehe hierzu auch § 8 Abs. 1 Satz 1 TPG).

Die Auswahlkriterien für Spender beruhen daher vor dem Hintergrund der einleitenden Ausführungen des Anhangs I zur Richtlinie 2006/17/EG auf einer Risikoanalyse im Zusammenhang mit der Verwendung der spezifischen Gewebe. Anzeichen für solche Risiken sind durch die körperliche Untersuchung, eine Anamnese, biologische Untersuchungen, die postmortale Untersuchung bei verstorbenen Spendern und durch sonstige hierfür geeignete Untersuchungen zu ermitteln.

Falls die Spende nicht aufgrund einer dokumentierten Risikobewertung gerechtfertigt ist, die von dem entnehmenden Arzt durchgeführt wird, sind Spender von der Spende auszuschließen, sofern eine der Voraussetzungen, bzw. Ausschlusskriterien des Anhang I (für Spender von Geweben und Zellen, ausgenommen Spender von Keimzellen) oder des Anhang III (für Spender von Keimzellen) der Richtlinie 2006/17/EG auf sie zutrifft.

Bestehen für Gewebe zusätzliche oder speziell auf sie ausgerichtete Auswahlkriterien für Spender, wie z.B. in Deutschland mit den Bestimmungen des bereits erwähnten Transplantationsgesetzes, den Richtlinien der Bundesärztekammer zur Hämotherapie, zu Knochen, Augenhornhäuten oder anderen Geweben und Zellen (siehe hierzu auch Punkt 19.2. des GFP-Leitfadens), den Empfehlungen medizinischer Fachgesellschaften, wie die der Deutschen Gesellschaften für Unfallchirurgie sowie Orthopädie und Orthopädische Chirurgie zur autologen Chondrozyten-Transplantation oder von Seiten der belieferten Hersteller bzw. Be- oder Verarbeiter, sind auch diese Vorgaben zur Beurteilung der Spendertauglichkeit zu berücksichtigen.

Ferner ist den jeweils zuständigen medizinischen Fachgesellschaften in diesem Zusammenhang zu empfehlen, weitere, d.h. entsprechend gewebstypische Auswahlkriterien für Spender oder auch Empfänger zu definieren und festzulegen, falls solche Richtlinien oder Empfehlungen für bestimmte Gewebe oder Zellen, hieraus hergestellter Zubereitungen und deren indikationsbezogener therapeutischer Anwendung in Anbetracht evidenzbasierter Erkenntnisse sinnvoll sind und noch nicht bestehen.

Ein- und Ausschlusskriterien für Gewebespender einschließlich der erforderlichen Labortests und Freigabeverfahren müssen im QS-System der Entnahmeeinrichtung festgelegt werden, wobei die einschlägigen gesetzlichen Vorgaben und Richtlinien, insbesondere des § 8d TPG, sowie der jeweils aktuelle Stand der medizinischen Wissenschaft und Technik zu berücksichtigen sind.

9.3. Laboruntersuchungen zur Prüfung der Spendereignung

Die im Zusammenhang mit der Risikobewertung und des Ausschlusses eines Spenders erforderlichen Laboruntersuchungen sowie die Anforderungen an deren Durchführung sind in Art. 4 der Richtlinie 2006/17/EG i. V. m. den Anhängen II und III für lebende und tote Spender, die autologe und allogene Spende sowie für die Spende von Keimzellen (einschließlich Partnerspende und Spende von Dritten) beschrieben.

Obligatorische Tests für Spender (ausgenommen Keimzellspender) gemäß Artikel 4 Abs. 1 und dem Anhang II, Nr. 1 zur Richtlinie 2006/17/EG sind serologische Untersuchungen zu HIV-1, HIV-2, HBV und HCV sowie zu Syphilis, wobei unter bestimmten Bedingungen und je nach Vorgeschichte des Spenders und den Merkmalen der gespendeten Gewebe oder Zellen zusätzliche Laboruntersuchungen erforderlich sein können (z.B. RhD, HLA, Malaria, CMV, Toxoplasma, EBV, Trypanosoma cruzi).

Die jeweils erforderlichen Laboruntersuchungen für Gewebespender gemäß des im Lichte des Art. 4 der Richtlinie 2006/17/EG zu interpretierenden § 8d Abs. 1 Satz 2 Nr. 3 TPG dürfen nach § 8e TPG nur von einem Untersuchungslabor vorgenommen werden, dem eine Erlaubnis nach § 20b Abs. 1 AMG erteilt worden ist oder das unter vertraglicher Bindung mit einem Hersteller oder Be- oder Verarbeiter tätig ist, dem die Erlaubnis für die vertragliche Tätigkeit des Untersuchungslabors erteilt wurde (§ 20b Abs. 2 AMG).

Das Untersuchungslabor ist dabei verpflichtet, eine Qualitätssicherung für die nach § 8d Abs. 1 Satz 2 Nr. 3 TPG vorgeschriebenen Laboruntersuchungen sicherzustellen. Die Art der für Laboruntersuchungen angewandten Verfahren ist gemäß Anhang II, Nr. 2.1. zur Richtlinie 2006/17/EG mit Blick auf den Verwendungszweck nach dem Stand von Wissenschaft und Technik zu validieren. Kritische Prüfverfahren müssen regelmäßig dahingehend bewertet werden, ob sie noch valide sind und müssen ggf. revalidiert werden.

Erforderliche Laboruntersuchungen sind nach zuvor erstellten Standardarbeitsanweisungen (Prüfanweisung) durchzuführen und vollständig zu protokollieren (Prüfprotokoll). Alle Abweichungen im Prozess und von den Festlegungen der Spezifikation müssen dokumentiert und gründlich untersucht werden.

Die für die Laborergebnisse verantwortliche Person hat im Prüfprotokoll mit Datum und Unterschrift zu bestätigen, dass die Prüfung entsprechend der Prüfanweisung durchgeführt worden ist.

Laboruntersuchungen zur Feststellung der Spendereignung können auch durch den Hersteller bzw. den Be- oder Verarbeiter durchgeführt werden, sofern dies in einem entsprechenden Vertrag mit der Entnahmeeinrichtung geregelt ist (siehe hierzu auch Punkt 3.3. des GMP-Leitfadens). Wenn das Untersuchungslabor über keine eigene Erlaubnis nach § 20b Abs. 1 AMG verfügt, hat der Hersteller bzw. der Be- oder Verarbeiter gemäß § 20b Abs. 1 Satz 3 Nr. 4 AMG eine Qualitätssicherung für die nach § 8d Abs. 1 Satz 2 Nr. 3 TPG vorgeschriebenen Laboruntersuchungen sicherzustellen.

10. Spende- und Entnahmeverfahren

10.1. Einwilligung und Spenderidentifizierung

Gemäß § 8 Abs. 2 Satz 4 TPG muss vor der Gewebeentnahme bei lebenden Spendern der Arzt bestätigen und dokumentieren, dass die Spendeeinwilligung nach § 8 Abs. 2 Satz 1 und 2 TPG vorliegt. Im Lichte des Anhangs IV, Nr. 1.1.1. zur Richtlinie 2006/17/EG ist auch die zuverlässige Spenderidentifikation zu dokumentieren.

Der Spenderaufklärung – insbesondere auch im Sinne der Guten Fachlichen Praxis – kommt für die Spendeeinwilligung eine ganz wesentliche Bedeutung zu. In § 8 Abs. 2 Satz 1 TPG wurde daher präzisiert, dass der Spender durch einen Arzt in verständlicher Form aufzuklären ist über:

(1) den Zweck und die Art des Eingriffs
(2) die Untersuchungen sowie das Recht, über deren Ergebnisse unterrichtet zu werden
(3) die Maßnahmen, die dem Schutz des Spenders dienen, sowie den Umfang und mögliche, auch mittelbare Folgen und Spätfolgen der beabsichtigten Gewebeentnahme für seine Gesundheit
(4) die ärztliche Schweigepflicht
(5) die zu erwartende Erfolgsaussicht der Gewebeübertragung und sonstige Umstände, denen er eine Bedeutung für die Spende beimisst
(6) die Erhebung und Verwendung personenbezogener Daten

Ein weiterer, wichtiger Hintergrund der Spenderaufklärung ist, dass eine Gewebeentnahme – auch wenn sie von einem Arzt nach dem Stand der medizinischen Wissenschaft und Technik durchgeführt wird – im juristischen Sinne eine tatbestandsmäßige Körperverletzung darstellt. Um eine Gewebeentnahme rechtmäßig vornehmen zu können, bedarf es daher zu ihrer Rechtfertigung der Einwilligung des Spenders.

Die alleinige schriftliche Aufklärung in Form der vielfach verwendeten Aufklärungsbögen erfüllt nicht die von der Rechtssprechung gesetzten Erfordernisse an eine Aufklärung. Die Aufklärung hat daher grundsätzlich durch ein Arzt-Patienten-Gespräch zu erfolgen. In diesem Gespräch ist dem Spender die Möglichkeit der Nachfrage zu geben. Seine Fragen müssen vollständig und richtig beantwortet werden. Bestehende Risiken dürfen nicht verharmlost werden. Der Spender muss darüber informiert werden, dass seine Einwilligung Voraussetzung für die Gewebeentnahme ist.

Ist der Spender gleichzeitig Empfänger müssen ggf. bestehende Behandlungsalternativen angesprochen werden (gleiches ist auch bei der Empfängeraufklärung zu beachten, wenn Spender und Empfänger nicht personenidentisch sind). Dies gilt insbesondere für solche Alternativmethoden, die bei vergleichbarer therapeutischer Wirksamkeit mit einem geringeren Risikopotential für Spender oder Empfänger verbunden sind.

Nach erfolgter Aufklärung soll der Spender in der Lage sein, das „Für und Wider“ des Eingriffs und der Spende eigenständig abzuwägen, um so sein Selbstbestimmungsrecht in angemessener Art und Weise wahrnehmen zu können. Dazu gehört nach der Guten Fachlichen Praxis auch, dass ihm eine angemessene Bedenkzeit eingeräumt wird, damit er die Informationen des Arztes verarbeiten und abwägen kann. Der Spender soll seine Entscheidung ohne Zeitdruck treffen können. Wie lang eine ausreichende Bedenkzeit ist, richtet sich nach dem Einzelfall, unter anderem auch nach dem Risiko der Entnahme.

Für das Aufklärungsgespräch ist es außerdem erforderlich, dass der Spender die volle Entscheidungsfreiheit besitzt. Wenn z.B. bereits Schlafmittel oder andere Sedativa verabreicht wurden, verfügt er nicht mehr über die erforderliche Entscheidungsfreiheit.

Die Aufklärung zur Spende muss von einem fachkundigen Arzt vorgenommen werden, der auch entsprechende Sachkenntnisse in der jeweiligen Gewebeentnahme haben muss. Im Falle der Gewebeentnahme von lebenden Spendern zur allogenen Verwendung muss der Spender gemäß § 8 Abs. 2 Satz 3 TPG – außer im Falle der Knochenmarkspende – in Anwesenheit eines weiteren Arztes aufgeklärt werden.

Die Anwesenheit eines weiteren Arztes bei der Aufklärung ist jedoch bei der Gewebeentnahme im Rahmen einer medizinischen Behandlung (§ 8b TPG – z.B. Femurkopfentnahme bei der Primärimplantation einer Hüftendoprothese) und bei der Entnahme von Gewebe zur Rückübertragung (§ 8c TPG – z.B. autologe Chondrozyten-Transplantation) nicht erforderlich.

Nicht notwendig ist, dass der aufklärende Arzt auch derjenige ist, der später das Gewebe entnimmt. Eine Aufklärung durch Pflegepersonal ist unzulässig. Bei Vorliegen einer fehlerhaften Aufklärung, z.B. auch bei Aufklärung nach bereits durchgeführter Spende, ist von einer unwirksamen Einwilligung auszugehen. Eine Gewebeentnahme ohne Einwilligung des Spenders ist ethisch nicht vertretbar, strafbar und ist daher zu unterlassen. Es ist in diesem Zusammenhang auch zu empfehlen, standardisierte Aufklärungsbögen zu verwenden, damit alle Aspekte und Risiken der Spende berücksichtigt und keine relevanten Inhalte der Aufklärung übersehen werden. Ist ein Spender der deutschen Sprache nicht ausreichend mächtig, muss die Aufklärung mit Hilfe eines geeigneten Übersetzers durchgeführt werden.

Es ist ergänzend im Lichte des Anhangs IV, Nr. 1.1.2. zur Richtlinie 2006/17/EG darauf hinzuweisen, dass ein lebender Spender zu bestätigen hat, dass er alle Angaben im Zusammenhang mit der Gewebespende nach bestem Wissen und Gewissen gemacht hat. Gemäß § 8 Abs. 3 Satz 1 TPG ist die Entnahme auch nur dann zulässig, wenn der Spender sich zu einer ärztlich empfohlenen Nachbetreuung bereit erklärt hat.

Nach § 8 Abs. 2 Satz 4 TPG ist die Spendeeinwilligung schriftlich mit Angabe der Unterschrift des Spenders oder seines gesetzlichen Vertreters, des aufklärenden Arztes und – sofern erforderlich – der Unterschrift des weiteren Arztes zu dokumentieren. Die Niederschrift soll zur Dokumentation des Zeitpunktes der Aufklärung datiert werden.

Sie muss auch eine Angabe über die versicherungsrechtliche Absicherung der gesundheitlichen Risiken des Entnahmeeingriffs enthalten. Der Spender kann seine Einwilligung schriftlich oder mündlich widerrufen.

Bei Minderjährigen ist für eine Fremdspende nur die Entnahme von Knochenmark zulässig und zwar nur dann, wenn die zusätzlichen Anforderungen des § 8a TPG erfüllt sind. Der gesetzliche Vertreter eines minderjährigen Spenders ist entsprechend der vorstehend beschriebenen Art und Weise aufzuklären. Auch der Minderjährige selbst ist aufzuklären, soweit dies im Hinblick auf sein Alter und seine geistige Reife möglich ist. Eine von ihm zum Ausdruck gebrachte Ablehnung der Entnahme ist zu beachten.

Bei toten Spendern ist eine Gewebeentnahme im Inland nur dann zulässig, wenn ihr Hirntod nach den einschlägigen Richtlinien der Bundesärztekammer festgestellt worden ist (§§ 3 Abs. 1 Satz 1 Nr. 2, 16 Abs. 1 Satz 1 Nr. 1 TPG). Im Übrigen richtet sich bei toten Spendern die Zulässigkeit der Gewebeentnahme nach § 4 TPG. Sie ist hiernach nur zulässig, sofern der Spender in die Entnahme schriftlich eingewilligt hat. Fehlt es an einer solchen Einwilligung und liegt auch kein schriftlicher Widerspruch des potentiellen Spenders vor, so ist der nächste Angehörige (§ 1a Nr. 5 TPG) des Spenders zu befragen, ob ihm eine Erklärung des Verstorbenen zur Gewebespende bekannt ist. Ist dies nicht der Fall, so ist die Entnahme nur zulässig, wenn ein Arzt den nächsten Angehörigen über eine in Betracht kommende Gewebeentnahme unterrichtet hat und dieser zugestimmt wurde. Kommt eine Entnahme von Organen und Geweben in Betracht, soll die Einholung der Zustimmung zusammen erfolgen (einzügige Aufklärung). Der nächste Angehörige ist darauf hinzuweisen, dass er bei seiner Entscheidung den mutmaßlichen Willen des Verstorbenen zu berücksichtigen hat. Der Arzt hat bei der Befragung festzustellen, ob der nächste Angehörige in den letzten zwei Jahren vor dem Tot des Spenders persönlichen Kontakt zu diesem hatte. Hatte der Verstorbene die Entscheidung über die Gewebeentnahme einer anderen Person übertragen, so tritt diese an die Stelle des nächsten Angehörigen.

Im Falle der Entnahme von Geweben bei toten Föten und Embryonen sind die Vorgaben des § 4a TPG maßgeblich.

10.2. Spenderevaluierung (dieser Abschnitt gilt nicht für die Partnerspende von Keimzellen und für autologe Spender)

Zu den gemäß § 8d Abs. 1 Satz 2 Nr. 1 TPG nach dem Stand der medizinischen Wissenschaft und Technik einzuhaltenden Anforderungen an das Entnahmeverfahren zählt vor dem Hintergrund des Anhangs IV, Nr. 1.2.1. zur Richtlinie 2006/17/EG, dass die einschlägigen medizinischen und verhaltensbezogenen Informationen zur Spenderevaluierung von einer hierzu befugten Person nach den unter Punkt 11 (Spenderdokumentation) des vorliegenden GFP-Leitfadens beschriebenen Anforderungen zu erheben und zu dokumentieren sind.

Zur Erhebung der entsprechenden Informationen sind verschiedene zweckdienliche Quellen zu nutzen, darunter mindestens eine Befragung des Spenders – sofern es sich um einen lebenden Spender handelt – sowie ggf. folgende Informationsquellen (vgl. Anhang IV, Nr. 1.2.2. zur Richtlinie 2006/17/EG):

(1) die Krankenakte des Spenders
(2) bei verstorbenen Spendern die Befragung einer Person, die den Spender gut kannte
(3) eine Befragung des behandelnden Arztes
(4) eine Befragung des Hausarztes
(5) der Autopsiebericht

Darüber hinaus ist beim verstorbenen Spender und – sofern gerechtfertigt – beim lebenden Spender eine körperliche Untersuchung durchzuführen, um etwaige Anzeichen zu erkennen, die allein bereits für den Ausschluss des Spenders ausreichen oder die anhand der medizinischen und persönlichen Vorgeschichte des Spenders überprüft werden müssen. Die gesamte Spenderakte ist unter Berücksichtigung der Vorgaben der Richtlinie 2006/17/EG (Anhang IV, Nr. 1.2.4.) von einem qualifizierten Angehörigen eines Gesundheitsberufs auf die Eignung des Spenders zu überprüfen und zu bewerten sowie mit Angabe des Datums von ihm zu unterschreiben.

10.3. Entnahmeverfahren für Gewebe

Die jeweiligen Entnahmeverfahren müssen der Art der Spende und der gespendeten Gewebe angemessen sein. Entsprechend der Forderung des Anhang IV, Nr. 1.3. zur Richtlinie 2006/17/EG müssen die verwendeten Entnahmetechniken und -verfahren die Sicherheit und Gesundheit des lebenden Spenders gewährleisten und diejenigen Eigenschaften der Gewebe schützen, die für ihre vorgesehene klinische Verwendung erforderlich sind. Darüber hinaus muss das verwendete Entnahmeverfahren das Risiko einer mikrobiellen Kontamination oder einer anderen schädlichen Verunreinigung minimieren, insbesondere dann, wenn die Gewebe und Zellen anschließend nicht sterilisiert werden können (vgl. 2006/17/EG, Anhang IV, Nr. 1.3.2.).

Unabhängig davon, ob es sich beim Spender um eine lebende oder tote Person handelt, ist die Entnahme und alle mit ihr zusammenhängenden Maßnahmen unter Achtung der Würde des Spenders in einer der ärztlichen Sorgfaltspflicht entsprechenden Weise durchzuführen. Beim toten Spender bedeutet dies auch, dass sobald Gewebe oder Zellen entnommen wurden, sein Leichnam wieder so herzustellen ist, dass er größtmögliche Ähnlichkeit mit seiner ursprünglichen anatomischen Form aufweist (vgl. 2006/17/EG, Anhang IV, Nr. 1.3.5.). Der Leichnam des Spenders muss in würdigem Zustand zur Bestattung übergeben werden. Vor der Übergabe an den Bestatter ist dem nächsten Angehörigen Gelegenheit zu geben, den Leichnam zu sehen (§ 6 Abs. 2 TPG).

Weitere Anforderungen an die Entnahme von Geweben bei lebenden und toten Spendern hinsichtlich der apparativen, räumlichen, hygienischen und personellen Ausstattung sind unter den Punkten 5 bis 7 des vorliegenden GFP-Leitfadens beschrieben.

10.4. Entnahmeanweisungen und Entnahmeprotokoll

Zu den gemäß § 8d Abs. 1 Satz 2 Nr. 1 TPG nach dem Stand der medizinischen Wissenschaft und Technik einzuhaltenden Anforderungen an das Entnahmeverfahren zählt es vor dem Hintergrund des Art. 2 Abs. 5 der Richtlinie 2006/17/EG, dass die Gewebeentnahme einschließlich aller Maßnahmen, die dazu bestimmt sind, das Gewebe in einem be- oder verarbeitungsfähigen Zustand zu erhalten, zu kennzeichnen und zu transportieren nach einer zuvor erstellten Standardarbeitsanweisung (Entnahmeanweisung) unter Berücksichtigung der oben beschriebenen Voraussetzungen und in Übereinstimmung mit der Guten Fachlichen Praxis durchgeführt werden.

Bei Geweben oder deren Zubereitungen, die nach § 21a AMG genehmigt wurden, muss die Entnahmeanweisung den Genehmigungsunterlagen entsprechen. Die Entnahmeanweisung muss dabei mindestens Regelungen enthalten:

(1) zur Identifizierung und Feststellung der Eignung des Spenders
(2) zur Entnahme der Spenden sowie zum Umgang mit dem entnommenen Material, einschließlich der einzusetzenden Ausrüstung
(3) zu den Entnahmeverfahren und zur Verhinderung einer bakteriellen oder sonstigen Kontamination bei der Entnahme, sowie erforderlichenfalls weiterer Maßnahmen zur Minimierung von Kontaminationen der Produkte
(4) zur Angabe des Entnahmeorts bei verstorbenen Spendern, soweit dieser außerhalb der Einrichtung liegt, und dort erforderlichenfalls einzuhaltender Bedingungen, sowie der Dokumentation des Zeitraums zwischen Eintritt des Todes und der Entnahme der Spende
(5) zu Anforderungen an die Spendenbehältnisse sowie an die verwendeten Aufbewahrungs- und Transportlösungen
(6) zur Kennzeichnung der Spenden
(7) sowie zu Bedingungen der eventuellen Zwischenlagerung der Spenden bis zu ihrem Transport zur Be- oder Verarbeitung.

Die Gewebeentnahme ist gemäß der Entnahmeanweisung durchzuführen und unbeschadet der Dokumentationspflichten aus § 8d Abs. 2 TPG vollständig zu protokollieren (Entnahmeprotokoll). Alle Abweichungen im Prozess und von der Festlegung der Spezifikation sind zu dokumentieren und gründlich zu untersuchen.

Die für die Gewebeentnahme verantwortliche Person hat im Entnahmeprotokoll mit Datum und Unterschrift zu bestätigen, dass die Entnahme entsprechend der Entnahmeanweisung durchgeführt worden ist.

Darüber hinaus ist jeglicher während der Entnahme auftretende Zwischenfall, der einem lebenden Spender Schaden zugefügt hat oder zugefügt haben kann oder der sich auf die Sicherheit und Qualität des entnommenen Gewebes auswirken kann sowie das Ergebnis jeglicher Untersuchungen zur Feststellung der entsprechenden Ursache zu dokumentieren und in Verantwortung der verantwortlichen ärztlichen Person zu überprüfen (siehe hierzu auch Punkt 14 und 15 des GFP-Leitfadens).

11. Spenderdokumentation

Zu den gemäß § 8d Abs. 1 Satz 2 Nr. 1 TPG nach dem Stand der medizinischen Wissenschaft und Technik einzuhaltenden Anforderungen an die Spenderdokumentation zählt es vor dem Hintergrund des Anhangs IV, Nr. 1.4.1., für jeden Spender eine Akte mit folgenden Angaben anzulegen:

(1) Spenderidentität (Vorname, Familienname und Geburtsdatum). Sind Mutter und Kind an der Spende beteiligt, sowohl den Namen und das Geburtsdatum der Mutter als auch den Namen, soweit bekannt, und das Geburtsdatum des Kindes

(2) Alter, Geschlecht, medizinische und Verhaltensanamnese (die erhobenen Informationen müssen ausreichen, um ggf. die Anwendung der Ausschlusskriterien zu ermöglichen)

(3) ggf. Befund der körperlichen Untersuchung

(4) ggf. Hämodilutionsformel (siehe hierzu auch Anhang II, Nr. 2.3. zur Richtlinie 2006/17/EG)

(5) klinische Daten, Ergebnisse der Labortests und sonstiger durchgeführter Tests

(6) wurde eine Autopsie vorgenommen, sind deren Ergebnisse in die Akte aufzunehmen (bei Geweben und Zellen, die nicht langfristig gelagert werden können, ist ein vorläufiger mündlicher Autopsiebericht aufzuzeichnen)

(7) bei Spendern hämatopoetischer Vorläuferzellen ist die Eignung des Spenders für den ausgewählten Empfänger zu dokumentieren. Sind Spender und Empfänger genetisch nicht verwandt und hat die für die Entnahme verantwortliche Organisation nur begrenzten Zugang zu den Empfängerdaten, müssen der Transplantationseinrichtung die zur Bestätigung der Eignung zweckdienlichen Spenderdaten zur Verfügung gestellt werden

Sofern das Gewebe nicht in der gleichen Abteilung oder Einrichtung be- oder verarbeitet wird, in der es entnommen wurde, ist zusätzlich zur Spenderakte und dem Entnahmeprotokoll ein Entnahmebericht zu erstellen, der an den Hersteller bzw. den Be- oder Verarbeiter zu übermitteln ist. Der Entnahmebericht muss die ordnungsgemäße Anamnese und Bewertung der Spendereignung einschließlich der Spenderaufklärung bestätigen und in Anbetracht des Anhangs IV, Nr. 1.4.2. zur Richtlinie 2006/17/EG mindestens folgende zusätzliche Informationen enthalten:

(1) die Identifizierung, Name und Anschrift der be- oder weiterverarbeitenden Stelle, die die Gewebe bzw. Zellen erhalten soll
(2) Angaben über die Spenderidentität (einschließlich der Angabe, wie und von wem der Spender identifiziert wurde)
(3) Beschreibung und Identifizierung der entnommenen Gewebe bzw. Zellen (einschließlich der zur Testung entnommenen Gewebe oder Zellen)
(4) Identität der für diese Entnahme zuständigen Person, einschließlich deren Unterschrift
(5) Datum, Uhrzeit (wenn zweckdienlich, Beginn und Ende), Ort der Entnahme und das verwendete Verfahren (SOP), einschließlich etwaiger Zwischenfälle, ggf. Umgebungsbedingungen in der Entnahmeeinrichtung (Beschreibung des Bereichs, wo die Entnahme stattfand)
(6) bei verstorbenen Spendern Beschreibung der Bedingungen, unter denen die Leiche aufbewahrt wurde (z.B. gekühlt oder nicht), ggf. Zeitpunkt des Beginns und des Endes der Kühlung
(7) Identifizierung/Chargennummern der verwendeten Reagenzien und Transportlösungen
(8) sofern möglich, muss der Bericht bei verstorbenen Spendern, Ort und Zeitpunkt des Todes enthalten

Wird Sperma zu Hause gewonnen, ist dies im Entnahmebericht anzugeben. Der Bericht enthält in diesem Falle nur:

(1) die Identifizierung, den Namen und die Anschrift der Gewebebank, die das Sperma erhalten soll

(2) Angaben über die Spenderidentität

(3) sofern möglich, können Datum und Uhrzeit der Entnahme angegeben werden

Es ist ergänzend darauf hinzuweisen, dass Einrichtungen der medizinischen Versorgung entsprechend § 13a TPG dafür zu sorgen haben, dass für Zwecke der Rückverfolgung oder für Zwecke der Risikoerfassung nach den Vorschriften des Arzneimittelgesetzes oder anderen Rechtsvorschriften auch jedes übertragene Gewebe von dem behandelnden Arzt oder unter dessen Verantwortung dokumentiert werden muss. Eine Rechtsverordnung auf Grundlage des § 16a TPG steht hierzu noch aus. Weitere allgemeine und spezielle Anforderungen an die Dokumentation sind unter Punkt 4.1. und 4.2. des vorliegenden GFP-Leitfadens beschrieben.

12. Verpackung, Lagerung und Kennzeichnung entnommener Gewebe

Vor dem Hintergrund des Anhangs IV, Nr. 1.5. zur Richtlinie 2006/17/EG sind alle gewonnenen Gewebe nach durchgeführter Entnahme so zu lagern und zu verpacken, dass das Kontaminationsrisiko minimiert wird. Die verwendeten Behälter müssen für die Lagerung und den Transport des jeweiligen biologischen Materials geeignet sein. Sie müssen die Sicherheit und Qualität der darin enthaltenen Gewebe schützen und gewährleisten.

Gewebe sind unter Bedingungen und bei Temperaturen aufzubewahren, bei denen ihre Merkmale und biologischen Funktionen erhalten bleiben. Höchstlagerfristen (einschließlich Transportzeiten) sind in diesem Zusammenhang zu spezifizieren und festzulegen. Sie dürfen nicht zu einer Beeinträchtigung der erforderlichen Gewebeeigenschaften führen.

Die Transportverfahren müssen validiert sein. Primärbehältnisse und Materialien mit direktem Gewebekontakt müssen qualifiziert sein. Behälter und Materialien zur Primär- und Sekundärverpackung werden im Idealfall vom Hersteller bzw. dem Be- oder Verarbeiter zur Verfügung gestellt.

Die Verpackung muss außerdem die Kontaminierung der für die Verpackung und den Transport der Gewebe verantwortlichen Personen vermeiden (vgl. Anhang IV, Nr. 1.5.1. zur Richtlinie 2006/17/EG).

Jede Gewebe enthaltende Verpackung ist zum Zeitpunkt der Entnahme zu kennzeichnen. Die Verpackungs- und Kennzeichnungsvorgänge sind in entsprechenden Vorschriften, z.B. in SOPs, niederzulegen und einzuhalten.

Vor dem Hintergrund des Anhangs IV, Nr. 1.6. zur Richtlinie 2006/17/EG muss der Gewebe enthaltende Primärbehälter mindestens Angaben zur Spenderidentität und zum Spenderkode sowie zur Art des Gewebes tragen. Ist der Primärbehälter groß genug, muss er zusätzlich mit folgenden Angaben versehen werden:

(1) Art der Spende und Spenderidentität oder Spenderkode
(2) Datum und, sofern möglich, Uhrzeit der Entnahme
(3) Warnung vor einem möglichen Gefährdungspotenzial
(4) sofern vorhanden, Art der verwendeten Zusätze
(5) bei autologen Spenden der Hinweis „Nur zur autologen Verwendung“ und bei gerichteten Spenden die Angaben zum Empfänger

Sofern eine der Angaben 2 bis 5 nicht auf dem Primärbehälter angebracht werden kann, ist sie auf einem Begleitdokument auszuweisen, das dem Primärbehälter beigelegt wird. Auch zur Testung beigefügte Gewebe- oder Blutproben sind genau zu kennzeichnen, um die Zuordnung zum Spender zu ermöglichen und um Verwechslungen ausschließen zu können. Außerdem müssen auch diese Proben mit Angaben über den Ort und die Zeit der Entnahme versehen werden.

Werden die Gewebe von einem Dritten (z.B. von einem Transportunternehmen) befördert, muss entsprechend den Vorgaben des Anhangs IV, Nr. 1.7. zur Richtlinie 2006/17/EG jeder Transportbehälter mindestens folgende Angaben tragen:

(1) „Vorsicht“, „Gewebe und Zellen“
(2) Identität der Einrichtung, aus der die Packung transportiert wird (Anschrift und Telefonnummer) sowie Ansprechpartner für Problemfälle
(3) Identität der weiterverarbeitenden Stelle oder Bestimmungsgewebebank (Anschrift und Telefonnummer) und des Ansprechpartners für die Anlieferung des Behälters
(4) Datum und Uhrzeit des Transportbeginns

(5) Angaben über die Transportbedingungen, die für die Sicherheit und Qualität der Gewebe bzw. Zellen relevant sind

(6) bei allen Zellproben ist hinzuzufügen: „Nicht bestrahlen“

(7) weist der Spender bekanntermaßen ein positives Testergebnis für einen Marker einer relevanten Infektionskrankheit auf, ist hinzuzufügen: „Biologische Gefährdung“

(8) bei autologen Spendern ist hinzuzufügen: „Nur zur autologen Verwendung“

(9) Angaben über die Lagerungsbedingungen (wie z. B. „Nicht einfrieren“)

13. Transport

Der Transport von entnommenen Geweben zum Hersteller bzw. zum Be- oder Verarbeiter muss unter sicheren und kontrollierten Bedingungen stattfinden, die den Erhalt der für die spätere klinische Anwendung erforderlichen Eigenschaften der Gewebe einschließlich deren Sterilität gewährleisten. Die verwendeten Transportverfahren müssen grundsätzlich geeignet sein und sind gemäß Art. 2 Abs. 5 der Richtlinie 2006/17/EG schriftlich festzulegen. Transportanweisungen müssen die Art des Transportbehältnisses und dessen Kennzeichnung sowie die Mitgabe eventueller Proben und des Entnahmeberichts an die be- oder verarbeitende Einrichtung festlegen.

Bei der Verfahrensvalidierung zum Transport sind Anforderungen an Temperatur sowie an biologische, chemische und physikalische Parameter zu beachten. Auch jahreszeitliche Temperaturschwankungen sind ggf. zu berücksichtigen. Muss z.B. durch zusätzliche Kühlung ein bestimmter Temperaturbereich während des Transports eingehalten werden, empfiehlt sich die Anwendung eines geeigneten Thermoindikators der in der Umverpackung angebracht werden kann. Ein temperaturstabiler Versand kann dadurch überwacht und dokumentiert werden. Für den Transport sind unter den jeweils festgelegten Bedingungen Transportzeiten zu spezifizieren, die den Erhalt der erforderlichen Zell- und Gewebeeigenschaften gewährleisten.

Der Abholtermin bei der Entnahmeeinrichtung und die Übergabe beim Hersteller bzw. beim Be- oder Verarbeiter muss dokumentiert werden. Der Zugriff unberechtigter Dritter ist auch während des Transports auszuschließen. Ggf. muss ein äußerer Transportbehälter verwendet werden, der versiegelt wird. Abweichungen oder Transportzwischenfälle müssen der Entnahmeeinrichtung und dem Hersteller bzw. dem Be- oder Verarbeiter gemeldet werden.

Transportverträge müssen mit geeigneten Unternehmen abgeschlossen werden. Das Unternehmen muss gewährleisten, dass die validierten Transportbedingungen eingehalten werden können.

Entnahmeeinrichtungen können über einen Verantwortungsabgrenzungsvertrag den Hersteller bzw. den Be- oder Verarbeiter oder Dritte mit dem Transport von entnommenen Geweben oder Zellen beauftragen (siehe hierzu auch Punkt 3.3.).

14. Maßnahmen bei Auftreten oder Verdacht schwerwiegender Zwischenfälle oder schwerwiegend unerwünschter Reaktionen

Schwerwiegende Zwischenfälle sind im TPG (§ 1a Nr. 10) und im AMG (§ 63 c Abs. 6) definiert, wobei das TPG noch näher ausführt, dass auch jede fehlerhafte Identifizierung oder Verwechslung von Keimzellen oder Embryonen im Rahmen von Maßnahmen einer medizinisch unterstützen Befruchtung als schwerwiegender Zwischenfall zu verstehen ist.

Schwerwiegender Zwischenfall in Entnahmeeinrichtungen ist jedes Ereignis im Zusammenhang mit der Gewinnung, Aufbewahrung und Abgabe des Gewebes, das bestimmte unerwünschte Folgen haben kann.

Schwerwiegende unerwünschte Reaktionen sind ebenfalls im TPG (§ 1a Nr. 11) und im AMG (§ 63c Abs. 7) definiert. Dabei handelt es sich, soweit Entnahmeeinrichtungen betroffen sind, um unbeabsichtigte Reaktionen – einschließlich der Übertragung einer Krankheit auf den Spender – die im Zusammenhang mit der Gewebegewinnung auftreten und bestimmte unerwünschte Folgen haben können (schwerwiegend unerwünschte Reaktionen können auch beim Empfänger im Zusammenhang mit der Übertragung der Gewebezubereitung auftreten).

Bei Auftreten oder dem Verdacht von schwerwiegenden Zwischenfällen oder unerwünschten Reaktionen bei der Gewinnung, aber auch der Anwendung von Geweben oder deren Zubereitungen ist unverzügliches Handeln erforderlich. Hierfür zuständig ist der Arzt, der den jeweiligen Vorgang durchführt (also z.B. die Entnahme).

Er wird ggf. unverzüglich den Rat der verantwortlichen ärztlichen Person einholen, um die notwendigen Maßnahmen zur Abwendung oder Minimierung gesundheitlicher Schäden und Risiken aller potentiell hiervon betroffener Patienten und Personen zu veranlassen. Entsprechend geeignete Handlungsweisungen für Mitarbeiter sind im QS-System der Entnahmeeinrichtung aufzunehmen (siehe hierzu auch Punkt 15 des GFP-Leitfadens). Die Durchführung dieser Vorgaben ist bei Auftreten oder Verdacht von schwerwiegenden Zwischenfällen oder schwerwiegend unerwünschten Reaktionen von der verantwortlichen ärztlichen Person zu überwachen.

Verfügt eine Entnahmeeinrichtung nicht über die Möglichkeit angemessene Hilfsmaßnahmen bei Auftreten oder Verdacht unerwünschter Ereignisse einzuleiten (z.B. bei einem Entnahmezwischenfall zum Schutz des Lebens oder der Gesundheit eines Spenders), ist eine Gewebeentnahme zu unterlassen.

Dieser GFP-Leitfaden erfasst nicht die Meldung von Verdachtsfällen von Nebenwirkungen gemäß § 63b AMG bei nach dem AMG zulassungspflichtigen Gewebezubereitungen (das sind Zubereitungen, die nicht unter den § 21a AMG fallen, weil sie mit industriellen Verfahren be- oder verarbeitet werden und deren wesentliche Be- oder Verarbeitungsverfahren in der EU nicht hinreichend bekannt sind und deren Wirkungen und Nebenwirkungen nicht aus wissenschaftlichem Erkenntnismaterial ersichtlich sind).

15. Meldepflichten

Gewebeeinrichtungen und damit auch Entnahmeeinrichtungen müssen gemäß § 13c Abs. 1 TPG ein Rückverfolgungsverfahren festlegen, mit dem sie jedes Gewebe, das durch einen schwerwiegenden Zwischenfall oder durch eine schwerwiegende unerwünschte Reaktion beeinträchtigt sein könnte, unverzüglich aussondern, von der Abgabe ausschließen und die belieferten Einrichtungen der medizinischen Versorgung (§ 1a Nr. 9 TPG) unterrichten können.

Einrichtungen der medizinischen Versorgung müssen jeden schwerwiegenden Zwischenfall, der auf Tätigkeiten in der Entnahmeeinrichtung zurückgeführt werden könnte, sowie unerwünschte Reaktionen die bei oder nach der klinischen Anwendung von Geweben oder deren Zubereitungen auftreten und die in Zusammenhang mit ihrer Qualität oder Sicherheit stehen, unverzüglich nach deren Feststellung dokumentieren und dem Hersteller bzw. dem Be- oder Verarbeiter, von dem sie das Gewebe erhalten haben, unverzüglich melden (§ 13b TPG).

Der Inhaber der Genehmigung für das Inverkehrbringen nach § 21a AMG hat gemäß 63c Abs. 1 und 2 AMG ausführliche Unterlagen über jeden Verdacht eines schwerwiegenden Zwischenfalls, der sich auf die Qualität oder Sicherheit der Gewebezubereitung auswirken kann und über jeden Verdacht einer schwerwiegend unerwünschten Reaktion, die die Qualität oder Sicherheit der Gewebezubereitung beeinflussen oder auf sie zurückgeführt werden kann, zu führen und die Verdachtsfälle der Bundesoberbehörde – dem Paul-Ehrlich-Institut (PEI) – unverzüglich, spätestens aber innerhalb von 15 Tagen nach Bekanntwerden zu melden.

Bei nicht genehmigungspflichtigen Geweben oder Gewebezubereitungen hat die Gewebeeinrichtung – und damit auch die Entnahmeeinrichtung – nach § 63c Abs. 3 AMG jeden Verdacht eines schwerwiegenden Zwischenfalls, der sich auf die Qualität oder Sicherheit der Gewebe oder deren Zubereitungen auswirken kann und jeden Verdacht einer schwerwiegend unerwünschten Reaktion, die die Qualität oder Sicherheit der Gewebe bzw. Gewebezubereitung beeinflussen oder auf sie zurückgeführt werden kann, zu dokumentieren und unverzüglich nach Bekanntwerden der zuständigen Überwachungsbehörde zu melden. Die angezeigten Zwischenfälle und Reaktionen sind auf ihre Ursache und Auswirkung zu untersuchen und zu bewerten. Die Ergebnisse müssen der Überwachungsbehörde unverzüglich mitgeteilt werden, ebenso die ergriffenen Maßnahmen zur Rückverfolgung und zum Schutz von Spender und Empfänger.

Entsprechende Anweisungen und Zuständigkeiten zur Erfassung, Analyse, Bewertung, Dokumentation und Meldung von schwerwiegenden Zwischenfällen oder unerwünschten Reaktionen sind unter Berücksichtigung der jeweils gültigen gesetzlichen Bestimmungen im QS-System der Entnahmeeinrichtung festzulegen.

Für die Erfüllung der Meldepflichten bei Erkennung oder Verdacht von schwerwiegenden Zwischenfällen oder unerwünschten Reaktionen ist die verantwortliche ärztliche Person der Entnahmeeinrichtung zuständig.

Eine Entnahmeeinrichtung hat gemäß § 8d Abs. 3 TPG eine Dokumentation über ihre Tätigkeiten zu führen und diese öffentlich zugänglich zu machen sowie dem Paul-Ehrlich-Institut jährlich einen Bericht zukommen zu lassen.

16. Literatur (Auswahl) und Anmerkungen zum Text

1. Eine Entnahmeeinrichtung i. S. d. Klammerdefinition des § 20b Abs. 1 AMG ist stets auch eine Gewebeeinrichtung i. S. d. TPG (§ 1a Nr. 8 TPG). Die Definition der Entnahmeeinrichtung in § 2 Nr. 11 AMWHV hat gegenüber der Klammerdefinition in § 20b Abs. 1 AMG keinen eigenständigen Regelungsgehalt. Die in § 2 Nr. 11 AMWHV enthaltene Bezugnahme auf § 13 AMG ist infolge des Gewebegesetzes überholt und soll im Rahmen der Änderung der AMWHV durch die als Referentenentwurf vorliegende Änderungsverordnung (Stand 07.08.2007) entfallen.

2. ABl.-EG L 102, S. 48.

3. ABl.-EG L 38, S. 40.

4. Gesetz über Qualität und Sicherheit von menschlichen Geweben und Zellen (Gewebegesetz) vom 20.07.2007, BGBl 2007 Teil I, S. 1574.

5. Vgl. Bundestag Drucksache 16/5443 (elektronische Vorabfassung), zu Nr. 30a (Einfügung des § 16b TPG), S. 99.

6. Siehe EG-GMP-Leitfaden, Bundesanzeiger Nr. 210 vom 09.11.2006, S. 2523.

7. Gaissmaier C, Fritz J, Angele P, Niethard FU, Weise K, Bauer H, Pannenbecker A. Das Gewebegesetz – neue gesetzliche Bestimmungen für die Gewinnung von Geweben oder Zellen für die Herstellung eines Arzneimittels. Mitteilungen der Deutschen Gesellschaft für Chirurgie 2007; Heft 4: 369-374.

8. Verordnung über die Anwendung der Guten Klinischen Praxis bei der Durchführung von klinischen Prüfungen mit Arzneimitteln zur Anwendung am Menschen, Bundesgesetzblatt 2004, Teil I S. 2081, zuletzt geändert durch Art. 4 der VO zur Ablösung der PharmBetrV (Bundesgesetzblatt 2006, Teil I S. 2542).

9. Centers for Disease Control and Prevention (CDC). Guideline for prevention of surgical site infection. ICHE 1999; 20: 247-280.

10. Hansis M, Arens S. Pathophysiologie der postoperativen Infektentstehung an Knochen und Weichteilen. Akt Traumatol 1996; 26: 183-191.

11. Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen. Mitteilungen der Kommission für Krankenhaushygiene und Infektionsprävention am Robert-Koch-Insitut. Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2000; 43: 644-648.

12. Task Force vCJK am Robert-Koch-Institut (RKI): Die Variante der Creutzfeldt-Jakob-Krankheit (vCJK). Epidemiologie, Erkennung, Diagnostik und Prävention unter besonderer Berücksichtigung einer iatrogenen Übertragung durch Medizinprodukte, insbesondere chirurgische Instrumente. Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2002; 45: 376-394.

13. Veen MR, Bloem RM, Petit PL. Sensitivity and negative predictive value of swab cultures in musculoskeletal allograft procurement. Clin Orthop Rel Res 1994; 300: 259-263.

14. Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz – IfSG). BGBl 2000 Teil I, S. 1045, zuletzt geändert durch Art. 6 des Gewebegesetzes, BGBl 2007 Teil I, S. 1574.

17. Abkürzungsverzeichnis

AMG	Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz)
AMWHV	Arzneimittel- und Wirkstoffherstellungsverordnung
BÄK	Bundesärztekammer
BDSG	Bundesdatenschutzgesetz
BGBl	Bundesgesetzblatt
BMG	Bundesministerium für Gesundheit
CMV	Cytomegalievirus
DGCH	Deutsche Gesellschaft für Chirurgie
EBV	Epstein-Barr-Virus
EG	Europäische Gemeinschaft
EU	Europäische Union

GCP	Gute klinische Praxis (Good Clinical Practice)
GFP	Gute Fachliche Praxis
GMP	Gute Herstellungspraxis (Good Manufacturing Practice)
HBV	Hepatitis-B-Virus
HCV	Hepatitis-C-Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
IfSG	Infektionsschutzgesetz
PEI	Paul-Ehrlich-Institut
QM	Qualitätsmanagement
QS	Qualitätssicherung
RhD	Rhesusfaktor D
RKI	Robert-Koch-Institut
SGB	Sozialgesetzbuch
SOP	Standardarbeitsanweisung (Standard Operation Procedure)
TFG	Gesetz zur Regelung des Transfusionswesens (Transfusionsgesetz)
TPG	Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben (Transplantationsgesetz)
TSE	Übertragbare spongiforme Enzephalopathie (Transmissible Spongiform Encephalopathy)
VAV	Verantwortungsabgrenzungsvertrag

18. Glossar

(nach den Begriffsdefinitionen des TPG (mit Stern (*) gekennzeichnet) und der Richtlinien 2004/83/EG, 2006/17/EG und 2006/86/EG)

allogene Verwendung: die Entnahme von Zellen oder Geweben von einer Person und ihre Übertragung auf eine andere Person

autologe Verwendung: die Entnahme von Zellen oder Geweben und ihre Rückübertragung auf ein und dieselbe Person

Beschaffung: ein Prozess, durch den Gewebe oder Zellen verfügbar gemacht werden

Direktverwendung: jegliches Verfahren, bei dem Zellen gespendet und verwendet werden, ohne in eine Gewebebank aufgenommen zu werden

*Einrichtung der medizinischen Versorgung: ein Krankenhaus oder eine andere Einrichtung mit unmittelbarer Patientenbetreuung, die fachlich-medizinisch unter ständiger ärztlicher Leitung steht und in der ärztliche medizinische Leistungen erbracht werden

*Entnahme: die Gewinnung von Organen oder Geweben

Entnahmeeinrichtung: eine Einrichtung des Gesundheitswesens oder eine Krankenhausabteilung oder eine andere Stelle, die zur Entnahme menschlicher Gewebe und Zellen tätig wird und möglicherweise nicht als Gewebebank akkreditiert, benannt, zugelassen oder lizenziert ist

gerichtete Spende: Spende, deren Zuordnung zum Empfänger bereits zum Zeitpunkt der Entnahme vom Spender bekannt ist

*Gewebe: alle aus Zellen bestehenden Bestandteile des menschlichen Körpers, die keine Organe im Sinne der Organdefinition sind, einschließlich einzelner menschlicher Zellen

*Gewebeeinrichtung: eine Einrichtung, die Gewebe zum Zwecke der Übertragung entnimmt, untersucht, aufbereitet, be- oder verarbeitet, konserviert, kennzeichnet, verpackt, aufbewahrt oder an andere abgibt

Keimzellen: alle Gewebe und Zellen, die für die Verwendung zur assistierten Reproduktion bestimmt sind

Konservierung: der Einsatz chemischer Stoffe, veränderter Umgebungsbedingungen oder sonstiger Mittel während der Verarbeitung mit dem Ziel, eine biologische oder physikalische Beeinträchtigung von Zellen oder Geweben zu verhüten oder zu verzögern

kritisch: mit möglichem Einfluss auf Qualität und/oder Sicherheit oder mit den Zellen und Geweben in Berührung kommend

Lagerung: die Aufbewahrung des Produkts unter angemessenen kontrollierten Bedingungen bis zur Verteilung

*nächste Angehörige: in der Rangfolge ihrer Aufzählung a) der Ehegatte oder der eingetragene Lebenspartner, b) die volljährigen Kinder, c) die Eltern oder, sofern der mögliche Organ- oder Gewebespender zur Todeszeit minderjährig war und die Sorge für seine Person zu dieser Zeit nur einem Elternteil, einem Vormund oder einem Pfleger zustand, dieser Sorgeinhaber, d) die volljährigen Geschwister, e) die Großeltern

*nicht regenerierungsfähige Organe: alle Organe, die sich beim Spender nach der Entnahme nicht wieder bilden können

*Organe: mit Ausnahme der Haut, alle aus verschiedenen Geweben bestehenden Teile des menschlichen Körpers, die in Bezug auf Struktur, Blutgefäßversorgung und Fähigkeit zum Vollzug physiologischer Funktionen eine funktionale Einheit bilden, einschließlich der Organteile und einzelnen Gewebe oder Zellen eines Organs, die zum gleichen Zweck wie das ganze Organ im menschlichen Körper verwendet werden können

Partnerspende: die Spende von Keimzellen zwischen einem Mann und einer Frau, die angeben, eine Intimbeziehung zu führen

Qualitätsmanagement: die koordinierten Tätigkeiten zur Leitung und Kontrolle einer Einrichtung in Bezug auf Qualität

Qualitätssystem: die Organisationsstruktur, festgelegte Zuständigkeiten, Verfahren, Prozesse und Ressourcen für die Durchführung des Qualitätsmanagements, einschließlich aller Tätigkeiten, die direkt oder indirekt zur Qualität beitragen

Rückverfolgbarkeit: die Möglichkeit, das Gewebe bzw. die Zelle auf jeder Stufe von der Entnahme über die Verarbeitung, Testung und Lagerung bis zur Weitergabe an den Empfänger oder zur Entsorgung zu lokalisieren und zu identifizieren, einschließlich der Möglichkeit, den Spender und die Gewebebank oder die Produktionseinrichtung, welche die Gewebe bzw. Zellen erhält, verarbeitet oder lagert, zu ermitteln, sowie der Möglichkeit, in der/den die Gewebe bzw. Zellen transplantierenden medizinischen Einrichtung(en) den/die jeweiligen Empfänger zu ermitteln; Rückverfolgbarkeit bedeutet auch die Möglichkeit, alle zweckdienlichen Daten im Zusammenhang mit den Produkten und Materialien zu lokalisieren und zu ermitteln, die mit diesen Geweben bzw. Zellen in Berührung kommen

*schwerwiegende unerwünschte Reaktion: eine unbeabsichtigte Reaktion, einschließlich einer übertragbaren Krankheit, beim Spender oder Empfänger im Zusammenhang mit der Entnahme oder der Übertragung von Geweben, die tödlich oder lebensbedrohend verläuft, eine Behinderung oder einen Fähigkeitsverlust zur Folge hat oder einen Krankenhausaufenthalt erforderlich macht oder verlängert oder zu einer Erkrankung führt oder diese verlängert

*schwerwiegender Zwischenfall: jedes unerwünschte Ereignis im Zusammenhang mit der Entnahme, Untersuchung, Aufbereitung, Be- oder Verarbeitung, Konservierung, Aufbewahrung oder Abgabe von Geweben, das die Übertragung einer ansteckenden Krankheit, den Tod oder einen lebensbedrohenden Zustand, eine Behinderung oder einen Fähigkeitsverlust von Patienten zur Folge haben könnte oder einen Krankenhausaufenthalt erforderlich machen oder verlängern könnte oder zu einer Erkrankung führen oder diese verlängern könnte; als schwerwiegender Zwischenfall gilt auch jede fehlerhafte Identifizierung oder Verwechslung von Keimzellen oder Embryonen im Rahmen von Maßnahmen einer medizinisch unterstützten Befruchtung

Spende: die Abgabe von zur Verwendung beim Menschen bestimmten menschlichen Geweben oder Zellen

Spender: jeder lebende oder verstorbene Mensch, der als Quelle von menschlichen Zellen oder Geweben fungiert

Standardarbeitsanweisungen (SOP): schriftliche Anweisungen zur Beschreibung der einzelnen Schritte eines spezifischen Verfahrens, einschließlich der zu verwendenden Materialien und Methoden sowie des erwarteten Endprodukts

*Übertragung: die Verwendung von Organen oder Geweben in oder an einem menschlichen Empfänger sowie die Anwendung beim Menschen außerhalb des Körpers

Validierung (oder „Qualifizierung“ in Bezug auf Anlagen oder Umgebungen): Erbringung eines dokumentierten Nachweises, der mit hoher Sicherheit belegt, dass ein spezifischer Prozess, Standardverfahren, Ausrüstungsgegenstand oder eine Umgebung ausnahmslos ein Produkt herstellt, das den vorher festgelegten Spezifikationen und Qualitätsmerkmalen entspricht; ein Prozess wird validiert, um zu bewerten, wie effektiv die Leistung eines Systems für den Verwendungszweck ist

Verarbeitung: sämtliche Tätigkeiten im Zusammenhang mit der Aufbereitung, Handhabung, Konservierung und Verpackung von zur Verwendung beim Menschen bestimmten Geweben oder Zellen

*vermittlungspflichtige Organe: Herz, Lunge, Leber, Niere, Bauchspeicheldrüse und Darm im Sinne der Organdefinition, die nach § 3 oder § 4 TPG entnommen worden sind

Verteilung: die Beförderung und Abgabe von zur Verwendung beim Menschen bestimmter Geweben oder Zellen

Verwendung beim Menschen: den Einsatz von Geweben oder Zellen in oder an einem menschlichen Empfänger sowie extrakorporale Anwendungen (siehe auch Übertragung)

19. Gesetze, Verordnungen, Richtlinien, Leitlinien und Empfehlungen die bei der Umsetzung des GFP-Leitfadens besonders zu beachten sind

19.1. Gesetze und Verordnungen

(es ist ggf. die jeweils gültige Fassung zu beachten)

Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz – AMG)

Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben (Transplantationsgesetz – TPG)

Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV)

Gesetz zur Regelung des Transfusionswesens (Transfusionsgesetz – TFG)

Verordnung über das Meldewesen nach §§ 21 und 22 des Transfusionsgesetzes (Transfusionsgesetz-Meldeverordnung – TFGMV)

Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz – IfSG)

Bundesdatenschutzgesetz (BDSG)

Gesetz über Medizinprodukte (Medizinproduktegesetz – MPG)

Medizinproduktebetreiberverordnung (MPBetreibV)

Gesetz über die Haftung für fehlerhafte Produkte (Produkthaftungsgesetz – ProdHaftG)

Verordnung über den Schutz vor Schäden durch ionisierende Strahlen (Strahlenschutzverordnung – StrlSchV)

Richtlinie 2004/23/EG des Europäischen Parlaments und des Rates vom 31. März 2004 zur Festlegung von Qualitäts- und Sicherheitsstandards für die Spende, Beschaffung, Testung, Verarbeitung, Konservierung, Lagerung und Verteilung von menschlichen Geweben und Zellen

Richtlinie 2006/17/EG der Kommission vom 8.2.2006 zur Durchführung der Richtlinie 2004/23/EG des Europäischen Parlaments und des Rates hinsichtlich technischer Vorschriften für die Spende, Beschaffung und Testung von menschlichen Geweben und Zellen

19.2. Richtlinien, Leitlinien und Empfehlungen der Bundesärztekammer

(es ist ggf. die jeweils gültige Fassung zu beachten, siehe hierzu auch: www.bundesärztekammer.de, unter: Richtlinien, Leitlinien und Empfehlungen)

Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie)

Richtlinien für die allogene Knochenmarktransplantation mit nichtverwandten Spendern

Richtlinien der Bundesärztekammer zur Transplantation peripherer Blutstammzellen

Richtlinien der Bundesärztekammer zur Transplantation von Stammzellen aus Nabelschnurblut (CB = Cord Blood)

Richtlinien zum Führen einer Hornhautbank

Richtlinien zum Führen einer Knochenbank

Richtlinien zur Verwendung fetaler Zellen und fetaler Gewebe

Richtlinien zur Organtransplantation

Richtlinie zur Qualitätssicherung in der Transplantationsmedizin

Richtlinien zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen

Richtlinien zur Qualitätssicherung in der Immunhämatologie

Empfehlungen zur ärztlichen Fortbildung

(Muster-)Berufsordnung für die deutschen Ärztinnen und Ärzte

20. Beteiligte Fachgesellschaften, Autoren und Danksagung

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МИНИСТЕРСТВО ЗА ЗДРАВСТВО

Врз основа на член 64 од Законот за лековите и медицинските помагала („Службен весник на Република Македонија" бр. 106/07), министерот за здравство донесе

ПРАВИЛНИК ЗА НАЧИНОТ И ПОСТАПКАТА ЗА КЛИНИЧКИТЕ ИСПИТУВАЊА НА ЛЕКОВИТЕ И СОДРЖИНАТА НА ДОКУМЕНТАЦИЈАТА

I. ОПШТИ ОДРЕДБИ

Член 1

Со овој правилник се пропишува начинот и постапката за клиничките испитувања на лековите и содржината на документацијата.

Член 2

Оделни изрази употребени во овој правилник го имаат следното значење:

1. Постмаркетиншко интервенциско клиничко испитување на лек е испитување во кое лекот се применува во согласност со условите наведени во одобрението за ставање на лекот во промет и во кое се применуваат дополнителни дијагностички процедури, како и процедури за следење кои се дефинирани со протоколот за клиникото испитување на лекот.

2. Постмаркетиншко неинтервенциско клиничко испитување на лек (фармако-епидемиолошко испитување) е испитување во кое лекот се применува во согласност со условите наведени во одобрението за ставање на лекот во промет и во кое изборот на доброволците и/или пациентите не е однапред одреден со протоколот на клиничкото испитување на лекот туку спаѓа во востановената секојдневна пракса на лекување, со тоа што препишувањето на лекот е јасно одвоено од одлуката доброволецот и/или пациентот да се вклучи во испитување. Не се применуваат дополнителни дијагностички процедури или процедури на следење, а добиените резултати се анализираат со епидемиолошки методи.

3. Лек кој клинички се испитува е фамацевтска дозирана форма на активната супстанција која се испитува или плацебо со кое испитуваната супстанција се споредува, како и лек кој има одобрение за ставање во промет кога е изменета формата или пакувањето, односно кога се користи поинаков начин на употреба од дефинираниот во одобрението за промет, кога лекот се испитува во нова индикација или кога лекот се користи за добивање на нови информации за одобрената употреба на лекот.

4. Испитаник е лице кое учествува во клиничкото испитување на лекот, било да го прима испитуваниот лек, или е вклучен во контролната група.

5. Информирана согласност на испитаникот е писмена изјава на испитаникот, датирана и потпишана, за учествување во одредено клиничко испитување на лек, дадена од лице кое е способно да даде согласност или ако лицето не е способно да даде согласност, дадена од неговиот старател во согласност со закон, а која е дадена доброволно после целосно информирање за природата, значењето, последиците и ризикот по здравјето.

6. Безбедност на испитаникот е физичкиот и менталниот интегритет, односно безбедноста на испитаникот кој учествува во клиничко испитување на лекот.

7. Идентификациона шифра на испитаникот е единствена ознака која испитувачот ја доделува на секој испитаник наместо име, поради заштита на идентитетот на испитаникот

при пријавување на несакани реакции од лекот, односно на други податоци од клиничкото испитување на лекот.

8. Испитувач во клиничкото испитување на лекот е доктор на медицина или доктор на стоматологија кој е непосредно вклучен и одговорен за лекување и нега на пациентите или учесниците во испитувањето и е одговорен за спроведување на клиничкото испитување. Ако клиничкото испитување на лекот го спроведува истражувачки тим од повеќе испитувачи, испитувачот кој е одговорен за спроведувањето на клиникото испитување на лекот е главен испитувач.

9. Брошура на испитувачот е документ кој содржи аналитички, фармаколошко-токсиколошки и клинички податоци за лекот кој се испитува, а кои се важни за испитување на влијанието на лекот на луѓе.

10. Документација на клиничкото испитување на лекот е комплетна евиденција во било која форма (вклучувајќи пишани, електронски, магнетни и оптички записи, како и снимки, рентгенски снимки, електрокардиограм и друго) со која се опишуваат или бележат методите, спроведувањето и резултатите на испитувањето, сите превземени активности, како и факторите кои влијаат на клиничкото испитување на лекот.

11. Мислење на Етичката комисија е мислење кое го дава Етичката комисија за тоа дали клиничкото испитување на лекот може да се изведе на предложеното место на испитувањето, во рамките на ограничувањата кои ги дефинирала Етичката комисија и начелата на Добра клиничка пракса во клинички испитувања, во согласност со Законот за лекови и медицински помагала и овој правилник.

12. Протокол на клиничкото испитување на лекот (во натамошниот текст: протокол) е документ кој ги содржи целите, планот, методологијата на испитувањето, начинот на обработка на податоците и организација на клиничкото испитување на лекот во согласност со начелата на Добра клиничка пракса во клиничките испитувања.

13. Спонзор на клиничкото испитување на лекот е физичко лице или правно лице кое го обезбедува започнувањето, спроведувањето, односно финансирањето на клиничкото испитување на лекот.

14. Извештај од клиничкото испитување на лекот е документ за комплетното испитување на тераписката, профилактичката или дијагностичката ефикасност или безбедноста на лекот кој се испитува, во кој се наведени сите клинички и статистички значајни податоци, наоди и анализа на добиените резултати во испитувањето (извештај за текот, резултатите и заклучоците во испитувањето во согласност со начелата на Добра клиничка пракса во клиничките испитувања).

15. Извештај за текот на клиничкото испитување на лекот е извештај за резултатите од клиничкото испитување на лекот кој содржи процена заснована на спроведени анализи за одреден временски интервал во тек на клиничкото испитување.

16. Изворна документација се оригинали на документи, податоци и досијеа (на пример: историја на болест, клинички и административни документи, лабораториски наоди, меморандуми, дневници на испитаниците, тест листи на испитаниците, евиденција за издадени лекови, автоматски записи, копии или преписи заверени после проверка на веродостојноста, негативи на фотографии, микрофилмови или магнетни записи, рентгенски снимки, евиденција која се чува во аптека, лабораторија или медицинско-технички служби вклучени во клиничкото испитување на лекот).

17. Изворни податоци се сите оригинални податоци од изворната документација.

18. Компаративен лек е референтен, маркетиран лек кој претставува активна контрола, или плацебо со кој се споредува лекот кој клинички се испитува.

19. Контрола на квалитетот означува оперативни техники и активности кои се превземаат за обезбедување на проверка на квалитетот на работа при спроведување на клиникото испитување.

20. Место на клиничкото испитување на лекот е здравствена установа или повеќе здравствени установи во кои се лекува испитаникот, а во кои се спроведува клиничкото испитување.

21. Набљубувач е посебно оспособено лице кое за потребите на спонзорот го следи спроведувањето на клиничкото испитување на лекот и гарантира дека текот, документацијата и извештаите од клиничкото испитување на лекот се во согласност со протоколот, стандардните оперативни процедури (SOP), начелата на Добра клиничка пракса и важечките прописи.

22. Стандардни оперативни процедури (SOP) се детални писмени упатства за постигнување униформност на сите постапки при изведување на клиничкото испитување на лекот.

23. Извештај на набљудувачот е писмен извештај кој набљудувачот го доставува на подносителот на барањето за клиничкото испитување на лекот после секоја посета на местото на испитувањето, како и извештај за сите други податоци во врска со клиничкото испитување на лекот, во согласност со стандардните оперативни постапки (SOP) на подносителот на барањето на клиничкото испитување на лекот.

24. Одитор е посебно оспособено лице кое во име на подносителот на барањето независно ја оценува усогласеноста на сите активности кои се поврзани со клиничкото испитување на лекот, со протоколот, стандардните оперативни процедури (SOP), начелата на Добра клиничка пракса во клиничкото испитување, законот и овој правилник.

25. Извештај на одиторот е писмен извештај на одиторот за резултатите на спроведениот одит.

26. Основна документација се документи кои поединечно и збирно овозможуваат процена на спроведувањето на клиничкото испитување на лекот и на квалитетот на добиените податоци.

27. Претклиничко испитување на лекот е испитување кое не се спроведува на луѓе.

28. Тест листа е печатен, оптички или електронски документ за секој испитаник кој е наменет за бележење на сите податоци кои се бараат во протоколот.

29. Несакана реакција на лек е секој несакан и штетен одговор на лекот што се јавува при употреба на лекот според пропишаниот начин на употреба или при примена на било која доза на лекот во текот на клиничко испитување.

30. Сериозна несакана реакција е секоја несакана реакција што предизвикува смрт, закана по животот, задржување на пациентот во болница или продолжување на престојот во болница, траен или значителен хендикеп/неспособност или конгенитална аномалија/ вроден дефект.

31. Неочекувана несакана реакција е секоја неочекувана и несакана реакција чија природа, тежина и исход не е во согласност со збирниот извештај на особините на лекот или не се опишани во брошурата на испитувачот.

32. Несакан настан е несакана појава која се случила за време на примената на лекот и за која причинско-последичната врска со примената на лекот ,може и да не биде докажана.

33. Сериозен несакан настан е секој неочекуван настан кој има за последица смрт, закана по животот, задржување на пациентот во болница или продолжување на престојот во болница, траен или значителен хендикеп/неспособност или конгенитална аномалија/ вроден дефект.

34. Мултицентрично клиничко испитување е клиничко испитување кое се изведува според единствен протокол на повеќе места на испитување и го спроведуваат поголем број на испитувачи, без оглед на тоа дали местата на испитување се во иста држава или во различни држави.

35. Слепо клиничко испитување на лекот е метод со кој се обезбедува една или повеќе страни во испитувањето да немаат увид во која тераписка група припаѓаат испитаниците.

Едноструко-слеп пристап значи испитаникот да нема увид во која тераписка група припаѓа.

Двоструко-слеп пристап значи дека испитаникот, испитувачот, набљудувачот, во одредени случаи, како и аналитичарот на податоците, немаат увид во која тераписка група припаѓаат испитаниците.

II. КЛИНИЧКО ИСПИТУВАЊЕ НА ЛЕК

1. Заеднички одредби

Член 3

При спроведување на клиничко испитување на лек, правата, безбедноста и интересот на испитаниците се приоритетни во однос на правата, безбедноста и интересот на науката и општеството во целина.

Клиничкото испитување на лекот треба да биде испланирано и спроведено на начин што овозможува на најмала можна мерка да се намалат болката, нелагодноста, стравот и било кој друг предвидлив ризик по здравјето на испитаниците (прагот на ризик и степенот на болка треба да се дефинираат и да се под постојан надзор).

Член 4

Документацијата што се доставува кон барањето за клиничкото испитување на лекот се архивира во Агенцијата и се смета и се постапува како за класифицирана информација согласно прописите за класифицирани информации и заштита на личните податоци.

Член 5

Одредбите на овој правилник не се однесуваат на неинтервенциски клинички испитувања, освен ако со овој правилник тоа поинаку не е утврдено.

2. Заштита на испитаниците во клиничкото испитување на лекот

Член 6

При изборот на целна група треба да се земе во предвид степенот на ризик за поединечни групи на испитаници.

Во клиничко испитување не се вклучуваат лица кои не се способни сами да одлучуваат за учествување во клиничкото испитување на лекот ако истото испитување може да се спроведе на лица кои можат сами да одлучуваат за учествување во клиничкото испитување.

Одредени старосни групи (деца, стари луѓе и други) се вклучуваат само во посебни клинички испитувања на лек во согласност со овој правилник.

Член 7

Главниот испитувач и секој член на истражувачкиот тим треба да го обезбеди правото на испитаникот на физичкиот и менталниот интегритет на испитаникот, како и приватност и заштита на податоците кои се достапни само на овластени лица.

Во тек на клиничкото испитување на лекот, главниот испитувач или член на истражувачкиот тим треба да го извести испитаникот за секоја важна информација која се однесува на планирање и спроведување на клиничкото испитување на лекот.

Член 8

Ако во текот на клиничкото испитување на лекот дошло до појава на несакани реакции, односно до сериозни несакани реакции, испитаникот треба да ја добие потребната здравствена заштита во време и после завршување на клиничкото испитување на лекот.

2.1.Заштита на малолетни испитаници во клиничкото испитување на лекот

Член 9

Ако е тоа неопходно, со превземање на посебни мерки на претпазливост, клиничко испитување може да се врши и кај лица на возраст до 18 години кои се болни од болест или ја имаат состојбата за која е наменет лекот кој клинички се испитува.

Покрај случаите од став 1 на овој член, клиничко испитување на лек кај малолетни испитаници може да се спроведува и во следните случаи:

1) ако родителот, односно старателот дал писмена согласност (писмената согласност мора да ја претставува претпоставената желба на малолетникот и може да биде повлечена во било кој момент, без штета по малолетникот);

2) малолетникот ја примил информацијата во согласност со своите можности да ја разбере и тоа од страна на лице кое има искуство во работата со малолетници, а истата се однесува на текот на клиничкото испитување, ризикот и користа по здравјето на испитаникот;

3) ако писмената согласност е дадена без поттикнување на учествување во клиничкото испитување, со нудење или давање на било каква материјална или друга корист;

4) ако Етичката комисија проценила дека со клиничкото испитување на лекот кај малолетни испитаници се остварува директна корист за одредена група на пациенти, како и дека таквото истражување е битно за процена на податоците кои се добиени со клиничко испитување извршено на лица кои се спосопобни самостојно да дадат согласност; и

5) ако позитивната одлука за спроведување на клиничкото испитување на лекот во здравствена установа ја донела Етичката комисија врз основа на мислење на доктор-специјалист од областа на педијатрија, со посебен осврт на клиничките, етичките и психо-социјалните проблеми во спроведување на клиничкото испитување на лекот.

Член 10

Во тек на спроведување на клиничкото испитување на лекот, малолетник кој е способен да формира мислење и ги процени информациите кои ги добил за учество во клиничкото испитување, може да донесе одлука во било кој момент да го прекине своето учество во клиничкото испитување на лекот за што го известува главниот испитувач или испитувач кој е член на истражувачкиот тим.

2.2.Заштита на полнолетни лица кои не се во состојба да дадат писмена согласност во тек на клиничкото испитување на лек

Член 11

Клиничко испитување на лек кај полнолетен испитаник кој не е во состојба да даде писмена согласност (несвесна состојба, ограничена физичка или психичка способност и друго), односно кај полнолетен испитаник кој не ја одбил согласноста да учествува во клиничко испитување на лек пред почеток на својата неспособност, се спроведува ако:

1) писмена согласност за учество во клиничкото испитување на лекот дал старател на полнолетниот испитаник кој не е во состојба да даде писмена согласност (писмената согласност треба да ја претпоставува писмената желба на испитаникот и може да биде повлечена во било кој момент, без штета по него);

2) полнолетниот испитаник кој не е во состојба да даде писмена согласност ја примил информацијата во согласност со своите можности да ја разбере и тоа од страна на лице кое има искуство во работата со такви лица, а истата се однесува на текот на клиничкото испитување, ризикот и користа по здравјето на испитаникот;

3) ако писмената согласност е дадена без поттикнување на учествување во клиничкото испитување на лекот со нудење или давање на било каква материјална или друга корист;

4) ако се процени дека со клиничкото испитување на лекот на тоа лице се добива директна корист за групата пациенти чија болест, односно состојба одговара на болеста, односно состојбата на испитаникот; и

5) ако позитивно мислење за спроведување на клиничкото испитување на лекот во здравствена установа донела Етичката комисија врз основа на мислење на доктор-специјалист за одредена болест или состојби на испитаниците, односно за популација на пациенти на која клиничкото испитување на лекот се однесува, со посебен осврт на клиничките, етичките и психо-социјалните проблеми во спроведување на клиничкото испитување на лекот.

3. Поднесување на барање за клиничко испитување на лек

Член 12

Подносителот на барањето за клиничкото испитување на лекот ги врши следните работи:

1) ја подготвува целосната документација која е потребна за добивање на одобрение за клиничкото испитување на лекот, како и документацијата потребна за измена и дополнение на протоколот, односно одобрението за клиничкото испитување на лекот;

2) го определува главниот испитувач кој потпишува изјава дека се согласува со предложениот протокол и со извршување на работите во врска со клиничкото испитување на лекот, во согласност со овој правилник;

3) го определува местото на клиничкото испитување на лекот (една или повеќе здравствени установи) во кое ќе се спроведува клиничкото испитување на лекот, како и главното место на клиничкото испитување на лекот врз основа на договор со здравствената установа за употреба на простор, опрема и кадар на здравствената установа за изведување на клиничкото испитување на лекот;

4) обезбедува доволно претклинички и клинички податоци за лекот кој се испитува и ги става на располагање на главниот испитувач;

5) го известува главниот испитувач, Агенцијата за лекови (во натамошниот текст: Агенцијата) и Етичката комисија за сите нови релевантни податоци кои се однесуваат на лекот кој се испитува;

6) обезбедува податоци за квалитетот на лекот кој клинички се испитува, како и податоци за претходно спроведени претклинички и клинички испитувања на тој лек;

7) му обезбедува на испитаникот целосна здравствена заштита за лекување на болести или состојби кои се последица на клиничкото испитување на лекот; и

8) обезбедува набљудувач во клиничкото испитување на лекот.

9) благовремено ја известува агенцијата и главниот испитувач за измените и дополненијата на протоколот во согласност со Законот за лековите и медицинските помагала и овој правилник.

Член 13

Подносителот на барањето на клиничкото испитување на лекот е должен да обезбеди доволна количина на лекот кој клинички се испитува.

Лекот од став 1 на овој член треба да биде обележан и на надворешното пакување мора да ги има најмалку следните податоци:

1) име на лекот, заштитено име, INN или генеричко име или друга ознака за идентификација;

2) име на производителот;

3) рок на употреба;

4) број на серија и

5) други потребни ознаки во однос на видот на клиничко испитување на лекот.

Надворешното пакување на лекот од став 1 на овој член мора да има натпис: "за клиничко испитување".

Ако клиничкото испитување на лекот од став 1 на овој член се врши со слепа метода, лекот треба да биде обележан и со посебна шифра.

4. Главен испитувач и истражувачки тим во клиничко испитување на лек

Член 14

Главниот испитувач во клиничкото испитување на лекот е лице со завршен медицински или стоматолошки факултет кое има специјализација во областа во која примарно се применува лекот кој клинички се испитува и кој е вработен во здравствената установа во која се одвива клиничкото испитување на лекот и кој е непосредно одговорен за лекување на пациентот.

Главниот испитувач во клиничко испитување на лек мора да има и дополнително знаење од областа на Добра клиничка пракса во клиничко испитување.

Главниот испитувач истовремено може да води најмногу три клинички испитувања кои се во фаза на активно вклучување на испитаници или активно спроведување на клиничкото испитување.

Член 15

Пред почеток на клиничкото испитување главниот испитувач ги врши следните работи:

1) му ја доставува на подносителот на барањето за клиничкото испитување на лекот својата биографија и документацијата која ја докажува неговата стручност и оспособеност за главен испитувач;

2) потпишува изјава дека е запознат со особините на лекот кој клинички се испитува, со целта на клиничкото испитување на лекот, дека ќе ги извршува работите во врска со клиничкото испитување на лекот во согласност со приложениот протокол и во согласност со важечките прописи; и

3) му го доставува на подносителот на барањето списокот на членови на истражувачкиот тим.

Член 16

Во постапката на предлагање на истражувачки тим од член 15 точка 3) на овој правилник главниот истражувач ги запознава членовите на истражувачкиот тим со протоколот, претклиничките и клиничките податоци за лекот, тест листите и редовно ги известува за важните измени и дополнувања на протоколот и проблемите при изведување на клиничкото испитување на лекот.

Членовите на истражувачкиот тим треба да го известат главниот испитувач за несаканите реакции и/или настани на лекот кој клинички се испитува и мерките кои е неопходно да се превземат за заштита на здравјето на испитаниците.

Член 17

Главниот испитувач и истражувачкиот тим ги изведуваат и следниве работи во текот на клиничкото испитување на лекот:

1) одредуваат доволен број на испитаници во согласност со критериумите на протоколот за вклучување и исклучување на испитаници;

2) усмено и писмено даваат објаснување на испитаниците на начин кој е разбирлив за нив, а се однесува на податоци за лекот кој клинички се испитува, целта и планот за изведување на клиничкото испитување, ризикот и користа за испитаниците, начинот за избор на испитаници, приближен број на испитаници и другите можни начини на лекување, како и за нивните предности и негативни страни;

3) обезбедуваат доброволна писмена согласност за испитаниците за учество во клиничкото испитување на лекот;

4) му обезбедуваат на испитаникот соодветна здравствена заштита за време на траењето на клиничкото испитување на лекот и после завршувањето на клиничкото испитување на лекот ако продолжува лекувањето или ако болеста или состојбата се последица на клиничкото испитување на лекот;

5) обезбедуваат точност, потполност, читливост и ажурираност на податоците во врска со клиничкото испитување на лекот, како и тајност на податоците кои се достапни на надзорот, подносителот на барањето и Агенцијата; и

6) ги чуваат во тајност шифрите на испитаникот и лекот кој се испитува, а кои можат да станат достапни само во итни случаи, кои се поврзани со заштита на здравјето на испитаникот.

Член 18

Главниот испитувач во текот на клиничкото испитување на лекот е должен:

1) го определува датумот на почетокот и завршување на клиничкото испитување на лекот во договор со подносителот на барањето на клиничкото испитување, како и да го извести подносителот на барањето на клиничкото испитување за прекинување на клиничкото испитување на лекот;

2) на соодветен начин да го чува лекот кој клинички се испитува, да го евидентира издавањето и потрошувачката на примероците од лекот кој клинички се испитува, како и на прописен начин да ги чува неупотребените примероци од лекот и во договор со подносителот на барањето на клиничкото испитување на лекот да изврши нивно уништување;

3) во случај на непосредна опасност за испитаникот да го извести подносителот на барањето на клиничкото испитување на лекот за прекин на клиничкото испитување на лекот; и

4) подготвува извештај за завршеното клиничко испитување, а по потреба и на барање на Агенцијата, доставува извештај за текот на клиничкото испитување на лекот.

Ако е тоа потребно, главниот испитувач треба да предложи измени и дополнување на протоколот за испитување, а во случај предложената промена да се одобри треба да обезбеди сите испитаници да се запознаат со одобрената промена и дополнување на протоколот и да се продолжи лекувањето во согласност со промената и дополнувањето на протоколот.

Член 19

Во состав на истражувачкиот тим во клиничкото испитување на лекот кое се врши во здравствена установа која дава секундарна односно терциерна здравствена заштита мора да биде вклучен и доктор на медицина, специјалист по клиничка фармакологија во случај кога се спроведува прва фаза на клиничкото испитување.

Во поедини делови на клиничкото испитување на лекот покрај доктор на медицина и доктор на стоматологија, во истражувачкиот тим се вклучуваат и стручњаци со други соодветни наобразби: дипл.фармацевт, односно специјалист по медицинска биохемија или специјалист по клиничка биохемија, статистичари, медицински сестри, здравствени техничари и др.

5. Место на клиничкото испитување на лекот

Член 20

Клиничкото испитување на лекот може да се спроведе во една или повеќе здравствени установи кои ги предлага подносителот на барањето на клиничкото испитување на лекот.

Ако клиничкото испитување на лекот се спроведува во повеќе здравствени установи на територијата на Република Македонија, подносителот на барањето на клиничкото испитување на лекот го одредува главното место на клиничкото испитување на лекот.

Член 21

Подносителот на барањето за клиничкото испитување на лекот потпишува договор со здравствената установа за спроведување на клиничкото испитување на лекот.

Договорот од став 1 на овој член содржи: услови и начин на спроведување на одреденото клиничкото испитување на лекот во здравствената установа, висината и начинот на плаќање на надоместокот која подносителот на барањето за клиничкото испитување на лекот ја исплатува на здравствената установа за користење на капацитетите на здравствената установа за спроведување на клиничкото испитување на лекот, број на здравствени работници и други лица кои учествуваат во спроведување на клиничкото испитување на лекот, а кои се вработени во здравствената установа, како и други важни прашања за регулирање на нивните меѓусебни односи.

Здравствената установа од став 1 на овој член мора да обезбеди услови за работа на истражувачите, односно главниот испитувач, како и непречена работа на набљудувачот, одиторот и овластеното лице од Агенцијата за контрола на спроведувањето на клиничкото испитување на лекот во согласност со Законот за лековите и медицинските помагала, овој правилник и водичите на добра клиничка пракса во клиничкото испитување.

6. Етичка Комисија

Член 22

Клиничкото испитување на лекот може да биде одобрено од страна на Агенцијата само ако Етичката комисија донесе позитивна одлука за негово спроведување.

Етичката комисија треба да даде мислење за предложеното клиничко испитување најдоцна до 30 дена од денот на приемот на комплетна документација пропишана со овој правилник.

По исклучок на став 2 од овој член, Етичката комисија треба задолжително да даде мислење за предложеното клиничко испитување најдоцна до 90 дена од денот на приемот на комплетната документација доколку се работи за клиничко испитување на готови лекови наменети за генетска терапија, лекување со соматски клетки вклучувајќи и лекови кои содржат генетски модифицирани организми.

Времето на давање на мислење од став 3 на овој член може да се продолжи за дополнителни 90 дена доколку е потребно советување со други стручни лица.

За ксеногенични лекови не е ограничено времето за давање на мислење.

Пред давање на мислењето од став 1 на овој член Етичката комисија ги разгледува следниве документи:

1. протокол на клиничкото испитување на лекот;
2. евалуација на очекуваната корист во однос на потенцијалниот ризик по здравјето на испитаниците (документ за процена на претклиничката и клиничката документација со евалуација на односот корист-ризик) ;
3. стручност на главниот испитувач и истражувачкиот тим;
4. брошура на испитувачот;
5. доказ за писмена согласност која му се дава на испитаникот е соодветна документација;
6. дали е оправдано спроведувањето на клиничкото испитување на лекот на испитаници кои не се способни да дадат писмена согласност;
7. дали е оправдано спроведувањето на клиничкото испитување на лекот на здрави жени во фертилен период, трудници, доилки, стари особи и тешки болни, како и на одредени старосни групи на испитаници (на пр: деца, постари особи, односно дали клиничкото испитување на лекот може да се изврши на други лица); и
8. доказ за осигурување на испитаниците од страна на подносителот на барањето во случај да настане штета по здравјето на испитаникот која е предизвикана од клиничкото испитување на лекот (повреда или смрт на испитаникот).

Член 23

Етичката комисија може да му предложи на подносителот на барањето на клиничкото испитување на лекот, односно на главниот испитувач, да се прекине клиничко испитување на лек, ако за тоа постојат оправдани причини.

7. Постапка и содржина на документацијата за одобрување на клиничкото испитување

Член 24

Подносителот на барањето за клиничкото испитување на лек кој нема одобрение за ставање во промет на лекот во Република Македонија, пред почетокот на клиничкото испитување поднесува до Агенцијата барање за добивање на одобрение за спроведување на клиничко испитување.

Барањето за одобрување на клиничкото испитување на лекот од став 1 на овој член содржи:

1. пропратно писмо на подносителот на барањето;
2. пополнет образец на барање за одобрување на клиничкото испитување на лекот - пријава на клиничкото испитување;
3. доказ дека подносителот на барањето за клиничко испитување на лекот (производителот на лекот, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот Регистар на Република Македонија;
4. доказ за пренесени овластувања на подносителот на барањето;
5. протокол на клиничкото испитување на лекот;
6. брошура за истражувачот;
7. примерок на тест-листа (CRF) ;
8. позитивно мислење од Етичката комисија;

9. писмена согласност на здравствената установа во која ќе се врши клиничкото испитување на лекот;

10. евалуација на очекуваната корист во однос на потенцијалниот ризик по здравјето на испитаниците (документ за процена на претклиничката и клиничката документација со евалуација на односот корист-ризик);

11. GMP сертификат од производната локација на лекот кој клинички се испитува, сертификат за анализа со стручно мислење на квалитетот на лекот, доказ дека обележувањето на испитуваниот и компаративниот лек е изведено согласно член 13 на овој правилник;

12. писмена изјава на главниот испитувач дека е запознат со особините на лекот во клиничкото испитување на лекот, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;

13. кратка биографија и референца на главниот испитувач;

14. доказ за осигурување на испитаниците од страна на подносителот на барањето за случај за настанување на штета по здравјето на испитаникот (повреда или смрт на испитаникот);

15. примерок на информирана согласност која ја потпишуваат испитаниците;

16. други информации за испитаниците (дневник за пациентот, упатства и други документи) (ако има);

17. список на држави во кои лекот добил одобрение за ставање во промет (писмена изјава од подносителот на барањето на клиничкото испитување) (ако има);

18. список на држави во кои е веќе одобрено или е во постапка на одобрување клиничко испитување на истиот лек (ако има);

19. список на држави во кои се врши истото клиничко испитување на лекот, ако се работи за мултицентрично клиничко испитување кое се изведува во повеќе држави;

20. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата; и

21. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на лекот.

Член 25

Подносителот на барањето за клиничкото испитување на лек кој има одобрение за ставање во промет во Република Македонија, пред почетокот на постмаркетиншко интервенциско клиничко испитување поднесува до Агенцијата барање за добивање на одобрение за спроведување на клиничкото испитување.

Барањето за одобрување на клиничкото испитување на лекот од став 1 на овој член содржи:

1. пропратно писмо на подносителот на барањето;

2. пополнет образец на барање за одобрување на клиничкото испитување на лекот - пријава на клиничкото испитување;

3. доказ дека подносителот на барањето (производителот на лекот, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот Регистар на Република Македонија;

4. доказ за пренесени овластувања на подносителот на барањето;

5. протокол на клиничкото испитување на лекот;

6. одобрен збирен извештај за особините на лекот (SmPC);

7. примерок на тест-листа (CRF);

8. позитивно мислење од Етичката комисија;

9. писмена согласност на здравствената установа во која ќе се врши клиничкото испитување на лекот;

10. писмена изјава на главниот испитувач дека е запознат со особините на лекот во клиничкото испитување, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;

11. кратка биографија и референца на главниот испитувач;

12. доказ за осигурување на испитаниците од страна на подносителот на барањето за случај за настанување на штета по здравјето на испитаникот (повреда или смрт на испитаникот);

13. примерок на информирана согласност која ја потпишуваат испитаниците;

14. други информации за испитаниците (дневник за пациентот, упатства и други документи) (ако има);

15. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата; и

16. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на лекот.

Подносителот на барањето за клиничкото испитување на лек кој има одобрение за ставање во промет во Република Македонија, пред почетокот на постмаркетиншко неинтервенциско клиничко испитување доставува барање за добивање на одобрение за спроведување на клиничкото испитување.

Барањето за одобрување на клиничкото испитување на лекот од став 3 од овој член содржи:

1. пропратно писмо на подносителот на барањето;

2. пополнет образец на барање за одобрување на клиничкото испитување на лекот - пријава на клиничкото испитување;

3. доказ дека подносителот на барањето (производителот на лекот, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот Регистар на Република Македонија;

4. доказ за пренесени овластувања на подносителот на барањето;

5. протокол на клиничкото испитување на лекот;

6. одобрен збирен извештај за особините на лекот (SmPC);

7. примерок на тест-листа (CRF);

8. позитивно мислење од Етичката комисија;

9. писмена изјава на главниот испитувач дека е запознат со особините на лекот во клиничкото испитување, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;

10. кратка биографија и референца на главниот испитувач;

11. примерок на информирана согласност која ја потпишуваат испитаниците;

12. други информации за испитаниците (дневник за пациентот, упатства и други документи) (ако има);

13. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата; и

14. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на лекот.

Член 26

Подносителот на барањето за изведување на студија на биоеквивалентност и студија на биолошка расположивост, ја известува Агенцијата за спроведување на клиничкото испитување.

Известувањето за спроведување на клиничкото испитување на лекот од став 1 на овој член содржи:

1. пропратно писмо на подносителот на барањето;
2. пополнет образец на барање за одобрување на клиничкото испитување на лекот - пријава на клиничкото испитување;
3. доказ дека подносителот на барањето (производителот на лекот, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот Регистар на Република Македонија;
4. доказ за пренесени овластувања на подносителот на барањето;
5. протокол на клиничкото испитување на лекот;
6. збирен извештај за особините на лекот (SmPC);
7. примерок на тест-листа (CRF);
8. позитивно мислење од Етичката комисија;
9. евалуација на потенцијалниот ризик по здравјето на испитаниците (документ за процена на претклиничката и клиничката документација со евалуација на ризиците по испитаниците);
10. GMP сертификат од производната локација на лекот кој клинички се испитува;
11. сертификат за анализа на квалитетот на серијата што ќе се користи во испитувањето;
12. писмена изјава на главниот испитувач дека е запознат со особините на лекот во клиничкото испитување, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;
13. кратка биографија и референца на главниот испитувач;
14. доказ за осигурување на испитаниците од страна на подносителот на барањето за случај за настанување на штета по здравјето на испитаникот (повреда или смрт на испитаникот) ;
15. примерок на информирана согласност која ја потпишуваат испитаниците;
16. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата; и
17. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на лекот.

Член 27

Барањето за одобрување на клиничкото испитување на лекот - пријава на клиничкото испитување на лекот е дадено во Прилог бр.1 и е составен дел на овој правилник.

Член 28

Пропратното писмо на подносителот на барањето содржи:

1. лого, назив и адреса на подносителот на барањето;
2. содржина на барањето за одобрување на клиничкото испитување на лекот;
3. резиме на протоколот на македонски јазик;
4. назив на клиничкото испитување;
5. назив на лекот кој клинички се испитува;
6. фармацевтска форма и јачина на лекот;
7. име на производителот; и

8. датум и потпис на главниот испитувач.

Член 29

Протоколот на клиничкото испитување на лекот содржи:

1. вовед (кратка содржина на студијата, одговорности, основни информации за лековите во испитувањето и т.н.);
2. цел на клиничкото испитување на лекот;
3. дизајн на студијата;
4. избор на испитаници;
5. податоци за лекување на испитаниците;
6. процена на ефикасноста;
7. процена на безбедноста;
8. статистичка обработка на податоците;
9. податоци за контрола и обезбедување на квалитет;
10. етички аспекти на клиничкото испитување на лекот;
11. податоци за ракување о податоците и чувањето на документацијата;
12. начин на објавување на резултатите на клиничкото испитување на лекот; и
13. други прилози.

Член 30

Брошурата на испитувачот содржи:

1. насловна страна;
2. изјава за тајност на податоците;
3. содржина;
4. резиме;
5. вовед;
6. физичко-хемиски и фармацевтски својства на фармацевтскиот облик на лекот;
7. податоци за предклиничките испитувања на лекот;
8. податоци за клиничките испитувања на лекот; и
9. заклучок.

Податоците во брошурата во однос на ефикасноста и безбедноста на лекот се однесуваат на лекот кој клинички се испитува и на компаративниот лек.

8. Издавање на одобрение за клиничко испитување на лекот

Член 31

Комплетноста на барањето за одобрување на клиничкото испитување на лекот се оценува од страна на Агенцијата најдоцна до 30 дена од денот на поднесување на барањето.

Доколку барањето од став 1 на овој член не е комплетно, подносителот на барањето во писмена форма се известува од страна на Агенцијата да го дополни барањето со дополнителни податоци во одреден временски рок.

9. Промена и дополнување на протоколот, односно на одобрението за клиничко испитување на лекот

Член 32

Врз основа на научно-техничкиот развој на струката, резултатите од фармаковигиланцата и други релевантни податоци, подносителот на барањето на клиничкото испитување на

лекот може да предложи до Агенцијата промени и дополнување на протоколот, односно на одобрението за клиничко испитување на лекот.

Член 33

Целосното барање за одобрение на промените и дополнувањата во протоколот, односно одобрението за клиничко испитување содржи:

1) пропратно писмо на подносителот на барањето;

2) пополнет образец за промени и дополнување на протоколот, односно на одобрението за клиничко испитување на лекот;

3) документција која се однесува на промените и дополнувањето на протоколот, односно на одобрението за клиничко испитување на лекот;

4) одобрение од Етичка комисија во случај да промените и дополнувањата на протоколот значајно влијаат на етичките аспекти од клиничкото испитување врз основа на проценка на Агенцијата; и

5) доказ дека е платен соодветниот надомест на Агенцијата.

Барањето за одобрение на промените и дополнувањето на протоколот за клиничко испитување е дадено во Прилог бр.2 и е составен дел на овој правилник.

Член 34

Пропратното писмо од член 33 точка 1 на овој правилник содржи:

1) лого, име и адреса на подносителот на барањето;

2) предмет: кратко известување за промените и дополнувањата;

3) наслов на клиничкото испитување на лекот;

4) името на лекот што клинички се испитува;

5) фармацевтска форма, јачина и пакување на лекот;

6) име на производителот на лекот; и

7) датум и потпис на одговорното лице за клиничкото испитување на лекот.

10. Известување за спроведување на клиничкото испитување на лекот

Член 35

Во случај на прекин на клиничкото испитување, подносителот на барањето за клиничко испитување на лекот е должен да ја извести Агенцијата за привремен прекинот на клиничкото испитување на лекот во Република Македонија или во други држави во кои истото се спроведува.

Подносителот на барањето за клиничко испитување на лекот треба да ја извести Агенцијата и за предвремено завршување на клиничкото испитување на лекот во Република Македонија или во други држави во кои истото се спроведува и тоа независно од причината за прекинот.

Подносителот на барањето за клиничко испитување на лекот е должен да ја извести Агенцијата за настаните од став 1 и став 2 на овој член во рок од 15 дена од денот на прекин на клиничкото испитување на лекот (известување за прекин на клиничкото испитување).

11. Следење на несаканите дејства на лекот

Член 36

За следењето на несаканите дејства на лекот што клинички се испитува се применуваат одредбите на актот со кој се пропишува начинот на пријавување, собирање и следење на несаканите дејства на лекот.

III. ПРЕОДНИ И ЗАВРШНИ ОДРЕДБИ

Член 37

Започнатите постапки за добивање на одобрение за клиничко испитување на лекот пред денот на влегување во сила на овој правилник ќе продолжат согласно прописите по кои се започнати.

Член 38

Со денот на влегувањето во сила на овој правилник престанува да се применува Правилникот за клиничко испитување на лек („Службен лист на СФРЈ" бр.2/89).

Член 39

Овој правилник влегува во сила осмиот ден од денот на објавувањето во „Службениот весник на Република Македонија".

Бр. 15-1686/1
февруари 2009 година
Скопје

Министер,
д-р **Бујар Османи**, с.р.

Прилог 1

БИРО ЗА ЛЕКОВИ - Р.МАКЕДОНИЈА

50 Дивизија бб-Скопје, Р.Македонија, тел.: + 389 (0)2/3112-500 , факс: + 389 (0)2/3298-435

Број на барањето:	Примил/а:
Датум на прием:	Датум на барање за дополнителна документација:
Датум на добивање на дополнителна документација:	Датум на потполно барање:

Пополнува Бирото за лекови на Р.Македонија

БАРАЊЕ ЗА ОДОБРУВАЊЕ НА КЛИНИЧКО ИСПИТУВАЊЕ НА ЛЕК – ИЗВЕСТУВАЊЕ ЗА КЛИНИЧКО ИСПИТИВАЊЕ

Барање за одобрување на клиничко испитивања ☐
Известување за клиничко испитивање ☐

Наслов на испитувањето:

Број на протоколот на клиничкото испитивање, вклучувајќи го и бројот на измена и дополнување ако е потребно:

Подносител (име, адреса):

Подносител на барање согласно член 57 од Закон за лековите и медицинските помагала (име, адреса, телефон, факс, e-mail):

Подносител на барање: производител ☐ спонзор ☐ овластен претставник ☐

Испитуван лек, име,фармацевтска дозирана форма на лекот, јачина/-и[1]:

Производител на лекот (име, адреса):

Лекот е регистриран во РМ: да ☐ Број на одобрението не ☐

Постапката за издавање на одобрение е во тек во РМ: да ☐ не ☐

Лекот бил веќе испитуван во РМ: да ☐ не ☐

Лекот е регистриран во други држави: не ☐ да ☐

Начин на примена на лекот: Дозирање во клиничкото испитување:

Активна супстанција/-и, име (за радиофармацевтски лекови - радионуклеид):

Лекот содржи супстанција која е веќе регистрирана во светот : не ☐ да ☐

Производител на активната супстанција (име, адреса):

Категорија на лек:

Радиофармацевтски лек	☐	Имунолошки лек	☐
Лек кој содржи синтетска активна супстанција	☐	Дериват на крв	☐
Хербален лек	☐	Биотехнолошки лек	☐
Лек за стоматолошка употреба	☐	Друга категорија (да се наведе која)	☐
Лек кој содржи наркотична или психотропна супстанција	☐		

Други лекови кои се предвидени за употреба при испитивањето да ☐ не ☐

Да се набројат другите лекови кои се предвидени за употреба при испитивањето:
(име на лекот, фармацевтски дозирани форми на лекот и јачина/-и)

Споредбена употреба на друг регистриран лек е дозволена како стандардна терапија да ☐ не ☐

Карактеристики на испитивањето

Главна цел на испитувањето:

Други цели (ако има):

Тераписка област:

Кардиоваскуларна ☐ ЦНС ☐ Респираторна ☐

Антимикробна ☐ Онкологија ☐ Гастроинтестинална ☐

Ендокринологија ☐ Дерматологија ☐ Друга ☐ Да се наведе која :

Фаза на испитувањето: I. ☐ II. ☐ III. ☐ IV. ☐ Испитивање на биоеквиваленција ☐

Видови на испитување:

Нова индикација ☐ Фармакокинетичка испитувања ☐ Одредување на доза ☐

Нова група на пациенти ☐ Нова комбинација на лек ☐ Нов фармацевтски облик ☐

Зголемен број на испитаници ☐ Постмаркетиншко интервенциско испитување ☐

Постмаркетиншко неинтервенциско испитување ☐

Други испитувања ☐ Да се наведе:

Ако се испитува ефикасноста на лекот, да се наведат индикациите :

Начин на испитување:

Рандомизирано ☐ Вкрстено ☐ Компаративно ☐ Плацебо контролирано ☐

Отворено ☐ Едноструко слепо ☐ Двоструко слепо ☐ Double dummy ☐

Друго ☐ Да се наведе:

Испитаници: Здрави доброволци ☐ Пациенти ☐

Испитување: Во еден центар ☐ Во повеќе центри во РМ ☐ Меѓународно мултицентрично ☐

Да се наведат државите:

Установа во која се врши испитивањето

Име: Адреса (вклучувајќи и поштенски број на местото): Име на истражувачот:

Контрола на квалитетот на испитивањето да ☐ не ☐

Набљудувач ☐ Одитор ☐ Друга ☐ Да се наведе:

Предвиден датум за почетокот на испитувањето:

Испитивањето е поврзано со добивање на одобрение за ставање на лекот во промет во РМ да ☐ не ☐

Клиничкото испитивање е веќе одобрено во други држави да ☐ не ☐

Поднесена документација

Пропратно писмо	☐
Доказ дека подносителот е правно лице со седиште во РМ	☐
Доказ за овластување на подносителот на барањето	☐
Протокол	☐
Брошура за истражувачот/	☐
Збирен извештај за особините на лекот	☐
Позитивно мислење од Етичка Комисија	☐
Документ за евалуација корист/ризик	☐
GMP сертификат	☐
Писмена изјава на Главниот испитувач	☐
CV на Главниот испитувач	☐
Доказ за осигурување на испитаниците	☐
Информирана согласност на македонски јазик	☐
Други докунети за испитаниците (ако има)	☐
Список на држави во кои лекот има одобрение за промет	☐
Список на држави во кои е веќе одобрено или е во постапка на одобрување клиничкото испитување	☐
Список на држави во кои е веќе одобрено истото клиничко испитување, ако се работи за мултицентрично клиничкото испитување	☐

Изјавувам дека податоците во барањето со пропратната документација се вистинити и дека ниту еден важен податок кој може да влијае на безбедноста на учесникот во испитувањето и веродостојноста на заклучокот не е сокриен.

Име, презиме и стручна подготовка на одговорното лице

Датум Потпис на одговорната особа

Прилог 2

БИРО ЗА ЛЕКОВИ - Р.МАКЕДОНИЈА

50 Дивизија бб-Скопје, Р.Македонија, тел.: + 389 (0)2/3112-500 , факс: + 389 (0)2/3298-435

Број на барањето:	Примил/а:
Датум на прием:	Датум на барање за дополнителна документација:
Датум на добивање на дополнителна документација:	Датум на потполно барање:

Пополнува Бирото за лекови на Р.Македонија

БАРАЊЕ ЗА ОДОБРУВАЊЕ НА ПРОМЕНА И ДОПОЛНУВАЊЕ НА ПРОТОКОЛОТ – ОДОБРЕНИЕТО ЗА КЛИНИЧКО ИСПИТУВАЊЕ

Промена и дополнување на протоколот на клиничкото испитување ☐
Промена и дополнување на одобрението за спроведување на клиничкото испитување ☐

Наслов на испитувањето:

Број на протоколот на клиничкото испитување, вклучувајќи го и бројот на поромената и дополнувањето, ако е потребно:

Подносител (име, адреса):

Подносител на барањето согласно член 57 од Закон за лековите и медицинските помагала (име, адреса, телефон, факс, e-mail):

Подносител на барање: производител ☐ спонзор ☐ овластен претставник ☐

Вид на промена и дополнување на клиничкото испитување

Овие промени и дополнувања најмногу се однесуваат на безбедносните мерки кои веќе се применуваат
да ☐ не ☐

Причини за промена и дополнување на клиничкото испитување:

Промени настанати во безбедноста и интегритетот на испитаникот	да ☐	не ☐
Промени настанати во толкување на стручната документација/резултати на испитувањето	да ☐	не ☐
Промени настанати во квалитетот на испитуваниот медицински производ	да ☐	не ☐

Промени во текот на изведувањето на клиничкото испитување:

Промени на местото на испитување	да ☐	не ☐
Вклучување на дополнително место на испитување	да ☐	не ☐
Промена на главниот испитувач	да ☐	не ☐
Промена на подносителот на барањетона клиничкото испитувањето	да ☐	не ☐
Останати промени	да ☐	не ☐

Да се наведе:

Друго: да ☐ не ☐

Да се наведе:

Содржина на промената и дополнувањето на клиничкото испитување:

Промена и дополнување на информациите наведени во одобрението на клиничкото испитување	да ☐	не ☐
Промени и долонувања на протоколот на клиничкото испитување	да ☐	не ☐
Промена и дополнување на другите дополнителни документи	да ☐	не ☐

Да се наведе:

Друго: да ☐ не ☐

Да се наведе:

Причини за промена и дополнување:

Краток опис на промената и дополнувањето:

Доставена документација:

Листа на променети документи ☐

Преглед на предложените промени и дополнувања ☐

Пропратна документација ☐

Други документи ☐

да се наведе:

Изјавувам дека податоците во барањето и пропратната документација се вистинити и дека ниту еден важен податок кој може да влијае на безбедноста на учесникот во испитувањето и веродостојноста на заклучокот не е прикриен.

Име, презиме и стручна подготовка на одговорното лице

Датум

Потпис на одговорното лице

20120120421

МИНИСТЕРСТВО ЗА ЗДРАВСТВО

Врз основа на член 64 од Законот за лековите и медицинските помагала („Службен весник на Република Македонија“ бр. 106/07,88/10, 36/11, 53/11 и 136/11), министерот за здравство, донесе

ПРАВИЛНИК ЗА ИЗМЕНУВАЊЕ НА ПРАВИЛНИКОТ ЗА НАЧИНОТ И ПОСТАПКАТА ЗА КЛИНИЧКИТЕ ИСПИТУВАЊА НА ЛЕКОВИТЕ И СОДРЖИНАТА НА ДОКУМЕНТАЦИЈАТА

Член 1

Во Правилникот за начинот и постапката за клиничките испитувања на лековите и содржината на документацијата („Службен весник на Република Македонија" бр. 29/09,91/10) во член 24 во ставот 2 по точката 3. се додава нова точка 3-а која гласи:

"доказ дека набљудувачот на клиничкото испитување е соодветно овластен од спонзорот на клиничкото испитување согласно со член 2 точка 21 од овој правилник, и е вработен во фирма запишана во Централниот Регистар на Република Македонија".

Член 2

Овој правилник влегува во сила наредниот ден од денот на објавувањето во „Службен весник на Република Македонија".

Бр. 15-410/1
18 јануари 2012 година
Скопје

Министер,
Никола Тодоров, с.р.

20100911643

МИНИСТЕРСТВО ЗА ЗДРАВСТВО

Врз основа на член 64 од Законот за лековите и медицинските помагала („Службен весник на Република Македонија” бр.106/2007), министерот за здравство донесе

ПРАВИЛНИК ЗА ИЗМЕНУВАЊЕ НА ПРАВИЛНИКОТ ЗА НАЧИНОТ И ПОСТАПКАТА ЗА КЛИНИЧКИТЕ ИСПИТУВАЊА НА ЛЕКОВИТЕ И СОДРЖИНАТА НА ДОКУМЕНТАЦИЈАТА

Член 1

Во Правилникот за начинот и постапката за клиничките испитувања на лековите и содржината на документацијата („Службен весник на Република Македонија” бр. 29/2009) во членот 14 став 3 зборот “три” се заменува со зборот “пет”.

Член 2

Овој правилник влегува во сила наредниот ден од денот на објавувањето во „Службен весник на Република Македонија”.

Бр. 15-3873/1
2 јули 2010 година
Скопје

Министер,
д-р **Бујар Османи**, с.р.

20100621111

МИНИСТЕРСТВО ЗА ЗДРАВСТВО

Врз основа на член 137 од Законот за лековите и медицинските помагала („Службен весник на Република Македонија" бр. 106/07), министерот за здравство донесе

ПРАВИЛНИК ЗА ПОТРЕБНАТА ДОКУМЕНТАЦИЈА И НАЧИНОТ НА ПРИЈАВУВАЊЕ НА КЛИНИЧКИТЕ ИСПИТУВАЊА НА МЕДИЦИНСКИТЕ ПОМАГАЛА И НАСТАНАТИТЕ ПРОМЕНИ И, ИЗВЕСТУВАЊЕ ЗА НЕСАКАНИ РЕАКЦИИ И НАСТАНИ, ОДНОСНО ИНЦИДЕНТИ, КАКО И УСЛОВИТЕ КОИ ТРЕБА ДА ГИ ИСПОЛНАТ ПРАВНИТЕ ЛИЦА КОИ ВРШАТ КЛИНИЧКИ ИСПИТУВАЊА НА МЕДИЦИНСКИ ПОМАГАЛА

I. ОПШТИ ОДРЕДБИ

Член 1

Со овој правилник се пропишува начинот на пријавување на клиничките испитувања на медицинските помагала и настанатите промени и, известување за несакани реакции и настани, односно инциденти, како и условите кои треба да ги исполнат правнте лица кои вршат клинички испитувања на медицински помагала.

II. КЛИНИЧКО ИСПИТУВАЊЕ НА МЕДИЦИНСКО ПОМАГАЛО

1.Заеднички одредби

Член 2

При спроведување на клиничко испитување на медицинското помагало, правата, безбедноста и интересот на испитаниците се приоритетни во однос на правата, безбедноста и интересот на науката и општеството во целина.

Клиничкото испитување на медицинското помагало треба да биде испланирано и спроведено на начин што овозможува на најмала можна мерка да се намалат болката, нелагодноста, стравот и било кој друг предвидлив ризик по здравјето на испитаниците (прагот на ризик и степенот на болка треба да се дефинираат и да се под постојан надзор).

Член 3

Документацијата што се доставува кон барањето за клиничкото испитување на медицинското помагало се архивира во Агенцијата за лекови (во натамошниот текст: Агенцијата) и се смета и се постапува како за класифицирана информација согласно прописите за класифицирани информации и заштита на личните податоци.

2.Заштита на испитаниците во клиничкото испитување на медицинското помагало

Член 4

При изборот на целна група треба да се земе во предвид степенот на ризик за поединечни групи на испитаници.

Во клиничко испитување не се вклучуваат лица кои не се способни сами да одлучуваат за учествување во клиничкото испитување на медицинското помагало ако истото испитување може да се спроведе на лица кои можат сами да одлучуваат за учествување во клиничкото испитување.

Одредени старосни групи (деца, стари луѓе и други) се вклучуваат само во посебни клинички испитувања на медицинското помагало во согласност со овој правилник.

Член 5

Главниот испитувач и секој член на истражувачкиот тим треба да го обезбеди правото на испитаникот на физичкиот и менталниот интегритет на испитаникот, како и приватност и заштита на податоците кои се достапни само на овластени лица.

Во тек на клиничкото испитување на медицинското помагало, главниот испитувач или член на истражувачкиот тим треба да го извести испитаникот за секоја важна информација која се однесува на планирање и спроведување на клиничкото испитување на медицинското помагало.

Член 6

Ако во текот на клиничкото испитување на медицинското помагало дошло до појава на несакани реакции, односно до сериозни несакани реакции, испитаникот треба да ја добие потребната здравствена заштита во време и после завршување на клиничкото испитување на медицинското помагало.

2.1.Заштита на малолетни испитаници во клиничкото испитување на медицинското помагало

Член 7

Ако е тоа неопходно, со превземање на посебни мерки на претпазливост, клиничко испитување може да се врши и кај лица на возраст до 18 години кои се болни од болест или ја имаат состојбата за која е наменето медицинското помагало кое клинички се испитува.

Покрај случаите од став 1 на овој член, клиничко испитување на медицинското помагало кај малолетни испитаници може да се спроведува и во следните случаи:

1) ако родителот, односно старателот дал писмена согласност (писмената согласност треба да ја претставува претпоставената желба на малолетникот и може да биде повлечена во било кој момент, без штета по малолетникот);

2) малолетникот ја примил информацијата во согласност со своите можности да ја разбере и тоа од страна на лице кое има искуство во работата со малолетници, а истата се однесува на текот на клиничкото испитување, ризикот и користа по здравјето на испитаникот;

3) ако писмената согласност е дадена без поттикнување на учествување во клиничкото испитување, со нудење или давање на било каква материјална или друга корист;

4) ако Етичката комисија проценила дека со клиничкото испитување на медицинското помагало кај малолетни испитаници се остварува директна корист за одредена група на пациенти, како и дека таквото истражување е битно за процена на податоците кои се добиени со клиничко испитување извршено на лица кои се способни самостојно да дадат согласност и

5) ако позитивната одлука за спроведување на клиничкото испитување на медицинското помагало во здравствена установа ја донела Етичката комисија врз основа на мислење на доктор-специјалист од областа на педијатрија, со посебен осврт на клиничките, етичките и психо-социјалните проблеми во спроведување на клиничкото испитување на медицинското помагало.

Член 8

Во тек на спроведување на клиничкото испитување на медицинското помагало, малолетник кој е способен да формира мислење и ги процени информациите кои ги добил за учество во клиничкото испитување, може да донесе одлука во било кој момент да го прекине своето учество во клиничкото испитување на медицинското помагало за што го известува главниот испитувач или испитувач кој е член на истражувачкиот тим.

2.2.Заштита на полнолетни лица кои не се во состојба да дадат писмена согласност во тек на клиничкото испитување на медицинско помагало

Член 9

Клиничко испитување на медицинското помагало кај полнолетен испитаник кој не е во состојба да даде писмена согласност (несвесна состојба, ограничена физичка или психичка способност и друго), односно кај полнолетен испитаник кој не ја одбил согласноста да учествува во клиничко испитување на медицинското помагало пред почеток на својата неспособност, се спроведува ако:

1) писмена согласност за учество во клиничкото испитување на медицинското помагало дал старател на полнолетниот испитаник кој не е во состојба да даде писмена согласност (писмената согласност треба да ја претставува писмената желба на испитаникот и може да биде повлечена во било кој момент, без штета по него);

2) полнолетниот испитаник кој не е во состојба да даде писмена согласност ја примил информацијата во согласност со своите можности да ја разбере и тоа од страна на лице кое има искуство во работата со такви лица, а истата се однесува на текот на клиничкото испитување, ризикот и користа по здравјето на испитаникот;

3) ако писмената согласност е дадена без поттикнување на учествување во клиничкото испитување на медицинското помагало со нудење или давање на било каква материјална или друга корист;

4) ако се процени дека со клиничкото испитување на медицинското помагало на тоа лице се добива директна корист за групата пациенти чија болест, односно состојба одговара на болеста, односно состојбата на испитаникот и

5) ако позитивно мислење за спроведување на клиничкото испитување на медицинското помагало во здравствена установа донела Етичката комисија врз основа на мислење на доктор-специјалист за одредена болест или состојби на испитаниците, односно за популација на пациенти на која клиничкото испитување на медицинското помагало се однесува, со посебен осврт на клиничките, етичките и психо-социјалните проблеми во спроведување на клиничкото испитување на медицинското помагало.

3. Поднесување на барање за клиничко испитување на медицинското помагало

Член 10

Подносителот на барањето за клиничкото испитување на медицинското помагало ги врши следните работи:

1) ја подготвува целосната документација која е потребна за добивање на одобрение за клиничкото испитување на медицинското помагало, како и документацијата потребна за измена и дополнение на протоколот, односно одобрението за клиничкото испитување на медицинското помагало;

2) го определува главниот испитувач кој потпишува изјава дека се согласува со предложениот протокол и со извршување на работите во врска со клиничкото испитување на медицинското помагало, во согласност со овој правилник;

3) го определува местото на клиничкото испитување на медицинското помагало (една или повеќе здравствени установи) во кое ќе се спроведува клиничкото испитување на медицинското помагало, како и главното место на клиничкото испитување на медицинското помагало врз основа на договор со здравствената установа за употреба на простор, опрема и кадар на здравствената установа за изведување на клиничкото испитување на медицинското помагало;

4) обезбедува доволно претклинички и клинички податоци за медицинското помагало кој се испитува и ги става на располагање на главниот испитувач;

5) го известува главниот испитувач, Агенцијата и Етичката комисија за сите нови релевантни податоци кои се однесуваат на медицинското помагало кое се испитува;

6) обезбедува податоци за квалитетот на медицинското помагало кое клинички се испитува, како и податоци за претходно спроведени претклинички и клинички испитувања на тоа медицинското помагало;

7) му обезбедува на испитаникот целосна здравствена заштита за лекување на болести или состојби кои се последица на клиничкото испитување на медицинското помагало и

8) обезбедува набљудувач во клиничкото испитување на медицинското помагало.

9) благовремено ја известува агенцијата и главниот испитувач за измените и дополненијата на протоколот во согласност со Законот за лековите и медицинските помагала и овој правилник.

Член 11

Подносителот на барањето на клиничкото испитување на медицинското помагало е должен да обезбеди доволна количина на медицинското помагало кое клинички се испитува.

Медицинското помагало од став 1 на овој член треба да биде обележано и на надворешното пакување треба да ги има најмалку следните податоци:

1) име на медицинското помагало, заштитено име и/ или генеричко име или друга ознака за идентификација;

2) име на производителот;

3) рок на употреба;

4) број на серија и

5) други потребни ознаки во однос на видот на клиничко испитување на медицинското помагало.

Надворешното пакување на медицинското помагало од став 1 на овој член треба да има натпис: „за клиничко испитување”.

Ако клиничкото испитување на медицинското помагало од став 1 на овој член се врши со слепа метода, медицинското помагало треба да биде обележано и со посебна шифра.

4. Главен испитувач и истражувачки тим во клиничко испитување на медицинското помагало

Член 12

Главниот испитувач во клиничкото испитување на медицинското помагало е лице со завршен медицински или стоматолошки факултет кое има специјализација во областа во која примарно се применува медицинското помагало кое клинички се испитува и кој е вработен во здравствената установа во која се одвива клиничкото испитување на медицинското помагало и кој е непосредно одговорен за лекување на пациентот.

Главниот испитувач во клиничко испитување на медицинското помагало треба да има и дополнително знаење од областа на Добра клиничка пракса во клиничко испитување.

Главниот испитувач истовремено може да води најмногу три клинички испитувања кои се во фаза на активно вклучување на испитаници или активно спроведување на клиничкото испитување.

Член 13

Пред почеток на клиничкото испитување главниот испитувач ги врши следните работи:

1) му ја доставува на подносителот на барањето за клиничкото испитување на медицинското помагало својата биографија и документацијата која ја докажува неговата стручност и оспособеност за главен испитувач;

2) потпишува изјава дека е запознат со особините на медицинското помагало кое клинички се испитува, со целта на клиничкото испитување на медицинското помагало, дека ќе ги извршува работите во врска со клиничкото испитување на медицинското помагало во согласност со приложениот протокол и во согласност со важечките прописи и

3) му го доставува на подносителот на барањето списокот на членови на истражувачкиот тим.

Член 14

Во постапката на предлагање на истражувачки тим од член 13 точка 3) од овој правилник главниот истражувач ги запознава членовите на истражувачкиот тим со протоколот, претклиничките и клиничките податоци за медицинското помагало, тест листите и редовно ги известува за важните измени и дополнувања на протоколот и проблемите при изведување на клиничкото испитување на медицинското помагало.

Членовите на истражувачкиот тим треба да го известат главниот испитувач за несаканите реакции и/или настани на медицинското помагало кое клинички се испитува и мерките кои е неопходно да се превземат за заштита на здравјето на испитаниците.

Член 15

Главниот испитувач и истражувачкиот тим ги изведуваат и следниве работи во текот на клиничкото испитување на медицинското помагало:

1) одредуваат доволен број на испитаници во согласност со критериумите на протоколот за вклучување и исклучување на испитаници;

2) усмено и писмено даваат објаснување на испитаниците на начин кој е разбирлив за нив, а се однесува на податоци за медицинското помагало кое клинички се испитува, целта и планот за изведување на клиничкото испитување, ризикот и користа за испитаниците, начинот за избор на испитаници, приближен број на испитаници и другите можни начини на лекување, како и за нивните предности и негативни страни;

3) обезбедуваат доброволна писмена согласност за испитаниците за учество во клиничкото испитување на медицинското помагало;

4) му обезбедуваат на испитаникот соодветна здравствена заштита за време на траењето на клиничкото испитување на медицинското помагало и после завршувањето на клиничкото испитување на медицинското помагало ако продолжува лекувањето или ако болеста или состојбата се последица на клиничкото испитување на медицинското помагало;

5) обезбедуваат точност, потполност, читливост и ажурираност на податоците во врска со клиничкото испитување на медицинското помагало, како и тајност на податоците кои се достапни на надзорот, подносителот на барањето и Агенцијата и

6) ги чуваат во тајност шифрите на испитаникот и медицинското помагало кој се испитува, а кои можат да станат достапни само во итни случаи, кои се поврзани со заштита на здравјето на испитаникот.

Член 16

Главниот испитувач во текот на клиничкото испитување на медицинското помагало треба:

1) да го определува датумот на почетокот и завршување на клиничкото испитување на медицинското помагало во договор со подносителот на барањето на клиничкото испитување, како и да го извести подносителот на барањето на клиничкото испитување за прекинување на клиничкото испитување на медицинското помагало;

2) на соодветен начин да го чува медицинското помагало кое клинички се испитува, да го евидентира издавањето и потрошувачката на примероците од медицинското помагало кој клинички се испитува, како и на прописен начин да ги чува неупотребените примероци од медицинското помагало и во договор со подносителот на барањето на клиничкото испитување на медицинското помагало да изврши нивно уништување;

3) во случај на непосредна опасност за испитаникот да го извести подносителот на барањето на клиничкото испитување на медицинското помагало за прекин на клиничкото испитување на медицинското помагало и

4) подготвува извештај за завршеното клиничко испитување, а по потреба и на барање на Агенцијата, доставува извештај за текот на клиничкото испитување на медицинското помагало.

Ако е тоа потребно, главниот испитувач треба да предложи измени и дополнување на протоколот за испитување, а во случај предложената промена да се одобри треба да обезбеди сите испитаници да се запознаат со одобрената промена и дополнување на протоколот и да се продолжи лекувањето во согласност со промената и дополнувањето на протоколот.

Член 17

Во состав на истражувачкиот тим во клиничкото испитување на медицинското помагало кое се врши во здравствена установа која дава секундарна односно терциерна здравствена заштита треба да биде вклучен и доктор на медицина, односно специјалист по соодветната гранка од областа за која се употребува медицинското помагало во случај кога се спроведува прва фаза на клиничкото испитување.

Во поедини делови на клиничкото испитување на медицинското помагало покрај доктор на медицина и доктор на стоматологија, во истражувачкиот тим се вклучуваат и стручњаци со други соодветни наобразби: специјалист од соодветната област, дипл.фармацевт, односно специјалист по медицинска биохемија или специјалист по клиничка биохемија, статистичари, медицински сестри, здравствени техничари и др.

5. Место на клиничкото испитување на медицинското помагало

Член 18

Клиничкото испитување на медицинското помагало може да се спроведе во една или повеќе здравствени установи кои ги предлага подносителот на барањето на клиничкото испитување на медицинското помагало.

Ако клиничкото испитување на медицинското помагало се спроведува во повеќе здравствени установи на територијата на Република Македонија, подносителот на барањето на клиничкото испитување на медицинското помагало го одредува главното место на клиничкото испитување на медицинското помагало.

Член 19

Подносителот на барањето за клиничкото испитување на медицинското помагало потпишува договор со здравствената установа за спроведување на клиничкото испитување на медицинското помагало.

Договорот од став 1 на овој член содржи: услови и начин на спроведување на одреденото клиничкото испитување на медицинското помагало во здравствената установа, висината и начинот на плаќање на надоместокот која подносителот на барањето за клиничкото испитување на медицинското помагало ја исплатува на здравствената установа за користење на капацитетите на здравствената установа за спроведување на клиничкото испитување на медицинското помагало, број на здравствени работници и други лица кои учествуваат во спроведување на клиничкото испитување на медицинското помагало, а кои се вработени во здравствената установа, како и други важни прашања за регулирање на нивните меѓусебни односи.

Здравствената установа од став 1 на овој член треба да обезбеди услови за работа на истражувачите, односно главниот испитувач, како и непречена работа на набљудувачот, одиторот и овластеното лице од Агенцијата за контрола на спроведувањето на клиничкото испитување на медицинското помагало во согласност со Законот за лековите и медицинските помагала, овој правилник и водичите на добра клиничка пракса во клиничкото испитување.

6. Етичка Комисија

Член 20

Клиничкото испитување на медицинското помагало може да биде одобрено од страна на Агенцијата само ако Етичката комисија донесе позитивна одлука за негово спроведување.

Етичката комисија треба да даде мислење за предложеното клиничко испитување најдоцна до 30 дена од денот на приемот на комплетна документација пропишана со овој правилник.

Пред давање на мислењето од став 1 на овој член Етичката комисија ги разгледува следниве документи:

1. протокол на клиничкото испитување на медицинското помагало;
2. евалуација на очекуваната корист во однос на потенцијалниот ризик по здравјето на испитаниците (документ за процена на претклиничката и клиничката документација со евалуација на односот корист-ризик);
3. стручност на главниот испитувач и истражувачкиот тим;
4. брошура на испитувачот;
5. доказ за писмена согласност која му се дава на испитаникот е соодветна документација;
6. дали е оправдано спроведувањето на клиничкото испитување на медицинското помагало на испитаници кои не се способни да дадат писмена согласност;
7. дали е оправдано спроведувањето на клиничкото испитување на медицинското помагало на здрави жени во фертилен период, трудници, доилки, стари особи и тешки болни, како и на одредени старосни групи на испитаници (на пр: деца, постари особи, односно дали клиничкото испитување на медицинското помагало може да се изврши на други лица) и
8. доказ за осигурување на испитаниците од страна на подносителот на барањето во случај да настане штета по здравјето на испитаникот која е предизвикана од клиничкото испитување на медицинското помагало (повреда или смрт на испитаникот).

Член 21

Етичката комисија може да му предложи на подносителот на барањето на клиничкото испитување на медицинското помагало, односно на главниот испитувач, да се прекине клиничко испитување на медицинското помагало ако за тоа постојат оправдани причини.

7. Постапка и содржина на документацијата за одобрување на клиничкото испитување

Член 22

Подносителот на барањето за клиничкото испитување на медицинското помагало кое нема одобрение за ставање во промет на медицинското помагало во Република Македонија, пред почетокот на клиничкото испитување поднесува до Агенцијата барање за добивање на одобрение за спроведување на клиничко испитување.

Барањето за одобрување на клиничкото испитување на медицинското помагало од став 1 на овој член содржи:

1. пропратно писмо на подносителот на барањето;
2. пополнет образец на барање за одобрување на клиничкото испитување на медицинското помагало - пријава на клиничкото испитување;
3. доказ дека подносителот на барањето за клиничко испитување на медицинското помагало (производителот на медицинското помагало, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот регистар на Република Македонија;
4. доказ за пренесени овластувања на подносителот на барањето;
5. протокол на клиничкото испитување на медицинското помагало;
6. брошура за истражувачот;
7. примерок на тест-листа (ЦРФ);
8. позитивно мислење од Етичката комисија;
9. писмена согласност на здравствената установа во која ќе се врши клиничкото испитување на медицинското помагало;
10. евалуација на очекуваната корист во однос на потенцијалниот ризик по здравјето на испитаниците (документ за процена на претклиничката и клиничката документација со евалуација на односот корист-ризик);
11. ГМП сертификат од производната локација на медицинското помагало кое клинички се испитува, сертификат за анализа со стручно мислење на квалитетот на медицинското помагало, доказ дека обележувањето на испитуваниот и компаративниот медицинското помагало е изведено согласно член 13 од овој правилник;
12. писмена изјава на главниот испитувач дека е запознат со особините на медицинското помагало во клиничкото испитување на медицинското помагало, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;
13. кратка биографија и референца на главниот испитувач;
14. доказ за осигурување на испитаниците од страна на подносителот на барањето во случај за настанување на штета по здравјето на испитаникот (повреда или смрт на испитаникот);
15. примерок на информирана согласност која ја потпишуваат испитаниците;
16. други информации за испитаниците (дневник за пациентот, упатства и други документи) (ако има);
17. список на држави во кои медицинското помагало има одобрение за ставање во промет (писмена изјава од подносителот на барањето на клиничкото испитување) (ако има);

18. список на држави во кои е веќе одобрено или е во постапка на одобрување клиничко испитување на истото медицинско помагало (ако има);

19. список на држави во кои се врши истото клиничко испитување на медицинското помагало, ако се работи за мултицентрично клиничко испитување кое се изведува во повеќе држави;

20. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата и

21. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на медицинското помагало.

Член 23

Подносителот на барањето за клиничкото испитување на медицинското помагало кое има одобрение за ставање во промет во Република Македонија, пред почетокот на постмаркетиншко интервенциско клиничко испитување поднесува до Агенцијата барање за добивање на одобрение за спроведување на клиничкото испитување.

Барањето за одобрување на клиничкото испитување на медицинското помагало од став 1 на овој член содржи:

1.пропратно писмо на подносителот на барањето;

2. пополнет образец на барање за одобрување на клиничкото испитување на медицинското помагало - пријава на клиничкото испитување;

3. доказ дека подносителот на барањето (производителот на медицинското помагало, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот регистар на Република Македонија;

4. доказ за пренесени овластувања на подносителот на барањето;

5. протокол на клиничкото испитување на медицинското помагало;

6. упатство за употреба на медицинското помагало

7. позитивно мислење од Етичката комисија;

8. писмена согласност на здравствената установа во која ќе се врши клиничкото испитување на медицинското помагало;

9. писмена изјава на главниот испитувач дека е запознат со особините на медицинското помагало во клиничкото испитување, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;

10. кратка биографија и референца на главниот испитувач;

11. доказ за осигурување на испитаниците од страна на подносителот на барањето за случај за настанување на штета по здравјето на испитаникот (повреда или смрт на испитаникот);

12. примерок на информирана согласност која ја потпишуваат испитаниците;

13. други информации за испитаниците (дневник за пациентот, упатства и други документи) (ако има);

14. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата и

15. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на медицинското помагало.

Подносителот на барањето за клиничкото испитување на медицинското помагало кое има одобрение за ставање во промет во Република Македонија, пред почетокот на постмаркетиншко неинтервенциско клиничко испитување доставува барање за добивање на одобрение за спроведување на клиничкото испитување.

Барањето за одобрување на клиничкото испитување на медицинското помагало од став 3 на овој член содржи:

1. пропратно писмо на подносителот на барањето;
2. пополнет образец на барање за одобрување на клиничкото испитување на медицинското помагало - пријава на клиничкото испитување;
3. доказ дека подносителот на барањето (производителот на медицинското помагало, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот регистар на Република Македонија;
4. доказ за пренесени овластувања на подносителот на барањето;
5. протокол на клиничкото испитување на медицинското помагало;
6. примерок на тест-листа (ЦРФ);
7. позитивно мислење од Етичката комисија;
8. писмена изјава на главниот испитувач дека е запознат со особините на медицинското помагало во клиничкото испитување, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;
9. кратка биографија и референца на главниот испитувач;
10. примерок на информирана согласност која ја потпишуваат испитаниците;
11. други информации за испитаниците (дневник за пациентот, упатства и други документи) (ако има);
12. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата и
13. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на медицинското помагало.

Член 24

Подносителот на барањето за изведување на студија на биоеквивалентност и студија на биолошка расположивост, ја известува Агенцијата за спроведување на клиничкото испитување.

Известувањето за спроведување на клиничкото испитување на медицинското помагало од став 1 на овој член содржи:
1. пропратно писмо на подносителот на барањето;
2. пополнет образец на барање за одобрување на клиничкото испитување на медицинското помагало - пријава на клиничкото испитување;
3. доказ дека подносителот на барањето (производителот на медицинското помагало, спонзорот на испитувањето или неговиот овластен претставник) се запишани во Централниот регистар на Република Македонија;
4. доказ за пренесени овластувања на подносителот на барањето;
5. протокол на клиничкото испитување на медицинското помагало;
6. збирен извештај за особините на медицинското помагало;
7. примерок на тест-листа (ЦРФ);
8. позитивно мислење од Етичката комисија;
9. евалуација на потенцијалниот ризик по здравјето на испитаниците (документ за процена на претклиничката и клиничката документација со евалуација на ризиците по испитаниците);
10. ГМП сертификат од производната локација на медицинското помагало кој клинички се испитува;
11. сертификат за анализа на квалитетот на серијата што ќе се користи во испитувањето;

12. писмена изјава на главниот испитувач дека е запознат со особините на медицинското помагало во клиничкото испитување, со целта на клиничкото испитување, како и дека испитувањето ќе се врши во согласност со важечките прописи и начела на добрата клиничка пракса во клиничкото испитување;

13. кратка биографија и референца на главниот испитувач;

14. доказ за осигурување на испитаниците од страна на подносителот на барањето за случај за настанување на штета по здравјето на испитаникот (повреда или смрт на испитаникот) ;

15. примерок на информирана согласност која ја потпишуваат испитаниците;

16. дополнителни информации кои се однесуваат на заштита на здравјето на испитаниците на барање на Агенцијата и

17. доказ дека се платени пропишаните трошоци на Агенцијата за издавање на одобрение за клиничко испитување на медицинското помагало.

Член 25

Барањето за одобрување на клиничкото испитување на медицинското помагало - пријава на клиничкото испитување на медицинското помагало е дадено во Прилог бр.1 кој е составен дел на овој правилник.

Член 26

Пропратното писмо на подносителот на барањето содржи:

1. лого, назив и адреса на подносителот на барањето;

2. содржина на барањето за одобрување на клиничкото испитување на медицинското помагало;

3. резиме на протоколот на македонски јазик;

4. назив на клиничкото испитување;

5. назив на медицинското помагало кој клинички се испитува;

6. тип, форма и јачина на медицинското помагало;

7. име на производителот и

8. датум и потпис на главниот испитувач.

Член 27

Протоколот на клиничкото испитување на медицинското помагало содржи:

1. вовед (кратка содржина на студијата, одговорности, основни информации за медицинското помагало во испитувањето и т.н.);

2. цел на клиничкото испитување на медицинското помагало;

3. дизајн на студијата;

4. избор на испитаници;

5. податоци за лекување на испитаниците;

6. процена на ефикасноста;

7. процена на безбедноста;

8. статистичка обработка на податоците;

9. податоци за контрола и обезбедување на квалитет;

10. етички аспекти на клиничкото испитување на медицинското помагало;

11. податоци за ракување и чувањето на документацијата;

12. начин на објавување на резултатите на клиничкото испитување на медицинското помагало и

13. други прилози.

Член 28

Брошурата на испитувачот содржи:

1. насловна страна;
2. изјава за тајност на податоците;
3. содржина;
4. резиме;
5. вовед;
6. физичко-хемиски и фармацевтски својства на медицинското помагало;
7. податоци за предклиничките испитувања на медицинското помагало;
8. податоци за клиничките испитувања на медицинското помагало и
9. заклучок.

Податоците во брошурата во однос на ефикасноста и безбедноста на медицинското помагало се однесуваат на медицинското помагало кое клинички се испитува и на компаративниот производ.

8. Издавање на одобрение за клиничко испитување на медицинско помагало

Член 29

Комплетноста на барањето за одобрување на клиничкото испитување на медицинското помагало се оценува од страна на Агенцијата најдоцна до 30 дена од денот на поднесување на барањето.

Доколку барањето од став 1 на овој член не е комплетно, подносителот на барањето во писмена форма се известува од страна на Агенцијата да го дополни барањето со дополнителни податоци во одреден временски рок.

9. Промена и дополнување на протоколот, односно на одобрението за клиничко испитување на медицинското помагало

Член 30

Врз основа на научно-техничкиот развој на струката, резултатите од материовигиланцата и други релевантни податоци, подносителот на барањето на клиничкото испитување на медицинското помагало може да предложи до Агенцијата промени и дополнување на протоколот, односно на одобрението за клиничко испитување на медицинското помагало.

Член 31

Целосното барање за одобрение на промените и дополнувањата во протоколот, односно одобрението за клиничко испитување содржи:

1) пропратно писмо на подносителот на барањето;

2) пополнет образец за промени и дополнување на протоколот, односно на одобрението за клиничко испитување на медицинското помагало;

3) документција која се однесува на измените и дополнувањето на протоколот, односно на одобрението за клиничко испитување на медицинското помагало;

4) одобрение од Етичка комисија во случај да измените и дополнувањата на протоколот значајно влијаат на етичките аспекти од клиничкото испитување врз основа на проценка на Агенцијата и

5) доказ дека е платен соодветниот надомест на Агенцијата.

Барањето за одобрение на измените и дополнувањето на протоколот за клиничко испитување е дадено во Прилог бр.2 кој е составен дел на овој правилник.

Член 32

Пропратното писмо од член 31 точка 1 на овој правилник содржи:

1) лого, име и адреса на подносителот на барањето;

2) предмет: кратко известување за промените и дополнувањата;

3) наслов на клиничкото испитување на медицинското помагало;

4) името на медицинското помагало што клинички се испитува;

5) категорија и класа на медицинското помагало,

6) име на производителот на медицинското помагало;

7) датум и потпис на одговорното лице за клиничкото испитување на медицинското помагало.

10. Известување за спроведување на клиничкото испитување на медицинското помагало

Член 33

Во случај на прекин на клиничкото испитување, подносителот на барањето за клиничко испитување на медицинското помагало е должен да ја извести Агенцијата за привремен прекин на клиничкото испитување на медицинското помагало во Република Македонија или во други држави во кои истото се спроведува.

Подносителот на барањето за клиничко испитување на медицинското помагало треба да ја извести Агенцијата и за предвремено завршување на клиничкото испитување на медицинското помагало во Република Македонија или во други држави во кои истото се спроведува и тоа независно од причината за прекинот.

Подносителот на барањето за клиничко испитување на медицинското помагало е должен да ја извести Агенцијата за настаните од ставовите 1 и 2 на овој член во рок од 15 дена од денот на прекин на клиничкото испитување на медицинското помагало (известување за прекин на клиничкото испитување).

11. Следење на несаканите дејства на медицинското помагало

Член 34

За следењето на несаканите дејства на медицинското помагало што клинички се испитува се применуваат одредбите на актот со кој се пропишува начинот на пријавување, собирање и следење на несаканите дејства на медицинското помагало.

III. ПРЕОДНИ И ЗАВРШНИ ОДРЕДБИ

Член 35

Започнатите постапки за добивање на одобрение за клиничко испитување на медицинското помагало пред денот на влегување во сила на овој правилник ќе продолжат согласно прописите по кои се започнати.

Член 36

Овој правилник влегува во сила осмиот ден од денот на објавување во „Службениот весник на Република Македонија”.

Бр. 15-2189/1
април 2010 година
Скопје

Министер,
д-р **Бујар Османи,** с.р.

Прилог 1

БИРО ЗА ЛЕКОВИ – Р.МАКЕДОНИЈА

50 Дивизија бб-Скопје, Р.Македонија, тел.: + 389 (0)2/3112-500 , факс: + 389 (0)2/3298-435

Број на барањето:	Примил/а:
Датум на прием:	Датум на барање за дополнителна документација:
Датум на добивање на дополнителна документација:	Датум на потполно барање:

Пополнува Бирото за лекови на Р.Македонија

БАРАЊЕ ЗА ОДОБРУВАЊЕ НА КЛИНИЧКО ИСПИТУВАЊЕ НА МЕДИЦИНСКО ПОМАГАЛО – ИЗВЕСТУВАЊЕ ЗА КЛИНИЧКО ИСПИТИВАЊЕ

Барање за одобрување на клиничко испитување ☐
Известување за клиничко испитување ☐

Наслов на испитувањето:

Број на протоколот на клиничкото испитивање, вклучувајќи го и бројот на измена и дополнување ако е потребно:

Подносител (име, адреса):

Подносител на барање согласно член 133 од Закон за лековите и медицинските помагала (име, адреса, телефон, факс, e-mail):

Подносител на барање: производител ☐ спонзор ☐ овластен претставник ☐

Испитувано медицинско помагало име, класа, тип, и/или форма и јачина

Производител на медицинското помагало (име, адреса):

Медицинското помагало е регистрирано во РМ: да ☐ Број на одобрението не ☐

Постапката за издавање на одобрение е во тек во РМ: да ☐ не ☐

Медицинското помагало било веќе испитувано во РМ: да ☐ не ☐

Медицинското помагало е регистрирано во други држави: не ☐ да ☐

Начин на примена на медицинското помагало: Начин на примена во клиничкото испитување:

Активна супстанција (доколку содржи помагалото):

Медицинското помагало содржи супстанција која е веќе регистрирана во светот : не ☐ да ☐

Производител на активната супстанција (име, адреса):

Категорија и класа на медицинското помагало:

Класа I ☐

Класа IIа ☐

Класа IIб

Класа III ☐

Ин витро ☐

АИМД медицински помагала ☐

Активни имплантибилни средства ☐

Неактивни имплатибилни средства ☐

Стоматолошки средства ☐

Електро-механички средства ☐

Болничко-апаратурна опрема ☐

Ин-витро дијагностички средства ☐

Анестезиски и респираторни средства ☐

Офталмолошки оптички средства ☐

Инструменти за повеќекратна употреба ☐

Средства за еднократна употреба ☐

Технички средства за хендикепирани лица ☐

Дијагностички и терапевтски средства во радиологија ☐

Други медицински помагала/лекови кои се предвидени за употреба при испитивањето да ☐ не ☐

Да се набројат другите медицински помагала/ лекови кои се предвидени за употреба при испитивањето:
(класа,тип,форма на помагалото/ име на лекот, фармацевтски дозирани форми на лекот и јачина/-и)

Споредбена употреба на друго регистрирано медицинско помагало е дозволена како стандардна терапија
да ☐ не ☐

Карактеристики на испитивањето

Главна цел на испитувањето:

Други цели (ако има):

Тераписка област:

Кардиоваскуларна ☐ ЦНС ☐ Респираторна ☐
Антимикробна ☐ Онкологија ☐ Гастроинтестинална ☐
Ендокринологија ☐ Дерматологија ☐ Друга ☐ Да се наведе која :

Фаза на испитувањето: I. ☐ II. ☐ III. ☐ IV. ☐ Испитивање на биоеквиваленција ☐

Видови на испитување:

Нова индикација ☐ Фармакокинетичка испитувања ☐ Одредување на доза ☐
Нова група на пациенти ☐ Нова комбинација на лек ☐ Нов фармацевтски облик ☐
Зголемен број на испитаници ☐ Постмаркетиншко интервенциско испитување ☐
Постмаркетиншко неинтервенциско испитување ☐
Други испитувања ☐ Да се наведе:
Ако се испитува ефикасноста на медицинското помагало, да се наведат индикациите :

Начин на испитување:

Рандомизирано ☐ Вкрстено ☐ Компаративно ☐ Плацебо контролирано ☐
Отворено ☐ Едноструко слепо ☐ Двоструко слепо ☐ Double dummy ☐

Друго ☐ Да се наведе:

Испитаници: Здрави доброволци ☐ Пациенти ☐

Испитување: Во еден центар ☐ Во повеќе центри во РМ ☐ Меѓународно мултицентрично ☐

Да се наведат државите:

Установа во која се врши испитивањето

Име: Адреса (вклучувајќи и поштенски број на местото): Име на истражувачот:

Контрола на квалитетот на испитувањето да ☐ не ☐

Набљудувач ☐ Одитор ☐ Друга ☐ Да се наведе:

Предвиден датум за почетокот на испитувањето:

Испитувањето е поврзано со добивање на одобрение за ставање на медицинското помагало во промет во РМ
да ☐ не ☐

Клиничкото испитување е веќе одобрено во други држави да ☐ не ☐

Поднесена документација

Пропратно писмо ☐
Доказ дека подносителот е правно лице со седиште во РМ ☐
Доказ за овластување на подносителот на барањето ☐
Протокол ☐
Брошура за истражувачот/ ☐
Збирен извештај за особините на лекот ☐
Позитивно мислење од Етичка Комисија ☐
Документ за евалуација корист/ризик ☐

GMP сертификат	☐
Писмена изјава на Главниот испитувач	☐
CV на Главниот испитувач	☐
Доказ за осигурување на испитаниците	☐
Информирана согласност на македонски јазик	☐
Други докунети за испитаниците (ако има)	☐
Список на држави во кои лекот има одобрение за промет	☐
Список на држави во кои е веќе одобрено или е во постапка на одобрување клиничкото испитување	☐
Список на држави во кои е веќе одобрено истото клиничко испитување, ако се работи за мултицентрично клиничкото испитување	☐

Изјавувам дека податоците во барањето со пропратната документација се вистинити и дека ниту еден важен податок кој може да влијае на безбедноста на учесникот во испитувањето и веродостојноста на заклучокот не е сокриен.	
Име, презиме и стручна подготовка на одговорното лице	
Датум	Потпис на одговорната особа

Прилог 2

БИРО ЗА ЛЕКОВИ – Р.МАКЕДОНИЈА

50 Дивизија бб-Скопје, Р.Македонија, тел.: + 389 (0)2/3112-500 , факс: + 389 (0)2/3298-435

Број на барањето:	Примил/а:
Датум на прием:	Датум на барање за дополнителна документација:
Датум на добивање на дополнителна документација:	Датум на потполно барање:

Пополнува Бирото за лекови на Р.Македонија

БАРАЊЕ ЗА ОДОБРУВАЊЕ НА ПРОМЕНА И ДОПОЛНУВАЊЕ НА ПРОТОКОЛОТ – ОДОБРЕНИЕТО ЗА КЛИНИЧКО ИСПИТУВАЊЕ

Промена и дополнување на протоколот на клиничкото испитување ☐
Промена и дополнување на одобрението за спроведување на клиничкото испитување ☐

Наслов на испитувањето:

Број на протоколот на клиничкото испитување, вклучувајќи го и бројот на поромената и дополнувањето, ако е потребно:

Подносител (име, адреса):

Подносител на барањето согласно член 133 од Закон за лековите и медицинските помагала (име, адреса, телефон, факс, e-mail):

Подносител на барање: производител ☐ спонзор ☐ овластен претставник ☐

Вид на промена и дополнување на клиничкото испитување

Овие промени и дополнувања најмногу се однесуваат на безбедносните мерки кои веќе се применуваат
да ☐ не ☐

Причини за промена и дополнување на клиничкото испитување:

Промени настанати во безбедноста и интегритетот на испитаникот	да ☐	не ☐
Промени настанати во толкување на стручната документација/резултати на испитувањето	да ☐	не ☐
Промени настанати во квалитетот на испитуваниот медицински производ	да ☐	не ☐

Промени во текот на изведувањето на клиничкото испитување:

Промени на местото на испитување	да ☐	не ☐
Вклучување на дополнително место на испитување	да ☐	не ☐
Промена на главниот испитувач	да ☐	не ☐
Промена на подносителот на барањето на клиничкото испитувањето	да ☐	не ☐
Останати промени	да ☐	не ☐

Да се наведе:

Друго: да ☐ не ☐

Да се наведе:

Содржина на промената и дополнувањето на клиничкото испитување:

Промена и дополнување на информациите наведени во одобрението на клиничкото испитување	да ☐	не ☐
Промени и долонувања на протоколот на клиничкото испитување	да ☐	не ☐
Промена и дополнување на другите дополнителни документи	да ☐	не ☐

Да се наведе:

Друго: да ☐ не ☐

Да се наведе:

Причини за промена и дополнување:

Краток опис на промената и дополнувањето:

Доставена документација:

Листа на променети документи ☐

Преглед на предложените промени и дополнувања ☐

Пропратна документација ☐

Други документи ☐

да се наведе:

Изјавувам дека податоците во барањето и пропратната документација се вистинити и дека ниту еден важен податок кој може да влијае на безбедноста на учесникот во испитувањето и веродостојноста на заклучокот не е прикриен.

Име, презиме и стручна подготовка на одговорното лице

Датум

Потпис на одговорното лице

1033.
Na osnovu člana 95 tačke 3 Ustava Crne Gore donosim

UKAZ

O PROGLAŠENJU ZAKONA O ZAŠTITI PODATAKA O LIČNOSTI

("Sl. list Crne Gore", br. 79/08 od 23.12.2008, 70/09 od 21.10.2009, 44/12 od 09.08.2012)

Proglašavam Zakon o zaštiti podataka o ličnosti, koji je donijela Skupština Crne Gore 23. saziva, na šestoj sjednici drugog redovnog zasijedanja u 2008. godini, dana 17. decembra 2008. godine.

Broj: 01-2111/2
Podgorica, 22. decembra 2008. godine

Predsjednik Crne Gore,
Filip Vujanović, s.r.

ZAKON

O ZAŠTITI PODATAKA O LIČNOSTI

I. OPŠTE ODREDBE

Član 1

Zaštita podataka o ličnosti obezbjeđuje se pod uslovima i na način propisan ovim zakonom, a u skladu sa principima i standardima sadržanim u potvrđenim međunarodnim ugovorima o ljudskim pravima i osnovnim slobodama i opšte prihvaćenim pravilima međunarodnog prava.

Član 2

Podaci o ličnosti (u daljem tekstu: lični podaci) moraju se obrađivati na pošten i zakonit način.
Lični podaci ne mogu se obrađivati u većem obimu nego što je potrebno da bi se postigla svrha obrade niti na način koji nije u skladu sa njihovom namjenom.
Lični podaci koji su prikupljeni u statističke ili naučne svrhe u skladu sa zakonom mogu se obrađivati ukoliko su preduzete odgovarajuće mjere zaštite.
Kad se lični podaci daju na korišćenje radi obrade u statističke ili naučno-istraživačke svrhe, ti podaci se moraju dati na korišćenje u obliku koji ne otkriva identitet lica.

Član 3

Lični podaci koji se obrađuju moraju biti tačni i potpuni i moraju se ažurirati.
Ukoliko rokovi za čuvanje obrađenih ličnih podataka nijesu određeni zakonom, lični podaci koji omogućavaju utvrđivanje identiteta lica mogu se čuvati samo za vrijeme koje je potrebno za namjenu za koju se lični podaci obrađuju.

Član 4

Zaštita ličnih podataka obezbjeđuje se svakom licu bez obzira na državljanstvo, prebivalište, rasu, boju kože, pol, jezik, vjeru, političko i drugo uvjerenje, nacionalnost, socijalno porijeklo, imovno stanje, obrazovanje, društveni položaj ili drugo lično svojstvo.

Član 4a

Svrhu i način obrade ličnih podataka utvrđuje rukovalac zbirke ličnih podataka, ako nijesu propisani zakonom.
Rukovalac zbirke ličnih podataka može biti državni organ, organ državne uprave, organ lokalne samouprave ili lokalne uprave, privredno društvo ili drugo pravno lice, preduzetnik ili fizičko lice, koji vrše obradu ličnih podataka u skladu sa ovim zakonom.
Kad sam vrši obradu ličnih podataka ili kad se ti podaci obrađuju u njegovo ime, rukovalac zbirke ličnih podataka

mora da obezbijedi da se ta obrada vrši u skladu sa čl. 2 i 3 ovog zakona.

Član 5

Po ovom zakonu obavezni su da postupaju rukovaoci zbirki ličnih podataka koji obrađuju lične podatke na teritoriji Crne Gore ili van Crne Gore gdje se u skladu sa međunarodnim pravom primjenjuju propisi Crne Gore.

Ovaj zakon primjenjuje se i na rukovaoca zbirke ličnih podataka koji je osnovan van Crne Gore ili nema prebivalište u Crnoj Gori, ako se oprema za obradu ličnih podataka nalazi u Crnoj Gori, izuzev ako se ta oprema koristi samo za prenos ličnih podataka preko teritorije Crne Gore.

Rukovalac zbirke ličnih podataka obavezan je da, u slučaju iz stava 2 ovog člana, odredi predstavnika ili zastupnika sa sjedištem, odnosno prebivalištem u Crnoj Gori odgovornog za primjenu ovog zakona.

Član 6

U slučaju kad su namjena ličnih podataka i način njihove obrade propisani zakonom, rukovalac zbirke ličnih podataka određuje se tim zakonom.

Član 7

Ovaj zakon se primjenjuje na obradu ličnih podataka koja se vrši automatski, u cjelosti ili djelimično ili na drugi način, a sastavni je dio ili će postati dio zbirke ličnih podataka.

Član 8

Ovaj zakon, izuzev odredaba o nadzoru, ne primjenjuje se na obradu ličnih podataka za potrebe odbrane i nacionalne bezbjednosti, ukoliko posebnim zakonom nije drukčije propisano.

Ovaj zakon ne primjenjuje se na fizičko lice, kad obradu ličnih podataka vrši za sopstvene potrebe.

Član 9

Pojedini izrazi upotrijebljeni u ovom zakonu imaju sljedeće značenje:

1) lični podaci su sve informacije koje se odnose na fizičko lice čiji je identitet utvrđen ili se može utvrditi;
2) obrada ličnih podataka je radnja kojom se automatski ili na drugi način lični podaci prikupljaju, evidentiraju, snimaju, organizuju, čuvaju, mijenjaju, povlače, koriste, vrši uvid u njih, otkrivaju putem prenosa, objavljuju ili na drugi način čine dostupnim, svrstavaju, kombinuju, blokiraju, brišu, uništavaju, kao i bilo koja druga radnja koja se vrši na ličnim podacima;
3) zbirka ličnih podataka je strukturalno uređen, centralizovan, decentralizovan ili razvrstan po funkcionalnim ili geografskim osnovama skup ličnih podataka koji su predmet obrade i koji mogu biti dostupni u skladu sa propisanim kriterijumima;
4) treća strana, odnosno korisnik ličnih podataka je svako fizičko ili pravno lice, državni organ, organ državne uprave, organ lokalne samouprave ili lokalne uprave i drugi subjekti koji vrše javna ovlašćenja, koji imaju pravo da obrađuju lične podatke, a nije lice čiji se lični podaci obrađuju, prvobitni rukovalac zbirke ličnih podataka, obrađivač ličnih podataka ili lice zaposleno kod rukovaoca zbirke ličnih podataka ili obrađivača ličnih podataka;
5) obrađivač ličnih podataka je državni organ, organ državne uprave, organ lokalne samouprave i lokalne uprave, privredno društvo ili drugo pravno lice, preduzetnik ili fizičko lice, kome rukovalac zbirke ličnih podataka povjerava, da u njegovo ime vrši poslove u vezi sa obradom ličnih podataka;
6) saglasnost je slobodno data izjava u pisanoj formi ili usmeno na zapisnik, kojom lice nakon što je informisano o namjeni obrade, izražava pristanak da se njegovi lični podaci obrađuju za određenu namjenu;
7) posebne kategorije ličnih podataka su lični podaci koji se odnose na rasno ili etničko porijeklo, političko mišljenja, vjersko ili filozofsko uvjerenje, članstvo u sindikalnim organizacijama, kao i podaci koji se odnose na zdravstveno stanje ili seksualni život;
8) biometrijski podaci su podaci o fizičkim ili fiziološkim karakteristikama koje posjeduje svako fizičko lice, a koje su specifične, jedinstvene i nepromjenljive i na osnovu kojih je moguće, neposredno ili posredno, utvrditi identitet lica;
9) lice je fizičko lice čiji je identitet utvrđen ili se može utvrditi, neposredno ili posredno, a naročito pozivanjem na ličnu identifikacionu oznaku ili jednu ili više karakteristika koje su specifične za fizički, fiziološki, mentalni, ekonomski, kulturni ili društveni identitet tog lica.

II. OBRADA LIČNIH PODATAKA

1. Uslovi

Član 10

Obrada ličnih podataka može se vršiti po prethodno dobijenoj saglasnosti lica čiji se lični podaci obrađuju, koja se može opozvati u svakom trenutku.

Obrada ličnih podataka vrši se bez saglasnosti lica ako je to neophodno radi:

1) izvršavanja zakonom propisanih obaveza rukovaoca zbirke ličnih podataka;
2) zaštite života i drugih vitalnih interesa lica koje nije u mogućnosti da lično da saglasnost;
3) izvršenja ugovora ako je lice ugovorna strana ili radi preduzimanja radnji na zahtjev lica prije zaključivanja ugovora;
4) obavljanja poslova od javnog interesa ili u vršenju javnih ovlašćenja koja su u djelokrugu rada, odnosno nadležnosti rukovaoca zbirke ličnih podataka ili treće strane, odnosno korisnika ličnih podataka;
5) ostvarivanja na zakonu zasnovanog interesa rukovaoca zbirke ličnih podataka ili treće strane, odnosno korisnika ličnih podataka, izuzev ako takve interese treba ograničiti radi ostvarivanja i zaštite prava i sloboda lica.

Saglasnost iz stava 1 ovog člana, za lice lišeno poslovne sposobnosti daje staratelj, a za maloljetno lice roditelji ili usvojioci, odnosno staratelj, osim ako saglasnost nije u suprotnosti sa interesima maloljetnog lica.

Saglasnost za obradu ličnih podataka za umrlo lice daju njegovi nasljednici, određeni u skladu sa zakonom kojim se uređuje pravo nasljeđivanja, ukoliko umrlo lice nije zabranilo obradu ličnih podataka.

Član 11

Briše se. ("Sl. list CG", br. 44/12)

Član 12

Lični podaci koji se odnose na maloljetno lice obrađuju se u skladu sa zakonom, na način koji je u najboljem interesu maloljetnog lica.

Član 13

Posebne kategorije ličnih podataka mogu se obrađivati samo:

1) uz izričitu saglasnost lica;
2) kad je obrada ličnih podataka neophodna radi zapošljavanja u skladu sa zakonom kojim se uređuju radni odnosi, pri čemu se moraju propisati adekvatne mjere zaštite;
3) kad je obrada ličnih podataka neophodna radi otkrivanja, prevencije i dijagnostikovanja bolesti i liječenja lica, kao i radi upravljanja zdravstvenim službama, ako te podatke obrađuje zdravstveni radnik ili drugo lice koje ima obavezu čuvanja tajne;
4) kad je to neophodno radi zaštite života ili drugih vitalnih interesa lica na koje se odnose lični podaci ili drugog lica, a to lice nije u mogućnosti da lično da saglasnost, kao i u drugim slučajevima propisanim zakonom;
5) ako je lice na očigledan način lične podatke učinilo dostupnim javnosti ili je obrada neophodna za ostvarivanje ili zaštitu pravnih interesa tog lica pred sudom ili drugim organima;
6) kad se obrada ličnih podataka vrši u okviru zakonite djelatnosti nevladine organizacije, odnosno udruženja ili druge neprofitne organizacije sa političkim, filozofskim, vjerskim ili sindikalnim ciljevima, ako se ti podaci odnose samo na članove te organizacije ili lica koja imaju stalan kontakt sa njom u vezi sa svrhom njene djelatnosti i ako se ti podaci ne objavljuju bez saglasnosti tih lica.

Posebne kategorije ličnih podataka posebno se označavaju i štite radi sprječavanja neovlašćenog pristupa tim podacima.

Način označavanja i zaštite ličnih podataka iz stava 2 ovog člana utvrđuje ministarstvo nadležno za poslove javne uprave.

Član 14

Obrada ličnih podataka koja se odnosi na krivična djela, izrečene krivične i prekršajne kazne ili mjere bezbjednosti može se vršiti samo od strane ili pod nadzorom nadležnog državnog organa i ako su obezbijeđene mjere zaštite ličnih podataka u skladu sa zakonom.

Član 15

Prije obrade ličnih podataka u svrhe direktnog marketinga, licu se mora dati mogućnost da se usprotivi obradi podataka.

Ukoliko se u svrhe direktnog marketinga koriste podaci iz člana 13 ovog zakona, neophodna je saglasnost lica čiji se podaci obrađuju.

Član 15a

Prilikom odlučivanja o pravima, obavezama i interesima lica, procjenjivanje njegovih ličnih svojstava i sposobnosti (rezultati rada na radnom mjestu, pouzdanost, kreditna sposobnost, ponašanje i sl.), koji su od značaja za odlučivanje, ne mogu se zasnivati isključivo na automatskoj obradi podataka.

Izuzetno od stava 1 ovog člana, odlučivanje se može zasnovati samo na automatskoj obradi podataka samo ako je:

1) u toku zaključivanja ili izvršavanja ugovora uvažen zahtjev lica čiji se podaci obrađuju ili postoje odgovarajuće mjere zaštite njegovih zakonitih interesa (mogućnost da lice izrazi svoje mišljenje i sl.);
2) to zakonom propisano, pod uslovom da su propisane mjere zaštite zakonitih interesa lica.

2. Povjeravanje

Član 16

Rukovalac zbirke ličnih podataka može pojedine poslove u vezi sa obradom ličnih podataka iz svog djelokruga povjeriti obrađivaču ličnih podataka ugovorom, koji mora biti u pisanoj formi.

Ugovorom iz stava 1 ovog člana uređuju se međusobna prava i obaveze rukovaoca zbirke ličnih podataka i obrađivača ličnih podataka a naročito obaveza obrađivača da postupa po uputstvima rukovaoca zbirki ličnih podataka.

Poslovi iz stava 1 ovog člana mogu se povjeriti samo obrađivaču ličnih podataka koji ispunjava uslove za sprovođenje tehničkih, kadrovskih i organizacionih mjera za zaštitu ličnih podata-ka, u skladu sa ovim zakonom.

Obrađivač ličnih podataka je obavezan da lične podatke nakon obrade uništi ili vrati rukovaocu zbirke ličnih podataka.

3. Davanje ličnih podataka na korišćenje drugim rukovaocima zbirki ličnih podataka

Član 17

Ukoliko su ispunjeni uslovi iz čl. 10 i 13 ovog zakona, rukovalac zbirke ličnih podataka mora trećoj strani, odnosno korisniku ličnih podataka, na njegov zahtjev, dati lične podatke koji su mu potrebni.

Zahtjev iz stava 1 ovog člana sadrži informacije o kategorijama ličnih podataka koji se traže, njihovoj namjeni, pravnom osnovu za korišćenje i davanje podataka na korišćenje, vremenu korišćenja i dovoljno podataka za identifikaciju lica čiji se podaci traže.

U slučaju kad se lični podaci traže na korišćenje za potrebe nacionalne bezbjednosti, odbrane i pretkrivičnog i krivičnog postupka, zahtjev može da sadrži i vrijeme do kad lice čiji se podaci traže ne može znati da su njegovi podaci korišćeni.

Izuzetno, treće lice, odnosno korisnik ličnih podataka može tražiti na korišćenje lične podatke lica i na osnovu informacija koje nijesu dovoljne za identifikaciju lica u smislu stava 2 ovog člana, ako je to propisano posebnim zakonom.

Član 18

Lični podaci mogu se koristiti samo za vrijeme potrebno za ostvarivanje svrhe koja je navedena u zahtjevu za davanje podataka na korišćenje, ako posebnim zakonom nije drukčije određeno.

Po proteku vremena iz stava 1 ovog člana, korisnik ličnih podataka je dužan da briše lične podatke, ako posebnim zakonom nije drukčije određeno.

Član 19

Rukovalac zbirke ličnih podataka vodi evidenciju o trećim stranama, odnosno korisnicima ličnih podataka, ličnim podacima koji su dati na korišćenje, namjeni za koju su dati, pravnom osnovu za korišćenje i davanje podataka na korišćenje i vremenu korišćenja.

Evidencija iz stava 1 ovog člana vodi se za period od 10 godina, nakon čega se podaci iz evidencije brišu.

4. Obaveza obavještavanja lica o obradi, ažuriranju i brisanju ličnih podataka

Član 20

Rukovalac zbirke ličnih podataka mora, osim ako posebnim zakonom nije drukčije propisano, licu od kojeg neposredno prikuplja podatke radi obrade dati obavještenje o:

1) svom ličnom imenu, odnosno nazivu i adresi, kao i ličnom imenu, odnosno nazivu i adresi svog predstavnika ili zastupnika iz člana 5 stav 3 ovog zakona;
2) svrsi i pravnom osnovu za obradu ličnih podataka;
3) trećoj strani, odnosno korisniku ličnih podataka i pravnom osnovu za davanje podataka na korišćenje;
4) tome da li je davanje ličnih podataka obavezno ili dobrovoljno i o mogućim posljedicama odbijanja davanja tih podataka;
5) pravu pristupa ličnim podacima i pravu na ispravljanje ličnih podataka koji se odnose na to lice.

Obavještenje iz stava 1 tač. 1, 2, 4 i 5 ovog člana daje se u trenutku prikupljanja ličnih podataka, a obavještenje iz tačke 3 ovog člana najkasnije u trenutku davanja ličnih podataka na korišćenje.

Član 21

Rukovalac zbirke ličnih podataka obavezan je da, kad podaci nijesu prikupljeni neposredno od lica na koje se odnose, najkasnije neposredno prije početka obrade ličnih podataka to lice obavijesti o:

1) svom ličnom imenu, odnosno nazivu, prebivalištu ili boravištu, odnosno sjedištu, kao i o svom predstavniku;
2) namjeni i pravnom osnovu za obradu ličnih podataka;
3) vrsti ličnih podataka koji se obrađuju;
4) trećoj strani, odnosno korisniku ličnih podataka;
5) pravu pristupa ličnim podacima i pravu na ispravljanje podataka koji se na njega odnose.

Izuzetno od stava 1 ovog člana, rukovalac zbirke ličnih podataka nije obavezan da obavijesti lice na koje se podaci odnose kad se lični podaci daju na korišćenje za statističke ili naučno - istraživačke svrhe ili je obrada ličnih podataka propisana zakonom, ako je dostavljanje tih podataka nemoguće ili zahtijeva aktivnosti koje nijesu srazmjerne cilju obavještavanja.

U slučaju iz stava 2 ovog člana, rukovalac zbirke ličnih podataka je obavezan da predvidi odgovarajuće mjere zaštite.

Član 22

Rukovalac zbirke ličnih podataka obavezan je da obezbijedi da lični podaci koje obrađuje budu tačni i potpuni, uzimajući u obzir svrhu za koju su prikupljeni.

Kad utvrdi da su lični podaci nepotpuni ili netačni, rukovalac zbirke ličnih podataka je obavezan da ih dopuni ili izmijeni.

Član 23

Rukovalac zbirke ličnih podataka obavezan je da, na zahtjev lica, briše lične podatke ako njihova obrada nije u skladu sa zakonom.

Dok traje postupak po zahtjevu iz stava 1 ovog člana, odnosno postupak provjere da li su lični podaci tačni i potpuni u smislu člana 22 ovog zakona, pristup obrađenim podacima se obustavlja.

5. Mjere za zaštitu ličnih podataka prilikom obrade

Član 24

Rukovalac zbirke ličnih podataka i obrađivač ličnih podataka obavezni su da obezbijede tehničke, kadrovske i organizacione mjere zaštite ličnih podataka, radi zaštite od gubitka, uništenja, nedopuštenog pristupa, promjene, objavljivanja, kao i od zloupotrebe.

Mjere zaštite ličnih podataka iz stava 1 ovog člana moraju odgovarati prirodi i karakteru podataka koji se obrađuju, uzimajući u obzir najviši nivo tehnologije i troškove njihovog sprovođenja.

Ako se obrada ličnih podataka vrši elektronskim putem, rukovalac zbirke ličnih podataka obavezan je da obezbijedi da se u informacionom sistemu automatski evidentiraju korisnici ličnih podataka, podaci koji su obrađivani, pravni osnov za korišćenje podataka, broj predmeta, vrijeme odjave i prijave sa sistema i po potrebi datum do kad podaci o korisniku nijesu dostupni licu čiji su podaci obrađivani.

Rukovalac zbirke ličnih podataka obavezan je da odredi koji zaposleni i kojim ličnim podacima imaju pristup, kao i kategorije podataka koje se mogu dati na korišćenje i pod kojim uslovima.

Rukovalac zbirke ličnih podataka dozvoljava pristup zbirkama ličnih podataka i vodi evidenciju o korisnicima ličnih podataka u skladu sa svojim aktom.

Član 25

Službena i druga lica koja u državnom organu, organu državne uprave, organu lokalne samouprave i lokalne uprave, privrednom društvu i drugom pravnom licu vrše obradu ličnih podataka postupaju isključivo po uputstvima starješine organa, odnosno odgovornog lica u pravnom licu i obavezni su da čuvaju tajnost ličnih podataka za koje su saznali prilikom obavljanja svojih poslova, ukoliko zakonom nije drukčije propisano.

6. Evidencije i registri zbirki podataka o ličnosti

Član 26

Rukovalac zbirke ličnih podataka vodi evidenciju podataka o zbirkama ličnih podataka koje ustanovljava.

Evidencija iz stava 1 ovog člana sadrži:

1) naziv zbirke ličnih podataka;
2) pravni osnov za obradu ličnih podataka;
3) lično ime, odnosno naziv rukovaoca zbirke, njegovo sjedište, odnosno prebivalište ili boravište i adresu;
4) svrhu obrade ličnih podataka;
5) kategorije lica;
6) vrste ličnih podataka sadržanih u zbirci ličnih podataka;
7) rok čuvanja i korišćenja ličnih podataka;
8) lično ime, odnosno naziv treće strane, odnosno korisnika ličnih podataka, njegovo sjedište, odnosno prebivalište ili boravište i adresu;
9) podatke o iznošenju ličnih podataka iz Crne Gore sa naznakom države u koju se podaci iznose, odnosno međunarodne organizacije ili drugog stranog korisnika ličnih podataka, svrhu iznošenja utvrđenu potvrđenim međunarodnim ugovorom i zakonom, odnosno određenu pisanom saglasnošću lica;
10) interna pravila obrade i zaštite ličnih podataka rukovaoca zbirke, koja omogućavaju prethodnu analizu adekvatnosti mjera u cilju obezbjeđivanja bezbjednosti obrade.

Obrazac i način vođenja evidencije iz stava 1 ovog člana utvrđuje ministarstvo nadležno za poslove javne uprave.

Član 27

Rukovalac zbirke ličnih podataka obavezan je da prije uspostavljanja automatske zbirke ličnih podataka dostavi obavještenje nadzornom organu koje sadži podatke iz člana 26 stav 2 ovog zakona. Na isti način će postupiti rukovalac zbirke ličnih podataka kad dođe do značajne izmjene u obradi ličnih podataka.

Obaveza iz stave 1 ovog člana ne odnosi se na javne registre i evidencije uspostavljene u skladu sa zakonom.

Rukovalac zbirke ličnih podataka obavezan je da, nakon uspostavljanja automatske zbirke ličnih podataka, odredi lice odgovorno za zaštitu ličnih podataka. Rukovalac zbirke ličnih podataka koji ima manje od 10 službenika koji vrše obradu ličnih podataka nije obavezan da odredi lice odgovorno za zaštitu ličnih podataka.

Član 28

Ukoliko rukovalac zbirke ličnih podataka planira automatsku obradu ličnih podataka koja predstavlja poseban rizik za prava i slobode lica, obavezan je da prije svake automatske obrade ličnih podataka dobije saglasnost nadzornog organa, a naročito ako se:

1) predviđa obrada posebnih kategorija ličnih podataka;
2) predviđa obrada ličnih podataka koji se odnose na procjenu ličnosti, sposobnosti ili ponašanje;
3) obrađuju biometrijski podaci.

Odredbe stava 1 ovog člana ne primjenjuju se ako se obrada ličnih podataka vrši na osnovu zakona, ako je lice dalo saglasnost za obradu ličnih podataka ili je obrada neophodna za ispunjavanje ugovora između rukovaoca zbirke ličnih podataka i lica.

Član 29

Registar evidencija o zbirkama ličnih podataka iz člana 26 stav 1 ovog zakona (u daljem tekstu: Registar) vodi nadzorni organ.

U Registar se unose podaci iz člana 26 stav 2 ovog zakona.

Izuzetno od stava 2 ovog člana, u Registar se ne unose podaci o zbirkama ličnih podataka kad to zahtijevaju interesi odbrane, nacionalne i javne bezbjednosti, kao i zaštite života i zdravlja ljudi, po pribavljenom mišljenju nadzornog organa.

Član 30

Evidencije iz Registra dostupne su javnosti na način utvrđen pravilima o radu nadzornog organa, u skladu sa zakonom.

III. POSEBNI VIDOVI OBRADE LIČNIH PODATAKA

1. Biometrijske mjere

Član 31

Utvrđivanje i upoređivanje svojstva lica, radi utvrđivanja i dokazivanja njegovog identiteta, obradom biometrijskih podataka (u daljem tekstu: biometrijske mjere) mogu se vršiti u skladu sa ovim zakonom.

Član 32

Državni organ, organ državne uprave, organ lokalne samouprave i lokalne uprave, privredno društvo i drugo pravno lice i preduzetnik koji vrši javna ovlašćenja (u daljem tekstu: javni sektor) mogu primjenjivati biometrijske mjere u vezi sa ulaskom u poslovni, odnosno službeni prostor i prisustvom zaposlenih na poslu, ako su te mjere propisane zakonom.

Mjere iz stava 1 ovog člana mogu se propisati ako je to neophodno radi bezbjednosti lica ili imovine ili radi zaštite tajnih podataka ili poslovnih tajni, ako se to ne može postići na drugi način ili radi izvršavanja obaveza iz međunarodnih ugovora i utvrđivanja identiteta lica koja prelaze državnu granicu.

2. Evidencija o ulasku i izlasku iz poslovnog ili službenog prostora

Član 33

Radi zaštite lične i imovinske bezbjednosti poslovnog, odnosno službenog prostora, javni sektor, privredno društvo, drugo pravno lice i preduzetnik može zahtijevati od lica koje ulazi u poslovni, odnosno službeni prostor da:

1) saopšti razlog ulaska u poslovni, odnosno službeni prostor;
2) da lične podatke;
3) stavi na uvid identifikacioni dokument, ako je to potrebno.

Identifikacioni dokument iz stava 1 tačka 3 ovog člana je dokument o utvrđivanju identiteta izdat u skladu sa zakonom.

Lični podaci iz stava 1 tačka 2 ovog člana su lično ime, vrsta i broj identifikacionog dokumenta, prebivalište ili boravište, adresa i zaposlenje.

Član 34

O ulascima i izlascima iz poslovnog, odnosno službenog prostora može se voditi evidencija.

Evidencija iz stava 1 ovog člana može da sadrži lične podatke iz člana 33 stav 3 ovog zakona, datum, vrijeme, razlog ulaska u poslovni, odnosno službeni prostor ili objekat i izlaska iz njih.

Evidencija iz stava 1 ovog člana ima snagu javne isprave, ako se podaci koriste radi zaštite maloljetnog lica i obavljanja policijskih i obavještajno - bezbjednosnih poslova.

Lični podaci iz evidencije iz stava 1 ovog člana čuvaju se najduže jednu godinu od dana prikupljanja, nakon čega se brišu, ako zakonom nije drukčije određeno.

3. Video nadzor

Član 35

Javni sektor, privredno društvo, drugo pravno lice i preduzetnik može da vrši video nadzor pristupa u službeni ili poslovni prostor, radi bezbjednosti lica i imovine, kontrole ulaska ili izlaska iz službenog ili poslovnog prostora ili, ako zbog prirode posla, postoji mogući rizik za zaposlene.

Odluku o uvođenju video nadzora iz stava 1 ovog člana donosi starješina državnog organa, organa državne uprave, organa lokalne samouprave ili lokalne uprave ili odgovorno lice u privrednom društvu ili drugom pravnom licu, odnosno preduzetnik, ukoliko uvođenje video nadzora nije propisano zakonom.

Odluka iz stava 2 ovog člana donosi se u pisanoj formi i sadrži razloge za uvođenje video nadzora.

Video nadzor iz stava 1 ovog člana vrši se na način kojim se ne prikazuju snimci unutrašnjosti stambenih zgrada koji

nijesu povezani sa ulazom u službene i poslovne prostorije, niti snimci ulaza u stanove.

Zaposleni koji rade u prostoru pod video nadzorom iz stava 1 ovog člana moraju, u pisanom obliku, biti obaviješteni o vršenju video nadzora.

Zabranjen je pristup snimcima sistema video nadzora iz stava 1 ovog člana preko interne kablovske televizije, javne kablovske televizije, interneta ili drugih sredstava za elektronske komunikacije kojima se takvi snimci mogu prenijeti, bilo u trenutku njihovog nastanka ili nakon toga.

Član 36

Javni sektor, privredno društvo i drugo pravno lice i preduzetnik može da vrši video nadzor u službenom ili poslovnom prostoru ako to nalažu razlozi zaštite bezbjednosti lica ili imovine ili tajnih podataka i poslovnih tajni i ako se to ne može ostvariti na drugi način.

Video nadzor nije dozvoljen u službenom i poslovnom prostoru van radnog mjesta, naročito u garderobama, liftovima i sanitarnim prostorijama i u prostoru predviđenom za stranke i posjetioce.

Odluku o uvođenju video nadzora iz stava 1 ovog člana, ukoliko uvođenje video nadzora nije propisano zakonom, donosi starješina državnog organa, organa lokalne samouprave i lokalne uprave ili odgovorno lice u privrednom društvu ili drugom prav-nom licu, odnosno preduzetnik.

Lica iz stava 3 ovog člana dužna su da, prije donošenja odluke o uvođenju video nadzora, pribave mišljenje reprezentativnog sindikata, odnosno predstavnika zaposle-nih.

Zaposleni moraju biti obaviješteni o uvođenju video nadzora u pisanom obliku prije početka vršenja video nadzora.

Odredba stava 4 ovog člana ne primjenjuju se na službeni i poslovni prostor državnih organa nadležnih za poslove u oblasti odbrane, nacionalne i javne bezbjed-nosti i zaštite tajnih podataka.

Član 37

O video nadzoru iz člana 35 stav 1 i člana 36 stav 1 ovog zakona vodi se evidencija.

Evidencija iz stava 1 ovog člana može da sadrži: snimak lica (sliku ili zvuk, odnosno sliku i zvuk), datum i vrijeme snimanja ulaska i izlaska, a po potrebi i lično ime snimljenog lica, njegovo prebivalište ili boravište i adresu, zaposlenje, vrstu i broj identifikacionog dokumenta, razloge ulaska, ako su lični podaci koji su uneseni prikupljeni pored snimka ili putem snimka sistema video nadzora.

Lični podaci iz evidencije iz stava 1 ovog člana čuvaju se najduže godinu dana od dana nastanka.

Član 38

U stambenim zgradama može da se vrši video nadzor ulaza i izlaza u zgradu, kao i zajedničkih prostorija.

Za uvođenje video nadzora u stambenoj zgradi potrebna je saglasnost skupštine etažnih vlasnika, u pisanoj formi.

Saglasnost iz stava 2 ovog člana data je ako se za nju izjasne članovi skupštine vlasnika stambene zgrade, lamele ili ulaza kojima pripada više od 70% vlasništva.

Ne može se vršiti video nadzor ulaza u stanove.

Član 39

Javni sektor, privredno društvo i drugo pravno lice i preduzetnik koji vrši video nadzor obavezan je da istakne javno obavještenje da se vrši video nadzor.

Obavještenje iz stava 1 ovog člana mora biti istaknuto na vidnom mjestu na način koji omogućava licima da se sa vršenjem video nadzora upoznaju prije početka vršenja video nadzora, a najkasnije u trenutku kad počinje vršenje video nadzora.

Obavještenje iz stava 1 ovog člana sadrži podatke o:

1) zvanju lica koje vrši video nadzor;

2) broju telefona na koji se mogu dobiti informacije gdje se i koliko dugo čuvaju snimci iz sistema video nadzora.

Isticanjem obavještenja iz stava 1 ovog člana smatra se da je lice obaviješteno o obradi ličnih podataka putem video nadzora.

Sistem video nadzora koji se koristi za vršenje video nadzora mora biti zaštićen od pristupa neovlašćenih lica.

Član 40

Odredbe člana 35 ovog zakona shodno se primjenjuju na vršenje video nadzora javnih površina, ako posebnim zakonom nije drukčije određeno.

IV. IZNOŠENJE LIČNIH PODATAKA IZ CRNE GORE

Član 41

Lični podaci koji se obrađuju mogu se iznositi iz Crne Gore u drugu državu ili davati na korišćenje međunarodnoj organizaciji, koja primjenjuje adekvatne mjere zaštite ličnih podataka propisane ovim zakonom, na osnovu prethodno pribavljene saglasnosti nadzornog organa.

Adekvatnost mjera zaštite iz stava 1 ovog člana procjenjuje se na osnovu konkretnih okolnosti u kojima se sprovodi postupak prenosa ličnih podataka ili postupak prenosa skupa tih podataka, pri čemu se posebno uzima u obzir:

1) priroda ličnih podataka;
2) svrha i trajanje predloženog postupka ili postupka obrade;
3) država porijekla i država krajnjeg odredišta;
4) zakonom propisana pravila koja su na snazi u državi u koju se iznose podaci;
5) pravila profesije i bezbjedonosne mjere koje se moraju poštovati u toj zemlji.

Za iznošenje ličnih podataka radi povjeravanja pojedinih poslova obrade, u smislu člana 16 ovog zakona, neophodna je saglasnost nadzornog organa, osim u slučaju iz člana 42 tačka 6 ovog zakona.

Član 42

Saglasnost iz člana 41 stav 1 ovog zakona nije obavezna kad:

1) je iznošenje ličnih podataka propisano posebnim zakonom ili međunarodnim ugovorom koji obavezuje Crnu Goru;
2) je od lica čiji se podaci iznose dobijena prethodna saglasnost i lice upoznato sa mogućim posljedicama iznošenja podataka;
3) je iznošenje ličnih podataka potrebno radi izvršavanja ugovora između pravnog ili fizičkog lica i rukovaoca zbirke ličnih podataka ili ispunjavanja predugo-vornih obaveza;
4) je iznošenje ličnih podataka potrebno radi spašavanja života lica na koje se podaci odnose ili kad je to u njegovom interesu;
5) se iznošenje ličnih podataka obavlja iz registara ili evidencija koje su, u skladu sa zakonom ili drugim propisima, dostupne javnosti;
6) se iznose podaci u države članice Evropske Unije i evropskog ekonomskog prostora ili države koje se nalaze na listi Evropske Unije koje imaju adekvatan stepen zaštite podataka o ličnosti;
7) je prenos ličnih podataka neophodan radi ostvarivanja javnog interesa ili radi ostvarivanja ili zaštite pravnih interesa lica na koje se podaci odnose;
8) rukovalac zbirke ličnih podataka zaključi ugovor, koji sadrži odgovarajuće ugovorne obaveze prihvaćene od strane država članica Evropske Unije, sa obrađivačem ličnih podataka iz države koja nije članica Evropske Unije;i
9) je prenos ličnih podataka potreban radi zaključenja ili ispunjavanja ugovora između rukovaoca zbirke ličnih podataka sa pravnim ili fizičkim licem, kad je ugovor u interesu lica čiji se podaci obrađuju.

V. PRAVA LICA NA ZAŠTITU LIČNIH PODATAKA

Član 43

Rukovalac zbirke ličnih podataka obavezan je da, na pisani zahtjev lica, odnosno njegovog zakonskog zastupnika ili punomoćnika, nakon utvrđivanja identiteta tog lica, najkasnije u roku do 15 dana od dana podnošenja zahtjeva, dostavi obavještenje o tome da li se lični podaci koji se na njega odnose obrađuju.

Ukoliko se podaci o licu obrađuju, rukovalac zbirke ličnih podataka je dužan u obavještenju iz stava 1 ovog člana dati dodatne informacije o:

1) ličnom imenu, odnosno nazivu i adresi rukovaoca zbirke ličnih podataka;
2) imenu, odnosno nazivu i adresi obrađivača ličnih podataka u slučaju kad se to izričito zahtjeva;
3) sadržaju podataka koji se obrađuju;
4) svrsi i pravnom osnovu za obradu ličnih podataka;
5) o izvoru podataka prema raspoloživim informacijama;
6) trećoj strani, odnosno korisniku;
7) načinu automatske obrade ličnih podataka u slučaju iz člana 15a ovog zakona.

Obavještenje iz stave 1 ovog člana daje se u pisanom obliku i mora biti razumljivo.

Član 44

Rukovalac zbirke ličnih podataka obavezan je da, na pisani zahtjev lica na koje se podaci odnose, odnosno njegovog

zakonskog zastupnika ili punomoćnika, u roku do 15 dana od dana podnošenja zahtjeva:

1) dopuni nepotpun ili izmijeni, odnosno izbriše netačan lični podatak;
2) briše lični podatak, ako njegova obrada nije u skladu sa zakonom.

O izvršenoj dopuni ili izmjeni i brisanju ličnih podataka iz stava 1 ovog člana, rukovodilac zbirke podataka je obavezan da, u roku od osam dana, obavijesti lice, odnosno njegovog zakonskog zastupnika ili punomoćnika, kao i treću stranu, odnosno korisnika ličnih podataka, izuzev ako se to pokaže nemogućim.

Ako rukovalac zbirke ličnih podataka ne postupi u skladu sa st. 1 i 2 ovog člana ili odbije zahtjev iz stava 1 ovog člana, lice ima pravo da podnese prigovor rukovaocu zbirke ličnih podataka u skladu sa posebnim zakonom ili da zahtijeva zaštitu prava kod nadzornog organa.

Član 45

Prava lica iz čl. 43 i 44 ovog zakona mogu se ograničiti ako je to potrebno radi odbrane, nacionalne i javne bezbjednosti, sprječavanja izvršenja krivičnih djela, otkrivanja i gonjenja učinilaca krivičnih djela, zaštite privrednog ili finansijskog interesa, kao i radi zaštite lica ili prava i sloboda drugih, u obimu koji je nužan za ostvarivanje svrhe radi koje je ograničenje utvrđeno, u skladu sa posebnim zakonom.

Član 46

Troškove postupka iz čl. 43 i 44 ovog zakona snosi rukovalac zbirke ličnih podataka, ako zakonom nije drukčije propisano.

Član 47

Lice koje smatra da su mu povrijeđena prava propisana ovim zakonom može podnijeti zahtjev za zaštitu prava nadzornom organu.

Nadzorni organ je dužan da po zahtjevu odluči rješenjem, u roku od 60 dana od dana podnošenja zahtjeva.

Postupak i odlučivanje po zahtjevu iz stava 1 ovog člana sprovodi se u skladu sa odredbama čl. 66 do 73 ovog zakona.

Do donošenja odluke iz stava 2 ovog člana, nadzorni organ može, na pisani zahtjev lica koje je podnijelo zahtjev za zaštitu prava, rješenjem privremeno zabraniti dalju obradu ličnih podataka, ako postoji ili je učinjena vjerovatnom povreda prava utvrđena ovim zakonom.

Protiv rješenja iz stava 2 ovog člana može se pokrenuti upravni spor.

Član 48

Za štetu koju je lice pretrpjelo zbog povrede prava propisanih ovih zakonom odgovara rukovalac zbirke ličnih podataka u skladu sa opštim pravilima o naknadi štete.

VI. AGENCIJA ZA ZAŠTITU LIČNIH PODATAKA

Član 49

Za vršenje poslova nadzornog organa utvrđenih ovim zakonom osniva se Agencija za zaštitu ličnih podataka (u daljem tekstu: Agencija).

Agencija je u vršenju poslova iz svog djelokruga samostalna i nezavisna.

Agencija ima svojstvo pravnog lica.

Član 50

Agencija:

1) vrši nadzor nad sprovođenjem zaštite ličnih podataka u skladu sa ovim zakonom;
2) rješava po zahtjevima za zaštitu prava;
3) daje mišljenja u vezi primjene ovog zakona;
4) daje saglasnost u vezi sa uspostavljanjem zbirki ličnih podataka;
5) daje mišljenje u slučaju kad postoji sumnja da li se određeni skup ličnih podataka smatra zbirkom u smislu ovog zakona;
6) prati primjenu organizacionih i tehničkih mjera za zaštitu ličnih podataka i predlaže poboljšanje tih mjera;
7) daje predloge i preporuke za unaprjeđenje zaštite ličnih podataka;
8) daje mišljenje da li određeni način obrade ličnih podataka ugrožava prava i slobode lica;
9) sarađuje sa organima nadležnim za nadzor nad zaštitom ličnih podataka u drugim zemljama;

10) sarađuje sa nadležnim državnim organima u postupku pripreme propisa koji se odnose na zaštitu ličnih podataka;
11) daje predlog za ocjenu ustavnosti zakona, odnosno ustavnosti i zakonitosti drugih propisa i opštih akata kojima se uređuju pitanja obrade ličnih podataka;
12) obavlja i druge poslove u skladu sa zakonom kojim se uređuje slobodan pristup informacijama i ovim zakonom.

Član 51

Organi Agencije su Savjet Agencije i direktor.

Član 52

Savjet Agencije ima predsjednika i dva člana.

Predsjednika i članove Savjeta Agencije imenuje Skupština Crne Gore (u daljem tekstu: Skupština), na predlog nadležnog radnog tijela.

Predsjednik i članovi Savjeta Agencije imenuju se na period od pet godina i na te dužnosti ne mogu biti imenovani više od dva puta.

Predsjednik i članovi Savjeta Agencije za svoj rad odgovaraju Skupštini.

Član 53

Za predsjednika, odnosno člana Savjeta Agencije može biti imenovano lice koje:
1) je crnogorski državljanin;
2) ima visoku stručnu spremu;
3) pet godina radnog iskustva u obavljanju poslova iz oblasti ljudskih prava i sloboda.

Član 54

Za predsjednika i člana Savjeta Agencije ne može biti imenovano lice koje je:
1) poslanik ili odbornik;
2) članovi Vlade;
3) imenovala ili postavila Vlada Crne Gore;
4) funkcioner političke stranke (predsjednik stranke, član predsjedništva, njihov zamjenik, član izvršnog i glavnog odbora i drugi stranački funkcioner);
5) pravosnažno osuđeno za krivično djelo koje se goni po službenoj dužnosti, bez obzira na izrečenu sankciju ili je pravosnažno osuđeno za drugo krivično djelo na kaznu zatvora u trajanju dužem od šest mjeseci, u periodu dok traju pravne posljedice osude.
6) bračni drug lica iz tač. 1, 2 i 3 ovog stava ili su sa njima u srodstvu po prvoj liniji, u pobočnoj liniji do drugog stepena i u srodstvu po tazbini.

Kandidat za člana Savjeta Agencije je dužan da nadležnom radnom tijelu iz člana 52 stav 2 ovog zakona dostavi pisanu izjavu da ne postoje smetnje za imenovanje utvrđene ovim zakonom.

Član 55

Predsjednik, odnosno član Savjeta Agencije može biti razriješen prije isteka vremena na koje je imenovan:
1) na lični zahtjev;
2) zbog trajnog gubitka radne sposobnosti za obavljanje funkcije;
3) ako nastanu okolnosti iz člana 54 ovog zakona;
4) ako prekrši obavezu čuvanja ličnih podataka.

Član 56

Savjet Agencije:
1) donosi pravila Agencije;
2) donosi statut i akt o sistematizaciji, uz saglasnost radnog tijela iz člana 52 stav 2 ovog zakona, kao i druge akte Agencije;
3) priprema godišnji i posebni izvještaj o stanju zaštite ličnih podataka;
4) utvrđuje godišnji plan rada i godišnji izvještaj o radu Agencije;
5) utvrđuje predlog finansijskog plana i završnog računa;
6) donosi odluke po prigovoru iz člana 68 stav 3 ovog zakona;
6a) odlučuje u skladu sa zakonom kojim se uređuje slobodan pristup informacijama;

7) obavlja i druge poslove utvrđene zakonom i statutom Agencije.

Pravila iz stava 1 tačka 1 ovog člana objavljuju se u "Službenom listu Crne Gore"..

Član 57

Savjet Agencije odlučuje većinom glasova od ukupnog broja članova Savjeta.

Član 58

Direktora Agencije imenuje Savjet Agencije, na osnovu javnog konkursa, na period od četiri godine.

Za direktora Agencije ne može biti imenovano lice koje ne ispunjava uslove da bude član Savjeta Agencije po ovom zakonu.

Član 59

Direktor Agencije:

1) zastupa i predstavlja Agenciju;
2) organizuje i vodi Agenciju;
3) izvršava odluke Savjeta Agencije;
4) predlaže Savjetu Agencije planove rada, izvještaje o stanju zaštite ličnih podataka, mišljenja u vezi primjene ovog zakona, mišljenja u slučaju kad postoji sumnja da li se određeni skup ličnih podataka smatra zbirkom u smislu ovog zakona, mišljenja da li određeni način obrade ličnih podataka ugrožava prava i slobode lica, predloge i preporuke za unaprjeđenje zaštite ličnih podataka, podnošenje predloge za ocjenu ustavnosti zakona, odnosno ustavnosti i zakonitosti drugih propisa i opštih akata kojima se uređuju pitanja obrade ličnih podataka;
5) obavlja i druge poslove utvrđene ovim zakonom i statutom Agencije.

Član 59a

Zarada predsjednika i članova Savjeta Agencije, kao i direktora Agencije, utvrđuju se Statutom Agencije.

Član 60

Agencija ima stručnu službu.

Na prava, obaveze i odgovornost zaposlenih u stručnoj službi Agencije primjenjuju se opšti propisi o radu.

Član 61

Agencija ima statut.

Statut Agencije naročito sadrži:

1) sjedište i djelatnost Agencije;
2) unutrašnju organizaciju Agencije;
3) način rada, odlučivanja i nadležnosti organa Agencije.

Član 62

Agencija podnosi godišnji izvještaj o stanju zaštite ličnih podataka Skupštini do 31. marta tekuće godine za prethodnu godinu.

Agencija podnosi Skupštini posebni izvještaj o stanju zaštite ličnih podataka:

1) na zahtjev Skupštine,
2) ako Agencija ocijeni da za to postoje posebni razlozi.

U izvještaju iz stava 1 ovog člana objavljuje se analiza stanja u oblasti zaštite ličnih podataka, postupaka pokrenutih na osnovu ovog zakona i naloženih mjera, kao i podaci o stepenu poštovanja prava lica prilikom obrade ličnih podataka.

Izvještaji iz st. 1 i 2 ovog člana moraju se učiniti dostupnim javnosti.

Član 63

Sredstva za rad Agencije obezbjeđuju se u budžetu Crne Gore i iz drugih izvora, u skladu sa zakonom.

Član 64

Predsjednik i član Savjeta, direktor Agencije i zaposleni u Agenciji dužni su da kao tajnu, u skladu sa propisima kojima se uređuje tajnost podataka, čuvaju sve podatke za koje saznaju u obavljanju svojih dužnosti.

Obaveza iz stava 1 ovog člana traje i po prestanku obavljanja dužnosti direktora Agencije, odnosno po prestanku radnog odnosa zaposlenog u Agenciji.

VII. NADZOR

Član 65

Agencija vrši nadzor u skladu sa ovim zakonom preko zaposlenih lica u tom organu, koja su ovlašćena za obavljanje poslova nadzora, u skladu sa aktom o sistematizaciji (u daljem tekstu: kontrolor).

Kontrolor može biti lice koje, pored opštih uslova propisanih zakonom, ispunjava i sljedeće uslove:

1) ima visoku stručnu spremu;
2) ima pet godina radnog iskustva;
3) ima položen stručni ispit za rad u državnim organima;
4) nije osuđivano za krivično djelo koje ga čini nepodobnim za vršenje službe u državnom organu;
5) protiv koga se ne vodi krivični postupak.

Postupak nadzora iz stava 1 ovog člana pokreće se i vodi po službenoj dužnosti.

Svako može podnijeti inicijativu za pokretanje postupka nadzora.

Član 66

Kontrolor ima pravo pristupa ličnim podacima sadržanim u zbirkama ličnih podataka, bez obzira da li se evidencije o tim zbirkama vode u Registru, kao i pravo pristupa spisima i drugoj dokumentaciji koja se odnosi na obradu ličnih podataka i sredstvima elektronske obrade ličnih podataka.

Pravo pristupa ličnim podacima iz stava 1 ovog člana kontrolor, u obavljanju poslova iz svoje nadležnosti, ima bez obzira na stepen tajnosti podataka.

Član 67

Rukovalac zbirke ličnih podataka, korisnik ili obrađivač ličnih podataka obavezni su da omoguće pristup zbirkama, spisima i drugoj dokumentaciji, kao i sredstvima elektronske obrade i da, na zahtjev kontrolora, dostave tražene spise i drugu dokumentaciju.

Član 68

O izvršenom nadzoru iz člana 65 ovog zakona sačinjava se zapisnik, u roku od 15 dana od dana izvršenog nadzora i dostavlja rukovaocu zbirke ličnih podataka.

Kad se nadzor vrši po zahtjevu za zaštitu prava iz člana 47 ovog zakona, kontrolor je dužan da sprovede postupak i sačini zapisnik odmah, a najkasnije u roku od osam dana od dana podnošenja zahtjeva.Zapisnik se dostavlja podnosiocu zahtjeva za zaštitu prava i rukovaocu zbirke ličnih podataka.

Na zapisnik iz st. 1 i 2 ovog člana rukovalac zbirke ličnih podataka, kao i lice koje je podnijelo zahtjev za zaštitu prava može, u roku od osam dana od dana prijema zapisnika, podnijeti prigovor Agenciji.

Član 69

Ukoliko Agencija utvrdi da je prigovor rukovaoca zbirke ličnih podataka na zapisnik u kojem su konstatovane nezakonitosti i nepravilnosti prilikom obrade ličnih podataka neosnovan, izreći će mjere iz člana 71 ovog zakona.

U slučaju iz stava 1 ovog člana Agencija će podnijeti zahtjev za pokretanje prekršajnog postupka.

Član 70

Ako Agencija, na osnovu zapisnika o izvršenom nadzoru, utvrdi da ne postoje nezakonitosti i nepravilnosti prilikom obrade ličnih podataka na koje se ukazuje u zahtjevu za zaštitu prava, odnosno u prigovoru na zapisnik, rješenjem će odbiti zahtjev.

Kad Agencija, postupajući po prigovoru podnosioca zahtjeva za zaštitu prava na zapisnik, u kojem je konstatovano da ne postoje nezakonitosti i nepravilnosti prilikom obrade ličnih podataka koje se na njega odnose, utvrdi da je prigovor osnovan, rukovaocu zbirke ličnih podataka će izreći mjere iz člana 71 ovog zakona.

Član 71

U vršenju nadzora Agencija je ovlašćena da rješenjem:

1) naredi da se nepravilnosti u obradi ličnih podataka otklone u određenom roku;
2) privremeno zabrani obradu ličnih podataka koji se obrađuju suprotno ovom zakonu;

3) naredi brisanje ličnih podataka prikupljenih bez pravnog osnova;
4) zabrani iznošenje ličnih podataka iz Crne Gore ili davanje na korišćenje ličnih podataka korisnicima ličnih podataka suprotno ovom zakonu;
5) zabrani povjeravanje poslova obrade ličnih podataka kada obrađivač ličnih podataka ne ispunjava uslove u pogledu zaštite ličnih podataka ili je povjeravanje navedenih poslova sprovedeno suprotno ovom zakonu.

Član 72

Protiv rješenja Agencije može se voditi upravni spor.

Član 73

Na postupak i način vršenja nadzora, obaveze i ovlašćenja kontrolora i druga pitanja od značaja za vršenje nadzora shodno se primjenjuju propisi kojima je uređen inspekcijski nadzor i upravni postupak, ako ovim zakonom nije drukčije određeno.

Član 73a

Trgovačka udruženja i ostala tijela koja predstavljaju posebne kategorije rukovaoca zbirki ličnih podataka moraju Agenciji dostaviti pravila rada i ponašanja, kao i akte na osnovu kojih vrše obradu ličnih podataka.

Agencija daje saglasnost i ocjenjuje usklađenost pravila sa ovim zakonom.

VIII. KAZNENE ODREDBE

Član 74

Novčanom kaznom od 500 eura do 20.000 eura kazniće se za prekršaj pravno lice, ako:

1) vrši obradu ličnih podataka suprotno članu 10 ovog zakona;
2) obrađuje posebne kategorije ličnih podataka suprotno članu 13 ovog zakona;
3) obrađuje lične podatke u vezi sa krivičnim i prekršajnim postupkom suprotno članu 14 ovog zakona;
4) ukoliko se podaci koji pripadaju jednoj od posebnih kategorija koriste u svrhe; direktnog marketinga bez saglasnost lica (član 15 stav 2);
5) poslove obrade ličnih podataka iz svog djelokruga povjeri obrađivaču ličnih podataka koji nije registrovan za obavljanje djelatnosti obrade ličnih podataka ili koji ne ispunjava uslove za sprovođenje tehničkih, kadrovskih i organizacionih mjera za zaštitu ličnih podataka (član 16 stav 3);
6) ako ne vodi evidenciju o trećim stranama, odnosno korisnicima ličnih podataka (član 19 stav 1);
7) ne izbriše lične podatke ako njihova obrada nije u skladu sa zakonom (član 23 stav 1);
8) ne obezbijedi tehničke, kadrovske i organizacione mjere zaštite ličnih podataka, radi zaštite od gubitka,uništenja, nedopuštenog pristupa, promjene, objavljivanja, kao i od zloupo trebe (član 24 stav 1);
9) prije uspostavljanja automatske zbirke ličnih podataka ne dostavi obavještenje nad zornom organu (član 27 stav 1);
10) vrši video nadzor na način kojim se prikazuju snimci unutrašnjosti stambenih zgrada koji nemaju uticaja na ulaz u stambene i poslovne prostorije ili snima ulaz u stanove (član 35 stav 4);
11) zaposlene u prostoru pod video nadzorom ne obavijesti, u pisanom obliku, o vršenju video nadzora i ne donese odluku (član 35 st. 2 i 5);
12) vrši video nadzor u službenom i poslovnom prostoru van radnog mjesta (član 36 stav 2);
13) zaposlene ne obavijesti, u pisanom obliku, o uvođenju video nadzora prije početka vršenja video nadzora (član 36 stav 5);
14) vrši video nadzor ulaza u stanove (član 38 stav 4);
15) na vidnom mjestu ne istakne javno obavještenje da se vrši video nadzor (član 39 st. 1 i 2);
16) javno obavještenje da se vrši video nadzor ne sadrži propisane informacije (član 39 stav 3);
17) sistem video nadzora koji se koristi za vršenje video nadzora ne zaštiti od pristupa neovlašćenih lica (član 39 stav 5);
18) licu ne dostavi obavještenje u roku od 15 dana od dana podnošenja zahtjeva (član 43 stav 1);
19) u roku od 15 dana od dana podnošenja zahtjeva ne izvrši dopunu ili izmjenu i brisa nje ličnih podataka (član 44 stav 1);
20) u roku od osam dana ne obavijesti lice, odnosno njegovog zakonskog zastupnika ili punomoćnika, kao i treću stranu, odnosno korisnika ličnih podataka o izvršenoj dopuni ili izmi jeni i brisanju ličnih podataka (član 44 stav 2);
21) korisnik ili obrađivač ne postupi po nalogu ili zabrani Agencije (član 71).

Za prekršaj iz stava 1 ovog člana kazniće se i odgovorno lice u pravnom licu u državnom organu, organu državne uprave, organu lokalne uprave, organu lokalne samouprave i fizičko lice novčanom kaznom od 150 eura do 2.000 eura.
Za prekršaj iz stava 1 ovog člana kazniće se preduzetnik novčanom kaznom od 150 eura do 6.000 eura.

IX. PRELAZNE I ZAVRŠNE ODREDBE

Član 75

Imenovanje predsjednika i članova Savjeta Agencije, u skladu sa ovim zako-nom, izvršiće se u roku od šest mjeseci od dana stupanja na snagu ovog zakona.
Imenovanje direktora Agencije izvršiće se u roku od tri mjeseca od dana imenovanja Savjeta Agencije.

Član 75a

Agencija za zaštitu ličnih podataka osnovana u skladu sa Zakonom o zaštiti podataka o ličnosti ("Službeni list CG", br.79/08) nastavlja sa radom pod nazivom Agencija za zaštitu ličnih podataka i slobodan pristup informacijama.

Član 76

Podzakonski akti za sprovođenje ovog zakona donijeće se u roku od tri mjeseca od od dana imenovanja Savjeta Agencije.

Član 77

Zbirke ličnih podataka uspostavljene do stupanja na snagu ovog zakona uskladiće se sa ovim zakonom, u roku od devet mjeseci od dana stupanja na snagu ovog zakona.
Rukovaoci zbirki obavezni su da uspostave evidenciju iz člana 26 ovog zakona i da je dostave Agenciji u roku od 15 mjeseci od dana stupanja na snagu ovog zakona.
Javni sektor, privredno društvo, drugo pravno lice i preduzetnik obavezni su da usklade evidencije o ulasku i izlasku iz prostorija i vršenje video nadzora sa ovim zakonom u roku od 18 mjeseci od dana stupanja na snagu ovog zakona.

Član 78

Danom početka primjene ovog zakona prestaje primjena Zakona o zaštiti ličnih podataka ("Službeni list SRJ", br. 24/98).

Član 79

Ovaj zakon stupa na snagu osmog dana od dana objavljivanja u "Službenom listu Crne Gore", a primjenjivaće se nakon isteka roka od šest mjeseca od dana stupanja na snagu.

SU-SK Broj 01-1021/11
Podgorica, 17. decembra 2008. godine

Skupština crne Gore
Predsjednik,
Ranko Krivokapić, s.r.

Act of 30 June 2006 No. 56 on ethics and integrity in research

Section 1. Purpose of the Act

This Act seeks to ensure that research carried out by public and private institutions is conducted in accordance with recognised ethical standards.

Section 2. Autonomy

Committees and commissions appointed pursuant to this Act shall be state bodies that are autonomous in professional matters.

Section 3. National research ethics committees

National research ethics committees that collectively cover all disciplines shall be established. These committees shall serve as advisory bodies on research ethics. The Ministry will establish such committees, determine the committees' fields of responsibility and appoint members.

The committees shall have expertise in relevant research disciplines, ethics and law. They shall also have lay members.

Section 4. Regional committees for medical and health research ethics

Regional committees for medical and health research ethics shall be established. The Ministry will establish such committees, determine the committee's fields of responsibility and appoint members. Members shall be appointed on the basis of proposals from relevant bodies. The committees shall have expertise in relevant research disciplines, ethics and law. They shall also have lay members.

Research projects in Norway that involve experiments on human subjects shall be submitted to the committee for approval. Research projects conducted outside Norway shall be submitted to the committee for approval if the research is being carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

Appeals against decisions made by the committees may be lodged with the National Committee for Medical and Health Research Ethics. The decision of the National Committee is final and may not be further appealed.

Section 5 The National Commission for the Investigation of Scientific Misconduct

A national commission for the investigation of scientific misconduct shall be established. The commission shall give a statement as to whether scientific misconduct has occurred in research conducted in Norway. The commission shall also give a statement on research conducted outside Norway if the research has been carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

Scientific misconduct is defined as falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research.

The members of the commission shall be appointed by the Ministry. The commission chair shall have judicial experience. The composition of the commission shall ensure that the commission has the necessary expertise in the field of research and research ethics.

The commission may in individual cases decide that the documents relating to a case shall not be made public until a final statement has been given.

The Ministry is the administrative appeals body for appeals regarding the administrative procedures of the commission. Appeals regarding the content of the statement shall be dealt with by a specially appointed commission. A special commission shall be appointed for each appeal and shall comprise members with the necessary professional or technical, research ethics and legal expertise. The decision of the special commission is final.

Section 6 Regulations

The Ministry may make supplementary regulations regarding the appointment and administrative procedures of committees and commissions pursuant to this Act.

Section 7 Commencement

This Act shall enter into force from the date decided by the King.

Z A K O N

O PREVENCIJI I DIJAGNOSTICI GENETIČKIH BOLESTI, GENETIČKI USLOVLJENIH ANOMALIJA I RETKIH BOLESTI

I. OSNOVNE ODREDBE

Predmet

Član 1.

Ovim zakonom uređuju se prava, obaveze i odgovornosti učesnika u medicinskim postupcima prevencije i dijagnostikovanja genetičkih bolesti, genetički uslovljenih anomalija i retkih bolesti, u svrhu zaštite ljudskog zdravlja i dostojanstva, a naročito kod ispitivanja i analize bioloških uzoraka namenjenih da identifikuju genske karakteristike koje se nasleđuju ili stiču tokom ranog prenatalnog razvoja.

Područje primene

Član 2.

Odredbe ovog zakona odnose se na testiranja i analize izvršene u okviru genetičkih ispitivanja kod ljudi, uključujući prenatalna genetička ispitivanja embriona i fetusa tokom oplodnje i trudnoće, kao i ciljana ispitivanja dece i odraslih kod sumnje na retke bolesti.

Odredbe ovog zakona ne odnose se na multifaktorijalne bolesti, genetička ispitivanja koja su usmerena na naučno-istraživački rad, utvrđivanje očinstva ili materinstva, niti na primenu genetike u krivičnim i drugim pravnim postupcima.

Značenje pojmova

Član 3.

U smislu ovog zakona određeni su pojmovi:

1) *genetičko ispitivanje* je svako ispitivanje čiji je cilj: pregled pacijenta ili analiza radi identifikacije genetičkih osobina ili postavljanja dijagnoze bolesti; prenatalna dijagnostika kojom se dobija genetička informacija o prisustvu određene bolesti kod ploda;

2) *genetička analiza* u širem smislu reči podrazumeva bilo koju analizu usmerenu na određivanje karakteristika naslednog materijala, kao što su: analiza hromozoma (citogenetičke i molekularno-citogenetičke analize); određivanje prisustva greške na genima (mutacije i epimutacije) odnosno na molekulu dezoksiribonukleinske kiseline ili ribonukleinske kiseline; analiza proizvoda nukleinskih kiselina, najčešće proteina i enzima; analiza koncentracije supstrata koji ne može da se metaboliše ili toksičnih produkata koji nastaju aktivacijom sporednih metaboličkih puteva kao posledice mutacije u genima, odnosno analiza drugih supstanci koje nastaju kao posledica mutacije gena;

3) *genetička usluga:* zdravstvena usluga u oblasti preventivne medicine, kao i usluga u svrhu dijagnostike i lečenja a obuhvata genetičko informisanje, genetičko savetovanje kao i genetičko ispitivanje;

4) *genetičke odnosno genske karakteristike* znače genske informacije koje se nalaze zapisane u genomu jedne osobe;

5) *genom* je celokupna količina dezoksiribonukleinske kiseline (DNK) u ćeliji, koja je sadržana u jedru i mitohondrijama ćelija;

6) *odgovorno lice* označava lice koje indikuje i/ili vrši genetičko ispitivanje u medicinske svrhe;

7) *dijagnostičko genetičko ispitivanje* označava svako genetičko ispitivanje u cilju objašnjenja stanja ili potvrde dijagnoze bolesti na koju se sumnja na osnovu kliničke slike i drugih analiza. Cilj dijagnostike je karakterizacija već postojeće bolesti ili poremećaja zdravlja, primena terapije, ili prenatalna dijagnostika;

8) *prediktivna dijagnostika* označava svako genetičko ispitivanje u cilju razjašnjenja: predviđanja ili procene svake buduće bolesti ili poremećaja zdravlja; otkrivanje nosioca, odnosno otkrivanje predispozicije za bolesti ili poremećaje zdravlja kod potomstva;

9) *prenatalna dijagnostika* se odnosi na dijagnozu bolesti kod embriona ili fetusa u porodicama sa rizikom; kod monogenskih bolesti preduslov za prenatalno testiranje je okončana dijagnostika i utvrđena mutacija kod indeksnog pacijenta;

10) *genetički uzorak* označava bilo koji uzorak biološkog materijala koji je odabran u svrhu korišćenja u genetičkim analizama;

11) *genetički podaci* označavaju sve podatke u vezi sa osobinama naslednog materijala dobijene putem genetičkog ispitivanja;

12) *genetički uslovljene anomalije* su nepravilnosti tkiva, pojedinih organa ili više organa, prisutne i vidljive na rođenju;

13) *dijagnoza* je kratak lekarski zaključak o suštini bolesti i stanju pacijenta iskazan terminima savremene medicinske nauke i rezultat primenjene dijagnostike, odnosno određenih dijagnostičkih mera;

14) *pacijent* je svako lice, bez obzira da li je zdravo ili obolelo, prema kome se preduzimaju određene medicinske mere, odnosno genetičke analize u cilju postavljanja ili negiranja dijagnoze; kod prenatalne dijagnostike pacijentom se smatra trudna žena kao subjekt prava i obaveza, dok nerođeno dete koje ona nosi preko nje uživa svu moralnu i pravnu zaštitu;

15) *embrion* jeste oplođena jajna ćelija (zigot) koja se deli u toku prvih 56 dana, izuzev vremena tokom koga je razvoj bio zaustavljen, sposobna za dalji razvoj i to od trenutka spajanja jedra i dalje svaka totipotentna ćelija embriona koja se u za to neophodnim uslovima može dalje deliti i razvijati u individuu;

16) *fetus* je ljudski organizam tokom njegovog razvoja počev od 57-og dana od dana oplodnje ili stvaranja, izuzev vremena kada je razvoj bio zaustavljen, do njegovog rođenja;

17) *novorođenče* (novorođeno dete) je dete starosne dobi od rođenja do 29 dana;

18) *laboratorijska ispitivanja* su ona koja po potrebi uključuju biohemijske, hematološke, serološke i bakteriološke analize;

19) *biološki uzorci* označavaju: bilo koji uzorak biološkog materijala (krv, koža, koštane ćelije, krvna plazma i sl.) u kome su prisutne nukleinske kiseline i koji sadrži karakterističnu genetičku strukturu nekog pojedinca; biološki uzorci uzeti u svrhu testa koga se tiču, kao i biološki uzorci prethodno uzeti u neku drugu svrhu;

20) *genetički skrining* (genetički probir) znači svako genetičko ispitivanje u medicinske svrhe koje se nudi sistematski i zajednički za celu populaciju ili za određenu grupu stanovništva, pri čemu se pretpostavlja da pojedinci iz populacije odnosno grupe imaju specifične genske karakteristike za koje se traži da ih ispitivanje identifikuje ili da se na vreme postavi dijagnoza genetičke bolesti radi uspešne terapije ili prenatalne dijagnostike;

21) *invazivni postupak*: biološko uzimanje uzorka korišćenjem metoda koji uključuje prodiranje u ljudsko telo, kao što je dobijanje krvnog uzorka upotrebom igle i šprica;

22) *neinvazivni postupak*: biološko uzimanje uzorka korišćenjem metoda koji ne uključuje prodiranje u ljudsko telo, kao što su oralni sekreti;

23) *davalac usluge*: zdravstvena ustanova koja ima organizovanu i ovlašćenu službu pružanja genetičkih usluga u okviru rada savetovališta, rada na humanoj genetici ili referentnih centara za retke bolesti, kao i svaki oblik privatne prakse koji u okviru svoje delatnosti i po odobrenju ministarstva nadležnog za poslove zdravlja (u daljem tekstu: Ministarstvo) pruža genetičku uslugu.

Svi pojmovi koji se koriste u ovom zakonu u muškom gramatičkom rodu, a koji imaju rodno značenje, obuhvataju ravnopravno i na jednak način muški i ženski rod.

Načela zaštite genetičkog i reproduktivnog zdravlja

Član 4.

Načelo zaštita genetičkog i reproduktivnog zdravlja ostvaruje se u odnosu na očuvanje i zaštitu naslednog potencijala svakog pojedinca kao deo opšte društvene brige za zdravlje.

Preventivna, prenatalna i postnatalna zdravstvena zaštita predstavljaju ulaganje u budućnost zdravlja svih, a posebno žena i novorođene dece.

Zdravstvena zaštita dece kod prevencije, dijagnostike i lečenja genetičkih bolesti i anomalija u smislu ovog zakona obezbeđuje se u najboljem interesu deteta.

Genetička usluga

Član 5.

Genetičku uslugu pruža davalac usluge, u cilju da se pojedincu, parovima, populacionoj grupi ili porodici pomogne u rešavanju zdravstvenog problema i da se sačini nalaz u vezi sa pojavom ili rizikom od nastanka ili ponovne pojave genetičke bolesti, genetički uslovljene anomalije ili retke bolesti.

Genetičko informisanje je postupanje u cilju obaveštavanja u kome se pacijent ili članovi njegove porodice, koji su pod rizikom od genetički uslovljene bolesti, upoznaju sa posledicama te bolesti, verovatnoćom njenog prenošenja i načinima njene prevencije i lečenja.

Genetičko savetovanje se odvija na način koji je razumljiv i bez uticaja na volju lica kome se savet daje.

Članovi porodice treba da budu uključeni u genetičko informisanje pacijenta koji se ispituje, ukoliko se sumnja da mogu biti nosioci određenih genskih karakteristika koji su od značaja za sprečavanje, otkrivanje ili lečenje određene genetičke bolesti, genetički uslovljene anomalije ili retke bolesti.

Odredba stava 4. ovog člana primenjuje se na slučajeve kad se genetsko ispitivanje sprovodi na embrionu ili fetusu.

Lekar kao odgovorno lice

Član 6.

Genetičko ispitivanje u smislu kliničkog rada u genetičkoj ambulanti ili konsultacije na bolničkim odeljenjima može da sprovodi samo za to ovlašćen i kvalifikovan lekar.

Dijagnostika putem genetičkog ispitivanja i genetičkih analiza može da se obavlja od strane lekara koji ima odgovarajuću specijalizaciju, odnosno užu specijalizaciju i koji radi u ustanovi tercijarnog ranga zdravstvene zaštite.

Dijagnostika iz stava 2. ovog člana može da se obavlja i od strane drugog lekara koji u okviru oblasti svoje specijalizacije dobije takav sertifikat, subspecijalizaciju ili se stručno dokvalifikuje za sprovođenje genetičkih ispitivanja.

Genetička dijagnoza

Član 7.

Genetičko ispitivanje u medicinske svrhe shodno ovom zakonu dopušteno je samo u cilju predviđanja ili otkrivanja genetičke bolesti, genetički uslovljene anomalije ili retke bolesti kad na to pacijent izričito pristane u pisanoj formi, odnosno kad na to pristane trudna žena kao pacijent u pogledu dijagnostike embriona ili fetusa.

U toku genetičkog ispitivanja dobrobit pacijenta ima prioritet u odnosu na druge nemedicinske i isključivo naučne interese.

Pravo na privatnost i zaštita podataka o ličnosti

Član 8.

Pacijent ima pravo na poštovanje svoje fizičke i psihičke privatnosti i na poverljivost podataka o ličnosti, a u okviru toga i na posebnu zaštitu kad su ti podaci rezultat genetičkog testiranja.

Biološki uzorci koji se koriste za analize treba da se čuvaju pod uslovima koji garantuju njihovu bezbednost i poverljivost. Podaci o biološkim uzorcima, kao i podaci o rezultatima genetičkog testiranja smatraju se podacima koji se odnose na zdravstveno stanje lica.

Pacijent ima pravo na zaštitu podataka o ličnosti u skladu sa zakonima koji uređuju zaštitu podataka o ličnosti.

Zabrana diskriminacije u postupku genetičkog ispitivanja

Član 9.

Niko ne sme da bude diskriminisan niti doveden u nepovoljan položaj zbog njegovih genetičkih karakteristika, genetičkih osobina njemu genetički povezanog lica, ili zbog samog preduzimanja ili nepreduzimanja genetičkog ispitivanja.

Zabrana selekcije pola

Član 10.

Zabranjeno je da se dijagnostički postupak pre začeća ili u toku trudnoće koristi u svrhu selekcije pola deteta, osim ako se to čini radi izbegavanja teške nasledne bolesti vezane za pol.

Dozvolu za dijagnostički postupak iz stava 1. ovog člana daje Uprava za biomedicinu Republike Srbije, na osnovu mišljenja multidisciplinarnog konzilijarnog veća za pitanja dijagnostike.

Član 11.

Zabranjeno je prikupljanje genetičkih podataka i uzoraka radi sticanja imovinske ili bilo koje druge koristi, kao i oglašavanje takvih aktivnosti u medijima ili na bilo kom drugom nosiocu oglasne poruke.

Svako ima pravo na pravičnu naknadu štete koja nastane kao posledica genetičkih ispitivanja.

II. PREVENCIJA GENETIČKIH BOLESTI, GENETIČKI USLOVLJENIH ANOMALIJA I RETKIH BOLESTI

Preventivne mere

Član 12.

Davalac usluge je dužan da:

1) u okviru preventivnih programa obavlja prenatalni i neonatalni skrining kao organizovane oblike sprovođenja dijagnostike naslednih bolesti;

2) u okviru obaveznih mera zdravstvene zaštite obavlja testiranja na određene genetičke bolesti.

Preventivne mere iz stava 1. ovog člana sprovodi davalac usluge organizovanjem posebnih predavanja ili davanja saveta, a u cilju podizanja svesti ljudi i obezbeđivanja zdravstvenih usluga u odgovarajućim intervalima za grupacije stanovništva koje su izložene povećanom riziku obolevanja.

Genetički skrining

Član 13.

Genetički skrining koji uključuje širu populaciju može da se obavlja samo ako je cilj takvog ispitivanja da se utvrdi da li lica koja se ispituju poseduju takve genetičke osobine koje su, prema opšteprihvaćenom stavu medicinske nauke i struke, značajne u smislu prevencije, lečenja ili izbegavanja genetički uslovljenih bolesti, anomalija i retkih bolesti.

Genetički skrining iz stava 1. ovog člana sprovodi se u okviru odobrenih javno-zdravstvenih programa za skrining u Republici Srbiji, kao i na osnovu pribavljenog mišljenja o opravdanosti koju procenjuje Etički odbor Srbije, uz ispunjenje sledećih uslova:

1) program je relevantan za zdravlje ukupne populacije ili jednog dela stanovništva;

2) postoji naučna vrednost i dokazani efekti programa;

3) raspoložive su preventivne i terapijske mere za bolesti ili poremećaje koji su predmet programa;

4) postoje odgovarajuće mere da se obezbedi jednak pristup programu;

5) predviđene su mere za obaveštavanje o svrsi programa i dobrovoljnoj prirodi učešća u njemu.

III. PRAVA I OBAVEZE UČESNIKA U DIJAGNOSTICI

Pravo na dijagnozu

Član 14.

Pacijent ima pravo na dijagnozu, uvek kad je ona moguća i dostupna prema stanju razvoja biomedicinskih i tehnoloških saznanja.

Kod ozbiljnih teškoća ili nejasnih stanja u pogledu dijagnoze, kad nema dijagnoze, ona će se postaviti konzilijarno i hipotetički kao privremena ili radna dijagnoza.

Dijagnoza u smislu ovog zakona prethodi lečenju i sastavni je deo obaveštenja koje se duguje pacijentu, kako bi se on samoodredio u odnosu na predloženo lečenje i dao svoj pristanak uz punu informisanost.

Lekar je kao odgovorno lice dužan da postavi dijagnozu na osnovu uzete anamneze i pregleda obavljenog u skladu sa pravilima struke i sa dužnom pažnjom.

Lekar je dužan da postupa u skladu sa važećim medicinskim standardom u dijagnostici.

Lekar ima slobodu izbora dijagnostičkog postupka, pri čemu je dužan da vodi računa o ličnosti pacijenta i da primereno njegovom stanju primeni sva moguća i raspoloživa izvorna naučna medicinska saznanja u toj oblasti.

Ako prvobitna dijagnoza nije sigurna lekar je dužan da je proveri i da iscrpi druge mogućnosti ispitivanja i dijagnostikovanja.

Zabranjena je preterana dijagnostika u postavljanju dijagnoze u vidu nepotrebnih i prekomernih dijagnostičkih postupaka.

Kod invazivnih dijagnostičkih postupaka povećanog rizika, lekar je dužan da napravi razmak između ovih postupaka kako ne bi naštetio pacijentu.

Rana dijagnostika je prioritet i obaveza je lekara da pravovremeno postavi dijagnozu.

Nove dijagnostičke metode

Član 15.

Lekar koji obavlja zdravstvenu delatnost kod davaoca usluge, dužan je da usvaja i usavršava nove dijagnostičke, terapijske i preventivne metode koje su naučno utemeljene, za koje je davalac usluge dobio saglasnost nadležne komisije Ministarstva.

Primena nove eksperimentalne dijagnostičke metode nalaže dužnost lekara da proceni odnos koristi i rizika po pacijenta u odnosu na njeno preduzimanje, odnosno nepreduzimanje.

Nova metoda se ne može sprovoditi u druge svrhe osim u cilju prevencije i lečenja stanja i bolesti.

Obaveštenje o dijagnostičkoj meri

Član 16.

Pre pribavljanja pristanka pacijenta na genetičko ispitivanje, odgovorno lice je dužno da informiše pacijenta o prirodi, značenju i obimu ispitivanja, ostavljajući pacijentu dovoljno vremena za odlučivanje o davanju pristanka.

Dužnost obaveštenja iz stava 1. ovog člana bliže uključuje:

1) objašnjenje u pogledu namene, vrste, obima i značenja genetičkog ispitivanja, kao i osnovne informacije o ograničenjima primenjene metode;

2) objašnjenje određenih rizika po zdravlje onog ko se ispituje u odnosu na saznanje o rezultatu genetičkog ispitivanja ili uzimanje genetičkih uzoraka potrebnih za to, uključujući i slučajeve trudne žene i objašnjenja rizika po embrion odnosno fetus u vezi sa vršenjem ispitivanja i uzimanja potrebnih genetičkih uzoraka;

3) objašnjenje prava pacijenta da povuče svoj pristanak u bilo koje vreme;

4) objašnjenje u pogledu prava pacijenta da odbije saopštavanje rezultata bez ograničenja, delimično ili u celosti, uključujući tu i pravo da ne podigne rezultat ispitivanja, kao i da rezultat bude uništen;

5) objašnjenje onom ko se ispituje u slučaju masovnog genetskog skrininga o rezultatima evaluacije programa.

Odgovorno lice koje postupa u ispitivanju treba da unese u medicinsku dokumentaciju sadržaj svakog od ovih objašnjenja u vreme pre njegovog obavljanja.

Obaveštenje o dijagnozi kod utvrđene bolesti, genetički uslovljene anomalije ili retke bolesti saopštava isključivo lekar koji preduzima dijagnostičku meru.

Pristanak na dijagnostičku meru

Član 17.

Dijagnostičke mere nad pacijentom sprovode se samo uz njegov pristanak, osim izuzetno kad razlozi hitnosti to ne dopuštaju.

Pacijent može dati pristanak na predloženu dijagnostičku meru izričitom izjavom ili radnjama koje znače njegovo saglašavanje.

Genetička dijagnostika u vidu ispitivanja ili analize, kao i uzimanje uzorka u tu svrhu, može da se sprovodi samo pošto je pacijent pismeno dao pristanak.

Odgovorno lice i zdravstvena ustanova dužni su da poseduju dokaz o pismeno datom pristanku.

Pristanak pacijenta iz stava 3. ovog člana odnosi se na obim genetičkog ispitivanja, kao i na mogućnost da rezultat ispitivanja može da bude dostupan i drugim licima.

Pacijent može u svakom trenutku, sa dejstvom za ubuduće, da opozove svoj pristanak medicinski odgovornom licu, bilo usmeno bilo u pisanoj formi. Svaki usmeni opoziv pristanka treba da bude ubeležen u medicinsku dokumentaciju.

Genetičko ispitivanje pacijenta kome nedostaje sposobnost odlučivanja

Član 18.

Kad pacijent ne poseduje sposobnost da razume prirodu, značaj ili domašaj predloženog ispitivanja ili davanja neophodnog uzorka ili po zakonu nema pravo da izjavi pristanak, genetičko ispitivanje u medicinske svrhe može se obaviti samo uz pismeni pristanak zakonskog zastupnika pacijenta i ako je prema opšteprihvaćenom stavu medicinske struke i nauke to neophodno radi izbegavanja, prevencije ili lečenja genetički izazvane bolesti, njenih komplikacija, kao i radi preduzimanja terapije lekovima koja može da utiče na genske karakteristike.

U slučaju da pacijent iz stava 1. ovog člana nema zakonskog zastupnika ili zakonski zastupnik nije dostupan, genetičko ispitivanje može se obaviti uz prethodno pribavljeno mišljenje nadležnog Etičkog odbora zdravstvene ustanove i odobrenje nadležnog organa starateljstva.

Pristanak zakonskog zastupnika može se opozvati.

Pacijent iz stava 1. ovog člana, bez obzira na pristanak zastupnika, biće uključen u proces donošenja odluke o genetičkom testiranju u onoj meri u kojoj je sposoban da date informacije razume.

Član 19.

Izuzetno je dopušteno da se genetičko ispitivanje preduzima bez pristanka pacijenta iz člana 18. ovog zakona, ako ispitivanje ne može da se odloži, ako očekivana korist za pacijenta ne može da se postigne na drugi način, i ako je to u skladu sa principom srazmere koristi i štete koja se odmerava.

Mišljenje o ispunjenosti uslova izuzetka iz stava 1. ovog člana daje nadležni etički odbor.

Član 20.

Biološki uzorci za analize stanja koja su predmet ovog zakona uzimaju se uz slobodan pisani pristanak pacijenta, a smeštaju se i čuvaju u zdravstvenim ustanovama na propisan način.

Način, postupak i kriterijume uzimanja uzoraka u cilju genetičkih analiza, postupak čuvanja kao i obavezne laboratorijske testove opštim aktom uređuje ministar.

Pravo na obaveštenje o nalazu

Član 21.

Pacijent kome se vrši genetički test ima pravo da dobije punu informaciju o svom genetičkom zdravlju, u delu u kome je ona rezultat testiranja i saopštena u dostupnoj i jasnoj formi.

Izuzetak od stava 1. ovog člana predstavlja:

1) odluka pacijenta da ne bude obavešten o nalazu testa;

2) kad se zakonom ograničava vršenje ovog prava u korist pacijenta ili trećeg lica.

Pravo na uvid u rezultat genetičkog ispitivanja ima samo pacijent, odnosno njegov zakonski zastupnik kad daje pristanak, a dužnost saopštavanja i čuvanja ima lekar koji je naložio analizu i kao odgovorno lice bio zajedno sa ovlašćenim

medicinskim osobljem neposredno uključen u izvođenje i procesuiranje rezultata prema pravilima medicinske struke.

Korišćenje i uništavanje genetičkih uzoraka

Član 22.

Genetički uzorci mogu da se koriste samo za namene za koje su uzeti, nakon čega se uništavaju, u skladu sa zakonom.

Genetički uzorci iz stava 1. ovog člana mogu da se koriste i u druge medicinske i naučne svrhe u meri u kojoj je takvo iskorišćavanje dozvoljeno drugim zakonskim propisima, ili u slučajevima kad je pacijent od koga potiče odgovarajući genetički uzorak, nakon što je u potpunosti informisan o nameravanoj drugoj medicinskog i naučnoj svrsi, dao svoj pismeni pristanak na to.

Čuvanje i uklanjanje rezultata genetičkog ispitivanja i analize

Član 23.

Rezultati genetičkih ispitivanja i analize čuvaju se u skladu sa propisima kojima se uređuje zdravstvena dokumentacija i evidencija u oblasti zdravstva kao i podzakonskim aktima donetim za sprovođenje ovog zakona.

Izuzetno od stava 1. ovog člana, rezultati genetičkih ispitivanja uklanjaju se na zahtev pacijenta, odnosno njegovog zakonskog zastupnika o čemu odgovorno lice sačinjava zapisnik.

IV. PREDIKTIVNA DIJAGNOSTIKA

Član 24.

U postupku prediktivne dijagnostike obavezno je sprovesti genetičko savetovanje i testove u cilju predviđanja monogenskih bolesti, otkrivanja genske predispozicije ili osetljivosti na bolesti, kao i identifikacije lica koje može biti zdravi nosilac gena odgovornog za bolest.

Način i obim genetičkog savetovanja treba da bude u skladu sa očekivanim rezultatom testa i njegovim značenjem za pacijenta koji se ispituje, posebno kad se to čini prema ženi kao pacijentu, njenom partneru ili članu porodice.

Genetički savet o začeću ili rođenju deteta saopštava se na način koji uvažava slobodu žene u pogledu njenog reproduktivnog ponašanja.

Posebni dijagnostički slučajevi

Član 25.

Prediktivno ispitivanje za koje ne postoji pristanak iz člana 17. stav 3. ovog zakona, dopušteno je samo kao izuzetak, i to :

1) kad je u slučaju planirane trudnoće ili ispitivanja genetički povezanog lica, na osnovu opšteprihvaćenog stava medicinske nauke nemoguće na drugi način utvrditi da li je neka bolest genetički uslovljena, odnosno da li će se pojaviti kod genetički povezanog lica ili njegove dece;

2) kad je verovatno da zdravlje pacijenta neće biti narušeno ili opterećeno na bilo koji način koji je veći od uobičajenog rizika od uzimanja neophodnog genetičkog uzorka;

3) kad je verovatno da pacijent neće pretrpeti nikakvo fizičko ili psihičko oštećenje usled rezultata ispitivanja.

Genetičko ispitivanje i prikupljanje genetičkih podataka i uzoraka može se vršiti sa umrlog lica ako time želi da se izbegne neka bolest ili genetički uslovljena anomalija kod članova njegove porodice ili da se bolest leči na osnovu dobijenih rezultata ispitivanja.

Genetičko ispitivanje iz stava 2. ovog člana dopušteno je samo uz prethodno dobijenu saglasnost porodice i nadležnog etičkog odbora u skladu sa zakonom.

V. PRENATALNA DIJAGNOSTIKA

Prenatalna genetička dijagnoza

Član 26.

Prenatalna dijagnostika se preduzima u svrhu dovođenja do zdravog i željenog potomstva u kom cilju se utvrđuje ili isključuje postojanje određene genetičke bolesti, genetički uslovljene anomalije ili retke bolesti kod embriona ili fetusa.

Lekar kao odgovorno lice dužan je da na osnovu nalaza i shodno važećem medicinskom standardu proceni da li postoji i koliki je stepen verovatnoće da će se dete roditi sa genetičkom bolešću ili genetički uslovljenom anomalijom koja je posebno teška u vreme njenog otkrivanja.

Prenatalno genetičko ispitivanje može da se vrši samo onda kad je to u svrhu zdravlja, odnosno radi utvrđivanja određene genske karakteristike embriona ili fetusa čije zdravlje može biti ugroženo pre ili nakon rođenja, ili radi lečenja embriona ili fetusa sa lekovima čije je dejstvo vezano za genetičke faktore, i pod uslovom da je trudna žena o tome po zakonu obaveštena i dala pristanak.

Ukoliko se prilikom ispitivanja iz stava 3. ovog člana ili na osnovu drugog prenatalnog ispitivanja utvrdi pol embriona ili fetusa, takva informacija može da se saopšti trudnoj ženi tek po isteku desete nedelje trudnoće.

Lekar kao odgovorno lice dužan je da trudnu ženu obavesti o njenom pravu na genetičko savetovanje, pre nego što se sprovede prenatalno ispitivanje i dobije rezultat, a u skladu sa ovim zakonom i zakonom kojim se uređuje postupak prekida trudnoće. Beleška o savetovanju sastavni je deo medicinske dokumentacije.

Ako se prenatalno genetičko ispitivanje sprovodi na trudnoj ženi koja nema sposobnost da razume prirodu, značenje i obim ispitivanja pa usled toga nije u stanju ni da izjavi volju, ispitivanje se može obaviti samo ako je zakonski zastupnik trudne žene u potpunosti obavešten i ako je lekar kao odgovorno lice dao savet i pribavio pristanak zakonskog zastupnika u skladu sa ovim zakonom.

Dijagnostičke metode koje lekar kao odgovorno lice koristi u prenatalnoj dijagnostici treba da budu prevashodno manje invazivne metode koje su deo dobre prakse prenatalne genetičke zaštite, izuzev onda kad je indikovano da se preduzme potrebno invazivno prenatalno ispitivanje.

Lekar kao odgovorno lice dužan je da o rezultatu genetičkog ispitivanja obavesti partnera trudne žene, ukoliko on učestvuje u postupku genetičkog savetovanja.

Odredba ovog člana primenjuje se i na postupke preimplatacione genetičke dijagnostike kod postupaka biomedicinski potpomognutog oplođenja.

Član 27.

Lekar kao odgovorno lice utvrđuje indikacije za upućivanje trudne žene u genetičko savetovalište koje je prilagođeno stanju koje se istražuje na način da se omogući:

1) procena rizika za nerođeno dete da pati od posebno teške bolesti, s obzirom na porodičnu istoriju i medicinske nalaze ispitivanja tokom trudnoće;

2) informisanje trudne žene o karakteristikama bolesti, načinu otkrivanja, terapijskim mogućnostima, o uspešnosti rezultata koji se mogu dobiti iz analize, kao i o njihovim mogućim posledicama;

3) informisanje trudne žene o skrivenim rizicima uzoraka i njihovim ograničenjima;

4) informisanje trudne žene o činjenici da će se dete roditi sa telesnim ili duševnim nedostacima predstavlja zakonsku indikaciju za prekid trudnoće u postupku na zahtev trudne žene, a po odobrenju nadležnog konzilijuma lekara, odnosno Etičkog odbora zdravstvene ustanove.

Lekar kao odgovorno lice treba da se uveri da je trudna žena razumela obaveštenje.

VI. POSTNATALNA DIJAGNOSTIKA

Član 28.

Mere obaveznog skrininga propisuju se posebnim stručno-metodološkim uputstvom koga odobrava ministar.

Obavezan skrining novorođene dece sprovodi se u skladu sa odgovarajućim skrining programom i treba da bude završen pre nego što se novorođenče otpusti iz bolnice, a ukoliko to nije slučaj, najkasnije u roku od 30 dana nakon otpuštanja iz porodilišta.

Ako rezultat određene analize za novorođenče bude pozitivan, odgovorno lice je dužno da daljim laboratorijskim pretragama izvrši proveru postavljene sumnje na genetičku bolest i da potvrdi nalaz.

Novorođenčetu sa genetički uslovljenom anomalijom postavlja se dijagnoza, koja se kod određenih stanja daje na osnovu kliničke slike na rođenju.

VII. CILJANA DIJAGNOSTIKA KOD DECE I ODRASLIH

Dijagnostika retkih bolesti

Član 29.

U preduzimanju dijagnostičkih mera, lekar je kao odgovorno lice dužan da uputi pacijenta na opsežnu ciljanu dijagnostiku kada je na osnovu kliničkih simptoma dijagnoza nejasna, odnosno kada postoji sumnja na retku bolest ili stanje kod pacijenta.

Genetički test u svrhu dijagnostike retke bolesti ili stanja preduzima se uz individualni pristup pacijentu i uz dužan lekarski nadzor, uzimajući u obzir i procenat rizika od greške.

Dijagnostika iz stava 1. ovog člana sprovodi se u vidu merenja i tumačenja dobijenog rezultata od strane ovlašćene laboratorije.

Član 30.

Ministar rešenjem određuje zdravstvene ustanove na tercijarnom nivou koje obavljaju poslove centra za retke bolesti, u skladu sa zakonom.

Centar iz stava 1. ovog člana po potrebi obrazuje multidisciplinarno konzilijarno veće za pitanja dijagnostike (u daljem tekstu: Veće).

Član 31.

Kad preduzeta genetička analiza nema jasan ishod, zbog čega pacijent ostaje bez potvrđene dijagnoze, odnosno bez mogućnosti daljih dijagnostičkih postupaka duže od šest meseci, a zdravstveno stanje pacijenta se ozbiljno pogoršava, Veće je dužno da bez odlaganja sačini izveštaj o preduzetim dijagnostičkim postupcima i da mišljenje da li je moguće obezbediti sprovođenje dodatnih dijagnostičkih postupaka u Republici Srbiji.

Ako nije moguće obezbediti sprovođenje dodatnih dijagnostičkih postupaka u Republici Srbiji, Veće u svom izveštaju daje predlog o potrebi sprovođenja dodatnih dijagnostičkih postupaka u inostranoj zdravstvenoj ustanovi. Predlog sadrži mišljenje o neophodnosti slanja biološkog materijala u inostranu zdravstvenu ustanovu ili o upućivanju pacijenta u inostranu zdravstvenu ustanovu radi sprovođenja dodatnih dijagnostičkih postupaka.

Odluku o neophodnosti upućivanje biološkog materijala ili osiguranog lica u inostranu zdravstvenu ustanovu radi sprovođenja dodatnih dijagnostičkih postupaka donosi Republički fond za zdravstveno osiguranje, odnosno odluku o dodeli sredstava iz Budžetskog fonda za lečenje obolenja, stanja i povreda koje se ne mogu lečiti u Republici Srbiji, radi sprovođenja dodatnih dijagnostičkih postupaka, donosi ministar zdravlja.

VIII. ODGOVORNOST ZA ŠTETU KOJU PRETRPI PACIJENT

Član 32.

Lekar odnosno drugi zdravstveni radnik, odgovara za štetu ako u preduzimanju dijagnostičkih mera postupa protivno važećim pravilima medicinske struke ili protivno pravilima zakonom propisane dužne pažnje, usled čega njegovom krivicom dođe do štete po telo, zdravlje ili život pacijenta.

Osnov odgovornosti lekara nalazi se u zanemarivanju medicinskog standarda, jer nije u svemu postupao stručno i pažljivo, a ne u dijagnozi kao sudu vrednosti i rezultatu takvog postupanja koja može biti usled toga netačna, nepotpuna, propuštena ili zadocnela, što se ceni u svakom konkretnom slučaju.

Odgovornost se izvodi saglasno odredbama zakona kojim se uređuju obligacionopravni odnosi i naknada štete po osnovu subjektivne i objektivne građanskopravne odgovornosti.

Član 33.

Ako je dete rođeno sa genetički uslovljenom bolešću ili anomalijom, što ga čini osobom sa invaliditetom, ili ga ozbiljno i trajno onesposobljava, ili mu daje lošu životnu prognozu, a da takvo stanje kod njega nije bilo prethodno medicinski prepoznato niti dijagnostikovano u toku embrionalnog ili fetalnog razvoja, lekar koji je postupao protivno važećem standardu medicinske struke ili nije poštovao medicinski protokol i postupao protivno pravnom standardu dužne pažnje u obavljanju profesionalne delatnosti, odgovara detetu za time nastalu štetu.

Dete iz stava 1. ovog člana, ima pravo na naknadu štete prema opštim pravilima o odgovornosti za štetu.

Šteta koju u tom slučaju trpi dete ne sastoji se u otkrivenoj genetičkoj bolesti, genetički uslovljenoj anomaliji ili retkoj bolesti, niti u činjenici da je dete rođeno, već u posledicama koje zbog bolesti, odnosno anomalije neželjeno rođenje uzrokuje u vidu povećanih troškova lečenja i nege za dete.

Član 34.

Lekar je odgovoran za štetu roditeljima deteta koje je rođeno genetički oštećeno, zbog povrede njihovog prava da budu obavešteni o zdravstvenom stanju deteta pre rođenja, kako bi tako informisani dali svoj pristanak na dalji tretman, odnosno kako bi slobodno odlučili da li žele da takvu trudnoću dovedu do kraja ili da je prevremeno iz tih razloga prekinu, a sve u okviru zakonom dopuštenih indikacija za prekid trudnoće.

Šteta koju u tom slučaju trpe roditelji sastoji se iz duševnih bolova usled detetove onesposobljenosti, genetički uslovljene bolesti i anomalije, koju nisu očekivali i na koju zbog izostalih laboratorijskih pretraga i genetičkih informacija nisu bili upozoreni.

Roditelji imaju pravo na naknadu štete prema opštim pravilima o odgovornosti za štetu.

Član 35.

Odgovornost lekara odnosno drugog zdravstvenog radnika za štetu isključuje se kad postoji tehnička greška u samom nalazu izdatom od laboratorije, kad postoji slučaj u smislu građanskog prava, i kad su jedan ili oba roditelja znali za rizik da će dete biti rođeno onesposobljeno nastalom bolešću ili genetički uslovljenom anomalijom i na to su pristali.

IX. KAZNENE ODREDBE

Prekršaji

Član 36.

Novčanom kaznom u iznosu od 300.000 do 1.000.000 dinara kazniće se za prekršaj zdravstvena ustanova ako:

1) obavlja genetičko istraživanje, odnosno zahvat na ljudskom genomu suprotno članu 7. ovog zakona;

2) postupi suprotno odredbama čl. 9. i 10. ovog zakona u pogledu zabrane diskriminacije i selekcije pola;

3) prikuplja genetičke podatke i uzorke radi sticanja imovinske ili bilo koje druge koristi, kao i ako oglašava te aktivnosti u medijima ili na bilo kom drugom nosiocu oglasne poruke (član 11.);

4) ne uništi genetički uzorak bez odlaganja po prestanku potrebe za ispitivanjem ili ako je pacijent, odnosno njegov zakonski zastupnik opozvao pismeni pristanak (član 22.);

Novčanom kaznom od 300.000 do 500.000 dinara za prekršaj iz stava 1. ovog člana kazniće se preduzetnik.

Novčanom kaznom od 40.000 do 50.000 dinara za prekršaj iz stava 1. ovog člana kazniće se i odgovorno lice u pravnom licu.

Novčanom kaznom od 40.000 do 50.000 dinara za prekršaj iz stava 1. ovog člana kazniće se i zdravstveni radnik u pravnom licu.

X. PRELAZNE I ZAVRŠNE ODREDBE

Član 37.

Ako su pitanja koja su predmet ovog zakona na drugačiji način uređena drugim zakonom primenjuju se odredbe ovog zakona i propisa donetih za sprovođenje ovog zakona.

Član 38.

Na sva pitanja koja se odnose na prevenciju i dijagnostiku genetičkih i retkih bolesti a koja nisu uređena ovim zakonom shodno se primenjuju odredbe zakona kojima se uređuju zdravstvena zaštita, zdravstveno osiguranje, prava pacijenata, zdravstvena dokumentacija i evidencija u oblasti zdravstva, zabrana diskriminacije, kao i zakona kojim se uređuje lečenje neplodnosti postupcima biomedicinski potpomognutog oplođenja.

Član 39.

Propisi za čije je donošenje ovim zakonom ovlašćen ministar doneće se u roku od šest meseci od dana stupanja na snagu ovog zakona.

Član 40.

Obrasce pristanka i izjava iz čl. 16, 17. i 18. ovog zakona propisuje ministar u roku od tri meseca od dana stupanja na snagu ovog zakona.

Član 41.

Nadzor nad sprovođenjem ovog zakona vrši Ministarstvo.

Član 42.

Ovaj zakon stupa na snagu osmog dana od dana objavljivanja u „Službenom glasniku Republike Srbije.“

ЗАКОН

О ТРАНСПЛАНТАЦИЈИ ОРГАНА

"Сл. гласник РС", бр. 72/2009 од 3.9.2009. године.

I. ОСНОВНЕ ОДРЕДБЕ

Члан 1.

Овим законом уређује се узимање органа или делова органа са живог или умрлог лица због пресађивања у тело другог лица ради лечења, надзор над спровођењем овог закона и друга питања од значаја за организацију и спровођење трансплантације органа или делова органа.

За обављање одређених послова државне управе у области трансплантације органа или делова органа, ћелија и ткива, поступака биомедицински потпомогнутог оплођења, као и трансфузије крви, овим законом оснива се Управа за биомедицину као орган у саставу Министарства здравља и утврђује њена надлежност.

Примена прописа

Члан 2.

Ако је трансплантација органа или делова органа са живог или умрлог лица због пресађивања у тело другог лица ради лечења на друкчији начин уређена другим законом, примењују се одредбе овог закона и прописа донетих за спровођење овог закона.

У погледу организације здравствене службе и остваривању права из здравственог осигурања примењују се одредбе закона којим се уређује здравствена заштита, као и закона којим се уређује обавезно здравствено осигурање, ако овим законом није друкчије одређено.

Значење израза

Члан 3.

Изрази употребљени у овом закону, ако није друкчије одређено, имају следеће значење:

1) трансплантација органа или делова органа (у даљем тексту: трансплантација) јесте медицински поступак узимања органа, односно делова органа са живог или умрлог лица због пресађивања у тело другог лица ради лечења, укључујући све процедуре за припрему, обраду, очување, праћење озбиљних нежељених појава и озбиљних нежељених реакција, као и дистрибуцију органа, односно делова органа;

2) орган је витални део људског тела састављен од различитих ткива, који има сопствену структуру, васкуларизацију и способност развоја физиолошких функција са значајним нивоом аутономије;

3) узимање органа, односно делова органа (у даљем тексту: узимање органа) јесте медицински поступак којим се путем одстрањивања из тела живог или умрлог лица добија орган, односно део органа ради пресађивања у тело другог лица;

4) пресађивање органа јесте медицински поступак којим се узети орган уноси, односно инплантира у тело другог живог лица ради лечења;

5) давалац органа јесте живо, односно умрло лице од кога се добија орган или део органа;

6) прималац органа јесте живо лице коме се ради лечења пресађује орган, односно органи или делови органа;

7) донирање јесте поступак давања органа без накнаде са живог или умрлог лица ради пресађивања у тело другог лица ради лечења;

8) обрада јесте свака радња која се обавља приликом припреме, руковања, очувања и паковања органа намењених за трансплантацију, ради лечења;

9) очување јесте поступак коришћења хемијских средстава, односно промењених услова средине или других средстава и поступака у обради како би се спречило или успорило биолошко или физичко пропадање органа;

10) дистрибуција јесте превоз и испорука органа, односно делова органа са места где су узети на место где се пресађују;

11) озбиљна нежељена појава јесте свака појава у вези са узимањем, пресађивањем, обрадом, очувањем и дистрибуирањем органа која може да доведе до преношења заразних болести, смрти или угрожавања живота, односно настанка инвалидитета или неспособности код пацијената или која може да доведе до хоспитализације или оболевања, односно да продужи хоспитализацију или оболевање;

12) озбиљна нежељена реакција јесте нежељен одговор, укључујући и појаву заразне болести даваоца или примаоца која је повезана са добијањем органа, односно делова органа као и њиховом применом код одређеног лица и који је штетан, опасан по живот и здравље, који доводи до појаве инвалидитета или неспособности код пацијента, односно доводи до хоспитализације или обољења, односно до продужења хоспитализације или оболевања;

13) следивост јесте могућност идентификовања даваоца и примаоца органа и лоцирање органа у свакој фази од узимања, добијања, обраде, очувања, тестирања и дистрибуције, до пресађивања органа или одбацивања органа који је пресађен;

14) члан породице јесте супружник, односно ванбрачни партнер, сродник у правој линији без обзира на степен сродства, побочној линији закључно са трећим степеном сродства, усвојитељ и усвојеник;

15) независни сведок јесте пунолетно пословно способно лице које ни на који начин није повезано са поступком обављања трансплантације органа;

16) промоција добровољног давалаштва органа јесте континуирано упознавање и давање информација грађанима о значају трансплантације, могућностима и условима за донирање органа, како би се грађани за живота одлучили да постану даваоци органа, односно делова органа и како би чланове своје породице, односно правне заступнике упознали са својом жељом да буду даваоци органа, као и давање потребних информација здравственим радницима;

17) типизација ткива јесте поступак одређивања имунолошких параметара који су од значаја за правилан избор, односно подударност органа, односно делова органа за трансплантацију;

18) недобитне услуге јесу услуге у вези са трансплантацијом органа, односно делова органа чија се цена утврђује само на основу зарачунавања нужних трошкова узимања, давања, пресађивања, припреме, обраде, очувања, без остваривања добити, односно које се не пружају ради остваривања добити;

19) систем квалитета јесте поступак утврђивања унутрашње организације за обављање послова узимања, донирања, обраде, очувања, пресађивања, дистрибуције, односно трансплантације на начин који обезбеђује стално унапређење квалитета рада и безбедности пацијента, као и спречавање настанка штетних последица по живот и здравље пацијента, уз обављање свих послова у складу са овим законом и прописима донетим за спровођење овог закона;

20) управљање квалитетом јесте поступак координисања активности које за циљ имају усмеравање и контролисање организације и спровођења поступка трансплантације са становишта квалитета;

21) стандардни оперативни поступци јесу писмена упутства која описују процедуре у одређеном поступку укључујући и материјале који се користе, као и очекивани крајњи исход.

II. НАЧЕЛА ПОСТУПКА ТРАНСПЛАНТАЦИЈЕ

Начело солидарности

Члан 4.

Начело солидарности између даваоца и примаоца органа остварује се организацијом поступка донирања, односно примања органа који се заснива на уважавању приоритених интереса за очување живота и здравља, односно који се заснива на добровољности, неплаћеном донирању, анонимности даваоца и примаоца органа, као и алтруизму даваоца.

Начело медицинске оправданости трансплантације

Члан 5.

Начело медицинске оправданости трансплантације остварује се спровођењем поступка трансплантације ради лечења само у случају када није могуће предузети друкчији начин лечења који има упоредиву ефикасност, односно уколико трансплантација не доводи до неприхватљивог ризика за живот даваоца и примаоца органа и уколико су претходно, у складу са правилима струке, обављена сва потребна медицинска испитивања помоћу којих је могуће са великом вероватноћом предвидети безбедност за даваоца и за примаоца органа и успех медицинске интервенције.

Начело заштите интереса и достојанства

Члан 6.

Начело заштите интереса и достојанства даваоца и примаоца органа остварује се спровођењем поступка трансплантације на начин који обезбеђује да интерес и добробит појединца буду изнад интереса друштва и науке, који гарантује поштовање достојанства и интереса појединца и његових законом утврђених права, без дискриминације.

Начело доступности и забране дискриминације

Члан 7.

Начело доступности и забране дискриминације остварује се на начин којим се обезбеђују једнаке могућности за трансплантацију свим примаоцима органа код којих је то медицински оправдано без обзира на пол, вероисповест, националну припадност, године живота, материјално стање, социјални статус, политичко или друго убеђење и искључиво уз поштовање етичких принципа, као и медицинских критеријума за узимање и донирање органа.

Начело безбедности

Члан 8.

Начело безбедности остварује се тако што се поступак трансплантације обавља у складу са достигнућима и развојем медицинске науке, највишим професионалним стандардима и кодексом професионалне етике, као и медицинско-етичким принципима заснованим на безбедним трансплантационим техникама.

III. ОРГАНИЗАЦИЈА ОБАВЉАЊА ПОСЛОВА ТРАНСПЛАНТАЦИЈЕ ОРГАНА

Здравствене установе које обављају послове трансплантације

Члан 9.

Послове трансплантације обављају здравствене установе из Плана мреже здравствених установа који је донела Влада (у даљем тексту: План мреже), односно делови тих здравствених установа, које су добиле дозволу за обављање послова узимања, пресађивања, дистрибуције, типизације ткива, односно послова трансплантације, у складу са овим законом.

Послове трансплантације може обављати здравствена установа, односно делови здравствене установе из става 1. овог члана (у даљем тексту: здравствена установа), и то:

1) здравствена установа у којој је дозвољено узимање и дистрибуција, односно у којој се дијагностикује и утврђује мождана смрт;

2) здравствена установа за пресађивање органа;

3) здравствена установа за утврђивање подударности, односно типизацију ткива;

4) здравствена установа за трансплантацију која обавља и послове узимања, дистрибуције и пресађивања органа.

За обављање послова из става 1. овог члана у здравственим установама организују се тимови за трансплантацију.

Поступак акредитације здравствених установа из става 1. овог члана обавља се у складу са законом којим се уређује здравствена заштита, а на основу стандарда за акредитацију здравствених установа које обављају послове трансплантације, које прописује министар надлежан за послове здравља (у даљем тексту: министар).

Здравствене установе које обављају послове трансплантације остварују средства за рад у складу са законом.

Издавање дозволе

Члан 10.

На основу захтева здравствене установе из члана 9. овог закона министар издаје дозволу за обављање послова узимања, диструбуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације, у складу са овим законом, ако:

1) здравствена установа испуњава услове за обављање здравствене делатности за одређену врсту здравствене установе, у складу са законом којим се уређује здравствена заштита и прописима донетим за спровођење тог закона;

2) здравствена установа испуњава услове за обављање послова узимања, пресађивања, дистрибуције, утврђивања подударности, односно типизације ткива, односно послова трансплантације, у складу са овим законом и прописима донетим за спровођење овог закона.

Уз захтев за издавање дозволе из става 1. овог члана здравствена установа дужна је да поднесе доказ о испуњености услова из става 1. овог члана.

Захтев из става 1. овог члана подноси се министарству надлежном за послове здравља (у даљем тексту: Министарство) преко Управе за биомедицину, основане у складу са овим законом (у даљем тексту: Управа за биомедицину).

Министар издаје дозволу на предлог директора Управе за биомедицину, а на основу налаза надлежног инспектора о испуњености услова за обављање послова трансплантације, у складу са овим законом.

Министар издаје дозволу за обављање послова из члана 9. став 2. овог закона здравственој установи, односно делу здравствене установе.

Само она здравствена установа која је добила дозволу из става 1. овог члана (у даљем тексту: овлашћена здравствена установа) може да обавља послове узимања, пресађивања, дистрибуције, утврђивања подударности, односно типизације ткива, односно послове трансплантације у складу са овим законом.

Дозвола из става 1. овог члана издаје се на време од пет година и може се обновити.

Забрањено је да други облик здравствене службе основан у складу са законом којим се уређује здравствена заштита (у даљем тексту: приватна пракса) обавља послове узимања, пресађивања, дистрибуције, утврђивања подударности, односно типизације ткива, односно послове трансплантације.

Услове у погледу простора, опреме, кадра, односно тимова за трансплантацију, као и друге услове из става 1. тачка 2) овог члана прописује министар.

Обнова дозволе

Члан 11.

Здравствена установа која је добила дозволу за обављање послова трансплантације из члана 9. став 2. овог закона подноси захтев за обнову дозволе најкасније 90 дана пре истека времена за које је добила дозволу.

Захтев за обнову дозволе из става 1. овог члана подноси се Министарству преко Управе за биомедицину.

Приликом прослеђивања захтева за обнову дозволе Управа за биомедицину доставља Министарству последњи налаз надлежне инспекције о извршеном редовном надзору над обављањем послова из члана 9. овог закона.

Здравствена установа је дужна да у поступку обнове дозволе поднесе и све друге потребне доказе на захтев Управе за биомедицину.

Министар доноси решење о обнављању дозволе на предлог директора Управе за биомедицину по поступку и на начин прописан за издавање дозволе.

Одузимање дозволе

Члан 12.

Министар може овлашћеној здравственој установи да одузме дозволу за обављање послова трансплантације и пре истека рока на који је дозвола издата, ако:

1) престане да испуњава услове за обављање здравствене делатности за одређену врсту здравствене установе прописане законом којим се уређује здравствена заштита и прописима донетим за спровођење тог закона;

2) престане да испуњава услове за обављање послова узимања, пресађивања, дистрибуције, типизације ткива, односно послова трансплантације, у складу са овим законом и прописима донетим за спровођење овог закона;

3) се у поступку надзора над радом, односно у поступку стручног надзора утврди да поступа супротно закону и правилима медицинске струке;

4) се у поступку контроле квалитета рада, односно континуираног праћења квалитета рада овлашћене здравствене установе утврди да је квалитет поступка узимања, дистрибуције, пресађивања, типизације ткива, односно трансплантације испод утврђених стандарда, односно да се не обављају у складу са стандардним оперативним процедурама и водичима добре праксе, као и да су озбиљне нежељене појаве и озбиљне нежељене реакције проузроковане пропустима у раду овлашћене здравствене установе;

5) не постиже упоредиве резултате у току једне календарске године, у складу са стандардима медицинске струке.

Министар доноси решење о одузимању дозволе на предлог директора Управе за биомедицину.

Доношење решења о давању, обнављању, односно одузимању дозволе

Члан 13.

Министар издаје, обнавља, односно одузима дозволу решењем, у складу са овим законом и законом којим се уређује општи управни поступак.

Решење из става 1. овог члана коначно је у управном поступку и против њега се може покренути управни спор.

Координатор у овлашћеној здравственој установи

Члан 14.

У свакој овлашћеној здравственој установи директор одређује координатора за трансплантацију органа (у даљем тексту: координатор), уз претходну сагласност министра.

За координатора може бити одређено лице из реда запослених у овлашћеној здравственој установи које има завршен медицински факултет, положен стручни испит, одговарајућу специјализацију, које је истакнути стручњак за област узимања, дистрибуције, пресађивања, типизације ткива, односно трансплантације и које има најмање пет година радног искуства на наведеним пословима после положеног специјалистичког испита.

Послови координатора

Члан 15.

Координатор:

1) координира рад тимова за трансплантацију из члана 9. став 3. овог закона на пословима узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, пресађивања, односно трансплантације;

2) одговоран је за организацију поступка праћења озбиљних нежељених појава и озбиљних нежељених реакција и вођење евиденције у складу са овим законом;

3) одговоран је за утврђивање и праћење система квалитета у поступцима узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације;

4) одговоран је за организацију и спровођење континуиране едукације здравствених радника и здравствених сарадника који учествују у поступцима узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације;

5) сарађује са Управом за биомедицину, доставља податке и извештаје о раду у складу са овим законом;

6) остварује сарадњу са другим овлашћеним здравственим установама у складу са овим законом;

7) обавља друге послове у складу са овим законом.

За обављање послова из става 1. овог члана координатору припада накнада за рад у складу са прописима којима се уређује финансирање обавезног здравственог осигурања.

Подношење извештаја од стране координатора

Члан 16.

Координатор подноси тромесечне извештаје о раду Управи за биомедицину, као и годишњи извештај, који садржи:

1) податке о дијагностикованим и утврђеним можданим смртима, у складу са овим законом;

2) податке о броју и врсти узетих, дистрибуираних, пресађених, односно трансплантираних органа, са живих, односно умрлих лица;

3) податке о озбиљним нежељеним реакцијама и озбиљним нежељеним појавама;

4) податке о старосним групама пацијената, односно давалаца органа, полу и породичном стању пацијената, односно давалаца органа;

5) предузете мере ради обезбеђења квалитета трансплантације;

6) проблеме у остваривању поступка трансплантације;

7) друге податке по захтеву Управе за биомедицину.

Извештај из става 1. овог члана треба да садржи и предлог мера за унапређивање резултата рада, односно квалитета здравствене заштите.

Етички одбор

Члан 17.

Етички одбор основан у здравственој установи која обавља послове трансплантације, у складу са законом којим се уређује здравствена заштита, у поступку трансплантације органа обавља следеће послове:

1) даје сагласност за узимање органа од живог даваоца органа;

2) даје мишљење о етичким и другим питањима у поступку трансплантације;

3) обавља и друге послове на предлог координатора и на основу захтева етичког одбора надлежног за биомедицину.

Сагласност из става 1. тачка 1) овог члана, Етички одбор даје након увида у медицинску документацију, тако што сви чланови Етичког одбора стављају свој потпис испод потписа даваоца на изјави о пристанку живог даваоца.

IV. ПОСТУПАК ТРАНСПЛАНТАЦИЈЕ

Добровољност давања органа

Члан 18.

Донирање органа је добровољно и без финансијске надокнаде, осим надокнаде нужних трошкова.

Врсту и висину нужних трошкова, као и начин и поступак надокнаде нужних трошкова из става 1. овог члана прописује министар.

Недобитност пружања услуга у вези са трансплантацијом

Члан 19.

Услуге у вези са узимањем, дистрибуцијом, пресађивањем, утврђивањем подударности, односно типизацијом ткива, односно трансплантацијом обављају се као недобитне услуге, осим ако овим законом није друкчије прописано.

Медицинска оправданост трансплантације

Члан 20.

Поступак трансплантације може се обављати само ако је то медицински оправдано, односно ако је то најповољнији начин лечења, уз поштовање начела поступка трансплантације прописаних овим законом.

Писмени пристанак пунолетног примаоца

Члан 21.

Пресађивање органа обавља се само ако је пунолетни пословно способни прималац пре пресађивања, као израз слободне воље, дао писмени пристанак за пресађивање органа.

Садржај обрасца изјаве о пристанку из става 1. овог члана прописује министар.

Здравствени радник који учествује у поступку пресађивања органа дужан је да примаоцу органа ради доношења одлуке о давању пристанка из става 1. овог члана пружи потпуне информације о сврси и природи пресађивања органа, поступку трансплантације, вероватноћи успеха, уобичајеним последицама пресађивања, као и о могућим ризицима, односно забележеним озбиљним нежељеним реакцијама и озбиљним нежељеним појавама, као и о могућим алтернативама трансплантације.

Писмени пристанак малолетног примаоца, односно примаоца коме је одузета пословна способност

Члан 22.

Малолетном лицу које нема пословну способност, као и пунолетном лицу коме је судском одлуком у потпуности одузета пословна способност, пресађивање органа може се обавити само уз писмени пристанак законског заступника, односно старатеља, и под условом да не постоји изричито противљење малолетног лица које је старије од 15 година живота.

Лицу коме је судском одлуком делимично одузета пословна способност пресађивање органа може се обавити под условом да је пре пресађивања то лице дало писмени пристанак у складу са степеном способности да самостално доноси одлуке и уз присуство и сагласност старатеља који потписом потврђује исказану вољу тог лица.

Са писменим пристанком старатеља из ст. 1. и 2. овог члана мора да се сагласи орган старатељства.

Здравствени радник који учествује у поступку трансплантације дужан је да информације из члана 21. став 3. овог закона пружи лицу, односно старатељу који дају пристанак, односно сагласност из става 1. овог члана.

Садржај обрасца изјаве о пристанку из ст. 1. и 2. овог члана прописује министар.

Републичка листа чекања за трансплантацију органа

Члан 23.

Ради обезбеђивања доступности органа и правичности поступка трансплантације у Републици Србији, за пацијенте код којих постоји медицинска оправданост за трансплантацију, сачињава се јединствена републичка листа чекања за примаоце органа (у даљем тексту: Републичка листа чекања).

Републичка листа чекања из става 1. овог члана сачињава се према врсти потребних органа.

Републичку листу чекања из става 2. овог члана сачињава и води Управа за биомедицину.

Ради обезбеђивања трансплантације за пацијенте који се налазе на Републичкој листи чекања министар доноси републички програм за трансплантацију.

Средства за спровођење програма из става 4. овог члана обезбеђују се у буџету Републике Србије, као и из средстава обавезног здравственог осигурања.

Овлашћена здравствена установа која обавља поступак трансплантације, односно пресађивања органа сачињава листу чекања по врсти органа потребних за пацијенте који се лече у тој здравственој установи, а која мора бити усклађена са Републичком листом чекања из става 1. овог члана.

Садржину, начин и поступак сачињавања и вођења Републичке листе чекања и достављања података од овлашћених здравствених установа, критеријуме за стављање на Републичку листу чекања, услове за утврђивање приоритета примаоца органа и друга питања од значаја за сачињавање и вођење Републичке листе чекања, прописује министар.

Размена органа ради лечења

Члан 24.

Уколико за поједини орган умрлог даваоца у Републици Србији није могуће наћи одговарајућег примаоца органа са Републичке листе чекања, орган се може понудити одговарајућој међународној организацији, међународној институцији и страној држави са којима је успостављена узајамна сарадња за размену органа ради лечења у складу са овим законом.

Узајамна сарадња из става 1. овог члана успоставља се на основу међународног уговора са међународном организацијом, међународном институцијом и страном државом.

Размена органа ради лечења дозвољена је искључиво под условом да је заснована на правима и обавезама преузетим међународним уговором из става 2. овог члана, као и ако су испуњени највиши професионални стандарди медицинске науке и струке којима се обезбеђује безбедност, квалитет и спречавање преношења заразних болести.

Размена органа, на основу међународног уговора из става 2. овог члана, врши се на принципу реципроцитета, а забрањено је у поступку размене органа примити орган који не задовољава највише професионалне стандарде медицинске науке и струке.

Забрањена је размена органа која се обавља у супротности са међународним уговором о размени органа из става 2. овог члана.

Забрањено је при размени органа нудити, давати или примати новчану накнаду као и било коју другу материјалну или нематеријалну корист осим надокнаде нужних трошкова који се утврђују међународним уговором из става 2. овог члана.

Управа за биомедицину координира рад овлашћених здравствених установа у поступку размене органа у складу са међународним уговором из става 2. овог члана.

Министар, на предлог Управе за биомедицину, уколико су испуњени услови прописани овим законом и међународним уговором из става 2. овог члана, без одлагања даје дозволу за сваки појединачни случај размене органа у складу са међународним уговором из става 2. овог члана.

Овлашћена здравствена установа дужна је да пре започињања поступка трансплантације обавести Управу за биомедицину о сваком случају трансплантације који се обавља у складу са међународним уговором из става 2. овог члана, као и да о томе води посебне евиденције.

Забрана стицања користи од донирања и примања органа, односно трансплантације

Члан 25.

У поступку донирања и примања органа, односно трансплантације забрањено је нудити, односно давати било какву накнаду или другу имовинску, односно неимовинску корист даваоцу од стране примаоца органа, за дате, односно примљене органе.

Забрана из става 1. овог члана не односи се на:

1) накнаду живом даваоцу органа за изгубљену зараду или другу врсту прихода за време проведено у здравственој установи или у току опоравка, односно за време привремене спречености за рад, односно накнаду било којих других оправданих трошкова које је давалац органа имао због поступка узимања органа;

2) оправдану накнаду у вези са плаћањем здравствених или других услуга у вези са узимањем органа;

3) накнаду у случају прекомерне штете која је настала као последица узимања органа са живог даваоца.

Накнаде из става 2. тач. 1) и 2) овог члана за обавезно осигурана лица обезбеђују се у складу са законом којим се уређује обавезно здравствено осигурање и прописима донетим за спровођење тог закона, односно може их обезбедити прималац органа или друго правно или физичко лице, у висини утврђеној тим прописима.

Накнада из става 2. тачка 3) овог члана обезбеђује се у складу са законом којим се уређује накнада штете.

Забрана оглашавања, односно рекламирања

Члан 26.

Забрањено је оглашавање, односно рекламирање потреба за органима, као и оглашавање донирања, са или без нуђења, односно давања новчане накнаде или друге материјалне или нематеријалне користи, као и оглашавање, односно рекламирање здравствених установа и здравствених радника који обављају поступак трансплантације у средствима јавног информисања, као и на другим носиоцима огласних порука, односно на било који други начин.

Забрана оглашавања, односно рекламирања из става 1. овог члана не односи се на промоцију добровољног давалаштва органа која се организује и спроводи у складу са овим законом.

На забрану оглашавања, односно рекламирања примењују се одредбе закона којим се уређује рекламирање, односно оглашавање здравствених услуга, здравствених установа и приватне праксе.

Забрана трговине органима

Члан 27.

Забрањена је трговина органима.

Здравствени радник који учествује у поступку трансплантације, уколико посумња да је орган који се трансплантира предмет комерцијалне трговине, дужан је да одбије учешће у поступку трансплантације и да без одлагања, усмено и писмено обавести надлежне државне органе и Управу за биомедицину.

Под трговином органима у смислу овог закона не сматра се давање накнаде из члана 25. овог закона, као ни плаћање трошкова узимања, односно донирања органа са живог или умрлог лица због пресађивања у тело другог лица ради лечења која укључује припрему, обраду, очување и дистрибуцију, у складу са овим законом.

Спречавање ризика преношења болести, као и очување квалитета органа

Члан 28.

Овлашћена здравствена установа, као и друго правно и физичко лице укључено у поступак трансплантације дужно је да предузме све потребне мере како би се спречио, односно умањио ризик од преношења заразне, односно било које друге болести на примаоца органа.

Правно и физичко лица из става 1. овог члана дужно је да у поступку припреме, обрађивања, очувања, карантина и дистрибуције поступа на такав начин да се обезбеди максимална стабилност органа до момента пресађивања органа, као и да се минимализује ризик од контаминације у складу са стандардима медицинске науке.

Ближе услове о начину и поступку спречавања ризика преношења болести у поступку узимања органа, односно трансплантације, укључујући и све процедуре за припрему, обраду, чување и дистрибуцију, прописује министар.

Финансирање поступка трансплантације

Члан 29.

За поступак узимања и пресађивања органа, односно за здравствену заштиту која је у вези са поступком трансплантације за одређену врсту органа, као и за праћење здравственог стања пре и после извршене трансплантације (у даљем тексту: право на трансплантацију), за осигурана лица средства обезбеђује организација обавезног здравственог осигурања за осигурана лица.

Право на трансплантацију које се не обезбеђује на начин прописан у ставу 1. овог члана може се обезбедити осигураницима који право на здравствену заштиту остварују из средстава добровољног здравственог осигурања.

Давалац органа има право на здравствену заштиту на терет средстава обавезног здравственог осигурања без плаћања партиципације ако је дао орган за ону врсту трансплантације која се као право обезбеђује из средстава обавезног здравственог осигурања, као и у случају ако је узимањем органа претрпео озбиљно погоршање здравственог стања, за све време док траје потреба за лечењем, односно за дуготрајном и континуираном здравственом заштитом која је директна последица донирања, као и за време привремене спречености за рад.

Давалац органа који нема својство обавезно осигураног лица у складу са законом, а који је орган донирао за лице које има својство обавезно осигураног лица у складу са законом, има право на здравствену заштиту из средстава обавезног здравственог осигурања, ако је узимањем органа претрпео озбиљно погоршање здравља које је директна последица узимања органа.

Праћење озбиљних нежељених реакција, као и озбиљних нежељених појава

Члан 30.

Овлашћене здравствене установе које обављају послове трансплантације, у складу са овим законом, дужне су да прате озбиљне нежељене реакције, као и озбиљне нежељене појаве и да о сумњи на озбиљне нежељене реакције, као и озбиљне нежељене појаве без одлагања, обавесте Управу за биомедицину.

Овлашћене здравствене установе воде евиденцију о свакој појединачној озбиљној нежељеној реакцији, као и озбиљној нежељеној појави за сваког даваоца, односно примаоца органа.

На основу евиденција из става 2. овога члана овлашћена здравствена установа дужна је да тромесечно, као и на крају календарске године Управи за биомедицину достави анализу података о озбиљним нежељеним реакцијама, као и озбиљним нежељеним појавама за одређене врсте органа који су трансплантирани са предлогом мера за спречавање озбиљних нежељених реакција, као и озбиљних нежељених појава.

Овлашћена здравствена установа у којој је извршено узимање органа од живог даваоца прати здравствено стање живог даваоца од момента донирања и надаље, у складу са стандардима

медицинске струке, осим ако давалац органа то не прихвата о чему даје писмену изјаву која се чува у здравственој установи као медицинска документација у складу са законом.

Овлашћена здравствена установа дужна је да обезбеди следивост органа који се трансплантира и да о томе води евиденције.

Садржај обрасца за праћење озбиљних нежељених реакција и озбиљних нежељених појава, као и писмену изјаву даваоца да не прихвата праћење здравственог стања, као и образац следивости органа из става 5. овог члана прописује министар.

Службена тајна

Члан 31.

Подаци о даваоцу и примаоцу органа представљају службену тајну, коју су дужна да чувају сва лица која учествују у поступку трансплантације и лица којима су ти подаци доступни.

Забрана давања и коришћења података

Члан 32.

Забрањено је примаоцу органа давати податке о личности умрлог даваоца органа или његове породице.

Забрањено је породици умрлог даваоца органа давати податке о личности примаоца органа и његове породице.

Забрањено је да лице које обавља одређене послове у давању, пријављивању, евидентирању, обради или достављању било којих података који се односе на даваоца и примаоца органа за трансплантацију, као и лица која учествују у поступку донирања, посредовању, узимању и пресађивању органа, даје податке о личности даваоца или примаоца органа, као и податке о лицима која су обавештена о намераваној или могућој трансплантацији, осим ако овим законом није друкчије уређено.

Сви подаци о личности даваоца и примаоца органа, укључујући и генетске податке који су доступни трећим лицима, морају да буду анонимни тако да није могуће идентификовати даваоца, односно примаоца органа.

Подаци о даваоцу и примаоцу органа не смеју се прикупљати, обрађивати или користити у друге сврхе осим у сврху трансплантације, у складу са овим законом.

Могућност коришћења података о трансплантацији

Члан 33.

Здравствени радник који обавља послове изабраног лекара даваоца и примаоца органа у складу са законом којим се уређује здравствено осигурање (у даљем тексту: изабрани лекар), као и други надлежни здравствени радник који у складу са законом треба да има увид у здравствено стање даваоца и примаоца органа, има право на увид у податке о извршеној трансплантацији који се односе на здравствено стање тих лица, у складу са овим законом.

Други здравствени радници, осим здравствених радника из става 1. овог члана, не могу имати могућност коришћења података, односно увид у податке о извршеној трансплантацији који се односе на здравствено стање даваоца и примаоца органа.

Резултати поступка трансплантације могу се користити у научноистраживачке сврхе.

Прикупљање, обрада, вођење, чување и коришћење података о даваоцу, односно примаоцу органа и медицинска документација

Члан 34.

Подаци о даваоцу и примаоцу органа прикупљају се, обрађују, воде, чувају и користе у складу са овим законом, као и прописима којима се уређује заштита података о личности.

Податке о даваоцу, односно примаоцу органа прикупља, обрађује, води, чува и користи Управа за биомедицину, као и овлашћена здравствена установа, у складу са овим законом.

Дозвољено је да овлашћена здравствена установа обрађује, води, чува и користи само оне податке који се односе на део послова у вези са трансплантацијом коју обавља.

О свим поступцима трансплантације, односно о узимању, пресађивању, донирању, пристанку примаоца органа, пристанку даваоца органа, односно чланова породице, обради, конзервирању, дистрибуцији, озбиљним нежељеним реакцијама и озбиљним нежељеним појавама, као и другим подацима од значаја за трансплантацију води се медицинска документација у складу са овим законом и законом којим се уређује медицинска документација.

Податке који се воде о даваоцу и примаоцу органа, медицинска документација која се води у поступку трансплантације, као и начин и поступак обраде, вођења, чувања, коришћења и размене података између овлашћених здравствених установа и Управе за биомедицину из ст. 2-4. овог члана, односно филијале обавезног здравственог осигурања, прописује министар.

Заштита података о даваоцу, односно примаоцу органа

Члан 35.

Управа за биомедицину и овлашћене здравствене установе дужне су да обезбеде заштиту података које прикупљају, обрађују, чувају, воде и користе, односно који су им доступни и које размењују, како би се спречило њихово неовлашћено коришћење, уништавање, промена и злоупотреба.

Ради заштите података из става 1. овог члана и спречавања њиховог неовлашћеног коришћења, одређени подаци морају да се замене идентификационом шифром коју давалац, односно прималац органа добија при пријави и уносу података у јединствену информациону базу података.

Начин и поступак заштите података из ст. 1. и 2. овог члана прописује министар.

Рок чувања података и медицинске документације

Члан 36.

Подаци о даваоцу и примаоцу органа из члана 34. овог закона, односно целокупна медицинска документација прописана овим законом чува се најмање 30 година у овлашћеној здравственој установи која је узела или пресадила орган, односно која је извршила типизацију ткива, односно која је извршила поступак трансплантације и може да се уништити најкасније по истеку 12 месеци од истека наведеног рока, осим ако законом није друкчије уређено.

Подаци које води Управа за биомедицину чувају се и уништавају у роковима прописаним ставом 1. овог члана.

Забрана коришћења и изношења података о личности даваоца, односно примаоца органа

Члан 37.

Забрањено је коришћење и изношење података о личности даваоца, односно примаоца органа у научне, образовне и статистичке сврхе, као и у средствима јавног информисања на начин који може да открије идентитет лица на које се подаци односе.

Изузетно од става 1. овог члана, на основу писменог пристанка даваоца, односно примаоца органа подаци о личности ових лица могу се употребљавати и износити у научне, образовне и статистичке сврхе, као и у средствима јавног информисања.

Обавештавање Управе за биомедицину

Члан 38.

О сваком намераваном донирању о коме здравствена установа има податке, извршеном узимању и пресађивању органа, као и размени органа ради пресађивања у складу са овим законом, овлашћена здравствена установа обавештава Управу за биомедицину.

Начин и поступак обавештавања, као и садржај обрасца о обавештавању из става 1. овог члана прописује министар.

Стандардне оперативне процедуре и водичи добре праксе

Члан 39.

Поступак узимања, пресађивања, типизације ткива, односно трансплантације, као и дистрибуције ради лечења обавља се у складу са стандардним оперативним процедурама, као и водичима добре праксе.

Стандардне оперативне процедуре и водиче добре праксе доноси министар на предлог директора Управе за биомедицину.

Промоција добровољног давалаштва органа

Члан 40.

Министарство врши промоцију добровољног давалаштва органа у складу са овим законом.

Министарство, ради промоције, обезбеђује све информације у вези са трансплантацијом стручној и општој јавности.

Давање информација из става 2. овог члана не сматра се рекламирањем, односно оглашавањем.

Министар може да донесе решење којим ће овластити друго правно, односно физичко лице да врши промоцију.

Информације из става 2. овог члана садрже све потребне медицинске, законске, социолошке, етичке и друге податке који су од значаја за промоцију поступка трансплантације, податке који се односе на овлашћене здравствене установе, као и друге информације од значаја за трансплантацију.

Програм промоције доноси министар.

Средства за спровођење програма из става 6. овог члана обезбеђују се у буџету Републике Србије.

V. УЗИМАЊЕ ОРГАНА ОД ЖИВОГ ДАВАОЦА ОРГАНА

Услови за узимање органа од живог даваоца органа

Члан 41.

Узимање органа од живог даваоца органа због пресађивања у тело другог лица ради лечења дозвољено је ако су истовремено испуњени следећи услови:

1) ако нема другог одговарајућег органа који је доступан од умрлог лица;

2) ако не постоји алтернативни медицински поступак упоредиве ефикасности за лечење примаоца органа;

3) ако тим за трансплантацију овлашћене здравствене установе да мишљење да ће пресађивањем тог органа доћи до излечења, односно побољшања здравственог стања примаоца органа;

4) ако је извршена процена ризика по живот и здравље даваоца органа;

5) ако је дат писмени пристанак даваоца органа;

6) ако су испуњени други услови прописани овим законом.

Лица која могу бити даваоци органа

Члан 42.

Давалац органа може бити лице које је старије од 18 година живота, под условом да има потпуну пословну способност, односно способност за расуђивање и доношење одлука и које је сродник примаоца у правој линији без обзира на степен сродства, као и побочни сродник закључно са трећим степеном сродства.

Изузетно од става 1. овог члана, давалац органа може бити супружник, односно ванбрачни партнер, усвојитељ, усвојеник, као и друго блиско лице са којим је прималац органа у присном личном односу који је свима очигледан, ако не постоји могућност да лице из става 1. овог члана буде давалац органа.

Писмени пристанак живог даваоца органа

Члан 43.

Узимање органа од живог даваоца органа дозвољено је под условом да је живи давалац органа дао писмени пристанак који је израз његове слободне воље даваоца.

Писмени пристанак даваоца органа даје се за тачно одређену медицинску интервенцију, односно само за узимање одређеног органа.

Писмени пристанак даје се за тачно одређеног примаоца органа.

Писмени пристанак чува се у здравственој установи као медицинска документација, у складу са законом.

Садржај обрасца изјаве о пристанку прописује министар.

Процена ризика по живот и здравље даваоца органа

Члан 44.

Узимање органа од живог даваоца органа дозвољено је ако је ризик по живот и здравље даваоца органа, према медицинским критеријумима, у границама прихватљивог.

Забрањено је узимање органа од живог даваоца органа ако постоји ризик по живот и здравље даваоца органа који према медицинским критеријумима није у границама прихватљивости, односно ако је ризик по живот и здравље живог даваоца органа у несразмери са очекиваном користи за здравље примаоца органа.

Процену ризика узимања органа по здравље живог даваоца органа цени тим за трансплантацију овлашћене здравствене установе у којој се трансплантација обавља.

Етички одбор овлашћене здравствене установе, основан у складу са законом којим се уређује здравствена заштита, даје претходну сагласност за узимање органа са живог даваоца органа због пресађивања у тело другог лица ради лечења.

Пре узимања органа морају да се изврше сви потребни медицински поступци у складу са стандардним оперативним процедурама и водичима добре праксе ради утврђивања здравственог стања даваоца органа, као и ради смањења физичких и психичких ризика по његово здравље и спречавања преношења заразних и других болести.

Право на непристрасно информисање даваоца органа ради давања писменог пристанка

Члан 45.

Ради давања писменог пристанака из члана 43. овог закона здравствени радник који не учествује у поступку узимања и пресађивања органа, односно који није изабрани лекар примаоца органа, а који има одговарајуће искуство у процени ризика по живот и здравље даваоца органа, дужан је да пре давања писменог пристанка, даваоца органа упозна са његовим правима у складу са овим законом, а посебно са правом на непристрасан савет у погледу ризика по живот и здравље, као и са током медицинског поступка, вероватноћом успеха и уобичајеним ризицима, с тим да дате информације не смеју бити сугестивне.

Информације које даје здравствени радник морају се дати у присуству другог здравственог радника.

Документ о информисању са подацима из става 1. овог члана сачињава се у писменој форми.

Саставни део документа из става 3. овог члана је и писмени пристанак из члана 43. овог закона, односно повлачење писменог пристанка из члана 47. овог закона који потписује давалац органа, као и присутни здравствени радник.

Садржај обрасца документа из става 3. овог члана прописује министар.

Информисање даваоца органа о поступку трансплантације

Члан 46.

Здравствени радник који учествује у поступку узимања органа дужан је да после давања писменог пристанка из члана 43. овог закона, даваоца органа у потпуности информише о поступку и начину узимања органа, могућим директним и индиректним последицама по његово здравље које могу настати узимањем органа, као и о очекиваном исходу трансплантације и осталим битним околностима, као и све друге информације по захтеву даваоца органа.

Повлачење писменог пристанка даваоца органа

Члан 47.

Овлашћена здравствена установа дужна је да обезбеди да давалац органа може да повуче писмени пристанак из члана 43. овог закона, а најкасније до момента почетка његове припреме за поступак узимања органа ради пресађивања у тело другог лица, односно до момента почетка припреме пацијента за поступак трансплантације.

Изјава о повлачењу пристанка даје се у писменој форми по поступку прописаном овим законом за давање пристанка.

VI. УЗИМАЊЕ ОРГАНА ОД УМРЛОГ ЛИЦА

Утврђивање смрти

Члан 48.

Узимање органа од умрлог лица због пресађивања другом лицу ради лечења може се извршити искључиво после дијагностиковања и утврђивања мождане смрти на основу медицинских критеријума у складу са законом.

Мождану смрту дијагностикује надлежни здравствени радник у складу са овим законом и прописима донетим за спровођење овог закона.

Мождану смрт утврђује надлежна комисија здравствене установе у складу са овим законом и прописима донетим за спровођење овог закона.

Здравствена установа дужна је да води регистар пацијената код којих је дијагностикована и утврђена мождана смрт.

Здравствена установа дужна је да врши месечну анализу узрока мождане смрти и да о томе подноси извештај Управи за биомедицину.

Медицинске критеријуме, начин и поступак, услове за дијагностиковање и утврђивање мождане смрти лица чији део тела може да се узме због пресађивања у тело другог лица ради лечења у складу са овим законом, медицинску документацију о дијагностиковању и утврђивању мождане смрти, састав комисије надлежне за утврђивање мождане смрти, као и начин и поступак вођења и пријављивања регистра мождане смрти који се води у здравственој установи, прописује министар.

Комисија за утврђивање мождане смрти

Члан 49.

Мождану смрт утврђује Комисија за утврђивање мождане смрти смрти (у даљем тексту: Комисија), коју именује директор здравствене установе.

Чланови Комисије из става 1. овог члана не могу бити здравствени радници који учествују у поступку трансплантације, односно узимања и пресађивања органа, као ни лица која су на било који начин заинтересована за трансплантацију и повезана са њом.

Одлука о утврђивању мождане смрти мора бити донета на основу самосталне стручне одлуке сваког члана Комисије, с тим да одлука мора бити донета једногласно.

О утврђеној мождановој смрти саставља се записник који потписују сви чланови Комисије.

Записник из става 4. овог члана представља медицинску документацију и чува се у складу са законом.

Моменат утврђивања мождане смрти од стране Комисије на основу одлуке из става 3. овог члана, сматра се моментом смрти лица код кога је дијагностикована и утврђена мождана смрт.

Писмени пристанак за узимање органа

Члан 50.

Са умрлог лица дозвољено је узимање органа због пресађивања у тело другог лица ради лечења уколико је пунолетни пословно способан давалац пре смрти поступио на један од следећих начина, и то:

1) дао и лично потписао писмени пристанак за донирање у случају смрти у присуству најмање једног независног сведока који потврђује веродостојност потписа и слободно изражену вољу даваоца органа;

2) дао налог другом лицу да у његово име потпише писмени пристанак за донирање у случају смрти уз сопствено присуство потписивању пристанка и у присуству најмање једног независног сведока који потврђује веродостојност потписа и слободно изражену вољу даваоца органа.

На основу писменог пристанка из става 1. овог члана даваоцу органа се могу у случају смрти узети орган, односно органи после претходног обавештења чланова породице о донацији органа, изузев уколико се чланови породице томе изричито усмено, односно писмено успротиве уз навођење јасних и неоспорних чињеница из којих се може недвосмислено закључити да је умрло лице за живота променило став о донирању.

Давање писменог пристанка

Члан 51.

Изјава о писменом пристанку из члана 50. овог закона може се дати:

1) здравственом раднику који је изабрани лекар даваоца органа;

2) овлашћеном лицу за евидентирање писменог пристанка у филијали Републичког завода за здравствено осигурање у поступку издавања, односно оверавања здравствене књижице, односно друге здравствене исправе којом се утврђује својство осигураника (у даљем тексту: здравствена књижица);

3) овлашћеном лицу за евидентирање писменог пристанка у Управи за биомедицину;

4) овлашћеном лицу за евидентирање писменог пристанка у здравственој установи која обавља послове трансплантације.

Изјава о пристанку из става 1. овог члана даје се у писменој форми на обрасцу који прописује министар.

Писмени пристанак из става 1. овог члана дат на прописаном обрасцу чува се 30 година од смрти даваоца органа у овлашћеној здравственој установи, односно филијали обавезног здравственог осигурања, односно Управи за биомедицину, на начин и по поступку прописаним овим законом за медицинску документацију.

Евидентирање писменог пристанка

Члан 52.

Писмени пристанак из члана 51. овог закона обавезно се евидентира у здравствену књижицу.

Изабрани лекар, као и друго овлашћено лице из члана 51. овог закона дужни су да, пре давања писменог пристанка, свако заинтересовано лице упознају са значајем трансплантације ради лечења и да том лицу дају потпуне информације које не смеју бити сугестивне и које су засноване на медицинским доказима о могућности донирања, условима за донирање, односно за узимање органа у случају мождане смрти у складу са овим законом.

После давања информација из става 2. овог члана лицу које је заинтересовано да постане давалац органа потребно је оставити разумно време да донесе одлуку о давању писменог пристанка.

Забрана узимања органа

Члан 53.

Свако пунолетно и пословно способно лице може изричито забранити узимање својих органа у случају мождане смрти.

Изјава о забрани узимања органа даје се у писменој форми здравственом раднику, односно овлашћеном лицу из члана 51. став 1. овог закона.

Образац изјаве о забрани узимања органа прописује министар.

Писмена изјава о забрани узимања органа из става 2. овог члана чува се 12 месеци од дана смрти тог лица у здравственој установи, односно филијали обавезног здравственог осигурања, односно Управи за биомедицину, на начин и по поступку прописаним овим законом за медицинску документацију.

Забрана узимања органа евидентира се у здравственој књижици.

Издавање донаторске картице

Члан 54.

На основу датог и евидентираног писменог пристанка у складу са овим законом, установа, орган, односно организација коју је овластио министар издају даваоцу донаторску картицу у којој је изричито евидентиран пристанак за давање органа.

Начин и поступак давања изјаве о пристанку и евидентирање писменог пристанка у здравственој књижици, односно забрана узимања органа, вођење евиденције о датим изјавама о пристанку, односно забрани узимања органа, заштите података о даваоцу органа, образац донаторске картице, као и услове које треба да испуни установа, орган, односно организација који дају донаторску картицу, прописује министар.

Узимање органа од умрлог лица које није дало писмени пристанак

Члан 55.

Са умрлог лица које је држављанин Републике Србије и које има стално пребивалиште у Републици Србији, могу се узимати органи због пресађивања другом лицу ради лечења и у случају када то лице није дало писмени пристанак у складу са овим законом, ако то лице за живота није изричито, писмено или усмено, забранило узимање органа, у складу са овим законом.

У случају из става 1. овог члана за узимање органа потребна је писмена сагласност чланова породице умрлог лица.

Ако умрло лице нема живе чланове породице, односно ако они нису доступни у разумном времену које не угрожава узимање и трансплантацију а доступно је друго блиско лице, са којим је умрли био у присном личном односу који је свима очигледан најмање последње две године пре смрти лица, за узимање органа довољна је сагласност тог блиског лица.

Информисање и давање сагласности члана породице лица које није дало писмени пристанак

Члан 56.

Лице које је овластио директор здравствене установе дужно је да информише једног од чланова породице умрлог лица, уколико су чланови породице доступни, о могућности узимања и потреби за органом са умрлог лица.

Лице које је овластио директор здравствене установе дужно је да информише једног од чланова породице умрлог лица о праву да се са узимањем органа сагласи или одбије давање сагласности.

Члановима породице умрлог лица потребно је дати разумно време да донесу одлуку, односно оно време које неће угрозити могућност узимања органа, ради пресађивања у тело другог лица.

Раније дата сагласност члана породице умрлог лица може се повући до момента припреме пацијента за трансплантацију о чему се обавештава надлежни здравствени радник.

Члан породице може дати сагласност само у случају да је у последње две године пре смрти умрлог лица био лично у контакту са умрлим лицем.

Уколико постоји више чланова породице истог степена сродства, довољно је да само један од њих да сагласност, с тим ако члан породице који је ближи по степену сродства није доступан у разумном времену, које не угрожава узимање органа и трансплантацију дозвољено је да сагласност да члан породице следећи по степену сродства који је доступан.

Ако умрло лице нема живе чланове породице, односно ако они нису доступни у разумном времену које не угрожава узимање органа и трансплантацију, а доступно је друго блиско лице из члана 55. став 3. овог закона, на давање сагласности тог лица примењују се одредбе ст. 1-5. овог члана.

Изјаву о давању сагласности, о одбијању давања сагласности или о повлачењу сагласности члан породице, односно друго блиско лице из става 6. овог члана даје на обрасцу писмене сагласности, који прописује министар.

Узимање органа од умрлог лица које није држављанин Републике Србије

Члан 57.

Са умрлог лица које није држављанин Републике Србије и које нема стално пребивалиште у Републици Србији, а које није дало писмени пристанак у складу са овим законом, могу се узимати органи због пресађивања другом лицу ради лечења само уз писмену сагласност члана породице.

Информисање и давање сагласности члана породице, односно другог блиског лица из члана 55. став 3. овог закона, за умрло лице које није држављанин Републике Србије и нема стално пребивалиште у Републици Србији а није дало писмени пристанак у складу са овим законом, обавља се у складу са чланом 56. овог закона.

Узимање органа од малолетног лица, односно од лица које нема пословну способност

Члан 58.

Са умрлог малолетног лица, односно од лица које нема потпуну пословну способност, као и пунолетног лица коме је за живота на основу одлуке надлежног органа делимично или у потпуности одузета пословна способност, дозвољено је узимање органа због пресађивања другом лицу ради лечења под условима и на начин прописан у чл. 55. и 56. овог закона.

Поступак трансплантације

Члан 59.

Поступак трансплантације обавља се у складу са највишим стандардима медицинске науке.

Начин и поступак узимања органа и донирања од живог или умрлог лица, припрему, обраду, очување, карантин, употребу, дистрибуцију, односно трансплантацију прописује министар.

Јединствен републички регистар давалаца органа

Члан 60.

Управа за биомедицину води јединствени републички регистар лица која су за живота дала писмени пристанак за узимање органа у случају своје смрти због пресађивања у тело другог лица ради лечења, у складу са овим законом (у даљем тексту: Јединствени републички регистар давалаца).

Начин и поступак, вођење и упис давалаца органа у Јединствени републички регистар давалаца, подаци који се воде, чување и заштиту података, поступак приступа подацима који се воде у Јединственом републичком регистру давалаца, начин и поступак давања и чувања шифре за добијање одобрења за позивање на податке који се воде, брисање података, начин и поступак меморисања свих позивања на податке који се воде, као и друга питања од значаја за вођење Јединственог републичког регистра давалаца, прописује министар.

Доступност података из Јединственог републичког регистра давалаца

Члан 61.

Подаци из Јединственог републичког регистра давалаца доступни су искључиво лицима која имају овлашћење да траже и добију податке који се воде, и то:

1) лицу које је за живота дало писмени пристанак за узимање органа, у складу са овим законом, о подацима који се односе искључиво на личне податке о личности тог лица;

2) овлашћеном здравственом раднику коме је Јединствени републички регистар давалаца доделио шифру за добијање одобрења за позивање на податке који се воде у Јединственом републичком регистру давалаца.

Лице из става 1. тачка 1) овог члана може добити податке који се воде у Јединственом републичком регистру давалаца искључиво на основу писменог захтева и ти подаци се у року од 15 дана од дана подношења захтева писмено достављају подносиоцу захтева.

Министарство може користити статистичке податке из Јединственог републичког регистра давалаца ради утврђивања здравствене политике у области трансплантације.

Прибављање пристанка, односно сагласности, као и других података пре започињања поступка узимања органа, односно трансплантације

Члан 62.

Овлашћени здравствени радник може да започне поступак узимања органа од умрлог лица, ако:

1) располаже доказом о писменом пристанку умрлог лица, односно донаторском картицом, односно у разговору са члановима породице или другим блиским лицем провери да умрло лице за живота није променило одлуку о пристанку за донацију органа о чему здравствени радник сачињава службену белешку у медицинској документацији, односно ако прибави податке о евиденцији умрлог лица у Јединственом републичком регистру давалаца;

2) не располаже доказом о писменом пристанку умрлог лица, односно донаторском картицом, односно ако не постоји доказ о евидентирању писменог пристанка умрлог лица у Јединственом републичком регистру давалаца под условом да је члан породице умрлог лица, односно друго блиско лице дало сагласност у складу са овим законом.

Право на пијетет

Члан 63.

При узимању органа, односно делова органа сви учесници овог поступка дужни су да тело умрлог даваоца третирају са поштовањем достојанства умрлог лица и чланова породице умрлог, као и да предузму све потребне мере како би се повратио спољашњи изглед умрлог даваоца (леша).

VII. УПРАВА ЗА БИОМЕДИЦИНУ

Оснивање Управе за биомедицину

Члан 64.

Ради обављања послова државне управе у области биомедицине оснива се Управа за биомедицину која обавља послове који се односе на:

1) трансплантацију органа;

2) трансплантацију ћелија и ткива, као и за биомедицински потпомогнуто оплођење;

3) трансфузију крви.

Управа за биомедицину нема својство правног лица.

Седиште Управе за биомедицину је у Београду.

Директор Управе за биомедицину

Члан 65.

Управом за биомедицину руководи директор.

Директора поставља Влада на пет година, на предлог министра, према закону којим се уређује положај државних службеника.

За директора може бити постављено лице које је истакнути стручњак за област трансплантације, односно за области из надлежности Управе за биомедицину из члана 64. став 1. овог закона.

Директор за свој рад одговара министру.

Директор решава у управним стварима из делокруга Управе за биомедицину и одлучује о правима и дужностима запослених.

Помоћници директора Управом за биомедицину

Члан 66.

Директор Управе за биомедицину има три помоћника.

Помоћници директора руководе пословима у једној или више међусобно повезаних области рада Управе за биомедицину из члана 64. став 1. овог закона.

Помоћници директора за свој рад одговарају директору и министру.

Помоћника директора поставља Влада на пет година, на предлог министра, према закону којим се уређује положај државних службеника.

Етички одбор за биомедицину

Члан 67.

Образује се Етички одбор за биомедицину.

Министар именује чланове етичког одбора за биомедицину из реда истакнутих стручњака за област биомедицине која је у надлежности Управе за биомедицину.

Етички одбор за биомедицину има седам чланова.

Задаци етичког одбора за биомедицину уређују се актом министра о именовању чланова.

Стручне и административно-техничке послове за потребе Етичког одбора за биомедицину обавља Управа за биомедицину.

Етички одбор за биомедицину:

1) предлаже основна начела професионалне етике здравствених радника који обављају послове трансплантације;

2) прати примену начела професионалне етике здравствених радника у обављању трансплантације на територији Републике Србије;

3) координира рад етичких одбора, из члана 17. овог закона, у здравственим установама;

4) одлучује и даје мишљење о спорним питањима која су од значаја за трансплантацију у здравственим установама;

5) прати спровођење одлука и разматра стручна питања у вези са трансплантацијом у здравственим установама и о томе обавештава Етички одбор Србије;

6) подноси годишњи извештај Министарству о спровођењу трансплантације у здравственим установама, као и о уоченим проблемима, недостацима и примедбама на рад етичких одбора у здравственим установама;

7) разматра и друга питања професионалне етике у спровођењу трансплантације.

Спољни експерти Управе за биомедицину

Члан 68.

За стручна питања из делокруга Управе за биомедицину, директор може ангажовати спољне експерте уз претходну сагласност министра.

Министар утврђује листу спољних експерата.

Спољни експерти из става 2. овог члана јесу истакнути домаћи или инострани стручњаци у области за коју се именују.

Спољни експерти из става 2. овог члана именују се на период од пет година.

Спољни експерти дају мишљење Управи за биомедицину по питањима из надлежности Управе за биомедицину.

За рад спољним експертима припада накнада коју утврђује директор Управе за биомедицину.

Послови Управе за биомедицину који се односе на трансплантацију органа

Члан 69.

Управа за биомедицину обавља послове који се односе на трансплантацију органа у оквиру посебне организационе јединице (у даљем тексту: Србија-трансплант), и то:

1) координира рад здравствених установа које су добиле дозволу из члана 10. овог закона и предлаже мере за унапређивање квалитета рада здравствених установа које обављају послове трансплантације;

2) обавља послове контроле квалитета рада, односно континуираног праћења квалитета рада;

3) обезбеђује и координира дистрибуцију и размену органа између здравствених установа у земљи, као и са надлежним правним лицима, органима и организацијама у иностранству са којима се остварује сарадња у складу са овим законом;

4) утврђује и контролише испуњеност услова за обављање послова у здравственим установама које обављају послове трансплантације у погледу простора, кадра и опреме прописаних овим законом и прописима донетим за спровођење овог закона;

5) предлаже министру издавање, обнављање, односно одузимање дозволе за обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације, води евиденције о размени органа у складу са овим законом;

6) води Јединствени регистар давалаца, у складу са овим законом;

7) води јединствене листе чекања по врстама органа у складу са овим законом;

8) учествује у поступку промоције трансплантације и предлаже министру програм за промоцију трансплантације;

9) учествује у припреми предлога прописа за спровођење овог закона које доноси министар;

10) обезбеђује континуиран и непрекидни проток информација, као и њихову доступност овлашћеним здравственим радницима о подацима које воде у складу са овим законом;

11) обезбеђује, организује и одржава јединствен информациони систем за трансплантацију и овлашћеном здравственом раднику у поступку трансплантације додељује шифру за добијање одобрења за позивање на податке које води, у складу са овим законом и прописима донетим за спровођење овог закона;

12) врши инспекцијски надзор над радом здравствених установа које су добиле дозволу у складу са чланом 10. овог закона;

13) прати научна достигнућа у области трансплантације органа и предлаже мере за примену у Републици Србији;

14) учествује у припреми водича добре праксе и стандардних оперативних процедура за обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације;

15) подноси министру извештаје о раду у складу са овим законом;

16) обавља и друге послове у складу са законом.

Радно време Управе за биомедицину за обављање послова из става 1. овог члана усклађује је са радним временом здравствених установа из члана 9. овог закона.

О радном времену из става 2. овог члана одлуку доноси директор Управе за биомедицину.

Други послови Управе за биомедицину

Члан 70.

Поред послова из члана 69. овог закона Управа за биомедицину обавља и послове који се односе на трансплантацију ћелија и ткива и биомедицински потпомогнуто оплођење, који се уређују законом којим се уређује трансплантација ћелија и ткива, односно законом којим се уређује биомедицински потпомогнуто оплођење, као и послове који се односе на трансфузију крви уређују се законом којим се уређује трансфузиолошка делатност.

Надзор који спроводи инспектор за трансплантацију

Члан 71.

У вршењу надзора над обављањем послова здравствених установа које обављају послове трансплантације, инспектор за трансплантацију овлашћен је да:

1) прегледа опште и појединачне акте, документацију и евиденције које се односе на обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације;

2) прегледа просторије, објекте и опрему, као и документацију о прописаном кадру који обавља послове узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације;

3) саслуша и узме изјаву од одговорних лица, здравствених радника и других заинтересованих лица која учествују у поступку трансплантације;

4) наложи отклањање утврђених неправилности и недостатака у обављању послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације органа, у року који не може бити краћи од 15 дана ни дужи од шест месеци од дана пријема акта којим је та мера наложена, а у хитним случајевима нареди отклањање утврђених неправилности одмах;

5) наложи извршење прописаних мера здравственој установи која чини републичку службу за трансплантацију у року који не може бити краћи од 15 дана ни дужи од три месеца од дана пријема акта којим је та мера наложена, а у хитним случајевима нареди извршење прописаних мера одмах;

6) привремено забрани обављање послова овлашћеној здравственој установи ако не поступи у складу са наложеним мерама предвиђеним тачком 4) овог члана, у року који не може бити краћи од 30 дана ни дужи од шест месеци од дана пријема акта којим је та мера изречена;

7) привремено забрани обављање послова овлашћеној здравственој установи ако није отклонила утврђене неправилности и недостатке, односно ако није извршила наложене мере које је изрекао инспектор за трансплантацију, односно здравствени инспектор и покрене поступак за одузимање дозволе за обављање послова утврђених дозволом у складу са овим законом;

8) нареди забрану употребе одређеног органа уколико је орган узет у супротности са овим законом;

9) предузме и друге мере у складу са законом.

Надзор из става 1. овог члана обавља се континуирано, а најмање једном у две године.

На спровођење ванредног стручног надзора над здравственим установама које обављају послове трансплантације, сходно се примењују одредбе закона којим се уређује здравствена заштита.

Члан 72.

Овлашћена здравствена установа дужна је да инспектору за трансплантацију омогући несметано обављање послова у складу са овим законом, односно да омогући неометан преглед просторија, опреме, узетих органа за трансплантацију, медицинске документације и друге евиденције које се воде у складу са законом.

Инспектор из става 1. овог члана има право да, ради спречавања могућег прикривања доказа, одузме предмете, односно органе, као и медицинску документацију и друге евиденције које се воде у складу са законом, уз обавезу издавања потврде о привременом одузимању предмета, органа, односно медицинске документације и друге евиденције.

Члан 73.

О извршеном прегледу и предузетим радњама инспектор за трансплантацију дужан је да сачини записник који садржи налаз чињеничног стања утврђеног у овлашћеној здравственој установи.

Записник из става 1. овог члана доставља се здравственој установи над којом је надзор извршен.

Инспектор за трансплантацију дужан је да, на основу записника из става 1. овог члана, донесе решење којим се налажу мере, радње, као и рокови за извршење наложених мера у здравственој установи.

Против решења из става 3. овог члана може се изјавити жалба министру.

Решење министра из става 4. овог члана коначно је у управном поступку и против њега се може покренути управни спор.

Ако инспектор за трансплантацију оцени да је поступањем, односно непоступањем здравствене установе учињено кривично дело, привредни преступ или прекршај, дужан је да без одлагања поднесе надлежном органу пријаву за учињено кривично дело, привредни преступ, односно за покретање прекршајног поступка.

Члан 74.

Инспектор за трансплантацију самосталан је у свом раду у границама овлашћења утврђених овим законом и прописима донетим за спровођење овог закона.

Инспектор за трансплантацију дужан је да поступа савесно и непристрасно у вршењу послова надзора, односно да чува као службену тајну податке до којих дође у току вршења надзора, а посебно податке о личности и здравственом стању даваоца, односно примаоца органа.

На вршење надзора од стране инспектора за трансплантацију примењују се одредбе закона којим је уређен општи управни поступак, закона којим је уређен рад државне управе, као и закона којим је уређена здравствена заштита, ако овим законом није друкчије уређено.

Члан 75.

Послове инспектора за трансплантацију може вршити лице које има завршен медицински факултет, одговарајућу специјализацију, најмање пет година радног искуства након положеног специјалистичког испита, стручни испит за рад у државним органима и које је стекло посебна стручна знања за област трансплантације.

Инспектор из става 1. овог члана има службену легитимацију коју је дужан да покаже на захтев одговорног лица или другог заинтересованог лица приликом вршења надзора.

Образац и садржину легитимације из става 2. овог члана прописује министар.

Члан 76.

Трошкове настале у поступку утврђивања испуњености услова за обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације органа сноси подносилац захтева.

Висину трошкова из става 1. овог члана прописује министар.

Средства из става 1. овог члана подносилац захтева уплаћује на одговарајући рачун за уплату јавних прихода буџета Републике Србије.

VIII. НАДЗОР

Члан 77.

Надзор над спровођењем овог закона и прописа донетих за спровођење овог закона врши Министарство.

IX. КАЗНЕНЕ ОДРЕДБЕ

Кривична дела

Члан 78.

Ко силом или претњом, довођењем у заблуду или одржавањем у заблуди, злоупотребом овлашћења, поверења, односа зависности, тешких прилика другог, задржавањем личних исправа или давањем или примањем новца или друге користи присили једно лице да мимо своје слободне воље да писмени пристанак за давање органа за живота ради трансплантације том или другом лицу и коме се на основу тог писменог пристанка узме орган, или ако мимо своје воље потпише писмени пристанак за давање органа после своје смрти за трансплантацију том или другом лицу, казниће се затвором од две до десет година.

За дело из става 1. овог члана учињено према малолетном лицу учинилац ће се казнити казном прописаном за то дело и када није употребио силу, претњу или неки други од наведених начина.

Ако је дело из става 1. овог члана учињено према малолетном лицу, учинилац ће се казнити затвором најмање три године.

Ако је услед дела из ст. 1. и 3. овог члана наступила тешка телесна повреда даваоца органа, учинилац ће се казнити затвором од три до 15 година.

Ако је услед дела из ст. 1. и 3. овог члана наступила смрт даваоца органа, учинилац ће се казнити затвором најмање десет година.

Ко се бави вршењем кривичних дела из ст. 1-3. овог члана или је дело извршено од стране организоване групе, казниће се затвором најмање пет година.

Члан 79.

Ко уз било какву накнаду да свој орган или орган другог лица ради трансплантације или нуди свој или орган другог лица уз накнаду ради трансплантације или врбује, превози, пребацује, предаје, продаје, купује, посредује у продаји или посредује на било који други начин у трансплантацији органа или учествује у поступку трансплантације који је предмет комерцијалне трговине, казниће се затвором од две до десет година.

Ако је дело из става 1. овог члана учињено према малолетном лицу, учинилац ће се казнити затвором најмање три године.

Ако је услед дела из ст. 1. и 2. овог члана наступила тешка телесна повреда даваоца органа, учинилац ће се казнити затвором од три до 15 година.

Ако је услед дела из ст. 1. и 2. овог члана наступила смрт даваоца органа, учинилац ће се казнити затвором најмање десет година.

Ко се бави вршењем кривичних дела из ст. 1. и 2. овог члана или је дело извршено од стране организоване групе, казниће се затвором најмање пет година.

Члан 80.

Ко обави пресађивање органа или учествује у поступку пресађивања органа лицу које није дало писмени пристанак за пресађивање органа или узме орган од умрлог лица, односно учествује у узимању органа од умрлог лица код кога није дијагностикована и утврђена мождана смрт на начин и у складу са поступком прописаним овим законом, или ако обави узимање органа или учествује у поступку узимања органа од лица које је за живота забранило давање органа у случају своје смрти или ако писмени пристанак није дао члан породице или друго блиско лице у складу са овим законом, казниће се затвором од две до десет година.

Ако је дело из става 1. овог члана учињено према малолетном лицу, учинилац ће се казнити затвором најмање три године.

Ако је услед дела из ст. 1. и 2. овог члана наступила тешка телесна повреда даваоца органа, учинилац ће се казнити затвором од три до 15 година.

Ако је услед дела из ст. 1. и 2. овог члана наступила смрт даваоца органа, учинилац ће се казнити затвором најмање десет година.

Ко се бави вршењем кривичних дела из ст. 1. и 2. овог члана или је дело извршено од стране организоване групе, казниће се затвором најмање пет година.

Прекршаји

Члан 81.

Новчаном казном од 500.000,00 до 1.000.000,00 динара казниће се за прекршај правно лице - здравствена установа ако:

1) обавља послове узимања, диструбуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације органа без дозволе добијене у складу са овим законом (члан 10. став 5);

2) услуге узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације органа обавља као профитне услуге (члан 19);

3) обавља размену органа у супротности са међународним уговором о размени органа у складу са овим законом, који потписује министар, односно ако нуди, даје или прима новчану накнаду као и било коју другу материјалну или нематеријалну корист при размени органа, осим надокнаде трошкова за узимање, обраду, очување, карантин и дистрибуцију органа ради лечења у складу са тим међународним уговором (члан 24. ст. 5. и 6);

4) оглашава, односно рекламира потребу за органима као и оглашавање давања органа, са или без нуђења, односно давања новчане накнаде или друге материјалне или нематеријалне користи или ако оглашава, односно рекламира здравствену установу или здравствене раднике који обављају поступак трансплантације у средствима јавног информисања, као и на другим носиоцима огласних порука, односно на било који други начин (члан 26. став 1);

5) не предузме све потребне мере како би се спречио, односно умањио ризик од преношења заразне, односно било које друге болести на примаоца органа (члан 28);

6) не омогући праћење озбиљних нежељених реакција, као и озбиљних нежељених појава код даваоца, односно примаоца органа и да о сумњи на озбиљне нежељене реакције, као и озбиљне нежељене појаве, одмах, без одлагања, не обавести Управу за биомедицину или ако не води евиденције о озбиљним нежељеним реакцијама, као и озбиљним нежељеним појавама за сваког даваоца, односно примаоца органа, или ако не обезбеди следивост органа који се трансплантирају и о томе не води евиденције (члан 30. ст. 1, 2. и 5);

7) податке о даваоцу и примаоцу органа прикупља, обрађује или користи у друге сврхе осим у сврху трансплантације, у складу са овим законом (члан 32. став 4);

8) прикупља, обрађује, води, чува, користи и штити друге податке осим података који су неопходни за део послова који обавља та здравствена установа (члан 34. став 3);

9) не обезбеди заштиту података које води, односно који су им доступни и које размењује (члан 35. став 1);

10) не чува податке о даваоцу и примаоцу органа, односно ако не чува целокупну медицинску документацију прописану овим законом најмање 30 година, односно ако је уништи пре истека рока прописаног овим законом (члан 36. став 1);

11) користи и износи податке о личности даваоца, односно примаоца органа у научне, образовне и статистичке сврхе, као и у средствима јавног информисања на начин који може да открије идентитет лица на кога се подаци односе, а о чему давалац, односно прималац органа није дао писмени пристанак (члан 37);

12) о сваком могућем донирању о коме здравствена установа има податке, извршеном узимању и пресађивању органа, као и размени органа ради пресађивања у складу са овим законом не обавести Управу за биомедицину достављањем образаца о обавештавању (члан 38);

13) поступак узимања, пресађивања, типизације, односно трансплантације, као и дистрибуције органа ради лечења не обавља у складу са стандардним оперативним процедурама, као и водичима добре праксе (члан 39. став 1);

14) омогући узимање са живог даваоца органа у супротности са чланом 41. овог закона;

15) омогући узимање органа од живог даваоца органа код кога постоји ризик по живот и здравље даваоца који према медицинским критеријумима нису у границама прихватљивости, односно ако је ризик по живот и здравље живог даваоца органа у несразмери са очекиваном користи за здравље примаоца органа (члан 44. став 2);

16) омогући узимање органа од живог даваоца органа без писменог пристанка даваоца органа или ако у здравственој установи не чува писмени пристанак као медицинску документацију у складу са законом (члан 43. ст. 1. и 4);

17) омогући узимање органа са умрлог лица које је држављанин Републике Србије, односно који има стално пребивалиште у Републици Србији које није дало писмени пристанак у складу са овим законом, односно које је изричито писмено или усмено забранило узимање органа, без писмене сагласности члана породице, односно другог блиског лица са којим је умрли био у присном личном својству који је свима очигледан а најмање последње две године пре смрти тог лица (члан 55);

18) омогући узимање органа са умрлог лица које није држављанин Републике Србије и нема стално пребивалиште у Републици Србији, а није дало писмени пристанак у складу са овим законом, без писмене сагласности члана породице, односно другог блиског лица (члан 57);

19) омогући узимање органа са умрлог малолетног лица, односно од лица које нама потпуну пословну способност, као и од пунолетног лица коме је на основу одлуке надлежног органа одузета пословна способност без писмене сагласности родитеља, односно законског заступника (члан 58);

За прекршај из става 1. овог члана казниће се и одговорно лице у здравственој установи новчаном казном од 50.000 динара.

За прекршај из става 1. тач. 5) до 18) овог закона казниће се и здравствени радник, односно друго лице новчаном казном од 50.000 динара.

Члан 82.

Новчаном казном од 50.000 динара казниће се за прекршај физичко лице ако:

1) не чува податке о даваоцу или примаоцу органа као службену тајну (члан 31);

2) примаоцу органа даје податке о умрлом даваоцу органа или његовој породици, односно ако породици умрлог даваоца органа даје податке о примаоцу органа и његовој породици, односно ако даје податке о донирању, посредовању, узимању и пресађивању органа који су везани за даваоца или примаоца органа, као и податке о лицима која су обавештена о намераваној или могућој трансплантацији, осим ако овим законом није друкчије уређено (члан 32. ст. 1-3);

3) започне поступак узимања органа од умрлог лица у супротности са чланом 62. овог закона.

Члан 83.

Новчаном казном од 50.000 динара казниће се за прекршај предузетник ако обавља послове узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације.

Поред новчане казне из става 1. овог члана предузетнику ће се изрећи заштитна мера забране обављања здравствене делатности у трајању од три године.

X. ПРЕЛАЗНЕ И ЗАВРШНЕ ОДРЕДБЕ

Члан 84.

Управа за биомедицину почиње са радом најкасније 1. јула 2010. године.

Члан 85.

Овлашћене здравствене установе дужне су да ускладе организацију рада, као и опште акте са одредбама овог закона у року од 12 месеци од дана ступања на снагу овог закона.

Овлашћене здравствене установе у складу са прописима који су важили до дана ступања на снагу овог закона настављају са радом у складу са тим прописима до усклађивања рада са одредбама овог закона.

Члан 86.

Прописи за спровођење овог закона донеће се у року од 18 месеци од дана почетка рада Управе за биомедицину.

До доношења прописа из става 1. овог члана примењују се прописи који су важили до дана ступања на снагу овог закона.

Члан 87.

Поступак трансплантације који је започет пре ступања на снагу овог закона завршиће се по прописима који су били на снази до дана ступања на снагу овог закона.

Члан 88.

До организовања обављања послова инспектора за трансплантацију утврђених овим законом, послове инспекцијског надзора обављаће здравствена инспекција основана у складу са законом којим се уређује област здравствене заштите.

Члан 89.

Даном ступања на снагу овог закона престају да важе одредбе чл. 78. до 85. Закона о здравственој заштити ("Службени гласник РС", бр. 17/92, 26/92, 50/92, 52/93, 53/93, 67/93, 48/94, 25/96, 18/02, 101/05 и 107/05), Закон о узимању и пресађивању делова људског тела у сврху лечења ("Службени гласник СРС", број 22/81) и Закон о узимању и пресађивању делова људског тела ("Службени лист СФРЈ", бр. 63/10, 22/91, 24/94 и 28/96 и "Службени гласник РС", број 101/05).

Члан 90.

Овај закон ступа на снагу осмог дана од дана објављивања у "Службеном гласнику Републике Србије", а примењиваће се од 1. јануара 2010. године.

ЗАКОН

О ТРАНСПЛАНТАЦИЈИ ЋЕЛИЈА И ТКИВА

"Сл. гласник РС", бр. 72/2009 од 3.9.2009. године.

I. ОСНОВНЕ ОДРЕДБЕ

Члан 1.

Овим законом уређује се добијање, донирање, тестирање, обрада, очување, складиштење и дистрибуција људских ћелија и ткива намењених за примену код људи; оснивање банака ћелија и ткива; надзор над спровођењем овог закона и обављање одређених послова државне управе у области трансплантације ћелија и ткива, као и друга питања од значаја за организацију и спровођење трансплантације ћелија и ткива.

Примена прописа

Члан 2.

Ако је трансплантација људских ћелија и ткива за примену код људи, као и донирање, добијање и тестирање људских ћелија и ткива за примену у индустријским производима који се добијају из људских ћелија и ткива и који су намењени за примену код људи на друкчији начин уређена другим законом, примењују се одредбе овог закона и прописа донетих за спровођење овог закона.

У погледу организације здравствене службе и остваривања права из здравственог осигурања примењују се одредбе закона којим се уређује здравствена заштита и закона којим се уређује здравствено осигурање, ако овим законом није друкчије одређено.

На поступак добијања, донирања, тестирања, обраде, очувања, складиштења и дистрибуцију крвотворних ћелија и матичних ћелија хематопоезе из периферне крви, крви из плаценте и коштане сржи, репродуктивних ћелија, ткива и ћелија фетуса и матичних ћелија одраслих организама и ембриона примењују се одредбе овог закона, осим ако овим законом није друкчије уређено.

Употреба ћелија и ткива као аутологних трансплантата у истом хируршком поступку, као и крви и компонената крви, обавља се у складу са законом.

Значење израза

Члан 3.

Изрази употребљени у овом закону, ако није друкчије одређено, имају следеће значење:

1) трансплантација ћелија, односно ткива (у даљем тексту: трансплантација) јесте медицински поступак добијања ћелија, односно ткива са живог или умрлог лица ради пресађивања, односно употребе у тело другог лица укључујући и све процедуре за узимање, донирање, обраду, очување, карантин, употребу и дистрибуцију ћелија и ткива, као и праћење озбиљних нежељених појава и озбиљних нежељених реакција;

2) ћелије су појединачне људске ћелије или скупови људских ћелија који нису повезани ниједном врстом везивног ткива;

3) ткиво је саставни део људског тела кога чине ћелије и везивно ткиво;

4) индустријски производ јесте ћелијски продукт који ћелија ствара и излучује, а који се поред употребе у медицини и научним истраживањима, може користити и у индустријској производњи, односно у комерцијалне сврхе;

5) давалац јесте живо, односно умрло лице од кога се добијају људске ћелије, односно ткива;

6) донирање јесте давање људских ћелија и ткива без накнаде са живог или умрлог лица ради примене код људи;

7) добијање јесте поступак којим се долази до ћелија и ткива;

8) обрада јесте свака радња која се обавља приликом припреме, руковања, очувања и паковања ћелија и ткива намењених за примену код људи ради лечења;

9) очување јесте поступак коришћења хемијских средстава, односно промењених услова средине или других средстава и поступака у обради како би се спречило или успорило биолошко или физичко пропадање ћелија и ткива;

10) карантин јесте статус добијања ћелија и ткива, односно изолација ткива физички или на неки други начин у очекивању одлуке о њиховом прихватању или одбијању;

11) складиштење јесте чување ћелија и ткива, односно индустријских производа у одговарајућим контролисаним условима до дистрибуције;

12) дистрибуција јесте превоз и испорука ћелија и ткива намењених за примену код људи;

13) примена код људи јесте коришћење ћелија и ткива на или у људском примаоцу, као и вантелесна примена;

14) озбиљна нежељена појава јесте свака појава у вези са добијањем, испитивањем, обрадом, складиштењем и дистрибуцијом ћелија и ткива која може да доведе до преношења заразних болести, смрти или угрожавања живота, односно настанка инвалидитета или неспособности код пацијената или која може да доведе до хоспитализације или оболевања, односно да продужи хоспитализацију или оболевање;

15) озбиљна нежељена реакција јесте нежељен одговор, укључујући и појаву заразних болести, даваоца или примаоца која је повезана са добијањем ћелија и ткива или њиховом применом код људи, а која је фатална, опасна по живот, односно која доводи до појаве инвалидитета или неспособности код пацијента, односно доводи до хоспитализације или оболевања, односно до продужења хоспитализације или оболевања;

16) банка ћелија и ткива јесте здравствена установа или део здравствене установе или друго правно лице, у којој се обављају послови обраде, очувања, карантина, складиштења и дистрибуције људских ћелија и ткива, а која може бити задужена и за добијање или тестирање ћелија и ткива, под условима прописаним овим законом и прописима донетим за спровођење овог закона;

17) алогена трансплантација јесте употреба ћелија, односно ткива који су одстрањени од једног живог или умрлог лица и употребљени код другог лица;

18) аутологна трансплантација јесте употреба ћелија, односно ткива који се одстрањују и употребљавају код истог лица;

19) репродуктивне ћелије су ћелије и ткива намењени употреби у биомедицински потпомогнутом оплођењу;

20) донирање међу партнерима јесте донирање репродуктивних ћелија између супружника, односно ванбрачних партнера;

21) систем квалитета јесте поступак утврђивања унутрашње организације за послове узимања, донирања, обраде, очувања, карантина, употребе, дистрибуције, односно трансплантације на начин који обезбеђује стално унапређење квалитета рада и безбедности ћелија и ткива, као и пацијента; спречавање настанка штетних последица по живот и здравље пацијента и живих давалаца приликом обављања свих послова у складу са овим законом и прописима донетим за спровођење овог закона;

22) управљање квалитетом јесте поступак координисања активности које за циљ имају усмеравање и контролисање организације и спровођење поступка узимања, давања, обраде, очувања, карантина, употребе, дистрибуције, односно трансплантације, са становишта квалитета;

23) стандардни оперативни поступци јесу писана упутства која описују процедуре у одређеном поступку укључујући и материјале који се користе, као и очекивани крајњи исход;

24) валидација јесте израда документованих поступака који са високим степеном сигурности пружају уверавање да одређени процес, стандардни оперативни поступци, опрема или средина доследно дају производ који задовољава унапред утврђене спецификације и захтеве квалитета, с тим да се процес валидира како би се оценио учинак система са становишта његове делотворности на планирану намену;

25) следивост јесте могућност лоцирања и идентификовања ћелија и ткива у свакој фази од узимања, донирања, обраде, чувања, карантина, складиштења, диструбуције, односно трансплантације примаоцу или одбацивања, што подразумева могућност идентификовања даваоца и банке ћелија и ткива или производног објекта који прима, обрађује или складишти ћелије и ткива, као и могућност идентификовања примаоца у здравственим установама где се ћелије и ткива пресађују примаоцу, што укључује и могућност лоцирања и идентификовања свих

релевантних података везаних за индустријске производе и материјале који долазе у додир са тим ћелијама и ткивима;

26) критично јесте потенцијални догађај који може да утиче на квалитет, односно безбедност или контакт са ћелијама и ткивима;

27) члан породице јесте супружник, односно ванбрачни партнер, сродник у правој линији без обзира на степен сродства, побочној линији закључно са трећим степеном сродства, усвојитељ и усвојеник;

28) независни сведок јесте пунолетно пословно способно лице које ни на који начин није повезано са поступком обављања трансплантације ћелија или ткива;

29) промоција добровољног давалаштва ћелија и ткива јесте континуирано упознавање и давање информација грађанима о значају трансплантације, могућностима и условима за донирање, како би се грађани за живота одлучили да постану даваоци, и како би чланове своје породице, односно правне заступнике упознали са својом жељом да буду даваоци, као и давање потребних информација здравственим радницима;

30) недобитне услуге јесу услуге у вези са узимањем, донирањем, обрадом, очувањем, карантином, употребом, дистрибуцијом, односно трансплантацијом ћелија и ткива чија се цена утврђује само на основу зарачунавања нужних трошкова, без остваривања добити, односно које се не пружају ради остваривања добити.

II. НАЧЕЛА ПОСТУПКА ТРАНСПЛАНТАЦИЈЕ ЋЕЛИЈА И ТКИВА

Начело солидарности

Члан 4.

Начело солидарности између даваоца и примаоца ћелија и ткива остварује се организацијом поступка донирања, односно примања ћелија и ткива који се заснива на уважавању приоритетних интереса за очување живота и здравља, односно који се заснива на добровољности, неплаћеном донирању, анонимности даваоца и примаоца под условима прописаним овим законом, као и алтруизму даваоца.

Начело медицинске оправданости трансплантације

Члан 5.

Начело медицинске оправданости трансплантације и примене код људи остварује се спровођењем поступка трансплантације ради лечења само у случају када није могуће предузети друкчији начин лечења који има упоредиву ефикасност, односно уколико трансплантација ћелија, односно ткива не доводи до неприхватљивог ризика за живот даваоца и примаоца и уколико су претходно, у складу са правилима струке, обављена сва потребна медицинска испитивања помоћу којих је могуће са великом вероватноћом предвидети безбедност за даваоца и за примаоца и успех медицинске интервенције.

Начело заштите интереса и достојанства

Члан 6.

Начело заштите интереса и достојанства даваоца и примаоца ћелија, односно ткива остварује се спровођењем поступка трансплантације на начин који обезбеђује да интерес и добробит појединца буду изнад интереса друштва и науке који гарантује поштовање достојанства и интереса појединца и његових законом утврђених права, без дискриминације.

Начело доступности и забране дискриминације

Члан 7.

Начело доступности и забране дискриминације остварује се на начин којим се обезбеђују једнаке могућности за трансплантацију ћелија и ткива свим примаоцима код којих је то медицински оправдано, без обзира на пол, вероисповест, националну припадност, године живота, материјално стање, социјални статус, политичко или друго убеђење и искључиво уз поштовање етичких принципа, као и медицинских критеријума за узимање и давање ћелија и ткива.

Начело безбедности

Члан 8.

Начело безбедности остварује се тако што се поступак трансплантације ћелија, односно ткива обавља у складу са достигнућима и развојем медицинске науке, највишим професионалним стандардима и кодексом професионалне етике, као и медицинско-етичким принципима заснованим на безбедним трансплантационим техникама.

III. ОРГАНИЗАЦИЈА ОБАВЉАЊА ПОСЛОВА ТРАНСПЛАНТАЦИЈЕ ЋЕЛИЈА И ТКИВА

Здравствена установа која обавља послове трансплантације ћелија, односно ткива

Члан 9.

Послове трансплантације ћелија, односно ткива обављају здравствене установе из Плана мреже здравствених установа који доноси Влада (у даљем тексту: План мреже), односно делови тих здравствених установа, које су добиле дозволу за обављање послова узимања, пресађивања, дистрибуције, типизације, односно послова трансплантације, у складу са овим законом.

Послове трансплантације ћелија, односно ткива, може обављати само она здравствена установа, односно делови здравствене установе из става 1. овог члана (у даљем тексту: здравствена установа), и то:

1) здравствена установа у којој је дозвољено узимање и дистрибуција ћелија, односно ткива;

2) здравствена установа за пресађивање ћелија, односно ткива;

3) здравствена установа за утврђивање подударности, односно типизацију ткива;

4) здравствена установа за трансплантацију ћелија, односно ткива која обавља и послове узимања, дистрибуције и пресађивања ћелија, односно ткива.

За обављање послова из става 1. овог члана у здравственим установама организују се тимови за трансплантацију.

Поступак акредитације здравствених установа из става 1. овог члана обавља се у складу са законом којим се уређује здравствена заштита, а на основу стандарда за акредитацију здравствених установа које обављају послове трансплантације ћелија, односно ткива, које прописује министар надлежан за послове здравља (у даљем тексту: министар).

Здравствене установе које обављају послове трансплантације ћелија, односно ткива остварују средства за рад у складу са законом.

Издавање дозволе

Члан 10.

На основу захтева здравствене установе из члана 9. овог закона министар издаје дозволу за обављање послова узимања, диструбуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија, односно ткива, у складу са овим законом, ако:

1) здравствена установа испуњава услове за обављање здравствене делатности за одређену врсту здравствене установе, у складу са законом којим се уређује здравствена заштита и прописима донетим за спровођење тог закона;

2) здравствена установа испуњава услове за обављање послова узимања, пресађивања, дистрибуције, утврђивања подударности, односно типизације, односно послова трансплантације ћелија, односно ткива, у складу са овим законом и прописима донетим за спровођење овог закона.

Уз захтев за издавање дозволе из става 1. овог члана здравствена установа дужна је да поднесе доказ о испуњености услова из става 1. овог члана.

Захтев из става 1. овог члана подноси се Министарству здравља (у даљем тексту: Министарство) преко Управе за биомедицину основане у складу са законом којим се уређује трансплантација органа (у даљем тексту: Управа за биомедицину).

Министар издаје дозволу на предлог директора Управе за биомедицину, а на основу налаза инспектора о испуњености услова за обављање послова трансплантације, у складу са законом.

Министар може да изда дозволу за обављање послова из члана 9. овог закона здравственој установи у целини или делу здравствене установе.

Само она здравствена установа која је добила дозволу из става 1. овог члана (у даљем тексту: овлашћена здравствена установа) може да обавља послове узимања, пресађивања, дистрибуције, утврђивања подударности, односно типизације, односно послове трансплантације у складу са овим законом.

Дозвола из става 1. овог члана издаје се на време од пет година и може се обновити.

Забрањено је да други облик здравствене службе основан у складу са законом којим се уређује здравствена заштита (у даљем тексту: приватна пракса), обавља послове узимања, пресађивања, дистрибуције, утврђивања подударности, односно типизације, односно послове трансплантације.

Услове у погледу простора, опреме, кадра, односно тимова за трансплантацију, као и друге услове из става 1. тачка 2) овог члана, прописује министар.

Обнова дозволе

Члан 11.

Здравствена установа која је добила дозволу за обављање послова трансплантације подноси захтев за обнову дозволе најкасније 90 дана пре истека времена за које је добила дозволу.

Захтев за обнову дозволе из става 1. овог члана подноси се Министарству преко Управе за биомедицину.

Приликом прослеђивања захтева за обнову дозволе Управа за биомедицину доставља Министарству последњи налаз надлежне инспекције о извршеном редовном надзору над обављањем послова из члана 9. овог закона.

Здравствена установа дужна је да у поступку обнове дозволе поднесе и све друге потребне доказе на захтев Управе за биомедицину.

Министар доноси решење о обнављању дозволе на предлог директора Управе за биомедицину по поступку и на начин прописаном за издавање дозволе.

Одузимање дозволе

Члан 12.

Министар може овлашћеној здравственој установи да одузме дозволу за обављање послова трансплантације и пре истека рока на који је дозвола издата, ако:

1) престане да испуњава услове за обављање здравствене делатности за одређену врсту здравствене установе прописане законом којим се уређује здравствена заштита и прописима донетим за спровођење тог закона;

2) престане да испуњава услове за обављање послова узимања, пресађивања, дистрибуције, типизације, односно послова трансплантације, у складу са овим законом и прописима донетим за спровођење овог закона;

3) се у поступку надзора над радом, односно у поступку стручног надзора утврди да поступа супротно закону и правилима медицинске струке;

4) се у поступку контроле квалитета рада, односно континуираног праћења квалитета рада овлашћене здравствене установе утврди да је квалитет поступака узимања, дистрибуције, пресађивања, типизације ткива, односно трансплантације испод утврђених стандарда, односно да се не обављају у складу са стандардним оперативним процедурама и водичима добре праксе, као и да су озбиљне нежељене појаве и озбиљне нежељене реакције проузроковане пропустима у раду овлашћене здравствене установе;

5) не постиже упоредиве резултате у току једне календарске године, у складу са стандардима медицинске струке.

Министар доноси решење о одузимању дозволе на предлог директора Управе за биомедицину.

Доношење решења о издавању, обнављању, односно одузимању дозволе

Члан 13.

Министар доноси решење о издавању, обнављању, односно одузимању дозволе, у складу са овим законом и законом којим се уређује општи управни поступак.

Решење из става 1. овог члана је коначно у управном поступку и против њега се може покренути управни спор.

Координатор у овлашћеној здравственој установи

Члан 14.

У свакој овлашћеној здравственој установи директор одређује координатора за трансплантацију ћелија, односно за трансплантацију ткива (у даљем тексту: координатор), уз претходну сагласност министра.

За координатора може бити одређено лице из реда запослених у овлашћеној здравственој установи које има завршен медицински факултет, положен стручни испит, одговарајућу специјализацију и које је истакнути стручњак за област узимања, дистрибуције, пресађивања, типизације ткива, односно трансплантације ћелија, односно ткива и које има најмање пет година радног искуства на наведеним пословима после положеног специјалистичког испита.

Послови координатора

Члан 15.

Координатор:

1) координира рад тимова за трансплантацију из члана 9. став 3. овог закона на пословима узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, пресађивања, односно трансплантације ћелија, односно ткива;

2) одговоран је за организацију поступка праћења озбиљних нежељених појава и озбиљних нежељених реакција и за вођење евиденције у складу са овим законом;

3) одговоран је за утврђивање и праћење система квалитета у поступцима узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, пресађивања, односно трансплантације ћелија, односно ткива;

4) одговоран је за организацију и спровођење континуиране едукације здравствених радника и здравствених сарадника који учествују у поступцима узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, пресађивања, односно трансплантације ћелија, односно ткива;

5) сарађује са Управом за биомедицину, доставља податке и подноси извештаје о раду у складу са овим законом;

6) остварује сарадњу са другим овлашћеним здравственим установама у складу са овим законом;

7) обавља друге послове у складу са овим законом.

За обављање послова из става 1. овог члана координатору припада накнада за рад у складу са прописима којима се уређује финансирање обавезног здравственог осигурања.

Подношење извештаја од стране координатора

Члан 16.

Координатор подноси тромесечне извештаје о раду Управи за биомедицину, као и годишњи извештај, који садржи:

1) податке о броју и врсти узетих, дистрибуираних, пресађених, односно трансплантираних ћелија, односно ткива, са живих, односно умрлих лица;

2) податке о озбиљним нежељеним реакцијама и озбиљним нежељеним појавама;

3) податке о старосним групама пацијената, односно давалаца ћелија, односно ткива, полу и породичном стању пацијената, односно давалаца;

4) предузете мере ради обезбеђења квалитета трансплантације ћелија, односно ткива;

5) проблеме у остваривању поступака трансплантације ћелија, односно ткива;

6) друге податке по захтеву Управе за биомедицину.

Извештај из става 1. овог члана треба да садржи и предлог мера за унапређивање резултата рада, односно квалитета здравствене заштите.

Етички одбор

Члан 17.

Етички одбор основан у здравственој установи која обавља послове трансплантације ћелија, односно ткива, у складу са законом којим се уређује здравствена заштита, у поступку обављања трансплантације ћелија, односно ткива, врши следеће послове:

1) даје сагласност за узимање ћелија, односно ткива од живог даваоца, у складу са овим законом;

2) даје мишљење о етичким и другим питањима у поступку трансплантације;

3) обавља и друге послове у складу са овим законом и актима донетим за спровођење овог закона.

Сагласност из става 1. тачка 1) овог члана, етички одбор даје након увида у медицинску документацију, тако што сви чланови етичког одбора стављају свој потпис испод потписа на изјави о пристанку живог даваоца.

IV. ПОСТУПАК ТРАНСПЛАНТАЦИЈЕ ЋЕЛИЈА И ТКИВА

Добровољност давања ћелија и ткива

Члан 18.

Давање ћелија и ткива је добровољно.

Недобитне услуге

Члан 19.

Услуге у вези са узимањем, донирањем, обрадом, очувањем, карантином, употребом, дистрибуцијом, односно трансплантацијом ћелија и ткива обављају се као недобитне услуге, осим ако овим законом није друкчије прописано.

Медицинска оправданост поступка трансплантације

Члан 20.

Поступак трансплантације ћелија и ткива може се обављати само ако је то медицински оправдано, односно ако је то најповољнији начин лечења, уз поштовање начела поступка трансплантације прописаних овим законом.

Писмени пристанак пунолетног примаоца

Члан 21.

Пресађивање ћелија и ткива може да се обави само под условом да је пунолетни пословно способни прималац пре пресађивања ћелија и ткива, као израз слободне воље, дао писмени пристанак за пресађивање ћелија и ткива.

Садржај обрасца изјаве о пристанку из става 1. овог члана прописује министар.

Здравствени радник који учествује у поступку пресађивања дужан је да примаоцу ћелија и ткива ради доношења одлуке о давању писменог пристанка из става 1. овог члана, пружи потпуне информације о сврси и природи пресађивања, вероватноћи њеног успеха, уобичајеним последицама пресађивања, као и о могућим ризицима, односно забележеним озбиљним нежељеним реакцијама и озбиљним нежељеним појавама, као и о могућим алтернативама трансплантације.

Писмени пристанак малолетног примаоца,
односно примаоца коме је одузета пословна способност

Члан 22.

Малолетном лицу које нема пословну способност, као и пунолетном лицу коме је судском одлуком у потпуности или делимично одузета пословна способност, пресађивање ћелија, односно ткива може се обавити само уз писмени пристанак законског заступника, односно старатеља под условом да не постоји изричито противљење малолетног лица које је старије од 15 година живота, односно делимично пословно способног лица.

Са писменим пристанком старатеља из става 1. овог члана мора да се сагласи орган старатељства.

Здравствени радник који учествује у поступку трансплантације, дужан је да информације из члана 21. става 3. овог закона пружи лицу, односно старатељу, који дају пристанак из става 1. овог члана.

Садржај обрасца изјаве из става 1. овог члана прописује министар.

Републичка листа чекања за трансплантацију

Члан 23.

Ради обезбеђивања доступности ћелија, односно ткива и правичности поступка трансплантације у Републици Србији, за пацијенте код којих постоји медицинска оправданост за трансплантацију ћелија, односно ткива сачињава се јединствена листа чекања (у даљем тексту: Републичка листа чекања).

Републичка листа чекања из става 1. овог члана сачињава се по врсти потребних ћелија, односно ткива.

Републичку листу чекања из става 2. овог члана сачињава и води Управа за биомедицину.

Изузетно од ст. 1. и 2. овог члана, Управа за биомедицину, на основу стандарда медицинске науке и специфичности примене одређених врста ћелија, односно ткива, може донети одлуку да се за поједину врсту ћелија, односно ткива не сачињава Републичка листа чекања.

Ради обезбеђивања трансплантације ћелија, односно ткива за пацијенте који се налазе на Републичкој листи чекања, односно из става 4. овог члана министар доноси републички програм за трансплантацију.

Средства за спровођење програма из става 5. овог члана обезбеђују се у буџету Републике Србије, као и из средстава обавезног здравственог осигурања.

Овлашћена здравствена установа за пресађивање ћелија и ткива, односно која обавља поступке трансплантације сачињава листу чекања по врсти потребних ћелија, односно ткива за пацијенте који се лече у тој здравственој установи, а која мора бити усклађена са Републичком листом чекања из става 1. овог члана.

Садржину, начин и поступак сачињавања и вођења Републичке листе чекања и достављања података од овлашћених здравствених установа, критеријуме за стављање на Републичку листу чекања, услове за утврђивање приоритета примаоца и друга питања од значаја за сачињавање и вођење Републичке листе чекања, прописује министар.

Јединствени републички регистар давалаца ћелија, односно ткива

Члан 24.

Управа за биомедицину води јединствени регистар лица која су за живота дала писмени пристанак на узимање ћелија, односно ткива, ради пресађивања, односно трансплантације у тело другог лица ради лечења, у складу са овим законом (у даљем тексту: Јединствени републички регистар давалаца).

Министар може да овласти одређену овлашћену здравствену установу, односно банку ћелија и ткива да води Јединствени републички регистар давалаца из става 1. овог члана за одређену врсту ћелија и ткива на предлог директора Управе за биомедицину.

Овлашћена здравствена установа, односно банка ћелија и ткива из става 2. овог члана води Јединствени републички регистар давалаца као поверени посао, у складу са законом.

Начин и поступак, вођење и упис давалаца у Јединствени републички регистар давалаца, подаци који се воде, чување и заштиту података, поступак приступа подацима који се воде у Јединственом републичком регистру давалаца, начин и поступак давања и чувања шифре за добијање одобрења за позивање на податке који се воде, брисање података, начин и поступак меморисања свих позивања на податке који се воде, као и друга питања од значаја за вођење Јединственог републичког регистра давалаца, прописује министар.

Доступност података из Јединственог републичког регистра давалаца

Члан 25.

Подаци из Јединственог републичког регистра давалаца доступни су искључиво лицима која имају овлашћење да траже и добију податке који се воде, и то:

1) лицу које је дало писмени пристанак за живота за узимање ћелија, односно ткива, у складу са овим законом, о подацима који се односе искључиво на податке о личности тог лица;

2) овлашћеном здравственом раднику коме је додељена шифра за добијање одобрења за позивање на податке који се воде у Јединственом републичком регистру давалаца.

Лице из става 1. тачка 1) овог члана може добити податке који се воде у Јединственом републичком регистру давалаца искључиво на основу писменог захтева, и ти подаци се, у року од 15 дана од дана подношења захтева, писмено достављају подносиоцу захтева.

Министарство може користити статистичке податке из Јединственог републичког регистра давалаца ради утврђивања здравствене политике у области трансплантације ћелија, односно ткива.

Забрана стицања користи од поступка трансплантације

Члан 26.

У поступку давања, примања, односно трансплантације ћелија, односно ткива забрањено је нудити, односно давати било какву накнаду или другу имовинску, односно неимовинску корист даваоцу од стране примаоца, за дате, односно примљене ћелије, односно ткива.

Забрана из става 1. овог члана не односи се на:

1) накнаду живом даваоцу за изгубљену зараду или другу врсту прихода за време проведено у здравственој установи или у току опоравка, односно за време привремене спречености за рад, односно накнаду других оправданих трошкова које је давалац имао због поступка узимања ћелија, односно ткива (превоз, смештај, трошкови исхране и др.);

2) оправдану накнаду у вези са плаћањем здравствених или других услуга у вези са узимањем ћелија, односно ткива;

3) накнаду у случају прекомерне штете која је настала као последица узимања ћелија, односно ткива са живог даваоца.

Накнада из става 2. тач. 1) и 2) овог члана за обавезно осигурана лица обезбеђује се у складу са законом којим се уређује обавезно здравствено осигурање и прописима донетим за спровођење тог закона, односно може је обезбедити прималац или друго правно или физичко лице.

Накнада из става 2. тачка 3) овог члана обезбеђује се у складу са законом којим се уређује накнада штете.

Забрана оглашавања, односно рекламирања

Члан 27.

Забрањено је оглашавање, односно рекламирање потреба за ћелијама и ткивима, као и оглашавање давања ћелија и ткива, са или без нуђења, односно давања новчане накнаде или друге материјалне или нематеријалне користи, као и оглашавање, односно рекламирање здравствених установа и здравствених радника који обављају поступак трансплантације, као и банки ћелија и ткива, у средствима јавног информисања, као и на другим носиоцима огласних порука, односно на било који други начин.

Забрана оглашавања, односно рекламирања из става 1. овог члана не односи се на промоцију добровољног давалаштва ћелија, односно ткива која се организује и спроводи у складу са овим законом.

На забрану оглашавања, односно рекламирања примењују се одредбе закона којим се уређује рекламирање, односно оглашавање здравствених услуга и здравствених установа и приватне праксе.

Забрана трговине ћелијама и ткивима

Члан 28.

Забрањена је трговина ћелијама и ткивима.

Под трговином ћелијама, односно ткивима у смислу овог закона не сматра се давање накнаде из члана 26. став 2. овог закона, као ни трошкови узимања, донирања, обраде, очувања, карантина, употребе, дистрибуције ћелија и ткива ради пресађивања у тело другог лица ради лечења које се обавља у складу са овим законом.

Здравствени радник који учествује у поступку трансплантације, уколико посумња да су ћелије, односно ткива који се трансплантирају предмет комерцијалне трговине, дужан је да одбије учешће у поступку трансплантације и да без одлагања, усмено и писмено обавести надлежне државне органе и Управу за биомедицину.

Размена ћелија и ткива ради лечења

Члан 29.

Ради обезбеђивања потребних ћелија, односно ткива могу се закључивати међународни уговори са међународним организацијама, међународним институцијама, односно другим страним државама с циљем успостављања узајамне сарадње за размену ћелија и ткива ради лечења, у складу са овим законом.

На основу међународног уговора из става 1. овог члана овлашћене здравствене установе, односно здравствене установе које обављају послове банке ћелија, односно ткива, могу вршити непосредну размену ћелија, односно ткива ако су испуњени највиши професионални стандарди медицинске науке и струке којима се обезбеђује безбедност, квалитет и спречавање преношења заразних болести.

Забрањено је у поступку размене ћелија, односно ткива примати ћелије, односно ткива који не задовољавају највише професионалне стандарде медицинске науке и струке.

Забрањена је размена ћелија, односно ткива у супротности са међународним уговором из става 1. овог члана.

Управа за биомедицину координира рад овлашћених здравствених установа у поступку размене ћелија, односно ткива у складу са међународним уговором из става 1. овог члана.

Министар, на предлог Управе за биомедицину, уколико су испуњени услови прописани овим законом и међународним уговором из става 1. овог члана, без одлагања даје дозволу за сваки појединачни случај размене ћелија, односно ткива у складу са међународним уговором из става 1. овог члана.

Здравствена установа дужна је да обавести Управу за биомедицину о извршеним трансплантацијама ћелија, односно ткива који се обезбеђују у складу са међународним уговором из става 1. овог члана и о којима се води посебна евиденција.

Забрана употребе ћелија, односно ткива

Члан 30.

Забрањено је употребљавати људске ћелије, односно ткива у производњи или изради козметичких производа.

Забрана из става 1. овог члана не односи се на индустријске производе у смислу овог закона.

Увоз, односно извоз ћелија, односно ткива

Члан 31.

Ако се одговарајуће ћелије, односно ткива који су намењени трансплантацији ради лечења, не могу обезбедити у Републици Србији, може се извршити увоз ћелија или ткива у складу са овим законом.

Увоз, односно извоз ћелија, односно ткива врши овлашћена здравствена установа, као и банке ћелија и ткива преко овлашћеног дистрибутера који мора да испуњава услове прописане овим законом и прописима донетим за спровођење овог закона.

У поступку увоза, односно извоза ћелија, односно ткива мора се обезбедити следивост увезених, односно извезених ћелија, односно ткива од даваоца до примаоца и обрнуто.

У поступку увоза, односно извоза ћелија, односно ткива морају се обезбедити и услови квалитета и безбедности дистрибуције.

Ако се у Републици Србији не могу обезбедити одговарајуће ћелије, односно ткива за научноистраживачке сврхе, може се извршити увоз ћелија, односно ткива, под условима прописаним овим законом.

Министар на предлог Управе за биомедицину даје дозволу за сваки појединачни случај увоза, односно извоза ћелија, односно ткива ценећи оправданост извоза, односно увоза.

Поред одредаба овог закона на увоз, односно извоз ћелија, односно ткива примењују се прописи којима се уређује спољнотрговинско пословање.

Следивост ћелија и ткива

Члан 32.

Овлашћена здравствена установа, односно банка ћелија и ткива дужна је да обезбеди следивост ћелија и ткива од даваоца до примаоца и обрнуто.

Следивост свих ћелија и ткива обезбеђује се увођењем система идентификације даваоца, примаоца, као и идентификације индустријских производа и свих материјала који су повезани са давањем и примањем ћелија и ткива.

Овлашћена здравствена установа, односно банка ћелија и ткива дужна је да чува све податке и документацију који су потребни како би се обезбедила следивост ћелија, односно ткива у свим фазама поступка узимања, донирања, обраде, очувања, карантина, употребе, складиштења, дистрибуције, односно трансплантације ћелија, односно ткива.

Документацију из става 3. овог члана овлашћене здравствене установе и банке ћелија и ткива, дужне су да чувају најмање 30 година после клиничке употребе и могу се уништити 12 месеци од истека наведеног рока.

Документација из става 4. овог члана чува се у писменом и електронском облику.

Ближе услове у погледу начина и поступка обезбеђивања и спровођења следивости ћелија и ткива прописује министар.

Поступак трансплантације

Члан 33.

Поступак трансплантације обавља се у складу са највишим стандардима медицинске науке.

Начин и поступак узимања и донирања ћелија, односно ткива са живог или умрлог лица, обраду, очување, карантин, употребу, дистрибуцију, односно трансплантацију ћелија, односно ткива прописује министар.

Спречавање ризика преношења болести, као и очување квалитета ћелија, односно ткива

Члан 34.

Овлашћена здравствена установа, банка ћелија и ткива, као и друго правно и физичко лице укључени у поступак трансплантације дужни су да предузму све потребне мере како би се спречио, односно умањио ризик од преношења заразне, односно било које друге болести са даваоца на примаоца.

Правно и физичко лице из става 1. овог члана дужно је да предузме све мере, односно да избегне све радње које би могле утицати на квалитет узетих ћелија, односно ткива.

У поступку узимања, донирања, обраде, очувања, карантина, складиштења и дистрибуције, односно трансплантације правно и физичко лице из става 1. овог члана дужно је да поступа тако да се обезбеди максимална стабилност ћелија, односно ткива до момента пресађивања, као и да се минимализује ризик од контаминације у складу са стандардима медицинске науке.

Ближе услове у погледу начина и поступка спречавања ризика преношења болести у току руковања ћелијама, односно ткивима, као и очувања квалитета узетих ћелија, односно ткива, прописује министар.

Финансирање поступка трансплантације

Члан 35.

За поступак узимања, односно донирања и пресађивања, односно за здравствену заштиту која је у вези са поступком трансплантације за одређену врсту ћелија, односно ткива, као и за праћење здравственог стања пре и после извршене трансплантације (у даљем тексту: право на трансплантацију), за осигурана лица средства обезбеђује организација обавезног здравственог осигурања.

Право на трансплантацију које се не обезбеђује на начин прописан у ставу 1. овог члана може се обезбедити осигураницима који право на здравствену заштиту остварују из средстава добровољног здравственог осигурања.

Давалац има право на здравствену заштиту на терет средстава обавезног здравственог осигурања без плаћања партиципације, ако је дао ћелију, односно ткиво за ону врсту трансплантације која се као право обезбеђује из средстава обавезног здравственог осигурања, као и у случају ако је узимањем ћелија, односно ткива нарушено здравствено стање даваоца, за све време док траје потреба за лечењем, односно за дуготрајном и континуираном здравственом заштитом која је директна последица давања ћелија, односно ткива, односно за време привремене спречености за рад.

Давалац који нема својство обавезно осигураног лица у складу са законом, а који је ћелије, односно ткиво дао за лице које има својство обавезно осигураног лица у складу са законом, има право на здравствену заштиту из средстава обавезног здравственог осигурања ако је узимањем ћелија, односно ткива претрпео озбиљно погоршање здравља које је директна последица узимања ћелија, односно ткива, за све време док траје потреба за здравственом заштитом.

Праћење озбиљних нежељених реакција и озбиљних нежељених појава

Члан 36.

Овлашћена здравствена установа дужна је да прати озбиљне нежељене реакције и озбиљне нежељене појаве код даваоца, односно примаоца и да о сумњи на њих без одлагања обавесте Управу за биомедицину.

Овлашћена здравствена установа води евиденцију за сваког даваоца, односно примаоца ћелија, односно ткива о озбиљним нежељеним реакцијама и озбиљним нежељеним појавама.

Садржај обрасца за пријављивање озбиљних нежељених реакција и озбиљних нежељених појава, као и евиденције које води овлашћена здравствена установа прописује министар.

На основу евиденција из става 2. овога члана овлашћена здравствена установа дужна је да тромесечно, као и на крају календарске године Управи за биомедицину достави анализу података о озбиљним нежељеним реакцијама и озбиљним нежељеним појавама за одређене врсте ћелија, односно ткива који су трансплантирани са предлогом мера за спречавање озбиљних нежељених реакција и озбиљних нежељених појава.

Организовање система за обавештавање о озбиљним нежељеним реакцијама и о озбиљним нежељеним појавама

Члан 37.

Управа за биомедицину организује систем за извештавање, истраживање, регистровање и преношење информација између здравствених установа, банака ћелија и ткива и Управе за биомедицину, о озбиљним нежељеним реакцијама и о озбиљним нежељеним појавама које могу да утичу на квалитет и безбедност ткива и ћелија и које су последица узимања, донирања, обраде, очувања, карантина, употребе и дистрибуције ћелија и ткива, као и о свим озбиљним нежељеним реакцијама уоченим током или након клиничке примене ћелија, односно ткива.

Овлашћене здравствене установе, као и банке ћелија и ткива дужне су да се укључе у систем извештавања, истраживања, регистровања и преношења информација о озбиљним нежељеним реакцијама, као и о озбиљним нежељеним појавама које организује Управа за биомедицину.

Овлашћене здравствене установе, као и банке ћелија и ткива дужне су да међусобно размењују и достављају све информације о озбиљним нежељеним реакцијама, о озбиљним нежељеним појавама, као и да те податке достављају Управи за биомедицину, како би се омогућила следивост и обезбедила контрола квалитета и безбедност ћелија, односно ткива.

Свако правно лице које користи људске ћелије, односно ткива и на било који начин рукује ћелијама, односно ткивима дужно је да има утврђене стандардне оперативне поступке за тачно, брзо и поверљиво повлачење свих ћелија, односно ткива, односно индустријског производа у случају пријављених и евидентираних озбиљних нежељених реакција и озбиљних нежељених појава.

Управа за биомедицину сачињава годишњи извештај о озбиљним нежељеним реакцијама и о озбиљним нежељеним појавама који са предлогом мера за њихово спречавање доставља овлашћеним здравственим установама, као и банкама ћелија и ткива.

Начин и поступак организовања система за извештавање, истраживање, регистровање и преношење информација из става 1. овог члана, прописује министар.

Службена тајна

Члан 38.

Подаци о даваоцу и примаоцу ћелија, односно ткива представљају службену тајну, коју су дужна да чувају сва лица која учествују у поступку трансплантације ћелија, односно ткива и лица којима су ти подаци доступни.

Забрана давања и коришћења података

Члан 39.

Давање ћелија, односно ткива је анонимно, осим ако овим законом није друкчије одређено.

Забрањено је податке о примаоцу дати даваоцу, односно његовој породици, као и податке о даваоцу дати примаоцу, односно његовој породици.

Изузетно од ст. 1. и 2. овог члана, у случају донирања репродуктивних ћелија примењују се одредбе закона којим се уређује лечење неплодности поступцима биомедицински потпомогнутог оплођења.

Забрањено је да лице које учествује у давању, пријављивању, евидентирању, обради или достављању било којих података о личности који се односе на даваоца и примаоца ћелија, односно ткива, као и лице које учествује у поступку донирања, посредовању, узимању и пресађивању ћелија, односно ткива, даје податке о личности везане за даваоца или примаоца, као и податке о лицима која су обавештена о намераваној или могућој трансплантацији, осим ако овим законом није друкчије уређено.

Сви подаци о личности даваоца и примаоца ћелија, односно ткива, укључујући и генетске податке који су доступни трећим лицима, морају бити анонимни, тако да није могуће идентификовати даваоца и примаоца.

Ради заштите података из става 5. овог члана сви учесници у поступку трансплантације дужни су да предузимају мере заштите података о личности, као и мере заштите од неовлашћеног додељивања података, брисања или мењања података у бази података који се воде и у евиденцијама, као и података о одлагању и преношењу информација.

Поред заштите података из става 6. овог члана, сви учесници у поступку трансплантације дужни су да предузму мере за спречавање неподударности података и неовлашћеног откривања информација које се воде у бази података уз истовремено гарантовање следивости донирања ћелија и ткива.

Подаци о личности даваоца и примаоца могу се прикупљати, обрађивати или користити у складу са овим законом само ради трансплантације.

Могућност коришћења података

Члан 40.

Изабраном лекару даваоца и примаоца ћелија, односно ткива као и другом надлежном лекару који у складу са законом треба да има увид у здравствено стање ових лица, мора се због медицински оправданих разлога и заштите здравља даваоца или примаоца ћелија, односно ткива омогућити увид у податке о извршеној трансплантацији ћелија и ткива који се односе на здравствено стање тих лица.

Резултати поступака трансплантације могу се користити у научноистраживачке сврхе.

Прикупљање, обрада, вођење и коришћење података о даваоцу, односно примаоцу и медицинска документација

Члан 41.

Подаци о даваоцу и примаоцу прикупљају се, обрађују, воде, чувају и користе у складу са овим законом и прописима којима се уређује заштита података о личности.

Податке о даваоцу, односно примаоцу прикупља, обрађује, води, чува и користи Управа за биомедицину, банка ћелија и ткива, као и овлашћена здравствена установа у складу са овим законом.

Овлашћена здравствена установа и банка ћелија и ткива прикупља, обрађује, чува и користи само оне податке који су неопходни за део послова који обавља.

О свим поступцима трансплантације, односно о узимању, пресађивању, донирању, сагласности примаоца, пристанку даваоца, сагласности даваоца, односно чланова породице, обради, очувању, дистрибуцији, озбиљним нежељеним реакцијама и озбиљним нежељеним појавама, као и другим подацима од значаја за трансплантацију води се медицинска документација у складу са овим законом и законом којим се уређује медицинска документација.

Подаци који се воде о даваоцу и примаоцу ћелија, медицинска документација која се води о поступку трансплантације ћелија, односно ткива, као и начин и поступак обраде, вођења, чувања, коришћења и размене података између овлашћених здравствених установа и Управе за биомедицину из ст. 2-4. овог члана, односно филијале обавезног здравственог осигурања, прописује министар.

Заштита података даваоца, односно примаоца

Члан 42.

Управа за биомедицину, банка ћелија и ткива, као и овлашћена здравствена установа дужни су да обезбеде заштиту података који се прикупљају, обрађују, чувају, воде и користе, односно који су им доступни и које размењују, како би се спречило њихово неовлашћено коришћење, уништавање, промена и злоупотреба.

Ради заштите података из става 1. овог члана и спречавања њиховог неовлашћеног коришћења, одређени подаци могу да се замене идентификационим кодом који давалац, односно прималац добија при пријави и уносу података у јединствену информациону базу података.

Начин и поступак заштите података из ст. 1. и 2. овог члана прописује министар.

Рок чувања података и медицинске документације

Члан 43.

Подаци о даваоцу и примаоцу из члана 41. овог закона, односно целокупна медицинска документација о поступку трансплантације ћелија, односно ткива прописана овим законом и прописима донетим за спровођење овог закона, чува се најмање 30 година у овлашћеној

здравственој установи, односно банци ћелија и ткива после клиничке употребе и може се уништити најкасније по истеку 12 месеци од истека наведеног рока.

Забрана коришћења и изношења података о личности даваоца, односно примаоца

Члан 44.

Забрањено је коришћење и изношење података о личности даваоца, односно примаоца ћелија и ткива у научне, образовне и статистичке сврхе, као и у средствима информисања на начин који може да открије идентитет лица на које се подаци односе.

Изузетно од става 1. овог члана, на основу писменог пристанка даваоца, односно примаоца подаци о личности даваоца, односно примаоца могу се употребљавати у научне, образовне и статистичке сврхе, као и у средствима информисања.

Обавештавање Управе за биомедицину

Члан 45.

О сваком намераваном донирању о коме здравствена установа има податке, извршеном узимању и пресађивању ћелија и ткива, као и размени ћелија и ткива ради пресађивања у складу са овим законом, овлашћена здравствена установа обавештава Управу за биомедицину.

Начин и поступак обавештавања, као и садржај обрасца о обавештавању из става 1. овог члана прописује министар.

Стандардне оперативне процедуре и водичи добре праксе

Члан 46.

Поступак узимања, пресађивања, типизације, односно трансплантације, као и дистрибуције ћелија, односно ткива ради лечења обавља се у складу са стандардним оперативним процедурама, као и водичима добре праксе.

Стандардне оперативне процедуре и водиче добре праксе прописује министар на предлог директора Управе за биомедицину.

Промоција добровољног давалаштва ћелија и ткива

Члан 47.

Министарство врши промоцију добровољног давалаштва ћелија и ткива (у даљем тексту: промоција) у складу са овим законом.

Министарство, ради промоције, обезбеђује све информације у вези са трансплантацијом ћелија и ткива, стручној и општој јавности.

Давање информација из става 2. овог члана не сматра се рекламирањем, односно оглашавањем.

Министар може да донесе решење којим ће овластити друго правно или физичко лице да врши промоцију.

Информације из става 2. овог члана садрже све потребне медицинске, законске, социјалне, етичке и друге податке који су од значаја за промоцију, податке који се односе на овлашћене здравствене установе, као и друге информације од значаја за трансплантацију.

Програм промоције доноси министар.

Средства за спровођење програма из става 6. овог члана обезбеђују се у буџету Републике Србије.

V. УЗИМАЊЕ ЋЕЛИЈА И ТКИВА ОД ЖИВОГ ДАВАОЦА

Услови за узимање ћелија и ткива од живог даваоца

Члан 48.

Узимање ћелија и ткива од живог даваоца ради трансплантације дозвољено је ако су истовремено испуњени следећи услови:

1) ако нема других одговарајућих ћелија и ткива које су доступне од умрлог лица;

2) ако не постоји алтернативни медицински поступак упоредиве ефикасности за лечење примаоца;

3) ако тим за трансплантацију овлашћене здравствене установе да мишљење да ће пресађивањем ћелија и ткива, доћи до излечења, односно побољшања здравственог стања примаоца;

4) ако је дат писмени пристанак даваоца;

5) ако је извршена процена ризика по здравље даваоца.

Процена ризика по здравље даваоца

Члан 49.

Узимање ћелија и ткива од живог даваоца дозвољено је ако је ризик по његово здравље, према медицинским критеријумима, у границама прихватљивог.

Забрањено је узимање ћелија и ткива од живог даваоца ако постоји ризик по живот и здравље даваоца који према медицинским критеријумима није у границама прихватљивости, односно ако је ризик по здравље живог даваоца у несразмери са очекиваном користи за примаоца.

Процену ризика узимања ћелија и ткива по здравље даваоца цени тим за трансплантацију ћелија, односно ткива овлашћене здравствене установе у којој се узимање ћелија и ткива обавља.

Етички одбор здравствене установе основан у складу са законом којим се уређује здравствена заштита даје претходну сагласност за узимање ћелија, односно ткива са живог даваоца ради пресађивања у тело другог лица ради лечења.

Изузетно од става 4. овог члана, за поједине врсте ћелија, односно ткива, полазећи од стандарда медицинске науке, односно специфичности узимања одређених ћелија, односно ткива, министар на предлог директора Управе за биомедицину доноси одлуку код којих врста ћелија, односно ткива, није потребна претходна сагласност етичког одбора здравствене установе за узимање ћелија, односно ткива због пресађивања у тело другог лица ради лечења, односно ради примене код људи.

Пре узимања ћелија и ткива морају да се изврше сви потребни медицински поступци у складу са стандардним оперативним процедурама и водичима добре праксе ради утврђивања здравственог стања даваоца, као и ради смањења физичких и психичких ризика по здравље даваоца и спречавања преношења заразних и других болести.

Писмени пристанак живог даваоца

Члан 50.

Узимање ћелија и ткива од живог даваоца дозвољено је под условом да је живи давалац дао писмени пристанак који је израз његове слободне воље.

Писмени пристанак даје се само на планирану медицинску интервенцију, односно само на узимање одређених ћелија, односно ткива.

Писмени пристанак даје се за одређеног примаоца.

Узимање ћелија, односно ткива од малолетног живог даваоца врши се у складу са чланом 51. овог закона.

Писмени пристанак из става 1. овог члана чува се у здравственој установи као медицинска документација, у складу са законом.

Садржај обрасца изјаве о пристанку живог даваоца прописује министар.

Лица која могу бити даваоци ћелија и ткива

Члан 51.

Давалац ћелија, односно ткива може бити лице које је старије од 18 година живота, под условом да има потпуну пословну способност, односно способност за расуђивање и доношење одлука.

Изузетно од става 1. овог члана, давалац регенеративних ткива, може бити и лице које је млађе од 18 година живота, односно лице коме је судском одлуком делимично одузета пословна способност, ако су истовремено испуњени следећи услови:

1) да не постоји одговарајући давалац који је дао писмени пристанак у складу са овим законом;

2) да је прималац ткива родитељ, брат или сестра даваоца;

3) да се давање ткива обавља ради спашавања живота примаоца;

4) да је прибављена писмена сагласност за узимање регенеративног ткива од законског заступника, односно старатеља даваоца малолетног лица, односно делимично пословно способног лица;

5) да се давалац не противи давању регенеративног ткива, односно да је такво лице старије од 15 година живота дало писмени пристанак за давање регенеративног ткива ради лечења лица из тачке 2) овог става.

Етички одбор здравствене установе основан у складу са законом којим се уређује здравствена заштита даје сагласност за узимање ткива у случају из става 2. овог члана.

Изузетно од става 1. овог члана, од малолетних лица дозвољено је:

1) узимање и чување крвотворних матичних ћелија прикупљених из издвојене пупчане врпце живорођеног детета које се могу употребљавати за пресађивање, односно коришћење код сродника и несродних лица живорођеног детета;

2) узимање оних ћелија за чије је узимање на основу стандарда медицинске науке утврђен минимални ризик и минимално оптерећење за даваоца.

У случају из става 4. тачка 1) овог члана, за узимање и чување крвотворних матичних ћелија потребан је писмени пристанак мајке, односно оба родитеља, односно старатеља ако је неко од ових лица под старатељством, или колизијског старатеља, ако орган старатељства оцени да постоје супротни интереси детета и његових законских заступника.

У случају из става 4. тачка 2) овог члана, ћелије се могу узети под условом прописаним у ставу 2. тачка 5) овог члана.

Поступак прикупљања, чувања и употребе ћелија из става 4. овог члана прописује министар.

Давалац репродуктивних ћелија може да буде лице које је одређено законом којим се уређује лечење неплодности поступцима биомедицински потпомогнутог оплођења.

Право на непристрасно информисање даваоца ћелија, односно ткива ради давања писменог пристанака

Члан 52.

Ради давања писменог пристанака из члана 50. овог закона здравствени радник који не учествује у поступку узимања, пресађивања, односно употребе ћелија, односно ткива, који није изабрани лекар примаоца, а који има одговарајуће искуство у процени ризика по живот и здравље даваоца, дужан је да пре давања писменог пристанка, даваоца упозна са његовим правима у складу са овим законом, а посебно са правом на непристрасан савет у погледу ризика по живот и здравље, као и са током медицинског поступка, вероватноћом успеха и уобичајеним ризицима, с тим да дате информације не смеју бити сугестивне.

Информације које даје здравствени радник морају се дати у присуству другог здравственог радника.

Документ о информисању са подацима из става 1. овог члана сачињава се у писменој форми.

Саставни део документа из става 3. овог члана је и писмени пристанак, односно повлачење писменог пристанка који потписује давалац ћелија, односно ткива, као и присутни здравствени радник.

Садржај обрасца документа из става 3. овог члана, прописује министар.

Информисање даваоца ћелија, односно ткива о поступку трансплантације

Члан 53.

Здравствени радник који учествује у поступку узимања ћелија, односно ткива дужан је да после давања писменог пристанка из члана 50. овог закона, даваоца у потпуности информише о поступку и начину узимања ћелија, односно ткива, могућим директним и индиректним последицама по његово здравље које могу настати узимањем ћелија, односно ткива, као и о очекиваном исходу трансплантације и осталим битним околностима, као и све друге информације по захтеву даваоца ћелија, односно ткива.

Повлачење писменог пристанка

Члан 54.

Овлашћена здравствена установа дужна је да обезбеди да давалац ћелија, односно ткива може да повуче писмени пристанак из члана 50. овог закона, а најкасније до момента почетка његове припреме за поступак узимања ћелија, односно ткива ради пресађивања, односно употребе код другог лица, односно до момента почетка припреме пацијента за поступак трансплантације ћелија, односно ткива.

Изјава о повлачењу пристанка даје се у писменој форми, по поступку прописаном овим законом за давање пристанка.

VI. УЗИМАЊЕ ТКИВА ОД УМРЛОГ ЛИЦА

Утврђивање смрти

Члан 55.

Узимање ткива од умрлог лица због пресађивања другом лицу ради лечења може се извршити искључиво после дијагностиковања и утврђивања мождане смрти на основу медицинских критеријума, у складу са законом.

Начин и поступак дијагностиковања и утврђивања мождане смрти утврђује се у складу законом којим се уређује трансплантација органа, као и подзаконским актима донетим за спровођење тог закона.

Писмени пристанак за узимање ткива

Члан 56.

Са умрлог лица дозвољено је узимање ткива због пресађивања, односно употребе код другог лица ради лечења уколико је пунолетни давалац пре смрти поступио на један од следећих начина, и то:

1) дао и лично потписао писмени пристанак за давање ткива у случају смрти у присуству најмање једног независног сведока који потврђује веродостојност потписа и слободно изражену вољу даваоца;

2) дао налог другом лицу да у његово име потпише писмени пристанак за давање ткива у случају смрти уз сопствено присуство потписивању пристанка и у присуству најмање једног независног сведока који потврђује веродостојност потписа и слободно изражене воље даваоца.

На основу писменог пристанка из става 1. овог члана даваоцу се могу у случају смрти узети ткива после претходног обавештења чланова породице о донацији ткива, изузев уколико се чланови породице томе изричито усмено, односно писмено успротиве уз навођење јасних и

неоспорних чињеница из којих се може недвосмислено закључити да је умрло лице за живота променило став о давању ткива.

Са умрлог лица могу се узети ткива само ако поступак узимања ткива не омета спровођење судског поступка, односно обдукцију умрлог лица.

Давање писменог пристанка

Члан 57.

Изјава о пристанку из члана 56. овог закона може се дати:

1) здравственом раднику који је изабрани лекар даваоца;

2) овлашћеном лицу за евидентирање писменог пристанка у филијали обавезног здравственог осигурања у поступку издавања, односно оверавања здравствене књижице, односно друге здравствене исправе којом се утврђује својство осигураника (у даљем тексту: здравствена књижица);

3) овлашћеном лицу за евидентирање писменог пристанка у Управи за биомедицину;

4) овлашћеном лицу за евидентирање писменог пристанка у здравственој установи која обавља послове трансплантације.

Изјава о пристанку из става 1. овог члана даје се у писменој форми на обрасцу који прописује министар.

Писмени пристанак из става 1. овог члана дат на прописаном обрасцу чува се 30 година од дана смрти тог лица у овлашћеној здравственој установи, односно филијали обавезног здравственог осигурања, односно у Управи за биомедицину, на начин и по поступку прописаном овим законом за медицинску евиденцију.

Евидентирање писменог пристанка

Члан 58.

Писмени пристанак из члана 56. овог закона обавезно се евидентира у здравствену књижицу.

Изабрани лекар, као и друго овлашћено лице из члана 55. овог закона дужни су да, пре давања писменог пристанка, свако заинтересовано лице упознају са значајем трансплантације ткива ради лечења и да том лицу дају потпуне информације које не смеју бити сугестивне и које су засноване на медицинским доказима о могућности давања ткива у случају мождане смрти, условима за давање, односно за узимање ткива у случају мождане смрти у складу са овим законом.

После давања информација из става 2. овог члана лицу које је заитересовано да постане давалац ткива потребно је оставити разумно време да донесе одлуку о давању писменог пристанка.

Забрана узимања ткива

Члан 59.

Свако пунолетно и пословно способно лице може изричито забранити узимање својих ткива у случају мождане смрти.

Изјава о забрани узимања ткива даје се у писменој форми здравственом раднику, односно овлашћеном лицу из члана 57. став 1. овог закона.

Образац изјаве о забрани узимања ткива прописује министар.

Писмена изјава о забрани узимања ткива из става 2. овог члана чува се 12 месеци од дана смрти тог лица у здравственој установи, односно филијали обавезног здравственог осигурања, односно у Управи за биомедицину, на начин и по поступку прописаним овим законом за медицинску евиденцију.

Забрана узимања ткива евидентира се у здравствену књижицу.

Издавање донаторске картице

Члан 60.

На основу датог и евидентираног писменог пристанка у складу са овим законом, установа, орган или организација које је овластио министар издају даваоцу донаторску картицу.

Начин и поступак давања изјаве о пристанку и евидентирање писменог пристанка у здравствену књижицу, односно о забрани узимања ткива, вођење евиденције о изјавама о пристанку, односно забрани узимања ткива, заштите података о даваоцу, образац донаторске картице, као и услове које треба да испуњава установа, орган, односно организација који дају донаторску картицу, прописује министар.

Узимање ткива од лица које није дало писмени пристанак

Члан 61.

Са умрлог лица које је држављанин Републике Србије и које има стално пребивалиште у Републици Србији, могу се узимати ткива због пресађивања другом лицу ради лечења и у случају када то лице није дало писмени пристанак у складу са овим законом, ако то лице за живота није изричито, писмено или усмено, забранило узимање ткива, у складу са овим законом.

У случају из става 1. овог члана за узимање ткива потребна је писмена сагласност чланова породице умрлог лица.

Ако умрло лице нема живе чланове породице, односно ако они нису доступни у разумном времену, које не угрожава узимање и трансплантацију ткива, а доступно је друго блиско лице са којим је умрли био у присном личном односу који је свима очигледан најмање последње две године пре смрти лица, за узимање ткива довољна је сагласност тог блиског лица.

Информисање и давање сагласности члана породице лица које није дало писмени пристанак

Члан 62.

Лице које је овластио директор здравствене установе дужно је да информише једног од чланова породице умрлог лица о праву да се са узимањем ткива сагласи или одбије давање сагласности.

Овлашћено лице из здравствене установе дужно је да информише једног од чланова породице умрлог лица о праву да се са узимањем ткива сагласи или о праву да одбије давање сагласности.

Члановима породице умрлог лица потребно је дати разумно време да донесу одлуку, односно оно време које неће угрозити могућност узимања ткива, ради пресађивања, односно употребу у телу другог лица.

Раније дата сагласност члана породице умрлог лица може се повући до момента припреме пацијента за трансплантацију ткива о чему се обавештава надлежни здравствени радник.

Члан породице може дати сагласност само у случају ако је у последње две године пре смрти умрлог лица био лично у контакту са умрлим лицем.

Уколико постоји више чланова породице истог степена сродства, довољно је да само један од њих да сагласност, с тим да ако члан породице који је ближи по степену сродства није доступан у разумном времену, које не угрожава узимање и трансплантацију ткива, дозвољено је да сагласност да члан породице следећи по степену сродства који је доступан.

Ако умрло лице нема живе чланове породице, односно ако они нису доступни у разумном времену које не угрожава узимање и трансплантацију ткива, а доступно је друго блиско лице из члана 61. став 3. овог закона, на давање сагласности тог лица примењују се одредбе ст. 1-5. овог члана.

Изјаву о давању сагласности, о одбијању давања сагласности или о повлачењу сагласности члан породице, односно друго блиско лице из става 6. овог члана дају на обрасцу који прописује министар.

Узимање ткива од умрлог лица
које није држављанин Републике Србије

Члан 63.

Са умрлог лица које није држављанин Републике Србије и које нема стално пребивалиште у Републици Србији и које није дало писмени пристанак у складу са овим законом, могу се узимати ткива због пресађивања, односно употребе код другог лица ради лечења само уз писмену сагласност члана породице.

Информисање и давање сагласности чланова породице, односно другог блиског лица, за умрло лице које није држављанин Републике Србије и нема стално пребивалиште у Републици Србији а које није дало писмени пристанак у складу са овим законом, обавља се у складу са чланом 62. овог закона.

Узимање ткива од малолетног лица,
односно од лица које нема пословну способност

Члан 64.

Са умрлог малолетног лица, односно од лица које нема потпуну пословну способност, као и од пунолетног лица коме је за живота на основу одлуке надлежног органа одузета пословна способност, дозвољено је узимање ткива због пресађивања, односно употребе код другог лица ради лечења под условима и на начин прописан у чл. 61. и 62. овог закона.

Прибављање пристанка, односно сагласности као и других података
пре започињања поступка узимања ткива

Члан 65.

Овлашћени здравствени радник може да започне поступак узимања ткива од умрлог лица, ако:

1) располаже доказом о писменом пристанку умрлог лица, односно донаторском картицом, односно у разговору са члановима породице или другим блиским лицем провери да умрло лице за живота није променило одлуку о пристанку за донацију ткива о чему здравствени радник сачињава службену белешку у медицинској документацији, односно ако прибави податке о евиденцији умрлог лица у Јединственом републичком регистру давалаца;

2) не располаже доказом о писменом пристанку умрлог лица, односно донаторском картицом, односно ако не постоји доказ о евидентирању писменог пристанка умрлог лица у Јединственом републичком регистру давалаца под условом да је члан породице умрлог лица, односно друго блиско лице дало сагласност у складу са овим законом.

Право на пијетет

Члан 66.

При узимању ткива сви учесници овог поступка дужни су да тело умрлог даваоца третирају са поштовањем достојанства умрлог лица и чланова породице умрлог, као и да предузму све потребне мере како би се повратио спољашњи изглед умрлог даваоца.

VII. БАНКЕ ЋЕЛИЈА И ТКИВА

Оснивање банке ћелија и ткива

Члан 67.

Ради добијања, тестирања, обраде, очувања, карантина, складиштења и дистрибуирања људских ћелија и ткива за примену код људи оснивају се банке ћелија и ткива.

Банка из става 1. овог члана може се основати као јавна или приватна банка ћелија и ткива.

Банка ћелија и ткива може се основати као самостално правно лице или као део овлашћене здравствене установе, ако испуњава услове прописане овим законом и прописима донетим за спровођење овог закона.

У јавној банци могу се узимати и чувати ћелије, односно ткива које се дају и чувају за чланове породице ради лечења када је то медицински оправдано и ако не постоји други начин лечења осим употребе ћелија и ткива чланова породице.

Банка ћелија и ткива која је основана као јавна банка обавља послове за које је добила дозволу у складу са овим законом, као недобитне услуге.

Приватна банка може обављати послове за које је добила дозволу као добитне услуге.

Средства за оснивање и рад банке ћелије и ткива обезбеђује оснивач.

У јавну банку ћелије, односно ткива могу да дају сва лица, као и да сва лица којима је то потребно, користе дате ћелије, односно ткива под условима прописаним овим законом.

Услове, начин и поступак донирања и коришћења ћелија, односно ткива у јавној банци ћелија и ткива прописује министар.

Издавање дозволе за банку ћелија и ткива

Члан 68.

На основу захтева овлашћене здравствене установе или другог правног лица министар издаје дозволу за обављање послова банке ћелија и ткива, уколико су испуњени услови прописани овим законом и прописима донетим за спровођење овог закона.

Захтев из става 1. овог члана подноси се Министарству преко Управе за биомедицину.

Министар доноси решење о издавању дозволе из става 1. овог члана на предлог директора Управе за биомедицину, а на основу налаза надлежног инспектора о испуњености услова за обављање послова банке ћелија и ткива, у складу са овим законом.

Дозволом се утврђује делатност банке ћелија и ткива која се не може мењати без промене решења о издавању дозволе из става 3. овог члана.

Дозвола се издаје на рок од пет година и може се обновити под условима прописаним овим законом.

Услове за издавање и обнављање дозволе за јавне или приватне банке у погледу простора, опреме и кадра, начин и поступак пријема ћелија и ткива, евиденције које води банка ћелија и ткива, услове за увођење система квалитета, избор, оцењивање и добијање ћелија и ткива, као и критеријуме и поступак за избор давалаца ћелија и ткива, и њихов пријем у банци ћелија и ткива, врсте лабораторијских тестирања давалаца ћелија и ткива, као и поступак избора ћелија и ткива, обраду, складиштење, обележавање, документовање и амбалажу ћелија и ткива, поступак идентификације, дистрибуирање ћелија и ткива, однос између банке ћелија и ткива и трећих лица, висину трошкова за издавање дозволе, као и друга питања од значаја за оснивање и рад банке ћелија и ткива прописује министар.

Обнова дозволе

Члан 69.

Банка ћелија и ткива која је у складу са овим законом добила дозволу може поднети захтев за обнову дозволе најкасније 90 дана пре истека рока из решења о издавању дозволе у складу са овим законом.

Захтев за обнову дозволе подноси се Министарству преко Управе за биомедицину.

Министар доноси решење о обнављању дозволе на предлог директора Управе за биомедицину, а на основу налаза надлежног инспектора о испуњености услова за обављање послова банке ћелија и ткива, у складу са овим законом.

Одузимање дозволе за банку ћелија и ткива

Члан 70.

Министар може да одузме дозволу из члана 68. овог закона и пре истека рока од пет година, односно истеком тог рока ако банка ћелија и ткива:

1) престане да испуњава услове прописане овим законом и прописима донетим за спровођење овог закона за обављање послова банке ћелија и ткива;

2) ако не обавља послове добијања, тестирања, обраде, очувања, карантина, складиштења и дистрибуирања људских ћелија и ткива, праћења озбиљних нежељених појава и озбиљних нежељених реакција, као и квалитет рада, односно квалитет ћелија и ткива, на начин и по поступку прописаном овим законом и прописима донетим за спровођење овог закона, односно у складу са стандардним оперативним процедурама.

Министар доноси решење о одузимању дозволе на предлог директора Управе за биомедицину, а на основу налаза надлежног инспектора којим је констатовано да је банка ћелија и ткива престала да испуњава услове за обављање послова банке ћелија и ткива, у складу са овим законом.

Доношење решења о издавању, обнављању, односно одузимању дозволе

Члан 71.

Министар доноси решење о издавању, обнављању, односно одузимању дозволе из чл. 68-70. овог закона.

Решење из става 1. овог члана министар доноси на основу овог закона и закона којим се уређује општи управни поступак.

Решење из чл. 68. и 69. овог закона доноси се у року од 90 дана од дана подношења захтева.

Решење из става 1. овог члана коначно је у управном поступку и против њега се може покренути управни спор.

Инспекцијски надзор над банком ћелија и ткива

Члан 72.

Инспекцијски надзор над банком ћелија и ткива врши се континуирано, а најмање једном у две године.

Инспекцијски надзор над банком ћелија и ткива врши Министарство преко инспектора овлашћених за надзор над употребом и руковањем ћелија и ткива (у даљем тексту: инспектор).

У вршењу инспекцијског надзора инспектор је овлашћен да:

1) утврђује, односно надзире испуњеност услова прописаних овим законом и прописима донетим за спровођење овог закона, односно прегледа просторије, опрему и документацију о прописаном кадру који обавља послове у банци ћелија и ткива;

2) надзире поступак добијања, тестирања, обраде, очувања, карантина, складиштења и дистрибуције људских ћелија и ткива који обавља банка ћелија и ткива;

3) прегледа опште и појединачне акте, документацију и евиденције које се односе на добијање, тестирање, обраду, очување, карантин, складиштење и дистрибуцију људских ћелија и ткива;

4) саслуша и узме изјаву од одговорног лица у банци ћелија и ткива, као и других лица у банци ћелија и ткива;

5) наложи отклањање утврђених неправилности и недостатака у поступку добијања, тестирања, обраде, очувања, карантина, складиштења и дистрибуције људских ћелија и ткива, у року који не може бити краћи од 15 дана ни дужи од шест месеци од дана пријема акта којим је та мера наложена, а у хитним случајевима нареди отклањање утврђених неправилности без одлагања;

6) наложи извршење прописаних мера банци ћелија и ткива у року који не може бити краћи од 15 дана ни дужи од три месеца од дана пријема акта којим је та мера наложена, а у хитним случајевима нареди извршење прописаних мера без одлагања;

7) привремено забрани обављање послова банке ћелија и ткива ако нису отклоњене утврђене неправилности и недостаци, односно ако није извршена наложена мера;

8) нареди забрану употребе одређених ћелија, односно ткива уколико су узети у супротности са овим законом;

9) предузме и друге мере у складу са законом.

На надзор банке ћелија и ткива сходно се примењују одредбе чл. 91-95. овог закона.

Евиденције које води банка ћелија и ткива и обавеза извештавања

Члан 73.

Банке ћелија и ткива воде евиденцију о даваоцима ћелија и ткива, о врстама и количинама ћелија и ткива који су добијени, тестирани, очувани, обрађени, ускладиштени, дистрибуирани или на други начин отуђени, као и о пореклу и одредишту ћелија и ткива намењених примени код људи.

Банке ћелија и ткива дужне су да Управи за биомедицину достављају тромесечни и годишњи извештај о пословима на основу евиденције из става 1. овог члана.

Регистар банки, ћелија и ткива

Члан 74.

Управа за биомедицину води регистар банки ћелија и ткива у који се уносе подаци о банци ћелија и ткива, оснивачу, идентификациони број банке ћелија и ткива, делатност банке ћелија и ткива, одговорно лице у банци ћелија и ткива, као и други потребни подаци.

Управљање системом квалитета

Члан 75.

Банка ћелија и ткива дужна је да уведе и ажурира систем квалитета заснован на принципима добре праксе.

У управљању системом квалитета банка ћелија и ткива дужна је да обезбеди најмање следећу документацију:

1) стандардне оперативне процедуре;

2) смернице;

3) приручнике за обуку и референтне приручнике,

4) обрасце за извештавање;

5) евиденције о даваоцима;

6) податке о крајњем одредишту ткива или ћелија;

7) друге податке за обезбеђивање и управљање системом квалитета.

Ради обезбеђивања система квалитета и следивости банка ћелија и ткива дужна је да чува податке у року прописаном овим законом.

Одговорно лице за управљање системом квалитета

Члан 76.

Свака банка ћелија и ткива дужна је да има одговорно лице за управљање системом квалитета које испуњава најмање следеће услове, и то:

1) завршен медицински факултет са одговарајућом специјализацијом или други одговарајући факултет на коме се стичу знања из области медицине или биологије са одговарајућим специјализацијама за област ћелија и ткива, односно посебним стручним знањем за област ћелија и ткива;

2) најмање пет година искуства у области рада са ћелијама и ткивима.

Одговорно лице из става 1. овог члана дужно је да:

1) управља системом квалитета у банци ћелија и ткива у складу са овим законом и подзаконским актима донетим за спровођење овог закона;

2) обезбеђује да се поступак добијања, тестирања, обраде, очувања, карантина, паковања, складиштења и дистрибуције ћелија и ткива намењених за примену код људи у банци ћелија и ткива обавља у складу са овим законом и подзаконским актима донетим за спровођење овог закона;

3) доставља податке, извештаје и евиденције Управи за биомедицину, у складу са овим законом;

4) прикупља, анализира и прослеђује, односно доставља све информације о озбиљним нежељеним реакцијама и озбиљним нежељеним појавама;

5) обавља послове у вези са оцењивањем и избором даваоца у складу са овим законом и прописима донетим за спровођење овог закона;

6) контролише стручни рад и обуку запослених у банци ћелија и ткива на пословима донирања, добијања, тестирања, обраде, очувања, карантина, паковања, складиштења и дистрибуције ћелија и ткива;

7) обезбеђује спровођење споразума између банке ћелија и ткива са трећим лицима, у складу са овим законом и прописима донетим за спровођење овог закона;

8) обавља и друге послове у складу са овим законом и прописима донетим за спровођење овог закона.

Запослени у банци ћелија и ткива

Члан 77.

Лица запослена у банци ћелија и ткива која обављају послове у вези са донирањем, добијањем, тестирањем, обрадом, паковањем, складиштењем и дистрибуирањем ћелија и ткива морају бити лица са завршеним медицинским, односно другим одговарајућим факултетом, и са знањима из области ћелија и ткива.

Поред лица запослених из става 1. овог члана у банци ћелија и ткива могу бити запослена и друга лица која обављају послове из надлежности банке ћелија и ткива.

Лица из ст. 1. и 2. овог члана дужна су да се стално стручно усавршавају за област донирања, добијања, тестирања, обраде, паковања, складиштења и дистрибуирања људских ћелија и ткива.

Избор, оцењивање и добијање ћелија и ткива

Члан 78.

Избор, оцењивање и добијање ћелија и ткива врши се у складу са критеријумима и поступком за избор даваоца ћелија и ткива и њиховим пријемом у банци.

Пријем ћелија и ткива

Члан 79.

Банка ћелија и ткива дужна је да изврши лабораторијско тестирање давалаца ћелија и ткива, као и да избор и прихватање ћелија и ткива врши у складу са утврђеним поступцима добијања ћелија и ткива и њиховим пријемом у банку ћелија и ткива.

Банка ћелија и ткива потврђује и евидентира чињеницу да је амбалажа примљене људске ћелије и ткива у складу са поступком добијања ћелија и ткива и њиховим пријемом у банку.

Све ћелије и ткива који нису у складу са захтевима из става 1. овог члана, банка ћелија и ткива је дужна да одбије.

О прихватању или одбијању ћелија и ткива банка ћелија и ткива дужна је да води документацију.

Банка ћелија и ткива дужна је да обезбеди да ћелије и ткива буду правилно идентификовани на тај начин што се свакој испоруци или шаржи ћелија и ткива додељује идентификациони код у складу са овим законом.

Ћелије и ткива држе се у банци ћелија и ткива у карантину до испуњавања услова за избор, оцењивање и добијање из члана 78. овог закона.

Обрада ћелија и ткива

Члан 80.

Банка ћелија и ткива дужна је да утврди стандардне оперативне поступке за сваки процес обраде ћелија и ткива којим се обезбеђује квалитет и безбедност ћелија и ткива.

Банка ћелија и ткива дужна је да стандардне оперативне поступке из става 1. овог члана да на увид надлежном инспектору у поступку вршења инспекцијског надзора, а, по захтеву, да их достави и Управи за биомедицину.

Банка ћелија и ткива обезбеђује да се сви поступци обраде ћелија и ткива обављају у контролисаним условима.

За сваку измену процеса обраде ћелија и ткива из става 1. овог члана банка ћелија и ткива мора да има стандардне оперативне поступке којима се обезбеђује квалитет и безбедност ћелија и ткива.

Стандардни оперативни поступци из ст. 1. и 2. овог члана односе се на обраду ћелија и ткива, валидацију и контролу опреме, простора и процеса рада, као и на руковање одбаченим ћелијама и ткивима како би се спречила контаминација других ћелија и ткива, опреме за обраду или запослених лица.

Услови складиштења ћелија и ткива

Члан 81.

Банка ћелија и ткива дужна је да обезбеди да сви поступци у вези са складиштењем ћелија и ткива буду документовани, као и да се обављају у складу са стандардним оперативним поступцима.

Банка ћелија и ткива обезбеђује да се сви поступци складиштења обављају у контролисаним условима.

Банка ћелија и ткива дужна је да примењује све поступке контроле амбалаже и складишних простора како би се спречиле појаве које могу негативно да утичу на функционисање или интегритет ћелија и ткива, односно на квалитет ћелија и ткива.

Обрађене ћелије и ткива не смеју се дистрибуирати док се не испуне услови прописани овим законом и прописима донетим за спровођење овог закона.

У случају престанка рада банке ћелија и ткива из било којих разлога, банка ћелија и ткива дужна је да ускладиштене ћелије и ткива пребаци у другу банку ћелија и ткива, односно у другу надлежну здравствену установу, које имају дозволу за обављање послова употребе и руковања ћелијама и ткивима.

Обележавање, документовање и амбалажа

Члан 82.

Банка ћелија и ткива дужна је да обезбеди да се поступак добијања ћелија и ткива и њихов пријем у банку обележи на одговарајући начин, као и да о томе постоји одговарајућа документација.

Банка ћелија и ткива дужна је да обезбеди одговарајућу амбалажу за ћелије и ткива.

Идентификација ћелија, односно ткива

Члан 83.

Сваки узорак ћелија и ткива мора бити идентификован посебном ознаком која садржи информације о поступку добијања ћелија и ткива и њиховој пријави у банци ћелија и ткива, као и подацима о узимању, давању, обради, очувању, карантину, складиштењу, дистрибуцији, односно трансплантацији ћелија и ткива.

Банка ћелија и ткива дужна је да додели јединствен идентификациони код сваком узорку ћелија, односно ткиву који се донира у банци ћелија и ткива, осим у случају донирања репродуктивних ћелија између супружника, односно ванбрачних партнера, како би се омогућила правилна идентификација даваоца и следивост донираних ћелија и ткива, као и како би се доставиле информације о најважнијим особинама и својствима ћелија и ткива.

Јединствен идентификациони код из става 2. овог члана садржи најмање следеће податке:

1) идентификацију донирања са јединственим идентификационим бројем и идентификацијом банке ћелија и ткива;

2) идентификацију индустријског производа са бар кодом производа (основна номенклатура), број подскупа лота (ако се примењује) и рока важења.

Садржај јединственог идентификационог кода из става 2. овог члана, ради размене ћелија и ткива, односно ради увоза и извоза, може се ускладити са прихваћеним кодним системом земаља Европске уније са којима се тај поступак обавља.

Дистрибуција

Члан 84.

Банка ћелија и ткива дужна је да обезбеди квалитет и безбедност ћелија и ткива у току дистрибуције.

Однос између банке ћелија и ткива и трећих лица

Члан 85.

Банка ћелија и ткива закључује писмене уговоре са трећим лицима за обављање свих послова који утичу на квалитет и безбедност ћелија и ткива, а који се обрађују у сарадњи са трећим лицима, посебно у следећим случајевима:

1) када банка ћелија и ткива једну од фаза у обради ћелија и ткива повери трећем лицу;

2) када треће лице испоручује производе или услуге који утичу на обезбеђивање квалитета и безбедности ћелија и ткива, укључујући и њихово дистрибуирање;

3) када банка ћелија и ткива пружа услуге другој банци ћелија и ткива;

4) када банка ћелија и ткива дистрибуира ћелије и ткива које је обрадило треће лице.

Банка ћелија и ткива дужна је да оцењује и бира трећа лица са којима закључује уговоре из става 1. овог члана на основу њихове способности да задовоље услове прописане овим законом и прописима донетим за спровођење овог закона.

Банка ћелија и ткива води списак свих уговора из става 1. овог члана.

У уговору из става 1. овог члана утврђују се и обавезе трећих лица и детаљни стандардни оперативни поступци.

Банка ћелија и ткива дужна је да на захтев Министарства, односно Управе за биомедицину достави копије уговора са трећим лицима из става 1. овог члана.

VIII. НАУЧНОИСТРАЖИВАЧКИ РАД

Дозвола за спровођење научноистраживачког рада

Члан 86.

Министар издаје дозволу за спровођење научноистраживачког рада на ћелијама, односно ткивима здравственој установи, односно другом правном лицу, који испуњавају услове прописане законом за обављање научноистраживачког рада, односно главном истраживачу на основу мишљења Управе за биомедицину.

Здравствена установа, односно друго правно лице из става 1. овог члана мора да има главног истраживача одговорног за спровођење научноистраживачког рада.

Главни истраживач из става 1. овог члана коме је издата дозвола за спровођење научноистраживачког рада на ћелијама, односно ткивима мора да има закључен уговор са здравственом установом, односно другим правним лицем, који испуњавају услове прописане законом за обављање научноистраживачког рада како би се спроводио поступак научноистраживачког рада на основу дозволе из става 1. овог члана.

Главни истраживач мора да испуњава услове у погледу научног звања у складу са законом.

Дозвола из става 1. овог члана издаје се за тачно утврђену врсту, поступак и време трајања научноистраживачког рада.

Управа за биомедицину прати спровођење научноистраживачког рада из става 1. овог члана и о томе подноси извештај министру најмање једном годишње.

Министар може одузети дозволу из става 1. овог члана и пре истека рока за који је дозвола издата, уколико на основу извештаја Управе за биомедицину, утврди да је спровођење научноистраживачког рада у супротности са издатом дозволом, односно да је у супротности са правилима медицинске науке и професионалне етике.

Министар може да продужи рок из става 3. овог члана за који је дозвола издата.

Министар доноси решење о издавању дозволе за спровођење научноистраживачког рада на ћелијама, односно ткивима у року од 90 дана од дана подношења захтева.

У поступку доношења решења о издавању, односно одузимању дозволе примењује се закон којим се уређује општи управни поступак.

Решење из става 9. овог члана коначно је у управном поступку и против њега се може покренути управни спор.

Дозвола за увођење нових здравствених технологија у поступку лечења применом ћелија, односно ткива

Члан 87.

Под новим здравственим технологијама у поступку лечења применом ћелија, односно ткива подразумева се увођење нових здравствених метода и поступака који се нису примењивали у Републици Србији, односно у одређеној здравственој установи, који се могу користити ради унапређивања здравља људи применом ћелија и ткива, односно ћелијске терапије, која обухвата безбедне, квалитетне и ефикасне лекове и медицинска средства, медицинске процедуре, као и услове за пружање здравствене заштите.

Министар издаје дозволу за увођење и коришћење нових здравствених технологија из става 1. овог члана на основу предлога Управе за биомедицину.

Ради припреме предлога за издавање дозволе из става 2. овог члана Управа за биомедицину прибавља мишљење о новим здравственим технологијама из става 1. овог члана од експерата

Управе за биомедицину са листе експерата формиране у складу са законом којим се уређује трансплантација органа.

Овлашћена здравствена установа подноси Управи за биомедицину захтев за издавање дозволе за увођење и коришћење нових здравствених технологија из става 1. овог члана.

Министар доноси решење о издавању дозволе из става 2. овог члана.

Решење из става 5. овог члана коначно је у управном поступку и против њега се може покренути управни спор.

На увођење нових здравствених технологија из става 1. овог члана не примењују се одредбе закона којим се уређује здравствена заштита, а које се односе на процену здравствених технологија.

Могућност обављања научноистраживачког рада

Члан 88.

Научноистраживачки рад на ћелијама и ткивима дозвољен је искључиво ради очувања и побољшања човековог здравља.

На ћелијама и ткивима дозвољен је научноистраживачки рад ако се истраживањем на животињама или на неки други начин не би постигли тражени резултати.

Приликом научноистраживачког рада морају се поштовати савремени стандарди медицинске науке, као и медицинске етике.

Дозвољен је научноистраживачки рад на крвотворним ћелијама периферне крви, крви из плаценте, матичним ћелијама из коштане сржи, репродуктивним ћелијама, ткивима и ћелијама фетуса и матичним ћелијама одраслих организама и ембриона који не испуњавају услове и критеријуме за употребу ради лечења, односно који нису довољни за поступак лечења, односно који нису потребни за поступак лечења одређеног пацијента.

За обављање научноистраживачког рада на ћелијама, односно ткивима из става 4. овог члана потребан је писмени пристанак лица од кога се ћелије и ткива узимају, односно добијају.

Главни истраживач, поред друге документације која је потребна за давање дозволе за научноистраживачки рад, Управи за биомедицину доставља и копију писменог пристанка из става 5. овог члана.

Образац изјаве о пристанку из става 5. овог члана прописује министар.

Изјава о пристанку из става 5. овог члана чува се у здравственој установи у којој су узете ћелије, односно ткива 30 година од дана давања изјаве.

IX. НАДЛЕЖНОСТ УПРАВЕ ЗА БИОМЕДИЦИНУ

Послови Управе за биомедицину који се односе на трансплантацију ћелија и ткива

Члан 89.

Послови Управе за биомедицину који се односе на трансплантацију ћелија и ткива јесу:

1) координирање рада здравствених установа које су добиле дозволу из члана 10. овог закона и предлаже мере за унапређивање квалитета рада здравствене установе које обавља послове трансплантације ћелија и ткива;

2) обављање послова контроле квалитета рада, односно континуираног праћења квалитета рада;

3) обезбеђивање и координирање дистрибуције и размене ћелија и ткива између здравствених установа у земљи, као и са надлежним правним лицима, органима и организацијама у иностранству са којима се остварује сарадња у складу са овим законом;

4) утврђивање и контролисање испуњености услова за обављање послова у здравственим установама које обављају послове трансплантације ћелија и ткива у погледу простора, кадра и опреме прописаних овим законом и прописима донетим за спровођење овог закона;

5) предлагање министру издавање, обнављање, односно одузимање дозволе за обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације

ткива, односно трансплантације ћелија и ткива, вођење евиденције о размени ћелија и ткива, у складу са овим законом;

6) вођење Јединственог регистра давалаца ћелија и ткива, у складу са овим законом;

7) вођење Републичке листе чекања за трансплантацију ћелија и ткива у складу са овим законом;

8) учествовање у поступку промоције трансплантације и предлаже министру програм за промоцију трансплантације ћелија и ткива;

9) учествовање у припреми прописа за спровођење овог закона које доноси министар;

10) обезбеђивање континуираног и непрекидног протока информација, као и доступности тих информација овлашћеним здравственим радницима о подацима које воде у складу са овим законом;

11) обезбеђивање, организовање и одржавање јединственог информационог система за трансплантацију и овлашћеном здравственом раднику у поступку трансплантације додељује шифру за добијање одобрења за позивање на податке које води, у складу са овим законом и прописима донетим за спровођење овог закона;

12) вршење инспекцијског надзора над радом здравствених установа које су добиле дозволу у складу са чланом 10. овог закона;

13) праћење научних достигнућа у области трансплантације ћелија и ткива и предлаже мере за примену у Републици Србији;

14) учествовање у припреми водича добре праксе и стандардних оперативних поступака за обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија и ткива;

15) подношење министру извештаја о раду у складу са овим законом;

16) обављање и других послова у складу са законом.

Надзор који спроводи Управа за биомедицину у вези са пословима трансплантације ћелија и ткива

Члан 90.

У вршењу надзора над обављањем послова овлашћених здравствених установа инспектор за трансплантацију ћелија и ткива овлашћен је да:

1) прегледа опште и појединачне акте, документацију и евиденције које се односе на обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија и ткива;

2) прегледа просторије, објекте и опрему, као и документацију о прописаном кадру који обавља послове узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија и ткива;

3) саслушава и узима изјаву од одговорних лица, здравствених радника и других заинтересованих лица;

4) наложи отклањање утврђених неправилности и недостатака у обављању послова узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија и ткива, у року који не може бити краћи од 15 дана ни дужи од шест месеци од дана пријема акта којим је та мера наложена, а у хитним случајевима нареди отклањање утврђених неправилности без одлагања;

5) наложи извршење прописаних мера овлашћеној здравственој установи у року који не може бити краћи од 15 дана ни дужи од три месеца од дана пријема акта којим је та мера наложена, а у хитним случајевима нареди извршење прописаних мера без одлагања;

6) привремено забрани обављање послова овлашћеној здравственој установи ако не поступи у складу са наложеним мерама предвиђеним тачком 4) овог члана, у року који не може бити краћи од 30 дана ни дужи од шест месеци од дана пријема акта којим је та мера изречена;

7) привремено забрани обављање послова овлашћеној здравственој установи ако није отклонила утврђене неправилности и недостатке, односно ако није извршила наложене мере које је изрекао инспектор за трансплантацију ћелија и ткива, односно здравствени инспектор и покрене поступак за одузимање дозволе за обављање послова за које је добила дозволу у складу са овим законом;

8) нареди забрану употребе одређених ћелија и ткива уколико су ћелије и ткива узети у супротности са овим законом;

9) предузме и друге мере у складу са законом.

Надзор из става 1. овог члана обавља се континуирано, а најмање једном у две године.

На спровођење ванредног стручног надзора над овлашћеним здравственим установама, сходно се примењују одредбе закона којим се уређује здравствена заштита.

Члан 91.

Овлашћена здравствена установа дужна је да инспектору за трансплантацију ћелија и ткива омогући несметано обављање послова у складу са овим законом, односно да омогући неометан преглед просторија, опреме, узетих ћелија и ткива за трансплантацију, медицинске документације и друге евиденције које се воде у складу са законом.

Инспектор из става 1. овог члана има право да, ради спречавања могућег прикривања доказа, одузме предмете, ћелије, односно ткива, као и медицинску документацију и друге евиденције које се воде у складу са законом, уз обавезу издавања потврде о њиховом привременом одузимању.

Члан 92.

О извршеном прегледу и предузетим радњама инспектор за трансплантацију ћелија и ткива дужан је да сачини записник који садржи налаз чињеничног стања утврђеног у овлашћеној здравственој установи.

Записник из става 1. овог члана доставља се здравственој установи над којом је надзор извршен.

Инспектор за трансплантацију ћелија и ткива дужан је да, на основу записника из става 1. овог члана донесе решење којим се налажу мере, радње, као и рокови за извршење наложених мера у здравственој установи.

Против решења из става 3. овог члана може се изјавити жалба министру.

Решење министра из става 4. овог члана коначно је у управном поступку и против њега се може покренути управни спор.

Ако инспектор за трансплантацију ћелија и ткива оцени да је поступањем, односно непоступањем здравствене установе учињено кривично дело, привредни преступ или прекршај, дужан је да без одлагања поднесе надлежном органу пријаву за учињено кривично дело, привредни преступ, односно за покретање прекршајног поступка.

Члан 93.

Инспектор за трансплантацију ћелија и ткива самосталан је у свом раду у границама овлашћења утврђених овим законом и прописима донетим за спровођење овог закона.

Инспектор за трансплантацију ћелија и ткива дужан је да поступа савесно и непристрасно у вршењу послова надзора, односно да чува као службену тајну податке до којих дође у вршењу надзора, а посебно податке о личности и здравственом стању даваоца, односно примаоца ћелија и ткива.

На вршење надзора од стране инспектора за трансплантацију ћелија и ткива примењују се одредбе закона којим је уређен општи управни поступак, закона којим је уређен рад државне управе, као и закона којим је уређена здравствена заштита, ако овим законом није друкчије уређено.

Члан 94.

Послове инспектора за трансплантацију ћелија и ткива може вршити лице које има завршен медицински факултет, одговарајућу специјализацију и најмање пет година радног искуства по положеном специјалистичком испиту, стручни испит за рад у државним органима, као и које је стекло посебна стручна знања за област трансплантације.

Инспектор из става 1. овог члана има службену легитимацију којом се идентификује и коју је дужан да покаже на захтев одговорног лица или другог заинтересованог лица приликом вршења надзора.

Образац и садржину службене легитимације из става 2. овог члана прописује министар.

Члан 95.

Трошкове настале у поступку утврђивања испуњености услова за обављање послова узимања, дистрибуције, пресађивања, утврђивања подударности, типизације ткива, трансплантације, односно банке ћелија и ткива сноси подносилац захтева.

Средства из става 1. овог члана подносилац захтева уплаћује на одговарајући рачун за уплату јавних прихода буџета Републике Србије.

Висину трошкова из става 1. овог члана прописује министар.

X. НАДЗОР

Члан 96.

Надзор над спровођењем овог закона и прописа донетих за спровођење овог закона врши Министарство у складу са законом.

XI. ОБАВЉАЊЕ ПОСЛОВА ТРАНСПЛАНТАЦИЈЕ ЋЕЛИЈА И ТКИВА У УСТАНОВАМА КОЈЕ НИСУ У ПЛАНУ МРЕЖЕ

Члан 97.

Послове трансплантације, поред овлашћених здравствених установа, могу обављати и здравствене установе које нису у Плану мреже при чему се на обављање тих послова примењују одредбе овог закона о: начелима поступка трансплантације ћелија и ткива (чл. 4-8), поступку издавања, обнављања и одузимања дозволе (чл. 10-13), организовању координатора за обављање послова трансплантације (чл. 14-15), подношењу извештаја од стране координатора (члан 16), Етичком одбору (члан 17), поступку трансплантације ћелија и ткива (чл. 18-47), узимању ћелија и ткива од живог даваоца (чл. 48-54), узимању ткива од умрлог лица (чл. 55-66), банци ћелија и ткива (чл. 67-85), научноистраживачком раду (чл. 86-88), као и надзору над обављањем послова трансплантације (чл. 90-96).

XII. КАЗНЕНЕ ОДРЕДБЕ

Кривична дела

Члан 98.

Ко силом или претњом, довођењем у заблуду или одржавањем у заблуди, злоупотребом овлашћења, поверења, односа зависности, тешких прилика другог, задржавањем личних исправа или давањем или примањем новца или друге користи присили једно лице да мимо своје слободне воље да писмени пристанак за давање ћелија, односно ткива за живота ради трансплантације том или другом лицу и коме се на основу тог писменог пристанка узме ћелија или ткиво, или ако мимо своје воље потпише писмени пристанак за давање ткива после своје смрти за трансплантацију том или другом лицу, казниће се затвором од две до десет година.

За дело из става 1. овог члана учињено према малолетном лицу учинилац ће се казнити казном прописаном за то дело и када није употребио силу, претњу или неки други од наведених начина.

Ако је дело из става 1. овог члана учињено према малолетном лицу, учинилац ће се казнити затвором најмање три године.

Ако је услед дела из ст. 1. и 3. овог члана наступила тешка телесна повреда даваоца ћелија, односно ткива, учинилац ће се казнити затвором од три до 15 година.

Ако је услед дела из ст. 1. и 3. овог члана наступила смрт даваоца ћелија, односно ткива, учинилац ће се казнити затвором најмање десет година.

Ко се бави вршењем кривичних дела из ст. 1-3. овог члана или је дело извршено од стране организоване групе, казниће се затвором најмање пет година.

Члан 99.

Ко уз било какву накнаду да своје ћелије, односно ткива или ћелије или ткива другог лица ради трансплантације или нуди своје ћелије, односно ткива или ћелије, односно ткива другог лица уз накнаду ради трансплантације или врбује, превози, пребацује, предаје, продаје, купује, посредује у продаји или посредује на било који други начин у трансплантацији ћелија, односно ткива или учествује у поступку трансплантације ћелија или ткива који су предмет комерцијалне трговине, казниће се затвором од две до десет година.

Ако је дело из става 1. овог члана учињено према малолетном лицу, учинилац ће се казнити затвором најмање три године.

Ако је услед дела из ст. 1. и 2. овог члана наступила тешка телесна повреда даваоца ћелија, односно ткива, учинилац ће се казнити затвором од три до 15 година.

Ако је услед дела из ст. 1. и 2. овог члана наступила смрт даваоца ћелија, односно ткива, учинилац ће се казнити затвором најмање десет година.

Ко се бави вршењем кривичних дела из ст. 1. и 2. овог члана или је дело извршено од стране организоване групе, казниће се затвором најмање пет година.

Члан 100.

Ко обави пресађивање ћелија, односно ткива или учествује у поступку пресађивања ћелија, односно ткива лицу које није дало писмени пристанак за пресађивање ћелија, односно ткива или узме ткива од умрлог лица, односно учествује у узимању ткива од умрлог лица код кога није дијагностикована и утврђена мождана смрт на начин и у складу са поступком прописаним законом, или ако обави узимање ткива или учествује у поступку узимања ткива од лица које је за живота забранило давање ткива у случају своје смрти или ако писмени пристанак није дао члан породице или друго блиско лице у складу са овим законом, казниће се затвором од две до десет година.

Ако је дело из става 1. овог члана учињено према малолетном лицу, учинилац ће се казнити затвором најмање три године.

Ако је услед дела из ст. 1. и 2. овог члана наступила тешка телесна повреда даваоца ћелија, односно ткива, учинилац ће се казнити затвором од три до 15 година.

Ако је услед дела из ст. 1. и 2. овог члана наступила смрт даваоца ћелија, односно ткива, учинилац ће се казнити затвором најмање десет година.

Ко се бави вршењем кривичних дела из ст. 1. и 2. овог члана или је дело извршено од стране организоване групе, казниће се затвором најмање пет година.

Прекршаји

Члан 101.

Новчаном казном од 500.000 до 1.000.000 динара казниће се за прекршај правно лице - здравствена установа, односно банка ћелија и ткива ако:

1) обавља послове узимања, диструбуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија, односно ткива без дозволе добијене у складу са овим законом (члан 10. став 5);

2) услуге добијања, тестирања, обраде, очувања, карантина, складиштења и дистрибуције људских ћелија и ткива не обавља као недобитне услуге (члан 19);

3) не сачини листу чекања за обављање поступка пресађивања ћелија, односно ткива по врсти потребних ћелија, односно ткива за пацијенте који се лече у тој здравственој установи, и која није усклађена са републичком листом чекања (члан 23. став 7);

4) оглашава, односно рекламира потребу за ћелијама и ткивима, као и оглашавање давања ћелија и ткива, са или без нуђења, односно давања новчане накнаде или друге материјалне или нематеријалне користи или ако оглашава, односно рекламира здравствену установу или здравствене раднике који обављају поступак трансплантације, као и банке ћелија и ткива у средствима јавног информисања, као и на другим носиоцима огласних порука, односно на било који други начин (члан 27. став 1);

5) обавља размену ћелија, односно ткива у супротности са уговором о размени ћелија, односно ткива у складу са овим законом, који потписује министар (члан 29. став 4);

6) употребљава ћелије и ткива у производњи или изради козметичких производа (члан 30. став 1);

7) не предузме све потребне мере како би се спречио, односно умањио ризик од преношења заразне, односно било које друге болести са даваоца на примаоца ћелија, односно ткива (члан 34. став 1);

8) не омогући праћење озбиљних нежељених реакција, као и озбиљних нежељених појава код даваоца, односно примаоца и да о сумњи на озбиљне нежељене реакције, као и озбиљне нежељене појаве, без одлагања, не обавести Управу за биомедицину или ако не води евиденције о озбиљним нежељеним реакцијама, као и озбиљним нежељеним појавама за сваког даваоца, односно примаоца ћелија, односно ткива, или ако не обезбеди следивост ћелија, односно ткива који се трансплантирају и о томе не води евиденције (члан 36. ст. 1. и 2);

9) податке о даваоцу и примаоцу прикупља, обрађује или користи у друге сврхе осим у сврху трансплантације, у складу са овим законом (члан 39. став 8);

10) прикупља, обрађује, води, чува, користи и штити друге податке осим података који су неопходни за део послова који обавља та здравствена установа (члан 41. став 3);

11) не обезбеди заштиту података које води, односно који су им доступни и које размењује (члан 42. став 1);

12) не чува податке о даваоцу и примаоцу из члана 41. овог закона, односно ако не чува целокупну медицинску документацију прописану овим законом најмање 30 година, односно ако је уништи пре истека рока прописаног овим законом (члан 43);

13) користи и износи податке о личности даваоца, односно примаоца ћелија, односно ткива у научне, образовне и статистичке сврхе, као и у средствима информисања на начин који може да открије идентитет лица на кога се подаци односе, а о чему давалац, односно прималац није дао писмени пристанак (члан 44. став 1);

14) о сваком могућем донирању о коме здравствена установа има податке, извршеном узимању и пресађивању ћелија и ткива, као и размени ћелија и ткива ради пресађивања у складу са овим законом не обавести Управу за биомедицину достављањем образаца о обавештавању (члан 45. став 1);

15) поступак узимања, пресађивања, типизације, односно трансплантације, као и диструбуције ћелија, односно ткива ради лечења не обавља у складу са стандардним оперативним процедурама, као и водичима добре праксе (члан 46. став 1);

16) омогући узимање са живог даваоца ћелије, односно ткива у супротности са чланом 48. овог закона;

17) омогући узимање ћелија, односно ткива од живог даваоца код кога постоји ризик по живот и здравље даваоца који према медицинским критеријумима нису у границама прихватљивости, односно ако је ризик по живот и здравље живог даваоца у несразмери са очекиваном користи за здравље примаоца (члан 49. став 2);

18) омогући узимање ћелија, односно ткива у супротности са чланом 50. овог закона;

19) омогући узимање ћелија, односно ткива у супротности са чланом 51. овог закона;

20) омогући узимање ћелија, односно ткива са умрлог лица које је држављанин Републике Србије, у супротности са чланом 61. овог закона;

21) омогући узимање ћелија, односно ткива са умрлог лица које није држављанин Републике Србије, односно који нема стално пребивалиште у Републици Србији које није дало писмени пристанак у складу са овим законом, без писмене сагласности члана породице, односно другог блиског лица (члан 63);

22) омогући узимање ткива са умрлог малолетног лица, односно од лица које нема потпуну пословну способност, као и од пунолетног лица коме је на основу одлуке надлежног органа одузета пословна способност без писмене сагласности родитеља, односно законског заступника (члан 64);

23) обавља послове банке ћелија и ткива без дозволе издате од стране министра, односно ако послове банке ћелија и ткива обавља у супротности са подзаконским актом донетим за спровођење овог закона (члан 68. ст. 1. и 6);

24) не именује одговорно лице из члана 76. овог закона;

25) спроводи научноистраживачки рад у супротности са чланом 86. овог закона (члан 86. ст. 1-5);

26) уводи нове здравствене технологије у поступку лечења применом ћелија, односно ткива без дозволе министра (члан 87. став 2);

27) обавља научноистраживачки рад у супротности са чланом 88. овог закона (члан 88).

За прекршаје из става 1. овог члана казниће се и одговорно лице у здравственој установи новчаном казном од 50.000 динара.

За прекршаје из става 1. овог члана казниће се и физичко лице - здравствени радник, односно друго лице новчаном казном од 50.000 динара.

Члан 102.

Новчаном казном од 40.000 до 50.000 динара казниће се за прекршај физичко лице ако:

1) не чува податке о даваоцу или примаоцу органа као службену тајну (члан 38);

2) учествује у давању, пријављивању, обради или достављању било којих података о личности који се односе на даваоца или примаоца ћелија, односно ткива, као и ако учествује у поступку донирања, посредовања, узимања и пресађивања ћелија, односно ткива и даје податке о личности даваоца или примаоца, као и податке о лицима која су обавештена о намераваној или могућој трансплантацији (члан 39. став 4);

3) започне поступак узимања ћелија, односно ткива од умрлог лица у супротности са чланом 65. овог закона;

4) спроводи научноистраживачки рад без дозволе министра за спровођење научноистраживачког рада или ако нема закључен уговор са здравственом установом, односно другим правним лицем који испуњава услове прописане законом за обављање научноистраживачког рада (члан 86. ст. 1. и 3).

Члан 103.

Новчаном казном од 400.000 до 500.000 динара казниће се за прекршај предузетник ако обавља послове узимања, дистрибуције, пресађивања, утврђивања подударности, односно типизације ткива, односно трансплантације ћелија, односно ткива.

Поред новчане казне из става 1. овог члана предузетнику ће се изрећи заштитна мера забране обављања здравствене делатности у трајању од три године.

XIII. ПРЕЛАЗНЕ И ЗАВРШНЕ ОДРЕДБЕ

Члан 104.

Здравствене установе које обављају послове трансплантације ћелија, односно ткива дужне су да ускладе организацију рада, као и опште акте са одредбама овог закона у року од 12 месеци од дана ступања на снагу овог закона.

Здравствене установе које обављају послове трансплантације ћелија, односно ткива у складу са прописима који су важили до дана ступања на снагу овог закона настављају са радом у складу са тим прописима до момента усклађивања рада са одредбама овог закона, а најдуже до истека рока из става 1. овог члана.

Члан 105.

Прописи за спровођење овог закона донеће се у року од 18 месеци од дана почетка рада Управе за биомедицину.

До доношења прописа из става 1. овог члана примењују се прописи који су важили до дана ступања на снагу овог закона.

Члан 106.

Поступак трансплантације ћелија, односно ткива који је започет пре ступања на снагу овог закона окончаће се по прописима који су били на снази до дана ступања на снагу овог закона.

Члан 107.

До организовања обављања послова инспектора за трансплантацију ћелија, односно ткива утврђених овим законом, послове инспекцијског надзора обављаће здравствена инспекција основана у складу са законом којим се уређује област здравствене заштите.

Члан 108.

Захтев за оснивање банке ћелија и ткива може се поднети 12 месеци од дана почетка рада Управе за биомедицину.

Здравствене установе, односно делови здравствених установа који обављају одређене послове банака ћелија и ткива у Републици Србији дужни су да ускладе свој рад са одредбама овог закона у року од 12 месеци од дана почетка рада Управе за биомедицину.

Ако банке из става 2. овог члана не ускладе свој рад са одредбама овог закона у року од 12 месеци од дана почетка рада Управе за биомедицину, министар доноси решење о забрани обављања делатности.

Члан 109.

Даном почетка примене овог закона престаје да важи одредба члана 48. став 3. Закона о здравственој заштити ("Службени гласник РС", број 107/05), у делу који се односи на узимање, чување и пресађивање делова људског тела.

Члан 110.

Овај закон ступа на снагу осмог дана од дана објављивања у "Службеном гласнику Републике Србије", а примењиваће се од 1. јануара 2010. године.

ORDEN SCO/256/2007, DE 5 DE FEBRERO, POR LA QUE SE ESTABLECEN LOS PRINCIPIOS Y LAS DIRECTRICES DETALLADAS DE BUENA PRÁCTICA CLÍNICA Y LOS REQUISITOS PARA AUTORIZAR LA FABRICACIÓN O IMPORTACIÓN DE MEDICAMENTOS EN INVESTIGACIÓN DE USO HUMANO

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Los ensayos clínicos con medicamentos de uso humano están regulados en el título III de la Ley 29/2006, de 26 de julio, de Garantías y Uso Racional de los Medicamentos y Productos Sanitarios, que recoge en su articulado parte muy importante de los principios garantistas que ya contaban con previsiones normativas precedentes. En particular, el vigente Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos, que incorporó al ordenamiento jurídico español la Directiva 2001/20/CE del Parlamento Europeo y del Consejo, de 4 de abril de 2001, relativa a la aproximación de las disposiciones legales, reglamentarias y administrativas de los Estados miembros sobre la aplicación de buenas prácticas clínicas en la realización de ensayos clínicos de medicamentos de uso humano. Esta Directiva estableció la obligación de adoptar los principios y directrices de buena práctica clínica y de las normas de correcta fabricación de medicamentos en investigación, así como las directrices detalladas para la autorización de la fabricación o importación de medicamentos en investigación.

Posteriormente, el Real Decreto 2183/2004, de 12 de noviembre, por el que se modifica el Real Decreto 1564/1992, de 18 de diciembre, por el que se desarrolla y regula el régimen de autorización de los laboratorios farmacéuticos e importadores de medicamentos y la garantía de calidad en su fabricación industrial, transpuso la Directiva 2003/94/CE de la Comisión, de 8 de octubre de 2003, por la que se establecen los principios y directrices de las prácticas correctas de fabricación de los medicamentos de uso humano y de los medicamentos en investigación de uso humano.

Más recientemente, la Directiva 2005/28/CE de la Comisión, de 8 de abril de 2005, por la que se establecen los principios y las directrices detalladas de las buenas prácticas clínicas respecto a los medicamentos en investigación de uso humano, así como los requisitos para autorizar la fabricación o importación de dichos productos, incluye asimismo las directrices detalladas sobre la documentación relativa a los ensayos clínicos, el archivo, la cualificación de los inspectores y los procedimientos de inspección.

Mediante esta disposición se incorpora al ordenamiento jurídico interno la Directiva 2005/28/CE de la Comisión, de 8 de abril de 2005.

En la aplicación de los requisitos y las directrices contempladas en esta Orden se deberán tener en cuenta las directrices comunitarias publicadas por la Comisión Europea en los distintos volúmenes de las normas sobre medicamentos de la Unión Europea.

En la tramitación de esta Orden han sido oídos los sectores afectados.

Esta Orden se dicta al amparo de lo establecido en la disposición final segunda del Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.

En su virtud, con la aprobación previa del Ministro de Administraciones Públicas y de acuerdo con el Consejo de Estado, dispongo:

Artículo 1. Objeto.

Esta Orden regula los principios y las directrices de buena práctica clínica en los ensayos clínicos con medicamentos en investigación de uso humano, los requisitos para autorizar la fabricación o importación de estos medicamentos, las directrices detalladas sobre la documentación relativa a dichos ensayos, así como su archivo, y la cualificación de los inspectores y los procedimientos de inspección.

Artículo 2. Principios y directrices de buena práctica clínica.

En la realización de ensayos clínicos con medicamentos en investigación de uso humano se deberá observar lo siguiente:

a) Los derechos, la seguridad y el bienestar de los sujetos del ensayo prevalecerán por encima de los intereses de la ciencia y de la sociedad.

b) Cada persona que participe en la realización de un ensayo estará capacitada por su titulación, formación y experiencia para ejecutar sus tareas.

c) Los ensayos clínicos, en todos sus aspectos, deberán tener una sólida base científica y deberán regirse por principios éticos.

d) Deberán adoptarse los procedimientos necesarios que aseguren la calidad de cada uno de los aspectos del ensayo clínico.

e) La información disponible sobre un medicamento en investigación, tanto clínica como no clínica, deberá ser adecuada para avalar el ensayo clínico propuesto.

f) Los ensayos clínicos deberán realizarse de acuerdo con la Declaración de Helsinki sobre los principios éticos para las investigaciones médicas en seres humanos, aprobada por la Asamblea General de la Asociación Médica Mundial.

g) El protocolo deberá establecer los criterios de inclusión, exclusión y retirada de los sujetos que participen en un ensayo, el plan de monitorización y el plan de publicación.

h) El investigador y el promotor tendrán en cuenta todas las instrucciones para la realización de ensayos clínicos en España o, en su caso, las directrices de la Comisión Europea relativas al inicio, realización y finalización del ensayo clínico publicadas por la Agencia Española de Medicamentos y Productos Sanitarios.

i) Toda la información sobre el ensayo clínico deberá registrarse, tratarse y conservarse de forma que pueda ser comunicada, evaluada y verificada de manera precisa, protegiendo al mismo tiempo el carácter confidencial de los registros de los sujetos del ensayo.

j) Los Comités Éticos de Investigación Clínica adoptarán los procedimientos normalizados de trabajo necesarios para la realización de sus funciones, de acuerdo con lo establecido en el Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.

Los Comités conservarán todos los documentos esenciales, relacionados con cada ensayo clínico evaluado, durante al menos tres años tras la finalización del mismo, o durante un período más largo si así lo establece la Agencia Española de Medicamentos y Productos Sanitarios o la autoridad competente de la Comunidad Autónoma correspondiente. Esta documentación debe archivarse preferentemente agrupada por protocolos, en un lugar que permita garantizar la confidencialidad de la información durante el tiempo de archivo requerido. En caso de cese de la actividad del Comité, la institución en la que esté constituido el Comité debe mantener el archivo de la documentación durante el plazo establecido. Para cada ensayo clínico debe incluir, como mínimo, lo siguiente:

1º El protocolo, las modificaciones y toda la documentación presentada por el promotor o su representante legal.

2º Los dictámenes o informes emitidos por el Comité (Comité Ético de Investigación Clínica de Referencia si el ensayo clínico es multicéntrico), especificando la versión de los documentos revisados.

3º Copia de la correspondencia con el investigador y/o el promotor o su representante.

4º La documentación relativa a las actividades de seguimiento del ensayo clínico.

5º El informe anual sobre la marcha del ensayo clínico.

6º Copia de cualquier correspondencia con la Agencia Española de Medicamentos y Productos Sanitarios y/o con las autoridades competentes de la Comunidad Autónoma donde este localizado el comité.

7º Copia de las notificaciones y correspondencia relevantes con los Comités implicados y/o el Comité de referencia, de un ensayo multicéntrico.

8º Las sospechas de reacciones adversas recibidas y los informes de seguridad presentados por el promotor.

9º Notificación de la finalización del ensayo clínico, ya sea prematura o programada.

10º Resumen del informe final del ensayo clínico presentado por el promotor.

11º Cualquier otra documentación relevante.

Los Comités deben mantener archivada la documentación relacionada con su funcionamiento y actividad. En caso de cese de la misma, esta documentación debe conservarse en la institución durante al menos tres años, transcurridos desde la finalización del último estudio evaluado. Debe incluir como mínimo, lo siguiente:

1º Resoluciones de acreditación y de posteriores modificaciones.

2º Currículum vitae de los miembros actuales o que hayan pertenecido al Comité.

3º Convocatoria y actas de las reuniones del Comité.

4º Procedimientos normalizados de trabajo del Comité, versión actual y archivo histórico.

k) La Agencia Española de Medicamentos y Productos Sanitarios establecerá los procedimientos que garanticen la transmisión de información entre la Agencia y los Comités Éticos de Investigación Clínica.

l) El promotor de un ensayo clínico podrá delegar la totalidad o una parte de sus funciones en un particular, empresa, institución u organismo, que deberá poner en marcha un sistema de garantía y control de calidad. Las obligaciones del promotor establecidas en las normas de buena práctica clínica que se hayan delegado serán de aplicación al particular, empresa, institución u organismo contratado. No obstante, en estos casos, el promotor seguirá siendo el responsable de garantizar que la realización del ensayo clínico y los datos finales generados en dicho estudio se ajustan a lo dispuesto en el Real Decreto 223/2004, de 6 de febrero, y en esta Orden. Cualquier transferencia de funciones del promotor en relación con un ensayo clínico debe quedar específicamente documentada.

m) El investigador y el promotor podrán ser la misma persona física.

n) La información del manual del investigador y sus actualizaciones se presentarán de forma concisa, sencilla, objetiva, equilibrada y no promocional, comprensible para los posibles investigadores y que les permita realizar una evaluación no sesgada de los riesgos y beneficios y de la pertinencia del ensayo clínico propuesto. Este documento servirá como referencia para la evaluación del carácter esperado, o no, de las reacciones adversas graves que pudieran ocurrir durante la realización del ensayo.

ñ) En caso de medicamentos autorizados en algún Estado miembro de la Unión Europea, cuando el medicamento se utilice en las condiciones de uso autorizadas, el manual del investigador podrá reemplazarse por la ficha técnica autorizada.

o) El manual del investigador debe validarse y actualizarse de manera regular por el promotor, al menos una vez al año.

Artículo 3. Requisitos de la solicitud para la autorización de fabricación o importación.

1. Será necesaria la autorización previa otorgada por la Agencia Española de Medicamentos y Productos Sanitarios para la fabricación total o parcial, incluyendo las diversas operaciones de división, acondicionamiento o presentación, de medicamentos en investigación, incluso en los casos en que los medicamentos fabricados estén destinados a la exportación. La autorización será necesaria también para las importaciones procedentes de terceros países.

2. No se exigirá la citada autorización para el acondicionamiento final, en caso de que se realice en un Servicio de Farmacia autorizado, siempre que los medicamentos en investigación estén destinados a ser utilizados únicamente en un centro sanitario dependiente de dicho servicio.

Cuando en el contexto de un ensayo clínico específico cuyo promotor sea un investigador o un grupo de investigadores, un Servicio de Farmacia autorizado desee realizar una operación de fabricación distinta de las contempladas anteriormente, deberá solicitar una autorización previa a la Agencia Española de Medicamentos y Productos Sanitarios y únicamente se podrá utilizar el medicamento en el ensayo clínico concreto. La Agencia Española de Medicamentos y Productos Sanitarios acordará con las Comunidades Autónomas los procedimientos de verificación de las normas de correcta fabricación en estos casos.

3. El solicitante deberá disponer de manera permanente y continua de una persona cualificada o de un director técnico, conforme a lo establecido en el Real Decreto 1564/1992, de 18 de diciembre, por el que se desarrolla y regula el régimen de autorización de los laboratorios farmacéuticos e importadores de medicamentos y la garantía en su fabricación industrial.

4. La solicitud para la autorización de fabricación o importación deberá incorporar los datos y documentos siguientes:

a) Los tipos de medicamentos y formas farmacéuticas que se pretenden fabricar o importar.

b) Las operaciones de fabricación o importación de que se trate.

c) El proceso de fabricación, cuando proceda, como en el caso de inactivación de agentes virales o no convencionales.

d) La identificación del lugar en el que se fabricarán los productos, que deberá contar, para la fabricación o importación de los medicamentos y formas farmacéuticas, de los locales, el equipo técnico y los medios de control adecuados y suficientes que se ajusten a los requisitos que establece el Real Decreto 1564/1992, de 18 de diciembre, en lo que respecta a la fabricación, el control y el almacenamiento de los productos.

5. Los tipos de medicamentos referidos en el apartado 4.a) de este artículo incluyen medicamentos hemoderivados, inmunológicos, de terapia celular, de terapia génica, biotecnológicos, de origen humano o animal, plantas medicinales, homeopáticos, radiofármacos y de origen químico.

6. La autorización establecida en el apartado 1 de este artículo se notificará en el plazo de 90 días desde la presentación de una solicitud válida, por la Agencia Española de Medicamentos y Productos Sanitarios, una vez comprobada la exactitud de los datos facilitados por el solicitante. En caso de que la Agencia precise datos complementarios, el plazo para resolver quedará en suspenso hasta que se faciliten los mismos.

La citada autorización podrá estar condicionada al cumplimiento de determinadas obligaciones impuestas en el momento de la concesión de la autorización o en una fecha posterior, con el fin de garantizar el cumplimiento de los requisitos establecidos en la misma.

La autorización únicamente será válida para las instalaciones, los tipos de medicamentos y las formas farmacéuticas solicitadas.

Artículo 4. Obligaciones del titular de la autorización de fabricación o importación.

1. El titular de la autorización deberá cumplir, como mínimo, los requisitos siguientes:

a) Disponer de los medios personales, materiales y técnicos necesarios, que respondan a las exigencias legales para la fabricación y control establecidos en el Real Decreto 1564/1992, de 18 de diciembre.

b) Disponer de los medicamentos en investigación o autorizados, conforme a lo dispuesto en el Real Decreto 223/2004, de 6 de febrero.

c) Permitir en todo momento el acceso a sus instalaciones a los inspectores.

d) Permitir que la persona cualificada o el director técnico pueda cumplir las funciones establecidas en función de su cargo.

e) Respetar los principios y directrices de las normas de correcta fabricación de medicamentos previstos en la normativa europea.

2. Para modificar los requisitos establecidos en los apartados 3 y 4 del artículo 3, el titular de una autorización de fabricación deberá solicitarlo a la Agencia Española de Medicamentos y Productos Sanitarios. En el caso de que la modificación se refiera a los tipos y formas farmacéuticas autorizadas o afecte al director técnico, la duración del procedimiento relativo a esta solicitud no será superior a 30 días. En casos excepcionales, este plazo podrá ser prorrogado hasta 90 días.

3. El incumplimiento de los requisitos establecidos será causa de suspensión o revocación de la autorización de fabricación de forma parcial o total.

4. Sólo podrán importar medicamentos en investigación los importadores que estén en posesión de la autorización de importación prevista en el artículo 3, otorgada por la Agencia Española de Medicamentos y Productos Sanitarios.

Artículo 5. Adquisición de medicamentos para ensayos clínicos.

1. Medicamentos comercializados en España y en el resto de la Unión Europea: Cuando los medicamentos que se vayan a utilizar en un ensayo clínico estén comercializados en España o en otro Estado miembro de la Unión Europea, el promotor de un ensayo clínico podrá obtenerlos bien a través de un distribuidor autorizado, tal como un almacén mayorista, o directamente del titular de la autorización de comercialización, previa presentación de la autorización de la Agencia Española de Medicamentos y Productos Sanitarios para ese ensayo clínico.

2. Medicamentos procedentes de un tercer país: Podrá importar medicamentos en investigación un importador autorizado por la Agencia Española de Medicamentos y Productos Sanitarios, previa solicitud de la importación del medicamento en investigación de un ensayo clínico a la Agencia.

Para obtener la autorización de importación de medicamentos procedentes de un tercer país sin un acuerdo de mutuo reconocimiento vigente, es necesario que aporte un certificado del director técnico o persona cualificada en el que se acredite que cada lote importado se ha fabricado en unas condiciones equivalentes a las normas de correcta fabricación de la Unión Europea o, si no se puede emitir ese certificado, un certificado de liberación de estos lotes firmado también por el director técnico, en el que se acredite que se han llevado a cabo, en la Unión Europea, los análisis, pruebas o controles necesarios para evaluar su calidad conforme a la información presentada para la autorización del ensayo.

Artículo 6. Archivo maestro del ensayo y métodos de archivo.

1. La documentación relativa al ensayo clínico constituye el archivo maestro del mismo y constará de los documentos esenciales que permitan la evaluación de la realización de un ensayo clínico y de la calidad de los datos obtenidos. Estos documentos deberán demostrar el cumplimiento por parte del investigador y el promotor de los principios y directrices de buena práctica clínica y de todos los requisitos aplicables y, en particular, del anexo II sobre normas y protocolos analíticos, farmacotoxicológicos y clínicos relativos a la realización de pruebas de medicamentos del Real Decreto 767/1993, de 21 de mayo, por el que se regula la evaluación, autorización, registro y condiciones de dispensación de especialidades farmacéuticas y otros medicamentos de uso humano fabricados industrialmente.

2. El archivo maestro del ensayo proporcionará la base para las auditorías que pueda realizar el auditor independiente del promotor y las inspecciones de las autoridades competentes.

3. El contenido de los documentos esenciales deberá ajustarse al carácter específico de cada fase del ensayo clínico. Se deberán tener en cuenta las orientaciones suplementarias sobre el contenido de dichos documentos publicados por la Comisión Europea.

4. El promotor y el investigador conservarán los documentos esenciales de cada ensayo clínico durante al menos cinco años tras la finalización del ensayo, o durante un período más largo si así lo disponen otros requisitos aplicables, como en el caso de que el estudio se presente como base para el registro de un medicamento en que se deberá cumplir el anexo II del Real Decreto 767/1993, de 21 de mayo, o un acuerdo entre el promotor, el investigador y el centro.

5. Los documentos esenciales deberán archivarse de forma que se puedan poner fácilmente a disposición de las autoridades competentes, en caso de que los soliciten.

6. La historia clínica del sujeto del ensayo deberá ser custodiada con arreglo a lo dispuesto en la Ley 41/2002, de 14 de noviembre, Básica Reguladora de la Autonomía del Paciente y de Derechos y Obligaciones en materia de Información y Documentación Clínica, y conforme al período máximo permitido por el hospital, la institución o la consulta privada.

7. Todos los cambios en la titularidad de los datos y documentos deberán documentarse. El nuevo titular asumirá las responsabilidades de las tareas de archivo y conservación de los datos.

8. El promotor nombrará a la persona de su organización responsable de los archivos y el acceso a los mismos deberá limitarse a las personas designadas.

9. Los soportes utilizados para conservar los documentos esenciales deberán garantizar que los documentos permanecen completos y legibles durante el período previsto de conservación y que estén a disposición de las autoridades competentes en caso de que los soliciten. Cualquier modificación de los registros habrá de ser trazable, permitiendo conocer el dato inicial y el corregido, así como la fecha y la firma del autor.

Artículo 7. Titulación, formación y experiencia de los inspectores de buena práctica clínica.

1. Los inspectores deberán tener la debida cualificación y formación universitaria en medicina, farmacia, farmacología, toxicología u otras disciplinas pertinentes.

2. Las administraciones sanitarias garantizarán la formación de los inspectores, asegurándose de que:

a) Reciban la formación adecuada, se evalúen periódicamente sus necesidades de formación y se adopten medidas adecuadas para mantener y mejorar su cualificación.

b) Tengan información referente a:

1º Los principios y procedimientos referentes al desarrollo de medicamentos y de la investigación clínica.

2º La legislación europea y nacional aplicable a ensayos clínicos.

3º Las directrices aplicables a la realización de ensayos clínicos y a la concesión de autorizaciones de comercialización.

4º Los procedimientos y sistemas de registro de datos clínicos, así como sobre la organización y regulación del sistema de asistencia sanitaria de su competencia y, cuando proceda, de terceros países.

3. Las administraciones sanitarias garantizarán que los inspectores tienen experiencia previa suficiente para llevar a cabo una inspección.

4. Las administraciones sanitarias competentes deberán designar los inspectores. A tal efecto mantendrán un registro actualizado que incluya la titulación, formación y experiencia del inspector en temas de inspección de buena práctica clínica.

Artículo 8. Normas comunes para la inspección de buena práctica clínica.

1. Para armonizar la realización de inspecciones por parte de las distintas administraciones sanitarias competentes, los inspectores deberán seguir para su actuación procedimientos normalizados de trabajo, que se aprobarán en el seno del órgano competente de coordinación técnica de inspecciones de la Agencia Española de Medicamentos y Productos Sanitarios creado a tal efecto, se actualizarán periódicamente de acuerdo con el avance científico y técnico y se harán públicos.

2. Las inspecciones se realizarán de conformidad con los documentos sobre inspecciones elaborados por la Agencia Europea de Medicamentos, para apoyar el reconocimiento mutuo de las conclusiones de las inspecciones dentro de la Unión Europea. Estos documentos serán utilizados a nivel nacional como orientadores de los procedimientos normalizados de trabajo de inspección, aprobados por el órgano competente de coordinación técnica de inspecciones de la Agencia Española de Medicamentos y Productos Sanitarios creado a tal efecto.

3. Se facilitará a cada inspector un documento con dichos procedimientos normalizados de trabajo, así como sus responsabilidades y funciones.

4. Los inspectores de buena práctica clínica deberán firmar un documento de confidencialidad antes de iniciar las actividades como inspector.

5. La actividad de inspección de buena práctica clínica tendrá carácter confidencial. Deberán cumplir los requisitos en cuanto a la protección de los datos personales, establecidos en la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

6. Los inspectores contarán con los medios adecuados de identificación facilitados por la administración sanitaria correspondiente.

7. El inspector firmará una declaración de intereses, para comunicar cualquier vínculo económico o de otro tipo con las partes que serán objeto de inspección. Esta declaración

se tendrá en cuenta a la hora de designar a los inspectores para una inspección determinada.

8. Sin perjuicio de las incompatibilidades establecidas para los inspectores en el ejercicio de sus actividades, asimismo serán incompatibles con cualquier tipo de intereses económicos directos derivados de la investigación clínica, así como de la fabricación, elaboración, distribución y comercialización de los medicamentos.

9. Se podrán nombrar equipos de inspectores y expertos con cualificaciones y experiencia adecuadas para cumplir de forma conjunta la cualificación necesaria para realizar la inspección.

Artículo 9. Inspecciones de buena práctica clínica.

1. Las inspecciones de buena práctica clínica podrán realizarse antes, durante o después de la realización de los ensayos clínicos y podrán iniciarse como parte de la verificación de las solicitudes de autorización de comercialización, como seguimiento de éstas o como consecuencia de una denuncia.

2. Se podrán hacer inspecciones, entre otras, al centro de investigación, al lugar de fabricación del medicamento en investigación, a cualquier laboratorio de análisis utilizado en el ensayo clínico, a las instalaciones del promotor y/o de las organizaciones o empresas de investigación implicadas por contrato en la realización del ensayo y al Comité Ético de Investigación Clínica.

3. Los objetivos principales de las inspecciones de buena práctica clínica serán:

a) Verificar que se han protegido los derechos, el bienestar y la seguridad de los sujetos que participan en los ensayos clínicos.

b) Garantizar la validez de los datos procedentes de ensayos clínicos que se presentan como base para la autorización de comercialización de los medicamentos o como seguimiento de ésta.

c) Garantizar la calidad de los ensayos clínicos que se realicen en centros sanitarios públicos y privados.

4. Realizada la inspección de buena práctica clínica, se elaborará un informe de inspección que deberá enviarse al inspeccionado y poner a disposición del promotor salvaguardando los aspectos confidenciales.

5. El informe de la inspección, previa solicitud motivada, se podrá poner a disposición de:

a) El Comité Ético de Investigación Clínica.

b) La Agencia Española de Medicamentos y Productos Sanitarios y las autoridades sanitarias de las Comunidades Autónomas.

c) Las autoridades sanitarias de la Unión Europea.

d) La Agencia Europea de Medicamentos.

6. En caso de que las desviaciones encontradas durante la inspección fueran calificadas de muy graves, de acuerdo con el artículo 101 de la Ley 29/2006, de 26 de julio de Garantías y Uso Racional de los Medicamentos y Productos Sanitarios, se enviará el informe al Comité Ético de Investigación Clínica, así como a la Agencia Española de Medicamentos y Productos Sanitarios o a la Comunidad Autónoma correspondiente según quien haya realizado la inspección.

Artículo 10. Competencias en materia de inspección de buena práctica clínica.

1. La Agencia Española de Medicamentos y Productos Sanitarios llevará a cabo actuaciones de inspección en los siguientes casos:

a) Para verificar los resultados de los ensayos clínicos presentados en las solicitudes de autorización de medicamentos mediante los procedimientos de reconocimiento mutuo, descentralizado y nacional.

b) Para verificar los resultados de los ensayos clínicos presentados en las solicitudes de autorización de un medicamento mediante el procedimiento centralizado y coordinadas por la Agencia Europea de Medicamentos, dentro del ámbito de aplicación del Reglamento (CE) núm. 726/2004 del Parlamento Europeo y del Consejo, de 31 de marzo de 2004, por el que se establecen procedimientos comunitarios para la autorización y el control de los medicamentos de uso humano y veterinario y por el que se crea la Agencia Europea de Medicamentos.

c) Cuando se trate de inspecciones a realizar en el territorio de las Comunidades Autónomas que no hubieran recibido los correspondientes traspasos de la competencia de ejecución de la legislación de productos farmacéuticos.

2. Podrán realizar inspecciones de buena práctica clínica, en todo el territorio español, los inspectores españoles acreditados, previa conformidad por la autoridad competente de la inspección del centro a inspeccionar. La Agencia Española de Medicamentos y Productos Sanitarios y las Comunidades Autónomas con competencia en materia de inspección de buena práctica clínica podrán solicitar la colaboración y/o participación de inspectores no adscritos a su ámbito de competencia cuando lo estimen necesario. Si alguna Comunidad Autónoma considera necesaria la realización de una inspección de buena práctica clínica fuera del ámbito territorial de su competencia, lo solicitará a la Agencia Española de Medicamentos y Productos Sanitarios, que dará traslado de la solicitud a la Comunidad Autónoma competente de la inspección. Corresponde a la administración sanitaria de esta última, autorizar la inspección y determinar si se lleva a cabo por inspectores propios o de la comunidad que la solicitó.

3. La relación con las autoridades competentes de los Estados miembros de la Unión Europea en materia de inspección de buena práctica clínica, se llevará a cabo a través de la Agencia Española de Medicamentos y Productos Sanitarios.

4. Las autoridades competentes de terceros países que vayan a realizar inspecciones de buena práctica clínica en España, deberán notificarlo a la Subdirección General de Inspección y Control de Medicamentos de la Agencia Española de Medicamentos y Productos Sanitarios con tiempo suficiente para que pueda acudir a la citada inspección, si fuera pertinente. La Agencia informará de la inspección a la Comunidad Autónoma donde se encuentre el centro a inspeccionar. El promotor será responsable de informar a la autoridad competente del tercer país de esta obligación de notificación.

5. La Agencia Española de Medicamentos y Productos Sanitarios elaborará los procedimientos pertinentes para las siguientes actividades:

a) Solicitar inspecciones o ayuda de otros Estados miembros de la Unión Europea y cooperar en las inspecciones realizadas en centros de otro país de la Unión Europea.

b) Realizar inspecciones en terceros países.

Modificado por art. único de Orden núm. SCO/362/2008, de 4 febrero 2008 .

Artículo 11. Recursos y bases de datos de las inspecciones de buena práctica clínica.

1. Las administraciones sanitarias competentes en materia de inspección de buena práctica clínica proporcionarán recursos personales y materiales suficientes para garantizar la comprobación efectiva del cumplimiento de las normas de buena práctica clínica.

2. La Agencia Española de Medicamentos y Productos Sanitarios creará una base de datos con las inspecciones nacionales y, en su caso, internacionales, incluyendo la situación de cumplimiento de buena práctica clínica, así como de su seguimiento. Para ello, las administraciones sanitarias competentes en materia de inspección remitirán a la Agencia los siguientes datos de todas las inspecciones de buena práctica clínica que se realicen en su territorio: código EudraCT del ensayo inspeccionado, datos del centro donde se realiza la inspección (nombre y dirección completa), tipo de centro inspeccionado, fecha de inspección y situación de cumplimiento de buena práctica clínica.

Disposición Adicional primera. Normas de buena práctica clínica y directrices de la Unión Europea.

La Agencia Española de Medicamentos y Productos Sanitarios publicará las normas de buena práctica clínica aplicables en los ensayos clínicos realizados en España.

También se tendrán en cuenta las directrices publicadas por la Comisión Europea.

Disposición Adicional segunda. Exención de la autorización de fabricación para medicamentos de terapia celular.

En el caso de medicamentos de terapias avanzadas procesados en entidades de naturaleza pública integradas en el Sistema Nacional de Salud, dichas entidades no precisarán autorización de fabricación hasta la publicación de una norma específica.

Disposición Final primera. Título competencial.

Esta Orden se dicta al amparo del artículo 149.1.16ª de la Constitución Española, que atribuye al Estado competencia exclusiva en materia de legislación sobre productos farmacéuticos.

Disposición Final segunda. Incorporación de derecho de la Unión Europea.

Mediante esta Orden se incorpora al derecho español la Directiva 2005/28/CE de la Comisión, de 8 abril de 2005, por la que se establecen los principios y las directrices detalladas de las buenas prácticas clínicas respecto a los medicamentos en investigación de uso humano, así como los requisitos para autorizar la fabricación o importación de dichos productos.

Disposición Final tercera. Entrada en vigor.

La presente Orden entrará en vigor el día siguiente al de su publicación en el «Boletín Oficial del Estado».

Afectado-por:

• art. 10

- Modificado por art. único de Orden núm. SCO/362/2008, de 4 febrero 2008

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

This is an unofficial English translation of the Royal Decree 1090/2015, revised by the Spanish Agency of Medicines and Medical Devices

Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for Investigation with medicinal products and the Spanish Clinical Studies Registry

Clinical research with medicinal products is the basic element that allows medicinal products to be authorised by medicinal product agencies, to be marketed by their marketing authorisation holders with the guarantees required by law, and finally to be used in clinical practice for the benefit of patients. It also allows new or more efficient forms of use to be investigated once the medicinal products have been marketed. In summary, clinical research enables high-quality knowledge to be generated and therapeutic tools to be developed that improve those already available and contributes to prevention, alleviation and cure of diseases and improvement of quality of life of the population.

Clinical research must therefore be conducted in an environment that guarantees the protection of individuals who participate in it in accordance with elements such as the Declaration of Helsinki, approved by the World Medical Association, and the Council of Europe Convention for the protection of human rights and human dignity with regard to the application of biology and medicine, signed in Oviedo. Likewise, it must guarantee the basic principles set out in Act 41/2002, of 14 November, regulating patient autonomy and rights and obligations in terms of clinical documentation and information, and Act 26/2011, of 1 August, on the adaptation to the International Convention on the Rights of People with Disabilities. Finally, it must also guarantee that the results derived from it are of quality and useful for the purposes previously expressed and should therefore be conducted in a context of maximum transparency.

At the same time, it is necessary to promote clinical research of orphan medicinal products and medicinal products aimed at the treatment of population groups such as children, women, and elderly people who traditionally have been poorly represented in clinical research.

The European Harmonisation regarding clinical trials takes due account of both the general regulations on medicinal products and, specifically, Directive 2001/20/EC of the European Parliament and of the Council, of 4 April 2001, on the approximation of the laws, regulations and administrative provisions of the Member States as regards the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. In Spain, Royal Decree 223/2004, of 6 February, regulating clinical trials with medicinal products incorporated this directive into the Spanish legal system in its entirety, establishing the principles and basic requirements that

have regulated until the present time the conduct of clinical trials with medicinal products and Ethics Committees as guarantors of their ethical and scientific quality. Subsequently, Act 29/2006, of 26 July, on guarantees and the rational use of medicinal products and medical devices, as well as currently the consolidated text approved by Royal Legislative Decree 1/2015, of 24 July, covering clinical trials with medicinal products in its Title III under the heading "On the guarantees of research in medicinal products for human use" and, additionally, Order SCO/256/2007, of 5 February, establishing detailed principles and guidelines of good clinical practice and the requirements for authorisation of the manufacture or importation of investigational medicinal products for human use incorporated in its entirety into national law Commission Directive 2005/28/EC, of 8 April, laying down the principles and guidelines of good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacture or importation of said products.

However, the regulation of clinical trials with medicinal products has been the object of some criticism in recent years and public analyses that have focused on the complexity of the procedure of trial authorisation, which imposed a disproportionate bureaucratic burden on authorisation that has hindered clinical research in the European Union. Although the European Commission published various documents to further improve and harmonise the application of legislation, Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, has finally been published, in which profound changes are proposed seeking to simplify procedures without compromising guarantees for participants in clinical trials.

The new Regulation sets out, on the one hand, common procedures for clinical trial authorisation throughout Europe, urging Member States to cooperate in assessment by means of a single common position, but on the other hand, leaves outside of this cooperation those aspects of an intrinsically national nature requiring assessment by each Member State. Moreover, to promote clinical research in the European Union, it sets very tight periods for assessing an application dossier, maintains the concept of tacit authorisation and sets no minimum timelines for authorisation.

The new European Regulation also introduces some changes in definitions that are of great relevance, particularly but not only, for research sponsored by academic investigators. Thus, it introduces the concept of "low-intervention clinical trial", in which it calls for less rigorous rules in aspects such as monitoring, the content of the master file, or traceability, without prejudice to the safety of the individuals participating in these trials.

In summary, and given that the European Commission has opted for the legal form of a Regulation, the aspects regulated in this are directly applicable for Member States and shall result in a lower variability in the application of the rules. However, the same regulation leaves to national development basic aspects such as the system by which each State reaches a single position in assessment, assessment of ethical issues and informed consent, or mechanisms of compensation,

among others. On the other hand, given that the date of application of the Regulation has been delayed to not before May 2016, maintaining the possibility that the Sponsor requests the authorisation of a clinical trial under Directive 2001/20/EC of the European Parliament and of the Council, of 4 April 2001, for at least three years after the date of publication of the Regulation, some aspects of the transposition of said Directive should be maintained on a temporary basis.

The changes made in Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, therefore require the introduction of significant amendments to national legislation to allow for compliance when the Regulation is applicable. However, after 10 years of implementation of Royal Decree 223/2004, of 6 February, some potential improvements had also been identified as needing to be made in the procedure for authorisation of clinical trials in Spain. In line with those included in the new Regulation, these cover aspects such as increased efficiency in processes of communication and assessment or identification of the responsibilities of all agents involved. This has made it advisable not to wait to the date of application of the Regulation to adopt those necessary amendments to national legislation so as to adapt rapidly to the new Regulation and maintain a competitive position of Spain in the European and international context of clinical research.

In this regard, there are two aspects of national development of legislation that deserve separate comment. On the one hand, it is necessary to include the Ethics Committees for Clinical Investigation in the development of Act 14/2007, of 3 July, on biomedical research. This Act determines in its third transitory provision that Ethics Committees for Clinical Investigation shall cease to exist when Ethics Committees for Investigation are constituted. In the development of Act 14/2007, of 3 July, it was also planned to create a National Authority for Ethics Committees for Investigation to be in charge of the general aspects of coordination and the registration of these Committees. However, given the specific characteristics of clinical research with medicinal products and the requirements imposed in the new Regulation, coordination of the single decision for clinical trials with medicinal products, as well as other aspects of supervision concerning those Ethics Committees for Investigation accredited for assessment of studies with medicinal products, shall correspond, according to this Royal Decree, to the Spanish Agency of Medicines and Medical Devices. Furthermore, the additional requirements to be met by the Ethics Committees for Investigation in order to be accredited as Ethics Committees for Investigation with medicinal products are established, taking into account the specificities applicable to clinical investigation with medicinal products and medical devices, and taking as a reference the accreditation criteria that are determined in the development of this Act.

Finally, this Royal Decree develops an aspect of the consolidated text of the Act on guarantees and rational use of medicines and medical devices approved by Royal Legislative Decree 1/2015, of 24 July which, in its article 62, lays the foundation for the publicly accessible and free of charge national registry of clinical trials with medicinal products for human use as a necessary measure for transparency. For this, the Royal Decree establishes that the Spanish Agency of Medicines and

Medical Devices must provide the general public with certain information about authorised clinical trials on its website. In this Royal Decree, the Spanish Clinical Studies Registry is developed from a broader perspective to also permit registration of non-interventional studies with medicinal products that are classified by the Spanish Agency of Medicines and Medical Devices. In addition, the creation of this registry takes into consideration the public utility proposed in the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices, for clinical trials with medicinal products, extending it, on a voluntary basis, to all prospective clinical studies outside the scope of medicinal products. Thus, the registry shall be mandatory and complete with regard to clinical trials with medicinal products, but is open to use as a voluntary registry for any other clinical study when its sponsors wish to use it for the purposes set forth in the World Health Organization International Clinical Trials Registry Platform.

For the World Health Organization, the registration, publication, and public access to the relevant contents of clinical trials is a scientific, ethical, and moral responsibility. The World Health Organization itself has established the minimal data set of a clinical trial that should be made public. This standard is the same as that adopted by the European Parliament and the Council to make publicly accessible the data contained in the EudraCT database which contains information on the clinical trials with medicinal products in which any site located in the European Economic Area and that has been authorised by the competent national authority participates. The content of the Spanish Clinical Studies Registry meets the standards set in the WHO International Clinical Trials Registry Platform. It has also been taken into account that the applicant for authorisation of a clinical trial with medicinal products or for classification of non-interventional studies already provides information on the clinical trial with medicinal products to the Spanish Agency of Medicines and Medical Devices in accordance with the Spanish and European regulation on this matter. Thus, information and communication technologies shall be used to streamline processing.

This Royal Decree aims, therefore, to adapt Spanish legislation so as to make feasible the current and future application of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, and to develop those aspects that the Regulation leaves to national legislation. This is intended to promote and facilitate clinical research with medicinal products in Spain, the generation of knowledge, transparency, the safety of participants and the usefulness of the results or, in summary, to consolidate the confidence of society in research and to foster its progress.

Pursuant to article 149.1.16 of the Constitution, this Royal Decree is enacted according to the sole authority held by the State regarding legislation on pharmaceutical products, while guaranteeing with regard to the processing of personal data, respect for Organic Act 15/1999, of 13 December, on Personal Data Protection, and its development regulations.

In accordance with Act 16/2003, of 28 May, on cohesion and quality of the National Health System, this Royal Decree has been subject to prior opinion by the Advisory Committee and the

Plenary Session of the Inter-Territorial Board of the National Health System. Furthermore, the Spanish Data Protection Agency has issued its mandatory opinion, pursuant to the provisions in Organic Act 15/1999, of 13 December, and the Statute of this Agency, enacted by Royal Decree 428/1993, of 26 March.

In the preparation process of this Royal Decree, the Autonomous Communities, the cities of Ceuta and Melilla, and the interested stakeholders have been consulted.

By virtue of the above, at the proposal of the Ministry of Health, Social Services and Equality, with prior approval of the Ministry of Finance and Public Administration, in accordance with the State Council and after deliberation by the Council of Ministers at its meeting of 4 December 2015,

I HEREBY DECREE:

CHAPTER I

General provisions

Article 1. *Purpose.*

1. This Royal Decree shall apply to clinical trials with medicinal products for human use conducted in Spain and has as its purpose:

a) To develop specific regulations for application in Spain of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, on clinical trials on medicinal products for human use, and by which Directive 2001/20/EC, regarding clinical trials with medicinal products for human use conducted in Spain is repealed.

b) To regulate Ethics Committees for Research with medicinal products, as well as the Spanish Clinical Studies Registry, formed by both clinical trials and non-interventional post-authorisation studies conducted with medicinal products for human use.

To this end, the administration of an investigational medicinal product to individual patients within the scope of standard medical practice and with the sole fundamental aim of achieving a therapeutic benefit for those patients shall not be considered a clinical trial with medicinal products. In this case, use of unauthorised medicinal products or under conditions of use different from those authorised shall be governed by the provisions laid down in Royal Decree 1015/2009, of 19 June, regulating the availability of medicinal products in special situations.

2. Clinical practice and the freedom of prescription of the physician or other healthcare professionals shall under no circumstances protect the conduct of unauthorised clinical trials or the use of secret remedies or others which have not been declared to the health authorities.

Article 2. *Definitions*:

1. For the purposes of this Royal Decree, the following definitions shall apply:

a) "Medicinal product for human use": Any substance or combination of substances presented as having properties for treating or preventing disease in human beings or which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

b) "Radiopharmaceutical": Any medicinal product which, when ready for use for therapeutic or diagnostic purposes, contains one or more radionuclides (radioactive isotopes).

c) "Adverse reaction": Any noxious and unexpected response to a medicinal product.

d) "Serious adverse reaction": Any adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. For reporting purposes, suspected adverse reactions that are judged to be medically important shall also be considered serious, even if they do not meet the preceding criteria, such as those that endanger the patient or require an intervention to prevent any of the aforementioned outcomes and all suspected transmissions of an infectious agent via a medicinal product.

e) "Immediate packaging": The container or any other form of packaging immediately in contact with the medicinal product.

f) "Outer packaging": The packaging into which the immediate packaging is placed.

g) "Medical device": Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by their manufacturer to be used specifically for diagnostic and/or therapeutic purposes and and necessary for its proper application,, intended by the manufacturer to be used for human beings for the purpose of:

1. Diagnosis, prevention, monitoring, treatment or alleviation of a disease.

2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.

3. Investigation, replacement or modification of the anatomy or of a physiological process.

4. Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

h) "Clinical study": Any research in relation to humans intended:

1. To discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products.

2. To identify any adverse reaction to one or more medicinal products.

3. To study the absorption, distribution, metabolism and excretion of one or more medicinal products, with the objective of ascertaining the safety and/or efficacy of said medicinal products.

i) "Clinical trial": A clinical study which fulfils any of the following conditions:

1. The assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned.

2. The decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study.

3. Diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

j) "Low-intervention clinical trial": A clinical trial which fulfils all of the following conditions:

1. The investigational medicinal products, excluding placebos, are authorised.

2. According to the protocol of the clinical trial:

1. The investigational medicinal products are used in accordance with the terms of the marketing authorisation; or

2. The use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned.

3. The additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned.

k) "Non-interventional study": A clinical study other than a clinical trial.

l) "Investigational medicinal product": A medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial.

m) "Normal clinical practice": The treatment regime typically followed to treat, prevent, or diagnose a disease or a disorder.

n) "Advanced therapy investigational medicinal product": An investigational medicinal product which is an advanced therapy medicinal product as defined in point (a) of article 2(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council, of 13 November 2007, on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

ñ) "Auxiliary medicinal product": A medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational medicinal product.

o) "Authorised investigational medicinal product": A medicinal product authorised in accordance with Regulation (EC) No 726/2004 or in any Member State concerned in accordance with Directive

2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an investigational medicinal product.

p) "Authorised auxiliary medicinal product": A medicinal product authorised in accordance with Regulation (EC) No 726/2004, or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an auxiliary medicinal product.

q) "Member State concerned": The Member State where an application for authorisation of a clinical trial or a substantial modification has been submitted under Chapters II or III of Regulation (EC) No 536/2014 of the European Parliament and of the Council of 16 April 2014.

r) "Substantial modification": Any change to any aspect of the clinical trial which is made after notification of the decision referred to in articles 8, 14, 19, 20 or 23 of Regulation (EC) No 536/2014 of the European Parliament and of the Council of 16 April 2014 and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial.

s) "Sponsor": An individual, company, institution or organisation which takes responsibility for the initiation, management and setting up the financing of the clinical trial.

t) "Investigator": An individual responsible for the conduct of a clinical trial at a clinical trial site.

u) "Principal Investigator": An investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site.

v) "Trial subject": An individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control;

w) "Informed consent": A subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject’s decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial.

x) "Protocol": A document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial. The term "protocol" encompasses successive versions of the protocol and protocol modifications.

y) "Investigator's brochure": A compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of said product or products in humans.

z) "Manufacturing": The total and partial manufacture, as well as the various processes of dividing up, packaging and labelling (including blinding).

aa) "Start of a clinical trial": The first act of recruitment of a potential subject for a specific clinical trial, unless defined differently in the protocol.

ab) "End of a clinical trial": The last visit of the last subject or at a later point in time as defined in the protocol.

ac) "Early termination of a clinical trial": The premature end of a clinical trial due to any reason before the conditions specified in the protocol are complied with.

ad) "Temporary halt of a clinical trial": An interruption not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it.

ae) "Suspension of a clinical trial": Interruption of the conduct of a clinical trial by a Member State.

af) "Good clinical practice": A set of detailed ethical and scientific quality requirements for designing, conducting, performing, monitoring, auditing, recording, analysing and reporting clinical trials ensuring that the rights, safety and well-being of subjects are protected, and that the data generated in the clinical trial are reliable and robust.

ag) "Inspection": The act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the clinical trial site, at the sponsor's and/or contract research organisation's facilities, or at any other establishments which the competent authority sees fit to inspect.

ah) "Adverse event": Any untoward medical occurrence in a trial subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment.

ai) "Serious adverse event": Any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistente or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death.

aj) "Unexpected serious adverse reaction": A serious adverse reaction, whose nature, severity or outcome is not consistent with the reference safety information.

ak) "Clinical study report": Report on the clinical trial presented in an easily searchable format, prepared in accordance with Annex I, Part I, Module 5 of Directive 2001/83/EC and accompanying an application for marketing authorisation.

2. The following definitions shall also be applied:

a) " Ethics Committee for Investigation (hereinafter CEI)": An independent body with a multidisciplinary composition whose main purpose is to oversee the protection of the rights, safety and well-being of subjects participating in a biomedical investigation project and offer public

assurance in this respect by giving an opinion on the corresponding documentation of the investigation project, taking into account the views of laypersons, in particular, patients or patient organisations.

b) "Ethics Committee for investigation with medicinal products (hereinafter CEIm)": Ethics Committee for Investigation which is also accredited in accordance with the terms of this Royal Decree to issue an opinion on a clinical study with medicinal products and on a clinical investigation with medical devices.

c) "Co-sponsors": Those sponsors who conduct together a clinical trial and are subject to the obligations of a sponsor under this Royal Decree, unless the sponsors establish otherwise in a written contract setting out their respective responsibilities.

d) "Clinical investigation with medical devices": Any systematic investigation in one or more human subjects undertaken to assess the safety or performance of a device.

e) "Non-commercial clinical research": Investigation conducted by investigators without the participation of the pharmaceutical or medical devices industry, which fulfil all the following characteristics:

1. The sponsor is a university, hospital, public scientific organisation, non-profit institution, patient organisation or individual investigator.

2. The ownership of the investigation data belongs to the sponsor from the inception of the study.

3. There are no agreements between the sponsor and third parties that allow them to use the data for regulatory or marketing purposes.

4. The design, conduct, recruitment, recording of data and reporting of the results of the investigation remains under the control of the sponsor.

5. Given their characteristics, these studies cannot be part of the development programme for a marketing authorisation of a medicinal product.

f) "Coordinating investigator": Investigator responsible for coordinating the investigators of the sites participating in a multicentre trial.

g) "Contracted clinical investigator": An investigator contracted by the site or related investigation entities to conduct one or more clinical trials, provided they have the required qualification to perform their assigned functions and are able to develop these in the clinical setting of the site.

h) "Minor": A trial subject who is, according to Act 41/2002 of 14 November regulating patient autonomy and rights and obligations in terms of clinical documentation and information, under the age of legal competence to give his/her informed consent.

i) "Monitor": A qualified professional with the necessary training and clinical and/or scientific competence, chosen by the sponsor, who is responsible for the direct follow-up of the conduct of the trial. The monitor is the link between the sponsor and the principal investigator when they are not the same person. In no case should the monitor be part of the investigator team.

j) "Contract research organisation (hereinafter CRO)": A natural or legal person contracted by the sponsor to perform the sponsor's functions or duties in connection with the clinical trial.

k) "Incapacitated subject": A trial subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving his/her informed consent according to national law.

l) "Spanish Clinical Studies Registry": A database owned by Spanish Agency of Medicines and Medical Devices, accessible on its website, publicly accessible and free of charge for any user, whose purpose is to serve as a source of information on clinical trials for the general public.

For the purposes of this Registry, any investigation that prospectively assigns participating subjects to one or more health-related interventions that are not medicinal products to study their effects on health indicators shall be considered as "another type of clinical study".

m) "Legal representative of the sponsor": A person accredited by the sponsor to represent him/her when the sponsor is not established in a Member State of the European Union.

n) "Legally designated representative": A natural or legal person, authority or body which, in accordance with the national law of the Member State concerned, is empowered to give informed consent on behalf of a subject who is an incapacitated subject or a minor.

ñ) "Substudy": A study that is part of the clinical trial but that may be related or not to the primary study objective, in which some of the subjects included in the clinical trial participate voluntarily and for which an additional informed consent is requested, for example, pharmacokinetic or pharmacogenetic substudies.

CHAPTER II
Protection of trial subjects and informed consent

Article 3. *General requirements*.

1. A clinical trial subject to this Regulation may only be conducted when the CEIm and the Spanish Agency of Medicines and Medical Devices have considered that all of the following conditions are met:

a) The clinical trial is ethically and methodologically sound and is designed to obtain reliable and robust data.

b) The anticipated benefits for the subjects or public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored. However, the rights, safety, human dignity, and well-being of the subjects prevail over any other interest.

c) Freely given informed consent is obtained and documented from each trial subject before the subject is included in the trial in accordance with the terms laid down in articles 4 to 8.

d) The rights of the subjects as regards their physical and mental integrity, privacy and the protection of the data concerning them are safeguarded in accordance with Organic Act 15/1999, of 13 December, on Personal Data Protection, and its development regulation, as well as European regulations in force on this matter.

e) The clinical trial has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the trial subjects and both the level of risk and the degree of discomfort are specifically defined in the protocol and constantly monitored.

f) The medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor, a qualified dental practitioner or any other healthcare professional, always in accordance with their competencies to provide this necessary care.

g) The trial subject or, where the subject is not able to give informed consent, his/her legally designated representative has been provided with the contact details of an entity where further information can be received in case of need. In the case of persons with a disability, this supplemental information shall be provided according to the rules established by the design for all principle, so that it is accessible and comprehensible to them.

h) No undue influence, including that of a financial nature, is exerted on trial subjects to participate in the clinical trial.

In this regard, subjects participating in trials with a potential direct benefit for the subject or their legal representatives may only receive reimbursement from the sponsor of extraordinary expenses and losses of productivity resulting from their participation in the trial. In special situations, the CEIm may report favourably on compensation of trial subjects for the discomfort resulting from their participation in said trial, provided that it is ensured that such compensation does not influence the decision of the subject to participate in the study.

Whatever compensation may have been agreed for voluntary participation in the trial, it shall always be received by the subject, although it shall be reduced in proportion to his/her participation in the investigation, in the event that the subject decides to revoke consent and withdraw from the trial.

i) The insurance or equivalent financial guarantee referred to in article 9.2 has been arranged, or the coverage specified in article 9.4 for "low-intervention clinical trials" is available.

2. Clinical trials should be conducted in accordance with the Declaration of Helsinki on ethical principles for medical research in human beings, approved by the General Assembly of the World Medical Association, and taking into account the Oviedo Convention for the protection of human rights and human dignity with regard to the application of Biology and Medicine, as well as any other regulations that may apply.

3. In the case of collection of biological samples being envisaged in the clinical trial, appropriate provisions shall be made so that on completion of the trial their use in research is in accordance with the provisions of Royal Decree 1716/2011, of 18 November, which establishes the basic requirements for authorisation and operation of biobanks for biomedical research purposes and the processing of human biological samples, and regulates the operation and organisation of the National Registry of Biobanks for biomedical research, particularly with regard to the relevant sections of informed consent and possible documents for transfer of biological materials.

Article 4. *Informed consent.*

1. The obtaining and contents of the informed consent shall conform to the provisions of article 29 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014, as well as to articles 8 and 9 of Act 41/2002 of 14 November.

2. When the person who is to give consent is an disabled person, the information shall be provided in appropriate formats in accordance with the rules established by the design for all principle, so that it is accessible and comprehensible for them, and the pertinent support measures shall be agreed so as to facilitate their ability to provide their own consent.

3. In the case of minors or incapacitated persons, where consent has been given by their legally designated representative, when their capacity to give their consent has been attained or recovered, their consent must be obtained to continue participating in the clinical trial.

4. The person participating in the trial, particularly in the case of patients with special vulnerability, shall be informed of the routes of access to the normal clinical practice for their pathology.

5. The person participating in a clinical trial, alone or with the assistance of his/her legally designated representative, or a family member or other person close to the participant, may revoke his/her consent at any time, without giving a reason and without it resulting in any detriment or responsibility for the person participating. Withdrawal of consent shall not affect activities performed based on the subject's consent before it was withdrawn, while also ensuring that neither the data or samples obtained based on said consent may be used in analyses or studies after the date of withdrawal unless the subject's consent is subsequently obtained to use them or, if the purpose is legitimate, the information can be obtained from publicly accessible sources.

6. When collection of biological samples is envisaged in the clinical trial, the potential participant must be informed about the provisions with regard to the future use of the samples. In accordance with Royal Decree 1716/2011 of 18 November, the samples may be destroyed after the study is completed, be incorporated into a collection or an authorised biobank. In the last two cases, the participant shall be informed of the biobank or the person responsible for collection, as well as the location where the samples shall be kept.

7. When a clinical trial is to be conducted exclusively in Spain, without prejudice to the provisions in the previous paragraphs and notwithstanding the provisions in article 3 and in articles 5

to 8 of this Royal Decree, the investigator may be allowed to obtain informed consent by the simplified means set out in paragraph 2 of article 30 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014, provided all conditions set out in paragraph 3 of the aforementioned article 30 are fulfilled.

Article 5. *Clinical trials on minors.*

1. A clinical trial on minors may be conducted only when, in addition to the conditions set out in articles 3 and 4 of this Royal Decree, all the conditions listed in article 32 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, are met.

2. The CEIm who is in charge of assessing Part II of the assessment report of a clinical trial on minors must have paediatric experts among its members or have obtained advice on the clinical, ethical and psychosocial issues in the field of paediatrics.

3. Prior informed consent of the parents who hold custody or of the legal representative of the minor must be obtained, and the minor, if under 12 years of age, must be heard if the minor has sufficient judgment. The informed consent form of the parents shall be valid provided it is signed by one of them with the express or tacit consent of the other, which should be adequately documented, as stipulated in article 156 of the Civil Code. When the subject's condition allows, or in any case when the minor is twelve years of age or older, the subject must also give his/her consent to participate in the trial.

Article 6. *Clinical trials on incapacitated subjects.*

1. A clinical trial may only be conducted on adults who are not in a state to give informed consent and have not given, or refused to give consent prior to being incapacitated, when, in addition to the conditions set out in articles 3 and 4 of this Royal Decree, all the conditions listed in article 31 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, are met.

2. The protocol must be approved by an CEIm that has experts in the disease in question or has obtained advice from experts on the clinical, ethical and psychosocial problems in the field of the relevant disease and the patient population concerned.

3. Prior informed consent must have been obtained from the legal representative of the person participating in a clinical trial or consent from a family member or other person close to the participant, as appropriate. In any case, the investigator shall make reasonably sure that there are no previous instructions of the person expressed in this regard before suffering a change in his/her capacity, which must be respected. This possibility and the procedure to be followed must be provided for in the trial documentation approved by the CEIm.

Article 7. *Clinical trials in emergency situations.*

1. Notwithstanding the provisions laid down in article 3.1.c) and articles 4 to 6 of this Royal Decree, when the clinical trial has a specific interest for the population where the investigation is conducted, and the reasons for the need to administer the investigational medicinal product are justified, a person may be included in a clinical trial without obtaining prior informed consent when all the conditions listed in article 35, paragraphs 1 and 2, of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, are met.

2. In this case, whenever circumstances permit, family members or other persons close to the subject shall be previously consulted.

3. This possibility and the procedure to be followed must be provided for in the trial documentation approved by the CEIm, and the person or his/her legally designated representative shall be informed as soon as possible and must give their consent to continue in the trial, where appropriate, or ratify it in any case.

4. If the trial subject or, if applicable, his/her legal designated representative cannot give their consent, they shall be informed of their right to object to the use of the data obtained from the clinical trial.

Article 8. *Clinical trials on pregnant or breastfeeding women.*

A clinical trial may only be conducted on pregnant or breastfeeding women if, in addition to the conditions set out in articles 3 to 6 of this Royal Decree, all the conditions listed in article 33 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, are met.

CHAPTER III
Damage compensation and liability scheme

Article 9. *Damage compensation.*

1. In clinical studies other than "low-intervention clinical trials", the sponsor shall ensure that the trial subject is compensated for any damage suffered as a result of the trial. This compensation shall be independent of the financial capacity of the sponsor, investigator, and site.

2. The trial sponsor is responsible for contracting insurance or a financial guarantee covering the damage indicated in paragraph 1, as well as any liability that might be incurred by the sponsor, principal investigator and members of the investigator team, including contracted clinical investigators, and the hospital or site where the clinical trial is conducted, which must be documented prior to the trial, unless it is a "low-intervention clinical trial".

3. In the case of clinical trials included in the definition of "non-commercial clinical research", an application may be submitted without having contracted the insurance or financial guarantee referred to in paragraph 2. However, in the event of a favourable opinion from the CEIm, the decision on

authorisation of the trial shall be subject to the submission of this documentation to the CEIm within thirty calendar days and the study may not be started until the required insurance or financial guarantee is considered available.

4. Damage to the study subject that could result from a low-intervention clinical trial shall not need to be covered by the insurance or financial guarantee referred to in paragraph 2 if it is covered by the insurance of individual or collective professional civil liability insurance or equivalent financial guarantee of the site where the clinical trial is conducted.

5. When the sponsor and principal investigator are the same person and the clinical trial is conducted in a health centre belonging to the public health administration, the administration may take the measures it deems appropriate to facilitate the guarantee of the specific risks resulting from the trial in the terms set out in the above paragraphs, with the aim of promoting research.

6. The actions of "contracted clinical investigators" related to the medical care to the subject which is provided during the conduct of the trial for reasons not related to or arising from the trial must be covered by insurance similar or equivalent to that protecting the rest of the site personnel for those aspects not covered by the clinical trial insurance.

Article 10. *Liability scheme.*

1. It shall be presumed, unless proven otherwise, that any harm to the health of a trial subject during the course of the trial and within one year from the end of treatment has occurred as a result of the trial. However, once the year has concluded, the trial subject is obliged to prove the connection between the trial and the harm caused.

2. For the purposes of the liability scheme set out in this article, all expenses derived from impairment in the health or physical status of the subject undergoing the clinical trial shall be considered liable for compensation, as well as any economic losses directly derived from such impairment, provided this is not inherent to the disease under study or due to the natural course of the disease as a result of the ineffectiveness of treatment.

3. The minimum amount that shall be guaranteed as civil liability shall be 250,000 Euros per subject undergoing the clinical trial, which may be received as a flat rate payment or as an income equivalent to the same capital. A maximum insured capital or maximum amount of the financial guarantee per clinical trial and per year of 2,500,000 Euros may be established.

CHAPTER IV

Ethics Committees for investigation with medicinal products

Article 11. *Supervision and coordination of the Ethics Committees for investigation with medicinal products.*

1. The CEIm shall be supervised in ethical, training and material aspects in the same way as other Ethics Committees for Investigation (CEI), in accordance with the regulations of the latter.

2. The Spanish Agency of Medicines and Medical Devices shall facilitate the assessment procedure and issuing of an opinion by the CEIm in clinical trials with medicinal products in order to integrate the assessment of one and the other into a single opinion per clinical trial, valid throughout the Spanish State. For the integrated assessment to be positive, the assessment by the Spanish Agency of Medicines and Medical Devices and the opinion of the CEIm must both be positive.

3. For coordination of the opinion in clinical trials with medicinal products, the Spanish Agency of Medicines and Medical Devices shall carry out the following activities:

a) Facilitate the exchange of information between the Spanish Agency of Medicines and Medical Devices and the CEIm.

b) Coordinate with the Autonomous Communities, the supervisory bodies of the CEI and the CEIm, the development and maintenance of a single integrated information system for clinical trials with medicinal products.

c) Manage the database of clinical trials with medicinal products of the national network of CEIm.

d) Provide advice to the CEIm on issues related to the procedure of clinical trials with medicinal products.

e) Any other action related to the activities of the CEIm that fall under its responsibility in accordance with applicable regulations.

Article 12. *Functions of Ethics Committees for investigation with medicinal products.*

1. The CEIm, in addition to the functions that could be commissioned as a CEI, shall perform the following functions with regard to the assessment of clinical trials with medicinal products or medical devices:

a) Assess the methodological, ethical and legal aspects and issue the respective opinion.

b) Assess substantial modifications to authorised clinical trials and issue the respective opinion.

c) Conduct a follow-up of the study from its initiation to receipt of the final report.

2. To perform these functions in clinical trials with medicinal products, the provisions set out in Chapter V should be taken into account.

Article 13. *Accreditation of Ethics Committees for investigation with medicinal products.*

1. In addition to the requirements established for the accreditation of the CEI in Act 14/2007, of 3 July, on Biomedical Research and its development regulations, CEIm must meet the specific requirements for accreditation set out in this Royal Decree.

2. CEIm shall be accredited by the competent health authority in each Autonomous Community or, in the case of sites belonging to the General State Administration, by the competent State body. The Spanish Agency of Medicines and Medical Devices, in coordination with the Autonomous Communities, through the Technical Inspection Committee, shall set common specific criteria for the accreditation, inspection, and renewal of accreditation of these committees.

3. This accreditation must be renewed periodically by the competent health authority, without prejudice to the procedure provided for maintenance of accreditation as a CEI, according to the procedures and timelines established by the Technical Inspection Committee. Both the initial accreditation and its renewals must be notified to the Spanish Agency of Medicines and Medical Devices, which shall publish them on its website, as well as to whom is determined in the applicable regulations of the CEI.

Article 14. *Technical secretariat.*

1. Each accredited CEIm must have a stable professional technical secretary integrated in the organisational chart of the institution to which this person is assigned or from its supporting institutions.

2. The technical secretariat shall have the following functions:

a) To manage the activity of the CEIm.

b) To act as the interlocutor on behalf of the CEIm as regards communication with all agents concerned, including the Spanish Agency of Medicines and Medical Devices.

c) To ensure that the necessary on-site and non-on-site meetings are held so that the CEIm complies with its duties in the established time periods.

d) To prepare, in collaboration with the members of the CEIm, any reports that are requested by the Spanish Agency of Medicines and Medical Devices or any other competent authority to maintain its accreditation as an CEIm.

3. The technical secretariat must have the following resources and facilities:

a) A person in charge holding a higher degree and with knowledge of medicine, investigation methodology, bioethics, pharmacology, and medicinal product regulation and biomedical investigation in general.

b) Specific facilities for the performance of their work under conditions that ensure confidentiality. They should have an appropriate space for holding meetings and for the handling and filing of confidential documents.

c) Computer equipment with sufficient capacity to handle all the information received and generated by the committee and connection to the information system of the country-specific database of clinical trials with medicinal products and "EU portal" and "EU database", when they are available.

d) A specific annual financial budget, approved by the management of the institution, to be used for training activities organised for members of the CEIm and, where appropriate, a budget allocated to allowances for attendance of its members or possible experts or guests.

Article 15. *Composition of Ethics Committees for investigation with medicinal products.*

1. The CEIm shall include a minimum of ten members, at least one of which shall be a layperson outside the field of biomedical investigation or clinical care, who shall represent the interests of patients.

The members of this committee shall include physicians, one of whom shall be a clinical pharmacologist, a hospital or primary care pharmacist and a certified or graduate nurse.

If there is a Committee for Investigation or an Ethics Committee for clinical practice in the site, a member of each should be included in the CEIm.

At least two members must be professionals outside the field of healthcare, one of whom should have a law degree.

In addition, at least one of its members must have accredited training in bioethics.

2. The composition of the CEIm should ensure the independence of its decisions and the competence and experience of its members in the methodological, ethical and legal aspects of research, pharmacology, and clinical care practice in both hospital and community medicine.

3. The CEIm shall have a Chair, a Vice-Chair, and a technical secretary who shall simultaneously have the consideration of committee members.

The Chair shall be the representative of the committee and its holder shall be chosen by the members in such a way that independence is ensured.

The Vice-Chair shall be selected similarly and shall perform the functions of the Chair in cases of vacancy, absence or illness of its holder.

The head of the technical secretariat shall correspond to the person mentioned in article 14.3.a).

All committee members shall have one vote of equal value except for the holder of the technical secretariat who shall have voice but no vote.

4. The CEIm shall ensure a system for renewal of members that allows new members to be incorporated on a regular basis while also maintaining the experience of the committee.

5. Membership of an CEIm shall be incompatible with any other class of interests derived from

the manufacture or sale of medicines and medical devices. Members of the CEIm must ensure the confidentiality of the information to which they have access and must make a public conflict of interest statement.

6. The competent authorities with regard to the CEIm shall establish criteria by which the activities of its members may have a positive impact on their professional career.

Article 16. *General rules on the functioning of Ethics Committees for investigation with medicinal products.*

1. Neither the CEIm as a whole nor any of its members may receive directly nor indirectly any remuneration from the study sponsor.

2. The collection of fees for performance of any of the functions of the CEIm referred to in article 12 shall be governed by article 33.

An agreement between the site and the sponsor for payment of administrative expenses shall be possible, but it must always be regulated as an additional economical condition to those specified in the contract referred to in article 32.1, or be published by the competent national or autonomic health authority in their respective official journals and, in any event, may never be established as an item contingent on compliance with any of the functions of the CEIm referred to in article 12.

3. The CEIm must prepare and follow standard operating procedures for its functioning, which should refer to at least the following:

a) The composition and requirements that must be fulfilled by its members.

b) The frequency of on-site and non-on-site meetings which must at least ensure compliance with the assessment timelines of this Royal Decree. The CEIm shall make public the schedule of its meetings with information about its availability for assessment of new clinical studies at each meeting.

c) The procedure for convening its members.

d) The aspects relating to administrative functioning.

e) The cases in which an expedited review of the documentation of a clinical study may be performed and the procedure to be followed in these cases, including "low-intervention clinical trials".

f) The initial assessment of protocols and the procedure for follow-up of studies.

g) The mechanisms for ordinary and extraordinary decision-making which should include a written procedure for decision-making.

h) The preparation and approval of the minutes of the meetings.

i) The archiving and storage of committee documentation and that related to assessed clinical trials in accordance with paragraph 7.

j) A procedure to declare an incompatibility occurring in a member of the CEIm and the guarantees to ensure confidentiality in its internal functioning.

4. When the CEIm does not possess the knowledge and experience necessary to evaluate a specific clinical study, it shall seek the advice of at least one expert not belonging to the committee, who shall be obliged to maintain confidentiality. This advice shall be considered specifically when:

a) The committee assesses clinical research protocols with surgical procedures, diagnostic techniques, medical devices or advanced therapies. In this case, it shall be advised by at least one expert in the procedure or technology to be assessed.

b) The committee assesses clinical trials on subjects with special vulnerability. In this case, it shall be advised by at least one person with experience in the treatment of the study population and, if applicable, in the treatment of the disease.

5. The principal investigator or members of the investigator team of a clinical study cannot be take part in the assessment or give an opinion on their own protocol, even when they are members of the committee. When such circumstances occur, it shall be noted in the minutes referring to the assessment of the trial by the committee that this principle was respected.

6. Non-on-site meetings may be held by telephone multiconference, videoconference or any other analogous system, so that members of the CEIm can attend this meeting by the indicated system, provided communication between them is ensured in real time and, therefore, the unity of the act.

Each meeting of the CEIm shall be recorded in the corresponding minutes, which as a minimum shall specify the members in attendance, both on-site and non-on-site, and the consultants attending, if applicable, and it shall be indicated that for each assessed study the aspects included in the applicable regulation have been considered and the decision adopted for each study shall be recorded.

7. The committees shall keep all essential documents related to each clinical study assessed for at least three years after completion of the study or for a longer period if this is established by the Spanish Agency of Medicines and Medical Devices in collaboration with the Autonomous Communities. The contents of the clinical trial file shall be indicated in the instructions for the conduct of clinical trials in Spain that are published by the Spanish Agency of Medicines and Medical Devices.

CHAPTER V

Submission, validation, and procedure for assessment and authorisation of clinical trials with medicinal products

Section 1. Common provisions

Article 17. *Requirements for the conduct of clinical trials.*

1. Clinical trials with medicinal products shall be subject to prior authorisation from the Spanish Agency of Medicines and Medical Devices, after a scientific and ethical assessment of Parts I and II.

2. In order to start a clinical trial with medicinal products in a site, the following shall be required:

a) The favourable opinion issued by an CEIm in Spain as indicated in article 24, which shall be single and binding.

b) The decision for authorisation by the Spanish Agency of Medicines and Medical Devices.

c) The agreement of the participating site management which shall be expressed by the signing of the contract between the sponsor and the site referred to in article 32. Only in clinical trials in which the sponsor/investigator belongs to the site and signing of the contract is not required shall the express agreement of the participating site management be required.

This contract may be concluded at any time and shall be effective when the clinical trial is authorised by the Spanish Agency of Medicines and Medical Devices and the favourable opinion of the CEIm for conducting the trial at said site is available.

3. No clinical trials with gene therapy medicinal products which result in modifications to the subject's germ line genetic identity may be conducted.

Article 18. *Collaboration and information exchange between the Spanish Agency of Medicines and Medical Devices and the CEIm.*

1. The Spanish Agency of Medicines and Medical Devices shall establish the mechanisms and procedures for cooperation and exchange of information on clinical studies with medicinal products and clinical investigations with medical devices with the CEIm, which shall be made public.

2. This shall be set out in a "collaboration memo" containing and specifying the responsibilities of the CEIm and of the Spanish Agency of Medicines and Medical Devices, as well as those aspects which, in accordance with article 22 and successive articles, shall be subject to assessment and responsibility by each of them, so as to ensure the greatest efficiency and guarantees in the assessment and permit, in the multinational clinical trials conducted in the European Union, a single decision for Spain.

3. The "collaboration memo" shall establish which parts of the application dossier shall be submitted in Spanish and which may be accepted in a language commonly understood in the medical field as indicated in Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

Article 19. *Exchange of information between the Spanish Agency of Medicines and Medical Devices and the Autonomous Communities.*

1. The Spanish Agency of Medicines and Medical Devices shall establish with the competent bodies of the Autonomous Communities the framework of cooperation and a procedure for exchange of information on clinical studies with medicinal products and clinical investigations with medical devices.

2. The instructions for the conduct of clinical trials in Spain published by the Spanish Agency of Medicines and Medical Devices shall contain the contact points of the Autonomous Communities to which the information must be sent while this process is still not available.

Article 20. *Aspects of a clinical trial requiring assessment.*

1. The CEIm and the Spanish Agency of Medicines and Medical Devices shall assess the clinical trial documentation.

2. The assessment shall be differentiated into two parts, called Part I and Part II of the assessment report:

a) Part I shall include the aspects listed in article 6 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of April 16 2014.

b) Part II shall include the aspects listed in article 7 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014. The assessment referred to in point h) of paragraph 1 of article 7 must include the arrangements as regards the collection, storage and possible future use of the biological samples of trial subjects obtained at the same site or collaborating sites, including pre-screening samples of the subjects, ensuring that no procedure is performed that would prevent future application of article 3.2 of Royal Decree 1716/2011, of 18 November.

3. The Spanish Agency of Medicines and Medical Devices and CEIm shall agree in the "collaboration memo" on the distribution of responsibilities for the assessment of applications.

4. In accordance with article 29.5 of Royal Decree Act 9/2014, of 4 July, establishing the standards of quality and safety for the donation, procurement, testing, processing, safeguarding, storage and distribution of human tissues and cells and approving the standards of coordination and operation for use in humans, in cell therapy clinical trials, in addition to the provisions in paragraph 2, the Spanish Agency of Medicines and Medical Devices shall request a report from the National Transplant Organisation. This report must be issued in the form and timelines required for fulfilling the requirements set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

Section 2. Procedure for authorisation of a clinical trial

Article 21. *Submission of applications and receipt of notifications.*

1. The sponsors shall submit their applications and communications and shall receive notifications through the portal mentioned in article 80 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014 ("EU portal"), addressed to the Spanish Agency of Medicines and Medical Devices and the CEIm that has accepted the assessment.

2. The documentation that must accompany the application for authorisation and an opinion on the clinical trial is set out in Annex I of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, in current European guidelines and, if applicable, in the instructions for the conduct of clinical trials in Spain which, developing the aforementioned Annex I, are published by the Spanish Agency of Medicines and Medical Devices.

Article 22. *Validation of the application.*

1. The Spanish Agency of Medicines and Medical Devices shall assess whether or not to accept the status of "clinical trial" for the study and shall verify that the application is complete with regard to the documents of Part I, so as to perform the assessment referred to in article 6 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. The CEIm shall verify that the application is complete regarding the documents of Part II so as to perform the assessment referred to in article 7 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

3. The validation shall be performed in accordance with the timelines and the procedure set out in article 5 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

Article 23. *Part I of the assessment report.*

1. The Spanish Agency of Medicines and Medical Devices shall be responsible for notifying the sponsor of Part I of the assessment report, including those aspects that have been assessed by the CEIm, in such a way that the sponsor is notified in the timelines and according to the procedure indicated in article 6 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. The participation of the CEIm in the assessment of Part I shall be established in the collaboration memo referred to in article 18, as well as the timelines for transmitting its report to the Spanish Agency of Medicines and Medical Devices, so that the indications in the preceding paragraph can be adhered to.

3. In the case of an assessment coordinated by a reporting Member State, the terms specified in paragraph 2 of article 8 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, shall be borne in mind.

Article 24. *Part II of the assessment report.*

The CEIm shall be responsible for preparing Part II of the assessment report so that it is in compliance with the timelines and the procedure specified in article 7 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

Article 25. *Decision on authorisation.*

1. The Director of the Spanish Agency of Medicines and Medical Devices, within five days as prescribed in article 8 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, shall issue the decision authorising the clinical trial, authorising the clinical trial subject to conditions, or refusing the authorisation.

2. This decision ends the administrative proceedings, so the interested party may file an appeal for reversal or reconsideration in accordance with the provisions set forth in articles 116 and 117 of Act 30/1992, of 26 November, on the Legal Regime of Public Administration and Common Administrative Procedure or a contentious-administrative appeal in accordance with Act 29/1998, of 13 July, on Contentious-Administrative Jurisdiction.

3. The authorisation of the clinical trial shall be understood to be granted without prejudice to the application, where appropriate, of Act 9/2003, of 25 April, on the legal regime of confined utilisation, voluntary release and commercialisation of genetically modified organisms.

Article 26. *Modification of the conditions of authorisation of clinical trials.*

1. Any "substantial modification" in the authorised conditions for a clinical trial may not be made without the prior favourable opinion of the CEIm and authorisation from the Spanish Agency of Medicines and Medical Devices.

However, should there be any circumstances that might affect the safety of the participating subjects, the sponsor and the investigator shall take the appropriate urgent safety measures to protect the subjects against any immediate risk. The sponsor shall inform both the Spanish Agency of Medicines and Medical Devices and the CEIm of these circumstances and the measures taken as soon as possible.

2. As a rule, the CEIm and the Spanish Agency of Medicines Products and Medical Devices shall assess those aspects on which they had already reached a decision in the initial assessment report referred to in articles 23 and 24, without prejudice to when the "collaboration memo" referred to in article 18 establishes a different distribution of the tasks.

3. The application must be submitted to the Spanish Agency of Medicines and Medical Devices and to the CEIm that assessed the initial application as indicated in Chapter III and article 25 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, in current European guidelines and, where appropriate, in the corresponding part of the instructions for the conduct of clinical trials in Spain published by the Spanish Agency of Medicines and Medical Devices.

4. The validation and assessment of Part II of the substantial modification by the CEIm, where applicable, shall be in accordance with the deadlines and assessment procedure set out in articles 20, 21 and 22 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

5. The validation and assessment of Part I of the substantial modification by the Spanish Agency of Medicines and Medical Devices shall be in accordance with the terms specified in articles 17, 18, 21 and 22 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

6. The authorisation decision shall be issued taking into account the provisions contained in articles 19, 20, and 23 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, and as indicated in article 25 of this Royal Decree. However, in the event of substantial modifications that only involve changes in aspects included in Part II of the assessment report, the authorisation shall be considered granted or refused on the date when the CEIm informs the sponsor of its decision with the conclusions of Part II of the assessment report.

Article 27. *Suspension or revocation of the authorisation of a clinical trial.*

1. The authorisation of the clinical trial shall be suspended or revoked, ex officio or on the justified request by the sponsor, by decision of the Spanish Agency of Medicines and Medical Devices in the cases listed in article 77 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. The decision to suspend or revoke authorisation of the trial shall be adopted by the Spanish Agency of Medicines and Medical Devices after initiating the appropriate procedure, including granting a hearing to the interested party who must reply within seven calendar days from notification of the start of the procedure.

Once this decision is adopted, the Spanish Agency of medicines and Medical Devices shall notify the decision reached, expressly indicating the reasons, to the CEIm, the European Commission, the European Medicines Agency, the health authorities of the Autonomous Communities and the health authorities of other Member States.

3. The health authorities of the Autonomous Communities may order a precautionary suspension of the clinical trial in the cases laid down in paragraph 1 and shall notify it immediately, accompanied by a duly detailed and justified report, to the Spanish Agency of Medicines and Medical Devices, which, in accordance with that established in paragraph 2, shall decide on suspension or revocation of the clinical trial authorisation or, where appropriate, lift the precautionary measure.

4. This decision ends the administrative proceedings, so the interested party may file an appeal for reversal or reconsideration in accordance with the provisions set forth in articles 116 and 117 of Act 30/1992, of 26 November, or a contentious-administrative appeal in compliance with Act 29/1998, of 13 July.

Article 28. *Corrective measures to be adopted by the Spanish Agency of Medicines and Medical Devices.*

1. The Spanish Agency of Medicines and Medical Devices, ex officio or on justified request by the CEIm may require the sponsor to modify any aspect of the clinical trial.

2. The decision to require modification of any aspect of the trial shall be adopted after initiating the appropriate procedure, including granting of a hearing to the interested party, who must reply within seven calendar days from notification of the start of the procedure.

3. This decision ends the administrative proceedings, so the interested party may file an appeal for reversal or reconsideration in accordance with the provision set forth in articles 116 and 117 of Act 30/1992, of 26 November, or a contentious-administrative appeal in accordance with Act 29/1998, of 13 July.

Article 29. *Reporting of serious breaches.*

1. Serious breaches of the authorised protocol or of this Royal Decree occurring in Spain must be reported by the sponsor without undue delay and no later than seven calendar days from becoming aware of the breach to the Spanish Agency of Medicines and Medical Devices and the CEIm by the means indicated in article 21.

2. To this end, a serious breach shall be defined as a breach that may significantly affect the safety and rights of the trial subjects or the reliability and robustness of the data generated in the clinical trial.

3. The Spanish Agency of Medicines and Medical Devices shall inform the health authorities of the Autonomous Communities on those serious breaches directly affecting sites belonging to their community.

Article 30. *End of a clinical trial, temporary halt and early termination of a clinical trial and submission of the results.*

1. The sponsor shall notify the date of the end of the clinical trial in Spain, the date of the end of the clinical trial in all countries where the trial has been conducted, as well as any temporary halt of the trial and the results thereof in accordance with the timelines and the procedure indicated in articles 37 and 38 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. In the event of early termination of the clinical trial, the notification shall indicate the reasons for such action and shall specify the follow-up measures, without prejudice to the subsequent sending of the summary of the results required in Annexes IV and V of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014. This information shall be transmitted to the health authorities of the Autonomous Communities as specified in article 19. The

date of the end of the clinical trial and the reasons for early termination must be published by the Spanish Agency of Medicines and Medical Devices.

CHAPTER VI
Continuation of treatment after the trial

Article 31. *Continuation of treatment with a medicinal product without marketing authorisation in Spain after the end of the trial.*

Any continuation in the administration of an investigational medicinal product without marketing authorisation in Spain to subjects who have completed their participation in a clinical trial, for as long as the medicinal product is not actually marketed in Spain for those conditions of use, shall be governed by the rules established in Royal Decree 1015/2009, of 19 June, regulating the availability of medicinal products in special situations. Supply of these medicinal products should adhere to the provisions contained in paragraph f) of article 39.3, if the sponsor obtains any information from the administration and use of said medicinal product under these conditions.

CHAPTER VII
Financial aspects

Article 32. *Financial aspects of a clinical trial.*

1. All financial aspects related to a clinical trial must be reflected in a contract between the sponsor and each of the sites where the trial is to be conducted.

A financial budget for the project including all the aspects specified in the contract of all participating sites must be sent to the CEIm.

2. The competent health administrations for each health department shall establish common requirements and conditions for financing and shall agree on a single contract form which shall be valid for the whole National Health System. This single contract form shall be prepared in accordance with the general principles of coordination agreed by the Inter-Territorial Board of the National Health System and must have its approval before it is used.

3. The contract shall state:

a) The initial budget for the clinical trial, specifying the indirect costs that shall be applied by the site as well as the extraordinary direct costs, considering as such any extra expenses to those which would have been incurred if the subject had not participated in the clinical trial, such as:

1. Additional laboratory tests and examinations.

2. Changes in the duration of the care afforded to patients.

3. Reimbursement of expenses to patients.

4. Purchase of devices and compensation for trial subjects and investigators.

b) The payment terms and periods.

c) Any other subsidiary liability assumed by the parties in accordance with the conditions established in each site.

4. No additional amounts to those foreseen in the financial budget submitted to the CEIm may be required by the sites, except for those which may be approved in accordance with article 31 and that referred to in article 16.

Article 33. *Fees.*

1. Pursuant to article 87 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, payment of a single fee shall be required for the assessment of a clinical trial, regardless of whether various organisations are involved in the assessment. This fee shall be set in the current legislation in a transparent manner and on the basis of cost recovery principles. The sponsor must pay this fee to the Spanish Agency of Medicines and Medical Devices which shall be responsible for transferring to the CEIm the part corresponding to their assessment.

2. In no case may the payment of fees not covered in the corresponding legal framework be required by the sites with regard to the conduct of the trial or in connection with the performance of any of the functions of an CEIm related to the assessments referred to in article 12.

3. Clinical studies corresponding to the definition of "non-commercial clinical research" shall benefit from the exemptions of fees or reduced fees, in accordance with the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015, of 24 July.

CHAPTER VIII
Medicinal products used in a clinical trial

Article 34. *Manufacture and importation of investigational medicinal products or auxiliary medicinal products.*

1. The manufacture and importation of investigational medicinal products for their use in the context of a clinical trial can only be performed by manufacturers and importers of medicinal products that have the appropriate authorisation in accordance with the provisions of Royal Decree 824/2010, of 25 June, regulating pharmaceutical laboratories, manufacturers of active substances for pharmaceutical use and foreign trade in medicinal products and investigational medicinal products.

2. The aforementioned authorisation shall not be required for relabelling or repackaging, if it is performed at an authorised pharmacy department of a participating site, provided the investigational medicinal products are intended to be used only in hospitals, health centres, or clinics participating in the same clinical trial.

3. When in the context of a specific clinical trial whose sponsor is an investigator or a group of investigators, an authorised pharmacy of a participating site wishes to perform a manufacturing operation different from those previously considered, it must request prior authorisation from the Spanish Agency of Medicines and Medical Devices and the medicinal product may only be used in the specific clinical trial. The Spanish Agency of Medicines and Medical Devices shall agree with the Autonomous Communities on the verification procedures of good manufacturing practice of medicinal products applicable in these cases.

4. In addition, the authorisation as a manufacturer and importer of medicinal products indicated in paragraph 1 shall not be required for sites linked to the National Health System where investigational advanced therapy medicinal products are prepared for use in clinical trials approved by the Spanish Agency of Medicines and Medical Devices, without prejudice to the requirement for specific quality standards.

5. The manufacture of investigational medicinal products must comply with the applicable guidelines of good manufacturing practice in the European Union.

6. The manufacturer must have permanently and continuously at their disposal a qualified person or technical director, in accordance with the provisions of Royal Decree 824/2010, of 25 June. The responsibilities of the qualified person or technical director are established in the aforementioned Royal Decree.

In the case of an investigational medicinal product from a third country and that has a marketing authorisation in that country, when documentation cannot be obtained to certify that each manufacturing batch was manufactured according to correct manufacturing practices at least equivalent to those indicated above, the qualified person or technical director must ensure that each manufacturing batch has been subject to all the pertinent analyses, tests or checks required to verify its quality.

7. The authorisation for the importation of investigational medicinal products for use in the context of a clinical trial shall be considered as granted if within sixty calendar days from receipt of the application, the Spanish Agency of Medicines and Medical Devices has not notified any reasoned objections to the sponsor, provided that the trial is authorised.

8. The application for importation of investigational medicinal products may be requested in a single act with the application for conduct of the clinical trial for which they are intended.

The authorisation for manufacture or importation of blood derivatives, narcotics or psychotropic agents shall be governed by the specific regulations in this area.

Article 35. *Labelling.*

1. Labelling of the investigational or auxiliary medicinal products shall be as indicated in articles 66 to 68 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April

2014, taking into account the requirements set out in the detailed guidelines for good manufacturing practice applicable to investigational medicinal products in the European Union and, where applicable, the instructions of the Spanish Agency of Medicines and Medical Devices.

2. Except for justified exceptions, labelling should appear in at least the official language of the State.

Article 36. *Purchase of medicinal products for clinical trials.*

1. Wholesalers and pharmaceutical manufacturers may supply to the sponsor of an authorised clinical trial the medicinal products included in this trial, against prior presentation by the same of the authorisation issued by the Spanish Agency of Medicines and Medical Devices for the trial.

2. When the medicinal products to be used in a clinical trial come from a third country, the provisions in article 34 as regards importation of investigational medicinal products shall be borne in mind.

Article 37. *Remaining medication of a clinical trial.*

1. In the case of investigational medicinal products and auxiliary medicinal products marketed in Spain, once the clinical trial has ended, the remaining packs that are unchanged, that is, which have not been modified either in their inmediate or outer packaging, may be used in normal clinical practice, in the conditions stipulated in its marketing authorisation and always under express and previous authorisation by the sponsor.

2. In the case of investigational medicinal products not marketed in Spain, after finalisation of the clinical trial the sponsor may request the use of unaltered remaining packs for continuation of treatment outside the study in accordance with the terms specified in article 31.

CHAPTER IX
Good clinical practice guidelines

Article 38. *Good clinical practice guidelines.*

1. The sponsor of a clinical trial and the investigator shall ensure that the clinical trial complies with the protocol and with the principles of good clinical practice.

2. Without prejudice to other provisions, the sponsor and the investigator, when preparing the protocol and applying this Royal Decree to the protocol, shall take duly into account the quality standards and guidelines of the International Conference on Harmonisation (ICH) on good clinical practice.

3. Clinical trials with advanced therapy medicinal products shall additionally comply with the guidelines for good clinical practice which are specific for advanced therapy medicinal products.

4. The Spanish Agency of Medicines and Medical Devices shall make the good clinical practice guidelines referred to in this article publicly accessible.

Article 39 *Sponsor.*

1. The sponsor or his/her legal representative must be established in one of the Member States of the European Union.

2. The sponsor is responsible for signing the application for an opinion by the CEIm and the application for authorisation by the Spanish Agency of Medicines and Medical Devices.

3. The responsibilities of the sponsor are:

a) To establish and maintain a quality assurance and quality control system with written standard operating procedures so as to ensure that trials are conducted and data are generated, documented and reported in compliance with the protocol, good clinical practice guidelines and the provisions of this Royal Decree. The sponsor should have in place standard operating procedures to ensure quality standards in all the phases of documentation of an adverse event, data collection, validation, assessment, archiving, reporting and follow-up.

b) To sign jointly with the relevant investigator the protocol and any amendment to the protocol.

c) To select the most suitable investigator based on his/her qualifications and available resources, and to ensure said investigator conducts the trial as specified in the protocol.

d) To provide all the basic and clinical information available on the investigational product and maintain it updated throughout the duration of the trial.

e) To request the opinion of the CEIm and the authorisation by the Spanish Agency of Medicines and Medical Devices, as well as notifying them of the start of the trial, serious breaches of the protocol and other required information, and to obtain the relevant authorisations, without prejudice to the notifications that must be submitted to Autonomous Communities in accordance with article 19.

f) To provide the investigational medicinal products at no cost and to ensure that they have been prepared according to good manufacturing practice and the samples are suitably packaged and labelled. The sponsor is also responsible for the storage of samples and their manufacturing and quality control protocols, keeping records of the samples delivered and ensuring that the site where the trial is conducted establishes a procedure for the correct handling, storage and use of these samples.

In clinical trials sponsored by an investigator of a site or a non-profit scientific entity, or in those where there is mutual agreement with the site management where the clinical trial is to be conducted, other means of supply may be agreed with the site, particularly when treatment of the patients in the trial, or part of it, was that they would receive in the event of having decided not to participate in the trial.

g) To ensure that participation of a subject in the clinical trial shall involve no other additional cost than that which the subject would have had to incur in the context of normal clinical practice.

h) To appoint the monitor who shall supervise the conduct of the trial.

i) To report suspected unexpected serious adverse reactions in accordance with articles 49 to 53.

j) To immediately provide the investigator, the Spanish Agency of Medicines and Medical Devices and the CEIm with any significant information related to the clinical trial to which the sponsor has access during the trial.

k) To comply with the obligations of damage compensation according to the terms provided in article 9. To provide the legal and financial cover to the investigator in these cases, except when the injury arises from negligence or malpractice on the part of the investigator.

l) To agree with the investigator on the obligations for data processing, preparation of reports and publication of results. In any case, the sponsor is responsible for preparing the final report and annual reports of the clinical trial and for submitting them to the appropriate authorities.

m) The sponsor shall provide a contact point where the trial subjects may obtain further information about the clinical trial, which may be optionally delegated to the investigator.

n) To comply with the obligations that are imposed by the Spanish Clinical Studies Registry for publication of the clinical trials of which it is the sponsor.

ñ) To agree with the investigator, the site management and the CEIm on alternative modes of distribution in those cases where the site has no Pharmacy Department. In this case, shipments of the investigational products to the research site by the sponsor shall be possible, the investigator of this site assuming the responsibilities as regards correct administration, custody and delivery of these medicinal products, in accordance with that specified in the study protocol.

4. The sponsor of a clinical trial may delegate all or part of his/her tasks to an individual, a contract research organisation (CRO), an institution or body, which must have a quality assurance and quality control system.

5. Sponsor obligations established in good clinical practice guidelines that have been delegated shall apply to the contracted individual, CRO, company, institution or body. However, in these cases, the sponsor shall still be responsible for ensuring that the conduct of the clinical trial and the final data generated in this study comply with the provisions in this Royal Decree. Any delegation of sponsor functions in connection with a clinical trial should be specifically documented in a contract between both parties.

6. The sponsor and the investigator may be the same person.

7. If a clinical trial has more than one sponsor, all co-sponsors shall assume the sponsor responsibilities established in this article, unless they decide otherwise in a contract detailing their respective responsibilities. If the contract does not specify to which co-sponsor a given responsibility is attributed, this shall fall on all of them.

8. Without prejudice to paragraph 7, all co-sponsors shall be jointly responsible for designating:

a) A sponsor responsible for compliance with the sponsor obligations regarding the authorisation procedures established in Chapter V.

b) A sponsor responsible for being the contact point for receiving and answering all questions of the trial subjects, investigators, the CEIm, or the Spanish Agency of Medicines and Medical Devices relating to the clinical trial.

c) A sponsor responsible for applying any corrective measures that are imposed on him/her.

Article 40. *Monitor.*

1. The responsibilities of the monitor are:

a) To work according to sponsor standard operating procedures, visit the investigator before, during and after the trial, according to the type of study, to control compliance with the protocol and ensure that all data are correctly and completely recorded and reported, as well as ensuring that informed consent is obtained from all subjects prior to their enrolment in the clinical trial.

b) To ensure that the investigators and the sites where the trial is conducted are adequate for this purpose throughout the duration of the clinical trial.

c) To ensure that both the principal investigator and the members of the team of investigators have been adequately informed and to guarantee that communications between the investigator and the sponsor are prompt at all times, particularly with regard to supervision of trial safety.

d) To verify that the investigator complies with the protocol and all its approved modifications.

e) To check that the storage, distribution, returns and documentation of the investigational medicinal products is safe and appropriate.

f) To submit to the sponsor reports on monitoring visits and all relevant contacts with the investigator.

2. Under no circumstance may the monitor be part of the research team.

Article 41. *Investigator.*

1. The investigator directs and is responsible for the practical conduct of the clinical trial in a certain site.

2. Only a doctor or a person practising a profession recognised in Spain for conducting investigations given his/her scientific background and experience in the required patient care can act as the investigator.

3. The responsibilities of the investigator are:

a) To sign the protocol of the clinical trial together with the sponsor.

b) To be thoroughly familiar with the properties of the investigational medicinal products.

c) To ensure that informed consent is obtained in compliance with this Royal Decree.

d) To collect, record and report trial-related data appropriately and to ensure their accuracy.

e) To follow the instructions for the reporting of adverse events established in the protocol.

f) To notify the sponsor immediately of any serious breaches of the protocol.

g) To ensure that all persons involved in the clinical trial shall respect the confidentiality of any information concerning trial subjects, as well as the protection of their personal data.

h) To submit regular progress reports to the CEIm on the status of the clinical trial.

i) To be jointly responsible with the sponsor for the preparation of the final report of the clinical trial, and signing of the same report to confirm his/her agreement.

4. Each person participating in the conduct of a clinical trial shall be qualified by his/her education, training, and experience to perform his/her tasks. Likewise, the investigator shall ensure that his/her research team is informed about the protocol, the investigational medicinal products and their functions in the study.

5. The principal investigator may delegate tasks to the members of the research team. Such delegation does not exempt the investigator from being responsible for conducting the clinical trial in accordance with current legislation. The investigator responsibility delegation sheet of each clinical trial must not only state the participating personnel but also the co-investigators, to whom the performance of any function has been delegated, as well as their functions and responsibilities. If changes are made, they should be noted.

6. Contracted personnel must be authorised by the management of the site, specifying if they have access or not to the clinical history and personal data of the subjects included in the trial. This authorisation may be accomplished in two ways, by:

a) The signing of a contract, if the personnel are contracted by the site.

b) A separate access document if the personnel are contracted by third parties.

Article 42. *Publications.*

1. The sponsor is obliged to publish the results, whether positive or negative, of authorised clinical trials, preferably, in scientific journals before being disclosed to the non-healthcare public, regardless of the obligations of publication of the summary of the results in the Spanish Clinical Studies Registry (REec) and of the applicable provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. Whenever research work or studies on medicinal products directed to the scientific community are published, they shall state the funds obtained by the author for or by the conduct of the study and the funding source.

3. The anonymity of the subjects participating in the clinical trial shall be maintained at all times.

4. Treatments of as yet undetermined efficacy shall not be made known in a premature or sensationalist fashion, nor shall their efficacy be exaggerated. No advertising shall be made of interim results that may compromise the reliability of the final results of the trial.

5. Advertising of investigational medicinal products for human use is strictly prohibited, as specified in the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices approved by Royal Legislative Decree 1/2015, of 24 July, in Royal Decree 1416/1994, of 25 June, regulating the advertising of medicinal products for human use, in Royal Decree 1907/1996, of 2 August, on advertising and commercial promotion of products, activities, and services for alleged health purposes, and in General Act 34/1988, of 11 November, on advertising.

6. In all cases, publication of general research results once the clinical trial is completed shall be in accordance with the European Commission guidelines and, where appropriate, the instructions of the Spanish Agency of Medicines and Medical Devices.

7. When a substudy of a clinical trial ends on a later date than the rest of the clinical trial, it shall be required to publish the summary of its results in the year following its completion, without this implying a delay in submitting the results of the rest of the clinical trial.

Article 43. *Content and archiving of the clinical trial master file.*

1. The clinical trial master file shall comply with the provisions laid down in articles 57 and 58 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014. The content must take into account the supplementary guidelines in this regard published by the European Commission.

2. The sponsor and investigator shall keep the contents of the master file in paper or digital format of each clinical trial during at least twenty-five years after the end of the clinical trial, or for a longer period if this is laid down in other applicable requirements, such as in the event of the study being submitted as a basis for the authorisation of a medicinal product which must comply with Annex I of Royal Decree 1345/2007, of 11 October, or an agreement between the sponsor, the investigator and the site.

3. The contents of the master file shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities.

4. The clinical history of trial subjects shall be kept in safekeeping as provided for under the provisions laid down in Act 41/2002, of 14 November, and in accordance with the maximum period allowed by the hospital, institution or private clinic.

5. Any transfer of ownership of the content of the clinical trial master file shall be documented and the new owner shall assume the responsibilities set out in this article.

6. The sponsor shall appoint individuals within its organisation to be responsible for archives and access to these archives shall be restricted to those designated individuals.

7. The media used to archive the essential documents shall generally be in electronic format and they must ensure that the content remains complete and legible throughout the planned period of retention and is accessible, upon request, to the competent authorities. Any alteration to the records must be traceable, allowing the original and corrected data entry to be known, along with the date and signature of the author.

This documentation must be archived, preferably grouped by protocols, in a location that ensures the confidentiality of the information throughout the required archiving period.

In the case of pending legal proceedings, the essential documents shall be kept while there is no final court decision.

CHAPTER X

Verification of compliance with the good clinical practice guidelines

Article 44. *General provisions regarding inspection.*

1. The Spanish Agency of Medicines and Medical Devices and the competent health authorities of the Autonomous Communities, within the scope of their respective competences, shall verify compliance with this Royal Decree, good clinical practice guidelines and good manufacturing practice guidelines in clinical trials conducted in Spain through the corresponding inspections.

2. The authorities of the General State Administration and the competent Autonomous Communities shall provide mutual assistance in these inspections.

3. In the activity of inspection of good clinical practice, they must comply with the requirements on personal data protection set out in Organic Act 15/1999, of 13 December.

4. The inspections shall be carried out in accordance with the guidelines prepared at European level to support mutual recognition of the conclusions of inspections within the European Union.

5. The relationship with the competent authorities of the Member States of the European Union regarding inspection of good clinical practice shall be carried out through the Spanish Agency of Medicines and Medical Devices.

6. When a health authority of a Member State of the European Union requests information related to an inspection by a reasoned letter, the Spanish Agency of Medicines and Medical Devices shall send the relevant report. For this, where appropriate, the report shall be requested from the competent authorities of the Autonomous Community in which the site is situated.

7. Likewise, when information needs to be requested from another Member State on an inspection carried out in that State, the Spanish Agency of Medicines and Medical Devices shall address the competent body of that State by a reasoned letter, and shall request the relevant information.

8. The competent authorities of third countries that are to carry out inspections of good clinical practice in Spain must inform the Spanish Agency of Medicines and Medical Devices with sufficient time. The sponsor shall be responsible for informing the competent authority of the third country of this obligation of notification. The Spanish Agency of Medicines and Medical Devices shall inform the Autonomous Community where the site to be inspected is located.

9. The Spanish Agency of Medicines Products and Medical Devices shall inform the European Medicines Agency on the inspections carried out in Spain and their results. For this purpose, the Autonomous Communities shall send to the Spanish Agency of Medicines and Medical Devices the information on the inspections carried out in the format agreed in the Technical Inspection Committee.

Article 45. *Inspection procedure.*

1. Inspections shall be carried out by duly qualified inspectors, appointed for this purpose, in the sites related to the conduct of the clinical trials and, among others, in the trial site or sites where the clinical trial is being conducted, the manufacturing site of the investigational medicinal product, any laboratory used for analyses in the clinical trial, the CEIm, and the facilities of the sponsor and/or research organisations or companies involved by contract in the conduct of the trial.

2. At the end of each inspection, inspectors shall draw up a regulatory inspection report that shall be signed by the inspector or inspectors performing the inspection as well as by the inspected parties. The report shall contain the facts and most relevant findings resulting from the inspection actions.

3. Subsequently, the inspectors shall write a report on compliance with good clinical practice and the requirements established in this Royal Decree, which shall conform to the agreed format by the European Union. Before adopting the report, the inspected entity shall be given the opportunity to submit observations on the inspection made.

4. This report must be made available to the inspected parties, the competent authorities in Spain, and the sponsor, safeguarding the confidential aspects. Upon reasoned request, the report can be made available to the corresponding CEIm, if it had not been direct object of the inspection, as well as to the health authorities of the European Union, European Medicines Agency and health authorities with which there are agreements.

5. In the event of the inspection having found serious breaches, as defined in article 52.2 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, or having led to the adoption of the precautionary measures stated in article 109 of the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices approved by Royal Legislative Decree 1/2015, of 24 July the health authority approving the precautionary measure should immediately inform this to the sponsor, the CEIm and other health authorities according to their respective competences.

CHAPTER XI

Communications

Article 46. *Information systems.*

1. The Spanish Agency of Medicines and Medical Devices shall be the national contact point established by article 83 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. All communications between the agents involved in the application, assessment, and authorisation of clinical trials with medicinal products shall be submitted, when available, through the EU portal and the EU database to which reference is made in articles 80 and 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

3. Until the information systems referred to in paragraph 2 are available or as a complement to them:

a) The Spanish Agency of Medicines and Medical Devices shall enter in the European clinical trials database (EudraCT) the data related to the clinical trials with medicinal products for human use conducted in Spain.

b) The Spanish Agency of Medicines and Medical Devices shall maintain the information system for clinical trials with medicinal products for human use conducted in Spain. This information system shall serve as the single contact point for the sponsor in all matters relating to their clinical trials, redirecting the information, as appropriate, to the Spanish Agency of Medicines and Medical Devices and the CEIm, as well as to the competent authorities of the Autonomous Communities and the REec.

4. The information system referred to in the previous paragraph shall also serve for all types of communication and transmission of decisions between the Spanish Agency of Medicines and Medical Devices and the CEIm with the sponsor, as well as communication and transmission of opinions or other documents between the CEIm and the Spanish Agency of Medicines and Medical Devices.

Article 47. *Spanish Clinical Studies Registry (REec).*

1. The Spanish Agency of Medicines and Medical Devices shall maintain a registry of clinical studies with medicinal products for human use on its website.

2. The REec shall include the following information:

a) Compulsorily, clinical trials with medicinal products for human use that are authorised by the Spanish Agency of Medicines and Medical Devices, in accordance with this Royal Decree.

b) Compulsorily, non-interventional post-authorisation studies that are to be conducted and have been classified by the Spanish Agency of Medicines and Medical Devices.

c) Voluntarily, as with other similar databases, other types of clinical studies sponsored by national or international, public or private entities, provided they have at least one participating site located in Spain including cases, or although not including cases, that have a Spanish contribution considered as significant.

3. Registration of a clinical trial or study in the REec shall be compatible with inclusion in other national or international registries. The REec shall include prospective information in its scope of application from the start of its operation.

4. The REec shall include for each study the information specified in the Annex, including the data set required in the International Clinical Trials Registry Platform of the World Health Organisation. The Spanish Agency of Medicines and Medical Devices shall publish the correspondence between these fields and those of the application form for authorisation of the clinical trial submitted to the Agency for the case of clinical trials with medicinal products, as well as those of the application form for classification of non-interventional studies.

5. In all cases, the sponsor must publish in this registry the results of the registered research studies when they have concluded. This shall be done in accordance with the standard and the timelines indicated in the European Commission guidelines and, where appropriate, in the instructions published by the Spanish Agency of Medicines and Medical Devices.

Article 48. *Procedure for publication of a study in the REec.*

1. The REec aims to provide reliable and comprehensible information for the general public so the information contained in some fields could be limited in extent and should be written in a simple and accessible language to the public with no special scientific knowledge.

In order for the REec to be included in the WHO International Clinical Trials Registry Platform, all information shall be available in Spanish and English.

2. The sponsor shall be responsible for the quality, accuracy, and regular updating of all study information included in the REec. The Spanish Agency of Medicines and Medical Devices shall confirm before inclusion that the data are complete and appropriate for its purposes.

3. The registration of the study must be processed, in any case, after obtaining all the authorisations deemed necessary according to current regulations and before the inclusion of the first subject in the study, regardless of whether the study has been previously registered in another public registry or included or not in the WHO International Clinical Trials Registry Platform.

4. As a general rule, publication of the clinical trials shall be performed in accordance with one of the procedures established in paragraphs 5, 6 and 7.

5. The information on clinical trials with medicinal products, which is common to the European Union Clinical Trials Registry, shall be published by the Spanish Agency of Medicines and Medical Devices at the time of trial authorisation. The sponsor of a clinical trial with medicinal products shall

have a maximum of 14 calendar days from the notification of this authorisation to complete the required additional information in the REec, with a brief summary of the clinical trial and participating sites.

6. For registration of non-interventional post-authorisation studies in the REec, the sponsor shall include the study data in the registry before its initiation or within 14 calendar days after obtaining the relevant authorisations according to the applicable regulations for those studies requiring prior authorisation.

7. The sponsor of the type of studies included in article 47.2.c) may freely choose to register their data in the REec once the study has a favourable opinion from a REC and, where appropriate, the relevant administrative authorisation. The opinion of the REC shall be submitted to the Spanish Agency of Medicines and Medical Devices on applying for registration in the registry.

However, the Spanish Agency of Medicines and Medical Devices reserves the final right to verify the information received and permit its publication in the REec or, if the information cannot be validated, not to include it.

In any case, the Spanish Agency of Medicines and Medical Devices shall publish a document listing the rules to be complied with for registration of studies in the REec.

8. The Spanish Agency of Medicines and Medical Devices may decide to make public partial information about a clinical trial or a non-interventional post-authorisation study in which the sponsor has failed to comply with the periods for submitting the information, expressly stating the sponsor details and the reasons why this information of the registry is partial. This shall be independent of the imposing of any punitive actions that might be applicable in accordance with current legislation.

9. It is the responsibility of the sponsor to update regularly the information included in the REec. This update shall be mandatory with regard to the study start date in Spain, the participating sites, the recruitment completion date in Spain, substantial modifications involving a change in the data included in the registry and the study completion date in Spain. Updating shall be done on an overall basis and in any event at annual intervals until the end of the study and publishing of the results.

CHAPTER XII

Monitoring of the safety of investigational medicinal products

Article 49. *Obligations of investigators in the recording and reporting of adverse events.*

1. The investigator shall record and document any adverse events or abnormal laboratory results that are identified in the protocol as critical to the assessment of safety and report them to the sponsor in accordance with the reporting requirements and within the periods specified in the protocol, as established in article 41 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. The investigator shall report all serious adverse events to the sponsor without undue delay but not later than 24 hours from the time he/she has knowledge of these events, unless, for certain serious adverse events, the protocol provides that no immediate reporting is required. The investigator, where applicable, shall send a follow-up report to the sponsor to allow the sponsor to assess whether the serious adverse event has impact on the benefit-risk balance of the clinical trial. The initial and follow-up reports shall identify the trial subjects only by a subject identification code assigned in the trial, specific for each of them.

3. If the death of a subject participating in a clinical trial has been reported, the investigator shall provide the sponsor and the CEIm with any additional information requested.

4. If the investigator becomes aware of a serious adverse event with a suspected causal relationship to the investigational medicinal product that occurs after the end of the clinical trial in a subject treated by him/her, this serious adverse event shall be reported, without undue delay, to the sponsor.

5. In any case, the indications specified in the European Commission guidelines should be taken into account or, where appropriate, in the procedures established in the instructions for the conduct of clinical trials in Spain published by the Spanish Agency of Medicines and Medical Devices.

Article 50. *Other obligations of the sponsor in the recording, assessment and reporting of adverse events.*

1. The sponsor shall keep detailed records of all adverse events which are reported to the sponsor by the investigators. These adverse events shall be submitted to the Spanish Agency of Medicines and Medical Devices upon its request.

2. The sponsor is responsible for the continuous assessment of the benefit-risk balance of the clinical trial, which includes a continuous safety assessment of the investigational medicinal products using all the information available. Likewise, the sponsor must report to the Spanish Agency of Medicines and Medical Devices and the CEIm, without undue delay, in the period of fifteen calendar days, by the means indicated in article 21, any information substantially affecting the benefit-risk balance of the clinical trial, except for suspected unexpected serious adverse reactions which shall be reported according to article 51. This reporting shall be made in accordance with the European Commission guidelines or, where appropriate, the procedures established in the instructions for the conduct of clinical trials in Spain published by the Spanish Agency of Medicines and Medical Devices.

3. The sponsor shall promptly report to the investigators any important information that could adversely affect the safety of the subjects or the conduct of the clinical trial. Reporting of this information shall be concise and practical. Reporting shall conform to the criteria and the procedure specified in the European Commission guidelines.

Article 51. *Reporting of suspected unexpected serious adverse reactions to the Spanish Agency of Medicines and Medical Devices.*

1. The sponsor shall report to the Spanish Agency of Medicines and Medical Devices all suspected unexpected adverse reactions associated with investigational medicinal products of which it becomes aware, which have occurred in the clinical trial, whether occurring in Spain or in other countries. In addition, any suspected serious adverse reactions and, at the same time, unexpected occurring outside the clinical trial shall be reported according to the criteria established in the European Commission guidelines.

2. In all cases, this reporting shall be carried out through European Eudravigilance CTM database.

3. The timelines for reporting suspected unexpected serious adverse reactions by the sponsor to the Spanish Agency of Medicines and Medical Devices shall depend on the seriousness of the reaction and shall be determined as follows:

a) In the case of fatal or life-threatening suspected unexpected serious adverse reactions, as soon as possible and, in any event, not later than seven days after the sponsor became aware of the reaction.

b) In the case of non-fatal or non-life-threatening suspected unexpected serious adverse reactions, not later than fifteen days after the sponsor became aware of the reaction.

c) In the case of suspected unexpected serious adverse reactions which were initially considered to be non-fatal or non-life-threatening but which turns out to be fatal or life-threatening, as soon as possible and, in any event, not later than seven days after the sponsor became aware of the reaction being fatal or life-threatening.

When required to ensure prompt reporting, the sponsor may submit an incomplete initial report which must be completed as far as possible in the following eight days.

4. The reporting of serious and unexpected adverse reactions by the sponsor to the Spanish Agency of Medicines and Medical Devices shall conform, in any event, to the criteria and the procedure specified in articles 42, 45 and 46 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

Article 52. *Exchange of information about clinical trials with the competent bodies of the Autonomous Communities.*

1. The Spanish Agency of Medicines and Medical Devices shall provide a system by which suspected unexpected serious adverse reactions associated with the investigational medicinal product and occurring in patients included in a clinical trial in Spain are available to the competent bodies of the Autonomous Communities in real time through the clinical trial information system.

2. Until a valid system of electronic exchange of information is available for all Autonomous Communities, as indicated in article 19, reporting to the Autonomous Communities by the sponsor shall be carried out according to the criteria established in the relevant instructions of the Spanish Agency of Medicines and Medical Devices.

Article 53. *Annual safety report and other safety reports.*

1. The sponsors of clinical trials shall prepare an annual safety report in which the safety of the investigational medicinal product is assessed taking into account all the information available. This report shall be submitted to the Spanish Agency of Medicines and Medical Devices and the CEIm.

2. Irrespective of the annual safety report, the sponsor shall prepare an "ad hoc" assessment report whenever there is a relevant safety problem. This report shall be submitted immediately to the Spanish Agency of Medicines and Medical Devices and the CEIm as stated in the previous paragraph.

3. Submission of the annual safety report and other safety reports by the sponsor shall conform in all cases to the criteria and the procedure specified in articles 43, 45 and 53 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

4. The sponsors of clinical trials in which the investigational medicinal products, excluding placebos, are authorised and, according to the clinical trial protocol, are used in accordance with the terms of marketing authorisation, may submit a simplified report in accordance with the instructions for the conduct of clinical trials in Spain published by the Spanish Agency of Medicines Products and Medical Devices.

CHAPTER XIII
Infringements

Article 54. *Administrative infringements related to clinical trials*.

Administrative infringements shall be those laid down in Chapter II of Title IX of the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices , approved by Royal Legislative Decree 1/2015, of 24 July, and they shall be sanctioned in accordance with article 114 of this Act.

First additional provision. *Ethics Committees for Clinical Investigation.*

1. Within the period of two years from the effective date of this Royal Decree, Ethics Committees for Clinical Investigation may be accredited as CEIm by the competent health authorities of the Autonomous Communities, taking into account for this purpose the criteria established in Chapter IV.

2. Once this period of two years has elapsed, those Ethics Committees for Clinical Investigation that are not CEIm may continue to perform the functions of Ethics Committees for Investigation not related to the assessment of clinical trials with medicinal products or medical devices until the specifications established in the third transitional provision of Act 14/2007, of 3 July, are met.

3. The references to Ethics Committees for Clinical Investigation indicated in the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices approved by Royal Legislative Decree 1/2015, of 24 July shall be understood to be performed by the CEIm under the terms established in this Royal Decree.

Second additional provision. *Non-interventional studies.*

Without prejudice to the provisions specified in Chapter IV in articles 18, 47 and 48, the non-interventional studies defined in paragraph k) of article 2.1 shall be governed by their specific regulations.

Third additional provision. *Clinical investigations with medical devices.*

1. Clinical investigations with medical devices shall be governed by the ethical and methodological principles and those of protection of trial subjects laid down in this Royal Decree, taking into account the provisions of the medical devices regulation.

2. The CEIm shall issue an opinion on clinical investigations with medical devices. This shall be done, taking into account, in particular, the provisions specified in article 16.4.a). When this research is conducted in various sites, the opinion shall be issued by an CEIm in Spain and shall be single and binding.

3. The start of clinical research with medical devices bearing CE marking and which are used for the same indications included in the conformity assessment procedure shall be notified to the Spanish Agency of Medicines and Medical Devices whenever any intervention modifying standard clinical practice is performed in these investigations.

Fourth additional provision. *Collegiate bodies of the Spanish Agency of Medicines and Medical Devices.*

Within a year from the effective date of this Royal Decree, the Spanish Agency of Medicines and Medical Devices shall submit a proposal to the Ministry of Finance and Public Administration for rationalisation of the collegiate bodies attached to it, pursuant to Royal Decree 776/2011, of 3 June, dissolving certain collegiate bodies and establishing criteria for the standardisation of the creation of collegiate bodies in the General State Administration and its Public Bodies.

Fifth additional provision. *No increase in personnel costs.*

The measures provided for in this Royal Decree shall not involve any increase in remuneration, provisions or other personnel costs.

Sixth additional provision. *Application of this Royal Decree to health services of the Armed Forces.*

Pending development of the stipulations contained in the second additional provision of the consolidated text of the Act on guarantees and rational use of medicinal products and medical devices approved by Royal Legislative Decree 1/2015, of 24 July application of this Royal Decree to the health services of the Armed Forces shall be according to the following rules:

a) The Ministry of Health, Social Services and Equality shall hold the accreditation as the CEIm of the health services of the Armed Forces.

b) The Ministry of Defence, through the General Public Health Inspection of Defence, shall exercise the competences concerning inspection, receipt of communications and reports and other matters that are attributed by this Royal Decree to the Autonomous Communities, in their area of competences.

Seventh additional provision. *Adoption of developing instructions.*

The Spanish Agency of Medicines and Medical Devices is empowered to adopt the good clinical practice guidelines and instructions for the conduct of clinical trials in Spain, which it shall maintain updated on its website.

First transitional provision. *Transitional regime related to the functions of assessment of clinical studies with medicinal products or medical devices of the Ethics Committees for Clinical Investigation.*

During the two years following entry into force of this Royal Decree, Ethics Committees for Clinical Investigation already accredited at the time of its entry into force shall assume the functions of Ethics Committees for Investigation with medicinal products related to assessment of clinical studies with medicinal products or medical devices and shall be supervised and coordinated in respect of these functions in the same manner as the latter.

Second transitional provision. *Procedure for applications for clinical trial authorisation and modification, communications and notifications before full functionality of the EU portal and the EU database.*

1. Until the date of full application of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, as provided in its article 99, the submission of applications and communications and receipt of notifications listed in articles 21.1, 26.3, 30.1, 51.2, 51.4 and 53.3 of

this Royal Decree, shall conform to the provisions of the following paragraphs taking into account the provisions in article 46, paragraphs 3 and 4:

a) Applications for authorisation and an opinion on the clinical trial, as well as all subsequent communications, shall be submitted by the sponsor only via or by electronic means and simultaneously to the Spanish Agency of Medicines and Medical Devices and the CEIm who accepts assessment at the proposal of the sponsor, in accordance with the provisions of article 27.6 of Act 11/2007, of 22 June, on citizen electronic access to public services, unless it is justified that access and availability of the required technological resources is not guaranteed. In any case, if this simultaneous submission did not occur, the date of the last application submitted shall be considered for the purpose of processing of the procedure.

b) For submission by electronic means, the Portal of Clinical Trials with medicinal products of the Ministry of Health, Social Services and Equality has been enabled, which may be accessed at the electronic headquarters of the Spanish Agency of Medicines and Medical Devices.

Alternatively, electronic submission may be performed without a recognised digital certificate by submitting in the registry of the Spanish Agency of Medicines Medical Devices or the CEIm, as appropriate, the proof of the electronic submission with a handwritten signature.

c) Notifications of the Spanish Agency of Medicines and Medical Devices to the sponsor shall be made electronically. The sponsor must therefore appear at the electronic headquarters of the Spanish Agency of Medicines and Medical Devices. Likewise, the CEIm shall send its notifications by e-mail.

d) To make the submission electronically and receive electronic notifications, the sponsor must have a computer, an Internet connection and a recognised digital certificate issued by any of the certification service providers that are registered in the registry of the Secretary of State for Telecommunications and Information Society in accordance with article 30 of the Electronic Signature Act 59/2003, of 19 December. Furthermore, to receive electronic notifications, the sponsor must have an e-mail account and have expressed his/her consent when submitting the application.

e) When a sponsor, due to lack of resources, is unable to report a suspected unexpected serious adverse reaction to the Eudravigilance CTM database, he/she may report it to the Spanish Agency of Medicines and Medical Devices according to the procedure established in the instructions for the conduct of clinical trials in Spain published by said Agency.

2. In accordance with the provisions of article 98 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, during the year following the date of full application of this Regulation, the sponsor may choose to request authorisation of a clinical trial pursuant to article 21.1 of this Royal Decree or as indicated in the previous paragraph. In this latter case, subsequent notifications referring to the clinical trial shall continue to be made in accordance with the terms in this provision up to three years after the date of full application of this Regulation (EU).

Third transitional provision. *Procedure for authorisation of a clinical trial before full functionality of the EU portal and the EU database.*

Until full application of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, as provided in its article 99, the procedure for authorisation of a clinical trial, regulated in articles 21 to 30 of this Royal Decree, must conform to the following rules:

a) For validation of an application, the sponsor must submit an application containing all the necessary documents related to Part I and Part II. In the case of clinical trials with a medicinal product not authorised in any country of the European Economic Area which contains an active substance or a combination of active substances not authorised in Spain, qualification as “a product under clinical investigation” (producto en fase de investigación clínica or PEI) shall be requested for this medicinal product.

The Spanish Agency of Medicines and Medical Devices and CEIm shall notify the sponsor if the application for Part I and Part II, respectively, are complete in a maximum period of ten calendar days. If any part is incomplete, this shall be notified to the sponsor setting a maximum period of ten calendar days for this sponsor to submit his/her comments. This period may be extended to thirty calendar days in the case of clinical trials meeting the definition of "Non-commercial Clinical Research".

If the sponsor does not answer within the stipulated period, the application shall be deemed to have lapsed and shall be so notified. If the sponsor submits supplementary documentation that permits the application to be completed, the CEIm, or the Agency, as appropriate, shall report the assessment schedule to the sponsor within five calendar days, which shall start from the day following the date of receipt of this documentation which, for the purposes of this article, shall be considered as the valid application date.

b) For Part I of the assessment report, regulated in article 23 of this Royal Decree, the Spanish Agency of Medicines and Medical Devices shall be responsible for sending to the sponsor the conclusions of Part I of the assessment report, including those aspects which have been assessed by the CEIm, within the periods stipulated in article 6 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014. However, the assessment period shall start from the valid application date.

c) With regard to Part II of the assessment report, regulated in article 24, it should be borne in mind that the assessment period shall start from the valid application date.

d) Regarding the authorisation decision, regulated in article 25, the Director of the Spanish Agency of Medicines and Medical Devices, in a period of five days from the last date of notification to the sponsor of the conclusions of Part I and Part II, shall issue the decision authorising the clinical trial, authorising the clinical trial subject to conditions, or refusing the authorisation.

e) A clinical trial cannot commence without prior written authorisation from the Spanish Agency of Medicines and Medical Devices in the following cases:

1. Clinical trials where the Agency has notified objections to the sponsor within the 45 day period referred to in article 6 of Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014.

2. Clinical trials with medicinal products requiring qualification as a product under clinical investigation.

3. Clinical trials with advanced therapy medicinal products, as well as clinical trials with medicinal products containing genetically modified organisms.

In these cases, if after the period of five days specified in paragraph d), no notification of the decision has been made to the interested party, it shall be understood that the application has been refused.

For the authorisation of subsequent clinical trials with an investigational medicinal product previously considered a product under clinical investigation, the documentation mentioned in article 22.1 should be updated, whenever necessary.

f) With regard to the modification of the clinical trial authorisation conditions, regulated in article 26, it shall be borne in mind that the assessment period shall start from the valid application date.

g) Finally, concerning the application of article 30, it shall be taken into account that, regardless of the result of the clinical trial, within a year from completion of the trial the sponsor shall send the Spanish Agency of Medicines and Medical Devices and the CEIm the summary of results of the trial in accordance with the current European guidelines.

Sole repeal provision. *Statutory repeal.*

Any provisions of equal or lower rank that are contrary to the provisions in this Royal Decree are hereby repealed and, in particular, Royal Decree 223/2004, of 6 February, regulating clinical trials with medicinal products, as well as Order SCO/256/2007, of 5 February, establishing detailed principles and guidelines of good clinical practice and requirements to authorise the manufacture or importation of investigational medicinal products for human use.

First final provision. *Modification of the Statute of the Spanish Agency of Medicines and Medical Devices approved by Royal Decree 1275/2011, of 16 September, establishing the State Agency "Spanish Agency for Medicinal Products and Medical Devices" and approving its Statute.*

A new article is added to the Statute of the Spanish Agency for Medicinal Products and Medical Devices approved by Royal Decree 1275/2011, of 16 September, establishing a State Agency "Spanish Agency of Medicines and Medical Devices" and approving its Statute, as follows:

"Article 28 bis. *The Medical Devices Committee.*

1. The Medical Devices Committee is the collegiate body that provides advice on technical, scientific and clinical matters related to the safety, efficacy, and quality of medical devices in all procedures undertaken by the Spanish Agency of Medicines and Medical Devices, both as the competent authority and as notified body.

2. The functions of the Medical Devices Committee are:

a) To propose to the Spanish Agency of Medicines and Medical Devices the conduct of studies and investigations it considers necessary regarding medical devices.

b) To advise the Spanish Agency of Medicines and Medical Devices on issues related to safety, clinical efficacy, performance, quality, information, and proper use of medical devices.

c) To advise the Spanish Agency of Medicines and Medical Devices in the performance of the function of evaluation of adverse incidents in its area of responsibility within the framework of the Medical Devices Vigilance System, as well as in the evaluation of risks that may arise with marketed medical devices.

d) To provide technical advice to the Spanish representatives in working groups and meetings on medical devices held in the European Union and other international organisations.

e) To provide opinion on testing methods and technical standards.

f) To advise on the measures to be adopted that are aimed at safeguarding public health and protection of patients and users with regard to medical devices, as well as on the recommendations to be issued for protection of the health of the population, safe use of the products and follow-up and treatment of patients.

g) To issue a report at the request of the Director of the Spanish Agency of Medicines and Medical Devices, on the "CE" certification procedures of medical devices.

h) To provide opinion about any other issue related to medical devices.

3. The Medical Devices Committee shall consist of the following members:

a) Five members based on their position:

1. The Director of the Spanish Agency of Medicines and Medical Devices or designee.

2. The Head of the Department of Medical Devices of the Spanish Agency of Medicines and Medical Devices.

3. The person responsible for the area of vigilance and market surveillance of the Department of Medical Devices of the Spanish Agency of Medicines and Medical Devices.

4. The person responsible for the area of certification of the Spanish Agency of Medicines and Medical Devices.

5. The person who chairs the Technical Inspection Committee.

b) Four members on behalf of:

1º. The Spanish Ministry of Health, Social Services and Equality.

2º. The Carlos III Health Institute, proposed by its supreme governing body.

3º. The National Institute of Toxicology and Forensic Sciences, proposed by its supreme governing body.

4º. The Higher Council for Scientific Research, proposed by its supreme governing body.

4. By virtue of the provisions of article 29.3, the Committee may request the collaboration of as many experts as it deems appropriate.

5. The Chair of the Committee shall be the Director of the Spanish Agency of Medicines and Medical Devices, or person designated as his/her replacement, and one of the members of the Spanish Agency of Medicines and Medical Devices shall act as Secretary. In the event of vacancy, absence or illness, the Chair of Committee shall correspond to the Head of the Department of Medical Devices of the Spanish Agency of Medicines and Medical Devices.

6. The Medical Devices Committee shall hold such meetings as are required by its advisory functions, in response to the needs of the Spanish Agency of Medicines and Medical Devices, working in plenary sessions or in Committees, in accordance with the regulations established in its Internal Rules of Operation.

Likewise, it may hold remote meetings and issue reports and adopt decisions by written procedure, without the need to resort to the on-site meeting of its members."

Second final provision. *Qualifying title.*

This Royal Decree is enacted under the provisions of article 149.1.16 of the Spanish Constitution, which grants the State the sole authority regarding the legislation on medicinal products.

Third final provision. *Development powers.*

The Minister of Health, Social Services and Equality is empowered to issue the necessary measures for the development of this Royal Decree, and for the updating of its Annex, according to the advance of scientific and technical knowledge and in accordance with the guidelines of the European Union. In particular, the Minister of Health, Social Services and Equality is empowered to revise the limits established in article 10.3.

Fourth final provision. *Entry into force.*

This Royal Decree shall enter into force twenty days after its publication in the Official State Journal, except for paragraph 1 of article 21, article 22, paragraphs 1 and 3 of article 23 and

paragraph 1 of article 25 which shall be effective as from the date on which Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, is fully applicable as provided in its article 99.

Done at Madrid, on 4 December 2015.

FELIPE R.

The Ministry of Health, Social Services and Equality

ALFONSO ALONSO ARANEGUI

ANNEX

Data to be included in the REec

1. Study identification number in the primary registry.

2. Date of registration in the REec.

3. Secondary identification numbers.

4. Brief summary with rationale for the study.

5. Source of funding or material support.

6. Sponsor.

7. Contact for queries by the general public.

8. Contact for scientific queries.

9. Public study title.

10. Scientific study title and acronym, if the study has one.

11. Countries where it is planned to recruit subjects.

12. Trial sites.

13. Disease or health problem under study.

14. Interventions being studied.

15. Main inclusion and exclusion criteria.

16. Type and scope of study.

17. Date of recruitment of the first subject in Spain.

18. Sample size (number of subjects to be included).

19. Study status (uninitiated; recruitment started; recruitment concluded, temporarily discontinued or discontinued; completed in Spain; completed in all participating countries).

20. Primary objective and study variables and times when they will be assessed.

21. Secondary objectives and study variables and times when they will be assessed.

22. Date of opinion by CEIm and authorisation by the Spanish Agency of Medicines and Medical Devices or by the corresponding Autonomous Community (where applicable).

23. Study portal (if applicable).

24. Study results (the registry will contain a link to the scientific publications of the study. Submission of the results will conform, where applicable, to the EU standard).

25. Date of last modification of the record in the REec.

BOE 16 febrero 2008, núm. 41/2008 [pág. 8738]

Orden SCO/362/2008, de 4 febrero 2008. Modifica la Orden SCO/256/2007, de 5-2-2007 (RCL 2007\270), por la que se establecen los principios y las directrices detalladas de buena práctica clínica y los requisitos para autorizar la fabricación o importación de medicamentos en investigación de uso humano .

En aplicación de lo previsto en el Acuerdo del Consejo de Ministros de 11 de mayo de 2007, se modifica la Orden SCO/256/2007, de 5 de febrero, por la que se establecen los principios y las directrices detalladas de buena práctica clínica y los requisitos para autorizar la fabricación o importación de medicamentos en investigación de uso humano.

El mencionado Acuerdo del Consejo de Ministros es consecuencia del requerimiento de incompetencia elevado por la Generalitat de Cataluña al Gobierno, que solicitaba la modificación de la Orden SCO/256/2007, de 5 de febrero. Este Acuerdo decide modificar el artículo 10 de la mencionada Orden en sus apartados 1.d), 3 y 5, para evitar interpretaciones en la aplicación de esta Norma que pudieran afectar a las competencias ejecutivas que en materia de inspección de productos farmacéuticos ostentan diversas Comunidades Autónomas.

El alcance de la modificación del artículo 10 se concreta en la supresión del apartado 1 d), referente a la actuación de inspección que se atribuía la Agencia Española de Medicamentos y Productos Sanitarios en caso de que el ensayo clínico no estuviera autorizado por ella, y del apartado 3, en el que se regulaba la conformidad que debería dar la Agencia Española de Medicamentos y Productos Sanitarios a las peticiones de inspección formuladas por las autoridades competentes en materia de inspección de los Estados miembros cuando tuvieran que inspeccionar los centros donde se realizasen los ensayos clínicos, previa información a las Comunidades Autónomas correspondientes. Por último, se modifica el apartado 5 para facilitar una correcta interpretación del mismo, recogiendo un inciso dentro del apartado donde se establece la obligación por parte de la Agencia Española de Medicamentos y Productos Sanitarios de informar a la Comunidad Autónoma donde se encuentre el centro a inspeccionar, cuando las autoridades competentes de terceros países vayan a realizar inspecciones de buena práctica clínica en España.

En la elaboración de esta disposición han sido oídos los sectores afectados y consultadas las Comunidades Autónomas.

Esta Orden se dicta al amparo de lo dispuesto en la disposición final segunda del Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.

En su virtud, dispongo:

Artículo único. Modificación de la Orden SCO/256/2007, de 5 de febrero, por la que se establecen los principios y las directrices detalladas de buena práctica clínica y los

requisitos para autorizar la fabricación o importación de medicamentos en investigación de uso humano.

El artículo 10 de la Orden SCO/256/2007, de 5 de febrero, queda redactado como sigue:

«Artículo 10. *Competencias en materia de inspección de buena práctica clínica.* 1. La Agencia Española de Medicamentos y Productos Sanitarios llevará a cabo actuaciones de inspección en los siguientes casos: a) Para verificar los resultados de los ensayos clínicos presentados en las solicitudes de autorización de medicamentos mediante los procedimientos de reconocimiento mutuo, descentralizado y nacional. b) Para verificar los resultados de los ensayos clínicos presentados en las solicitudes de autorización de un medicamento mediante el procedimiento centralizado y coordinadas por la Agencia Europea de Medicamentos, dentro del ámbito de aplicación del Reglamento (CE) núm. 726/2004 del Parlamento Europeo y del Consejo, de 31 de marzo de 2004, por el que se establecen procedimientos comunitarios para la autorización y el control de los medicamentos de uso humano y veterinario y por el que se crea la Agencia Europea de Medicamentos. c) Cuando se trate de inspecciones a realizar en el territorio de las Comunidades Autónomas que no hubieran recibido los correspondientes traspasos de la competencia de ejecución de la legislación de productos farmacéuticos. 2. Podrán realizar inspecciones de buena práctica clínica, en todo el territorio español, los inspectores españoles acreditados, previa conformidad por la autoridad competente de la inspección del centro a inspeccionar. La Agencia Española de Medicamentos y Productos Sanitarios y las Comunidades Autónomas con competencia en materia de inspección de buena práctica clínica podrán solicitar la colaboración y/o participación de inspectores no adscritos a su ámbito de competencia cuando lo estimen necesario. Si alguna Comunidad Autónoma considera necesaria la realización de una inspección de buena práctica clínica fuera del ámbito territorial de su competencia, lo solicitará a la Agencia Española de Medicamentos y Productos Sanitarios, que dará traslado de la solicitud a la Comunidad Autónoma competente de la inspección. Corresponde a la administración sanitaria de esta última, autorizar la inspección y determinar si se lleva a cabo por inspectores propios o de la comunidad que la solicitó. 3. La relación con las autoridades competentes de los Estados miembros de la Unión Europea en materia de inspección de buena práctica clínica, se llevará a cabo a través de la Agencia Española de Medicamentos y Productos Sanitarios. 4. Las autoridades competentes de terceros países que vayan a realizar inspecciones de buena práctica clínica en España, deberán notificarlo a la Subdirección General de Inspección y Control de Medicamentos de la Agencia Española de Medicamentos y Productos Sanitarios con tiempo suficiente para que pueda acudir a la citada inspección, si fuera pertinente. La Agencia informará de la inspección a la Comunidad Autónoma donde se encuentre el centro a inspeccionar. El promotor será responsable de informar a la autoridad competente del tercer país de esta obligación de notificación. 5. La Agencia Española de Medicamentos y Productos Sanitarios elaborará los procedimientos pertinentes para las siguientes actividades: a) Solicitar inspecciones o ayuda de otros Estados miembros de la Unión Europea y cooperar en las inspecciones realizadas en centros de otro país de la Unión Europea. b) Realizar inspecciones en terceros países».

Disposición Final única. Entrada en vigor.

La presente Orden entrará en vigor el día siguiente al de su publicación en el «Boletín Oficial del Estado».

ORDEN SAS/3470/2009, DE 16 DE DICIEMBRE, POR LA QUE SE PUBLICAN LAS DIRECTRICES SOBRE ESTUDIOS POSAUTORIZACIÓN DE TIPO OBSERVACIONAL PARA MEDICAMENTOS DE USO HUMANO

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El Real Decreto 1344/2007, de 11 de octubre, por el que se regula la farmacovigilancia de medicamentos de uso humano, en su artículo 19 apartado 2 dispone que la Agencia Española de Medicamentos y Productos Sanitarios establecerá un Comité de Coordinación de Estudios Posautorización. Dicho Comité contará con la participación de los representantes de todas las Comunidades Autónomas y de la Agencia Española de Medicamentos y Productos Sanitarios.

Así mismo, dicho artículo prevé que las administraciones sanitarias establecerán de común acuerdo las condiciones en las que se llevarán a cabo los estudios posautorización de tipo observacional, con la finalidad de favorecer aquellos que puedan contribuir al conocimiento del medicamento o a mejorar la práctica clínica, así como que las directrices de los procedimientos comunes que cada Comunidad Autónoma ejercerá en su ámbito competencial, serán objeto de debate en el citado comité.

En cumplimiento de lo anteriormente expuesto, el Comité de Coordinación de Estudios Posautorización, fue constituido con fecha 24 de septiembre de 2008, procediendo en ejercicio de sus funciones a adoptar unas directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano.

Mediante esta Orden se publican las «Directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano», que establecen los procedimientos comunes que cada Comunidad Autónoma ejecutará en su ámbito competencial, con el fin de facilitar su difusión y conocimiento.

En su tramitación se ha obtenido el informe preceptivo de la Agencia Española de Protección de Datos, y han sido oídos los sectores afectados y consultadas las Comunidades Autónomas.

En su virtud y previa aprobación de la Vicepresidenta Primera del Gobierno y Ministra de la Presidencia, dispongo:

Artículo único. Publicación de las Directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano.

Esta Orden tiene por objeto publicar las Directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano, que figuran como anexo a la misma, y que han sido adoptadas por el Comité de Coordinación de Estudios Posautorización, en el ejercicio de sus funciones.

Disposición Final primera. Título competencial.

Esta Orden tiene carácter de legislación de productos farmacéuticos a los efectos previstos en el artículo 149.1.16ª de la Constitución.

Disposición Final segunda. Entrada en vigor.

La presente Orden entrará en vigor el día siguiente al de su publicación en el «Boletín Oficial del Estado».

ANEXO
DIRECTRICES DE ESTUDIOS POSAUTORIZACIÓN DE TIPO OBSERVACIONAL PARA MEDICAMENTOS DE USO HUMANO

1. ANTECEDENTES Y BASE LEGAL

Los estudios posautorización se consideran necesarios para la obtención de un conocimiento que los ensayos clínicos controlados realizados durante el desarrollo clínico de los medicamentos no aportan. Dicho conocimiento es fundamental para orientar la práctica clínica y favorecer un uso racional de los medicamentos.

El Real Decreto 711/2002, de 19 de julio, por el que se regulaba la farmacovigilancia de medicamentos de uso humano y la Circular 15/2002 de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) constituyeron un primer paso en el control de estos estudios y en la garantía de los fines de los mismos. En este Real Decreto se prohibía expresamente la utilización de estudios posautorización como este tipo de prácticas promocionales encubiertas y se establecía que las administraciones sanitarias, en el ámbito de sus competencias, debían regular las condiciones en las que se realizarían dichos estudios, al objeto de favorecer los que tuvieran verdadero interés científico e impedir aquellos con fines promocionales. Este mandato se desarrolló a través de normativas específicas por cada una de las Comunidades Autónomas (CC AA) con competencias en ejecución de la legislación sobre productos farmacéuticos, que tomaron como referencia el anexo VI de la citada Circular 15/2002. A la AEMPS le asignaba dicho Real Decreto la responsabilidad de mantener un registro común para todo el Estado de todas las propuestas de estudio que se solicitaran. Dicho registro (base de datos GESTO) está operativo desde 2003 y es accesible para todas las CC AA.

La citada regulación, y en particular, la autorización previa de los estudios posautorización de seguimiento prospectivo por parte de las CC AA, ha permitido mejorar el control y la calidad de estos estudios. Superada esta etapa, por tanto, procede actualizar la normativa de referencia con el objeto de diferenciar con claridad los distintos tipos de estudios posautorización, e introducir mecanismos que permitan reducir la carga burocrática de aquellos que sean de gran interés para la salud pública, como son, entre otros, los requeridos por las autoridades sanitarias por motivos de

seguridad o los financiados con fondos públicos. Las bases legales para esta diferenciación fueron introducidas por el nuevo Real Decreto 1344/2007, de 11 de octubre, por el que se regula la farmacovigilancia de medicamentos de uso humano.

Un elemento clave que ha introducido el Real Decreto 1344/2007, de 11 de octubre ha sido el mandato de crear un Comité de Coordinación de Estudios Posautorización, formado por representantes de todas las CC AA y de la AEMPS, como foro de debate en el que se acuerden las directrices de los procedimientos comunes que tendrán que aplicar las CC AA en su ámbito de competencia. Dicho Comité fue constituido el 24 de septiembre de 2008. Las presentes directrices son el fruto de las deliberaciones de dicho Comité y reflejan por tanto la participación de todas las CC AA y la AEMPS en el proceso de toma de decisiones y el común acuerdo sobre su redactado.

Para la elaboración de estas directrices se ha tenido en cuenta, además, lo estipulado en el Capítulo I.7 sobre Estudios Posautorización promovidos por compañías farmacéuticas del Volumen 9A de las Normas sobre Medicamentos de la Unión Europea.

2. ÁMBITO DE APLICACIÓN DE LAS DIRECTRICES

Las directrices se aplican a todos los estudios posautorización de tipo observacional que se realicen con medicamentos de uso humano. No obstante, se establecen cuatro procedimientos diferentes en función del tipo de estudio posautorización observacional de que se trate.

Cuando un estudio posautorización tenga carácter de ensayo clínico, de conformidad con la definición que figura en el artículo 58 de la Ley 29/2006, de 26 de julio, de Garantías y Uso Racional de Medicamentos y Productos Sanitarios, no se regirá por lo dispuesto en las presentes directrices sino que le resultará de aplicación la normativa específica sobre ensayos clínicos, en particular el Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.

3. DEFINICIONES

Datos de carácter personal: (Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal): Cualquier información numérica, alfabética, gráfica, fotográfica, acústica o de cualquier otro tipo concerniente a personas físicas identificadas o identificables.

Procedimiento de disociación: (Real Decreto 1720/2006, de 21 de diciembre): Todo tratamiento de datos personales que permita la obtención de datos disociados.

Estudio posautorización: (Real Decreto 1344/2007, de 11 de octubre): Cualquier estudio clínico o epidemiológico realizado durante la comercialización de un medicamento según las condiciones autorizadas en su ficha técnica, o bien en condiciones normales

de uso, en el que el medicamento o los medicamentos de interés son el factor de exposición fundamental investigado. Este estudio podrá adoptar la forma de un ensayo clínico o un estudio observacional.

Estudio posautorización de seguridad: (Real Decreto 1344/2007, de 11 de octubre): Estudio farmacoepidemiológico o ensayo clínico efectuado de conformidad con las disposiciones de la autorización de comercialización y realizado con el propósito de identificar, caracterizar o cuantificar los riesgos asociados a los medicamentos autorizados.

Estudio observacional: (Ley 29/2006, de 26 de julio): Estudio en el que los medicamentos se prescriben de la manera habitual, de acuerdo con las condiciones establecidas en la autorización. La asignación de un paciente a una estrategia terapéutica concreta no estará decidida de antemano por el protocolo de un ensayo, sino que estará determinada por la práctica habitual de la medicina, y la decisión de prescribir un medicamento determinado estará claramente disociada de la decisión de incluir al paciente en el estudio. No se aplicará a los pacientes ninguna intervención, ya sea diagnóstica o de seguimiento, que no sea la habitual de la práctica clínica, y se utilizarán métodos epidemiológicos para el análisis de los datos recogidos.

En el Capítulo I.7 del Volumen 9A, se aclara que «las entrevistas, los cuestionarios y las muestras de sangre se pueden considerar como práctica clínica habitual». En todo caso, para el manejo de muestras biológicas se seguirá lo dispuesto en la Ley 14/2007, de 3 de julio, de Investigación Biomédica.

Estudio posautorización de tipo observacional: Estudio epidemiológico que cumple las condiciones de ser posautorización y observacional.

Estudio posautorización observacional de seguimiento: Todo aquel estudio posautorización de tipo observacional en el que los pacientes son seleccionados por su exposición a un determinado medicamento y son después seguidos durante un período de tiempo suficiente en relación con el acontecimiento de interés. Se consideran prospectivos cuando el período de estudio es posterior al inicio de la investigación y retrospectivos cuando el período de estudio es todo él anterior al inicio de la investigación.

Fuente de información: Origen de los datos que se utilizan para la realización del estudio.

4. OBJETIVOS DE LOS ESTUDIOS POSAUTORIZACIÓN

El objetivo de los estudios posautorización es generar información adicional sobre los efectos de los medicamentos, así como las características relacionadas con su utilización, en las condiciones autorizadas en su ficha técnica o bien en condiciones normales de uso, con el fin de completar la información obtenida durante las fases I, II y III y contribuir a su mejor utilización.

Más concretamente, los estudios posautorización pueden realizarse con alguno de los siguientes fines:

Determinar la efectividad de los fármacos, es decir sus efectos beneficiosos en las condiciones de la práctica clínica habitual, así como los factores modificadores de la misma, tales como el incumplimiento terapéutico, la polimedicación, la gravedad de la enfermedad, presencia de enfermedades concomitantes, grupos especiales (ancianos, niños, etc.), factores genéticos o factores relacionados con el estilo de vida.

Identificar y cuantificar los efectos adversos del medicamento, en especial los no conocidos antes de la autorización, e identificar los posibles factores de riesgo o modificadores de efecto (características demográficas, medicación concomitante, factores genéticos, etc.). Con frecuencia, esto sólo podrá estudiarse con precisión en grupos amplios de población y durante tiempos de observación prolongados.

Obtener nueva información sobre los patrones de utilización de medicamentos (dosis, duración del tratamiento, utilización apropiada).

Evaluar la eficiencia de los medicamentos, es decir la relación entre los resultados sanitarios y los recursos utilizados, utilizando para ello análisis farmacoeconómicos, tales como los de coste-efectividad, coste-utilidad, coste-beneficio o comparación de costes.

Conocer los efectos de los medicamentos desde la perspectiva de los pacientes (calidad de vida, satisfacción con los tratamientos recibidos, etc.).

5. CONSIDERACIONES ÉTICAS

Para que un estudio sea éticamente justificable debe estar bien diseñado y cumplir con los principios éticos básicos contenidos en la Declaración de Helsinki de la Asociación Médica Mundial sobre principios éticos para las investigaciones médicas en seres humanos, y en sus posteriores revisiones.

Todos los estudios posautorización de tipo observacional deben ser sometidos a la consideración de un Comité Ético de Investigación Clínica (CEIC) (o Comité de Ética de la Investigación, en su caso) acreditado, con la excepción de aquellos estudios que se realicen mediante la utilización de información ya existente que no contengan datos de carácter personal.

En los estudios que requieran entrevistar al sujeto o en aquellos en los que, utilizando otras fuentes de información, no sea posible adoptar un procedimiento de disociación seguro que garantice que la información que se maneja no contenga datos de carácter personal, se solicitará el consentimiento informado de los sujetos, el cual deberá ser otorgado por escrito, de acuerdo con la normativa vigente.

Cuando los sujetos sean menores o incapaces se solicitará el consentimiento informado de los tutores legales.

El promotor y los investigadores del estudio deben garantizar la confidencialidad de los datos de los sujetos y velar por que se cumpla en todo momento con lo establecido por la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal y Real Decreto 1720/2007, de 21 de diciembre.

Los estudios posautorización de tipo observacional están exentos de la obligatoriedad de suscripción de un seguro.

Cuando se trate de un estudio posautorización observacional de seguimiento prospectivo, el promotor y el investigador principal deberán expresar específicamente en el protocolo los procedimientos que se emplearán para garantizar que la realización del estudio no modificará los hábitos de prescripción del médico, o de dispensación del farmacéutico (en caso de medicamentos que no requieran prescripción). La prescripción del medicamento habrá de seguir los cauces habituales. Si se considera necesario un suministro del medicamento diferente al habitual, deberá justificarse apropiadamente en el protocolo.

Los investigadores deberán asegurarse de que su participación en el estudio no interfiere con sus cometidos asistenciales.

Los investigadores podrán recibir una compensación proporcional al tiempo y responsabilidades adicionales dedicados al estudio, sin perjuicio de las normas internas de las entidades empleadoras de los investigadores relativas a esta cuestión. La percepción económica habrá de ser, en todo caso, explícita y transparente y deberá ser puesto en conocimiento del CEIC que evalúe el estudio. La participación en el estudio de los investigadores habrá de ser libre, voluntaria e independiente.

6. IDENTIFICACIÓN DE LOS RESPONSABLES Y ELEMENTOS QUE DEBE CONTENER EL PROTOCOLO DEL ESTUDIO

6.1. Identificación de los responsables del estudio.

En todos los estudios deben identificarse las figuras del promotor y el investigador principal o coordinador como responsables últimos de la investigación.

Es promotor de un estudio posautorización toda aquella persona física o jurídica que tiene interés en su realización y asume las siguientes obligaciones:

a) Firmar con el investigador coordinador el protocolo y cualquier modificación del mismo.

b) Suministrar a los investigadores el protocolo y la ficha técnica de los medicamentos a estudiar.

c) Remitir el protocolo al CEIC (o Comité de Ética de la Investigación, en su caso).

d) Solicitar la autorización de la Administración, cuando proceda, y presentar la documentación correspondiente.

e) Presentar los informes de seguimiento y final, en los plazos establecidos y comunicar, en su caso, la interrupción y las razones de la misma.

f) Entregar copia del protocolo y de los documentos que acrediten el seguimiento de los procedimientos establecidos en las presentes directrices a los responsables de las entidades proveedoras de servicios de atención a la salud donde se vaya a realizar el estudio.

g) Aplicar un control de calidad en la obtención y el manejo de datos para asegurar que los datos son fiables.

h) Comunicar las sospechas de reacciones adversas graves que surjan a lo largo del estudio al punto de contacto designado por el órgano competente en materia de farmacovigilancia de la Comunidad Autónoma donde ejerza su actividad el profesional sanitario que comunicó el caso.

i) Identificar las fuentes de financiación del estudio

j) Firmar, en su caso, el contrato con la entidad competente

k) Hacer públicos los resultados del estudio, a ser posible, a través de una revista científica.

El promotor podrá designar a un monitor como vínculo entre él y los investigadores. Su principal obligación es asegurarse de que el estudio se está realizando conforme a lo exigido en el protocolo. Para ello, podrá realizar cuantas comprobaciones considere necesarias.

Los profesionales sanitarios que contribuyan al estudio recogiendo información serán considerados como investigadores. Son obligaciones de éstos:

a) Firmar un compromiso en el que se reconocen como investigadores del estudio y afirman que conocen el protocolo y cualquier modificación del mismo, y están de acuerdo con él en todos sus términos.

b) Informar a los sujetos de investigación y obtener su consentimiento.

c) Recoger, registrar y notificar los datos de forma correcta respondiendo de su actualización y calidad ante las auditorías oportunas.

d) Notificar al promotor los acontecimientos adversos según se establezca en el protocolo.

e) Respetar la confidencialidad de los datos del sujeto.

f) Facilitar las visitas de monitorización del monitor, las auditorías del promotor y las inspecciones de las autoridades sanitarias.

g) Saber responder sobre los objetivos, metodología básica y significado de los resultados del estudio ante la comunidad científica y profesional.

Es investigador coordinador el profesional sanitario que dirige científicamente el estudio. Son obligaciones específicas del investigador coordinador las enumeradas anteriormente más las siguientes:

a) Firmar el protocolo y cualquier modificación del mismo junto con el promotor.

b) Co-responsabilizarse con el promotor de la elaboración de los informes de seguimiento y finales.

c) Contribuir a difundir los resultados del estudio, en colaboración con el promotor.

6.2. Elementos del Protocolo.

Siempre que sea posible, los protocolos deberán ajustarse, de forma general, a la siguiente estructura (basada en Capítulo I.7. Volumen 9A, Tabla I.7.B):

A. Título descriptivo y versión del protocolo.

B. Responsable del estudio (nombres, títulos, grados, especialidad, lugar de trabajo y direcciones de todos los responsables, incluyendo investigador coordinador, otros investigadores y monitor cuando proceda).

C. Promotor (nombre y dirección. En su caso, titular de la autorización de comercialización).

D. Resumen:

1. Identificación del promotor y dirección.

2. Título del estudio.

3. Código del protocolo (según normas oficiales de codificación).

4. Investigador principal y dirección.

5. Tipo de centros donde se prevé realizar el estudio.

6. CEIC que lo evalúa.

7. Objetivo principal.

8. Diseño.

9. Enfermedad o trastorno en estudio.

10. Datos de los medicamentos objeto de estudio.

11. Población en estudio y número total de sujetos.

12. Calendario.

13. Fuente de financiación.

E. Plan de trabajo (tareas, hitos y cronología del estudio).

F. Objetivos generales y específicos. Fundamentos.

G. Revisión crítica de la literatura.

H. Métodos:

1. Diseño y justificación.

2. Población de estudio.

3. Fuente de información.

4. Definición operativa de variables de resultado, exposición y otras.

5. Tamaño de la muestra previsto y bases para su determinación.

6. Métodos para la obtención de los datos.

7. Manejo de los datos.

8. Análisis de los datos.

9. Control de calidad.

10. Limitaciones del diseño, de la fuente de información y de los métodos de análisis.

I. Aspectos éticos/protección de los sujetos participantes:

1. Evaluación beneficio-riesgo para los sujetos de investigación.

2. Consideraciones sobre información a los sujetos y consentimiento informado.

3. Confidencialidad de los datos.

4. Interferencia con los hábitos de prescripción del médico.

J. Manejo y comunicación de reacciones adversas.

K. Planes para la difusión de los resultados.

L. Recursos para la realización del estudio y asignación de tareas. Forma de suministro del medicamento. Financiación.

M. Bibliografía.

N. Modificaciones del protocolo.

Ñ. Consideraciones prácticas:

1. Informes de seguimiento y final.

2. Difusión de los resultados

O. Anexos (al menos los siguientes):

1. Anexo 1: Cuaderno de recogida de datos.

2. Anexo 2: Compromiso del investigador coordinador.

3. Anexo 3: Conformidad del CEIC.

4. Anexo 4: Ficha Técnica del medicamento investigado.

5. Anexo 5: Hoja de información a los sujetos.

6. Anexo 6: Formulario de consentimiento informado.

7. Anexo 7: Memoria económica.

6.3. Identificación de estudio.

Sin perjuicio del código interno del protocolo de cada promotor, todos los protocolos de estudios posautorización deben identificarse con un código de 12 dígitos siguiendo las siguientes normas de codificación:

Posiciones 1-3: tres primeras letras del promotor

Posiciones 4-6: tres primeras letras del principio activo de interés (uno de ellos si hay más de uno)

Posiciones 7-10: año en curso

Posiciones 11-12: Número secuencial de 2 dígitos

Ejemplo: El promotor PANDORA desea hacer un estudio con el principio activo ACTIVINA, en el año 2002 siendo el cuarto que hace este año con dicho principio activo.

Código: PAN-ACT-2002-04

Sólo se consignará un código por protocolo. Por ejemplo, si un mismo estudio se va a realizar en 4 CC AA, en todas ellas se identificará por el mismo código.

7. PROCEDIMIENTOS ADMINISTRATIVOS PARA LOS ESTUDIOS POSAUTORIZACIÓN DE TIPO OBSERVACIONAL

En el Real Decreto 1344/2007, de 11 de octubre, en su artículo 19.3 establece que «la Agencia mantendrá un registro de las propuestas de estudio posautorización de tipo observacional, al que tendrán acceso los órganos competentes de las Comunidades Autónomas, e informará a cada promotor sobre los procedimientos a seguir en cada caso. A tal efecto, el promotor del estudio deberá remitir a la Agencia Española de Medicamentos y Productos Sanitarios el protocolo del estudio».

De acuerdo con esto, la AEMPS realizará una clasificación previa de todos los estudios clínicos o epidemiológicos no aleatorizados, que se realicen con seres humanos o con registros médicos y que tengan uno o varios medicamentos como exposición de interés en el plazo máximo de 30 días naturales desde su recepción. Para ello el promotor deberá remitir a la AEMPS el protocolo completo o un resumen amplio del mismo, donde queden perfectamente explícitos los objetivos y el diseño del estudio, indicando que el destinatario es la División de Farmacoepidemiología y Farmacovigilancia de la AEMPS. Es relevante que en esta comunicación se indique claramente que se remite para su CLASIFICACIÓN, así como la dirección postal y electrónica y el teléfono de contacto del promotor.

Se podrá presentar el protocolo en paralelo a la AEMPS para clasificación y al CEIC para evaluación. Una vez recibido el protocolo o su resumen amplio, la AEMPS remitirá al solicitante la resolución correspondiente indicando la clasificación del estudio y la ruta administrativa que el mismo deberá seguir (ver cuadro I). Para los casos de dudosa clasificación la AEMPS solicitará formalmente un informe al Comité de Coordinación de Estudios Posautorización. En dicho caso se producirá una suspensión del plazo por el tiempo que medie entre la petición de dicho informe, que será comunicada al interesado, y la recepción del mismo. Este plazo de suspensión no podrá exceder en ningún caso de tres meses.

Toda aquella documentación que se remita a la AEMPS para la clasificación de un estudio, no tendrá que ser reenviada en el momento de la solicitud de autorización y/o registro del mismo.

La AEMPS mantendrá una base de datos con la información relativa a todos los estudios posautorización que se remitan para su registro, a la que tendrán acceso para consulta y, en su caso, carga de la información correspondiente, los órganos competentes de las CC AA. En dicha base de datos constarán los aspectos administrativos y metodológicos fundamentales de los estudios.

Todos aquellos estudios que se consideren ensayos clínicos deberán seguir la normativa específica.

En el Cuadro I se resumen de forma esquemática los procedimientos administrativos que se detallan a continuación para cada tipo de estudio.

7.1. Procedimiento para la autorización de estudios posautorización de tipo observacional que sean una condición establecida en el momento de la autorización de un medicamento, o bien constituya una exigencia de la autoridad competente para aclarar cuestiones relativas a la seguridad del medicamento, o forme parte del plan de gestión de riesgos.

Este tipo de estudios se abreviarán como EPA-LA.

La normativa aplicable es el Real Decreto 1344/2007, de 11 de octubre, donde se recoge en el artículo 19.5 lo siguiente:

«Cuando la realización de un estudio posautorización de tipo observacional sea una condición establecida en el momento de la autorización de un medicamento, o bien constituya una exigencia de la autoridad competente para aclarar cuestiones relativas a la seguridad del medicamento, o forme parte del plan de gestión de riesgos que debe llevar a cabo el titular requerirá únicamente la autorización de la Agencia Española de Medicamentos y Productos Sanitarios, según los procedimientos que se establezcan al efecto. La Agencia Española de Medicamentos y Productos Sanitarios informará de estos estudios a las Comunidades Autónomas donde se vayan a realizar y los incluirá en el registro referido en el apartado 3».

Para todos los estudios clasificados como EPA-LA, el promotor deberá presentar la documentación siguiente, indicando como destinatario la División de Farmacoepidemiología y Farmacovigilancia de la AEMPS:

Carta de presentación dirigida a la División de Farmacoepidemiología y Farmacovigilancia de la AEMPS donde se solicite la autorización del estudio e indique la dirección y contacto del solicitante y la relación de documentos que se incluyen. En el caso de que el promotor no sea quien presente la documentación, se deberá incluir en la misma un documento que indique las responsabilidades delegadas por el promotor a la persona o empresa que actúa en su nombre.

Formulario resumen del protocolo (disponible en: www.aemps.es).

Protocolo completo, incluidos los anexos y cuaderno de recogida de datos, y donde conste el número de pacientes que se pretenden incluir en España.

Dictamen favorable del estudio por un CEIC acreditado en España.

Acreditación documental de que el estudio ha sido requerido por la autoridad competente, o que forme parte del plan de gestión de riesgos del producto.

Acreditación documental de la revisión por parte de la autoridad sanitaria competente que instó la realización del estudio.

Listado de CC AA y centros sanitarios en los que se pretende realizar el estudio, así como los investigadores participantes.

Si el estudio se pretende realizar en otros países, situación del mismo en éstos.

La AEMPS evaluará la pertinencia del estudio y resolverá favorable o desfavorablemente el mismo en el plazo máximo de 60 días naturales desde su recepción. Si pasado este plazo, la AEMPS no ha emitido informe desfavorable se dará por aprobado el estudio.

En el caso de que fuera precisa la aportación de cualquier documentación o información adicional a efectos de la autorización del estudio, y una vez requerida la misma, se podrá suspender el plazo para la resolución del procedimiento de acuerdo con lo establecido en el artículo 42.5 de la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común, siendo en este caso notificada dicha suspensión al interesado en la comunicación del requerimiento.

Una vez aprobado el estudio por la AEMPS, deberá contratarse la realización con los centros sanitarios donde se vaya a realizar, siguiendo los requisitos que cada Comunidad Autónoma establezca, lo que incluirá necesariamente la resolución de la AEMPS por la que se autoriza el estudio.

Para los estudios que formen parte del plan de gestión de riesgos, es necesario que se solicite su autorización de manera independiente a la presentación en la AEMPS del plan de gestión de riesgos.

La AEMPS mantendrá informados a los órganos competentes de las CC AA sobre la autorización de estos estudios, a través de la aplicación informática de registro de estudios posautorización u otro procedimiento alternativo que se acuerde.

No se podrán realizar estudios EPA-LA sin la preceptiva autorización de la AEMPS. El incumplimiento de lo anteriormente expuesto dará lugar a la incoación del correspondiente expediente sancionador.

7.2. Procedimiento simplificado para la autorización de estudios posautorización de tipo observacional de seguimiento prospectivo promovidos por las Administraciones sanitarias o financiados con fondos públicos.

Este tipo de estudios se abreviarán como EPA-AS

De acuerdo con el artículo 19.6 del Real Decreto 1344/2007, de 11 de octubre, «cuando se trate de estudios promovidos por las Administraciones sanitarias o financiados con fondos públicos, se establecerán procedimientos simplificados al objeto de facilitar su realización y que se acordarán en el Comité de Coordinación de Estudios Posautorización».

El promotor de un estudio posautorización de seguimiento prospectivo que responda a los criterios mencionados, enviará el protocolo del estudio, junto con el formulario resumen del mismo (disponible en www.aemps.es) y el dictamen favorable del CEIC, a la Secretaría del Comité de Coordinación de Estudios Posautorización (División de Farmacoepidemiología y Farmacovigilancia de la AEMPS).

La Secretaría del Comité distribuirá el protocolo del estudio a sus miembros, junto con un informe en el que consten las razones de su inclusión en la categoría de estudios promovidos por las Administraciones sanitarias o financiados con fondos públicos. El Comité emitirá informe sobre la solicitud de autorización del estudio, correspondiendo a la AEMPS, de acuerdo con el pronunciamiento previo del Comité, emitir la resolución correspondiente. Dicha resolución se emitirá en un plazo máximo de 30 días naturales a

contar desde la solicitud de autorización. Si pasado este plazo, la AEMPS no ha emitido informe favorable se dará por autorizado el estudio.

En el caso de que fuera precisa la aportación de cualquier documentación o información adicional a efectos de la autorización del estudio, y una vez requerida la misma, se podrá suspender el plazo para la resolución del procedimiento de acuerdo con lo establecido en el artículo 42.5 de la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común, siendo en este caso notificada dicha suspensión al interesado en la comunicación del requerimiento.

El promotor informará a los responsables de las entidades proveedoras de servicios sanitarios donde prevea llevarse a cabo el estudio, o a los organismos que la Comunidad Autónoma haya designado para este fin, y les entregará copia del protocolo y de los documentos que acrediten su aprobación. La gestión y formalización del contrato estará sujeta a los requisitos específicos de cada Comunidad Autónoma.

7.3. Procedimiento para la autorización de estudios posautorización de tipo observacional de seguimiento prospectivo con medicamentos, no incluidos en los epígrafes anteriores (7.1 y 7.2).

Este tipo de estudios se abreviarán como EPA-SP.

Una vez clasificado el estudio como EPA-SP por la AEMPS, el promotor presentará el protocolo del estudio, junto con el material informativo que se prevea enviar a los profesionales sanitarios, a los órganos competentes de las CC AA donde se vaya a realizar el estudio y simultáneamente a la AEMPS, una vez obtenida la conformidad de un CEIC acreditado, junto con el formulario resumen del estudio (disponible en www.aemps.es). El promotor hará constar en el protocolo si el estudio se ha presentado con anterioridad a algún otro CEIC e informará del resultado de su evaluación.

El promotor deberá presentar en las CC AA donde se pretenda realizar el estudio la siguiente documentación:

Carta de presentación dirigida a los responsables de esta materia en la Comunidad Autónoma en la que se solicite la autorización del estudio e indique la dirección y contacto del solicitante y la relación de documentos que se incluyen. En el caso de que el promotor no sea quien presente la documentación, se deberá incluir en la misma un documento que indique las responsabilidades delegadas por el promotor a la persona o empresa que actúa en su nombre.

Formulario resumen del protocolo (disponible en: www.aemps.es).

Resolución de la AEMPS sobre la clasificación del estudio

Protocolo completo incluidos los anexos, y donde conste el número de pacientes que se pretenden incluir en España, desglosado por Comunidad Autónoma.

Dictamen favorable del estudio por un CEIC acreditado en España.

Listado de centros sanitarios donde se pretende realizar el estudio, desglosado por Comunidad Autónoma.

Listado de investigadores participantes en la Comunidad Autónoma.

Si el estudio se pretende realizar en otros países, situación del mismo en éstos.

Documento acreditativo de haber satisfecho las tasas correspondientes, en aquellas CC AA donde se exijan.

Los órganos competentes de las CC AA evaluarán la pertinencia del estudio y resolverán favorable o desfavorablemente el mismo en el plazo máximo de 90 días naturales desde su recepción. Si pasado este plazo la Comunidad Autónoma correspondiente no ha emitido informe desfavorable se dará por aprobado el estudio en el ámbito de dicha Comunidad Autónoma.

En el caso de que fuera precisa la aportación de cualquier documentación o información adicional a efectos de la autorización del estudio, y una vez requerida la misma, se podrá suspender el plazo para la resolución del procedimiento de acuerdo con lo establecido en el artículo 42.5 de la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común, siendo en este caso notificada dicha suspensión al interesado en la comunicación del requerimiento.

La Comunidad Autónoma informará de la resolución a la AEMPS (normalmente a través de la aplicación informática), y al promotor.

El promotor informará a los responsables de las entidades proveedoras de servicios sanitarios donde prevea llevarse a cabo el estudio, o a los organismos que la Comunidad Autónoma haya designado para este fin, y les entregará copia del protocolo y de los documentos que acrediten su aprobación. La gestión y formalización del contrato estará sujeta a los requisitos específicos de cada Comunidad Autónoma.

Para la evaluación de los protocolos de los estudios y la revisión de los informes de seguimiento y finales, las CC AA podrán solicitar la colaboración de expertos, entre los que se encontrarán los técnicos correspondientes del Sistema Español de Farmacovigilancia de medicamentos de uso humano.

No se podrán realizar estudios EPA-SP sin la preceptiva autorización de los órganos competentes de las Comunidades Autónomas involucradas. El incumplimiento de lo anteriormente expuesto dará lugar a la incoación del correspondiente expediente sancionador.

7.4. Procedimiento a seguir para otros estudios posautorización de tipo observacional.

Este tipo de estudios se abreviarán como EPA-OD.

En este grupo se encuentran los estudios posautorización que no hayan sido categorizados como EPA-LA y respondan a diseños diferentes al de «seguimiento prospectivo», por ejemplo, estudios de casos y controles, estudios transversales o

estudios de cohorte retrospectivos. Una vez clasificado el estudio como EPA-OD por la AEMPS, el promotor deberá remitir a la AEMPS el protocolo junto con la aprobación del mismo por un CEIC acreditado en España y el formulario resumen del protocolo (disponible en www.aemps.es). Si para la clasificación del estudio se presenta esta documentación, no requerirá ningún trámite adicional. La AEMPS procederá a registrar oportunamente el estudio e informará a los órganos competentes de las CC AA. En el caso de que el promotor no sea quien presente la documentación, se deberá incluir en la misma un documento que indique las responsabilidades delegadas por el promotor a la persona o empresa que actúa en su nombre.

Los estudios EPA-OD no requieren autorización por parte de la AEMPS ni de los órganos competentes de las CC AA donde se vayan a realizar, si bien el promotor tendrá que informar a los responsables de las entidades proveedoras de servicios sanitarios donde se lleve a cabo el estudio y les entregará copia del protocolo y de los documentos que acrediten la aprobación por parte del CEIC y la clasificación de la AEMPS. Asimismo estos documentos se entregarán a los órganos competentes de las CC AA, cuando sea requerido. La gestión y formalización del contrato estará sujeta a los requisitos específicos de cada Comunidad Autónoma.

7.5. Procedimiento para la realización de estudios observacionales que no sean posautorización.

Estos estudios se abreviarán como No-EPA.

Se trata de aquellos estudios en los que el factor de exposición fundamental investigado no son medicamentos. En caso de que se recoja información sobre medicamentos, el protocolo tendrá que ser presentado a la AEMPS para su clasificación. La AEMPS procederá a registrar oportunamente el estudio e informará a los órganos competentes de las CC AA.

Los estudios No-EPA no requieren autorización por parte de la AEMPS ni de los órganos competentes de las CC AA donde se vayan a realizar, pero sí es necesario presentarlo a un CEIC acreditado y obtener su dictamen favorable. El promotor tendrá que informar a los responsables de las entidades proveedoras de servicios sanitarios donde se lleve a cabo el estudio y les entregará copia del protocolo y de los documentos que acrediten la aprobación por parte del CEIC y, en su caso, la clasificación de la AEMPS. Asimismo estos documentos se entregarán a los órganos competentes de las CC AA, cuando sea requerido. La gestión y formalización del contrato estará sujeta a los requisitos específicos de cada Comunidad Autónoma.

8. SEGUIMIENTO DE LOS ESTUDIOS POSAUTORIZACIÓN

Todos los estudios posautorización requerirán para su inicio el oportuno contrato del promotor con los responsables de las entidades proveedoras de servicios sanitarios donde prevea llevarse a cabo el estudio o el visto bueno del director del centro conforme a los procedimientos específicos que se manejen en cada centro.

El promotor comunicará la fecha efectiva de comienzo del estudio a los órganos competentes de las CC AA donde se prevea realizar y a la AEMPS, a menos que ya venga indicado en el propio protocolo.

8.1. Enmiendas al protocolo

Cuando la enmienda afecte a aspectos fundamentales del protocolo del estudio (en particular a los apartados de objetivos, métodos, aspectos éticos-ver 6.2), se someterá de nuevo a la evaluación del CEIC que informó favorablemente sobre el mismo y se solicitará autorización administrativa para dicha enmienda a quien corresponda en función del tipo de estudio. Para el resto de enmiendas bastará con que se informe de las modificaciones efectuadas, justificando por qué dicha enmienda no afecta a aspectos fundamentales del protocolo del estudio.

En caso de duda sobre la consideración de la enmienda, se puede remitir consulta a la AEMPS a través de la dirección de correo electrónico farmacoepi@aemps.es .

8.2. Informes de seguimiento y finales.

Para los estudios EPA-LA, EPA-SP y EPA-AS que sean considerados como de seguimiento prospectivo el promotor deberá enviar un informe de seguimiento anual, o antes si así se solicita. Asimismo, el promotor informará de forma inmediata sobre cualquier incidencia relevante (interrupción, problema grave de seguridad, etc.) que pueda producirse en el transcurso del estudio. Todas estas comunicaciones se presentarán a los órganos competentes de las CC AA involucradas y a la AEMPS.

Para todos los estudios posautorización, el promotor deberá remitir un informe final entre los tres y seis meses después de la finalización del estudio, a la AEMPS y a los órganos competentes de las CC AA donde se realizó.

8.3. Comunicación de sospechas de reacciones adversas

Para los estudios catalogados como EPA-SP, EPA-AS y para los EPA-LA que sean considerados como de seguimiento prospectivo, las sospechas de reacciones adversas graves que se detecten durante el transcurso del estudio se notificarán al punto de contacto designado por el órgano competente en materia de farmacovigilancia de la Comunidad Autónoma donde ejerza su actividad el profesional sanitario que notifique el caso, en el plazo máximo de 15 días naturales desde que se tuvo conocimiento de la sospecha de reacción adversa. Esta notificación se realizará obligatoriamente de forma electrónica si el promotor es una compañía farmacéutica, por parte del responsable de farmacovigilancia siguiendo las instrucciones publicadas la AEMPS. La AEMPS pondrá a disposición del titular de la autorización de comercialización dentro de los 15 días naturales siguientes a su recepción, las notificaciones sobre sospechas de reacciones adversas graves que se detecten en el transcurso de un EPA, haciendo referencia al código del estudio.

En el caso de que el promotor sea un grupo de profesionales (v. gr. sociedades científicas) podrá optar por una de la dos siguientes opciones: 1) tarjeta amarilla al centro autonómico de farmacovigilancia correspondiente, indicando en observaciones el nombre y el código del estudio del cual proviene; o 2) utilizar la carga «on-line» a

través del portal SINAEM de la AEMPS, siguiendo las instrucciones publicadas por la AEMPS (esta segunda opción es la recomendada).

Si el promotor es un profesional sanitario notificará las sospechas de reacciones adversas a través de tarjeta amarilla al centro autonómico de farmacovigilancia correspondiente, indicando igualmente el nombre y el código del estudio del cual proviene.

De acuerdo con el Capítulo I.7 del Volumen 9A, aquellos estudios en los que no sea posible o no sea apropiado hacer una evaluación individual de la relación de causalidad entre los acontecimientos clínicos y los medicamentos de interés, la notificación individual de sospechas de reacciones adversas no será necesaria. Los estudios etiquetados como EPA-OD, o EPA-LA que no sean de seguimiento prospectivo, entran dentro de esta categoría y para ellos no se precisará la notificación expeditiva de sospechas de reacciones adversas, a menos que se indique otra cosa por la AEMPS en el momento del registro del estudio.

Además de lo especificado en el párrafo anterior, cualquier problema de seguridad relevante que se detecte durante el transcurso del estudio será puesto en conocimiento de la AEMPS y de los órganos competentes de las CC AA involucradas, con independencia del diseño y catalogación del estudio.

8.4. Archivo de los documentos del estudio:

La documentación relativa al estudio posautorización constituye el archivo maestro del mismo y constará de los documentos esenciales que permitan la evaluación de la realización de un estudio posautorización y de la calidad de los datos obtenidos. Estos documentos deberán demostrar el cumplimiento por parte del investigador y del promotor de los requisitos establecidos para los estudios posautorización.

El archivo maestro del estudio posautorización proporcionará la base para las auditorías que pueda realizar el promotor a través de auditores independientes y para las inspecciones de las autoridades competentes.

El promotor y el investigador conservarán los documentos y materiales esenciales de cada estudio durante al menos cinco años tras la finalización del mismo, o durante un período más largo si así lo disponen otros requisitos aplicables.

Los documentos y materiales esenciales deberán archivarse de forma que se puedan poner fácilmente a disposición de las autoridades competentes, en caso de que los soliciten.

La historia clínica de cada paciente del estudio deberá ser custodiada con arreglo a lo dispuesto en la Ley 41/2002, de 14 de noviembre, básica Reguladora de la Autonomía del Paciente y de Derechos y Obligaciones en Materia de Información y Documentación Clínica, y la legislación autonómica aplicable, y conforme al período máximo establecido por el hospital, la institución o la consulta privada. Asimismo, se deberá contemplar lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal y el Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de dicha Ley.

Todos los cambios en la titularidad de los datos, documentos y materiales deberán documentarse. El nuevo titular asumirá las responsabilidades de las tareas de archivo y conservación de los datos.

El promotor nombrará la persona de su organización responsable de los archivos y el acceso a los mismos deberá limitarse a las personas designadas.

Los soportes utilizados para la conservación de los documentos esenciales deberán garantizar que los documentos y materiales permanezcan completos y legibles durante el período de conservación previsto y que estén a disposición de las autoridades competentes en caso de que los soliciten. Cualquier modificación de los registros habrá de ser trazable, permitiendo conocer el dato inicial y el corregido, así como la fecha y firma del autor del cambio.

8.5. Inspecciones:

Las autoridades sanitarias competentes de las CC AA, en el ámbito de sus competencias, verificarán el cumplimiento de las prescripciones legales relativas a los estudios posautorización que se realicen en España, a través de las correspondientes inspecciones y de acuerdo con los procedimientos que se establezcan.

Las inspecciones serán llevadas a cabo antes, durante o después de la realización del estudio por inspectores debidamente cualificados. Se podrán hacer inspecciones en los lugares relacionados con la realización del estudio y, entre otros, en el centro o centros sanitarios en los que se lleve a cabo el estudio, en cualquier laboratorio de análisis o centro de diagnóstico utilizado, en las instalaciones del promotor y/o de las organizaciones o empresas de investigación implicadas por contrato en la realización del estudio y al CEIC que lo evaluó.

CUADRO I: Rutas administrativas de los Estudios Posautorización

Ver figura

Abreviaturas y leyendas en el Cuadro I:

* En alguna Comunidad Autónoma este paso es previo a la autorización de la Administración Sanitaria.

EPA: Estudio posautorización.

EPA-LA: Estudios posautorización cuya realización tiene lugar a instancia de las autoridades reguladoras y ligada a la autorización de comercialización (AEMPS o Agencia Europea de Medicamentos). Se incluyen en esta vía administrativa tanto los estudios ligados a la autorización como los estudios de seguridad a requerimiento de las autoridades sanitarias y los incluidos en los planes de gestión de riesgos.

EPA-AS: Estudio posautorización promovido por las Administraciones Sanitarias (AS) o financiado con fondos públicos.

EPA-SP: Estudio posautorización de seguimiento prospectivo que no corresponde a ninguna de las dos categorías anteriores.

EPA-OD: Estudios posautorización con diseño diferente al de seguimiento prospectivo, por ejemplo, estudios transversales o retrospectivos.

No-EPA: Estudios en los que el factor de exposición fundamental investigado no es un medicamento; por ejemplo estudios de incidencia o de prevalencia de enfermedades, etcétera.

servicios con terceros, que deberán ser además para la realización de sus funciones.

c) Perspectivas de actuación para los años de duración del programa operativo parcial.

3. *Duración y objetivos perseguidos por el proyecto de programa operativo*

Se deberán especificar detalladamente los objetivos a perseguir teniendo especialmente en cuenta lo dispuesto en la letra a) del apartado 4 del artículo 15 del Reglamento (CE) n.º 2200/96.

4. *Medidas desglosadas por acciones y acciones desglosadas en inversiones y conceptos de gasto a realizar para alcanzar los objetivos fijados*

a) Para cada acción, inversión y concepto de gasto previstas, deberán presentar:

Descripción detallada de las mismas.

Comunidad autónoma donde va a llevarse a cabo.

Objetivos de su realización de entre los enumerados en el apartado 4 del Reglamento CE) n.º 2200/96.

Medios humanos y materiales necesarios para su realización.

Presupuesto detallado por unidades de obra.

Justificación de la necesidad de su realización.

b) Anexo conteniendo la ubicación de las inversiones o realización de gastos desglosados por comunidades autónomas.

5. *Aspectos financieros*

a) Calendario de realización de las medidas, acciones, inversiones y conceptos de gasto, por años.

b) Calendario de financiación de las medidas, acciones, inversiones y conceptos de gasto, por años.

ANEXO VII

Documentación que debe acompañar a los proyectos de programas operativos parciales

a) Compromiso de la asociación de organizaciones de productores de cumplir las disposiciones de los Reglamentos (CE) 2200/96 y 1433/03.

b) Certificación emitida por el secretario de la asociación de que los miembros de la asociación de organizaciones de productores que no tengan la condición de organización de productores en virtud del Reglamento (CE) n.º 2200/96 no han participado en la toma de decisiones que afecten del programa operativo parcial ni se benefician directamente de disposiciones financiadas por la Comunidad.

c) Certificación emitida por el secretario de la asociación que acredite el cumplimiento de lo dispuesto en la letra b) del apartado 1 del artículo 21 de este real decreto.

d) Compromiso de la asociación de organizaciones de productores de no acogerse, directa o indirectamente, a una doble financiación, comunitaria o nacional, por las medidas incluidas en el programa operativo parcial.

e) Para la primera anualidad del programa operativo parcial la documentación que figura en el apartado 1 del artículo 23 de este real decreto.

f) Una certificación emitida por el secretario de la asociación de organizaciones de productores que acredite que el programa operativo parcial ha sido aprobado por la asamblea u órgano equivalente de la asociación, en función de su personalidad jurídica. En dicha certificación deberán figurar las líneas directrices del proyecto de programa operativo parcial, especificando medidas y acciones a desarrollar.

g) Certificado de la entidad financiera depositaria de la cuenta bancaria para el movimiento exclusivo del fondo con indicación de su sucursal, el número de cuenta y la denominación de ésta: «Programa operativo parcial de la asociación de organizaciones de productores... (denominación de la asociación)».

MINISTERIO DE SANIDAD Y CONSUMO

1916 *REAL DECRETO 65/2006, de 30 de enero, por el que se establecen requisitos para la importación y exportación de muestras biológicas.*

El control fronterizo de cualquier sustancia con implicaciones sobre la salud pública ha venido siendo una constante en nuestro ordenamiento jurídico y, desde la aprobación de la Constitución Española en 1978, es una competencia atribuida en exclusiva al Estado, recogida en el artículo 149.1.16.ª Desde entonces, y con la finalidad de evitar cualquier riesgo sanitario, se controlan los alimentos, los medicamentos y las materias primas para su fabricación, así como las muestras de cualquier tipo. Estos controles se realizan a través de la estructura periférica de la Administración General de Estado bajo las directrices del Ministerio de Sanidad y Consumo, y se han establecido las diferencias necesarias en cuanto al tipo de productos y las unidades administrativas especializadas en llevarlos a cabo.

La variedad de los productos objeto de importación y exportación aconseja establecer normas en cuanto a la documentación sanitaria y los demás documentos exigibles a los importadores y exportadores, que al mismo tiempo permitan un despacho rápido de los productos que puedan alterarse. Por ello, este real decreto especifica las condiciones para la importación y exportación de muestras de sustancias biológicas y establece un sistema de registro voluntario que permite su importación y exportación continua, lo que resulta imprescindible en estos momentos por el incremento constante de la importación y la exportación de muestras con finalidad diagnóstica, analítica o de investigación.

En el establecimiento del registro de importadores y exportadores se ha tenido presente la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal, en lo que se refiere a las muestras de personas físicas que deban aparecer identificadas por sus datos personales, y asimismo se han mantenido las cautelas de dicha ley en el tratamiento informático y los derechos que reconoce sobre acceso, rectificación y cancelación de los datos.

Este real decreto, que establece los requisitos para la importación y exportación de muestras biológicas, se dicta al amparo de lo dispuesto en el artículo 149.1.16.ª de la Constitución Española y de acuerdo con lo establecido en la Ley Orgánica 3/1986, de 14 de abril, de medidas especiales en materia de Salud Pública, y en el artículo 38 de la Ley 14/1986, de 25 de abril, General de Sanidad.

En su virtud, a propuesta de la Ministra de Sanidad y Consumo, con la aprobación previa del Ministro de Administraciones Públicas, de acuerdo con el Consejo de Estado y previa deliberación del Consejo de Ministros en su reunión del día 27 de enero de 2006,

D I S P O N G O :

Artículo 1. *Objeto.*

Este real decreto establece los requisitos para la importación y exportación de muestras biológicas para el diagnóstico o la investigación en seres humanos y crea un registro voluntario de importadores y exportadores de este tipo de muestras.

Artículo 2. *Ámbito de aplicación.*

1. A los efectos de este real decreto se considera muestra biológica cualquier material humano o de otra procedencia, así como cualquier sustancia, patógena o no, que se destine al diagnóstico o investigación en seres humanos, incluidas las sustancias infecciosas tal como se definen en las normas para el transporte de sustancias infecciosas y especímenes diagnósticos aprobadas por la Organización Mundial de la Salud.

Se incluyen también las muestras destinadas a la evaluación del funcionamiento de reactivos de diagnóstico in vitro, siempre que sean de aplicación en seres humanos; así como la importación y exportación de células progenitoras hematopoyéticas, exclusivamente para las realizadas por la Organización Nacional de Trasplantes en la búsqueda de donantes no emparentados.

2. Quedan excluidas del ámbito de este real decreto las materias primas destinadas a la elaboración de medicamentos, productos sanitarios, productos sanitarios para diagnóstico in vitro, cosméticos, productos de higiene y biocidas de uso clínico o personal.

De igual forma, se excluye la importación y exportación de embriones y gametos humanos, sangre del cordón umbilical, células y tejidos fetales, células progenitoras hematopoyéticas, células troncales adultas y embrionarias y células de la médula ósea, así como los órganos y tejidos humanos para trasplante, con finalidad terapéutica o de restauración de funciones.

Artículo 3. *Definiciones.*

A los efectos de este real decreto se entiende por:

a) Sustancia infecciosa: una sustancia que contiene un microorganismo viable, tal como una bacteria, un virus, un parásito, un hongo y un prión, que se sabe o se sospecha de forma razonable que causa enfermedad en humanos o animales.

b) Espécimen diagnóstico: cualquier material humano o animal incluyendo, pero no limitando, excretas, sangre o sus componentes, tejidos y fluidos tisulares, colectados con el propósito de hacer un diagnóstico, excluyendo animales vivos infectados.

Artículo 4. *Puntos habilitados para la entrada y salida de muestras.*

La entrada y salida de este tipo de muestras sólo se efectuará en los recintos aduaneros relacionados en el anexo I.

Artículo 5. *Requisitos para la importación y exportación de muestras biológicas.*

1. Sin perjuicio de lo dispuesto en el artículo 6 para los importadores y exportadores inscritos en este Registro, la importación y exportación de muestras biológicas quedan sujetas a los requisitos generales previstos en este artículo.

2. Para la importación de muestras biológicas, el interesado deberá dirigir una solicitud a la Dirección General de Salud Pública en la que se manifieste el tipo de muestra que se pretende importar. A esta solicitud se acompañará la documentación siguiente:

a) Certificación sanitaria de origen en la que la autoridad competente en origen identifique el envío, sus características y el posible riesgo sanitario si lo hubiere. Se cumplimentará el anexo II, si se trata de importadores ocasionales, o el anexo III, si se trata de importadores registrados.

b) Declaración escrita en la que el destinatario del producto se responsabilice de su correcta utilización y destrucción.

c) Acreditación de la actividad del importador: el organismo importador debe estar suficientemente acreditado en función de su actividad y cumplir la normativa de seguridad laboral aplicable a estos productos.

d) Modelo de despacho cumplimentado, según anexo IV.

Los envíos cumplirán las normas de transporte, embalaje, etiquetado y documentación que estipulan las normas nacionales e internacionales.

La resolución por la que se autorice o deniegue la importación de muestras biológicas se adoptará según lo previsto en la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común.

3. Para la exportación de muestras biológicas, el interesado deberá presentar una declaración a la Dirección General de Salud Pública en la que figure la información necesaria para identificar la muestra y su destino.

La resolución por la que se autorice o deniegue la exportación de muestras biológicas se adoptará según lo previsto en la Ley 30/1992, de 26 de noviembre.

En el caso de que la autoridad sanitaria de destino exija un certificado sanitario de origen, éste se solicitará a la citada Dirección General, que establecerá en cada caso los requisitos correspondientes. Este certificado se expedirá de forma automática si el interesado se encuentra inscrito en el Registro de importadores y exportadores de muestras biológicas.

Artículo 6. *Registro voluntario de importadores y exportadores de muestras biológicas.*

1. Los importadores y exportadores, personas físicas o jurídicas, que de forma regular –al menos una vez al trimestre– efectúen operaciones de importación y exportación de muestras, podrán solicitar su inscripción en el Registro de importadores y exportadores de muestras biológicas, que se crea en el Ministerio de Sanidad y Consumo, adscrito a la Dirección General de Salud Pública y que será gestionado por la Subdirección General de Sanidad Exterior.

2. La inscripción en este Registro, en el caso de las importaciones, exime de la obligación de presentar el certificado de la autoridad sanitaria de origen descrito en el artículo 5.2.a) y, en el caso de las exportaciones, permite la obtención automática del certificado en el que se determine el tipo de productos y el período de tiempo en el que se efectúan las correspondientes operaciones.

Artículo 7. *Requisitos para la inscripción en el Registro.*

1. Los importadores que soliciten estar incluidos en el Registro de importadores y exportadores de muestras biológicas deberán cumplir los siguientes requisitos:

a) Aportar el documento de la autoridad sanitaria competente en el país de origen o de los centros autorizados a tal efecto, que certifique que el centro expedidor cuenta con la autorización sanitaria para la manipulación y exportación de muestras, especificando el tipo de muestras para el que está autorizado.

b) Presentar el certificado de la autoridad sanitaria española en el que se indique que cuenta con los medios adecuados para la manipulación y posterior destrucción del producto una vez utilizado, por sí mismo o a través de empresas especializadas. En este caso se indicará también el tipo de muestras para el que está autorizado.

En el caso de donantes de progenitores hematopoyéticos y bancos de sangre de cordón umbilical de países no pertenecientes a la Unión Europea, reconocidos por la Asociación Mundial de Donantes de Médula (WMDA), así como en la búsqueda de donantes no emparentados, bastará para la inscripción en este Registro que se aporte por la Organización Nacional de Trasplantes una relación que incluya los Centros que realizan esta función y se encuentren acreditados para ello.

En el supuesto de personas físicas o jurídicas inscritas en este Registro, bastará que citen en cada envío su número de inscripción y aporten la documentación que identifica las muestras, según los anexos III y IV. En el caso de las muestras a que se refiere el párrafo anterior, se cumplimentará el documento que figura como anexo V.

2. Las personas físicas o jurídicas que pretendan exportar muestras de forma permanente presentarán el certificado de la autoridad sanitaria competente, dirigido a la Dirección General de Salud Pública, en el que se indique que cuentan con los medios adecuados para la obtención y manipulación de las muestras, así como para su adecuado envasado y transporte.

Artículo 8. *Validez de la inscripción.*

Los importadores y exportadores inscritos en este Registro deberán renovar la documentación cada cinco años o actualizarla cuando exista una modificación en el tipo de muestra a importar o exportar, para lo que aportarán la documentación indicada en el artículo anterior.

La falta de renovación, así como cualquier variación en el tipo de muestras no autorizadas, dará lugar a la baja en el Registro de importadores y exportadores.

Artículo 9. *Resolución sobre la inscripción en el Registro.*

La resolución sobre la inclusión y exclusión en este Registro corresponde a la Dirección General de Salud Pública, que deberá resolver y notificar en el plazo de un mes; las solicitudes sobre las que no haya recaído resolución expresa transcurrido dicho plazo se considerarán aprobadas.

Contra las resoluciones por las que se conceda o deniegue la inscripción se podrá recurrir según lo establecido en la Ley 30/1992, de 26 de diciembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común.

Artículo 10. *Tratamiento de datos de carácter personal.*

1. En el caso de que fuera necesario solicitar datos de carácter personal, referidos a las muestras de personas físicas concretas, para su inclusión en el Registro de importadores o exportadores, se estará a lo dispuesto en el artículo 5.1 de la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal, informándoles de modo expreso e inequívoco:

a) De la existencia de un fichero o tratamiento de datos de carácter personal, de la finalidad de la recogida de estos datos y de los destinatarios de la información.

b) Del carácter obligatorio o facultativo de su respuesta a las preguntas que les sean planteadas.

c) De las consecuencias de la obtención de los datos o de la negativa a suministrarlos.

d) De la posibilidad de ejercer los derechos de acceso, rectificación, cancelación y oposición.

e) De la identidad y dirección del responsable del tratamiento o, en su caso, de su representante.

2. Este Registro no será público y sólo se expedirá certificación de los datos personales inscritos en él a solicitud de la persona inscrita; de las administraciones competentes en materia de sanidad exterior o de seguridad de la Unión Europea; de terceros países o de los organismos internacionales, previa justificación por los mismos de la necesidad de los datos. A estos efectos, se entenderá prestado el consentimiento por el interesado mediante su solicitud de inclusión en el Registro, extremo del que se le informará expresamente. Cuando se expidan certificaciones para las administraciones aludidas, se les hará la advertencia de que los datos certificados no son públicos y que sólo pueden ser utilizados para la finalidad exclusiva que haya justificado la expedición de la certificación.

A este fin se incluye en el dorso de los correspondientes anexos de este real decreto una nota informativa, referida únicamente a las personas físicas, en la que se hacen constar estos derechos.

3. En relación con la estructura del Registro de importadores y exportadores, se estará a lo dispuesto en el artículo 20.2 de la Ley Orgánica 15/1999, de 13 de diciembre. La responsabilidad sobre el uso interno por la Administración General del Estado de los datos de carácter personal recogidos en este Registro corresponderá a la Dirección General de Salud Pública, que también asegurará el ejercicio de los derechos de acceso, rectificación, cancelación y oposición.

Artículo 11. *Facultades de la Administración General del Estado.*

En los supuestos en que existan sospechas de que en una importación o exportación de productos a los que se refiere este real decreto estos puedan resultar potencialmente peligrosos en determinadas situaciones, la autoridad sanitaria adoptará las medidas necesarias para impedir su exportación o importación o para someter las autorizaciones a condiciones especiales.

Artículo 12. *Colaboración con las comunidades autónomas.*

Una vez inscrito en el Registro un importador o exportador, el Ministerio de Sanidad y Consumo informará a los servicios competentes de la comunidad autónoma donde radique el centro autorizado para la manipulación de muestras biológicas sobre las características de la inclusión del importador o exportador en el Registro y el tipo de muestras para las que se encuentra autorizado.

Artículo 13. *Infracciones.*

1. Son infracciones graves los siguientes incumplimientos a lo dispuesto en este real decreto:

a) La importación de muestras sin la autorización establecida en el artículo 5.2, cuando no se genere riesgo para la salud, en conexión con el artículo 35.B).1.ª de la Ley 14/1986, de 25 de abril, General de Sanidad.

b) La exportación de muestras sin presentar a la Dirección General de Salud Pública la declaración establecida en el artículo 5.3, cuando no se genere riesgo para la salud, en conexión con el artículo 35.B).1.ª de la Ley General de Sanidad.

c) El incumplimiento de los requerimientos específicos que formule la Dirección General de Salud Pública,

siempre que se produzca por primera vez, con arreglo al artículo 35.B).4.ª de la Ley General de Sanidad.

d) La resistencia a suministrar datos, facilitar información o prestar colaboración a la autoridad sanitaria o a sus agentes, con arreglo a lo previsto en el artículo 35.B).5.ª de la Ley General de Sanidad.

2. Son infracciones muy graves los siguientes incumplimientos a lo dispuesto en este real decreto:

a) La importación de muestras sin la autorización establecida en el artículo 5.2, cuando se genere riesgo para la salud, en conexión con el artículo 35.C).1.ª de la Ley General de Sanidad.

b) La exportación de muestras sin presentar a la Dirección General de Salud Pública la declaración establecida en el artículo 5.3, cuando se genere riesgo para la salud, en conexión con el artículo 35.C).1.ª de la Ley General de Sanidad.

c) Las que sean concurrentes con otras infracciones sanitarias graves, o hayan servido para facilitar o encubrir su comisión, con arreglo al artículo 35.C).1.ª de la Ley General de Sanidad.

d) El incumplimiento reiterado de los requerimientos específicos que formule la Dirección General de Salud Pública, con arreglo al artículo 35.C).4.ª de la Ley General de Sanidad.

e) La negativa absoluta a facilitar información o prestar colaboración a la autoridad sanitaria o a sus agentes, con arreglo a lo previsto en el artículo 35.C).5.ª de la Ley General de Sanidad.

f) La resistencia, coacción, amenaza, represalia, desacato o cualquier otra forma de presión ejercida sobre las autoridades sanitarias o sus agentes, con arreglo a lo previsto en el artículo 35.C).6.ª de la Ley General de Sanidad.

Artículo 14. *Sanciones.*

Las infracciones a lo dispuesto en este real decreto serán sancionadas conforme a lo dispuesto en el artículo 36 de la Ley General de Sanidad.

Disposición derogatoria única. *Derogación normativa.*

Quedan derogadas cuantas disposiciones de igual o inferior rango se opongan a lo establecido en este real decreto.

Disposición final primera. *Título competencial.*

Este real decreto se dicta al amparo de lo dispuesto en el artículo 149.1.16.ª de la Constitución Española, de acuerdo con lo establecido en la Ley Orgánica 3/1986, de 14 de abril, de medidas especiales en materia de Salud Pública y en el artículo 38 de la Ley 14/1986, de 25 de abril, General de Sanidad.

Disposición final segunda. *Facultad de desarrollo.*

Se faculta al Ministro de Sanidad y Consumo para dictar, en el ámbito de sus competencias, las disposiciones necesarias para el desarrollo de lo dispuesto en este real decreto y para la modificación de sus anexos.

Disposición final tercera. *Entrada en vigor.*

El presente Real Decreto entrará en vigor el día siguiente al de su publicación en el «Boletín Oficial del Estado».

Dado en Madrid, el 30 de enero de 2006.

JUAN CARLOS R.

La Ministra de Sanidad y Consumo,

ELENA SALGADO MÉNDEZ

ANEXO I

Puntos fronterizos autorizados

Barcelona.
Bilbao.
Madrid.
Sevilla.
Valencia.
Málaga.

ANEXO II

Certificado sanitario para la importación de muestras biológicas y sustancias infeccionas, para fines diagnósticos analíticos y de investigación. Importación ocasional

Datos del envío:

Naturaleza del material (si se trata de muestras diagnósticas y/o sustancias infecciosas): .....
.....
Descripción del producto: .....
N.º de envases: ..... Peso neto: .....
N.º UN (1): ..... Riesgo subsidiario en caso de alteración del envase: Si No
Uso al que va destinado: .....

Origen del producto:

Nombre y dirección del laboratorio/institución remitente: .....
.....

Destino del producto:

El producto se envía
de: .....
a: .....
Nombre y dirección del expedidor (transportista): .....
Medio de transporte (2): .....
Nombre y dirección del destinatario: .....
.....
Nombre y dirección del laboratorio/institución destinatario: .....
.....

Certificación:

El abajo firmante, como responsable sanitario, certifica que:

1. El envío se corresponde con los datos reseñados en este certificado.
2. El material ha sido acondicionado, conservado, envasado, embalado y etiquetado siguiendo las normas establecidas para el transporte seguro de sustancias infecciosas y especímenes de diagnóstico de la OMS (WHO/EMC/97.3). Regulaciones de la Asociación Internacional de Transporte Aéreo (IATA). Sección 5 Embalajes. Formularios N.º 602 y N.º 650 y Sección 3. 3.6.2 – División 6.2. Sustancias Infecciosas.
3. La institución/laboratorio remitente cumple con las normas nacionales e internacionales de bioseguridad.
4. En el caso de sustancias infecciosas, la empresa de transporte está autorizada para ello.

Hecho en ....., a .....

FIRMA Y SELLO OFICIAL DE LA AUTORIDAD SANITARIA DE ORIGEN

(1) Número internacional de Naciones Unidas que acredita el riesgo humano o animal (2014 humano, 2900 animal)

(2) Deberá cumplir las normas internacionales de transporte en todo caso

(dorso del impreso)

Cualquier dato de carácter personal que figure en este anexo se encuentra protegido por la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. Los datos de carácter personal que figuran en este anexo se encuentran exclusivamente a disposición de la autoridad sanitaria, no pudiendo ser cedidos a terceros. Los interesados tienen derecho a solicitar que cualquier muestra biológica figure bajo clave que no pueda relacionarse con un paciente concreto y, en el caso de que sea identificada, aún con su consentimiento, pueden ejercer los derechos de acceso, rectificación, cancelación y oposición ante la Dirección General de Salud Pública.

ANEXO III

Certificado sanitario para la importación de muestras biológicas y sustancias infeccionas, para fines diagnósticos analíticos y de investigación. Importadores registrados

Datos del envío:

Naturaleza del material (si se trata de muestras diagnósticas y/o sustancias infecciosas): .....
.....
Descripción del producto: .....
N.º de envases: ..... Peso neto: .....
N.º UN (1): ..... Riesgo subsidiario en caso de alteración del envase: Si No
Uso al que va destinado: .....

Origen del producto:

Nombre y dirección del laboratorio/institución remitente: .....
.....

Destino del producto:

El producto se envía
de: .....
a: .....
Nombre y dirección del expedidor (transportista): .....
Medio de transporte (2): .....
Nombre y dirección del destinatario: .....
.....
Nombre y dirección del laboratorio/institución destinatario: .....
.....

Certificación:

El abajo firmante, como responsable del Centro, acredita que:

1. El envío se corresponde con los datos reseñados en este documento de acreditación.
2. El material ha sido acondicionado, conservado, envasado, embalado y etiquetado siguiendo las normas establecidas para el transporte seguro de sustancias infecciosas y especímenes de diagnóstico de la OMS (WHO/EMC/97.3). Regulaciones de la Asociación Internacional de Transporte Aéreo (IATA). Sección 5 Embalajes. Formularios N.º 602 y N.º 650 y Sección 3. 3.6.2 – División 6.2. Sustancias Infecciosas.
3. La institución/laboratorio remitente cumple con las normas nacionales e internacionales de bioseguridad.
4. En el caso de sustancias infecciosas, la empresa de transporte está autorizada para ello.

Hecho en ....., a .....

FIRMA Y SELLO OFICIAL DE LA AUTORIDAD SANITARIA DE ORIGEN

(1) Número internacional de Naciones Unidas que acredita el riesgo humano o animal (2014 humano, 2900 animal)

(2) Deberá cumplir las normas internacionales de transporte en todo caso

(dorso del impreso)

Cualquier dato de carácter personal que figure en este anexo se encuentra protegido por la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. Los datos de carácter personal que figuran en este anexo se encuentran exclusivamente a disposición de la autoridad sanitaria, no pudiendo ser cedidos a terceros. Los interesados tienen derecho a solicitar que cualquier muestra biológica figure bajo clave que no pueda relacionarse con un paciente concreto y, en el caso de que sea identificada, aún con su consentimiento, pueden ejercer los derechos de acceso, rectificación, cancelación y oposición ante la Dirección General de Salud Pública.

ANEXO IV

Modelo de despacho cumplimentado

DATOS DEL ENVÍO

Descripción: ……

Número de envases: ……

Destinatario: ……

País de origen: ……

Expedidor: ……

Medio de transporte: ……

Puesto de inspección de: ……

DECLARACIÓN …… (Cumplimiento del Real Decreto ……)

El Inspector

ANEXO V

Certificado sanitario para la importación de muestras para fines analíticos en las búsquedas de donantes no emparentados

Datos del envío

Naturaleza del material: Muestra para uso diagnóstico.

Descripción y uso del producto:

☐ Muestra de sangre humana para realización de tipaje HLA confirmatorio.

☐ Muestra de sangre humana para confirmación de serología por parte del centro de trasplante.

Código del donante: ☐

Cantidad de ml de sangre solicitada: .....

Riesgo subsidiario:

Origen del producto

Registro de donantes remitente: .....
Dirección: .....
País: ..... Teléfono: ..... Fax: .....
e-mail: .....

Destino del producto

Nombre del centro: .....
Servicio: ..... Responsable: .....
Dirección: .....
Ciudad: ..... Teléfono: ..... Fax: .....
e-mail: .....

Medio de transporte :

Certificación

El abajo firmante como Director médico del Centro, certifica que ha sido solicitada al Registro de donantes ....., la muestra referida anteriormente con finalidad diagnóstica para la búsqueda de donante no emparentado para la realización de un trasplante alogénico.

....., de ..... de .....

(dorso del impreso)

Cualquier dato de carácter personal que figure en este anexo se encuentra protegido por la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. Los datos de carácter personal que figuran en este anexo se encuentran exclusivamente a disposición de la autoridad sanitaria, no pudiendo ser cedidos a terceros. Los interesados tienen derecho a solicitar que cualquier muestra biológica figure bajo clave que no pueda relacionarse con un paciente concreto y, en el caso de que sea identificada, aún con su consentimiento, pueden ejercer los derechos de acceso, rectificación, cancelación y oposición ante la Dirección General de Salud Pública.

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Care Act 2014

Status:
This is the original version (as it was originally enacted).

Collapse all

Introductory Text

Collapse
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General responsibilities of local authorities
1. Promoting individual well-being
2. Preventing needs for care and support
3. Promoting integration of care and support with health services etc.
4. Providing information and advice
5. Promoting diversity and quality in provision of services
6. Co-operating generally
7. Co-operating in specific cases
Meeting needs for care etc.
8. How to meet needs
Assessing needs
9. Assessment of an adult's needs for care and support
10. Assessment of a carer's needs for support
11. Refusal of assessment
12. Assessments under sections 9 and 10: further provision
13. The eligibility criteria
Charging and assessing financial resources
14. Power of local authority to charge
15. Cap on care costs
16. Cap on care costs: annual adjustment
17. Assessment of financial resources
Duties and powers to meet needs
18. Duty to meet needs for care and support
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21. Exception for persons subject to immigration control
22. Exception for provision of health services
23. Exception for provision of housing etc.
Next steps after assessments
24. The steps for the local authority to take
25. Care and support plan, support plan
26. Personal budget
27. Review of care and support plan or of support plan
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29. Care account
30. Cases where adult expresses preference for particular accommodation
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31. Adults with capacity to request direct payments
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33. Direct payments: further provision
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35. Deferred payment agreements and loans: further provision
36. Alternative financial arrangements
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37. Notification, assessment, etc.
38. Case where assessments not complete on day of move
Establishing where a person lives, etc.
39. Where a person's ordinary residence is
40. Disputes about ordinary residence or continuity of care
41. Financial adjustments between local authorities
Safeguarding adults at risk of abuse or neglect
42. Enquiry by local authority
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46. Abolition of local authority's power to remove persons in need of care
47. Protecting property of adults being cared for away from home
Provider failure
48. Temporary duty on local authority
49. Section 48: cross-border cases
50. Temporary duty on local authority in Wales
51. Temporary duty on Health and Social Care trust in Northern Ireland
52. Sections 48 to 51: supplementary
Market oversight
53. Specifying criteria for application of market oversight regime
54. Determining whether criteria apply to care provider
55. Assessment of financial sustainability of care provider
56. Informing local authorities where failure of care provider likely
57. Sections 54 to 56: supplementary
Transition for children to adult care and support, etc.
58. Assessment of a child's needs for care and support
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Health and Social Care Act 2012

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Mental Capacity Act 2005

Changes to legislation:
Mental Capacity Act 2005 is up to date with all changes known to be in force on or before 08 August 2026. There are changes that may be brought into force at a future date.

View outstanding changes

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SCOTTISH EXECUTIVE HEALTH DEPARTMENT

RESEARCH GOVERNANCE FRAMEWORK for HEALTH AND COMMUNITY CARE

Second Edition, 2006

Preface to the Second Edition, 2006

This update of the Research Governance Framework for Health and Community Care in Scotland takes account of a number of developments that have taken place since the framework was first published in 2001. Regulations on clinical trials involving medicines took effect in 2004. The regulations clarify specific legal duties of sponsors, investigators and others in such clinical trials. The change in the law stimulated wide debate on good practice and regulatory process in collaborative trials. The lessons drawn are visible throughout this edition and recognise the need to achieve a proper balance by safeguarding the rights of patients involved in clinical trials while avoiding a disproportionate impact on those who carry them out. Related changes in the sponsor responsibilities for other research are also reflected in this edition. There are also revisions to take account of changes in the organisation of NHS research ethics committees.

We hope that these changes combined with further clarification of a number of details will provide a solid base on which to move forward, encouraging greater public confidence in research and further investment and activity.

Chief Scientist Office
Scottish Executive Health Department

February 2006

RESEARCH GOVERNANCE FRAMEWORK

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Research Governance

- Sets out principles, requirements and standards
- Defines mechanisms to deliver them
- Describes monitoring and assessment arrangements
- Improves research quality and safeguards the public by:

  - enhancing ethical and scientific quality
  - promoting good practice
  - reducing adverse incidents and ensuring lessons are learned
  - forestalling poor performance and misconduct

- Is for all those who:

  - design research studies
  - participate in research
  - host research in their organisation
  - fund research proposals or infrastructure
  - manage research
  - undertake research

- Is for all managers and staff, in all professional groups, no matter how senior or junior
- Is for those working in all health and community care environments, including:

  - primary care
  - secondary care
  - tertiary care
  - community care
  - public health

1. PURPOSE AND SCOPE

1.1 The Scottish Executive is committed to enhancing the contribution of research to health and community care, and the partnership between services and science. Research is essential to the successful promotion and protection of health and well-being and also to modern, effective health and community care services services. At the same time research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Proper governance of research is therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and community care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

1.2 This document sets out a framework for the governance of research in health and community care. The principles underpinning the framework apply to all research which relates to the responsibilities of the Minister for Health and Community Care. That is, research concerned with the protection and promotion of public health, research undertaken in or by the Scottish Executive Health Department, (SEHD), its non-Departmental Public Bodies and the NHS, and community care research. Within this context, it applies to clinical and non-clinical research; research undertaken by NHS or community care staff using the resources of health and community care organisations; and any research undertaken by industry, charities, research councils and universities within the health and community care systems that might have an impact on the quality of those services.

1.3 This framework does not apply to research concerned with the delivery of local authority services outwith the Minister for Health and Community Care's responsibilities unless they are carried out in NHS settings or in collaboration with NHS care providers. In addition, the framework does not apply to research in the Scottish Prison Service except where this involves medical treatment or the provision of other health services. Although this work is governed by separate arrangements, the principles underpinning this framework should be applied whenever possible.

1.4 Important differences between health and community care research mean that the precise mechanisms by which relevant standards and requirements are achieved will differ. Compared with much research in the NHS, research in community care differs in nature, scale, volume and funding as well as in the mix of stakeholders, the organisational context and the range of academic disciplines. This framework focuses on requirements and standards, delivery mechanisms, and arrangements to monitor quality for health research. It is expected that organisations involved in community care research will develop their own mechanisms for the delivery, monitoring and assessment of research which reflect the principles set out in this framework, are proportionate to the risk involved and have regard to existing codes of good practice. The Scottish Executive is reviewing and improving existing ethical assurance processes for social research it commissions or undertakes to support Ministers and policy development taking account of the framework principles.

1.5 The aim of this framework is to bring together general principles of good practice. It refers to the law on clinical trials involving medicines. That does not mean it imposes the same procedures on other research when the interests of participants and the research methods do not call for them. The checklist of responsibilities in Section 3 are there to help everyone reach agreement on arrangements that are proportionate to risk, and for

health research to be in line with Good Clinical Practice. Therefore, the framework is offered also as a model for the governance of research in areas outside the direct responsibility of the Minister for Health and Community Care where poor practice could have a direct impact on the health or well-being of the public.

1.6 The framework is of direct relevance to all those who host, conduct, participate in, fund and manage research. It is not just for investigators, managers or any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the conduct of research. Participants in research and the public in general can also help to ensure that standards are understood and met.

1.7 This framework seeks to promote improvements in research quality across the board. As with clinical governance, research governance involves bringing general performance up to that of those at the leading edge. The framework provides a context for the encouragement of creative and innovative research and for the effective transfer of learning, technology and best practice to improve care.

1.8 The framework aims to forestall poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified. Learning from adverse events will promote good practice, enhance the ethical and scientific quality of research, and safeguard the public.

1.9 Health and community care generate and draw upon a wide range of innovative work and ideas from professionals, organisations and the public. Services must promote innovation while protecting participants from risk and waste. Innovation embraces a much wider range of activities than those managed formally as research.

1.10 Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.[1] This document sets out the responsibilities and standards that apply to work managed within the formal research context. Other documents on quality and governance in the NHS and community care set out standards and systems for assuring the quality of innovative work in non-research contexts.

1.11 Inquiries into adverse incidents relating to research have criticised a lack of clarity about responsibility and accountability. This is important, given the very wide range of individuals and organisations that can be involved. The framework pays particular attention to clarifying responsibilities and accountabilities. Listed are some of the individuals and organisations involved in health and community care research:

- The Public
- Research workers
- NHS staff
- Universities
- Students and their supervisors
- Research ethic committees
- Non-commercial research funders
- Health and community care professionals
- Health and community care organisations
- The pharmaceutical and other industries

[1] This definition includes studies that aim to generate hypotheses as well as studies that aim to test them.

- Local authorities

1.12 Achieving high quality in research depends on co-operation between all those involved. SEHD will continue to work with patients, service users, carers and care professionals, the public and its research partners to develop and implement this research governance framework to assure quality in health and community care research.

2. STANDARDS

2.1 Clinical governance aims continually to improve the overall standards of clinical care in the NHS and to reduce unacceptable variations in clinical practice. Clinical Governance and Risk Management (CGRM) standards[2] were launched by Quality Improvement Scotland (QIS) in 2005. The performance of NHS Boards and Special Health Boards will be assessed against these standards which include compliance with research governance.

2.2 Health research is not the province of a single discipline, profession or organisation and no single document adequately captures the full range of legislation, standards and good practice guidelines that apply to this wide- ranging body of work. They are presented here in six domains:

- ethics
- science
- information
- health and safety
- finance
- quality research culture.

2.3 Each domain has been grouped as follows:

- requirements in legislation and regulations
- standards required by SEHD
- other established principles of good practice from recognised international and national authorities and professional organisations.

2.4 The Chief Scientist Office website will provide regular updates of detail. The following sections set out principles in each domain.

Ethics

2.5 The dignity, rights, safety and well-being of participants must be the primary consideration in any research study.

2.6 SEHD requires that all health research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.[3] Informed consent is at the heart of ethical research. Most studies involving individuals must have appropriate arrangements for obtaining consent and the NHS ethics review process pays particular attention to those arrangements.[4] The law gives special protection to people who are unable to give consent on their own behalf. For example, The Adults with Incapacity (Scotland) Act 2000 provides safeguards for adults who lack

[2] Clinical Governance and Risk Management Standards (QIS, 2005)
[3] Under the Medicines for Human Use (Clinical Trials) Regulations 2004 it is against the law to start or conduct a clinical trial or to recruit participants to a clinical trial involving a medicine until there is a favourable opinion from an ethics committee and authorisation from the licensing authority.
[4] The NHS Code of Practice on Protecting Patient Confidentiality published in August 2003 provides guidance on obtaining consent. NHS HDL (2003)37 on The Use of Personal Health Information in NHSScotland to Support Patient Care provides further information.

capacity to consent to research.[5] Care is needed when seeking consent from children and from vulnerable adults, such as those with mental health problems or learning difficulties. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form and that the role and responsibilities of parents, carers or supporters are clearly explained and understood.

2.7 Care is also needed when research involves tissue or organs. The consent of the person concerned or the relatives of the deceased must always be obtained. It must be recognised that agreeing to such research involves relatives in difficult choices. Arrangements must be described for the respectful disposal of material once the research is completed, and for the reporting of the findings of the research to relatives, if they wish it.

2.8 The appropriate use and protection of patient data are also key. All those involved in health research must be aware of their legal and ethical duties in this respect. Particular attention must be given to systems for ensuring confidentiality of personal information and to the security of those systems.

2.9 It is essential that health research reflects the practicalities of care delivery. To that end, relevant service users and carers or their representative groups should be involved wherever possible in the design, conduct, analysis and reporting of research.

2.10 Research, and those pursuing it, should respect the diversity of human society and conditions and the multi-cultural nature of society. Whenever relevant, it should take account of age, disability, gender, sexual orientation, race, culture, and religion in its design, undertaking and reporting. The body of research evidence available to policy makers should reflect the diversity of the population.

2.11 Some research may involve an element of risk to those participating in it. If there are any risks to participants, the risks must be in proportion to the potential benefit[6]. Risks, pain or discomfort must always be kept to a minimum and explained clearly both to the relevant ethics committee and to participants. It must always be explained whether there are arrangements for compensation in the unlikely event of non-negligent harm.

2.12 Some essential research into important illnesses and treatments can be conducted only with animals. When undertaking research which could involve the use of animals, three principles should be followed:

- replacement of animals by non-animal methods wherever possible;
- reduction of numbers to the minimum necessary to obtain valid results where replacement is not possible; and
- refinement of all procedures to minimise adverse effects.

Wherever possible, alternatives such as cells, tissues, computers, bacteria and plants must be used instead. Where animal use is unavoidable, there are strict controls,

[5] Also, under the Medicines for Human Use (Clinical Trials) Regulations 2004, specific conditions and principles apply to informed consent, and to the recruitment of minors and incapacitated adults.
[6] Unless the risk to them is negligible, it is unethical to involve adults without capacity to consent, or minors, in research that could have no therapeutic benefit for the group involved.

enforced by the Home Office. Before a researcher can use animals, a series of special licences must be obtained. Primates are only to be used if less advanced animals could not provide the information. Researchers must have the necessary skills, training and experience, and the research laboratory must have the facilities to care for the animals properly. The highest standards of animal husbandry and welfare under veterinary supervision must be maintained and an ethical review process must operate in accordance with Home Office requirements.

Science

2.13 All existing sources of evidence, especially systematic reviews, must be considered carefully before undertaking health research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is unethical. Every proposal for health research must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. Arrangements for peer review should be in proportion to the scale of the research and the risks involved. For example, in some circumstances, an external panel of independent experts may be invited to review a programme or a controversial or costly proposal. In others, many organisations allow established research teams to determine details of the elements of an overall programme of research which has been reviewed externally. For student research projects, the university supervisor is normally able to provide adequate review.

2.14 The Medicines for Human Use (Clinical trials) Regulations 2004[7] regulate trials of medicines on people. Authorisation by the Medicines and Healthcare products Regulatory Agency is required. The Agency offers advice and undertakes inspections for such trials - and the manufacture and assembly of products used in them - against international standards. The same Agency regulates research involving new medical devices. The principles of Good Clinical Practice apply to all health research involving patients, not just clinical trials.[8]

2.15 Special regulations govern the use of human embryos, the release of genetically modified organisms and food or food processes and further information on these areas should be sought where appropriate.

2.16 Data collected in the course of health research must be retained for an appropriate period to allow further analysis by the original or other research teams subject to consent and to support monitoring by regulatory and other authorities.

Information

2.17 Health research is conducted for the benefit of patients, users, care professionals, and the public in general. There should be free access to information both on research being conducted[9] and on the findings of the research - positive or negative - once these have been subjected to appropriate scientific review. Information

[7] The Medicines for Human Use (Clinical Trials) Regulations transposed Directive 2001/20/EC into UK law.
[8] The Medical Research Council (MRC) issued guidelines in 1998 for Good Clinical Practice in clinical trials in the public and charity sectors. The MRC guidelines apply the principles of Good Clinical Practice in the 1996 statement of the International Conference on Harmonisation (ICH GCP).
[9] There is an international consensus that, with certain exemptions, information identifying a clinical trial of a treatment should be available on a public register from the time the first participant is recruited.

should be presented in a format understandable to the public. Reports need to be comprehensible and take language and other needs into account.

2.18 Some advances in healthcare need to be developed commercially if they are to be made widely available. Medicines, medical devices and aids for disabled people are examples. Successful commercial development often depends upon the protection of intellectual property or commercial confidentiality at critical points in the innovation process. The timing of the publication of research findings needs to take account of this.

2.19 All those conducting health research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made accessible to those participating[10] and to all those who could benefit from them. This may be through publication and/or other means appropriate to the type of research. Data relevant to findings should also be accessible.

Health and Safety

2.20 Health research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and of research and other staff must be given priority at all times, and health and safety regulations must be strictly observed - including the provision of information, containment, shielding and monitoring as required.

Finance

2.21 Financial probity and compliance with the law and with the rules laid down by the Scottish Executive and H M Treasury for the use of public funds are as important in research as in any other area. Organisations employing researchers must be in a position to compensate anyone harmed by their negligence. If an organisation offers to compensate participants in the event of non-negligent harm, it must be in a position to do so. Consideration must be given to the exploitation of intellectual property rights.[11]

Quality research culture

2.22 Some of the principles and requirements applying to health research are clear-cut but many require judgement and interpretation. A quality research culture, where excellence is promoted and where there is visible and strong research leadership and expert management, is essential if researchers and managers are to understand and apply standards, principles and requirements correctly.

2.23 The key elements of a quality research culture are:

- respect for participants' dignity, rights, safety and well being
- valuing the diversity within society
- personal and scientific integrity
- leadership

[10] Including the relatives of deceased patients who have consented to the use of organs or tissue in the research.
[11] Guidance for NHSScotland is set out in the document "A Framework and Guidance on the Management of Intellectual Property in the NHSScotland" (HDL (2004) 9).

- honesty
- accountability
- openness
- clear and supportive management

2.24 Box A illustrates how research is managed in a health organisation with a quality research culture. A quality research culture is essential for proper governance of health research.

BOX A: FEATURES OF A QUALITY RESEARCH CULTURE IN THE NHS

Quality Research Culture

- The organisation supports and promotes high quality research as part of a service culture receptive to the development and implementation of best practice in the delivery of care. There is strong leadership of research and a clear strategy linking research to national priorities and needs, the organisation's business, and to clinical governance.
- The organisation's research strategy values diversity in its patients or service users and its staff, and promotes their active participation in the development, undertaking and use of research.

Ethics

- To safeguard the dignity, rights, safety and well-being of participants all research involving patients, service users, carers or care professionals and other staff, or their organs, tissue or data, is referred for independent ethical review.
- Consent is sought in the way agreed during ethical review.
- Research is pursued with the active involvement of service users and carers including, where appropriate, those from hard- to- reach groups such as homeless people.
- If organs or tissue are used following post mortems, informed consent is obtained from relatives, and there is a commitment to respectful disposal of material.
- If using animals is unavoidable, the highest standards of animal husbandry are maintained under veterinary supervision.

Science

- There is commitment to the principle and practice of scientific review by independent experts, with scrutiny of the suitability of protocols or proposals and research teams for all work in the organisation.
- There is close collaboration with partner organisations in higher education and care to ensure quality and relevance of joint work and avoidance of unnecessary duplication of functions.
- The organisation's human resource strategy includes commitment to support research careers (full and part-time) by earmarking funds specifically for R&D training across the professions. The organisation plays its role in developing research capacity with appropriate training and updating. This includes taking action to ensure that the diversity of the workforce reflects society, and developing the capacity of consumers to participate.
- The organisation promotes a high standard of health and safety in laboratory work. It follows Good Laboratory Practice, Good Manufacturing Practice in manufacturing products for clinical trials and Good Clinical Practice in conducting clinical trials.
- Systems are in place to monitor compliance with standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research.
- The organisation assesses its research outputs and their impact and value for money.

Information

- Information is available on all research being undertaken in the organisation. This is held on a database containing details of research providers, funding, intellectual property rights, recruitment, research outputs and impact.
- The organisation ensures patients, service users and carers, care professionals and other staff have easy access to information on research. Where necessary, special arrangements are made to ensure access to information for those who do not have English as a first language, cannot read, or who may need information in different formats because of a disability e.g. Braille.
- An information service provides access from a single point to all up-to-date regulatory and advisory documentation pertaining to research governance, together with procedural guidance, for example, for applications for ethical approval.
- When established, findings (including negative findings) are published in ways that allow critical review and dissemination to those who could benefit from them. Other researchers have access to the data on which the findings are based.
- There is a strategy for making research findings accessible which addresses different media and writing styles for different audiences.
- Unless the research ethics committee agrees otherwise, those consenting to be involved in a study (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) have ready access to the findings at the end of the study.

Finance

- The organisation is aware of the activity involved in supporting research and of what it costs. Research expenditure is planned and accounted for.
- The organisation demonstrates financial probity and compliance with the law and rules laid down by the Scottish Executive and H M Treasury. It complies with all audit required by external funders or sponsors and has systems in place to deter, detect and deal with fraud.
- When research findings have commercial potential the organisation takes action to protect and exploit them, in collaboration with its research partners and – when appropriate – commercial organisations.

3. RESPONSIBILITIES AND ACCOUNTABILITIES

General

3.1 Everyone involved in research with human participants, their organs, tissue or data is responsible for knowing and following the law and the principles of good practice relating to ethics, science, information, health and safety, and finance set out in this framework.

3.2 All those involved in research also have a duty to ensure that they and those they manage are appropriately qualified, both by education and experience, for the role they play in relation to any research. They must be aware of, and have ready access to, sources of information and support in undertaking that role.

Agreements

3.3 A complex array of organisations and individuals may be involved in a health research study. It is essential that clear agreements describing allocation of responsibilities and rights are reached, documented and enacted.

3.4 Many agreements will relate to individual studies. Organisations that collaborate on a range of research work are encouraged to develop and document framework agreements to facilitate the agreement of responsibilities for specific studies; for example:

- NHS organisations who work together regularly on research, whether or not in a formal network;
- Universities and NHS organisations, primary care practices and research networks that work together regularly on research;
- local authorities and/or other community care providers, NHS organisations, and primary care practices that work together regularly on research whether or not in a formal research network.

3.5 It is particularly important to reach clear, documented agreements for complex studies where there may be:

- work on more than one site; and/or
- researchers employed by more than one organisation; and/or
- patients, service users and carers, and care professionals from more than one care organisation; and/or
- more than one funder.

A recommended approach is for the scheme of organisation in the protocol to include a detailed allocation of responsibilities. Each site can then subscribe to its own responsibilities by an exchange of letters that refer to the protocol.

Specific Responsibilities

3.6 Box B describes the terms used in this research governance framework for the main people and organisations involved in a health research study.

3.7 The key responsibilities of the people and organisations accountable for the proper conduct of a health study are summarised in Box C. Box D illustrates the responsibilities with a scenario. The remainder of this section sets out these responsibilities in more detail.

BOX B MAIN PEOPLE AND ORGANISATIONS INVOLVED IN A HEALTH RESEARCH STUDY

Participant - patient, service user, and carer, relative of the deceased, professional carer, other employee or member of the public, who consents to take part in a study. (In law, participants in clinical trials involving medicines are known as subjects).

Researchers - those conducting the study.

Investigator - the person responsible, individually or as the leader of the researchers at a site, for the conduct of a study at that site. For clinical trials involving medicines, an investigator must be an authorised health professional.

Chief Investigator – the person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study whether or not that person is an investigator at any particular site.

Principal Investigator – the leader responsible for a team of individuals conducting a study at a site.

Funder - organisation providing funding for a study through contracts, grants or donations to an authorised member of the employing and/or care organisation. The main funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money.

Sponsor - individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study).

Employing Organisation - the organisation employing the chief investigator, investigators or other researchers. Employers remain liable for the work of their employees. The organisation employing the chief investigator normally holds the contract or grant agreement with the funder of the study. Organisations holding contracts with funders remain responsible for the management of the funds provided.

Organisation Providing Care - the organisation responsible for providing care to patients and/or service users and carers participating in a study. Health organisations remain liable for the quality of care and for their duty towards anyone who might be harmed by a study.

Responsible Care Professional - doctor, nurse or other practitioner formally responsible for the care of participants while they are taking part in the study.

Research Ethics Committee – committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the committee must be one recognised by the United Kingdom Ethics Committee Authority.

BOX C SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS ACCOUNTABLE FOR THE PROPER CONDUCT OF A HEALTH RESEARCH STUDY

Chief Investigator, Investigators, other Researchers

- Developing proposals that are scientifically sound and ethical.
- Submitting the design for independent expert review.
- Submitting the study (or proposal) for independent ethical review.
- Conducting a study to the agreed protocol (or proposal), in accordance with legal requirements, guidance and accepted standards of good practice.
- Preparing and providing information for participants.
- Ensuring participants' welfare while in the study.
- Arranging to make findings and data accessible following expert review.
- Feeding back results of research to participants.

See 3.10, 3.11 to 3.13

Main Funder

- Assessing the scientific quality of the research as proposed.
- Establishing the value for money of the research as proposed.
- Considering the suitability of the research environment in which the research will be undertaken, particularly the experience and expertise of the chief investigator, principal investigator(s) and other key researchers involved.
- Requiring that a sponsor takes on responsibility before the research begins.

See 3.14 to 3.18

Sponsor

- Confirming that everything is ready for the research to begin:
  - taking on responsibility for putting and keeping in place arrangements to initiate, manage and fund the study;
  - satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance;
  - satisfying itself the study has ethical approval before it begins;
  - for clinical trials involving medicines, seeking a clinical trial authorisation and making arrangements for investigational medicinal products. (The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the responsibilities that have to be taken by or on behalf of sponsors of trials involving medicines).
- Satisfying itself that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions.

See 3.19 to 3.24

BOX C SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS ACCOUNTABLE FOR THE PROPER CONDUCT OF A HEALTH RESEARCH STUDY (CONTINUED)

Employing Organisation

- Promoting a quality research culture.
- Ensuring researchers understand and discharge their responsibilities.
- Ensuring studies are properly designed and submitted for independent review.
- Ensuring studies are managed, monitored, and reported as agreed, according to the protocol.
- Providing written procedures, training and supervision.
- Taking action if misconduct or fraud is suspected.

See 3.25 to 3.28

Organisation Providing Care/ Responsible Care Professional

- Arranging for an appropriate person to give permission for research involving their patients, service users, carers or staff, before the research starts.
- Ensuring any such research is conducted to the standards set out in this research governance framework.
- Requiring evidence of ethical review before recruitment to any research that affects their duty of care.
- Before recruitment to trials with medicines, requiring evidence of a positive ethical opinion and a clinical trials authorisation.
- Retaining responsibility for the care of participants to whom they have a duty.

See 3.29 to 3.34

BOX D SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN HEALTH RESEARCH

SCENARIO: WHO IS RESPONSIBLE FOR WHAT? SOME QUESTIONS AND ANSWERS

The Scenario: the Medical Research Council (MRC) awards a university Senior Lecturer in General Practice a grant for a clinical trial of a medicine. The grant is paid to the university. The MRC was closely involved in developing the trial design. The research is taking place in general practices. The Medicines and Healthcare products Regulatory Agency (MHRA) has agreed that the university and the relevant NHS Board form a group to take on the sponsor's responsibilities. The manufacturer of the drug has agreed to provide it free. The drug has a marketing authorisation covering the use of the product described in the research protocol.

PATIENT

Q: I did tell my GP that I might be interested in joining the study, but that does not commit me definitely, does it?
A: Your GP agreed to collaborate with the research team, and invite her patients to participate. Whether or not you agree is entirely up to you. Unless you consent, you won't be in the study.

Q: How can I know the study is worthwhile?
A: Through independent expert review ("peer review"), the MRC assessed the clinical importance of the questions addressed by the study. It also assessed the design and oversight arrangements. An ethics committee checked it is ethical. The MHRA authorised it.

Q: How can I find out more about it?
A: You can take away this patient information leaflet to study, and you can ask your GP or anyone on the research team for further details.

Q: What if the drug involved does not agree with me?
A: Your GP is still responsible for your care. She knows how we plan to monitor people who are in the trial. We will advise her immediately if we detect any problems, and you can approach her at any time. It is important for you to say if you have a bad reaction to the drug.

G.P.

Q: How do I know that this study is well designed?
A: The university and NHS Board are together sponsoring the study. The protocol names the sponsors' contact points. The scientific design went through the MRC's review system. It has ethical approval, and regulatory approval from the licensing authority. But you must decide whether you feel able to collaborate with it.

Q: Who is responsible for the care of my patients if they agree to take part?
A: You are. The protocol explains the procedures the research team will follow and the circumstances when they will alert you to anything they observe in your patients. You must ensure you are satisfied with these arrangements and discuss them with the chief investigator if you are not.

Q: Who is responsible for ensuring that the study follows the protocol and data are monitored to detect any possible problems?
A: The chief investigator is responsible for ensuring that you and every other person involved in the study is well informed, and able to carry out their roles properly. This is a trial of a medicine, so there is a legal responsibility to follow the protocol. If you have any concerns about this, you should contact the chief investigator. If you are not satisfied, you should inform the sponsor's representative.

Q: Who is responsible for the quality of the drugs?
A: The pharmaceutical company supplying the drugs is responsible for their quality. Medicines have to be made in licensed facilities, and must be correctly labelled for trials.

BOX D SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH (CONTINUED)

Q: I have agreed to join the study, but a number of my patients are having trouble understanding what they are being asked to take part in. It's taking up an enormous amount of time. What should I do?

A: Please talk to the chief investigator. A better understanding of the consent process could resolve the issues. Perhaps communication with your patients could be improved, for example by revising the patient information leaflet. If there are still problems you are free to withdraw.

Q: One of my patients seems much worse since I entered him into the trial. He is keen to continue, but I am concerned. What should I do?

A: Your primary responsibility is the patient's care. You have a duty to put his safety before anything required by the research. You should advise him to withdraw if you think that the trial drug caused his problems. Explain to him that you will talk to the research team on his behalf. It is very important you inform the chief investigator of any concerns about treatment under the trial. In trials of medicines, it is a legal requirement to report harmful reactions to the MHRA so that everyone can learn from them.

CHIEF INVESTIGATOR

Q: How do I know when the trial is authorised?

A: **As it falls under the Medicines for Human Use (Clinical Trials) Regulations 2004, the trial has to be authorised by the MHRA. The MHRA notifies sponsors when trials are authorised. The sponsor's representative will tell you when the drugs can be released for use in the trial**.

Q: What about ethical review?

A: **You have submitted the study to an ethics committee recognised for this kind of study, using the electronic form available on the Central Office for Research Ethics Committees (COREC) website. You need a positive ethics committee opinion as well as a Clinical Trial Authorisation before you can start the trial.**

Q: To whom must I report an adverse event?

A: For this trial, the sponsors have delegated to you the responsibility for recording and reporting adverse events. The MHRA will issue the Clinical Trial Authorisation on that basis so you have to follow the agreed process for recording adverse events, assessing seriousness, relatedness and expectedness, and reporting. You must arrange to report any worrying reaction immediately to the patient's GP. Adverse drug reactions must also be reported to the Trial Steering Committee, the drug manufacturer, the MHRA, the ethics committee and the Data Monitoring Committee. Under the Clinical Trials Regulations, there is a legal obligation to report suspected unexpected serious adverse reactions (SUSARs) to the MHRA within a set period.

Q: I am concerned that the staff in the university labs may not follow health and safety rules. What do I do?

A: You should raise this concern through the university's local health and safety systems.

Q: I am concerned that not all the investigators will follow the protocol closely. What should I do?

A: Inform the sponsor's representative immediately and agree a course of action.

Q: If my team need training, whom should I talk to?

A: Their employer is normally responsible for their training.

Q: To whom do I talk if I suspect a university colleague is fabricating data?

A: Your university as your colleague's employer is responsible for investigating the suspected misconduct. Others such as the General Medical Council may also be responsible for looking into your suspicions if they appear to involve professional misconduct. If you suspect someone employed by another organisation, raise your concerns with your employer, who as sponsor will contact your colleague's employer. In any case, record the evidence carefully so that there can be a proper investigation.

Q: I have new information that makes me think that we could improve the design of this study. What do I do?

A: You should discuss this with the Trial Steering Committee. If they agree, you will need to draw up a revised protocol, and submit it to the MRC. The sponsor's representative will then submit the amendment to the MHRA and you need to go back to the relevant ethics committee. You must not implement substantial changes to the protocol without formal agreement from those who gave permission for the study (particularly the MHRA and the ethics committee). When an amendment is authorised you need to tell all investigators to follow the new protocol from a specified time.

Q: I may generate some important intellectual property (IP). What should I do?

A: Your employer is one of the sponsors and will have a policy on IP that complies with the terms of funding. You should refer to and comply with this policy. Your employer may have an IP unit that can help you follow the right procedures.

Q: What if the MHRA does a Good Clinical Practice inspection?

A: You must co-operate. The inspectors have legal powers to ask for documents and take enforcement action. Generally, they look for evidence of good systems that are proportionate to the risks involved. The MHRA will point out any improvements needed for trial sites to comply with the law. They seek a prosecution only if it would be in the public interest because of very serious or persistent failure.

Responsibilities of Participants

3.8 Effective and responsive services depend on good research. Through this framework and related provisions, the Government and its partners strive to ensure that research conducted in Scotland offers the likelihood of real benefits either to those who participate, or to those who use services subsequently, or to both. Anyone using health services should give serious consideration to becoming involved in developing or undertaking research studies.

3.9 Researchers are responsible for selecting means of communication that ensure that potential participants are fully informed before deciding whether or not to join a study. In clinical trials involving medicines, there is a legal requirement to provide an interview with a member of the research team and a contact point offering further information about the trial. Potential participants should not hesitate to ask if they do not understand the information and explanations given.

Responsibilities of Researchers

3.10 Researchers bear the primary day-to-day responsibility for the conduct of research. They are responsible for:

- Ensuring that any research they undertake follows the current version of the agreed protocol (or proposal);
- helping care professionals to ensure that participants receive appropriate care while involved in research;
- reporting any adverse drug reactions or other adverse events;
- protecting the integrity and confidentiality of clinical and other records and data generated by the research; and reporting any failures in these respects, or suspected misconduct, through the appropriate systems.

Responsibilities of Investigators and the Chief Investigator

3.11 A senior individual must be designated as the chief investigator for the research. This person normally takes responsibility for the conduct of the research at a site and is accountable for it to their employer, and, through them, to the sponsor of the research. They are also directly accountable to the care organisation(s) where the research takes place (or through which the research team has access to participants, their organs, tissue or data). If the research is at more than one site, the chief investigator takes on personal responsibility for the design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

3.12 Chief investigators must have suitable experience and expertise in the design and conduct of research[12] so that they are able either to undertake the design, conduct, analyses and reporting of the study to the standards set out in this framework or lead and manage others with delegated responsibility for some of these aspects.

3.13 It is the chief investigator's responsibility to ensure that:

[12] For clinical trials involving medicines, the chief investigator and other investigators must be authorised healthcare professionals as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

- The research team gives priority at all times to the dignity, rights, safety and well-being of participants;
- The study complies with all legal and ethical requirements;
- The research is carried out to the standards in this research governance framework;
- Controlled trials are registered and for clinical trials involving medicines, the research follows any conditions imposed by the licensing authority;
- The Chief Executive of the care organisation(s) involved and/or any other individual(s) with responsibilities within this framework are informed that the study is planned, and their permission is obtained before the research starts;
- When a study involves participants under the care of a doctor, nurse or other worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate and agree to retain overall responsibility for their care;
- When the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate and is fully aware of the arrangements for dealing with any disclosures or other relevant information;
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate;
- The study is submitted for ethics review and it does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion;
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research;
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study and their qualifications are documented;
- Each investigator in a clinical trial involving medicines is aware of his/her legal duties;
- Students and new researchers have adequate supervision, support and training;
- Unless urgent safety measures are necessary,[13] the research follows the protocol or proposal agreed by the relevant ethics committee and by the sponsor[14];
- Substantive changes to the protocol or proposal are submitted for ethical review and for the sponsor's agreement. These amendments are implemented only when approved;[15]
- Procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage[16];
- Arrangements are made for the appropriate archiving of data when the research has finished and to make it accessible;

[13] Investigators in clinical trials involving medicines have to report serious adverse events immediately.
[14] For clinical trials involving medicines, it is a legal requirement to follow the protocol approved by the licensing authority (the Medicines and Healthcare products Regulatory Agency).
[15] Also, for clinical trials involving medicines, to the licensing authority.
[16] Also, for clinical trials involving medicines, procedures to comply with legal requirements concerning Good Clinical Practice during the trial, and Good Manufacturing Practice in manufacturing investigational medicinal products.

- Reports on the progress and outcomes of the work required by the sponsor, funders, or others with a legitimate interest are produced on time and to an acceptable standard;
- The findings from the work are opened to critical review through the accepted scientific and professional channels;
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants;
- The chief investigator accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs;
- Arrangements are kept in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising;
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.

Responsibilities of Research Funders

3.14 Organisations that fund health research have a responsibility for ensuring that the work is a proper use of the funds they control and provides value for money.

3.15 The main research funder plays a critical role in assuring the quality of a study. It will normally take the lead in establishing that the research proposal is worthwhile, of high scientific quality, and represents good value for money.[17]

3.16 The main research funder is normally the organisation that makes the arrangements for independent expert review to assess the quality of the research proposed; the experience and expertise of the chief investigator and other key researchers involved; whether there is appropriate research infrastructure for the study: for example, management and governance arrangements, access to potential participants (or their organs, tissue or data); specialised facilities such as equipment, materials or support staff; and for trials on medicines, expert clinical trial management and the capacity to comply with the principles of Good Clinical Practice. If the main funder is unable to arrange for the independent expert review, it should expect the sponsor to arrange for it before taking on responsibility for the research, or to require another organisation to arrange for it. It is good practice for funders to make scientific judgements related to their responsibilities with expert advice independent of the investigators.

3.17 Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

3.18 Funders are expected to make their funding conditional on identifying a sponsor. Organisations wishing to fund research which requires the collaboration of the NHS in Scotland will either take on sponsorship themselves, or collaborate with another organisation which is willing and able to do so.

[17] The value for money assessment compares the potential benefits with the resources that the study requires. These resources include any additional care or treatment costs, as well as the research costs that the funder is to meet.

Responsibilities of the Sponsor

3.19 The sponsor is the individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study[18]. For any research that takes place in the context of the NHS in Scotland, there must be a sponsor. Normally, the sponsor will be one of the organisations taking the lead for particular aspects of the arrangements for the study. It may be the chief investigator's employing organisation, or the lead organisation providing healthcare, or the main funder. If the sponsor is outside the United Kingdom, it must have a legal representative in the United Kingdom.[19] For any health research study covered by this research governance framework, it is for the sponsor to be satisfied that clear agreements are reached, documented and carried out, providing for proper initiation, management, monitoring and financing. Others will rely on reasonable assurances that the sponsor has taken steps to do this.

3.20 The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and that arrangements are in place allocating responsibilities for the management, monitoring and reporting of the research. The sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, particularly those which put the safety of individuals at risk and to approve any modifications to the design, obtain any regulatory authority required, implement them and make them known.

3.21 It is the sponsor's responsibility to be satisfied with the arrangements for management and monitoring. Normally, if the chief investigator's employer takes on the sponsor's responsibilities (alone or as a member of a group), it will assume responsibility for operating the management and monitoring systems in collaboration with the employers of other members of the research team. Exceptionally, it may be inappropriate for the organisation employing the chief investigator to take responsibility for the management and monitoring of a study. In that case, the sponsor should make arrangements with one or more other organisations that will operate the management and monitoring systems.

3.22 Provided the sponsor keeps in place arrangements for performance management and audit, the responsibility for design and management may be delegated to the research team. The extent of delegation should be specified, even for a research team with proven expertise and track record. Commercial sponsors may arrange their own audit processes.

3.23 When no external sponsor takes on responsibility for it, a study may proceed only if a care organisation takes on sponsorship. For example, an NHS organisation may be willing and able to act as the sponsor for research which does not have an

[18] For clinical trials involving medicines, the sponsor is defined as the person (e.g. individual, institution, company or organisation) who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial. Such sponsors have specific legal duties under the Medicines for Human Use (Clinical Trials) Regulations 2004. Regulation 3 defines options for sponsorship, including single sponsorship, joint sponsorship and allocation of sponsorship responsibilities within a group.

[19] The Regulations require a sponsor to be established, or have a legal representative, in the European Community. Neither of them need to be established in the United Kingdom.

external sponsor. When research is undertaken for research training purposes, research supervisors normally carry out the sponsorship responsibilities on behalf of their employers. Exceptionally, a university may authorise a suitably experienced postgraduate student to carry out these responsibilities on its behalf.

3.24 It is the sponsor's responsibility to be satisfied that:

- The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals;
- An appropriate process of independent expert review has demonstrated that the research proposal is worthwhile, of high scientific quality and good value for money;
- An appropriate ethics committee has given a favourable opinion;
- In the case of a clinical trial involving a medicine, someone acting on behalf of the sponsor obtains a clinical trial authorisation and the arrangements for the trial comply with the law;
- Appropriate arrangements are in place for the registration of a trial;
- The chief investigator, and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully;
- The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources proposed are those required to allow appropriate data analysis and data protection;
- Arrangements proposed for the work are consistent with this research governance framework;
- Organisations and individuals involved in the research agree the division of responsibilities between them;
- There is written agreement about the arrangements for the management and monitoring of the study;
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments[20] occur as the study progresses, whether in relation to the safety of individuals or to scientific direction[21];
- Agreement has been reached about compensation in the event of harm to research participants[22]and if any organisation, or the sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements;
- There are arrangements for the conclusion of the study including appropriate plans for disseminating the findings;
- Scientific judgements made by the sponsor in relation to these responsibilities should be based on independent and expert advice;
- The sponsor is expected to assist any enquiry, audit or investigation related to the funded work.

[20] For clinical trials involving medicines, these include serious adverse events, serious adverse reactions, and suspected unexpected serious adverse reactions as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

[21] For clinical trials involving medicines, the sponsor has a legal duty to record and report suspected unexpected serious adverse reactions as soon as possible. The sponsor also has to provide annually a list of all such reactions occurring in the past year, and a report on the safety of the participants in the trial.

[22] For clinical trials involving medicines it is a legal requirement that there should be insurance or indemnity to cover the liabilities of sponsors and investigators.

Responsibilities of Universities and others Employing Researchers

3.25 Employers of staff involved in research have responsibility for developing and promoting a high quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. This will involve careful attention to training, career planning and development, and the use of clear codes of practice and systems for monitoring compliance, dealing with non-compliance or misconduct, and learning from errors and complaints. These responsibilities apply to both private and public sector employers.

3.26 Organisations that employ chief investigators and other researchers have responsibility for ensuring that those researchers understand and discharge the responsibilities set out for them in this framework, and under the law. They may do this, for example, through terms of employment, staff handbooks, and training. They will normally take on some or all of the responsibility for ensuring that a study is properly managed and for monitoring its progress. When the employing organisation is not the sponsor, it should agree its responsibilities with the sponsor and the organisation(s) providing care. The sponsor has to be satisfied with the arrangements for the management of a study, and that there is agreement on appropriate arrangements for monitoring and reporting[23].

3.27 Employers should ensure there are agreements between them and their staff and between them and research funders and care organisations about ownership, exploitation and income from any intellectual property that may arise from research conducted by their employees. They have a responsibility for ensuring that employees identify and protect intellectual property.

3.28 Universities and other employers of staff engaged in research are responsible for:

- Compliance with all current employment and health and safety legislation;
- Demonstrating the existence of clear codes of practice in other areas for their staff and mechanisms to monitor and assess compliance;
- Ensuring that investigators and other research staff are aware of understand and comply with this framework;
- Discharging their agreed role in the management and monitoring of work undertaken by their organisation;
- Demonstrating systems for continuous professional development of staff at all levels;
- Having agreements and systems to identify, protect and exploit intellectual property;
- Ensuring that they are able to compensate anyone harmed as a result of negligence on the part of staff, students and others for whom they have liability; and, if they have agreed to do so, to compensate participants for non-negligent harm arising from the research;
- Having systems to detect and address fraud, and other scientific or professional misconduct by their staff;

[23] For clinical trials involving medicines, the sponsor has to put and keep in place arrangements for the purpose of ensuring that the conditions and principles of Good Clinical Practice are satisfied or adhered to.

- Having systems to process, address and learn lessons from any errors or complaints brought against their employees;
- Permitting and assisting in any statutory inspection, audit, or investigation arising from errors or complaints associated with their employees.

Responsibilities of Organisations Providing Care

3.29 It is the responsibility of organisations providing healthcare in Scotland to be aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation. Care providers remain responsible for the quality of all aspects of the care of their patients or service users and carers, whether or not they are involved in research and whoever conducts or funds that research. Chief Executives of NHS organisations are accountable for the quality of care and for the environment in which it is provided under the Duty of Care. They should ensure that their patients, service users and carers, and care professionals are provided with information about any research which may have a direct impact on their care, their experience of care, or their work in the organisation. They should ensure that activity is presented as research only if it is managed as research within this framework.

3.30 Organisations providing healthcare are responsible for satisfying themselves that there are adequate arrangements and resources for any research involving their patients, service users and carers, or staff to meet the standards set out in this framework. No research with human participants, their organs, tissue or data, may begin before an identified sponsor has taken on responsibility for that research, the study has received a positive ethical opinion and the allocation of responsibilities is agreed and documented. Accountability for this lies with the Chief Executive or Agency Director. He or she will normally delegate responsibility to a qualified and senior person.

3.31 Academic staff (university/college medical, nursing, and allied health professionals and other research workers) who, in the course of their NHS research duties, interact with individuals in a way which has a direct bearing on the quality of their care should hold an NHS honorary contract.[24] When universities and healthcare organisations are both involved in employing clinical academic staff, they are expected to make joint arrangements for appointment, supervision and appraisal.

3.32 The main responsibilities of organisations providing healthcare are to:

- Retain responsibility for the quality of all aspects of participants' care whether or not some aspects of care are part of a research study;
- Be aware and maintain a record of all research work undertaken through or within the organisation including research undertaken by students as part of their training;
- Ensure patients or service users and carers are provided with information on any research that may affect their care;

[24] If there is negligent harm during a study with NHS permission when the NHS body owes a duty of care to the person harmed, NHS indemnity covers NHS staff, academic staff with honorary contracts (as defined in paragraph 3.31) and those conducting the study. Guidance for the NHSScotland can be found in the document "Guidance Note on Research Governance and Honorary Contracts", (Health Department, March, 2004).

- Be aware of current legislation relating to research and ensure that it is implemented and followed within the organisation;
- Require that no research study with human participants for whom the organisation is responsible (or their organs, tissue or data), begins until a sponsor has confirmed it has taken responsibility; the proposed research has a favourable ethical opinion (and if the study is a trial of a medicine, that there is a clinical trial authorisation); and a person authorised to do so has given written permission on behalf of the organisation providing care[25];
- Ensure that written agreements are in place about responsibilities for all research involving an external partner, funder and/or sponsor including agreement with the University or other employer on supervision of student research;
- Maintain the necessary links with clinical governance and/or best value processes;
- Ensure that NHS honorary contracts are issued where appropriate[26]. There should be clear accountability and understanding of responsibilities;
- Put and keep in place systems to identify and learn from errors or failures associated with any research undertaken through or within the organisation;
- Ensure that significant lessons learnt from errors or complaints and from internal enquiries are communicated to funders, sponsors and other partners;
- Ensure that adverse incidents in the context of research are reported in line with the standard procedures of the organisation;
- Permit and assist with any monitoring, auditing or inspection by relevant authorities.

Responsibilities of Care Professionals

3.33 Healthcare staff retain responsibility for the care of their patients or service users when they are participating in research within the NHS.

3.34 Before agreeing to their patients or service users and carers being approached by the research team, care professionals should satisfy themselves that the chief investigator has the permission of the appropriate authorities within their organisation or agency. Before enrolling patients in a clinical study, NHS staff should look for evidence that the study has the ethical and regulatory approval it needs. They should then take care to follow the currently approved version of the protocol.

Responsibilities Relating to Research Ethics Committees

3.35 No research study within the NHS involving individuals, their organs, tissue or data may begin until it has a favourable opinion from a research ethics committee.

3.36 From 2004, the United Kingdom Ethics Committee Authority has been responsible for recognising ethics committees to review clinical trials under the Medicines for Human Use (Clinical Trials) Regulations 2004.

3.37 The NHS is responsible for establishing, supporting and monitoring NHS research ethics committees (RECs). The duties of NHS bodies in relation to NHS RECs are set out in the good practice guidance *Governance Arrangements for Research Ethics Committees in Scotland* (SEHD, 2001). Those outside the NHS may also

[25] See section 4.4.
[26] See footnote 24.

seek the advice of these committees. Community care research involving human participants to whom the NHS has a duty of care (or their organs, tissue or data) must have a favourable opinion from the relevant NHS REC.

3.38 RECs are required to be independent when formulating advice on the ethics of the proposed research. Ethics review must be seen to be impartial. Whilst operating within a framework of standards and NHS management, neither SEHD nor NHS bodies are entitled to interfere with NHS RECs' decisions. RECs' appointing authorities must have systems in place to appoint members and convene them, to seek recognition if the law requires it, and to support them and monitor their performance.

3.39 RECs provide an independent opinion. The decision whether or not to give permission for research in a care organisation rests with that organisation. Healthcare organisations will not normally withhold permission provided that a sponsor has been identified, the ethical opinion is favourable, the agreements for allocation of responsibilities or indemnity and/or insurance are acceptable to the organisation, and conducting the research will not conflict with service delivery in some way due to local issues that might not have been considered by the ethics approval or sponsor.

3.40 It is not for RECs or reviewers to give legal advice, nor are they liable for any of their opinions in this respect. It is the researchers and the healthcare organisations[27] who have the responsibility not to break the law. If a REC suspects that a research proposal might contravene the law, it is expected to advise both the chief investigator and the appropriate authority. Then the chief investigator and the organisation will need to seek legal advice.

3.41 RECs require researchers working in the NHS to keep them informed of the progress of a study. The committees are responsible for reviewing their advice on the ethical acceptability of a study in the light of such information. The chief investigator and his or her employer, the sponsor and the care organisation are responsible for ensuring that a study follows the agreed protocol, and for monitoring and reporting on its progress.[28]

[27] and the sponsor, for clinical trials involving medicines.

[28] For clinical trials of medicines, sponsors have a legal duty to notify the ethics committee and the licensing authority if there are adverse events, a change to the design of the trial, and the conclusion of the trial.

4. ACHIEVING GOVERNANCE

4.1 Organisations conducting, sponsoring, funding or hosting health research must have systems to ensure that they and their staff understand and follow the standards and good practice set out in this framework.

Delivery

4.2 They must have access to independent expert review that enables the main funder and the sponsor to be satisfied of the scientific and ethical standing of the work, its strategic relevance and value for money. This review must be appropriate to the scale and complexity of each research proposal.

4.3 Sponsors must be satisfied there are arrangements to ensure that each study is conducted according to the current agreed protocol, monitor and report on its general progress, and require written agreement on behalf of the sponsor to any modifications to the protocol or proposal, (and if necessary, ethical and regulatory approval). One of the organisations involved in the research will normally manage these arrangements. The sponsor must satisfy itself that a suitable organisation has accepted this responsibility.

4.4 Healthcare providers must have systems that ensure they are aware of research conducted in or through their organisation, whether or not it is externally funded. No study should begin until a person with authority to do so has given written permission[29] on behalf of the care organisation. Healthcare organisations are expected to manage risk, minimise bureaucratic process and facilitate high quality research. They are not normally expected to withhold permission when a sponsor offers reasonable assurances that there are arrangements to carry out the responsibilities set out in this framework.

4.5 Healthcare providers may take on the sponsor's responsibilities if they have systems to discharge them. It is acceptable for an individual employee to be a sponsor only with the written permission of that person's employer.[30]

4.6 Nothing in this research governance framework is intended to transfer the legal duties of healthcare organisations to sponsors or to others. Whoever takes on sponsorship, if a study affects a healthcare organisation's duties, it remains that organisation's responsibility to satisfy itself that there are systems to conduct the study to appropriate scientific and ethical standards.

4.7 Healthcare organisations are responsible for providing a safe system of care and should normally expect to be kept informed of any study involving their staff, contractors or independent practitioners. However, they do not have responsibility

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[29] Additional guidance can be found in "Research Governance: NHS Approval for R&D Involving NHS Patients" (SEHD, 2004).

[30] For clinical trials of medicines, it is within the law for an individual to be the sponsor (further guidance on this can be found at www.ct-toolkit.ac.uk/_db/_documents/sponsorship.pdf). Employers should ensure that, if their employees take on sponsorship, there is a system to record whether the employee has permission to do so as a private individual or is authorised to do so on behalf of the employer. Healthcare organisations should authorise their employees to take on sponsorship only if there are arrangements to perform the functions in the Medicines for Human Use (Clinical Trials) Regulations 2004.

for private research that is clearly separate from the healthcare provided on behalf of the NHS. That is when the study is clearly undertaken in a private capacity, the REC is fully aware of the circumstances and participants understand the NHS accepts no liability.

4.8 RECs and reviewers should have systems to identify, record and address conflicts of interest that may compromise, or appear to compromise, the independence of their advice. They must also have systems in place to record their decisions and the reasons for them, and to record operational details of their meetings and handling of applications.

4.9 Delivery systems should be designed to facilitate adherence to requirements, and to detect failures whether such failures arise by intent or oversight. Such systems should include a risk-based programme of routine and random monitoring and audit. They should require, facilitate and support reporting of critical incidents, near misses, systems failures and misconduct either by self-reporting or whistle-blowing.

4.10 SEHD will work with key stakeholders to develop and issue explanatory material from time to time to help organisations discharge their responsibilities for research governance effectively and efficiently.

4.11 SEHD will work with NHS care providers to ensure that they understand their legal and other responsibilities, have systems to discharge them, and take account of relevant guidance.

4.12 Research governance depends critically on research workers and research managers understanding their responsibilities and having the skills to discharge them. SEHD will work with other relevant parties to help to promote the coverage of research governance.

Adherence to the Framework

4.13 Organisations and individuals are expected to be ready to demonstrate adherence to this framework, reassure patients, service users and care professionals of the quality of their services and assure their reputation in high quality research and care.

4.14 There are powerful incentives to adhere to the principles, requirements and standards of good practice set out in the framework. These include the law, duties of care and the high professional and ethical standards that most care professionals and researchers uphold. Mechanisms to monitor the quality of clinical work, such as inspection, audit, risk management and staff appraisal, can assist in the monitoring of research governance. Coherent systems are needed to monitor performance, to identify best practice and shortfalls, to enhance public confidence and help to prevent adverse events. It is an offence not to comply with the law for clinical trials involving medicines. For other research, those involved may be liable under common law if they are negligent. SEHD will work with its partners to develop coherent systems for monitoring research governance and addressing shortcomings.

4.15 Arrangements will be established to work with and through structures which already exist or are being developed in healthcare, government departments, research councils, universities and charities to promote and monitor quality. These arrangements will monitor the extent to which the standards set out in this framework are being followed by bodies who undertake the responsibilities of sponsors of health research, healthcare organisations participating in research, universities and other organisations employing researchers, and other organisations on which this framework depends.

4.16 Research governance is one of a set of quality systems for healthcare. Reporting, inspection and review supports organisations' systems for meeting standards and managing risk. Clinical trials of medicines require authorisation by the Medicines and Healthcare products Regulatory Agency. The Agency operates a system of Good Clinical Practice and Good Manufacturing Practice inspections which can involve trial sites, units manufacturing investigational medicinal products, and sponsors. Similar arrangements apply to medical devices.

4.17 Healthcare organisations which either lead or participate in research should have systems to ensure that the principles and requirements of this research governance framework are consistently applied. Failures in NHS organisations to comply with this framework will be addressed through the normal lines of accountability and performance management. NHS QIS will be responsible for reviewing the performance of NHS Boards against clinical governance and risk management standards launched by QIS in 2005. Research governance forms part of these standards and to support the review process, a self assessment tool to measure compliance with research governance will be launched by SEHD in 2006.

4.18 Failures on the part of staff in SEHD or the NHS to meet responsibilities relating to this framework will be addressed through the normal management channels and disciplinary procedures. It is the responsibility of other organisations to have appropriate systems to address failures by their staff. University employees with NHS honorary contracts may have their contracts withdrawn, subject to a joint NHS/university investigation.

4.19 In the case of misconduct, professional groups are subject to disciplinary action by their professional bodies. The Council for Healthcare Regulatory Excellence will promote best practice and co-operation between regulatory bodies. For example, doctors are responsible to the General Medical Council for their professional conduct as researchers as well as clinicians. Similarly, nurses, midwives and health visitors are responsible to the Nursing and Midwifery Council. State registered practitioners are responsible to the Health Professions Council for their professional conduct as researchers as well as clinicians.

4.20 There is public and professional concern about research misconduct and fraud, though its extent is unknown. Monitoring of compliance with research governance will check whether there are mechanisms to detect and investigate possible fraud and to take appropriate action if fraud is found. In addition, healthcare organisations should seek assurances that universities and any other organisations with whom they develop local partnerships have systems for detecting, investigating and addressing fraud by their employees. Universities UK aim to establish a UK Panel for Research Integrity in Health and Biomedical Sciences. It

will provide advice on maintaining high standards of scientific integrity and support to those investigating allegations of research misconduct. Its advice and support will be available to employers of researchers including healthcare organisations. SEHD will continue to work with universities and others on measures to promote integrity in research.

4.21 SEHD looks to those with responsibilities for other organisations to address any shortcomings in them. SEHD and NHS funds for health research will be allocated to those competent to manage them and the work they support.

4.22 The Annex to the Research Governance Framework for Health and Social Care in England contains further information on legislative requirements, standards and good practice guidelines applying to research. This can be found on the Department of Health in England's website at: http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/fs/en . Professional judgement is involved in the interpretation of this guidance. Quality in research depends on those responsible being appropriately qualified, with the skills and experience to use their professional judgement effectively in the delivery of dependable research.

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Medicines Act 1968

Changes to legislation:
Medicines Act 1968 is up to date with all changes known to be in force on or before 15 August 2026. There are changes that may be brought into force at a future date.
View outstanding changes

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The Ionising Radiation (Medical Exposure) Regulations 2000

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S T A T U T O R Y I N S T R U M E N T S

2011 No. 1567

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011

Made	*21st June 2011*
Laid before Parliament	*28th June 2011*
Coming into force	*25th July 2011*

The Secretary of State for Health is a Minister designated(1) for the purposes of section 2(2) of the European Communities Act 1972(2) in relation to the making of safety measures in regard to radioactive substances and the emission of ionising radiation.

The Secretary of State makes the following Regulations, in exercise of the powers conferred by section 2(2) of that Act:—

Citation and commencement

1. These Regulations may be cited as the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011 and shall come into force on 25th July 2011.

Amendment

2. At the end of regulation 3(a) (application) of the Ionising Radiation (Medical Exposure) Regulations 2000(3) after "medical diagnosis or treatment" insert ", including any exposure of an asymptomatic individual".

Signed by authority of the Secretary of State for Health.

Anne Milton
Parliamentary Under-Secretary of State,
Department of Health

21st June 2011

EXPLANATORY NOTE
(This note is not part of the Regulations)

These Regulations amend the Ionising Radiation (Medical Exposure) Regulations 2000 ("the Principal Regulations") which implement in part, as respects Great Britain, Council Directive 97/43/Euratom (OJ No L180, 9.7.97, p 22) laying down basic measures for the health protection of individuals against dangers of ionising radiation in relation to medical exposure. The Principal Regulations impose duties on those responsible for administering ionising radiation to protect persons undergoing medical exposure whether as part of their own medical diagnosis or treatment or as part of occupational health surveillance, health screening, voluntary participation in research or medico-legal procedures and these Regulations clarify an aspect of this.

Regulation 2 makes it explicit that individual health assessments of asymptomatic individuals fall within the ambit of regulation 3 (application) of the Principal Regulations.

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(1) S.I. 1977/1718; there are no relevant amendments.

(2) 1972 c.68; s. 2(2) is amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a) and the European Union (Amendment) Act 2008 (c. 7), section 3(3) and Schedule 1, Part 1.

(3) S.I. 2000/1059; there are no relevant amendments.

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The Medicines for Human Use (Clinical Trials) Regulations 2004

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The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

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The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008

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Introductory Text

1. Citation, commencement and interpretation

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3. Amendment of regulation 15 of the Clinical Trials Regulations

4. Amendment of Schedule 1 to the Clinical Trials Regulations

5. Amendment of Schedule 2 to the Clinical Trials Regulations

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STATUTORY INSTRUMENTS

2006 No. 2984

MEDICINES

The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006

Made - - - -	*15th November 2006*
Laid before Parliament	*21st November 2006*
Coming into force - -	*12th December 2006*

The Secretary of State makes the following Regulations in exercise of the powers conferred upon her by section 2(2) of the European Communities Act 1972(**a**). She has been designated for the purposes of that section in relation to medicinal products(**b**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 and shall come into force on 12th December 2006.

(2) In these Regulations, the "Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004(**c**).

Amendment of the Clinical Trials Regulations

2. In Schedule 1 to the Clinical Trial Regulations (conditions and principles of good clinical practice and for the protection of clinical trial subjects), in Part 1 (application and interpretation), in paragraph 1—

(a) in sub-paragraph (4), for "If" substitute "Subject to sub-paragraphs (6) and (7), if"; and

(b) after sub-paragraph (5), insert the following sub-paragraphs—

"(6) Sub-paragraph (7) applies if treatment is being, or is about to be, provided for a subject who is an incapacitated adult as a matter of urgency and, having regard to the nature of the clinical trial and of the particular circumstances of the case—

(a) it is also necessary to take action for the purposes of the clinical trial as a matter of urgency; but

(b) it is not reasonably practicable to meet the conditions set out in paragraphs 1 to 5 of Part 5.

(7) Where this sub-paragraph applies, paragraphs 1 to 5 of Part 5 shall not apply in relation to the subject if the action specified in sub-paragraph (6) is carried out in accordance with a procedure approved by an ethics committee or by an appeal panel appointed under Schedule 4 at the time it gave its favourable opinion.".

(**a**) 1972 c.68.
(**b**) S.I. 1972/1811.
(**c**) S.I. 2004/1031; as amended by S.I. 2005/2754 and 2759 and 2006/1928.

Amendment of the Adults with Incapacity (Scotland) Act 2000

3. In section 51 of the Adults with Incapacity (Scotland) Act 2000(**a**) (authority for research) in subsection (3A)—

(a) omit "and" at the end of paragraph (a); and

(b) after paragraph (b), insert—

"(c) without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

(i) treatment is being, or is about to be, provided for an adult who is incapable in relation to a decision about participation in the research as a matter of urgency;

(ii) having regard to the nature of the clinical trial and of the particular circumstances of the case it is necessary to take action for the purposes of the clinical trial as a matter of urgency;

(iii) it has not been reasonably practicable to obtain the consent of any such person;

(iv) it has not been reasonably practicable to obtain the consent of any of the persons mentioned in paragraph (b)(ii)(A) or (B); and

(v) the action to be taken is carried out in accordance with a procedure approved by the Ethics Committee or any other ethics committee or by an appeal panel appointed under Schedule 4 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) at the time it gave its favourable opinion in relation to the clinical trial.".

Signed by authority of the Secretary of State for Health

Andy Burnham
Minister of State
Department of Health

15th November 2006

(**a**) 2000 asp 4; section 51 was amended by paragraph 21 of Part 1 of Schedule 10 to S.I. 2004/1031.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Clinical Trials) Regulations 2004 (the Clinical Trials Regulations) which implement Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use(**a**).

Regulation 28(1) of, and Schedule 1 to, the Clinical Trials Regulations implement, among other provisions, article 5(a) of that Directive, which requires that an incapacitated adult cannot be included in a clinical trial of a medicine without the consent of his legal representative.

Regulation 2 amends Schedule 1 to creates an exception to the general rule that an incapacitated adults cannot be included in a clinical trial unless the conditions in paragraphs 1 to 5 of Part 5 of Schedule 1 have been met; in particular that the adult's legal representative (as defined) has given informed consent. The exception applies only when the following conditions are met: (i) treatment is required urgently; (ii) the nature of the trial also requires urgent action; (iii) it is not reasonably practicable to meet the conditions in paragraphs 1 to 5 of Part 5 (obtaining consent etc); and (iv) an ethics committee has given approval to the procedure under which the action is taken.

Regulation 3 amends the Adults with Incapacity (Scotland) Act 2000 consequentially.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ and copies have been placed in the library of both Houses of Parliament.

(**a**) OJ No. L121, 1.5.2001, p.34.

STATUTORY INSTRUMENTS

2006 No. 2984

MEDICINES

The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006

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Genetically Modified Organisms (Deliberate Release) Regulations 2002

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Expand + **SCHEDULE 2** Information to be included in applications for consent to release or market organisms other than genetically modified higher plants

Expand + **SCHEDULE 3** Information to be included in applications for consent to market genetically modified organisms

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Expand + **SCHEDULE 5 REVOCATIONS**

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The Genetically Modified Organisms (Contained Use) Regulations 2014

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PART 1
Interpretation and General

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2014 and come into force on 1st October 2014.

Interpretation

2.—(1) In these Regulations—

"the 1974 Act" means the Health and Safety at Work etc. Act 1974;

"the 2000 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 2000(1);

"accident" means an incident involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment;

"class" in relation to a contained use involving micro-organisms, means one of the four classes set out in Schedule 1;

"competent authority" means, in relation to premises situated in, or contained use taking place in—

(a) England and Wales, the Secretary of State and the Executive, acting jointly; or

(b) Scotland, the Scottish Ministers and the Executive, acting jointly,

and the expressions "competent authority as regards England and Wales" and "competent authority as regards Scotland" are to be construed accordingly;

"contained use" means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

"emergency plan" means a plan required by regulation 21;

"emergency services" means the police, fire and ambulance services;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both) and within the terms of this definition—

(a) genetic modification occurs at least through the use of the techniques listed in Part 1 of Schedule 2; and

(b) the techniques set out in Part 2 of Schedule 2 are not considered to result in genetic modification,

and "genetically modified" is to be construed accordingly;

"joint competent authority" means the competent authority as regards England and Wales and the competent authority as regards Scotland acting jointly;

"larger GMO" means an organism which is genetically modified or is the subject of genetic modification which is not a micro-organism;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

"notifier" means, except in regulation 14, the person who submits or has submitted a notification to the competent authority under regulation 9(2), 10(2), 11(2), 12(2) or 33(3);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human, human embryo or human admixed embryo and for the purposes of this definition—

(a) "human admixed embryo" has the same meaning as in the Human Fertilisation and Embryology Act 1990(2) by virtue of section 4A(6) and (11) of that Act; and

(b) "human embryo" has the same meaning as "embryo" in the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;

"person responsible for contained use" or "person responsible for the contained use" means—

(a) a person who has the authority to determine whether a particular contained use takes place; or

(b) a person who has control of the planning or conduct (or both) of that contained use,

and there may be more than one person responsible for the same contained use;

"premises" means both single buildings and a site made up of more than one building;

"risk assessment" means, in the context of contained use involving—

(a) genetically modified micro-organisms, an assessment carried out as required by regulation 5(1); or

(b) larger GMOs, an assessment carried out as required by regulation 6(1);

"transboundary movement" has the meaning assigned to it by Article 3 of Regulation (EC) No 1946/2003 of the European Parliament and the Council on transboundary movements of genetically modified organisms(3);

"user" means a person who undertakes or proposes to undertake a contained use;

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday specified in Schedule 1 to the Banking and Financial Dealings Act 1971(4).

(2) A reference in these Regulations to the competent authority is to be construed as a reference to the joint competent authority in relation to premises or contained use where the relevant notification is required to be submitted to the joint competent authority in accordance with regulation 9(5) or 13(1).

(3) In these Regulations—

(a) a reference to an appropriate containment level is a reference to the containment level assigned to a contained use involving micro-organisms in accordance with paragraphs 3(i) and 4 of Part 2 of Schedule 3;

(b) any reference to a contained use in a numbered class is a reference to a contained use involving micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(j) and (k) of Part 2 of Schedule 3.

(4) The measures in—

(a) Part 2 of Schedule 8 are to be applied in accordance with Part 1 of that Schedule; and

(b) Tables 1a, 1b and 1c in Part 2 of Schedule 8 are to be applied in accordance with the notes set out at the end of the table in question.

Application

3.—(1) These Regulations (except regulation 18) do not apply to the genetic modification of organisms solely by any of the techniques referred to in Part 3 of Schedule 2 nor to any organisms so modified.

(2) These Regulations do not apply to any activity in which—

(a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a product marketed in accordance with—

(i) the consent of any of the following granted under section 111(1) of the Environmental Protection Act 1990(5)—

(aa) the Secretary of State;

(bb) the Scottish Ministers, as regards Scotland;

(cc) the Welsh Ministers, as regards Wales;

(ii) a consent granted by the Northern Ireland Department of the Environment under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(6);

(iii) a written consent given by the competent authority of an EEA state in accordance with Article 15(3), 17(6), or 18(2) of Directive (EC) No 2001/18 of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms(7),

and, in each case, that activity is conducted in accordance with any conditions or limitations attached to that consent;

(b) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in—

(i) a medicinal product for human or veterinary use marketed in accordance with Regulation (EC) No 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(8);

(ii) food or feed authorised in accordance with the provisions of Regulation (EC) No 1829/2003 of the European Parliament and the Council on genetically modified food and feed(9); or

(iii) food products notified to the Commission in accordance with the provisions of Article 8.1, or feed products notified to the Commission in accordance with the provisions of Article 20.1, of Regulation (EC) No 1829/2003 of the European Parliament and the Council;

(c) genetically modified organisms are released or marketed in cases or circumstances in which—

(i) the consent of any of the following is required under section 111(1) of the Environmental Protection Act 1990—

(aa) the Secretary of State;

(bb) the Scottish Ministers, as regards Scotland;

(cc) the Welsh Ministers, as regards Wales; or

(ii) the consent of the Northern Ireland Department of the Environment is required under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.

(3) Regulations 7, 9 to 17, 18(2) and (4), 19, 20, and 23 to 25 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(4) Regulation 5 applies to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 5(1), the person undertaking that assessment is not required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.

(5) These Regulations do not extend to Northern Ireland.

(6) In this regulation, "product" means a product consisting of, or containing, a genetically modified organism or a combination of genetically modified organisms.

Meaning of "work" and "at work" and modification of the 1974 Act

4.—(1) For the purpose of these Regulations and Part 1 of the 1974 Act, the meaning of "work" is extended to include any contained use and the meaning of "at work" is extended accordingly.

(2) Sections 2(1), (2) and (3) and 7 of the 1974 Act are modified in relation to contained use as follows—

(a) those sections have effect as if a reference to—

(i) an employer includes a reference to an educational establishment providing a course of study; and

(ii) an employee includes a reference to a student undertaking contained use in that educational establishment to the extent that the contained use is under the control of that educational establishment.

(3) Section 3(2) of the 1974 Act is modified in relation to contained use so as to have effect as if the reference in that section—

(a) to a self-employed person were a reference to any person (except a student) undertaking contained use who is not an employer or an employee; and

(b) to that person's undertaking includes a reference to that contained use.

(4) In this regulation—

"educational establishment" means a university, college, school or similar educational or technical institute; and

"student" means any person studying at an educational establishment.

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(1) S.I. 2000/2831. The 2000 Regulations and all its amending instruments are revoked by these Regulations (see regulation 35).

(2) 1990 c. 37. Sections 1(1) and (6) were substituted by section 1(2) and (5) of the Human Fertilisation and Embryology Act 2008 (c. 22) and section 4A was inserted by section 4(2) of that Act.

(3) OJ No L 287, 5.11.2003, p1.

(4) 1971 c. 80. Schedule 1 was amended by section 1 of the St Andrew's Day Bank Holiday (Scotland) Act 2007 (2007 asp. 2).

(5) 1990 c. 43. The functions of the Secretary of State under section 111(1) are exercisable in relation to Scotland by the Scottish Ministers, by virtue of section 53 of the Scotland Act 1998 (c. 46). The functions of the Secretary of State under section 111(1) are exercisable in relation to Wales by the Welsh Ministers. Those functions were originally conferred on the National Assembly for Wales under S.I. 1999/672, which was an Order in Council made under section 22 of the Government of Wales Act 1998 (c. 38). Functions which had been conferred on the Assembly under an Order in Council under section 22 were transferred to the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).

(6) S.I. 1991/1714 (N.I.19).

(7) OJ No L 106, 17.04.2001, p1. Under Article 4.4 member States must designate a competent authority responsible for complying with the requirements of the Directive.

(8) OJ No L 136, 30.4.2004, p1 as amended by Regulation (EC) No 1901/2006 (OJ No L 378, 27.12.2006, p1), Regulation (EC) No 1394/2007 (OJ No L 324, 10.12.2007, p121), Regulation (EC) No 219/2009 (OJ No L 87, 31.3.2009, p109), Regulation (EC) No 470/2009 (OJ No L 152, 16.6.2009, p11), Regulation (EU) No 1235/2010 (OJ No L 348, 31.12.2010, p1) (which was corrected by Corrigendum, OJ No L 201, 27.7.2012, p138) and Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p38).

(9) OJ No L 268 18.10.2003, p1 as amended by Regulation (EC) No 1981/2006 (OJ No L 368, 23.12.2006, p[99) and Regulation (EC) No 298/2008 (OJ No L 97 9.4.2008, p64).

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The Medical Devices Regulations 2002

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2. Interpretation
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Collapse -
PART II *General Medical Devices*
5. Interpretation of Part II
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7. Classification of general medical devices
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10. CE marking of general medical devices
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12. Exemptions from regulations 8 and 10
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Collapse -
PART III *Active Implantable Medical Devices*
20. Interpretation of Part III
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27. Procedures for affixing a CE marking to active implantable medical devices
28. Procedures for custom-made active implantable medical devices
29. Procedures for active implantable medical devices for clinical investigations
30. Manufacturers etc. and conformity assessment procedures for active implantable medical devices
31. UK notified bodies and the conformity assessment procedures for active implantable medical devices

Collapse -
PART IV *In Vitro Diagnostic Medical Devices*
32. Interpretation of Part IV
33. Scope of Part IV
34. Essential requirements for *in vitro* diagnostic medical devices
35. Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements
36. CE marking of *in vitro* diagnostic medical devices
37. CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive
38. *In vitro* diagnostic medical devices not ready for use
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SCHEDULE 2 MUTUAL RECOGNITION AGREEMENTS

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The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

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Expand + **SCHEDULE 3**
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Expand + **SCHEDULE 5 Information required for a notification under regulation 9(2)**
Expand + **SCHEDULE 6 Information required for a notification under regulations 10(2), 11(2) or 12(2)**
Expand + **SCHEDULE 7 General principles of good microbiological practice and of good occupational safety and hygiene**
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Good practice in research:

Internet-mediated research

December 2016

Introduction

This document is part of a series from the UK Research Integrity Office giving guidance on particular aspects of academic, scientific and medical research. It focusses on ethical considerations and other issues applicable to internet-mediated research. The guidance covers issues relevant to all disciplines of research but does not put forward a 'one-size-fits-all' approach.

The aim is not to be prescriptive, but to highlight particular challenges relating to internet-mediated research and foster discussion on what might constitute good practice in this field. As with all of our publications, it is underpinned by 'lessons learned' from UKRIO's confidential Advisory Service on the conduct of research, which has operated since 2006 and covers all disciplines, from the arts and the humanities to health and biomedicine.

Research organisations will be able to use this guidance to raise awareness of the practicalities of internet-mediated research, and also as material for staff and student development and training. This document can also be used as a reference tool by organisations who wish to create specific policies on internet-mediated research or revise existing policies. The document complements existing guidance on internet-mediated research, such as provided by the Association of Internet Researchers, the British Psychological Society and the Economic and Social Research Council, and does not seek to replace them.

Advice and guidance from UKRIO is not mandatory but instead reflects and reinforces best practice. As the internet is an emerging research landscape, and technologies available to researchers are also emerging, it is not recommended to apply the guidance in this document prescriptively.

It is unsurprising that, as our lives have become mediated and digitised, and the internet has become pervasive, an increasing number of researchers are choosing the internet as a tool for data collection, for recruitment and as a research landscape. The ubiquitous nature of the internet and the digitisation of our lives is reflected in the number of disciplines interested in using the internet as a research tool or landscape. In turn, this new landscape requires consideration of the ethics in research practice online.

Research Ethics Committees (REC), whether operating in higher education organisations or at a national level, are currently assessing the ethical issues related to internet-mediated research without much guidance or informed support available (Morris, 2016; McKee and Porter, 2009; British Sociological Association[1]). Research Councils and professional membership bodies in the UK are becoming reactive to these issues and developing guidance. However, this scarcity of literature leads to ethical review occurring without sufficient guidance. This is challenging for higher education organisations and researchers alike, and may limit research that is subject to higher education ethical review processes.

In addition to existing guidance on internet-mediated research, the guidance presented here by UKRIO will assist in RECs developing their knowledge around internet-mediated research, embedding relevant principles and considerations and embedding this guidance into research culture to assist in ethical review, research practice and consideration of ethical issues.

The aim of this document is to assist researchers, research organisations and higher education institutions at a time where guidance and the use of this research landscape is still emerging.

Footnote to the first edition

As noted, the internet is an emerging research landscape. Similarly, the technologies available are also emerging. Consequently, UKRIO feels that giving explicit, 'one-size-fits-all' guidance on internet-mediated research would not be helpful. Instead, we wish to raise awareness of known and emerging issues of good practice in this field.

As internet-mediated research evolves further, good practice will continue to develop. This document will be revised periodically, to reflect such developments and highlight those new challenges which emerge. UKRIO will seek feedback from the research community to inform the revision of this document

Equally, if consensus develops on what *explicit* guidance on good practice in this field should look like, then this document will be revised accordingly.

[1] British Sociological Association: "*Members should take special take care when carrying out research via the Internet. Ethical standards for internet research are not well developed as yet. Eliciting informed consent, negotiating access agreements, assessing the boundaries between public and the private, and ensuring the security of data transmissions are all problematic in Internet research. Members who carry out research online should ensure that they are familiar with ongoing debates on the ethics of Internet research, and might wish to consider erring on the side of caution in making judgements affecting the wellbeing of online research participants.*"

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Defining internet-mediated research

The term 'internet-mediated research' is a generalised term for undertaking research on the internet. Examples could be where a researcher is exploring digital lives; using social media to recruit to a study; using the internet as a data collection tool; using online communication methods to undertake focus groups, hold discussions or conduct interviews; to collect data from a social media platform to undertake textual analysis.

Internet research is defined by the Norwegian National Committee for Research Ethics in the Social Sciences and the Humanities (NESH, 2014) as:

1. research ***on*** the Internet as a phenomenon in its own right, its structure and technology (production systems, technical design, programs, codes, etc.);
2. ***use of*** the Internet as a research tool (collection of data and information using informants, surveys, archives, logs, algorithms, etc.); and
3. research on production, communication and interaction ***using*** the Internet (e-mail, social media, blogs, Internet forums, discussion pages, comments fields, or the use of computer games, search engines, web pages, etc.).

And it is defined by the Association of Internet Researchers Ethics Working Committee (2012) as inquiry that:

1. utilizes the internet to collect data or information, e.g., through online interviews, surveys, archiving, or automated means of data scraping;
2. studies how people use and access the internet, e.g., through collecting and observing activities or participating on social network sites, listservs, web sites, blogs, games, virtual worlds, or other online environments or contexts;
3. utilizes or engages in data processing, analysis, or storage of datasets, databanks, and/or repositories available via the internet;
4. studies software, code, and internet technologies;
5. examines the design or structures of systems, interfaces, pages, and elements;
6. employs visual and textual analysis, semiotic analysis, content analysis, or other methods of analysis to study the web and/or internet-facilitated images, writings, and media forms; and
7. studies large scale production, use, and regulation of the internet by governments, industries, corporations, and military forces.

In addition to an increasing number of researchers choosing the internet for their research due to the pervasiveness of the internet and the digitisation of lives, there are valuable benefits and new opportunities that the internet provides. Glaser, J (2002, pp.177-193 and 189-90) states that *"the anonymity of the internet permits research into marginal groups for whom self-disclosure may have costs, and where participants may be suspicious of researchers and outsiders."* and Illingworth (2001) suggests that the internet affords an efficient way of recruiting specialist participants. Both Glaser and Illingworth are suggesting that the internet allows

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researchers to recruit hard to reach groups where the anonymity or distance provided by the internet allows internet users and research participants to disclose or speak about something sensitive or challenging. With such groups it is important to consider the disruption that research could cause to supportive communities that develop online and to the intent individuals have when going online to seek support or community.

1. The ethical principles applied within ethical review in the UK

The British Psychological Society (2013, p2) suggests a return to the first ethical principles as the landscape of internet-mediated research is and will be rapidly changing. The development of the practice of research ethics committees (in particular at a University level) are informed by ethical principles developed internationally and the guidance from the Association of Research Ethics Committees, GAFREC principles[2] (Governance Arrangements for Research Ethics Committees, 2011), UKRIO and professional membership bodies.

The Association of Research Ethics Committees 'Framework of Policies and Procedures for University Research Ethics Committees' (2013) states that the basic principles of ethical research are[3]:

- **Autonomy:** The participant must normally be as aware as possible of what the research is for and be free to take part in it without coercion or penalty for not taking part, and also free to withdraw at any time without giving a reason and without a threat of any adverse effect.
- **Beneficence:** The research must be worthwhile in itself and have beneficial effects that outweigh any risks; it follows that the methodology must be sound so that best results will be yielded.
- **Non-maleficence:** Any possible harm must be avoided or at least mitigated by robust precautions.
- **Confidentiality:** Personal data must remain unknown to all but the research team (unless the participant agrees otherwise or in cases where there is an overriding public interest, or where participants wish their voices to be heard and identified).
- **Integrity:** The researcher must be open about any actual or potential conflicts of interest, and conduct their research in a way that meets recognised standards of research integrity.

2. Specific items to consider

Offline, online or neither

"Often organisations simply cannot keep up, providing internet researchers with too little guidance and inappropriate guidance that applies overboard generalisations or make false comparisons between offline

[2] http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/
[3] The Association of Research Ethics Committees 'Framework of Policies and Procedures for University Research Ethics Committees' 2013

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and online research." McKee, Heidi A. & Porter, James E. (2009) *The ethics of Internet research: a rhetorical, case-based process* p.31

It is important to consider proportionately when considering the ethics of a study and when undertaking ethical review of any project but this focus may be even more pertinent for online studies. This is reinforced by the concern expressed above by McKee and Porter (2009); to facilitate ethically sound research, while also allowing researchers professional discretion.

Communities, individuals and data

The complexities of researching online with 'people', be that themselves or their data or both, depends on participants being identified to the researcher, the researcher being identified to participants and if so (on both sides) the verification of that identity. Much of this is dependent on the scale of the research, whether the scope is at a micro or macro level, the sensitivity of the topic and whether identifiable data are collected or not.

Communities

The British Psychological Society's guidance on internet-mediated research (2013) suggests that consideration must be given to working within communities online and asks the researcher to consider the principle of 'do no harm' with the potential of disruption of a community and the potential harm of disclosing as a researcher. BPS (2013) suggest seeking gatekeeper permission from a forum moderator if a researcher is navigating how to approach a group and negotiating the benefits or risks of disclosing as a researcher to a group. Particular consideration should be given to data or people where the interaction or data collection are undertaken in a password protected environment or environment that may be perceived by the user as private.

Deception

The British Psychological Society are a useful resource when considering using deception within a study. The use of deception is sometimes accompanied by a debriefing process following the research activity. The use of deception must be justifiable and balanced with the research objective and the anticipated risks or harms.

Valid consent

As with deception of identity it could also be said that the anonymity permitted by the internet may allow for deception and the challenge of ensuring that a participant has fully understood the study and therefore giving fully informed and valid consent. The chosen approach of informing potential participants and going consent needs to be appropriate and proportionate to the sensitivity of the topic; the potential group(s); and the nature of the study.

Age

The verification of identity, age and of valid consent is challenging. Age is perhaps the most challenging when considering either researching or not researching with children and young people. If a research project intends to not include minors, there are ways attempting to mitigate against that risk but as with many risks in research there may not be method of eliminating all risk. Uncertainty is a characteristic of

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much research online during the research activity and beyond the activity with regard to the data which is touched on further in the data management section of this document. To use social media as an example, on some social media platforms there are minimum age limits - e.g. Facebook asks users to be 13 and older; however, age is not verified in what may be seen in the 'off line' world as a valid method of verifying age and therefore researching on that social media platform may involve minors unknowingly. This must be considered on a case by case basis within ethical review dependant on the sensitivity of the topic and the approach of the researcher.

Researchers are often using a social media platform without having any capacity to control the age of users, the other uses of data and the fate of those data. Elgesum (2002, 197) acknowledges that the media often have an agenda that is different than of a research project and this puts researchers into a precarious position between using a platform which is out of their control and making attempts to protect research participants and their data to avoid causing harm.

The NESH (2014) guidelines state that "Researchers must not assume that all Internet users have a conscious view of or knowledge of which information will actually be made public and which information will not be made public." It was indicated from the backlash of the Facebook emotional contagion study[4] (Kramer et al. 2013) that researchers cannot assume how informed social media users are about how their data are being used potentially without their knowing.

Research involving security-sensitive material

Internet-mediated research, as with other forms of research, can involve security-sensitive material. UKRIO published a position statement on this issue in February 2016, included as Annex 1 of this document.

3. Social media

Social media research requires just as broad a definition as internet-mediated research. Social media research could entail any of the following:

1. Collecting data generated by the web (e.g. this could include data generated by purchases, interests, movement online demonstrating what people do as opposed to what people say, as well as data generated by the individual)
2. Data mining
3. Collecting and visualising data
4. Lurking or observation
5. Collecting textual led data
6. Interacting with groups, communities or individuals via interview, discussion, survey etc.
7. Surveillance
8. Researching key influencers or individuals with a public profile e.g. politicians, celebrities

[4] http://www.pnas.org/content/111/24/8788.full

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What are the specific considerations raised by social media research?

1. In social media research it is challenging, perhaps impossible, to only research an individual in isolation but to also include in the data collected the secondary and tertiary links of that individual but also of their networked relations, Ess (2007) and NESH (2014) indicate that ethical responsibilities in research are shared and distributed, from the researcher, not just to the research participant but also to their networked relations.
2. It is not feasible for data to be a discrete dataset and owned or controlled by the researcher- In the conference proceedings of the Academy of Social Sciences conference on Social Media (21 March 2016) Professor Susan Halford in her keynote stated that ethical review in research organisations makes the following assumptions that datasets are discrete; are of a micro scale and therefore managed and owned by the researcher; and that researchers are looking at individuals rather than tracing of social networks, social groups or connections.
3. Knowing that dataset can be altered or removed, how does a researcher navigate this; how does this affect the research record; how does that allow replicability/reproducibility of a dataset?
4. How does a researcher navigate the legal framework within which they're working – especially in areas where there is clear conflict, as an example the Twitter terms and conditions state that any quotes (verbatim or paraphrased) must include the full twitter handle and should not be altered however if a researcher is attempting to paraphrase, use pseudonym, protect the identity by anonymising or using pseudonym is a researcher excepted to breach the terms and conditions of the platform they are collecting data from? How is a researcher expected to balance the interests of the participant, the researcher's institution and the platform they are collecting data from?
5. There is a turn to maximise the value of research data by encouraging data sharing, re-use and open-access publication – this can be problematic if those data are subject to potential change if sourced from its originator or if sharing from e.g. a data repository how can this be stored and retained and are the data valid if they cannot be replicated if those data have been subject to alterations
6. Special considerations, for the participant and for the researcher are required for 'insider research' (for example researching a group or network the researcher is already within or one which they will become integrated into) as the researcher needs to prepare for the blurring boundaries, the need to create boundaries and if they are disclosing as a researcher how are they best to do this. Researchers are opting to set up separate social media accounts for their professional profile or for a specific research project to make boundaries clear from the offset.
7. Are researchers obligated to anonymise data as a default action? If so how are researchers to navigate if a participant wish to be attributed to those data

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4. Private or public spaces and data

"While much internet communication is often effectively public through greater visibility, traceability and permanence, it is not always apparent whether this makes it ethically acceptable to use such data freely for research purposes." (BPS 2013, 7)

The difficulty with privacy is that expressed concerns about privacy are often not expressed in internet user's behaviour (Spiekermann et al. 2001, Morris 2016). The MRS Delphi Report[5] evidenced the view that users accept that there is political economy or marketable value in their data without always understanding that trade and what it means to them. Elgesum (2002, 202) It is important that researchers consider this in a potential project and that ethical review takes into consideration that the public may not have informed expectations about the processing of their information and the political and fiscal value in their data. It is pertinent at this point to acknowledge that data are used by market researchers and advertisers as well as researchers and that the intent of the corporations leading social media platforms, as an example, is not to develop a platform where researcher's lives are made easy or for research to be ethically facilitated.

"As a researcher, you don't get an ethical free pass because a user checked a box next to a link to a website's terms of use. The researcher is responsible for making sure all participants are properly consented. In many cases, study staff will verbally go through lengthy consent forms with potential participants, point by point. Researchers will even quiz participants after presenting the informed consent information to make sure they really understand[6]."

Researchers are using research specific platforms like surveymonkey, Prolific Academic[7] and callforparticipants where it is easier to unpick the legal and data management workings of a platform. This may alleviate the concerns for a researcher who is navigating the need for balance between the interests of the research, the participant and their data (identifiable or not) and the online platform.

It is important to acknowledge again the uncertainty or lack of power researchers have o the state of data they may have collected but do not own. The technology available and change in legislation which may change the permanence of data. The European right to be forgotten (the right to request the removal of data) is potentially problematic for research replicability or reproducibility. A researcher can access tools which can uncover removed data, which may or may not be considered hacking, or can potentially be using research data which has since been removed. (Morris 2016).

Researchers need to be supported in the acknowledgement that some of the complexities that researchers are being asked to navigate while researching online, particularly in social media for a, which is a landscape led by conflicts between the central interests of research and the interests of those external to the research process (Elgesum 2002, 197).

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[5] Acknowledgement: Panel: Privacy, ethics and publicness in digital media environments Dr Ansgar Koene "Participant consent and withdrawal when using publicly archived data" HORIZON Digital Economy Research, University of Nottingham BAAL SIG workshop on the Ethics of Online Research Methods 17 April 2015

[6] Arthur, Charles quoting Masnick, Max June 2014 http://www.theguardian.com/technology/2014/jun/30/facebook-emotion-study-breached-ethical-guidelines-researchers-say Accessed 22/06/15

[7] Prolific Academic site http://www.prolific.ac/, it is acknowledged that this site is purely for recruitment but acts as an example of academics taking the online world into their own hands.

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The complexities, lack of control and uncertainty could be considered as similar to ethnographic methods which have learned to use a situational ethics where professional discretion and self-reflexivity are crucial. It could be proposed that undertaking research online, particularly using social media platforms, could share a similar approach. Situational ethics is used in the Association of Internet Researchers guidance (2012) where the focus is on situation ethics and contextual reflection, asking questions of values, discussion and negotiation.

5. Data management

Robust research data management are an indicator of academic rigour and therefore important regardless of research being undertaken on or off-line. This being said, research online can present specific data management difficulties predominantly because the researcher is invariably not in complete control of the original dataset and can therefore only be in control of the dataset collected by the researcher.

Unless a researcher is using a tool where the country of users or participants can be limited, online studies have no geographic boundaries. The researcher must meet the data protection standards and legislation of their home institution and of the countries in which they are undertaking research, however if the country of a user is not disclosed to the researcher this places the researcher in a predicament to meet all data protection expectations – in this situation the researcher should be encouraged to meet the standards and legislation applicable to their home institution.

Considerations are required for

1. Data protection considerations
2. Data security and sharing
3. Copyright law and any other relevant legislation
4. Presenting findings
5. Anonymity
6. the legal and/or moral duty to disclose or break confidentiality and the limitations of that if participants are not known to the researcher.

The consideration of data management is growing, particularly for European funded research and therefore the guidance available to researchers is growing. Some institutions, particularly in the UK, are expanding their capacity for research data management which is predominantly being led by libraries.

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Annex 1: UKRIO position statement on research involving security-sensitive material (February 2016)

Internet-mediated research, as with other forms of research, can involve security-sensitive material. UKRIO published the following position statement on this issue in February 2016, available at www.ukrio.org/publications/ .

Research involving security-sensitive research material raises a number of issues for researchers and research organisations. These include legal matters, questions about IT specifications related to the storage of such material, and issues of research ethics and research integrity.

UKRIO has no remit or ability to give any advice or opinion on legal matters. Similarly, questions concerning IT fall clearly outside of UKRIO's remit[8].

An important ethics issue for any research is the need to ensure the safety of researchers and others involved in the research, including any legal risks. Another issue is to address risks accruing to institutions under whose auspices the research is carried out. We note that guidance from Universities UK[9] on the oversight of security-sensitive research material was published a number of years ago, while legislation on security issues is an on-going and changing process.

We would therefore strongly recommend that the ethical review process of any research involving security-sensitive research material should check for evidence of independent legal assurance that the research carried out is within the provisions of the current law and that the research would not put researchers, other employees, students, participants or the institution itself in legal jeopardy.

[8] Those needing advice on IT specifications may wish to consult their organisation's IT department; universities may wish to seek external advice from JISC (https://www.jisc.ac.uk/).
[9] Universities UK (2012). *Oversight of security-sensitive research material in UK universities*.

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Annex 2: acknowledgements and further reading

This document was written by Isla-Kate Morris, UKRIO Adviser and University of Southampton (formerly University of Sussex), with James Parry of UKRIO.

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The Medical Devices (Amendment) Regulations 2008

Status:
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Introductory Text

1. Citation, commencement and interpretation

2. Amendment of regulation 2 of the principal Regulations

3. Amendment of regulation 3 of the principal Regulations

4. Amendment of regulation 5 of the principal Regulations

5. Amendment of regulation 8 of the principal Regulations

6. Amendment of regulation 9 of the principal Regulations

7. Amendment of regulation 14 of the principal Regulations

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11. Amendment of regulation 19 of the principal Regulations

12. Amendment of regulation 21 of the principal Regulations

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14. Amendment of regulation 30 of the principal Regulations

15. Amendment of regulation 31 of the principal Regulations

16. Amendment of regulation 47 of the principal Regulations

17. Amendment of regulation 60 of the principal Regulations

18. Amendment of regulation 63 of the principal Regulations

Signature

Explanatory Note

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Data Protection Act 1998

Changes to legislation:
Data Protection Act 1998 is up to date with all changes known to be in force on or before 13 August 2026. There are changes that may be brought into force at a future date.

View outstanding changes

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3. The special purposes.
4. The data protection principles.
5. Application of Act.
6. The Commissioner . . . .

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Data Protection Act 1998

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The Health Service (Control of Patient Information) Regulations 2002

STATUTORY INSTRUMENTS

2002 No. 1438

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

The Health Service (Control of Patient Information) Regulations 2002

Made	*23rd May 2002*
Coming into force	*1st June 2002*

Whereas a draft of the following Regulations was laid before Parliament in accordance with section 64(3) of the Health and Social Care Act 2001(1) and was approved by resolution of each House of Parliament:

Now, therefore, the Secretary of State for Health, in exercise of the powers conferred on him by sections 60(1) and 64(6), (7) and (8) of the Health and Social Care Act 2001 and all other powers enabling him in that behalf, having consulted such bodies as appear to him to represent the interests of those likely to be affected by the Regulations in accordance with section 60(7) of that Act and having sought and had regard to the views of the Patient Information Advisory Group(2) on the proposed Regulations in accordance with section 61(2) of that Act, hereby makes the following Regulations—

Citation, commencement, interpretation and extent

1.—(1) These Regulations may be cited as the Health Service (Control of Patient Information) Regulations 2002 and shall come into force on 1st June 2002.

(2) In these Regulations—

"the Act" means the Health and Social Care Act 2001,

"public authority" has the same meaning as in section 3(1) of the Freedom of Information Act 2000(3);

"public health laboratory service" means the microbiological service provided by the Public Health Laboratory Service Board under section 5(2)(c) and (4) of the National Health Service Act 1977(4);

"research ethics committee" means a local research ethics committee established or recognised by a health authority within its area or a multi-centre research ethics committee which is recognised by Secretary of State in respect of research carried out within five or more health authority areas or any other research ethics committee recognised by the Secretary of State.

(3) Any notice given under these Regulations shall be—

(a) in writing; or

(b) transmitted by electronic means in a legible form which is capable of being used for subsequent reference.

(4) Any reference in these Regulations to a numbered regulation is a reference to the regulation which bears that number in these Regulations and any reference to a numbered paragraph in a regulation is a reference to the paragraph which bears that number in that regulation.

(5) These Regulations extend to England and Wales only.

Medical purposes related to the diagnosis or treatment of neoplasia

2.—(1) Subject to paragraphs (2) to (3) and regulation 7, confidential patient information relating to patients referred for the diagnosis or treatment of neoplasia may be processed for medical purposes approved by the Secretary of State which comprise or include—

(a) the surveillance and analysis of health and disease;

(b) the monitoring and audit of health and health related care provision and outcomes where such provision has been made;

(c) the planning and administration of the provision made for health and health related care;

(d) medical research approved by research ethics committees;

(e) the provision of information about individuals who have suffered from a particular disease or condition where—

(i) that information supports an analysis of the risk of developing that disease or condition; and

(ii) it is required for the counseling and support of a person who is concerned about the risk of developing that disease or condition.

(2) For the purposes of this regulation, "processing" includes (in addition to the use, disclosure or obtaining of information) any operations, or set of operations, which are undertaken in order to establish or maintain databases for the purposes set out in paragraph (1), including—

(a) the recording and holding of information;

(b) the retrieval, alignment and combination of information;

(c) the organisation, adaption or alteration of information;

(d) the blocking, erasure and destruction of information.

(3) The processing of confidential patient information for the purposes specified in paragraph (1) may be undertaken by bodies or persons who (either individually or as members of a class) are—

(a) approved by the Secretary of State, and

(b) authorized by the person who lawfully holds the information.

(4) Where the Secretary of State considers that it is necessary in the public interest that confidential patient information is processed for a purpose specified in paragraph (1), he may give notice to any body or person who is approved and authorized under paragraph (3) to require that body or person to process that information for that purpose and any such notice may require that the information is processed forthwith or within such period as is specified in the notice.

(5) Where confidential information is processed under this regulation, the bodies and persons approved under paragraph (3) shall make available to the Secretary of State such information as he may require to assist him in the investigation and audit of that processing and in his annual consideration of the provisions of these Regulations which is required by section 60(4) of the Act.

Communicable disease and other risks to public health

3.—(1) Subject to paragraphs (2) and (3) and regulation 7, confidential patient information may be processed with a view to—

(a) diagnosing communicable diseases and other risks to public health;

(b) recognising trends in such diseases and risks;

(c) controlling and preventing the spread of such diseases and risks;

(d) monitoring and managing—

(i) outbreaks of communicable disease;

(ii) incidents of exposure to communicable disease;

(iii) the delivery, efficacy and safety of immunisation programmes;

(iv) adverse reactions to vaccines and medicines;

(v) risks of infection acquired from food or the environment (including water supplies);

(vi) the giving of information to persons about the diagnosis of communicable disease and risks of acquiring such disease.

(2) For the purposes of this regulation, "processing" includes any operations, or set of operations set out in regulation 2(2) which are undertaken for the purposes set out in paragraph (1).

(3) The processing of confidential patient information for the purposes specified in paragraph (1) may be undertaken by—

(a) the Public Health Laboratory Service;

(b) persons employed or engaged for the purposes of the health service;

(c) other persons employed or engaged by a Government Department or other public authority in communicable disease surveillance.

(4) Where the Secretary of State considers that it is necessary to process patient information for a purpose specified in paragraph (1), he may give notice to any body or person specified in paragraph (3) to require that body or person to process that information for that purpose and any such notice may require that the information is processed forthwith or within such period as is specified in the notice.

(5) Where confidential information is processed under this regulation, the bodies and persons specified in paragraph (3) shall make available to the Secretary of State such information as he may require to assist him in the investigation and audit of that processing and in his annual consideration of the provisions of these Regulations which is required by section 60(4) of the Act.

Modifying the obligation of confidence

4. Anything done by a person that is necessary for the purpose of processing confidential patient information in accordance with these Regulations shall be taken to be lawfully done despite any obligation of confidence owed by that person in respect of it.

General

5. Subject to regulation 7, confidential patient information may be processed for medical purposes in the circumstances set out in the Schedule to these Regulations provided that the processing has been approved—

(a) in the case of medical research, by both the Secretary of State and a research ethics committee, and

(b) in any other case, by the Secretary of State.

Registration

6.—(1) Where an approval granted by the Secretary of State under regulation 5 permits the transfer of confidential patient information between bodies or persons who may determine the purposes for which, and the manner in which, the information may be processed, he shall record in a register the name and address of the bodies or persons to whom that information may be transferred together with the particulars specified in paragraph (2).

(2) The following particulars are specified for inclusion in each entry in the register—

(a) a description of the confidential patient information to which the approval relates;

(b) the medical purposes for which the information may be processed;

(c) the provisions in the Schedule to these Regulations under which the information may be processed; and

(d) such other particulars as the Secretary of State may consider appropriate to enter in the register.

(3) The Secretary of State shall retain the particulars of each entry in the register for so long as confidential patient information may be processed under an approval to which the entry relates and for not less than 12 months after the termination of that approval.

(4) The Secretary of State shall, in such manner and to the extent to which he considers it appropriate, publish entries in the register.

Restrictions and exclusions

7.—(1) Where a person is in possession of confidential patient information under these Regulations, he shall not process that information more than is necessary to achieve the purposes for which he is permitted to process that information under these Regulations and, in particular, he shall—

(a) so far as it is practical to do so, remove from the information any particulars which identify the person to whom it relates which are not required for the purposes for which it is, or is to be, processed;

(b) not allow any person access to that information other than a person who, by virtue of his contract of employment or otherwise, is involved in processing the information for one or more of those purposes and is aware of the purpose or purposes for which the information may be processed;

(c) ensure that appropriate technical and organisational measures are taken to prevent unauthorised processing of that information;

(d) review at intervals not exceeding 12 months the need to process confidential patient information and the extent to which it is practicable to reduce the confidential patient information which is being processed;

(e) on request by any person or body, make available information on the steps taken to comply with these Regulations.

(2) No person shall process confidential patient information under these Regulations unless he is a health professional or a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.

(3) For the purposes of paragraph (2) "health professional" has the same meaning as in section 69(1) of the Data Protection Act 1998(5).

Enforcement Procedure

8.—(1) Any person who does not comply with a requirement imposed on him under regulation 2(4) or (5), 3(4) or (5) or 7 may be subject to a civil penalty of not exceeding £5000.

(2) The Secretary of State may determine whether any person has not complied with such a requirement and he may assess whether it is appropriate to impose the maximum civil penalty, a lesser penalty or no penalty having regard to the seriousness of any non-compliance, the circumstances of any person who has not complied and the need to ensure the compliance in respect of any such future requirements.

(3) Any penalty payable under this regulation shall be recoverable by the Secretary of State as a civil debt.

Signed by authority of the Secretary of State for Health

Hazel Blears
Parliamentary Under Secretary of State,
Department of Health

23rd May 2002

THE SCHEDULE
General Provisions

Regulations 5 and 6(2)(c)

Circumstances in which confidential patient information may be processed for medical purposes under regulation 5 and particulars for registration under regulation 6.

1. The processing of confidential patient information for medical purposes with a view to making the patient in question less readily identifiable from that information.

2. The processing of confidential patient information that relates to the present or past geographical locations of patients (including where necessary information from which patients may be identified) which is required for medical research into the locations at which disease or other medical conditions may occur.

3. The processing of confidential patient information to enable the lawful holder of that information to identify and contact patients for the purpose of obtaining consent—

(a) to participate in medical research;

(b) to use the information for the purposes of medical research, or

(c) to allow the use of tissue or other samples for medical purposes.

4. The processing of confidential patient information for medical purposes from more than one source with a view to—

(a) linking information from more than one of those sources;

(b) validating the quality or completeness of—

(i) confidential patient information, or

(ii) data derived from such information;

(c) avoiding the impairment of the quality of data derived from confidential patient information by incorrect linkage or the unintentional inclusion of the same information more than once.

5. The audit, monitoring and analysing of the provision made by the health service for patient care and treatment.

6. The granting of access to confidential patient information for one or more of the above purposes.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for the processing of patient information, including confidential patient information.

Regulation 1 contains definitions of the terms used in the Regulation and provides that the Regulations apply to England and Wales only.

Regulation 2 makes provision relating to the processing of patient information in connection with the construction and maintenance of databases by bodies (known as "cancer registries") which undertake the surveillance of health and disease of patients referred for the diagnosis or treatment of neoplasia. Regulation 2(4) provides powers under which the Secretary of State may require certain persons to process information for those purposes. Regulation 2(5) makes provision for information on the operation of these Regulations to be passed to the Secretary of State.

Regulation 3 makes provision for the processing of patient information for the recognition, control and prevention of communicable disease and other risks to public health. Regulation 3(4) provides powers under which the Secretary of State may require certain persons who perform health service or other public functions to process information where, for example, there is a need to assess whether there is a significant risk to public health. Regulation 3(5) makes provision for information on the operation of these Regulations to be passed to the Secretary of State.

Regulation 4 provides that information may be processed in accordance with these Regulations notwithstanding any common law obligation of confidence.

Regulation 5 and the Schedule to these Regulations makes general provision in relation to the processing of patient information. Such processing is restricted to that approved by the Secretary of State and, in the case of processing for research purposes, the relevant ethics committee.

Regulation 6 requires the Secretary of State to record and make public particulars relating to approvals which permit the transfer of confidential patient information.

Regulation 7 restricts the processing of information under the Regulations, for example by requiring the removal of particulars by which the persons to whom information relates can be identified if that is practical (regulation 7(1)(a)).

Regulation 8 provides for enforcement by civil penalty of requirements imposed under regulations 2(4) or (5), 3(4) or (5) or 7.

The Schedule to these Regulations sets out the circumstances in which confidential patient information may be processed for medical purposes under regulation 5. The provisions relate, for example, to the processing of confidential patient information in order to identify who should be invited to participate in medical research (paragraph 3) or to enable the auditing, monitoring and analysing the provision made by the health service (paragraph 5).

A Regulatory Impact Assessment has not been prepared for these Regulations. In general the Regulations enable the flow of information and impose no obligations. Where obligations are imposed, they are imposed primarily on those performing functions for public authorities and so any burden imposed on business is considered negligible.

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(1) 2001 c. 15.

(2) *See* S.I. 2001/2836.

(3) 2000 c. 36.

(4) 1977 c. 49; subsections (2)(c) and (4) of section 5 were amended by the Public Health Laboratory Service Act 1979 (c. 23), section 1.

(5) 1998 c. 29.

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Human Tissue Act 2004

Changes to legislation:

Human Tissue Act 2004 is up to date with all changes known to be in force on or before 15 August 2026. There are changes that may be brought into force at a future date.

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The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006

Status:
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Collapse all -

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Signature

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Explanatory Note

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The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

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Introductory Text

Collapse -

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Signature

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Human Tissue (Scotland) Act 2006

Changes to legislation:
There are currently no known outstanding effects for the Human Tissue (Scotland) Act 2006.

Collapse all -

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Human Fertilisation and Embryology Act 1990

Changes to legislation:
Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 15 August 2026. There are changes that may be brought into force at a future date.

View outstanding changes

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Human Fertilisation and Embryology Act 2008

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Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 14 August 2026. There are changes that may be brought into force at a future date.
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Ministry : Ministry of Health and Family Welfare

Department/Board : Health

Notification No. : GSR53(E)

Date of Notification : 30.01.2013

Drugs and Cosmetics (First Amendment) Rules, 2013

G.S.R.53(E).--Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health), number G.S.R. 821(E), dated the 18th November, 2011, in the Gazette of India, Extraordinary, Part II, section 3 sub-section (i), dated the 18th November 2011, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 24th November, 2011;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now therefore in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 2013.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules),-

(i) after rule 122DAA, the following rule shall be inserted, namely:-

"122-DAB. - Compensation in case of injury or death during clinical trial.-

(1) In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

(2) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(3) In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation, as per the order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of such subject.

(4) The expenses on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

(5) Any injury or death of the subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee(s), as the case may be, are entitled for financial compensation for such injury or death:

(a) adverse effect of investigational product(s);

(b) violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator;

(c) failure of investigational product to provide intended therapeutic effect;

(d) use of placebo in a placebo-controlled trial;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;

(f) for injury to a child in-utero because of the participation of parent in clinical trial;

(g) any clinical trial procedures involved in the study.

(6) The Sponsor, whether a pharmaceutical company or an institution shall give an undertaking along with the application for clinical trial permission to the Licensing Authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.

(7) In case the Sponsor fails to provide medical management for the injury to the subject and/or financial compensation to the trial subject for clinical trial related injury or financial compensation to the subject's nominee(s) in case of clinical trial related death of the subject, the Licensing Authority may after giving an opportunity to show cause why such an order should not be passed,

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by an order in writing, stating the reasons thereof, suspend or cancel the clinical trial and/or restrict Sponsor including his representative(s) to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

(ii) in the said rules, in Schedule Y, in paragraph 2 relating to Clinical Trial,

(a) in sub paragraph (2) relating to Responsibilities of Sponsor,-

(i) clause (iv) shall be substituted with the following, namely:-

"(iv) Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the Sponsor to Chairman of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority as defined under rule 21(b) under Appendix XII with a copy of the report to the Licensing Authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the Sponsor to the Licensing Authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.",

(b) after clause (iv), the following shall be inserted, namely:-

"(v) in case of injury or death occurring to the clinical trial subject, the Sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII;

(vi) the Sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.";

(c) in sub paragraph (3) relating to Responsibilities' of the investigator(s),-

(i) the sub paragraph "(3)" shall be numbered as "(3)(i)";

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(ii) in the so numbered, clause (i), the words and figures "Sponsor Within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 7 working days of their occurrence" shall be substituted with the words, figures and brackets "Licensing Authority defined under clause (b) of rule 21, the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, and the Ethics Committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the Investigator to Chairman of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.";

(iii) after the so numbered clause (i), the following clause shall be inserted, namely:-

"(ii) The Investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or his/her nominee(s) of their rights to contact the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.";

(d) in clause (5) relating to Responsibilities of the Ethics Committee, after sub-clause (iii), the following sub-clause shall be inserted, namely:-

"(iv) In case of serious adverse event of death occurring to the clinical trial subject, the Ethics Committee shall forward it's report on the serious adverse event of death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee constituted by the Licensing Authority under Appendix XII

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with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death. In case of serious adverse event, other than death occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event."

(e) after sub paragraph (5), the following shall be inserted namely:-

"5(A). Serious Adverse Events

(1) A serious adverse event is an untoward medical occurrence during clinical trial that is associated with death, in patient hospitalisation (in case the study was being conducted on out-patient), prolongation of hospitalisation (in case the study was being conducted on in-patient), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life threatening.

(2) The Investigator shall report alt serious and unexpected adverse events to the Licensing Authority as defined under clause (b) of rule 21, the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, and the Ethics Committee that accorded approval to the study protocol, within twenty four hours of their occurrence as per Appendix XI, and the said Licensing Authority shall determine the cause of injury or death as per the procedure prescribed under Appendix XII and pass orders as deemed necessary.".

(iii) in APPENDIX V.

(A) in serial number 1, in sub serial number 1.1, the entries against item number 9 shall be substituted with the following, namely:-

"9. Statement describing the financial compensation and medical management as under:

(a) In the event of an injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.

(b) In the event of a trial related injury or death, the Sponsor or his

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representative, whosoever has obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation for the injury or death."

(B) in serial number 2, after the line "Date of Birth/Age....." the following shall be inserted, namely:-

"Address of the Subject.....

Qualification.....

Occupation: Student/Self-Employed/Service/Housewife/Others (Please tick as appropriate)

Annual Income of the subject.....

Name and address of the nominee(s) and his relation to the subject..... (for the purpose of compensation in case of trial related death).";

(C) after the words, "Name of the witness....." occurring at the end, the following shall be inserted, namely:-

"(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his/her attendant).";

(iv) after APPENDIX XI, the following shall be inserted, namely:-

"APPENDIX XII

Compensation in case of injury or death during clinical trial

(1) In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

(2) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(3) In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation, as per the order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(4) The financial compensation for clinical trial related injury or death could be in the form of:-

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(a) payment for medical management;

(b) financial compensation for trial related injury;

(c) financial compensation to nominee(s) of the trial subject in case of death;

(d) financial compensation for the child injured in-utero because of the participation of parent in clinical trial.

(5) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation, if the injury or death has occurred because of any of the following reasons, namely:-

(a) adverse effect of investigational product(s);

(b) any clinical trial procedures involved in the study;

(c) violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the Investigator;

(d) failure of investigational product to provide intended therapeutic effect;

(e) use of placebo in a placebo-controlled trial;

(f) adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;

(g) injury to the child in-utero because of the participation of parent in clinical trial.

(6) Procedure for payment of financial compensation

(a) The Investigator shall report all serious and unexpected adverse events to the Licensing Authority as defined under clause (b) of rule 21, the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial and the Ethics Committer that accorded approval to the study protocol, within twenty four hours of their occurrence as per Appendix XI.

(b) (i) The cases of serious adverse events of death shall be examined as under:

(A) An independent Expert Committee shall be constituted by the licensing Authority as defined under rule 21(b) to examine the cases and recommend to the Licensing Authority for the purpose of arriving at the cause of death and quantum of compensation in case of clinical trial related death.

(B) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the

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Investigator shall forward their reports on serious adverse event of death after due analysis to Chairman of the Ethics Committee and Chairman of the Expert Committee with a copy of the report to the Licensing Authority as defined under rule 21(b) and the head of the Institution where the trial has been conducted, within ten calendar days of occurrence of the serious adverse event of death.

(C) The Ethics Committee shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death.

(D) The Expert Committee shall examine the report of serious adverse event of death and give its recommendations to the Licensing Authority for the purpose of arriving at the cause of the adverse event within thirty days of receiving the report from the Ethics Committee, and the Expert Committee while examining the event, may take into consideration, the reports of the Investigator, Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Ethics Committee.

(E) In the case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

(F) The Licensing Authority shall consider the recommendations of the Expert Committee and shall determine the cause of death and pass orders as deemed necessary.

(G) In case of clinical trial related death, the Licensing Authority, after considering the recommendations of the Expert Committee, shall decide the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

(ii) Cases of serious adverse events, other than deaths, shall be examined as under:

(A) The Sponsor or his representative, whosoever had obtained permission

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from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Licensing Authority as defined under rule 21(b), Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(B) The Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Licensing Authority within twenty one calendar days of occurrence of the serious adverse event.

(C) The Licensing Authority shall determine the cause of injury and pass order as deemed necessary. The Licensing Authority shall have the option to constitute an independent Expert Committee, wherever considered necessary, to examine such serious adverse events of injury, which will recommend to the Licensing Authority for arriving at the cause of the injury and also the quantum of compensation in case of clinical trial related injury, to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

(D) In case of clinical trial related injury, the Licensing Authority, shall decide the quantum of compensation to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

(c) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, shall pay the compensation in case of clinical trial related injury or death as per the order of the Licensing Authority as defined under rule 21 (b) within thirty days of the receipt of such order.

[F. No. X-11014/6/2011-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot note: The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1) dated the 21st December, 1945 and last amended vide notification number G.S.R. 844(E), dated the 26th November, 2012.

HONG KONG SPECIAL ADMINISTRATIVE REGION

Ordinance No. 20 of 2016

L.S.

John TSANG
Acting Chief Executive
8 June 2016

An Ordinance to amend the Human Reproductive Technology Ordinance to provide for a new offence in respect of publishing or distributing advertisements promoting sex selection services.

[ ]

Enacted by the Legislative Council.

1. Short title and commencement

(1) This Ordinance may be cited as the Human Reproductive Technology (Amendment) Ordinance 2016.

(2) This Ordinance comes into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

2. Human Reproductive Technology Ordinance amended

The Human Reproductive Technology Ordinance (Cap. 561) is amended as set out in sections 3 and 4.

3. Section 15A added

After section 15—

Add

"**15A. Prohibition against publishing or distributing advertisements promoting sex selection services**

(1) A person must not cause to be published or distributed, or knowingly publish or distribute, an advertisement promoting sex selection services, whether or not the services are provided in Hong Kong.

(2) For the purposes of subsection (1), publishing or distributing an advertisement includes publishing or distributing a hyperlink that gives access to an advertisement.

(3) It is a defence for a person charged with an offence for contravening subsection (1) to show that the advertisement was—

(a) contained in a publication of a technical character for circulation amongst specified persons;

(b) published or distributed for academic teaching, or academic discussion, for specified persons; or

(c) contained in a private correspondence.

(4) Subsection (3)(c) does not apply if—

(a) the correspondence was published or distributed in the course of a business of promoting sex selection services (whether or not carried on by the person charged with the offence); or

(b) the advertisement was accessible through a hyperlink provided in the correspondence and the person charged with the offence (whether by the person or by any officer, employee or agent of the person)—

(i) devised the contents of the advertisement, either in whole or in part; or

(ii) selected, added to, modified or otherwise exercised control over the contents of the advertisement.

(5) It is a defence for a person charged with an offence for contravening subsection (1) to show that—

(a) the conduct was engaged in by the person—

(i) in the course of the person's employment; and

(ii) in accordance with instructions given by the person's employer in the course of that employment; and

(b) at the time the conduct was engaged in, the person was not in a position to make or influence a decision regarding the conduct.

(6) For the purposes of this section—

(a) conduct engaged in by an employee in the course of employment is to be treated as engaged in by the employer, as well as by the employee (whether or not the conduct was engaged in with the employer's knowledge or approval); and

(b) conduct engaged in by an agent with the authority of the principal is to be treated as engaged in by the principal, as well as by the agent (whether the authority was express or implied, and whether the authority is precedent or subsequent).

(7) If the employer or principal is charged with an offence for contravening subsection (1) in respect of

conduct alleged to have been engaged in by the employee or agent (as the case may be), it is a defence for the employer or principal to show that the employer or principal took all such steps as were reasonable and exercised all due diligence to prevent the employee or agent (as the case may be) from—

(a) engaging in the conduct; or

(b) engaging in conduct of that description in the course of the employee's employment or the agent's authority.

(8) To avoid doubt, for a person who owns, manages or controls a physical space or website (***relevant person***), subsection (1) does not apply to the publication or distribution of the advertisement on the physical space or website if—

(a) the physical space or website is used by another person (other than an officer, employee or agent of the relevant person) to effect the publication or distribution; and

(b) the relevant person has removed the advertisement from the physical space or website as soon as practicable after the relevant person becomes aware of the publication or distribution.

(9) In this section—

conduct (行為) includes acts and omissions;

correspondence (通訊) includes correspondence in electronic form;

sex selection services (性別選擇服務) means services provided for selecting the sex of an embryo by means of a reproductive technology procedure, whether

directly or indirectly (including by the implantation of an embryo of a particular sex in the body of a woman);

specified person (指明人士) means any of the following persons—

(a) registered medical practitioners;

(b) the medical and para-medical staff of—

(i) premises to which a licence relates;

(ii) a hospital or maternity home to which the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) applies;

(iii) a clinic to which the Medical Clinics Ordinance (Cap. 343) applies;

(iv) a hospital, maternity home or clinic maintained by the Government, The Chinese University of Hong Kong or the University of Hong Kong;

(v) a hospital, maternity home or clinic managed or controlled by the Hospital Authority established under the Hospital Authority Ordinance (Cap. 113).".

4. Section 39 amended (offences)

Section 39(1), after "(5),"—

Add

"15A(1),".

臨床研究法（平成二十九年法律第十六号）

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附則

第一章　総則

（目的）

第一条　この法律は、臨床研究の実施の手続、認定臨床研究審査委員会による審査意見業務の適切な実施のための措置、臨床研究に関する資金等の提供に関する情報の公表の制度等を定めることにより、臨床研究

の対象者をはじめとする国民の臨床研究に対する信頼の確保を図ることを通じてその実施を推進し、もって保健衛生の向上に寄与することを目的とする。

（定義）

第二条　この法律において「臨床研究」とは、医薬品等を人に対して用いることにより、当該医薬品等の有効性又は安全性を明らかにする研究（当該研究のうち、当該医薬品等の有効性又は安全性についての試験が、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（昭和三十五年法律第百四十五号。以下この条において「医薬品医療機器等法」という。）第八十条の二第二項に規定する治験に該当するものその他厚生労働省令で定めるものを除く。）をいう。

２　この法律において「特定臨床研究」とは、臨床研究のうち、次のいずれかに該当するものをいう。

一　医薬品等製造販売業者又はその特殊関係者（医薬品等製造販売業者と厚生労働省令で定める特殊の関係のある者をいう。以下同じ。）から研究資金等（臨床研究の実施のための資金（厚生労働省令で定める利益を含む。）をいう。以下同じ。）の提供を受けて実施する臨床研究（当該医薬品等製造販売業者が製造販売（医薬品医療機器等法第二条第十三項に規定する製造販売をいう。以下同じ。）をし、又は

しようとする医薬品等を用いるものに限る。）

二　次に掲げる医薬品等を用いる臨床研究（前号に該当するものを除く。）

イ　次項第一号に掲げる医薬品であって、医薬品医療機器等法第十四条第一項又は第十九条の二第一項の承認を受けていないもの

ロ　次項第一号に掲げる医薬品であって、医薬品医療機器等法第十四条第一項又は第十九条の二第一項の承認（医薬品医療機器等法第十四条第九項（医薬品医療機器等法第十九条の二第五項において準用する場合を含む。）の変更の承認を含む。以下ロにおいて同じ。）を受けているもの（当該承認に係る用法、用量その他の厚生労働省令で定める事項（以下ロにおいて「用法等」という。）と異なる用法等で用いる場合に限る。）

ハ　次項第二号に掲げる医療機器であって、医薬品医療機器等法第二十三条の二の五第一項若しくは第二十三条の二の十七第一項の承認若しくは医薬品医療機器等法第二十三条の二の二十三第一項の認証を受けていないもの又は医薬品医療機器等法第二十三条の二の十二第一項の規定による届出が行われていないもの

ニ　次項第二号に掲げる医療機器であって、医薬品医療機器等法第二十三条の二の五第一項若しくは第二十三条の二の十七第一項の承認（医薬品医療機器等法第二十三条の二の五第十一項（医薬品医療機器等法第二十三条の二の十七第五項において準用する場合を含む。）の変更の承認を含む。以下ニにおいて同じ。）若しくは医薬品医療機器等法第二十三条の二の二十三第一項の認証（同条第六項の変更の認証を含む。以下ニにおいて同じ。）を受けているもの又は医薬品医療機器等法第二十三条の二の十二第一項の規定による届出（同条第二項の規定による変更の届出を含む。以下ニにおいて同じ。）が行われているもの（当該承認、認証又は届出に係る使用方法その他の厚生労働省令で定める事項（以下ニにおいて「使用方法等」という。）と異なる使用方法等で用いる場合に限る。）

ホ　次項第三号に掲げる再生医療等製品であって、医薬品医療機器等法第二十三条の二十五第一項又は第二十三条の三十七第一項の承認を受けていないもの

ヘ　次項第三号に掲げる再生医療等製品であって、医薬品医療機器等法第二十三条の二十五第一項又は第二十三条の三十七第一項の承認（医薬品医療機器等法第二十三条の二十五第九項（医薬品医療機器等法第二十三条の三十七第五項において準用する場合を含む。）の変更の承認を含む。以下へにおい

て同じ。）を受けているもの（当該承認に係る用法、用量その他の厚生労働省令で定める事項（以下へにおいて「用法等」という。）と異なる用法等で用いる場合に限る。）

3　この法律において「医薬品等」とは、次に掲げるものをいう。

一　医薬品医療機器等法第二条第一項に規定する医薬品（同条第十四項に規定する体外診断用医薬品を除く。）

二　医薬品医療機器等法第二条第四項に規定する医療機器

三　医薬品医療機器等法第二条第九項に規定する再生医療等製品

4　この法律において「医薬品等製造販売業者」とは、医薬品等に係る医薬品医療機器等法第十二条第一項、第二十三条の二第一項又は第二十三条の二十第一項の許可を受けている者をいう。

第二章　臨床研究の実施

（臨床研究実施基準）

第三条　厚生労働大臣は、厚生労働省令で、臨床研究の実施に関する基準（以下「臨床研究実施基準」という。）を定めなければならない。

２　臨床研究実施基準においては、次に掲げる事項について定めるものとする。

一　臨床研究の実施体制に関する事項

二　臨床研究を行う施設の構造設備に関する事項

三　臨床研究の実施状況の確認に関する事項

四　臨床研究の対象者に健康被害が生じた場合の補償及び医療の提供に関する事項

五　特定臨床研究（前条第二項第一号に掲げるものに限る。）に用いる医薬品等の製造販売をし、又はしようとする医薬品等製造販売業者及びその特殊関係者の当該特定臨床研究に対する関与に関する事項

六　その他臨床研究の実施に関し必要な事項

３　厚生労働大臣は、臨床研究実施基準を定め、又は変更するときは、あらかじめ、厚生科学審議会の意見を聴かなければならない。

（臨床研究実施基準の遵守）

第四条　臨床研究（特定臨床研究を除く。）を実施する者は、臨床研究実施基準に従ってこれを実施するよう努めなければならない。

２　特定臨床研究を実施する者は、臨床研究実施基準に従ってこれを実施しなければならない。

（実施計画の提出）

第五条　特定臨床研究を実施する者は、特定臨床研究ごとに、次に掲げる事項を記載した特定臨床研究の実施に関する計画（以下「実施計画」という。）を作成し、厚生労働省令で定めるところにより、厚生労働大臣に提出しなければならない。

一　氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

二　特定臨床研究の目的及び内容並びにこれに用いる医薬品等の概要

三　特定臨床研究の実施体制に関する事項

四　特定臨床研究を行う施設の構造設備に関する事項

五　特定臨床研究の実施状況の確認に関する事項

六　特定臨床研究の対象者に健康被害が生じた場合の補償及び医療の提供に関する事項

七　特定臨床研究（第二条第二項第一号に掲げるものに限る。）に用いる医薬品等の製造販売をし、又はしようとする医薬品等製造販売業者及びその特殊関係者の当該特定臨床研究に対する関与に関する事項

八　特定臨床研究について第二十三条第一項に規定する審査意見業務を行う同条第五項第二号に規定する認定臨床研究審査委員会（以下この章において「認定臨床研究審査委員会」という。）の名称

九　その他厚生労働省令で定める事項

２　実施計画には、次に掲げる書類を添付しなければならない。

一　次項の規定による意見の内容を記載した書類

二　その他厚生労働省令で定める書類

３　特定臨床研究を実施する者は、第一項の規定により実施計画を提出する場合においては、厚生労働省令で定めるところにより、実施計画による特定臨床研究の実施の適否及び実施に当たって留意すべき事項について、当該実施計画に記載されている認定臨床研究審査委員会の意見を聴かなければならない。

（実施計画の変更）

第六条　前条第一項の規定により実施計画を提出した者（以下「特定臨床研究実施者」という。）は、当該実施計画の変更（厚生労働省令で定める軽微な変更を除く。次項本文において同じ。）をするときは、その変更後の実施計画を、厚生労働省令で定めるところにより、厚生労働大臣に提出しなければならない。

２　前条第二項及び第三項の規定は、前項の実施計画の変更について準用する。ただし、同条第二項第二号に掲げる書類については、既に厚生労働大臣に提出されている当該書類の内容に変更がないときは、その添付を省略することができる。

３　特定臨床研究実施者は、実施計画について、第一項の厚生労働省令で定める軽微な変更をしたときは、その変更の日から十日以内に、その内容を、当該実施計画に記載されている認定臨床研究審査委員会に通知するとともに、厚生労働大臣に届け出なければならない。

（実施計画の遵守）

第七条　特定臨床研究実施者は、第五条第一項又は前条第一項の規定により提出した実施計画（同項の厚生労働省令で定める軽微な変更をしたときは、当該変更後のもの）に従って特定臨床研究を実施しなければならない。

（特定臨床研究の中止）

第八条　特定臨床研究実施者は、特定臨床研究を中止したときは、その中止の日から十日以内に、その旨を、当該特定臨床研究の実施計画に記載されている認定臨床研究審査委員会に通知するとともに、厚生労働

大臣に届け出なければならない。

（特定臨床研究の対象者等の同意）

第九条　特定臨床研究を実施する者は、当該特定臨床研究の対象者に対し、あらかじめ、当該特定臨床研究の目的及び内容並びにこれに用いる医薬品等の概要、当該医薬品等の製造販売をし、若しくはしようとする医薬品等製造販売業者又はその特殊関係者から研究資金等の提供を受けて実施する場合においては第三十二条に規定する契約の内容その他厚生労働省令で定める事項について、厚生労働省令で定めるところにより説明を行い、その同意を得なければならない。ただし、疾病その他厚生労働省令で定める事由により特定臨床研究の対象者の同意を得ることが困難な場合であって、当該対象者の配偶者、親権を行う者その他厚生労働省令で定める者のうちいずれかの者に対し、説明を行い、その同意を得たとき、その他厚生労働省令で定めるときは、この限りでない。

（特定臨床研究に関する個人情報の保護）

第十条　特定臨床研究を実施する者は、当該特定臨床研究の対象者の個人情報（個人に関する情報であって、当該情報に含まれる氏名、生年月日その他の記述等により特定の個人を識別することができるもの（他

の情報と照合することにより、特定の個人を識別することができることとなるものを含む。）をいう。以下この条において同じ。）の漏えい、滅失又は毀損の防止その他の個人情報の適切な管理のために必要な措置を講じなければならない。

（秘密保持義務）

第十一条　特定臨床研究に従事する者又は特定臨床研究に従事する者であった者は、正当な理由がなく、特定臨床研究の実施に関して知り得た当該特定臨床研究の対象者の秘密を漏らしてはならない。

（特定臨床研究に関する記録）

第十二条　特定臨床研究を実施する者は、当該特定臨床研究の対象者ごとに、医薬品等を用いた日時及び場所その他厚生労働省令で定める事項に関する記録を作成し、厚生労働省令で定めるところにより、これを保存しなければならない。

（認定臨床研究審査委員会への報告）

第十三条　特定臨床研究実施者は、特定臨床研究の実施に起因するものと疑われる疾病、障害若しくは死亡又は感染症（次条及び第二十三条第一項において「疾病等」という。）の発生を知ったときは、厚生労働

省令で定めるところにより、その旨を当該特定臨床研究の実施計画に記載されている認定臨床研究審査委員会に報告しなければならない。

２　前項の規定により報告を受けた認定臨床研究審査委員会が特定臨床研究実施者に対し意見を述べたときは、当該特定臨床研究実施者は、当該意見を尊重して必要な措置をとらなければならない。

（厚生労働大臣への報告）

第十四条　特定臨床研究実施者は、特定臨床研究の実施に起因するものと疑われる疾病等の発生に関する事項で厚生労働省令で定めるものを知ったときは、厚生労働省令で定めるところにより、その旨を厚生労働大臣に報告しなければならない。

（厚生科学審議会への報告）

第十五条　厚生労働大臣は、毎年度、前条の規定による報告の状況について厚生科学審議会に報告し、必要があると認めるときは、その意見を聴いて、特定臨床研究の実施による保健衛生上の危害の発生又は拡大を防止するために必要な措置をとらなければならない。

２　厚生科学審議会は、前項の場合のほか、特定臨床研究の実施による保健衛生上の危害の発生又は拡大を

防止するために必要な措置について、調査審議し、必要があると認めるときは、厚生労働大臣に意見を述べることができる。

3　厚生労働大臣は、第一項の規定による報告又は措置を行うに当たっては、前条の規定による報告に係る情報の整理を行うとともに、必要があると認めるときは、同条の規定による報告に関する調査を行うものとする。

（機構による情報の整理及び調査の実施）

第十六条　厚生労働大臣は、独立行政法人医薬品医療機器総合機構（以下この条において「機構」という。）に、前条第三項に規定する情報の整理を行わせることができる。

2　厚生労働大臣は、機構の求めに応じ、機構が前項の規定による情報の整理を行うために、第十四条の規定による報告に係る特定臨床研究の内容その他厚生労働省令で定める事項に関する情報を提供することができる。

3　厚生労働大臣は、機構に第一項の規定による情報の整理を行わせるときは、その旨を公示しなければならない。

４　厚生労働大臣が、機構に第一項の規定による情報の整理を行わせるときは、第十四条の規定による報告をする者は、同条の規定にかかわらず、厚生労働省令で定めるところにより、機構に報告しなければならない。

５　機構は、第一項の規定による情報の整理を行ったときは、遅滞なく、当該情報の整理の結果を、厚生労働大臣に報告しなければならない。

６　第一項、第二項及び前項の規定は、前条第三項に規定する調査について準用する。

（認定臨床研究審査委員会への定期報告）

第十七条　特定臨床研究実施者は、厚生労働省令で定めるところにより、定期的に、特定臨床研究の実施状況について、当該特定臨床研究の実施計画に記載されている認定臨床研究審査委員会に報告しなければならない。

２　前項の規定により報告を受けた認定臨床研究審査委員会が特定臨床研究実施者に対し意見を述べたときは、当該特定臨床研究実施者は、当該意見を尊重して必要な措置をとらなければならない。

（厚生労働大臣への定期報告）

第十八条　特定臨床研究実施者は、厚生労働省令で定めるところにより、定期的に、特定臨床研究の実施状況について、厚生労働大臣に報告しなければならない。

２　厚生労働大臣は、前項の規定により報告を受けたときは、当該報告を取りまとめ、その概要を公表しなければならない。

（緊急命令）

第十九条　厚生労働大臣は、特定臨床研究の実施による保健衛生上の危害の発生又は拡大を防止するため必要があると認めるときは、特定臨床研究を実施する者に対し、当該特定臨床研究を停止することその他保健衛生上の危害の発生又は拡大を防止するための応急の措置をとるべきことを命ずることができる。

（改善命令等）

第二十条　厚生労働大臣は、この章の規定又はこの章の規定に基づく命令に違反していると認めるときは、特定臨床研究を実施する者に対し、当該特定臨床研究を臨床研究実施基準に適合させること、実施計画を変更することその他当該違反を是正するために必要な措置をとるべきことを命ずることができる。

２　厚生労働大臣は、特定臨床研究を実施する者が前項の規定による命令に従わないときは、当該特定臨床

研究を実施する者に対し、期間を定めて特定臨床研究の全部又は一部の停止を命ずることができる。

（特定臨床研究以外の臨床研究を実施する者が講ずべき措置）

第二十一条　臨床研究（特定臨床研究を除く。）を実施する者は、第五条第一項の規定に準じてその実施に関する計画を作成するほか、当該計画を作成し、又は変更する場合においては、認定臨床研究審査委員会の意見を聴くよう努めるとともに、第七条及び第九条から第十二条までの規定に準じて、必要な措置を講ずるよう努めなければならない。

（適用除外）

第二十二条　この章の規定は、臨床研究のうち、医薬品等を用いることが再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）第二条第一項に規定する再生医療等に該当する場合については、適用しない。

第三章　認定臨床研究審査委員会

（臨床研究審査委員会の認定）

第二十三条　臨床研究に関する専門的な知識経験を有する者により構成される委員会であって、次に掲げる

業務（以下「審査意見業務」という。）を行うもの（以下この条において「臨床研究審査委員会」という。）を設置する者（病院（医療法（昭和二十三年法律第二百五号）第一条の五第一項に規定する病院をいう。）若しくは診療所（同条第二項に規定する診療所をいい、同法第五条第一項に規定する医師又は歯科医師の住所を含む。）の開設者又は医学医術に関する学術団体その他の厚生労働省令で定める団体（法人でない団体にあっては、代表者又は管理人の定めのあるものに限る。）に限る。）は、その設置する臨床研究審査委員会が第四項各号に掲げる要件に適合していることについて、厚生労働大臣の認定を受けなければならない。

一　第五条第三項（第六条第二項において準用する場合を含む。）の規定により意見を求められた場合において、実施計画について臨床研究実施基準に照らして審査を行い、特定臨床研究を実施する者に対し、特定臨床研究の実施の適否及び実施に当たって留意すべき事項について意見を述べる業務

二　第十三条第一項の規定により報告を受けた場合において、必要があると認めるときは、特定臨床研究実施者に対し、当該報告に係る疾病等の原因の究明又は再発防止のために講ずべき措置について意見を述べる業務

三　第十七条第一項の規定により報告を受けた場合において、必要があると認めるときは、特定臨床研究実施者に対し、当該報告に係る特定臨床研究の実施に当たって留意すべき事項又は改善すべき事項について意見を述べる業務

四　前三号のほか、必要があると認めるときは、その名称が第五条第一項第八号の認定臨床研究審査委員会として記載されている実施計画により特定臨床研究を実施する者に対し、当該特定臨床研究を臨床研究実施基準に適合させるために改善すべき事項又は疾病等の発生防止のために講ずべき措置について意見を述べる業務

２　前項の認定を受けようとする者は、厚生労働省令で定めるところにより、次に掲げる事項を記載した申請書を厚生労働大臣に提出して、同項の認定の申請をしなければならない。

一　氏名又は名称及び住所並びに法人にあっては、その代表者（法人でない団体にあっては、その代表者又は管理人）の氏名

二　臨床研究審査委員会の名称

三　臨床研究審査委員会の委員の氏名

四　審査意見業務を行う体制に関する事項

五　その他厚生労働省令で定める事項

3　前項の申請書には、次項第二号に規定する業務規程その他の厚生労働省令で定める書類を添付しなければならない。

4　厚生労働大臣は、第一項の認定（以下この条において単に「認定」という。）の申請があった場合において、その申請に係る臨床研究審査委員会が次に掲げる要件に適合すると認めるときは、認定をしなければならない。

一　臨床研究に関する専門的な知識経験を有する委員により構成され、かつ、審査意見業務の公正な実施に支障を及ぼすおそれがないものとして厚生労働省令で定める体制が整備されていること。

二　審査意見業務の実施の方法、審査意見業務に関して知り得た情報の管理及び秘密の保持の方法その他の審査意見業務を適切に実施するための方法に関する業務規程が整備されていること。

三　前二号に掲げるもののほか、審査意見業務の適切な実施のために必要なものとして厚生労働省令で定める基準に適合するものであること。

5　厚生労働大臣は、前項の規定により認定をしたときは、次に掲げる事項を公示しなければならない。

一　認定を受けた者（以下「認定委員会設置者」という。）の氏名又は名称及び住所

二　認定に係る臨床研究審査委員会（以下「認定臨床研究審査委員会」という。）の名称

（欠格事由）

第二十四条　前条第四項の規定にかかわらず、次の各号のいずれかに該当するときは、同条第一項の認定を受けることができない。

一　申請者が、禁錮以上の刑に処せられ、その執行を終わり、又は執行を受けることがなくなるまでの者であるとき。

二　申請者が、この法律その他国民の保健医療に関する法律で政令で定めるものの規定により罰金の刑に処せられ、その執行を終わり、又は執行を受けることがなくなるまでの者であるとき。

三　申請者が、第三十一条第一項の規定により前条第一項の認定を取り消され、その認定の取消しの日から起算して三年を経過しない者（認定の取消しの処分に係る行政手続法（平成五年法律第八十八号）第十五条第一項の規定による通知があった日（以下この条において「通知日」という。）前六十日以内に

当該認定を取り消された法人の役員（いかなる名称によるかを問わず、これと同等以上の職権又は支配力を有する者を含む。以下この条において同じ。）であった者で当該認定の取消しの日から起算して三年を経過しないもの及び通知日前六十日以内に認定を取り消された団体の代表者又は管理人であった者で当該認定の取消しの日から起算して三年を経過しないものを含む。）であるとき。ただし、当該認定の取消しが、認定の取消しの処分の理由となった事実及び当該事実の発生を防止するための認定委員会設置者による体制の整備についての取組の状況その他の当該事実に関して当該認定委員会設置者が有していた責任の程度を考慮して、この号本文に規定する認定の取消しに該当しないこととすることが相当であると認められる認定の取消しとして厚生労働省令で定めるものに該当する場合を除く。

四　申請者が、第三十一条第一項の規定による前条第一項の認定の取消しの処分に係る通知日から当該処分をする日又は処分をしないことを決定する日までの間に第二十七条第一項の規定による廃止の届出をした者（当該廃止について相当の理由がある者を除く。）で、当該届出の日から起算して三年を経過しないものであるとき。

五　申請者が、前条第一項の認定の申請前三年以内に審査意見業務に関し不正又は著しく不当な行為をし

た者であるとき。

六　申請者が、法人であって、その役員のうちに前各号のいずれかに該当する者があるとき。

七　申請者が、法人でない団体であって、その代表者又は管理人のうちに第一号から第五号までのいずれかに該当する者があるとき。

（変更の認定）

第二十五条　認定委員会設置者は、第二十三条第二項第三号又は第四号に掲げる事項の変更（厚生労働省令で定める軽微な変更を除く。）をするときは、厚生労働大臣の認定を受けなければならない。

2　認定委員会設置者は、前項の厚生労働省令で定める軽微な変更をしたときは、遅滞なく、その内容を厚生労働大臣に届け出なければならない。

3　第二十三条第二項から第五項までの規定は、第一項の変更の認定について準用する。

4　認定委員会設置者は、第二十三条第二項第一号、第二号若しくは第五号に掲げる事項又は同条第三項に規定する書類に記載した事項に変更があったとき（当該変更が厚生労働省令で定める軽微なものであるときを除く。）は、遅滞なく、その内容を厚生労働大臣に届け出なければならない。

５　第二十三条第五項の規定は、同項各号に掲げる事項について前項の規定により届出があった場合について準用する。

（認定の有効期間）

第二十六条　第二十三条第一項の認定の有効期間は、当該認定の日から起算して三年とする。

２　前項の有効期間（当該有効期間についてこの項の規定により更新を受けたときにあっては、更新後の当該有効期間をいう。以下この条において単に「有効期間」という。）の満了後引き続き認定臨床研究審査委員会を設置する認定委員会設置者は、有効期間の更新を受けなければならない。

３　前項の更新を受けようとする認定委員会設置者は、有効期間の満了の日の九十日前から六十日前までの間（以下この項において「更新申請期間」という。）に、厚生労働大臣に前項の更新の申請をしなければならない。ただし、災害その他やむを得ない事由により更新申請期間に更新の申請をすることができないときは、この限りでない。

４　前項の申請があった場合において、有効期間の満了の日までに当該申請に対する処分がされないときは、従前の認定は、有効期間の満了後もその処分がされるまでの間は、なお効力を有する。

５　前項の場合において、第二項の更新がされたときは、有効期間は、当該更新前の有効期間の満了の日の翌日から起算するものとする。

６　第二十三条（第二項から第四項までに限る。）及び第二十四条（第三号から第五号までを除く。）の規定は、第二項の更新について準用する。ただし、第二十三条第三項に規定する書類については、既に厚生労働大臣に提出されている当該書類の内容に変更がないときは、その添付を省略することができる。

（認定臨床研究審査委員会の廃止）

第二十七条　認定委員会設置者は、その設置する認定臨床研究審査委員会を廃止するときは、厚生労働省令で定めるところにより、あらかじめ、その旨をその名称が第五条第一項第八号の認定臨床研究審査委員会として記載されている実施計画により特定臨床研究を実施する者に通知するとともに、厚生労働大臣に届け出なければならない。

２　厚生労働大臣は、前項の規定による届出があったときは、その旨を公示しなければならない。

（秘密保持義務）

第二十八条　認定臨床研究審査委員会の委員若しくは審査意見業務に従事する者又はこれらの者であった者

は、正当な理由がなく、その審査意見業務に関して知り得た秘密を漏らしてはならない。

（厚生労働大臣への報告）

第二十九条　認定臨床研究審査委員会は、第二十三条第一項第二号から第四号までの意見を述べたときは、遅滞なく、厚生労働大臣にその内容を報告しなければならない。

（改善命令）

第三十条　厚生労働大臣は、認定臨床研究審査委員会が第二十三条第四項各号に掲げる要件のいずれかに適合しなくなったと認めるときは、認定委員会設置者に対し、これらの要件に適合させるために必要な措置をとるべきことを命ずることができる。

２　厚生労働大臣は、前項に定めるもののほか、認定委員会設置者がこの章の規定又はこの章の規定に基づく命令に違反していると認めるとき、その他審査意見業務の適切な実施を確保するため必要があると認めるときは、認定委員会設置者に対し、審査意見業務を行う体制の改善、第二十三条第四項第二号に規定する業務規程の変更その他必要な措置をとるべきことを命ずることができる。

（認定の取消し）

第三十一条　厚生労働大臣は、認定委員会設置者について、次の各号のいずれかに該当するときは、第二十三条第一項の認定を取り消すことができる。

一　偽りその他不正の手段により第二十三条第一項の認定、第二十五条第一項の変更の認定又は第二十六条第二項の更新を受けたとき。

二　認定臨床研究審査委員会が第二十三条第四項各号に掲げる要件のいずれかに適合しなくなったとき。

三　第二十四条各号（第三号及び第四号を除く。）のいずれかに該当するに至ったとき。

四　この章の規定又はこの章の規定に基づく命令に違反したとき。

五　正当な理由がなくて第三十五条第一項の規定による報告若しくは物件の提出をせず、若しくは虚偽の報告若しくは虚偽の物件の提出をし、又は同項の規定による検査を拒み、妨げ、若しくは忌避し、若しくは同項の規定による質問に対し、答弁をせず、若しくは虚偽の答弁をしたとき。

２　厚生労働大臣は、前項の規定により第二十三条第一項の認定を取り消したときは、その旨を公示しなければならない。

第四章　臨床研究に関する資金等の提供

（契約の締結）

第三十二条　医薬品等製造販売業者又はその特殊関係者は、特定臨床研究を実施する者に対し、当該医薬品等製造販売業者が製造販売をし、又はしようとする医薬品等を用いる特定臨床研究についての研究資金等の提供を行うときは、当該研究資金等の額及び内容、当該特定臨床研究の内容その他厚生労働省令で定める事項を定める契約を締結しなければならない。

（研究資金等の提供に関する情報等の公表）

第三十三条　医薬品等製造販売業者又はその特殊関係者は、当該医薬品等製造販売業者が製造販売をし、又はしようとする医薬品等を用いる特定臨床研究についての研究資金等の提供に関する情報のほか、特定臨床研究を実施する者又は当該者と厚生労働省令で定める特殊の関係のある者に対する金銭その他の利益（研究資金等を除く。）の提供に関する情報であってその透明性を確保することが特定臨床研究に対する国民の信頼の確保に資するものとして厚生労働省令で定める情報について、厚生労働省令で定めるところにより、インターネットの利用その他厚生労働省令で定める方法により公表しなければならない。

（勧告等）

第三十四条　厚生労働大臣は、前二条の規定に違反する医薬品等製造販売業者又はその特殊関係者があるときは、当該医薬品等製造販売業者又はその特殊関係者に対し、これらの規定に従って第三十二条に規定する契約を締結すべきこと又は前条に規定する情報を公表すべきことを勧告することができる。

２　厚生労働大臣は、前項の規定による勧告を受けた医薬品等製造販売業者又はその特殊関係者がこれに従わなかったときは、その旨を公表することができる。

第五章　雑則

（報告徴収及び立入検査）

第三十五条　厚生労働大臣は、この法律の施行に必要な限度において、特定臨床研究を実施する者、認定委員会設置者若しくは医薬品等製造販売業者（その製造販売をし、又はしようとする医薬品等が特定臨床研究に用いられる者に限る。第四十二条において同じ。）若しくはその特殊関係者に対して、必要な報告若しくは帳簿、書類その他の物件の提出を求め、又はその職員に、これらの者の事業場に立ち入り、その帳簿、書類その他の物件を検査させ、若しくは関係者に質問させることができる。

２　前項の規定により職員が立ち入るときは、その身分を示す証明書を携帯し、関係者に提示しなければな

らない。

３　第一項の規定による権限は、犯罪捜査のために認められたものと解してはならない。

（権限の委任）

第三十六条　この法律に規定する厚生労働大臣の権限は、厚生労働省令で定めるところにより、地方厚生局長に委任することができる。

２　前項の規定により地方厚生局長に委任された権限は、厚生労働省令で定めるところにより、地方厚生支局長に委任することができる。

（経過措置）

第三十七条　この法律の規定に基づき命令を制定し、又は改廃する場合においては、その命令で、その制定又は改廃に伴い合理的に必要と判断される範囲内において、所要の経過措置（罰則に関する経過措置を含む。）を定めることができる。

（厚生労働省令への委任）

第三十八条　この法律に規定するもののほか、この法律の実施のため必要な手続その他の事項は、厚生労働

省令で定める。

第六章　罰則

第三十九条　第十九条の規定による命令に違反した者は、三年以下の懲役若しくは三百万円以下の罰金に処し、又はこれを併科する。

第四十条　第十一条又は第二十八条の規定に違反して秘密を漏らした者は、一年以下の懲役又は百万円以下の罰金に処する。

第四十一条　特定臨床研究を実施する者が次の各号のいずれかに該当するときは、五十万円以下の罰金に処する。

一　第五条第一項の規定に違反して、正当な理由がなくて実施計画を提出せず、又はこれに記載すべき事項を記載せず、若しくは虚偽の記載をしてこれを提出して、特定臨床研究を実施した者

二　第六条第一項の規定に違反して、正当な理由がなくて実施計画を提出せず、又はこれに記載すべき事項を記載せず、若しくは虚偽の記載をしてこれを提出して、特定臨床研究を実施した者

三　第十二条の規定に違反して正当な理由がなくて記録の作成若しくは保存をしなかった者又は虚偽の記

録を作成した者

四　第二十条第二項の規定による命令に違反した者

五　正当な理由がなくて第三十五条第一項の規定による報告若しくは物件の提出をせず、若しくは虚偽の報告若しくは虚偽の物件の提出をし、又は同項の規定による検査を拒み、妨げ、若しくは忌避し、若しくは同項の規定による質問に対し、答弁をせず、若しくは虚偽の答弁をした者

第四十二条　医薬品等製造販売業者又はその特殊関係者が、正当な理由がなくて第三十五条第一項の規定による報告若しくは物件の提出をせず、若しくは虚偽の報告若しくは虚偽の物件の提出をし、又は同項の規定による検査を拒み、妨げ、若しくは忌避し、若しくは同項の規定による質問に対し、答弁をせず、若しくは虚偽の答弁をしたときは、三十万円以下の罰金に処する。

第四十三条　法人（法人でない団体で代表者又は管理人の定めのあるものを含む。以下この条において同じ。）の代表者若しくは管理人又は法人若しくは人の代理人、使用人その他の従業者が、その法人又は人の業務に関して第三十九条又は前二条の違反行為をしたときは、行為者を罰するほか、その法人又は人に対しても各本条の罰金刑を科する。

２　法人でない団体について前項の規定の適用がある場合には、その代表者又は管理人が、その訴訟行為につき法人でない団体を代表するほか、法人を被告人又は被疑者とする場合の刑事訴訟に関する法律の規定を準用する。

附　則

（施行期日）

第一条　この法律は、公布の日から起算して一年を超えない範囲内において政令で定める日から施行する。ただし、附則第四条、第五条及び第八条の規定は、公布の日から施行する。

（検討）

第二条　政府は、この法律の施行後二年以内に、先端的な科学技術を用いる医療行為その他の必ずしも十分な科学的知見が得られていない医療行為についてその有効性及び安全性を検証するための措置について検討を加え、その結果に基づき、法制上の措置その他の必要な措置を講ずるものとする。

２　政府は、この法律の施行後五年以内に、この法律の施行の状況、臨床研究を取り巻く状況の変化等を勘案し、この法律の規定に検討を加え、必要があると認めるときは、その結果に基づいて所要の措置を講ず

るものとする。

（経過措置）

第三条　この法律の施行の際現に特定臨床研究を実施している者が実施する当該特定臨床研究については、この法律の施行の日（以下「施行日」という。）から起算して一年を経過する日までの間（当該期間内に当該特定臨床研究の実施計画を提出した者については、当該提出の日までの間）は、第四条第二項及び第五条第一項の規定は、適用しない。

２　第九条及び第十二条の規定は、施行日以後に開始する特定臨床研究について適用する。

３　この法律の施行の際現に第二十一条に規定する臨床研究を実施している者については、施行日から起算して一年を経過する日までの間は、同条の規定は、適用しない。

（施行前の準備）

第四条　厚生労働大臣は、臨床研究実施基準を定めようとするときは、施行日前においても、厚生科学審議会の意見を聴くことができる。

第五条　第二十三条第一項の認定を受けようとする者は、施行日前においても、同条第二項及び第三項の規

定の例により、その認定の申請をすることができる。

２　厚生労働大臣は、前項の規定により第二十三条第一項の認定の申請があった場合においては、施行日前においても、同条第四項及び第二十四条の規定の例により、その認定をすることができる。この場合において、その認定は施行日において厚生労働大臣が行った第二十三条第一項の認定とみなす。

（独立行政法人医薬品医療機器総合機構法の一部改正）

第六条　独立行政法人医薬品医療機器総合機構法（平成十四年法律第百九十二号）の一部を次のように改正する。

第十五条第一項に次の一号を加える。

八　特定臨床研究（臨床研究法（平成二十九年法律第十六号）第二条第二項に規定する特定臨床研究をいう。）に関する次に掲げる業務

イ　臨床研究法第十六条第一項（同条第六項において準用する場合を含む。）の規定による情報の整理及び調査を行うこと。

ロ　イに掲げる業務に附帯する業務を行うこと。

第二十九条第一項第三号中「及び第七号」を「から第八号まで」に改める。

（厚生労働省設置法の一部改正）

第七条　厚生労働省設置法（平成十一年法律第九十七号）の一部を次のように改正する。

第八条第一項第四号中「再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）」の下に「、臨床研究法（平成二十九年法律第十六号）」を加える。

（政令への委任）

第八条　この附則に規定するもののほか、この法律の施行に関し必要な経過措置は、政令で定める。

Ver.2 December, 2016
Personal Information Protection Commission, Japan

Amended Act on the Protection of Personal Information (Tentative Translation)

This is an English translation of the amended Act on the Protection of Personal Information, to be put into full effect on May 30, 2017.

NOTICE

*This translation has neither had its texts checked by a native English speaker nor legal language editor, and thus may be subject to change.

*The Japanese original legal texts only shall remain in force, while their English translation is presented for ease of non-Japanese speakers' understanding and reference.

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Chapter I General Provisions

(Purpose)

Article 1 This Act aims to protect an individual's rights and interests while considering the utility of personal information including that the proper and effective application of personal information contributes to the creation of new industries and the realization of a vibrant economic society and an enriched quality of life for the people of Japan; by setting forth the overall vision for the proper handling of personal information, creating a governmental basic policy with regard to this, and establishing other matters to serve as a basis for measures to protect personal information, as well as by clarifying the responsibilities etc. of the central and local governments and establishing obligations etc. that a personal information handling business operator shall fulfill, in light of the significantly expanded utilization of personal information as our advanced information- and communication-based society evolves.

(Definition)

Article 2

(1) "Personal information" in this Act means that information relating to a living individual which falls under any of each following item:

(i) those containing a name, date of birth, or other descriptions etc. (meaning any and all matters (excluding an individual identification code) stated, recorded or otherwise expressed using voice, movement or other methods in a document, drawing or electromagnetic record (meaning a record kept in an electromagnetic form (meaning an electronic, magnetic or other forms that cannot be recognized through the human senses; the same shall apply in the succeeding paragraph, item (ii)); the same shall apply in Article 18, paragraph (2)); hereinafter the same) whereby a specific individual can be identified (including those which can be readily collated with other information and thereby identify a specific individual)

(ii) those containing an individual identification code

(2) An "individual identification code" in this Act means those prescribed by cabinet order which are any character, letter, number, symbol or other codes falling under any of each following item.

(i) those able to identify a specific individual that are a character, letter, number, symbol or other codes into which a bodily partial feature of the specific individual has been converted in order to be provided for use by

computers

(ii) those character, letter, number, symbol or other codes which are assigned in regard to the use of services provided to an individual or to the purchase of goods sold to an individual, or which are stated or electromagnetically recorded in a card or other document issued to an individual so as to be able to identify a specific user or purchaser, or recipient of issuance by having made the said codes differently assigned or, stated or recoded for the said user or purchaser, or recipient of issuance

(3) “Special care-required personal information” in this Act means personal information comprising a principal's race, creed, social status, medical history, criminal record, fact of having suffered damage by a crime, or other descriptions etc. prescribed by cabinet order as those of which the handling requires special care so as not to cause unfair discrimination, prejudice or other disadvantages to the principal.

(4) A “personal information database etc.” in this Act means those set forth in the following which are a collective body of information comprising personal information (excluding those prescribed by cabinet order as having little possibility of harming an individual’s rights and interests considering their utilization method).

(i) those systematically organized so as to be able to search for particular personal information using a computer;

(ii) besides those set forth in the preceding item, those prescribed by cabinet order as having been systematically organized so as to be able to easily search for particular personal information.

(5) A "personal information handling business operator" in this Act means a person providing a personal information database etc. for use in business; however, excluding a person set forth in the following;

(i) a central government organization;

(ii) a local government;

(iii) an incorporated administrative agency etc. (meaning an independent administrative agency etc. prescribed in Article 2, paragraph (1) of the Act on the Protection of Personal Information Held by Incorporated Administrative Agencies (Act No. 59 of 2003); hereinafter the same);

(iv) a local incorporated administrative agency (meaning a local incorporated administrative agency prescribed in Article 2, paragraph (1) of the Local Incorporated Administrative Agencies Act (Act No. 118 of 2003); hereinafter the same);

(6) “Personal data” in this Act means personal information constituting a personal information database etc.

(7) “Retained personal data” in this Act means personal data which a personal information handling business operator has the authority to disclose, correct, add or delete the contents of, cease the utilization of, erase, and cease the third-party provision of, and which shall be neither those prescribed by cabinet order as likely to harm the public or other interests if their presence or absence is made known nor those set to be deleted within a period of no longer than one year that is prescribed by cabinet order.

(8) A “principal” in relation to personal information in this Act means a specific individual identifiable by personal information.

(9) “Anonymously processed information” in this Act means information relating to an individual that can be produced from processing personal information so as neither to be able to identify a specific individual by taking action prescribed in each following item in accordance with the devisions of personal information set forth in each said item nor to be able to restore the personal information.

(i) personal information falling under paragraph (1), idem (i);

Deleting a part of descriptions etc. contained in the said personal information (including replacing the said part of descriptions etc. with other descriptions etc. using a method with no regularity that can restore the said part of descriptions etc.)

(ii) personal information falling under paragraph (1), item (ii);

Deleting all individual identification codes contained in the said personal information (including replacing the said individual identification codes with other descriptions etc. using a method with no regularity that can restore the said personal identification codes)

(10) An “anonymously processed information handling business operator” in this Act means a person who provides for use in business a collective body of information comprising anonymously processed information which has been systematically organized so as to be able to search using a computer

for specific anonymously processed information or similar others prescribed by cabinet order as systematically organized so as to be able to search easily for specific anonymously processed information (referred to as an "anonymously processed information database etc." in Article 36, paragraph (1)). However, a person set forth in each item of paragraph (5) is excluded.

(Overall Vision)

Article 3 Personal information, considering it should be carefully handled under the vision of respecting the personality of an individual, shall be made subject to proper handling.

Chapter II Responsibilities etc. of the Central and Local Governments

(Responsibilities of the Central Government)

Article 4 The central government shall have the responsibilities for comprehensively developing and implementing necessary measures to ensure the proper handling of personal information in conformity with the purport of this Act.

(Responsibilities of the Local Governments)

Article 5 The local governments shall have the responsibilities for developing and implementing necessary measures to ensure the proper handling of personal information based on the characteristics of their local area in conformity with the purport of this Act.

(Legislative Action etc.)

Article 6 The government shall, considering the nature and utilization method of personal information, take necessary legislative and other action so as to be able to take discreet action for protecting personal information that especially requires ensuring the strict implementation of its proper handling in order to seek enhanced protection of an individual's rights and interests, and shall take necessary action in collaboration with the governments in other countries to construct an internationally conformable system concerning personal information through fostering cooperation with an international organization and other international framework.

Chapter III Measures etc. for the Protection of Personal Information

Section 1 Basic Policy on the Protection of Personal Information

Article 7

(1) The government shall establish a basic policy on the protection of personal information (hereinafter referred to as a “basic policy”) in order to seek to comprehensively and integrally promote measures concerning the protection of personal information.

(2) A basic policy shall prescribe those matters set forth in the following.

(i) a basic direction for promoting measures concerning the protection of personal information

(ii) a matter concerning action to be taken by the central government for the protection of personal information

(iii) a basic matter concerning action to be taken by a local government for the protection of personal information

(iv) a basic matter concerning action to be taken by an incorporated administrative agency etc. for the protection of personal information

(v) a basic matter concerning action to be taken by a local incorporated administrative agency for the protection of personal information

(vi) a basic matter concerning action to be taken by a personal information handling business operator, an anonymously processed information handling business operator and an accredited personal information protection organization prescribed in Article 50, paragraph (1) for the protection of personal information

(vii) a matter concerning dealing smoothly with a complaint about the handling of personal information

(viii) other important matters concerning promoting measures for the protection of personal information.

(3) The Prime Minister shall call for a cabinet decision on a basic policy developed by the Personal Information Protection Commission.

(4) The Prime Minister shall, when a cabinet decision was made pursuant to the provisions of the preceding paragraph, disclose a basic policy to the public without delay.

(5) The provisions under the preceding two paragraphs shall apply mutatis mutandis when altering a basic policy.

Section 2 Measures by the Central Government

(Support to a Local Government etc.)

Article 8 The central government shall provide information, develop guidelines to ensure the proper and effective implementation of action to be taken by a business operator etc., and take other necessary action in order to support measures for the protection of personal information developed or implemented by a local government and activities undertaken by a Japanese citizen, or a business operator etc. in relation to seeking the proper handling of personal information.

(Action for Dealing with a Complaint)

Article 9 The central government shall take necessary action to seek the proper and prompt dealing of a complaint caused between a business operator and a principal about the handling of personal information.

(Action for Ensuring the Proper Handling of Personal Information)

Article 10 The central government shall, through the appropriate division of roles between a local government and itself, take necessary action prescribed in the succeeding Chapter in order to ensure the proper handling of personal information by a personal information handling business operator.

Section 3 Measures by the Local Governments

(Protection of Personal Information Retained by a Local Government etc.)

Article 11

(1) A local government shall, considering the nature of personal information it retains, the purpose of retaining the personal information, and so on, strive to take necessary action so as to ensure the proper handling of the retained personal information.

(2) A local government shall, in response to the characteristics and business contents of a local incorporated administrative agency that it has established, strive to take necessary action so as to ensure the proper handling of personal information that the agency retains.

(Support to a Business Operator etc. in a Local Area)

Article 12 A local government shall, in order to ensure the proper handling of personal information, strive to take necessary action to support a business operator and a resident in a local area.

(Mediation etc. for Dealing with a Complaint)

Article 13 A local government shall, in order for a complaint caused between a business operator and a principal about the handling of personal information to be dealt with appropriately and promptly, strive to mediate dealing with the complaint and take other necessary action.

Section 4 Cooperation between the Central and Local Governments

Article 14 The central and local governments shall cooperate with one another in implementing measures relating to the protection of personal information.

Chapter IV Obligations etc. of a Personal Information Handling Business Operator

Section 1 Obligations of a Personal Information Handling Business Operator

(Specifying a Utilization Purpose)

Article 15

(1) A personal information handling business operator shall, in handling personal information, specify the purpose of utilizing the personal information (hereinafter referred to as a “utilization purpose”) as explicitly as possible.

(2) A personal information handling business operator shall, in case of altering a utilization purpose, not do so beyond the scope recognized reasonably relevant to the pre-altered utilization purpose.

(Restriction due to a Utilization Purpose)

Article 16

(1) A personal information handling business operator shall not handle personal information without obtaining in advance a principal's consent beyond the necessary scope to achieve a utilization purpose specified pursuant to the provisions under the preceding Article.

(2) A personal information handling business operator shall, in case of having acquired personal information accompanied with succeeding a business from another personal information handling business operator because of a merger or other reason, not handle the personal information without obtaining in advance a principal's consent beyond the necessary scope to achieve the pre-succession utilization purpose of the said personal information.

(3) The provisions under the preceding two paragraphs shall not apply to those cases set forth in the following.

(i) cases based on laws and regulations

(ii) cases in which there is a need to protect a human life, body or fortune, and when it is difficult to obtain a principal's consent

(iii) cases in which there is a special need to enhance public hygiene or promote fostering healthy children, and when it is difficult to obtain a principal's consent

(iv) cases in which there is a need to cooperate in regard to a central government organization or a local government, or a person entrusted by them performing affairs prescribed by laws and regulations, and when there is a possibility that obtaining a principal's consent would interfere with the performance of the said affairs

(Proper Acquisition)

Article 17

(1) A personal information handling business operator shall not acquire personal information by deceit or other improper means.

(2) A personal information handling business operator shall, except in those cases set forth in the following, not acquire special care-required personal information without obtaining in advance a principal's consent.

(i) cases based on laws and regulations

(ii) cases in which there is a need to protect a human life, body or fortune, and when it is difficult to obtain a principal's consent

(iii) cases in which there is a special need to enhance public hygiene or promote fostering healthy children, and when it is difficult to obtain a principal's consent

(iv) cases in which there is a need to cooperate in regard to a central government organization or a local government, or a person entrusted by them performing affairs prescribed by laws and regulations, and when there is a possibility that obtaining a principal's consent would interfere with the performance of the said affairs

(v) cases in which the said special care-required personal information is being open to the public by a principal, a government organization, a local government, a person set forth in each item of Article 76, paragraph (1) or other persons prescribed by rules of the Personal Information Protection Commission

(vi) other cases prescribed by cabinet order as equivalent to those cases set forth in each preceding item

(Notification etc. of a Utilization Purpose when Acquiring)

Article 18

(1) A personal information handling business operator shall, in case of having acquired personal information except in cases where a utilization purpose has been disclosed in advance to the public, promptly inform a principal of, or disclose to the public, the utilization purpose.

(2) A personal information handling business operator shall, notwithstanding the provisions under the preceding paragraph, in cases where it acquires, accompanied by concluding a contract with a principal, the principal's personal information stated in a written contract or other document (including an electromagnetic record; hereinafter the same in this paragraph) or other similar cases where it acquires directly from a principal his or her personal information stated in a written document, state a utilization purpose

explicitly to the said principal. This, however, shall not apply in cases where there is an urgent need to protect a human life, body or fortune.

(3) A personal information handling business operator shall, in case of altering a utilization purpose, inform a principal of, or disclose to the public, a post-altered utilization purpose.

(4) The provisions of the preceding three paragraphs shall not apply in those cases set forth in the following.

(i) cases in which there is a possibility that informing a principal of, or disclosing to the public, a utilization purpose would harm a principal or third party's life, body, fortune or other rights and interests

(ii) cases in which there is a possibility that informing a principal of, or disclosing to the public, a utilization purpose would harm the rights or legitimate interests of the said personal information handling business operator

(iii) cases in which there is a need to cooperate in regard to a central government organization or a local government performing affairs prescribed by laws and regulations, and when there is a possibility that informing a principal of, or disclosing to the public, a utilization purpose would interfere with the performance of the said affairs

(iv) cases in which it can be recognized, judging from the acquisitional circumstances, that a utilization purpose is clear

(Assurance etc. about the Accuracy of Data Contents)

Article 19 A personal information handling business operator shall strive to keep personal data accurate and up to date within the scope necessary to achieve a utilization purpose, and to delete the personal data without delay when such utilization has become unnecessary.

(Security Control Action)

Article 20 A personal information handling business operator shall take necessary and appropriate action for the security control of personal data including preventing the leakage, loss or damage of its handled personal data.

(Supervision over Employees)

Article 21 A personal information handling business operator shall, in having its employees handle personal data, exercise necessary and appropriate supervision over the employees so as to seek the security control of the personal data.

(Supervision over a Trustee)

Article 22 A personal information handling business operator shall, in case of entrusting a whole or part of the handling of personal data, exercise necessary and appropriate supervision over an entrusted person so as to seek the security control of the personal data of which the handling has been entrusted.

(Restriction on Third Party Provision)

Article 23

(1) A personal information handling business operator shall, except in those cases set forth in the following, not provide personal data to a third party without obtaining in advance a principal's consent.

(i) cases based on laws and regulations

(ii) cases in which there is a need to protect a human life, body or fortune, and when it is difficult to obtain a principal's consent

(iii) cases in which there is a special need to enhance public hygiene or promote fostering healthy children, and when it is difficult to obtain a principal's consent

(iv) cases in which there is a need to cooperate in regard to a central government organization or a local government, or a person entrusted by them performing affairs prescribed by laws and regulations, and when there is a possibility that obtaining a principal's consent would interfere with the performance of the said affairs

(2) A personal information handling business operator, in regard to personal data provided to a third party (excluding special care-required personal information; hereinafter the same in this paragraph), may, in cases where it is set to cease in response to a principal's request a third-party provision of personal data that can identify the principal and when pursuant to rules of

the Personal Information Protection Commission it has in advance informed a principal of those matters set forth in the following or put them into a state where a principal can easily know, and notified them to the Personal Information Protection Commission, provide the said personal data to a third party notwithstanding the provisions of the preceding paragraph.

(i) to set a third-party provision as a utilization purpose

(ii) the categories of personal data provided to a third party

(iii) a method of a third-party provision

(iv) to cease, in response to a principal's request, a third-party provision of personal data that can identify the principal

(v) a method of receiving a principal's request

(3) A personal information handling business operator shall, in case of altering those matters set forth in item (ii), item (iii) or item (v) of the preceding paragraph, in advance inform a principal of the contents to be altered or put them into a state where a principal can easily know and notify them to the Personal Information Protection Commission pursuant to rules of the Personal Information Protection Commission.

(4) The Personal Information Protection Commission shall, when notified pursuant to paragraph (2), disclose to the public a matter relating to the notification pursuant to rules of the Personal Information Protection Commission. The same shall apply when notified pursuant to the preceding paragraph.

(5) In those cases set forth in the following, a person receiving the provision of the said personal data shall not fall under a third party in regard to applying the provisions of each preceding paragraph.

(i) cases in which personal data is provided accompanied by a personal information handling business operator entrusting a whole or part of the handling of the personal data within the necessary scope to achieve a utilization purpose

(ii) cases in which personal data is provided accompanied with business succession caused by a merger or other reason

(iii) cases in which personal data to be jointly utilized by a specified person is

provided to the specified person, and when a principal has in advance been informed or a state has been in place where a principal can easily know to that effect as well as of the categories of the jointly utilized personal data, the scope of a jointly utilizing person, the utilization purpose for the utilizing person and the name or appellation of a person responsible for controlling the said personal data

(6) A personal information handling business operator shall, in case of altering a utilization purpose for a utilizing person or the name or appellation of a person responsible for controlling personal data prescribed in item (iii) of the preceding paragraph, in advance inform a principal of the contents to be altered or put them into a state where a principal can easily know.

(Restriction on Provision to a Third Party in a Foreign Country)

Article 24 A personal information handling business operator, except in those cases set forth in each item of the preceding Article, paragraph (1), shall, in case of providing personal data to a third party (excluding a person establishing a system conforming to standards prescribed by rules of the Personal Information Protection Commission as necessary for continuously taking action equivalent to the one that a personal information handling business operator shall take concerning the handling of personal data pursuant to the provisions of this Section; hereinafter the same in this Article) in a foreign country (meaning a country or region located outside the territory of Japan; hereinafter the same) (excluding those prescribed by rules of the Personal Information Protection Commission as a foreign country establishing a personal information protection system recognized to have equivalent standards to that in Japan in regard to the protection of an individual's rights and interests; hereinafter the same in this Article), in advance obtain a principal's consent to the effect that he or she approves the provision to a third party in a foreign country. In this case, the provisions of the preceding Article shall not apply.

(Keeping etc. of a Record on a Third-Party Provision)

Article 25

(1) A personal information handling business operator shall, when having provided personal data to a third party (excluding a person set forth in each item of Article 2, paragraph (5); hereinafter the same in this Article and the succeeding Article), keep a record pursuant to rules of the Personal Information Protection Commission on the date of the personal data provision, the name or appellation of the third party, and other matters prescribed by rules of the Personal Information Protection Commission. This, however, shall not apply in cases where the personal data provision

falls under any of each item of Article 23, paragraph (1) or paragraph (5) (this means, in case of a personal data provision pursuant to the provisions of the preceding Article, any of each item of Article 23, paragraph (1)).

(2) A personal information handling business operator shall maintain a record under the preceding paragraph for a period of time prescribed by rules of the Personal Information Protection Commission from the date when it kept the record.

(Confirmation etc. when Receiving a Third Party Provision)

Article 26

(1) A personal information handling business operator shall, when receiving the provision of personal data from a third party, confirm those matters set forth in the following pursuant to rules of the Personal Information Protection Commission. This, however, shall not apply in cases where the said personal data provision falls under any of each item of Article 23, paragraph (1) or paragraph (5).

(i) the name or appellation and address of the third party and, for a corporate body, the name of its representative (for a non-corporate body having appointed a representative or administrator, the said representative or administrator)

(ii) circumstances under which the said personal data was acquired by the said third party

(2) A third party under the preceding paragraph shall, in cases where a personal information handling business operator confirms pursuant to the provisions of the preceding paragraph, not deceive the personal information handling business operator on a matter relating to the confirmation.

(3) A personal information handling business operator shall, when having confirmed pursuant to the provisions of paragraph (1), keep a record pursuant to rules of the Personal Information Protection Commission on the date when it received the provision of personal data, a matter concerning the said confirmation, and other matters prescribed by rules of the Personal Information Protection Commission.

(4) A personal information handling business operator shall maintain a record under the preceding paragraph for a period of time prescribed by rules of the Personal Information Protection Commission from the date when it kept the record.

(Public Disclosure etc. on Matters relating to Retained Personal Data)

Article 27

(1) A personal information handling business operator shall, concerning its retained personal information, put those matters set forth in the following into a state where a principal can know (including those cases in which it, at the request of a principal, responds without delay).

(i) the name or appellation of the said personal information handling business operator

(ii) the utilization purpose of all retained personal data (excluding those cases falling under item (i) through item (iii) of Article 18, paragraph (4))

(iii) the procedures for responding to a request pursuant to the provisions of the succeeding paragraph or a demand pursuant to the provisions of the succeeding Article, paragraph (i); Article 29, paragraph (1); or Article 30, paragraph (1) or paragraph (3) (including, when the amount of a fee has been decided pursuant to the provisions of Article 33, paragraph (2), the amount of the fee)

(iv) besides those set forth under the preceding three items, those prescribed by cabinet order as a necessary matter to ensure the proper handling of retained personal data

(2) A personal information handling business operator shall, when requested by a principal to get informed of a utilization purpose of retained personal data that can identify the principal, inform the said principal thereof without delay. This, however, shall not apply in those cases falling under any of each following item.

(i) cases in which the utilization purpose of retained personal data that can identify the said principal is clear pursuant to the provisions of the preceding paragraph

(ii) cases falling under item (i) through item (iii) of Article 18, paragraph (4)

(3) A personal information handling business operator shall, when having been requested based on the provisions of the preceding paragraph but decided not to inform a principal of the utilization purpose of retained personal data, inform the principal to that effect without delay.

(Disclosure)

Article 28

(1) A principal may demand of a personal information handling business operator disclosing retained personal data that can identify him or herself.

(2) A personal information handling business operator shall, when having received a demand pursuant to the provisions of the preceding paragraph, disclose retained personal data to a principal without delay pursuant to a method prescribed by cabinet order. However, in cases where disclosing such data falls under any of each following item, a whole or part thereof may not be disclosed.

(i) cases in which there is a possibility of harming a principal or third party's life, body, fortune or other rights and interests

(ii) cases in which there is a possibility of interfering seriously with the said personal information handling business operator implementing its business properly

(iii) cases of violating other laws or regulations

(3) A personal information handling business operator shall, when having decided not to disclose a whole or part of retained personal data in connection with a demand pursuant to the provisions of paragraph (1) or when the retained personal data does not exist, inform a principal thereof without delay.

(4) In cases where a whole or part of retained personal data that can identify a principal is to be disclosed to the principal pursuant to the provisions of other laws or regulations using a method equivalent to that prescribed in the main clause of paragraph (2), the provisions of paragraph (1) and paragraph (2) shall not apply in regard to the said whole or part of retained personal data.

(Correction etc.)

Article 29

(1) A principal may, when the contents of retained personal data that can identify the principal are not factual, demand of a personal information handling business operator making a correction, addition or deletion (hereinafter referred to as a "correction etc." in this Article) in regard to the

contents of the retained personal data.

(2) A personal information handling business operator shall, in case of having received a demand pursuant to the provisions of the preceding paragraph except in cases where special procedure concerning a correction etc. of the contents is prescribed by the provisions of other laws or regulations, conduct a necessary investigation without delay to the extent necessary to achieve a utilization purpose and, based on the result thereof, make a correction etc. of the contents of the retained personal data.

(3) A personal information handling business operator shall, when having made a correction etc. on a whole or part of the contents of the retained personal data in connection with a demand pursuant to the provisions under paragraph (1) or when having made a decision not to make a correction etc., inform a principal without delay to that effect (including, when having made a correction etc., the contents thereof).

(Utilization Cease etc.)

Article 30

(1) A principal may, when retained personal data that can identify the principal is being handled in violation of the provisions of Article 16 or has been acquired in violation of the provisions of Article 17, demand of a personal information handling business operator a utilization cease or deletion (hereinafter referred to as a “utilization cease etc.” in this Article) of the retained personal data.

(2) A personal information handling business operator shall, in case of having received a demand pursuant to the provisions of the preceding paragraph and when it has become clear that there is a reason in the demand, fulfill a utilization cease etc. of the said retained personal data to the extent necessary to redress a violation without delay. This, however, shall not apply in cases where a utilization cease etc. of the said retained personal data requires a large amount of expenses or other cases where it is difficult to fulfil a utilization cease etc. and when necessary alternative action is taken to protect a principal’s rights and interests.

(3) A principal may, when retained personal data that can identify the principal is being provided to a third party in violation of the provisions of Article 23, paragraph (1) or Article 24, demand of a personal information handling business operator ceasing a third-party provision of the retained personal data.

(4) A personal information handling business operator shall, in case of having received a demand pursuant to the provisions of the preceding paragraph and when it has become clear that there is a reason in the demand, cease a third-party provision of the retained personal data without delay. This, however, shall not apply in cases where ceasing a third-party provision of the said retained personal data requires a large amount of expenses or other cases where it is difficult to cease a third-party provision and when necessary alternative action is taken to protect a principal's rights and interests.

(5) A personal information handling business operator shall, when having fulfilled a utilization cease etc. or decided not to fulfill a utilization cease etc. of a whole or part of retained personal data in connection with a demand pursuant to the provisions of paragraph (1), or when having ceased a third-party provision or decided not to cease a third-party provision of a whole or part of retained personal data in connection with a demand pursuant to the provisions of paragraph (3), inform a principal to that effect without delay.

(Explanation of Reason)

Article 31 A personal information handling business operator shall, in case of informing a principal to the effect that, as regards a whole or part of action requested or demanded by the principal pursuant to the provisions of Article 27, paragraph (3); Article 28, paragraph (3); Article 29, paragraph (3); or the preceding Article, paragraph (5), the action will not be taken, or to the effect that different action from the said action will be taken, strive to explain a reason therefor to the said principal.

(Procedure for Responding to a Demand etc. for Disclosure etc.)

Article 32

(1) A personal information handling business operator may, as regards a request pursuant to the provisions of Article 27, paragraph (2) or a demand pursuant to the provisions of Article 28, paragraph (1); Article 29, paragraph (1); Article 30, paragraph (1) or paragraph (3) (hereinafter referred to as a "demand etc. for disclosure etc." in this Article and Article 53, paragraph (1)), decide on a method of receiving a request or demand pursuant to those prescribed by cabinet order. In this case, a principal shall make a demand etc. for disclosure etc. in accordance with the method.

(2) A personal information handling business operator may, as regards a demand etc. for disclosure etc., request a principal to present a matter sufficient to specify retained personal data subject to the demand etc. In this

case, a personal information handling business operator shall take appropriate action in consideration of a principal's convenience such as providing information conducive to specify the retained personal data so that the principal would be able to easily and precisely make a demand etc. for disclosure etc.

(3) A demand etc. for disclosure etc. may be made through an agent pursuant to those prescribed by cabinet order.

(4) A personal information handling business operator shall, in establishing a procedure for responding to a demand etc. for disclosure etc. based on the provisions of the preceding three paragraphs, give consideration so as not to impose excessive burden on a principal.

(Fee)

Article 33

(1) A personal information handling business operator may, when having been requested to inform of a utilization purpose pursuant to the provisions of Article 27, paragraph (2) or when having received a demand for disclosure pursuant to the provisions of Article 28, paragraph (1), collect a fee in relation to taking such action.

(2) A personal information handling business operator shall, in case of collecting a fee pursuant to the provisions of the preceding paragraph, decide on the amount of the fee within a range recognized as reasonable considering actual expenses.

(Advance Demand)

Article 34

(1) A principal may, when intending to file a lawsuit in connection with a demand pursuant to the provisions of Article 28, paragraph (1); Article 29, paragraph (1); or Article 30, paragraph (1) or paragraph (3), not file the lawsuit unless the principal had previously issued the demand against a person who should become a defendant in the lawsuit and two weeks have passed from the delivery day of the issued demand. This, however, shall not apply when the person who should become a defendant in the lawsuit has rejected the demand.

(2) A demand under the preceding paragraph is deemed as having been delivered at the time when such a demand should have normally been

delivered.

(3) The provisions of the preceding two paragraphs shall apply mutatis mutandis to a petition for a provisional disposition order in connection with a demand pursuant to the provisions of Article 28, paragraph (1); Article 29, paragraph (1); or Article 30, paragraph (1) or paragraph (3).

(Personal Information Handling Business Operator's Dealing with a Complaint)

Article 35

(1) A personal information handling business operator shall strive to deal appropriately and promptly with a complaint about the handling of personal information.

(2) A personal information handling business operator shall strive to establish a system necessary to achieve a purpose under the preceding paragraph.

Section 2 Duties of an Anonymously Processed Information Handling Business Operator etc.

(Production etc. of Anonymously Processed Information)

Article 36

(1) A personal information handling business operator shall, when producing anonymously processed information (limited to those constituting anonymously processed information database etc.; hereinafter the same), process personal information in accordance with standards prescribed by rules of the Personal Information Protection Commission as those necessary to make it impossible to identify a specific individual and restore the personal information used for the production.

(2) A personal information handling business operator, when having produced anonymously processed information, shall, in accordance with standards prescribed by rules of the Personal Information Protection Commission as those necessary to prevent the leakage of information relating to those descriptions etc. and individual identification codes deleted from personal information used to produce the anonymously processed information, and information relating to a processing method carried out pursuant to the provisions of the preceding paragraph, take action for the security control of such information.

(3) A personal information handling business operator, when having produced anonymously processed information, shall, pursuant to rules of the Personal Information Protection Commission, disclose to the public the categories of information relating to an individual contained in the anonymously processed information.

(4) A personal information handling business operator, when having produced anonymously processed information and providing the anonymously processed information to a third party, shall, pursuant to rules of the Personal Information Protection Commission, in advance disclose to the public the categories of information concerning an individual contained in anonymously processed information to be provided to a third party and its providing method, and state to the third party explicitly to the effect that the information being provided is anonymously processed information.

(5) A personal information handling business operator shall, when having produced anonymously processed information and making itself handle the anonymously processed information, not collate the said anonymously processed information with other information in order to identify a principal concerned with personal information used to produce the said anonymously processed information.

(6) A personal information handling business operator shall, when having produced anonymously processed information, strive to take itself necessary and appropriate action for the security control of the anonymously processed information and necessary action for ensuring the proper handling of the anonymously processed information such as dealing with a complaint about the handling, including producing, of the said anonymously processed information, and strive to disclose to the public the contents of such action taken.

(Provision of Anonymously Processed Information)

Article 37 An anonymously processed information handling business operator, when providing anonymously processed information (excluding those which it produced itself by processing personal information; hereinafter the same in this Section) to a third party, shall, pursuant to rules of the Personal Information Protection Commission, in advance disclose to the public the categories of personal information contained in anonymously processed information to be provided to a third party and state to the third party explicitly to the effect that the provided information is anonymously processed information.

(Prohibition against the Act of Identifying)

Article 38 An anonymously processed information handling business operator, shall, in handling anonymously processed information, neither acquire information relating to those descriptions etc. or individual identification codes deleted from the personal information and information relating to a processing method carried out pursuant to the provisions of Article 36, paragraph (1), nor collate the said anonymously processed information with other information in order to identify a principal concerned with personal information used to produce the anonymously processed information.

(Security Control Action etc.)

Article 39 An anonymously processed information handling business operator shall strive to take itself necessary and appropriate action for the security control of anonymously processed information and necessary action to ensure the proper handling of anonymously processed information such as dealing with a complaint about the handling of anonymously processed information, and shall strive to disclose to the public the contents of such action taken.

Section 3 Supervision

(Report and Onsite Inspection)

Article 40

(1) The Personal Information Protection Commission may, to the extent necessary to implement the provisions under the preceding two Sections and this Section, require a personal information handling business operator or anonymously processed information handling business operator (hereinafter referred to collectively as a “personal information handling business operator etc.”) to submit necessary information or material relating to the handling of personal information or anonymously processed information (hereinafter referred to collectively as “personal information etc.”), or have its officials enter a business office or other necessary place of a personal information handling business operator etc., inquire about the handling of personal information etc., or inspect a book, document and other property.

(2) An official who conducts an onsite inspection pursuant to the provisions of the preceding paragraph shall carry a certificate for identification, and present it when requested by a person concerned.

(3) An onsite inspection authority pursuant to the provisions of paragraph (1) shall not be construed as granted for a criminal investigation.

(Guidance and Advice)

Article 41 The Personal Information Protection Commission may, to the extent necessary to implement the provisions under the preceding two Sections, provide a personal information handling business operator etc. with necessary guidance or advice on the handling of personal information etc.

(Recommendation and Order)

Article 42

(1) The Personal Information Protection Commission may, when recognizing there is a need for protecting an individual's rights and interests in cases where a personal information handling business operator has violated the provisions under Article 16 through Article 18, Article 20 through Article 22, Article 23 (excluding paragraph (4)), Article 24, Article 25, Article 26 (excluding paragraph (2)), Article 27, Article 28 (excluding paragraph (1)), Article 29, paragraph (2) or (3), Article 30 (2), paragraph (4) or (5), Article 33, paragraph (2) or Article 36 (excluding paragraph (6)) or in cases where an anonymously processed information handling business operator has violated the provisions under Articles 37 or 38, recommend the personal information handling business operator etc. to suspend the act of violating or take other necessary action to rectify the violation.

(2) The Personal Information Protection Commission may, when recognizing that a serious infringement of an individual's rights and interests is imminent in cases where a personal information handling business operator etc. having received a recommendation pursuant to the provisions under the preceding paragraph did not take action in line with the recommendation without legitimate ground, order the personal information handling business operator etc. to take action in line with the said recommendation.

(3) The Personal Information Protection Commission may, notwithstanding the provisions under the preceding two paragraphs when recognizing there is a need to take urgent action because there is a fact that seriously harms an individual's rights and interests in cases where a personal information handling business operator has violated the provisions of Article 16, Article 17, Article 20 through Article 22, Article 23, paragraph (1), Article 24 or Article 36, paragraph (1), paragraph (2) or paragraph (5) or in cases where an anonymously processed information handling business operator has violated the provisions under Article 38, order the personal information

handling business operator etc. to take necessary action to rectify the violation such as suspending the act of violation.

(Restriction on the Personal Information Protection Commission's Exercising the Authority)

Article 43

(1) The Personal Information Protection Commission shall, in the course of requiring the submission of a report or material from, conducting an onsite inspection of, or giving a guidance, advice, recommendation or order to, a personal information handling business operator etc., not hinder the freedom of expression, freedom of academia, freedom of religion, and freedom of political activity.

(2) In light of the purport of the provisions of the preceding paragraph, the Personal Information Protection Commission shall not exercise the authorities in regard to a personal information handling business operator's act of providing personal information etc. to a person set forth in each item of Article 76, paragraph (1) (limited to those cases where each person handles personal information etc. for a purpose stipulated in each said item respectively).

(Delegation of Authority)

Article 44

(1) The Personal Information Protection Commission may, when recognizing that there is a need for effectively giving a personal information handling business operator a recommendation or order pursuant to the provisions of Article 42 because there is a need to urgently and intensively seek ensuring the proper handling of personal information etc. or similar other circumstances prescribed by cabinet order, delegate an authority under the provisions of Article 40, paragraph (1) to a business jurisdictional minister as prescribed by cabinet order.

(2) A business jurisdictional minister shall, when having exercised an authority delegated pursuant to the provisions of the preceding paragraph, report the results thereof to the Personal Information Protection Commission as prescribed by cabinet order.

(3) A business jurisdictional minister may, as prescribed by cabinet order, delegate a whole or part of an authority delegated pursuant to the provisions of paragraph (1) or a whole or part of an authority pursuant to the provisions

of the preceding paragraph to a head of a local branch bureau under Article 43 of the Act for Establishment of the Cabinet Office (Act No.89 of 1999) or other bureau or organ prescribed by cabinet order.

(4) The Prime Minister delegates an authority delegated pursuant to the provisions of paragraph (1) and an authority under the provisions of paragraph (2) (limited to those relating to the Financial Services Agency's jurisdiction and excluding those prescribed by cabinet order) to a Commissioner of the Financial Services Agency.

(5) A Commissioner of the Financial Services Agency may, as prescribed by cabinet order, delegate part of an authority delegated pursuant to the provisions of the preceding paragraph to the Securities and Exchange Surveillance Commission.

(6) A Commissioner of the Financial Services Agency may, as prescribed by cabinet order, delegate part of an authority delegated pursuant to the provisions of paragraph (4) (excluding those delegated to the Securities and Exchange Surveillance Commission pursuant to the provisions of the preceding paragraph) to a Director-General of a local finance bureau or local finance branch bureau.

(7) The Securities and Exchange Surveillance Commission may, as prescribed by cabinet order, delegate part of an authority delegated pursuant to the provisions of paragraph (5) to a Director-General of a local finance bureau or local finance branch bureau.

(8) As for administrative affairs relating to an authority delegated to a Director-General of a local finance bureau or local finance branch bureau pursuant to the provisions of the preceding paragraph, the Securities and Exchange Surveillance Commission directs and supervises a Director-General of a local finance bureau or local finance branch bureau.

(9) In case of paragraph (5), a request for administrative review concerning the Securities and Exchange Surveillance Commission's requiring the submission of a report or material (including those cases in which a Director-General of a local finance bureau or local finance branch bureau do so pursuant to the provisions of paragraph (7)) may only be filed against the Securities and Exchange Surveillance Commission.

(Request by Business Jurisdictional Minister)

Article 45 A business jurisdictional minister may, when recognizing that there is a need for ensuring the proper handling of personal information etc. by a

personal information handling business operator etc. including that there is an act of a personal information handling business operator etc. violating the provisions under the preceding two Sections, request the Personal Information Protection Commission to take appropriate action in accordance with the provisions of this Act.

(Business Jurisdictional Minister)

Article 46 A business jurisdictional minister in the provisions of this Section shall be as follows.

(i) as for those relating to employment management involved in the handling of personal information etc. by a personal information handling business operator etc.; a Minister of Health, Labor and Welfare (as for those relating to a mariner's employment management; a Minister of Land, Infrastructure, Transport and Tourism), and a minister having jurisdiction over a business conducted by a said personal information handling business operator or the National Public Safety Commission (referred to collectively as a "Minister etc." in the succeeding item)

(ii) as for those other than the ones set forth in the preceding item involved in the handling of personal information etc. by a personal information handling business operator etc.; a Minister etc. having jurisdiction over a business conducted by a said personal information handling business operator

Section 4 Private-Sector Body's Promotion for the Protection of Personal Information

(Accreditation)

Article 47

(1) A corporation (including a non-corporate body which has appointed a representative or administrator; the same shall apply in the succeeding Article, item (iii), (b)) which intends to render the following services in order to ensure the proper handling of personal information etc. by a personal information handling business operator etc. may receive an accreditation from the Personal Information Protection Commission.

(i) dealing with a complaint under the provisions of Article 52 about the handling of personal information etc. by a personal information handling business operator covered by the services (hereinafter referred to as a "covered business operator")

(ii) providing a covered business operator with information concerning a matter contributory to ensuring the proper handling of personal information etc.

(iii) besides those set forth in the preceding two items, rendering necessary services related to ensuring the proper handling of personal information etc. by a covered business operator

(2) A person who intends to receive an accreditation under the preceding paragraph shall, as prescribed by cabinet order, apply to the Personal Information Protection Commission.

(3) The Personal Information Protection Commission shall, when having granted an accreditation under the paragraph (1), announce to the public to that effect.

(Disqualification)

Article 48 A person falling under any of each following item shall not receive an accreditation under the paragraph (1) of the preceding Article.

(i) a person who has been sentenced to imprisonment pursuant to the provisions of this Act and for whom two years have not elapsed since the date of either the completion of, or the conclusion of being subject to, the execution of the sentence

(ii) a person whose accreditation was rescinded pursuant to the provisions of Article 58, paragraph (1) and for whom two years have not elapsed since the date of the rescission

(iii) those of which the directors rendering the said services (including a representative or administrator of a non-corporate body which has appointed a representative or administrator; hereinafter the same in this Article) encompass a person who falls under any of the following

(a) a person who has been sentenced to imprisonment or a severer punishment or who has been sentenced pursuant to the provisions of this Act and for whom two years have not elapsed since the date of either the completion of, or the conclusion of being subject to, the execution of the sentence

(b) a person who was a director of a corporation whose accreditation was rescinded pursuant to the provisions of Article 58, paragraph (1) within thirty days prior to the date of the rescission and for whom two years

have not elapsed since the date of the rescission

(Accreditation Standards)

Article 49 The Personal Information Protection Commission shall not grant an accreditation unless it recognizes that an accreditation application under Article 47, paragraph (1) conforms to all of each following item.

(i) a service-rendering method has been devised necessary to perform properly and assuredly those services set forth in each item of Article 47, paragraph (1)

(ii) knowledge, capability and financial base have been demonstrated as sufficient to perform properly and assuredly those services set forth in each item of Article 47, paragraph (1)

(iii) in cases where services other than those services set forth in each item of Article 47, paragraph (1) are being rendered, there is no possibility that rendering such other services disturb the fairness of those services set forth in each item of the said paragraph

(Notification of Termination)

Article 50

(1) A person who has received an accreditation under Article 47, paragraph (1) (hereinafter referred to as an “accredited personal information protection organization”) shall, when intending to terminate services concerning the accreditation (hereinafter referred to as “accredited services”), in advance notify the Personal Information Protection Commission to that effect as prescribed by cabinet order.

(2) The Personal Information Protection Commission shall, when notified pursuant to the provisions of the preceding paragraph, announce to the public to that effect.

(Covered Business Operator)

Article 51

(1) An accredited personal information protection organization shall make its covered business operators composed of a personal information handling business operator etc. who is a constituent of the said accredited personal

information protection organization or who has consented to becoming covered by the accredited services.

(2) An accredited personal information protection organization shall announce to the public the name or appellation of its covered business operators.

(Dealing with a Complaint)

Article 52

(1) An accredited personal information protection organization shall, when petitioned by a principal or other concerned person to resolve a complaint about its covered business operator's handling of personal information etc., hold consultation, give necessary advice to the petitioner and investigate circumstances surrounding the complaint, as well as inform the covered business operator of the complaint contents and request its expeditious resolution.

(2) An accredited personal information protection organization may, when recognizing that there is a need in regard to the resolution of a complaint in connection with a petition under the preceding paragraph, request the covered business operator to provide a written or oral explanation or submit a referential material.

(3) A covered business operator shall, when requested by an accredited personal information protection organization pursuant to the provisions of the preceding paragraph, not refuse the request without a justifiable reason.

(Personal Information Protection Guideline)

Article 53

(1) An accredited personal information protection organization shall, for the purpose of ensuring a covered business operator's proper handling of personal information etc., strive to develop a guideline conformable to the purport of the provisions of this Act (hereinafter referred to as a "personal information protection guideline") by asking a person representing consumers or other concerned person for their opinion in regard to a matter related to personal information including utilization purpose specification, security control action and procedures for responding to a demand etc. for disclosure etc. as well as a matter related to anonymously processed information including its production method and security control action for such information.

(2) An accredited personal information protection organization shall, when having developed a personal information protection guideline pursuant to the provisions of the preceding paragraph, notify without delay the Personal information Protection Commission of the personal information protection guideline pursuant to rules of the Personal Information Protection Commission. When this has been modified, the same shall apply.

(3) The Personal Information Protection Commission shall, when having been notified of a personal information protection guideline under the provisions of the preceding paragraph, announce to the public the personal information protection guideline pursuant to rules of the Personal Information Protection Commission.

(4) An accredited personal information protection organization shall, when a personal information protection guideline has been announced to the public pursuant to the provisions of the preceding paragraph, take action against a covered business operator such as providing guidance or recommendation necessary to make the covered business operator follow the said personal information protection guideline.

(Prohibition of Utilization for Unintended Purpose)

Article 54 An accredited personal information protection organization shall not utilize information obtained in the course of rendering accredited services for the other purposes than for use in such accredited services.

(Restriction on Use of Appellation)

Article 55 A person who is not an accredited personal information protection organization shall not use the appellation of the accredited personal information protection organization or any other confusing appellation therewith.

(Calling for a Report)

Article 56 The Personal Information Protection Commission may, to the extent necessary to implement the provisions under this section, call for an accredited personal information protection organization to report on its accredited services.

(Order)

Article 57 The Personal Information Protection Commission may, to the extent necessary to implement the provisions of this section, order an accredited

personal information protection organization to improve a method of rendering accredited services, amend a personal information protection guideline, or take any other necessary action.

(Rescinding the Accreditation)

Article 58

(1) The Personal Information Protection Commission may, when an accredited personal information protection organization falls under any of each following item, rescind the accreditation.

(i) when having led to falling under Article 48, item (i) or item (iii)

(ii) when having become unconformable to any of each item of Article 49

(iii) when having violated the provisions of Article 54

(iv) when disobeying an order under the preceding Article

(v) when having received an accreditation under Article 47, paragraph (1) by improper means

(2) The Personal Information Protection Commission shall, when having rescinded an accreditation pursuant to the provisions of the preceding paragraph, announce to the public to that effect.

Chapter V The Personal Information Protection Commission

(Establishment)

Article 59

(1) The Personal Information Protection Commission (hereinafter referred to as the “Commission”) is to be established based on the provisions of Article 49, paragraph (3) of the Act for Establishment of the Cabinet Office.

(2) The Commission belongs to the jurisdiction of the Prime Minster.

(Duties)

Article 60 The Commission is to assume the duties of pursuing ensuring the

proper handling of personal information (including taking action such as giving guidance and advice to an individual number utilizing business etc. related implementer (meaning an individual number utilizing business etc. related implementer prescribed in Article 12 of the Act on the Use of Numbers to Identify a Specific Individual in the Administrative Procedure (Act No.27 of 2013; hereinafter referred to as the "Numbers Use Act"))) in order to protect an individual's rights and interests while considering the utility of personal information including that the proper and effective application of personal information contributes to the creation of new industries and the realization of a vibrant economic society and an enriched quality of life for the people of Japan.

(Jurisdictional Affairs)

Article 61 The Commission is to administer the following affairs in order to fulfil the duties under the preceding Article.

(i) affairs related to the formulation and promotion of a basic policy

(ii) affairs related to supervision over the handling of personal information and anonymously processed information, and those related to necessary mediation on a lodged complaint and cooperation offered to a business operator who deals with the complaint (excluding those set forth in item (iv))

(iii) affairs related to an accredited personal information protection organization

(iv) affairs related to monitoring and supervision over the handling of specific personal information (meaning specific personal information prescribed in Article 2, paragraph (8) of the Numbers Use Act; the same shall apply in Article 63, paragraph (4)) and those related to necessary mediation on a lodged complaint and cooperation offered to a business operation who deals with the complaint

(v) affairs related to specific personal information protection assessment (meaning specific personal information protection assessment prescribed in Article 27, paragraph (1) of the Numbers Use Act)

(vi) affairs related to public relations and an enlightenment campaign on the protection of, and the proper and effective application of, personal information

.

(vii) affairs related to an investigation or research necessary to administer those affairs set forth in each preceding item

(viii) affairs related to international cooperation on the jurisdictional affairs

(ix) besides those set forth in each preceding item, those affairs which have been made by law (including an order based thereon) to belong to the Commission

(Independence on Exercising the Authority)

Article 62 A chairperson and commissioners of the Commission are to exercise their official authority independently.

(Organization etc.)

Article 63

(1) The Commission is to be composed of a chairperson and eight commissioners.

(2) Four of the commissioners are to serve on a part-time basis.

(3) A chairperson and a commissioner are to be appointed by the Prime Minister with consent of both Houses of the Diet from among those with high character and deep insight.

(4) A chairperson and commissioners are to encompass a person who has academic experience concerning the protection of, and the proper and effective application of, personal information, a person who has sufficient knowledge and experience concerning the protection of consumers, a person who has academic experience concerning information processing technologies, a person who has academic experience concerning public administrative fields utilizing specific personal information, a person who has sufficient knowledge and experience concerning private-sector business practices, and a person recommended by a federate organization (meaning a federate organization under Article 263-3, paragraph (1) of the Local Autonomy Act (Act No.67 of 1947) that has given a notification pursuant to the provisions of the said paragraph).

(Term of Office etc.)

Article 64

(1) The term of office for a chairperson and a commissioner is to be five years; however, the term of office of a chairperson or a commissioner appointed to fill a vacancy shall be the remaining term of office of his or her predecessor.

(2) A chairperson and a commissioner may be reappointed.

(3) When the term of office for a chairperson or a commissioner has expired, the chairperson or commissioner are to continue to fulfil their duties until their successor is appointed.

(4) In cases where the term of office of a chairperson or a commissioner has expired or where a vacancy has occurred, when consent by both Houses of the Diet cannot be obtained due to the closing of the Diet or the dissolution of the House of Representatives, the Prime Minister may, notwithstanding the provisions of the preceding Article, paragraph (3), appoint a chairperson or a commissioner from among those persons who have those qualifications prescribed in the said paragraph.

(5) In those cases under the preceding paragraph, an ex post facto approval by both Houses of the Diet shall be obtained in the first Diet session after the appointment. In this case, when the ex post facto approval cannot be obtained by both Houses of the Diet, the Prime Minister shall immediately dismiss the chairperson or the commissioner.

(Guarantee of Status)

Article 65 A chairperson and a commissioner shall not be dismissed against their will while in office except in those cases falling under any of each following item.

(i) when having received a decision on the commencement of bankruptcy proceedings

(ii) when having been punished in violation of this Act or the Numbers Use Act

(iii) when having been punished by imprisonment without work or severer sentence

(iv) when, by the Commission, having been recognized to be incapable of fulfilling his or her duties because of a mental or physical disorder, or having been recognized to be committing a violation of obligation in the course of duties or other misconduct unbecoming to a chairperson or a commissioner

(Dismissal)

Article 66 The Prime Minister shall, when a chairperson or a commissioner falls under any of each item of the preceding Article, dismiss the chairperson or the commissioner.

(Chairperson)

Article 67

(1) A chairperson is to preside over the rules and proceedings of the Commission and represent the Commission.

(2) The Commission shall designate in advance from among full-time commissioners a person to be an acting chairperson in cases where the chairperson is in an accident.

(Meeting)

Article 68

(1) A meeting of the Commission is to be called by a chairperson.

(2) The Commission may, unless a chairperson and four or more commissioners are present, neither hold a meeting nor make a decision.

(3) A decision of the Commission is to be adopted by a majority of attendees, and when in a tie, a chairperson is to make a decision.

(4) A recognition pursuant to the provisions of Article 65, item (iv), notwithstanding the provisions of the preceding paragraph, shall be allowed with the unanimous concurrence of all commissioners except for the commissioner concerned.

(5) With regard to applying the provisions of this Article, paragraph (2) in cases where a chairperson is in an accident, a person to be an acting chairperson prescribed in the preceding Article, paragraph (2) shall be deemed as a chairperson.

(Specialist Commissioner)

Article 69

(1) In the Commission may a specialist commissioner be posited to have a specialized matter investigated.

(2) A specialist commissioner is to be appointed by the Prime Minister based on a proposal made by the Commission.

(3) A specialist commissioner shall be relieved of his or her post when an investigation into the specialized matter has been finished.

(4) A specialist commissioner is to serve on a part-time basis.

(Secretariat)

Article 70

(1) For the purpose of having commissionary affairs administered, a secretariat is to be posited.

(2) In a secretariat are a secretary general and other staff to be posited.

(3) A secretary general is to administer secretarial affairs under the order of a chairperson.

(Prohibition of a Political Campaign etc.)

Article 71

(1) A chairperson and commissioners shall, while in office, neither become a director of a political party or other political organization nor actively conduct a political campaign.

(2) A chairperson and a full-time commissioner shall, while in office except in those cases where there has been permission from the Prime Minister, not engage in any other duties paying remuneration, operate a profit-making business, or perform other services for the purpose of gaining monetary profit.

(Confidentiality Obligation)

Article 72 A chairperson, commissioner, specialist commissioner and secretarial staff shall not divulge or use by stealth any secret that may have come to their knowledge in the course of duties. The same shall also apply

after they have left their position.

(Remuneration)

Article 73 The remuneration of a chairperson and a commissioner shall be prescribed separately by law.

(Establishment of Rules)

Article 74 The Commission may establish rules of the Personal Information Protection Commission regarding its jurisdictional affairs in order to enforce a law or cabinet order, or on the basis of a special delegation under a law or cabinet order.

Chapter VI Miscellaneous Provisions

(Scope of Application)

Article 75 The provisions of Article 15, Article 16, Article 18 (excluding paragraph (2)), Article 19 through Article 25, Article 27 thorough Article 36, Article 41, Article 42, paragraph (1), Article 43 and the following Article shall also apply in those cases where a personal information handling business operator who in relation to supplying a good or service to a person in Japan has acquired personal information relating to the person being as a principal handles in a foreign country the personal information or anonymously processed information produced by using the said personal information.

(Exclusion from Application)

Article 76

(1) To a person set forth in each following item who is a personal information handling business operator shall the provisions of Chapter IV not apply when a whole or part of the purpose of handling personal information etc. is a purpose prescribed in each said item respectively.

(i) a broadcasting institution, newspaper publisher, communication agency and other press organization (including an individual engaged in the press as his or her business): a purpose of being provided for use in the press

(ii) a person who practices writing as a profession: a purpose of being provided for use in writing

(iii) a university and other organization or group aimed at academic studies, or a person belonging thereto: a purpose of being provided for use in academic studies

(iv) a religious body: a purpose of being provided for use in a religious activity (including those activities accessory thereto)

(v) a political body: a purpose of being provided for use in a political activity (including those activities accessory thereto)

(2) The “press” prescribed in item (1) of the preceding paragraph means informing a large number of unspecified people of an objective fact as such (including stating an opinion or view based thereon).

(3) A personal information handling business operator etc. set forth in each item of paragraph (1) shall strive to take itself necessary and appropriate action for the security control of personal data or anonymously processed information and necessary action to ensure the proper handling of personal information etc. such as dealing with a complaint about the handling of personal information etc., as well as announce to the public the contents of such action taken.

(Affairs Administered by a Local Government)

Article 77 Administrative affairs belonging to the Commission’s authority prescribed in this Act and an authority delegated to a business jurisdictional minister or a Commissioner of the Financial Services Agency pursuant to the provisions of Article 44, paragraph (1) or paragraph (4) may be managed by a head of a local government or other executive agency as prescribed by cabinet order.

(Information Provision to the Foreign Enforcement Authorities)

Article 78

(1) The Commission may provide the foreign authorities enforcing those foreign laws and regulations equivalent to this Act (hereinafter referred to as the “foreign enforcement authorities” in this Article) with information recognized as contributory to fulfilling their duties (limited to those equivalent to the Commission’s duties prescribed in this Act; the same shall apply in the succeeding paragraph).

(2) Concerning the provision of information pursuant to the preceding paragraph, appropriate action shall be taken so that the information is

neither used for purposes other than for the foreign enforcement authorities fulfilling their duties nor used for a foreign criminal case investigation (limited to the one conducted after the criminal facts subject to the investigation have been specified) or adjudication (hereinafter collectively referred to as an "investigation etc.") without consent pursuant to the succeeding paragraph.

(3) The Commission may, when having received a request from the foreign enforcement authorities, consent that the information it provided pursuant to paragraph (1) be used for a foreign criminal case investigation etc. in connection with the request except for those cases falling under any of each following item.

(i) when a crime subject to the criminal case investigation etc. in connection with the said request is a political crime, or when the said request is recognized to have been made for the purpose of conducting the investigation etc. into a political crime

(ii) when an act relating to the crime subject to a criminal case investigation etc. in connection with the said request, if it were committed in Japan, shall not constitute a criminal offense according to the laws and regulations in Japan

(iii) when there is no assurance that the requesting country will accept the same kind of request from Japan

(4) The Commission shall, in case of consenting under the preceding paragraph, obtain a Minister of Justice's confirmation of the case not falling under item (i) and item (ii) of the preceding paragraph, and a Minister of Foreign Affairs' confirmation of the case not falling under item (iii) of the preceding paragraph respectively.

(Report to the Diet)

Article 79 The Commission shall annually report to the Diet through the Prime Minister the current status of administering its jurisdictional affairs, and announce to the public a summary thereof.

(Communication and Cooperation)

Article 80 The Prime Minister and a head of an administrative organization related to the implementation of this Act (meaning an organization established in the Cabinet based on the provisions of laws (excluding the Cabinet Office), an organization under the jurisdiction of the Cabinet, the Cabinet Office, the Imperial Household Agency, an organization prescribed in Article 49,

paragraph (1) and paragraph (2) of the Act for Establishment of the Cabinet Office, and an organization prescribed in Article 3, paragraph (2) of the National Government Organization Act (Act No.120 of 1948)) shall closely communicate and cooperate with one another.

(Delegation to Cabinet Order)

Article 81 A matter necessary to implement this Act other than those prescribed in this Act is to be prescribed by cabinet order.

Chapter VII Penal Provisions

Article 82 A person who has divulged or used by stealth a secret in violation of the provisions of Article 72 shall be punished by imprisonment with work for not more than two years or a fine of not more than 1,000,000 yen.

Article 83 A personal information handling business operator (or its director, representative or administrator if it is a corporate body (including a non-corporate body having appointed a representative or administrator; the same shall apply in Article 87, paragraph (1)), its employee, or a person who used to be such a business operator or employee shall, when having provided or used by stealth personal information database etc. (including their wholly or partially duplicated or processed ones) that they handled in relation to their business for the purpose of seeking their own or a third party's illegal profits, be punished by imprisonment with work for not more than one year or a fine of not more than 500,000 yen.

Article 84 A person who has violated an order pursuant to the provisions of Article 42, paragraph (2) or paragraph (3) shall be punished by imprisonment with labor for not more than six months or a fine of not more than 300,000 yen.

Article 85 A person falling under any of each following item shall be punished by a fine of not more than 300,000 yen.

(i) a person who has failed to submit a report or material under the provisions of Article 40, paragraph (1) or did falsely submit a report or material, or who failed to answer a question posed by the staff concerned or did falsely answer a question, or refused, obstructed or evaded an inspection

(ii) a person who failed to submit a report under the provisions of Article 56, or did falsely submit a report

Article 86 The provisions of Article 82 and Article 83 shall apply to a person

who has committed an offense under these Articles outside of Japan.

Article 87

(1) When a representative of a corporate body, or an agent, employee or other worker of a corporate body or natural person has committed a violating act under Article 83 through Article 85 in relation to the corporate body or natural person's business, the actor shall be punished, and a fine set forth in the respective Articles shall be imposed on the said corporate body or natural person.

(2) In cases where the provisions of the preceding paragraph apply to a non-corporate body, its representative or administrator shall represent the non-corporate body in regard to an act of litigation, and the provisions of a law on a criminal suit in the cases where a corporate body is a defendant or suspect shall apply mutatis mutandis.

Article 88 A person falling under any of each following item shall be punished by a non-criminal fine of not more than 100,000 yen.

(i) a person who has violated the provisions of Article 26, paragraph (2), or Article 55

(ii) a person who failed to submit a notification or did falsely submit a notification under the provisions of Article 50, paragraph (1)

Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information（Tentative Translation）

This is an English translation of the Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information, to be put into full effect on May 30, 2017.

NOTICE
*This translation has neither had its texts checked by a native English speaker nor legal language editor, and thus may be subject to change.
*The Japanese original legal texts only shall remain in force, while their English translation is presented for ease of non-Japanese speakers' understanding and reference.

(Individual Identification Code)

Article 1　Those character, letter, number, symbol or other codes prescribed by cabinet order under Article 2, paragraph (2) of the Act on the Protection of Personal Information (hereinafter referred to as the "Act") shall be those set forth in the following.

(i) Those character, letter, number, symbol or other codes produced by having converted any of the following bodily features thereinto so as to be provided for use in computers which conform to standards prescribed by rules of the Personal Information Protection Commission as sufficient to identify a specific individual.

(a) base sequence constituting Deoxyribonucleic Acid (alias DNA) taken from a cell;

(b) appearance decided by facial bone structure and skin color as well as the position and shape of eyes, nose, mouth or other facial elements;

(c) a linear pattern formed by an iris' surface undulation;

(d) vocal cords' vibration, glottis' closing motion as well as the shape of vocal tract and its change when uttering;

(e) bodily posture and both arms' movements, step size and other physical appearance when walking;

(f) Intravenous shape decided by the junctions and endpoints of veins lying under the skin of the inner or outer surface of hands or fingers;

(g) a finger or palm print.

(ii) Number of passport set forth in Article 6, paragraph (1), item (i) of the Passport Act (Act No. 267 of 1951)

(iii) Basic pension number set forth in Article 14 of the National Pension Act (Act No. 141 of 1959)

(iv) Number of a driver's license set forth in Article 93, paragraph (1), item (i) of the Road Traffic Act (Act No. 105 of 1960)

(v) Resident record code set forth in Article 7, item (xiii) of the Basic Resident Registration Act (Act No. 81 of 1967)

(vi) Individual number set forth in Article 2, paragraph (5) of the Act on the Use of Numbers to Identify a Specific Individual in the Administrative Procedure (Act No. 27 of 2013)

(vii) Those character, letter, number, symbol or other codes prescribed by rules of the Personal Information Protection Commission which are stated on a certificate set forth in the following in a way to give each person who receives its issuance a different one.

(a) A health insurance card under Article 9, paragraph (2) of the National Health Insurance Act (Act No. 192 of 1958);

(b) An insured person's certificate under Article 54, paragraph (3) of the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982)

(c) An insured person's certificate under Article 12, paragraph (3) of the Long-Term Care Insurance Act (Act No. 123 of 1997)

(viii) Any other character, letter, number, symbol or other codes prescribed by rules of the Personal Information Protection Commission as equivalent to each preceding item.

(Special care-required personal Information)

Article 2 Those descriptions etc. prescribed by cabinet order under Article 2, paragraph (3) of the Act shall be those descriptions etc. which contain any of those matters set forth in the following (excluding those falling under a principal's medical record or criminal history)

(i) the fact of having physical disabilities, intellectual disabilities, mental disabilities (including developmental disabilities), or other physical and mental functional disabilities prescribed by rules of the Personal Information Protection Commission;

(ii) the results of a medical check-up or other examination (hereinafter referred to as a "medical check-up etc." in the succeeding item) for the prevention and early detection of a disease conducted on a principal by a medical doctor or other person engaged in duties related to medicine (hereinafter referred to as a "doctor etc." in the succeeding item);

(iii) the fact that guidance for the improvement of the mental and physical conditions, or medical care or prescription has been given to a principal by a doctor etc. based on the results of a medical check-up etc. or for reason of disease, injury or other mental and physical changes;

(iv) the fact that an arrest, search, seizure, detention, institution of prosecution or other procedures related to a criminal case have been carried out against a principal as a suspect or defendant;

(v) the fact that an investigation, measure for observation and protection, hearing and decision, protective measure or other procedures related to a juvenile protection case have been carried out against a principal as a juvenile delinquent or a person suspected thereof under Article 3, paragraph (1) of the Juvenile Act.

(Personal Information Database etc.)

Article 3 Those prescribed by cabinet order as having little possibility of harming an individual's rights and interests considering their utilization method under Article 2, paragraph (4) of the Act shall be those falling under all of each following item.

(i) those which have been issued for the purpose of being sold to a large number of unspecified persons and the issuance of which has not been conducted in violation of the provisions of a law or order based thereon;

(ii) those which can be, or could have been, purchased at any time by a large number of unspecified persons;

(iii) those which are being provided for their original purpose without adding other information relating to a living individual.

(2) Those prescribed by cabinet order under Article 2, paragraph (4), item (ii) of the Act shall be a collective body of information including a table of contents, index or similar others to facilitate search of information that has been systematically organized by arranging personal information contained in the database according to a certain rule that enables specified personal information to be readily searched for.

(Those Excluded from Retained Personal Data)

Article 4 Those prescribed by cabinet order under Article 2, paragraph (7) shall be those set forth in the following.

(i) those in relation to which there is a possibility that if the presence or absence of

the said personal data is made known, it would harm a principal or third party's life, body or fortune;

(ii) those in relation to which there is a possibility that if the presence or absence of the said personal data is made known, it would encourage or induce an illegal or unjust act;

(iii) those in relation to which there is a possibility that if the presence or absence of the said personal data is made known, it would undermine national security, destroy a trust relationship with a foreign country or international organization, or suffer disadvantage in negotiations with a foreign country or international organization;

(iv) those in relation to which there is a possibility that if the presence or absence of the said personal data is made known, it would hinder the maintenance of public safety and order such as the prevention, suppression or investigation of a crime.

(Period within Which Those Exempted from Retained Personal Data are Deleted)

Article 5　A period prescribed by cabinet order under Article 2, paragraph (7) of the Act shall be six months.

(Anonymously Processed Information Database etc.)

Article 6　Those prescribed by cabinet order under Article 2, paragraph (10) of the Act mean a collective body of information including a table of contents, index or similar others to facilitate search of information that has been systemically organized by arranging anonymously processed information contained in the database etc. according to a certain rule that enables specified anonymously processed information to be readily searched for.

(Cases in which special care-required personal information may be acquired without a principal's consent)

Article 7 Those cases prescribed by cabinet order under Article 17, paragraph (2), item (vi) of the Act shall be those cases set forth in the following.

(i) cases in which seemingly-clear special care-required personal information is acquired by visual observation, filming or photographing of a principal;

(ii) when receiving the provision of special care-required personal information organized as personal data in those cases set forth in each item of Article 23, paragraph (5) of the Act.

(Necessary Matter relating to Ensuring the Proper Handling of Retained Personal Data)

Article 8 Those prescribed by cabinet order under Article 27, paragraph (1), item (iv) of the Act shall be those set forth in the following;

(i) where to lodge a complaint about the handling of retained personal data by the said personal information handling business operator;

(ii) In those cases where the said personal information handling business operator is a covered business operator of an accredited personal information protection organization, the appellation of the accredited personal information protection organization and where to lodge a petition for resolving a complaint.

(Personal Information Handling Business Operator's Method of Disclosing Retained Personal Data)

Article 9 A method prescribed by cabinet order under Article 28, paragraph (2) of the Act shall be the one by delivering a written document (when there is a method agreed on by a person having requested disclosure, that method).

(Method of Receiving a Demand etc. for Disclosure etc.)

Article10 Those matters which a personal information handling business operator may prescribe as a method of receiving a demand etc. for disclosure etc. pursuant to the provisions of Article 32, paragraph (1) of the Act, shall be as set forth in the following:

(i) where to file a demand etc. for disclosure etc.;

(ii) a format of a document (including an electromagnetic record; the same shall apply in Article 14, paragraph (1) and Article 21, paragraph (3)) to be submitted at the time of making a demand etc. for disclosure etc. and other forms wherein a demand etc. for disclosure etc. may be made;

(iii) a method of confirming that a person making a demand etc. for disclosure etc. is a principal or an agent prescribed in the following Article;

(iv) a method of collecting a fee under Article 33, paragraph (1) of the Act.

(Agent who may Make a Demand etc. for Disclosure etc.)

Article 11 An agent who may make a demand etc. for disclosure etc. pursuant to the provisions of Article 32, paragraph (3) of the Act shall be an agent set forth in the following:

(i) a statutory agent of a minor or adult ward;

(ii) an agent entrusted by a principal with making a demand etc. for disclosure etc.

(Circumstances Prescribed by Cabinet Order under Article 44, paragraph (1) of the Act)

Article 12 Circumstances prescribed by cabinet order under Article 44, paragraph (1) of the Act shall be those circumstances falling under any of each following item;

(i) there is a need to urgently and intensively ensure the proper handling of personal information etc.;

(ii) besides the preceding item, there is a particular need to apply expert knowledge gained by a business jurisdictional minister in order to effectively and efficiently ensure the proper handling of personal information etc.

(Delegation of an Authority to a Business Jurisdictional Minister)

Article 13 The Personal Information Protection Commission shall, in case of delegating an authority under the provisions of Article 40, paragraph (1) of the Act, pursuant to the provisions of Article 44, paragraph (1) of the Act, delegate the authority to a business jurisdictional minister by deciding a scope of administrative affairs to be delegated and an applicable term for delegation. This, however, shall not preclude the Personal Information Protection Commission from solely exercising the authority.

(2) The Personal Information Protection Commission shall, when deciding a scope of administrative affairs to be delegated and an applicable term for delegation pursuant to the provisions of the preceding paragraph, consult in advance with a business jurisdictional minister.

(3) The Personal Information Protection Commission shall, when delegating an authority pursuant to the provisions of paragraph (1), announce to the public a business jurisdictional minister to whom the authority is delegated, a scope of administrative affairs to be delegated, and an applicable term for delegation.

(Report on the Results of an Exercised Authority)

Article 14 A report pursuant to the provisions of Article 44, paragraph (2) of the Act shall be made in a document which states or records a matter set forth in the following regarding the results of an exercised authority at every time when a term set by the Personal Information Protection Commission has passed during an applicable term for delegation set forth in paragraph (1) of the preceding Article (or immediately if it has been recognized that a personal information handling business operator etc. committed a violating act of the provisions under Chapter IV Section 1 or Section 2).

(i) facts ascertained as a result of an ordered submission of a report or material or a conducted onsite inspection;

(ii) other referential matters

(2) The Personal Information Protection Commission shall, when deciding a reporting term pursuant to the provisions of the preceding paragraph, consult in advance with a business jurisdictional minister.

(Delegation of an Authority to Head etc. of a Local Branch Bureau etc.)

Article 15 A business jurisdictional minister may delegate an authority delegated pursuant to the provisions of Article 44, paragraph (1) and an authority under the provisions of paragraph (2) of the said Article to a head of an agency under Article 49, paragraph (1) of the Act for Establishment of the Cabinet Office (Act No. 89 of 1999) (excluding a Commissioner of the Financial Services Agency; the same shall apply hereinafter in this Article.), to a head of an agency under Article 3, paragraph (2) of the National Government Organization Act (Act No. 120 of 1948), or to a Commissioner General of the National Police Agency.

(2) A business jurisdictional minister (or a head of an agency in cases where, an authority has been delegated pursuant to the provisions of the preceding paragraph to the head of an agency under Article 49, paragraph (1) of the Act for Establishment of the Cabinet Office or to the head of an agency under Article 3, paragraph (2) of the National Government Organization Act) may delegate an authority delegated pursuant to the provisions of Article 44, paragraph (1) (or an authority delegated pursuant to the provisions of the preceding paragraph in the said case (excluding an authority pursuant to the provisions of paragraph (2) of that Article)) to a head of a secretariat, bureau, or department under Article 17 or Article 53 of the Act for Establishment of the Cabinet Office; to an official under Article 17, paragraph (1) or Article 62, paragraph (1) or paragraph (2) of that Act; to a head of a local branch bureau under Article 43 or Article 57 of that Act; to a head of a secretariat, bureau, or department under Article 7 of the National Government Organization Act; to a head of a local branch bureau under Article 9 of that Act; or to an official under Article 20, paragraph (1) or paragraph (2) of that Act.

(3) A Commissioner General of the National Police Agency may delegate an authority delegated pursuant to the provisions of paragraph (1) (excluding an authority under the provisions of Article 44, paragraph (2) of the Act) to a head of the Commissioner General's Secretariat or a bureau under Article 19, paragraph (1) of the Police Act (Act No. 162 of 1954); a department under paragraph (2) of that Article; or a regional institution under Article 30, paragraph (1) of that Act.

(4) A business jurisdictional minister, a head of an agency under Article 49, paragraph (1) of the Act for Establishment of the Cabinet Office, a head of an agency under Article 3, paragraph (2) of the National Government Organization Act, or a Commissioner General of the National Police Agency shall, when delegating an authority pursuant to the provisions of the preceding three paragraphs, announce to the public the governmental position of an official granted delegation, a scope of administrative affairs subject to delegation and an applicable term for delegation.

(Delegation etc. of an Authority to the Securities and Exchange Surveillance Commission)

Article 16 A Commissioner of the Financial Services Agency delegates an authority delegated pursuant to the provisions of Article 44, paragraph (4) (except for an authority under the provisions of paragraph (2) of the said Article and limited to those matters made to belong to the authority of the Securities and Exchange Surveillance Commission pursuant to the provisions of the Financial Instruments and Exchange Act (Act No.25 of 1948), Act on Investment Trusts and Investment Corporations (Act No.198 of 1951), Act on the Securitization of Assets (Act No.105 of 1998) and Act on Book Entry of Corporate Bonds and Shares (Act No. 75 of 2001)) to the Securities and Exchange Surveillance Commission. This, however, shall not preclude a Commissioner of the Financial Services Agency from solely exercising the authority.

(2) The Securities and Exchange Surveillance Commission shall, when having exercised an authority delegated pursuant to the provisions of the preceding paragraph, report the results therefrom promptly to a Commissioner of the Financial Services Agency.

(Delegation of an Authority to a Director-General of a Local Finance Bureau etc.)

Article 17　A Commissioner of the Financial Services Agency delegates an authority delegated pursuant to the provisions of Article 44, paragraph (4) (excluding an authority delegated to the Securities and Exchange Surveillance Commission pursuant to the provisions of paragraph (2) and paragraph (5) of the said Article) to a Director-General of a Local Finance Bureau which has jurisdiction over the location of a primary office or business establishment (referred to as a “primary office etc.” in the succeeding item and the paragraph (1) of the succeeding Article) of a personal information handling business operator (or a Director-General of the Fukuoka Local Finance Branch Bureau in cases where the said location is in the jurisdictional district of the Fukuoka Local Finance Branch Bureau). This, however, shall not preclude a Commissioner of the Financial Services Agency from solely exercising the authority.

(2) An authority delegated pursuant to the preceding paragraph and related to the other offices than a primary office etc. (hereinafter referred to as a “secondary office etc.” in this paragraph and paragraph (2) of the succeeding Article) may be exercised by a Director-General of a Local Finance Bureau or a Director-General of the Fukuoka Local Finance Branch Bureau prescribed in the preceding paragraph, as well as a Director-General of a Local Finance Bureau which has jurisdiction over the location of the secondary office etc. (or a Director-General of the Fukuoka Local Finance Branch Bureau in cases where the said location is in the jurisdictional district of the Fukuoka Local Finance Branch Bureau).

Article 18　The Securities and Exchange Surveillance Commission delegates an authority delegated pursuant to the provisions of Article 44, paragraph (5) to a Director-General of a Local Finance Bureau which has jurisdiction over the location of a primary office etc. of a personal information handling business operator etc. (or a Director-General of the Fukuoka Local Finance Branch Bureau in cases where the said location is in the jurisdictional district of the Fukuoka Local Finance Branch Bureau). This, however, shall not preclude the Securities and Exchange Surveillance Commission from solely exercising the authority.

(2) An authority delegated pursuant to the provisions of preceding paragraph and related to a secondary office etc. may be exercised by a Director-General of a Local Finance Bureau or a Director-General of the Fukuoka Local Finance Branch Bureau prescribed in the said paragraph, as well as a Director-General of a Local Finance Bureau which has jurisdiction over the location of the secondary office

etc. of a personal information handling business operator etc. (or a Director-General of the Fukuoka Local Finance Branch Bureau in cases where the said location is in the jurisdictional district of the Fukuoka Local Finance Branch Bureau)

(Application for Accreditation to Become an Accredited Personal Information Protection Organization)

Article19 An application for accreditation pursuant to the provisions of Article 47, paragraph (2) of the Act, shall be filed by submitting a written application containing those matters set forth in the following to the Personal Information Protection Commission:

(i) the appellation and address, and the name of a representative or administrator;

(ii) the location of an office where services relating to an application for accreditation would be rendered;

(iii) a summary of services relating to an application for accreditation (including whether information handled by a covered business operator is personal information or anonymously processed information)

(2) A written application under the preceding paragraph shall have a document set forth in the following attached thereto:

(i) articles of incorporation, articles of endowment and other basic governing documents;

(ii) a document wherein a person applying to be accredited pledges that it does not fall under the provisions of each item of Article 48 of the Act;

(iii) a document stating a method of rendering services relating to an application for accreditation;

(iv) a document demonstrating sufficient knowledge and capability to properly and

assuredly render services relating to an application for accreditation;

(v) a document demonstrating financial bases including the latest business year's annual report, balance sheet, income and expenditure account statement, property inventory list (in case of a corporation established in the business year encompassing the day of the application, a property inventory list as of the time of the establishment);

(vi) a document stating the name, address and brief personal history of a director;

(vii) a document stating the name or appellation of a covered business operator, and a document verifying that the covered business operator is either a constituent member of a person who intends to receive an accreditation or a person who has agreed to be covered by services relating to an application for accreditation;

(viii) in case of performing other services than those relating to an application for accreditation, a document stating the type and outline of the other services;

(ix) a document stating other referential matters.

(3) An accredited personal information protection organization shall, when a matter set forth in each item of paragraph (1) or matters stated in a document set forth in item (ii) through item (iv), item (vi), or item (viii) of the preceding paragraph have changed, submit a notification to that effect to the Personal Information Protection Commission without delay (including a reason for a change when a matter stated in a document set forth in item (iii) of that paragraph has changed).

(Notifying the Termination of Accredited Services)

Article 20 An accredited personal information protection organization shall, when intending to terminate accredited services, submit a notification stating those matters set forth in the following to the Personal Information Protection Commission by not later than three months before the date it intends to terminate the services:

(i) the appellation and address, and the name of a representative or administrator;

(ii) the date of intending to finish receiving a petition under Article 52, paragraph (1) of the Act;

(iii) the date of intending to terminate accredited services;

(iv) a reason for terminating accredited services.

(Administrative Affairs Handled by a Local Government Head etc.)

Article 21 Administrative affairs belonging to the authority of the Personal Information Protection Commission under the provisions of paragraph (1), Article 40 (hereinafter in this Article referred to as “inspection etc. related affairs”) are to be handled by a head of a local government or other enforcement agency (hereinafter in this Article referred to as a “local government head etc.”) in cases where the said authority has been delegated to a business jurisdictional minister pursuant to Article 44, paragraph (1) or to a Commissioner of the Financial Services Agency pursuant to the provisions of paragraph (4) of the said Article, and when a whole or part of administrative affairs belonging to an authority related to collecting a report or conducting an inspection in connection with that business which a personal information handling business operator performs and which the said business jurisdictional minister or the said Commissioner of the Financial Services Agency have jurisdiction over are to be conducted by the local government head etc. pursuant to the provisions of other laws and regulations. If, in such cases as this, there are two or more local government heads that are to handle the said affairs, none of them shall be precluded from solely handling inspection etc. related affairs.

(2) The provisions of the preceding paragraph shall not preclude a business jurisdictional minister or a Commissioner of the Financial Services Agency from solely conducting inspection etc. related affairs.

(3) A local government head etc. having conducted inspection etc. related affairs pursuant to the provisions of paragraph (1) shall report to the Personal Information Protection Commission through a business jurisdictional minister or a Commissioner of the Financial Services Agency at every time when a term

decided by the Personal Information Protection Commission pursuant to the provisions of Article 14, paragraph (1) has elapsed (or immediately when it has been recognized that a personal information handling business operator etc. committed a violating act of the provisions under Chapter Ⅳ, Section 1 or Section 2 of the Act) in a written document which states or records a matter set forth in each item of the said Article concerning the results of inspection etc. related affairs conducted during the said term.

(4) In cases where a local government head etc. conduct inspection etc. related affairs pursuant to the provisions of paragraph (1), the provisions of Article 40 of the Act relating to the Personal Information Protection Commission concerning the inspection etc. related affairs shall apply to the local government head etc. as the provisions relating to the local government head etc.

Enforcement Rules for the Act on the Protection of Personal Information (Tentative translation)

This is an English translation of the Enforcement Rules for the Act on the Protection of Personal Information, to be put into full effect on May 30, 2017.

NOTICE

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*The Japanese original legal texts only shall remain in force, while their English translation is presented for ease of non-Japanese speakers' understanding and reference.

(Definition)

Article 1　Terms used in these rules are governed by the terms used in the Act on the Protection of Personal Information (hereinafter referred to as the "Act").

(Standards in the character, letter, number, symbol or other codes produced by having bodily features converted thereinto so as to be provided for use in computers)

Article 2　Standards prescribed by rules of the Personal Information Protection Commission under Article 1, item (i) of the Order to Enforce the Act on the Protection of Personal Information (hereinafter referred to as the "Order") shall be to convert for the purpose of being provided for use in computers an appropriate scope by using an appropriate method so as to ensure the level of ability to identify a specific individual.

(Character, letter, number, symbol or other codes which are stated on a certificate in a way to give each person who receives its issuance a different one)

Article 3　Character, letter, number, symbol or other codes prescribed by rules

of the Personal Information Protection Commission under Article 1, item (vii) of the Order shall be, for a certificate set forth in each following item, those prescribed in each said item respectively.

(i) a certificate set forth in Article 1, item (vii), (a) of the Order;
Symbol and number of, and insurer's number on, a certificate set forth in Article 1, item (vii), (a) of the Order

(ii) a certificate set forth in Article 1, item (vii), (b) and (c) of the Order;
Number of, and insurer's number on, a certificate set forth in Article 1, item (vii), (b) and (c) of the Order

(Character, letter, number, symbol or other codes which are equivalent to a passport number etc.)

Article 4 Character, letter, number, symbol or other codes prescribed by rules of the Personal Information Protection Commission under Article 1, item (viii) of the Order shall be those set forth in the following.

(i) symbol and number of, and insurer's number on, an insured person's certificate under Article 47, paragraph (2) of the Ordinance for Enforcement of the Health Insurance Act (Ordinance of Home Ministry No. 36 of 1926)

(ii) symbol and number of, and insurer's number on, an elderly recipient's certificate under Article 52, paragraph (1) of the Ordinance for Enforcement of the Health Insurance Act

(iii) symbol and number of, and insurer's number on, an insured person's certificate under Article 35, paragraph (1) of the Ordinance for Enforcement of the Mariner Insurance Act (Ordinance of the Ministry of Welfare No.5 of 1940)

(iv) symbol and number of, and insurer's number on, an elderly recipient's certificate under Article 41, paragraph (1) of the Ordinance for Enforcement of the Mariner Insurance Act

(v) number of a passport (excluding those issued by the Japanese government) under Article 2, item (v) of the Immigration Control and Refugee Recognition Act (Cabinet Order No. 319 of 1951)

(vi) number of a residence card under Article 19-4, paragraph (1), item (v) of the Immigration Control and Refugee Recognition Act

(vii) subscriber number on a subscriber's certificate under Article 1-7 of the Ordinance for Enforcement of Private School Personnel Mutual Aid (Ordinance of the Ministry of Education No. 28 of 1953)

(viii) subscriber number on a subscriber's dependent certificate under Article 3, paragraph 1 of the Ordinance for Enforcement of Private School Personnel Mutual Aid;

(ix) subscriber number on an elderly recipient's certificate under Article 3-2, paragraph (1) of the Ordinance for Enforcement of Private School Personnel Mutual Aid

(x) symbol and number of, and insurer's number on, an elderly recipient's certificate under Article 7-4, paragraph (1) of the Ordinance for Enforcement of National Health Insurance Act (Ordinance of the Ministry of Health and Welfare No.53 of 1958)

(xi) symbol and number of, and insurer's number on, a member certificate under Article 89 of the Ordinance for Enforcement of National Public Servants Mutual Aid Association Act (Ordinance of the Ministry of Finance No. 54 of 1958)

(xii) symbol and number of, and insurer's number on, a member's dependent certificate under Article 95, paragraph (1) of the Ordinance for Enforcement of National Public Servants Mutual Aid Association Act

(xiii) symbol and number of, and insurer's number on, an elderly recipient's certificate under Article 95-2, paragraph (1) of the Ordinance for Enforcement of National Public Servants Mutual Aid Association Act

(xiv) symbol and number of, and insurer's number on, a mariner member certificate and a mariner member's dependent certificate under Article 127-2, paragraph (1) of the Ordinance for Enforcement of National Public Servants Mutual Aid Association Act

(xv) symbol and number of, and insurer's number on, a member certificate under Article 93, paragraph (2) of the Ordinance for Enforcement of Local Public Care Service Mutual Aid Association Act (Ordinance of the Prime Minister's Office, Ministry of Education, Ministry of Home Affairs No. 1 of 1962)

(xvi) symbol and number of, and insurer's number on, a member's dependent certificate under Article 100, paragraph (1) of the Ordinance for Enforcement of Local Public Care Service Mutual Aid Association Act

(xvii) symbol and number of, and insurer's number on, an elderly recipient's certificate under Article 100-2, paragraph (1) of the Ordinance for Enforcement of Local Public Care Service Mutual Aid Association Act

(xviii) symbol and number of, and insurer's number on, a mariner member certificate and a mariner member's dependent certificate under Article 176-2, paragraph (2) of the Ordinance for Enforcement of Local Public Care Service Mutual Aid Association Act

(xix) insured person's number on an employment insurance-insured person's certificate under Article 10, paragraph (1) of the Ordinance for Enforcement of the Employment Insurance Act (Ordinance of Ministry of Labor No. 3 of 1975)

(xx) number of a special permanent resident certification under the Special Act on the Immigration Control of, Inter Alia, Those who have Lost Japanese Nationality Pursuant to the Treaty of Peace with Japan (Act No. 71 of 1991)

(Special Care-Required Personal Information)

Article 5 Physical and mental functional disabilities prescribed by rules of the Personal Information Protection Commission under Article 2, item (i) of the Order shall be those disabilities set forth in the following.

(i) physical disabilities set forth in an appended table of the Act for Welfare of Persons with Physical Disabilities (Act No.283 of 1949)

(ii) intellectual disabilities referred to under the Act for the Welfare of Persons with Intellectual Disabilities (Act No.37 of 1960)

(iii) mental disabilities referred to under the Act for the Mental Health and Welfare of the Persons with Mental Disabilities (Act No.123 of 1950) (including developmental disabilities prescribed in Article 2, paragraph (2) of the Act on Support for Persons with Development Disabilities, and excluding intellectual disabilities under the Act for the Welfare of Persons with Intellectual Disabilities)

(iv) a disease with no cure methods established thereof or other peculiar diseases of which the severity by those prescribed by cabinet order under Article 4, paragraph (1) of the Act on Comprehensive Support for Daily and Social Lives of Persons with Disabilities (Act No. 123 of 2005) is equivalent to those prescribed by the Minister of Health, Labor and Welfare under the said paragraph

(Person prescribed by rules of the Personal Information Protection Commission under Article 17, paragraph (2), item (v) of the Act)

Article 6 A person prescribed by rules of the Personal Information Protection Commission under Article 17, paragraph (2), item (v) shall be a person falling under any of each following item.

(i) a foreign government, a foreign governmental organization, a local government in a foreign country, or an international organization

(ii) a person who is equivalent to a person set forth in each item of Article 76, paragraph (1) of the Act in a foreign country

(Advance notification etc. regarding a third-party provision)

Article 7 Action for informing or putting into a state where a principal can easily know pursuant to the provisions of Article 23, paragraph (2) and paragraph (3) is to be carried out as set forth in the following.

(i) setting a necessary period for a principal identifiable by the provided personal data (referred to as “the principal” in the succeeding item) to request the provision to be ceased.

(ii) adopting an appropriate and reasonable method to enable the principal to recognize without fail a matter set forth in each item of Article 23, paragraph (2) of the Act.

(2) A notification pursuant to the provisions of Article 23, paragraph (2) or paragraph (3) shall be given by any of each method set forth in the following.

(i) a method using an electronic data processing system (meaning an electronic data processing system connecting a computer relating to use by the Personal Information Protection Commission and a computer relating to use by a notifying person via electronic telecommunication line) as prescribed by the Personal Information Protection Commission.

(ii) a method submitting a written notification in an appended form No. 1 and an optical disc (including, an object that can assuredly keep a record of certain matters by an equivalent method to such an optical disc; hereinafter referred to as an “optical disc etc.”) that has kept a record of a matter to be stated in the written notification.

(3) A personal information handling business operator shall, in case of giving a notification pursuant to the provisions of Article 23, paragraph (2) or paragraph (3) of the Act by an agent, submit to the Personal Information Protection Commission a document (including an electromagnetic record;

hereinafter the same.) verifying the power of agency in an appended form No. 2.

(An agent for a personal information handling business operator in a foreign country)

Article 8 A personal information handling business operator in a foreign county shall, in case of giving a notification pursuant to the provisions of Article 23, paragraph (2) or paragraph (3) of the Act, appoint a person domiciled in Japan who has the authorization to act for the personal information handling business operator on any action relating to the notification. In this case, the said personal information handling business operator shall submit a document (including texts translated into Japanese) verifying that it has conferred the power of agency on the person domiciled in Japan to the Personal Information Protection Commission at the same time of giving the said notification.

(Public disclosure by the Personal Information Protection Commission regarding a third-party provision)

Article 9 Public disclosure pursuant to the provisions of Article 23, paragraph (4) of the Act shall be made without delay by utilizing the Internet or other appropriate method after a notification has been given under paragraph (2) or paragraph (3) of the said Article.

(Public disclosure by a personal information handling business operator regarding a third-party provision)

Article 10 A personal information handling business operator shall, promptly after public disclosure pursuant to the provisions of Article 23, paragraph (4) of the Act has been made, disclose to the public those matters set forth in paragraph (2) of the said Article (when a matter set forth in item (ii), item (iii) or item (v) has been modified, a post-modified matter set forth in each said item) by utilizing the Internet or other appropriate method.

(Standards in the system necessary for continuously taking measures equivalent to those which shall be taken by a personal information handling business operator)

Article 11 Standards prescribed by rules of the Personal Information Protection Commission under Article 24 of the Act are to be falling under any of each following item.

(i) a personal information handling business operator and a person who receives the provision of personal data have ensured in relation to the handling of personal data by the person who receives the provision the implementation of measures in line with the purport of the provisions under Chapter IV, Section 1 of the Act by an appropriate and reasonable method

(ii) a person who receives the provision of personal data has obtained a recognition based on an international framework concerning the handling of personal information

(Keeping a Record regarding a Third-party Provision)

Article 12 A method of keeping a record under Article 25, paragraph (1) of the Act pursuant to the said paragraph shall be a method to keep it by using a written document, electromagnetic record or microfilm.

(2) A record under Article 25, paragraph (1) of the Act shall be kept promptly at each time of personal data having been provided to a third party (meaning a third party set forth in the said paragraph; the same shall apply in this Article, the succeeding Article, and from Articles 15 to 17.). Such a record, however, may not be kept at each time of provision if personal data has been provided (excluding a provision pursuant to the provisions of Article 23, paragraph (2) of the Act; the same shall apply in this paragraph.) continuously or repeatedly to the third party, or if a certainty has been anticipated that personal data will be provided continuously or repeatedly to the said third party.

(3) Notwithstanding the provisions of the preceding paragraph, in cases where

personal data relating to a principal, pursuant to the provisions of Article 23, paragraph (1) or Article 24 of the Act, has been provided to a third party in connection with supplying goods or services to the principal with having his or her consent obtained and when a matter prescribed in each item of paragraph (1) of the succeeding Article is stated in a contract or other document produced in connection with the said supply, such a document may substitute for a record relating to the said matter.

(Matter to be recorded regarding a third-party provision)

Article 13 Matters prescribed by rules of the Personal Information Protection Commission under Article 25, paragraph (1) of the Act shall be, in accordance with the categories of those cases set forth in each following item, those matters prescribed in each said item respectively.

(i) cases in which personal data has been provided to a third party pursuant to the provisions of Article 23, paragraph (2) of the Act; a matter set forth in the following (a) to (d)

(a) the date on which the personal data was provided

(b) the name or appellation of the third party or other matter sufficient to identify the said third party (when provided to a large number of unspecified persons, the fact to that effect)

(c) the name of a principal identifiable by the personal data and other matter sufficient to specify the principal

(d) the categories of the personal

(ii) cases in which personal data has been provided to a third party pursuant to the provisions of Article 23, paragraph (1) or Article 24 of the Act; a matter set forth in the following (a) and (b)

(a) the fact to the effect that a principal's consent has been obtained under Article 23, paragraph (1) or Article 24 of the Act

(b) a matter set forth in (b) to (d) under the preceding item.

(2) Regarding those matters prescribed in each item of the preceding paragraph which are identical in contents to those matters contained in a record already kept by using a method prescribed in the preceding Article (limited to those in the case of such a record having been maintained), a record on the said matters may be omitted.

(A record-maintaining period regarding a third-party provision)

Article 14 A period of time prescribed by rules of the Personal Information Protection Commission under Article 25, paragraph (2) of the Act shall be, in accordance with the categories of those cases set forth in each following item, a period of time prescribed in each said item respectively.

(i) cases in which a record was kept by using a method prescribed in the provisions of Article 12, paragraph (3);
a period of time up to the day on which one year has passed from the last date of personal data relating to the record having been provided

(ii) cases in which a record was kept by using a method prescribed in the provisions of the proviso under Article 12, paragraph (2);
a period of time up to the day on which three years have passed from the last date of personal data relating to the record having been provided

(iii) cases other than the preceding two items; three years

(Confirmation when receiving a third-party provision)

Article 15 A method of confirming those matters set forth in Article 26, paragraph (1), item (i) of the Act pursuant to the provisions of the said paragraph shall be a reasonable method such as receiving a declaration from a third party who provides personal data.

(2) A method of confirming those matters set forth in Article 26, paragraph (1), item (ii) of the Act pursuant to the provisions of the said paragraph shall be a

reasonable method such as receiving from a third party the production of a contract or other document showing those circumstances under which the personal data was acquired by the third party.

(3) Notwithstanding the provisions of the preceding two paragraphs, a method of confirming those matters which have already been confirmed when receiving the provision of other personal data from a third party (limited to those in cases where a record has been kept and maintained by using a method prescribed in the succeeding Article relating to the confirmation) shall be a method to confirm that the said matters are identical in contents to those matters set forth in each item of Article 26, paragraph (1) relating to the said provision.

(Keeping a record regarding a confirmation when receiving a third-party provision)

Article 16 A method of keeping a record under Article 26, paragraph (3) of the Act pursuant to the said paragraph shall be a method to keep it by using a written document, electromagnetic record or microfilm.

(2) A record under Article 26, paragraph (3) of the Act shall be kept promptly at each time when the provision of personal data has been received from a third party. Such a record, however, may not be kept at each time of receipt if the provision of personal data has been received continuously or repeatedly from the third party (excluding a provision pursuant to the provisions of Article 23, paragraph (2) of the Act; hereinafter the same in this Article.), or when a certainty has been anticipated that the provision of personal data will be received continuously or repeatedly from the said third party.

(3) Notwithstanding the provisions of the preceding paragraph, in cases where the provision of personal data relating to a principal has been received from a third party in connection with supplying the principal with goods or services and when a matter prescribed in each item of the succeeding Article, paragraph (1) is stated in a contract or other document produced in connection with the supply, such a document may substitute for a record

relating to the matter.

(Matter to be recorded when receiving a third-party provision)

Article 17 Matters prescribed by rules of the Personal Information Protection Commission under Article 26, paragraph (3) of the Act shall be, in accordance with the categories of those cases set forth in each following item, those matters prescribed in each said item respectively.

(i) cases in which a personal information handling business operator has received the provision of personal data pursuant to the provisions of Article 23, paragraph (2) of the Act;
a matter set forth in the following (a) to (e)

(a) the date on which the provision of personal data was received

(b) a matter set forth in each item of Article 26, paragraph (1) of the Act

(c) the name of a principal identifiable by the personal data and other matters sufficient to specify the principal

(d) the categories of the personal data

(e) the fact to the effect that disclosure has been made pursuant to the provisions of Article 23, paragraph (4) of the Act.

(ii) cases in which a personal information handling business operator has received the provision of personal data pursuant to the provisions of Article 23, paragraph (1) or Article 24 of the Act;
a matter set forth in the following (a) and (b)

(a) the fact to the effect that a principal's consent has been obtained under Article 23, paragraph (1) or Article 24 of the Act

(b) a matter set forth in (b) to (d) under the preceding item

(iii) cases in which the provision of personal data has been received from a third party (excluding a person falling within the purview of a personal information handling business operator)

(a) a matter set forth in (b) to (d) under item (i).

(2) Regarding those matters prescribed in each item of the preceding paragraph which are identical in contents to matters contained in a record already kept by using a method prescribed in the preceding Article (limited to those in the case of such a record having been maintained), a record on the said matters may be omitted.

(A record-maintaining period when receiving a third-party provision)

Article 18 A period of time prescribed by rules of the Personal Information Protection Commission under Article 26, paragraph (4) of the Act shall be, in accordance with the categories of those cases set forth in each following item, a period of time prescribed in each said item respectively.

(i) cases in which a record was kept by using a method prescribed in Article 16, paragraph (3);
a period of time up to the day on which one year has passed from the last date on which the provision of personal data relating to the record was received

(ii) cases in which a record was kept by using a method prescribed in the proviso under Article 16, paragraph (2); a period of time up to the day on which three years have passed from the last date on which the provision of personal data relating to the record was received

(iii) cases other than the preceding two items; three years

(Standards in the methods of producing anonymously processed information)

Article 19 Standards prescribed by rules of the Personal Information Protection Commission under Article 36, paragraph (1) of the Act shall be as

follows.

(i) deleting a whole or part of those descriptions etc. which can identify a specific individual contained in personal information (including replacing such descriptions etc. with other descriptions etc. using a method with no regularity that can restore the whole or part of descriptions etc.)

(ii) deleting all individual identification codes contained in personal information (including replacing such codes with other descriptions etc. using a method with no regularity that can restore the individual identification codes)

(iii) deleting those codes (limited to those codes linking mutually plural information being actually handled by a personal information handling business operator) which link personal information and information obtained by having taken measures against the personal information (including replacing the said codes with those other codes which cannot link the said personal information and information obtained by having taken measures against the said personal information using a method with no regularity that can restore the said codes)

(iv) deleting idiosyncratic descriptions etc. (including replacing such descriptions etc. with other descriptions etc. using a method with no regularity that can restore the idiosyncratic descriptions etc.)

(v) besides action set forth in each preceding item, taking appropriate action based on the results from considering the attribute etc. of personal information database etc. such as a difference between descriptions etc. contained in personal information and descriptions etc. contained in other personal information constituting the personal information database etc. that encompass the said personal information

(Standards in the security control action concerning processing method etc. related information)

Article 20 Standards prescribed by rules of the Personal Information

Protection Commission under Article 36, paragraph (2) of the Act shall be as follows.

(i) defining clearly the authority and responsibility of a person handling information relating to those descriptions etc. and individual identification codes which were deleted from personal information used to produce anonymously processed information and information relating to a processing method carried out pursuant to the provisions of Article 36, paragraph (1) (limited to those which can restore the personal information by use of such relating information) (hereinafter referred to as “processing method etc. related information” in this Article.)

(ii) establishing rules and procedures on the handling of processing method etc. related information, handling appropriately processing method etc. related information in accordance with the rules and procedures, evaluating the handling situation, and based on such evaluation results, taking necessary action to seek improvement

(iii) taking necessary and appropriate action to prevent a person with no legitimate authority to handle processing method etc. related information from handling the processing method etc. related information

(Public disclosure by a personal information handling business operator when producing anonymously processed information)

Article 21 Public disclosure pursuant to the provisions of Article 36, paragraph (3) of the Act shall, without delay after anonymously processed information has been produced, be made by utilizing the Internet or other appropriate method.

(2) In cases where a personal information handling business operator entrusted by another personal information handling business operator has produced anonymously processed information, the said other personal information handling business operator shall disclose the categories of information relating to an individual contained in the anonymously processed information by a method prescribed in the preceding paragraph. In such cases, it shall

be deemed that the public disclosure of the said categories has been made by the said entrusted personal information handling business operator.

(Public Disclosure etc. by a personal information handling business operator when providing anonymously processed information to a third party)

Article 22 Public disclosure pursuant to the provisions of Article 36, paragraph (4) of the Act shall be made by utilizing the Internet or other appropriate method.

(2) An explicit statement pursuant to the provisions of Article 36, paragraph (4) of the Act shall be given by sending an e-mail, delivering a written document or employing other appropriate method.

(Public Disclosure etc. by an Anonymously Processed Information Handling Business Operator when Providing Anonymously Processed Information to a Third Party)

Article 23 The provisions of the preceding Article, paragraph (1) shall apply mutatis mutandis to public disclosure pursuant to the provisions of Article 37 of the Act.

(2) The provisions of the preceding Article, paragraph (2) shall apply mutatis mutandis to an explicit statement pursuant to the provisions of Article 37 of the Act.

(Notifying a Personal Information Protection Guideline)

Article 24 A notification pursuant to the provisions of Article 53, paragraph (2) shall be given in writing in an appended form No. 3.

(Public Disclosure of a Personal Information Protection Guideline by the Personal Information Protection Commission)

Article 25 Public disclosure pursuant to the provisions of Article 53, paragraph (3) of the Act shall be made by utilizing the Internet or other appropriate

method.

(Public Disclosure of a Personal Information Protection Guideline by an Accredited Personal Information Protection Organization)

Article 26 An accredited personal information protection organization shall, without delay after a personal information protection guideline has been disclosed to the public pursuant to the provisions of Article 53, paragraph (3) of the Act, disclose the personal information protection guideline to the public by utilizing the Internet or other appropriate method.

遺伝子治療等臨床研究に関する指針

平成２７年８月１２日

厚　生　労　働　省

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第一章　総則

第一　目的

この指針は、遺伝子治療等の臨床研究（以下「遺伝子治療等臨床研究」という。）に関し遵守すべき事項を定め、もって遺伝子治療等臨床研究の医療上の有用性及び倫理性を確保し、社会に開かれた形での適正な実施を図ることを目的とする。

第二　用語の定義

一　この指針において「遺伝子治療等」とは、疾病の治療や予防を目的として遺伝子又は遺伝子を導入した細胞を人の体内に投与することをいう。

二　この指針において「被験者」とは、遺伝子治療等臨床研究において、遺伝子治療等の対象となる者をいう。

三　この指針において「研究者」とは、遺伝子治療等臨床研究を実施する者をいう。

四　この指針において「研究責任者」とは、研究機関において、遺伝子治療等臨床研究を実施する研究者に必要な指示を行うほか、遺伝子治療等臨床研究を総括する立場にある研究者をいう。

五　この指針において「総括責任者」とは、他の研究機関と共同して実施する遺伝子治療等臨床研究において、研究者及び研究責任者に必要な指示を行うほか、当該遺伝子治療等臨床研究に係る業務を総括する研究責任者をいう。

六　この指針において「研究機関」とは、遺伝子治療等臨床研究を実施する法人、行政機関及び個人事業主をいう。

七　この指針において「研究機関の長」とは、遺伝子治療等臨床研究を実施する法人の代表者、行政機関の長及び個人事業主をいう。

八　この指針において「共同研究機関」とは、研究計画書に基づいて遺伝子治療等臨床研究を共同して実施する研究機関をいう。

九　この指針において「倫理審査委員会」とは、遺伝子治療等臨床研究の実施又は継続の適否その他遺伝子治療等臨床研究に関し必要な事項について、倫理的及び科学的な観点から調査審議するために設置された合議制の機関をいう。

十　この指針において「試料」とは、血液、体液、組織、細胞、排泄（せつ）物及びこれらから抽出したＤＮＡ等、人の体の一部であって研究に用いられるもの（死者に係るものを含む。）をいう。

十一　この指針において「研究に用いられる情報」とは、被験者の診断及び治療を通じて得られた傷病名、投薬内容、検査又は測定の結果等、人の健康に関する情報その他の情報であって研究に用いられるもの（死者に係るものを含む。）をいう。

十二　この指針において「試料・情報」とは、試料及び研究に用いられる情報をいう。

十三　この指針において「インフォームド・コンセント」とは、被験者又はその代諾者（以下「被験者等」という。）が、実施又は継続されようとする遺伝子治療等臨床研究に関して、当該遺伝子治療等臨床研究の目的及び意義並びに方法、被験者に生じる負担、予測される結果（リスク及び利益を含む。）等について十分な説明を受け、それらを理解した上で自由意思に基づいて研究責任者等（研究責任者又は研究責任者の指示を受けた医師である研究者をいう。以下同じ。）に対し与える、当該遺伝子治療等臨床研究（試料・情報の取扱いを含む。）を実施又は継続されることに関する同意をいう。

十四　この指針において「代諾者」とは、被験者の意思及び利益を代弁できると考えられる者であって、当該被験者がインフォームド・コンセントを与える能力を欠くと客観的に判断される場合に、当該被験者の代わりに、研究責任者等に対してインフォームド・コンセントを与えることができる者をいう。

十五　この指針において「インフォームド・アセント」とは、インフォームド・コンセントを与える能力を欠くと客観的に判断される被験者が、実施又は継続されようとする遺伝子治療等臨床研究に関して、その理解力に応じた分かりやすい言葉で説明を受け、当該遺伝子治療等臨床研究を実施又は継続されることを理解し、賛意を表することをいう。

十六　この指針において「最終産物」とは、被験者に投与する最終的に作製された疾病の治療又は予防のための遺伝子が組み込まれたＤＮＡ又はこれを含むウイルスその他の粒子（以下「組換え遺伝子等」という。）等をいう。

十七　この指針において「個人情報」とは、生存する個人に関する情報であって、当該情報に含まれる氏名、生年月日その他の記述等により特定の個人を識別することができるものをいい、他の情報と容易に照合することができ、それにより特定の個人を識別することができることとなるものを含む。

十八　この指針において「個人情報等」とは、個人情報に加えて、死者について特定の個人を識別することができる情報を含めたものをいう。

十九　この指針において「匿名化」とは、特定の個人（死者を含む。以下同じ。）を識別することができることとなる記述等の全部又は一部を取り除き、代わりに当該個人と関わりのない符合又は番号を付すこという。

　なお、個人情報等のうち、それ自体では特定の個人を識別することができないものであっても、他で入手できる情報と照合することにより特定の個人を識別することができる場合には、照合に必要な情報の全部又は一部を取り除いて、特定の個人を識別することができないようにすることを含むものとする。

二十　この指針において「連結可能匿名化」とは、必要な場合に特定の個人を識別することができるように、当該個人と新たに付された符号又は番号との対応表を残す方法による匿名化をいう。

二十一　この指針において「有害事象」とは、実施された遺伝子治療等臨床研究との因果関係の有無を問わず、被験者に生じた全ての好ましくない若しくは意図しない傷病又はその徴候（臨床検査値の異常を含む。）をいう。

二十二　この指針において「重篤な有害事象」とは、有害事象のうち、次に掲げるいずれかに該当するものをいう。

①　死に至るもの
②　生命を脅かすもの
③　治療のための入院又は入院期間の延長が必要となるもの
④　永続的又は顕著な障害・機能不全に陥るもの
⑤　子孫に先天異常を来すもの

二十三　この指針において「モニタリング」とは、遺伝子治療等臨床研究が適正に行われることを確保するため、遺伝子治療等臨床研究がどの程度進捗しているか並びにこの指針及び研究計画書に従って行われているかについて、研究責任者が指定した者に行わせる調査をいう。

二十四　この指針において「監査」とは、遺伝子治療等臨床研究の結果の信頼性を確保するため、遺伝子治療等臨床研究がこの指針及び研究計画書に従って行われたかについて、研究責任者が指定した者に行わせる調査をいう。

第三　適用範囲

一　適用される研究

この指針は、我が国の研究機関により実施され、又は日本国内において実施される遺伝子治療等臨床研究を対象とする。

ただし、第十二から第三十四までの規定は、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（昭和35年法律第145号）に定める治験に該当する遺伝子治療等臨床研究及び遺伝子を導入した細胞を人の体内に投与する遺伝子治療等臨床研究については、適用しない。

二　日本国外において実施される研究

１　我が国の研究機関が日本国外において遺伝子治療等臨床研究を実施する場合（海外の研究機関と共同して遺伝子治療等臨床研究を実施する場合を含む。）は、この指針に従うとともに、実施地の法令、指針等の基準を遵守しなければならない。ただし、この指針の規定と比較して実施地の法令、指針等の基準の規定が厳格な場合には、この指針の規定に代えて当該実施地の法令、指針等の基準の規定により遺伝子治療等臨床研究を実施するものとする。

２　この指針の規定が日本国外の実施地における法令、指針等の基準の規定より厳格であり、この指針の規定により遺伝子治療等臨床研究を実施することが困難な場合であって、次に掲げる事項が研究計画書に記載され、当該遺伝子治療等臨床研究の実施について倫理審査委員会の意見を聴いて我が国の研究機関の長が許可したときには、この指針の規定に代えて当該実施地の法令、指針等の基準の規定により遺伝子治療等臨床研究を実施することができるものとする。

①　インフォームド・コンセントについて適切な措置が講じられる旨

②　遺伝子治療等臨床研究の実施に伴って取得される個人情報等の保護について適切な措置が講じられる旨

第四　遺伝子治療等臨床研究の対象の要件

遺伝子治療等臨床研究の対象は、次のすべての要件に適合するものに限る。

１　遺伝子治療等臨床研究による治療・予防効果が、現在可能な他の方法と比較して同等以上であることが十分予測されるものであること。

２　被験者にとって遺伝子治療等臨床研究により得られる利益が、不利益を上回ることが十分予測されるものであること。また、当該遺伝子治療等臨床研究が予防を目的とする場合には、利益が不利益を大きく上回ることが十分予測されるものであること。

第五　有効性及び安全性

遺伝子治療等臨床研究は、有効かつ安全なものであることが十分な科学的知見に基づき予測されるものに限る。

第六　品質等の確認

遺伝子治療等臨床研究に使用される遺伝子その他の人に投与される物質については、医薬品の臨床試験の実施の基準に関する省令（平成９年厚生省令第28号）第17条若しくは再生医療等製品の臨床試験の実施の基準に関する省令（平成26年厚生労働省令第89号）第25条において求められる水準に達している施設又は再生医療等の安全性の確保等に関する法律（平成25年法律第85号）第２条第８項の特定細胞加工物製造事業者が、同法第35条第１項の許可若しくは同法

第39条第１項の認定を受けた又は第40条第１項の規定による届出をした細胞培養加工施設において製造され、その品質、有効性及び安全性が確認されているものに限る。

第七　生殖細胞等の遺伝的改変の禁止

人の生殖細胞又は胚（一の細胞又は細胞群であって、そのまま人又は動物の胎内において発生の過程を経ることにより一の個体に成長する可能性のあるもののうち、胎盤の形成を開始する前のものをいう。以下同じ。）の遺伝的改変を目的とした遺伝子治療等臨床研究及び人の生殖細胞又は胚の遺伝的改変をもたらすおそれのある遺伝子治療等臨床研究は、行ってはならない。

第八　適切な説明に基づくインフォームド・コンセントの確保

遺伝子治療等臨床研究は、適切な説明に基づくインフォームド・コンセントが確実に確保されて実施されなければならない。

第九　公衆衛生上の安全の確保

遺伝子治療等臨床研究は、公衆衛生上の安全が十分確保されて実施されなければならない。

第十　情報の公開

遺伝子治療等臨床研究は、第十九の一に規定するデータベースに登録され、その情報は適切かつ正確に公開されなければならない。

第十一　被験者の選定

被験者の選定に当たっては、人権保護の観点から、病状、年齢、同意能力等を考慮し、慎重に検討しなければならない。

第二章　研究者等の責務等

第十二　研究者の基本的責務等

一　研究者は、次の業務を行わなければならない。

１　被験者等への配慮

⑴　研究者は、被験者の生命、健康及び人権を尊重して、遺伝子治療等臨床研究を実施しなければならない。

⑵　研究者は、遺伝子治療等臨床研究を実施するに当たっては、あらかじめインフォームド・コンセントを受けなければならない。

⑶　研究者は、被験者等及びその関係者からの相談、問合せ、苦情等（以下「相談等」という。）に適切かつ迅速に対応しなければならない。

⑷　研究者は、遺伝子治療等臨床研究の実施に携わる上で知り得た情報を正当な理由なく漏らしてはならない。遺伝子治療等臨床研究の実施に携わらなくなった後も、同様とする。

⑸　研究者は、遺伝子治療等臨床研究に関連する情報の漏えい等、被験者等の人権を尊重する観点又は遺伝子治療等臨床研究の実施上の観点から重大な懸念が生じた場合には、速やかに研究機関の長及び研究責任者に報告しなければならない。

２　遺伝子治療等臨床研究の倫理的妥当性及び科学的合理性の確保等

⑴　研究者は、法令、指針等を遵守し、倫理審査委員会及び厚生労働大臣の意見を尊重し、研究機関の長が許可した研究計画書に従って、適正に

研究を実施しなければならない。

⑵　研究者は、研究責任者を補助し遺伝子治療等臨床研究の研究計画に関する資料を作成するとともに、当該計画を実施し、研究責任者に対し必要な報告を行わなければならない。

⑶　研究者は、遺伝子治療等臨床研究の倫理的妥当性若しくは科学的合理性を損なう事実若しくは情報又は損なうおそれのある情報を得た場合（⑷に該当する場合を除く。）には、速やかに研究責任者に報告しなければならない。

⑷　研究者は、遺伝子治療等臨床研究の実施の適正性若しくは研究結果の信頼を損なう事実若しくは情報又は損なうおそれのある情報を得た場合には、速やかに研究責任者又は研究機関の長に報告しなければならない。

３　教育・研修

研究者は、遺伝子治療等臨床研究の実施に先立ち、遺伝子治療等臨床研究に関する倫理並びに当該遺伝子治療等臨床研究の実施に必要な知識及び技術に関する教育・研修を受けなければならない。また、研究期間中も適宜継続して、教育・研修を受けなければならない。

二　研究者は、遺伝子治療等臨床研究を適正に実施するために必要な専門的知識又は臨床経験を有する者とする。

第十三　研究責任者の責務

一　研究責任者は、次の業務を行わなければならない。

１　研究計画書の作成及び研究者に対する遵守徹底

⑴　研究責任者は、遺伝子治療等臨床研究の実施に関して国内外の入手し得る資料及び情報に基づき、遺伝子治療等臨床研究の医療上の有用性及び倫理性について検討を行い、その検討の結果を踏まえて、遺伝子治療等臨床研究の遂行に必要な体制を整え、あらかじめ、研究計画書を作成し、研究機関の長の許可を求めなければならない。研究計画書を変更するときも同様とする。

⑵　研究責任者は、当該遺伝子治療等臨床研究に関連して被験者に生じた健康被害に対する補償を行うために、あらかじめ、保険への加入その他の必要な措置を適切に講じなければならない。

⑶　研究責任者は、第十九の規定により、研究の概要その他の遺伝子治療等臨床研究に関する情報を適切に登録するとともに、遺伝子治療等臨床研究の結果については、これを公表しなければならない。

⑷　研究責任者は、研究計画書に従って遺伝子治療等臨床研究が適正に実施され、その結果の信頼性が確保されるよう、当該遺伝子治療等臨床研究の実施に携わる研究者を指導・管理しなければならない。

２　遺伝子治療等臨床研究の進捗状況の管理・監督及び有害事象等の把握・報告

⑴　研究責任者は、遺伝子治療等臨床研究の実施に係る必要な情報を収集するなど、遺伝子治療等臨床研究の適正な実施及び研究結果の信頼性の確保に努めなければならない。

⑵　研究責任者は、遺伝子治療等臨床研究の倫理的妥当性若しくは科学的合理性を損なう事実若しくは情報又は損なうおそれのある情報であって遺伝子治療等臨床研究の継続に影響を与えると考えられるものを得た場合（⑶に該当する場合を除く。）には、速やかに、研究機関の長及び総括責任者に対して報告し、必要に応じて、遺伝子治療等臨床研究を停止

し、若しくは中止し、又は研究計画書を変更しなければならない。

⑶　研究責任者は、遺伝子治療等臨床研究の実施の適正性若しくは研究結果の信頼を損なう事実若しくは情報又は損なうおそれのある情報を得た場合には、速やかに研究機関の長及び総括責任者に報告し、必要に応じて、遺伝子治療等臨床研究を停止し、若しくは中止し、又は研究計画書を変更しなければならない。

⑷　研究責任者は、遺伝子治療等臨床研究の実施において、当該遺伝子治療等臨床研究により期待される利益よりも予測されるリスクが高いと判断される場合又は当該遺伝子治療等臨床研究により十分な成果が得られた若しくは十分な成果が得られないと判断される場合には、当該遺伝子治療等臨床研究を中止しなければならない。

⑸　研究責任者は、研究計画書に定めるところにより、遺伝子治療等臨床研究の進捗状況及び遺伝子治療等臨床研究の実施に伴う有害事象の発生状況等を、研究機関の長、総括責任者及び倫理審査委員会に文書で報告しなければならない。この場合において、進捗状況に関しては少なくとも、年１回以上、報告する。

⑹　研究責任者は、遺伝子治療等臨床研究を終了（中止の場合を含む。以下同じ。）したときは、研究機関の長及び総括責任者に必要な事項について報告しなければならない。

⑺　研究責任者は、他の研究機関と共同で遺伝子治療等臨床研究を実施する場合には、共同研究機関の研究責任者に対し当該遺伝子治療等臨床研究に関連する必要な情報を共有しなければならない。

３　遺伝子治療等臨床研究の実施後の被験者への対応

⑴　研究責任者は、遺伝子治療等臨床研究の実施後においても、被験者が当該遺伝子治療等臨床研究の成果を含め必要な最善の予防、診断及び治療を受けることができるよう努めなければならない。

⑵　研究責任者は、遺伝子治療等臨床研究の実施後においても、安全性及び有効性の確保の観点から、遺伝子治療等による効果及び副作用について適当な期間の追跡調査その他の必要な措置を講ずるように努めなければならない。また、その結果については、研究機関の長及び総括責任者に報告しなければならない。

４　研究責任者は、１から３までに定めるもののほか、自らの研究機関における遺伝子治療等臨床研究を総括するにあたって必要な措置を講じなければならない。

二　研究責任者は、１件の遺伝子治療等臨床研究について１研究機関につき１名とし、一に掲げる業務を適確に実施できる者とする。

第十四　総括責任者の責務

一　総括責任者は、次の業務を行わなければならない。

１　総括責任者は、遺伝子治療等臨床研究の実施に関して国内外の入手し得る資料及び情報に基づき、遺伝子治療等臨床研究の医療上の有用性及び倫理性について検討を行い、その検討の結果を踏まえて、あらかじめ、研究計画書を作成し、自らが所属する研究機関の長の許可を求めなければならない。研究計画書を変更するときも同様とする。

２　総括責任者は、遺伝子治療等臨床研究を総括し、他の研究責任者に必要な指示を与えるとともに、適宜、他の研究責任者に対する教育及び研修を行わなければならない。

３　総括責任者は、第十三の一の２⑵又は⑶の規定により報告を受けた場合は、自らが所属する研究機関の長及び全ての研究責任者に対し、速やかに、その旨を報告しなければならない。
４　総括責任者は、１から３までに定めるもののほか、遺伝子治療等臨床研究を総括するに当たって必要な措置を講じなければならない。
二　他の研究機関と共同して実施する遺伝子治療等臨床研究において、総括責任者は、遺伝子治療等臨床研究１件につき１名とし、各研究機関の研究責任者の中から１名に限り選任するものとする。
三　総括責任者は、研究責任者の業務を行うとともに、他の研究責任者から依頼された第十九の一の規定による遺伝子治療等臨床研究の研究概要等の登録を代表して行うことができる。この場合には、当該遺伝子治療等臨床研究を実施する全ての研究機関に関する情報も登録しなければならない。

第十五　研究機関
研究機関は、次のすべての要件を満たさなければならない。
一　十分な臨床観察及び検査並びにこれらの結果の分析及び評価を行うことができる人的能力及び施設機能を備えたものであること。
二　被験者の病状に応じた必要な措置を採ることができる人的能力及び施設機能を備えたものであること。

第十六　研究機関の長の責務
研究機関の長は、次の業務を行わなければならない。
一　研究に対する総括的な監督
１　研究機関の長は、実施を許可した遺伝子治療等臨床研究について、適正に実施されるよう必要な監督を行うとともに、最終的な責任を負うものとする。
２　研究機関の長は、研究者に、被験者の生命、健康及び人権を尊重して遺伝子治療等臨床研究を実施することを周知徹底しなければならない。
３　研究機関の長は、その業務上知り得た情報を正当な理由なく漏らしてはならない。その業務に従事しなくなった後も、同様とする。
４　研究機関の長は、遺伝子治療等臨床研究に関する業務の一部を委託する場合には、委託を受けた者が遵守すべき事項について、文書による契約を締結するとともに、委託を受けた者に対する必要かつ適切な監督を行わなければならない。
二　遺伝子治療等臨床研究の実施のための体制・規程の整備等
１　研究機関の長は、遺伝子治療等臨床研究を適正に実施するために必要な体制・規程を整備しなければならない。
２　研究機関の長は、当該研究機関の実施する遺伝子治療等臨床研究に関連して被験者に健康被害が生じた場合、これに対する補償その他の必要な措置が適切に講じられることを確保しなければならない。
３　研究機関の長は、研究結果等、遺伝子治療等臨床研究に関する情報が適切に公表されることを確保しなければならない。
４　研究機関の長は、当該研究機関における遺伝子治療等臨床研究がこの指針に適合していることについて、必要に応じ、自ら点検及び評価を行い、その結果に基づき適切な対応をとらなければならない。
５　研究機関の長は、遺伝子治療等臨床研究に関する倫理並びに遺伝子治療等臨床研究の実施に必要な知識及び技術に関する教育・研修を当該研究機

関の研究者が受けることを確保するための措置を講じなければならない。また、自らもこれらの教育・研修を受けなければならない。

６　研究機関の長は、当該研究機関において定められた規程により、この指針に定める権限又は事務を当該研究機関内の適当な者に委任することができる。

三　研究の許可等

１　研究機関の長は、研究責任者から、遺伝子治療等臨床研究の実施又は当該遺伝子治療等臨床研究の重大な変更の許可を求められたときは倫理審査委員会及び厚生労働大臣に、その他の当該遺伝子治療等臨床研究の変更の許可を求められたときは倫理審査委員会に意見を求め、その意見を尊重し、当該許可又は不許可その他研究に関し必要な措置について決定しなければならない。なお、他の研究機関と共同して実施する遺伝子治療等臨床研究について厚生労働大臣に意見を求める場合には、一括して意見を求めることができる。

２　研究機関の長は、遺伝子治療等臨床研究の継続に影響を与えると考えられる事実又は情報について報告を受けた場合には、必要に応じて倫理審査委員会に意見を求め、その意見を尊重するとともに、必要に応じて速やかに、遺伝子治療等臨床研究の停止、原因の究明等、適切な対応をとらなければならない。なお、研究機関の長は、倫理審査委員会の意見を聴く前に、必要に応じ、研究責任者に対し、遺伝子治療等臨床研究の中止又は暫定的な措置を講ずるよう、指示することができる。

３　研究機関の長は、倫理審査委員会及び厚生労働大臣が行う調査に協力しなければならない。

４　研究機関の長は、遺伝子治療等臨床研究の実施の適正性若しくは研究結果の信頼を損なう事実若しくは情報又は損なうおそれのある情報について報告を受けた場合には、速やかに必要な措置を講じなければならない。

５　研究機関の長は、研究責任者から遺伝子治療等臨床研究の終了について報告を受けたときは、当該遺伝子治療等臨床研究に関する審査を行った倫理審査委員会に必要な事項について報告をしなければならない。

四　厚生労働大臣への報告等

１　研究機関の長は、遺伝子治療等臨床研究の進捗状況及び研究結果について、研究責任者又は倫理審査委員会から報告又は意見を受け、必要に応じ、研究責任者に対しその留意事項、改善事項等に関して指示を与えるとともに厚生労働大臣に対し報告を行わなければならない。

２　研究機関の長は、研究責任者から受理した総括報告書の写しを速やかに厚生労働大臣に提出しなければならない。

３　研究機関の長は、第十二の一の１⑸又は第十三の一の２⑵若しくは⑶の規定による報告を受けた場合等、遺伝子治療等臨床研究の継続に影響を与えると考えられる事実又は情報について、速やかに厚生労働大臣に報告しなければならない。

４　研究機関の長は、当該研究機関が実施している又は過去に実施した遺伝子治療等臨床研究について、この指針に適合していないことを知った場合には、速やかに倫理審査委員会の意見を聴き、必要な対応を行うとともに、不適合の程度が重大な場合であるときは、その対応の状況・結果を厚生労働大臣に報告し、公表しなければならない。

第三章　研究計画書

第十七　研究計画書に関する手続

一　研究計画書の作成・変更

１　研究責任者は遺伝子治療等臨床研究を実施（研究計画書を変更して実施する場合を含む。第二十四の一を除き以下同じ。）しようとするときは、あらかじめ研究計画書を作成し、研究機関の長の許可を受けなければならない。

２　研究責任者は、他の研究機関と共同して遺伝子治療等臨床研究を実施しようとする場合には、各共同研究機関の研究責任者の役割及び責任を明確にした上で、第十四の一の１の規定により総括責任者が作成する研究計画書を踏まえて研究計画書を作成しなければならない。

３　研究責任者は、当該研究責任者の所属する研究機関における遺伝子治療等臨床研究に関する業務の一部について委託しようとする場合には、当該委託業務の内容を定めた上で研究計画書を作成しなければならない。

二　倫理審査委員会への付議

１　研究機関の長は、研究責任者から、当該研究機関における遺伝子治療等臨床研究の実施の許可を求められたときは、当該遺伝子治療等臨床研究の実施の適否について、倫理審査委員会の意見を聴かなければならない。

２　研究機関の長は、他の研究機関と共同して実施する遺伝子治療等臨床研究について倫理審査委員会の意見を聴く場合には、共同研究機関における遺伝子治療等臨床研究の実施の許可、他の倫理審査委員会における審査結果及び当該遺伝子治療等臨床研究の進捗に関する状況等の審査に必要な情報についても倫理審査委員会へ提供しなければならない。

３　研究機関の長は、他の研究機関と共同して実施する遺伝子治療等臨床研究に係る研究計画書について、一つの倫理審査委員会による一括した審査を求めることができる。

三　研究機関の長による許可

研究機関の長は、倫理審査委員会及び厚生労働大臣の意見を尊重し、遺伝子治療等臨床研究の実施の許可又は不許可その他遺伝子治療等臨床研究について必要な措置を決定しなければならない。この場合において、研究機関の長は、倫理審査委員会又は厚生労働大臣が研究の実施について不適当である旨の意見を述べたときには、当該研究の実施を許可してはならない。

四　研究中の手続

１　研究責任者は、研究計画書に定めるところにより、遺伝子治療等臨床研究の進捗状況及び遺伝子治療等臨床研究の実施に伴う有害事象の発生状況等を、研究機関の長、総括責任者及び倫理審査委員会に文書で報告しなければならない。この場合において、進捗状況に関しては少なくとも年１回以上の報告とする。

２　研究機関の長は、遺伝子治療等臨床研究の進捗状況及び遺伝子治療等臨床研究の実施に伴う有害事象の発生状況等について、研究責任者又は倫理審査委員会から報告又は意見を受け、必要に応じ、研究責任者に対しその留意事項、改善事項等に関して指示を与えるとともに、厚生労働大臣に対し報告を行わなければならない。

五　研究終了後の対応

１　研究責任者は、遺伝子治療等臨床研究の終了後直ちに次の事項を記載した総括報告書を作成し、速やかに研究機関の長（総括責任者を置く場合にあっては、研究機関の長及び総括責任者。）に報告しなければならない。

①　遺伝子治療等臨床研究の名称

② 研究責任者及びその他の研究者（他の研究機関と共同して研究を実施する場合には、総括責任者及び共同研究機関の研究責任者を含む。）の氏名
③ 研究機関及び共同研究機関の名称及び所在地
④ 遺伝子治療等臨床研究の目的及び意義
⑤ 遺伝子治療等臨床研究の実施方法及び期間
⑥ 遺伝子治療等臨床研究の結果及び考察
⑦ その他必要な事項

２ 研究機関の長は、研究責任者から１の規定による報告を受けたときは、当該遺伝子治療等臨床研究に関する審査を行った倫理審査委員会に、遺伝子治療等臨床研究が終了した旨及びその結果の概要を文書により報告するとともに、総括報告書の写しを速やかに厚生労働大臣に提出しなければならない。

第十八 研究計画書の記載事項

一 第十七の一の１の研究計画書には、次の事項を記載しなければならない。
① 遺伝子治療等臨床研究の名称
② 研究責任者及びその他の研究者（他の研究機関と共同して研究を実施する場合には、総括責任者及び共同研究機関の研究責任者を含む。）の氏名並びに当該遺伝子治療等臨床研究において果たす役割
③ 研究機関及び共同研究機関の名称及びその所在地
④ 遺伝子治療等臨床研究の目的及び意義
⑤ 遺伝子治療等臨床研究の実施方法及び期間
⑥ 対象疾患及びその選定理由
⑦ 被験者の選定方針
⑧ 導入する遺伝子及び遺伝子の導入方法
⑴ 開発の経緯
⑵ 導入する遺伝子
⑶ 遺伝子の導入方法
⑷ 被験者に投与する最終産物の組成
⑨ 特性解析と品質試験
⑩ 被験者への投与に用いられる特殊な機器及び医療材料
⑪ 非臨床試験における安全性及び有効性の評価
⑴ 臨床的有効性を予測するための試験
⑵ 生体内分布
⑶ 非臨床試験における安全性の評価
⑷ 非臨床試験の成績の総括
⑫ 遺伝子治療等臨床研究の実施が可能であると判断した理由
⑬ 第二十二の規定によるインフォームド・コンセントを受ける手続等（同規定による説明及び同意に関する事項を含む。）
⑭ 個人情報等の取扱い（匿名化する場合にはその方法を含む。）
⑮ 被験者に生じる負担並びに予測されるリスク及び利益、これらの総合的評価並びに当該負担及びリスクを最小化する対策
⑯ 試料・情報（研究に用いられる情報に係る資料を含む。）の保管及び廃棄の方法
⑰ 研究機関の長及び倫理審査委員会への報告内容及び方法
⑱ 研究の資金源等、研究機関の遺伝子治療等臨床研究に係る利益相反及び

個人の収益等、研究者の遺伝子治療等臨床研究に係る利益相反に関する状況
⑲　遺伝子治療等臨床研究に関する情報公開の方法
⑳　被験者等及びその関係者からの相談等への対応
㉑　代諾者からインフォームド・コンセントを受ける場合には、第二十三の規定による手続（第二十二及び第二十三の規定による代諾者の選定方針並びに説明及び同意に関する事項を含む。）
㉒　インフォームド・アセントを得る場合には、第二十三の規定による手続（説明に関する事項を含む。）
㉓　被験者に経済的負担又は謝礼がある場合には、その旨及びその内容
㉔　重篤な有害事象が発生した際の対応
㉕　遺伝子治療等臨床研究によって生じた健康被害に対する補償の有無及びその内容
㉖　被験者への遺伝子治療等臨床研究の実施後における医療の提供に関する対応
㉗　遺伝子治療等臨床研究の実施に伴い、被験者の健康、子孫に受け継がれ得る遺伝的特徴等に関する重要な知見が得られる可能性がある場合には、被験者に係る研究結果（偶発的所見を含む。）の取扱い
㉘　遺伝子治療等臨床研究に関する業務の一部を委託する場合には、当該業務内容及び委託先の監督方法
㉙　被験者から取得された試料・情報について、被験者等から同意を受ける時点では特定されない将来の研究のために用いられる可能性又は他の研究機関に提供する可能性がある場合には、その旨と同意を受ける時点において想定される内容
㉚　第三十三の規定によるモニタリング及び監査の実施体制及び実施手順
㉛　その他必要な事項

二　一の研究計画書には、次の資料を添付しなければならない。
①　研究者の略歴及び研究業績
②　研究機関の施設設備の状況
③　研究機関における当該遺伝子治療等臨床研究に関する有効性を示唆する試験及び安全性に関する研究の成果がある場合には、当該試験及び研究の成果
④　遺伝子治療等臨床研究に関連する研究機関以外の国内外の研究状況
⑤　インフォームド・コンセントにおける説明文書及び同意文書の様式
⑥　その他必要な資料

三　研究計画書には、その概要を可能な限り平易な用語を用いて記載した要旨を添付しなければならない。

第十九　研究に関する登録・公表

一　研究の概要及び結果の登録

研究責任者（他の研究機関と共同して実施する遺伝子治療等臨床研究の場合にあっては、総括責任者又は研究責任者。）は、遺伝子治療等臨床研究について、国立大学附属病院長会議、一般財団法人日本医薬情報センター又は公益社団法人日本医師会が設置している公開データベースに、当該遺伝子治療等臨床研究の概要をその実施に先立って登録し、研究計画書の変更及び遺伝子治療等臨床研究の進捗に応じて適宜更新しなければならず、また、遺伝子治療等臨床研究を終了したときは、遅滞なく、当該遺伝子治療等臨床研究

の結果を登録しなければならない。ただし、被験者等及びその関係者の人権又は研究者及びその関係者の権利利益の保護のため非公開とすることが必要な内容として、倫理審査委員会の意見を受けて研究機関の長が許可したものについては、この限りでない。

二　研究結果の公表

研究責任者は、遺伝子治療等臨床研究を終了したときは、遅滞なく、被験者等及びその関係者の人権又は研究者及びその関係者の権利利益の保護のために必要な措置を講じた上で、当該遺伝子治療等臨床研究の結果を公表しなければならない。また、結果の最終の公表を行ったときは、遅滞なく研究機関の長へ報告しなければならない。

第四章　倫理審査委員会

第二十　倫理審査委員会の設置等

一　倫理審査委員会の設置の要件

倫理審査委員会の設置者は、次に掲げる要件を満たしていなければならない。

①　審査に関する事務を的確に行う能力があること。

②　倫理審査委員会を継続的に運営する能力があること。

③　倫理審査委員会を中立的かつ公正に運営する能力があること。

二　倫理審査委員会の設置者の責務

１　倫理審査委員会の設置者は、当該倫理審査委員会の組織及び運営に関する規程を定め、当該規程により、倫理審査委員会の委員及びその事務に従事する者に業務を行わせなければならない。

２　倫理審査委員会の設置者は、当該倫理審査委員会が審査を行った遺伝子治療等臨床研究に関する審査資料を当該遺伝子治療等臨床研究の終了について報告された日から10年を経過した日まで適切に保管しなければならない。

３　倫理審査委員会の設置者は、当該倫理審査委員会の運営を開始するに当たって、倫理審査委員会の構成、組織及び運営並びに公開その他遺伝子治療等臨床研究の審査に必要な手続に関する規則を定め、倫理審査委員会報告システムにおいて公表しなければならない。

また、倫理審査委員会の設置者は、年１回以上、当該倫理審査委員会の開催状況及び審査の概要について、倫理審査委員会報告システムにおいて公表しなければならない。ただし、審査の概要のうち、被験者等及びその関係者の人権又は研究者及びその関係者の権利利益の保護のため非公開とすることが必要な内容として倫理審査委員会が判断したものについては、この限りでない。

４　倫理審査委員会の設置者は、当該倫理審査委員会の委員及びその事務に従事する者が審査及び関連する業務に関する教育・研修を受けることを確保するため必要な措置を講じなければならない。

５　倫理審査委員会の設置者は、当該倫理審査委員会の組織及び運営がこの指針に適合していることについて、厚生労働大臣又はその委託を受けた者が実施する調査に協力しなければならない。

第二十一　倫理審査委員会の役割・責務等

一　役割・責務

１　倫理審査委員会は、研究機関の長から遺伝子治療等臨床研究の実施の適

否等について意見を求められたときは、この指針に基づき、倫理的観点及び科学的観点から、研究機関及び研究者の利益相反に関する情報も含めて中立的かつ公正に審査を行い、文書により意見を述べなければならない。

２　倫理審査委員会は、審査が公正に行われるようその活動の自由及び独立が保障されていなければならない。

３　倫理審査委員会は、１の規定により審査を行った遺伝子治療等臨床研究について、倫理的観点及び科学的観点から必要な調査を行い、研究機関の長に対して、研究計画書の変更、当該遺伝子治療等臨床研究の中止その他当該遺伝子治療等臨床研究に関し必要な意見を述べることができる。

４　倫理審査委員会は、１の規定により審査を行った遺伝子治療等臨床研究について、当該遺伝子治療等臨床研究の実施の適正性及び研究結果の信頼性を確保するために必要な調査を行い、研究機関の長に対して、研究計画書の変更、当該遺伝子治療等臨床研究の中止その他当該遺伝子治療等臨床研究に関し必要な意見を述べることができる。

５　倫理審査委員会の委員及びその事務に従事する者は、その業務上知り得た情報を正当な理由なく漏らしてはならない。その業務に従事しなくなった後も同様とする。

６　倫理審査委員会の委員及びその事務に従事する者は、１の規定により審査を行った遺伝子治療等臨床研究に関連する情報の漏えい等、被験者等の人権を尊重する観点並びに当該遺伝子治療等臨床研究の実施上の観点及び審査の中立性又は公正性の観点から重大な懸念が生じた場合には、速やかに倫理審査委員会の設置者に報告しなければならない。

７　倫理審査委員会の委員及びその事務に従事する者は、審査及び関連する業務に先立ち、倫理的観点及び科学的観点からの審査等に必要な知識を習得するための教育・研修を受けなければならない。また、その後も、適宜継続して教育・研修を受けなければならない。

二　構成及び会議の成立要件等

１　倫理審査委員会の構成は、研究計画書の審査等の業務を適切に実施できるよう、次に掲げる要件の全てを満たさなければならず、①から③までに掲げる者については、それぞれ他を同時に兼ねることはできない。また、会議の成立についても同様の要件とする。

①　分子生物学、細胞生物学、遺伝学、臨床薬理学、病理学等の専門家及び遺伝子治療等臨床研究の対象となる疾患に係る臨床医が含まれていること。

②　法律に関する専門家及び生命倫理に関する意見を述べるにふさわしい識見を有する者を含めて構成されるものであること。

③　被験者の観点も含めて一般の立場から意見を述べることのできる者が含まれていること。

④　倫理審査委員会の設置者の所属機関に所属しない者が複数含まれていること。

⑤　男女両性で構成されていること。

⑥　５名以上であること。

２　審査の対象となる遺伝子治療等臨床研究の実施に携わる研究者は、倫理審査委員会の審議及び意見の決定に同席してはならない。ただし、当該倫理審査委員会の求めに応じて、その会議に出席し、当該遺伝子治療等臨床研究に関する説明を行うことはできる。

３　審査を依頼した研究機関の長は、倫理審査委員会の審議及び意見の決定

に参加してはならない。ただし、倫理審査委員会における当該審査の内容を把握するために必要な場合には、当該倫理審査委員会の同意を得た上で、その会議に同席することができる。

４　倫理審査委員会は、審査の対象、内容等に応じて有識者に意見を求めることができる。

５　倫理審査委員会は、特別な配慮を必要とする者を被験者とする研究計画書の審査を行い、意見を述べる際は、必要に応じてこれらの者について識見を有する者に意見を求めなければならない。

６　倫理審査委員会の意見は、全会一致をもって決定するよう努めなければならない。

三　迅速審査

倫理審査委員会は、次に掲げるいずれかに該当する審査について、当該倫理審査委員会が指名する委員による審査（以下「迅速審査」という。）を行い、意見を述べることができる。迅速審査の結果は倫理審査委員会の意見として取り扱うものとし、当該審査結果は全ての委員に報告されなければならない。

①　他の研究機関と共同して実施される遺伝子治療等臨床研究であって、既に当該遺伝子治療等臨床研究の全体について共同研究機関において倫理審査委員会の審査を受け、その実施について適当である旨の意見を得ている場合の審査

②　研究計画書の軽微な変更に関する審査

四　他の研究機関が実施する研究に関する審査

１　研究機関の長が、自らの研究機関以外に設置された倫理審査委員会に審査を依頼する場合には、当該倫理審査委員会は、遺伝子治療等臨床研究の実施体制について十分把握した上で審査を行い、意見を述べなければならない。

２　倫理審査委員会は、他の研究機関が実施する遺伝子治療等臨床研究について審査を行った後、継続して当該研究機関の長から当該遺伝子治療等臨床研究に関する審査を依頼された場合には、審査を行い、意見を述べなければならない。

第五章　インフォームド・コンセント等

第二十二　インフォームド・コンセントを受ける手続等

一　インフォームド・コンセントを受ける手続等

研究責任者等が遺伝子治療等臨床研究を実施しようとするときは、研究機関の長の許可を受けた研究計画書に定めるところにより、あらかじめ、三の規定による説明事項を記載した文書により、インフォームド・コンセントを受けなければならない。

二　研究計画書の変更

研究責任者等は、研究計画書を変更して遺伝子治療等臨床研究を実施しようとする場合には、変更箇所について、原則として改めて一の規定によるインフォームド・コンセントの手続等を行わなければならない。ただし、倫理審査委員会の意見を受けて研究機関の長が、改めて一の規定によるインフォームド・コンセントの手続等を要しないことについて許可した変更箇所については、この限りでない。

三　説明事項

インフォームド・コンセントを受ける際に被験者等に対し説明すべき事項

は、原則として以下のとおりとする。ただし、倫理審査委員会及び厚生労働大臣の意見を受けて研究機関の長が許可した事項については、この限りでない。

① 遺伝子治療等臨床研究の名称及び当該遺伝子治療等臨床研究の実施について研究機関の長の許可を受けている旨

② 研究機関の名称及び研究責任者の氏名（他の研究機関と共同して遺伝子治療等臨床研究を実施する場合には、共同研究機関の名称及び共同研究機関の研究責任者の氏名並びに総括責任者の氏名を含む。）

③ 遺伝子治療等臨床研究の目的及び意義

④ 遺伝子治療等臨床研究の方法（被験者から取得された試料・情報の利用目的を含む。）及び期間

⑤ 被験者として選定された理由

⑥ 被験者に生じる負担並びに予測されるリスク及び利益

⑦ 遺伝子治療等臨床研究が実施又は継続されることに同意した場合であっても随時これを撤回できる旨（被験者等からの撤回の内容に従った措置を講じることが困難となる場合があるときは、その旨及びその理由。）

⑧ 遺伝子治療等臨床研究が実施又は継続されることに同意しないこと又は同意を撤回することによって被験者等が不利益な取扱いを受けない旨

⑨ 遺伝子治療等臨床研究に関する情報公開の方法

⑩ 被験者等の求めに応じて、他の被験者等の個人情報等の保護及び当該遺伝子治療等臨床研究の独創性の確保に支障がない範囲内で研究計画書及び遺伝子治療等臨床研究の方法に関する資料を入手又は閲覧できる旨並びにその入手又は閲覧の方法

⑪ 個人情報等の取扱い（匿名化をする場合にはその方法を含む。）

⑫ 試料・情報の保管及び廃棄の方法

⑬ 研究の資金源等、研究機関の遺伝子治療等臨床研究に係る利益相反及び個人の収益等、研究者の遺伝子治療等臨床研究に係る利益相反に関する状況

⑭ 被験者等及びその関係者からの相談等への対応

⑮ 被験者等に経済的負担又は謝礼がある場合には、その旨及びその内容

⑯ 他の治療方法等に関する事項

⑰ 被験者への遺伝子治療等臨床研究の実施後における医療の提供に関する対応

⑱ 遺伝子治療等臨床研究の実施に伴い、被験者の健康、子孫に受け継がれ得る遺伝的特徴等に関する重要な知見が得られる可能性がある場合には、被験者に係る研究結果（偶発的所見を含む。）の取扱い

⑲ 遺伝子治療等臨床研究によって生じた健康被害に対する補償の有無及び内容

⑳ 被験者から取得された試料・情報について、被験者等からの同意を受ける時点では特定されない将来の研究のために用いられる可能性又は他の研究機関に提供する可能性がある場合には、その旨と同意を受ける時点において想定される内容

㉑ 被験者の秘密が保全されることを前提として、モニタリングに従事する者及び監査に従事する者、倫理審査委員会並びに厚生労働大臣が、必要な範囲内において当該被験者に関する試料・情報を閲覧する旨

四　同意を受ける時点で特定されなかった研究への試料・情報の利用の手続

研究責任者等は、被験者等から同意を受ける時点で想定される試料・情報

の利用目的等について可能な限り説明した場合であって、その後、利用目的等が新たに特定されたときは、研究計画書を作成又は変更した上で、新たに特定された利用目的等についての情報を被験者等に通知し、又は公開し、研究が実施されることについて、被験者等が同意を撤回できる機会を保障しなければならない。

五　同意の撤回等

研究責任者等は、被験者等から次に掲げるいずれかに該当する同意の撤回又は拒否があった場合には、遅滞なく、当該撤回又は拒否の内容に従った措置を講じるとともに、その旨を当該被験者等に説明しなければならない。ただし、当該措置を講じることが困難な場合であって、当該措置を講じないことについて倫理審査委員会の意見を聴いた上で研究機関の長が許可したときは、この限りでない。なお、その場合、当該撤回又は拒否の内容に従った措置を講じない旨及びその理由について、研究責任者等が被験者等に説明し、理解を得るよう努めなければならない。

①　遺伝子治療等臨床研究が実施又は継続されることに関して与えた同意の全部又は一部の撤回

②　代諾者が同意を与えた遺伝子治療等臨床研究について、被験者からのインフォームド・コンセントの手続における、当該遺伝子治療等臨床研究が実施又は継続されることの全部又は一部に対する拒否

第二十三　代諾者からのインフォームド・コンセントを受ける場合の手続等

一　代諾の要件等

１　研究責任者等が、第二十二の規定による手続において代諾者からインフォームド・コンセントを受ける場合には、次に掲げる要件がいずれも満たされていなければならない。

⑴　研究計画書に次に掲げる事項が記載されていること。

①　代諾者の選定方針

②　代諾者への説明事項（③に関する説明を含む。）

③　⑵①又は②に該当する者を被験者とすることが必要な理由

⑵　被験者が次に掲げるいずれかに該当していること。

①　未成年者であること。

②　成年であって、インフォームド・コンセントを与える能力を欠くと客観的に判断される者であること。

２　研究責任者等が、第二十二の規定による手続において代諾者からインフォームド・コンセントを受ける場合には、１⑴①の選定方針に従って代諾者を選定し、当該代諾者に対して、第二十二の三の規定によるほか１⑴②の説明事項を説明しなければならない。

３　研究責任者等が、代諾者からインフォームド・コンセントを受けた場合であって、被験者が中学校等の課程を修了している又は16歳以上の未成年者であり、かつ、遺伝子治療等臨床研究を実施されることに関する十分な判断能力を有すると判断されるときには、当該被験者からもインフォームド・コンセントを受けなければならない。

二　インフォームド・アセントを得る場合の手続等

１　研究責任者等が、代諾者からインフォームド・コンセントを受けた場合であって、被験者が遺伝子治療等臨床研究を実施されることについて自らの意向を表することができると判断されるときには、インフォームド・アセントを得るよう努めなければならない。ただし、一の３の規定により被

験者からインフォームド・コンセントを受けるときは、この限りでない。

２　研究責任者は、１の規定によるインフォームド・アセントの手続を行うことが予測される遺伝子治療等臨床研究を実施しようとする場合には、あらかじめ被験者への説明事項及び説明方法を研究計画書に記載しなければならない。

３　研究責任者等は、１の規定によるインフォームド・アセントの手続において、被験者が、遺伝子治療等臨床研究が実施又は継続されることの全部又は一部に対する拒否の意向を表した場合には、その意向を尊重するよう努めなければならない。ただし、当該遺伝子治療等臨床研究を実施又は継続することにより被験者に直接の健康上の利益が期待され、かつ、代諾者がそれに同意するときは、この限りでない。

第六章　厚生労働大臣の意見等

第二十四　厚生労働大臣の意見

一　厚生労働大臣は、研究機関の長の求めに応じ、あらかじめ遺伝子治療等臨床研究の実施又は当該遺伝子治療等臨床研究の重大な変更に関し意見を述べるものとする。

二　研究機関の長は、第十六の三の１の規定に基づき厚生労働大臣に対し意見を求めるに当たって、次の書類を提出しなければならない。

①　研究計画書及び当該研究計画書に添付する資料

②　倫理審査委員会における審査の過程及び結果を示す書類

③　第二十の二の３に定める規則

三　厚生労働大臣は、二の規定に基づき意見を求められた場合において、複数の有識者の意見を踏まえ、当該遺伝子治療等臨床研究が次に掲げる事項のいずれかに該当すると判断するときは、当該遺伝子治療等臨床研究の医療上の有用性及び倫理性について厚生科学審議会の意見を聴くものとする。

①　組換え遺伝子であって、当該遺伝子を細胞内に導入する際に用いられる新規のもの又は新規の遺伝子投与方法を用いていること。

②　新規の疾病を対象としていること。

③　新規の遺伝子治療等の方法を用いていること（①又は②に該当するものを除く。）。

④　その他個別の審査を必要とするような事項を含んでいること。

四　厚生労働大臣は、三の規定による厚生科学審議会からの意見の聴取が必要ないと判断する場合には、意見を求められた日から30日以内に、当該遺伝子治療等臨床研究の実施に関し意見を述べるものとする。

第二十五　重篤な有害事象等に係る厚生労働大臣の意見

厚生労働大臣は、第十六の四の３及び第三十の四の３の規定に基づき研究機関の長から報告を受けた場合には、必要に応じ、遺伝子治療等臨床研究に関して意見を述べるものとする。

第二十六　厚生労働大臣の調査等

厚生労働大臣は、第二十四の一又は第二十五の規定に基づき意見を述べるときその他必要があると認めるときは、研究機関の長に対し第二十四の二に定める書類以外の資料の提出を求めるとともに、当該研究機関の長の承諾を得て当該研究機関の調査その他必要な調査を行うものとする。

第七章　個人情報等

第二十七　個人情報等に係る基本的責務

一　個人情報等の保護

１　研究者及び研究機関の長は、個人情報の取扱いに関して、この指針の規定のほか、個人情報の保護に関する法律（平成15年法律第57号）、行政機関の保有する個人情報の保護に関する法律（平成15年法律第58号）、独立行政法人等の保有する個人情報の保護に関する法律（平成15年法律第59号）及び地方公共団体において制定される条例等を遵守しなければならない。

２　研究者及び研究機関の長は、死者の尊厳及び遺族等の感情に鑑み、死者について特定の個人を識別することができる情報に関しても、生存する個人に関するものと同様に、二及び第二十八の規定により適切に取り扱い、必要かつ適切な措置を講じなければならず、また、第二十九の規定に準じて適切に対応し、必要な措置を講じるよう努めなければならない。

二　適正な取得等

１　研究者は、遺伝子治療等臨床研究の実施に当たって、偽りその他不正の手段により個人情報等を取得してはならない。

２　研究者は、原則としてあらかじめ被験者等から同意を受けている範囲を超えて、遺伝子治療等臨床研究の実施に伴って取得された個人情報等を取り扱ってはならない。

第二十八　安全管理

一　適正な取扱い

１　研究者は、遺伝子治療等臨床研究の実施に伴って取得された個人情報等であって当該研究者の所属する研究機関が保有しているもの（委託して保管する場合を含む。以下「保有する個人情報等」という。）について、漏えい、滅失又はき損の防止その他の安全管理のため、適切に取り扱わなければならない。

２　研究責任者は、遺伝子治療等臨床研究の実施に際して、保有する個人情報等が適切に取り扱われるよう、研究機関の長と協力しつつ、当該情報を取り扱う他の研究者に対して、必要な指導・管理を行わなければならない。

二　安全管理のための体制整備、監督等

１　研究機関の長は、保有する個人情報等の漏えい、滅失又はき損の防止その他保有する個人情報等の安全管理のため、必要かつ適切な措置を講じなければならない。

２　研究機関の長は、当該研究機関において遺伝子治療等臨床研究の実施に携わる研究者に保有する個人情報等を取り扱わせようとする場合には、その安全管理に必要な体制及び規程を整備するとともに、研究者に対して、保有する個人情報等の安全管理が図られるよう必要かつ適切な監督を行わなければならない。

第二十九　保有する個人情報の開示等

一　保有する個人情報に関する事項の公表等

１　研究機関の長は、被験者等に係る個人情報に関し、第二十二の規定により、被験者等に説明し、又は個人情報の取扱いを含む遺伝子治療等臨床研究の実施についての情報を被験者等に通知し、若しくは公開している場合を除き、遺伝子治療等臨床研究の実施に伴って取得された個人情報であって当該研究機関が保有しているもの（委託して保管する場合を含む。以下

「保有する個人情報」という。）に関し、次に掲げる事項について、当該個人情報によって識別される特定の個人（以下「本人」という。）又はその代理人が容易に知り得る状態（本人又はその代理人（以下「本人等」という。）の求めに応じて遅滞なく回答する場合を含む。以下同じ。）に置かなければならない。

① 研究機関の名称及び研究機関の長の氏名

② 保有する個人情報の利用目的について、遺伝子治療等臨床研究に用いられる情報にあっては遺伝子治療等臨床研究に用いられる旨（他の研究機関へ提供される場合には、その旨を含む。）、遺伝子治療等臨床研究に用いられる情報でないものにあってはその用途

③ ２又は二の１、３、４若しくは６の規定による求め（以下「開示等の求め」という。）に応じる手続（二の２の規定により手数料の額を定めた場合には、その手数料の額を含む。）

④ 保有する個人情報の取扱いに関する相談等の窓口

２ 研究機関の長は、本人等から、保有する個人情報のうちその本人を識別することができるものについて、その利用目的の通知を求められた場合には、その求めをした本人等（以下「請求者」という。）に対し、遅滞なく、これを通知しなければならない。

３ １の②及び２の規定は、次に掲げるいずれかに該当する場合には適用しない。

① 利用目的を容易に知り得る状態に置くこと又は請求者に対して通知することにより、被験者等又は第三者の生命、身体、財産その他の権利利益を害するおそれがある場合

② 利用目的を容易に知り得る状態に置くこと又は請求者に対して通知することにより、当該研究機関の権利又は正当な利益を害するおそれがある場合

４ 研究機関の長は、２の規定による利用目的の通知について、３の規定により通知しない旨の決定をした場合には、請求者に対し、遅滞なく、その旨を通知しなければならない。また、請求者に対し、その理由を説明し、理解を得るよう努めなければならない。

二 開示等の求めへの対応

１ 研究機関の長は、本人等から、保有する個人情報のうちその本人を識別することができるものについて、開示（保有する個人情報にその本人が識別されるものが存在しない場合に、その旨を通知することを含む。以下同じ。）を求められた場合には、請求者に対し、遅滞なく、該当する個人情報を開示しなければならない。ただし、開示することにより次に掲げるいずれかに該当する場合には、その全部又は一部を開示しないことができる。また、法令の規定により、保有する個人情報の開示について定めがある場合には、当該法令の規定によるものとする。

① 被験者等又は第三者の生命、身体、財産その他の権利利益を害するおそれがある場合

② 研究機関の研究業務の適正な実施に著しい支障を及ぼすおそれがある場合

③ 法令に違反することとなる場合

２ 研究機関の長は、一の２の規定による利用目的の通知又は１の規定による開示を求められたときは、その措置の実施に関し、手数料を徴収することができる。ただし、その場合には、実費を勘案して合理的と認められる

範囲内において、その手数料の額を定めなければならない。

３　研究機関の長は、本人等から、保有する個人情報のうちその本人を識別することができるものについて、その内容が事実でないという理由によって、当該内容の訂正、追加又は削除（以下「訂正等」という。）を求められた場合には、当該内容の訂正等に関して法令の規定により特別の手続が定められている場合を除き、利用目的の達成に必要な範囲内において、遅滞なく必要な調査を行い、その結果に基づき、当該内容の訂正等を行わなければならない。

４　研究機関の長は、本人等から、保有する個人情報のうちその本人を識別することができるものについて、第二十七の二の１の規定に反して取得されたものであるという理由又は同２の規定に反して取り扱われているという理由によって、該当する個人情報の利用の停止又は消去（以下「利用停止等」という。）を求められた場合であって、その求めが適正と認められるときは、当該規定に反していることを是正するために必要な限度で、遅滞なく、当該個人情報の利用停止等を行わなければならない。ただし、当該個人情報の利用停止等を行うことが困難な場合であって、当該本人の権利利益を保護するため必要なこれに代わるべき措置をとるときは、この限りでない。

５　研究機関の長は、１の規定により求められた措置の全部若しくは一部について当該措置をとらない旨の決定をした場合又は３若しくは４の規定により求められた措置の全部若しくは一部について当該措置をとった場合若しくは当該措置をとらない旨の決定をした場合には、請求者に対し、遅滞なく、その旨（訂正等を行った場合には、その内容を含む。）を通知しなければならない。また、１、３又は４の規定により、本人等から求められた措置の全部又は一部について、当該措置をとらない旨を通知する場合又は当該措置と異なる措置をとる旨を通知する場合には、請求者に対し、その理由を説明し、理解を得るよう努めなければならない。

６　研究機関の長は、本人等から、匿名化されていない試料・情報であってその本人を識別することができるものが第二十二の規定に反して他の研究機関（共同研究機関を含む。以下同じ。）に提供されているという理由によって、当該試料・情報の他の研究機関への提供の停止を求められた場合であって、その求めが適正と認められるときは、遅滞なく、当該試料・情報の他の研究機関への提供を停止しなければならない。ただし、当該試料・情報の他の研究機関への提供を停止することが困難な場合であって、当該本人の権利利益を保護するため必要なこれに代わるべき措置をとるときは、この限りでない。

７　研究機関の長は、６の規定により提供の停止を求められた匿名化されていない試料・情報の全部又は一部について、他の研究機関への提供を停止した場合又は他の研究機関への提供を停止しない旨の決定をした場合には、請求者に対し、遅滞なく、その旨を通知しなければならない。また、他の研究機関への提供を停止しない旨を通知する場合又は他の研究機関への提供の停止と異なる措置をとる旨を通知する場合には、請求者に対し、その理由を説明し、理解を得るよう努めなければならない。

８　研究機関の長は、開示等の求めに応じる手続として、次に掲げる事項を定めることができる。なお、その場合には本人等に過重な負担を課するものとならないよう、その負担の軽減に努めなければならない。また、本人等が当該手続によらずに開示等の求めを行ったときは、請求者に対し、開

示等の求めに応じることが困難である旨を通知することができる。

① 開示等の求めの申出先

② 開示等の求めに際して提出すべき書面（電子的方式、磁気的方式その他人の知覚によっては認識することができない方式で作られる記録を含む。）の様式その他の開示等の求めの方式

③ 開示等の求めをする者が本人等であることの確認の方法

④ ２の規定により手数料を定めた場合には、その徴収方法

９ 研究機関の長は、本人等から開示等の求めがあった場合において、請求者に対し、その対象となる保有する個人情報を特定するに足りる事項の提示を求めることができる。なお、本人等が容易かつ的確に開示等の求めを行うことができるよう、当該個人情報の特定に資する情報の提供その他本人等の利便を考慮するとともに、本人等に過重な負担を課するものとならないよう配慮しなければならない。

第八章 重篤な有害事象への対応

第三十 重篤な有害事象への対応

一 研究者の対応

研究者は、遺伝子治療等臨床研究の実施において重篤な有害事象の発生を知った場合には、四の１の規定による手順書等に従い、被験者等への説明等、必要な措置を講じるとともに、速やかに研究責任者に報告しなければならない。

二 研究責任者の対応

研究責任者は、遺伝子治療等臨床研究の実施において重篤な有害事象の発生を知った場合には、速やかに、その旨を研究機関の長及び総括責任者に報告するとともに、四の１の規定による手順書等に従い、適切な対応を図らなければならない。また、速やかに当該遺伝子治療等臨床研究の実施に携わる研究者に対して、当該有害事象の発生に係る情報を共有しなければならない。

三 総括責任者の対応

総括責任者は、二の規定により報告を受けた場合は、自らが所属する研究機関の長及び全ての研究責任者に対し、速やかに、その旨を報告しなければならない。

四 研究機関の長の対応

１ 研究機関の長は、遺伝子治療等臨床研究を実施しようとする場合には、あらかじめ、重篤な有害事象が発生した際に研究者が実施すべき事項に関する手順書を作成し、当該手順書に従って適正かつ円滑に対応が行われるよう必要な措置を講じなければならない。

２ 研究機関の長は、二の規定により研究責任者から重篤な有害事象の発生について報告がなされた場合には、手順書に従って速やかに必要な対応を行うとともに、当該有害事象について倫理審査委員会の意見を聴き、必要な措置を講じなければならない。なお、研究機関の長は、倫理審査委員会の意見を聴く前に、必要に応じ、研究責任者に対し、遺伝子治療等臨床研究の中止又は暫定的な措置を講ずるよう、指示することができる。

３ 研究機関の長は、重篤な有害事象について、速やかに厚生労働大臣に報告しなければならない。

第九章 研究の信頼性確保

第三十一 利益相反の管理

一　研究者は、遺伝子治療等臨床研究を実施するときは、個人の収益等、当該遺伝子治療等臨床研究に係る利益相反に関する状況について、その状況を研究責任者に報告し、透明性を確保するよう適切に対応しなければならない。
二　研究責任者は、遺伝子治療等臨床研究を実施するときは、当該遺伝子治療等臨床研究に係る利益相反に関する状況を把握し、研究計画書に記載しなければならない。
三　研究者は、二の規定により研究計画書に記載された利益相反に関する状況を、第二十二に規定するインフォームド・コンセントを受ける手続において被験者等に説明しなければならない。

第三十二　研究に係る試料及び情報等の保管
一　研究者は、遺伝子治療等臨床研究に用いられる情報及び当該情報に係る資料（以下「情報等」という。）を正確なものにしなければならない。
二　研究責任者は、被験者等から取得された試料及び情報等を保管するときは、三の規定による手順書に基づき、研究計画書にその方法を記載するとともに、研究者が情報等を正確なものにするよう指導・管理し、被験者等から取得された試料及び情報等の漏えい、混交、盗難、紛失等が起こらないよう必要な管理を行わなければならない。
三　研究機関の長は、被験者等から取得された試料及び情報等の保管に関する手順書を作成し、当該手順書に従って、当該研究機関が実施する遺伝子治療等臨床研究に係る被験者等から取得された試料及び情報等が適切に保管されるよう必要な監督を行わなければならない。
四　研究責任者は、三の規定による手順書に従って、二の規定による管理の状況について研究機関の長へ報告しなければならない。
五　研究責任者は、被験者が将来新たに病原体に感染した場合等に、その原因が遺伝子治療等臨床研究に起因するかどうかを明らかにするため、最終産物を一定期間保管するとともに、当該被験者に最終産物を投与する前後の血清等の試料及び情報等について、総括報告書を研究機関の長及び総括責任者に提出した日から少なくとも10年以上の必要とされる期間保存するものとする。また、研究機関の長は、当該期間、最終産物等が適切に保管されるよう必要な監督を行わなければならない。また、連結可能匿名化された情報について、当該研究機関が対応表を保管する場合には、対応表の保管についても同様とする。
六　研究機関の長は、被験者等から取得された試料及び情報等を廃棄する場合には、匿名化されるよう必要な監督を行わなければならない。

第三十三　モニタリング及び監査
一　研究責任者は、遺伝子治療等臨床研究の信頼性の確保に努めなければならず、研究機関の長の許可を受けた研究計画書に定めるところにより、モニタリング及び必要に応じて監査を実施しなければならない。
二　研究責任者は、研究機関の長の許可を受けた研究計画書に定めるところにより適切にモニタリング及び監査が行われるよう、モニタリングに従事する者及び監査に従事する者に対して必要な指導・管理を行わなければならない。
三　研究責任者は、監査の対象となる遺伝子治療等臨床研究の実施に携わる者及びそのモニタリングに従事する者に、監査を行わせてはならない。
四　モニタリングに従事する者は、当該モニタリングの結果を研究責任者に報告しなければならない。また、監査に従事する者は、当該監査の結果を研究

責任者及び研究機関の長に報告しなければならない。

五　モニタリングに従事する者及び監査に従事する者は、その業務上知り得た情報を正当な理由なく漏らしてはならない。その業務に従事しなくなった後も同様とする。

六　研究機関の長は、一の規定によるモニタリング及び監査の実施に協力するとともに、当該実施に必要な措置を講じなければならない。

第十章　雑則

第三十四　啓発普及

研究者は、あらゆる機会を利用して遺伝子治療等臨床研究に関し、情報の提供等啓発普及に努めるものとする。

第三十五　施行期日

この指針は、平成二十七年十月一日から施行する。

第三十六　経過措置

この指針の施行前に廃止前の遺伝子治療臨床研究に関する指針（平成16年文部科学省・厚生労働省告示第２号）等の規定によってした手続その他の行為であって、この指針に相当の規定があるものは、この指針の相当の規定によってしたものとみなす。

このヒトに関するクローン技術等の規制に関する法律（平成１３年６月６日施行）の翻訳は、「法令用語日英標準対訳辞書」（平成１８年３月版）に準拠して作成したものです。
なお、この法令の翻訳は公定訳ではありません。法的効力を有するのは日本語の法令自体であり、翻訳はあくまでその理解を助けるための参考資料です。この翻訳の利用に伴って発生した問題について、一切の責任を負いかねますので、法律上の問題に関しては、官報に掲載された日本語の法令を参照してください。
This English translation of the Act on Regulation of Human Cloning Techniques (Effective June 6, 2001) has been prepared in compliance with the Standard Bilingual Dictionary (March 2006 edition).
This is an unofficial translation. Only the original Japanese texts of laws and regulations have legal effect, and the translations are to be used solely as reference material to aid in the understanding of Japanese laws and regulations.
The Government of Japan shall not be responsible for the accuracy, reliability or currency of the legislative material provided in this Website, or for any consequence resulting from use of the information in this Website. For all purposes of interpreting and applying law to any legal issue or dispute, users should consult the original Japanese texts published in the Official Gazette.

Act on Regulation of Human Cloning Techniques (Act No. 146 of 2000)

Article 1 (Purpose)

The purpose of this Act is, in light of the risk that certain techniques including the Cloning Techniques (hereinafter referred to as the "Cloning Techniques, etc.") among the techniques for manipulating Embryos or Germ Cells of a human or an Animal could, depending on the way they are applied, create an individual with the same gene structure as a certain individual (hereinafter referred to as a "Human Clone Individual") or an individual which cannot be clearly classified as a human or an Animal (hereinafter referred to as an "Hybrid Individual"), or artificially create other similar individuals, and have a serious influence on the preservation of human dignity, safety for human life and body, and maintenance of public order (hereinafter referred to as the "Preservation of Human Dignity, etc."), to prevent creation of Human Clone Individuals and Hybrid Individuals and to regulate artificial creation of individuals similar to them by means of prohibiting transfer of Embryos produced by the Cloning Techniques or Specified Fusion/Aggregation Techniques among Cloning Techniques, etc. into a human or Animal uterus, regulating production, receipt by assignment and import of Embryos created by Cloning Techniques, etc., and taking other measures for securing appropriate handling of such Embryos, thereby ensuring the development of science and technology in harmony with society and citizens lives.

Article 2 (Definitions)

(1) In this Act, the meanings of the terms listed in the following items shall be as

prescribed respectively in those items:

(i) Embryo-A cell (except for a Germ Cell) or a cell group which has the potential to grow into an individual through the process of development *in utero* of a human or an Animal and remains at a stage prior to placental formation

(ii) Germ Cell — A sperm (including a spermatid and a spermatocyte whose number of chromosomes is equal to the number of chromosomes of the sperm; the same shall apply hereinafter) and an Unfertilized Egg

(iii) Unfertilized Egg — An unfertilized ovum and oocyte (limited to an oocyte whose number of chromosomes is equal to the number of chromosomes of the ovum)

(iv) Somatic Cell — A cell (except for a Germ Cell) taken from an individual (including a dead individual) or a Fetus (including a dead Fetus) belonging to the class Mammalia, or a cell produced by division of such a cell, excluding an Embryo or a cell constituting an Embryo

(v) Embryonic Cell — A cell taken from an Embryo or a cell produced by division of such a cell, excluding an Embryo

(vi) Human Fertilized Embryo — An Embryo produced by fertilization between a human Sperm and a human Unfertilized Egg (including each Embryo which is produced successively by single or multiple splitting of such an Embryo and is not a Human Split Embryo)

(vii) Fetus — A cell group lying *in utero* of a human or an Animal which has the potential to grow into an individual through the process of development *in utero* and has begun formation of a placenta, and which shall include the placenta and other appendages

(viii) Human Split Embryo — An Embryo produced by splitting *ex utero* of a Human Fertilized Embryo or a Human Embryonic Nuclear Transfer Embryo

(ix) Human Embryonic Nuclear Transfer Embryo — An Embryo produced by Fusion between a Human Enucleated Egg and a Human Fertilized Embryo or Human Split Embryo at the one-cell stage or an Embryonic Cell with a cell nucleus of a Human Fertilized Embryo, Human Split Embryo or Human-Human Chimeric Embryo

(x) Human Somatic Cell Nuclear Transfer Embryo — An Embryo produced by Fusion between a Human Enucleated Egg and a human Somatic Cell with a cell nucleus (including each Embryo produced successively by single or multiple splitting of such an Embryo)

(xi) Cloning Techniques — The techniques for producing a Human Somatic Nuclear Transfer Embryo

(xii) Human-Human Chimeric Embryo — Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced as a result of aggregation of two or more of Human Fertilized Embryos, Human Split Embryos, Human Embryonic Nuclear Transfer Embryos or Human Somatic Cell Nuclear Transfer Embryos (including an Embryo produced as a result of aggregation of such an Embryo and either a Human Somatic Cell or an Embryonic Cell of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo)

(b) An Embryo produced as a result of aggregation of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, or Human Somatic Cell Nuclear Transfer Embryo and either a human Somatic Cell or an Embryonic Cell of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo

(xiii) Human-Animal Hybrid Embryo — Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced by fertilization between a human Germ Cell and an Animal Germ Cell

(b) An Embryo produced by Fusion between a human or Animal Enucleated Egg and an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a)

(xiv) Human-Animal Clone Embryo — Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced by Fusion between an Animal Enucleated Egg and either a human Somatic Cell or a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo at the one-cell stage or an Embryonic Cell with a cell nucleus of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, Human Somatic Cell Nuclear Transfer Embryo or Human-Human Chimeric Embryo

(b) An Embryo produced by Fusion between a Human Enucleated Egg and an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a)

(xv) Human-Animal Chimeric Embryo — Any of the following Embryos which is not a Human-Human Chimeric Embryo, Animal Embryo or Animal-Human Chimeric Embryo (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced as a result of aggregation of two or more Embryos (including an Embryo produced as a result of aggregation of such an Embryo

and a Somatic or Embryonic Cell)

(b) An Embryo produced as a result of aggregation of an Embryo and a Somatic or Embryonic Cell

(c) An Embryo produced by Fusion between an Embryonic Cell with a cell nucleus of an Embryo listed in (a) or (b) and a human or Animal Enucleated Egg

(xvi) Specified Fusion/Aggregation Techniques — Techniques to produce a Human-Animal Hybrid Embryo, Human-Animal Clone Embryo or Human-Animal Chimeric Embryo

(xvii) Animal — An individual except for a Human belonging to the class Mammalia

(xviii) Animal Embryo — Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced by fertilization between an Animal sperm and an Animal Unfertilized Egg

(b) An Embryo produced by Fusion between an Animal Enucleated Egg and either an Animal Somatic Cell or an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a)

(c) An Embryo produced as a result of aggregation of two or more Embryos listed in (a) or (b) (including an Embryo produced as a result of aggregation of such an Embryo and either an Animal Somatic Cell or an Embryonic Cell of an Embryo listed in (a) or (b))

(d) An Embryo produced as a result of aggregation of an Embryo listed in (a) or (b) and either an Animal Somatic Cell or an Embryonic Cell of an Embryo listed in (a) or (b)

(xix) Animal-Human Clone Embryo — Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced by Fusion between a Human Enucleated Egg and either an Animal Somatic Cell or an Animal Embryo at the one-cell stage or an Embryonic Cell with a cell nucleus of an Animal Embryo

(b) An Embryo produced by Fusion between an Animal Enucleated Egg and either an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a)

(xx) Animal-Human Chimeric Embryo — Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of such an Embryo):

(a) An Embryo produced as a result of aggregation of two or more Animal-Human Clone Embryos (including an Embryo produced as a result of aggregation of such an Embryo and a Somatic or Embryonic Cell)

(b) An Embryo produced as a result of aggregation of one or more Animal-Human Clone Embryos and one or more Animal Embryos or Somatic or Embryonic Cells

(c) An Embryo produced as a result of aggregation of one or more Animal Embryos and Human Somatic Cells or Embryonic Cells of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, Human Somatic Cell Nuclear Transfer Embryo, Human-Human Chimeric Embryo, Human-Animal Hybrid Embryo, Human-Animal Clone Embryo, Human-Animal Chimeric Embryo or Animal-Human Clone Embryo (including an Embryo produced as a result of aggregation of such an Embryo and either an Animal Somatic Cell or an Embryonic Cell of an Animal Embryo)

(d) An Embryo produced by Fusion between a Human or Animal Enucleated Egg and an Embryonic Cell with a cell nucleus of an Embryo listed in (a) to (c) inclusive

(xxi) Fusion — Production of a single cell through combination of more than one cell without fertilization, which includes transfer of the nucleus of a single cell to another enucleated cell

(xxii) Enucleation — Removal of the nucleus from a cell or destruction of the nucleus of a cell

(xxiii) Human Enucleated Egg — An enucleated human Unfertilized Egg or an enucleated Human Fertilized Embryo or Human Split Embryo at the one-cell stage

(xxiv) Animal Enucleated Egg — An enucleated Animal Unfertilized Egg or an enucleated Animal Embryo at the one-cell stage

(2) With regard to application of the provisions shown in Column A of the following table, an Embryo or cell shown in Column B of the same table shall be regarded as an Embryo or cell shown in Column C of the same table which is mentioned in the said provisions.

	Column A	Column B	Column C
(i)	Article 2(1)(viii)	Human Split Embryo	Human Fertilized Embryo
(ii)	Article 2(1)(ix)	Human Embryonic Nuclear Transfer Embryo	Human Fertilized Embryo
(iii)	Article 2(1)(x)	Human Somatic Cell Nuclear Transfer Embryo at the one-cell stage, or Embryonic Cell of a Human Somatic Cell Nuclear Transfer Embryo	Human Somatic Cell
(iv)	Article 2(1)(xii) (a) and (b)	Embryonic Cell of a Human-Human Chimeric	Embryonic Cell of a Human Somatic Cell

		Embryo	Nuclear Transfer Embryo
(v)	Article 2(1)(xiii)(b)	Human-Animal Hybrid Embryo	Embryo described in (a)
(vi)	Article 2(1)(xiv)(a)	Human-Animal Clone Embryo	Human Somatic Cell Nuclear Transfer Embryo
(vii)	Article 2(1)(xiv)(b)	Human-Animal Clone Embryo	Embryo described in (a)
(viii)	Article 2(1)(xviii)(b)	Animal Embryo	Embryo described in (a)
(ix)	Article 2(1)(xviii)(c) and (d)	Embryonic Cell of an Animal Embryo	Embryonic Cell of an Embryo described in (a)
(x)	Article 2(1)(xix)(a)	Animal-Human Clone Embryo	Animal Embryo
(xi)	Article 2(1)(xix)(b)	Animal-Human Clone Embryo	Embryo described in (a)
(xii)	Article 2(1)(xx)(c)	Embryonic Cell of an Animal-Human Chimeric Embryo	Embryonic Cell of an Animal Embryo
(xiii)	Article 2(1)(xxiii)	Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo	Human Fertilized Embryo
(xiv)	Article 2(1)(xxiv)	Human-Animal Hybrid Embryo, Human-Animal Clone Embryo or Animal-Human Clone Embryo	Animal Embryo

Article 3 (Prohibited acts)

No person shall transfer a Human Somatic Cell Nuclear Transfer Embryo, Human-Animal Hybrid Embryo, Human-Animal Clone Embryo or Human-Animal Chimeric Embryo into a human or Animal uterus.

Article 4 (Guidelines)

(1) The Minister of Education, Culture, Sports, Science and Technology (hereinafter referred to as the "Minister") shall, in light of the risk that a Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, Human Somatic Cell Nuclear Transfer Embryo, Human-Human Chimeric Embryo, Human-Animal Hybrid Embryo, Human-Animal Clone Embryo, Human-Animal Chimeric Embryo, Animal-Human Clone Embryo or Animal-Human Chimeric Embryo (hereinafter

referred to as a "Specified Embryo") could, when transferred into a human or Animal uterus, develop into a Human Clone Individual or Hybrid Individual or an individual that has a similar influence on the Preservation of Human Dignity, etc., establish guidelines on the handling of Specified Embryos (hereinafter referred to as the "Guidelines") while taking into consideration scientific knowledge related to the clarification of the phenomenon of life, in order to secure appropriate production, receipt by assignment or import and subsequent handling of Specified Embryos (hereinafter referred to as the "Handling of Specified Embryos").

(2) The Guidelines shall prescribe the following matters:
  (i) Matters concerning the requirement of consent by the donor of the Embryos or cells necessary for production of a Specified Embryo and other requirements for allowable production of Specified Embryos
  (ii) In addition to what is listed in the preceding item, matters concerning the requirements for allowable Handling of Specified Embryos
  (iii) In addition to what is listed in the preceding two items, procedures and other matters to be considered in the Handling of Specified Embryos
(3) When the Minister intends to establish or change the Guidelines, he or she shall consult the heads of the relevant administrative organs and hear the opinions of the Council for Science and Technology Policy in advance.
(4) When the Minister establishes or changes the Guidelines, he or she shall announce such establishment or change without delay.

Article 5 (Compliance obligation)

The Handling of Specified Embryos shall be conducted in accordance with the Guidelines.

Article 6 (Notification of production, receipt by assignment or import of Specified Embryo)

(1) A person who intends to produce, receive by assignment or import a Specified Embryo shall notify the following matters to the Minister pursuant to the provisions of an Ordinance of the Ministry of Education, Culture, Sports, Science and Technology (hereinafter referred to as an "Ordinance of MEXT"):
  (i) The name and domicile and, in the case of a juridical person, the name of its representative
  (ii) The type of the Embryo to be produced, to be received by assignment, or to be imported
  (iii) The purpose of production, receipt by assignment or import and, in the case of production, its method
  (iv) The scheduled date of production, receipt by assignment or import

(v) The method of the handling after the production, receipt by assignment or import

(vi) In addition to what is listed in the preceding items, matters specified by an Ordinance of MEXT

(2) If a person who has made the notification under the preceding paragraph intends to change any matters pertaining to the notification, he or she shall notify such change to the Minister pursuant to the provisions of an Ordinance of MEXT.

Article 7 (Order to change or abolish the plan, etc)

(1) Where the notification under paragraph 1 or 2 of the preceding Article has been made, if the Minister finds that the Handling of the Specified Embryo pertaining to the notification does not conform to the Guidelines, he or she may, within sixty days from the date of acceptance of the notification, order the person who has made the notification to change or abolish the plan concerning the method of the said Handling of the Specified Embryo or to take other necessary measures.

(2) If the Minister finds that the contents of the matters pertaining to the notification under paragraph 1 or 2 of the preceding Article are reasonable, he or she may shorten the period prescribed in the preceding paragraph. In this case, the Minister shall give notice of the shortened period to the person who has made the notification, without delay.

Article 8 (Limitation on execution)

A person who has made the notification under Article 6, paragraph 1 or 2 shall not produce, receive by assignment or import the Specified Embryo pertaining to the notification, or change any matters pertaining to the notification until sixty days (if the notice under the second sentence of paragraph 2 of the preceding Article has been served, the period pertaining to the notice) have passed from the date of acceptance of the notification.

Article 9 (Notification of production of Specified Embryo by chance cause)

A person who has made the notification under Article 6, paragraph 1 shall, in the case the Specified Embryo pertaining to the notification has produced a different type of Specified Embryo by a chance cause, promptly notify the following matters to the Minister pursuant to the provisions of an Ordinance of MEXT; provided, however, that this shall not apply to the case where such produced Specified Embryo is immediately disposed of:

(i) The name and domicile and, in the case of a juridical person, the name of its representative

(ii) The type of the produced Embryo

(iii) The date of the production

(vi) In addition to what is listed in the preceding three items, matters specified by an Ordinance of MEXT

Article 10 (Record)

(1) A person who has made the notification under Article 6, paragraph 1 or the preceding Article shall make a record of the following matters with regard to the Specified Embryo pertaining to the notification, pursuant to an Ordinance of MEXT:

(i) The type of the Embryo which has been produced, received by assignment or imported

(ii) The date of production, receipt by assignment or import

(iii) The process of the handling after production, receipt by assignment or import

(iv) In addition to what is listed in the preceding three items, matters specified by an Ordinance of MEXT

(2) The record prescribed in the preceding paragraph shall be preserved pursuant to the provisions of an Ordinance of MEXT.

Article 11 (Notification of assignment, etc. of Specified Embryo)

A person who has made the notification under Article 6, paragraph 1 or Article 9 shall, in the case he or she has assigned, exported, destroyed or disposed of the Specified Embryo pertaining to the notification, notify the following matters to the Minister without delay, pursuant to the provisions of an Ordinance of MEXT:

(i) The name and domicile and, in the case of a juridical person, the name of its representative

(ii) The type of the Embryo which has been assigned, exported, destroyed or disposed of

(iii) The date of the assignment, export, destruction or disposal and, in the case of destruction or disposal, the manner of destruction or disposal

(iv) In addition to what is listed in the preceding three items, matters specified by an Ordinance of MEXT

Article 12 (Order to take measures with regard to the Handling of Specified Embryo)

If the Minister finds that the Handling of a Specified Embryo by a person who has made the notification under Article 6, paragraph 1 or Article 9 does not conform to the Guidelines, he or she may order the person who has made the notification to discontinue or improve the method of the Handling of the Specified Embryo or to take other necessary measures.

Article 13 (Protection of personal information)

A person who has made the notification under Article 6, paragraph 1 or Article 9 shall endeavor to take necessary measures for the prevention of leakage of Personal Information (information about an individual, which can identify the specific individual by name, date of birth or other description contained in such information [including information that can be compared with other information and thereby identify the specific individual]; hereinafter the same shall apply in this Article) of the donor of the Embryos or cells used for producing the Specified Embryo pertaining to the notification, and for the proper management of the Personal Information.

Article 14 (Collection of report)

The Minister may, within the limit necessary for enforcement of this Act, ask a person who has made the notification under Article 6, paragraph 1 or Article 9 to report on the state of the Handling of the Specified Embryo pertaining to the notification and of other necessary matters.

Article 15 (Entry and Inspection)

(1) The Minister may, within the limit necessary for enforcement of this Act, have officials of the ministry enter the office or research facility of a person who has made the notification under Article 6, paragraph 1 or Article 9, inspect documents and other necessary materials of the said person, and ask questions of the persons concerned.

(2) When an official enters the office or research facility pursuant to the provisions of the preceding paragraph, he or she shall carry a certificate for identification and produce it upon request of the persons concerned.

(3) The authority under paragraph 1 shall not be construed as that approved for the purpose of criminal investigation.

Article 16 (Penal Provisions)

A person who has violated the provisions of Article 3 shall be punished by imprisonment with work for not more than ten years or a fine of not more than ten million yen, or both.

Article 17

A person who falls under any of the following items shall be punished by imprisonment with work for not more than one year or a fine of not more than one million yen:

(i) A person who has, without making the notification under Article 6, paragraph 1 or by making false notification, produced, received by assignment or imported a Specified Embryo

(ii) A person who has, without making the notification under Article 6,

paragraph 2 or by making false notification, changed the matters prescribed in the same paragraph

(iii) A person who has violated the order prescribed in Article 7, paragraph 1

(iv) A person who has violated the order prescribed in Article 12

Article 18

A person who has violated the provisions of Article 8 shall be punished by imprisonment with work for not more than six months or a fine of not more than five hundred thousand yen.

Article 19

A person who falls under any of the following items shall be punished by a fine of not more than five hundred thousand yen:

(i) A person who has failed to make the notification under Article 9 or has made false notification

(ii) A person who has failed to make the record under Article 10, paragraph 1 or has made a false record

(iii) A person who has violated the provisions of Article 10, paragraph 2

(iv) A person who has failed to make the notification under Article 11 or has made false notification

(v) A person who has failed to make the report under Article 14 or has made a false report

(vi) A person who has defied, obstructed or evaded the entry or inspection, or has failed to make a statement or has made a false statement in response to the question under Article 15, paragraph 1

Article 20

When the representative of a juridical person, or an agent, employee or other worker of a juridical person or individual has committed an act in violation of the provisions from Article 16 to the preceding Article inclusive with regard to the business of said juridical person or individual, not only the offender shall be punished but also said juridical person or individual shall be punished by the fine prescribed in the respective Articles.

Supplementary Provisions

Article 1 (Effective Date)

This Act shall come into force as from the day on which six months from the day of promulgation have elapsed; provided, however, that the following provisions shall come into force as from the date described in each item:

(i) The provisions of Article 4, paragraph 3 of this Act and Article 3 of the Supplementary Provisions — the day of promulgation

(ii) The provisions of Article 4, paragraphs 1, 2 and 4, from Articles 5 to 15 inclusive, from Articles 17 to 19 inclusive and Article 20 (limited to the portion pertaining to Articles 17 to 19 inclusive) of this Act — the date specified by a Cabinet Order within a period not exceeding one year from the day of promulgation

Article 2 (Review)

The Government shall, within three years of enforcement of this Act, review the provisions of this Act based on the results of study by the Council for Science and Technology Policy and others on how Human Fertilized Embryos should be handled as the emerging potential of human life, while taking into consideration the state of enforcement of this Act and changes in the circumstances surrounding the Cloning Techniques, etc., and take necessary measures based on the results of the review.

Article 3 (Transitional measures)

With regard to application of the provisions of Article 4, paragraph 3, during the period from the day of promulgation of this Act until the day before the effective date (January 6, 2001) of the Act for Partial Revision of the Cabinet Act (Act No. 88 of 1999), the term "Minister of Education, Culture, Sports, Science and Technology" in the same paragraph shall be deemed to be replaced with "Prime Minister," and the term "Council for Science and Technology Policy" shall be deemed to be replaced with "Council for Science and Technology".

Article 4 (Partial revision of the Act for Punishment of Organized Crimes, Control of Crime Proceeds and Other Matters)

A part of the Act for Punishment of Organized Crimes, Control of Crime Proceeds and Other Matters (Act No. 136 of 1999) shall be revised as follows.

The following item shall be added to the appended table:

lxi An offense prescribed in Article 16 (Transfer of a Human Somatic Clone Embryo or other Specified Embryo into a human or Animal uterus) of the Act on Regulation of Human Cloning Techniques, etc. (Act No. 146 of 2000)

再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）

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附則

第一章　総則

（目的）

第一条　この法律は、再生医療等に用いられる再生医療等技術の安全性の確保及び生命倫理への配慮（以下「安全性の確保等」という。）に関する措置その他の再生医療等を提供しようとする者が講ずべき措置を明らかにするとともに、特定細胞加工物の製造の許可等の制度を定めること等により、再生医療等の迅速かつ安全な提供及び普及の促進を図り、もって医療の質及び保健衛生の向上に寄与することを目的とする。

（定義）

第二条　この法律において「再生医療等」とは、再生医療等技術を用いて行われる医療（医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（昭和三十五年法律第百四十五号。以下「医薬品医療機器等法」という。）第八十条の二第二項に規定する治験に該当するものを除く。）をいう。

２　この法律において「再生医療等技術」とは、次に掲げる医療に用いられることが目的とされている医療

技術であって、細胞加工物を用いるもの（細胞加工物として再生医療等製品（医薬品医療機器等法第二十三条の二十五又は第二十三条の三十七の承認を受けた再生医療等製品をいう。第四項において同じ。）のみを当該承認の内容に従い用いるものを除く。）のうち、その安全性の確保等に関する措置その他のこの法律で定める措置を講ずることが必要なものとして政令で定めるものをいう。

一　人の身体の構造又は機能の再建、修復又は形成

二　人の疾病の治療又は予防

3　この法律において「細胞」とは、細胞加工物の原材料となる人又は動物の細胞をいう。

4　この法律において「細胞加工物」とは、人又は動物の細胞に培養その他の加工を施したものをいい、「特定細胞加工物」とは、再生医療等に用いられる細胞加工物のうち再生医療等製品であるもの以外のものをいい、細胞加工物について「製造」とは、人又は動物の細胞に培養その他の加工を施すことをいい、「細胞培養加工施設」とは、特定細胞加工物の製造をする施設をいう。

5　この法律において「第一種再生医療等技術」とは、人の生命及び健康に与える影響が明らかでない又は相当の注意をしても人の生命及び健康に重大な影響を与えるおそれがあることから、その安全性の確保等

に関する措置その他のこの法律で定める措置を講ずることが必要なものとして厚生労働省令で定める再生医療等技術をいい、「第一種再生医療等」とは、第一種再生医療等技術を用いて行われる再生医療等をいう。

6　この法律において「第二種再生医療等技術」とは、相当の注意をしても人の生命及び健康に影響を与えるおそれがあることから、その安全性の確保等に関する措置その他のこの法律で定める措置を講ずることが必要なものとして厚生労働省令で定める再生医療等技術（第一種再生医療等技術に該当するものを除く。）をいい、「第二種再生医療等」とは、第二種再生医療等技術を用いて行われる再生医療等をいう。

7　この法律において「第三種再生医療等技術」とは、第一種再生医療等技術及び第二種再生医療等技術以外の再生医療等技術をいい、「第三種再生医療等」とは、第三種再生医療等技術を用いて行われる再生医療等をいう。

8　この法律において「特定細胞加工物製造事業者」とは、第三十五条第一項の許可若しくは第三十九条第一項の認定を受けた者又は第四十条第一項の規定による届出をした者をいう。

第二章　再生医療等の提供

第一節　再生医療等提供基準

第三条　厚生労働大臣は、厚生労働省令で、再生医療等の提供に関する基準（以下「再生医療等提供基準」という。）を定めなければならない。

２　再生医療等提供基準は、第一種再生医療等、第二種再生医療等及び第三種再生医療等のそれぞれにつき、次に掲げる事項（第三種再生医療等にあっては、第一号に掲げる事項を除く。）について定めるものとする。

一　再生医療等を提供する病院（医療法（昭和二十三年法律第二百五号）第一条の五第一項に規定する病院をいう。以下同じ。）又は診療所（同条第二項に規定する診療所をいう。以下同じ。）が有すべき人員及び構造設備その他の施設に関する事項

二　再生医療等に用いる細胞の入手の方法並びに特定細胞加工物の製造及び品質管理の方法に関する事項

三　前二号に掲げるもののほか、再生医療等技術の安全性の確保等に関する措置に関する事項

四　再生医療等に用いる細胞を提供する者及び再生医療等（研究として行われる場合その他の厚生労働省令で定める場合に係るものに限る。）を受ける者に対する健康被害の補償の方法に関する事項

五　その他再生医療等の提供に関し必要な事項

3　再生医療等は、再生医療等提供基準に従って提供されなければならない。

第二節　再生医療等の提供の開始、変更及び中止の手続

第一款　通則

（再生医療等提供計画の提出）

第四条　再生医療等を提供しようとする病院又は診療所（医療法第五条第一項に規定する医師又は歯科医師の住所を含む。第三号を除き、以下同じ。）の管理者（同項に規定する医師又は歯科医師を含む。以下この章及び次章において同じ。）は、厚生労働省令で定めるところにより、あらかじめ、第一種再生医療等、第二種再生医療等及び第三種再生医療等のそれぞれにつき厚生労働省令で定める再生医療等の区分ごとに、次に掲げる事項（第二号に掲げる再生医療等が第三種再生医療等である場合にあっては、第三号に掲げる事項を除く。）を記載した再生医療等の提供に関する計画（以下「再生医療等提供計画」という。）を厚生労働大臣に提出しなければならない。

一　当該病院又は診療所の名称及び住所並びに当該管理者の氏名

二　提供しようとする再生医療等及びその内容

三　前号に掲げる再生医療等について当該病院又は診療所の有する人員及び構造設備その他の施設

四　第二号に掲げる再生医療等に用いる細胞の入手の方法並びに当該再生医療等に用いる特定細胞加工物の製造及び品質管理の方法（特定細胞加工物の製造を委託する場合にあっては、委託先の名称及び委託の内容）

五　前二号に掲げるもののほか、第二号に掲げる再生医療等に用いる再生医療等技術の安全性の確保等に関する措置

六　第二号に掲げる再生医療等に用いる細胞を提供する者及び当該再生医療等（研究として行われる場合その他の厚生労働省令で定める場合に係るものに限る。）を受ける者に対する健康被害の補償の方法

七　第二号に掲げる再生医療等について第二十六条第一項各号に掲げる業務を行う認定再生医療等委員会（同条第五項第二号に規定する認定再生医療等委員会をいう。以下この章において同じ。）の名称及び委員の構成

八　その他厚生労働省令で定める事項

２　再生医療等を提供しようとする病院又は診療所の管理者は、前項の規定により再生医療等提供計画を提出しようとするときは、当該再生医療等提供計画が再生医療等提供基準に適合しているかどうかについて、あらかじめ、当該再生医療等提供計画に記載される認定再生医療等委員会の意見を聴かなければならない。

３　第一項の再生医療等提供計画には、次に掲げる書類を添付しなければならない。

一　再生医療等提供計画に記載された認定再生医療等委員会が述べた第二十六条第一項第一号の意見の内容を記載した書類

二　その他厚生労働省令で定める書類

（再生医療等提供計画の変更）

第五条　再生医療等提供計画の変更（厚生労働省令で定める軽微な変更を除く。次項において同じ。）をしようとする病院又は診療所の管理者は、厚生労働省令で定めるところにより、あらかじめ、その変更後の再生医療等提供計画を厚生労働大臣に提出しなければならない。

２　前条第二項及び第三項の規定は、再生医療等提供計画の変更について準用する。ただし、同項第二号に

掲げる書類については、既に厚生労働大臣に提出されている当該書類の内容に変更がないときは、その添付を省略することができる。

3　第一項の厚生労働省令で定める再生医療等提供計画の軽微な変更をした病院又は診療所の管理者は、厚生労働省令で定めるところにより、その変更の日から十日以内に、その旨を、再生医療等提供計画に記載された認定再生医療等委員会に通知するとともに、厚生労働大臣に届け出なければならない。

（再生医療等の提供の中止）

第六条　再生医療等提供機関（第四条第一項又は前条第一項の規定により提出された再生医療等提供計画に係る病院又は診療所をいう。以下同じ。）の管理者は、再生医療等提供計画に記載された再生医療等の提供を中止したときは、厚生労働省令で定めるところにより、その中止の日から十日以内に、その旨を、再生医療等提供計画に記載された認定再生医療等委員会に通知するとともに、厚生労働大臣に届け出なければならない。

第二款　第一種再生医療等の提供に関する特則

（第一種再生医療等提供計画に記載される認定再生医療等委員会の要件）

第七条　第一種再生医療等提供計画（第一種再生医療等に係る再生医療等提供計画をいう。以下同じ。）に記載される第一種再生医療等について第二十六条第一項各号に掲げる業務を行う認定再生医療等委員会は、特定認定再生医療等委員会（認定再生医療等委員会であって、同条第四項各号に掲げる要件のいずれにも適合するものをいう。第十一条において同じ。）でなければならない。

（第一種再生医療等提供計画の変更命令等）

第八条　厚生労働大臣は、第四条第一項の規定による第一種再生医療等提供計画の提出があった場合において、当該第一種再生医療等提供計画に記載された第一種再生医療等が再生医療等提供基準に適合していないと認めるときは、その提出があった日から起算して九十日以内に限り、当該第一種再生医療等提供計画に係る再生医療等提供機関の管理者に対し、当該第一種再生医療等提供計画の変更その他必要な措置をとるべきことを命ずることができる。

２　厚生労働大臣は、第四条第一項の規定による第一種再生医療等提供計画の提出があった場合において、前項の期間内に同項の命令をすることができない合理的な理由があるときは、同項の期間を延長することができる。この場合においては、同項の期間内に、当該第一種再生医療等提供計画に係る再生医療等提供

機関の管理者に対し、その旨、延長後の期間及び延長する理由を通知しなければならない。

3　厚生労働大臣は、第四条第一項の規定による第一種再生医療等提供計画の提出があった場合において、当該第一種再生医療等提供計画に記載された第一種再生医療等が再生医療等提供基準に適合していると認めるときは、第一項の期間を短縮することができる。この場合においては、当該第一種再生医療等提供計画に係る再生医療等提供機関の管理者に対し、遅滞なく、短縮後の期間を通知しなければならない。

（第一種再生医療等の提供の制限）

第九条　第四条第一項の規定により提出された第一種再生医療等提供計画に係る再生医療等提供機関の管理者は、前条第一項の期間（同条第二項又は第三項の規定による通知があったときは、その通知に係る期間）を経過した後でなければ、当該第一種再生医療等提供計画に記載された第一種再生医療等を提供してはならない。

（準用）

第十条　前二条の規定は、第一種再生医療等提供計画の変更（第五条第一項の厚生労働省令で定める軽微な変更を除く。）について準用する。この場合において、必要な技術的読替えは、政令で定める。

２　第一種再生医療等提供計画の変更をする再生医療等提供機関の管理者は、前項において準用する前条の規定にかかわらず、同条に規定する期間が経過する日までの間、第一種再生医療等（変更前の第一種再生医療等提供計画に従って行われていたものに限る。）を提供することができる。

第三款　第二種再生医療等の提供に関する特則

第十一条　第二種再生医療等提供計画（第二種再生医療等に係る再生医療等提供計画をいう。第二十六条第四項第一号において同じ。）に記載される第二種再生医療等について同条第一項各号に掲げる業務を行う認定再生医療等委員会は、特定認定再生医療等委員会でなければならない。

第三節　再生医療等の適正な提供に関する措置

（特定細胞加工物の製造の委託）

第十二条　再生医療等提供機関の管理者は、特定細胞加工物の製造を委託しようとするときは、特定細胞加工物製造事業者に委託しなければならない。

（再生医療等提供計画の確認）

第十三条　医師又は歯科医師は、再生医療等を行おうとするときは、次に掲げる事項を確認しなければなら

ない。

一　当該再生医療等が第四条第一項又は第五条第一項の規定により提出された再生医療等提供計画に記載された再生医療等であること。

二　当該再生医療等が第一種再生医療等である場合にあっては、当該第一種再生医療等が記載された第一種再生医療等提供計画について第九条（第十条第一項において準用する場合を含む。）に規定する期間が経過していること。

（再生医療等に関する説明及び同意）

第十四条　医師又は歯科医師は、再生医療等を行うに当たっては、疾病のため本人の同意を得ることが困難な場合その他の厚生労働省令で定める場合を除き、当該再生医療等を受ける者に対し、当該再生医療等に用いる再生医療等技術の安全性の確保等その他再生医療等の適正な提供のために必要な事項について適切な説明を行い、その同意を得なければならない。

２　医師又は歯科医師は、再生医療等を受ける者以外の者から再生医療等に用いる細胞の採取を行うに当たっては、疾病のため本人の同意を得ることが困難な場合その他の厚生労働省令で定める場合を除き、当該

細胞を提供する者に対し、採取した細胞の使途その他当該細胞の採取に関し必要な事項について適切な説明を行い、その同意を得なければならない。

（再生医療等に関する個人情報の保護）

第十五条　再生医療等提供機関の管理者は、再生医療等に用いる細胞を提供する者及び再生医療等を受ける者の個人情報（個人に関する情報であって、当該情報に含まれる氏名、生年月日その他の記述等により特定の個人を識別することができるもの（他の情報と照合することにより、特定の個人を識別することができることとなるものを含む。）をいう。以下この条において同じ。）の漏えい、滅失又は毀損の防止その他の個人情報の適切な管理のために必要な措置を講じなければならない。

（再生医療等に関する記録及び保存）

第十六条　医師又は歯科医師は、再生医療等を行ったときは、厚生労働省令で定めるところにより、当該再生医療等を行った日時及び場所、当該再生医療等の内容その他の厚生労働省令で定める事項に関する記録を作成しなければならない。

２　前項の記録は、再生医療等提供機関の管理者が、厚生労働省令で定めるところにより、保存しなければ

ならない。

（認定再生医療等委員会への疾病等の報告）

第十七条　再生医療等提供機関の管理者は、再生医療等提供計画に記載された再生医療等の提供に起因するものと疑われる疾病、障害若しくは死亡又は感染症の発生を知ったときは、厚生労働省令で定めるところにより、その旨を再生医療等提供計画に記載された認定再生医療等委員会に報告しなければならない。

２　前項の場合において、認定再生医療等委員会が意見を述べたときは、再生医療等提供機関の管理者は、当該意見を尊重して必要な措置をとらなければならない。

（厚生労働大臣への疾病等の報告）

第十八条　再生医療等提供機関の管理者は、再生医療等提供計画に記載された再生医療等の提供に起因するものと疑われる疾病、障害若しくは死亡又は感染症の発生に関する事項で厚生労働省令で定めるものを知ったときは、厚生労働省令で定めるところにより、その旨を厚生労働大臣に報告しなければならない。

（厚生科学審議会への報告）

第十九条　厚生労働大臣は、毎年度、前条の規定による報告の状況について厚生科学審議会に報告し、必要

があると認めるときは、その意見を聴いて、再生医療等の提供による保健衛生上の危害の発生又は拡大を防止するために必要な措置をとるものとする。

２　厚生科学審議会は、前項の規定による措置のほか、再生医療等の提供による保健衛生上の危害の発生又は拡大を防止するために必要な措置について、調査審議し、必要があると認めるときは、厚生労働大臣に意見を述べることができる。

（認定再生医療等委員会への定期報告）

第二十条　再生医療等提供機関の管理者は、再生医療等提供計画に記載された再生医療等の提供の状況について、厚生労働省令で定めるところにより、定期的に、再生医療等提供計画に記載された認定再生医療等委員会に報告しなければならない。

２　前項の場合において、認定再生医療等委員会が意見を述べたときは、再生医療等提供機関の管理者は、当該意見を尊重して必要な措置をとらなければならない。

（厚生労働大臣への定期報告）

第二十一条　再生医療等提供機関の管理者は、再生医療等提供計画に記載された再生医療等の提供の状況に

ついて、厚生労働省令で定めるところにより、定期的に、厚生労働大臣に報告しなければならない。

２　厚生労働大臣は、前項の規定による報告を取りまとめ、その概要を公表しなければならない。

（緊急命令）

第二十二条　厚生労働大臣は、再生医療等の提供による保健衛生上の危害の発生又は拡大を防止するため必要があると認めるときは、再生医療等を提供する病院又は診療所の管理者に対し、当該再生医療等の提供を一時停止することその他保健衛生上の危害の発生又は拡大を防止するための応急の措置をとるべきことを命ずることができる。

（改善命令等）

第二十三条　厚生労働大臣は、再生医療等技術の安全性の確保等その他再生医療等の適正な提供のため必要があると認めるときは、この章の規定の施行に必要な限度において、再生医療等提供機関の管理者に対し、再生医療等提供計画の変更その他再生医療等の適正な提供に関し必要な措置をとるべきことを命ずることができる。

２　厚生労働大臣は、再生医療等提供機関の管理者が前項の規定による命令に従わないときは、当該管理者

に対し、期間を定めて再生医療等提供計画に記載された再生医療等の全部又は一部の提供を制限することを命ずることができる。

（立入検査等）

第二十四条　厚生労働大臣は、この章の規定の施行に必要な限度において、再生医療等提供機関の管理者若しくは開設者（医療法第五条第一項に規定する医師又は歯科医師を含む。次項及び第二十六条第一項において同じ。）に対し、必要な報告をさせ、又は当該職員に、再生医療等提供機関に立ち入り、その構造設備若しくは帳簿、書類その他の物件を検査させ、若しくは関係者に質問させることができる。

２　厚生労働大臣は、前項に定めるもののほか、病院若しくは診療所の管理者がこの章の規定若しくはこの章の規定に基づく命令若しくは処分に違反していると認めるとき、又は再生医療等技術の安全性の確保等その他再生医療等の適正な提供のため必要があると認めるときは、病院若しくは診療所の管理者若しくは開設者に対し、必要な報告をさせ、又は当該職員に、病院若しくは診療所に立ち入り、その構造設備若しくは帳簿、書類その他の物件を検査させ、若しくは関係者に質問させることができる。

３　前二項の規定により職員が立ち入るときは、その身分を示す証明書を携帯し、関係者に提示しなければ

ならない。

4　第一項及び第二項の規定による権限は、犯罪捜査のために認められたものと解してはならない。

（厚生労働省令への委任）

第二十五条　この章に定めるもののほか、再生医療等の提供に関し必要な手続その他の事項は、厚生労働省令で定める。

第三章　認定再生医療等委員会

（再生医療等委員会の認定）

第二十六条　再生医療等に関して識見を有する者から構成される委員会であって、次に掲げる業務（以下「審査等業務」という。）を行うもの（以下この条において「再生医療等委員会」という。）を設置する者（病院若しくは診療所の開設者又は医学医術に関する学術団体その他の厚生労働省令で定める団体（法人でない団体にあっては、代表者又は管理人の定めのあるものに限る。）に限る。）は、その設置する再生医療等委員会が第四項各号に掲げる要件（当該再生医療等委員会が第三種再生医療等提供計画（第三種再生医療等に係る再生医療等提供計画をいう。以下同じ。）のみに係る審査等業務を行う場合にあっては、

同項第一号（第三種再生医療等提供計画に係る部分を除く。）に掲げる要件を除く。）に適合していることについて、厚生労働大臣の認定を受けなければならない。

一　第四条第二項（第五条第二項において準用する場合を含む。）の規定により再生医療等を提供しようとする病院若しくは診療所又は再生医療等提供機関の管理者から再生医療等提供計画について意見を求められた場合において、当該再生医療等提供計画について再生医療等提供基準に照らして審査を行い、当該管理者に対し、再生医療等の提供の適否及び提供に当たって留意すべき事項について意見を述べること。

二　第十七条第一項の規定により再生医療等提供機関の管理者から再生医療等の提供に起因するものと疑われる疾病、障害若しくは死亡又は感染症の発生に関する事項について報告を受けた場合において、必要があると認めるときは、当該管理者に対し、その原因の究明及び講ずべき措置について意見を述べること。

三　第二十条第一項の規定により再生医療等提供機関の管理者から再生医療等の提供の状況について報告を受けた場合において、必要があると認めるときは、当該管理者に対し、その再生医療等の提供に当た

って留意すべき事項若しくは改善すべき事項について意見を述べ、又はその再生医療等の提供を中止すべき旨の意見を述べること。

四　前三号に掲げる場合のほか、再生医療等技術の安全性の確保等その他再生医療等の適正な提供のため必要があると認めるときは、当該再生医療等委員会の名称が記載された再生医療等提供計画に係る再生医療等提供機関の管理者に対し、当該再生医療等提供計画に記載された事項に関し意見を述べること。

2　前項の認定を受けようとする者は、厚生労働省令で定めるところにより、次に掲げる事項を記載した申請書を厚生労働大臣に提出しなければならない。

一　氏名又は名称及び住所並びに法人にあっては、その代表者（法人でない団体で代表者又は管理人の定めのあるものにあっては、その代表者又は管理人）の氏名

二　当該再生医療等委員会の名称

三　当該再生医療等委員会の委員の氏名及び職業

四　当該再生医療等委員会が第三種再生医療等提供計画のみに係る審査等業務を行う場合にあっては、その旨

五　審査等業務を行う体制に関する事項

六　審査等業務に関し手数料を徴収する場合にあっては、当該手数料の算定の基準

七　その他厚生労働省令で定める事項

３　前項の申請書には、次に掲げる書類を添付しなければならない。

一　当該再生医療等委員会の委員の略歴を記載した書類

二　当該再生医療等委員会の審査等業務に関する規程

三　その他厚生労働省令で定める書類

４　厚生労働大臣は、第一項の認定の申請があった場合において、その申請に係る再生医療等委員会が次に掲げる要件（当該再生医療等委員会が第三種再生医療等提供計画のみに係る審査等業務を行う場合にあっては、第一号（第三種再生医療等提供計画に係る部分を除く。）に掲げる要件を除く。）に適合すると認めるときは、その認定をするものとする。

一　第一種再生医療等提供計画、第二種再生医療等提供計画及び第三種再生医療等提供計画について、第一種再生医療等、第二種再生医療等及び第三種再生医療等のそれぞれの再生医療等提供基準に照らして

審査等業務を適切に実施する能力を有する者として医学又は法律学の専門家その他の厚生労働省令で定める者から構成されるものであること。

二　その委員の構成が、審査等業務の公正な実施に支障を及ぼすおそれがないものとして厚生労働省令で定める基準に適合すること。

三　審査等業務の実施の方法、審査等業務に関して知り得た情報の管理及び秘密の保持の方法その他の審査等業務を適切に実施するための体制が整備されていること。

四　審査等業務に関し手数料を徴収する場合にあっては、当該手数料の算定の基準が審査等業務に要する費用に照らし、合理的なものとして厚生労働省令で定める基準に適合するものであること。

五　前各号に掲げるもののほか、審査等業務の適切な実施のために必要なものとして厚生労働省令で定める基準に適合するものであること。

5　厚生労働大臣は、前項の規定により認定をしたときは、次に掲げる事項を公示しなければならない。

一　当該認定を受けた者（以下「認定委員会設置者」という。）の氏名又は名称及び住所

二　当該認定に係る再生医療等委員会（以下「認定再生医療等委員会」という。）の名称

三　当該再生医療等委員会が第三種再生医療等提供計画のみに係る審査等業務を行うものとして認定された場合には、その旨

（変更の認定等）

第二十七条　認定委員会設置者は、前条第二項第三号、第五号又は第六号に掲げる事項を変更しようとするときは、厚生労働大臣の認定を受けなければならない。ただし、厚生労働省令で定める軽微な変更については、この限りでない。

２　認定委員会設置者は、前項ただし書の厚生労働省令で定める軽微な変更をしたときは、遅滞なく、その旨を厚生労働大臣に届け出なければならない。

３　前条第二項から第四項までの規定は、第一項の変更の認定について準用する。

４　認定委員会設置者は、前条第二項第一号、第二号若しくは第七号に掲げる事項又は同条第三項各号に掲げる書類に記載した事項に変更があったとき（当該変更が厚生労働省令で定める軽微なものであるときを除く。）は、遅滞なく、その旨を厚生労働大臣に届け出なければならない。

５　前条第五項の規定は、同項第一号又は第二号に掲げる事項について前項の規定による届出があった場合

について準用する。

（認定の有効期間等）

第二十八条　第二十六条第一項の認定の有効期間は、当該認定の日から起算して三年とする。

２　前項の有効期間の満了後引き続き認定再生医療等委員会を設置しようとする認定委員会設置者は、その有効期間の更新を受けなければならない。

３　前項の有効期間の更新を受けようとする認定委員会設置者は、第一項の有効期間の満了の日の九十日前から六十日前までの間（以下この項において「更新申請期間」という。）に、厚生労働大臣に有効期間の更新の申請をしなければならない。ただし、災害その他やむを得ない事由により更新申請期間にその申請をすることができないときは、この限りでない。

４　前項の申請があった場合において、第一項の有効期間の満了の日までにその申請に対する処分がされないときは、従前の認定は、同項の有効期間の満了後もその処分がされるまでの間は、なお効力を有する。

５　前項の場合において、第二項の有効期間の更新がされたときは、その認定の有効期間は、従前の認定の有効期間の満了の日の翌日から起算するものとする。

6　第二十六条（第一項を除く。）の規定は、第二項の有効期間の更新について準用する。ただし、同条第三項各号に掲げる書類については、既に厚生労働大臣に提出されている当該書類の内容に変更がないときは、その添付を省略することができる。

（秘密保持義務）

第二十九条　認定再生医療等委員会の委員若しくは認定再生医療等委員会の審査等業務に従事する者又はこれらの者であった者は、正当な理由がなく、当該審査等業務に関して知り得た秘密を漏らしてはならない。

（認定再生医療等委員会の廃止）

第三十条　認定委員会設置者は、その設置する認定再生医療等委員会を廃止しようとするときは、厚生労働省令で定めるところにより、あらかじめ、その旨を厚生労働大臣に届け出なければならない。

2　厚生労働大臣は、前項の規定による届出があったときは、その旨を公示しなければならない。

（報告の徴収）

第三十一条　厚生労働大臣は、認定再生医療等委員会の審査等業務の適切な実施を確保するため必要があると認めるときは、認定委員会設置者に対し、当該審査等業務の実施状況について報告を求めることができ

る。

（適合命令及び改善命令）

第三十二条　厚生労働大臣は、認定再生医療等委員会が第二十六条第四項各号に掲げる要件（当該認定再生医療等委員会が第三種再生医療等提供計画のみに係る審査等業務を行う場合にあっては、同項第一号（第三種再生医療等提供計画に係る部分を除く。）に掲げる要件を除く。）のいずれかに適合しなくなったと認めるときは、認定委員会設置者に対し、これらの要件に適合するために必要な措置をとるべきことを命ずることができる。

２　厚生労働大臣は、前項に定めるもののほか、認定委員会設置者がこの章の規定又はこの章の規定に基づく命令若しくは処分に違反していると認めるとき、その他当該認定再生医療等委員会の審査等業務の適切な実施を確保するため必要があると認めるときは、当該認定委員会設置者に対し、当該審査等業務を行う体制の改善、当該審査等業務に関する規程の変更その他必要な措置をとるべきことを命ずることができる。

（認定の取消し）

第三十三条　厚生労働大臣は、認定委員会設置者について、次の各号のいずれかに該当するときは、第二十

六条第一項の認定を取り消すことができる。

一　偽りその他不正の手段により第二十六条第一項の認定、第二十七条第一項の変更の認定又は第二十八条第二項の有効期間の更新を受けたとき。

二　その設置する認定再生医療等委員会が第二十六条第四項各号に掲げる要件（当該認定再生医療等委員会が第三種再生医療等提供計画のみに係る審査等業務を行う場合にあっては、同項第一号（第三種再生医療等提供計画に係る部分を除く。）に掲げる要件を除く。）のいずれかに適合しなくなったとき。

三　前二号に掲げるもののほか、この章の規定又はこの章の規定に基づく命令若しくは処分に違反したとき。

２　厚生労働大臣は、前項の規定により第二十六条第一項の認定を取り消したときは、その旨を公示しなければならない。

（厚生労働省令への委任）

第三十四条　この章に定めるもののほか、認定再生医療等委員会に関し必要な事項は、厚生労働省令で定める。

第四章　特定細胞加工物の製造

（特定細胞加工物の製造の許可）

第三十五条　特定細胞加工物の製造をしようとする者（第四十条第一項の規定に該当する者を除く。）は、厚生労働省令で定めるところにより、細胞培養加工施設ごとに、厚生労働大臣の許可を受けなければならない。

２　前項の許可を受けようとする者は、厚生労働省令で定めるところにより、次に掲げる事項を記載した申請書に細胞培養加工施設の構造設備に関する書類その他厚生労働省令で定める書類を添付して、厚生労働大臣に提出しなければならない。

一　氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

二　細胞培養加工施設の管理者の氏名及び略歴

三　製造をしようとする特定細胞加工物の種類

四　その他厚生労働省令で定める事項

３　厚生労働大臣は、第一項の許可の申請に係る細胞培養加工施設の構造設備が第四十二条の基準に適合し

ていないと認めるときは、同項の許可をしてはならない。

4　厚生労働大臣は、申請者が、次の各号のいずれかに該当するときは、第一項の許可をしないことができる。

一　第四十九条の規定により許可を取り消され、その取消しの日から三年を経過しない者（当該許可を取り消された者が法人である場合においては、当該取消しの処分に係る行政手続法（平成五年法律第八十八号）第十五条の規定による通知があった日前六十日以内に当該法人の役員（業務を執行する社員、取締役、執行役又はこれらに準ずる者をいい、相談役、顧問その他いかなる名称を有する者であるかを問わず、法人に対し業務を執行する社員、取締役、執行役又はこれらに準ずる者と同等以上の支配力を有するものと認められる者を含む。第四号において同じ。）であった者で当該取消しの日から三年を経過しないものを含む。）

二　禁錮以上の刑に処せられ、その執行を終わり、又は執行を受けることがなくなった日から三年を経過しない者

三　前二号に該当する者を除くほか、この法律、移植に用いる造血幹細胞の適切な提供の推進に関する法

律（平成二十四年法律第九十号）若しくは医薬品医療機器等法その他薬事に関する法令で政令で定めるもの又はこれらに基づく処分に違反し、その違反行為があった日から二年を経過しない者

四　法人であって、その業務を行う役員のうちに前三号のいずれかに該当する者があるもの

５　厚生労働大臣は、第一項の許可の申請があったときは、当該申請に係る細胞培養加工施設の構造設備が第四十二条の基準に適合するかどうかについての書面による調査又は実地の調査を行うものとする。

（許可の更新）

第三十六条　前条第一項の許可は、三年を下らない政令で定める期間ごとにその更新を受けなければ、その期間の経過によって、その効力を失う。

２　前条（第一項を除く。）の規定は、前項の許可の更新について準用する。

（変更の届出）

第三十七条　第三十五条第一項の許可を受けた者（以下「許可事業者」という。）は、当該許可に係る細胞培養加工施設について構造設備その他厚生労働省令で定める事項を変更したときは、三十日以内に、その旨を厚生労働大臣に届け出なければならない。

（機構による調査の実施）

第三十八条　厚生労働大臣は、独立行政法人医薬品医療機器総合機構（以下「機構」という。）に第三十五条第五項（第三十六条第二項において準用する場合を含む。）の調査（以下この条において単に「調査」という。）を行わせることができる。

２　厚生労働大臣は、前項の規定により機構に調査を行わせるときは、当該調査を行わないものとする。この場合において、厚生労働大臣は、第三十五条第一項の許可又は第三十六条第一項の許可の更新をするときは、機構が第四項の規定により通知する調査の結果を考慮しなければならない。

３　厚生労働大臣が第一項の規定により機構に調査を行わせることとしたときは、第三十五条第一項の許可又は第三十六条第一項の許可の更新の申請者は、機構が行う当該調査を受けなければならない。

４　機構は、調査を行ったときは、遅滞なく、当該調査の結果を厚生労働省令で定めるところにより厚生労働大臣に通知しなければならない。

５　機構が行う調査に係る処分（調査の結果を除く。）又はその不作為については、厚生労働大臣に対し、行政不服審査法（昭和三十七年法律第百六十号）による審査請求をすることができる。

（外国における特定細胞加工物の製造の認定）

第三十九条　外国において、本邦において行われる再生医療等に用いられる特定細胞加工物の製造をしようとする者は、厚生労働省令で定めるところにより、細胞培養加工施設ごとに、厚生労働大臣の認定を受けることができる。

２　第三十五条（第一項を除く。）及び前三条の規定は、前項の認定について準用する。この場合において、これらの規定中「許可」とあるのは、「認定」と読み替えるものとするほか、必要な技術的読替えは、政令で定める。

（特定細胞加工物の製造の届出）

第四十条　細胞培養加工施設（病院若しくは診療所に設置されるもの、医薬品医療機器等法第二十三条の二十二第一項の許可（厚生労働省令で定める区分に該当するものに限る。）を受けた製造所に該当するもの又は移植に用いる造血幹細胞の適切な提供の推進に関する法律第三十条の臍（さい）帯血供給事業の許可を受けた者が臍（さい）帯血供給事業の用に供するものに限る。以下この条において同じ。）において特定細胞加工物の製造をしようとする者は、厚生労働省令で定めるところにより、細胞培養加工施設ごとに、次に掲げる事項

を厚生労働大臣に届け出なければならない。

一　氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

二　細胞培養加工施設の管理者の氏名及び略歴

三　製造をしようとする特定細胞加工物の種類

四　その他厚生労働省令で定める事項

2　前項の規定による届出には、当該届出に係る細胞培養加工施設の構造設備に関する書類その他厚生労働省令で定める書類を添付しなければならない。

3　第一項の規定による届出をした者は、当該届出に係る細胞培養加工施設について構造設備その他厚生労働省令で定める事項を変更したときは、三十日以内に、その旨を厚生労働大臣に届け出なければならない。

（廃止の届出）

第四十一条　特定細胞加工物製造事業者は、特定細胞加工物の製造を廃止したときは、厚生労働省令で定めるところにより、三十日以内に、その旨を厚生労働大臣に届け出なければならない。

（構造設備の基準）

第四十二条　細胞培養加工施設の構造設備は、厚生労働省令で定める基準に適合したものでなければならない。

（管理者の設置）

第四十三条　特定細胞加工物製造事業者は、厚生労働省令で定めるところにより、特定細胞加工物の製造を実地に管理させるために、細胞培養加工施設ごとに、特定細胞加工物に係る生物学的知識を有する者その他の厚生労働省令で定める基準に該当する者を置かなければならない。

（特定細胞加工物製造事業者の遵守事項）

第四十四条　厚生労働大臣は、厚生労働省令で、細胞培養加工施設における特定細胞加工物の製造及び品質管理の方法、試験検査の実施方法、保管の方法並びに輸送の方法その他特定細胞加工物製造事業者がその業務に関し遵守すべき事項を定めることができる。

（特定細胞加工物の製造に関する記録及び保存）

第四十五条　特定細胞加工物製造事業者は、厚生労働省令で定めるところにより、製造をした特定細胞加工物の種類、当該製造の経過その他の厚生労働省令で定める事項に関する記録を作成し、これを保存しなけ

ればならない。

（厚生労働大臣への定期報告）

第四十六条　特定細胞加工物製造事業者は、特定細胞加工物の製造の状況について、厚生労働省令で定めるところにより、定期的に、厚生労働大臣に報告しなければならない。

（緊急命令）

第四十七条　厚生労働大臣は、特定細胞加工物の製造による保健衛生上の危害の発生又は拡大を防止するため必要があると認めるときは、特定細胞加工物の製造をする者に対し、当該特定細胞加工物の製造を一時停止することその他保健衛生上の危害の発生又は拡大を防止するための応急の措置をとるべきことを命ずることができる。

（改善命令等）

第四十八条　厚生労働大臣は、許可事業者又は第四十条第一項の規定による届出をした者（以下「届出事業者」という。）が設置する当該許可又は届出に係る細胞培養加工施設の構造設備が第四十二条の基準に適合していないときは、当該許可事業者又は届出事業者に対し、その構造設備の改善を命じ、又はその改善

を行うまでの間当該細胞培養加工施設の全部若しくは一部の使用を禁止することができる。

２　厚生労働大臣は、許可事業者又は届出事業者にこの章の規定又はこの章の規定に基づく命令若しくは処分に違反する行為があった場合において、再生医療等技術の安全性の確保等その他再生医療等の適正な提供のため必要があると認めるときは、当該許可事業者又は届出事業者に対し、その業務の運営の改善に必要な措置をとるべきことを命ずることができる。

（許可の取消し等）

第四十九条　厚生労働大臣は、許可事業者が次の各号のいずれかに該当するときは、その許可を取り消し、又は期間を定めて特定細胞加工物の製造の業務の全部若しくは一部の停止を命ずることができる。

一　当該許可に係る細胞培養加工施設の構造設備が第四十二条の基準に適合しなくなったとき。

二　第三十五条第四項各号のいずれかに該当するに至ったとき。

三　前二号に掲げる場合のほか、この法律、移植に用いる造血幹細胞の適切な提供の推進に関する法律若しくは医薬品医療機器等法その他薬事に関する法令で政令で定めるもの又はこれらに基づく処分に違反したとき。

（認定の取消し等）

第五十条　厚生労働大臣は、第三十九条第一項の認定を受けた者（以下この条において「認定事業者」という。）が次の各号のいずれかに該当するときは、その者が受けた同項の認定の全部又は一部を取り消すことができる。

一　厚生労働大臣が、必要があると認めて、当該認定事業者に対し、厚生労働省令で定めるところにより必要な報告を求めた場合において、その報告がされず、又は虚偽の報告がされたとき。

二　厚生労働大臣が、必要があると認めて、当該職員に、当該認定事業者の当該認定に係る細胞培養加工施設又は事務所においてその構造設備又は帳簿、書類その他の物件を検査させ、関係者に質問させようとした場合において、その検査が拒まれ、妨げられ、若しくは忌避され、又はその質問に対し、正当な理由なしに答弁がされず、若しくは虚偽の答弁がされたとき。

三　次項において準用する第四十八条の規定による請求に応じなかったとき。

四　この法律、移植に用いる造血幹細胞の適切な提供の推進に関する法律若しくは医薬品医療機器等法その他薬事に関する法令で政令で定めるもの又はこれらに基づく処分に違反したとき。

２　第四十八条の規定は、認定事業者について準用する。この場合において、同条第一項中「許可又は届出」とあるのは「認定」と、「命じ、又はその改善を行うまでの間当該細胞培養加工施設の全部若しくは一部の使用を禁止する」とあるのは「請求する」と、同条第二項中「命ずる」とあるのは「請求する」と読み替えるものとする。

３　厚生労働大臣は、機構に、第一項第二号の規定による検査又は質問を行わせることができる。この場合において、機構は、当該検査又は質問をしたときは、厚生労働省令で定めるところにより、当該検査又は質問の結果を厚生労働大臣に通知しなければならない。

（停止命令）

第五十一条　厚生労働大臣は、届出事業者が次の各号のいずれかに該当するときは、期間を定めて特定細胞加工物の製造の業務の全部又は一部の停止を命ずることができる。

一　当該届出に係る細胞培養加工施設の構造設備が第四十二条の基準に適合しなくなったとき。

二　第三十五条第四項各号のいずれかに該当するに至ったとき。

三　前二号に掲げる場合のほか、この法律、移植に用いる造血幹細胞の適切な提供の推進に関する法律若

しくは医薬品医療機器等法その他薬事に関する法令で政令で定めるもの又はこれらの規定に基づく処分に違反したとき。

（立入検査等）

第五十二条　厚生労働大臣は、許可事業者又は届出事業者が設置する当該許可又は届出に係る細胞培養加工施設の構造設備が第四十二条の基準に適合しているかどうかを確認するため必要があると認めるときは、当該許可事業者若しくは届出事業者に対し、必要な報告をさせ、又は当該職員に、当該細胞培養加工施設若しくは事務所に立ち入り、その構造設備若しくは帳簿、書類その他の物件を検査させ、若しくは関係者に質問させることができる。

２　厚生労働大臣は、前項に定めるもののほか、細胞培養加工施設においてこの章の規定若しくはこの章の規定に基づく命令若しくは処分に違反する特定細胞加工物の製造が行われていると認めるとき、又は再生医療等技術の安全性の確保等その他再生医療等の適正な提供のため必要があると認めるときは、特定細胞加工物の製造をする者に対し、必要な報告をさせ、又は当該職員に、細胞培養加工施設若しくは事務所に立ち入り、その構造設備若しくは帳簿、書類その他の物件を検査させ、若しくは関係者に質問させること

ができる。

３　第二十四条第三項の規定は前二項の規定による立入検査について、同条第四項の規定は前二項の規定による権限について準用する。

（機構による立入検査等の実施）

第五十三条　厚生労働大臣は、機構に、前条第一項又は第二項の規定による立入検査又は質問を行わせることができる。

２　機構は、前項の規定による立入検査又は質問をしたときは、厚生労働省令で定めるところにより、当該立入検査又は質問の結果を厚生労働大臣に通知しなければならない。

３　第一項の規定により機構の職員が立入検査又は質問をするときは、その身分を示す証明書を携帯し、関係者に提示しなければならない。

（厚生労働省令への委任）

第五十四条　この章に定めるもののほか、特定細胞加工物の製造に関し必要な手続その他の事項は、厚生労働省令で定める。

第五章　雑則

（厚生科学審議会の意見の聴取）

第五十五条　厚生労働大臣は、次に掲げる場合には、あらかじめ、厚生科学審議会の意見を聴かなければならない。

一　第二条第二項の政令の制定又は改廃の立案をしようとするとき。

二　第二条第五項又は第六項の厚生労働省令を制定し、又は改廃しようとするとき。

三　再生医療等提供基準を定め、又は変更しようとするとき。

四　第八条第一項（第十条第一項において準用する場合を含む。）の規定による命令をしようとするとき。

（権限の委任）

第五十六条　この法律に規定する厚生労働大臣の権限は、厚生労働省令で定めるところにより、地方厚生局長に委任することができる。

２　前項の規定により地方厚生局長に委任された権限は、厚生労働省令で定めるところにより、地方厚生支局長に委任することができる。

（手数料）

第五十七条　次の各号に掲げる者は、それぞれ当該各号の申請に対する審査に要する実費の額を考慮して政令で定める額の手数料を納めなければならない。

一　第三十六条第一項の許可の更新を申請する者

二　第三十九条第二項において準用する第三十六条第一項の認定の更新を申請する者

2　機構が行う第三十八条第一項（第三十九条第二項において準用する場合を含む。）の調査を受けようとする者は、当該調査に要する実費の額を考慮して政令で定める額の手数料を機構に納めなければならない。

3　前項の規定により機構に納められた手数料は、機構の収入とする。

（経過措置）

第五十八条　この法律の規定に基づき政令又は厚生労働省令を制定し、又は改廃する場合においては、それぞれ、政令又は厚生労働省令で、その制定又は改廃に伴い合理的に必要と判断される範囲内において、所要の経過措置（罰則に関する経過措置を含む。）を定めることができる。

第六章　罰則

第五十九条　第二十二条の規定による命令に違反した者は、三年以下の懲役若しくは三百万円以下の罰金に処し、又はこれを併科する。

第六十条　次の各号のいずれかに該当する者は、一年以下の懲役又は百万円以下の罰金に処する。

一　第四条第一項の規定に違反して、第一種再生医療等提供計画を提出せず、又はこれに記載すべき事項を記載せず、若しくは虚偽の記載をしてこれを提出して、第一種再生医療等を提供した者

二　第五条第一項の規定に違反して、変更後の第一種再生医療等提供計画を提出せず、又はこれに記載すべき事項を記載せず、若しくは虚偽の記載をしてこれを提出して、第一種再生医療等を提供した者

三　第八条第一項（第十条第一項において準用する場合を含む。）の規定による命令に違反した者

四　第九条（第十条第一項において準用する場合を含む。）の規定に違反した者

五　第十三条の規定に違反して第一種再生医療等を行った者

六　第二十三条第二項（第一種再生医療等に係る部分に限る。）の規定による命令に違反した者

七　第二十九条の規定に違反して秘密を漏らした者

第六十一条　次の各号のいずれかに該当する者は、六月以下の懲役又は三十万円以下の罰金に処する。

一　第三十五条第一項の規定に違反して許可を受けないで特定細胞加工物の製造をした者

二　第四十七条の規定による命令に違反した者

三　第四十八条第一項の規定による細胞培養加工施設の使用禁止の処分に違反した者（許可事業者に限る。）

四　第四十八条第二項の規定による命令に違反した者（許可事業者に限る。）

五　第四十九条の規定による命令に違反した者

第六十二条　次の各号のいずれかに該当する者は、五十万円以下の罰金に処する。

一　第四条第一項の規定に違反して、再生医療等提供計画を提出せず、又はこれに記載すべき事項を記載せず、若しくは虚偽の記載をしてこれを提出して、再生医療等を提供した者（第六十条第一号の規定に該当する者を除く。）

二　第五条第一項の規定に違反して、変更後の再生医療等提供計画を提出せず、又はこれに記載すべき事項を記載せず、若しくは虚偽の記載をしてこれを提出して、再生医療等を提供した者（第六十条第二号の規定に該当する者を除く。）

三　第十三条の規定に違反して再生医療等を行った者（第六十条第五号の規定に該当する者を除く。）

四　第十六条第一項の規定に違反して記録を作成せず、又は虚偽の記録を作成した者

五　第十六条第二項の規定に違反して記録を保存しなかった者

六　第二十三条第二項（第一種再生医療等に係る部分を除く。）の規定による命令に違反した者

七　第二十四条第一項若しくは第二項の報告をせず、若しくは虚偽の報告をし、同条第一項若しくは第二項の規定による立入検査を拒み、妨げ、若しくは忌避し、又は同条第一項若しくは第二項の規定による質問に対し、正当な理由なしに答弁せず、若しくは虚偽の答弁をした者

第六十三条　次の各号のいずれかに該当する者は、二十万円以下の罰金に処する。

一　第四十条第一項の規定に違反して、届出をしないで、又は虚偽の届出をして、特定細胞加工物の製造をした者

二　第四十八条第一項の規定による細胞培養加工施設の使用禁止の処分に違反した者（許可事業者を除く。）

三　第四十八条第二項の規定による命令に違反した者（許可事業者を除く。）

四　第五十一条の規定による命令に違反した者

五　第五十二条第一項若しくは第二項の報告をせず、若しくは虚偽の報告をし、同条第一項若しくは第二項の規定による立入検査（第五十三条第一項の規定により機構が行うものを含む。）を拒み、妨げ、若しくは忌避し、又は第五十二条第一項若しくは第二項の規定による質問（第五十三条第一項の規定により機構が行うものを含む。）に対し、正当な理由なしに答弁せず、若しくは虚偽の答弁をした者

第六十四条　法人の代表者又は法人若しくは人の代理人、使用人その他の従業者が、その法人又は人の業務に関して第五十九条、第六十条（第七号を除く。）又は前三条の違反行為をしたときは、行為者を罰するほか、その法人又は人に対しても各本条の罰金刑を科する。

附　則

（施行期日）

第一条　この法律は、薬事法等の一部を改正する法律（平成二十五年法律第八十四号）の施行の日から施行する。ただし、附則第六条から第十条まで及び第十三条の規定は、公布の日から施行する。

（検討）

第二条　政府は、この法律の施行後五年以内に、この法律の施行の状況、再生医療等を取り巻く状況の変化等を勘案し、この法律の規定に検討を加え、必要があると認めるときは、その結果に基づいて所要の措置を講ずるものとする。

（経過措置）

第三条　この法律の施行の際現に再生医療等を提供している病院又は診療所が提供する当該再生医療等については、この法律の施行の日（以下「施行日」という。）から起算して一年を経過する日までの間（当該期間内に第四条第一項の規定による当該再生医療等が記載された再生医療等提供計画の提出があったときは、当該提出の日までの間）は、第三条第三項、第四条第一項及び第十三条の規定は適用せず、第十五条及び第十六条第二項の規定の適用については、これらの規定中「再生医療等提供機関」とあるのは、「再生医療等を提供する病院又は診療所」とする。

２　この法律の施行の際現に第一種再生医療等を提供している病院又は診療所が提供する当該第一種再生医療等であって、施行日から起算して一年を経過する日までの間に第四条第一項の規定により提出された第一種再生医療等提供計画に記載されたものについては、第九条及び第十三条（第二号に係る部分に限る。

）の規定は、適用しない。

第四条　この法律の施行の際現に特定細胞加工物の製造をしている者（第四十条第一項の規定に該当する者を除く。）については、施行日から起算して六月を経過する日までの間（その者が当該期間内に第三十五条第一項の許可の申請をした場合において、当該期間内に許可の拒否の処分があったときは当該処分のあった日までの間、当該期間を経過したときは当該申請について許可又は許可の拒否の処分があるまでの間）は、同項の許可を受けないで、引き続き特定細胞加工物の製造をすることができる。

第五条　この法律の施行の際現に特定細胞加工物の製造をしている者（第四十条第一項の規定に該当する者に限る。）については、施行日から起算して六月を経過する日までの間は、同項の規定による届出をしないで、引き続き特定細胞加工物の製造をすることができる。

（施行前の準備）

第六条　厚生労働大臣は、第五十五条第一号から第三号までに掲げる場合には、施行日前においても、厚生科学審議会の意見を聴くことができる。

第七条　第二十六条第一項の認定を受けようとする者は、施行日前においても、同条第二項及び第三項の規

定の例により、その認定の申請をすることができる。

２　厚生労働大臣は、前項の規定による認定の申請があった場合には、施行日前においても、第二十六条第四項及び第五項の規定の例により、その認定及び公示をすることができる。この場合において、その認定を受けた者は施行日において同条第一項の認定を受けたものと、その公示は施行日において同条第五項の規定によりした公示とみなす。

第八条　第三十五条第一項の許可を受けようとする者は、施行日前においても、同条第二項の規定の例により、その許可の申請をすることができる。

２　厚生労働大臣は、前項の規定による許可の申請があった場合には、施行日前においても、第三十五条第三項から第五項までの規定の例により、その許可をすることができる。この場合において、その許可を受けた者は、施行日において同条第一項の許可を受けたものとみなす。

３　第三十九条第一項の認定を受けようとする者は、施行日前においても、同条第二項において準用する第三十五条第二項の規定の例により、その認定の申請をすることができる。

４　厚生労働大臣は、前項の規定による認定の申請があった場合には、施行日前においても、第三十九条第

二項において準用する第三十五条第三項から第五項までの規定の例により、その認定をすることができる。この場合において、その認定を受けた者は、施行日において第三十九条第一項の認定を受けたものとみなす。

5　特定細胞加工物の製造をしようとする者（第四十条第一項の規定に該当する者に限る。）は、施行日前においても、同項及び同条第二項の規定の例により厚生労働大臣に届け出ることができる。この場合において、その届出をした者は、施行日において同条第一項の規定による届出をしたものとみなす。

（登録免許税法の一部改正）

第九条　登録免許税法（昭和四十二年法律第三十五号）の一部を次のように改正する。

別表第一第七十七号の次に次のように加える。

七十七の二　特定細胞加工物の製造の許可又は外国における特定細胞加工物の製造の認定		
㈠　再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）第三十五条第一項（特定細胞加工物の製造の許可）の特定細胞加工物の製造の許可（更新の許可を除く。）	許可件数	一件につき九万円

㈡　再生医療等の安全性の確保等に関する法律第三十九条第一項（外国における特定細胞加工物の製造の認定）の外国における特定細胞加工物の製造の認定（更新の認定を除く。）	認定件数	一件につき九万円

（登録免許税法の一部改正に伴う経過措置）

第十条　この法律の公布の日から施行日の前日までの間に受ける前条の規定による改正後の登録免許税法別表第一第七十七号の二(一)に掲げる許可及び同号(二)に掲げる認定に係る同号の規定の適用については、同号(一)中「第三十五条第一項（特定細胞加工物の製造の許可）の特定細胞加工物の製造の許可（更新の許可を除く。）」とあるのは「附則第八条第二項前段（施行前の準備）の許可」と、同号(二)中「第三十九条第一項（外国における特定細胞加工物の製造の認定）の外国における特定細胞加工物の製造の認定（更新の認定を除く。）」とあるのは「附則第八条第四項前段の認定」とする。

（独立行政法人医薬品医療機器総合機構法の一部改正）

第十一条　独立行政法人医薬品医療機器総合機構法（平成十四年法律第百九十二号）の一部を次のように改正する。

第六条中「及び同条第二項」を「並びに同条第二項第一号及び第二号」に改める。

第十五条第一項に次の一号を加える。

七　再生医療等（再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）第二条第一項に規定する再生医療等をいう。）に関する次に掲げる業務

イ　再生医療等の安全性の確保等に関する法律第三十八条第一項（同法第三十九条第二項において準用する場合を含む。）の調査を行うこと。

ロ　イに掲げる業務に附帯する業務を行うこと。

第十五条第二項に次の一号を加える。

三　再生医療等の安全性の確保等に関する法律第五十三条第一項の規定による立入検査及び質問

第二十九条第一項第三号中「第十五条第一項第六号」の下に「及び第七号」を加える。

（厚生労働省設置法の一部改正）

第十二条　厚生労働省設置法（平成十一年法律第九十七号）の一部を次のように改正する。

第八条第一項第四号中「感染症の予防及び感染症の患者に対する医療に関する法律」を「再生医療等の

安全性の確保等に関する法律（平成二十五年法律第八十五号）、感染症の予防及び感染症の患者に対する医療に関する法律」に改める。

（政令への委任）

第十三条　この附則に規定するもののほか、この法律の施行に関し必要な経過措置は、政令で定める。

○厚生労働省令第百十号

再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）第二条第五項及び第六項、第三条第一項及び第二項第四号、第四条第一項及び第三項第二号（同法第五条第二項において準用する場合を含む。）、第五条第一項及び第三項、第六条、第十四条第一項及び第二項、第十六条第一項及び第二項、第十七条第一項、第十八条、第二十条第一項、第二十一条第一項、第二十五条、第二十六条第一項及び第二項、第三項第三号並びに第四項（これらの規定を同法第二十七条第三項及び第二十八条第六項において準用する場合を含む。）、第二十七条第一項ただし書、第二項及び第四項、第三十条第一項、第三十四条、第三十五条第一項及び第二項（同法第三十六条第二項及び第三十九条第二項において準用する場合を含む。）、第三十七条及び第三十八条第四項（これらの規定を同法第三十九条第二項において準用する場合を含む。）、第三十九条第一項、第四十条第一項から第三項、第四十一条、第四十二条、第四十三条、第四十四条、第四十五条、第四十六条、第五十条第一項第一号及び第三項、第五十三条第二項、第五十四条並びに第五十六条第一項の規定に基づき、再生医療等の安全性の確保等に関する法律施行規則を次のように定める。

平成二十六年九月二十六日

再生医療等の安全性の確保等に関する法律施行規則

厚生労働大臣　塩崎　恭久

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第一章　総則

（用語の定義）

第一条　この省令において、次の各号に掲げる用語の定義は、それぞれ当該各号に定めるところによる。

一　「幹細胞」とは、自己複製能（自己と同一の能力を有する細胞を複製する能力をいう。）及び多分化能（異なる系列の細胞に分化する能力をいう。）を有する細胞をいう。

二　「人工多能性幹細胞」とは、人工的に多能性（内胚葉、中胚葉及び外胚葉の細胞に分化する性質をいう。）を誘導された幹細胞をいう。

三　「人工多能性幹細胞様細胞」とは、前号以外の細胞であって人工多能性幹細胞と類似の性質を有する細胞をいう。

四　「相同利用」とは、採取した細胞が再生医療等（再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号。以下「法」という。）第二条第一項に規定する再生医療等をいう。以下同じ。）を受ける者の再生医療等の対象となる部位の細胞と同様の機能を持つ細胞の投与方法をいう。

五　「細胞提供者」とは、再生医療等に用いる細胞（再生医療等製品（医薬品、医療機器等の品質、有効

性及び安全性の確保等に関する法律（昭和三十五年法律第百四十五号。以下「医薬品医療機器等法」という。）第二十三条の二十五又は第二十三条の三十七の承認を受けた再生医療等製品をいう。以下同じ。）の構成細胞を除く。以下同じ。）が人の受精胚（はい）である場合には当該受精胚（はい）を作製する人の精子（再生医療等の安全性の確保等に関する法律施行令（平成二十六年政令第二百七十八号。以下「施行令」という。）第一条第三号に規定する人の精子をいう。）を提供する男性及び人の未受精卵（施行令第一条第三号に規定する未受精卵をいう。）を提供する女性並びに再生医療等に用いる細胞が人の受精胚（はい）以外の人の細胞である場合には当該細胞を採取される者をいう。

六　「代諾者」とは、細胞を採取される者又は再生医療等の提供を受ける者の親権を行う者、配偶者、後見人その他これらに準じる者をいう。

七　「提供機関管理者」とは、再生医療等提供機関（法第六条に規定する再生医療等提供機関をいう。以下同じ。）の管理者をいう。

八　「施設管理者」とは、法第四十三条に規定する者をいう。

九　「資材」とは、特定細胞加工物（法第二条第四項に規定する特定細胞加工物をいう。以下同じ。）の

容器、被包及び表示物をいう。

十　「作業所」とは、製造作業を行う場所をいう。

十一　「ロット」とは、一の製造期間内に一連の製造工程により均質性を有するように製造された特定細胞加工物及び原料（以下「特定細胞加工物等」という。）の一群をいう。

十二　「管理単位」とは、同一性が確認された資材の一群をいう。

十三　「清浄度管理区域」とは、作業所のうち、特定細胞加工物等（無菌操作により取り扱う必要のあるものを除く。）の調製作業を行う場所及び滅菌される前の容器等が作業所内の空気に触れる場所をいう。

十四　「無菌操作等区域」とは、作業所のうち、無菌操作により取り扱う必要がある特定細胞加工物等の調製作業を行う場所、滅菌された容器等が作業所内の空気に触れる場所及び無菌試験等の無菌操作を行う場所をいう。

十五　「ドナー動物」とは、再生医療等に用いる細胞を提供する動物をいう。

十六　「照査」とは、設定された目標を達成する上での妥当性及び適切性を判定することをいう。

（第一種再生医療等技術）

第二条　法第二条第五項の厚生労働省令で定める再生医療等技術は、次のいずれかに該当する医療技術とする。

一　人の胚（はい）性幹細胞、人工多能性幹細胞又は人工多能性幹細胞様細胞に培養その他の加工を施したものを用いる医療技術

二　遺伝子を導入する操作を行った細胞又は当該細胞に培養その他の加工を施したものを用いる医療技術（前号に掲げるものを除く。）

三　動物の細胞に培養その他の加工を施したものを用いる医療技術（前二号に掲げるものを除く。）

四　投与を受ける者以外の人の細胞に培養その他の加工を施したものを用いる医療技術（前三号に掲げるものを除く。）

（第二種再生医療等技術）

第三条　法第二条第六項の厚生労働省令で定める再生医療等技術は、前条各号に掲げる医療技術以外であって、次のいずれかに該当する医療技術とする。

一　培養した幹細胞又は当該細胞に培養その他の加工を施したものを用いる医療技術

二　培養した細胞又は当該細胞に培養その他の加工を施したものを用いる医療技術のうち人の身体の構造又は機能の再建、修復又は形成を目的とする医療技術（前号に掲げるものを除く。）

三　細胞の相同利用ではない医療技術（前二号に掲げるものを除く。）

第二章　再生医療等の提供

第一節　再生医療等提供基準

（再生医療等提供基準）

第四条　法第三条第一項の厚生労働省令で定める再生医療等の提供に関する基準（以下「再生医療等提供基準」という。）は、次条から第二十六条までに定めるところによる。

（人員）

第五条　第一種再生医療等（法第二条第五項に規定する第一種再生医療等をいう。以下同じ。）又は第二種再生医療等（法第二条第六項に規定する第二種再生医療等をいう。以下同じ。）の提供を行う再生医療等提供機関は、当該第一種再生医療等又は第二種再生医療等に関する業務の実施を統括するため、当該業務に係る責任者（以下「実施責任者」という。）を置かなければならない。

２　実施責任者は、医師又は歯科医師であって、実施する第一種再生医療等又は第二種再生医療等の対象となる疾患及び当該疾患に関連する分野について、十分な科学的知見並びに医療に関する経験及び知識を有していなければならない。

３　第一種再生医療等又は第二種再生医療等を共同研究として行う再生医療等提供機関は、当該共同研究として行う再生医療等に係る業務を統括するため、共同研究を行う再生医療等提供機関の実施責任者の中から、統括責任者を選任しなければならない。

（構造設備その他の施設）

第六条　第一種再生医療等又は第二種再生医療等に係る再生医療等提供機関は、当該再生医療等提供機関において再生医療等を受ける者に対し、救急医療に必要な施設又は設備を有していなければならない。ただし、他の医療機関（医療法（昭和二十三年法律第二百五号）第一条の五第一項に規定する病院又は同条第二項に規定する診療所をいう。以下同じ。）と連携することにより、当該者に対し、救急医療を行うために必要な体制があらかじめ確保されている場合には、この限りでない。

（細胞の入手）

第七条　再生医療等を行う医師又は歯科医師は、再生医療等に用いる細胞が、次に掲げる要件を満たすことを確認し、必要に応じ検査等を行い、当該細胞を再生医療等に用いることが適切であることを確認しなければならない。

一　次に掲げる要件を満たした医療機関等において細胞の提供（細胞提供者からの細胞の提供に限る。以下同じ。）又は動物の細胞の採取が行われたこと。

イ　適切に細胞の提供を受け又は動物の細胞の採取をし、当該細胞の保管に当たり必要な管理を行っていること。

ロ　細胞の提供を受けること又は動物の細胞の採取をすること並びに当該細胞の保管に関する十分な知識及び技術を有する者を有していること。

二　細胞の提供を受ける際に、細胞提供者の健康状態、年齢その他の事情を考慮した上で、当該細胞提供者の選定がなされたこと。

三　細胞の提供を受ける際に、細胞提供者が細胞の提供を行うのに十分な適格性を有するかどうかの判定をするために、利用の目的に応じて、既往歴の確認、診察、検査等を行ったこと。

四　細胞の提供を受けた後に、感染症の感染後、検査をしても感染を証明できない期間があることを勘案し、検査方法、検査項目等に応じて、可能な範囲で、適切な時期に再検査を実施していること。

五　死亡した者から細胞を採取する場合にあっては、礼意を失わないように注意し、遺族に対して、細胞の使途その他細胞の採取に関し必要な事項について、できる限り平易な表現を用い、文書により適切な説明を行い、文書により同意を得ていること。

六　細胞の提供を受ける際に、細胞提供者に対し、次に掲げる事項について、できる限り平易な表現を用い、文書により適切な説明を行い、文書により同意を得ていること。

イ　当該細胞の使途

ロ　当該細胞の提供により予期される危険及び不利益

ハ　細胞提供者となることは任意であること。

ニ　同意の撤回に関する事項

ホ　当該細胞の提供をしないこと又は当該細胞の提供に係る同意を撤回することにより不利益な取扱いを受けないこと。

ヘ　当該細胞の提供に係る費用に関する事項

ト　当該細胞の提供による健康被害に対する補償に関する事項

チ　細胞提供者の個人情報の保護に関する事項

リ　当該細胞を用いる再生医療等に係る特許権、著作権その他の財産権又は経済的利益の帰属に関する事項

ヌ　その他当該細胞を用いる再生医療等の内容に応じ必要な事項

七　細胞の提供を受ける際に、細胞提供者の代諾者の同意を得る場合にあっては、当該代諾者に対し、次に掲げる事項について、できる限り平易な表現を用い、文書により適切な説明を行い、文書により同意を得ていること。

イ　当該細胞の使途

ロ　当該細胞の提供により予期される危険及び不利益

ハ　代諾者となることは任意であること。

ニ　代諾者の同意の撤回に関する事項

ホ　代諾者の同意を行わないこと又は代諾者の同意を撤回することにより不利益な取扱いを受けないこと。

ヘ　当該細胞の提供に係る費用に関する事項

ト　当該細胞の提供による健康被害に対する補償に関する事項

チ　細胞提供者及び代諾者の個人情報の保護に関する事項

リ　当該細胞を用いる再生医療等に係る特許権、著作権その他の財産権又は経済的利益の帰属に関する事項

ヌ　その他当該細胞を用いる再生医療等の内容に応じ必要な事項

八　細胞の提供を受ける際に、代諾者の同意を得た場合には、代諾者の同意に関する記録及び代諾者と細胞提供者との関係についての記録が作成されていること。

九　細胞提供者が当該細胞を再生医療等に用いることについて同意した場合であって、当該細胞に培養その他の加工が行われるまでの間について、当該細胞提供者が同意を撤回することができる機会が確保されていること。

十　人の受精胚の提供を受ける場合にあっては、当該細胞の提供に係る同意があった後、少なくとも三十日間は人の胚性幹細胞の樹立に供することなく医療機関において当該細胞を保管し、細胞提供者に対し、当該者が同意を撤回することができる機会が確保されていること。

十一　人の受精胚の提供を受ける場合にあっては、次に掲げる要件を満たしたものであること。

イ　生殖補助医療に用いる目的で作成された受精胚であって、当面当該目的に用いる予定がないもののうち、当該受精胚を滅失させることについて提供者の意思が確認できたものであること。

ロ　凍結保管がされているものであること。

ハ　凍結保管されている期間を除き、受精後十四日以内のものであること。

ニ　その他人の胚性幹細胞の樹立の適正な実施のために必要な手続を経たものであること。

十二　細胞の提供が無償で行われたこと。ただし、細胞の提供に際し発生した交通費その他の実費に相当するものについてはこの限りでない。

十三　細胞の提供を受ける際に、その過程における微生物等による汚染を防ぐために必要な措置が講じられていること。

十四　細胞の提供を受けた当該細胞について、微生物等による汚染及び微生物等の存在に関する適切な検査を行い、これらが検出されないことを、必要に応じ、確認したものであること。

十五　細胞の採取を行う場合にあっては、細胞の採取を優先し、医学的処置、手術及びその他の治療の方針を変更することにより採取された細胞でないこと。

十六　動物の細胞を用いる場合にあっては、細胞の採取に当たり、次に掲げる要件を満たしていること。

イ　細胞を採取される動物の状態その他の事情を考慮した上で、当該動物の選定がなされたこと。

ロ　細胞の採取の際に、当該動物が細胞を採取されるにつき十分な適格性を有するかどうかの判定をするために、利用の目的に応じて既往歴の確認、診察、検査等を行ったこと。

ハ　動物の細胞の採取の過程における微生物等における汚染を防ぐために必要な措置が講じられていること。

（特定細胞加工物の製造及び品質管理の方法）

第八条　提供機関管理者は、再生医療等に特定細胞加工物を用いる場合においては、当該特定細胞加工物の名称、構成細胞及び製造方法等を記載した特定細胞加工物概要書（以下「特定細胞加工物概要書」という。

）を作成しなければならない。

２　提供機関管理者は、再生医療等に特定細胞加工物を用いる場合においては、特定細胞加工物製造事業者に、法第四十四条に規定する特定細胞加工物製造事業者の業務に関し遵守すべき事項に従って細胞培養加工施設における特定細胞加工物の製造及び品質管理を行わせなければならない。

（再生医療等を行う医師又は歯科医師の要件）

第九条　再生医療等を行う医師又は歯科医師は、当該再生医療等を行うために必要な専門的知識及び十分な臨床経験を有する者でなければならない。

（再生医療等を行う際の責務）

第十条　医師又は歯科医師は、再生医療等を行う際には、その安全性及び妥当性について、科学的文献その他の関連する情報又は十分な実験の結果に基づき、倫理的及び科学的観点から十分検討しなければならない。

２　医師又は歯科医師は、再生医療等に特定細胞加工物を用いる場合においては、特定細胞加工物製造事業者に特定細胞加工物の製造を行わせる際に、特定細胞加工物概要書に従った製造が行われるよう、必要な

指示をしなければならない。

3　医師又は歯科医師は、再生医療等に特定細胞加工物を用いる場合においては、再生医療等を受ける者に対し、特定細胞加工物の投与を行う際に、当該特定細胞加工物が特定細胞加工物概要書に従って製造されたものか確認する等により、当該特定細胞加工物の投与の可否について決定しなければならない。

（再生医療等を行う際の環境への配慮）

第十一条　医師又は歯科医師は、環境に影響を及ぼすおそれのある再生医療等を行う場合には、環境へ悪影響を及ぼさないよう必要な配慮をしなければならない。

（再生医療等を受ける者の選定）

第十二条　医師又は歯科医師は、研究として再生医療等を行う際には、病状、年齢その他の事情を考慮した上で、再生医療等を受けることとなる者の選定をしなければならない。

（再生医療等を受ける者に対する説明及び同意）

第十三条　再生医療等を行う医師又は歯科医師は、再生医療等を受ける者に対し、当該再生医療等について、文書により同意を得なければならない。

２　再生医療等を行う医師又は歯科医師は、前項の同意を得るに際し、次に掲げる事項について、できる限り平易な表現を用い、文書により再生医療等を受ける者に説明を行わなければならない。

一　提供される再生医療等の内容

二　当該再生医療等の実施により予期される効果及び危険

三　他の治療法の有無、内容、他の治療法により予期される効果及び危険との比較

四　再生医療等を受けることを拒否することは任意であること。

五　再生医療等を受けることを拒否すること又は同意を撤回することにより不利益な取扱いを受けないこと。

六　同意の撤回に関する事項

七　当該再生医療等の実施による健康被害に対する補償に関する事項（研究として行われる再生医療等に係るものに限る。）

八　再生医療等を受ける者の個人情報の保護に関する事項

九　当該再生医療等の実施に係る費用に関する事項

十　その他当該再生医療等の提供に関し必要な事項

（再生医療等を受ける者の代諾者に対する説明及び同意）

第十四条　再生医療等を受ける者の代諾者に対する説明及び同意については前条の規定を準用する。この場合において、同条中「再生医療等を受ける者に」とあるのは「代諾者に」と、「再生医療等を受けること」とあるのは「代諾者の同意」と、「再生医療等を受ける者の個人情報」とあるのは「再生医療等を受ける者及び代諾者の個人情報」と読み替えるものとする。

２　再生医療等を行う医師又は歯科医師は、再生医療等を受ける者の代諾者の同意を得た場合には、代諾者の同意に関する記録及び代諾者と再生医療等を受ける者との関係についての記録を作成しなければならない。

（細胞の安全性に関する疑義が生じた場合の措置）

第十五条　再生医療等を行う医師又は歯科医師は、細胞提供者又は細胞を採取した動物の遅発性感染症の発症の疑いその他の当該細胞の安全性に関する疑義が生じたことを知った場合には、再生医療等の安全性の確保等を図るために必要な措置をとらなければならない。

（試料の保管）

第十六条　提供機関管理者は、再生医療等を受ける者が感染症を発症した場合等の原因の究明のため、細胞提供者又は細胞を採取した動物の細胞の一部等の適当な試料について、採取を行った日から一定期間保存しなければならない。ただし、保存しないこと又は保存できないことについて、採取した細胞が微量である場合その他合理的な理由がある場合には、この限りでない。

２　提供機関管理者は、再生医療等を受ける者が感染症を発症した場合等の原因の究明のため、当該再生医療等に用いた細胞加工物の一部について、再生医療等を行った日から一定期間保存しなければならない。ただし、保存しないこと又は保存できないことについて、細胞加工物が微量である場合その他合理的な理由がある場合には、この限りでない。

（疾病等の発生の場合の措置）

第十七条　再生医療等を行う医師又は歯科医師は、再生医療等の提供によるものと疑われる疾病、障害、若しくは死亡又は感染症の発生（以下「疾病等の発生」という。）を知ったときは、次の各号に掲げる場合の区分に応じ、当該各号に定める者に対し、速やかにその旨を報告しなければならない。

一　第一種再生医療等又は第二種再生医療等を行っている場合（次号に掲げる場合を除く。）　提供機関管理者及び実施責任者

二　第一種再生医療等又は第二種再生医療等を共同研究として行っている場合　提供機関管理者、実施責任者及び統括責任者

三　前二号に掲げる場合以外の場合　提供機関管理者

2　前項第三号に掲げる場合であって、再生医療等を共同研究として行っているときは、前項の報告を受けた提供機関管理者は、当該報告の内容を共同研究を行っている他の提供機関管理者に報告しなければならない。

3　前二項の報告を受けた提供機関管理者、実施責任者又は統括責任者は、当該再生医療等を行う医師又は歯科医師に対し、当該再生医療等の中止その他の必要な措置を講ずるよう指示しなければならない。

4　第一項又は第二項の報告を受けた提供機関管理者、実施責任者又は統括責任者は、次の各号に掲げる場合の区分に応じ、当該各号に定める者に対し、発生した事態及び講じた措置について速やかに通知しなければならない。

一　特定細胞加工物を用いた再生医療等を行っていた場合　当該再生医療等に用いる特定細胞加工物を製造した特定細胞加工物製造事業者

二　再生医療等製品を用いた再生医療等を行っていた場合　当該再生医療等に用いる再生医療等製品の製造販売業者（当該再生医療等製品が医薬品医療機器等法第二十三条の三十七第一項の承認を受けている場合にあっては、同条第四項に規定する選任外国製造再生医療等製品製造販売業者）

（再生医療等の提供終了後の措置等）

第十八条　再生医療等を行う医師又は歯科医師は、再生医療等の提供を終了した後においても、安全性及び科学的妥当性の確保の観点から、再生医療等の提供による疾病等の発生についての適当な期間の追跡調査、効果についての検証その他の必要な措置を講ずるよう努めなければならない。また、その結果については、前条第一項各号に掲げる場合の区分に応じ、当該各号に定める者に対し、報告しなければならない。

（再生医療等を受ける者に関する情報の把握）

第十九条　再生医療等を行う医師又は歯科医師は、再生医療等の提供に起因するものと疑われる疾病等の発生の場合に当該疾病等の情報を把握できるよう、及び細胞加工物に問題が生じた場合に再生医療等を受け

た者の健康状態等が把握できるよう、あらかじめ適切な措置を講じなければならない。

（実施状況の確認）

第二十条　次の各号に掲げる場合の区分に応じて当該各号に定める者は、再生医療等が再生医療等提供計画（法第四条第一項に規定する再生医療等提供計画をいう。以下同じ。）及び再生医療等提供基準に従い、適正に実施されていることを随時確認するとともに、再生医療等の適正な実施を確保するために必要な指示をしなければならない。

一　第一種再生医療等又は第二種再生医療等を行っている場合（次号に掲げる場合を除く。）　提供機関管理者及び実施責任者

二　第一種再生医療等又は第二種再生医療等を共同研究として行っている場合　提供機関管理者、実施責任者及び統括責任者

三　前二号に掲げる場合以外の場合　提供機関管理者

２　実施責任者は、提供機関管理者に対して、再生医療等の提供の状況について、随時報告しなければならない。

（再生医療等を受ける者に対する健康被害の補償を行う場合）

第二十一条　法第三条第二項第四号の厚生労働省令で定める場合は、研究として行われる場合とする。

（細胞提供者等に対する補償）

第二十二条　提供機関管理者又は再生医療等に用いる細胞の提供を受ける者は、細胞提供者が再生医療等を受ける者以外の者である場合には、当該細胞の提供に伴い生じた健康被害の補償のために、保険への加入その他の必要な措置を講じておかなければならない。

２　提供機関管理者は、再生医療等（研究として行われる場合に限る。）の実施に当たっては、当該再生医療等の実施に伴い生じた健康被害の補償のために、保険への加入その他の必要な措置を講じておかなければならない。

（細胞提供者等に関する個人情報の取扱い）

第二十三条　細胞提供者及び再生医療等を受ける者に関する個人情報を保有する者は、当該個人情報について匿名化を行う場合にあっては、連結可能匿名化（必要な場合に特定の個人を識別できる情報を保有しつつ行う匿名化をいう。）した上で、当該個人情報を取り扱わなければならない。

（個人情報の保護）

第二十四条　提供機関管理者は、個人情報の適正な取扱いの方法を具体的に定めた実施規程（以下「個人情報取扱実施規程」という。）を定めなければならない。

（教育又は研修）

第二十五条　提供機関管理者又は実施責任者は、再生医療等を適正に実施するために定期的に教育又は研修の機会を確保しなければならない。

２　再生医療等を行う医師又は歯科医師その他の再生医療等の提供に係る関係者は、再生医療等を適正に実施するために定期的に適切な教育又は研修を受け、情報収集に努めなければならない。

（苦情及び問合せへの対応）

第二十六条　提供機関管理者は、苦情及び問合せに適切かつ迅速に対応するため、苦情及び問合せを受け付けるための窓口の設置、苦情及び問合せの対応の手順の策定その他の必要な体制の整備に努めなければならない。

第二節　再生医療等提供計画

（再生医療等提供計画の提出）

第二十七条　法第四条第一項の規定による提出は、様式第一による計画を提出して行うものとする。

２　前項の提出を行ったときは、速やかにその旨を当該再生医療等提供計画に記載された認定再生医療等委員会（法第二十六条第五項第二号に規定する認定再生医療等委員会をいう。以下同じ。）に通知しなければならない。

３　法第四条第一項の厚生労働省令で定める再生医療等の区分は、再生医療等技術の区分とする。

４　法第四条第一項第六号の厚生労働省令で定める場合は、研究として行われる場合とする。

５　法第四条第一項第八号の厚生労働省令で定める事項は、次に掲げる事項とする。

一　共同研究機関（共同研究として再生医療等を行う再生医療等提供機関をいう。）に関する事項

二　再生医療等製品を用いる場合にあっては、再生医療等製品に関する事項

三　審査等業務（法第二十六条第一項に規定する審査等業務をいう。以下同じ。）を行う認定再生医療等委員会の認定番号

四　細胞提供者及び再生医療等を受ける者に関する個人情報の取扱いの方法

五　教育又は研修の方法

六　苦情及び問合せへの対応に関する体制の整備状況

6　法第四条第三項第二号（法第五条第二項において準用する場合を含む。）の厚生労働省令で定める書類は、次に掲げる書類とする。

一　提供する再生医療等の詳細を記した書類

二　実施責任者及び再生医療等を行う医師又は歯科医師の氏名、所属、役職及び略歴（研究に関する実績がある場合には、当該実績を含む。）を記載した書類

三　再生医療等に用いる細胞の提供を受ける場合にあっては、細胞提供者又は代諾者に対する説明文書及び同意文書の様式

四　再生医療等を受ける者に対する説明文書及び同意文書の様式

五　再生医療等提供計画に記載された再生医療等と同種又は類似の再生医療等に関する国内外の実施状況を記載した書類

六　特定細胞加工物を用いる場合にあっては、再生医療等提供計画に記載された再生医療等に用いる細胞

に関連する研究を記載した書類

七　特定細胞加工物を用いる場合にあっては、特定細胞加工物概要書、第九十六条に規定する特定細胞加工物標準書、第九十七条第一項に規定する衛生管理基準書、同条第二項に規定する製造管理基準書及び同条第三項に規定する品質管理基準書

八　再生医療等製品を用いる場合にあっては、当該再生医療等製品の添付文書等（医薬品医療機器等法第六十五条の三に規定する添付文書等をいう。）

九　再生医療等提供計画に記載された再生医療等の内容をできる限り平易な表現を用いて記載したもの

十　特定細胞加工物の製造を委託する場合にあっては、委託契約書の写しその他これに準ずるもの

十一　個人情報取扱実施規程

（再生医療等提供計画の変更の提出）

第二十八条　法第五条第一項の規定による変更は、変更後の再生医療等提供計画及び様式第二による届書を提出して行うものとする。

（再生医療等提供計画の軽微な変更の範囲）

第二十九条　法第五条第一項の厚生労働省令で定める軽微な変更は、次に掲げる変更以外の変更とする。

一　当該再生医療等の安全性に影響を与える再生医療等の提供方法の変更

二　特定細胞加工物を用いる場合にあっては、当該再生医療等の安全性に影響を与える特定細胞加工物の製造及び品質管理の方法の変更

三　再生医療等製品を用いる場合にあっては、当該再生医療等製品に係る医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律施行規則（昭和三十六年厚生省令第一号。以下「医薬品医療機器等法施行規則」という。）第百三十七条の二十八第四号に掲げる変更

四　再生医療等が研究として行われる場合にあっては、研究の実施方法の変更

五　前各号に掲げる変更のほか、当該再生医療等の安全性に影響を与えるもの

（再生医療等提供計画の軽微な変更の届出）

第三十条　法第五条第三項の規定による届出は、様式第三による届書を提出して行うものとする。

（再生医療等の提供の中止の届出）

第三十一条　法第六条の規定による届出は、様式第四による届書を提出して行うものとする。

第三節　再生医療等の適正な提供に関する措置

（再生医療等を行う場合に説明及び同意が不要な場合）

第三十二条　法第十四条第一項の厚生労働省令で定める場合は、次に掲げる場合とする。

一　単独で説明を受け、同意を与えることが困難な者に対し、再生医療等を行う場合であって、次に掲げる場合のいずれかに該当する場合

イ　当該再生医療等を行うことに合理的理由があることについて、認定再生医療等委員会の審査を受けた場合であって、次の(1)から(5)までのいずれも満たす場合

(1)　当該再生医療等を受けることとなる者に緊急かつ明白な生命の危険が生じていること。

(2)　その他の治療方法では十分な効果が期待できないこと。

(3)　当該再生医療等を受けることにより生命の危険が回避できる可能性が十分にあると認められること。

(4)　当該再生医療等を受けることとなる者に対する予測される不利益が必要な最小限度のものであること。

(5)　代諾者となるべき者と直ちに連絡を取ることができないこと。

ロ　イの場合以外の場合であって、当該再生医療等を行うことに合理的理由があることについて、認定再生医療等委員会の審査を受けており、当該再生医療等を受けることとなる者の代諾者の同意を得ている場合

二　十六歳未満の者に対し、再生医療等を行う場合であって、次に掲げる場合のいずれかに該当する場合（前号に掲げる場合を除く。）

イ　当該再生医療等を受けることとなる者が再生医療等を受けることについての説明を十分理解できる能力を有しており、当該者の理解を得ている場合であって、前号イの(1)から(5)までのいずれも満たす場合

ロ　イの場合以外の場合であって、当該再生医療等を受けることとなる者が再生医療等を受けることについての説明を十分理解できる能力を有し、かつ、当該者の理解を得ており、当該再生医療等を受けることとなる者の代諾者の同意を得ている場合

（再生医療等を受ける者以外の者から細胞の採取を行う場合に説明及び同意が不要な場合）

第三十三条　法第十四条第二項の厚生労働省令で定める場合は、次に掲げる場合とする。

一　単独で説明を受け、同意を与えることが困難な者から再生医療等に用いる細胞の採取を行う場合であって、次に掲げる場合のいずれかに該当する場合

イ　当該採取を行うことに合理的理由があることについて、認定再生医療等委員会の審査を受けた場合であって、次の(1)及び(2)を満たす場合

(1)　当該細胞を採取されることとなる者が、あらかじめ、再生医療等に用いられるために自らの細胞を提供する意思を表示していること。

(2)　代諾者となるべき者と直ちに連絡を取ることができないこと。

ロ　イの場合以外の場合であって、当該採取を行うことに合理的理由があることについて、認定再生医療等委員会の審査を受けており、当該細胞を採取されることとなる者の代諾者の同意を得ている場合

二　十六歳未満の者から再生医療等に用いる細胞の採取を行う場合であって、次に掲げる場合のいずれかに該当する場合（前号に掲げる場合を除く。）

イ　当該細胞を採取されることとなる者が当該細胞の採取を行うことについての説明を十分理解できる

能力を有しており、当該者の理解を得ている場合であって、前号イの(1)及び(2)を満たす場合

ロ　イの場合以外の場合であって、当該細胞を採取されることとなる者が当該細胞の採取を行うことについての説明を十分理解できる能力を有し、かつ、当該者の理解を得ており、当該細胞を採取されることとなる者の代諾者の同意を得ている場合

（再生医療等に関する記録及び保存）

第三十四条　法第十六条第一項の記録は、再生医療等を受けた者ごとに作成しなければならない。

２　法第十六条第一項の厚生労働省令で定める事項は、次に掲げる事項とする。

一　再生医療等を受けた者の住所、氏名、性別及び生年月日

二　病名及び主要症状

三　使用した特定細胞加工物又は再生医療等製品の種類、投与方法その他の再生医療等の内容及び評価

四　再生医療等に用いる細胞に関する情報

五　特定細胞加工物の製造を委託した場合は委託先及び委託業務の内容

六　再生医療等を行った年月日

七　再生医療等を行った医師又は歯科医師の氏名

３　提供機関管理者は、再生医療等が行われたときは、法第十六条第一項に規定する記録を、再生医療等提供計画、同意に係る文書及び特定細胞加工物概要書とともに、次に掲げる場合に応じ、次の各号に掲げる期間、保存しなければならない。

一　指定再生医療等製品（医薬品医療機器等法第六十八条の七第三項に規定する指定再生医療等製品であって、同法第二十三条の二十五又は第二十三条の三十七の承認の内容に従わずに用いるものに限る。以下同じ。）又は指定再生医療等製品の原料と類似の原料から成る特定細胞加工物を用いる場合　三十年間

二　前号に掲げる指定再生医療等製品又は特定細胞加工物以外の細胞加工物を用いる場合　十年間

（認定再生医療等委員会への疾病等の報告）

第三十五条　提供機関管理者は、再生医療等提供計画に記載された再生医療等の提供について、次に掲げる事項を知ったときは、それぞれ当該各号に定める期間内に当該事項を、再生医療等提供計画に記載された認定再生医療等委員会に報告しなければならない。

一　次に掲げる疾病等の発生のうち、当該再生医療等の提供によるものと疑われるもの又は当該再生医療等の提供によるものと疑われる感染症によるもの　七日

イ　死亡

ロ　死亡につながるおそれのある症例

二　次に掲げる疾病等の発生のうち、当該再生医療等の提供によるものと疑われるもの又は当該再生医療等の提供によるものと疑われる感染症によるもの　十五日

イ　治療のために医療機関への入院又は入院期間の延長が必要とされる症例

ロ　障害

ハ　障害につながるおそれのある症例

ニ　重篤である症例

ホ　後世代における先天性の疾病又は異常

三　再生医療等の提供によるものと疑われる又は当該再生医療等の提供によるものと疑われる感染症による疾病等の発生（前二号に掲げるものを除く。）　再生医療等提供計画を厚生労働大臣に提出した日か

ら起算して六十日ごとに当該期間満了後十日以内

（厚生労働大臣への疾病等の報告）

第三十六条　法第十八条の厚生労働省令で定める事項は、前条第一号及び第二号に掲げる事項とする。

２　前条（第三号を除く。）の規定は、法第十八条の規定による厚生労働大臣への報告について準用する。この場合において、前条中「再生医療等提供計画に記載された認定再生医療等委員会」とあるのは「厚生労働大臣」と読み替えるものとする。

（認定再生医療等委員会への定期報告）

第三十七条　法第二十条第一項の規定に基づき、提供機関管理者は、再生医療等の提供の状況について、再生医療等提供計画に記載された再生医療等技術ごとに、次に掲げる事項について、当該再生医療等提供計画に記載された認定再生医療等委員会に報告しなければならない。

一　当該再生医療等を受けた者の数

二　当該再生医療等に係る疾病等の発生状況及びその後の経過

三　当該再生医療等の安全性及び科学的妥当性についての評価

四　当該再生医療等の提供を終了した場合にあっては、終了した日

２　前項の報告は、再生医療等提供計画を厚生労働大臣に提出した日から起算して、一年ごとに、当該期間満了後九十日以内に行わなければならない。

（厚生労働大臣への定期報告）

第三十八条　法第二十一条第一項の規定に基づき、提供機関管理者は、再生医療等の提供の状況について、再生医療等提供計画に記載された再生医療等技術ごとに、前条第一項各号に掲げる事項について、厚生労働大臣に報告しなければならない。

２　提供機関管理者は、前項の報告の際には、前条第一項の報告に対し当該認定再生医療等委員会が意見を述べた場合には、当該意見を添えなければならない。

３　第一項の報告は、再生医療等提供計画を厚生労働大臣に提出した日から起算して、一年ごとに、当該期間満了後九十日以内に行わなければならない。

（認定再生医療等委員会の意見を聴く際の手続）

第三十九条　提供機関管理者は、法第四条第二項の規定により認定再生医療等委員会（当該再生医療等提供

機関の開設者が設置したものを除く。）に意見を聴くときは、当該認定再生医療等委員会の審査等業務に関する規程及び委員名簿を入手しなければならない。

（認定再生医療等委員会の審査等業務に係る契約）

第四十条　提供機関管理者は、認定再生医療等委員会（当該再生医療等提供機関の開設者が設置した認定再生医療等委員会及び当該再生医療等提供機関を有する法人が設置したものを除く。）に審査等業務を行わせることとする場合には、あらかじめ、次に掲げる事項を記載した文書により認定委員会設置者（法第二十六条第五項第一号に規定する認定委員会設置者をいう。以下同じ。）との契約を締結しなければならない。

一　当該契約を締結した年月日

二　当該再生医療等提供機関及び当該認定再生医療等委員会の名称及び所在地

三　当該契約に係る業務の手順に関する事項

四　当該認定再生医療等委員会が意見を述べるべき期限

五　細胞提供者及び再生医療等を受ける者の秘密の保全に関する事項

六　その他必要な事項

（講じた措置についての認定再生医療等委員会への報告）

第四十一条　提供機関管理者は、認定再生医療等委員会から法第二十六条第一項各号に規定する意見を述べられた場合には、当該意見を受けて講じた再生医療等提供計画の変更その他の措置について、当該認定再生医療等委員会に対し報告を行わなければならない。

第三章　認定再生医療等委員会

（再生医療等委員会を設置できる団体）

第四十二条　法第二十六条第一項の厚生労働省令で定める団体は、次に掲げる団体とする。

一　医学医術に関する学術団体

二　一般社団法人又は一般財団法人

三　特定非営利活動促進法（平成十年法律第七号）第二条第二項に規定する特定非営利活動法人

四　私立学校法（昭和二十四年法律第二百七十号）第三条に規定する学校法人（医療機関を有するものに限る。）

五　独立行政法人通則法（平成十一年法律第百三号）第二条第一項に規定する独立行政法人（医療の提供等を主な業務とするものに限る。）

六　国立大学法人法（平成十五年法律第百十二号）第二条第一項に規定する国立大学法人（医療機関を有するものに限る。）

七　地方独立行政法人法（平成十五年法律第百十八号）第二条第一項に規定する地方独立行政法人（医療機関を有するものに限る。）

２　再生医療等委員会を前項第一号から第三号までに掲げる団体が設置する場合は、当該者は次に掲げる要件を満たすものでなければならない。

一　定款その他これに準ずるものにおいて、再生医療等委員会を設置する旨の定めがあること。

二　その役員（いかなる名称によるかを問わず、これと同等以上の職権又は支配力を有する者を含む。次号において同じ。）のうちに医師、歯科医師、薬剤師、看護師その他の医療関係者が含まれていること。

三　その役員に占める次に掲げる者の割合が、それぞれ三分の一以下であること。

イ　特定の医療機関の職員その他の当該医療機関と密接な関係を有する者

ロ　特定の法人の役員又は職員その他の当該法人と密接な関係を有する者

四　再生医療等委員会の設置及び運営に関する業務を適確に遂行するに足りる財産的基礎を有していること。

五　財産目録、貸借対照表、損益計算書、事業報告書その他の財務に関する書類をその事務所に備えて置き、一般の閲覧に供していること。

六　その他再生医療等委員会の業務の公正かつ適正な遂行を損なうおそれがないこと。

（再生医療等委員会の認定の申請）

第四十三条　法第二十六条第二項の規定による申請は、様式第五による申請書を提出して行うものとする。

２　法第二十六条第二項第七号（法第二十七条第三項及び第二十八条第六項において準用する場合を含む。）の厚生労働省令で定める事項は、再生医療等委員会の所在地及び再生医療等委員会の連絡先とする。

３　法第二十六条第三項第三号（法第二十七条第三項及び第二十八条第六項において準用する場合を含む。）の厚生労働省令で定める書類は、次に掲げる場合に応じ、それぞれ当該各号に定める書類とする。

一　前条第一項第一号から第三号までに掲げる団体が第一項の申請をしようとする場合

イ　再生医療等委員会を設置する者に関する証明書類

ロ　再生医療等委員会を設置する者が再生医療等委員会を設置する旨を定めた定款その他これに準ずるもの

ハ　第四十二条第二項第二号及び第三号の要件を満たすことを証明する書類

ニ　財産的基礎を有していることを証明する書類

二　医療機関の開設者又は前条第一項第四号から第七号までに掲げる団体が第一項の申請をしようとする場合　再生医療等委員会を設置する者に関する証明書類

（第一種再生医療等提供計画又は第二種再生医療等提供計画に係る審査等業務を行う再生医療等委員会の委員の構成要件）

第四十四条　第一種再生医療等提供計画（法第七条に規定する第一種再生医療等提供計画をいう。以下同じ。）又は第二種再生医療等提供計画（法第十一条に規定する第二種再生医療等提供計画をいう。以下同じ。）に係る審査等業務を行う再生医療等委員会の法第二十六条第四項第一号の厚生労働省令で定める者は、次に掲げる者とする。ただし、各号に掲げる者は当該各号以外に掲げる者を兼ねることができない。

一　分子生物学、細胞生物学、遺伝学、臨床薬理学又は病理学の専門家
二　再生医療等について十分な科学的知見及び医療上の識見を有する者
三　臨床医（現に診療に従事している医師又は歯科医師をいう。以下同じ。）
四　細胞培養加工に関する識見を有する者
五　法律に関する専門家
六　生命倫理に関する識見を有する者
七　生物統計その他の臨床研究に関する識見を有する者
八　第一号から前号までに掲げる者以外の一般の立場の者

（第三種再生医療等提供計画のみに係る審査等業務を行う再生医療等委員会の委員の構成要件）

第四十五条　第三種再生医療等提供計画のみに係る審査等業務を行う再生医療等委員会の法第二十六条第四項第一号の厚生労働省令で定める者は、次に掲げる者とする。ただし、各号に掲げる者は当該各号以外に掲げる者を兼ねることができない。

一　再生医療等について十分な科学的知見及び医療上の識見を有する者を含む二名以上の医学又は医療の

専門家（ただし、所属機関が同一でない者が含まれ、かつ、少なくとも一名は医師又は歯科医師であること。）

二　法律に関する専門家又は生命倫理に関する識見を有する者その他の人文・社会科学の有識者

三　前二号に掲げる者以外の一般の立場の者

（第一種再生医療等提供計画又は第二種再生医療等提供計画に係る審査等業務を行う再生医療等委員会の委員の構成基準）

第四十六条　第一種再生医療等提供計画又は第二種再生医療等提供計画に係る審査等業務を行う再生医療等委員会の法第二十六条第四項第二号の厚生労働省令で定める基準は、次のとおりとする。

一　男性及び女性がそれぞれ二名以上含まれていること。

二　再生医療等委員会を設置する者と利害関係を有しない者が含まれていること。

三　同一の医療機関（当該医療機関と密接な関係を有するものを含む。）に所属している者が半数未満であること。

（第三種再生医療等提供計画のみに係る審査等業務を行う再生医療等委員会の委員の構成基準）

第四十七条　第三種再生医療等提供計画のみに係る審査等業務を行う再生医療等委員会の法二十六条第四項第二号の厚生労働省令で定める基準は、次のとおりとする。

一　委員が五名以上であること。

二　男性及び女性がそれぞれ一名以上含まれていること。

三　再生医療等委員会を設置する者と利害関係を有しない者が含まれていること。

（手数料の算定の基準）

第四十八条　法第二十六条第四項第四号の厚生労働省令で定める基準は、再生医療等委員会が、審査等業務に関して徴収する手数料の額を、委員への報酬の支払等、当該再生医療等委員会の健全な運営に必要な経費を賄うために必要な範囲内とし、かつ、公平なものとなるよう定めていることとする。

（審査等業務の適切な実施のために必要な基準）

第四十九条　法第二十六条第四項第五号の厚生労働省令で定める基準は、次のとおりとする。

一　審査等業務が適正かつ公正に行えるよう、その活動の自由及び独立が保障されていること。

二　審査等業務に関する規程が定められ、かつ、公表されていること。

三　審査等業務を継続的に実施できる体制を有すること。

（再生医療等委員会の認定証の交付）

第五十条　厚生労働大臣は、法第二十六条第四項の規定による認定をしたときは、認定を申請した者に対し、様式第六による認定証を交付しなければならない。法第二十八条第二項の規定による更新をしたときも、同様とする。

（認定再生医療等委員会の変更の認定の申請）

第五十一条　法第二十七条第一項の規定による認定の申請は、変更後の第四十三条第一項に規定する申請書及び様式第七による申請書を厚生労働大臣に提出して行うものとする。

（法第二十七条第一項ただし書の軽微な変更の範囲）

第五十二条　法第二十七条第一項ただし書の厚生労働省令で定める軽微な変更は、次に掲げる変更とする。

一　当該再生医療等委員会の委員の氏名の変更であって、委員の変更を伴わないもの

二　当該再生医療等委員会の委員の職業の変更であって、委員の構成要件（第四十四条及び第四十五条に規定する要件をいう。次号において同じ。）を満たさなくなるもの以外のもの

三　当該再生医療等委員会の委員の増減に関する変更であって、委員の構成要件を満たさなくなるもの以外のもの

四　審査等業務を行う体制に関する事項の変更であって、審査等業務の適切な実施に支障を及ぼすおそれのないもの

（法第二十七条第二項の軽微な変更の届出）

第五十三条　法第二十七条第二項の規定による届出は、様式第八による届書を提出して行うものとする。

（法第二十七条第四項の軽微な変更の範囲）

第五十四条　法第二十七条第四項の厚生労働省令で定める軽微な変更は、次に掲げる変更とする。

一　地域の名称の変更又は地番の変更に伴う変更

二　当該認定再生医療等委員会の委員の略歴の追加に関する変更

三　再生医療等委員会を設置する旨の定めをした定款その他これに準ずるものの変更であって、次に掲げるもの

イ　法その他の法令の制定又は改廃に伴い当然必要とされる規定の整理

ロ　第一号及びイに掲げるもののほか、用語の整理、条、項又は号の繰上げ又は繰下げその他の形式的な変更

（法第二十七条第四項の変更の届出）

第五十五条　法第二十七条第四項の規定による届出は、様式第九による届書を提出して行うものとする。

２　法第二十六条第三項各号に掲げる書類に記載した事項に変更があった場合には、前項の届書に、変更後の法第二十六条第三項各号に掲げる書類を添えなければならない。

（認定再生医療等委員会の認定証の書換え交付の申請）

第五十六条　認定委員会設置者は、認定証の記載事項に変更を生じたときは、様式第十による申請書及び認定証を厚生労働大臣に提出してその書換えを申請することができる。

（認定再生医療等委員会の認定証の再交付）

第五十七条　認定委員会設置者は、認定再生医療等委員会の認定証を破り、汚し、又は失ったときは、様式第十一による申請書を厚生労働大臣に提出してその再交付を申請することができる。この場合において、認定証を破り、又は汚した認定委員会設置者は、申請書に当該認定証を添えなければならない。

２　認定委員会設置者は、認定証の再交付を受けた後、失った認定証を発見したときは、遅滞なく、厚生労働大臣にこれを返納しなければならない。

（再生医療等委員会の認定の更新の申請）

第五十八条　法第二十八条第六項において準用する法第二十六条第二項の規定による更新の申請は、様式第十二による申請書を提出して行うものとする。

２　前項の申請書には、申請に係る認定証を添えなければならない。

（認定再生医療等委員会の廃止）

第五十九条　法第三十条第一項の規定による届出は、様式第十三による届書を提出して行うものとする。

２　認定委員会設置者が前項の届出を行おうとするときは、あらかじめ、当該認定再生医療等委員会に再生医療等提供計画を提出していた再生医療等提供機関に、その旨を通知しなければならない。

（認定再生医療等委員会の廃止後の手続）

第六十条　認定委員会設置者は、その設置する認定再生医療等委員会を廃止したときは、速やかに、その旨を当該認定再生医療等委員会に再生医療等提供計画を提出していた再生医療等提供機関に通知しなければ

ならない。

２　前項の場合において、認定委員会設置者は、当該認定再生医療等委員会に再生医療等提供計画を提出していた再生医療等医療機関に対し、当該再生医療等提供機関における再生医療等の提供の継続に影響を及ぼさないよう、他の認定再生医療等委員会を紹介することその他の適切な措置を講じなければならない。

（再生医療等委員会の認定証の返納）

第六十一条　認定委員会設置者は、法第三十三条第一項の規定により認定再生医療等委員会の認定の取消を受けたとき、又は当該認定再生医療等委員会を廃止したときは、遅滞なく、厚生労働大臣に認定証を返納しなければならない。

（再生医療等委員会の認定台帳）

第六十二条　厚生労働大臣は、法第二十六条第四項の規定による認定に関する台帳を備え、次に掲げる事項を記載するものとする。

一　認定番号及び認定年月日

二　認定委員会設置者の氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

三　認定再生医療等委員会の名称及び所在地

（第一種再生医療等提供計画又は第二種再生医療等提供計画に係る審査等業務）

第六十三条　認定再生医療等委員会が、第一種再生医療等提供計画又は第二種再生医療等提供計画に係る審査等業務を行う際には、次に掲げる要件を満たさなければならない。

一　過半数の委員が出席していること。

二　男性及び女性の委員がそれぞれ二名以上出席していること。

三　次に掲げる者がそれぞれ一名以上出席していること。

イ　第四十四条第二号に掲げる者

ロ　第四十四条第四号に掲げる者

ハ　第四十四条第五号又は第六号に掲げる者

ニ　第四十四条第八号に掲げる者

ホ　技術専門委員（審査等業務の対象となる再生医療等の対象疾患等に対する専門的知識を有する者をいう。以下同じ。）（第四十四条第二号又は第三号に掲げる者が、審査等業務の対象となる再生医療

等の対象疾患等に対する専門知識を有する場合には、当該者）

四　出席した委員の中に、審査等業務の対象となる再生医療等提供計画を提出した医療機関（当該医療機関と密接な関係を有するものを含む。）と利害関係を有しない委員が過半数含まれていること。

五　認定委員会設置者と利害関係を有しない委員が含まれていること。

２　認定再生医療等委員会は、第一種再生医療等提供計画又は第二種再生医療等提供計画の変更に係る審査であって、次に掲げる要件を満たすものを行う場合には、前項の規定にかかわらず、当該認定再生医療等委員会における審査等業務に関する規程に定める方法により、これを行うことができる。

一　当該再生医療等提供計画の変更が、認定再生医療等委員会の審査を経て指示を受けたものである場合

二　当該再生医療等提供計画の変更が、再生医療等の提供に重要な影響を与えないものである場合

（第三種再生医療等提供計画に係る審査等業務）

第六十四条　認定再生医療等委員会が、第三種再生医療等提供計画に係る審査等業務を行う際には、次に掲げる要件を満たさなければならない。

一　過半数の委員が出席していること。

二　五名以上の委員が出席していること。

三　男性及び女性の委員がそれぞれ一名以上出席していること。

四　次に掲げる者がそれぞれ一名以上出席していること。ただしイに掲げる者が医師又は歯科医師である場合にあっては、ロを兼ねることができる。

イ　第四十五条第一号に掲げる者のうち再生医療等について十分な科学的知見及び医療上の識見を有する者

ロ　第四十五条第一号に掲げる者のうち医師又は歯科医師

ハ　第四十五条第二号に掲げる者

ニ　第四十五条第三号に掲げる者

五　出席した委員の中に、審査等業務の対象となる再生医療等提供計画を提出した医療機関（当該医療機関と密接な関係を有するものを含む。）と利害関係を有しない委員が二名以上含まれていること。

六　認定委員会設置者と利害関係を有しない委員が含まれていること。

2　認定再生医療等委員会は、第三種再生医療等提供計画の変更に係る審査であって、次に掲げる要件を満

たすものを行う場合には、前項の規定にかかわらず、当該認定再生医療等委員会における審査等業務に関する規程に定める方法により、これを行うことができる。

一　当該再生医療等提供計画の変更が、認定再生医療等委員会の審査を経て指示を受けたものである場合

二　当該再生医療等提供計画の変更が、再生医療等の提供に重要な影響を与えないものである場合

（認定再生医療等委員会の判断及び意見）

第六十五条　審査等業務の対象となる再生医療等提供計画を提出した提供機関管理者、当該再生医療等提供計画に記載された再生医療等を行う医師又は歯科医師及び実施責任者（実施責任者を置いている場合に限る。）並びに認定再生医療等委員会の運営に関する事務に携わる者は、当該認定再生医療等委員会の審査等業務に参加してはならない。ただし、認定再生医療等委員会の求めに応じて、当該認定再生医療等委員会において説明することを妨げない。

2　認定再生医療等委員会における審査等業務に係る結論を得るに当たっては、原則として、出席委員（技術専門委員が出席する場合にあっては、当該委員を除く。以下この項において同じ。）の全員一致をもって行うよう努めなければならない。ただし、認定再生医療等委員会において議論を尽くしても、出席委員

全員の意見が一致しないときは、出席委員の大多数の同意を得た意見を当該認定再生医療等委員会の結論とすることができる。

（厚生労働大臣への報告）

第六十六条　認定委員会設置者は、当該認定再生医療等委員会が再生医療等提供計画に記載された再生医療等の提供を継続することが適当でない旨の意見を述べたときは、遅滞なく、厚生労働大臣にその旨を報告しなければならない。

（帳簿の備付け等）

第六十七条　認定委員会設置者は、法第二十六条第一項各号に掲げる業務に関する事項を記録するための帳簿を備えなければならない。

２　認定委員会設置者は、第一項の帳簿を、最終の記載の日から十年間、保存しなければならない。

（審査等業務に関する規程及び委員名簿の公表）

第六十八条　認定委員会設置者は、当該認定再生医療等委員会の審査等業務に関する規程及び委員名簿を公表しなければならない。

（事務を行う者の選任）

第六十九条　認定委員会設置者は、認定再生医療等委員会の運営に関する事務を行う者を選任しなければならない。

（委員の教育又は研修）

第七十条　認定委員会設置者は、認定再生医療等委員会の委員の教育又は研修の機会を確保しなければならない。

（認定再生医療等委員会の審査等業務の記録等）

第七十一条　認定委員会設置者は、当該認定再生医療等委員会における審査等業務の過程に関する記録を作成し、個人情報、研究の独創性及び知的財産権の保護に支障を生じるおそれのある事項を除き、これを公表しなければならない。

２　認定委員会設置者は、審査等業務に係る再生医療等提供計画及び前項の記録を、当該計画に係る再生医療等の提供が終了した日から少なくとも十年間保存しなければならない。

第四章　特定細胞加工物の製造

（特定細胞加工物の製造の許可の申請）

第七十二条　法第三十五条第一項の規定による許可の申請は、様式第十四による申請書（正副二通）を提出して行うものとする。

２　法第三十五条第二項第四号（法第三十六条第二項及び第三十九条第二項において準用する場合を含む。）に規定する厚生労働省令で定める事項は、次に掲げる事項とする。

一　細胞培養加工施設の名称及び所在地

二　申請者が法人である場合は、その業務を行う役員の氏名

三　申請者（申請者が法人である場合は、その業務を行う役員を含む。）の欠格条項に関する事項

四　申請者の連絡先

３　法第三十五条第二項（法第三十六条第二項において準用する場合を含む。）の厚生労働省令で定める書類は、次に掲げる書類とする。

一　申請者が法人である場合は、登記事項証明書

二　製造をしようとする特定細胞加工物の一覧表

（特定細胞加工物の製造の許可証の交付）

第七十三条　厚生労働大臣は、法第三十五条第一項の規定による許可をしたときは、許可を申請した者に対し、様式第十五による許可証を交付しなければならない。法第三十六条第一項の規定による更新をしたときも、同様とする。

（許可事業者の届出を要する変更の範囲）

第七十四条　法第三十七条の厚生労働省令で定める事項は、次に掲げる事項とする。

一　法第三十五条第一項の許可を受けた者（以下「許可事業者」という。）の氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

二　細胞培養加工施設の名称及び所在地

三　施設管理者の氏名

四　許可事業者が法人である場合は、その業務を行う役員の氏名

五　許可事業者（許可事業者が法人である場合は、その業務を行う役員を含む。）の欠格条項に関する事項

六　製造をしようとする特定細胞加工物の種類

七　許可事業者の連絡先

（許可事業者の変更の届出）

第七十五条　法第三十七条の規定による届出は、様式第十六による届書を提出して行うものとする。

（特定細胞加工物の製造の許可証の書換え交付の申請）

第七十六条　許可事業者は、特定細胞加工物の製造の許可証の記載事項に変更を生じたときは、様式第十七による申請書及び許可証を厚生労働大臣に提出してその書換えを申請することができる。

２　前項の申請をする者は、二千円の手数料を納めなければならない。この場合において、手数料は、申請書に収入印紙を貼って納めるものとする。

（特定細胞加工物の製造の許可証の再交付）

第七十七条　許可事業者は、特定細胞加工物の製造の許可証を破り、汚し、又は失ったときは、様式第十八による申請書を厚生労働大臣に提出してその再交付を申請することができる。この場合において、許可証を破り、又は汚した特定細胞加工物製造事業者は、申請書に当該許可証を添えなければならない。

２　前項の申請をする者は、二千円の手数料を納めなければならない。この場合において、手数料は、申請書に収入印紙を貼って納めるものとする。

３　特定細胞加工物製造事業者は、特定細胞加工物の製造の許可証の再交付を受けた後、失った許可証を発見したときは、遅滞なく、厚生労働大臣にこれを返納しなければならない。

（特定細胞加工物の製造の許可の更新の申請）

第七十八条　法第三十六条第二項において準用する法第三十五条第二項の規定による申請は、様式第十九による申請書（正副二通）を厚生労働大臣に提出して行うものとする。

２　前項の申請書には、申請に係る許可証を添えなければならない。

（製造の許可証の返納）

第七十九条　特定細胞加工物の製造の許可事業者は、法第四十九条の規定により特定細胞加工物の製造の許可の取消を受けたとき、又はその業務を廃止したときは、遅滞なく、厚生労働大臣に許可証を返納しなければならない。

（特定細胞加工物の製造の許可台帳）

第八十条　厚生労働大臣は、法第三十五条第一項の規定による許可に関する台帳を備え、次に掲げる事項を記載するものとする。

一　施設番号及び許可年月日

二　許可事業者の氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

三　細胞培養加工施設の名称及び所在地

四　施設管理者の氏名

（機構に対する特定細胞加工物の製造の許可又は許可の更新に係る調査の申請）

第八十一条　法第三十八条第一項の規定により独立行政法人医薬品医療機器総合機構（以下「機構」という。）に法第三十五条第五項（法第三十六条第二項において準用する場合を含む。）に規定する調査を行わせることとしたときは、法第三十五条第一項の許可又は法第三十六条第一項の許可の更新の申請者は、機構に当該調査の申請をしなければならない。

２　前項の申請は、様式第二十による申請書を、法第三十五条第一項の許可又は法第三十六条第一項の許可の更新の申請書に添付して地方厚生局長を経由して行うものとする。

（機構による特定細胞加工物の製造の許可等に係る調査の結果の通知）

第八十二条　法第三十八条第四項の規定による通知は、様式第二十一による通知書によって行うものとする。

（外国における特定細胞加工物の製造の認定の申請）

第八十三条　法第三十九条第一項の規定による認定の申請は、様式第二十二による申請書（正副二通）を厚生労働大臣に提出して行うものとする。

２　法第三十九条第二項の規定において準用する法第三十五条第二項の厚生労働省令で定める書類は、次に掲げる書類とする。

一　施設管理者の履歴書

二　製造をしようとする特定細胞加工物の一覧表

（準用）

第八十四条　法第三十九条第一項の規定による認定については、第七十三条から第八十二条までの規定を準用する。この場合において、これらの規定中「法第三十五条第一項」とあるのは「法第三十九条第一項」と、「許可」とあるのは「認定」と、「許可証」とあるのは「認定証」と、「法第三十六条第一項」とあ

るのは「法第三十九条第二項において準用する法第三十六条第一項」と、「許可事業者」とあるのは「認定事業者」と読み替えるほか、次の表の上欄に掲げる規定中同表の中欄に掲げる字句は、それぞれ同表の下欄に掲げる字句に読み替えるものとする。

第七十三条	様式第十五	様式第二十三
第七十四条	法第三十七条	法第三十九条第二項において準用する法第三十七条
第七十五条	法第三十七条	法第三十九条第二項において準用する法第三十七条
	様式第十六	様式第二十四
第七十六条第二項	二千円	二千四百円
第七十七条第二項	二千円	二千四百円
第七十八条	法第三十六条第二項において準用する法第三十五条第二項	法第三十九条第二項において準用する法第三十六条第二項

	様式第十九	様式第二十五
第七十九条	法第四十九条	法第五十条第一項
第八十条	許可年月日	認定年月日
第八十一条第一項	法第三十八条第一項	法第三十九条第二項において準用する法第三十八条第一項
	法第三十五条第五項	法第三十九条第二項において準用する法第三十五条第五項
	法第三十六条第二項	法第三十九条第二項において準用する法第三十六条第二項
第八十一条第二項	様式第二十	様式第二十六
	地方厚生局長	厚生労働大臣
第八十二条	法第三十八条第四項	法第三十九条第二項において準用する法第三十八条第四項

（特定細胞加工物の製造の届出）

第八十五条　法第四十条第一項の規定による届出は、様式第二十七による届書を提出して行うものとする。

２　法第四十条第一項の厚生労働省令で定める区分は、医薬品医療機器等法施行規則第百三十七条の九第一号に規定する区分とする。

３　法第四十条第一項第四号の厚生労働省令で定める事項は、次に掲げる事項とする。

一　届出をする者の区分

二　細胞培養加工施設の名称及び所在地

三　届出をする者が法人である場合は、その業務を行う役員の氏名

四　届出をする者（届出をする者が法人である場合には、その業務を行う役員を含む。）の停止事由に係る事項

五　届出をする者の連絡先

４　法第四十条第二項の厚生労働省令で定める書類は、次に掲げる書類とする。

一　届出をする者が法人であるときは、登記事項証明書

二　製造をしようとする特定細胞加工物の一覧表

三　届出をする者が医薬品医療機器等法第二十三条の二十二第一項の許可（医薬品医療機器等法施行規則第百三十七条の九第一号に規定する区分に該当するものに限る。）を受けている場合にあっては、当該許可証の写し

四　届出をする者が移植に用いる造血幹細胞の適切な提供の推進に関する法律（平成二十四年法律第九十号）第三十条の臍帯血供給事業の許可を受けている場合にあっては、当該許可証の写し

（届出事業者の届出を要する変更の範囲）

第八十六条　法第四十条第三項の厚生労働省令で定める事項は、次に掲げる事項とする。

一　法第四十条第一項の規定による届出をした者（以下「届出事業者」という。）の氏名又は名称及び住所並びに法人にあっては、その代表者の氏名

二　届出事業者の区分

三　細胞培養加工施設の名称及び所在地

四　施設管理者の氏名

五　届出事業者が法人である場合は、その業務を行う役員の氏名

六　届出事業者（届出事業者が法人である場合は、その業務を行う役員を含む。）の停止事由に関する事項

七　製造をしようとする特定細胞加工物の種類

八　届出事業者の連絡先

（届出事業者の変更の届出）

第八十七条　法第四十条第三項の規定による届出は、様式第二十八による届書を提出して行うものとする。

（廃止の届出）

第八十八条　法第四十一条の規定による届出は、様式第二十九による届書を提出して行うものとする。

（細胞培養加工施設の構造設備）

第八十九条　法第四十二条の細胞培養加工施設の構造設備の基準は、次のとおりとする。

一　当該細胞培養加工施設において特定細胞加工物を製造するのに必要な設備及び器具を備えていること。

二　特定細胞加工物等及び資材の混同並びに汚染を防止し、円滑かつ適切な作業を行うのに支障のないよ

う配置されており、かつ、清掃及び保守が容易なものであること。

三　手洗設備及び更衣を行う場所、その他必要な衛生設備を有すること。

四　原料の受入れ、特定細胞加工物の保管等を行う区域は、特定細胞加工物の製造を行う他の区域から区分されていること。

五　原料の受入れ、特定細胞加工物の保管等を行う区域は、これらを行うために必要な構造及び設備を有すること。

六　作業所は、次に掲げる要件に適合するものであること。

イ　照明及び換気が適切であり、かつ、清潔であること。

ロ　常時居住する場所及び不潔な場所から明確に区別されていること。

ハ　作業を行うのに支障のない面積を有すること。

ニ　防じん、防虫及び防そのための構造又は設備を有すること。

ホ　廃水及び廃棄物の処理に要する設備又は器具を備えていること。

ヘ　特定細胞加工物等により有毒ガスを取り扱う場合には、その処理に要する設備を有すること。

七　作業所のうち、作業室は、次に掲げる要件に適合するものであること。

イ　屋外に直接面する出入口（非常口を除く。）がないこと。ただし、屋外からの汚染を防止するのに必要な構造及び設備を有している場合においては、この限りでない。

ロ　出入口及び窓は、閉鎖することができるものであること。

ハ　室内の排水設備は、作業室の汚染を防止するために必要な構造であること。

ニ　作業室の天井は、ごみの落ちるおそれのないような構造であること。

ホ　室内のパイプ、ダクト等の設備は、表面にごみがたまらないような構造であること。ただし、清掃が容易である場合においてはこの限りでない。

八　作業所のうち作業室又は作業管理区域（作業室及び廊下等から構成されていて、全体が同程度に清浄の維持ができるように管理される区域をいう。）は、温度及び必要に応じて湿度を維持管理できる構造及び設備を有すること。

九　作業所のうち、清浄度管理区域は、次に掲げる要件に適合するものであること。

イ　天井、壁及び床の表面は、なめらかでひび割れがなく、かつ、じんあいを発生しないものであるこ

と。また、清掃が容易で、消毒液等による噴霧洗浄に耐えるものであること。

ロ　設備及び器具は、滅菌又は消毒が可能なものであること。

ハ　排水設備は、有害な廃水による汚染を防止するために適切な構造のものであること。

ニ　排水口を設置していないこと。ただし、やむを得ないと認められる場合には、作業室の汚染を防止するために必要な構造であること。

十　作業所のうち、無菌操作等区域は、次に定めるところに適合するものであること。

イ　天井、壁及び床の表面は、なめらかでひび割れがなく、かつ、じんあいを発生しないものであること。また、清掃が容易で、消毒液等による噴霧洗浄に耐えるものであること。ただし、無菌操作が閉鎖式操作で行われ無菌性が確保できる場合は、この限りではない。

ロ　設備及び器具は、滅菌又は消毒が可能なものであること。

ハ　排水設備は、有害な廃水による汚染を防止するために適切な構造のものであること。

ニ　排水口を設置していないこと。

ホ　流しを設置していないこと。

十一　作業所のうち、動物又は微生物を用いる試験を行う区域及び特定細胞加工物の製造に必要のない動物組織又は微生物を取り扱う区域は、当該特定細胞加工物の製造を行う他の区域から明確に区別されており、かつ、空気処理システムが別系統にされていること。

十二　作業所のうち、無菌操作を行う区域は、フィルターにより処理された清浄な空気を供し、かつ、適切な差圧管理を行うために必要な構造及び設備を有すること。ただし、無菌操作が閉鎖式操作で行われ無菌性が確保できる場合は、この限りではない。

十三　作業所のうち、病原性を持つ微生物等を取り扱う区域は、適切な陰圧管理を行うために必要な構造及び設備を有すること。

十四　無菌操作等区域で使用した器具の洗浄、消毒及び滅菌のための設備並びに廃液等の処理のための設備を有すること。

十五　空気処理システムは、微生物等による特定細胞加工物等の汚染を防止するために適切な構造のものであること。

十六　配管、バルブ及びベント・フィルターは、使用の目的に応じ、容易に清掃又は滅菌ができる構造の

ものであること。

十七　製造又は試験検査に使用する動物（ドナー動物を含む。以下「使用動物」という。）を管理する施設は、次に定めるところに適合するものであること。

イ　使用動物を検査するための区域は、他の区域から隔離されていること。

ロ　害虫の侵入のおそれのない飼料の貯蔵設備を有していること。

ハ　製造に使用する動物の飼育室と試験検査に使用する動物の飼育室をそれぞれ有していること。

ニ　使用動物の飼育室は、他の区域と空気処理システムが別系統にされていること。ただし、野外での飼育が適当と認められる動物については、この限りでない。

ホ　使用動物に抗原等を接種する場合には、接種室を有していること。この場合、接種室は動物の剖検室と分離されていること。

十八　特定細胞加工物等及び資材を区分して、衛生的かつ安全に貯蔵するために必要な設備を有すること。

十九　貯蔵設備は、恒温装置、温度計その他必要な計器を備えたものであること。

二十　次に掲げる試験検査の設備及び器具を備えていること。ただし、当該特定細胞加工物製造事業者の

他の試験検査設備又は他の試験検査機関を利用して自己の責任において当該試験検査を行う場合であって、支障がないと認められるときは、この限りでない。

イ　密封状態検査を行う必要がある場合には、密封状態検査の設備及び器具

ロ　異物検査の設備及び器具

ハ　特定細胞加工物等及び資材の理化学試験の設備及び器具

ニ　無菌試験の設備及び器具

ホ　発熱性物質試験を行う必要がある場合には、発熱性物質試験の設備及び器具

ヘ　生物学的試験を行う必要がある場合には、生物学的試験の設備及び器具

（施設管理者の基準）

第九十条　法第四十三条の厚生労働省令で定める基準は、特定細胞加工物に係る生物学的知識を有する者であることとする。

２　施設管理者は、細胞培養加工施設ごとに一名置かなければならない。

（特定細胞加工物製造事業者の遵守事項）

第九十一条　法第四十四条の厚生労働省令で定める特定細胞加工物製造事業者の遵守事項は、次条から第百十条までに定めるところによる。

（品質リスクマネジメント）

第九十二条　特定細胞加工物製造事業者は、製造管理及び品質管理を行う際に、品質リスクマネジメント（特定細胞加工物の品質に対するリスクについて適切な手続に従い評価、管理等を行うことをいう。）の活用を考慮するものとする。

（製造部門及び品質部門）

第九十三条　特定細胞加工物製造事業者は、細胞培養加工施設ごとに、施設管理者の監督の下に、製造管理に係る部門（以下「製造部門」という。）及び品質管理に係る部門（以下「品質部門」という。）を置かなければならない。

２　品質部門は、製造部門から独立していなければならない。

（施設管理者）

第九十四条　施設管理者は、次に掲げる業務を行わなければならない。

一　製造管理及び品質管理に係る業務（以下「製造・品質管理業務」という。）を統括し、その適正かつ円滑な実施が図られるよう管理監督すること。

二　品質不良その他特定細胞加工物の品質に重大な影響が及ぶおそれがある場合においては、所要の措置が速やかに採られていること及びその進捗状況を確認し、必要に応じ、再生医療等提供機関の医師又は歯科医師へ報告し、得られた指示に基づき、改善等所要の措置を採るよう指示すること。

２　特定細胞加工物製造事業者は、施設管理者が業務を行う際に支障を生ずることがないようにしなければならない。

（職員）

第九十五条　特定細胞加工物製造事業者は、製造・品質管理業務を適正かつ円滑に実施し得る能力を有する責任者（以下「業務責任者」という。）を、細胞培養加工施設の組織、規模及び業務の種類等に応じ、適切に置かなければならない。

２　特定細胞加工物製造事業者は、細胞培養加工施設の組織、規模及び業務の種類等に応じ、適切な人数の業務責任者を配置しなければならない。

３　特定細胞加工物製造事業者は、製造・品質管理業務を適切に実施し得る能力を有する人員を十分に確保しなければならない。

４　特定細胞加工物製造事業者は、製造・品質管理業務に従事する職員（施設管理者及び業務責任者を含む。）の責務及び管理体制を文書により適切に定めなければならない。

（特定細胞加工物標準書）

第九十六条　特定細胞加工物製造事業者は、特定細胞加工物ごとに、次に掲げる事項について記載した特定細胞加工物標準書を当該特定細胞加工物の製造に係る細胞培養加工施設ごとに作成し、保管するとともに、品質部門の承認を受けるものとしなければならない。

一　特定細胞加工物概要書記載事項

二　製造手順（前号に掲げる事項を除く。）

三　品質に関する事項（前二号に掲げる事項を除く。）

四　その他所要の事項

（手順書等）

第九十七条　特定細胞加工物製造事業者は、細胞培養加工施設ごとに、構造設備の衛生管理、職員の衛生管理その他必要な事項について記載した衛生管理基準書を作成し、これを保管しなければならない。

２　特定細胞加工物製造事業者は、細胞培養加工施設ごとに、特定細胞加工物等の保管、製造工程の管理その他必要な事項について記載した製造管理基準書を作成し、これを保管しなければならない。

３　特定細胞加工物製造事業者は、細胞培養加工施設ごとに、検体の採取方法、試験検査結果の判定方法その他必要な事項を記載した品質管理基準書を作成し、これを保管しなければならない。

４　特定細胞加工物製造事業者は、前三項に定めるもののほか、製造管理及び品質管理を適正かつ円滑に実施するため、次に掲げる手順に関する文書（以下「手順書」という。）を細胞培養加工施設ごとに作成し、これを保管しなければならない。

一　細胞培養加工施設からの特定細胞加工物の提供の管理に関する手順

二　第百二条の検証又は確認に関する手順

三　特定細胞加工物の品質の照査に関する手順

四　第百四条の変更の管理に関する手順

五　第百五条の逸脱の管理に関する手順
六　品質等に関する情報及び品質不良等の処理に関する手順
七　重大事態報告等に関する手順
八　自己点検に関する手順
九　教育訓練に関する手順
十　文書及び記録の管理に関する手順
十一　その他製造管理及び品質管理を適正かつ円滑に実施するために必要な手順

5　特定細胞加工物製造事業者は、特定細胞加工物標準書、衛生管理基準書、製造管理基準書、品質管理基準書及び手順書（以下「手順書等」と総称する。）を細胞培養加工施設に備え付けなければならない。

（特定細胞加工物の内容に応じた構造設備）

第九十八条　細胞培養加工施設の構造設備は、製造する特定細胞加工物の内容に応じ、適切なものでなければならない。

（製造管理）

第九十九条　特定細胞加工物製造事業者は、製造部門に、手順書等に基づき、次に掲げる製造管理に係る業務を適切に行わせなければならない。

一　製造工程における指示事項、注意事項その他必要な事項を記載した製造指図書を作成し、これを保管すること。

二　製造指図書に基づき特定細胞加工物を製造すること。

三　特定細胞加工物の製造に関する記録をロットごと（ロットを構成しない特定細胞加工物については製造番号ごと。以下同じ。）に作成し、これを保管すること。

四　特定細胞加工物の資材についてロットごとにそれが適正である旨を確認するとともに、その結果に関する記録を作成し、これを保管すること。

五　特定細胞加工物等についてはロットごとに、資材については管理単位ごとに適正に保管し、出納を行うとともに、その記録を作成し、これを保管すること。

六　構造設備の清浄を確認するとともに、その結果に関する記録を作成し、これを保管すること。

七　構造設備を定期的に点検整備するとともに、その記録を作成し、これを保管すること。また、計器の

校正を適切に行うとともに、その記録を作成し、これを保管すること。

八　製造、保管及び出納並びに衛生管理に関する記録により製造管理が適切に行われていることを確認し、その結果を品質部門に対して文書により報告すること。

九　作業室又は作業管理区域については、製造する特定細胞加工物の種類、構造、特性、製造工程及び当該作業室又は作業管理区域で行う作業内容等に応じて、清浄の程度等作業環境の管理の程度を適切に設定し、管理すること。

十　特定細胞加工物等及び資材については、製造する特定細胞加工物の種類、構造、特性及び製造工程等に応じて、微生物等の数等必要な管理項目を適切に設定し、管理すること。

十一　製造工程において、特定細胞加工物等及び資材の微生物等による汚染等を防止するために必要な措置を採ること。

十二　製造する特定細胞加工物の種類、構造、特性及び製造工程等に応じて、特定細胞加工物の微生物等による汚染を回避するために重要な工程等については、工程管理のために必要な管理値を適切に定め、管理すること。

十三　製造用水については、その用途に応じ、所要の微生物学的項目及び物理化学的項目に係る管理値を適切に定め、管理すること。

十四　製造工程において、特定細胞加工物等に含まれる微生物等を不活化し、又は除去する場合においては、当該不活化又は除去が行われていない特定細胞加工物等による汚染を防止するために必要な措置を採ること。

十五　製造工程において、培養槽中に連続的に培地を供給し、かつ、連続的に培養液を排出させる培養方式を用いる場合においては、培養期間中の当該培養槽における培養条件を維持するために必要な措置を採ること。

十六　微生物等により汚染された全ての物品（製造の過程において汚染されたものに限る。）等を、保健衛生上の支障が生ずるおそれのないように処置すること。

十七　製造に使用する細胞の株の取扱いについて、次に掲げる事項に関する記録を作成し、これを保管すること。

イ　細胞の株の名称及び容器ごとに付された番号

ロ　譲受けの年月日並びに相手方の氏名及び住所（法人にあっては、名称及び所在地）

ハ　生物学的性状及びその検査年月日

ニ　継代培養の状況

十八　特定細胞加工物の製造に使用する生物（植物を除く。）に由来する原料（以下「特定細胞加工物生物由来原料」という。）については、当該特定細胞加工物生物由来原料が当該特定細胞加工物の特定細胞加工物標準書に照らして適切なものであることを確認するとともに、その結果に関する記録を作成し、これを保管すること。

十九　第八号及び前号の記録を、製造する特定細胞加工物のロットごとに作成し、これを保管すること。

二十　異なる細胞提供者又はドナー動物から採取した細胞を取り扱う場合においては、当該細胞の混同及び交さ汚染を防止するために必要な措置を採ること。

二十一　再生医療等に用いる細胞について、受入れ時に、次に掲げる事項に関する記録により、当該特定細胞加工物の特定細胞加工物標準書に照らして適切なものであることを確認するとともに、その結果に関する記録を作成し、これを保管すること。

イ　当該細胞の提供又は動物の細胞の採取が行われた施設

ロ　当該細胞の提供又は動物の細胞の採取が行われた年月日

ハ　当該細胞が人に係るものである場合においては、ドナースクリーニング（細胞提供者について、問診、検査等による診断を行い、再生医療等に用いる細胞を提供するにつき十分な適格性を有するかどうかを判定することをいう。）のための細胞提供者の問診、検査等による診断の状況

ニ　当該細胞が動物に係るものである場合においては、ドナー動物の受入れの状況並びにドナースクリーニング（ドナー動物について、試験検査及び飼育管理を行い、再生医療等に用いる細胞を提供するにつき十分な適格性を有するかどうかを判定することをいう。）のためのドナー動物の試験検査及び飼育管理の状況

ホ　当該細胞の提供又は動物の細胞の採取に係る作業の経過

ヘ　当該細胞の輸送の経過

ト　イからヘまでに掲げるもののほか、特定細胞加工物の品質の確保に関し必要な事項

二十二　ドナー動物から細胞を採取する場合においては、採取の過程における微生物等による汚染を防止

するために必要な措置を採るとともに、当該措置の記録を作成し、これを保管すること。

二十三　特定細胞加工物について、特定細胞加工物ごとに、当該特定細胞加工物の提供先の施設名、提供日及びロットを把握するとともに、その記録を作成し、これを保管すること。

二十四　輸送について、特定細胞加工物の品質の確保のために必要な措置を採るとともに、当該措置の記録を作成し、これを保管すること。

二十五　第二十一号から前号までの記録を、ロット（第二十三号の記録にあっては、特定細胞加工物）ごとに作成し、これを保管すること。

二十六　次に定めるところにより、職員の衛生管理を行うこと。

イ　製造作業に従事する職員以外の者の作業所への立入りをできる限り制限すること。

ロ　現に作業が行われている清浄度管理区域又は無菌操作等区域への職員の立入りをできる限り制限すること。

ハ　人若しくは動物の細胞又は微生物等の培養その他の加工等（その製造工程において現に原料等として使用されているものを除く。）に係る作業に従事する職員による汚染の防止のための厳重な手順を

定め、これを遵守する場合を除き、特定細胞加工物の作業室又は作業管理区域に立入りさせないこと。

ニ　製造作業に従事する職員を、使用動物（その製造工程において現に使用されているものを除く。）の管理に係る作業に従事させないこと。

二十七　次に定めるところにより、清浄度管理区域又は無菌操作等区域で作業する職員の衛生管理を行うこと。

イ　製造作業に従事する職員に、消毒された作業衣、作業用のはき物、作業帽、作業マスク及び作業手袋を着用させること。

ロ　製造作業に従事する職員が清浄度管理区域又は無菌操作等区域へ立ち入る際には、当該区域の管理の程度に応じて、更衣等を適切に行わせること。

ハ　職員が特定細胞加工物等を微生物等により汚染するおそれのある疾病にかかっていないことを確認するために、職員に対し、定期的に健康診断を行うこと。

ニ　職員が特定細胞加工物等を微生物等により汚染するおそれのある健康状態にある場合（皮膚若しくは毛髪の感染症若しくは風邪にかかっている場合、負傷している場合又は下痢若しくは原因不明の発

熱等の症状を呈している場合を含む。）においては、当該職員を清浄度管理区域又は無菌操作等区域における作業に従事させないこと。

ホ　職員が細胞の採取又は加工の直前に細胞を汚染するおそれのある微生物等を取り扱っている場合においては、当該職員を清浄度管理区域又は無菌操作等区域における作業に従事させないこと。

ヘ　前号及びイからホまでの記録を作成し、これを保管すること。

二十八　その他製造管理のために必要な業務

2　前項に規定する特定細胞加工物に係る記録は、製造に使用した特定細胞加工物生物由来原料に関する記録から当該特定細胞加工物生物由来原料を使用して製造された特定細胞加工物に関する記録までの一連のものを適切に確認できるように保管されなければならない。

（品質管理）

第百条　特定細胞加工物製造事業者は、品質部門に、手順書等に基づき、次に掲げる特定細胞加工物の品質管理に係る業務を計画的かつ適切に行わせなければならない。

一　特定細胞加工物等についてはロットごとに、資材については管理単位ごとに試験検査を行うのに必要

な検体を採取するとともに、その記録を作成し、これを保管すること。

二　採取した検体について、ロットごと又は管理単位ごとに試験検査（当該特定細胞加工物製造事業者の他の試験検査設備又は他の試験検査機関を利用して自己の責任において行う試験検査であって、当該利用につき支障がないと認められるものを含む。以下同じ。）を行うとともに、その記録を作成し、これを保管すること。

三　試験検査に関する設備及び器具を定期的に点検整備するとともに、その記録を作成し、これを保管すること。また、試験検査に関する計器の校正を適切に行うとともに、その記録を作成し、これを保管すること。

四　第二号の試験検査の結果の判定を行い、その結果を製造部門に対して文書により報告すること。

五　検体の混同及び交さ汚染を防止するために、検体を適切な識別表示により区分すること。

六　品質管理上重要であり、かつ、特定細胞加工物では実施することができない試験検査については、製造工程の適切な段階で実施すること。

七　微生物等により汚染された全ての物品（試験検査の過程において汚染されたものに限る。）等を、保

健衛生上の支障が生ずるおそれのないように処置すること。

八　試験検査に細胞の株を使用する場合においては、次に掲げる事項に関する記録を作成し、これを保管すること。

イ　細胞の株の名称及び容器ごとに付された番号

ロ　譲受けの年月日並びに相手方の氏名及び住所（法人にあっては、名称及び所在地）

ハ　生物学的性状及びその検査年月日

ニ　継代培養の状況

九　試験検査結果の記録を、製造する特定細胞加工物のロットごとに作成し、これを保管すること。

十　ドナー動物の受入れ時及び受入れ後の試験検査を行うことその他必要な業務を自ら行い、又は当該業務の内容に応じてあらかじめ指定した者に行わせること。

十一　前号に規定する業務の記録を作成し、これを保管すること。

十二　その他の品質管理のために必要な業務

２　前項に規定する特定細胞加工物に係る記録は、製造に使用した特定細胞加工物生物由来原料に関する記

録から当該特定細胞加工物生物由来原料を使用して製造された特定細胞加工物に関する記録までの一連のものを適切に確認できるように保管されなければならない。

3　特定細胞加工物製造事業者は、品質部門に、手順書等に基づき、前条第一項第八号の規定により製造部門から報告された製造管理に係る確認の結果をロットごとに確認させなければならない。

（特定細胞加工物の取扱い）

第百一条　特定細胞加工物製造事業者は、品質部門に、手順書等に基づき、製造管理及び品質管理の結果を適切に評価し、その結果を踏まえ、製造した特定細胞加工物の取扱いについて決定する業務を行わせなければならない。

2　前項の業務を行う者は、当該業務を適正かつ円滑に実施し得る能力を有する者でなければならない。

3　特定細胞加工物製造事業者は、第一項の業務を行う者が当該業務を行う際に支障が生ずることがないようにしなければならない。

（検証又は確認）

第百二条　特定細胞加工物製造事業者は、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を

行わせなければならない。この場合において、特定細胞加工物製造事業者は、必要に応じ、再生医療等提供機関の医師又は歯科医師の指示を受けるものとする。

一　次に掲げる場合において細胞培養加工施設の構造設備並びに手順、工程その他の製造管理及び品質管理の方法（以下「製造手順等」という。）が期待される結果を与えることを検証し、これを文書とすること又は製造手順等が期待される結果を与えたことを確認し、これを文書とすること。

イ　当該細胞培養加工施設において新たに特定細胞加工物の製造を開始する場合

ロ　製造手順等に特定細胞加工物の品質に大きな影響を及ぼす変更がある場合

ハ　その他特定細胞加工物の製造管理及び品質管理を適切に行うために必要と認められる場合

二　前号の検証又は確認の計画及び結果を品質部門に対して文書により報告すること。

2　特定細胞加工物製造事業者は、前項第一号の検証又は確認の結果に基づき、製造管理又は品質管理に関し改善が必要な場合においては、所要の措置を採るとともに、当該措置の記録を作成し、これを保管しなければならない。

（特定細胞加工物の品質の照査）

第百三条　特定細胞加工物製造事業者は、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を行わせなければならない。

一　製造工程の一貫性及び特定細胞加工物等の規格の妥当性について検証することを目的として、定期的に又は随時、特定細胞加工物の品質の照査を行うこと。

二　前号の照査の結果を品質部門に対して文書により報告し、確認を受けること。

２　特定細胞加工物製造事業者は、品質部門に、手順書等に基づき、前項第二号の確認の記録を作成させ、保管させるとともに、施設管理者に対して文書により適切に報告させなければならない。

３　特定細胞加工物製造事業者は、第一項第一号の照査の結果に基づき、製造管理若しくは品質管理に関し改善が必要な場合又は前条第一項第一号の検証若しくは確認を行うことが必要な場合においては、必要に応じて再生医療等提供機関の医師又は歯科医師の指示を受け、所要の措置を採るとともに、当該措置に関する記録を作成し、これを保管しなければならない。

（変更の管理）

第百四条　特定細胞加工物製造事業者は、製造手順等について、特定細胞加工物の品質に影響を及ぼすおそ

れのある変更を行う場合においては、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を行わせなければならない。この場合において、特定細胞加工物製造事業者は、必要に応じ、再生医療等提供機関の医師又は歯科医師の指示を受けるものとする。

一　当該変更による特定細胞加工物の品質への影響を評価し、その評価の結果をもとに変更を行うことについて品質部門の承認を受けるとともに、その記録を作成し、これを保管すること。

二　前号の規定により品質部門の承認を受けて変更を行うときは、関連する文書の改訂、職員の教育訓練その他所要の措置を採ること。

2　特定細胞加工物製造事業者は、品質部門に、手順書等に基づき、前項第一号の承認の記録を作成させ、保管させるとともに、施設管理者に対して文書により適切に報告させなければならない。

3　特定細胞加工物製造事業者は、前項の報告を受けた施設管理者に、当該報告の内容について、当該製造した特定細胞加工物の提供先の再生医療等提供機関に対して報告させなければならない。

（逸脱の管理）

第百五条　特定細胞加工物製造事業者は、製造手順等からの逸脱（以下単に「逸脱」という。）が生じた場

合においては、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を行わせなければならない。この場合において、特定細胞加工物製造事業者は、必要に応じ、再生医療等提供機関の医師又は歯科医師の指示を受けるものとする。

一　逸脱の内容を記録すること。

二　重大な逸脱が生じた場合においては、次に掲げる業務を行うこと。

イ　逸脱による特定細胞加工物の品質への影響を評価し、所要の措置を採ること。

ロ　イに規定する評価の結果及び措置について記録を作成し、保管するとともに、品質部門に対して文書により報告すること。

ハ　ロの規定により報告された評価の結果及び措置について、品質部門の確認を受けること。

２　特定細胞加工物製造事業者は、品質部門に、手順書等に基づき、前項第二号ハにより確認した記録を作成させ、保管させるとともに、同号ロの記録とともに、施設管理者に対して文書により適切に報告させなければならない。

３　特定細胞加工物製造事業者は、前項の報告を受けた施設管理者に、当該報告の内容について、当該特定

細胞加工物製造事業者が製造した特定細胞加工物の提供先の再生医療等提供機関に対して報告させなければならない。

（品質等に関する情報及び品質不良等の処理）

第百六条　特定細胞加工物製造事業者は、特定細胞加工物に係る品質等に関する情報（以下「品質情報」という。）を得たときは、その品質情報に係る事項が当該細胞培養加工施設に起因するものでないことが明らかな場合を除き、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を行わせなければならない。この場合において、特定細胞加工物製造事業者は、必要に応じ、再生医療等提供機関の医師又は歯科医師の指示を受けるものとする。

一　当該品質情報に係る事項の原因を究明し、製造管理又は品質管理に関し改善が必要な場合においては、所要の措置を採ること。

二　当該品質情報の内容、原因究明の結果及び改善措置を記載した記録を作成し、保管するとともに、品質部門に対して文書により速やかに報告すること。

三　前号の報告について、品質部門の確認を受けること。

２　特定細胞加工物製造事業者は、前項第三号の確認により品質不良又はそのおそれが判明した場合には、品質部門に、手順書等に基づき、当該事項を施設管理者に対して文書により報告させなければならない。

３　特定細胞加工物製造事業者は、前項の報告を受けた施設管理者に、当該報告の内容について、当該特定細胞加工物製造事業者が製造した特定細胞加工物の提供先の再生医療等提供機関に対して報告させなければならない。

（重大事態報告等）

第百七条　特定細胞加工物製造事業者は、特定細胞加工物の安全性の確保に重大な影響を及ぼすおそれがある事態が生じた場合には、必要な措置を講じるとともに、その旨を速やかに当該特定細胞加工物製造事業者が製造した特定細胞加工物の提供先の再生医療等提供機関及び厚生労働大臣に報告しなければならない。

２　前項の措置に係る特定細胞加工物を保管する場合においては、当該特定細胞加工物を区分して一定期間保管した後、適切に処理しなければならない。

（自己点検）

第百八条　特定細胞加工物製造事業者は、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を

行わせなければならない。

一　当該細胞培養加工施設における特定細胞加工物の製造管理及び品質管理について定期的に自己点検を行うこと。

二　自己点検の結果を施設管理者に対して文書により報告すること。

三　自己点検の結果の記録を作成し、これを保管すること。

２　特定細胞加工物製造事業者は、前項第一号の自己点検の結果に基づき、製造管理又は品質管理に関し改善が必要な場合においては、所要の措置を採るとともに、当該措置の記録を作成し、これを保管すること。

（教育訓練）

第百九条　特定細胞加工物製造事業者は、あらかじめ指定した者に、手順書等に基づき、次に掲げる業務を行わせなければならない。

一　製造・品質管理業務に従事する職員に対して、製造管理及び品質管理に関する必要な教育訓練を計画的に実施すること。

二　製造又は試験検査に従事する職員に対して、特定細胞加工物の製造のために必要な衛生管理、微生物

学、医学その他必要な教育訓練を実施すること。

三　清浄度管理区域及び無菌操作等区域等での作業に従事する職員並びに特定細胞加工物の製造に使用する人若しくは動物の細胞又は微生物等の培養その他の加工等に係る作業に従事する職員に対して、微生物等による汚染を防止するために必要な措置に関する教育訓練を実施すること。

四　教育訓練の実施状況を施設管理者に対して文書により報告すること。

五　教育訓練の実施の記録を作成し、これを保管すること。

（文書及び記録の管理）

第百十条　特定細胞加工物製造事業者は、第四章に規定する文書及び記録について、あらかじめ指定した者に、手順書等に基づき、次に掲げる事項を行わせなければならない。

一　文書を作成し、又は改訂する場合においては、手順書等に基づき、承認、配付、保管等を行うこと。

二　手順書等を作成し、又は改訂する場合においては、当該手順書等にその日付を記載するとともに、それ以前の改訂に係る履歴を保管すること。

三　第四章に規定する文書及び記録を、作成の日（手順書等については使用しなくなった日）から次に掲

げる期間（教育訓練に係る記録にあっては、五年間）保管すること。

イ　指定再生医療等製品の原料と類似の原料からなる特定細胞加工物にあっては、三十年間

ロ　イに規定する特定細胞加工物以外の特定細胞加工物にあっては、十年間

（特定細胞加工物の製造に関する記録に関する事項）

第百十一条　法第四十五条の厚生労働省令で定める事項は、次のとおりとする。

一　製造をした特定細胞加工物の種類

二　特定細胞加工物の提供先の再生医療等提供機関の名称及び住所

三　委託を受けて製造をした場合には、委託元及び委託業務の内容

四　再生医療等に用いる細胞の種類

五　再生医療等に用いる細胞の提供が行われた医療機関等の名称及び細胞の提供が行われた年月日

六　再生医療等に用いる細胞が適切なものであることを検査等により確認した結果

七　特定細胞加工物の製造の経過

八　特定細胞加工物が再生医療等に用いるために適切なものであることを検査等により確認した結果

九　特定細胞加工物の輸送の方法及び輸送業者
十　特定細胞加工物の提供日
２　特定細胞加工物製造事業者は、法第四十五条の記録を、次に掲げる期間、保存しなければならない。
一　指定再生医療等製品の原料と類似の原料からなる特定細胞加工物に係る記録にあっては、その提供日から起算して少なくとも三十年間
二　前号に掲げる特定細胞加工物以外の特定細胞加工物に係る記録にあっては、その提供日から起算して少なくとも十年間
（定期報告）
第百十二条　法第四十六条の規定に基づき、特定細胞加工物の製造の状況について、次に掲げる事項を報告しなければならない。
一　特定細胞加工物の製造件数
二　苦情の処理状況
三　特定細胞加工物の提供先の再生医療等提供機関から第十七条第四項第一号の規定により通知を受けた

疾病等の発生に係る次に掲げる情報

イ　疾病等の発生があった年月日

ロ　疾病等の発生に対する措置状況

ハ　特定細胞加工物製造業者による対策等

２　前項の報告は、法第三十五条第一項の規定による許可又は法第三十九条第一項の規定による認定を受けた日若しくは法第四十条第一項の規定による届出をした日から起算して、一年ごとに、当該期間満了後六十日以内に行わなければならない。

第五章　監督

（身分を示す証明書）

第百十三条　法第二十四条第三項（法第五十二条第三項において準用する場合を含む。）に規定する身分を示す証明書は、様式第三十によるものとする。

（報告）

第百十四条　厚生労働大臣は、法第二十四条第一項の規定により、提供機関管理者若しくは開設者（医療法

第五条第一項に規定する医師又は歯科医師を含む。以下この条において同じ。）に対して、必要な報告をさせるとき、法第二十四条第二項の規定により、医療機関の管理者若しくは開設者に対して必要な報告をさせるとき、法第三十一条の規定により、認定委員会設置者に対して、報告を求めるとき、法第五十条第一項第一号の規定により、法第三十九条第一項の認定を受けた者（以下「認定事業者」という。）に対して、必要な報告を求めるとき、法第五十二条第一項の規定により、許可事業者若しくは届出事業者に対し、必要な報告をさせるとき又は法第五十二条第二項の規定により、特定細胞加工物を製造する者に対し、必要な報告をさせるときは、その理由を通知するものとする。

（機構による認定事業者に対する検査又は質問の結果の通知）

第百十五条　法第五十条第三項の規定による通知は、様式第三十一による通知書により行うものとする。

（機構による許可事業者又は届出事業者に対する立入検査等の結果の通知）

第百十六条　法第五十三条第二項の規定による通知は、様式第三十二による通知書により行うものとする。

（機構の職員の身分を示す証明書）

第百十七条　法第五十三条第三項の身分を示す証明書は、様式第三十三によるものとする。

第六章　雑則

（権限の委任）

第百十八条　法第五十六条第一項の規定により、次に掲げる厚生労働大臣の権限は、地方厚生局長に委任する。ただし、厚生労働大臣が第六号、第七号、第十二号から第十四号まで及び第二十号から第二十三号までに掲げる権限を自ら行うことを妨げない。

一　法第四条第一項に規定する権限（第二種再生医療等及び第三種再生医療等に係るものに限る。）

二　法第五条第一項及び第三項に規定する権限（第二種再生医療等及び第三種再生医療等に係るものに限る。）

三　法第六条に規定する権限（第二種再生医療等及び第三種再生医療等に係るものに限る。）

四　法第十八条に規定する権限（第二種再生医療等及び第三種再生医療等に係るものに限る。）

五　法第二十一条第一項に規定する権限（第二種再生医療等及び第三種再生医療等に係るものに限る。）

六　法第二十三条に規定する権限

七　法第二十四条第一項及び第二項に規定する権限

八　法第二十六条第一項、第二項及び第四項（これらの規定を法第二十七条第三項において準用する場合を含む。）並びに第五項（法第二十七条第五項において準用する場合を含む。）に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

九　法第二十七条第一項、第二項及び第四項に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

十　法第二十八条第三項に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

十一　法第三十条第一項及び第二項に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

十二　法第三十一条に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

十三　法第三十二条第一項及び第二項に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

十四　法第三十三条第一項及び第二項に規定する権限（特定認定再生医療等委員会以外の認定再生医療等委員会に係るものに限る。）

十五　法第三十五条第一項及び第二項から第五項まで（これらの規定を法第三十六条第二項において準用する場合を含む。）に規定する権限

十六　法第三十七条に規定する権限

十七　法第四十条第一項及び第三項に規定する権限

十八　法第四十一条に規定する権限

十九　法第四十六条に規定する権限

二十　法第四十八条第一項及び第二項に規定する権限

二十一　法第四十九条に規定する権限

二十二　法第五十一条に規定する権限

二十三　法第五十二条第一項及び第二項に規定する権限

２　第五十六条及び第五十七条第一項及び第二項（特定認定再生医療等委員会以外の認定再生医療等委員会

に係るものに限る。）、第七十六条第一項、第七十七条第一項及び第三項並びに第百七条第一項に規定する厚生労働大臣の権限は、地方厚生局長に委任する。

（邦文記載）

第百十九条　厚生労働大臣又は機構に提出する計画、申請書、届書その他の書類は、邦文で記載されていなければならない。ただし、特別の事情により邦文をもって記載することができない書類であって、その翻訳文が添付されているものについては、この限りでない。

（フレキシブルディスクによる手続）

第百二十条　次の表の上欄に掲げる規定中同表の下欄に掲げる書類については、これらの書類の各欄に掲げる事項を記録したフレキシブルディスクその他これに準ずる物として厚生労働大臣が定めたもの並びに提出を行う者、申請者又は届出をする者の氏名及び住所並びに提出、申請又は届出の趣旨及びその年月日を記載した書類（次項において「フレキシブルディスク等」という。）をもってこれらの書類に代えることができる。

第二十七条第一項	様式第一による計画

第二十八条	様式第二による届書
第三十条	様式第三による届書
第三十一条	様式第四による届書
第四十三条第一項	様式第五による申請書
第五十一条	様式第七による申請書
第五十三条	様式第八による届書
第五十五条第一項	様式第九による届書
第五十六条	様式第十による申請書
第五十七条第一項	様式第十一による申請書
第五十八条第一項	様式第十二による申請書
第五十九条第一項	様式第十三による申請書
第七十二条第一項	様式第十四による申請書
第七十五条	様式第十六による届書

第七十六条第一項（第八十四条において準用する場合を含む。）	様式第十七による申請書
第七十七条第一項（第八十四条において準用する場合を含む。）	様式第十八による申請書
第七十八条第一項	様式第十九による申請書
第八十一条第二項	様式第二十による申請書
第八十三条第一項	様式第二十二による申請書
第八十四条において準用する第七十五条	様式第二十四による届書
第八十四条において準用する第七十八条	様式第二十五による申請書
第八十四条において準用する第八十一条第二項	様式第二十六による申請書
第八十五条第一項	様式第二十七による届書
第八十七条	様式第二十八による届書
第八十八条	様式第二十九による届書

２　前項の規定により同項の表の下欄に掲げる書類に代えてフレキシブルディスク等が提出される場合においては、当該フレキシブルディスク等は当該書類とみなす。

（フレキシブルディスクの構造）

第百二十一条　前条第一項のフレキシブルディスクは、日本工業規格Ｘ六二二三号に適合する九十ミリメートルフレキシブルディスクカートリッジでなければならない。

（フレキシブルディスクへの記録方式）

第百二十二条　第百二十条第一項のフレキシブルディスクへの記録は、次に掲げる方式に従ってしなければならない。

一　トラックフォーマットについては、日本工業規格Ｘ六二二四号又は日本工業規格Ｘ六二二五号に規定する方式

二　ボリューム及びファイル構成については、日本工業規格Ｘ〇六〇五号に規定する方式

（フレキシブルディスクに貼り付ける書面）

第百二十三条　第百二十条第一項のフレキシブルディスクには、日本工業規格Ｘ六二二三号に規定するラベ

ル領域に、次に掲げる事項を記載した書面を貼り付けなければならない。

一　提出者、申請者又は届出をする者の氏名

二　提出年月日、申請年月日又は届出年月日

（電子情報処理組織による手続）

第百二十四条　法第四条第三項（法第五条第二項において準用する場合を含む。）、法第二十六条第三項（法第二十七条第三項及び第二十八条第六項において準用する場合を含む。）及び法第三十五条第二項（法第三十六条第二項及び第三十九条第二項において準用する場合を含む。）の規定による書類の添付は電子情報処理組織（厚生労働省の使用に係る電子計算機と、同条の規定による添付をしようとする者の使用に係る入出力装置とを電気通信回線で接続した電子情報処理組織をいう。）を用いて入力し、送信することをもってこれらの書類に代えることができる。

附　則

（施行期日）

第一条　この省令は、法の施行の日（平成二十六年十一月二十五日）から施行する。

（保険医療機関及び保険薬局の指定並びに保険医及び保険薬剤師の登録に関する省令の一部改正）

第二条　保険医療機関及び保険薬局の指定並びに保険医及び保険薬剤師の登録に関する省令（昭和三十二年厚生省令第十三号）の一部を次のように改正する。

様式第一号（裏面）及び第二号（裏面）を次のように改める。

←

（厚生労働省の所管する法令の規定に基づく民間事業者等が行う書面の保存等における情報通信の技術の利用に関する省令の一部改正）

第三条　厚生労働省の所管する法令の規定に基づく民間事業者等が行う書面の保存等における情報通信の技術の利用に関する省令（平成十七年厚生労働省令第四十四号）の一部を次のように改正する。

別表第一表一に次のように加える。

再生医療等の安全性の確保等に関する法律施行規則（平成二十六年厚生労働省令第百十号）	第三十四条第二項の規定による法第十六条第一項に規定する記録、再生医療等提供計画、同意に係る文書及び特定細胞加工物概要書の保存	
	第六十七条第二項の規定による帳簿の保存	
	第七十一条第二項の規定による審査等業務に係る再生医療等提供計画及び同条第一項の記録の保存	
	第九十七条第五項の規定による手順書等の備付け	
	第百十条第三号の規定による記録の保管	
	第百十一条第二項の規定による記録の保存	

別表第二に次のように加える。

再生医療等の安全性の確保等に関する法律施行規則	第八条第一項の規定による特定細胞加工物概要書の作成
	第十四条第二項の規定による記録の作成
	第三十四条第一項の規定による記録の作成
	第七十一条第一項の規定による審査等業務の過程に関する記録の作成
	第九十六条の規定による特定細胞加工物標準書の作成
	第九十七条第一項の規定による衛生管理基準書の作成
	第九十七条第二項の規定による製造管理基準書の作成
	第九十七条第三項の規定による品質管理基準書の作成
	第九十七条第四項の規定による手順書の作成
	第九十九条第一項第一号の規定による製造指図書の作成

（心神喪失等の状態で重大な他害行為を行った者の医療及び観察等に関する法律に基づく指定医療機関等に関する省令の一部改正）

第四条　心神喪失等の状態で重大な他害行為を行った者の医療及び観察等に関する法律に基づく指定医療機関等に関する省令（平成十七年厚生労働省令第百十七号）の一部を次のように改正する。

第四条第三号中「又は」を「、」に改め、「第七十五条の二第一項」の下に「又は再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）第二十三条、第四十八条若しくは第四十九条」を加える。

（障害者の日常生活及び社会生活を総合的に支援するための法律施行規則の一部改正）

第五条　障害者の日常生活及び社会生活を総合的に支援するための法律施行規則（平成十八年厚生労働省令第十九号）の一部を次のように改正する。

第六十三条第二号中「又は」を「、」に改め、「第七十五条の二第一項」の下に「又は再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号）第二十三条、第四十八条若しくは第四十九条」を加える。

（厚生労働省組織規則の一部改正）

第六条　厚生労働省組織規則（平成十三年厚生労働省令第一号）の一部を次のように改正する。

第七百七条中第二号の二及び第二号の三を次のように改める。

二の二　再生医療等の安全性の確保等に関する法律（平成二十五年法律第八十五号。以下「再生医療等安全性確保法」という。）第四条第一項に規定する再生医療等提供計画の提出及び再生医療等を提供する医療機関の監督に関すること。

二の三　再生医療等安全性確保法第二十六条第一項の規定による再生医療等委員会の認定及び認定再生医療等委員会の監督に関すること。

同条第二号の三の次に次の一号を加える。

二の四　再生医療等安全性確保法第三十五条第一項の規定による特定細胞加工物の製造の許可及び同法第四十条第一項の規定による特定細胞加工物の製造の届出並びに特定細胞加工物の製造をする者の監督に関すること。

第七百十四条中第二号の二及び第二号の三を次のように改める。

二の二　再生医療等安全性確保法第四条第一項に規定する再生医療等提供計画の提出及び再生医療等を提供する医療機関の監督に関すること。

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同条第二号の三の次に次の一号を加える。

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GUIDELINES

Regulation of Clinical Trials in the Philippines

CLINICAL TRIAL UNIT
POLICY PLANNING AND ADVOCACY DIVISION
FOOD AND DRUG ADMINISTRATION

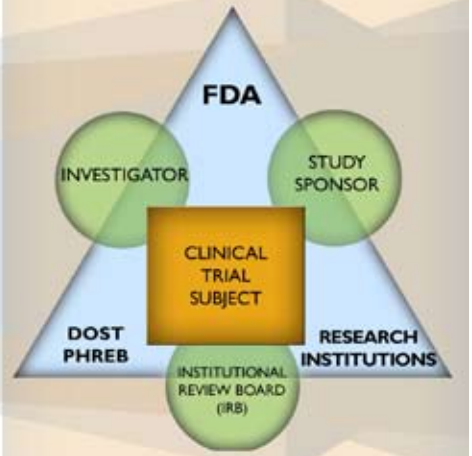

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FDA CIRCULAR 2012-007

June 7, 2012

FDA Circular
No. 2012-007

SUBJECT: Recognition of Ethical Review Board/Committee (ERB/ERC) For Purposes of the Conduct of Clinical Trials on Investigational Medicinal Products in the Philippines and for Other Purposes

I. RATIONALE AND BACKGROUND

The Philippines: An Emerging Destination for Global Clinical Trials

In recent years there has been an increase in the number of clinical trials in the Philippines. Of the 10 countries in Southeast Asia, the Philippines ranks third in terms of the number of clinical trials (US NIH, http://clinicaltrials.gov/ct2/search/browse?brwse=locn_cat_SE, Accessed on May 19, 2012).Based on the 2009 report by the European Medicines Agency, the Philippines is ranked as number 8 among the top 10 countries worldwide with a high annual growth rate of 30.9 % in clinical trials. Clinical trials emanating from the European Union increased from 2 in 2005 to 25 in 2008 with a corresponding increase in the number of trial participants from 67 to 3,042 respectively. Likewise, trials emanating from the US increased from 3 in 2000 to 363 in 2009. The Philippines currently ranks third in Southeast Asia with 528 ongoing global trials, after Thailand with 1094, and Singapore with 958 (www.clinicaltrials.gov, accessed on June 5, 2012). FDA received 396 clinical trial applications in 2009; 339 in 2010, and 335 in 2011.

As recruitment for volunteers become more intense with the anticipated increase in clinical studies and given the vulnerabilities of the majority of our people because of poor health, economic status, abuse or poor orientation and lack of awareness of their rights, there is an urgent need to improve regulatory function and promote cooperation between DOH-FDA and other quasi-regulatory agencies suchas the Philippine Health Research Ethics Board (PHREB) of the Philippines National Research Health System (PNHRS) to better ensure that every Filipino patient who volunteers to participate in clinical research studies is accorded due protection as embodied in the Philippine Constitution.

As part of the quest to attain a higher level of competitiveness for the country, there is a need to find a more efficient system that should be benchmarked with global models.

II. OBJECTIVES

In addition to the objectives laid down in the Rules and Regulations implementing Republic Act No. 9711, this Order is hereby formulated to:

To accord due protection to human subjects of clinical trials and ensure the generation of research findings of strong scientific merit, FDA grants recognition and empowersselected institution-based

Ethical Review Board/Committees (ERB/ERCs)undertaketheethical and technical evaluation of clinical trials for the purpose of recommending, to the FDA, the approval of such studies for conduct in the Philippines.

To require mandatory ethical and technical reviews by accredited independent review committees of experts in accordance with existing national regulations (PNHRS Ethics Guidelines) as well as Good Clinical Practice (GCP ICH-E6 1996) guidelines and any supplements and amendments thereof, which are hereby adopted.

To require mandatory inclusion for all clinical trials (Phases I, II, III and IV) in the Philippine Clinical Trials Registry (http://registry.healthresearch.ph).

III. COVERAGE AND SCOPE

This Circular covers the recognition of ERB/ERCs to serve as ethical and technical reviewers for clinical trial applications and is for the compliance is for the compliance of the sponsor companies, Clinical Research Organizations (CROs), and Ethical Review Board/Committees (ERB/ERCs).

This regulation covers Phase I, II, III and IV clinical trials of investigational medicinal products defined as any substance or combinationof substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Investigational medicinal products cover new chemical entities under the investigational phase of drug development as well as existing drug preparations already in the market seeking approval for new or additional indications.

IV. DECLARATION OF POLICIES

Pursuant to the mandates provided under the 1987 Constitution to protect and promote the right to health of the people, Republic Act 3720, as amended by Executive Order 175, otherwise known as the "Food, Drugs and Devices, and Cosmetics Act", to adopt measures that ensure the purity and safety of foods and cosmetics, and, in addition to purity and safety, the efficacy and quality of drugs and devices in the country and as reiterated by Republic Act No. 9711 or the "The Food and Drug Administration (FDA) Act of 2009," the adoption of the International Conference on Harmonization Guideline for Good Clinical Practice or ICH GCP (E6) in the review, approval and regulation of clinical trials not only for vaccines but for all pharmaceutical products as may be applicable or supported by local guidelines as expressed under Administrative Order 47-a, series of 2001 entitled Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials and Lot or Batch Release Certification of Vaccines and Biologic Products is hereby reiterated.

This circular strengthens the technical and ethical review through the use of independent ethical and technical panels that have been audited and accredited by Philippine Health Research Ethics Board (PHREB), the national body constituted under the Philippine National Health Research System (PNHRS)under the Department of Science and Technology (DOST) to ensure that ERB/ERCs comply with international and national standards in the performance of their function. In keeping with international standards to safeguard the quality of research and protect the public from the negative effects of biased reporting and publication, clinical trials are hereby mandatorily required to be posted on the clinical trials registry established under the mandate of PNHRS.

A. FDA Recognition of PHREB-Accredited IRBs to Serve as Ethical and Technical Reviewers for Clinical Trial Applications

The FDA recognizes the following IRBs/ERCs of institutions based on the recommendation of the PHREB:

1. University of the Philippines Manila –National Institutes of Health (UPM-NIH)
2. De La Salle University Health Sciences Institute
3. St. Luke's Medical Center for Clinical Trials

The list will be subject to updating based on PHREB's continuing accreditation of institutions and compliance with other requirements of FDA.

As shown in Figure 1, the ERB/ERCs will submit recommendations to the FDAfor the approval or denial of clinical trial protocols subjected to review. FDA, after due deliberation will renderthe decision for approval or denial.

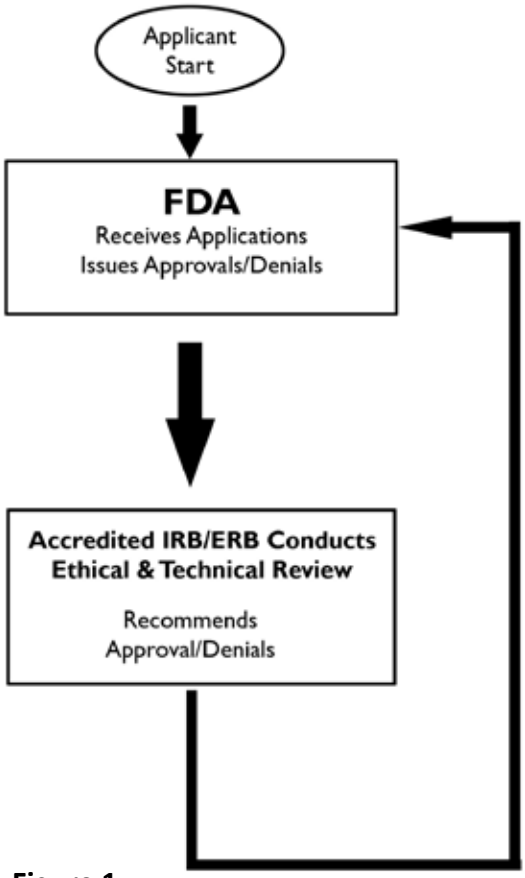

Figure 1
Approval Process for Clinical Trial Applications

The FDA will also coordinate with the ERB/ERCs as well as the PHREB on all matters related to the applications under review to resolve whatever issues will arise.

B. Mandatory FDA Approval for All Phase I to IV Clinical Trials

All clinical studies, from Phase I to IV, including amendment(s) thereto, require mandatory approval from the FDA to ensure that clinical trials intended to be conducted in the country that involve the recruitment of Filipinos as volunteer subjects conform to the highest ethical and technical standards of clinical research. Approval will be based on results of the evaluation that will be carried out by accredited ERB/ERBs.

V. IMPLEMENTATION GUIDELINES

A. In line with the recognition of accredited ERB/ERCs, the Policy Planning and Advocacy Division (PPAD) of the FDA is mainly responsible for providing supervision and oversight (VI. Supervision and Oversight) in the regulation of clinical trials. The Clinical Trial Management Unit under PPAD will be:

1. Responsible for handling the filing of the application, issuance of the ***Clinical Trial Reference No***. and ***"Permit for ERB/ERC Review"*** and approval to conduct clinical trials. PPAD is also responsible for handling amendments to the clinical trial protocols that must be approved by the FDA Director.
2. Responsible for coordinating with the ERB/ERCs on matters relevant to the conduct of the ethical and technical review of clinical trial protocols.
3. Coordinating with PSD who will conduct the review of Part B- Pharmaceutical Data and the issuance of the ***Import Permit***.In addition, PPAD must ascertain that the Regulation Division I beproperly informed of ***Import Permit*** issuances to facilitate processing with the Bureau of Customs.
4. Receiving and acting on amendments and other changes to the clinical trial protocol and coordinating closely with ERB/ERCs
5. Monitoring compliance to mandatory requirement for participation in the Philippines Clinical Trial Registry
6. PPAD will be responsible for conducting on-site inspections of clinical trials; it is imperative that capacity for this be developed as soon as possible.
7. Coordinating with the FDA ADR Unit which is mainly responsible for receiving, analyzing and reporting on Safety Reporting
8. Responsible for maintaining data on statistics and formulating reports for submission regularly to the FDA Director.

B. The Product Services Division is responsible for evaluating the pharmaceutical data of new pharmaceutical products to ascertain that Chemistry, Manufacturing and Controls (CMC) and Good Manufacturing Practice (GMP) standards are met to ascertain the safety of the product for use by clinical trial subjects. Furthermore, PSD is also responsible for issuing the ***Import Permit***. The review of pharmaceutical data must be accomplished within a reasonably efficient timeframe not to exceed thirty (30) calendar days from receipt thereof from PPAD, and issuance of the ***Import Permit*** not to exceed seven (7) working days from receipt of application.

C. The ADR Unit will be the unit responsible for receiving and analyzing reports on Adverse Events.

D. FDA reserves the right to terminate any clinical trial found to be violative of existing regulations or deviates from the approved protocol and monitoring plan.

E. Submission of Application to the FDA

1. Applicant company files applications to the FDA which will set one day of the week, schedule subject to announcement, for receiving applications from eight (8) in the morning to three (3) in the afternoon.

2. Steps in the filing:
   a. File application to PPAD-PAICS for assessment
   b. Go to Accounting Section for validation of Order of Payment
   c. Go to Cashier Section to pay the fee and secure an Official Receipt (OR)
   d. Return to PPAD-PAICS, present OR and secure Clinical Trial Reference Number. Submit documents and receive "Permit for ERB/ERC Review" which will signal the accredited ERB/ERCs to conduct the ethical and technical review.

3. Documents to be submitted will include those in Parts A, B and C and such other documents or data as hereinafter be required by FDA to ascertain safety, efficacy and quality of the products

that will be subject to clinical study.

a. PART A: Clinical Trial Protocol and other Pertinent Documents
   - Name and dosage form of product
   - Title and aim of the trial
   - Description of the trial design
   - Description of the subjects
   - Treatment profile
   - Operational aspects
   - Adverse events
   - Evaluation of results
   - Informed consent form, Case Report Form and Patient Information Sheet
   - Resumes of Principal and other Investigators
   - For multi-center studies, a list of Principal Investigators (and CVs) including trial sites

b. PART B: Pharmaceutical Data
   To ascertain the quality and safety of the IPand to protect clinical trial subjects, FDA needs to ensure that the IP's CMC and manufacturing process is in compliance with acceptable standards (GMP).
   - GMP statement from manufacturing/Certificate from Regulatory Body
   - Certificate of Analysis
   - Stability Data (storage conditions)
   - Manufacturing Data & Formulation
   - Product labeling (coded & labeled: blinding)

c. PART C: Investigator's Brochure (Efficacy and Safety Data)

   Safety Data:
   - Non-Clinical Studies
   - Pharmacology; PK/PD studies
   - Toxicology Studies
   - Marketing Experience, Periodic Safety Update Reports (PSUR), product status if marketed abroad
   - Risks and ADR anticipated

   Efficacy Data
   - PK/PD Data in human subjects
   - In-house preliminary data
   - Summaries of clinical trial studies conducted (Phase I, II, III)
   - Published clinical data

4. Submission of documents:
   Documents may be submitted as hardcopy or electronic file based on preference of FDA and ERB/ERC.
   Figure 2 below shows algorithm of submission of application to the FDA.

Figure2

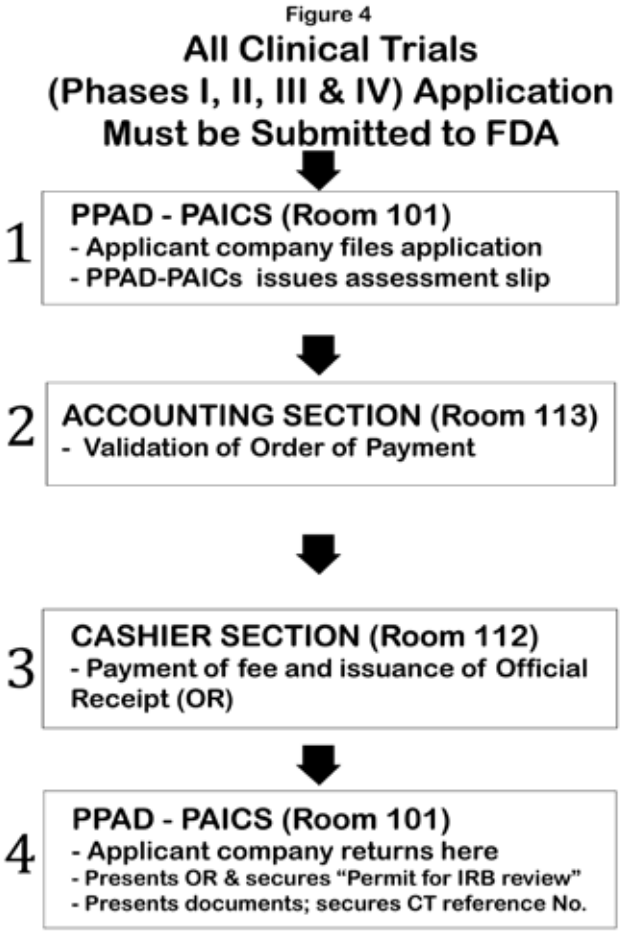

5. Amendments, notifications and other reports to be submitted to the FDA will be coursed through the same process (Figure 4). Any amendment to the protocol and accompanying documents will have to be approved by the FDA in close coordination with the ERB/ERCs.

B. Ethical/Technical Review of Applications for Clinical Trials by ERB/ERC

The FDA will accredit the ERB/ERCs of institutions based on the recommendation of the PHREB and the list will be subject to updating based on PHREB's continuing accreditation of institutions. Guidance on the filing, review and approval process must be guided by the following:

1. Approvals of study proposals will be guided by the highest ethical and technical standards.
2. As shown in Figure 3, the initial step entails the submission of an application to the FDA which will issue the Permit for the ethical and technical review of the clinical trial protocol to be done by an accredited ERB/ERC.Accreditation is based on the recommendation of PHREB which conducts audits to assess the capability of ERB/ERCs all over the Philippines.
3. The accredited ERB/ERCs should be guided by the following conditions:
   a. Fees to be charged per project as fee for technical and ethical review by the ERB/ERC will be standardized at THIRTY THOUSAND PESOS. This amount will be subject to regular review every two years.

b. The timeline for the review from acceptance to completion should not exceed 60 days.

c. The institutions will ensure that the individuals who will conduct the review process must have established competence in their areas of specializations and properly disclose conflicts of interest. Participation in the review process, by its nature, grants access to privileged information and thus, is subject to exercising confidentiality on the details of the documents submitted for review by the study sponsor. Reviewers and the study sponsor must adhere to a strict code of ethical conduct that ensures independence of reviewers and objectivity as basis for decisions.

4. FDA will be in close coordination with the ERB/ERCs during the process and will be provided information on the progress of the review and all pertinent matters of the review.

5. The FDA will give the final decision to approve or deny an application based on the recommendation, submitted in written format, emanating from the ERB/ERC review. A document granting approval for the conduct of a clinical trial based on the completed technical and ethical review by the ERB/ERC will be issued by the FDA to the study sponsor.

C. Mandatory inclusion of clinical trials in the Philippine Clinical Trial Registry

All clinical trials are required to be uploaded in the Philippine Clinical Trial Registry. It is the responsibility of the study sponsor to upload information related to the clinical trial it is conducting to the Registry (http://registry.healthresearch.ph) 30 days after the application to conduct the clinical trial has been granted.

Figure 3

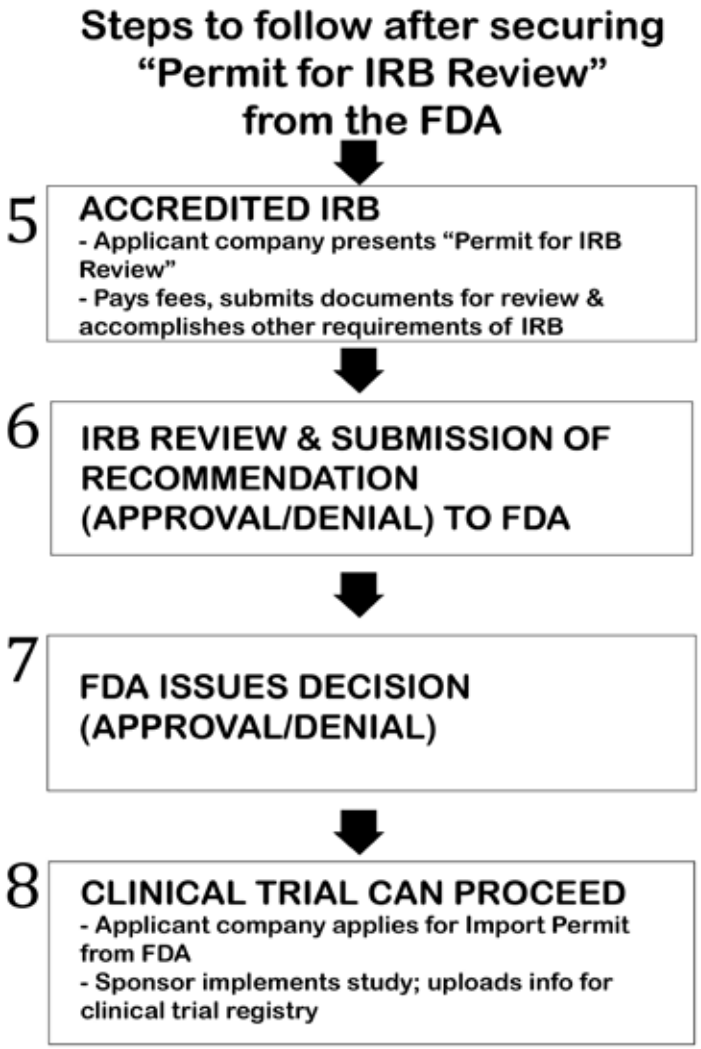

D. Access to medicines for use in clinical trials using the Import Permit

The FDA, as mandated by law, grants approval to all locally manufactured and imported drug products seeking entry into the Philippine market by the issuance of a Certificate of Product Registration (CPR). Only such drug products with CPRs are allowed to be imported and sold in the country. For purposes of clinical trials use, medicines not registered by the FDA can be accessed by an Import Permit. In addition to drug products, the Import Permit allows the inclusion of ancillary supplies such as laboratory kits, reagents, and other materials to be used for the clinical trial concerned to be imported.

The procedure to secure an Import Permit will be defined by FDA based on what capacity is available at its disposal. Specifically, it is currently done under the existing practice of securing permits using a manual system but may, in the futureand pending ongoing feasibility studies, utilize a computerized online system such as the National Single Window (NSW).

1. The Import Permit authorizes the importation ofdrug products and materials for purposes of clinical trials provided that the clinical trials protocol has been reviewed and ascertained to comply with acceptable ethical and technical standards by a duly-accredited Institutional Review Board and granted the approval to proceed by the FDA.
2. The following can apply for the Import Permit:
   a. Principal investigator
   b. Authorized representative of the Study sponsor (registered pharmaceutical company with permanent address in the Philippines
   c. CRO, with permanent Philippine address, representing the sponsor through a letter of authorization
3. To secure an Import Permit, the application must be supported by the FDA document attesting to the approval of the clinical trials to proceed based on compliance to ethical and technical requirements as ascertained by the ERB/ERC.
4. Under the existing FDA system, the Import Permit will be issued by PSD with the cooperation of the Regulation Division I which has linkage with the Bureau of Customs in this regard.

E. Inspections of clinical trials:

FDA shall conduct random inspections on the clinical trial sites to monitor complianceto the approved study protocol and monitoring plan of the sponsor. It shall specifically look into adherence to the GCP:

F. Safety Reporting

Reporting must be consistent with ICH Topic E2A- Clinical Data Management: Definitions and Standards for Safety Reporting.

1. Suspected Unexpected Serious Adverse Drugs Reactions (SUSARs)
   a. Fatal or Life-Threatening Unexpected ADRs

      All adverse drug reactions (ADRs) that are both serious and unexpected are subject to expedited reporting. Fatal (deaths) or life-threatening, serious unexpected ADRs occurring in clinical trials, onsite or offsite (for multi-site studies) should be reported. The FDA should be notified (landline/mobile phone, facsimile transmission, email or written letter) as soon as possible **but no later than 7 calendar days** after first knowledge by the sponsor that a case qualifies, followed by a complete report as soon as possible **within 8 additional calendar days**. The CIOMS-I form has been a widely accepted standard for expedited adverse event reporting

b. All Other Unexpected Serious ADRs

Serious, unexpected reactions (ADRs) that are not fatal or life-threatening, whether onsite or offsite, must be filed as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

2. ExpectedAdverse Drug Reactions

a. Serious adverse drug reactions which are expected based on information from Investigator's Brochure will be reported in the regular progress report and final report.

b. Adverse drug reactions which are not serious will also be reported in the regular progress report and final report.

G. Termination of Clinical Trial and Sanctions

For the effective implementation of this Circular, this Office shall order the termination of an on-going clinical trial without need of a hearing should the result of random trial sites inspections reveal any major violation(s), notifying only the concerned establishment of such termination. Other sanction(s) to concerned entities shall be imposed respectively under the following instances of violations and the table below:

1. The result of the random clinical trial sites inspections shall have the following categories:
   a. No violation - No objectionable conditions or practices were found during the inspection, or the significance of the documented objectionable conditions found does not justify further FDA action (from USFDA). Compliant to GCP rules and approved protocol
   b. Minor violations - Regulatory violations uncovered during the inspection are few and do not seriously impact subject safety or data integrity.
   c. Major violations-The regulatory violation(s) uncovered is/are significant/serious and/or numerous, and the scope, severity, or pattern of violation(s) support a finding that:
      1) Subjects under the care of the investigator would be or have been exposed to an unreasonable and significant risk of illness or injury.
      2) Subjects' rights would be or have been seriously compromised. OR
      3) Data integrity or reliability is or has been compromised.
      4) Non disclosure of conflict of interest by the investigator and other members of the trial team
      5) Failure to get an informed consent is a major violation

Any pharmaceutical product the clinical trial of which has been ordered terminated by FDA shall be a ground for the invalidation of data for drug registration purposes and accordingly disapproval of subsequent application for product registration pursuant to Paragraphs (1) or (6), Item B, Section 4, Article I, Book II of the Implementing Rules and Regulations of Republic Act No. 9711 on ground that application requirements does not meet the required technical requirements or appropriate standards, or such other analogous grounds or causes as determined by the FDA.

2. Disciplinary actions shall be imposed on the following after finalizing the Inspection Report by the Legal Division of the FDA.

Entity/Individual	Minor Violation(s)	Major Violation(s)
Researcher	Warning, re-inspection	Suspension from conduct of researches from (range in months or years) depending on the type and degree of violation
Sponsor	Warning, re-inspection	Termination of trial, invalidation of data for drug registration purposes
Ethics Review Committee The FDA shall recommend appropriate action to the PHREB based on inspection findings.	Warning, re-inspection	Suspension from the conduct of reviews for (range in months/ years) depending on the type and degree of violation

H. Archiving and Database Management

All original and latest approved versions of CT protocols, IB, Informed Consent, ERC proof of approval, summary of amendments, and final CT report including summary of safety reports shall be recorded, filed and archived by the clinical unit of the FDA.

Stored files shall be accessed only by duly authorized personsand shall be stored and disposed thereafter in a manner as may be provided by existing laws, rules and regulations. Disposal of files shall be in coordination with the Records Section of the Administrative Division which shall seek approval from the National Archives of the Philippines.

VI. SUPERVISION AND OVERSIGHT

The Policy Planning and Advocacy Division (PPAD) shall supervise and provide technical guidance in the implementation of this Circular. The Clinical Trial Management staff shall prepare and submit quarterly reports to the Chief of the PPAD on the status of implementation, issues and problems and proposed solutions.

Likewise, the PPAD shall provide the FDA MANCOM an annual report on the implementation of this Circular.

In pursuit of good governance and transparency the PPAD shall organize and convene regular meetings with concerned partners and networks to provide updates and reports on the implementation or any matter concerning this Circular.

VII. SEPARABILITY AND REPEALING CLAUSE

In the event that a rule, section, paragraph, sentence, clause or words of this Circular is declared invalid for any reason, the other provisionsnot affected/ or without material significance shall remain in force and effect.

All provisions of previous issuances and other related issuances inconsistent or contrary with the provisions of this Circular are hereby revised, modified, repealed or rescinded accordingly. All other relevant provisions of existing issuances supporting this Circular shall remain valid and in effect.

VIII. EFFECTIVITY

This Circular shall take effect immediately. A Task Force to facilitate the transition has been set up under the supervision of PHREB to coordinate the smooth transitioning into the new system that will involve the technical and ethical evaluation to be carried out by the institutional ERB/ERCs.

(Signed)
SUZETTE H. LAZO, MD
Acting Director IV, FDA

DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

CLINICAL TRIAL REGISTRATION & APPLICATION FORM

APPLICATION NO.:_____

1. STUDY SPONSOR:					
2. ADDRESS:					
3. STUDY TITLE:					
4. DATE OF SUBMISSION		TELEPHONE:		FAX:	
5. THIS SUBMISSION CONTAINS THE FOLLOWING *(Check all that apply)*	☐ INITIAL APPLICATION	PROTOCOL AMENDMENT ☐ CHANGE IN PROTOCOL ☐ ADDITIONAL INVESTIGATOR ☐ ADDITIONAL STUDY SITE(S) ☐ RESPONSE TO REQUEST FOR INFORMATION ☐ INFORMATION AMENDMENTS	OTHERS:		
6. PHASE(S) OF CLINICAL TRIAL TO BE CONDUCTED:	☐ PHASE I	☐ PHASE II	☐ PHASE III	☐ PHASE IV (POST MARKETING SURVEILLANCE)	
7. NAME OF DRUG:	*(Include Proprietary, Generic, Code):*				
10. STUDY DURATION:					
11. STUDY SITE(s):					
12. PRINCIPAL INVESTIGATOR:	NAME:				
	TELEPHONE/MOBILE:	EMAIL ADDRESS:			
	(other) IRB Approval Details				
8. IS ANY PART OF THE CLINICAL TRIAL TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION (CRO):	☐ YES ☐NO If YES, state the name of the CRO:_____ *Attach a statement containing the name and address of CRO and the summary of responsibility*				
9 . NAME AND CONTACT DETAILS OF PERSON RESPONSIBLE FOR MONITORING CONDUCT AND PROGRESS OF THE CLINICAL TRIAL:	NAME:				
	TELEPHONE/ MOBILE:	EMAIL ADDRESS:			

13. Documents Submitted	PART A: Clinical Trial Protocol and other Pertinent Documents ☐ Name and dosage form of product ☐ Title and aim of the trial ☐ Description of the trial design ☐ Description of the subjects ☐ Treatment profile ☐ Operational aspects ☐ Adverse events ☐ Evaluation of results ☐ Informed consent form, Case Report Form and Patient Information Sheet ☐ Resumes of Principal and other Investigators ☐ For multi-center studies, a list of Principal Investigators (and CVs) including trial sites
	PART B: Pharmaceutical Data ☐ GMP statement from manufacturing/Certificate from Regulatory Body ☐ Certificate of Analysis ☐ Stability Data (storage conditions) ☐ Manufacturing Data & Formulation ☐ Product labeling (coded & labeled: blinding)
	PART C: Investigator's Brochure (Efficacy and Safety Data) Safety Data: ☐ Non-Clinical Studies ☐ Pharmacology; PK/PD studies ☐ Toxicology Studies ☐ Marketing Experience, Periodic Safety Update Reports (PSUR), product status if marketed abroad ☐ Risks and ADR anticipated Efficacy Data: ☐ PK/PD Data in human subjects ☐ In-house preliminary data ☐ Summaries of clinical trial studies conducted (Phase I, II, III) ☐ Published clinical data
14. Submitted by:	
CLINICAL TRIAL REFERENCE (CTR) NUMBER:	
DATE OF ISSUE:	
RECEIVED BY:	

2

DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

PERMIT FOR ERB/ERC REVIEW

PERMIT NO._____

STUDY SPONSOR		
ADDRESS:		
CRO (REPRESENTING SPONSOR)		
ADDRESS		
CONTACT INFO:	TELEPHONE/FAX:_____ MOBILE:_____ EMAIL ADDRESS:_____	
3. NAME OF DRUG	*(Include Proprietary, Generic, Code):*	
4. STUDY TITLE		
5. STUDY SITE(s)	1. 2. 3.	
6. PRINCIPAL INVESTIGATOR:	NAME:	
	TELEPHONE/MOBILE:	EMAIL ADDRESS:
7. ERB/ERC REVIEW TO BE CONDUCTED AT:	☐ UP NIH ☐ De La Salle University ☐ St. Luke's Medical Center	☐ _____ ☐ _____ ☐ _____
CLINICAL TRIAL REFERENCE (CTR) NUMBER:		

_____

THERESE IRYNNE GONZALEZ
Chief of PPAD

DATE:_____

FDA ASSESSMENT FORM

FDA Form No _____

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

I. ADMINISTRATIVE INFORMATION		
1. Clinical trial number		<FDA-issued unique code>
2. Clinical trial protocol title		<Full protocol title>
3. Clinical trial version number		<As indicated in the protocol>
4. Clinical trial version date		< As indicated in the protocol> <dd/mm/yyyy>
5. Clinical trial phase (*Note: Review by FDA-recognized institutions is limited to phases indicated in this form*)		___ Phase 1 ___ Phase 2 ___ Phase 3 ___ Phase 4 *Type*: _____
6. Sponsor-applicant:		<Name of sponsor>
7. CRO-applicant:		<Name of CRO>
8. Date received by institution:		<dd/mm/yyyy>
9. Reviewing institution:		<Name of reviewing institution>
	9.1. Address	
	9.2. Signatory official:	<Title, Name, Surname>
	9.3. Position & Designation:	<Institutional position & review designation>
	9.4. Signature:	
	9.5. Review date:	<dd/mm/yyyy>
	9.6. Telephone:	
	9.7. Fax:	
	9.8. Email:	

10. Declaration of conflict of interest (COI)

The <NAME OF INSTITUTION> declares that the institution and the experts involved in this review have no COI in any form related to the abovementioned clinical trial/that the <institution/experts involved in this review/both> have <financial, proprietary, professional> conflict of interest related to the abovementioned clinical trial due to <describe COI> and managed such COI by <describe COI management>.

11. Confidentiality Agreement

The <NAME OF INSTITUTION> as well as the experts involved in this review agreed to take reasonable measures to protect the confidential information pertinent to this review, subject to applicable legislation, not to disclose confidential information to any person; not to use confidential information for any purpose outside this review, and in a manner which would result in a benefit to itself or any third party; and to return all confidential information and documents (including any minutes or notes) upon demand of the FDA.

12. Recommendations to the FDA:

☐ **Approval**

☐ **Deferment of action** pending resolution of conditions detailed under **Section 8** (see assessment information)

☐ **Disapproval** of the conduct of clinical trial in the Philippines due to:

- Objections as indicated in: <indicate relevant sections>
- Deficiencies as indicated in: <indicate relevant sections>

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

II. ASSESSMENT INFORMATION

Information under this section should be compiled through full board deliberation of the documents submitted to the relevant committee in the institution that performed this review. Recommendations issued through this review are based on the assessment of components outlined in this section. This template is accomplished electronically, but must be printed, then verified and signed by the designated institutional signatory official. A fully accomplished form should be signed and submitted to the FDA within 30 days of receipt of protocol package.

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	ASSESSMENT
1. SCIENTIFIC AND SOCIAL VALUE	**Yes**	**No**		
1.1. Philippine community health priority addressed				
1.2. Disease priority addressed				
1.3. Potential Impact on deeply-held values of the Filipino				
1.4. Conclusions on the potential **SCIENTIFIC AND SOCIAL VALUE** of this clinical trial:				

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	ASSESSMENT
2. PRE-CLINICAL DATA	**Yes**	**No**		
2.1. Toxicology				
2.2. Environmental risk				
2.3. Conclusions on the **PRE-CLINICAL DATA** supporting this clinical trial application:				

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	ASSESSMENT *(Dose-response studies, clinical studies in special populations such as pediatric populations, pooled and meta-analysis, and other supporting studies)*
3. PRIOR CLINICAL DATA	**Yes**	**No**		
3.1. Pharmacodynamics and pharmacokinetics				
3.2. Phase 1 (completed)				Years conducted
				Sites

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				Enrolment: <number of patients>
				Findings
3.3. Phase 2 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.4. Phase 3 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.5. Conclusions on the **PRIOR CLINICAL DATA** supporting this clinical trial application:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
4. STUDY DESIGN	**Yes**	**No**		
4.1. Duration				
4.1.1. Main phase				<time><N/A>
4.1.2. Run-in phase				<time><N/A>
4.1.3. Extension phase				<time><N/A>
4.2. Hypothesis				<Superiority> < Equivalence> <Non-inferiority> <Exploratory: specify> <Others: specify>
4.3. Treatment groups				
4.3.1. Group 1				<treatment>,<duration>, <number randomized>
4.3.2. Group 2				<treatment>,<duration>, <number randomized>
4.3.3. Group 3				<treatment>,<duration>, <number randomized>
4.3.4. <if placebo group included>				<scientific and methodological justification for the use of placebo>
4.4. Endpoints and definitions				
4.4.1. Primary				<appropriateness of endpoint and method of measurement>
4.4.2. Secondary/Other (specify)				<appropriateness of endpoint and method of measurement>
4.4.3. Secondary/Other (specify)				<appropriateness of endpoint and method of measurement>
4.4.4. <add rows as needed>				<appropriateness of endpoint and method of measurement>
4.5. Statistical analysis for primary endpoint				<Intent to treat> <Per protocol> <other: specify><time point>
4.6. Statistical analysis for				<Intent to treat> <Per protocol>

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secondary endpoint				<other: specify><time point>
4.7. Conclusions on the **STUDY DESIGN** proposed for this clinical trial:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
5. CLINICAL SAFETY	**Yes**	**No**		
5.1. Expected adverse events				
5.2. Expected serious adverse events and deaths				
5.3. Expected adverse laboratory events				
5.4. Safety in special populations				<adequate identification of populations wherein precaution/ safety measures/exclusion is exercised>
5.5. Adverse immunological events (if applicable)				
5.6. Drug-drug interactions and other interactions				
5.7. Pharmacovigilance system and plan				<adequacy of compliance with regulatory reporting systems for AEs>
5.8. Risk management system and plan				<appropriateness of risk management method *vis à vis* expected risks>
5.9. Conclusions on the **CLINICAL SAFETY** plan proposed for this clinical trial:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
6. BENEFIT-RISK ASSESSMENT	**Yes**	**No**		
6.1. Beneficial effects of the intervention to the target population				<Uncertainty/certainty in the knowledge about the beneficial effects>
6.2. Unfavorable effects of the intervention to				<Uncertainty/certainty in the knowledge about the unfavorable

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the target population				effects>
6.3. Vulnerable populations involved				<Justification of risks to vulnerable populations>
6.4. Use of placebo				<Compliance with international and national ethical guidelines in the use of placebo>
6.5. Benefit-risk balance				<Significance of favorable and unfavorable effects as detailed above>
6.6. Conclusions on the **BENEFIT-RISK** ratio of this clinical trial: <favorable or unfavorable>				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	
7. STUDY SITES	**Yes**	**No**		
7.1. List of sites				

STUDY SITES	TYPE	PROFILE	ERC	If none
7.1.1.<Name of site>	<tertiary/ secondary> <teaching hospital> <others: specify>	Facilities, accreditation, government classification, etc	<PHREB registration number>	<justification if no institutional or local ERC>
7.1.2.<add rows as needed>				

7.2. Conclusions on the appropriateness of the proposed **STUDY SITES** for this clinical trial:

8. SUMMARY OF RECOMMENDED CONDITIONS FOR APPROVAL OF IMPLEMENTATION OF CLINICAL TRIAL IN THE PHILIPPINES (with reference to the above discussions)

8.1. Social and Scientific Value

8.2. Assessment of Pre-Clinical Data

8.3. Assessment of Prior Clinical Data

8.4. Study design assessment

8.5. Safety assessment

8.6. Benefits and risks assessment

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8.7. Study Sites Assessment
9. SUMMARY OF REGULATIONA APPLICABLE TO THIS CLINICAL TRIAL APPLICATION (and used in this assessment)
9.1. Regulation 1
9.2. Regulation 2
9.3. Regulation 3
9.4. Regulation 4
10. SUMMARY OF INTERNATIONAL AND NATIONAL GUIDELINES APPLICA TO THIS CLINICAL TRIAL APPLICATION (and used in this assessment)
10.1. Guideline 1
10.2. Guideline 2
10.3. Guideline 3
10.4. Guideline 4
11. SUMMARY OF OTHER REFERENCES USED IN THIS ASSESSMENT
11.1. Reference 1
11.2. Reference 2
11.3. Reference 3
11.4. Reference 4

DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

APPROVAL TO CONDUCT CLINICAL TRIAL

APPROVAL NO:_____

1. STUDY SPONSOR		
CRO (If represented)		
2. ADDRESS		
3. NAME OF DRUG	*(Include Proprietary, Generic, Code):*	
4. STUDY TITLE		
5. STUDY SITE(s)		
6. PRINCIPAL INVESTIGATOR:	NAME:	
	TELEPHONE/MOBILE:	EMAIL ADDRESS:
7. ERB/ERC REVIEW CONDUCTED AT:	(Please attach recommendation)	
8. DATE COMPLETED		
CLINICAL TRIAL REFERENCE (CTR) NUMBER:		

Approval is hereby granted to conduct the clinical trial.

APPROVED:

_____

ASEC NICHOLAS LUTERO III, Esq., CESO III

OFFICER-IN-CHARGE, FDA

DATE OF APPROVAL:_____

LIST OF ACCREDITED INSTITUTIONS AS OF JULY 2012
AND THEIR
STANDARD OPERATING PROCEDURES OF ACCREDITED INSTITUTIONS

ACCREDITED INSTITUTIONS

1. De La Salle Health Sciences Institute
2. Research Institute for Tropical Medicine
3. Philippine Heart Center
4. St. Luke's Medical Center
5. University of Santo Tomas
6. University of the Philippines

De La Salle Health Sciences Institute

Dasmarinas City, Cavite, 4114 Philippines

Guidelines for Regulatory Review of Clinical Trials

1. The company or study sponsor must first file an application for assessment at the Food and Drugs Administration (FDA). The applicant company shall likewise obtain necessary papers for the conduct of an ethical and technical review and submit to the FDA the required documents to ascertain safety, efficacy and quality of the products that will be subject to clinical study.

2. The FDA shall inform the applicant company to which Institutional Review Board/Ethics Review Board (IRB/ERB) they shall be assigned to. Study sponsors assigned to the De La Salle Health Sciences Institute (DLSHSI) IRB/ERB shall submit the protocols and other requirements to Mr. Andrew Casipi, the Project Coordinator for Clinical Trials, at the following address:

   Office of the Vice Chancellor for Research
   3/F Room 6301, Angelo King Medical Research Center,
   De La Salle Health Sciences Institute,
   Gov. D. Mangubat Ave., Burol Main,
   Dasmariñas City, Cavite 4114

3. Documents to be submitted will include those in Parts A, B and C and such other documents or data as required by FDA to ascertain safety, efficacy and quality of the products that will be subject to clinical study.

   3.1 PART A: Clinical Trial Protocol and other Pertinent Documents

   3.1.1 Name and dosage form of product
   3.1.2 Title and aim of the trial
   3.1.3 Description of the trial design
   3.1.4 Description of the subjects
   3.1.5 Treatment profile
   3.1.6 Operational aspects
   3.1.7 Adverse events
   3.1.8 Evaluation of results
   3.1.9 Informed Consent Form, Case Report Form and Patient Information Sheet
   3.1.10 Resumes of Principal and other Investigators
   3.1.11 For multi-center studies, a list of Principal Investigators (and CVs) including Trial Sites

3.2 PART B: Pharmaceutical Data to ascertain the quality and safety of the Investigational Product and to protect clinical trial subjects, FDA needs to ensure that the IP's CMC and manufacturing process is in compliance with acceptable standards (GMP).

3.2.1 GMP statement from manufacturing/Certificate from Regulatory Body
3.2.2 Certificate of Analysis
3.2.3 Stability Data (storage conditions)
3.2.4 Manufacturing Data & Formulation
3.2.5 Product labeling (coded & labeled: blinding)

1.3 PART C: Investigator's Brochure (Efficacy and Safety Data)

1.3.1 Safety Data
3.3.1a Non-Clinical Studies
3.3.1b Pharmacology; PK/PD studies
3.3.1c Toxicology Studies
3.3.1d Marketing Experience, Periodic Safety Update Reports (PSUR), product status if marketed abroad
3.3.1e Risks and ADR anticipated

1.3.2 Efficacy Data
3.3.2a PK/PD Data in human subjects
3.3.2b In-house preliminary data
3.3.2c Summaries of clinical trial studies conducted (Phase I, II, III)
3.3.2d Published clinical data

3 The following are required to be submitted for the regulatory review at DLSHSI:
3.3 One (1) electronic copy (compact disc) of Parts A and C.
3.4 Four (4) hard copies of Parts A and C
3.5 One (1) hard copy of Part B
3.6 Clinical Trial Reference Number from FDA
3.7 Permit for Regulatory Review from FDA
3.8 Check payment for Regulatory Review

4 The check payment must be payable to De La Salle Health Sciences Institute in the amount of Thirty Thousand Pesos (PhP 30,000.00 – not subject to tax). The review process will commence only upon receipt of the full payment for regulatory review. You will be provided with an Official Receipt and a Regulatory Review Receipt Form by the Project Coordinator.

5 A tracking system that is secure yet accessible to FDA and the study sponsor will be used to monitor the status of the screening process. To have access to this tracking system, the sponsor should provide the project coordinator with an e-mail address of their designated contact person. We will also inform you through text, email, or telephone call.

5.1 If applicable or necessary, an Interim Recommendation from DLSHSI IRB/ERB will be communicated to the FDA and the Study Sponsor within thirty (30) days from the start of the review process. The study sponsor should respond to DLSHSI IRB/ERB within two (2) weeks upon receipt of the Interim Recommendation.

5.2 A final recommendation from the DLSHSI IRB/ERB will be communicated to the FDA within sixty (60) days from the start of the review process.

For further inquiries, please contact:

Mr. Andrew C. Casipi
Project Coordinator for Clinical Trials
Mobile No: 09207316391 or 09166194617
Telefax: (046) 481-8000 local 4000
e-mail: casipi_andrew@yahoo.com

RITM-FDA-ERB SUBMISSION SOP

(TIMELINES EXPRESSED HERE ARE IN WORKING DAYS, EXCLUDES WEEKENDS AND HOLIDAYS)

	Steps	Timeline
1	FDA sends review packet to RITM-FDA-ERB Subcommittee	Day 0
2	RITM-FDA-ERB gives a statement to pay the review fee	Day 0
3	Sponsor pay **PhP 30,000 (net of tax)** to the **Research Institute for Tropical Medicine, Dept of Health. Proceed to the cashier's counter of the RITM and an government receipt will be issued upon payment.**	Day 0
4	RITM-FD-ERB Subcommittee Secretariat checks completeness of packet The sponsor must provide a checklist of all documents submitted in duplicate copies, one is retained by sponsor as acknowledgment copy and the other to be retained by RITM-FD-ERB. Five (5) copies of all documents (5 sets of documents) must be submitted to the Chair through the Secretariat of RITM-ERB.	Day 0
5	RITM-FD-ERB Subcommittee Chair assigns review panel and sends out review packet to reviewers together with the declaration of the conflict of interest and assessment form. Any member who withdraws due to COI will be replaced from the pool of RITM-ERB members	Day 2
6	Reviewers perform the review the protocol and other materials within twelve working days using the assessment form.	Day 4– 17
7	All reviewers send their assessment forms to the RITM-FD-ERB.	Day 18
8	Chair of the RITM-FD-ERB Subcommittee collates the assessment forms	Day 19
9	Chair of the RITM-FD-ERB Subcommittee schedules the committee meeting	Day 21
10	RITM-FD-ERB Subcommittee Chair convenes the board to discuss the RITM-FDA-ERB Sub Committee recommendations.	Day 25
11	RITM-FDA-ERB Subcommittee finalizes its recommendation.	Day 25
11a	If final recommendation go to item 18	Day 25
11b	If recommendation is to obtain additional documentation, Secretariat communicates request to sponsor. Sponsor will be given 5 days to submit additional requirements.	Day 26
12	Additional document requirements expected to be received by RITM-FDA-ERB	Day 31
13	Additional document requirements sent out to reviewers.	Day 32
14	Reviewers review additional document requirements for three days.	Day 33 - 35
15	All reviewers send their assessment forms to the RITM-FDA-ERB.	Day 36
16	Chair of the RITM-FDA-ERB Subcommittee collates the assessment forms	Day 37
17	RITM-FDA-ERB Subcommittee finalizes its recommendation.	Day 38
18	RITM-FD-ERB Subcommittee prepares communication of its decision to the FDA.	Day 25/40
19	RITM-FD-ERB Subcommittee Secretariat submits final recommendation to the FDA.	Day 26/41
20	RITM-FD-ERB Subcommittee returns all documents used for the review to the sponsor.	Day 27/42

by: Gemiliano D. Aligui, MD, MPH,PhD
Co-chair, RITM IRB

15 August 2012

1. Purpose

To describe how the Institutional Ethics Review Board (IERB) manages protocol submitted by sponsor/s for regulatory review by FDA-PPAD.

2. Scope

It covers the actions done from the time of submission of documents for IERB review by the sponsor to the IERB Secretariat to the return of same regulatory review documents to the FDA-PPAD.

3. Responsibility

Secretariat – receives the initial protocol package and payment for the protocol review
PPAD – sends the notification letter to the PHC IERB
Sponsor – submits protocol package and payment for protocol review to PHC IERB
IERB – evaluates the protocol and sends report and recommendations to FDA-PPAD

4. Policy

4.1 The PHC IERB shall receive permit letter regarding a protocol for regulatory review from FDA-PPAD.

4.2 The sponsor shall submit a protocol package to the PHC IERB.

4.3 Requirements for protocol submission can be accessed from the IERB Secretariat or through email (irbphc@gmail.com). The protocol package will be send by FDA to IERB.

4.4 The sponsor shall pay PHC-IERB an amount of P30,000.00 for every protocol review.

4.4.1 The sponsor shall give payment to PHC cashier for PHC IERB protocol review.

4.4.2 A copy of official receipt shall be forwarded to the IERB secretariat.

4.5 The Chairman shall invite an independent consultant for non-cardiology and non-pulmonary protocol.

4.6 The Board Secretary shall document all meetings regarding review of all protocols including decisions and recommendations to the FDA-PPAD.

4.7 The Chairman shall designate the secretariat to be the liaison officer to the Task Force and FDA-PPAD.

5 Procedure

5.1 Receipt of the protocol package

The Secretariat:

5.1.1 receives the notification from FDA-PPAD

5.1.2 receives ten (10) copies of the initial protocol package with Initial IERB Application Form - PHC-IERB-03-21-01

5.1.3 stamps "RECEIVED" on the protocol package and signs the document receipt form

5.1.4 encodes the accession number of the protocol package to the assigned FDA-PPAD database.

5.2 Management of the protocol package

The Secretariat:

5.2.1 Prepares copies of the protocol package for distribution to the reviewers.

5.3 Conduct of Full Board Review

5.3.1 The IERB Chairman schedules the protocol review

5.3.2 The IERB evaluates the protocol as a full board review in an en banc meeting.

5.3.3 The IERB makes a decision and gives recommendations to the FDA-PPAD.

5.3.4 The IERB members sign the IERB's decision form.

5.4 Communication of recommendation to FDA -PPAD

5.4.1 The recommendations to FDA-PPAD are categorized into:

5.4.1.1 Approval

5.4.1.2 Deferment of action pending recommendation of condition under section 8

5.4.1.3 Disapproval

5.4.2 The IERB copy furnishes the FDA-PPAD of all communications with the sponsor.

5.4.3 The IERB gives final recommendation/s to the FDA-PPAD within 60 days.

5.4.4 The Secretariat returns all regulatory review documents to FDA-PPAD for archiving.

7 Annex

Annex 1 - Document Receipt Form - PHC-IERB-03-14-01
Annex 2 - Initial IERB Application Form - PHC-IERB-03-21-01

8 References

8.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
8.2 FERCAP SOP 2006
8.3 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

Annex 1

PHILIPPINE HEART CENTER
Institutional Ethics Review Board
8/F Medical Arts Building
East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

PHC-IERB-03-14-01

Document Receipt Form

1. Accession Number:			Submitted date:
2. Source of Fund:	☐ PHC Funded		☐ Non-PHC Funded
3. Protocol Number:		Sponsor Number	
4. Sponsor	PHC		
5. Principal Investigator:			
6. Protocol Title:			
7. Type of Submission:	___Initial Review ___Resubmission for a re-review ___Protocol Amendments		___Continuing Review ___Approved Protocols ___Protocol Termination
8. Delivery Route:	☐ Post		☐ In Person
9. Documents Submitted	☐ Full Protocol ☐ Declaration of No Conflict of Interest ☐ Data Collection Form(s) ☐ Informed Consent Form (English & Local Dialect) ☐ Assent Form (English & Local Dialect) ☐ Subject Worksheets/ Patient Diary /Alert Cards (English and Tagalog Versions) ☐ Pharmacokinetics ICF (English and Tagalog Versions) ☐ Questionnaire (English and Tagalog Versions) ☐ Philippine Food and Drug Administration (PFDA) Approval		☐ GANTT Chart ☐ Ads for Advertisement, if applicable ☐ Information for subjects ☐ Case Report Forms (CRF) ☐ Investigator's Brochure ☐ Certificate of Insurance ☐ (if applicable) ☐ CV of Proponent; GCP Certification ☐ Others .....
10. Remarks	☐ Complete		☐ Incomplete, will submit on_____
11. Documents to be submitted later	___Information for subjects ___Informed consent/assent form ___Others.....		___Study budget ___Investigator's brochure ___Case report forms (CRF)
12. Submitted by:		13. Signature:	14. Date submitted:
15. Received by:		16. Signature:	17. Date received:

NOTE TO APPLICANTS: Please make sure that you have a copy of this form duly signed by the person who received the application

Annex 2

PHC-IERB-03-21-01

PHILIPPINE HEART CENTER
Institutional Ethics Review Board
8/F Medical Arts Building
East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

Initial IERB Application Form

For Initial IERB Review Only

Accession No.	
Protocol No.	

Administrative Information

Sponsor No.		Date of this Request	
Study Title			
Department		Division	

Role	Name	Email	Mobile/Phone /Fax	License #
Principal Investigator				
Contact Person				
Co-Investigator				
All personnel listed above have completed GCP training *Please attach current certificate*			☐ Yes	☐ No

Category Review

Select the category of review you believe your study falls under	☐ Full Board Review ☐ Expedited Review Expedited Review Category ☐ The research presents no more than the minimal risk of harm to subjects; explain:

Study Summary

Summarize your study. The summary should be written in language intelligible to a moderately educated, non-scientific layperson. It should contain a clear statement of the rationale and hypothesis of your study, a concise description

Summary	
Proposed length (time period) of the study *State number of years, months, or weeks*	
Purpose of the Study	
Research Procedures *Describe the source of the data and the data collection procedures*	
Risks	☐ Minimal; justify why this category is appropriate ☐ Greater than minimal What precautions have been taken to minimize these risks and what is their likely effectiveness? Describe other alternative and accepted procedures, if any, that were considered and why they will not be used: ☐ Unknown, describe
Vulnerable subjects *If this study involves vulnerable subjects describe additional safeguards included in the protocol to protect the rights and welfare of these subjects*	☐ No ☐ Yes, describe:
More than Minimal Risk of Harm *If the research involves more than minimal risk of harm to subjects, describe the provisions for monitoring the data to ensure the safety of subjects*	☐ No ☐ Yes, describe:
Benefits *Assess the potential benefits to science and/or society which may occur as a result of this research. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits*	

General Study Information

Participants Recruitment Numbers	Participant Ages (Please check)
_____Females _____Males **Estimated Project Duration** Start Date: _____ End Date:_____	☐ 0-7 (parental permission and child assent) ☐ 7-11(parental permission and Child assent) ☐ 12-17 (parental permission and Child assent) ☐ 18-65 ☐ 65+
Will this Study Involve Long-Term Follow-Up with participants:	☐ Yes ☐ No.

1. **PURPOSE**
   To ensure a standard process of submission of protocols for regulatory review.

2. **SCOPE**
   From the submission of protocol package, payment of regulatory review fee, conduct of review and forwarding of final recommendation to FDA

3. **FLOWCHART**

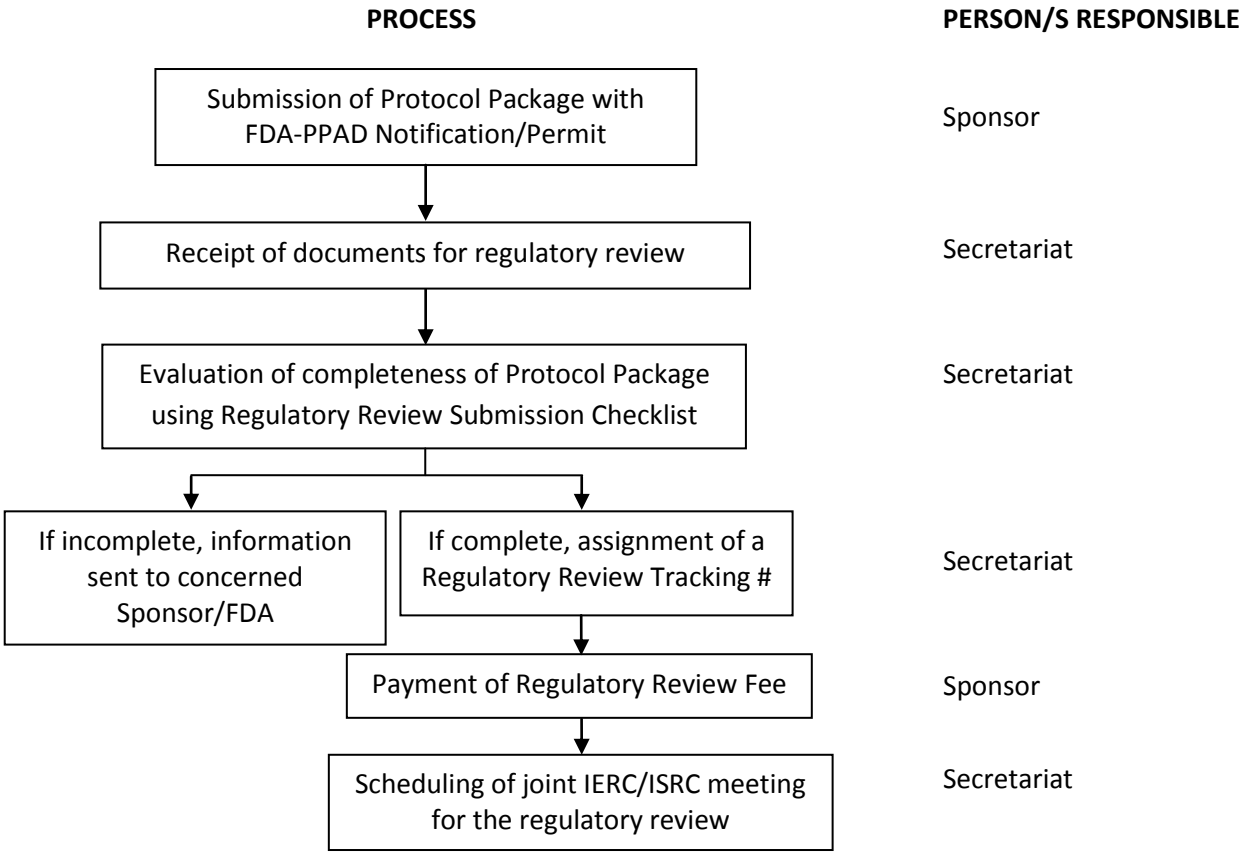

4. **PROCEDURE**
   4.1. Submission of Protocol: The sponsor shall submit the complete protocol package to:

St. Luke's-Institutional Ethics Review Committee
Research and Biotechnology Division, Center for Clinical Trials
Annex III, 5th Floor
St. Luke's Medical Center-Quezon City
279 E. Rodriguez Sr., Blvd, Quezon City
Philippines 1102
Contact Person: **Anita B. Ahorro**
Clinical Trials Administrator
Tel. No.: (632) 727-5562/7230101 local 7391

4.2. Receipt of documents for regulatory review.

4.2.1. The Secretariat shall receive the complete protocol package with the following:

- FDA Clinical Trial Reference No.
- Permit to Review from FDA

4.2.2. The Secretariat shall log receipt of the protocol package using the Regulatory Review Tracking Form and a designated logbook. ***(Refer to SL-IERC Form #20A)***

4.3. Evaluation of completeness of the protocol package based on the Regulatory Review **Submission Checklist**. ***(Refer to SL-IERC Form#20B)***

- If the protocol package is incomplete, Secretariat informs the concerned sponsor/FDA. This is logged in the appropriate Tracking Form.
- If the protocol package is complete, the Secretariat assigns a Regulatory Review Tracking # (RRT#) to the protocol.

4.4. Payment of Regulatory Review Fee

4.4.1. Regulatory Review Fee shall be paid in cash or cheque upon confirmation of completeness of protocol package submitted.

4.4.2. All cheque payments shall be made payable to St. Luke's Medical Center.

4.5. Schedule for review: Secretariat shall

- schedule the meeting for the regulatory review after payment of the regulatory review fee.
- inform the sponsor of the schedule of the meeting
- notify the concerned sponsor that a representative shall be present in case the committee en banc raises issues or questions.

---Nothing Follows---

UNIVERSITY OF SANTO TOMAS
FACULTY OF MEDICINE AND SURGERY

UST FACULTY OF MEDICINE & SURGERY – INSTITUTIONAL REVIEW BOARD (USTFMS – IRB)

LIST OF REQUIREMENTS FOR RESEARCH PROTOCOL REVIEW AND APPROVAL

Protocol for the study should include the following:

I. Research Protocol
- 1.1 Title – with protocol number, protocol/version dates
- 1.2 Objectives of the study
- 1.3 Methodology
- 1.4 Subject selection
- 1.5 Contemplated sample size
- 1.6 Control of bias e.g. randomization of samples, blinding, techniques,
- 1.7 Dose, route, duration of administration and clinical laboratory examinations
- 1.8 Statistical design (suggest prior consultation with a biostatistician regarding data collection, data handling and statistical analysis to form statistically valid conclusions)

II. Endorsement letter by the Chairman of the Division
III. Cover letter addressed to the Chairman of IRB signed by the Investigator
IV. Written Informed Consent Form (in English and Tagalog)
V. Case Report Form (CRF)
VI. Budget for the study (including honorarium to the investigator)
VII. BFAD product registration for marketed study drug or BFAD import permit if study drug is not yet BFAD registered. (for drug trials)
VIII. List of local and international names of investigators in other institutions or countries if study is multinational or multicenter with contact numbers and address
IX. Investigator's Brochure
X. Curriculum Vitae of Investigator
XI. Good Clinical Practice (GCP) Certificate of Attendance of Investigator
XII. IRB Review Fee P 30,000. Check payable to **UST Faculty of Medicine & Surgery** and must be given before the initial review of research protocol.

** Please provide 5 sets of the above requirements with a blank page for the comments and recommendations.*

BERNARDO M. CUEVAS, JR. MD
Chair, USTFMS - IRB
Office of the Dean, Faculty of Medicine & Surgery
2nd Floor St. Martin de Porres Building
University of Santo Tomas
España, Manila
740-9707 / 741-5314

UST 400 UNENDING GRACE

FACULTY OF MEDICINE AND SURGERY, 2nd Floor St. Martin De Porres Building, UST España Boulevard, Sampaloc, Manila, Philippines 1015
Tel. Nos.: (63-2) 741-5314 / (63-2) 406-1611 loc. 8239 Telefax: (63-2) 731-3126 • Website: www.ust.edu.ph

UNIVERSITY OF SANTO TOMAS
FACULTY OF MEDICINE AND SURGERY

UST FACULTY OF MEDICINE & SURGERY – INSTITUTIONAL REVIEW BOARD

USTFMS-IRB COMMITTEE COMPOSITION
for the period of August 2012 to _____

Name of Members	Title and Occupation
Bernardo M. Cuevas Jr. MD	*Chair, USTFMS-IRB* Department of Surgery & Clinical Epidemiology Finished ICH Good Clinical Practice Course Master of Science in Clinical Epidemiology
Ma. Graciela M. Garayblas-Gonzaga, MD	*Member, USTFMS-IRB* Department of Medicine & Pharmacology Finished ICH Good Clinical Practice Course Masters of Science in Health Development & Management & Clinical Epidemiology
Victoria Edna G. Monzon, MD	*Member / Bioethicist, USTFMS-IRB* Department of Medicine & Bioethics Finished ICH Good Clinical Practice Course Units in Masters in Public Administration
Nilo C. Delos Santos, MD	*Member / Biostatistician, USTFMS-IRB* Department of Surgery & Clinical Epidemiology Finished ICH Good Clinical Practice Course Master of Science in Epidemiology
Mary Agnes S. Regal, MD	*Member, USTFMS-IRB* Department of Pediatrics & Clinical Epidemiology Finished ICH Good Clinical Practice Course Masters of Science in Clinical Epidemiology

UST 400 UNENDING GRACE

FACULTY OF MEDICINE AND SURGERY, 2nd Floor St. Martin De Porres Building, UST España Boulevard, Sampaloc, Manila, Philippines 1015
Tel. Nos.: (63-2) 741-5314 / (63-2) 406-1611 loc. 8239 Telefax: (63-2) 731-3126 • Website: www.ust.edu.ph

University of the Philippines Manila
NATIONAL INSTITUTES OF HEALTH

UPM-NIH FDA REVIEW

SPONSOR SUBMISSION PROCESS

Step 1 : Sponsor submits review package to UPM-NIH FDA Review Panel Secretariat.

DR. VICENTE Y. BELIZARIO, JR
Executive Director
National Institutes of Health
University of the Philippines Manila

Delivery Address :
c/o Office of the Deputy Executive Director
(Attn: FDA Review Panel Secretariat)
G/F National Institutes of Health Building
623 Pedro Gil St., Ermita, Manila
Tel No : (02) 528-4041, 526-4349
Fax No : (02) 525-0395
Email : nih-ded@post.upm.edu.ph

Step 2 : Secretariat assesses completeness of review package based on the document checklist. This should include the permit to review issued by the FDA.

Step 3 : Secretariat issues billing statement with instructions to Sponsor.

Step 4 : Sponsor pays review service fee to UPMDFI, Inc and submits proof of payment to Secretariat.

Once Steps 1-4 is completed, FDA review timeline starts at UPM-NIH.

OVERVIEW OF THE REVIEW PROCESS

Step 1 : FDA Review Panel Chair assigns a lead and a secondary reviewer for each protocol.

Step 2 : Secretariat provides a copy of the protocol and the FDA Review Assessment Form to each reviewer.

Step 3 : Reviewers submit their review to the FDA Review Panel Secretariat who disseminates copies of the completed assessment forms to all panel members.

Step 4 : FDA Review Panel meets en banc and discusses the protocol, finalizes the assessment and makes its recommendation.

Step 5 : Secretariat completes all documentation and completes the FDA review recommendation package.

Step 6 : Secretariat informs FDA that the package is ready for pickup.

GENERAL TIMELINE

If the review will not require a clarification from the Sponsor, UPM-NIH expects to complete the FDA assessment form and submit its recommendation within 45 days.

If the review will require a clarification from the Sponsor, UPM-NIH will complete the FDA assessment form and submit its recommendation after 60 days, excluding the time spent for the Sponsor to respond to UPM-NIH's request for additional documents or attendance to a clarificatory interview/discussion with the Review Panel.

PROCESS OF SUBMISSION OF RECOMMENDATION TO FDA

Once the Review Panel has completed the Assessment Form and has prepared its recommendation to the FDA, the Secretariat will compile the following to be submitted back to the FDA:

1. All documents submitted by the Sponsor, including additional documents, as applicable
2. Completed FDA Assessment Form, signed off by the NIH Executive Director

The following documents will be retained and filed by UPM-NIH:

1. Permit to review issued by the FDA
2. Copy of the completed FDA Assessment Form
3. Minutes of the meeting of the Review Panel

FERCAP-NRCT Update Training
for Surveyors / Accreditors
Feb. 10-11, 2012

ACCREDITATION
AND
NATIONAL REGULATIONS
AND GUIDELINES

SOPIT THAMAREE

CONTENT

National Ethics Committee

Accreditation System, NECAST

- Structure and Administration of NECAST
- NECAST Standards
- Factors facilitating the NECAST

National Regulations

Guidelines

RESEARCH ETHICS COMMITTEE ACCREDITATION SYSTEM

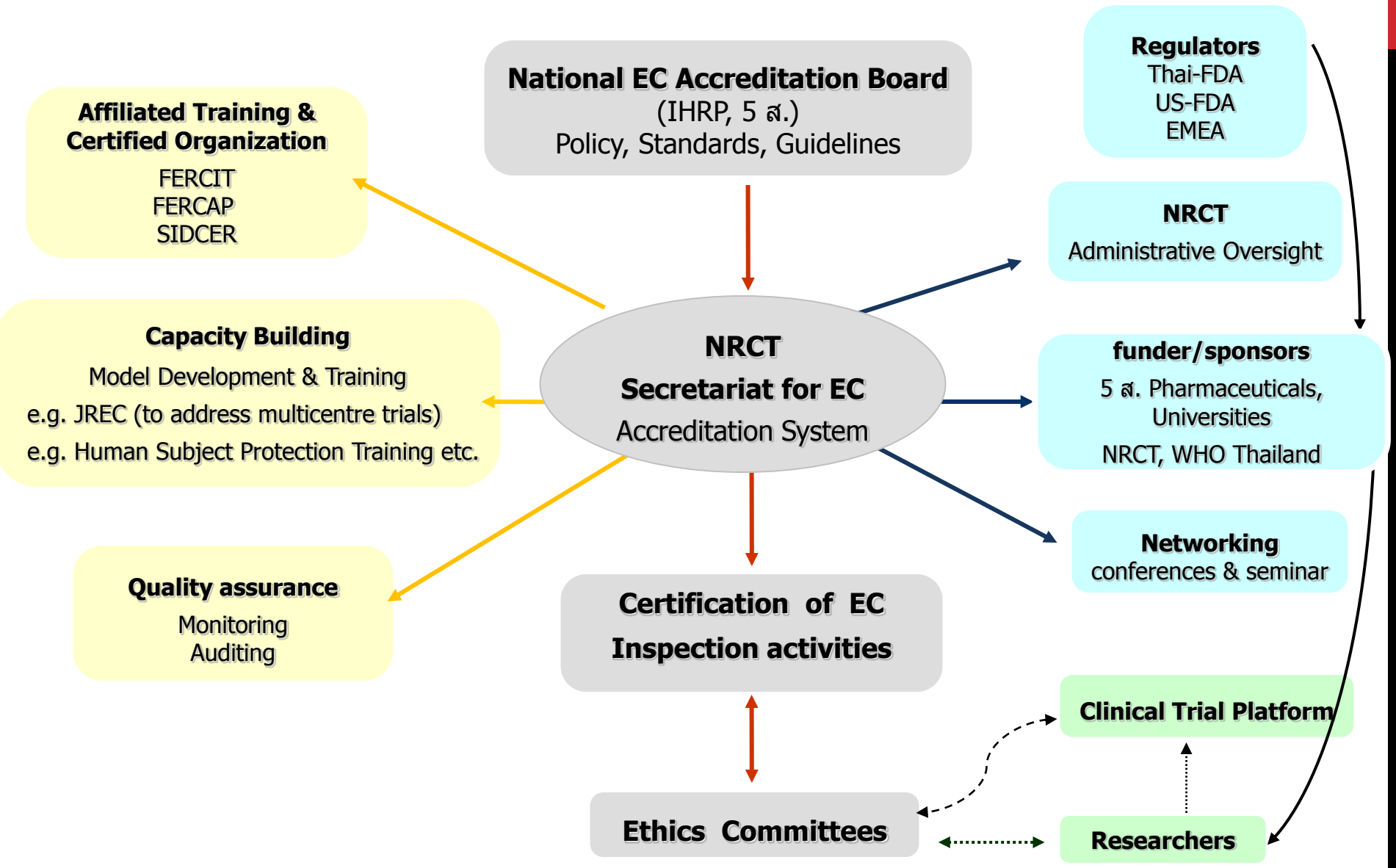

Structure and Administration of NECAST

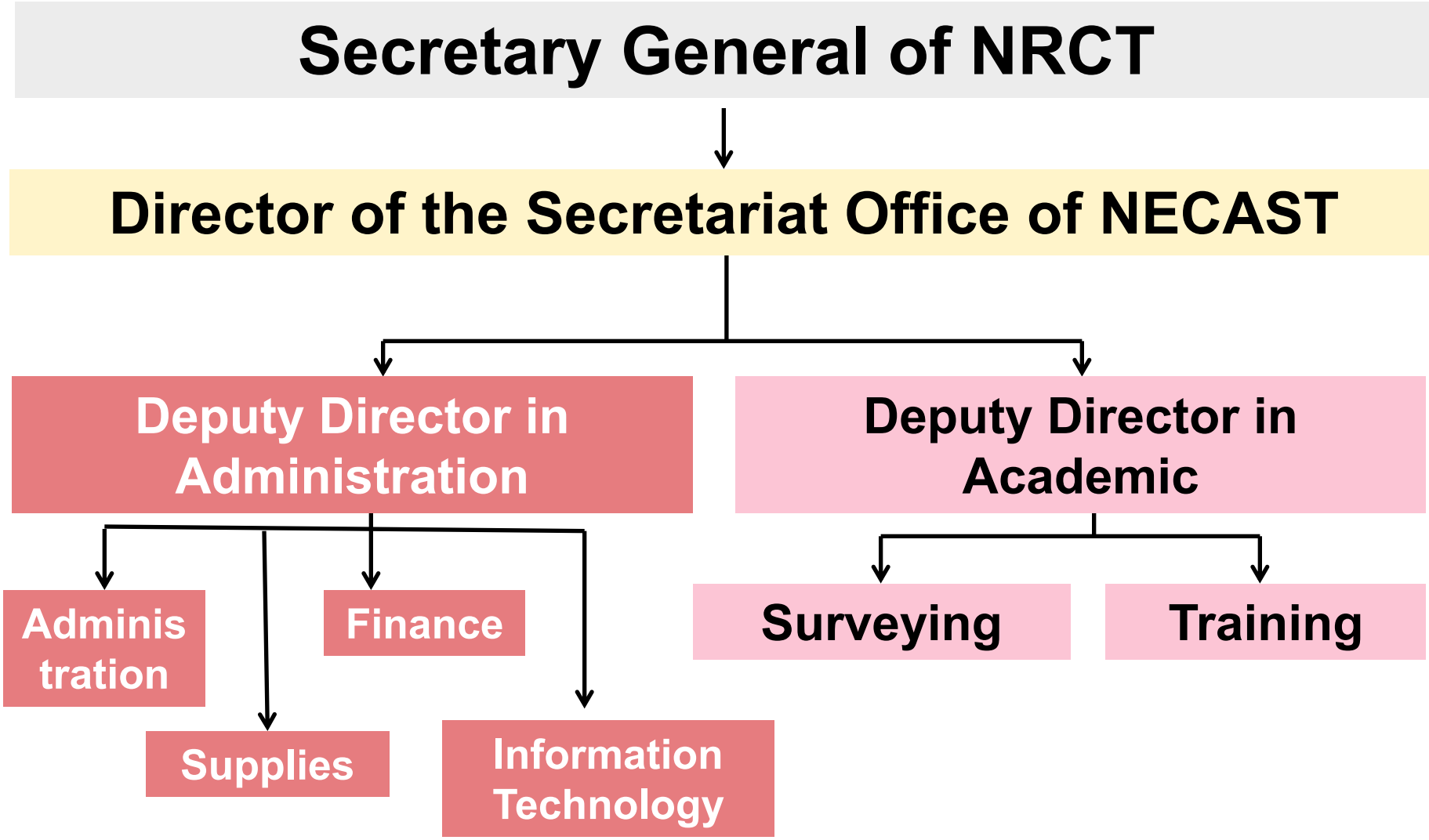

NECAST STANDARDS

- **International Standards**
- **Adoption of the** SIDCER Recognition Standards

  SIDCER=The Strategic Initiative for Developing Capacity of Ethical Review)
- 12 SOPs to cover the function of survey

APPLICATION FOR ACCREDITATION

Criteria	National – NECAST	International- SIDCER-NECAST
Duration of IRB appointment	1 year	3 years
No. of protocol reviewed	30	30/year
Duration of SOPs implementation	6 months	6 months

FACTORS FACILITATING THE NECAST

1. STANDARDS.....SIDCER
2. SOPS FOR SURVEY..SIDCER-NECAST
3. SURVEYOR.... >14 THAI SURVEYORS
4. SECRETARIAT OFFICE....NRCT
5. RESOURCE PERSONS & TEAMWORK .....FERCIT, FERCAP, +++
6. FULLY FINANCIAL SUPPORT FROM NRCT

National Regulations

No specific **law** involving research in human subjects.

The Civil and Commercial Code as well as the Criminal Code are applicable.

National Regulatory Authorities

Drug Act and Ministerial Regulations

Medical Device Act and Regulations

Medical Profession Laws

The Enforcement Rules of the Medical Councils of Thailand (TMC)

National Regulations

Public Health Acts

National Health Assurrance Act (2002)

Emergency Medicine Act (2008)

National Health Act (2007)

Declaration of Patients' Rights (1997)

Research Funding Agencies (TRF=สกว, NRCT=วช, etc.)

National Guidelines (issued by FERCIT and TMC)

Other Laws and Regulations

Medical Profession Act

พระราชบัญญัติวิชาชีพเวชกรรม

Since B.E. 2511 (AD 1968)

Regularly revised many times

.....2526, 2544, **2549** (AD 1983, 2001, **2006**) **Section 9, Articles 47, 48, 49, 50, 51**

Medical Profession Act
พระราชบัญญัติวิชาชีพเวชกรรม

Articles 47: Medical practitioners who perform research and experiments on human subjects must obtain their prior **consents** and should be alert to prevent any harm occurring to the subjects as a result of the research or experiment.

Medical Profession Act

พระราชบัญญัติวิชาชีพเวชกรรม

Articles 48: Medical practitioners should base their conducts towards research subjects on the **same codes of conduct** towards patients in the practice of medicine…

Medical Profession Act
พระราชบัญญัติวิชาชีพเวชกรรม

Articles 49: Medical practitioners must assume **responsibility** for any harm or damage suffered by research subjects as a result of the research or experiment except when the subjects themselves are at fault.

Medical Profession Act
พระราชบัญญัติวิชาชีพเวชกรรม

Articles 50: Medical practitioners who conduct or collaborate in a research or experiment conducted on human subjects shall commence the study in question only after explicit **approval from the relevant ethical committees**.

Medical Profession Act:
Stem Cell Transplantation for Treatment
B.E. 2552 (A.D. 2009)

Articles 2:

2.1 Stem cell transplantation for treatment in human must be well established to be standard treatment and approved by the TMC

2.2 Stem cell research

2.2.1 Approval from IRB

2.2.2 Approval from the TMC's EC

Medical Profession Act:

Stem Cell Transplantation for Treatment

B.E. 2552 (A.D. 2009)

Articles 3:

3.1 The medical practitioners must be specialized / qualified in that particular disease and

3.2 be registered from the TMC to be able to perform the stem cell transplantation for treatment

Declaration of Patients' Rights, 1997

10 Articles

Article No.8 *The patient has the rights to know or demand complete current information regarding his role in the research, in order to make decision to participate in/or withdraw from the study being carried out by their health care provider."*

National Health Act AD 2007

Article 9

"Freely Informed Consent" to participate and withdraw from the research.

National Health Act AD 2007

หมวด ๑ สิทธิและหน้าที่ด้านสุขภาพ

มาตรา ๙ ในกรณีที่ผู้ประกอบวิชาชีพด้านสาธารณสุข **ประสงค์จะใช้ผู้รับบริการเป็นส่วนหนึ่งของการทดลองใน**งานวิจัย ผู้ประกอบวิชาชีพด้านสาธารณสุขต้องแจ้งให้ผู้รับบริการทราบล่วงหน้า และ**ต้องได้รับความยินยอมเป็นหนังสือจากผู้รับบริการก่อน**จึงจะดำเนินการได้ ความยินยอมดังกล่าว ผู้รับบริการจะเพิกถอนเสียเมื่อใดก็ได้

CHILDREN'S ASSENT
TO CLINICAL TRIAL PARTICIPATION

No regulation

but most IRBs consider that child at the minimum age of 7 years old is reasonable for some kind of assent process.

National Regulatory Authorities (NRA) Drug Act and Ministerial Regulations

In 2004, an agreement on

"Asia Harmonization on

Pharmaceutical Registration"

that allied countries will adopt the

International Standard Guidelines,

including, the ICH/GCP.

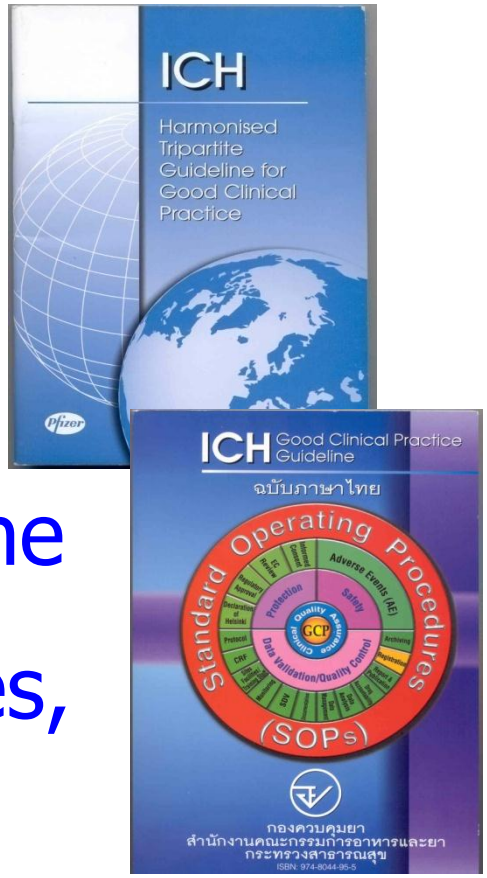

National Regulatory Authorities (NRA) Drug Act and Ministerial Regulations

No official enforcement or regulation on CTs. Most institutions and researchers voluntarily adopt the ICH/GCP.

Many clinical trial centers (CTC) applied for GCP Inspection and certification.

National Regulatory Authorities (NRA) Drug Act and Ministerial Regulations

✶ To import non-licensed drugs for research, Thai FDA alleviates the regulation by giving permission to Pharma after the research protocols are reviewed by the EC of Ministry of Public Health or Institutional REC (or IEC) for human research.

✶ Report of ADRs that are both serious and unexpected to the sponsor, then to the NRA complyingly to GCP.

National Regulatory Authorities (NRA) Drug Act and Ministerial Regulations

- 10 IRBs are recognized(standards requirement??)
- Revision the regulations and forms (น.ย.ม.1)

Changes on the move

- Official requirement of GCP Compliance
- GCP Inspection and certification
- Certify the ECs recognized by SIDCER

National Regulatory Authorities (NRA) Drug Act and Ministerial Regulations

Medical Devices are categorized into 3 classes as prescribed by the announcement of the Minister of MOPH, those require

- licence
- product characteristics
- Certificate of Free Sale

Medical Devices may be categorized, based on risk, into

- Non-significant Risk Device (NSR)
- and Significant Risk Device (SR)

Ethical Guideline for Research in Human in Thailand, 2007

(แนวทางจริยธรรมการทำวิจัยในคน

ในประเทศไทย พ.ศ. 2550)

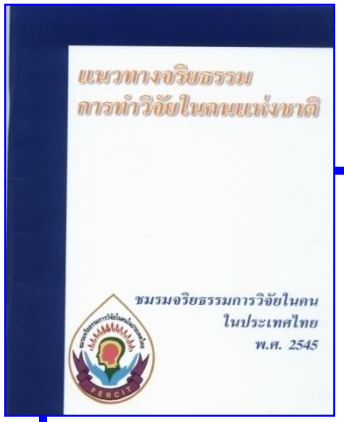

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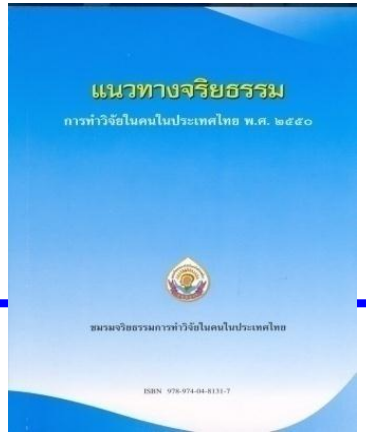

2007

Rvised by FERCIT ชมรมจริยธรรมการวิจัยในคนในประเทศไทย
and Medical Council of Thailand
9คณะทำงานของคณะอนุกรรมการส่งเสริมการศึกษาวิจัยในคน (แพทยสภา)

Good Research Practice Guideline

- **Ethics for Researchers** issued by the National Research Council of Thailand (NRCT) since 1998
- Currently, the **"Code of Conduct for Researcher"**
- **Morals**

Code of Conduct for Researcher

NRCT

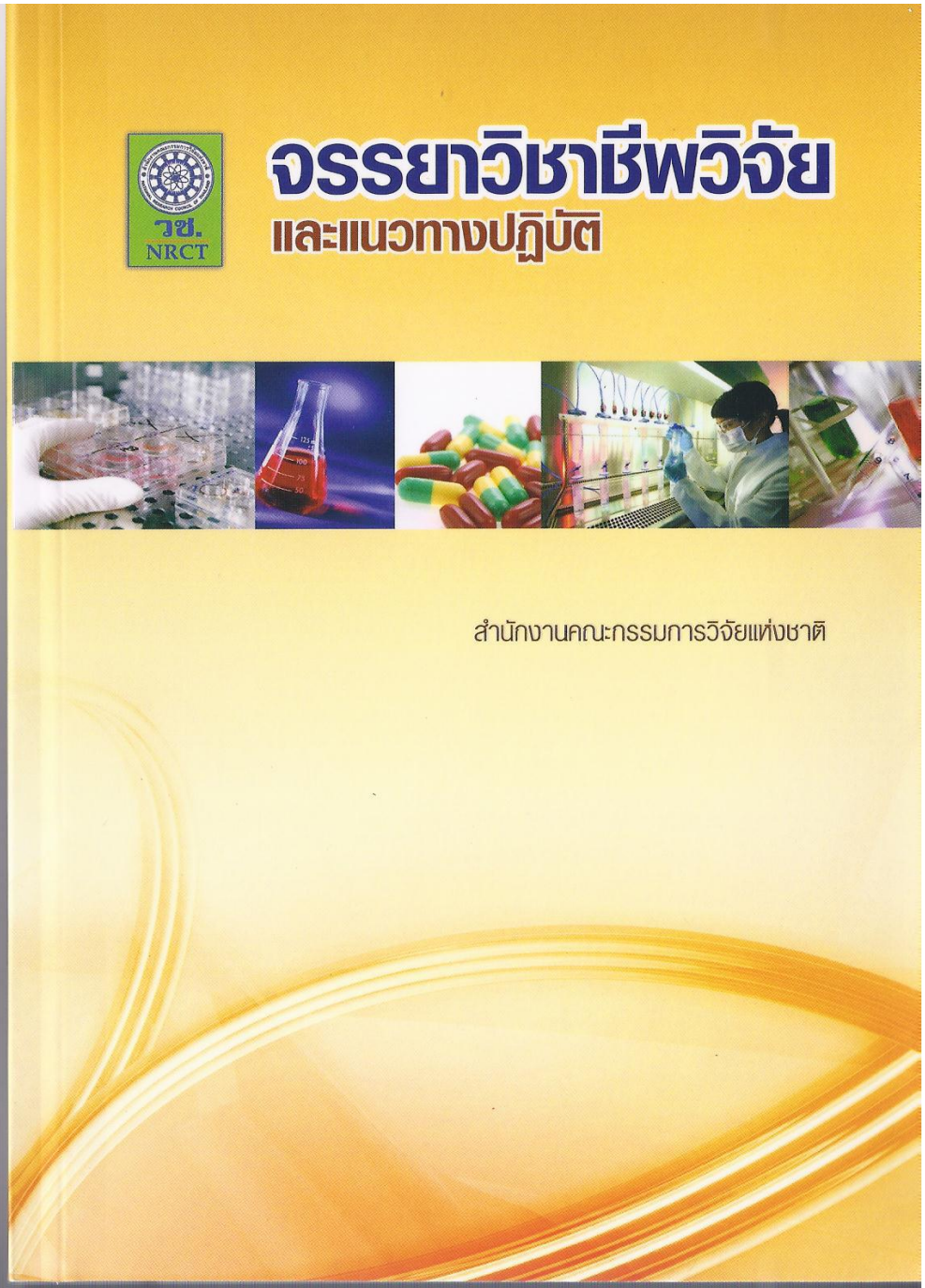

Thai Guidelines for Research Involving Human Subjects

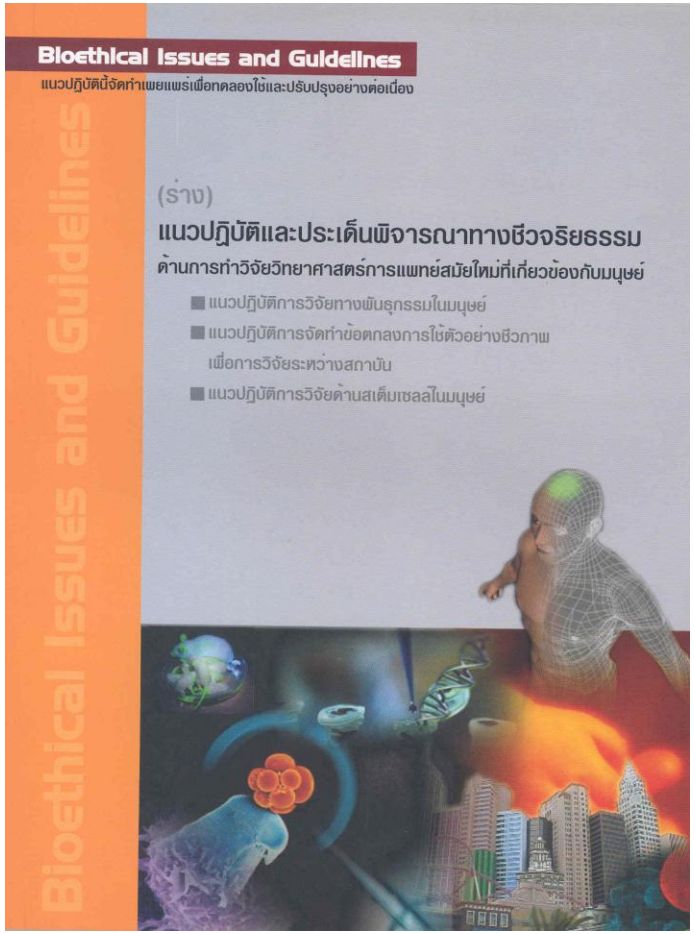

Guidelines for Genetics and Stem Cell Research in Human and Guidelines for Material Transfer Agreement

2002

Thank You for Your Attention

The Ethical Guidelines for Research

on Human Subject in Thailand, 2007

Forum for Ethical Review Committees in Thailand

Editors

Tada Sueblinwong

Punkae Mahaisavariya

Suthee Panichkul

Disclaimer!

The material is prepared from prepublished manuscript. There is minor change of format. Although an effort has been made to verify the content with published version, reader may refer to published version when necessary.

The Ethical Guidelines for Research on Human Subject in Thailand 2007

Forum for Ethical Review Committees in Thailand

Editors
Tada Sueblinvong
Pankae Mahaisavariya
Suthee Panichkul

Foreword and Acknowledgement

The Ethical Guidelines for Research on Human Subjects in Thailand, B.E. 2550 follow the revised edition of the National Guidelines for Ethical Research on Human Subjects, B.E. 2545. Apart from a minor change in the Thai title, major revisions of Chapter 7, Specific Types of Research on Human Subjects, have been made. Ethical issues in modern biomedical research, i.e., medical devices, vaccine trials, epidemiology, human genetics, research involving human gametocytes, embryonic tissues, placenta, fetal hematocytes and stem cells were added. These are the first guidelines on modern biomedical ethics published in Thailand.

The Ethical Guidelines for Research on Human Subjects in Thailand, B.E. 2550 is designed to comprise of both Thai and English language in one book. It has been edited to present the contents of both languages correspondingly. Translation from Thai to English was accomplished by professional translator, Dr. Suchart Chongprasert, then edited by Mr. Thomas McManamon .

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The Forum for Ethical Review Committee in Thailand (FERCIT) wishes that this book "The Ethical Guidelines for Research on Human Subjects in Thailand, B.E. 2550" will be beneficial to ethics committee members, medical doctors, dentists, pharmacists, nurses and all researchers who do research on human subjects. The most ambitious purpose of writing these guidelines is to achieve the goal of best protection for all human volunteers as well as the accomplishment of advanced biomedical research.

Tada Sueblinvong

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Chairperson, The Forum for Ethical Review Committee in Thailand (FERCIT)

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CHAPTER 1

DEVELOPMENT OF THE ETHICAL GUIDELINES FOR RESEARCH ON HUMAN SUBJECTS IN THAILAND

1.1 Introduction

Nowadays, countries around the world, especially developed countries, have established human rights laws covering several aspects, including the law governing the conduct of research on humans or animals. Developed countries also have attempted to stipulate regulations and guidelines for research on human subjects, and promote the adoption of the regulations/guidelines in developing countries, such as guidelines for manufacturing of pharmaceuticals or patent application. Prior to being accepted for publication or granted a patent, or conduct a scientific research investigation involving human subjects, researchers are required to obtain ethical approval from a recognized ethics committee. In addition, seminars and conferences have been conducted on the ethical principles or guidelines for research in human subjects in both developing and developed countries; the outcomes of which have been several declarations. The most prominent and widely accepted and most commonly referred to is the Declaration of Helsinki of the World Medical Association (WMA), firstly adopted in Helsinki, Finland in B.E. 2507. The Declaration has been regularly amended to keep pace with advanced science, technology and social changes. The last amendment was formulated and adopted in Scotland in B.E. 2543. Later, several declarations concerning the conduct of a research on human subjects have also been adopted. The most essential element of those declarations is to protect the dignity, rights, safety, and well being of human volunteers or research participants.

Various institutions at national and international levels are aware of the ethical issues of research on human subjects. As a result, an ethics committee is appointed whose responsibility it is to monitor that the research conducted within the institution adheres to the ethical principles established in the Declaration of Helsinki or other declarations.

In Thailand, the Ministry of Public Health in co-operation with nine Faculties of Medicine have organized a series of seminars at the Faculty of Medicine, Chulalongkorn University. This resulted in the establishment of the Forum for Ethical Review Committees in Thailand or FERCIT. The FERCIT aims to develop plans for promoting ethical research on human subjects. A Working Group was then appointed to draft ethical guidelines for research on human subjects, which are intended to serve as national guidelines. The national ethical guidelines were developed considering of the ethical principles that have their origin in several international guidelines, such as the Declaration of Helsinki of the World Medical Association, the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, the Council for International Organizations of Medical Science (CIOMS), and the Canadian Ethical Conduct for Research involving Humans, etc. The ethical guidelines has been published and distributed since B.E. 2545, and its English version was available in B.E. 2550.

1.2 Need for Research on Human Subjects

Research on human subjects is necessary for promoting scientific progress and building a better understanding in order to improve human well-being. Researchers, universities, governments, and private organizations have various reasons for conducting or sponsoring research on human subjects. Such reasons include, for example, alleviating suffering from illness, evaluating social values or scientific theories, eliminating ignorance, analyzing policies, creating better understanding of human behavior and related purposes. In summary, research on human subjects serves three main purposes, i.e.,

1.2.1 To generate a new body of knowledge and new understanding;

1.2.2 To enhance scientific advancement that benefits the research subjects.

1.2.3 Through research, the subjects may gain benefits from the development of new treatment, from new findings for higher living standard, from new discoveries, from writing, speech, and traditional culture, or from satisfaction in improving society;

1.2.4 Also, research provides benefits for the society at large or for certain groups of people or has influence on political behavior, which may lead to an improved health policy. The statistical information about the disease incidence may help to improve public health. The information about living conditions and behavior may lead to social development.

1.3 Objectives of the Ethical Guidelines for Research on Human Subjects in Thailand

Thailand has established three basic objectives regarding research on humans:

1.3.1 To ensure that the dignity, rights, safety and well-being of subjects participating in research are protected, and the results of the research are credible;

1.3.2 To serve as guidelines for researchers, ethics committees, organizations, institutions, and people who are related to research ethics;

1.3.3 To serve as a basis for an ethics committee to derive a standard operating procedure (SOP) for the review and approval of biomedical research conducted within each institution.

1.4 Related Terms and Definitions

1.4.1 **Research on human subjects** means a research study, inquiry, interviews in social science, environment and environmental conditions, a clinical trial of pharmaceutical products and medical devices, a study of the nature of disease, the diagnosis of, the treatment of, the health promotion of, and the prevention of a disease related to human or conducted in human. Also, such research includes research studies using information from patient medical records or databases, laboratory specimens, body fluids, human tissues, and studies about the physiology, biochemistry, pathology, responses to treatment in physique, biochemistry, psychology of normal subjects and patients. These research projects are collectively called **biomedical research**.

1.4.2 **Ethics Committee** or **Research Ethics Committee** means a committee appointed by an institution, organization, or agency whose responsibility is to review the ethical aspects of research studies and experiments on human subjects so that the rights, safety, and well-being of research subjects are protected. The ethics committee has been defined in the Medical Council's Regulation on the Preservation of Ethics of the Medical Profession (No. 5) B.E. 2545, Section 6. The ethics committee is also called differently, for example an Ethics Committee for Research on Human Subjects.

1.4.3 **Ethical Guidelines for Research on Human Subjects** means ethical guidelines or criteria related to research studies or experiments on human subjects, for example, the Declaration of Helsinki and other ethical guidelines established by each institution.

1.5 Revision of the Ethical Guidelines for Research on Human Subjects in Thailand

Thanks to rapid advances in science and technology, the first version of the Ethical Guidelines, published in B.E. 2545, could not cover or keep pace with contemporary issues. It is therefore necessary to revise the first Ethical Guidelines. The Medical Council of Thailand as a regulatory body has assigned the Sub-committee on the Promotion of the National Ethical Guidelines for Research on Human Subjects to be in charge of the revision. The process was completed by the Working Group for Revising the Ethical Guidelines, where members of the working group were mainly from the Working Group for the Development of the Ethical Guidelines previously appointed in B.E. 2545. The Chairperson and the Secretary for the two Working Groups remain the same persons. Some new members joined the Working Group for Revising the Ethical Guidelines, Annex 10).

CHAPTER 2

ETHICS FOR RESEARCH ON HUMAN SUBJECTS

2.1 General Ethical Principles

Three basic ethical principles consist of:

First, **respect for persons**;
Second, **beneficence**;
Third, **justice**

2.2 Principle of Respect for Person

The principle covers the following aspects.

2.2.1 Respect for human dignity. This aspect is the heart of research ethics, which provides for the protection of diverse interests relevant to the body, mind, and cultural security of a person. This is the foundation of the other following principles. Respect for freely given informed consent. This means the subject needs to be fully informed of all aspects of the research without hidden or biased information using an easy-to-understand language for the subjects. The information should cover the details of the procedures, rights, obligations, requirement for informed consent and the freedom of decision making. Also, the subjects have the rights to withdraw their consent any time without giving any reason. In practice, the informed consent may appear in a form of conversation.

2.2.2 Respect for vulnerable persons. Respect for human dignity leads to an ethical requirement for vulnerable people who have inferior or lack physical capacities or have diminished capacities for making a reasonable decision, such as children, pregnant women, psychiatric patients, unconscious patients, and prisoners. These vulnerable people need to be protected from being forced to participate in a research involuntarily. In practice, a special treatment is needed for the protection of their benefits.

2.2.3 Respect for privacy and confidentiality. This principle is fundamental to the respect for human's dignity found in various cultures, and it helps to protect the security of mind. Therefore, the standards applied for the respect for privacy and confidentiality help to protect the access to, retention of, and distribution of personal information.

2.3 Principle of Beneficence

This principle covers the following aspects.

2.3.1 Balancing between risks and benefits; An analysis of risks and benefits being exposed to the subjects is a key ethical issue of research on human subjects. Research ethics for human subjects in modern times requires a balance between potential risks and benefits, with the desired goal being that the benefits must outweigh the risks and that the potential risks are acceptable for the subjects and received prior to review and approval from an ethics committee. The analysis of the risks and benefits affects the welfare and rights of the subjects. However, sometimes the estimation of risks and benefits of all aspects of the research is difficult to achieve. Therefore, the key principle of respect for human dignity always requires a proper and reliable research design, especially biomedical or health research, which needs prior research studies conducted in both laboratory and animal models to ensure safety. Moreover, it requires adequate review of the existing knowledge of the proposed research. Although the analysis of risks and benefits may not be obvious in some research areas, such as the political sciences, economics, or

history (including a personal biography), the risks still remain as the research results may potentially destroy the credit or grace of an organization or individuals.

2.3.2 Minimizing harm; Researchers are required to protect their subjects from all possible harm or to minimize the dangers. The subjects must not be exposed to unnecessary risks. To achieve excellent scientific and social results, it is truly unavoidable to conduct research on human subjects. The subject sample size should then be as small as possible, but still maintaining scientific integrity, i.e., the smallest sample size adequate for a reliable statistical analysis of the results.

2.3.3 Maximizing benefits; The principle of beneficence relies on compassion, which mandates maximal benefits be entitled to others. This principle is actually supportive of the practice of researchers in certain professions, e.g., healthcare providers, psychologists, social workers, and educators. As mentioned above, the aims of research on human subjects are to provide direct benefits to participating subjects and then to others or the society at large, or contribute to scientific progress. Currently, most research is primarily beneficial to society and the progress of science.

2.4 Principle of Justice

This principle covers the following aspects.

The principle of justice includes both fairness and equity. In terms of procedural justice, a standardized procedure with a fair and independent review of research protocols is required. Also, justice requires the distribute of both the burdens and the benefits of a research equally, which leads to the consideration that research should not be performed simply to gain scientific progress in vulnerable people who cannot protect their rights and benefits, as has been witnessed in several cases in the past. In addition, the subjects participating in a research study should be entitled to any direct benefits from the research. Justice is then reflected by not neglecting or discriminating against people or groups of people that may benefit from the progress of research.

CHAPTER 3

CONDUCTING RESEARCH ACCORDING TO THE PRINCIPLE OF RESPECT FOR PERSONS

3.1 Informed Consent Process

Conducting a research in conformity with international standards requires correct and appropriate informed consent and invitation to be given to subjects. The process is not to force the subjects to participate in the research directly or indirectly without giving them a chance to be informed about the research procedures or without giving any opportunity to make their own decision. Examples are that patients have a dependent relationship with physicians, or that physicians conduct experiments in patients using one or more medicines or new unproven treatment without informing the patients, or that payment or compensation in either money or gifts or the promise to give something beyond necessity is given, or that the instructions or explanation about research procedures are given in a technical language too difficult for the subjects to understand. In providing information or invitation to potential subjects to participate in a research, it is important to always adhere to the three ethical principles, i.e., respect for persons, beneficence, and justice.

In providing the information or invitation for decision making, the investigator may separate the documents into two parts, i.e., the information sheet explaining research procedures, risks, benefits, what the subjects should be aware of in making their decision, and the informed consent form. The two parts can be combined into one, but it should cover the details of both parts. The language used should be suitable for lay persons to understand and cover medical information as appropriate, including legal and financial aspects of the study. The informed consent is not only to protect the research subjects, but also to protect the investigator, the sponsor, and the ethics committee. Therefore, the investigator is responsible for preparing the details of the research procedures and the information sheet by himself/herself. In case the subjects cannot personally give a written informed consent, the informed consent given verbally with an impartial witness should be specified. In addition, it should specify in what case the legal guardian is to be informed and consent granted.

3.1.1 Advice for the preparation of the information sheet and informed consent form

The information sheet and the informed consent process to be given for the subject's decision making should contain the following elements:

(1) the title of the study;

(2) an invitation describing why the subject should participate in the study;

(3) the objective(s) and the research procedures that the investigator and the subject have to follow;

(4) the duration of the subject's participation in the study;

(5) the expected benefits of the study, which may directly benefit the subject, the community, or society, or for gaining scientific knowledge;

(6) the plan for access to the products or the treatments that are proven from the research to be safe and effective for the subject or the community after the study;

(7) the subject treatment, risks, discomforts, or any inconvenience that may happen to the subject (or others) participating in the study;

(8) available alternative products or treatments that may be useful for the subject vis-à-vis the study product or treatment;

(9) the scope of confidentiality and protection of the subject's records;

(10) the disclosure policy for genetic study results at appropriate time;

(11) the investigator's responsibilities (if any) in providing the services to the subject;

(12) the availability of free medical treatment and care in case of study-related injuries or damages;

(13) availability of payment/compensation for damages in the form of either money or other offers for each subject (if any), and the type and quantity of which should be specified;

(14) the funding resources, the sponsor and the participating institutions;

(15) whether the results of the study will be disclosed to the subject and how;

(16) whether the biological materials collected from the study will be destroyed; if not, the details of the storage and the plan for future use should be provided, and whether such a use is limited;

(17) whether there would be any products derived from the biological materials collected from the study;

(18) whether the subjects or their families or the persons under the subject's supervision will receive any compensation for damage or death resulting from the study;

(19) that the subject has the freedom to deny or withdraw from the study at anytime without losing any benefits, and must not affect standard treatments that the subject is normally entitled to;

(20) that the study protocols have been reviewed and approved by the ethics committee for research in human subjects.

3.1.2 Practical guidelines that should be followed

The guidelines below clarify several relevant ethical considerations.

(1) Obtaining informed consent is not merely having the subjects or their legally acceptable representatives sign on the consent form. Rather, the process should reflect a good relationship between the investigator and the subjects. The process should provide clear and complete information sufficient for the subjects to make their decisions. The investigator should pay attention to the care and the physical and mental well being of the subjects during the course of the research.

(2) The language used should be suitable to the subject's capacity and avoid technical terms;

(3) The investigators must ensure that the potential subjects are aware of their participation in the study, and understand clearly the research procedures;

(4) According to the principle of beneficence and non-maleficence, the researcher must inform the subjects in advance of any procedures or treatments other than the diagnosis, treatments or prevention that are useful to the subjects. Advantages or disadvantages of participating in the study should be provided so that the subjects can make their own decisions;

(5) Upon the completion of the study, whether the subjects are entitled to continuous access to the medicine, instruments, or others should be specified.

3.2 Inducement

In recruiting the subjects into a study, the ethical principle that should be followed is that the subject should be invited to participate in the study. Please note that the words "invitation" and "volunteer" mean that the potential subjects are informed correctly, and voluntarily participate in the

study. The information given should include both advantages, disadvantages to be incurred to the subjects themselves, to the community, or just for scientific benefit. The subjects should make their own decisions, not be forced to do so, or induced unduly. The subjects can also withdraw from the study any time. Several aspects of inducement that should receive consideration include:

3.2.1 Payment or compensation either money or other benefits to be given to the subjects should not be too much to induce the subject to decide to participate in the study without carefully considering the risks that may happen in the study;

3.2.2 For a phase I clinical trial usually conducted in normal subjects, the subjects would not obtain direct medical benefits from the study results. Therefore, it is necessary to compensate for travel expenses, loss of work or other payments, as appropriate. On the contrary, for a phase III study, the subjects usually obtain direct benefit from the study.

3.2.3 Enforced participation in a study may happen to institutionalized people, such as soldiers, prisoners, and students who have to obey or cooperate with their corresponding authorities. In recruiting these people into a study, it is necessary that they are informed and are given opportunity to make their own decisions without any interference from the higher authority.

3.2.4 3.2.4 Payment given to investigators by pharmaceutical companies or sponsors in the form of money or other means that are excessive, or payment methods, such as the given payment is based on the number of subjects participating in the trial, may cause deviation in the case that the investigator attempts to recruit as many subjects as possible for their own benefit.

3.3 Privacy and Confidentiality Protection

No. 21 of the Declaration of Helsinki B.E. 2543 states, “The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information, and to minimize the impacts of the study on the subject's physical and mental integrity and on the personality of the subject."

3.3.1 Confidentiality protection

(1) The subjects must be informed about their rights to have their personal information protected strictly.

(2) During the informed consent discussion, the investigator must inform the subjects in advance of the measures used to protect their confidentiality before signing the consent form.

(3) The subjects must sign the informed consent form before the information is to be distributed in case the information can cause danger to them.

(4) The possible leakage of the research results containing the subject's confidentiality should be minimized to the lowest level. In general, the best way to protect the subject's confidentiality is to remove the subject's identification from all stages of the study, and to control or restrict access to the data.

(5) The subjects should be made aware of the investigator's limitations in keeping their confidentiality. An example is when, the investigator has to transfer the subject’s information from the case report forms to the national regulatory authorities or the sponsor. This also includes where a regulatory requirement exists to report certain events, such as communicable disease, child molestation abuse, and child's negligence, directly to the responsible agency. Under these circumstances, the investigator must inform the subjects of the limitations for keeping confidentiality before the subjects participate in the study.

(6) The subjects should be made aware of the social impact on them if there would be any leakage of the data. For example, if the subject's participation in the

studies on AIDS medicines or vaccines is made public, it is risky for the subjects to receive social discrimination. Such risks should be carefully considered in the same manner as those for any treatment risk resulting from drug or vaccine studies.

(7) In the case where the ethics committee decides that signing the informed consent form can be waived, the investigator should explore other means to protect the subject's confidentiality.

3.3.2 Confidentiality between physicians and patient subjects

The Declaration of Patients' Rights, issued by the four health professional associations and the Ministry of Public Health, states, “Patients have the right to receive strict protection of their own information.” Any disclosure of the patient’s information to anyone who needs the information, such as doctors, nurses, technical scientists, competent authority, or other researchers, can be made only if the patients or their legally acceptable representative gives prior permission.

3.3.3 Data from medical records

(1) In practice, it is quite difficult for a researcher who conducts a study using the information from medical records to have a patient's informed consent form kept in each patient's medical record either by having patients sign the form in advance and keeping it in the medical record or by calling for patients to sign later. In this case, therefore, the ethics committee may consider waiving the signing of the informed consent form. However, the evidence should be provided to prove that the subjects are informed about the methods for collecting the data. For example, the methods are to be included on the information sheet for patients being hospitalized, or the permission to use the data in medical records may be given from the hospital director or other authorized persons.

(2) The collection of the data from the medical records must receive approval from the ethics committee, and the patient's confidentiality must be strictly protected.

(3) The investigator is allowed to use the data from the patient's medical records only as specified in the research protocol.

3.3.4 Risks to Groups of People

Research results from certain fields such as epidemiology, genetics, and the social sciences, whatever conclusions are reached, may cause risks to community, society, races or minors such as stigmatization, injustice or discrimination.. An example is research results showing that certain groups of people may be subjected to alcoholism at a greater rate. The investigator must take steps to protect the confidentiality of these groups of people both during study and at the end of the study, including all related published articles. The ethics committee should review the impacts that may happen to groups of people, especially in a research study about ethinic and racial groups. Individual informed consent as well as community permission should be obtained.

3.4 Research Studies in Vulnerable Subjects

Vulnerable groups of people are those who need to depend on others, and are unable to express their opinion freely or to make their own decisions. These include hospitalized patients, prisoners, children, the mentally impaired, critically ill patients, psychotic patients, pregnant women, and the economically disadvantaged. They are easily taken advantage of. As a consequence, the protection of vulnerable groups of people is of prime importance. Investigators should not select these groups of people simply because of easy management or convenience for

the conduct of a research study due to their economic or health constraints. However, if a valid need exists to conduct a study on these people, some recommendations should be followed.

3.4.1 An irrefutable rationale for conducting research in these population groups should be clearly explained in the protocols.

3.4.2 Precautions against possible physical and mental harm should be exercised especially when the study is conducted on children.

3.4.3 The research procedures used in the study should be appropriate for the specific groups of these people.

3.4.4 In a study involving pregnant women, adequate information on the safety and impacts to the fetus should beprovided.

3.4.5 In a study involving minors, psychiatric patients, or the incompetent, the informed consent should be obtained from their parents, or guardians or legal representatives.

3.4.6 It should be ensured that parents, guardians, or legally acceptable representatives are fully informed about the study.

3.4.7 The rights of the minors and the economically disadvantaged should be respected for making their voluntary decisions.

3.4.8 It should be shown that the research participants have freedom in voluntarily participating in a research study, including for example a research study conducted on prisoners, inmates, and refugees.

3.4.9 Precautions against harm and protection of confidentiality should be strictly exercised when conducting research studies in subjects with illegal careers, such as sex workers or illegal drug users.

3.4.10 In the case where a study is conducted on the vulnerable people without direct health benefit to them, the possible risks should not be greater than the minimal risk normally found in a general physical or psychiatric examination, or unless the research ethics committee allows for a greater-than-minimal risk.

CHAPTER 4

CONDUCTING RESEARCH ACCORDING TO THE PRINCIPLE OF BENEFICENCE

4.1 Nature and Scope of Risks and Benefits

The principle of beneficence requires that a research study be justified to conduct on humans by an assessment of a favorable risk and benefit ratio. In the context of research involving human subjects, the term "risk" means the possibility to receive harm, whereas the term "benefit" denotes that which gives a positive value to health or well being.

Please note that benefits do not indicate an opportunity or possibility. By this definition, a benefit is then opposite to a harm. An assessment of a risk and benefit ratio requires the consideration of both probability and the dimension of possible harm and expected benefits.

The common types of harm that occur to subjects include physical harm or injuries or psychological harm. In addition, other harm may be overlooked such as legal, social, and economic impacts. Moreover, the types of the expected benefits may be consistent with the types of potential harm that may happen.

Risks and benefits in a research may affect each subject directly, subject's family, and society at large, or special subject groups in a general society. Before initiating the study, an assessment of risks and discomfort that may happen to the subjects compared with the expected benefits is required. Please be aware that the rights, safety, and wellbeing of the subjects must prevail over the benefits to science and society.

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4.2 Systematic Assessment of Risks and Benefits

In most cases it is very difficult to precisely assess a risk and benefit ratio. Because of the lack of a quantitative technique for such assessment, it is necessary to conduct the risk and benefit analysis systematically and reasonably as practical as possible. This can be done in practice by collecting and evaluating the data covering all aspects of the research. Other available alternatives should be considered systematically, which would help to evaluate the research precisely and rigorously.

4.3 Basic Guidelines for Justifying a Research Containing the Minimum Elements:

4.3.1 A demonstrated real need exists to conduct a study in human subjects

4.3.2 Brutal or cruel treatments to subjects are completely unjustified.

4.3.3 Risks are minimized as much as possible, but research objective(s) are still achieved

4.3.4 When research involves a significant risk capable of serious damage, special confirmation is needed in justifying the risk.

4.3.5 When a research is conducted in vulnerable people, the rationale and need should be clearly explained and any and all harm avoided.

4.3.6 The relevant risks and benefits are clearly specified and fully provided in the informed consent form.

4.4 Additional Guidelines for Considering Risks and Benefits of a Research Protocol

4.4.1. An ethics committee needs to assess both risks and benefits. A research protocol should maximize benefits and minimize risks or harm.

4.4.2. A research protocol should demonstrate measures used to reduce risks, including preventive measures and immediate treatment measures once harm occurs to a research participant.

4.4.3. If the benefits do not directly go to the subjects, such as new knowledge, a

rigorous review on the proper and careful design of the research for potential risks is required.

4.4.4. For research conducted in a community, a private sponsor should provide health services to the community, as appropriate. Or in case a clinical drug trial is conducted with the conclusion that the new drugs are more efficacious than or equal to the active control drugs, the sponsors should provide the benefits to the participating subjects in the control group or in all groups by giving them the new drugs for a certain period after the completion of the study. Research conducted to explore a new indication not previously approved in the product leaflet must be done in comparison with the approved drug.

4.4.5 In case the subjects cannot personally give an informed consent to participate in the study, the risk that may happen must be a minimal risk. Otherwise, research with slightly greater than a minimal risk would be acceptable only if the research's objective(s) are important enough, and the research provides only good effects to the participating subjects.

The assessment of risks and benefits will be very useful to the individuals involved in research on human subjects. For the investigator, the assessment helps to check if the research is properly designed. For the ethics committee, it helps to determine if the risks and benefits that may happen to the subjects are justified. And for the research subjects, it helps to decide whether to participate in the research or not.

CHAPTER 5

CONDUCTING RESEARCH ACCORDNG TO THE PRINCIPLE OF JUSTICE

The selection of groups of people of communities for research should be based on a fair distribution of burdens and benefits. Exclusion of any people or communities from any research should be justified.

According to the Thai Dictionary of the Royal Academy of Thailand B.E. 2542, the word "justice" (or *yutti-tham* in the Thai language) is defined as fairness, legitimacy, or reasonably justified, which is a widely known or often referred to definition. In the context of research on human subjects, however, the term "justice" is referred to as distributive justice, which requires that both burdens and benefits entitled to the subject participating in the research be distributed equally. Therefore, the key questions of this principle are 1) who bears the burdens and 2) who receives the benefits from the research. Injustice then occurs when the benefits that one is entitled to receive are denied unreasonably, or when the subjects have to bear burdens unreasonably.

Since the principle focuses on the distribution of the burdens and the benefits to the subjects participating in a research study, the application of this principle in reviewing research on human subjects is clearly made in the process of subject selection. Fairness must serve for the selection of the research participants in both the practical procedures and the outcomes. The justice in the subject selection is considered in two levels i.e., individual and societal.

Regarding the individual justice in the subject selection, the investigator is required to include the subjects based on the criteria with fairness and non-discrimination, i.e., there should be no offering of benefits to a favorite group of people or recruiting those who are not favored into a risky study. The social justice requires that differences must be made among groups of people that should or should not be included into a particular research study. In doing so, the capacities of individuals in the groups or communities who can bear the potential burdens in the study, or the suitability of the individuals to bear further burdens must be considered. Social justice then deals with setting an order or a priority that needs to be considered before enrolling any groups of people into any studies (for example, adult before children, male before female).

Likewise, the principle of distributive justice can also be applied at community and country levels, i.e., that which the community bears the burdens, or which the community takes the benefits must be in accordance with the principle of distributive justice as well. A common problem of injustice occurring at the community level is exemplified in the case of trials for product development of drugs, vaccines or medical devices that are sponsored by companies or organizations in developed countries. The trials are conducted in developing countries, but after the end of the trials, drugs or vaccines or medical devices under the studies cannot be made beneficial to the participating populations or countries. One of the causes is due to the lack of access to those drugs or vaccines because of their high cost, or the lack of disease or illness for such drugs or vaccines in those communities in developing countries occurs. Thus, the principle must be carefully and thoroughly considered to bring justice to all levels from the individual to the society.

However, please be aware that in reviewing research on human subjects based on this principle, deviation from the principle of distributive justice may sometimes happen reasonably as well, but the differences of related factors such as experiences, sex, physical impairment, capacity, and position must be taken into careful and appropriate consideration. This is to serve as criteria for decision making in the case that different treatments are given to individuals, and this consideration should be made on an individual basis.

CHAPTER 6

ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS

A research protocol involving human subjects must be subject to review and approval by an ethics committee for research on human subject before initiating a study. Thus, institutions or organizations with established research protocols or investigators have to appoint and authorize the ethics committee to decide about the research protocol. The institution or organization should establish regulations on the appointment of the ethics committee, the submission of a research protocol for ethical review, the criteria for decision making, and the monitoring of the procedures or the results of ongoing studies.

6.1 Operational Guidelines

6.1.1 The institution or organization with investigators or research studies that involve human subjects should establish its own ethics committee or jointly organize it with other institutions or organization(s). Also, the institution should provide for protection and support for the operation of the ethics committee so that the committee can fulfill its functions fairly, independently, and without any intervention from any parties.

6.1.2 Upon the establishment of the ethics committee, the institution or organization has to determine the committee's scope of responsibilities, relation with the investigators both inside and outside the institution. Also, the mechanism for reporting the summary of the committee's performance and a member's term of holding office should be established.

6.1.3 The institution or organization should provide for the ethics committee adequate resources, including stationery supplies, facilities, clerical personnel, training opportunity, and payment/honorarium (if any) so that it can function efficiently.

6.1.4 The institution or organization (alone or in collaboration with other institutions) should provide for legal liability protection for the ethics committee.

6.1.5 The institution or organization not having its own ethics committee should arrange for a written agreement with other institutions or organizations having their own ethics committees so that the institution can have its personnel to serve as the committee members and share legal and other liabilities, as appropriate.

6.1.6 The institution or organization should appoint the ethics committee by its highest authority. However, the number of the sub-committees under the ethics committee may vary based upon the workload for protocol review so that the committee can function efficiently.

6.1.7 The main function of the ethics committee is to protect the rights and well-being of the research participants, whereas the key role of each member of the committee is to independently decide if the protocols provide for adequate protection of the rights and welfare of the research participants.

6.1.8 The ethics committee should advise the affiliated institution or organization concerning a system for ethical training to be given to the investigators within the institution.

6.1.9 The ethics committee in cooperation with its institution or organization should establish a database of experts, both inside and outside the institution/organization, who can provide their advice on specific issues to the ethics committee. An honorarium paid for the experts should be determined, as appropriate.

6.1.10 The ethics committee should establish the requirements for protocol submission along with the required documents, such as an application form, the number of copies of a research protocol to be submitted, subject’s information sheet, informed consent form, and case report form, and should thoroughly communicate to personnel or staff within the institution.

6.1.11 The institution or organization by the advice of the ethics committee should develop standard operating procedures (SOPs) and revise them at an appropriate time interval.

6.2 Composition of Ethics Committee

6.2.1 The ethics committee should consist of at least five members, both male and female, and with the following qualifications:

(1) At least one member should have knowledge and experience in the current research field(s) regularly reviewed by the committee (e.g., medicine, public health, social science, epidemiology, as appropriate) in order to ensure that the proposed research methodology of the protocol can yield the correct result of the research problem, or is scientifically valid;

(2) At least one member should be a lawyer or endowed with knowledge of law.

(3) At least one member should be independent of the institution or organization, and is an outsider whose current job is not in the field of medicine, science, or law. If possible, that member should be drawn from the community where the institution or organization is located.

(4) At least two members should have knowledge or experience in the current practices of patient care, counseling, or treatment to people (e.g., physician, psychiatrist, social worker, and nurse, as appropriate).

6.2.2 The institution or organization should ensure that at least one third of the total committee members are knowledgeable in research ethics or have ever been undergone training about human research ethics.

6.2.3 The institution or organization should make available a list of the committee members showing names and qualifications, dates of appointment and termination from the office upon the request of the investigators or others.

6.3 Appointment of a Member of an Ethics Committee

6.3.1 The institution or organization should establish the composition of the ethics committee, the term of service of the members, and the criteria for selecting the members of the ethics committee, as appropriate.

6.3.2 Each member must be appointed officially as evidenced by a written document. In addition, the member should have a document that assures legal protection in case of legal liability during the course of duty as an ethics committee member.

6.4 Ethical Review Process

6.4.1 The ethics committee should review the ethical aspects of a research protocol in accordance with current international ethical guidelines taking into account local or national laws, religions, traditions, and cultures.

6.4.2 The institution or organization and the ethics committee should establish the regulations or operating guidelines for committee meetings, such as the frequency of the meetings, announced dates of the meetings, timeframe for protocol review, quorum requirements, decision-making procedures, channels of communicating the decision, complaint process, reviewing fee (if any), protection of confidentiality of the protocols, and prevention of possible conflicts of interests.

6.4.3 In case the ethics committee cannot reach a definite decision on any scientific aspects, the committee may seek for other expert's opinions. However, it must ensure that the experts have no conflicts of interest with the research protocols, and that the experts can maintain the confidentiality of the protocols. Otherwise, the ethics committee may forward the protocols to a scientific committee or an epidemiology committee or to other committees within the institution or organization, asking for their opinions before conducting the ethical review.

6.4.4. The ethics committee may communicate its decision upon the protocol review to the investigators in four categories namely:

(1) approval/favorable opinion;

(2) approval after the investigator amends or modifies the protocol or clarifies points according to the committee's suggestions;

(3) the investigator needs to amend the protocol as suggested by the committee and resubmits it for the next review meeting, or the review is postponed for temporarily;

(4) disapproval/negative opinion.

The ethics committee is required to provide an explanation for its disapproval decisions so that the investigator can clarify and request the committee to review its decision.

6.4.5. The ethics committee should establish a system along with procedures for an expedited review of the research protocols that imposes a minimal risk, or of protocol amendment with no additional risk. The committee should also establish the criteria for what research protocols could fit the expedited review.

6.4.6 The ethics committee should determine the types of protocols that can be conducted with no ethical review submission.

6.4.7 The ethics committee should establish the conditions whereby the informed consent discussion and/or signing a consent form can be waived.

6.4.8 The ethics committee should implement an efficient system for recording minutes and archiving to allow for an audit upon request and receive prior permission from the head of the institution or organization or from a competent authority. The duration for document storage should be in accordance with the applicable regulatory requirements *mutatis mutandis*, but at least for three years.

6.5 Committee Member with a Conflict of Interest

6.5.1 In case one or more members of the committee have a conflict of interest (e.g., being a principal investigator of, or being on a list of investigators of the protocols under review, or being a competitive investigator of similar research areas), those committee members should not participate in the review and approval process. They, however, can provide relevant opinions, and disclose their conflict of interest with the protocols. The committee should respect the rights of the applicant to oppose.

6.6 Review of an Ongoing Research

6.6.1 After the committee has approved the research study, the investigators have to report the progress of the research to the committee at an appropriate interval. For research protocol with high risks, the investigator should report the progress more frequently than a low risk protocol. The applicant should propose to the committee how often he/she will submit a research progress report to the committee from the date of protocol submission for ethical review, but at least once a year.

6.6.2 Upon the termination of the trial protocol for whatever reasons, the investigator should report the summary of the research results to the committee.

6.7 Ethical Review of a Multi-center Trial

6.7.1 A multi-center trial may be referred to as a trial that is conducted in more than one institution or organization by a single or several investigators. It may also be defined as a trial conducted by a group of investigators from different institutions or from jointly collaborating organizations, and as a trial conducted by investigators who later change their original affiliated institution or organization to a new affiliation.

6.7.2 The multi-center protocols submitted to each institution or organization should contain the same details and meaning of the text, and should specify the quality control techniques of the research procedures to ensure that the practices are the same in each institution in order to obtain credible data.

6.7.3 The ethics committee in each institution or organization should be free to decide about the multi-center protocols, the outcome of which may not necessarily be the same as those of the committees in the other institutions. The research protocols should specify what part(s) of the protocol cannot be amended as it may affect the validity of the data and what part(s) can be modified by the committees as it does not affect the data as a whole. However, it is advised that the committee in each institution or organization consult with one another in case of any possible

different opinions about the main principle so as to reach a clearly agreed upon decision. The investigator should amend the protocols' minor details as suggested by the committee in his/her institution.

6.7.4. The ethics committee of each institution or organization may accept entirely the decision made by other institutions or organizations, or accept only the scientific aspect, but request minor amendment for the ethical aspect. This is to facilitate an efficient review and approval of the multi-center protocols.

6.7.5 The investigator should inform the ethics committee where the protocol has been submitted for ethical review as well as the review's outcome.

6.8 Monitoring of a Research

6.8.1 The institution or organization should appoint a committee independent of the ethics committee to monitor the progress of the research.

6.8.2 The purpose of the research monitoring committee is to ensure that the research complies with the proposed procedures specified in the protocol, and that the advice is given to the subject, as appropriate.

6.8.3 The research monitoring committee should establish its own criteria and mechanisms for monitoring the research protocol.

6.9 Termination or Suspension of Research

6.9.1 The ethics committee may withdraw or suspend its approval given to the research so as to protect the rights and welfare of the research participants. This includes when serious adverse effects are reported, or when the conduct of the research does not comply with the protocols approved by the committee.

6.9.2 In case of premature termination of any research protocols made by the investigator, the reasons for the termination must be reported to the ethics committee.

CHAPTER 7

SPECIFIC TYPES OF RESEARCH ON HUMAN SUBJECTS

7.1 CLINICAL DRUG TRIAL

A clinical drug trial is a study of drug on either patients or healthy people in order to study the therapeutic or preventive effects of the drug.

In general, an investigational drug used in clinical trial falls into one of four categories, namely: (1) new drugs; (2) unregistered drugs in Thailand (3) registered drugs by the national drug authority, but being studied in new doses or indications not previously approved; and (4) locally produced drugs which required efficacy testing.

Phases of Clinical Drug Trials

For new drugs, adequate evidence derived from animal studies must be available to ensure safety and determine toxicity levels prior to conducting a study in humans.

A Clinical Drug Trail Can Be Classified in Four Phases.

Phase I

This is a first-in-human trial using a new chemical entity that is usually conducted in healthy volunteers to study acute toxicity that is associated with the dose range of the drug. Because of drug side effects, the study should be conducted in well-equipped facilities in the hospital, and should not be conducted on children, the elderly, or women with childbearing potential. Anesthesia or anticancer drugs should not be used in the healthy volunteers as a result of its high toxicity. In general, the number of the subjects should not exceed 30 subjects. Every subject should give written informed consent before participating in the study. The study in this phase is usually an open study without any control group, i.e., both subjects and investigators know the trial drug. Studies in phase I also involve two stages. Stage I studies employ a small dose, i.e., about 1/50 or 1/100 of the dose used successfully in the animal studies. When the results demonstrate safety, the second stage is then followed by gradually escalating the dose. Once the results are satisfactory, phase II studies are conducted.

Phase I trials also include the studies done on the patients suffering from a specific disease with no hope from currently available treatments, such as studies in terminally ill cancer patients.

Phase II

Phase II studies are conducted on patients with the target treatment of the drug that was satisfactorily studied in Phase I. The primary objective of the trial in this phase is to study short-term pharmacological toxicity in details, while the secondary objective is about the drug's preliminary efficacy. Anesthesia and anticancer drugs are allowed in the Phase II trials. If possible, a trial design should be randomized and be open label. The subjects and investigators may not know whether the drugs received are investigational drugs or comparator drugs. Approximately, 100-200 subjects are employed in Phase II trials. If serious adverse events are reported frequently, the trials should be stopped temporarily. Once the safety is confirmed, a Phase III trial can then be conducted.

Phase III

Phase III studies are conducted in patients with the target treatment using the new chemical entity being tested successfully in Phase II. The primary and secondary objectives are to evaluate the pharmacological effectiveness and to study short-term toxicity, respectively. The number of the subjects in Phase II trials may be considerably increased to several thousands depending on sample size determination using a statistical method in conjunction with the existing preliminary data. Most Phase III trials involve a comparative control group, which is usually the group receiving no investigational new drugs. In the Phase III trials, control procedures are implemented beginning from subject selection, group randomization, treatment allocation, follow up, and evaluation. The trial in this phase is aimed to increase patient survival or to improve

patient quality of life. Then, the trial design should be randomized, double blinded, i.e., both the investigators and the subjects do not know what drugs either investigational or comparative are given. When the drug gives the favorable results under the Phase III trials, they are likely authorized for marketing.

Phase IV

This phase is also called a post marketing surveillance study. The study is done after the drug has been registered, with the objectives being to study the therapeutic uses, any adverse effects, and toxicity of the drug in a larger numbers of patients who have been using the drug for a longer period of time, or to explore additional effectiveness for other indications other than the approved ones. Also, the study in this phase can be done in other population groups that have never been studied.

Ethical Considerations on Each Phase of the Clinical Drug Trial

7.1.1 Phase I Clinical Trials

(1) The ethics committee should be independent of the trial sponsor, conduct a rigorous review of a research protocol, and continuously monitor the trial.

(2) As the trial in this phase is conducted in healthy subjects where the sponsor of new drugs pay for the study, the ethical review should focus on the following aspects:

a. the subject sample selection;
b. a freely given informed consent process;
c. the meaning of the message in the consent form;
d. the qualifications of the committee's members and performance of the ethics committee;
e. applicable regulatory requirements (if any).

(3) Specific ethical considerations are needed for the review of the drug trial conducted in patients suffering from an illness with no hope from currently available treatments. As the conduct of the trial under this situation may distort the awareness of the patients, the family, and the investigator in weighing the risks and benefits of the trial, and may affect the freely given informed consent and the termination or the withdrawal criteria, therefore, both the investigator and the ethics committee should co-operate and consult each other throughout the course of the trial.

7.1.2 Phase II and Phase III Clinical Trials

Generally, the trials in these phases involve the use of a placebo in the control group. Placebos should not be used in a control group if standard treatments are available because the subjects will lose medical benefits from participating in the trial. In addition to a focus on the freely informed consent process, ethical considerations in a placebo-controlled trial should pay attention to an appropriate design so as to maximize the benefits and minimize harms to patients.

7.1.3 Phase IV

The trial in this phase is usually conducted in the private practice of physicians who use the drugs already available on the market. Frequently, the sponsor pays the investigator based on the number of patients recruited in order to study the side effects of drugs and to build acceptance in using the drugs among patients and other physicians. This case may impose an obligation to the investigator. Therefore, the investigator and the ethics committee should consider appropriate benefits and payment to be given to the subjects for their participation.

7.1.4 Clinical Trial of Medical Equipment

A clinical trial using a medical device for human use, either invasive or non

invasive, requires similar ethical considerations as clinical drug trials in four phases, in particular the medical device that is to be inserted into the body. In such a case, a specific consideration is required depending on the types of devices. For example, the conduct of a trial using a cardiac pace maker, which is a very expensive device, requires surgery to evaluate its safety and effectiveness. Considerations are also extended to the costs of the surgery and of a patent license requested by the device's manufacturer.

Slight differences between the clinical trials of drugs and devices can be noted. The ethics committee should pay attention to the differences as well, such as

(1) A medical device for human use may not be tested previously in animal models such as retractors because of different human and animal anatomies.

(2) Certain types of medical devices should not be studied in healthy human subjects because the research procedures and/or the use of the device may impose extremely high risks and harm, but create no benefits to the subjects. For example, the trials using artificial joints, artificial cardiac valves, or a cardiac pace maker.

(3) The clinical trial of a new drug is not regarded as a trial with a minimal risk because the mechanism of action may not be clear. As a result, it is impossible to predict possible side effects. On the contrary, the trial using an external medical device, which is known for its mechanism of action, allows us to predict the possible side effects. The trial can be regarded as imposing a minimal risk. Details will be discussed later.

(4) A comparative study using a medical device and a placebo or other comparators to evaluate the effectiveness or efficiency of the treatments may not be conducted because ethical justification if the use of that device is the only opportunity for the subject to obtain benefit from the treatment, such as surgery to insert the artificial joint to replace irreversibly impaired joints.

In general, a sham surgery in the comparator group is regarded as ethically inappropriate as it can greatly impose risks and harm to the subjects, while it provides no benefits. The sham surgery, however, used in the clinical trial of a medical device may be conducted under certain circumstances of extreme necessity, provided that the risks must be minimized as much as possible and the subject must be given full and correct information before freely deciding to participate in the trial.

As mentioned above, in several cases, a medical device that has clear mechanisms of action may be designed by the physician who directly takes care of the patient. In addition a device available on the market may be altered or further developed and used in the treatment for patients unable to access other available treatments. The investigator or the sponsor of this type of trial may get less financial support than that from drug companies in the case of a clinical drug trial. Hence, the design of a clinical study of a medical device to prove its effectiveness, efficiency and safety may be an observational study instead of a randomized controlled trial, which is the standard for a clinical trial of new drugs. The observational study allows for collecting the data completely and completing the follow-up for all patients for a sufficiently long time. This is demonstrated by the study of artificial joints and cardiac valves that are widely recognized.

Systematic consideration of research using a medical device may start from the division of the devices into two categories, i.e., devices with minimal risk or non-significant risk and devices with significant risk, by considering the general characteristics and the use of the devices.

Medical devices with significant risks are referred to as devices that

- risk death upon usage;
- risk permanent disability upon usage;
- require a surgery or certain drugs to prevent death and/or disability that may be caused by that device.

The risks related to the use of the devices also include the risks that are caused by the procedures and techniques used, for example, the risk caused by a surgery and general anesthesia used in the process of inserting the devices into the body.

If the device to be used in research is similar to or has been used under the approved indications as that of the device available on the market, the advantages and disadvantages of the device to be studied in comparison with the available device should be considered.

For example, the conduct of a trial using an electrical pacemaker, despite its high risk, inserted into the patient's body which contains the property and usage not significantly different from those of the available device on the market may be ethically acceptable according to the principle of beneficence (see list of devices with classified risks in the annex).

Deciding which type of risk the trial of a medical device or the device itself falls into is the responsibility of the ethics committee. If the committee decides that the trial and the device used impose a minimal risk, the trial of the device should pass ethical clearance according to the principle of beneficence.

However, if the committee decides that the clinical trial of a device imposes a high risk, comparison should be made with similar devices available on the market. Just as exemplified previously, if the device to be used in the trial is greatly different from the devices on the market, the trial should be reviewed according to the general ethical principles applied in clinical trials taking into account the specific characteristics of the trial of medical devices explained earlier.

Finally, the investigator and the subject should always realize that devices inserted into the human body undergo failure both in short and long term. The failure of the device may result in damage, even death. When such a risk exists, the investigator is responsible for objectively reporting the event to the sponsor, the ethics committee and the subjects.

7.1.5 Research Budget

The ethics committee should review the research budget to ensure that the issue of benefits has been taken into account. In general, the sponsor will pay the investigator based on the number of subjects. Payment calculated based on the number of recruited subjects is an ethical issue, because it is possible that the investigator has conflicting thoughts between the payment to be received and the beneficial and appropriate health service to be given to the subject. This is the case in particular when the patient or the subject trusts the investigator.

Research conducted in public hospitals or public health care facilities involve expenditures to cover such as laboratory tests, and lump sum fees determined by the institution. The disclosure of the payment and the other budget items helps the ethics committee to evaluate any conflict of interest, and helps the investigator to decide whether to conduct the trial.

7.1.6 Placebo-Controlled Trial

It is generally unacceptable to use a placebo in a control group in a trial where standard treatments or medically proven medicines are available, because patients will lose medical benefits entitled to from participating in the clinical trial. However, the use of a placebo in a control group may be allowed in the following cases.

(1) no standard drug medically recognized for the treatment of the disease is available;
(2) the available drug for the treatment yields uncertain outcomes;
(3) the standard drug for the treatment is available, but it causes serious adverse drug reactions or adverse events that the subjects cannot tolerate;
(4) the illness to be studied is managed by itself due to a placebo effect;

(5) the disease to be studied is a minor condition and treating with a placebo causes the only discomfort or the illness is alleviated slowly or negligibly, and causes no serious or irreversible harm to the subjects;

(6) compelling scientific and methodological reasons are necessary to use a placebo-controlled group in determining the effectiveness and the safety of a study drug.

In addition to the focus on freely informed consent, the ethical consideration of a placebo-controlled trial should focus on an appropriate design to maximize benefits and minimize harm to patients.

7.1.7 Analysis and Distribution of Research Results

In most clinical trials, the sponsor has rights as agreed upon for the analysis and interpretation of research results. However, the investigator and the ethics committee should ensure that:

(1) The final analysis and interpretation of the research results will rest with the investigator to ensure that the results would be actually complete and accurate.

(2) When the trial of Phase I, II and III is required to stop according to the rules, there must be an independent interim analysis. However, prior to implementing the termination rules, it should be identified that either positive or negative long-term effects of the drug may be obscured by either good or bad short term drug effects.

(3) The main responsibility of the investigator is to circulate the research findings to the community of investigators. However, it is found that frequently the research results of several trials, in particular the negative results, are not published or distributed. Not only does the case create an inappropriate scientific conduct and produce no actual research results, but also the research results and the resources invested in the research become in vain.

7.2 EPIDEMIOLOGICAL RESEARCH

Epidemiological research is an integral part of public health or health service research, which is necessary for the prevention of and the control of diseases or for improving the efficiency and the performance of a health care system. This leads to the improved health of the population. Certain epidemiological research may be required to study in a large population, and thus a multi-center study is needed.

The epidemiological research is different from other types of research in that it involves the use and the keeping of medical information and the tissue samples of patients or populations. Then, an ethical consideration is needed for the use of the data or the tissues regardless of whether the data or the tissues would be stored for the purpose of the treatment.

Types of Personal Information

Epidemiological research involves the use of the following types of data.

a. identified data, which are referred to as, for example, name, date of birth, or address, including such a minor details as a zip code that may be used as an identifier;

b. potentially identifiable, coded, re-identifiable data, which are referred to as the data of the identifier, which has been removed and replaced by a new code that can re-identify the individuals. They are then regarded as “identifiable data.”

c. de-identified, not re-identifiable, anonymous data, which are referred to as the data that have been permanently removed from their identifiers, and as a consequence, the data cannot identify any individuals if the existing identifiers are permanently destroyed or the data are collected without any identifiers.

7.2.1 It is required that all epidemiological research be reviewed by an ethics committee, based on international ethical guidelines. In the epidemiological study that needs to use identified or identifiable data, the individual informed

consent from each subject for his/her participation should be obtained. The ethics committee should ensure that:

(1) the research is conducted according to the applicable policy / laws / regulations related to the personal rights, the privacy, and the disclosure of information, etc.
(2) searching for medical records or other records or patients' reports for research purposes should be restricted to only the investigators knowledgeable in the relevant fields or to the attending physicians. However, research assistants may be allowed when many records are searched.

7.2.2 The ethics committee may approve the search for identified or identifiable data from the records if the following criteria are fulfilled.
(1) the informed consent process possibly causes excessive worries to the subjects or reduces the scientific value of the research, whereas the subjects or the relatives or the involved communities do not gain any benefit or the informed consent cannot practically be obtained;
(2) the research is conducted by the attending physician of the patients, and the risks are minimal, and the research does not involve any abnormality of the genetics;
(3) the public benefit is of high degree for the proposed research topic;
(4) the informed consent process possibly causes excessive worries to the subjects or reduces the scientific value of the research, whereas the subjects, the relatives or the involved communities do not gain any benefits or the informed consent cannot practically be obtained because of too many or outdated medical records, or it is difficult to contact for the informed consent; or
(5) the public interests from the research prevail over the private interests

7.2.3 When the ethics committee allows the use of coded identifiable data, it should be decided whether a third party should hold the code.
7.2.4 When the research is conducted in a community, it should be guaranteed that the conduct complies completely with the requirements on the research in the community.
7.2.5 When identified or the re-identifiable data are used in research, the ethics committee should ensure that the collection, handling, and storage of the data comply with the principle of rights of personal information. If the data are to be used for purposes other than those specified in the approved protocol, a new protocol should be submitted for ethical review.
7.2.6 If the research involves the linkage of a set of data, the ethics committee may approve the use of the identifier to assure correct linkage. When the linkage is finished, the ethics committee should require that the emerging data be coded or the identifier be removed.
7.2.7 If the identified or identifiable data are used for other purposes in the research or by other people other than those listed in the previously approved protocol, a new protocol needs to be submitted for ethical review.
7.2.8 The information derived from epidemiological research both short- and long-term should be securely kept from the access of unauthorized people.
7.2.9. When screening the data for the statistical analysis and concluding, the investigator should maintain the confidentiality of the research participants.
7.2.10 The research results should not be published in a manner that can identify the individuals participating in the research and can affect the culture or other sensitivities.
7.2.11 If the emerging new knowledge during the course of the research has clinical implications or indicates the adjustment of the current treatment, the new knowledge should be disclosed to the relevant competent authority. If possible, both the research participants and the attending physician should be informed

as well.

7.3 SOCIAL SCIENCE RESEARCH

Similarly, the ethical principles applied in social science research consist of the principles of respect for person, beneficence, and justice.

7.3.1 The investigator should protect each subject from any physical or mental harm.

7.3.2 The investigator should respect the faith, belief, culture, religion, and basic rights of the subject.

7.3.3 The investigator should conduct only the research that benefits mankind.

7.3.4 The investigator should ensure that the design of the study is suitable to the objectives of the study.

7.3.5 The investigator should fully inform the subjects so that they can freely decide whether to participate in the research.

7.3.6 The investigator should protect the confidentiality and undisclosed names of the subjects.

7.3.7 The investigator should provide for health care to the subject as much as possible.

7.3.8 If the inclusion criteria are sensitive issues, the investigator should carefully conduct the study to avoid the disclosure of the subjects' identity. The investigators may sometimes conduct the study in a non-targeted population to prevent the members of the community from being aware of what is conducted.

7.3.9 In case the study is conducted using medical records consisting of the confidentiality of patients, only the authorized medical personnel are allowed to access the data in the records, which can identify the patients. The access should be permitted by the highest authority of the institution.

7.3.10 The investigator should provide appropriate payment, benefits, or privileges to the subjects, and ensure that it should not be too much to induce the subjects to participate in the study.

7.4 VACCINE TRIAL

The guidelines for conducting clinical drug trials are also applied to vaccine trials. However, the phase of the vaccine study may have additional details as explained below.

7.4.1 Phase I: This is a first-in-human trial to study the safety and biological effects, in particular the immunogenicity of a vaccine. Doses and routes of administration will be studied in this phase, and the trial is conducted in a low risk population.

7.4.2 Phase II: The trial is conducted in a limited number of patients to firstly explore the efficacy of a vaccine. The vaccine trial also serves for preventive purposes. Therefore, the trial involving a preventive vaccine must be conducted in healthy volunteers, while the trial involving a treatment vaccine is done in the patients of targeted disease.

7.4.3 Phase III: The trial in this phase focuses on the effectiveness of a vaccine for disease prevention. More subjects are then needed for the study in this phase (a thousand subjects and up). The trial is usually a multi-center trial, including a control group.

7.4.4 Precautions in a vaccine trial where the vaccines are produced from live-attenuated microorganisms should be exercised as the vaccines may cause infection in the subjects, despite its low possibility. Therefore, it is essential to inform the potential subjects in advance about the risk.The subjects in the control group not receiving the real vaccine must also be protected from the disease or be informed that they have a chance to contact the disease from the experimental subject group.

7.4.5 In case of a trial using a recombinant DNA vaccine, the adverse effects of which are not yet clear, the investigator has to strictly follow the regulations of the Ministry of Public Health.

7.5 USE OF HUMAN TISSUE SAMPLES

Human tissue samples mean anything being taken out or excreted from a human body or a corpse. The tissue samples also include other tissues, blood, secretions, and excretions from all organ systems. The objective of using the tissue samples is for the diagnosis of a disease or for other purposes.

The human tissue samples may be obtained by one of the following means.

a. taken directly from the body of the subject for research use where the donors of the tissues give their informed consent;

b. taken from the body for treatment, diagnosis, or other objectives (e.g., learning and teaching, organ donation for transplantation;

c. taken from either of the aforementioned sources above, and kept under the applicable regulatory requirements, institutional regulations or by the subject's approval. In this case, the donors of the tissue samples usually do not know the objectives of the use of the samples of future research.

In a research protocol that uses human tissue samples, the ethics committee should review it according to the international ethical guidelines at least those as described below.

7.5.1 Prospective studies

The investigator should follow the guidelines below.

(1) obtain the written informed consent to use the samples from the donor, giver of the tissue samples or from the legal owner of the corpse;

(2) provide detailed information to the donor, giver of the tissue samples or legal owner of the corpse about the objectives of the use of the samples in research or the overall research plan. The information sheet should specify the possibility or the plan to use the samples for future research, storage duration of the samples, and the rights of the subject to request for destruction of the samples when the research is complete;

(3) collect the samples from the body of the owner by a specialist with correct and appropriate medical practice;

(4) utilize the techniques and systems for the storage of the tissue samples that are appropriate and secured from access by unauthorized persons;

(5) use the appropriate data recording, storing, and retrieving systems that ensure protection of the confidentiality of the owner of the tissue samples;

(6) appoint a personnel staff responsible for the handling and storage of the tissue samples;

(7) The institution or organization that allows the use of human tissue samples for research purposes should lay down the guidelines for the conduct of the research using the tissue samples and for the ethnical review and approval of the research protocols. The guidelines should be in compliance with the applicable laws and regulations, and the institutional ethical guidelines should provide detailed procedures and possible conditions for the use of the tissue samples in the research. The guidelines will be used for the investigator to follow when asking for the subject's donation of the tissue samples used in the research, and for the ethics committee to review the protocols taking into

consideration international ethical principles, i.e., respect for persons, beneficence, and justice;

(8) A material transfer agreement should be made in case the tissue samples are transferred to other institutions to ensure consistency with the principle of respect for persons.

7.5.2 Retrospective Studies Using Stored Human Tissue Samples

(1) The institution and the ethics committee should established the rules and regulations that determine what circumstances the investigator can waive the informed consent from the owner of the tissue samples so as to use the stored samples for research;

(2) Whenever a physician has received a human tissue sample for purposes of the treatment or diagnosis of the patient's disease, the physician should make the best attempt to maintain the confidentiality of the patient. When research is conducted using stored tissue samples, searching for the patients or the patients' information should be done as little as possible and only as necessary for achieving the research objectives only.

(3) If the results of the research may affect the health of patients, the ethics committee may require the investigator to search for the patients and contact them for treatment or follow-up;

(4) Under certain situations, the ethics committee may agree for the waiver of the informed consent from the tissue owners in using the stored tissue samples for the research by taking into considerations:

a. the modes of obtaining the tissue samples (e.g., from pathology storage, blood bank);
b. the scope and content of the informed consent given previously by the owner of the samples (if any);
c. the reasons behind the waiver of the informed consent by the investigator, including difficulty of obtaining the informed consent;
d. the possibility that the process of obtaining the informed consent may violate the privacy of the owners of the tissues, or cause damages to the physical and/or mental health of the donor or to the donor's social status;
e. the proposal to protect the privacy and confidentiality of the tissue owners;
f. the risk that may happen is a minimal risk;
g. the relationship between the previously approved protocols and the new protocols;
h. the potential commercial benefits or intellectual property;
i. the regulatory requirements.

(5) A material transfer agreement should be made in case the tissue samples are transferred to other institutions to ensure the consistency with the principle of respect for persons.

7.6 HUMAN GENETIC RESEARCH

Human genetic research is the study of genes and their interactions with the surrounding factors that affect the health of individuals and populations. Not only does the research enlarge the body of knowledge that impacts the individual's health, but it may also affects the health of the individuals and their families in the future, which paves the way for protection from genetic diseases.

Regarding the ethics in human genetic research, some additional elements are needed to be considered apart from those applied for other research involving human subjects because of the specific nature of this type of research. For example, the co-operation of the subjects and their families is very much needed for genetic research, and the data or the research results collected from one family may not only benefit those who participate in the research, but also those who do not directly join the research, but are the relatives of the subjects involved in the research.

Therefore, in certain situations, those relatives have to be informed of the data collected from the other related groups for the benefit of their own families' health care, such as a married couple who pays attention to the health of their unborn baby.

In addition, the information generated by the results of the human genetic research may directly impact the subjects, e.g., causing social stigma or discrimination. Therefore, the investigator should be aware of these potential impacts, and should have measures for solving problems that may arise. The procedures for strictly protecting the subject's privacy and the confidentiality of the data should be implemented.

Generally, researchers should be aware of the following important considerations when conducting human genetic research.

7.6.1 Individuals, Families, and Biological Relatives:

(1) The investigator should provide the information and obtain the individual informed consent from relevant people.

(2) The outcomes of the research are to be disclosed to appropriate persons free of charge (appropriate persons mean the research participants who inform in advance that they need to know the results).

(3) Human genetic researches is often conducted in groups of families or in communities that are related to one another, e.g., the study of a family tree or history or the linkage study on the same chromosome. In case that the study causes a conflict between family members, the investigator must take responsibility for solving the problem by communicating and informing correctly and honestly the information regarding the purposes, benefits, and disadvantages of the research to the families in question.

7.6.2 Privacy, Confidentiality, Loss of Benefits, and Risks

(1) The investigator and the ethics committee should ensure that the confidentiality and the results of the genetic research be securely kept from unauthorized access by a third party, such as employer or insurance companies.

(2) The investigator studying about the family's or population's genetics should review the scope of possible physical and mental impact that may happen to the relevant persons, and demonstrate those to the ethics committee.

7.6.3 Genetic Counseling

The investigator and the ethics committee should ensure that the research protocols provide correct and appropriate genetic counseling for the potential subjects.

7.6.4 Genetic Alterations

A genetic alteration of a human embryonic cell or a human gamete is regarded as a violation of research ethics. The research study on gene alteration then must not be approved, except for gene therapy that may need to be considered on a case by case basis to receive ethical approval for the research.

7.6.5 Eugenic Concern

The objectives of the human genetic research are related to improved knowledge and understanding of genetic diseases that may affect human health only, including health care, and not for eugenic purposes. Additionally, attention must be paid to the subjects' free decision making on the problems that may arise, in particular, for the married couple who needs to make a decision after being informed about a risk imposed upon the intrauterine fetus to develop a disease. The investigator should provide moral support for the married couple who decides to carry on the pregnancy after they are aware that the fetus would develop a disease.

7.6.6 Banking of Genetic Materials

Although establishing a bank for collecting genetic materials is expected to be of benefit in the future, it may impose risks to individuals who are the owners of
the genetic materials and their families. Therefore, the following guidelines are recommended.

(1) The investigator involved the storage of the genetic materials in the bank should demonstrate to the ethics committee and to the subjects the operating procedures used for keeping confidentiality, privacy, and retention of the materials as well the data and the research results.

(2) The duration of storing the genetics materials should be specified, including the operating procedures for the destruction of the materials upon completing the storage time.

(3) The duration of storing the genetics materials should be specified, including the operating procedures for the destruction of the materials upon completing storage time. Uses of the materials for purposes other than those specified in the approved protocol should receive informed consent from the research participants or their heirs. Furthermore, their families are able to contact for the data or for the withdrawal from the research at anytime without any conditions.

7.6.7 Commercial use of genetic data

The investigator must specify the commercial benefits that may be derived from the results or the data of the research using human genetics in research protocols to create further awareness in the ethics committee and the subjects.

7.7 RESEARCH ON HUMAN GAMETES, EMBRYO, EMBRYONIC STEM CELL, AND THE FETUS

Research using advanced reproductive heath technology influence the practices of research ethics, researcher's ethics, and people at large. The regulations issued by the Medical Council, by the advice of the Royal College of Obstetrics and Gynecology of Thailand, have already laid down the medical practice guidelines on the standards of services concerning reproduction technology. In addition, in conducting research involving human gametes, embryos, and the fetus, the risks imposed to the embryo or fetus, the informed consent, and the respect for the rights of the embryo and fetus should be considered. The following criteria are recommended.

7.7.1 Research involving human gametes

(1) Obtaining the informed consent from the owners of the gametes is required in research using human gametes, which follows the principles and practices applied in other research involving human subjects.

(2) The collection of the human gametes from a deceased person is not allowed, as the informed consent from the donor of the gametes cannot be obtained. Any research conducted using commercialized gametes, or
inducing artificial cross-fertilization between the human gamete and an animal gamete, is considered unethical.

7.7.2 Research on human embryos and embryonic stem cells

(1) The fertilization of human gamete results in an embryo, and it is unethical to create human embryos merely for research purposes. However, if the research is conducted for the benefit of reproductive health according to the principles and practices mentioned previously, it would be considered ethical.

(2) Research on the alteration of human genes or the internal compositions of the human gametes or in the human embryo must not be conducted. When the

research using an embryo is conducted, and no information about the future problem being likely to happen to the fetus is available, the embryo must not be implanted in the uterus to induce pregnancy. The experiment on the human embryo is allowed within the period of fourteen days after its fertilization.

(3) A human cloning research for reproduction is not approved. Also, induced cross-fertilization between the human gamete and an animal gamete is unethical.

7.7.3 Research involving the intrauterine fetus

Research designed for the diagnosis or treatment of the intrauterine fetus that suffers from genetic diseases or congenital anomaly could be conducted if the mother has given her consent after being thoroughly informed about the treatment in detail, since the diagnosis or treatment of the fetus cannot be done separately from that of the mother, and both need to be treated simultaneously.

7.7.4 Research involving the use of fetal tissues, placenta and its blood

Research that uses fetal tissues must be conducted in accordance with the ethical principles as applied in other human experimentation. The fetus is a human, not merely tissues. Therefore, obtaining the informed consent from the parents, who are considered the legally acceptable representatives of the tissues, is required.

The conduct of research using fetal tissues to generate stem cells must adhere to the practice guidelines established in the Medical Council's Regulation on the Preservation of the Ethics of Medical Profession (NO. 6) B.E. 2545, Section 9 on the Medical Practice of Blood Stem Cell Transplantation from Donors.

ANNEXES

ANNEX 1

THE MEDICAL COUNCIL'S REGULATION ON RESEARCH STUDIES AND EXPERIMENTS IN HUMAN SUBJECTS B.E. 2525

1. **"Research study and experiment in human subjects"** refers to a research study and an experiment using a pharmaceutical product or medical devices, or a study of a natural course of a disease, or the diagnosis, treatment, health promotion, and prevention of a disease which is conducted in human subjects. This also includes a research study conducted using the information from medical records and any specimens taken from the human body.

"Ethics Committee" refers to a committee or board appointed by an institution, organization, or agency, which is responsible for conducting an ethical review of researches and experiments in human subjects. This is to protect the rights, safety, and well being of the subjects who participate in the research and experiments.

"Ethical Guidelines for Research Studies and Experiments in Human Subjects" refer to ethical guidelines or ethical principles for research and experiments in human subjects, such as the Declaration of Helsinki and any ethical guidelines for a research study in human subjects established by an institution.

"Ethics for Researchers," refers to the Ethical Guidelines of the National Research Council of Thailand.

2. Medical practitioners who conduct research or experiment in human subjects must obtain informed consent from potential subjects, and ready to protect the subjects from any harm that occurs from the experiment.

3. Medical practitioners must treat the subjects in the same manner that they treat a patient during the course of the medical practice as applied *mutatis mutandis* by Section 3 of the Council's Regulations.

4. Medical practitioners must be responsible for the dangers and damage that happen to the subjects in the experiment and such dangers or damage are not due to the subjects' mistakes.

5. Medical practitioners who conduct or participate in research studies or experiments in human subjects can initiate the research studies only if the research or experimental proposals have been reviewed and approved by an ethics committee.

6. Medical practitioners who conduct or participate in research studies or experiments in human subjects must adhere to the **Ethical Guidelines for Research Studies and Experiments in Human Subjects and the Ethics for Researchers.**

ANNEX 2

THE MEDICAL COUNCIL'S REGULATION ON THE PRESERVATION OF THE ETHICS OF MEDICAL PROFESSION B.E. 2545

By virtue of Section 21 (3) (๑) and with the approval of the Special Council of Chairman according to Section 25 of the Medical Profession Act BE 2525, which contains some provisions that restrict the rights and freedom of individuals, however, Sections 29 and 50 of the Constitution of the Kingdom of Thailand allow the act according to the provisions of the Act. The Medical Council Committee hereby issues the regulation as follows.

1. This regulation shall be called, "the Medical Council's Regulation on the Preservation of the Ethics of Medical Profession (No.6) B.E. 2545"

2. The following statements shall be added as Section 9 of the Medical Council's Regulation on the Preservation of the Ethics of Medical Profession B.E. 2526.

"Section 9"
Medical Practice involving Blood Stem Cell Transplantation from Donors

1. In this Section

"Blood Stem Cell Transplantation" means the medical practice that involves blood stem cell transplantation from bone marrow, blood, or placenta's blood.

"Donors" mean an individual who donates blood stem cells or placenta's blood for the blood stem cells transplantation to other people.

2. Medical practitioners who conduct the blood stem cell transplantation shall have the following qualifications.

(1) being a hematologist or hematological pediatrician who has received a certificate or diploma from the Medical Council; or
(2) being either an internist or a pediatrician who has been trained in a blood stem cell transplantation course approved by the Medical Council.

3. Medical practitioners who conduct the blood stem cell transplantation shall have additional qualifications apart from those described in 2 if the donors and the recipients of the stem cells are unrelated donors.

(1) having experience in the bone marrow transplantation not less than 2 years; and
(2) having been certified by the Subcommittee on Blood Stem Cell Transplantation

4. There shall be a Subcommittee on Blood Stem Cell Transplantation consisting of one representative from the Bone Marrow Transplantation Association of Thailand, one representative from the Hematology Association of Thailand, one representative from the National Blood Center, Thai Red Cross Society, and a total of at least four but not more than five representatives from institutes experienced in bone marrow transplantation with one representative being from each institute, and two members from the Medical Council.

The Subcommittee in the first paragraph shall have the following authorities.

(1) certify the medical practitioners according to 3.
(2) revoke the certification in case the medical practitioners are not qualified or do not comply with the criteria established under this Section

5. The Subcommittee on Blood Stem Cell Transplantation shall grant the certification of the medical practice described in 3 according to the following criteria.

(1) the medical practice is done in a clinic where the number of patients under the bone marrow transplantation from brothers and/or sisters with the same HLA not less than ten patients annually;

(2) the medical practice is done in clinics which have the following qualifications

2.1 having other medical specialists, e.g.;

(a) pediatrics and /or internists in cardiology, infectious disease, gastrointestinal disease, kidney disease, and pulmonary disease;

(b) surgery;

(c) blood bank

2.2 having permanent nurses at the bone marrow transplantation ward at the proportion between nurses and patients not less than 1:3

2.3 other components

(a) having a separate room for the treatment of patients with low white blood cells

(b) having an intensive care unit

(c) being able to provide laboratory testing and radiology for 24 hours

(d) being able to provide blood and blood component infusion for 24 hours

6. In case the bone marrow or blood stem cell transplantation is to be done where the donors and the recipients are not biological relatives, the National Blood Service Center, Thai Red Cross Society, shall make a donor registration list by establishing the National Stem Cell Donor Program under the supervision of the Medical Council.

7. In blood stem cell transplantation, the medical practitioners who conduct the transplantation shall comply with the following criteria.

(1) conduct a physical examination of the donor to check if he/she is healthy, and suitable for donating blood stem cells

(2) inform and explain to the donors the possible risks to harm that may occur to the donors both during and after the donation. Once the donors understand and are willing to donate the stem cells, then the donors sign an informed consent form for donating the blood stem cells. The written informed consent form is attached to this regulation.

In case the blood stem cell transplantation is done using the blood from the unbiblical cord, the donor or her husband shall sign the informed consent form.

(3) written document shall be made to show that no payment is given to the donors of blood stem cells.

8. The medical practitioners who transplant the blood stem cells can store the blood stem cells in the laboratory for future transplantation, as appropriate.

3. This regulation shall come into force when the period of 60 days after the publication date in the Government Gazette has lapsed.

It is hereby announced.

Given on the Thirtieth Day of April B.E. 2545.

Somsak Lohlaekha, M.D.
Chairman, Medical Council

ANNEX 3

THE MEDICAL COUNCIL'S ANNOUCEMENT NO. 21/2545 ON THE STANDARDS OF SERVICES INVOLVING REPRODUCTION TECHNOLOGY (NO.2)

As the Medical Council had issued the announcement no. 1/2540 dated 22 October B.E. 2540 on establishing the standards of services involving reproduction technology by medical practitioners, it is now time to additionally establish the standards of services to provide for more appropriate protection to service receivers.

By virtue of Section 21(1) of the Medical Profession Act B.E. 2525 where the Act contains certain provisions that restrict the rights and freedom of individuals, however, Sections 29 and 50 of the Constitution of the Kingdom of Thailand allow for the act according to the provisions of the Act. The Medical Council then reached its resolution at the 10/2545 meeting dated 11 October B.E. 2545 to issue the announcement as follows.

1. The following statements shall be added as no. 4/1 and no. 4/2 of the Medical Council's Announcement No. 1/2540 on Standards of Services involving Reproduction Technology dated 22 October 2540 as follows.

"No. 4/1 The services involving reproduction technology shall not be conducted in a way of human cloning for reproduction.

No. 4/2 Medical practitioners who are responsible for the services according to (3), or are the providers of the services involving the reproduction technology shall maintain the standard of services that involve the donation of male or female gametes or an embryo to be employed in a reproductive process as follows.

(1) In the case a married couple would like to have a baby by having the wife to carry out pregnancy, the medical practitioner may provide the services
   (a) using the donor's gamete for fertilization either *in vivo* or *in vitro*;
   (b) requesting for donation of an embryo for pregnancy

(2) In the case a married couple who wishes to have a baby by having another woman who is not the wife to carry out the pregnancy instead, the medical practitioner shall provide for the services by using only the embryo derived from the fertilization of the gametes of the married couple.

(3) Providing the services in (1) and (2) shall adhere to the following conditions.
   (a) no payment is given to the donor of the gamete in a manner that can be mistaken as selling-buying;
   (b) no payment is given to the other woman who carries out the pregnancy instead that may be misunderstood as hired pregnancy;
   (c) the woman who carries out the pregnancy instead must be a biological relative of the couple either the husband or the wife;
   (d) Pre-implantation genetic diagnosis of an embryo shall be conducted only for diagnosis purposes, as necessary and as appropriate. Such a conduct shall not be made in a way that may be understood as gender selection, and a written informed consent shall be obtained according to the form attached to this regulation.

(4) For any services other than the standards established in (1), (2), and (3), the medical practitioners who are responsible for, or are the service providers shall obtain an approval from the Royal College of Obstetrics and Gynecology of Thailand prior to providing all the services."

2. This announcement shall come into force since the date next to the publication date in the Royal Gazette.

It is hereby announced.

Given on the Twentieth Day of June B.E. 2545.

(Somsak Lohlaekha, M.D.)
Chairman, Medical Council

ANNEX 4

THE ETHICAL GUIDELINES FOR RESEARCHERS, THE OFFICE OF NATIONAL RESEARCH COUNCIL OF THAILAND

The Office of National Research Council of Thailand has established the following ethical guidelines for researchers.

1. Researchers must be honest and hold moral responsibility in both science and management.

2. Researchers must be aware of the obligation for the conduct of research as agreed with a sponsoring agency and their affiliated institution.

3. Researchers must be knowledgeable in the field of their research.

4. Researchers must be responsible for the subjects used in studies, either living or non-living things.

5. Researchers must pay respect to the dignity and rights of human subjects participating in a research.

6. Researchers must hold freedom of thought without any bias throughout all stages of research.

7. Researchers should utilize their research results in an appropriate manner.

8. Researchers should respect the scientific opinions of other researchers.

9. Researchers should be responsible for society at all levels.

ANNEX 5

ROLES AND RESPONSIBILITIES OF SPONSOR[1]

1. Quality Assurance and Quality Control

1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

1.4 Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.

2. Contract Research Organization (CRO)

2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

2.2 Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.

2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.

2.4 All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial related duties and functions of a sponsor.

3. Medical Expertise

The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.

4. Trial Design

4.1 The sponsor should utilize qualified individuals (e.g. biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports.

4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s) (see 6.), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol and conduct.

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* This part is adopted from the Chapter on Sponsor of the ICH GCP Guidelines, as the Thai version is directly translated from the ICH GCP Guidelines. Re-translating the Thai version back to the English language may cause slight deviation from the original meaning. Therefore, adopting the original English version is made to best preserve the accuracy of the text.

5. Trial Management, Data Handling, and Record Keeping

5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

5.2 The sponsor may consider establishing an independent data-monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings.

5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

(a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).

(b) Maintains SOPs for using these systems.

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).

(d) Maintain a security system that prevents unauthorized access to the data.

(e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3).

(f) Maintain adequate backup of the data.

(g) Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).

5.4 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.

5.5 The sponsor should use an unambiguous subject identification code (see 1.58) that allows identification of all the data reported for each subject.

5.6 The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial (see 8. Essential Documents for the Conduct of a Clinical Trial).

5.7 The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).

5.8 If the sponsor discontinues the clinical development of an investigational product (i.e., for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least two years after formal discontinuation or in conformance with the applicable regulatory requirement(s).

5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the regulatory authorities.

5.10 Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s).

5.11 The sponsor specific essential documents should be retained until at least two years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least two years have elapsed since the formal discontinuation of clinical development of the investigational

product. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or if needed by the sponsor.

5.12 The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial related records are no longer needed.

6. Investigator Selection

6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s) are to be utilized in multi-centre trials, their organization and/or selection are the sponsor's responsibility.

6.2 Before entering an agreement with an investigator/institution to conduct a trial, the sponsor should provide the investigator(s)/institution(s) with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

6.3 The sponsor should obtain the investigator's/institution's agreement:

(a) to conduct the trial in compliance with GCP, with the applicable regulatory requirement(s) (see 4.1.3), and with the protocol agreed to by the sponsor and given approval/favorable opinion by the IRB/IEC (see 4.5.1);

(b) to comply with procedures for data recording/reporting;

(c) to permit monitoring, auditing and inspection (see 4.1.4) and

(d) to retain the trial related essential documents until the sponsor informs the investigator/institution these documents are no longer needed (see 4.9.4 and 5.5.12).

The sponsor and the investigator/institution should sign the protocols, or an alternative document, to confirm this agreement.

7. Allocation of Responsibilities

Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

8. Compensation to Subjects and Investigators

8.1 If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s).

8.3 When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s).

9. Financing

The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

10. Notification/Submission to Regulatory Authority(ies)

Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s)) should submit any required application(s) to

the appropriate authority(ies) for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s). Any notification/submission should be dated and contain sufficient information to identify the protocol.

11. Confirmation of Review by IRB/IEC

11.1 The sponsor should obtain from the investigator/institution:

(a) The name and address of the investigator's/institution's IRB/IEC.

(b) A statement obtained from the IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.

(c) Documented IRB/IEC approval/favorable opinion and, if requested by the sponsor, a current copy of the protocols, written informed consent form(s) and any other written information to be provided to subjects, subject recruiting procedures, and documents related to payments and compensation available to the subjects, and any other documents that the IRB/IEC may have requested.

11.2 If the IRB/IEC conditions its approval/favorable opinion upon change(s) in any aspect of the trial, such as modification(s) of the protocol, written informed consent form and any other written information to be provided to subjects, and/or other procedures, the sponsor should obtain from the investigator/institution a copy of the modification(s) made and the date approval/favorable opinion was given by the IRB/IEC.

11.3 The sponsor should obtain from the investigator/institution documentation and dates of any IRB/IEC re-approvals/re-evaluations with favorable opinion, and of any withdrawals or suspensions of approval/favorable opinion.

12. Information on Investigational Product(s)

12.1 When planning trials, the sponsor should ensure that sufficient safety and efficacy data from non-clinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available (see 7. Investigator's Brochure).

13. Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)

13.1 The sponsor should ensure that the investigational product(s) (including active comparator(s) and placebo, if applicable) is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labeled in a manner that protects the blinding, if applicable. In addition, the labeling should comply with applicable regulatory requirement(s).

13.2 The sponsor should determine, the investigational product(s), acceptable storage temperatures, storage conditions (e.g. protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g. monitors, investigators, pharmacists, storage managers) of these determinations.

13.3 The investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

13.4 In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency, but does not permit undetectable breaks of the blinding.

13.5 If significant formulation changes are made in the investigational or comparative product(s) during the course of clinical development, the results of any additional studies of the formulated product(s) (e.g. stability, dissolution rate, bioavailability) needed to assess whether these changes would significantly alter the pharmacokinetic profile of the product

should be available prior to the use of the new formulation in clinical trials.

14. Supplying and Handling Investigational Product(s)

14.1 The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

14.2 The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g. approval/favorable opinion from IRB/IEC and regulatory authority(ies)).

14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

14.4 The sponsor should:

(a) Ensure timely delivery of investigational product(s) to the investigator(s).

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s) (see 8. Essential Documents for the Conduct of a Clinical Trial).

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g. for deficient product recall, reclaim after trial completion, expired product reclaim).

(d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

14.5 The sponsor should:

(a) Take steps to ensure that the investigational product(s) are stable over the period of use.

(b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

15. Record Access

15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

15.2 The sponsor should verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.

16. Safety Information

16.1 The sponsor is responsible for the ongoing safety evaluation of the investigational product(s).

16.2 The sponsor should promptly notify all concerned investigator(s)/institution(s) and the regulatory authority(ies) of findings that could affect adversely the safety of subjects, impact the conduct of the trial, or alter the IRB/IEC's approval/favorable opinion to continue the trial.

17. Adverse Drug Reaction Reporting

17.1 The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority(ies) of all adverse drug reactions (ADRs) that are both serious and unexpected.

17.2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

17.3 The sponsor should submit to the regulatory authority(ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

18. Monitoring

18.1 Purpose

The purposes of trial monitoring are to verify that:

(a) The rights and well-being of human subjects are protected.

(b) The reported trial data are accurate, complete, and verifiable from source documents.

(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

18.2 Selection and Qualifications of Monitors

(a) Monitors should be appointed by the sponsor.

(b) Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented.

(c) Monitors should be thoroughly familiar with the investigational product(s), the protocols, written informed consent form and any other written information to be provided to subjects, the sponsor's SOPs, GCP, and the applicable regulatory requirement(s).

18.3 Extent and Nature of Monitoring

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general there is a need for on-site monitoring, before, during, and after the trial; however in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP. Statistically controlled sampling may be an acceptable method for selecting the data to be verified.

18.4 Monitor's Responsibilities

The monitor(s) in accordance with the sponsor's requirements should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

(a) Acting as the main line of communication between the sponsor and the investigator.

(b) Verifying that the investigator has adequate qualifications and resources (see 4.1, 4.2, 5.6) and remain adequate throughout the trial period, and that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period.

(c) Verifying, for the investigational product(s):

- That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.
- That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
- That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).
- That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.
- That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.

(d) Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.

(e) Verifying that written informed consent was obtained before each subject's participation in the trial.

(f) Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).

(g) Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.

(h) Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocols and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

(i) Verifying that the investigator is enrolling only eligible subjects.

(j) Reporting the subject recruitment rate.

(k) Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained.

(l) Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

(m) Checking the accuracy and completeness of the CRF entries, source documents and other trial-related records against each other. The monitor specifically should verify that:

- The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents.
- Any dose and/or therapy modifications are well documented for each of the trial subjects.
- Adverse events, concomitant medications and inter-current illnesses are reported in accordance with the protocol on the CRFs.
- Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs.
- All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRFs.

(n) Informing the investigator of any CRF entry error, omission, or illegibility. The

monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialed by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.

(o) Determining whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).

(p) Determining whether the investigator is maintaining the essential documents (see 8. Essential Documents for the Conduct of a Clinical Trial).

(q) Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

18.5 Monitoring Procedures

The monitor(s) should follow the sponsor's established written SOPs as well as those procedures that are specified by the sponsor for monitoring a specific trial.

18.6 Monitoring Report

(a) The monitor should submit a written report to the sponsor after each trial-site visit or trial-related communication.

(b) Reports should include the date, site, name of the monitor, and name of the investigator or other individual(s) contacted.

(c) Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken and/or actions recommended to secure compliance.

(d) The review and follow-up of the monitoring report with the sponsor should be documented by the sponsor's designated representative.

19. Audit

If or when sponsors perform audits, as part of implementing quality assurance, they should consider:

19.1 Purpose

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

19.2 Selection and Qualification of Auditors

(a) The sponsor should appoint individuals, who are independent of the clinical trials/systems, to conduct audits.

(b) The sponsor should ensure that the auditors are qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented.

19.3 Auditing Procedures

(a) The sponsor should ensure that the auditing of clinical trials/systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

(b) The sponsor's audit plan and procedures for a trial audit should be guided by the importance of the trial to submissions to regulatory authorities, the number of subjects in the trial, the type and complexity of the trial, the level of risks to the trial subjects, and

any identified problem(s).

(c) The observations and findings of the auditor(s) should be documented.

(d) To preserve the independence and value of the audit function, the regulatory authority(ies) should not routinely request the audit reports. Regulatory authority(ies) may seek access to an audit report on a case by case basis when evidence of serious GCP non-compliance exists, or in the course of legal proceedings.

(e) When required by applicable law or regulation, the sponsor should provide an audit certificate.

20. Noncompliance

20.1 Noncompliance with the protocols, SOPs, GCP, and/or applicable regulatory requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance.

20.2 If the monitoring and/or auditing identifies serious and/or persistent noncompliance on the part of an investigator/institution, the sponsor should terminate the investigator's/institution's participation in the trial. When an investigator's/institution's participation is terminated because of noncompliance, the sponsor should notify promptly the regulatory authority(ies).

21. Premature Termination or Suspension of a Trial

If a trial is prematurely terminated or suspended, the sponsor should promptly inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB/IEC should also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

22. Clinical Trial/Study Reports

Whether the trial is completed or prematurely terminated, the sponsor should ensure that the clinical trial reports are prepared and provided to the regulatory agency(ies) as required by the applicable regulatory requirement(s). The sponsor should also ensure that the clinical trial reports in marketing applications meet the standards of the ICH Guideline for Structure and Content of Clinical Study Reports. (NOTE: The ICH Guideline for Structure and Content of Clinical Study Reports specifies that abbreviated study reports may be acceptable in certain cases.)

23. Multi-centre Trials

For multi-centre trials, the sponsor should ensure that:

23.1 All investigators conduct the trial in strict compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and given approval/favorable opinion by the IRB/IEC.

23.2 The CRFs are designed to capture the required data at all multi-centre trial sites. For those investigators who are collecting additional data, supplemental CRFs should also be provided that are designed to capture the additional data.

23.3 The responsibilities of coordinating investigator(s) and the other participating investigators are documented prior to the start of the trial.

23.4 All investigators are given instructions on following the protocol, on complying with a uniform set of standards for the assessment of clinical and laboratory findings, and on completing the CRFs.

23.5 Communication between investigators is facilitated.

ANNEX 6

CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)[2]

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

1. General Information

1.1 Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

1.2 Name and address of the sponsor and monitor (if other than the sponsor).

1.3 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

1.4 Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.

1.5 Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

1.6 Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

1.7 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

2. Background Information

2.1 Name and description of the investigational product(s).

2.2 A summary of findings from non-clinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

2.3 Summary of the known and potential risks and benefits, if any, to human subjects.

2.4 Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).

2.5 A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).

2.6 Description of the population to be studied.

2.7 References to literature and data that are relevant to the trial, and that provide background for the trial.

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* This part is adopted from the Chapter on Clinical Trial Protocol and Protocol Amendment(s) of the ICH GCP Guidelines, as the Thai version is directly translated from the ICH GCP Guidelines. Re-translating the Thai version back to the English language may cause slight deviation from the original meaning. Therefore, adopting the original English version is made to best preserve the accuracy of the text.

3. Trial Objectives and Purpose

A detailed description of the objectives and the purpose of the trial.

4. Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design, should include:

4.1 A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

4.2 A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.

4.3 A description of the measures taken to minimize/avoid bias, including:

(a) Randomization.

(b) Blinding.

4.4 A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labeling of the investigational product(s).

4.5 The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.

4.6 A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.

4.7 Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.

4.8 Maintenance of trial treatment randomization codes and procedures for breaking codes.

4.9 The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

5. Selection and Withdrawal of Subjects

5.1 Subject inclusion criteria.

5.2 Subject exclusion criteria.

5.3 Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:

(a) When and how to withdraw subjects from the trial/ investigational product treatment.

(b) The type and timing of the data to be collected for withdrawn subjects.

(c) Whether and how subjects are to be replaced.

(d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.

6. Treatment of Subjects

6.1 The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.

6.2 Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.

6.3 Procedures for monitoring subject compliance.

7. Assessment of Efficacy

7.1 Specification of the efficacy parameters.

7.2 Methods and timing for assessing, recording, and analyzing efficacy parameters.

8. Assessment of Safety

8.1 Specification of safety parameters.

8.2 The methods and timing for assessing, recording, and analyzing safety parameters.

8.3 Procedures for eliciting reports of and for recording and reporting adverse event and inter-current illnesses.

8.4 The type and duration of the follow-up of subjects after adverse events.

9. Statistics

9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).

9.2 The number of subjects planned to be enrolled. In multi-centre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.

9.3 The level of significance to be used.

9.4 Criteria for the termination of the trial.

9.5 Procedure for accounting for missing, unused, and spurious data.

9.6 Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).

9.7 The selection of subjects to be included in the analyses (e.g., all randomized subjects, all dosed subjects, all eligible subjects and evaluable subjects).

10. Direct Access to Source Data/Documents

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

11. Quality Control and Quality Assurance

12. Ethics

Description of ethical considerations relating to the trial.

13. Data Handling and Record Keeping

14. Financing and Insurance

Financing and insurance if not addressed in a separate agreement.

15. Publication Policy

Publication policy, if not addressed in a separate agreement.

16. Supplements

(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guideline for Structure and Content of Clinical Study Reports.)

ANNEX 7

EXAMPLES OF MEDICAL DEVICES AND INHERENT RISKS

Examples of medical devices that may be regarded as being highly risky

- Artificial organs or tissues such as artificial cochlear, injectable collagen, all types of artificial joints, artificial lenses, artificial bones, blood vessel stents and internal stents, including for example stents used in the gall bladder duct, or in the urinary tract system, artificial valve, and artificial blood vessels
- Devices used for cardiovascular system, such as cardiac pace maker
- Cardiopulmonary resuscitation, laser used for dilating clotted blood vessels and devices for cardiopulmonary bypass used in the open heat operation
- Devices for stone destruction
- Devices for haemodialysis
- The intestinal stapler
- Absorbable haemostatic agents
- Infusion pumps etc.

Examples of medical devices that may be regarded as being low risky

- Contact lenses
- Gastroscope and Colonoscope; Cystoscope
- Laparoscope and hysteroscope
- Dressing devices for external wound, except burns
- Urinary and gall bladder ducts catheter connected to an external bag
- Nerve stimulator

ANNEX 8

MODEL TEMPLATE FOR MATERIAL TRANSFER AGREEMENT

MTA No……..

1. The parties to this Agreement are:
   1.1 ……[1]……(hereinafter referred to as ....[2]…..);
   1.2 ……[3]……(hereinafter referred to as the RECIPIENT) and ;
   1.3 The RECIPIENT includes RECIPIENT's Scientists as well as Principal Investigator / Laboratory Supervisor/ Instructor

   ....[2]….. agrees to provide the RECIPIENT with MATERIAL, as hereinafter defined, for use in accordance with the terms and conditions of this agreement.

2. In this agreement:

   Material means original material, progeny, and unmodified derivatives.

   Progeny means unmodified descendant from the MATERIAL, for example, virus from virus, cell from cell, or organism from organism.

   Unmodified Derivatives mean substances created by RECIPIENT, which constitute an unmodified functional sub-unit or an expression product of the original MATERIAL, such as purified or fractionated sub-sets of the original MATERIAL, sub-clones of unmodified cell lines, monoclonal antibodies secreted by a hybridoma cell line, proteins expressed by DNA/RNA supplied by ....[2]….., sub-sets of the original MATERIAL, for example, novel plasmids or vectors.

   Modifications mean substances created by RECIPIENT, which contain or incorporate the MATERIAL (Original Material, Progeny or Unmodified Derivatives).

   Commercial purposes mean the sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license, product development and seeking pre-marketing approval.

3. The MATERIAL covered by this agreement includes:
   3.1 All biological materials, living or dead, originated from within the Kingdom of Thailand/or else where as listed in Attachment A
   3.2 Any associated know-how, data and information
   3.3 Any Progeny, Unmodified Derivatives and Modifications
   3.4 Any cells or DNA, molecules replicated or derived there from

4. The RECIPIENT agrees that:
   4.1 The MATERIAL is the property of ....[2]….. and is to be used by the RECIPIENT solely for (check only one that applies)
   [ ] research purposes.
   [ ] test, reference, bioassay and control (covering only their use within the framework of corresponding official international test, bioassay and control protocols)
   [ ] training and teaching purposes

   at the RECIPIENT' s institution and only under the direction of the RECIPIENT.

   The research / test to be conducted by the RECIPIENT is restricted to the project/ test described in Attachment B, Entitled, "…….…….…… ……....." (Principal Investigator / Laboratory Supervisor / Instructor : …… …… …… ……)

   4.2 The MATERIAL will not be used in human subjects or in clinical trials involving human subjects without the written permission of ....[2]…...

5. The RECIPIENT agrees not to transfer the MATERIAL to anyone who does not work under his or her direct supervision at the RECIPIENT' s institution without the prior written consent of ....[2]…... The RECIPIENT shall refer nay request for the MATERIAL to ....[2]…...
6. The RECIPIENT agrees to use the MATERIAL in appropriate containment facilities by fully trained and competent staff.
7. The RECIPIENT will notify....[2]….. of all research results related to the MATERIAL in writing within one year after completion of the research project.
8. The RECIPIENT agrees to acknowledge....[2]….. as the source of the MATERIAL and data in any and all publications and patent applications based on or relating to the MATERIAL, replicas, or derivatives there of and any research thereon.
9. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except provided in this agreement, no expressed or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of ....[2]…..., including any altered forms of the MATERIAL made by ....[2]…... In particular, no expressed or implied licenses or other rights are provided to use the MATERIAL, modifications, or any related patents of the MATERIAL for commercial purposes.
10. If the RECIPIENT desires to use or license the MATERIAL or Modifications for commercial purposes. ....[2]….. AGREES, IN ADVANCE OF SUCH USE, TO NEGOTIATE IN GOOD FAITH WITH RECIPIENT TO ESTABLISH THE TERMS OF A COMMERCIAL LICENSE.
11. The RECIPIENT will use the MATERIAL in compliance with all his/her national and international laws and regulations, including Pathogens and Animal Toxins Act B.E.2525 as amended by Pathogens and Animal Toxins Act (No.2) B.E. 2544. The MATERIAL is experimental in nature and it is provided by ....[2]….. without warranty of any sort, expressed or implied. ....[2]….. makes no representation the use of the MATERIAL will not infringe any patent or other proprietary right. The RECIPIENT will indemnify ....[2]….. and its employees and hold ....[2]….. and its employees from any claims or liabilities which may arise as a result of the use of the MATERIAL by the RECIPIENT.
12. The MATERIAL is provided at no cost; however, fee is requested solely for its preparation and distribution cost. The amount shall be indicated in Attachment A
13. The RECIPIENT shall promptly return or destroy all information and the MATERIAL upon demand therefore by ....[2]…...
14. The agreement shall be effective on the date of last signing below, apply to all information and the MATERIAL received from ....[2]….. and terminate on completion of the RECIPIENT' s current research with the MATERIAL (within……..years after the effective date) unless the parties agree in writing to extend the agreement
15. ....[2]….. and the RECIPIENT shall use their best efforts to settle in a fair and reasonable manner any disputes arising in connection with this Agreement. If such dispute cannot be settled by the parties between themselves, it shall be first submitted to mediation by a mediator chosen jointly by the parties.

    In the event that mediation does not bring a resolution of the dispute within 30 days, the dispute shall be submitted to arbitration before a single arbitrator pursuant to the Arbitration Rule of Thailand. Any such arbitration will be subject to such rules.

Signed for and on behalf of the RECIPIENT	**Signed for and on behalf of the ....[2]…..**
Name……	Name…….
(……..…..)	(.....)
Position: ……..	Position: .....
Date……..	Date……...

Signature of Witness

Name……
(..……..)
Position : ……
Date……..

Signature of Witness

Name……
(……..……..)
Position: ……
Date……

Attachment A **MTA No……..**

Material Transfer Record

……[1]….. agrees to transfer the following materials to …[3]… as follows:

No.	Material	Quantity	Remark
1			
2			
3			
4			
5			
6			

Preparation costs ……..Baht/……unit Total……..Baht
Distribution fees……..Baht
[ ] The materials will be picked up on ……/……/……(Please notify…….days/weeks in advance.)
[ ] The materials are requested to be shipped to Recipient's investigators/ Laboratory supervisor/ Instructor shown below.

FOM SCIENTIST

Signature: .....

Printed Name: .....

Unit/Dept: .....

Faculty / Institute……

Date: .....

RECIPIENT SCIENTIST

Signature: .....

Printed Name: .....

Unit/Dept: .....

Address: .....

Date: .....

Explanatory Note:

[1] Fill the name, address of the Faculty/Institution that provides the materials, for example, Faculty of Medicine, Chiang Mai University 110 Intavaroros Road, Sriphum District, Muang, Chiang Mai 50200, Thailand
[2] Fill the brief name of the Faculty/Institution, for example, Faculty of Medicine
[3] Fill the name, address of the Faculty/Institution that receives the materials

Attachment B is the protocol.

ANNEX 9

LIST OF MEMBERS, THE WORKING GROUP FOR THE DEVELOPMENT OF NATIONAL ETHICAL GUIDELINES FOR RESEARCH IN HUMAN SUBJECTS B.E. 2545-2547

1. Vichai Chokevivat, M.D. — Advisor
   Food and Drug Administration, Ministry of Public Health
2. Professor Anek Areebhak, M.D. — Advisor
   Faculty of Medicine, Chulalongkorn University
3. Somboon Kiatinun, M.D. — Chairlady
   Faculty of Medicine, Thammasart University
4. Professor Manit Sritpramote, M.D. — Member
   Bangkok Medical College, Bangkok Metropolitan Administration
5. Assoc. Prof. Nimit Morakote, Ph.D. — Member
   Associate Dean for Research Affairs,
   Faculty of Medicine, Chiangmai University
6. Assoc. Prof. Col. Aphornpirom Ketpanya, M.D — Member
   Phramonkutklao Medical College, the Royal Thai Army
7. Assoc. Prof. Rojana Sirisriro, M.D. — Member
   Faculty of Medicine, Ramathibodi Hospital, Mahidol University
8. Suchart Chongprasert, Ph.D. — Member
   Food and Drug Administration, Ministry of Public Health
9. Korakot Juthasmith, M.D. — Member
   Department of Medical Services, Ministry of Public Health
10. Wiwat Rojanapityakorn, M.D. — Member
    Office for International Development of Health Policies
11. Assoc. Prof. Sopit Thammaree — Member & Secretary
    Faculty of Medicine, Chulalongkorn University

ANNEX 10

LIST OF MEMBERS,
THE WORKING GROUP FOR REVISING THE ETHICAL GUIDELINES FOR RESEARCH IN HUAMN SUBJECTS IN THAILAND
B.E. 2548-2550

1. Somboon Kiatinun, M.D. Faculty of Medicine, Thammasart University	Chairperson
2. Vichai Chokevivat, M.D. Director General, Department for the Development of Thai and Alternative Medicines, Ministry of Public Health	Member
3. Assoc. Prof. Nimit Morakote, Ph.D. Faculty of Medicine, Chiangmai University	Member
4. Assoc. Prof. Major. Gen. Aphornpirom Ketpunya, M.D. Department of the Royal Thai Army	Member
5. Assist. Prof. Phanuwat Lertsitthichai, M.D. Faculty of Medicine, Ramathibodi Hospital, Mahidol University	Member
6. Assoc. Prof. Sopit Thammaree Faculty of Medicne, Chulalongkorn University	Member & Secretary
7. Assist. Prof. Col. Suthee Panichkul, M.D. Phramongkutklao College of Medicine	Editorial Team
8. Prof. Pankhae Mahaisawariya, M.D. Faculty of Medicine, Siriraj Hospital, Mahidol University	Editorial Team
9. Prof. Tada Sueblinvong, M.D. Faculty of Medicine, Chulalongkorn University	Editorial Team

ANNEX 11

LIST OF MEMBERS,
THE MEDICAL COUNCIL'S SUB-COMMITTEE FOR THE PROMOTION OF RESEARCHES IN HUMAN SUBJECTS
B.E. 2548-2550

1. Anek Areebhak, M.D.	Chairman
2. Vichai Chokevivat, M.D.	Member
3. Jomjug Juntarasakul, M.D.	Member
4. Somboon Kiatinun, M.D.	Member
5. Banharn Koranantakul, M.D.	Member
6. Pinit Kulawanit, M.D.	Member
7. Sumalee Nimmannit, M.D.	Member
8. Tada Sueblinvong, M.D.	Member
9. Piyatat Tasanawiwat, M.D.	Member
10. Hatern Thintara, M.D.	Member
11. Pakorn Siriyong, M.D.	Member
12. Yotee Thongpenyai, M.D.	Member
13. Phanuwat Lertsitthichai, M.D.	Member
14. Suwat Lertsukprasert, M.D.	Member
15. Nimit Morakote, Ph.D.	Member
16. Aphornpirom Ketpunya, M.D.	Member
17. Sopit Thammaree,MSc (Pharm.).	Member & Secretary

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MINISTRY OF HEALTH	THE SOCIALIST REPUBLIC OF VIETNAM
	Independence – Freedom - Happiness
No: 111 /QĐ - BYT	

Hanoi, January 11, 2013

DECISION

On promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at grass-root level

MINISTER OF HEALTH

Based on the Decree No.63/2012/NĐ-CP dated August 31, 2012 by the Government stipulating functions, tasks, mandate and organizational structure of the Ministry of Health;

Considering the request by the Director of Bureau of Science, Technology and Training (BSTT),

DECIDE:

Article 1. Issued in attachment to this Decision is the Regulation on Organization and Operation of the Council of Ethics in Biomedical Research at grass-root level (CEBR).

Article 2. This decision comes into force and effect from the date of signing and promulgation.

Article 3. Mandate the Director of BSTT to roll out and monitoring enforcement of this Regulation.

Article 4. Heads of Ministerial Administration Office, Ministerial Inspectorate, Directors of bureaus, directors of departments under HOH, leaders of units and organizations under MOH, leaders of relevant organizations and Chairman of the Review Board, shall enforce this Decision./.

MINISTER OF HEALTH

(signed)

Nguyễn Thị Kim Tiến

Recipient:
- As listed in Article 4;
- Vice ministers (for information);
- General Association of Medicine of Vietnam, Vietnam Association of Pharmacy;
- MOH Website;
- Office filing: VT, TCCB; K2ĐT (02).

REGULATION ON ORGANIZATION AND OPERATION OF COUNCIL OF ETHICS IN BIOMEDICAL RESEARCH AT GRASS-ROOT LEVEL

(Issued under Decision No.111/QĐ - BYT
dated January 11, 2013 by Minister of Health)

Chapter I

GENERAL PROVISIONS

Article 1. General Principles

Prior to putting into implementation, all biomedical research on human subjects in Vietnam is subject to review and evaluation for ethics in research in accordance with current provisions and guidelines of this Regulation

Article 2. Biomedical research on human subject

Biomedical research on human subject includes clinical medical trial research (new medicine, medical materials, traditional medicines, vaccine, other biological products used in illness prevention and treatment, biological utility research and biological evaluation), health equipment and facilities, research on methods of treatment, diagnosis, biological samples, epidemiological survey, social survey, psychological survey conducted on human subjects.

Article 3. Mandate of establishment and appraisal of CEBRGL

1. CEBRGL is established in units with a view to performing ethnical and scientific review and assessment on biomedical research conducted in organizations and units in accordance with laws and regulations.

2. Based on specific functions and tasks of the organization or unit conducting the research, the leader/head shall decide to establish, appoint, dismiss or substitute members of the CEBRGL.

3. Ministry of Health shall consider, evaluate and grant operating code, supervise and inspect operations of the CEBRGL in units and organizations. If appropriate, Ministry of Health reserves the right to suspend the service of CEBRGL.

Article 4. Scope and mandate of CEBRGL

1. For research or project at ministerial level, or research on international relations, clinical medical trial (new medicine, medical materials, traditional medicines, vaccine, other biological products used in illness prevention and treatment, biological utility research and biological evaluation, treatment equivalence); research on clinical trial of health equipment; research on first-time application of new technology, method on human in Vietnam, CEBR shall consider and assess ethics in research prior to submitting research documents to SEBR of MOH for consideration and evaluation (SEBR of Ministry of Health).

2. For research at grass-root level beyond the list specified in the Clause 1, ethics in research shall be reviewed and assessed by SERBGL.

3. In special cases, Ministry of Health shall mandate the tasks of reviewing and assessing ethics in biomedical research and project on human subject falling under the appraisal mandate of the CERB of MOH to qualified CERBGL.

Chapter II

ORGANIZATION OF COUNCIL OF ETHICS IN BIOMEDICAL RESEARCH AT GRASS-ROOT LEVEL

Article 5. Function, task, mandate and responsibility of Council of Ethics in Biomedical Research at Grass-root level (hereinafter referred to as Council)

1. Function:

Review, assess ethical and scientific aspect in biomedical research as basis to provide advisory opinions to the leader of organization or unit that hosts the research.

2. Task:

a) Assess research ethics in documents of biomedical research (research outline, reports and relevant papers) prior to commencing implementation.

b) Monitoring, inspecting research for its compliance with the outline and guidelines on ethics in research; assess records, reporting and resolution of problems happening during the course of research implementation;

c) Assess research results according to approved outline and current guidelines and regulations;

d) Exercise archiving and control of operating documentations of the council.

3. Mandate:

a) Approve, request for revision of the research outline prior to giving official approval or disapproval of documents of biomedical documents as basis for decision-making authority to decide on implementing the research;

b) Approve or disapprove modifications concerning research contents during the course of implementation;

c) Request to suspend research upon detecting non-compliance of good clinical practice (GCP), non compliance of research outline or the risk to research subject during the course of research conducting;

d) Inspect and supervise compliance with research outline, principles of GCP at the time of research, and data, results and documentations related to research.

4. Responsibility:

a) Protect rights, safety and health of all subjects taking part in the research and concerned communities, rights of researchers;

b) Safeguard fairness to all subjects taking part in the research (risk and benefit sharing by social class, age, gender, economic, cultural, ethnic and religious status);

c) Ensure fairness, democracy, honesty and promptness of assessment of ethics in research;

d) Ensure legality and appropriateness and confidentiality of research and documents.

Article 6. Number, composition, title and membership eligibility of the council

1. Number of member:

a) The council has at least five members and at most 11 members, among whom one shall be the member cum chief secretary of the council;

b) Secretariat shall assist the Council. Secretariat is based in the Science Research Management Office or an appropriate office decided by the Head of the Organization. Secretariat has two or three members.

c) Secretariat shall receive documents/applications and process them, prepare necessary things for the work of the council, complete letters or documents by the council and roll out tasks required by the council.

2. Council composition:

Chairman;

Deputy chairman (if appropriate);

Council members;

Council secretary.

3. Eligibility of council member:

3.1. General eligibility

Council members must be honest, having objective viewpoint, good experience and knowledge about ethics in biomedical research in order to protect rights and interests for research subjects and members.

Council secretary must be honest, having objective viewpoint and good knowledge about management of science and technology, science research and ethics in biomedical research, be trained in administration, book-keeping and managerial tasks.

Chairman, deputy chairman, members and secretary of the council must hold a certificate of good clinical practice issued by Ministry of Health or organizations accredited by Ministry of Health, and get regular training to understand and update new issues related to ethical aspects in biomedical research.

3.2. Specific eligibility

a) Chairman, deputy chairman of the council should be prestigious scientist. In order to ensure fairness and objectivity, the leader of the organization shall not act as the council chairman.

b) Council members include the following:

- Members of both genders;
- Members out of biomedical field, members in biomedical field;
- Members not related to the unit/organization that host the research;
- Member with professional qualification in law or ethics;
- Members as medical doctor
- Other members are scientists with deep knowledge in the subject issue.

Article 7. Review and assessment of ethical aspect in organizations/unit without council

For units without CEBRGL established, ethical review and assessment shall be performed by the Scientific Council of the unit. The leader of the unit shall issue a decision on amending the tasks of ethical assessment in biomedical research for the scientific council on the condition that two thirds of the members have GCP certificate issued by Ministry of Health.

For units without Ethical Council or Scientific Council established, ethical review and assessment shall be performed by CEBRGL which is mandated by the Ministry of Health to assess biomedical research on human subject in the local area.

Chapter III

OPERATION F COUNCIL OF ETHICS IN BIOMEDICAL RESEARCH AT GRASS-ROOT LEVEL

Article 8. Working Regulation of the Council

1. The council works on the basis of three to five year term and specified in the council establishment decision.

2. The council works in the principle of collectivity, democracy upon considering and making decisions. Council meetings are legally valid if having presence of at least two thirds of council members to vote and the meeting must have the minute of meeting.

3. The council chairman (or deputy chairman) shall chair meetings of the council, make conclusions for the meetings and report to the leader of the

organization/unit as basis to make decisions.

4. In necessary cases, the council may invite counselors who have no conflict of interest with the research. The counselor may attend the meeting without voting.

5. Upon assessing research documents and conclusions, the council shall attention to the following:

a) Risks and benefits for research participants;

b) Risks are minimal and appropriate compared with presumably attained outcomes;

c) Protection and care for research participants;

d) Voluntary participation of research participants/subjects

e) Fairness in selection of research participant

f) Integrity of data collected;

g) Respect for privacy and confidentiality of participants

h) Protective conditions for vulnerable subjects

i) Scientific design of research outline

j) Implementation model and feasibility of research

Article 9. Working principle of council members

1. Council members shall work in the principle of independence, objectivity, honesty and individual responsibility for their own decision made upon reviewing and assessing research issues prior to implementing them, during implementation and acceptance of research outcomes.

2. Only members free of conflict of interest with the research shall be eligible to assess and vote.

3. Before meetings on review of documents, members and experts shall study the documents, prepare comments sheets to the secretariat.

4. Members shall be subject to comply with standard procedures of practice of the council.

5. Council members reserve the right to report to the head of organization that directly manage the council to handle non-compliances against working

principles by council chairman or any council member.

Article 10. Assessment procedure of council

Units should refer to operating regulations of the Review Board of Ethics in Biomedical Research, Ministry of Health (issued under Decision No.460/QD-BYT dated February 16, 2012) to develop assessment procedure for the council of your own organization.

Article 11: Registration forms for ethical assessment in biomedical research

The registration forms for ethical assessment in biomedical research for clinical trial research can be referred in the Circular No.03/2012/TT-BYT dated February 02, 2012 by Ministry of Health. For other research, the organizations may refer current regulation on scientific and technological management.

Article 12. Financing source for council operation

Fund for council operation is guided by existing financial regulations applicable to scientific studies and research, for research, project without using state fund, researchers and donors must prepare a cost plan to cover all expenses of the council by their own account.

Article 13. Major documents subject to review, assessment by the council

a) Research outline;

b) Information sheet, voluntary participation acceptance sheet;

c) Procedures for participant selection and advertisement;

d) Information sheet for security of interest and confidentiality of participant;

e) Procedures for monitoring, assessment, resolution of problems and issues (for research on subjects);

f) Product information sheet for researchers (for clinical trial research);

g) Professional profile, qualifications and certificates of researchers

Chapter IV

IMPLEMENTATION

Article 14. Implementation provisions

This regulation shall apply to all agencies, units under Ministry of Health, department of health under provinces and centrally-run cities, sectoral health, local and foreign people upon conducting research related to human in Vietnam. Heads of above-listed organizations shall instruct and guide enforcement of this regulation.

Article 15. Implementation

For any problems and issues happening during the course of implementation, the heads of organizations shall report to Ministry of Health (Bureau of Science, Technology and Training) for consideration and amendment. Any complaints regarding ethical assessment in biomedical research from organizations and individuals to higher science and technology management agency shall be resolved in accordance with specified level and laws.

MINISTER

(signed)

Nguyễn Thị Kim Tiến

MINISTRY OF HEALTH --------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No.: 460 /QD - BYT	*Hanoi, February 16th 2012*

DECISION

On the promulgation of Regulations on organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 - 2017

MINISTER OF HEALTH

Pursuant to Decree No. 188/2007/ND-CP dated 27/12/2007 of the Government stipulating functions, duties, powers, and organizational structure of Ministry of Health;

Pursuant to Decision No. 458/QD-BYT dated 16/02/2012 of Minister of Health on the establishment of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 - 2017;

At the request of Director of Sciences and Training Department, Director of Personnel Department.

DECIDES:

Article 1. To promulgate with this Decision the Regulations on organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 – 2017.

Article 2. To assign the standing office of the Ethical Evaluation Committee in biomedical research of Ministry of Health period 2012 – 2017 to implement and inspect the implementation of this Regulation.

Article 3. This Decision becomes effective since the date of signing.

Article 4. The Chief Secretariat of the Ministry's Office, Chief Inspector of the Ministry, General Director, Directors of General Departments, Directors of Departments under Ministry of Health, Heads of relevant units under Ministry of Health, Heads of relevant units and Chairman of the Ethical Evaluation Committee shall be responsible to carry out this Decision./.

Recipients:
- As in Article 4;
- Deputy Ministers;
- Vietnam Medical Association, Vietnam Pharmaceutical Association;
- Website of Ministry of Health;
- Archived.

MINISTER

(Signed)

Nguyen Thi Kim Tien

MINISTRY OF HEALTH --------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 460 /QD - BYT	*Hanoi, February 16th 2012*

REGULATIONS

On the organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 - 2017

(Promulgated with Decision No.: 460/QD-BYT dated February 16th 2012 of Minister of Health)

Chapter I
GENERAL PROVISIONS

Article 1. This Regulation governs the organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 – 2017 which was established with Minister of Health's Decision No. 458/QD-BYT dated February 16th 2012.

Subjects of governing of this Regulation include members of Ethical Evaluation Committee in biomedical research Ministry of Health period 2012 - 2017 and individuals and organizations in Ministry of Health who are related to the implementation, supervision, evaluation, and management of biomedical research on human.

Article 2. Biomedical research in this Regulation comprise of: clinical drug trial, medical equipment; treatment methods, diagnostic methods; research using biological samples; epidemiological, socio-medical and psychological research on human subjects.

Article 3. Before carrying out any research, all biomedical research on human subjects (hereinafter referred to as biomedical research) in Vietnam shall have to be examined and evaluated by Ethical Evaluation Committee in biomedical research (hereinafter referred to as Ethical Evaluation Committee) in terms of research ethical aspects and specialized scientific aspects in compliance with this Regulation and Guidelines of Good Clinical Practices promulgated with Decision No. 799/QD-BYT dated 7/3/2008 of Minister of Health and Guidance on clinical trial in Circular No. 03/2012/TT-BYT dated 02/02/2012 of Minister of Health.

Article 4. The Standing Office locating at the Ministry of Health shall assist the Ethical Evaluation Committee. The Standing Office of the Ethical Evaluation Committee shall have legal status and use the stamp and account of the Ethical

Evaluation Committee for transactions within their functions and duties. Budget for the operation of Ethical Evaluation Committee shall be from the State budget and other assistance fund in compliance with current regulations.

Chapter II
FUNCTIONS, DUTIES, POWERS, RESPONSIBILITIES AND ORGANIZATIONAL STRUCTURE OF ETHICAL EVALUATION COMMITTEE

Article 5. Functions, duties, powers, responsibilities of Ethical Evaluation Committee

1. Functions

Ethical Evaluation Committee is the advisor to the Minister of Health in terms of ethical issues in biomedical research.

2. Duties

a) To evaluate the ethical issues in biomedical research documents (research proposals, relevant reports and documents) to ensure their legality, objectivity, and honest.

b) To monitor, examine, and supervise the research in compliance with Good Clinical Practices and regulations on research ethics.

c) To evaluate the research results of the approved research proposals based on the current guidelines and regulations.

d) To train, guide, and improve the researchers for the health sector regarding research ethics and Good Clinical Practices (GCP).

3. Powers

a) To accept or not accept biomedical research documents, serving as basis for management authorities to approve the conducting of research.

b) To accept or not accept changes in research contents during implementation.

c) To propose the termination of research upon signs of incompliance of GCP or discovery of risks to the research subjects's safety which may possibly happen during the research process.

d) To request the main researchers, organizations conducting clinical trials to report on the figures, data, research results and research-related documents.

đ) To examine and supervise the compliance with Good Clinical Practices at research field and the figures, data, research results and research-related documents.

4. Responsibilities

a) To protect the safety of research subjects and the community.

b) To protect the rights of research subjects and researchers.

c) To ensure justice for all research stakeholders.

d) To ensure the scientific aspects and feasibility of the research.

Article 6. Structure, membership, number of, positions and membership requirements of Ethical Evaluation Committee.

1. Organizational structure

- Ethical Evaluation Committee comprises of Standing office, Standing subcommittee, 3 specialized subcommittees: Pharmaceuticals, Traditional medicines, Vaccines and secretary team.

- Leaders of the Ethical Evaluation Committee include Chairman and Vice Chairmen.

- The subcommittees include the Head of subcommittee and members.

- The Standing office of the Ethical Evaluation Committee has its head office at Ministry of Health (138 A Giang Vo, Ba Dinh district, Hanoi) and its standing unit in Pasteur Institute Ho Chi Minh city (167 Pasteur, Precinct 8, District 3, Ho Chi Minh city).

2. Membership, number of members:

a) Chairman, Vice Chairmen of the Ethical Evaluation Committee are scientists capable of embracing the fields related to the Committee's duties.

b) The Standing office of the Ethical Evaluation Committee comprises of the Chairman, Vice Chairmen of the Ethical Evaluation Committee and members of the Standing subcommittee. Members of the standing subcommittee has the following membership structure:

- Including members of both sexes.

- Including members representing the scientific management authorities, with good management skills and good legal knowledge.

- Including members representing rights of research subjects, who are honest, impartial, with good sense of morality and good knowledge.

- Including members who are lawyers or jurists to ensure the legality of research documents, to protect legitimate rights of research subjects as well as researchers, members of research teams.

- Including members who are scientists with in-depth knowledge of clinical, epidemiology, pharmacy, medical statistics, research approach.

c) Each specialized subcommittee comprises of 07 - 09 members who are scientists with in-depth knowledge of their specialized fields of pharmaceutical chemistry, traditional medicines, vaccines and medical biological products.

d) The Secretary team comprises of 07 - 09 members who possess good management skills and knowledge of biomedical research.

đ) Members of the subcommittees and secretary team must be provided with Ministry of Health's training program on "Good Clinical Practices".

Article 7. Functions, duties, powers of the Standing office of the Ethical Evaluation Committee

1. Functions

The Standing office of the Ethical Evaluation Committee assists the Ethical Evaluation Committee in developing planning, plans, arranging the examination, evaluation, inspection, supervision, and management of clinical trial research.

2. Duties

a) To develop long- and short-term plans on the development of Ethical Evaluation Committee's operations in compliance with international standards and Vietnamese regulations, including: examination, evaluation, inspection, supervision, and management of clinical trial research;

b) To coordinate for the development of standard procedures on examination, evaluation, inspection, supervision, and management of clinical trial research;

c) To coordinate for the implementation and to supervise the implementation of standard procedures on examination, evaluation, inspection, supervision, and management of clinical trial research;

d) To act as a focal point in working with international and domestic organizations to develop the Ethical Evaluation Committee's operations in compliance with international standards and Vietnamese regulations;

đ) To prepare documents, to record and store the minutes of regular and ad-hoc meetings of the Ethical Evaluation Committee and relevant documents;

e) To settle the payment of expenditures and prepare the final account of budget for the Ethical Evaluation Committee and Standing office of the Ethical Evaluation Committee in compliance with current financial regulations;

f) To compile 3-month, 6-month and annual reports on the performance of the Ethical Evaluation Committee.

3. Powers

a) To be entitled to select officers, civil servants, officials to work concurrently or as secondee at the Standing office of the Ethical Evaluation Committee in compliance with the current regulations to submit to the Ethical Evaluation Committee for consideration and further submit to the leaders of Ministry of Health for approval;

b) To recruit and sign contract with domestic and international consultants, contract employees to work for the Standing office of the Ethical Evaluation Committee depending on the work demand in compliance with current regulations;

c) To use public service budget for science and other sources of funding for the operations of Ethical Evaluation Committee and the Standing office of the Ethical Evaluation Committee in compliance with current regulations;

d) The Standing office of the Ethical Evaluation Committee is entitled to use the stamp and account of the Ethical Evaluation Committee for transactions within their functions and duties.

đ) The Chief Secretariat of the Ethical Evaluation Committee Standing office is the Account Holder of the Ethical Evaluation Committee.

Article 8. Structure of the Ethical Evaluation Committee Standing Office:

1. The Chief Secretariat of the Ethical Evaluation Committee Standing office is appointed and dismissed by the Chairman of the Ethical Evaluation Committee;

2. Staff of the Ethical Evaluation Committee Standing office comprises of 3 – 5 specialized officers who are experts from Department of Science and Training and other concurrent officers and secondees recruited by the Chief Secretariat of the Ethical Evaluation Committee Standing office to submit to the Ministry's leaders for approval;

3. Besides, the Ethical Evaluation Committee Standing office has other experts, officers, and staff recruited by the Chief Secretariat of the Ethical Evaluation Committee Standing office for short-term working contracts in compliance with current regulations.

Chapter III
OPERATION OF THE ETHICAL EVALUATION COMMITTÊ

Article 9. Principles for the operation of the Ethical Evaluation Committee

The Ethical Evaluation Committee shall operate as a team with the democratic principles.

The members shall work with the principles of independence, objectivity, honest and personal responsibility for their decisions when examining and evaluating research contents before implementation, changes during the implementation and evaluating research results.

Only members of the Ethical Evaluation Committee who have no conflict of interests with the research shall have the right to evaluate and vote.

Members of the subcommittees shall be responsible to provide general and specific evaluation of the documents assigned by the head of the specialized subcommittee.

Before the meetings to evaluate the documents, the members and critic experts shall study the documents, complete and send the evaluation sheets to the Standing office of the Ethical Evaluation Committee.

Members of the Ethical Evaluation Committee shall be responsible to comply with the Committee's Standard operational Practices (SOPs).

Members of the Ethical Evaluation Committee shall have the responsibilities and rights to directly report to the Minister regarding the violations of working principles by the Committee Chairman or any Committee member.

Article 10. Working methods of Ethical Evaluation Committee

Ethical Evaluation Committee's activities comprise of plenary meetings, subcommittee meetings, periodical and ad-hoc investigation and supervision activities.

Ethical Evaluation Committee 's activities are carried out in compliance with the processes and procedures provided for in the standard operational practices of the Ethical Evaluation Committee.

The Standing subcommittee shall meet monthly, the specialized subcommittees shall attend the same meeting with the standing subcommittee when there are relevant documents to be considered.

The Ethical Evaluation Committee Standing Office shall be responsible to assign the critic members, and to invite independent experts to provide criticism on the documents.

The conclusion of the evaluation meeting must be based on ballot results. The meeting's approval conclusion shall only be valid by at least 2/3 affirmative votes.

With regard to the evaluation of documents on clinical trial of medicines, vaccines (different periods), new treatment methods, clinical trial of medical equipment, such documents shall be examined and evaluated by the standing subcommittee and specialized subcommittees in accordance with the complete procedures.

With regard to the research documents on amendment and supplementation, periodic evaluation and approval, reporting of adverse events, reporting on incompliance with proposal, epidemiological and sociological surveys on human subjects, and other researches shall be examined and evaluated by the standing subcommittee in accordance with the reduced procedures and submit to the Committee Chairman for approval.

Article 11. Physical and technical conditions for Ethical Evaluation Committee:

The Ethical Evaluation Committee and its Standing office shall be provided with sufficient physical facilities to perform their duties: including offices, equipment, supervision and monitoring tools, and operating budget to satisfy the management requirements and plan implementation as provided for in this Regulation.

The Ministry's Office shall be responsible to arrange offices for the Ethical Evaluation Committee Standing office at the Ministry of Health's head office. In case it is impossible to arrange an office at the Ministry of Health's head office, the Ethical Evaluation Committee Standing office is allowed to rent an office.

The Ethical Evaluation Committee shall be provided office equipment and supplies and stationery to serve the meetings and other equipment and supplies to perform their functions and duties.

Chapter IV
IMPLEMENTATION PROVISIONS

Article 12. This Regulation shall be applicable since the date of effectiveness. Based on this Regulation, the Ethical Evaluation Committee shall consider the development of the standard operational practices (SOPs) for the Committee's specific activities.

The agencies and entities under the Ministry of Health shall carry out their research activities in compliance with this Regulation in order to organize and develop the Operating Rules of their own Ethical Evaluation Committees to ensure compliance with the fundamental principles of research ethics.

If there are any difficulties during the implementation, individual and organizations shall report to the Ministry of Health (Department of Science and Training) for consideration to amend and supplement this Regulation. All complaints on ethical evaluation in biomedical research shall be sent to the Ethical Evaluation Committee Standing Office for examination and resolution in compliance with current law./.

MINISTER

(signed)

Nguyen Thi Kim Tien

THE NATIONAL ASSEMBLY	SOCIALIST REPUBLIC OF VIET NAM
No: 34/2005/QH11	Independence - Freedom - Happiness
	Ha Noi, day 14 month 06 year 2005

LAW ON PHARMACY

Pursuant to the 1992 Constitution of the Socialist Republic of Vietnam, which was amended and supplemented under Resolution No. 51/2001/QH10 of December 25, 2001, of the X th National Assembly, the 10 th session;

This Law provides for activities in the domain of pharmacy.

Chapter I

GENERAL PROVISIONS

Article 1.- Governing scope and subjects of application

1. This Law provides for drug trading; drug registration and circulation; drug use; drug supply; drug information and advertisement; clinical trial of drugs; management of habit-forming drugs, psychotrops, pre-substances used as drugs and radioactive drugs; drug quality standards and drug assay.

2. This Law applies to domestic and foreign agencies, organizations and individuals in Vietnam.

Where international treaties to which the Socialist Republic of Vietnam is a contracting member contain provisions different from those of this Law, the provisions of such international treaties shall apply.

Article 2.- Interpretation of terms

In this Law, the following terms shall be construed as follows:

1. Pharmacy means drugs and drug-related activities.

2. Drugs mean substances or mixtures of substances for human use for purposes of prophylaxis, therapy or diagnosis of disease or modification of physiological functions of human bodies, and consist of finished drugs, raw materials for drug manufacture, vaccines and medical biological products other than functional foods.

3. Vaccines mean preparations containing antigens that provoke immune responses of human bodies, and used for the purpose of prophylaxis.

4. Medical biological products mean products of biological origin used for the purposes of prophylaxis, therapy and diagnosis of human diseases.

5. Raw materials for drug manufacture means substances constituting products in the process of drug manufacture.

6. Pharmaceutical ingredients (also called active ingredients) mean substances or mixture of substances with therapeutic activity, which are used in drug manufacture.

7. Finished drugs mean medicinal product forms that have undergone all stages of manufacture, including packaging in their final containers and labeling.

8. Drugs from materia medica mean those manufactured from raw materials of natural animal, plant or mineral origin.

Drugs containing pure active ingredients extracted from materia medica, drugs being a combination of materia medica and synthetic chemical active ingredients are not called drugs from materia

medica.

9. Traditional medicaments mean drugs prepared from materia medica under theories and by methods of traditional medicine of oriental countries.

10. Prescription drugs mean those which may cause hazards to human life or health if they are used not in accordance with indications of prescribers; require specific prescriptions when being dispensed, retailed or used; and are included in the list of prescription drug groups.

11. Non-prescription drugs mean those which, when being dispensed, sold or used, require no specific prescription.

12. Habit-forming drugs means those which, when being used for a prolonged period, may form bad habits, and are included in the list of habit-forming drugs promulgated by the Health Minister and compliant with treaties to which the Socialist Republic of Vietnam is a contracting party.

13. Psychotrops mean drugs which have effects on the central nervous system, may lead to users dependence if not used properly, and are included in the list of psychotrops promulgated by the Health Minister and compliant with treaties to which the Socialist Republic of Vietnam is a contracting party.

14. Pre-substances used as drugs mean chemicals which are indispensable to the process of preparation and manufacture of habit-forming drugs or psychotrops, are used as formula components of habit-forming drugs or psychotrops, and included in the list of pre-substances promulgated by the Health Minister and compliant with treaties to which the Socialist Republic of Vietnam is a contracting party.

15. Radioactive drugs mean those containing one or more radioactive substances, and used for diagnosis or treatment of disease.

16. Essential drugs mean those satisfying healthcare demands of a vast majority of people, and included in the list of essential drugs promulgated by the Health Minister.

17. Main drugs mean those satisfying treatment demands of medical examination and treatment establishments, compatible with the disease structure in Vietnam, and included in the list of main drugs for use in medical examination and treatment establishments promulgated by the Health Minister.

18. New drugs means those containing new pharmaceutical ingredients or those with a new combination of pharmaceutical ingredients already in circulation.

19. Specifics mean drugs having trade names given by manufacturing establishments and different from original names or international generic names.

20. Adverse reactions of drugs mean undesirable effects of drugs harmful to health, which may appear at normal doses.

21. Expiry date of drugs means use duration fixed for a specific lot of drug, after which such drug is no longer permitted for use.

22. Drug quality standards include regulations on criteria, technical requirements, assay methods, packaging, labeling, transportation, preservation and other requirements related to quality of drugs.

Drug quality standards are expressed in the form of technical documents.

23. Drugs of inferior quality mean those which are not up to quality standards already registered with competent agencies.

24. Counterfeit drugs mean products manufactured in any form of drug with a deceitful intention, and falling into one of the following cases:

a/ They have no pharmaceutical ingredients;

b/ They have pharmaceutical ingredients, which are, however, not at registered contents;

c/ They have pharmaceutical ingredients different from those listed in their labels;

d/ They imitate names and industrial designs of drugs which have been registered for industrial property protection of other manufacturing establishments.

25. Drug trading means the performance of one, a number or all of the stages of the investment process, from manufacture to sale of drugs or provision of drug-related services in the market for profit-making purposes.

26. Pharmacy practice means the use of pharmaceutical qualifications of individuals for drug trading.

27. Good practice means sets of principles and standards promulgated by the Health Ministry for manufacture, preservation, assay and circulation of drugs, and culture, cultivation, harvest and processing of materia medica.

28. Pre-clinical drug trial means scientific activities of studying the effects of drugs in order to evaluate and prove the effectiveness and safety of drugs on animals, as a procedural step for clinical trial.

29. Clinical drug trial means scientific activities of systematically studying the effects of drugs on human beings for the purpose of determining clinical effectiveness, recognizing and detecting adverse reactions of studied products; the absorption, distribution, metabolism and excretion of such products for the purpose of ascertaining the safety and effectiveness of drugs.

30. Drug information means activities of gathering and supplying information related to drugs to organizations or individuals directly engaged in medical or pharmaceutical activities or drug users.

31. Drug assay means the sampling and examination of technical standards, performance of corresponding and necessary tests for the purpose of determining whether or not raw materials, semi-finished products or finished products meet the technical standards before deciding to accept or reject such drugs.

32. Drug price declaration means reporting by drug-trading establishments to competent state agencies on expected import prices, wholesale prices and retail prices according to the provisions of law on prices.

Article 3.- State policies on pharmacy

The State shall materialize the following policies on pharmacy:

1. To develop pharmacy into a spearhead techno-economic branch, and prioritize the development of the pharmaceutical industry.

Projects on application of advanced technologies to manufacture of drugs, raw materials for drug manufacture, main drugs, drugs as substitutes for imported drugs, drugs for prevention and treatment of social diseases, vaccines, medical biological products, drugs from materia medica and traditional medicaments shall enjoy the investment preferences provided for by law;

2. To encourage organizations and individuals at home and broad as well as overseas Vietnamese to conduct scientific research into preparation technologies and biotechnologies for manufacturing new drugs; to invest in production of raw materials for drug manufacture and finished drugs suitable to the disease structure and drug use demands of people;

3. To encourage research into and inheritance of traditional medicine recipes and experiences, and harmoniously combine traditional medicine and modern medicine as well as pharmacy; to explore, exploit and use new materia medica and export materia medica; to materialize policies on

preferences and supports for culture and planting of materia medica, rational exploitation of natural materia medica, thus ensuring the preservation and development of genetic sources of materia medica; to modernize the manufacture of drugs from materia medica;

4. To provide drug-related supports in appropriate forms to social policy beneficiaries, areas inhabited by ethnic minority people, areas being under particularly difficult socio-economic conditions and areas under difficult socio-economic conditions;

5. To develop a network of circulation, distribution and supply of drugs, thus ensuring sufficient quality drugs to meet the people's drug use demands;

6. To protect lawful rights and interests of organizations and individuals in drug research, trading and use in Vietnam.

Article 4.- National drug reserve

1. The State sets up a national reserve of drugs for use for the following purposes:

a/ Preventing and combating diseases and epidemics, and overcoming consequences of natural calamities or catastrophes;

b/ Maintaining defense and security;

c/ Contributing to stabilizing the drug market.

2. The setting up, organization, management, administration and use of the national drug reserve shall comply with the provisions of law.

Article 5.- State management over drug prices

1. The State manages drug prices on the principle that drug-manufacturing, exporting, importing or trading establishments shall fix prices by themselves, compete with one another in price and bear responsibility therefor before law; and takes measures to stabilize market prices of drugs in service of public healthcare.

2. The Government stipulates in detail the management of drug prices suitable to the socio-economic situation in each period on the following principles:

a/ Drugs, before being circulated in the market, must have their prices declared or re-declared in case of any change thereof by manufacturing or importing establishments with competent state agencies, ensuring that drug prices at home are not higher than drug prices in regional countries which have healthcare and commercial conditions similar to Vietnam's;

b/ Drug-manufacturing or -importing establishments must be responsible before law for their declared prices;

c/ Drug wholesale or retail prices must be posted up;

d/ Competent state agencies shall publicly announce declared drug prices; and periodically announce ceiling prices of drugs paid with the state budget and medical insurance;

e/ The Health Ministry shall assume the prime responsibility for, and coordinate with the Finance Ministry, the Industry Ministry, the Trade Ministry, the Planning and Investment Ministry and other concerned state agencies in, performing the state management over drug prices as assigned by the Government.

Article 6.- Agencies in charge of state management over pharmacy

1. The Government performs the unified state management over pharmacy.

2. The Health Ministry is answerable to the Government for performing the state management over pharmacy.

3. Ministries and ministerial-level agencies shall have to coordinate with the Health Ministry in

performing the state management over pharmacy under the Government's assignment.

4. People's Committees at all levels perform the state management over pharmacy within their respective localities, as decentralized by Government.

Article 7.- Pharmacy inspectorate

The pharmacy inspectorate under the Health Ministry's Inspectorate has the function of specialized inspection of pharmacy.

The organization, functions, tasks and powers of the pharmacy inspectorate shall comply with the provisions of law on inspection.

Article 8.- Pharmaceutical societies and associations

1. Pharmaceutical societies and associations are socio-professional organizations of pharmacists and persons engaged in pharmacy.

2. Pharmacists and persons engaged in pharmacy have the right to join and found pharmaceutical societies and associations.

3. The organization and operation of pharmaceutical societies and associations shall comply with the provisions of law.

Article 9.- Prohibited acts

1. Trading in drugs without certificates of satisfaction of drug trading conditions.

2. Practicing pharmacy without pharmacy practice certificates.

3. Trading in drugs of unidentified origins, counterfeit drugs, drugs of inferior quality, expired drugs, drugs on the list of drugs banned from import, drugs subject to clinical trials, drugs not yet permitted for circulation, sample drugs used for registration or introduction to medical doctors.

4. Forging, renting, borrowing, leasing or lending pharmacy practice certificates or certificates of satisfaction of drug trading conditions.

5. Supplying untruthful information on or making untruthful advertisements for drugs, causing consumers' confusion; advertising drugs in contravention of historical and cultural traditions, ethics, fine traditions and customs of the Vietnamese nation.

6. Selling drugs at places which are not lawful drug-selling establishments.

7. Taking advantage of monopoly in drug trading to earn illicit profits, dumping drugs, raising drug prices in contravention of law.

8. Conducting drug sale promotion in contravention of law.

9. Selling drugs belonging to national target programs and aid drugs which are not for sale according to regulations; drugs supplied as humanitarian aid and non-commercially imported drugs.

10. Retailing prescription drugs without prescription.

11. Taking advantage of drug prescription to seek personal benefits.

12. Destroying precious materia medica sources.

13. Other acts which are strictly prohibited in pharmaceutical activities according to the provisions of law.

Chapter II

DRUG TRADING

Section I. DRUG TRADING CONDITIONS

Article 10.- Forms of drug trading

Drug trading covers drug manufacture, export, import, wholesale, retail, preservation service and assay service.

Article 11.- Conditions and competence for granting certificates of satisfaction of drug trading conditions

1. Drug trading is a conditional business line. Drug-trading agencies, organizations and individuals (hereinafter referred collectively to as drug-trading establishments) must have certificates of satisfaction of drug-trading conditions.

2. To be granted certificates of satisfaction of drug-trading conditions, drug-trading establishments must fully satisfy the following conditions:

a/ Having material and technical foundations and personnel with professional qualifications necessary for each form of drug trading;

b/ Having pharmaceutically professional managers who have been granted pharmacy practice certificates suitable to their trading forms.

3. Competence to grant certificates of satisfaction of drug-trading conditions is stipulated as follows:

a/ The Health Ministry shall grant certificates of satisfaction of drug-trading conditions to establishments manufacturing drugs, providing drug preservation services or drug assay services;

b/ Provincial/municipal Health Services shall grant certificates of satisfaction of drug-trading conditions to establishments conducting drug trading in other business forms, except for the cases specified at Point a of this Clause.

4. Competent state agencies defined in Clause 3 of this Article shall have to grant certificates of satisfaction of drug-trading conditions within thirty days after receiving complete and valid dossiers. In case of refusal to grant certificates, they must issue written replies clearly stating the reasons therefor.

5. The Government shall specify conditions for each form of drug trading; time limit, dossiers, procedures for granting, supplementing, renewing, extending or withdrawing certificates of satisfaction of drug-trading conditions.

Article 12.- Certificates of satisfaction of drug-trading conditions

1. A certificate of satisfaction of drug-trading conditions must clearly state the name, address, professional manager, trading form and scope of the trading establishment, and its valid term.

2. Drug trading establishments may operate only at the already registered places and within the trading scope already stated in their certificates of satisfaction of drug-trading conditions. Where their trading scope is broadened or their trading place is changed, they shall have to carry out procedures for supplementing or renewing their certificates of satisfaction of trading conditions.

Article 13.- Pharmacy practice certificates

1. To be granted a pharmacy practice certificate, applicants must fully satisfy the following conditions:

a/ Possessing professional diplomas and certificates suitable to requirements of each drug-trading form;

b/ Having practiced for at least between two and five years at a lawful pharmaceutical establishment for each trading form;

c/ Possessing professional ethics;

d/ Being physically fit for practicing pharmacy.

2. The following persons shall not be granted a pharmacy practice certificate:

a/ Those who are banned from practicing pharmacy under court judgments or rulings;

b/ Those who are being examined for penal liability;

c/ Those who are serving criminal sentences or rulings of courts, or executing decisions on application of administrative handling measures such as consignment into a reformatory or medical treatment establishment, or administrative probation;

d/ Those who are in the period of being disciplined in the form of caution or serving a severer disciplining form for their violations related to the medical or pharmaceutical profession;

e/ Those who have lost civil act capacity or restricted civil act capacity.

3. Competence to grant pharmacy practice certificates is provided for as follows:

a/ The Health Minister shall grant pharmacy practice certificates to individuals who register to practice pharmacy with foreign investment capital;

b/ Directors of provincial/municipal Health Services shall grant pharmacy practice certificates to individuals who register to practice pharmacy, except for the cases specified at Point a of this Clause;

4. The Government shall specify professional diplomas and certificates and duration of practice at pharmaceutical establishments for each form of drug trading; dossiers and procedures for granting, renewing, extending and withdrawing pharmacy practice certificates.

Article 14.- Fees for grant of certificates of satisfaction of drug trading conditions and pharmacy practice certificates

Drug-trading establishments applying for certificates of satisfaction of drug trading conditions, and individuals applying for pharmacy practice certificates must pay fees therefor according to the provisions of law.

Section II. CTURE

Article 15.- Rights of drug-manufacturing establishments

1. To enjoy capital, land and tax preferences and other preferences for manufacture of drugs in the domains specified in Article 3 of this Law and other relevant provisions of law.

2. To supply information on and/or make advertisements for drugs according to the provisions of law on advertising for the purpose of introducing and promoting sale of their products.

3. Other rights provided for by law.

Article 16.- Obligations of drug-manufacturing establishments

1. To comply with regulations on good practice in drug manufacture, distribution, preservation and assay, and relevant professional regulations.

2. To manufacture drugs in strict accordance with the registered manufacture process and quality standards; to report to competent state agencies on changes in the manufacture process.

3. To bear responsibility for the quality of drugs they manufacture and deliver from their factories only drugs up to the registered quality standards.

4. To have technical facilities and professional personnel satisfying requirements of inspection of quality and management of drugs they manufacture.

5. To keep samples of drugs in each manufacture lot for at least one year after the expiry date of such drugs; documents on manufacture and other documents necessary for the inspection and evaluation of all drug-manufacturing activities according to the provisions of law.

6. To monitor the quality of drugs they have manufactured and circulated in the market, and to recover drugs according to the provisions of this Law.

7. To register drugs; to declare drug prices before circulating such drugs in the market.

8. To pay damages to drug users in cases where damage is caused by their faults.

9. Other obligations provided for by law.

Article 17.- Drugs prepared at drugstores, medical examination and treatment establishments

1. Drugs prepared according to prescriptions at drugstores and drugs prepared at medical examination and treatment establishments shall not be subject to drug registration but shall only be dispensed or retailed at such establishments. Files on drug preparation must be kept for one year after such drugs are prepared.

2. Owners of drugstores, pharmaceutically professional managers of medical examination and treatment establishments shall bear responsibility for the quality of drugs prepared at their establishments; pay damages to drug users in case of damage caused by errors in drug preparation.

Section III. DRUG EXPORT AND IMPORT

Article 18.- Rights and obligations of drug-exporting or importing enterprises

1. To export, import, entrust the export or import and undertake entrusted export or import of drugs of types specified by the Health Ministry.

2. To comply with regulations on good practice in drug preservation and distribution, and declaration of drug prices.

3. To export or import only drugs satisfying the quality standards; to monitor and bear responsibility for the quality of drugs they have exported or imported for circulation in the market.

4. To pay damages to drug users in case of damage caused by their faults.

5. Other rights and obligations provided for by law.

Article 19.- Entrusted export or import of drugs

1. Drug-trading establishments have the right to entrust export or import of drugs.

2. The entrustment of export or import of drugs shall comply with the provisions of the Commercial Law and other relevant provisions of law.

Article 20.- Scope of import of drugs

1. Drugs with registration numbers in Vietnam may be imported without quantity limitations, except for vaccines, medical biological products and drugs on the list of drugs subject to special control, as provided for in Article 63 of this Law.

2. Drugs without registration numbers may be imported in specified quantities in the following cases:

a/ They contain pharmaceutical ingredients with or without registration numbers, which are, however, insufficient to fully meet treatment needs;

b/ They are imported to meet urgent needs of disease or epidemic prevention and combat, overcoming of consequences of natural calamities or catastrophes, and special treatment needs;

c/ They are imported in service of national health programs;

d/ They are donations or humanitarian donations;

e/ They are imported for clinical trials, for use as registration samples or for exhibitions or trade fairs;

f/ They are carried along for personal treatment;

g/ They are imported in other non-commercial forms.

3. The Prime Minister shall specify the import of drugs of types defined in Clause 2 of this Article.

Section IV. WHOLESALE OF DRUGS

Article 21.- Drug wholesale establishments

Drug wholesale establishments include:

1. Drug-trading enterprises;

2. Cooperatives or individual business households manufacturing or trading in materia medica, traditional medicaments and/or drugs from materia medica;

3. Sale agents for vaccines and medical biological products.

Article 22.- Rights of drug wholesale establishments

1. To purchase raw materials for drug manufacture, finished drugs, vaccines or medical biological products from drug-manufacturing or drug wholesale establishments.

2. To sell raw materials for drug manufacture, finished drugs, vaccines or medical biological products to establishments with drug-trading functions and to medical examination and treatment establishments.

Article 23.- Obligations of drug wholesale establishments

1. To preserve drugs under the conditions stated in drug labels.

2. To keep intact drug packing, not to change drug packing and labels. In cases where they change labels or packing of drugs already registered, written authorization of drug-manufacturing establishments and written approval of the Health Ministry are required.

3. To assure that the delivery, receipt and preservation of drugs are conducted by professionally qualified persons.

4. To keep vouchers and documents relating to each drug lot for at least one year after the expiry date of drugs.

5. To post up drug wholesale prices and comply with other regulations on drug price management.

6. To pay damages to drug users in case of damage caused by faults of drug-manufacturing establishments.

7. To comply with regulations on good practice in preservation, distribution or withdrawal of drugs and other relevant provisions of law.

Section V. RETAIL OF DRUGS

Article 24.- Drug-retailing establishments

1. Drug-retailing establishments include:

a/ Drugstores;

b/ Dispensaries;

c/ Drug sale agents of enterprises;

d/ Drug cabinets of health stations.

2. Medical examination and treatment establishments and drug wholesale establishments which wish to retail drugs must set up drug-retailing establishments.

3. The Health Minister shall specify geographical areas where drug-retailing establishments are

allowed to be set up in the form of dispensaries, drug sale agents of enterprises or drug cabinets of health stations in suitability with their socio-economic conditions, actual capability of medical workers and the people's medical examination and treatment demands in each period.

Article 25.- Professional qualifications of owners of drug-retailing establishments or drug retailers

1. Professional qualifications of owners of drug-retailing establishments are stipulated as follows:

a/ Drugstores must be owned by pharmacists of university degree;

b/ Dispensaries must be owned by pharmacists of intermediate or higher degree;

c/ Drug sale agents of enterprises must be owned by persons having professional qualifications of assistant pharmacist or higher qualifications;

d/ Drug cabinets of health stations must be owned by persons having professional qualifications of assistant pharmacist or higher qualifications; in the absence of such a person, drug cabinets of health stations must be owned by persons having professional qualifications of assistant doctor or higher qualifications;

e/ Drug-retailing establishments, which are specialized in selling traditional medicaments or drugs from materia medica, must be owned by pharmacists of intermediate or higher degree or persons having diplomas or certificates of traditional medicine or traditional pharmacy.

2. Drug retailers at drug-retailing establishments defined at Points a, b, c and e, Clause 1 of this Article must have professional qualifications of assistant pharmacist or higher qualifications; drug retailers at those defined at Point d, Clause 1 of this Article must be professionally qualified in medicine or pharmacy.

Article 26.- Operation scope of drug-retailing establishments

1. The operation scope of drug-retailing establishments is provided for as follows:

a/ Drugstores are allowed to retail finished drugs and prepare drugs according to prescriptions;

b/ Dispensaries are allowed to retail finished drugs;

c/ Drug sale agents of enterprises are allowed to retail drugs on the list of essential drugs;

d/ Drug cabinets of health stations are allowed to sell drugs on the list of essential drugs used for commune-level healthcare establishments;

e/ Traditional medicament- and herbal drug-retailing establishments are allowed to sell traditional medicaments and drugs from materia medica.

2. Drug-retailing establishments defined at Points b, c, d and e, Clause 1 of this Article are not allowed to sell habit-forming drugs and radioactive drugs.

Drug-retailing establishments are not allowed to sell pharmaco-chemical raw materials for drug manufacture.

3. The Health Minister shall provide for conditions for drugstores to prepare drugs according to prescriptions.

Article 27.- Rights of drug retailers and owners of drug-retailing establishments

1. Drug retailers shall have the following rights:

a/ To retail drugs to users;

b/ To refuse to sell drugs when prescriptions are improperly made or drug buyers are incapable of following necessary instructions;

c/ Drug retailers who are pharmacists of university degree shall have the right to substitute one drug with another having the same active ingredients, preparation form and dose when buyers so

agree;

d/ To exercise the rights of an owner of a drug-retailing establishment within the ambit of authorization.

2. Owners of drug-retailing establishments shall have the following rights:

a/ The rights defined at Points a and b, Clause 1 of this Article;

b/ To buy drugs from drug wholesale establishments for retail, and to buy raw materials for preparation of drugs according to prescriptions;

c/ To authorize their staffs who have the equivalent or higher professional qualifications to administer their establishments in their absence.

Article 28.- Obligations of drug retailers and owners of drug-retailing establishments

1. Drug retailers shall have the following obligations:

a/ To check prescriptions before selling drugs;

b/ To clearly write the names and concentrations of drugs on their packing when retailed drugs are not contained in their outer packing;

c/ To sell only drugs indicated in prescriptions, except for cases specified at Point c, Clause 1, Article 27 of this Law;

d/ In cases where drugs are substituted under the provisions at Point c, Clause 1, Article 27 of this Law, they are obliged to clearly write the names, contents, concentrations, quantities and use methods of substitute drugs in prescriptions and bear responsibility for such substitution;

e/ To be answerable to owners of drug-retailing establishments for their acts within the ambit of authorization.

2. Owners of drug-retailing establishments shall have the following obligations:

a/ To personally manage and administer all activities of their establishments;

b/ To post up the time of selling drugs; to affix retail prices on products, except where retail prices have been printed on products; not to sell drugs at prices higher than posted-up prices;

c/ To be responsible before law for all activities of their establishments, even in case of authorization.

3. Drug retailers and owners of drug-retailing establishments shall have to pay damages to drug users in case of damage caused by their faults.

Section VI. DRUG PRESERVATION SERVICES

Article 29.- Conditions on enterprises providing drug preservation services

Enterprises providing drug preservation services must attain the standards on good practice in drug preservation.

Article 30.- Rights of enterprises providing drug preservation services

1. To undertake to preserve drugs for organizations and individuals under preservation contracts.

2. To transport and deliver drugs to organizations and individuals when so authorized by service hirers.

3. To enjoy charges for drug preservation services.

Article 31.- Obligations of enterprises providing drug preservation services

1. To preserve drugs according to preservation requirements inscribed on drug labels and in contracts between parties.

2. To pay compensations for damage caused by breach of regulations in the course of drug preservation and transportation.

Section VII. DRUG ASSAY SERVICES

Article 32.- Conditions on enterprises providing drug assay services

Enterprises providing drug assay services must meet the standards on good practice in drug assay. In cases where assay laboratories of drug-trading enterprises wish to provide drug assay services, such enterprises shall have to carry out procedures for adding the function of providing drug assay services to their certificates of satisfaction of drug trading conditions as provided for by law.

Article 33.- Rights of enterprises providing drug assay services

1. To assay raw materials for drug manufacture, semi-finished drugs and finished drugs.

2. To notify assay results of assayed drug samples.

3. To enjoy charges for drug assay services.

Article 34.- Obligations of enterprises providing drug assay services

1. To bear responsibility for assay results of assayed drug samples.

2. To pay compensations according to the provisions of law to organizations or individuals for damage caused by wrong assay results.

Chapter III

DRUG REGISTRATION AND CIRCULATION

Article 35.- Drug registration

1. Bases for drug registration includes:

a/ Results of clinical trials of the effectiveness and safety of drugs, except for those exempt from clinical trials defined in Article 55 of this Law;

b/ Technical documents on drugs;

c/ Vietnam's national policies on drugs.

2. Establishments registering drugs must pay registration fee upon filing of dossiers according to the provisions of law.

3. Within six months after receiving complete and valid dossiers, the Health Minister shall grant drug registration numbers. In case of refusal to grant registration numbers, he/she shall have to reply in writing, clearly stating the reasons therefor.

4. The Health Minister shall specify procedures and dossiers for drug registration, the valid duration of drug registration numbers and the withdrawal of drug registration numbers.

Article 36.- Drug circulation

1. Drugs circulated in the market must fully satisfy the following conditions:

a/ Being up to the registered quality standards;

b/ Fully satisfying requirements on labeling of drugs according to the provisions of Article 37 of this Law and other provisions of law;

c/ Being packed with materials and in a form as required to ensure drug quality;

d/ Having a registration number, or having no registration number but being imported according to the provisions at Points a and b, Clause 2, Article 20 of this Law;

e/ Having their prices declared according to the provisions of this Law; for imported drugs, their prices must not be higher than those of drugs imported into regional countries with the healthcare

and commercial conditions similar to those of Vietnam at the same time.

2. Home-made drugs for national health programs and imported drugs specified at Points c, d, e and f, Clause 2, Article 20 of this Law must be used for proper purposes and objects; drug labels must comply with the provisions of Article 37 of this Law; and retail packing of such drugs must be printed with the words "Not for sale" except for cases defined at Point e, Clause 2, Article 20 of this Law.

Article 37.- Labels of drugs circulated in the market

1. A label of a drug circulated in the market must fully have the following contents:

a/ The names of the drug;

b/ The preparation form;

c/ The composition of the drug;

d/ Packing specifications;

e/ The name and address of the manufacturing establishment;

f/ The registration number, serial number of the manufacture lot, date of manufacture, expiry date.

g/ Conditions for drug preservation and other necessary information.

For specifics which are composed of single substances, their original names or international generic names must be shown below their specific names.

2. Drugs must have use instructions in Vietnamese.

Article 38.- Withdrawal of drugs

1. Drugs circulated in the market shall be withdrawn in the following cases:

a/ They are not of the right categories due to mistakes in the course of dispensing, delivery and receipt;

b/ They fail to fully satisfy the conditions specified at Points a, b, c and d, Clause 1, Article 36 of this Law;

c/ There are drug withdrawal notices of manufacturing establishments or Vietnamese or foreign agencies in charge of state management over pharmacy.

2. For cases of drug withdrawal defined at Points b and c, Clause 1 of this Article, before the withdrawal, there must be circulation termination decisions of the Vietnamese agency in charge of state management over pharmacy.

3. Upon receipt of drug withdrawal notices of manufacturing establishments or circulation termination decisions of the Vietnamese agency in charge of state management over pharmacy, drug-trading organizations or individuals, medical examination and treatment establishments, drug prescribers and drug users shall have to immediately terminate the trading, information, advertising, prescription, dispensing and use of the drugs stated in withdrawal notices.

4. Establishments importing, manufacturing, registering or supplying drugs shall have to organize the withdrawal subject to circulation termination and pay damages according to the provisions of law.

The agency in charge of state management over pharmacy shall have to inspect the organization of drug withdrawal.

5. The Health Minister shall specify the order and procedures of drug withdrawal, classification of withdrawal, scope of drug circulation termination and disposal of withdrawn drugs.

Chapter IV

TRADITIONAL MEDICAMENTS AND DRUGS FROM MATERIA MEDICA

Article 39.- Planting of medicinal herbs and raising of medicinal animals

The planting of medicinal herbs and rearing of medicinal animals and the process of harvesting and exploiting their products for manufacture of drugs must comply with the standards on good practice in, planting, rearing and harvesting of materia medica.

Article 40.- Quality of materia medica

Materia medica put in the manufacture and processing or weighed into traditional medicament doses must satisfy the quality standards. Organizations and individuals that supply materia medica must bear responsibility for the origin and quality of such materia medica.

Article 41.- Preservation of materia medica

1. Materia medica must be processed and preserved according to regulations after they are exploited or harvested. The level of residues of plant protection chemicals and preservatives must not exceed the permitted level.

The Health Minister shall specify the conditions for processing and preservation of materia medica and the permitted level of residues of plant protection chemicals and preservatives in materia medica.

2. When transported, materia medica must be packaged. Packing of materia medica must be affixed with labels showing the names of materia medica, places of manufacture, quality and packaging date.

Article 42.- Sale of traditional medicaments and drugs from materia medica at medical examination and treatment establishments

Traditional medicine doctors, traditional medicine assistant doctors and herbalists working at medical examination and treatment establishments are allowed to retail traditional medicaments and drugs from materia medica at such medical examination and treatment establishments.

Article 43.- Registration and circulation of traditional medicaments and drugs from materia medica

1. The registration of traditional medicaments and drugs from materia medica shall comply with the provisions of Article 35 of this Law and the following regulations:

a/ Traditional medicaments and drugs from materia medica manufactured at home or imported for circulation in the market must all be registered;

b/ Traditional medicament doses weighed according to prescriptions at traditional medicine examination and treatment establishments, unprocessed materia medica and processed pellets shall not have to be registered. Owners of retail establishments or medical examination and treatment establishments must bear responsibility for the quality of such types of drugs.

c/ The circulation and withdrawal of traditional medicaments and drugs from materia medica shall comply with the provisions of Articles 36 and 38 of this Law.

3. Drugs which are combinations of materia medica and pure active ingredients extracted from natural substances or synthetic chemical active ingredients shall comply with the provisions of this Law and not be allowed to be registered as traditional medicaments or drugs from materia medica.

Article 44.- Manufacture of traditional medicaments and drugs from materia medica

1. Establishments manufacturing traditional medicaments and drugs from materia medica from the stage of preparing finished products to the stage of packaging must abide by the regulations on good practice in manufacture of traditional medicaments and drugs from materia medica, and comply with the provisions of Section II, Chapter II of this Law.

2. Traditional medicaments and drugs from materia medica which are composed of materia medica

containing toxic, habit-forming, psychotrops or pre-substances must have their technical files clearly stating concentrations, contents, standards and assay methods of such materia medica.

3. The Health Minister shall promulgate a list and regulations on management of materia medica containing toxic substances, habit-forming substances, psychotrops and pre-substances.

Article 45.- Export, import, wholesale or retail of traditional medicaments and drugs from materia medica

The export, import, wholesale or retail of traditional medicaments and drugs from materia medica shall comply with the provisions of Sections III, IV and V, Chapter II of this Law.

Chapter V

PRESCRIPTIONS AND USE OF DRUGS

Article 46.- Prescriptions

1. Prescriptions serve as a lawful basis for the sale of drugs, dispensing of drugs, preparation of drugs, weighing of drugs according to prescriptions and use of drugs. The name of a drug written in a prescription must include its original name or international generic name, except for drugs containing many active ingredients.

2. The Health Minister shall specify prescriptions, groups of prescription drugs and the sale of drugs according to prescriptions.

Article 47.- Use of drugs

1. Drug users have the right to choose drug-retailing establishments to buy drugs.

2. When using prescription drugs, drug users must strictly follow instructions given in prescriptions. When using non-prescription drugs, drug users must strictly follow written use instructions as well as instructions of drug retailers.

3. After taking drugs, if their bodies show abnormal signs, drug users should promptly notify the nearest medical establishments, drug prescribers or drug retailers thereof for timely remedies.

4. Drug prescribers and owners of drug-retailing establishments shall have to notify competent health agencies of abnormal signs of drug users. Drug prescribers shall be held responsible for drug prescriptions they have made up.

Chapter VI

SUPPLY OF DRUGS IN MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 48.- Conditions for supply of drugs

1. The supply of drugs in medical examination and treatment establishments must comply with regulations on good practice in distribution and preservation of drugs and other relevant provisions of law.

2. Drug dispensers in medical examination and treatment establishments must dispense drugs strictly according to medical orders or drug prescriptions, clearly write the names and concentrations of drugs on their packing and give instructions to drug users.

3. Doctors, assistant doctors, nurses, midwives and convalescent attendants must not sell drugs to patients, except for cases specified in Article 42 of this Law.

Article 49.- Assurance of supply of drugs

1. Medical examination and treatment establishments shall have to assure the supply of sufficient quality drugs on the list of main drugs for use in medical examination and treatment establishments in service of emergency, medical examination and treatment needs at such establishments.

The Health Minister shall promulgate a list of drugs for emergency needs and their dose quantities,

a list of main drugs for use in medical examination and treatment establishments, and the supply of drugs in state-owned medical establishments, except for the purchase of drugs mentioned in Clause 2 of this Article.

2. The purchase of drugs on the list of main drugs by state-owned medical establishments and drugs paid with the state budget shall comply with the provisions of bidding law and ensure the following principles:

a/ Priority shall be given to purchase of home-made drugs of the same types, equivalent quality and at prices not higher than those of imported drugs;

b/ Bid-winning drug prices must not be higher than drug prices periodically announced by competent state agencies according to the provisions of Point d, Clause 2, Article 5 of this Law.

The Health Minister shall coordinate with the Planning and Investment Minister and the Finance Minister in guiding the purchase of drugs according to the provisions of this Clause.

Article 50.- Preparation of drugs in medical examination and treatment establishments

1. Medical examination and treatment establishments which fully satisfy the criteria and conditions for preparation of drugs shall be allowed to prepare drugs according to prescriptions for their treatment needs according to the provisions of Article 17 of this Law.

2. The Health Minister shall provide for the criteria and conditions for preparation of drugs in medical examination and treatment establishments.

Chapter VII

DRUG INFORMATION AND ADVERTISEMENT

Article 51.- Drug information

1. Drug information aims to provide instructions on rational and safe use of drugs to medical workers and drug users.

2. Drug information must be adequate, objective, accurate, truthful, easy to understand and not misleading.

3. Responsibilities for drug information are provided for as follows:

a/ Establishments manufacturing, buying, selling and supplying drugs are responsible for supplying drug information to medical officials and workers and drug users;

b/ Medical establishments are responsible for disseminating and managing drug information within their units;

c/ Medical officials and workers are responsible for supplying relevant drug information to drug users in the course of medical examination and treatment;

d/ The state management agency in charge of pharmacy is responsible for publicizing information on drugs.

4. Responsibilities to monitor adverse reactions of drugs are provided for as follows:

a/ Medical examination and treatment establishments, medical officials and workers are responsible for monitoring and reporting to persons in charge of such establishments and agencies competent to manage drugs on adverse reactions of drugs;

b/ In the course of circulation of drugs, drug-manufacturing and distributing establishments must monitor and report to persons in charge of such establishments and agencies competent to manage drugs on adverse reactions of drugs they have manufactured and distributed.

5. Organizations and individuals providing drug information shall be held responsible for such information.

6. The Health Minister shall have to organize the drug information system and monitor adverse reactions of drugs in order to assure the rational and safe use of drugs for people; and regulations on activities of drug information in medical establishments.

Article 52.- Drug advertisement

1. Drug advertisement must be conducted by drug-trading establishments or advertising service providers and comply with provisions of law on advertisement.

2. It is prohibited to use material benefits, or take advantage of names of organizations and individuals, assorted correspondence and clinical research results not yet recognized by the Health Ministry and similar forms to advertise drugs.

Article 53.- Scope of drug advertisement

1. Prescription drugs must not be advertised to the public in any form.

2. Non-prescription drugs are permitted for advertisement on various advertising means. Drugs advertised on radio or television must fully satisfy the following conditions:

a/ Having active ingredients on the list of drugs permitted for advertisement on radio or television, promulgated by the Health Ministry;

b/ Having registration numbers in Vietnam which are still valid.

Chapter VIII

CLINICAL TRIALS

Article 54.- Drugs subject to clinical trial

1. New drugs must be clinically tried.

2. Drugs subject to clinical trial must satisfy the following requirements:

a/ Having already been studied in the pre-clinical stage;

b/ Having a stable preparation form;

c/ Being up to the quality standards according to their clinical trial registration dossiers.

3. Labels of drugs subject to clinical trial must have the words "Product for clinical trial. Its use for other purposes is prohibited."

Article 55.- Drugs exempt from clinical trial

1. Drugs in their original names.

2. Foreign drugs which have not yet been granted numbers of registration in Vietnam but have already been lawfully circulated for at least five years in such foreign countries; have been widely used for many patients and certified as safe and effective by competent state agencies of the countries of manufacture; have the same way of taking, the same concentrations and indications in Vietnam identical to indications in such countries.

3. Traditional medicine recipes already recognized by the Health Ministry.

4. The Health Minister shall specify cases where drugs are exempt from clinical trial or exempt from a number of clinical trial stages.

Article 56.- Conditions of clinical trial participants

1. Clinical trial participants must be volunteers, satisfy professional requirements and enter into contracts with organizations undertaking to conduct clinical trials, except for those who have restricted civil act capacity, lost civil act capacity or no civil act capacity.

2. Where clinical trial participants are minors or persons who have restricted civil act capacity or

lost civil act capacity, their representatives' consent is required according to the provisions of law.

3. The Health Minister shall specify cases where clinical trial participants are pregnant women.

Article 57.- Rights of clinical trial participants

1. To be supplied with sufficient and truthful information on clinical trials before such trials are conducted and possible risks.

2. To be compensated for damage, if any, caused by clinical trials by organizations or individuals having drugs subject to clinical trial.

3. To have their relevant personal information kept secret.

4. To be free from liability for unilateral termination of contracts for participation in clinical trials.

5. To lodge complaints or denunciations about law violations by organizations or individuals having drugs subject to clinical trial or undertaking to conduct clinical trial.

Article 58.- Rights of organizations or individuals having drugs subject to clinical trial

1. To select organizations satisfying requirements on material foundations and professional personnel for clinical trial of drugs.

2. To own all research results of clinically tried drugs.

Article 59.- Obligations of organizations and individuals having drugs subject to clinical trial

1. To apply for written permits of the Health Minister before clinical trials are conducted.

2. To pay damages to clinical trial participants for risks caused by clinical trials according to the provisions of law.

3. To enter into contracts for clinical trials of drugs with organizations undertaking to conduct such trials.

Article 60.- Rights of organizations undertaking to conduct clinical trials of drugs

1. To be supplied with drugs and money by organizations and individuals having drugs subject to clinical trial strictly according to the provisions of law.

2. To use research results of clinical trials of drugs according to agreements with organizations or individuals having drugs subject to clinical trial.

Article 61.- Obligations of organizations undertaking to conduct clinical trials of drugs

1. To comply with regulations on good practice in clinical trials of drugs; to report on clinical trial process and results and make urgent reports in case of necessity to the Health Ministry.

2. To enter into contracts for clinical trials of drugs with organizations and/or individuals having drugs subject to clinical trial and with clinical trial participants.

Article 62.- Stages and procedures of clinical trials of drugs

1. Clinical trials of drugs must be conducted through various stages of and comply with regulations on good practice of clinical trial of drugs.

2. The Health Minister shall specify the conditions, dossiers, order and stages of clinical trial of drugs.

Chapter IX

MANAGEMENT OF HABIT-FORMING DRUGS, PSYCHOTROPS, PRE-SUBSTANCES USED AS DRUGS AND RADIOACTIVE DRUGS

Article 63.- Drugs on the list of drugs subject to special control

1. Habit-forming drugs, psychotrops, pre-substances used as drugs and radioactive drugs are those

on the list of drugs subject to special control.

2. The Health Minister shall promulgate a list of drugs subject to special control in compliance with treaties to which the Socialist Republic of Vietnam is a contracting party.

Article 64.- Conditions for trading in and use of drugs on the list of drugs subject to special control

1. Establishments trading in, preparing or dispensing drugs on the list of drugs subject to special control must satisfy the drug trading conditions provided for by the Government.

2. The import, export and transport of drugs on the list of drugs subject to special control shall comply with provisions of law.

3. Drugs on the list of drugs subject to special control shall be used for purposes of prophylaxis, treatment, diagnosis of disease, modification of physiological functions of human body and scientific research and must not be used for other purposes.

Article 65.- Responsibilities of establishments trading in, preparing or dispensing drugs on the list of drugs subject to special control

1. Establishments trading in, preparing or dispensing drugs on the list of drugs subject to special control have the following responsibilities:

a/ To make periodical or extraordinary reports to competent state management agencies;

b/ To keep vouchers and documents relating to each drug for at least two years after its expiry date.

2. The destruction of drugs on the list of drugs subject to special control must be conducted in strict compliance with the set order and procedures and in accordance with provisions of law.

Chapter X

QUALITY STANDARDS AND ASSAY OF DRUGS

Article 66.- Quality standards of drugs

1. Vietnam's quality standards of drugs include national standards and establishment standards.

2. The national quality standards of drugs and methods of assaying drugs are specified in the Pharmacopoeia of Vietnam.

Establishment standards shall be formulated and publicized by drug manufacturing establishments. Establishment standards must not be lower than the national quality standards of drugs.

3. The Government shall stipulate the promulgation of the Pharmacopoeia of Vietnam, the application of foreign and international pharmacopoeias in Vietnam.

Article 67.- Drug assay

1. Drug assay must be conducted in strict accordance with the registered drug quality standards of manufacturing establishments. Where assay methods other than those specified in the registered standards are applied, the Health Ministry's approval is required.

2. Where there is a doubt about the composition or quality of drugs, State-owned drug assay establishments may apply methods other than those specified in the registered standards to inspect and produce drug quality assay results.

3. The Health Minister shall specify the order and procedures for sampling and keeping of drug samples, and contents of drug quality assay.

Article 68.- Drug assay establishments

Drug assay establishments include state-owned drug assay establishments, enterprises providing drug assay services and drug assay laboratories of drug trading establishments.

Article 69.- State-owned drug assay establishments

1. State-owned drug assay establishments assist the state management agency in charge of pharmacy in ascertaining the quality of drugs.

2. State-owned drug assay establishments have the same rights and obligations as enterprises providing drug assay services defined in Articles 33 and 34 of this Law.

3. The Government provides for the organizational system and operation of State-owned drug assay establishments.

Article 70.- Settlement of complaints about drug quality conclusions

1. Drug trading establishments are entitled to lodge complaints about drug quality conclusions of the state management agency in charge of pharmacy.

2. The Government shall specify the order and procedures and designate agencies for settling complaints about drug quality conclusions.

Chapter XI

IMPLEMENTATION PROVISIONS

Article 71.- Transitional provisions

Organizations and individuals granted the certificates of satisfaction of pharmaceutical practice conditions before the effective date of this Law, which are still valid, shall not have to apply for re-grant thereof.

Article 72.- Implementation effect

This Law takes effect as of October 1, 2005.

All previous stipulations which are contrary to this Law are hereby annulled.

Article 73.- Provisions on implementation detailing and guidance

The Government shall detail and guide the implementation of this Law.

This Law was passed on June 14, 2005, by the XIth National Assembly at its 7th session.

THE NATIONAL ASSEMBLY

CHAIRMAN

(Đã ký)

Nguyen Van An

MINISTRY OF HEALTH	SOCIALIST REPUBLIC OF VIETNAM
No: 799/QĐ-BYT	**Independence - Freedom - Happiness**

Hanoi, date March 7th, 2008

DECISION

On the issuance of Guideline on "Good Clinical Practice"

MINISTER OF HEALTH

Pursuant to Decree No. 188/2003/NĐ-CP dated December 27, 2007 of the Government detailing functions, obligations, and authority and structural organization of Ministry of Health;

Pursuant to Decree No. 79/2006/NĐ-CP dated August 9, 2006 detailing on the implementation of provisions of Drug Law;

At proposal of Head of Department of Science and Training and Director of Vietnam Drug Administration,

DECIDES:

Article 1: To issue the "Guideline for Good Clinical Practice – GCP" (hereafter referred as Guideline for GCP) in conjunction with this Decision.

Article 2: Assign Head of Department of Science and Training to cooperate with related Departments to be responsible for propagating, instructing, monitoring, inspecting of the implementing and deploying of this Guidelines.

Article 3: This Decision takes effect since the issuing date.

Article 4: Chief of secretariat, Director of Health Inspector, Heads of Departments, Offices, and Entities attached to Ministry of Health, Manager of Health Departments of the provinces and centrally-run cities, Head of Health department of agencies shall implement this Decision.

Receipt:	**FOR THE MINISTER**
- As in Article 4; - Minister of Health; - Deputy Minister of Health - Vietnam Medical Association, Vietnam Pharmaceutical Association; - Ministry of Health's Website; - Keep as achieves at DST and DAV	**DEPUTY MINISTER** **Signed** **Nguyen Thi Kim Tien**

MINISTRY OF HEALTH

GUIDELINE FOR GOOD CLINICAL PRACTICE

Abbreviated: Guideline for GCP

Issued in the conjunction with Decision No: 799 /2007/QĐ-BYT

Date 07 month March 2007 of Minister of Health.

Chapter I

GENERAL PROVISIONS

1. Scope

This document instructs on the preparation of dossier, protocol, review process, approval and carry out the implementation, monitoring, checking and inspection Clinical trials in Vietnam in order to satisfy requirements of Good Clinical Trial of World Health Organization and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human use and comply with current legislation in Vietnam.

2. Subject

This guideline applies to organization, person whose activities relate to clinical trial of pharmaceutical product in Vietnam.

3. Definition

The terms in this Guideline are understood as below:

Clinical trial of pharmaceutical products

Clinical trial of pharmaceutical product is a scientific practice in human in order to identify clinical effect, detect unexpected adverse reaction of pharmaceutical product, the absorption, distribution, metabolism and excretion of pharmaceutical product so that the safety and the effect of pharmaceutical products are demonstrated.

Terms of “clinical trial of pharmaceutical products”, “Clinical trial” and/or “pharmaceutical products clinical trial” have the same meaning. Hereafter, only term of Clinical trial is used within this document.

Good clinical practice

Good clinical practice-GPC is an international standard guideline instructing the investigator, Head of Sponsor, researching staff, sponsor, aid agencies, competent authorities; reviewing committees (including scientific and ethnic committees) of assessing the ethics and science in designing, conducting, implementing, monitoring, and assessing, recording, analyzing and reporting clinical trials.

GCP assures the reliability, accuracy of reported data of clinical trial results and the international acceptance to clinical results together with simultaneously protects the safety and rights of trial subjects.

The term of Good Clinical Practice on pharmaceutical product is the same and translated from "Good Clinical Practice – GCP" in English. Within this document, it is unified to use term "Good Clinical Practice"

Investigator and research organization

Investigator (also known as researcher) is person responsible for conducting the clinical trial at the trial site. In case the clinical trial is conducted by cohort, group leader (also known as the principal investigator or the manager of the project) shall be essentially responsible for such clinical trial.

In addition to the principal investigator, there are also Investigators and collaborators including experts and local people who is under the instruction of principal investigator of project on assignment, management and monitoring in order to conduct researching process related to clinical trial.

Research organization (organization who conducts the clinical trial)

Research organization (organization who conducts the clinical trial) is medical unit which has functions in scientific research, has adequate man power and material facilities for the clinical trial which are reviewed and approved by MOH. Research organization is one to be responsible for legal matters concerning to the clinical trial.

Besides researching organization, there may be collaborative organization in addition to said stakeholder of the clinical trial if necessary. Such collaborative

organization assumes responsibility in several certain stages and/or parts of the clinical trial according to the allocation of researching organization.

Organization/person who have drug in clinical trial

Organization/person who have drug in clinical trial have function in researching, producing, importing, exporting or distributing drug which is in need of clinical trial.

Sponsor

The sponsor may be an individual, an enterprise or an entity or an organization. The sponsor assumes responsibility in proposal, management and/or financial supply of the clinical trial.

Institutional Review Board (IRB)/ Independent Ethics Committee (IEC)

Independent Ethics Committee-IEC (also known as Ethics Committee) which is an independent entity is established local or national level. IEC includes medical experts and non-medical members. IEC is responsible for reviewing the scientific aspects of protocol and matters related to subject's voluntarily so that the safety, rights, health of trial subjects and the publicity are assured and giving the approval or not to the clinical trial.

Investigator's brochures - IB

Investigator's brochures – IB is document recording clinical and pre-clinical data of investigational products, whose information needs to be brief, simple, clear and not to be advertisement in order to provide investigators needed information about investigational products and process to control safety – which allows clinical physician or investigator may understand and self-determine exactly the risk/benefit of the proposed clinical trial.

Standard Operation Practice

Standard of Practice (SOP) is document which is developed by related units to define activities and unified operations in order to get the agreements when implement.

Monitoring, audit

- Monitoring are those of clinical trial process to assure that the trial is conducted, recorded and reported in accordance with the research outline, standard operation process, GPC and other regulations being applied in the country.

- Monitor is a person entrusted by the sponsors or the investigators in an agreement, such person assume responsibility in monitoring and reporting clinical trial process and verifying the data.

- Audit

Audits are activities of competent authorities which base on the reviewing, evaluation of documents and report in order to checking the compliance to protocol.

- Inspection

Inspection is official inspection activity of related competent authorities to review the compliance to GCP.

Chapter II

TARGET AND PRINCIPLES OF GCP

1. Target of GCP

Target of the issuance of GCP as follows:

- To protect the trial subjects in clinical trial:

+ To assure the safety of the trial subject.

+ To assure rights or the trial subject including rights to be informed, to self-determine joining the research, to give up the research at the any time, to be protected individual information and other rights.

- To assure the quality of the research based on the scientific unity of the research process, research target, quality of the performance, monitoring made to the clinical trials.

- To assure the unity in the management process, monitoring, analysis and report made to the clinical trial, so that given out results are accepted under the international standard guidelines.

- To assure the reliability and the effective performance of the quality monitoring system.

2. Principles of GCP

GCP gives out 13 principles, each of them intends to obtain one ore more targets of GCP. The principles of GCP present the international recognition of ethic and quality target of clinical the trials.

There is no principle setting up the independent responsibility of each party joining the clinical trial (such as investigator, sponsor, IEC, IRB or competent authorities). However, all of 13 principles require for jointly liability of the related parties to the clinical trial. Principles of GCP include:

- ***Principle 1:*** The clinical trial should be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki.

- ***Principle 2:*** Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society.

- ***Principle 3:*** The clinical trial should be conducted only if anticipated benefits clearly prevail over the foreseeable risks. Scientific and social benefit should be carefully considered so that the rights, the safety and health of trial subjects are assured.

- ***Principle 4:*** The clinical trial should be conducted in strict compliance with the protocol approved by IEC, IRB and competent authorities.

- ***Principle 5:*** The approval to clinical trial, clinical trial methods of a certain product shall be carefully considered, such action must be supported by non-clinical, clinical information and other available research results relating to the product.

- ***Principle 6:*** The clinical trial should be conducted in the compliance with scientific protocol as specified in the approved research process.

- ***Principle 7:*** The trial subjects optionally agree to participate in the trial and those should be fully provided with information of the clinical trial as well as other related one. Trial subjects are entitled to request for the explanation, clarification of the information relating to the clinical trial and their own culture,

custom should be respected. Participating in the clinical trial, the trial subjects are provided healthcare services for free and this matter should be pre-notified. In case, the trial subjects are not qualified by the awareness or the legal personality to make the agreement, such agreement should be obtained from their legal representatives.

- ***Principle 8:*** The medical care given to, and medical decisions made on subjects should be the responsibility of the qualified physician in the clinical trials.

- ***Principle 9:*** Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s) in the clinical trials.

- ***Principle 10:*** All clinical trial information should be recorded, handled and stored in such way that allows accurate reporting, interpretation, monitoring the reliability thereof.

- ***Principle 11:*** The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulation of each country.

- ***Principle 12:*** Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP) and they should be used in accordance with the approved protocol.

- ***Principle 13:*** Systems that assure the quality and method for assuring the quality of every aspect of the trial should be fully implemented in the compliance with the Guideline for GCP and regulation of each country.

It is required to approach the principles of GCP from the position of a manager, law maker, sponsor or investigator. Each of such position should approach and apply the principles of GCP in the suitable way.

Chapter III

RIGHTS AND RESPONSIBILITY OF IEC, THE SPONSORS, INVESTIGATOR AND RESEARCH ORGANIZATION

1. Right of Independent Ethics Committee (IEC)

Review and approve for ethnic aspect of research and specific scientific aspect of protocol in clinical trial in which subjects is human according to regulations and consult to Minister for the approval before implementing trials as well as for the changes in implementing process.

2. Responsibility of IEC

- IRB/IEC takes responsibility for scientific and ethnic aspects of trial in order to assure rights, the safety and health of the trial subject, especially clinical trials with sensitive subjects.

IRB/IEC should conduct the assessment and reply for proposal of the clinical trial in an appropriate time and their opinion should be in written documents.

- *IRB/IEC should consider the followings:*

+ The scientific aspects of protocol

+ Related ethnic aspects and the compliance of other legislation applied in the trial

+ The assurance of the right of subjects, even in case subject does not finish the trial

+ Qualification and ability of Manager of trial and investigator

+ The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

+ Composition, Functions and Operations of IRB/IEC is stipulated in current guideline " Regulation of constructional organization and operation or the ethic Committee in medical research"

+ The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3

years after completion of the trial and make them available upon request from the competent authorities.

The investigators, sponsors or regulatory authorities may ask the IRB/IEC to provide its written procedures and membership lists.

2. Rights of the sponsor (organization or individual have researching drug)

- The sponsor may transfer any or all trial-related duties to the investigators or the research organization as recorded in the agreement. However, the ultimate responsibility for quality and integrity of the trial data always resides with the sponsor.

- The sponsor may establish and conduct the irregular or regular monitoring; such protocol is independent with the daily and/or regular, and/or irregular monitoring of the investigators, the research organization, Ethics Committee and competent authorities.

- The sponsor may apply the emergency measures to suspend or terminate the investigators, research organization's participation upon identifying serious infringements, noncompliance with the trial protocol or unexpected adverse reaction that seriously impact on health of the trial subjects.

- The sponsor may reserve the ownership of investigation results, rights to publish the investigation results, register of copyright, intellectual property right (if it satisfies the requirement as stipulated by law), right to publish document relating to the clinical trial in accordance with the applicable regulation and after get the agreement with Head of organization or individual having researching drug.

3. Responsibility of the sponsor

- The sponsor should draft and provide the investigator's brochures introducing, assuring quality as well as stability of the investigational products. The sponsor should be responsible for reliability of information related to the investigational product recorded in the investigator's brochures.

- The sponsor should provide investigator's brochures to investigator and should jointly assume responsibility in designing the research, the clinical trial protocol, and products of the sponsor.

- Submit investigator's brochure to competent authorites

- After obtaining the approval of Ethics Committee, Science Committee and the management office, the sponsor should sign a pharmaceutical product's trial agreement with the principal investigator (chief of the trial) and research organization (the entity that holds the trial).

- The sponsor assumes responsibility in manufacture, package, labeling and encoding the investigational products. Such products should be manufactured in compliance with the applicable GMP issued by the competent authorities in order to assure its quality. As to the trial wherein the blinding is conducted, the investigational products should be labeled, encoded and blinded in compliance with the approved protocol, and the product's label should be designed in accordance with the applicable regulation.

- The sponsor only provides the investigators with the pharmaceutical product after it is approved by the ethics committee and the competent authorities. The sponsor should assume the responsibility in revoking and destroying the unused, ruined and remained products after completing the clinical trial.

- The sponsor should monitor and control trial's quality, trial subject's safety and the adverse effects or inconvenience occurred to the trial subject as well as trial data, the compliance with approved protocol.

- The sponsor is responsible for regular and irregular reports on rate of progress, safety of the trial subjects, the compliance with the approved protocol, the management of investigational products as well as the safety and unexpected adverse reaction of the investigational products to IEC and the management office.

- The sponsor is responsible for management, accession and the confidentiality of the trial subjects, in cooperating with the investigator to comply with the approved protocol.

- After publishing the trial result and manufacturing the products, the sponsor also assumes the ultimate responsibility for the safety, quality of products as well as the diagnostic or treatment or prevention's effect of the investigational products.

- The sponsor should supply the investigator with finance and other resources in accordance with the approved outline and investigation agreement signed between the sponsor and the investigator.

- The sponsor should provide the investigator and the research organization with the compensation including financial and legal coverage for damage arisen (if any) in accordance with the applicable regulation, except that such damages arisen from negligent of the investigators and the research organization.

- The sponsor should provide the trial subjects with compensation including property and spirit and legal coverage in case of unexpected adverse reaction that seriously impact on research subject's health (such as death or invalidity. etc…). However, the compensation should be made in case such damage involves products that provided by the sponsor.

4. Right and responsibility of the principal investigator (manager of the research)

- The principal investigator may select investigators and management office and cooperate with related offices to propose to the sponsor.

- The principal investigator may select the laboratory that meets GLP's requirements in accordance with the applicable regulation. In case the selected laboratory does not satisfy requirement of GLP, it must be approved by an assessment committee established by the management office.

- The principal investigator should be paid for clinical investigational products. They may share responsibility and rights with the sponsor in the trial. Rights or the investigator and the research organization should be recorded in written documents in the research design and the research contract.

- They may publish the trial results provided that such action is agreed by the sponsor and it is recorded in written documents in the research contract.

- Discoveries of products that are not recorded in the approved research design or the research agreement should be own by the investigator.

- Rights to conduct the clinical trial, to select the trial subjects, to audit and monitor the clinical trial according to the approved trial design and protocol.

- Investigator may suspend or terminate the clinical trial if the unexpected adverse reaction that seriously affect the trial subjects and the community.

- They may propose the amendment of the research protocol to IRB/IEC, the sponsors and the competent authorities if it is necessary. Such amendment should be performed if it is approved in written by IRB/IEC, sponsors and the management office.

- The principal investigator may sign the trial agreement with the sub-investigator and/or incorporating entity to conduct any stage of the clinical trial or the medical care for the trial subjects (if any) in accordance with the approved research protocol.

5. Responsibility of the principal investigator

- The principal investigator is responsible for selecting qualified investigators, medical expert that educated in the fields related to the clinical trial and proposing them to the sponsors for assessment and approval.

- The investigator takes responsibility in drafting the outline of the research, trial protocol, process and standards for selecting trial subjects, coordinating with the sponsor to complete science profile, ethics documents in accordance with current Vietnam's regulation.

- The investigator assume the responsibility on negotiating, drafting and signing the research agreement with the sponsor (including finance for the research, assessment, approval, monitoring and management of the trial) and settling the payment in accordance with the research agreement signed between the investigator and the sponsor.

- The investigator is responsible to coordinate with the sponsor in submitting the trial document to IEB/IEC and the competent authorities for the approval.

- After obtaining the approval of IRB/IEC and the competent authorities, the investigator is responsible for conducting the clinical trial in accordance with the approved trial design. It is also responsible for obtaining the agreement of the consent from the trial subject and selecting trial subject in order to assure that such selection is random.

- The investigator assumes the responsibility for the compliance with the approved trial protocol. Any amendment (if any) made to such protocol is

performed only after it is approved by IRB/IEC and the competent authorities in written document. Such amendment should be reported to the sponsor.

- The investigator should conduct the procedure of blinding the products (if any) in compliance with the design, and assure the confidentiality of the blinding procedure. It should be decoded after finishing the trial or it is required by the sponsor, IRB/IEC and the management office in case of involving to the safety of the trial subjects.

- The investigator takes responsibility in recording, reporting and storing data, original profiles of the clinical trial and handling, analyzing data, making judgment and regularly/irregularly reporting to the sponsor, management office, IRB/IEC on sub-reaction, adversity, safety and effect of the investigational products. It is also responsible for drafting the final report of the clinical trial to the sponsor, management office, IRB/IEC and drafting checking over report as required by the competent authorities.

- The investigator is responsible for providing the sponsor, IRB/IEC or the competent authorities with the profile, data and other documents relating to the clinical trial if it is required in accordance with the applicable regulation. It is required to assist the auditor, monitor designed by the sponsor, competent authorities, IRB/IEC to audit, monitor and inspect the clinical trial.

- It is responsible for monitoring, storing and providing the investigational product to the subjects according to the approved trial design, protocol. Beside, it is required to take responsibility in revoking, managing and delivering remained product to the sponsor after finishing the clinical trial.

- The investigator is responsible for paying allowance (if any) to the trial subjects, medical caring trial subjects in compliance with trial design and conducting medical care that relating to the clinical trial.

- The investigator should provide the trial subjects with compensation including property and spirit and legal coverage in case of unexpected adverse reaction that seriously impact on research subject's health (such as death or invalidity. etc…) in such damage involves to incompliance to approved protocol.

6. Right of research organization

- Manage and control activities related to clinical trial

- Terminate or early finish if discovers any unexpected adverse effects of researching product which seriously impact to the health of subject or community.

7. Responsibility of research organization

- The research organization is responsible for assisting the investigators, sponsor, IRB/IEC and the management office in matters relating to resources (employment, properties including equipments, devices, etc.), legal basis and other condition of the clinical trial in accordance with the approved trial design and contract.

- Sign and liquidate the contract

- The research organization should coordinate with the investigator in monitoring, assuring the quality as well as effect and the safety of the clinical trial.

- The research organization should monitor regularly and report to sponsor, IEC and competent authorities according to regulation in protocol and contract.

- The research organization should comply with the Guideline for GCP, applicable guideline on ethics in research and clinical trial of Vietnam.

CHAPTER V

REVIEWING PROCEDURE AND APPROVAL FOR CLINICAL TRIAL

(Attached with diagram in reviewing procedure of dossier for clinical trial and check list of minimised documents needed for implementing clinical trial)

1. Registration of clinical trial

- Sponsor prepare for registration dossier including: form for proposal of clinical trial, proposal for principal investigator and research organization attached with product's dossier (according to form in annex 1, 2a and 2b).

- Submit above dossier to MOH (Department of Science and Training). Withthin 15 working days since the day of receiving completed dossier, MOH will reply to sponsor for next steps.

2. Design of protocol

Base on approved document of MOH, Sponsor cooperate with principal investigator to develop protocol of clinical trial (according to forms in annex 3, 4 and 5), that includes:

- Sponsor provides investigation's brochure, legal dossier and proposal for protocol to the Principal Investigator and management office.
- Principal Investigator in co-operation with sponsor and investigator group to develop the design of protocol, prepare the completed dossier, protocol and related legal dossiers as requested in the list of needed document to conduct clinical trial.

3. Submission of clinical trial's dossier.

Dossier of clinical trial should be sent to MOH (DST) to review, consider and approve. Responsibilites is assumed under of each unit as the following:

- Sponsor is responsible for submission of investigation's brochure and proposal of clinical trial to competent authorities to review and consider as stipulated in Guideline for list of document.

- Principal investigator and Management Office are responsible for submitting protocol to IEC for reviewing and approving as stipulated in Guideline for list of document.

Permanent staff of IEC and competent authorities are located at Department of Science and Training (DST-MOH). Only dossier submitted to MOH before 20th monthly (based on receiving date of Administrative department – MOH) can be reviewed in such month. For dossier submitted after that day will be reviewed in the next month.

4. Reviewing and approving for clinical trial.

- Reviewing the investigation's brochure

Within 30 working days after receiving completed application dossier, MOH will conduct a reviewing board according to legal regulation

- Reviewing application dossier

Within 30 working days after receiving completed application dossier, parallel with reviewing the IB, MOH will conduct the IEC meeting in medical research according to legal regulation.

- Informing the result

Within 15 working days after getting reviewing result of IB's reviewing board and IEC, DST will summary, complete the dossier and minute (according the form in annex 7) and inform to sponsor and management office to supplement, complete application dossier for clinical trial (if needed).

- Approving for clinical trials

Within 15 working days, DST will summary. Complete dossier and protocol of clinical trial to submit to Minister for approval.

Only application dossier approved by both above reviewing procedures (including reviewing IB and researching dossier) will be considered to approved by MOH.

MOH will inform sponsor and management office in case application dossier is not approved by any of two above revewing procedures or both.

CHAPTER V

IMPLEMENTATION AND CONDUCTING CLINICAL TRIAL

1. Implementing clinical trial

since application dossier is accepted to be legitimate, Ministry of Health shall hold a meeting between Science and Ethics Board to assess the dsier.

For dossier of clinical trial approved and accepted to be put into trial by Science and Ethics Board, the Board shall send conclusion and/or notification of acceptance to Ministry of Health. For dossier of clinical trial need to be corrected, the correction, repair, supplement and completment of protocol according to conclusion of Board shall be completed by Sponsor and investigator within at least of ten days counted from the end of Board's meeting. For application dossier of clinical trial not accepted by Science and Ethics Board, Ministry of Health shall issue a notification for Investigator and Sponsor right after recieving Board's conclusion.

After 15 working days counted from the date of recieving conclusion and/or notification of acceptance of Science and Ethics Board, Minister of Health shall issue a Decision of approving clincial trial protocol.

Sponsor and Investigator shall be conducted trial only after recieving notification of acceptance of Ethics Board and approval Decision of approriate authorities.

During the implementation, Sponsor only signs a contract with investigator being principal one (project manager) and research organization shall preside at trial. Enclosure sub-contracts (if any) when signing with research co-operation organizations and investigator shall be directly signed by leader of trial and approved by research organization (management organization).

3. Implementing investigation

Investigator provides investigational information for trial subject or legal representative to vulnerable subjects who are incapble of giving consent.

Collect volunteer willingness in participation of subject into agreement.

Organize, implement the investigation in accordance with approved protocol and procedure.

Investigator holds the implementation, records and monitors investigation regularly, updates data, keeps and preserves original data, keep confidence of each subject and requires specific person directly access to original data.

Investigator periodically reports each three months to sponsor, IRP/IEC on the safety of investigational products, side effects, progress, unexpectedly reports if these adverse effects seriously impact on subject's health. In case, it is found that the said effects seriously impact on subject's health, the investigator has right of stopping the investigation and shall immediately report in written document to sponsor, IRB/IEC and research organization.

Sponsor periodically performs the monitor, audit six months at trial site and sends monitoring report, audit to IRB/IEC and management office. During the process of monitoring, if sponsor finds out that the investigator do not comply with progress with serious level, investigator has the right of stopping the trial and sending report to IRB/IEC and management office and inform investigator.

- IRB/IEC execute an/a unnotified or periodical report planned, audited and sent to sponsors and investigator by IRB/IEC. Audit and monitor should be performed one time in at least on year.

- Management office may hold the inspection or audit based on report of investigator, sponsor, IRB/IEC and build audit and inspection plan and simultaneously inform relevant parts.

4. Finishing investigation

- Clincial trial which has approved decision of Minister of Health can be conducted.

- Procedures of clinical trial only can conducted affter having written agreement of subject or legal representatives of subject.

- Principal investigator and management office are responsible for conducting the research according to approved protocol design and procedures.

- Request of dossier and document in implementing duration to principal investigator and sponsoer is regulated in Guideline of document list. All documents used in clinical trial must be available in checking of sponsor or investigating of competent authorities.

- Principal investigator reports every 03 months to sponsor and IEC about safety of investigating product, adverse effects and rate of progress; irregular reports if has any serious adverse effect which serioulsy impact to subject's health. In that case, principal investigator has right to stop the clinical trial and immediately inform to sponsor, IEC and competent authorites by written document.

- Sponsor delegates Clinical Research Associate (CRA) to regularly monitor at least 6 months in field and send the report to IEC and competent authorities. In monitoring process, if sponsor discovers any serious incompliance, sponsor has right to stop the clinical trial and send the report to IEC, competent authorities and inform to Principal investigator.

- IEC conduct irregular checking and irregular checking which is planned by committee and inform to sponsor or principal investigator.

- Competent can conduct the inspection or checking which bases on report of principal investigator, sponsor and IEC. The inspection or checking must be planned and inform to related unit.

2. Record, report and statistical analysia

a. Record and report

- Principal investigator must ensure the accuracy and completeness of entry data. If clinical data is directly entered into computer, the investigator should ensure the legibility and unity in saving in accordance with regulation. Any change in personal receipt and data should be clear, not obscure the original entry and inform unit of measurement. The final report of investigator should conform to investigation protocol signed by sponsors, monitors, investigators and statisticians. Investigator should submit the coded list, identify trial subjects to regulatory authorities after finishing clinical trial and keep confidential.

- When using electronic data systems, sponsor should use legitimate data handling programs and standard operating process for these systems should be available. Sponsor should ensure the legibility in handling data, identify entry data of each trial subject by non-sense coding method, maintain list of people accepted to amend the data.

- Monitor should propose suitable measures to avoid losing data or disuniting data.

b. Statistical analysis

- Sponsor and investigator should gain agreement of location, statistician as well as information relating to statistical analysis, even name of the assigned statistician should be written in protocol of clinical trial. Kind of statistical analysis will be used should be pre-identified and written down in protocol. Any change in comparison with protocol in practicing should be disclosed at the final report. Statistical analysis is planned and implemented, evaluated by experienced and competent statistician. Investigator and monitor should ensure the integrity of data when handling.

- The result of statistical analysis in presentation should show out the importance of clinical trial. It should be taken into account confidential, unused or

unidentified data in statistical analysis, therefore, the measures of protecting, verifying and monitoring are required.

3. Monitoring and check/audit

- *Monitoring*

Objectives of monitoring are to protect rights and health of trial subject, consider data report, the implementation of investigator to ensure the accuracy, completeness and reality of data resource. Consider whether the implementation complies with protocol or changes in comparison the first protocol conform to GCP and management requirement.

Monitor should be appointed by sponsor and is a communication between sponsor and investigator.

Monitor should have specific clinical knowledge needed to monitor clinical trial, be familar with investigational products, protocol, written informed consent form and other written information to be provided to subjects, the sponsor's SOPs, understand GBP and management requirements which are being applied in each country relating to clinical trial.

The scope and nature of monitoring is to consider based on objective, purpose, design, complexity, blinding technique, size, endpoint of trial. There is a need for on-site monitoring before, during, after clinical trial. The responsibility of monitor is to monitor the process of clinical trial and ensure the investigation is conducted in accordance with GCP, to record, report data true according to procedure, management requirement and investigational ethics, to be a main line of communication between the sponsor and investigator.

Particular responsibility of monitor:

- Evaluating the site of clinical trial before, during, after conducting clinical trial

- Verifying qualification and resources of investigator

- Verifying for investigational products (storage time, condition provided for trial subject).

- Verifying that investigator follows the approved protocol and all approved amendment(s).

- Reverifying the consent of subject's participation in the trial and the compliance with procedure of selecting subject of investigator.

- Monitoring should be in accordance with standard operating procedures and sponsor's requirements. Monitor has responsibility of completing monitoring report according to sponsor's requirement.

- *Check/ Audit*

The objectivies of audit is to evaluate the compliance of investigator to protocol, of procedure, management of SOPs and GCP.

Sponsor appoints auditor in independence with clinial trial. Auditor should have qualification and experience in indepently auditing clinical trials.

Auditing procedure and plan and formality should be submitted to regulatory authorities. In case, there is a serious infringement of GCP, the audit report should be submitted to regulatory authorities, in general, the report should be submitted to the sponsor.

Audit is separated from monitor

4. Finish the clinical trial

Requirements of dossir and documents when finish the clinical trial of Principal Investigator and sponsor are included in Guideline of document list.

- When complete the clinial trial, even in case of stop or early finish for any reason, principal investigator must inventory researching drugs, payment and send reports to sponsor, competent authorities and IEC.
- Principal investigator is responsible for stored the original dossier for at least 15 years till the time sponsors inform that they want to take back the original dossier or inform that principal does not need to store this one.
- Principal write the clinical trial result according to stipulated forms, then send to sponsor, IEC and competent authorities to review.
- Competent authorities are responsible for setting up Committee and checking/evalutating the clinical trial result.
- Sponsor and Principal investigator set up the checking/evaluating document to liquidate contract after the trial is checked/evaluated.

- Sponsor takes back the products and conduct to destroy drugs togerther with destroying document sent to principal investigator and competent authorites.
- Sponsor pay the fee and handle all existing issues with principal investigaror before investigator submits the final report to sponsor.

5. Report and publication of clinical trial results

There are many kinds of reports and each kind has specific objective and conforms to a required form of each one according to guideline for GCP and of each countries with particular requirement.

- Monitoring report means a written report of monitor sent to sponsor after each trial site visit and/or clinical trial relating communication acccording sponsor's SOPs.

- Check/audit report is a written evaluation by the sponsor's auditor of the results of the audit, the report is independent of monitoring report.

- Clinical trial report is a written description of a trial report of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects.

- The clinical and statistical description, presentations, and analyses are fully integrated into a single report and comply with the guideline for structure and content of GCP.

- Unscheduled and/or interim report is a written report of intermediate results and their evaluation based on analyses performed during the course of a trial.

In addition to above mentioned reports, there also include other ones such as: investigational report, drug adverse report, sponsor's report, investigator's report, early finished report, final report.

- Final report is a complete description of clinical trial after finishing comprising description of clinical trial method (including statistic method) and relevant documents. The report is a presentation and evaluation of result, statistical analysis, ethics of clinical trial.

- The final report shall be written in a required form of each countries.

- Publication should be agreed by sponsor and written in investigation protocol and/or investigation contract. Publication and writing in press of trial results also depend on regulation of each publisher and scientific evaluation.

6. Finance in clinical trial

- Expenditure for clinical trial includes the fee paid for professional staff, lost material, support to the volunteer, insurance which principal investigator and management office cooperating with sponsor dicuss, develop and sign in a contract.

- Management expenditure for clinical trial (including: reviewing the dossier, holding the meeting of Committee, approving, conducting GCP training for investigator, monitoring, checking, investigating at site) is defined in contract which is agreed by sponsor and principal investigator.

- The payment for activities is responsibilities of sponsor, principal investigator and managing office which is stipulated in regulation and signed/approved contract.

FOR THE MINISTER

DEPUTY MINISTER

Signed

Nguyen Thi Kim Tien

1 – GUIDELINES FOR NEEDED DOCUMENT LIST BEFORE CONDUCTING THE CLINICAL TRIAL

No	Document name	Objectives	Responsibility of		Form
			Investigator/ Management office	Sponsor	
1.1	Application form for clinical trial	Provide summary product information about drug proposed for clinical trial and proposed principal investigator		√	Annex 1
1.2	Investigator's brochure	To improve for scientific information provided to principal investigator, which is available and related to researching product	√		Annex 2a, 2b
1.3	Application for approval of protocol		√		Annex 3
1.4	Protocol & CRF	Protocol provide detailed SOP, checking/audit, evaluation and CRF	√	√	Annex 4
1.5	Contract for clinical trial between sponsor and principal investigator/ management office	To prove for the agreement about finance aspect between sponsor and principal investigator/ management office	√	√	Annex 5
1.6	The agreement for participating which is signed between related unit, for example: - Investigator – investigator of sub entities between sponsor - Investigator /management office and authorities at site (if needed)	To confirm for the agreement to participate in clinical according to current regulation	√	√	

1.7	Information provided to subject + Information card and consent form (including suitable information to communicate to subject) + Any other information in written	To confirm for the voluntary to participate in clinical trial To prove that subject will be provided suitable information in written (including content and communication way) to assist for the handling the voluntary form To prove that selecting method is suitable and not forced – to ensure for the ethnic aspect in clinical trial	√ √	√ √	Annex 6
1.8	Insurance contract	To improve that the subject will have compensation if has damage in the trial	√	√	
1.9	Form for approval of IEC	Prove for the approval of IEC/MOH in clinical trial			Annex 7
1.10	Date of approval for dossier/ approval of basic reviewing committee/ independent IEC for the followings: + Protocol any any	To confirm the approval for clinial trial of of basic reviewing committee/ independent IEC. To confirm the version and approved	√	√	Minute of IEC

	admendement + Report for any disease case + Consent form + Any information in written to provide subject + Notice for selection of subject (if applicable) +Compensation for suject + Any documents represented for agreement	date of documents			
1.11	Members of IEC/MOH	To prove that IEC is established according to requirement of GCP	√	√	Decision in estb. of committee
1.12	Approval of competent authorities to protocol	To confirm the approval of competent authorities before conducting clinical trial according to current regulations	√	√	Decision for MOH's approval of protocol
1.13	CV and GCP certificate issued by MOH of investigators (including management officers of clinical trial, pharmacist	To prove for unified qualifications and abilities to conduct clinical trial and monitor/medically check to	√	√	
1.14	Institution obtained GCP requirement (site, document storage, monitoring, discussion area, official equipments...) and GLP requirements (standard lab, standard technical procedures...) or approval for instution by MoH.	To document ability of the institution, equipments for in-vitro testes of the trial.	√	√	
1.15	Sample of label (s) attached to investigational product container (s).	To document compliance with applicable labelling regulations and appropriateness of		√	

		instruction provived to the subjects.			
1.16	Instructions for handling of investigational products ans trial-related materials (if not included in protocol or Investigatior's Brochure).	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational products and trial-related materials.	√	√	
1.17	Shipping records for investigational products and trial –related materials.	To document shipment dates, batch numbers, and method of shipment of investigational products and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability.	√	√	
1.18	Certificate (s) of analysis of investigational products shippded.	To document indentity, purity, and strengthen of investigational products to be used in the trial.		√	
1.19	Decoding procedures for blinded trials.	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subject'treatment.	√	√	
1.20	Standard Operating Procedure (SOP) of techniques in the trial.	To document and ensure techniques used in the trial be consolidated, scientific, objective and accurate.			
1.21	Random list	To document that the method of subject selection is random.		√	

2- ESSENTIAL DOCUMENT FOR THE CONDUCT OF A CLINICAL TRIAL DURING THE CLINICAL CONDUCT OF THE TRIAL

	Tittle of Document	Purpose	Located in Files of		Sample
			Investigator /Institution	Sponsor	
2.1	Investigator's Brochure updates	To document that investigator is informed in a timely manner of relevant information as it becomes available.	√	√	
2.2	Any revison to: • Protocol/amendment(s) and CRF • Informed consent form • Any other written information provided to subjects. • Advertisement for subject recruitment (if used)	To document revisions of these trial-related documents that take effect during trial.	√	√	
2.3	Dated, documented approval/favourable opinion of Competent Authority/Independent Ethics Committee (IEC) of the following : • Protocol amendment (s) • Revision (s) of: - Inform Consent Form. - Any other written information to be provided to the subject. - Advertisement for subject recruitment (if used). - Any other documents given approval/favourable opinion. - Continuing review of trial (where required)	To document that the amendment (s) and/or revision (s) have been subject to Competent Authority/IEC review and were given approval/farourable opinion. To identify the version number and date of the document (s).	√	√	
2.4	Regulatory authority (ies) authorizations/approvals/notifications where required for: • Protocol (amendments) and other documents	To document compliance with applicable regulatory requirements.	√	√	
2.5	Curriculum vitae, GCP certificated for new investigators (s) or sub-investigators which issued by MoH	To document ability and feasibility to conduct the trial and/or medical mornitor the subjects.	√	√	
2.6	Updates to normal value (s)/range (s) for	To document normal values and ranges that	√		√

	medical/laboratory/technical procedure (s)/test (s) included in the protocol.	are revised during the trial.			
2.7	Medical centers/laboratory/technical procedures/testes: • Certificate or • Established quality control and/or esternal quality assessment or • Other validation (where required)	To document that tests remain adequate throughout the trial period.	√	√	
2.8	Documentation of investigational products and trial-related materals shipment.		√	√	
2.9	Certificate (s) of analysis for new batches of investigational products.			√	
2.10	Monotoring visit reports	To document site visits by, and findings of the monitor.		√	
2.11	Relevant communications other than site visits: • Letters • Meeting notes • Notes of telephone calls.	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event reporting.	√	√	
2.12	Signed informed consent forms.	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission.	√		
2.13	Source documents	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject.			
2.14	Signed; dated and completed case report forms (CRF).	To document that the investigator or authorized member of the investigator's staff confirms the observations recorded.	√ (copy)		√ (original)
2.15	Documentation of CRF corrections	To document all changes/additions or corrections made to CRF after initial data were recorded	√ (copy)		√ (original)

2.16	Notification by origination investigator to sponsor of serious adverse events and related reports.	Notification by origination investigator to sponsor of serious adverse events and proper related reports.	√		√
2.17	Notification by sponsor and/or investigator, where applicable, to regulatory authority (ies), IEC of unexpected serious adverse drug reaction.	Notification by sponsor and/or investigator, where applicable, to regulatory authority (ies), IEC of unexpected serious adverse drug reaction.	√		√
2.18	Notification by sponsor to investigator of safety information.	Notification by sponsor to investigator of safety information.	√	√ (where required)	
2.19	Interim and annual reports of IRB/IEC and authority (ies).	Interim and annual reports of IRB/IEC and authority (ies).	√	√ (where required)	
2.20	Subject identification code list	To document that investigator/institution keep confidential list of names of all subjects allocated to trial number on enrolling in the trial.	√		
2.21	Subject code log	To document the participation of the subjects by trial code.	√		
2.22	Investigatinal product (s) accountability at the site.	To document the investigational products have been used according to the protocol.	√	√	
2.23	Signature sheet	To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs.	√	√	
2.24	Record of retained body fluids/tissue samples (if any)	To document location and identification of retained samples if assays need to be repeated.	√	√	

3- ESSENTIAL DOCUMENT FOR THE CONDUCT OF A CLINICAL TRIAL

AFTER COMPLETION OR TERMINATION OF THE TRIAL

After completion or termination of the trial, all of the documents identified in section 1 and 2 should be in the file together with the following:

	Tittle of Document	Purpose	Located in Files of		Sample
			Investigator/Institution	Sponsor	
3.1	Investigational product (s) accountability at the site.	To document that the investigational product (s) have been used according to the protocol. To document the final accounting of investigational product (s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor.	√	√	
3.2	Documentation of investigational product destruction	To document destruction of unused investigational products by sponsor or at site.	√ (if destroy at site)	√	
3.3	Completed subject identification code list	To permit identification of all subjects enrolled in the trial in case follow up is required. List should be kept in a confidential manner and for agreed upon time.	√		
3.4	Final trial close-out monitoring report.	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files.		√	
3.5	Treatment allocation and decoding documentation.	Return to sponsor to document any decoding that may have occurred.		√	
3.6	Final report by investigator to IRB/IEC and regulatory authority (ies).	To document completion of the trial.	√		
3.7	Clinical study report	To document results and interpretation of trial.	√ (if applicable)	√	Annex 8

Annex 2a

INVESTIGATOR'S BROCHURE

(Apply to pharmaceutical products and traditional medicines)

1. Introduction

The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product (s) that are relevant to the study of the product (s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such ad the dose, dise frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-bevefit assessment of the appropriateness of the proposed trial. Fof this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.

This guideline delineated the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatoty authorities, a basic product information brochure, package leaflet, or labeling may be an appropriate alternativem provided that it inclides current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a vew indication), an IB specific to that vew use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures. More requent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with Good Clinical Practice, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Board (IRB)/Independent Ethics Committees (IECs) and/or regulatory authorities before it is included in a revesed IB.

Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator (s) and the investigators are responsible for providing the up-to-date IB to the responsible IRB/IECs. In the case of an

investigator sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, the he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol, as a the minimum current information described in this guideline.

2. General Considerations

The IB should include:

2.1. Title Page

This should provide the sponsor's name, the identify of each investigational product (i.e., research number, chemical or approved generic name , and trade name (s) where legally persissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.

2.2. Confidentiality Statement

The sponsor may wish to include a statement instruction the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.

3. Contents of the IB

The IB should contain the following sections, each with literature references where appropriate:

3.1.Table of contents

An example of the table of contents is given in Appendix 2.

3.2. Summary

A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmakinetic, metabolic, and clinical information available that is relevant to the stage of clinical development of the investigational product.

3.3. Introduction

A brief introductory statement should be provided that contains the chemicals name (and generic and trade name (s) when approved) of the investigational product (s), all active ingredients, the investigational products (s) pharmacological classd and its expected position within this class (e.g. advantages), the anticipated prophylactic, therapeutic, or diagnostic indication (s). Finally, the introductory statement should provide the general approach to the followed in evaluating the investigational product.

3.4. Physical, chemical, and pharmaceutical properties and formulation.

A description should be provided of the investigational product substance (s) (including the chemical and/or structural formulae, and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation (s) to be used, including excipients, should be provided and justified if clinically relevant. Instructions for the storage and handling of the dosage form (s) should also be given.

Any structural similarities to other known compounds should be mentioned.

3.5. Nonclinical studies

Introduction:

The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavourable and unintended effects in humans.

The information provided may include the following, as appropriate, if known/available:

- Species tested
- Number and sex of animals in each group
- Unit dose (e.g., milligram/kilogram)
- Dose interval
- Route of administration
- Duration of post-exposure follow-up
- Results, including the following aspects:
  - Nature and frequency of pharmacological or toxic effects
  - Severity or intensity of pharmacological or toxic effects.
  - Time to onset of effects
  - Reversibility of effects
  - Duration of effects
  - Dose response

Tabular format/listing should be used whenever possible to enhance the clarity of the presentation.

The following sections should discussion the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed). The relevance of this information to the proposed human dosing should be addressed. Whenever possible, comparisons should be made in terms of blood/tissue levels rather than on a mg/kg basis.

a) Nonclincal Pharmacology:
A summary of the pharmacological of the investigational product and, where appropriate, its significant metabolites stidied in animals, should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g., efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect (s)).

b) Pharmacokinetics and Product Metabolism in animals:
A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the lical and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.

c) Toxicology
A summary of the toxicological effects found in relevant studies conducted in different animal species should be described under the following headings where appropriate:
- Single dose
- Repeated dose
- Carcinogenicity
- Special studies (e.g., irritancy and sensitization)
- Reproductive toxicity
- Genotoxicity (mutagenicity)

3.6. Effects in Humans

Introduction:
A thorough discussion of the known effects of the investigational product (s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacidynamics, dise response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should be provided regarding results of any use of the investigational product (s) other than from in clinical trials, such as from experience during marketing.

a) Pharmacikinetics and Product Metabolisn in Humans
- A summary of information on the pharmacokineticsd if the investigational product(s) should be presented, including the following, if available:
- Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).
- Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.
- Population subgroups (e.g., gender, age, and impaired organ function).
- Interactions (e.g., product-product interactions and effects of food)

- Other phamarcokinetic data (e.g., results of population studies performed within clinical trial (s).

b) Safety and efficacy

A summary of information should be provided about the investigational products, (including metabolites, where appropriate), safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trials in humans (healthy volunteers and/or patients). The implications of this information should be discussed. In cases where a number of clinical trials have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data. Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications) should be usefull. Important differences in adverse drug reaction patterns/incidences across indications or subgroups should be discussed.

The IB should provide a description of the possible risks and adverse drug reactions to be anticipated on the basis of prior experiences with the product under investigation and with related products. A description should also be provided of the precautions or special monitoring to be done as part of the investigational use of the products.

c) Marketing experience

The IB should identify countries where the investigational product has been marketed or approved. Any significant information arising from the marketed use should be summaried (e.g., formulation, dosages, routes of administration, and adverse product reactions). The IB should also identify all the countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

3.7. Summary of data and guidance for the Investigator

This section should provide an overall discussion of the nonclinical and clinical data, and should summarise the information from various sources on different aspects of the investigational product(s), whenever possible. In this way, the investigator can be provided with the most informative interpretation of the available data and with an assessment of the implications of the information for future clinical trials.

Where appropriate, the published reports on trlated products should be discussed. This could help the investigator to anticipate adverse drug reaction or other problems in clinical trials.

The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial. This understanding should be based on the available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information on the investigational product(s). Guidance should also be provided to the clinical

investigator on the recognition and treatment of possible overdose and adverse drug reactions that is based on previous human experience and on the pharmacolocy of the investigational product.

Annex 2b

INVESTIGATOR'S BROCHURE

(Apply to vaccine and medical biological products)

1. Introduction

The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product (s) that are relevant to the study of the product (s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such ad the dose, dise frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-bevefit assessment of the appropriateness of the proposed trial. Fof this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.

This guideline delineated the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatoty authorities, a basic product information brochure, package leaflet, or labeling may be an appropriate alternativem provided that it inclides current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a vew indication), an IB specific to that vew use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures. More requent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with Good Clinical Practice, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Board (IRB)/Independent Ethics Committees (IECs) and/or regulatory authorities before it is included in a revesed IB.

Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator (s) and the investigators are responsible for providing the up-to-date IB to the responsible IRB/IECs. In the case of an

investigator sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, the he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol, as a the minimum current information described in this guideline.

2. General Considerations

The IB should include:

- Title Page

This should provide the sponsor's name, the identify of each investigational product (i.e., research number, chemical or approved generic name , and trade name (s) where legally persissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.

- Confidentiality Statement

The sponsor may wish to include a statement instruction the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.

3. Contents of the IB

The IB should contain the following sections, each with literature references where appropriate:

3.1. Summary

A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmakinetic, metabolic, and clinical information available that is relevant to the stage of clinical development of the investigational product.

3.2. Introduction

A brief introductory statement should be provided that contains:

- Investigational product name (generic and trade name (s) when approved)
- Physical property
- Component in a human single dose:

+ Active ingredients.
+ Excipients (if used)
+ Preservative (if used)
+ Stabilizer (if used)

- Indications
- Considering indications (if any)

- Contra-indication (if any)
- Interactions (if any)
- Presentation
- Storage and delivery
- Shelf life

Finally, the introductory statement should provide the general approach to the followed in evaluating the investigational product.

3.3. Nonclinical studies

The results of all relevant nonclinical studies as specific safety, general safety, potency, immunogenicity, pyrogen … should be provided in summary form. However, application of nonclinical trial should be depended on substance of each vaccine.

This summary should provide used method, result and their comparison with permitted specifications (if available).

- General requirements for all clinical trials:
  + Species tested
  + Species of animal
  + Number, sex, old, weight of animals in each group
  + Unit dose: immunological dose, route.
  + Total immunological dose
  + Dose interval (if vaccine with schedule of more than 2 doses)
  + Route of administration
  + Duration of post-exposure follow-up
  + Results, including the following aspects:
    - Method of result assessment: the specifications of assessment will be different basing on each trial, e.g., health status, weight, temperature, specific symptoms…
    - Time to onset and duration of symtoms
    - Specific result of investigational products
      - Substance and frequency of pharmacology or toxic effects.
      - Severity or sensitivity of pharmaxological and toxic effects.
      - Time to onset of effects
      - Reversibility of effects
      - Duration of effects
      - Dose response

The following sections should discussion the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed). The relevance of this information to the proposed human dosing should be addressed.

a) Nonclincal Pharmacology:

A summary of the pharmacological of the investigational product and, where appropriate, its significant metabolites stidied in animals, should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g., efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect (s)).

b) Pharmacokinetics and Product Metabolism in animals:
A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the lical and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.
c) Specific safety
- Determine reviving ability of vaccine attenuated strains.
- Detemine inactivation of inactivated vaccines.
- Determine inactivation and reviving ability of toxoid.
If investigational vaccine is proposed to trial on different administrations, safety and toxic studies in proper animal are required.
c) General safety
General safety trial should conduct following with WHO requirement for each vaccine which orgines from bacteria and virus.
d) Potency and immunogenicity
- Potency: summary of toxicology in relavant studies should be described as following titles:
  + Single dose
  + Booster dose
  + Oncology
  + Specific studies (e.g., anaphylactic, allergic…)
  + Toxic on reproduction
  + Genetic change

- Effects in Humans:

Introduction:
A thorough discussion of the known effects of the investigational product (s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacidynamics, dise response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should be provided regarding results of any use of the investigational product (s) other than from in clinical trials, such as from experience during marketing.

The potency trial can conduct during time of vaccine development. There are many different method to conduct the potency trial. The best is challenge method (e.g., rabid vaccine, pertussis vaccine..). An other method can be

used is seroconversion determination. However, chemical property assessment can be acceptable with vaccine which their antigen is polysaccharide.

Nowaday, potency trial in living organism intends to be replaced by in-vitro testes when the knowledge of immunogenicity and protection of vaccine is increasing.

- Immunogenicity:

Data of immugenicity studies on animal model can support to select dose, schedule, route which will assess in the clinical trial. Nonclinical trial should be designed to assess relevant immuno respond, e.g., seroconverion rate, GMT, cell-mediated immuno respond in the animals. In case vaccine contains many antigents, the trial of immunogenicity should be conducted in each kind of antigen. Although immunogenicity is necessary during time of vaccine development, it is always not a specification for release (e.g., conjugated Hib vaccine).

- Pyrogen: This trial is conducted following WHO requirement
- Some other remarkable aspects:

+ Adjuvant: Adjuvant used in vaccine must be obtained with national pharmacopie requirement and do not have unexpected reaction. The evidence of interaction between adjuvant and antigen should be provide (can use result of studies which were conducted in the past). In case of adjuvant is new without toxic studied data, it must study toxicology for such adjuvant firstly. Nonclinical study should assess the combination between adjuvant and antigen when they are formulated and became vaccine.

+ Excipient and preservative: If these material are new for use, the toxicology study of each material is required.

+ Some vaccine should be notified:

Combined vaccine: The combination of antigen or sero type should be studied about immunogenicity in animal model before its clinical trial is conducted. Combination assessment by comparing between separated antigens in animal to determine immuno respond is the best way.

The interfere between the live vaccine strains should be studied on immunogenicity in animals.

- ADN vaccine: base on guildance of WHO on assessment the quality of ADN vaccine to conduct the pre-clinical assessment

- recombinant vaccine: Base on guildance of WHO on assessment the quality of recombinant vaccine to conduct the pre-clinical assessment

- peptit synthetic vaccine: Base on guildance of WHO on assessment the quality of peptit synthetic vaccine to conduct the pre-clinical assessment.

- Live attenuated vaccine: The major concerns for this type of vaccine is the ability to recover the toxic, transmit and exchange the genetic information which apply on wild strains or other biological strains. Results to recongnise the attenuated strains should be indicated (genetic order). It can be continue to use in the clinical study to monitor the results of eliminated agents and duration of all stages of clinical assessment. OPV vaccine (Oral Polio Vaccine) is a typical example for attenuated vaccine.

a) Pharmacokinetic and metabolism agents in animals.

It is necessary to summary the information on pharmacokinetic of investigations drug (s) including the below information, if any:

Pharmacokinetic (include metabolism, aborbtion, binding ability with plasma protein, distribution and eliminate)

Bioavailibility of investigational drug (abolutely, relatively) which use other dosage form to control.

The sub population (for example sex, age, function of organization will be impaired)

Interation (for example the interaction between the products and affects by food)

Other pharmacokinetic (for example the results from population which conducts in the frame of clinical studies).

b) Safety and Efficacy

It is necessary to provide the summary of information of safety of investigational drug (include the metabolized agents if have), pharmacokinetic, efficacy, dosage respond which had in previous studies in human (in healthy volunteer and/or patients). The raising matters from this information should be exchanged. In case when several clinical studies were completed, the usage of summary information on safety many times through the indications in sub-population also brings the benefit to make data clearly. Summary by tables about adverse events in clincal studies (include the indications which were studied)

The major differences between forms/hypersensivity in these indications or in sub-group should be exchanged.

IB need to provide the description about risks and anaphylactic shock that can be occured in order to estimate which base on the previous experiences of investigational drug and relevant product. It is necessary to provide the

description about precautions or special follow up as a part of investigational vaccine.

c) Advertisement

IB should be clearly state the countries which investigational vaccine were advertised or approved. Any significant information which arise from usage of vaccine in market should be summary (for example the way to prepare the vaccine, dosage and route of administration and adverse events of investigational vaccine). IB should be clearly state the list of countries which not approve for investigational vaccine or withdraw from market/registration.

- *Summary the data and instructions for investigators.*

This section should provide, exchange the pre-clinical data and clinical data and summary the information from different sources on different aspects of investigational drug (s). Follow this way, investigator should be provided the explainations which consistent with available data and the treatment with information arise from future clinical study.

If can, the document which public for relevant product should be exchanged. It will help the investigator to know the anaphylactic shock or other matters in the clinical study.

The overall objectives of this section will provide the investigators more clear about risks and anaphylactic shock can be occured, and for detail experiments, obsevations and precautions that needed in the clinical study for investigational drug. It is necessary to have guildance for clinician investigator about the way to recognize and treatment when overdosage and adverse events can be occured on human base on experiences and characteristic of investigational drugs.

Annex 3

(Form of Application for clinical trial)

SOCIALIST REPUBLIC OF VIETNAM
Indepence – Freedom - Happiness

……., date … month … year …

APPLICATION FOR CLINICAL TRIAL

To: Ministry of Health
(Department of Science and Training)

Full name of Principal Investigator:

ID or Passport number:

Presidential organization:

Office address:

Tel: Fax:

Email:

Account number:

Would like to request Ministry of Health to consider and approval for conducting the clinical trial:

◊ Name of drug

◊ Batch Number

◊ Strength

◊ Content

◊ Dosage form

◊ Route of admistration

◊ Shelf life

Classification:

◊ Western Medicine

◊ Oriental Medicine

- ◊ Vaccine
- ◊ Bio-pharmaceutical product

Request to conduct of clinical trial on the stage

Or propose to conduct of clinical trial from stage... to stage

The clinical trial for said drug was finished on the stage

Accompanied documents

Request the Ministry of Health considers and permit the above drug to be conducted clinical trial.

Principal Investigator and Presidential agency (The organization accept to conduct the clinical trial) commit to implement the ethics principles which stated in the protocol endorsed by Ministry of Health in right way.

Principal Investigator

Head of Presidential Agency (Organization accept to conduct the clinical trial)

Signed and sealed.

Annex 4

Ministry of Health
THESIS OF THE CLINICAL TRIAL

I. General information of clinical trial

1. *Title*	**2**. *Code*
3. *Time of conducting* (From..../200.. to ..../200..)	**4**. *Under management of* State leve ☐ Ministry/ Local ☐. Province
5. *Expense* Total: In which, from SNKH national budget: From other sources: please indicate resource's name	
6	The study applying for conducting the clinical trial on state (please indicate) ☐ Or proposing to conduct clinical trial on the stages (please indicate) ☐
7 *Principal Investigator* Full name: Academic tilte/Diplomas: Scientific title: Tel: (Office)/ (Home phone) Fax: Mobile: E-mail: Office address: Home address:	
8 *Presidential entity (Agency, organization accept to conduct the clinical trial)* Name of agency, organization: Tel: Fax: E-mail: Address:	

9	*Agency or individual who order the clinical trial (the agency that is permitted to use the copyright of the products to be subjected to clincal trial and the clinical trial result in order to manufacture or to use such products or to conduct the trial on the next stage)*

Name of organization:

Tel: Fax: E-mail:

Office Address:

Name (in case the individual orders):

Academic title/Diplomas:

Scientific title:

Tel: (Office)/ (Home) Fax:

Mobile:

E-mail:

Office address:

Home address:

Note:

In case the organization and individual need to interpret or supplement some section in this thesis, it may be longer, number of pages is not limited

II. Content of clinical trial

(To clarify the sections in accordance with the regulation on Clinical trial Regulations and the content of Experimental stages)

10	***Objective of the study***

11	***Background of the domestic/foreignes studies***

- Overview of the studied products

- Overview of the study of clinical trial

Foreign:

Domestic:

12	***Method of approaching, studying contend and technology to be used: indicate the method of approaching, study's design, method for selecting sample, size of samples, standard for selecting trial object, method of studying, technology to be used, standard operating procedures (SOPs) for each of technology that will be used in study – compre those with similar methods, quota of the study, the unique, the inventive step of the study design and method of studying)***

12.1 Place of study

12.2 Duration of study:

12.3 Method of study: Describing the type of study (random, blind, open), study's design (parallel group, capture technique), blind technique (single blind and double blind), and method and procedure to choose randomly.

12.4 Study's objects: Describing the objects of study (selected standards and exclusion of potential subjects), standards operating procedures (SOPs) applying for selection the objects who participate in the study: method, standards and time to indicate the subjects in studying groups.

12.5 Sample size: The quantity of subjects need to meet the objective of the study, which base on statistical mathemetic.

12.6 Schedule to use the investigational products: Build up the standard operating procedures (SOPs): Describing and detail the route for use, dosage, interval and treatment duration applying for investigational products and compared products. Person who has responsibility for technology, procedure for use the drugs. The criteria for monitor and assessment. The relationship of responded dosage should be intersted.

12.7 Spontaneous treatment: Any other treatments were identified and allowed to use spontaneously.

12.8 Usage testing: Develop the Standard Operating Procedures (SOPs): The clinical and

laboratory testing, pharmacological analysis,... testing will be implemented. Responsible people, procedure to take samples, storage, technical. The criteria for assessment, compare the results.

12.9 Assessment the side effects level: Describe the procedure how is a respond will be recorded (describe and assess the method and frequent of measure), process to monitor and measure to identify the compliance with treatment among the subjects.

12.10 Exclusived criteria of subjects in the process of study: Exclusived criteria for subjects and instructions on complete the whole study or a part of a study.

12.11 Record and report the adverse events: The method to record and report the cases of adverse events, relevant provisions relate to compliance.

12.12 Technical of blind and protect the identification of participated subjects: The procedures to maintain the list of identificated subjects, treated dossier, randomized list of subjects and/or case report forms (CRFs). The dossier must allow to identify the patients or parcipated subjects seperately as well as check and restructure the data.

12.13 Rules for open the code: Information on set up the code of the study, place to storage the list and who, when and how open the code in urgent cases.

12.14 Storage the investigational drug: Method will be implemented to ensure the safety of packaging and storage of investigational drugs and comparable products if use, and speed up and identify the compliance with the treatment and other guildance.

12.15 Method for assess the results: Describe the method which used to assess the results, (include the statistical method) and report of patients or subjects who will withdraw from study.

12.16 Method for handle the adverse events

12.17 The way to provide information for subjects: Information should be described for participated subjects, including how they will be provided information about the study, how and when collect their agreement.

12.18 Training for group of study: Training for group of study who participate in the clinical study (include Principal Investigator, Branch Principal Investigator, coordinate investigators, investigators, Pharmacist, nurse, technician): Basic content on the study, information of the way to conduct the study, standard operating procedures (SOPs) and procedures to manage and use the drugs.

12.19 Ethical matters: Precautions and methods of ethics relate to the study.

12.20 Caring the health of subjects after participate in the study: Caring the health of subjects after participate in the study should be provided, scheme of treatment after complete the study.

12.21 Plan of implementation

12.22 Plan of monitor, audit, inspection:

- Monitor the Principal Investigator and group of study
- Monitor of sponsor
- Monitor and audit of inspectors from competent authorities, Ethics Committee.

Contents of ethics in bio-pharmaceutical research:

(Include: Information about the study, informed consent form, agreement to implement the instructions on ethics in study)

13	***International co-operation***

Content of co-operation	Name of partners

14	***Implementation speed***			
No	Main works to be conducted (main milestones for the assessment)	Products to obtain	Duration (Start-End)	Performer
1	*2*	*3*	*4*	*5*

III. Study results

15	***Expected forms of study results***	
I	**II**	**III**
♦	♦	♦ Diagram
♦	♦	♦ Data table
♦	♦	♦ Analytical report
♦	♦	♦ Foreseeing document
♦		♦ Process of treatment
♦		♦
♦		♦

IV. Organizations/individuals joining the study

16	***Activities of organization co-operating to conduct the study (recording all organizations joining the study and their work within such study)***		
No	Name of organization	Address	Activity/contribution to the study
1			
2			
3			

17	***Team of investigators***		
No	Full name	Scientific title – place of work	Certificate of GCP training
A	Principal Investigator		
B 1 2 3...	Investigators		

V. Budget for conducting study and source of budgets (see the enclosed appendix for detailed explaination)

Unit: million VND

18	***Budgets for conducting the study assigned to expenses***						
No	Source of budget	Total	Wherein				
			Specialized rentals	Materials, energy	Equipment, specialized devices	Small construction, repairment	Other expense
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*
	Total Budgets Wherein:						
1	SNKH Budgets						
2	Other sources (details) Sponsor, purchase order of organizations, individuals - Other (mobilized capital, incidental capital....)						

....., date month year 200..

Head of Presidential (Full name, signature and stamp)

Principal investigator (full name and signature)

....., date month year 200..

For the Minister of Health
Head of Department of Science and Training

ESTIMATE OF EXPENDITURE FOR THE STUDY

Unit: Million VND

No	***Description***	***Total***		***Source***		
		Expenditures	***Percent (%)***	***SNKH Budget***	***Sponsor***	***Other***
1.	Specialized rentals					
2.	Materials, Energy					
3.	Equipment, specialized devices					
4.	Small construction, repairment					
5.	Other expense					

Explanation of expenditures
(million VND)

Item 1: Specialized rentals

No	***Details of rentals***	Total expenditure	***Source***		
			SNKH Budget	***Sponsor***	***Other***

Item 2: Materials, Energy

No	***Description***	***Unit of measurement***	***Quantity***	***Unit price***	***Amount***	***Source***		
						SNKH Budget	***Sponsor***	***Other***
2.1	*Materials*							
2.2	*Equioments, accessories*							
2.3	*Energy, fuels*							
	- Coal							
	- Electricity	kW/h						
	- Petrol, kerosene							
	- Other fuels							
2.4	*Water*	m^3						
2.5	*Purchasing book, reference documents, data*							

Item 3: Equipments, specilized devices

No	***Description***	***Unit of measurement***	***Quantity***	***Unit price***	***Amount***	***Source***		
						SNKH Budget		
3.1	*Purchasing technical device*							
3.2	*Purchasing testing means, measuring devices*							
3.3	*Equipment depreciation*							
3.4	*Facility rental*							
3.5	*Transportation and installation*							

Item 4: Small construction, repairment

No	Description	Expenditures	Sources		
			SNKH Budget	Sponsor	Other
4.1	Expenses for building m^2 facility, laboratory				
4.2	Expenses for repairing m^2 m^2 facility, laboratory				
4.3	Expenses for installation of water and electricity system				
4.4	Other expense				
	Total:				

Item 5: Other expense

No	Description	Expenditures	Sources		
			SNKH Budget	Sponsor	Other
5.1	*Expenditure for business trips*				
5.2	*Management of the entities*				
5.3	*Cost for assessments, checking and finalization*				
	- Validation fee				
	- Fee for approval the dossier				
	- Fee for audit				
	- Fee for monitor, intermediate finalization				
	- Fee for internal finalization				
	- Fee for official finalization				
5.4	*Other expense*				
	- Training				
	- Meeting				
	- Printing and stationery				
	- Translation				
	.....				
5.5	*Allowance paid for the principal investigator*				

Annex 5

(Form of Clinical trial agreement)

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom - Happiness

…….,date.....month.....year

CLINICAL TRIAL AGREEMENT

Legal basis: .....

Base on demand and capability of relevant parties:....

Representative of party A (Agency, organization, individual) who have drus to be subjected to clinical trial:

Full name: (Individual or Representative of Organization, who register for clinical trial:

Position:

Address: Office or private house (as to individual)

Tel:

Fax:

Email:

ID number or Passport number:

Representative of the party B (Agency, Organization who accept to conduct the clinical trial)

Full name: Individual and Representative of organization who accept to conduct the clinical trial:

Position:

Address (as to agency and Organization):

Tel:

Fax:

Email:

Together wish to enter into this clinical trial agreement for the drug product (product's name, concentration, content, formulation, route of administration, classification, indication, treatment, dosage and usage)

Request to conduct of clinical trial on the stage:

Or request to conduct of clinical trial from the stage.....to stage

Or request to conduct the assessment the tolerbility on Vietnamese people

With the following content:

1- Content of Agreement

2- Time and Schedule

3- Expenditure

4- Obligations of the Parties

5- Right of Parties

6- Common Regulations

Representative of the Party A	**Representative of the Party B**
(Signed. Stamped or certified by Local People's Committee where the invidual resides (in case of individual)	*(Signed and sealed)*

Annex 6

INFORMED CONSENT FORM

(including the provided information form and informed consent form)

Name of study:

Version: ICF Date …../…../……...

Name of sponsor:

Subject's code: ……

This document was informed to all participated subjects adequately, not omit any pages or any items. This content of the document should be explained clearly by oral to participated subjects.

1. Describle all matters related to the study

   Objectives of the study

   Estimated time

   Method of conducting (detail all contents will be conducted)

2. Inclusion criteria the subjects into the clinical trial
3. Exclusion criteria the subjects in clinical trial
4. Who will be person to assess the private information and medical information to select the subjects to participate the study?
5. Number of subjects will participate the study
6. Describe the risk and disadvantages
7. Describe the advantages of subjects or other people
8. Expenditures will be paid in the study
9. Publication the methods and alternative treatments
10. Describe the filing dossier confidentially but can regconise the title

11. Clearly point out the competent authorities that can check the dossier of subjects

12. Compensation / medical treatment if occurs the injuries (Where can have other information)

13. Person to contact when have the questions relate to

- The study
- The rights of subjects
- In case of having injuries relate to study

It is necessary to state that participation in the study is volunteer, not to be punish if refuse to continue to participate in the study at any time without lacking the rights.

Signature of volunteer subjects

Date of signing the consent form

Informed consent form

I,

_____

verified that

- I have read the information provided for the field trial..... .....at....., ICF version.....date...../...../....., page).....and I have been explained by investigators about this study as well as the procedures to volunteer the study.
- I have chances to ask all questions relate to this study and I satisfy with answers and explainations.
- I have time and chance to consider the ability to participate the study.
- I understood that I have rights to access the data provided in information sheet by responsible people
- I understood that I can withdrawn the study at any point with any reasons.

I agreed that our main doctors who take care my health will be informed the participation of myself in this study.

Tick in appropriate place (this decision will not affect on ability of yourself to participate in the study):

Yes	**No**

I agree to participate in this study:

Signature of subject …….....…	Date/month/year …….....……
If needed,	
* Signature of witness …….....…	Date/month/year …….....……
* Full name of witness …….....…	
Signature of guildance person …….....…	Date/month/year …….....……
Full name of guildance person …….....…	

Annex 7

FORM OF APPROVAL FOR CLINICAL TRIAL OF ETHIC COMMITTEE

Ministry of Health SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom - Happiness

No: …….. /HĐĐĐ ---------o0o--------

Regarding: Approval for DDNCYSH

Hanoi, date……month……..year

APPROVING CERTIFICATE OF ETHICS COMMITTEE IN BIO-PHARMACEUTICAL RESEARCH

Base on Decision No ……., date….month…year of Minister of Health on establish the Ethics Committee in bio-pharmaceutical research.

Base on the meeting minute of Ethics Committess in bio-pharmaceutical research of Ministry of Health date…month….year (please enclosed the meeting minute)

Ethics Committee in bio-pharmaceutical research approve on ethics aspect for the study:

1. Name of study:……...……...…….....……..…

2. Principal Investigator: …….…….....……..

3. Presidential organizations (Organizations to accept the clinical trial): …….....

4. Place of implementation.....……..

5. Studying time: ……

Approving date: Date…….month……year

Director of Committee

(Sign, full name)

ANNEX 8

Form of report on result of the study

Cover page 1

MINISTRY OF HEALTH

REPORT ON RESULT OF THE CLINICAL TRIAL

Title:

Principal Investigator:

Presidential organization (entities):

Management level: Ministry of Health

Implementation time: from month.....year..... to month.....year.....

Total expenses to implemen the studt.....million VND

Wherein: SNKH budget.....million VND

Other sources (if have).....million VND

Year 200..

Title page

REPORT
ON RESULTS OF THE CLINICAL TRIAL

1. Title of study
2. Name of investigational products
3. Content of the study (if not describe in the title of study, brief introduction (1-2 sentences) about design, comparative method, duration, dosage and populations)
4. Name of sponsor
5. Study code
6. Stage of the study.
7. Date of starting the study
8. Data of ending the study
9. Name and title of main investigator
10. Name of supervisor of sponsor.
11. Commiment to comply with Good Clinical Practice (GCP).
12. Reported date

Cover page 3

TABLE OF STUDYING SUMMARY

Cover page 4

ABBREVIATED WORDS

Cover page 5

CONTENT

THE NEEDED CONTENT IN THE SUMMARY REPORT

1) **Rationale**
2) **Objective of the study**
3) **Plan of the study**

3.1- Plan and design of study
3.2- Discussion on design of the study, slection of placebo
3.3- Selection the subjects of study (population) (inclusion, exclusion criteria, criteria to remove the participation of subjects or assessment)
3.4 Investigational products
3.5 Ensure the quality of data
3.6 Statistical method which is mentioned in the protocol and identification the sample size
3.7 Changes when conduct the study and analysis follow the plan.

4) **Subjects who participate in the study (patients/volunteer)**
   a) The situation of patients who participate in the study
   b) Errors compare with the protocol

5) **Assessment the efficacy**

5.1- Data is analized

It is necessary to identify these patients who will be used in the analysis for efficacy correctly, and these cases will be eliminated, reasons.

5.2- Characteristic of anthropology and the other basic features

Establish the summary table the characteristic of anthropology of each patient.

5.3- Identify the suitable of investigational drug

Summary and analysize any result which assess the suitable of each patient with dosage scheme in the study such as concentration of drug in biological solution according to the time

5.4- Treatment efficacy and data table for each patient

i) Efficient analysis
ii) Analysis/statistic
iii) Set up the data table of responde for each patient
iv) Dosage, concentration and relationship with respond
v) Interactions drugs-drugs, drugs-patients
vi) Describe the data of each patient
vii) Conclusion about the efficacy
viii)

6. Safety Assessment

Analysis the data relate to the safety which was mentioned on 3 levels:

- Exposed level (dosage, duration of usage, quantity of patients) will be checked in order to identify the safy level of investigational drug.
- Adverse events will be occurred in more common frequent or testings or changes will be identified, as well as the factors affect to frequent of ADR and undersirable effects.
- Serious undersirable effects, significant undersirable effects which common occurs in patients which withdraw from study before term or death patients although these advents relate or not to the investigational drugs.

7. Exposed level

Exposed level with investigational drugs (and controlled drugs or placebo) will be needed to assess according to the quantity of used patients, usage interval and dosage level.

8. Adverse events (AE)

Summary about AE
Describe the AE
Analysis the AE
List the AE for each patient

9. Deadth and other serious AE

List of deadth and other serious AE
Report the cases of deadth, serious AE and symptoms of the other AE
Analysis and discussion on deadth and other serious AE

10. Testing assessment

List down the testing value of each patient (annex) and abnormal value
Assessment each of testing parameter

11. Survival signals, physiological symptoms and other observations relate to the safety.

Analysis the survival signals, physiological symptoms and other observations

12. Safety conclusion

Summary about the safety of investigational drugs, especially focus on the changes of dosage, AEs lead to stop using, interfere of medical method or deadth….

13. Discussion and Conclusion

General assessment on the efficacy and safety of investigational drugs, relationship between the risks and benefits.

14. Table, diagram and related graph

15. List of reference document

16. Annex

List down the annex which have in the report

PROCESS OF APPROVAL, REVIEW DOSSIER FOR CLINICAL TRIAL

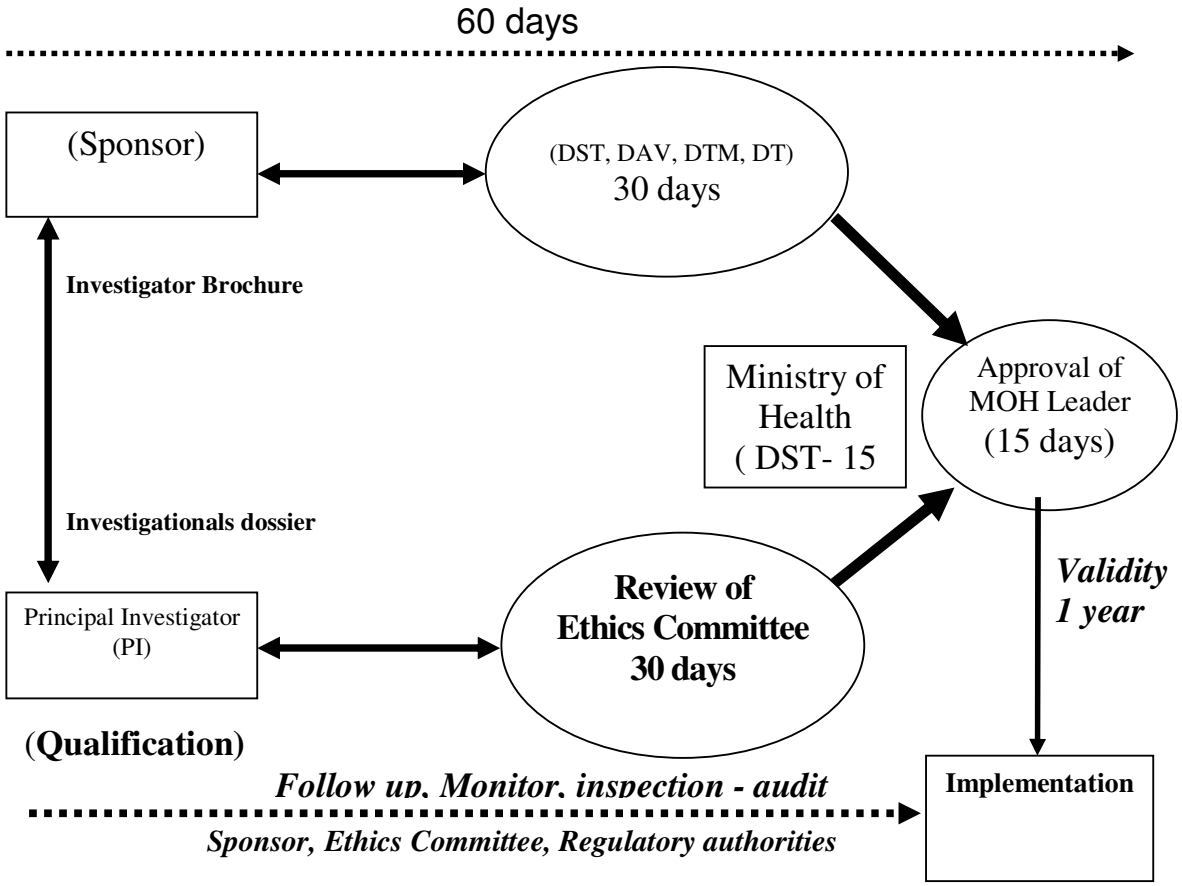

DST: Department of Science and Training

DAV: Drug Administration of Vietnam

DTM: Department of Traditional Medicines

DT: Department of Treatment

MINISTRITY OF HEALTH	REPUBLIC SOCIALIST OF VIETNAM
No: 03/2012/TT-BYT	**Independence – Liberty - Happiness**

Hanoi, 02 February 2012

CIRCULAR
Guidelines for Clinical trials on Drugs

Based on the Law on Pharmacy of 14.6.2005 and Decree No. 79/2006/ND-CP dated 09/08/2006 guiding implementation of some provisions of the Law on Pharmacy;
Pursuant to Decree No. 188/2007/ND-CP dated 27/12/2007 of the Government regulating functions, duties, powers and organizational structure of Ministry of Health,
The Ministry of Health provides the following guidelines for clinical practice for trials on Drugs:

Chapter I
GENERAL PROVISIONS

Article 1. Scope

This Circular provides guidelines for drugs subject to clinical trials, drugs exempt from full clinical trials, drugs exempt from some phases of clinical trials, conditions applying to the conduct for clinical trials; registration, review and approval of clinical trials, phases of clinical trials, rights and obligations of related parties and the supervision, inspection, evaluation for acceptability of clinical trials in Vietnam for research purposes and the marketing authorization of pharmaceuticals, biologics, vaccines and oriental medicines, drugs made of medicinal materials, used in the diagnosis, treatment and prevention of disease in humans (hereafter referred to as Drugs)

Article 2. Interpretation of terms
In this Circular, the following terms are construed as follows:

1. Reference country is any country among the UK, France, Germany, USA, Japan, Australia, Canada or the European Medicines Agency (EMA).

2. A multi-center clinical trial is a trial conducted in two or more research centers to ensure the inclusiveness of participants and demographic, anthropologic diversity.

3. Agencies, organizations, individuals having the candidate drugs are agencies, organizations and individuals with a mandate for research, production, import, export, distribution of medicines which are in need to undertake clinical trials on their drugs.

4. Host institutions (in receipt of the trials) are medical establishments with a mandate for scientific research, with functionally qualified personnel, premises, facilities and equipments to carry out clinical trials and which are appraised, authorized by the Ministry of Health to do so.

5. Trial subjects are patients or healthy individuals who participate voluntarily in clinical trials.

6. Clinical Research Organization (Contract Research Organization CRO) is an organization with legal status, with appropriately qualified personnel meeting Ministry of Health's requirements, is independent from the Agencies, organizations, individuals owing the candidate drug(s), which is contracted by the latter to perform trial-related duties the like of writing research protocol, trial monitoring, data analysis.

7. Site Management Organization (SMO) is an organization with legal status, functionally qualified in accordance with Ministry of Health's requirements, is independent from Agencies, organizations, individuals having the candidate drug(s) or the Host institution, which is contracted by either of the latter two entities to perform duties in support of the management of the trial site.

8. Foreign clinical data are methods and results of clinical studies which have been undertaken abroad.

9. Ethnic factors are factors related to large population with common genetic characteristics, culture, traditions and environment.

10. International regulations for clinical trial on drugs recognized by the Health Ministry are guidelines for good practices for clinical trials of jurisdictions party to the The *International Conference on Harmonisation* (*ICH*) and Guidelines for good clinical practice for trials on pharmaceutical products (Good Clinical Practice - GCP) of the World Health Organization (WHO).

Article 3. Principles of clinical trials

1. Clinical trials shall be conducted in accordance with the provisions of this Circular, regulatory requirements on science and technology, good clinical practice for trials on drugs and international treaties to which Vietnam is a signatory.

2. Selection of trial subjects shall be in compliance with ethical principles for biomedical research.

Article 4. Prohibited Acts

1. Conduct clinical trials without Ministry of Health's authorization.

2. Unilaterally amend, supplement the content of drug dossiers, research protocols after they have been approved by Ministry of Health.

3. Use the drug(s) under clinical trials for other purposes.

4. Coerce subjects into participating in trials or withhold information from, or not provide information as required to trial subjects.

Chapter II
DRUGS SUBJECT TO CLINICAL TRIALS, DRUGS EXEMPT FROM FULL CLINICAL TRIALS AND DRUGS EXEMPT FROM SOME PHASES OF CLINICAL TRIALS

Article 5. Drugs which are subject to full clinical trials

1. Pharmaceutical products, biomedical products:

a) Pharmaceuticals that contain a new active ingredient or products with new combination of a marketed ingredient.
b) Newly developed biologics or biologics with a new combination of a marketed ingredient.

c) Pharmaceuticals, biologics which have been legally marketed but for a period of less than 5 years in the country of origin (or a country of reference if provided for under international treaties to which Vietnam is a signatory).

d) Pharmaceuticals, biologics for which a clinical trial has been conducted before the effective date of this Circular but which has not met the requirements of Ministry of Health's good practice for clinical trials or those of international guidelines on good clinical practice for trials on medicines recognized by Ministry of Health.

2. Vaccines:

a) Newly developed vaccines, manufactured and put to use for the first time.

b) Foreign vaccines which have been legally marketed but for a period of less than 5 years in the country of origin (or a reference country if provided for under international treaties to which Vietnam is a signatory).

c) Vaccines for which a clinical trials has been conducted before the effective date of this Circular but which has not met the requirements of Ministry of Health's good practice for clinical trials or those of international guidelines on good clinical practice for trials on medicines recognized by Ministry of Health.

3. Oriental medicines or drugs made from medicinal materials:

a) Drugs containing new ingredients which are first used in humans.

b) Drugs for which a clinical trial has been conducted before the effective date of this Circular but which has not met the requirements of Ministry of Health's good practice for clinical trials or those of international guidelines on good clinical practice for trials on medicines recognized by Ministry of Health.

Article 6. Drugs which are exempt from clinical trials

1. Pharmaceutical products, biological products

a) Pharmaceutical drugs with non-proprietary name (Generic drugs).

b) Foreign drugs for which a registration number for marketing in Vietnam has not been granted but which have been legally marketed for at least 5 years in the country of origin (or a country of reference if provided for under international treaties to which Vietnam is a signatory) and which have been certified as safe and effective by the respective country's competent authority, for the same route of administration, formulation and indications with those intended for use in Vietnam.

c) Foreign drugs for which a registration number for marketing in Vietnam has been granted, but have undergone modifications or supplementations in relation to indications, route of administration, dosage forms identical with those of the same drugs which have been legally marketed in the country of origin

for at least 5 years (or a reference country if provided for by international treaties to which Vietnam is a signatory).

2. Vaccines:

a) Foreign vaccines with a valid registration number for marketing in Vietnam, which are imported into Vietnam for the final step of labeling, packaging.

b) Re-registration of vaccines in Vietnam due to expiry of existing marketing registration number without the vaccines undergoing any modification.

3. Oriental medicines, drugs made of medicinal materials:

a) Oriental prescriptions which have been recognized by the Health Ministry.

b) Oriental medicines, drugs made from foreign medicinal materials for which a registration number for marketing in Vietnam has not been granted but which have been legally marketed for at least 05 years in the country of origin (or reference country if provided for under international treaties of which Vietnam is a signatory) and which have been certified as safe and effective by the respective country's competent authority for the same route of administration, formulation and indications with those intended for use in Vietnam.

Article 7. Drugs which are exempt from some phases of clinical trials

1. Pharmaceutical products, biological products:
Foreign drugs for which a registration number for marketing in Vietnam has been granted but have undergone modifications or supplementations in relation to indications, route administration, dosage forms different from those of the same drugs which have been legally marketed for at least 5 years in the country of origin (or a country of reference if provided for under international treaties to which Vietnam is a signatory). These drugs are subject to:

a) Clinical trials for the assessment of safety;
b) Clinical trials for the assessment of effectiveness if this has not been performed before or if the assessment has been performed but it failed to meet the requirements of Ministry of Health's good practice for clinical trials or those of international guidelines for good clinical practice for trials on medicines recognized by Ministry of Health.

2. Vaccines:

Clinical trials for the assessment of safety shall be conducted for:

a) Foreign vaccines for which a registration number for marketing in Vietnam has not been granted, which have been legally marketed for at least 05 years in the country of origin (or reference country if provided for under international treaties to which Vietnam is a signatory) and which have been certified as safe and effective by the respective country's competent authority for the same route of administration, formulation and indications as those intended for use in Vietnam.

b) Vaccines manufactured in Vietnam from imported semi-finished products with components having been legally marketed for at least 5 years in the country of origin (or a country of reference if provided for under international treaties to which Vietnam is a signatory).

c) Vaccines for which a registration number for marketing in Vietnam has been granted but which have undergone modifications or supplementations in relation to excipients, preservatives, changes in production facilities (no change in production processes).

Clinical trials for the assessment of safety and immunogenicity in phase 3 shall be conducted for:

a) Foreign vaccines which have been legally marketed for at least 5 years in the country of origin (or a reference country if provided for under international treaties to which Vietnam is a signatory) for which manufacturing technology is transferred to Vietnam.

b) Vaccines manufactured in Vietnam from imported intermediates with components having been legally marketed for at least 5 years in the country of origin (or a country of reference if provided for under international treaties of which Vietnam is a signatory).

a) Vaccines for which a registration number for marketing in Vietnam has been granted but which have undergone modifications or supplementations in relation to manufacturing process, dosage forms, indications, target population (age, sex, race), route of administration, dosage, vaccination schedule.

3. Oriental medicines, drugs made from medicinal materials:

Clinical trials for the assessment of safety shall be conducted for:

Drugs for which a registration number for marketing in Vietnam has been granted and other oriental prescriptions recognized by the Ministry of Health but which have undergone modifications or supplementations in relation to indications, route of administration, formulation, dosage forms different from those of the same drugs which have been legally marketed for at least 05 years in the country of origin (or reference country if provided for in international treaties to which Vietnam is a signatory).

Article 8. Clinical trials in special cases involving health security emergencies

Minister of Ministry of Health with advice from the Advisory Council for Marketing Licensing and the Ministry of Health Biomedical research Ethics Committee shall consider and grant exemption from clinical trials for the following cases:

:

1. Drugs for use in special cases relating to emergency health security including:

a) Pharmaceuticals, biologics, vaccines which have been legally marketed but for a period of less than 5 years in the country of origin (or a reference country if provided for under international treaties to which Vietnam is a signatory), for which clinical trial data from multicenter trial conducted in Vietnam and Asia is available, of which safety and effectiveness have been proven by trial results for the same formulation, indications, route of administration with those in use in the respective country.

b) Pharmaceuticals, oriental medicines or drugs from medicinal materials which meet special therapeutic demands, which are listed in the list of rare drugs published by Ministry of Health, with particular dosage forms not yet manufacturable domestically, for which no substitute is available, without which patients' life would be compromised, for which a registration number for marketing in Vietnam has not been

granted, which have been legally marketed in the country of origin but for a period of less than 5 years (or country of reference if provided for under international treaties to which Vietnam is a signatory) and which have been certified as safe and effective by the respective country's competent authority for the same route of administration, formulation and indications as those intended for use in Vietnam.
c) Vaccines for use in the prevention of emerging infectious diseases of yet to be known pathogen or deadly highly infectious diseases capable of rapid and wide scale spread with high mortality rate, for which a registration number for marketing in Vietnam has not been granted, which have been legally marketed in the country of origin but for a period of less than 5 years (or a reference country if provided for under international treaties to which Vietnam is a signatory) and which have been certified as safe and effective by the respective country's competent authority for the same route of administration, formulation and indications as those intended for use in Vietnam.

2.. Drugs which are products resulted from research projects, research grants of ministerial equivalent or higher level, which were conducted prior to the effective date of this Circular in strict compliance with provisions of this Circular and guidelines on good clinical practice for trials, which have been evaluated for acceptability and authorized for marketing by the ministerial equivalent or higher level council of science and technology.

Chapter III
CONDITIONS FOR CLINICAL TRIALS

Article 9. Conditions which apply to investigational drugs (*)

(*) translator note:– not clear whether "Thuốc thử trên lâm sàng" covers all investigational drugs used inthe trial only the candidate drug.

Investigational Drugs shall meet the following requirements:

1. Pre-clinical studies on the drugs have been conducted, for which safety has been proven and documented making the drugs eligible for progressing to the next trial phase.

.
2. Formulation, dosage forms and manufacturing process of the drugs have been stabilized.

.
3. Availability of results of previous phases of the clinical trial on the drugs if the application is for the authorization to progress to the next phase.

4. Meeting quality standards as stated in the dossier for the registration of clinical trials.

5. Investigational Drugs shall be clearly labeled with the wordings "Products for clinical trials. Use for other purposes is prohibited"

Article 10. Conditions which apply to the clinical trial dossier

Dossier for registration of clinical trial shall be in Vietnamese (01 original, legally signed, sealed and 03

copies), comprising of:

1. Application for authorization to conduct a clinical trial by the agencies, organizations, individuals having the candidate drug(s) (Appendix 1 attached to this Circular).

2. Investigator's brochure in Vietnamese or in English accompanied by a summary in Vietnamese (Appendix 2 of this Circular).

3. Application requesting for review, approval of the trial protocol by the Host institution (Appendix 3 of this Circular).

4. Agreement between Agencies, organizations, individuals having the candidate drugs and the Host institution and Agreement between Agencies, organizations, individuals having the candidate drugs and the Contract research organization, the Site management organization, if applicable (Appendix 4 of this Circular).

5. Explanatory Notes to the trial protocol (Appendix 5 of this Circular).

6. Professional Curriculum Vitae and Certificate of good practice on clinical trial of the Principal investigator/Chief researcher issued by Ministry of Health or other agencies recognized by Ministry of Health.

7. Clinical trial Information sheet and the Informed Consent form (Appendix 6 of Circular).

8. Minutes of the local (Host institution) Biomedical research Ethics committee's opinion on the scientific aspects and ethical considerations of the clinical trials.

9. Written confirmation of participation by the participating research institutions in case of multi-center trials conducted in Vietnam.

10. Notice by the people's committee of provinces, cities reporting to central government, accepting to participate in the clinical trials which take place in their respective localities.

11. Documentation on the investigational drugs(s) comprising of:

a) Documentation on investigational drugs: composition, formulation, manufacture processes, quality standards, drug testing slips (for pharmaceutical drugs, oriental medicines or drugs from medicinal materials: testing slips by the central testing agency or manufacturers meeting good manufacturing practice standards (GMP); for vaccines: quality certificate by national quality control agency or ex-factory delivery certificate by respective national drug regulatory agency for imported vaccine lots, biologics).

b) Documentation of pre-clinical studies of investigational drug on pharmacology, toxicology, safety and proposed dosage, route and method of administration.

c) Documentation of the preceding phases of the clinical trials (if application is for the authorization to progress to the next phase of the trials)

.
12. For investigational drugs which are candidate of safety assessment, clinical trial phase 4: A certified copy of the certificate of pharmaceutical product (CPP) or free sale certificate (FSC) and certificate of good manufacturing practice (GMP) of the respective state regulatory authority.

13. Labels of investigational drugs as stipulated in Clause 6 Article 9 of this Circular and photographs of the drug samples.

Article 11. Conditions which apply to Host institutions, the Principal investigator and participating investigators

1. Host Institutions shall satisfy the standards of good clinical practice for trials on pharmaceutical products (GCP), be independent financially and with respect to personnel from Individuals, organizations having the candidate drugs and shall undertake to carry out the trials free from any conflict of interests.

.
2. The Principal investigator shall be qualified with in depth technical knowledge, clinically experienced, operationally competent to ensure compliance with the principles of good clinical practice, be thoroughly familiar with the requirements of clinical trials, be capable of implementing the trial as per the approved protocol in full and to schedule, be GCP certified by the Ministry of Health or organizations recognized by the Ministry of Health.

3. The participating investigators shall have appropriate expertise, be trained on the subject matter and skills necessary for the conduct of the trials, be GCP certified by Ministry of Health or other organizations recognized by Ministry of Health.

Article 12. Conditions for trial subjects

1. Trial subjects shall be volunteers meeting the needs of the trial, shall sign an informed consent with the Host institution, except when s/he is restricted in his or her civil act capacity, has lost his or her civil act capacity or is without civil act capacity.

2. Where the trial subject is under 18 years old, is restricted in his or her civil act capacity, has lost his or her civil act capacity or is without civil act capacity, consent shall be obtained from the representative in accordance with the law.

3. Where trial subject is a woman who is pregnant or breast-feeding, the rationale for the selection of the subject shall be given in the Investigator's Brochure, be approved by Minister of Health with due consideration given to the opinion of the Ministry of Health Ethics Committee for Biomedical research on the scientific and ethical nature of the selection.

Article 13. Conditions which apply to funding of clinical trials

1. Funding shall be sufficient to cover all trial related activities (including budget lines for studies, management fee, supervision, inspection) shall be provided by the Agencies, organizations, individuals having the candidate drugs through contractual agreements between the latter and the Host institution.

2. For drugs which are object of government funded programs, research grants under collaboration with national or foreign entities, the Lead researcher and Host institutions shall budget for the clinical trials as part of the total grant allocated.

3. The Host institution and the Principal investigator shall be responsible for managing their allocated budget to ensure expenditures are appropriate and to cost norms in accordance with relevant regulatory requirements or contractual terms between two parties.

Chapter IV
REGISTRATION, REVIEW AND AUTHORIZATION FOR CLINICAL TRIALS

Article 14. Registration for clinical trials

1. The Agencies, organizations, individuals having the candidate drugs shall submit to the Ministry of Health a registration dossier comprising of documents stipulated in Clause 1, Clause 2, Article 10 of this Circular.

2 Within 15 working days from the date of receipt of registration, Ministry of Health shall give written notice to the Agencies, organizations, individuals having the drug(s) regarding required next steps.

Article 15. Formulating the Trial Protocol

Based on Ministry of Health's written authorization, the Agencies, organizations, individuals having the candidate drugs in conjunction with the Principal investigator and the Host institution shall prepare the Trial Protocol as follows:

1. The Agencies, organizations, individuals having the candidate drugs shall provide the Principal investigator and the Host institution with documents specified in paragraphs 1, 2, 7, 11, 12 and 13, Article 10 of this Circular.

2. The Principal investigator, in conjunction with the Agencies, organizations, individuals having the candidate drugs and members of the research group, shall formulate the Trial Protocol, ensure the dossier's completeness as stipulated by Article 10 of the Circular this.

Article 16. Application for Authorization to conduct clinical trials

1. A clinical trial dossier as stipulated in Article 10 of this Circular shall be sent to Ministry of Health which serves as the basis for the review, consideration and authorization.

2. Dossiers received at the Health Ministry before the 20th of each month shall be evaluated in the same month. Dossiers submitted after this timeline shall be evaluated in the following month.

3. Information regarding registration, preparation and submission of application can be accessed via the Ministry of Health electronic portal www.iecmoh.vn or the Ministry of Health Biomedical research Ethics Committee's web site www.iecmoh.vn.

Article 17. Review and Authorization of clinical trials

1. Review the clinical trial dossier
Within 30 working days from the date of receipt of a complete dossier as stipulated in Article 10 of this Circular, Ministry of Health shall convene a Biomedical research Ethics Committee meeting.

2. Notice of results
Within 15 working days from the date the results of the Biomedical research Ethics committee's review become available, Department of Science and Training shall finalize the dossier and give written notice of results to the Agencies, organizations, individuals having the candidate drugs, the Host institution.

3. Authorization
Within 15 working days after notification of results and completion of supplementary documents (if any), Department of Science and Training shall compile the dossier and submit to Minister of Health for authorization.

Chapter V
PHASES OF CLINICAL TRIAL ON DRUGS AND THE CONDUCT OF CLINICAL TRIALS

Article 18. Phases of clinical trials on pharmaceutical products, biological products

Phase 1:
a) Is the first phase of trials on of a new active ingredient or new formulations in humans (usually done in healthy volunteers).

b) Purpose of phase 1 trials: to establish a preliminary assessment of safety and a first outline of pharmacokinetic and pharmacodynamic profile of the active ingredient in humans.

c) Sample size: shall be considered carefully based on results of preclinical studies, sample size of 10-30 subjects.

Phase 2:
a) Is the phase with trials conducted on a limited number of patients.

b) Purpose of phase 2: to evaluate the therapeutic activity and to assess safety of the active ingredient in patients, to determine the appropriate dose ranges and regimens in order to provide an optimal therapeutic plan for clinical trial.

c) Sample size: a minimum of 50 subjects.

Phase 3:
a) Is the phase with trials conducted in larger number of patients. The conditions under which these trials are carried out should be close to normal conditions. These are often multicenter trials, of randomized, controlled design.

b) Purpose of phase 3: to determine the stability of the formulation, the short and long term safety, effectiveness of the active ingredient, to assess the overall therapeutic value, to investigate any frequent adverse reactions and explore any special features of the products.

c) Sample size: A minimum of 200 subjects.

Phase 4:

a) These are clinical studies performed after the drugs have been marketed. Study designs may vary but the same scientific and ethical standards as in pre-marketing phase shall apply. Purpose of phase 4: clinical trials at this phase are conducted on the basis of product characteristics under which the marketing authorization was granted and normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.

c) Sample size: a minimum of 1,000 subjects.

Article 19. Phases of clinical trials on vaccines

1. Phase 1:
a) Is the first phase of small scale trials for the preliminary assessment of new vaccine's safety through information collected on tolerability of the vaccine. Phase 1 is usually performed on adult healthy volunteers, at low risk of infection and complications before it being administered on target recipients.
b) Phase 1 studies are usually open label, non-randomized with a placebo controlled group, can be done on different age and population groups to determine dose range, safety, vaccination schedule, method of delivery .

c) Live attenuated vaccine (virus or bacteria) capable of infecting recipients or contacts should be closely monitored on dosage, clinical signs of infection, immune response (immediate, early and late). Phase 1 trials can provide preliminary information on distribution, reversibility of toxic effects, communicability and the genetic stability of the vaccine strains.

d) Sample size: shall be considered carefully based on results of pre-clinical studies, sample size of 30-50 subjects.

2. Phase 2:

a) Is conducted after completion of phase 1 with results approved by the Ministry of Health Biomedical research Ethics Committee. Phase 2 trials aim to demonstrate the immunogenicity of the active ingredients, the safety of the vaccines tested on target population, to evaluate the immune response related to age, race, sex. These trials are of randomized controlled design.

b) For live attenuated vaccines, in addition to the monitoring of parameters specified in phase 1 trials, the presence and existence of antibody titer should be noted: neutralizing antibodies or cross agglutination antibodies or cell-mediated immunity and interactions impacting the immune system (e.g., interactions with pre-existing antibodies, other drugs concurrently taken).

c) Sample size: a minimum 200 subjects.

3. Phase 3:

a) Phase 3 trials are done on a large scale, multi-center to evaluate the protective effectiveness and safety of the immunogen of the vaccine in the target recipient.

b) Sample size: a minimum of 500 subjects.

4. Phase 4:

a) Phase 4 studies are conducted after the vaccines have been licensed for marketing. Phase 4 is considered as post licensing surveillance or post licensing studies with the purpose of determining adverse effects and monitoring the protective effectiveness after the vaccines have been used as per indications widely on in the community. Phase 4 can be performed to assess:

- The optimized conditions for the use of vaccines (optimal age for vaccination, concomitant use with other vaccines and other conditions).
- Protective effectiveness for at risk groups (elderly, immune compromised patients, people with certain diseases).
- Sustainability of effectiveness and long-term safety.

b) Sample size: a minimum of 10,000 subjects.

Article 20. Phases for clinical trials on oriental medicines, drugs made of medicinal materials

1. Phase 1:

a) Trials are often conducted on volunteers who meet the clinical trials' criteria for the purpose of determining safe dose range (highest strength dose is the dose that should cause no serious side effects), specifically:

b) The starting dose administered must be equal to 1/3 - 1/5 of the dose predicted by preclinical studies. Multiple smaller doses may be administered in the interval between the starting and the highest strength dose. This phase ends once the safe dose has been determined.

c) Sample size: shall be considered carefully based on results of pre-clinical studies, sample size of 10-30 subjects.

2.Phase 2:
a) These trials are to evaluate the safety and efficacy of the drugs and should be of randomized controlled design with a minimum of 25 subjects in each group.

b) Therapeutic dose: doses used in this phase must be based on phase 1 studies' results.
c) Sample size: a minimum of 50 subjects.

3. Phase 3:
a) To validate the safety and effectiveness in extended conditions. Study subjects were assigned by randomized controlled or self controlled method.
b) Sample size: a minimum of 100 patients.

4. Phase 4:

a) Provisions for Pharmaceutical drugs apply.
b) Sample size: a minimum of 200 patients.

Article 21. Multicenter clinical trials

1. When conducting trials at different sites, the Host institution shall establish a joint steering committee comprising of one Principal investigator and principal investigators from other branches (?) and representatives of lead research institutions (?) in order to reach agreements on the trial's objectives, content, evaluation criteria, plans and timelines.

2. For supranational clinical trials of which Vietnam is a participant, procedures shall be in strict compliance with provisions of this Circular. Objectives and contents of the trials conducted in Vietnam, joint study activities conducted in conjunction with other countries shall be detailed in the trial protocol.

Article 22. Objectives, contents and sample size

Minister of Health shall decide on specific objectives, content, sample size for clinical trials as stipulated in Article 18, 19, 20 and 21 of this Circular based on the advice of the Ethics Committee for biomedical research specific to each dossier, trial protocol.

Article 23. Handling adverse events during the clinical trial

Procedures for handling untoward events in the course of the trials are as follows:

1. In case a serious adverse event occurs threatening the life of trial subject(s) the Investigator and Host institution shall discontinue the trial on the subject immediately, take rescue actions, overcome and resolve the consequences, document the events, and expedite reporting to local Ethics committee, Ministry of Health Ethics committee, Department of Science and Training.

2. In case of trials causing injury to or compromising the subjects' health, the Principal investigator shall suspend the trial for the treatment of the subject's condition and monitor its development and make judgment as to continue or discontinue the clinical trial.

3. In the occurrence of untoward events which were anticipated and for which measures to overcome have been effectively adopted, the clinical trials shall continue.

Article 24. Information and data collection

1. Information which is derived from the course of the trials shall be recorded in the case report form (CRFs). Case report form shall be considered as source documents, be kept and archived in accordance with applicable regulatory requirements, and forms the basis for monitoring, evaluation for acceptability of the trials' results.

2. Relevant documentation necessary for clinical assessments (lab tests' results, diagnostic images, prescriptions) shall be copied from the original, clearly marked with the full name of the cross checking person (?), and its source, and shall be managed, stored in accordance with applicable regulatory requirements.

Article 25. Data processing

1. The trial data shall be processed using biostatistical methods and by an agency, organization which is independent from the Host institution to ensure objectivity, integrity and reliability.

2. Results of statistical analysis shall be clearly presented to facilitate the interpretation of differences in clinical outcomes; the evaluation of therapeutic value shall be based on confidence intervals and results obtained from statistical analysis. The final report of the clinical trials shall be consistent with the results of statistical analysis.

Article 26. Archiving of clinical trial records

1. Data, source documents, lab test results, diagnostic images, trial-related documentation gathered, minutes of committee meetings, monitoring records, progress reports, registration documents and other documents related to the clinical trial shall be preserved, retained at the research facilities for at least 15 years from the date of completion of the trials.

2. The Principal investigator shall be responsible for the whole process of preserving and archiving of documentation pertinent to the clinical trials and for making them available upon request of the inspection, supervision teams and competent regulatory agencies.

Article 27. Reports of the clinical trial results

1. Reports of the clinical trial results shall be made in compliance with the prescribed template (Appendix 7, of this Circular), containing full information on the drugs, describing the research methods, the trials' processes, data analysis, results evaluation, in comparison with the trial objectives and purposes, providing accurate conclusions, unbiased and objective. Contents of the report must be consistent with the trial objectives and contents outlined in the approved trial protocol.

2. The Principal investigator shall be responsible for the scientific soundness, accuracy and integrity of

data, findings, observations and other contents of the report.

Article 28. Management of investigational drugs

1. The export, import of investigational drugs shall be in compliance with current regulations on importation and exportation of drugs.

2. The management of investigational drugs shall be conducted in accordance with current regulatory requirements from sampling, quality testing, packaging, transportation, delivery, storage, labeling to distribution.

3. A journal shall be maintained to track the use of investigational drugs, along with information on drugs quantity, quality.

4. Unfinished drugs and drugs in storage shall be managed stringently, kept separated and preserved in accordance with relevant regulatory requirements. Unused drugs shall be handed over to the Agencies, individuals having the candidate drugs.

5. Minutes of disposition shall be prepared for drugs which do not meet quality standards in accordance with Ministry of Health's requirements.

6. Drugs samples (03 smallest packaged units) shall be preserved at the Host institutions' site for a minimum 3 years (36 months) from the termination of the trials.

Chapter VI
RIGHTS AND OBLIGATIONS OF TRIAL SUBJECTS, INDIVIDUALS (?) HAVING THE CANDIDATE DRUGS AND HOST INSTITUTIONS

Article 29. Rights of Trial subjects

1. Be provided with complete and truthful information before the trial about the trial process and possible associated risks that may occur.

2. Be compensated by the Agencies, organizations, individuals having the candidate drugs for any damages suffered, if these are caused by the trial.

3. Have confidentiality of pertinent personal information safeguarded.

4. Bear no liability when unilaterally withdraw him/herself from participating in the trials.

5. File complaints, denunciations against the Organizations, individuals having the candidate drugs and Host institution for their acts of law infringement.

6. Be provided with medical care during the trials in accordance with the approved trial protocol.

Article 30. Rights of Agencies, organizations, individuals having the candidate drug(s)

1. Select and propose entities meeting the trial requirements with respect to premises, facilities and qualified personnel for the conduct of the clinical trial.
2. Have ownership of all the trial results on the drug(s).
3. Have the right to terminate the trial if the Host institution is in serious breach of the trial protocol.

Article 31. Obligations of agencies, organizations and individuals having the candidate drug(s)

1. Apply and be granted with an Authorization by the Ministry of Health before initiating the trials.

2. Compensate trial subjects for damages suffered if these are caused by adverse events during the trial in accordance with relevant regulatory requirements.

3. Sign contract with the Host institution or the clinical research organization (if any) for the conduct of clinical trials

4. Be responsible before law for the safety and quality of drugs supplied by them.

Article 32. Rights of Host institutions

1. Be supplied by Agencies, organizations and individuals having the candidate drugs with investigational drugs and funding for the conduct of clinical trials in accordance with the law.

2. Be allowed to make use of the trial results in accordance with agreements with the Agencies, organizations, individuals having the candidate drugs.

Article 33. Obligations of Host institutions

1. Comply with the standards of Good clinical practice for trials on drugs, submit to Ministry of Health reports on trial progress, results and ad hoc reports as need be.

2. Sign contracts for the conduct of the clinical trial with Agencies, organizations, individuals having the candidate drugs and Trial subjects.

3. Continue to monitor trial subjects' health conditions as agreed in the contract and outlined in the trial protocol.

Chapter VII
SUPERVISION AND INSPECTION FOR QUALITY ASSURANCE OF CLINICAL TRIALS

Article 34. Supervision of the conduct of clinical trials

1. Supervision and inspection shall be performed to ensure the protection of rights, interests and well being of trial subjects, the complete, accurate, timely recording of trials' data in accordance with the approved trial protocol.

2. Ministry of Health shall establish supervision team for periodic inspections and ad hoc inspection in specific cases.

3. Competent state authorities, Agencies, organizations, individuals having the candidate drug(s), Clinical research organizations (CRO) or Site management organizations (SMO) with written approval by the Ministry of Health, may assign personnel for the monitoring, supervision of the clinical trial process in a systematic manner. Person(s) assigned to the supervision function shall not be member of the research team, shall adhere strictly to requirements on confidentiality of trial data and information pertinent to the trial subjects and be responsible before law for his/her performance.

4. The Principal investigator and participating investigators shall be responsible for the facilitation of inspectors' direct access to trial data when required.

5. The supervision, inspection teams shall be responsible for the inspection, documentation, recommendation to competent state authorities for the latter to take appropriate action in accordance with the law.

Article 35. Ensuring credibility of the clinical trial results

1. To ensure the clinical trial's credibility of trials, analysis, findings and conclusions shall derive from raw data. All clinical data and lab test values shall be verified at every phase of the trials.

2. When necessary the evaluation board of different levels may invite expert evaluator for the evaluation of results, data verification, inspection of trial products or establish Data and Safety Monitoring Board (DSMB) as required by regulatory agencies.

Chapter VIII
FINAL EVALUATION OF THE CLINICAL TRIAL RESUTLS

Article 36. Procedures for evaluation for acceptability of clinical trial results

1. Final evaluation for acceptability of clinical trial results shall be performed in accordance with the relevant regulatory requirements on acceptability evaluation for science and technology research projects and good clinical practice for trials on drugs.

2. The evaluation shall be conducted at two levels: the local level and Ministry of Health level. At the end of the trials, the Principal investigator shall be responsible to report to the Host institution for the latter to conduct the local level evaluation and compile a final report to Ministry of Health for the acceptability evaluation at ministerial level.

Article 37. Dossier for the Ministry of Health's acceptability evaluation

Dossier for the ministerial acceptability evaluation (01 original, legally signed, and 03 copies), including:

1. Official note from the Host institution requesting the ministerial acceptability evaluation.

2. Copy of the approved trial protocol.

3. Decision of approval of the trial protocol.

4. Decision for the establishment of the local acceptability evaluation board.

5. Minutes of the local acceptability evaluation board meeting.

6. Full-text report of the clinical trial results in accordance with regulatory requirements with possible supplementary documents as deemed appropriate.

Article 38. Completion of clinical trials

1. Within 30 working days from the date of receipt of the complete dossier requesting for the acceptability evaluation, Ministry of Health shall convene an acceptability evaluation board meeting in accordance with relevant regulatory requirements.

2. Clinical trials shall only be deemed complete after the final report of the trials has been evaluated for acceptability and any supplementary documents submitted by the Principal investigator at the request of the Board's member have been accepted.

3. Data and results of the clinical trials shall only be published after approval by Ministry of Health Biormedical research Ethics committee.

Chapter IX
IMPLEMENTATION

Article 39. Responsibility for implementation

The Department of Science and Training shall lead and coordinate with the relevant departments, divisions to

1. Receive and review registration dossiers, provide guidance to Organizations, individuals having the candidate drugs for the implementation of this Circular in compliance with its provisions and those of other relevant regulations.

2. Conduct appraisal of the conditions for clinical trials applied for in the dossiers, personnel's technical qualifications, premises and facilities and the legality of the Host institutions, the Contract research organizations, Site management organizations and report to the Ministry's leadership for the granting of an authorization for the conduct of the clinical trials.

3. Organize Ministry of Health Biomedical research Ethics committee meetings to review the trial protocols, consider the ethical aspects of the studies and in the relevant science, evaluate the trial result for acceptability and submit its recommendations to the Ministry leadership for approval.

4. Provide supervision, conduct periodic or ad hoc inspection of the trial processes.

5. Disseminate the contents of this Circular, provide implementation guidance to pertinent agencies, organizations, individuals, ensure their compliance with guidelines of good clinical practice for trials and ethical standards in biomedical research.

Article 40. Transitional provisions

Dossiers for the registration of clinical trials on drugs submitted before the effective date of this Circular shall be reviewed and evaluated in accordance with the "Regulations on clinical trials" issued by Decision No. 01/2007/QD -BYT dated 11/01/2007 of the Minister of Health.

Article 41. Effective date

1. This Circular shall take effect from the date of 20th March 2012.

2. Decision 01/2007/QD-BYT dated 11 January 2007 for the promulgation of the "Regulations on clinical trials" shall be rescinded from the effective date of this Circular.

Should issues arise during the implementation process please report promptly to the Ministry of Health for revision, supplementation as appropriate./.

MINISTER OF HEALTH

NGUYEN THI KIM TIENG

Recipients:
- The Government Office (Official Gazette, Electronic Portal CP);
- Ministries, ministerial-level agencies;
- Ministry of Justice (Bureau of Inspection of legal documents);
- Ministry of Science and Technology (Legal Department);
- Deputy Ministers of Health;
- People's Committees of provinces and cities under central authority;
- Departments of Health of the provinces and cities under central authority;
- Hospitals under the Ministry of Health, Medical facilities of Ministries and line agencies;
- Departments, Divisions, General departments, Office of the Ministry, the Inspectorate of the Ministry - Ministry of Health;
- Ministry of Health Electronic Portal;
- For file: VT, PC, K2DT. ¬

Constitution
of
The Arab Republic of Egypt
2014

Unofficial Translation

Unofficial translation

The Issuance

of The Amended Constitution of The Arab Republic of Egypt

The Head of the State

Cognizant of the results of the referendum on the draft of the constitutional amendments into the suspended constitution of 2012 that was held on January 14-15, 2014,

And cognizant of Article 247 of the amended constitution of the Arab Republic of Egypt, the amended constitution of the Arab Republic of Egypt is issued with the attached text.

Cairo on Rabei Awwal 17, 1435;
January 18, 2014;

Adly Mansour

Unofficial Translation

In the Name of Allah, Most Gracious, Most Merciful

This is Our Constitution, Egypt is the gift of the Nile for Egyptians and the gift of Egyptians to humanity.

With its unique location and history, Egypt is the Arab heart of the world. It is the meeting point of world civilizations and cultures and the crossroads of its maritime transportation and communications. It is the head of Africa on the Mediterranean and the estuary of its greatest river: the Nile.

This is Egypt, an immortal homeland for Egyptians, and a message of peace and love to all peoples.

In the outset of history, the dawn of human conscience arose adn shone forth in the hearts of our great ancestors, whose goodwill banded together to found the first central State that regulated and organized the life of Egyptians on the banks of the Nile. It is where they created amazing wonders of civilization, and where their hearts looked up to heavens before earth knew the three Abrahamic religions.

Egypt is the cradle of belief and the banner of glory of the revealed religions.

On its land, Prophet Moses - to whom Allah spoke - grew up and on Mount Sinai, the Revelation of Allah shone on his heart and Divine message descended.

On its land, Egyptians harbored in their bosoms Virgin Mary and her baby and offered thousands of martyrs in defense of the Church of Jesus, Peace Be Upon Him.

When the Seal of the Messengers Mohammad (Peace and Blessings Be Upon Him) was sent to all mankind to perfect the sublime morals, our hearts and minds were opened to the light of Islam, and we, labeled the best soldiers on Earth fighting for the cause of Allah, disseminated the message of truth and sciences of religion across the world.

This is Egypt, a homeland in which we live and in our souls it lives.

In modern age, minds were enlightened, humanity became mature, and nations and peoples progressed on the path of knowledge, raising the banners of freedom and equality. Mohamed Ali founded the modern Egyptian State with a national army as its pillar. Refaa, the Azharian, called for having the homeland "… a place of happiness shared by all its people." We, Egyptians, strived to keep up with the pace of advancement and offered up martyrs and made sacrifices in several uprisings and revolutions until our patriotic army stood up for the overwhelming will of the people in the “Jan 25 – June 30” Revolution that called for freedom, human dignity and social justice for all, and for Egypt to regain its independent will.

Unofficial Translation

This revolution is continuation of national struggle whose brightest symbols were Ahmed Oraby, Mostafa Kamel, and Mohamed Farid, and is a culmination of two great revolutions in our modern history:

The 1919 revolution that had rid Egypt and the Egyptians of the British protection, established the principle of citizenship and equality for all the people. Its leader, Saad Zaghloul, and his successor, Mosfata El-Nahhas, in adopting democracy asserted that "Right is above power and the nation is above government". During this revolution, Talaat Harb laid down the cornerstone of the national economy.

The July 23, 1952 revolution led by Gamal Abdel Nasser and embraced by the popular will rendered true the dream of generations for independence and evacuation of foreign forces. Egypt affirmed its Arab allegiance, opened up to its African continent and Muslim world, supported liberation movements across continents, and took firm steps on the path of development and social justice.

This revolution is an extension of the revolutionary march of Egyptian patriotism, and enhances the strong bond between the Egyptian people and their national army that assumed the duty and shouldered the responsibility of protecting the homeland, by virtue of which we achieved victory in our greatest battles including driving off the 1956 Tripartite Aggression to defeating our defeat through the glorious victory of October 1973 that gave President Sadat a special place in our recent history.

Compared to major revolutions in the history of mankind, the Jan 25 – June 30 Revolution is unique with its high density of popular participation - estimated to be in the tens of millions - and the prominent role of youth aspiring at a brighter future. It is also unique in that the masses transcended class and ideology divides to reach out to more expansive horizons, the people's will was defended by their army, and that it had the blessings of Al-Azhar and the Egyptian church. This Revolution is further unique because of its peacefulness and ambition to achieve freedom and social justice combined.

This revolution is both a sign and a good omen; a sign of a past that is still present and a good omen of a future at which all humanity aspires.

The world is about to turn the last few leaves of this era that has been torn up by conflicts of interest between the East and the West, and the North and the South; an era where disputes and wars erupted between classes and peoples, where dangers grew threatening the existence of mankind and life on Earth which Allah entrusted us to preserve. As humanity hopes to move from the age of maturity to the age of wisdom to build a new world where truth and justice prevail, and where freedoms and human rights are protected, we, Egyptians, believe that our revolution is a resumption of our contribution to drafting a new history for humanity.

Unofficial Translation

We believe that we are capable of using the past as an inspiration, stirring up the present, and making our way to the future. We are capable of raising this homeland and rising with it.

We believe that every citizen is entitled to live in this homeland safe and secure, and that every citizen has the right to live at present and in the future.

We believe in democracy as a path, a future, and mode of living, political pluralism and the peaceful rotation of power. We affirm the right of the people to make and determine their future. The Egyptian people, is the sole source of authority. Freedom, human dignity, and social justice are the rights of every citizen. We and our future generations are masters in a sovereign homeland that is master of its destiny.

We are now drafting a Constitution that embodies the dream of generations for a prosperous consolidated society and a just State that realizes the present and future ambitions for the individual and the community.

We are now drafting a Constitution that seeks the completion of building a modern democratic State having a civil government.

We are drafting a Constitution that prevents any corruption or tyranny and by which we heal the wounds of the past, from the days of the old Eloquent Peasant to the victims of negligence and the martyrs of the revolution in our present time, and relieve our people who have – for long – been suffering injustice.

We are drafting a Constitution that affirms that the principles of Islamic Sharia are the principal source of legislation, and that the reference for the interpretation of such principles lies in the body of the relevant Supreme Constitutional Court Rulings.[1]

We are drafting a Constitution that paves the way to the future for us, and which is consistent with the Universal Declaration of Human Rights which we participated in drafting and adopted..

We are drafting a Constitution that maintains our freedom and protects our nation against any peril that threatens it or our national unity.

We are drafting a Constitution that holds all of us equal in rights and duties without discrimination of any kind.

We the citizens, women and men, the Egyptian people, sovereigns in a sovereign homeland, this is the manifestation of our volition, this is the Constitution of our revolution.

This is our Constitution.

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[1] The rulings are to be deposited in the minutes.

Unofficial Translation

Part I

The State

Article (1)

The Arab Republic of Egypt is a sovereign, united, indivisible State, where no part may be given up, having a democratic republican system that is based on citizenship and rule of law.

The Egyptian people are part of the Arab nation seeking to enhance its integration and unity. Egypt is part of the Islamic world, belongs to the African continent, cherishes its Asian dimension, and contributes to building human civilization.

Article (2)

Islam is the religion of the State and Arabic is its official language. The principles of Islamic Sharia are the main source of legislation.

Article (3)

The principles of Christian and Jewish Sharia of Egyptian Christians and Jews are the main source of legislations that regulate their respective personal status, religious affairs, and selection of spiritual leaders.

Article (4)

Sovereignty belongs only to the people, who shall exercise and protect it. The people are the source of powers, and safeguard their national unity that is based on the principles of equality, justice and equal opportunities among all citizens, as stated in the Constitution.

Article (5)

The political system is based on political and partisan pluralism, peaceful rotation of power, separation and balance of powers, the inevitable correlation between powers and responsibilities, and respect for human rights and freedoms, as stated in the Constitution.

Article (6)

Nationality is a right to anyone born to an Egyptian father or an Egyptian mother, and legal recognition through official papers proving his/her personal data, is a right guaranteed and regulated by Law.

Requirements for acquiring nationality shall be specified by law.

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Part II

Basic Components of the Society

Chapter One

Social Components

Article (7)

Al-Azhar is an independent Islamic scientific institution, with exclusive competence over its own affairs. It is the main reference for religious sciences and Islamic affairs. It is responsible for calling to Islam, as well as, disseminating religious sciences and the Arabic language in Egypt and all over the world.

The State shall provide sufficient financial allocations thereto so that it can achieve its purposes.

Al-Azhar's Grand Sheikh is independent and may not be dismissed. The Law shall regulate the method of appointing the Grand Sheikh from amongst the members of Council of Senior Scholars.

Article (8)

Society is based on social solidarity.

The State shall achieve social justice and provide the means to achieve social interdependence, in order to ensure a decent life for all citizens, as regulated by Law.

Article (9)

The State shall ensure equal opportunities for all citizens without discrimination.

Article (10)

The family is the nucleus of society, and is founded on religion, morality, and patriotism. The State shall ensure its cohesion, stability and the establishment of its values.

Article (11)

The State shall ensure the achievement of equality between women and men in all civil, political, economic, social, and cultural rights in accordance with the provisions of this Constitution.

The State shall take the necessary measures to ensure the appropriate representation of women in the houses of representatives, as specified by Law. The State shall also guarantee women's right

Unofficial Translation

of holding public and senior management offices in the State and their appointment in judicial bodies and authorities without discrimination.

The State shall protect women against all forms of violence and ensure enabling women to strike a balance between family duties and work requirements.

The State shall provide care to and protection of motherhood and childhood, female heads of families, and elderly and neediest women.

Article (12)

Work is a right, duty and honor guaranteed by the State. No citizen may be forced to work except as required by Law and for the purpose of performing a public service for a fixed period in return for a fair consideration, and without prejudice to the basic rights of those obliged to carry out such work.

Article (13)

The State shall protect workers' rights and strive to build balanced work relationships between both parties to the production process. It shall ensure means for collective negotiations, protect workers against work risks, guarantee the fulfillment of the requirements of security, safety and occupational health, and prohibit unfair dismissal, all as regulated by Law.

Article (14)

Public offices are a competence-based right for all citizens without bias or favoritism, and are deemed a mandate to serve the people. The State shall ensure the rights and protection of public servants and that they perform their respective duties in serving the interests of the people. They may not be dismissed without disciplinary procedures except in the cases specified by Law.

Article (15)

Peaceful strike is a right regulated by Law.

Article (16)

The State shall honor the martyrs of the nation; shall care for revolution-wounded persons, veterans and wounded warriors, families of those missing in war and its equivalents, and persons wounded in security operations, as well as their wives, children and parents; and shall strive to provide all of them with job opportunities, all as regulated by Law.

The State shall encourage the participation of the civil society organizations in achieving those objectives.

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Article (17)

The State shall ensure that social insurance services are provided.

All citizens who do not benefit from the social insurance system have the right to social security, in a manner that ensures a decent life in the event of being incapable to provide for themselves and their families, as well as in cases of incapacity to work, old age or unemployment.

In accordance with Law, the State shall strive to provide suitable pensions to small farmers, agricultural workers and fishermen, and irregular labor.

The funds of social insurance and pensions are deemed private funds that enjoy all aspects and forms of protection afforded to public funds. Those funds along with their returns are the rights of their respective beneficiaries; they shall be safely invested, and shall be managed by an independent entity in accordance with the Law.

The State shall guarantee social insurance and pension funds.

Article (18)

Every citizen has the right to health and to comprehensive health care which complies with quality standards. The State shall maintain and support public health facilities that provide health services to the people, and shall enhance their efficiency and their equitable geographical distribution.

The State shall allocate a percentage of government spending to health equivalent to at least 3% of Gross National Product (GNP), which shall gradually increase to comply with international standards.

The State shall establish a comprehensive health insurance system covering all diseases for all Egyptians; and the Law shall regulate citizens' contribution to or exemption from its subscriptions based on their income rates.

Refusing to provide any form of medical treatment to any human in emergency or life-threatening situations is a crime.

The State shall improve the conditions of physicians, nursing staff, and health sector workers.

All health facilities as well as health-related products, materials and means of advertisement shall be subject to State control. The State shall encourage the participation of private and non-governmental sectors in providing health care services according to the Law.

Article (19)

Every citizen has the right to education. The goals of education are to build the Egyptian character, preserve the national identity, root the scientific method of thinking, develop talents

Unofficial Translation

and promote innovation, establish cultural and spiritual values, and found the concepts of citizenship, tolerance and non-discrimination. The State shall observe the goals of education in the educational curricula and methods, and provide education in accordance with international quality standards.

Education is compulsory until the end of the secondary stage or its equivalent. The State shall provide free education in the various stages in the State's educational institutions according to the Law.

The State shall allocate a percentage of government spending to education equivalent to at least 4% of the Gross National Product (GNP), which shall gradually increase to comply with international standards.

The State shall supervise education to ensure that all public and private schools and institutes abide by its educational policies.

Article (20)

The State shall encourage and develop technical and technological education as well as vocational training, and expand all their types in accordance with international quality standards and in accordance with labor market needs.

Article (21)

The State shall guarantee the independence of universities and scientific and linguistic academies, and provide university education in accordance with international quality standards. It shall develop and ensure free provision of, university education in State universities and institutes according to the Law.

The State shall allocate a percentage of government spending to university education equivalent to at least 2% of the Gross National Product (GNP), which shall gradually increase to comply with international standards.

The State shall encourage the establishment of non-profit, non-governmental universities. The State shall guarantee the quality of education in private and non-governmental universities, ensure that they comply with international quality standards and the = build their own faculty members and researchers, and allocate a sufficient percentage of their returns to educational and research development.

Article (22)

Teachers, and faculty members and their assistants, are the main pillars of education. The State shall guarantee the development of their academic competencies and professional skills and shall care for their financial and moral rights in order to ensure the quality of education and achieve its goals.

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Article (23)

The State shall ensure freedom of scientific research and encourage scientific research institutions as a mean to achieve national sovereignty and build a knowledge economy. The State shall sponsor researchers and inventors and allocate a percentage of government spending to scientific research equivalent to at least 1% of the Gross National Product (GNP), which shall gradually increase to comply with international standards.

The State shall ensure effective means of contribution by private and non-governmental sectors and the participation of Egyptian expatriates in the progress of scientific research.

Article (24)

Arabic Language, Religious Education and National History, in all its stages, are core subjects in public and private pre-university education. Universities shall teach human rights and professional values and ethics of the various academic disciplines.

Article (25)

The State shall develop a comprehensive plan to eradicate alphabetical and digital illiteracy among citizens of all ages. The State shall develop its implementation mechanisms with the participation of civil society organizations within a definite timeline.

Article (26)

The creation of civil titles is prohibited.

Chapter Two

Economic Components

Article (27)

The economic system aims at achieving prosperity through sustainable development and social justice so as to raise the real growth rate of the national economy and the standard of living, increase job opportunities, reduce unemployment rates and eliminate poverty.

The economic system shall adhere to transparency and good governance standards; enhance pillars of competitiveness, encourage investment, ensure balanced geographical, sectorial, and environmental growth, prohibit monopolistic practices, maintain financial and trade balances and a fair tax system, in the context of a regulated economy guaranteeing the various types of ownership and striking a balance between the interests of various stakeholders preserving the rights of workers and protecting consumers.

From a social perspective, the economic system shall ensure equal opportunities and fair distribution of development returns, reduce the differences among incomes and adhere to a

Unofficial Translation

minimum wage and pension ensuring a decent life, as well as a maximum one in State agencies for every salaried employee according to the Law.

Article (28)

The productive, service and information related economic activities are key components of the economy. The State shall protect them and strive to increase their competiveness; provide investment-attracting environment, increase productivity, encourage exports, and regulate imports.

The State shall pay special attention to small, medium and micro enterprises in all fields, and shall regulate and rehabilitate the informal sector.

Article (29)

Agriculture is a basic component of the economy.

The State shall protect and expand agricultural land, and shall criminalize encroachments thereon. It shall develop rural areas; raise the standard of living of their population and protect them from environmental risks; and shall strive to on develop agricultural and animal production and encourage industries based thereon.

The State shall provide agricultural and animal production requirements, and shall buy basic agricultural crops at suitable prices generating profit margins for farmers in agreement with agricultural unions, syndicates and associations. The State shall also allocate a percentage of reclaimed lands to small farmers and youth graduates, and protect farmers and agricultural workers against exploitation. All the foregoing shall be as regulated by Law.

Article (30)

The State shall protect fish resources, as well as protect and support fishermen and empower them to carry out their work without jeopardizing ecosystems, as regulated by Law.

Article (31)

The security of cyberspace is an integral part of the economic system and national security. The State shall take the necessary measures to preserve it as regulated by Law.

Article (32)

The State's natural resources belong to the people. The State shall preserve and effectively exploit them, may not deplete them, and shall observe the rights of future generations to them.

The State shall make the best use of renewable energy sources, motivate investment therein, and encourage relevant scientific research. The State shall encourage the manufacture of raw materials and increase their added value as per economic feasibility.

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Disposing of State's public properties is prohibited. Granting the right of exploitation of natural resources or public utility concessions shall be by virtue of a law for a period not exceeding thirty (30) years.

Granting the right of exploitation of quarries, small mines and slatterns, or granting public utility concession shall be based on a law for a period not exceeding fifteen (15) years.

The Law shall define provisions of disposing of the State's private properties as well as the regulating rules and procedures.

Article (33)

The State shall protect ownership with its three types: the public, the private and the cooperative.

Article (34)

Public properties are inviolable and may not be infringed upon. Protection thereof is a duty according to the Law.

Article (35)

Private properties shall be protected, and the right to inheritance thereto is secured. It is not permissible to impose guardianship thereon except in the cases defined by Law and by virtue of a court judgment. Expropriation shall be allowed only in the public interest and for its benefit, and against fair compensation to be paid in advance according to the Law.

Article (36)

The State shall motivate the private sector to undertake its social responsibility in serving the economy and society.

Article (37)

Cooperative ownership shall be protected. The State shall give due care to cooperatives, and the Law shall guarantee their protection, support and independence.

It is prohibited to dissolve cooperatives or their board of directors except by virtue of a court judgment.

Article (38)

The tax system, as well as other public liabilities, aim at developing State resources and achieving social justice and economic development.

Unofficial Translation

Public taxes may not be created, altered, or cancelled except by a law; and exemption therefrom may only be made in the cases defined by the law. No person may be required to pay other taxes or fees except as provided for in the Law.

Multi sources shall be observed in imposing taxes. Progressive multi bracket taxes shall be imposed on incomes of individuals according to their respective financial capabilities. Taxation system shall ensure promoting labor-intensive economic activities and motivating their role in the economic, social and cultural development.

The State shall improve the taxation system and develop modern systems that guarantee efficiency, easiness and control in tax collection. The Law shall define the methods and tools of collecting taxes, charges and any other sovereign proceeds, and amounts thereof to be deposited into the State public treasury.

Tax payment is a duty and tax evasion is a crime.

Article (39)

Saving is a national duty protected and encouraged by the State that shall guarantee savings, as regulated by the law.

Article (40)

General confiscation of properties is prohibited.

Specific confiscation is impermissible except by virtue of a court judgment.

Article (41)

The State shall implement a population program aiming at striking a balance between population growth rates and available resources; and shall maximize investments in human resources and improve their characteristics in the framework of achieving sustainable development.

Article (42)

Workers shall have a share in the management and profits of enterprises according to the law, and shall develop production and implement the respective plans of their productive units. Preserving production tools is a national duty.

Workers shall be represented by 50% of the elected members of the boards of directors of public sector units. Their representation in the boards of directors of public enterprise sector companies shall be subject to the Law.

The Law shall regulate the representation of small farmers and craftsmen with a minimum representation percentage of 80% in the boards of directors of agricultural, industrial and handicraft cooperatives.

Unofficial Translation

Article (43)

The State shall protect and develop the Suez Canal and preserve it as an international waterway owned by the State. The State shall also develop the Canal sector as a distinguished economic center.

Article (44)

The State shall protect the River Nile, preserve Egypt's historical rights thereto, rationalize and maximize its use, and refrain from wasting or polluting its water. The State shall also protect groundwater; adopt necessary means for ensuring water security; and support scientific research in that regard.

Every citizen is guaranteed the right to enjoy the River Nile. It is prohibited to trespass the riverbank reserve or harm the riverine environment. The State shall guarantee eliminating any trespass against the River Nile as regulated by Law.

Article (45)

The State shall protect its seas, shores, lakes, waterways and natural protectorates.

Trespassing, polluting or misusing any of them is prohibited. Every citizen is guaranteed the right of enjoying them. The State shall protect and develop the green space in the urban areas; preserve plant, animal and fish resources and protect those under the threat of extinction or danger; guarantee humane treatment of animals, all according to the law.

Article (46)

Every person has the right to a sound healthy environment. Environment protection is a national duty. The State shall take necessary measures to protect and ensure not to harm the environment; ensure a rational use of natural resources so as to achieve sustainable development; and guarantee the right of future generations thereto.

Chapter Three

Cultural Components

Article (47)

The State shall maintain the Egyptian cultural identity with its diversified branches of civilization.

Article (48)

Culture is a right to every citizen. The State shall secure and support this right and make available all types of cultural materials to all strata of the people, without any discrimination

Unofficial Translation

based on financial capability, geographic location or others. The State shall give special attention to remote areas and the neediest groups.

The State shall encourage translation from and into Arabic.

Article (49)

The State shall protect and preserve monuments and give due care to monumental sites. It shall also maintain and restore them; recover stolen antiquities; and organize and supervise excavation operations.

Presenting monuments as gifts or exchanging them is prohibited.

Aggression against or trafficking in monuments is a crime that is not subject to prescription.

Article (50)

Egypt's civilization and cultural heritage, whether physical or moral, including all diversities and principal milestones – namely Ancient Egyptian, Coptic, and Islamic – is a national and human wealth. The State shall preserve and maintain this heritage as well as the contemporary cultural wealth, whether architectural, literary or artistic, with all diversities. Aggression against any of the foregoing is a crime punished by Law. The State shall pay special attention to protecting components of cultural pluralism in Egypt.

Unofficial Translation

Part III

Public Rights, Freedoms & Duties

Article (51)

Dignity is the right of every human being and may not be violated. The State shall respect and protect human dignity.

Article (52)

Torture in all forms and types is a crime that is not subject to prescription.

Article (53)

All citizens are equal before the Law. They are equal in rights, freedoms and general duties, without discrimination based on religion, belief, sex, origin, race, color, language, disability, social class, political or geographic affiliation or any other reason.

Discrimination and incitement of hatred is a crime punished by Law.

The State shall take necessary measures for eliminating all forms of discrimination, and the Law shall regulate creating an independent commission for this purpose.

Article (54)

Personal freedom is a natural right, shall be protected and may not be infringed upon. Except for the case of being caught in *flagrante delicto*, it is not permissible to arrest, search, detain, or restrict the freedom of anyone in any way except by virtue of a reasoned judicial order that was required in the context of an investigation.

Every person whose freedom is restricted shall be immediately notified of the reasons therefore; shall be informed of his/her rights in writing; shall be immediately enabled to contact his/her relatives and lawyer; and shall be brought before the investigation authority within twenty four (24) hours as of the time of restricting his/her freedom.

Investigation may not start with the person unless his/her lawyer is present. A lawyer shall be seconded for persons who do not have one. Necessary assistance shall be rendered to people with disability according to procedures prescribed by Law.

Every person whose freedom is restricted, as well as others, shall have the right to file grievance before the court against this action. A decision shall be made on such grievance within one (1) week as of the date of action; otherwise, the person must be immediately released.

Unofficial Translation

The Law shall regulate the provisions, duration, and causes of temporary detention, as well as the cases in which damages are due on the state to compensate a person for such temporary detention or for serving punishment thereafter cancelled pursuant to a final judgment reversing the judgment by virtue of which such punishment was imposed.

In all events, it is not permissible to present an accused for trial in crimes that may be punishable by imprisonment unless a lawyer is present by virtue of a power of attorney from the accused or by secondment by the court.

Article (55)

Every person who is either arrested, detained, or his freedom is restricted shall be treated in a manner that maintains his dignity. He/she may not be tortured, intimidated, coerced, or physically or morally harmed; and may not be seized or detained except in places designated for that purpose, which shall be adequate on human and health levels. The State shall cater for the needs of people with disability.

Violating any of the aforementioned is a crime punished by Law.

An accused has the right to remain silent. Every statement proved to be made by a detainee under any of the foregoing actions, or threat thereof, shall be disregarded and not be relied upon.

Article (56)

A prison is a place of correction and rehabilitation.

Prisons and places of detention shall be subject to judiciary supervision, where actions inconsistent with human dignity or which endanger human health shall be prohibited.

The Law shall regulate the provisions of reform and rehabilitation of convicted persons and facilitating decent lives after their release.

Article (57)

The right to privacy may not be violated, shall be protected and may not be infringed upon..

Postal, telegraphic and electronic correspondences, telephone calls, and other means of communication are inviolable, and their confidentiality is guaranteed. They may not be confiscated, revealed or monitored except by virtue of a reasoned judicial order, for a definite period, and only in the cases defined by Law.

The State shall protect citizens' right to use all forms of public means of communications. Interrupting or disconnecting them, or depriving the citizens from using them, arbitrarily, is impermissible. This shall be regulated by Law.

Unofficial Translation

Article (58)

Privacy of homes is inviolable. Except for cases of danger or call for help, homes may not be entered, inspected, monitored or eavesdropped except by a reasoned judicial warrant specifying the place, the time and the purpose thereof. This is to be applied only in the cases and in the manner prescribed by Law. Upon entering or inspection, the residents of houses must be apprised and have access to the warrant issued in this regard.

Article (59)

Everyone has the right to a safe life. The State shall provide security and reassurance for its citizens and all those residing in its territory.

Article (60)

The human body is inviolable and any assault, deformation or mutilation committed against it shall be a crime punishable by Law. Organs trade shall be prohibited, and it is not permissible to perform any medical or scientific experiment thereon without a certified free consent according to established principles in medical sciences and as regulated by Law.

Article (61)

Tissue and organ donation is a gift for life. Every person shall have the right to donate his body organs either during his lifetime or after his death by virtue of consent or a certified will. The State shall develop a mechanism regulating the rules of organ donation and transplantation in accordance with the Law.

Article (62)

Freedom of movement, residence and emigration shall be guaranteed.

No citizen may be expelled from the State territory or prevented from returning thereto.

No citizen may be prevented from leaving the State territory, placed under house arrest or prevented from residing in a certain place except by a reasoned judicial order for a specified period of time and in the cases as defined by the Law.

Article (63)

All forms and types of arbitrary forced displacement of citizens shall be prohibited and shall be a crime that does not lapse by prescription.

Unofficial Translation

Article (64)

Freedom of belief is absolute.

The freedom of practicing religious rituals and establishing worship places for the followers of Abrahamic religions is a right regulated by Law.

Article (65)

Freedom of thought and opinion is guaranteed.

Every person shall have the right to express his/her opinion verbally, in writing, through imagery, or by any other means of expression and publication.

Article (66)

Freedom of scientific research is guaranteed. The State is committed to sponsor researchers and inventors and to provide protection for and endeavor to apply their innovations.

Article (67)

Freedom of artistic and literary creativity is guaranteed. The State shall encourage arts and literature, sponsor creative artists and writers and protect their productions, and provide the means necessary for achieving this end.

No lawsuit may be initiated or filed to stop or confiscate any artistic, literary, or intellectual works, or against their creators except by the Public Prosecutor. No freedom restricting sanction may be inflicted for crimes committed because of the publicity of artistic, literary or intellectual product. As for crimes related to the incitement of violence, discrimination between citizens, or impingement of individual honor, the Law shall specify the penalties therefore.

In such cases, the court may obligate the sentenced to pay punitive compensation to the victim of the crime, in addition to the original compensations due to the victim for the damages incurred. All the foregoing shall be in accordance with the Law.

Article (68)

Information, data, statistics and official documents are the property of the People and the disclosure thereof from their various sources is a right guaranteed by the State for all citizens. The State is committed to provide and make them available to citizens in a transparent manner. The Law shall regulate the rules for obtaining them and terms for their availability and confidentiality; the rules for their deposit and storage; and the rules for and filing complaints against the refusal to provide them. The Law shall also impose penalties for withholding information or deliberately providing wrong information.

Unofficial Translation

The State institutions shall deposit official documents with the National Library and Archives once they are no longer in use. The State institutions shall also protect, and secure such documents against loss or damage, as well as restoring and digitizing them using all modern means and instruments according to the Law.

Article (69)

The State shall protect all types of intellectual property rights in all fields, and establish a specialized agency to uphold such rights and their legal protection as regulated by Law.

Article (70)

Freedom of the press, printing and paper, visual, audio and electronic publication is guaranteed. Every Egyptian - whether being natural or legal, public or private person – shall have the right to own and issue newspapers and establish visual, audio and digital media outlets.

Newspapers may be issued once notification is given as regulated by Law. The Law shall regulate the procedures of establishing and owning visual and radio broadcast stations and online newspapers.

Article (71)

It is prohibited to censor, confiscate, suspend or shut down Egyptian newspapers and media outlets in any way. By way of exception, they may be subject to limited censorship in times of war or general mobilization.

No freedom restricting penalty shall be imposed for publication or publicity crimes. As for crimes related to the incitement of violence, discrimination between citizens, or impingement of individual honor, the Law shall stipulate the penalties therefor.

Article (72)

The State shall ensure the independence of all State-owned press institutions and media outlets, in a manner ensuring their neutrality and presentation of all political and intellectual opinions and trends as well as social interests and also guaranteeing equality and equal opportunities in addressing public opinion.

Article (73)

Citizens shall have the right to organize public meetings, marches, demonstrations and all forms of peaceful protests, without carrying arms of any kind, by serving a notification as regulated by Law.

The right to peaceful and private assembly is guaranteed without need for prior notification. Security forces may not attend, monitor or eavesdrop on such meetings.

Unofficial Translation

Article (74)

All citizens shall have the right to form political parties by notification as regulated by Law. No political activity may be practiced and no political parties may be formed on the basis of religion or discrimination based on sex, or origin, or on sectarian basis or geographic location. No activity that is hostile to democratic principles, secretive, or of military or quasi-military nature may be practiced.

Political parties may not be dissolved except by virtue of a court judgment.

Article (75)

All citizens shall have the right to form non-governmental associations and foundations on democratic basis, which shall acquire legal personality upon notification.

Such associations and foundations shall have the right to practice their activities freely, and administrative agencies may not interfere in their affairs or dissolve them, or dissolve their boards of directors or boards of trustees save by a court judgment.

The establishment or continuation of non-governmental associations and foundations, whose statutes or activities are secretive or conducted in secret or which are of military or quasi-military nature is prohibited as regulated by Law.

Article (76)

The establishment of syndicates and federations on democratic basis is a right guaranteed by Law. Syndicates and federations shall acquire legal personality, shall have the right to practice their activities freely, shall improve the level of efficiency among their members and defend their rights and interests.

The State shall guarantee the independence of all syndicates and federations and their boards of directors may only be dissolved by a court judgment.

No syndicate or federation may be established in the military or police agencies.

Article (77)

The Law shall regulate the establishment of professional syndicates and the administration thereof on a democratic basis, shall guarantee their independence and shall specify their resources and the manner of recording their members, and holding them accountable for their conduct in practicing their professional activities according to the codes of ethics and professional conduct.

No profession may have more than one syndicate for the regulation of its affairs. Receivership may not be imposed on any syndicate. Administrative bodies may not interfere in the affairs

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thereof. The board of directors of any syndicate may not be dissolved save by a court judgment. The opinion of the syndicate shall be sought on draft legislations pertaining to it.

Article (78)

The State shall ensure the citizens' right to adequate, safe and healthy housing in a manner which preserves human dignity and achieves social justice.

The State shall devise a national housing plan which upholds the environmental particularity and ensures the contribution of personal and collaborative initiatives in its implementation. The State shall also regulate the use of State lands and provide them with basic utilities within the framework of comprehensive urban planning which serves cities and villages and a population distribution strategy. This is to be applied in a manner serving the public interest, improving the quality of life for citizens and safeguards the rights of future generations.

The State shall also devise a comprehensive national plan to address the problem of unplanned slums, which includes re-planning, provision of infrastructure and utilities, and improvement of the quality of life and public health. In addition, the State shall guarantee the provision of resources necessary for implementing such plan within a specified period of time.

Article (79)

Each citizen has the right to healthy and sufficient food and clean water. The State shall ensure food resources to all citizens. The State shall also ensure sustainable food sovereignty and maintain agricultural biological diversity and types of local plants in order to safeguard the rights of future generations.

Article (80)

Anyone under the age of 18 shall be considered a child. Each child shall have the right to a name, identity documents, free compulsory vaccination, health and family or alternative care, basic nutrition, safe shelter, religious education, and emotional and cognitive development.

The State shall ensure the rights of children with disabilities, their rehabilitation and their integration in the society.

The State shall provide children with care and protection from all forms of violence, abuse, mistreatment and commercial and sexual exploitation.

Every child shall be entitled to acquire early education in a childhood center until the age of six. It is prohibited to employ children before the age of completing their preparatory education (six years of primary and three years of preparatory) or in jobs which subject them to danger.

The State shall also develop a judicial system for children that have been victims and or are witnesses. Children may not be held criminally accountable or detained save as provided in the

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Law and for the period of time specified therein. In such a case, they shall be provided with legal assistance and detained in appropriate locations separate from those allocated for the detention of adults.

The State shall endeavor to achieve the best interest of children in all measures taken against them.

Article (81)

The State shall guarantee the health, economic, social, cultural, entertainment, sporting and educational rights of persons with disabilities and dwarves, strive to provide them with job opportunities, allocate a percentage of job opportunities to them, and adapt public facilities and their surrounding environment to their special needs. The State shall also ensure their exercise of all political rights and integration with other citizens in compliance with the principles of equality, justice and equal opportunities.

Article (82)

The State shall guarantee the provision of care to the youth and youngsters shall endeavour to discover their talents; develop their cultural, scientific, psychological, physical and creative abilities, encourage their engagement in group and volunteer activities and enable them to participate in public life.

Article (83)

The State shall guarantee the health, economic, social, cultural and entertainment rights of the elderly people, provide them with appropriate pensions which ensure a decent life for them, and enable them to participate in public life. In its planning of public facilities, the State shall take into account the needs of the elderly. The State shall encourage civil society organizations to participate in taking care of the elderly people.

All the foregoing is to be applied as regulated by Law.

Article (84)

Everyone has the right to exercise sports. The State institutions and civil society shall endeavor to discover and sponsor the talented athletes and take the necessary measures to encourage the exercise of sports.

The Law shall regulate the affairs of sports and non-governmental sporting agencies in accordance with international standards and shall regulate the manner of settling sporting disputes.

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Article (85)

Every individual shall have the right to address public authorities in writing and under his own signature. Public authorities may not be addressed in the name of any groups except for any entity having a legal personality e.

Article (86)

Protecting national security is a duty. The responsibility of all parties to uphold national security is guaranteed by the Law.. . Defending the nation and the protection of its land are an honor and a sacred duty. Military service is mandatory according to the Law.

Article (87)

Participation of citizens in the public life is a national duty. Every citizen shall have the right to vote, run for elections, and express his/her opinion in referendums. The Law shall regulate the exercise of these rights. There may be exemption from the performance of this duty in certain cases to be specified by Law.

The State shall be responsible for entering the name of each citizen in the voters database without request therefrom provided he/she satisfies the conditions for voting. The State shall also purge this database on a periodic basis in pursuance of the Law. The State shall guarantee the safety, neutrality and integrity of referendum and election procedures. It is prohibited to use public funds, government agencies, public facilities, worship places, business sector institutions and non-governmental organizations and institutions for political purposes or election publicity.

Article (88)

The State shall safeguard the interests of Egyptians living abroad, protect them and protect their rights and freedoms, enable them to perform their public duties towards the State and society, and encourage their contribution to the development of the nation.

The Law shall regulate the participation of Egyptians living abroad in elections and referendums in a manner consistent with their particular circumstances, without being restricted by the provisions of voting, counting of ballots and announcing of results, set forth in this Constitution. This is without prejudice to providing guarantees to ensure the integrity and neutrality of the election and referendum process.

Article (89)

All forms of slavery, oppression, forced exploitation of human beings, sex trade, and other forms of human trafficking are prohibited and criminalized by Law.

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Article (90)

The State shall encourage the charitable endowment system for the establishing and sponsoring of scientific, cultural, health, social institutions and others, and shall ensure the independence thereof. The affairs of such institutions shall be managed in accordance with the conditions set by the person who created the endowment, as regulated by Law.

Article (91)

The State may grant political asylum to any foreigner persecuted for defending the interests of people, human rights, peace or justice.

Extradition of political refugees is prohibited. All of the foregoing shall be according to the Law.

Article (92)

Inalienable rights and freedoms of citizens may not be suspended or reduced.

No law regulating the exercise of rights and freedoms may restrict such rights and freedoms in a manner prejudicing the substance and the essence thereof.

Article (93)

The State shall be bound by the international human rights agreements, covenants and conventions ratified by Egypt, and which shall have the force of law after publication in accordance with the prescribed conditions.

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Part IV

Rule of Law

Article (94)

The rule of law shall be the basis of governing in the State.

The State shall be governed by Law. The independence, immunity and impartiality of the judiciary are essential guarantees for the protection of rights and freedoms.

Article (95)

Penalties are personal. There shall be no crime or punishment except pursuant to a law, and a penalty may only be inflicted by a court judgment. Penalty shall only be imposed for acts committed after the effective date of the law imposing it.

Article (96)

The accused person is presumed innocent until proven guilty in a fair legal trial in which the right to defend himself is guaranteed.

The law shall regulate the appeal of judgments passed on felonies.

The State shall provide protection to victims, witnesses, accused and informants as necessary and in accordance with the Law.

Article (97)

Litigation is a right that is safeguarded and an inalienable right for all. The State shall guarantee the accessibility of judicature for litigants and rapid adjudication on cases. It is prohibited to immunize any administrative act or decision from judicial review. No person may be tried except before the ordinary judge. Exceptional courts are prohibited.

Article (98)

The right of defense either in person or by proxy is guaranteed. The independence of the legal profession and the protection of its rights is a guarantee for the right of defense.

The law shall provide all means by which those who are financially unable can resort to justice and defend their rights.

Unofficial Translation

Article (99)

Any violation of personal freedom, or the sanctity of the private life of citizens, or any other public rights and freedoms which are guaranteed by the Constitution and the Law is a crime. The criminal and civil lawsuit arising of such crime shall not abate by prescription. The affected party shall have the right to bring a direct criminal action.

The State shall guarantee fair compensation for the victims of such violations. The National Council for Human Rights may file a complaint with the Public Prosecution of any violation of these rights, and it may intervene in the civil lawsuit in favor of the affected party at its request. All of the foregoing is to be applied in the manner set forth by Law.

Article (100)

Court judgments shall be issued and enforced in the name of the People. The State shall guarantee the means of the enforcement thereof as regulated by Law. Refraining from or delay in the enforcement of such judgments by the competent public servants is a crime punishable by Law. In such a case, the party in favor of whom the judgment is passed shall have the right to bring a direct criminal action before the competent court.. The Public Prosecution shall, at the request of the party in favor of whom the judgment is passed, initiate criminal action against the public servant refraining from executing the judgment or interrupting such execution.

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Part V

The System of Government

Chapter One

The Legislative Power

(House of Representatives)

Article (101)

In the manner stated in the Constitution, the House of Representatives is entrusted with the authority to enact legislations and approve the general policy of the State, the general plan of economic and social development and the State budget. It exercises oversight over the actions of the executive power.

Article (102)

The House of Representatives is composed of no less than four hundred and fifty members elected by direct secret public ballot.

A candidate for the membership of the House must be an Egyptian citizen, enjoying civil and political rights, a holder of at least the certificate of basic education, and should not be below 25 Gregorian years of age on the day of opening candidacy registration.

Other candidacy requirements, the electoral system, and division of electoral constituencies shall be defined by law in a manner which observes fair representation of the population and governorates and equitable representation of voters. Elections based on the plurality voting system or proportional list, or a combination of both at whatsoever ratio may be adopted.

The President of the Republic may appoint no greater than 5% of the members, the method of nomination thereof shall be stipulated by Law.

Article (103)

A member of the House of Representatives shall devote him/herself on a full time basis for the tasks of membership and his/her post shall be reserved for him/her in accordance with the Law.

Article (104)

As a condition for undertaking his/her duties, a House of Representatives member shall take the following oath: “I swear by The Almighty God to loyally uphold the republican system, respect

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the Constitution and the Law, fully uphold the interests of the People, and to safeguard the independence of the nation and the integrity and safety of ."

Article (105)

A House of Representatives member shall receive a remuneration determined by Law. In case the remuneration is changed, such change will only come into force at the commencement of the legislative term following the one during which the change was adopted.

Article (106)

The term of membership in the House of Representatives is five calendar years, commencing from the date of its first session.

Elections for a new House of Representatives shall be held during the sixty days preceding the end of the term of previous House.

Article (107)

The Court of Cassation shall have jurisdiction over the validity of membership in the House of Representatives. Appeals shall be submitted to the Court of Cassation within a period not exceeding thirty days from date on which the final election results are announced. Appeals shall be adjudicated within sixty days from the date of the receipt thereof.

In the event that a judgment declares a membership invalid, the invalidity of the membership shall be effective as of the date on which the court judgment is notified to the House.

Article (108)

In case a seat of a House of Representatives becomes vacant at least six months prior to the expiry of his tenure, the vacant position must be filled in accordance with Law within sixty days from the date on which the House reports the vacancy.

Article (109)

Throughout its membership tenure, no House of Representatives member may, whether in person or by proxy, buy, rent or lease any asset owned by the State or a public-law legal persons or a public sector company or a public enterprise sector company; sell to or barter with the state any part of its own property or conclude a contract with the State as a vendor, supplier, contractor or otherwise as set out by Law. Any of such acts shall be void.

A member must submit a financial estate disclosure upon taking membership and at the end of membership and at the end of each year of membership.

In case a House of Representatives member receives cash or in-kind gift because of or in connection with his/her membership, title thereto shall devolve to the State public treasury.

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All the foregoing shall be as regulated by Law.

Article (110)

Membership in the House of Representatives may only be dropped or cancelled if a member has lost confidence and esteem or ceases to satisfy any membership condition based on which he was elected or if he has violated the duties of membership.

The decision of cancellation must be issued by a majority of two-thirds of the members of the House of Representatives.

Article (111)

The House of Representatives shall accept resignation of its members, which must be submitted in writing. To be accepted, a resignation must not be submitted after the House has initiated procedures for cancelling the membership of the resigning member.

Article (112)

A House of Representatives member shall not be held accountable for any opinions expressed concerning the performance of his duty in the House or its committees.

Article (113)

Except in cases of *flagrante delicto*, it shall be prohibited to take any criminal action, under the Articles of felonies and misdemeanors, against a House of Representatives member without the prior permission from the House. In case the House of Representatives is not in session, a permission must be obtained from the House's Bureau, and the House must be notified at its first session.

In all cases, a decision should be taken on any motion for permission to take legal action against a House of Representatives member within thirty days; otherwise, the motion shall be deemed accepted.

Article (114)

The seat of the House of Representatives shall be in Cairo.

However, in exceptional circumstances, the House may hold its sessions elsewhere, at the request of the President of the Republic or one-third of the members of the House of Representatives.

Any meetings held otherwise and any resolutions passed thereby shall be void.

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Article (115)

The President of the Republic shall invite the House of Representatives for its annual ordinary session before the first Thursday of October; failing such invitation, the House is required by the Constitution to meet on the stated day.

The ordinary session shall continue for at least nine months. The President of the Republic shall bring each session to close with the approval of the House. This shall not be permissible except after State's General Budget has been approved.

Article (116)

At the President of the Republic's request or upon a motion signed by at least one tenth of the House members, the House of Representatives may hold an extraordinary meeting to consider an urgent issue.

Article (117)

At the first meeting of its annual regular session, the House of Representatives shall elect, from among its members, a speaker and two deputies for the full legislative term. If the office of any of the aforementioned persons becomes vacant, a substitute shall be elected by the House. The House's internal regulations shall provide for the rules and procedures of election. If any of the aforementioned persons fails to fulfill the duties of his office, one-third of the House members may request to relieve him of his office. The relevant decision shall be issued by a majority of two-thirds of the members.

In all cases, neither the Speaker nor any of the two deputies may be elected for more than two consecutive legislative terms.

Article (118)

The House of Representatives shall set its own internal regulations of its work and the manner of exercising its authorities and maintaining order therein. Such internal regulations shall be issued by a law.

Article (119)

The House of Representatives shall be competent to maintain order therein and this duty shall be incumbent upon the Speaker of the House.

Article (120)

The sessions of the House of Representatives shall be held in public.

The House may hold a secret session at the request of the President of the Republic, the Prime Minister, the Speaker of the House, or at least twenty of the House members. By the majority of

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its members, the House shall decide whether the discussion in question is to be conducted in a public or a secret session.

Article (121)

The meetings of the House and resolutions passed thereby shall not be deemed valid unless attended by the majority of its members.

In cases other than those requiring a special majority, resolutions shall be passed by the absolute majority of the members present. In case there is a tie of votes, the subject matter in deliberation shall be deemed rejected.

Laws shall be issued by the absolute majority of the members present, provided that such majority constitutes not less than one third of the House members.

The Laws deemed complementary to the Constitution shall be issued by a majority of of two thirds of the House members. Laws regulating presidential or parliamentary or municipal elections, political parties, the judiciary, related to judicial bodies and judicial organizations, and those regulating the rights and freedoms stipulated in the Constitution shall be deemed complementary to the Constitution.

Article (122)

The President of the Republic, the Cabinet, and every House member shall have the right to propose laws.

Every bill presented by the government or one tenth of the House members shall be referred to the competent specialized committees of the House for review and submission of a report to the House. A committee may seek the opinion of experts on the matter in question.

No bill presented by a member can be referred to the specialized committee unless it has been permitted by the committee responsible for proposals and approved by the House. If the committee responsible for proposals rejects a bill, it must provide a reasoned decision.

Any bill or proposed law rejected by the House may not be re-presented during the same legislative term.

(Article 123)

The President of the Republic has the right to issue laws or reject them.

If the President of the Republic objects to a draft law approved by the House of Representatives, he/she shall refer it back to the House of Representatives within thirty (30) days as of the date when the House of Representatives notified the President of such approval. If the President does

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not refer the draft law back to the House of Representatives within this period, the draft law shall be deemed a Law and shall be issued.

If the draft law is referred back to the House of Representatives within the aforementioned period and approved again by a majority of two-thirds of its members, it shall be deemed a Law and shall be issued.

Article (124)

The State budget shall include all of its revenues and expenditures without exception. The draft budget shall be submitted to the House of Representatives at least ninety (90) days before the beginning of the fiscal year; and shall not be effective unless approved thereby. Voting thereon shall be made on a section-by-section basis.

The House of Representatives may alter the expenditures stated in the draft budget, except for those allocated to honor a specific State liability.

Should such alteration result in an increase in total expenditures, the House of Representatives must reach an agreement with the Government on the means to procure sources of revenue so as to restore a balance between both. The State budget shall be issued by a law which may include an amendment of another existing law to the extent necessary to achieve such balance.

In all cases, the budget law may not include any provision that puts new burdens on citizens.

The Law shall specify the fiscal year, the method of preparing the State budget, and the provisions of the budgets of public bodies and organizations and their accounts.

The House of Representatives must approve the transfer of any funds from one section of the State budget to another, as well as any expenditure not included therein or in excess of its estimate. Such approval shall be issued by a law.

Article (125)

The final accounts of the State budget must be submitted to the House of Representatives within a period not exceeding six (6) months as of the end of the fiscal year. The annual report of the Central Auditing Organization (CAO) and the latter's notes on the final accounts shall be submitted therewith.

The final accounts shall be put to vote on a section-by-section basis and shall be issued by a law.

The House of Representatives has the right to ask CAO for any additional data or reports.

Article (126)

The Law shall regulate the basic rules for the collection of public funds and the procedures for their disbursement.

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Article (127)

The executive power may not obtain a loan or funding or engage in a project that is not listed in the approved State budget which entails expenditure from the State treasury within a subsequent period, except with the approval of the House of Representatives.

Article (128)

The Law shall specify the rules for setting salaries, pensions, indemnities, subsidies, and bonuses which are paid from the State treasury; and shall set out the cases in which exception from such rules may be made, as well as, the authorities in charge of their application.

Article (129)

Every member of the House of Representatives may direct any question to the Prime Minister, or one of his/her deputies, or a minister, or one of his/her deputies on any matter that falls within their respective authorities; and the latter must respond to such question during the same annual session.

The member may withdraw the question at any time. A question may not be converted to an interrogation in the same session.

Article (130)

Every member of the House of Representatives may direct an interrogation to the Prime Minister, or one of his/her deputies or a minister or one of his/her deputies in order to hold them accountable for matters that fall within their respective authorities.

The House of Representatives shall discuss the interrogation at least seven (7) days after its submission, within a maximum of sixty (60) days, except in cases of urgency as determined by the House and agreed by the Government.

Article (131)

The House of Representatives may decide to withdraw confidence from the Prime Minister, or one of his/her deputies or a minister or one of his/her deputies.

Filing a motion of no confidence may not be made except after an interrogation and upon a proposal submitted by at least one-tenth of the members of the House of Representatives. The House of Representatives shall issue a decision after considering the interrogation. Withdrawal of confidence requires the affirmative vote of a majority of the House members.

In all cases, a no-confidence motion may not be filed in connection with an issue that has already been decided upon in the same annual session.

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If the House of Representatives decides to withdraw confidence from the Prime Minister, or one of his/her deputies, or a minister or one of his/her deputies, with whom the Government has announced its solidarity with before voting, then that Government must resign. If the no-confidence resolution concerns a certain member of the Government, that member must resign.

Article (132)

At least 20 members of the House of Representatives may request the discussion of a public issue for the purpose of seeking a clarification on the Government's policy relating to such issue.

Article (133)

Any member of the House of Representatives may present a proposed recommendation on a public issue to the Prime Minister or one of his/her deputies, or a minister or one of his/her deputies.

Article (134)

Every member of the House of Representatives may submit an early day motion or urgent statement to the Prime Minister or one of his/her deputies, or a minister or one of his/her deputies in relation to urgent matters of public importance.

Article (135)

The House of Representatives may form a special fact-finding committee or entrust one of its existing committees with finding facts on a public matter or inspect the activities of an administrative body, public agency or public projects, for the purpose of finding facts on a specific issue, and inform the House of Representatives of the true financial, administrative or economic status, or to conduct investigations on a past activity or otherwise. The House of Representatives shall decide what it deems appropriate in this regard.

In order to carry out its mission, such a committee may collect the evidence it deems necessary and may summon individuals to give statements. All bodies shall comply with the committee's requests and place at its disposal all the documents, evidence, or anything otherwise required.

In all cases, every member of the House of Representatives is entitled to obtain any data or information from the executive power which is related to its performance of his/her duties at the House of Representatives.

Article (136)

The Prime Minister and his deputies, and the ministers and their deputies may attend the sessions of either the House of Representatives or any of its committees. Their attendance shall be obligatory if requested by the House. They may seek assistance from senior officials of their choice.

Unofficial Translation

They must be heard whenever they request to speak. They must answer questions relating to issues under discussion, without having the right to vote.

Article (137)

The President of the Republic may not dissolve the House of Representatives except in cases of necessity, by a reasoned decision and following a public referendum. The House of Representatives may not be dissolved for the same reason which caused the dissolution of the previous House.

The President of the Republic shall issue a decision to suspend the sessions of the House and hold a referendum on the dissolution within no more than twenty days. If the voters agree by majority of valid votes, the President of the Republic shall issue the decision of dissolution, and call for new elections within no more than thirty days from the date of the stated decision. The new House shall convene within the ten days following the announcement of final the results.

Article (138)

Every citizen may submit written proposals to the House of Representatives regarding public issues, and may also submit complaints to the House of Representatives to be referred to the competent ministers. If the House of Representatives so requests, the Minister must provide clarifications, and the concerned person shall be informed of the result.

Chapter Two

The Executive Power

Branch I

The President of the Republic

Article (139)

The President of the Republic is the head of State and the head of executive power. He shall care for the interests of the people, safeguard the independence of the nation and the territorial integrity and safety of its lands, abide by the provisions of the Constitution, and assume his authorities as prescribed therein.

Article (140)

The President of the Republic shall be elected for a period of four calendar years, commencing from the day following the termination of the term of his predecessor. The President may only be reelected once.

Unofficial Translation

The procedures for electing the President of the Republic shall be initiated at least one hundred twenty days prior to the end of the presidential term. The result must be announced at least thirty days prior to the end of such term.

The President of the Republic may not hold any partisan position throughout his presidential term.

Article (141)

A presidential candidate must be an Egyptian born to Egyptian parents, and neither he or his parents or his spouse may have held any other nationality. He must enjoy civil and political rights, must have performed the military service or have been exempted therefrom by law, and shall not be less than forty calendar years of age on the day of commencing candidacy registration. Other requirements for candidacy shall be set out by Law.

Article (142)

To be accepted as a candidate for the presidency, candidates must receive the recommendation of at least twenty elected members of the House of Representatives, or support from at least twenty five thousand citizens enjoying the right to vote, in at least fifteen governorates, with a minimum of one thousand supporter from each governorate.

In all cases, no one can support more than one candidate as regulated by Law.

Article (143)

The President of the Republic shall be elected by direct secret ballot, with an absolute majority of valid votes.

Procedures for electing the President of the Republic are regulated by Law.

Article (144)

As a condition for assuming his duties, the President of the Republic shall take the following oath before the House of Representatives: "I swear by The Almighty God to loyally uphold the republican system, respect the Constitution and the Law, fully uphold the interests of the People and to safeguard the independence of the nation and the integrity and safety of its territories."

In case of the absence of the House of Representatives, the oath shall be taken before the General Assembly of the Supreme Constitutional Court.

Article (145)

The salary of the President of the Republic shall be determined by Law. The President may not receive any other salary or remuneration. No modification to the salary may come into effect during the presidential term during which it is approved. Throughout his presidential term, the

Unofficial Translation

President may not, whether in person or by proxy, be self-employed, engage in commercial, financial or industrial activity, buy, rent or lease any property owned by the state or by a public-law legal person, or a public enterprise sector company, sell or barter any part of his own property with the State, or conclude a contract with the State as a vendor, supplier, contractor or otherwise as set out by Law. Any of such acts shall be void.

The President must submit a financial estate disclosure upon taking office, upon leaving it, and at the end of each year of service. Such financial estate disclosure is to be published in the Official Gazette.

Throughout the presidential term, the President of the Republic may not award himself any orders, decorations or medals.

In case the President of the Republic receives, in person or by proxy a cash or in-kind gift because of or in connection with the presidential office, title thereto shall devolve to the State public treasury.

Article (146)

The President of the Republic shall assign a Prime Minister to form the government and introduce his/her program to the House of Representatives. If his government does not win the confidence of the majority of the members of the House of Representatives within thirty days at the most, the President shall appoint a Prime Minister who is nominated by the party or the coalition that holds the majority or the highest number of seats in the House of Representatives. If the government of such prime minister fails to win the confidence of the majority of the members of the House of Representatives within thirty days, the House shall be deemed dissolved, and the President of the Republic shall call for the election of a new House of Representatives within sixty days from the date on which the dissolution is announced.

In all cases, the total periods for choice of government set forth in this Article shall not exceed sixty days.

In case the House of Representatives is dissolved, the Prime Minister shall present to the new House of Representatives the formation of his government and its program, at its first session.

In the event the government is chosen from the party or the coalition that holds the majority or the highest number of seats in the House of Representatives, the President of the Republic shall, in consultation with the Prime Minister, choose the Ministers of Defense, Interior, Foreign Affairs and Justice.

Article (147)

The President of the Republic may relieve the government from carrying out its duties, subject to the approval of the majority of the members of the House of Representatives.

Unofficial Translation

The President of the Republic may conduct a cabinet reshuffle after consultation with the Prime Minister and approval of the House of Representatives by an absolute majority of the members present , which must not be less than one third of its members.

Article (148)

The President of the Republic may delegate some of his powers to the Prime Minister, his deputies, ministers, or governors. None of them may delegate such authorities to others. All of the foregoing shall be regulated by Law.

Article (149)

The President of the Republic may call the government to convene a meeting to consult on important issues, and the President shall preside over the meetings that he attends.

Article (150)

Jointly with the Cabinet, the President of the Republic shall set the State's General Policy and oversee its implementation as stated in the Constitution.

The President of the Republic may deliver a statement on the State's General Policy before the House of Representatives at the opening of its annual regular session.

The President may deliver other statements or address other messages to the House.

Article (151)

The President of the Republic shall represent the State in its foreign relations and conclude treaties and ratify them after the approval of the House of Representatives. Such treaties shall acquire the force of law following their publication in accordance with the provisions of the Constitution.

Voters must be called for referendum on the treaties related to making peace and alliance, and those related to the rights of sovereignty. Such treaties shall only be ratified after the announcement of their approval in the referendum.

In all cases, no treaty may be concluded which is contrary to the provisions of the Constitution or which results in ceding any part of state territories.

Article (152)

The President of the Republic is the Supreme Commander of the Armed Forces. The President shall not declare war, or send the armed forces to a combat mission outside the State borders,

Unofficial Translation

except after consultation with the National Defense Council and obtaining the approval of the House of Representatives by a majority of two-thirds of the members.

In case the House of Representatives has not been elected, the Supreme Council of the Armed Forces (SCAF) must be consulted and the approval of both the Cabinet and National Defense Council must be obtained.

Article (153)

The President of the Republic shall appoint and dismiss civil and military employees and political representatives and accredit political representatives of foreign States and bodies in accordance with the Law.

Article (154)

After consultation with the Cabinet, the President of the Republic may declare the state of emergency as regulated by Law. Such declaration must be presented to the House of Representatives within the following seven days to decide thereon as it deems fit.

If the declaration takes place while the House of Representatives is not in regular session, the House must be invited to convene immediately in order to consider such declaration.

In all cases, the declaration of the state of emergency must be approved by a majority of the members of the House of Representatives. The state of emergency shall be declared for a specified period not exceeding three months, which may only be extended for another similar period after obtaining the approval of two-thirds of the House members. In case the House of Representatives has not been elected, the matter shall be referred to the Cabinet for approval provided, however, that it is presented to the new House of Representatives at its first session.

The House of Representatives may not be dissolved while the state of emergency is in force.

Article (155)

After consultation with the Cabinet, the President of the Republic may issue a pardon or reduce a sentence.

General amnesty may only be granted by virtue of a law, ratified by the majority of the members of the House of Representatives.

Article (156)

In case an event which requires taking urgent measures, which cannot be delayed, occurs while the House of Representatives is not in session, the President of the Republic shall call the House for an urgent meeting to present the matter thereto. If the House of Representatives has not been elected, the President of the Republic may issue decrees having the force of law, provided that

Unofficial Translation

they are then presented to, discussed and approved by the new House of Representatives within fifteen days from the commencement of its session. If such decrees are neither presented nor discussed by the House, or if they are presented but not ratified thereby, their force of law shall retroactively be revoked without need for issuing a decision to that effect, unless the House confirms its effectiveness during the previous period or decides to settle the consequences thereof.

Article (157)

Without prejudice to the provisions of the Constitution, the President of the Republic may call for a referendum on issues relating to the supreme interests of the State.

In case a call for referendum involves more than one issue, voting must be made separately on each issue.

Article (158)

The President of the Republic may submit his resignation to the House of Representatives. If the House has not been elected, he shall submit the same to the General Assembly of the Supreme Constitutional Court.

Article (159)

Accusing the President of the Republic of violating the provisions of the Constitution, treason or any other felony must be based on a motion signed by at least the majority of the members of the House of Representatives. The indictment shall only be issued by the majority of two-thirds of the members of the House of Representatives and after carrying an investigation by the Prosecutor General. In case the Prosecutor General is prevented from same, he shall be replaced by one of his assistants.

As soon as this indictment is issued, the President of the Republic shall be stopped from carrying out his duties; this is considered as a temporary impediment precluding the President from performing his competences until a verdict is issued in the case.

The President of the Republic shall be tried before a special court headed by the President of the Supreme Judicial Council with the membership of the most senior deputy of the President of the Supreme Constitutional Court, the most senior deputy of the President of the State Council, and the two most senior Presidents of the Courts of Appeal; prosecution is to be carried out before such court by the Prosecutor General. In case one of the aforementioned persons is prevented from serving, he shall be replaced by the person following him in seniority. The court verdicts shall be final and not subject to appeal.

The Law shall regulate the investigation and trial procedures. In case of conviction, the President of the Republic shall be relieved of his post without prejudice to any other penalties.

Unofficial Translation

Article (160)

In case the President of the Republic is temporarily prevented from assuming his powers, the Prime Minister shall act in his place.

If the President of the Republic's office becomes vacant due to his resignation, death, or permanent inability to work, the House of Representatives shall announce the vacancy. If such vacancy is attributable to any other reason, such announcement shall be made by a majority of at least two thirds of the members of House of Representatives. The House of Representatives shall then notify the National Electoral Commission, and the Speaker of the House of Representatives shall temporarily assume the powers of the President of Republic.

In case the House of Representatives has not been elected, the General Assembly of the Supreme Constitutional Court and its Chairman shall replace the House of Representatives and its Speaker with respect to the above.

In all events, a new President must be elected within a period not exceeding ninety (90) days as of the date of vacancy. In such a case, the presidential term shall start as of the date of announcement of the election results.

The interim President may not run for presidency or request any amendment to the Constitution or dissolve the House of Representatives or dismiss the Government.

Article (161)

The House of Representatives may propose to withdraw confidence from the President of the Republic and hold early presidential elections upon filing a reasoned motion to be signed by at least the majority of the members of the House of Representatives and upon approval of two-thirds of its members. The motion may only be filed once for the same reason within the presidential term.

Upon approval of the proposal to withdraw confidence, the matter of withdrawing confidence from the President of the Republic and holding early presidential elections shall be put to public referendum to be called by the Prime Minister. If the majority approves the decision to withdraw confidence, the President of the Republic shall be relieved from his office, the office of the President of the Republic shall be deemed vacant, and early presidential elections shall be held within sixty (60) days as of the date of announcing the results of referendum. If the result of the referendum is in the negative, the House of Representatives shall be deemed dissolved, and the President of the Republic shall call for election of a new House of Representatives within thirty (30) days as of the date of dissolution.

Unofficial Translation

Article (162)

If the vacancy of the presidential office coincides with the holding of a referendum or the election of the House of Representatives, the presidential elections shall be given priority. The then existing House of Representatives shall remain in place until the completion of the presidential elections.

Branch II

The Government

Article (163)

The government is the supreme executive and administrative body of the State, and consists of the Prime Minister, his/her deputies , the Ministers, and their deputies.

The Prime Minister shall head the government, oversee its work, and direct the performance of its functions.

Article (164)

The Prime Minister shall be an Egyptian citizen born to Egyptian parents and neither he/she nor his/her spouse may hold the nationality of any other country, shall enjoy civil and political rights, shall have been drafted into or legally exempted from the military service, and shall be at least thirty five (35) Gregorian years of age at the time of appointment.

Anyone appointed as a member of the government shall be an Egyptian citizen, shall enjoy all civil and political rights, shall have been drafted into or legally exempted from the military service, and shall be at least thirty (30) Gregorian years of age at the time of appointment.

It is prohibited to combine between the membership of the government and the membership of the House of Representatives. . If a member of the House of Representatives is appointed to the government, the seat thereof in the House shall become vacant as at the date of this appointment.

Article (165)

As a condition for assuming their duties, the Prime Minister and members of government shall take the following oath before the President of the Republic: “I swear by Allah, the Almighty, to loyally uphold the republican system, to respect the Constitution and the law, to fully uphold the interest of the People, and to safeguard the independence of the nation and the integrity and safety of its territories.”

Unofficial Translation

Article (166)

The salary of the Prime Minister and the members of government shall be defined by Law, and they may not receive any other salary or remuneration, nor engage, throughout the term of their respective offices, whether in person or through an intermediary, in self-professions, or commercial, financial or industrial business activities. Further, they shall not buy or rent any property owned by the state or a public legal person or a public sector company, or a public enterprise sector company, nor lease or sell any of their property to, or barter the same with the State, nor conclude a contract with the State as vendors, suppliers, contractors or otherwise. Any such actions shall be deemed null and void.

The Prime Minister and the members of government shall submit a financial estate disclosure upon taking office, upon leaving the same, and at the end of each year of service. The financial estate disclosure shall be published in the Official Gazette.

If the Prime Minister or any of the members of government receive cash or in-kind gifts, because of or in relation to their posts, the ownership thereof shall transfer to the State's treasury. The foregoing shall be regulated by Law.

Article (167)

The government shall particularly exercise the following functions:

1- To collaborate with the President of the Republic in developing the general policy of the State, and to supervise its implementation;

2- To maintain the security of the nation, and to protect the rights of citizens and the interest of the State;

3- To direct, coordinate and follow up on the work of the ministries and their affiliated public bodies and organizations;

4- To prepare draft bills and decrees;

5- To issue administrative decrees in accordance with the law, and to follow up on their implementation;

6- To develop the draft for the general plan of the State;

7- To prepare the draft annual budget of the State;

8- To conclude loan contracts and to grant the same in accordance with the provisions of the Constitution;

9- To implement the laws.

Unofficial Translation

Article (168)

Within the framework of the State's general policy, the minister shall develop the Ministry's general policy in collaboration with the competent authorities, supervise the implementation thereof and provide guidance and oversight.

Top management posts in all ministries shall include a permanent undersecretary to ensure institutional stability and raising the level of efficient implementation of its policy.

Article (169)

Any member of the government may make a statement before the House of Representatives, or one of its committees, concerning any matters falling within his/her mandate.

The House or the committee shall discuss such statement and convey its opinion regarding it.

Article (170)

The Prime Minister shall issue the necessary regulations for the execution of laws, in a manner that shall not involve any disruption of, amendment to, or exemption from their execution, and shall have the right to delegate others in issuing them, unless the law designates who shall issue the required executive regulations.

Article (171)

Upon the approval of the Council of Ministries, the Prime Minister shall issue the decrees necessary for the creation and organization of public utilities and services.

Article (172)

Upon the approval of the Council of Ministries, the Prime Minister shall issue the disciplinary regulations.

Article (173)

The Prime Minister and the members of the government shall be subject to the general rules governing investigation and trial procedures, in case that they commit crimes while or by reason of exercising the functions of their posts. The end of their term of service shall not preclude the institution or resumption of prosecution against them.

In case that the Prime Minister or any of the members of the government is accused of treason, the provisions stipulated in Article 159 herein shall apply.

Unofficial Translation

Article (174)

In case of resignation of the Prime Minister, the letter of resignation shall be submitted to the President of the Republic. If a minister offers resignation, it shall be submitted to the Prime Minister.

Branch III

The Local Administration

Article (175)

The State shall be divided into administrative units that enjoy legal personality. Such units shall include governorates, cities and villages. Other administrative units that have the legal personality may be established, if public interest so requires.

When establishing or abolishing local units or amending their boundaries, the economic and social conditions shall be taken into account. All the foregoing shall be regulated by Law.

Article (176)

The state shall ensure administrative, financial, and economic decentralization. The law shall regulate the methods of empowering administrative units to provide, improve, and well manage public facilities, and shall define the timeline for transferring powers and budgets to the local administration units.

Article (177)

The State shall ensure the fulfillment of the needs of local units in terms of scientific, technical, administrative and financial assistance, and the equitable distribution of facilities, services and resources, and shall bring development levels in these units to a common standard and achieve social justice between these units, as regulated by Law.

Article (178)

Local units shall have independent financial budgets.

The resources of local units shall include, in addition to the resources allocated to them by the State, taxes and duties of a local nature, whether primary or auxiliary. The same rules and procedures for the collection of public funds by the State shall apply to collection of such taxes and duties.

The foregoing shall be regulated by law.

Unofficial Translation

Article (179)

The law shall regulate the manner in which governors and heads of other local administrative units are appointed or elected, and shall determine their competences.

Article (180)

Every local unit shall elect a local council by direct and secret ballot for a term of four years. A candidate shall be at lease twenty one (21) Gregorian years of age. The law shall regulate the other conditions for candidacy and procedures of election, provided that one quarter of the seats shall be allocated to youth under thirty five (35) years of age and one quarter shall be allocated for women, and that workers and farmers shall be represented by no less than 50 percent of the total number of seats, and these percentages shall include an appropriate representation of Christians and people with disability.

Local councils shall be competent to follow up the implementation of the development plan, f monitor of the different activities, exercise of oversight over the executive authorities using tools such as providing proposals, and submitting questions, briefing motions, interrogations and others, and to withdraw confidence from the heads of local units, as regulated by Law.

The law shall define the competences of other local councils, their financial sources, guarantees of their members, and the independence of such councils.

Article (181)

Local councils' resolutions that are issued within their respective mandates shall be final. They shall not be subject to the interference by the executive authority, except to prevent the council from overstepping its jurisdiction, or causing damage to the public interest or the interest of other local councils.

Any dispute pertaining to the jurisdiction of these local councils in villages, centers or towns shall be settled by the governorate-level local council. Disputes regarding the jurisdiction of governorate-level local councils shall be resolved, as a matter of urgency, by the General Assembly of the Legal Opinion and Legislation Departments of the State Council. The foregoing shall be regulated by Law.

Article (182)

Every local council shall develop its own budget and final accounts, as regulated by Law.

Article (183)

Local councils shall not be dissolved by virtue of a general administrative action.

The Law shall regulate the manner of dissolving and re-electing local councils.

Unofficial Translation

Chapter Three

The Judiciary

Branch I

General Provisions

Article (184)

The Judiciary is an autonomous authority that carries out its tasks through courts of all types and degrees. Courts shall issue their rulings in accordance with the law, and the law shall define the jurisdiction of the courts. Interference in the affairs of the courts or in the lawsuits under their consideration shall constitute a crime that does not lapse by prescription.

Article (185)

Each judicial body or organization shall manage its own affairs, and shall have an independent budget, the components of which shall be fully examined by the House of Representatives. Upon its approval, this budget shall be included in the State budget under one budget line. Each judicial body or organization shall be consulted with regards to the bills regulating its affairs.

Article (186)

Judges are independent and immune to dismissal, are subject to no other authority but the law, and are equal in rights and duties. The conditions and procedures for their appointment, secondment and retirement shall be regulated by the law. The law shall further regulate their disciplinary accountability. They may not be fully or partly seconded except to the agencies determined by the law and to perform the tasks set forth therein. All the foregoing shall be in the manner that maintains the independence and impartiality of the judiciary and judges, and shall prevent conflicts of interest. The rights, duties and guarantees granted to them shall be specified by Law.

Article (187)

Court sessions shall be public, unless the court decides on its secrecy to safeguard public order or public morals. In all cases, court judgments shall be pronounced in publicly held sessions.

Branch II

The Judiciary & The Prosecution

Article (188)

The judiciary shall decide on all disputes and crimes, except those falling within the jurisdiction of other judicial bodies. It shall solely have the jurisdiction to settle disputes relating to its own

Unofficial Translation

members. The affairs of the judiciary shall be managed by a Supreme Council, the structure and jurisdiction of which shall be regulated by Law.

Article (189)

The Public Prosecution is an integral part of the judiciary. It shall carry out the investigation and prosecution of criminal cases, except those excepted by the law. The law shall determine its other jurisdictions.

The Prosecutor General shall be in charge of the Public Prosecution. He shall be chosen by the Supreme Council of the Judiciary from among those ranked as Vice presidents of the Court of Cassation, or from those ranked as Presidents of the Courts of Appeal or from the Assistants to the Prosecutor General. He shall be appointed by virtue of a Presidential Decree for four years or for the remaining years until he reaches the age of retirement whichever is earlier, and this appointment shall be only once during his term of service.

Branch III

The State Council

Article (190)

The State Council is an autonomous judicial body, and it shall have the exclusive jurisdiction to settle administrative disputes and disputes relevant to the execution of all its rulings. It shall have jurisdiction over disciplinary suits and appeals, and the exclusive jurisdiction to provide advice regarding legal issues to the administrative bodies determined by the law. It shall also review and draft bills and decrees of legislative nature, and shall review draft contracts to which the state or any other public authority is a party. The law shall determine its other jurisdictions.

Chapter Four

The Supreme Constitutional Court

Article (191)

The Supreme Constitutional Court is an autonomous and independent judicial body having its headquarters in Cairo. However, in cases of emergency it may, upon the approval of its General Assembly, hold its sessions elsewhere in Egypt. It shall have an independent budget, which shall be fully examined by the House of Representatives. Upon its approval, this budget shall be included in the State budget under one budget line. The General Assembly of the court shall manage its affairs and it shall be consulted regarding bills relevant to its affairs.

Unofficial Translation

Article (192)

The Supreme Constitutional Court shall be solely competent to decide on the constitutionality of laws and regulations, to interpret legislative provisions, and to adjudicate on disputes pertaining to the affairs of its members, on jurisdictional disputes between judicial bodies and entities that have judicial jurisdiction, on disputes pertaining to the implementation of two final contradictory judgments, one of which is rendered by a judicial body or an authority with judicial jurisdiction and the other is rendered by another , and on disputes pertaining to the execution of its judgments and decisions.

The law shall determine the Court's other competences and regulate the procedures that are to be followed before the Court.

Article (193)

The Court shall be composed of a President and a sufficient number of deputies to the President.

The Commissioners of the Supreme Constitutional Court shall have a President and a sufficient number of Commission presidents, advisors and assistant advisors.

The General Assembly of the Court shall elect its President from among the most senior three vice-presidents of the Court. It shall further choose the vice-presidents and the members of its Commissioners, and the appointment thereof shall be made by virtue of a decree by the President of the Republic. The foregoing shall be regulated by Law.

Article (194)

The President and the vice-presidents of the Supreme Constitutional Court, and the President and members of its Commissioners are independent and immune to dismissal, and are subject to no other authority but the law. The law shall set out the conditions they must meet. The Court shall be responsible for their disciplinary accountability, as stated by the law. All rights, duties and guarantees granted to other members of the judiciary shall apply to them.

Article (195)

The judgments and decisions issued by the Supreme Constitutional Court shall be published in the Official Gazette, and they shall be binding upon everyone and all of the State authorities. They shall have *Res judicata* vis-à-vis all of them.

The law shall regulate the consequences of a judgment rendering a text of law unconstitutional.

Unofficial Translation

Chapter Five

Judicial Organizations

Article (196)

The State Lawsuits Authority is an independent judicial organization. It undertakes the legal representation of the State in lawsuits filed by or against the State, and of proposing amicable settlement of disputes at any stage of litigation. It shall further have technical oversight on the departments of legal affairs of the State administrative bodies with regard to cases handled thereby. It shall draft contracts referred thereto by administrative bodies and to which the State is party. The foregoing shall be regulated by Law.

Other competences of the Organization shall be defined by the law. Its members shall have all of the guarantees, rights and duties assigned to other members of the Judiciary. Their disciplinary accountability shall be regulated by the law.

Article (197)

The Administrative Prosecution is an independent judicial organization. It undertakes investigations into financial and administrative violations, and also those referred to it. Regarding these violations, the Administrative Prosecution shall have the authorities of the administrative body to impose disciplinary penalties. Challenges against the decision of the Prosecution shall be filed before the competent disciplinary court at the State Council. It shall further initiate actions, appeals, and disciplinary proceedings before the State Council courts. All the foregoing shall be regulated by Law.

Other competences of the Administrative Prosecution shall be defined by law. All guarantees, rights and duties assigned to other members of the Judiciary shall apply to its members. Their disciplinary accountability shall be regulated by the law.

Chapter Six

The Legal Profession

Article (198)

The legal profession is a free profession which participates with the Judicial Authority in the establishment of justice and the rule of law, and ensures the right to defense. It shall be practiced by independent attorneys, and attorneys of public authorities, public sector companies and public enterprise sector companies. All attorneys shall have, while performing their duties to uphold the right to defense before the courts, the guarantees and protection granted to them by the law. Such rights shall also be granted to them before investigation and inquiry authorities. Except in cases of *flagrante delicto*, the arrest or detention of attorneys while exercising their right to defense shall be prohibited. The foregoing shall be determined by the law.

Unofficial Translation

Chapter Seven

Experts

Article (199)

Judicial experts, forensic medicine experts, and notary public's technical staff undertake their duties independently, and shall have the guarantees and protection required for them to perform their tasks, as regulated by the Law.

Chapter Eight

The Armed Forces & The Police

Branch I

The Armed Forces

Article (200)

The Armed Forces belong to the People, and their duty is to protect the country, and preserve its security and the integrity of its territories. Only the State shall be entitled to establish the Armed Forces. No individual, organization, entity, or group shall be allowed to create military or quasi-military squadrons, groups or organizations.

The Armed Forces shall have a supreme council, as regulated by Law.

Article (201)

The Minister of Defense is the Commander in Chief of the Armed Forces, and shall be appointed from among its officers.

Article (202)

The Law regulates the military mass mobilization, and determines the conditions of the military service, promotion and retirement in the Armed Forces.

The judicial committees for officers and personnel of the Armed Forces shall be solely competent to adjudicate on all administrative disputes pertaining to decisions affecting them. The Law regulates the rules and procedures for challenging the decisions made by these committees.

Unofficial Translation

Branch II

National Defense Council

Article (203)

National Defense Council shall be chaired by the President of the Republic and comprise the membership of the Prime Minister, the Speaker of the House of Representatives, the Minister of Defense, the Minister of Foreign Affairs, the Minister of Finance and the Minister of Interior, the Chief of the General Intelligence Service, the Chief of Staff of the Armed Forces as well as the Commanders of the Navy, the Air Forces and Air Defense, the Chief of Operations of the Armed Forces, and the Head of Military Intelligence.

The Council shall be competent to examine the matters pertaining to preserving the security and integrity of the country, and to discuss the budget of the Armed Forces, which shall be included in the State budget under one budget line. The opinion of the Council shall be obtained on the bills concerning the Armed Forces.

Other competences of the Council shall be specified by Law.

Upon discussing the budget, the Head of the Financial Affairs Department of the Armed Forces and the heads of the Planning and Budgeting Committee and the National Security Committee at the House of Representatives shall join the Council.

The President of the Republic may invite any person having relevant expertise to attend the Council's meetings without having the right to vote.

Branch III

Military Courts

Article (204)

The Military Court is an independent judicial body exclusively competent to adjudicate on all crimes pertaining to the Armed Forces, the officers and personnel thereof, and their equivalents, and on the crimes committed by the personnel of the General Intelligence while and by reason of performing their duties.

No civilian shall face trial before the Military Court, except for crimes that constitute a direct assault against military facilities or camps of the Armed Forces, or their equivalents, against military zones or border zones determined as military zones, against the Armed Forces' equipment, vehicles, weapons, ammunition, documents, military secrets, or its public funds, or against military factories; crimes pertaining to military service; or crimes that constitute a direct assault against the officers or personnel of the Armed Forces by reason of performing their duties.

Unofficial Translation

The law shall define such crimes, and specify the other competences of the Military Court.

Members of the Military Court shall be independent and shall be immune to dismissal. They shall have all the guarantees, rights and duties stipulated for the members of other judicial bodies.

Branch IV

National Security Council

Article (205)

The National Security Council shall be chaired by the President of the Republic, and comprise the membership of the Prime Minister, the Speaker of the House of Representatives, the Minister of Defense, the Minister of Interior, the Minister of Foreign Affairs, the Minister of Finance, the Minister of Justice, the Minister of Health, the Minister of Communication and the Minister of Education, the Chief of the General Intelligence Service, and the Head of the Committee of Defense and National Security at the House of Representatives.

The Council shall be responsible for adopting strategies for establishing the security of the country and facing disasters and crises of all kinds, shall take the necessary measures to contain them, to identify sources of threat to the Egyptian national security, inside the country or abroad, and to undertake the necessary actions to address them at both official and popular levels.

The Council may invite any person having relevant expertise to attend its meetings without having the right to vote.

The law shall determine the other competences of the Council and its regulations.

Branch V

The Police

Article (206)

The police force is a statutory civil body that is dedicated to the service of the People and its loyalty shall be to the People. It shall ensure safety and security of the citizens, preserve public order and morality. It shall comply with the duties set out in the Constitution and the law, and shall respect human rights and fundamental freedoms. The State shall guarantee that the staff of the Police force perform their duties, and the relevant guarantees shall be regulated by Law.

Unofficial Translation

Article (207)

A supreme police council shall be formed from among the most senior officers of the police force and the Head of the Legal Opinion Department at the State Council. The Council shall be competent to assist the Minister of Interior in the organization of the Police force and management of the affairs of its staff members. The other competences of the Council shall be determined by Law. The Council shall be consulted in connection with any laws pertaining to the police force.

Chapter Nine

National Elections Commission

Article (208)

The National Elections Commission is an independent authority and shall be solely competent to administer referenda and elections of the president, the parliament and the local councils. Such administration shall include the development and updating of a database for voters, proposing the division of constituencies, determination of controls for promotion and funding of electoral campaigns, as well as electoral expenditure, the disclosure of such expenditure, the supervision of such controls, the facilitation of the procedures for out-of-country voting by expatriate Egyptians, and other procedures till the announcements of the results.

The foregoing shall be regulated by law.

Article (209)

The National Elections Commission shall be administered by a board composed of 10 members to be equally assigned on full time basis from among those ranked as Vice-presidents of the Court of Cassation, those ranked as Presidents of the Courts of Appeal, Vice-presidents of the State Council, the State Lawsuits Organization and the Administrative Prosecution. They shall be selected by the Supreme Judicial Council and special councils of the aforementioned judicial bodies and organizations, as the case may be, provided that they are not members thereof. They shall be appointed by virtue of a decree by the President of the Republic. They shall be assigned to work on a full time basis at the Commission for one term of six years. The Commission shall be chaired by the most senior judge at the Court of Cassation.

Half of the members of the Council shall be replaced every three years.

The Commission may seek the assistance of independent public figures, specialists, and those deemed to have relevant expertise in the field of elections. They shall not have the right to vote.

Unofficial Translation

The Commission shall have a permanent executive body. The law shall determine the composition and constitution of such executive body, and the rights, duties and guarantees of its members in a way that achieves their neutrality, independence and integrity.

Article (210)

Voting and counting of votes in referenda and elections shall be administered by members of the Commission under the overall supervision of its Board. It may seek the help of members of judicial organizations.

The voting and counting of votes in elections and referenda which take place during the 10 years following the effective date of this Constitution shall be totally overseen by members of judicial bodies and organizations according to the Law.

The High Administrative Court shall be competent to adjudicate on challenges filed against the Commission's decisions pertaining to referenda, presidential and parliamentary elections, and the results thereof. Challenges against elections of local councils shall be filed before the Administrative Courts. Dates to file challenges against these decisions shall be specified by law, provided that challenges shall be finally decided within ten days from the date of recording the challenge.

Chapter Ten

Supreme Council for the Regulation of Media

Article (211)

The Supreme Council for the Regulation of Media is an independent entity that has a legal personality, and enjoys technical, financial and administrative independence, and has an independent budget.

The Council shall be competent to regulate the affairs of audio and visual media and regulate the printed and digital press, and other media means.

The Council shall bear the responsibility for guaranteeing and protecting the freedom of press and media as stipulated in the Constitution, safeguarding its independence, neutrality, plurality and diversity, preventing monopolistic practices, monitoring the legality of the sources of funding of press and media institutions and developing the controls and criteria necessary to ensure compliance by the press and media outlets with the professional and ethical standards, and national security needs as stated in the Law.

The law shall determine the composition and regulations of the Council, and the employment conditions for its staff.

Unofficial Translation

The Council shall be consulted with respect to the bills and regulations related to its scope of competence..

Article (212)

The National Press Organization is an independent organization that shall manage and develop state-owned press institutions and their assets, as well as ensure their modernization, independence, neutrality and their adherence to good professional, administrative and economic standards.

The law shall determine the composition and regulations of the Organization, and the employment conditions for its staff.

It shall be consulted with respect to the bills and regulations pertaining to its scope of work. .

Article (213)

The National Media Organization is an independent organization that shall manage and develop state-owned visual, audio and digital media outlets and their assets, as well as ensure their development, independence, neutrality and their adherence to good professional, administrative and economic standards.

The law shall determine the composition and regulations of the Organization and the employment conditions for its staff.

It shall be consulted with respect to the bills and regulations pertaining to its scope of work. .

Chapter Eleven

National Councils, Autonomous Organizations & Control Agencies

Branch I

National Councils

Article (214)

The law shall specify the independent national councils, including the National Council for Human Rights, the National Council for Women, the National Council for Childhood and Motherhood, and the National Council for Disabled Persons. The law shall state the composition, mandates, and guarantees for the independence and neutrality of their respective members. Each council shall have the right to report to the competent authorities any violations pertaining to their fields of work.

Unofficial Translation

These councils shall have legal personalities and shall be technically, financially, and administratively independent. They shall be consulted with respect to the bills and regulations pertaining to their affairs and fields of work.

Branch II

Autonomous Organizations and Control Agencies

Article (215)

Autonomous Organizations and control agencies shall be specified by Law. These organizations and agencies shall have legal personality, and shall be technically, financially and administratively independent. They shall be consulted with respect to the bills and regulations that relate to their fields of work. These bodies and agencies shall include the Central Bank, the Egyptian Financial Supervisory Authority (EFSA), the Central Auditing Organization (CAO), and the Administrative Control Authority.

Article (216)

The formation of each individual autonomous organization or regulatory agency shall be enacted by a law defining its competences and regulations, and stipulating guarantees for its independence, the necessary protection for its members, and their employment conditions in a way that ensures their neutrality and independence.

The President of the Republic shall appoint the heads of such organizations and regulatory agencies, upon the approval of the House of Representatives by a majority of its members, for a one-time renewable term of four years. They shall not be dismissed, except in the cases stated in the law. The same prohibitions applicable to the Ministers shall apply to these heads.

Article (217)

Autonomous organizations and control agencies shall submit annual reports to the President of the Republic, the House of Representatives and the Prime Minister, immediately after their issuance.

The House of Representatives shall examine such reports and take the appropriate action within a period not exceeding four months from the date of receipt. The reports shall be made available to the public.

Autonomous organizations and control agencies shall notify the competent investigation authorities of any evidence discovered in relation to violations or crimes. They shall take the necessary measures with regards to these reports within a specified period of time. The foregoing shall be regulated by Law.

Unofficial Translation

Article (218)

The State shall fight corruption, and the competent control agencies and organizations shall be identified by Law.

Competent control agencies and organizations shall coordinate their activities in combating corruption, enhancing the values of integrity and transparency in order to ensure the sound performance of public functions and preserve public funds, and shall develop and follow up execution of a national strategy to combat corruption in collaboration with other competent agencies and organizations, as regulated by Law.

Article (219)

The Central Auditing Organization shall be responsible for monitoring the funds of the State, the funds of the State public and independent legal persons and other authorities as specified by Law; s well as being responsible for monitoring the implementation of the State budget and independent budgets and for auditing its final accounts.

Article (220)

The Central Bank shall be responsible for developing and overseeing the implementation of monetary, credit, and banking polices, and for monitoring the performance of banks. It is solely entitled to issue banknotes. It shall maintain the integrity of the monetary and banking system, and the stability of prices within the framework of the State general economic policy, as regulated by Law.

Article (221)

The Egyptian Financial Supervisory Authority (EFSA) shall be responsible for monitoring and supervising financial non-banking markets and instruments including capital markets, futures exchanges, insurance activities, mortgage finance, financial leasing, and factoring and securitization, as regulated by Law.

Unofficial Translation

Part VI

General & Transitional Provisions

Chapter One

General Provisions

Article (222)

The city of Cairo is the capital of the Arab Republic of Egypt.

Article (223)

The national flag of the Arab Republic of Egypt consists of three colors; black, white, and red with an eagle taken from the "Eagle of Salah El Din" in golden yellow. The emblem, decorations, insignia, seal and the national anthem shall be determined by Law.

Desecration of the Egyptian flag shall be a crime punishable under the law.

Article (224)

All the provisions stipulated by laws and regulations prior to the promulgation of this Constitution shall remain in force, and they may neither be amended nor repealed except in accordance with the regulations and procedures prescribed herein.

The state shall be obliged to issue laws executing the provisions of this Constitution.

Article (225)

Laws shall be published in the Official Gazette within 15 days from the date of their issuance, to be effective after 30 days from the day following the date of publication, unless the law specifies a different date.

Provisions of the laws shall only apply from the date of their entry into force. However, in articles pertaining to non-criminal and non-tax-related matters, the contrary may be provided for in the law, upon approval by a majority of two thirds of the members of House of Representatives.

Article (226)

The amendment of one or more articles of the Constitution may be requested by the President of the Republic or one-fifth of the members of the House of Representatives. The request shall specify the articles requested to be amended and the reasons for such amendment.

Unofficial Translation

In all cases, the House of Representatives shall discuss the amendment request within 30 days from the date of its receipt. The House shall issue its decision to accept the request in whole or in part by a majority of its members.

If the request is rejected, the same articles may not be requested to be amended again before the next legislative term.

If the amendment request is approved by the House, it shall discuss the text of the articles requested to be amended within 60 days from the date of approval. If approved by a two-thirds majority of the House's members, the amendment shall be put to a public referendum within 30 days from the date the approval is issued. The amendment shall be effective from the date on which the referendum's result and the approval of a valid majority of the participants in the referendum are announced.

In all cases, texts pertaining to the re-election of President of the Republic or the principles of freedom or equality stipulated in this Constitution may not be amended, unless the amendment brings more guarantees.

Article (227)

The Constitution and its preamble and all its provisions constitute an integral text and an indivisible whole, and its provisions constitute one coherent unit.

Chapter Two

Transitional Provisions

Article (228)

The High Electoral Committee and the Presidential Election Committee existing at the time this Constitution comes into force shall undertake the full supervision of the first parliamentary and presidential elections following the effective date of the Constitution. The funds of the two committees shall be transferred to the National Electoral Commission, immediately upon its formation.

Article (229)

The elections of the House of Representatives following the date on which this Constitution comes into effect shall take place in accordance with the provisions of Article 102 hereof.

Article (230)

Election of the President of the Republic or the House of Representatives shall take place as regulated by Law, provided that the first of either elections shall take place within a period not

Unofficial Translation

less than 30 days and not more than 90 days after the date on which this Constitution comes into effect.

In all cases, the following electoral procedures shall commence within a period not exceeding six months as of the date on which the Constitution comes into effect.

Article (231)

The presidential term following the effective date of this Constitution shall commence as of the date on which the final result of the election is announced.

Article (232)

The Interim President of the Republic shall continue to exercise presidential powers stipulated herein until the elected President of the Republic takes the constitutional oath.

Article (233)

If the Interim President of the Republic is rendered unable to exercise his powers by reason of a temporary impediment, the Prime Minister shall replace him.

If the Interim Presidential office becomes vacant due to resignation, death, permanent disability or any other reason, the most senior Vice-President of the Supreme Constitutional Court shall replace him with the same powers.

Article (234)

The Minister of Defense shall be appointed upon the approval of the Supreme Council of the Armed Forces. The provisions of this article shall remain in force for two full presidential terms starting from the date on which this Constitution comes into effect.

Article (235)

In its first legislative term following the effective date of this Constitution, the House of Representatives shall issue a law to regulate constructing and renovating churches, in a manner that guarantees the freedom to practice religious rituals for Christians.

Article (236)

The State shall guarantee setting and implementing a plan for the comprehensive economic and urban development of border and underprivileged areas, including Upper Egypt, Sinai, Matrouh, and Nubia. This shall be made with the participation of the residents of these areas in the development projects, and they shall be given a priority in benefiting therefrom, taking into account the cultural and environmental patterns of the local community, within ten years from the date that this Constitution comes into effect, as regulated by Law.

Unofficial Translation

The State shall work on setting and implementing projects to bring back the residents of Nubia to their original territories and develop such territories within 10 years, as regulated by law.

Article (237)

The State shall fight all types and forms of terrorism, and track its funding sources as a threat to the nation and its citizens, within a specific timeframe while guaranteeing basic rights and freedoms. .

The law shall regulate the provisions and procedures of fighting terrorism, and fair compensation for the damages resulting therefrom and because thereof.

Article (238)

The State guarantees gradual performance of its obligation to allocate the minimum government expenditure rates on education, higher education, health and scientific research that are stipulated in this Constitution as at the date on which it enters into effect, provided it is fully compliant in the State budget of the fiscal year 2016/2017.

The State shall provide compulsory education until the completion of the secondary stage in a gradual manner to be completed by school year 2016/2017.

Article (239)

The House of Representatives shall issue a law organizing the rules for assigning judges and members of judicial bodies and organizations, ensuring the cancellation of full and partial assignment to non-judicial bodies or committees with judicial jurisdiction, or for managing justice affairs or overseeing elections, within a period not exceeding five years from the date on which this Constitution comes into effect.

Article (240)

The State shall ensure providing financial and human resources necessary to appealing the judgments issued by criminal courts on felonies within 10 years from the date on which this Constitution comes into effect. The foregoing shall be regulated by Law.

Article (241)

In its first legislative term after the enforcement of this Constitution, the House of Representatives shall issue a law on transitional justice that ensures revealing the truth, accountability, proposing frameworks for national reconciliation, and compensating victims, in accordance with international standards.

Unofficial Translation

Article (242)

The existing system of municipal administration shall continue to be in force until the system stipulated herein is gradually implemented within five years of the date of entry into force of this Constitution, without prejudice to Article 180 thereof.

Article (243)

The State shall endeavor that workers and farmers be appropriately represented in the first House of Representatives to be elected after this Constitution is approved, as regulated by law.

Article (244)

The State shall endeavor that youth, Christians, persons with disability and Egyptians living abroad be appropriately represented in the first House of Representatives to be elected after this Constitution is approved, as regulated by law.

Article (245)

The employees of the Shoura Council who are still in service on the date that this Constitution comes into force shall be transferred to the House of Representatives with the same job levels and seniority on that date. Their salaries, allowances, bonuses, and their other financial entitlements granted to them on an individual basis shall be maintained. All funds of the Shoura Council shall be transferred to the House of Representatives.

Article (246)

The Constitutional Declaration issued on July 5th, 2013, the Constitutional Declaration issued on July 8th, 2013, and any constitutional texts or provisions of the Constitution issued in 2012 but not covered by this constitutional document shall be deemed repealed as of the date that this Constitution comes into effect. Their consequential effects shall however remain in force.

Article (247)

This Constitution shall come into effect as at the date on which it is announced that the People have approved it in a referendum through a majority of valid votes of the participants.

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Bolivia (Plurinational State of)'s Constitution of 2009

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Translated by Max Planck Institute

- Motives for writing constitution
- Preamble
- Source of constitutional authority

Preamble

- Ownership of natural resources
- Reference to country's history

In ancient times mountains arose, rivers moved, and lakes were formed. Our Amazonia, our swamps, our highlands, and our plains and valleys were covered with greenery and flowers. We populated this sacred Mother Earth with different faces, and since that time we have understood the plurality that exists in all things and in our diversity as human beings and cultures. Thus, our peoples were formed, and we never knew racism until we were subjected to it during the terrible times of colonialism.

We, the Bolivian people, of plural composition, from the depths of history, inspired by the struggles of the past, by the anti-colonial indigenous uprising, and in independence, by the popular struggles of liberation, by the indigenous, social and labor marches, by the water and October wars, by the struggles for land and territory, construct a new State in memory of our martyrs.

- Right to water
- Reference to fraternity/solidarity
- Human dignity

A State based on respect and equality for all, on principles of sovereignty, dignity, interdependence, solidarity, harmony, and equity in the distribution and redistribution of the social wealth, where the search for a good life predominates; based on respect for the economic, social, juridical, political and cultural pluralism of the inhabitants of this land; and on collective coexistence with access to water, work, education, health and housing for all.

We have left the colonial, republican and neo-liberal State in the past. We take on the historic challenge of collectively constructing a Unified Social State of Pluri-National Communitarian law, which includes and articulates the goal of advancing toward a democratic, productive, peace-loving and peaceful Bolivia, committed to the full development and free determination of the peoples.

We women and men, through the Constituent Assembly (Asamblea Constituyente) and with power originating from the people, demonstrate our commitment to the unity and integrity of the country.

- God or other deities

We found Bolivia anew, fulfilling the mandate of our people, with the strength of our Pachamama and with gratefulness to God.

Honor and glory to the martyrs of the heroic constituent and liberating effort, who have made this new history possible.

PART I. FUNDAMENTAL BASES OF THE STATE: RIGHTS, DUTIES AND GUARANTEES

TITLE I. FUNDAMENTAL BASES OF THE STATE

CHAPTER I. Model of the State

Article 1

Bolivia is constituted as a Unitary Social State of Pluri-National Communitarian Law (Estado Unitario Social de Derecho Plurinacional Comunitario) that is free, independent, sovereign, democratic, inter-cultural, decentralized and with autonomies. Bolivia is founded on plurality and on political, economic, juridical, cultural and linguistic pluralism in the integration process of the country.

- Right to self determination
- Reference to country's history

Article 2

Given the pre-colonial existence of nations and rural native indigenous peoples and their ancestral control of their territories, their free determination, consisting of the right to autonomy, self-government, their culture, recognition of their institutions, and the consolidation of their territorial entities, is guaranteed within the framework of the unity of the State, in accordance with this Constitution and the law.

- Citizenship of indigenous groups
- Protection of environment

Article 3

The Bolivian nation is formed by all Bolivians, the native indigenous nations and peoples, and the inter-cultural and Afro-Bolivian communities that, together, constitute the Bolivian people.

- Freedom of religion
- Official religion
- Separation of church and state

Article 4

The State respects and guarantees freedom of religion and spiritual beliefs, according to their view of the world. The State is independent of religion.

Article 5

- Official or national languages

I. The official languages of the State are Spanish and all the languages of the rural native indigenous nations and peoples, which are Aymara, Araona, Baure, Bésiro, Canichana, Cavineño, Cayubaba, Chácobo, Chimán, Ese Ejja, Guaraní, Guarasu'we, Guarayu, Itonama, Leco, Machajuyai-kallawaya, Machineri, Maropa, Mojeñotrinitario, Mojeño-ignaciano, Moré, Mosetén, Movima, Pacawara, Puquina, Quechua, Sirionó, Tacana, Tapiete, Toromona, Uruchipaya, Weenhayek, Yaminawa, Yuki, Yuracaré and Zamuco.

- Official or national languages

II. The Pluri-National Government and the departmental governments must use at least two official languages. One of them must be Spanish, and the other shall be determined taking into account the use, convenience, circumstances, necessities and preferences of the population as a whole or of the territory in question. The other autonomous governments must use the languages characteristic of their territory, and one of them must be Spanish.

Article 6

- National capital
- National anthem
- National flag

I. Sucre is the Capital of Bolivia.

II. The symbols of the State are the red, yellow and green tri-color flag; the Bolivian national anthem; the coat of arms; the wiphala; the rosette; the kantuta flower and the patujú flower.

CHAPTER II. Principals, Values and Purposes of the State

Article 7

Sovereignty resides in the Bolivian people and is exercised directly and by delegation. The functions and attributes of the organs of public power emanate, by delegation, from sovereignty; it is inalienable and unlimited.

Article 8

I. The State adopts and promotes the following as ethical, moral principles of the plural society: ama qhilla, ama llulla, ama suwa (do not be lazy, do not be a liar or a thief), suma qamaña (live well), ñandereko (live harmoniously), teko kavi (good life), ivi maraei (land without evil) and qhapaj ñan (noble path or life).

- Reference to fraternity/solidarity
- Human dignity

II. The State is based on the values of unity, equality, inclusion, dignity, liberty, solidarity, reciprocity, respect, interdependence, harmony, transparency, equilibrium, equality of opportunity, social and gender equality in participation, common welfare, responsibility, social justice, distribution and redistribution of the social wealth and assets for well being.

Article 9

The following are essential purposes and functions of the State, in addition to those established in the Constitution and the law:

1. To construct a just and harmonious society, built on decolonization, without discrimination or exploitation, with full social justice, in order to strengthen the Pluri-National identities.

- Right to development of personality
- Right to culture
- Human dignity

2. To guarantee the welfare, development, security and protection, and equal dignity of individuals, nations, peoples, and communities, and to promote mutual respect and intra-cultural, inter-cultural and plural language dialogue.

3. To reaffirm and strengthen the unity of the country, and to preserve the Pluri-National diversity as historic and human patrimony.

4. To guarantee the fulfillment of the principles, values, rights and duties recognized and consecrated in this Constitution.

- Right to work

5. To guarantee access of all people to education, health and work.

- Ownership of natural resources
- Protection of environment

6. To promote and guarantee the responsible and planned use of natural resources, and to stimulate their industrialization through the development and strengthening of the productive base in its different dimensions and levels, as well as to preserve the environment for the welfare of present and future generations.

Article 10

I. Bolivia is a pacifist State that promotes the culture of peace and the right to peace, as well as cooperation among the peoples of the region and the World, for the purpose of contributing to mutual understanding, equitable development, and the promotion of an inter-cultural character, with full respect for the sovereignty of states.
II. Bolivia rejects every war of aggression as a means of resolving differences and conflicts between states, and it reserves the right to its legitimate defense in the event of aggression that threatens the independence and integrity of the State.
III. The installation of foreign military bases on Bolivian territory is prohibited.

CHAPTER III. System of Government

- Type of government envisioned

Article 11

I. The Republic of Bolivia adopts a participatory democratic, representative and communal form of government, with equal conditions for men and women.
II. Democracy is exercised in the following forms, which shall be developed by law:
    1. Direct and participatory, through referendum, citizen legislative initiative, revocation of terms of office, assembly, councils and prior consultation. The assemblies and councils shall have a deliberative character in accordance with the law.

- Referenda

    2. Representative, by means of the election of representatives by universal, direct and secret vote, in accordance with the law.

- Claim of universal suffrage
- Secret ballot

    3. Communal, by means of the election, designation or nomination of the authorities and representatives pursuant to the norms and procedures of the native indigenous nations and peoples, among others, in accordance with the law.

Article 12

- Judicial independence
- Claim of executive independence

I. The State organizes and structures its public power through Legislative, Executive, Judicial and Electoral bodies. The organization of the State is based on the independence, separation, coordination and cooperation among these bodies.
II. Control, Defense of the Society, and Defense of the State are functions of the state.

- Judicial independence
- Claim of executive independence

III. The functions of the public bodies may not be united in a single body nor may they be delegated.

TITLE II. FUNDAMENTAL RIGHTS AND GUARANTEES

CHAPTER I. General Matters

Article 13

- Legal status of treaties
- International law

I. The rights recognized in this Constitution are inviolable, universal, inter-dependent, indivisible and progressive. The State has the duty to promote, protect and respect them.
II. The rights declared in this Constitution shall not be understood to deny other rights that are not enumerated.
III. The classification of the rights established in this Constitution does not determine any hierarchy or superiority of some rights over others.
IV. International treaties and conventions ratified by the Pluri-National Legislative Assembly (Asamblea Legislativa), which recognize human rights and prohibit their limitation in States of Emergency, prevail over internal law. The rights and duties consecrated in this Constitution shall be interpreted in accordance with the International Human Rights Treaties ratified by Bolivia.

Article 14

- General guarantee of equality
- Equality regardless of political party
- Equality regardless of religion
- Equality regardless of language
- Equality regardless of origin
- Equality regardless of financial status
- Equality regardless of age
- Equality regardless of skin color
- Equality regardless of creed or belief
- Equality regardless of gender
- Equality regardless of sexual orientation
- Equality regardless of nationality
- Equality regardless of social status
- Equality for persons with disabilities
- Principle of no punishment without law

I. Every human being, without distinction, has legal status and capacity under the law and enjoys the rights recognized in this Constitution.
II. The State prohibits and punishes all forms of discrimination based on sex, color, age, sexual orientation, gender identity, origin, culture, nationality, citizenship, language, religious belief, ideology, political affiliation or philosophy, civil status, economic or social condition, type of occupation, level of education, disability, pregnancy, and any other discrimination that attempts to or results in the annulment of or harm to the equal recognition, enjoyment or exercise of the rights of all people.
III. The State guarantees everyone and all collectives, without discrimination, the free and effective exercise of the rights established in this Constitution, the laws and international human rights treaties.
IV. In the exercise of rights, no one shall be obligated to do anything that is not mandated by the Constitution or laws, nor be deprived of that which they do not prohibit.
V. Bolivian laws are applied to every person, natural and legal, Bolivian and foreign, within Bolivian territory.
VI. Foreigners who are in Bolivian territory have the rights, and must fulfill the duties, established in the Constitution, except for the restrictions that it may contain.

CHAPTER II. Fundamental Rights

Article 15

- Prohibition of torture
- Prohibition of capital punishment
- Right to life
- Prohibition of cruel treatment

I. Every person has the right to life and physical, psychological and sexual integrity. No one shall be tortured, nor suffer cruel, inhuman, degrading or humiliating treatment. The death penalty does not exist.
II. Everyone, in particular women, have the right not to suffer physical, sexual or psychological violence, in the family as well as in the society.
III. The State shall adopt the necessary measures to prevent, eliminate and punish sexual and generational violence, as well as any action or omission intended to be degrading to the human condition, to cause death, pain, and physical, sexual or psychological suffering, whether in public or private spheres.
IV. No person shall be submitted to a forced disappearance for any reason or under any circumstance.

- Prohibition of slavery

V. No person shall be submitted to servitude or slavery. The trade and trafficking of persons is prohibited.

Article 16

- Right to water

I. Every person has the right to water and food.
II. The State has the obligation to guarantee food security, by means of healthy, adequate and sufficient food for the entire population.

- Access to higher education

Article 17

Every person has the right to receive an education at all levels, which is universal, productive, free, comprehensive and inter-cultural, and without discrimination.

- Right to health care

Article 18

I. Every person has the right to health.
II. The State guarantees the inclusion and access to health for all persons, without any exclusion or discrimination.
III. There shall be a single health system, which shall be universal, free, equitable, intra-cultural, intercultural, and participatory, with quality, kindness and social control. The system is based on the principles of solidarity, efficiency and co-responsibility, and it is developed by public policies at all levels of the government.

Article 19

- Right to shelter

I. Every person has the right to an adequate habitat and home that dignifies family and community life.
II. The State, at all levels of the government, is responsible for promoting the development of housing for social benefit, using adequate financing systems, based on principles of solidarity and equity. These plans shall be directed preferentially to families with scarce resources, to disadvantaged groups and to rural areas.

Article 20

- Telecommunications
- Right to water

I. Every person has the right to universal and equitable access to basic services of potable water, sewer systems, electricity, gas services in their domicile, postal, and telecommunications services.

- Telecommunications

II. It is the responsibility of the State, at all levels of government, to provide basic services through public, mixed, cooperative or community entities. In the case of electricity, gas and telecommunications services, these may be provided by contracts with private companies. The provision of services should respond to the criteria of universality, responsibility, accessibility, continuity, quality, efficiency, equitable fees and necessary coverage; with social participation and control.

- Right to water

III. Access to water and sewer systems are human rights, neither are the object of concession or privatization, and are subject to a regimen of licensing and registration, in accordance with the law.

CHAPTER III. Civil and Political Rights

Section I. Civil Rights

Article 21

Bolivians have the following rights:

- Right to culture

1. To cultural self-identification.

- Human dignity

2. To privacy, intimacy, honor, their self image and dignity.

- Right to privacy
- Freedom of opinion/thought/conscience
- Freedom of religion

3. To freedom of belief, spirituality, religion and cult, expressed individually or collectively, in public and in private, for legal purposes.

- Freedom of association
- Freedom of religion
- Freedom of assembly
- Freedom of expression
- Right to information
- Freedom of movement

4. To freedom of assembly and association, publicly and privately, for legal purposes.
5. To freely express and disseminate thoughts and opinions by any means of oral, written or visual communication, individually or collectively.
6. To have access to information and to interpret, analyze and communicate it freely, individually or collectively.
7. To freedom of residence, permanence and circulation throughout the territory of Bolivia, which includes the right to leave and enter the country.

- Inalienable rights
- Human dignity

Article 22

The dignity and freedom of persons is inviolable. It is the primary responsibility of the State to respect and protect them.

Article 23

- Privileges for juveniles in criminal process
- Prison registry

I. Every person has the right to freedom and personal security. Personal liberty may only be restricted within the limits set forth by law to assure the discovery of the true facts concerning acts in jurisdictional processes.
II. The imposition of measures depriving the liberty of adolescents shall be avoided. Every adolescent who is deprived of liberty shall receive preferential treatment on the part of the judicial, administrative and police authorities. They shall assure at all times respect for the dignity of the adolescent and their anonymity. The detention shall be carried out in premises distinct from those assigned to adults, taking into account the needs of his or her age.
III. No one shall be detained, apprehended or deprived of liberty, except in the cases and according to the forms established by the law. The execution of a warrant shall require that it be issued by a competent authority in writing.
IV. Any person found in flagrant commission of a crime may be arrested by any other person, even without a warrant. The sole purpose of the arrest shall be to bring the person before a competent judicial authority, who must resolve their legal status within a maximum period of twenty-four hours.
V. At the time that a person is deprived of liberty, he shall be informed of the reasons for his detention, as well as the charges or complaint formulated against him.
VI. Those responsible for the detention centers must keep a registry of the persons deprived of liberty. They shall not receive any person without copying the corresponding warrant in the registry. Failure to fulfill this duty shall give rise to the procedures and sanctions set forth in the law.

- Right of petition

Article 24

Every person has the right to petition, individually and collectively, whether orally or in writing, and to receive a formal and prompt response. To exercise this right, the only requirement is to identify the petitioner.

- Regulation of evidence collection
- Right to privacy

Article 25

I. Every person has the right to the inviolability of his home and to the confidentiality of private communications of all forms, except as authorized by a court.
II. Correspondence, private papers and private statements contained in any medium are inviolable and may not be seized except in cases determined by law for criminal investigation, based on a written order issued by a competent judicial authority.
III. No public authority, person or organization may intercept private conversations or communications by an installation that monitors or centralized them.
IV. The information and proof obtained by violation of correspondence and communications, in whatever form, has no legal effect.

Section II. Political Rights

Article 26

- Right to form political parties
- Claim of universal suffrage
- Secret ballot
- Compulsory voting
- Indigenous right to representation
- Indigenous right to vote

I. All citizens have the right to participate freely in the formation, exercise and control of political power, directly or through their representatives, individually or collectively. Participation shall be equitable and under equal conditions for men and women.

II. The right to participate includes:

1. Organization for purposes of political participation, in accordance with the Constitution and the law.
2. The right to suffrage, by equal, universal, direct, individual, secret, free and obligatory vote, which is publicly counted.
3. Where communitarian democracy is practiced, the electoral processes shall be exercised according to their own norms and procedures, and shall supervised by the Electoral Organ (Organo Electoral) only if the electoral act is not subject to equal, universal, direct, secret, free and obligatory vote.
4. The direct election, designation and nomination of the representatives of the nations and the rural native indigenous peoples, in accordance with their own norms and procedures.
5. The monitoring of the acts of public function.

- Restrictions on voting

Article 27

I. Bolivians who reside outside the country have the right to participate in the election of the President and Vice President of the State, and in other elections as established by law. The right to vote is exercised by registration and recording carried out by the Electoral Organ (Organo Electoral).

II. Foreigners resident in Bolivia have the right to vote in municipal elections, in accordance with the law, pursuant to the application of principles of international reciprocity.

- Conditions for revoking citizenship
- Restrictions on voting

Article 28

The exercise of political rights is suspended in the following instances after a sentence has been executed and while the sentence has not been completed:

1. For having taken up arms and serving in the armed forces of the enemy in times of war.

2. For embezzlement of public funds.

3. For acts of treason against the country.

- Protection of stateless persons
- International law

Article 29

I. The right of foreigners to request and receive asylum or political refuge for ideological or political persecution is recognized in accordance with the laws and international treaties.

II. Anyone who has been granted asylum or refuge in Bolivia shall not be expelled or deported to a country where his life, bodily integrity, security or liberty is endangered. The State shall attend in a positive, humanitarian and efficient manner to requests for family reunification presented by parents or children who are given asylum or refuge.

CHAPTER IV. Rights of the Nations and Rural Native Indigenous Peoples

- Right to culture

Article 30

I. A nation and rural native indigenous people consists of every human collective that shares a cultural identity, language, historic tradition, institutions, territory

I. and world view, whose existence predates the Spanish colonial invasion.
II. In the framework of the unity of the State, and in accordance with this Constitution, the nations and rural native indigenous peoples enjoy the following rights:
1. To be free.
2. To their cultural identity, religious belief, spiritualities, practices and customs, and their own world view.
3. That the cultural identity of each member, if he or she so desires, be inscribed together with Bolivian citizenship in his identity card, passport and other identification documents that have legal validity.
4. To self-determination and territoriality.
5. That its institutions be part of the general structure of the State.
6. To the collective ownership of land and territories.
7. To the protection of their sacred places.
8. To create and administer their own systems, means and networks of communication.
9. That their traditional teachings and knowledge, their traditional medicine, languages, rituals, symbols and dress be valued, respected and promoted.
10. To live in a healthy environment, with appropriate management and exploitation of the ecosystems.
11. To collective ownership of the intellectual property in their knowledge, sciences and learning, as well as to its evaluation, use, promotion and development.
12. To an inter-cultural, intra-cultural and multi-language education in all educational systems.
13. To universal and free health care that respects their world view and traditional practices.
14. To the practice of their political, juridical and economic systems in accord with their world view.
15. To be consulted by appropriate procedures, in particular through their institutions, each time legislative or administrative measures may be foreseen to affect them. In this framework, the right to prior obligatory consultation by the State with respect to the exploitation of nonrenewable natural resources in the territory they inhabit shall be respected and guaranteed, in good faith and upon agreement.
16. To participate in the benefits of the exploitation of natural resources in their territory.
17. To autonomous indigenous territorial management, and to the exclusive use and exploitation of renewable natural resources existing in their territory without prejudice to the legitimate rights acquired by third parties.
18. To participate in the organs and institutions of the State.

III. The State guarantees, respects and protects the rights of the nations and the rural native indigenous peoples consecrated in this Constitution and the law.

- Right to self determination
- Protection of language use
- Protection of environment
- Provisions for intellectual property
- Reference to science
- Right to health care
- Ownership of natural resources
- Ownership of natural resources
- Ownership of natural resources

Article 31

I. The nations and the rural native indigenous peoples that are in danger of extinction, in voluntary isolation and not in contact, shall be protected and respected with respect to their forms of individual and collective life.
II. The nations and the rural native indigenous peoples that live in isolation and out of contact enjoy the right to maintain themselves in that condition, and to the legal definition and consolidation of the territory which they occupy and inhabit.

Article 32

The Afro-Bolivian people enjoy, in everything corresponding, the economic, social, political and cultural rights that are recognized in the Constitution for the nations and the rural native indigenous peoples.

CHAPTER V. Social and Economic Rights

Section I. Environmental Rights

- Protection of environment

Article 33

Everyone has the right to a healthy, protected, and balanced environment. The exercise of this right must be granted to individuals and collectives of present and future generations, as well as to other living things, so they may develop in a normal and permanent way.

- Protection of environment

Article 34

Any person, in his own right or on behalf of a collective, is authorized to take legal action in defense of environmental rights, without prejudice to the obligation of public institutions to act on their own in the face of attacks on the environment.

Section II. Right to Health and Social Security

Article 35

I. The State, at all levels, shall protect the right to health and promote public policies designed to improve the quality of life, the collective well being, and free access of the population to health services.
II. The health system is unitary and includes traditional medicine of the nations and the rural native indigenous peoples.

Article 36

- Right to health care

I. The State shall guarantee access to universal health care.
II. The State shall control the practice of public and private health services and shall regulate them by law.

Article 37

The State has the irrevocable obligation to guarantee and sustain the right to health care, which is a supreme function and primary financial responsibility. The promotion of health and the prevention of diseases shall be prioritized.

Article 38

I. Public health goods and services are State property and may not be privatized or licensed to others.
II. Health services shall be provided in uninterrupted form.

Article 39

I. The State shall guarantee public health services, and it recognizes private health services; it shall regulate and oversee the quality through sustained medical audits that evaluate the work of personnel, the infrastructure and equipment, in accordance with the law.
II. The law punishes negligent actions and omissions committed in the practice of medicine.

Article 40

The State shall guarantee the organized participation of the population in decision-making and in the management of the entire public health system.

Article 41

I. The State shall guarantee the access of the population to medicines.
II. The State shall prioritize generic medicines through the promotion of their domestic production and, if need be, shall decide to import them.

- Provisions for intellectual property

III. The right to access medicine shall not be restricted by intellectual property rights and commercial rights, and it contemplates quality standards and first generation medicines.

Article 42

I. It is the responsibility of the State to promote and guarantee the respect for, and the use, research and practice of traditional medicine, rescuing ancestral knowledge and practices created from the thinking and values of all the nations and the rural native indigenous peoples.

- Provisions for intellectual property

II. The promotion of traditional medicine shall include the registry of natural medicines and of their curative properties, as well as the protection of their knowledge as intellectual, historic, cultural property and as patrimony of the nations and the rural native indigenous peoples.

III. The law shall regulate the practice of traditional medicine and shall guarantee the quality of service.

Article 43

The law shall regulate the donations and transplants of cells, tissue or organs, based on principles of humanity, solidarity, opportunity, providing them free of charge, and efficiency.

Article 44

I. No one shall be submitted to surgical intervention, medical examination or laboratory test without his or her consent or that of legally authorized third persons, except when his or her life is in imminent danger.

II. No one shall be submitted to scientific experiments without his or her consent.

Article 45

I. Every Bolivian has the right to social security.

II. Social security is provided under the principles of universality, comprehensiveness, equity, solidarity, unity of management, economy, opportunity, its inter-cultural character, and effectiveness.

III. The social security system covers assistance for the following reasons: sickness, epidemics and catastrophic diseases; maternity or paternity; professional and work risks, and risks in farm labor; disability and special necessities; unemployment and loss of employment; being an orphan, crippled, widowed, of old age, and death; housing, family allowances and other social reasons.

IV. The State guarantees the right to retirement, which is universal, supportive and equitable.

V. Women have the right to a safe maternity, with an inter-cultural practice and vision; they shall enjoy the special assistance and protection of the State during pregnancy and birth and in the prenatal and postnatal periods.

VI. The public social security services shall not be privatized nor licensed to others.

Section III. Right to Work and Employment

Article 46

- Right to just remuneration
- Right to work
- Right to safe work environment
- Right to reasonable standard of living

I. Every person has the following rights:

1. To dignified work, with industrial and occupational health and safety, without discrimination, and with a fair, equitable and satisfactory remuneration or salary that assures a dignified existence for the worker and his or her family.
2. To a stable source of work under equitable and satisfactory conditions.

II. The State shall protect the exercise of work in all its forms.

III. All forms of forced work or other analogous exploitation that obligates a person to work without his or her consent and without fair remuneration is prohibited.

- Right to establish a business

Article 47

I. Every person has the right to dedicate him or herself to business, industry or any other legal economic activity under conditions which do not harm the collective well being.
II. The workers in small urban or rural productive units, or who are self-employed, and guild members in general, shall enjoy special protection on the part of the State through a policy of equitable commercial exchange and fair prices for their products, as well as a preferential allowance of financial economic resources to promote their production.
III. The State shall protect, promote and strengthen communitarian forms of production.

Article 48

I. The social and labor dispositions are of obligatory fulfillment.
II. The labor norms shall be interpreted and applied based on the following principles: the protection of workers as the primary productive force of society; the primacy of the labor relation; work continuity and stability; non discrimination and the making of investments in favor of the worker.
III. The recognized rights and benefits in favor of workers cannot be waived, and agreements that are contrary to, or that tend to deride their effects, are null and void.
IV. The salaries or earned pay, labor rights, social benefits and contributions to social security, which are not paid, have a privilege and priority over any other debt and may not be attached or made unenforceable.
V. The State shall promote the incorporation of women into the workforce and shall guarantee them the same remuneration as men for work of equal value, both in the public and private arena.
VI. Women shall not be discriminated against or fired because of their civil status, because of pregnancy, because of their age or physical features, or because of the number of children they have. It is guaranteed that pregnant women and parents cannot be dismissed from employment until the child completes one year of age.
VII. The State guarantees the incorporation of youth into the productive system, in accordance with their capacity and training.

Article 49

I. The right of collective bargaining is recognized.
II. The following shall be regulated by law: labor relations related to contracts and collective agreements; general sector minimum wages and salary increases; reincorporation; paid vacations and holidays; calculation of seniority, the work day, extra hours, night time overtime, Sunday work; Christmas bonuses, vouchers, bonuses and other systems of participation in the profits of the enterprise; indemnification and severance pay; maternity leave; professional training and formation; and other social rights.
III. The State shall protect the stability of employment. Unjustified dismissal and all forms of labor harassment are prohibited. The law shall determine the corresponding sanctions.

- Right to rest and leisure

Article 50

The State, through the courts and specialized administrative bodies, shall resolve all conflicts arising from labor relations between employer and employee, including those of industrial safety and social security.

- Right to join trade unions

Article 51

I. All workers have the right to organize unions pursuant to the law.
II. The State shall respect the union principles of unity, union democracy, political pluralism, self financing, solidarity and internationalism.

III. Unionization is recognized as a form of defense, representation, support, education and culture of workers in the countryside and in the city.
IV. The State shall respect the ideological and organizational independence of the unions. The unions shall have legal personality derived from the sole fact of being organized, and they shall be recognized by their parent entities.
V. The tangible and intangible property of union organizations is inviolable; it may not be attached or delegated.
VI. The union leaders enjoy union privileges; they may not be fired for one year after the end of their office term, and their social rights may not be diminished; nor may they be subjected to persecution or deprivation of liberty for acts undertaken in fulfillment of their union work.
VII. Workers who are self employed have the right to organize to defend their interests.

Article 52

I. The right of free business association is recognized and guaranteed.
II. The State shall guarantee recognition of the legal personality of business associations, as well as democratic forms of business organizations, according to their own statutes.
III. The State recognizes the training institutions of business organizations.
IV. The tangible and intangible property of business organizations is inviolable and may not be attached.

- Right to strike

Article 53

The right to strike is guaranteed as the exercise of the legal power of workers to suspend work to defend their rights, in accordance with the law.

Article 54

- Right to work

I. It is the obligation of the State to establish employment policies that avoid unemployment and underemployment and that have as their objective the creation, maintenance and generation of conditions that guarantee workers the possibility of dignified work and fair remuneration.
II. It is the duty of the State and society to protect and defend industrial equipment and that of state services.
III. The workers, in defense of their source of work and to safeguard the social interest, shall, in accordance with the law, reactivate and reorganize enterprises that are in the process of bankruptcy, insolvency or liquidation, or closed or abandoned unjustifiably, and they shall form communitarian or social enterprises. The State shall support the actions of the workers.

Article 55

The cooperative system is based on principles of solidarity, equality, reciprocity, equity of distribution, social purpose, and the non profit motive of its members. The State shall promote and regulate the organization of cooperatives by means of the law.

Section IV. Right to Property

Article 56

- Right to own property
- Right to own property
- Right to transfer property

I. Everyone has the right to private, individual or collective property, provided that it serves a social function.
II. Private property is guaranteed provided that the use made of it is not harmful to the collective interests.
III. The right to inheritance is guaranteed.

- Protection from expropriation

Article 57

Expropriation shall be imposed for reasons of necessity or public utility, defined in accordance with the law and upon prior fair indemnification. Urban real estate is not subject to reversion.

Section V. Rights of Children, Adolescents and Youth

- Rights of children

Article 58

Every person of minor age is considered a child or adolescent. Children and adolescents have rights recognized in the Constitution, with the limits established by it, and they have the specific rights inherent to their development; to their ethnic, socio-cultural, gender and generational identity; and to the satisfaction of their needs, interests and aspirations.

- Rights of children

Article 59

- Rights or duties of parents
- Rights or duties of parents
- State support for children
- Right to culture

I. Every child and adolescent has the right to physical development.
II. Every child and adolescent has the right to live and to grow up in the bosom of his or her natural or adoptive family. When that is not possible, or is contrary to his or her best interests, he or she shall have the right to a substitute family in accordance with the law.
III. Every child and adolescent, without regard to origin, has equal rights and duties with respect to his or her parents. Discrimination among offspring on the part of parents shall be punished by law.
IV. Every child and adolescent has the right to identity and filial relationship with respect to his or her parents. When the parents are not known, the conventional surname chosen by the person responsible for his or her care will be used.
V. The State and society guarantee the protection, promotion and active participation of youth in productive, political, social, economic and cultural development, without any discrimination whatsoever, in accordance with the law.

- State support for children

Article 60

It is the duty of the State, society and the family to guarantee the priority of the best interests of the child or adolescent, which includes the preeminence of his or her rights, the priority of receiving protection and aid in any circumstance, priority in the attention of public and private services, and access to prompt and appropriate administration of justice, and the assistance of specialized personnel.

Article 61

- Limits on employment of children

I. Any form of violent punishment against children or adolescents is prohibited, both in the family as well as in society.
II. Forced work and child labor is prohibited. The activities of children and adolescents within their families and society shall be directed to their full development as citizens, and they shall have a formative function. Their rights, guarantees, and the institutional mechanisms for their protection shall be the object of special regulation.

Section VI. Rights of the Family

- Right to found a family

Article 62

The State recognizes and protects the family as the fundamental nucleus of society, and guarantees the social and economic conditions necessary for its full development. Every member has equal rights, obligations and opportunities.

Article 63

- Provision for matrimonial equality
- Provision for civil marriage

I. The marriage between a man and a woman is formed by legal bond and is based on equality of the rights and duties of the spouses.
II. The free unions or de facto unions, which meet the conditions of stability and singularity and that are maintained between a man and a women without legal impediment, shall have the same effects as a civil marriage, both in the personal and property relations of the couple as well as with respect to adopted children or to children born to the couple.

Article 64

- Rights or duties of parents

I. Spouses or cohabitants have the duty, in equal conditions and by common effort, to attend to the maintenance and responsibility of the home, and to the education and development of the children while they are minors or have some disability.
II. The State shall protect and assist those who are responsible for the family in the exercise of their obligations.

Article 65

Because of the best interests of children and adolescents and their right to the identity, presumed parentage shall be validated by indication of the mother or father. This presumption shall be valid in the absence of proof of the contrary, with the burden of proof on the person who denies parentage. In case that the proof negates the presumption, the costs incurred shall correspond to the one who indicated parentage.

Article 66

Women and men are guaranteed the exercise of sexual rights and their reproductive rights.

Section VII. Rights of the Elderly Adults

- State support for the elderly

Article 67

I. In addition to the rights recognized in this Constitution, every person of adult age has the right to a dignified old age that has quality and human warmth.
II. The State shall provide an old age pension within the framework of full social security, in accordance with the law.

- State support for the elderly

Article 68

I. The State shall adopt public policies for the protection, attention, recreation, rest and social occupation of elderly adults, in accordance with their capacities and possibilities.
II. All forms of mistreatment, abandonment, violence and discrimination against elderly persons is prohibited and punished.

Article 69

The war veterans deserve the gratitude and respect of the public and private institutions and of the population in general; they shall be considered heroes and defenders of Bolivia and shall receive a life pension from the State as established by the law.

Section VIII. Rights of Disabled Persons

- State support for the disabled

Article 70

Everyone who has a disability enjoys the following rights:

1. To be protected by his or her family and by the State.
2. To a free education and physical health.
3. To an alternative language of communication.
4. To work in appropriate conditions, consistent with his or her possibilities and capacities, with fair remuneration that assures a dignified life.
5. To the development of his or her individual potential.

- State support for the disabled

Article 71

I. Any kind of discrimination, mistreatment, violence and exploitation of anyone who is disabled shall be prohibited and punished.
II. The State shall adopt measures of affirmative action to promote the effective integration of disabled persons into the productive, economic, political, social, and cultural sphere, without any discrimination whatsoever.
III. The State shall create the conditions that permit the development of individual potential of disabled persons.

- State support for the disabled

Article 72

The State shall guarantee disabled persons comprehensive prevention and rehabilitation services, as well as other benefits that are established by law.

Section IX. Rights of Persons Deprived of Liberty

Article 73

- Human dignity

I. Every person who is submitted to any form of deprivation of liberty shall be treated with the respect due to human dignity.
II. Every person deprived of liberty has the right to communicate freely with his or her defense lawyer, interpreter, family and close friends. Deprivation of communication is prohibited. Any limitation of communication may only take place in the context of investigation of the commission of crimes, and shall last a maximum of twenty four hours.

Article 74

I. It is the responsibility of the State to reinsert into society the persons deprived of liberty, to assure respect for their rights and their retention and custody in an adequate environment, according to the classification, nature and seriousness of the crime, as well as the age and sex of the persons detained.
II. Persons deprived of liberty shall have the opportunity to work and to study in penitentiary centers.

Section X. Rights of Users of Services and Consumers

- Protection of consumers

Article 75

The users and consumers enjoy the following rights:

1. To the supply of food, pharmaceuticals, and products in general, in harmless and quality condition, in sufficient and adequate quantity, and with efficient service and timely supply.

2. To reliable information about the characteristics and contents of the products they consume and of the services they use.

Article 76

I. The State guarantees access to a comprehensive system of public transportation in diverse modalities. The law shall determine that the system of transportation be efficient and effective, and that it generates benefits to the users and to the providers.
II. No customs controls, squads or control points of any kind may exist in Bolivian territory, except those that have been created by law.

CHAPTER VI. Education, Cultural Diversity and Cultural Rights

Section I. Education

Article 77

I. Education is one of the most important functions and primary financial responsibilities of the State, which has the mandatory obligation to sustain, guarantee and coordinate it.
II. The State and society have complete control of the educational system, which consists of regular education, alternative and special education, and higher education for professional training. The educational system develops its processes on the basis of the criteria of harmony and coordination.
III. The educational system is composed of public educational institutions, private educational institutions and those which are contracted.

Article 78

I. Education is unitary, public, universal, democratic, participatory, communitarian, decolonizing and of quality.
II. Education is intra-cultural, inter-cultural and multi-lingual throughout the entire educational system.
III. The educational system is based on education that is open, humanistic, scientific, technical and technological, productive, territorial, theoretical and practical, liberating and revolutionary, critical and supportive.
IV. The State guarantees vocational education and humanist technical learning for men and women, which is related to life, work and productive development.

- Reference to science

Article 79

Education shall promote civic-mindedness, intercultural dialogue and ethical moral values. The values shall incorporate gender equality, non differentiation of roles, non-violence, and the full enforcement of human rights.

Article 80

- Protection of environment

I. Education shall have as its objectives the full development of persons and the strengthening of social conscience that is critical in and for life. Education shall be directed toward the following: individual and collective development; the development of the competencies, attitudes, and physical and intellectual skills that link theory to productive practice; the conservation and protection of the environment, biodiversity and the land to assure well being. Its regulation and fulfillment shall be established by law.
II. Education shall contribute to strengthening the unity and identity of everyone as part of the Pluri-National State (Estado Plurinacional), as well as strengthening the identity and cultural development of the members of each nation and rural native indigenous people, and the intercultural understanding and enrichment within the State.

- Compulsory education

Article 81

I. Education is obligatory up to the secondary school diploma.
II. Public education is free at all levels including higher education.
III. Upon completion of studies at the secondary level, a bachelor diploma shall be awarded immediately and without charge.

- Free education

- Access to higher education

Article 82

I. The State shall guarantee access to education and continuing education to all citizens under conditions of full equality.
II. The State shall give priority support to the students with less economic possibilities so that they can achieve different levels in the educational system, by providing economic resources, meal programs, clothing, transportation, school materials, and student residences in the distant areas, according to the law.

III. Students of excellent achievement shall be rewarded at all levels of the educational system. Every child and adolescent with natural, outstanding talent has the right to be attended to educationally with the teaching methodology and learning that makes possible the best development of his or her aptitudes and skills.

Article 83

Social participation, community participation, and the participation of the parents in the educational system are recognized and guaranteed by means of representative organizations at all levels of the State and in the nations and the rural native indigenous peoples. Their composition and attributes shall be established by the law.

Article 84

The State and society have the duty to eradicate illiteracy through programs compatible with the cultural and linguistic reality of the population.

Article 85

The State shall promote and guarantee the continuing education of children and adolescents with disabilities, or of those with extraordinary talents in learning, under the same structure, principles and values of the educational system, and shall establish a special organization and development curriculum.

Article 86

Freedom of thought, faith and religious education, as well as the spirituality of the nations and the rural native indigenous peoples, shall be recognized and guaranteed in the educational centers. Mutual respect and coexistence among persons of diverse religions shall be promoted, without dogmatic imposition. There shall be no discrimination on the basis of religious choice with respect to the acceptance and permanence of students in these centers.

Article 87

The operation of contracted educational units for purposes of social service, which offer free access and are non-profit, shall be recognized and respected. They shall operate under the supervision of public authorities, respecting the right of the administration of religious entities over said educational units, without prejudice to that established in national dispositions, and they shall be governed by the same norms, policies, plans and programs of the educational system.

Article 88

I. Private educational units are recognized and respected at all levels and in all modalities; they shall be governed by the policies, plans, programs and authorities of the educational system. The State guarantees their operation pursuant to prior verification of the conditions and compliance with the requisites established by law.
II. The right of mothers and fathers to choose the education they prefer for their sons and daughters is respected.

Article 89

The follow up, measurement, evaluation and accreditation of the quality of education in the entire educational system, shall be entrusted to a technically specialized public institution, which is independent of the Ministry of the branch. Its composition and operation shall be determined by the law.

Article 90

- Reference to art

I. The State shall recognize the validity of institutes of humanistic, technical and technological training, at middle and higher levels, upon prior fulfillment of the conditions and requisites established in the law.
II. The State shall promote technical, technological, productive, artistic and linguistic training through technical institutes.
III. The State, through the educational system, shall promote the creation and organization of distance educational programs and popular education programs for those who have not attended school, with the objective of elevating the cultural level and developing the Pluri-National consciousness of the people.

Section II. Higher Education

Article 91

- Reference to science
- Reference to art

I. Higher education develops processes of professional training for the generation and dissemination of knowledge aimed at the full development of society, for which purpose the universal and collective knowledge of the nations and rural native indigenous peoples shall be taken into account.
II. Higher education is intra-cultural, intercultural and multi-lingual, and it has as its mission the comprehensive formation of highly qualified and professionally competent human resources for the following objectives: to develop processes for scientific research to solve problems of the productive base and of social conditions; to promote policies of extension and social interaction to strengthen scientific, cultural and linguistic diversity; to participate together with the people in all the processes of social liberation in order to construct a society with greater equity and social justice.
III. Higher education is composed of the public and private universities, the colleges for teacher training, and the technical, technological and artistic institutes.

Article 92

I. Public universities are autonomous and equal in hierarchy. The autonomy consists of the free administration of their resources; the naming of their officials, and teaching and administrative personnel; the elaboration and approval of their statues, study plans and annual budgets; the receipt of bequests and donations, as well as the signing of contracts to carry out their purposes and to sustain and improve their institutes and faculties. The public universities may negotiate loans with the guarantee of their assets and resources, upon prior legislative approval.
II. In exercise of their autonomy, the public universities shall form the Bolivian University, which shall coordinate and program their goals and functions by means of a central body, pursuant to a university development plan.
III. The public universities shall be authorized to give academic diplomas and professional titles with validity throughout the entire State.

Article 93

I. The State shall be obligated to sufficiently subsidize the public universities, independently of the departmental, municipal and their own resources, which have been or are to be created.
II. The public universities, within the framework of their statutes, shall establish mechanisms for social participation that are consultative, coordinating and advisory in character.
III. The public universities shall establish mechanisms for making reports and provide transparency of the use of their resources through the presentation of financial statements to the Pluri-National Legislative Assembly (Asamblea Legislativa), the Controller General (Contraloria General) and the Executive Organ (Organo Ejecutivo).
IV. The public universities, within the framework of their statutes, shall establish decentralized academic and inter-cultural programs pursuant to the necessities of the State and the nations and rural native indigenous peoples.

V. The State, in coordination with the public universities, shall promote the creation and operation of universities and multicultural communitarian institutes in rural areas, assuring social participation. The opening and operation of these universities shall address the needs of strengthening production in the region, based on its potential.

Article 94

I. The private universities shall be governed by the policies, plans, programs and authorities of the educational system. Their operation is authorized by supreme decree, upon prior verification of compliance with the conditions and requisites established by law.
II. The private universities shall be authorized to issue academic diplomas. Professional titles, which are valid throughout the country, shall be granted by the State.
III. For the granting of academic diplomas in all modalities of titles in the private universities, examination tribunals shall be formed which shall be composed of titled professors, named by the public universities, under the conditions established by the law. The State shall not subsidize private universities.

Article 95

I. The universities must create and maintain inter-cultural centers for technical and cultural education and training, which is freely accessible to the public and consistent with the principles and purposes of the educational system.
- Protection of language use

II. The universities must implement programs for the recovery, preservation, development, learning and dissemination of the different languages of the nations and rural native indigenous peoples.
III. The universities shall promote centers for the creation of productive units, in coordination with community, public and private productive initiatives.

Article 96

- Reference to science

I. The formation and training of teachers for public schools, by means upper level training schools, is the responsibility of the State. The training of teachers shall be exclusive, public, free of charge, intra-cultural, inter-cultural, multi-language, scientific and productive, and it shall be based on social commitment and a vocation for service.
II. School teachers must participate in the process of continual updating and pedagogical training.
III. The teaching career is secure, and teaching personnel may not be removed, in conformity with the law. Teachers shall receive a dignified salary.

- Reference to science

Article 97

Post graduate training at all levels shall have as its fundamental mission the qualification of professionals in different areas, through processes of scientific research and the generation of knowledge linked to reality in order to contribute to the comprehensive development of society. Post-graduate training shall be coordinated by a body formed by the universities of the educational system, in accordance with the law.

Section III. Cultures

- Right to culture

Article 98

I. Cultural diversity constitutes the essential basis of the Pluri-National Communitarian State (Estado Unitario Social de Derecho Plurinacional Comunitario). The inter-cultural character is the means for cohesion and for harmonic and balanced existence among all the peoples and nations. The intercultural character shall exist with respect for differences and in conditions of equality.
II. The State takes strength from the existence of rural native indigenous cultures, which are custodians of knowledge, wisdom, values, spiritualities and world views.

III. It shall be a fundamental responsibility of the State to preserve, develop, protect and disseminate the existing cultures of the country.

- Right to culture

Article 99

I. The cultural patrimony of the Bolivian people is inalienable, and it may not be attached or limited. The economic resources that they generate are regulated by law to give priority to their conservation, preservation and promotion.
II. The State shall guarantee the registry, protection, restoration, recovery, revitalization, enrichment, promotion and dissemination of its cultural patrimony, in accordance with the law.
III. The natural, architectural, paleontological, historic, and documentary riches, and those derived from religious cults and folklore, are cultural patrimony of the Bolivian people, in accordance with the law.

- Right to culture
- Provisions for intellectual property

Article 100

I. The world views, myths, oral history, dances, cultural practices, knowledge and traditional technologies are patrimony of the nations and rural native indigenous peoples. This patrimony forms part of the expression and identity of the State.
II. The State shall protect this wisdom and knowledge through the registration of the intellectual property that safeguards the intangible rights of the nations and rural native indigenous peoples and of the intercultural and Afro-Bolivian communities.

- Reference to art
- Right to culture

Article 101

The intangible aspects of the manifestations of art and popular industries shall enjoy the special protection of the State. Likewise, the tangible and intangible aspects of places and activities, which are declared cultural patrimony of humanity, shall be protected.

- Reference to art
- Provisions for intellectual property
- Reference to science

Article 102

The State shall register and protect individual and collective intellectual property in the works and discoveries of authors, artists, composers, inventors and scientists, under the conditions determined by law.

Section IV. Science, Technology and Research

- Reference to science

Article 103

- Right to enjoy the benefits of science

I. The State shall guarantee the development of science and scientific, technical and technological research for the benefit of the general interest. The necessary resources shall be provided, and state science and technology systems shall be created.
II. The State shall adopt a policy of implementing strategies to incorporate the knowledge and application of new information and communication technologies.
III. In order to strengthen the productive base and to stimulate full development of society, the State, the universities, the productive and service enterprises, both public and private, and the nations and rural native indigenous peoples, shall develop and coordinate processes of research, innovation, promotion, and dissemination, and the application and transfer of science and technology, in accordance with the law.

Section V. Sports and Recreation

Article 104

Everyone has the right to sports, physical culture and recreation. The State guarantees access to sports without distinction as to gender, language, religion, political orientation, territorial location, social, cultural membership or any other characteristic.

Article 105

The State shall promote, by educational, recreation and public health policies, the development of physical culture and the practice of sports in their preventive, recreational, training and competitive levels, with special attention given to persons with disabilities. The State shall guarantee the methods and necessary economic resources to make them effective.

CHAPTER VII. Social Communication

- Freedom of press

Article 106

- Freedom of expression

I. The State guarantees the right to communication and the right to information.
II. The State guarantees the right of Bolivians to freedom of expression, opinion and information, to rectification and reply, and the right to freely publish ideas by whatever means of dissemination, without prior censorship.
III. The State guarantees freedom of expression and the right to communication and information to workers of the press.
IV. The conscience clause of the information workers is recognized.

- State operation of the media

Article 107

I. The public means of communication must contribute to the promotion of the ethical, moral and civic-minded values of the different cultures of the country with the production and dissemination of multi-lingual educational programs and in an alternative language for the disabled.
II. Information and opinions issued by the public means of communication must respect the principles of truth and responsibility. These principles shall be put into practice through the rules of ethics and self-regulation of the organizations of journalists and of the means of communication and their law.
III. The public means of communication shall not form, either directly or indirectly, monopolies or oligopolies.
IV. The State shall support the creation of communitarian means of communication with equal conditions and opportunities.

TITLE III. DUTIES

Article 108

The duties of Bolivians are:

- Duty to obey the constitution

1. To know, comply with, and ensure the enforcement of the Constitution and the laws.

2. To know, respect, and promote the rights recognized in the Constitution.

3. To promote and spread the practice of the values and principles proclaimed by the Constitution.

4. To defend, promote, and contribute to the right to peace, and to encourage a culture of peace.

- Duty to work

5. To work, according to one's physical and intellectual capacity, in legal and socially useful activities.

6. To educate oneself in the educational system up to the diploma of bachelor.

- Duty to pay taxes

7. To pay taxes in proportion to one's economic capacity, according to the law.

8. To denounce and combat every act of corruption.

9. To care for, feed, and education their children.

10. To care for, protect, and help their ancestors.

11. To provide aid, with all the help necessary, in cases of natural disaster and other contingencies.

- Duty to serve in the military

12. To serve in the military, which is obligatory for boys.

13. To defend the unity, sovereignty and territorial integrity of Bolivia, and to respect its symbols and values.

14. To safeguard, defend and protect the natural, economic and cultural patrimony of Bolivia.

15. To protect and defend the natural resources, and to contribute to their sustainable use in order to preserve the rights of future generations.

- Protection of environment

16. To protect and defend an environment suitable for the development of living beings.

TITLE IV. JURISDICTIONAL GUARANTEES AND ACTIONS OF DEFENSE

CHAPTER I. Jurisdictional Guarantees

Article 109

I. All the rights recognized in the Constitution are directly applicable and enjoy equal guarantees of their protection.
II. The rights and guarantees may be regulated only by the law.

- Binding effect of const rights

Article 110

I. Persons who violate constitutional rights are subject to the jurisdiction and competence of the Bolivian authorities.
II. The intellectual and material perpetrators of violations of constitutional rights are to be held responsible.
III. The immediate perpetrators of attacks against personal security are to be held liable, and are not excused from liability for having committed them under orders of superiors.

Article 111

The crimes of genocide, offenses against humanity, treason, and war crimes are not extinguishable.

Article 112

The crimes committed by public servants that are perpetrated against the patrimony of the State and cause serious economic harm, are not extinguishable, and no immunities are to be applied.

Article 113

I. Victims of violations of their rights are granted the right to timely indemnification, reparation and compensation for damages and prejudices.
II. In the event that a sentence requires the State to repair damages and prejudices, it shall interpose the same action against the authority or public servant responsible for the act or omission that caused the damage.

Article 114

- Prohibition of torture
- Regulation of evidence collection

I. All forms of torture, disappearances, confinement, coercion, exaction and any other form of physical and moral violence are prohibited. The public servants or officials, who apply, instigate or consent to them shall be dismissed and replaced, without prejudice to the sanctions determined by law.

II. The statements, actions or omissions which are obtained or undertaken through the employment of torture, coercion, exaction, or by any other form of violence, are null to the full extent of the law.

Article 115

- Guarantee of due process

I. Everyone shall be protected in the exercise of his or her rights and legitimate interests in a timely and effective manner by the judges and courts.

II. The State guarantees the right to due process and defense, and to plural, prompt, appropriate, free, and transparent justice without delays.

Article 116

- Presumption of innocence in trials
- Principle of no punishment without law
- Protection from ex post facto laws

I. The presumption of innocence is guaranteed. During the process, in the event of a doubt concerning the applicable norm, the one most favorable to the accused or the defendant shall govern.

II. Every sanction must be based on a law existing prior to the commission of the punishable act.

Article 117

- Guarantee of due process
- Prohibition of double jeopardy
- Rights of debtors

I. No one may be condemned without having been previously heard and tried pursuant to due process. No one shall be subject to a criminal sanction that has not been imposed by a competent judicial authority as a final judgment.

II. No one shall be tried or sentenced more than once for the same act. The rights that are restricted shall be immediately restored upon fulfillment of the sentence.

III. No sanction of deprivation of liberty may be imposed for debts or property obligations, except in the cases established by law.

Article 118

I. Dishonor, civil death and confinement are prohibited.

II. The maximum criminal sentence shall be thirty years of deprivation of liberty without the right to pardon.

III. The fulfillment of sentences of deprivation of liberty and the security measures imposed are directed toward the education, rehabilitation and reinsertion in society of the condemned persons, with respect for their rights.

Article 119

- Right to counsel
- Inalienable rights

I. During the legal process, the parties in conflict enjoy equal opportunities to exercise the faculties and rights that may help them, whether in an ordinary process or by rural native indigenous process.

II. Everyone has the inviolable right to a defense. The State shall provide a defense lawyer free of charge to persons accused or denounced in the event that they do not have the necessary economic resources.

Article 120

- Right to fair trial
- Trial in native language of accused

I. Every person has the right to be heard by a competent, impartial and independent jurisdictional authority, and may not be tried by special commissions or submitted to other jurisdictional authorities other than those established prior to the time the facts of the case arose.

II. Every person submitted to legal process has the right to be tried in his or her language; in case of exception, the person must be assisted by a translator or interpreter.

Article 121

- Protection from self-incrimination

I. In criminal matters, no person can be forced to make a statement against him or herself, or against his or her blood relatives to the fourth degree or against non-blood relatives up to the second degree. The right to remain silent shall not be considered an indication of guilt.

- Protection of victim's rights
- Right to counsel

II. The victim in a criminal process shall be able to intervene in accordance with the law, and shall have the right to be heard before each judicial decision. In the event that he or she does not have the necessary economic resources, he or she will be assisted free of charge by a lawyer appointed by the State.

- Ultra-vires administrative actions

Article 122

The acts of persons who usurp functions, which are not their responsibility, as well as the acts of those who exercise jurisdiction or power that does not emanate from the law, are null and void.

Article 123

The law stipulates only with respect to future acts and shall have no retroactive effect, except in the following cases: in labor matters when it expressly makes determinations in favor of workers; in criminal matters, when it benefits the accused; in corruption matters in order to investigate, process and sanction crimes committed by public servants against the interests of the State; and in the rest of the cases set forth by the Constitution.

Article 124

I. The Bolivian who engages in the following acts commits the crime of treason against the country:

1. Takes up arms against his or her country, puts him or herself at the service of participating foreign states, or enters into complicity with the enemy in the case of an international war against Bolivia.
2. Violates the constitutional regime of natural resources.
3. Attacks the unity of the country.

II. This crime shall deserve the maximum criminal sanction.

CHAPTER II. Actions of Defense

Section I. Action for Liberty

- Protection from unjustified restraint

Article 125

Anyone who believes his or her life is in danger, that he or she is being illegally persecuted, unjustly tried or deprived of personal liberty, shall file a claim of Action for Liberty (Accion de Libertad) and present him or herself, either in writing or orally, on his or her own behalf or by anyone in his or her name, and without any formal procedure, before any judge or competent court in criminal matters, and shall request that his or her life be protected, that the unjustified persecution be halted, that the legal formalities be reestablished, or that his or her right to liberty be restored.

Article 126

I. The judicial authority shall immediately set the day and hour of the public hearing, which shall take place within twenty four hours of the filing of the claim, and shall stipulate that the claimant be brought into its presence, or it shall go to the place of detention. With said order, it shall execute the citation, in person or by service of process, to the authority or person accused, which order shall be obeyed, without excuse, both by the authority or person accused as well as by those in charge of the jails or places of detention, without their having the possibility, once served, of disobeying.

II. In no event may the hearing be suspended. In the absence of the defendant for failure to attend or abandonment, the process will continue in default.
III. With knowledge of the background and having heard the allegations, the judicial authority shall be obligated and have the responsibility to dictate the sentence at the same hearing. The sentence shall order the safeguarding of the claimant's life, the restitution of the right to liberty, the correction of the legal defects, the cessation of the illegal persecution, or the remanding of the case to a competent judge. In every case, the parties shall be notified of the reading of the sentence.
IV. The judicial decision shall be executed immediately. Without prejudice to it, the decision shall be taken on appeal, sua sponte, to the Pluri-National Constitutional Court (Tribunal Constitucional Plurinacional), within the term of twenty four hours after its issuance.

Article 127

I. Public servants and individuals who resist compliance with the judicial decisions in the cases foreseen for this action shall be remanded by order of the authority that heard the case to the Public Ministry for criminal process for threatening constitutional guarantees.
II. The judicial authority that does not proceed pursuant to that stipulated by this article shall be subject to sanction, in accordance with the Constitution and the law.

Section II. Action of Constitutional Protection

- Right to amparo
- Binding effect of const rights
- Ultra-vires administrative actions

Article 128

The Action for Constitutional Protection (Accion de Amparo Constitucional) shall take place against the illegal or unjustified acts or omissions of public servants or of individuals or collectives, who restrict, suppress or threaten to restrict or suppress rights recognized by the Constitution and the law.

- Right to amparo

Article 129

I. The Action for Constitutional Protection shall be presented by the person who believes him or herself affected, by another with sufficient power to act in his or her name, or by the corresponding authority pursuant to the Constitution, to any judge or competent court, provided that there is no other existing means or legal recourse for the immediate protection of the rights and guarantees that have been restricted, suppressed or threatened.
II. The Action for Constitutional Protection shall be filed within the maximum term of six months, computed from the commission of the alleged violation or the notification of last administrative or judicial decision.
III. The defendant authority or person shall be summoned in the manner set forth by the Action for Liberty, in order for the defendant to provide information or make a presentation in his case of the facts concerning the act complained of, in the maximum term of forty eight hours from the presentation of the Action.
IV. The final resolution shall be announced in a public hearing immediately after receiving the information from the defendant authority or person and, in the absence of that information, it will be made on the basis of the proof offered by the plaintiff. The judicial authority shall examine the competence of the public servant or of the defendant and, in the event it finds the complaint to be certain and true, shall grant the protection requested. The decision that is pronounced shall be taken, sua sponte, for review before the Pluri-National Constitutional Court (Tribunal Constitucional Plurinacional) in the term of twenty four hours following the issuance of the decision.
V. The final decision that grants the Action for Constitutional Protection shall be immediately executed and without comment. In the event of resistance, the case shall proceed pursuant to that set forth in the Action for Liberty. The judicial authority that does not proceed pursuant to that set forth in this article shall be subject to the sanctions set forth in the law.

Section III. Action for Protection of Privacy

Article 130

- Right to protect one's reputation

I. Every individual, or collective, that believes he or she to be unjustly or illegally impeded from knowing, objecting to, or achieving the elimination or correction of information registered by any physical electronic, magnetic or computerized form, in public or private files or data banks, or that might affect his or her fundamental right to intimacy and personal or family privacy, or his or her own image, honor and reputation, shall file a complaint of Action for Protection of Privacy.

II. The Action for Protection of Privacy (Accion de Protección de Privacidad) shall not proceed to uncover confidential material of the press.

Article 131

I. The Action for Protection of Privacy shall take place pursuant to the procedure set forth for the Action of Constitutional Protection.

II. If the competent court or judge admits the action, it shall order the revelation, elimination or correction of the data, the registration of which was challenged.

III. The decision shall be taken on appeal, sua sponte, to the Pluri-National Constitutional Court within the term of twenty four hours following the issuance of the decision, without suspension of its execution.

IV. The final decision granted in the Action for Protection of Privacy shall be immediately executed and without comment. In the event of resistance, the procedure shall be pursuant to that set forth in the Action for Liberty. The judicial authority that does not proceed pursuant to that set forth in this article shall be subject to the sanctions set forth in the law.

Section IV. Action for Unconstitutionality

- Constitutionality of legislation

Article 132

Every person or collective affected by a juridical norm contrary to the Constitution shall have the right to present an Action for Unconstitutionality (Accion de Inconstitucionalidad), pursuant to the procedures established by law.

Article 133

The decision that declares a law, decree, or any other kind of nonjudicial resolution unconstitutional makes the challenged norm inapplicable and has full effect with respect to everyone.

Section V. Action for Compliance

- Ultra-vires administrative actions

Article 134

I. The Action for Compliance (Accion de Cumplimiento) shall apply to the case of non compliance with provisions of the constitutional or the law on the part of public servants, and has as its objective the guaranteeing of the execution of the norm.

II. The action shall be filed by the affected individual or collective, or by another with sufficient power in name of the affected party, before a competent judge or court, and shall be processed in the same manner as the Action for Constitutional Protection.

III. The final resolution shall be pronounced at a public hearing immediately after receiving the information from the defendant authority and, in the absence of that information, it shall be made on the basis of the proof offered by the plaintiff. The judicial authority shall examine the background and, if it finds the complaint to be true and certain, it shall admit the action and order immediate compliance with the omitted duty.

IV. The decision shall be taken up on appeal, sua sponte, to the Pluri-National Constitutional Court within the term of twenty four hours following the issuance of the decision, without suspension of its execution.
V. The final decision granted in the Action for Compliance shall be immediately executed without comment. In the event of resistance, the procedure shall be pursuant to that set forth in the Action for Liberty. The judicial authority that does not proceed pursuant to that set forth in this article shall be subject to the sanctions set forth in the law.

Section VI. Popular Action

- Ultra-vires administrative actions

Article 135

The Popular Action (la Accion Popular) shall proceed against any act or omission by the authorities or individuals or collectives that violates or threatens to violate rights and collective interests related to public patrimony, space, security and health, the environment and other rights of a similar nature that are recognized by this Constitution.

Article 136

I. The Popular Action shall be filed during the period in which the violation or threat to the rights and collective interests continues. To file this action it is not necessary to exhaust the judicial or administrative processes that might exist.
II. Any person, in his or her individual name or on behalf of a collective, may file this action, and it shall be filed obligatorily by the Public Ministry and the Public Defender (Ministerio Público y el Defensor del Pueblo) when, in the exercise of their functions, they have knowledge of these acts. The procedure for the Action for Constitutional Protection shall be applied.

- Emergency provisions

CHAPTER III. States of Emergency

Article 137

In the case of danger to the security of the State, external threat, internal disturbance or national disaster, the President of the State shall have the power to declare a state of emergency, wherever necessary in all or part of the territory. The declaration of the state of emergency shall not, in any case, suspend the guarantees of rights, nor the fundamental rights, the right of due process, the right to information and the rights of persons deprived of liberty.

Article 138

I. The validity of the declaration of the state of emergency shall depend on the subsequent approval of the Pluri-National Legislative Assembly, which shall take place as soon as circumstances permit, and in all cases, within seventy two hours following the declaration of the state of emergency. The approval of the declaration shall indicate the powers conferred, and it shall maintain strict relation and proportion to the case of necessity addressed by the state of emergency. In general, the rights consecrated in the Constitution shall not be suspended by the declaration of the state of emergency.
II. Once the state of emergency ends, no other state of emergency may be declared within one year following, except upon prior legislative authorization.

Article 139

I. The Executive shall report to the Pluri-National Legislative Assembly concerning the reasons for the declaration of the state of emergency, as well as the use that has been made of the powers conferred by the Constitution and the law.
II. Those persons who violate the rights established in this Constitution shall be subject to criminal process for violation of rights.
III. The states of emergency shall be regulated by law.

Article 140

I. Neither the Pluri-National Legislative Assembly, nor any other body or institution, nor association or popular group of any kind, shall grant to a body or person any extraordinary authorities different than those established in this Constitution.
II. Public Power may not be accumulated, nor may any body or person be granted supremacy over the rights and guarantees recognized in this Constitution.
III. The reform of the Constitution may not be initiated while there is a state of emergency in force.

TITLE V. NATIONALITY AND CITIZENSHIP

CHAPTER I. Nationality

- Requirements for birthright citizenship
- Requirements for naturalization

Article 141

Bolivian nationality is acquired by birth or by naturalization. Persons who are born in the territory of Bolivia are Bolivians by birth, with the exception of children of foreign personnel on diplomatic mission; persons born abroad of a Bolivian mother or father are Bolivians by birth.

- Requirements for naturalization

Article 142

I. Foreigners may acquire Bolivian nationality by naturalization if they are legally in the country for more than three years of uninterrupted residence under the supervision of the State, and they expressly manifest their desire to obtain Bolivian nationality and comply with the requisites established by law.
II. The time of residence shall be reduced to two years in the case of foreigners who are in one of the following situations:
    1. They have a Bolivian spouse, a Bolivian child or children, or Bolivian adoptive parents. Foreign citizens who acquire citizenship by marriage with Bolivian citizens do not lose it in the case of widowhood or divorce.
    2. They serve in the Bolivian military at the required age and pursuant to the law.
    3. They obtain Bolivian nationality granted by the Pluri-National Legislative Assembly for their service to the country.
III. The time of residence for obtaining Bolivian nationality may be modified when there are reciprocal conventions with other states, first and foremost those of Latin America.

Article 143

I. Bolivians who marry foreign citizens shall not lose their nationality of origin. Nor shall Bolivian nationality be lost by acquiring foreign citizenship.
II. Foreigners who acquire Bolivian nationality shall not be obligated to renounce their nationality of origin.

CHAPTER II. Citizenship

- Requirements for birthright citizenship

Article 144

I. All Bolivians are citizens and exercise their citizenship rights from the age of 18, whatever may be their level of education, occupation or income.
II. Citizenship rights consist of:
    1. Taking part as an elector or being eligible to be part of and exercise functions in the bodies of popular power, and
    2. The right to exercise public functions without any requisites, except those established by law.
III. The rights of citizens are suspended for reasons and in the manner set forth in article 28 of this Constitution.

- Restrictions on voting
- Conditions for revoking citizenship

PART II. FUNCTIONAL STRUCTURE AND ORGANIZATION OF THE STATE

TITLE I. LEGISLATIVE ORGAN

CHAPTER I. Composition and Attributes of the Pluri-National Legislative Assembly

- Structure of legislative chamber(s)

Article 145

The Pluri-National Legislative Assembly is composed of two chambers, the Chamber of Deputies (Camara de Diputados) and the Chamber of Senators (Camara de Senadores), and it is the only body with authority to approve and sanction laws that govern the entire Bolivian territory.

- First chamber selection
- Size of first chamber
- Right to culture
- Indigenous right to vote
- Indigenous right to representation
- Electoral districts
- Electoral districts
- Electoral districts

Article 146

I. The Chamber of Deputies shall have 130 members.
II. In each Department, half of the Deputies (Diputados) shall be elected by direct voting electoral districts. The other half shall be elected by proportional voting electoral districts, from lists headed by candidates for President, Vice President and the Senators of the Republic.
III. Deputies are elected by universal, direct and secret vote. In the single Districts, they are elected by simply majority of the voters; in the multiple districts, by a system of representation established by law.
IV. The number of Deputies must reflect the proportional vote obtained by each party, citizen group or indigenous people.
V. The total distribution of seats among the departments shall be determined by the Electoral Organ (Organo Electoral) on the basis of the number of inhabitants in each one of them, pursuant to the latest National Census, according to law. For equity, the law shall assign a minimum number of seats to the departments that have the least population and least economic development. If the distribution of seats for any department is an uneven number, preference will be given to the single districts for the assignment of the seats.
VI. The single districts must have geographical continuity, affinity and territorial continuity; they may not extend beyond the borders of each department and must be based on criteria of population and territorial extension. The Electoral Organ shall define the single districts.
VII. The special rural native indigenous districts shall be governed by the principle of density of population in each department. They shall not cross department borders. They shall be established only in a rural area in those departments in which those nations and native indigenous rural peoples constitute a minority population. The Electoral Organ shall define the special districts. These districts form part of the total number of deputies.

- Right to culture
- Indigenous right to representation

Article 147

I. The equal participation of men and women shall be guaranteed in the election of the members of the assembly.
II. Proportional participation of the nations and rural native indigenous peoples shall be guaranteed in the election of members of the assembly.
III. The law shall define the special districts of the rural native indigenous peoples, in which population density and geographical continuity shall not be considered as conditional criteria.

- Size of second chamber

Article 148

I. The Chamber of Senators shall consist of a total of 36 members.

- Second chamber selection

II. In each department, four Senators shall be elected in departmental districts by universal, direct and secret vote.
III. The assignment of seats for Senators in each department shall be made by a proportional system pursuant to the Law.

- Age restrictions on second chamber
- Eligibility for first chamber
- Age restrictions on first chamber
- Eligibility for second chamber

Article 149

To be a candidate to the Pluri-National Legislative Assembly, one must satisfy the general requisites for public service, be 18 years of age at the time of election, and have resided permanently for at least two years immediately prior to the election in the corresponding district.

Article 150

- Replacement of legislators

I. The Pluri-National Legislative Assembly shall have alternate members who do not receive remuneration except in the case that they must actually serve as substitutes. The law shall determine the manner of substitution of the members.

- Outside professions of legislators

II. The members of the assembly shall not carry out any other public function, under penalty of losing their mandate, with the exception of university teaching.
III. The resignation of a member of the assembly shall be final, without the possibility of being able to obtain permission or the grant of temporary substitution for the purpose of carrying out other functions.

- Immunity of legislators

Article 151

I. The members of the assembly shall enjoy personal privilege during the time of their mandate, and afterwards they may not be criminally processed for their opinions, communications, representations, requests, questions, denouncements, proposals, expressions or any legislative act or act of reporting or control, which they formulate or undertake while performing their functions.
II. The domicile, residence or habitat of the members of the assembly may not be violated, and they shall not be searched under any circumstance. This provision shall be applied to the vehicles of their personal or official use and to their legislative offices.

- Immunity of legislators

Article 152

The members of the assembly do not enjoy immunity. Preventive detention shall not be applied to them in criminal processes during their mandate, except in cases of flagrant crimes.

Article 153

I. The Vice President of the State shall preside over the Pluri-National Legislative Assembly.
II. The ordinary sessions of the Pluri-National Legislative Assembly shall start on the 6th of August of every year.

- Length of legislative sessions

III. The ordinary sessions of the Pluri-National Legislative Assembly shall be continuous, and each one will have two recesses of fifteen days per year.
IV. By decision of the Plenary and the convocation of its President, the Pluri-National Legislative Assembly may hold sessions in a different place other than the habitual one within the territory of the State.

- Legislative committees
- Extraordinary legislative sessions
- Standing committees

Article 154

During recesses, the Assembly Commission (Comision de Asamblea) shall function, in the form and with the attributes determined by the Rules of the Chamber of Deputies (Reglamento de la Camara de Diputados). In extraordinary cases, for matters of urgency, the Assembly can be convoked by its President or by the President of the State. It shall only take up the matters set forth in the convocation.

Article 155

The Pluri-National Legislative Assembly shall inaugurate its sessions on the 6th of August in the Capital of Bolivia, unless expressly called by its President.

- Term length for first chamber
- Term limits of second chamber
- Term length of second chamber
- Term limits for first chamber

Article 156

The term of the mandate of the members of the assembly is five years, and they may be reelected for a single additional continuous term.

- Removal of individual legislators
- Attendance by legislators

Article 157

The mandate of the member of the assembly ends in the following circumstances: the death or resignation of the member; the revocation of the member's mandate; the final condemnatory sentence of the member in a criminal case; or the unjustified abandonment of his or her functions for more than six continuous working days or eleven non continuous working days a year, as determined in accordance with the Rules.

Article 158

I. The attributes of the Pluri-National Legislative Assembly, in addition to those determined by this Constitution and the law are the following:

- Compensation of legislators
- Supreme court selection
- Constitutional court selection
- Establishment of judicial council
- Economic plans
- Budget bills
- Treaty ratification
- Legislative oversight of the executive
- Cabinet removal

1. To approve and execute its budget autonomously; to name and remove its administrative personnel; and to attend to everything related to its internal governance and economy.
2. To set the remuneration of the members, which, in no case, may be higher than that of the Vice President of the State. Any additional income from a remunerated activity is prohibited.
3. To dictate, interpret, repeal, abrogate and modify laws.
4. To elect six of its members to the Pluri-National Electoral Organ, by two-thirds vote of the members present.
5. To pre-select the candidates to form the Pluri-National Constitutional Court (Tribunal Constitucional Plurinacional), the Supreme Court of Justice (Tribunal Supremo de Justicia), the Agro-Environmental Court (Tribunal Agroambiental) and the Council of Magistrates (Consejo de la Magistratura).
6. To approve the creation of new territorial units and to establish their boundaries, pursuant to the Constitution and the law.
7. To approve the economic and social development plan presented by the Executive Organ).
8. To approve the laws in matters of budgets, indebtedness, control and supervision of state resources, of public credit, and of subsidies for the undertaking of public works and social needs.
9. To make decisions on indispensable state economic measures in case of public necessity.
10. To approve the contracting of loans that commit general income of the State, and to authorize universities to contract loans.
11. To approve the General State Budget presented by the Executive Organ. Once the draft law is received, it must be considered by the Pluri-National Legislative Assembly within the term of sixty days. In case it is not approved within this time frame, the draft law shall be considered approved.
12. To approve the contracts of public importance with regard to natural resources and strategic areas, signed by the Executive Organ.
13. To approve the disposal of assets of public dominion of the State.
14. To ratify international treaties signed by the Executive, in the manner established by the Constitution.
15. To establish the monetary system.
16. To establish the system of measures.
17. To monitor and oversee the organs of the State and the public institutions.
18. To question, at the initiative of any of the members of the assembly, the Ministers of State, individually or collectively, and to censure by the vote of two-thirds of the members of the Assembly. The questioning shall be

I. 18. requested by either of the Chambers. The censure shall imply the replacement of the Minister.

- Legislative oversight of the executive
- Legislative committees

19. To undertake investigations within the framework of their supervisory attributes, by way of a commission or commissions elected for that purpose, without prejudice to the control exercised by the competent bodies.

20. To monitor and oversee public enterprises, those of mixed capital and every entity that has State economic participation.

- Designation of commander in chief

21. To authorize the use of military troops, armaments and war materiel outside of the territory of the State, and to determine the purpose and time of the absence of troops.

22. To authorize in exceptional cases the entrance and temporary transit of foreign armed forces, determining the purpose and length of their stay.

- Tax bills

23. At the initiative of the Executive Organ, to create or modify taxes at the central level of the State. Nevertheless, the Pluri-National Legislative Assembly, at the request of one of its members, shall request that the Executive Organ present bills on the matter. If the Executive Organ, within the term of twenty days does not present the requested bill, or the justification for not having done so, the representative who had requested it or another, shall present his or her own bill for consideration and approval.

II. The organization and functions of the Pluri-National Legislative Assembly shall be regulated by the Rules of the Chamber of Deputies.

Article 159

The attributes of the Chamber of Deputies, in addition to those determined by this Constitution and the law, are:

1. To draft and approve its Rules.

2. To describe the credentials granted by the Pluri-National Electoral Organ.

- Leader of first chamber

3. To elect its executive committee; and to determine its internal organization and functions.

4. To apply sanctions to deputies, pursuant to the Rules, by a decision of two-thirds of the members present.

5. To approve and execute its budget; to name and remove its administrative personnel; and to attend to everything related to its internal economy and governance.

- First chamber reserved policy areas

6. To initiate the approval of the General State Budget.

- Economic plans
- First chamber reserved policy areas

7. To initiate the approval of the economic and social development plan presented by the Executive Organ.

- First chamber reserved policy areas

8. To the initiate the approval or modification of the tax laws, laws of public credit or subsidies.

- First chamber reserved policy areas

9. To initiate the approval of the contracting of loans which commit the general revenues of the State, and to authorize universities to contract loans.

10. In each legislature, to approve the armed forces that should be maintained in peace time.

- Constitutional court removal
- Supreme/ordinary court judge removal

11. To accuse, before the Chamber of Senators, the members of the Pluri-National Constitutional Court, of the Supreme Court and of the Administrative Control of Justice who have committed crimes in the exercise of their functions.

12. To propose lists of candidates to the President of the State for the designation of the presidents of the economic and social entities and other positions in which the State participates, by absolute majority pursuant to the Constitution.

13. To pre-select the candidates for the Administrative Control of Justice and to send the names of the candidates to the Pluri-National Electoral Organ so that

13. this Organ may carry out the sole and exclusive organization of the electoral process.

Article 160

The attributes of the Chamber of Senators, in addition to those determined by this Constitution and the law, are:

1. To draft and approve its Rules.
2. To qualify the credentials granted by the Pluri-National Electoral Organ.
3. To elect its executive committee, and determine its internal organization and functions.
4. To apply sanctions to Senators, pursuant to the Rules, by decision of two-thirds of the members present.
5. To approve and execute its budge; to name and remove its administrative personnel and to attend to everything related to its internal economy and governance.
6. To be the sole instance to try the members of the Pluri-National Constitutional Court, of the Supreme Court, of the Agro-Environmental Court and of the Administrative Control of Justice for crimes committed in the exercise of their functions, whose sentences shall be approved by at least two-thirds of the members present, pursuant to the law.
7. To recognize with public honors those who are deserving of it for eminent service to the State.
8. To ratify the promotions, proposed by the Executive Organ, to General of the Army, of the Air Force, of the Division and of the Brigade; to Admiral, Vice Admiral, Rear Admiral, and General of the Bolivian Police.
9. To approve or deny the appointments of ambassadors and plenipotentiary Ministers proposed by the President of the States.

- Leader of second chamber
- Supreme/ordinary court judge removal
- Constitutional court removal
- Selection of active-duty commanders

Article 161

The Chambers shall meet in Pluri-National Legislative Assembly to exercise the following functions, as well as those set forth in the Constitution:

1. To inaugurate and close its sessions.
2. To receive the oath of the President and Vice President of the State.
3. To accept or reject the resignation of the President of the State and of the Vice President of the State.
4. To consider the laws vetoed by the Executive Organ.
5. To consider bills approved in the Chamber of origin that were not approved in the reviewing Chamber.
6. To approve states of emergency.
7. To authorize the trial of the President or of the Vice President of the State.
8. To designate the Attorney General of the State and the Public Defender.

- Joint meetings of legislative chambers
- Veto override procedure
- Emergency provisions
- Head of state immunity
- Attorney general
- Ombudsman

CHAPTER II. Legislative Procedure

Article 162

- Initiation of general legislation
- Legislative initiatives by citizens

I. The following have the authority to initiate legislation, which the Pluri-National Legislative Assembly is obligated to process:
  1. Citizens.
  2. Members of the assembly in each of the Chambers.
  3. The Executive Organ.
  4. The Supreme Court, with respect to initiatives related to the administration of justice.
  5. The autonomous governments of the territorial entities.

II. The law and rules of each Chamber shall develop the procedures and requisites for exercising the authority of legislative initiative.

- Division of labor between chambers

Article 163

The legislative process shall develop in the following manner:

- Legislative committees

1. The presentation of a bill by members of one of the Chambers of the assembly shall initiate the legislative process in that Chamber, which shall remand it to the corresponding commission or commissions for its treatment and initial approval.

- Legislative committees

2. The bill presented by other initiative shall be sent to the Chamber of Deputies, which shall remand it to a commission or commissions.

- Second chamber reserved policy areas

3. The legislative initiatives in matters of decentralization, autonomies and land registry and regulations shall be received by the Chamber of Senators.

- Legislative committees

4. When a bill has been reported by the corresponding commission or commissions, it shall be sent for consideration by the plenary of the Chamber, where it shall be discussed and approved in full and in detail. Each approval shall require an absolute majority of the members present.

5. The bill approved by the Chamber of origin shall be remanded to the reviewing Chamber for its decision. If the reviewing Chamber approves it, it shall be sent to the Executive Organ for its promulgation.

6. If the reviewing Chamber amends or modifies the bill, this shall be considered as approval if the originating Chamber accepts the amendments or modification by the vote of an absolute majority of the members present. In the event that it does not accept the changes, the two Chambers shall meet at the request of the originating Chamber within the term of twenty days following and shall debate the bill. The decision shall be made by the Plenary of the Pluri-National Legislative Assembly by an absolute majority of the members present.

7. In the event that thirty days pass without pronouncement on the bill by the reviewing Chamber, the bill shall be considered by the Plenary of the Pluri-National Legislative Assembly.

8. The approved bill, once confirmed, shall be sent to the Executive Organ for its promulgation as law.

9. A bill that has been rejected may be reintroduced in the next Legislature.

- Approval or veto of general legislation
- Legislative committees

10. The law, which has been approved by the Pluri-National Legislative Assembly and sent to the Executive Organ, may be commented on by the President within ten working days from the time of its receipt. The observations of the Executive Organ shall be sent to the Assembly. If the latter should be in recess, the President shall send his or her observations to the Commission of the Assembly (Comision de Asamblea).

- Veto override procedure
- Approval or veto of general legislation

11. If the Pluri-National Legislative Assembly considers the observations of the President to be well founded, it will modify the law accordingly and will return the law to Executive Organ for its promulgation. In the event that it does not consider the observations to be well founded, the law shall be promulgated by

11. the President of the Assembly. The decisions of the Assembly shall be made by the vote of the absolute majority of the members present.

- Approval or veto of general legislation

12. The law on which no observations are made within the corresponding term of time shall be promulgated by the President of the State. The laws not promulgated by the Executive Organ in the terms set forth in the sections above shall be promulgated by the President of the Assembly.

Article 164

I. The promulgated law shall be published immediately in the Official Gazette.
II. Compliance with the law is obligatory from the date of its publication, except for those that establish a different term for entrance into force.

TITLE II. EXECUTIVE ORGAN

CHAPTER I. Composition and Attributes of the Executive Organ

Section I. General Matters

- Establishment of cabinet/ministers

Article 165

- Deputy executive
- Name/structure of executive(s)

I. The Executive Organ consists of the President of the State, the Vice President of the State, and the Ministers of State.
II. The Council of Ministers is collectively responsible for the decisions they adopt.

Section II. Presidency and Vice Presidency of the State

- Deputy executive
- Head of state selection

Article 166

I. The President and Vice President of the State shall be elected by universal, obligatory, direct, free and secret vote. The candidates who receive fifty percent plus one of the valid votes cast, or the candidate who has received a minimum of forty percent of the valid votes cast, with a difference of at least ten percent in relation to the candidate in second place, shall be proclaimed President or Vice President.
II. In the event that none of the candidates meet these conditions, a second electoral round shall be carried out between the two candidates who received the most votes, within the term of sixty days counted from the prior voting. The candidate who receives the majority of votes shall be declared President or Vice President of the State.

- Age restrictions on head of state
- Eligibility for head of state

Article 167

To be a candidate for President or Vice President of the State, one must satisfy the general conditions to be a public servant, be thirty years of age on the day of the election, and have resided permanently in the country for at least five years immediately prior to the election.

- Head of state term limits
- Head of state term length

Article 168

The period of the mandate of the President or Vice President is five years, and they may be reelected once for a continuous term.

Article 169

- Head of state replacement

I. In the event of an impediment or definitive absence of the President, he or she shall be replaced by the Vice President and, in the absence of the latter, by the President of the Senate, and in his or her absence by the President of the Chamber of Deputies. In this last case, new elections shall be called within a maximum period of ninety days.

II. In case of temporary absence, the Vice President shall assume the Presidency for a term not to exceed ninety days.

- Head of state removal

Article 170

The mandate of the President of the State shall end in the following circumstances: upon his or her death; by the presentation of his or her resignation to the Pluri-National Legislative Assembly; by definitive absence or impediment; by the imposition of a final condemnatory sentence in a criminal matter; or by the revocation of his or her mandate.

- Head of state replacement

Article 171

In the event the mandate is revoked, the President of State shall immediately cease in his or her functions; the Vice President must assume the Presidency and immediately call elections for the Presidency of the State to take place within a maximum period of ninety days.

- Head of state powers

Article 172

The attributes of the President of the State, in addition to those established by this Constitution and the law, are the following:

- Duty to obey the constitution

1. To comply with and enforce the Constitution and the laws.
2. To maintain and preserve the unity of the Bolivian State.
3. To propose and direct the policies of the government of the State.
4. To direct the public administration and coordinate the actions of the Ministers of State.
5. To direct foreign policy; sign international treaties; name public diplomats and consuls pursuant to the law; and to admit foreign officials in general.

- Treaty ratification
- Foreign affairs representative
- Extraordinary legislative sessions

6. To request the calling of an extraordinary session of the Pluri-National Legislative Assembly.
7. To promulgate the laws approved by the Pluri-National Legislative Assembly.

- Head of state decree power

8. To issue supreme decrees and resolutions.
9. To administer the state revenues and to decree their investment by the Ministry of the appropriate branch in accordance with the laws and strictly subject to the General Budget of the State.

- Economic plans

10. To present the economic and social development plan to the Pluri-National Legislative Assembly.

- Budget bills

11. To present to the Pluri-National Legislative Assembly, during the first thirty sessions, the proposed law of the General Budget of the State for the following fiscal year, and to propose, during its term, the modifications he or she considers necessary. The report on public expenses pursuant to the budget shall be presented annually.

- Legislative oversight of the executive

12. To present annually to the Pluri-National Legislative Assembly, in its first session, the written report on the course and state of Public Administration during the yearly management, accompanied by the ministerial reports.
13. To enforce the decisions of the courts.

- Power to pardon

14. To decree amnesty or pardon, with the approval of the Pluri-National Legislative Assembly.

- Central bank

15. To name the following, from among the candidates proposed by the Pluri-National Legislative Assembly: the Controller General of the State, the President of the Bank of Bolivia, the maximum authority of the Regulatory Organ of the

15. Banks and Financial Entities, and the Presidents of the entities, in which the State participates, that have a social and economic function.

16. To preserve the security and defense of the State.

- Designation of commander in chief

17. To designate and substitute the Commander in Chief of the Armed Forces and the Commanders of the Army, the Air Force and the Navy.

18. To designate and substitute the General Commander of the Bolivian Police.

- Selection of active-duty commanders

19. To propose to the Pluri-National Legislative Assembly the promotions to General of the Army, of the Air Force, of the Division and of the Brigade, to Admiral, Vice Admiral, and Rear Admiral, and to General of the Police, in accordance with the report on their service and promotions.

20. To create and construct ports.

21. To designate its representatives to the Electoral Organ.

- Eligibility for cabinet
- Cabinet selection
- Right to culture
- Indigenous right to representation
- Initiation of general legislation

22. To designate the Ministers of State, respecting the Pluri-National character of the country and gender equity in the composition of the ministerial cabinet.

23. To designate the Attorney General of the State.

24. To present proposed laws of economic urgency for consideration by the Pluri-National Legislative Assembly, which must give them priority attention.

- Designation of commander in chief

25. To hold the position of Commander in Chief of the Armed Forces, and to deploy them for the defense, independence and territorial integrity of the State.

- Emergency provisions

26. To declare a state of emergency.

27. To exercise maximum authority over the Bolivian Agrarian Reform Service and to grant executable titles in the distribution and redistribution of land.

Article 173

The President of the State may absent him or herself from Bolivian territory for official missions for a maximum period of up to ten days without authorization of the Pluri-National Legislative Assembly.

- Deputy executive

Article 174

The attributes of the Vice President of the State, in addition to those established in this Constitution and the laws, are as follows:

1. To assume the Presidency of the State in the cases established in this Constitution.

2. To coordinate the relations between the Executive Organ, the Pluri-National Legislative Assembly, and the autonomous governments.

3. To participate in the sessions of the Council of Ministers.

4. To contribute, with the President of the State, to the guidance of the general policy of the Government.

5. To participate jointly with the President of the State in the formulation of foreign policy, as well as to carry out diplomatic missions.

Section III. Ministers of State

Article 175

- Powers of cabinet

I. The Ministers of State are public servants and have the following authority, in addition to those established in this Constitution and the laws:

I. 1. To Propose and contribute to the formulation of the general policies of the Government.
2. To propose and direct the governmental policies in their sector.
3. To manage Public Administration in their corresponding branch.
4. To issue administrative norms in the area of their competence.
5. To propose drafts of supreme decrees and to sign them with the President of the State.
6. To resolve, as last recourse, any administrative matter that corresponds to his or her Ministry.
7. To present to the Pluri-National Legislative Assembly the reports that it requests.
8. To coordinate, together with other Ministries, the planning and execution of the policies of the government.

- Legislative oversight of the executive

II. The Ministers of State are responsible for the administrative acts adopted in the areas of their respective portfolios.

- Eligibility for cabinet

Article 176

To be designated a Minister, a person must meet the following requisites: satisfy the general requirements for entering public service, be twenty five years of age on the day of his or her nomination, not be a member of the Pluri-National Legislative Assembly, nor a director, shareholder or owner of financial entities or enterprises that have a contractual relationship or conflicts of interest with the State; not be the spouse or natural parent or related in the second degree to the acting President or Vice President of the State.

- Eligibility for cabinet

Article 177

Anyone who, whether directly or as the legal representative of a legal person, has a contract pending fulfillment or is indebted to the State may not be designated as a Minister.

TITLE III. JUDICIAL ORGAN AND PLURI-NATIONALCONSTITUTIONAL COURT

CHAPTER I. General Matters

Article 178

- Right to fair trial
- Right to speedy trial
- Judicial independence
- Right to public trial

I. The power to impart justice emanates from the Bolivian people and is based on the principles of independence, impartiality, juridical security, publicity, probity, promptness, being free of charge, legal pluralism, being inter-cultural, equity, service to society, citizen participation, social harmony and respect for rights.

- Protection of judges' salaries

II. The guarantees of judicial independence are:
1. The performance of the judges in accordance with a judicial career.
2. The budgetary autonomy of the judicial bodies.

Article 179

- Indigenous right to self governance
- Structure of the courts
- Right to culture

I. The judicial function is singular. Ordinary jurisdiction is exercised by the Supreme Court of Justice, the departmental courts of justice, the sentencing courts and the judges; the agro-environmental jurisdiction is exercised by the Agro-Environmental Court and judges; and the rural native indigenous jurisdiction is exercised by their own authorities. There shall be specialized jurisdictions regulated by the law.

II. Ordinary jurisdiction and rural native indigenous jurisdiction enjoy equal status.

- Right to culture
- Establishment of constitutional court

III. Constitutional justice is imparted by the Pluri-National Constitutional Court (Tribunal Constitucional Plurinacional).

- Establishment of judicial council

IV. The Council of Judges is part of the Judicial Organ (Organo Judicial).

CHAPTER II. Ordinary Jurisdiction

Article 180

- Guarantee of due process
- Right to fair trial
- Right to speedy trial
- Right to public trial
- Right to appeal judicial decisions
- Establishment of military courts

I. Ordinary jurisdiction is based on the following procedural principles: application free of charge, publicity, transparency, the right to be heard, promptness, probity, honesty, legality, efficiency, accessibility, immediacy, material truth, due process, and equality of the parties before the judge.
II. The principle of the right to challenge in judicial processes is guaranteed.
III. Ordinary jurisdiction shall not recognize privileges or extraordinary courts. The military jurisdiction shall try the crimes of military nature regulated by the law.

Sole Section. Supreme Court of Justice

- Structure of the courts

Article 181

The Supreme Court of Justice is the highest court of ordinary jurisdiction. It is made up of Magistrates. It is internally organized into specialized chambers. Their composition and organization shall be determined by law.

- Constitutional court selection
- Supreme court selection

Article 182

I. The Magistrates of the Supreme Court of Justice shall be elected by universal suffrage.
II. The Pluri-National Legislative Assembly, by two-thirds of the members present, shall determine the pre-selection of the candidates for each department and shall send the names of those selected to the electoral body so that it may organize the sole and exclusive electoral process.
III. No candidate or any other person shall make an electoral campaign in favor of the candidacies, under penalty of their being stricken. The Electoral Organ is the only entity responsible for publicizing the merits of the candidates.
IV. The magistrates may not belong to political organizations.
V. The candidates that obtain a simple majority of the votes shall be elected. The President of the State shall administer the oath of office.
VI. In order to become a Magistrate of the Supreme Court of Justice one must meet the following requirements: satisfy the general requisites established for public servants; be thirty years of age; have a law degree; have honestly and ethically performed judicial functions, practiced as a lawyer or have been a university professor for eight years; and not have been sanctioned with dismissal by the Council of Magistrates. The determination of merit shall take into account performance as a native authority under its system of justice.
VII. The system of prohibitions and incompatibilities applied to Magistrates of the Supreme Court of Justice shall be the same as that applied to public servants.

- Eligibility for supreme court judges
- Age restrictions on supreme court judges
- Eligibility for supreme court judges

Article 183

I. The Magistrates may not be re-elected. The period of their mandate shall be six years.
II. The Magistrates of the Supreme Court of Justice shall cease in their functions upon completion of their mandate, imposition of a final sentence arising from a trial of responsibilities, resignation, death and other causes set forth in the law.

- Supreme court term length
- Supreme court term limits
- Constitutional court term limits
- Supreme/ordinary court judge removal
- Constitutional court term length
- Constitutional court removal

Article 184

- Supreme court powers

The following are the attributes of the Supreme Court of Justice, in addition to those provided by law:

1. To act as the court of cassation and hear appeals of nullity in cases expressly provided for by law.

2. To resolve conflicts of competencies arising among the departmental courts of justice.

- Extradition procedure
- Head of state immunity
- Ordinary court selection
- Initiation of general legislation

3. To hear, resolve and request, as the sole instance, the processes of extradition.

4. To try, in plenary as a collegial court and as the sole instance, the President of the State, or the Vice President of the State, for crimes committed in the performance of their mandate. The trial shall be undertaken upon prior authorization of the Pluri-National Legislative Assembly, by a vote of at least two-thirds of the members present, and a request supported by the Prosecutor or the Attorney General of the State who shall formulate the accusation if he believes that the investigation provides the basis for trial. The process shall be oral, public, continuous and uninterrupted. The law shall determine the procedure.

5. To designate the voting judges of the departmental courts of justice, from the lists presented by the Council of Magistrates.

6. To prepare proposed judicial laws and present them to the Pluri-National Legislative Assembly.

7. To hear and resolve cases of extraordinary review of sentences.

Article 185

The judicial functions of the Supreme Court of Justice shall be exercised in an exclusive manner.

CHAPTER III. Agro-Environmental Jurisdiction

Article 186

The Agro-Environmental Court (Tribunal Agroambiental) is the highest court specialized in agro-environmental jurisdiction. It is governed specifically by the principles of social benefit, comprehensiveness, immediacy, sustainability and being inter-cultural.

Article 187

To be elected Magistrate of the Agro-Environmental Court, one must meet the same requirements as those for members of the Supreme Court of Justice, in addition to the following: have expertise in these matters and have performed well, ethically and honestly as an agrarian judge; have practiced law or have been a university professor in the subject matter for a period of eight years. In the pre-selection of candidates, pluralistic composition shall be guaranteed by considering the criteria of pluri-nationality.

Article 188

I. The Magistrates of the Agro-Environmental Court shall be elected by universal suffrage, pursuant to the procedures, mechanisms and formalities for the members of the Supreme Court of Justice.
II. The system of prohibitions and incompatibilities applicable to the Magistrates of the Agro-Environmental Court shall be those that are applied to public servants.
III. The term of the performance, permanence and cessation of the position that is established for Magistrates of the Supreme Court of Justice (Tribunal Supremo de Justicia) shall be applied to the members of the Agro-Environmental Court.

Article 189

The following are the attributes of the Agro-Environmental Court, in addition to those set forth in the law:

1. To resolve appeals of cassation and nullity in actions involving agrarian real estate, forestry, environmental, water, rights of use and enjoyment of natural renewable, hydraulic, and forest resources, and biodiversity; and to resolve complaints involving practices that endanger the ecological system and the conservation of species or animals.

2. To hear and resolve, as the sole instance, the complaints of nullity and cancellation of titles.

3. To hear and resolve, as the sole instance, the cases brought against the State resulting from contracts, negotiations, authorizations, licenses, distribution and redistribution of rights of exploitation of natural renewable resources, and other acts and administrative resolutions.

4. To organize the agro-environmental courts.

CHAPTER IV. Rural Native Indigenous Jurisdiction

- Right to culture
- Indigenous right to self governance

Article 190

I. The nations and native indigenous rural peoples shall exercise their jurisdictional functions and competency through their authorities, and shall apply their own principles, cultural values, norms and procedures.
II. The rural native indigenous jurisdiction respects the right to life, the right to defense and other rights and guarantees established in this Constitution.

- Right to culture
- Indigenous right to self governance

Article 191

I. The rural native indigenous jurisdiction is based on the specific connection between the persons who are members of the respective nation or rural native indigenous people.
II. The rural native indigenous jurisdiction is exercised in the following areas of personal, material and territorial legal effect:
    1. Members of the nation or rural native indigenous people are subject to this jurisdiction whether they act as plaintiffs or defendants, claimants or accusers, whether they are persons who are denounced or accused, or are appellants or respondents.
    2. This jurisdiction hears rural native indigenous matters pursuant to that established in a law of Jurisdictional Demarcation.
    3. This jurisdiction applies to the relations and juridical acts that are carried out, or the effects of which are produced, within the jurisdiction of a rural native indigenous people.

- Right to culture
- Indigenous right to self governance

Article 192

I. Each public authority or person shall obey the decisions of the rural native indigenous jurisdiction.
II. To secure compliance with the decisions of the rural native indigenous jurisdiction, its authorities may request the support of the competent bodies of the State.
III. The State shall promote and strengthen rural native indigenous justice. The law of Jurisdictional Demarcation shall determine the mechanisms of coordination and cooperation between rural native indigenous jurisdiction and ordinary jurisdiction and agro-environmental jurisdiction and all the recognized constitutional jurisdictions.

CHAPTER V. Council of Ministers of Justice

- Establishment of judicial council

Article 193

I. The Council of Ministers of Justice is the instance responsible for the following: the disciplinary regime for the ordinary, agro-environmental and the specialized jurisdictions; the monitoring and supervision of their administrative and financial management; and the formulation of procedural policies. The Council of Ministers of Justice shall be governed by the principle of citizen participation.
II. Its formation, structure and functions are determined by the law.

Article 194

- Establishment of judicial council

I. The members of the Council of Ministers of Justice shall be elected by universal vote from among the candidates proposed by the Pluri-National Legislative Assembly. The Pluri-National Electoral Organ shall be in charge of the organization and implementation of the electoral process.
II. In addition to the general conditions necessary to enter public service, the members of the Council of Ministers of Justice shall be thirty years old, possess knowledge of the material under their jurisdiction, and have performed their duties ethically and honestly.
III. The members of the Council of Ministers of Justice shall remain in their posts for six years and may not be re-elected.

- Establishment of judicial council

Article 195

The powers of the Council of Ministers of Justice, in addition to those established in the Constitution and the laws, are the following:

- Constitutional court removal
- Supreme/ordinary court judge removal

1. To initiate the revocation of the mandate of Judges of the Supreme Court of Justice and of the Agro-environmental Court, when they commit serious omissions in the exercise of their duties as determined by law.

- Supreme/ordinary court judge removal

2. To exercise disciplinary control over the voting judges and the auxiliary administrative personnel of the Judicial Organ. The exercise of this authority shall include the possibility of removal from their post for serious disciplinary infractions, which are expressly established by law.

3. To monitor and oversee the economic financial administration and assets of the Judicial Organ.

4. To evaluate the performance of the administrators and the administrators of justice and auxiliary personnel.

5. To draft judicial audits and the audits of financial management.

6. To undertake technical and statistical studies.

- Ordinary court selection

7. To make the pre-selection of candidates for the formation of courts of justice of the departments who will be designated by the Supreme Court of Justice.

- Civil service recruitment

8. To designate the trial judges and judges of instruction, through a process of competitive evaluation of merit and examination of competency.

9. To designate its administrative personnel.

CHAPTER VI. Pluri-National Constitutional Court

- Constitutional interpretation
- Establishment of constitutional court

Article 196

I. The Pluri-National Constitutional Court (Tribunal Constitucional Plurinacional) assures the supremacy of the Constitution, exercises constitutional control, and safeguards respect for and enforcement of constitutional rights and guarantees.
II. As criteria to be applied in its interpretive role, the Pluri-National Constitutional Court shall give preference to the intent of the constituent assembly as demonstrated in its documents, acts and resolutions, as well as the literal tenor of the text.

- Eligibility for const court judges

Article 197

- Indigenous right to representation
- Right to culture

I. The Pluri-National Constitutional Court shall consist of Judges elected on the basis of pluri-nationality, with representation from the ordinary system and the rural native indigenous system.
II. The substitute Judges of the Pluri-National Constitutional Court shall not receive remuneration, and shall assume functions only in the case of the absence of the

II. titled Judge or for other reasons established by law.
III. The composition, organization and functions of the Pluri-National Constitutional Court shall be regulated by law.

- Constitutional court selection

Article 198

The Judges of the Pluri-National Constitutional Court shall be elected by universal suffrage, pursuant to the procedure, mechanism and formalities used for the election of the members of the Supreme Court of Judges.

Article 199

- Age restrictions on constitutional court judges
- Eligibility for const court judges

I. To become a Judge of the Pluri-National Constitutional Court, in addition to the general requisites to become a public servant, one must be thirty five years of age and have specialized or credited experience of at least eight years in the disciplines of Constitutional law, Administrative law or Human Rights law. For purposes of determining merit, experience as a native authority under its system of justice shall be taken into account.

- Constitutional court selection
- Right to culture

II. The candidates for the Pluri-National Constitutional Court shall be proposed by organizations of civil society and the nations and rural native indigenous peoples.

- Constitutional court removal
- Constitutional court term length
- Constitutional court term limits

Article 200

The time of service, permanence and removal from office established for the Judges of the Supreme Court of Justice shall be applied to the members of the Pluri-National Constitutional Court.

Article 201

The Judges of that Pluri-National Constitutional Court shall be governed by the same system of prohibitions and incompatibilities as applied to public servants.

- Constitutional court powers

Article 202

In addition to those established by law, the powers of the Pluri-National Constitutional Court, are to hear and resolve the following:

- Constitutionality of legislation
- Federal review of subnational legislation

1. As the court of jurisdiction in the matters of pure law concerning the unconstitutionality of laws, Autonomous Statutes, Constitutional Charters, decrees and every type of ordinance and non-judicial resolution. If the case is of abstract character, only the President of the Republic, Senators, Deputies, Legislators and the maximum authorities of the autonomous territorial entities may present it to the court.

2. The conflicts of jurisdiction and powers among the organs of popular power.

3. The conflicts of jurisdiction between the Pluri-National government and the autonomous and decentralized territorial entities, and between the latter.

4. The appeals of fees, taxes, rates, licenses, rights or contributions that are created, modified or suppressed in violation of that set forth in the Constitution.

5. The appeals of resolutions of the Legislative Organ, when its resolutions affect one or more rights, regardless of who might be affected.

6. The review of the actions of Liberty, Constitutional Protection, Protection of Privacy, Popular actions and those for Compliance. This review shall not impede the immediate and obligatory application of the resolution that decided the action.

- Constitutionality of legislation

7. The legal consultations of the President of the Republic, of the Pluri-National Legislative Assembly, the Supreme Court of Justice or the Agro-Environmental Court on the constitutionality of proposed bills. It is obligatory to comply with the decision of the Constitutional Court.

8. The legal consultations of the rural native indigenous authorities on the application of their juridical norms as applied in a concrete case. Compliance with the decision of the Constitutional Court is obligatory.

- Legal status of treaties
- Treaty ratification
- International law

9. The review of the constitutionality of international treaties prior to their ratification.
10. The constitutionality of the procedure of partial reform of the Constitution.
11. The conflicts of authority between the rural native indigenous jurisdiction and ordinary and agro-environmental jurisdiction.
12. The direct appeals of nullity.

Article 203

The decisions and sentences of the Pluri-National Constitutional Court are binding and of obligatory compliance, and no subsequent ordinary appeal of them is allowed.

Article 204

The law shall determine the procedures that govern the processes brought before the Pluri-National Constitutional Court.

TITLE IV. ELECTORAL ORGAN

CHAPTER I. Pluri-National Electoral Organ

Article 205

I. The Pluri-National Electoral Organ (Organo Electoral) shall be composed of:
   1. The Supreme Electoral Court.
   2. The Departmental Electoral Courts.
   3. The Electoral Judges.
   4. The Juries of the polling places.
   5. The Electoral Notaries.

II. The jurisdiction, competency and powers of the Electoral Organ and its different levels are defined in this Constitution and the law.

Article 206

I. The Supreme Electoral Court is the highest level of the Electoral Organ, and has national jurisdiction.

- Electoral court term length
- Right to culture
- Indigenous right to representation
- Electoral court term limits
- Electoral court selection

II. The Supreme Electoral Court is composed of seven members, who shall remain in office for six years without the possibility of re-election, and at least two of them shall be of rural native indigenous origin.

III. The Pluri-National Legislative Assembly shall elect six of the members of the Pluri-National Electoral Organ, by two-thirds of the votes of the members present. The President of the State shall designate one of its members.

- Civil service recruitment
- Electoral court selection

IV. The election of the members of the Pluri-National Electoral Organ requires the prior public announcement, and the determination of the capacity and merits by public selection process.

V. The Departmental Legislative Assemblies or the Departmental Councils shall select, by two thirds votes of their members present, a list of candidates for each one of the voting members of the Departmental Electoral Courts. The Chamber of Deputies (Camara de Diputados) shall, by two third votes of the members present, elect from the lists the members of the Departmental Electoral Courts, guaranteeing that at least one of its members belong to the nations and rural native indigenous peoples of the Department.

- Eligibility for electoral court judges
- Age restrictions on electoral court judges

Article 207

To be designated a Voting member of the Supreme Electoral Court and the Departmental Electoral Court, once must satisfy the general requirements for being a public servant, to be thirty years of age at the time of his or her designation and to have academic education.

- Electoral court powers

Article 208

I. The Supreme Electoral Court is responsible for organizing, administering and carrying out the electoral processes, and for proclaiming the results.
II. The Court shall guarantee that the voting is carried out effectively, pursuant to that set forth in Article 26 of this Constitution.
III. It is the function of the Supreme Electoral Court to organize and administer the Civil Registry and the Electoral Roll.

CHAPTER II. Political Representation

- Right to culture

Article 209

The candidates for public elected posts, with the exception of the elected positions of the Judicial Organ and the Pluri-National Constitutional Court (Tribunal Constitucional Plurinacional), shall be proposed by the organizations of the nations and rural native indigenous peoples, citizen associations and political parties, in equal conditions and pursuant to the law.

Article 210

- Right to culture
- Restrictions on political parties

- Restrictions on political parties

- Indigenous right to vote
- Right to culture

I. The organization and functioning of the organizations of the nations, rural native indigenous peoples, and citizen associations and political parties must be democratic.
II. The internal election of the leaders and the candidates of the citizen associations, and of the political parties, shall be regulated and supervised by the Pluri-National Electoral Organ, which shall guarantee the equal participation of men and women.
III. The nations and rural native indigenous peoples may elect their candidates according to their own democratic communitarian norms.

- Indigenous right to representation
- Right to culture
- Indigenous right to self governance
- Indigenous right to vote

Article 211

I. The nations and rural native indigenous peoples may elect their political representatives whenever required, in accordance with their own forms of election.
II. The Electoral Organ shall assure that the norms of those peoples and nations will be complied with strictly in the elections of authorities, representatives and candidates of the nations and rural native indigenous peoples, using their own norms and procedures.

Article 212

No candidate may be proposed for more than one elective post or for more than one electoral district at the same time.

TITLE V. FUNCTIONS OF CONTROL, DEFENSE OF SOCIETY AND DEFENSE OF THE STATE

CHAPTER I. Function of Control

Sole Section. General Comptroller

Article 213

I. The General Comptroller of the State (Contraloria General) is the technical institution that monitors the administration of the public entities and those in which the State has economic participation or interest. The Comptroller is authorized to determine signs of administrative, executive, civil and criminal responsibility; it is functionally, financially, administratively and organizationally autonomous.
II. Its organization, function and attributes must be based on principals of legality, transparency, efficacy, efficiency, economy, equity, opportunity and objectivity, and are determined by the law.

- Civil service recruitment

Article 214

The Comptroller or Comptroller General of the State shall be designated by two third votes of the members present of the Pluri-National Legislative Assembly. The election shall require prior public notice, and determination of the professional capacity and merits through a public process.

Article 215

To be designated as Comptroller or Comptroller General of the State, one must fulfill the general requisites for public service; be at least thirty years old at the time of designation; have obtained a professional degree in an area related to the post and have practiced as a professional for a minimum of eight years; to have shown personal and ethical integrity, determined by public observation.

Article 216

The Comptroller or Comptroller General of the State shall carry out his or her functions for a period of six years, without the possibility of being reappointed.

Article 217

I. The Comptroller General of the State shall be responsible for the supervision and later external monitoring of public entities and those in which the State has economic participation or interest. The supervision and monitoring also shall be carried out over the administration, management and disposition of the strategic assets and services of collective importance.
II. The Office of Comptroller General of the State shall present each year a report on its supervision of the public sector to the Pluri-National Legislative Assembly.

CHAPTER II. Function of Defense of Society

- Ombudsman

Section I. Public Defender

Article 218

I. The Public Defender (Defensor del Pueblo) shall oversee the enforcement, promotion, dissemination of and compliance with human rights, both individual and collective, that are established in the Constitution, laws and international instruments. The function of the Public Defender shall extend to the administrative activity of the entire public sector and the activity of private institutions that provide public services.
II. The Public Defender shall also promote the defense of the rights of the nations and rural native indigenous peoples, of urban and intercultural communities, and of Bolivians who are abroad.
III. The Public Defender is an institution with operational, financial and administrative autonomy, in accordance with the law. Its functions shall be governed by the principles of free services, accessibility, swiftness and solidarity. In the exercise of its functions it does not receive instructions from the organs of the State.

Article 219

I. The Office of the Public Defender shall be directed by the Public Defender, who shall performs his or her functions for a period of six years, without possibility of a new designation.
II. The Public Defender shall not be subjected to prosecution, detention, accusation or trial for acts carried out in the exercise of his or her authority.

- Civil service recruitment

Article 220

The Public Defender shall be designated by at least two-thirds of the members present of the Pluri-National Legislative Assembly. The designation shall require a prior public announcement and determination of professional capacity and merit through a public competition among persons recognized for their career in defense of human rights.

Article 221

To be designated as Public Defender one must satisfy the general conditions to be a public servant, be thirty years old at the time of designation and have proven personal and ethical integrity determined by public observation.

Article 222

The powers of the Office of the Public Defender, in addition to those established in the Constitution and the law, are the following:

- Constitutionality of legislation

1. To file actions of Unconstitutionality, of Liberty, of Constitutional Protection, of Protection of Privacy, Popular actions, actions for Compliance and the direct appeal of nullity, without the requirement of having a mandate.

- Initiation of general legislation

2. To present bills and modifications of laws, decrees and non-judicial resolutions in matters of its competence.

3. To investigate, on its own or at the request of a party, the acts or omissions that imply violations of rights, individual and collective, that are established in the Constitution, laws and international instruments, and request that the Public Ministry initiate the corresponding legal actions.

4. To request information from the authorities and public servants with respect to the investigations that the Public Defender is carrying out, to which no objection may be posed.

5. To formulate recommendations, reminders of legal duties, and suggestions for the immediate adoption of corrective measures for all the organs and institutions of the State, and to issue public censure for acts or behavior contrary to these formulations.

6. To have free access to the center of detention and prisons, to which no one may pose an objection.

7. To exercise its functions without interruption of any kind, even in the case of a declaration of a state of emergency.

8. To attend to the persons who request its services promptly and without discrimination.

9. To draft the regulations needed for the exercise of its functions.

Article 223

Each year, the Public Defender shall report to the Pluri-National Legislative Assembly and to the Office of Social Control concerning the situation of human rights in the country and on the management of its administration. The Public Defender may be

called on at any moment by the Pluri-National Legislative Assembly or the Social Control to provide a report with respect to the exercise of its authority.

Article 224

Each year, the Ombudswoman or Ombudsman shall report to the Pluri-National Legislative Assembly and to the Institution of Social Control on the situation of human rights in the country and the management of its administration. The Ombudswoman or Ombudsman may be summoned at any moment by the Pluri-National Legislative Assembly or by the Institution of Social Control, in order to provide a report on the exercise of its functions.

- Attorney general

Section II. The Public Ministry

Article 225

I. The Public Ministry shall defend the law and the general interests of society, and it shall bring public criminal actions. The Public Ministry has operational, administrative and financial autonomy.
II. The Public Ministry shall exercise its functions pursuant to the principles of legality, timeliness, objectivity, responsibility, autonomy, unity and hierarchy.

Article 226

I. The Prosecutor or General Prosecutor of the State is the highest authority hierarchically of the Public Ministry and represents the institution.
II. The Public Ministry shall have departmental prosecutors, prosecutors of specific matters and the other prosecutors established by the law.

- Civil service recruitment

Article 227

I. The Prosecutor or the General Prosecutor of the State is designated by two-thirds vote of the members present of the Pluri-National Legislative Assembly. The designation shall require prior public announcement, and qualification of professional capacity and merits through a competitive public process.
II. The Prosecutor or the General Prosecutor of the State shall satisfy the general requisites for public servants, as well as the specific requisites established by the Council of Judges of the Supreme Court of Justice.

Article 228

The Prosecutor or the General Prosecutor of the State shall exercise his or her functions for six years, with no possibility of being designated again.

- Attorney general

CHAPTER III. Function of the Defense of the State

Sole Section. Office of the Attorney General of the State

Article 229

The Office of the Attorney General of the State is the institution of public juridical representation, which has the power to promote, defend and safeguard the interests of the State. Its organization and structure shall be determined by law.

Article 230

I. The Office of the Attorney General of the State is composed of the Attorney General, who shall direct it, and other public servants as determined by the law.
II. The designation of the Attorney General of the State corresponds to the President of the State. The person designated must satisfy the requisites required for the Judges of the Supreme Court of Justice.
III. The appointment may be vetoed by decision of at least two thirds of the members present of the Pluri-National Legislative Assembly within a period not

III. exceeding sixty calendar days from the appointment. The veto shall have the effect of terminating the functions of the appointed person.

Article 231

The powers of the Office of the Attorney General of the State, in addition to those determined by the Constitution and the laws, are the following:

1. To defend judicially and extra-judicially the interests of the State, assuming its legal representation and intervening as the government representative with full rights in all judicial and administrative actions, within the framework of the Constitution and the law.

2. To present ordinary appeals and actions in defense of the interests of the State.

3. To evaluate and oversee the carrying out of legal proceedings by the legal units of the Public Administration in the processes that are brought before the jurisdictional or administrative authorities. In the case of negligent action, it should urge the initiation of the appropriate actions.

4. To request the information considered necessary from public servants and individual persons for purposes of exercising its authority. This information may not be denied for any reason or cause; the law shall establish the corresponding penalties.

5. To request of the maximum executive authority of public entities the trial of public servants who, for negligence or corruption, cause damage to the patrimony of the State.

6. To attend to the complaints and claims made by citizens and entities which make up Social Control in the cases that adversely affect the interests of the State.

7. To request that the Prosecutor General of the State undertake the judicial actions that should be brought for crimes committed against public patrimony of which it has knowledge.

8. To present bills on matters related to its competence.

- Initiation of general legislation

CHAPTER IV. Public Servants

Article 232

The Public Administration is governed by the principles of legitimacy, legality, publicity, social commitment and interest, ethics, transparency, equality, competence, efficiency, quality, friendliness, honesty, responsibility and results.

Article 233

Public Servants are persons who perform public functions. Public servants form part of the administrative personnel, except for those who are in elected posts, those who are designated, and those who are appointed to perform duties.

- Eligibility for supreme court judges
- Attorney general
- Eligibility for cabinet
- Eligibility for electoral court judges
- Eligibility for const court judges
- Eligibility for head of state
- Eligibility for second chamber
- Eligibility for first chamber

Article 234

To perform public functions, one must satisfy the following requisites:

1. Have Bolivian nationality.

2. Be of adult age.

3. Have completed military duty.

4. Have no criminal charges against him or her, nor final sentences in criminal matters that are pending completion.

5. Not be included in the cases of prohibitions and incompatibilities established in the Constitution.

6. Be inscribed in the voting rolls.

7. Speak at least two of the official languages of the country.

Article 235

The following are the obligations of public servants:

- Duty to obey the constitution

1. To comply with the Constitution and the laws.

2. To fulfill his or her responsibilities, in accordance with the principles of public administration.

- Earnings disclosure requirement

3. To provide a sworn declaration of assets and income, before, during and after performing in the post.

4. To provide reports on the economic, political, technical and administrative responsibilities carried out in the public administration.

5. To respect and protect the assets of the State, and abstain from using them for electoral purposes or any other purpose outside of the public function.

Article 236

The prohibitions in carrying out the public function are as follows:

I. To perform simultaneously more than one full-time remunerated public job.

II. To act when his or her interests conflict with those of the entity he or she serves, and to enter into contracts or carry out business with the Public Administration, directly, indirectly or on behalf of a third party.

III. To name to public administration persons with whom he or she has a blood relation in the 4th degree and second of affinity.

Article 237

I. The obligations for the exercise of the public administration:
   1. Inventory and care for the documents belonging to the public administration in public offices, with the prohibition of taking them out or destroying them. The law shall regulate the management of archives and the conditions under which public documents may be destroyed.
   2. Maintain the confidentiality of classified information, which may not be divulged even after they have left their duties. The procedure for characterizing classified information shall be set forth in the law.

II. The law shall determine the sanctions for violation of these obligations.

- Eligibility for supreme court judges
- Eligibility for head of state
- Eligibility for first chamber
- Eligibility for const court judges

Article 238

Persons who fall within the following grounds are ineligibility to hold elective public office:

1. Those that were or are directors of enterprises or corporations that have contracts or agreements with the State and who have not resigned at least three months before the day of the election.

2. Those who have been directors of foreign international enterprises that have contracts or agreements with the State and have not resigned at least five years prior to the date of the election.

3. Those who hold elected positions, or who hold positions by designation or appointment, who have not resigned from them at least three months prior to

3. the date of the election, with the exception of the President or Vice President.

- Restrictions on the armed forces

4. The members of the Armed Forces and the Bolivian Police in active service who have not resigned at least three months prior to the date of the election.

5. The ministers of any religious cult who have not resigned at least three months prior to the date of the election.

- Outside professions of legislators

Article 239

The following are not compatible with the performance of public functions:

1. The acquisition or leasing of public assets on behalf of the public servant or third persons.

2. The signing of administrative contracts with or obtaining any other kind of personal benefit from the State.

3. Professional service as employees, representatives, advisors, managers of entities, companies or enterprises that have a contractual relationship with the State.

- Removal of individual legislators
- Head of state removal

Article 240

I. The mandate of anyone who occupies an elected position, with the exception of those of the Judicial Organ, may be revoked, in accordance with the law.
II. The revocation of a mandate can be requested when at least half the term of the mandate has been completed. The revocation of a mandate cannot take place during the last year of the term in office.
III. The revocation referendum shall commence by citizen initiative, at the request of at least fifteen percent of the voters of the electoral roll of the district that elected the public servant.
IV. The revocation of a mandate of a public servant shall be carried out pursuant to the law.
V. The revocation of a mandate shall result in the immediate cessation of service in the post, providing for his or her substitution according to the law.
VI. The revocation shall take place only once during the constitutional mandate of the person elected.

- Referenda

TITLE VI. PARTICIPATION AND SOCIAL CONTROL

Article 241

I. The sovereign people shall participate, through the organized civil society, in the design of public policies.
II. Organized Civil Society shall exercise public monitoring of public management at all levels of the State, and of businesses, public enterprises, and private ventures that administer public fiscal resources.
III. It will exercise public monitoring of the quality of public services.
IV. The law shall establish the general framework for the exercise of public monitoring.
V. Civil society shall organize itself to define the structure and composition of public participation and monitoring.
VI. The entities of the State shall create spaces of participation and public monitoring on the part of society.

Article 242

Participation and public monitoring implies the following activities, in addition to those established in the Constitution and the law:

1. To participate in the formulation of the policies of the State.

2. To support the Legislative Organ in the collective development of the laws.

3. To develop social oversight at all levels of the government and of the autonomous, self sufficient, decentralized and de-concentrated territorial entities.

4. To create transparent management of information and use of resources in all of the places of public management. The information requested for public monitoring may not be denied and shall be delivered in complete, truthful, adequate and timely form.

5. To formulate reports that support the petition for revocation of mandate, in accordance with the procedure established in the Constitution and the law.

6. To hear and comment on the reports of the activities of the organs and functions of the State.

7. To coordinate the planning and monitoring with the organs and functions of the State.

8. To file complaints with the corresponding institutions for investigation and processing in the cases considered appropriate.

9. To participate in the public scrutiny of candidates in appointment procedures who are subject to them.

10. To help the electoral organ publicize the nominations of candidates for the corresponding public posts.

TITLE VII. ARMED FORCES AND BOLIVIAN POLICE

CHAPTER I. Armed Forces

Article 243

The Armed Forces of the State are organically comprised of the Commander in Chief, the Army, the Air Force and the Navy of Bolivia, the forces of which shall be defined by the Pluri-National Legislative Assembly at the proposal of the Executive Organ.

Article 244

The fundamental mission of the Armed Forces is the following: the defense and preservation of the independence, security and stability of the State, and the honor and sovereignty of the country; to assure the supremacy of the Constitution; to guarantee the stability of the legitimately constituted Government; and to participate in the development of the country.

Article 245

The organization of the Armed Forces is based on its hierarchy and discipline. It is essentially subservient, is not a deliberative body, and is subject to the laws and military regulations. As an institutional organ, it does not carry out any political activity; individually, its members enjoy and exercise the rights of citizens under the conditions established by the law.

- Designation of commander in chief

Article 246

I. The Armed Forces are subordinate to the President of the State and receive their orders administratively through the Minister of Defense as an intermediary, and with respect to technical aspects, from the Commander in Chief.
II. In the event of war, the Commander in Chief of the Armed Forces shall direct the operations.

Article 247

- Restrictions on minister of defense

I. No foreigner may exercise command, nor be employed or occupy an administrative post in the Armed Forces without the prior authorization of the Captain General.
II. To occupy their positions, the Commander in Chief of the Armed Forces, the Chief of Staff, the Commanders and Chiefs of Staff of the Army, the Air Force, and the Navy of Bolivia, and of the large units, must be Bolivian by birth and meet the requisites set forth in the law. The same requisites are necessary for the Vice Minister of the Ministry of Defense.

Article 248

The Supreme Council of Defense of the Pluri-National State, the composition, organization and faculties of which are to be determined by law, shall be presided over by the Captain General of the Armed Forces.

- Duty to serve in the military

Article 249

Every Bolivian shall be obligated to render military service in accordance with the law.

Article 250

The promotions in the Armed Forces shall be granted in accordance with the respective law.

CHAPTER II. Bolivian Police

Article 251

I. The Bolivian Police, as a public force, has the specific mission to defend the society and conserve public order, and to assure compliance with the law in the entire territory of Bolivia. It shall carry out the police function in a comprehensive, indivisible manner and under a single command, pursuant to the Organic Law of the Bolivian Police and the other laws of the State.
II. As an institution, it does not deliberate nor participate in party political activities, but individually its members enjoy and exercise their rights as citizens, in accordance with the law.

Article 252

The Bolivian Police Force is subordinate to the President of the State, through the intermediary of the Minister of Government.

Article 253

To be designated Commander General of the Bolivian Police, it is necessary to be a Bolivian by birth, a General of the institution, and to meet the requisites set forth in the law.

Article 254

In the event of international war, the forces of the Bolivian Police shall be subordinated to the Commander in Chief of the Armed Forces for the time that the conflict lasts.

TITLE VIII. INTERNATIONAL RELATIONS, BORDERS, INTEGRATION AND MARITIME RESTORATION

CHAPTER I. International Relations

- International law

Article 255

I. International relations and the negotiation, signing and ratification of international treaties serve the objectives of the state in terms of sovereignty and the interests of the people.
II. The negotiation, signing and ratification of international relations shall be guided by the principles of:
1. Independence and equality among states, the no intervention in internal matters and the peaceful resolution of conflicts.
2. Rejection and condemnation of all forms of dictatorship, colonialism, neocolonialism and imperialism.
3. Defense and promotion of human, economic, social, cultural and environmental rights, with repudiation of all forms of racism and discrimination.
4. Respect for the rights of native indigenous rural peoples.
5. Cooperation and solidarity among states and peoples.
6. Preservation of patrimony, capacity of State management and regulation.
7. Harmony with nature, defense of biodiversity, and prohibition of forms of private appropriation for exclusive use and exploitation of plants, animals, microorganisms and any living matter.
8. Food security and sovereignty for the entire population; the prohibition of importation, production and commercialization of genetically modified organisms and toxic elements that harm health and the environment.
9. Access of the entire population to basic services for their wellbeing and development.
10. Preservation of the right of the population to have access to all medications, primarily genetic medications.
11. Protection and preference for Bolivian production, and promotion of exports with added value.

- Protection of environment

- International law
- Legal status of treaties

Article 256

I. The international treaties and instruments in matters of human rights that have been signed and/or ratified, or those that have been joined by the State, which declare rights more favorable than those contained in the Constitution, shall have preferential application over those in this Constitution.
II. The rights recognized in the Constitution shall be interpreted in agreement with international human rights treaties when the latter provide more favorable norms.

Article 257

I. Ratified international treaties are part of domestic law with the force of law.
II. International treaties that involve any of the following matters shall require prior approval by binding popular referendum:
1. Questions of borders.
2. Monetary integration.
3. Structural economic integration.
4. Grant of institutional authority to international or supra-national organisms, in the context of processes of integration.

- Legal status of treaties
- Treaty ratification

- Treaty ratification

Article 258

The procedures for approval of international treaties shall be regulated by the law.

- Treaty ratification

Article 259

I. Any international treaty shall require approval by popular referendum when it is requested by five percent of the citizens registered on the voting rolls, or thirty five percent of the representatives of the Pluri-National Legislative Assembly.

- Referenda

I. These initiatives can be used also to request that the Executive Organ sign a treaty.
II. The announcement of the convocation of a referendum shall suspend, according to the time periods established by law, the process of ratification of the international treaty until the results are obtained.

- International law
- Treaty ratification

Article 260

- Customary international law

I. The repudiation of the international treaties shall follow the procedures established in the same international treaty, the general norms of international law, and the procedures established in the Constitution and the law for its ratification.
II. The repudiation of ratified treaties must be approved by the Pluri-National Legislative Assembly before being executed by the President of the State.
III. The treaties approved by referendum must be submitted to a new referendum prior to their repudiation by the President of State.

CHAPTER II. Borders of the State

Article 261

The territorial integrity, preservation and the development of the border zones are a duty of the State.

Article 262

- Restrictions on rights of groups

I. The fifty kilometers from the borderline constitute the border zone security. No foreign person, individual or company, may acquire property in this space, directly or indirectly, nor possess any property right in the waters, soil or subsoil, except in the case of state necessity declared by express law approved by two-thirds of the Pluri-National Legislative Assembly. The property or the possession affected in the event of non compliance with this prohibition shall pass to the benefit of the State, without any indemnification.
II. The border zone security is subject to a special legal, economic, administrative and security regime, oriented to promote and prioritize its development and to the guarantee of the integrity of the State.

Article 263

The defense, security and control of border zone security are the fundamental duty of the Armed Forces. The Armed Forces shall participate in the policies of comprehensive and sustainable development of these zones, and shall guarantee their physical presence in them.

Article 264

I. The State shall establish a permanent policy of harmonic, comprehensive, sustainable and strategic development of the frontiers, for the purpose of improving the living conditions of its population, and especially the nations and rural native indigenous peoples living on the border.
II. It is the duty of the State to execute policies of preservation and control of the natural resources in the border areas.
III. The regulation of the border system shall be established by law.

CHAPTER III. Integration

- Regional group(s)
- International organizations

Article 265

I. The State shall promote the relations of social, political, cultural and economic integration with other states, nations and peoples of the world and, in particular, Latin American integration, based on the principles of a just, equitable relationship with recognition of asymmetry.

II. The state shall strengthen the integration of its nations and rural native indigenous peoples with the indigenous peoples of the world.

- International organizations

Article 266

The representatives of Bolivia to the supra-state parliamentary bodies emerging from the integration processes shall be elected by universal vote.

CHAPTER IV. Maritime Restoration

- Accession of territory
- Colonies

Article 267

I. The Bolivian government declares its inalienable and indefeasible right to the territory that gives access to the Pacific Ocean and sea space.
II. The effective solution to the maritime dispute through peaceful means and the full exercise of sovereignty over that territory is a permanent and inalienable objective of the Bolivian State.

Article 268

The development of maritime interests, rivers and lakes, and shipping will be the priority of the State and its administration and protection shall be exercised by the Bolivian Navy, according to the law.

PART III. STRUCTURE AND ORGANIZATION OF THE STATE TERRITORIES

TITLE I. TERRITORIAL ORGANIZATION OF THE STATE

CHAPTER I. General Matters

Article 269

- Subsidiary unit government

I. Bolivia is organized territorially into departments, provinces, municipalities and rural native indigenous territories.
II. The creation, modification and definition of the territorial units shall be made by the democratic will of their inhabitants, in accordance with the conditions established in the Constitution and law.

- Subsidiary unit government

III. The regions shall form part of the territorial organization, under the terms and conditions determined by law.

Article 270

The principles that govern territorial organization and the decentralized and autonomous territorial entities are: unity, voluntariness, solidarity, equity, the common good, self government, equality, complementariness, reciprocity, gender equity, subsidiarity, gradualness, coordination and institutional faithfulness, transparency, public participation and control, provision of economic resources and the pre-existence of the nations and rural native indigenous peoples, under the terms established in this Constitution.

- Subsidiary unit government

Article 271

- Municipal government

I. The Framework Law of Autonomies and Decentralization shall regulate the procedures for the following: drafting the autonomous Statutes and the Organic Charters, the transference and delegation of authority, the financial economic system, and the coordination between the central level and the decentralized and autonomous territorial entities.

- Supermajority required for legislation

II. The Framework Law of Autonomies and Decentralization shall be approved by two-thirds of the votes of the members of the Pluri-National Legislative Assembly who are present.

- Subsidiary unit government
- Municipal government

Article 272

Autonomy implies the direct election of the authorities by the citizens, the administration of its economic resources, and the exercise of legislative, regulatory, fiscal and executive authority by the organs of the autonomous government in the area of its jurisdiction, competence and authority.

Article 273

The law shall regulate the formation of the communities among municipalities, regions and rural native indigenous territories for the purpose of achieving their objectives.

- Subsidiary unit government

Article 274

In the decentralized departments, the election of the prefects and departmental councils shall be carried out by universal suffrage. These departments may become autonomous departments by referendum.

Article 275

Each deliberative organ of the territorial entities shall draft, in a participatory manner, the proposed Statute or Organic Charter, which must be approved by two-thirds of the total of its members. Upon prior constitutional review, it shall enter into force as the basic institutional norm of the territorial entity by means of referendum to approve it in its jurisdiction.

Article 276

The autonomous territorial entities shall not be subordinate to each other and shall have equal constitutional rank.

CHAPTER II. Departmental Autonomy

- Subsidiary unit government

Article 277

The autonomous departmental government is composed of a Departmental Assembly, which has deliberative, fiscal, and legislative departmental authority in the area of its competence, and of an executive organ.

- Subsidiary unit government

Article 278

- Right to culture
- Indigenous right to vote

I. The Departmental Assembly shall be composed of members elected by universal, direct, free, secret and obligatory vote; and by members elected by the nations and rural native indigenous peoples, in accordance with their own norms and procedures.

II. The law shall determine the general criteria for the election of members of the departmental assemblies, taking into account population, territorial, cultural identity and linguistic representation when there are rural native indigenous minorities, and parity and alternation of gender. The Statutes of Autonomy shall define its application in accordance with the specific reality and conditions of its jurisdiction.

- Subsidiary unit government

Article 279

The departmental executive organ is directed by the Governor as the highest executive authority.

CHAPTER III. Regional Autonomy

Article 280

I. The region is composed of various municipalities or provinces that have geographic continuity, which cross the borders of departments that share culture, language, history, economy and ecosystems in each department. The region shall constitute an area of planning and management. In exceptional cases, a region can be formed by a single province, which by itself has the characteristics that define a region. Metropolitan regions can be formed in the suburbs that are larger than 500,000 inhabitants.

II. The Framework Law of Autonomies and Decentralization shall establish the terms and procedures for the orderly and planned formation of the regions. Provincial authorities cannot be elected in the areas where regions are formed.

- Referenda

III. At the initiative of the municipalities belonging to it, the region may establish regional autonomy by way of referendum in its jurisdictions. Its powers must be conferred by two-thirds of the total votes of the members of the deliberative departmental organ.

- Subsidiary unit government

Article 281

The government of each autonomous region shall consist of a Regional Assembly with deliberative, normative-administrative and supervisory authority within the areas of its competence, and an executive organ.

Article 282

I. The members of the Regional Assembly shall be elected in each municipality, together with the lists of candidates for the municipal councils, in accordance with criterion of population and territory.

II. The region shall draft its Statute in a participatory manner, in accordance with the procedures established for autonomous regions.

CHAPTER IV. Municipal Autonomy

- Municipal government

Article 283

The autonomous municipal government shall consist of a Municipal Council with deliberative, supervisory and legislative municipal authority within the area of its competence; and an executive organ presided over by the Mayor.

- Municipal government

Article 284

I. The Municipal Council shall be composed of council members elected by universal suffrage.

- Right to culture

II. The nations or rural native indigenous peoples in the municipalities, which do not constitute a rural native indigenous autonomy, may elect their representatives to the Municipal Council directly, pursuant to their own norms and procedures and in accordance with the Organic Municipal Charter.

III. The law shall determine the general criterion for the election and determine the number of municipal council members. The Organic Municipal Charter shall define its application, according to the specific reality and conditions of its jurisdiction.

IV. The Municipal Council may draft the proposed Organic Charter, which shall be approved according to that set forth in this Constitution.

CHAPTER V. Executive Organs of the Autonomous Governments

- Subsidiary unit government

Article 285

I. To be a candidate for an elective position in the executive organs of autonomous governments, one must satisfy the general conditions for being a public servant,

- Municipal government

I. and:
   1. Have resided permanently in the corresponding department, region or municipality for at least the two years immediately prior to the election.
   2. In the case of the election of the Mayor and the regional authority, the person must be twenty one years of age.
   3. In the case of the election of the Prefect or Governor, the person must be twenty five years of age.

II. The period of the mandate of the highest executive authorities of the autonomous governments is five years, and he or she may be re-elected once for a continuous mandate.

- Subsidiary unit government

Article 286

I. The temporary substitution of the highest executive authority of an autonomous government shall correspond to the Council or Assembly, pursuant to the Statute of Autonomy or the Organic Charter as the case may be.

II. In the event of the resignation or death, permanent disability, or revocation of the mandate of the highest executive authority of the autonomous government, a new election shall be called, provided that half of the term of the mandate has not elapsed. If half the term has elapsed, the substitute shall be an authority already elected as defined pursuant to the Statute of Autonomy or the Organic Charter, as the case may be.

CHAPTER VI. Legislative, Deliberative and Supervisory Organs of Autonomous Governments

Article 287

I. The candidates for the councils and assemblies of the autonomous governments must satisfy the general conditions for being a public servant, and:
   1. Have resided permanently in the corresponding jurisdiction for at least two years immediately prior to the election.
   2. Be eighteen years of age on the day of the election.

II. The election of the Assemblies and Councils of the autonomous governments shall be carried out with lists that are separate from the election of the executives.

Article 288

The period of the mandate of the members of the Councils and Assemblies of the autonomous governments shall be five years, and they may be reelected once for a continuous mandate.

CHAPTER VII. Rural Native Indigenous Autonomy

- Right to culture
- Indigenous right to self governance

Article 289

Rural native indigenous autonomy consists in self-government as an exercise of free determination of the nations and rural native indigenous peoples, the population of which shares territory, culture, history, languages, and their own juridical, political, social and economic organization or institutions.

- Right to culture
- Indigenous right to self governance

Article 290

I. The formation of rural native indigenous autonomy is based on ancestral territories, currently inhabited by those peoples and nations, and pursuant to the will of their population as expressed through consultation, in accordance with the Constitution and the law.

II. The self-governance of the rural native indigenous autonomies is exercised according to their norms, institutions, authorities and procedures, in accordance with their authority and competences, and in harmony with the Constitution and the law.

Article 291

I. The rural native indigenous autonomies are rural native indigenous territories and the municipalities and regions that adopt that character, pursuant to that established in the Constitution and the law.
II. Two or more rural native indigenous peoples can form a single rural native indigenous autonomy.

- Indigenous right to self governance
- Right to culture

Article 292

Each rural, native, or indigenous autonomy shall draft its Statute according to its own norms and procedures, in conformity with the Constitution and the law.

Article 293

I. The indigenous autonomy, based on consolidated indigenous territories and those undergoing that process and once consolidated, shall be formed by the express will of the population through consultation, as the only necessary requisite, pursuant to their own norms and procedures.
II. If the establishment of an indigenous originary peasant autonomy affects the boundaries of municipal districts, the indigenous originary peasant nation or people and the municipal government must agree on a new district demarcation. If it affects municipal boundaries, a procedure for its approval shall be conducted by the Pluri-National Legislative Assembly, following the fulfillment of the special requirements and conditions provided for by statute.
III. Statute shall establish the minimum population requirements and other modalities for the constitution of an indigenous peasant farmer autonomy.
IV. To constitute an indigenous originary peasant autonomy extending to territories in one or more municipalities, statute shall determine the articulation, coordination and cooperation mechanisms for the exercise of its government.

- Right to culture

Article 294

I. The decision to form a rural native indigenous autonomy shall be adopted pursuant to the norms and procedures for consultations, according to the requisites and conditions established in the Constitution and the law.
II. The decision to convert a municipality into a rural native indigenous autonomy shall be adopted by referendum, pursuant to the requisites and conditions established by law.
III. A new municipality may be formed by the municipalities where there are rural communities with their own organizational structures, which draw them together and have geographic continuity, following the procedure for its approval before the Pluri-National Legislative Assembly, upon prior compliance with the requisites and conditions set forth in the Constitution and the law.

- Right to culture

Article 295

I. To form a rural native indigenous region that affects municipal boundaries, the procedure before the Pluri-National Legislative Assembly must be followed beforehand, fulfilling the particular requisites and conditions set forth in the Constitution and the law.
II. The aggregation of municipalities, municipal districts and/or rural native indigenous autonomies to form a rural native indigenous region, shall be decided by referendum and/or in accordance with their norms and procedures for consultation as the case may be, and pursuant to the requisites and conditions established by the Constitution and the law.

- Indigenous right to self governance
- Right to culture

Article 296

The government of the rural native indigenous autonomies is exercised through their own norms and forms of organization, with the name that corresponds to each town, nation or community, as established in their statutes and subject to the Constitution and the law.

CHAPTER VIII. Distribution of Authority

- Subsidiary unit government

Article 297

I. The authorities defined in this Constitution are as follows:
1. Prerogative: those that the legislation, regulation and execution of which cannot be transferred or delegated, and which are reserved to the central level of the State.
2. Exclusive: those which a level of government has legislative, regulatory and executive authority over a determined subject, the latter two of which may be delegated or transferred.
3. Concurrent: those in which the legislation corresponds to the central level of the State, and the other levels exercise simultaneous regulatory and executive authority.
4. Shared: those subject to basic legislation of the Pluri-National Legislative Assembly, the legislative development of which corresponds to the autonomous territorial entities, according to its character and nature. The regulation and execution shall correspond to the autonomous territorial entities.

II. Every authority which is not included in this Constitution shall be attributed to the central level of the State, which may transfer or delegate it by law.

Article 298

I. The following are the areas of prerogative authority of the central level of the State:
1. Financial system.
2. Monetary policy, the Central Bank, the monetary system, and the policy of foreign exchange.
3. System of measures and weights, as well as the determination of the official time.
4. Customs regime.
5. Foreign Commerce.
6. State Security, defense, the Armed Forces, and the Bolivian Police.
7. Weapons and explosives.
8. Foreign policy.
9. Nationality, citizenship, laws applicable to foreigners, the right to asylum and refuge.
10. Control of the borders in relation to the security of the State.
11. Immigration regulation and policies.
12. Creation, monitoring and administration of strategic public enterprises at the central level of the State.
13. Administration of the Pluri-National State patrimony and the patrimony of public entities at the central level of the State.
14. Control of air space and air transit throughout the entire national territory. The construction, maintenance, and administration of the international airports and inter-departmental air traffic.
15. The Civil Registry.
16. The official census.
17. General policy over land and territory and title to them.
18. Hydrocarbons.
19. Creation of national taxes, rates and special tax contributions of the central level of the State.
20. General policy of Biodiversity and Environment.
21. Substantive and procedural codification in civil, family, criminal, tax, labor, commercial, mining and electoral matters.
22. National economic and planning policy.

- Central bank
- Census
- Protection of environment
- Economic plans

II. The central level of the State has exclusive authority over the following:
1. National electoral system for the election of national and sub-national authorities.
2. General communications and telecommunications systems.
3. Postal service.
4. Strategic natural resources, which include minerals, the electromagnetic spectrum, genetic and biogenetic resources, and water sources.

- Telecommunications
- Ownership of natural resources

II.

- Protection of environment

5. General system of hydraulic resources and services.
6. General system of biodiversity and environment.
7. Forestry policy and the general system for soils, forestry and woods.
8. Policy of generation, production, control, transmission and distribution of energy en the interconnected system.
9. Planning, design, construction, conservation and administration of highways of the Fundamental Network.
10. Construction, maintenance and administration of railroad lines and railroads of the Fundamental Network.
11. Public works of important infrastructure of the central level of the State.
12. Elaboration and approval of plans and official cartographic maps; surface maps.
13. Elaboration and approval of official statistics.
14. Granting of legal status to social organizations that carry out activities in more than one Department.
15. Granting and registration of legal status to Non-Governmental Organizations, Foundations and not for profit civil entities that carry out activities in more than one Department.
16. Social Security system.
17. Policies of the educational and health systems.
18. System of Real Property in obligatory coordination with municipal technical registration.
19. Protected areas under the responsibility of the central level of the State.
20. Fiscal reserves with respect to natural resources.
21. Health and safety of livestock.
22. Control of agrarian administration and rural land registry.
23. Tax policy.
24. Administration of Justice.

- Reference to science
- Reference to art

25. Promotion of culture and the conservation of important cultural, historic, artistic, monumental, architectural, archeological, paleontological, scientific, tangible and intangible patrimony at the central level of the State.

- Protection from expropriation

26. Expropriation of real estate for reasons of public utility and necessity, in accordance with the procedures established by law.
27. Centers of information and documentation, archives, libraries, museums, periodical libraries and others of importance of the central level of the State.
28. Public enterprises at the central level of the State.
29. Rural settlements
30. Policies of basic services.
31. Labor policies and systems.
32. Transportation, ground, air, river and others when they transit more than one department.
33. Policies of territorial planning and land registry and regulations.
34. Internal and external public debt.
35. General policies of productive development.
36. General housing policies.
37. General tourism policies.
38. Regimen for land. The law shall determine the authorities to be transferred or delegated to the autonomies.

- Subsidiary unit government

Article 299

I. The following authorities are exercised in shared form between the central level of the State and the autonomous territorial entities:

1. The departmental and municipal electoral systems.
2. Fixed and mobile telephone and telecommunications services.

- Telecommunications

3. Urban electrification.
4. Lottery games and gambling.
5. International relations within the framework of the foreign policy of the State.
6. The establishment of forums of citizen conciliation for the resolution of conflicts between neighbors in municipal matters.
7. Regulation for the creation and/or modification of taxes that are the exclusive domain of autonomous governments.

II. The following authorities shall be exercised concurrently by the central level of the State and the autonomous territorial entities.

- Protection of environment

1. To preserve, conserve and contribute to the protection of the environment and the wild fauna maintained in ecological equilibrium, and the control of environmental contamination.
2. Management of the health and educational systems.
3. Science, technology and research.
4. Conservation of soil, forest resources and woods.

- Protection of environment

5. Weather Service.
6. Electromagnetic frequencies in the areas of their jurisdiction and within the framework of the policies of the State.
7. Promotion and administration of hydraulic and energy projects.
8. Industrial waste and toxic materials.
9. Potable water projects and treatment of solid waste.
10. Irrigation projects.
11. Protection of basins.
12. Administration or river ports.
13. Public security.
14. System of government control.
15. Housing and public housing.
16. Agriculture, livestock, hunting and fishing.

- Subsidiary unit government

Article 300

I. The autonomous departmental governments have exclusive authority over the following in their jurisdictions:

1. To elaborate their Statute pursuant to the procedures established in the Constitution and the law.
2. To plan and develop human development in their jurisdiction.
3. Initiation and convocation of departmental consultations and referenda on matters within their competence.
4. Promotion of employment and improvement of working conditions, within the framework of national policies.
5. Elaboration and execution of the Plans of land registry and regulations and the use of soils, in coordination with the plans at the central level of the State, municipalities and rural native indigenous peoples.
6. Projects of generation and transport of energy in isolated systems.
7. Planning, design, construction, conservation and administration of highways of the departmental network in accordance with state policies, including those of the Fundamental Network in the absence of the central level, in accordance with the norms established by the latter.
8. Construction and maintenance of rail lines and railroads in the department in accordance with state policies, pursuant to the norms established by the state.
9. Inter-provincial ground, river, railroad and other means of transportation en the department.
10. Construction, maintenance and administration of the public departmental airports.
11. Departmental statistics.
12. To grant legal personality to public organizations that carry out activities in the department.
13. To grant legal personality to Non Governmental Organizations, foundations and not for profit civil entities that carry out activities in the department.
14. Services of agricultural health and safety.
15. Projects for rural electrification.
16. Projects of alternative and renewable sources of energy within the department, preserving food security.
17. Sports in the area of its jurisdiction.
18. Promotion and conservation of departmental natural patrimony.

- Reference to art
- Reference to science

19. Promotion and conservation of culture, cultural, historic, artistic, monumental, architectural, archeological, paleontological, scientific, tangible and intangible departmental patrimony.
20. Departmental tourism policies.
21. Projects for departmental infrastructure to support production.

I. 22. Creation and administration of taxes of departmental character, the imposition of which is not analogous to national or municipal taxes.
23. Creation and administration of fees and special contributions of departmental character.
24. Commerce, industry and services for development and competitiveness within the department.
25. Expropriation of real estate in its jurisdiction for reasons of public utility and necessity.
26. To elaborate, approve and execute is programs of operation and its budget.
27. Fiduciary funds, investment funds and mechanisms of transfer of necessary and inherent resources within its competences.
28. Departmental centers of information and documentation, archives, libraries, museums, periodical libraries and others.
29. Departmental public enterprises.
30. Promotion and development of projects and policies for children and adolescents, women, the elderly and persons with disabilities.
31. Promotion and administration of services for productive and agricultural development.
32. Elaboration and execution of departmental economic and social development plans.
33. To participate in enterprises of industrialization, distribution and commercialization of hydrocarbons in the departmental territory in association with the national entities of the sector.
34. Promotion of private investment in the department within the framework of national economic policies.
35. Planning of departmental development in concordance with national planning.
36. Administration of its royalties received within the framework of the general budget of the nation, which shall be transferred automatically to the Departmental Treasury.

II. The Autonomous Departmental Statues may define some of the exclusive authority as concurrent authority with other territorial entities of the department.

III. The competences that may be transferred or delegated will also be of departmental execution.

- Subsidiary unit government

Article 301

The region, once constituted as a regional autonomy, shall receive the authority that may be transferred or delegated.

- Municipal government

Article 302

I. The following are the exclusive authority of the autonomous municipal governments, within their jurisdiction:
1. To draft the Municipal Organic Charter pursuant to the procedures established in this Constitution and the law.
2. To plan and promote human development in their jurisdiction.
3. Initiative and convocation of municipal consultations and referenda in matters of their competence.
4. Promotion of employment and the improvement of working conditions within the framework of national policies.
5. To preserve, conserve and contribute to the protection of the environment and natural resources, wild fauna and domestic animals.
6. Elaboration of land registry and regulations plans and the use of soils, in coordination with the plans of the central level of the State, the Departments and indigenous levels.
7. To plan, design, construct, conserve and administer roads in coordination with the rural native indigenous villages when necessary.
8. Construction, maintenance and administration of local public airports.
9. Municipal statistics.
10. Urban land registry in the area of their jurisdiction pursuant to the precepts and technical parameters established by the Municipal Governments.

- Protection of environment

- Reference to science
- Reference to art

- Reference to art

I.
11. Municipal protected areas in accordance with the parameters and conditions established by the Municipal Governments.
12. Projects of alternative and renewable sources of energy, preserving food security within the municipality.
13. To control the quality and sanitation of the elaboration, transport and sale of food products for human and animal consumption.
14. Sports in the area of their jurisdiction.
15. Promotion and conservation of natural municipal patrimony.
16. Promotion and conservation of culture and municipal cultural, historic, artistic, monumental, architectural, archeological, paleontological, scientific, tangible and intangible municipal patrimony.
17. Local tourism policies.
18. Urban transportation, registration of automobile ownership, road regulation and education, administration and control of urban traffic.
19. Creation and administration of municipal taxes, the imposition of which may not be analogous to the national or departmental taxes.
20. Creation and administration of fees, certificates for economic activity and special contributions of municipal character.
21. Projects for productive infrastructure.
22. Expropriation of real property in their jurisdiction for reasons of public utility and necessity, pursuant to the procedures established by law, as well as establishing administrative limitations and right of passage for reasons of technical, legal order and public importance.
23. To elaborate, approve and execute their programs of operation and their budgets.
24. Fiduciary funds, investment funds and mechanisms of transference of necessary and inherent resources within the areas of their authority.
25. Municipal centers of information, archives, libraries, museums, periodical libraries and others.
26. Public municipal enterprises.
27. Urban sanitation, management and treatment of solid waste within the framework of State policy.
28. To design, construct, equip and maintain the infrastructure and works of public importance and the assets of municipal dominion, within their jurisdictional territory.
29. Urban development and urban settlements.
30. Public lighting service of their jurisdiction.
31. Promotion of culture and artistic activities in their jurisdiction.
32. Public shows and recreational games.
33. Urban publicity and announcements.
34. To promote and sign agreements of association or municipal community with other municipalities.
35. Agreements and/or contracts with natural or collective persons, public and private, for the development and fulfillment of their powers, authority and purposes.
36. To construct and regulate the Municipal Guard for contribute to the fulfillment, exercise and execution of their authority as well as compliance with the municipal norms and the resolutions that are issued.
37. Policies that guarantee the defense of consumers and users in the municipal area.
38. Systems of micro-irrigation in coordination with rural native indigenous villages.
39. Promotion and development of projects and policies for children and adolescents, women, the elderly and persons with disabilities.
40. Basic services as well as approval of the corresponding fees in their jurisdiction.
41. Grains and sharecroppers, in coordination with the rural native indigenous villages, when appropriate.
42. Planning of municipal development in accordance with departmental and national planning.
43. To participate in enterprises of industrialization, distribution and commercialization of Hydrocarbons in the municipal territory in association with the national entities of the sector.

II. The authorities that may be transferred or delegated to them shall also be executed by municipalities.

Article 303

I. The rural native indigenous villages, in addition to their authority, shall assume that of municipalities, in accordance with a process of institutional development and with their own cultural characteristics in conformity with the Constitution and the Framework Law of Autonomies and Decentralization.
II. The rural native indigenous region shall assume the authority that may be transferred or delegated to it.

- Indigenous right to self governance
- Right to culture

Article 304

I. The rural native indigenous autonomies shall exercise the following exclusive authorities:
1. To elaborate their Statute for the exercise of their autonomy pursuant to the Constitution and the law.
2. Definition and management of their own forms of economic, social, political, organizational and cultural development, in accord with their identity and the vision of each village.
3. Management and administration of renewable natural resources, in accord with the Constitution.
4. Elaboration of Plans of Land Regulation and land use, in coordination with the plans at the central State, departmental and municipal levels.
5. Electrification in isolated places in their jurisdiction.
6. Maintenance and administration of local and communal roads.
7. Administration and preservation of protected areas within their jurisdiction, within the framework of the policy of the State.
8. Exercise of rural native indigenous jurisdiction for the application of justice and the resolution of conflict through their own norms and procedures in accordance with the Constitution and the law.
9. Sports, leisure activity and recreation.
10. Tangible and intangible cultural patrimony. The safeguard, stimulation and promotion of its cultures, art, identity, archeological centers, religious and cultural places, and museums.
11. Tourism policies.
12. To create and administer fees, certificates and special contributions in the area of its jurisdiction in accordance with the law.
13. Administrate the taxes within its authority in the area of its jurisdiction.
14. To elaborate, approve and execute its programs of operation and its budget.
15. Planning and management of territorial occupation.
16. Housing, town planning and redistribution of population in accordance with the cultural practices in the area of its jurisdiction.
17. To promote and sign agreements of cooperation with other towns and public and private entities.
18. Maintenance and administration of its micro-irrigation systems.
19. Stimulation and development of productive activity.
20. Construction, maintenance and administration of the infrastructure necessary for development in its jurisdiction.
21. To participate in, develop and execute the mechanisms of prior, free and informed consultations related to the application of legislative, executive and administrative measures that affect them.
22. Preservation of the habitat and the landscape, in accordance with its principles, norms, and cultural, technological, special and historical practices.
23. Development and practice of democratic institutions pursuant to its own norms and procedures.

- Reference to art

II. The rural native indigenous villages can exercise the following shared authority:
1. International exchanges within the framework of the foreign policy of the State.
2. Participation and control in the use of grains.
3. The safeguard and registration of collective intellectual property related to knowledge of genetic resources, traditional medicine and germ plasma, in accordance with the law.

- Protection of environment

II. 4. Control and regulation of foreign institutions and organizations that carry out activities in their jurisdiction, which are inherent to the development of their institutions, culture, environment and natural patrimony.

III. The rural native indigenous autonomies may exercise the following concurrent authority:
1. Organization, planning and execution of health policy in their jurisdiction.
2. Organization, planning and execution of plans, programs and projects related to education, science, technology and research, within the framework of State legislation.
3. Conservation of forestry resources, biodiversity and the environment.
4. Irrigation systems, hydraulic resources, sources of water and energy, within the framework of State policy, within their territory.
5. Construction of micro-irrigation systems.
6. Construction of local and communal roads.
7. Promotion of the building of productive infrastructure.
8. Promotion and stimulation of agriculture and raising of livestock.
9. Control and socio-environmental monitoring of the activities of hydrocarbon and mining activities carried out in their jurisdiction.
10. Systems of financial control and administration of assets and services.

IV. The resources necessary for carrying out their responsibilities shall be transferred automatically by the Pluri-National State in accordance with the law.

Article 305

Every assignment or transfer of authority must be accompanied by the determination of the source of economic and financial resources necessary for its exercise.

PART IV. ECONOMIC STRUCTURE AND ORGANIZATION OF THE STATE

TITLE I. ECONOMIC ORGANIZATION OF THE STATE

CHAPTER I. General Matters

Article 306

I. The Bolivian economic model is plural and seeks to improve the quality of life and the well being of all Bolivians.

II. The plural economy is composed of forms of community, state, private and public cooperative economic organization.

III. The plural economy articulates different forms of economic organization based on the principles of complementariness, reciprocity, solidarity, redistribution, equality, legal security, sustainability, equilibrium, justice and transparency.

IV. The forms of economic organization recognized in this Constitution may form joint ventures.

V. The State places the highest value on human beings and assures development through the equitable redistribution of economic surplus in the social policies of health, education, culture, and the re-investment in productive economic development.

Article 307

The State shall recognize, respect, protect and promote community economic development. This form of community economic organization includes productive and reproductive systems of public life, founded on the principles and visions of the nations and rural native indigenous peoples.

Article 308

I. The State recognizes, respects and protects private initiative that contributes to the economic and social development and the strengthening of economic independence of the country.
II. Free enterprise and full exercise of business activities, which shall be regulated by law, are guaranteed.

Article 309

The form of state economic organization includes the enterprises and other economic entities that are state property, which shall comply with the following objectives:

- Ownership of natural resources

1. To administer property rights over natural resources on behalf of the Bolivian people, and to exercise strategic control of the productive chain and industrialization of these resources.
2. To manage basic services of potable water and sewer systems directly or by means of public, community, cooperative or mixed enterprises.
3. To directly produce goods and services.
4. To promote economic democracy and achieve the food sovereignty of the population.
5. To guarantee public participation and control over its organization and management, as well as the participation of workers in decision making and in the profits.

Article 310

The State recognizes and protects the cooperatives as forms of solidarity and cooperation, which are not for profit. The organization of cooperatives shall be promoted primarily in production activities.

Article 311

- Economic plans
- Ownership of natural resources

I. All forms of economic organization established in this Constitution shall enjoy equality before the law.
II. The pluralistic economy includes the following aspects:
    1. The State shall exercise total direction of economic development and the processes of planning.
    2. The natural resources are the property of the Bolivian people and shall be managed by the State. Individual and collective property rights in land shall be respected and guaranteed. Agriculture, raising of livestock, as well as hunting and fishing not involving protected species, are activities that are governed by Part Four of this Constitution relating to the economic structure and organization of the State.
    3. The industrialization of natural resources to overcome dependence on the export of raw materials and to achieve an economy with a productive base, within the framework of sustainable development in harmony with nature.
    4. The State may intervene in every part of the chain of productivity in the strategic sectors, seeking to guarantee its supply in order to preserve the quality of life of all Bolivians.
    5. Respect for enterprise initiative and legal security.
    6. The State shall stimulate and promote the community area of the economy as a supportive alternative in rural and urban areas.

Article 312

I. Every economic activity must contribute to the strengthening of the economic sovereignty of the country. The private accumulation of economic power to the

I. degree that it might endanger the economic sovereignty of the State shall not be permitted.

- Mentions of social class

II. All forms of economic organization have the obligation to generate dignified work and to contribute to the reduction of inequalities and to the eradication of poverty.

- Protection of environment

III. All forms of economic organization have the obligation to protect the environment.

Article 313

To eliminate poverty and social and economic exclusion, and in order to achieve well being in its multiple dimensions, the economic organization of Bolivia has the following goals:

1. The generation of social wealth within the framework of respect for individual rights, as well as the rights of the peoples and nations.
2. The fair production, distribution and redistribution of wealth and economic surplus.
3. The reduction of inequality of access to productive resources.
4. The reduction of regional inequalities.
5. The productive development of the industrialization of natural resources.
6. The active participation of the public and community economies in the productive apparatus.

- Right to competitive marketplace

Article 314

Private monopolies and oligopolies are prohibited, as well as any other form of association or public or private legal agreement by Bolivian or foreign persons, who attempt to control and have exclusivity over production and commercialization of goods and services.

Article 315

I. The State recognizes the title to land of all legal persons that are legally constituted in the national territory, provided that it be used to fulfill the objective of the creation of an economic agent, the generation of employment, and the production and commercialization of goods and/or services.

II. The legal persons mentioned in the paragraph above that are formed after the adoption of the present Constitution shall have a corporate structure with the number of owners no less than the division of the total surface by five thousand hectares, rounding up the result to the immediately higher whole number.

CHAPTER II. Function of the State in the Economy

Article 316

The function of the State in the economy consists of the following:

- Economic plans

1. To conduct the process of economic and social planning, with the participation of, and in consultation with, the citizens. The law shall establish a system of comprehensive state planning, which shall incorporate all the territorial entities.
2. To direct the economy and to regulate the processes of production, distribution and commercialization of goods and services, according to the principles established in this Constitution.
3. To exercise the direction and control of the strategic sectors of the economy.
4. To directly participate in the economy by way of incentive and the production of economic and social goods and services in order to promote economic and social

4. equity, and to stimulate development, preventing oligopolistic control of the economy.

5. To promote the integration of different economic forms of production, with the objective of achieving economic and social development.

- Protection of environment

6. To promote primarily the industrialization of renewable and nonrenewable natural resources, within the framework of respect for and protection of the environment, in order to guarantee the generation of employment and the economic and social consumption of the population.

- Mentions of social class

7. To promote policies of equitable distribution of wealth and of the economic resources of the country, for the purpose of preventing inequality, social and economic exclusion, and to eradicate poverty in its multiple dimensions.

8. To establish state monopoly over productive and commercial activities that are considered indispensable in the event of pubic need.

9. To periodically formulate, with the participation of and in consultation with the citizenry, the general development plan, the execution of which is obligatory for every form of economic organization.

10. To administer economic resources for research, technical assistance and transfer of technology to promote productive activities and industrialization.

11. To regulate aeronautic activity in the air space of the country.

Article 317

The State shall guarantee the creation, organization and performance of a participatory planning entity that includes representatives of the public institutions and organized civil society.

CHAPTER III. Economic Policies

Article 318

I. The State shall determine the policy for industrial and commercial production that guarantees a sufficient supply of goods and services to adequately cover basic domestic needs and to strengthen export capacity.
II. The State recognizes and shall prioritize support for the organization of associative structures of micro, small and medium productive enterprises, both urban and rural.
III. The State shall strengthen the productive, manufacturing and industrial infrastructure and basic services for the productive sector.
IV. The State shall prioritize the promotion of rural productive development as fundamental to the development policies of the country.
V. The State shall promote and support the export of value added goods and of services.

Article 319

- Protection of environment

I. The industrialization of natural resources shall be a priority in the economic policies, within the framework of respect for and protection of the environment and of the rights of the rural native indigenous nations and peoples and their territories. The articulation of the exploitation of natural resources with internal productive apparatus shall be a priority in the economic policies of the State.
II. In setting the price for the commercialization of strategic natural and energy resources, the State shall consider taxes, royalties and the corresponding participations that must be paid to the public treasury.

Article 320

I. Bolivian investment shall take priority over foreign investment.

II. Every foreign investment shall submit to Bolivian jurisdiction, laws and authorities, and no one may cite an exceptional situation, nor appeal to diplomatic claims to obtain a more favorable treatment.
III. The economic relations with foreign states or enterprises shall be carried out under conditions of independence, mutual respect and equity. More favorable conditions may not be granted to foreign States or enterprises than those established for Bolivians.
IV. The State acts independently in all of its decisions on internal economic policy, and shall not accept demands or conditions imposed on this policy by states, banks or Bolivian or foreign financial institutions, multilateral entities or transnational enterprises.
V. The public policies shall promote internal consumption of products made in Bolivia.

Section I. Fiscal Policy

Article 321

I. The economic and financial administration of the State and all of the public entities is governed by its budget.
II. The determination of expenses and public investment shall be made by means of participatory mechanisms involving the citizenry, technical planning and the state executive. The allocations shall attend especially to education, health, nutrition, housing and productive development.

- Budget bills

III. The Executive Organ shall present to the Pluri-National Legislative Assembly, at least two months before the end of each fiscal year, the proposed law of the General Budget for the following term, which shall include all of the entities of the public sector.
IV. Every bill that implies expenses or investments for the State must establish the source of the funding, the way in which they will be covered, and the manner of their investment. If the bill was not presented by initiative of the Executive Organ, it requires prior consultation with it.
V. The Executive Organ, through the Ministry of the relevant branch, shall have direct access to the information concerning the expenses that are budgeted and spent in every public sector. This access shall include information on the expenses budgeted and spent by the Bolivian Armed Forces and Police.

Article 322

I. The Pluri-National Legislative Assembly shall authorize the contracting of public debt when the capacity to generate revenue to cover the capital and interest is demonstrated, and when the most advantageous conditions in the rates, payment schedules, amounts and other circumstances are technically justified.
II. Public debt may not include obligations that have not been authorized and expressly guaranteed by the Pluri-National Legislative Assembly.

Article 323

I. The fiscal policy is based on the principles of economic capacity, equality, progressiveness, proportionality, transparency, universality, control, administrative simplicity and ability to collect.

- Subsidiary unit government
- Municipal government

II. The taxes which belong to the national tax domain shall be approved by the Pluri-National Legislative Assembly. The taxes that belong to the exclusive domain of the departmental or municipal autonomies, shall be approved, modified or eliminated by their Councils or Assemblies at the request of the executive organs. The tax domain of the Decentralized Departments and regions shall be made up of departmental taxes, fees and special contributions, respectively.
III. The Pluri-National Legislative Assembly shall classify and define the taxes that by law belong to the national, departmental and municipal tax domains.
IV. The creation, suppression or modification of taxes under the dominion of the autonomous governments with taxing authority, shall be effected under the following limitations:
    1. No taxes may be created that impose taxes which are analogous to those corresponding to existing national taxes or other departmental or

IV. 1. municipal taxes, independently of the tax domain to which they belong.
2. No taxes may be created that encumber goods, economic activity or patrimony outside of their territorial jurisdiction, except revenues generated by their citizens or enterprises outside of the country. This prohibition extends to fees, certificates and special contributions.
3. No taxes may be created that impede the free circulation and establishment of persons, assets, activities or services within the territorial jurisdiction. This prohibition extends to fees, certificates and special contributions.
4. No taxes may be created that generate privileges for residents in a discriminatory manner. This prohibition extends to fees, certificates and special contributions.

Article 324

The debts for economic damages caused to the state never expire.

Article 325

Illicit economic activity, speculation, hoarding, money changing, usury, contraband, tax evasion and other related economic crimes shall be punished by the law.

Section II. Monetary Policy

- Central bank

Article 326

I. The State, through the Executive Organ, shall determine the goals of the monetary and exchange policies of the country in coordination with the Central Bank of Bolivia.
II. Public transactions in the country shall be carried out in the national currency.

- Central bank

Article 327

The Central Bank of Bolivia is an institution of public law, with its own legal personality and patrimony. Within the framework of the economic policy of the State, it is the function of the Central Bank of Bolivia to maintain stability of the internal purchasing power of the currency in order to contribute to the economic and social development.

- Central bank

Article 328

I. In addition to those set forth in the law, the powers of the Central Bank of Bolivia, in coordination with the economic policy determined by the Executive Organ, are as follows:
1. To determine and execute the monetary policy.
2. To execute the exchange policy.
3. To regulate the system of payments.
4. To authorize the issuance of currency.
5. To manage the international reserves.

- Central bank

Article 329

I. The Board of Directors of the Central Bank of Bolivia shall be composed of a President and five directors designated by the President of the State from lists of candidates presented by the Pluri-National Legislative Assembly for each one of the positions.
II. The members of the Board of Directors of the Central Bank of Bolivia shall have terms of five years, and are not eligible for re-election. They shall be considered public servants, pursuant to the Constitution and the law. The specific requisites for the position shall be determined by law.
III. The members of the Board of Directors of the Central Bank of Bolivia shall report and give accounts on the performance of the institution as often as requested by the Pluri-National Legislative Assembly or its Chambers. The Central Bank of Bolivia shall deliver an annual report to the Legislative Assembly and is subject to the governmental and fiscal system of control of the State.

Section III. Financial Policy

Article 330

I. The State shall regulate the financial system based on criterion of equality of opportunity, solidarity, equitable distribution and redistribution.
II. The State, through its financial policy, shall prioritize the demand for financial services of the sectors of micro and small enterprises, artisans, commerce, service, community organizations and production cooperatives.
III. The State shall stimulate the creation of non bank financial entities for the purpose of socially productive investment.
IV. The Central Bank of Bolivia and the public entities and institutions shall not recognize the debts of private banks or financial entities. These banks and entities have the obligation to contribute to and strengthen a fund for financial restructuring, which shall be used in the event of bank insolvency.
V. The financial operations of the Public Administration, at the different levels of government, shall be carried out by a public banking entity. The law shall provide for its creation.

Article 331

The activities of financial intermediation, the provision of financial services and any other activities related to the management, use and investment of savings, are matters of public interest and may only be exercised with prior authorization of the State, in accordance with the law.

Article 332

I. The financial entities shall be regulated and supervised by an institution of banking and financial entity regulation. This institution shall be a public law institution and shall have jurisdiction in the entire territory of Bolivia.
II. The highest authority of the institution for banking and financial entity regulation shall be designated by the President of the State from among a list of candidates proposed by the Pluri-National Legislative Assembly, in accordance with the procedure established by the law.

Article 333

The financial operations carried out by natural or legal persons, whether by Bolivians or foreigners, shall enjoy the right of confidentiality, except in judicial procedures in cases of the alleged commission of financial crimes, those in which fortunes are being investigated and others defined by the law. The entities, which are designated by law to investigate such cases, shall have the authority to obtain information about said financial operations without the need for judicial authorization.

Section IV. Sector Policies

Article 334

In the context of sectoral policies, the State shall protect and promote:

1. The rural economic organizations, and the associations or organizations of small urban producers and artisans, as supportive and reciprocal alternatives. The economic policy shall facilitate access to technical training and technology, to credits, to the opening of markets, and the improvement of productive processes.

2. The guild sector, the self-employed, and retail commerce, in the areas of production, services and sales, shall be strengthened by means of access to credit and technical assistance.

3. Production of crafts with cultural identity.

4. The micro and small enterprises, as well as the rural economic organizations, and organizations or associations of small producers, which shall enjoy preference in the purchases made by the State.

Article 335

The public service cooperatives shall be non profit organizations of collective interest and submitted to governmental control, and they shall be administered democratically. The election of their administrative and supervisory authorities shall be carried out according to their own statutory norms and supervised by the Pluri-National Electoral Organ. Their organization and operation shall be regulated by law.

Article 336

The State shall provide support to community economic organizations so that they may receive credits and financing.

Article 337

- Protection of environment

I. Tourism is a strategic economic activity, which must be developed in a sustainable manner that takes into account respect for the treasures of the culture and the environment.
II. The State shall promote and protect community tourism with the objective of benefiting urban and rural communities, and the rural native indigenous nations and peoples where this activity is carried out.

Article 338

The State recognizes the economic value of housework as a source of wealth, and it shall be quantified in public accounts.

CHAPTER IV. Assets and Resources of the State and Their Distribution

Article 339

I. The President of the Republic may only decree payments that are not authorized by the budget law in order to attend to necessities, which cannot be delayed, arising from public calamities, internal disturbance or the exhaustion of resources destined to maintain services, the paralysis of which would cause serious harm. The expenses destined for these objectives shall not exceed one percent of the total expenditures authorized by the General Budget.
II. The assets that are State patrimony and those of public entities are property of the Bolivian people, and they may not be violated, attached, limited or expropriated; they may not be employed to the benefit of any individual. Their description, inventory, administration, disposition, obligatory registration, and the kinds of claims shall be regulated by law.
III. The income of the State shall be invested pursuant to the general economic and social development plan of the country, the General Budget of the State and the law.

- Subsidiary unit government
- Municipal government

Article 340

I. State revenue is divided into revenue of the nation, departments, municipalities and the rural native indigenous peoples, and it shall be invested independently by their Treasuries, pursuant to their respect budgets.
II. The law shall classify the national, departmental and municipal income and that of the rural native indigenous peoples.
III. The departmental and municipal resources, and those of the rural native indigenous autonomies, and the judicial and university resources, which are collected by dependent offices at the national level, shall not be centralized in the National Treasury.
IV. The national Executive Organ shall establish the norms for the elaboration and presentation of the proposed budgets of the entire public sector, including the

IV. autonomies.

- Subsidiary unit government

Article 341

The following are the resources of departments:

1. The departmental royalties created by law.
2. Participation in the revenue derived from taxes on the Hydrocarbons, according to the percentages set forth in the law.
3. Taxes, fees, special contributions and departmental certificates on natural resources.
4. The transfers from the General Treasury of the Nation which are allocated to cover the expenses of personal health, education and social assistance.
5. The extraordinary transfers of the General Treasury of the Nation, in the cases established in article 339.I of this Constitution.
6. The internal and foreign credits and loans contracted pursuant to the norms of public debt of the system of the National Treasury and Public Credit.
7. The income derived from the sale of goods, services and the sale of assets.
8. Bequests, donations and other similar income.

TITLE II. ENVIRONMENT, NATURAL RESOURCES, LAND AND TERRITORY

- Protection of environment

CHAPTER I. Environment

Article 342

It is the duty of the State and the population to conserve, protect and use natural resources and the biodiversity in a sustainable manner, as well as to maintain the equilibrium of the environment.

Article 343

The population has the right to participate in environmental management, and to be consulted and informed prior to decisions that could affect the quality of the environment.

Article 344

I. The manufacture and use of chemical, biological and nuclear weapons on Bolivian territory is prohibited, as well as the internment, transit and deposit of nuclear and toxic wastes.
II. The State shall regulate the internment, production, sale and employment of techniques, methods, supplies and substances that affect health and the environment.

Article 345

The policies of environmental management are based on the following:

1. Participatory planning and management, with public control.
2. The application of systems of evaluation of environmental impact and control of the quality of the environment, without exception and in a way that traverses all activity of production of goods and services that use, transform or affect natural resources and the environment.

3. Liability for the conducting of any activity that produces environmental harm; civil, criminal and administrative penalties for non compliance with the norms for the protection of the environment.

Article 346

The natural assets are of public importance and of strategic character for the sustainable development of the country. Their conservation and use for the benefit of the population shall be the responsibility and exclusive authority of the State, and sovereignty over natural resources may not be compromised. The law shall establish the principles and disposition for its management.

Article 347

I. The State and the society shall promote the mitigation of harmful effects on the environment and of the environmental contamination and damage that affect the country. Liability will be declared for damage to historic environments, and liability for environmental crimes shall not lapse.
II. Those who carry out activities that impact the environment must, at all stages of production, avoid, minimize, mitigate, remediate, repair and make compensation for the harms caused to the environment and the health of persons, and shall establish the security measures necessary to neutralize the possible effects of environmental contamination and damage.

CHAPTER II. Natural Resources

Article 348

I. Minerals in all of their states, the hydrocarbons, water, air, soil and the subsoil, the forests, the biodiversity, the electromagnetic spectrum and all the elements and physical forces capable of use, are considered natural resources.
II. The natural resources are of strategic character and of public importance for the development of the country.

- Ownership of natural resources

Article 349

I. The natural resources are the property and direct domain, indivisible and without limitation, of the Bolivian people, and their administration corresponds to the State on behalf of the collective interest.
II. The State shall recognize, respect and grant individual and collective ownership rights to land, as well as the rights to use and enjoyment of natural resources.
III. Agriculture, livestock, as well as the activities of hunting and fishing that do not involve protected animal species, are activities that are governed by that which is established in Part Four of this Constitution related to the economic organization and structure of the State.

Article 350

Any title granted over fiscal reserves shall be null and void, except by express authorization for state necessity and public utility, in accordance with the law.

Article 351

I. The State, shall assume control and direction of the exploration, exploitation, industrialization, transport and sale of strategic natural resources through public, cooperative or community entities, which may in turn contract private enterprises and form mixed enterprises.
II. The State shall sign contracts of association with legal persons, Bolivian or foreign, for the use of natural resources. It must assure the reinvestment of economic profits in the country.
III. The management and administration of natural resources shall be carried out guaranteeing social participation and control in the design of the sector policies. Mixed enterprises may be established for the management and administration,

III. with representation of the state and society, and the collective welfare shall be safeguarded.
IV. Private enterprises, whether Bolivian or foreign, shall pay taxes and royalties when they take part in the exploitation of natural resources, and the payments that might be made shall not be reimbursable. The royalties for the use of natural resources are a right and a compensation for their exploitation, and they shall be regulated by the Constitution and the law.

- Right to culture

Article 352

The exploitation of natural resources in a determined territory shall be subject to a process of consultation with the affected population, called by the State, which shall be free, prior in time and informed. Citizen participation is guaranteed in the process of the management of the environment, and the conservation of ecosystems shall be promoted, in accordance with the Constitution and the law. In the nations and rural native indigenous peoples, the consultation will be carried out with respect given to their own norms and procedures.

- Right to culture

Article 353

The Bolivian people shall have equitable access to the benefits which come from the use of all the natural resources. Priority participation shall be assigned to the territories where these resources are found, and to the nations and rural native indigenous peoples.

Article 354

The State shall develop and promote research related to the management, conservation and use of natural resources and to biodiversity.

Article 355

I. The industrialization and sale of natural resources shall be a priority of the State.
II. The profits obtained from the exploitation and sale of the natural resources shall be distributed and reinvested to promote economic diversification in the different territorial levels of the State. The percentage of profits to be distributed shall be approved by the law.
III. The processes of industrialization shall be carried out with preference given to the place of origin of the production, and conditions shall be created which favor competitiveness in the internal and international market.

Article 356

The activities of exploration, exploitation refining, industrialization, transport and sale of nonrenewable natural resources shall have the character of state necessity and public utility.

Article 357

Since it is social property of the Bolivian people, no foreign person or enterprise, nor any private Bolivian person or enterprise, may register the property title to Bolivian natural resources in stock markets, nor can they use them as means for financial operations that grant title to or use them as security. The annotation and registry of reserves is the exclusive authority of the State.

Article 358

The rights to the use and exploitation of natural resources shall be subject to the Constitution and the law. These rights shall be subject to periodic review for compliance with the technical, economic and environmental regulations. The violation of the law shall lead to the reversion or nullification of the rights of use and exploitation.

CHAPTER III. Hydrocarbons

Article 359

- Ownership of natural resources

I. The hydrocarbons, in whatever state they are found or form in which they are, are the inalienable and unlimited property of the Bolivian people. The State, on behalf of and in representation of the Bolivian people, is owner of the entire hydrocarbon production of the country and is the only one authorized to sell them. The totality of the income received by the sale of hydrocarbons shall be the property of the State.
II. No contract, agreement or convention, whether direct or indirect, tacit or express, may violate totally or partially that which is established in this article. In the event of violation, the contracts shall be null and void as a matter of law, and those who have agreed to, signed, approved or executed them, have committed the crime of treason.

Article 360

The state shall define the policy for hydrocarbons, shall promote their comprehensive, sustainable and equitable development, and shall guarantee energy sovereignty.

Article 361

I. Yacimientos Petroliferos Fiscales Bolivianos (YPFB) is a self-sufficient enterprise of pubic law, which cannot be subject to attachment, with autonomy of administrative, technical and economic management, within the framework of the state hydrocarbon policy. YPFB, under the legal protection of the Ministry of the branch and as the operative arm of the State, is the only one authorized to carry out activities in the productive chain of hydrocarbons and their sale.
II. YPFB may not transfer its rights or obligations in any form or modality, whether tacit or express, direct or indirectly.

Article 362

I. The YPFB is authorized to sign contracts for services with public, mixed or private enterprises, Bolivian or foreign, so that said enterprises, in their name and representation, carry out determined activities in the productive chain in exchange for compensation or payment for their services. In no case may the signing of these contracts signify losses for YPFB or the State.
II. The contracts referring to activities of exploration and exploitation of hydrocarbons must have prior authorization and express approval of the Pluri-National Legislative Assembly. In the event this authorization is not obtained, they shall be null and void as a matter of law, without the necessity of a judicial or extra-judicial declaration.

Article 363

I. The Bolivian Enterprise of Hydrocarbon Industrialization (EBIH) is a self sufficient, public law enterprise, with autonomy in its administrative, technical and economic management, under the legal protection of the Ministry of the branch and the YPFB, which acts in the area of state hydrocarbon policy. EBIH, in representation of the State and within its territory, shall be responsible for carrying out the industrialization of the hydrocarbons.
II. YPFB may form associations or mixed economic enterprises for the execution of the activities of exploration, exploitation, refining, industrialization, transport and sale of hydrocarbons. In these associations and companies, YPBF must have a shareholder participation of no less than fifty one percent of the total capital of the company.

Article 364

YPFB, on behalf and in representation of the Bolivian State, shall operate and exercise property rights in the territories of other states.

Article 365

A self-sufficient institution of public law, with autonomy in its administrative, technical and economic management, under the legal protection of the Ministry of the branch, it shall be responsible for the regulations, control, supervision and fiscal control of the activities of the entire productive chain up to industrialization, within the framework of the state hydrocarbon policy, in accordance with the law.

Article 366

Every foreign enterprise that carries out activities in the chain of production of hydrocarbons in name and representation of the State shall submit to the sovereignty of the State, and to the laws and authority of the State. No foreign court case or foreign jurisdiction shall be recognized, and they may not invoke any exceptional situation for international arbitration, nor appeal to diplomatic claims.

Article 367

The exploitation, consumption and sale of hydrocarbons and its derivatives must be subjected to a policy of development that guarantees internal consumption. The exportation of the excess production shall incorporate the greatest quantity of value added possible.

Article 368

The departments that are producers of hydrocarbons shall receive a royalty of eleven percent of their audited departmental production of hydrocarbons. Similarly, the non producer departments of hydrocarbons and the General Treasury of the State shall obtain a participation in the percentages, which shall be fixed by a special law.

- Ownership of natural resources

CHAPTER IV. Mining and Metalurgy

Article 369

I. The State shall be responsible for the mineralogical riches that are found in the soil and subsoil, whatever may be their origin, and their application shall be regulated by law. The private mining industry and cooperative companies shall be recognized as productive actors of the state mining industry.
II. The non metallic natural resources existing in the salts, brines, evaporations, sulfurs and others substances are of strategic character for the country.
III. The direction of the mining and metallurgy policy is the responsibility of the State, as well as the stimulation, promotion and control of mining activity.
IV. The State shall exercise control of and audit the entire productive chain of mining and of the activities developed by the owners of mining rights, mining contracts or pre-existing rights.

Article 370

I. The State shall grant mining rights in the entire chain of production, and it shall sign mining contracts with individual and collective persons upon prior compliance with the norms established in the law.
II. The State shall promote and strengthen cooperative mines so that they contribute to the social economic development of the country.
III. The mining rights in the entire chain of production as well as mining contracts must fulfill a social economic function, carried out directly by their owners.
IV. Mining rights, which include investments and prospecting, exploration, exploitation, concentration, industrialization or sale of minerals and metals, are controlled by the owners. The law shall define the extent of this right.
V. The mining contract shall obligate the beneficiaries to develop mining activities to satisfy the social economic interest. The failure to fulfill this obligation shall lead to the immediate dissolution of the contract.
VI. The State, through self-sufficient entities, shall promote and develop policies for the administration, prospecting, exploration, exploitation, industrialization,

VI. commercialization, and for technical, geological and scientific information and evaluation of non-renewable natural resources for mining development.

Article 371

I. The areas of mining exploitation granted by contract are not transferable, not attachable, and cannot pass by hereditary succession.
II. The legal domicile of the mining enterprises shall be established in the local jurisdiction where the greatest amount of mining exploitation is carried out.

Article 372

I. The nationalized mining groups, their industrial plants and their foundries are the property of the people, which cannot be transferred or adjudicated as property of private enterprises pursuant to any title.
II. The high level direction and administration of the mining industry shall be entrusted to a self sufficient entity with the attributes that are determined by the law.
III. The State shall participate in the industrialization and sale of mineralogical, metallic and non metallic resources, as regulated by law.
IV. The new self-sufficient enterprises created by the State shall establish their legal domicile in the departments of greatest mining production, Potosi and Oruro.

CHAPTER V. Water Resources

Article 373

- Right to water
- Ownership of natural resources

I. Water constitutes a fundamental right for life, within the framework of the sovereignty of the people. The State shall promote the use and access to water on the basis of principles of solidarity, complementariness, reciprocity, equity, diversity and sustainability.
II. Water resources in all their states, surface and subterraneous, constitute finite, vulnerable, strategic resources, and serve a social, cultural and environmental function. These resource cannot be the object of private appropriation and they, as well as water services, shall not be given as concessions and are subject to a system of licensing, registration and authorization pursuant to the law.

Article 374

I. The State shall protect and guarantee the priority use of water for life. It is the duty of the State to manage, regulate, protect and plan the adequate and sustainable use of water resources, with social participation, guaranteeing access to water for all the habitants. The law shall establish the conditions and limitations of all the uses.
II. The State shall recognize, respect and protect the uses and customs of the community, of its local authorities and the rural native indigenous organizations over the right, management and administration of sustainable water.
III. The fossil, glacial, wetland, subterraneous, mineral, medicinal and other waters are priorities for the State, which must guarantee its conservation, protection, preservation, restoration, sustainable use and complete management; they are inalienable, not attachable and cannot be limited.

Article 375

I. It is the duty of the State to develop plans for the use, conservation, management and sustainable exploitation of the river basins.
II. The State shall regulate the management and sustainable administration of the water resources and the basins for irrigation, food security and basic services, respecting the uses and customs of the communities.
III. It is the duty of the State to carry out the studies for the identification of fossil waters and their consequent protection, management and sustainable administration.

Article 376

Water resources of the rivers, lakes and lagoons that form the water basins are considered strategic resources for the development and sovereignty of Bolivia because of their potential, for the variety of natural resources that they contain, and because they are a fundamental part of the ecosystems. The State shall avoid actions in the sources and intermediary zones of rivers that may cause damages to the ecosystems or diminish the flow volume, shall preserve the natural state, and shall watch over the development and welfare of the population.

Article 377

- International law

I. Every international treaty on water resources that the State signs shall guarantee the sovereignty of the country and shall prioritize the interest of the State.
II. The State shall safeguard permanently the border and trans border waters for the conservation of the water riches that contribute to the integration of peoples.

CHAPTER VI. Energy

Article 378

- Protection of environment

I. The different forms of energy and their sources constitute a strategic resource; access to them is a fundamental and essential right for full development and the social development of the country; and they shall be governed by the principles of efficiency, continuity, adaptability, and environmental preservation.
II. It is the exclusive authority of the State to develop the chain of energy production in the phases of generation, transport, and distribution, by means of public, mixed enterprises, non profit institutions, cooperatives, private enterprises, and community and social enterprises, with public participation and control. The chain of energy production may not be held exclusively by private interests, nor may it be licensed. Private participation shall be regulated by law.

Article 379

I. The State shall develop and promote research, as well as the use of new forms of the production of alternative energy, compatible with the conservation of the environment.
II. The State shall guarantee the generation of energy for internal consumption; the export of excess energy must anticipate the reserves necessary for the country.

CHAPTER VII. Biodiversity, Coca, Protected Areas and Forest Resources

Section I. Biodiversity

Article 380

I. The renewable natural resources shall be exploited in a sustainable way, respecting the characteristics and natural value of each ecosystem.
II. In order to guarantee ecological equilibrium, the land must be used in accordance with its capacity for greater use within the framework of the process of the organization of use and occupation of lands, taking into account their biophysical, socioeconomic, cultural characteristics, and institutional policies.

Article 381

- Provisions for intellectual property

I. Native animal and vegetable species are natural assets. The State shall establish the measures necessary for their conservation, exploitation and development.
II. The State shall protect all genetic and micro-organic resources, which are found in the ecosystems of the territory, as well as the knowledge associated with their use and exploitation. For their protection, a system of registry that safeguards

II. their existence shall be established, as well as a registry of the intellectual property in the name of the State or the local individuals who claim it. The State shall establish procedures for protection under the law of all those resources that are not registered.

Article 382

The State has the authority and duty to defend, recover, protect and repatriate biological material derived from natural resources, from ancestral knowledge and other sources that originate within the territory.

Article 383

The State shall establish measures for the partial or total, temporary or permanent, restriction of the uses of extracts from the resources of biodiversity. The measures shall be directed toward the need to preserve, conserve, recover and restore the biodiversity at risk of extinction. Illegal possession, handling and trafficking of species of biodiversity shall be criminally punished.

Section II. Coca

Article 384

The State protects the native and ancestral coca as cultural patrimony, as a renewable natural resource of the biodiversity of Bolivia, and as a factor of social unity. In its natural state coca is not a narcotic. The revaluation, production, sale and industrialization of coca shall be governed by law.

Section III. Protected Areas

Article 385

I. The protected areas constitute a common good, and they form part of the natural and cultural patrimony of the country. They perform environmental, cultural, social and economic functions for sustainable development.
II. Wherever rural native indigenous protected areas and territories are recovered, shared management shall be undertaken, subject to the norms and procedures of the rural native indigenous nations and peoples, and respecting the goal of creating these areas.

Section IV. Forest Resources

Article 386

The natural forests and woodlands are strategic for the development of the Bolivian people. The State shall recognize the rights to exploit the forests for the benefit of communities and individual traders. In addition, it shall promote activities of conservation and sustainable exploitation, the generation of added value to its products, and the rehabilitation and reforestation of degraded areas.

Article 387

I. The State shall guarantee the conservation of natural forests in the areas of native forests, their sustainable exploitation, and the conservation and recovery of the flora, fauna, and degraded areas.
II. The law shall regulate the protection and exploitation of the species of trees that have socioeconomic, social and ecological importance.

- Right to culture

Article 388

The rural native indigenous communities located within forest areas shall have the exclusive right to their exploitation and their management, in accordance with the law.

Article 389

I. The conversion of tree-covered land to agricultural and other uses, shall only be carried out in areas legally allocated for that use, in accordance with the planning policies and in accordance with the law.
II. The law shall determine the ecological rights of way and zoning for internal uses in order to guarantee the long term conservation of the land and bodies of water.
III. Every conversion of land in areas not classified for such purposes shall constitute a punishable infraction and shall give rise to the obligation to repair the damages caused.

CHAPTER VIII. Amazonia

Article 390

I. Because of its high environmental sensitivity, existing biodiversity, water resources and for the eco-regions, the Bolivian Amazonia basin constitutes a strategic area of special protection for the comprehensive development of the country.
II. The Bolivian Amazonia includes the entire Department of Pando, Iturralde Province of the Department of La Paz and the provinces of Vaca Diez and Ballivan of the Department of Beni. The full development of the Bolivian Amazonia, as a territorial area of tropical rain forests, in accordance with the specific characteristics of the extract and harvesting resources, shall be governed by a special law in benefit of the region and the country.

Article 391

- Protection of environment

I. The State shall prioritize the sustainable, integral development of the Bolivian Amazonia, through a comprehensive, participatory, shared and equitable administration of the Amazon jungle. The administration shall be directed to the generation of employment and the improvement of the income of its inhabitants, within the framework of protection and sustainability of the environment.
II. The State shall encourage access to financing for tourism, eco-tourism and other initiatives of regional enterprise.
III. The State, in coordination with the rural native indigenous authorities and the inhabitants of the Amazonia, shall create a special, decentralized organ, with headquarters in the Amazonia, to promote its own activities in the region.

Article 392

- Right to culture

I. The State shall implement special policies to benefit the rural native indigenous nations and peoples of the region in order to generate the necessary conditions for the reactivation, encouragement, industrialization, commercialization, protection and conservation of traditional extract products.
II. The historical cultural and economic value of the siringa and the castano, symbols of the Bolivian Amazonia, is recognized, and cutting them down shall be punished, except in cases of public interest as regulated by the law.

CHAPTER IX. Land and Territory

- Ownership of natural resources

Article 393

The State recognizes, protects and guarantees individual and communitarian or collective property of land, as long as it fulfills a social purpose or social economic purposes, as the case may be.

Article 394

I. Individual agrarian property is classified as small, medium and business, according to the surface area, the production, and the development criteria. Its maximum and minimum dimensions, characteristics and forms of conversion shall

I. be regulated by law. Legally acquired rights by individual owners, whose piece of land is inside rural native indigenous territories, are guaranteed.
II. The small property is indivisible; it constitutes a family asset that cannot be attached, and it is not subject to agrarian property taxes. The indivisibility does not affect the right of hereditary succession under conditions established by law.
III. The State recognizes, protects and guarantees communitarian or collective property, which includes rural native indigenous territory, native, intercultural communities and rural communities. Collective property is indivisible, may not be subject to prescription or attachment, is inalienable and irreversible, and it is not subject to agrarian property taxes. Communities can be owners, recognizing the complementary character of collective and individual rights, respecting the territorial unity in common.

Article 395

- Right to culture
- Provisions for wealth redistribution

I. The lands that are taken over shall be given to rural native indigenous peoples, intercultural indigenous communities, Afro-Bolivian and rural communities, which do not possess them or have insufficient lands, in accordance with state policy concerned with the ecological and geographic realities, as well as the population, social, cultural and economic necessities. The endowment shall be carried out according to the policies of sustainable rural development and the right of women to access, distribution and redistribution of land, without discrimination based on civil status or marital union.
II. Double endowment, the purchase and sale, and exchange and donation of lands delivered by endowment are prohibited.
III. Since it is contrary to the collective interest, the obtaining of income generated by the speculative use of the land is prohibited.

Article 396

I. The State shall regulate the land market, preventing the accumulation of surface areas greater than that recognized by law, as well as its division into surfaces areas less than that established for small property.
II. Foreigners may not acquire lands of the State under any title whatsoever.

- Restrictions on rights of groups

Article 397

I. Work is the fundamental means by which agrarian property is acquired and maintained. Properties must be used to serve a social purpose or a social economic purpose in order to safeguard the right to them, depending on the nature of the property.
II. Social purpose shall be understood to mean the sustainable exploitation of the land by peoples and rural native indigenous communities, as well as that carried out in small properties, and it constitutes the source of subsistence and welfare and socio-cultural development of its owners. The norms of the communities are recognized in the fulfillment of social purpose.
III. The social economic purpose must be understood as the sustainable use of the land in the development of productive activities, in accordance with its capacity for extended use, for the benefit of the society, the collective interest and its owner. The corporate property is subject to review in accordance with the statute, to verify the compliance with the social economic purpose.

- Mentions of social class

Article 398

Latifundio and double title are prohibited because they are contrary to the collective interest and development of the country. Latifundio is understood to mean the non-productive holding of land; the land that does not fulfill a social economic function; the exploitation of land that applies a system of servitude, quasi-slavery and slavery in labor relations; or the property that surpasses the maximum surface area established in the law. In no case may the maximum surface exceed five thousand hectares.

- Protection from expropriation

Article 399

I. The new limits of zoned agrarian property shall be applied to pieces of land that have been acquired after this Constitution enters into force. For purposes of the non retroactivity of the law, the rights of possession and agrarian property are recognized and respected in accordance with the law.
II. The surface areas exceeding those that fulfill the Social Economic Function shall be expropriated. The double title set forth in the prior article refers to the double endowments processed before the ex-National Council of Agrarian Reform, CNRA. The prohibition of double endowment is not applied to legally acquired rights of third parties.

Article 400

Because it affects sustainable exploitation and is contrary to the collective interest, the division of land into areas less than the maximum area of small property as recognized in the law is prohibited. The maximum area for small property established by law shall take into account the characteristics of the geographic zone.

- Protection from expropriation

Article 401

I. The failure to fulfill the social economic function or the holding of latifundio shall result in the reversion of the land, and the land shall pass into the domain and property of the Bolivian people.
II. The expropriation of land shall occur for reasons of necessity and public utility and upon prior payment of fair indemnification.

Article 402

The State has the obligation to:

- Protection of environment

1. Encourage plans for human settlement to achieve rational demographic distribution and better exploitation of the land and natural resources, granting to new settlements the facilities to have access to education, health, food security and production, within the framework of the Territorial Organization of the State and the conservation of the environment.

2. To promote policies aimed at eliminating all forms of discrimination against women in the access to, ownership and inheritance of land.

- Right to culture

Article 403

I. The integrity of rural native indigenous territory is recognized, which includes the right to land, to the use and exclusive exploitation of the renewable natural resources under conditions determined by law, to prior and informed consultation, to participation in the benefits of the exploitation of the non-renewable natural resources that are found in their territory, to the authority to apply their own norms, administered by their structures of representation, and to define their development pursuant to their own cultural criteria and principles of harmonious coexistence with nature. The rural native indigenous territories may be composed of communities.
II. The rural native indigenous territory includes areas of production, areas of exploitation and conservation of natural resources, and spaces for social, spiritual and cultural reproduction. The law shall establish the procedure for recognition of these rights.

Article 404

The Bolivian Agrarian Reform Service (Servicio Boliviano de Reforma Agraria), the maximum authority of which is the President of the State, is the entity responsible for planning, executing and consolidating the agrarian reform process, and it has jurisdiction in the entire territory of the country.

TITLE III. COMPREHENSIVE SUSTAINABLE RURAL DEVELOPMENT

Article 405

Comprehensive, sustainable rural development is a fundamental part of the economic policies of the State, which shall prioritize its actions to encourage all communitarian economic undertakings and those of the group of rural actors, placing emphasis on food security and sovereignty, by means of the following:

1. The sustained and sustainable increase of agricultural, livestock, manufacturing, agro-industrial, and tourist industry productivity, as well as their commercial capacity.

2. The articulation and internal complementary form of the structures of agricultural, livestock and agro-industrial production.

3. Achievement of better conditions for economic exchange of the rural productive sector in relations to the rest of the Bolivian economy.

4. The importance and respect of the rural native indigenous communities in all dimensions of their life.

5. The strengthening of the economy of the small agricultural and livestock producers and of the family and communitarian economy.

Article 406

I. The State shall guarantee the sustainable comprehensive rural development by means of policies, plans, programs and comprehensive projects that encourage agricultural, artisan, and forestry production, and tourism, with the goal of obtaining better exploitation, transformation, industrialization and commercialization of renewable natural resources.
II. The State shall promote and strengthen the rural economic productive organizations, among which are the artisans, the cooperatives, the associations of agricultural producers and manufacturers, and the micro, small and medium communitarian agricultural enterprises, which contribute to the social economic development of the country, in accord with their cultural and productive identity.

Article 407

The objectives of the policy of the State for comprehensive rural development, in coordination with the autonomous and decentralized territorial entities, are the following:

1. To guarantee food security and sovereignty, prioritizing the production and consumption of agricultural foods produced in the territory of Bolivia.

2. To establish mechanisms for the protection of Bolivian agricultural production.

3. To promote the production and sale of ecological agricultural products.

4. To protect agricultural and agro-industrial production from natural disasters and inclement climate, and geological catastrophes. The law shall provide for the creation of agricultural insurance.

5. To implement and develop technical, productive, and ecological education, at all levels and in all modalities.

6. To establish policies and sustainable projects, obtaining the conservation and recuperation of the soil.

7. To promote irrigation systems for the purpose of guaranteeing agricultural and livestock production.

8. To guarantee technical assistance and to establish mechanisms of innovation and transfer of technology in the entire agricultural productive chain.
9. To establish the creation of a seed bank and centers of genetic research.
10. To establish policies to encourage and support the productive agricultural sectors that have natural structural weaknesses.
11. To control the exit and entrance into the country of biological and genetic resources.
12. To establish policies and programs to guarantee agricultural sanitation and food safety.
13. To provide productive, manufacturing and industrial infrastructure and basic services for the agricultural sector.

Article 408

The State shall determine the incentives for the benefit of small and medium producers for the purpose of compensating for the disadvantages of unequal exchange between agricultural and livestock products and the rest of the economy.

Article 409

The production, importation and commercialization of genetically altered products shall be regulated by law.

PART V. NORMATIVE HIERARCHY AND CONSTITUTIONAL REFORM

SOLE TITLE. SUPREMACY AND REFORM OF THE CONSTITUTION

Article 410

- Legal status of treaties
- National vs subnational laws
- International law

I. Every person, natural and legal, as well as public organs, public functions and institutions, are subject to the present Constitution.
II. The Constitution is the supreme norm of Bolivian law and enjoys supremacy before any other normative disposition. The components of constitutional law include the international Treaties and Conventions in the matter of human rights and the norms of Communitarian Law, which have been ratified by the country. The application of the legal norms shall be governed by the following hierarchy, in accordance with the authority of the territorial entities:
    1. Constitution of the State
    2. International treaties
    3. National laws, statutes of the autonomies, organic charters and the other departmental, municipal and indigenous legislation.
    4. Decrees, regulations and other resolutions issued by the corresponding executive organs.

- Joint meetings of legislative chambers
- Referenda
- Constitution amendment procedure

Article 411

I. The total reform of the Constitution, or that which affects its fundamental premises, affects rights, duties and guarantees, or the supremacy and reform of the Constitution, shall take place through an original plenipotentiary Constituent Assembly, put into motion by popular will through referendum. The convocation of the referendum shall be carried out by citizen initiative, with the signatures of

I. at least twenty percent of the electorate; by absolute majority vote of the members of the Pluri-National Legislative Assembly; or by the President of the State. The Constituent Assembly (Asamblea Constituyente) shall draft its own regulations for all effects. The constitutional text must be approved by two-thirds of the members present. The validity of the reform shall require approval by constitutional referendum.
II. The partial reform of the Constitution may be initiated by popular initiative with the signatures of at least twenty percent of the electorate, or by the Pluri-National Legislative Assembly through a law of constitutional reform approved by two-thirds of the total members present of the Pluri-National Legislative Assembly. Any partial reform shall require approval by constitutional referendum.

TRANSITORY PROVISIONS

First

I. Within a term of 60 days from the promulgation of the present Constitution, the Congress of the Republic shall approve a new electoral regimen for the election of the Pluri-National Legislative Assembly, the President, and the Vice President of the Republic. The election shall take place on December 6, 2009.
II. The mandates prior to the time this Constitution enters into force shall be taken into account for purposes of computing the new terms of office.
III. The elections of departmental and municipal authorities shall take place on April 4, 2010.
IV. As an exception, the mandates of the Mayors, Municipal Councils and the Prefects of Departments shall be extended until the taking of office by the newly elected authorities pursuant to the previous paragraph.

Second

The Pluri-National Legislative Assembly shall approve, within the maximum term of one hundred and eighty days from the time of its installation, the law of the Pluri-National Electoral Organ, the law of the Judicial Organ, the law of the Pluri-National Constitutional Court, and the Law of the Framework of Autonomy and Decentralization.

Third

I. The departments that opted for departmental autonomy in the referendum of July 2, 2006, shall directly adopt the system of departmental autonomy, pursuant to the Constitution.
II. The departments that opted for departmental autonomy in the referendum of July 2, 2006, must adjust their statutes to this Constitution and subject themselves to constitutional control

Fourth

The election of the authorities of the organs included in the second disposition shall be carried our pursuant to the electoral calendar established by the Pluri-National Electoral Organ.

Fifth

The laws necessary for the development of the constitutional dispositions shall be approved during the first mandate of the Pluri-national Legislative Assembly.

Sixth

In the maximum time of one year after the law of the Judicial Organ enters into force, and pursuant to it, the judicial posts shall be reviewed.

Seventh

For purposes of application of paragraph I of article 293 of this Constitution, indigenous territory shall have as the basis of its demarcation the Communitarian Lands of Origin. Within the term of one year from the election of the Executive and Legislative Organ, the category of Communitarian Land of Origin shall be subject to administrative process to convert it to Rural Native Indigenous Territory, within the framework established in this Constitution.

Eighth

I. In the period of one year from the election of the Executive Organ and the Legislative Organ, the concessions on natural resources, electricity, telecommunications and basic services shall be adjusted to the new juridical system. In no case shall the transfer of the concessions to the new juridical system signify the failure to recognize the rights acquired.
II. In the same period, the mining concessions of metallic and non-metallic minerals, crystals, salts, sulfur and others, granted in the fiscal reserves of Bolivian territory, shall cease to be in effect.
III. The mining concessions granted to national and foreign enterprises prior to the promulgation of this Constitution, must be adjusted to it within a period of a year by means of mining contracts.
IV. The State recognizes and respects the pre-existing rights of the cooperative mining companies for their social productive character.
V. The concessions over radioactive minerals granted prior to the promulgation of the Constitution are dissolved and shall revert to the State.

Ninth

The international treaties existing prior to the Constitution, which do not contradict it, shall be maintained in the internal legal order with the rank of law. Within the period of four years after the election of the new Executive Organ, the Executive shall renounce and, in that case, renegotiate the international treaties that may be contrary to the Constitution.

Tenth

The requisite of speaking at least two of the official languages for the performance of public functions, as determined in Article 235.7, shall be applied progressively in accordance with the law.

ABROGATING PROVISION

Abrogating provision. The Constitution of the State of 1967 and its subsequent reforms are abrogated.

FINAL PROVISION

This Constitution, approved by referendum by the Bolivian people shall enter into force on the day of its publication in the Official Gazette.

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RESOLUTION -RDC No. 9, 20 FEBRUARY 2015

DOU 03/03/2015

Regarding Regulation for realization of clinical trials of medication in Brazil.

The Board of the National Health Surveillance Agency, using the powers that are conferred on it in sections III and IV of art. 15 of Law No. 9,782, of January 26, 1999, item II and paragraphs 1 and 3 of art. 54 of the Bylaws approved under Annex I of Ordinance No. 354 of ANVISA, of August 11, 2006, and its updates, in view of the provisions of sections III, Art. 2, III and IV of art. 7 of Law No. 9782, 1999 in art. 35 of Decree no. 3.029 of 16 April 2009, and the Agency Process Improvement Regulations, established by Decree 422 of 16 April 2008, at a meeting held on 5 February 2015 adopts the following Resolution of the Board and I, Substitute President-Director, determine its publication:

Chapter I
INITIAL PROVISIONS
Section 1
Objective

Art. 1 This Resolution's objective is to define the procedures and requirements for conducting clinical trials for medications, including submission of the Drug Clinical Development Dossier (DDCM) to be approved by ANVISA.

Section II
Scope

Art. 2 This Resolution applies to all clinical trials with drugs that have all or part of their clinical development in Brazil in order to secure registration.

Sole paragraph. Clinical trials for medications registered in Brazil must follow all provisions of this Resolution when providing support for:

I- new therapeutic indication;

II- new method of administration;

III- new concentration;

IV- new pharmaceutical form;

V- expansion of use;

VI new dosage;

VII - new associations; or

VIII any post-registration change that requires clinical data, including renewal of registration.

Art. 3. Post-commercialization clinical trials (Phase IV) are not the primary object of this standard, subject only to Notification of Clinical Trial, being initiated only after obtaining ethical approvals, according to current legislation.

I- clinical trials phase is exempt from the provisions in the caput

IV involving vaccines and trials that aim to evaluate efficacy and safety to obtain registration or renewal, which are considered as phase 3 clinical trials;

II For Phase 4 clinical trials for a product that already has a Drug Clinical Development Dossier (DDCM) approved in ANVISA, the notification of petition must be linked to the DDCM;

III Phase 4 clinical trials and observational phase that are not part of a previously approved DDCM and involve import or export procedures, will be subject to Notification of Clinical Trial and issuing of a Specific Special Bulletin (SSB) within thirty (30) calendar days of receipt from the date of notification by ANVISA,

IV the Clinical Trial Notification must include the following documents:

a)duly filled out form for clinical trial presentation, available on the website of ANVISA;

b) proof of payment or exemption of the Health Surveillance fees as provided by the Tax Liability Form (GRU);

c) clinical trial protocol in accordance with GCP;

d) registration confirmation of the clinical trial in the database of the International Clinical Trials Registration Platform/World Health Organization (ICTRP/WHO) or others recognized by the International Committee of Medical Journal Editors (ICMJE); and

e) Consubstantiative opinion of the Ethics in Research Committee (ERC) issued for the first clinical trial center and forwarding the protocol for review by the ERC.

Art. 4 This Resolution shall not apply to studies of bioequivalence and relative bioavailability for clinical trials with cosmetics, with health products, with food, with gene therapy and stem cells, which must comply with specific regulations.

Art. 5 ANVISA may issue guidelines on the applicability of this resolution for cases not provided for clinical drug trials.

Section III

Definitions

Art. 6 For purposes of this Resolution the following definitions are adopted:

I- Audit - systematic and independent review of activities and documents relating to the study to determine whether the evaluated activities were performed and data registered, analyzed and reported accurately to comply with the protocol and standard operational procedures defined by the sponsor, Good Clinical Practices (GCP) and the applicable regulatory requirements;

II- Good Clinical Practice (GCP) - Standard for planning, conducting, performing, monitoring, auditing, recording, analysis and reporting of clinical trials that provides the assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of clinical trial participants are protected, according to

GCP guidelines established in the Document of the Americas and Manual of Good Clinical Practices of the International Conference on Harmonization (Document E6);

III-Good Manufacturing Practices (GMP) - part of the Quality Guarantee which ensures that products are consistently produced and controlled with appropriate quality standards for desired use and required by the record;

IV-Good Laboratory Practice (GLP) – quality system that covers the organizational process and the conditions in which clinical studies related to health and safety of the environment are planned, developed, monitored, recorded, archived and reported;

V- Investigator's Brochure - compiled clinical and non-clinical data on the product(s) found that have relevance the study in human beings;

VI- Center for Clinical Trials – private or public organization, legally constituted, duly registered in the National Register of Health Facilities (CNES) in which clinical trials are conducted;

VII- Ethics in Research Committee (ERC) - interdisciplinary and independent body, of public relevance, consultative, deliberative, and educational, created to defend the interests of research participants regarding integrity and dignity and to contribute to the development of research in ethical standards;

VIII- Independent Committee of Security- independent monitoring committee, constituted to monitor specific safety data collected by one or more clinical trials in defined intervals. Recommends to the sponsor if the study should be continued, modified or discontinued;

IX -Special Bulletin (SB) - document of authoritative character issued by ANVISA, upon review and approval of DDCM and can be used in requests for import or export of clinical trial;

X- Specific Special Bulletin (SSB) - document issued by ANVISA, necessary for request of import or export of a clinical trial subject to the notification system for a clinical trial subject described in Chapter X (From Transitory Dispositions) of this norm;

XI –Cargo Knowledge - document issued on unloading date of product or product, by carrier or consolidator, consisting of international transport contract and proof of viability of good or product for import;

XII - Clinical Trial Start Date - corresponds to the inclusion dated the first clinical trial participant abroad;

XIII - Clinical Trial Start Date in Brazil – corresponds to date of inclusion of the first clinical trial participant in Brazil;

XIV –Clinical Trial End Date - corresponds to appearance of the last clinical trial participant in a location abroad or another definition of sponsor explicitly provided by the specific protocol of the clinical trial;

XV Clinical Trial End Date in Brazil – corresponds to date of the last visit of the last clinical trial participant in Brazil or another definition of sponsor explicitly provided in the specific protocol of the clinical trial;

XVI Clinical Trial Protocol Violation - any non-compliance with procedures or requirements defined in the approved clinical trial version without major implications for testing integrity, data quality, rights of safety of trial participants;

XVII- Document of delegation of responsibility for importation-document issued by the sponsor of the research, which includes the appointment of the authorized importer and the responsibilities relating to the transport and clearance of imported merchandise;

XVIII Document for Importation of Product(s) under investigation by the Drug Clinical Development Dossier (DDCM): Document issued by ANVISA, with the goal of evaluating inherent steps in the development of an experimental medication for import or export to a clinical trial, necessary in cases of non-manifestation of the DDCM;

XIX Drug Clinical Development Dossier(DDCM) - compiled documents to be submitted to ANVISA for the purpose of evaluating the steps involved in the development of a experimental drug in order to obtain information to support registration or post-registration changes of the product;

XX- Specific Dossier for each Clinical Trial – compilation of documents to be submitted to ANVISA for the purpose of obtaining information relating to clinical trials, to be conducted in Brazil, which are part of the Experimental Medication Development Plan;

XXI Amendment to the clinical trial protocol – any modification proposal in an original clinical trial protocol, always presented with the rationale that motivate it; such modification may be substantial or not;

XII Clinical trial - research conducted on human beings in order to discover or verify the clinical effects and/or pharmacological effects and/or other pharmaodynamic effect of experimental medication and/or identify any adverse reaction to experimental medication and/or to study absorption, distribution, metabolism and excretion of the experimental drug to verify its safety and/or efficacy;

XXIII Adverse Event (AE) - Adverse event (AE): any adverse medical occurrence in a patient or research participant, which does not necessarily have a causal relationship with the treatment. As a result, an AE can be any unfavorable and unintended sign, symptom or disease (including results of laboratory tests outside the range of normality) associated with the use of a medical device under investigation, whether it is related to it or not;

XXIV Grave Adverse Event-one that results in any adverse experience with drugs, biological products or devices, occurring at any dosage which results in any of the following outcomes:

a) death;
b) threat to life;
c) disability/ persistent or significant disability;
d) requirement of hospitalization or prolonged hospitalization;
e) congenital anomaly or birth defect;
f) infecting agent suspected of transmission by medication
g) clinically significant event.

XXV Unexpected Adverse Event - an event not described as an adverse reaction in the brochure of the experimental drug or informational insert.

XXVI- Case Report Form - printed document, optical or electronic designed to record all information about each participant's clinical trial, according to the clinical trial protocol, that should be reported to the sponsor;

XXVII- Inspection – Act on the part of the regulatory authority to conduct an official review of documents, facilities, records and any other resources considered by the authority as relative to the trial and that may located where the trial is conducted, at the sponsor, CRO, or in other site locations that regulatory authority considers appropriate;

XXVIII- Active Pharmaceutical Ingredient (AFI) – any substance introduced in formulating of a pharmaceutical form which, when administered in a patient, acts as active ingredient. Such substances may exert direct pharmacological activity or other effect in the diagnosis, cure, treat or prevent an illness, may also affect the structure and function of the human organism;

XXIX- Researcher - responsible for the conduct of a clinical trial in the place where the trial is conducted. If the study is led by a group of people, the investigator is the leader of the group and will be called the principal investigator;

XXX-Investigator-Sponsor – individual responsible for conducting and coordinating clinical trials, either alone or in a group, under their immediate direction and in an independent manner, developed with the researcher's own financial and material resources, that of national or international entities to encourage research, private entities and other non-profit entities;

XXXI-Experimental Medication – In a pharmaceutical trial, object of the DDCM, to be used in the clinical trial, for the purpose of obtaining information on its registration or post-registration;

XXXII- Monitoring - act of continually reviewing the process of a clinical trial and ensuring that it is conducted, recorded, and reported according to the protocol, standard operating procedures, GCP and the applicable regulatory requirements;

XXXIII- Contract Clinical Research Organization (CRO) -every company regularly installed in national territory hired by the sponsor or by the researcher-sponsor, which partially or wholly assumes the responsibilities of the sponsor of the clinical trial with ANVISA;

XXXIV- Sponsor - individual, company, institution or organization responsible for starting, managing, controlling and/or financing of clinical study;

XXXV- Placebo - formulation without pharmacological effect, administrated to participant in clinical trial for the purpose of acting as a masking and or comparator;

XXXVI- Product under investigation - experimental drug, placebo, active comparator or any other product to be utilized in the clinical trial;

XXXVII- Clinical Trial Protocol - document that describes objectives, design, methodology, statistical considerations and organization of the trial. Also provides context and guidelines for clinical trial.

XXXVIII- Annual report- annual document containing specific information about the conduct of a particular clinical trial in centers in Brazil, according to the clinical protocol and GCP;

XXXIX- Safety Update Report for development of the experimental drug - harmonized periodic report containing information on safety and development of experimental drug;

XL Final Report - document containing specific information about the conduct of a particular clinical trial at all study participants centers, according to the clinical protocol and GCP;

XLI- Active Substance - substance with pharmacological effect for intended therapeutic activity, used in the production of certain biological products;

XLII- Clinical Trial Protocol Deviation – deviation of clinical trial and protocol that can affect the quality of the data, which compromises the integrity of the study or may affect the safety and rights of trial participants;

Chapter II
RESPONSIBILITIES

Art. 7 The major responsibilities in this chapter include those set out in Good Clinical Practice, without prejudice to other legal and ethical accountabilities.

Section I
The Sponsor's Responsibilities

Art. 8. The sponsor is responsible for required information for the correct execution of DDCM throughout the range of researchers and skill centers, thus ensuring that the clinical trial is conducted according to the protocols and BPC.

Art. 9. The sponsor should utilize qualified professionals to supervise the overall conduct of clinical trials, to manage data, conduct statistical analysis and prepare reports.

Art. 10. The sponsor should ensure that quality assurance and quality control are implemented in all areas of the institutions involved in the development of experimental medication.

Art. 11. The sponsor should maintain the clinical trial data on file, physical or digital, for a period of five (5) years after the last approval of a request for registration in Brazil.

Sole paragraph. In case of discontinuation of clinical development or completion of application for registration is not achieved, the sponsor should maintain the clinical trial data in physical or digital file, for at least two (2) years after discontinuation of clinical development or formal conclusion of development.

Art. 12. The sponsor is responsible for all costs related to procedures and trials, especially those related to diagnosis, treatment and hospitalization of the participant of the trial, and other actions necessary for the resolution of adverse events related to the clinical trial.

Art. 13. The sponsor should ensure that the data obtained regarding safety and efficacy of the investigational medical product are sufficient s to support human exposure by proposed means of administration, the chosen dosage, the duration of the proposed treatment and the population being studied.

Art. 14. The sponsor should ensure that the investigational product, modified comparator drug and placebo, when used, are manufactured according to GMP and are coded and labeled to protect blinding, if applicable, and characterized as products under clinical investigation.

Sole paragraph. In studies using active comparators, the sponsor must use those made in accordance with the GMP.

Art. 15. The sponsor is responsible for importing the necessary amount required to run the trial.

Art. 16. The sponsor is responsible for distributing the product(s) under investigation only to institutions reported in the clinical trial submission form contained in the Specific Dossier for each Clinical Trial and authorized by the Ethical Research Committee.

Art. 17. The sponsor is responsible for disposal of medications and products that have not been used in the clinical trial.

Art. 18. The sponsor should ensure the appropriate monitoring and auditing of clinical trials.

Art. 19. The sponsor shall immediately inform those involved in the trial if it is finished prematurely or suspended for any reason.

Art. 20. The sponsor may transfer its functions to a Clinical Research Organization CRO.

Paragraph 1. The transfer of what is contained in the caput does not remove the ultimate responsibility of the sponsor for the quality and integrity of clinical trial data.

Paragraph 2 Any functions related to the clinical trial to be transferred to a CRO and assumed by this must be specified in writing in a document signed by the sponsor and CRO.

Section II

The Investigator Responsibilities

Art. 21. The investigator shall conduct the trial according to the protocol agreed upon by the sponsor, with GCP, with regulatory and current and in force ethical requirements.

Art. 22. The investigator shall personally supervise the clinical trial and may only delegate tasks but not responsibilities.

Art. 23. The investigator should allow for monitoring, audits and inspections.

Art. 24. The investigator must ensure appropriate medical care for trial participants regarding any adverse events related to the clinical trial, including clinically significant laboratory costs, without any onus on the participant.

Art. 25. The investigator should promptly inform the trial participants if the trial is finished prematurely or suspended for any reason, and ensure appropriate therapy and monitoring for participants.

Art. 26. The investigator is responsible for using the investigational product only in the clinical trial and should store them as specified by the sponsor and in accordance with applicable regulatory requirements.

Section III

The Investigator-Sponsor Responsibilities

Art. 27. In the case of a clinical trial developed by sponsor-investigator, the institution with which the individual is linked to is the primary sponsor.

Paragraph 1 The primary sponsor may delegate responsibilities to the researcher, who will be responsible for conducting the clinical testing at the institution, and in this case, the sponsor-investigator will be the secondary sponsor.

Paragraph2 In the case of delegation of responsibilities and activities, a written authorization must be signed by the parties.

Paragraph3 The primary sponsor may not delegate quality assurance activities, audits and monitoring of clinical trials to investigator-sponsor, but can delegate them to a CRO.

Paragraph4 The primary sponsor shall submit its own or outsourced structure with at least the following units:

I - management of adverse events;
II - project management;
III - data management;
IV - training;
V - information technology;
VI - quality assurance and;
VII - monitoring.

Paragraph5 The institution referred to in the caput should be the one at which the trial will be held.

Paragraph 6. The major responsibilities in this article do not exclude the provisions of Sections I and II of this chapter on the sponsor and investigator responsibilities.

Art. 28. In the case of donation of medication already registered in Brazil for clinical testing, the donor will be the sponsor, if there is any agreement for transfer of ownership or ownership of the data obtained in donor research.

Art. 29. In the case of donation of medication not registered in Brazil for clinical testing, the donor shares the responsibilities of the sponsor.

Section IV

Structure of the Clinical Trial Center

Art. 30. The clinical trial center must have adequate facilities to conduct the protocol with regard to the physical structure, equipment, instruments and human resources, and also be consistent with the clinical trial population, for example, the elderly, children, persons with special needs, among others.

Art. 31. The management of the institution must be notified that the trial will be conducted.

Chapter III
Requirements for submission of clinical medication development dossier (DDCM)

Art. 32. The documentation in the DDCM should assure safety and rights of participants in all phases of clinical development, the quality of the investigational medicinal product and the data obtained in the clinical phases of development so that it may allow for evaluation of the efficacy and safety of the drug.

Art. 33. The DDCM may be presented to ANVISA at any stage of clinical development of the drug for one or more phases of clinical trials.

Section I
General Requirements for the Request

Art. 34. The sponsor must submit a DDCM to ANVISA only if it intends to conduct clinical trials of medication in Brazil.

Sole paragraph. For analysis of the DDCM, at least one specific dossier must be filed for a clinical trial to be held in Brazil.

Art. 35. A Special Bulletin (SB) will be emitted through the DDCM mentioning all clinical trials to be conducted in Brazil.

Sole paragraph. Only clinical trials listed in the SB can be initiated in the country, respecting the other ethical approvals.

Art. 36. Upon receipt of the DDCM, ANVISA has ninety (90) days to evaluate.

Paragraph 1. If there is no response from ANIVSA in ninety (90) calendar days after receipt of DDCM by ANVISA, clinical development can be started after the relevant ethical approvals.

Paragraph 2. In cases of non-manifestation, ANVISA will issue a document for Importation of Product(s) under investigation by the DDCM, will be presented at the location of unloading for import or export of product(s) under investigation, needed to conduct the clinical trial.

Paragraph 3 Not applying to the provisions of the caput and in Paragraph1 are clinical development submissions that fall into at least one of the following: national development, clinical development of biological products - including vaccines - and clinical development Phase I or Phase II. For these cases, the technical area will evaluate the DDCM within 180 (one hundred and eighty) days after receipt of DDCM by ANVISA and the clinical trial may be initiated only after approval by ANVISA.

Art. 37. The DDCM can be submitted by the sponsor, sponsor-investigator or CRO.

Paragraph1 The party responsible for submitting the DDCM to ANVISA must be the same for all subsequent submissions related to this.

Paragraph2 Submissions by a CRO can only be made when the sponsor has no headquarters or subsidiary in Brazil.

Paragraph3 The DDCM of a sponsor-investigator should be done through the primary sponsor.

Section II

Content and Request Format

Art. 38. The DDCM submitted to ANVISA must include the following documents:

I - Application form duly completed, according to the model available on the ANVISA website;

II - proof of payment or exemption of payment of the Health Surveillance Inspection Fee by the Tax Liability Payment Form (GRU);

III - Drug Development plan containing a description of the following topics:

a) IFA or active substance;

b) category of medication (synthetic, organic, herbal or radiopharmaceutical);

c) therapeutic class;
d) means of administration;
e) mechanism of action;
f) indications to be studied;
g) general objectives and the planned duration of clinical development; and
h) information about phases, designs, outcomes, comparators, objectives, population to be studied, hypothesis/hypotheses, estimated number of participants and statistical design for each clinical trial planned.

IV - Investigator's brochure containing a description of the following topics:
a) experimental drug;
b) formulation;
c) pharmacological and toxicological effects of the experimental drug in animals and in humans, where applicable;
d) information on safety and efficacy in humans obtained from clinical trials that have already been carried out; and
e) possible risks and adverse events related to experimental medications, based on past experience, as well as precautions or special procedures to be followed during development.

V – a summary of the safety aspects based on previous experience in humans with the experimental drug (for example, expanded access programs and compassionate use) as well as post-marketing experience in other countries, if applicable;

VI- information regarding the discontinuation of development or withdrawal of the experimental drug market of any country, for security reasons or lack of efficacy, if applicable. Those countries with discontinuation of access should be identified, as well as the reasons for interruption/withdrawal of the product;

VII - Experimental Drug dossier containing the following documents:
a) description of the AFI or active substance, including:
1. Physical and chemical characteristics, organoleptic and biological;
2. name and address of the manufacturer;
3. general method of obtaining;
4. validated analytical methodology and acceptable ranges to assure identity, quality and purity; and
5. Results of stability studies.
b) description of the experimental drug, including:
1. list of all active and inactive components with their respective functions, including those not present in the finished product;
2. quantitative composition;
3. General description of the manufacturing process and packaging with information about the capacity of the equipment;
4. the analytical methodology and the acceptable limits as to ensure the identity; and
5. Results of stability studies showing that the use of the investigational product in planned clinical trials.
c) description of the placebo, where applicable, including:
1. composition;
2. organoleptic characteristics;
3. manufacturing process; and
4. analytical controls.
d) description of comparator medicine when it is modified to perform the clinical trial, including information that ensures the maintenance of the original characteristics of the product;
e) documentation referring to the transmissibility of the Transmissible Spongiform Encephalopathies (TSE), in accordance with current health conditions or justifications for the absence of this document;

f) model(s) for label of product(s) under investigation;

g) critical analysis of non-clinical pharmacological and toxicological studies to ensure safety in performance of the proposed clinical development and information about location conducting these studies, as well as where records are available for inspection, including a statement that each study was conducted according to GLP compliance or justification for the absence. Description of the risks known about the experimental drug based on toxicological studies in animal models or in vitro tests, already conducted, or studied therapeutic class; risk/benefit related to the development plan;

h) critical analysis of already realized clinical trials, if applicable, including the basis for efficacy and safety. Description of already known risks about the experimental drug based on clinical trials already carried out or studied therapeutic class, evaluation of risk/benefit related to the development plan;

i) in the case of the experimental drug already on record in Brazil, only the information that supports the post-registration proposed changes must be submitted in the DDCM;

j) in the cases for in which the investigator-sponsor wishes to conduct a clinical trial with a drug that already has a DDCM approved by ANVISA, it may use the information already submitted by the holder of the initial DDCM, if agreed, without the need to resubmit all documentation. When authorization of the original holder is not presented, the investigator-sponsor shall submit to ANVISA all information through updated and indexed literature that supports the rational of the proposed development;

VIII - Specific dossier for each clinical trial to be held in Brazil. These files must be filed as individual processes for each clinical trial. Each process should be linked to DDCM and submitted by the sponsor or CRO. The file should consist of the following documents:

a) clinical trial application form duly completed, available on the website of ANVISA;

b) proof of payment or exemption, the Health Surveillance Inspection Fee by the Tax Liability Payment Form (GRU);

c) clinical trial protocol in accordance with GCP;

d) registration confirmation of the clinical trial in the data base of the International Clinical Trials Registration Platform/World Health Organization (ICTRP/WHO) or other recognized by the International Committee of Medical Journal Editors (ICMJE); and

e) Consubstantiated opinion of the Ethics in Research Committee (ERC) issued for the first clinical trial center to forward the protocol for analysis by the ERC

Art. 39. All documentation that is filed manually, including compliance requirements, must be accompanied by an electronic media copy (pdf file or word).

Paragraph1 Electronic documents should allow for text search.

Paragraph 2. The submission of electronic media applies to the adoption by ANVISA of information technology tools that allow the electronic submission of the requested documents.

Art. 40 Forms with start date and end of the trial in Brazil must be filed as a secondary petition to the corresponding clinical trial dossier process, within thirty (30) calendar days after each start and end date.

Art. 41. ANVISA may at any time request other information it judges necessary for evaluation and monitoring of clinical development.

Chapter IV

MODIFICATIONS TO THE DDCM

Art. 42. Substantial modifications to the DDCM should be filed and shall await manifestation of ANVISA prior to implementation, according to the timetable set out in Art. 36.

Sole paragraph. Modifications to the DDCM must be submitted to ANVISA in the form of secondary petition attached to the DDCM protocol to which it is linked.

Art. 43. For purposes of this Resolution, substantial changes are:

I – inclusion of clinical study protocol(s) not previously established in the initial development plan,

II – exclusion of clinical study protocol(s)

III - alterations that potentially impact quality or safety of the investigational product, active comparator or placebo.

Art. 44. Modifications to the DDCM arising from recommendations or warnings issued by health authorities should be reported before they are implemented and may be executed, regardless of prior approval of ANVISA.

Art. 45. Modifications to DDCM not considered substantial must be submitted to ANVISA as part of the Safety Update Report of the development of the experimental drug.

Chapter V

AMENDMENTS TO THE CLINICAL TRIAL PROTOCOL

Art. 46. All amendments to a clinical trial protocol must be submitted to ANVISA, identifying the part of the protocol to be modified and their justifications.

Sole paragraph. Any amendment should be implemented only after obtaining ethical approval in accordance with current legislation.

Art. 47. Substantial amendments to clinical trial protocols must be filed and must await manifestation of ANVISA prior to implementation, according to the timetable set out in Art. 36.

Paragraph1 Substantial amendments shall be submitted to ANVISA in the form of secondary petition attached to the method of its clinical trial protocol to which it is linked.

Paragraph2 The petition of substantial amendments should contain the new protocol and the Opinion of the Ethics in Research Committee (ERC) issued for the first clinical trial center to forward the protocol for analysis by the ERC.

Paragraph3 Exceptions to the provisions in the caput of the amendments are those designed to eliminate immediate hazards to the safety of trial participants. These can be implemented and reported to ANVISA immediately.

Art. 48. For purposes of this Resolution, an amendment shall be sufficient if at least one of the following criteria is met:

I- change in the clinical trial protocol which affects the safety or physical or mental integrity of the participants;

II- change in the scientific value of the clinical trial protocol.

Art. 49. Amendments to the clinical trial protocol not considered substantial must be submitted to ANVISA as part of the annual report for clinical trial protocol monitoring.

Chapter VI

SUSPENSION AND CANCELLATIONS

Art. 50. The sponsor may cancel or suspend the DDCM or clinical trial at any time, provided that the appropriate technical and scientific justification is sent, as well as a follow-up plan for clinical trial participants.

Paragraph1 After canceling a specific DDCM, no clinical trials related to it can be continued in the country (Brazil).

Paragraph2 If a DDCM or clinical trial is canceled for safety reasons, the sponsor must technically and scientifically justify the reasons for the cancellation and outline measures to minimize/mitigate risk to clinical trial participants.

Paragraph3 The suspensions and clinical trial cancellations or of the DDCM must be submitted to ANVISA in the form of secondary petition attached to the respective file.

Art. 51. The sponsor shall notify the ANVISA regarding the decision to suspend or terminate a clinical trial of DDCM. After decision for suspension or cancellation, the sponsor must notify ANVISA within fifteen (15) calendar days.

Art. 52. In the case of temporary suspension of a clinical trial or DDCM as an immediate safety measure, the sponsor must notify ANVISA within 7 (seven) calendar days from the suspension date, justifying the reasons.

Sole paragraph. The reasons, scope, interruption of treatment, and the suspension of recruitment of participants must be explained clearly in the notification of the temporary suspension.

Art. 53. Requests for reactivation of clinical trials protocols or suspended DDCMs should be sent to ANVISA, accompanied by justifications for trials to be restarted.

Sole paragraph. The clinical trial(s) and DDCM(s) will be restated only after approval by ANVISA.

Art. 54. ANVISA may, at any time, cancel or suspend the DDCM or any related clinical trial if it considers that the approval conditions are not met or if any safety or efficacy reports show significant effects on the trial participants or on the scientific validity of data, informing the sponsor of the reasons.

Chapter VII

SECURITY AND ALERTS MONITORING

Section I

The Adverse Event Monitoring

Art. 55. The sponsor should monitor all adverse events, including non-serious adverse events during the development of the experimental drug.

Art. 56. The sponsor or Independent Safety Monitoring Committee should systematically collect and evaluate aggregated data on adverse events occurring in the clinical trial, submitting the results of this assessment to ANVISA in the security update report in development of the experimental drug.

Art. 57. The sponsor should establish a monitoring plan for the detection of late-occuring adverse events, justifying the proposed period.

Sole paragraph. In the case of pregnancy, the investigator and the sponsor must accompany the mother and the child.

Subsection I

The Immediate Measures

Art. 58. In the event of a serious adverse event occurred during the clinical trial at any stage of drug development, the sponsor and the investigator should take immediate safety measures to protect trial participants against any imminent risk.

Sole paragraph. In case of serious adverse event to be notified, the following must be stated: which measures have been taken, the action plan on new events of the same

nature, location data where treatment was, together with other data requested in the report form, especially those that allow the traceability of the event and the affected participant.

Art. 59. The notification of unexpected grave adverse events, whose causality is possible, probable or definite, independent of the Investigator's Brochure submission, amendments, or early end of the trial.

Art. 60. The development of phase III clinical trial must be monitored by Safety Monitoring Independent Committees and recommendations should be reported to ANVISA by the sponsor.

Sole paragraph. In cases where there is no constitution of Independent Safety Monitoring Committees there must be justification presented.

Subsection II

Communication of Adverse Events by Investigator

Art. 61. The investigator shall report the occurrence of any adverse events to the sponsor and must provide any requested information and must express their opinion regarding the causal link between the adverse event and the product under investigation.

Sole paragraph. Adverse events or abnormalities in laboratory test results that affect the safety of participants must be reported to the sponsor according to GCP and protocol.

Art. 62. All adverse events should be treated and the affected participants monitored by the principal investigator and his/her team until reaching resolution or stabilization.

Subsection III

Adverse Events Reporting by Sponsor

Art. 63. The sponsor shall notify ANVISA, through a specific electronic form, of unexpected serious adverse events occurring in the country, in which causality is possible, probable or defined for the product under investigation.

Sole paragraph. The sponsor shall keep detailed records of adverse events reported by investigators. ANVISA may request such records at any time.

Art. 64. The sponsor should inform the researchers involved in the clinical trial about serious unexpected adverse events, in which causality is possible, probable or definite, and adopt procedures for updating of the investigator's brochure, in addition to re-evaluating the risks and benefits to participants.

Subsection IV

Deadlines

Art. 65. The investigator shall inform the sponsor of serious adverse events within 24 (twenty four) hours of the event being discovered.

Art. 66. The sponsor should ensure that all relevant information on adverse events referred to in Art. 63 that are fatal or life-threatening are documented and reported to ANVISA, through electronic form in no more than seven (7) days starting from the date of knowledge of the case by the sponsor.

Sole paragraph. The additional information on the monitoring of adverse events mentioned in the caput should be included in the application up to eight (8) calendar days from the date of notification.

Art. 67. All other adverse events that are unexpected, serious, whose causality is possible, probable or definite for the products under investigation should be reported to ANVISA within 15 (fifteen) calendar days from the date of knowledge of the case by the sponsor.

Section II

Accompanying Reports

Subsection I

Reports on Monitoring Clinical Trials Protocols

Art. 68. The sponsor should submit to ANVISA annual monitoring reports containing the following information, exclusively from Brazilian centers, in tabulated form, for each clinical trial protocol:

I- title of the clinical trial;

II- protocol code;

III- status of participants recruited for clinical trial;

IV -breakdown of the number of participants recruited by center;

V- number and description of the deviations and protocol violations by center; and

VI description of all adverse events occurring at the center during this period, identifying the trial participants with the codes used in the Case Report Form adopted in the clinical trial protocol.

Paragraph1 The Annual clinical trial protocol monitoring report should be submitted to ANVISA in the form of secondary petition attached to the respective protocol process to which it is linked.

Paragraph 2. The annual report shall be filed within sixty (60) calendar days, from the beginning of the trial date in Brazil.

Art. 69. Upon completion of the activities of a clinical trial in all participating countries, for whatever reason, the sponsor shall submit a final report to ANVISA, containing least the following information:

I- title of the clinical trial;

II protocol code;

III breakdown of the number of participants recruited removed from the clinical trial;

IV description of patients included in each statistical analysis and those who were excluded from the analysis of efficacy;

V- demographic description of participants recruited for clinical trial;

VI-statistical analysis;

VII- number and description of protocol deviations and violations;

VIII relating of all adverse events and laboratory abnormalities with causality assessment, occurring in participants;

IX -the results obtained in the measurement of outcomes for each participant in the clinical trial; and

X-rationale for the early termination of development in Brazil or elsewhere in the world, where applicable.

Paragraph 1. The end of the clinical trial protocol must be submitted to ANVISA in the form of a secondary petition attached to the respective protocol to which it is linked.

Paragraph 2. The final report must be filed within 12 (twelve) months of clinical trial end date.

Subsection II

Security Update Report for development of the investigated product

Art. 70. The sponsor must submit to ANVISA annual safety update reports on the development of the experimental drug.

Sole paragraph. The annual report must be filed within a maximum of sixty (60) calendar days starting from the DDCM approval date by ANVISA or determined date in international development.

Chapter VIII

INSPECTIONS

Section I

Inspections to verify Good Clinical Practice compliance

Art. 71. In order to ensure the protection of the rights, safety and wellbeing of participants in addition to ensuring accuracy and reliability of the data to be obtained or submitted for health registration, ANVISA may carry out GCP inspections in clinical trials centers, sponsors, CRO, laboratories and other institutions involved in the development of the experimental drug to verify level of compliance of current Brazilian legislation and compliance with GCP, and to ensure the rights and duties concerning the scientific community and the State.

Paragraph1 Inspections in GCP will follow the harmonized guidelines in the Document of the Americas, Manual of Good Clinical Practices of the International Conference on Harmonization (Document E6) and specific GCP inspection standards published by ANVISA.

Paragraph2 Depending on the outcome of the GCP review, ANVISA can determine:

I- temporary interruption of the clinical trial;

II- the definitive cancellation of the clinical trial in question;

III- the definitive cancellation of the clinical trial in all centers in Brazil; or

IV invalidation of data from the centers and clinical trials that are not in compliance with GCP.

Section II

Inspections to verify compliance of Good Practice Manufacture of Products under Investigation

Art. 72. ANVISA may carry out inspections in BMP of the experimental drug or product under investigation produced or modified by the sponsor in order to verify the chemical information, production and quality control in DDCM and to report if the drug is safe enough to administer to trial participants.

Chapter IX

IMPORTATION

Art. 73. The importation of the products under investigation for exclusive use in a clinical trial should be subject only to inspection/regulation by the sanitary authority in the location of unloading.

Sole paragraph. Exceptions are investigated products subject to special control that have, in addition to monitoring in the location of unloading, must have prior authorization of shipment by the responsible technical area at ANVISA.

Art. 74. The following documents must be submitted after the arrival of the product under investigation in the country (Brazil):

I - copy of the Special Bulletin (SB), Special Specific Communication (SSB) or Document for Importing of Product (s) under investigation by DDCM issued by the competent technical area of ANVISA in its headquarters;

II - in the case of imports made by a body other than the holder of DDCM, a copy of the document of delegation of responsibilities for importation must be submitted;

III – term of responsibility for imports intended for clinical research provisions in health regulation of goods and imported products;

IV - embedded copy cargo knowledge; and

V – copy of commercial invoice.

Art. 75. The competent health authority for the product under investigation being unloaded will verify compliance with the packaging instructions, transport and storage, according to specific information in the SB, SSB, or Document for Importing Product(s) under the DDCM, subsidiary alternative to those provided by the manufacturer or sponsor.

Sole paragraph. The external or shipping containers used for shipping the products referred to in this Chapter shall include:

a) SB number, SSB number or Document for Importing Product (s) under investigation by the Drug Clinical Development Dossier (DDCM) to which the investigational product is subject;

b) amount of imported material;

c) information on special care for storage, such as temperature, humidity and light;

d) information on physical form or pharmaceutical form referring to the presentation of the product;

e) information on the validity of the product and, where applicable, the medical device; and

f) lot number or serial number.

Art. 76. The qualitative information and specifications of the products under investigation for use in clinical trials will be reported in the Special Bulletin (SB), the Specific Special Bulletin (SSB) and in the Document for Importing Product (s) under investigation in the DDCM.

Sole paragraph. In case of change of purpose of products investigated and its specifications informed the SB, SSB or in the Document for Importing Product(s) under investigation by the Drug Clinical Development Dossier (DDCM), this must be reported to the competent technical area of ANVISA at its headquarters. SB, SSB or Document for Importing Product (s) under investigation in the DDCM date must be presented at clearance site.

Art. 77. The entry of a products into the country for products under investigation that are not in accordance with the SB, SSB or Document for Importing Product (s) under investigation by the DDCM for the purpose of clinical trials regulated by this resolution is strictly prohibited.

Sole paragraph. Any change in purpose of imported goods and products mentioned in this resolution is strictly prohibited.

Chapter X

TRANSITORY PROVISIONS

Art. 78. The approval processes for clinical trials protocolled/filed at ANVISA that predate the publication of this resolution and are still awaiting technical analysis will be assessed in accordance with the resolutions in force at the time of protocol submission.

Paragraph1 Petitions that are awaiting analysis and are within the scope of 90 (ninety) days as provided by Art. 36 of this Resolution, may commence clinical trials after the deadline contained in that referred to article and after the relevant ethical approvals.

Paragraph2 For the cases referred to in Paragraph1, will be issued a SSB will be issued for the purposes of import or export, according to the current resolution at the time of the submission protocol at ANVISA.

Paragraph3 The time frame established by Paragraph 3 of Art. 36 does not apply to consent for those awaiting technical analysis and is found in the caput of this article.

Art. 79. In filing a DDCM, the holder shall link all approval processes for consent in clinical trials related to experimental drug trials they have already been submitted for assessment by ANVISA at some moment.

Art. 80. The approval processes for clinical trials already approved by ANVISA must comply with the current resolution at the time of its approval, so that the process is inserted in a DDCM, if applicable.

Chapter XI

FINAL PROVISIONS

Art. 81 ANVISA publishes guides and manuals to assist in the following specific procedures related to this Resolution.

Art. 82. Failure to comply with the provisions of this Resolution is considered a health violation, with the offender subject to penalty as provided by Law No. 6437 of August 20, 1977.

Art. 83 Omissions will be resolved in consideration of other national and international guideline standards.

Art. 84 The following are hereby repealed Resolution - RDC No. 39, of 5 June 2008 Resolution - RDC No. 36 of June 27, 2012 and items 1 and 1.1. Section I of Chapter XXVI Resolution—RDCN No. 81, of November 5, 2008.

Art. 85. This Resolution shall enter into force on the date of its publication.

JAIME CÉSAR DE MOURA OLIVEIRA

REPUBLICA DE COLOMBIA

MINISTERIO DE SALUD

RESOLUCION NUMERO 8430 DE 1993

(Octubre 4)

Por la cual se establecen las normas científicas, técnicas y administrativas para la investigación en salud.

EL MINISTRO DE SALUD

En ejercicio de sus atribuciones legales en especial las conferidas por el Decreto 2164 DE 1992 y la Ley **10** de 1990

CONSIDERANDO

- Que el artículo **8**o de la Ley 10 de 1990, por la cual se organiza el Sistema Nacional de Salud y se dictan otras disposiciones, determina que corresponde al Ministerio de Salud formular las políticas y dictar todas las normas científico- administrativas, de obligatorio cumplimiento por las entidades que integran el Sistema,

- Que el artículo 2o del Decreto 2164 de 1992, por el cual se reestructura el Ministerio de Salud y se determinan las funciones de sus dependencias, establece que éste formulará las normas científicas y administrativas pertinentes que orienten los recursos y acciones del Sistema,

RESUELVE:

TITULO 1.
DISPOSICIONES GENERALES.

ARTICULO 1. Las disposiciones de estas normas científicas tienen por objeto establecer los requisitos para el desarrollo de la actividad investigativa en salud.

ARTICULO 2. Las instituciones que vayan a realizar investigación en humanos, deberán tener un Comité de Etica en Investigación, encargado de resolver todos los asuntos relacionados con el tema.

ARTICULO 3. Las instituciones, a que se refiere el artículo anterior, en razón a sus reglamentos y políticas internas, elaborarán su manual interno de procedimientos con el objeto de apoyar la aplicación de estas normas

ARTICULO 4. La investigación para la salud comprende el desarrollo de acciones que contribuyan:

a. Al conocimiento de los procesos biológicos y sicológicos en los seres humanos.

b. Al conocimiento de los vínculos entre las causas de enfermedad, la práctica médica y la estructura social.

c. A la prevención y control de los problemas de salud.

d. Al conocimiento y evaluación de los efectos nocivos del ambiente en la salud.

e. Al estudio de las técnicas y métodos que se recomienden o empleen para la prestación de servicios de salud.

f. A la producción de insumos para la salud.

TITULO II.
DE LA INVESTIGACION EN SERES HUMANOS.

CAPITULO 1.
DE LOS ASPECTOS ETICOS DE LA INVESTIGACION EN SERES HUMANOS.

ARTICULO 5. En toda investigación en la que el ser humano sea sujeto de estudio, deberá prevalecer el criterio del respeto a su dignidad y la protección de sus derechos y su bienestar.

ARTICULO 6. La investigación que se realice en seres humanos se deberá desarrollar conforme a los siguientes criterios:

a. Se ajustará a los principios científicos y éticos que la justifiquen.

b. Se fundamentará en la experimentación previa realizada en animales, en laboratorios o en otros hechos científicos.

c. Se realizará solo cuando el conocimiento que se pretende producir no pueda obtenerse por otro medio idóneo.

d. Deberá prevalecer la seguridad de los beneficiarios y expresar claramente los riesgos (mínimos), los cuales no deben, en ningún momento, contradecir el artículo 11 de esta resolución.

e. Contará con el Consentimiento Informado y por escrito del sujeto de investigación o su representante legal con las excepciones dispuestas en la presente resolución.

f. Deberá ser realizada por profesionales con conocimiento y experiencia para cuidar la integridad del ser humano bajo la responsabilidad de una entidad de salud, supervisada por las las autoridades de salud, siempre y cuando cuenten con los recursos humanos y materiales necesarios que garanticen el bienestar del sujeto de investigación.

g. Se llevará a cabo cuando se obtenga la autorización: del representante legal de la institución investigadora y de la institución donde se realice la investigación; el Consentimiento Informado de los participantes; y la aprobación del proyecto por parte del Comité de Etica en Investigación de la institución.

ARTICULO 7. Cuando el diseño experimental de una investigación que se realice en seres humanos incluya varios grupos, se usarán métodos aleatorios de selección, para obtener una asignación imparcial de los participantes en cada grupo, y demás normas técnicas determinadas para este tipo de investigación, y se tomarán las medidas pertinentes para evitar cualquier riesgo o daño a los sujetos de investigación.

ARTICULO 8. En las investigaciones en seres humanos se protegerá la privacidad del individuo, sujeto de investigación, identificándolo solo cuando los resultados lo requieran y éste lo autorice.

ARTICULO 9. Se considera como riesgo de la investigación la probabilidad de que el sujeto de investigación sufra algún daño como consecuencia inmediata o tardía del estudio.

ARTICULO 10. El grupo de investigadores o el investigador principal deberán identificar el tipo o tipos de riesgo a que estarán expuestos los sujetos de investigación.

ARTICULO 11. Para efectos de este reglamento las investigaciones se clasifican en las siguientes categorías:

a. Investigación sin riesgo: Son estudios que emplean técnicas y métodos de investigación documental restrospectivos y aquellos en los que no se realiza ninguna intervención o modificación intencionada de las variables biológicas, fisiológicas, sicológicas o sociales de los individuos que participan en el estudio, entre los que se consideran: revisión de historias clínicas, entrevistas, cuestionarios y otros en los que no se le identifique ni se traten aspectos sensitivos de su conducta

b. Investigación con riesgo mínimo: Son estudios prospectivos que emplean el registro de datos a través de procedimientos comunes consistentes en: exámenes físicos o sicológicos de diagnóstico o tratamientos rutinarios, entre los que se consideran: pesar al sujeto, electrocardiogramas, pruebas de agudeza auditiva, termografías, colección de excretas y secreciones externas, obtención de placenta durante el parto, recolección de líquido amniótico al romperse las membranas, obtención de saliva, dientes deciduales y dientes permanentes extraidos por indicación terapéutica, placa dental y cálculos removidos por procedimientos profilácticos no invasores, corte de pelo y uñas sin causar desfiguración, extracción de sangre por punción venosa en adultos en buen estado de salud, con frecuencia máxima de dos veces a la semana y volúmen máximo de 450 ml en dos meses excepto durante el embarazo, ejercicio moderado en voluntarios sanos, pruebas sicológicas a grupos o individuos en los que no se manipulará la conducta del sujeto, investigación con medicamentos de uso común, amplio márgen terapéutico y registrados en este Ministerio o su autoridad delegada, empleando las indicaciones, dósis y vías de administración establecidas y que no sean los medicamentos que se definen en el artículo **55** de esta resolución.

c. Investigaciones con riesgo mayor que el mínimo: Son aquellas en que las probabilidades de afectar al sujeto son significativas, entre las que se consideran: estudios radiológicos y con microondas, estudios con los medicamentos y modalidades que se definen en los títulos III y IV de esta resolución, ensayos con nuevos dispositivos, estudios que incluyen procedimientos quirúrgicos, extracción de sangre mayor al 2% del volumen circulante en neonatos, amniocentesis y otras técnicas invasoras o procedimientos mayores, los que empleen métodos aleatorios de asignación a esquemas terapéuticos y los que tengan control con placebos, entre otros.

ARTICULO 12. El investigador principal suspenderá la investigación de inmediato, al advertir algún riesgo o daño para la salud del sujeto en quien se realice la investigación. Así mismo, será suspendida de inmediato para aquellos sujetos de investigación que así lo manifiesten.

ARTICULO 13. Es responsabilidad de la institución investigadora o patrocinadora, proporcionar atención médica al sujeto que sufra algún daño, si estuviere relacionado directamente con la investigación, sin perjuicio de la indemnización que legalmente le corresponda.

ARTICULO 14. Se entiende por Consentimiento Informado el acuerdo por escrito, mediante el cual el sujeto de investigación o en su caso, su representante legal, autoriza su participación en la investigación, con pleno conocimiento de la naturaleza de los procedimientos, beneficios y riesgos a que se someterá, con la capacidad de libre elección y sin coacción alguna.

ARTICULO 15. El Consentimiento Informado deberá presentar la siguiente, información, la cual será explicada, en forma completa y clara al sujeto de investigación o, en su defecto, a su representante legal, en tal forma que puedan comprenderla.

a. La justificación y los objetivos de la investigación.

b. Los procedimientos que vayan a usarse y su propósito incluyendo la identificación de aquellos que son experimentales.

c. Las molestias o los riesgos esperados.

d. Los beneficios que puedan obtenerse.

e. Los procedimientos alternativos que pudieran ser ventajosos para el sujeto.

f. La garantía de recibir respuesta a cualquier pregunta y aclaración a cualquier duda acerca de los procedimientos, riesgos, beneficios y otros asuntos relacionados con la investigación y el tratamiento del sujeto.

g. La libertad de retirar su consentimiento en cualquier momento y dejar de participar en el estudio sin que por ello se creen perjuicios para continuar su cuidado y tratamiento.

h. La seguridad que no se identificará al sujeto y que se mantendrá la confidencialidad de la información relacionada con su privacidad.

i. El compromiso de proporcionarle información actualizada obtenida durante el estudio, aunque ésta pudiera afectar la voluntad del sujeto para continuar participando.

j. La disponibilidad de tratamiento médico y la indemnización a que legalmente tendría derecho, por parte de la institución responsable de la investigación, en el caso de daños que le afecten directamente, causados por la investigación.

k. En caso de que existan gastos adicionales, éstos serán cubiertos por el presupuesto de la investigación o de la institución responsable de la misma.

ARTICULO 16. El Consentimiento Informado, del sujeto pasivo de la investigación, para que sea válido, deberá cumplir con los siguientes requisitos:

a) Será elaborado por el investigador principal, con la información señalada en el artículo **15** de ésta resolución.

b) Será revisado por el Comitéde Etica en Investigación de la institución donde se realizará la investigación.

c) Indicará los nombres y direcciones de dos testigos y la relación que éstos tengan con el sujeto de investigación.

d) Deberá ser firmado por dos testigos y por el sujeto de innvestigación o su representante legal, en su defecto. Si el sujeto de investigación no supiere firmar imprimirá su huella digital y a su nombre firmará otra persona que él designe.

e) Se elaborará en duplicado quedando un ejemplar en poder del sujeto de investigación o su representante legal.

PARAGRAFO PRIMERO. En el caso de investigaciones con riesgo mínimo, el Comité de Etica en Investigación de la institución investigadora, por razones justificadas, podrá autorizar que el Consentimiento Informado se obtenga sin formularse por escrito y

tratándose de investigaciones sin riesgo, podrá dispensar al investigador de la obtención del mismo.

PARAGRAFO SEGUNDO. Si existiera algún tipo de dependencia, ascendencia o subordinación del sujeto de investigación hacia el investigador que le impida otorgar libremente su consentimiento, éste deberá ser obtenido por otro miembro del equipo de investigación,o de la institución donde se realizará la investigación, completamente independiente de la relación investigador-sujeto.

PARAGRAFO TERCERO. Cuando sea necesario determinar la capacidad mental de un individuo para otorgar su consentimiento, el investigador principal deberá acudir a un neurólogo, siquiatra o sicólogo para que evalúe la capacidad de entendimiento, razonamiento y lógica del sujeto, de acuerdo con los parámetros aprobados por el Comité de Etica en Investigación de la institución investigadora.

PARAGRAFO CUARTO. Cuando se presuma que la capacidad mental de un sujeto hubiere variado en el tiempo, el Consentimiento Informado de éste o, en su defecto, de su representante legal, deberá ser avalado por un profesional (neurólogo, siquiatra, sicólogo) de reconocida capacidad científica y moral en el campo específico, así como de un observador que no tenga relación con la investigación, para asegurar la idoneidad del mecanismo de obtención del consentimiento, así como su validez durante el curso de la investigación.

PARAGRAFO QUINTO. Cuando el sujeto de investigación sea un enfermo siquiátrico internado en una institución, además de cumplir con lo señalado en los artículos anteriores, será necesario obtener la aprobación previa de la autoridad que conozca del caso.

CAPITULO II.
DE LA INVESTIGACION EN COMUNIDADES.

ARTICULO 17. Las investigaciones, referidas a la salud humana, en comunidades, serán admisibles cuando el beneficio esperado para éstas sea razonablemente asegurado y cuando los estudios anteriores efectuados en pequeña escala determinen la ausencia de riesgos.

ARTICULO 18. En las investigaciones en comunidades,el investigador principal deberá obtener la aprobación de las autoridades de salud y de otras autoridades civiles de la comunidad a estudiar, además de obtener la carta de Consentimiento Informado de los individuos que se incluyan en el estudio, dándoles a conocer la información a que se refieren los artículos **14**, **15** y **16** de esta resolución.

ARTICULO 19. Cuando los individuos que conforman la comunidad no tengan la capacidad para comprender las implicaciones de participar en una investigación, el Comité de Etica en Investigación de la entidad a la que pertenece el investigador principal, o de la Entidad en donde se realizará la investigación, podrá autorizar o no que el Consentimiento Informado de los sujetos sea obtenido a través de una persona confiable con autoridad moral sobre la comunidad.

En caso de no obtener autorización por parte del Comité de Etica en Investigación, la Investigación no se realizará.

Por otra parte, la participación de los individuos será enteramente voluntaria.

ARTICULO 20. Las investigaciones experimentales en comunidades solo podrán ser realizadas por establecimientos que cuenten con Comités de Etica en Investigación y la autorización previa de este Ministerio para llevarla a cabo, sin perjuicio de las

atribuciones que corresponden a otras dependencias del Estado, y hubieren cumplido en todo caso con los estudios previos de toxicidad y demás pruebas de acuerdo con las características de los productos y el riesgo que impliquen para la salud humana.

ARTICULO 21. En todas las investigaciones en comunidad, los diseños de investigación deberán ofrecer las medidas prácticas de protección de los individuos y asegurar la obtención de resultados válidos acordes con los lineamientos establecidos para el desarrollo de dichos modelos.

ARTICULO 22. En cualquier investigación comunitaria, las consideraciones éticas aplicables a investigación en humanos, deberán ser extrapoladas al contexto comunal en los aspectos pertinentes.

CAPITULO III.
DE LAS INVESTIGACIONES EN MENORES DE EDAD O DISCAPACITADOS.

ARTICULO 23. Además de las disposiciones generales de ética que deben cumplirse en toda investigación en seres humanos, aquella que se realice en menores de edad o en discapacitados físicos y mentales, deberá satisfacer plenamente todas las exigencias que se establecen en este capítulo.

ARTICULO 24. Cuando se pretenda realizar investigaciones en menores de edad, se deberá asegurar que previamente se hayan hecho estudios semejantes en personas mayores de edad y en animales inmaduros; excepto cuando se trate de estudios de condiciones que son propias de la etapa neonatal o padecimientos específicos de ciertas edades.

ARTICULO 25. Para la realización de investigaciones en menores o en discapacitados físicos y mentalesdeberá, en todo caso, obtenerse, además del Consentimiento Informado de quienes ejerzan la patria potestad o la representación legal del menor o del discapacitado de que se trate, certificación de un neurólogo, siquiatra o sicólogo, sobre la capacidad de entendimiento, razonamiento y lógica del sujeto.

ARTICULO 26. Cuando la capacidad mental y el estado sicológico del menor o del discapacitado lo permitan, deberá obtenerse, además, su aceptación para ser sujeto de investigación después de explicarle lo que se pretende hacer. El Comité de Etica en Investigación de la respectiva entidad de salud deberá velar por el cumplimiento de éstos requisitos.

ARTICULO 27. Las investigaciones clasificadas con riesgo y con probabilidades de beneficio directo para el menor o el discapacitado, serán admisibles cuando:

a) El riesgo se justifique por la importancia del beneficio que recibirá el menor o el discapacitado.

b) El beneficio sea igual o mayor a otras alternativas ya establecidas para su diagnóstico y tratamiento.

ARTICULO 28. Las investigaciones clasificadas como de riesgo y sin beneficio directo al menor o al discapacitado, serán admisibles de acuerdo con las siguientes consideraciones:

PARAGRAFO PRIMERO. CUANDO EL RIESGO SEA MINIMO

a) La intervención o procedimiento deberá representar para el menor o el discapacitado una experiencia razonable y comparable con aquellas inherentes a su actual situación médica, psicológica, social o educacional.

b) La intervención o procedimiento deberá tener alta probabilidad de obtener resultados positivos o conocimientos generalizables sobre la condición o enfermedad del menor o del discapacitado que sean de gran importancia para comprender el trastorno o para lograr su mejoría en otros sujetos.

PARAGRAFO SEGUNDO. CUANDO EL RIESGO SEA MAYOR AL MINIMO

a) La investigación deberá tener altas probabilidades de atender, prevenir o aliviar un problema grave que afecte la salud y el bienestar de la niñez o de los discapacitados físicos o mentales.

b) El Comité de Etica en Investigación de la institución investigadora, establecerá una supervisión estricta para determinar si aumenta la magnitud de los riesgos previstos o surgen otros y suspenderá la investigación en el momento en que el riesgo pudiera afectar el bienestar biológico, psicológico o social del menor o del discapacitado.

CAPITULO IV.
DE LA INVESTIGACION EN MUJERES EN EDAD FERTIL, EMBARAZADAS, DURANTE EL TRABAJO DE PARTO, PUERPERIO, LACTANCIA Y RECIEN NACIDOS; DE LA UTILIZACION DE EMBRIONES, OBITOS Y FETOS Y DE LA FERTILIZACION ARTIFICIAL.

ARTICULO 29. En las investigaciones clasificadas como de riesgo mayor que el mínimo, que se realicen en mujeres en edadfértil, deberán cumplir con los siguientes requisitos:

a) Certificar que las mujeres no están embarazadas previamente a su aceptación como sujetos de investigación.

b) Disminuir en lo posible las probabilidades de embarazo durante el desarrollo de la investigación.

ARTICULO 30. Para realizar investigaciones en mujeres embarazadas, durante el trabajo de parto, puerperio y lactancia; en nacimientos vivos o muertos; de la utilización de embriones, óbitos o fetos; y para la fertilización artificial, se requiere obtener el Consentimiento Informado de la mujer y de su cónyuge o compañero de acuerdo a lo estipulado en los artículos **15** y **16** de éste reglamento, previa información de los riesgos posibles para el embrión, feto o recién nacido en su caso.

El Consentimiento Informado del cónyuge o compañero solo podrá dispensarse en caso de incapacidad o imposibilidad fehaciente o manifiesta para proporcionarlo; porque el compañero no se haga cargo de la mujer o, bien, cuando exista riesgo inminente para la salud o la vida de la mujer, embrión, feto o recién nacido.

ARTICULO 31. Las investigaciones que se realicen en mujeres embarazadas deberán estar precedidas de estudios realizados en mujeres no embarazadas que demuestren seguridad, a excepción de estudios específicos que requieran de dicha condición.

ARTICULO 32. Las investigaciones sin beneficio terapéutico en mujeres embarazadas cuyo objetivo sea obtener conocimientos generalizables sobre el embarazo, no deberán representar un riesgo mayor al mínimo para la mujer, el embrión o el feto.

ARTICULO 33. Las investigaciones en mujeres embarazadas que impliquen una intervención o procedimiento experimental no relacionado con el embarazo, pero con beneficio terapéutico para la mujer, como sería en casos de toxemia gravídica, diabetes, hipertensión y neoplasias, entre otros, no deberán exponer al embrión o al feto a un riesgo mayor al mínimo, excepto cuando el empleo de la intervención o procedimiento se

justifique para salvar la vida de la mujer.

ARTICULO 34. Las investigaciones en mujeres embarazadas, con beneficio terapéutico relacionado con el embarazo, se permitirán cuando:

a) Tengan por objeto mejorar la salud de la embarazada con un riesgo mínimo para el embrión o el feto.

b) Estén encaminadas a incrementar la viabilidad del feto, con un riesgo mínimo para la embarazada.

ARTICULO 35. Durante la ejecución de investigaciones en mujeres embarazadas:

a) Los investigadores no tendrán autoridad paradecidir sobre el momento, método o procedimiento empleados para terminar el embarazo, ni participación en decisiones sobre la viabilidad del feto.

b) Queda estrictamente prohibido otorgar estímulos, monetarios o de otro tipo, para interrumpir el embarazo, por el interés de la investigación o por otras razones.

ARTICULO 36. El Consentimiento Informado para investigaciones durante el trabajo de parto deberá obtenerse de acuerdo con lo estipulado en los artículos **14**, **15** y **16** de éste reglamento, antes de que aquél se inicie y señalando expresamente que éste puede ser retirado en cualquier momento del tabajo de parto.

ARTICULO 37. Las investigaciones en mujeres durante el puerperio se permitirán cuando no interfieran con la salud de la madre ni con la del recién nacido.

ARTICULO 38. Las investigaciones en mujeres durante la lactancia serán autorizadas cuando no exista riesgo para el lactante o cuando la madre decida no amamantarlo; se asegure su alimentación por otro método y se obtenga el Consentimiento Informado de acuerdo con lo estipulado en los artículos 14, 15 y 16 de ésta resolución.

ARTICULO 39. Los fetos serán sujetos de investigación solamente si las técnicas y medios utilizados proporcionan máxima seguridad para ellos y la embarazada.

ARTICULO 40. Los recién nacidos serán sujetos de investigación solamente si las técnicas y medios utilizados proporcionan máxima seguridada para ellos y la madre.

ARTICULO 41. Los recién nacidos no serán sujetos de investigación, excepto cuando ésta tenga por objeto: aumentar su probabilidad de sobrevivencia hasta la fase de viabilidad; los procedimientos no causen el cese de funciones vitales, o cuando, sin agregar ningún riesgo, se busque obtener conocimientos generalizables importantes que no puedan obtenerse de otro modo.

ARTICULO 42. Los nacimientos vivos podrán ser sujetos de investigación si se cumple con las disposiciones sobre investigación en menores, indicadas en ésta resolución.

ARTICULO 43. Las investigaciones con embriones, óbitos, fetos, nacimientos muertos, materia fecal macerada, células, tejidos y órganos extraidos de éstos, serán realizadas de acuerdo con lo dispuesto en este reglamento.

ARTICULO 44. La investigación sobre fertilización artificial solo será admisible cuando se aplique a la solución de problemas de esterilidad que no se puedan resolver de otra manera, respetándose el punto de vista moral, cultural y social de la pareja.

CAPITULO V.

DE LAS INVESTIGACIONES EN GRUPOS SUBORDINADOS.

ARTICULO 45. Se entiende por grupos subordinados los siguientes: estudiantes, trabajadores de los laboratorios y hospitales, empleados y miembros de las fuerzas armadas, internos en reclusorios o centros de readaptación social y otros grupos especiales de la población, en los que el Consentimiento Informado pueda ser influenciado por alguna autoridad.

ARTICULO 46. Cuando se realicen investigaciones en grupos subordinados, en el Comité de Etica en Investigación, deberá participar uno o más miembros de la población de estudio, capaz de representar los valores morales, culturales y sociales del grupo en cuestión y vigilar:

a) Que la participación, el rechazo de los sujetos a intervenir o retiro de su consentimiento durante el estudio, no afecte su situación escolar, laboral, militar o la relacionada con el proceso judicial al que estuvieren sujetos y las condiciones de cumplimiento de sentencia del caso.

b) Que los resultados de la investigación no sean utilizados en perjuicio de los individuos participantes.

c) Que la institución investigadora y los patrocinadores se responsabilicen del tratamiento médico de los daños ocasionados y, en su caso, de la indemnización que legalmente corresponda por las consecuencias perjudiciales de la investigación.

CAPITULO VI.
DE LA INVESTIGACION EN ORGANOS, TEJIDOS Y SUS DERIVADOS, PRODUCTOS Y CADAVERES DE SERES HUMANOS.

ARTICULO 47. La investigación a que se refiere este capítulo comprende la que incluye la utilización de órganos, tejidos y sus derivados, productos y cadáveres de seres humanos, así como el conjunto de actividades relativas a su obtención, conservación, utilización, preparación y destino final.

ARTICULO 48. Esta investigación deberá observar además del debido respeto al cadáver humano, las disposiciones aplicables del presente reglamento y demás normas relacionadas con disposición de órganos, tejidos y cadáveres de seres humanos.

TITULO III.
DE LAS INVESTIGACIONES DE NUEVOS RECURSOS PROFILACTICOS, DE DIAGNOSTICO, TERAPEUTICOS Y DE REHABILITACION.

CAPITULO I.
DISPOSICIONES GENERALES.

ARTICULO 49. Cuando se realice investigación en seres humanos, sobre nuevos recursos profilácticos, de diagnóstico, terapéuticos y de rehabilitación, o se pretenda modificar los ya conocidos, deberá observarse en lo aplicable, lo dispuesto en los artículos anteriores y satisfacer lo contemplado en este título.

ARTICULO 50. El Comité de Etica en Investigación de la entidad de salud será el encargado de estudiar y aprobar los proyectos de investigación y solicitará los siguientes documentos:

a) Proyecto de investigación que deberá contener un análisis objetivo y completo de los

riesgos involucrados, comparados con los riesgos de los métodos de diagnóstico y tratamiento establecidos y la expectativa de las condiciones de vida con y sin el procedimiento o tratamiento propuesto y demás información pertinente a una propuesta de investigación.

b) Carta del representante legal de la institución investigadora y ejecutora, cuando haya lugar, autorizando la realización de la investigación.

c) Descripción de los recursos disponibles, incluyendo áreas, equipos, y servicios auxiliares de laboratorio que se utilizarán para el desarrollo de la investigación.

d) Descripción de los recursos disponibles para el manejo de urgencias médicas.

e) Hoja de vida de los investigadores que incluya su preparación académica, su experiencia y su producción científica en el área de la investigación propuesta.

f) Los requisitos señalados en los artículos **57** y **61** de esta resolución, según el caso.

ARTICULO 51. Cuando exista patrocinio u otras formas de remuneración, deberán establecerse las medidas necesarias para evitar que estos originen conflictos de interés al investigador en la protección de los derechos de los sujetos de investigación, aunque hayan dado su consentimiento en la preservación de la veracidad de los resultados y en la asignación de los recursos.

ARTICULO 52. En el desarrollo de las investigaciones contempladas en éste título deberán cumplirse las siguientes obligaciones:

a) El investigador principal informará al Comité de Etica en Investigación de la institución investigadora o de la institución ejecutora, de todo efecto adverso probable o directamente relacionado con la investigación.

b) El director de la institución investigadora notificará al Comité de Etica en Investigación, cuando así se requiera, de la presencia de cualquier efecto adverso, dentro de un plazo máximo de 15 días hábiles siguientes a su presentación.

c) El Comité de Etica en Investigación deberá suspender o cancelar la investigación ante la presencia de cualquier efecto adverso que sea impedimento desde el punto de vista ético o técnico para continuar con el estudio.

d) d.La institución investigadora rendirá al Comité de Etica en Investigación y al Ministerio de Salud, cuando así se requiera, un informe dentro de los quince (15) días hábiles siguientes a la suspensión de la investigación, que especifique el efecto advertido, las medidas adoptadas y las secuelas producidas.

CAPITULO II.
DE LA INVESTIGACION FARMACOLOGICA.

ARTICULO 53. Para efectos de este reglamento, se entiende por investigación farmacológica a las actividades científicas tendientes al estudio de medicamentos y productos biológicos para uso humano sobre los cuales no se tenga experiencia previa en el país, que no estén contemplados en las Normas Farmacológicas en este Ministerio y por lo tanto, no sean distribuidos en forma comercial, así como los medicamentos registrados y aprobados para su venta, cuando se investigue su uso con modalidades, indicaciones, dosis o vías de administración diferentes a las establecidas, incluyendo su empleo en combinaciones.

ARTICULO 54. Las investigaciones de medicamentos en farmacología clínica comprende

la secuencia de estudios que se llevan a cabo desde que se administra por primera vez al ser humano, hasta que se obtienen datos sobre su eficacia y seguridad terapéutica en grandes grupos de población. Para tal efecto, se consideran las siguientes fases:

a. FASE I: Es la administración por primera vez de un medicamento de investigación al ser humano sano, en dosis únicas o múltiples, en pequeños grupos hospitalizados, para establecer parámetros farmacológicos iniciales en el hombre.

b. FASE II: Es la administración, al ser humano enfermo, de un medicamento de investigación, en dosis únicas o múltiples, en grupos pequeños hospitalizados, para establecer parámetros farmacológicos en el organismo enfermo.

c. FASE III. Es la administración, a grandes grupos de pacientes, de un medicamento de investigación, generalmente externos, para definir su utilidad terapéutica e identificar reacciones adversas, interacciones y factores externos, que puedan alterar el efecto farmacológico.

d. FASE IV: Son estudios que se realizan después de que se conceda al medicamento, registro sanitario para su venta y tiene por objeto generar nueva información sobre la seguridad del medicamento durante su empleo generalizado y prolongado.

ARTICULO 55. Todas las investigaciones en farmacología clínica que se realicen, deberán estar precedidas por estudios preclínicos completos que incluyan características fisicoquímicas actividad farmacológica, toxicidad, farmacocinética, absorción, distribución, metabolismo y excreción del medicamento en diferentes especies animales; frecuencias, vías de administración y duración de las dosis estudiadas que puedan servir como base para la seguridad de su administración en el ser humano; también se requieren estudios sobre mutagénesis, teratogénesis y carcinogénesis.

ARTICULO 56. Los estudios de toxicología preclínica requeridos para cada fármaco estarán en función de éste en particular, de la toxicología potencial conocida de otros con estructura química similar y de la vía y tiempo de administración que se pretenda utilizar en el ser humano.

ARTICULO 57. El empleo en seres humanos de medicamentos de investigación durante su valoración a través de las Fases I a IV de investigación farmacológica clínica, se hará con la autorización del Comité de Etica en Investigación, al cual se deberá presentar la documentación que indica el artículo **50** de éste reglamento, además de la siguiente:

a) La información farmacológica básica y preclínica del medicamento.

b) La información previamente obtenida sobre farmacología clínica en casos de las fases II, III y IV y pruebas de biodisponibilidad cuando se requieran.

ARTICULO 58. Los estudios de farmacología clínica Fase I, de medicamentos nuevos antineoplásicos y de otros con índice terapéutico muy reducido, serán permitidos cuando:

a) Estén fundamentados en estudios preclínicos que demuestren la actividad farmacológica del medicamento e indique con claridad las características de su toxicidad.

b) Se realicen solamente en sujetos voluntarios con la enfermedad específica, confirmada por medios de diagnóstico adicionales, que no hayan presentado respuesta terapéutica a ningún otro tratamiento disponible y en quienes el medicamento nuevo pudiera ofrecer un beneficio terapéutico.

c) No ocasione gastos al paciente.

ARTICULO 59. En el tratamiento de urgencias, en condiciones que amenacen la vida de

una persona cuando se considera necesario usar un medicamento de investigación o un medicamento conocido empleando indicaciones, dosis y vías de administración diferentes de las establecidas, el médico deberá obtener el dictamen favorable del Comité de Etica en Investigaciones de las instituciones investigadoras y el Consentimiento Informado del sujeto de investigación o de su representante legal, según lo permitan las circustancias de acuerdo con las siguientes bases:

a) El Comité de Etica en Investigación será informado del empleo del medicamento en investigación de manera anticipada, si el investigador puede preveer la necesidad de su uso en casos de urgencia, o en forma retrospectiva, si el uso del medicamento, la indicación, dosis o vías de administración nuevas surgieran como necesidades no previstas. En ambos casos el Comité de Etica en Investigación emitirá dictamen en favor o en contra de aprobar el uso planeado o la repetición del uso no previsto del medicamento.

b) El Consentimiento Informado será obtenido del sujeto de investigación, o en su defecto, del representante legal o del familiar más cercano en vínculo, excepto cuando: la condición del sujeto le incapacite o impida otorgarlo, el representante legal o el familiar no estén disponibles o cuando el dejar de usar el medicamento en investigación represente un riesgo absoluto de muerte.

CAPITULO III.
DE LA INVESTIGACION DE OTROS NUEVOS RECURSOS.

ARTICULO 60. Para los efectos de éste reglamento, se entiende por investigación de otros nuevos recursos o modalidades diferentes de las establecidas, las actividades científicas tendientes al estudio de materiales, injertos, trasplantes, prótesis, procedimientos físicos, químicos y quirúrgicos, instrumentos, aparatos, órganos artificiales y otros métodos de prevención, diagnóstico, tratamiento y rehabilitación que se realicen en seres humanos o en sus productos biológicos, excepto los farmacológicos.

ARTICULO 61. Toda investigación a la que se refiere este capítulo deberá contar con la autorización del Comité de Etica en Investigación. Al efecto, las instituciones investigadoras deberán presentar la documentación que se indica en el artículo **50** de esta resolución, además de lo siguiente:

a) Los fundamentos científicos, información sobre experimentación previa realizada en animales o en laboratorio.

b) Estudios previos de investigación clínica cuando los hubiere.

ARTICULO 62. Todas las investigaciones sobre injertos y trasplantes deberán observar,además de las disposiciones aplicables de éste reglamento, lo estipulado en materia de control sanitario de la disposición de órganos, tejidos y cadáveres de seres humanos.

TITULO IV.
DE LA BIOSEGURIDAD DE LAS INVESTIGACIONES.

CAPITULO I.
DE LA INVESTIGACION CON MICROORGANISMOS PATOGENOS O MATERIALBIOLOGICO QUE PUEDA CONTENERLOS.

ARTICULO 63. Las instituciones investigadoras en las que se realice investigación con microorganismos patógenos o material biológico que pueda contenerlos deberá:

a) Contar con las instalaciones y equipo de laboratorio de acuerdo con las normas técnicas, que al efecto emita este Ministerio, que garanticen el manejo seguro de tales gérmenes.

b) Elaborar un manual de procedimientos para los laboratorios de microbiología y ponerlo a disposición del personal profesional, técnico, de servicios y de mantenimiento.

c) Adiestrar al personal sobre la manipulación, transporte, utilización, descontaminación y eliminación de desechos.

d) Determinar la necesidad de vigilancia médica del personal que participa en las investigaciones y en su caso, implementarla.

e) Establecer un programa de supervisión y seguimiento de seguridad en los laboratorios de microbiología.

f) Disponer de bibliografía actualizada y un archivo sobre la seguridad de los equipos, la disponibilidad de sistemas de contención, normas y reglamentos, riesgos involucrados y otros aspectos relacionados.

g) Cumplir con las demás disposiciones que determine este Ministerio.

ARTICULO 64. En las instituciones de investigación mencionadas en el artículo anterior, los laboratorios de microbiología cumplirán con los requisitos que señalen las normas técnicas que dicte este Ministerio y se clasificarán en tres tipos así:

a) Laboratorio básico de microbiología.

b) Laboratorio de seguridad microbiológica.

c) Laboratorio de máxima seguridad microbiológica.

ARTICULO 65. El manual de procedimientos al que se refiere el literal b del artículo **63** de ésta reglamentación,describirá los siguientes aspectos:

a) Prácticas de laboratorio.

b) Seguridad personal de los empleados.

c) Manejo y mantenimiento de las instalaciones y equipos.

d) Situaciones de urgencia.

e) Restricciones de entrada y tránsito.

f) Recepción y trasporte de materiales biológicos.

g) Disposición de desechos.

h) Descontaminación.

i) Las demás que se consideren necesarias para lograr la seguridad microbiológica.

ARTICULO 66. El investigador principal de acuerdo con el Comité de Etica Hospitalaria, o el Comité de Etica en Investigación, y el representante legal de la institución investigadora, determinarán conforme a las normas técnicas existentes, el tipo de laboratorio en el que se realizarán las investigaciones propuestas; así como los

procedimientos respectivos tomando en cuenta el grado de riesgo de infección que presenten los microorganismos a utilizar.

ARTICULO 67. Para evaluar el grado de riesgo a que se refiere el artículo anterior este Ministerio emitirá la norma técnica correspondiente y clasificará los microorganismos dentro de cuatro grupos, según las siguientes criterios:

a) GRUPO DE RIESGO I: Microorganismos que representan escaso riesgo para el individuo y para la comunidad.

b) GRUPO DE RIESGO II: Microorganismos que representan riesgo moderado para el individuo y limitado para la comunidad.

c) GRUPO DE RIESGO III: Microorganismos que representan riesgo elevado para el individuo y escaso para la comunidad.

d) GRUPO DE RIESGO IV: Microorganismos que representan riesgo elevado para el individuo y para la comunidad.

ARTICULO 68. Los microorganismos que se clasifiquen en los grupos de riesgo I y II deberán manejarse en laboratorios de tipo básico de microbiología, empleando gabinetes de seguridad cuando se considere necesario.

ARTICULO 69. Los microorganismos que se clasifiquen en el grupo de riesgo III deberán manejarse en laboratorios de seguridad microbiológica.

ARTICULO 70. Los microorganismos que se clasifiquen en el grupo de riesgo IV deberán manejarse en laboratorios de máxima seguridad microbiológica, bajo la autorización y control de las autoridades sanitarias correspondientes.

ARTICULO 71. Durante el desarrollo de las investigaciones a las que se refiere éste capítulo, el investigador principal tendrá a su cargo:

a) Determinar los riesgos reales y potenciales de las investigaciones propuestas y, en caso de que se aprueben por parte de los Comités de la institución investigadora, darlos a conocer a los demás investigadores que conformen el grupo y al personal técnico y auxiliar que participe en la investigación.

b) Determinar el nivel apropiado de contención física, seleccionar las prácticas microbiológicas idóneas y diseñar procedimientos para atender posibles accidentes durante la investigación e instruir al personal participante sobre estos aspectos.

c) Vigilar que el personal participante cumpla con los requerimientos de profilaxis médica, vacunas o pruebas serológicas.

d) Supervisar que el trasporte de materiales infecciosos se haga en forma rápida, de acuerdo con las normas técnicas emitidas por este Ministerio.

e) Informar a la Comisión de Bioseguridad sobre la ocurrencia de enfermedad entre el personal participante en la investigación que pudiera atribuirse a la inoculación transcutánea, ingestión o inhalación de materiales infecciosos, así como accidentes que causen contaminación que pueda afectar al personal o al ambiente.

f) Reportar a la Comisión de Bioseguridad las dificultades o fallas en la implantación de los procedimientos de seguridad, corregir errores de trabajo que pudieran ocasionar la liberación de material infeccioso y asegurar la integridad de las medidas de contención física.

ARTICULO 72. El Comité de Etica en Investigación de la institución investigadora deberá realizar visitas periódicas para evaluar el cumplimiento de las medidas y recomendar modificaciones a las prácticas de laboratorio, incluyendo la suspensión temporal o definitiva de las investigaciones que representen un riesgo no controlado de infección o contaminación para los trabajadores de laboratorio, la comunidad o el medio ambiente.

CAPITULO II.
DE LA INVESTIGACION QUE IMPLIQUE CONSTRUCCION Y MANEJO DEACIDOS NUCLEICOS RECOMBINANTES.

ARTICULO 73. Para los efectos de este reglamento, se entenderá por ácidos nucléicos recombinantes a las nuevas combinaciones de material genético obtenidas fuera de una célula viviente, por medio de la inserción de segmentos naturales o sintéticos de ácido desoxirribonucléico en un virus, plásmido bacteriano u otras moléculas de ácido desoxirribonucléico que sirven como sistema vector para permitir su incorporación en una célula huésped, en la que no se encuentran en forma natural, pero en las que serán capaces de replicarse. Igualmente quedan comprendidas las moléculas de ácido desoxirribonucléico que resulten de dicha replicación.

ARTICULO 74. Las investigaciones con ácidos nucléicos recombinantes deberán diseñarse de tal forma que se logre el máximo nivel de contención biológica, seleccionando los sistemas de huésped y vector idóneos, que disminuyan la probabilidad de diseminación de las moléculas recombinantes fuera del laboratorio, tomando en cuenta el orígen del material genético y las normas técnicas que emita este Ministerio.

ARTICULO 75. El investigador principal de acuerdo con: su superior jerárquico, el Comité de Etica en Investigación, la Comisión de Bioseguridad y el representante legal de la institución investigadora, determinarán conforme con las normas técnicas emitidas por este Ministerio, el tipo de laboratorio de microbiología en el que se realizarán los experimentos a que se refiere éste capítulo, tomando en cuenta el material genético que se pretende replicar.

ARTICULO 76. Se requiere autorización de este Ministerio para iniciar los siguientes tipos de experimentación:

a) Formación de ácido desoxirribonucléico recombinante derivado de los microorganismos patógenos que queden clasificados en los grupos de riesgo III y IV a que se refiere el artículo **71** de esta resolución, así como la formación de material genético recombinante derivado de las células que son infectadas por tales agentes, independientemente del sistema de huésped y vector que se use.

b) Construcción intencional de ácidos nucléicos recombinantes para inducir la biosíntesis de toxinas potentes para los vertebrados.

c) Liberación intencionada al medio ambiente de cualquier microorganismo que porte ácidos nucléicos recombinantes.

d) Transferencia de resistencia a los antibióticos de microorganismos que no lo adquieren en la naturaleza, si tal trasferencia pudiera afectar negativamente el empleo del antibiótico en medicina humana.

e) Experimentar con microorganismos o con ácidos nucléicos recombinantes en cultivos mayores de diez (10) litros debido a que su contención física y biológicas es más difícil a menos que las moléculas recombinantes se hayan caracterizado rigurosamente y se demuestre la ausencia de genes peligrosos en ellas. Quedan excluidos aquellos procesos de carácter industrial y agropecuario no relacionados directa y específicamente con las actividades establecidas en el artículo **1**o de ésta resolución.

CAPITULO III.
DE LA INVESTIGACION CON ISOTOPOS RADIACTIVOS Y DISPOSITIVOSY GENERADORES DE RADIACIONES IONIZANTES Y ELECTROMAGNETICAS.

ARTICULO 77. La investigación médica que implique el uso en seres humanos, de isótopos radioactivos y dispositivos generadores de radiaciones ionizantes y electromagnéticas deberán realizarse de acuerdo con las leyes, reglamentos y normas sobre seguridad radiológica, que rijan en el territorio nacional.

ARTICULO 78. En las instituciones donde se realicen estas investigaciones la Comisión de Bioseguridad vigilará que para cada estudio se identifique, ante el respectivo Organismo Nacional, a la persona responsable de la seguridad radiológica y física de dichas instituciones, para el cumplimiento de los requisitos y obligaciones, como encargado de la seguridad radiológica.

ARTICULO 79. La persona responsable a la que se alude en el artículo anterior deberá:

a) Tener el entrenamiento, calificación y certificación exigidos legalmente para dicha función.

b) Elaborar un manual de procedimientos acorde con las leyes, normas y reglamentos vigentes y con las características de la instalación o equipos, el cual deberá estar disponible para todo el personal, en el que se describan: la identificación y control de las fuentes de radiación, áreas controladas y vigiladas, seguimiento dosimétrico del personal, plan de emergencias, plan de gestión de desechos y capacitación del personal involucrado en procedimientos y seguridad radiológica.

c) Definir, implantar y vigilar el cumplimiento de las medidas de seguridad radiológica y física.

d) Informar al personal involucrado en la investigación acerca de dichas normas y adiestrarlo sobre los procedimientos de trabajo y las características del laboratorio y del equipo.

ARTICULO 80. Teniendo en cuenta que cada exposición involucra un riesgo, queda estrictamente prohibido exponerse indebidamente, a las radiaciones ionizantes. Los límites de Dosis Equivalente legalmente establecidos deberán considerarse como límites superiores y no de diseño o de control. Las medidas de protección contra las radiaciones ionizantes deben optimizarse, de modo que el número de personas expuestas y las Dosis Equivalente recibidas por el investigador o el paciente sometido a la investigación, sean tan bajos como sea razonablemente posible, tomando en cuenta los factores socio-económicos del medio en que se trabaja.

ARTICULO 81. En el examen o tratamiento que forme parte de un programa de investigación médica y que conlleve un beneficio neto para el paciente, la justificación del procedimiento se realizará con los mismos criterios de justificación que para una exposición médica de rutina. No obstante, dado el carácter experimental, dicha justificación se someterá a un escrutinio minucioso de manera individual, descartando otros métodos diagnósticos o terapéuticos susceptibles de evaluarse comparativamente.

ARTICULO 82. La irradiación deliberada de personal durante los procedimientos con propósitos de investigación que no persiga un beneficio directo a las personas irradiadas, se efectuará únicamente por personas adecuadamente calificadas y adiestradas, y con el permiso respectivo de la institución donde se vaya a efectuar la irradiación, bajo la asesoría del Ente Nacional responsable de la protección radiológica en armonía con las normas vigentes de vigilancia y control radiológico.

ARTICULO 83. El personal ocupacionalmente expuesto debe ser mayor de 18 años, y se tendrán en cuenta los límites de exposición ocupacional que determine la entidad nacional autorizada, con especial consideración en el caso de mujeres en edad fértil y embarazadas.

PARAGRAFO. Las mujeres embarazadas o en período de lactancia, no deberán trabajar en lugares de alto riesgo de incorporación de materiales radioactivos.

ARTICULO 84. Se debe informar a las personas, incluidas en el procedimiento, sobre el riesgo de la irradiación a que se someterán, para que su participación sea bajo su libre voluntad y con conocimiento de causa. Es necesario el Consentimiento Informado de los familiares o del responsable legal cuando el sujeto de la investigación no esté en condiciones de decidir sobre su aceptación.

ARTICULO 85. Estas investigaciones deben someterse a evaluación individual, seguida de un plan de procedimeintos y un protocolo final aprobado por la autoridad competente en la materia, que las analice exhaustivamente desde el punto de vista de la radioprotección y de la condición de verdaderos voluntarios de las personas que no van a recibir un beneficio neto del procedimiento, puesto que no se puede fijar límites de dosis especiales en estos casos.

ARTICULO 86. Se prohibe el uso de radiaciones ionizantes con carácter de investigación en mujeres embarazadas y menores de edad, y se restringe a estudios específicos previos a la investigación en mujeres en edad reproductiva.

PARAGRAFO. En los anteriores casos se podrá hacer reconsideración al tratarse de procedimientos terapéuticos en procesos patológicos considerados especiales por su pronóstico o por sus características, con la previa autorización escrita de la persona involucrada, o del familiar, o persona legalmente responsable.

TITULO V.
LA INVESTIGACION BIOMEDICA CON ANIMALES.

ARTICULO 87. En toda investigación en la que los animales sean sujeto de estudio deberán tenerse en cuenta, además de las disposiciones determinadas en la Ley 84 de 1989, las siguientes:

a) Siempre que sean apropiados, deben usarse métodos tales como modelos matemático, simulación en computador y sistemas biológicos in vitro.

b) La experimentación en animales solamente se debe realizar después de estudiar su importancia para la salud humana o animal y para el avance del conocimiento biológico.

c) Los animales seleccionados para la experimentación deben ser de una especie y calidad apropiada, y utilizar el mínimo número requerido para obtener resultados científicamente válidos.

d) Solamente se emplearán animales adquiridos legalmente y se mantendrán en condiciones adecuadas y que cumplan con las reglamentaciones sanitarias vigentes.

e) Los investigadores y demás personal nunca deben dejar de tratar a los animales como seres sensibles y deben considerar como un imperativo ético el cuidado y uso apropiado y evitar o minimizar el disconfort, la angustia y el dolor.

f) Los investigadores deben presumir, qué procedimientos que causarían dolor en seres humanos también causen dolor en otras especies vertebradas, aún cuando todavía falta

mucho por saber sobre la percepción del dolor en los animales.

g) Todo procedimiento, que pueda causar en los animales más que un dolor o una angustia momentánea o mínima, debe ser realizado con sedación, analgesia o anestesia apropiada y conforme con la práctica veterinaria aceptada. No se deben realizar procedimientos quirúrgicos o dolorosos en animales no anestesiados, paralizados por agentes químicos.

La eutanasia de los animales se efectuará con anestésicos apropiados, aprobados por la asociación veterinaria.

h) Cuando se requiera apartarse de lo establecido en el inciso anterior, la decisión no debe ser tomada solamente por el investigador directamente involucrado, sino que debe ser tomada por el Comité de Etica, establecido por la ley 84 de 1989. Estas excepciones no deben hacerse solamente con fines de demostración o enseñanza.

i) Al final del experimento, o cuando sea apropiado durante el mismo, los animales que puedan sufrir dolor crónico o severo, angustia, disconfort o invalidez que no pueda ser mitigada, deben ser sacrificados sin dolor.

j) Los animales mantenidos con propósitos biomédicos deben tenerse en las mejores condiciones de vida, de ser posible bajo la supervisión de veterinarios con experiencia en animales de laboratorio. En todo caso se debe disponer de cuidado veterinario cuando sea requerido.

k) El director del instituto, departamento o unidad donde se usen animales es el responsable de asegurar que los investigadores y demás personal tengan calificación apropiada o experiencia para realizar procedimientos en animales. Debe proporcionar oportunidades adecuadas de entrenamiento en servicio que incluya la preocupación por un trato humano y apropiado para con los animales que están bajo su cuidado.

ARTICULO 88. El uso de animales en la investigación, enseñanza y ensayos es aceptado solamente cuando promete contribuir a la comprensión y avance del conocimiento de los principios fundamentales biológicos o al desarrollo de mejores medios para la protección de la salud y el bienestar tanto del hombre como del animal.

ARTICULO 89. Los animales deben ser utilizados, en caso que el investigador haya descartado otras alternativas, para tal fin se sigue el principio de Russell Burch "3R", remplazo, reducción y refinamiento.

ARTICULO 90. Los bioterios deberán estar de acuerdo con la especie, conformación corporal, hábitos, preferencias posturales y características locomotoras de los animales, para proporcionarles comodidad, excepto cuando las variables experimentales justifiquen otras situaciones.

ARTICULO 91. Los bioterios de producción o mantenimiento crónico serán supervisados por el personal profesional calificado y competente en la materia y deberán permitir el crecimiento, maduración, reproducción y comportamiento normal de los animales, de conformidad con las normas que la propia institución emita.

ARTICULO 92. El director de la institución donde se realice investigación en animales, deberá establecer y vigilar el cumplimiento de las medidas de seguridad para el cuidado y manejo de los animales, así como las medidas de profilaxis y vacunación necesarias para la protección del personal ocupacionalmente expuesto.

ARTICULO 93. El director de la institución donde se realice investigación en animales, deberá vigilar, ordenar o ejecutar, se tengan en cuenta las siguientes medidas de seguridad, según el caso:

a) Aislamiento.

b) La cuarentena.

c) La observación personal.

d) La vacunación de personas.

e) La vacunación de animales, en cuanto esté referida a la salud humana.

f) La destrucción o control de insectos y otra fauna, transmisora y nociva, en cuanto esté referida a la salud humana.

g) La suspensión de trabajos o servicios.

h) El aseguramiento y destrucción de objetos o productos o substancias.

i) Desalojo de casas, edificios, establecimientos y en general de cualquier predio.

j) La prohibición del uso de ciertas especies, y

k) Las demás de índole sanitaria que determine este Ministerio o entidad competente de su nivel, que puedan evitar que se causen o continúen causando riesgos o daños a la salud.

ARTICULO 94. La presente resolución rige a partir de la fecha de su publicación.

PUBLIQUESE Y CUMPLASE

Dada en Santafé de Bogotá D.C. a los cuatro días del mes de octubre de mil novecientos noventa y tres.

1. OBJETIVO:

Brindar los lineamientos que debe tener en cuenta el usuario para la conformación, procedimientos, seguimiento, vigilancia e interacción de los Comités de Ética Independientes con el INVIMA.

2. ALCANCE:

El presente documento informativo está dirigido a los comités de ética y actores involucrados en la investigación con seres humanos en el territorio Nacional (IPS, EPS, Universidades, Patrocinadores, Entes territoriales, Investigadores, sujetos de investigación o cualquier entidad que quiera llevar a cabo un proyecto de investigación con medicamentos en seres humanos).

3. DEFINICIONES

Remitirse a las definiciones establecidas en la Resolución 2378 de 2008 del 27 de Junio del 2008.

4. COMITÉ DE ÉTICA

El Comité de Ética es la organización responsable de garantizar la protección de los derechos, seguridad y bienestar de los seres humanos involucrados en un estudio clínico por medio de la revisión, aprobación y seguimiento constante del proyecto de Investigación, enmiendas, consentimiento informado de los participantes del estudio, entre otros documentos relacionados.

Esta evaluación siempre debe estar enfocada hacia la integridad del participante del estudio, por encima de la factibilidad que implica la realización de un estudio de investigación en un Centro o IPS.

Por esta razón el Comité de Ética es la máxima autoridad dentro del Centro de Investigación en lo que tiene que ver con el mantenimiento de la integridad del participante de investigación.

5. PROCEDIMIENTOS DEL COMITÉ DE ÉTICA

El Comité de Ética debe tener un documento (guía, estatuto, etc.), que incluya todos los procedimientos que debe realizar en la Investigación. Estos procedimientos deben estar en constante actualización y socialización de acuerdo a los avances en materia de las Buenas Prácticas Clínicas.

Se deben definir las responsabilidades mínimas que debe cumplir un Comité de Ética, de acuerdo a la normatividad nacional vigente y apoyado en la normatividad internacional.

6. RESPONSABILIDADES

Toda investigación que se realice en seres humanos debe ser evaluada y aprobada por el Comité de Ética. El Comité debe evaluar el proyecto de investigación, las competencias del investigador y las competencias de su equipo de investigación; el formulario de consentimiento informado, la información conocida sobre el fármaco (incluidos los informes de eventos adversos inesperados y esperados) y toda publicidad potencial planificada para obtener posibles participantes, además de cualquier cambio en el protocolo por insignificante que este sea.

Los proyectos de investigación de las instituciones que no cuenten con un Comité de Ética Institucional, deberán estar aprobados por un Comité de Ética de otra institución que haya sido evaluada y certificada en el cumplimento de las Buenas Prácticas Clínicas, documento expedido por el Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA.

Se deberá acoger los lineamientos nacionales e internacionales de Buenas Practicas Clínicas y el marco ético deberá basarse en los principios contemplados entre otros, en el Código de Ética de Nuremberg, la Declaración de Helsinki, el Informe Belmont y las pautas éticas internacionales para la investigación biomédica en seres humanos (CIOMS).

Todo Comité de Ética debe definir su código de conducta, su política de manejo de conflictos de interés y su funcionamiento debe ser consecuente con los mismos, de tal manera que se impida parcialidad o sesgos en los resultados del ejercicio del Comité.

A. Salvaguardar los derechos de los participantes en la investigación: El objetivo que el Comité de Ética debe tener como prioridad en la evaluación de los estudios de investigación –por encima de la factibilidad- es asegurar la protección de los derechos, la seguridad y el bienestar de los participantes.

Esto se tiene que hacer siempre que se reciba cualquier documento o cambio al proyecto de investigación. Las responsabilidades de dicho proceso recaen en primera instancia en el presidente del Comité de Ética.

B. Evaluar y aprobar o reprobar, antes de su inicio, las investigaciones propuestas: Para la evaluación y posterior aprobación o reprobación de las investigaciones propuestas, el Comité de Ética debe definir la metodología, las herramientas y los procedimientos previamente concertados para cumplir esta responsabilidad.

- **Primero:** El Comité debe establecer los criterios que tendrá en cuenta para la evaluación de los diferentes documentos que se analicen.
- **Segundo:** Definir de acuerdo a las competencias de los miembros, las funciones de los mismos respecto a la evaluación de los aspectos del proyecto.
- **Tercero:** Estandarizar procedimientos para la socialización de los resultados de la evaluación, seguimiento y vigilancia de las recomendaciones a los proyectos de Investigación, dentro de los tiempos establecidos según la normativa y las características del proyecto de investigación.
- **Cuarto:** Definir las medidas que se tomarán en caso de incumplimiento de sus decisiones.
- **Quinto:** El Comité debe precisar criterios para expresar potenciales conflictos de interés de sus integrantes, definir y registrar las medidas generadas.

C. Obtener y mantener la documentación requerida de cada estudio puesto a su consideración: El Comité de Ética debe tener un archivo de acceso restringido y con las condiciones adecuadas de seguridad y confidencialidad.

Por lo anterior es indispensable que exista una infraestructura que asegure el cumplimiento de esta responsabilidad, acatando las normas de archivo documental vigentes.

Se debe establecer el tiempo mínimo de custodia de la documentación y definirlo en el contrato que se suscriba con el centro de investigación.

Tener un personal calificado para la custodia y manejo del archivo, con estas funciones específicas.

El Comité de Ética puede tener un archivo magnético, siempre y cuando este cumpla con los criterios de seguridad y confidencialidad de la información, que no sean modificables posteriormente y que

además estén alineados con el sistema de gestión de calidad de la Institución a la que el Comité pertenezca.

D. Considerar la competencia de los investigadores: Establecer los criterios mínimos que debe cumplir el equipo investigador que va a desarrollar el proyecto de Investigación.

Estos criterios de evaluación deben tener en cuenta lo siguiente:

- La evaluación de las hojas de vida y los correspondientes soportes de todo el equipo investigador (investigador principal (IP), co-investigador o investigador secundario (IS), coordinador de estudios, personal técnico -(si lo hubiere)-, bacteriólogo y químico farmacéutico).

- Títulos profesionales (diploma con su respectiva acta de grado) y un documento que certifique que la IPS ha verificado el titulo profesional con la universidad respectiva, homologaciones de posgrados realizados en el exterior por parte de la entidad nacional competente, tarjeta profesional nacional y de la secretaria seccional de acuerdo a la profesión, certificaciones en buenas prácticas clínicas de dos años de vigencia, tipo de contratación laboral con el centro de investigación y contrato laboral que contemple las funciones con respecto al estudio, fotocopia de la cédula de ciudadanía actualizada o de extranjería.

- En la carta de sometimiento del Investigador Principal o Secundario al Comité de ética, se debe especificar el tiempo de dedicación al cual se compromete el investigador para realizar la investigación en el estudio y se debe nombrar el número de protocolos en los que realiza investigación, con el fin de que el Comité de Ética determine si el tiempo dedicado por parte del investigador es adecuado para realizar el estudio. Anexando los soportes respectivos de la hoja de vida. La responsabilidad de la aprobación de cada investigador (IP o IS) es del Comité de ética, por lo cual sólo se someterá al INVIMA el Investigador Principal.

- Evaluación investigadores: Las competencias del Investigador, deben ser acordes a la especialidad clínica del proyecto de investigación. Si el IP tiene la experiencia en investigación pero no cumple con la experiencia clínica asistencial relacionada con la especialidad, ésta puede ser complementada por el IS.

- Que la experiencia profesional clínica asistencial sea de un mínimo de 3 años.

- Que la experiencia en Investigación del IP, sea de un mínimo de 2 años.

- Se acepta por parte del INVIMA que un Investigador principal sea un profesional en el área de la salud especializado en un postgrado en investigación (epidemiologia, ensayista clínico, salud pública) y la experiencia mínima en la misma, siempre y cuando se encuentre apoyado por un IS con la especialidad clínica del tema del proyecto de investigación y que dentro de las funciones de este se encuentre la valoración clínica, aplicación de los criterios de inclusión, de exclusión, decisiones médicas y seguimiento clínico a los sujetos de investigación.

Equipo Investigador:

- **Coordinador de estudios:** Debe ser un profesional en el área de la salud, con experiencia en investigación, soportada en la capacitación, certificación en Buenas Prácticas Clínicas, actualizada y con vigencia de dos años.

- **Bacteriólogo:** Debe ser un profesional en bacteriología con certificación IATA (International Air Transport Association) vigente, certificación en buenas prácticas clínicas con vigencia de dos años y con tarjeta profesional vigente.

- **Químico Farmacéutico:** Debe ser un profesional en química farmacéutica, con tarjeta profesional del colegio de químicos farmacéuticos y de la secretaria seccional, con certificación en buenas prácticas clínicas con vigencia de dos años.

E. **Evaluar periódicamente el progreso de los estudios aprobados y en desarrollo:** Dentro de los procedimientos que se deben establecer se encuentra el seguimiento y evaluación periódica que debe tener el Comité de Ética definido antes de la aprobación inicial del proyecto de investigación.

7. COMPOSICIÓN

Debe ser un grupo multidisciplinario, el cual está en la capacidad de realizar un análisis profundo de los proyectos de investigación y elevar un criterio de aprobación sustentado en las competencias, profesionalismo y experiencia de sus miembros.

Todos los miembros del comité deben tener un sentido crítico de los aspectos propios del proyecto de investigación, el cual debe estar reflejado en las conclusiones que hace en cada uno de los documentos analizados.

Todos los miembros deben estar entrenados y certificados en las Buenas Prácticas Clínicas, certificación que tiene una vigencia de dos años.

A. Número de Miembros que debe tener un Comité de Ética: El número mínimo descrito en la normativa es de cinco miembros, pero es necesario contemplar los siguientes aspectos antes de definirlo.

- Debe garantizar todas las competencias mínimas necesarias para valorar un proyecto de Investigación.
- Debe estar de acuerdo al número de estudios que el Comité tenga en seguimiento, siempre garantizando que no exista alteración de su análisis por sobrecarga laboral.
- Pueden existir subcomités evaluadores que asumen algunos roles en la evaluación de los Proyectos de investigación sin poder de decisión.
- Los miembros del Comité deben disponer de un tiempo adecuado y suficiente para el análisis y la evaluación de las tareas establecidas.

B. Balance por género y edad: El balance de edad y de género debe existir entre los miembros del Comité de Ética.

C. Carácter multidisciplinario: El Comité debe tener un carácter multidisciplinario, por las características que se van a evaluar en un proyecto de investigación, pues los diferentes puntos de vista hacen del análisis una herramienta invaluable para ser lo más preciso en la decisión final de aprobación.

Es necesario que exista al menos un miembro cuya área primaria de interés sea un área no científica. Ésta es una competencia necesaria para tener un punto de vista diferente al médico o en general al personal del área de la salud.

Debe existir al menos un médico. Éste profesional debe ser una persona con la competencia y la experiencia en investigación, para la evaluación de los aspectos clínicos del Proyecto de Investigación. La evaluación clínica debe estar sustentada en la experiencia y en la medicina basada en la evidencia.

En la norma se especifica que "*debe existir al menos un miembro que sea independiente de la institución/sitio donde se llevará a cabo el estudio*". Por lo anterior se debe tener en cuenta que esta afirmación debe guardar la independencia propia del comité, evitando alguna subordinación laboral.

Adicional a las características descritas en la multidisciplinariedad del Comité, es claro que se requieren las siguientes competencias para la evaluación y seguimiento de un Proyecto de Investigación.

- Un miembro que tenga entrenamiento en bioética, para tener un criterio más preciso en la evaluación de un Proyecto de Investigación en éste aspecto.
- Un miembro que tenga entrenamiento en metodología de la investigación, para tener un criterio más preciso en la evaluación del protocolo en cuanto a sus características técnicas.
- Un miembro que tenga entrenamiento en epidemiología o alguna otra especialidad enfocada en la investigación, con experiencia en investigación clínica, revisión de tema y análisis de bases de datos; herramientas que son muy útiles en la evaluación de un proyecto de Investigación.
- Un miembro que sea de la rama del derecho, para asesorar al Comité de Ética en todos los aspectos legales que puedan surgir en la evaluación de un proyecto de investigación.
- Un miembro que sea químico farmacéutico, para asesorar en la evaluación de la parte farmacológica del proyecto de investigación y de la evaluación de los eventos adversos en lo que tiene que ver con las interacciones medicamentosas.
- Con respecto a los representantes de la comunidad, se debe garantizar que este personal también posea un criterio analítico pero siempre enfocado al punto de vista del participante de investigación y al proyecto de investigación. Seria apropiado si ha sido previamente un participante de algún estudio en investigación.

Todos los miembros anteriormente descritos, con la excepción del representante de la comunidad, pueden ser convocados bajo la figura de asesores externos o consultores y dependerá de cada comité si estos asesores externos tienen o no voz y voto.

Dentro de los miembros del Comité de Ética pueden existir investigadores de los proyectos de investigación que se evalúan u otros miembros del equipo investigador. Sin embargo, un investigador tiene la restricción para ser miembro del comité cuando:

- Es el Presidente del Comité
- Tiene conflictos de interés porque participe en el desarrollo de estudios evaluados por el Comité, o porque sus afiliaciones o relaciones impliquen parcialidad para el desarrollo de la evaluación por parte del Comité. Se debe tener en cuenta que si es el único IP o IS de la mayoría de estudios que el Comité lleva en seguimiento, no sería procedente perder un miembro del comité por impedimentos permanentes.
- Tiene algún interés desde el punto de vista laboral, personal, familiar, económico, social, religioso y/o académico con el patrocinador del estudio que este llevando a cabo el protocolo.
- No informa oportunamente si surge un conflicto de intereses en el ejercicio como miembro del Comité.

D. **Sobre la participación de consultores (cuando aplique):** La participación de los consultores externos se da por la formación específica de éstos en temas donde no se cuenta con el perfil dentro de los miembros del Comité para que realice el análisis de una propuesta de investigación que requiera de un concepto especializado en cualquier área.

Se debe asegurar la independencia de los consultores externos con relación a los patrocinadores o a cualquier otra entidad que genere conflictos de interés.

E. Requisitos y procesos para la selección de los miembros en cuanto a los siguientes aspectos: La(s) persona(s) encargadas de seleccionar los miembros del Comité debe(n) ser absolutamente independiente(s) de las personas encargadas de revisar la conveniencia y factibilidad del proyecto de investigación dentro del centro de investigación.

Por lo general, es mejor que este nombramiento sea propio del Comité de Ética y que exista un consenso general para la evaluación del nuevo miembro. Es fundamental que existan varios candidatos.

Es necesario que se definan cuales son los conflictos de interés e inhabilidades que se tendrán en cuenta para definir al candidato. A continuación se enumeran algunos de ellos:

- Hacer parte de una entidad o ser actor directo del proyecto de investigación (Patrocinador, Investigador o centro de investigación) o de cualquier otra entidad que tenga interés económico en el proyecto de investigación.
- Que se tenga un vínculo laboral, contractual, familiar o de asesoría con entidades que tengan intereses económicos en los proyectos de investigación a evaluar.

F. Condiciones del nombramiento de los miembros del comité:

- Estar de acuerdo en hacer pública alguna información personal para efectos legales.
- Tener establecidas para cada miembro, las funciones generales y las que debe cumplir durante la evaluación de cada estudio y el soporte de aceptación de las mismas.
- Estar de acuerdo en registrar y tener disponible la información referente a los pagos y reembolsos recibidos por su trabajo como miembros del Comité (si los hay).
- Firmar un acuerdo de confidencialidad por parte de cada uno de los miembros del Comité sobre todos los temas tratados en cada sesión y en la información general del Comité.
- Registrar conocimiento de política de conflicto de interés y código de conducto del Comité.

G. Términos de la membrecía: Se debe contemplar dentro de los estatutos un periodo de nombramiento, que puede ser de dos (2) años prorrogables de acuerdo a las políticas definidas dentro de cada Comité de Ética.

Se deben tener contempladas, dentro de los procedimientos del Comité, las políticas sobre la descalificación, sustitución de los miembros del Comité y renuncia, las cuales deben incluir entre otros factores: los conflictos de interés, la inhabilidad con sus violaciones, así como los eventos que puedan afectar la participación de un miembro dentro del Comité (incapacidades, carga laboral, capacitaciones etc.).

Deben ser verificables los registros de declaración de conflictos de interés de los miembros del Comité, así como las acciones generadas.

Además, se deben definir las responsabilidades y las funciones de acuerdo al cargo que se ocupa dentro del Comité:

Presidente.

- Presidir las reuniones y será el vocero del comité para su socialización.
- Firmar las actas, correspondencia, formato de consentimiento informado y el formato establecido por el INVIMA para el sometimiento de Instituciones, Protocolos nuevos y demás documentos relacionados.
- Ser el vocero ante el INVIMA de las decisiones, inquietudes, medidas y preguntas que se tengan dentro de un proyecto de investigación.
- Asignar las funciones a los miembros del Comité.

Secretario.
Coordinar la entrega oportuna y de acuerdo a las competencias, de toda la correspondencia y documentos que serán sometidos a evaluación a cada uno de los miembros del Comité.

Se tiene que aclarar que puede existir el secretario en propiedad del Comité de Ética que puede tener voz y voto y el Secretario administrativo con un perfil técnico para el manejo del archivo y la correspondencia, quién no tiene voz ni voto, funciones que deberán ser definidas para cada uno de los casos.

Miembro Activo.
Deberá cumplir las funciones que le sean asignadas por parte del Presidente del Comité de ética dentro del Comité, como las funciones dentro de la evaluación del estudio.

H. Requisitos sobre quórum para sesionar y deliberar: Se debe establecer el número de miembros requeridos para sesionar y el número mínimo, las disciplinas y las calificaciones para cumplimiento del quórum. Estas directrices deben ser definidas por el presidente del Comité.

El quórum mínimo podría establecerse de la siguiente manera:

- Debe ser la mitad mas uno (1)
- Ser de cinco miembros mínimo.
- Debe estar el Presidente
- Debe estar por lo menos un miembro médico
- Debe estar por lo menos un miembro no científico
- Debe estar el Representante de la comunidad.

Consideraciones:
No se recomienda sesionar un proyecto de investigación nuevo con el quórum mínimo o cualquier otro sometimiento en donde en la evaluación se sospeche daño al participante de investigación.

En caso de ausencia del Presidente del Comité, debe existir un presidente encargado que asuma las funciones propias del cargo para esa sesión.

I. Descripción del entrenamiento o capacitación que deben tener los miembros del Comité.

Debe existir un programa de capacitación continua en temas de investigación tales como:

- Metodología de la investigación
- Bioética en investigación
- Análisis de bases de datos
- Consentimiento Informado
- Actualización en Buenas Prácticas Clínicas
- Normativa en Investigación
- Interacciones Medicamentosas
- Eventos adversos en los proyectos de investigación.

II. Código de Conducta, Política de conflictos de intereses y Política de confidencialidad

Existen situaciones que pueden generar un potencial conflicto de interés por parte de los miembros del Comité y por tanto sesgar el desarrollo idóneo de las funciones del mismo. Estas situaciones deben declararse y comunicarse oportunamente con el fin de generar acciones pertinentes, como la abstención

de evaluación y seguimiento de estudios específicos. A su vez el Comité deberá establecer y documentar cómo manejar la situación.

Algunas circunstancias que generan conflicto de interés para los miembros del Comité se mencionan a continuación: Vínculos laborales con el patrocinador tales como consultorías o acuerdos de asesorías, participación simultánea como miembro evaluador del Comité y como investigador de estudios de investigación, propiedad de valores de firmas involucradas en estudios sometidos a evaluación del Comité, relación de familia conocida con participantes y responsables del estudio en evaluación, relación de negocios con participantes y responsables del estudio en evaluación, relación pasada o presente con participantes y responsables del estudio en evaluación, relaciones tal como amistad, personal, cercana o enemistad que pudieran afectar el juicio del evaluador, entre otras.

La membresía al Comité permite acceso a información con restricciones de publicación, por lo cual debe considerarse una política de confidencialidad que impida el uso de la información reservada.

8. PROCEDIMIENTO

A. Autoridad institucional bajo la cual se encuentra establecido el Comité

Se debe definir bajo qué autoridad dentro del Centro de Investigación (Institución) se encuentra constituido el Comité de Ética en Investigación.

Para definir la subordinación es necesario aclarar que el Comité de Ética es la máxima autoridad en el centro de investigación en lo que tiene que ver con el mantenimiento de la seguridad del participante de investigación.

Por lo anterior el Comité siempre debe estar encima en el mapa de procesos, de los encargados de aprobar, revisar y definir la factibilidad financiera dentro de la institución, tal como: el investigador, oficina financiera, dirección clínica o científica (si estas dos oficinas tienen esta función).

Debe estar como ente asesor del representante legal pero nunca subordinado él.

B. Si se encuentra libre de subordinación directa de esa autoridad para deliberar y decidir.

Es necesario que la independencia del Comité de ética sea absoluta no solo desde el punto de vista legal, sino también en sus conceptos y decisiones, los cuales deben ser acatados por todos los actores dentro de la organización a la que pertenecen.

C. La metodología que sigue el Comité para evaluar las propuestas, debe estar establecida por escrito y especificar como mínimo:

- El Procedimiento debe estar en las Guías Operativas del Comité de acuerdo al Sistema de Gestión de la Calidad.
- Debe incluir un listado de los documentos mínimos que se van a someter.
- Debe tener una herramienta (lista de chequeo, bitácora, etc.) que permita evaluar todos los documentos del proyecto de investigación. Esta herramienta deberá tener una lista de chequeo que contemple los criterios de evaluación de los documentos y tener un espacio que sea de obligatorio diligenciamiento en donde el miembro evaluador exponga sus puntos de vista. Se recomienda tener una de estas herramientas aparte para cada uno de los documentos.

D. Documentos mínimos que se deben evaluar por cada proyecto de investigación

- **Manual del Investigador:** El propósito general de este documento es facilitar al investigador un conocimiento claro de los posibles riesgos y reacciones adversas, así como de las pruebas específicas, observaciones y precauciones que pueden ser necesarias en un ensayo clínico.

  Éste documento debe contener toda la información disponible sobre datos de seguridad, farmacodinamia, farmacocinética, toxicidad, teratogenicidad, propiedades físicas y químicas, etc de la molécula en investigación, además de información confiable de estudios preclínicos (farmacológicos y no farmacológicos) y clínicos previos que justifiquen el uso de la molécula en seres humanos. Así mismo debe plasmar la información de los estudios clínicos fase I, II, III (de haberlos, según sea el caso), interacciones medicamentosas, efectos secundarios, reacciones adversas, todo enfocado a la protección del participante.

- **Hoja de vida del equipo investigador.**

- **Protocolo de investigación:** Se deben evaluar los aspectos que implican la calidad técnica del protocolo de investigación, así como su posterior desarrollo dentro del sitio de investigación.

  Hay que tener en cuenta, aspectos como: la socialización del estudio, las barreras de acceso, los factores económicos que puedan afectar al participante de investigación, el método de aleatorización, cegamiento, confidencialidad de la información, método estadístico y la factibilidad del proyecto de la investigación (posibilidad de alcanzar las conclusiones esperadas, balance de beneficio/riesgo e inconvenientes para los participantes, financiación y recursos necesarios) entre otros documentos. Dentro del protocolo también es necesario revisar los mecanismos (de haberlos) con los que se pretende compensar o retribuir la participación de los sujetos.

- **Consentimiento Informado:** En este documento se deben evaluar aspectos como materiales y métodos que van a ser utilizados para obtener el consentimiento informado de los participantes en el estudio. Así mismo se debe obtener un consentimiento informado dado libremente de cada sujeto, previamente a su participación en el estudio, que se encuentre con letra clara, legible, adecuada para el nivel sociocultural donde se va aplicar, con un volumen adecuado, completo, que no tenga ambigüedades, que se explique el cubrimiento de la atención de eventos adversos, información pertinente a la investigación, consideraciones con respecto a poblaciones vulnerables, tiempo presupuestado para la toma del consentimiento informado, personas que deberían ser las testigos y todo lo contemplado en la Resolución 8430 del 1993.

  Es importante tener en cuenta que la participación de menores de edad debe seguir los lineamientos establecidos en la Resolución 8430 del 1993.

  Igualmente debe evaluarse el consentimiento informado para muestras genéticas, en la que el patrocinador especifique la utilización de dichas muestras, el tiempo de conservación y el manejo de la confidencialidad de esta información.

- **Anuncios de reclutamiento y materiales entregados a los participantes:** Estos documentos y sus equivalentes se deben analizar siempre pensando en el bienestar y la confidencialidad del sujeto de investigación.

- **Presupuesto del Estudio**: El Comité de Ética deberá verificar en el presupuesto que se tendrá contemplado para la realización del protocolo, que todos los gastos que tienen que ver con el proyecto de investigación sean cubiertos por el mismo presupuesto del estudio y que no se recurrirá a los recursos propios del participante de investigación, contemplando el presupuesto destinado a alimentación y transporte para el participante del estudio, si aplica.

- **Póliza de seguros para los participantes:** El comité deberá verificar que la póliza se encuentre vigente, el cual cubra los eventos adversos del estudio, indemnizaciones en caso de muerte y además deberá verificar la accesibilidad de dicha póliza.

- **Contrato:** Debe existir un acuerdo contractual entre el patrocinador y la institución/investigador, el cual debe estar firmado por el representante legal de cada una de las partes, documento que debe incluir aspectos como: término del contrato, presupuesto y forma de pago, responsabilidades de las partes, confidencialidad, seguro o indemnización, conflictos de interés, medidas o sanciones en caso de incumplimiento, tiempo de conservación del archivo, entre otros.

  Igualmente, los pactos realizados entre otras partes implicadas en el ensayo clínico deben constar por escrito, entre la institución y servicios contratados como son el comité de ética, laboratorio clínico u otros servicios contratados.

- Se debe definir de acuerdo al perfil del miembro del Comité de Ética quien debe evaluar cada uno de los documentos del proyecto de investigación. Este procedimiento dependerá también del tiempo de evaluación de cada documento y la carga laboral de cada uno de los miembros. Estas funciones deben ser definidas por el Presidente del Comité o por quien él delegue, como también los documentos mínimos que cada miembro deberá evaluar.

Debe existir un soporte documental de dicha evaluación, el cual debe contener las consideraciones y opiniones de cada uno de los evaluadores. Todos los miembros del comité deberán participar activamente dentro de la evaluación del proyecto de investigación.

Se debe considerar un tiempo máximo de evaluación de cada uno de los documentos; este tiempo debe estar coordinado con el cronograma de reuniones. Se debe establecer el método predefinido para alcanzar una decisión (por consenso, por votación) y los mecanismos de decisión cuando no se logra un consenso, los cuales pueden ser citación al investigador, patrocinador o consultor externo para ampliación de información. En caso de que uno o más miembros declaren tener conflictos de intereses, se debe definir una Política de restricciones para establecer los mecanismos de cómo estas personas podrán participar en la evaluación de las propuestas.

E. El comité debe establecer los requisitos y los mecanismos para realizar una aprobación expedita/extraordinaria, que incluya:

- Los estudios que pueden ser evaluados mediante este tipo de aprobación.
- Tener claro que este procedimiento es aceptable únicamente para aquellos estudios y/o procedimientos que conlleven solo un riesgo mínimo para el sujeto de investigación.
- El procedimiento a seguir para la revisión
- El mecanismo para la ratificación por parte del comité de la decisión tomada en forma expedita.
- Esta excluida la aprobación de estudios con medicamentos por primera vez.

F. El Comité debe notificar por escrito dentro de un periodo de dos semanas después de la reunión al investigador las decisiones tomadas respecto al proyecto sometido a evaluación. Esta notificación debe incluir, como mínimo:

- Identificación del estudio.
- Documentos estudiados.
- Fecha de evaluación y número del acta de la sesión correspondiente.
- Decisiones u opiniones relacionadas con el estudio.
- Motivos de las decisiones, en especial en caso de reprobación.

- Procedimientos que debe seguir el investigador para someter el proyecto a reconsideración.

G. El Comité debe contar con medidas tendientes a asegurar el éxito de sus sesiones. Estas incluyen:

- Programar las sesiones del Comité con la debida anterioridad.
- Notificar oportunamente a los miembros.
- Enviar a cada miembro previamente los documentos necesarios para la sesión.
- Consignar en un acta lo discutido y decidido.
- Conservar el archivo de las actas.
- Mantener los archivos de correspondencia a los miembros del Comité.

H. Deben especificarse por escrito los procedimientos establecidos por el Comité para seguir el curso de los estudios desde su aprobación hasta su terminación.

El Comité debe contar con un procedimiento para realizar el seguimiento a cada uno de los proyectos de investigación que sean sometidos a su consideración.

Cuando el Comité aprueba el proyecto de investigación por primera vez, debe definir en esa aprobación y teniendo en cuenta las características propias del estudio, cada cuanto el Investigador debe reportarle los avances. Este reporte debe hacerse por lo menos una vez al año según la regulación nacional, pero el Comité está en la libertad de establecer un tiempo menor de acuerdo al caso.

Para el Informe periódico se debe tener en cuenta como mínimo lo siguiente: número de sujetos reclutados, última versión del proyecto, resumen de eventos adversos, resumen de problemas no anticipados, resumen de nueva información disponible y copia del consentimiento actual.

El comité debe tener establecido un mecanismo de auditorías de evaluación a los centros de investigación en donde se llevan a cabo los estudios sometidos. La periodicidad es establecida libremente por el Comité pero debe ser predefinida de acuerdo al tipo de estudio. Para estas auditorías se debe diseñar un formato de auditoría que incluya todos los aspectos que se encuentran en la norma adicionando los criterios propios del comité. En estas auditorías se debe revisar entre otros, lo siguiente: el avance de los estudios sometidos, la evaluación de los eventos adversos serios, las desviaciones y violaciones presentadas al protocolo, la tasa de reclutamiento y la meta propuesta de reclutamiento.

I. El comité debe establecer procedimientos y medidas en caso de encontrar irregularidades.

Se deben definir las medidas que se van a tomar en caso de encontrar irregularidades en la conducción de los Proyectos de Investigación. Las acciones que pueden generar dichas medidas, son entre otras:

- Inclusión de participantes en un estudio antes de que el comité emita su aprobación por escrito.
- Implementar sin previo aviso cambios – enmiendas en el proyecto.
- Incumplimiento en la presentación de los informes para el seguimiento de los proyectos.
- La ausencia de notificación, por parte del investigador, de las desviaciones al proyecto y de las reacciones o eventos adversos.
- Que el investigador no notifique sobre nueva información que pueda afectar la seguridad de los participantes o la conducción del estudio.

Se debe informar a los investigadores sobre las sanciones que ocasionan el incumplimiento de este numeral.

El Comité de Ética por su constitución no puede tomar medidas judiciales de carácter sanitario contra el Centro de Investigación, ni contra el Investigador o el patrocinador del estudio, pero si puede imponer

sanciones cuando en defensa de la protección del bienestar de los participantes de investigación, lo considere necesario. Estas sanciones pueden ser entre otras:

- Llamado de atención
- Amonestación
- Suspensión de la Aprobación del Proyecto de investigación, medida que genera inmediatamente remisión o reporte al ente regulador (INVIMA) y al patrocinador.

9. CONSIDERACIONES ACERCA DEL COMITÉ DE ÉTICA

Dentro de las consideraciones acerca del Comité de Ética se debe establecer lo siguiente:

El Comité de Ética es la máxima autoridad en lo relacionado con la seguridad del participante de investigación; por lo tanto, no estará sometido a ninguna influencia externa y todos los actores (patrocinador, centro de investigación, grupo investigador) deberán acatar las decisiones y/o medidas que de él se generen.

En caso de que no se acaten dichas decisiones, el Comité tendrá el apoyo y la obligación de reportar dichas irregularidades al INVIMA. El Comité, en virtud de su composición y competencia, puede refutar los análisis, decisiones y cambios en el proyecto de investigación, que de acuerdo a su criterio afecte la seguridad del participante en el centro que está avalando. De acuerdo a lo anterior el Comité puede definir la calificación de un evento adverso no serio a un evento adverso serio por encima del criterio del investigador, siempre y cuando esta decisión afecte al participante.

En caso de desviaciones o violaciones cometidas por el investigador principal, el Comité de Ética es quien establece si este reporte es adecuado, de acuerdo a lo contemplado en el protocolo y a la seguridad del participante.
El Comité debe tener un Presupuesto con recursos propios, bien sea generado por el centro de investigación al cuál se encuentre adscrito, o por recursos derivados de sus servicios. Este presupuesto debe ser manejado soberanamente por el Comité, el cual puede hacerse público y debe tener rubros destinados para el funcionamiento rutinario, papelería, mantenimiento de oficina, recurso humano, manejo de archivo, capacitaciones y, si se tiene contemplado, el pago de honorarios de sus miembros.

El comité de ética no debe recibir directamente presupuesto del patrocinador, éste deberá ser manejado por la institución certificada por lo cual en el contrato entre el Comité de ética y la institución se deberá especificar como es el pago de honorarios, cuando aplique.

LEY ORGANICA DE SALUD.
Ley 67, Registro Oficial Suplemento 423 de 22 de Diciembre del 2006.

EL CONGRESO NACIONAL

Considerando:

Que el numeral 20 del artículo 23 de la Constitución Política de la República, consagra la salud como un derecho humano fundamental y el Estado reconoce y garantiza a las personas el derecho a una calidad de vida que asegure la salud, alimentación y nutrición, agua potable, saneamiento ambiental,...;

Que el artículo 42 de la Constitución Política de la República, dispone que "El Estado garantizará el derecho a la salud, su promoción y protección, por medio del desarrollo de la seguridad alimentaria, la provisión de agua potable y saneamiento básico, el fomento de ambientes saludables en lo familiar, laboral y comunitario, y la posibilidad de acceso permanente e ininterrumpido a servicios de salud, conforme a los principios de equidad, universalidad, solidaridad, calidad y eficiencia.";

Que el Código de la Salud aprobado en 1971, contiene disposiciones desactualizadas en relación a los avances en salud pública, en derechos humanos, en ciencia y tecnología, a la situación de salud y enfermedad de la población, entre otros;

Que el actual Código de la Salud ha experimentado múltiples reformas parciales que lo han convertido en un cuerpo legal disperso y desintegrado;

Que ante los actuales procesos de reforma del Estado, del sector salud y de globalización, en los que se encuentra inmerso nuestro país, la legislación debe priorizar los intereses de la salud de la población por sobre los comerciales y económicos;

Que el Ecuador ha ratificado convenios y tratados internacionales que determinan compromisos importantes del país en diferentes materias como derechos humanos, derechos sexuales y reproductivos, derechos de niños, niñas y adolescentes, entre otros;

Que se hace necesario actualizar conceptos normativos en salud, mediante la promulgación de una ley orgánica que garantice la supremacía sobre otras leyes en esta materia; y,

En ejercicio de sus facultades constitucionales y legales expide la siguiente:.

LEY ORGANICA DE SALUD

TITULO PRELIMINAR

CAPITULO I
Del derecho a la salud y su protección

Art. 1.- La presente Ley tiene como finalidad regular las acciones que permitan efectivizar el derecho universal a la salud consagrado en la Constitución Política de la República y la ley. Se rige por los principios de equidad, integralidad, solidaridad, universalidad, irrenunciabilidad, indivisibilidad, participación, pluralidad, calidad y eficiencia; con enfoque de derechos, intercultural, de género, generacional y bioético.

Art. 2.- Todos los integrantes del Sistema Nacional de Salud para la ejecución de las actividades relacionadas con la salud, se sujetarán a las disposiciones de esta Ley, sus reglamentos y las normas establecidas por la autoridad sanitaria nacional.

Art. 3.- La salud es el completo estado de bienestar físico, mental y social y no solamente la ausencia de afecciones o enfermedades. Es un derecho humano inalienable, indivisible, irrenunciable e intransigible, cuya

protección y garantía es responsabilidad primordial del Estado; y, el resultado de un proceso colectivo de interacción donde Estado, sociedad, familia e individuos convergen para la construcción de ambientes, entornos y estilos de vida saludables.

CAPITULO II
De la autoridad sanitaria nacional, sus competencias y Responsabilidades

Art. 4.- La autoridad sanitaria nacional es el Ministerio de Salud Pública, entidad a la que corresponde el ejercicio de las funciones de rectoría en salud; así como la responsabilidad de la aplicación, control y vigilancia del cumplimiento de esta Ley; y, las normas que dicte para su plena vigencia serán obligatorias.

Art. 5.- La autoridad sanitaria nacional creará los mecanismos regulatorios necesarios para que los recursos destinados a salud provenientes del sector público, organismos no gubernamentales y de organismos internacionales, cuyo beneficiario sea el Estado o las instituciones del sector público, se orienten a la implementación, seguimiento y evaluación de políticas, planes, programas y proyectos, de conformidad con los requerimientos y las condiciones de salud de la población.

Art. 6.- Es responsabilidad del Ministerio de Salud Pública:

1. Definir y promulgar la política nacional de salud con base en los principios y enfoques establecidos en el artículo 1 de esta Ley, así como aplicar, controlar y vigilar su cumplimiento;
2. Ejercer la rectoría del Sistema Nacional de Salud;
3. Diseñar e implementar programas de atención integral y de calidad a las personas durante todas las etapas de la vida y de acuerdo con sus condiciones particulares;
4. Declarar la obligatoriedad de las inmunizaciones contra determinadas enfermedades, en los términos y condiciones que la realidad epidemiológica nacional y local requiera; definir las normas y el esquema básico nacional de inmunizaciones; y, proveer sin costo a la población los elementos necesarios para cumplirlo;
5. Regular y vigilar la aplicación de las normas técnicas para la detección, prevención, atención integral y rehabilitación, de enfermedades transmisibles, no transmisibles, crónico-degenerativas, discapacidades y problemas de salud pública declarados prioritarios, y determinar las enfermedades transmisibles de notificación obligatoria, garantizando la confidencialidad de la información;
6. Formular e implementar políticas, programas y acciones de promoción, prevención y atención integral de salud sexual y salud reproductiva de acuerdo al ciclo de vida que permitan la vigencia, respeto y goce de los derechos, tanto sexuales como reproductivos, y declarar la obligatoriedad de su atención en los términos y condiciones que la realidad epidemiológica nacional y local requiera;
7. Establecer programas de prevención y atención integral en salud contra la violencia en todas sus formas, con énfasis en los grupos vulnerables;
8. Regular, controlar y vigilar la donación, obtención, procesamiento, almacenamiento, distribución, transfusión, uso y calidad de la sangre humana, sus componentes y derivados, en instituciones y organismos públicos y privados, con y sin fines de lucro, autorizados para ello;
9. Regular y controlar el funcionamiento de bancos de células, tejidos y sangre; plantas industriales de hemoderivados y establecimientos de aféresis, públicos y privados; y, promover la creación de éstos en sus servicios de salud;
10. Emitir políticas y normas para regular y evitar el consumo del tabaco, bebidas alcohólicas y otras sustancias que afectan la salud;
11. Determinar zonas de alerta sanitaria, identificar grupos poblacionales en grave riesgo y solicitar la declaratoria del estado de emergencia sanitaria, como consecuencia de epidemias, desastres u otros que pongan en grave riesgo la salud colectiva;

12. Elaborar el plan de salud en gestión de riesgos en desastres y en sus consecuencias, en coordinación con la Dirección Nacional de Defensa Civil y demás organismos competentes;

13. Regular, vigilar y tomar las medidas destinadas a proteger la salud humana ante los riesgos y daños que pueden provocar las condiciones del ambiente;

14. Regular, vigilar y controlar la aplicación de las normas de bioseguridad, en coordinación con otros organismos competentes;

15. Regular, planificar, ejecutar, vigilar e informar a la población sobre actividades de salud concernientes a la calidad del agua, aire y suelo; y, promocionar espacios y ambientes saludables, en coordinación con los organismos seccionales y otros competentes;

16. Regular y vigilar, en coordinación con otros organismos competentes, las normas de seguridad y condiciones ambientales en las que desarrollan sus actividades los trabajadores, para la prevención y control de las enfermedades ocupacionales y reducir al mínimo los riesgos y accidentes del trabajo;

17. Regular y vigilar las acciones destinadas a eliminar y controlar la proliferación de fauna nociva para la salud humana;

18. Regular y realizar el control sanitario de la producción, importación, distribución, almacenamiento, transporte, comercialización, dispensación y expendio de alimentos procesados, medicamentos y otros productos para uso y consumo humano; así como los sistemas y procedimientos que garanticen su inocuidad, seguridad y calidad, a través del Instituto Nacional de Higiene y Medicina Tropical Dr. Leopoldo Izquieta Pérez y otras dependencias del Ministerio de Salud Pública;

19. Dictar en coordinación con otros organismos competentes, las políticas y normas para garantizar la seguridad alimentaria y nutricional, incluyendo la prevención de trastornos causados por deficiencia de micro nutrientes o alteraciones provocadas por desórdenes alimentarios, con enfoque de ciclo de vida y vigilar el cumplimiento de las mismas;

20. Formular políticas y desarrollar estrategias y programas para garantizar el acceso y la disponibilidad de medicamentos de calidad, al menor costo para la población, con énfasis en programas de medicamentos genéricos;

21. Regular y controlar toda forma de publicidad y promoción que atente contra la salud e induzcan comportamientos que la afecten negativamente;

22. Regular, controlar o prohibir en casos necesarios, en coordinación con otros organismos competentes, la producción, importación, comercialización, publicidad y uso de sustancias tóxicas o peligrosas que constituyan riesgo para la salud de las personas;

23. Regular, vigilar y controlar en coordinación con otros organismos competentes, la producción y comercialización de los productos de uso y consumo animal y agrícola que afecten a la salud humana;

24. Regular, vigilar, controlar y autorizar el funcionamiento de los establecimientos y servicios de salud, públicos y privados, con y sin fines de lucro, y de los demás sujetos a control sanitario;

25. Regular y ejecutar los procesos de licenciamiento y certificación; y, establecer las normas para la acreditación de los servicios de salud;

26. Establecer políticas para desarrollar, promover y potenciar la práctica de la medicina tradicional, ancestral y alternativa; así como la investigación, para su buena práctica;

27. Determinar las profesiones, niveles técnicos superiores y auxiliares de salud que deben registrarse para su ejercicio;

28. Diseñar en coordinación con el Ministerio de Educación y Cultura y otras organizaciones competentes, programas de promoción y educación para la salud, a ser aplicados en los establecimientos educativos estatales, privados, municipales y fiscomisionales;

29. Desarrollar y promover estrategias, planes y programas de información, educación y comunicación social en salud, en coordinación con instituciones y organizaciones competentes;

30. Dictar, en su ámbito de competencia, las normas sanitarias para el funcionamiento de los locales y establecimientos públicos y privados de atención a la población;

31. Regular, controlar y vigilar los procesos de donación y trasplante de órganos, tejidos y componentes anatómicos humanos y establecer mecanismos que promuevan la donación voluntaria; así como regular, controlar y vigilar el uso de órtesis, prótesis y otros implantes sintéticos en el cuerpo humano;

32. Participar, en coordinación con el organismo nacional competente, en la investigación y el desarrollo de la ciencia y tecnología en salud, salvaguardando la vigencia de los derechos humanos, bajo principios bioéticos;

33. Emitir las normas y regulaciones sanitarias para la instalación y funcionamiento de cementerios, criptas, crematorios, funerarias, salas de velación y tanatorios;

34. Cumplir y hacer cumplir esta Ley, los reglamentos y otras disposiciones legales y técnicas relacionadas con la salud, así como los instrumentos internacionales de los cuales el Ecuador es signatario.

Estas acciones las ejecutará el Ministerio de Salud Pública, aplicando principios y procesos de desconcentración y descentralización; y,

35. Las demás previstas en la Constitución Política de la República y otras leyes.

CAPITULO III
Derechos y deberes de las personas y del Estado en relación con la salud

Art. 7.- Toda persona, sin discriminación por motivo alguno, tiene en relación a la salud, los siguientes derechos:

a) Acceso universal, equitativo, permanente, oportuno y de calidad a todas las acciones y servicios de salud;

b) Acceso gratuito a los programas y acciones de salud pública, dando atención preferente en los servicios de salud públicos y privados, a los grupos vulnerables determinados en la Constitución Política de la República;

c) Vivir en un ambiente sano, ecológicamente equilibrado y libre de contaminación;

d) Respeto a su dignidad, autonomía, privacidad e intimidad; a su cultura, sus prácticas y usos culturales; así como a sus derechos sexuales y reproductivos;

e) Ser oportunamente informada sobre las alternativas de tratamiento, productos y servicios en los procesos relacionados con su salud, así como en usos, efectos, costos y calidad; a recibir consejería y asesoría de personal capacitado antes y después de los procedimientos establecidos en los protocolos médicos. Los integrantes de los pueblos indígenas, de ser el caso, serán informados en su lengua materna;

f) Tener una historia clínica única redactada en términos precisos, comprensibles y completos; así como la confidencialidad respecto de la información en ella contenida y a que se le entregue su epicrisis;

g) Recibir, por parte del profesional de la salud responsable de su atención y facultado para prescribir, una receta que contenga obligatoriamente, en primer lugar, el nombre genérico del medicamento prescrito;

h) Ejercer la autonomía de su voluntad a través del consentimiento por escrito y tomar decisiones respecto a su estado de salud y procedimientos de diagnóstico y tratamiento, salvo en los casos de urgencia, emergencia o riesgo para la vida de las personas y para la salud pública;

i) Utilizar con oportunidad y eficacia, en las instancias competentes, las acciones para tramitar quejas y reclamos administrativos o judiciales que garanticen el cumplimiento de sus derechos; así como la reparación e indemnización oportuna por los daños y perjuicios causados, en aquellos casos que lo ameriten;

j) Ser atendida inmediatamente con servicios profesionales de emergencia, suministro de medicamentos e insumos necesarios en los casos de riesgo inminente para la vida, en cualquier establecimiento de salud público o privado, sin requerir compromiso económico ni trámite administrativo previos;

k) Participar de manera individual o colectiva en las actividades de salud y vigilar el cumplimiento de las acciones en salud y la calidad de los servicios, mediante la conformación de veedurías ciudadanas u otros mecanismos de participación social; y, ser informado sobre las medidas de prevención y mitigación de las amenazas y situaciones de vulnerabilidad que pongan en riesgo su vida; y,

l) No ser objeto de pruebas, ensayos clínicos, de laboratorio o investigaciones, sin su conocimiento y consentimiento previo por escrito; ni ser sometida a pruebas o exámenes diagnósticos, excepto cuando la ley

expresamente lo determine o en caso de emergencia o urgencia en que peligre su vida.

Art. 8.- Son deberes individuales y colectivos en relación con la salud:

a) Cumplir con las medidas de prevención y control establecidas por las autoridades de salud;
b) Proporcionar información oportuna y veraz a las autoridades de salud, cuando se trate de enfermedades declaradas por la autoridad sanitaria nacional como de notificación obligatoria y responsabilizarse por acciones u omisiones que pongan en riesgo la salud individual y colectiva;
c) Cumplir con el tratamiento y recomendaciones realizadas por el personal de salud para su recuperación o para evitar riesgos a su entorno familiar o comunitario;
d) Participar de manera individual y colectiva en todas las actividades de salud y vigilar la calidad de los servicios mediante la conformación de veedurías ciudadanas y contribuir al desarrollo de entornos saludables a nivel laboral, familiar y comunitario; y,
e) Cumplir las disposiciones de esta Ley y sus reglamentos.

Art. 9.- Corresponde al Estado garantizar el derecho a la salud de las personas, para lo cual tiene, entre otras, las siguientes responsabilidades:

a) Establecer, cumplir y hacer cumplir las políticas de Estado, de protección social y de aseguramiento en salud a favor de todos los habitantes del territorio nacional;
b) Establecer programas y acciones de salud pública sin costo para la población;
c) Priorizar la salud pública sobre los intereses comerciales y económicos;
d) Adoptar las medidas necesarias para garantizar en caso de emergencia sanitaria, el acceso y disponibilidad de insumos y medicamentos necesarios para afrontarla, haciendo uso de los mecanismos previstos en los convenios y tratados internacionales y la legislación vigente;
e) Establecer a través de la autoridad sanitaria nacional, los mecanismos que permitan a la persona como sujeto de derechos, el acceso permanente e ininterrumpido, sin obstáculos de ninguna clase a acciones y servicios de salud de calidad;
f) Garantizar a la población el acceso y disponibilidad de medicamentos de calidad a bajo costo, con énfasis en medicamentos genéricos en las presentaciones adecuadas, según la edad y la dotación oportuna, sin costo para el tratamiento del VIH-SIDA y enfermedades como hepatitis, dengue, tuberculosis, malaria y otras transmisibles que pongan en riesgo la salud colectiva;
g) Impulsar la participación de la sociedad en el cuidado de la salud individual y colectiva; y, establecer mecanismos de veeduría y rendición de cuentas en las instituciones públicas y privadas involucradas;
h) Garantizar la asignación fiscal para salud, en los términos señalados por la Constitución Política de la República, la entrega oportuna de los recursos y su distribución bajo el principio de equidad; así como los recursos humanos necesarios para brindar atención integral de calidad a la salud individual y colectiva; e,
i) Garantizar la inversión en infraestructura y equipamiento de los servicios de salud que permita el acceso permanente de la población a atención integral, eficiente, de calidad y oportuna para responder adecuadamente a las necesidades epidemiológicas y comunitarias.

LIBRO I
De las acciones de salud

TITULO I

CAPITULO I
Disposiciones comunes

Art. 10.- Quienes forman parte del Sistema Nacional de Salud aplicarán las políticas, programas y normas de atención integral y de calidad, que incluyen acciones de promoción, prevención, recuperación, rehabilitación y

cuidados paliativos de la salud individual y colectiva, con sujeción a los principios y enfoques establecidos en el artículo 1 de esta Ley.

Art. 11.- Los programas de estudio de establecimientos de educación pública, privada, municipales y fiscomicionales, en todos sus niveles y modalidades, incluirán contenidos que fomenten el conocimiento de los deberes y derechos en salud, hábitos y estilos de vida saludables, promuevan el auto cuidado, la igualdad de género, la corresponsabilidad personal, familiar y comunitaria para proteger la salud y el ambiente, y desestimulen y prevengan conductas nocivas.

La autoridad sanitaria nacional, en coordinación con el Ministerio de Educación y Cultura, vigilará que los establecimientos educativos públicos, privados, municipales y fiscomisionales, así como su personal, garanticen el cuidado, protección, salud mental y física de sus educandos.

Art. 12.- La comunicación social en salud estará orientada a desarrollar en la población hábitos y estilos de vida saludables, desestimular conductas nocivas, fomentar la igualdad entre los géneros, desarrollar conciencia sobre la importancia del autocuidado y la participación ciudadana en salud.

Los medios de comunicación social, en cumplimiento de lo previsto en la ley, asignarán espacios permanentes, sin costo para el Estado, para la difusión de programas y mensajes educativos e informativos en salud dirigidos a la población, de acuerdo a las producciones que obligatoriamente, para este efecto, elaborará y entregará trimestralmente la autoridad sanitaria nacional.

La autoridad sanitaria nacional regulará y controlará la difusión de programas o mensajes, para evitar que sus contenidos resulten nocivos para la salud física y psicológica de las personas, en especial de niños, niñas y adolescentes.

Art. 13.- Los planes y programas de salud para los grupos vulnerables señalados en la Constitución Política de la República, incorporarán el desarrollo de la autoestima, promoverán el cumplimiento de sus derechos y se basarán en el reconocimiento de sus necesidades particulares por parte de los integrantes del Sistema Nacional de Salud y la sociedad en general.

Art. 14.- Quienes forman parte del Sistema Nacional de Salud, implementarán planes y programas de salud mental, con base en la atención integral, privilegiando los grupos vulnerables, con enfoque familiar y comunitario, promoviendo la reinserción social de las personas con enfermedad mental.

Art. 15.- La autoridad sanitaria nacional en coordinación con otras instituciones competentes y organizaciones sociales, implementará programas para la prevención oportuna, diagnóstico, tratamiento y recuperación de las alteraciones del crecimiento y desarrollo.

CAPITULO II
De la alimentación y nutrición

Art. 16.- El Estado establecerá una política intersectorial de seguridad alimentaria y nutricional, que propenda a eliminar los malos hábitos alimenticios, respete y fomente los conocimientos y prácticas alimentarias tradicionales, así como el uso y consumo de productos y alimentos propios de cada región y garantizará a las personas, el acceso permanente a alimentos sanos, variados, nutritivos, inocuos y suficientes.

Esta política estará especialmente orientada a prevenir trastornos ocasionados por deficiencias de micro nutrientes o alteraciones provocadas por desórdenes alimentarios.

Art. 17.- La autoridad sanitaria nacional conjuntamente con los integrantes del Sistema Nacional de Salud, fomentarán y promoverán la lactancia materna durante los primeros seis meses de vida del niño o la niña, procurando su prolongación hasta los dos años de edad.

Garantizará el acceso a leche materna segura o a sustitutivos de ésta para los hijos de madres portadoras de VIH-SIDA.

Art. 18.- La autoridad sanitaria nacional, en coordinación con los gobiernos seccionales, las cámaras de la producción y centros universitarios desarrollará actividades de información, educación, comunicación y participación comunitaria dirigidas al conocimiento del valor nutricional de los alimentos, su calidad, suficiencia e inocuidad, de conformidad con las normas técnicas que dicte para el efecto el organismo competente y de la presente Ley.

Art. 19.- La autoridad sanitaria nacional velará por la protección de la salud en el control de las enfermedades por deficiencia de yodo, mediante el control y monitoreo de la yodización de la sal para consumo humano.

CAPITULO III
De la salud sexual y la salud reproductiva

Art. 20.- Las políticas y programas de salud sexual y salud reproductiva garantizarán el acceso de hombres y mujeres, incluidos adolescentes, a acciones y servicios de salud que aseguren la equidad de género, con enfoque pluricultural, y contribuirán a erradicar conductas de riesgo, violencia, estigmatización y explotación de la sexualidad.

Art. 21.- El Estado reconoce a la mortalidad materna, al embarazo en adolescentes y al aborto en condiciones de riesgo como problemas de salud pública; y, garantiza el acceso a los servicios públicos de salud sin costo para las usuarias de conformidad con lo que dispone la Ley de Maternidad Gratuita y Atención a la Infancia.

Los problemas de salud pública requieren de una atención integral, que incluya la prevención de las situaciones de riesgo y abarque soluciones de orden educativo, sanitario, social, psicológico, ético y moral, privilegiando el derecho a la vida garantizado por la Constitución.

Art. 22.- Los servicios de salud, públicos y privados, tienen la obligación de atender de manera prioritaria las emergencias obstétricas y proveer de sangre segura cuando las pacientes lo requieran, sin exigencia de compromiso económico ni trámite administrativo previo.

Art. 23.- Los programas y servicios de planificación familiar, garantizarán el derecho de hombres y mujeres para decidir de manera libre, voluntaria, responsable, autónoma, sin coerción, violencia ni discriminación sobre el número de hijos que puedan procrear, mantener y educar, en igualdad de condiciones, sin necesidad de consentimiento de terceras personas; así como a acceder a la información necesaria para ello.

Art. 24.- Los anticonceptivos importados por la autoridad sanitaria nacional, requerirán del registro sanitario nacional además del registro sanitario del país de origen, así como el control de calidad y seguridad del producto, previo a su distribución.

Art. 25.- Los integrantes del Sistema Nacional de Salud promoverán y respetarán el conocimiento y prácticas tradicionales de los pueblos indígenas y afroecuatorianos, de las medicinas alternativas, con relación al embarazo, parto, puerperio, siempre y cuando no comprometan la vida e integridad física y mental de la persona.

Art. 26.- Los integrantes del Sistema Nacional de Salud, implementarán acciones de prevención y atención en salud integral, sexual y reproductiva, dirigida a mujeres y hombres, con énfasis en los adolescentes, sin costo para los usuarios en las instituciones públicas.

Art. 27.- El Ministerio de Educación y Cultura, en coordinación con la autoridad sanitaria nacional, con el organismo estatal especializado en género y otros competentes, elaborará políticas y programas educativos de implementación obligatoria en los establecimientos de educación a nivel nacional, para la difusión y orientación en materia de salud sexual y

reproductiva, a fin de prevenir el embarazo en adolescentes, VIH-SIDA y otras afecciones de transmisión sexual, el fomento de la paternidad y maternidad responsables y la erradicación de la explotación sexual; y, asignará los recursos suficientes para ello.

Los medios de comunicación deberán cumplir las directrices emanadas de la autoridad sanitaria nacional a fin de que los contenidos que difunden no promuevan la violencia sexual, el irrespeto a la sexualidad y la discriminación de género, por orientación sexual o cualquier otra.

Art. 28.- Los gobiernos seccionales, en coordinación con la autoridad sanitaria nacional, desarrollarán actividades de promoción, prevención, educación y participación comunitaria en salud sexual y reproductiva, de conformidad con las normas que ella dicte, considerando su realidad local.

Art. 29.- Esta Ley, faculta a los servicios de salud públicos y privados, a interrumpir un embarazo, única y exclusivamente en los casos previstos en el artículo 447 del Código Penal. Estos no podrán negarse a atender a mujeres con aborto en curso o inevitables, debidamente diagnosticados por el profesional responsable de la atención.

Art. 30.- La autoridad sanitaria nacional, con los integrantes del Sistema Nacional de Salud, fomentará y promoverá la planificación familiar, con responsabilidad mutua y en igualdad de condiciones.

CAPITULO IV
De la violencia

Art. 31.- El Estado reconoce a la violencia como problema de salud pública.

Es responsabilidad de la autoridad sanitaria nacional, de los servicios de salud, organismos seccionales, otros organismos competentes y de la sociedad en su conjunto, contribuir a la disminución de todos los tipos de violencia, incluidos los de género, intrafamiliar, sexual y su impacto sobre la salud.

Art. 32.- En todos los casos de violencia intrafamiliar y sexual, y de sus consecuencias, se brindará atención de salud integral a las personas afectadas.

El personal de los servicios de salud tiene la obligación de atender los casos de violencia intrafamiliar y sexual.

Deberán suministrar, entre otros, anticoncepción de emergencia, realizar los procedimientos y aplicar los esquemas profilácticos y terapéuticos necesarios, para detectar y prevenir el riesgo de contraer infecciones de transmisión sexual, especialmente el VIH y hepatitis B, previa consejería y asesoría a la persona afectada, con su consentimiento informado expresado por escrito.

Art. 33.- La autoridad sanitaria nacional en coordinación con el Ministerio Fiscal y otros organismos competentes implementará acciones para armonizar las normas de atención e instrumentos de registro de los distintos tipos de violencia y delitos sexuales, unificándolos en un manual de procedimientos de aplicación obligatoria en los distintos niveles de salud y en el Sistema Nacional de Salud.

CAPITULO V
De los accidentes

Art. 34.- La autoridad sanitaria nacional, en coordinación con el Consejo Nacional de Tránsito y Transporte Terrestres, el Ministerio del Trabajo y Empleo, otros organismos competentes, públicos y privados, y los gobiernos seccionales, impulsarán y desarrollarán políticas, programas y acciones para prevenir y disminuir los accidentes de tránsito, laborales, domésticos, industriales y otros; así como para la atención, recuperación, rehabilitación y reinserción social de las personas afectadas.

El Estado reconoce a los accidentes de tránsito como problema de salud pública, en cuanto sus consecuencias afecten la integridad física y mental de las personas.

CAPITULO VI
De los desastres

Art. 35.- La autoridad sanitaria nacional colaborará con los gobiernos seccionales y con los organismos competentes para integrar en el respectivo plan vigente el componente de salud en gestión de riesgos en emergencias y desastres, para prevenir, reducir y controlar los efectos de los desastres y fenómenos naturales y antrópicos.

Art. 36.- Los integrantes del Sistema Nacional de Salud implementarán, en colaboración con los organismos competentes, un sistema permanente y actualizado de información, capacitación y educación en gestión de riesgos en emergencias y desastres, con la participación de la sociedad en su conjunto.

Art. 37.- Todas las instituciones y establecimientos públicos y privados de cualquier naturaleza, deberán contar con un plan de emergencias, mitigación y atención en casos de desastres, en concordancia con el plan formulado para el efecto.

CAPITULO VII

Del tabaco, bebidas alcohólicas, psicotrópicos, estupefacientes y otras substancias que generan dependencia

Art. 38.- Declárase como problema de salud pública al consumo de tabaco y al consumo excesivo de bebidas alcohólicas, así como al consumo de sustancias estupefacientes y psicotrópicas, fuera del ámbito terapéutico.

Es responsabilidad de la autoridad sanitaria nacional, en coordinación con otros organismos competentes, adoptar medidas para evitar el consumo del tabaco y de bebidas alcohólicas, en todas sus formas, así como dotar a la población de un ambiente saludable, para promover y apoyar el abandono de estos hábitos perjudiciales para la salud humana, individual y colectiva.

Los servicios de salud ejecutarán acciones de atención integral dirigidas a las personas afectadas por el consumo y exposición al humo del tabaco, el alcoholismo, o por el consumo nocivo de psicotrópicos, estupefacientes y otras substancias que generan dependencia, orientadas a su recuperación, rehabilitación y reinserción social.

SECCION I
DEL CONTROL DEL CONSUMO DE PRODUCTOS DEL TABACO

Art. 39.- La autoridad sanitaria nacional en coordinación con el Ministerio de Educación y Cultura, las universidades, los gobiernos seccionales y la sociedad civil, diseñará y ejecutará planes y programas de educación y prevención del consumo del tabaco y sus productos.

Art. 40.- Se prohíbe la distribución o entrega de productos del tabaco, sea a título gratuito u oneroso, a personas menores de 18 años; así como su venta y consumo en establecimientos educativos, de salud y de expendio de medicamentos.

Art. 41.- Se prohíbe la publicidad, sea directa o indirecta, la promoción por cualquier medio, así como el patrocinio de cigarrillos y otros productos del tabaco, en eventos educativos, culturales o deportivos. La autoridad sanitaria nacional vigilará y controlará el cumplimiento de esta disposición.

Art. 42.- Las cajetillas de cigarrillos y los envases de otros productos del tabaco deben incluir de forma clara, visible y comprensible, la advertencia de su carácter nocivo para la salud, sujetándose a lo dispuesto en la Ley Orgánica de Defensa del Consumidor.

Art. 43.- A más de lo dispuesto en la Ley Orgánica de Defensa del Consumidor, se prohíbe fumar en instituciones públicas, establecimientos educativos y deportivos, sean públicos o privados, servicios de salud, lugares de trabajo, medios de transporte colectivo, salas de cine y teatro, auditorios, ascensores, depósitos y sitios de provisión de combustible, fábricas o depósitos de explosivos, lugares donde existan productos de fácil combustión y otros espacios que se definan en los reglamentos correspondientes, emitidos por la autoridad sanitaria nacional.

Todos los establecimientos, públicos y privados, colocarán advertencias visibles que indiquen la prohibición de fumar.

Art. 44.- Los derechos y obligaciones establecidos en la presente Ley, no excluyen ni se oponen a aquellos contenidos en la legislación destinada a regular la protección del ser humano de la exposición al humo del tabaco, desde antes de su nacimiento, del medio ambiente y el desarrollo sustentable y otras leyes relacionadas con el control del consumo del tabaco.

Art. 45.- Las empresas tabacaleras extranjeras que comercialicen sus productos en el Ecuador, deberán contar en el país con un representante legal con plenos poderes para ejercitar derechos y cumplir obligaciones derivadas de la aplicación de la presente Ley.

SECCION II
DE LA PREVENCION DEL CONSUMO DE BEBIDAS ALCOHOLICAS

Art. 46.- La autoridad sanitaria nacional en coordinación con el Ministerio de Educación y Cultura, las universidades, los gobiernos seccionales y la sociedad civil, diseñará y ejecutará planes y programas de educación y prevención del consumo de bebidas alcohólicas.

Art. 47.- Se prohíbe la distribución o entrega de bebidas alcohólicas, sea a título gratuito u oneroso, a personas menores de 18 años; así como su venta y consumo en establecimientos educativos, de salud y de expendio de medicamentos.

Art. 48.- La publicidad de bebidas alcohólicas por ningún motivo se vinculará a la salud, al éxito deportivo o a la imagen de la mujer como símbolo sexual. La autoridad sanitaria nacional vigilará y controlará el cumplimiento de esta disposición.

Art. 49.- Los envases de bebidas alcohólicas, deben incluir de forma clara, visible y comprensible, la advertencia de su carácter nocivo para la salud; y, para la impresión de la advertencia, se seguirán las especificaciones previstas en el reglamento correspondiente.

Art. 50.- Salvo en los actos autorizados por la autoridad competente, se prohíbe consumir bebidas alcohólicas y de moderación, en instituciones públicas, establecimientos educativos, sean públicos o privados, servicios de salud, lugares de trabajo, medios de transporte colectivo, salas de cine y teatro, y otros espacios que se definan en los reglamentos correspondientes emitidos por la autoridad sanitaria nacional. En estos establecimientos se colocarán advertencias visibles que indiquen la prohibición del consumo de bebidas alcohólicas.

SECCION III
DEL USO Y CONSUMO DE PSICOTROPICOS, ESTUPEFACIENTES Y OTRAS SUBSTANCIAS QUE GENERAN DEPENDENCIA

Art. 51.- Está prohibido la producción, comercialización, distribución y consumo de estupefacientes y psicotrópicos y otras substancias adictivas, salvo el uso terapéutico y bajo prescripción médica, que serán controlados por la autoridad sanitaria nacional, de acuerdo con lo establecido en la legislación pertinente.

TITULO II
Prevención y control de enfermedades

CAPITULO I
De las inmunizaciones

Art. 52.- La autoridad sanitaria nacional proveerá a los establecimientos de salud los biológicos e insumos para las enfermedades inmunoprevenibles contempladas en el esquema básico nacional de vacunación, en forma oportuna y permanente, asegurando su calidad y conservación, sin costo al usuario final.

Art. 53.- Es obligación de los servicios de salud y otras instituciones y establecimientos públicos y privados, inmunizar a los trabajadores que se encuentren expuestos a riesgos prevenibles por vacunación, de conformidad con la normativa emitida por la autoridad sanitaria nacional.

Art. 54.- El Estado garantizará y transferirá oportunamente, a través del organismo competente, los recursos económicos suficientes para el cumplimiento de las acciones del Programa Ampliado de Inmunizaciones, de conformidad con lo señalado en la ley.

Art. 55.- Los biológicos importados por el Estado a través del Fondo Rotatorio o de los convenios de gobierno a gobierno, no requieren de registro sanitario nacional, siendo obligatorio el del país de origen y la comprobación de la calidad y seguridad del producto antes de su distribución y utilización.

Art. 56.- Los biológicos adquiridos a cualquier título por instituciones públicas o privadas, producidos en el país o importados, serán sometidos a los procesos establecidos por la autoridad sanitaria nacional para liberación de lotes con el fin de preservar su calidad e inocuidad.

Art. 57.- Los biológicos importados por el Ministerio de Salud Pública a su arribo al país, deben pasar al Banco Nacional de Vacunas, en un plazo no mayor de cuarenta y ocho horas, debiéndose garantizar el mantenimiento de la cadena de frío y la calidad de los productos, siendo esto responsabilidad de la autoridad aduanera y de la autoridad sanitaria nacional.

Art. 58.- Las instituciones públicas y privadas de salud administrarán, sin costo a la población, de acuerdo a lo que establezca el reglamento aplicable, los biológicos contemplados en el esquema básico nacional de vacunación, cuando éstos hayan sido suministrados por la autoridad sanitaria nacional.

Las instituciones públicas y privadas reportarán obligatoriamente a la autoridad sanitaria nacional sobre las personas inmunizadas.

Art. 59.- Los padres y madres de familia, tutores o representantes legales de los niños, niñas y adolescentes, entidades educativas, instituciones públicas y privadas con población cautiva en riesgo, tienen la obligación y la responsabilidad de vigilar que se aplique y cumpla el esquema básico nacional de vacunación establecido por la autoridad sanitaria nacional.

Art. 60.- Las instituciones públicas y privadas para la administración y expendio de biológicos deben contar con la autorización de la autoridad sanitaria nacional y cumplir con los requisitos establecidos para garantizar una vacuna segura.

CAPITULO II
De las enfermedades transmisibles

Art. 61.- Las instituciones públicas y privadas, los profesionales de salud y la población en general, reportarán en forma oportuna la existencia de casos sospechosos, probables, compatibles y confirmados de enfermedades declaradas por la autoridad sanitaria nacional como de notificación obligatoria y aquellas de reporte internacional. Las instituciones y profesionales de salud, garantizarán la confidencialidad de la información entregada y recibida.

Art. 62.- La autoridad sanitaria nacional elaborará las normas, protocolos y procedimientos que deben ser obligatoriamente cumplidos y utilizados para la vigilancia epidemiológica y el control de las enfermedades transmisibles, emergentes y reemergentes de notificación obligatoria, incluyendo las de transmisión sexual.

Garantizará en sus servicios de salud, atención, acceso y disponibilidad de medicamentos, con énfasis en genéricos, exámenes de detección y seguimiento, para las enfermedades señaladas en el inciso precedente, lo cual también debe garantizar el sistema nacional de seguridad social.

Art. 63.- La autoridad sanitaria nacional en coordinación con otros organismos competentes ejecutará campañas de información y educación dirigidas al personal de salud y a la población en general, para erradicar actitudes discriminatorias contra las personas afectadas por enfermedades transmisibles.

Art. 64.- En casos de sospecha o diagnóstico de la existencia de enfermedades transmisibles, el personal de salud está obligado a tomar las medidas de bioseguridad y otras necesarias para evitar la transmisión y propagación de conformidad con las disposiciones establecidas por la autoridad sanitaria nacional.

Art. 65.- Los gobiernos seccionales deben cumplir con las disposiciones emanadas por la autoridad sanitaria nacional para evitar la proliferación de vectores, la propagación de enfermedades transmisibles y asegurar el control de las mismas.

Art. 66.- Las personas naturales y jurídicas, nacionales y extranjeras, que se encuentren en territorio ecuatoriano deben cumplir las disposiciones reglamentarias que el gobierno dicte y las medidas que la autoridad sanitaria nacional disponga de conformidad con el Reglamento Sanitario Internacional, los convenios internacionales suscritos y ratificados por el país, a fin de prevenir y evitar la propagación internacional de enfermedades transmisibles.

Art. 67.- El Estado reconoce al contagio y la transmisión del VIH-SIDA, como problema de salud pública.

La autoridad sanitaria nacional garantizará en sus servicios de salud a las personas viviendo con VIH-SIDA atención especializada, acceso y disponibilidad de medicamentos antiretrovirales y para enfermedades oportunistas con énfasis en medicamentos genéricos, así como los reactivos para exámenes de detección y seguimiento.

Las responsabilidades señaladas en este artículo corresponden también al sistema nacional de seguridad social.

Art. 68.- Se suministrará la anticoncepción que corresponda, previo consentimiento informado, a mujeres portadoras de VIH y a aquellas viviendo con SIDA. Esto incluye anticoncepción de emergencia cuando el caso lo requiera, a juicio del profesional responsable de la atención.

CAPITULO III
De las enfermedades no transmisibles

Art. 69.- La atención integral y el control de enfermedades no transmisibles, crónico - degenerativas, congénitas, hereditarias y de los problemas declarados prioritarios para la salud pública, se realizará mediante la acción coordinada de todos los integrantes del Sistema Nacional de Salud y de la participación de la población en su conjunto.

Comprenderá la investigación de sus causas, magnitud e impacto sobre la salud, vigilancia epidemiológica, promoción de hábitos y estilos de vida saludables, prevención, recuperación, rehabilitación, reinserción social de las personas afectadas y cuidados paliativos.

Los integrantes del Sistema Nacional de Salud garantizarán la disponibilidad y acceso a programas y medicamentos para estas enfermedades, con énfasis en medicamentos genéricos, priorizando a los grupos vulnerables.

CAPITULO IV
De la sangre, sus componentes y derivados

Art. 70.- Se declara de prioridad nacional la disponibilidad de sangre segura y sus componentes.

El Estado, a través de la autoridad sanitaria nacional, tomará las medidas necesarias para garantizar la disponibilidad y el acceso a sangre y componentes seguros en cantidades suficientes para quien la necesite, siendo obligatoria su provisión en las instituciones públicas, privadas y autónomas, en caso de riesgo inminente para la vida, independientemente de la capacidad de pago.

La autoridad sanitaria nacional está obligada a promover la donación voluntaria y altruista de sangre.

Art. 71.- La autoridad sanitaria nacional dictará las normas relativas a los procesos de donación, transfusión, uso y vigilancia de la calidad de la sangre humana con sus componentes y derivados, con el fin de garantizar el acceso equitativo, eficiente, suficiente y seguro, la preservación de la salud de los donantes y la máxima protección de los receptores así como del personal de salud.

Art. 72.- La autoridad sanitaria nacional licenciará, a través de la instancia competente, a los servicios de sangre (hemocentros, bancos, depósitos y servicios de transfusión) y a las plantas industriales de fraccionamiento de plasma, públicos y privados, de acuerdo a la normativa vigente.

Art. 73.- Los hemocentros, bancos, depósitos y servicios de transfusión de sangre humana, deben mantener programas de gestión y control de calidad interna y externa, así como cumplir con las demás normas y disposiciones que para el efecto dicte la autoridad sanitaria nacional.

Art. 74.- Se prohíbe la comercialización, publicidad de la misma y el lucro en el proceso de donación, obtención, procesamiento, distribución y utilización de sangre, sus derivados y componentes, por parte de personas naturales o jurídicas, públicas o privadas.

Las instituciones que realicen los procesos señalados en el inciso precedente pueden recuperar únicamente lo correspondiente a gastos de operación de los procedimientos que se realicen; cualquier cobro en exceso será sancionado.

Art. 75.- Los establecimientos autorizados para colectar unidades de sangre, previamente a su utilización en transfusiones, están obligados a realizar las pruebas para determinar el grupo y factor sanguíneo y la presencia de anticuerpos irregulares, así como las serológicas para los marcadores de infección, determinados en la reglamentación correspondiente de acuerdo con el perfil epidemiológico local, regional y nacional y los avances tecnológicos.

La separación de componentes se realizará cumpliendo las normas técnicas aplicables con el fin de asegurar la función terapéutica de los mismos.

Art. 76.- La transfusión de sangre y sus componentes, debe ser prescrita por un médico, legalmente habilitado para ejercer la profesión, practicada bajo su responsabilidad y supervisión, en condiciones que garanticen la seguridad del procedimiento y de conformidad con lo establecido en las normas técnicas.

Art. 77.- La aceptación o negativa para transfusión de sangre y sus componentes, debe realizarse por escrito de parte del potencial receptor o a través de la persona legalmente capaz para ejercer su representación, exceptuándose los casos de emergencia o urgencia.

Art. 78.- La donación voluntaria de sangre requiere de la expresa autorización libre, voluntaria y por escrito del donante.

Art. 79.- La exportación de plasma para procesamiento industrial sólo podrá realizarse hacia plantas procesadoras acreditadas y siempre que los derivados obtenidos sean recuperados para consumo nacional.

Art. 80.- Prohíbese la exportación de sangre y sus componentes, salvo casos expresos de donación originados por razones de emergencia y humanitarias según lo señalado en el artículo anterior.

TITULO III
De los trasplantes de órganos, tejidos y disposición de cadáveres

CAPITULO I
De los trasplantes de órganos y tejidos

Art. 81.- Prohíbese la comercialización de componentes anatómicos de personas vivas o fallecidas. Ninguna persona podrá ofrecer o recibir directa o indirectamente beneficios económicos o de otra índole, por la entrega u obtención de órganos y otros componentes anatómicos de personas vivas o fallecidas.

Art. 82.- La donación de órganos u otros componentes anatómicos de una persona viva, requiere de su expresa autorización, manifestada en forma libre y voluntaria.

Igualmente se podrá realizar entre personas con antígenos de histocompatibilidad entre donante y receptor, siempre que el primero exprese su deseo de ser donante voluntario.

La autoridad sanitaria nacional promoverá campañas para la donación voluntaria de órganos y tejidos.

Art. 83.- La utilización de órganos u otros componentes anatómicos de una persona con muerte cerebral confirmada de acuerdo a la regulación pertinente, se realizará si en vida la persona expresó su consentimiento, en la cedula de identidad y/o ciudadanía u otro documento legal, o se cuente con la autorización de las personas facultadas por ley.

Art. 84.- La autoridad sanitaria nacional, normará, licenciará y controlará el funcionamiento de los servicios de salud especializados, públicos y privados, para el ejercicio de actividades relacionadas con el trasplante de órganos u otros componentes anatómicos. Igualmente controlará el ejercicio profesional de quienes realicen dichas actividades.

Art. 85.- La autoridad sanitaria nacional normará la organización de los bancos de tejidos y de células, bajo los parámetros técnicos y estándares que se establezcan para el efecto.

La asignación de órganos u otros componentes anatómicos debe realizarse bajo los parámetros nacionales e internacionales, establecidos por un sistema nacional creado para este efecto.

Art. 86.- Los xenotrasplantes podrán realizarse únicamente cuando se garanticen condiciones científicas y tecnológicas que aseguren la calidad del procedimiento con sujeción a principios bioéticos, y estarán sujetos a la autorización de la autoridad sanitaria nacional a través del organismo competente.

CAPITULO II
De la disposición y manejo de cadáveres

Art. 87.- La instalación, construcción y mantenimiento de cementerios, criptas, crematorios, morgues o sitios de conservación de cadáveres, lo podrán hacer entidades públicas y privadas, para lo cual se dará cumplimiento a las normas establecidas en esta Ley.

Previamente se verificará la ubicación y la infraestructura a emplearse y que no constituyan riesgo para la salud. Deberán contar con el estudio de impacto ambiental y la correspondiente licencia ambiental.

Los cementerios y criptas son los únicos sitios autorizados para la inhumación de cadáveres y deben cumplir las normas establecidas por la autoridad sanitaria nacional y la correspondiente municipalidad.

Art. 88.- Practicada la necropsia, el cadáver debe ser obligatoriamente tratado, inhumado o cremado.

Ningún cadáver podrá mantenerse insepulto o sin someterse a cremación por más de setenta y dos horas, excepto cuando medie orden judicial o no sean reconocidos o reclamados por sus familiares o derechohabientes, en cuyo caso debe garantizarse su mantenimiento en los sitios autorizados y en condiciones de conservación adecuadas que no comprometan la integridad del cadáver ni alteren las posibles evidencias.

Art. 89.- Los cadáveres no identificados o que no fueren reclamados en el plazo de treinta días posteriores a su fallecimiento, se entregarán a título de donación a las facultades de Ciencias Médicas o de la Salud legalmente establecidas dando preferencia a las estatales, o se inhumarán de conformidad con las disposiciones pertinentes.

De los cadáveres no identificados, previa a su donación o inhumación se extraerán muestras que permita la obtención del perfil genético de la persona. Esta información será registrada en un banco de datos de cadáveres no identificados.

Art. 90.- No se podrá proceder a la inhumación o cremación de un cadáver sin que se cuente con el certificado médico que confirme la defunción y establezca sus posibles causas, de acuerdo a su diagnóstico. Esta responsabilidad corresponde a los cementerios o crematorios según el caso.

Art. 91.- La exhumación para efectos legales podrá practicarse en cualquier tiempo por orden de autoridad competente.

Art. 92.- El traslado de cadáveres, dentro del país, en los casos y condiciones establecidos en el reglamento de esta Ley, así como su ingreso al territorio nacional requiere autorización de la autoridad sanitaria nacional, quien establecerá las normas de conservación y seguridad.

Art. 93.- Las necropsias deben ser realizadas bajo responsabilidad de médicos patólogos o forenses, excepto en las localidades donde estos profesionales no existan, en cuyo caso se realizarán de acuerdo con lo establecido en el Código de Procedimiento Penal, sin costo para los familiares o deudos en las instituciones públicas.

Art. 94.- Es obligatoria la necropsia cuando:

a) No se conozca la causa del fallecimiento;
b) Por muerte repentina;
c) El Ministerio Público lo disponga;
d) En casos de emergencia sanitaria;
e) Por razones de salud pública; y,
f) Por petición y consentimiento del representante legal o pariente más cercano hasta el cuarto grado de consanguinidad y segundo de afinidad.

LIBRO II
Salud y seguridad ambiental

Disposición común

Art. 95.- La autoridad sanitaria nacional en coordinación con el Ministerio de Ambiente, establecerá las normas básicas para la preservación del ambiente en materias relacionadas con la salud humana, las mismas que serán de cumplimiento obligatorio para todas las personas naturales, entidades públicas, privadas y comunitarias.

El Estado a través de los organismos competentes y el sector privado está obligado a proporcionar a la población, información adecuada y veraz respecto del impacto ambiental y sus consecuencias para la salud individual y colectiva.

TITULO UNICO

CAPITULO I
Del agua para consumo humano

Art. 96.- Declárase de prioridad nacional y de utilidad pública, el agua para consumo humano.

Es obligación del Estado, por medio de las municipalidades, proveer a la población de agua potable de calidad, apta para el consumo humano.

Toda persona natural o jurídica tiene la obligación de proteger los acuíferos, las fuentes y cuencas hidrográficas que sirvan para el abastecimiento de agua para consumo humano. Se prohíbe realizar actividades de cualquier tipo, que pongan en riesgo de contaminación las fuentes de captación de agua. La autoridad sanitaria nacional, en coordinación con otros organismos competentes, tomarán medidas para prevenir, controlar, mitigar, remediar y sancionar la contaminación de las fuentes de agua para consumo humano.

A fin de garantizar la calidad e inocuidad, todo abastecimiento de agua para consumo humano, queda sujeto a la vigilancia de la autoridad sanitaria nacional, a quien corresponde establecer las normas y reglamentos que permitan asegurar la protección de la salud humana.

CAPITULO II

De los desechos comunes, infecciosos, especiales y de las radiaciones ionizantes y no ionizantes

Art. 97.- La autoridad sanitaria nacional dictará las normas para el manejo de todo tipo de desechos y residuos que afecten la salud humana; normas que serán de cumplimiento obligatorio para las personas naturales y jurídicas.

Art. 98.- La autoridad sanitaria nacional, en coordinación con las entidades públicas o privadas, promoverá programas y campañas de información y educación para el manejo de desechos y residuos.

Art. 99.- La autoridad sanitaria nacional, en coordinación con los municipios del país, emitirá los reglamentos, normas y procedimientos técnicos de cumplimiento obligatorio para el manejo adecuado de los desechos infecciosos que generen los establecimientos de servicios de salud, públicos o privados, ambulatorio o de internación, veterinaria y estética.

Art. 100.- La recolección, transporte, tratamiento y disposición final de desechos es responsabilidad de los municipios que la realizarán de acuerdo con las leyes, reglamentos y ordenanzas que se dicten para el efecto, con observancia de las normas de bioseguridad y control determinadas por la autoridad sanitaria nacional. El Estado entregará los recursos necesarios para el cumplimiento de lo dispuesto en este artículo.

Art. 101.- Las viviendas, establecimientos educativos, de salud y edificaciones en general, deben contar con sistemas sanitarios adecuados de disposición de excretas y evacuación de aguas servidas.

Los establecimientos educativos, públicos y privados, tendrán el número de baterías sanitarias que se disponga en la respectiva norma reglamentaria.

El Estado entregará a los establecimientos públicos los recursos necesarios para el cumplimiento de lo dispuesto en este artículo.

Art. 102.- Es responsabilidad del Estado, a través de los municipios del país y en coordinación con las respectivas instituciones públicas, dotar a la

población de sistemas de alcantarillado sanitario, pluvial y otros de disposición de excretas y aguas servidas que no afecten a la salud individual, colectiva y al ambiente; así como de sistemas de tratamiento de aguas servidas.

Art. 103.- Se prohíbe a toda persona, natural o jurídica, descargar o depositar aguas servidas y residuales, sin el tratamiento apropiado, conforme lo disponga en el reglamento correspondiente, en ríos, mares, canales, quebradas, lagunas, lagos y otros sitios similares. Se prohíbe también su uso en la cría de animales o actividades agropecuarias.

Los desechos infecciosos, especiales, tóxicos y peligrosos para la salud, deben ser tratados técnicamente previo a su eliminación y el depósito final se realizará en los sitios especiales establecidos para el efecto por los municipios del país.

Para la eliminación de desechos domésticos se cumplirán las disposiciones establecidas para el efecto.

Las autoridades de salud, en coordinación con los municipios, serán responsables de hacer cumplir estas disposiciones.

Art. 104.- Todo establecimiento industrial, comercial o de servicios, tiene la obligación de instalar sistemas de tratamiento de aguas contaminadas y de residuos tóxicos que se produzcan por efecto de sus actividades.

Las autoridades de salud, en coordinación con los municipios, serán responsables de hacer cumplir esta disposición.

Art. 105.- Las personas naturales o jurídicas propietarias de instalaciones o edificaciones, públicas o privadas, ubicadas en las zonas costeras e insulares, utilizarán las redes de alcantarillado para eliminar las aguas servidas y residuales producto de las actividades que desarrollen; y, en los casos que inevitablemente requieran eliminarlos en el mar, deberán tratarlos previamente, debiendo contar para el efecto con estudios de impacto ambiental; así como utilizar emisarios submarinos que cumplan con las normas sanitarias y ambientales correspondientes.

Art. 106.- Los terrenos por donde pasen o deban pasar redes de alcantarillado, acueductos o tuberías, se constituirán obligatoriamente en predios sirvientes, de acuerdo a lo establecido por la ley.

Las autoridades de salud, en coordinación con los municipios, serán responsables de hacer cumplir esta disposición.

Art. 107.- La autoridad sanitaria nacional en coordinación con otros organismos competentes, dictará las normas para el manejo, transporte, tratamiento y disposición final de los desechos especiales. Los desechos radioactivos serán tratados de acuerdo con las normas dictadas por el organismo competente en la materia o aceptadas mediante convenios internacionales.

Art. 108.- Corresponde a la autoridad sanitaria nacional, en coordinación con la Comisión Ecuatoriana de Energía Atómica y más organismos competentes, vigilar el cumplimiento de las normas establecidas en materia de radiaciones ionizantes y no ionizantes.

Art. 109.- Ninguna persona será sometida o expuesta a radiaciones ionizantes y no ionizantes más allá de las dosis o límites permisibles, conforme a las normas pertinentes.

Los equipos diagnósticos y terapéuticos que utilicen radiaciones ionizantes y no ionizantes se instalarán en edificaciones técnicamente apropiadas y que cumplan con requisitos sanitarios y de seguridad, establecidos por la autoridad sanitaria nacional y la Comisión Ecuatoriana de Energía Atómica; estarán sujetos a mantenimientos rigurosos y periódicos, debiendo contar con los certificados de control de calidad.

Art. 110.- Los importadores de artículos y dispositivos electrónicos que emiten radiaciones no ionizantes, deberán asegurarse que los mismos cumplan con las normas sanitarias vigentes, no estén prohibidos en su país de origen o en otros países; y, lleven la rotulación de precauciones e indicaciones claras sobre su uso.

CAPITULO III
Calidad del aire y de la contaminación acústica

Art. 111.- La autoridad sanitaria nacional, en coordinación con la autoridad ambiental nacional y otros organismos competentes, dictará las normas técnicas para prevenir y controlar todo tipo de emanaciones que afecten a los sistemas respiratorio, auditivo y visual.

Todas las personas naturales y jurídicas deberán cumplir en forma obligatoria dichas normas.

Art. 112.- Los municipios desarrollarán programas y actividades de monitoreo de la calidad del aire, para prevenir su contaminación por emisiones provenientes de fuentes fijas, móviles y de fenómenos naturales. Los resultados del monitoreo serán reportados periódicamente a las autoridades competentes a fin de implementar sistemas de información y prevención dirigidos a la comunidad.

Art. 113.- Toda actividad laboral, productiva, industrial, comercial, recreativa y de diversión; así como las viviendas y otras instalaciones y medios de transporte, deben cumplir con lo dispuesto en las respectivas normas y reglamentos sobre prevención y control, a fin de evitar la contaminación por ruido, que afecte a la salud humana.

CAPITULO IV
Plaguicidas y otras sustancias químicas

Art. 114.- La autoridad sanitaria nacional, en coordinación con el Ministerio de Agricultura y Ganadería y más organismos competentes, dictará e implementará las normas de regulación para la utilización y control de plaguicidas, fungicidas y otras sustancias químicas de uso doméstico, agrícola e industrial, que afecten a la salud humana.

Art. 115.- Se deben cumplir las normas y regulaciones nacionales e internacionales para la producción, importación, exportación, comercialización, uso y manipulación de plaguicidas, fungicidas y otro tipo de sustancias químicas cuya inhalación, ingestión o contacto pueda causar daño a la salud de las personas.

Art. 116.- Se prohíbe la producción, importación, comercialización y uso de plaguicidas, fungicidas y otras sustancias químicas, vetadas por las normas sanitarias nacionales e internacionales, así como su aceptación y uso en calidad de donaciones.

CAPITULO V
Salud y seguridad en el trabajo

Art. 117.- La autoridad sanitaria nacional, en coordinación con el Ministerio de Trabajo y Empleo y el Instituto Ecuatoriano de Seguridad Social, establecerá las normas de salud y seguridad en el trabajo para proteger la salud de los trabajadores.

Art. 118.- Los empleadores protegerán la salud de sus trabajadores, dotándoles de información suficiente, equipos de protección, vestimenta apropiada, ambientes seguros de trabajo, a fin de prevenir, disminuir o eliminar los riesgos, accidentes y aparición de enfermedades laborales.

Art. 119.- Los empleadores tienen la obligación de notificar a las autoridades competentes, los accidentes de trabajo y enfermedades laborales, sin perjuicio de las acciones que adopten tanto el Ministerio del Trabajo y Empleo como el Instituto Ecuatoriano de Seguridad Social.

Art. 120.- La autoridad sanitaria nacional, en coordinación con el Ministerio del Trabajo y Empleo y el Instituto Ecuatoriano de Seguridad Social, vigilará y controlará las condiciones de trabajo, de manera que no resulten nocivas o insalubres durante los períodos de embarazo y lactancia de las mujeres trabajadoras.

Los empleadores tienen la obligación de cumplir las normas y adecuar las actividades laborales de las mujeres embarazadas y en período de lactancia.

Art. 121.- Las instituciones públicas o privadas cuyo personal esté expuesto a radiación ionizante y emisiones no ionizantes, están obligadas a proveer de dispositivos de cuidado y control de radiación y de condiciones de seguridad en el trabajo que prevengan riesgos para la salud.

El incumplimiento de esta disposición por parte de los empleadores, que ocasione daño a la salud del trabajador, dará lugar a la aplicación de la sanción determinada por la ley.

CAPITULO VI
Del control de la fauna nociva y las zooantroposis

Art. 122.- La autoridad sanitaria nacional organizará campañas para erradicar la proliferación de vectores y otros animales que representen riesgo para la salud individual y colectiva.

Las personas naturales y jurídicas colaborarán con estas campañas.

Art. 123.- Es obligación de los propietarios de animales domésticos vacunarlos contra la rabia y otras enfermedades que la autoridad sanitaria nacional declare susceptibles de causar epidemias, así como mantenerlos en condiciones que no constituyan riesgo para la salud humana y la higiene del entorno.

El control y manejo de los animales callejeros es responsabilidad de los municipios, en coordinación con las autoridades de salud.

Art. 124.- Se prohíbe dentro del perímetro urbano instalar establos o granjas para criar o albergar ganado vacuno, equino, bovino, caprino, porcino, así como aves de corral y otras especies.

Art. 125.- Se prohíbe el faenamiento, transporte, industrialización y comercialización de animales muertos o sacrificados que hubieren padecido enfermedades nocivas para la salud humana.

Art. 126.- El ingreso de animales al país está sujeto al cumplimiento de las disposiciones legales y normativas emitidas por las autoridades correspondientes, los convenios internacionales y otras leyes que regulen el tráfico de animales.

Se prohíbe la entrada al país de animales afectados por enfermedades transmisibles a la población o sospechosos de estarlo, o que sean portadores de agentes patógenos cuya diseminación pueda constituir peligro para la salud de las personas.

Art. 127.- Toda persona procederá al exterminio de artrópodos, roedores y otras especies nocivas para la salud que existan en su vivienda, otros inmuebles y anexos de su propiedad o de su uso.

Será, además, obligación de la autoridad sanitaria nacional, impulsar campañas masivas para hacer efectivo el cumplimiento de este propósito.

Art. 128.- Las empresas que se dediquen al exterminio o control de plagas y vectores transmisores de enfermedades como dengue, rabia y paludismo, deberán obtener el respectivo permiso emitido por la autoridad sanitaria nacional para operar. Todos los químicos usados por dichas empresas deberán ser aprobados por dicha autoridad.

LIBRO III

Vigilancia y control sanitario

Disposiciones comunes

Art. 129.- El cumplimiento de las normas de vigilancia y control sanitario es obligatorio para todas las instituciones, organismos y establecimientos públicos y privados que realicen actividades de producción, importación, exportación, almacenamiento, transporte, distribución, comercialización y expendio de productos de uso y consumo humano.

La observancia de las normas de vigilancia y control sanitario se aplican también a los servicios de salud públicos y privados, con y sin fines de lucro, autónomos, comunitarios y de las empresas privadas de salud y medicina prepagada.

Art. 130.- Los establecimientos sujetos a control sanitario para su funcionamiento deberán contar con el permiso otorgado por la autoridad sanitaria nacional. El permiso de funcionamiento tendrá vigencia de un año calendario.

Art. 131.- El cumplimiento de las normas de buenas prácticas de manufactura, almacenamiento, distribución, dispensación y farmacia, será controlado y certificado por la autoridad sanitaria nacional.

Art. 132.- Las actividades de vigilancia y control sanitario incluyen las de control de calidad, inocuidad y seguridad de los productos procesados de uso y consumo humano, así como la verificación del cumplimiento de los requisitos técnicos y sanitarios en los establecimientos dedicados a la producción, almacenamiento, distribución, comercialización, importación y exportación de los productos señalados.

Art. 133.- La autoridad sanitaria nacional podrá delegar a los municipios, dentro de sus funciones, el ejercicio de las acciones necesarias para el control sanitario, quienes las realizarán de acuerdo con las disposiciones y normas emitidas por dicha autoridad.

Art. 134.- La instalación, transformación, ampliación y traslado de plantas industriales, procesadoras de alimentos, establecimientos farmacéuticos, de producción de biológicos, de elaboración de productos naturales procesados de uso medicinal, de producción de homeopáticos, plaguicidas, productos dentales, empresas de cosméticos y productos higiénicos, están sujetos a la obtención, previa a su uso, del permiso otorgado por la autoridad sanitaria nacional.

Art. 135.- Compete a la autoridad sanitaria nacional autorizar la importación de todo producto inscrito en el registro sanitario, incluyendo muestras médicas y aquellos destinados a consumo interno procedentes de zonas francas.

No se autorizará la importación de productos, ni aún con fines promocionales, si previamente no tienen el registro sanitario nacional, salvo las excepciones determinadas en esta Ley.

Art. 136.- Las materias primas para elaboración de productos sujetos a registro sanitario, no requieren para su importación cumplir con este registro, siempre que justifiquen su utilización en dichos productos.

TITULO UNICO

CAPITULO I
Del registro sanitario

Art. 137.- Están sujetos a registro sanitario los alimentos procesados, aditivos alimentarios, medicamentos en general, productos nutracéuticos, productos biológicos, naturales procesados de uso medicinal, medicamentos homeopáticos y productos dentales; dispositivos médicos, reactivos bioquímicos y de diagnóstico, productos higiénicos, plaguicidas para uso doméstico e industrial, fabricados en el territorio nacional o en el exterior, para su

importación, exportación, comercialización, dispensación y expendio, incluidos los que se reciban en donación.

Las donaciones de productos sujetos a registro sanitario se someterán a la autorización y requisitos establecidos en el reglamento que para el efecto dicte la autoridad sanitaria nacional.

Art. 138.- La autoridad sanitaria nacional a través de su organismo competente, Instituto Nacional de Higiene y Medicina Tropical Dr. Leopoldo Izquieta Pérez, quien ejercerá sus funciones en forma desconcentrada, otorgará, suspenderá, cancelará o reinscribirá el certificado de registro sanitario, previo el cumplimiento de los trámites, requisitos y plazos señalados en esta Ley y sus reglamentos, de acuerdo a las directrices y normas emitidas por la autoridad sanitaria nacional, la misma que fijará el pago de un importe para la inscripción y reinscripción de dicho certificado de registro sanitario, cuyos valores estarán destinados al desarrollo institucional, que incluirá de manera prioritaria un programa nacional de control de calidad e inocuidad posregistro.

La autoridad sanitaria nacional, ejercerá control administrativo, técnico y financiero del Instituto Nacional de Higiene y Medicina Tropical Dr. Leopoldo Izquieta Pérez y evaluará anualmente los resultados de la gestión para los fines pertinentes.

El informe técnico analítico para el otorgamiento del registro sanitario, así como los análisis de control de calidad posregistro, deberán ser elaborados por el Instituto Nacional de Higiene y Medicina Tropical, Dr. Leopoldo Izquieta Pérez, y por laboratorios, universidades y escuelas politécnicas, previamente acreditados por el organismo competente, de conformidad con la normativa aplicable, procedimientos que están sujetos al pago del importe establecido por la autoridad sanitaria nacional.

Art. 139.- El registro sanitario tendrá vigencia de cinco años, contados a partir de la fecha de su concesión. Todo cambio de la condición en que el producto fue aprobado en el registro sanitario debe ser notificado obligatoriamente a la autoridad sanitaria nacional a través del Instituto Nacional de Higiene y Medicina Tropical Dr. Leopoldo Izquieta Pérez y, dará lugar al procedimiento que señale la ley y sus reglamentos.

Para el trámite de registro sanitario no se considerará como requisito la patente de los productos.

El registro sanitario de medicamentos no da derecho de exclusividad en el uso de la fórmula.

Art. 140.- Queda prohibida la importación, exportación, comercialización y expendio de productos procesados para el uso y consumo humano que no cumplan con la obtención previa del registro sanitario, salvo las excepciones previstas en esta Ley.

Art. 141.- El registro sanitario será suspendido o cancelado por la autoridad sanitaria nacional a través del Instituto Nacional de Higiene y Medicina Tropical Dr. Leopoldo Izquieta Pérez, en cualquier tiempo si se comprobase que el producto o su fabricante no cumplen con los requisitos y condiciones establecidos en esta Ley y sus reglamentos o cuando el producto pudiere provocar perjuicio a la salud, y se aplicarán las demás sanciones señaladas en esta Ley.

En todos los casos, el titular del registro o la persona natural o jurídica responsable, deberá resarcir plenamente cualquier daño que se produjere a terceros, sin perjuicio de otras acciones legales a las que hubiere lugar.

Art. 142.- La autoridad sanitaria nacional a través de sus organismos competentes, realizará periódicamente controles posregistro de todos los productos sujetos a registro sanitario mediante toma de muestras para análisis de control de calidad e inocuidad, sea en los lugares de fabricación, almacenamiento, transporte, distribución o expendio. Realizará además

inspecciones a los establecimientos. Si detectare que alguna entidad comercial o industrial usare un número de registro sanitario no autorizado para ese producto, la autoridad sanitaria nacional suspenderá la comercialización del o los productos, sin perjuicio de las sanciones de ley.

Art. 143.- La publicidad y promoción de los productos sujetos a registro sanitario deberá ajustarse a su verdadera naturaleza, composición, calidad u origen, de modo tal que se evite toda concepción errónea de sus cualidades o beneficios, lo cual será controlado por la autoridad sanitaria nacional.

Se prohíbe la publicidad por cualquier medio de medicamentos sujetos a venta bajo prescripción.

Art. 144.- La autoridad sanitaria nacional podrá autorizar la importación de medicamentos, productos biológicos, dispositivos médicos, reactivos bioquímicos y de diagnóstico no inscritos en el registro sanitario, en casos de emergencia sanitaria o para personas que requieren tratamientos especializados no disponibles en el país, así como para fines de investigación clínica humana, previo el cumplimiento de los requisitos establecidos para el efecto. Los medicamentos, productos biológicos, dispositivos médicos, reactivos bioquímicos y de diagnóstico autorizados serán los específicos para cada situación.

CAPITULO II
De los alimentos

Art. 145.- Es responsabilidad de los productores, expendedores y demás agentes que intervienen durante el ciclo producción consumo, cumplir con las normas establecidas en esta Ley y demás disposiciones vigentes para asegurar la calidad e inocuidad de los alimentos para consumo humano.

Art. 146.- En materia de alimentos se prohíbe:

a) El uso de aditivos para disimular, atenuar o corregir las deficiencias tecnológicas de producción, manipulación o conservación y para resaltar fraudulentamente sus características;
b) La utilización, importación y comercialización de materias primas no aptas para consumo humano;
c) La inclusión de substancias nocivas que los vuelvan peligrosos o potencialmente perjudiciales para la salud de los consumidores;
d) El uso de materias primas y productos tratados con radiaciones ionizantes o que hayan sido genéticamente modificados en la elaboración de fórmulas para lactantes y alimentos infantiles;
e) El procesamiento y manipulación en condiciones no higiénicas;
f) La utilización de envases que no cumplan con las especificaciones técnicas aprobadas para el efecto;
g) La oferta de un alimento procesado con nombres, marcas, gráficos o etiquetas que hagan aseveraciones falsas o que omitan datos de manera que se confunda o lleve a error al consumidor;
h) El almacenamiento de materias primas o alimentos procesados en locales en los que se encuentren substancias nocivas o peligrosas;
i) Cualquier forma de falsificación, contaminación, alteración o adulteración, o cualquier procedimiento que produzca el efecto de volverlos nocivos o peligrosos para la salud humana; y,
j) La exhibición y venta de productos cuyo período de vida útil haya expirado.

Art. 147.- La autoridad sanitaria nacional, en coordinación con los municipios, establecerá programas de educación sanitaria para productores, manipuladores y consumidores de alimentos, fomentando la higiene, la salud individual y colectiva y la protección del medio ambiente.

Art. 148.- El control del expendio de alimentos y bebidas en la vía pública lo realizarán los municipios, en coordinación con la autoridad sanitaria nacional y de conformidad con lo establecido en la Ley Orgánica de Régimen Municipal.

Art. 149.- El desarrollo, tratamiento, elaboración, producción, aplicación, manipulación, uso, almacenamiento, transporte, distribución, importación, comercialización y expendio de alimentos para consumo humano que sean o contengan productos genéticamente modificados, se realizará cuando se demuestre ante la autoridad competente, mediante estudios técnicos y científicamente avanzados, su inocuidad y seguridad para los consumidores y el medio ambiente.

Para cumplir con este propósito, la autoridad sanitaria nacional deberá coordinar con los organismos técnicos públicos y privados correspondientes.

Art. 150.- La donación de alimentos que contengan productos genéticamente modificados, así como su utilización, uso y manejo en planes y programas y planes de ayuda alimentaria, serán aceptados si es que mediante procedimientos técnicos y científicamente avanzados, demuestren su inocuidad y seguridad ante la autoridad sanitaria nacional.

Para cumplir con este propósito, la autoridad sanitaria nacional actuará de conformidad con los principios universales en materia de salud pública y lo establecido en el inciso segundo del artículo precedente.

Art. 151.- Los envases de los productos que contengan alimentos genéticamente modificados, sean nacionales o importados, deben incluir obligatoriamente, en forma visible y comprensible en sus etiquetas, el señalamiento de esta condición, además de los otros requisitos que establezca la autoridad sanitaria nacional, de conformidad con la ley y las normas reglamentarias que se dicten para el efecto.

Art. 152.- La autoridad sanitaria nacional, en coordinación con los organismos competentes, establecerá e implementará un sistema nacional integrado para garantizar la inocuidad de los alimentos.

CAPITULO III
De los medicamentos

Art. 153.- Todo medicamento debe ser comercializado en establecimientos legalmente autorizados.

Para la venta al público se requiere de receta emitida por profesionales facultados para hacerlo, a excepción de los medicamentos de venta libre, clasificados como tales con estricto apego a normas farmacológicas actualizadas, a fin de garantizar la seguridad de su uso y consumo.

Art. 154.- El Estado garantizará el acceso y disponibilidad de medicamentos de calidad y su uso racional, priorizando los intereses de la salud pública sobre los económicos y comerciales.

Promoverá la producción, importación, comercialización, dispensación y expendio de medicamentos genéricos con énfasis en los esenciales, de conformidad con la normativa vigente en la materia. Su uso, prescripción, dispensación y expendio es obligatorio en las instituciones de salud pública.

Art. 155.- Los medicamentos en general, incluyendo los productos que contengan nuevas entidades químicas que obtengan registro sanitario nacional y no sean comercializados por el lapso de un año, serán objeto de cancelación de dicho registro sanitario.

Art. 156.- La autoridad sanitaria nacional autorizará la importación de medicamentos en general, en las cantidades necesarias para la obtención del requisito sanitario, de conformidad con lo previsto en el reglamento correspondiente.

Art. 157.- La autoridad sanitaria nacional garantizará la calidad de los medicamentos en general y desarrollará programas de fármaco vigilancia y estudios de utilización de medicamentos, entre otros, para precautelar la seguridad de su uso y consumo.

Además realizará periódicamente controles posregistro y estudios de utilización de medicamentos para evaluar y controlar los estándares de calidad, seguridad y eficacia y sancionar a quienes comercialicen productos que no cumplan dichos estándares, falsifiquen o adulteren los productos farmacéuticos.

Art. 158.- El desarrollo, la producción, manipulación, uso, almacenamiento, transporte, distribución, importación, comercialización y expendio de productos nutraceúticos, será permitido cuando se demuestre técnica y científicamente ante la autoridad sanitaria nacional, su seguridad para el consumidor y el ambiente. El registro y control sanitarios de estos productos se sujetará a las regulaciones vigentes para medicamentos.

Art. 159.- Corresponde a la autoridad sanitaria nacional la fijación, revisión y control de precios de los medicamentos de uso y consumo humano a través del Consejo Nacional de Fijación y Revisión de Precios de Medicamentos de Uso Humano, de conformidad con la ley.

Se prohíbe la comercialización de los productos arriba señalados sin fijación o revisión de precios.

Art. 160.- Para efectos de la fijación y revisión de precios de los medicamentos de uso y consumo humano, los gastos de publicidad y promoción serán regulados de conformidad con la ley y la normativa vigente, para que no afecten al acceso a los medicamentos y a los derechos de los consumidores.

Art. 161.- Para la fijación y revisión de precios de medicamentos importados, se considerará el precio en el puerto de embarque (FOB) del país de origen del producto, el mismo que no podrá ser superior a los precios de venta al distribuidor o mayorista del país de origen.

Art. 162.- Los precios de venta al público deben estar impresos en los envases de manera que no puedan ser removidos. Se prohíbe alterar los precios o colocar etiquetas que los modifiquen.

Art. 163.- Los laboratorios farmacéuticos, distribuidoras farmacéuticas, casas de representación de medicamentos, dispositivos médicos, productos dentales, reactivos bioquímicos y de diagnóstico, en las ventas que realicen a las instituciones públicas descontarán un porcentaje no inferior al 15% del precio de venta a farmacia.

CAPITULO IV
De los productos naturales procesados de uso medicinal

Art. 164.- Los productos naturales procesados de uso medicinal, se producirán, almacenarán, comercializarán e importarán siempre que cuenten con registro sanitario nacional, de conformidad con la ley y el reglamento correspondiente y bajo las normas de calidad emitidas por la autoridad sanitaria nacional.

CAPITULO V
De los establecimientos farmacéuticos

Art. 165.- Para fines legales y reglamentarios, son establecimientos farmacéuticos los laboratorios farmacéuticos, casas de representación de medicamentos, distribuidoras farmacéuticas, farmacias y botiquines, que se encuentran en todo el territorio nacional.

Art. 166.- Las farmacias deben atender al público mínimo doce horas diarias, ininterrumpidas y cumplir obligatoriamente los turnos establecidos por la autoridad sanitaria nacional. Requieren obligatoriamente para su funcionamiento la dirección técnica y responsabilidad de un profesional químico farmacéutico o bioquímico farmacéutico, quien brindará atención farmacéutica especializada.

Los botiquines estarán a cargo de personas calificadas y certificadas para el manejo de medicamentos. La autorización para su funcionamiento es transitoria y revocable.

La autoridad sanitaria nacional implementará farmacias y botiquines institucionales, debidamente equipados, en todas sus unidades operativas de acuerdo al nivel de complejidad.

Art. 167.- La receta emitida por los profesionales de la salud facultados por ley para hacerlo, debe contener obligatoriamente y en primer lugar el nombre genérico del medicamento prescrito.

Quien venda informará obligatoriamente al comprador sobre la existencia del medicamento genérico y su precio.

No se aceptarán recetas ilegibles, alteradas o en clave.

Art. 168.- Son profesionales de la salud humana facultados para prescribir medicamentos, los médicos, odontólogos y obstetrices.

Art. 169.- La venta de medicamentos al público al por menor sólo puede realizarse en establecimientos autorizados para el efecto.

Art. 170.- Los medicamentos, para su venta deben cumplir con los siguientes requisitos:

a) Estar debidamente identificados y etiquetados, sin alteraciones ni enmiendas;
b) Contener en sus etiquetas el número de registro sanitario nacional, el precio de venta al público y la fecha de expiración;
c) No estar caducados;
d) No provenir de instituciones de servicio social, de programas sociales estatales, de donaciones o ser muestras médicas;
e) No haber sido introducidos clandestinamente al país;
f) No ser falsificados o adulterados; y,
g) No tener colocados elementos sobre las etiquetas que impidan la visibilidad de la información del producto, incluidas las que contienen los precios.

Art. 171.- Es prohibida la venta de medicamentos que contengan sustancias psicotrópicas y estupefacientes que no cuenten con receta emitida por profesionales autorizados para prescribirlas. Cuando se requiera la prescripción y venta de medicamentos que contengan estas sustancias, se realizará conforme a las normas emitidas por la autoridad sanitaria nacional y la Ley de Sustancias Estupefacientes y Psicotrópicas.

Art. 172.- En las farmacias y botiquines no se podrá ofrecer o dar consulta médica, obstétrica, odontológica, aplicar tratamientos, realizar toma de muestras ni tener laboratorios clínicos.

Art. 173.- Todo establecimiento farmacéutico debe contar con la responsabilidad técnica de un profesional químico farmacéutico o bioquímico farmacéutico, quien puede tener bajo su responsabilidad técnica uno o más establecimientos farmacéuticos, de conformidad con lo que establezca el reglamento.

El reglamento de aplicación de esta Ley normará lo relacionado a este servicio, en los lugares en donde no existan suficientes profesionales ni establecimientos farmacéuticos.

Art. 174.- Se prohíbe a los expendedores de farmacias recomendar la utilización de medicamentos que requieran receta médica o cambiar la sustancia activa prescrita, sin la autorización escrita del prescriptor.

Art. 175.- Sesenta días antes de la fecha de caducidad de los medicamentos, las farmacias y botiquines notificarán a sus proveedores, quienes tienen la obligación de retirar dichos productos y canjearlos de acuerdo con lo que establezca la reglamentación correspondiente.

Art. 176.- Los medicamentos caducados referidos en el artículo anterior deben ser destruidos y eliminados por los fabricantes o importadores, conforme

a los procedimientos establecidos por la autoridad sanitaria nacional y bajo su supervisión.

CAPITULO VI
Otros establecimientos sujetos a control sanitario

Art. 177.- Es responsabilidad de la autoridad sanitaria nacional, expedir normas y controlar las condiciones higiénico sanitarias de establecimientos de servicios de atención al público y otros sujetos a control sanitario, para el otorgamiento o renovación del permiso de funcionamiento.

En el caso de establecimientos educativos públicos y privados, vigilará, controlará y evaluará periódicamente la infraestructura y condiciones higiénico sanitarias requisitos necesarios para su funcionamiento.

Art. 178.- Los establecimientos de producción, almacenamiento, envase o expendio de productos naturales de uso medicinal y de medicamentos homeopáticos, requieren para su instalación y funcionamiento del permiso otorgado por la autoridad sanitaria nacional.

Art. 179.- Las casas de representación y distribuidoras de productos dentales, dispositivos médicos, reactivos bioquímicos y de diagnóstico, para su funcionamiento deberán obtener el permiso de la autoridad sanitaria nacional.

LIBRO IV
De los servicios y profesiones de salud

TITULO UNICO

CAPITULO I
De los servicios de salud

Art. 180.- La autoridad sanitaria nacional regulará, licenciará y controlará el funcionamiento de los servicios de salud públicos y privados, con y sin fines de lucro, autónomos, comunitarios y de las empresas privadas de salud y medicina prepagada y otorgará su permiso de funcionamiento.

Regulará los procesos de licenciamiento y acreditación.

Regulará y controlará el cumplimiento de la normativa para la construcción, ampliación y funcionamiento de estos establecimientos de acuerdo a la tipología, basada en la capacidad resolutiva, niveles de atención y complejidad.

Art. 181.- La autoridad sanitaria nacional regulará y vigilará que los servicios de salud públicos y privados, con y sin fines de lucro, autónomos y las empresas privadas de salud y medicina prepagada, garanticen atención oportuna, eficiente y de calidad según los enfoques y principios definidos en esta Ley.

Art. 182.- La autoridad sanitaria nacional, regulará y aprobará las tarifas de los servicios de salud y las de los planes y programas de las empresas de servicios de salud y medicina prepagada, de conformidad con el reglamento que se emita para el efecto.

Art. 183.- El contrato de prestación de servicios de medicina prepagada debe ser aprobado por la autoridad sanitaria nacional.

Es obligación de las empresas de medicina prepagada obtener dicha aprobación y hacerla constar en el contrato respectivo.

Art. 184.- Es obligación de los servicios de salud exhibir en sitios visibles para el público, las tarifas que se cobran por sus servicios, las mismas que deben estar aprobadas por la autoridad sanitaria nacional.

Art. 185.- Los servicios de salud funcionarán, de conformidad con su ámbito de competencia, bajo la responsabilidad técnica de un profesional de la salud.

Art. 186.- Es obligación de todos los servicios de salud que tengan salas de emergencia, recibir y atender a los pacientes en estado de emergencia. Se prohíbe exigir al paciente o a las personas relacionadas un pago, compromiso económico o trámite administrativo, como condición previa a que la persona sea recibida, atendida y estabilizada en su salud.

Una vez que el paciente haya superado la emergencia, el establecimiento de salud privado podrá exigir el pago de los servicios que recibió.

Art. 187.- Los valores no recuperados por el servicio de salud por la atención a un paciente en estado de emergencia, cuya imposibilidad de pago esté debidamente comprobada, se deducirán del impuesto a la renta de conformidad con las disposiciones de la Ley de Régimen Tributario Interno.

Art. 188.- La autoridad sanitaria nacional, regulará y vigilará que los servicios de salud públicos y privados apliquen las normas de prevención y control de infecciones nosocomiales.

CAPITULO II
De las medicinas tradicionales y alternativas

Art. 189.- Los integrantes del Sistema Nacional de Salud respetarán y promoverán el desarrollo de las medicinas tradicionales, incorporarán el enfoque intercultural en las políticas, planes, programas, proyectos y modelos de atención de salud, e integrarán los conocimientos de las medicinas tradicionales y alternativas en los procesos de enseñanza - aprendizaje.

Art. 190.- La autoridad sanitaria nacional promoverá e impulsará el intercambio de conocimientos entre los distintos agentes de las medicinas tradicionales, fomentará procesos de investigación de sus recursos diagnósticos y terapéuticos en el marco de los principios establecidos en esta Ley, protegiendo los derechos colectivos de los pueblos indígenas y negros o afroecuatorianos.

Art. 191.- La autoridad sanitaria nacional implementará procesos de regulación y control, para evitar que las prácticas de las medicinas tradicionales atenten a la salud de las personas.

Art. 192.- Los integrantes del Sistema Nacional de Salud respetarán y promoverán el desarrollo de las medicinas alternativas en el marco de la atención integral de salud.

Las medicinas alternativas deben ser ejercidas por profesionales de la salud con títulos reconocidos y certificados por el CONESUP y registrados ante la autoridad sanitaria nacional.

Las terapias alternativas requieren para su ejercicio, el permiso emitido por la autoridad sanitaria nacional.

CAPITULO III
De las profesiones de salud, afines y su ejercicio

Art. 193.- Son profesiones de la salud aquellas cuya formación universitaria de tercer o cuarto nivel está dirigida específica y fundamentalmente a dotar a los profesionales de conocimientos, técnicas y prácticas, relacionadas con la salud individual y colectiva y al control de sus factores condicionantes.

Art. 194.- Para ejercer como profesional de salud, se requiere haber obtenido título universitario de tercer nivel, conferido por una de las universidades establecidas y reconocidas legalmente en el país, o por una del exterior, revalidado y refrendado. En uno y otro caso debe estar registrado ante el CONESUP y por la autoridad sanitaria nacional.

Art. 195.- Los títulos de nivel técnico superior o tecnológico así como los de auxiliares en distintas ramas de la salud, para su habilitación deben ser registrados en las instancias respectivas e inscritos ante la autoridad sanitaria nacional.

Art. 196.- La autoridad sanitaria nacional analizará los distintos aspectos relacionados con la formación de recursos humanos en salud, teniendo en cuenta las necesidades nacionales y locales, con la finalidad de promover entre las instituciones formadoras de recursos humanos en salud, reformas en los planes y programas de formación y capacitación.

Art. 197.- Para la habilitación del ejercicio profesional y el registro correspondiente, los profesionales de salud deben realizar un año de práctica en las parroquias rurales o urbano marginales, con remuneración, en concordancia con el modelo de atención y de conformidad con el reglamento correspondiente en los lugares destinados por la autoridad sanitaria nacional, al término del cual se le concederá la certificación que acredite el cumplimiento de la obligación que este artículo establece.

La autoridad sanitaria nacional en coordinación con organismos seccionales y organizaciones de base, controlará la asignación y el cumplimiento del año obligatorio por parte de los profesionales que cumplen el año de salud rural.

Se prohíbe el ejercicio de la práctica rural en unidades operativas urbanas de segundo y tercer nivel.

Art. 198.- Los profesionales y técnicos de nivel superior que ejerzan actividades relacionadas con la salud, están obligados a limitar sus acciones al área que el título les asigne.

Art. 199.- Corresponde a la autoridad sanitaria nacional la investigación y sanción de la práctica ilegal, negligencia, impericia, imprudencia e inobservancia en el ejercicio de las profesiones de la salud, sin perjuicio de la acción de la justicia ordinaria.

Art. 200.- El profesional que ampare con su título o con su firma el ejercicio de las profesiones de la salud a personas no autorizadas, sin perjuicio de lo establecido en esta Ley, será sancionado de acuerdo con la legislación aplicable.

Art. 201.- Es responsabilidad de los profesionales de salud, brindar atención de calidad, con calidez y eficacia, en el ámbito de sus competencias, buscando el mayor beneficio para la salud de sus pacientes y de la población, respetando los derechos humanos y los principios bioéticos.

Es su deber exigir condiciones básicas para el cumplimiento de lo señalado en el inciso precedente.

Art. 202.- Constituye infracción en el ejercicio de las profesiones de salud, todo acto individual e intransferible, no justificado, que genere daño en el paciente y sea resultado de:

a) Inobservancia, en el cumplimiento de las normas;
b) Impericia, en la actuación del profesional de la salud con falta total o parcial de conocimientos técnicos o experiencia;
c) Imprudencia, en la actuación del profesional de la salud con omisión del cuidado o diligencia exigible; y,
d) Negligencia, en la actuación del profesional de la salud con omisión o demora injustificada en su obligación profesional.

Art. 203.- Los servicios de salud, serán corresponsables civilmente, de las actuaciones de los profesionales de la salud que laboran en ellos.

Art. 204.- El consentimiento o autorización del paciente o de la persona que le representa legalmente, no exime de responsabilidad al profesional o al servicio de salud en aquellos casos determinados en el artículo 202 de esta Ley.

CAPITULO IV
De la capacitación sanitaria

Art. 205.- Créase la carrera sanitaria para los recursos humanos del Sistema Nacional de Salud, basada en el criterio de clasificación por niveles de formación y estructura ocupacional, con el propósito de establecer sus obligaciones y derechos, así como los incentivos que permitan garantizar la equidad, calidad en la atención y el servicio, la asignación adecuada y suficiente de recursos humanos en las distintas zonas del país.

La autoridad sanitaria nacional promoverá y desarrollará, dentro de la carrera sanitaria, un plan nacional de educación permanente con enfoque de género y pluricultural, para mejorar la productividad, calidad del desempeño laboral y promoción de sus recursos humanos.

Art. 206.- La autoridad sanitaria nacional establecerá planes de capacitación y evaluación permanente de los profesionales y recursos humanos en salud e implementará promociones e incentivos.

LIBRO V
TITULO UNICO

Investigación científica en salud, genética y sistema de información en salud

CAPITULO I
De la investigación científica en salud

Art. 207.- La investigación científica en salud así como el uso y desarrollo de la biotecnología, se realizará orientada a las prioridades y necesidades nacionales, con sujeción a principios bioéticos, con enfoques pluricultural, de derechos y de género, incorporando las medicinas tradicionales y alternativas.

Art. 208.- La investigación científica tecnológica en salud será regulada y controlada por la autoridad sanitaria nacional, en coordinación con los organismos competentes, con sujeción a principios bioéticos y de derechos, previo consentimiento informado y por escrito, respetando la confidencialidad.

CAPITULO II
De la genética humana

Art. 209.- La autoridad sanitaria nacional normará, licenciará y controlará el funcionamiento de los servicios de salud especializados, públicos y privados, para el ejercicio de actividades relacionadas con la investigación y desarrollo de la genética humana. Igualmente controlará el ejercicio profesional de quienes realicen dichas actividades, que deberán necesariamente tener especialidad en el área de genética o afines.

Art. 210.- Sólo podrán hacerse pruebas de identificación humana, filiación y compatibilidad de antígenos para:

a) Trasplantes;
b) Estudios mutacionales;
c) Ligamiento genético;
d) Pruebas predictivas de enfermedades genéticas.
e) Pruebas para detectar la predisposición genética a una enfermedad;
f) Fines terapéuticos; y,
g) Otras que se desarrollen con fines de salud genética.

Estas pruebas deberán contar con asesoramiento y supervisión genético especializado, siguiendo procedimientos científicamente probados, con sujeción y respeto a los principios bioéticos.

Art. 211.- Se prohíbe toda forma de discriminación de una persona a causa de su patrimonio genético.

Es obligatorio guardar confidencialidad respecto al genoma individual de la persona.

Art. 212.- Se prohíbe la intervención genética sobre células de la línea germinal y células madre, con fines de experimentación y lucro.

Podrán efectuarse intervenciones sobre el genoma humano, células de la línea germinal y células madre únicamente por razones predictivas, preventivas, diagnósticas o terapéuticas, siempre que se disponga de asesoramiento genético especializado, procedimientos científicamente probados y seguros, previo consentimiento informado, expreso y escrito de la persona y que sea de beneficio social y eugenésico.

Art. 213.- No se podrán patentar genes ni derivados celulares humanos naturales.

Art. 214.- Se prohíben las prácticas de clonación de seres humanos, así como la obtención de embriones humanos con fines de experimentación.

La autoridad sanitaria nacional procurará y fomentará la integración y trabajo cooperativo de los centros de investigación y desarrollo de la genética.

CAPITULO III
Del sistema común de información

Art. 215.- La autoridad sanitaria nacional con la participación de los integrantes del Sistema Nacional de Salud, implementará el sistema común de información con el fin de conocer la situación de salud, identificar los riesgos para las personas y el ambiente, dimensionar los recursos disponibles y la producción de los servicios, para orientar las decisiones políticas y gerenciales y articular la participación ciudadana en todos los niveles, entre otras.

Este sistema incorporará los enfoques pluricultural, multiétnico, de género, las particularidades regionales y poblacionales, así como la división político - administrativa del país.

LIBRO SEXTO
Jurisdicción, competencia, procedimiento, sanciones y definiciones

CAPITULO I
De la jurisdicción y competencia

Art. 216.- La jurisdicción y competencia administrativa, en materia de salud nacen de esta Ley.

Art. 217.- Tienen jurisdicción para conocer, juzgar e imponer las sanciones previstas en esta Ley y demás normas vigentes, las siguientes autoridades de salud:

a) El Ministro de Salud Pública;
b) El Director General de Salud;
c) Los directores provinciales de salud; y,
d) Los comisarios de salud.

Art. 218.- Los comisarios de salud deben ser doctores en jurisprudencia o abogados con experiencia mínima de tres años de ejercicio profesional.

Art. 219.- El Ministro de Salud Pública y el Director General de Salud, tienen competencia en todo el territorio nacional.

Los directores provinciales de salud y los comisarios de salud, tienen competencia en el ámbito provincial.

Art. 220.- La Fuerza Pública está obligada a colaborar con las autoridades de salud para hacer cumplir las disposiciones de esta Ley, cuando se requiera su intervención.

CAPITULO II
Del procedimiento

Art. 221.- Las autoridades de salud señaladas en el Capítulo anterior, actuarán de oficio, por denuncia o informe para conocer y sancionar las infracciones señaladas en esta Ley. Las denuncias se presentarán en forma verbal o por escrito.

Art. 222.- Las autoridades de salud señaladas en el artículo 217, que no cumplieren adecuadamente su obligación de conocer, juzgar e imponer las sanciones previstas en esta Ley, serán sancionadas de conformidad con el reglamento correspondiente y demás normas atinentes a la materia, sin perjuicio de las acciones administrativas, civiles y penales a que hubiere lugar.

Art. 223.- Se concede acción pública para denunciar cualquier infracción a las disposiciones de la presente Ley.

Art. 224.- Cuando se actúe de oficio o mediante informe o denuncia, la autoridad de salud correspondiente dictará un auto inicial que contendrá:

a) La relación sucinta de los hechos y del modo como llegaron a su conocimiento;
b) La orden de citar al presunto infractor, disponiendo que señale domicilio para entregar las notificaciones, bajo prevención de que será juzgado en rebeldía en caso de no comparecer;
c) La orden de agregar al expediente el informe o denuncia, si existieren, y de que se practiquen las diligencias que sean necesarias para comprobar la infracción;
d) El señalamiento del día y hora para que tenga lugar la audiencia de juzgamiento; y,
e) La designación del secretario que actuará en el proceso.

Art. 225.- Corresponde conocer y resolver las causas en primera instancia:

a) Al comisario de salud, las infracciones sancionadas en los artículos 241, 242, 243, 244 y 245 de esta Ley;
b) Al director provincial de salud, las infracciones sancionadas en los artículos 246, 247, 248 y 256 de esta Ley; y,
c) Al Director General de Salud, las infracciones sancionadas en los artículos 249, 250, 251, 252, 254 y 255 de esta Ley.

De no ser competente la autoridad se inhibirá de conocer la causa y la remitirá de oficio, a quien corresponda.

Art. 226.- En caso de que la infracción tenga indicios de responsabilidad penal, el expediente se remitirá a la autoridad competente.

Art. 227.- La citación con el auto inicial, se hará personalmente al infractor, en su domicilio o lugar de trabajo; si no se le encontrare, se le citará mediante tres boletas dejadas en el domicilio o lugar de trabajo, en diferentes días, sentando la razón de la citación.

Art. 228.- En la audiencia de juzgamiento, se oirá al infractor, que intervendrá por sí o por medio de su abogado; se recibirán las pruebas que presente y se agregarán al proceso, de lo cual se dejará constancia en acta firmada por el compareciente, la autoridad de salud correspondiente y el secretario.

Art. 229.- De solicitarlo cualquiera de las partes o de oficio, en la misma diligencia, se abrirá la causa a prueba por el término de seis días, en la cual se practicarán todas las pruebas que se soliciten.

Art. 230.- De no haberse solicitado que se abra la causa a prueba, la autoridad de salud correspondiente procederá a dictar la resolución en el término de cinco días.

Art. 231.- Vencido el término de prueba y practicadas todas las diligencias oportunamente solicitadas y ordenadas, la autoridad de salud correspondiente dictará su resolución dentro del termino de cinco días.

Art. 232.- De las resoluciones del comisario de salud, podrá apelarse ante el director provincial de salud; de las que dicte el director provincial de salud, ante el Director General de Salud; y, de las de esta autoridad ante el Ministro de Salud Pública, siendo estas decisiones de segunda y definitiva instancia.

Las resoluciones podrán ser apeladas dentro del término de tres días luego de ser notificadas a las partes; la autoridad superior dentro del término de ocho días desde que avoca conocimiento deberá dictar la correspondiente resolución.

Unicamente podrán apelarse las resoluciones de primera instancia, las de segunda instancia causarán ejecutoria.

Art. 233.- Una vez que la resolución esté ejecutoriada, se emitirá la orden de pago, la misma que de no ser pagada por el sujeto pasivo, será cobrada por la vía coactiva por el Ministerio de Salud Pública de acuerdo a lo establecido en el artículo 941 del Código de Procedimiento Civil, en el cual se le concede al Estado y a sus instituciones, acción y jurisdicción coactiva a nivel nacional.

Art. 234.- Los bienes y productos que fueren comisados y puedan ser utilizados, se entregarán a las instituciones de beneficencia de la jurisdicción provincial en donde se haya cometido la infracción, de conformidad con el reglamento que al efecto emita la autoridad sanitaria nacional.

Art. 235.- Los bienes y productos que no puedan ser utilizados, serán destruidos por la autoridad correspondiente, dejando constancia en acta que suscribirá conjuntamente con el secretario, cuyo original se remitirá a la autoridad inmediata superior para su conocimiento.

Art. 236.- En todo lo no previsto en esta Ley, se actuará de conformidad con lo previsto en los Códigos Penal y Civil; y, de Procedimiento Penal y Civil.

CAPITULO III
De las sanciones

Art. 237.- Las infracciones en materia de salud serán sancionadas de conformidad con las disposiciones contenidas en esta Ley y sus reglamentos, sin perjuicio de las sanciones civiles, administrativas y penales a que hubiera lugar.

Art. 238.- En la concurrencia de más de una infracción a las disposiciones de esta Ley y sus reglamentos, la persona será juzgada por todas las cometidas.

Art. 239.- La reincidencia en el incumplimiento de esta Ley y sus reglamentos, será reprimida con el doble del máximo de la sanción para cada caso, sin perjuicio de las sanciones civiles o penales a que hubiere lugar.

Art. 240.- Las infracciones determinadas en esta ley se sancionarán con:

a) Multa;
b) Suspensión del permiso o licencia;
c) Suspensión del ejercicio profesional;
d) Decomiso; y,
e) Clausura parcial, temporal o definitiva del establecimiento correspondiente.

CAPITULO IV
De las infracciones

Art. 241.- Será sancionado con multa de un salario básico unificado del trabajador en general, el incumplimiento a lo dispuesto en los artículos 32, 53, 61, 64, 74 inciso segundo, 101, 111 inciso segundo, 115, 120 inciso segundo, 122, 123, 167, 195, 198 y 202 literal a), de esta Ley.

Art. 242.- Será sancionado con multa de un salario básico unificado del trabajador en general y clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en los artículos 40, 47, 58 inciso segundo, 97, 103 y 124 de esta Ley.

Art. 243.- Será sancionado con multa de cinco salarios básicos unificados del trabajador en general, el incumplimiento a lo dispuesto en los artículos 50, 57, 60, 74 inciso primero, 90, 118, 163, 175, 184 y 202 literal b), de esta Ley.

Art. 244.- Será sancionado con multa de cinco salarios básicos unificados del trabajador en general y clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en los artículos 105, 109, 166, 169, 172, 174, 178, 194, 200 y 212 de esta Ley.

Art. 245.- Será sancionado con multa de cinco salarios básicos unificados del trabajador en general y decomiso, el incumplimiento de lo dispuesto en el artículo 125 y primer inciso del artículo 153 de esta Ley.

Art. 246.- Será sancionado con multa de diez salarios básicos unificados del trabajador en general, el incumplimiento a lo dispuesto en los artículos 12 inciso segundo, 22, 29, 41, 48, 80, 110, 173 y 202 literal c), de esta Ley.

Art. 247.- Será sancionado con multa de diez salarios básicos unificados del trabajador en general y clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en los artículos 104, 116, 121, 143, 159 inciso segundo, 186 y 192 incisos segundo y tercero, de esta Ley.

Art. 248.- Será sancionado con multa de diez salarios básicos unificados del trabajador en general, decomiso y clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en los artículos 42, 49, 137, 140, 141 inciso primero, 146, 164 y 170 de esta Ley.

Art. 249.- Será sancionado con multa de veinte salarios básicos unificados del trabajador en general, el incumplimiento a lo dispuesto en los artículos 27 inciso segundo, 75, 162 y 202 literal d), de esta Ley.

Art. 250.- Será sancionado con multa de veinte salarios básicos unificados del trabajador en general y clausura temporal o definitiva, el incumplimiento a lo dispuesto en los artículos 149 y 183 inciso segundo, de esta Ley.

Art. 251.- Será sancionado con multa de veinte salarios básicos unificados del trabajador en general, decomiso y clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en los artículos 150 y 151, de esta Ley.

Art. 252.- Será sancionado con multa de cincuenta salarios básicos unificados del trabajador en general, el incumplimiento a lo dispuesto en los artículos 81 y 82 inciso primero, de esta Ley.

Art. 253.- La infracción a lo dispuesto en los artículos 213 y 214, será sancionada con suspensión del ejercicio profesional, multa de cien salarios básicos unificados del trabajador en general y clausura definitiva del establecimiento, sin perjuicio de las sanciones civiles y penales a que hubiere lugar.

Art. 254.- Será sancionado con multa de cinco salarios básicos unificados del trabajador en general, el incumplimiento a lo dispuesto en los artículos 130 y 134 de esta Ley.

Art. 255.- Será sancionado con la suspensión del ejercicio profesional por cinco años y clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en el artículo 210 de esta Ley.

Art. 256.- Será sancionado con clausura temporal o definitiva del establecimiento correspondiente, el incumplimiento a lo dispuesto en el artículo 185 de esta Ley.

Art. 257.- El producto de las multas que se recauden por infracciones a lo dispuesto por esta Ley y sus reglamentos, será utilizado en la respectiva jurisdicción en donde se las impusiere, debiendo destinarlo para la atención y mejoramiento de los servicios de salud de la respectiva dirección provincial.

Art. 258.- Para el cumplimiento de las disposiciones establecidas en la presente Ley, las autoridades de salud tendrán libre acceso a los lugares en los cuales deban cumplir sus funciones de inspección y control, pudiendo al efecto requerir la intervención de la fuerza pública, en caso de ser necesario.

CAPITULO V
De las definiciones

Art. 259.- Para efectos de esta Ley, se entiende por:

Acreditación de servicios de salud.- Es el proceso voluntario realizado con regularidad y periodicidad, de carácter reservado, a través del cual un servicio de salud, independientemente de su nivel es evaluado por un organismo técnico calificado, de acuerdo a un conjunto de normas que describe las actividades y estructuras que contribuyen en forma directa a los resultados deseados para los pacientes-usuarios, el cumplimiento de estas normas busca alcanzar un óptimo nivel de calidad de atención teniendo en cuenta los recursos disponibles.

Aditivos alimentarios.- Son sustancias o mezclas de sustancias de origen natural o artificial, que por sí solas no se consumen directamente como alimentos, tengan o no valor nutritivo y se adicionan en límites permitidos durante la producción, manipulación, fabricación, elaboración, tratamiento o conservación de alimentos.

Agentes de las medicinas tradicionales.- Son aquellos sanadores que intervienen en diferentes ámbitos de la salud, cuyas denominaciones son particulares a cada una de las nacionalidades y pueblos, y su reconocimiento proviene de las propias comunidades donde prestan sus servicios. Las condiciones y características formales y temporales de su formación son propias de su tradición y cultura ancestral.

Alimento.- Es todo producto natural o artificial que ingerido aporta al organismo de los seres humanos o de los animales, los materiales y la energía necesarios para el desarrollo de los procesos biológicos.

Comprende también las sustancias y mezclas de las mismas que se ingieren por hábito o costumbre, tengan o no valor nutritivo.

Alimentos genéticamente modificados.- Son aquellos que contienen o están compuestos por organismos genéticamente modificados o han sido producidos a partir de ellos.

Alimento natural.- Es aquel que se utiliza como se presenta en la naturaleza sin haber sufrido transformación en sus caracteres o en su composición, pudiendo ser sometido a procesos prescritos por razones de higiene, o las necesarias para la separación de partes no comestibles.

Alimento procesado.- Es toda materia alimenticia natural o artificial que para el consumo humano ha sido sometida a operaciones tecnológicas necesarias para su transformación, modificación y conservación, que se distribuye y comercializa en envases rotulados bajo una marca de fábrica determinada.

El término alimento procesado, se extiende a bebidas alcohólicas y no alcohólicas, aguas de mesa, condimentos, especias y aditivos alimentarios.

Atención farmacéutica.- Es la asistencia al paciente por parte del químico farmacéutico o bioquímico farmacéutico en el seguimiento del tratamiento fármaco terapéutico, dirigido a contribuir con el médico y otros profesionales de la salud, en la consecución de los resultados previstos y el logro del máximo beneficio terapéutico.

Bancos de sangre.- Son servicios de salud, técnicos, especializados y calificados, encargados de realizar la extracción, preparación, conservación, almacenamiento y suministro de la sangre humana, sus componentes y derivados.

Bancos de tejidos.- Son servicios de salud técnicos, especializados y calificados, que tienen por misión garantizar la calidad de los tejidos desde su obtención hasta su utilización clínica.

Botiquines.- Son establecimientos farmacéuticos autorizados para expender al público, únicamente la lista de medicamentos y otros productos que determine la autoridad sanitaria nacional; funcionarán en zonas rurales en las que no existan farmacias y deben cumplir en todo tiempo con prácticas adecuadas de almacenamiento.

Casas de representación.- Son los establecimientos farmacéuticos autorizados para realizar promoción médica, importación y venta al por mayor a terceros de los productos elaborados por sus representados. Deben cumplir con buenas prácticas de almacenamiento y distribución determinadas por la autoridad sanitaria nacional. Requieren para su funcionamiento de la dirección técnica responsable de un profesional químico farmacéutico o bioquímico farmacéutico.

Ciclo producción - consumo.- Son las etapas o fases involucradas en la producción, manipulación, almacenamiento, transporte, distribución, importación, exportación, comercialización, expendio y consumo de productos.

Componentes anatómicos.- Son los órganos, tejidos, células, sus derivados y en general todas las partes del organismo humano.

Desechos.- Son los residuos o desperdicios en cualquier estado de la materia, producto de actividades industriales, comerciales y de la comunidad; se clasifican en comunes, infecciosos y especiales o peligrosos.

Desechos comunes.- Son aquellos que no representan riesgo para la salud humana, animal o el ambiente.

Desechos peligrosos.- Son aquellos resultantes de un proceso de producción, transformación, reciclaje, utilización o consumo y que tengan algún compuesto con características reactivas, inflamables, corrosivas, infecciosas o tóxicas, que presenten un riesgo para la salud humana, los recursos naturales y el ambiente.

Desechos infecciosos.- Son aquellos que contienen gérmenes patógenos y representan riesgo para la salud; se generan en los establecimientos de salud humana, veterinarios, morgues y otros.

Dispositivos médicos.- Son los artículos, instrumentos, aparatos, artefactos o invenciones mecánicas, incluyendo sus componentes, partes o accesorios, fabricado, vendido o recomendado para uso en diagnóstico, tratamiento curativo o paliativo, prevención de una enfermedad, trastorno o estado físico anormal o sus síntomas, para reemplazar o modificar la anatomía o un proceso fisiológico o controlarla. Incluyen las amalgamas, barnices, sellantes y más productos dentales similares.

Distribuidoras farmacéuticas.- Son establecimientos farmacéuticos autorizados para realizar importación, exportación y venta al por mayor de medicamentos en general de uso humano, especialidades farmacéuticas, productos para la industria farmacéutica, auxiliares médico-quirúrgico, dispositivos

médicos, insumos médicos, cosméticos y productos higiénicos. Deben cumplir con las buenas prácticas de almacenamiento y distribución determinadas por la autoridad sanitaria nacional. Funcionarán bajo la representación y responsabilidad técnica de un químico farmacéutico o bioquímico farmacéutico.

Donante.- Es la persona de la cual, durante su vida o después de su muerte, se extraen componentes anatómicos en buen estado funcional, para trasplantarlos en otra persona o utilizarlos con fines terapéuticos o de investigación.

Emergencia sanitaria.- Es toda situación de riesgo de afección de la salud originada por desastres naturales o por acción de las personas, fenómenos climáticos, ausencia o precariedad de condiciones de saneamiento básico que favorecen el incremento de enfermedades transmisibles. Requiere la intervención especial del Estado con movilización de recursos humanos, financieros u otros, destinados a reducir el riesgo o mitigar el impacto en la salud de las poblaciones más vulnerables.

La emergencia sanitaria deberá ser declarada por el Presidente de la República conforme lo manda la Constitución Política.

Farmacias.- Son establecimientos farmacéuticos autorizados para la dispensación y expendio de medicamentos de uso y consumo humano, especialidades farmacéuticas, productos naturales procesados de uso medicinal, productos biológicos, insumos y dispositivos médicos, cosméticos, productos dentales, así como para la preparación y venta de fórmulas oficinales y magistrales. Deben cumplir con buenas prácticas de farmacia. Requieren para su funcionamiento la dirección técnica y responsabilidad de un profesional químico farmacéutico o bioquímico farmacéutico.

Genética.- Es la ciencia que trata de la reproducción, herencia, variación tanto en estado normal como anormal o de enfermedad, y del conjunto de fenómenos y problemas relativos a la descendencia.

Laboratorios farmacéuticos.- Son establecimientos farmacéuticos autorizados para producir o elaborar medicamentos en general, especialidades farmacéuticas, biológicos de uso humano o veterinario; deben cumplir las normas de buenas prácticas de manufactura determinadas por la autoridad sanitaria nacional; y, estarán bajo la dirección técnica de químicos farmacéuticos o bioquímicos farmacéuticos.

Licenciamiento de servicios de salud.- Es el procedimiento de carácter obligatorio por medio del cual la autoridad sanitaria nacional otorga el permiso de funcionamiento a las instituciones prestadoras de servicios de salud, públicas o privadas, según su capacidad resolutiva, niveles de atención y complejidad, previa verificación del cumplimiento de los requisitos o estándares mínimos indispensables.

Materia prima alimentaria.- Es la sustancia o mezcla de sustancias, natural o artificial permitida por la autoridad sanitaria nacional, que se utiliza para la elaboración de alimentos y bebidas.

Medicamento.- Es toda preparación o forma farmacéutica, cuya fórmula de composición expresada en unidades del sistema internacional, está constituida por una sustancia o mezcla de sustancias, con peso, volumen y porcentajes constantes, elaborada en laboratorios farmacéuticos legalmente establecidos, envasada o etiquetada para ser distribuida y comercializada como eficaz para diagnóstico, tratamiento, mitigación y profilaxis de una enfermedad, anomalía física o síntoma, o el restablecimiento, corrección o modificación del equilibrio de las funciones orgánicas de los seres humanos y de los animales.

Por extensión esta definición se aplica a la asociación de sustancias de valor dietético, con indicaciones terapéuticas o alimentos especialmente preparados, que reemplacen regímenes alimenticios especiales. (CONTINUA).

Art. 259.- (CONTINUACION)

Medicamento de venta libre.- Es el medicamento oral o tópico que por su composición y por la acción farmacológica de sus principios activos, es autorizado para ser expendido o dispensado sin prescripción facultativa.

Medicamento genérico.- Es aquel que se registra y comercializa con la Denominación Común Internacional (DCI) del principio activo, propuesta por la Organización Mundial de la Salud; o en su ausencia, con una denominación genérica convencional reconocida internacionalmente. Estos medicamentos deben mantener los niveles de calidad, seguridad y eficacia requeridos para los de marca.

Medicamento homeopático.- Es el preparado farmacéutico obtenido por técnicas homeopáticas, conforme a las reglas descritas en las farmacopeas oficiales aceptadas en el país, con el objeto de prevenir la enfermedad, aliviar, curar, tratar y rehabilitar a un paciente. Los envases, rótulos, etiquetas y empaques hacen parte integral del medicamento, por cuanto éstos garantizan su calidad, estabilidad y uso adecuado. Deben ser prescritos por profesionales autorizados para el efecto y dispensados o expendidos en lugares autorizados para el efecto.

Medicinas alternativas.- Son el conjunto de medicinas científicamente comprobadas, ejercidas por profesionales médicos, con título de cuarto nivel en la materia y reconocidas por la autoridad sanitaria nacional.

Medicinas tradicionales.- Son el conjunto de conocimientos y prácticas ancestrales de las nacionalidades, pueblos, comunidades indígenas, mestizas y afro descendientes que a lo largo del tiempo han constituido un saber específico, mantenido y difundido en un contexto cultural, de interrelación de elementos naturales, éticos, espirituales, mentales, psicológicos y afectivos y que se explica y funciona en ese mismo universo cultural. Sus prácticas se corresponden con saberes, técnicas y procedimientos propios de su cosmovisión y son ejercidas por sanadores de las medicinas tradicionales, reconocidos por sus comunidades y registrados por la autoridad sanitaria nacional.

Necropsia o autopsia.- Es el procedimiento técnico mediante el cual se observa y analiza un cadáver, externa e internamente para establecer las causas del fallecimiento de la persona.

Nueva entidad química.- Es el medicamento, ingrediente o principio activo de uso o consumo humano que nunca ha sido empleado para ninguna indicación terapéutica en el ámbito mundial. No se considerará nueva entidad química entre otros, los nuevos usos o segundos usos, ni las novedades o cambio de los siguientes aspectos: formas farmacéuticas, indicaciones o segundas indicaciones, nuevas combinaciones de entidades químicas conocidas, formulaciones, formas de dosificación, vías de administración, modificaciones de cualquier índole que no afecten el mecanismo de acción, condiciones de comercialización y empaque y en general, aquellas que impliquen nuevas presentaciones.

Organismos genéticamente modificados, OGM u organismo vivo modificado OVM.- Cualquier organismo vivo, con excepción de los seres humanos, que ha adquirido una combinación genética novedosa, generada a través del uso específico de técnicas de la biotecnología moderna.

Permiso de funcionamiento.- Es el documento otorgado por la autoridad sanitaria nacional a los establecimientos sujetos a control y vigilancia sanitaria que cumplen con todos los requisitos para su funcionamiento, establecidos en los reglamentos correspondientes.

Plantas procesadoras de alimentos.- Son establecimientos en los que se realizan operaciones de selección, purificación y transformación de materias primas para la producción, envasado y etiquetado de alimentos.

Producto natural procesado de uso medicinal.- Es el producto medicinal terminado y etiquetado, cuyos ingredientes activos están formados por cualquier parte de los recursos naturales de uso medicinal o sus combinaciones, como droga cruda, extracto o en una forma farmacéutica reconocida, que se utiliza con fines terapéuticos

No se considera un producto natural procesado de uso medicinal, si el recurso natural de uso medicinal se combina con sustancias activas definidas desde el punto de vista químico, inclusive constituyentes de recursos naturales, aislados y químicamente definidos.

Producto nutracéutico.- También llamado funcional o compuesto bioactivo, es cualquier producto semejante en apariencia a un alimento convencional que tiene uno o más beneficios intencionales, más allá de proporcionar una nutrición adecuada, como un mejor estado de salud o una reducción del riesgo de una enfermedad determinada.

Productos del tabaco.- Abarca los productos preparados totalmente o en parte utilizando como materia prima hojas de tabaco y destinados a ser fumados, chupados, inhalados, mascados o utilizados como rapé.

Reactivos bioquímicos.- Son todas las sustancias o productos que se utilizan con máquinas especiales o no, para reaccionar con líquidos o materias orgánicas y ayudar en el diagnóstico, monitoreo, control y tratamiento de las enfermedades de los seres humanos.

Receptor.- Es la persona en cuyo cuerpo se implantan componentes anatómicos provenientes de sí mismo, de otra persona o de otra especie.

Registro sanitario.- Es la certificación otorgada por la autoridad sanitaria nacional, para la importación, exportación y comercialización de los productos de uso y consumo humano señalados en el artículo 137 de esta Ley. Dicha certificación es otorgada cuando se cumpla con los requisitos de calidad, seguridad, eficacia y aptitud para consumir y usar dichos productos cumpliendo los trámites establecidos en la presente Ley y sus reglamentos.

Salud ambiental.- Son los conocimientos que se ocupan de las formas de vida, sustancias, fuerzas y condiciones del entorno del ser humano que pueden ejercer efectos nocivos sobre su salud y bienestar, así como las acciones para impedirlos o reducirlos, en el marco de la promoción y desarrollo de ambientes saludables.

Salud reproductiva.- Es el estado general de bienestar físico, mental y social y no de mera ausencia de enfermedades o dolencias, en todos los aspectos relacionados con el sistema reproductivo, sus funciones y procesos e implica el derecho de las personas a tomar decisiones respecto a ella.

Salud sexual.- Es el estado general de bienestar físico, mental y social y no de mera ausencia de enfermedades o dolencias, que permita a la persona en forma libre y responsable disfrutar de una vida sexual plena, placentera, libre de abuso sexual, coerción o acoso y de enfermedades sexualmente transmisibles.

Saneamiento ambiental.- Es el conjunto de actividades dedicadas a acondicionar, controlar y proteger el ambiente en que vive el ser humano, a fin de proteger su salud.

Servicios de salud.- Son aquellos que están destinados a brindar prestaciones de salud, de promoción, de prevención, de recuperación y rehabilitación en forma ambulatoria, domiciliaria o internamiento, son clasificados de acuerdo a la capacidad resolutiva, niveles de atención y complejidad.

Terapias alternativas.- Conjunto de métodos, técnicas y sistemas utilizados para prevención o tratamiento de enfermedades y se orientan a equilibrar el organismo en sus aspectos físico, mental o espiritual, y a establecer un balance entre el individuo y el entorno.

Trasplante de órganos.- Es la sustitución con fines terapéuticos de componentes anatómicos en una persona, por otros iguales y funcionales provenientes del mismo receptor o de un donante vivo o muerto.

Violencia.- Es toda acción, omisión o uso intencional de la fuerza física o el poder, real o por amenaza, de una persona, grupo o institución con el fin de dañar a otra en contra de su voluntad, caracterizada por la agresión contra la integridad física, sexual, psicológica, simbólica o cultural.

DISPOSICIONES GENERALES

PRIMERA.- Los servicios de control, inspecciones, autorizaciones, permisos, licencias, registros y otros de similar naturaleza que preste la autoridad sanitaria nacional, satisfarán el pago de derechos de conformidad con los reglamentos respectivos.

SEGUNDA.- El Presidente de la República dictará el reglamento general para la aplicación de la presente Ley, en un plazo máximo de noventa días.

TERCERA.- Derogatorias.- Deróganse todas las normas, disposiciones generales o especiales que se opongan a la presente Ley, en materia de salud.

Deróganse expresamente:

El Código de la Salud, expedido mediante Decreto Ejecutivo No. 188, publicado en el Registro Oficial No. 158 del 8 de febrero de 1971 y todas sus reformas.

Los artículos 8, 9, 10, 11 y el Capítulo VIII de la Ley de Producción, Importación, Comercialización y Expendio de Medicamentos Genéricos de Uso Humano, publicada en el Registro Oficial No. 59 de 17 de abril del 2000.

El artículo 99 de la Ley de Promoción de la Inversión y Participación Ciudadana, publicada en el Suplemento del Registro Oficial No. 144, de 18 de agosto del 2000.

El artículo 11 de la Ley de Trasplantes de Organos y Tejidos, publicada en el Registro Oficial No. 492 de 27 de julio de 1994.

CUARTA.- Efectúense las siguientes reformas:

a) En el artículo 2 de la Ley de Producción, Importación, Comercialización y Expendio de Medicamentos Genéricos de Uso Humano, publicada en el Registro Oficial No. 59 de 17 de abril del 2000, sustitúyase la palabra: "...emplean", por: "comercializan...";

b) En toda la Ley de Derechos y Amparo al Paciente, sustitúyase: "centros de salud", por: "servicios de salud";

c) En el artículo 98 de la Ley de Registro Civil, Identificación y Cedulación, a continuación del numeral 13, agréguese el siguiente:

"14. Autorización expresa del ciudadano para ser donante de órganos u otros componentes anatómicos, de conformidad con lo establecido en el artículo 83 de la Ley Orgánica de Salud.";

d) Sustitúyanse los artículos 1 y 2 de la Ley de Aprovisionamiento y Utilización de Sangre y sus Derivados, publicada en el Registro Oficial No. 559 de 7 de noviembre de 1986, por los siguientes.

"Art. 1.- La vigilancia y control del aprovisionamiento y utilización de sangre y sus derivados en el Ecuador, será responsabilidad de la autoridad sanitaria nacional.

Organizará en coordinación con la Cruz Roja Ecuatoriana, el sistema nacional de bancos y depósitos de sangre, en las ciudades y servicios de salud que los requieran, siempre que cuenten con las condiciones técnicas para ello.

La Cruz Roja Ecuatoriana, el Ministerio de Salud Pública, el Instituto Ecuatoriano de Seguridad Social, las Fuerzas Armadas y la Junta de Beneficencia de Guayaquil continuarán administrando los bancos y depósitos de sangre adscritos a sus servicios de salud.

Art. 2.- Prohíbese la exportación de sangre y sus derivados, salvo lo señalado en el artículo 79 de la Ley Orgánica de Salud."; y,

e) A continuación del inciso quinto del artículo 46 de la Ley Orgánica de Aduanas, inclúyase otro inciso con el siguiente texto:

"Se exceptúan también de la verificación en origen: las vacunas, biológicos, medicamentos e insumos importados por el Ministerio de Salud Pública.".

QUINTA.- Todas las capitales de provincia, sin excepción, contarán al menos con un hospital público de tercer nivel de atención, con la infraestructura, equipamiento, bienes, insumos, presupuestos y recursos humanos idóneos, suficientes y permanentes, facultados para dar solución a las necesidades de la población, de conformidad con la realidad epidemiológica local.

SEXTA.- Conforme lo previsto en el numeral 10 del artículo 35 de la Constitución Política de la República, se prohíbe la paralización, a cualquier título o por algún motivo, del servicio público de salud, bajo prevención de aplicar a los responsables las sanciones previstas en las leyes que regulan la relación laboral y el Código Penal.

DISPOSICION TRANSITORIA

Los reglamentos que sobre asuntos de salud están vigentes, seguirán aplicándose en todo lo que no se oponga a la presente Ley, hasta cuando se dicten otros.

Dada, en la ciudad de San Francisco de Quito, Distrito Metropolitano, en la sala de sesiones del Congreso Nacional del Ecuador, a los catorce días del mes de diciembre del año dos mil seis.

Ministerio de Salud Pública

Instituto Nacional de Donación y Trasplante de Órganos, Tejidos y Células - **INDOT**

Ley Orgánica de Donación y Trasplante de Órganos, Tejidos y Células

Publicada en el Registro Oficial No. 398 del 4 de marzo de 2011

www.donaciontrasplante.gob.ec

El proceso de donación y trasplantes constituye el mayor exponente de lo que significa el trabajo en equipo. Cada vez que se produce una donación se pone en marcha un despliegue logístico en el que diferentes colectivos profesionales tienen que actuar en pocas horas, con gran celeridad y en perfecta sincronización, para alcanzar el feliz resultado de dar vida.

El proceso de donación y trasplantes implica aspectos profundamente humanos, técnicos y éticos, que tocan nuestras concepciones más arraigadas respecto a la vida y a la aceptación de la muerte. Este proceso es posible mediante la constante formación de profesionales capaces de comprender el dolor intenso de las personas que pierden un ser querido, construyendo lazos de confianza y apoyando a la familia del donante en su duelo.

La actividad trasplantológica en el país está evolucionando gracias a la dotación de recursos técnicos, la responsabilidad de las unidades médicas públicas y privadas, la solidaridad de la sociedad al momento de aceptar la donación y al financiamiento del Estado, que garantiza que el acceso al trasplante no esté mediado por la condición económica del paciente.

La donación de órganos y tejidos, así como el trasplante no es solo un tema de salud, es de compromiso y cohesión social, es el reflejo del interés compartido por todos los ecuatorianos.

El presente articulado y su contexto jurídico consagran el principio de equidad, así como la construcción del Sistema Nacional Integrado de Donación y Trasplantes y el fortalecimiento de los servicios públicos para realizar estos procedimientos, promueve una cultura de donación de órganos y tejidos en el Ecuador y resalta su carácter voluntario, desinteresado y gratuito para situar el concepto de la donación como un acto natural y cotidiano.

Por eso, el objetivo y compromiso del Ministerio de Salud Pública y el Instituto Nacional de Donación de Trasplantes de Órganos, Tejidos y Células (Indot) con la sociedad ecuatoriana es lograr el consentimiento efectivo de las personas a la donación de órganos y tejidos, incrementar las tasas de trasplante y gestionar con trasparencia el proceso. Estamos conscientes de que hay mucho por hacer, pero estamos seguros que avanzamos por el camino correcto hacia el fortalecimiento del Sistema Nacional Integrado de Donación y Trasplantes en el Ecuador.

Ministerio de Salud Pública del Ecuador
Instituto Nacional de Donación y Trasplantes
de Órganos, Tejidos y Células. INDOT

ASAMBLEA NACIONAL
EL PLENO

Considerando:

Que, el inciso primero del artículo 32 de la Constitución de la República establece que la salud es un derecho que debe ser garantizado por el Estado;

Que, el inciso segundo del articulo 32 de la Constitución de la República expresa que la prestación de servicios de salud se regirá, entre otros, por los principios de precaución y bioética;

Que, el artículo 50 de la Constitución de la República garantiza a toda persona que sufra una enfermedad catastrófica o de alta complejidad el derecho a una atención especializada y gratuita, de manera oportuna y preferente;

Que, el numeral segundo del artículo 66 de la Constitución de la República reconoce y garantiza a las personas el derecho a una vida digna, que asegure su salud;

Que, el literal a) del numeral 3 del artículo 66 de la Constitución de la República garantiza el derecho a la integridad personal que incluye la integridad física, psíquica, moral y sexual;

Que, el literal d) del numeral 3 del artículo 66 de la Constitución de la República prohíbe el uso de material genético y la experimentación científica que atente contra los derecho humanos;

Que, el inciso primero del artículo 84 de la Constitución de la República establece la obligación de la Asamblea Nacional de adecuar, formal y materialmente, las leyes y demás normas jurídicas a los derechos previstos en la Constitución y los que sean necesarios para garantizar la dignidad del ser humano;

Que, el numeral segundo del artículo 133 de la Constitución de la República dispone que serán orgánicas las leyes que regulen el ejercicio de derechos y garantías constitucionales;

Que, de conformidad con lo consagrado en el artículo 361 de la Constitución de la República, el Estado ejercerá la rectoría del sistema nacional de salud a través de la autoridad sanitaria nacional;

Que, el artículo 358 de la Constitución de la República establece que el sistema nacional de salud tendrá por finalidad el desarrollo, protección y recuperación de las capacidades y potencialidades para una vida saludable e integral, tanto individual como colectiva, y reconocerá la diversidad social y cultural, y se guiará entre otros por los principios de bioética y suficiencia;

Que, el numeral 1 del artículo 363 de la Constitución de la República señala la responsabilidad del Estado de formular políticas públicas que garanticen la promoción, prevención, curación, rehabilitación y atención integral en salud y fomentar prácticas saludables en los ámbitos familiar, laboral y comunitario;

Que, el numeral 3 del articulo 385 de la Constitución de la República establece que es finalidad del sistema nacional de ciencia, tecnología, innovación y saberes ancestrales desarrollar tecnologías e innovaciones que mejoren la calidad de vida y contribuyan a la realización del buen vivir;

Que, la Declaración Americana de la Derechos y Deberes del Hombre establece el derecho a la preservación de la salud y al bienestar, manifestando que toda persona tiene derecho a que su salud sea preservada por medidas sanitarias y sociales relativas a la alimentación, vestido, vivienda y asistencia medica, correspondientes al nivel que permitan los recursos públicos y de la comunidad;

Que, en el año 1997, la Conferencia General de la Organización de las Naciones Unidas para la Educación, la Ciencia y la Cultura (UNESCO), en su 298va. reunión, aprobó la Declaración Universal sobre el Genoma Humano y los Derechos Humanos, que fue adoptada por la Asamblea General de la Organización de las Naciones Unidas en el año 1998;

Que, en el año 1999, la Conferencia General de la UNESCO, en su 308va. reunión, hizo suyas las orientaciones para la aplicación de la Declaración Universal sobre Genoma Humano y los Derechos Humanos aprobada por el Comité Intergubernamental de Bioética;

Que, la Organización Panamericana de la Salud/Organización Mundial de la Salud (OPS/OMS), en el Tercer Encuentro Latinoamericano de Derecho, Bioética y Genoma Humano, realizado en la cuidad de Santiago de Chile en el año 2001, expidió la Declaración Ibero-Latinoamericana sobre Derecho, Bioética y Genoma Humano;

Que, la 63va. Asamblea Mundial de la Salud revisó las Principios Rectores de la OMS sobre trasplante de células, tejidos y órganos humanos, invitando a los Estados miembros a adoptar la resolución recomendada;

Que, la Conferencia General de la UNESCO; celebrada el 19 de octubre de 2005, aprobó la Declaración Universal sobre Bioética y Derechos Humanos, cuyos principios se sustentan en el respeto a la vida y dignidad de las personas y sus libertades fundamentales, recogiendo fundamentalmente la interrelación entre ética y derechos humanos; y, que dicha Declaración reconoce que la identidad de una persona comprende dimensiones biológicas, psicológicas, educativas, afectivas, culturales y espirituales;

Que, uno de los principales objetivos de la Declaración Universal sobre Bioética y Derechos Humanos consiste en proporcionar un marco universal de principios y procedimientos que sirvan de guía a los Estados en la formulación de legislaciones, políticas u otros instrumentos en el ámbito de la bioética; al tiempo que determina que toda intervención médica preventiva, diagnóstica y terapéutica solamente habrá de llevarse a cabo previo consentimiento libre e informado de la persona interesada, basada en la información adecuada;

Que, la Conferencia General de la UNESCO sobre los Datos Genéticos, celebrada el 16 de octubre de 2003, reconoce que la información genética forma parte del acervo general de los datos médicos, y que el contenido de éstos se encuentra íntimamente ligado al contexto y depende de las circunstancias de cada caso; reconociendo, asimismo, que los datos genéticos humanos son singulares por su condición de datos sensibles y que los Estados e instituciones deben aplicar rigurosas exigencias de confidencialidad a todos los datos médicos;

Que, la Ley Orgánica de Salud, publicada en el Suplemento del Registro Oficial No. 423 de 22 de diciembre de 2006, regula los trasplantes de órganos, tejidos y disposición de cadáveres; y,

En uso de las atribuciones que le han sido conferidas por la Constitución de la República y la Ley, expide la siguiente:

LEY ORGÁNICA DE DONACIÓN Y TRASPLANTES DE ÓRGANOS, TEJIDOS Y CÉLULAS

TITULO PRELIMINAR
Del objeto y ámbito de aplicación

Art. 1.- Objeto.- La presente Ley garantiza el derecho a la salud en materia de trasplantes, a través de la regulación de las actividades relacionadas con la obtención y utilización clínica de órganos, tejidos y células de humanos, además de los productos derivados de ellos, incluyendo la promoción, donación, extracción, preparación, almacenamiento, transporte, distribución y trasplante.

Esta Ley tiene por objeto promover la actividad trasplantológica en el país, así como consolidar el Sistema Nacional Integrado de Donación y Trasplantes que fortalezca el sistema público y actúe bajo la rectoría del Estado, a través de la Autoridad Sanitaria Nacional, garantizando el cumplimiento de los derechos consagrados en la Constitución de la República y en estricta observancia con las disposiciones constantes en los tratados e instrumentos internacionales vigentes sobre el genoma humano, los datos genéticos y la bioética.

Art. 2.- Ámbito y aplicación.- Las disposiciones de la presente Ley son de aplicación obligatoria para todo el Sistema Nacional de Salud en los temas referentes al proceso de donación y trasplantes.

La presente norma incluye las nuevas prácticas y técnicas que la Autoridad Sanitaria Nacional reconoce como vinculadas a la implantación de órganos o tejidos en seres humanos.

Art. 3.- Responsabilidades de la Autoridad Sanitaria Nacional.- Corresponde a la Autoridad Sanitaria Nacional, en ejercicio de su rectoría, emitir las políticas públicas relacionadas con la donación y el trasplante de órganos, tejidos, células, de acuerdo a las siguientes responsabilidades:

a) Crear y desarrollar el Sistema Nacional Integrado de Donación y Trasplantes;
b) Generar mecanismos adecuados para la detección y notificación obligatoria, a la Autoridad Sanitaria Nacional, de potenciales donantes tanto en muerte encefálica como corazón parado, según lo determine el respectivo reglamento;
c) Garantizar el acceso a trasplantes para las y los ciudadanos ecuatorianos, y para las y los extranjeros residentes en el país, que lo requieran y cumplan con los criterios técnicos y/o médicos para someterse a los mismos;
d) Desarrollar la actividad trasplantológica, especialmente la implantación de bancos heterólogos de progenitores hematopoyéticos, bancos de tejidos así como unidades de trasplantes en los hospitales del Sistema Nacional de Salud, principalmente en el sistema público;
e) Desarrollar nuevas técnicas para trasplante, que sean aprobadas por organismos internacionales a los cuales se encuentra adscrito el país;
f) Desarrollar y fortalecer la capacitación del personal que forma parte del Sistema Nacional Integrado de Donación y Trasplantes;
g) Implementar acciones encaminadas a incrementar el número de donantes de órganos, tejidos y células en todo el Sistema Nacional de Salud; y,
h) Garantizar los recursos necesarios para implementar la política y el Sistema Nacional Integrado de Donación y Trasplantes de órganos, tejidos y células en todo el país.

TITULO I
De los Principios, Derechos y Generalidades

CAPÍTULO PRIMERO
De los principios

Art. 4.- Principios.- Además de los establecidos en la Constitución de la República y los tratados internacionales vigentes sobre la materia, la presente Ley se rige por los siguientes principios:

a) Altruismo.- Es la conducta humana que refleja una actitud de servicio voluntaria, manifestando preocupación o atención desinteresada por el otro;
b) Voluntariedad.- Actitud humana que manifiesta, libre y potestativamente, la intención de participar en un proceso de donación;
c) Gratuidad.- No se podrá ofrecer ni recibir compensación económica o valorable económicamente por la donación de órganos y/o tejidos humanos, por parte del donante o cualquier otra persona natural o jurídica;
d) Solidaridad.- Es uno de los principios de la filosofía social y política que determina una relación entre seres humanos, derivada de la justicia, fundamentada en la igualdad, que busca el bien del prójimo;
e) Transparencia.- Todos los procesos relacionados con la donación y trasplante de órganos y/o tejidos humanos se realizarán con transparencia, de manera que permitan y promuevan el conocimiento, contenidos, trazabilidad y fundamentos para la realización de los mismos;
f) Interculturalidad.- La consideración y garantía de respeto a la diversidad que en relación con la salud y la integridad de la persona tienen las y los miembros de los colectivos, comunas, comunidades, pueblos y nacionalidades; así como, el diálogo entre los saberes sobre la salud humana entre las culturas; y,
g) Bioética.- el examen moral, interdisciplinario y ético de las dimensiones de la conducta humana en el área de las ciencias de la vida y la salud, examinada a la luz de los valores y principios morales.

CAPITULO SEGUNDO
De los derechos de donantes y receptores

Art. 5.- Derechos.- Además de aquellos establecidos en la Constitución de la República y los tratados internacionales vigentes sobre la materia, las y los donantes y receptores gozarán, dentro de los procesos de donación, de los siguientes derechos:

a) A ser informados veraz, oportuna y previamente sobre las consecuencias de la decisión de participar en un procedimiento de donación y/o trasplante,
b) A expresar explícitamente y por escrito su consentimiento para participar en un procedimiento de donación y/o trasplante, sea como donante o receptor;
c) A que la información que se refiera a su identidad, que pueda afectar de cualquier manera sus derechos, no sea revelada y se respete su carácter confidencial.
d) A que todos los datos que se determinen u obtengan, producto del procedimiento de donación y/o trasplante, sean protegidos y precautelados en su confidencialidad por quien los posea;
e) A recibir, oportuna y gratuitamente, todas las facilidades para precautelar su salud, garantizando la asistencia precisa para su restablecimiento, sin perjuicio del lugar donde se realice el proceso de donación y/o trasplante;
f) A la garantía de que los componentes anatómicos, provenientes de una donación previa a su utilización, cumplan con todos los requisitos legales y técnicos en cada una de las etapas del proceso.
g) A que el Estado garantice los recursos necesarios para asegurar un lugar especializado para el tratamiento del paciente, y el alojamiento de la persona a su cuidado, manteniendo condiciones adecuadas para una evolución favorable y satisfactoria; y,
h) A recibir la medicación necesaria en forma gratuita, oportuna y permanente por parte del Estado para el mantenimiento del órgano trasplantado bajo los más altos estándares que garanticen su calidad y efectividad.

CAPÍTULO TERCERO
Generalidades
Sección Primera
Disposiciones comunes

Art. 6.- Órganos, tejidos y células.- Los órganos, tejidos y células, independientemente del lugar de su ablación o extirpación, una vez obtenidos de acuerdo a las normas de la presente Ley, son responsabilidad de la Autoridad Sanitaria Nacional, incluyendo su adecuado uso.

Art. 7.- Entrega de Información.- Todos los actores del Sistema Nacional Integrado de Donación y Trasplantes están obligados a entregar regularmente la información referente a la frecuencia, procesos y resultados a corto y mediano plazo al organismo regulador definido por la Autoridad Sanitaria Nacional. La Autoridad Sanitaria Nacional está obligada a realizar los respectivos controles periódicos, al menos una vez al año.

Art. 8.- Trato preferencial.- Toda persona, que haya recibido un órgano por trasplante, tendrá trato preferencial en la atención médica con la finalidad de conservar el órgano trasplantado y mejorar su calidad de vida. Del mismo modo, toda persona que habiendo recibido un órgano trasplantado no haya recuperado sus capacidades funcionales, orgánicas y/o laborales, será considerada como persona con discapacidad, a fin de que pueda obtener los beneficios legales pertinentes.

Se otorgará el mismo trato a toda o todo donante vivo que, por efectos de la donación, haya sufrido una alteración que signifique disminución o discapacidad en sus funciones orgánicas y de salud que, debidamente certificada por una institución médica calificada, le incapacite al menos parcialmente para las actividades que realizaba antes de la donación.

Art. 9.- Excepciones.- Las disposiciones de esta Ley no serán aplicables a los casos de sangre humana, sus componentes diferenciados, espermatozoides y óvulos. Las actividades médicas en las que se empleen estos elementos o partes del cuerpo humano, se regularán por las disposiciones internacionales, leyes de salud, y más cuerpos legales.

Sección Segunda
De la confidencialidad

Art. 10.- Protección de datos y confidencialidad.- La Autoridad Sanitaria Nacional, a través del organismo regulador designado, adoptará las medidas necesarias para garantizar que la información generada del proceso de donación y trasplante, se convierta en anónima, a fin de que la o el donante y la o el receptor no sean identificables.

En consecuencia, es deber de la Autoridad Sanitaria Nacional:

a) Adoptar medidas que garanticen la seguridad de los datos y la imposibilidad de su revelación no autorizada, así como establecer salvaguardias para evitar adiciones, supresiones o modificaciones de los datos en la fichas registros de las y los donantes;
b) Establecer procedimientos para solventar posibles discrepancias en los datos; y,
c) Reglamentar que los Bancos de Tejidos y Células conserven los datos necesarios durante un mínimo de treinta años, para garantizar su trazabilidad en todas las fases. Los datos serán archivados en soporte físico y electrónico.

Art. 11.- Prohibición de divulgación de información.- En ningún caso se facilitarán o divulgarán informaciones que permitan la identificación de la o el donante y/o de la o el receptor de los órganos, tejidos o células, salvo el caso de requerimiento de la función judicial, dentro del ámbito de su competencia, o mediante acción de habeas data, cuya audiencia tendrá carácter reservado.

El funcionario que divulgue la información considerada como confidencial por la presente ley, será inmediatamente destituido sin perjuicio de las acciones que se puedan iniciar en su contra.

Art. 12.- Identidad de la o el donante y/o receptor.- La o el donante no podrá conocer la identidad de la o el receptor, ni éste la de la o el donante, con excepción de los donantes vivos.

Art. 13.- Adopción de medidas preventivas.- El deber de confidencialidad no impedirá la adopción de medidas preventivas cuando se sospeche acerca de la existencia de riesgos para la salud individual o colectiva, en los términos previstos en la Constitución de la República, los tratados e instrumentos internacionales vigentes, la presente Ley y demás leyes vigentes que norman la salud pública en el país.

Art. 14.- Prohibición de compensación.- No se podrá percibir compensación económica o de otra índole por la donación de órganos, tejidos y/o células humanos a favor de la o el donante u otra persona.

Sección Tercera
Del Sistema Nacional Integrado de Donación y Trasplantes

Art. 15.- Sistema Nacional Integrado de Donación y Trasplantes.- Se crea el Sistema Nacional Integrado de Donación y Trasplantes, como parte del Sistema Nacional de Salud que actuará bajo la rectoría de la Autoridad Sanitaria Nacional.

El sistema estará coordinado por el organismo designado, para tal efecto, por la Autoridad Sanitaria Nacional y será responsable de ejecutar las políticas públicas en la materia.

Comprenderá las instituciones, programas, políticas, recursos, acciones y actores relacionados con la actividad trasplantológica de órganos, tejidos y células humanos.

El desarrollo del Sistema se basará en el análisis técnico de las potencialidades y capacidades de las instituciones del Sistema Nacional de Salud Pública, para propender a su especialización y fortalecimiento.

Art. 16.- Integrantes del Sistema Nacional Integrado de Donación y Trasplantes.- Todas las instituciones, entidades y/o profesionales, que formen parte del Sistema Nacional Integrado de Donación y Trasplantes, deberán contar con la acreditación respectiva emitida por la Autoridad Sanitaria Nacional.

Forman parte del Sistema Nacional Integrado de Donación y Trasplantes:

a) Los hospitales e instituciones del Sistema Nacional de Salud;
b) Los laboratorios clínicos generales de la red de salud y los laboratorios especiales de genética;
c) Los bancos de tejidos y bancos heterólogos de progenitores hematopoyéticos, acreditados por la Autoridad Sanitaria Nacional;
d) Los profesionales médicos o equipos médicos especializados en trasplantes;
e) Los centros de investigación científica que desarrollan actividades relacionadas con el trasplante de órganos, tejidos y/o células;
f) El Sistema aeroportuario del país, dentro del ámbito de su competencia;
g) La función judicial, dentro del ámbito de su competencia;
h) Los gobiernos autónomos descentralizados provinciales, distritales y municipales, dentro del ámbito de sus respectivas competencias;

Las Fuerzas Armadas, la Policía Nacional, las compañías de transporte aéreo, terrestre y fluvial; y, otras instituciones, serán entidades de apoyo logístico y operativo en los procesos de trasplante y cumplirán las disposiciones de la presente Ley y su reglamento.

Art. 17.- Optimización de unidades de alta complejidad.- La Autoridad Sanitaria Nacional, a través de los mecanismos pertinentes, creará y/o fortalecerá unidades de alta complejidad en el sistema público, con la finalidad de generar las capacidades suficientes y necesarias para desarrollar la actividad trasplantológica en el país, las mismas que formarán parte del Sistema Nacional Integrado de Donación y Trasplante, siendo responsables de la supervisión, seguimiento y evaluación en las fases de pre- trasplante, trasplante, y post- trasplante.

Art 18.- Capacitación del personal.- La Autoridad Sanitaria Nacional, priorizará la capacitación del personal sanitario y garantizará los recursos humanos suficientes y necesarios para tal fin.

Art. 19.- Autorización y Acreditación.- Los trasplantes de órganos, tejidos y células solamente podrán realizarse en hospitales e instituciones de salud que cuenten con la autorización de la Autoridad Sanitaria Nacional.

La acreditación será otorgada por la entidad o dependencia designada por la Autoridad Sanitaria Nacional. Los requisitos para la acreditación serán determinados por el reglamento que se expida para el efecto.

La Autoridad Sanitaria Nacional suspenderá o retirará, en forma inmediata y luego de la correspondiente inspección, la autorización y/o acreditación a los programas de trasplantes de los establecimientos de salud que no realicen estos procedimientos, de conformidad con el reglamento correspondiente.

Art. 20.- Responsabilidad.- La Autoridad Sanitaria Nacional será sólidamente responsable por los perjuicios que se deriven de la acreditación de establecimientos y profesionales que no hubieren cumplido con los requisitos establecidos en la presente Ley y sus reglamentos.

Las instituciones en las que se desarrolle la actividad trasplantológica y sus equipos de profesionales serán solidariamente responsables por cualquier violación a los preceptos de la presente Ley y sus reglamentos.

Art. 21.- Preparación del recurso humano.- Las instituciones de educación superior, en coordinación con la Autoridad Sanitaria Nacional, garantizarán la preparación del recurso humano profesional y de los equipos de trasplante, a través de procesos de formación y educación permanentes. Hasta que las instituciones de educación superior nacionales ofrezcan estudios avanzados y especializados de postgrado en esta materia, la preparación correspondiente se realizará a través de convenios de cooperación con instituciones educativas de otros países.

Art. 22.- Acreditación profesional.- Los actos médicos referidos al proceso de donación y trasplantes contemplados en esta Ley solamente podrán ser realizados por médicos o equipos acreditados, para tal efecto, por la Autoridad Sanitaria Nacional y reconocidos por la Secretaría de Educación Superior Ciencia, Tecnología e Innovación.

Art. 23.- Integración de equipos de trasplante.- Los equipos de trasplante se conformarán para cada tipo de trasplante. Los profesionales podrán participar de los equipos de trasplante para los cuales la Autoridad Sanitaria le haya otorgado su acreditación, pero no podrán participar de dos o más trasplantes simultáneos.

Los profesionales extranjeros podrán realizar su actividad en el país, siempre y cuando cumplan con los requisitos establecidos en esta Ley y en la Ley orgánica de educación superior.

Los profesionales que pertenezcan a los equipos de trasplante no podrán ser parte del organismo regulador.

Art. 24.- De las remuneraciones.- Los profesionales que forman parte del Sistema Nacional Integrado de Donación y Trasplantes percibirán una remuneración acorde con la actividad realizada, que garantice su dedicación permanente al Sistema.

Art. 25.- Lista de Espera Única Nacional.- Los órganos, tejidos y/o células serán distribuidos respetando la Lista de Espera Única Nacional; y, en casos específicos, en base de las escalas técnicas adoptadas para cada órgano y tejido en particular.

La Lista de Espera Única Nacional se establecerá de acuerdo a los parámetros definidos de conformidad con el reglamento que, para cada órgano y/o tejido, establezca la autoridad competente. La Autoridad Sanitaria Nacional administrará esta base de datos y asignará los componentes anatómicos respetando principios y criterios universales y constitucionales, en especial el interés superior de las niñas y niños y las condiciones de doble vulnerabilidad.

Se reconoce el derecho que tienen las y los ecuatorianos residentes en el exterior, que requieran algún trasplante, a ser incorporados en la Lista de Espera Única Nacional de acuerdo al reglamento que se dicte para el efecto y de acuerdo a los convenios internacionales referentes a la materia que suscriba el estado ecuatoriano.

Art. 26.- Asignación de componentes anatómicos.- La Autoridad Sanitaria Nacional, de acuerdo a escalas técnicas, diseñará los mecanismos operativos para la asignación de los componentes anatómicos provenientes de una donación.

Art. 27.- Referencia obligatoria.- Todo medico que diagnostique una enfermedad susceptible de ser tratada mediante un trasplante, tiene la obligación de notificar al paciente y referirlo a las unidades de salud correspondientes.

TITULO II
De la Donación y Ablación de Órganos y Tejidos

CAPITULO PRIMERO
De la Donación

Art. 28.- Sistema de identificación de donantes.- La Autoridad Sanitaria Nacional desarrollará un sistema de identificación de potenciales donantes. Este sistema será de aplicación obligatoria en todas las instituciones que forman parte del Sistema Nacional de Salud.

Art. 29.- Donación.- Las ecuatorianas, ecuatorianos y extranjeros residentes legales en el país, mayores de dieciocho años, al fallecer se convertirán en donantes, a menos que en vida hubieren manifestado, en forma expresa, su voluntad en contrario en una de las siguientes formas:

a) Manifestando su negativa a la donación de los órganos, tejidos o células de su cuerpo para posterior implante en seres humanos vivos o con fines de estudio o investigación; o,
b) Restringiendo, de modo específico, su voluntad afirmativa de donación a determinados órganos, tejidos y/o células.

Art. 30.- Expresión de la Voluntad.- La manifestación, restricción o condicionamiento de la voluntad para la donación de componentes anatómicos se hará constar en la cédula de ciudadanía en el caso de las y los ciudadanos ecuatorianos y en cualquier otro documento de identificación en el caso de los extranjeros residentes legalmente en el país.

La negativa de las personas a ser donantes no generará discriminación alguna y no podrá ser utilizada de modo público por ninguna autoridad, persona o medio de comunicación.

Art. 31.- Registro de la manifestación de voluntad.- Es obligación de la Dirección General de Registro Civil, Identificación y Cedulación de la República consultar y recabar de las personas mayores de dieciocho años, que concurran ante dicho organismo, la manifestación de su voluntad respecto de tener o no la calidad de donantes de órganos y registrarla en el documento de identificación respectivo.

Art. 32.- Autorización de donación de órganos, tejidos y células de menores de edad fallecidos.- Cuando se compruebe el diagnóstico de muerte cerebral de ecuatorianas, ecuatorianos o extranjeros residentes legalmente en el país, menores de dieciocho años de edad y que no sean emancipados, solamente sus padres y a falta de éstos su representante legal podrán autorizar, en forma exclusiva, la donación de sus órganos, tejidos y/o células especificando los alcances de la misma.

En ausencia de las personas mencionadas en el inciso anterior, podrán intervenir los jueces de la niñez y adolescencia competentes, para autorizar la donación.

Art. 33.- Requisitos de la donación en vida.- Cualquier persona podrá donar en vida sus componentes anatómicos, siempre y cuando se cumplan los siguientes requisitos:

a) Que la o el donante sea mayor de edad, en goce de plenas facultades mentales, con un estado de salud adecuado para el procedimiento y exista compatibilidad biológica, morfológica y funcional con la o el receptor;
b) Que la o el receptor tenga parentesco, hasta el cuarto grado de consanguinidad, con la o el donante, o se trate de su cónyuge o conviviente en unión libre; y, que, siendo el caso, se hubiere comprobado la compatibilidad entre donante y receptor mediante las pruebas médicas correspondientes. La misma regla se aplicará para los casos de filiación por adopción;
c) Que la o el donante y la o el receptor hayan sido previamente informados de las posibles consecuencias de su decisión y otorguen su consentimiento escrito y notariado, en forma libre, consciente y voluntaria. Dicho consentimiento deberá ser anexado a las respectivas historias clínicas;
d) Que la o el receptor sea una persona determinada en forma previa, de acuerdo al reglamento a la presente Ley;
e) Que la extracción de las partes o tejidos o la remoción de órganos no implique para la o el donante riesgo de incapacidad funcional permanente;
f) Que no existan indicios de prácticas ilegales de turismo para trasplante o tráfico de órganos; y,
g) En caso de donación cruzada, no constará la identidad de la o el receptor y será codificada por la Autoridad Sanitaria Nacional.

Art. 34.- Restricción de la donación en vida.- La extracción de órganos de donantes vivos se limitará a situaciones en las que se prevean grandes posibilidades de éxito del trasplante.

Art. 35.- Consentimiento expreso.- La donación de órganos, tejidos y/o células de donante vivo, para fines de trasplante, requerirá de la declaración del consentimiento informado de la o el donante, otorgada ante notario público. A esta declaración será incorporado el correspondiente informe psiquiátrico sobre la normalidad de sus facultades mentales. Para tal efecto, será necesario contar con el informe motivado del Comité de Ética del hospital trasplantador.

Art. 36.- Estado de salud.- El estado de salud físico y mental de la o el donante deberá ser certificado por un médico, distinto de aquellos que vayan a efectuar la extracción y el trasplante. Dicho profesional deberá informar al paciente respecto de los riesgos inherentes a la intervención, las consecuencias previsibles de orden somático o psicológico, las repercusiones que pueda suponer en su vida personal, familiar o profesional y los beneficios esperados.

Art. 37.- Documento de cesión.- El documento de cesión, donde se hace constar la conformidad con la donación, será firmado por la o el donante, el médico que ha de ejecutar la extracción y los demás asistentes. Cualquiera de ellos podrá oponerse, en forma expresa, a la donación en caso de dudar respecto de la idoneidad del consentimiento de la o el donante, lo que será notificado inmediatamente al organismo regulador.

Entre la firma del documento de cesión del órgano y la extracción del mismo, previa la autorización de la Autoridad Sanitaria Nacional, deberán transcurrir por lo menos veinticuatro horas.

Art. 38.- Revocatoria del consentimiento.- El consentimiento informado de la o el donante vivo no podrá ser sustituido ni complementado. Sin embargo, podrá ser revocado, en forma verbal, hasta el momento mismo de la intervención quirúrgica, mientras la o el donante conserve la capacidad para expresar su voluntad. Esta revocatoria no generará obligación de ninguna clase ni dará lugar a indemnización alguna por daños y perjuicios.

Art. 39.- Prohibición de expresar consentimiento por hijas e hijos menores de edad o representados vivos.- Los padres o los representantes legales no podrán otorgar el consentimiento para donar en vida con fines de trasplante u otra operación semejante, los órganos o tejidos de sus hijas o hijos menores de edad o representados. Se exceptúan de esta prohibición los casos de donación de médula osea, que podrá ser autorizada exclusivamente por los padres cumpliendo las condiciones y limitaciones establecidas en esta Ley y su reglamento.

Art. 40.- Trasplantes a extranjeros de donante vivo.- Las instituciones acreditadas para la realización de trasplantes estarán impedidas de realizar actos quirúrgicos de donación y/o implantación de órganos y tejidos a pacientes extranjeros que no sean residentes legales en la República del Ecuador.

En el caso particular del paciente extranjero que sea declarado en código cero, tendrá el mismo tratamiento que los pacientes nacionales.

Art. 41.- Donación cadavérica.- Una vez comprobada y certificada la muerte de una persona, se podrá disponer de todos o parte de sus órganos, tejidos y/o células, de conformidad con lo previsto en el articulo 29 de esta Ley.

Art. 42.- Muerte violenta.- En caso de muerte violenta de una persona, la extracción indicada en el artículo anterior solamente podrá realizarse cuando no interfiera con los resultados finales de la autopsia, siendo necesaria para la realización de la ablación de los órganos y tejidos la notificación previa al fiscal de turno.

Art. 43.- Xenotrasplante.- Los procedimientos de xenotrasplante están permitidos de acuerdo a las regulaciones que se establezcan en el reglamento a la presente Ley.

CAPITULO SEGUNDO
De la selección, donación y extracción

Art. 44.- Selección de órganos, tejidos y células.- Las actividades relacionadas con la selección, evaluación y obtención de órganos, tejidos y células se llevarán a cabo garantizando que estos procedimientos se efectúen de conformidad con los requisitos que, para el efecto, establecerá la Autoridad Sanitaria Nacional.

Art. 45.- Procedimiento de Ablación.- El retiro de órganos, tejidos y/o células de un cadáver será realizado por profesionales acreditados. La ablación de órganos, tejidos y células se realizará en estricto apego a los protocolos emitidos por la Autoridad Sanitaria Nacional.

Art.- 46.- Condiciones y requisitos para la ablación.- La obtención de órganos de donantes fallecidos se podrá realizar en todas las instituciones que cuenten unidades de cuidados intensivos y por personal debidamente acreditado por la Autoridad Sanitaria Nacional, de conformidad con el reglamento que dicte para el efecto.

Art. 47.- Componentes anatómicos que pueden ser objeto de ablación.- La Autoridad Sanitaria Nacional, de acuerdo con criterios técnicos y científicos, describirá en el respectivo reglamento los componentes anatómicos que pueden ser objeto de ablación.

Art. 48.- Banco de tejidos y/o células.- La Autoridad Sanitaria Nacional, en ejercicio de su rectoría, creará, autorizará y regulará el funcionamiento de banco de tejidos, progenitores no embrionarios ni fetales, hematopoyéticos y células no embrionarias ni fetales.

Las obligaciones de éstos se establecerán en el reglamento que se dicten para su efecto.

Art. 49.- Accesibilidad a Bancos de tejidos y/o células.- Los centros públicos y privados acreditados, que realizan implantación de tejidos y/o células, para que tengan acceso a los mismos, serán registrados en una base de datos y su entrega se realizará según el reglamento correspondiente.

Art. 50.- Condiciones de los bancos de tejidos y/o células.- Los bancos de tejidos y/o células garantizarán que todos los procedimientos asociados con su obtención, procesamiento, transporte, almacenamiento y distribución se encuentren documentados en manuales de procedimientos y se ajusten a las normativas internacionales y requisitos establecidos por la Autoridad Sanitaria Nacional.

Art. 51.- Personal de los bancos de tejidos y/o células.- Todo el personal de los bancos de tejidos y/o células que intervengan en las diferentes actividades relacionadas con la obtención, procesamiento, preservación, almacenamiento y distribución de células y tejidos deberá ser acreditado para el ejercicio de sus actividades. Su perfil, funciones y responsabilidades serán los previstos en el reglamento respectivo.

Art. 52.- Células hematopoyéticas.- Podrán realizarse en el país los tratamientos con células progenitoras, no embrionarias ni fetales, hematopoyéticas provenientes de la médula ósea, sangre periférica y cordón umbilical para el tratamiento de patologías, cuya eficacia haya sido comprobada y sean debidamente autorizados por la Autoridad Sanitaria Nacional.

Art. 53.- Células Madre.- La Autoridad Sanitaria Nacional controlará y regulará el uso, investigación y aplicación de células madre adultas, provenientes de sangre cordón umbilical del recién nacido, médula ósea, o cualquier otro componente anatómico adulto de donde se obtenga. Se excluye la aplicación de células madres embrionarias y fetales.

Toda nueva terapia con células madres adultas, no embrionarias ni fetales, que se quieran aplicar en el país, deberá contar con la aprobación de la Autoridad Sanitaria Nacional y ser aceptada por los organismos mundiales de salud de los que el Estado ecuatoriano sea parte.

La manipulación de células madre con fines de investigación, estará permitida siempre y cuando se cumpla con los siguientes requisitos:

a) Exista la autorización expresa de la autoridad competente;
b) No exista fines de lucro;
c) Exista el consentimiento informado de la o el donante y la o el receptor;
d) No se trate de células madres embrionarias y fetales; y,
e) Los demás que señale el respectivo reglamento.

Art. 54.- Autorización.- Se podrá realizar investigación con ingeniería tisular, previa autorización de la Autoridad Sanitaria Nacional y el auspicio de centros de investigación reconocidos.

Art. 55.- Prohibición.- Se prohíbe toda actividad que involucre la utilización de células y tejidos humanos que no se encuentren regulada en esta Ley y sus reglamentos.

TITULO III
DE LA AUTORIDAD REGULADORA

Art. 56.- Autoridad Reguladora.- La Autoridad Sanitaria Nacional, en ejercio de su rectoría, a través de la entidad o dependencia que designe para el efecto, normará, regulará y controlará la actividad trasplantológica en la República del Ecuador. Las funciones y atribuciones para su funcionamiento, serán las establecidas en el reglamento a la presente ley.

Art. 57.- Función.- La entidad o dependencia designada por la Autoridad Sanitaria Nacional, encargada de ejecutar la política pública de donación y trasplantes, estará adscrita a dicha Autoridad y gozará de autonomía técnica, administrativa y financiera. Se sujetará a lo establecido en la presente Ley y su reglamento, velando por su cumplimiento y promoviendo acuerdos internacionales de cooperación.

Art. 58.- Control de la actividad de las compañías de seguros y empresas privadas de salud y medicina prepagada.- La Autoridad Sanitaria Nacional regulará y controlará a las compañías de seguros y empresas privadas de salud y medicina prepagada en lo referente a la oferta de trasplante de órganos, tejidos y/o células.

Las compañías de seguros y las empresas privadas de salud y medicina prepagada están obligadas, en el marco de las políticas definidas por la Autoridad Sanitaria Nacional y de la presente ley, a cumplir las coberturas comprometidas para trasplantes que se establezcan en los respectivos contratos o pólizas, así como a cubrir los montos totales del trasplante y de las complicaciones médicas que se lleguen a presentar. En caso de incumplimiento, estas compañías serán administrativa y civilmente responsables. Sin perjuicio de las acciones penales que puedan iniciarse en contra de sus administradores y/o representantes legales.

Art. 59.- Campañas de educación e información.- La Autoridad Sanitaria Nacional a través de sus instancias competentes, realizará, coordinará y ejecutará campañas de educación e información para promover una conciencia solidaria en la población, a fin de promover la cultura de donación y explicar objetivamente los beneficios de los trasplantes.

Art. 60.- Campañas de educación en el Sistema Nacional de Educación.- La Autoridad Educativa Nacional en coordinación con la Autoridad Sanitaria Nacional, incorporará en los planes y programas del sistema nacional de educación la temática correspondiente a la importancia y necesidad de la donación de órganos, tejidos y/o células para trasplante.

Art. 61.- Difusión a unidades médicas y profesionales de la salud.- La Autoridad Sanitaria Nacional planificará, implementará y coordinará campañas internas y capacitación relacionadas con el trasplante de órganos, tejidos y/o células, en beneficio de las unidades médicas y los profesionales de la salud.

Art. 62.- Publicidad y Promoción.- El Estado garantizará a través de las instancias correspondientes, la difusión y promoción, mediante campañas de información nacional en los medios de comunicación masiva destinadas a orientar a la población hacia una cultura de donación y trasplante de órganos, tejidos y/o células, así como a informar respecto del derecho de la población a no ser donante.

TITULO IV
Del Procedimiento Administrativo, Prohibiciones y Sanciones

CAPITULO PRIMERO
De los Actos Administrativos

Art. 63.- Actos Administrativos.- Para la aplicación de la presente Ley, la Autoridad Sanitaria Nacional se regirá por la dispuesto en el Estatuto del Régimen Jurídico Administrativo de la Función Ejecutiva, incluyendo la impugnación, recursos administrativos, plazos para resolver y los efectos del silencio administrativo.

Art. 64.- Actos normativos.- Los actos normativos de la entidad o dependencia designada por la Autoridad Sanitaria Nacional serán expedidos de conformidad con lo previsto en el Estatuto del Régimen Jurídico Administrativo de la Función Ejecutiva. La iniciativa para la expedición deberá ir acompañada por los estudios e informes necesarios que justifiquen su legitimidad y oportunidad.

Art. 65.- Impugnación de actos normativos.- Las personas que se consideren afectadas directamente por las disposiciones de los actos normativos, emitidos de conformidad con lo previsto en el anterior artículo de esta Ley, podrán pedir su derogatoria o reforma en sede administrativa, sin perjuicio de su derecho a impugnarlos judicialmente.

CAPITULO SEGUNDO
De la competencia administrativa y procedimiento

Art. 66.- Competencia administrativa.- La entidad o dependencia designada por la Autoridad Sanitaria Nacional tendrá competencia administrativa para conocer, aplicar y ejecutar las disposiciones previstas en esta Ley y sancionar administrativamente las infracciones previstas en esta Ley a nivel nacional.

Art. 67.- Ejercicio de la competencia.- La competencia administrativa de la entidad o dependencia designada estará sujeta a las normas establecidas para la competencia ene el Estatuto del Régimen Jurídico Administrativo de la Función Ejecutiva.

Art. 68.- Procedimiento Administrativo.- Para efecto de lo dispuesto en esta Ley, inclusive en la aplicación de sanciones, la entidad o dependencia designada aplicará el procedimiento administrativo común establecido en el Estatuto del Régimen Jurídico Administrativo de la Función Ejecutiva; así mismo, para la presentación de recursos y reclamos administrativos se estará a lo dispuesto en el mencionado Estatuto.

Art. 69.- Responsabilidad de las autoridades de salud.- Las autoridades de salud, responsables de la aplicación de esta Ley, que no cumplieren adecuadamente con su obligación estarán sujetas a las acciones administrativas, civiles y penales a que hubiere lugar.

CAPITULO TERCERO
Del régimen de infracciones y sanciones administrativas

Sección Primera
De las medidas preventivas y actividades de inspección

Art. 70.- Verificación de cumplimiento.- La Autoridad Sanitaria Nacional será responsable de verificar el cumplimiento de esta Ley y sus reglamentos, mediante la realización de la inspecciones y peticiones de información que considere pertinentes.

Art. 71.- Medidas Preventivas.- En caso de verificarse acciones u omisiones que pudieren provocar daño o constituir un peligro para la salud de las personas, como consecuencia de las actividades relacionadas con esta Ley, la Autoridad Sanitaria Nacional establecerá las medidas preventivas a ser adoptadas, de conformidad con el reglamento correspondiente.

Sección Segunda
De las infracciones y sanciones administrativas

Art. 72.- Sanciones.- Las infracciones administrativas determinadas en esta Ley, serán sancionadas por la Autoridad Sanitaria Nacional con:

a) Multa;
b) Suspensión del permiso o licencia y acreditación;
c) Suspensión temporal o definitiva de la autorización o acreditación para realizar actividades de trasplante;
d) Suspensión temporal o definitiva del ejercicio profesional; y,
e) Clausura parcial, temporal o definitiva del establecimiento correspondiente.

Art. 73.- Sanciones por comercialización.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, será sancionado con:

a) Multa de cincuenta remuneraciones básicas unificadas del trabajador privado, quien comercialice órganos, tejidos, células y/o componentes anatómicos. En el caso de que éstos provengan de personas vivas, la multa será de cien remuneraciones básicas unificadas del trabajador privado; y,
b) Multa de cincuenta remuneraciones básicas unificadas del trabajador privado, quien facilite o proporcione a otro con animo de lucro, uno o más órganos propios para ser usados con fines de trasplante;

La donación de órganos solamente podrá realizarse a título gratuito. Se prohíbe, en consecuencia, y será nulo y no tendrá valor jurídico alguno, al acto o contrato que, a título oneroso o a cualquier otro tipo de compensación, contenga la promesa de entrega de uno o más órganos para efectuar un trasplante.

Art. 74.- Sanción por el uso indebido de información.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, será sancionado con multa de cien remuneraciones básicas unificadas del trabajador privado, quien, utilizando información privilegiada favoreciera a un receptor para el trasplante de órganos, tejidos y/o células, haciendo caso omiso de la Lista de Espera Única Nacional.

Art. 75.- Sanción por realizar turismo de trasplantes.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, quien o quienes fomenten o participen en actividades relacionadas con turismo para trasplante de órganos, de conformidad con las disposiciones de la Organización Panamericana de la Salud, será sancionado con multa de cien remuneraciones básicas unificadas del trabajador privado.

Art. 76.- Sanción por la realización de procedimientos de trasplante sin autorización.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, los establecimientos de salud públicos o privados en donde se realicen o se hayan realizado procedimientos regulados por esta Ley, sin contar con la autorización y acreditación emitida por la Autoridad Sanitaria Nacional, serán sancionados con multa de doscientas remuneraciones básicas unificadas del trabajador privado y clausura temporal o definitiva del establecimiento.

Art. 77.- Sanciones por falta de notificación.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, la máxima autoridad de la institución de salud, que teniendo conocimiento de la comisión de la infracción tipificada en el artículo anterior no hubiere notificado a la Autoridad Sanitaria Nacional, será sancionado con multa de cincuenta remuneraciones básicas unificadas del trabajador privado.

En caso de tratarse de un profesional de la salud se le suspenderá su ejercicio profesional por cinco años, y en caso de estar involucrado en cualquier otra actividad ilícita que haga relación a las actividades reguladas por esta Ley será suspendido definitivamente de su ejercicio profesional.

En caso de tratarse de una institución pública, su máxima autoridad será destituida, previo el correspondiente sumario administrativo, respetando el debido proceso.

Art. 78.- Actuación de los profesionales de la Salud.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, el profesional de la salud que hubiere realizado cualquiera de los procedimientos contemplados en esta Ley sin la debida autorización de la Autoridad Sanitaria Nacional será sancionado con:

a) Suspensión temporal del ejercicio profesional hasta cinco años; y,
b) Suspensión definitiva del ejercicio profesional, en caso de reincidencia.

Art. 79.- Irrespeto a la Lista Única Nacional.- Sin perjuicio de las sanciones civiles y penales a que hubiere lugar, la institución y/o profesional de la salud que incumplan lo dispuesto en esta ley respecto del orden establecido en la Lista de Espera Única Nacional serán sancionados de la siguiente manera:

a) Clausura temporal de la institución hasta por cinco años; y,
b) Suspensión de la autorización o acreditación del o la profesional de la salud para realizar actividades de trasplante hasta por cinco años.

En ambos casos se aplicará una multa de veinte remuneraciones básicas unificadas del trabajador privado; y, en caso de reincidencia, se impondrá la clausura definitiva de la institución o la suspensión definitiva de la autorización o acreditación del o la profesional de la salud para realizar actividades de trasplante.

Art. 80.- Incumplimiento en brindar facilidad para el transporte.- Sin perjuicio de las sanciones administrativas, civiles y penales a que hubiere lugar, quien incumpla lo dispuesto en la Disposición General Tercera de esta Ley será sancionado con multa de cien remuneraciones básicas unificadas del trabajador privado.

Art. 81.- Falta de pago de multas.- La falta de pago de las multas, aplicadas de conformidad con esta Ley, hará exigible su cobro por vía coactiva, constituyendo título ejecutivo suficiente el testimonio autenticado de la resolución condenatoria en firme.

Art. 82.- Reincidencias.- La reincidencia en el incumplimiento de esta Ley y sus reglamentos será reprimida con el doble de la sanción máxima establecida para el caso de las multas, con clausura definitiva para el caso de establecimientos y la suspensión definitiva del ejercicio profesional para el caso de profesionales de la salud.

Art. 83.- Destino de las multas.- El valor total de las multas que aplique la Autoridad Sanitaria Nacional será depositado en la Cuenta Única del Tesoro Nacional y se destinará al fortalecimiento de los procesos de donación y trasplante de órganos, tejidos y células en todo el territorio nacional, así como a los procesos de control de las actividades previstas en la presente Ley.

Art. 84.- Prescripción de las acciones administrativas.- Las acciones administrativas prescribirán en el plazo de tres (3) años contado desde la fecha de su comisión.

DEFINICIONES

Para la interpretación de las normas contenidas en la presente Ley se utilizarán las siguientes definiciones:

Ablación.- Separación o extirpación quirúrgica de una parte del cuerpo; amputación.

Almacenamiento.- Es el mantenimiento de los tejidos y/o células en condiciones controladas y adecuadas hasta su distribución.

Alogénico.- Es el trasplante entre individuos de una misma especie genéticamente diferentes.

Aplicación.- Es cualquier actividad que implique el uso de células y/o tejidos en un receptor humano y/o en aplicaciones extra corporales (se engloban las actividades de implantar, infundir, injertar, aplicar o trasplantar).

Asignación de órganos, tejidos y/o células.- Es el procedimiento mediante el cual, respetando los principios de bioética, las listas de espera y su reglamento, la Autoridad Sanitaria determina al beneficiario del o los órganos, tejidos y/o células.

Autoinjerto o trasplante unipersonal.- Es el reemplazo en una persona de componentes anatómicos por otros provenientes de su propio organismo.

Banco de tejidos.- Es la unidad de salud técnica, especializada y autorizada, que obtiene, procesa, almacena y preserva tejidos y/o células para su posterior implantación o utilización con fines terapéuticos y de investigación, bajo normas que permitan garantizar la calidad desde su obtención hasta la utilización clínica.

Banco autólogo.- Es la unidad de salud técnica, especializada y calificada que preserva tejidos y células de una misma persona.

Banco alogénico.- Es la unidad de salud técnica, especializada y calificada que preserva tejidos y células obtenidos de diversos donantes y utilizados para diferentes receptores.

Célula.- Es la unidad anatómica, funcional y genética de los seres vivos. Para fines de ésta Ley se entenderá por células al conjunto de células individuales que no están unidas por ninguna forma de tejido conectivo.

Células Madre.- Son aquellas células dotadas simultáneamente de la capacidad de autorenovación (es decir, producir más células madre) y de originar células hijas comprometidas en determinadas rutas de desarrollo, que se convertirán finalmente por diferenciación en tipos celulares especializados.

Código Cero.- Es la condición médica en la cual la vida del paciente está en inminente peligro y depende de un trasplante de extrema urgencia, considerándose con estricta prioridad en las listas de espera.

Componentes anatómicos.- Son los órganos, tejidos y/o células, y en general, todas las partes que constituyen el organismo humano.

Cuarentena.- La condición de espera para el tejido o células extraídas, previa a su implantación, mientras se toma una decisión sobre su aceptación o rechazo.

Distribución.- El transporte y la entrega de órganos, tejidos y/o células destinados a su implantación en el ser humano.

Donación.- Es el hecho de donar tejidos y/o células humanas destinadas a ser aplicadas en el ser humano.

Donante.- Es toda fuente humana viva o muerta de órganos, tejidos y/o células en buen estado funcional, para trasplantarlos en otra persona o utilizarlos con fines terapéuticos o de investigación.

Donante vivo.- Se considera donante vivo a aquella persona que, cumpliendo los requisitos establecidos en la presente Ley y su reglamento, efectúa la donación en vida de células, tejidos u órganos o parte de los mismos, cuya función sea compatible con la vida y pueda ser compensada por su organismo de forma adecuada y suficientemente segura.

Donante cadavérico.- Se considera donante cadavérico a aquella persona fallecida de la que se pretende extraer órganos, tejidos y/o células que, cumpliendo los requisitos establecidos en la presente Ley y su reglamento, no hubiere dejado constancia expresa de su oposición.

Efecto adverso grave.- Cualquier hecho desfavorable vinculado a la obtención, evaluación, procesamiento, almacenamiento y distribución de componentes anatómicos que pueda conducir a la trasmisión de una enfermedad, a la muerte del paciente, o a estados que hagan peligrar su vida, a discapacidades o incapacidades o que puedan dar lugar a hospitalización, o enfermedad, o la pueda prolongar.

Equipo de Trasplantes.- Grupo interdisciplinario de profesionales con formación académica y experiencia certificada en los diferentes procesos relacionados a la procuración de órganos, ablación y/o trasplante de órganos, tejidos y células, calificados por la Autoridad Sanitaria Nacional.

Lista de Espera Única Nacional.- Es el registro ordenado de las o los pacientes con patologías susceptibles de trasplante, manejado directa y exclusivamente por la Autoridad Sanitaria Nacional, que se encuentran en espera de un órgano, tejidos y/o células correspondientes y que ha cumplido con los requisitos establecidos, de conformidad con el reglamento correspondiente.

Muerte.- Para fines de esta Ley, es el "cese permanente de la función del organismo como un todo. Esta definición implica que el mantenimiento por medios artificiales de la función cardiovascular y ventilatoria se reduce al funcionamiento de "subsistemas" independientes y que la función del organismo "como un todo" se ha perdido; teniendo en cuenta que el encéfalo es el responsable de la función del organismo como un todo" se considera que la "muerte encefálica" es equivalente a la muerte.

Muerte encefálica.- Cese irreversible de las funciones encefálicas, aún en presencia de un funcionamiento cardiovascular y ventilatorio artificial, certificada de acuerdo al protocolo que la Autoridad Sanitaria Nacional reglamente.

Órgano.- Una parte diferenciada y vital del cuerpo humano formada por diferentes tejidos, que mantiene su estructura, vascularización y capacidad para desarrollar funciones fisiológicas con un nivel de autonomía importante.

Preservación.- La utilización de agentes físicos y químicos, u otros medios durante la obtención, procesamiento y mantenimiento de los órganos y/o tejidos, a fin de retrasar el deterioro biológico o físico de los mismos.

Procuración.- Es el conjunto de actividades relacionadas con la detección, identificación, evaluación y mantenimiento de un potencial donante cadavérico; con el diagnostico y certificación de muerte, obtención del consentimiento familiar o de procurador en el caso de niños, niñas y adolescentes o de personas que no pueden expresar su voluntad de acuerdo a la Ley; coordinación de los equipos de ablación, acondicionamiento y mantenimiento de los órganos, tejidos y células en condiciones de viabilidad para su implante. Así como la asignación, búsqueda y localización de receptores.

Protocolos.- Son los documentos que definen las normas y procedimientos técnicos y administrativos del proceso de los trasplantes y en los cuales constan todos los datos e información que deben ser cumplidos obligatoriamente por los responsables de las diferentes fases de los trasplantes.

Receptor.- Es la persona en cuyo cuerpo se implantan componentes anatómicos provenientes de otro organismo humano o de otra especie.

Tejido.- Toda parte constituyente del cuerpo humano formada por células unidas por algún tipo de tejido conectivo.

Tráfico de órganos.- Es la extracción u obtención, transporte, trasferencia, encubrimiento y/o recepción de componentes anatómicos de personas vivas o fallecidas con la finalidad de obtener o extraer sus órganos, tejidos o células, con fines de trasplante; mediante una amenaza, uso de la fuerza u otras formas de coacción, plagio, fraude, abuso de poder, o la entrega y recepción de pagos o beneficios.

Trasplante.- Es el remplazo, con fines terapéuticos, de componentes anatómicos en una persona, por otros iguales y funcionales, provenientes del mismo receptor, de un donante vivo o cadavérico.

Trazabilidad.- Capacidad de localizar e identificar tejidos o células durante cualquier etapa, desde su obtención, pasando por el procesamiento, evaluación y almacenamiento, hasta su distribución al receptor o su desestimación o eliminación, incluyendo la capacidad de identificar al donante, el banco de tejidos y células, las instalaciones que lo reciben, procesan o almacenan los órganos, tejidos o células, los receptores y cualquier producto y material que entre en contacto con esos tejidos o células y que pueda afectar a la calidad y seguridad de los mismos.

Turismo de trasplantes.- Es el traslado de órganos, donantes, receptores del trasplante fuera de sus fronteras de jurisdiccionales originales, dirigido a realizar un trasplante en el Ecuador, sin contar con la categoría de inmigrante en el país.

Validación.- Es la evidencia documental que prueba, con un elevado nivel de garantía, que un determinado proceso, equipo o parte de un equipo o condición ambiental acaba produciendo, de forma consistente y reproducible, un determinado producto que cumple las especificaciones, cualidades y atributos que se habían predeterminado. Un proceso es validado con vistas a probar su efectividad para un uso determinado.

Xenotrasplante.- Es el trasplante de órganos, tejidos o células de una especie a otra. Es decir, la utilización de órganos, tejidos o células de animales para su implantación en el ser humano.

DISPOSICIONES GENERALES

PRIMERA.- Los trasplantes de órganos, tejidos y células serán considerados como prácticas de técnica corriente y no experimental y se sujetarán a los procedimientos técnicos y jurídicos de control de calidad que establecerá la Autoridad Sanitaria Nacional.

SEGUNDA.- Es obligación de la Autoridad Sanitaria Nacional fortalecer los servicios públicos de salud, para que sean éstos los que desarrollen los procedimientos de trasplantes de órganos, tejidos y células a nivel nacional.

TERCERA.- Las compañías de transporte aéreo, terrestre, marítimo y fluvial deberán brindar todas las facilidades para transportar todo el equipo humano, órgano, tejido, célula o componente anatómico que sea necesario para realizar un procedimiento de trasplante.

DISPOSICIONES TRANSITORIAS

PRIMERA.- El Presidente de la República, dentro del plazo de noventa días contado a partir de la vigencia de esta Ley, emitirá el Reglamento que cree o ratifique al, organismo regulador de trasplante de órganos, tejidos y células de la República del Ecuador. Mientras tanto, el Organismo Nacional de trasplante de Órganos y Tejidos, creado a través del Decreto Ejecutivo No. 2302, publicado en el Registro Oficial No. 516 de 18 de febrero de 2002, seguirá cumpliendo sus funciones y atribuciones.

SEGUNDA.- El Presidente de la República, dentro del plazo de noventa días contados a partir de la vigencia de esta Ley, emitirá todos los reglamentos pertinentes para su debida aplicación.

TERCERA.- Una vez promulgada la presente Ley, la Dirección General del Registro Civil, Identificación y Cedulación en coordinación con la Autoridad Sanitaria Nacional, implementarán en un plazo no mayor a 360 días, los mecanismos necesarios para la aplicación de lo dispuesto en el artículo 30 de la presente Ley.

CUARTA.- La Autoridad Sanitaria Nacional, una vez promulgada la presente Ley y en coordinación con las entidades relacionadas, en el transcurso del año subsiguiente de la promulgación, llevará a cabo una campaña informativa y educativa nacional al respecto del contenido de esta Ley, así como, de concientización de donación de órganos y los mecanismos de acceso a los servicios; una vez trascurrido el año al que se hace referencia en la presente disposición, se hará efectivo lo dispuesto en el artículo 29 de la ley.

DISPOSICIONES REFORMATORIAS

PRIMERA.- Sustitúyase en numeral 14 del Artículo 98 de la Ley General del Registro Civil Identificación y Cedulación, agregado por la ley No. 67, publicada en el Suplemento del Registro Oficial No. 423 de 22 de Diciembre del 2006, por el siguiente:

"14o.- Manifestación, restricción o condicionamiento de la voluntad para la donación de órganos, tejidos o células del ciudadano, de conformidad con lo establecido en la Ley Orgánica de Donación y Trasplantes de Órganos, Tejidos y Células".

SEGUNDA.- Sustitúyase el artículo innumerado, que consta en el Capítulo agregado por la Ley 2005-2, promulgada en el Registro oficial No. 45 de 23 de junio de 2005, por el siguiente:

"Artículo... (1) Quien dolosamente incumpla con las obligaciones o viole las prohibiciones previstas en los artículos 11, 19, 58, 69, 74, 76, 77, 78 y 79 de la Ley Orgánica de Donación y Trasplante de Órganos, Tejidos y Células; quien falsifique o adultere un protocolo de donación de trasplante, documento definido en la misma Ley, será reprimido con reclusión menor ordinaria de (3) a seis (6) años.

En caso de incumplimiento e inobservancia de las obligaciones o prohibiciones antes señaladas, cuando se refiera a instituciones o personas jurídicas, se presumirá la responsabilidad penal de máxima autoridad de la institución o representante legal de la persona jurídica.

Quien, comercie dolosamente o trafique con órganos, tejidos, sustancias corporales o cualquier material anatómico proveniente de cadáveres humanos será reprimido con reclusión menor extraordinaria de nueve (9) a doce (12) años. Igual, pena se impondrá a quien los seleccione, extraiga, evalúe, prepare, obtenga, almacene, transporte, asigne, distribuya o trasplante dolosamente.

La pena será de reclusión mayor extraordinaria de doce (12) a dieciséis (16) años, si las actividades referidas en el inciso anterior se realizan con órganos, tejidos, sustancias corporales o cualquier material anatómico que provengan de personas vivas.

Se impondrá pena de reclusión mayor exxtraordinaria de doce (12) a dieciséis años, a las personas que extraigan o trasplanten cualquier componente anatómico humano, en centros médicos no acreditados por la Autoridad Sanitaria Nacional.

Si los componentes anatómicos extraídos o trasplantados dolosamente, provienen de niños, niñas o de adolescentes o personas con discapacidad, la pena será de reclusión mayor especial de de dieciséis (16) a veinticinco (25) años".

TERCERA.- Agréguese, a continuación del artículo inumerado, agregado en el capítulo agregado por la Ley 2005-2, agregado en el capítulo agregado por la ley 2005-2, promulgada en el Registro Oficial No. 45 de 23 de junio de 2005, el siguiente artículo:

"Art... (2).- Quien traslade órganos, donantes, receptores o profesionales de la salud especializados en trasplantes, fuera de sus fronteras jurisdiccionales originales, con la finalidad de realizar uno o más trasplantes en la República de Ecuador, sin contar con la categoría inmigrante en el país o con los permisos correspondientes de la Autoridad Sanitaria Nacional, será reprimido con la apena de reclusión mayor extraordinaria de doce (12) meses a dieciséis (16) años."

DISPOSICIONES DEROGATORIAS

PRIMERA.- Derógase la Ley de Trasplantes de Órganos y Tejidos, Ley No. 58, publicada en el Registro Oficial No. 492 de 27 de julio de 1994.

SEGUNDA.- Derógase el artículo 82 de la Ley Orgánica de Salud, Ley No. 67 publicada en el Suplemento del Registro Oficial No. 432 de 22 de diciembre de 2006.

TERCERA.- Derógase el artículo 83 de la Ley Orgánica de Salud, Ley No. 67, publicada en el Registro Oficial No. 432 de 22 de diciembre de 2006.

CUARTA.- Derógase el artículo 252 de la Ley Orgánica de Salud, Ley No. 67, publicada en el Suplemento del Registro Oficial No. 432 de 22 de diciembre de 2006.

QUINTA.- Derógase expresamente todas aquellas normas que se contrapongan a la presente Ley.

Artículo final.- La presente Ley entrará en vigencia partir de la fecha de su publicación en el Registro Oficial.

Dado y suscrito en la Asamblea Nacional, ubicada en el Distrito Metropolitano de Quito, Provincia de Pichincha, a los catorce días del mes de febrero de dos mil once. f) FERNANDO CORDERO CUEVA Presidente f) DR. ANDRÉS SEGOVIA S. Secretario General.

CERTIFICO que la Asamblea Nacional discutió y aprobó la **LEY ORGÁNICA DE DONACIÓN Y TRASPLANTES DE ÓRGANOS, TEJIDOS Y CÉLULAS**, en primer debate el 28 de octubre de 2010, en segundo debate 4 y 6 de enero de 2011 y se pronunció sobre la objeción parcial del Presidente de la República el 14 de febrero de 2011.

Quito, 21 de febrero de 2011

f.) Dr. Andrés Segovia S., Secretario General.

MATRIZ COMPARATIVA
LEY ORGÁNICA DE DONACIÓN Y TRASPLANTES DEL 2011
vs. LEY DE TRASPLANTES DE 1994

EJE TEMÁTICO	LEY ANTERIOR	LEY ACTUAL
Sobre el Rol de la Autoridad Sanitaria Nacional	No se encontraba claramente definido en la ley	Encargado de la Emisión de políticas públicas sobre la Donación y Trasplante y su aplicación a través de: La creación y desarrollo del Sistema Integrado Nacional de Donación y Trasplante; la generación de mecanismos para la detección y notificación obligatoria de potenciales donantes; el desarrollo de la actividad trasplantológica (creación de bancos e implementación de unidades de trasplante); el desarrollo de nuevas técnicas de trasplante; la capacitación de personal; la creación de mecanismos de incremento de Donantes; y la garantía de recursos.
Sobre los Principios de la Donación	No hace referencia	Establece 7 Principios: Altruismo, Voluntariedad, Gratuidad, Solidaridad, Transparencia, Interculturalidad y Bioética.
Sobre los Derechos de los Donantes y Receptores	No se los establece explícitamente, ya que se encuentran implícitos en cada uno de los procesos regulados.	Se definen 8 derechos fundamentales: El derecho a la Información; a expresar su consentimiento; a precautelar su identidad; a la confidencialidad sobre datos, productos y procesos en la donación y trasplante; derecho a la Oportunidad y Gratuidad; a la Garantía sobre los componentes anatómicos; a un lugar especializado y manutención de la persona que la cuida; y a la medicación necesaria para mantener su trasplante.
Jurisdicción sobre órganos, tejidos y/o células	El Ministerio de Salud Pública llevará un registro Nacional de Órganos y Componentes anatómicos.	Independientemente de su lugar de ablación o extirpación son responsabilidad de la Autoridad Sanitaria Nacional.
Entrega de Información	No hace referencia	Establece como una obligación para todos los actores del SNIDYT
Trato Preferencial	No hace referencia	Para el Receptor y Donante
Confidencialidad	No hace referencia	Hace énfasis en la no identificación del donante y/o receptor y el establecimiento de mecanismos para resguardar datos; así como la obligación de mantener información clínica por 30 años bancos de tejidos; y la prohibición de divulgación de información.
Sistema Nacional Integrado de Donación y Trasplantes	No hace referencia	Crea dicho sistema el cual va estar compuesto por las instituciones, programas, políticas, recursos, acciones y actores relacionados con la actividad trasplantológica; que será coordinado por el ONTOT quien ejecutará las políticas de trasplante.
Acreditación	Establece la acreditación de hospitales e instituciones y sus condiciones técnicas de manera general	Establece la acreditación de cada uno de los miembros del SINDYT, entre los cuales se incluyen los profesionales médicos y equipos médicos. Establece además que no se puede realizar ningún proceso de trasplante sin que la entidad o los médicos y equipo médico se encuentren debidamente acreditados. Definiendo la responsabilidad solidaria frente a las acciones de sus profesionales.
Lista de Espera	No hace referencia	Administrada por la Autoridad Sanitaria Nacional; en base a principios y criterios universales y constitucionales (interés superior de las niñas y niños y doble vulnerabilidad). Establece que los órganos, tejidos y/o células serán distribuidos respetando la Lista de Espera Única Nacional, de acuerdo a escalas técnicas por cada órgano y tejido en particular; y reconociendo además el derecho de ecuatorianas y ecuatorianos residentes en el exterior.
Asignación de órganos	Distribución de órganos de acuerdo a un estricto orden de prioridad científica; hay una comisión de delegados.	La Autoridad Sanitaria establecerá mecanismos de designación en base a escalas técnicas.
Referencia Obligatoria	No hace referencia	Todo médico que diagnostique una enfermedad de ser tratada mediante un trasplante tiene la obligación de referir al paciente a las unidades de salud correspondientes.
Voluntad	a) Donación Previa; b) Consentimiento escrito de los familiares, dentro del cuarto grado de consanguineidad y segundo grado de afinidad; c) Consentimiento presunto sin objeción alguna.	Voluntad Presunta: “todos somos donantes a menos que hubiésemos manifestado lo contrario, según los mecanismos establecidos por la ley”.
Restricción de la Voluntad	Se hará constar, sin formalidad especial, en la ficha de ingreso del centro médico o en su historia clínica, siempre y cuando no lo hubiera expresado antes. Esta restricción puede ser total o parcial.	La restricción de la voluntad o condicionamiento de la misma se hará constar en la cédula, por lo tanto la Dirección General del Registro Civil, cedulación e Identificación, es el órgano encargado de consultar y registrar la voluntad.
Autorización de donación de menores de edad	Ni los padres, ni representantes podrán otorgar el consentimiento para donar con fines de trasplante los componentes de hijos, pupilos y representados. Se exceptúa la donación de médula ósea.	Si se ha diagnosticado la muerte encefálica, los padres y a falta de estos sus representantes legales podrán autorizar la donación, especificando el alcance de la misma. No se podrá autorizar la donación en vida de menores de edad, a menos de que sea donación de médula ósea y lo harán sus padres o representantes legales.
Donación en vida	**Condiciones del Donante:** Mayor de Edad; Goce facultades mentales; Estado de salud adecuado; Debe ser padre, madre, hijo o hermanos; excepcional cuarto grado de consanguinidad y segundo de afinidad. Consentimiento Informado del donante y receptor. **Condiciones del Proceso:** El receptor debe ser determinado; No debe provocar incapacidad funcional temporal o permanente al donante; Declaración del Consentimiento Notariado.	**Condiciones del Donante:** Mayor de edad, Goce de sus facultades mentales, Estado de Salud Adecuado, Compatibilidad biológica, morfológica y funcional, Parentesco hasta el cuarto grado de consanguineidad, o cónyuge o conviviente en unión libre; **Condiciones del Proceso:** Objeto lícito (No tráfico de órganos/ no Turismo de trasplante, No haya riesgo de incapacidad permanente; Receptor determinado. Requisitos Formales: Certificado de un Médico distinto al que efectuará la extracción y el trasplante; Consentimiento Informado y Notariado; Historia Clínica; Informe Psiquiátrico; Informe Motivado del Comité de Ética; Documento de Cesión y **Autorización de la Autoridad Sanitaria Nacional.**
Revocatoria del Consentimiento de la Donación en Vida	Se podrá revocar hasta el momento mismo de la intervención quirúrgica y esto no representará obligación alguna.	Este criterio se mantiene en la nueva ley.

EJE TEMÁTICO	LEY ANTERIOR	LEY ACTUAL
Trasplante a extranjeros	No hay ninguna referencia	Prohibición de realizar cualquier acto quirúrgico de donación o trasplante a pacientes extranjeros que no sean residentes legales den el país. Excepto código cero.
Donación Cadavérica	Una vez comprobada la muerte encefálica y determinada la voluntad de donar, se procederá inmediatamente con el proceso de ablación.	Una vez comprobada y certificada la muerte se podrá disponer total o parcialmente de los órganos de acuerdo a lo establecido en el art. 29.
Muerte Violenta	Los médicos que hubieren realizado la extracción de materiales anatómicos deberán presentar al juez un informe detallado sobre el estado del material anatómico retirado. Este proceso se hará siempre y cuando no interfiera en los resultados finales de la autopsia y en presencia del médico legista y de las autoridades legales competentes.	Solo podrá realizarse cuando no interfiera en los resultados finales de la autopsia, previa notificación al fiscal de turno.
Xenotrasplante	No hace referencia	Está permitido en los términos establecidos en el reglamento.
Selección	No hace referencia	La selección, evaluación y obtención de órganos, tejidos y células se harán de acuerdo a los requisitos establecidos por la Autoridad Sanitaria Nacional.
Extracción	El retiro de los componentes anatómicos se efectuará por los médicos que integran el equipo de trasplantes o por profesionales médicos autorizados por este, quienes suscribirán un acta de constancia del estado de los componentes retirados.	Será realizado por profesionales acreditados, quienes se deberán apegar a los protocolos establecidos por la Autoridad Sanitaria Nacional. Las entidades generadoras de donantes deberán contar con las unidades de cuidados intensivos.
Bancos de Tejidos y Células	El Ministerio de Salud Pública creará o autorizará el funcionamiento de bancos de órganos, componentes anatómicos y líquidos orgánicos. Podrán ser dependientes al Ministerio o estar vinculados obligatoriamente a un centro de asistencial u hospitalario que hubiesen obtenido la correspondiente licencia de funcionamiento.	La Autoridad Sanitaria Nacional los creará, autorizará y regulará; Los procedimientos de obtención, procesamiento, transporte, almacenamiento y distribución deben ser documentados en manuales de procedimiento; Todo su personal debe ser debidamente acreditado; Los centros públicos o privados que realicen procesos de implantación de células o tejidos para que tengan acceso a los mismos deben estar previamente registrados.
Células Madre	No hace referencia	La Autoridad Sanitaria Nacional controlará su uso, investigación y aplicación. Se realizarán tratamientos con célula madre adultas cuya eficacia haya sido debidamente comprobada y hayan sido autorizados por la Autoridad Sanitaria Nacional. Las nuevas terapias deben ser autorizada por la Autoridad Sanitaria Nacional y reconocidas por organismos mundiales de los cuales forma parte el Ecuador. Se establecen condiciones para la Investigación, y define que para la investigación con Ingeniería Tisular, se requiere autorización de la Autoridad Sanitaria Nacional y el auspicio de un centro de Investigación reconocido. Queda prohibida toda práctica no aprobada.
Sobre la Autoridad Reguladora	No hace referencia	La Autoridad Sanitaria Nacional designará la entidad o dependencia que normará, regulará y controlará la actividad trasplantológica en el país. Ejecutará la política de donación y trasplante; Estará adscrita a la Autoridad Sanitaria Nacional; Gozará de autonomía técnica, administrativa y financiera. Se sujetará a esta ley y su reglamento e cumplirá y promoverá Acuerdos Internacionales de cooperación.
Control actividades compañías de seguro, empresas privadas de salud y medicina prepagada	No hace referencia	Están obligadas a cumplir con las coberturas para trasplantes, que se establezcan en los respectivos contratos o pólizas, así como a cubrir los montos totales para el trasplante y de las complicaciones médicas que se llegaren a presentar. En caso de incumplimiento serán administrativa y civilmente responsables.
Campañas de Educación e Información, Promoción y Difusión	Ministerio de Salud Pública realizará, autorizará y coordinará campañas de educación e información, para todo nivel de la población.	La Autoridad Sanitaria Nacional a través de las instancias competentes coordinará y ejecutará campañas de educación e información. En coordinación con la Autoridad Educativa Nacional incorporará en los planes y programas del Sistema Nacional de Educación la temática correspondiente a la importancia y necesidad de la donación. Realizará además campañas a favor de las Unidades Médicas y profesionales de la Salud. El Estado garantizará a través de las instancias correspondientes, la difusión y promoción, mediante campañas de información nacional mediantes los medios de comunicación masiva, la cultura de la donación y el trasplante y respecto del derecho de la población a no ser donante.
Procedimientos de la Administración	No hace referencia	Actos administrativos, normativos e impugnación de dichos actos, se regirán por lo dispuesto en el Estatuto del Régimen Jurídico Administrativo de la Función Ejecutiva.
Competencia Administrativa y su ejercicio	No hace referencia	La entidad o dependencia designada por la Autoridad tendrá competencia administrativa para conocer, aplicar y ejecutar la ley y sancionar las infracciones cometidas sobre esta. El ejercicio de la competencia se hará en base a lo establecido en el ERJAFE. Las Autoridades de Salud son las responsables de la aplicación de esta ley, en caso de incumplimiento serán responsables administrativamente, civil y penalmente.
Régimen de Infracciones y Sanciones	Prohíbase la comercialización de órganos y componentes anatómicos. Quienes violaren esta disposición y ofrecieren o recibieren, directa o indirectamente, beneficios económicos u otros semejantes para la entrega y obtención de órganos u otros materiales anatómicos de personas vivas o fallecidas, serán reprimidos con prisión de uno o tres años.	**Tipos:** Comercialización, Uso inadecuado de información (favorece a un receptor), Turismo de trasplante, Procedimiento de trasplante sin autorización, Falta de notificación, Actuación de profesionales sin acreditación, Irrespeto a la lista de espera única, Incumplimiento en brindar facilidades de transporte. **Sanciones:** Multa, Suspensión permiso licencia o acreditación, Suspensión temporal o definitiva acreditación, Suspensión temporal o definitiva ejercicio profesional, Clausura temporal, parcial o definitiva del establecimiento.

CÓDIGO DE LA SALUD

Contexto Jurídico para la Ley Orgánica de Donación y Trasplantes

TITULO III
De los trasplantes de órganos, tejidos y disposición de cadáveres

CAPITULO I
De los trasplantes de órganos y tejidos

Art. 81.- Prohíbese la comercialización de componentes anatómicos de personas vivas o fallecidas. Ninguna persona podrá ofrecer o recibir directa o indirectamente beneficios económicos o de otra índole, por la entrega u obtención de órganos y otros componentes anatómicos de personas vivas o fallecidas.

Art. 82.- (Derogado por la Ley Orgánica de Donación y Trasplante de Órganos, Tejidos y Células publicada mediante Registro Oficial No. 398 del 4 de marzo de 2011)

Art. 83.- (Derogado por la Ley Orgánica de Donación y Trasplante de Órganos, Tejidos y Células publicada mediante Registro Oficial No. 398 del 4 de marzo de 2011)

Art. 84.- La Autoridad Sanitaria Nacional, normará, licenciará y controlará el funcionamiento de los servicios de salud especializados, públicos y privados, para el ejercicio de actividades relacionadas con el trasplante de órganos u otros componentes anatómicos. Igualmente controlará el ejercicio profesional de quienes realicen dichas actividades.

Art. 85.- La Autoridad Sanitaria Nacional normará la organización de los bancos de tejidos y de células, bajo los parámetros técnicos y estándares que se establezcan para el efecto.

La asignación de órganos u otros componentes anatómicos debe realizarse bajo los parámetros nacionales e internacionales, establecidos por un sistema nacional creado para este efecto.

Art. 86.- Los xenotrasplantes podrán realizarse únicamente cuando se garanticen condiciones científicas y tecnológicas que aseguren la calidad del procedimiento con sujeción a principios bioéticos, y estarán sujetos a la autorización de la autoridad sanitaria nacional a través del organismo competente.

CAPITULO II
De la genética humana

Art. 210.- Sólo podrán hacerse pruebas de identificación humana, filiación y compatibilidad de antígenos para:

a) Trasplantes;
b) Estudios mutacionales;
c) Ligamiento genético;
d) Pruebas predictivas de enfermedades genéticas.
e) Pruebas para detectar la predisposición genética a una enfermedad;
f) Fines terapéuticos; y,
g) Otras que se desarrollen con fines de salud genética.

Estas pruebas deberán contar con asesoramiento y supervisión genético especializado, siguiendo procedimientos científicamente probados, con sujeción y respeto a los principios bioéticos.

Art. 252.-(Derogado por la Ley Orgánica de Donación y Trasplante de Órganos, tejidos y células publicada mediante Registro Oficial No. 398 del 4 de marzo de 2011)

Ministerio de Salud Pública
Instituto Nacional de Donaci ón y Trasplantes
de Órganos, Tejidos y C élulas. INDOT

Reglamento General a la Ley Orgánica de Donación y Trasplantes de Órganos, Tejidos y Células

La actividad trasplantológica en el Ecuador presenta una constante evolución por la intervención del Estado que cumple su rol a cabalidad de ser el garante de los derechos de los ciudadanos, la capacitación de profesionales de alto nivel, el fortalecimiento de entidades públicas y privadas que a través de un trabajo mancomunado hacen posible mejorar y salvas vidas. Son los rostros de niños, adolescentes, hombres y mujeres llenos de ilusiones y sueños que tras recibir una donación de un órgano o tejido evidencian una nueva oportunidad de vida.

Los trasplantes se concretan mediante la solidaridad y actitud positiva de familias que en medio del dolor y tristeza de perder a un ser querido deciden respetar su voluntad y manifiestan un sí a la donación. Es un proceso que implica un verdadero compromiso social.

El Reglamento General que regula el desarrollo y aplicación a la Ley Orgánica de Donación y Trasplantes de Órganos, Tejidos y Células en el país entró en vigencia el 13 de julio del 2012, tras su publicación en el Registro Oficial. En el se constituye el Instituto Nacional de Donación y Trasplantes de Órganos, Tejidos y Células (Indot), entidad adscrita al Ministerio de Salud Pública con autonomía técnica, administrativa y financiera responsable de la regulación y coordinación de la actividad trasplantológica en el país.

La vigencia de este cuerpo legal constituye un logro más para el Estado y todos los actores que participan en el proceso de la donación y trasplantes. Consagra el principio de equidad, promueve una cultura de donación en el marco del respeto de lineamientos bioéticos y de transparencia y fortalece los servicios de salud implicados en esta compleja actividad. Además, afianza el Sistema Nacional de Donación y Trasplantes que consolida los derechos de la ciudadanía a recibir un trasplante.

Se están superando las expectativas en materia de trasplantes y se continúa laborando en apego a los principios del Plan Nacional del Buen Vivir y a la Constitución con el compromiso de todos los actores del Sistema Integrado de Donación y Trasplantes para que renazcan más esperanzas de vida.

El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplantes de Órganos, Tejidos y Células (Indot) tiene el reto de constituir al Ecuador en referente regional e internacional de la gestión y coordinación de la donación y trasplantes de órganos, tejidos y células con solidez, credibilidad, eficiencia y eficacia mediante la promoción de una cultura social de apoyo a la donación que permite maximizar las oportunidades de acceso a los distintos procesos de trasplantes de forma técnica, equitativa y oportuna.

Ministerio de Salud Pública del Ecuador
Instituto Nacional de Donación y Trasplantes
de Órganos , Tejidos y Células. INDOT

No. 1205

RAFAEL CORREA DELGADO
PRESIDENTE CONSTITUCIONAL DE LA REPÚBLICA

CONSIDERANDO:

Que el artículo 32 de la Constitución de la República del Ecuador, establece que el derecho a la salud debe ser garantizado por el Estado, y que su realización se vincula al ejercicio de otros derechos;

Que el artículo 50 de la Constitución de la República del Ecuador, garantiza a las personas que sufren de enfermedades catastróficas o de alta complejidad, el derecho a la atención especializada y gratuita, de manera oportuna y preferente;

Que en el Registro Oficial N° 398 de marzo 4 de 2011, se promulgó la Ley Orgánica de Donación y Trasplantes de Órganos, Tejidos y Células;

Que la Disposición Transitoria Segunda de la Ley Orgánica de Donación y Trasplantes de Organos, Tejidos y Células, establece que el Presidente de la República, deberá expedir el Reglamento de aplicación de la Ley;

En ejercicio de las facultades previstas en el artículo 147, número 13, de la Constitución de la República del Ecuador,
DECRETA:

Expedir el **REGLAMENTO GENERAL A LA LEY ORGÁNICA DE DONACIÓN Y TRASPLANTES DE ÓRGANOS, TEJIDOS Y CÉLULAS.**

Capítulo I
Del Ambito y Objeto

Artículo 1.- Ámbito.- El presente reglamento general tiene por objeto regular el desarrollo y la aplicación de la Ley Orgánica de Donación y Trasplante de Órganos, Tejidos y Células, en adelante ley.

La actividad de donación y trasplante de órganos, tejidos y células, incluida la terapia celular o regenerativa, la ingeniería tisular y el xenotrasplante, estará sujeta a las disposiciones señaladas en la ley, a las previstas en este reglamento y a las disposiciones y resoluciones .que emita la Autoridad Sanitaria Nacional y el Instituto Nacional de Donación
y Trasplante de órganos, tejidos y células, en adelante INDOT.

Capítulo II
De la Autoridad Reguladora

Instituto Nacional de Donación y Trasplante de Órganos, Tejidos y Células

Artículo 2.- Instituto Nacional de Donación y Trasplante de órganos, tejidos y células.- Créase el Instituto Nacional de Donación y Trasplante de órganos, tejidos y células, en adelante INDOT, como entidad adscrita a la Autoridad Sanitaria Nacional, con autonomía técnica, administrativa, financiera y de gestión.

Su domicilio será la ciudad de Quito y contará con coordinaciones zonales de acuerdo a la división territorial del Estado y la epidemiología de cada zona.

Artículo 3.- Atribuciones y Facultades.- El INDOT, cumplirá con las siguientes atribuciones y facultades:

1. Ser el ejecutor de las políticas públicas de donación y trasplantes de órganos, tejidos y células, dentro del territorio nacional;
2. Coordinar y gestionar la provisión de órganos, tejidos y células para trasplante;
3. Coordinar y gestionar el Sistema Nacional Integrado de Donación y Trasplantes;
4. Planificar todo lo relacionado con la actividad de donación y trasplante de órganos, tejidos y células;
5. Controlar y regular a las instituciones, hospitales, bancos de tejidos y/o células y a los profesionales que desarrollan actividades relacionadas con los procesos de donación y trasplantes de órganos, tejidos y células;
6. Promocionar y difundir la donación de órganos, tejidos y células para trasplantes;
7. Desarrollar y coordinar programas de capacitación de los profesionales que forman parte del Sistema Nacional Integrado de Donación y Trasplantes;
8. Acreditar a las instituciones y equipos médicos relacionados con la actividad de donación y trasplante de órganos, tejidos y células;
9. Administrar la Lista de Espera Unica Nacional de órganos, tejidos y células;
10. Asignar y distribuir los órganos, tejidos y células provenientes de la donación;
11. Conocer, aplicar y ejecutar las disposiciones previstas en la ley, este reglamento y las resoluciones que emita la Autoridad Sanitaria Nacional, y sancionar administrativamente su incumplimiento;
12. Normar la actividad de donación y trasplante de órganos, tejidos y células, incluida la terapia celular e ingeniería tisular;
13. Financiar la procuración de donantes y ablación de órganos, tejidos y células en las instituciones privadas y/o públicas, independientemente del lugar donde sean identificados los donantes, siempre y cuando no sea cubierta por otro financiador;
14. Organizar un sistema logístico informativo ágil e integrado de manera progresiva en todo el territorio nacional.
15. Realizar proyectos de investigación en todo lo referente a donación y trasplante de órganos, tejidos y células, incluida la terapia celular e ingeniería tisular;
16. Autorizar y monitorear los procesos de investigación clínica referente a donación y trasplante de órganos, tejidos y células, incluida la terapia celular e ingeniería tisular;
17. Controlar, regular y autorizar el uso, investigación y aplicación de células madre provenientes de sangre de cordón umbilical del recién nacido, médula ósea o cualquier otro componente anatómico adulto de donde se obtenga;
18. Implementar y administrar bancos públicos de tejidos y /o células con fines de trasplante;
19. Autorizar la donación en vida de órganos para trasplante;
20. Autorizar la importación y exportación de órganos, tejidos y/o células, destinados a procedimientos de donación y trasplante, una vez cumplidos los requisitos establecidos para el efecto;
21. Regular y controlar a las empresas privadas de salud y medicina pre pagada en lo referente a la oferta de trasplante de órganos, tejidos y/o células;
22. Controlar el origen y destino de órganos, tejidos y células y su trazabilidad; y,
23. Otras que la Autoridad Sanitaria Nacional le delegue.

Artículo 4.- Medidas Preventivas.- Sin perjuicio a las sanciones establecidas en la ley, el INDOT podrá adoptar como medida preventiva la suspensión inmediata de las prácticas que contravinieren lo establecido en la ley, el presente reglamento general y las resoluciones que emita la Autoridad Sanitaria Nacional.

Las medidas preventivas no podrán tener una duración mayor de noventa (90) días o hasta que el INDOT emita una resolución definitiva.

Capítulo III
De la Promoción y Publicidad de la Donación

Artículo 5.- Promoción y Publicidad para la Donación de órganos, células y tejidos para trasplante.- Toda actividad de promoción y publicidad en apoyo de la donación de órganos, células y tejidos deberá cumplir con las directrices y disposiciones legales y reglamentarias establecidas.

La normativa incluirá restricciones o prohibiciones adecuadas en materia de publicidad sobre su uso y utilidad de los trasplantes de órganos células y tejidos, con el objetivo de que no sea posible impulsar el ofrecimiento o la obtención de un beneficio económico o una ventaja comparable. No se podrán promocionar terapias que se encuentren en proceso de experimentación.

Toda información promocional relacionada con donación y trasplante de órganos, tejidos y células deberá ser veraz, objetiva, demostrable, sustentada en datos y experiencias avaladas por organismos de salud de los cuales el Estado es miembro, además debe ser de carácter público y estar sujeta a verificación.

Artículo 6.- Prohibiciones a los Medios de Comunicación.- Se prohíbe que por cualquiera de los medios de comunicación se realice lo siguiente:
1. La difusión de los nombres de donantes y receptores o cualquier dato que permita su identificación o vinculación entre éstos;
2. La oferta de órganos, tejidos y células por cualquier medio, con finalidad de trasplante u otra relacionada, que promocione o induzca a un intercambio comercial;

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3. La difusión de información que promueva o de lugar al tráfico de órganos o turismo de trasplante.

Capítulo IV
Régimen de Acreditación

Artículo 7.- Acreditación.- Es un proceso que tiene como objetivo la evaluación y garantía pública de que los procedimientos de donación y trasplantes de órganos, tejidos y células, incluida la terapia celular o regenerativa, la ingeniería tisular y el xenotrasplante, realizados por instituciones, hospitales, bancos de tejidos y/o células y profesionales, cumplan con lo establecido en la ley, el presente reglamento general y las demás resoluciones que emita la Autoridad Sanitaria Nacional y el INDOT.

La acreditación otorgada a las instituciones, hospitales y profesionales relacionadas con la actividad trasplantológica será concedida para cada órgano, tipo de tejido o aplicación regenerativa específico/a de acuerdo al órgano, tejido o célula utilizada, tanto para terapia celular, ingeniería tisular como para el xenotrasplante.

La acreditación otorgada es pública por lo que podrá ser consultada por los usuarios a través de la página web del Ministerio de Salud Pública y exhibida en la oficina principal de las instituciones, hospitales y bancos de tejidos y/o células.

Los requisitos y el procedimiento de acreditación serán establecidos por el INDOT.

Capítulo V
De la asignación de órganos, tejidos y células

Artículo 8.- Lista de Espera Única Nacional.- La Lista de Espera Única Nacional es el registro de datos de los paciencites preparados y listos para recibir un transplante de órganos y tejidos que tengan el estado de ACTIVO, inscritos por las unidades acreditadas.

La responsabilidad de la administración de la Lista de Espera Única Nacional le corresponde únicamente al INDOT, el cual deberá emitir los lincamientos de regulación y control correspondientes.

Artículo 9.- Asignación de órganos, tejidos y células.- El INDOT emitirá la normativa sobre los criterios técnicos de asignación para cada órgano, tejido y células, tomando en cuenta los siguientes parámetros:

1. Los pacientes declarados en código cero se convertirán en casos prioritarios;
2. Respeto al principio de interés superior de las niñas y niños, menores de edad y condiciones de doble vulnerabilidad; y,
3. Escalas de orden técnico, ético y científico de acuerdo al tipo de órganos, tejidos y células.

Esta enunciación no reflejará necesariamente el orden de asignación.

Capítulo VI
De la Voluntad de Donación

Artículo 10.- Voluntad Presunta.- Es la presunción legal que establece que todos los ecuatorianos y extranjeros residentes legalmente en el país, mayores de dieciocho años, al fallecer se convertirán en donantes a menos que en vida hubiesen manifestado su voluntad en contrario, de acuerdo a lo establecido en el artículo 29 de la ley.

El INDOT informará y protegerá el derecho de la población a decidir el no ser donante.

Artículo 11.- Registro de la voluntad en contrario.- La Dirección General de Registro Civil, Identificación y Cedulación es la entidad responsable de consultar y registrar la manifestación de voluntad de los ciudadanos y de los extranjeros residentes legalmente en el país, con respecto a su condición de donante de órganos y tejidos; desarrollará todos los mecanismos necesarios de constancia sobre la consulta y registro de la voluntad dentro de la base de datos nacional, obligándose a implementar las medidas necesarias en sus procedimientos y sistemas para velar por el cumplimiento del principio de confidencialidad.

El registro de la manifestación de la voluntad por parte de los usuarios, constará en el documento de identificación.

En caso de que los ciudadanos manifiesten su voluntad contraria o parcial, la Dirección General de Registro Civil, Identificación y Cedulación entregará un formulario, el cual debe estar obligatoriamente firmado por el titular o su representante legal según sea el caso.

En el caso de ciudadanos mayores de edad incapaces absolutos, la Dirección General de Registro Civil, Identificación y Cedulación, realizará la respectiva consulta respecto a la condición de donante al representante legal. En caso de manifestar su voluntad en contrario o parcial, se entregará el formulario que deberá estar obligatoriamente suscrito por el representante legal del mayor incapaz absoluto.

Artículo 12.- Verificación de la Donación.- Producida la muerte de una persona en los términos establecidos en la ley y resoluciones del INDOT, se podrá disponer de todos o parte de sus órganos y tejidos, cuando la no oposición a la donación se haya confirmado, previa consulta a la Dirección General de Registro Civil, Identificación y Cedulación, por parte del INDOT.

Para dicha confirmación la unidad médica donde se encuentre el posible donante, deberá notificar al INDOT, con el nombre y número de cédula del fallecido.

La Dirección General de Registro Civil, Identificación y Cedulación garantizará el acceso rápido a la consulta de la voluntad del donante, con el fin de agilitar la logística, los desplazamientos y la gestión del proceso de donación y trasplante.

Ninguna institución, ni persona podrá consultar la base de datos de la Dirección General de Registro Civil, Identificación y Cedulación, antes de que se haya confirmado el fallecimiento por criterios de muerte encefálica y/o parada cardiaca del potencial donante.

Los campos de consulta se limitan al número de cédula de ciudadanía o identidad, nombres completos, fecha de nacimiento, fecha de registro de su voluntad y demás que considere el INDOT en coordinación con la Dirección General de Registro Civil, Identificación y Cedulación; los cuales estarán contenidos en una certificación de la voluntad.

En los casos de existir voluntad contraria a la donación debidamente certificada por la Dirección General de Registro Civil, Identificación y Cedulación, en los fallecimientos por muerte encefálica debidamente certificados, se procederán a retirar los soportes artificiales y a realizar los trámites legales pertinentes.

Artículo 13.- Sujetos no identificados.- En el caso de no poder identificar al posible donante, no se podrá realizar proceso de donación y procuración de órganos y/o tejidos alguno.

Artículo 14.- Muerte violenta.- En caso de fallecimiento por causa violenta, el coordinador de la unidad médica notificará al Fiscal de Turno previa verificación de que se trata de un donante, por cualquier medio comprobable ya sea este en físico o digital.

Una vez producida la ablación, la unidad médica entregará a la Fiscalía en copias certificadas la siguiente documentación:

1. Certificación de muerte;
2. Formulario de Valoración de Donante Cadavérico;
3. Informes de extracción en el que se describirá el estado de cada uno de los órganos y/o tejidos ablacionados; y,
4. Demás documentación que determine la Fiscalía en coordinación con el INDOT.

La extracción a la que se refiere este artículo sólo podrá realizarse cuando no interfiera en los resultados finales de la autopsia.

Artículo 15.- Información a la familia del donante cadavérico.- Los familiares del donante cadavérico deben ser debidamente informados a través del protocolo respectivo de la manera más cálida, humana y brindando ayuda a la familia para que acepte la muerte. Adicionalmente el personal de la unidad médica o del INDOT informará acerca del procedimiento de procuración y ablación, su duración, cuáles van a ser los órganos y/o tejidos donados, las condiciones en las que se entregará el cadáver a la familia, entre otros. Esta

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información estará contenida en un acta suscrita por uno de los miembros del Equipo de Procuración y por uno de los familiares del donante.

En caso de no concurrir ningún familiar, se notificará a la Policía Nacional para que realice todas las gestiones necesarias para localizarlos, pero si en dos (2) horas de producida la notificación no se ha podido ubicarlos, se hará constar en el Acta este particular y se procederá a la procuración de órganos y tejidos de quienes tengan la condición de donantes, previa comunicación del particular al INDOT.

Artículo 16.- Prohibición de donación.- No podrán obtenerse órganos y/o tejidos de personas con deficienaias psíquicas o enfermedades mentales que presenten alteración cognoscitiva. A menos que su representante legal lo autoricen.

Además, no podrán obtenerse órganos y/o tejidos provenientes del cadáver de una mujer gestante.

Capítulo VII
Apoyo Logístico

Artículo 17.- Apoyo Logístico.- El INDOT coordinará el apoyo logístico y operativo de las entidades que forman parte del Sistema Nacional Integrado de Donación y Trasplantes, para el traslado de profesionales, equipos de trasplantes, material biológico, componentes anatómicos e insumos necesarios para el trasplante; traslado de pacientes críticos que requieran un trasplante; y las demás actividades que, dentro del ejercicio de sus facultades legales, requiera el INDOT.

Capítulo VIII
De la Donación en Vida

Artículo 18.- Requisitos y condiciones.- Las unidades acreditadas solicitarán al INDOT la autorización de todo procedimiento de trasplante con donante vivo, exceptuando el autotrasplante y la donación de tejidos y/o células, para los cual, el INDOT establecerá el procedimiento respectivo.

El INDOT establecerá los requisitos y el procedimiento de determinación del receptor y de la donación en vida.

En los casos de donación de médula ósea de menores de edad, las condiciones y limitaciones para la autorización emitida por los padres serán determinadas por el INDOT.

Artículo 19.- Órganos susceptibles de donación en vida.- Unicamente se podrán donar en vida los órganos pares o fracciones de un órgano regenerable.

Artículo 20.-Xenotrasplante.- El INDOT regulará todas las prácticas relacionadas con el xenotrasplante, incluida la investigación, bajo los parámetros y normas establecidas para el efecto.

Capítulo IX
Regulación de Costos

Artículo 21.- Regulación de Costos.- La Autoridad Sanitaria Nacional a través del INDOT velará por la aplicación del tarifario de prestaciones de servicios de trasplantes diferenciado por procesos.

Será obligación del INDOT elaborar y/o adaptar los tarifarios de aquellos procedimientos relacionados con los trasplantes que no se encuentren incluidos en el tarifario de prestaciones de servicios para el Sistema Nacional de Salud.

DISPOSICIONES TRANSITORIAS

PRIMERA.- Transfiérase todas las representaciones, delegaciones, derechos, obligaciones, unidades, presupuesto, personal; así como, los recursos, patrimonio y en general, todos los activos y pasivos del Organismo Nacional de Trasplantes de Órganos y Tejidos al Instituto Nacional de Donación y Trasplante de órganos, tejidos y células, para lo cual éste podrá estructurar las unidades de apoyo y ejecución que sean necesarias para cumplir lo establecido en la Ley, este Reglamento General, la Política Nacional de Donación y Trasplante y resoluciones emitidas por la Autoridad Sanitaria Nacional.

SEGUNDA.- Los servidores que vienen prestando sus servicios con nombramientos o contrato o bajo cualquier modalidad en el Organismo Nacional de Trasplantes de Órganos y Tejidos, continuarán prestando sus servicios para el Instituto Nacional de Donación y Trasplante de órganos, tejidos y células con sus mismos derechos y obligaciones, y serán sujetos a procesos de evaluación y selección a efectos de determinar su continuidad en la nueva institución, de acuerdo a los requerimientos estructurales y orgánicos de ésta. Una vez realizado el proceso de evaluación y selección, se determinarán los puestos que continuarán siendo necesarios y se crearán aquellos que de acuerdo a la estructura y competencias del Instituto Nacional de Donación y Trasplante de órganos, tejidos y células se requieran, para lo cual se analizarán los expedientes individuales de las servidoras y servidores, y aquellos puestos que de acuerdo con la nueva estructura orgánica funcional de la Institución no sean necesarios, serán suprimidos de conformidad con la Ley Orgánica del Servicio Público, su Reglamento General y demás normas pertinentes.

TERCERA.- Los Bancos de Córneas del Hospital Eugenio Espejo en la ciudad de Quito, Hospital Abel Gilbert Pontón de la ciudad de Guayaquil y Hospital Vicente Corral Moscoso de la ciudad de Cuenca, se incorporarán al Banco Nacional de Tejidos una vez que se cree, incluyendo su equipamiento y recurso humano con los contratos y partidas correspondientes.

Todos los equipos, insumos y materiales registrados por el Hospital Eugenio Espejo, para la creación e implementación del Banco Nacional de Tejidos, deberán ser transferidos a favor del INDOT.

CUARTA.- Si el documento de identificación es obtenido mediante el sistema AS/400 de la Dirección General de Registro Civil, Identificación y Cedulación, la manifestación de voluntad contraria total o parcial del usuario será registrada en la base de datos institucional de esta entidad a fin de garantizar la confidencialidad de la información, hasta que realice la renovación del documento de identificación que contenga chip.

DISPOSICIÓN FINAL
El presente Reglamento entrará en vigencia a partir de su publicación en el Registro Oficial.

Dado en el Palacio Nacional, en Quito, a 26 de Junio 2012.

Rafael Correa Delgado
PRESIDENTE CONSTITUCIONAL DE LA REPÚBLICA

Carina Vance Mafla
MINISTRA DE SALUD (E)

Yo soy donante
Tú eres donante

Todos podemos ser donantes
porque todos podemos necesitar un trasplante

Para mayor información:

comunicacion@indot.gob.ec Indot @IndotEcuador

Quito: Av. de la Prensa N44-08 y Edmundo Carvajal.
Telf: 02 244 93 94 , 02 2447 642 ext. 101.

Zonal 1: Quito - Av. de la Prensa N44-08 y Edmundo Carvajal.
Telf: 02 244 93 94 , 02 2447 642 - 099 680 2503.

Zonal 2: Guayaquil - Av. Francisco de Orellana y Miguel H. Alcívar.
Edificio Centro Empresarial "Las Cámaras", Torre A, oficina 8.
Telf: 099 680 8811 - 099 685 9670.

Zonal 3: Cuenca - Hospital Vicente Corral Moscoso, Planta Baja.
Telf: 07 4098 499 - 099 657 3189 - 099 6573186

Dirección Técnica de Bancos de Tejidos y Células - INDOT

Banco Nacional de Tejidos y Células - BANTEC.

Quito: Hospital de Especialidades Eugenio Espejo. Av. Gran Colombia s/n y Yaguachi.
Telf: 02 2558 502 - 099 685 9675.

Guayaquil: BANCO DE OJOS. Hospital Dr. Abel Gilbert Pontón. La 29 y Galápagos,
Suburbio de Guayaquil
Telf: 04 2597400 ext. 3786

Cuenca: BANCO DE OJOS. Hospital Vicente Corral Moscoso.
Telf: 07 4098 499

Guía nacional para la integración y el funcionamiento de los Comités de Ética en Investigación

SALUD
SECRETARÍA DE SALUD

CONBIOÉTICA
Comisión Nacional de Bioética

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Presentación

En un contexto de avances científicos, tecnológicos y socioculturales, la bioética ofrece un enfoque multidisciplinario para enriquecer el análisis de los dilemas que se suscitan, principalmente en el campo de la biomedicina y el desarrollo de políticas públicas, con un enfoque incluyente y perspectiva de género, en beneficio de la población.

La Secretaria de Salud Mercedes Juan, a lo largo de su gestión, ha impulsado la consolidación de la rectoría de la Comisión Nacional de Bioética, con el objeto de fortalecer los mecanismos institucionales que promuevan el respeto y la protección a los sujetos de investigación en salud, por encima de intereses científicos, políticos, profesionales y comerciales, entre otros.

La Comisión Nacional de Bioética promueve la organización y el funcionamiento de Comités Hospitalarios de Bioética y Comités de Ética en Investigación, en las instituciones de salud públicas y privadas. Asimismo, establece mediante la *Guía nacional para la integración y el funcionamiento de los Comités Ética en Investigación*, los criterios para el desarrollo de las actividades y la capacitación de los miembros de los cuerpos colegiados.

El Decreto por el que se adiciona el Artículo 41 Bis y se reforma el artículo 98 de la Ley General de Salud -publicado en el Diario Oficial de la Federación, el 14 de diciembre de 2011- señala la obligatoriedad de los establecimientos de atención médica, que lleven a cabo actividades de investigación en seres humanos, de contar con Comités de Ética en Investigación (CEI).

Los CEI son responsables de evaluar y dictaminar los protocolos de investigación en seres humanos, formular las recomendaciones de carácter ético que correspondan, elaborar lineamientos y guías éticas institucionales para la investigación en salud y dar seguimiento a sus dictámenes.

La Guía nacional de CEI, de carácter vinculante, ofrece un marco conceptual que puede propiciar el diálogo entre la Comisión Nacional de Bioética y los Comités, con la finalidad de establecer un proceso de actualización continua en temas relativos a actividades clínicas, docencia en salud y desarrollo profesional, entre otros.

Asimismo, establece la importancia de contar con un mecanismo de autoevaluación, así como de lineamientos y guías éticas institucionales para afrontar los aspectos prácticos de la docencia médica y promover la formación en bioética de sus miembros, personal del establecimiento de salud, pacientes y familiares.

De la misma manera, se presentan las características, objetivos, funciones, integración, operatividad, control y seguimiento del Comité, además de los requisitos para obtener el registro ante la Comisión, su actualización y las consideraciones mínimas para la revisión de protocolos desde el punto de vista ético.

La quinta edición de la *Guía nacional para la integración y el funcionamiento de los Comités de Ética en Investigación* ratifica el compromiso de la Comisión Nacional de Bioética en la consolidación de la infraestructura institucional en bioética y la promoción de una cultura de la ética de la investigación.

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Presidente del Consejo
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Marco Conceptual

El término *bioética*, desarrollado por Fritz Jahr como imperativo bioético definió por primera vez la ética de las relaciones de los seres humanos con los animales y la naturaleza. Van Rensselaer Potter lo incorporó al discurso académico contemporáneo y la cultura general en el artículo *Bioethics, the science of survival, publicado en 1970 y en su libro Bioethics: bridge to the future*[1].

Para la Comisión Nacional de Bioética *CONBIOÉTICA*, la bioética es la rama de la ética aplicada que reflexiona, delibera y hace planteamientos normativos y de políticas públicas para regular y resolver conflictos en la vida social, especialmente en las ciencias de la vida, así como en la práctica y en la investigación médica que afecten la vida en el planeta, tanto en la actualidad, como en futuras generaciones. Esta noción de bioética, formulada con el apoyo y aval del Consejo de la Comisión, deriva de dos aspectos fundamentales: la necesidad de contar con una aproximación conceptual -en tanto no se cuenta con una definición de carácter universal- y la relevancia de trasladarla al terreno operativo y llevarla a la práctica.

La bioética es esencial en los debates públicos sobre temas que involucran los desarrollos científicos y tecnológicos, así como sus repercusiones en todas las dimensiones de la vida, de ahí que se ha incluido en el diálogo nacional e internacional para que la toma de decisiones en el espacio público recoja la perspectiva ética que las sociedades contemporáneas necesitan y demandan.

La aplicación del conocimiento y el desarrollo de la cultura bioética son favorables para garantizar el bienestar individual y social. La disciplina promueve los conceptos de equidad, solidaridad y calidad de los servicios; los principios de beneficencia, no maleficencia, justicia y autonomía, así como la protección a los derechos de las personas.

La investigación con seres humanos conlleva riesgos, esto hace necesario garantizar condiciones éticamente aceptables en la producción de conocimiento, considerando que el marco legal no es suficiente para elucidar o resolver los conflictos de orden moral o ético que se presentan en la actividad científica.

La bioética, sin ser un código de preceptos, integra la actividad analítica y se fundamenta en principios filosóficos y criterios científicos, a fin de orientar la práctica en las distintas áreas de la salud y la investigación. La información y el conocimiento se han globalizado, la disciplina transita por una reflexión permanente que incluye el ámbito internacional, ejemplo de ello es la Declaración de Principios Éticos para las Investigaciones Médicas en Seres Humanos de la Asociación Médica Mundial, adoptada en Helsinki, Finlandia, en 1964 y sus actualizaciones.[2]

Se consideran también las declaraciones emitidas por la Organización de las Naciones Unidas para la Educación, la Ciencia y la Cultura (UNESCO), entre las que destacan la Declaración Universal sobre el Genoma Humano y los Derechos Humanos (1997); la Declaración sobre las Responsabilidades de las Generaciones Actuales hacia las Generaciones Futuras (1997); la Declaración Internacional sobre los Datos Genéticos Humanos (2003); y la Declaración Universal sobre Bioética y Derechos Humanos (2005).

1 *Cfr.* González, J. (2008). Perspectivas de Bioética. México: Fondo de Cultura Económica. Disponible en línea en: http://www.bioetica.unam.mx/que%20etica%20para%20la%20bioetica.pdf

2 La última actualización del documento se realizó en Fortaleza, Brasil, en octubre de 2013.
El texto se encuentra disponible en línea en la liga http://www.wma.net/es/30publications/10policies/b3/

La Convención para la Protección de los Derechos Humanos y de la Dignidad del Ser Humano ante las Aplicaciones de la Biología y la Medicina del Consejo de Europa (1997), conocida como Convenio de Oviedo, es el único instrumento en el mundo que cuenta con la jerarquía de un tratado internacional adoptado por 29 países del continente europeo.

Estos instrumentos ponen de manifiesto diversos compromisos, como son la protección de los derechos humanos, respeto a la dignidad y a la privacidad, evitar toda forma de discriminación, equidad en la atención a la salud con calidad y realizar investigaciones en seres humanos sólo si el objetivo justifica el riesgo para el sujeto de investigación, asegurando su integridad y bienestar.

Para afrontar tales responsabilidades, han surgido en diversos países comisiones o comités nacionales de ética/bioética, estas instancias asesoran a los representantes políticos y a los gobiernos, fomentan el debate democrático y público, así como el análisis y la elaboración de políticas públicas en campos éticos complejos. Su función no es estrictamente normativa, dichas comisiones definen los problemas, los estudian y exponen puntos de vista con la finalidad de explorar posibles soluciones y formular recomendaciones.

Las repercusiones de la institucionalización de la bioética trascienden en los distintos órdenes de la vida social. El Estado mexicano crea en 1992, a través de la Secretaría de Salud, la Comisión Nacional de Bioética y en 2005 le concede, mediante decreto presidencial, el carácter de órgano desconcentrado, otorgándole facultades para coadyuvar a la salvaguarda de la dignidad y el respeto a los derechos humanos en la atención médica y la investigación en salud.

Actualmente la infraestructura nacional en bioética está conformada por la Comisión Nacional de Bioética, las Comisiones Estatales de Bioética, los Comités Hospitalarios de Bioética y los Comités de Ética en Investigación. De esta manera, la bioética se lleva al campo de la acción pública y gubernamental para apoyar en la formulación y evaluación de políticas públicas. Asimismo, las legislaturas federales y estatales se pronuncian con mayor intensidad a favor de la regulación en temas relacionados con la materia.

Investigación y principios éticos

Toda investigación que involucre seres humanos debe llevarse a cabo de acuerdo con normas éticas universalmente reconocidas.[3] A fin de reducir al mínimo la posibilidad de causar daño, se han establecido una serie de principios éticos que deben acatar los protocolos de investigación: respeto de la autonomía, no maleficencia, beneficencia y justicia, reflejados en las guías y lineamientos nacionales e internacionales.

Estos principios, sin embargo, no son limitativos, es necesario complementarlos con otros aspectos éticos, propios de la investigación, como son la integridad científica, la confidencialidad en el manejo de información sensible o el valor social de la investigación.[4]

3 *Cfr.* Emanuel E.; Grady C., Crouch R.; Lie R. K. (2008). Oxford Textbook of Clinical Research Ethics. Oxford University Press Inc.
4 *Vid.* Koepsell D., Ruiz de Chávez M. (2015). Ética de la investigación, Integridad científica. CONBIOÉTICA / CONACYT: México. Disponible en formato eBook en: http://www.conbioetica-mexico.salud.gob.mx/

Respeto a la autonomía

El respeto a la autonomía reconoce la capacidad de las personas para la toma de decisiones. Este principio se materializa, a través del proceso del consentimiento informado. Es importante enfatizar que a diferencia de la práctica médica, en la que el principal beneficio es el alivio o curación del paciente, en la investigación el objetivo principal es generar conocimiento para lo cual es indispensable que el sujeto esté informado sobre la naturaleza de la investigación y, de manera libre, acepte su participación.

Para asegurar las decisiones informadas, debe existir una descripción comprensible de los procedimientos de investigación, propósito, riesgos y beneficios. El consentimiento libre e informado implica que no existen influencias o coerción. Es difícil no ejercer cierta influencia, sin embargo, ésta no debe implicar un riesgo inaceptable, como es el caso de un estímulo financiero o el condicionamiento del acceso a los servicios de salud, en función de la participación en el estudio. En el caso de investigaciones en las que participan individuos incapaces de consentir se deben considerar mecanismos adicionales de protección.

Beneficencia y no maleficencia

Estos principios están contenidos en el imperativo ético de maximizar los posibles beneficios y minimizar los daños o riesgos potenciales. En investigación, el principio de beneficencia obliga a asegurar la pertinencia científica, la competencia de los investigadores y la protección de los participantes en las investigaciones. Debe considerarse que, si bien las investigaciones confieren un riesgo, éste sólo debe asumirse cuando no exista otra alternativa con resultados similares.

La investigación en salud, sólo debe autorizarse si existe equilibrio entre riesgos y beneficios tanto físicos como psicológicos para el sujeto, incluso si da su consentimiento para participar.

Justicia

El principio de justicia comprende la equidad e igualdad. En la investigación con seres humanos esto implica que la distribución de cargas y beneficios sea equilibrada.

La justicia tiene implicaciones en la selección de los participantes y en las investigaciones en países con recursos limitados. Es importante que el tipo de investigación responda a las necesidades de una población específica y que los beneficios se distribuyan equitativamente.

Importancia de la Guía nacional para la integración y el funcionamiento de los Comités de Ética en Investigación

La investigación en salud requiere intervenir en condiciones experimentales -con incertidumbre para los individuos que aceptan participar voluntariamente- por lo que nunca está exenta de riesgos, el quehacer de un CEI es asegurar que se minimicen y se respeten los principios éticos.

Con el registro y seguimiento de los CEI se armoniza la integración y funcionamiento de estos cuerpos colegiados, brindando la certeza de su operación, de acuerdo con estándares éticos mundiales, enfatizando el compromiso de evitar posibles conflictos de interés que comprometan su funcionamiento, transparencia y libertad en la toma de decisiones.

Esta Guía no agota los temas relacionados con ética en investigación y bioética; señala pautas para el funcionamiento y operatividad de los CEI, que deben ser complementadas con el manual de organización, reglamento interior y procedimientos normalizados de operación, que marcarán el actuar cotidiano, así como la delimitación de las atribuciones de cada institución o establecimiento.[5]

Normatividad

La CONBIOÉTICA ha participado en la generación, promoción y difusión de la normatividad nacional, que permite dar cumplimiento a su Decreto de Creación, publicado en el Diario Oficial de la Federación el 07 de septiembre de 2005.[6] Dichas acciones se reflejan en diversas reformas a la legislación sanitaria, fortaleciendo el marco jurídico, como consecuencia de la incorporación y observancia de los derechos humanos.

En diciembre de 2011, se publica en el Diario Oficial de la Federación **el Decreto de reforma a la Ley General de Salud, por el que se adiciona el artículo 41 Bis y se reforma el 98** de la citada Ley, que obliga a los establecimientos de salud del sector público, privado y social a contar con Comités Hospitalarios de Bioética y Comités de Ética en Investigación, bajo los lineamientos de la Comisión Nacional de Bioética.[7]

En octubre de 2012, se publica en el Diario Oficial de la Federación **el Acuerdo por el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los Comités de Ética en Investigación y se establecen las unidades hospitalarias que deben contar con ellos, de conformidad con los criterios establecidos por la Comisión Nacional de Bioética.[8]**

El 02 de abril de 2014, se publican en el Diario Oficial de la Federación las reformas al Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, a través de la cual se establece que **el registro de Comités de Ética en Investigación estará a cargo de la Comisión Nacional de Bioética.[9]**

El 11 de enero de 2016, se publica en el Diario Oficial de la Federación el ACUERDO por el que se reforma y adiciona el diverso por el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los Comités de Ética en Investigación y se establecen las unidades hospitalarias que deben contar con ellos, de conformidad con los criterios establecidos por la Comisión Nacional de Bioética, publicado el 31 de octubre de 2012. (D.O.F. 11/01/16).

Marco jurídico nacional

En México, el marco jurídico en materia de salud se ha transformado en las últimas décadas. A continuación se enuncian los instrumentos normativos más relevantes en el estudio de los temas bioéticos y de ética en investigación. No obstante, cada caso analizado por un Comité de Ética en Investigación tiene particularidades que requieren de consideraciones legales específicas:

5 Para información más detallada, la CONBIOÉTICA cuenta con un extenso acervo bibliohemerográfico especializado en bioética, disponible en: amigosconbioetica.salud.gob.mx
6 Publicado en el Diario Oficial de la Federación el 07 de septiembre de 2005. http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/6._NAL._Decreto_CNB.pdf
7 Reformas a la Ley General de Salud (Artículos 41 BIS y 98) http://dof.gob.mx/nota_detalle.php?codigo=5224260&fecha=14/12/2011
8 Publicado en el Diario Oficial de la Federación el 31 de octubre de 2012. http://www.dof.gob.mx/nota_detalle.php?codigo=5276107&fecha=31/10/2012
9 Publicado en el Diario Oficial de la Federación el 02 de abril de 2014 http://www.dof.gob.mx/nota_detalle.php?codigo=5339162&fecha=02/04/2014

- Constitución Política de los Estados Unidos Mexicanos.[10]
- Ley Orgánica de la Administración Pública Federal.[11]
- Ley General de Salud.[12]
- Ley General de Transparencia y Acceso a la Información Pública.[13]
- Ley Federal de Transparencia y Acceso a la Información Pública Gubernamental.[14]
- Ley Federal de Protección de Datos Personales en Posesión de los Particulares.[15]
- Ley Federal de Procedimiento Administrativo.[16]
- Reglamento de la Ley General de Salud en Materia de Investigación para la Salud.[17]
- Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica.[18]
- Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios.[19]
- Reglamento Interior de la Secretaría de Salud.[20]
- Decreto por el que se crea el órgano desconcentrado denominado Comisión Nacional de Bioética.[21]
- Acuerdo por el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los CEI y se establecen las unidades hospitalarias que deben contar con ellos, de conformidad con los criterios establecidos por la Comisión Nacional de Bioética.[22]
- Acuerdo por el que se reforma y adiciona el diverso por el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los Comités de Ética en Investigación y se establecen las unidades hospitalarias que deben contar con ellos, de conformidad con los criterios establecidos por la Comisión Nacional de Bioética, publicado el 31 de octubre de 2012. (D.O.F. 11/01/16).
- Acuerdo que establece los lineamientos que deberán observarse en los establecimientos públicos que presten servicios de atención médica para regular su relación con los fabricantes y distribuidores de medicamentos y otros insumos para la salud, derivada de la promoción de productos o la realización de actividades académicas, de investigación o científicas.[23]

10 Compromiso por la transparencia en la relación entre los médicos e instituciones de atención a la salud y la industria farmacéutica.
11 *Cfr.* Ley Orgánica de la Administración Pública Federal, Última reforma publicada en el Diario Oficial de la Federación el 27 de enero de 2015. http://www.diputados.gob.mx/LeyesBiblio/ref/loapf.htm
12 *Cfr.* Ley General de Salud. Última reforma publicada en el Diario Oficial de la Federación el 17 de marzo de 2015 http://www.diputados.gob.mx/LeyesBiblio/ref/lgs/LGS_orig_07feb84_ima.pdf
13 *Cfr.* Ley General de Transparencia y Acceso a la Información Pública Nueva Ley DOF 04-05-2015 http://www.diputados.gob.mx/LeyesBiblio/pdf/LGTAIP.pdf
14 *Cfr.* Ley Federal de Transparencia y Acceso a la Información Pública Gubernamental. Última reforma publicada en el Diario Oficial de la Federación el 14 de julio de 2014
15 *Cfr.* Ley Federal de Protección de Datos Personales en Posesión de los Particulares. Última reforma publicada en el Diario Oficial de la Federación el 05 de julio de 2010. http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf
16 *Cfr.* Ley Federal de Procedimiento Administrativo Última reforma publicada en el Diario Oficial de la Federación el 09 de abril de 2012. http://www.diputados.gob.mx/LeyesBiblio/pdf/112.pdf
17 *Cfr.* Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, Última reforma publicada en el Diario Oficial de la Federación el 02 de abril de 2014. http://biblio.juridicas.unam.mx/libros/5/2292/63.pdf
18 *Cfr.* Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica. Última reforma publicada en el Diario Oficial de la Federación el 24 de marzo 2014. http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmpsam.html
19 *Cfr.* Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios. Publicado en el Diario Oficial de la Federación el 13 de abril de 2004.http://www.salud.gob.mx/unidades/cdi/nom/compi/r130404.html
20 *Cfr.* Reglamento Interior de la Secretaría de Salud. Publicado en el Diario Oficial de la Federación el 19 de enero de 2004 http://www.salud.gob.mx/unidades/cdi/nom/compi/ri190104.html
21 Publicado en el Diario Oficial de la Federación el 07 de septiembre de 2005. http://www.CONBIOÉTICA-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/6._NAL._Decreto_CNB.pdf
22 Publicado en el Diario Oficial de la Federación el 07 de septiembre de 2005. http://www.CONBIOÉTICA-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/6._NAL._Decreto_CNB.pdf
23 Publicado en el Diario Oficial de la Federación el 31 de octubre de 2012. http://www.dof.gob.mx/nota_detalle.php?codigo=5276107&fecha=31/10/2012

- Norma Oficial Mexicana NOM-012-SSA3-2012, que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos.[24]
- Norma Oficial Mexicana NOM-220-SSA1-2002, Instalación y operación de la farmacovigilancia.[25]
- Compromiso por la transparencia en la relación entre los médicos e instituciones de atención a la salud y la industria farmacéutica.[26]

Documentos internacionales relevantes para la investigación en seres humanos[27]

Existen en la normatividad internacional pautas, guías o recomendaciones en materia de ética en investigación, sin embargo es necesario aclarar que no necesariamente son de carácter vinculante y constituyen criterios para guiar las investigaciones conforme a principios éticos. Algunos de los principales documentos internacionales, que abordan el tema de ética en investigación son:

- Código de Nüremberg; Juicio de Nüremberg por el Tribunal Internacional de Nüremberg, 1947.[28]
- Declaración de Helsinki, Asociación Médica Mundial, 2013.[29]
- Informe Belmont, Comisión Nacional para la Protección de los Sujetos de Investigación Biomédica y de Conducta, 1979.[30]
- Guías Operacionales para Comités de Ética que revisan Investigación Biomédica (Operational Guidelines for Ethics Committees That Review Biomedical Research) World Health Organization, 2000.[31]
- Estándares y guías operacionales para la revisión ética de investigación en salud con participantes humanos (Standards and Operational Guidance for Ethics Review of Health -Related Research with Human Participants) World Health Organization, 2011.[32]
- Comités de ética en Investigación, conceptos básicos para la construcción de infraestructura (Research ethics committees: basic concepts for capacity-building) World Health Organization, 2009.[33]

24 Publicado en el Diario Oficial de la Federación el 12 de agosto de 2008. http://www.dof.gob.mx/nota_detalle.php?codigo=5056216&fecha=12/08/2008

25 *Cfr.* Norma Oficial Mexicana NOM-220-SSA1-2012, Instalación y operación de la farmacovigilancia Publicada en el Diario Oficial de la Federación el 7 de enero de 2013 http://www.dof.gob.mx/nota_detalle.php?codigo=5284236&fecha=07/01/2013

26 Compromiso por la transparencia en la relación entre los médicos e instituciones de atención a la salud y la industria farmacéutica. http://conbioetica-mexico.salud.gob.mx/descargas/pdf/temadelmes/compromiso.pdf

27 International Compilation of Human Research Standards 2016 Edition http://www.hhs.gov/ohrp/international/index.html

28 Fue publicado el 20 de agosto de 1947, como producto del Juicio de Nüremberg por el Tribunal Internacional de Nüremberg, Este documento puede ser consultado en línea en la página de la Oficina de Investigación con Sujetos Humanos del National Institutes of Health: https://www.research.buffalo.edu/rsp/irb/forms/Nuremberg_Code.pdf

29 Fue desarrollada por representantes de la Asociación Médica Mundial en 1964, como una propuesta de principios éticos para investigación médica en seres humanos, incluida la investigación del material humano y de información identificables. Después de 50 años ha tenido siete enmiendas, la más reciente en la Asamblea General en octubre de 2013 World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects La Declaración así como sus enmiendas pueden ser consultadas en el portal web de la Asociación Médica Mundial: http://www.wma.net/es/30publications/10policies/b3/.

30 El "Informe Belmont", establece los principios de respeto por la autonomía de las personas, beneficencia y justicia, como rectores en las actividades relacionadas con este tipo de investigación. National Commission for the Protection of Human Subject of Biomedical and Behavioral Research. El Informe puede ser consultado en línea en la página de la Oficina de Investigación con Sujetos Humanos del National Institutes of Health: http://www.recerca.uab.es/ceeah/docs/Belmont%20Report.pdf

31 World Health Organization (2000) Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneve: World Health Organization. Este documento puede ser consultado en línea en: http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf

32 World Health Organization (2011) Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants. Operational Guidelines for Ethics Committees that Review Biomedical Research Geneve: World Health Organization. Este documento puede ser consultado en línea en http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf

33 World Health Organization (2009) Research ethics committees Basic concepts for capacity-building World Health Organization. Operational Guidelines for Ethics Committees that Review Biomedical Research: Geneve: World Health Organization. Este documento puede ser consultado en http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf

- Pautas Éticas Internacionales para la Investigación Biomédica en Seres Humanos del Consejo para Organizaciones Internacionales de Ciencias Médicas (Council for International Organizations of Medical Sciences, CIOMS, 2002).[34]
- Pautas Éticas Internacionales para estudios epidemiológicos del Consejo para Organizaciones Internacionales de Ciencias Médicas (Council for International Organizations of Medical Sciences, CIOMS, 2008).[35]
- Conferencia Internacional de Armonización (ICH) Guías de Buenas Prácticas Clínicas, (Good Clinical Practices GCP) Food and Drug Administration, 2000.[36]
- Código de Regulaciones Federales, Título 45, Parte 46 (45CRF46) "Protection of Human Subjects"; Departamento de Salud y Servicios Humanos de EEUU, 2009.[37]
- Declaración Universal de Derechos Humanos, UNESCO, 1948.[38]
- Declaración Universal de los Derechos Humanos de las Generaciones Futuras, UNESCO, 1994.[39]
- Declaración sobre las Responsabilidades de las Generaciones Actuales para con las Generaciones Futuras. UNESCO, 1997.[40]
- Declaración Internacional sobre los Datos Genéticos Humanos, UNESCO, 2003.[41]
- Declaración Universal sobre Bioética y Derechos Humanos, UNESCO, 2005.[42]
- Convención para la Protección de los Derechos Humanos y de la Dignidad del Ser Humano ante las Aplicaciones de la Biología y la Medicina, Consejo de Europa, 1997.[43]

Comités de Ética en Investigación

Los CEI forman parte del compromiso de transparencia institucional, que asumen los establecimientos que realizan investigación en seres humanos, con las instancias reguladoras, los participantes en las investigaciones y la sociedad en su conjunto.

La inclusión de los aspectos éticos en los protocolos es un indicador de calidad, equiparable al rigor metodológico de una investigación científica. Los CEI deben ser los garantes de que responda, desde el punto de vista ético, a los intereses y necesidades de la ciudadanía. Por ello, y de conformidad con lo dispuesto en la Ley General de Salud, deberán instalarse y funcionar en todas las instituciones y establecimientos públicos y privados, en los que se lleve a cabo investigación en seres humanos.

34 Council for International Organizations of Medical Sciences (2002) Geneve: Council for International Organizations of Medical Sciences. Disponible en: http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm
35 Council for International Organizations of Medical Sciences (2008) International Ethical Guidelines for Epidemiological Studies. Operational Guidelines for Ethics Committees that Review Biomedical Research Geneve: Council for International Organizations of Medical Sciences. Disponible en http://www.ufrgs.br/bioetica/cioms2008.pdf
36 Food and Drug Administration (2000) General: Good Clinical Practice and Human Subject Protections in FDA Regulated Clinical Trials: Operational Guidelines for Ethics Committees that Review Biomedical Research. Disponible en: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf
37 U.S. Department of Health and Human Services (2009) Code of Federal Regulations Title 45 Public Welfare Department of Health And Human Services, Part 46 Protection of Human. Disponible en: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
38 Adoptada y proclamada por la Asamblea General en su resolución 217 A (III) de 10 de diciembre de 1948. Disponible en: http://portal.unesco.org/es/ev.php-URL_ID=26053&URL_DO=DO_TOPIC&URL_SECTION=201.html
39 Proclamada por la UNESCO, el equipo Cousteau y la Universidad de La Laguna, el 26 de febrero de 1994.
40 Adoptada el 12 de noviembre de 1997 por la Conferencia General de la UNESCO en su 29ª reunión. Disponible en: http://www.unesco.org/cpp/sp/declaraciones/generaciones.htm
41 Adoptada el 16 de octubre de 2003 por la UNESCO. Disponible en: http://portal.unesco.org/es/ev.php-RL_ID=17720&URL_DO=-DO_TOPIC&URL_SECTION=201.html
42 Proclamada el 19 de octubre de 2005 por la UNESCO. Disponible en: http://unesdoc.unesco.org/images/0014/001461/146180s.pdf
43 Para acceder al contenido del Convenio consultado en el portal del Consejo de Europa: http://conventions.coe.int/treaty/en/Treaties/Html/164.htm

El propósito del CEI es revisar protocolos de investigación en seres humanos y salvaguardar la dignidad, derechos y seguridad de los involucrados en el proceso, enfatizando su protección.[44] En este sentido, los Comités deben ser:

- **Autónomos:** Son independientes de influencias de tipo profesional, institucionales, políticas, de mercado, entre otras.
- **Institucionales:** Pertenecen a un establecimiento para la atención médica o instituciones de salud o de enseñanza superior[45] del sector público, social o privado del Sistema Nacional de Salud, donde se realice investigación con seres humanos. Los establecimientos deberán contar con Licencia Sanitaria para Establecimientos de Atención Médica emitida por la Secretaria de Salud.
- **Multidisciplinarios:** Hacen converger los conocimientos de distintas disciplinas, deben incluir especialistas en asuntos científicos, metodológicos y buenas prácticas clínicas. Al menos un integrante deberá tener conocimientos en bioética y ética en investigación; es recomendable contar con la participación de enfermería, trabajo social, abogados, entre otros, y un representante del núcleo afectado o usuario de los servicios de salud. En caso necesario, debe considerarse la invitación de expertos en áreas específicas.
- **Plurales:** Reconocen y promueven la diversidad y tratan de alcanzar acuerdos entre diversas posturas, en una discusión que parta de mínimos compartidos.
- **Consultivos:** Asesoran al cuerpo de gobierno. Buscan determinar los valores de la ética social y fungir como órganos de primera instancia para la emisión de dictámenes, opiniones o recomendaciones de carácter general.

Los CEI constituyen espacios de deliberación, en los que se desarrolla la discusión y la reflexión, en un ambiente de libertad y tolerancia. Desempeñan un rol social con el investigador para resolver de manera prudente y adecuada, los dilemas éticos que plantea cada una de las investigaciones en las que participan seres humanos. De lo anterior, se puede decir que los CEI representan:

- Guía y apoyo de la conciencia del investigador.
- Protección de los participantes en la investigación.
- Garantía pública de respeto a la dignidad, igualdad y derechos humanos.
- Fomento de la educación interdisciplinaria y multisectorial.
- Conciencia bioética institucional y de la integridad científica.

Objetivos

Los objetivos del Comité de Ética en Investigación son:

- Contribuir a salvaguardar la dignidad, los derechos, la seguridad y el bienestar de los actuales o potenciales participantes en las investigaciones, así como de las comunidades

44 *Cfr.* Lisker, R. (2013) Investigación Clínica. PAC Medicina General 5. Tomo 1. México: Intersistemas SA de CV.

45 De acuerdo a la definición del numeral 4.11 de la NORMA Oficial Mexicana NOM-012-SSA3-2012, Que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos Institución o establecimiento donde se realiza investigación para la salud, a todo aquel donde se proporcionen servicios de atención médica, perteneciente a los sectores público, social o privado, cualquiera que sea su denominación, que pueda efectuar actividades preventivas, diagnósticas, terapéuticas y de rehabilitación, por si misma o subrogadas, dirigidas a mantener o reintegrar el estado de salud de las personas y efectuar actividades de formación y desarrollo de personal para la salud, así como de investigación: 8.1. Toda investigación en seres humanos, deberá realizarse en una institución o establecimiento, el cual deberá contar con la infraestructura y capacidad resolutiva suficiente, para proporcionar la atención médica adecuada o en su caso, a través de terceros, ante la presencia de cualquier efecto adverso de la maniobra experimental expresada en el proyecto o protocolo de investigación autorizado. 8.6 Toda institución o establecimiento, en el que se lleve a cabo o se pretenda realizar una investigación, debe contar con un servicio para la atención de urgencias médicas. En su caso, se deberá contar con un convenio suscrito con un establecimiento para la atención médica de mayor capacidad resolutiva, que a manera de tercero, brinde dicha atención de urgencias.

involucradas, tomando en consideración la regulación nacional e internacional en materia de ética en la investigación.
- Actuar en el interés de los sujetos de investigación.
- Asesorar a los titulares de los establecimientos e instituciones sobre la autorización de investigaciones en sus unidades de responsabilidad.
- Vigilar la aplicación de la legislación, normatividad y contenidos éticos vigentes en materia de investigación y las demás disposiciones aplicables, así como auxiliar a los investigadores para la realización óptima de sus estudios.
- Fomentar que los beneficios y las responsabilidades de la investigación sean distribuidos entre los grupos sociales, tomando en cuenta la edad, género, estatus económico, cultura y consideraciones étnicas.

Funciones

Función resolutiva

Prevé la responsabilidad de los CEI para:

- Analizar y revisar los protocolos de investigación puestos a su consideración, así como apoyar los en la toma de decisiones respecto de los problemas o dilemas bioéticos que se presenten en la investigación.
- Evaluar y dictaminar, desde el punto de vista ético, los contenidos que se presenten en la investigación, en forma transparente, independiente, competente, oportuna, de calidad, libre de influencia indebida, institucional, profesional y comercial, así como su integridad científica.
- Solicitar la interrupción o suspensión de una investigación en caso de que la integridad de los sujetos esté amenazada.

Función de control y seguimiento

Da continuidad a las resoluciones emitidas por el CEI, de acuerdo con lo establecido en esta guía y los manuales de procedimientos de cada institución. En ejercicio de estas funciones, podrán:

- Vigilar la aplicación de la legislación vigente, la normatividad, los lineamientos, los criterios que establezca la CONBIOÉTICA, en materia de bioética en investigación en seres humanos y demás disposiciones aplicables.
- Dar seguimiento al desarrollo de la investigación asegurando la protección de los participantes.
- Informar a las autoridades competentes las conductas que deberían ser sancionadas.
- Asegurar que el investigador notifique a los responsables de la institución o del establecimiento, las autoridades sanitarias y al patrocinador, la ocurrencia de eventos adversos serios.

El CEI no actúa como verificador por lo que el investigador principal, patrocinador u organización de investigación clínica, deben comprometerse a informarle cualquier circunstancia significativa para la protección de los sujetos.

Función educativa

Promueve entre sus integrantes la capacitación en bioética y ética en investigación de forma permanente. Es importante que el CEI establezca estrategias educativas para el personal del establecimiento de salud sede y los posibles sujetos en la investigación.

Derivado de las funciones anteriormente descritas, comprende las siguientes actividades:

- Elaborar lineamientos y guías éticas institucionales en materia de investigación para la salud, apegadas a las disposiciones normativas vigentes.
- Realizar el seguimiento a las recomendaciones de carácter ético que correspondan a los protocolos de investigación en seres humanos y apoyar a los investigadores para la óptima realización ética de sus protocolos.
- Coadyuvar en la aplicación de la Ley General de Salud y su Reglamento en Materia de Investigación para la Salud, así como las demás disposiciones aplicables en materia de investigación en salud.
- Establecer mecanismos de colaboración con otros CEI, para la evaluación conjunta de protocolos de investigación cuando así se amerite.
- Elaborar los informes de acuerdo a la normatividad y lineamientos establecidos y proporcionarla a las instancias que proceda.
- Participar en el Comité Interno de Trasplantes, como lo indica el Reglamento de la Ley General de Salud en Materia de Trasplantes en su artículo 32, fracción VI.[46]

Integración

Los establecimientos para la atención médica o instituciones de salud en donde se realice investigación en seres humanos, deberán conformar un CEI, el cual se encargará de la revisión de los aspectos éticos de los protocolos de investigación y en caso de ser aprobados dar seguimiento a los mismos, observando que en las acciones directamente relacionadas con los participantes en la investigación no se vulneren su integridad, dignidad y derechos.[47] La función del CEI no se limita a la aprobación del protocolo de investigación, ésta debe continuar durante y después de la investigación y asegurar la integridad en la comunicación sobre los resultados.

El CEI deberá integrarse por personal médico, investigadores y profesionales de la salud, psicología, enfermería, trabajo social, sociología, antropología, filosofía y derecho, entre otras. Podrán o no estar adscritos al establecimiento. De preferencia con capacitación en ética en investigación y bioética.

El CEI deberá contar con representantes del núcleo de personas afectado o de personas usuarias de los servicios de salud, hasta el número convenido de sus integrantes, procurando equilibrio de género.

Corresponde a los integrantes, de acuerdo con sus áreas de formación, la precisión de los aspectos teóricos y metodológicos de los protocolos.

El CEI se integrará por:

- Presidente.
- Vocales (mínimo cuatro, de entre los cuales se nombra al secretario).
- Representante del núcleo afectado o de las personas usuarias de los servicios de salud.

El CEI, para el cumplimiento de sus funciones, se auxiliará de un Secretario (uno de los vocales) que será nombrado por el Presidente. Asimismo, se podrán invitar y consultar a especialistas internos o externos, cuya intervención se considere necesaria para la toma de decisiones relacionadas con los asuntos a tratar en las sesiones.

46 *Cfr.* Reglamento de la ley General de Salud en Materia de Trasplantes publicado en DOF 26-03-2014. Disponible en: http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf

47 *Cfr.* Artículos 41 bis y 98 de la Ley General de Salud. Ver en apartado de normatividad.

La participación de los integrantes del CEI, tendrá carácter honorífico. Se recomienda que las autoridades consideren la participación en el Comité para efectos de valoración del mérito al interior de sus establecimientos.

En el caso de los Comités de reciente creación y/o cuando dentro de la institución, no se logre reunir a las personas adecuadas, el Titular del establecimiento junto con el Presidente del CEI, podrán solicitar apoyo y asesoría de los Comités de Ética institucionales constituidos en el Sistema Nacional de Salud.

Requisitos de los integrantes

En la selección de los integrantes del Comité se deberán considerar las características siguientes:[48]

- Contar con referencias personales y profesionales que hagan constar su conducta ética referencias laborales de trabajo, de la comunidad o de la organización a la que pertenece).
- Documentar su experiencia profesional en el campo de la investigación o ética en investigación.
- Tener alguna formación, capacitación o experiencia en bioética o ética en investigación y buenas prácticas clínicas.
- Adquirir el compromiso de capacitarse continuamente en el conocimiento de la bioética, y la ética en investigación.
- Ser respetuoso, tolerante, abierto al diálogo, flexible, prudente, honesto y de conducta conciliadora.
- No tener conflictos de interés con las funciones encomendadas dentro del CEI.

Selección

El CEI deberá establecer en sus reglas de funcionamiento el proceso por el cual se elegirán a los integrantes y prever una política para la renovación de los nombramientos, determinar el procedimiento de renuncia y su sustitución escalonada.

Para poder cumplir con las responsabilidades, deberán tener la experiencia y conocimientos en el campo de las investigaciones que revisa y existir un balance de integrantes con conocimientos científicos, metodológicos, filosóficos, bioéticos y legales; considerarán la perspectiva de los usuarios de los servicios de salud.

El Presidente del CEI no podrá presidir el Comité de Investigación ni el de bioseguridad. Es importante que los integrantes puedan expresar sus puntos de vista al considerar los aspectos éticos involucrados en las investigaciones que revisan, por lo que ningún integrante deberá pertenecer al cuerpo directivo de la institución.

El CEI puede establecer una lista de consultores externos que aporten experiencia en algunos protocolos de investigación para evaluarlos. Los consultores pueden ser especialistas en aspectos éticos o legales, enfermedades o metodologías específicas y podrán participar en las sesiones o enviar sus comentarios, pero no pueden participar en la deliberación.

48 Con excepción del representante de los usuarios de servicios de salud.

Los representantes del núcleo afectado o los usuarios de los servicios de salud serán propuestos por el Presidente o Vocal Secretario, a consideración de los demás integrantes del CEI. Se deberá asegurar que no existan conflictos de interés en la revisión de los protocolos. En temas sensibles para un grupo específico (adicciones, VIH o violencia familiar) deberá asegurarse que el representante del núcleo afectado o usuario no pueda identificar a los sujetos de investigación.

Es requisito fundamental para el funcionamiento del CEI que los integrantes del Comité deliberen libres de conflictos de interés, con respecto a los investigadores y patrocinadores. Los mecanismos para asegurar esta independencia deben estar establecidos en los lineamientos de operación.
El reconocimiento como autoridad del Comité se adquiere a través de su trabajo. Es importante demostrar la imparcialidad, transparencia y capacidad de fomentar el diálogo con los demás actores involucrados en la investigación biomédica.

Designación

El mecanismo para la designación de los integrantes del CEI debe ser transparente y libre de influencias que puedan comprometer su independencia. En el caso de reciente creación, el titular de la institución o del establecimiento deberá nombrar al Presidente, quien tendrá la facultad de proponer al Titular de la institución al resto de los integrantes. El Secretario será nombrado por el presidente de entre los Vocales y tendrá como función principal auxiliar al CEI en el cumplimiento de sus funciones, el período de gestión será de tres años. Al término de la primera gestión, los integrantes propondrán una terna al Titular de la institución a fin de designar a la persona para el cargo de Presidente, así como la renovación de los integrantes restantes, procurando la sustitución escalonada, por una sola ocasión.

La constancia de designación debe ser expedida por el titular de la institución o del establecimiento a cada uno de los integrantes del CEI y deberá contener al menos los requisitos siguientes:

- Nombre completo de la persona designada.
- Duración del nombramiento.
- Cláusula de confidencialidad con relación a las solicitudes, información del investigador y de los sujetos de investigación que se someten a consideración del CEI, así como de las reuniones en las que se delibera sobre los protocolos.
- El señalamiento expreso de que la incorporación al CEI será con carácter honorífico.
- Declaración firmada de no conflicto de interés.[49]

La capacitación es un requisito para los integrantes del Comité, debe incluir temas básicos como: introducción a la bioética, ética en investigación, aspectos regulatorios nacionales, principales normativas internacionales y el conocimiento de la Guía de CEI. Es importante establecer un programa de capacitación en bioética/ética en investigación y buenas prácticas clínicas, así como mantenerse actualizado en la normatividad nacional.

49 El integrante del Comité que participe directamente o indirectamente en una investigación, se deberá excusar de su asistencia y participación en la sesión correspondiente.

El expediente de cada uno de los integrantes del CEI, deberá establecer en un documento firmado que contenga:

- El compromiso de velar por el interés de los participantes de la investigación, de confidencialidad, resguardo y uso de la información, así como la aceptación y cumplimiento de los objetivos y funciones del CEI y de abstenerse de revisar cualquier protocolo en el que participe, independientemente del rol que desempeñe;
- Constancia de capacitación.

Los consultores externos y los representantes del núcleo afectado o de las personas usuarias de los servicios de salud, también deberán firmar cláusula de confidencialidad y declaración de no conflicto de interés.

Funciones de los integrantes

Presidente

- Coordinar las actividades del CEI, así como convocar, organizar y presidir las sesiones conforme a los criterios establecidos en los lineamientos del CEI.
- Instrumentar mecanismos de prevención y detección de conflictos de interés dentro del CEI.
- Realizar el proceso de asignación y renovación de los integrantes conforme al reglamento interno del CEI.
- Fomentar las actividades de capacitación continua interna y externa del CEI que incluya la población del área de influencia.
- Notificar y firmar los dictámenes y resoluciones emitidas por el CEI a las instancias que correspondan.
- Emitir la información de las actividades para proporcionarla a las instancias que tengan facultades legales y administrativas para requerirla.
- Llevar a cabo todas aquellas funciones, afines a las señaladas.
- Deberán asistir al menos al 80% de las sesiones, de manera presencial.

Vocal Secretario

- Convocar a los vocales, a petición expresa del presidente, a las reuniones del CEI.
- Elaborar y proporcionar las agendas de trabajo de las reuniones y remitir a los integrantes del CEI la documentación necesaria, de conformidad a lo establecido en los lineamientos de operación, a excepción de las sesiones expeditas.
- Coordinar la elaboración de los documentos e instrumentos normativos y de operación para la integración y desarrollo de actividades del CEI.
- Elaborar el acta de las sesiones, recabando la firma de los participantes para su formalización y distribución donde proceda.
- Recibir los asuntos que se propongan para ser tratados en las sesiones del CEI y revisar que la información sea adecuada y suficiente para incluirlas en las agendas de trabajo.
- Integrar el programa anual de actividades que incluya acciones consultivas, capacitación y seguimiento solicitando las aportaciones de los integrantes del CEI.
- Colaborar en actividades de formación, actualización en bioética y difusión entre el personal de la institución o del establecimiento.
- Asegurar que la documentación de las decisiones tomadas durante las sesiones se encuentre disponible para revisión en caso necesario.
- Elaborar los informes de evaluaciones y dictámenes solicitados al CEI para emitirlos con oportunidad a quienes proceda.

- Integrar y remitir a las instancias que proceda los dictámenes y resoluciones emitidos por el CEI en tiempo y forma.
- Establecer los mecanismos de información al presidente y a los integrantes, de las comunicaciones recibidas en el CEI.
- Efectuar el registro de las asignaciones, donaciones y valores destinados al CEI.
- Mantener actualizados los archivos del CEI, mediante el registro de actividades y evidencia documental.
- Desempeñar cualquier otra función que le sea asignada por el presidente relacionado con el CEI.
- Deberán asistir al menos al 80% de las sesiones, de manera presencial.

Vocales

- Revisar sistemáticamente los protocolos de investigación o cualquier otra información o documento que les sean asignados por el Presidente para dar cumplimiento a las funciones y objetivos del CEI.
- Participar en las reuniones para el análisis, evaluación y dictamen de los protocolos de investigación, para la emisión de resoluciones consensadas por el Comité.
- Dar seguimiento a los acuerdos tomados e identificar temas que pudieran ser motivo de deliberación por parte del CEI.
- Colaborar en la selección y renovación de los integrantes del Comité, mediante la revisión del cumplimiento de los requisitos para su designación.
- Colaborar en actividades de formación, actualización en bioética y otras acciones del CEI con el personal y la población del área de influencia del establecimiento.
- Desempeñar cualquier otra función, relacionada con el Comité, que le asigne el Presidente.
- Deberán asistir al menos al 80% de las sesiones, de manera presencial.

Representantes del núcleo afectado o los usuarios de los servicios de salud

- Asegurar que el formato de consentimiento informado sea lo suficientemente explícito para ser comprendido por los posibles participantes en la investigación.
- No forman parte de la vocalía.

Consultores externos

- Asesorar al CEI en aspectos específicos en la revisión de un protocolo y que a su juicio los comentarios pudieran enriquecer la discusión y la protección de los sujetos participantes. Puede participar personalmente en las sesiones o enviando sus comentarios técnicos.
- Participar con probidad y sin tener conflictos de interés en las sesiones a las que sea expresamente convocado.

Competencias de los integrantes del Comité de Ética en Investigación

Los integrantes de los CEI requieren una capacitación inicial y educación continua en bioética, ética en investigación y aspectos relevantes para esta tarea, también deberán ser capaces de evaluar:

La protección a los sujetos de investigación

- Entender los principios fundamentales para la protección de los participantes en investigaciones.
- Identificar los riesgos y beneficios de los protocolos y asegurar el balance de estos.
- Reconocer las investigaciones cuyo riesgo es inaceptable.
- Evaluar el formato de consentimiento informado y asegurar que la participación es voluntaria, y la capacidad ha sido evaluada, que no existe coerción o influencia indebida y que se describen los riesgos y beneficios.

- Informar sobre otras opciones de tratamiento, especificar que se trata de un estudio de investigación y establecer las medidas a tomar en caso de daño derivado de la investigación.
- Vigilar la aplicación de lo estipulado en leyes, reglamentos, y disposiciones mexicanas y asegurar que la investigación cumpla con los estándares éticos internacionales.
- Cerciorarse que los procedimientos propuestos en el protocolo para el reclutamiento de los participantes sea justo.
- Evaluar aspectos relevantes que surgen en la investigación de grupos vulnerables.
- Aplicar lo establecido en la presente Guía, así como los procedimientos y reglamento del CEI en el que participa.
- Asegurar la privacidad y confidencialidad de los datos personales contenidos en los documentos revisados.

Diseño y análisis del estudio

- Asegurar que el protocolo sea revisado y dictaminado por el Comité de Investigación (en el manual de procedimientos deberá especificarse si ambos comités sesionan conjuntamente).
- Analizar los mecanismos de monitorización de riesgo y notificación de eventos adversos.

Investigación en comunidades

- Conocer las características de la comunidad objeto del estudio, tomando en cuenta las diferentes implicaciones sociales y culturales de la investigación, para garantizar la protección de los participantes y de sus datos personales

Comunicación de los resultados de investigación

- Velar que la autoría y derechos intelectuales de los participantes se respeten, de acuerdo con los estándares establecidos.

Conflictos de interés

- Reconocer la existencia de conflictos de interés financiero o de otra índole.
- Reconocer posibles conflictos de interés, resultado de la interacción entre el investigador o la institución con patrocinadores.
- Reconocer, investigar y denunciar la conducta indebida, incluyendo la falsificación de resultados y plagio.
- Definir las políticas en el manejo de conflictos de interés.

Competencias y responsabilidades del investigador

- La investigación deberá ser realizada por expertos y profesionales de la salud, bajo la responsabilidad de una institución de atención a la salud,[50] que actúe bajo la supervisión de las autoridades sanitarias competentes y que cuente con los recursos humanos y materiales necesarios, que garanticen el bienestar del sujeto de investigación.[51]
- El investigador deberá conocer los aspectos relevantes de la ética en investigación.
- El investigador será directamente responsable de los aspectos científicos y éticos del estudio y de someter al Comité la solicitud de revisión.

50 *Cfr.* Artículo 114 del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud. Última Reforma DOF 02-04-2014.

51 *En el caso de la investigación médica en seres humanos, esta debe ser llevada a cabo sólo por personas con la educación, formación y calificaciones científicas y éticas apropiadas. La investigación en pacientes o voluntarios sanos necesita la supervisión de un médico u otro profesional de la salud competente y calificad apropiadamente.* Declaración de Helsinki 2013.

- Para que el CEI pueda realizar una revisión completa, el protocolo deberá contener toda la información pertinente, incluyendo posibles conflictos de interés.
- Debe conducir la investigación de acuerdo con lo establecido en el protocolo aprobado por el Comité. Cualquier enmienda o desviación del protocolo deberá ser informada al CEI. Las enmiendas que modifiquen sustancialmente el protocolo o le confieran un riesgo adicional o distinto a los sujetos de investigación deberán ser aprobadas por el Comité. Es responsabilidad del investigador tomar medidas en situaciones que requieran una acción inmediata para evitar daños innecesarios.

Instalación

El CEI deberá instalarse bajo la responsabilidad del titular de la institución o del establecimiento de salud, de conformidad con lo dispuesto en la Ley General de Salud, haciendo constar dicho acto formal en el acta de instalación. La información correspondiente se encuentra disponible en el portal web de la Comisión Nacional: http://www.conbioetica- mexico.salud.gob.mx/interior/registrocomites/Dictamen_CEI2.html

El acta de instalación especificará los requisitos siguientes:

- Denominación o razón social del establecimiento.
- Domicilio de la institución o del establecimiento al que pertenece el CEI.
- Nombre, profesión y cargo que ocupan los integrantes del CEI.
- Fundamento jurídico que contenga las facultades del titular para la constitución del CEI.
- Manifestación del titular de la institución o del establecimiento en la que conste que bajo su responsabilidad se constituye el CEI.
- Firma autógrafa del titular responsable de la institución o del establecimiento.
- Lugar, fecha y hora de instalación.

El CEI deberá contar con un reglamento, lineamientos o manuales de operación en el que se establecerán los procedimientos para las funciones que llevará a cabo, mismos que deben estar disponibles para su revisión a solicitud de los interesados.

Operatividad

Los CEI en el desarrollo de sus actividades deberán respetar y dar cumplimiento a los principios bioéticos y jurídicos previstos en la normatividad vigente. Tal compromiso se refleja en los diversos informes de actividades presentados ante las autoridades sanitarias correspondientes, mismas que pueden ser supervisados por la instancia competente.

Financiamiento de operación

Los gastos de operación del CEI deben estar previstos en la estructura programática de los establecimientos, de acuerdo con los lineamientos internos aplicables. El establecimiento podrá recibir apoyos de fuentes externas por evaluar protocolos. Dichos apoyos no deberán ser otorgados directamente a ninguno de los integrantes del CEI; las aportaciones no deberán traducirse en conflicto de interés entre la fuente de financiamiento y las funciones del CEI. Asimismo, las evaluaciones del Comité no deben significar ganancias financieras para éste.

Los apoyos al CEI no deberán ser utilizados en otros fines que no sean para su funcionamiento y deberán ser manejados con total transparencia. Es importante que los integrantes reciban apoyo por parte de las autoridades del establecimiento en los aspectos siguientes:

- Tiempo para su participación en las sesiones del CEI.
- Reconocimientos académicos o laborales por su desempeño en el CEI.
- Apoyo para la capacitación de bioética y ética en investigación dentro y fuera de la institución.
- Espacio físico para la sede del CEI, tanto para sesionar, como para la recepción de documentos y resguardo de la documentación de los protocolos, los dictámenes y las minutas.
- Ayuda administrativa para la actividad del CEI, toda vez que se requiere un registro formal de consultas hechas al CEI.

Sesiones

El CEI deberá sesionar en forma ordinaria al menos una vez cada dos meses, y en forma extraordinaria en cualquier momento a solicitud de su presidente o de la mayoría de sus integrantes (Anexo 1). Se deberá considerar en aquellas instituciones en las que exista gran actividad en investigación la posibilidad de sesionar con mayor frecuencia.

- **Sesiones ordinarias:** se establecen a través del programa anual de trabajo, determinando fechas, horarios de sesiones y términos de la convocatoria.
- **Sesiones extraordinarias:** se llevan a cabo a petición expresa y en función de situaciones relacionadas con el quehacer del CEI, los investigadores, los participantes o la institución. Se realizan por convocatoria del Presidente.
- **Sesiones expeditas:** se llevan a cabo para resolver cambios administrativos, registro de nuevos investigadores, cambios de fecha, etcétera.

El CEI podrá sesionar de manera conjunta con el Comité de Investigación para la valoración integral de los protocolos. En la evaluación de estudios multicéntricos, el Comité podrá sesionar de forma conjunta con CEI de otros establecimientos del país para la valoración y dictamen único de estos protocolos, respetando la normatividad de cada una de las instituciones participantes.

Toma de decisiones

Las decisiones deben basarse en un proceso de discusión y deliberación incluyente. Durante las reuniones se iniciará una discusión sobre la documentación sometida para consideración del CEI. La reunión se llevará a cabo en un ambiente de respeto permitiendo que los distintos puntos de vista puedan ser expresados.

Se sugiere que el Presidente del CEI estimule la participación de todos los integrantes, asegurándose que se dispone del tiempo suficiente para la deliberación. Solamente los presentes durante la deliberación podrán emitir opiniones para la toma de decisiones sobre el estudio. El Presidente es responsable del proceso y de determinar, cuando sea necesario, el consenso para la toma de decisiones. Los investigadores, patrocinadores y otras personas directamente involucradas en el estudio no deberán estar presentes durante la deliberación.

Las decisiones por consenso implican que ninguno de los integrantes deberá considerar esta decisión inaceptable. Los integrantes del CEI deben estar conscientes de sus limitaciones relacionadas con temas específicos y buscar asesoría externa cuando sea necesaria. Nunca se tomarán decisiones por votación.

Las resoluciones deberán contener argumentos sólidos y fundamentados. En caso de que la decisión esté condicionada, el CEI deberá brindar sugerencias claras para la nueva revisión del protocolo. Las decisiones negativas deberán fundamentarse en argumentos claros y específicos, enunciando el procedimiento para someter a revisión nuevamente la solicitud.

Procedimientos de revisión de protocolos

La bioética no recomienda un conjunto específico de reglas o políticas, sino que proporciona una estructura para evaluar problemas y determinar los cursos de acción apropiados.

- Los protocolos sometidos a revisión por el CEI, deberán cumplir con los criterios establecidos.[52]
- Los CEI deberán estar familiarizados con las diferentes metodologías y hacer las consideraciones éticas aplicables para cada tipo de investigación propuesta.
- El análisis ético de las investigaciones deberá reflejar lo estipulado en la legislación nacional, la normativa internacional, los valores culturales y los instrumentos de derechos humanos.
- Deben basar sus decisiones en una metodología coherente y consistente.
- Sus decisiones deberán ser transparentes y señalar los fundamentos en los que se basa su decisión.

A continuación se enlistan los aspectos que los CEI deben considerar como mínimo al evaluar un protocolo:[53]

- **Valor científico**

  Para ser ética, la investigación en seres humanos debe tener valor científico o social, y en consecuencia, ayudar a mejorar la salud o bienestar de la población, probar una hipótesis que pueda generar información importante acerca de la estructura o la función de los sistemas biológicos humanos, aun cuando tal información no tenga aplicaciones prácticas inmediatas.

  Algunos ejemplos de investigación clínica sin valor científico ni social incluyen la investigación que duplica parcial o totalmente resultados comprobados, no generalizables, una hipótesis banal o una en la que la intervención no puede llevarse a cabo en forma práctica aun cuando sea eficaz. El valor social es un requisito ético que asegura el uso responsable de recursos limitados y evita la explotación.

- **Pertinencia científica en el diseño y conducción del estudio**

  Todo proceso de investigación se inicia con la selección de una pregunta, seguida del diseño apropiado para responder a ésta, el desarrollo de un protocolo, la implementación del estudio, la recolección de datos, el análisis de los resultados y la publicación de los mismos. Las consideraciones éticas son parte integral de la investigación a lo largo de la misma. Si bien la responsabilidad fundamental de los CEI es la revisión de los aspectos éticos de las investigaciones en las que participan seres humanos, debe evaluar si la investigación carece de la pertinencia y rigor científico que pudiera causar un daño o riesgos mayores a los participantes y por lo tanto no sea ética, la pertinencia científica es una exigencia no negociable.

52 *Cfr.* Norma Oficial Mexicana NOM-012-SSA3-2012.
53 Emanuel, E. J., Wendler, D. & Grady, C. (2000) What Makes Clinical Research Ethical? Chicago: American Medical Association. Disponible en: http://jama.jamanetwork.com/article.aspx?articleid=192740

- **Selección de los participantes**
  La identificación y selección de los posibles sujetos de investigación debe ser equitativa, requiere que sea la ciencia y no la vulnerabilidad, el estigma social, la impotencia o factores no relacionados con la finalidad de la investigación, la que determine a los posibles participantes. La selección equitativa requiere que a todos los grupos se les ofrezca la oportunidad de participar en la investigación a menos que existan buenas razones científicas o de riesgo que restrinjan su elegibilidad.

- **Proporcionalidad en los riesgos y beneficios**
  El riesgo se define como la combinación de la probabilidad de que se produzca un evento con consecuencias negativas. En la investigación el grado de riesgo y beneficio es incierto y en el caso de la investigación en seres humanos solamente puede justificarse cuando: 1. Los riesgos potenciales se minimizan; 2. Los posibles beneficios para los participantes de manera individual o para la sociedad se maximizan; y 3. Los posibles beneficios son proporcionales o exceden a los riesgos anticipados.[54]

  Desde la perspectiva principialista la búsqueda del mayor beneficio y el menor riesgo atiende los principios de beneficencia y no maleficencia. En la investigación clínica, esto se traduce en la necesidad de maximizar los beneficios de la investigación tanto para el sujeto individual como para la sociedad. Se requiere tener la seguridad de que los beneficios exceden los riesgos para evitar la explotación de las personas.[55]

- **Evaluación independiente**
  Los posibles conflictos de interés para la autorización de un protocolo se reducen al mínimo cuando la evaluación es independiente, haciendo que la investigación clínica sea revisada por expertos que no estén involucrados en el estudio y que tengan autoridad para aprobar, condicionar o, en casos extremos, cancelar la investigación.

- **Respeto a los participantes**
  Es importante proteger la privacidad de los participantes de la investigación, ofrecer la posibilidad de retirarse del estudio y asegurar que están siendo evaluados de manera continua durante el estudio.

- **Consentimiento informado**
  El consentimiento informado es un proceso mediante el cual un individuo, después de recibir la información necesaria, toma la decisión voluntaria de participar, o no, en un estudio de investigación. El consentimiento informado se registra por medio de un documento, firmado y fechado. Consta de dos partes, la primera en la que se proporciona información sobre la investigación que se propone y la segunda que es el acto formal en el cual el sujeto de investigación con su firma acepta participar en la investigación:

54 *Cfr.* Artículo 15 del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud. Última Reforma DOF 02-04-2014.

55 *Cfr.* Artículo 70 del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud señala: Los estudios de farmacología clínica fase I, de medicamentos nuevos antineoplásicos y de otros con índice terapéuticos muy reducido, serán permitidos cuando: I. Estén fundamentados en estudios preclínicos que demuestren la actividad farmacológica del medicamento e indiquen con claridad las características de su toxicidad; II. Se realicen solamente en sujetos voluntarios con la enfermedad específica avanzada, confirmada por medios de diagnóstico adicionales, que no hayan presentado respuesta terapéutica a ningún otro tratamiento disponible y en quienes el medicamento nuevo pudiera ofrecer un beneficio terapéutico, y III. No ocasionen gastos al paciente.

a. Información

El documento escrito será la base o la guía para la explicación verbal y la discusión del estudio al sujeto o su representante legal. Quedará consignado por escrito cualquier otro documento que sea utilizado durante la investigación. Debe incluirse un apartado en el que se estipule que los fármacos, productos y procedimientos relacionados con el estudio serán gratuitos, así como el registro de los responsables de su financiamiento.

b. Consentimiento

Es el proceso que da validez ética y legal a la intervención o la investigación médica, su finalidad es facilitar la toma de decisiones a través de la comunicación y el dialogo, con respeto a la autonomía del sujeto. Un aspecto importante a considerar es la capacidad de tomar decisiones, esto es, la habilidad de comprender la información y entender las consecuencias de su decisión. Se considera que todos los adultos son capaces, a menos que exista evidencia de lo contrario. En el caso de menores e individuos incapaces el consentimiento es proporcionado por el tutor o representante legal y, en su caso, los niños mayores de 7 años proporcionarán su asentimiento.[56] (Ver anexo 5).

Resultados y dictámenes de las evaluaciones de protocolos

Aprobado

Cumple con todos los requisitos establecidos.

Pendiente de aprobación

a. Requiere modificaciones mayores y deberá ser evaluado por el CEI, en pleno, cuando se realicen dichas modificaciones;

b. Requiere modificaciones menores y podrá ser evaluado de manera expedita, conforme a lo asentado en el capítulo correspondiente;

c. Condicionado o en proceso de valoración. Se requiere mayor información o surgieron dudas durante el proceso de revisión del protocolo.

No aprobado

Protocolo rechazado por razones éticas que ameritan una restructuración mayor.

Comunicación del resultado de la revisión del protocolo

Las decisiones deberán ser notificadas por escrito al solicitante en el lapso indicado en el reglamento interno del CEI, se sugiere sea enviada en un lapso no mayor a cinco días hábiles después de haberse reunido. Las aprobaciones tienen vigencia de un año.[57] En los Anexo 5 se presentan algunas recomendaciones para la comunicación de la decisión, particularmente en el caso de ensayos clínicos que deben ser autorizados por la Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS).

56 *Cfr.* Artículo Art 20, 21, 22 Fracción V Reglamento de la Ley General de Salud en Materia de Investigación para la Salud. Última Reforma DOF 02-04-2014.

57 En investigaciones con riesgo elevado, estudios Fase 0 o Fase I, el CEI podrá determinar una vigencia menor.

Las decisiones tomadas por el Comité sólo serán válidas cuando exista el *quórum* establecido, de cuando menos el cincuenta por ciento de los integrantes más uno. Asimismo, al recibir el documento de dictamen, el investigador entregará al CEI una carta compromiso con fecha y firma que deberá contener por lo menos los siguientes apartados:

- Mecanismo para la entrega de reporte(s) de los avances o en su caso, la terminación o cancelación del protocolo.
- Mecanismo para notificar al CEI, si hubiese enmiendas al protocolo (no las enmiendas que involucren sólo aspectos logísticos o administrativos del estudio).
- Mecanismo para notificar al CEI, en el caso de enmiendas del material de reclutamiento y la información para los potenciales participantes en la investigación o al formato de consentimiento informado.
- Mecanismo para reportar eventos adversos serios e inesperados relacionados con la conducción del estudio o circunstancias imprevistas.

Uso de medicamentos no aprobados en situaciones de urgencia y emergencia

El CEI será informado de manera anticipada del empleo del medicamento de investigación, si el investigador anticipa la necesidad de su uso en situaciones de urgencia. Posteriormente, si el uso del medicamento, indicación, dosis o vías de administración nuevas, surgieran como necesidades no previstas, el CEI emitirá el dictamen en favor o en contra de aprobar el uso planeado o la repetición del uso no previsto del medicamento.[58]

En el marco de una emergencia sanitaria, se podrá modificar el proceso de aprobación de un medicamento, reduciendo el número de fases del ensayo clínico, con la intervención de la autoridad sanitaria correspondiente.

Seguimiento de protocolos

El CEI debe establecer procedimientos para el seguimiento de los estudios que aprobó, desde el momento en que la decisión fue tomada, hasta la culminación de la investigación y el reporte de los resultados. En el procedimiento de seguimiento debe tomarse en consideración lo siguiente:

1. Responsabilidades del CEI durante el seguimiento:[59]
   a. El intervalo en el seguimiento de los protocolos será determinado por el CEI y debe llevarse a cabo al menos una vez al año. El Comité informará al investigador principal la renovación o cualquier otra decisión que surgiera como resultado de la revisión del estudio, relacionada con la protección de los participantes.
2. Responsabilidades del investigador:
   a. Comunicar al CEI:
      - Cualquier enmienda del protocolo que eventualmente pudiera afectar los derechos, la seguridad o el bienestar de los participantes en la investigación.
      - Cualquier situación o nuevo conocimiento que mostrara un mayor riesgo para los participantes.
      - La terminación o suspensión prematura del estudio, las razones y los resultados obtenidos.
      - Al completar el estudio.
   b. Enviar resumen final de los resultados del estudio e informar sobre la publicación del mismo.

58 *Cfr.* Artículo 71, Fracción V Reglamento de la Ley General de Salud en Materia de Investigación para la Salud. Última Reforma DOF 02-04-2014

59 Los requisitos de quórum, el procedimiento de revisión y el procedimiento de comunicación para revisiones de seguimiento, no difieren de los requisitos para la evaluación inicial.

Eventos adversos

Una vez aprobada la investigación, el investigador debe informar al CEI de todo Evento Adverso (EA), es decir, cualquier signo, síntoma o enfermedad asociado con el uso de un producto medicinal, independientemente de que pudiera estar relacionado con el medicamento.[60]

A menos que se haya definido un marco temporal distinto cuando se aprobó el estudio, el investigador principal deberá informar al Comité de todo EA. Asimismo, deberá informarle, con la periodicidad establecida en los manuales de operación, sobre la ausencia de Eventos Adversos en los proyectos o protocolos de investigación que estén bajo su responsabilidad. En caso de reportar un EA, el CEI revisará el mismo y el Presidente decidirá si es necesario tomar acciones para minimizar el riesgo potencial a los sujetos.

Eventos adversos serios

Los eventos adversos serios (EAS) se definen como cualquier evento médico, asociado con el uso de un producto medicinal, independientemente de que pudiera estar relacionado con el medicamento que resulte en la muerte del individuo o ponga en peligro su vida.[61]

Cuando el EAS ocurre en el establecimiento en el que el CEI aprobó el protocolo, el investigador deberá informar al Comité en un periodo no mayor a 7 días (o de acuerdo a lo establecido en el manual de procedimientos).[62] El investigador deberá informar al patrocinador en los términos establecidos en el manual del investigador y a la autoridad sanitaria en un periodo no mayor a 15 días naturales.[63] El mecanismo de reporte puede realizarse por medios electrónicos o por vía telefónica.[64] Es confidencialidad del CEI asegurar la protección de los participantes en la investigación y, por tanto, debe evaluar la necesidad de suspender transitoriamente un estudio o de que los participantes vuelvan a dar su consentimiento con la nueva información.[65]

Consideraciones sobre la recolección de material biológico

El material biológico humano incluye todo tipo de muestras, desde las estructuras subcelulares como el ADN hasta células, tejidos (sanguíneos, musculares, óseos, conectivos, cutáneos, entre otros), órganos y residuos biológicos. Su uso y asociación con datos personales es cada vez más frecuente e importante en las investigaciones biomédicas. La recolección de estos materiales y la posibilidad de obtener, a través de éstos, informaciones genéticas representa un reto desde el punto de vista ético, jurídico y social. Es por esto que la población debe tener la confianza de que el material será manejado con confidencialidad.[66]

60 *Cfr.* European Medicines Agency (1995). Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. London: European Medicines Agency. Disponible en: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002749.pdf

61 *Cfr.* ICH. Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. Switzerland: ICH. Disponible en: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002749.pdf

62 *Cfr.* Code of Federal Regulations, Title 21, Part 312 Section 32 (U.S. Government Printing Office, Washington, D.C.).

63 *Cfr.* Guías, lineamientos y requerimientos de farmacovigilancia. Guía de Farmacovigilancia en Investigación Clínica.

64 *Cfr.* ICH. Harmonised Tripartite Guideline, Guideline for Good Clinical Practice. & ICH Harmonised Tripartite Guideline, Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

65 *Cfr.* Artículo 68, Fracciones I y III del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud. Ultima reforma DOF 02-04-2014

66 *Cfr.* Steering Committee on Bioethics/ Council of Europe (2012) Guide for Research Ethics Committee Members. Strasbourg: Council of Europe.

Desde la perspectiva ética, es importante considerar los siguientes aspectos:

- El consentimiento informado relacionado con el uso y almacenamiento del material biológico, debe dejar claro que no será utilizado para un fin diferente al planteado de manera inicial, a menos que se garantice la privacidad del donador y el CEI apruebe el protocolo.
- Deberá informar que el investigador no podrá comercializar las muestras.
- No ejercerá influencia indebida a través de estímulos económicas a los donadores de tejidos.
- La recolección de material genético deberá ser evaluada y en su caso aprobada por el CEI.

El consentimiento en el que el donador proporciona el tejido debe abordar algunos de los siguientes puntos:

- Tipo y cantidad de tejido que se solicita.
- La forma en que éste se obtendrá (señalar los riesgos, si el procedimiento es invasivo, si se realizará con ese sólo propósito o durante un procedimiento diagnóstico o terapéutico).
- Las estrategias para proteger la confidencialidad conforme a Ley.
- Tiempo que será almacenado y cómo se preservará.
- Los planes para comunicar al donador alguna información relevante.
- Permiso para otros usos.

Consideraciones relevantes en la recolección de tejidos:

- La recolección y transferencia de material biológico no debe, bajo ninguna circunstancia, poner en riesgo el cuidado médico y la seguridad del sujeto de investigación.
- El CEI enviará al departamento legal, para su revisión y aprobación, cualquier propuesta que implique una transferencia monetaria o algún tipo de remuneración, relacionada con el uso de material biológico.
- Es necesario el consentimiento informado específico para recolectar tejidos o realizar pruebas genéticas, en ningún caso la autorización deberá estar contenida en el mismo formato que la propia autorización para participar en un ensayo clínico.
- Cuando se recolecten datos genéticos humanos, datos proteómicos humanos o muestras biológicas con fines de investigación médica y científica, la persona de que se trate podrá revocar su consentimiento, a menos que esos datos estén irreversiblemente disociados de una persona identificable.
- Ante la revocación del consentimiento, deben dejar de utilizarse los datos genéticos, datos proteómicos y muestras biológicas, a menos que estén irreversiblemente asociados a la persona. Los datos y las muestras biológicas que no estén irreversiblemente asociados deberán tratarse conforme a los deseos del interesado.[67]
- El CEI debe exigir límites de tiempo para el uso del material y prohibir el uso irrestricto del material.

Consideraciones éticas en estudios epidemiológicos

Las principales preocupaciones éticas en los estudios epidemiológicos son la protección de la privacidad y la confidencialidad de los participantes. En los estudios que involucran la revisión de expedientes en los que los individuos no sean contactados, el CEI deberá asegurarse que la privacidad de los individuos estará protegida. En los casos en los que se establezca contacto con individuos o familiares, el CEI estará obligado a tomar las consideraciones necesarias. Un aspecto a considerar es el Consentimiento Informado en estudios retrospectivos y de muestras almacenadas.[35]

35 Council for International Organizations of Medical Sciences (2008) International Ethical Guidelines for Epidemiological Studies. Operational Guidelines for Ethics Committees that Review Biomedical Research Geneve: Council for International Organizations of Medical Sciences. Disponible en http://www.ufrgs.br/bioetica/cioms2008.pdf

67 *Cfr.* Declaración Internacional sobre los Datos Genéticos Humanos.
Disponible en: http://portal.unesco.org/es/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

Desempeño del Comité de Ética en Investigación

Existe cada vez mayor interés de asegurar que los CEI cumplen con su mandato para la revisión y seguimiento de protocolos, de acuerdo con estándares éticos que aseguren la protección de los participantes en las investigaciones. En este sentido, la CONBIOÉTICA impulsa con esta Guía el desarrollo de procedimientos estandarizados que promuevan la aplicación consistente de los principios éticos y así cada CEI pueda asegurar y comprobar la calidad en la revisión y el seguimiento de las investigaciones en las que participan seres humanos.

Es necesario que el CEI informe a la Comisión anualmente sobre su trabajo. El informe debe incluir el número de sesiones ordinarias, extraordinarias y expeditas realizadas, número de protocolos revisados, aprobados, rechazados, el seguimiento y cualquier otra información pertinente, que la Comisión considere en el formato que al efecto establezca. Estos informes no deberán contener datos confidenciales de la investigación o de sus participantes.

La CONBIOÉTICA realizará visitas aleatorias a los CEI con registro, para asegurar:

- El apego a la Guía Nacional para la integración y funcionamiento de los CEI,
- El seguimiento de los procedimientos establecidos en cada CEI,
- Que la conformación del CEI sea concordante con el tipo de investigación y el número de protocolos revisados y su seguimiento,
- Las comunicaciones con los investigadores,
- Las prácticas apropiadas en el archivo de la documentación.

El vínculo entre la CONBIOÉTICA y la Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS), busca asegurar que la investigación en seres humanos se lleve a cabo con estándares éticos y científicos. En aquellos casos en los que exista algún cuestionamiento sobre la protección de los participantes en las investigaciones por métodos inadecuados en la revisión de protocolos o falta de seguimiento, la COFEPRIS realizará una visita al CEI y la Comisión podrá suspender temporal o definitivamente el registro del CEI en cumplimiento a la resolución emitida por la autoridad competente. Toda información deberá estar fundamentada y los procedimientos deberán ser trasparentes.

Conflictos de interés[4]

El Instituto de Medicina de los Estados Unidos definió al conflicto de interés como las circunstancias que ocasionan el riesgo de que el juicio o las acciones del profesional con respecto de un interés primario estén indebidamente influenciados por un interés secundario.[68] *La Organización de Naciones Unidas, lo define como cualquier circunstancia o situación en la que el juicio profesional o la integridad de las acciones de un individuo o de la institución respecto a un interés primario se ve indebidamente afectado por un interés secundario, los cuales pueden ser financieros o personales, como el reconocimiento profesional, académico, concesiones o privilegios a terceros.*[69]

Para los fines de esta Guía es importante explicitar que en la investigación con seres humanos el interés primario comprende la promoción y protección del bienestar de los sujetos y la integridad de la investigación.

4 *Vid.* Koepsell D., Ruiz de Chávez M. (2015). Ética de la investigación, Integridad científica. CONBIOÉTICA / CONACYT: México. Disponible en formato eBook en: http://www.conbioetica-mexico.salud.gob.mx/

68 *Cfr.* Lo B, Field MJ, eds. Conflict of interest in medical research, education, and practice. National Academies Press, 2009.

69 Organización de Naciones Unidas. Asesoramiento y orientación éticos Conflictos de intereses Disponible en : http://www.un.org/es/ethics/conflictofinterest.shtml

Los CEI registrados ante la CONBIOÉTICA establecerán lineamientos o directrices por escrito para evitar que algún conflicto de interés afecte negativamente la protección de los participantes en investigaciones, la integridad científica y la credibilidad del CEI y de la institución. Para mayor información sírvase consultar el capítulo cuatro del libro *Ética de la Investigación, Integridad Científica.* Durante el seguimiento de los CEI registrados, deberá demostrarse bajo protesta de decir verdad ante la Comisión que cualquier interés económico está separado de la revisión ética del CEI. En el Anexo 6 se presenta un ejemplo de formato para la declaración de conflictos de interés.

Recomendaciones para evitar conflictos de interés:[70]

- Establecer las medidas necesarias para evitar conflictos de interés en la protección de los derechos de los sujetos de investigación.[71]
- Transparentar posibles conflictos de interés de los investigadores e integrantes del CEI.
- Desarrollar material informativo sobre conflictos de interés.
- Considerar los casos en los que el investigador es también el médico tratante.
- Establecer criterios para proporcionar compensaciones para los sujetos, que sean proporcionales a los inconvenientes de la investigación, sin embargo, no debe significar una influencia indebida.

Políticas sobre la interacción del evaluador del CEI con el patrocinador de la investigación y Organizaciones de Investigación por Contrato (CRO, por sus siglas en inglés).

Los integrantes del CEI no deberán comunicarse con el patrocinador del estudio. Todo contacto con el patrocinador se hará a través del investigador principal, a quien solicitará cualquier información adicional.[72] El CEI al igual que en el caso de los patrocinadores, no establecerá comunicación con las CRO.[73]

Registro de los Comités Ética en Iinvestigación

Los establecimientos de atención médica del Sistema Nacional de Salud o las instituciones de salud en donde se realice investigación para la salud en seres humanos deberán solicitar ante la CONBIOÉTICA, a través del director general,[74] titular o representante legal,[75] de acuerdo a la naturaleza jurídica del establecimiento solicitante, el registro del CEI de su establecimiento. La Comisión como órgano desconcentrado de la Secretaría de Salud atenderá la solicitud conforme a lo establecido en el artículo 101 del Reglamento de la Ley General de Salud, en materia de Investigación para la Salud, el Acuerdo por el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los Comités de Ética en Investigación y el Acuerdo por el que se reforma y adiciona el diverso por

70 Los servidores públicos deberán cumplir con lo establecido en la los artículos 7, 8 y 9 de La Ley Federal de Responsabilidades Administrativas de los Servidores Públicos. Disponible en : http://www.sep.gob.mx/work/models/sep1/Resource/fe27ab92-1e15-4cc0-b36b-eb2af344f06/ley_fed_resp_admvas_serv_pub.pdf últimas versión publicada en el D.O.F el Última reforma publicada DOF 14-07-2014

71 *Cfr.* Artículo 63 RLGS en Materia de Investigación para la Salud. Cuando exista patrocinio u otras formas de remuneración, deberán establecerse las medidas necesarias para evitar que éstos originen conflictos de interés al investigador principal en la protección de los derechos de los sujetos de investigación, aunque hayan dado su consentimiento en la preservación de la veracidad de los resultados y en la asignación de los recursos.

72 Shuchman M. Commercializing clinical trials -- risks and benefits of the CRO boom. N Engl J Med 2007;357:1365-1368

73 *Cfr.* Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, Schulman KA. ethical and scientific implications of the globalization of clinical research. New England Journal of Medicine. 2009;360:816–823

74 Es un cargo dentro de un establecimiento que corresponde a la jerarquía más alta en la estructura orgánica de la institución, cuya función principal es coordinar o dirigir. Generalmente las facultades, a favor de los directores, para crear nuevos órganos al interior del establecimiento, como lo son los Comités, están previstas en el Manual de Organización Específico o en un poder para actos de administración.

75 Es la persona que, por virtud de un acto jurídico, actúa a nombre del representado (empresa o establecimiento) para llevar a cabo determinadas acciones.

el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los Comités de Ética en Investigación y se establecen las unidades hospitalarias que deben contar con ellos, de conformidad con los criterios establecidos por la Comisión Nacional de Bioética, publicado el 31 de octubre de 2012. (D.O.F. 11/01/16).

Los establecimientos que podrán contar con el registro del CEI serán aquellos que reúnan los requisitos previstos en la Ley General de Salud y su Reglamento en Materia de Investigación para la Salud, cuya infraestructura deberá garantizar la capacidad técnica, material, humana y financiera, así como las instalaciones, equipo y tecnología para realizar las pruebas, estudios, ensayos, y demás actividades necesarias para llevar a cabo la investigación en seres humanos, respetando los derechos humanos y la dignidad de los sujetos participantes en la investigación.

Solicitud

La solicitud deberá presentarse en días y horas hábiles, en las instalaciones de la CONBIOÉTICA por correo certificado con acuse de recibo, en el formato preestablecido. Toda la información que se envíe a la Comisión deberá ser dirigida a la Presidencia del Consejo de la Comisión, ubicada en Calzada Arenal número 134, Colonia El Arenal Tepepan, Delegación Tlalpan, C.P. 14610, México, Distrito Federal.

El formato a que hace referencia el párrafo anterior deberá contener:

Datos del establecimiento:

1. Nombre, denominación o razón social.
2. Nombre del representante legal.
3. Nombre del responsable sanitario.
4. Nombre de la persona para recibir notificaciones.
5. Licencia sanitaria emitida por la Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) para establecimientos de atención médica.
6. CLUES.

6. (bis) RENIECYT

Domicilio del establecimiento:

7. Calle, número y colonia.
8. Delegación o municipio.
9. Ciudad.
10. Entidad Federativa.
11. Código Postal.
12. Correo electrónico.
13. Teléfono con lada.

Características del Comité:

14. Tipo de servicio que presta el establecimiento al que pertenece el CEI.
15. Tipo de investigación que revisa el CEI.
16. Tipos de estudio revisados por el CEI.

Integración del CEI:

17. Fecha de instalación.
18. Nombre del Presidente del CEI.

19. Correo electrónico del Presidente del CEI.
20. Teléfono del Presidente del CEI, nombre, sexo, cargo al interior del CEI, profesión y número de cédula profesional de cada uno de los integrantes del CEI.

Integrantes:

21. Nombre, apellido paterno, apellido materno.
22. Género.
23. Cargo en el CEI.
24. Profesión y número de cédula profesional.
25. Documentos que acompañan la solicitud.
26. Lugar.
27. Fecha.
28. Nombre y firma del Director o Titular.

Clasificación de la documentación presentada

El solicitante deberá clasificar la documentación que presente a la CONBIOÉTICA como información pública o información confidencial. En caso de ser confidencial deberá señalar entre corchetes los datos que son confidenciales. Los documentos deberán contener las leyendas: información pública o información confidencial, justificando, en caso de esta última, la razón por la cual se le asigna el carácter de información confidencial o reservada.

Deberán presentarse dos originales de la solicitud con firma autógrafa del titular de la institución en la que se declare bajo protesta de decir verdad, que los datos que se proporcionan son correctos y en la que se comprometa a facilitar a petición de la Comisión Nacional de Bioética, la información, datos o documentos que le sean requeridos. Adicionalmente para cotejo deberá presentarse la documentación solicitada, en medio magnético, con las siguientes características:

a. Las imágenes en formato PDF y TIF (archivos tipo imagen), que sea compatible con Windows XP o posteriores.
b. Un disco para la versión pública y otro para la versión confidencial, debidamente identificados.
c. Los CD/DVD no regrabables y etiquetados o rotulados, con tinta indeleble o en dispositivo USB.

Términos y plazos

En un término de diez días hábiles, la CONBIOÉTICA admitirá el trámite o, en su caso, prevendrá al solicitante para que subsane las omisiones. El solicitante tendrá un plazo de quince días hábiles para atender la prevención; en caso de no hacerlo se tendrá por no presentada la solicitud.

Es necesario que el CEI de la institución o establecimiento cuente con un registro vigente para que los dictámenes de los protocolos o el seguimiento de los mismos tengan validez ante la autoridad sanitaria nacional. De no contar con registro vigente, el CEI tiene la obligación de informar a la institución, investigador y patrocinador. En caso de tener investigaciones en curso y no contar con registro vigente, el titular o director del establecimiento deberá asegurar que el seguimiento de los protocolos se realice por un CEI con registro vigente.

La Comisión en un plazo de treinta días hábiles, contados a partir de la admisión a trámite de la solicitud o cumplimentación del requerimiento, notificará al solicitante, sobre la procedencia de su solicitud y, en caso de ser aplicable, emitirá la constancia de registro correspondiente.

Elementos de la constancia de registro

La constancia de registro, además de los requisitos de todo acto administrativo previstos en la Ley Federal de Procedimiento Administrativo y el Código Federal de Procedimientos Civiles de aplicación supletoria, deberá contener los siguientes requisitos:

1. Nombre, denominación o razón social del establecimiento al que pertenece el CEI.
2. Domicilio del establecimiento en la que se encuentre el CEI.
3. Clave alfanumérica de registro único.
4. Fecha de emisión.
5. Vigencia.

Vigencia

La constancia de registro tendrá una vigencia de tres años. Deberá ser exhibida en la página electrónica del establecimiento, en caso de que aplique, y señalar el número de registro en los dictámenes emitidos a protocolos de investigación; deberán publicarse el objeto y las funciones del CEI, en un lugar visible para los usuarios del establecimiento.

Renovación

La solicitud de renovación del registro deberá presentarse dentro de los 45 días hábiles anteriores al vencimiento de la vigencia, para lo cual se deberán presentar:

1. Solicitud de renovación en el formato previamente establecido por la CONBIOÉTICA.
2. Constancias de capacitación de cada uno de los integrantes del CEI.
3. Acuse de recibo de los tres últimos informes anuales presentados ante la Comisión.
4. Constancias de designación los integrantes.
5. Copia simple de la cédula profesional de los integrantes del CEI.

Documentos a inscribirse en la renovación

1. La constancia de registro del CEI que haya concluido su trámite.
2. Los cambios de integrantes del CEI.[76]
3. Cambio de representante legal del establecimiento (en caso de que aplique).
4. Documento con el que se acredite la representación legal del establecimiento.
5. Informes anuales.
6. Información acerca del número de protocolos evaluados, tipos de dictámenes emitidos y el seguimiento de los mismos.
7. Los convenios que celebren los establecimientos con otras instituciones para la revisión de protocolos de investigación por el CEI.
8. Los demás actos que afecten el funcionamiento del CEI.

76 Las modalidades de cambio de los integrantes del CEI pueden ser por: a) baja de integrantes; b) alta de nuevos integrantes; c) alta y baja simultáneas de integrantes; y d) cambio de cargo al interior del CEI.

Actualización

Los establecimientos que cuenten con registro del CEI y que requieran la actualización de datos del comité, podrán solicitar por mediante escrito libre constancia de cambios de algunos de los integrantes de comité. La solicitud deberá estar dirigida al Titular de la CONBIOÉTICA con la siguiente información:

1. Nombre, denominación o razón social del establecimiento solicitante;
2. Domicilio para recibir notificaciones y correo electrónico;
3. La petición que se formula (relacionada con el número de expediente);
4. Los hechos o razones que dan motivo a la petición;
5. Cartas de designación de los integrantes
6. Estar firmado por el director, titular del establecimiento.

A la solicitud se deberán anexar los documentos probatorios que correspondan a lo solicitado y, en caso de que los cambios solicitados afecten ya sea de forma directa o indirecta a los sujetos que participan en la investigación para la salud, deberán demostrar las medidas implementadas para que los sujetos de investigación sean protegidos y no vulnerados durante su participación en la investigación.

La CONBIOÉTICA emitirá el oficio correspondiente dentro del término de 15 días hábiles en los supuestos previstos en las fracciones 3,4 y 6 y dentro del término de 45 días hábiles en los demás supuestos previstos en el apartado de documentos a inscribirse. En caso de cambio de domicilio, o la suspensión temporal del establecimiento o CEI y, en general, aquellos que afecten la protección de los participantes en la investigación, la Comisión podrá solicitar información que considere necesaria para garantizar la protección de los sujetos de investigación. En los supuestos previstos en las fracciones 10 y 11, el registro seguirá la suerte del acto principal.

Instituciones de Educación Superior

Las Universidades y centros de educación superior tienen un papel importante en la investigación biomédica. Los CEI de estas instituciones deben revisar los protocolos de investigación, de acuerdo con los lineamientos éticos que regulan la investigación nacional e internacional.

Los CEI pertenecientes a Universidades y centros de educación superior -con Registro Nacional de Instituciones y Empresas Científicas y Tecnológicas (RENIECyT)- podrán solicitar el registro ante la CONBIOÉTICA, de conformidad con los criterios correspondientes.

Anexos
Anexo 1
Solicitud de registro de comité de ética en investigación

1. DATOS DEL ESTABLECIMIENTO			
(1) Nombre, denominación o razón social*			
(2) Nombre del representante legal *	Nombre (s)	Apellido Paterno	Apellido Materno
(3) Nombre del responsable sanitario *			
(4) Nombre de la persona para recibir notificaciones			
(5) Licencia Sanitaria es obligatoria*			
(6) CLUES			
(6 bis) RENIECYT			

2. DOMICILIO DEL ESTABLECIMIENTO			
(7) Calle, número y colonia *			
(8) Delegación o Municipio*		(9) Ciudad *	
(10) Entidad Federativa *		(11) Código Postal *	
(12) Correo electrónico *		(13) Teléfono (con lada) *	

3. CARACTERÍSTICAS DEL COMITÉ				
(14) Tipo de servicio que presta el Establecimiento al que pertenece el CEI *	Público ☐ Social ☐ Privado ☐	(15) Tipo de investigación que revisa el CEI*	Sin riesgo ☐ Con riesgo mínimo ☐ Con riesgo mayor al mínimo ☐	
(16) Tipos de estudio revisados por el CEI*	Investigaciones sociales ☐ Ensayos clínicos ☐ Dispositivos médicos ☐		Investigaciones epidemiológicas ☐ Investigación con muestras biológicas ☐ Bioequivalencia ☐	

4. INTEGRACIÓN DEL COMITÉ			
(17) Fecha de instalación *			
(18) Nombre del Presidente *	Nombre (s)	Apellido Paterno	Apellido Materno
(19) Correo electrónico del Presidente*		(20) Teléfono (con lada) del Presidente*	

INTEGRANTES *					
(21) Nombre (s)	Apellido Paterno	Apellido Materno	(22) Género (M o F)	(23) Cargo en el CEI *	(24) Profesión y No. Cédula Profesional *

(25) **5. SEÑALE CON UNA (X) LOS DOCUMENTOS QUE SE ACOMPAÑAN** *	
( )	Formato de autoevaluación.
( )	Acta de instalación del Comité.
( )	Constancias de designación de cada uno de los integrantes del Comité.
( )	Copia de la cédula profesional de cada uno de los integrantes del Comité.
( )	Currículum vitae de cada uno de los integrantes del Comité
( )	Constancias de capacitación en bioética y/o ética en investigación de los integrantes del Comité, excepto del representante del núcleo afectado o de las personas usuarias de los servicios de salud.
( )	Documento con el que se acredite la representación legal del Establecimiento.
( )	Licencia Sanitaria del Establecimiento.
( )	Aviso de designación de responsable sanitario del Establecimiento.
( )	Reglas de funcionamiento del Comité.
( )	Políticas, lineamientos o guías en apego a las buenas prácticas clínicas del Establecimiento
( )	Procedimiento de operación para dar seguimiento a los protocolos autorizados

( )	Manifestación bajo protesta de decir verdad de que el Establecimiento se encuentra en los supuestos previstos en los artículos 41 BIS y 98 de la Ley General de Salud y cuenta con la infraestructura que garantice la capacidad técnica, material, humana y financiera, así como las instalaciones, equipo y tecnología para llevar a cabo las pruebas, estudios, ensayos, verificaciones y demás actividades necesarias para llevar a cabo actividades de investigación en seres humanos, de conformidad con los criterios establecidos en la normatividad vigente.
( )	En su caso, manifestación bajo protesta de decir verdad de que el Establecimiento solicitante cuenta con las instalaciones necesarias para proteger a los participantes en investigaciones, el personal y equipo necesario para la atención de cualquier urgencia médica, los procedimientos para el internamiento de pacientes en caso de ser necesario y demás lineamientos establecidos en las Buenas Prácticas de Investigación y normatividad vigente.
( )	Otros:

Declaro bajo protesta de decir verdad, que los datos que se proporcionan son correctos y me comprometo a facilitar a petición de la Comisión Nacional de Bioética, la información, datos o documentos que sean requeridos.

(26) Lugar *		(28) Nombre y firma del Director o Titular*
(27) Fecha *		

A efecto de garantizar la seguridad de los sujetos participantes en las investigaciones y la integridad científica en éstas, la Comisión se reserva el derecho de solicitar documentación o información adicional.

Instrucciones de llenado

El presente formato deberá llenarse a máquina o con letra legible, no deberá de contener abreviaturas, tachaduras ni enmendaduras. Los datos marcados con asterisco (*) son obligatorios.

(1) Asentar el nombre, denominación o razón social del Establecimiento solicitante al que pertenece el Comité, tal como aparece en el documento con el que se acredite la autorización sanitaria para realizar investigación en seres humanos.

(2) Señalar el nombre completo del representante legal del Establecimiento en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin hacer referencia a grados académicos, el cual deberá de coincidir con el documento con el que se acredite la representación legal del Establecimiento.

(3) Asentar el nombre completo del responsable sanitario del Establecimiento en el orden siguiente: nombre(s), apellido paterno y apellido materno, tal como aparece en sus documentos oficiales, sin señalar el grado académico.

(4) En su caso, señalar el nombre completo de la persona autorizada para oír y recibir notificaciones, en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin señalar el grado académico.

(5) Indique el número de Licencia Sanitaria del Establecimiento.

(6) Señalar la Clave Única de Establecimientos de Salud, emitida por la Dirección General de Información en Salud

(6bis) Registro Nacional de Instituciones y Empresas Científicas y Tecnológicas (RENIECyT) del Consejo Nacional de Ciencia y Tecnología (CONACYT). No obligatorio para las instituciones de salud.

(7) Indicar el nombre de la calle, número y colonia, en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(8) Indicar la Delegación o Municipio del inmueble en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(9) Señalar la Ciudad en donde se encuentra ubicado el Establecimiento al que pertenece el Comité

(10) Indicar la Entidad Federativa en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(11) Indicar el Código Postal en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(12) Indicar el correo electrónico al que podrán enviarse avisos para el Comité.

(13) Señalar el teléfono con clave lada en el que se podrán dar avisos para el Comité.

(14) Marcar el tipo de servicio que presta el Establecimiento:

Públicos: Son servicios de salud que se prestan a la población en general los que se presten en establecimientos públicos de salud a los residentes del país que así lo requieran, regidos por criterios de universalidad y de gratuidad en el momento de usar los servicios, fundados en las condiciones socioeconómicas de los usuarios.

Sociales: Son servicios de salud que se presten, directamente o mediante la contratación de seguros individuales o colectivos, los grupos y organizaciones sociales a sus integrantes y a los beneficiarios de los mismos.

Privados: Son servicios de salud que se presten a personas físicas o morales en las condiciones que convengan con los usuarios, sujetas a los ordenamientos legales, civiles y mercantiles.

(15) Indique el tipo de investigación revisada por el Comité, pudiéndose marcar más de una opción.

Investigación sin riesgo: Son estudios que emplean técnicas y métodos de investigación documental retrospectivos y aquéllos en los que no se realiza ninguna intervención o modificación intencionada en las variables fisiológicas, psicológicas y sociales de los individuos que participan en el estudio, entre los que se consideran: cuestionarios, entrevistas, revisión de expedientes clínicos y otros, en los que no se le identifique ni se traten aspectos sensitivos de su conducta.

Investigación con riesgo mínimo: Estudios prospectivos que emplean el riesgo de datos a través de procedimientos comunes en exámenes físicos o psicológicos de diagnósticos o tratamiento rutinarios, entre los que se consideran: pesar al sujeto, pruebas de agudeza auditiva; electrocardiograma, termografía, colección de excretas y secreciones externas, obtención de placenta durante el parto, colección de líquido amniótico al romperse las membranas, obtención de saliva, dientes deciduales y dientes permanentes extraídos por indicación terapéutica, placa dental y cálculos removidos por procedimiento profilácticos no invasores, corte de pelo y uñas sin causar desfiguración, extracción de sangre por punción venosa en adultos en buen estado de salud, con frecuencia máxima de dos veces a la semana y volumen máximo de 450 ml. en dos meses, excepto durante el embarazo, ejercicio moderado en voluntarios sanos, pruebas psicológicas a individuos o grupos en los que no se manipulará la conducta del sujeto, investigación con medicamentos de uso común, amplio margen terapéutico, autorizados para su venta, empleando las indicaciones, dosis y vías de administración establecidas y que no sean los medicamentos de investigación que se definen en el artículo 65 del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, entre otros.

Investigación con riesgo mayor que el mínimo: Son aquéllas en que las probabilidades de afectar al sujeto son significativas, entre las que se consideran: estudios radiológicos y con microondas, ensayos con los medicamentos y modalidades que se definen en el artículo 65 del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, ensayos con nuevos dispositivos, estudios que incluyan procedimientos quirúrgicos, extracción de sangre mayor al 2% del volumen circulante en neonatos, amniocentesis y otras técnicas invasoras o procedimientos mayores, los que empleen métodos aleatorios de asignación a esquemas terapéuticos y los que tengan control con placebos, entre otros.

(16) Indique el tipo de estudios revisados por el Comité de Ética en Investigación del mismo.

Investigaciones sociales: Proceso que, utilizando el método científico, permite obtener nuevos conocimientos en el campo de la realidad social o que permite estudiar una situación social para diagnosticar necesidades y problemas a los efectos de aplicar los conocimientos con finalidades prácticas.

Investigaciones epidemiológicas: Investigación sistemática de las características de un caso y del contexto epidemiológico en el que éste ocurre.

Ensayo clínico: Cualquier investigación que se lleva a cabo en humanos y que podrá tener como objetivos: descubrir o verificar los efectos clínicos, farmacológicos y/u otros efectos farmacodinámicos de un producto en investigación; identificar cualquier reacción adversa de un producto en investigación, y estudiar la absorción, distribución, metabolismo y excreción con el objetivo de evaluar la eficacia y la seguridad de un medicamento de investigación.

Muestra biológica humana: Parte del cuerpo humano separada del mismo, que alberga ácidos nucleicos y que contiene la dotación genética característica de una persona.

Dispositivos médicos: Investigaciones con cualquier instrumento, aparato, artefacto, equipo biomédico u otro artículo similar o relacionado, utilizado sólo en combinación, incluyendo sus componentes, partes, accesorios y programas informáticos utilizados para prevenir, diagnosticar o sustituir el funcionamiento de alguna parte del cuerpo.

Bioequivalencia: Estudios para verificar la equivalencia terapéutica entre un fármaco en estudio farmacéuticamente equivalente y un fármaco autorizado de referencia.

(17) Indicar la fecha de instalación del Comité en el orden siguiente: día, mes, año.

(18) Señalar el nombre completo del Presidente del Comité en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin indicar el grado académico.

(19) Indicar el correo electrónico del Presidente del Comité al que podrán enviarse avisos para el Comité.

(20) Señalar el teléfono con clave lada del Presidente del Comité en el que se podrán dar avisos para el Comité.

(21) Señalar el nombre completo de cada uno de los integrantes del Comité en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin hacer referencia a grados académicos.

(22) Asentar el género, debiendo señalar (H) Hombre o (M) Mujer.

(23) Mencionar el cargo que cada uno de los integrantes ocupa al interior del Comité, incluyendo a la representación del núcleo afectado o de los usuarios de los servicios de salud, en cuyo caso de pondrá tal situación. En caso de que sea insuficiente el espacio, se podrá reproducir el formato cuantas veces sea necesario.

(24) Indicar la profesión y el número de Cédula Profesional del integrante del Comité, expedida por la Secretaría de Educación Pública. Se exceptúa el caso de la representación del núcleo afectado o de las personas usuarias de los servicios de salud, en cuyo caso se podrá señalar "NO APLICA".

(25) Marcar con una (X) los documentos que se acompañan a la solicitud.

(26) Mencione el lugar en el que se suscribe la solicitud.

(27) Indique la fecha en la que se suscribe la solicitud en el orden siguiente: día, mes, año.

(28) Asentar el nombre completo en el orden siguiente: nombre(s), apellido paterno y apellido materno, así como la firma del Director o Titular del Establecimiento solicitante.

Anexo 2
Solicitud de renovación de registro de Comité de Ética en Investigación

1. DATOS DEL ESTABLECIMIENTO			
(1) Nombre y razón social del establecimiento al que pertenece el CEI *			
(2) Nombre del representante legal *	Nombre (s)	Apellido Paterno	Apellido Materno
(3) Nombre del responsable sanitario *			
(4) Nombre de la persona para recibir notificaciones			
(5) Licencia Sanitaria*		(6) CLUES	
(6 bis) RENIECYT			
DOMICILIO DEL ESTABLECIMIENTO			
(7) Calle, número y colonia *			
(8) Delegación o Municipio*		(9) Ciudad *	
(10) Entidad Federativa *		(11) Código Postal *	
(12) Correo electrónico *		(13) Teléfono (con lada) *	
2. DEL COMITÉ			
(14) Número de Registro del Comité de Ética en Investigación *			
(15) Nombre del Presidente del Comité *	Nombre (s)	Apellido Paterno	Apellido Materno
(16) Correo electrónico *		(17) Teléfono (con lada)*	

INTEGRANTES *					
(18) Nombre (s)	Apellido Paterno	Apellido Materno	(19)Género (M o F)	(20) Cargo en el CEI *	(21) Profesión y No. Cédula Profesional

(22) SEÑALE CON UNA (X) LOS DOCUMENTOS QUE SE ACOMPAÑAN *

( )	Constancias de designación de los integrantes del Comité.
( )	Copia de la cédula profesional de los integrantes del Comité.
( )	Currículum vitae de los integrantes del Comité.
( )	Constancias de capacitación en bioética y/o ética en investigación de los integrantes del Comité, excepto del representante del núcleo afectado o de las personas usuarias de los servicios de salud.
( )	Acuse de recibo de los tres últimos informes anuales presentados ante la Comisión.
( )	Documento con el que se acredite la representación legal del Establecimiento.
( )	Licencia Sanitaria del Establecimiento.
( )	Otros.

Declaro bajo protesta de decir verdad, que los datos que se proporcionan son correctos y me comprometo a facilitar a petición de la Comisión Nacional de Bioética, la información, datos o documentos que sean requeridos.

(23) Lugar *		(25) Nombre y firma del Director o Titular *
(24) Fecha *		

Instrucciones de llenado

El presente formato deberá llenarse a máquina o con letra legible, no deberá de contener abreviaturas, tachaduras ni enmendaduras. Los datos marcados con asterisco (*) son obligatorios

(1) Asentar el nombre, denominación o razón social del Establecimiento solicitante al que pertenece el Comité, tal como aparece en el documento con el que se acredite la autorización sanitaria para realizar investigación en seres humanos.

(2) Señalar el nombre completo del representante legal del Establecimiento en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin hacer referencia a grados académicos, el cual deberá de coincidir con el documento con el que se acredite la representación legal del Establecimiento.

(3) Asentar el nombre completo del responsable sanitario del Establecimiento en el siguiente orden: nombre(s), apellido paterno y apellido materno, tal como aparece en sus documentos oficiales, sin señalar el grado académico.

(4) En su caso, señalar el nombre completo de la persona autorizada para oír y recibir notificaciones, en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin señalar el grado académico.

(5) Indique el número de Licencia Sanitaria del Establecimientos de Atención Médica

(6) Señalar la Clave Única de Establecimientos de Salud, emitida por la Dirección General de Información en Salud.

(6bis) Registro Nacional de Instituciones y Empresas Científicas y Tecnológicas (RENIECyT) del Consejo Nacional de Ciencia y Tecnología (CONACYT). No obligatorio para las instituciones de salud.

(7) Indicar el nombre de la calle, número oficial y colonia, en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(8) Indicar la Delegación o Municipio en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(9) Señalar la Ciudad en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(10) Indicar la Entidad Federativa en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(11) Indicar el Código Postal en donde se encuentra ubicado el Establecimiento al que pertenece el Comité.

(12) Indicar el correo electrónico al que podrán enviarse avisos para el Comité.

(13) Señalar el teléfono con clave lada en el que se podrán dar avisos para el Comité.

(14) Indicar el número de registro otorgado por la Comisión.

(15) Señalar el nombre completo del Presidente del Comité en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin indicar el grado académico.

(16) Indicar el correo electrónico del Presidente del Comité al que podrán enviarse avisos para el Comité.

(17) Señalar el teléfono con clave lada del presidente del Comité, en el que se podrán dar avisos para el Comité.

(18) Señalar el nombre completo de cada uno de los integrantes del Comité en el orden siguiente: nombre(s), apellido paterno y apellido materno, sin hacer referencia a grados académicos.

(19) Asentar el género, debiendo señalar (H) Hombre o (M) Mujer.

(20) Mencionar el cargo que cada uno de los integrantes ocupa al interior del Comité, incluyendo a la representación del núcleo afectado o de los usuarios de los servicios de salud, en cuyo caso de pondrá tal situación. En caso de que sea insuficiente el espacio, se podrá reproducir el formato cuantas veces sea necesario.

(21) Indicar la profesión y el número de Cédula Profesional del integrante del Comité, expedida por la Secretaría de Educación Pública. Se exceptúa el caso de la representación del núcleo afectado o de las personas usuarias de los servicios de salud, en cuyo caso se podrá señalar "NO APLICA".

(22) Marque con una (X) los documentos que se acompañan a la solicitud.

(23) Mencione el lugar en el que se suscribe el documento.

(24) Indique la fecha en la que se suscribe el documento.

(25) Asentar el nombre completo en el orden siguiente: nombre(s), apellido paterno y apellido materno, así como la firma del Director o Titular del Establecimiento solicitante.

Anexo 3
Procedimientos del Comité de Ética en Investigación
Requisitos de las sesiones

Las sesiones del CEI deberán cumplir las siguientes condiciones:

- El CEI deberá sesionar al menos una vez cada dos meses. En aquellas instituciones en las que exista gran actividad en investigación se deberá considerar la posibilidad de sesionar con mayor frecuencia.
- Las fechas programadas serán anunciadas con anticipación a los interesados. El calendario anual deberá darse a conocer en enero.
- El orden del día y los documentos correspondientes a cada sesión, se entregarán cuando menos siete días hábiles antes de la reunión. En el caso de las sesiones extraordinarias, éstos se entregarán con tres días de antelación.
- El mínimo de integrantes requeridos para completar un quórum deberá ser mayor al 50% de los integrantes, entre los cuales deberá estar el presidente.[77]
- El presidente y/o el secretario deben estar presentes como uno de los mínimos requeridos para formar quórum. Sin su presencia no se puede dar inicio a las sesiones del CEI.
- A consideración del CEI, el investigador puede ser invitado a presentar la propuesta o a profundizar en cuestiones específicas del mismo, esta práctica es deseable para abreviar tiempos y optimizar la comunicación entre CEI e investigador.
- Pueden ser invitados a las sesiones o a presentar comentarios por escrito, un representante de la comunidad involucrada en el estudio específico a evaluar, así como los consultores externos quienes deberán apegarse a los criterios de confidencialidad aplicables al resto de los integrantes del CEI.
- Las sesiones extraordinarias serán solicitadas por convocatoria del Presidente del CEI. y a petición expresa, o cuando lo soliciten la mayoría de sus integrantes.
- El CEI podrá sesionar de manera conjunta con el Comité de Investigación para la valoración integral de los protocolos de investigación.
- En los casos que por su naturaleza así se requiera, como en la evaluación de estudios multicéntricos, el CEI podrá sesionar con CEI de otros establecimientos de manera conjunta, para la valoración y dictamen único de estos protocolos.
- En el caso de existir conflicto de interés en alguno de los integrantes del CEI, deberá declararse inhabilitado para esa deliberación en particular y no podrá contarse para completar el quórum. Esta condición deberá enunciarse en las actas correspondientes.
- Las revisiones expeditas no requieren el quórum necesario para las reuniones ordinarias y extraordinarias. Los asuntos de estas reuniones pueden ser revisadas por el presidente y/o el secretario. Las observaciones realizadas en estas revisiones deberán informarse en la siguiente reunión del CEI, para su conocimiento.
- Para los efectos legales y administrativos en las reuniones deben elaborarse minutas, así como establecer, en el reglamento interno del CEI, el procedimiento de aprobación de las mismas, su resguardo y archivo.

77 Excepto las sesiones expeditas

Información y archivos

Los archivos deberán ser resguardados en la oficina del CEI conforme a lo estipulado en la Ley General de Transparencia y Acceso a la Información Pública, en la Ley Federal de Protección de Datos Personales en Posesión de los Particulares, lo que se determine en la normatividad de las Entidades Federativas, así como en las demás disposiciones aplicables en la materia. Una vez transcurrido el periodo establecido, el CEI podrá trasladar la documentación a un lugar destinado para estos fines, bajo resguardo y registrando este acto en la base de datos del CEI.

Toda la documentación y las comunicaciones de un CEI deben fecharse, numerarse y archivarse de acuerdo a los procedimientos escritos. Se requiere una definición del procedimiento de acceso y de recuperación de documentos, expedientes y archivos, especificando las personas autorizadas para tales efectos. Será responsabilidad del presidente en turno del CEI, resguardar los archivos de los protocolos de investigación durante cinco años, a partir de que finalice el protocolo.
En los archivos internos del CEI se deberá incluir:

1. Acta de instalación del CEI.
2. Reglamento del CEI.
3. Manual de Procedimientos del CEI.
4. Guías operacionales, manuales, normas nacionales, normas internacionales, documentos técnicos, textos reglamentarios aplicables.
5. Programación de las sesiones del CEI.
6. Copia de los nombramientos de los integrantes.
7. Lista de identificación y la currícula actualizada de los integrantes del CEI.
8. Protocolos evaluados con toda la documentación analizada.
9. Acta de aprobación, copia de informes de seguimiento, reportes y enmiendas.
10. Informes de las decisiones, actas de aprobación e informes de rechazo y suspensión (ordenadas correlativamente y foliadas por año).
11. Reportes de eventos adversos serios en cada investigación o ensayo clínico.
12. Minutas de las reuniones enumeradas correlativamente por año y copia de todo el material enviado por el solicitante.
13. Informes periódicos sobre el estudio y el informe final, dejando copia en el archivo correspondiente al protocolo donde deberá estar toda la documentación referida al estudio: protocolo en sus distintas versiones, manual del investigador, consentimiento informado, currícula de los investigadores, acta de aprobación o rechazo, informes y correspondencia ordenada por fecha correlativa (es obligación que cada protocolo esté resguardado en un archivo identificado con el título, código, nombre de la institución patrocinadora, nombre del investigador y lugar o centro donde se lleva a cabo la investigación, así como fecha de inicio y de término).
14. Correspondencia recibida, la documentación enviada por los investigadores, la correspondencia intercambiada con ellos y otros actores.
15. Registros de gastos o uso de los recursos recibidos de conformidad con los principios expresados en la presente guía y con los lineamientos de la institución.
16. Correspondencia despachada.

Anexo 4
Carta de aprobación de protocolos por el Comité de Ética en Investigación

Es recomendable que la comunicación de la decisión incluya la siguiente información:

1. El título exacto de la propuesta de investigación revisada.
   - a. Descripción detallada de los documentos evaluados y aprobados en idioma español, citando versión y fecha:[78]
   - b. Nombre completo del investigador principal con la documentación necesaria para corroborar sus credenciales, resumen curricular fechado y firmado de los investigadores.
   - c. Manual del investigador que especifique el idioma y las fechas de las versiones revisadas.
   - d. Formato de solicitud de revisión del investigador principal y el sitio de investigación (razón social o denominación social y dirección del centro en donde se llevará a cabo la investigación).
   - e. Consentimiento informado que especifique el idioma y las fechas de las versiones revisadas.
   - f. Convocatoria (propaganda, anuncios, entre otros) mediante la cual se reclutarán a los voluntarios y todo el material escrito que se proporcionará a los sujetos.
   - g. En caso de que el CEI esté dictaminando un protocolo de un sitio de investigación distinto a la institución a la que pertenece el CEI, deberá incluir los datos del sitio y las autorizaciones correspondientes emitidas por la autoridad sanitaria.
2. Descripción clara del estatus para aprobación de los documentos.
3. Todas las comunicaciones realizadas por el CEI deberán hacerse en papel membretado en el que se indique el establecimiento al que pertenece y el número de registro emitido por la CONBIOÉTICA.
4. En el caso de los protocolos aprobados:
   - a. Título exacto y número de protocolo.
   - b. Nombre del investigador principal.
   - c. Descripción detallada de los documentos aprobados en idioma español, citando versión y fecha (protocolo, consentimiento, material para pacientes).
5. En el caso del Formato de Consentimiento Informado (FCI):
   - a. Todos los FCI aprobados por el CEI tendrán dos fechas: 1. la de aprobación por el CEI; y 2. la del periodo de vigencia establecido por el CEI.
   - b. El CEI deberá establecer en sus procedimientos la forma para la identificación de los FCI aprobados (por ejemplo, un sello). Las cartas aprobadas con el identificador podrán fotocopiarse, asegurando siempre que el identificador se mantenga visible; esto garantiza que sólo los FCI aprobados por el CEI sean utilizados para el consentimiento de los sujetos.
   - c. Vigencia de la aprobación del protocolo (no podrá ser mayor a un año).
6. En los casos en los que el protocolo no esté aprobado (condicionados o rechazados):
   - Explicitar las razones por las cuales se tomó la decisión.
   - Precisar las condiciones necesarias para su aprobación.
   - Emitir comentarios al FCI, en su caso.
   - Especificar los requerimientos del CEI y el procedimiento para una nueva revisión.
   - Especificar las acciones requeridas, en caso de una decisión pendiente de aprobación.

78 U.S. Department of Health and Human Services/ Food and Drug Administration/ Center for Drug Evaluation and Research/Center for Biologics Evaluation and Research (1996) Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. Disponible en: en http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

7. Explicitar el no conflicto de interés de los integrantes de CEI.
   - Ningún integrante del CEI presenta conflicto de interés.
   - Señalar los integrantes que no participaron en sesión del CEI por presentar algún conflicto de interés.
8. La fecha y firma del presidente o del secretario del CEI (de acuerdo con lo señalado en el registro).
9. Lista de los participantes en la sesión.[79]

Anexo 5
Consentimiento Informado[80]

Formato de Consentimiento Informado

El formato de consentimiento informado debe reflejar la información proporcionada a los sujetos de investigación,[81] el lenguaje que se emplee a lo largo del documento deberá estar al nivel de un estudiante con nivel de educación primaria. El formato comprende dos secciones, la primera en la que se proporciona la información del estudio, y la segunda, en la que el participante acepta participar al firmar el formato junto con dos testigos.

Primera parte. Información

1. En este documento se informará al participante de la investigación sobre el carácter voluntario de su participación.
2. Información sobre qué es una investigación.
3. El objetivo o propósito del estudio.
4. El /los tratamientos del estudio.

79 Es importante transparentar las actividades de los CEI si es necesario indicar que integrantes de los CEI participaron en el dictamen de los protocolos. Aun cuando no es indispensable, se puede mencionar cargo, representación, género y grado académico de los participantes en la reunión de CEI, por ejemplo: Presidente- Representante Científico-Masculino–Medico, Doctor en Ciencias; Vocal Secretario-Femenino– Abogada, Maestra en Bioética; Vocal, -Femenina-Licenciada en Enfermería; Vocal, Masculino–Antropólogo; Representante de los usuarios de servicios de salud, Femenina, secretaria; Consultor externo, Masculino- Médico Psiquiatra.

80 *Cfr.* Norma Oficial Mexicana NOM-04-SSA3-2012 del expediente clínico http://dof.gob.mx/nota_detalle.php?codigo=5272787&fecha=15/10/2012Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/policy/consentckls.html
Cfr. Code of Federal Regulations Title 45 Public Welfare Department Of Health And Human Services Part 46 Protection Of Human Subjects §46.116 General requirements for informed consent. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116
Cfr. Consent Procedures for Vulnerable and Other Special Populations Including Consent by a Legally Authorized Representative http://humansubjects.stanford.edu/hrpp/Chapter12.html#ch12_1
Cfr. Drafting the Informed Consent Form http://www.research.uci.edu/compliance/human-research-protections/researchers/drafting-consent-form.html
Cfr. Formatos para documentos de Consentimiento Informado elaborados por la OMS http://www.uchile.cl/portal/investigacion/centro-interdisciplinario-de-estudios-en-bioetica/documentos/75657/documentos-de-consentimiento-informado-elaborados-por-la-oms

81 *Cfr.* Norma Oficial Mexicana NOM-04-SSA3-2012 del expediente clínico http://dof.gob.mx/nota_detalle.php?codigo=5272787&fecha=15/10/2012Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/policy/consentckls.html
Cfr. Code of Federal Regulations Title 45 Public Welfare Department Of Health And Human Services Part 46 Protection Of Human Subjects §46.116 General requirements for informed consent. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116
Cfr. Consent Procedures for Vulnerable and Other Special Populations Including Consent by a Legally Authorized Representative http://humansubjects.stanford.edu/hrpp/Chapter12.html#ch12_1
Cfr. Drafting the Informed Consent Form http://www.research.uci.edu/compliance/human-research-protections/researchers/drafting-consent-form.html
Cfr. Formatos para documentos de Consentimiento Informado elaborados por la OMS http://www.uchile.cl/portal/investigacion/centro-interdisciplinario-de-estudios-en-bioetica/documentos/75657/documentos-de-consentimiento-informado-elaborados-por-la-oms

5. La forma y probabilidad de asignación a cada tratamiento, en caso de que sean estudios comparativos.
6. Los procedimientos que se llevarán a cabo.
7. Los riesgos o molestias y aspectos experimentales del estudio.
8. Los beneficios esperados; si no hubieran beneficios directos para el paciente se debe de especificar este aspecto.
9. Las alternativas de tratamiento.
10. Los compromisos del investigador.
11. Los compromisos que asume el sujeto de investigación.
12. La gratuidad de todos los fármacos, productos y los procedimientos.
13. El tratamiento médico que se proporcionará en caso de daños derivados o lesión relacionada con el estudio.
14. Debe hacerse constar que la participación es voluntaria, puede rehusarse a participar o retirarse del estudio en cualquier momento, sin necesidad de expresar las razones de su decisión o sin pérdida de los beneficios a los que tiene derecho.
15. El permiso para acceder en forma directa a los registros de la investigación.
16. Se deberán incluir los nombres de monitores, auditores y proporcionarlos al CEI y a la autoridad sanitaria competente, señalando sus alcances, respetando la confidencialidad de la persona.
17. Información acerca de que los datos de identificación se mantendrán en forma confidencial asegurando que si los resultados del estudio se publican, la identidad se mantendrá en forma confidencial y resguardada.
18. Las circunstancias por las cuales se puede dar por terminado el estudio.
19. La duración del estudio.
20. El número aproximado de participantes en la investigación.
21. Nombres y datos de contacto del investigador principal y el presidente del CEI. Se deberá firmar el formato por el sujeto o su representante y dos testigos, se entregará un duplicado de la hoja informativa, así como la hoja de firmas.

Segunda Parte. Carta de Consentimiento Informado
Ejemplo

Título de la Investigación

Esta sección puede ser redactada en primera persona. Deberá incluir una breve explicación acerca de la investigación.

He sido invitado a participar en una investigación para_____ .Me han informado que los riesgos_____ .También, me han informado que recibiré de forma gratuita el medicamento_____.

Mi médico me dio una explicación clara y leí la información sobre la investigación, tuve oportunidad de hacer preguntas y mis dudas han sido resueltas. Acepto voluntariamente participar en este estudio y entiendo que tengo derecho a retirarme de la investigación, sin perder mis derechos como paciente de este hospital.

Nombre del participante_____
Dirección_____ Teléfono _____
Firma del Participante _____Fecha Día/mes/año

Nombre del Testigo _____ Parentesco _____
Dirección_____ Teléfono _____
Firma del Testigo _____ Fecha Día/mes/año

Nombre del Testigo _____ Parentesco _____
Dirección_____ Teléfono _____
Firma del Testigo _____ Fecha Día/mes/año

Nombre y firma de quien solicitó el Consentimiento_____

Aspectos a considerar

1. Debe asegurarse que no exista influencia indebida o coerción (una influencia indebida en la población mexicana que asiste a las instituciones públicas podría consistir en mencionar que al participar en el estudio recibirá mejor atención o se reclasificará el nivel socioeconómico).
2. La información deberá actualizarse y revisarse cuando surjan datos que puedan ser relevantes para el consentimiento del sujeto y deberá ser aprobado por el CEI.
3. Debe verificarse la comprensión de la información y contar con el tiempo suficiente para resolver dudas.
4. Si la persona o su representante legal no pueden leer, deberán participar al menos dos testigos que puedan hacerlo.

5. En el caso de estudios en los que participen menores de edad o disminución en la capacidad intelectual, la persona deberá ser informada sobre el estudio, y deberá firmar un asentimiento.

Consentimiento Informado en poblaciones especiales

Población en situación de vulnerabilidad

La vulnerabilidad puede definirse como la presencia de ciertas situaciones en las que individuos y/o grupos se encuentran disminuidos en su autonomía debido a la imposición de estructuras sociales, políticas y/o económicas que los excluyen del acceso a mecanismos e instancias decisivas para su calidad de vida.[82] Tradicionalmente se ha reconocido vulnerabilidad en la condición de ser menor de edad, mujer, una persona con discapacidad, adulto mayor, padecer alguna enfermedad mental, ser inmigrante, analfabeta, pertenecer a minorías étnicas o raciales, desempleado, no tener hogar, estar recluso.

Sin embargo, un individuo o grupo nunca será vulnerable per se, por lo que es preferible hablar de situación de vulnerabilidad debido a que una de las características de ésta es su condición dinámica y relacional, depende de un espacio y tiempo definidos.

De acuerdo con el Informe Belmont, "El respeto por las personas incorpora por lo menos dos convicciones éticas: la primera es que los individuos deben ser tratados como agentes autónomos y la segunda es que las personas con autonomía disminuida tienen derecho a ser protegidas".
Al revisar las investigaciones en las que participan las poblaciones vulnerables, los CEI deberán garantizar que se implementen mecanismos de seguridad adicionales para minimizar los riesgos específicos para cada grupo.

Niños

La participación de menores en una investigación deberá siempre tener un beneficio directo en el menor o será el único tratamiento disponible para el tratamiento de su enfermedad. También deberá asegurarse de que los resultados de la investigación que se pretende llevar a cabo en niños no podrían obtenerse con la participación de adultos.

- El uso de placebos debe estar científicamente justificado y no deben ser utilizados en substitución de tratamientos efectivos.
- El asentimiento deberá estar firmado por los padres o el representante legal. Adicionalmente, los niños que puedan comprender la investigación propuesta, deben ser informados sobre la investigación, expresar sus dudas. Se debe considerar la firma de asentimiento en menores de 7 a18 años. El asentimiento no reemplaza el consentimiento de los padres.[83]
- En el texto del asentimiento se debe asegurar que la información proporcionada es apropiada para la comprensión de los niños.
- Cuando dos personas ejerzan la patria potestad de un menor, sólo será admisible el consentimiento de una de ellas si existe imposibilidad fehaciente o manifiesta de la otra para proporcionarlo o en caso de riesgo inminentes para la salud o la vida del menor o incapaz.
- En la investigación en áreas sensibles, por ejemplo, uso de drogas ilegales.

82 *Cfr.* Bayón, M, C, Mier y Terán, M, (2010) Familia y vulnerabilidad en México. Realidades y percepciones. Cuaderno de Investigación, No. 42. México: Instituto de Investigaciones Sociales-UNAM.
83 *Cfr.* The Process of Obtaining Informed Consent. World Health Organization. http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf

- Sexualidad en adolescentes, abuso sexual, el CEI debe asegurase que el investigador tiene establecidas estrategias adecuadas para proteger la privacidad y la confidencialidad.
- Cuando la capacidad mental y estado psicológico del menor o incapaz lo permitan, deberá obtenerse, además, su aceptación para ser sujeto de investigación, después de explicarle lo que se pretende hacer. El CEI podrá dispensar el cumplimiento de estos requisitos por causas justificadas.[84]
- Las mismas consideraciones son aplicables cuando se realiza investigación en personas incapaces de decidir.

Personas en situación de cárcel[85]

La investigación en este grupo de personas representa un reto para los CEI ya que por protección a los derechos humanos con frecuencia se evita llevar a cabo investigación en estas personas, sin embargo, existen algunas circunstancias en las que esta población en específico podría ser beneficiada, por ejemplo, en el caso de las investigaciones de tuberculosis multiresistente que es de alta prevalencia en estas circunstancias.

Es conveniente que en la sesión CEI en la que se revisa un protocolo en donde se incluye la participación de personas en situación de cárcel, cuente con un representante con experiencia para para revisar los aspectos éticos de este grupo de individuos. La autonomía de estas se manifiesta en su derecho a decidir si desean o no participar en investigación biomédica.

Los requisitos específicos para el consentimiento informado en estos individuos son:

- Asegurar que los riesgos son equivalentes a los que se aprobarían para cualquier individuo.
- Revisar y asegurar que no existe manipulación de parte de las autoridades u otros prisioneros.
- Evitar que cualquier ventaja durante el encarcelamiento en las condiciones de vida, atención médica, alimentos, etcétera, ejerzan influencia indebida.
- Asegurar que no existen ventajas para alcanzar libertad provisional al participar en la investigación.

Mujeres embarazadas y fetos[17]

La investigación en mujeres embarazadas y fetos solamente estará permitida si ésta representa una oportunidad para entender, prevenir o aliviar alguna patología grave.

- Las mujeres embarazadas no deberán ser excluidas de las investigaciones si los riesgos para el feto son mínimos, el consentimiento informado deberá mencionar el posible riesgo para el feto.
- Para el uso de materiales biológicos derivados de abortos el consentimiento informado deberá ser independiente del que se otorgue para realizar el aborto y no deberá incluir una compensación económica.[37]

17 *Cfr.* Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, Última reforma publicada en el Diario Oficial de la Federación el 02 de abril de 2014. http://biblio.juridicas.unam.mx/libros/5/2292/63.pdf

37 U.S. Department of Health and Human Services (2009) Code of Federal Regulations Title 45 Public Welfare Department of Health And Human Services, Part 46 Protection of Human. Disponible en: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

84 *Cfr.* Requisitos establecidos en el Reglamento de la Ley General de Salud en Materia de Investigación y demás disposiciones contenidas en el CAPITULO III De la Investigación en Menores de Edad o Incapaces Artículos 34-39

85 *Cfr.* Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research/ Board on Health Sciences Policy/ Institute of Medicine (2007) Considerations FOR Research Involving Prisoners. Washington, D.C.: The National Academies Press. Disponible en: http://www.nap.edu/catalog/11692/ethical-considerations-for-research-involving-prisoners Ethical Considerations for Research Involving Prisoners. Disponible en https://rgs.usu.edu/irb/investigator-handbook/chapter-7-research-involving-vulnerable-populations

- Para realizar investigaciones en mujeres embarazadas, durante el trabajo de parto, puerperio y lactancia, en nacimientos vivos o muertos, en la utilización de embriones, óbitos o fetos y para la fertilización asistida, se requiere obtener la carta de consentimiento informado de la mujer y de su cónyuge o concubinario, previa información de los riesgos posibles para el embrión, feto o recién nacido en su caso.
- El consentimiento del cónyuge o concubinario sólo podrá dispensarse en caso de incapacidad o imposibilidad fehaciente o manifiesta para proporcionarlo, porque el concubinario no se haga cargo de la mujer, o bien, cuando exista riesgo inminente para la salud o la vida de la mujer, embrión, feto o recién nacido.[86]
- Sólo con la autorización del CEI podrá modificarse el método para terminar el embarazo con propósitos de investigación, cuando tales modificaciones signifiquen un riesgo mínimo para la salud de la madre y no representen riesgo alguno para la sobrevivencia del feto, y en todo caso queda estrictamente prohibido otorgar estímulos monetarios o de otro tipo para interrumpir el embarazo, por el interés de la investigación o por otras razones.[87]

Subordinados y estudiantes

Son grupos subordinados los siguientes: estudiantes, trabajadores de laboratorios y hospitales, empleados, miembros de las fuerzas armadas, internos en reclusorios o centros de readaptación social y otros grupos especiales de la población, en los que el consentimiento informado pueda ser influenciado por alguna autoridad.[88]

- El investigador principal debe definir claramente las razones por las que planea reclutar empleados o estudiantes; además, todas las estrategias de reclutamiento deben ser estipuladas.
- Es un requisito para la aprobación del protocolo, una declaración por escrito del jefe inmediato o la autoridad correspondiente de que no ha existido coacción.
- Si médicos residentes o socios son reclutados para la investigación, el director del programa deberá proporcionar al CEI una carta de apoyo, este escrito debe provenir de una figura sin lazos con el estudio (por ejemplo: si el Director del programa realiza una investigación en los residentes, la carta debe provenir del Director del departamento o de la autoridad a cargo del programa académico).
- Es importante considerar para el grupo de subordinados y estudiantes la cuestión de confidencialidad de los datos de investigación, dependiendo de la naturaleza del estudio y de la información recolectada. Una violación a la confidencialidad puede afectar las posibilidades de empleo de la persona, su desarrollo profesional, planes de estudio o relaciones sociales dentro de la comunidad escolar o del hospital. El CEI pondrá especial atención a los planes del Investigador principal para salvaguardar la seguridad de los datos.

Actualización del consentimiento

En ciertas circunstancias puede ser necesario que los sujetos vuelvan a dar su consentimiento para participar en un estudio, por lo que el CEI determinará en qué casos es necesario solicitarlo nuevamente, de acuerdo con el seguimiento de la investigación.

86 Requisitos establecidos en el Artículo 43 del Reglamento de la Ley General de Salud en Materia de Investigación. Última reforma DOF 02-04-2014

87 *Cfr.* Requisitos establecidos en el Artículo 43 del Reglamento de la Ley General de Salud en Materia de Investigación. Última reforma DOF 02-04-2014

88 *Cfr.* Requisitos establecidos en el Artículo 58 del Reglamento de la Ley General de Salud en Materia de Investigación para la Salud Secretaría General Secretaría de Servicios Parlamentarios Última Reforma DOF 02-04-2014

El CEI puede pedir que un sujeto vuelva a dar su consentimiento si el sujeto participa en un estudio longitudinal. Si el estudio es particularmente largo, puede ser que la persona vuelva a dar su consentimiento para garantizar que entiende las actividades de investigación relevantes. Los investigadores deben presentar un plan para mantener el consentimiento informado cuando someten protocolos a los que se les dará seguimiento por largo tiempo.

Si se hacen enmiendas al protocolo, se presentan Eventos Adversos Serios (EAS) o se descubre nueva información relevante para que el sujeto siga participando, los investigadores deben definir si es necesario volver a dar el consentimiento.

Anexo 6
Formato de declaración de no conflicto de interés

Existe conflicto de interés potencial o verdadero cuando los compromisos y obligaciones principales están indebidamente influenciadas por otros intereses materiales o personales, especialmente si estos no están debidamente transparentados.

En este formato deberá indicar si usted considera que existe un interés secundario que pudiera influir indebidamente en su responsabilidad de proteger a los sujetos de investigación.

Se le pide que responda a las preguntas concernientes a usted y a sus "familiares directos".[89] Este formato pretende identificar y abordar los conflictos de intereses, existentes y potenciales. Se incluyen cuatro preguntas.

1. Tengo algún conflicto de interés que reportar	Si	No
Tengo los siguientes conflictos que declarar:		
2. Relación comercial o económica directa con el patrocinador	Si	No
3. Relación profesional directa con el patrocinador	Si	No
4. Cualquier otra cosa que pudiera afectar su objetividad o independencia en el desempeño de sus funciones	Si	No

Si usted contestó afirmativamente a cualquiera de las preguntas formuladas arriba, por favor proporcione los detalles:

_____

_____

_____

_____

Declaro bajo protesta de decir verdad que la información señalada es correcta.

Fecha y Firma del Investigador

89 A efectos de este formulario, "familiares directos" son: (i) su cónyuge o pareja de hecho; y (ii) sus hijos.

Glosario

Asentimiento Informado
Documento que señala la voluntad de cooperación del niño(a) para participar en un estudio clínico.

Asignación Aleatoria
Proceso de asignación de los sujetos de un estudio a los grupos de tratamiento o de control, utilizando el azar.

Atención médica
Conjunto de servicios que se proporcionan al individuo con el fin de promover, proteger y restaurar su salud.

Bienestar
Integridad física y mental de los sujetos que participan en un estudio clínico.

Buena Práctica Clínica (BPC)
Estándar para el diseño, conducción, realización, monitoreo, auditoría, registro, análisis y reporte de estudios clínicos que proporciona una garantía de que los datos y los resultados reportados son creíbles y precisos y de que están protegidos los derechos, integridad y confidencialidad de los sujetos del estudio.

Carta de consentimiento informado
Documento escrito, signado por el investigador principal, el paciente o su familiar, tutor o representante legal y dos testigos, mediante el cual el sujeto de investigación acepta participar voluntariamente en una investigación y que le sea aplicada una maniobra experimental, una vez que ha recibido la información suficiente, oportuna, clara y veraz sobre los riesgos y beneficios esperados. Deberán indicarse los nombres de los testigos, su dirección y la relación que tienen con el sujeto de investigación.

Confidencialidad
No revelar a otros –a menos que sea personal autorizado- la información o identidad de un sujeto.

Estudio clínico o ensayo clínico controlado
Cualquier investigación que se lleva a cabo en humanos con el objetivo de descubrir o verificar los efectos clínicos, farmacológicos y/o farmacodinámicos de un producto en investigación y/o identificar cualquier reacción adversa de un producto en investigación y/o estudiar la absorción, distribución, metabolismo y excreción, con el objetivo de evaluar la eficacia y la seguridad de un medicamento de investigación. Los términos de estudio clínico y ensayo clínico son sinónimos.

Estudios clínicos Fase 0
Estudios exploratorios sin fines terapéuticos o diagnósticos.

Estudios clínicos Fase I
Administración por primera vez de un medicamento de investigación al ser humano sano, sin beneficio diagnóstico o terapéutico, en dosis únicas o múltiples, en grupos pequeños hospitalizados, para establecer parámetros farmacológicos iniciales en el ser humano.[90]

90 Casi nunca tiene el diseño de ensayo clínico

Estudios clínicos Fase II
Administración de un medicamento de investigación en sujetos enfermos, en dosis únicas o múltiples, en grupos pequeños hospitalizados, para determinar su eficacia inicial y otros parámetros farmacológicos en el organismo enfermo.[91]

Estudios clínicos Fase III
Administración de un medicamento de investigación a grupos grandes de sujetos (generalmente externos), para definir su utilidad terapéutica e identificar reacciones adversas, interacciones y factores externos que puedan alterar el efecto farmacológico generalizado y prolongado.[92]

Estudios clínicos Fase IV
Estudios que se realizan después de que se concede al medicamento registro y autorización de nueva información sobre la seguridad de medicamento durante su empleo generalizado y prolongado. Estos estudios se clasifican como: de intervención y de no intervención.[93]

Estudios clínicos fase IV (de intervención)
Cuando además de nueva información sobre la seguridad del medicamento, se busquen nuevas indicaciones, rutas de administración, tratamientos, combinaciones terapéuticas, y/o dosis.

Estudios de fase IV (de no intervención)
Estudios observacionales, realizados durante el uso regular del medicamento, para determinar la asociación entre efectos y factores causales y/o vigilar su perfil de seguridad, de acuerdo con las condiciones de autorización del mismo.

Estudios de post comercialización temprana
Aquellos que, a solicitud de la autoridad, se realizan en los primeros 2 o 3 años de comercialización de todas las moléculas nuevas, para seguimiento del perfil de la seguridad e incluyen aquellas actividades encaminadas a identificar y caracterizar los riesgos potenciales de los medicamentos a través de una vigilancia activa.

Estudios de farmacovigilancia intensiva
Método de la farmacovigilancia que consiste en obtener información de las sospechas de reacciones a medicamentos de manera sistemática, de calidad y completa, caracterizada por su alta calidad y fiabilidad; especialmente cuando se hace necesario determinar la frecuencia de reacciones adversas, identificar factores predisponentes y patrones de uso de medicamentos, entre otros.

Evento adverso
Conjunto de signos y síntomas no calculados e inesperados que se presentan en un sujeto de investigación, como consecuencia de la aplicación de maniobras experimentales previstas en un protocolo o proyecto de investigación para la salud en seres humanos y que potencialmente representen un riesgo para su salud.

91 Frecuentemente no tiene el diseño de ensayo clínico controlado
92 Esta fase es la que siempre tiene diseño de ensayo clínico controlado
93 Rara vez tienen diseño de ensayo clínico controlado

Enmienda
Cualquier cambio a un documento que forma parte del proyecto o protocolo de investigación, derivado de variaciones a la estructura metodológica, sustitución del investigador principal o ante la identificación de riesgos en los sujetos de investigación. Los documentos susceptibles de enmienda son: proyecto o protocolo, carta de consentimiento informado, manual del investigador, documentos para el paciente, escalas de medición y cronograma.

Informe anual de actividades
Es el documento que contiene información acerca de las actividades desarrolladas por el comité de ética en investigación durante el ejercicio fiscal anterior al año que se presenta. Es entregado tanto al titular del establecimiento como a la CONBIOÉTICA.

Institución o establecimiento
Donde se realiza investigación para la salud, a todo aquel donde se proporcionen servicios de atención médica, perteneciente a los sectores público, social o privado, cualquiera que sea su denominación, que pueda efectuar actividades preventivas, diagnósticas, terapéuticas y de rehabilitación, por si misma o subrogadas, dirigidas a mantener o reintegrar el estado de salud de las personas y efectuar actividades de formación y desarrollo de personal para la salud, así como de investigación.

Investigación para la salud en seres humanos
En la que el ser humano es el sujeto de investigación y que se desarrolla con el único propósito de realizar aportaciones científicas y tecnológicas, para obtener nuevos conocimientos en materia de salud.

Investigador principal
Profesional de la salud, responsable de conducir, coordinar y vigilar el desarrollo de dicha investigación.

Maniobra experimental
Empleo de medicamentos o materiales, respecto de los cuales aún no se tenga evidencia científica suficiente de su eficiencia terapéutica o rehabilitatoria o se pretenda la modificación de las indicaciones terapéuticas de productos ya conocidos, en un sujeto de investigación, con la finalidad de obtener información científica respecto de la eficacia de su uso con fines preventivos, diagnósticos, terapéuticos o rehabilitatorios.

Medicamentos o materiales
Principios farmacológicos, químicos, biológicos, materiales y dispositivos médicos, utilizados o aplicados en seres humanos con fines de investigación científica, respecto de los cuales no se tenga evidencia científica suficiente para probar su eficacia preventiva, terapéutica o rehabilitatoria.

Monitoreo
Acto de vigilar el proceso de un estudio clínico y asegurarse de que éste sea conducido, registrado y reportado de acuerdo con el protocolo, Procedimientos Estándar de Operación (PEOs), la Buena Práctica Clínica (BPC) y los requerimientos regulatorios aplicables.

Núcleo afectado
Se refiere al grupo de personas quienes cursan con la patología o con las características señaladas en la investigación.

Organización de Investigación por Contrato (Contract Research Organizations) (CRO)
Persona u organización comercial, académica o de otro tipo) contratada por el patrocinador para realizar una o más de las labores y funciones del patrocinador relacionadas con el estudio.

Patrocinador
Persona física o moral que acepta responsabilidades para financiar una investigación.

Placebo
Substancia inerte, físicamente indistinguible del medicamento en estudio.

Procedimiento invasivo
Aquel que se vale de una o varias técnicas médicas que invaden el cuerpo, con un fin diagnóstico o terapéutico.

Proyecto o protocolo de investigación para la salud en seres humanos
Documento que describe la propuesta de una investigación para la salud en seres humanos, conforme al objetivo y campo de aplicación de esta norma, integrado al menos por los capítulos de: planeación, programación, organización y presupuestación estructurado de manera metodológica y sistematizada en sus diferentes fases de trabajo, que se realizarán bajo la responsabilidad, conducción y supervisión de un investigador principal.

Sitios de investigación o sitios
Cualquier establecimiento pública o privada, o instalación médica donde se conducen los estudios clínicos.

Sujeto de investigación
Individuo que otorga su consentimiento informado, por sí mismo o por conducto de su representante legal, para que en su persona sean practicados determinados procedimientos con fines de investigación para la salud en seres humanos.

UNESCO
Organización de las Naciones Unidas para la Educación, la Ciencia y la Cultura.

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LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

Nueva Ley publicada en el Diario Oficial de la Federación el 18 de marzo de 2005

TEXTO VIGENTE
Última reforma publicada DOF 11-05-2022

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República.

VICENTE FOX QUESADA, Presidente de los Estados Unidos Mexicanos, a sus habitantes sabed:

Que el Honorable Congreso de la Unión, se ha servido dirigirme el siguiente

DECRETO

"EL CONGRESO DE LOS ESTADOS UNIDOS MEXICANOS, DECRETA:

SE EXPIDE LA LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS.

ARTÍCULO ÚNICO: Se expide la Ley de Bioseguridad de Organismos Genéticamente Modificados, para quedar como sigue:

LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

TÍTULO PRIMERO
Disposiciones Generales

CAPÍTULO I
Objeto y Finalidades

ARTÍCULO 1.- La presente Ley es de orden público y de interés social, y tiene por objeto regular las actividades de utilización confinada, liberación experimental, liberación en programa piloto, liberación comercial, comercialización, importación y exportación de organismos genéticamente modificados, con el fin de prevenir, evitar o reducir los posibles riesgos que estas actividades pudieran ocasionar a la salud humana o al medio ambiente y a la diversidad biológica o a la sanidad animal, vegetal y acuícola.

ARTÍCULO 2.- Para cumplir su objeto, este ordenamiento tiene como finalidades:

I. Garantizar un nivel adecuado y eficiente de protección de la salud humana, del medio ambiente y la diversidad biológica y de la sanidad animal, vegetal y acuícola, respecto de los efectos adversos que pudiera causarles la realización de actividades con organismos genéticamente modificados;

II. Definir los principios y la política nacional en materia de bioseguridad de los OGMs y los instrumentos para su aplicación;

III. Determinar las competencias de las diversas dependencias de la Administración Pública Federal en materia de bioseguridad de los OGMs;

IV. Establecer las bases para la celebración de convenios o acuerdos de coordinación entre la Federación, por conducto de las Secretarías competentes y los gobiernos de las entidades federativas, para el mejor cumplimiento del objeto de esta Ley;

V. Establecer las bases para el funcionamiento de la Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados, a través de la cual las Secretarías que la integran deban colaborar de manera coordinada, en el ámbito de sus competencias, en lo relativo a la bioseguridad de los organismos genéticamente modificados;

VI. Establecer procedimientos administrativos y criterios para la evaluación y el monitoreo de los posibles riesgos que puedan ocasionar las actividades con organismos genéticamente modificados en la salud humana o en el medio ambiente y la diversidad biológica o en la sanidad animal, vegetal o acuícola;

VII. Establecer el régimen de permisos para la realización de actividades de liberación experimental, de liberación en programa piloto y de liberación comercial, de organismos genéticamente modificados, incluyendo la importación de esos organismos para llevar a cabo dichas actividades;

VIII. Establecer el régimen de avisos para la realización de actividades de utilización confinada de organismos genéticamente modificados, en los casos a que se refiere esta Ley;

IX. Establecer el régimen de las autorizaciones de la Secretaría de Salud de organismos genéticamente modificados que se determinan en esta Ley;

X. Crear y desarrollar el Sistema Nacional de Información sobre Bioseguridad y el Registro Nacional de Bioseguridad de los Organismos Genéticamente Modificados;

XI. Determinar las bases para el establecimiento caso por caso de áreas geográficas libres de OGMs en las que se prohíba y aquellas en las que se restrinja la realización de actividades con determinados organismos genéticamente modificados, así como de cultivos de los cuales México sea centro de origen, en especial del maíz, que mantendrá un régimen de protección especial;

XII. Establecer las bases del contenido de las normas oficiales mexicanas en materia de bioseguridad;

XIII. Establecer medidas de control para garantizar la bioseguridad, así como las sanciones correspondientes en los casos de incumplimiento o violación a las disposiciones de esta Ley, sus reglamentos y las normas oficiales mexicanas que deriven de la misma;

XIV. Establecer mecanismos para la participación pública en aspectos de bioseguridad materia de esta Ley, incluyendo el acceso a la información, la participación de los sectores privado, social y productivo a través del Consejo Consultivo Mixto de la CIBIOGEM, y la consulta pública sobre solicitudes de liberación de OGMs al ambiente, y

XV. Establecer instrumentos de fomento a la investigación científica y tecnológica en bioseguridad y biotecnología.

ARTÍCULO 3.- Para los efectos de esta Ley, se entiende por:

I. Accidente: La liberación involuntaria de organismos genéticamente modificados durante su utilización y que pueda suponer, con base en criterios técnicos, posibles riesgos para la salud humana o para el medio ambiente y la diversidad biológica.

II. Actividades: La utilización confinada, la liberación experimental, la liberación en programa piloto, la liberación comercial, la comercialización, la importación y la exportación de organismos genéticamente modificados, conforme a esta Ley.

III. Autorización: Es el acto administrativo mediante el cual la Secretaría de Salud, en el ámbito de su competencia conforme a esta Ley, autoriza organismos genéticamente modificados determinados expresamente en este ordenamiento, a efecto de que se pueda realizar su comercialización e importación para su comercialización, así como su utilización con finalidades de salud pública o de biorremediación.

IV. Biorremediación: El proceso en el que se utilizan microorganismos genéticamente modificados para la degradación o desintegración de contaminantes que afecten recursos y/o elementos naturales, a efecto de convertirlos en componentes más sencillos y menos dañinos o no dañinos al ambiente.

V. Bioseguridad: Las acciones y medidas de evaluación, monitoreo, control y prevención que se deben asumir en la realización de actividades con organismos genéticamente modificados, con el objeto de prevenir, evitar o reducir los posibles riesgos que dichas actividades pudieran ocasionar a la salud humana o al medio ambiente y la diversidad biológica, incluyendo los aspectos de inocuidad de dichos organismos que se destinen para uso o consumo humano.

VI. Biotecnología moderna: Se entiende la aplicación de técnicas in vitro de ácido nucleico, incluidos el ácido desoxirribonucleico (ADN y ARN) recombinante y la inyección directa de ácido nucleico en células u organelos, o la fusión de células más allá de la familia taxonómica, que supera las barreras fisiológicas naturales de la reproducción o de la recombinación y que no son técnicas utilizadas en la reproducción y selección tradicional, que se aplican para dar origen a organismos genéticamente modificados, que se determinen en las normas oficiales mexicanas que deriven de esta Ley.

VII. Caso por caso: La evaluación individual de los organismos genéticamente modificados, sustentada en la evidencia científica y técnica disponible, considerando, entre otros aspectos, el organismo receptor, el área de liberación y las características de la modificación genética, así como los antecedentes que existan sobre la realización de actividades con el organismo de que se trate y los beneficios comparados con opciones tecnológicas alternas para contender con la problemática específica.

VIII. Centro de origen: Es aquella área geográfica del territorio nacional en donde se llevó a cabo el proceso de domesticación de una especie determinada.

IX. Centro de diversidad genética: Es aquella área geográfica del territorio nacional donde existe diversidad morfológica, genética o ambas de determinadas especies, que se caracteriza por albergar poblaciones de los parientes silvestres y que constituye una reserva genética.

X. Comercialización: Es la introducción al mercado para distribución y consumo de organismos genéticamente modificados en calidad de productos o mercancías, sin propósitos de liberación intencional al medio ambiente y con independencia del ánimo de lucro y del título jurídico bajo el cual se realice.

XI. CIBIOGEM: La Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados.

XII. CONACyT: El Consejo Nacional de Ciencia y Tecnología.

XIII. Diversidad biológica: La variabilidad de organismos vivos de cualquier fuente, incluidos, entre otras cosas, los ecosistemas terrestres y marinos y otros ecosistemas acuáticos y los complejos

ecológicos de los que forman parte; comprende la diversidad dentro de cada especie, entre las especies y de los ecosistemas.

XIV. Inocuidad: La evaluación sanitaria de los organismos genéticamente modificados que sean para uso o consumo humano o para procesamiento de alimentos para consumo humano, cuya finalidad es garantizar que dichos organismos no causen riesgos o daños a la salud de la población.

XV. Liberación: La introducción en el medio ambiente de un organismo o combinación de organismos genéticamente modificados, sin que hayan sido adoptadas medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas o biológicas, para limitar su contacto con la población y el medio ambiente.

XVI. Liberación comercial: Es la introducción, intencional y permitida en el medio ambiente, de un organismo o combinación de organismos genéticamente modificados, sin que hayan sido adoptadas medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas o biológicas, para limitar su contacto con la población y el medio ambiente, que se realiza con fines comerciales, de producción, de biorremediación, industriales y cualesquiera otros distintos de la liberación experimental y de la liberación en programa piloto, en los términos y condiciones que contenga el permiso respectivo.

XVII. Liberación experimental: Es la introducción, intencional y permitida en el medio ambiente, de un organismo o combinación de organismos genéticamente modificados, siempre que hayan sido adoptadas medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas o biológicas, para limitar su contacto con la población y el medio ambiente, exclusivamente para fines experimentales, en los términos y condiciones que contenga el permiso respectivo.

XVIII. Liberación en programa piloto: Es la introducción, intencional y permitida en el medio ambiente, de un organismo o combinación de organismos genéticamente modificados, con o sin medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas o biológicas, para limitar su contacto con la población y el medio ambiente, que constituye la etapa previa a la liberación comercial de dicho organismo, dentro de las zonas autorizadas y en los términos y condiciones contenidos en el permiso respectivo.

XIX. Medio Ambiente: El conjunto de elementos naturales y artificiales o inducidos por el hombre que hacen posible la existencia y desarrollo de los seres humanos y demás organismos vivos que interactúan en un espacio y tiempo determinados, fuera del área de las instalaciones o del ámbito de la utilización confinada de organismos genéticamente modificados.

XX. Organismo: Cualquier entidad biológica viva capaz de reproducirse o de transferir o replicar material genético, quedando comprendidos en este concepto los organismos estériles, los microorganismos, los virus y los viroides, sean o no celulares. Los seres humanos no deben ser considerados organismos para los efectos de esta Ley.

XXI. Organismo genéticamente modificado: Cualquier organismo vivo, con excepción de los seres humanos, que ha adquirido una combinación genética novedosa, generada a través del uso específico de técnicas de la biotecnología moderna que se define en esta Ley, siempre que se utilicen técnicas que se establezcan en esta Ley o en las normas oficiales mexicanas que deriven de la misma.

XXII. OGM u OGMs: Organismo u organismos genéticamente modificados.

XXIII. Paso a paso: Enfoque metodológico conforme al cual, todo OGM que esté destinado a ser liberado comercialmente debe ser previamente sometido a pruebas satisfactorias conforme a los estudios de riesgo, la evaluación de riesgos y los reportes de resultados aplicables en la realización de actividades

de liberación experimental y de liberación en programa piloto de dichos organismos, en los términos de esta Ley.

XXIV. Permiso: Es el acto administrativo que le corresponde emitir a la SEMARNAT o a la SAGARPA, en el ámbito de sus respectivas competencias conforme a esta Ley, necesario para la realización de la liberación experimental, la liberación en programa piloto, la liberación comercial y la importación de OGMs para realizar dichas actividades, en los casos y términos establecidos en esta Ley y en las normas oficiales mexicanas que de ella deriven.

XXV. Productos que contengan organismos genéticamente modificados: Son aquellos que contienen algún o algunos organismos genéticamente modificados en su composición para comercialización.

XXVI. Productos derivados: Son aquellos en los que hubieren intervenido organismos genéticamente modificados como insumos en su proceso de producción, incluyendo sus extractos, siempre que no contengan en su composición para su comercialización organismos genéticamente modificados vivos y que, por ello, no tienen la capacidad de transferir o replicar su material genético.

XXVII. Registro: El Registro Nacional de Bioseguridad de los Organismos Genéticamente Modificados.

XXVIII. Residuos: Cualquier material de desecho generado en la utilización confinada de organismos genéticamente modificados, incluidos los propios organismos genéticamente modificados.

XXIX. Secretarías: La Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, la Secretaría de Medio Ambiente y Recursos Naturales y la Secretaría de Salud, respecto de sus respectivos ámbitos de competencia establecidos en esta Ley.

XXX. SAGARPA: La Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación.

XXXI. SEMARNAT: La Secretaría de Medio Ambiente y Recursos Naturales.

XXXII. SHCP: La Secretaría de Hacienda y Crédito Público.

XXXIII. SSA: La Secretaría de Salud.

XXXIV. Utilización confinada: Cualquier actividad por la que se modifique el material genético de un organismo o por la que éste, así modificado, se cultive, almacene, emplee, procese, transporte, comercialice, destruya o elimine, siempre que en la realización de tales actividades se utilicen barreras físicas o una combinación de éstas con barreras químicas o biológicas, con el fin de limitar de manera efectiva su contacto con la población y con el medio ambiente. Para los efectos de esta Ley el área de las instalaciones o el ámbito de la utilización confinada no forma parte del medio ambiente.

XXXV. Zonas autorizadas: Las áreas o regiones geográficas que se determinen caso por caso en la resolución de un permiso, en las cuales se pueden liberar al ambiente organismos genéticamente modificados que se hubieren analizado.

XXXVI. Zonas restringidas: Los centros de origen, los centros de diversidad genética y las áreas naturales protegidas, dentro de los cuales se restrinja la realización de actividades con organismos genéticamente modificados, en los términos de esta Ley.

ARTÍCULO 4.- Es materia de esta Ley la bioseguridad de todos los OGMs obtenidos o producidos a través de la aplicación de las técnicas de la biotecnología moderna a que se refiere el presente ordenamiento, que se utilicen con fines agrícolas, pecuarios, acuícolas, forestales, industriales, comerciales, de biorremediación y cualquier otro, con las excepciones que establece esta Ley.

ARTÍCULO 5.- También es materia de esta Ley la autorización de los OGMs que se destinen a su uso o consumo humano o al procesamiento de alimentos para consumo humano, para poder realizar su comercialización e importación para su comercialización. Asimismo es materia de este ordenamiento la autorización de OGMs, distintos de los anteriores, que se destinen a una finalidad de salud pública o a la biorremediación.

ARTÍCULO 6.- Quedan excluidos del ámbito de aplicación de esta Ley:

I. Las actividades de utilización confinada, liberación experimental, liberación en programa piloto y liberación comercial, comercialización, importación y exportación de OGMs, cuando la modificación genética de dichos organismos se obtenga por técnicas de mutagénesis tradicional o de fusión celular, incluida la de protoplastos de células vegetales, en que los organismos resultantes puedan producirse también mediante métodos tradicionales de multiplicación o de cultivo in vivo o in vitro, siempre que estas técnicas no supongan la utilización de organismos genéticamente modificados como organismos receptores o parentales;

II. La utilización de las técnicas de fertilización in vitro, conjugación, transducción, transformación o cualquier otro proceso natural y la inducción poliploide, siempre que no se empleen moléculas de ácido desoxirribonucleico (ADN) recombinante ni de organismos genéticamente modificados;

III. La producción y proceso de medicamentos y fármacos con OGMs generados a partir de procesos confinados cuya regulación corresponde a la Ley General de Salud;

IV. El control sanitario de los productos derivados y los procesos productivos confinados en los que intervengan OGMs autorizados conforme a esta Ley, para uso o consumo humano o animal, los cuales quedan sujetos a las disposiciones de la Ley General de Salud y sus reglamentos aplicables a todos los productos y procesos;

V. El genoma humano, el cultivo de células troncales de seres humanos, la modificación de células germinales humanas y la bioseguridad de hospitales, cuya regulación corresponde a la Ley General de Salud, y a los Tratados Internacionales en los que los Estados Unidos Mexicanos sean parte;

VI. La colecta y el aprovechamiento de recursos biológicos, cuya regulación corresponde a la Ley General del Equilibrio Ecológico y la Protección al Ambiente, a la Ley General de Vida Silvestre, y a los Tratados Internacionales en los que los Estados Unidos Mexicanos sean parte, y

VII. La propiedad intelectual de los productos y procesos biotecnológicos, lo que es materia de la Ley de Propiedad Industrial, de la Ley Federal de Variedades Vegetales y de los Tratados Internacionales en los que los Estados Unidos Mexicanos sean parte.

ARTÍCULO 7.- Las actividades, organismos y productos sujetos al ámbito de esta Ley, no requerirán, en materia de bioseguridad e inocuidad, de otros permisos, autorizaciones, avisos y, en general, requisitos, trámites y restricciones que los establecidos en este ordenamiento.

Se exceptúa de lo dispuesto en el párrafo anterior:

I. Las medidas que en materia de salubridad general corresponda adoptar a la Secretaría de Salud en los términos de la Ley General de Salud y sus reglamentos, salvo en lo relativo a la tramitación y expedición de autorizaciones que regula esta Ley;

II. Las medidas que en materia de sanidad animal, vegetal y acuícola corresponda adoptar a la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, en los términos de la Ley

Federal de Sanidad Animal, de la Ley Federal de Sanidad Vegetal, de la Ley de Pesca, de la Ley de Desarrollo Rural Sustentable, y de las demás disposiciones aplicables, y

III. Las medidas que en materia ambiental corresponda adoptar a la Secretaría de Medio Ambiente y Recursos Naturales en los términos de la Ley General del Equilibrio Ecológico y la Protección al Ambiente, de la Ley General de Vida Silvestre, de la Ley General de Desarrollo Forestal Sustentable y de otras leyes aplicables en dicha materia, salvo en lo relativo a:

A) La evaluación del impacto ambiental y del estudio de riesgo regulados en la Sección V del Capítulo IV del Título Primero y en el Capítulo V del Título Cuarto, de la Ley General del Equilibrio Ecológico y la Protección al Ambiente, y

B) La tramitación y expedición de permisos y los demás instrumentos de control y monitoreo que regula esta Ley.

ARTÍCULO 8.- A falta de disposición expresa en el presente ordenamiento, se estará a lo establecido en la Ley Federal de Procedimiento Administrativo.

CAPÍTULO II
Principios en Materia de Bioseguridad

ARTÍCULO 9.- Para la formulación y conducción de la política de bioseguridad y la expedición de la reglamentación y de las normas oficiales mexicanas que deriven de esta Ley, se observarán los siguientes principios:

I. La Nación Mexicana es poseedora de una biodiversidad de las más amplias en el mundo, y en su territorio se encuentran áreas que son centro de origen y de diversidad genética de especies y variedades que deben ser protegidas, utilizadas, potenciadas y aprovechadas sustentablemente, por ser un valioso reservorio de riqueza en moléculas y genes para el desarrollo sustentable del país;

II. El Estado tiene la obligación de garantizar el derecho de toda persona a vivir en un medio ambiente adecuado para su alimentación, salud, desarrollo y bienestar;

III. La bioseguridad de los OGMs tiene como objetivo garantizar un nivel adecuado de protección en la esfera de la utilización confinada, la liberación experimental, la liberación en programa piloto, la liberación comercial, la comercialización, la importación y la exportación de dichos organismos resultantes de la biotecnología moderna que puedan tener efectos adversos para la conservación y utilización sustentable del medio ambiente y de la diversidad biológica, así como de la salud humana y de la sanidad animal, vegetal y acuícola;

IV. Con el fin de proteger el medio ambiente y la diversidad biológica, el Estado Mexicano deberá aplicar el enfoque de precaución conforme a sus capacidades, tomando en cuenta los compromisos establecidos en tratados y acuerdos internacionales de los que los Estados Unidos Mexicanos sean parte. Cuando haya peligro de daño grave o irreversible, la falta de certeza científica absoluta no deberá utilizarse como razón para postergar la adopción de medidas eficaces en función de los costos para impedir la degradación del medio ambiente y de la diversidad biológica. Dichas medidas se adoptarán de conformidad con las previsiones y los procedimientos administrativos establecidos en esta Ley;

V. La protección de la salud humana, del medio ambiente y de la diversidad biológica exigen que se preste la atención debida al control y manejo de los posibles riesgos derivados de las actividades con OGMs, mediante una evaluación previa de dichos riesgos y el monitoreo posterior a su liberación;

VI. Los conocimientos, las opiniones y la experiencia de los científicos, particularmente los del país, constituyen un valioso elemento de orientación para que la regulación y administración de las actividades con OGMs se sustenten en estudios y dictámenes científicamente fundamentados, por lo cual debe fomentarse la investigación científica y el desarrollo tecnológico en bioseguridad y en biotecnología;

VII. En la utilización confinada de OGMs con fines de enseñanza, investigación científica y tecnológica, industriales y comerciales, se deberán observar las disposiciones de esta Ley, sus reglamentos y las normas oficiales mexicanas que de ella deriven, así como las normas y principios de prevención que establezcan las propias instituciones, centros o empresas, sean públicos o privados, que realicen dichas actividades;

VIII. Los posibles riesgos que pudieran producir las actividades con OGMs a la salud humana y a la diversidad biológica se evaluarán caso por caso. Dicha evaluación estará sustentada en la mejor evidencia científica y técnica disponible;

IX. La liberación de OGMs en el ambiente debe realizarse "paso a paso" conforme a lo cual, todo OGM que esté destinado a ser liberado comercialmente debe ser previamente sometido a pruebas satisfactorias conforme a los estudios de riesgo, la evaluación de riesgos y los reportes de resultados aplicables en la realización de actividades de liberación experimental y de liberación en programa piloto de dichos organismos, en los términos de esta Ley;

X. Deben ser monitoreados los efectos adversos que la liberación de los OGMs pudieran causar a la diversidad biológica, teniendo también en cuenta los posibles riesgos para la salud humana;

XI. Los procedimientos administrativos para otorgar permisos y autorizaciones para realizar actividades con OGMs, deben ser eficaces y transparentes; en la expedición de los reglamentos y las normas oficiales mexicanas que deriven de esta Ley, se deberán observar los compromisos establecidos en tratados y acuerdos internacionales en los que los Estados Unidos Mexicanos sean parte, de manera que su contenido y alcances sean compatibles con dichos tratados y acuerdos;

XII. Es necesario apoyar el desarrollo tecnológico y la investigación científica sobre organismos genéticamente modificados que puedan contribuir a satisfacer las necesidades de la Nación;

XIII. Para el análisis de soluciones a problemas particulares se evaluarán caso por caso los beneficios y los posibles riesgos del uso de OGMs. Este análisis podrá también incluir la evaluación de los riesgos de las opciones tecnológicas alternas para contender con la problemática específica para la cual el OGM fue diseñado. Dicho análisis comparativo deberá estar sustentado en la evidencia científica y técnica, así como en antecedentes sobre uso, producción y consumo, y podrá ser elemento adicional al estudio de evaluación del riesgo para decidir, de manera casuística, sobre la liberación al medio ambiente del OGM de que se trate;

XIV. Se deberá contar con la capacidad y con la normativa adecuadas para evitar la liberación accidental al medio ambiente de OGMs provenientes de residuos de cualquier tipo de procesos en los que se hayan utilizado dichos organismos;

XV. La aplicación de esta Ley, los procedimientos administrativos y criterios para la evaluación de los posibles riesgos que pudieran generar las actividades que regula esta Ley, los instrumentos de control de dichas actividades, el monitoreo de las mismas, sus reglamentos y las normas oficiales mexicanas que de ella deriven, los procedimientos de inspección y vigilancia para verificar y comprobar el cumplimiento de esta Ley y de las disposiciones que de ella deriven, la implantación de medidas de seguridad y de urgente aplicación, y la aplicación de sanciones por violaciones a los preceptos de esta Ley y las disposiciones que de ella emanen, son la forma en que el Estado Mexicano actúa con precaución, de manera prudente y con bases científicas y técnicas para prevenir, reducir o evitar los posibles riesgos que

las actividades con OGMs pudieran ocasionar a la salud humana o al medio ambiente y la diversidad biológica;

XVI. La bioseguridad de los productos agropecuarios, pesqueros y acuícolas se encuentra estrechamente relacionada con la sanidad vegetal, animal y acuícola, por lo que la política en estas materias deberá comprender los aspectos ambientales, de diversidad biológica, de salud humana y de sanidad vegetal y animal;

XVII. El Estado Mexicano cooperará en la esfera del intercambio de información e investigación sobre los efectos socioeconómicos de los OGMs, especialmente en las comunidades indígenas y locales;

XVIII. El Estado Mexicano garantizará el acceso público a la información en materia de bioseguridad y biotecnología a que se refiere esta Ley, de conformidad con lo establecido en este ordenamiento y en las disposiciones aplicables a la materia de acceso a la información pública gubernamental, y

XIX. La experimentación con OGMs o con cualquier otro organismo para fines de fabricación y/o utilización de armas biológicas queda prohibida en el territorio nacional.

CAPÍTULO III
De las Competencias en Materia de Bioseguridad

ARTÍCULO 10.- Son autoridades competentes en materia de bioseguridad:

I. La SEMARNAT;

II. La SAGARPA, y

III. La SSA.

La SHCP tendrá las facultades que se establecen en esta Ley, en lo relativo a la importación de OGMs y de productos que los contengan.

ARTÍCULO 11.- Corresponde a la SEMARNAT el ejercicio de las siguientes facultades respecto de actividades con todo tipo de OGMs, salvo cuando se trate de OGMs que correspondan a la SAGARPA:

I. Participar en la formulación y aplicar la política general de bioseguridad;

II. Analizar y evaluar caso por caso los posibles riesgos que las actividades con OGMs pudieran ocasionar al medio ambiente y a la diversidad biológica, con base en los estudios de riesgo y los reportes de resultados que elaboren y presenten los interesados, en los términos de esta Ley;

III. Resolver y expedir permisos para la realización de actividades de liberación al ambiente de OGMs, así como establecer y dar seguimiento a las condiciones y medidas a las que se deberán sujetar dichas actividades, conforme a las disposiciones del presente ordenamiento, incluyendo la liberación de OGMs para biorremediación;

IV. Realizar el monitoreo de los efectos que pudiera causar la liberación de OGMs, permitida o accidental, al medio ambiente y a la diversidad biológica, de conformidad con lo que dispongan esta Ley y las normas oficiales mexicanas que de ella deriven;

V. Participar en la elaboración y expedición de las listas a que se refiere esta Ley;

VI. Suspender los efectos de los permisos, cuando disponga de información científica y técnica de la que se deduzca que la actividad permitida supone riesgos superiores a los previstos, que puedan afectar negativamente al medio ambiente, a la diversidad biológica o a la salud humana o la sanidad animal, vegetal o acuícola. Estos dos últimos supuestos, a solicitud expresa de la SAGARPA o de la SSA, según su competencia conforme a esta Ley, con apoyo en elementos técnicos y científicos;

VII. Ordenar y aplicar las medidas de seguridad o de urgente aplicación pertinentes, con bases científicas y técnicas y en el enfoque de precaución, en los términos de esta Ley;

VIII. Inspeccionar y vigilar el cumplimiento de la presente Ley, sus reglamentos y las normas oficiales mexicanas que deriven de la misma;

IX. Imponer sanciones administrativas a las personas que infrinjan los preceptos de esta Ley, sus reglamentos y las normas oficiales mexicanas que de ella deriven, sin perjuicio, en su caso, de las penas que correspondan cuando los actos u omisiones constitutivos de infracciones a este ordenamiento sean también constitutivos de delito, y de la responsabilidad civil y ambiental que pudiera resultar, y

X. Las demás que esta Ley le confiere.

ARTÍCULO 12.- Corresponde a la SAGARPA el ejercicio de las facultades que le confiere esta Ley, cuando se trate de actividades con OGMs en los casos siguientes:

I. Vegetales que se consideren especies agrícolas, incluyendo semillas, y cualquier otro organismo o producto considerado dentro del ámbito de aplicación de la Ley Federal de Sanidad Vegetal, con excepción de las especies silvestres y forestales reguladas por la Ley General de Vida Silvestre y la Ley General de Desarrollo Forestal Sustentable, respectivamente, y aquellas que se encuentren bajo algún régimen de protección por normas oficiales mexicanas derivadas de esas leyes;

II. Animales que se consideren especies ganaderas y cualquier otro considerado dentro del ámbito de aplicación de la Ley Federal de Sanidad Animal, con excepción de las especies silvestres reguladas por la Ley General de Vida Silvestre y aquellas que se encuentren bajo algún régimen de protección por normas oficiales mexicanas derivadas de esas leyes;

III. Insumos fitozoosanitarios y de nutrición animal y vegetal;

IV. Especies pesqueras y acuícolas, con excepción de aquellas que se encuentren bajo algún régimen de protección por normas oficiales mexicanas;

V. OGMs que se utilicen en la inmunización para proteger y evitar la diseminación de las enfermedades de los animales;

VI. OGMs que sean hongos, bacterias, protozoarios, virus, viroides, espiroplasmas, fitoplasmas, y otros microorganismos, que tengan fines productivos agrícolas, pecuarios, acuícolas o fitozoosanitarios, y

VII. En los demás organismos y productos que determine el reglamento de esta Ley.

ARTÍCULO 13.- En los casos establecidos en el artículo anterior, corresponde a la SAGARPA el ejercicio de las siguientes atribuciones:

I. Participar en la formulación y aplicar la política general de bioseguridad;

II. Analizar y evaluar caso por caso los posibles riesgos que las actividades con OGMs pudieran ocasionar a la sanidad animal, vegetal y acuícola, así como al medio ambiente y a la diversidad biológica,

con base en los estudios de riesgo y los reportes de resultados que elaboren y presenten los interesados, en los términos de esta Ley;

III. Resolver y expedir permisos para la realización de actividades con OGMs, así como establecer y dar seguimiento a las condiciones y medidas a las que se deberán sujetar dichas actividades, conforme a las disposiciones del presente ordenamiento;

IV. Realizar el monitoreo de los efectos que pudiera causar la liberación de OGMs, permitida o accidental, a la sanidad animal, vegetal y acuícola, y a la diversidad biológica, de conformidad con lo que dispongan esta Ley y las normas oficiales mexicanas que de ella deriven;

V. Participar en la elaboración y expedición de las listas a que se refiere esta Ley;

VI. Suspender los efectos de los permisos, cuando disponga de información científica y técnica superveniente de la que se deduzca que la actividad permitida supone riesgos superiores a los previstos, que puedan afectar negativamente a la sanidad animal, vegetal o acuícola, a la diversidad biológica o a la salud humana. Estos dos últimos supuestos, a solicitud expresa de la SEMARNAT o de la SSA, según sea su competencia conforme a esta Ley, con apoyo en elementos técnicos y científicos;

VII. Ordenar y aplicar las medidas de seguridad o de urgente aplicación pertinentes, con bases técnicas y científicas y en el enfoque de precaución, en los términos de esta Ley;

VIII. Inspeccionar y vigilar el cumplimiento de la presente Ley, sus reglamentos y las normas oficiales mexicanas que deriven de la misma;

IX. Imponer sanciones administrativas a las personas que infrinjan los preceptos de esta Ley, sus reglamentos y las normas oficiales mexicanas que de ella deriven, sin perjuicio, en su caso, de las penas que correspondan cuando los actos u omisiones constitutivos de infracciones a este ordenamiento sean también constitutivos de delito, y de la responsabilidad civil que pudiera resultar, y

X. Las demás que esta Ley le confiere.

ARTÍCULO 14.- En los casos en que a la SEMARNAT le corresponda el conocimiento, tramitación y resolución de una solicitud de permiso, tratándose de especies silvestres y forestales, deberá remitir el expediente respectivo a la SAGARPA para que emita la opinión que corresponda.

ARTÍCULO 15.- En los casos que son competencia de la SAGARPA, a la SEMARNAT le corresponderá lo siguiente:

I. Emitir el dictamen de bioseguridad que corresponda, previo a la resolución de la SAGARPA, como resultado del análisis y evaluación de riesgos que realice con base en el estudio que elaboren y presenten los interesados, sobre los posibles riesgos que la actividad con OGMs de que se trate pueda causar al medio ambiente y a la diversidad biológica, cuando se trate de solicitudes de permisos para liberación experimental de dichos organismos, o con base en los reportes de resultados y la información que adjunten los interesados a sus solicitudes de permisos para liberación en programa piloto y para liberación comercial;

II. Requerir a la SAGARPA la suspensión de los efectos de los permisos que expida dicha Secretaría, cuando disponga de información científica y técnica de la que se deduzca que la liberación permitida supone riesgos superiores a los previstos que pueden afectar negativamente el medio ambiente y la diversidad biológica, y

III. El ejercicio de las facultades establecidas en las fracciones I, II, IV, V, VII y VIII del artículo 11 de esta Ley.

El dictamen de bioseguridad a que se refiere la fracción I de este artículo tendrá carácter vinculante, previo al otorgamiento de los permisos que le corresponda emitir a la SAGARPA, y se expedirá en los términos del artículo 66 de esta Ley.

ARTÍCULO 16.- Corresponde a la SSA el ejercicio de las siguientes facultades en relación con los OGMs:

I. Participar en la formulación y aplicar la política general de bioseguridad;

II. Evaluar caso por caso los estudios que elaboren y presenten los interesados sobre la inocuidad y los posibles riesgos de los OGMs sujetos a autorización en los términos del Título Quinto de esta Ley;

III. Resolver y expedir las autorizaciones de OGMs a que se refiere la fracción anterior;

IV. Participar en la elaboración y expedición de las listas a que se refiere esta Ley;

V. Ordenar y aplicar las medidas de seguridad o de urgente aplicación pertinentes, con bases técnicas y científicas y en el enfoque de precaución, en los términos de esta Ley;

VI. Solicitar a la SEMARNAT o a la SAGARPA, según se trate, con apoyo en elementos técnicos y científicos, la suspensión de los efectos de los permisos de liberación al ambiente de OGMs, cuando disponga de información de la que se deduzca que la actividad permitida por esas Secretarías supone riesgos superiores a los previstos que pudieran afectar a la salud humana;

VII. Inspeccionar y vigilar el cumplimiento de la presente Ley, sus reglamentos y normas oficiales mexicanas;

VIII. Imponer sanciones administrativas a las personas que infrinjan los preceptos de esta Ley, sus reglamentos y las normas oficiales mexicanas que deriven de esta Ley, sin perjuicio, en su caso, de las penas que correspondan cuando los actos u omisiones constitutivos de infracciones a este ordenamiento sean también constitutivos de delito, y de la responsabilidad civil que pudiera resultar, y

IX. Las demás que esta Ley le confiere.

La SSA realizará las acciones de vigilancia sanitaria y epidemiológica de los OGMs y de los productos que los contengan y de los productos derivados, de conformidad con la Ley General de Salud y sus disposiciones reglamentarias.

ARTÍCULO 17.- En caso de liberación accidental de OGMs, las Secretarías se coordinarán para que, en el ámbito de sus respectivas competencias conforme a esta Ley, impongan las medidas necesarias para evitar afectaciones negativas a la diversidad biológica, a la salud humana o a la sanidad animal, vegetal y acuícola, según se trate.

ARTÍCULO 18.- Corresponde a la SHCP el ejercicio de las siguientes facultades, respecto de la importación de OGMs y de productos que los contengan:

I. Revisar en las aduanas de entrada del territorio nacional, que los OGMs que se importen y destinen a su liberación al ambiente o a las finalidades establecidas en el artículo 91 de esta Ley, cuenten con el permiso y/o la autorización respectiva, según sea el caso en los términos de este ordenamiento;

II. Revisar que la documentación que acompañe a los OGMs que se importen al país, contenga los requisitos de identificación establecidos en las normas oficiales mexicanas que deriven de esta Ley;

III. Participar, de manera conjunta con las Secretarías, en la expedición de normas oficiales mexicanas relativas al almacenamiento o depósito de OGMs o de productos que los contengan en los recintos aduaneros del territorio nacional;

IV. Dar aviso inmediato a la SEMARNAT, a la SAGARPA y/o a la SSA, sobre la probable comisión de infracciones a los preceptos de esta Ley, en materia de importación de OGMs, y

V. Impedir la entrada al territorio nacional de OGMs y productos que los contengan, en los casos en que dichos organismos y productos no cuenten con permiso y/o autorización, según corresponda, para su importación, conforme a esta Ley.

La SHCP ejercerá las facultades anteriores, sin perjuicio de las que le confiera la legislación aduanera, aplicables a la importación de todas las mercancías.

CAPÍTULO IV
De la Coordinación y Participación

ARTÍCULO 19.- La CIBIOGEM es una Comisión Intersecretarial que tiene por objeto formular y coordinar las políticas de la Administración Pública Federal relativas a la bioseguridad de los OGMs, la cual tendrá las funciones que establezcan las disposiciones reglamentarias que deriven de esta Ley, conforme a las siguientes bases:

I. La CIBIOGEM estará integrada por los titulares de las Secretarías de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación; Medio Ambiente y Recursos Naturales; Salud; Educación Pública; Hacienda y Crédito Público, y Economía, así como por el Director General del CONACyT;

II. La CIBIOGEM tendrá una Presidencia que será rotatoria entre los titulares de las Secretarías de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, de Medio Ambiente y Recursos Naturales y de Salud, y cuyo ejercicio, funciones y duración se determinarán en las disposiciones reglamentarias correspondientes. También habrá una Vicepresidencia cuyo titular será el Director General del CONACyT, quien presidirá las sesiones en ausencia del Presidente, coadyuvará con la Comisión y con el Secretario Ejecutivo en el ejercicio de sus funciones y realizará las actividades que le encomiende la propia CIBIOGEM en los términos que establezcan las disposiciones reglamentarias que deriven de la presente Ley;

III. La CIBIOGEM podrá invitar a otras dependencias a participar, con voz, en los acuerdos y decisiones de los asuntos que tengan relación con su objeto, así como a los miembros del Consejo Consultivo;

IV. La CIBIOGEM contará con un Secretario Ejecutivo que será designado por el Presidente de la República, a propuesta del Director General del CONACyT, aprobada por la propia CIBIOGEM. Tendrá las atribuciones y facultades que se determinen en las disposiciones reglamentarias que deriven de este ordenamiento, y ejecutará y dará seguimiento a los acuerdos de la propia Comisión y ejercerá las demás funciones que se le encomienden;

V. La Secretaría Ejecutiva de la CIBIOGEM contará con la estructura orgánica que se apruebe en los términos de las disposiciones aplicables, y será considerada una unidad administrativa por función del CONACyT, de conformidad con la Ley Orgánica de dicha entidad paraestatal, y

VI. La CIBIOGEM también contará con un Comité Técnico integrado por los coordinadores, directores generales o equivalentes competentes en la materia que designen los titulares de las dependencias y entidades que formen parte de la CIBIOGEM. Dicho Comité podrá proponer la creación de subcomités especializados para la atención de asuntos específicos y tendrá las atribuciones que se determinen en las disposiciones reglamentarias que deriven de esta Ley.

ARTÍCULO 20.- Se crea el Consejo Consultivo Científico de la CIBIOGEM que fungirá como órgano de consulta obligatoria de la propia CIBIOGEM en aspectos técnicos y científicos en biotecnología moderna y bioseguridad de OGMs. Se integrará por un conjunto de personas expertas en diferentes disciplinas, provenientes de centros, instituciones de investigación, academias o sociedades científicas de reconocido prestigio, que ejercerán su función a título personal, con independencia de la institución, asociación o empresa de la que formen parte o en la que presten sus servicios. Dichas personas expertas manifestarán expresamente en carta compromiso, al momento de ser designadas como integrantes del Consejo Consultivo Científico, no tener ningún conflicto de interés.

La selección de las personas integrantes del Consejo Consultivo Científico se realizará mediante convocatoria pública que emitan conjuntamente el CONACyT y el Foro Consultivo Científico y Tecnológico previsto en la Ley de Ciencia y Tecnología, garantizando el principio de paridad de género. Entre las funciones del Consejo Consultivo se preverá la formulación de protocolos de investigación, análisis y metodologías y dictámenes técnicos, que podrán ser remunerados. Las funciones específicas del Consejo Consultivo y los mecanismos para que la renovación de sus integrantes sea progresiva y escalonada, se establecerán en las disposiciones reglamentarias que deriven de esta Ley. Los dictámenes técnicos que emita el Consejo Consultivo Científico deberán ser considerados por la CIBIOGEM en las decisiones que adopte.

Artículo reformado DOF 11-05-2022

ARTÍCULO 21.- Se crea el Consejo Consultivo Mixto de la CIBIOGEM que fungirá como órgano auxiliar de consulta y opinión de la propia CIBIOGEM. Se integrará garantizando el principio de paridad de género, por representantes de asociaciones, cámaras o empresas de los sectores privado, social y productivo. Su función fundamental será conocer y opinar sobre aspectos sociales, económicos, y otros aspectos relativos a las políticas regulatorias y de fomento, así como sobre las prioridades en la normalización y el mejoramiento de trámites y procedimientos en materia de bioseguridad de los OGMs. Las funciones específicas del Consejo Consultivo Mixto y los mecanismos para la incorporación de sus integrantes serán establecidas por la CIBIOGEM.

Artículo reformado DOF 11-05-2022

ARTÍCULO 22.- La CIBIOGEM emitirá sus reglas de operación en las que se establecerán los mecanismos de participación para que integrantes y representantes de los sectores académico, científico, tecnológico, social y productivo, de reconocido prestigio y experiencia en los temas relacionados directamente con las actividades que son materia de esta Ley, puedan participar mediante opiniones, estudios y consultas en el conocimiento y evolución de las políticas de bioseguridad y de fomento de la investigación en bioseguridad y biotecnología, así como también para recibir opiniones, estudios y consultas en dichas materias.

ARTÍCULO 23.- El CONACyT contará en su presupuesto con los recursos necesarios para el desarrollo de las actividades de la CIBIOGEM, de la Secretaría Ejecutiva y del Consejo Consultivo Científico, conforme al presupuesto que se autorice en los términos de las disposiciones aplicables. Dichos recursos serán administrados y ejercidos por el Secretario Ejecutivo de la CIBIOGEM.

Los programas, proyectos, apoyos, así como las demás acciones que se lleven a cabo por la aplicación de la presente Ley y demás disposiciones en la materia, en los que se ejerzan recursos de carácter federal, se sujetarán a la disponibilidad de recursos que se determinen para tal fin en el

Presupuesto de Egresos de la Federación del ejercicio fiscal correspondiente, y deberán observar las disposiciones aplicables en materia presupuestaria.

ARTÍCULO 24.- Las Secretarías podrán establecer comités técnicos científicos que les proporcionen apoyo en la resolución de expedientes de solicitudes de permisos y autorizaciones, así como en materia de avisos. Las disposiciones reglamentarias de esta Ley determinarán las bases de organización y funcionamiento de dichos comités.

CAPÍTULO V
De la Coordinación con las Entidades Federativas

ARTÍCULO 25.- La Federación, por conducto de las Secretarías en el ámbito de su competencia y en los términos de las disposiciones aplicables, con el conocimiento de la CIBIOGEM, podrá celebrar convenios o acuerdos de coordinación con los gobiernos de las entidades federativas, con el objeto de:

I. Establecer la colaboración concurrente en el monitoreo de los riesgos que pudieran ocasionar las actividades de liberación de OGMs al ambiente, sea experimental o en programa piloto, que se determinen en dichos convenios o acuerdos, y

II. En su caso, en la realización de acciones para la vigilancia del cumplimiento de las disposiciones de esta Ley.

ARTÍCULO 26.- Los convenios o acuerdos de coordinación que suscriban la Federación con los gobiernos de las entidades federativas para los propósitos a que se refiere el artículo anterior, deberán ajustarse a las disposiciones aplicables y a las siguientes bases:

I. Definirán con precisión las materias y actividades que constituyan el objeto del convenio o acuerdo;

II. El propósito de los convenios o acuerdos deberá ser congruente con la política en materia de bioseguridad;

III. Se describirán los bienes y recursos que aporten las partes esclareciendo cuál será su destino específico y su forma de administración, para lo cual la Federación contribuirá al fortalecimiento de sus capacidades financieras e institucionales;

IV. Se determinarán los medios, procedimientos y recursos necesarios que aporten las Secretarías competentes, con la finalidad de que los gobiernos de las entidades federativas puedan realizar las acciones y las actividades objeto de los convenios o acuerdos de coordinación;

V. Se especificará la vigencia del convenio o acuerdo, sus formas de terminación y de solución de controversias y, en su caso, de prórroga;

VI. Definirán el órgano u órganos que llevarán a cabo las acciones que resulten de los convenios o acuerdos de coordinación;

VII. Determinarán las acciones para promover y participar conjuntamente en el apoyo a la investigación científica y tecnológica en bioseguridad y biotecnología;

VIII. Se establecerá la obligación de presentar informes detallados sobre el cumplimiento del objeto de los convenios y acuerdos de coordinación, y

IX. Contendrán las demás estipulaciones que las partes consideren necesarias para el correcto cumplimiento del convenio o acuerdo.

Los convenios a que se refiere este artículo deberán publicarse en el **Diario Oficial de la Federación** y en el órgano de difusión oficial del gobierno local respectivo.

ARTÍCULO 27.- Los gobiernos de las entidades federativas tendrán acceso permanente a la información que se inscriba en el Registro Nacional de Bioseguridad de los Organismos Genéticamente Modificados. Asimismo, la CIBIOGEM, por conducto de su Secretaría Ejecutiva, notificará las solicitudes de permisos de liberación comercial al ambiente de OGMs, a los gobiernos de las entidades federativas en las que se pretenda llevar a cabo dicha actividad, a efecto de que tengan conocimiento de esa situación y puedan emitir sus opiniones en los términos de esta Ley. La notificación deberá realizarse dentro de los veinte días siguientes a aquel en que la CIBIOGEM haya recibido la solicitud de permiso correspondiente para su inscripción en el Registro.

CAPÍTULO VI
Del Fomento a la Investigación Científica y Tecnológica en Bioseguridad y Biotecnología

ARTÍCULO 28.- El Ejecutivo Federal fomentará, apoyará y fortalecerá la investigación científica y tecnológica en materia de bioseguridad y de biotecnología a través de las políticas y los instrumentos establecidos en esta Ley y en la Ley de Ciencia y Tecnología. En materia de biotecnología, estos apoyos se orientarán a impulsar proyectos de investigación y desarrollo e innovación, formación de recursos humanos especializados y fortalecimiento de grupos e infraestructura de las universidades, instituciones de educación superior y centros públicos de investigación, que se lleven a cabo para resolver necesidades productivas específicas del país y que beneficien directamente a los productores nacionales.

En materia de bioseguridad se fomentará la investigación para obtener conocimientos suficientes que permitan evaluar los posibles riesgos de los OGMs en el medio ambiente, la diversidad biológica, la salud humana y la sanidad animal, vegetal y acuícola; para generar las consideraciones socioeconómicas de los efectos de dichos organismos para la conservación y el aprovechamiento de la diversidad biológica, y para valorar y comprobar la información proporcionada por los promoventes. Asimismo, se impulsará la creación de capacidades humanas, institucionales y de infraestructura para la evaluación y monitoreo de riesgos.

ARTÍCULO 29.- Para lograr el fomento a la investigación científica y tecnológica en materia de bioseguridad y de biotecnología se establecerá un programa para el desarrollo de la bioseguridad y la biotecnología que será considerado como un programa cuya formulación estará a cargo del CONACyT con base en las propuestas que presenten las Secretarías y las demás dependencias y entidades de la Administración Pública Federal que apoyen o realicen investigación científica y desarrollo tecnológico. En dicho proceso se tomarán en cuenta las opiniones y propuestas de las comunidades científica, académica, tecnológica y sector productivo, convocadas por el Foro Consultivo Científico y Tecnológico, y de la CIBIOGEM.

Dicho programa formará parte del Programa Especial de Ciencia y Tecnología que establece la Ley de Ciencia y Tecnología.

ARTÍCULO 30.- El programa para el desarrollo de la bioseguridad y la biotecnología deberá contener, cuando menos, diagnósticos, políticas, estrategias y acciones generales y sectoriales en cuanto a:

I. Investigación científica;

II. Innovación y desarrollo tecnológico;

III. Formación de investigadores, tecnólogos y profesionales de alto nivel;

IV. Apoyo a los centros públicos de investigación;

V. Proyectos de investigación científica y de innovación y desarrollo tecnológico orientados a la solución de problemas nacionales y en actividades que redunden en beneficio para los productores agropecuarios, forestales y acuícolas del país;

VI. Nuevos centros de investigación y transferencia tecnológica en áreas primordiales del desarrollo nacional, de acuerdo con las necesidades locales o regionales de conservación y protección ambiental o de producción silvícola, agropecuaria e industrial;

VII. Difusión del conocimiento científico y tecnológico;

VIII. Colaboración nacional e internacional;

IX. Fortalecimiento de la cultura de la bioseguridad, y

X. Descentralización y desarrollo regional.

El Ejecutivo Federal, por conducto de las Secretarías competentes, se asegurará de poner a disposición de las empresas semilleras de las organizaciones de campesinos y de productores, de manera preferente y accesible, los resultados de la investigación científica y de innovación y desarrollo tecnológico contenidos en el Programa para el desarrollo de la bioseguridad y la biotecnología.

ARTÍCULO 31.- El CONACyT llevará a cabo las acciones de Fomento y Apoyo a la Investigación Científica y Tecnológica en Bioseguridad y Biotecnología de conformidad con lo dispuesto en la presente Ley, en la Ley de Ciencia y Tecnología, y demás disposiciones aplicables.

Artículo reformado DOF 06-11-2020

TÍTULO SEGUNDO
De los Permisos

CAPÍTULO I
Disposiciones Comunes

ARTÍCULO 32.- Requerirá de permiso la realización de las siguientes actividades:

I. La liberación experimental al ambiente, incluyendo la importación para esa actividad, de uno o más OGMs;

II. La liberación al ambiente en programa piloto, incluyendo la importación para esa actividad, de OGMs, y

III. La liberación comercial al ambiente, incluyendo la importación para esa actividad, de OGMs.

ARTÍCULO 33.- Una vez que las Secretarías correspondientes reciban una solicitud de permiso de liberación al ambiente de OGMs, y siempre y cuando cumpla con la información y los requisitos establecidos en esta Ley, deberán remitirla al Registro, para su inscripción y publicidad respectivas. Una vez realizado lo anterior, la Secretaría a la que le corresponda resolver la solicitud de permiso de liberación de OGMs al ambiente, pondrá a disposición del público dicha solicitud, para su consulta

pública, debiendo observar las previsiones sobre confidencialidad establecidas en esta Ley. Dicha Secretaría podrá hacer uso de los medios que considere idóneos a efecto de poner a disposición del público la solicitud del permiso respectivo.

Cualquier persona, incluyendo a los gobiernos de las entidades federativas en las que se pretenda realizar la liberación respectiva, podrá emitir su opinión, que deberá estar sustentada técnica y científicamente, en un plazo no mayor de veinte días hábiles contados a partir de la fecha en que la solicitud respectiva sea puesta a disposición del público en los términos de este artículo.

Las opiniones que se emitan de conformidad con lo establecido en el párrafo anterior serán consideradas por las Secretarías correspondientes para el establecimiento de medidas de bioseguridad adicionales, en caso de que proceda expedir el permiso de liberación de OGMs al ambiente que corresponda, en los términos de esta Ley.

ARTÍCULO 34.- La Secretaría correspondiente expedirá su resolución, debidamente fundada y motivada, una vez analizada la información y documentación aportados por el interesado, el dictamen o la opinión que hubieran expedido las Secretarías a las que les corresponde emitirlos de conformidad con esta Ley y, cuando proceda, la autorización del OGM que expida la SSA en los términos de este ordenamiento. La Secretaría correspondiente en su resolución podrá:

I. Expedir el permiso para la realización de la actividad de liberación al ambiente de que se trate, pudiendo establecer medidas de monitoreo, control, prevención y seguridad adicionales a las que fueron propuestas por el interesado en la solicitud del permiso, o

II. Negar el permiso en los siguientes casos:

A) Cuando la solicitud no cumpla con lo establecido en esta Ley o las normas oficiales mexicanas como requisitos para el otorgamiento del permiso;

B) Cuando la información proporcionada por el interesado, incluyendo la relativa a los posibles riesgos que pudieran ocasionar los OGMs sea falsa, esté incompleta o sea insuficiente, o

C) Cuando la Secretaría correspondiente concluya que los riesgos que pudieran presentar los OGMs de que se trate, afectarán negativamente a la salud humana o a la diversidad biológica, o a la sanidad animal, vegetal o acuícola, pudiéndoles causar daños graves o irreversibles.

ARTÍCULO 35.- Los plazos establecidos en esta Ley para la resolución de una solicitud de permiso de liberación al ambiente de OGMs, sea experimental o en programa piloto, serán prorrogables, en caso de que el interesado no cuente con la autorización expedida por la SSA en los términos de este ordenamiento, siempre y cuando dicha autorización sea requisito para la expedición del permiso respectivo.

ARTÍCULO 36.- Los permisos para liberación experimental, en programa piloto o comercial de OGMs al ambiente, surtirán efectos de permisos de importación de dichos organismos para ser liberados en forma experimental, en programa piloto o comercial, según sea el caso, en los términos y condiciones que se establezcan en los propios permisos. Lo anterior, sin perjuicio de que la importación de los OGMs de que se trate, quede sujeta al régimen fitosanitario o acuícola establecido en la legislación de la materia que corresponda.

ARTÍCULO 37.- Las medidas de monitoreo, prevención, control y seguridad de los posibles riesgos de la utilización del OGM que establezca la Secretaría correspondiente en los permisos, podrán comprender entre otros, los siguientes aspectos:

I. Manejo del OGM;

II. Medidas de seguridad para que el posible riesgo se mantenga dentro de los límites de tolerancia aceptados en la evaluación, y

III. Monitoreo de la actividad de que se trate, en relación con los posibles riesgos que dicha actividad pudiera generar.

ARTÍCULO 38.- La Secretaría que expida el permiso podrá modificar las medidas de monitoreo, control y prevención, requerir al interesado la implantación de nuevas medidas, así como suspender o revocar dicho permiso, previa audiencia que se otorgue a los interesados, cuando disponga de información científica o técnica de la que se deduzca que la actividad puede suponer riesgos superiores o inferiores a los previstos originalmente en los estudios correspondientes. Lo anterior deberá ser establecido en los permisos que expidan las Secretarías competentes.

ARTÍCULO 39.- El titular del permiso estará obligado a observar y cumplir las medidas de monitoreo, prevención, control y seguridad que establezca el permiso, así como las disposiciones de este ordenamiento, sus reglamentos y las normas oficiales mexicanas que de él deriven, que resulten aplicables a la liberación de que se trate. El incumplimiento de las medidas y disposiciones a que se refiere este artículo, dará lugar a la determinación de la responsabilidad respectiva y a la aplicación de las sanciones que correspondan conforme esta Ley.

ARTÍCULO 40.- No se permitirá la importación de OGMs o de productos que los contengan al territorio nacional, en los casos en que dichos organismos se encuentren prohibidos en el país de origen o se encuentren clasificados en las listas como no permitidos para su liberación comercial o para su importación para esa actividad.

ARTÍCULO 41.- Se prohíbe realizar actividades con OGMs o con cualquier otro organismo cuya finalidad sea la fabricación y/o utilización de armas biológicas.

CAPÍTULO II
Requisitos para la Obtención de Permisos

SECCIÓN I
Permiso para liberación experimental al ambiente

ARTÍCULO 42.- La solicitud del permiso para realizar la liberación experimental al ambiente de OGMs, incluyendo su importación para esa actividad, deberá acompañarse de la siguiente información:

I. Caracterización del OGM, en la que se deberá considerar lo que establezcan para cada caso las normas oficiales mexicanas que deriven de esta Ley;

II. La identificación de la zona donde se pretende liberar experimentalmente el OGM, incluyendo la especificación de la superficie total en la que se realizará la liberación;

III. Un estudio de los posibles riesgos que la liberación de los OGMs pudiera generar al medio ambiente y a la diversidad biológica. Además, en los casos que sean de la competencia de la SAGARPA, el estudio deberá contener lo relativo a los posibles riesgos que la liberación de dichos organismos pudieran causar a la sanidad animal, vegetal o acuícola;

IV. Las medidas y procedimientos de monitoreo de la actividad y de bioseguridad, que se llevarán a cabo al momento de realizarla y las posteriores a la liberación;

V. En su caso, los antecedentes de liberación de los OGMs de que se trate en otros países;

VI. En su caso, se presentarán consideraciones sobre los riesgos de las alternativas tecnológicas con las que se cuente para contender con el problema para el cual se construyó el organismo genéticamente modificado que se pretende liberar, y

VII. La información que para cada caso determinen las normas oficiales mexicanas que deriven de esta Ley.

Será requisito para obtener el permiso de liberación experimental al ambiente, que el solicitante cuente con la autorización del OGM que expida la SSA de conformidad con esta Ley, cuando dicho organismo tenga finalidades de salud pública o se destine a la biorremediación. El interesado podrá iniciar el trámite para obtener dicho permiso ante la Secretaría competente, pero no le será otorgado hasta que acredite en el expediente respectivo haber obtenido la autorización de la SSA.

ARTÍCULO 43.- Los interesados en importar OGMs para su liberación experimental al ambiente, además de lo establecido en el artículo anterior, deberán adjuntar a su solicitud la información y documentación que acredite que el OGM esté permitido conforme la legislación del país de origen, para su liberación, al menos, en etapa experimental, adjuntando para tales efectos la autorización o documentación oficial que ampare dicha situación.

ARTÍCULO 44.- La resolución a una solicitud de permiso para liberación experimental de OGMs deberá expedirse en un plazo máximo de seis meses contados a partir del día siguiente a aquel en que la Secretaría que deba resolver haya recibido la solicitud del permiso y la información aportada por el interesado esté completa.

ARTÍCULO 45.- En caso de que, con posterioridad al otorgamiento del permiso, en la realización de la liberación experimental de un OGM al ambiente se presente lo siguiente:

I. Se produzca cualquier modificación en la liberación que pueda incrementar o disminuir los posibles riesgos para el medio ambiente y la diversidad biológica, o

II. Se disponga de nueva información científica y técnica sobre dichos riesgos.

En estos casos, el titular del permiso estará obligado a:

A. Informar a la Secretaría correspondiente, de manera inmediata, dicha situación;

B. Revisar las medidas de monitoreo y de bioseguridad especificadas en la documentación, y

C. Adoptar las medidas de bioseguridad necesarias.

ARTÍCULO 46.- El titular del permiso de liberación experimental al ambiente, deberá informar a la Secretaría que lo expidió, mediante un reporte, los resultados de la o las liberaciones realizadas en relación con los posibles riesgos para el medio ambiente y la diversidad biológica. Las características y contenido del reporte a que se refiere este artículo se establecerán en las normas oficiales mexicanas que deriven de esta Ley.

ARTÍCULO 47.- El titular del permiso estará obligado a informar inmediatamente a la Secretaría correspondiente, cualquier situación que en la realización de la liberación permitida, pudiera incrementar o disminuir los posibles riesgos para el medio ambiente, la diversidad biológica y/o la salud humana.

ARTÍCULO 48.- La Secretaría correspondiente podrá limitar la vigencia del permiso de liberación experimental al ambiente considerando los elementos del expediente.

ARTÍCULO 49.- Las liberaciones experimentales al ambiente de OGMs se realizarán al amparo y conforme a los términos y condiciones que establezca el permiso. En caso de que dicho permiso comprenda la realización de diversas liberaciones del mismo OGM en la misma área geográfica establecida en el permiso, en el mismo se podrá establecer el requisito de aviso de cada liberación.

SECCIÓN II
Permiso para liberación al ambiente en programa piloto

ARTÍCULO 50.- La solicitud del permiso para realizar la liberación al ambiente de OGMs en programa piloto, incluyendo su importación para esa actividad, deberá acompañarse de la siguiente información:

I. El permiso para la liberación experimental del OGM de que se trate;

II. Referencia y consideraciones sobre el reporte de los resultados de la o las liberaciones experimentales realizadas en relación con los posibles riesgos al medio ambiente y la diversidad biológica y, adicionalmente, a la sanidad animal, vegetal o acuícola en los casos que sean competencia de la SAGARPA conforme a esta Ley;

III. Información relativa a:

A) La cantidad total del OGM a liberar;

B) Las condiciones de manejo que se darán al OGM, y

C) Identificación de las zonas donde se pretende liberar el OGM, incluyendo la especificación de la superficie o superficies totales en las que se realizará la liberación.

IV. Las medidas de monitoreo y de bioseguridad a realizar durante la liberación y posteriores a dicha actividad, y

V. La información que para cada caso determinen las normas oficiales mexicanas que deriven de esta Ley.

Lo anterior, con la finalidad de que las Secretarías correspondientes cuenten con la información para que realicen el análisis y la evaluación de los posibles riesgos al medio ambiente y la diversidad biológica o a la sanidad animal, vegetal o acuícola, según les corresponda conforme a esta Ley.

Será requisito para obtener el permiso de liberación al ambiente en programa piloto, que el solicitante cuente con la autorización del OGM que expida la SSA de conformidad con esta Ley, cuando dicho organismo sea para uso o consumo humano. El interesado podrá iniciar el trámite para obtener dicho permiso ante la Secretaría competente, pero no le será otorgado hasta que acredite en el expediente respectivo haber obtenido la autorización de la SSA.

ARTÍCULO 51.- Los interesados en importar OGMs para su liberación al ambiente en programa piloto, además de lo establecido en el artículo anterior, deberán adjuntar a su solicitud la información y documentación que acredite que el OGM esté permitido conforme la legislación del país de origen, para su liberación, al menos, en esta clase de etapa, adjuntando para tales efectos la autorización o documentación oficial que ampare dicha situación.

ARTÍCULO 52.- La resolución a una solicitud de permiso para liberación al ambiente de OGMs en programa piloto deberá expedirse en un plazo máximo de tres meses contados a partir del día siguiente a aquel en que la Secretaría que deba resolver haya recibido la solicitud del permiso y la información aportada por el interesado esté completa.

La vigencia del permiso se determinará considerando los elementos del expediente.

ARTÍCULO 53.- El titular del permiso de liberación al ambiente en programa piloto, deberá informar a la Secretaría que lo expidió, mediante un reporte, los resultados de la o las liberaciones realizadas en relación con los posibles riesgos para el medio ambiente y la diversidad biológica. Las características y contenido del reporte a que se refiere este artículo se establecerán en las normas oficiales mexicanas que deriven de esta Ley.

ARTÍCULO 54.- El titular del permiso estará obligado a informar inmediatamente a la Secretaría correspondiente, cualquier situación que en la realización de la liberación permitida, pudiera incrementar o disminuir los posibles riesgos para el medio ambiente, la diversidad biológica y/o la salud humana.

SECCIÓN III
Permiso para liberación comercial al ambiente

ARTÍCULO 55.- La solicitud del permiso para realizar la liberación comercial al ambiente de OGMs, incluyendo su importación para esa actividad, deberá acompañarse de la siguiente información:

I. Los permisos para la liberación experimental y en programa piloto del OGM de que se trate;

II. Referencia y consideraciones sobre los reportes de resultados de la liberación experimental y de la liberación en programa piloto que se hayan realizado, en términos de los permisos a que se refiere la fracción anterior;

III. Instrucciones o recomendaciones específicas de almacenamiento, transporte y, en su caso, manejo;

IV. En su caso, condiciones para su liberación y comercialización;

V. En su caso, se presentarán consideraciones sobre los riesgos de las alternativas tecnológicas con las que se cuente para contender con el problema para el cual se construyó el OGM que se pretende liberar;

VI. En su caso, la información que disponga el solicitante sobre datos o resultados de la comercialización del mismo OGM en otros países, y

VII. La demás información que determinen las normas oficiales mexicanas que deriven de esta Ley.

Lo anterior, con la finalidad de que las Secretarías correspondientes cuenten con la información para que realicen el análisis y la evaluación de los posibles riesgos al medio ambiente y la diversidad biológica o a la sanidad animal, vegetal o acuícola, según les corresponda conforme a esta Ley.

ARTÍCULO 56.- Los interesados en importar OGMs para su liberación comercial, además de lo establecido en el artículo anterior, deberán adjuntar la información y documentación que acredite que el OGM esté permitido conforme la legislación del país de origen para su comercialización, adjuntando para tales efectos la autorización o documentación oficial que ampare dicha situación.

ARTÍCULO 57.- La resolución a una solicitud de permiso para liberación comercial al ambiente, deberá expedirse en el plazo de cuatro meses contados a partir del día siguiente a aquel en que la Secretaría que deba resolver haya recibido la solicitud del permiso y la información aportada por el interesado esté completa.

ARTÍCULO 58.- Las actividades e importaciones subsecuentes al permiso de liberación comercial al ambiente se realizarán sujetándose a los términos y condiciones que en el mismo se establezcan, y sin que requieran de permisos sucesivos. Se entenderá que las importaciones subsecuentes se realizan en los mismos términos y condiciones establecidos en el permiso de liberación comercial respectivo, cuando se trate del mismo OGM y la misma área de liberación. Lo anterior, con independencia de que dichas actividades e importaciones puedan ser objeto de monitoreo y de acciones de inspección y vigilancia, en los términos de esta Ley.

ARTÍCULO 59.- El permiso de liberación comercial al ambiente de un OGM conlleva la autorización de comercialización del organismo de que se trate y de los productos que lo contengan, en los términos de esta Ley.

CAPÍTULO III
Estudio y Evaluación del Riesgo

ARTÍCULO 60.- La evaluación del riesgo es el proceso por el cual se analizan caso por caso, con base en estudios fundamentados científica y técnicamente que deberán elaborar los interesados, los posibles riesgos o efectos que la liberación experimental al ambiente de OGMs pueden causar al medio ambiente y a la diversidad biológica, así como a la sanidad animal, vegetal y acuícola.

Los posibles riesgos a la salud humana serán materia de estudio de riesgos para la obtención de la autorización del OGM de que se trate, en los términos de esta Ley.

ARTÍCULO 61.- Para llevar a cabo el estudio y la evaluación del riesgo, se deberán observar los siguientes lineamientos:

I. Deben realizarse caso por caso de una forma transparente y basada en principios científicos y en el enfoque de precaución, en los términos de esta Ley, tomando en cuenta el asesoramiento de expertos;

II. Se realizarán en los campos de especialidad relevantes;

III. La falta de conocimiento o consenso científico no se interpretará necesariamente como indicador de un determinado nivel de riesgo, de ausencia de riesgo, o de la existencia de un riesgo aceptable;

IV. Deben tener como base mínima los posibles riesgos que se impondrían por la liberación de los organismos hospederos no modificados genéticamente o de los organismos parentales, cuando fueran liberados en ese medio ambiente;

V. Se deberá considerar el organismo receptor, la modificación genética, incluyendo la construcción genética y el método de inserción, y el ambiente en el que se pretende liberar el OGM, y

VI. La naturaleza y el nivel de detalle de la información que contengan pueden variar de un caso a otro, dependiendo del OGM de que se trate, su uso previsto y el probable ambiente receptor.

ARTÍCULO 62.- Las etapas básicas a seguir en el estudio y la evaluación del riesgo son las siguientes:

I. La identificación de características nuevas asociadas con el OGM que pudieran tener posibles riesgos en la diversidad biológica;

II. La evaluación de que estos posibles riesgos ocurran realmente, teniendo en cuenta el nivel y el tipo de exposición del OGM;

III. La evaluación de las consecuencias si posibles riesgos ocurrieran realmente;

IV. La estimación del posible riesgo global que represente el OGM, basada en la evaluación de la probabilidad de que los posibles riesgos y las consecuencias identificadas ocurran realmente, y

V. La recomendación sobre si los posibles riesgos son aceptables o manejables, o no lo son, incluyendo la determinación de estrategias para el manejo de esos posibles riesgos.

ARTÍCULO 63.- Cuando haya incertidumbre acerca del nivel del posible riesgo que los OGMs puedan causar a la diversidad biológica, las Secretarías correspondientes solicitarán dentro del procedimiento administrativo de permiso de la actividad de liberación al ambiente de OGMs de que se trate, información adicional sobre cuestiones concretas del estudio de riesgo o adoptarán estrategias apropiadas para el manejo del riesgo y/o el monitoreo del OGM en el ambiente receptor.

En caso de peligro de daño grave o irreversible, la incertidumbre acerca del nivel de los posibles riesgos que los OGMs puedan causar a la diversidad biológica o a la salud humana, no deberá utilizarse como razón para que la Secretaría correspondiente postergue la adopción de medidas eficaces que impidan la afectación negativa de la diversidad biológica o de la salud humana. En la adopción de dichas medidas, la Secretaría correspondiente tomará en cuenta la evidencia científica existente que le sirva de fundamento o criterio para el establecimiento de la medida o medidas; los procedimientos administrativos establecidos en esta Ley, y la normatividad comercial contenida en tratados y acuerdos internacionales de los que los Estados Unidos Mexicanos sean parte.

ARTÍCULO 64.- El interesado podrá presentar de manera adicional al estudio de los posibles riesgos, otros estudios o consideraciones en los que se analicen tanto la contribución del OGM a la solución de problemas ambientales, sociales, productivos o de otra índole, las consideraciones socioeconómicas que existan respecto de la liberación de OGMs al ambiente, como una evaluación de los riesgos de las opciones tecnológicas alternas para contender con la problemática específica para la cual el OGM fue diseñado. Estos análisis deberán estar sustentados en evidencias científicas y técnicas, en los antecedentes sobre uso, producción y consumo, y podrán ser considerados por las Secretarías competentes como elementos adicionales para decidir sobre la liberación experimental al ambiente, y consecuentes liberaciones al ambiente en programa piloto y comercial, respectivamente, del OGM de que se trate.

ARTÍCULO 65.- Las características y requisitos de los estudios de evaluación de los posibles riesgos, se establecerán en las normas oficiales mexicanas que deriven de esta Ley.

CAPÍTULO IV
De los Dictámenes

ARTÍCULO 66.- Los dictámenes que deberá emitir la SEMARNAT únicamente se requerirán tratándose de actividades de liberación experimental, de liberación en programa piloto y de liberación comercial de OGMs que sean de competencia de la SAGARPA. Dichos dictámenes deberán ser emitidos en un plazo de sesenta días contados a partir de que la SEMARNAT reciba el expediente administrativo remitido por la SAGARPA. Dicho plazo comprende tanto la expedición del dictamen correspondiente,

como su remisión a la SAGARPA. La SAGARPA expedirá el permiso de liberación de OGMs al ambiente que corresponda, siempre que el dictamen que emita la SEMARNAT sea favorable.

CAPÍTULO V
De la Reconsideración de las Resoluciones Negativas

ARTÍCULO 67.- Los interesados a los que la Secretaría correspondiente les haya negado el permiso solicitado, podrán pedir a dicha Secretaría la reconsideración de la resolución respectiva, cuando se considere que:

I. Se ha producido un cambio en las circunstancias que puede influir en el resultado del estudio de los posibles riesgos en el cual se basó la resolución, o

II. Se disponga de nueva información científica o técnica pertinente de la que se deduzca que los posibles riesgos identificados no son los previstos originalmente.

La Secretaría competente podrá emitir una resolución dentro de los dos meses siguientes. En caso de no hacerlo, se tendrá por desestimada la reconsideración.

ARTÍCULO 68.- La reconsideración a que se refiere el artículo anterior no constituye ningún recurso o medio de defensa, y podrá ser promovida por los interesados con independencia de que hagan valer el medio de impugnación establecido en esta Ley en contra de la resolución que les afecte.

CAPÍTULO VI
De la Revisión de los Permisos

ARTÍCULO 69.- La Secretaría correspondiente, en cualquier momento y sobre la base de nueva información científica o técnica acerca de los posibles riesgos que puedan provocar los OGMs a la salud pública o al medio ambiente y a la diversidad biológica, podrán revisar los permisos otorgados y, en su caso, suspender sus efectos o revocar dichos permisos, conforme a los procedimientos que establezcan las disposiciones reglamentarias que deriven de esta Ley, cuando considere como causas que:

I. Se presente un cambio en las circunstancias de las actividades que puede influir en el resultado del estudio de la evaluación de los posibles riesgos en el cual se basó el permiso, o

II. Se cuente con información científica o técnica adicional que pudiese modificar cualesquiera condiciones, limitaciones o requisitos del permiso.

CAPÍTULO VII
Confidencialidad

ARTÍCULO 70.- Los interesados podrán identificar claramente en su solicitud de permiso, aquella información que deba considerarse como confidencial conforme al régimen de propiedad industrial o de derechos de autor. La Secretaría correspondiente se sujetará a lo establecido en las leyes de la materia y se abstendrá de mandar registrar y de facilitar a terceros la información y los datos que estén protegidos por dichas leyes.

ARTÍCULO 71.- No tendrán el carácter de confidencial:

I. La descripción general de los OGMs;

II. La identificación del interesado o responsable de la actividad;

III. La finalidad y el lugar o lugares de la actividad;

IV. Los sistemas y las medidas de bioseguridad, monitoreo, control y emergencia, y

V. Los estudios sobre los posibles riesgos a la salud humana o al medio ambiente y a la diversidad biológica.

El acceso a la información a la que se refieren las fracciones anteriores se regirá, además, por las disposiciones aplicables en materia de acceso a la información pública gubernamental.

CAPÍTULO VIII
Exportación de OGMs que se destinen a su liberación al ambiente en otros países

ARTÍCULO 72.- Los interesados en exportar OGMs que se destinen a su liberación al ambiente en otros países, notificarán por sí, conforme se determine en las disposiciones reglamentarias que deriven de esta Ley, su intención de exportar dichos organismos, a las autoridades competentes del país respectivo. Dicha notificación sólo se realizará en los casos en que los tratados y acuerdos internacionales en los que los Estados Unidos Mexicanos sean parte, establezcan ese requisito para efectuar la exportación al país de que se trate. La información que el interesado adjunte a la notificación a que se refiere este artículo, deberá ser exacta, fidedigna y ajustada a lo que establezcan dichos tratados y acuerdos internacionales.

TÍTULO TERCERO
De la Utilización Confinada y Avisos

CAPÍTULO I
Utilización Confinada

ARTÍCULO 73.- La utilización confinada de OGMs puede ser con fines de enseñanza, de investigación científica y tecnológica, industriales o comerciales.

ARTÍCULO 74.- Quienes realicen actividades de utilización confinada sujetas al requisito de presentación de aviso en los términos de esta Ley, deberán cumplir con lo siguiente:

I. Llevar un libro de registro de las actividades de utilización confinada que realicen, el cual se deberá proporcionar a las Secretarías correspondientes cuando éstas lo soliciten;

II. Aplicar las medidas de confinamiento cuya ejecución deberá adaptarse a los conocimientos científicos y técnicos más modernos y avanzados en materia de manejo de riesgos y de tratamiento, disposición final y eliminación de residuos de OGMs generados en la realización de la actividad, y

III. En el caso de la utilización confinada con fines de enseñanza o de investigación científica y tecnológica, integrar una comisión interna de bioseguridad y aplicar los principios de las buenas prácticas de la investigación científica, así como las reglas de bioseguridad que defina la comisión interna de bioseguridad. Dicha comisión interna estará encargada de la seguridad en las instalaciones y de las buenas prácticas y la seguridad en el manejo de OGMs utilizados en la actividad señalada.

Las normas oficiales mexicanas que deriven de esta Ley establecerán:

A) Los requisitos y las características generales que debe contener el libro de registro a que se refiere este artículo, para cada tipo de actividad;

B) Los requisitos y características relativas al confinamiento, tratamiento, disposición final, destrucción y eliminación de residuos de OGMs;

C) Las condiciones de manejo que se requieran en las diversas formas de utilización confinada de dichos organismos, y

D) Acciones a realizar en caso de liberación accidental de OGMs.

ARTÍCULO 75.- El almacenamiento o depósito de OGMs o de productos que los contengan, que se realice en las aduanas del territorio nacional, se sujetará a lo que dispongan las normas oficiales mexicanas respectivas que expidan de manera conjunta las Secretarías competentes, con la participación de la SHCP.

ARTÍCULO 76.- El transporte de OGMs o de productos que los contengan, así como el tránsito de dichos organismos y productos por el territorio nacional, cuando tengan como destino otro país, se regirán por las normas oficiales mexicanas que expidan de manera conjunta las Secretarías competentes, con la participación de la Secretaría de Comunicaciones y Transportes.

CAPÍTULO II
De los Avisos

ARTÍCULO 77.- El aviso es la comunicación que deben presentar en formatos oficiales los sujetos señalados en esta Ley, a la SEMARNAT o a la SAGARPA, según corresponda conforme a este ordenamiento, respecto de la utilización confinada de OGMs en los casos que se establecen en este capítulo.

ARTÍCULO 78.- Los avisos se deberán presentar a la SEMARNAT o a la SAGARPA, conforme a las atribuciones que esta Ley les confiere, en los formatos oficiales que se expidan para tal efecto. El contenido de los formatos lo determinarán dichas Secretarías, con la previa aprobación de la Comisión Federal de Mejora Regulatoria. En dichos formatos se determinará la información y documentación que deba presentar el interesado. Los formatos se deberán publicar en el **Diario Oficial de la Federación**.

ARTÍCULO 79.- Requieren de presentación de aviso:

I. Los OGMs que se manejen, generen y produzcan con fines de enseñanza e investigación científica y tecnológica;

II. La integración de las comisiones internas de bioseguridad, incluyendo el nombre del o los responsables de dichas comisiones;

III. La primera utilización de laboratorios o instalaciones específicas de enseñanza o investigación científica y tecnológica en las que se manejen, generen y produzcan OGMs;

IV. La producción de OGMs que se utilicen en procesos industriales, y

V. La primera utilización de instalaciones específicas en donde se produzcan los OGMs a que se refiere la fracción anterior.

ARTÍCULO 80.- También requiere de presentación de aviso la importación de OGMs para su utilización confinada con fines industriales o comerciales, únicamente cuando se reúnan los supuestos siguientes:

I. Que se trate de OGMs que no requieran de permiso, en virtud de que se destinen exclusivamente a su utilización confinada y por tanto no se importen para su liberación al ambiente, y

II. Que se trate de OGMs que no requieran autorización sanitaria debido a que no se destinarán a uso o consumo humano o a finalidades de salud pública.

ARTÍCULO 81.- Los sujetos que deben presentar a la Secretaría correspondiente el aviso respectivo, son los siguientes:

I. En los casos a que se refieren las fracciones I, II y III del artículo 79, el responsable de la comisión interna de bioseguridad de la institución, centro o empresa en donde se realicen las actividades de enseñanza e investigación científica y tecnológica en las que se genere y produzca el OGM de que se trate;

II. En los casos a que se refieren las fracciones IV y V del artículo 79, el representante legal de la empresa en la que se produzcan los OGMs de que se trate, y

III. En el caso a que se refiere el artículo anterior, el importador del OGM.

ARTÍCULO 82.- Se exceptúa de la presentación de aviso, la utilización confinada o importación para esa actividad, en caso de que el OGM de que se trate se exente de dicho requisito en las listas que expidan las Secretarías conforme a esta Ley.

ARTÍCULO 83.- La utilización confinada de OGMs y la importación de dichos organismos para esa actividad, podrá realizarse a partir del momento en que la comisión interna de bioseguridad o el importador, según se trate, presente el aviso respectivo a la Secretaría correspondiente.

ARTÍCULO 84.- Una vez presentado el aviso, la Secretaría correspondiente podrá determinar, en su caso, con sustento científico y técnico:

I. Que en consideración del organismo genéticamente modificado y los posibles riesgos en su manejo, debe suspenderse la actividad;

II. En su caso, podrá resolver que la utilización confinada requiere de la adopción e implementación de requisitos y medidas de bioseguridad adicionales a los señalados por el propio interesado en el aviso, las cuales serán determinadas por dicha Secretaría, y deberán ser observadas y cumplidas por el interesado para continuar la realización de la actividad, o

III. La prohibición de la utilización confinada del organismo genéticamente modificado de que se trate o su importación para esa actividad.

Dicha resolución podrá ser impugnada a través del recurso de revisión establecido en el presente ordenamiento.

ARTÍCULO 85.- Las personas cuya actividad de utilización confinada esté sujeta al requisito de presentación de aviso estarán obligadas a observar y cumplir las demás disposiciones del presente ordenamiento y de las normas oficiales mexicanas que deriven del mismo, en lo que le sea aplicable.

TÍTULO CUARTO
Zonas Restringidas

CAPÍTULO I
Centros de Origen y de Diversidad Genética

ARTÍCULO 86.- Las especies de las que los Estados Unidos Mexicanos sea centro de origen y de diversidad genética así como las áreas geográficas en las que se localicen, serán determinadas conjuntamente mediante acuerdos por la SEMARNAT y la SAGARPA, con base en la información con la que cuenten en sus archivos o en sus bases de datos, incluyendo la que proporcione, entre otros, el Instituto Nacional de Estadística, Geografía e Informática, el Instituto Nacional de Investigaciones Forestales, Agrícolas y Pecuarias, el Instituto Nacional de Ecología, la Comisión Nacional para el Conocimiento y Uso de la Biodiversidad y la Comisión Nacional Forestal, así como los acuerdos y tratados internacionales relativos a estas materias. La SEMARNAT y la SAGARPA establecerán en los acuerdos que expidan, las medidas necesarias para la protección de dichas especies y áreas geográficas.

ARTÍCULO 87.- Para la determinación de los centros de origen y de diversidad genética se tomarán en cuenta los siguientes criterios:

I. Que se consideren centros de diversidad genética, entendiendo por éstos las regiones que actualmente albergan poblaciones de los parientes silvestres del OGM de que se trate, incluyendo diferentes razas o variedades del mismo, las cuales constituyen una reserva genética del material, y

II. En el caso de cultivos, las regiones geográficas en donde el organismo de que se trate fue domesticado, siempre y cuando estas regiones sean centros de diversidad genética.

ARTÍCULO 88.- En los centros de origen y de diversidad genética de especies animales y vegetales sólo se permitirá la realización de liberaciones de OGMs cuando se trate de OGMs distintos a las especies nativas, siempre que su liberación no cause una afectación negativa a la salud humana o a la diversidad biológica.

CAPÍTULO II
De las Actividades con OGMs en Áreas Naturales Protegidas

ARTÍCULO 89.- En las áreas naturales protegidas creadas de conformidad con lo dispuesto en la materia, sólo se permitirán actividades con OGMs para fines de biorremediación, en los casos en que aparezcan plagas o contaminantes que pudieran poner en peligro la existencia de especies animales, vegetales o acuícolas, y los OGMs hayan sido creados para evitar o combatir dicha situación, siempre que se cuente con los elementos científicos y técnicos necesarios que soporten el beneficio ambiental que se pretende obtener, y dichas actividades sean permitidas por la SEMARNAT en los términos de esta Ley.

Para los efectos de lo dispuesto en el párrafo anterior, queda prohibido realizar actividades con OGMs en las zonas núcleo de las áreas naturales protegidas.

En caso de que algún centro de origen o centro de diversidad genética se ubique dentro de alguna área natural protegida, las declaratorias de creación y los programas de manejo de dichas áreas se modificarán en los términos de la legislación de la materia, conforme se realicen las determinaciones a que se refiere el Artículo 86 de la presente Ley.

CAPÍTULO III
Zonas Libres de OGMs

ARTÍCULO 90.- Se podrán establecer zonas libres de OGMs para la protección de productos agrícolas orgánicos y otros de interés de la comunidad solicitante, conforme a los siguientes lineamientos generales:

I. Las zonas libres se establecerán cuando se trate de OGMs de la misma especie a las que se produzcan mediante procesos de producción de productos agrícolas orgánicos, y se demuestre científica y técnicamente que no es viable su coexistencia o que no cumplirían con los requisitos normativos para su certificación;

II. Dichas zonas serán determinadas por la SAGARPA mediante acuerdos que se publicarán en el **Diario Oficial de la Federación**, previo dictamen de la CIBIOGEM, con la opinión de la Comisión Nacional para el Conocimiento y Uso de la Biodiversidad, tomando en cuenta lo establecido en las normas oficiales mexicanas relativas a los productos agrícolas orgánicos;

III. La determinación de las zonas libres se realizará con base en los siguientes requisitos:

A. Se hará a solicitud escrita de las comunidades interesadas, por conducto de su representante legal;

B. Dicha solicitud deberá acompañarse de la opinión favorable de los gobiernos de las entidades federativas y los gobiernos municipales de los lugares o regiones que se determinarán como zonas libres;

C. Se realizarán las evaluaciones de los efectos que los OGMs pudieran ocasionar a los procesos de producción de productos agrícolas orgánicos o a la biodiversidad, mediante las cuales quede demostrado, científica y técnicamente, que no es viable su coexistencia o no cumplan con los requisitos normativos para su certificación, de acuerdo con las normas oficiales mexicanas que expida la SAGARPA. Las evaluaciones mencionadas se realizarán conforme lo establezca dicha Secretaría en normas oficiales mexicanas, y

IV. La SAGARPA establecerá en los acuerdos las medidas de seguridad que se podrán adoptar en las zonas libres de OGMs, a fin de garantizar la adecuada protección de los productos agrícolas orgánicos.

TÍTULO QUINTO
De la Protección de la Salud Humana en relación con los OGMs

CAPÍTULO I
De las Autorizaciones de OGMs

ARTÍCULO 91.- Los OGMs objeto de autorización son los siguientes:

I. Los que se destinen a su uso o consumo humano, incluyendo granos;

II. Los que se destinen al procesamiento de alimentos para consumo humano;

III. Los que tengan finalidades de salud pública, y

IV. Los que se destinen a la biorremediación.

Para los efectos de esta Ley, también se consideran OGMs para uso o consumo humano aquellos que sean para consumo animal y que puedan ser consumidos directamente por el ser humano.

ARTÍCULO 92.- La solicitud de autorización de un OGM deberá acompañarse de los siguientes requisitos:

I. El estudio de los posibles riesgos que el uso o consumo humano del OGM de que se trate pudiera representar a la salud humana, en el que se incluirá la información científica y técnica relativa a su inocuidad, y

II. Los demás requisitos que se determinen en las normas oficiales mexicanas que deriven de esta Ley.

Los lineamientos, criterios, características y requisitos de los estudios de los posibles riesgos que los OGMs puedan causar a la salud humana, serán determinados por la SSA en las normas oficiales mexicanas que expida conforme a esta Ley.

ARTÍCULO 93.- En el caso de solicitudes de autorización de un OGM para poder realizar su importación para las finalidades a que se refiere el artículo 91 de esta Ley, además de lo establecido en el artículo anterior, el interesado deberá adjuntar la información y documentación que acredite que el OGM esté autorizado conforme la legislación del país de origen. En su defecto, el interesado manifestará la inexistencia de dicha situación, y expondrá los elementos de consideración que sustenten el que la SSA pueda resolver la solicitud de autorización.

ARTÍCULO 94.- Una vez que la SSA reciba una solicitud de autorización, y siempre y cuando cumpla con la información y los requisitos establecidos en esta Ley, deberá remitirla al Registro, para su inscripción y publicidad respectivas.

ARTÍCULO 95.- Las autorizaciones deberán ser expedidas en un plazo no mayor a seis meses contados a partir de que la SSA reciba la solicitud de autorización por parte del interesado y la información aportada en dicha solicitud esté completa.

ARTÍCULO 96.- La SSA expedirá su resolución, una vez que haya analizado la información y documentación aportados por el interesado. Dicha Secretaría en su resolución podrá, fundada y motivadamente:

I. Expedir la autorización, o

II. Negar la autorización en los siguientes casos:

A) Cuando la solicitud no cumpla con lo establecido en esta Ley o las normas oficiales mexicanas como requisitos para el otorgamiento de la autorización;

B) Cuando la información proporcionada por el interesado sea falsa, esté incompleta o sea insuficiente, o

C) Cuando la SSA concluya que los riesgos que pueden presentar dichos organismos afectarán negativamente a la salud humana, pudiéndole causar daños graves o irreversibles.

La SSA basará sus resoluciones de acuerdo con la identificación científica y técnicamente sustentada de los posibles riesgos que pudieran generar los OGMs, y de la posibilidad real de afectación a la salud humana por dichos organismos.

ARTÍCULO 97.- Los OGMs autorizados por la SSA podrán ser libremente comercializados e importados para su comercialización, al igual que los productos que contengan dichos organismos y los productos derivados de los mismos. Lo anterior sin perjuicio de que dichos organismos autorizados, los productos que los contengan y los productos derivados queden sujetos al régimen de control sanitario

general que establece la Ley General de Salud y sus reglamentos y, en caso de que les sean aplicables, los requisitos fitozoosanitarios que correspondan.

ARTÍCULO 98.- Serán aplicables al procedimiento administrativo de autorización, las disposiciones relativas del Título Segundo, en cuanto a la Reconsideración de las Resoluciones Negativas, Revisión de los Permisos y Confidencialidad.

CAPÍTULO II
Disposiciones Adicionales

ARTÍCULO 99.- El envasado de OGMs y de productos que los contengan, para uso o consumo humano, se regirá por las normas oficiales mexicanas que expida la SSA, conjuntamente con la Secretaría de Economía, de conformidad con la Ley General de Salud y sus disposiciones reglamentarias, y con la Ley Federal sobre Metrología y Normalización.

ARTÍCULO 100.- El desarrollo, producción, comercialización y en general proceso de OGMs con efectos terapéuticos, adicionalmente a lo establecido en esta Ley, estará sujeto a lo dispuesto por la Ley General de Salud y demás ordenamientos aplicables a medicamentos y fármacos.

TÍTULO SEXTO
Etiquetado e Identificación de OGMs

ARTÍCULO 101.- Los OGMs o productos que contengan organismos genéticamente modificados, autorizados por la SSA por su inocuidad en los términos de esta Ley y que sean para consumo humano directo, deberán garantizar la referencia explícita de organismos genéticamente modificados y señalar en la etiqueta la información de su composición alimenticia o sus propiedades nutrimentales, en aquellos casos en que estas características sean significativamente diferentes respecto de los productos convencionales, y además cumplir con los requisitos generales adicionales de etiquetado conforme a las normas oficiales mexicanas que expida la SSA, de acuerdo con lo dispuesto en la Ley General de Salud y sus disposiciones reglamentarias, con la participación de la Secretaría de Economía.

La información que contengan las etiquetas, conforme a lo establecido en este artículo, deberá ser veraz, objetiva, clara, entendible, útil para el consumidor y sustentada en información científica y técnica.

El etiquetado de OGMs que sean semillas o material vegetativo destinados a siembra, cultivo y producción agrícola, quedará sujeto a las normas oficiales mexicanas que expida la SAGARPA con la participación de la Secretaría de Economía. Respecto de este tipo de OGMs, será obligatorio consignar en la etiqueta que se trata de organismos genéticamente modificados, las características de la combinación genética adquirida y sus implicaciones relativas a condiciones especiales y requerimientos de cultivo, así como los cambios en las características reproductivas y productivas.

La evaluación de la conformidad de dichas normas oficiales mexicanas la realizarán la SSA, la SAGARPA y la Secretaría de Economía en el ámbito de sus respectivas competencias y las personas acreditadas y aprobadas conforme a lo dispuesto en la Ley Federal sobre Metrología y Normalización.

ARTÍCULO 102.- Los requisitos de información que deberá contener la documentación que acompañe a los OGMs que se importen conforme a esta Ley, se establecerán en normas oficiales mexicanas que deriven del presente ordenamiento, considerando en su expedición la finalidad a la que se destinen dichos organismos y lo que se establezca en tratados internacionales de los que los Estados Unidos Mexicanos sean parte. Las normas oficiales mexicanas a que se refiere este artículo, serán expedidas conjuntamente por la SAGARPA, la SSA y la Secretaría de Economía. En caso de que la importación de

OGMs se realice con la finalidad de su liberación al ambiente, las normas oficiales mexicanas a que se refiere este artículo serán expedidas por las Secretarías señaladas conjuntamente con la SEMARNAT.

TÍTULO SÉPTIMO
De las Listas de OGMs

ARTÍCULO 103.- Las listas de OGMs que conforme a esta Ley se expidan y publiquen serán las siguientes:

I. Las de OGMs que cuenten con permiso para su liberación comercial o para su importación para esa actividad;

II. Las de OGMs que no cuenten con permiso para su liberación comercial o para su importación para esa actividad;

III. Las de OGMs que cuenten con autorización por la SSA, y

IV. Las de OGMs para realizar actividades de utilización confinada de OGMs con fines de enseñanza y de investigación científica y tecnológica.

Las listas de OGMs a que se refiere este artículo serán expedidas y publicadas por las Secretarías competentes con la periodicidad que establezcan las disposiciones reglamentarias que deriven de esta Ley y de acuerdo a lo establecido en el presente Título. Tendrán como finalidad dar a conocer a los interesados y al público en general el resultado de las resoluciones que expidan respecto de las solicitudes de permisos y autorizaciones.

ARTÍCULO 104.- La lista de OGMs a que se refieren las fracciones I y II del artículo anterior será elaborada considerando los resultados de la evaluación caso por caso y expedida conjuntamente por la SEMARNAT, la SSA y la SAGARPA, y se publicará para su conocimiento y difusión en el **Diario Oficial de la Federación**.

Las finalidades de la lista a que se refiere este artículo serán:

I. Indicar la situación jurídica en que se encuentren esos OGMs, y

II. Determinar los casos en los cuales los OGMs permitidos para su liberación comercial o para su importación para esa actividad puedan ser liberados e importados libremente en las áreas geográficas que se determinen conforme al análisis caso por caso.

En dicha lista, las Secretarías correspondientes podrán indicar los casos en que la importación, el uso, manejo y liberación de dichos organismos puedan realizarse sin condiciones, así como los casos en que se deban cumplir condiciones específicas.

ARTÍCULO 105.- La lista de OGMs que cuenten con autorización, será elaborada y expedida por la SSA, considerando los resultados de la evaluación caso por caso de los posibles riesgos de dichos organismos para la salud humana, y se publicará para su conocimiento y difusión en el **Diario Oficial de la Federación**. Sus finalidades serán indicar la situación jurídica en que se encuentren esos OGMs, y determinar los casos en los cuales los OGMs autorizados conforme a esta Ley puedan ser comercializados e importados.

ARTÍCULO 106.- La lista de OGMs para realizar actividades de utilización confinada de dichos organismos con fines de enseñanza y de investigación científica y tecnológica será expedida

conjuntamente por las Secretarías, y se publicará para su conocimiento y difusión en el **Diario Oficial de la Federación**.

ARTÍCULO 107.- En la formulación, expedición y modificación de las listas informativas de OGMs, se estará a lo que se establezca en las disposiciones reglamentarias que deriven del presente ordenamiento, tomando en cuenta los siguientes lineamientos:

Se formularán atendiendo:

I. La naturaleza del organismo genéticamente modificado;

II. La presencia en el país o región de interés, de especies sexualmente compatibles con el organismo genéticamente modificado;

III. El tipo de reproducción sexual del organismo genéticamente modificado y las especies nativas sexualmente compatibles;

IV. La naturaleza del organismo receptor o parental;

V. Las características del vector y del inserto de material genético utilizados en la operación;

VI. La capacidad y forma de propagación de los organismos genéticamente modificados;

VII. La existencia de especies silvestres parientes en alguna área o región del territorio nacional que sea su centro de origen;

VIII. La escala o volumen de manejo, y

IX. Los posibles efectos o riesgos que las distintas actividades con dichos organismos pudieran causar al medio ambiente y a la diversidad biológica o a la salud humana o a la sanidad animal, vegetal o acuícola.

TÍTULO OCTAVO
De la Información sobre Bioseguridad

CAPÍTULO I
Del Sistema Nacional de Información sobre Bioseguridad

ARTÍCULO 108.- La CIBIOGEM, a través de su Secretaría Ejecutiva, desarrollará el Sistema Nacional de Información sobre Bioseguridad que tendrá por objeto organizar, actualizar y difundir la información sobre bioseguridad. En dicho Sistema, la CIBIOGEM deberá integrar, entre otros aspectos, la información correspondiente al Registro.

La CIBIOGEM reunirá informes y documentos relevantes que resulten de las actividades científicas, académicas, trabajos técnicos o de cualquier otra índole en materia de bioseguridad, incluyendo la inocuidad de OGMs, realizados por personas físicas o morales, nacionales o extranjeras, los que serán remitidos y organizados por el Sistema Nacional de Información sobre Bioseguridad. Además, elaborará y publicará anualmente un informe detallado de la situación general existente en el país en materia de biotecnología y bioseguridad materia de esta Ley.

La CIBIOGEM, además, realizará los estudios y las consideraciones socioeconómicas resultantes de los efectos de los OGMs que se liberen al ambiente en el territorio nacional, y establecerá los

mecanismos para realizar la consulta y participación de los pueblos y comunidades indígenas asentadas en las zonas donde se pretenda la liberación de OGMs, considerando el valor de la diversidad biológica.

Asimismo, la Secretaría Ejecutiva de la CIBIOGEM fungirá como Centro Focal Nacional ante el Secretariado del Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica, siendo la responsable del enlace con dicho Secretariado y de dar cumplimiento a lo establecido en el Artículo 19 de dicho Tratado Internacional. La Secretaría Ejecutiva de la CIBIOGEM también se encargará de proporcionar al Centro de Intercambio de Información sobre Seguridad de la Biotecnología establecido en el mencionado Protocolo, cualquier información sobre:

I. Leyes, reglamentos y directrices nacionales existentes para la aplicación del Protocolo, así como la información y documentación que se requiera, en términos de esta Ley, para el procedimiento administrativo de permisos de importación de OGMs para ser liberados experimental, en programa piloto o comercialmente;

II. Acuerdos y arreglos bilaterales, regionales y multilaterales;

III. Resúmenes de las evaluaciones de riesgo de OGMs, así como información pertinente sobre productos derivados de OGMs;

IV. Las resoluciones definitivas acerca de la importación o liberación al ambiente de OGMs, así como de la modificación de resoluciones derivada de su revisión conforme a esta Ley;

V. Los efectos socioeconómicos de los OGMs, especialmente en las comunidades indígenas y locales, y

VI. Los informes sobre el cumplimiento de las obligaciones establecidas en el Protocolo, incluidos los relativos a la aplicación del procedimiento de importación de OGMs para ser liberados al ambiente en forma experimental, en programa piloto o comercial.

Las Secretarías competentes podrán proporcionar de manera directa al Centro de Intercambio de Información sobre Seguridad de la Biotecnología, la información a que se refieren las fracciones anteriores, informando simultáneamente a la Secretaría Ejecutiva de la CIBIOGEM.

CAPÍTULO II
Del Registro Nacional de Bioseguridad de los OGMs

ARTÍCULO 109.- El Registro, que estará a cargo de la Secretaría Ejecutiva de la CIBIOGEM, tendrá carácter público y tiene por objeto la inscripción de la información relativa a las actividades con OGMs, así como de los propios organismos. Su funcionamiento y lo que puede ser objeto de inscripción se determinarán en las disposiciones reglamentarias que deriven de esta Ley. La SEMARNAT, la SAGARPA y la SSA contribuirán a la organización y funcionamiento del Registro.

TÍTULO NOVENO
De las Normas Oficiales Mexicanas en Materia de Bioseguridad

ARTÍCULO 110.- Para garantizar la bioseguridad de las actividades con OGMs, las Secretarías, de manera conjunta o con la participación de otras dependencias de la Administración Pública Federal, expedirán normas oficiales mexicanas que tengan por objeto establecer lineamientos, criterios, especificaciones técnicas y procedimientos conforme a las disposiciones de esta Ley.

ARTÍCULO 111.- En la formulación de normas oficiales mexicanas en materia de bioseguridad deberá considerarse que el cumplimiento de sus previsiones deberá realizarse de conformidad con las características de cada actividad o proceso productivo con OGMs.

ARTÍCULO 112.- La aplicación de las normas oficiales mexicanas en materia de bioseguridad, así como los actos de inspección y vigilancia corresponderán exclusivamente a las Secretarías competentes en los términos de esta Ley. El cumplimiento de dichas normas podrá ser evaluado por los organismos de certificación, unidades de verificación y laboratorios de pruebas aprobados por dichas Secretarías de conformidad con las disposiciones reglamentarias que deriven del presente ordenamiento y con la Ley Federal sobre Metrología y Normalización.

TÍTULO DÉCIMO
Inspección y Vigilancia y Medidas de Seguridad o de Urgente Aplicación

CAPÍTULO I
Inspección y Vigilancia

ARTÍCULO 113.- Para verificar y comprobar el cumplimiento de esta Ley, sus reglamentos y las normas oficiales mexicanas que de ella deriven, las Secretarías competentes podrán realizar por conducto de personal debidamente autorizado, los actos de inspección y vigilancia que consideren necesarios, por conducto de las Unidades Administrativas facultadas legalmente para ello, conforme a esta Ley.

ARTÍCULO 114.- Por lo que hace a los requisitos y formalidades que deben observarse en la realización de visitas de inspección y vigilancia, son aplicables supletoriamente a este Capítulo las disposiciones del Capítulo Decimoprimero del Título Tercero de la Ley Federal de Procedimiento Administrativo. En materia de restauración o compensación de daños al medio ambiente o a la diversidad biológica, podrá ser aplicable lo dispuesto en el segundo párrafo del Artículo 168 de la Ley General del Equilibrio Ecológico y la Protección al Ambiente.

CAPÍTULO II
Medidas de Seguridad o de Urgente Aplicación

ARTÍCULO 115.- Las Secretarías, en el ámbito de su competencia conforme a esta Ley, ordenarán alguna o algunas de las medidas que se establecen en este artículo, en caso de que en la realización de actividades con OGMs se presente lo siguiente:

I. Surjan riesgos no previstos originalmente, que pudieran causar daños o efectos adversos y significativos a la salud humana o a la diversidad biológica o a la sanidad animal, vegetal o acuícola;

II. Se causen daños o efectos adversos y significativos a la salud humana o a la diversidad biológica o a la sanidad animal, vegetal o acuícola, o

III. Se liberen accidentalmente OGMs no permitidos y/o no autorizados al ambiente.

En estos casos, las medidas podrán ser las siguientes:

A. Clausura temporal, parcial o total, de los lugares y/o de las instalaciones en que se manejen o almacenen OGMs o se desarrollen las actividades que den lugar a los supuestos que originan la imposición de la medida;

B. El aseguramiento precautorio de OGMs, además de los bienes, vehículos, utensilios e instrumentos directamente relacionados con la acción u omisión que da lugar a la medida;

C. La suspensión temporal, total o parcial, de la actividad que motive la imposición de la medida;

D. La repatriación de OGMs a su país de origen;

E. La realización de las acciones y medidas necesarias para evitar que se continúen presentando los supuestos que motiven la imposición de la medida, y

F. La destrucción de OGMs de que se trate, a costa del interesado, para lo cual se deberá atender lo siguiente:

a) Procederá únicamente en caso de que los riesgos o daños sean graves o irreparables, y sólo mediante la imposición de esta medida sea posible evitar, atenuar o mitigar los riesgos o daños que la motivaron;

b) Para determinar la imposición de la medida, la Secretaría competente deberá emitir un dictamen, sustentado técnica y científicamente, mediante el cual se justifique la procedencia de la destrucción del OGM de que se trate, debiéndolo hacer del conocimiento del interesado, para que éste dentro de los cinco días siguientes exponga lo que a su derecho convenga y, en su caso, aporte las pruebas con que cuente, y

c) En tanto la Secretaría competente dicta la resolución que proceda, podrá ordenar, de manera previa, el aseguramiento precautorio de los OGMs, pudiéndolo llevar a cabo la propia Secretaría o a través del interesado.

Asimismo, la Secretaría competente que imponga las medidas a que se refiere este artículo podrá promover ante las otras Secretarías competentes, la ejecución de alguna o algunas medidas que se establezcan en otros ordenamientos.

ARTÍCULO 116.- Cuando las Secretarías competentes ordenen alguna de las medidas previstas en el artículo anterior, indicarán al interesado las acciones que debe llevar a cabo para subsanar las irregularidades que motivaron la imposición de dichas medidas, así como los plazos para su realización, a fin de que una vez cumplidas éstas, se ordene el retiro de las medidas impuestas.

Si el interesado se rehusare a llevar a cabo las acciones para subsanar las irregularidades que motivaron la imposición de la o las medidas de que se trate, la Secretaría que las haya impuesto las realizará inmediatamente, con cargo total al interesado renuente.

En el caso en que el interesado realice las medidas de seguridad o de urgente aplicación o subsane las irregularidades en que hubiere incurrido, previamente a que la Secretaría competente imponga alguna o algunas de las sanciones establecidas en esta Ley, dicha Secretaría deberá considerar tal situación como atenuante de la infracción cometida.

ARTÍCULO 117.- En caso de liberaciones accidentales de OGMs que se verifiquen en el territorio nacional, y que pudieran tener efectos adversos significativos a la diversidad biológica o a la salud humana de otro país, la Secretaría competente notificará tal situación a la autoridad correspondiente del país que pudiera resultar afectado por dicha liberación. Dicha notificación deberá incluir:

I. Información sobre las cantidades estimadas y las características y/o rasgos importantes del OGM;

II. Información sobre las circunstancias y la fecha estimada de la liberación accidental, así como el uso que tiene el OGM en el territorio nacional;

III. Información disponible sobre los posibles efectos adversos para la diversidad biológica y la salud humana;

IV. Información disponible sobre las posibles medidas de regulación, atención y control del riesgo, y

V. Un punto de contacto para obtener información adicional.

Sin perjuicio de lo anterior, las Secretarías, en el ámbito de sus competencias conforme a esta Ley, realizarán las acciones y medidas necesarias para reducir al mínimo cualquier riesgo o efecto adverso que los OGMs liberados accidentalmente pudieran ocasionar. Dichas acciones y medidas serán ordenadas por las Secretarías a quien haya ocasionado la liberación accidental de OGMs al ambiente, quien deberá cumplirlas de manera inmediata. En caso contrario, las Secretarías procederán conforme a lo establecido en el segundo párrafo del artículo anterior.

ARTÍCULO 118.- Son aplicables supletoriamente a este Capítulo las disposiciones del Capítulo Único del Título Quinto de la Ley Federal de Procedimiento Administrativo, excepto para lo dispuesto en el artículo anterior.

TÍTULO DECIMOPRIMERO
Infracciones, Sanciones y Responsabilidades

CAPÍTULO I
De las Infracciones

ARTÍCULO 119.- Incurre en infracciones administrativas a las disposiciones de esta Ley, la persona que, con pleno conocimiento de que se trata de OGMs:

I. Realice actividades con OGMs sin contar con los permisos y las autorizaciones respectivas;

II. Realice actividades con OGMs incumpliendo los términos y condiciones establecidos en los permisos y las autorizaciones respectivas;

III. Realice actividades de utilización confinada de OGMs, sin presentar los avisos en los términos establecidos en esta Ley;

IV. Realice actividades con OGMs que se encuentren sujetas o exentas de la presentación de aviso, incumpliendo las demás disposiciones de esta Ley, sus reglamentos y las normas oficiales mexicanas que deriven de aquella, que resulten aplicables a la actividad de que se trate o que sean comunes a todas las actividades en materia de bioseguridad;

V. Presente a las Secretarías competentes, información y/o documentación a que se refiere este ordenamiento que sea falsa, incluyendo la relativa a los posibles riesgos que las actividades con OGMs pudieran ocasionar a la salud humana o a la diversidad biológica;

VI. Incumpla las medidas sanitarias, de monitoreo, control y prevención señaladas por los interesados en la información y documentación aportada para obtener los permisos y las autorizaciones respectivas, y las establecidas por las Secretarías en los propios permisos y autorizaciones;

VII. Incumpla las medidas de control y de respuesta en caso de emergencia señaladas por los interesados en sus estudios de los posibles riesgos que las actividades con OGMs puedan ocasionar a la salud humana o a la diversidad biológica o a la sanidad animal, vegetal o acuícola;

VIII. Incumpla la obligación de informar o hacer del conocimiento a las Secretarías, en los supuestos establecidos en esta Ley;

IX. Incumpla la obligación de adoptar e implementar los requisitos y medidas adicionales de bioseguridad determinadas por las Secretarías, en los casos de actividades de utilización confinada sujetas a aviso, en que así se determine;

X. Incumpla la obligación de revisar, implantar o adoptar nuevas medidas sanitarias, de monitoreo, control y prevención, en los casos en que así lo determinen las Secretarías competentes conforme a lo dispuesto en esta Ley;

XI. Realice actividades con OGMs o con cualquier otro organismo cuya finalidad sea la fabricación y/o utilización de armas biológicas;

XII. Realice liberaciones de OGMs en los centros de origen y de diversidad genética, fuera de los casos establecidos en la presente Ley;

XIII. Realice actividades con OGMs en las áreas naturales protegidas señaladas en esta Ley, fuera de los casos establecidos por la misma;

XIV. Incumpla la obligación de informar a la SEMARNAT o a la SAGARPA, según su ámbito de competencia conforme a esta Ley, mediante el reporte correspondiente, los resultados de la realización de liberaciones experimentales o de liberaciones en programa piloto, que cuenten con el permiso respectivo;

XV. Importe OGMs que se encuentren prohibidos en el país de origen o se encuentren clasificados como no permitidos para su liberación comercial o para su importación para esa actividad en las listas a que se refiere esta Ley, cuando las Secretarías correspondientes no hubieren determinado positivamente que esas prohibiciones no son aplicables en el territorio nacional;

XVI. Presente los avisos a las Secretarías correspondientes sin ser firmados por la persona que debe hacerlo de conformidad con esta Ley;

XVII. No lleve y/o no proporcione a la Secretaría correspondiente el libro de registro de las actividades que se realicen en utilización confinada, en los términos establecidos en esta Ley y en las normas oficiales mexicanas que de ella deriven;

XVIII. No suspenda la actividad de utilización confinada en los casos en que las Secretarías correspondientes, una vez presentado el aviso por el interesado, determinen dicha situación y, en su caso, que la actividad requiere de requisitos o medidas de bioseguridad adicionales para continuar su realización;

XIX. Realice actividades de utilización confinada dejando de aplicar las medidas de confinamiento y de tratamiento, disposición final y eliminación de residuos de OGMs generados en la realización de la actividad;

XX. Incumpla las disposiciones relativas a la generación, tratamiento, confinamiento, disposición final, destrucción o eliminación de residuos de OGMs, que se establezcan en las normas oficiales mexicanas que deriven del presente ordenamiento;

XXI. No integre las comisiones internas de bioseguridad en los casos, formas y plazos que establezcan las disposiciones reglamentarias que deriven de esta Ley;

XXII. Incumpla la obligación de llevar a cabo las acciones y medidas de seguridad o de urgente aplicación que establezcan las Secretarías competentes, en los casos y términos establecidos en esta Ley;

XXIII. Incumpla lo dispuesto en esta Ley y en las normas oficiales mexicanas que deriven de la misma, relativas al etiquetado de productos que contengan OGMs y productos derivados de dichos organismos;

XXIV. Incumpla lo dispuesto en este ordenamiento y en las normas oficiales mexicanas que deriven del mismo, relativas a la identificación de OGMs;

XXV. Realice actividades de utilización confinada de OGMs, distintas a las manifestadas en los avisos presentados en los términos de esta Ley;

XXVI. Realice actividades con OGMs distintas de las permitidas, o destine los OGMs a fines diferentes de los permitidos o autorizados;

XXVII. Libere intencionalmente OGMs al ambiente sin contar con los permisos de liberación y, en su caso, las autorizaciones, que correspondan conforme a esta Ley, y

XXVIII. Libere al ambiente OGMs que hayan sido importados o producidos en el territorio nacional, en los términos de esta Ley, para consumo directo humano o animal, para procesamiento de alimentos para consumo humano, o para otros usos distintos a su liberación al ambiente.

CAPÍTULO II
De las Sanciones

ARTÍCULO 120.- Las infracciones a los preceptos de esta Ley, sus reglamentos y las normas oficiales mexicanas que de ella deriven, señaladas en el artículo anterior, serán sancionadas administrativamente por las Secretarías competentes, con una o más de las siguientes sanciones:

I. Multa de quinientos a quince mil días de salario mínimo general vigente en el Distrito Federal a quien cometa las infracciones previstas en las fracciones IV, V, VIII, XIV, XVI, XVII, y XXI del artículo 119 de esta Ley;

II. Multa de quince mil uno a treinta mil días de salario mínimo general vigente en el Distrito Federal a quien cometa las infracciones previstas en las fracciones I, II, III, VI, VII, IX, X, XI, XII, XIII, XV, XVIII, XIX, XX, XXII, XXIII, XXIV, XXV, XXVI y XXVII del artículo 119 de este ordenamiento.

En el caso de reincidencia, se duplicará el monto de la multa que corresponda. Para los efectos de esta fracción, se considera reincidente al infractor que incurra más de una vez en conductas que impliquen infracciones a un mismo precepto, en un periodo de dos años, contados a partir de la fecha en que la Secretaría competente determine mediante una resolución definitiva la comisión de la primera infracción, y siempre que ésta no hubiese sido desvirtuada;

III. Clausura temporal o definitiva, parcial o total, de las instalaciones en las que se hayan cometido las infracciones cuando:

A) Las infracciones generen posibles riesgos o efectos adversos a la salud humana o a la diversidad biológica o a la sanidad animal, vegetal o acuícola;

B) El infractor no hubiere cumplido en los plazos y condiciones impuestas por las Secretarías competentes, con las medidas de seguridad o de urgente aplicación ordenadas, o

C) Se trate de desobediencia reiterada al cumplimiento de alguna o algunas medidas de seguridad o de urgente aplicación impuestas por las Secretarías competentes;

IV. El decomiso de los instrumentos, ejemplares, organismos obtenidos o productos relacionados directamente con las infracciones cometidas;

V. La suspensión o revocación de los permisos y las autorizaciones correspondientes;

VI. Arresto administrativo hasta por treinta y seis horas, y

VII. Prohibición de la liberación experimental, de la liberación en programa piloto o de la comercialización de OGMs o de los productos que los contengan.

ARTÍCULO 121.- Con independencia de lo dispuesto en el Artículo anterior, toda persona que, con pleno conocimiento de que se trata de OGMs, cause daños a terceros en sus bienes o a su salud, por el uso o manejo indebido de dichos organismos, será responsable y estará obligada a repararlos en los términos de la legislación civil federal. Igual obligación asumirá la persona que dañe el medio ambiente o la diversidad biológica, por el uso o manejo indebido de OGMs, para lo cual será aplicable lo dispuesto en el Artículo 203 de la Ley General del Equilibrio Ecológico y la Protección al Ambiente.

Las personas afectadas directamente en sus bienes podrán solicitar al juez, que requiera a la Secretaría competente para que, por conducto de su respectivo comité técnico científico que establezca conforme a este ordenamiento, elabore un dictamen técnico cuyo objeto sea demostrar la existencia del daño, y sirva de base al juez para determinar, en su caso, la forma de su reparación. El dictamen técnico que se expida no generará costo alguno a cargo de los solicitantes.

En el caso de daños al medio ambiente o a la diversidad biológica, la SEMARNAT, a través de la Procuraduría Federal de Protección al Ambiente, ejercerá la acción de responsabilidad, pudiéndolo hacer en cualquiera de las siguientes formas:

I. De oficio, con base en el expediente relativo a actos de inspección y vigilancia que hayan concluido en definitiva, se haya determinado la comisión de infracciones a esta Ley y esta determinación no haya sido desvirtuada por cualquier medio de impugnación, o

II. Por denuncia, presentada por miembros de la comunidad afectada, de actos que pudieran contravenir lo establecido en esta Ley y demás disposiciones que de ella emanen. La denuncia deberá acompañarse de la información técnica y científica que la sustente, con la participación del Consejo Consultivo Científico de la CIBIOGEM, previa opinión de la Comisión Nacional para el Conocimiento y Uso de la Biodiversidad.

En los casos a que se refieren las fracciones anteriores, la Procuraduría Federal de Protección al Ambiente procederá a ejercitar la acción de responsabilidad con base en el dictamen técnico que para tal efecto elabore el comité técnico científico de la SEMARNAT. Para la formulación del dictamen, el comité técnico científico evaluará la información y los elementos con que cuente la Procuraduría Federal de Protección al Ambiente, sea que obren en el expediente administrativo o los que aporten los denunciantes, respectivamente, y determinará, en su caso, la existencia del daño. Serán competentes para conocer sobre las acciones de responsabilidad por daños al medio ambiente o a la diversidad

biológica en los términos de este Artículo, los juzgados de distrito en materia civil, conforme a la competencia territorial establecida en las disposiciones respectivas.

Las sanciones administrativas establecidas en el Artículo anterior se aplicarán sin perjuicio, en su caso, de las penas que correspondan cuando los actos u omisiones constitutivos de infracciones a esta Ley, sean también constitutivos de delito conforme a las disposiciones aplicables del Código Penal Federal.

ARTÍCULO 122.- Son aplicables supletoriamente a este Capítulo en cuanto a responsabilidades administrativas, las disposiciones del Capítulo Único del Título Cuarto de la Ley Federal de Procedimiento Administrativo, con excepción del artículo 70-A de dicho ordenamiento.

TÍTULO DECIMOSEGUNDO
Recurso de Revisión

ARTÍCULO 123.- Las resoluciones definitivas dictadas en los procedimientos administrativos con motivo de la aplicación de esta Ley, sus reglamentos y las normas que de ella deriven, podrán ser impugnadas por los afectados mediante el recurso de revisión, dentro de los quince días siguientes a la fecha de su notificación, o ante las instancias jurisdiccionales competentes.

El recurso de revisión se interpondrá directamente ante la Secretaría que emitió la resolución impugnada, quien en su caso, otorgará su admisión, y el otorgamiento o la denegación de la suspensión del acto recurrido, turnando el recurso a su superior jerárquico en la misma Secretaría para su resolución definitiva.

ARTÍCULO 124.- Por lo que se refiere a los demás trámites relativos a la substanciación del recurso de revisión a que se refiere el artículo anterior, se estará a lo dispuesto en el Título Sexto de la Ley Federal de Procedimiento Administrativo.

TRANSITORIOS

ARTÍCULO PRIMERO.- La presente Ley entrará en vigor a los treinta días hábiles siguientes de su publicación en el **Diario Oficial de la Federación**.

ARTÍCULO SEGUNDO.- Las Secretarías competentes deberán expedir y publicar en el **Diario Oficial de la Federación** los formatos de avisos a que se refiere este ordenamiento, dentro de los veinte días siguientes a la aprobación de los mismos por la Comisión Federal de Mejora Regulatoria.

ARTÍCULO TERCERO.- Una vez expedidos y publicados los formatos a que se refiere el artículo transitorio anterior, los interesados que de conformidad con esta Ley tengan la obligación de presentar avisos, deberán hacerlo en un plazo de noventa días contados a partir de la publicación de dichos formatos en el **Diario Oficial de la Federación**.

ARTÍCULO CUARTO.- Los titulares de las autorizaciones otorgadas con anterioridad a la expedición de esta Ley, no serán afectados por virtud de la entrada en vigor de este ordenamiento en los derechos y obligaciones consignados en las mismas.

ARTÍCULO QUINTO.- Las solicitudes de autorizaciones cuya tramitación haya iniciado con anterioridad a la expedición de la presente Ley, y que se encuentren pendientes de resolución, deberán ser resueltas conforme a las disposiciones jurídicas y administrativas vigentes al momento en que dichas solicitudes fueron ingresadas.

ARTÍCULO SEXTO.- La SHCP realizará los actos necesarios para transferir los recursos necesarios para el funcionamiento de la Secretaría Ejecutiva y del Consejo Consultivo Científico de la CIBIOGEM, y aprobará las plazas que sean necesarias para el funcionamiento de la Secretaría Ejecutiva de dicha CIBIOGEM, con cargo a los recursos que tenga aprobada dicha Comisión, así como aquellos que las dependencias y entidades que integran dicha Comisión, tengan aprobados para dichos fines, en los términos de las disposiciones aplicables.

Las acciones que se deriven del cumplimiento de esta Ley y demás disposiciones que de ella deriven, se atenderán con cargo a la disponibilidad presupuestaria aprobada para tal efecto a las dependencias y entidades de la Administración Pública Federal que integran la CIBIOGEM.

El Acuerdo Presidencial por el que se creó la CIBIOGEM continuará en vigor en lo que no se oponga a esta Ley, hasta en tanto se expidan las disposiciones reglamentarias correspondientes de este ordenamiento.

ARTÍCULO SÉPTIMO.- Las disposiciones reglamentarias relativas a lo dispuesto en el Capítulo IV del Título Primero de la presente Ley, así como las correspondientes a los Capítulos I y II del Título Octavo de este mismo ordenamiento, se deberán expedir en el plazo de seis meses contados a partir de la entrada en vigor del presente ordenamiento. La CIBIOGEM emitirá sus reglas de operación dentro de los sesenta días siguientes a la entrada en vigor de las disposiciones reglamentarias señaladas en este artículo.

ARTÍCULO OCTAVO.- La convocatoria para integrar el Consejo Consultivo se expedirá dentro de los treinta días siguientes a la entrada en vigor de esta Ley, y se integrará dentro de los tres meses siguientes a la publicación de la convocatoria.

ARTÍCULO NOVENO.- El CONACyT realizará lo necesario para modificar el fideicomiso que tiene establecido para el manejo de recursos de la Comisión Intersecretarial creada mediante el Acuerdo Presidencial publicado en el **Diario Oficial de la Federación** el 5 de noviembre de 1999, para dar cumplimiento a esta Ley, a efecto de que opere en lo sucesivo como el Fondo para el Fomento y Apoyo a la Investigación Científica y Tecnológica en Bioseguridad y Biotecnología que establece el presente ordenamiento.

ARTÍCULO DÉCIMO.- El programa para el desarrollo de la bioseguridad y la biotecnología a que se refiere el artículo 29 de esta Ley, se formulará y expedirá en un plazo no mayor a un año contado a partir de la entrada en vigor del presente ordenamiento.

ARTÍCULO DECIMOPRIMERO.- Los anteproyectos de las normas oficiales mexicanas a que se refieren los artículos 42, fracción VII, 50 fracción V, 55 fracción VII, 74, 101 y 102 de esta Ley, deberán ser presentados a los Comités Consultivos Nacionales de Normalización correspondientes e integrarse al Programa Nacional de Normalización, dentro de un plazo no mayor a seis meses contados a partir de la entrada en vigor del presente ordenamiento, de conformidad y para los efectos establecidos en la Ley Federal sobre Metrología y Normalización.

Los anteproyectos de las demás normas oficiales mexicanas a que se refiere esta Ley, se presentarán dentro del plazo de un año contado a partir de la entrada en vigor del presente ordenamiento, para los efectos señalados en el párrafo anterior.

En tanto se expiden las normas oficiales mexicanas a que se refieren los artículos 42, fracción VII, 50 fracción V y 55 fracción VII de esta Ley, la SEMARNAT y la SAGARPA, en sus respectivos ámbitos de su competencia, podrán determinar la información que se considere necesaria, con la participación que le corresponda a la Comisión Federal de Mejora Regulatoria, y en un plazo que no excederá de un año

contado a partir de la entrada en vigor del presente ordenamiento, a efecto de expedir los permisos correspondientes.

ARTÍCULO DECIMOSEGUNDO.- Se derogan todas las disposiciones legales que se opongan a la presente Ley.

México, D.F., a 15 de febrero de 2005.- Dip. **Manlio Fabio Beltrones Rivera**, Presidente.- Sen. **Diego Fernández de Cevallos Ramos**, Presidente.- Dip. **Marcos Morales Torres**, Secretario.- Sen. **Sara I. Castellanos Cortés**, Secretaria.- Rúbricas.**"**

En cumplimiento de lo dispuesto por la fracción I del Artículo 89 de la Constitución Política de los Estados Unidos Mexicanos, y para su debida publicación y observancia, expido el presente Decreto en la Residencia del Poder Ejecutivo Federal, en la Ciudad de México, Distrito Federal, a los diecisiete días del mes de marzo de dos mil cinco.- **Vicente Fox Quesada**.- Rúbrica.- El Secretario de Gobernación, **Santiago Creel Miranda**.- Rúbrica.

ARTÍCULOS TRANSITORIOS DE DECRETOS DE REFORMA

DECRETO por el que se reforman y derogan diversas disposiciones de la Ley para la Protección de Personas Defensoras de Derechos Humanos y Periodistas; de la Ley de Cooperación Internacional para el Desarrollo; de la Ley de Hidrocarburos; de la Ley de la Industria Eléctrica; de la Ley Federal de Presupuesto y Responsabilidad Hacendaria; de la Ley General de Protección Civil; de la Ley Orgánica de la Financiera Nacional de Desarrollo Agropecuario, Rural, Forestal y Pesquero; de la Ley de Ciencia y Tecnología; de la Ley Aduanera; de la Ley Reglamentaria del Servicio Ferroviario; de la Ley General de Cultura Física y Deporte; de la Ley Federal de Cinematografía; de la Ley Federal de Derechos; de la Ley del Fondo Mexicano del Petróleo para la Estabilización y el Desarrollo; de la Ley de Bioseguridad de Organismos Genéticamente Modificados; de la Ley General de Cambio Climático; de la Ley General de Víctimas y se abroga la Ley que crea el Fideicomiso que administrará el Fondo de Apoyo Social para Ex Trabajadores Migratorios Mexicanos.

Publicado en el Diario Oficial de la Federación el 6 de noviembre de 2020

ARTÍCULO DÉCIMO SEXTO. Se reforma el artículo 31 de la Ley de Bioseguridad de Organismos Genéticamente Modificados, para quedar como sigue:

……

Transitorios

Primero. El presente Decreto entrará en vigor el día siguiente al de su publicación en el Diario Oficial de la Federación.

Segundo. Se derogan todas las disposiciones que se opongan a lo dispuesto en el presente Decreto.

Tercero. Se abroga la Ley que crea el Fideicomiso que Administrará el Fondo para el Fortalecimiento de Sociedades y Cooperativas de Ahorro y Préstamo y de Apoyo a sus Ahorradores.

Cuarto. Las dependencias y entidades, por conducto de sus unidades responsables, deberán coordinar las acciones que correspondan para que a más tardar dentro de los 30 días naturales contados a partir de la entrada en vigor del presente Decreto concentren, en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal que corresponda, en la Tesorería de la Federación la totalidad de los recursos públicos federales que formen parte de los fideicomisos, mandatos y análogos públicos previstos en las disposiciones que se abrogan, reforman o derogan por virtud de este Decreto, salvo que la Secretaría de Hacienda y Crédito Público determine una fecha distinta para la concentración de los recursos.

A la extinción de los fideicomisos, y terminación de mandatos y análogos públicos las entidades concentrarán en sus respectivas tesorerías los recursos distintos a los fiscales, en el plazo señalado en el primer párrafo del presente Transitorio.

Los ingresos excedentes que se concentren en la Tesorería de la Federación al amparo del presente Transitorio se destinarán en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal correspondiente, con prioridad para el fortalecimiento de los programas y acciones en materia de salud, especialmente para los requerimientos derivados de la atención a la Pandemia generada por la enfermedad Covid-19, que ocasiona el Coronavirus SARS-CoV2, incluyendo, en su caso, la obtención de

la vacuna en el número de dosis necesarias, así como para procurar la estabilización del balance fiscal federal y el pago de las obligaciones previamente contraídas por los vehículos financieros a que se refiere el presente Decreto con anterioridad a la entrada en vigor del mismo.

Quinto. Los ejecutores de gasto, por conducto de sus unidades responsables, deberán coordinarse con las instituciones que fungen como fiduciarias para llevar a cabo los actos y procesos necesarios para extinguir los fideicomisos y dar por terminados los mandatos y análogos públicos a que se refieren las disposiciones que se reforman o derogan por virtud de este Decreto, con la finalidad de que durante el primer semestre del ejercicio 2021 se suscriban los convenios de extinción o terminación respectivamente, en términos de las disposiciones aplicables.

Los derechos y obligaciones derivados de los instrumentos jurídicos que por virtud del presente Decreto se extinguen o terminan, serán asumidos por los ejecutores de gasto correspondientes con cargo a su presupuesto autorizado, de conformidad con las disposiciones aplicables.

Sexto. Las dependencias y entidades que coordinen la operación de los fideicomisos, mandatos o análogos públicos serán las responsables de realizar todos los actos necesarios que permitan llevar a cabo la extinción o terminación de éstos, entre otros, por lo que se refiere a los activos y pasivos con los que cuente, en términos de la Ley Federal de Presupuesto y Responsabilidad Hacendaria y su Reglamento.

Séptimo. El Consejo Nacional de Ciencia y Tecnología, así como los Centros Públicos de Investigación llevarán a cabo las acciones necesarias para que los fideicomisos constituidos al amparo de la Ley de Ciencia y Tecnología, se ajusten a lo dispuesto en la Ley Federal de Presupuesto y Responsabilidad Hacendaria y su Reglamento, y en consecuencia concentren en la Tesorería de la Federación, en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal que corresponda, la totalidad de los recursos públicos federales que formen parte del patrimonio de dichos fideicomisos, en términos de las disposiciones aplicables, en la fecha que determine la Secretaría de Hacienda y Crédito Público en conjunto con el Consejo Nacional de Ciencia y Tecnología, sin que la misma rebase el 30 de junio de 2021. Por lo que a partir de la entrada en vigor del presente Decreto no podrán adquirir compromisos adicionales con cargo al patrimonio de dichos instrumentos.

Asimismo, deberán concentrar en sus tesorerías los recursos distintos a los señalados en el primer párrafo del presente Transitorio en el plazo previsto en el mismo.

El Consejo Nacional de Ciencia y Tecnología y los Centros Públicos de Investigación deberán coordinarse con las instituciones que fungen como fiduciarias para llevar a cabo los actos y procesos necesarios para extinguir los fideicomisos públicos constituidos al amparo de la Ley de Ciencia y Tecnología, con la finalidad de que durante el ejercicio fiscal de 2021 se suscriban los convenios de extinción en términos de las disposiciones aplicables.

Los fideicomisos públicos constituidos por Centros Públicos de Investigación para el cumplimiento exclusivo de obligaciones de carácter laboral o en materia de seguridad social continuarán operando con la finalidad de salvaguardar los derechos laborales de los trabajadores.

En caso de que los Centros Públicos de Investigación cuenten con fideicomisos que integren el cumplimiento de obligaciones de carácter laboral o en materia de seguridad social y otras obligaciones de distinta naturaleza en un solo instrumento, deberán llevar a cabo la modificación a los mismos dentro de un plazo de 30 días naturales contados a partir de la entrada en vigor del presente Decreto, a efecto de que dichos fideicomisos públicos conserven únicamente aquellas obligaciones de carácter laboral o en materia de seguridad social, y concentren los recursos no relacionados con dichos fines en términos del primer párrafo del presente Transitorio.

Los ingresos excedentes que se concentren en la Tesorería de la Federación al amparo del presente Transitorio se destinarán en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal correspondiente, de conformidad con lo dispuesto por el último párrafo del transitorio Cuarto de este Decreto.

A la entrada en vigor del presente Decreto, los fondos Sectorial CONACYT-Secretaría de Energía-Hidrocarburos; Sectorial CONACYT-Secretaría de Energía-Sustentabilidad Energética, y de Investigación Científica y Desarrollo Tecnológico del Instituto Mexicano del Petróleo, no podrán contraer obligaciones adicionales con cargo a sus respectivos patrimonios.

Los recursos a que se refiere el artículo 88 de la Ley Federal de Presupuesto y Responsabilidad Hacendaria, que se reforma por virtud del presente Decreto, se podrán destinar a cubrir los pagos derivados de los compromisos adquiridos por los fondos a que se refiere el párrafo anterior, previo a la entrada en vigor de este Decreto.

Octavo. El Consejo Nacional de Ciencia y Tecnología, deberá llevar a cabo las acciones que correspondan para que a partir de la entrada en vigor del presente Decreto no se adquieran compromisos adicionales con cargo al patrimonio del fideicomiso público denominado Fondo para el Fomento y Apoyo a la Investigación Científica y Tecnológica en Bioseguridad y Biotecnología, y se concentren en la Tesorería de la Federación, en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal que corresponda, la totalidad de los recursos públicos federales que formen parte del patrimonio del mismo en la fecha que determine la Secretaría de Hacienda y Crédito Público en conjunto con el Consejo Nacional de Ciencia y Tecnología, sin que la misma rebase el 30 de junio de 2021. Cumplido lo anterior, el fideicomiso deberá extinguirse durante el ejercicio fiscal de 2021.

Los ingresos excedentes que se concentren en la Tesorería de la Federación al amparo del presente Transitorio se destinarán en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal correspondiente, de conformidad con lo dispuesto por el último párrafo del Artículo Cuarto Transitorio de este Decreto.

Noveno. Se deroga el transitorio Tercero del Decreto por el que se reforman, adicionan y derogan diversas disposiciones de la Ley Aduanera, publicado en el Diario Oficial de la Federación el 1o. de enero de 2002.

Décimo. La Comisión Nacional de Cultura Física y Deporte realizará las acciones conducentes para el otorgamiento de un reconocimiento económico vitalicio a los deportistas que en representación oficial obtengan o hayan obtenido una o más medallas en Juegos Olímpicos o Paralímpicos, con cargo a su presupuesto autorizado, para lo cual el Reglamento de la Ley General de Cultura Física y Deporte establecerá los criterios y bases para el otorgamiento de dicho reconocimiento.

Décimo Primero. Dentro de un plazo de ciento ochenta días naturales, el Ejecutivo Federal deberá reformar los Reglamentos de las leyes que se reforman por virtud de la entrada en vigor del presente Decreto, en lo que resulte conducente.

Décimo Segundo. La Secretaría de Gobernación, con cargo a su presupuesto autorizado, asumirá las obligaciones pendientes de cumplimiento relacionadas con el Fondo de Apoyo Social para ex Trabajadores Migratorios Mexicanos, hasta su total cumplimiento.

Décimo Tercero. Los recursos que integran el patrimonio de los fideicomisos públicos denominados Fondo Metropolitano y Fondo Regional se concentrarán en la Tesorería de la Federación sujetándose a lo dispuesto en el transitorio Cuarto del presente Decreto. Los recursos aportados deberán ser destinados, en primer término, al Programa de Mejoramiento Urbano a cargo de la Secretaría de Desarrollo Agrario, Territorial y Urbano.

Décimo Cuarto. Los recursos que integran el patrimonio del fideicomiso público denominado Fondo para el Desarrollo de Zonas de Producción Minera se concentrarán en la Tesorería de la Federación sujetándose a lo dispuesto en el transitorio Cuarto del presente Decreto por lo que se refiere a los recursos obtenidos previo al ejercicio fiscal 2019. Por lo que se refiere a los recursos obtenidos durante el ejercicio fiscal 2019 se estará a lo dispuesto por la autoridad jurisdiccional competente y, en caso de resultar procedente se sujetarán a dicho Transitorio.

Una vez realizado lo anterior, la Secretaría de Economía por conducto de la unidad responsable de dicho fideicomiso público en conjunto con la institución fiduciaria procederán en términos de lo señalado en el transitorio Quinto.

Décimo Quinto. A la entrada en vigor del presente Decreto, el Fideicomiso para promover el acceso al financiamiento de MIPYMES y Emprendedores no podrá contraer obligaciones adicionales con cargo a su patrimonio, sin embargo, continuará cumpliendo con los compromisos derivados de los instrumentos de garantía contratados, conforme a las disposiciones aplicables, para el cumplimiento de sus fines.

Una vez cumplidas la totalidad de las obligaciones y se ejerzan los derechos derivados de los instrumentos a que se refiere el párrafo anterior, el Fideicomiso para promover el acceso al financiamiento de MIPYMES y Emprendedores se extinguirá en términos de las disposiciones aplicables.

A la extinción de dicho vehículo, la Secretaría de Economía por conducto de la unidad responsable, realizará las acciones necesarias para concentrar los recursos federales remanentes en la Tesorería de la Federación.

Los ingresos excedentes que se concentren en la Tesorería de la Federación al amparo del presente Transitorio se destinarán en términos de la Ley de Ingresos de la Federación para el ejercicio fiscal correspondiente.

Décimo Sexto. La Secretaría de Hacienda y Crédito Público, en su carácter de mandante en el contrato de Mandato para la Administración de los Recursos del Programa de Cooperación Energética para Países de Centroamérica y el Caribe, deberá coordinarse con la institución que funja con el carácter de mandataria para llevar a cabo las acciones necesarias para formalizar la terminación de dicho instrumento en términos del transitorio Quinto del presente Decreto. De igual forma, por conducto de la unidad responsable del mandato, deberá coordinar las acciones que correspondan para que concentre los recursos públicos federales en la Tesorería de la Federación, de conformidad con lo dispuesto en el transitorio Cuarto del presente Decreto.

Asimismo, la unidad responsable del Mandato deberá llevar a cabo las acciones conducentes para efectuar la recuperación de los créditos que, en su caso, se hubiesen otorgado con cargo a los recursos del Mandato a que se refiere el presente transitorio, a efecto de que dichos recursos sean concentrados en Tesorería de la Federación, en los términos previstos en el transitorio Cuarto del presente Decreto.

Décimo Séptimo. A partir de la entrada en vigor del presente Decreto, los ejecutores de gasto no podrán comprometer recursos públicos con cargo a los fideicomisos sin estructura orgánica, mandatos o análogos públicos, a que se refieren las disposiciones que se reforman o derogan por virtud de este Decreto y de sus disposiciones transitorias.

Décimo Octavo. Los recursos que integran el patrimonio del Fondo a que se refiere el segundo párrafo del artículo 22 de la Ley Orgánica de la Financiera Nacional de Desarrollo Agropecuario, Rural, Forestal y Pesquero que se deroga deberán ser reintegrados a la Financiera mismo que formará parte de su patrimonio, salvo el monto que, en su caso, la Secretaría de Hacienda y Crédito Público determine se reintegre a la Tesorería de la Federación. Asimismo, la Financiera, en conjunto con la institución crediticia

del citado Fondo, procederá en términos de lo señalado en los transitorios Cuarto y Quinto del presente Decreto.

Décimo Noveno. Se deroga el transitorio Noveno del Decreto por el que se expide la Ley General de Protección Civil publicado en el Diario Oficial de la Federación el 6 de junio de 2012.

A partir del 1o. de enero de 2021, el Fideicomiso Fondo de Desastres Naturales no asumirá compromisos adicionales a los adquiridos previamente, salvo los relativos a los gastos de operación, y únicamente podrán llevarse a cabo los actos tendientes a su extinción. Con los recursos a que se refiere el artículo 37 de la Ley Federal de Presupuesto y Responsabilidad Hacendaria se podrán cubrir las obligaciones que se tengan pendientes y que no se paguen con cargo al patrimonio del Fideicomiso.

Los remanentes de recursos de este Fideicomiso se deberán concentrar a más tardar el 30 de junio de 2021, por concepto de aprovechamientos, a la Tesorería de la Federación y se destinarán por la Secretaría de Hacienda y Crédito Público para la atención de desastres naturales, así como para cubrir las obligaciones pendientes y que no se paguen con cargo al patrimonio del Fideicomiso.

Vigésimo. Se faculta a la SHCP, para que en coordinación con la Fiduciaria establecida por la Ley del FIPAGO, en su caso, realice los convenios, acuerdos, y todos los actos jurídicos que sean necesarios, para dar cumplimiento a las obligaciones contraídas y convenios en proceso de formalización al 20 de septiembre de 2020. Asimismo, se faculta a la SHCP para realizar los convenios, acuerdos, y todos los actos jurídicos que se requieran, en coordinación con las Entidades Federativas en las que se localizan las citadas cajas de ahorro, para dar cumplimiento a las obligaciones contraídas y convenios en proceso de formalización que hayan sido reportados por la SHCP.

Ciudad de México, a 20 de octubre de 2020.- Dip. **Dulce María Sauri Riancho**, Presidenta.- Sen. **Oscar Eduardo Ramírez Aguilar**, Presidente.- Dip. **María Guadalupe Díaz Avilez**, Secretaria.- Sen. **Lilia Margarita Valdez Martínez**, Secretaria.- Rúbricas.**"**

En cumplimiento de lo dispuesto por la fracción I del Artículo 89 de la Constitución Política de los Estados Unidos Mexicanos, y para su debida publicación y observancia, expido el presente Decreto en la Residencia del Poder Ejecutivo Federal, en la Ciudad de México, a 4 de noviembre de 2020.- **Andrés Manuel López Obrador**.- Rúbrica.- La Secretaria de Gobernación, Dra. **Olga María del Carmen Sánchez Cordero Dávila**.- Rúbrica.

DECRETO por el que se reforman y adicionan diversas disposiciones de la Ley Federal de Defensoría Pública, de la Ley General de Salud, de la Ley General de Cultura Física y Deporte, de la Ley General de Cambio Climático, de la Ley Orgánica de la Procuraduría de la Defensa del Contribuyente, de la Ley Orgánica del Seminario de Cultura Mexicana, de la Ley de la Agencia Nacional de Seguridad Industrial y de Protección al Medio Ambiente del Sector Hidrocarburos, de la Ley de la Comisión Federal de Electricidad, de la Ley de la Comisión Nacional Bancaria y de Valores, de la Ley que Crea la Agencia de Noticias del Estado Mexicano, de la Ley del Sistema Público de Radiodifusión del Estado Mexicano, de la Ley de Instituciones de Seguros y de Fianzas, de la Ley del Fondo Mexicano del Petróleo para la Estabilización y el Desarrollo, de la Ley de la Industria Eléctrica, de la Ley de la Economía Social y Solidaria, Reglamentaria del Párrafo Octavo del Artículo 25 de la Constitución Política de los Estados Unidos Mexicanos, en lo referente al Sector Social de la Economía, de la Ley de la Casa de Moneda de México, de la Ley de Concursos Mercantiles, de la Ley de Bioseguridad de Organismos Genéticamente Modificados, de la Ley de Aguas Nacionales, de la Ley de Asistencia Social, de la Ley General de Desarrollo Social, de la Ley Orgánica de la Financiera Nacional de Desarrollo Agropecuario, Rural, Forestal y Pesquero, de la Ley Federal para la Administración y Enajenación de Bienes del Sector Público, de la Ley Federal de Variedades Vegetales, de la Ley Federal de Sanidad Vegetal, de la Ley Federal de Sanidad Animal, de la Ley Federal de Fomento a las Actividades Realizadas por Organizaciones de la Sociedad Civil, de la Ley Orgánica del Consejo Nacional de Ciencia y Tecnología, de la Ley de Protección al Ahorro Bancario, de la Ley de los Institutos Nacionales de Salud, de la Ley de Ciencia y Tecnología, en materia de paridad de género.

Publicado en el Diario Oficial de la Federación el 11 de mayo de 2022

Artículo Décimo Octavo. Se reforman los artículos 20 y 21 de la Ley de Bioseguridad de Organismos Genéticamente Modificados, para quedar como sigue:

……..

Transitorios

Primero. El presente Decreto entrará en vigor el día siguiente al de su publicación en el Diario Oficial de la Federación.

Segundo. De acuerdo con el artículo transitorio Tercero del Decreto por el que se reforman los artículos 2, 4, 35, 41, 52, 53, 56, 94, y 115; de la Constitución Política de los Estados Unidos Mexicanos, en materia de Paridad entre Géneros, se deberá observar el principio de paridad de manera progresiva, a partir de las nuevas designaciones y nombramientos que correspondan, de conformidad con la ley.

Tercero. Todas las obligaciones que se generen con la entrada en vigor del presente Decreto se cubrirán con cargo al presupuesto aprobado a los ejecutores de gasto responsables para el ejercicio fiscal en curso y subsecuentes, por lo que no se autorizarán recursos adicionales para tales efectos y, en caso de que se realice alguna modificación a su estructura orgánica, está también deberá ser cubierta con su presupuesto autorizado y conforme a las disposiciones jurídicas aplicables.

Ciudad de México, a 15 de marzo de 2022.- Dip. **Sergio Carlos Gutiérrez Luna**, Presidente.- Sen. **Olga Sánchez Cordero Dávila**, Presidenta.- Dip. **Luis Enrique Martínez Ventura**, Secretario.- Sen. **Verónica Noemí Camino Farjat**, Secretaria.- Rúbricas.**"**

En cumplimiento de lo dispuesto por la fracción I del Artículo 89 de la Constitución Política de los Estados Unidos Mexicanos, y para su debida publicación y observancia, expido el presente Decreto en la Residencia del Poder Ejecutivo Federal, en la Ciudad de México, a 2 de mayo de 2022.- **Andrés Manuel López Obrador**.- Rúbrica.- El Secretario de Gobernación, Lic. **Adán Augusto López Hernández**.- Rúbrica.

REGLAMENTO DE LA LEY GENERAL DE SALUD EN MATERIA DE TRASPLANTES

TEXTO VIGENTE
Nuevo Reglamento publicado en el Diario Oficial de la Federación el 26 de marzo de 2014

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República.

ENRIQUE PEÑA NIETO, Presidente de los Estados Unidos Mexicanos, en ejercicio de la facultad que me confiere el artículo 89, fracción I, de la Constitución Política de los Estados Unidos Mexicanos, y con fundamento en los artículos 39 de la Ley Orgánica de la Administración Pública Federal y 3o., fracción XXVI; 13, apartado A, fracción II; 17 Bis, párrafos primero y segundo, fracciones II, IV, VIII y X; 202; 375, fracción VI; 313 a 342; 393 a 401 Bis 2; 462 y 462 Bis, segundo párrafo, de la Ley General de Salud, he tenido a bien expedir el siguiente

REGLAMENTO DE LA LEY GENERAL DE SALUD EN MATERIA DE TRASPLANTES

TÍTULO PRIMERO
DISPOSICIONES GENERALES

Capítulo Único
De las Disposiciones Generales

Artículo 1. El presente Reglamento tiene por objeto regular la disposición de órganos, tejidos y células, con excepción de la sangre, componentes sanguíneos y células progenitoras o troncales, que se realice con fines de trasplantes. Sus disposiciones, son de orden público, interés social y aplicación obligatoria en todo el territorio nacional.

Artículo 2. Para efectos del presente Reglamento, además de las definiciones previstas en el artículo 314 de la Ley, se entenderá por:

I. CENATRA: El Centro Nacional de Trasplantes;

II. Centros Estatales de Trasplantes o Consejos Estatales de Trasplantes: Las estructuras administrativas o cuerpos colegiados que, establezcan los gobiernos de las entidades federativas o las ya existentes que tengan a su cargo realizar de manera coordinada con el CENATRA, las funciones vinculadas a la materia de Disposición de Órganos, Tejidos y células para fines de Trasplantes;

III. COFEPRIS: La Comisión Federal para la Protección contra Riesgos Sanitarios;

IV. Comité Interno de Coordinación para la Donación: El Comité a que se refiere el segundo párrafo del artículo 316 de la Ley;

V. Comité Interno de Trasplantes: El Comité a que se refiere el tercer párrafo del artículo 316 de la Ley;

VI. Compatibilidad: El grado de semejanza genética entre los individuos que se comprueba después de llevar a cabo los estudios correspondientes a grupo sanguíneo, inmunogenética,

antropometría o aquéllos necesarios, atendiendo al Órgano, Tejido o célula de que se trate y al avance científico; que prevenga el riesgo de rechazo del Órgano, Tejido o células trasplantadas;

VII. Coordinador Hospitalario: Al Coordinador Hospitalario de Donación de Órganos y Tejidos para Trasplantes al que se refiere la fracción XX del artículo 314 de la Ley;

VIII. Criterios Médicos: Los elementos clínicos, de laboratorio y de gabinete, definidos por los Comités Internos de Trasplantes, que permitan seleccionar a los candidatos a recibir un Órgano, Tejido o célula;

IX. Establecimientos de Salud**:** Las unidades clínicas u hospitalarias que realizan actos de Extracción, análisis, conservación, preparación, suministro y Trasplante de Órganos, Tejidos y células;

X. Extracción de Órganos, Tejidos o células: El acto quirúrgico a través del cual se obtienen uno o varios Órganos, Tejidos o células de un Donador vivo o fallecido para su posterior Trasplante en uno o varios Receptores;

XI. Histocompatibilidad: La semejanza entre dos o más Tejidos a nivel de sus características genéticas e inmunológicas;

XII. Ley: La Ley General de Salud;

XIII. Oportunidad del Trasplante: El conjunto de condiciones de tiempo, modo y lugar que permitan realizar un Trasplante;

XIV. Programa de Trasplante: El conjunto de servicios autorizados a un Establecimiento de Salud para proporcionar en forma integral a los pacientes que requieren de un Trasplante de un Órgano, Tejido o célula, coordinado por el Comité Interno de Trasplantes;

XV. Receptor Candidato: El paciente que ha sido aceptado por el Comité Interno de Trasplantes para ser Receptor de un Órgano, Tejido o célula y que ha sido inscrito en el Registro Nacional de Trasplantes, hasta antes de que se le realice el Trasplante;

XVI. Secretaría: La Secretaría de Salud, y

XVII. Urgencia de Trasplante o Código 0: El riesgo inminente de muerte de un paciente, que por su condición de gravedad, su única alternativa de vida es el Trasplante de Órganos.

Artículo 3. La interpretación para efectos administrativos del presente Reglamento corresponde a la Secretaría.

Artículo 4. Corresponde a la Secretaría por conducto del CENATRA:

I. Establecer programas y campañas orientados a difundir entre los responsables sanitarios y los profesionales de la salud, los requisitos sanitarios que se deben satisfacer en la Disposición de Órganos, Tejidos y células con fines de Trasplantes;

II. Fomentar en coordinación con las dependencias y entidades de la Administración Pública Federal y los gobiernos de las entidades federativas, acciones para promover la donación de Órganos, Tejidos y células, tanto en vida como después de acontecida la pérdida de la misma, con fines de Trasplantes;

III. Fomentar el desarrollo de programas de estudio e investigación relacionados con la Disposición de Órganos, Tejidos y células, en lo que respecta a Trasplantes;

IV. Informar y orientar a la población sobre la donación de Órganos, Tejidos y células con fines de Trasplante, así como, impulsar la participación de los medios de comunicación en la difusión de información relativa a las acciones que impliquen actividades a favor de la cultura de la donación de Órganos, Tejidos y células;

V. Coordinar el Subsistema Nacional de Donación y Trasplantes;

VI. Coordinar la Distribución y Asignación de Órganos, Tejidos y células de Donadores con pérdida de vida para Trasplante, y

VII. Operar el Registro Nacional de Trasplantes.

Artículo 5. En toda donación o Trasplante de Órganos, Tejidos y células obtenidos de Donadores que hubiesen perdido la vida, los responsables sanitarios de los Establecimientos de Salud y el personal de salud participante, deberán mantener en el anonimato la identidad entre el Donador y el Receptor.

TÍTULO SEGUNDO
LA DONACIÓN PARA FINES DE TRASPLANTES

Capítulo I
Del Consentimiento para la Donación con Fines de Trasplantes

Artículo 6. En ningún caso se podrá disponer de Órganos, Tejidos y células para fines de Trasplantes, en contra de la voluntad del Donador.

Artículo 7. La donación de la totalidad de un Órgano único, esencial para la conservación de la vida, sólo podrá hacerse una vez declarada la pérdida de la vida del Donador.

Los ojos y el tejido corneal sólo podrán extraerse con fines de Trasplante de Donadores que hayan perdido la vida, o por acto quirúrgico por indicación médica.

Artículo 8. El CENATRA dará a conocer, mediante publicación que se realice en el Diario Oficial de la Federación, el formato oficial que se utilizará para manifestar el consentimiento expreso para donar Órganos, Tejidos y células después de la muerte para que éstos sean utilizados en Trasplantes, en términos del segundo párrafo del artículo 329 de la Ley.

El formato a que se hace referencia en el párrafo anterior, contendrá por lo menos, el nombre completo de su otorgante, su edad, sexo, nacionalidad, estado civil, ocupación, referencias personales, y el señalamiento del documento con el que se haya identificado, así como si se trata de una donación amplia o limitada.

Artículo 9. El documento en el que el Donador exprese su consentimiento para la donación en vida de sus Órganos, Tejidos y células con fines de Trasplante, deberá ser obtenido por el Comité Interno de Trasplantes y al menos contener:

I. Nombre del Donador;

II. Domicilio del Donador;

III. Edad del Donador;

IV. Sexo del Donador;

V. Estado civil del Donador;

VI. Ocupación del Donador;

VII. Nombre y domicilio del cónyuge, concubina o concubino, si tuviere el Donador;

VIII. Nombre y domicilio de los padres y a falta de éstos, de alguno de sus familiares más cercanos, cuando el Donador se encuentre soltero;

IX. El señalamiento de que por propia voluntad y a título gratuito, consiente en la donación del Órgano, Tejido o célula de que se trate, expresándose que esta donación se entenderá hecha entre vivos, lo cual deberá ser acorde con las disposiciones jurídicas aplicables;

X. Nombre del Receptor del Órgano, Tejido o célula;

XI. El señalamiento de haber recibido información a su satisfacción sobre los riesgos de la operación y las consecuencias de la Extracción del Órgano, Tejido o célula;

XII. Nombre, firma y domicilio de los testigos cuando se trate de documento privado;

XIII. Lugar y fecha en que se emite el documento;

XIV. Firma o huella digital del Donador;

XV. El señalamiento de si la donación se hace a favor de alguna persona o institución determinada. En este caso, se deberá mencionar el nombre o denominación o razón social de dicha persona o institución, y

XVI. Las demás circunstancias de modo, lugar y tiempo que considere pertinentes el donante, así como cualquier otra que condicione la donación.

Tratándose de donación entre personas en las que no exista algún tipo de parentesco, se deberá exhibir además, el consentimiento expreso otorgado ante notario público, en términos de lo dispuesto por el artículo 333, fracción VI, inciso b), de la Ley.

Artículo 10. El documento en el que se haga constar el consentimiento que otorguen las personas a que se refiere el párrafo primero del artículo 324 de la Ley, será recabado por el Coordinador Hospitalario, una vez que se certifique la pérdida de la vida.

El documento en el que se haga constar el consentimiento a que se refiere el párrafo anterior deberá contener, cuando menos, lo siguiente:

I. Nombre del otorgante y fecha de nacimiento;

II. Domicilio del otorgante;

III. Nombre y datos generales del Donador, entre ellos, fecha de nacimiento, domicilio y nacionalidad;

IV. Relación del otorgante con el Donador que lo legitime a dar su consentimiento;

V. La manifestación de que fue informado acerca de la donación de que se trate, que se le dio oportunidad de hacer preguntas y que éstas fueron contestadas satisfactoriamente;

VI. La declaración de que siendo mayor de edad y estando en pleno uso de sus facultades mentales, autoriza libremente la donación total o parcial del cuerpo del Donador, a título gratuito, para ser utilizado con fines de Trasplante;

VII. Lugar y fecha en que se emite el documento, y

VIII. Firma o huella digital del otorgante y la de dos testigos.

Artículo 11. El escrito público o privado por el que la persona manifieste su negativa expresa a ser Donador, a que hace referencia el segundo párrafo del artículo 324 de la Ley, será redactado en formato libre, el cual deberá contener la firma de la persona que manifiesta dicha negativa o su huella digital en caso de no poder firmar.

Sin perjuicio de lo anterior, el Donador podrá expresar su negativa utilizando el formato que para tal efecto, dé a conocer el CENATRA, mediante publicación que se realice en el Diario Oficial de la Federación, el cual deberá contener por lo menos, el nombre completo de su otorgante, su edad, sexo, nacionalidad, estado civil, ocupación y el señalamiento del documento con el que se haya identificado.

Capítulo II
Del Coordinador Hospitalario

Artículo 12. Al Coordinador Hospitalario, además de lo señalado en la Ley, le corresponderá:

I. Constatar que los Cadáveres de los cuales se dispusieron Órganos, Tejidos o células para fines de Trasplante, sean entregados a sus familiares o a la autoridad competente, con la menor dilación posible;

II. Participar en la elaboración de programas y proyectos de trabajo, así como manuales de procedimientos médicos, técnicos y administrativos relativos a las actividades de Procuración de Órganos, Tejidos y células que el Establecimiento de Salud efectúe, así como dar seguimiento a su observancia;

III. Participar en la capacitación y evaluación del desempeño del personal a su cargo y, en su caso, coadyuvar en actividades docentes y de investigación en materia de Trasplantes;

IV. Promover y difundir estrategias y acciones que fomenten la donación voluntaria y altruista al interior del Establecimiento de Salud en el que laboren, y

V. Las demás que señalen otras disposiciones jurídicas aplicables.

Artículo 13. El Coordinador Hospitalario deberá realizar sus funciones en coordinación con el CENATRA, con los Centros Estatales de Trasplantes o Consejos Estatales de Trasplantes y, en su caso, con las Coordinaciones Institucionales respectivas.

Artículo 14. La capacitación del Coordinador Hospitalario, a que se refiere el artículo 316 Bis de la Ley, así como la expedición de la constancia que acredita dicha capacitación, estará a cargo del

CENATRA, para lo cual podrá auxiliarse de instituciones académicas, en términos de los convenios que para tal efecto se celebren.

Artículo 15. Además de la capacitación a que se refiere el artículo 316 Bis de la Ley, el Coordinador Hospitalario deberá acreditar cada cinco años, ante los integrantes de su Comité Interno de Coordinación para la Donación, o del Comité Interno de Trasplantes del Establecimiento de Salud en el que laboran, que cuenta con los conocimientos actualizados para desempeñar su función. Dicha acreditación deberá ser notificada al CENATRA.

TÍTULO TERCERO
LOS TRASPLANTES

Capítulo I
Disposiciones Comunes

Artículo 16. Cuando el presente Reglamento se refiera a Trasplante de Tejido, éste podrá ser de Tejido simple o compuesto, entendiéndose por Trasplante de Tejido simple, aquél que se realiza de un sólo Tejido, y de Tejido compuesto, aquel Trasplante que se realiza de diferentes Tejidos músculo-esquelético, utilizando o no anastomosis vasculares, entre los que se encuentran los de extremidades y cara.

Artículo 17. Una persona será considerada candidata para recibir un Trasplante cuando:

I. Tenga un padecimiento que pueda tratarse de manera eficaz por medio de un Trasplante de Órgano, Tejido o célula;

II. No presente otras enfermedades que pudieran poner en riesgo el éxito del Trasplante;

III. Tenga una condición física y mental que permita suponer que tolerará el Trasplante y su evolución, y

IV. Otorgue su consentimiento informado de conformidad con las disposiciones jurídicas aplicables.

En caso de menores de edad o incapacidad del paciente para otorgar su consentimiento para la realización del Trasplante, éste deberá ser otorgado por quienes ejerzan la patria potestad, el tutor o el representante legal, según corresponda.

Artículo 18. Si por alguna circunstancia en el Establecimiento de Salud al que le fue enviado un Órgano, Tejido o célula para ser trasplantado, no se pudiera realizar el Trasplante, deberá notificarlo de manera inmediata por escrito al Comité Interno de Coordinación para la Donación o al Comité Interno de Trasplantes del Establecimiento de Salud del que proceda el Órgano, Tejido o célula, informando las razones por las cuales no fue posible realizar dicho Trasplante, para que el Comité al que se haya informado determine una nueva Distribución del Órgano, Tejido o célula de que se trate. Dicha determinación deberá notificarse de manera inmediata al Registro Nacional de Trasplantes.

Artículo 19. El Establecimiento de Salud en el cual se realice la Extracción del Órgano, Tejido o células deberá conservar las evidencias documentales del proceso de donación, por lo menos durante cinco años contados a partir de la Extracción.

Capítulo II
De los Trasplantes de Donadores que hayan Perdido la Vida

Artículo 20. Para la Extracción de Órganos, Tejidos y células de un Donador en el que se haya certificado la pérdida de la vida, a fin de minimizar los riesgos de efectos adversos en el Receptor y no comprometer el éxito del Trasplante, se deberá comprobar mediante la evaluación médica correspondiente que el Donador cumpla con los siguientes requisitos:

I. Tener una edad fisiológica útil para fines de la donación al momento de la pérdida de la vida;

II. No haber presentado neoplasias malignas con riesgo de metástasis, infecciones u otros padecimientos que pudieren afectar al Receptor, y

III. No haber sufrido el efecto deletéreo de una agonía prolongada.

Artículo 21. En el caso de mujeres embarazadas en que se haya certificado la pérdida de la vida, se dará preferencia a la vida del producto de la concepción antes de disponer de Órganos, Tejidos o células para Trasplantes.

Artículo 22. Para la realización de un Trasplante de Órganos, Tejidos o células provenientes de un Donador en el que se haya certificado la pérdida de la vida, en pacientes extranjeros, se deberá de cumplir con los requisitos siguientes:

I. El Receptor deberá tener una condición de estancia en el territorio nacional de residente temporal, residente temporal estudiante o residente permanente y acreditar su permanencia ininterrumpida en el país de por lo menos seis meses previos a la realización del Trasplante, salvo en casos de Urgencia con diagnóstico de hepatitis fulminante, debidamente documentados, y

II. El Receptor deberá contar con resolución favorable del Comité Interno de Trasplantes del Establecimiento de Salud donde se vaya a realizar el Trasplante, firmada por todos sus integrantes, previa evaluación médica, clínica y psicológica. En dicha resolución se deberá manifestar que se ha constatado la inexistencia de circunstancias que pudieran hacer presumir actos de comercio o simulación jurídica que tengan por objeto la intermediación onerosa de Órganos, Tejidos y células.

La Secretaría podrá solicitar al Establecimiento de Salud donde se vaya a realizar el Trasplante, previo a que se realice el mismo, la documentación que compruebe el cumplimiento de los requisitos señalados.

Artículo 23. Los profesionales de la salud encargados de la Extracción de Órganos, Tejidos o células, deberán tratar con cuidado, respeto y dignidad al Cadáver, a fin de conservarlo y entregarlo en las mejores condiciones.

Artículo 24. El Cadáver se entregará a los familiares o a la autoridad competente según sea el caso, al concluir la Extracción de Órganos, Tejidos o células, para lo anterior se deberán agilizar los trámites hospitalarios correspondientes.

Capítulo III
De los Trasplantes entre Vivos

Artículo 25. En los casos de Trasplante con Donadores vivos, una vez que el Comité Interno de Trasplantes haya evaluado favorablemente, tanto al Donador como al Receptor Candidato, se deberá proporcionar, previo a la realización del Trasplante, la información correspondiente al Registro Nacional de Trasplantes, a través de su sistema informático.

Si después de haber proporcionado la información a que hace referencia el párrafo anterior, no se realiza el Trasplante, el Receptor Candidato conservará la antigüedad de su inscripción en el Registro Nacional de Trasplantes.

En los casos en que el Donador no tenga parentesco con el paciente, el Comité Interno de Trasplantes del Establecimiento de Salud donde se vaya a realizar el Trasplante, deberá emitir la resolución favorable para realizarlo, previo a la inscripción del Receptor Candidato en el Registro Nacional de Trasplantes. Esta resolución será firmada por todos los integrantes del Comité Interno de Trasplantes del Establecimiento de Salud, cuando el Donador o el Receptor sean de nacionalidad extranjera.

Artículo 26. La resolución a que se refiere el artículo 333, fracción VI, inciso a), de la Ley, deberá contener lo siguiente:

I. El resumen clínico del caso, incluyendo estudios de evaluación médica, clínica y psicológica del Receptor;

II. La evaluación médica, clínica y psicológica del Donador, y

III. El resultado de la investigación realizada por el Comité Interno de Trasplantes, la que deberá considerar el resultado de las evaluaciones médicas, clínicas y psicológicas practicadas al Donador y al Receptor, con la finalidad de descartar posibles conductas de simulación jurídica, comercio o coacción que tengan por objeto la intermediación onerosa de Órganos, Tejidos y células, manifestando que se ha constatado la inexistencia de dichas conductas.

Para tal efecto, el Comité Interno de Trasplantes, deberá agregar los documentos que le permitan comprobar la ausencia de ánimo de lucro y de hechos de coacción. Dichos documentos deberán integrarse en el expediente clínico.

Artículo 27. Para realizar Trasplantes entre vivos, cuando el Receptor, el Donador o ambos, sean extranjeros, además de cumplir con lo señalado en el artículo 333 de la Ley, se estará a lo siguiente:

I. En los casos en que no exista parentesco entre el Donador y el Receptor:

a) Deberán acreditar su condición de estancia regular en el país, en los términos de las disposiciones migratorias aplicables, con una permanencia comprobable en territorio nacional, de al menos seis meses previos a la realización del Trasplante, y

b) El Receptor deberá contar con un expediente clínico de al menos seis meses en el Establecimiento de Salud en el que vaya a realizarse dicho Trasplante;

II. En los casos en que exista parentesco entre el Donador y el Receptor:

a) Se deberá agregar al expediente clínico original o copia certificada de la documentación que compruebe la relación de parentesco, debidamente apostillada o, en su caso, legalizada en términos de las disposiciones jurídicas aplicables. Si la documentación exhibida estuviera redactada en idioma distinto al español, se deberá acompañar de la traducción que realice un perito traductor, y

b) El Comité Interno de Trasplantes deberá levantar un acta firmada por todos sus integrantes, en la que se haga constar que no existen circunstancias que hagan presumir una simulación

jurídica o comercio de Órganos, Tejidos y células, o bien, hechos de coacción hacia el Donador.

Para el levantamiento del acta a que se hace referencia en el párrafo anterior, se deberán tomar en cuenta las evaluaciones médicas, clínicas y psicológicas del Receptor y del Donador.

El Establecimiento de Salud en el que se vaya a realizar el Trasplante, deberá inscribir al Receptor Candidato del Órgano, Tejido o célula en el Registro Nacional de Trasplantes con una antelación de por lo menos quince días hábiles, si se trata de un Trasplante entre familiares por consanguinidad, civil o de afinidad hasta el cuarto grado, y en los demás casos, de al menos seis meses previos a la realización del Trasplante.

Artículo 28. En los casos previstos en los artículos 26, fracción III y 27, fracción II, inciso b), de este Reglamento, la COFEPRIS y el CENATRA, cuando lo consideren necesario, podrán solicitar cualquier otro elemento de convicción que permita acreditar la legalidad de la realización del Trasplante.

Capítulo IV
De los Comités Internos de Coordinación para la Donación y de Trasplantes

Artículo 29. Los Comités Internos de Coordinación para la Donación, así como los Comités Internos de Trasplantes, deberán instalarse bajo la responsabilidad de los directores o titulares de los Establecimientos de Salud, mediante la suscripción de un acta, que deberá estipular sus respectivas características, funcionamiento y operación, así como las personas que los integran, conforme a lo dispuesto por la Ley, el presente Reglamento y demás disposiciones jurídicas aplicables.

Artículo 30. Los Comités Internos de Coordinación para la Donación estarán integrados por:

I. El Director General o su equivalente del Establecimiento de Salud, y en su ausencia, su inmediato inferior que cuente con un alto nivel de conocimientos médicos, académicos y profesionales, quien lo presidirá;

II. Un representante del Comité Hospitalario de Bioética del Establecimiento de Salud;

III. Un representante del área jurídica del Establecimiento de Salud, en caso de contar con dicha área o de la institución a la que pertenece;

IV. El jefe de urgencias del Establecimiento de Salud;

V. El jefe de terapia intensiva del Establecimiento de Salud de existir ésta;

VI. El responsable sanitario del Establecimiento de Salud, en los casos en los que esta función no sea realizada por alguna de las personas señaladas en las fracciones que anteceden, y

VII. Los demás integrantes que para su correcto funcionamiento determine el Establecimiento de Salud, los cuales contarán con capacitación y conocimientos en la materia de Disposición de Órganos, Tejidos y células.

El Coordinador Hospitalario del Establecimiento de Salud fungirá como Secretario Técnico del Comité Interno de Coordinación para la Donación.

Las sesiones del Comité Interno de Coordinación para la Donación se considerarán válidas con la asistencia de la mayoría de sus integrantes y sus decisiones se tomarán por mayoría.

El Presidente del Comité Interno de Coordinación para la Donación contará con voto de calidad en caso de empate.

Artículo 31. Los Comités Internos de Coordinación para la Donación, además de las previstas por la Ley, tendrán las funciones siguientes:

I. Elaborar el acta correspondiente a cada sesión que se lleve a cabo, la cual una vez firmada por los integrantes se incorporará al libro de actas correspondiente. Tanto las actas como el libro deberán conservarse por un mínimo de cinco años. En el caso del libro de actas, los cinco años se computarán a partir de la fecha de la última acta registrada.

En el acta a que se hace referencia en el párrafo anterior, se hará constar, entre otros aspectos, los siguientes:

a) Los cambios de integrantes que se hayan presentado en los Comités Internos de Coordinación para la Donación y de Coordinadores Hospitalarios, y

b) Las disposiciones de Órganos, Tejidos y células efectuadas en el Establecimiento de Salud al cual pertenezcan, especificando los Criterios y argumentos Médicos, legales y científicos que se tomaron en cuenta para su Distribución;

II. Establecer la Distribución de Órganos, Tejidos y células a otros Establecimientos de Salud, de conformidad con los procedimientos que establezca el CENATRA, y

III. Coadyuvar con el responsable sanitario en proporcionar al Registro Nacional de Trasplantes, dentro de las cuarenta y ocho horas posteriores al evento, la información de su Establecimiento de Salud relativa a:

a) Los cirujanos de Trasplantes responsables de la Extracción, así como los Coordinadores Hospitalarios, y

b) La fracción III del artículo 338 de la Ley.

Artículo 32. Los Comités Internos de Trasplantes estarán integrados por:

I. El Director General o su equivalente del Establecimiento de Salud, y en su ausencia, su inmediato inferior que cuente con un alto nivel de conocimientos médicos, académicos y profesionales, quien lo presidirá;

II. El psiquiatra o psicólogo del Establecimiento de Salud, en caso de contar con dicho profesional;

III. Un representante del área jurídica del Establecimiento de Salud, en caso de contar con dicha área o de la institución a la que pertenece;

IV. Un representante de cada Programa de Trasplante de los servicios de salud que intervienen en el Trasplante de que se trate;

V. Un representante del Comité Hospitalario de Bioética del Establecimiento de Salud;

VI. Un representante del Comité de Ética en Investigación;

VII. El responsable sanitario del Establecimiento de Salud, en los casos en los que esta función no sea realizada por alguna de las personas señaladas en las fracciones que anteceden, y

VIII. Los demás integrantes que para su correcto funcionamiento determine el Establecimiento de Salud, los cuales contarán con capacitación y conocimientos en la materia de Disposición de Órganos, Tejidos y células.

El Coordinador Hospitalario del Establecimiento de Salud fungirá como Secretario Técnico del Comité Interno de Trasplantes.

Las sesiones del Comité Interno de Trasplantes se considerarán válidas con la asistencia de la mayoría de sus integrantes, salvo en los casos en que se traten asuntos relacionados con la selección de Donador y Receptor para Trasplantes en personas de nacionalidad extranjera, en cuyo caso será necesaria la participación de la totalidad de sus integrantes. Las decisiones del Comité Interno de Trasplantes se tomarán por mayoría.

El Presidente del Comité Interno de Trasplantes contará con voto de calidad en caso de empate.

Artículo 33. Los Comités Internos de Trasplantes, además de las previstas por la Ley, tendrán las funciones siguientes:

I. Realizar la selección de Donadores y Receptores para Trasplante, con excepción de los casos en los que la donación de Órganos, Tejidos o células se realice entre personas que tengan parentesco por consanguinidad, civil o de afinidad, en cuyo caso dicho Comité evaluará la viabilidad y factibilidad de realizar el Trasplante;

II. Supervisar que los Trasplantes que se lleven a cabo en el Establecimiento de Salud, además de cumplir con los principios a que hace referencia el artículo 327 de la Ley, se realicen con la máxima seguridad, de acuerdo con los principios de ética médica y de conformidad con los requisitos que establecen la Ley y este Reglamento;

III. Supervisar el desempeño del Coordinador Hospitalario, así como del equipo quirúrgico y de los diversos profesionales de la salud que participan en el Trasplante;

IV. Seleccionar el laboratorio de Histocompatibilidad que se utilizará para las pruebas relativas a los Trasplantes;

V. Evaluar, en su caso, la atención de las resoluciones o recomendaciones que emitan los Comités Hospitalario de Bioética, de Investigación y, de Ética en Investigación;

VI. Establecer la Asignación de Órganos, Tejidos y células, así como la Distribución de los mismos a otros Establecimientos de Salud, de conformidad con los procedimientos que establezca el CENATRA;

VII. Establecer los procedimientos para la conservación de Órganos, Tejidos y células;

VIII. Aprobar o rechazar la realización del Trasplante, previo dictamen de la disponibilidad de los recursos humanos, materiales e insumos necesarios para su realización;

IX. Evaluar los resultados de los Programas de Trasplantes con que cuente el Establecimiento de Salud;

X. Dictaminar, en su caso, sobre las publicaciones que pudieran derivar de los programas de trabajo o de investigación del Establecimiento de Salud dentro del área de Trasplantes;

XI. Coadyuvar con el responsable sanitario en proporcionar al Registro Nacional de Trasplantes, la información de su Establecimiento de Salud relativa a:

a) La fracción II del artículo 338 de la Ley, dentro de las cuarenta y ocho horas posteriores a la designación;

b) La fracción III del artículo 338 de la Ley, dentro de las cuarenta y ocho horas posteriores al evento;

c) La fracción IV del artículo 338 de la Ley, dentro de las setenta y dos horas posteriores al evento, y

d) La fracción V del artículo 338 de la Ley, dentro de las cuarenta y ocho horas posteriores a la resolución del Comité Interno de Trasplantes;

XII. Elaborar el acta correspondiente a cada sesión que se lleve a cabo, la cual una vez firmada por los integrantes se integrará al libro de actas correspondiente. Tanto las actas como el libro deberán conservarse por un mínimo de cinco años. En el caso del libro de actas, los cinco años se computarán a partir de la fecha de la última acta registrada.

En el acta a que se hace referencia en el párrafo anterior, se hará constar, entre otros aspectos, los siguientes:

a) Los cambios de integrantes que se hayan presentado en los Comités Internos de Trasplantes, de Coordinadores Hospitalarios, así como de los cirujanos responsables de la Extracción y Trasplantes de Órganos, Tejidos y células;

b) Los casos de aceptación de Receptores Candidatos y rechazo de pacientes para ser Receptores de Órganos, Tejidos y células para Trasplante, así como de donadores vivos;

c) Las disposiciones de Órganos, Tejidos y células efectuadas en el Establecimiento de Salud al cual pertenezcan, especificando los Criterios y argumentos Médicos, legales y científicos que se tomaron en cuenta para su Distribución, y

d) Los Trasplantes realizados en el Establecimiento de Salud al cual pertenezcan, especificando los Criterios y argumentos Médicos, legales, científicos y éticos que se tomaron en cuenta para su Asignación, y

XIII. Las demás que establezcan las disposiciones jurídicas aplicables.

Artículo 34. Los Comités Internos de Trasplantes deberán contar con un sistema de gestión de calidad de los Programas de Trasplantes, definido, en su caso, en coordinación con sus respectivas Coordinaciones Institucionales, el cual deberá ser remitido al CENATRA y a los Centros Estatales de Trasplantes o Consejos Estatales de Trasplantes, los que podrán formular las recomendaciones que estimen pertinentes.

Artículo 35. El responsable sanitario a que se refiere el artículo 338 de la Ley, deberá proporcionar al CENATRA, la información relativa a la integración del Comité Interno de Trasplantes y del Comité Interno de Coordinación para la Donación, en caso de existir este último, así como los cambios de sus integrantes o en su caso, la disolución del Comité.

Capítulo V
De la Distribución y Asignación de Órganos, Tejidos y Células con Fines de Trasplante

Artículo 36. Los Comités Internos de Coordinación para la Donación, y de Trasplantes de los Establecimientos de Salud, según corresponda, serán los responsables de realizar la Distribución y la Asignación de Órganos, Tejidos y células, de acuerdo con lo dispuesto en los artículos 316 y 339 de la Ley, con base en los criterios y requisitos previstos en dicho ordenamiento, este Reglamento, y demás disposiciones jurídicas aplicables.

Asimismo, los Comités a que se refiere el párrafo anterior, establecerán un procedimiento interno de Distribución para cada tipo de Órgano, Tejido y célula contemplado en sus Programas de Trasplantes, el cual deberá ser acorde con los procedimientos que establezca el CENATRA.

El procedimiento interno a que se refiere el párrafo anterior, deberá estar aprobado por el Director General, o su equivalente, del Establecimiento de Salud y por la Coordinación Institucional, de contar con esta última. Dicho procedimiento será enviado para su conocimiento al CENATRA, el cual podrá formular las recomendaciones que estime pertinentes.

Artículo 37. Los Comités Internos de Coordinación para la Donación, y de Trasplantes no podrán delegar su facultad para la Distribución y Asignación de Órganos, Tejidos y células, por lo que esta facultad no podrá ser ejercida por una sola persona.

Artículo 38. La Distribución por Establecimiento de Salud, en caso de no existir una Urgencia de Trasplante, se hará tomando en cuenta el siguiente orden:

I. Al Establecimiento de Salud en donde se lleve a cabo la donación, siempre que esté autorizado para realizar Trasplantes del tipo de Órgano, Tejido o célula de que se trate;

II. A la Institución de Salud a la que pertenezca el Establecimiento de Salud, para lo cual contará con el auxilio de sus Coordinaciones Institucionales, en su caso, para dicha Distribución;

III. A cualquier Establecimiento de Salud de la entidad federativa en la que se encuentre ubicado el Establecimiento de Salud en donde se llevó a cabo la donación, y

IV. A cualquier Establecimiento de Salud de una Institución de Salud a nivel nacional.

Tratándose de los supuestos a que hacen referencia las fracciones III y IV del presente artículo, el Comité Interno de Coordinación para la Donación o el de Trasplantes, según corresponda, procurará hacer llegar los Órganos, Tejidos y células generados en su Establecimiento de Salud, a Establecimientos de Salud de Instituciones de Salud de su propio sector, es decir, si el Establecimiento de Salud es público, buscará un Establecimiento de Salud de una Institución de Salud del sector público, y si es privado, a un Establecimiento de Salud de una Institución de Salud del sector privado.

Artículo 39. Los Comités Internos de Trasplantes podrán, en casos excepcionales y debidamente justificados, previa opinión del CENATRA, establecer esquemas de Distribución que permitan destinar Órganos, Tejidos y células a un Establecimiento de Salud que no pertenezca a su Institución de Salud, contando con la aprobación de la Coordinación Institucional a la que pertenezca, en su caso.

Las razones que justifiquen el establecimiento de esquemas excepcionales de Distribución a que se refiere el párrafo anterior, podrán ser circunstancias que hagan que sea más oportuno y viable considerar como primera opción un Establecimiento de Salud que no pertenece a su Institución de Salud.

Artículo 40. Para la Distribución y Asignación de Órganos, Tejidos y células de Donadores que hayan perdido la vida menores de 18 años de edad, denominados pediátricos, en caso de que no exista Urgencia de Trasplante, se dará preferencia a los Receptores que tengan menos de 18 años de edad.

Artículo 41. La notificación de una Urgencia de Trasplante por un Establecimiento de Salud, implica la Distribución y Asignación preferente a nivel nacional de un Órgano, Tejido o célula al paciente que ha sido calificado en tal condición.

La determinación de una Urgencia de Trasplante corresponde al Comité Interno de Trasplantes del Establecimiento de Salud en el que se realizará el Trasplante. La Urgencia de Trasplante deberá ser notificada al Registro Nacional de Trasplantes mediante el formato establecido para tal fin por el CENATRA, a efecto de activar una alerta en el Registro Nacional de Trasplantes, a los Establecimientos de Salud sobre la existencia de un paciente con estatus de Urgencia de Trasplante, para que éstos den prioridad para la Distribución y Asignación del Órgano en cuestión a dicho paciente.

La vigencia de una notificación sobre la existencia de un paciente con estatus de Urgencia de Trasplante será de setenta y dos horas contadas a partir de la recepción de la notificación en el Registro Nacional de Trasplantes, debiendo actualizarse las veces que sea necesario, mediante el procedimiento señalado en este artículo.

La documentación que soporte la Urgencia de Trasplante de un paciente, deberá ser resguardada por el Comité Interno de Trasplantes por un periodo de cinco años a partir de la notificación a que se refiere el segundo párrafo del presente artículo y estar disponible en cualquier momento para el caso de que las autoridades competentes la requieran. De llevarse a cabo el Trasplante el resguardo de la información será de cinco años a partir de la realización del mismo.

Artículo 42. Para los casos de Urgencia de Trasplante en la Asignación del corazón, el paciente debe presentar cualquiera de las siguientes condiciones, sin otra opción de tratamiento:

I. Pacientes con falla primaria del corazón trasplantado dentro de las primeras cuarenta y ocho horas;

II. Pacientes en situación de shock cardiogénico y con asistencia ventricular;

III. Pacientes en situación de shock cardiogénico y con balón intraaórtico de contrapulsación;

IV. Pacientes en situación de shock cardiogénico que requieren fármacos vasoactivos y ventilación mecánica, o

V. Pacientes hospitalizados en clase funcional IV refractario a tratamiento médico.

En caso de existir varias Urgencias de Trasplante de corazón, se estará al orden de prelación establecido en las fracciones anteriores.

En caso de existir dos o más del mismo grado de condición a que se refiere el párrafo primero de este artículo, se asignará por orden de inscripción en el Registro Nacional de Trasplantes.

Artículo 43. Para los casos de Urgencia de Trasplante en la Asignación del hígado, el paciente debe encontrarse en cualquiera de las situaciones siguientes:

I. Hepatitis fulminante o subfulminante, y

II. Falla primaria del hígado trasplantado.

En caso de existir varias Urgencias de Trasplante de hígado, se estará al orden de prelación establecido en las fracciones anteriores.

En caso de existir dos o más situaciones iguales a que se refiere el párrafo primero de este artículo, se asignará por orden de inscripción en el Registro Nacional de Trasplantes.

Artículo 44. La Asignación prioritaria de un riñón será en aquellos casos en que no exista posibilidad de someter al paciente a un tratamiento dialítico y su condición ponga en peligro su vida.

Los Receptores sometidos a Trasplante que pierdan la función del riñón trasplantado antes de un mes, conservarán su antigüedad en la base de datos del Registro Nacional de Trasplantes, una vez que sean registrados nuevamente.

Artículo 45. Se asignará prioritariamente una córnea, con independencia de que provenga del extranjero, al paciente que presente perforación corneal o úlcera con inminencia de pérdida del globo ocular.

Artículo 46. Cuando en un Establecimiento de Salud se identifique a un paciente que reúna las características señaladas en los artículos 44 o 45 de este Reglamento, el Comité Interno de Trasplantes deberá notificarlo a su Coordinación Institucional, de contar con ella, al CENATRA y a su Centro Estatal de Trasplantes o Consejo Estatal de Trasplantes, a fin de que dicho Trasplante se pueda concretar en el menor tiempo posible.

Artículo 47. Los bancos de córneas únicamente podrán distribuirlas a aquellos Establecimientos de Salud autorizados para Trasplante corneal con los que tengan celebrados convenios para tal efecto. La celebración de dichos convenios se hará del conocimiento del CENATRA.

Artículo 48. Las Instituciones de Salud que importen córneas, únicamente podrán utilizarlas para Trasplante en Receptores de sus propios Establecimientos de Salud.

Artículo 49. Se prohíbe el comercio de Órganos, Tejidos o células desprendidas o seccionadas por intervención quirúrgica, accidente o hecho ilícito.

TÍTULO CUARTO
LOS ESTABLECIMIENTOS DE SALUD Y RESPONSABLES SANITARIOS

Capítulo Único
De los Establecimientos de Salud y Responsables Sanitarios

Artículo 50. Los Establecimientos de Salud en términos del artículo 315 de la Ley, sólo podrán efectuar los actos que expresamente determine la autorización sanitaria correspondiente, en los términos que establezcan la Ley, este Reglamento y demás disposiciones jurídicas aplicables.

Artículo 51. Para la obtención de la autorización a que se refiere el artículo 315 de la Ley, los Establecimientos de Salud que realizan actos de Trasplantes de Órganos, Tejidos y células deberán contar con:

I. La especialidad médica o quirúrgica correlativa a los Trasplantes a realizar, con independencia de otras actividades de atención médica que presten;

II. Laboratorio de patología clínica;

III. Laboratorio de anatomía patológica o acceso a uno;

IV. Banco de sangre o un servicio de transfusión, capaces de proveer unidades de sangre y Componentes Sanguíneos en la cantidad y con la calidad requerida para el tipo de Trasplante que realizan;

V. Sala de recuperación;

VI. Unidad de cuidados intensivos;

VII. Personal médico especializado en el tipo de Trasplantes que realizan, y demás personal profesional, técnico y auxiliar de la salud de apoyo con experiencia en Trasplantes;

VIII. Medicamentos, equipo e instrumental médico quirúrgico adecuados al Trasplante que realizan, y

IX. Los demás que señale este Reglamento y otras disposiciones jurídicas aplicables.

Los Establecimientos de Salud que realizan exclusivamente Trasplante de córnea, deberán de reunir únicamente los requisitos que señalan las fracciones I, II, III, V, VII, VIII y IX, del presente artículo.

Artículo 52. Para la obtención de la autorización a que se refiere el artículo 315 de la Ley, los Establecimientos de Salud que realizan actos de Extracción, análisis, conservación, preparación y suministro de Órganos, Tejidos y células deberán contar con lo siguiente:

I. Un área física con privacidad y ambiente adecuado para atender a los familiares del potencial Donador;

II. Equipo necesario, así como personal capacitado para la certificación de la pérdida de la vida;

III. Un procedimiento que contemple el registro de las actividades que incluyan Extracción e intercambio de Órganos, Tejidos y células, que permitan la Trazabilidad de dichos Órganos, Tejidos y células;

IV. Recursos informáticos que garanticen una comunicación electrónica con el CENATRA, y

V. Los demás que señalen otras disposiciones jurídicas aplicables.

Artículo 53. La Secretaría podrá autorizar, para fines terapéuticos, la instalación de bancos de Órganos, Tejidos y células.

Para efectos de lo establecido en el párrafo anterior, se deberá contar con un manual interno de procedimientos que contenga los lineamientos técnicos que deben observarse en el análisis, conservación y preparación de los Órganos, Tejidos y células, a efecto de garantizar su viabilidad y Trazabilidad, así como cumplir con los requisitos de infraestructura y equipamiento, que se prevean en las disposiciones jurídicas aplicables.

Tratándose de bancos de Órganos y células, la Secretaría mediante disposiciones de carácter general que se publiquen en el Diario Oficial de la Federación, determinará las funciones que tendrán éstos y sus responsables sanitarios. Dichas funciones estarán orientadas a mantener en óptimas condiciones los Órganos y células para fines de Trasplantes, su Trazabilidad, así como a supervisar que se cumplan las disposiciones jurídicas aplicables.

Artículo 54. El suministro y la recepción de Órganos, Tejidos y células para fines terapéuticos, sólo podrán efectuarse entre Establecimientos de Salud que cuenten con la autorización específica de la Secretaría, para llevar a cabo la Extracción, conservación, suministro o Trasplantes del tipo de Órgano, Tejido o célula de que se trate.

Artículo 55. El responsable de la Extracción de Órganos y Tejidos compuestos deberá ser profesional médico y contar con una especialidad o posgrado, de acuerdo con el Programa de Trasplante para el cual el Establecimiento de Salud está autorizado.

La Extracción de tejido simple o células podrá ser realizada por personal médico o técnico capacitado.

Artículo 56. El responsable de cada Programa de Trasplante de Órganos, Tejidos y células, deberá ser profesional médico, con título legalmente expedido y registrado por las autoridades educativas competentes, y ser designado por el Comité Interno de Trasplantes, dando aviso al CENATRA. Dicha designación deberá establecerse en el acta correspondiente.

Artículo 57. Los bancos de Órganos, Tejidos y células deberán funcionar en coordinación con uno o varios Establecimientos de Salud autorizados para fines de este Reglamento.

Artículo 58. Los Bancos de Tejidos podrán ser:

I. De córnea;

II. De hueso;

III. De músculo esquelético;

IV. De piel;

V. De cardiovascular;

VI. De amnios, y

VII. Los demás que autorice la Secretaría, de acuerdo a los avances en la ciencia y la tecnología en esta materia.

Artículo 59. Los Bancos de Tejidos tendrán las siguientes funciones:

I. Recibir los Tejidos remitidos para su resguardo temporal de los Establecimientos de Salud autorizados, y

II. Mantener en óptimas condiciones el Tejido hasta su procesamiento o Destino Final, o bien, enviarlo a otro Establecimiento de Salud.

Artículo 60. Los responsables de los Bancos de Tejidos tendrán las siguientes funciones:

I. Vigilar que la Preservación y almacenamiento de los Tejidos se realice de acuerdo con lo establecido en la Ley, el presente Reglamento, los manuales internos de procedimientos aprobados en cada banco y demás disposiciones jurídicas aplicables;

II. Vigilar que la calidad de los Tejidos cumpla con los estándares internacionales establecidos para garantizar las condiciones óptimas del Trasplante;

III. Implementar y ejecutar acciones de Procuración de Tejidos que se encuentren bajo su resguardo, las cuales deberán ser acreditables;

IV. Garantizar la Trazabilidad de los Tejidos, de conformidad con las funciones que realiza el banco;

V. Celebrar convenios con los Establecimientos de Salud para promover la Distribución de Tejidos con fines de Trasplantes;

VI. Mantener las condiciones óptimas para el traslado del Tejido que garanticen su viabilidad para el Trasplante;

VII. Supervisar que se cumplan las disposiciones jurídicas aplicables, y

VIII. Las demás que determinen las disposiciones jurídicas aplicables.

TÍTULO QUINTO
REGISTRO NACIONAL DE TRASPLANTES

Capítulo Único
Del Registro Nacional de Trasplantes

Artículo 61. El Registro Nacional de Trasplantes operará bajo un sistema informático, el cual será administrado por el CENATRA.

Artículo 62. La integración, manejo y actualización de la información del Registro Nacional de Trasplantes, además de atender a las disposiciones de la Ley Federal de Transparencia y Acceso a la Información Pública Gubernamental, se sujetará a lo siguiente:

I. Los responsables sanitarios deberán mantener actualizados el registro de los cirujanos responsables de la Extracción y Trasplantes y el de los Coordinadores Hospitalarios de su Establecimiento de Salud, informando altas o bajas de dichas personas;

II. El responsable sanitario del Establecimiento de Salud en el que se realizará un Trasplante, deberá registrar al paciente dentro de las cuarenta y ocho horas posteriores a que el Comité Interno de Trasplantes otorgue su aceptación como Receptor Candidato a recibir un Trasplante;

III. El registro de un Receptor Candidato a recibir el Trasplante en el Registro Nacional de Trasplantes, en términos del artículo 338, fracción V, de la Ley, se hará únicamente por el Establecimiento de Salud público, social o privado en el que es atendido. En los casos de registro para recibir más de un Órgano, Tejido o célula, éste se hará en el o los Establecimientos de Salud en los que sea atendido, pudiéndose generar más de un registro por Receptor, pero sólo uno por cada Órgano, Tejido o célula de que se trate;

IV. Los pacientes que se transfieran de un Establecimiento de Salud a otro, conservarán su antigüedad en el Registro Nacional de Trasplantes;

V. El responsable sanitario del Establecimiento de Salud deberá mantener actualizada la información de los Receptores Candidatos a recibir un Trasplante, notificando al Registro Nacional de Trasplantes cualquier ingreso o cambio;

VI. El responsable sanitario del Establecimiento de Salud deberá efectuar el reporte de una donación o de un Trasplante, en los plazos previstos en el artículo 33, fracción XI, incisos b) y c), del presente Reglamento, y

VII. Las bases de datos del Registro Nacional de Trasplantes serán confidenciales, sólo podrá tener acceso a las mismas, de acuerdo a su ámbito de competencia, personal autorizado de:

a) CENATRA;

b) COFEPRIS;

c) Autoridades aduaneras;

d) Los Centros Estatales de Trasplantes o Consejos Estatales de Trasplantes;

e) Las Coordinaciones Institucionales, y

f) Los Establecimientos de Salud que cuenten con autorización en términos del artículo 315, de la Ley.

Artículo 63. Es responsabilidad del Director del Establecimiento de Salud, supervisar que el responsable sanitario actualice la información requerida en términos del artículo 338 de la Ley.

El CENATRA deberá notificar a la COFEPRIS, el incumplimiento del contenido del presente Capítulo, a fin de que dicha autoridad proceda en términos de las disposiciones jurídicas aplicables.

Artículo 64. Sólo podrán trasplantarse Órganos, Tejidos o células procedentes de Donadores fallecidos, a pacientes inscritos en el Registro Nacional de Trasplantes por lo menos cuarenta y ocho horas antes de la certificación de la pérdida de la vida del Donador. Podrán exceptuarse de lo anterior, los casos de Urgencia de Trasplante.

TÍTULO SEXTO
INTERVENCIÓN DEL MINISTERIO PÚBLICO Y DE LA AUTORIDAD JUDICIAL EN LA DONACIÓN DE ÓRGANOS, TEJIDOS O CÉLULAS

Capítulo Único
De la Intervención del Ministerio Público y de la Autoridad Judicial en la Donación de Órganos, Tejidos o Células

Artículo 65. En los casos en que la pérdida de la vida del Donador se encuentre relacionada con la investigación de un delito, se dará intervención al Ministerio Público, a efecto de que se pronuncie respecto de si la Extracción de los Órganos, Tejidos y células de dicho Donador interfiere con su investigación.

La intervención a que se refiere el párrafo anterior, se dará a la autoridad judicial en los casos en que ésta se encuentre conociendo del delito de que se trate.

La Extracción de Órganos, Tejidos y células que se realice sin dar la intervención al Ministerio Público o a la autoridad judicial, en términos del presente artículo, dará lugar a las responsabilidades administrativas y penales previstas en la legislación aplicable.

Artículo 66. Tratándose de personas en las que se haya certificado la pérdida de la vida, cuya identidad se desconozca o no se pueda localizar a sus parientes, se dará intervención al Ministerio Público a efecto de que manifieste si los hechos que ocasionaron la pérdida de la vida pueden constituir un delito y en caso afirmativo se estará a lo previsto en el artículo anterior.

Para el caso de que una autoridad judicial esté conociendo de los hechos que ocasionaron la pérdida de la vida de las personas cuya identidad se desconozca o no se pueda localizar a sus parientes, la intervención de la autoridad judicial se realizará en los mismos términos establecidos en el párrafo anterior.

Artículo 67. Las determinaciones del Ministerio Público o de la autoridad judicial competente que se expidan en términos de lo dispuesto en los artículos 65 y 66 de este Reglamento no constituyen una autorización para efectuar la Extracción de los Órganos, Tejidos y células.

Las determinaciones a que se refiere el párrafo anterior se harán del conocimiento del Coordinador Hospitalario para que, en su caso, éste realice las gestiones necesarias que permitan cumplir con los requisitos que establezcan la Ley, el presente Reglamento y demás disposiciones jurídicas aplicables para la Extracción de los Órganos, Tejidos y células.

TÍTULO SÉPTIMO
SUBSISTEMA NACIONAL DE DONACIÓN Y TRASPLANTES

Capítulo Único
Del Subsistema Nacional de Donación y Trasplantes

Artículo 68. El Subsistema Nacional de Donación y Trasplantes tiene por objeto coordinar acciones que faciliten la realización de Trasplantes a los pacientes que lo requieran, bajo los principios de confidencialidad, ausencia de ánimo de lucro, altruismo, factibilidad, transparencia, equidad y eficiencia, debiendo protegerse los datos personales en términos de las disposiciones jurídicas aplicables.

Artículo 69. La coordinación del Subsistema Nacional de Donación y Trasplantes está a cargo del CENATRA.

Para efectos del párrafo anterior, el CENATRA tendrá las siguientes funciones:

I. Coordinar las actividades en materia de donación y Trasplantes de Órganos, Tejidos y células, de los integrantes del Subsistema Nacional de Donación y Trasplantes;

II. Evaluar periódicamente los resultados alcanzados por los diferentes integrantes del Subsistema Nacional de Donación y Trasplantes, y

III. Convocar a consensos para definir la homologación de los criterios de atención médica integral en materia de Trasplantes, así como la difusión de los mismos.

TÍTULO OCTAVO
RECONOCIMIENTO AL MÉRITO Y ALTRUISMO DEL DONADOR Y DE SUS FAMILIAS

Capítulo Único
Del Reconocimiento al Mérito y Altruismo del Donador y de sus Familias

Artículo 70. El Coordinador Hospitalario del Establecimiento de Salud en el que se haya realizado la donación hará constar el mérito y altruismo del Donador y de su familia, mediante una carta de

reconocimiento, dirigida a la familia del Donador, haciendo referencia al mérito por haber respetado su voluntad. En la carta no se especificarán los Órganos, Tejidos o células, motivo de la donación.

Artículo 71. El CENATRA realizará anualmente, una ceremonia pública de entrega simbólica del reconocimiento al mérito y altruismo del Donador y de su familia.

Asimismo, el CENATRA promoverá que los Centros Estatales de Trasplantes o Consejos Estatales de Trasplantes, en el marco del Subsistema Nacional de Donación y Trasplantes, programen anualmente, preferentemente durante el mes de septiembre, la realización de una ceremonia pública de entrega del reconocimiento al mérito y altruismo del Donador y de su familia.

TÍTULO NOVENO
LA TRANSPORTACIÓN Y EMBALAJE DE ÓRGANOS, TEJIDOS Y CÉLULAS

Capítulo Único
De la Transportación y Embalaje de Órganos, Tejidos y Células

Artículo 72. El traslado de Órganos, Tejidos y células de seres humanos con fines de Trasplante, se hará en contenedores destinados específicamente para ello, que permitan su buen manejo, temperatura y conservación en relación con el tipo de Órgano, Tejido o célula y tiempo de isquemia de ser el caso.

Artículo 73. Los contenedores a que se refiere el artículo anterior, deberán identificarse mediante un documento adherido que tendrá los siguientes datos:

I. La leyenda “ÓRGANOS, TEJIDOS Y CÉLULAS PARA TRASPLANTE”;

II. Tipo de Órgano, Tejido o célula;

III. Nombre del Establecimiento de Salud donde se llevó a cabo la Extracción;

IV. Nombre del Establecimiento de Salud que recibirá el Órgano, Tejido o célula, y

V. Nombre del responsable del traslado.

Artículo 74. El contenedor deberá contar con tapa de cierre hermético y las medidas adecuadas de acuerdo al volumen del o los Órganos, Tejidos o células a transportar.

Artículo 75. Al contenedor se deberá acompañar un documento con la siguiente información:

I. Datos del Donador, consistentes en las iniciales de su nombre y el tipo de sangre;

II. Fecha y hora de la Extracción, a fin de determinar el inicio del periodo de isquemia fría;

III. Relación de Órganos, Tejidos o células que se encuentren en el contenedor;

IV. Establecimiento de Salud de destino y resultado de los exámenes de laboratorio que descarten un riesgo sanitario, y

V. Nombre del responsable del traslado.

Artículo 76. Para el manejo y conservación de los Órganos, Tejidos o células a trasplantarse, deberán utilizarse, según sea el caso, los materiales y equipos que garanticen una adecuada transportación y

Preservación de los mismos, en términos de las disposiciones jurídicas aplicables y mediante las técnicas internacionalmente aceptadas.

Artículo 77. Los vehículos dedicados al transporte de Órganos, Tejidos y células de seres humanos con fines de Trasplantes, deberán contar con el equipo y condiciones necesarias que garanticen el traslado adecuado de los mismos, en términos de las disposiciones jurídicas aplicables.

Por ningún motivo se podrá transportar en el mismo vehículo, los Órganos, Tejidos y células para el Trasplante y materiales, equipos, substancias o cualquier otro objeto que los pudiera contaminar, dañar o confundir.

Artículo 78. El traslado a que se refiere este Capítulo se hará bajo la responsabilidad de la persona que al efecto designe el Comité Interno de Trasplantes del Establecimiento de Salud al que se ha destinado el Órgano, Tejido o célula, quien deberá llevar consigo un documento que lo identifique y acredite como responsable en términos del presente artículo. El Comité Interno de Trasplantes antes de realizar el traslado, deberá dar aviso al CENATRA de la persona designada para tal efecto.

Artículo 79. En el expediente del Donador deberá registrarse el Establecimiento de Salud al que se destinaron los Órganos, Tejidos o células; la fecha de la Procuración, así como el nombre de la persona responsable del traslado a que se refiere el artículo anterior y los datos que se desprendan de la identificación oficial que porte, incluyendo el número de folio de la misma.

TÍTULO DÉCIMO
LOS PERMISOS Y AVISOS

Capítulo Único
De los Permisos y Avisos

Artículo 80. Se requerirá permiso sanitario, para la internación o salida del territorio nacional, según sea el caso, de Tejidos, células y sus Componentes para fines de Trasplantes.

Artículo 81. Para obtener el permiso sanitario para la internación al territorio nacional de Tejidos, células y sus Componentes con fines de Trasplantes, el interesado deberá presentar ante la COFEPRIS la solicitud en el formato oficial correspondiente, al cual se anexará la documentación que corresponda, de acuerdo con lo siguiente:

I. Documento que acredite el funcionamiento del Establecimiento de Salud expedido por la autoridad sanitaria del país de origen, y

II. Licencia sanitaria del Establecimiento con giro específico para Trasplante.

Artículo 82. Para la internación de Tejidos o células al territorio nacional, el Establecimiento de Salud que pretenda recibir el Tejido o célula, deberá justificar ante la COFEPRIS y el CENATRA la necesidad de su internamiento, así como la dificultad de su obtención en el país.

Artículo 83. Para obtener el permiso sanitario para la salida del territorio nacional de Tejidos y células, el interesado deberá presentar ante la COFEPRIS solicitud en el formato oficial correspondiente, al cual se anexará la documentación siguiente:

I. Copia de la autorización sanitaria del Establecimiento de Salud para efectuar la Disposición de Órganos, Tejidos y células;

II. Copia del documento que acredite el funcionamiento legal del Establecimiento de Salud que recibirá los Tejidos y células emitida por la autoridad competente, con fines de control del país de destino, y

III. Carta de aceptación del Establecimiento de Salud en el extranjero.

Artículo 84. Los documentos emitidos por el Establecimiento de Salud o el profesional en el extranjero se acompañarán de su traducción cuando estén redactados en idioma distinto al español, realizada por perito traductor.

Artículo 85. Deberá darse aviso a la COFEPRIS en los casos siguientes:

I. La baja, suspensión temporal y reanudación total o parcial de actividades de los Establecimientos de Salud que para su funcionamiento requieren autorización sanitaria, en términos de la Ley y el presente Reglamento;

II. Designación o baja del responsable sanitario de los Establecimientos de Salud, y

III. Los demás que determine la Ley, este Reglamento y otras disposiciones jurídicas aplicables.

TÍTULO DÉCIMO PRIMERO
VIGILANCIA

Capítulo Único
De la Vigilancia

Artículo 86. Corresponde a la Secretaría de Salud, la vigilancia del cumplimiento de este Reglamento y demás disposiciones jurídicas aplicables, la cual se realizará conforme al Título Décimo Séptimo de la Ley.

Artículo 87. Durante la visita de verificación sanitaria y cuando la autoridad sanitaria lo estime necesario, se realizarán los procedimientos que se requieran para comprobar que los Órganos, Tejidos, células, Donadores y Receptores, reúnen las condiciones sanitarias y requisitos que establecen la Ley, este Reglamento y demás disposiciones jurídicas aplicables. En caso de encontrar alguna irregularidad, deficiencia o anomalía, la autoridad sanitaria podrá ordenar las acciones necesarias para identificar el origen de las fallas o problemas.

Las actas que al efecto se levanten, se realizarán conforme a lo dispuesto por el artículo 401, fracción III, de la Ley y demás disposiciones jurídicas aplicables.

Artículo 88. La autoridad sanitaria podrá, en cualquier momento, determinar los casos en que los Órganos, Tejidos y sus Componentes y células no cumplen con los requisitos y condiciones óptimas para su utilización, en los términos establecidos por este Reglamento y en las demás disposiciones jurídicas aplicables.

Artículo 89. En el ejercicio de sus facultades, la autoridad sanitaria podrá solicitar el apoyo del personal de las áreas técnicas de la Secretaría que se consideren necesarias.

TRANSITORIOS

PRIMERO. El presente Reglamento entrará en vigor el día siguiente al de su publicación en el Diario Oficial de la Federación.

SEGUNDO. Se derogan las disposiciones del Reglamento de la Ley General de Salud en Materia de Control Sanitario de la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos, que se refieran a la donación, disposición y trasplante de órganos, tejidos y células, distintas a la sangre y sus componentes, células progenitoras hematopoyéticas o troncales, así como aquellas disposiciones que se opongan al presente Reglamento.

En consecuencia, se mantienen vigentes las Secciones Tercera y Cuarta del Capítulo III; el Capítulo IV, y el Capítulo V del Reglamento de la Ley General de Salud en Materia de Control Sanitario de la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos, así como las demás disposiciones del mismo ordenamiento, que resulten necesarias para la aplicación de dichas Secciones y Capítulos antes citados.

TERCERO. Se abroga el Acuerdo mediante el cual se establecen los lineamientos para la asignación y distribución de órganos y tejidos de cadáveres de seres humanos para trasplante, publicado en el Diario Oficial de la Federación el 23 de abril de 2009.

CUARTO. Se abroga el Acuerdo por el que se delega en el Titular de la Comisión Federal para la Protección contra Riesgos Sanitarios la atención del trámite que se indica, publicado en el Diario Oficial de la Federación el 16 de junio de 2011.

QUINTO. El Centro Nacional de Trasplantes tendrá un plazo de noventa días hábiles, contados a partir de la entrada en vigor del presente Reglamento, para la emisión de los formatos a que hacen referencia los artículos 8 y 11 del presente ordenamiento.

SEXTO. Los trámites y procedimientos administrativos relacionados con el objeto de este Reglamento que se encuentren en trámite al momento de su entrada en vigor, se resolverán conforme a las disposiciones vigentes en la fecha en que iniciaron dichos trámites y procedimientos.

SÉPTIMO. Las erogaciones que se generen con motivo de la entrada en vigor del presente Reglamento deberán cubrirse con cargo al presupuesto aprobado a la Secretaría de Salud, por lo que no requerirá de ampliaciones presupuestales adicionales y no se incrementará su presupuesto regularizable para el presente ejercicio fiscal.

Dado en la Residencia del Ejecutivo Federal, en la Ciudad de México, Distrito Federal, a veintiuno de marzo de dos mil catorce.- **Enrique Peña Nieto**.- Rúbrica.- La Secretaria de Salud, **María de las Mercedes Martha Juan López**.- Rúbrica.

REGLAMENTO DE LA LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

Nuevo Reglamento publicado en el Diario Oficial de la Federación el 19 de marzo de 2008

TEXTO VIGENTE
Última reforma publicada DOF 06-03-2009

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República.

FELIPE DE JESÚS CALDERÓN HINOJOSA, Presidente de los Estados Unidos Mexicanos, en ejercicio de la facultad que me confiere el Artículo 89, fracción I, de la Constitución Política de los Estados Unidos Mexicanos y con fundamento en los artículos 13, 32 bis, 34, 35, 38, y 39 de la Ley Orgánica de la Administración Pública Federal, y en la Ley de Bioseguridad de Organismos Genéticamente Modificados, he tenido a bien expedir el siguiente

REGLAMENTO DE LA LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

TÍTULO PRIMERO
Disposiciones generales

Capítulo Único

Artículo 1. El presente ordenamiento tiene por objeto reglamentar la Ley de Bioseguridad de Organismos Genéticamente Modificados, a fin de proveer a su exacta observancia.

Artículo 2. Para los efectos de este Reglamento se estará a las definiciones previstas en el artículo 3 de la Ley de Bioseguridad de Organismos Genéticamente Modificados y las siguientes:

I. Ley: Ley de Bioseguridad de Organismos Genéticamente Modificados;

II. México: Estados Unidos Mexicanos;

III. NOM: Norma Oficial Mexicana;

IV. OGM con finalidades de salud pública: Aquellos organismos cuya modificación genética tenga como objetivo generar mecanismos de prevención o control de enfermedades del ser humano, salvo aquellos a que se refiere el artículo 6, fracción III, de la Ley;

V. Protocolo de Cartagena: El Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica;

VI. SALUD: La Secretaría de Salud;

VII. Secretaría competente: SEMARNAT y SAGARPA en el ámbito de sus competencias conforme a la Ley;

VIII. Secretaría Ejecutiva: La Secretaría Ejecutiva de la CIBIOGEM;

IX. Solicitud integrada: Los datos y los documentos anexos, a que se refiere el artículo 5 de este Reglamento, y

X. UTM: Proyección Transversal Universal de Mercator, sistema utilizado para convertir coordenadas geográficas esféricas en coordenadas cartesianas planas.

Artículo 3. A falta de disposición expresa en el presente ordenamiento, se estará a lo establecido en la Ley Federal de Procedimiento Administrativo.

Artículo 4. Cuando se realice un trámite ante la Secretaría competente o SALUD, en su caso, se deberá adjuntar copia del pago de derechos, al momento que lo señale la Ley correspondiente.

TÍTULO SEGUNDO
Permisos para Actividades con OGMs

Capítulo I
De la solicitud de permisos

Artículo 5. Quienes pretendan realizar las actividades previstas en el artículo 32 de la Ley, deberán presentar ante la Secretaría competente, una solicitud por escrito, en el formato que al efecto expidan las Secretarías competentes, acompañada de la información a que hacen referencia los artículos 16, 17 y 19 del presente Reglamento. Deberá presentarse una solicitud por cada OGM, en original y copia. Los datos que contendrá la solicitud serán los siguientes:

I. Nombre, denominación o razón social del promovente y, en su caso, nombre del representante legal;

II. Domicilio para oír y recibir notificaciones, así como el nombre de la persona o personas autorizadas para recibirlas;

III. Dirección de correo electrónico para recibir notificaciones, en caso de que el promovente desee ser notificado por este medio;

IV. Modalidad de la liberación solicitada y las razones que dan motivo a la petición;

V. Señalar el órgano de la Secretaría competente, al que se dirige la solicitud;

VI. Lugar y fecha, y

VII. Firma del interesado o del representante legal, o en su caso, huella digital.

El promovente deberá adjuntar a su solicitud los documentos que acrediten su personalidad.

En caso de que cuente con el número de identificación en el registro de personas acreditadas, podrá citarlo en el escrito, sin necesidad de asentar la información prevista en las fracciones I, II y VII de este artículo, ni los documentos con los que acredite su personalidad, excepto la información prevista en las fracciones III, IV, V y VI, de este artículo.

El promovente no estará obligado a proporcionar datos o entregar juegos adicionales de documentos entregados previamente a la Secretaría competente, siempre y cuando señale los datos de identificación

del escrito en el que se citaron o con el que se acompañaron y el nuevo trámite lo realice ante dicha Dependencia.

Adicionalmente a los requisitos antes mencionados, deberán presentarse los datos y documentos anexos que contengan la información y requisitos establecidos en los artículos 42, 43, 50, 51, 55 y 56 de la Ley, y 16, 17 y 19 del presente Reglamento, según la modalidad de liberación que corresponda.

La solicitud deberá estar acompañada de dispositivos electrónicos de almacenamiento de información que contendrán la versión electrónica de la solicitud presentada por escrito, así como todos los datos y documentos anexos que contengan la información y requisitos establecidos en la Ley, el presente Reglamento y las NOM.

Dicha versión electrónica deberá presentarse en el formato que mediante acuerdo expedido conjuntamente por SEMARNAT y SAGARPA y publicado en el Diario Oficial de la Federación se determine.

Artículo 6. La solicitud integrada debe ser presentada en idioma español. Si se encuentra en un idioma distinto, deberán adjuntarse las versiones en ambos idiomas y, de existir controversia en cuanto a su contenido, prevalecerá lo manifestado en el idioma de origen.

Artículo 7. El interesado podrá identificar claramente dentro de la información proporcionada, aquella que sea considerada como confidencial, de acuerdo a los artículos 70 y 71 de la Ley.

Artículo 8. La Secretaría competente hará la revisión de la solicitud integrada, dentro de los diez días hábiles siguientes a que la reciba, y en caso de que la misma no cumpla con los datos o requisitos correspondientes, deberá prevenir a los interesados por escrito y por una sola vez, para que subsanen la omisión, en un plazo no mayor a veinte días hábiles, contados a partir del día siguiente de la notificación.

Transcurrido el plazo correspondiente sin que se haya desahogado la prevención, se desechará el trámite.

Para efectos de lo previsto en el artículo 44 de la Ley, se entiende que la solicitud integrada fue recibida y la información está completa, en los casos en que una vez presentada no se haga prevención o hecha ésta sea atendida por el promovente, sin perjuicio de las atribuciones que le confiere el artículo 34, fracción II de la Ley a la Secretaría competente.

Artículo 9.- Si la Secretaría competente no realiza la prevención en los términos señalados en el artículo anterior no podrá desechar el trámite argumentando que está incompleto.

Artículo 10. La Secretaría competente sólo podrá requerir información adicional, dentro de los veinte días posteriores a la admisión de la solicitud integrada, en los casos a que se refiere el artículo 63 de la Ley.

Artículo 11. El promovente contará con un plazo de veinte días hábiles, contados a partir del día siguiente a que haya surtido efectos la notificación, para atender el requerimiento a que se refiere el artículo 10 del presente Reglamento.

Transcurrido este plazo sin que el promovente haya presentado la información solicitada, la Secretaría competente podrá negar el permiso, de conformidad con lo dispuesto en la fracción II del artículo 34 de la Ley.

Durante el periodo de veinte días y el previsto para atender la prevención a que alude el artículo 8 de este ordenamiento, se suspenderán los plazos de resolución del permiso de la solicitud o de la emisión

del dictamen u opinión, y se reanudarán al día hábil siguiente a que el promovente desahogue el requerimiento.

Artículo 12. Dentro de los dos días hábiles siguientes a que la solicitud integrada sea admitida, la Secretaría competente remitirá al Registro copia de la misma para su inscripción y publicidad respectivas, en términos del artículo 33 de la Ley.

Artículo 13. Para efectos de la emisión del dictamen o la opinión a que se refiere el artículo 34 de la Ley, se procederá de la manera siguiente:

I. Dentro de los tres días hábiles siguientes a aquél en que la solicitud integrada de permiso fue admitida, la Secretaría competente deberá entregar una copia de la misma a la Secretaría que deba emitir el dictamen u opinión;

II. Cuando se requiera información adicional, en los casos a que se refiere el artículo 63 de la Ley, para la emisión del dictamen u opinión, la Secretaría que deba emitir este dictamen u opinión lo comunicará por escrito y por una sola vez a la Secretaría competente, para lo cual se observará lo previsto por los artículos 10 y 11 de este Reglamento.

El plazo para efectuar esta revisión y comunicar por escrito el resultado de la misma a la Secretaría competente, será de diez días hábiles contados a partir del día siguiente a que haya recibido la copia de la solicitud de permiso, y

III. En caso de que la Secretaría que deba emitir el dictamen u opinión, no solicite la información adicional, deberá emitir su dictamen u opinión con la información de la copia de la solicitud integrada a que se refiere la fracción I de este artículo, sin que pueda argumentar la falta de dicha información para emitir un dictamen u opinión en sentido negativo.

Artículo 14. La Secretaría que deba emitir el dictamen o la opinión, respecto de los permisos de liberación, incluyendo su importación, a que se refiere el artículo 32 de la Ley, tendrá los plazos siguientes para entregarlo a la Secretaría competente:

I. Para el caso de liberación experimental al ambiente, hasta ochenta días hábiles;

II. Para el caso de liberación al ambiente en programa piloto, hasta cuarenta días hábiles, y

III. Para el caso de liberación comercial al ambiente hasta cincuenta días hábiles.

Los plazos a que se refiere este artículo, se contarán a partir del día siguiente a aquel en que la Secretaría que deba emitir el dictamen o la opinión, reciba la copia de la solicitud integrada por parte de la Secretaría competente.

En caso de que la Secretaría que deba emitir el dictamen u opinión no lo entregue en los plazos previstos en este artículo, se entenderá que no existe objeción a las pretensiones del promovente.

Artículo 15. El dictamen o la opinión a que se refiere el artículo anterior deberá contener:

I. Declaración de la Secretaría que emite el dictamen u opinión, favorable o desfavorable sobre la solicitud integrada de permiso;

II. Cuando sea favorable, se indicarán:

a) Opinión respecto de la propuesta de vigencia del permiso y, de ser necesario, las medidas y procedimientos de monitoreo y de bioseguridad adicionales a las presentadas por el promovente;

b) Las razones por las que se determina adicionar tales medidas y procedimientos, y

c) Las disposiciones jurídicas en que basan las adiciones mencionadas en el inciso a) de esta fracción, y las razones científicas por las que se justifique establecer las medidas y procedimientos adicionales.

III. Cuando sea desfavorable, se indicarán:

a) De ser el caso, las razones por las que se considera que el promovente no atendió las cuestiones planteadas en el requerimiento a que se refiere el artículo 10 del Reglamento;

b) Las razones científicas o técnicas por las que se considera que los riesgos que pudieran presentar los OGM de que se trate, afectarán negativamente a la diversidad biológica, al medio ambiente, la sanidad animal, vegetal o acuícola, pudiéndoles causar daños graves o irreversibles;

c) Las razones por las que la liberación solicitada contraviene la Ley, el presente Reglamento y las demás disposiciones aplicables, y

d) Las demás determinaciones que formule la autoridad en ejercicio del enfoque precautorio establecido en la Ley.

De conformidad con el último párrafo del artículo 15 de la Ley, el dictamen de bioseguridad a que se refiere la fracción I de dicho artículo será vinculante para la SAGARPA en la resolución de las solicitudes de permisos que conforme a la Ley sean de su competencia.

Capítulo II
De los requisitos para los permisos de liberación al ambiente

Artículo 16. La información que deberá adjuntarse a la solicitud de permiso de liberación experimental de OGMs de conformidad con los artículos 5, 6 y 7 del presente Reglamento, será la siguiente:

I. Caracterización del OGM;

a) Identificador único del evento de transformación, de organismos internacionales de los que México sea parte, cuando exista;

b) Especies relacionadas con el OGM y distribución de éstas en México;

c) Especificación de la existencia de especies sexualmente compatibles;

d) Descripción de los hábitats donde el OGM puede persistir o proliferar en el ambiente de liberación;

e) Descripción taxonómica del organismo receptor y donador de la construcción genética;

f) País y localidad donde el OGM fue colectado, desarrollado o producido;

g) Referencia documental sobre origen y diversificación del organismo receptor;

h) Secuencia génica detallada del evento de transformación, incluyendo tamaño del fragmento insertado, sitio de inserción de la construcción genética, incluyendo las secuencias de los oligonucleótidos que permitan la amplificación del sitio de inserción;

i) Descripción de las secuencias flanqueantes, número de copias insertadas, y los resultados de los experimentos que comprueben los datos anteriores, así como la expresión de mensajeros del evento de transformación genética, incluyendo la demostración de los resultados;

j) Mapa de la construcción genética, tipo de herencia de los caracteres producto de los genes insertados, expresión de las proteínas y localización de las mismas;

k) Descripción del método de transformación;

l) Descripción, número de copias, sitios de inserción y expresión de las secuencias irrelevantes para la expresión de la modificación genética y en su caso, la identificación de los efectos no esperados;

m) Secuencia de aminoácidos y de las proteínas novedosas expresadas por el OGM, tamaño del producto del gen, expresión de copias múltiples;

n) Rutas metabólicas involucradas en la expresión del transgen y sus cambios;

o) Productos de degradación de la proteína codificada por el transgen en subproductos;

p) Secuencia nucleotídica de las secuencias reguladoras incluyendo promotores, terminadores y otras, y su descripción, número de copias insertadas, pertenencia de éstas secuencias a la especie receptora, inclusión de secuencias reguladoras homólogas a la especie receptora;

q) Patogenicidad o virulencia de los organismos donadores y receptores;

r) Genes de selección utilizados durante el desarrollo del OGM y el fenotipo que confiere estos genes de selección, incluyendo el mecanismo de acción de éstos genes;

s) Número de generaciones que mostraron estabilidad en la herencia del transgen, y

t) Referencia bibliográfica sobre los datos presentados.

II. Identificación de la zona o zonas donde se pretenda liberar el OGM:

a) Superficie total del polígono o polígonos donde se realizará la liberación;

b) Ubicación, en coordenadas UTM, del polígono o polígonos donde se realizará la liberación, y

c) Descripción de los polígonos donde se realizará la liberación y de las zonas vecinas a éstos según las características de diseminación del OGM de que se trate:

1. Listado de especies sexualmente compatibles y de las especies que tengan interacción en el área de liberación y en zonas vecinas a éstos;

2. Descripción geográfica, y

3. Plano de ubicación señalando las principales vías de comunicación.

III. Estudio de los posibles riesgos que la liberación de los OGMs pudiera generar al medio ambiente y a la diversidad biológica a los que se refiere el artículo 42, fracción III, de la Ley. Contendrá, además de lo dispuesto en el artículo 62 de la Ley, la información siguiente:

a) Estabilidad de la modificación genética del OGM;

b) Expresión del gen introducido, incluyendo niveles de expresión de la proteína de interés en los diversos tejidos, así como los resultados que lo demuestren;

c) Características del fenotipo del OGM;

d) Identificación de cualquier característica física y fenotípica nueva relacionada con el OGM que pueda tener efectos adversos sobre la diversidad biológica y en el medio ambiente receptor del OGM;

e) Comparación de la expresión fenotípica del OGM respecto al organismo receptor, la cual incluya al menos, ciclo biológico y cambios en la morfología básica;

f) Declaración sobre la existencia de efectos sobre la diversidad biológica y al medio ambiente que se puedan derivar de la liberación del OGM;

g) Descripción de uno o más métodos de identificación del evento específico del OGM, incluyendo niveles de sensibilidad y reproducibilidad, con la manifestación expresa del promovente de que los métodos de identificación son los reconocidos por el desarrollador del OGM para la detección del mismo;

h) Existencia potencial de flujo génico del OGM a especies relacionadas;

i) Bibliografía reciente de referencia a los datos presentados, y

j) Las demás que establezcan las NOM que deriven de la Ley.

IV. Medidas y procedimientos de monitoreo de la actividad y de bioseguridad a llevar a cabo:

a) Medidas y procedimientos de monitoreo de la actividad:

1. Plan de monitoreo detallado;

2. Estrategias de monitoreo posteriores a la liberación del OGM, con el fin de detectar cualquier interacción entre el OGM y especies presentes relevantes, directa o indirectamente, en la zona o zonas donde se pretenda realizar la liberación, cuando existan, y

3. Estrategias para la detección del OGM y su presencia posterior en la zona o zonas donde se pretenda realizar la liberación y zonas vecinas, una vez concluida la liberación.

b) Medidas y procedimientos de bioseguridad:

1. Medidas y procedimientos para prevenir la liberación y dispersión del OGM fuera de la zona o zonas donde se pretende realizar la liberación;

2. Medidas y procedimientos para disminuir el acceso de organismos vectores de dispersión, o de personas que no se encuentren autorizadas para ingresar al área de liberación a dicha zona o zonas;

3. Medidas para la erradicación del OGM en zonas distintas a las permitidas;

4. Medidas para el aislamiento de la zona donde se pretenda liberar experimentalmente el OGM;

5. Medidas para la protección de la salud humana y del ambiente, en caso de que ocurriera un evento de liberación no deseado, y

6. Métodos de limpieza o disposición final de los residuos de la liberación.

El promovente deberá distinguir claramente las medidas y procedimientos que se realizarán durante la liberación de los que se realizarán con posterioridad a la misma.

V. Antecedentes de liberación del OGM en otros países, cuando esto se haya realizado, debiendo anexar la información pertinente cuando ésta se encuentre al alcance del promovente:

a) Descripción de la zona en donde se realizó la liberación;

b) Efectos de la liberación sobre la flora y la fauna;

c) Estudio de los posibles riesgos de la liberación de los OGMs presentado en el país de origen, cuando haya sido requerido por la autoridad de otro país y se tenga acceso a él. La descripción de las medidas y procedimientos de monitoreo de bioseguridad establecidos deberá incluirse en el estudio.

d) En caso de que el promovente lo considere adecuado, otros estudios o consideraciones en los que se analicen tanto la contribución del OGM a la solución de problemas ambientales, sociales, productivos o de otra índole, así como las consideraciones socioeconómicas que existan respecto de la liberación de OGMs al ambiente. Estos análisis deberán estar sustentados en evidencias científicas y técnicas, en los antecedentes sobre uso, producción y consumo, y podrán ser considerados por las Secretarías competentes como elementos adicionales para decidir sobre la liberación experimental al ambiente, y consecuentes liberaciones al ambiente en programa piloto y comercial, respectivamente, del OGM de que se trata, y

e) En caso de importación copia legalizada o apostillada de las autorizaciones o documentación oficial que acredite que el OGM está permitido conforme a la legislación del país de origen, al menos para su liberación experimental, traducida al español. La Secretaría competente, de considerarlo necesario, podrá requerir copia simple de la legislación aplicable vigente en el país de exportación traducida al español.

VI. Consideraciones sobre los riesgos de las alternativas tecnológicas con que se cuente para contender con el problema para el cual se construyó el OGM, en caso de que tales alternativas existan;

VII. Número de autorización expedida por SALUD cuando el OGM tenga finalidades de salud pública o se destine a la biorremediación. En caso de no contar con la autorización al momento de

presentar la solicitud de permiso, el promovente podrá presentarla posteriormente anexa a un escrito libre, en el que se indique el número de autorización;

VIII. La propuesta de vigencia para el permiso y los elementos empleados para determinarla, y

IX. La información que en cada caso determinen las NOM.

Artículo 17. La información que deberá adjuntarse a la solicitud de permiso de liberación al ambiente de OGMs en programa piloto de conformidad con los artículos 5, 6 y 7 del presente Reglamento, será la siguiente:

I. Datos de identificación del permiso de liberación experimental o copia simple del referido permiso;

II. Referencia y consideraciones sobre el reporte de los resultados de la o las liberaciones experimentales realizadas en relación con los posibles riesgos al medio ambiente y la diversidad biológica y, adicionalmente, a la sanidad animal, vegetal o acuícola;

III. Cantidad del OGM a liberar;

IV. Condiciones de manejo que se darán al OGM;

V. Identificación de la zona o zonas donde se pretenda liberar el OGM:

a) Superficie total del predio o predios donde se realizará la liberación;

b) Ubicación, en coordenadas UTM, del polígono o polígonos donde se realizará la liberación, y

c) Descripción de los polígonos donde se realizará la liberación y de las zonas vecinas a éstos en un radio según las características de diseminación del OGM de que se trate:

1. Listado de especies sexualmente compatibles y de las especies que tengan interacción en el área de liberación y en zonas vecinas a éstos en el radio señalado en este inciso;

2. Descripción geográfica, y

3. Plano de ubicación señalando las principales vías de comunicación.

VI. Medidas de monitoreo y de bioseguridad a realizar:

a) Medidas de monitoreo:

1. Plan de monitoreo detallado;

2. Estrategias de monitoreo posteriores a la liberación del OGM, con el fin de detectar cualquier interacción entre el OGM y especies presentes en el área de la zona o zonas donde se pretenda realizar la liberación, cuando existan, y

3. Estrategias para la detección del OGM y su presencia posterior en la zona o zonas donde se pretenda realizar la liberación y zonas vecinas, una vez concluida la liberación.

b) Medidas de bioseguridad:

1. Medidas para la erradicación del OGM en zonas distintas a las permitidas, y

2. Medidas para la protección de la salud humana y el ambiente, en caso de que ocurriera un evento de liberación no deseado.

El promovente deberá distinguir claramente las medidas que se realizarán durante la liberación de los que se realizarán con posterioridad a la misma.

VII. Número de autorización expedida por SALUD, cuando el OGM se destine para uso o consumo humano, o se destine a procesamiento de alimentos para consumo humano, o tenga finalidades de salud pública o se destine a la biorremediación. En caso de no contar con la autorización al momento de presentar la solicitud de permiso, el promovente podrá presentarla posteriormente anexa a un escrito libre en el que se indique el número de autorización;

VIII. En caso de importación del OGM, copia legalizada o apostillada de las autorizaciones o documentación oficial que acredite que el OGM está permitido conforme a la legislación del país de origen, al menos para su liberación en programa piloto, traducida al español. La Secretaría competente, de considerarlo necesario, podrá requerir copia simple de la legislación aplicable vigente en el país de exportación traducida al español;

IX. La propuesta de vigencia del permiso y los elementos empleados para determinarla, y

X. La Información que en cada caso determinen las NOM.

Artículo 18. Conforme lo dispuesto en los artículos 46 y 53 de la Ley, los titulares del permiso de liberación experimental y liberación en programa piloto, deberán informar mediante un reporte a la Secretaría que expidió el permiso los resultados de las liberaciones realizadas en el momento que se establezca en los permisos correspondientes. El reporte contendrá lo siguiente:

I. Lineamientos del protocolo propuesto para la liberación experimental o en programa piloto;

II. Cambios fenotípicos del OGM respecto a su adaptación al área de liberación;

III. Efectos de los genes de selección y posibles efectos sobre la biodiversidad;

IV. Caracterización bioquímica y metabólica de todos los productos del gen novedoso con relación a su actividad, productos de degradación o subproductos, productos secundarios y rutas metabólicas;

V. Cambios en la capacidad competitiva del OGM en comparación con la contraparte no modificada, incluyendo supervivencia y reproducción, producción de estructuras reproductoras, periodos de latencia y duración del ciclo de vida;

VI. Posibles efectos al ambiente y a la diversidad biológica por la liberación del OGM, incluyendo, el protocolo utilizado para establecer estos posibles efectos;

VII. Efectos de las prácticas de uso y aprovechamiento, y

VIII. En su caso, referencia bibliográfica sobre los datos presentados.

En los permisos la Secretaría competente podrá establecer, caso por caso, requisitos específicos de contenido de reportes de resultados. Tratándose de liberaciones de OGMs que sean competencia de la

SAGARPA, dicha Secretaría considerará lo que se establezca en el dictamen vinculante que emita la SEMARNAT conforme a la Ley y el presente Reglamento.

Artículo 19. La información que deberá adjuntarse a la solicitud de permiso de liberación comercial al ambiente de OGMs, de conformidad con los artículos, 5, 6 y 7 del presente Reglamento, será la siguiente:

I. Datos de identificación del permiso de liberación experimental y del permiso de liberación en programa piloto, o copia simple de cada uno de los referidos permisos;

II. Descripción de la zona donde se realizará la liberación, la cual consistirá en lo siguiente:

a) Ubicación, en coordenadas UTM, del polígono o polígonos donde podrá realizar la liberación;

b) Municipio o municipios donde se encuentra cada uno de dichos polígonos, y

c) Estado o estados donde se ubica cada uno de dichos polígonos.

III. Referencia y consideraciones sobre los reportes de resultados de la liberación experimental y de la liberación en programa piloto que se hayan realizado, en términos de los permisos a que se refiere la fracción anterior;

IV. Instrucciones o recomendaciones específicas de transporte, de conformidad con las NOM a que se refiere el artículo 76 de la Ley, de almacenamiento y, en su caso, manejo;

V. Condiciones para su liberación y comercialización, en caso de ser necesarias;

VI. Consideraciones sobre los riesgos de las alternativas tecnológicas con que se cuente para contender con el problema para el cual se construyó el OGM, en caso de que tales alternativas existan;

VII. En su caso, la información que disponga el solicitante sobre datos o resultados de la comercialización del mismo OGM en otros países;

VIII. En caso de importación del OGM, copia legalizada o apostillada de las autorizaciones o documentación oficial que acredite que el OGM está permitido conforme a la legislación del país de origen, al menos para su liberación comercial, traducida al español;

IX. La Secretaría competente, de considerarlo necesario, podrá requerir copia simple de la legislación aplicable vigente en el país de exportación traducida al español, y

X. La información que en cada caso determinen las NOM.

Capítulo III
De la resolución de solicitudes de permiso y su vigencia

Artículo 20. La Secretaría competente resolverá al promovente su solicitud de permiso de liberación incluyendo lo relativo a la importación, dentro de los siguientes plazos máximos, contados a partir del día hábil siguiente a que dicha solicitud sea admitida:

I. Para liberación experimental al ambiente seis meses;

II. Para liberación al ambiente en programa piloto tres meses, y

III. Para liberación comercial al ambiente cuatro meses.

Se entiende que la solicitud es admitida en los casos en que la solicitud fue recibida y la información está completa, conforme a lo previsto por el artículo 8, último párrafo, de este Reglamento.

Artículo 21. En términos de lo señalado por el artículo 35 de la Ley, solamente en caso de que sea necesaria la autorización de SALUD y ésta aún no la haya emitido, el plazo para resolver la solicitud de permiso se prorrogará de forma que la Secretaría competente resuelva dentro de los diez días hábiles posteriores a que el interesado haya acreditado en el expediente respectivo la obtención de dicha autorización.

Artículo 22. La vigencia de los permisos para realizar la liberación experimental y en programa piloto será propuesta por el promovente con la justificación correspondiente, de conformidad con los artículos 16, fracción VIII, y 17, fracción IX, de este Reglamento.

La Secretaría competente podrá limitar la vigencia propuesta considerando los elementos del expediente.

Tratándose del permiso para realizar la liberación comercial, la vigencia será indefinida.

Los permisos contendrán de manera expresa, la vigencia de los mismos.

Una vez otorgado el permiso correspondiente, la Secretaría competente podrá modificar la vigencia del mismo, cuando de la información proporcionada por el interesado concluya que se evitarán daños graves e irreversibles a la diversidad biológica o a la sanidad vegetal, animal o acuícola, debiendo identificar en la resolución los daños que se evitarán, y establecer las razones científicas para justificar la modificación.

TÍTULO TERCERO
De las autorizaciones

Capítulo I
Disposiciones Generales

Artículo 23. Quienes pretendan obtener una autorización de alguno de los OGM a que se refiere el artículo 91 de la Ley, deberán presentar ante SALUD, una solicitud por escrito acompañada de la información a que se refiere el artículo 31 de este Reglamento. La solicitud deberá presentarse en original y una copia simple para acuse.

Artículo 24. Deberá presentarse una solicitud por cada OGM, debiendo contener los siguientes datos:

I. Nombre, denominación o razón social del promovente y, en su caso, nombre del representante legal;

II. Domicilio para oír y recibir notificaciones, así como el nombre de la persona o personas autorizadas para recibirlas;

III. Dirección de correo electrónico para recibir notificaciones, en caso de que el promovente desee ser notificado por este medio;

IV. Tipo del OGM, de conformidad con las fracciones del artículo 91 de la Ley, y las razones que dan motivo a la petición;

V. Señalar el órgano de Salud, al que se dirige la solicitud;

VI. Lugar y fecha, y

VII. Firma del interesado o del representante legal, o en su caso, huella digital.

El promovente deberá adjuntar a su solicitud los documentos que acrediten su personalidad.

En caso de que cuente con el número de identificación en el registro de personas acreditadas, podrá citarlo en el escrito, sin necesidad de asentar la información prevista en las fracciones I, II y VII de este artículo, ni los documentos con los que acredite su personalidad, excepto la información prevista en las fracciones III, IV, V y VI, de este artículo.

El promovente no estará obligado a proporcionar datos o entregar juegos adicionales de documentos entregados previamente a SALUD, siempre y cuando señalen los datos de identificación del escrito en el que se citaron o con el que se acompañaron y el nuevo trámite lo realice ante dicha Dependencia.

La solicitud deberá estar acompañada de dispositivos electrónicos de almacenamiento de información que contendrán la versión electrónica de la solicitud presentada por escrito, así como todos los datos y documentos anexos que contengan la información y requisitos establecidos en la Ley, el presente Reglamento y las NOM.

Dicha versión electrónica deberá presentarse en el formato que mediante acuerdo publicado en el Diario Oficial de la Federación determine SALUD.

Artículo 25. La documentación e información a que se refieren los artículos 23 y 24 del presente Reglamento debe ser presentada en idioma español. Si se encuentra en un idioma distinto al español, deberán adjuntarse ambas versiones y, de existir controversia en cuanto a su contenido, prevalecerá lo manifestado en la versión en el idioma de origen.

El interesado podrá identificar claramente dentro de la información proporcionada, aquella que sea considerada como confidencial, de acuerdo a los artículos 70 y 71 de la Ley.

Artículo 26. Las solicitudes de autorización se presentarán ante SALUD con los anexos correspondientes. En el original de la solicitud y en el acuse de recibo se asentará la fecha y hora de recepción.

Artículo 27. El plazo a que se refiere el artículo 95 de la Ley para expedir la autorización, comenzará a correr a partir del día hábil siguiente a aquél en que la solicitud sea admitida.

Artículo 28. Una vez admitida la solicitud, SALUD evaluará los datos y documentos presentados con la misma, para determinar si cumplen con la información y los requisitos establecidos en la Ley, el presente Reglamento y demás disposiciones aplicables. De ser necesario, prevendrá al promovente, por escrito y por una sola vez para que subsane la omisión.

El plazo para realizar la evaluación y requerir al promovente de la información o requisitos que no se ajusten a lo previsto en la Ley, el Reglamento y demás disposiciones aplicables, será de treinta días hábiles, contados a partir del día hábil siguiente a la presentación de la solicitud del trámite.

Artículo 29. El promovente contará con un plazo de veinte días hábiles contados a partir del día siguiente a que haya surtido efectos la notificación, para atender el requerimiento a que se refiere el artículo anterior. Durante este periodo se suspenderán los plazos de resolución de la solicitud de autorización, y se reanudarán al día hábil siguiente a aquél en que el promovente desahogue el requerimiento.

Transcurrido este plazo sin que el promovente haya desahogado la prevención, SALUD desechará el trámite.

Artículo 30. Una vez desahogada la prevención a que se refiere el artículo 28 de este Reglamento, o bien, si el requerimiento no se notifica al promovente o se notifica fuera del plazo o en términos distintos a los establecidos en dicho artículo, la autoridad no podrá desechar el trámite argumentando que está incompleto.

Para efectos de lo previsto en el artículo 95 de la Ley, se entiende que la solicitud fue recibida y la información está completa, en los casos en que una vez presentada no se haga prevención o hecha ésta sea atendida por el promovente, sin perjuicio de las atribuciones que le confiere el artículo 96, fracción II de la Ley a la autoridad.

Capítulo II
De los requisitos y de la resolución de solicitudes para las autorizaciones

Artículo 31. La información que deberá adjuntarse a la solicitud de autorización del OGM, de conformidad con los artículos 23 y 24 de este Reglamento, será la siguiente:

I. Estudio de posibles riesgos que el uso o consumo humano del OGM de que se trate pudiera representar a la salud humana, en el que se incluirá la información científica y técnica relativa a su inocuidad, consistente en:

a) Organismo receptor, sea vegetal, animal o microorganismo:

1. Identificación;

2. Designación taxonómica más reciente;

3. Origen, historia de uso seguro en alimentos, experiencias previas de uso o consumo;

4. Patogenicidad asociada a los géneros y especies, cualquier evidencia pertinente del potencial de producción de compuestos tóxicos o antinutrientes, y

5. Indicación de la presencia de plásmidos, transposones e integrones que contengan genes de resistencia a antimicrobianos.

b) Sobre cada organismo donante de genes:

1. Clasificación taxonómica más reciente;

2. Historia de uso;

3. Origen, y

4. Indicación de la presencia de plásmidos, transposones e integrones que contengan genes de resistencia a antimicrobianos.

c) En el caso de los microorganismos genéticamente modificados, sean receptores o donantes de genes:

1. Género, especie, subespecie, cepa y nombre común del receptor;

2. Estabilidad genética, potencial impacto inmunológico y a la salud humana, habilidad para formar esporas u otras estructuras de supervivencia, y

3. Infectividad, factores de virulencia y rango de receptores potencialmente susceptibles de ser infectados.

d) Sobre la introducción del material genético:

1. Función del ADN introducido;

2. Localización y orientación del material genético;

3. Para todo ADN introducido se deberá describir la secuencia del ADN o mapa de restricción, caracterización de todos los componentes genéticos incluyendo los genes marcadores, elementos reguladores, promotores, terminadores y otros que afectan la función del ADN;

4. Descripción detallada del método de transformación y número de secuencias codificadoras;

5. Regulación de la expresión del gen, identificación de cualquier marco de lectura abierto dentro del ADN insertado o creados por las modificaciones del ADN contiguo en el cromosoma;

6. Estabilidad de la modificación, y

7. Organismos hospedadores intermediarios.

e) Cuando se empleó un gen marcador como elemento de selección de los organismos modificados:

1. Razones de elección de dicho marcador, y

2. Si se tratase de un gen que confiere resistencia antimicrobiana, se deberá justificar su empleo y fundamentar la no elección de otro gen marcador.

f) En cuanto al OGM:

1. Organización del material genético insertado y los métodos empleados para su caracterización;

2. En el caso de que se hayan insertado porciones truncadas se deberá establecer su tamaño, mecanismo de acción del producto de expresión de los genes insertados;

3. Productos génicos o análisis de las transcripciones o de los productos expresados para identificar cualquier sustancia nueva que pueda estar presente en el alimento o, en el caso de tratarse de organismos empleados con la finalidad de biorremediación en el ambiente o salud pública cualquier efecto secundario en la bioquímica, fisiología y metabolismo del OGM;

4. Estabilidad de la construcción genética bajo diferentes condiciones de proceso y la expresión de nuevos materiales o modificación de materiales nativos, y

5. Caracterización, sensibilidad y especificidad de la acción designada sobre los productos de expresión de los transgenes insertados.

g) Cuando las modificaciones genéticas alteren la expresión de constituyentes naturales o metabolitos, se deberá informar sobre los posibles efectos secundarios sobre las rutas metabólicas relacionadas;

h) Sobre la expresión de los transgenes:

1. Cinética de expresión de los genes en el organismo modificado;

2. En el caso de los vegetales, nivel de expresión en las diferentes estructuras de la planta;

3. Demostrar si se han logrado los efectos buscados con la modificación y si todas las características expresadas se heredan de una manera estable en la cantidad de propagación necesaria para su uso en la producción de alimentos, biorremediación o salud pública y conformes a las leyes de la herencia;

4. Indicar si existen datos que sugieran que uno o más genes del organismo receptor han sido afectados por las modificaciones o por el proceso de intercambio genético, y

5. Tamaño y número de copias de todos los insertos detectables, tanto de los insertados completamente como los truncados.

i) Métodos de detección e identificación del OGM, incluyendo infraestructura requerida para su identificación, reactivos requeridos para las metodologías de extracción, purificación y detección de sus materiales, secuencias de primers y sondas evento específico para detectar el ADN transgénico, al menos 300 pb a un lado del sitio de inserción, anticuerpos específicos para la proteína exógena, y nivel de confiabilidad de cada método. Anexar muestras de los controles positivos y negativos que emplean. En el caso de los microorganismos genéticamente modificados, se deberá describir con detalle el método de identificación que permita su detección inequívoca; fundamentando su elección en su sensibilidad, especificidad y reproducibilidad;

j) Cuando el OGM se use como alimento o para procesamiento de alimentos:

1. Descripción del producto;

2. Uso propuesto, especificando información sobre su procesamiento;

3. Cualquier cambio introducido en el OGM que pueda alterar la forma en que éste interactúa con la matriz alimentaria y, cuando aplique, en la luz intestinal y con los microorganismos que cohabitan la luz intestinal;

4. Desarrollo de la expresión del transgen durante el ciclo de vida de la planta y partes donde el inserto es expresado, y

5. Estudios de equivalencia sustancial aplicado a condiciones de uso o consumo en México, que incluya:

i. Contenido de proteína verdadera, nitrógeno no proteico, perfil de aminoácidos;

ii. Si se ha introducido una nueva proteína: presencia y nivel en las diferentes partes de la planta y en el alimento propuesto, evidencias de consumo en otros alimentos, efectos de procesamiento, función biológica, digestibilidad;

iii. Composición cualitativa y cuantitativa de lípidos totales;

iv. Composición de la fracción hidratos de carbono;

v. Composición cualitativa y cuantitativa de vitaminas;

vi. Presencia de componentes antinutrimentales;

vii. Estabilidad durante el almacenamiento, especialmente degradación de nutrimentos y biodisponiblidad de nutrimentos, y

viii. Para cada caso se deberá determinar el impacto de los cambios en los componentes nutrimentales que pudieran afectar el perfil global de los nutrimentos.

k) En el caso de los microorganismos genéticamente modificados, proceso mediante el cual las materias primas se transforman en producto final, paso a paso, haciendo especial énfasis en los parámetros más relevantes para la caracterización del producto final con relación a los aspectos de seguridad y nutrimentales;

l) Estudios completos de toxicidad:

1. Aguda;

2. Subcrónica;

3. Crónica en aquellos casos donde el estudio subcrónico suponga o evidencie algún riesgo a largo plazo en la salud, de todos los productos de expresión de los transgenes, de acuerdo a si su finalidad es para uso o consumo humano, biorremedicación o salud pública;

4. En el caso de emplearse como alimento o para el procesamiento de alimentos, estudios de los constituyentes del alimento o componentes específicos que fueran alterados como consecuencia de la modificación genética, y

5. Cuando se utilice para el bioensayo, proteína transgénica obtenida a partir de cultivos bacterianos, se debe demostrar que la proteína expresada en el OGM posee el mismo peso molecular e inmunoreactividad que la proteína microbiana.

m) Estudios de alergenicidad completos. Los criterios pertinentes utilizados deben incluir los aspectos referentes al:

1. Origen del material genético transferido;

2. Homología de secuencias aminoacídicas entre la nueva proteína y alergenos conocidos;

3. Efecto del pH o de la digestión enzimática;

4. Estabilidad frente al calor o la elaboración;

5. Modificaciones post-transduccionales, y

6. Cuando, a pesar de que no exista homología entre la proteína transgénica y alergenos conocidos, pero las pruebas citadas de digestión enzimática, a pH y estabilidad al calor o elaboración, demuestren su potencial alergénico, se deberán aportar datos del análisis de reactividad cruzada de IgE entre una proteína de nueva expresión y un alergeno conocido;

n) Cuando se trate de eventos con combinación de genes, los eventos parentales involucrados en la generación de dicho evento deberán estar previamente autorizados. La información que deberá entregarse en este tipo particular de OGMs incluye:

1. Especificación de las siguientes categorías:

i. Categoría 1. Parentales con características fenotípicas no relacionadas;

ii. Categoría 2. Parentales que poseen características relacionadas pero su acción deriva de rutas diferentes o se incluyen a distintos modos de acción, y

iii Categoría 3. Parentales con características relacionadas con actividad en la misma ruta metabólica o biosintética.

2. Procedimiento aplicado para la obtención del evento con combinación de genes, incluyendo las características genotípicas y fenotípicas de sus líneas parentales:

i. Rutas metabólicas en las que actúen cada una de las proteínas transgénicas codificadas en el evento con combinación de genes;

ii. Estudios sobre la estabilidad de los genes insertados, y

iii. Estudios de equivalencia substancial, y

II. En caso de solicitudes de autorización de un OGM para poder realizar su importación para las finalidades a que se refiere el artículo 91 de la Ley, la información y documentación que acredite que el OGM esté autorizado conforme la legislación del país de origen o, en su defecto, manifestación del interesado de la inexistencia de dicha situación y exposición de los elementos de consideración que sustenten el que SALUD pueda resolver la solicitud de autorización, y

III. Los demás requisitos que determine SALUD en las NOM que deriven de la Ley.

Artículo 32. SALUD resolverá sobre la solicitud de autorización en un plazo no mayor de seis meses contados a partir del día hábil siguiente al que admita la solicitud.

Se entiende que la solicitud es admitida en los casos en que la solicitud fue recibida y la información está completa, conforme a lo previsto por el artículo 30, párrafo segundo, de este Reglamento.

TÍTULO CUARTO
De la reconsideración de las resoluciones negativas y la revisión de los permisos y autorizaciones

Capítulo I
De la reconsideración de las resoluciones negativas

Artículo 33. Para el supuesto que se establece en los artículos 67 y 98 de la Ley, la solicitud de reconsideración de una resolución negativa sobre un permiso o sobre una autorización deberá ser presentada ante la autoridad que la emitió, debiendo aportar los elementos en los que se sustente la pretensión del promovente en el mismo escrito de reconsideración.

En el escrito de reconsideración, el promovente deberá indicar:

I. Los datos de identificación de la resolución y la fecha en que fue emitida y

II. Los argumentos y elementos que demuestren que su solicitud se apega a los supuestos previstos en el artículo 67 de la Ley.

Artículo 34. En los casos en que se haya negado el permiso de liberación de OGMs al ambiente, debido a que SALUD no otorgó la autorización correspondiente, el promovente podrá presentar, de forma simultánea ante la Secretaría competente y SALUD, la solicitud de reconsideración. Sin embargo para que la Secretaría competente que negó el permiso resuelva la solicitud de reconsideración, deberá estar resuelta la presentada ante SALUD.

Dentro de los tres días hábiles siguientes al que se haya resuelto la reconsideración correspondiente SALUD enviará una copia de su resolución a la Secretaría competente que resolvió en sentido negativo la solicitud del permiso o de la autorización, a efecto de que esta última resuelva la reconsideración dentro de los cinco días hábiles siguientes.

Artículo 35. En caso de que la solicitud de permiso hubiese sido negada con base al dictamen de la SEMARNAT o en la opinión de la SAGARPA, la Secretaría competente que resolvió la solicitud de permiso deberá entregar la solicitud de reconsideración a la Secretaría que deba dictaminar u opinar, en un plazo no mayor a tres días hábiles, contado a partir de que el particular haya ingresado su solicitud de reconsideración.

Asimismo, la solicitud de reconsideración se remitirá a la Secretaría que deba dictaminar u opinar, cuando de la nueva información presentada en la reconsideración, deriven cuestiones que deban ser del conocimiento de la Secretaría que emita el dictamen u opinión.

La Secretaría que deba dictaminar u opinar tendrá un plazo no mayor a un mes, contado a partir del día siguiente a aquél en que le fue entregada la solicitud de reconsideración, para entregar su dictamen u opinión a la Secretaría competente que resolvió la solicitud de permiso.

Artículo 36. La Secretaría que resolvió negativamente la solicitud de permiso o de autorización deberá resolver la solicitud de reconsideración en un plazo no mayor a dos meses, contado a partir del día hábil siguiente a que el promovente haya entregado su solicitud de reconsideración.

Capítulo II
De la revisión de los permisos y las autorizaciones

Artículo 37. Las Secretarías competentes y SALUD podrán revisar los permisos y autorizaciones otorgados en el ámbito de su respectiva competencia, cuando se presenten cualquiera de los supuestos establecidos en los artículos 69 y 98 de la Ley.

La revisión de permisos y autorizaciones otorgados por las Secretarías se realizará conforme al siguiente procedimiento:

I. La Secretaría revisora notificará al titular del permiso o autorización el inicio del procedimiento de revisión, debiendo fundar y motivar las causas que dieron origen al procedimiento;

II. El titular del permiso o autorización contará con quince días hábiles para manifestar lo que a su derecho convenga y presentar cualquier elemento de convicción que tenga el carácter de prueba;

III. Una vez recibidas las manifestaciones y pruebas del titular del permiso o autorización, o sin ellas, la Secretaría revisora iniciará el proceso de evaluación y confrontará la información, a fin de emitir la resolución correspondiente;

IV. La resolución que recaiga a la revisión del permiso o autorización podrá:

a) Mantenerlo en los términos en que fue otorgado;

b) Modificar las condiciones bajo las cuales se otorgó;

c) Suspender sus efectos, o

d) Revocarlo, y

V. La Secretaría revisora contará con treinta días hábiles para la emisión de la resolución respectiva, la cual deberá ser hecha del conocimiento de las demás Secretarías y del titular del permiso o autorización objeto de la revisión, salvo en el caso del inciso a) de la fracción IV de este artículo, caso en el cual sólo se la debe notificar al titular del permiso o autorización.

Artículo 38. Cuando el permiso haya sido otorgado por la SAGARPA, y la SEMARNAT cuente con nueva información científica o técnica que permita establecer posibles riesgos al medio ambiente y a la diversidad biológica, esta dependencia lo hará del conocimiento de la SAGARPA para que inicie el procedimiento de revisión a que se refiere el artículo anterior.

Artículo 39.- Durante el proceso de evaluación a que se refiere la fracción III del artículo 37 del presente Reglamento, la SEMARNAT revisará su dictamen, con base en la nueva información científica o técnica y, de ser necesario, lo modificará. El dictamen que emita la SEMARNAT será vinculante para la resolución del procedimiento de revisión que realice la SAGARPA.

Artículo 40. La revisión de permisos y autorizaciones que practiquen las Secretarías competentes y SALUD en sus respectivos ámbitos de competencia y en los términos de la Ley y de este Reglamento, se realizará con independencia de las medidas de seguridad o de urgente aplicación que pudieran determinar las propias Secretarías conforme al artículo 115 de la Ley.

TÍTULO QUINTO
De la importación y exportación de los OGMs que se destinen a su liberación al ambiente

Capítulo Único

Artículo 41. Previo a la importación de OGMs que se pretendan liberar al ambiente, se deberá obtener el permiso correspondiente a la liberación que corresponda, el cual surtirá efectos de permiso de importación en los términos que establece la Ley.

Artículo 42. La notificación a que se refiere el artículo 72 de la Ley deberá realizarse por escrito, cumpliendo con los requisitos establecidos en los tratados y acuerdos internacionales de los que México sea parte, así como los que exijan las autoridades del país de destino de los OGMs.

TÍTULO SEXTO
De las comisiones internas de bioseguridad

Capítulo Único

Artículo 43. Las comisiones internas de bioseguridad a las que se refiere el artículo 74, fracción III, de la Ley, estarán integradas por un mínimo de tres personas que cuenten con experiencia y conocimiento en las actividades de utilización confinada de OGMs.

Artículo 44.- Las comisiones internas de bioseguridad serán permanentes y sus integrantes podrán ser sustituidos de acuerdo con las reglas internas que expidan para su funcionamiento y que deberán ser aprobadas por la instancia facultada de quienes realicen actividades de utilización confinada de OGMs.

Artículo 45. Las comisiones internas de bioseguridad deberán:

I. Emitir las reglas de bioseguridad, las cuales deben contener, entre otros aspectos, lo relativo a la prevención de liberaciones accidentales y la vigilancia del cumplimiento de las reglas y de las buenas prácticas;

II. Definir las buenas prácticas de la investigación científica que deben observarse;

III. Proporcionar asesoría científica y técnica a los responsables de las actividades de utilización confinada del OGM, en el ámbito de su competencia material;

IV. Emitir opinión técnica sobre los aspectos de bioseguridad de la enseñanza e investigaciones propuestas, previa revisión de las instalaciones y de los materiales a utilizar para el manejo seguro del OGM y métodos involucrados;

V. Garantizar la seguridad de las instalaciones en las que se realicen las actividades de utilización confinada, así como la seguridad en el manejo del OGM, y

VI. Garantizar la integridad física y biológica del personal expuesto y de las personas que realicen la utilización confinada.

TÍTULO SÉPTIMO
De los comités técnicos científicos

Capítulo Único

Artículo 46. Los comités técnicos científicos que podrán apoyar a las Secretarías respecto de las solicitudes de permisos y autorizaciones, así como respecto de los avisos, se integrarán por personas con conocimiento científico o tecnológico que cuenten con experiencia en materia de evaluación, control y gestión de riesgos de OGMs, ya sea a la salud humana, al medio ambiente y la diversidad biológica o a

la sanidad animal, vegetal y acuícola, o en biotecnología moderna aplicada a la investigación, creación y desarrollo de este tipo de organismos.

La designación de los integrantes corresponde al Titular de la Secretaría a la cual proporcionen el apoyo, o al servidor público en que éste delegue la facultad.

Artículo 47. Los comités a que se refiere el artículo anterior emitirán sus reglas de operación, previa validación de las Secretarías correspondientes.

Artículo 48. Los comités técnicos científicos deberán conducirse con estricto apego a los principios de objetividad, imparcialidad y legalidad en la emisión de las opiniones y dictámenes que les sean solicitados, observando las disposiciones sobre protección de información confidencial contenidas en los ordenamientos jurídicos respectivos.

TÍTULO OCTAVO
De las zonas restringidas

Capítulo Único
De los centros de origen y de diversidad genética

Artículo 49. Los acuerdos mediante los cuales se determinen los centros de origen y de diversidad genética a que se refiere el artículo 86 de la Ley deberán contener:

I. Listado de especies, incluyendo nombre científico y común;

II. Clasificación taxonómica;

III. Las poligonales del área o áreas geográficas en coordenadas UTM, y

IV. Las medidas necesarias para la protección de dichas especies.

Los acuerdos serán promovidos indistintamente por la SEMARNAT o la SAGARPA, y expedidos conjuntamente por ambas Secretarías.

TÍTULO NOVENO
De la Información sobre Bioseguridad

Capítulo I
Del Sistema Nacional de Información sobre Bioseguridad

Artículo 50. El Sistema Nacional de Información sobre Bioseguridad estará a cargo de la Secretaría Ejecutiva. La información que integre el Sistema estará disponible en portal de Internet de la CIBIOGEM y deberá ser actualizado permanentemente.

Artículo 51. El Sistema Nacional de Información sobre Bioseguridad contendrá:

I. La información del Registro de conformidad con lo dispuesto por el artículo 56 del presente Reglamento;

II. Las estadísticas nacionales en materia de bioseguridad y OGM;

III. Las zonas restringidas y el municipio o municipios donde se ubica, distinguiendo:

a) Centros de origen y de diversidad genética por especie; en coordenadas UTM;

b) Áreas naturales protegidas de competencia federal, en las coordenadas establecidas en sus instrumentos de creación;

c) Áreas naturales protegidas de competencia local, en las coordenadas establecidas en sus instrumentos de creación, en caso de que las autoridades locales deseen que estas áreas se encuentren en el Sistema Nacional de Información sobre Bioseguridad, y

d) Zonas libres de OGMs, en coordenadas UTM.

IV. Informes y documentos relevantes que resulten de las actividades científicas, académicas, trabajos técnicos o de cualquier otra índole en materia de bioseguridad incluyendo la inocuidad de OGMs, realizados por personas físicas o morales, nacionales o extranjeras;

V. La información sobre los formatos de los avisos a los que se refiere el artículo 78 de la Ley y las comunicaciones a que alude el artículo 59 de este Reglamento, las medidas tomadas por los permisionarios o por quienes realizan actividades de utilización confinada y las medidas tomadas por la autoridad, para atender las liberaciones accidentales o cualquier modificación en la liberación que pueda incrementar los posibles riesgos para el medio ambiente y la diversidad biológica al realizar actividades de liberación experimental o de liberación en programa piloto;

VI. La información relativa a las solicitudes de permiso, para efectos de lo previsto en el artículo 33 de la Ley, y

VII.- El informe anual a que se refiere el artículo 53 del Reglamento.

Artículo 52. La Secretaría Ejecutiva establecerá el sistema informático para recibir la información a que se refiere el artículo anterior, a efecto de incorporarla al Sistema Nacional de Información sobre Bioseguridad.

Serán responsables de incorporar a dicho sistema informático, en los plazos para ello establecidos, los que a continuación se indican:

I. Las Secretarías, de conformidad con lo dispuesto en el artículo 57 de este Reglamento, para efectos de la información prevista en la fracción I del artículo anterior;

II. La Secretaría competente que haya promovido el Acuerdo para la determinación de un centro de origen y de diversidad genética, para efectos de la información prevista en la fracción III, inciso a), del artículo anterior, y deberá hacerlo dentro de los cinco días hábiles siguientes a que se hayan publicado los Acuerdos;

III. La SEMARNAT, para efectos de la información prevista en la fracción III, inciso b), del artículo anterior, y deberá hacerlo dentro de los cinco días hábiles siguientes a que se haya creado un área natural protegida de carácter federal;

IV. La SAGARPA, para efectos de la información referente al inciso d) de la fracción III del artículo anterior, dentro de los cinco días hábiles siguientes a que se haya creado una zona libre de OGMs;

V. Las dependencias y entidades de la administración pública federal y los institutos de investigación nacionales y las personas que desarrollen biotecnología, que generen documentos relevantes sobre biotecnología,

VI. La Secretaría competente que admita una solicitud de permiso, para efectos de la fracción VI del artículo anterior, y

VII. La Secretaría competente que reciba una comunicación en términos del artículo 59 de este Reglamento, dentro de los cinco días hábiles siguientes a que se hayan decidido las medidas que adoptará la Secretaría competente.

Para efectos de la fracción II del artículo anterior, el Secretario Ejecutivo solicitará a las Secretarías y a los órganos de consulta y opinión de la CIBIOGEM la información necesaria para integrar las estadísticas.

Las Secretarías y los órganos de consulta y opinión de la CIBIOGEM deberán responder esas solicitudes ingresando en el sistema de información a que se refiere este artículo, los datos y documentos que le requiera la Secretaría Ejecutiva.

Capítulo II
Del seguimiento a la información sobre bioseguridad

Artículo 53. La CIBIOGEM elaborará y publicará en su portal de Internet un informe anual de la situación general existente en el país en materia de bioseguridad, considerando al menos las estadísticas derivadas de la información comprendida en el Registro sobre solicitudes, permisos, autorizaciones y avisos, así como aquella información sobre las acciones implementadas en cumplimiento del Protocolo de Cartagena.

Artículo 54. La consulta y participación de los pueblos y comunidades indígenas asentadas en las zonas donde se pretenda la liberación de los OGMs se realizará de conformidad con los mecanismos que para el efecto determine la CIBIOGEM.

Capítulo III
Del Registro

Artículo 55. El Registro es parte del Sistema Nacional de Información sobre Bioseguridad, tendrá carácter público y estará a cargo de la Secretaría Ejecutiva. Su objeto es la inscripción de información relativa a las actividades con OGMs, así como de los propios organismos sujetos a las disposiciones de la Ley y el presente Reglamento.

Artículo 56. Serán objeto de inscripción en el Registro:

I. Solicitudes de permisos y autorizaciones;

II. Resoluciones de permisos y autorizaciones, distinguiendo cuáles OGM son importados; así como las resoluciones a las que se refiere el artículo 37, fracción IV, de este Reglamento;

III. Suspensiones y revocaciones;

IV. Avisos de utilización confinada;

V. Requisitos y medidas adicionales para los avisos señalados en el artículo 84 de la Ley;

VI. Las comunicaciones a las que se refiere el artículo 59 de este Reglamento, y

VII. Los demás que establezcan las disposiciones aplicables.

TÍTULO DÉCIMO
De las Listas de OGMs

Capítulo Único

Artículo 57. Las listas de OGMs a que se refieren los artículos 103 y 104 de la Ley serán expedidas por las Secretarías competentes y SALUD, a través de un aviso que se publicará en el Diario Oficial de la Federación. Las listas a que se refieren las fracciones I y II del artículo 103 de la Ley, deberán publicarse de manera conjunta entre la SEMARNAT, SALUD y la SAGARPA.

Las listas a las que se refiere este artículo deberán ser publicadas dentro los primeros diez días hábiles del mes de febrero de cada año en el Diario Oficial de la Federación.

Una vez publicadas las listas sólo podrán ser modificadas por alguna de las causas a que se refiere el artículo 58 de este Reglamento, mediante aviso que será publicado en el Diario Oficial de la Federación dentro de los diez días hábiles siguientes a que verifique la causa de modificación respectiva.

En la publicación anual de las listas deberá observarse un enfoque sistémico que incluya todos los OGMs que hayan sido objeto de las listas anteriores, en los términos establecidos en los artículos 103 y 104 de la Ley.

Artículo 58. Son causas de modificación de las listas a que se refiere el artículo anterior:

I. La resolución de una autorización o permiso;

II. Cambio de la situación jurídica en que se encuentren los OGMs, a que se refieren las fracciones I y II del artículo 103 de la Ley, y

III. Los cambios de los casos a que se refiere el artículo 104, fracción II y último párrafo, de la Ley.

TÍTULO DÉCIMO PRIMERO
De la inspección, vigilancia, medidas de seguridad o de urgente aplicación y de las infracciones y sanciones

Capítulo Único

Artículo 59. En caso de la liberación accidental, los permisionarios o quienes realicen actividades de utilización confinada deberán comunicar dicha situación a la Secretaría que expidió el permiso o a la cual se presentó el aviso, dentro de las veinticuatro horas siguientes a que se tenga conocimiento de la misma. Las Secretarías competentes establecerán en el permiso el medio a través del cual el permisionario deberá realizar esta comunicación, y en los formatos de los avisos a que se refiere el artículo 72 de la Ley.

Inmediatamente después de tomar conocimiento de la liberación accidental, la Secretaría que expidió el permiso o recibió el aviso deberá informar a las otras Secretarías sobre el accidente ocurrido y los riesgos o afectaciones que pudieran producirse o se hayan producido a la salud humana, al medio ambiente, la diversidad biológica o la sanidad animal, vegetal o acuícola. Estas dependencias podrán

imponer en su ámbito de competencia las medidas de seguridad o de urgente aplicación que consideren necesarias para contender con dicha situación.

Adicionalmente a la comunicación señalada en el primer párrafo de este artículo, dentro de los tres días hábiles siguientes a que haya tenido conocimiento de la situación descrita en el párrafo anterior, el permisionario o quien realice actividades de utilización confinada deberá presentar un aviso por escrito a la Secretaría que le expidió el permiso o recibió el permiso, que contendrá:

I. Datos de identificación del permiso o del aviso;

II. El polígono donde ocurrió la liberación accidental, ubicado en coordenadas UTM;

III. Circunstancias y fecha estimada de la liberación accidental;

IV. Cantidades estimadas del OGM que fue liberado accidentalmente;

V. Información de que disponga el permisionario o quien realice actividades de utilización confinada sobre los posibles efectos adversos para la diversidad biológica y la salud humana;

VI. Medidas de atención y control de riesgo que aplicó y aplicará el permisionario o quien realice actividades de utilización confinada, y

VII. Nombre y teléfono de la persona que fungirá como punto de contacto.

Artículo 60. Las Secretarías, en su ámbito de competencia, podrán ordenar alguna o algunas de las medidas de seguridad o de urgente aplicación previstas en el artículo 115 de la Ley. Una vez recibida el acta de inspección por la autoridad ordenadora de los actos de inspección y vigilancia, mediante notificación personal o por correo certificado con acuse de recibo, requerirá al interesado que ejecute, por su cuenta y costo, las medidas de seguridad o de urgente aplicación que procedan, señalando los plazos para su cumplimiento.

Artículo 61. Cuando se imponga como medida de seguridad la repatriación, el interesado deberá cubrir los costos de la misma, pudiendo trasladar los gastos en que incurrió en contra del responsable de la infracción.

Artículo 62. Si como resultado de una visita de inspección y vigilancia, se ordena la imposición de medidas de seguridad o de urgente aplicación, el inspeccionado deberá notificar a la Secretaría competente el cumplimiento de cada una, en un término de cinco días hábiles contados a partir de la fecha de vencimiento del plazo concedido para la ejecución de cada una de ellas.

Artículo 63. Cuando la Secretaría competente emplace al presunto infractor y éste comparezca mediante escrito aceptando las irregularidades circunstanciadas en el acta de inspección, la Secretaría procederá, dentro de los veinte días hábiles siguientes, a dictar la resolución respectiva.

Artículo 64. La resolución administrativa que se dicte, señalará, además de las infracciones y sanciones, las medidas que deberán llevarse a cabo para corregir las deficiencias o irregularidades observadas durante la inspección y el plazo otorgado para cumplirlas, en los términos de la Ley.

TÍTULO DÉCIMO SEGUNDO
Del Régimen de protección especial del maíz

Capítulo Único

Artículo 65. Las actividades relacionadas con el maíz genéticamente modificado se sujetarán al presente Título, a las demás disposiciones generales aplicables a los OGM, así como a lo previsto en otros instrumentos que establezca la autoridad.

Artículo reformado DOF 06-03-2009

Artículo 66. Los particulares, al realizar las solicitudes de permiso de liberación experimental de maíz genéticamente modificado, adicionalmente a lo establecido en el artículo 16 del presente Reglamento, deberán proporcionar lo siguiente:

I. Los materiales de referencia que permitan la detección, identificación y cuantificación del maíz genéticamente modificado que pretenda liberarse, y

II. La información que les requieran las autoridades para determinar la procedencia de etapas de liberación subsecuentes.

Artículo adicionado DOF 06-03-2009

Artículo 67. No se permitirá la experimentación ni la liberación al ambiente de maíz genéticamente modificado que contenga características que impidan o limiten su uso o consumo humano o animal, o bien su uso en procesamiento de alimentos para consumo humano.

Artículo adicionado DOF 06-03-2009

Artículo 68. La SAGARPA, previo al otorgamiento del permiso de liberación experimental, deberá verificar que para el organismo que se pretende liberar no exista una variedad convencional alternativa. En caso afirmativo, la SAGARPA llevará a cabo el análisis comparativo entre las diferentes opciones tecnológicas. El resultado de este análisis deberá ser elemento adicional al estudio de evaluación del riesgo para resolver la solicitud de permiso.

Artículo adicionado DOF 06-03-2009

Artículo 69. En aquellos casos en que se considere que el desarrollo tecnológico propuesto por los particulares, mediante una solicitud de permiso de liberación, sea contrario al artículo 2 de la Ley Federal de Competencia Económica o que pudiera facilitar la realización de las prácticas prohibidas por los artículos 8, 9 y 10 del mismo ordenamiento legal, se deberá informar dicho suceso, de manera puntual y oportuna, a la Comisión Federal de Competencia, para los efectos legales a que haya lugar.

Artículo adicionado DOF 06-03-2009

Artículo 70. La SAGARPA y la SEMARNAT deberán promover la conservación *in situ* de razas y variedades de maíces criollos y sus parientes silvestres a través de los programas de subsidio u otros mecanismos de fomento para la conservación de la biodiversidad, sin que ello implique autorización alguna para el cambio del uso de suelo de forestal a agrícola.

Las dependencias señaladas en el párrafo anterior deberán fomentar el uso de semillas de maíces criollos en proyectos estratégicos que destinen su producción a mercados específicos y a la atención de oportunidades comerciales.

Artículo adicionado DOF 06-03-2009

Artículo 71. Las autoridades competentes en materia de bioseguridad promoverán el desarrollo de laboratorios para la detección, identificación y cuantificación de maíz genéticamente modificado.

Artículo adicionado DOF 06-03-2009

Artículo 72. En los casos en que las autoridades determinen la presencia no permitida de material genéticamente modificado en razas, variedades y parientes silvestres de maíz, deberán establecer medidas para eliminar, controlar o mitigar dicha presencia. Para el caso de las razas y variedades, la atribución corresponderá a la SAGARPA, y para el caso de los parientes silvestres, a la SEMARNAT.

Artículo adicionado DOF 06-03-2009

Artículo 73. Las actividades relacionadas con la protección especial del maíz contarán con un apartado específico en el Sistema Nacional de Información sobre Bioseguridad.

Artículo adicionado DOF 06-03-2009

TRANSITORIOS

PRIMERO. El presente Reglamento entrará en vigor al día siguiente de su publicación en el Diario Oficial de la Federación.

SEGUNDO. Las personas que actualmente realicen actividades de utilización confinada de OGMs con fines de enseñanza y de investigación científica y tecnológica, deberán conformar sus respectivas comisiones internas de bioseguridad dentro de los treinta días posteriores a la entrada en vigor de este Reglamento.

TERCERO. Los titulares de SALUD, la SEMARNAT y la SAGARPA, publicarán en el Diario Oficial de la Federación los acuerdos respectivos mediante los cuales se informa al público en general que las solicitudes de permiso y autorización, así como los avisos en materia de bioseguridad, se recibirán a través de las páginas electrónicas habilitadas para tal efecto. Dicha publicación deberá realizarse en un plazo no mayor a doce meses contados a partir de la entrada en vigor del presente Reglamento.

CUARTO. Para dar cabal cumplimiento a lo dispuesto en el artículo 51, fracción III, inciso b) y 52, fracción III, de este Reglamento, la SEMARNAT deberá incorporar en el sistema informático que determine la Secretaría Ejecutiva, la información referente a las áreas naturales protegidas creadas hasta el día en que entre en vigor el presente Reglamento. Para tal efecto, contará con un plazo de tres meses contados a partir del día siguiente al que entre en vigor este Reglamento.

QUINTO. Las solicitudes de permisos presentadas con antelación a la entrada en vigor del presente Reglamento y aquéllas que se presenten en tanto no se emitan los acuerdos a que se refiere el artículo 86 de la Ley, deberán ser resueltas por la Secretaría competente previa consulta con las instituciones señaladas en el citado artículo.

Artículo reformado DOF 06-03-2009

SEXTO. En tanto se expidan los Acuerdos a que se refiere el artículo 78 de la Ley, los formatos oficiales deberán contener lo siguiente:

I. Nombre, denominación o razón social de quien promueve, y documento que acredite su personalidad jurídica. Cuando exista más de un responsable de la comisión interna de bioseguridad, deberán asentarse los nombres de todos los responsables;

II. Nombre del representante legal, en su caso;

III. Domicilio para oír y recibir notificaciones;

IV. Dirección de correo electrónico para recibir notificaciones, en caso de que el promovente desee ser notificado por este medio;

V. Lugar donde se llevará a cabo la utilización confinada, en coordenadas UTM, así como la descripción de las instalaciones del confinamiento y de las medidas de bioseguridad;

VI. El objetivo y propósito de la utilización confinada;

VII. Datos del OGM incluyendo el nombre científico, común y comercial, y

VIII. El medio a través del cual deberá de realizarse la comunicación a que se refiere el artículo 59 de este Reglamento.

IX. El registro de personas acreditadas, si cuenta con él. En este caso, no deberá presentar la información a que se refieren las fracciones I a IV.

El aviso deberá ser presentado en los casos establecidos en los artículos 79 y 80 de la Ley.

SÉPTIMO. Las acciones derivadas del presente Reglamento se ejecutarán con cargo al presupuesto aprobado para las Dependencias y Entidades responsables de su aplicación.

OCTAVO. Derogado.

Artículo derogado DOF 06-03-2009

NOVENO. Los integrantes de la CIBIOGEM establecerán, dentro del año siguiente a la entrada en vigor de este Reglamento, políticas públicas para la protección, utilización, desarrollo y aprovechamiento sustentable de especies de las que México sea centro de origen y de diversidad genética.

DÉCIMO. Se derogan todas las disposiciones que se opongan al presente Reglamento.

Dado en la Residencia del Poder Ejecutivo Federal, en la Ciudad de México, Distrito Federal, a los catorce días del mes de marzo de dos mil ocho.- **Felipe de Jesús Calderón Hinojosa**.- Rúbrica.- El Secretario de Medio Ambiente y Recursos Naturales, **Juan Rafael Elvira Quesada**.- Rúbrica.- El Secretario de Economía, **Eduardo Sojo Garza Aldape**.- Rúbrica.- El Secretario de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, **Alberto Cárdenas Jiménez**.- Rúbrica.- La Secretaria de Educación Pública, **Josefina Eugenia Vázquez Mota**.- Rúbrica.- El Secretario de Salud, **José Ángel Córdova Villalobos**.- Rúbrica.

ARTÍCULOS TRANSITORIOS DE DECRETOS DE REFORMA

DECRETO por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados.

Publicado en el Diario Oficial de la Federación el 6 de marzo de 2009

ARTÍCULO PRIMERO.- Se **REFORMA** el artículo 65 y se **ADICIONAN** los artículos 66, 67, 68, 69, 70, 71, 72 y 73 del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados, para quedar como sigue:

…….

ARTÍCULO SEGUNDO.- Se **REFORMA** el artículo quinto transitorio y se **DEROGA** el artículo octavo transitorio del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados, para quedar como sigue:

…….

TRANSITORIOS

ÚNICO.- El presente Decreto entrará en vigor el día siguiente al de su publicación en el Diario Oficial de la Federación.

Dado en la Residencia del Poder Ejecutivo Federal, en la Ciudad de México, Distrito Federal, a cinco de marzo de dos mil nueve.- **Felipe de Jesús Calderón Hinojosa**.- Rúbrica.- El Secretario de Medio Ambiente y Recursos Naturales, **Juan Rafael Elvira Quesada**.- Rúbrica.- El Secretario de Economía, **Gerardo Ruiz Mateos**.- Rúbrica.- El Secretario de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, **Alberto Cárdenas Jiménez**.- Rúbrica.- La Secretaria de Educación Pública, **Josefina Eugenia Vázquez Mota**.- Rúbrica.- El Secretario de Salud, **José Ángel Córdova Villalobos**.- Rúbrica.

LEY FEDERAL DE PROTECCIÓN DE DATOS PERSONALES EN POSESIÓN DE LOS PARTICULARES

Nueva Ley publicada en el Diario Oficial de la Federación el 20 de marzo de 2025

TEXTO VIGENTE
Última reforma publicada DOF 14-11-2025

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República.

CLAUDIA SHEINBAUM PARDO, Presidenta de los Estados Unidos Mexicanos, a sus habitantes sabed:

Que el Honorable Congreso de la Unión, se ha servido dirigirme el siguiente

DECRETO

"EL CONGRESO GENERAL DE LOS ESTADOS UNIDOS MEXICANOS, DECRETA:

SE EXPIDEN LA LEY GENERAL DE TRANSPARENCIA Y ACCESO A LA INFORMACIÓN PÚBLICA; LA LEY GENERAL DE PROTECCIÓN DE DATOS PERSONALES EN POSESIÓN DE SUJETOS OBLIGADOS; LA LEY FEDERAL DE PROTECCIÓN DE DATOS PERSONALES EN POSESIÓN DE LOS PARTICULARES; Y SE REFORMA EL ARTÍCULO 37, FRACCIÓN XV, DE LA LEY ORGÁNICA DE LA ADMINISTRACIÓN PÚBLICA FEDERAL

Artículo Primero y Artículo Segundo.- ……..

Artículo Tercero.- Se **expide** la Ley Federal de Protección de Datos Personales en Posesión de los Particulares, para quedar como sigue:

LEY FEDERAL DE PROTECCIÓN DE DATOS PERSONALES EN POSESIÓN DE LOS PARTICULARES

Capítulo I
Disposiciones Generales

Artículo 1. La presente Ley es de orden público y de observancia general en todo el territorio nacional y tiene por objeto la protección de los datos personales en posesión de los particulares, con la finalidad de regular su tratamiento legítimo, controlado e informado, a efecto de garantizar la privacidad y el derecho a la autodeterminación informativa de las personas.

Quedan exceptuados de la aplicación de la presente Ley:

I. Las sociedades de información crediticia en los supuestos de la Ley para Regular las Sociedades de Información Crediticia y demás disposiciones aplicables, y

II. Las personas que lleven a cabo la recolección y almacenamiento de datos personales, que sea para uso exclusivamente personal, y sin fines de divulgación o utilización comercial.

Artículo 2. Para los efectos de esta Ley, se entenderá por:

I. **Aviso de Privacidad:** Documento a disposición de la persona titular de la información de forma física, electrónica o en cualquier otro formato generado por el responsable, a partir del momento en el cual se recaben sus datos personales, con el objeto de informarle los propósitos del tratamiento de los mismos, de conformidad con el artículo 14 de la presente Ley;

II. **Bases de datos:** Conjunto ordenado de datos personales referentes a una persona identificada o identificable condicionados a criterios determinados, con independencia de la forma o modalidad de su creación, tipo de soporte, procesamiento, almacenamiento y organización;

III. **Bloqueo:** Identificación y conservación de datos personales una vez cumplida la finalidad para la cual fueron recabados, con el único propósito de determinar posibles responsabilidades en relación con su tratamiento, hasta el plazo de prescripción legal o contractual de éstas. Durante dicho periodo, los datos personales no podrán ser objeto de tratamiento y, transcurrido este, se procederá a su cancelación en la base de datos que corresponda;

IV. **Consentimiento:** Manifestación de la voluntad libre, específica e informada de la persona titular de los datos mediante la cual se efectúa el tratamiento de los mismos;

V. **Datos personales:** Cualquier información concerniente a una persona identificada o identificable. Se considera que una persona es identificable cuando su identidad pueda determinarse directa o indirectamente a través de cualquier información;

VI. **Datos personales sensibles:** Aquellos datos personales que afecten a la esfera más íntima de la persona titular, o cuya utilización indebida pueda dar origen a discriminación o conlleve un riesgo grave para esta. De manera enunciativa más no limitativa se consideran sensibles los datos personales que puedan revelar aspectos como origen racial o étnico, estado de salud presente o futuro, información genética, creencias religiosas, filosóficas y morales, opiniones políticas y preferencia sexual;

VII. **Derechos ARCO:** Derechos de acceso, rectificación, cancelación y oposición al tratamiento de datos personales;

VIII. **Días:** Días hábiles;

IX. **Disociación:** Procedimiento mediante el cual los datos personales no pueden asociarse a la persona titular ni permitir, por su estructura, contenido o grado de desagregación, la identificación de la misma;

X. **Fuente de acceso público:** Aquellas bases de datos, sistemas o archivos que por disposición de ley puedan ser consultadas públicamente cuando no exista impedimento por una norma limitativa, y sin más exigencia que, en su caso, el pago de una contraprestación, tarifa o contribución. No se considerará fuente de acceso público cuando la información contenida en la misma sea obtenida o tenga una procedencia ilícita, conforme a las disposiciones establecidas por la presente Ley y demás disposiciones jurídicas aplicables;

XI. **Ley:** Ley Federal de Protección de Datos Personales en Posesión de los Particulares;

XII. **Persona encargada:** Persona física o jurídica que sola o conjuntamente con otras trate datos personales por cuenta del responsable;

XIII. **Reglamento:** Reglamento de la Ley Federal de Protección de Datos Personales en Posesión de los Particulares;

XIV. **Responsable:** Sujetos regulados a que se refiere la fracción XVI de este artículo;

XV. **Secretaría:** Secretaría Anticorrupción y Buen Gobierno;

XVI. **Sujetos regulados:** Personas físicas o morales de carácter privado que llevan a cabo el tratamiento de datos personales;

XVII. **Tercero:** Persona física o moral, nacional o extranjera, distinta de la persona titular o del responsable de los datos;

XVIII. **Titular:** Persona a quien corresponden los datos personales;

XIX. **Tratamiento:** Cualquier operación o conjunto de operaciones efectuadas mediante procedimientos manuales o automatizados aplicados a los datos personales, relacionadas con la obtención, uso, registro, organización, conservación, elaboración, utilización, comunicación, difusión, almacenamiento, posesión, acceso, manejo, aprovechamiento, divulgación, transferencia o disposición de datos personales, y

XX. **Transferencia:** Toda comunicación de datos personales dentro o fuera del territorio mexicano, realizada a persona distinta de la titular, del responsable o de la persona encargada del tratamiento.

Artículo 3. Los principios y derechos previstos en esta Ley, tendrán como límite en cuanto a su observancia y ejercicio, la protección de la seguridad nacional, el orden, la seguridad y la salud públicos, así como los derechos de terceros.

Artículo 4.- A falta de disposición expresa en esta Ley, se aplicarán de manera supletoria las disposiciones del Código Nacional de Procedimientos Civiles y Familiares y de la Ley Federal de Procedimiento Administrativo.

Párrafo reformado DOF 14-11-2025

Para la substanciación de los procedimientos de protección de derechos, de verificación e imposición de sanciones se observarán las disposiciones contenidas en la Ley Federal de Procedimiento Administrativo.

Capítulo II
De los Principios de Protección de Datos Personales

Artículo 5. El responsable deberá observar los principios de licitud, finalidad, lealtad, consentimiento, calidad, proporcionalidad, información y responsabilidad en el tratamiento de datos personales.

Artículo 6. Los datos personales deberán recabarse y tratarse de manera lícita conforme a lo previsto por esta Ley y demás disposiciones jurídicas aplicables.

El responsable no deberá obtener y tratar datos personales a través de medios engañosos o fraudulentos, y deberá privilegiar la protección de los intereses de la persona titular y la expectativa razonable de privacidad, entendida como la confianza que deposita cualquier persona en otra, respecto

de que los datos personales proporcionados serán tratados conforme a lo que acordaron en los términos establecidos por esta Ley.

Artículo 7. Todo tratamiento de datos personales estará sujeto al consentimiento de la persona titular, salvo las excepciones previstas por la presente Ley.

El consentimiento podrá manifestarse de forma expresa o tácita. Se deberá entender que el consentimiento es expreso cuando la voluntad de la persona titular se manifieste verbalmente, por escrito, por medios electrónicos, ópticos, signos inequívocos o por cualquier otra tecnología.

El consentimiento será tácito cuando habiéndose puesto a disposición de la persona titular el aviso de privacidad, esta no manifieste su voluntad en sentido contrario.

Por regla general será válido el consentimiento tácito, salvo que las disposiciones jurídicas aplicables exijan que la voluntad de la persona titular se manifieste expresamente.

Los datos financieros o patrimoniales requerirán el consentimiento expreso de la persona titular, salvo las excepciones a que se refieren los artículos 9 y 36 de la presente Ley.

El consentimiento podrá ser revocado en cualquier momento sin que se le atribuyan efectos retroactivos. Para revocar el consentimiento, el responsable deberá, en el aviso de privacidad, establecer los mecanismos y procedimientos para ello.

Artículo 8. Tratándose de datos personales sensibles, el responsable deberá obtener el consentimiento expreso y por escrito de la persona titular para su tratamiento, a través de su firma autógrafa, firma electrónica, o cualquier mecanismo de autenticación que al efecto se establezca.

No podrán crearse bases de datos que contengan datos personales sensibles, sin que se justifique la creación de las mismas para finalidades legítimas, concretas y acordes con las actividades o fines explícitos que persigue el sujeto regulado.

Artículo 9. El responsable no estará obligado a recabar el consentimiento de la persona titular para el tratamiento de los datos personales cuando:

I. Una disposición jurídica así lo disponga;

II. Los datos personales figuren en fuentes de acceso público;

III. Los datos personales se sometan a un procedimiento previo de disociación;

IV. Los datos personales se requieran para ejercer un derecho o cumplir obligaciones derivadas de una relación jurídica entre la persona titular y el responsable;

V. Exista una situación de emergencia que potencialmente pueda dañar a un individuo en su persona o en sus bienes;

VI. Los datos personales sean indispensables para efectuar un tratamiento para atención médica, la prevención, diagnóstico, la prestación de asistencia sanitaria, o la gestión de servicios sanitarios, mientras la persona titular no esté en condiciones de otorgar el consentimiento, en los términos que establece la Ley General de Salud y demás disposiciones jurídicas aplicables y que dicho tratamiento de datos se realice por una persona sujeta al secreto profesional u obligación equivalente, o

VII. Exista una orden judicial, resolución o mandato fundado y motivado de autoridad competente.

Artículo 10. El responsable procurará que los datos personales contenidos en las bases de datos sean exactos, completos, correctos y actualizados para los fines para los cuales fueron recabados.

Cuando los datos personales hayan dejado de ser necesarios para el cumplimiento de las finalidades previstas en el aviso de privacidad y que motivaron su tratamiento conforme a las disposiciones legales aplicables, deberán ser suprimidos previo bloqueo, en su caso, y una vez que concluya el plazo de conservación de los mismos.

El responsable estará obligado a eliminar los datos relativos al incumplimiento de obligaciones contractuales, una vez que transcurra un plazo de setenta y dos meses, contado a partir de la fecha calendario en que se presente el mencionado incumplimiento.

Artículo 11. El tratamiento de datos personales deberá limitarse al cumplimiento de las finalidades previstas en el aviso de privacidad, sin embargo, si el responsable pretende tratar los datos para una finalidad distinta a las establecidas en el aviso de privacidad, se requerirá obtener nuevamente el consentimiento de la persona titular.

Artículo 12. El tratamiento de datos personales será el que resulte necesario, adecuado y relevante en relación con las finalidades previstas en el aviso de privacidad, para los datos personales sensibles, el responsable deberá realizar esfuerzos razonables para limitar el periodo de tratamiento de los mismos a efecto de que sea el mínimo indispensable.

Artículo 13. El responsable velará por el cumplimiento de los principios de protección de datos personales establecidos por esta Ley, debiendo adoptar las medidas necesarias y suficientes para su aplicación, así como para garantizar que el aviso de privacidad dado a conocer a la persona titular, sea respetado en todo momento por él o por terceros con los que guarde alguna relación jurídica.

Artículo 14. El responsable tendrá la obligación de informar a la persona titular, a través del aviso de privacidad, la existencia y características principales del tratamiento al que serán sometidos sus datos personales, a fin de que pueda tomar decisiones informadas al respecto.

Artículo 15. El aviso de privacidad deberá contener, al menos, la siguiente información:

I. La identidad y domicilio del responsable;

II. Los datos personales que serán sometidos a tratamiento, identificando aquéllos que son sensibles;

III. Las finalidades del tratamiento de datos personales, distinguiendo aquéllas que requieren el consentimiento de la persona titular;

IV. Las opciones y medios que el responsable ofrezca a las personas titulares para limitar el uso o divulgación de los datos;

V. Los mecanismos, medios y procedimientos para ejercer los derechos ARCO, de conformidad con lo dispuesto en esta Ley, y

VI. El procedimiento y medio por el cual el responsable comunicará a las personas titulares de cambios al aviso de privacidad, de conformidad con lo previsto en esta Ley.

Artículo 16. El responsable debe poner a disposición de las personas titulares el aviso de privacidad, a través de formatos impresos, digitales, visuales, sonoros o cualquier otra tecnología de la siguiente manera:

I. Cuando los datos personales sean obtenidos personalmente a través de formatos impresos, deberá ser dado a conocer en ese momento, salvo que se hubiera facilitado el aviso con anterioridad, y

II. Cuando los datos personales sean obtenidos por cualquier medio electrónico, óptico, sonoro, visual, o a través de cualquier otra tecnología, deberá ser proporcionado en su modalidad simplificada la que deberá contener al menos la información a que se refieren las fracciones I a IV del artículo anterior, y señalar el sitio donde se podrá consultar el aviso de privacidad integral.

Artículo 17. Cuando los datos no hayan sido obtenidos directamente de la persona titular, el responsable deberá darle a conocer el cambio en el aviso de privacidad.

No resulta aplicable lo establecido en el párrafo anterior, cuando el tratamiento sea con fines históricos, estadísticos o científicos.

Cuando resulte imposible dar a conocer el aviso de privacidad a la persona titular de manera directa o ello exija esfuerzos desproporcionados, el responsable podrá instrumentar medidas compensatorias en términos del Reglamento de esta Ley.

Artículo 18. Todo responsable deberá establecer y mantener medidas de seguridad administrativas, técnicas y físicas que permitan proteger los datos personales contra daño, pérdida, alteración, destrucción o el uso, acceso o tratamiento no autorizado.

Los responsables no adoptarán medidas de seguridad menores a aquellas que mantengan para el manejo de su información. Asimismo, se tomará en cuenta el riesgo existente, las posibles consecuencias para las personas titulares, la sensibilidad de los datos y el desarrollo tecnológico.

Artículo 19. Las vulneraciones de seguridad ocurridas en cualquier fase del tratamiento de datos personales que afecten de forma significativa los derechos patrimoniales o morales de las personas titulares le serán informadas de forma inmediata por el responsable, a fin de que pueda tomar las medidas correspondientes a la defensa de sus derechos.

Artículo 20. El responsable o tercero deberá establecer controles o mecanismos que tengan por objeto que todas aquellas personas que intervengan en cualquier fase del tratamiento de datos personales, guarden confidencialidad respecto de estos, obligación que subsistirá aun después de finalizar sus relaciones con el mismo.

Capítulo III
De los Derechos de las Personas Titulares de Datos Personales

Artículo 21. Cualquier persona titular o, en su caso, su representante legal, podrá ejercer los derechos ARCO previstos en la presente Ley.

El ejercicio de cualquiera de los derechos ARCO no es requisito previo ni impide el ejercicio de otro.

Los datos personales deben ser resguardados de tal manera que permitan el ejercicio sin dilación de estos derechos.

Artículo 22. La persona titular tendrá derecho a acceder a sus datos personales que obren en posesión del responsable, así como conocer la información relacionada con las condiciones y generalidades de su tratamiento, a través del aviso de privacidad.

Artículo 23. La persona titular tendrá derecho a solicitar la rectificación o corrección de sus datos personales, cuando resulten ser inexactos, incompletos o no se encuentren actualizados.

Artículo 24. La persona titular tendrá en todo momento el derecho a solicitar la cancelación de sus datos personales de los archivos, registros, expedientes y sistemas del responsable, a fin de que los mismos ya no estén en posesión del responsable.

La cancelación de datos personales dará lugar a un periodo de bloqueo tras el cual se procederá a la supresión del dato, el responsable podrá conservarlos exclusivamente para efectos de las responsabilidades nacidas del tratamiento.

El periodo de bloqueo será equivalente al plazo de prescripción de las acciones derivadas de la relación jurídica que funda el tratamiento en los términos de la Ley aplicable en la materia, y una vez cancelado el dato se dará aviso a la persona titular.

Cuando los datos personales hubiesen sido transmitidos con anterioridad a la fecha de rectificación o cancelación y sigan siendo tratados por terceros, el responsable deberá hacer de su conocimiento dicha solicitud de rectificación o cancelación, para que proceda a efectuarla también.

Artículo 25. El responsable no estará obligado a cancelar los datos personales cuando:

I. Se refiera a las partes de un contrato privado, social o administrativo y sean necesarios para su desarrollo y cumplimiento;

II. Deban ser tratados por disposición legal;

III. Obstaculice las actuaciones judiciales o administrativas vinculadas a obligaciones fiscales, la investigación y persecución de delitos o la actualización de sanciones administrativas;

IV. Sean necesarios para proteger los intereses jurídicamente tutelados de la persona titular;

V. Sean necesarios para realizar una acción en función del interés público;

VI. Sean necesarios para cumplir con una obligación legalmente adquirida por la persona titular, y

VII. Sean objeto de tratamiento para la prevención o para el diagnóstico médico o la gestión de servicios de salud, siempre que dicho tratamiento se realice por un profesional de la salud sujeto a un deber de secreto.

Artículo 26. La persona titular tendrá derecho en todo momento y por causa legítima a oponerse al tratamiento de sus datos o exigir que se cese en el mismo cuando:

I. Exista causa legítima y su situación específica así lo requiera, lo cual debe justificar que aun siendo lícito el tratamiento, el mismo debe cesar para evitar que su persistencia le cause un daño o perjuicio, o

II. Sus datos personales sean objeto de un tratamiento automatizado, el cual le produzca efectos jurídicos no deseados o afecte de manera significativa sus intereses, derechos o libertades, y estén destinados a evaluar, sin intervención humana, determinados aspectos personales de la misma o analizar o predecir, en particular, su rendimiento profesional, situación económica, estado de salud, preferencias sexuales, fiabilidad o comportamiento.

No procederá el ejercicio del derecho de oposición en aquellos casos en los que el tratamiento sea necesario para el cumplimiento de una obligación legal impuesta al responsable.

Capítulo IV
Del Ejercicio de los Derechos de Acceso, Rectificación, Cancelación y Oposición

Artículo 27. La persona titular o su representante legal podrán solicitar al responsable en cualquier momento el ejercicio de los derechos ARCO, respecto de los datos personales que le conciernen.

Artículo 28. La solicitud para el ejercicio de los derechos ARCO deberá contener y acompañar lo siguiente:

I. El nombre de la persona titular y su domicilio o cualquier otro medio para recibir notificaciones;

II. Los documentos que acrediten la identidad de la persona titular o, en su caso, la personalidad e identidad de su representante;

III. La descripción clara y precisa de los datos personales respecto de los que se busca ejercer alguno de los derechos ARCO, salvo que se trate del derecho de acceso;

IV. La descripción del derecho ARCO que se pretende ejercer, o bien, lo que solicita la persona titular, y

V. Cualquier otro elemento o documento que facilite la localización de los datos personales.

Artículo 29. Todo responsable fomentará la protección de datos personales al interior de la organización y designará a una persona, o departamento de datos personales, quien dará trámite a las solicitudes de las personas titulares, para el ejercicio de los derechos a que se refiere la presente Ley.

Artículo 30. En el caso de solicitudes para el ejercicio del derecho de rectificación de datos personales, la persona titular deberá indicar, además de lo señalado en el artículo 29 de esta Ley, las modificaciones a realizarse y aportar la documentación que sustente su petición.

Artículo 31. El responsable comunicará a la persona titular, en un plazo máximo de veinte días, contados desde la fecha en que se recibió la solicitud para el ejercicio de los derechos ARCO, la determinación adoptada, a efecto de que, si resulta procedente, se haga efectiva la misma dentro de los quince días siguientes a la fecha en que se comunica la respuesta. Tratándose de solicitudes para el ejercicio del derecho de acceso a datos personales, procederá la entrega previa acreditación de la identidad del titular o representante legal, según corresponda.

Los plazos antes referidos podrán ser ampliados una sola vez por un periodo igual, siempre y cuando así lo justifiquen las circunstancias del caso.

Artículo 32. La obligación de acceso a los datos personales se dará por cumplida cuando se pongan a disposición de la persona titular los mismos; o bien, mediante la expedición de copias simples, documentos electrónicos o cualquier otro medio que determine el responsable en el aviso de privacidad.

En el caso de que la persona titular solicite el acceso a los datos a una persona que presume es el responsable y ésta resulta no serlo, bastará con que así se le indique a la persona titular por cualquiera de los medios a que se refiere el párrafo anterior, para tener por cumplida la solicitud.

Artículo 33. Las causas en las que el ejercicio de los derechos ARCO no serán procedentes y por tanto el responsable podrá negar los mismos son:

I. Cuando la persona titular o el representante legal no estén debidamente acreditados para ello;

II. Cuando los datos personales no se encuentren en posesión del responsable;

III. Cuando se lesionen derechos de un tercero;

IV. Cuando exista un impedimento legal, o la resolución de una autoridad competente, que restrinja el acceso a los datos personales, o no permita la rectificación, cancelación u oposición de los mismos, y

V. Cuando la rectificación, cancelación u oposición haya sido previamente realizada.

La negativa a que se refiere este artículo podrá ser parcial cuando alguno de los requerimientos descritos en la solicitud para el ejercicio de los derechos ARCO de la persona titular o de su representante no se encuentren en alguna de las causas antes referidas, en cuyo caso el responsable efectuará el acceso, rectificación, cancelación u oposición requerida.

En todos los casos anteriores, el responsable deberá informar el motivo de su decisión y comunicarla a la persona titular, o en su caso, al representante legal, en los plazos establecidos para tal efecto, por el mismo medio por el que se llevó a cabo la solicitud para el ejercicio de los derechos ARCO, acompañando, en su caso, las pruebas que resulten pertinentes.

Artículo 34. El ejercicio de los derechos ARCO es gratuito, solo podrán realizarse cobros para recuperar los costos de reproducción, copias o envío.

Cuando la persona titular proporcione el medio magnético, electrónico o el mecanismo necesario para reproducir los datos personales, los mismos deberán ser entregados sin costo a esta.

Cuando una misma persona titular o su representante reitera su solicitud en un periodo menor a doce meses, los costos no serán mayores a tres veces la Unidad de Medida y Actualización vigente, a menos que existan modificaciones sustanciales al aviso de privacidad que motiven nuevas consultas.

Capítulo V
De la Transferencia de Datos

Artículo 35. Cuando el responsable pretenda transferir los datos personales a terceros nacionales o extranjeros, distintos de la persona encargada deberá comunicar a éstos el aviso de privacidad y las finalidades a las que la persona titular sujetó su tratamiento.

El tratamiento de los datos se hará conforme a lo convenido en el aviso de privacidad, el cual contendrá una cláusula en la que se indique si la persona titular acepta o no la transferencia de sus datos, de igual manera, el tercero receptor, asumirá las mismas obligaciones que correspondan al responsable que transfirió los datos.

Artículo 36. Las transferencias nacionales o internacionales de datos podrán llevarse a cabo sin el consentimiento de la persona titular cuando se ubiquen en alguno de los supuestos siguientes:

I. La transferencia esté prevista en una Ley o Tratado en los que México sea parte;

II. La transferencia sea necesaria para la prevención o el diagnóstico médico, la prestación de asistencia sanitaria, tratamiento médico o la gestión de servicios sanitarios;

III. La transferencia sea efectuada a sociedades controladoras, subsidiarias o afiliadas bajo el control común del responsable, o a una sociedad matriz o a cualquier sociedad del mismo grupo del responsable que opere bajo los mismos procesos y políticas internas;

IV. La transferencia sea necesaria por virtud de un contrato celebrado o por celebrar en interés de la persona titular, por el responsable y un tercero;

V. La transferencia sea necesaria o legalmente exigida para la salvaguarda de un interés público, o para la procuración o administración de justicia;

VI. La transferencia sea precisa para el reconocimiento, ejercicio o defensa de un derecho en un proceso judicial, y

VII. La transferencia sea precisa para el mantenimiento o cumplimiento de una relación jurídica entre el responsable y la persona titular.

Capítulo VI
De la Autorregulación

Artículo 37. Las personas físicas o morales podrán convenir entre ellas o con organizaciones civiles o gubernamentales, nacionales o extranjeras, esquemas de autorregulación vinculante en la materia, que complementen lo dispuesto por la presente Ley. Dichos esquemas deberán contener mecanismos para medir su eficacia en la protección de los datos, consecuencias y medidas correctivas eficaces en caso de incumplimiento.

Los esquemas de autorregulación podrán traducirse en códigos deontológicos o de buena práctica profesional, sellos de confianza u otros mecanismos y contendrán reglas o estándares específicos que permitan armonizar los tratamientos de datos efectuados por los adheridos y facilitar el ejercicio de los derechos de las personas titulares. Dichos esquemas serán notificados de manera simultánea a las autoridades correspondientes y a la Secretaría.

Capítulo VII
De la Secretaría

Artículo 38. La Secretaría, para efectos de esta Ley, tendrá por objeto difundir el conocimiento del derecho a la protección de datos personales en la sociedad mexicana, promover su ejercicio y vigilar por la debida observancia de las disposiciones previstas en la presente Ley y que deriven de la misma; en particular aquellas relacionadas con el cumplimiento de obligaciones por parte de los sujetos regulados por este ordenamiento.

Artículo 39. La Secretaría tiene las siguientes atribuciones:

I. Vigilar y verificar el cumplimiento de las disposiciones contenidas en esta Ley, en el ámbito de su competencia, con las excepciones previstas por la legislación;

II. Interpretar en el ámbito administrativo la presente Ley;

III. Proporcionar apoyo técnico a los responsables que lo soliciten, para el cumplimiento de las obligaciones establecidas en la presente Ley;

IV. Emitir los criterios y recomendaciones, de conformidad con las disposiciones aplicables de esta Ley, para efectos de su funcionamiento y operación;

V. Divulgar estándares y mejores prácticas internacionales en materia de seguridad de la información, en atención a la naturaleza de los datos; las finalidades del tratamiento, y las capacidades técnicas y económicas del responsable;

VI. Conocer y resolver los procedimientos de protección de derechos y de verificación señalados en esta Ley e imponer las sanciones según corresponda;

VII. Cooperar con otras autoridades de supervisión y organismos nacionales e internacionales, a efecto de coadyuvar en materia de protección de datos;

VIII. Acudir a foros internacionales en el ámbito de la presente Ley;

IX. Elaborar estudios de impacto sobre la privacidad previos a la puesta en práctica de una nueva modalidad de tratamiento de datos personales o a la realización de modificaciones sustanciales en tratamientos ya existentes;

X. Difundir el conocimiento de las obligaciones en torno a la protección de datos personales y brindar capacitación a los sujetos obligados, y

XI. Las demás que le confieran esta Ley y demás ordenamientos aplicables.

Capítulo VIII
Del Procedimiento de Protección de Derechos

Artículo 40. El procedimiento se iniciará a instancia de la persona titular de los datos o de su representante legal, expresando con claridad el contenido de su reclamación y de los preceptos de esta Ley que se consideran vulnerados. La solicitud de protección de datos deberá presentarse ante la Secretaría dentro de los quince días siguientes a la fecha en que se comunique la respuesta a la persona titular por parte del responsable.

En el caso de que la persona titular de los datos no reciba respuesta por parte del responsable, la solicitud de protección de datos podrá ser presentada a partir de que haya vencido el plazo de respuesta previsto para el responsable. En este caso, bastará que la persona titular de los datos acompañe a su solicitud de protección de datos el documento que pruebe la fecha en que presentó la solicitud de acceso, rectificación, cancelación u oposición.

La solicitud de protección de datos también procederá en los mismos términos cuando el responsable no entregue a la persona titular los datos personales solicitados, o lo haga en un formato incomprensible,

se niegue a efectuar modificaciones o correcciones a los datos personales, la persona titular no esté conforme con la información entregada por considerar que es incompleta o no corresponda a la información requerida.

Recibida la solicitud de protección de datos ante la Secretaría, se dará traslado de la misma al responsable, para que, en el plazo de quince días, emita respuesta, ofrezca las pruebas que estime pertinentes y manifieste por escrito lo que a su derecho convenga.

La Secretaría admitirá las pruebas que estime pertinentes y procederá a su desahogo. Asimismo, podrá solicitar del responsable las demás pruebas que estime necesarias. Concluido el desahogo de las pruebas, la Secretaría notificará al responsable el derecho que le asiste para que, de considerarlo necesario, presente sus alegatos dentro de los cinco días siguientes a su notificación.

Para el debido desahogo del procedimiento, la Secretaría resolverá sobre la solicitud de protección de datos formulada, una vez analizadas las pruebas y demás elementos de convicción que estime pertinentes, como pueden serlo aquéllos que deriven de la o las audiencias que se celebren con las partes.

El Reglamento de la Ley establecerá la forma, términos y plazos conforme a los que se desarrollará el procedimiento de protección de derechos.

Artículo 41. La solicitud de protección de datos podrá interponerse por escrito libre o a través de los formatos, del sistema electrónico que al efecto proporcione la Secretaría y deberá contener la siguiente información:

I. El nombre de la persona titular o, en su caso, el de su representante legal, así como del tercero interesado, si lo hay;

II. El nombre del responsable ante el cual se presentó la solicitud de acceso, rectificación, cancelación u oposición de datos personales;

III. El domicilio para oír y recibir notificaciones;

IV. La fecha en que se le dio a conocer la respuesta del responsable, salvo que el procedimiento inicie con base en lo previsto en el artículo 45 de la presente Ley;

V. Los actos que motivan su solicitud de protección de datos, y

VI. Los demás elementos que se considere procedente hacer del conocimiento de la Secretaría.

La forma y términos en que deba acreditarse la identidad de la persona titular o bien, la representación legal, se establecerán en el Reglamento.

Asimismo, a la solicitud de protección de datos deberá acompañarse la solicitud y la respuesta que se recurre o, en su caso, los datos que permitan su identificación.

En el caso de falta de respuesta sólo será necesario presentar la solicitud.

En el caso de que la solicitud de protección de datos se interponga a través de medios que no sean electrónicos, deberá acompañarse de las copias de traslado suficientes.

Artículo 42. El plazo máximo para dictar la resolución en el procedimiento de protección de derechos será de cincuenta días, contados a partir de la fecha de presentación de la solicitud de protección de

datos. Cuando haya causa justificada, la Secretaría podrá ampliar por una vez y hasta por un período igual este plazo.

Artículo 43. En caso que la resolución de protección de derechos resulte favorable a la persona titular de los datos, se requerirá al responsable para que, en el plazo de diez días siguientes a la notificación o cuando así se justifique, uno mayor que fije la propia resolución, haga efectivo el ejercicio de los derechos objeto de protección, debiendo dar cuenta por escrito de dicho cumplimiento a la Secretaría dentro de los siguientes diez días.

Artículo 44. En caso de que la solicitud de protección de datos no satisfaga alguno de los requisitos a que se refiere el artículo 41 de esta Ley, y la Secretaría no cuente con elementos para subsanarlo, se prevendrá a la persona titular de los datos dentro de los veinte días siguientes a la presentación de la solicitud de protección de datos, por una sola ocasión, para que subsane las omisiones dentro de un plazo de cinco días. Transcurrido el plazo sin desahogar la prevención se tendrá por no presentada la solicitud de protección de datos. La prevención tendrá el efecto de interrumpir el plazo que tiene la Secretaría para resolver la solicitud de protección de datos.

Artículo 45. La Secretaría suplirá las deficiencias de la queja en los casos que así se requiera, siempre y cuando no altere el contenido original de la solicitud de acceso, rectificación, cancelación u oposición de datos personales, ni se modifiquen los hechos o peticiones expuestos en la misma o en la solicitud de protección de datos.

Artículo 46. Las resoluciones de la Secretaría podrán:

I. Sobreseer o desechar la solicitud de protección de datos por improcedente;

II. Confirmar, revocar o modificar la respuesta del responsable, o

III. Ordenar la entrega de los datos personales, en caso de omisión del responsable.

Artículo 47. La solicitud de protección de datos será desechada por improcedente cuando:

I. La Secretaría no sea competente;

II. La persona titular o su representante no acrediten debidamente su identidad y personalidad de este último;

III. La Secretaría haya conocido anteriormente de la solicitud de protección de datos contra el mismo acto y resuelto en definitiva respecto del mismo recurrente;

IV. Se esté tramitando ante los tribunales competentes algún recurso o medio de defensa interpuesto por la persona titular o, en su caso, por el tercero interesado, en contra del acto recurrido ante la Secretaría;

V. Se trate de una solicitud de protección de datos ofensiva o irracional, o

VI. Sea extemporánea por haber transcurrido el plazo establecido en el artículo 40 de la presente Ley.

Artículo 48. La solicitud de protección de datos será sobreseída cuando:

I. La persona titular fallezca;

II. La persona titular se desista de manera expresa;

III. Admitida la solicitud de protección de datos, sobrevenga una causal de improcedencia, y

IV. Por cualquier motivo quede sin materia la misma.

Artículo 49. La Secretaría podrá en cualquier momento del procedimiento buscar una conciliación entre la persona titular de los datos y el responsable.

De llegarse a un acuerdo de conciliación entre ambos, éste se hará constar por escrito y tendrá efectos vinculantes. La solicitud de protección de datos quedará sin materia y la Secretaría verificará el cumplimiento del acuerdo respectivo.

Para efectos de la conciliación a que se alude en el presente ordenamiento, se estará al procedimiento que se establezca en el Reglamento de esta Ley.

Artículo 50. Interpuesta la solicitud de protección de datos ante la falta de respuesta a una solicitud en ejercicio de los derechos ARCO por parte del responsable, la Secretaría dará vista al citado responsable para que, en un plazo no mayor a diez días, acredite haber respondido en tiempo y forma la solicitud, o bien dé respuesta a la misma. En caso de que la respuesta atienda a lo solicitado, la solicitud de protección de datos se considerará improcedente y la Secretaría deberá sobreseerlo.

En el segundo caso, la Secretaría emitirá su resolución con base en el contenido de la solicitud original y la respuesta del responsable que alude el párrafo anterior.

Si la resolución de la Secretaría a que se refiere el párrafo anterior determina la procedencia de la solicitud, el responsable procederá a su cumplimiento, sin costo alguno para la persona titular, debiendo cubrir el responsable todos los costos generados por la reproducción correspondiente y gastos de envío.

Artículo 51. Contra las resoluciones de la Secretaría, los particulares podrán promover juicio de amparo. Los juicios de amparo serán sustanciados por jueces y tribunales especializados en los términos del artículo 94 de la Constitución Política de los Estados Unidos Mexicanos.

Artículo 52. Todas las resoluciones de la Secretaría serán susceptibles de difundirse públicamente en versiones públicas, eliminando aquellas referencias a la persona titular de los datos que lo identifiquen o lo hagan identificable.

Artículo 53. Las personas titulares que consideren que han sufrido un daño o lesión en sus bienes o derechos como consecuencia del incumplimiento a lo dispuesto en la presente Ley por el responsable o la persona encargada, podrán ejercer los derechos que estimen pertinentes para efectos de la indemnización que proceda, en términos de las disposiciones legales correspondientes.

Capítulo IX
Del Procedimiento de Verificación

Artículo 54. La Secretaría verificará el cumplimiento de la presente Ley y de la normatividad que de ésta derive. La verificación podrá iniciarse de oficio o a petición de parte.

La verificación de oficio procederá cuando se dé el incumplimiento a resoluciones dictadas con motivo de procedimientos de protección de derechos a que se refiere el Capítulo anterior o se presuma fundada y motivadamente la existencia de violaciones a la presente Ley.

Artículo 55. En el procedimiento de verificación la Secretaría tendrá acceso a la información y documentación que considere necesarias, de acuerdo a la resolución que lo motive.

Las personas servidoras públicas estarán obligadas a guardar confidencialidad sobre la información que conozcan derivada de la verificación correspondiente.

El Reglamento desarrollará la forma, términos y plazos en que se sustanciará el procedimiento a que se refiere el presente artículo.

Capítulo X
Del Procedimiento de Imposición de Sanciones

Artículo 56. Si con motivo del desahogo del procedimiento de protección de derechos o del procedimiento de verificación que realice la Secretaría, ésta tuviera conocimiento de un presunto incumplimiento de alguno de los principios o disposiciones de esta Ley, iniciará el procedimiento de imposición de sanciones.

Artículo 57. El procedimiento de imposición de sanciones dará comienzo con la notificación que efectúe la Secretaría a la presunta persona infractora, sobre los hechos que motivaron el inicio del procedimiento y le otorgará un término de quince días para que rinda pruebas y manifieste por escrito lo que a su derecho convenga. En caso de no rendirlas, la Secretaría resolverá conforme a los elementos de convicción de que disponga.

La Secretaría admitirá las pruebas que estime pertinentes y procederá a su desahogo. Asimismo, podrá solicitar de la presunta persona infractora las demás pruebas que estime necesarias. Concluido el desahogo de las pruebas, la Secretaría notificará a la presunta persona infractora el derecho que le asiste para que, de considerarlo necesario, presente sus alegatos dentro de los cinco días siguientes a su notificación.

La Secretaría, una vez analizadas las pruebas y demás elementos de convicción que estime pertinentes, resolverá en definitiva dentro de los cincuenta días siguientes a la fecha en que inició el procedimiento sancionador. Dicha resolución deberá ser notificada a las partes.

Cuando haya causa justificada, la Secretaría podrá ampliar por una vez y hasta por un período igual este plazo.

El Reglamento desarrollará la forma, términos y plazos en que se sustanciará el procedimiento de imposición de sanciones, incluyendo presentación de pruebas y alegatos, la celebración de audiencias y el cierre de instrucción.

Capítulo XI
De las Infracciones y Sanciones

Artículo 58. Constituyen infracciones a esta Ley, las conductas llevadas a cabo por el responsable:

I. No cumplir con la solicitud para el ejercicio de los derechos ARCO de la persona titular, sin razón fundada, en los términos previstos en esta Ley;

II. Actuar con negligencia o dolo durante la sustanciación de las solicitudes para el ejercicio de los derechos ARCO;

III. Declarar dolosamente la inexistencia de datos personales, cuando exista total o parcialmente en las bases de datos del responsable;

IV. Dar tratamiento a los datos personales en contravención a los principios establecidos en la presente Ley;

V. Omitir en el aviso de privacidad, alguno o todos los elementos a que se refiere el artículo 15 de esta Ley;

VI. Mantener datos personales inexactos cuando resulte imputable al responsable, o no efectuar las rectificaciones o cancelaciones de los mismos que legalmente procedan cuando resulten afectados los derechos de las personas titulares;

VII. No cumplir con el apercibimiento a que se refiere la fracción I del artículo 59 de la presente Ley;

VIII. Incumplir el deber de confidencialidad establecido en el artículo 20 de esta Ley;

IX. Cambiar sustancialmente la finalidad originaria del tratamiento de los datos, sin observar lo dispuesto por el artículo 11 de esta Ley;

X. Transferir datos a terceros sin comunicar a estos el aviso de privacidad que contiene las limitaciones a que la persona titular sujetó la divulgación de los mismos;

XI. Vulnerar la seguridad de bases de datos, locales, programas o equipos, cuando resulte imputable al responsable;

XII. Llevar a cabo la transferencia o cesión de los datos personales, fuera de los casos en que esté permitida por la Ley;

XIII. Recabar o transferir datos personales sin el consentimiento expreso de la persona titular, en los casos en que éste sea exigible;

XIV. Obstruir los actos de verificación de la autoridad;

XV. Recabar datos en forma engañosa y fraudulenta;

XVI. Continuar con el uso ilegítimo de los datos personales cuando se ha solicitado el cese del mismo por la Secretaría o las personas titulares;

XVII. Tratar los datos personales de manera que se afecte o impida el ejercicio de los derechos ARCO establecidos en el artículo 16 de la Constitución Política de los Estados Unidos Mexicanos;

XVIII. Crear bases de datos en contravención a lo dispuesto por el artículo 8, segundo párrafo de esta Ley, y

XIX. Cualquier incumplimiento del responsable a las obligaciones establecidas a su cargo en términos de lo previsto en la presente Ley.

Artículo 59. Las infracciones a la presente Ley serán sancionadas por la Secretaría con:

I. El apercibimiento para que el responsable lleve a cabo los actos solicitados por la persona titular, en los términos previstos por esta Ley, tratándose de los supuestos previstos en la fracción I del artículo anterior;

II. Multa de 100 a 160,000 veces la Unidad de Medida y Actualización, en los casos previstos en las fracciones II a VII del artículo anterior;

III. Multa de 200 a 320,000 veces la Unidad de Medida y Actualización, en los casos previstos en las fracciones VIII a XVIII del artículo anterior, y

IV. En caso de que de manera reiterada persistan las infracciones citadas en los incisos anteriores, se impondrá una multa adicional que irá de 100 a 320,000 veces la Unidad de Medida y Actualización. En tratándose de infracciones cometidas en el tratamiento de datos sensibles, las sanciones podrán incrementarse hasta por dos veces, los montos establecidos.

Artículo 60. La Secretaría fundará y motivará sus resoluciones, considerando:

I. La naturaleza del dato;

II. La notoria improcedencia de la negativa del responsable, para realizar los actos solicitados por la persona titular, en términos de esta Ley;

III. El carácter intencional o no, de la acción u omisión constitutiva de la infracción;

IV. La capacidad económica del responsable, y

V. La reincidencia.

Artículo 61. Las sanciones que se señalan en este Capítulo se impondrán sin perjuicio de la responsabilidad civil o penal que resulte.

Capítulo XII
De los Delitos en Materia del Tratamiento Indebido de Datos Personales

Artículo 62. Se impondrán de tres meses a tres años de prisión al que, estando autorizado para tratar datos personales, con ánimo de lucro, provoque una vulneración de seguridad a las bases de datos bajo su custodia.

Artículo 63. Se sancionará con prisión de seis meses a cinco años al que, con el fin de alcanzar un lucro indebido, trate datos personales mediante el engaño, aprovechándose del error en que se encuentre la persona titular o la persona autorizada para transmitirlos.

Artículo 64. Tratándose de datos personales sensibles, las penas a que se refiere este Capítulo se duplicarán.

Artículo Cuarto.- ……..

Transitorios

Primero.- El presente Decreto entrará en vigor al día siguiente de su publicación en el Diario Oficial de la Federación, con excepción de lo previsto en el transitorio Tercero de este instrumento.

Segundo.- A la entrada en vigor del presente Decreto se abrogan las disposiciones siguientes:

I. La Ley Federal de Protección de Datos Personales en Posesión de los Particulares, publicada en el Diario Oficial de la Federación el 5 de julio de 2010;

II. La Ley General de Transparencia y Acceso a la Información Pública, publicada en el Diario Oficial de la Federación el 4 de mayo de 2015 y sus modificaciones posteriores;

III. La Ley Federal de Transparencia y Acceso a la Información Pública, publicada en el Diario Oficial de la Federación el 9 de mayo de 2016 y sus modificaciones posteriores;

IV. La Ley General de Protección de Datos Personales en Posesión de Sujetos Obligados, publicada en el Diario Oficial de la Federación el 26 de enero de 2017, y

V. El Acuerdo mediante el cual se aprueba el Programa Anual de Verificación y Acompañamiento Institucional para el cumplimiento de las obligaciones en materia de acceso a la información y transparencia por parte de los sujetos obligados del ámbito federal, correspondiente al ejercicio 2025, publicado en el Diario Oficial de la Federación el 21 de enero de 2025.

Tercero.- Los artículos 71 y 72 de la Ley General de Transparencia y Acceso a la Información Pública entrarán en vigor cuando se extingan la Comisión Federal de Competencia Económica y el Instituto Federal de Telecomunicaciones conforme a lo previsto en los transitorios Décimo y Décimo Primero del "Decreto por el que se reforman, adicionan y derogan diversas disposiciones de la Constitución Política de los Estados Unidos Mexicanos, en materia de simplificación orgánica", publicado en el Diario Oficial de la Federación el 20 de diciembre de 2024.

Para efectos del párrafo anterior, la Comisión Federal de Competencia Económica y el Instituto Federal de Telecomunicaciones deberán poner a disposición del público y actualizar la información a que se refiere el artículo 72, fracciones II y V, respectivamente, de la Ley Federal de Transparencia y Acceso a la Información Pública que se abroga por virtud del presente Decreto.

Cuarto.- Las menciones, atribuciones o funciones contenidas en otras leyes, reglamentos y, en general, en cualquier disposición normativa, respecto al Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales se entenderán hechas o conferidas a los entes públicos que adquieren tales atribuciones o funciones, según corresponda.

Quinto.- Los derechos laborales de las personas servidoras públicas del Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, serán respetados, en términos de la legislación aplicable. Los recursos humanos con que cuente el referido Instituto pasarán a formar parte de la Secretaría Anticorrupción y Buen Gobierno y Transparencia para el Pueblo.

El Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales transferirá los recursos correspondientes al valor del inventario o plantilla de plazas a la Secretaría de Hacienda y Crédito Público, dentro de los veinte días hábiles siguientes contados a partir de la entrada en vigor del presente Decreto, a fin de que esa dependencia realice las acciones que correspondan, conforme a las disposiciones jurídicas aplicables.

Las personas servidoras públicas del Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales que dejen de prestar sus servicios en el mencionado Instituto y que estén obligadas a presentar declaración patrimonial y de intereses, de conformidad con las disposiciones jurídicas aplicables, lo realizarán en los sistemas de la Secretaría Anticorrupción y Buen Gobierno

habilitados para tales efectos o en los medios que esta determine y conforme a la normativa aplicable a la Administración Pública Federal. Lo anterior también es aplicable a las personas que se hayan desempeñado como servidoras públicas en el mencionado Instituto y que a la fecha de entrada en vigor del presente Decreto aún tengan pendiente cumplir con dicha obligación.

Las personas que dentro de los diez días previos a la entrada en vigor del presente Decreto se hayan desempeñado como personas servidoras públicas del Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, incluyendo a las personas Comisionadas, deben presentar acta administrativa de entrega-recepción institucional e individual, según corresponda, a la persona servidora pública que la Secretaría Anticorrupción y Buen Gobierno designe y conforme a la normativa aplicable a la Administración Pública Federal, en los sistemas de la referida dependencia habilitados para tales efectos o en los medios que ésta determine, en el entendido que la entrega que se realice no implica liberación alguna de responsabilidades que pudieran llegarse a determinar por la autoridad competente con posterioridad.

Sexto.- Los recursos materiales con que cuente el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales serán transferidos a la Secretaría Anticorrupción y Buen Gobierno, dentro de los veinte días hábiles siguientes a la entrada en vigor del presente Decreto.

Séptimo.- El Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales transferirá los recursos financieros a la Secretaría de Hacienda y Crédito Público, de conformidad con las disposiciones jurídicas aplicables.

Asimismo, el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales deberá entregar a la citada dependencia la información y formatos necesarios para integrar la Cuenta Pública y demás informes correspondientes al primer trimestre, de conformidad con las disposiciones jurídicas aplicables, dentro de los diez días hábiles siguientes a la entrada en vigor del presente Decreto.

Octavo.- Los registros, padrones y sistemas, internos y externos, que integran la Plataforma Nacional de Transparencia con los que cuenta el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, así como los sistemas informáticos utilizados por dicho Instituto, incluso los que ya no se utilicen pero contengan registros históricos, incluida su documentación y titularidad, serán transferidos a la Secretaría Anticorrupción y Buen Gobierno dentro de los quince días hábiles siguientes a la entrada en vigor del presente Decreto.

Noveno.- Los procedimientos iniciados con anterioridad a la entrada en vigor de este Decreto ante el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, en materia de acceso a la información pública, se sustanciarán ante Transparencia para el Pueblo conforme a las disposiciones aplicables vigentes al momento de su inicio.

La defensa legal ante autoridades administrativas, jurisdiccionales y judiciales de los actos administrativos y jurídicos emitidos por el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, en materia de acceso a la información pública, se llevará a cabo por Transparencia para el Pueblo.

Transparencia para el Pueblo podrá remitir a la Autoridad garante competente aquellos asuntos que se mencionan en los párrafos anteriores que le corresponda conforme al ámbito de sus atribuciones para su atención.

Décimo.- Los procedimientos iniciados con anterioridad a la entrada en vigor de este Decreto ante el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, en materia de datos personales o cualquier otra distinta a la mencionada en el transitorio anterior, se

sustanciarán conforme a las disposiciones vigentes al momento de su inicio ante la Secretaría Anticorrupción y Buen Gobierno a que se refiere este Decreto.

La defensa legal ante autoridades administrativas, jurisdiccionales o judiciales de los actos administrativos y jurídicos emitidos por el Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales, en materia de datos personales o cualquier otra distinta a la mencionada en el transitorio anterior, así como el seguimiento de los que se encuentren en trámite, incluso los procedimientos penales y laborales, se llevará a cabo por la Secretaría Anticorrupción y Buen Gobierno.

La Secretaría Anticorrupción y Buen Gobierno podrá remitir a la Autoridad garante competente aquellos asuntos que se mencionan en los párrafos anteriores que le corresponda conforme al ámbito de sus atribuciones para su atención.

Décimo Primero.- Los municipios podrán cumplir con las obligaciones a su cargo en materia de transparencia y acceso a la información, en términos de lo previsto en el transitorio Décimo de la Ley General de Transparencia y Acceso a la Información Pública que se abroga por virtud de este Decreto.

Décimo Segundo.- La persona titular del Ejecutivo Federal deberá expedir las adecuaciones correspondientes a los reglamentos y demás disposiciones aplicables, incluida la emisión del Reglamento Interior de Transparencia para el Pueblo, dentro de los noventa días naturales siguientes a la entrada en vigor del presente Decreto, a fin de armonizarlos a lo previsto en el mismo.

Décimo Tercero.- Los expedientes y archivos que a la entrada en vigor del presente Decreto estén a cargo del Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales para el ejercicio de sus facultades sustantivas, competencias o funciones, de conformidad con la Ley General de Archivos y demás disposiciones jurídicas aplicables, serán transferidos a la Secretaría Anticorrupción y Buen Gobierno dentro de los veinte días hábiles siguientes a la entrada en vigor del presente Decreto.

La Secretaría Anticorrupción y Buen Gobierno, dentro de los treinta días naturales siguientes contados a partir de que se reciban los expedientes y archivos que se mencionan en el párrafo anterior, podrá transferirlos a la autoridad correspondiente.

Décimo Cuarto.- El Órgano Interno de Control del Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales queda extinto y sus asuntos y procedimientos que a la entrada en vigor del presente Decreto estén a su cargo, así como los expedientes y archivos, serán transferidos al Órgano Interno de Control de la Secretaría Anticorrupción y Buen Gobierno dentro de los veinte días hábiles siguientes a su entrada en vigor, y serán tramitados y resueltos por dicho órgano conforme a las disposiciones jurídicas vigentes al momento de su inicio.

Décimo Quinto.- Para efectos de lo dispuesto en los transitorios Quinto, Sexto, Séptimo, Octavo y Décimo Tercero del presente Decreto el Pleno del Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales deberá integrar, en la fecha de publicación de este instrumento, un Comité de Transferencia conformado por los Comisionados del mencionado Instituto y once personas servidoras públicas del mismo con al menos el nivel de Dirección de área o equivalente, que tengan conocimiento o que se encuentren a su cargo los asuntos que se mencionan en los propios transitorios.

El Comité de Transferencia estará vigente por un periodo de 30 días naturales, en el que sus integrantes participarán con las diversas autoridades competentes para recibir los asuntos que se señalan en los transitorios antes citados y realizar las demás acciones que se consideren necesarias para dichos efectos.

Décimo Sexto.- El Consejo del Sistema Nacional de Acceso a la Información Pública deberá instalarse a más tardar en sesenta días naturales, a partir de la entrada en vigor del presente Decreto, previa convocatoria que al efecto emita la Secretaría Anticorrupción y Buen Gobierno.

Hasta en tanto las legislaturas de las entidades federativas que correspondan armonizan su marco jurídico en materia de acceso a la información pública en términos de lo previsto en el transitorio Cuarto del Decreto por el que se reforman, adicionan y derogan diversas disposiciones de la Constitución Política de los Estados Unidos Mexicanos, en materia de simplificación orgánica, publicado en el Diario Oficial de la Federación el 20 de diciembre de 2024, la persona titular del poder ejecutivo local de que se trate será integrante del Consejo del Sistema Nacional de Acceso a la Información Pública.

Décimo Séptimo.- La persona titular de la Secretaría Ejecutiva del Consejo del Sistema Nacional de Acceso a la Información Pública propondrá las reglas de operación y funcionamiento que se señalan en el artículo 25, fracción XV, de la Ley General de Transparencia y Acceso a la Información Pública, para que sean aprobadas en la instalación de dicho Consejo.

Décimo Octavo.- El órgano de control y disciplina del Poder Judicial; los órganos internos de control de los órganos constitucionales autónomos; las contralorías internas del Congreso de la Unión; el Instituto Nacional Electoral; el Centro Federal de Conciliación y Registro Laboral y el Tribunal Federal de Conciliación y Arbitraje en un plazo máximo de treinta días naturales contados a partir de la entrada en vigor del presente Decreto deberán realizar las adecuaciones necesarias a su normativa interna para dar cumplimiento a lo dispuesto en este instrumento.

Para efectos de lo previsto en este transitorio, se suspenden por un plazo de noventa días naturales contados a partir de la entrada en vigor de este Decreto todos y cada uno de los trámites, procedimientos y demás medios de impugnación, establecidos en este instrumento y demás normativa aplicable, con excepción de la recepción y atención de las solicitudes de información que se tramitan a través de la Plataforma Nacional de Transparencia por las autoridades que se mencionan en el párrafo anterior.

Décimo Noveno.- Hasta en tanto las legislaturas de las entidades federativas, emitan legislación para armonizar su marco jurídico conforme al presente Decreto, los organismos garantes de las mismas continuarán operando y realizarán las atribuciones que le son conferidas a las Autoridades garantes locales, así como a los órganos encargados de la contraloría interna u homólogos de los poderes legislativo y judicial, así como los órganos constitucionales autónomos de las propias entidades federativas en la presente Ley.

Vigésimo.- El Poder Judicial de la Federación deberá habilitar juzgados de Distrito y tribunales Colegiados de Circuito especializados en materia de acceso a la información pública y protección de datos personales, en un plazo no mayor a ciento veinte días naturales contados a partir de la entrada en vigor del presente Decreto, a los cuales se remitirán los juicios de amparo en dichas materias que se encuentran en trámite para su resolución.

Para efectos de lo previsto en este transitorio, se suspenden por un plazo de ciento ochenta días naturales contados a partir de la entrada en vigor de este Decreto los plazos y términos procesales de los juicios de amparo en materia de acceso a la información pública y protección de datos personales que se encuentran en trámite ante juzgados de Distrito y tribunales Colegiados de Circuito.

Ciudad de México, a 20 de marzo de 2025.- Sen. Imelda Castro Castro, Vicepresidenta.- Dip. Sergio Carlos Gutiérrez Luna, Presidente.- Sen. Verónica Noemí Camino Farjat, Secretaria.- Dip. José Luis Montalvo Luna, Secretario.- Rúbricas.**"**

En cumplimiento de lo dispuesto por la fracción I del Artículo 89 de la Constitución Política de los Estados Unidos Mexicanos, y para su debida publicación y observancia, expido el presente Decreto en la Residencia del Poder Ejecutivo Federal, en la Ciudad de México, a 20 de marzo de 2025.- **Claudia Sheinbaum Pardo**, Presidenta de los Estados Unidos Mexicanos.- Rúbrica.- Lcda. **Rosa Icela Rodríguez Velázquez**, Secretaria de Gobernación.- Rúbrica.

ARTÍCULOS TRANSITORIOS DE DECRETOS DE REFORMA

DECRETO por el que se reforman diversas disposiciones de diversos ordenamientos legales, en materia de homologación normativa relativa al Código Nacional de Procedimientos Civiles y Familiares.

Publicado en el Diario Oficial de la Federación el 14 de noviembre de 2025

Artículo Trigésimo Octavo.- Se reforma el artículo 4 de la Ley Federal de Protección de Datos Personales en Posesión de los Particulares, para quedar como sigue:

……..

Transitorios

Primero. El presente Decreto entrará en vigor el día siguiente al de su publicación en el Diario Oficial de la Federación.

Segundo. La aplicación de lo dispuesto en el presente Decreto entrará en vigor en cada una de las entidades federativas al mismo tiempo que la Declaratoria de aplicación gradual que expidan los Congresos Locales para efecto de la entrada en vigor del Código Nacional de Procedimientos Civiles y Familiares, de conformidad con el Artículo Segundo Transitorio del Decreto publicado en el Diario Oficial de la Federación el 7 de junio de 2023.

En el orden federal, la aplicación de lo dispuesto en el presente Decreto entrará en vigor de conformidad con la Declaratoria de aplicación gradual que, indistinta y sucesivamente, realicen para el Código Nacional de Procedimientos Civiles y Familiares las Cámaras de Diputados y Senadores que integran el Congreso de la Unión.

En todos los casos, vencido el plazo sin que se hubiera emitido la Declaratoria respectiva, la entrada en vigor de lo previsto en el presente Decreto será automática a partir del 1o. de abril de 2027.

Tercero. Los procedimientos que se encuentren en trámite a la entrada en vigor del presente Decreto conforme con lo dispuesto en el artículo anterior, continuarán su sustanciación con la legislación aplicable al momento del inicio de los mismos, salvo que las partes conjuntamente opten por la regulación del contenido del Código Nacional de Procedimientos Civiles y Familiares.

No procederá la acumulación de procesos cuando alguno de ellos se tramite conforme con el Código Nacional de Procedimientos Civiles y Familiares y el otro proceso conforme a un Código abrogado.

Cuarto. El Artículo Cuadragésimo Primero, del presente Decreto, tendrá vigencia hasta en tanto no se abrogue la Ley Federal de Telecomunicaciones y Radiodifusión, de conformidad con lo previsto en el artículo Sexto Transitorio del Decreto por el que se expide la Ley en Materia de Telecomunicaciones y Radiodifusión y se abroga la Ley Federal de Telecomunicaciones y Radiodifusión, publicado en el Diario Oficial de la Federación el 16 de julio de 2025.

Ciudad de México, a 01 de octubre de 2025.- Sen. Laura Itzel Castillo Juárez, Presidenta.- Dip. Kenia López Rabadán, Presidenta.- Sen. María Martina Kantún Can, Secretaria.- Dip. Julieta Villalpando Riquelme, Secretaria.- Rúbricas.**"**

En cumplimiento de lo dispuesto por la fracción I del Artículo 89 de la Constitución Política de los Estados Unidos Mexicanos, y para su debida publicación y observancia, expido el presente Decreto en la

Residencia del Poder Ejecutivo Federal, en la Ciudad de México, a 13 de noviembre de 2025.- **Claudia Sheinbaum Pardo**, Presidenta de los Estados Unidos Mexicanos.- Rúbrica.- Lcda. **Rosa Icela Rodríguez Velázquez**, Secretaria de Gobernación.- Rúbrica.

REPUBLICA DE PANAMA
MINISTERIO DE SALUD

DECRETO EJECUTIVO N° 2
(De 21 de Enero de 2013)

Que establece las guías para la utilización de las células madre en la República de Panamá.

EL PRESIDENTE DE LA REPUBLICA
En uso de sus facultades constitucionales y legales, y

CONSIDERANDO:

Que la temática sobre la extracción, trasplantes y almacenamiento de células madre actualmente son procesos regulados por normas que dependen directamente de los países en los que están ubicados los laboratorios ligados a los trasplantes;

Que el Titulo V, Capítulo III de la Ley 3 de 8 de febrero de 2010, "General de Trasplante de Componentes Anatómicos", regula lo relativo a los Centros de Extracción y Trasplantes de Componentes Anatómicos de Donante Vivo;

Que resulta necesario que se establezcan buenas prácticas a través de guías para la legalización de células madre con el propósito que las empresas, entidades, instituciones y/o cualesquiera profesional de la salud que se dedique a la actividad, cumplan con los propósitos establecidos por las instituciones legales que rigen la materia, en el ámbito nacional, en concordancia con los altos estándares internacionales;

Que conforme el numeral 14 del artículo 184 de la Constitución Política de la República, corresponde al Presidente de la República con la participación del ministro respectivo, reglamentar las leyes que lo requieran para su mejor cumplimento, en consecuencia;

DECRETA:

ARTÍCULO 1. Establecer las guías para la utilización de las células madre en la República de Panamá, con el objeto de regular y garantizar el apropiado funcionamiento de los Centros de Extracción y/o Trasplantes de Componentes Anatómicos.

ARTÍCULO 2. Ámbito de Aplicación. Cualquier persona natural o jurídica sea de derecho público o privada relacionada a la actividad de células madre que se encuentren operando legalmente en el país con la debida autorización y poseedora de una de licencia sanitaria de funcionamiento expedida por el Ministerio de Salud antes de la publicación de estas guías, está exenta de estas regulaciones siempre y cuando opere basándose en técnicas o evidencias científicamente comprobadas con estudios clínicos avaladores. En caso contrario, se le otorgará un término de ciento veinte (120) días calendario para regular su situación y cumplir cabalmente con todos y cada uno de los requisitos exigidos.

Cumplido el término anterior y, si el Ministerio de Salud no le ha otorgado, por razones imputables a la compañía o institución, la licencia correspondiente, la empresa o institución no podrá continuar desarrollando esta actividad o cualquiera otra que le sea conexa.

ARTÍCULO 3. Para los efectos del presente Decreto Ejecutivo, los siguientes términos se entenderán así:

1. Almacenamiento: Mantenimiento de las células o tejidos bajo condiciones controladas y apropiadas hasta su distribución.

2. Aplicación: Cualquier actividad que implique el uso de células o tejidos en un receptor humano y/o en aplicaciones extra-corporales (comprenden las actividades de implantar, infundir, injertar, aplicar o trasplantar).
3. Células: - Cada uno de los elementos microscópicos constituidos por protoplasmas y dotados de vida propia que según la teoría celular son las unidades morfológicas fisiológicas que componen el cuerpo de todo ser vivo.
4. Célula madre: Es un tipo de célula que posee la capacidad de replicarse y de dar lugar a diversos tipos de células especializadas y a células idénticas.
5. Células madre alogénicas: Aquellas que se toman del cuerpo de un diferente paciente.
6. Células madre autólogas: Aquellas que se toman del cuerpo del propio paciente.
7. Células madre embrionarias: Son aquellas obtenidas de pre-embriones sobrantes de las técnicas de fecundación 'in vitro' y en fase de blastocito.
8. Células madre pluripotentes inducidas: Son un tipo de células madre con características pluripotenciales (capaces de generar la mayoría de los tejidos) derivadas artificialmente de una célula madre que inicialmente no era pluripotencial.
9. Células somáticas: Son aquellas células que forman el conjunto de tejidos y órganos de un ser vivo, procedentes de células madre originadas durante el desarrollo embrionario y que sufren un proceso de proliferación celular, diferenciación celular y apoptosis.
10. Diferenciación: Es el proceso por el que las células cambian de forma y de función cuando se desarrollan y adoptan un papel especializado.
11. Efecto adverso grave: Cualquier hecho desfavorable vinculado a la obtención, evaluación, procesamiento, almacenamiento y distribución de células y tejido que pueda conducir a la transmisión de una enfermedad, a la muerte del paciente, o a estados que hagan peligrar su vida, a minusvalías o incapacidades o que puedan dar lugar a hospitalización o enfermedad o que la pueda prolongar.
12. Investigación clínica: Investigación desarrollada mediante protocolos que incluyen los procedimientos de obtención y aplicación de células y tejidos humanos en humanos, cuando la eficacia o seguridad de los procedimientos o de las células o tejidos no están suficientemente comprobadas o cuando la indicación terapéutica no está suficientemente consolidada, y cuya finalidad es la comprobación de alguno de estos puntos.
13. Líneas celulares: Conjunto de células derivadas de una única célula madre o progenitora que permanecen estables y sin alteraciones fisiológicas durante un periodo de tiempo prolongado.
14. Modificación Genética: Tipo de modificación que no se da por multiplicación ni recombinación natural, sino por la introducción de un gen modificado o de un gen de otra variedad o especie.
15. Óvulo: Célula sexual femenina que se forma en el proceso de ovogénesis. Es una célula haploide de veintitrés (23) cromosomas, al igual que el espermatozoide; ambas células al fusionarse originan una célula diploide de cuarenta y seis (46) cromosomas.
16. Procesamiento: Operación u operaciones que implican la preparación, manipulación, preservación y acondicionamiento de los tejidos y las células destinados a su aplicación en el ser humano.
17. Reacción adversa grave: Respuesta inesperada del donante o del receptor, incluida una enfermedad transmisible, asociada a la obtención o aplicación en el ser humano de tejidos y células, que resulte mortal, potencialmente mortal, incapacitante, que produzca invalidez o incapacidad, o que dé lugar a hospitalización o enfermedad.
18. Sistema de calidad: Comprende la estructura orgánica, la definición de responsabilidades, los procedimientos, procesos y recursos, que se destinan a

desarrollar la gestión de la calidad. Incluye cualquier actividad que contribuya a la calidad total de forma directa o indirecta.

19. Sistema de gestión de calidad: Actividades coordinadas destinadas a la dirección y control de una organización en relación con la calidad.
20. Trasplante: Utilización terapéutica de los componentes anatómicos de un donante a un receptor.
21. Tejido: Toda parte constituyente del cuerpo humano formada por células unidas por algún tipo de tejido conectivo.
22. Uso alogénico: Proceso mediante el cual las células o tejidos son extraídos de una persona y aplicados a otra.
23. Uso autólogo: Proceso mediante el cual las células o los tejidos son extraídos y aplicados a la misma persona.
24. Validación: Evidencia documental que prueba, con un elevado nivel de garantía, que un determinado proceso, equipo o parte de un equipo o condición ambiental acaba produciendo, de forma consistente y reproducible, un determinado producto que cumple las especificaciones, cualidades y atributos que se habían predeterminado. Un proceso es validado con vistas a probar su efectividad para un uso determinado.

ARTÍCULO 4. Requisitos para establecer una empresa de células madres en Panamá. Toda compañía, empresa o institución que desee establecerse y operar en Panamá, para realizar actividades de cualquiera índole o naturaleza relacionadas con las células madre, deberá cumplir con los siguientes requisitos, los cuales serán evaluados y aprobados por la Dirección General de Salud Pública del Ministerio de Salud.

1. Estar debidamente registrada, en caso de persona jurídica, en Panamá con o sin fines de lucro.

2. Tener presencia física en Panamá habiendo establecido sistemas de calidad para Buenas Prácticas con Tejidos y poseer la documentación apropiada y válida al momento de realizarse la inspección y contar con un personal calificado mediante educación y entrenamiento formal en una Institución académica o de investigación reconocida por el Ministerio de Salud.

3. Por lo menos un miembro de la Junta Directiva de la empresa o institución debe ser panameño o tener residencia permanente.

4. La empresa o institución debe invertir un mínimo de dos millones de balboas (B/.2.000.000.00) en Panamá. Esta inversión puede darse mediante una combinación de compras de bienes raíces, equipo de laboratorio, materiales, insumos, o gastos en construcción de proyectos y otros gastos pertinentes al negocio.

5. Todos los tejidos y células, ya sean de la República de Panamá o de otro país deben ser evaluados en un Laboratorio de Células Madre aprobado por Panamá antes de su administración en humanos en Panamá y deben cumplir con los requisitos especificados en el artículo 18 de la Ley 3 de 8 de febrero de 2010.

6. Cualquier tratamiento a base de células usado en la República de Panamá, ya sea con células autólogas o alogénicas, que utilice células o tejidos originados fuera de la República de Panamá, primero debe ser sometido a las pruebas requeridas por el Ministerio de Salud. Sólo los tratamientos que reúnan los requisitos, análisis y las pruebas requeridas podrán ser utilizados clínicamente en Panamá.

7. Las solicitudes y/o tratamientos que no cumplan con las pruebas exigidas serán devueltas a su fuente de origen.

ARTÍCULO 5. Licencias para un Laboratorio de Células Madre y su personal. Los siguientes requisitos serán exigidos para el otorgamiento de licencias para Laboratorios de Células Madre:

1. Licencia sanitaria de funcionamiento del laboratorio: El Laboratorio de Células Madre debe estar registrado y autorizado luego de haber sido inspeccionado y aprobado por el Ministerio de Salud de Panamá de acuerdo con los requisitos especificados en el artículo 63 de la Ley 3 de 8 de febrero de 2010, y es un requisito el cumplimiento con las normas de GMP, GLP y GTP establecidas por Organización Mundial de la Salud, US FDA, o estándares de Estados Unidos o de la Unión Europea. El laboratorio debe tener un ambiente limpio, y cumplir con los estándares internacionales de acuerdo con el tipo de procedimiento realizado, es decir, cada sección del laboratorio debe cumplir con los niveles de control ambiental apropiados.

2. Todos los laboratorios de células madre tanto públicos como privados deben contar con al menos una acreditación o certificación mundialmente reconocida (AABB, FACT o ISO 9000).

3. Personal técnico del laboratorio: Un laboratorio de células madre debe contar con personal con al menos uno de los siguientes títulos: técnico, licenciado en biología o carreras afines, doctor en medicina, PhD, maestría o un título de postgrado pertinente a la actividad a realizar.

4. El personal debe estar debidamente autorizado por el Ministerio de Salud y debe presentar la documentación de autorización expedida por este Ministerio, basado en las leyes y otras normas existentes que rigen este tema.

5. Director de Laboratorio: Un laboratorio de células madre debe tener como director a un tecnólogo médico idóneo con entrenamiento formal en técnicas de manejo de células madre en laboratorio, con mínimo un año de experiencia en cultivo celular y/o mínimo un año de entrenamiento en cultivo de células madre.
6. Director Médico: debe ser un médico idóneo con especialidad en Medicina (Pediatría, Medicina Interna, Cardiología, Endocrinología), el cual será responsable de todos los aspectos médicos del laboratorio.
7. Director de Investigación: Debe ser un profesional debidamente calificado mediante educación y experiencia, y tener un entrenamiento científico formal, una carrera de doctor en medicina y/o un PhD y haber publicado en los últimos cinco años un artículo cuyo tema se encuentre dentro del campo de investigación de células madre en una revista científica internacional reconocida e indexada por expertos.
8. Investigadores: Los investigadores deben tener entrenamiento científico formal, un título de doctor en medicina, un PhD o estudios de postgrado.
9. Médicos: Los doctores en medicina que laboren en el campo de cédulas madres en Panamá que no tengan experiencia previa en este campo serán supervisados por el Director Médico responsable del Laboratorio de Células Madres.

En caso de tratarse de médicos extranjeros se requiere la autorización y aprobación por parte del el Ministerio de Salud.

ARTÍCULO 6. Parámetros para selección de donantes.

1. Historial clínico, examen físico, revisión de expediente médico.
2. Factores de riesgo o evidencia clínica de enfermedades y agentes transmisibles de relevancia.
3. Historial personal o familiar de enfermedades genéticas, cánceres u otras enfermedades pertinentes.
4. Pruebas de enfermedades infecciosas.
5. Firma de consentimiento informado antes de la donación o la terapia celular para asegurar que el paciente esté anuente de los riesgos y de la naturaleza experimental del tratamiento.

ARTÍCULO 7. Disposiciones de Bioseguridad. Todos los productos médicos que contengan células humanas viables, independientemente de su fuente biológica o geográfica, se le deben aplicar y exigir los estándares de manejo de riesgos y de procesamiento de las Buenas Prácticas con Tejidos establecidos por ISO 13022: 2012: Productos médicos conteniendo células humanas viables, (Medical products containing viable human cells) y además deben tener registros completos de control de calidad, incluyendo:

1. Pruebas obligatorias para determinar la presencia de enfermedades infecciosas, incluyendo:

    a. HBsAg (Antígeno de superficie de Hepatitis B)
    b. Anticuerpo para HIV1 y 2
    c. Anti-HCV (anticuerpo del virus de la Hepatitis C)
    d. VDRL o prueba equivalente para sífilis
    e. Anticuerpo para CMV-IgM
    f. Anticuerpo para Toxoplasma gondii IgM
    g. HTLV-1 y 2
    h. Chagas
    i. Pruebas de esterilidad
    j. Pruebas de endotoxinas
    k. Pruebas de viabilidad celular
    l. Prueba para microplasma
    m. Historia de derivación
    n. Identidad celular

2. Todos los reactivos utilizados en la producción de células y sus productos deben tener los siguientes registros completos de control de calidad expedidos por el Ministerio de Salud:
    a. Toxicidad
    b. Pruebas de esterilidad
    c. Pruebas de endotoxinas
    d. Inmunoreactividad
3. Las Células Madre Autólogas, la Fracción Vascular Estromal y productos basados en células derivados de una persona no serán considerados como un fármaco si son utilizados en la misma persona y su uso será permitido. Las células cultivadas y las células primarias, así como sus productos, están incluidas en esta categoría.

    a. Las células madre autólogas pueden ser aisladas de tejido adiposo, médula ósea, sangre periférica, dientes, sangre y/o tejido de cordón umbilical, placenta, amnios, líquido amniótico, piel y otros tejidos del paciente o persona.

    b. Los productos basados en células autólogas incluyen fuentes biológicas autólogas como plasma rico en plaquetas, lisado de plaquetas y extractos de citoquinas derivados de las células de la misma persona o de un cultivo de las mismas.

    c. El uso de estas células y sus productos podría requerir de datos de seguridad preclínicos para conducir ensayos clínicos en caso que así se considere por el Comité Nacional de Ética de la Investigación. Cada nueva ruta de administración y cada nueva enfermedad tratada requieren datos preclínicos y un ensayo clínico aprobado por el Comité Nacional de Ética de la Investigación antes de su comercialización.

4. Células madre alogénicas y productos basados en estas células: Las células derivadas del cuerpo de otra persona serán reguladas en una categoría más alta de riesgo.

    a. Debe existir validación sobre una adecuada documentación sobre su adquisición, procesamiento, pruebas realizadas, caracterización, sistemas de gestión de calidad y de seguridad para el tipo de células o producto a base de células.

b. Debe existir prueba de que no producen una respuesta inmune. La inmunosupresión puede ser utilizada en casos de enfermedades serias que amenacen la vida, pero no para uso electivo, como aplicaciones cosmiátricas o en lesiones ortopédicas.

c. La caracterización de las células o del producto a base de células debe ser documentada, incluyendo datos de citometría de flujo de al menos un marcador de superficie del tipo de célula (es decir CD90, CD105, CD73 para células de mesénquima; CD34 para células hematopoyéticas).

d. Los extractos de células alogénicas deben ser procesados de manera que los alérgenos sean removidos, por medio de filtración, separación celular, centrifugación o una combinación de estas técnicas. Debe haber prueba y validez de que el producto es seguro y no contiene alérgenos. Estos productos no autólogos pueden ser usados en el tratamiento de enfermedades o en uso electivo, como en cosmiatría.

ARTÍCULO 8. Recolección y almacenamiento de cordón umbilical. Los siguientes puntos deben ser cumplidos al recolectar y almacenar sangre de cordón umbilical:

1. No provocar daños al donante.

2. El momento exacto de la recolección debe ser definido.

3. Los padres deben ser correctamente informados acerca de los posibles riesgos y beneficios.

4. Se debe obtener un consentimiento escrito firmado por la madre.

5. Se deben seguir los Procedimientos Operativos Reconocidos por el Ministerio de Salud para la recolección, transporte, procesamiento, almacenamiento y envío para el uso clínico de las células madre de cordón umbilical.

ARTÍCULO 9. Administración de células madre. La administración de células en seres humanos está limitada a las provenientes de seres humanos.

ARTÍCULO 10. Células madre embrionarias. Un embrión no puede ser creado sólo para el propósito de obtener células madre. Las células embrionarias no pueden ser utilizadas si para su uso se requiere la destrucción del embrión.

Las células derivadas de óvulos humanos clonados, como la transferencia de núcleos celulares de células somáticas, no podrán ser utilizadas en humanos.

ARTÍCULO 11. Células madre fetales. La terapia con células madre fetales no será permitida. La terminación de un embarazo no puede hacerse para obtener células madre fetales ni para obtener beneficio financiero o terapéutico.

ARTÍCULO 12. Células con modificaciones genéticas. La administración de células madre derivadas de células somáticas con alguna modificación genética, incluyendo células madre pluripotenciales inducidas o cualquiera célula con posibilidad de pluripotencialidad está en etapa experimental, por lo cual debe realizarse sólo cuando:

1. Haya extensa evidencia de modelos pre-clínicos de seguridad y eficacia.

2. La investigación se lleve a cabo como parte de un ensayo clínico bien diseñado y aprobado por el Comité Nacional de Ética de la Investigación.

3. Se han realizado las siguientes pruebas adicionales:

a. Cariotipo

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MINISTERIO DE LA PRESIDENCIA

b. Prueba de estabilidad cromosómica.

ARTÍCULO 13. Las líneas celulares permanentes y productos basados en células. El uso en humanos de productos derivados de líneas celulares permanentes producidas en cultivos que no han demostrado formación de tumor o anormalidades citogenéticas será permitido después de transcurrido al menos un año de cultivo celular y de realización de cariotipo. Las líneas celulares para comercialización deben estar registradas y aprobadas por el Comité Nacional de Ética de la Investigación.

ARTÍCULO 14. Manipulación celular. La manipulación de células madre es permitida si las siguientes normas son cumplidas:

1. Cultivo: El cultivo de células madre puede ser realizado con ingredientes basados en animales o aditivos, siempre y cuando estos ingredientes provengan de un país libre de casos de encefalopatía espongiforme bovina o de un lote certificado por la FDA.

2. Diferenciación: La diferenciación de células madre está permitida siempre y cuando se haya probado que el producto celular diferenciado no ha demostrado anormalidades citogenéticas, anormalidades en su ADN, expresión de oncogenes u otras anormalidades.

3. Modificación genética: La modificación genética de células madre debe obedecer las normas legales relacionadas a células madre y las normas de terapia genética vigentes en la República de Panamá.

4. Ingredientes añadidos: La adición de ingredientes como un antibiótico, un factor de crecimiento, una hormona o una droga a un producto de células madre debe tener como base una evidencia científica de su utilidad, o debe realizarse como parte de un ensayo clínico.

5. Manipulación física: Las manipulaciones físicas deben ser realizadas en el laboratorio para probar la viabilidad de las células con pruebas que demuestren más de setenta y cinco por ciento (75%) de viabilidad celular.

6. Etiquetado: Cada producto de células madre debe estar debidamente etiquetado y tener una adecuada ficha de datos de control de calidad. La etiqueta del producto debe incluir la pureza y características de las células, el volumen e ingredientes de la suspensión o solución que contiene, el número total de células, y la viabilidad de las células, además de los requisitos citados en las normas de ISO 13022: 2012.

7. Administración: la administración intravenosa de células madre autólogas y productos de células madre autólogas es permitida. La administración intravenosa de células madre alogénicas será permitida sólo bajo supervisión directa por un médico o enfermera(o).

Cualquier inyección directa invasiva de células madre o un producto de células madre debe ser efectuada por un médico especialista en el área. El paciente debe quedarse en observación bajo cuidado médico al menos una noche en el Centro de Atención Médica después de los procedimientos en donde haya riesgo tardío de sangrado, sepsis, o alguna otra complicación grave (por ejemplo taponamiento cardíaco). Lo anterior según criterio médico.

ARTÍCULO 15. Almacenamiento de células y tejidos. En caso de cese de actividad del Laboratorio de Células Madres, las células y tejidos preservados o almacenados deberán ser transferidos a otro establecimiento de tejidos debidamente autorizado por la República de Panamá. Esta transferencia debe ser garantizada mediante acuerdos previamente establecidos con otros establecimientos los cuales deben estar autorizados por el Ministerio de Salud.

ARTÍCULO 16. Comité de Ética de Células Madre. El Comité Nacional de Ética de la Investigación revisará los estudios con células madre y puede solicitar la asesoría de expertos en el campo de terapias con células madre calificados por entrenamiento y experiencia demostrada.

ARTÍCULO 17. Requerimientos y Normas para los Ensayos Clínicos. Todas las terapias con células madre deben proveer una apropiada evidencia de investigación clínica, incluyendo las científicas y su publicación en revistas científicas internacional e indexadas.

1. Los ensayos clínicos con células madre pueden ser iniciados por un investigador, una compañía, o una institución (por ejemplo un hospital, un gobierno o una universidad). El diseño del estudio, el tamaño de la muestra, la duración y otros aspectos del ensayo clínico deben ser aprobados por el Comité Nacional de Ética de la Investigación.
2. Para minimizar los riesgos se requieren estudios clínicos de seguridad.
3. Para uso homólogo o autólogo en enfermedades en donde la aleatorización no es ética o es imposible, o para uso autólogo de células madre, el estudio de seguridad puede ser eliminado con la aprobación del Comité Nacional de Ética de la Investigación.
4. Todos los ensayos clínicos deben también ser registrados en la página web del US NIH (clinicaltrials.gov) para facilitar la exposición mundial de las actividades de investigación en Panamá, y para calificar para futuras presentaciones de artículos en revistas científicas de renombre internacional.

ARTÍCULO 18. Soporte económico para investigación en el campo de células madre. El Estado panameño puede proveer apoyo financiero para la investigación en el campo de células madre.

ARTÍCULO 19. El presente Decreto Ejecutivo entrará a regir a partir de su promulgación.

COMUNÍQUESE Y CÚMPLASE,

Dado en la ciudad de Panamá a los 21 días del mes de Enero de dos mil trece (2013).

RICARDO MARTINELLI B.
Presidente de la República

JAVIER DÍAZ
Ministro de Salud

PRESIDENCIA DE LA REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

GACETA OFICIAL DIGITAL

GOBIERNO NACIONAL
REPÚBLICA DE PANAMÁ

Año CVI **Panamá, R. de Panamá miércoles 10 de febrero de 2010** **Nº 26468-B**

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LA ASAMBLEA NACIONAL

DECRETA:

Artículo 1. El artículo 25 de la Ley 67 de 2009 queda así:

Artículo 25. Esta Ley entrará en vigencia el 12 de julio de 2010, con excepción de los artículos 17 y 18, que entrarán a regir en la fecha en que entre en vigencia el Código Procesal Penal.

Artículo 2. Esta Ley es de orden público y tendrá efectos retroactivos hasta el 11 de enero de 2010.

Artículo 3. La presente Ley modifica el artículo 25 de la Ley 67 de 30 de octubre de 2009.

Artículo 4. Esta Ley comenzará a regir el día siguiente al de su promulgación.

COMUNÍQUESE Y CÚMPLASE.

Proyecto 98 de 2010 aprobado en tercer debate en el Palacio Justo Arosemena, ciudad de Panamá, a los 26 días del mes de enero del año dos mil diez.

El Presidente,

José Luis Varela R.

El Secretario General,

Wigberto E. Quintero G.

ÓRGANO EJECUTIVO NACIONAL. PRESIDENCIA DE LA REPÚBLICA.
PANAMÁ, REPÚBLICA DE PANAMÁ, 5 DE febrero DE 2010.

RICARDO MARTINELLI BERROCAL
Presidente de la República

JOSÉ RAÚL MULINO
Ministro de Gobierno y Justicia

LEY 3
De 8 de febrero de 2010

General de trasplantes de componentes anatómicos

LA ASAMBLEA NACIONAL
DECRETA:

Título I
Materia y Alcance de la Ley

Capítulo I
Objeto, Ámbito de Aplicación y Definiciones

Artículo 1. El objeto de la presente Ley es ofrecer a toda persona que padezca una enfermedad que pueda ser mejorada o resuelta a través de un trasplante de componente anatómico la oportunidad de recibirlo, lo que permitirá mejorar su calidad de vida.

Artículo 2. Esta Ley tiene aplicación en todo el territorio de la República y regula todo lo relacionado con las actividades que incluyen donación, extracción, evaluación, procesamiento, preservación, almacenamiento, distribución y terapéutica de los componentes anatómicos.

Artículo 3. Para los efectos de la presente Ley, los siguientes términos se entenderán así:

1. *Almacenamiento.* Mantenimiento de los componentes anatómicos bajo condiciones controladas y apropiadas hasta su distribución.
2. *Banco de componente anatómico.* Entidad que se dedica a recibir, preservar, almacenar y disponer de componentes anatómicos que provengan de donantes.
3. *Célula.* Cada uno de los elementos microscópicos constituidos por protoplasmas y dotados de vida propia que según la teoría celular son las unidades morfológicas y fisiológicas que componen el cuerpo de todo ser vivo.
4. *Centro de extracción de componentes anatómicos de donante fallecido.* Centro hospitalario que, cumpliendo los requisitos especificados en la presente Ley, posee la autorización correspondiente para el desarrollo de la actividad de extracción de componente anatómico en donantes fallecidos.
5. *Centro de extracción de componentes anatómicos de donante vivo.* Centro hospitalario que, cumpliendo los requisitos especificados en esta Ley, posee la autorización correspondiente para el desarrollo de la actividad de extracción de componentes anatómicos en donantes vivos.
6. *Centro de trasplantes de componentes anatómicos.* Centro hospitalario que, cumpliendo los requisitos especificados en esta Ley, posee la autorización correspondiente para el desarrollo de la actividad de trasplantes de componente anatómico.
7. *Componentes anatómicos.* Órganos, tejidos, células y, en general, todas las partes que

constituyen un organismo.

8. *Donación.* Cesión gratuita y voluntaria de cualquier componente anatómico de origen humano para ser destinado a uso terapéutico en el cuerpo humano.

9. *Donación extraordinaria parcial.* Proceso mediante el cual los deudos de una persona fallecida ceden gratuita y voluntariamente una parte del cuerpo de esta para fines terapéuticos.

10. *Donación extraordinaria total.* Proceso mediante el cual los deudos de una persona fallecida ceden gratuita y voluntariamente la totalidad del cuerpo de esta para fines terapéuticos.

11. *Donación ordinaria parcial.* Dar en vida parte del cuerpo para ser utilizado con fines terapéuticos después de la muerte, de conformidad con la presente Ley.

12. *Donación ordinaria total.* Dar en vida la totalidad de su cuerpo para ser utilizado con fines terapéuticos después de la muerte, de conformidad con la presente Ley.

13. *Donante.* Persona que cede gratuita y voluntariamente componentes anatómicos para que sean utilizados de manera inmediata o diferida en otras personas con fines terapéuticos.

14. *Donante altruista.* Persona que en vida decide donar un componente anatómico a un receptor cuya identidad desconoce, haciéndolo de manera desinteresada y sin que medie compensación económica para que sea implantado de manera inmediata en un receptor en la Lista de Espera Nacional.

15. *Donante cruzado.* Donante que cuenta con un receptor relacionado no compatible y decide ceder un componente anatómico en donación para que, de manera recíproca, su receptor reciba un componente anatómico proveniente de un segundo donante no relacionado, pero compatible biológicamente en la misma situación. Este tipo de donación puede realizarse entre dos o más parejas.

16. *Donante fallecido.* Persona que, en vida, expresa su voluntad de que al morir se le extraigan componentes anatómicos de su cuerpo para donación, a fin de ser utilizados para trasplantes en otros seres humanos. También es donante fallecido quien, después de morir, sus deudos autorizan a que de su cuerpo se extraigan componentes anatómicos, con el propósito de ser utilizados para trasplantes en otras personas, con fines terapéuticos.

17. *Donante vivo no relacionado.* Cualquier otro donante vivo que no esté considerado en el numeral 18.

18. *Donante vivo relacionado.* Persona dentro del cuarto grado de consanguinidad o segundo de afinidad o en unión de hecho comprobada que, cumpliendo los requisitos establecidos en la ley, efectúe la donación en vida de componentes anatómicos cuya extracción sea compatible con la vida y cuya función pueda ser compensada por su organismo de forma adecuada y suficientemente segura.

19. *Extracción de componente anatómico.* Proceso por el cual se obtienen el componente o los componentes anatómicos de un donante para su posterior trasplante en uno o varios receptores.

20. *Fallecido.* Persona en la que se ha producido el cese irreversible de la función

encefálica, diagnosticada de conformidad con la presente Ley.

21. *Implantación diferida.* Trasplante realizado con componentes anatómicos, que previamente hayan sido destinados a un proceso de conservación por parte de un banco de componentes anatómicos.
22. *Implantación inmediata.* Trasplante de componentes anatómicos obtenidos de una persona viva o de un fallecido sin que previamente hayan sido destinados a conservación y utilización diferida por parte de un banco de componentes anatómicos.
23. *Muerte.* Cese irreversible de las funciones de todas las estructuras neurológicas intracraneales, tanto de los hemisferios centrales como del troncoencéfalo.
24. *Órgano.* Parte diferenciable del cuerpo humano constituida por diversos tejidos que mantiene su estructura, vascularización y capacidad para desarrollar funciones fisiológicas con un grado importante de autonomía y suficiencia.
25. *Paro cardiorrespiratorio.* Cese irreversible de la función cardiorrespiratoria tras el adecuado periodo de aplicación de maniobras de resucitación cardiopulmonar avanzada, constatada por la ausencia del pulso central por trazado electrocardiográfico y de ausencia respiratoria espontánea, ambos por un periodo de cinco minutos.
26. *Presunción legal de donación.* Se presume que un fallecido es donante si durante su vida no manifestó su oposición a serlo y si dentro de las seis horas después de realizado el diagnóstico de muerte encefálica o antes del inicio de la necropsia médico-legal sus deudos no expresan su oposición a la donación. En estos casos bastará con la prueba indiciaria de la condición de deudo. La presunción legal de donación no es aplicable a donante fallecido por parada cardiorrespiratoria.
27. *Receptor.* Persona que recibe el trasplante de un componente anatómico con fines terapéuticos.
28. *Tejido hematopoyético.* Tejido en que se forman las células sanguíneas nuevas. Sus fuentes pueden ser médula ósea, sangre periférica y sangre de cordón umbilical.
29. *Trasplante.* Utilización terapéutica de los componentes anatómicos de un donante a un receptor.
30. *Uso alogénico.* Proceso mediante el cual los tejidos hematopoyéticos o las células son extraídos de una persona y aplicados en otra.
31. *Uso autólogo.* Proceso mediante el cual se reemplazan componentes anatómicos en una persona por otros provenientes de su propio cuerpo.

Capítulo II

Protección al Donante y al Receptor

Artículo 4. La información relativa al donante y al receptor de componentes anatómicos humanos será recogida, tratada y custodiada en la más estricta confidencialidad por los centros hospitalarios, excepto cuando se sospeche la existencia de riesgos para la salud individual o colectiva.

Artículo 5. Las autoridades de salud a través de las instituciones públicas y privadas de salud, junto con la sociedad civil, promoverán campañas de información y educación a la población en materia de donación y trasplante, señalando su carácter voluntario, altruista, desinteresado y confidencial.

Artículo 6. Los procedimientos realizados en una institución pública de salud, relacionados a la extracción de componentes anatómicos, en ningún caso ocasionarán gastos para el donante vivo o para los familiares del fallecido, siempre que el trasplante se realice en una institución pública.

Artículo 7. Las instituciones públicas de salud en donde se efectúen trasplantes de componentes anatómicos asumirán los costos del procedimiento y de hospitalización del receptor que no cuente con recursos económicos, previa evaluación socioeconómica.

Artículo 8. Los costos de las intervenciones médico-quirúrgicas destinadas a la extracción de componentes anatómicos, así como los de su implantación posterior estarán sujetos a previo acuerdo entre el equipo de trasplantes y el receptor del componente anatómico donado, cuando se realice en un centro hospitalario privado.

Artículo 9. El Ministerio de Salud establecerá los procedimientos para la extracción de componentes anatómicos de donante fallecido que se efectúe en instituciones privadas de salud autorizadas.

Artículo 10. Al donante de componente anatómico que sea asegurado de la Caja de Seguro Social se le otorgará licencia con sueldo completo por el tiempo que el médico tratante determine sea necesario para su recuperación y no será sujeto de destitución por la donación.

Capítulo III
Disposiciones Fundamentales

Artículo 11. La muerte de una persona ocurre cuando se verifique de modo preciso la inactividad encefálica, corroborada por medios clínicos o técnicos de acuerdo con las diversas situaciones clínicas.

La verificación de la inactividad encefálica no será necesaria en caso de paro cardiorrespiratorio total e irreversible.

Artículo 12. El diagnóstico de muerte encefálica deberá ser constatado por dos o más médicos no interdependientes, que no formen parte del equipo extractor o trasplantador, quienes deberán ser especialistas idóneos en neurología, neurocirugía, medicina interna, medicina crítica o urgenciología. Las actuaciones médicas sobre el particular serán escritas en la historia clínica, con indicación de la fecha y hora de la muerte, dejando constancia del diagnóstico definitivo, y se firmará el certificado de defunción correspondiente.

El paro cardiorrespiratorio deberá ser constatado por dos o más médicos idóneos no interdependientes, que no formen parte del equipo extractor o trasplantador. Las actuaciones médicas sobre el particular serán escritas en la historia clínica, dejando constancia del diagnóstico definitivo.

Artículo 13. Cuando la muerte haya sido diagnosticada con sujeción a las disposiciones de la presente Ley, podrán realizarse procedimientos de perfusión asistida por medios artificiales, con el fin de mantener en óptimas condiciones los componentes anatómicos que estén destinados para trasplantes. Tales métodos podrán ser mantenidos aun durante los procedimientos de extracción de los componentes anatómicos.

La viabilidad de los componentes anatómicos mantenidos por la perfusión prevista en este artículo no desvirtúa la condición de fallecido, según se define en la presente Ley.

Artículo 14. El personal de salud deberá notificar a la coordinación hospitalaria de trasplantes la existencia de pacientes con diagnóstico de muerte encefálica en los cuartos de urgencias y unidades de cuidados intensivos del país.

Artículo 15. El Ministerio de Salud regulará las actividades de extracción, preservación, almacenamiento y procesamiento de componentes anatómicos extraídos de donantes.

Artículo 16. El trasplante de componentes anatómicos se realizará en toda persona que lo requiera luego de haber sido evaluada por el grupo médico trasplantador y que se haya dictaminado que el trasplante es la medida terapéutica más conveniente o vital para esta persona.

Artículo 17. El trasplante de componentes anatómicos provenientes de un donante fallecido se efectuará a nacionales, como primera opción, que formen parte de la Lista de Espera Nacional. En caso de ausencia de receptores nacionales, el componente anatómico será ofrecido a residentes extranjeros que estén en la Lista.

Artículo 18. El Ministerio de Salud autorizará la entrada o salida del país de componentes anatómicos provenientes de donantes fallecidos, siempre que existan acuerdos bilaterales con el Ministerio de Salud de cada país, para lo cual se cumplirán los siguientes criterios:

1. Entrada de componentes anatómicos a Panamá. El Ministerio de Salud admitirá la entrada de componentes anatómicos siempre que esta se efectúe a través de la conexión con una organización de intercambio de componentes anatómicos legalmente reconocida en el país de origen. Además, deberá constatarse que el componente anatómico reúne las garantías éticas y sanitarias exigibles en Panamá y que concurran las siguientes circunstancias:
    a. Que exista un receptor que tenga la misma nacionalidad del donante fallecido o, en su defecto, un receptor en la Lista de Espera Nacional.
    b. Que se disponga de un informe del centro extractor extranjero en el que consten los

estudios efectuados al donante, que demuestren la condición óptima del componente anatómico y la ausencia de enfermedad transmisible, susceptible de constituir un riesgo para el receptor.

2. Salida de componentes anatómicos de Panamá. El Ministerio de Salud admitirá la salida de componentes anatómicos siempre que estos sean para panameños en el extranjero y se efectúe a través de la conexión con una organización de intercambio de componentes anatómicos legalmente reconocida en el país de destino. Además, deberá constatarse que concurran las siguientes circunstancias:
   a. Que no exista receptor adecuado en Panamá.
   b. Que exista un receptor adecuado en el país de destino, siendo un panameño la primera opción.

Artículo 19. Para los efectos de esta Ley, cuando deba expresarse el consentimiento, como deudo de la persona fallecida o en otra condición, sin discriminación de sexo, se tendrá en cuenta en el siguiente orden:

1. El cónyuge o la cónyuge.
2. Los hijos e hijas.
3. El padre y la madre.
4. Los hermanos y hermanas.
5. Los abuelos y abuelas y, en su defecto, los nietos y nietas.
6. Los parientes consanguíneos en línea colateral hasta el tercer grado y los parientes afines hasta el segundo grado.

Cuando a personas ubicadas dentro del mismo numeral de este artículo corresponda expresar su consentimiento, en ausencia de otras con mayor derecho dentro del orden aquí señalado, y manifiesten su voluntad opuesta, prevalecerá la de la mayoría. En caso de empate, se entenderá aceptado el consentimiento.

Para los efectos de donación formal o para ejercer el derecho de oponerse, serán tomados en cuenta los deudos que se presenten y acrediten su condición como tales, dentro del lapso de las seis horas, de acuerdo con el numeral 26 del artículo 3 de la presente Ley.

Artículo 20. Los centros hospitalarios y similares autorizados por el Ministerio de Salud podrán disponer de los componentes anatómicos de los fallecidos no reclamados para fines docentes o de investigación.

Para los efectos del presente artículo, las respectivas autoridades del Ministerio de Salud y/o Ministerio Público determinarán, de acuerdo con las disposiciones legales y los reglamentos de dichas instituciones, el procedimiento para que las entidades autorizadas puedan disponer de las personas fallecidas no reclamadas.

Título II
Donación y Destino de Componentes Anatómicos

Capítulo I
Formas de Donación y Asignación de Componentes Anatómicos

Artículo 21. Los componentes anatómicos solo podrán ser extraídos y utilizados para fines de trasplantes en las siguientes formas de donación:

1. Donación formal, para su implantación inmediata, donado por una persona viva, siempre que no se comprometa su vida.
2. Donación formal, para su implantación diferida, con destino a un banco de componentes anatómicos cuando la donación sea realizada por una persona viva para que tenga efecto después de su muerte.
3. Presunción legal de donación, de conformidad con el numeral 26 del artículo 3 de la presente Ley.

Artículo 22. Para utilizar los componentes anatómicos con fines terapéuticos procedentes de un banco de componentes anatómicos se requiere:

1. Solicitud escrita, presentada conjuntamente por una autoridad médica representativa del centro hospitalario donde se practicará la intervención quirúrgica de trasplante o por el profesional médico, jefe del equipo que lo realizará, especificando claramente el tipo de componentes anatómicos solicitado.
2. Acompañar la solicitud con una copia de la historia clínica del receptor o, en su defecto, con un resumen que incluya información especializada sobre sus antecedentes clínicos patológicos y la necesidad de practicar el trasplante correspondiente.
3. Suscribir un compromiso formal de remitir al banco copia autenticada del protocolo quirúrgico de la operación de trasplante que incluya el resultado del examen anatomopatológico correspondiente del componente anatómico extraído del receptor, si lo hubiera, así como de suministrar la información sobre el seguimiento del caso y su resultado final.

La autenticación a que se refiere este numeral deberá ser hecha por el director del centro hospitalario en donde se practicó la intervención quirúrgica de trasplante o, en su defecto, por el director médico de los servicios de cirugía.

Artículo 23. Los componentes anatómicos para fines terapéuticos que procedan de un banco de componentes anatómicos o para su implantación inmediata se destinarán de acuerdo con los siguientes criterios:

1. Los casos de urgencia en los cuales el trasplante sea vital.
2. Que exista la mejor histocompatibilidad del donante con el receptor.
3. Tiempo de espera, edad pediátrica o antecedentes de donación previa, de acuerdo con el protocolo de cada programa de trasplante.

Capítulo II
Extracción de Componentes Anatómicos de Donante Vivo

Artículo 24. La extracción de componentes anatómicos procedentes de donantes vivos relacionados para su posterior trasplante podrá realizarse si se cumplen las siguientes condiciones y requisitos:

1. El donante debe ser mayor de edad, gozar de plenas facultades físicas y mentales.
2. El donante debe estar dentro del cuarto grado de consanguinidad o segundo de afinidad, en relación con el receptor. La afinidad cuando se refiera a la pareja debe estar determinada por el matrimonio o la unión libre consensuada válida o mantenida por más de cinco años, certificada por el alcalde o un notario.
3. El donante será informado previamente de las consecuencias de su decisión, debiendo otorgar su consentimiento de forma expresa, libre, consciente y desinteresada.
4. Debe tratarse de un componente anatómico o parte de él, cuya extracción sea compatible con la vida, cuya función pueda ser compensada por el organismo del donante de forma adecuada y suficientemente segura, y tenga por objeto un trasplante a una persona determinada con el propósito de mejorar sustancialmente su pronóstico vital o sus condiciones de vida.
5. El donante debe haber sido previamente informado sobre las consecuencias de su decisión, en cuanto pueden ser previsibles desde el punto de vista somático y sicológico, y sobre las eventuales repercusiones que la donación pueda tener sobre su vida personal, familiar y profesional, así como sobre los beneficios que con el trasplante se esperan para el receptor.
6. El donante, en el momento de la extracción, no debe padecer enfermedad susceptible de ser agravada por la extracción del componente anatómico donado y, si es mujer, no debe estar en estado de gravidez.
7. No debe existir compensación económica, ni en dinero ni en especie, por los componentes anatómicos donados, sin perjuicio de la protección que esta Ley le confiere a los donantes.
8. No podrá realizarse la extracción de componentes anatómicos a menores de edad, excepto cuando se trate de trasplante de tejidos hematopoyéticos o de células humanas.
9. Los privados de libertad solo podrán donar componentes anatómicos a sus familiares dentro del segundo grado de consanguinidad y primero de afinidad.

Artículo 25. El estado de salud mental del donante debe ser certificado por un médico siquiatra distinto al que forma parte del equipo médico de extracción o trasplante, quien informará sobre los riesgos inherentes a la intervención, las consecuencias previsibles de orden somático o sicológico, las repercusiones que pueda suponer en su vida personal, familiar o profesional, así como sobre los beneficios que con el trasplante reciba el receptor.

Artículo 26. Para proceder a la extracción de componentes anatómicos de donante vivo, el interesado deberá otorgar por escrito su consentimiento expreso, tras las explicaciones del médico responsable de la extracción o el trasplante.

Artículo 27. Entre la firma del documento de cesión de componentes anatómicos y la extracción de estos deberán transcurrir al menos veinticuatro horas. El donante podrá revocar su consentimiento en cualquier momento antes de la intervención sin sujeción a formalidad alguna. Dicha revocación no podrá dar lugar a ningún tipo de indemnización.

Artículo 28. La extracción de componentes anatómicos procedentes de donantes vivos solo podrá realizarse en los centros hospitalarios expresamente autorizados para ello. Deberá facilitarse al donante vivo asistencia médica para su restablecimiento.

Artículo 29. La donación de componentes anatómicos no genera derecho a indemnización para el donante o sus causahabientes.

Artículo 30. La extracción de componentes anatómicos procedentes de donantes vivos no relacionados se aplicará a la figura del donante cruzado y la del donante altruista, previa autorización del Ministerio de Salud. La extracción de componentes anatómicos procedentes de donante vivo no relacionado para su trasplante inmediato deberá cumplir con los requisitos establecidos en el artículo 24, excepto su numeral 2.

Capítulo III
Extracción de Componentes Anatómicos de Donante Fallecido

Artículo 31. Producida la muerte de una persona en los términos de la presente Ley y expedido su certificado de defunción, siempre que exista donación previa, abandono de fallecido o presunción legal de donación, se podrá disponer de todos o parte de sus componentes anatómicos aprovechables.

Por ningún motivo se podrá abandonar la atención del donante o extraer alguno de sus componentes anatómicos, sino hasta cuando la muerte le haya sido diagnosticada y registrada en la historia clínica.

Artículo 32. Las instituciones o los centros hospitalarios autorizados para efectuar trasplantes llevarán un archivo especial sobre los antecedentes clínicos patológicos de los donantes y de los componentes anatómicos provenientes de otro país. Cuando no fuera posible conocer tales antecedentes, el componente anatómico será rechazado.

Artículo 33. Es obligatorio que toda institución hospitalaria consigne en los documentos de admisión y en la historia clínica si el paciente es donante.

Artículo 34. La oposición a la donación que corresponda a la voluntad de los deudos de una persona deberá hacerse dentro de las seis horas siguientes al diagnóstico de muerte.

Artículo 35. La donación parcial o total podrá hacerse en un banco de componentes anatómicos autorizado, teniendo en cuenta el tipo de donación y la naturaleza de la licencia de funcionamiento que el Ministerio de Salud le haya otorgado.

Artículo 36. La donación ordinaria o extraordinaria de componentes anatómicos total o parcial deberá ser expresada en alguno de los siguientes documentos:

1. Historial clínico.
2. Declaración jurada ante un notario público.
3. Documento privado autenticado por un notario público.
4. Documento suscrito ante dos testigos hábiles.

El donante podrá revocar su decisión en cualquier tiempo utilizando alguno de los documentos señalados y su voluntad prevalecerá sobre el parecer contrario de sus deudos o de cualquier otra persona.

Artículo 37. Quienes hayan sido los representantes legales de los menores de edad o de las personas con discapacidad fallecidos podrán autorizar la donación o rechazarla.

Artículo 38. Siempre que se pretenda proceder a la extracción de componentes anatómicos de donante fallecido en un centro autorizado, la persona a quien corresponda dar la autorización para la extracción deberá verificar la información sobre si el donante hizo patente su voluntad en alguno de los documentos señalados en el artículo 36 de la presente Ley.

Artículo 39. La extracción de componentes anatómicos de un donante fallecido para fines terapéuticos será efectuada por los médicos que integren el equipo médico de extracción. De la intervención se levantará un acta suscrita por los médicos participantes, en la cual se dejará constancia de los componentes anatómicos extraídos.

En los registros clínicos correspondientes se dejará expresa constancia de que al donante fallecido y al receptor se les practicaron las pruebas inmunológicas correspondientes.

Artículo 40. La remoción de los componentes anatómicos se realizará de manera que no se produzcan mutilaciones innecesarias.

Cuando se practiquen enucleaciones de los globos oculares estos serán reemplazados por prótesis fungibles.

Artículo 41. La extracción de tejido ocular, piel y vasos periféricos de un donante fallecido podrá hacerse en lugar distinto al señalado en el artículo 38 de esta Ley, previa expedición del correspondiente certificado de defunción o la autorización para la práctica de necropsia médico-legal. Los procedimientos de extracción de componentes anatómicos a los cuales se

refiere el presente artículo serán practicados por médicos idóneos o profesionales técnicos en la materia.

Artículo 42. En los casos de que un donante muera traumática, violenta, repentina o súbitamente se efectuarán las técnicas de preservación para asegurar la viabilidad de los componentes anatómicos. La autoridad competente autorizará la extracción previo informe y explicación del médico forense, siempre que no se contamine el resultado de la instrucción sumarial.

Artículo 43. Los componentes anatómicos que se obtengan de donantes fallecidos sometidos a necropsias médico-legales solo podrán ser utilizados para fines terapéuticos o científicos y estarán destinados a los bancos de componentes anatómicos autorizados, siempre que se hayan inscrito ante las respectivas dependencias del Instituto de Medicina Legal y Ciencias Forenses.

Capítulo IV
Trasplante de Componentes Anatómicos de Donante Vivo

Artículo 44. El trasplante de componentes anatómicos de donante vivo requiere:

1. Que se cumplan las formas de donación señaladas en el artículo 21 de esta Ley.
2. Que tanto el donante como el receptor hayan sido previamente advertidos de los riesgos que pueden existir en el procedimiento y la imposibilidad de conocer situaciones imprevistas.
3. Que, en caso de trasplante de un órgano par, los dos órganos del donante sean anatómica y fisiológicamente normales.
4. Que, en caso de la donación de una porción de un órgano impar, el órgano restante del donante supla su función y sea compatible con su vida.
5. Que tanto al receptor como al donante le hayan realizado e informado de los resultados de los estudios inmunológicos u otros procedentes para el caso, entre donante y futuro receptor, llevados a cabo por un laboratorio de histocompatibilidad cuyo funcionamiento, métodos y detección inmunológica estén autorizados por el Ministerio de Salud, o dependa de una entidad hospitalaria autorizada para la práctica del trasplante correspondiente.
6. Que el receptor exprese por escrito su consentimiento para la realización del trasplante, si se trata de una persona mayor de edad.
7. Si el receptor fuera menor de edad, en curatela o en interdicción, el consentimiento deberá ser expresado por escrito por sus representantes legales. Cuando se trate de casos de urgencia y el consentimiento no pueda expresarse en la forma indicada, se procederá de conformidad con el artículo 16 de esta Ley.

Título III
Tejidos Hematopoyéticos y Células Humanas

Capítulo I
Selección y Procedimientos de Extracción

Artículo 45. La extracción de tejidos hematopoyéticos o de células se llevará a cabo de forma que garantice que la evaluación y selección de los donantes se realiza de acuerdo con los requisitos especificados en esta Ley.

Artículo 46. La aplicación de criterios de selección y evaluación estará basada en el análisis de la valoración de los riesgos en relación con el uso específico del tejido hematopoyético o el grupo celular.

Artículo 47. En caso de que el tejido hematopoyético o las células obtenidas vayan a ser enviadas a otro banco de componentes anatómicos o institución hospitalaria para su procesamiento, este podrá encargarse de completar la evaluación y selección del tejido hematopoyético o de las células.

Artículo 48. El procedimiento de extracción se realizará en los siguientes términos:

1. La extracción del tejido hematopoyético o de células deberá realizarse mediante procedimientos operativos estandarizados debidamente documentados y validados que sean adecuados para el grupo celular que se va a extraer, que garanticen calidad y seguridad y respeten su integridad.
2. El procedimiento de extracción deberá ser el adecuado para proteger debidamente aquellas propiedades de las células que son necesarias para su uso clínico, a la vez que se minimizarán los riesgos de contaminación microbiológica.
3. El procedimiento de extracción, empaquetado, etiquetado, mantenimiento y transporte hasta dicho centro deberá constar en un documento acordado entre la unidad de extracción y la institución de recepción.

Capítulo II
Procesamiento, Trazabilidad y Biovigilancia
de Tejido Hematopoyético o de Células Humanas

Artículo 49. Las actividades de procesamiento que se realicen en las instituciones hospitalarias o bancos de componentes anatómicos tendrán por objeto la preparación, preservación y almacenamiento de tejidos hematopoyéticos o de células para su uso clínico, tanto autólogo como alogénico, en procedimientos terapéuticos con indicaciones médicas establecidas o en procedimientos de aplicación en humanos en casos de utilidad y eficacia debidamente contrastada, o en procedimientos de investigación clínica debidamente documentada.

Artículo 50. La institución hospitalaria o banco de componentes anatómicos incluirá en sus manuales de procedimientos toda actividad de procesamiento de tejido hematopoyético o de

células y velará para que se realice en condiciones controladas. Se verificará que el equipo utilizado, el entorno de trabajo y la concepción, validación y condiciones de control de los procesos se ajusten a los requisitos exigidos por el Ministerio de Salud.

Artículo 51. Los tejidos hematopoyéticos o las células almacenadas estarán a disposición de los centros o unidades hospitalarias para usos alogénicos en procedimientos terapéuticos con indicaciones médicas establecidas en receptores adecuados.

Artículo 52. El Ministerio de Salud autorizará la entrada y salida del país de las células y tejidos hematopoyéticos de acuerdo con los siguientes criterios:

1. Se autorizará la salida de células y tejidos hematopoyéticos si concurren las siguientes circunstancias:
   a. Que haya disponibilidad suficiente de células y/o tejidos hematopoyéticos en los bancos de componentes anatómicos nacionales.
   b. Que exista un receptor adecuado en el país de destino.
2. Se autorizará el ingreso de células y/o tejidos hematopoyéticos cuando se cumplan las siguientes condiciones:
   a. Que exista un probado beneficio en la utilización de los tejidos hematopoyéticos y de las células que se pretenden aplicar.
   b. Que la finalidad de la entrada de los tejidos y/o células hematopoyéticas sea la utilización terapéutica en seres humanos.
   c. Que exista receptor adecuado en Panamá.
   d. Que no exista disponibilidad en los bancos de componentes anatómicos del país.
   e. Que se especifique la institución de destino.
   f. Que el banco de componentes anatómicos o el centro extractor extranjero presenten un informe donde hagan constar los estudios efectuados al donante, necesarios para demostrar las condiciones óptimas del componente anatómico y la ausencia de enfermedad transmisible, susceptible de constituir un riesgo para el receptor.
   g. Que reúnan las condiciones sanitarias exigibles en Panamá.

Artículo 53. En el caso de que el banco de componentes anatómicos o institución hospitalaria que ha procesado y almacenado las células no disponga de la infraestructura necesaria para una completa tipificación de las células que permita establecer compatibilidades e idoneidades cuando sea preciso, deberá enviar una muestra a otro establecimiento debidamente autorizado que sí esté dotado de la infraestructura adecuada y que se constituirá en establecimiento de referencia.

Artículo 54. La aplicación autóloga quedará encuadrada en el caso de procedimientos terapéuticos de eficacia demostrada en indicaciones médicas establecidas.

En el caso de que se realicen actividades de procesamiento para usos autólogos eventuales de los que no hay indicación médica establecida actual, los tejidos hematopoyéticos o las células así procesadas estarán disponibles para su aplicación alogénica.

Artículo 55. La solicitud para requerir un tejido hematopoyético o grupo celular a un banco de componentes anatómicos la efectuará el responsable de la aplicación a través del centro hospitalario que realizará la intervención. De no presentarse copia de la autorización correspondiente, esta será rechazada.

Artículo 56. Se establecerá un sistema de rastreo de origen y destino de todas las células humanas obtenidas con la finalidad de ser aplicadas en humanos.

Artículo 57. Los bancos de componentes anatómicos y las instituciones hospitalarias recogerán la información del destino de los tejidos hematopoyéticos o las células para la aplicación en humanos. Dicha información deberá ser facilitada por los bancos de componentes anatómicos o por las instituciones hospitalarias y enviada al Registro Nacional de Trasplantes para cada caso en particular, con el fin de asegurar la trazabilidad de los tejidos hematopoyéticos o las células.

Artículo 58. El rastreo de origen y destino se aplicará a los productos celulares y a los productos o materiales que entren en contacto con dichas células y tejidos hematopoyéticos y puedan tener efecto sobre su calidad y seguridad. La información se guardará y custodiará de forma segura durante al menos treinta años a partir de su codificación.

Artículo 59. Se establecerá un sistema único y obligatorio de codificación compatible con los sistemas de otros centros hospitalarios que permita identificar de forma única e inequívoca los tejidos hematopoyéticos o células obtenidos, procesados y distribuidos para su aplicación en humanos y se desarrollará igualmente un sistema técnico que sirva de soporte al sistema de codificación.

Artículo 60. A partir de la entrada en vigencia de la presente Ley, funcionará un sistema de biovigilancia que permita notificar, registrar y transmitir los efectos y reacciones adversas graves que puedan haber influido o influir en la calidad y seguridad de los tejidos hematopoyéticos o las células y que pudieran atribuírsele a los procesos de extracción, evaluación, procesamiento y distribución, así como toda reacción adversa grave observada durante o a raíz de la aplicación clínica de los tejidos hematopoyéticos o las células y que pudiera estar relacionada con su calidad y seguridad.

Título IV
Licencias Sanitarias

Capítulo I
Licencias Sanitarias

Artículo 61. El Ministerio de Salud expedirá, renovará o revocará mediante resolución motivada las siguientes licencias sanitarias de funcionamiento:

1. Para bancos de componentes anatómicos.
2. Para los centros de extracción de componentes anatómicos de donante fallecido.
3. Para los centros de extracción y trasplantes de componentes anatómicos de donante vivo.

Artículo 62. Las licencias sanitarias de funcionamiento de centros de extracción y/o trasplantes expedidas a establecimientos asistenciales u hospitalarios solo podrán desarrollar actividades conforme a la licencia sanitaria que les fue otorgada.

Las licencias sanitarias de funcionamiento que se otorguen a los bancos de componentes anatómicos no comprenden la autorización para realizar procedimientos de trasplantes ni extracción de componentes anatómicos.

Artículo 63. Para solicitar la expedición o renovación de las licencias sanitarias, se requerirá:

1. Solicitud por duplicado presentada por el interesado, en forma personal o mediante apoderado, ante el Ministerio de Salud, precisando el tipo de licencia que se tramita.
2. Nombre o razón social de la entidad solicitante con prueba adjunta de su existencia legal.
3. Número y fecha de la licencia sanitaria correspondiente del centro hospitalario autorizado.
4. Nombre y dirección del representante legal de la entidad solicitante.
5. Dirección o ubicación de la sede de la entidad solicitante.
6. Descripción de las características de la infraestructura de la entidad, así como su naturaleza jurídica, sus objetivos, disponibilidades técnica, científica y humana, precisando las funciones y demás datos relacionados con el personal profesional o técnico, incluyendo su grado de capacitación.
7. Indicación del centro hospitalario al cual está vinculado, si la licencia se solicita para un banco de componentes anatómicos.
8. Especificación de los tipos de trasplantes que se realizarán en el centro, si la licencia se solicita para la práctica de trasplantes en los centros extractores y trasplantadores.
9. Nombres del personal médico, enfermeras, técnicos en enfermería y laboratoristas responsables de los procedimientos en el centro extractor y/o trasplantador, así como su acreditación correspondiente.
10. Protocolos correspondientes de acuerdo con el centro hospitalario que desarrolle estas actividades.
11. Cualquier otro que determine el Ministerio de Salud.

Artículo 64. El Ministerio de Salud determinará los requisitos que debe reunir el personal que integra el equipo médico-quirúrgico y técnico de trasplantes, así como la infraestructura indispensable de los centros a los que se les haya expedido la licencia sanitaria.

Artículo 65. La licencia sanitaria para la práctica de extracción y/o trasplante de componentes anatómicos que expida el Ministerio de Salud indicará las intervenciones o los tipos de trasplantes que pueden practicar.

Artículo 66. Recibida la solicitud, si se encuentra completa la documentación, el Ministerio de Salud ordenará la práctica de una visita de inspección al establecimiento solicitante, con el objeto de constatar las condiciones físicas y técnicas del establecimiento de salud para el funcionamiento como centro extractor y/o trasplantador, así como el cumplimiento de las obligaciones establecidas en los artículos 72, 73 y 76 de la presente Ley.

Artículo 67. Las resoluciones mediante las cuales se conceden o niegan las licencias sanitarias son susceptibles de los recursos que señala la ley.

Artículo 68. Las licencias sanitarias se otorgarán por periodos de cinco años, contados a partir de la fecha de ejecutoria de la resolución de otorgamiento respectivo, y podrán renovarse por periodos iguales previa solicitud de renovación con no menos de noventa días hábiles de antelación a la fecha de vencimiento, siempre que no haya sido revocada.

Artículo 69. Las instituciones hospitalarias y los bancos de componentes anatómicos que, al entrar en vigencia la presente Ley, tengan licencias de funcionamiento para realizar trasplantes o para funcionar como bancos de componentes anatómicos mantendrán sus licencias, de conformidad con esta Ley.

Artículo 70. Vencida una licencia sanitaria, su titular podrá solicitar la renovación o la expedición de otro tipo de licencia sanitaria, de conformidad con los requisitos señalados en esta Ley.

Título V
Bancos, Centros de Extracción y/o de Trasplantes de Componentes Anatómicos

Capítulo I
Bancos de Componentes Anatómicos

Artículo 71. Se establecerán bancos de componentes anatómicos que hayan obtenido la correspondiente licencia de funcionamiento del Ministerio de Salud que se dedicarán a recibir, procesar, preservar, almacenar, transportar y distribuir los componentes anatómicos para su posterior trasplante.

Artículo 72. Los bancos de componentes anatómicos públicos o privados autorizados por el Ministerio de Salud deberán:

1. Contar con una organización y un régimen de funcionamiento que permita cumplir con las funciones para las cuales fueron autorizados.
2. Establecer una unidad de coordinación con los centros hospitalarios de trasplantes hasta que los componentes anatómicos sean requeridos para el trasplante.
3. Disponer del personal técnico y administrativo idóneo para mantener, almacenar, preservar y distribuir los componentes anatómicos que tienen bajo su responsabilidad.
4. Mantener en buenas condiciones las instalaciones y estructuras físicas adecuadas para almacenar, preservar y transportar los componentes anatómicos.

Capítulo II
Centros de Extracción de Componentes Anatómicos de Donante Fallecido

Artículo 73. La extracción de componentes anatómicos de donante fallecido solo podrá realizarse en centros hospitalarios públicos o privados que hayan sido expresamente autorizados por el Ministerio de Salud. Los centros de extracción de componentes anatómicos de donante fallecido deberán:

1. Contar con una organización y un régimen de funcionamiento que permita asegurar la ejecución de las operaciones de extracción de forma satisfactoria.
2. Establecer una unidad de coordinación con los bancos de componentes anatómicos y con los centros hospitalarios de trasplantes.
3. Disponer del personal idóneo, médicos, enfermeras, laboratoristas y técnicos en enfermería, con acreditación en extracción de componentes anatómicos.
4. Disponer de las instalaciones físicas y de un laboratorio clínico para la realización de los exámenes clínicos que se consideren necesarios para la evaluación clínica del donante fallecido y la correcta realización de las extracciones.
5. Contar con el apoyo de un laboratorio de histocompatibilidad debidamente autorizado por el Ministerio de Salud.
6. Proporcionar al Ministerio de Salud toda la información que les sea solicitada en relación con la actividad para la cual hayan sido autorizados.

Artículo 74. Cualquier tipo de modificación que se produzca en las instalaciones hospitalarias o en el funcionamiento del centro extractor de componentes anatómicos deberá ser notificado al Ministerio de Salud para que, luego de su revisión, se proceda a mantener la autorización o a su revocación considerando la trascendencia de la modificación, aun cuando no hubiera vencido el periodo de vigencia.

Artículo 75. Los centros hospitalarios autorizados para la extracción de componentes anatómicos de donante fallecido adoptarán las medidas necesarias a fin de garantizar que los deudos tengan pleno conocimiento de la regulación sobre donación y extracción del componente anatómico.

Capítulo III
Centros de Extracción y Trasplantes
de Componentes Anatómicos de Donante Vivo

Artículo 76. Los centros de extracción y trasplantes de componentes anatómicos, sean instituciones hospitalarias públicas o privadas, que hayan sido expresamente autorizados por el Ministerio de Salud deberán:

1. Garantizar la viabilidad y calidad del programa de trasplante en las actividades que desarrollen.
2. Disponer de los servicios que garanticen la realización de la intervención quirúrgica, el tratamiento y manejo de las eventuales complicaciones que presente el trasplante.
3. Disponer del personal idóneo con acreditación en extracción y trasplante, médicos, enfermeras y técnicos en enfermería.
4. Mantener en buenas condiciones las instalaciones físicas, los medios técnicos, los materiales necesarios y los servicios sanitarios que garanticen el proceso de trasplante.
5. Disponer de un servicio de patología con los medios técnicos y recurso humano idóneo para los estudios asociados al trasplante.
6. Disponer de un laboratorio clínico y de histocompatibilidad autorizado por el Ministerio de Salud, que cuente con los recursos técnicos y humanos necesarios para garantizar la realización de los estudios inmunológicos.
7. Establecer una Comisión de Trasplante Hospitalaria que asegure la selección de los receptores y el seguimiento de todo el proceso terapéutico.
8. Mantener registro de acceso restringido y confidencial de los trasplantes realizados en el que consten los datos precisos para la identificación del donante y del receptor, de forma que permita el seguimiento de los componentes anatómicos trasplantados en el centro, así como los resultados obtenidos.
9. Presentar informe periódico y detallado al Ministerio de Salud relacionado con las actividades para las cuales hayan sido autorizados.

Los centros médicos y quirúrgicos involucrados en los diferentes tipos de trasplantes se adecuarán, en todo momento, a los progresos científicos existentes en la materia y seguirán protocolos diagnósticos y terapéuticos actualizados, de acuerdo con la práctica médica generalmente aceptada.

Artículo 77. Cualquier tipo de modificación que se produzca en las instalaciones hospitalarias o en el funcionamiento del centro extractor y trasplantador de componentes anatómicos debe ser notificado al Ministerio de Salud para que, luego de su revisión, se proceda a mantener la autorización o a su revocación considerando la trascendencia de la modificación, aun cuando no hubiera vencido el periodo de vigencia.

Título VI
Organización

Capítulo I
Organización Panameña de Trasplantes

Artículo 78. Se crea la Organización Panameña de Trasplantes, adscrita al Ministerio de Salud, como la unidad técnica operativa que, siguiendo los principios de cooperación, eficacia, equidad, calidad y solidaridad, tiene como finalidad trabajar con el sistema de salud panameño, a fin de coordinar las actividades de promoción, donación, extracción, preservación, distribución, intercambio y trasplante de componentes anatómicos.

Artículo 79. La Organización Panameña de Trasplantes reemplazará a cualquiera otra organización creada previamente con fines similares.

Artículo 80. La Organización Panameña de Trasplantes tendrá las siguientes funciones:

1. Crear las coordinaciones hospitalarias de trasplantes a nivel nacional donde no las hubiera y desarrollar las existentes, las cuales conformarán una red nacional de donación de componentes anatómicos.
2. Seleccionar, designar y supervisar la labor de los coordinadores de trasplantes y del coordinador hospitalario de trasplantes.
3. Velar por la adecuada organización, funcionamiento y desarrollo de todos los programas de trasplantes de componentes anatómicos, cada uno de los cuales será dirigido por un médico especialista acreditado en trasplantes.
4. Coordinar la distribución de componentes anatómicos para trasplantes a nivel nacional.
5. Llevar el Registro Nacional de Donantes.
6. Actualizar el Registro Nacional de Trasplantes, que mantendrá los datos de origen y destino de componentes anatómicos a nivel nacional en las instituciones de salud públicas y privadas, así como la de los organismos internacionales.
7. Actualizar la Lista de Espera Nacional de trasplantes de componentes anatómicos en coordinación con los diferentes programas de trasplante.
8. Coordinar la logística del transporte de personal, equipo y de componentes anatómicos para trasplante, por lo que gestionará la ayuda de las entidades del Estado respectivamente.
9. Establecer los controles de seguridad y calidad de los componentes anatómicos obtenidos para trasplante.
10. Informar y promover las actividades relacionadas con la donación de componentes anatómicos en las entidades sanitarias a los profesionales y técnicos de la salud, a los agentes sociales y a la población en general.
11. Establecer y mantener relación y comunicación con organismos y organizaciones nacionales e internacionales relacionadas con trasplante.
12. Recomendar al Ministerio de Salud las políticas sobre las actividades de trasplante de componentes anatómicos que se consideren convenientes.

13. Gestionar ante las autoridades respectivas los recursos para que permanentemente se cuente con el equipo médico-quirúrgico y medicamentos necesarios para la adecuada implementación de los programas de trasplante.
14. Promover estudios e investigaciones que puedan hacer progresar los conocimientos y las tecnologías relacionadas con la obtención de órganos y tejidos y su trasplante.
15. Promover y desarrollar actividades orientadas a la formación continuada del personal sanitario que trabaje en la gestión de donación de componentes anatómicos o en los diferentes programas de trasplantes.
16. Ejercer cualquier otra función que le asigne el Ministerio de Salud.

Artículo 81. La Organización Panameña de Trasplantes estará dirigida por un Director General y un Subdirector General, quienes serán seleccionados, a través de concurso de oposición y sistema de méritos por el Ministerio de Salud, para un periodo de seis años y contará con las secciones administrativas necesarias para el desarrollo de su labor y con un consejo asesor de las organizaciones de pacientes y familiares.

Artículo 82. Los requisitos para ser Director General y Subdirector General son los siguientes:

1. Ser de nacionalidad panameña.
2. Ser médico idóneo acreditado en trasplante.
3. Tener experiencia en programas de trasplantes en las que haya participado activamente.
4. Tener conocimiento en procura de órganos y organización de programas de trasplante.

Artículo 83. El Director General de la Organización Panameña de Trasplantes tendrá las siguientes funciones:

1. Coordinar con las instituciones y organizaciones las actividades necesarias para el buen funcionamiento de programas de trasplantes.
2. Presentar las propuestas que reciba la Organización Panameña de Trasplantes.
3. Llevar las actas, los archivos, la correspondencia y demás documentos de la Organización Panameña de Trasplantes.
4. Generar propuestas tendientes a resolver los problemas técnicos y administrativos que se detecten para que sean consideradas e incluidas en el anteproyecto de presupuesto.
5. Llevar el Registro Nacional de Trasplantes, el Registro Nacional de Donantes y la Lista de Espera Nacional.
6. Rendir un informe mensual al Ministerio de Salud sobre las actividades que se desarrollen en materia de trasplantes.
7. Ejercer cualquiera otra que le sea asignada por el Ministerio de Salud.

Artículo 84. El Subdirector General de la Organización Panameña de Trasplantes tendrá las siguientes funciones:

1. Reemplazar al Director General en todas las ausencias temporales y absolutas.
2. Realizar cualquier otra función que le asigne el Director General o que establezca el Ministerio de Salud.

Artículo 85. Son causales de destitución del Director General o del Subdirector General de la Organización Panameña de Trasplantes las siguientes:

1. La comisión de delito doloso o delito contra la Administración Pública, previa sentencia judicial condenatoria.
2. La incapacidad manifiesta en el ejercicio de sus funciones, decretada por resolución ejecutiva del Ministerio de Salud.

Artículo 86. El Ministerio de Salud gestionará oportunamente ante el Ministerio de Economía y Finanzas las asignaciones presupuestarias para el funcionamiento de la Organización Panameña de Trasplantes y de los programas de trasplantes de componentes anatómicos que se desarrollen en los centros hospitalarios públicos autorizados.

Capítulo II
Comité Nacional de Trasplantes

Artículo 87. El Comité Nacional de Trasplantes es un organismo técnico consultivo y asesor del Ministerio de Salud en materia de trasplantes y estará integrado por:

1. Un médico idóneo acreditado en trasplante designado por el Ministerio de Salud, quien lo presidirá.
2. Un médico idóneo acreditado en trasplantes en representación de la Caja de Seguro Social.
3. Un médico idóneo acreditado en trasplante en representación de cada asociación médica, según las especialidades que efectúen trasplantes.
4. Un representante de la Asociación de Hospitales Privados que efectúan trasplantes.
5. Un representante de la Asociación de Enfermeras acreditadas en trasplante.
6. Un representante de la Asociación de Laboratoristas acreditados en trasplantes.
7. Un representante de la Asociación de Técnicos en Enfermería acreditados en trasplantes.

Las asociaciones mencionadas designarán a su representante principal y a un suplente, que lo reemplazará en sus ausencias. En caso de ausencia definitiva de ambos las asociaciones designarán nuevos representantes.

Artículo 88. El Comité Nacional de Trasplantes se reunirá por lo menos una vez al mes. El Director General de la Organización Panameña de Trasplantes asistirá a todas las reuniones con derecho a voz.

Artículo 89. El Comité Nacional de Trasplantes tendrá las siguientes funciones:

1. Elaborar su reglamento interno.
2. Asesorar en materia de trasplantes al Ministerio de Salud conforme al programa de trasplantes que se desarrolle a nivel nacional.
3. Vigilar que las actividades de trasplantes en general, tanto institucionales como privadas, cumplan con el contenido de esta Ley.

4. Promover con otras instituciones oficiales y privadas de salud, junto con entidades cívicas, campañas de divulgación y orientación educativa sobre el profundo sentido de solidaridad humana involucrada en la donación de componentes anatómicos.
5. Revisar y evaluar, en primera instancia, la documentación requerida por el Consejo Técnico de Salud para la acreditación de los profesionales y técnicos de la salud, en materia de trasplantes.
6. Vigilar que los miembros de los diferentes equipos de trasplantes sean profesionales y técnicos acreditados.
7. Verificar que en los centros hospitalarios se cuente con el equipo médico-quirúrgico y con los medicamentos necesarios para la adecuada ejecución del programa de trasplantes.
8. Establecer parámetros para la acreditación de los profesionales y técnicos en materia de trasplantes según los requisitos de las diferentes sociedades médicas y profesionales de la salud.

Artículo 90. En cada centro hospitalario o institución pública o privada en donde se practiquen procedimientos de trasplantes funcionará un Comité Hospitalario de Trasplantes integrado por:

1. El director de la entidad o su delegado.
2. Un representante de cada uno de los servicios involucrados en el programa o los programas de trasplantes.
3. Un representante del banco de componentes anatómicos y del banco de sangre.
4. Un representante del laboratorio de trasplantes.
5. Un representante de las enfermeras de la institución que trabajen en programas de trasplantes.
6. Un representante de los técnicos en enfermería acreditados en trasplantes.

Artículo 91. Los Comités Hospitalarios de Trasplantes tendrán las siguientes funciones:

1. Elaborar su propio reglamento interno, que necesariamente debe establecer lo relativo al seguimiento adecuado de los pacientes a quienes se les haya realizado trasplantes.
2. Coordinar y supervisar la actividad hospitalaria de trasplante con los servicios médicos y quirúrgicos, el laboratorio de trasplante, el departamento de enfermería y con el personal idóneo que compone los equipos de trasplantes.
3. Las demás que le señale el Ministerio de Salud y la presente Ley.

Título VII
Contravenciones, Sanciones y Procedimiento

Capítulo I
Faltas

Artículo 92. Se consideran faltas las contravenciones a esta Ley y a sus reglamentos complementarios.

Artículo 93. El Ministerio de Salud es la autoridad con derecho a establecer y conocer la existencia de faltas y aplicar las sanciones.

Artículo 94. Las faltas pueden ser:

1. Leves:
   a. Publicitar la donación no autorizada de componentes anatómicos en beneficio de personas o instituciones determinadas.
   b. Publicitar la necesidad de un componente anatómico o sobre su disponibilidad con la finalidad de una gratificación o remuneración.
   c. Extraer componentes anatómicos sin el consentimiento escrito.
   d. Ofrecer o conferir compensaciones económicas directas o indirectas, totales o parciales para lograr la donación de componentes anatómicos.
2. Graves:
   a. Poseer ilegítimamente un fallecido no reclamado.
   b. Extraer componentes anatómicos fuera de un centro hospitalario autorizado.
   c. Operar un centro hospitalario para la extracción de componentes anatómicos sin la debida licencia.
   d. Exportar, importar o reexportar sin la autorización del Ministerio de Salud componentes anatómicos con la finalidad de una gratificación o remuneración.
   e. Realizar la extracción de componentes anatómicos cuando medie coacción e intimidación.

Artículo 95. Se consideran circunstancias agravantes de una falta las siguientes:

1. La reincidencia.
2. Cometer la falta con pleno conocimiento de sus efectos perjudiciales o con la complicidad de subalternos o su participación bajo indebida presión.
3. Cometer una falta para ocultar otra.
4. Rehuir la responsabilidad o atribuírsela a otro u otros.
5. Incumplir varias obligaciones con la misma conducta.
6. Premeditar la ejecución de una infracción y sus modalidades.

Capítulo II
Sanciones

Artículo 96. Las sanciones deberán imponerse mediante resolución motivada, expedida por el Ministerio de Salud, y deberán notificarse personalmente al afectado dentro de los cinco días hábiles siguientes a la fecha de expedición.

Si no pudiera hacerse la notificación personal, se hará por edicto, de conformidad con lo dispuesto por el Procedimiento Administrativo General.

Artículo 97. La violación de las disposiciones de la presente Ley será sancionada por el Ministerio de Salud, con alguna o algunas de las siguientes sanciones:

1. Amonestación.
2. Multa hasta de cincuenta mil balboas (B/.50,000.00).
3. Decomiso de componentes anatómicos.
4. Suspensión o cancelación de la licencia.
5. Cierre temporal o definitivo del establecimiento o servicio respectivo.

Artículo 98. La amonestación consiste en la llamada de atención, por escrito, a quien ha violado cualquiera de las disposiciones de la presente Ley, aunque esa violación no implique peligro para la salud o la vida de las personas. Su propósito es denotar las consecuencias del hecho, de la actividad o de la omisión y advertir que se impondrá una sanción mayor si se reincide en la falta.

En el escrito de amonestación se precisará el plazo que se da al infractor para que cumpla las disposiciones violadas, si es el caso.

Artículo 99. La amonestación podrá ser impuesta por cualquiera de las autoridades del Ministerio de Salud o por un superior jerárquico.

Artículo 100. La multa consiste en la sanción pecuniaria que se impone a una persona, natural o jurídica, por la violación de las faltas señaladas, mediante la ejecución de una actividad o la omisión de una conducta.

Artículo 101. Las multas deberán pagarse teniendo en cuenta las disposiciones legales sobre la materia, dentro de los cinco días hábiles siguientes a la ejecutoria de la resolución que las impone. El no pago, en los términos y cuantías señaladas, podrá dar lugar a la cancelación de la licencia sanitaria o al cierre del establecimiento respectivo. La multa podrá hacerse efectiva por jurisdicción coactiva.

Artículo 102. El decomiso de componentes anatómicos consiste en su incautación cuando no se ajusten a las disposiciones de la presente Ley y con ello se atente contra la salud individual o colectiva.

Artículo 103. El decomiso será impuesto mediante resolución motivada expedida por el Ministro de Salud.

Artículo 104. El decomiso será realizado por el funcionario designado al efecto. De la diligencia se levantará un acta por triplicado, la cual suscribirán los funcionarios y las personas que intervengan en esta. Una copia se entregará a la persona en cuyo poder se hayan encontrado los bienes decomisados.

Artículo 105. La suspensión de una licencia sanitaria consiste en la privación temporal del derecho que confiere su otorgamiento, por haber incurrido en conductas contrarias a las

disposiciones de la presente Ley. La sanción de suspensión podrá tener una duración hasta de seis meses.

Artículo 106. La cancelación de una licencia sanitaria consiste en la privación definitiva de la autorización o el derecho que se había conferido por haber incurrido en conductas contrarias a las disposiciones de la presente Ley.

Artículo 107. La suspensión o la cancelación de las licencias sanitarias de funcionamiento, relacionadas con los establecimientos establecidos en esta Ley, comporta el cierre de estos.

Artículo 108. Se impondrá sanción de suspensión o cancelación de una licencia con base en la persistencia de la situación sanitaria objeto de sanciones, ya sea de amonestación, multa o decomiso, así como por no pagar las multas en los términos y las cuantías señalados.

Artículo 109. La persona o institución sancionada con la cancelación de una licencia no podrá solicitar durante un año una nueva licencia para el desarrollo de la misma actividad.

Artículo 110. La suspensión o cancelación de una licencia será impuesta mediante resolución motivada dictada por el funcionario que la haya otorgado.

Artículo 111. El cierre temporal o definitivo de establecimientos, edificaciones o servicios consiste en poner fin a las tareas que en ellos se desarrollan, por la existencia de hechos o conductas contrarias a las disposiciones de la presente Ley.

El cierre es temporal si se impone por un periodo de tiempo precisamente determinado por la autoridad sanitaria competente y es definitivo cuando no se fija un límite de tiempo.

El cierre podrá ordenarse para todo o parte del establecimiento, edificaciones o servicio.

Artículo 112. Se impondrá sanción de cierre temporal total o parcial, según sea el caso, cuando se presenten riesgos para la salud de las personas, cuya causa puede ser controlada en un tiempo determinado o determinable por la autoridad sanitaria que imponga la sanción.

Artículo 113. El cierre parcial o total, según sea el caso, será definitivo cuando se presenten riesgos para la salud humana y cuyas causas no puedan ser controladas en un tiempo determinado o determinable.

Artículo 114. El cierre definitivo total significa la clausura del establecimiento o servicio respectivo.

El cierre definitivo parcial ocasiona que la licencia no ampare la parte del establecimiento o servicio afectados.

Artículo 115. La sanción de cierre será impuesta mediante resolución motivada expedida por el Ministerio de Salud.

Artículo 116. A partir de la ejecutoria de la resolución por medio de la cual se imponga la sanción de cierre total, no podrá desarrollarse actividad alguna en el establecimiento, salvo la necesaria para evitar el deterioro de los equipos o para la conservación del inmueble y los componentes anatómicos. Si la sanción fuera cierre parcial, no podrá desarrollarse actividad alguna en la zona o el servicio afectados, salvo la necesaria para evitar el deterioro de los equipos o para la conservación del inmueble.

Artículo 117. Las sanciones que se impongan de conformidad con las disposiciones de la presente Ley no eximen de la responsabilidad civil, penal o de otro orden.

Artículo 118. Cuando una sanción se imponga por determinado periodo de tiempo, este empezará a contarse a partir de la ejecutoría de la resolución que la imponga, y se computará, para los efectos, el tiempo transcurrido bajo medidas de seguridad.

Capítulo III
Procedimiento

Artículo 119. El procedimiento administrativo para sancionar cualquier acción u omisión contraria a la presente Ley se iniciará de oficio o mediante información de funcionarios. También podrá iniciarse por denuncia o queja debidamente fundamentada presentada por cualquier persona.

Artículo 120. Si durante el procedimiento sancionatorio surgen hechos constitutivos de delitos, estos se pondrán en conocimiento de la autoridad competente y se acompañarán con copia de los documentos que correspondan.

Artículo 121. La existencia de un proceso penal o de otra índole no dará lugar a la suspensión del procedimiento administrativo previsto en esta Ley.

Artículo 122. Conocido el hecho o recibida la denuncia o el aviso, la autoridad competente ordenará la correspondiente investigación para verificar los hechos o las omisiones constitutivas de infracción a las disposiciones de la presente Ley.

Artículo 123. Para la verificación de los hechos o las omisiones podrán realizarse todas las diligencias que se consideren conducentes, como visitas, inspecciones o toma de muestras.

Artículo 124. Cuando la autoridad competente encuentre plenamente comprobado que el hecho investigado no ha existido, que el presunto infractor no lo cometió, que las disposiciones legales de carácter sanitario no lo consideran como violación o que el procedimiento de sanciones no podía iniciarse o proseguirse, procederá a declararlo así y ordenará cesar todo procedimiento contra el inculpado notificándole en forma personal sobre tal decisión.

Artículo 125. Realizadas las anteriores diligencias, mediante notificación personal al efecto, se pondrá en conocimiento al presunto infractor de los cargos que se le formulan.

El inculpado podrá conocer, fotocopiar y examinar el expediente administrativo personalmente o acompañado de un abogado.

Artículo 126. Si no fuera posible hacer la notificación por no encontrarse el representante legal del establecimiento, la persona responsable o la persona natural inculpada, se dejará una citación escrita para que la persona allí indicada concurra a notificarse, dentro de los cinco días hábiles. Si así no lo hiciera, se fijará un edicto, en lugar público visible de la secretaría de la oficina de la autoridad sanitaria competente, durante los cinco días hábiles, al vencimiento de los cuales se entenderá surtida la notificación.

Artículo 127. Dentro de los diez días hábiles siguientes al de la notificación, el presunto infractor, directamente o por medio de apoderado, podrá presentar sus descargos en forma escrita y aportar o solicitar la práctica de las pruebas que considere pertinentes.

Artículo 128. El Ministerio de Salud decretará la práctica de las pruebas que considere conducentes, señalando, para los efectos, un término que no podrá ser superior a diez días.

Artículo 129. Vencido el término de que trata el artículo anterior y dentro de los cinco días hábiles posteriores, la autoridad competente procederá a calificar la falta y a imponer la sanción correspondiente, de acuerdo con dicha calificación.

Artículo 130. Si se encontrara que no se ha incurrido en violación de alguna de las disposiciones de la presente Ley, se expedirá una resolución por medio de la cual se declara exonerado de responsabilidades al presunto infractor y se ordenará archivar el expediente.

Artículo 131. El recurso de reconsideración podrá ser interpuesto dentro de los cinco días hábiles, contados a partir de la notificación de la resolución de primera instancia. Una vez interpuesto el recurso, la autoridad dará en traslado del escrito a la contraparte si la hubiera, por el término de tres días hábiles para que objete o se pronuncie sobre el escrito.

La autoridad tendrá quince días para practicar las pruebas que resulten indispensables y tendrá treinta días para resolver el recurso señalado.

Artículo 132. El recurso de apelación será interpuesto ante la autoridad de primera o segunda instancia en el acto de notificación o por escrito, a través de apoderado judicial, dentro del término de cinco días hábiles, contado a partir de la fecha de la notificación de la resolución.

Si el apelante anuncia la presentación de nuevas pruebas en segunda instancia, se señalará un término de quince días hábiles para la práctica de estas.

La autoridad tendrá treinta días para resolver.

Artículo 133. Cuando, como resultado de una investigación adelantada por una autoridad sanitaria, se encontrara que la sanción a imponer es de competencia de otra autoridad, deberán remitirse a ella las diligencias adelantadas para lo que sea pertinente.

Artículo 134. Toda persona o entidad oficial distinta de las que integran el Sistema Nacional de Salud que tenga pruebas o indicios de conductas o hechos que se estén investigando deberán ponerlos a disposición del Ministerio de Salud, de oficio o a solicitud de este para lo que estime procedente.

Artículo 135. La Policía Nacional prestará toda su colaboración al Ministerio de Salud para que cumpla a cabalidad sus funciones.

Título VIII
Disposiciones Finales

Artículo 136. Quedan excluidos del ámbito de la presente Ley la sangre y los derivados sanguíneos, así como los procedimientos de investigación in vitro con células que no incluyan una aplicación en el cuerpo humano.

Artículo 137. El Ministerio de Salud establecerá los mecanismos de coordinación e integración de los servicios y equipos de trasplantes con la Caja de Seguro Social.

Artículo 138. La presente Ley será reglamentada por el Órgano Ejecutivo.

Artículo 139. Esta Ley deroga la Ley 52 de 12 de diciembre de 1995.

Artículo 140. Esta Ley empezará a regir el día siguiente al de su promulgación.

COMUNÍQUESE Y CÚMPLASE.

Proyecto 14 de 2009 aprobado en tercer debate en el Palacio Justo Arosemena, ciudad de Panamá, a los 26 días del mes de enero del año dos mil diez.

El Presidente,

José Luis Varela R.

El Secretario General,

Wigberto E. Quintero G.

ÓRGANO EJECUTIVO NACIONAL. PRESIDENCIA DE LA REPÚBLICA.
PANAMÁ, REPÚBLICA DE PANAMÁ, DE 8 DE febrero DE 2010.

RICARDO MARTINELLI BERROCAL
Presidente de la República

FRANKLIN VERGARA J.
Ministro de Salud

REPÚBLICA DE PANAMÁ

DECRETO No. 155
(de 29 de diciembre de 2009)

Por el cual se nombra a la Viceministra de Ordenamiento Territorial del Ministerio de Vivienda y Ordenamiento Territorial

EL PRESIDENTE DE LA REPÚBLICA
en uso de sus facultades constitucionales y legales,

DECRETA:

ARTÍCULO ÚNICO: Nómbrese a MARTA DE ÁLVAREZ, con cédula No.9-82-1418 y seguro social 231-0067, en el cargo de Viceministra de Ordenamiento Territorial del Ministerio de Vivienda y Ordenamiento Territorial, posición No.10, correspondiente a la planilla No.1, salario B/.3,000.00, con cargo a la Partida Presupuestaria 0.14.0.1.001.01.01.001 y Gastos de Representación por B/.3,000.00, Partida 0.14.0.1.001.01.01.030.

PARÁGRAFO: El presente Decreto entrará en vigencia a partir de la toma de posesión.

COMUNÍQUESE Y CÚMPLASE

Dado en la Ciudad de Panamá, a los veintinueve días del mes de diciembre del año dos mil nueve (2009).

RICARDO MARTINELLI BERROCAL
Presidente de la República

GACETA OFICIAL DIGITAL

GOBIERNO DE LA REPÚBLICA DE PANAMÁ

Año CXI **Panamá, R. de Panamá viernes 06 de febrero de 2015** **Nº 27716**

CONTENIDO

MINISTERIO DE LA PRESIDENCIA
Decreto Nº 197-A
(De jueves 11 de diciembre de 2014)

QUE DESIGNA AL SECRETARIO GENERAL ENCARGADO.

MINISTERIO DE LA PRESIDENCIA
Decreto Nº 11
(De martes 20 de enero de 2015)

QUE DESIGNA A LA MINISTRA Y AL VICEMINISTRO DE TRABAJO Y DESARROLLO LABORAL, ENCARGADOS.

MINISTERIO DE LA PRESIDENCIA
Decreto Nº 143
(De lunes 2 de febrero de 2015)

QUE DESIGNA AL ADMINISTRADOR GENERAL DE LA AUTORIDAD NACIONAL PARA LA INNOVACIÓN GUBERNAMENTAL, ENCARGADO.

MINISTERIO DE COMERCIO E INDUSTRIAS
Decreto Ejecutivo Nº 40
(De martes 3 de febrero de 2015)

QUE REGLAMENTA EL PROCEDIMIENTO DE REVISIÓN DE AJUSTES DE PRECIOS Y LA COMISIÓN DE AJUSTES DE PRECIOS.

MINISTERIO DE EDUCACIÓN
Decreto Ejecutivo Nº 7
(De martes 3 de febrero de 2015)

QUE CONCEDE AUTORIZACIÓN DE FUNCIONAMIENTO PROVISIONAL POR SEIS (6) AÑOS A LA UNIVERSIDAD PARTICULAR DENOMINADA UNIVERSIDAD EUROAMERICANA UEA.

MINISTERIO DE SALUD
Decreto Ejecutivo Nº 6
(De martes 3 de febrero de 2015)

QUE MODIFICA EL DECRETO EJECUTIVO NO. 1843 DE 16 DE DICIEMBRE DE 2014, QUE REGLAMENTA EL COMITÉ NACIONAL DE BIOÉTICA DE LA INVESTIGACIÓN DE PANAMÁ.

MINISTERIO DE SEGURIDAD PÚBLICA
Decreto Ejecutivo Nº 2
(De martes 3 de febrero de 2015)

QUE ESTABLECE LA COMISIÓN DE SEGUIMIENTO PARA LA REVISIÓN DE LAS SOLICITUDES PRESENTADAS POR LOS EX MIEMBROS DE LA FUERZA PÚBLICA DESTITUIDOS EN APLICACIÓN DEL ARTÍCULO 184 DE LA CONSTITUCIÓN POLÍTICA Y DE LAS JUBILACIONES ORDENADAS DURANTE EL PERIODO COMPRENDIDO ENTRE EL 1 DE JULIO DE 2009 AL 30 DE JUNIO DE 2014.

CORTE SUPREMA DE JUSTICIA
Fallo Nº S/N
(De viernes 21 de noviembre de 2014)

POR EL CUAL SE DECLARA NULO POR ILEGAL, EL ACUERDO NO. 101-40-55 DE 24 DE NOVIEMBRE DE 2009, CORREGIDO POR EL ACUERDO NO. 101-40-56 DE 1 DE DICIEMBRE DE 2009, EMITIDOS POR EL CONSEJO MUNICIPAL DE COLÓN.

AVISOS / EDICTOS

REPÚBLICA DE PANAMA

DECRETO N.º 197-A
De 11 de Diciembre de 2014

Que designa al Secretario General, encargado

EL PRESIDENTE DE LA REPÚBLICA
en uso de sus facultades constitucionales y legales,

DECRETA:

Artículo Único. Designese a **CONCEPCIÓN CORRO**, actual Asesora Legal del Despacho Superior del Ministerio de Seguridad Pública, como Secretaria General del Ministerio de Seguridad Pública, encargada, del 15 al 19 de diciembre de 2014, inclusive, mientras el titular, **ALVARO A. VARELA,** esté ausente.

Parágrafo. Esta designación rige a partir de la Toma de Posesión del cargo.

COMUNÍQUESE Y CÚMPLASE.

Dado en la ciudad de Panamá, a los 11 días del mes de diciembre de dos mil catorce (2014)

JUAN CARLOS VARELA RODRIGUEZ
Presidente de la República

PRESIDENCIA DE LA REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

REPÚBLICA DE PANAMÁ

Decreto No. 11
(Del 30 de Enero de 2015)

Que designa a la Ministra y al Viceministro de Trabajo y Desarrollo Laboral, Encargados

EL PRESIDENTE DE LA REPÚBLICA

En uso de sus facultades constitucionales y legales,

D E C R E T A:

ARTÍCULO 1. Desígnese a **ZULPHY SADAY SANTAMARIA**, actual Viceministra de Trabajo y Desarrollo Laboral, como Ministra de Trabajo y Desarrollo Laboral, encargada, del 27 al 29 de enero de 2015, inclusive, mientras el titular **LUIS ERNESTO CARLES**, esté de viaje en misión oficial.

ARTÍCULO 2. Desígnese a **SAMUEL RIVERA**, actual Secretario General del Ministerio de Trabajo y Desarrollo Laboral, como Viceministro de Trabajo y Desarrollo Laboral, encargado, del 27 al 29 de enero de 2015, inclusive, mientras la titular, **ZULPHY SADAY SANTAMARÍA**, ocupe el cargo de Ministra, Encargada.

PARÁGRAFO: Estas designaciones rigen a partir de la Toma de Posesión del cargo.

COMUNÍQUESE Y PUBLÍQUESE,

Dado en la ciudad de Panamá, a los 30 días del mes de Enero de 2015.

JUAN CARLOS VARELA
Presidente de la República

PRESIDENCIA DE LA REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA

DECRETO N.º 143
De 2 de Febrero de 2015

Que designa al Administrador General de la Autoridad Nacional para la Innovación Gubernamental, encargado

EL PRESIDENTE DE LA REPÚBLICA
en uso de sus facultades constitucionales y legales,

DECRETA:

ARTÍCULO 1. Se designa a **IGNACIO MOLINO**, actual Director de Finanzas y Administración de la Autoridad Nacional para la Innovación Gubernamental, como Administrador General de la Autoridad Nacional para la Innovación Gubernamental, encargado, del 20 de febrero al 8 de marzo de 2015, inclusive, mientras el titular **IRVIN HALMAN**, esté de viaje en misión oficial.

PARÁGRAFO. Esta designación rige a partir de la Toma de Posesión del cargo.

COMUNÍQUESE Y CÚMPLASE.

Dado en la ciudad de Panamá, a los Dos (2) días del mes de Febrero de dos mil quince (2015).

JUAN CARLOS VARELA RODRÍGUEZ
Presidente de la República

ÁLVARO ALEMÁN
Ministro de la Presidencia

PRESIDENCIA DE LA REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

REPÚBLICA DE PANAMÁ
MINISTERIO DE COMERCIO E INDUSTRIAS

DECRETO EJECUTIVO N.° 40
De 3 de Febrero de 2015

Que reglamenta el procedimiento de revisión de ajustes de precios y la Comisión de Ajustes de Precios

EL PRESIDENTE DE LA REPÚBLICA
en uso de sus facultades constitucionales y legales,

CONSIDERANDO:

Que los artículos 199 y 200 de la Ley 45 del 31 de octubre del 2007, facultan excepcionalmente al Órgano Ejecutivo para formular y reglamentar las políticas de regulación de precios;

Que en virtud de lo anterior, se emite el Decreto Ejecutivo N.°165 de 1 de julio de 2014, que fija temporalmente los precios máximos de venta al por menor de veintidós (22) productos de la canasta básica familiar de alimentos en la República de Panamá y se adoptan otras disposiciones;

Que el artículo 5 del precitado Decreto Ejecutivo, crea la Comisión de Ajustes de Precios conformada por el Ministerio de Comercio e Industrias quien la presidirá, el Ministerio de Desarrollo Agropecuario y el Ministerio de Economía y Finanzas;

Que la Comisión de Ajustes de Precios podrá realizar ajustes a los precios establecidos en el Decreto Ejecutivo N.°165 de 1 de julio de 2014, en la medida que las condiciones de los mercados así lo requiera;

Que con el propósito de atender eficazmente las solicitudes de revisión de ajuste de precios, se hace necesario establecer los procedimientos de solicitudes de revisión de control de precios y disposiciones relativas al funcionamiento de la Comisión de Ajustes de Precios, atendiendo la naturaleza especial que ostenta el referido régimen de control de precios,

DECRETA:

Artículo 1. Objetivo. Este Decreto Ejecutivo reglamenta los procedimientos de ajustes de precios que deberá realizar la Comisión de Ajuste de Precios, en adelante CAP, con el fin de establecer reglas claras para evaluar las solicitudes de revisión de control de precios ya sea por incremento de costos de producción o importación, por caso fortuito o fuerza mayor.

Artículo 2. Integrantes de la Comisión. La CAP está conformada por los siguientes miembros con derecho a voz y voto:

1. El Ministro de Comercio e Industrias, o quien éste designe, quien la presidirá.

2. El Ministro de Desarrollo Agropecuario, o quien éste designe.

3. El Ministro de Economía y Finanzas o quien éste designe.

Con el fin de atender eficientemente las solicitudes de revisión de control de precio, los comisionados podrán ser cubiertos por un suplente designado por el principal para suplirlo en sus ausencias.

Artículo 3. Convocatoria y quórum. La CAP se reunirá a requerimiento de alguno de sus integrantes. La solicitud de reunión se realizará por escrito y explicando el motivo de la convocatoria, la cual deberá hacerse al menos con tres (3) días hábiles de antelación a la fecha de la reunión.

El quórum reglamentario para iniciar las reuniones así como las decisiones tomadas será por mayoría simple.

Artículo 4. Funciones de la Comisión de Ajustes de Precios. La CAP tendrá las siguientes funciones:

1. Diligenciar las solicitudes de revisión de control de precios ya sea por fuerza mayor o caso fortuito, o por revisión de incremento de los costos de producción o importación de los productos.

2. Emitir criterio al Órgano Ejecutivo de las solicitudes de revisión de control de precio, ya sea por solicitud de revisión ordinaria: por incremento de costos de producción o importación; o revisión excepcional: por caso fortuito o fuerza mayor.

3. Asesorar al Órgano Ejecutivo sobre cualquier acción relacionada con la política de control de precios establecida.

Artículo 5. Facultados a requerir solicitudes de ajustes. Las solicitudes de revisión de precios, productos o especificaciones de los productos objeto de regulación en el Decreto N.°165 de 1 de julio de 2014, serán presentadas ante la CAP, por conducto del Ministerio de Comercio e Industrias y podrán requerirla los productores o importadores, ya sea de empresas individuales, asociaciones empresariales o gremios.

Artículo 6. Solicitudes de revisión. Las solicitudes de revisión podrán ser:

PRESIDENCIA DE LA REPÚBLICA DE PANAMÁ
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1. Solicitud de revisión de ajuste ordinario: Es aquella solicitud efectuada con sustento a las condiciones del mercado, ya sea por incremento de costos de producción, importación o distribución.

2. Solicitud de revisión de ajuste excepcional: Es aquella efectuada con sustento a condiciones de incremento en los costos por causas de fuerza mayor o caso fortuito.

Artículo 7. Solicitudes de revisión de ajuste ordinario. Deberán ser presentadas por medio escrito ante la CAP, por conducto de la persona natural o jurídica debidamente legitimada y con los aportes de una Estructura de Costos, del o los producto(s) que requieran revisión de ajustes, bajo el formulario de Solicitud de Ajuste de Precio especificado para tal fin.

Artículo 8. Procedimiento. Podrá darse curso a la solicitud de revisión de ajuste ordinario una vez se haya provisto a la CAP, de toda la información y documentos que sustentan la misma, en caso que haya sido requerida.

La CAP realizará convocatoria a reunión acorde a los procedimientos establecidos y circulará a los comisionados los documentos aportados por los solicitantes para las revisiones pertinentes.

En caso que la CAP lo estime necesario, solicitará la creación de sub-comisiones técnicas para solventar eficazmente la revisión y convocará cuantas reuniones sean necesarias para la toma de decisiones dentro del término establecido.

La CAP sesionará realizando la evaluación, una vez haya recibo oportunamente toda la información requerida con los documentos pertinentes, y adoptará su criterio por mayoría simple de todos los comisionados; para lo cual tendrá un término no mayor a treinta (30) días calendario para emitir criterio. Si en dicho término no ha resuelto la solicitud, se entenderá que la misma ha sido aprobada.

Artículo 9. Solicitudes de revisión de ajuste excepcional. En la eventualidad que surja un hecho de fuerza mayor o caso fortuito; se deberá comunicar el mismo en un término no mayor a diez (10) días hábiles luego de ocurrido el mismo, por conducto de la persona natural o jurídica de los importadores o productores afectados y debidamente legitimados.

Dicha solicitud se realizará por escrito a la CAP, evidenciando la revisión de ajuste excepcional con el debido aporte de las pruebas pertinentes, a menos que se traten de hechos notorios.

PROCURADURÍA DE LA REPÚBLICA DE PANAMÁ
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A partir de la solicitud de revisión de ajuste excepcional en debida forma, la CAP sesionará y adoptará su criterio por mayoría simple en un término no mayor a quince (15) días calendario, e igualmente, en caso de requerirlo se creará subcomisión técnica para tal fin.

En caso de no resolver la solicitud excepcional en el término descrito, se entenderá que la misma ha sido aprobada.

Artículo 10. Correspondencia. Se faculta al Presidente de la CAP, la firma de correspondencia y respuesta de notas que versen sobre aclaraciones al Decreto Ejecutivo N.°165 de 1 de julio del 2014, previa anuencia de los comisionados de la CAP.

Artículo 11. Vigencia. Este Decreto Ejecutivo comenzará a regir el día siguiente a partir de su promulgación.

FUNDAMENTO DE DERECHO: Decreto Ejecutivo N.°165 de 1 de julio de 2014, modificado por el Decreto Ejecutivo N.°303 de 24 de diciembre de 2014.

COMUNÍQUESE Y CÚMPLASE.

Dado en la ciudad de Panamá, a los 3 días del mes de Febrero de 2015.

JUAN CARLOS VARELA R.
Presidente de la República

MELITÓN A. ARROCHA R.
Ministro de Comercio e Industrias

PRESIDENCIA DE LA REPÚBLICA
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

REPÚBLICA DE PANAMÁ
MINISTERIO DE EDUCACIÓN

DECRETO EJECUTIVO N.° 7
De 3 de Febrero de 2015

Que concede autorización de funcionamiento provisional por seis (6) años a la universidad particular denominada Universidad Euroamericana UEA

EL PRESIDENTE DE LA REPÚBLICA,
en uso de sus facultades constitucionales y legales;

CONSIDERANDO:

Que la sociedad GRUPO EDUCATIVO EUROAMERICANO, S.A., inscrita a la Ficha 595565, Documento 1261221, de la sección de Personas Mercantil del Registro Público de Panamá, mediante memorial suscrito por la señora MARTHA ZALIME MOSTAFFA DURAN, mujer, venezolana, mayor de edad, portadora de la cédula de identidad personal N.°E-8-120915, presidenta y representante legal de la Sociedad, solicitó autorización de funcionamiento para la institución universitaria particular denominada Universidad Euroamericana UEA;

Que GRUPO EDUCATIVO EUROAMERICANO, S.A. aportó la propuesta educativa para la creación de la Universidad Euroamericana UEA, la cual está integrada por la certificación de Registro Público que acredita la existencia de su personería jurídica, copia del pacto social protocolizado a través de Escritura N.°20,658 de 11 de diciembre de 2007, proyecto institucional de la institución universitaria particular, proyecto de estatuto y reglamento universitario, oferta académica con las carreras de licenciatura en Administración de Empresa, licenciatura en Gerencia de Recursos Humanos, licenciatura en Gestión Ambiental, licenciatura en Administración en Turismo, licenciatura en Salud Ocupacional y licenciatura en Educación con énfasis en Estudios Virtuales, perfiles de formación de las autoridades académicas y sus docentes, evidencias de la infraestructura y el correspondiente presupuesto institucional y estudio económico;

Que el Consejo Nacional de Evaluación y Acreditación Universitaria de Panamá emitió concepto favorable a la creación de la Universidad Euroamericana UEA, a través del Informe Ejecutivo N.°10-2014 de 16 de junio de 2014, el cual, a su vez, está fundamentado en el Informe Favorable de la Comisión Técnica de Fiscalización N.°CTF-IT-0023-2014 de 11 de junio de 2014;

Que el informe favorable del Consejo Nacional de Evaluación y Acreditación Universitaria de Panamá expresa que el proyecto educativo Universidad Euroamericana UEA cuenta con los documentos que exige el artículo 32 de la Ley 30 de 20 de julio de 2006 y la Resolución N.°5 de 20 de junio de 2011, que aprueba la guía que dicho Consejo utiliza para evaluar las solicitudes de autorización para la creación y funcionamiento de las universidades;

Que el proyecto educativo Universidad Euroamericana UEA tiene la aprobación para impartir, en la sede principal de la ciudad de Panamá, las carreras de licenciatura en Administración de Empresa, licenciatura en Gerencia de Recursos Humanos, licenciatura en Gestión Ambiental, licenciatura en Administración en Turismo, licenciatura en Salud Ocupacional y licenciatura en Educación con énfasis en Estudios Virtuales;

Que las autoridades académicas y el personal docente del proyecto educativo Universidad Euroamericana UEA está integrado por profesionales idóneos, los cuales, deberán cumplir, como mínimo, los requisitos establecidos en el estatuto orgánico de la Universidad Euroamericana UEA;

Que el proyecto educativo Universidad Euroamericana UEA cuenta con recursos propios y con la infraestructura e instalaciones que ofrecen las condiciones físicas, técnicas y tecnológicas apropiadas para la misión que propone desarrollar;

Que la Universidad Euroamericana UEA realizará la promoción de grados académicos y la expedición de títulos profesionales de acuerdo con las regulaciones contenidas en su Estatuto Universitario;

Que en virtud de lo anterior, este Órgano considera viable otorgar la autorización de funcionamiento solicitada, toda vez que, el proyecto educativo Universidad Euroamericana UEA cumple con las exigencias establecidas en el artículo 32 de la Ley 30 de 20 de julio de 2006;

Que el artículo 33 de la Ley 30 de 20 de julio de 2006 y el artículo 107 del Decreto Ejecutivo N.°511 de 5 de julio de 2010, este último en orden reglamentario, establecen que le corresponde al Órgano Ejecutivo otorgar la autorización de funcionamiento de manera provisional por el período de seis (6) años, a las universidades particulares que reúnan lo establecido en el artículo 32 de la Ley 30 de 20 de julio de 2006 y que cuenten con el concepto favorable del Consejo Nacional de Evaluación y Acreditación Universitaria de Panamá, que se fundamentará en el informe favorable de la Comisión Técnica de Fiscalización;

Que es deber del Estado, por conducto del Ministerio de Educación, atender el servicio de la educación nacional en su aspecto intelectual, moral, cívico y físico, además de fijar las bases para el reconocimiento de títulos académicos y profesionales y otorgar autorización de funcionamiento a las universidades particulares en la República de Panamá, por lo tanto,

DECRETA:

Artículo 1. Autorizar el funcionamiento provisional, por seis (6) años, a la universidad particular denominada Universidad Euroamericana, identificada con la sigla UEA, bajo el amparo de GRUPO EDUCATIVO EUROAMERICANO, S.A., inscrita a la Ficha 595565, Documento 1261221, de la sección de Personas Mercantil del Registro Público de Panamá, la cual funcionará en la urbanización El Carmen, calle Ramón Arias con calle David de Castro, planta baja, pisos 1 y 2 del edificio ABSA, corregimiento de Bella Vista, ciudad y provincia de Panamá.

Artículo 2. En caso de apertura de una nueva sede la Universidad Euroamericana UEA deberá solicitar al Ministerio de Educación la correspondiente autorización de funcionamiento. Esta autorización de funcionamiento también estará sujeta a lo establecido en los artículos 32 y 33 de la Ley 30 de 20 de julio de 2006, así como a lo dispuesto en el artículo 107 del Decreto Ejecutivo 511 de 5 de julio de 2010 o a las regulaciones vigentes al momento de la respectiva solicitud.

Artículo 3. Cualquier modificación a los estatutos, planes de estudio y creación de nuevas carreras, requerirá autorización del Ministerio de Educación, previa aprobación del Consejo Nacional de Evaluación y Acreditación Universitaria de Panamá y de la Comisión Técnica de Fiscalización.

Artículo 4. Reconocer los títulos profesionales de pregrado, grado y postgrado que expida la Universidad Euroamericana UEA, siempre que hayan sido evaluados y aprobados por la Comisión Técnica de Fiscalización.

Artículo 5. La Universidad Euroamericana UEA podrá solicitar la exoneración del pago de impuestos fiscales, así como las tasas de correo y telégrafos en la República de Panamá, conforme lo establece el artículo 43 de la Ley 30 de 20 de julio de 2006.

Artículo 6. En caso que la Universidad Euroamericana UEA cese sus funciones, deberá comunicarlo oficialmente al Órgano Ejecutivo y deberá entregar al Ministerio de Educación

MINISTERIO DE LA PRESIDENCIA
REGISTRADO

toda la documentación de los estudiantes, docentes y de los programas, de acuerdo a lo establecido en el artículo 40 de la Ley 30 de 2006 y el artículo 143 del Decreto Ejecutivo N.°511 de 5 de julio de 2010.

Artículo 7. El presente Decreto Ejecutivo empezará a regir al día siguiente de su promulgación.

FUNDAMENTO DE DERECHO: Ley 30 de 20 de julio de 2006 y Decreto Ejecutivo N.°511 de 5 de julio de 2010.

Dado en la ciudad de Panamá, a los Tres (3) días del mes de Febrero de dos mil quince (2015).

COMUNÍQUESE Y CÚMPLASE.

JUAN CARLOS VARELA RODRÍGUEZ
Presidente de la República

MARCELA PAREDES DE VÁSQUEZ
Ministra de Educación

PRESIDENCIA DE LA REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

REPÚBLICA DE PANAMÁ
MINISTERIO DE SALUD

DECRETO EJECUTIVO N.° 6
De 3 de Febrero de 2015

Que modifica el Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014, Que reglamenta el Comité Nacional de Bioética de la Investigación de Panamá

EL PRESIDENTE DE LA REPÚBLICA
en uso de sus facultades constitucionales y legales,

CONSIDERANDO:

Que el artículo 83 de la Constitución Política de la República de Panamá, señala que el Estado formulará la política científica nacional destinada a promover el desarrollo de la ciencia y la tecnología y su artículo 109 establece que es función esencial del Estado velar por la salud de la población de la República;

Que el Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014, Que reglamenta el Comité Nacional de Bioética de la Investigación de Panamá, (CNBI), establece en el numeral 5 del artículo 9 que el CNBI se encargará de revisar y aprobar, de acuerdo a las Buenas Prácticas Clínicas, los protocolos de investigación multicéntricos;

Que igualmente, el artículo 30 del Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014, establece que los protocolos multicéntricos deberán ser aprobados por el CNBI;

Que es necesario fortalecer la especialización del Comité Nacional de Bioética de la Investigación en sus funciones de acreditación de comités de bioética de la investigación clínica, con la finalidad de promover la creación de los mismos e impulsar la investigación clínica de excelencia;

Que así mismo, es necesario fortalecer la especialización del CNBI en la evaluación de protocolos complejos en células madre y potenciar su función de garantía que ejerce en la protección de los intereses de los pueblos originarios relacionados con la investigación clínica;

Que en aras de organizar el Sistema Nacional de Investigación Clínica a fin de procurar su eficiencia y el acercamiento a los centros en los cuales evaluará la investigación clínica, esta institución ha considerado necesario la modificación del Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014, con la finalidad de que los protocolos multicéntricos sean aprobados por los Comités Institucionales de Bioética que estén acreditados por el CNBI;

Que el artículo 66 del Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014, establece que puede ser modificado parcial o totalmente por el Ministerio de Salud,

DECRETA:

Artículo 1. El artículo 9 del Decreto Ejecutivo N.º1843 de 16 de diciembre de 2014, queda así:

Artículo 9. El CNBI tendrá funciones consultivas, respecto de toda persona natural o jurídica con intereses en la investigación clínica nacional, incluyendo a los sujetos reclutados para la investigación clínica, en lo concerniente a todas las actividades inherentes a la investigación clínica nacional. En virtud de dichas funciones, el CNBI se encargará de:

1. Acreditar, supervisar y auditar los comités institucionales de bioética de la investigación.
2. Certificar y aprobar la puesta en funcionamiento de los nuevos comités de bioética de la investigación que se conformen a nivel nacional.
3. Revisar y aprobar, de acuerdo con las Buenas Prácticas Clínicas, los protocolos de investigación en los cuales los sujetos participantes pertenezcan a las comunidades indígenas que habitan en el territorio nacional, siendo dicha pertenencia uno de los criterios de inclusión en el estudio. En todo caso, el CNBI oirá el parecer de las autoridades tradicionales de los grupos indígenas incluidos en el estudio.
4. Revisar y aprobar, de acuerdo con las Buenas Prácticas Clínicas, los estudios referidos a la investigación clínica de células madre.
5. Fomentar la sistematización y el manejo virtual de los comités de bioética de la investigación para promover la transparencia en el ejercicio de sus funciones.
6. Crear y administrar el Sistema Nacional de Información de la Investigación Clínica que se realiza en el país; dicho sistema promoverá, entre otras las siguientes actividades, iniciativas y políticas:

   a. Páginas web de cada uno de los comités, a través de las cuales se pueda hacer un seguimiento pormenorizado del estado y de la evolución de cada uno de los protocolos de investigación hasta su terminación. Dichas páginas separarán la información de acceso general, de la de acceso restringido.
   b. Sitio web general del CNBI en la cual se separarán la información de acceso público, y aquella de acceso restringido.
   c. Creación de un programa de anticorrupción y transparencia de la investigación clínica, equivalente al programa norteamericano FCPA (Foreing Corrupt Practices Act).
   d. Política del "cero papel", de acuerdo con los lineamientos nacionales en la materia. En dicha política se incluyen los textos de los protocolos de investigación, los cuales se presentarán a la evaluación de los comités en formato digital exclusivamente, y se exceptúan los siguientes documentos:

d.1 Formulario del consentimiento informado.

d.2 Materiales con destino a los sujetos o pacientes.

d.3 Cartas de comunicación entre los Comités y los investigadores.

d.4 Carta para la Dirección Nacional de Farmacia y Drogas.

d.5 Formulario de declaración de confidencialidad de los investigadores respecto a los sujetos reclutados en la investigación clínica.

7. Recomendar políticas públicas que puedan contribuir a un mejor desarrollo de la investigación clínica nacional, armonizando la excelencia científica con el rigor y las exigencias de naturaleza ética.
8. Promover la formación y capacitación permanente de todos los actores involucrados en la investigación clínica nacional.

Artículo 2. El artículo 30 del Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014, queda así:

Artículo 30. En el caso de los protocolos multicéntricos, estos podrán ser aprobados por un solo comité, que se encuentre acreditado por el CNBI, salvo que una de las instituciones públicas en que hubiere de realizarse, indicase la competencia de un comité en especial; en dicho caso, tal protocolo podrá presentarse para su evaluación en más de un comité.

Artículo 3. El presente Decreto Ejecutivo comenzará a regir el día siguiente de su promulgación.

FUNDAMENTO DE DERECHO: Decreto Ejecutivo N.°1843 de 16 de diciembre de 2014.

COMUNÍQUESE Y CÚMPLASE.

Dado en la ciudad de Panamá, a los 3 días del mes de Febrero de dos mil quince (2015).

JUAN CARLOS VARELA RODRÍGUEZ
Presidente de la República

MIGUEL ANTONIO MAYO DI BELLO
Ministro de Salud, encargado

PRESIDENCIA DE LA REPÚBLICA
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

REPÚBLICA DE PANAMÁ
MINISTERIO DE SEGURIDAD

DECRETO EJECUTIVO N.º 2
De 3 de Febrero de 2015

Que establece la Comisión de Seguimiento para la revisión de las solicitudes presentadas por los ex miembros de la Fuerza Pública destituidos en aplicación del artículo 184 de la Constitución Política y de las jubilaciones ordenadas durante el periodo comprendido entre el 1 de julio de 2009 al 30 de junio de 2014

EL PRESIDENTE DE LA REPÚBLICA,
en uso de sus facultades constitucionales y legales,

CONSIDERANDO:

Que durante el mes de octubre de 2014, se recibió por parte de ex miembros de distintos componentes de la Fuerza Pública y el Servicio de Protección Institucional, sendas solicitudes de revisión de destituciones hechas conforme al artículo 184 de la Constitución Política y las jubilaciones ordenadas en el periodo 2009-2014;

Que el artículo 42 de la Constitución Política de la República de Panamá, establece que toda persona tiene derecho a acceder a la información personal contenida en bases de datos o registros públicos y privados y a requerir su rectificación y protección, así como su supresión de conformidad con lo previsto en la Ley;

Que se considera procedente establecer una comisión para dar seguimiento a la atención de dichas solicitudes y revisar cada caso individualmente,

RESUELVE:

Artículo 1. Se establece la Comisión de Seguimiento para la revisión de las destituciones efectuadas en aplicación del artículo 184 de la Constitución Política y de las jubilaciones ordenadas, ambas durante el período comprendido entre el 1ero de julio de 2004 al 30 de junio de 2014, e incluidas en la lista entregada a las autoridades en octubre de 2014 por los afectados.

Artículo 2. La Comisión de Seguimiento estará integrada así:

1. Cuatro representantes por el Ministerio de Seguridad Pública.
2. Dos representantes por el Ministerio de la Presidencia.
3. Tres representantes por parte de los afectados.

Artículo 3. Los representantes del Ministerio de Seguridad Pública serán designados por el ministro respectivo y estará integrada por:

1. Un representante del Ministro de Seguridad Pública, quien presidirá la Comisión de Seguimiento.
2. Un miembro de la Policía Nacional
3. Un miembro del Servicio Nacional de Fronteras
4. Un miembro del Servicio Nacional Aeronaval

Artículo 4. Los representantes del Ministerio de la Presidencia serán designados por el ministro respectivo y estará integrada por:

1. Un representante del Ministro de la Presidencia.
2. Un miembro del Servicio de Protección Institucional (SPI).

Artículo 5. Los representantes de los afectados serán designados por ellos.

Artículo 6. La Comisión de Seguimiento tendrá las siguientes funciones:

1. Revisar todos los casos presentados en la lista proporcionada en el mes de octubre de 2014.
2. Diseñar un cuadro explicativo de cada unidad y su recomendación en un plazo no mayor a 60 días a partir de la promulgación de este decreto.
3. Presentar el Presidente de la República, una explicación y recomendación legal para cada caso en particular.

Artículo 7. La Comisión de Seguimiento estará adscrita al Ministerio de Seguridad Pública, que designará lo necesario para que puedan reunirse y cumplir sus funciones.

Artículo 8. La actividad de la Comisión de Seguimiento debe entenderse sin colisión con las atribuciones constitucionales y legales de los entes responsables de administrar justicia, en relación a los procesos resueltos o en curso relacionados con los temas objeto de atención por la Comisión de Seguimiento.

Artículo 9. El presente Decreto Ejecutivo comenzará a regir a partir de su promulgación.

FUNDAMENTO LEGAL: Artículo 42 de la Constitución Política de la República de Panamá.

COMUNÍQUESE Y CÚMPLASE.

Dada en la ciudad de Panamá, a los 3 días del mes de Febrero del año dos mil quince (2015).

JUAN CARLOS VARELA RODRÍGUEZ
Presidente de la República

RODOLFO AGUILERA FRANCESCHI
Ministro de Seguridad Pública

FIDEDIGNIDAD DE LA REPÚBLICA DE PANAMÁ
MINISTERIO DE LA PRESIDENCIA
REGISTRADO

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REPÚBLICA DE PANAMÁ

ÓRGANO JUDICIAL

CORTE SUPREMA DE JUSTICIA

SALA TERCERA DE LO CONTENCIOSO ADMINISTRATIVO Y LABORAL

Panamá, veintiuno (21) de noviembre de dos mil catorce (2014).

VISTOS:

En la secretaría de esta Sala *(de lo Contencioso Administrativo y Laboral)* de la Corte Suprema de Justicia, se recibió, el ***martes trece (13) de enero de 2010***, por parte del Licenciado LUIS ANTONIO CHIFUNDO AYALA, con cédula de identidad personal Nº3-79-1716 e idoneidad Nº7,046, apoderado judicial especial del señor **VIRGILIO CERRUD ANDRADE**, con cédula de identidad personal **Nº3-64-2619**; formal escrito de **DEMANDA CONTENCIOSO ADMINISTRATIVA DE NULIDAD**, contra el **ACUERDO Nº101-40-55 de 24 de noviembre de 2009** *"Por medio del cual, se disuelve y elimina de la estructura del Municipio de Colón a la Comisión de Educación del Distrito de Colón"*, dictado por el **CONCEJO MUNICIPAL DE COLÓN**, a efectos de lograr que esta Sala declare que es **Nulo** por **Ilegal** el mismo y, para que se hagan otras declaraciones *(véase las fojas 1, 2 y 15 a 34 del Exp. Cont. Admtivo.)*.

Concluidas *-a la fecha-* todas las fases procesales y procedimentales predispuestas en nuestra legislación para casos de la naturaleza del que nos ocupa, la Secretaría de esta Sala procedió a remitir el presente expediente y sus antecedentes a quien ha correspondido, hasta entonces, la sustanciación de tal proceso para la elaboración del proyecto y consecuente veredicto *(véase la foja 64 del Exp. Cont. Admtivo.)*.

En razón de lo anterior, partiremos realizando precisas anotaciones dimanantes de lo medular de las argumentaciones expuestas para defender sus respectivas posturas, en tal sentido, nos referimos a las realizadas por la parte hoy demandante, como a las de la Procuraduría de la Administración, propiamente, ello a efectos de entender y a su vez, compartir con nuestros lectores, como y/o en qué radica el acierto o desacierto en la emisión del acto administrativo demandado, mismo que en su parte resolutiva dice así:

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ACUERDA:

Artículo N°1: Disolver y eliminar de la estructura Orgánica del Municipio de Colón la Comisión Municipal de Educación del Distrito en razón de lo expuesto
Artículo N°2: Dejar sin efecto legal alguno el Acuerdo N°101-40-2 del 4 de octubre de 1983.
Artículo N°3: Corresponderá a este Honorable Concejo instituir los mecanismo a través de las Juntas Comunales que se encargarán de cumplir a cabalidad con las funciones que debió realizar este ente.
Artículo N°4: Este Acuerdo empezará a regir a partir de su promulgación y sanción.
Dado en la Ciudad de Colón, a los veinticuatro (24) días del mes de noviembre del año Dos Mil Nueve (2009).
.../.

Asimismo, transcribiremos la parte resolutiva del Acuerdo N°101-40-56 de 1 de diciembre de 2009 *"Por medio del cual, se hace corrección en el Primer Considerando y en el Artículo Segundo del Acuerdo N°101-40-55, del 24 de noviembre de 2009"*, mismo que a la letra dice:

/...

ACUERDA:

Artículo Único: Corríjase como en efecto se hace, el Primer Considerando y el Artículo Segundo del Acuerdo N°101-40-55 del 24 de noviembre de 2009.
Dado en la Ciudad de Colón, al primer (1) día del mes de diciembre del año Dos Mil Nueve (2009).
.../.

Dado lo anterior, es preciso exponer lo siguiente:

I. ARGUMENTOS DE LA PARTE DEMANDANTE:

Se tiene que el señor **VIRGILIO CERRUD ANDRADE** *(parte hoy demandante)*, por conducto de su apoderado especial, sostiene *-en lo medular de su escrito de demanda-* que el **ACUERDO N°101-40-55 de 24 de noviembre de 2009**, al igual que el Acuerdo que lo corrige *(N°101-40-56 de 1 de diciembre de 2009)*, ambos dictados por el Concejo Municipal de Colón, son violatorios de diversas normas legales, en tal sentido se refiere al contenido de los artículos 34, 35, 36, 37 y 52 de la Ley N°38 de 31 de julio de 2000 y, el de los artículos 17 numerales 5, 6 y 9, 18 numeral 5 y 39 de la Ley N°106 de 8 de octubre de 1973; por cuanto que, en este caso, dicho Concejo carece de competencia para dictar actos, a través de los cuales se desconozcan leyes nacionales, como viene a ser la Ley N°47 de 27 de septiembre de 1946 *"Ley Orgánica de Educación"*. De allí entonces, que considera y pide se declare el referido Acuerdo y su enmienda es **Ilegal** y, por ende, **Nulo** por contravenir claras disposiciones legales vigentes.

De hecho, como complemento y elemento histórico, manifiesta que el Municipio de Colón, en cumplimiento de lo predispuesto en el artículo 18 de la Ley N°47 de 27 de septiembre de 1946, dictó el Acuerdo N°101-40-21 de 24 de noviembre de 1983, a través del cual, creó e implementó la Junta Municipal de Educación, denominándola *"Comisión Municipal de Educación del Distrito de Colón"*, misma que desde entonces se constituyó en un organismo estatal. De allí que no puede ser disuelta ni eliminada por virtud de un Acuerdo Municipal, como ha pretendido el Concejo Municipal de Colón.

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II. INFORME DE CONDUCTA:

Vale anotar que, si bien, consta que esta Sala requirió por conducto del Juzgado Segundo Municipal del Distrito de Colón, en este caso, al Presidente del Concejo Municipal de Colón *(véase las fojas 36, 41 y 43 del Exp. Cont. Admtivo.)*, el Informe Explicativo de Conducta de que trata el artículo 33 de la Ley Nº33 de 11 de septiembre de 1946, dicho funcionario, a pesar de haberse notificado *(el 13 de abril de 2010)*, no presentó el mismo.

III. CRITERIO DE LA PROCURADURÍA DE LA ADMINISTRACIÓN:

Por su parte, el señor Procurador de la Administración, en lo medular de su opinión, expone en su Vista Nº951 de 30 de agosto de 2010 *(visible de fojas 45 a 49 del exp. Cont. Admtivo.)*, que:

/...

Para los fines del presente concepto, este despacho considera pertinente aclarar que las denominaciones "Comisión Municipal de Educación", aprobada por el Concejo Municipal de Colón, y Junta Municipal de Educación, contemplada en la Ley Nº47 de 1946, se refieren al mismo organismo, toda vez que tienen igual finalidad. (Cfr. foja 10 del expediente judicial).

En relación a lo anterior, esta Procuraduría observa que la referida Comisión o Junta Municipal de Educación tiene su origen en los artículos 34 y 35 del decreto Ejecutivo 305 de 30 de abril de 2004, por el cual se aprueba el texto único de la Ley 47 de 24 de septiembre de 1946, .../ Conforme puede leerse en el numeral 5 del artículo 18 de la Ley 106 de 8 de octubre de 1973, sobre Régimen municipal, esta norma faculta a los Concejos Municipales a colaborar con los centros educativos ubicados en su respectiva área, en la labor cultural y educativa, al señalar lo siguiente:

"Artículo 18: Los Concejos Municipales tendrán además las siguientes funciones:

...

5. Difundir la cultura y cooperar en la gestión administrativa de escuelas primarias, industriales, vocacionales de bellas artes y especiales, bibliotecas, músicas y academias de enseñanza especiales..."

De acuerdo con lo dispuesto por las citadas disposiciones legales, esta Procuraduría es de opinión que la "Comisión Municipal de Educación" o Junta Municipal de Educación, es un ente de carácter administrativo y educativo, establecido por ley, el cual debe existir en cada Municipio, y actuar coordinadamente con las dependencias del ramo respectivo; por tanto, el hecho que dicho organismo maneje un porcentaje de los fondos municipales destinados a la enseñanza del nivel primario y educación física, en las escuelas primarias oficiales del distrito, tal como lo prevé el artículo 35 de la citada Ley 47 de 1946, denota que no está sujeto a las directrices aprobadas por los Concejos Municipales, puesto que, de acuerdo a lo que se infiere del artículo 34 de la comentada Ley 47 de 1946 y lo que indica claramente el Decreto 585 de 2 de diciembre de 1992, por el cual se reglamenta el funcionamiento de las Juntas Municipales de Educación, la representación de los miembros del Concejo dentro del seno de la junta es mínima. (Cfr. fojas 8 y 9 del expediente judicial).

En este contexto, este Despacho estima que los actos expedidos por el Concejo Municipal de Colón, son contrarios a derecho, debido a que esa corporación desconoció lo previsto en el artículo 36 de la Ley 38 de 2000, en virtud del cual ninguna autoridad podrá celebrar o emitir un acto para lo cual carezca de competencia de acuerdo a la ley y los reglamentos; circunstancia de hecho que claramente se presenta en esta ocasión, al haber el Concejo Municipal de Colón procedido a eliminar, a través de la emisión del acuerdo cuya declaratoria de nulidad se demanda, un organismo creado mediante una ley formal, en este caso, la Ley 47 de 1946.

.../.

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En fin, manifiesta el señor Procurador que con la emisión del acuerdo 101-40-55 de 24 de noviembre de 2009, corregido mediante el acuerdo 101-40-56 de 1 de diciembre de 2009, por parte del Concejo Municipal de Colón, sin gozar de competencia para ello, se configuró también, la causal de nulidad absoluta de los actos administrativos que contempla el numeral 2 del artículo 52 de la Ley 38 de 2000, por lo que, efectivamente, también se ha producido las infracciones que plantea el actor en relación con la Ley 47 de 24 de septiembre de 1946 y la Ley 106 de 8 de octubre de 1973; por lo que solicita a esta Sala se sirva declarar que es ilegal el referido acuerdo y su enmienda.

IV. COMPENDIO, RAZONAMIENTO, CRITERIO SOBRE LA SUPUESTA INFRACCIÓN DE NORMAS Y EL CONCEPTO DE LA VIOLACIÓN Y DECISIÓN DE LA SALA:

***Compendio*:**

Luego del recorrido procedimental y procesal, realizado sobre cada uno de los elementos y actuaciones de todos cuantos han intervenido dentro del presente caso, consideramos los integrantes de esta Sala que es oportuno externar algunas consideraciones que servirán de perspectiva a cada lector de este Fallo y, por surtidas cada una de las fases del proceso y en atención a cada uno de los hechos que conforman la demanda en cuestión, dictar el veredicto de lugar.

Como se ha anotado en párrafos precedentes, la Demanda Contencioso Administrativa de Nulidad que nos ocupa, deviene de la inconformidad planteada por el hoy demandante en su libelo de demanda, misma que *-a su juicio-* escora en una violación directa al contenido de los artículos 34, 35, 36, 37 y 52 de la Ley Nº38 de 31 de julio de 2000 y, el de los artículos 17 numerales 5, 6 y 9, 18 numeral 5 y 39 de la Ley Nº106 de 8 de octubre de 1973, mismos que en el orden citado dicen:

De la Ley Nº38 de 31 de julio de 2000:

Artículo 34. Las actuaciones administrativas en todas las entidades públicas se efectuarán con arreglo a normas de informalidad, imparcialidad, uniformidad, economía, celeridad y eficacia, garantizando la realización oportuna de la función administrativa, sin menoscabo del debido proceso legal, con objetividad y con apego al principio de estricta legalidad. Los Ministros y las Ministras de Estado, los Directores y las Directoras de entidades descentralizadas, Gobernadores y Gobernadoras, Alcaldes y Alcaldesas y demás Jefes y Jefas de Despacho velarán, respecto de las dependencias que dirijan, por el cumplimiento de esta disposición.

Las actuaciones de los servidores públicos deberán estar presididas por los principios de lealtad al Estado, honestidad y eficiencia, y estarán obligados a dedicar el máximo de sus capacidades a la labor asignada.

Artículo 35. En las decisiones y demás actos que profieran, celebren o adopten las entidades públicas, el orden jerárquico de las disposiciones que deben ser aplicadas será: la Constitución Política, las leyes o decretos con valor de ley y los reglamentos.

En el ámbito municipal, el orden de prioridad de las disposiciones jurídicas será: la Constitución Política, las leyes, decretos leyes, los decretos de gabinete, los decretos ejecutivos, las resoluciones de gabinete, los acuerdos municipales y los decretos alcaldicios.

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A nivel de las juntas comunales y las juntas locales debe aplicarse el siguiente orden jerárquico: la Constitución Política, leyes, decretos leyes, decretos de Gabinete, los decretos ejecutivos, las resoluciones de gabinete, los acuerdos municipales, decretos alcaldicios y los reglamentos que dicten las juntas comunales.

Artículo 36 . Ningún acto podrá emitirse o celebrarse con infracción de una norma jurídica vigente, aunque éste provenga de la misma autoridad que dicte o celebre el acto respectivo. Ninguna autoridad podrá celebrar o emitir un acto para el cual carezca de competencia de acuerdo con la ley o los reglamentos.

Artículo 37 . Esta Ley se aplica a todos los procesos administrativos que se surtan en cualquier dependencia estatal, sea de la administración central, descentralizada o local, incluyendo las empresas estatales, salvo que exista una norma o ley especial que regule un procedimiento para casos o materias específicas. En este último supuesto, si tales leyes especiales contienen lagunas sobre aspectos básicos o trámites importantes contemplados en la presente Ley, tales vacíos deberán superarse mediante la aplicación de las normas de esta Ley.

Artículo 52. Se incurre en vicio de nulidad absoluta en los actos administrativos dictados, en los siguientes casos:

1. Cuando así esté expresamente determinado por una norma constitucional o legal;
2. Si se dictan por autoridades incompetentes;
3. Cuando su contenido sea imposible o sea constitutivo de delito;
4. Si se dictan con prescindencia u omisión absoluta de trámites fundamentales que impliquen violación del debido proceso legal;
5. Cuando se graven, condenen o sancionen por un tributo fiscal, un cargo o causa distintos de aquellos que fueron formulados al interesado.

De la Ley N°106 de 8 de octubre de 1973:

ARTÍCULO 17.- Los Concejos Municipales tendrán competencia exclusiva, para el cumplimiento de las siguientes funciones:

/...

5. Promover la celebración de contratos con entidades públicas o privadas, para la creación de empresas municipales o mixtas, cuya finalidad sea la explotación de bienes y servicios;
6. Crear juntas, Comisiones o departamentos para la prestación de servicios públicos municipales, reglamentar las funciones, nombrar sus miembros y aprobar los presupuestos de rentas y gastos que éstos les presenten;

.../

9. Establecer impuestos, contribuciones, rentas, derechos y tasas, de conformidad con las leyes, para atender a los gastos de la administración, servicios e inversiones municipales;

ARTÍCULO 18.- Los Concejos Municipales tendrán además las siguientes funciones:

/...

5. Difundir la cultura y cooperar en los gastos de administración de escuelas primarias, industriales, vocacionales de bellas artes y especiales, bibliotecas, museos y academias de enseñanzas especiales.

.../.

ARTICULO 39 - Los acuerdos se promulgarán por medio de su fijación en tablillas ubicadas en la Secretaría del Concejo, en las de la Alcaldía y en las Corregidurías. Estos acuerdos serán fijados por el término de diez (10) días calendarios a fin de que surtan sus efectos legales.

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Los acuerdos referentes a impuestos, contribuciones, derechos, tasas y adjudicación de bienes municipales deben ser publicados en la Gaceta Oficial.

Como se ha anotado, arguye el demandante que se ha emitido un acto administrativo con carencia de competencia para lo que en el mismo se ha resuelto, es decir, que se expone que el Concejo Municipal, en este caso, de Colón, no ostenta facultades, ni competencia o capacidad legalmente conferida para dictar un acto en los términos contenidos, particularmente, en el Acuerdo 101-40-55 de 24 de noviembre de 2009, corregido mediante el Acuerdo 101-40-56 de 1 de diciembre de 2009. De hecho, es posible colegir que la inconformidad planteada por la parte actora, derivada de las violaciones anotadas, es compartida por el señor Procurador de la Administración, quien ha manifestado en su **Vista Nº951 de 30 de agosto de 2010** *(visible de fojas 45 a 49 del Exp. Cont. Admtivo.)*, que:

> /...
> De acuerdo con lo dispuesto por las citadas disposiciones legales, esta Procuraduría es de opinión que la "Comisión Municipal de Educación" o Junta Municipal de Educación, es un ente de carácter administrativo y educativo, establecido por ley, el cual debe existir en cada Municipio, y actuar coordinadamente con las dependencias del ramo respectivo; por tanto, el hecho que dicho organismo maneje un porcentaje de los fondos municipales destinados a la enseñanza del nivel primario y educación física, en las escuelas primarias oficiales del distrito, tal como lo prevé el artículo 35 de la citada Ley 47 de 1946, denota que no está sujeto a las directrices aprobadas por los Concejos Municipales, puesto que, de acuerdo a lo que se infiere del artículo 34 de la comentada Ley 47 de 1946 y lo que indica claramente el Decreto 585 de 2 de diciembre de 1992, por el cual se reglamenta el funcionamiento de las Juntas Municipales de Educación, la representación de los miembros del Concejo dentro del seno de la junta es mínima. (Cfr. fojas 8 y 9 del expediente judicial).
> En este contexto, este Despacho estima que los actos expedidos por el Concejo Municipal de Colón, son contrarios a derecho, debido a que esa corporación desconoció lo previsto en el artículo 36 de la Ley 38 de 2000, en virtud del cual ninguna autoridad podrá celebrar o emitir un acto para lo cual carezca de competencia de acuerdo a la ley y los reglamentos; circunstancia de hecho que claramente se presenta en esta ocasión, al haber el Concejo Municipal de Colón procedido a eliminar, a través de la emisión del acuerdo cuya declaratoria de nulidad se demanda, un organismo creado mediante una ley formal, en este caso, la Ley 47 de 1946.
> .../.

Razonamiento:

Estima *prima facie* esta Magistratura, ante las exposiciones vertidas por quienes constituyen el elenco cuyas actuaciones han sido admitidas y reconocidas dentro del presente proceso, aunado al contenido del caudal documental probatorio que forma parte integral del presente expediente; que, ciertamente, les asiste la razón a quienes se tiene en juicio *(Virgilio Cerrud Andrade y Procuraduría de la Administración)*, esto es, que han sido violadas en forma directa las disposiciones legales invocadas; pues ha quedado claro que el Concejo Municipal de Colón carece de competencia para dictar un acto administrativo en los términos que de él se desprenden, lo cual sólo lo puede llevar a una evidente ilegalidad y, en consecuencia, que se tenga que declarar nulo el mismo, como en efecto lo hará esta Sala.

Pues bien, atendiendo el caudal probatorio puesto a nuestra disposición y aquel que reposa en los anales de nuestra legislación, la demanda incoada contra el tantas veces referido Acuerdo y su enmienda, tiene lugar, pues a juicio de esta Sala, los miembros del Concejo Municipal de Colón, antes de proferir el

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acto en comento, en los términos resueltos; han debido tener presente *-esencialmente-* el contenido del artículo 17 de la Ley Nº106 de 8 de octubre de 1973 "Sobre Régimen Municipal" *(Publicada en la G.O. Nº17,458 de 24 de octubre de 1973) -sin perjuicio de las modificaciones o derogaciones de que haya sido objeto a la fecha de esta resolución-*, mismo que se refiere a ***la "Competencia del Concejo"***, en tal sentido tenemos que el mismo a la letra dice *-originariamente-*:

> ARTÍCULO 17.- Los Concejos Municipales tendrán competencia exclusiva, para el cumplimiento de las siguientes funciones:
>
> 6. Formular, con la colaboración y asesoría del Ministerio de Planificación y Política Económica, la política de desarrollo del distrito y de los Corregimientos;
> 7. Preparar, evaluar y ejecutar los programas y proyectos de desarrollo del distrito y de los corregimientos respectivos; con la colaboración y asesoría del Ministerio de Planificación y Politica Económica.
> 8. Estudiar, evaluar y aprobar el programa de inversiones públicas municipales y aprobar el plan de obras públicas que para cada ejercicio fiscal presente el Alcalde de Distrito, previa consulta con la Junta Comunal respectiva, y aprobar el presupuesto de rentas y gastos;
> 9. Crear empresas municipales o mixtas para la explotación de bienes y servicios, en especial, las que tiendan al desarrollo industrial, agrícola y pecuario; y fomentar la creación de empresas privadas, industriales y agrícolas;
> 10. Promover la celebración de contratos con entidades públicas o privadas, para la creación de empresas municipales o mixtas, cuya finalidad sea la explotación de bienes y servicios;
> 11. Crear juntas, Comisiones o departamentos para la prestación de servicios públicos municipales, reglamentar las funciones, nombrar sus miembros y aprobar los presupuestos de rentas y gastos que éstos les presenten;
> 12. Crear o suprimir empleos y determinar sus funciones, períodos, asignaciones y viáticos, de conformidad con lo que dispongan la Constitución y leyes vigentes;
> 13. Disponer de los bienes y derechos del Municipio y adquirir lo que sea necesario para la suficiente prestación de los servicios públicos municipales, con las limitaciones que establezca la Ley;
> 14. Establecer impuestos, contribuciones, rentas, derechos y tasas, de conformidad con las leyes, para atender a los gastos de la administración, servicios e inversiones municipales;
> 15. Reglamentar el uso, arrendamiento, ventas y adjudicación de solares o lotes y demás bienes municipales que se encuentren dentro de las áreas y ejidos de las poblaciones, y de los demás terrenos municipales;
> 16. Crear y mantener empresas y servicios de utilidad pública en especial, agua, luz, teléfonos, gas, transporte, alcantarillado y drenaje; prestar éstos, ya sea directamente o en forma de concesión y en este último caso preferentemente mediante licitación pública o mediante acuerdos con otras entidades estatales.
> También podrá municipalizar los servicios públicos para prestarlos directamente;
> 17. Autorizar y aprobar la celebración de contratos sobre concesiones de. Servicios públicos municipales y lo relativo a la construcción y ejecución de obras públicas municipales;
> 18. Construir mataderos, mercados, crematorios, cementerios públicos y reglamentar sus servicios.
> La construcción de mataderos estará sujeta a la reglamentación que dicte el Órgano Ejecutivo;
> 19. Construir, conservar y mejorar las plazas, parques, paseos y vías públicas municipales ***(Derogado parcialmente)***;
> 20. Efectuar la recolección, destrucción o aprovechamiento de basuras y residuos;

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21. Reglamentar lo relativo a las construcciones y servicios públicos municipales, teniendo en cuenta las disposiciones generales sobre salubridad, urbanismo y otras ***(Modificado parcialmente)***;
22. Ejercer los acciones constitucionales y legales a que haya lugar, en nombre del Municipio y en defensa de sus derechos ***(Declarado parcialmente inconstitucional)***;
23. Seleccionar al Alcalde de la terna que le remito el Gobernador y elegir al Vicepresidente y nombrar al Secretario del Consejo Municipal; al Tesorero, al Ingeniero, Agrimensor, Inspector de Obras Municipales y Abogado Consultor del Municipio, así como su respectivo representante ante organismos municipales, nacionales e internacionales, seg6n el coso ***(Modificado parcialmente)***;
24. Examinar la memoria e informe anuales que deben presentar los Alcaldes y demás jefes de dependencias municipales, para adoptar las medidas más convenientes en beneficio del Distrito y los Corregimientos ***(Modificado parcialmente)***;
25. Deslindar las tierras que formen porte de los ejidos del Municipio y del Corregimiento con la cooperación de la Junta Comunal respectiva;
26. Dar copia de sus actos, y demás documentos autenticados de su archivo, mediante el pago de la tasa correspondiente, cuando éstos sean pedidos por particulares;
27. Dictar medidas a fin de proteger a las personas y las cosas; y
28. Todas las demás señaladas por la Constitución y las Leyes.

(Lo que está entre paréntesis es de esta Sala).

Luego, ha debido considerar *-sin titubeos-*, el contenido del artículo 18 de la Ley Nº47 de 24 de septiembre de 1946 "Ley Orgánica de Educación" *(Publicada en la G. O. Nº10,113 de 2 de octubre de 1946)*, artículo este que consta reglamentado, a través del Decreto Nº314 de 5 de julio de 1961 *(G.O. Nº14,633 de 17 de mayo de 1962)*, mismo que fue modificado por el Decreto Nº320 de 10 de julio de 1961 *(G.O. Nº14,634 de 18 de mayo de 1962)*, en concomitancia con lo resuelto en el Decreto Nº585 de 2 de diciembre de 1992; para así evitar incurrir en las infracciones anotadas.

Lo anterior, responde al hecho que consta vigente un artículo (18) de una Ley (Nº47 de 1946), cuyo rango, según la pirámide de Hans Kelsen y por disposición de lo dispuesto en el artículo 35 de la Ley Nº38 de 31 de julio de 2000, modificada por la Ley Nº45 de 27 de noviembre de 2000; es superior a un Acuerdo, de allí que no podría *-legalmente hablando-* dictarse una decisión como la adoptada en dicho Acuerdo y más aún, cuando se carece de competencia para ello, en tal sentido, nos referimos al Concejo Municipal de Colón.

Dicho en otras palabras, ciertamente *-según lo expuesto en el artículo 242 de nuestra Constitución Política-*, "*... Es función del Concejo Municipal, sin perjuicio de otras que la Ley señale, expedir, modificar, reformar y derogar acuerdos y resoluciones municipales, .../*", y de hecho, así consta reconocido, particularmente, a través del contenido de los artículos 9, 14 y 38 de Ley 106 de 1973, del régimen municipal que establecen lo siguiente:

Artículo 9: La jurisdicción del municipio se extiende al respectivo distrito, el cual será denominado y delimitado por la Ley.

Artículo 14: Los Consejos Municipales regularán la vida jurídica de los Municipios por medio de Acuerdos que tienen fuerza de Ley dentro del respectivo Distrito.

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> Artículo 38: Los Concejos dictarán sus disposiciones por medio de acuerdos o resoluciones que serán de forzoso cumplimiento en el distrito respectivo tan pronto sean promulgadas, salvo que ellos mismos señalen otra fecha para su vigencia.

Sin embargo, estima esta Sala que ello no es razón para que, en este caso, el Concejo Municipal de Colón, disponga en los términos anotados en el Acuerdo *-hoy-* objeto de impugnación, una decisión de la cual carece de competencia *-como se ha venido anotando-*; pues es claro, desde la vigencia de la precitada Ley Nº106 de 1973 y de lo aludido en el referido artículo Constitucional, que el rango que sus decisiones *-adoptadas mediante acuerdo-* tienen, están subordinadas a la Constitución y a las leyes, por tanto, debe respetarse la jerarquía normativa y no excederse lo estipulado en una Ley, como vemos ha ocurrido. De allí entonces, que es oportuno recordar que las autoridades públicas deben aplicar en sus actuaciones el principio de legalidad *-desarrollado del contenido del art. 18 de la C.P.-* consistente en que "*los funcionarios solo pueden hacer lo que la Ley expresamente le permite*".

En concomitancia con lo anterior, anotamos que se ha podido colegir que el artículo 18 de la precitada Ley Nº47 de 24 de septiembre de 1946, dispone que:

> Artículo 18. En cada distrito municipal existirá una Junta Municipal de Educación compuesta de cinco (5) miembros nombrados así: uno (1) por el Ministerio de Educación, dos (2) elegidos por los Clubes de Padres de Familia y dos (2) por los maestros del Distrito. El Ministerio de Educación reglamentará estas elecciones.

Como apreciamos, se trata de una disposición que es parte integral de una Ley, que además de estar vigente, tiene rango superior a un Acuerdo, así entonces, ***lo resuelto*** a través del **ACUERDO Nº101-40-55 de 24 de noviembre de 2009** *"Por medio del cual, se disuelve y elimina de la estructura del Municipio de Colón a la Comisión de Educación del Distrito de Colón"* y el Acuerdo Nº101-40-56 de 1 de diciembre de 2009, ambos dictados por el **CONCEJO MUNICIPAL DE COLÓN**, ***viola de manera directa por comisión*** el contenido del artículo 18 de la precitada Ley Nº47 de 1946, artículo éste, que dicho sea de paso, ha sido reglamentado a través del Decreto Nº314 de 5 de julio de 1961, mismo que fue modificado por el Decreto Nº320 de 10 de julio de 1961. Es más, observamos que tal violación por vías de un Acuerdo Municipal, también ha alcanzado o mejor dicho, violó por comisión, lo resuelto por el entonces Presidente de la República y su Ministro del Ramo, Licdo. Guillermo Endara Galimany (q.e.p.d.) y Prof. Marco A. Alarcón Palomino (q.e.p.d.), a través del Decreto Nº585 de 2 de diciembre de 1992 *(véase de fojas 8 a 9 del Exp. Cont. Admtivo.)*.

Para un mejor entendimiento conceptual, encontramos preciso citar lo que se tiene doctrinal y jurisprudencialmente hablando, como ***"Violación Directa, por Comisión"***, en tal sentido tenemos que: *"Es una de las formas más comunes de violación de la Ley. Se da como se ha visto, cuando el acto impugnado dispone alguna cosa contraria a lo que establece la ley o una norma jerárquicamente superior al acto acusado. Al aplicar la ley, se desconoce un derecho, consagrado en forma clara en la disposición aplicada."*.

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Bien, se ha expuesto que la infracción o *violación*, en este caso, *directa por comisión*, ha girado en el presente caso o mejor dicho, ha tenido lugar, respecto al contenido de los artículos 34, 35, 36, 37 y 52 de la Ley Nº38 de 31 de julio de 2000 y, el de los artículos 17 numerales 5, 6 y 9, 18 numeral 5 y 39 de la Ley Nº106 de 8 de octubre de 1973, violación que el efecto estima esta Magistratura, ha tenido lugar; sin embargo, considera que vasta es la explicación dada en los párrafos precedentes, por lo que resulta innecesario para los suscritos, entrar a analizar en el fondo los cargos de ilegalidad endilgados al resto de las disposiciones legales anotadas. Ahora bien, lo que sí es de lugar es el tener presente lo que al respecto a casos como el que nos ocupa, esto es, a la competencia o incompetencia de emisión de actos; ha proferido esta Corporación de Justicia, en tal sentido tenemos que esta Sala de lo Contenciosos Administrativo y Laboral, expuso *-el 16 de julio de 2010, bajo la Ponencia del Ex–Magistrado Winston Spadafora Franco-* al tiempo de resolver la Demanda Contencioso Administrativa de Plena Jurisdicción – *entrada Nº783-2007-*, interpuesta por la Licda. **NADIA YARLENY MORENO GARCÍA**, en representación del **Banco Nacional de Panamá**, para que se declarase Nula por Ilegal, la **Resolución S.B.P. Nº22-2007 de 15 de marzo de 2007**, emitida por la **Superintendencia de Bancos**; que:

> /...
>
> Agotada la vía gubernativa, la Licda. Nadia Moreno acudió ante la Sala Tercera de la Corte, mediante demanda contenciosa-administrativa de plena jurisdicción, contra el citado acto administrativo. En ese sentido la letrada considera que el acto vulnera los artículos 34 y 52 de la Ley 38 de 2000 y los artículos 54 y 137 del Decreto Ley 9 de 1998.
>
> Como quiera que los artículos 34 y 52 de la Ley 38 de 2000, guardan estricta relación, conviene hacer su análisis en conjunto, ello por cuanto ambos hacen referencia al principio del debido proceso que deben llevarse en toda actuación administrativa.
>
> En ese orden de ideas los artículos 34 y 52 de la Ley 38 de 31 de julio de 2000, señalan lo siguiente:
>
> > "Artículo 34. Las actuaciones administrativas en todas las entidades públicas se efectuarán con arreglo a normas de informalidad, imparcialidad, uniformidad, economía, celeridad y eficacia, garantizando la realización oportuna de la función administrativa, sin menoscabo del debido proceso legal, con objetividad y con apego al principio de estricta legalidad. Los Ministros y las Ministras de Estado, los Directores y las Directoras de entidades descentralizadas, Gobernadores y Gobernadoras, Alcaldes y Alcaldesas y demás Jefes y Jefas de Despacho velarán, respecto de las dependencias que dirijan, por el cumplimiento de esta disposición.
> >
> > Las actuaciones de los servidores públicos deberán estar presididas por los principios de lealtad al Estado, honestidad y eficiencia, y estarán obligados a dedicar el máximo de sus capacidades a la labor asignada".
> >
> > Artículo 52. Se incurre en vicio de nulidad absoluta en los actos administrativos dictados, en los siguientes casos:
> >
> > 1. Cuando así esté expresamente determinado por una norma constitucional o legal;
> >
> > 2. Si se dictan por autoridades incompetentes;
> >
> > 3. Cuando su contenido sea imposible o sea constitutivo de delito;

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4. Si se dictan con prescindencia u omisión absoluta de trámites fundamentales que impliquen violación del debido proceso legal;

5. Cuando se graven, condenen o sancionen por un tributo fiscal, un cargo o causa distintos de aquellos que fueron formulados al interesado.

Sobre el particular es preciso indicar que si bien la Superintendencia de Bancos cuenta con una regulación propia o especial, y específicamente el procedimiento de las quejas presentadas ante el Departamento de Protección al Usuario de los Servicios Bancarios, está regulado por el Acuerdo N° 10-2002 de 2 de octubre de 2002, lo cierto es que la Ley 38 de 2000, constituye la normativa marco para el procedimiento administrativo general y que de manera supletoria resulta aplicable ante los vacíos en el procedimiento sobre materias específicas, en atención a lo dispuesto en los artículos 37 y 202 de la citada ley.

Este principio del debido proceso constituye el cimiento jurídico sobre el cual debe descansar todo proceso administrativo general y especial, del cual no escapa el procedimiento sobre las quejas que interponen los usuarios del servicio bancario ante la Superintendencia de Bancos, a fin que ésta absuelva las peticiones, reclamos o quejas ante las actuaciones de las entidades bancarias al realizar sus operaciones.

Adecuando los planteamientos anteriores al proceso que nos ocupa nuestra atención, esta Superioridad advierte que en la tramitación de las quejas presentadas por Steven Beraha contra el Banco Nacional de Panamá, la autoridad demandada ha incurrido en violación del debido proceso al emitir la resolución S.B.P., N° 22-2007 de 15 de marzo de 2007, así como en sus actos confirmatorios, que sancionó al Banco Nacional de Panamá, sin tomar en consideración el error incurrido por ella misma en la tramitación de la queja presentada por Steven Beraha.

Veamos en que consiste el error enunciado en el párrafo anterior. El señor Steven Behara, presentó dos quejas ante el Departamento de Protección al Usuario de los Servicios de la Superintendencia de Bancos contra el Banco Nacional, cuyas pretensiones son las siguientes:

1. Queja presentada el 24 de octubre de 2006, acogida mediante Acta 158-06, en donde el usuario solicita que el Banco Nacional de Panamá le informe por qué se procedió a secuestrar la cuenta N° 21055074 a nombre de la empresa King Kong International, S.A., ya que el oficio N° 2941 emitido por el Juzgado Cuarto Municipal Civil del Distrito de Panamá ordenó la retención de los fondos hasta la suma de B/. 1,187.50 a nombre de Steven Beraha con cádula N° PE-6-242.
2. Queja presentada el 1 de noviembre de 2006, acogida mediante Acta 158-06 adición, donde solicita que el Banco Nacional acredite los intereses que le corresponde a la cuenta N° 21055074 a nombre de King Kong International, S.A., de la cual es su representante legal.

Sobre el particular la Superintendencia de Bancos argumenta que luego de recibir las quejas de parte de Steven Beraha los días 24 de octubre y 1 de noviembre de 2006, procedió a girar la Nota SBP-DJ-PR-N1061-2006 de 8 de noviembre de 2006, al Banco Nacional de Panamá para que diera explicación sobre ambas quejas.

No obstante lo anterior, de la lectura de la Nota SBP-DJ-PR-N1061-2006 de 8 de noviembre de 2006, que corre traslado al Banco Nacional, se aprecia con claridad meridiana que sólo se hace mención a la queja presentada el 24 de octubre de 2006, acogida mediante Acta 158-06, además que se indica que se adjunta la documentación aportada por el quejoso, la cual únicamente guarda relación con respecto a la queja presentada el 24 de octubre de 2006.

Esto evidencia que en la citada nota nada se menciona sobre la queja presentada el 1 de noviembre de 2006, ni se le pone en conocimiento al Banco Nacional que esta queja se adicionó a la presentada el 24 de octubre de 2006. así las cosas el Banco Nacional de Panamá actuó correctamente al contestar sólo lo atinente a lo reclamado por Beraha

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en la queja presentada el 24 de octubre de 2006, pues desconocía la adición presentada el 1 de noviembre de 2006.

Teniéndose presente que el Banco Nacional de Panamá, no era sabedor de la queja interpuesta el 1 de noviembre de 2006, lo que procedía entonces era que la Superintendencia de Bancos le corriera un nuevo traslado con respecto a esta queja, en vez de concederle al Banco Nacional un término adicional de 8 días para que proporcionara la información, que según la autoridad demandada había sido requerida en la Nota SBP-DJ-PR-N1061-2006 de 8 de noviembre de 2006. No obstante, tal como se ha dicho en párrafos anteriores esta información no fue requerida en dicha nota.

Esto evidencia que la Nota reiterativa SBP-DJ-PR-N1220-2006 de 26 de diciembre de 2006, carece de sustento, pues no tiene razón de ser ni lógica reiterar una información que no se pidió previamente, en este caso en la Nota SBP-DJ-PR-N1061-2006 de 8 de noviembre de 2006.

Luego de este análisis la Sala colige que el Banco Nacional de Panamá, no ha incurrido en mora en la presentación de la información requerida por la Superintendecia de Bancos, por tanto no ha incumplido la normativa que regula el régimen bancario, específicamente el Decreto Ley 9 de 1998 y el Acuerdo 10-2002 de 2 de octubre de 2002.

Por otra parte el Superintendente de Bancos manifestó que el señor Beraha se presentó en dos ocasiones a presentar quejas contra el Banco Nacional sobre el mismo tema, por lo que procedieron a darle trámite en una sola queja. No obstante, es importante resaltar el hecho que si bien Steven Beraha presentó dos quejas, lo cierto es que cada una de ella llevaban pretensiones distintas. Ello es así puesto que la primera tenía como propósito se le explicara el porqué el Banco Nacional secuestró la cuenta de la empresa King Kong, S.A., si la nota enviada por el Juzgado Cuarto Municipal del Distrito de Panamá indicaba que el secuestro recaía sobre las cuentas de su persona y no sobre las de la empresa; en tanto que la segunda queja consistió en que el señor Beraha solicitaba se le explicara el por qué la cuenta 21055074 no generó intereses en ciertos meses.

Esto nos lleva a advertir que por tratarse de peticiones distintas, la Superintendencia de Bancos debió levantar dos expedientes a fin que cada reclamo se tramitara por separado, garantizándose a las partes todos los derechos y medios de defensa en cada caso en particular y con ello se evitaría la tramitación deficiente que se aprecia en el caso en análisis.

Siendo así las cosas, resulta innecesario analizar los demás cargos de ilegalidad expuesto por el demandante, pues ha quedado debidamente comprobado que el acto impugnado vulnera los artículos 34 y 52 de la Ley 38 de 2000, toda que por el mal procedimiento de la Superintendencia de Bancos en la tramitación de las quejas presentadas por Steven Beraha, se le impuso una multa a la entidad bancaria, sin que esta incurriera en mora en proporcionar la información requerida.

PARTE RESOLUTIVA

Por consiguiente, la Corte Suprema de Justicia, Sala Tercera de lo Contencioso Administrativo, administrando justicia en nombre de la República y por autoridad de la Ley, **DECLARA QUE ES ILEGAL** la Resolución S.B.P. N° 22-2007 de 15 de marzo de 2007, emitida por la Superintendencia de Bancos, así como sus actos confirmatorios; en consecuencia se declara que el Banco Nacional no ha incurrido en mora alguna en cuanto a información requerida, por lo que no es objeto de sanción pecuniaria alguna.

Notifíquese.

.../.

Ahora bien, no podemos concluir sin anotar que a la fecha de emisión del presente acto jurisdiccional consta que se han modificado y hasta derogado algunos numerales del aludido artículo 17 de

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la Ley N°106 de 8 de octubre de 1973, pero ello no es óbice para que se hagan las anotaciones y exponga el criterio que tiene esta Sala, sobre lo actuado por el Concejo Municipal, en este caso, de Colón, por cuanto que, aún con tales derogaciones o modificaciones, no subsiste o se establece facultad alguna para que el Concejo pueda actuar como lo ha hecho y, lo que es más grave aún, a través de un Acuerdo, respecto de una Ley.

Así las cosas, lo propio viene a ser que, por declarado Nulo lo resuelto a través del tantas veces citado Acuerdo y su enmienda, se reestablezca dentro de la estructura del Municipio de Colón, la Comisión de Educación del Distrito de Colón, como en efecto se declarará y ordenará seguidamente, dado el hecho que, es evidente la carencia de competencia para proferirse un acto como el acusado de ilegalidad, cuyo resultado infiere con lo resuelto mediante Ley, esto es, traspasándose los límites que se tienen, en este caso, como Concejo Municipal.

***Decisión de la Sala*:**

Por lo expuesto, la ***Sala Tercera de lo Contencioso Administrativo y Laboral de la Corte Suprema de Justicia***, administrando justicia en nombre de la República y por autoridad de la Ley, declara que **ES ILEGAL** y, por ende, **NULO** lo ***resuelto*** en el **ACUERDO N°101-40-55 de 24 de noviembre de 2009** *"Por medio del cual, se disuelve y elimina de la estructura del Municipio de Colón a la Comisión de educación del Distrito de Colón"* y su corrección, realizada, a través del ACUERDO N°101-40-56 de 1 de diciembre de 2009 *"Por medio del cual, se hace corrección en el Primer Considerando y en el Artículo Segundo del Acuerdo N°101-40-55, del 24 de noviembre de 2009"*, ambos dictados por el **CONCEJO MUNICIPAL DE COLÓN** y; en consecuencia, **ORDENA** que una vez en firme y debidamente ejecutoriada esta resolución, no sólo se **ARCHIVE** el presente expediente, luego de la anotación de salida en el libro de lugar; sino que se **ORDENA** comunicar lo aquí resuelto al Concejo Municipal de Colón, a efectos que proceda con el reestablecimiento de la Comisión de Educación del Distrito de Colón, dentro de la estructura funcional del Municipio de Colón.

Notifíquese,

VÍCTOR L. BENAVIDES P.
MAGISTRADO

LUIS RAMÓN FÁBREGA S.
MAGISTRADO

ABEL AUGUSTO ZAMORANO
MAGISTRADO

KATIA ROSAS
SECRETARIA

ORIGINAL
6 enero 2015

AVISOS

Para dar cumplimiento al Artículo 777 de Comercio e Industrias, se le comunica al público en general, la publicación de tres veces en la Gaceta Oficial que el señor **JOSÉ DEL CARMEN GONZÁLEZ A.**, con cédula No. 9-82-1410, con establecimiento comercial denominado **MINI SÚPER ANA CAROLINA**, ubicado en Urbanización Barriada El Educador, corregimiento y distrito de Santiago, provincia de Veraguas, con aviso de operación No. 186302, le traspasa al señor **WEI YAN CHEN**, con cédula No. N-21-98. L. 208-9572249. Tercera publicación.

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AVISO DE DISOLUCIÓN. Se informa al público que mediante escritura pública No. 504 con fecha del 12 de enero de 2015 de la Notaría Cuarta del Circuito de Panamá, se ha disuelto la sociedad **DISTRIBUIDOR GRIMAR, S.A., e**ste acto se inscribió el viernes 16 de enero de 2015 en la Sección Mercantil del Registro Público de Panamá, al Folio No. 461558, Asiento No. 2. L. 201-422492. Única publicación.

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AVISO DE DISOLUCIÓN. Se informa al público que, mediante la escritura pública No. 592 del 13 de enero de 2015 de la Notaría Cuarta del Circuito de Panamá, se ha disuelto la sociedad **OPEN SPACE GLOBAL, S.A.,** este acto se inscribió el 16 de enero de 2015 en la Sección Mercantil del Registro Público de Panamá, al Folio 780651, Asiento No. 2. L. 201-422408. Única publicación.

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AVISO. Yo, **EVARISTO DELGADO JIMÉNEZ**, con cédula de identidad personal número 7-115-830, le comunico al público que he vendido el aviso de operación número 362342, del establecimiento comercial denominado **VIDA FELIZ**, ubicado en el corregimiento de Tablas Abajo, calle principal, casa s/n, distrito de Las Tablas, provincia de Los Santos, al señor **LIRROY KINSOR DELGADO JIMÉNEZ**, con cédula de identidad personal número 7-704-232, ambos con demás generales descritas dentro del proceso. L. 201-422489. Primera publicación.

EDICTOS

Alcaldía de Arraiján

Republica de Panamá
Municipio de Arraiján

Dirección de Ingeniería
Sección de Catastro

EDICTO Nº 048-15

Arraiján, 8 de Enero del 2015

El suscrito Secretario General del Distrito de Arraiján

HACE SABER

Que la señora **Lurdes Rodríguez Fuller,** con cédula de identidad personal **Nº 8-397-420,** la señora Rose Milena Cañizales con cédula de identidad personal N° 8-779-1968 y el señor Kayser Jabal Rodríguez con cédula de identidad personal N° 8-802-1687 todos con domicilio en calle 11 de Octubre ha solicitado a este despacho la Adjudicación a título de COMPRA Y VENTA, de un lote de terreno que forma parte de la Finca **4375,** inscrita al Tomo **99,** Folio **142** de propiedad de este Municipio, ubicado en el Corregimiento de **Arraiján cabecera**, con un área de **454.38Mts²**, dentro de los siguientes linderos y medidas según el plano N° **80101-132764.**

NORTE: Calle 11 de Octubre	Y Mide: 17.90 MTS
SUR: Finca 4375 ocupado por Severina Vergara	Y Mide: 21.53 MTS
ESTE: Finca 4375 ocupada por Cecilio Rodríguez y Aarón Rodríguez	Y Mide: 21.87 MTS
OESTE: Finca 4375 ocupado por Luciardo Rodríguez	Y Mide: 23.11 MTS

Para que dentro del término de cinco (5) días hábiles siguientes a la última publicación se hagan valer los derechos a que haya lugar, en atención a lo que dispone el artículo doce del Acuerdo Nº 31 del 16 de junio del 2009, se ordena la publicación del presente EDICTO, por tres (3) días consecutivos en un periódico de circulación nacional, y diez (10) días en la Corregiduria del área y por diez (10) días en Secretaria General de este despacho Municipal copia del mismo se entregará al interesado para tal efecto.

Para que sirva de formal notificación a las partes, se fija el presente edicto en un lugar visible de la Alcaldía, hoy Tres (8) de Enero del dos mil quince (2015), siendo las once y treinta de la mañana y por el término de diez (10) días hábiles

FIJESE Y PUBLIQUESE

DISTRITO DE ARRAIJÁN SECRETARÍA GENERAL

ALEJANDRO CHIAM CLARKE
SECRETARIO GENERAL
DEL MUNICIPIO DE ARRAIJÁN

GACETA OFICIAL
Liquidación 2014224 91

REPUBLICA DE PANAMA
AUTORIDAD NACIONAL DE
ADMINISTRACION DE TIERRAS
DIRECCION NACIONAL DE TITULACION Y REGULARIZACION
PROVINCIA DE COCLE

EDICTO No. 008-15

EL SUSCRITO FUNCIONARIO SUSTANCIADOR DE LA AUTORIDAD NACIONAL DE TITULACION Y REGULARIZACION DE TIERRA PROVINCIA DE COCLÉ,

HACE SABER QUE:

Que **MARIA CONCEPCION BUITRAGO DE MONTENEGRO Y OTROS** vecino (a) de **PEL CONGO** Corregimiento **COCLÉ** del Distrito de **PENONOME** portador (a) de la cedula N°: **2-77-923** ha solicitado a la Dirección Nacional de Titulación y Regularización mediante solicitud No. **4-152-91** según plano aprobado N°. **25-03-5242,** adjudicación a título oneroso de una parcela de tierra baldía con una superficie total de **14 HAS + 9423.44 M2** Ubicada en la localidad de **EL CONGO,** Corregimiento de **COCLÉ,** Distrito de **PENONOMÉ** Provincia de **COCLE,** comprendidos dentro de los siguientes linderos:

NORTE: **GRUPO DE MAS DE CASA DE LA LOCALIDAD DEL CONGO – PAULINO MORENO – MANUEL GOMEZ**

SUR: **SERVIDUMBRE HACIA CARRETERA DEL CONGO HACIA OTROS LOTES DE 10.00 M2 – ROGELIO RAMOS**

ESTE: **GRUPOS DE AMAS DE CASA DE LA LOCALIDAD DEL CONGO – EPIFANIA TORRES – MARIA DE JESUS ORTEGA – ROGELIO BUITRAGO RAMOS**

OESTE: **SEVERO CASTILLO - AREAS PARA FUTURAS VIVIENDAS PROPIEDAD DE LA NACION SIN OCUPACION**

Para los efectos legales, se fija el presente edicto en lugar visible de la Dirección Nacional de Titulación y Regularización de Tierra en la Provincia de Coclé y en la Corregiduría de **COCLÉ** Copia del mismo se hará publicar en el órgano de publicidad correspondiente tal como lo ordena el Articulo 108 del Código Agrario.

Este edicto tendrá una vigencia de 15 días a partir de su última publicación.

DADO EN LA CIUDAD DE PENONOMÉ, HOY 30 DE ENERO DE 2015.

DAN-EL ROSAS ZAMBRANO
FUNCIONARIO SUSTANCIADOR
ANATI – COCLE

IRIA ICAZA
SECRETARIA AD-HOC

GACETA OFICIAL
Liquidación: 201-421688

EDICTO No 245

DIRECCION DE INGENIERIA MUNICIPAL DE LA CHORRERA - SECCION DE CATASTRO

ALCALDIA MUNICIPAL DEL DISTRITO DE LA CHORRERA.
El SUSCRITO ALCALDE DEL DISTRITO DE LA CHORRERA, HACE SABER:
QUE EL SEÑOR (A) CLARITA MARISELLI MONTILLA RODRIGUEZ, mujer, panamena mayor de edad, Soltera, residente en Barriada La Pesa, calle El Trebol, casa No.1280, telefono No.244-2036, portadora de la cedula de identidad personal No.8-312-755.....

En su propio nombre en representación de SU PROPIA PERSONA
Ha solicitado a este Despacho que se le adjudique a titulo de plena propiedad, en concepto de venta de un lote de terreno Municipal Urbano, localizado en el lugar denominado CALLE EL TREBOL, de la Barriada LA PESA, Corregimiento GUADALUPE, donde SE LLEVARA A CABO UNA distingue con el numero _____ y cuyo linderos y medidas son los siguiente:

NORTE: FINCA 9535 FOLIO 472 TOMO 297 PROPIEDAD DEL MUNICIPIO DE LA CHORRERA CON. 30.00 MTS

SUR: CALLE EL TREBOL CON. 30.00 MTS

ESTE: CALLE 1RA CON. 20.00 MTS

OESTE: FINCA 9535 FOLIO 472 TOMO 297 PROPIEDAD DEL MUNICIPIO DE LA CHORRERA CON. 20.00 MTS

AREA TOTAL DE TERRENO SEISCIENTOS METROS CUADRADOS (600.00 MTS.2)

con base a lo que dispone el Articulo 14 del Acuerdo Municipal No.11-A, del 6 de marzo de 1969, se fija el presente Edicto en un lugar visible al lote de terreno solicitado, por el término de DIEZ (10) dias, para que dentro dicho plazo o termino pueda oponerse la (s) que se encuentran afectadas. Entregueseles senda copia del presente Edicto al interesado, para su publicación por una sola vez En un periódico de gran circulación y en La Gaceta Oficial.

La Chorrera, 16 de septiembre de de dos mil catorce

ALCALDE INTERINO. (fdo.) SR. KLEBER GENARINO DELGADO V.

JEFA DE LA SECCION DE CATASTRO (fdo.) SRTA. IRISCELYS DIAZ G.

Es fiel copia de su original
La Chorrera, diesciseis (16)
de septiembre de dos mil catorce

SRTA. IRISCELYS DIAZ G.
JEFA DE LA SECCION DE CATASTRO MUNICIPAL

GACETA OFICIAL
Liquidación: 2014214647

EDICTO No. 310

DIRECCION DE INGENIERIA MUNICIPAL DE LA CHORRERA - SECCION DE CATASTRO.

ALCALDIA MUNICIPAL DEL DISTRITO DE LA CHORRERA.
EL SUSCRITO ALCALDE DEL DISTRITO DE LA CHORRERA. HACE SABER
QUE EL SEÑOR (A) OLGA JUDITH MARTINEZ RODRIGUEZ, panameña, mayor de edad, soltera. oficio Secretaria, con residencia en San Miguelito casa No.14A20, con cedula de identidad personal No.8-329-35.

En su propio nombre en representación de SU PROPIA PERSONA
Ha solicitado a este Despacho que se le adjudique a titulo de plena propiedad, en concepto de venta de un lote de terreno Municipal Urbano, localizado en el lugar denominado CALLE LOS VECINOS, de la Barriada CHORRITOS No.3
Corregimiento EL COCO ,donde SE LKLEVARA A CABO UNA CONSTRUCCION distingue con el numero y cuyo linderos y medidas son los siguiente:

NORTE:	FINCA 6028 FOLIO 104 TOMO 194 PROPIEDAD DEL MUNICIPIO DE LA CHORRERA	CON.15.241 MTS
SUR:	CALLE LOS VECINOS	CON.19.517 MTS
ESTE:	FINCA 6028 FOLIO 104 TOMO 194 PROPIEDAD DEL MUNICIPIO DE LA CHORRERA	CON.32.107 MTS
OESTE:	FINCA 6028 FOLIO 104 TOMO 194 PROPIEDAD DEL MUNICIPIODDE LA CHORRERA	COn.37.177 MTS

AREA TOTAL DE TERRENO QUINIENTOS OCHENTA Y OCHO METROS CUADRADOS CON SESENTA Y UNO DECIMETROS CUADRADOS (588.61 MTS.2)

con base a lo que dispone el Articulo 14 del Acuerdo Municipal No 11-A. del 6 de marzo de 1969. se fija el presente Edicto en un lugar visible al lote de terreno solicitado, por el de DIEZ (10) dias, para que dentro dicho plazo o termino pueda oponerse la (s) que se encuentran afectadas
Entréguesele senda copia del presente Edicto al interesado, para su publicación por una sola vez
En un periodico de gran circulación y en La Gaceta Oficial
La Chorrera 21 de marzo de dos mil catorce

ALCALDE: (fdo.) SR. TEMISTOCLES JAVIER HERRERA

JEFE DE LA SECCION DE CATASTRO. (fdo.) SRTA. IRISCELYS DIAZ G.

Es fiel copia de su original
La Chorrera, veintiuno (21)
de marzo de dos mil catorde

SRTA. IRISCELYS DIAZ G.
JEFA DE LA SECCION DE CATASTRO MUNICIPAL

GACETA OFICIAL
Liquidación 201-422501

EDICTO No. 369

DIRECCION DE INGENIERIA MUNICIPAL DE LA CHORRERA - SECCION DE CATASTRO.

ALCALDIA MUNICIPAL DEL DISTRITO DE LA CHORRERA.
El SUSCRITO ALCALDE DEL DISTRITO DE LA CHORRERA, HACE SABER:
QUE EL SEÑOR (A) EMMA DORIS MONTILLA RODRIGUEZ DE MARTINEZ, MUJER, panameña mayor de edad, portadora de la cedula de identidad personal No.8-209-2107.....

En su propio nombre en representación de SU PROPIA PERSONA
Ha solicitado a este Despacho que se le adjudique a titulo de plena propiedad, en concepto de venta de un lote de terreno Municipal Urbano, localizado en el lugar denominado CALLE ALBERTITO, de la Barriada OLLAS ABAJO, Corregimiento LOS DIAZ, donde HAY CASA distingue con el numero _____ y cuyo linderos y medidas son los siguiente:

NORTE: FINCA 109526 ROLLO 7035 DOC.12 PROPIEDAD DEL MUNICIPIO DE LA CHORRERA CON. 20.00 MTS
SUR: CALLE ALBERTITO CON. 20.00 MTS
ESTE: FINCA 109526 ROLLO 7035 DOC. 12 PROPIEDAD DEL MUNICIPIO DE LA CHORRERA CON. 30.00 MTS
OESTE: FINCA 109526 ROLLO 7035 DOC. 12 PROPIEDAD DEL MUNICIPIODDE LA CHORRERA CON. 30.00 MTS

AREA TOTAL DE TERRENO SEISCIENTOS METROS CUADRADOS (600.00 MTS.2)

con base a lo que dispone el Articulo 14 del Acuerdo Municipal No.11-A, del 6 de marzo de 1969, se fija el presente Edicto en un lugar visible al lote de terreno solicitado, por el término de DIEZ (10) dias, para que dentro dicho plazo o termino pueda oponerse la (s) que se encuentran afectadas. Entrégueseles senda copia del presente Edicto al interesado, para su publicación por una sola vez En un periódico de gran circulación y en La Gaceta Oficial

La Chorrera, 11 de diciembre de dos mil catorce

ALCALDE INTERINO: (fdo.) SR. KLEBER GENARINO DELGADO V.

JEFA DE LA SECCION DE CATASTRO. (fdo.) SRTA. IRISCELYS DIAZ G.

Es fiel copia de su original
La Chorrera, once (11) de
diciembre de dos mil catorce

SRTA. IRISCELYS DIAZ G.
JEFA DE LA SECCION DE CATASTRO MUNICIPAL

GACETA OFICIAL
Liquidación 201-92146 5

Ministerio de Salud Pública

MINISTERIO DEL INTERIOR

MINISTERIO DE RELACIONES EXTERIORES

MINISTERIO DE ECONOMÍA Y FINANZAS

MINISTERIO DE DEFENSA NACIONAL

MINISTERIO DE EDUCACION Y CULTURA

MINISTERIO DE TRANSPORTE Y OBRAS PÚBLICAS

MINISTERIO DE INDUSTRIA, ENERGÍA Y MINERÍA

MINISTERIO DE TRABAJO Y SEGURIDAD SOCIAL

MINISTERIO DE SALUD PÚBLICA

MINISTERIO DE GANADERÍA, AGRICULTURA Y PESCA

MINISTERIO DE TURISMO Y DEPORTE

MINISTERIO DE VIVIENDA, ORDENAMIENTO TERRITORIAL Y MEDIO AMBIENTE

MINISTERIO DE DESARROLLO SOCIAL

Montevideo, 2 JUN 2006

VISTO: la Ley N° 17.668 de 15 de julio 2003 modificativa de la Ley N° 14.005 de 17 de agosto de 1971;----------

RESULTANDO: que dichas disposiciones legales hacen referencia al marco jurídico de trasplantes de órganos y tejidos, a cargo del Instituto Nacional de Donación y Trasplante de Células, Tejidos y

Órganos – que funciona en el Hospital de Clínicas "Dr. Manuel Quintela" - Facultad de Medicina - Universidad de la República;------

CONSIDERANDO : I) el avance de la ciencia y la tecnología en la materia;----------

II) que se ha tomado como base científica, la Directiva 2004/23/CE del Parlamento Europeo y del Consejo Europeo de fecha 31 de marzo de 2004 relativa al establecimiento de normas de calidad y de seguridad para la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos humanos, contemplándose los conceptos de bioética y bioseguridad, así como las pautas socio culturales vigentes;----------

III) que el trasplante de células y tejidos humanos es un sector de la medicina que registra un fuerte crecimiento y entraña grandes oportunidades para el tratamiento de enfermedades hasta ahora incurables. Debe garantizarse la calidad y seguridad de estas sustancias, en particular a fin de evitar la transmisión de enfermedades. El Estado debe fomentar adecuados niveles de protección de la salud pública;----------

IV) que, la disponibilidad de células y tejidos humanos utilizados con fines terapéuticos depende de la disposición de las personas a realizar donaciones;----------

V) que, para proteger la salud pública, disminuir los efectos adversos y evitar la transmisión de enfermedades

infecciosas a través de estos tejidos y células, deben tomarse todas las medidas de seguridad durante su donación, obtención, evaluación, procesamiento, preservación, almacenamiento, distribución, uso y desecho;----------

VI) que dada la necesidad de prohibir el comercio de células y tejidos humanos, es necesario promover campañas de información y educación, tanto a escala nacional como regional, sobre la donación de células y tejidos humanos. El Estado debe promover la donación altruista de células y tejidos humanos, procurando satisfacer las necesidades asistenciales (Ley 17.668 de 15 de julio de 2003);----------

VII) que es menester disponer de un marco regulatorio a fin de garantizar normas de calidad y seguridad en cuanto a la obtención, evaluación, procesamiento, almacenamiento, distribución y desecho de células y tejidos humanos. Por consiguiente, es esencial que disposiciones nacionales aseguren las células y tejidos humanos de calidad y seguridad equivalentes con las exigidas regional e internacionalmente;----------

VIII) que las células y los tejidos destinados a la producción industrial, incluidos los productos sanitarios, deben ser regulados por la presente norma en lo que se refiere a la donación, obtención, procesamiento, evaluación y distribución;----------

IX) que el presente Decreto incluye todas las células y tejidos humanos. Se aplica, por lo tanto, a las células

madre, progenitoras hematopoyéticas de sangre periférica, células del cordón umbilical (sangre), células de la médula ósea y células troncales adultas y embrionarias;----------

X) que esta reglamentación se aplicará a las células y los tejidos utilizados únicamente como injerto autólogo dentro de un mismo procedimiento quirúrgico en lo que refiere al consentimiento y comunicación al Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos. Excluye la sangre y los productos sanguíneos Ley N° 12.072 de 4 de diciembre de 1953 y Decreto N° 385/00 de 26 de diciembre de 2000 (excepto las células progenitoras hematopoyéticas) y los órganos humanos Ley N° 14.005 de 17 de agosto de 1971;----------

XI) La utilización clínica de células y tejidos humanos para su uso con seres humanos podría verse restringida por una disponibilidad limitada. Es necesario que existan criterios para el acceso y adjudicación de estas células y tejidos humanos de manera transparente, sobre la base de una evaluación objetiva de las necesidades médicas;----------

XII) que es preciso incrementar la confianza en cuanto a la calidad y la seguridad de células y tejidos humanos donados, la protección de la salud de los donantes vivos y el respeto de los donantes fallecidos (Ley N° 14.005 de 17 de agosto de 1971 y Ley N° 17.668 de 15 de julio de 2003), y la seguridad del proceso de aplicación;----------

XIII) que las células y tejidos humanos utilizados para terapias alogénicas pueden proceder de donantes vivos y de donantes fallecidos. A fin de garantizar que el estado de salud de un donante vivo no se verá afectado por la donación es preciso realizar un reconocimiento médico previo. Asimismo, debe respetarse la dignidad de los donantes fallecidos (Ley N° 14005 de 17 agosto de 1971 y Ley N° 17.668 de 15 de julio de 2003);----------

XIV) que la utilización de células y tejidos humanos para su aplicación en el cuerpo humano puede provocar enfermedades y efectos no deseados. La mayor parte de éstos pueden evitarse con una evaluación detallada del donante y con la evaluación de cada donación de acuerdo con las normas establecidas y actualizadas de conformidad con los mejores conocimientos científicos disponibles;----------

XV) que los programas de aplicación de células y tejidos humanos deben basarse en el principio de la voluntariedad de las donaciones y la no remuneración, el anonimato del donante y el receptor, el altruismo del donante y la solidaridad entre donante y receptor (Ley N° 14.005 de 17 de agosto de 1971 y Ley N° 17.668 de 15 de julio de 2003);----------

XVI) que deben tomarse todas las medidas necesarias para garantizar a los posibles donantes de células y tejidos humanos la confidencialidad de cualquier información relacionada con su salud que se haya transmitido al personal

autorizado, de los resultados de las pruebas de sus donaciones y de la trazabilidad futura de su donación (Ley N° 17.668 de 15 de julio de 2003). Los datos personales procesados en aplicación de la presente norma quedan bajo la Ley de Protección de Datos de la República Oriental del Uruguay, de 24 de setiembre de 2004;------

XVII) que deben crearse los mecanismos de acreditación de centros de obtención y trasplante de células y tejidos humanos. El Ministerio de Salud Pública deberá organizar medidas de inspección y control, para garantizar que los centros cumplan con lo dispuesto en la presente normativa;----------

XVIII) que el personal que participe directamente en la donación, la obtención, la verificación y/o evaluación el procesamiento, la preservación, el almacenamiento, la distribución y el desecho de células y tejidos humanos debe poseer las calificaciones apropiadas y recibir una formación oportuna y adecuada;----------

XIX) que debería instaurarse un sistema adecuado que permita determinar el origen de las células y tejidos humanos. La trazabilidad debe reforzarse mediante procedimientos precisos de identificación de la sustancia, el donante, el receptor, el centro de obtención, el banco (cuando corresponda) y el laboratorio, así como con el mantenimiento de registros y un sistema apropiado de etiquetado;----------

XX) que las comisiones asesoras del Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos deben tener acceso a la mejor orientación científica posible en relación con el trasplante de células y tejidos humanos, en especial, para asistir a las autoridades en la adaptación de las disposiciones de la presente norma al progreso científico y técnico;----------

XXI) que las pruebas exigidas a los donantes deberán ser efectuadas por un laboratorio habilitado, acreditado, autorizado o designado por el Ministerio de Salud Pública;----------

XXII) que no debe revelarse la identidad del receptor o receptores al donante o a su familia, ni viceversa. A fin de incrementar la efectividad de la aplicación de las disposiciones adoptadas en el marco de la presente norma, se prevén sanciones (Ley N° 17.668 de 15 de julio de 2003);----------

XXIII) que la población debe tener acceso a la mejor orientación científica posible en relación con la seguridad de células y tejidos humanos;----------

XXIV) que la presente norma respeta los derechos fundamentales del Hombre y cumple los principios reflejados en la Declaración Universal de los Derechos Humanos (1948);----------

XXV) que, se hace necesario la reglamentación específica para el transplante de células y tejidos humanos, por lo que de acuerdo a lo previsto en la Constitución de la República en su Sección IX, Capítulo III, artículo 168 numeral 4°); y en las leyes Nos.

14.005 de 17 de agosto de 1971, 17.668 de 15 de julio de 2003 y 9.902 "Orgánica de Salud Pública" de 12 de enero de 1934;----------

ATENTO: a lo precedentemente expuesto;----------

EL PRESIDENTE DE LA REPÚBLICA

actuando en Consejo de Ministros

DECRETA:

CAPÍTULO I

DISPOSICIONES GENERALES

Artículo 1°.- Objetivo:----------

El presente Decreto establece normas de control, calidad y seguridad para el transplante de las células y tejidos humanos, con el objetivo de garantizar un adecuado nivel de protección de la salud humana e impedir la comercialización.---------

Artículo 2°.- Ámbito de aplicación:----------

1. Se aplicará a la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento, la distribución, el trasplante, el uso terapéutico, la investigación y el desecho de células y tejidos humanos, así como de productos elaborados derivados de estas células y tejidos. Cuando estos productos elaborados estén regulados por otras normas, la presente solamente se aplicará a la donación, obtención, trazabilidad y evaluación.-

2. La presente norma no se aplicará a:----------

a) la sangre (excepto las células progenitoras hematopoyéticas) y los componentes sanguíneos contemplados en Decreto Nº 385/000 de 20 de diciembre de 2000.----------

b) los órganos, o partes de órganos, contemplados en Ley N° 14005 de 17 de agosto de 1971 y Ley N° 17668 de 15 de julio de 2003.----------

Artículo 3°- Definiciones:----------

A efectos de la presente norma, se entenderá por:----

a) «células»: las células individuales de origen humano o una colección de células de origen humano cuando no estén unidas por ninguna forma de tejido conjuntivo; ----------

b) «tejido»: todas las partes constituyentes del cuerpo humano formadas por células;----------

c) «órgano»: una parte diferenciada y vital del cuerpo humano, formada por diferentes tejidos, que mantiene su estructura, vascularización y capacidad para desarrollar funciones fisiológicas con un nivel de autonomía importante;----------

d) «donante»: toda fuente humana, viva o muerta, de células, tejidos y órganos humanos;----------

e) «donación»: el hecho de donar células, tejidos y órganos humanos destinados a su aplicación en el ser humano;----------

f) «obtención»: un proceso por el que se pueden obtener las células y ablacionar los tejidos;---------

g) «procesamiento»: todas las operaciones que implica la preparación, manipulación, preservación y acondicionamiento de los tejidos y las células destinados a su aplicación en el ser humano;--------

h) «preservación»: la utilización de agentes químicos, alteraciones de las condiciones medioambientales u otros medios durante el procesamiento a fin de impedir o retrasar el deterioro biológico o físico de las células o los tejidos;----------

i) «cuarentena»: la situación del tejido o células extraídos o del tejido aislado físicamente o por otros medios efectivos, mientras se espera una decisión sobre su aceptación o rechazo;----------

j) «almacenamiento»: el mantenimiento del producto bajo condiciones controladas y apropiadas hasta su distribución;----------

k) «distribución»: el transporte y la entrega de tejidos o células;----------

l) «aplicación en el ser humano»: el uso de tejidos y células en un receptor humano y en aplicaciones extracorporales;----------

m) «efecto adverso grave»: cualquier hecho desfavorable vinculado con la obtención, evaluación, procesamiento, almacenamiento y distribución de tejidos y células que pueda conducir a la transmisión de una enfermedad transmisible o la muerte del paciente, o a estados que hagan peligrar su vida, a minusvalías o incapacidades, o que pueda dar lugar a hospitalización o enfermedad, o las pueda prolongar;----------

n) «reacción adversa grave»: una respuesta inesperada del donante o del receptor, incluida una enfermedad transmisible, asociada a la obtención o la aplicación en el ser humano de tejidos y células que resulte mortal, potencialmente mortal, discapacitante, que produzca invalidez o incapacidad o que dé lugar a hospitalización o enfermedad, o las prolongue;----------

o) centro de obtención, procesamiento, preservación, almacenamiento, distribución, uso terapéutico y desecho de células y tejidos humanos:

organización radicada en un establecimiento con identidad institucional habilitada;----------

p) «uso alogénico»: las células o los tejidos extraídos de una persona y aplicados a otra;----------

q) «uso autólogo»: las células o los tejidos extraídos y aplicados a la misma persona;----------

Células madre: sinonimia: células madre progenitoras, células troncales, células "stem", "stem cells".----------

Células madre: aquellas capaces de dividirse para producir células iguales a ellas mismas, de dar lugar a uno o más tipos de células diferenciadas específicas y de reconstituir uno o varios tipos de tejidos.----------

Tipos de células madre (terminología discutida): se clasifican de acuerdo al potencial de diferenciación.

Artículo 4°.- Aplicación:----------

1. El Ministerio de Salud Pública, a través del Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos serán responsables de aplicar las disposiciones de la presente norma.-------

2. Las donaciones serán voluntarias y no remuneradas y deberán respetar las condiciones de

la presente norma y de las Leyes Nos. 14.005 de 17 de agosto de 1971 y 17.668 de 15 de julio de 2003.--

3.Para la realización de las actividades a que se refiere la presente norma, el Ministerio de Salud Pública - Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos - podrán solicitar asistencia técnica o administrativa y gastos de apoyo a la identificación, preparación, gestión, seguimiento y control.----------

CAPÍTULO II

OBLIGACIONES DE LAS AUTORIDADES

Artículo 5°.- Supervisión de la obtención de células y tejidos humanos:----------

1. El Ministerio de Salud Pública a través del Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos tomará todas las medidas necesarias para garantizar que la obtención y la evaluación de células y tejidos humanos sean efectuadas por personal con la formación y experiencia adecuadas y que se realicen en las condiciones habilitadas, acreditadas, o autorizadas a tal fin.----------

2. El Ministerio de Salud Pública a través del Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos adoptará las medidas

necesarias para garantizar que la obtención de células y tejidos humanos sea notificada al dicho Instituto y que se cumplan los requisitos contemplados en el Anexo I del presente Decreto.----

Artículo 6°.- Habilitación o autorización de los centros de trasplante de células y tejidos:----------

1. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos garantizarán que solo los centros y programas de trasplante que hayan sido habilitados con ese fin, lleven a cabo las actividades relacionadas con la obtención, el procesamiento, preservación, almacenamiento, distribución y desecho de células humanas.----------

2. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos y el Ministerio de Salud Pública, establecerán los requisitos y condiciones que deban cumplirse.----------

3. Los equipos no podrán efectuar cambios sustanciales en sus actividades, sin el consentimiento previo por escrito de la autoridad competente : Ministerio de Salud Pública e Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos.----------

4. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos podrán suspender o retirar la habilitación o autorización a un centro de trasplante de células y tejidos humanos o a un método de preparación de tejidos o células si una inspección o una medida de control demuestra que no se cumplen los requisitos de la presente norma.---------

Artículo 7°.- Inspecciones y medidas de control:----------

1. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos podrán aplicar las medidas de control apropiadas para que los programas de trasplante de células y tejidos humanos cumplan los requisitos de la presente norma.----------

2. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos velarán también por que se apliquen las medidas de control apropiadas para la obtención y el trasplante de células y tejidos humanos.----------

3. El Ministerio de Salud Pública o quien este designe organizará inspecciones y aplicará medidas

de control periódicamente. El intervalo entre dos inspecciones no podrá ser superior a tres años.------

4. Se establecerán directrices relativas a las condiciones de las inspecciones y las medidas de control, así como sobre la formación y la calificación de los funcionarios encargados de ellas, con el fin de lograr un nivel uniforme de competencia y de resultados.----------

Artículo 8°.- Trazabilidad:----------

1. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos a través del Ministerio de Salud Pública exigirá la aplicación de todas las medidas necesarias para garantizar la trazabilidad del donante al receptor, y viceversa, de todas las células y tejidos obtenidos, tratados, almacenados o distribuidos en nuestro país.----------

Esta trazabilidad también se aplicará a todos los datos pertinentes sobre los productos y materiales que entren en contacto con dichas células y tejidos.-

2. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos garantizará la puesta en práctica de un sistema de identificación de donantes que asigne un código único a cada donación y a cada uno de los productos asociados con ella.--------

3. Todas las células y tejidos deberán estar identificados con una etiqueta que contenga la información o las referencias que permitan establecer un vínculo con la información contemplada en el Anexo II del presente Decreto.----

4. Para garantizar la trazabilidad íntegra de las células y los tejidos en todas sus fases, los datos se conservarán durante 20 años. Los datos también se podrán almacenar de forma electrónica.----------

5. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos establecerán los requisitos de trazabilidad para las células y los tejidos humanos, así como para los productos y materiales que entren en contacto con ellos y que tengan efectos sobre su calidad y su seguridad.----------

Artículo 9°.- Importación y exportación de células y tejidos humanos:----------

1. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos controlarán todas las importaciones de células y tejidos procedentes de terceros países y garantizarán que dichas células y tejidos cumplan con exigencias de calidad y

seguridad equivalentes a las establecidas en esta norma. ----------

2. El Ministerio de Salud Pública - Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos - tomarán todas las medidas necesarias para garantizar que todas las exportaciones de células y tejidos destinados a terceros países que cumplan con lo establecido en la presente norma.----------

3. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos podrán en caso de emergencia autorizar directamente la importación o la exportación de determinados tejidos y células.--------

4. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos verificará la equivalencia de las normas de calidad y seguridad.----------

Artículo 10°.- Registro de programas y obligaciones en materia de información:----------

1. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos mantendrán un registro accesible al público, de centros de trasplantes de células y

tejidos humanos, en el que se especificarán las actividades para las que están habilitados.----------

2. EL Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos mantendrá el registro de estas actividades. ----------

3. Los centros mantendrán un registro de sus actividades, incluidos los tipos y cantidades de células obtenidas, evaluadas, preservadas, procesadas, almacenadas, distribuidas, desechadas, o utilizadas de cualquier otra forma, y del origen y destino de las células y los tejidos humanos.----------

4. Los centros deberán comunicar al Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos en forma obligatoria la actividad referida a células y tejidos.----------

Artículo 11°.- Notificación de los efectos y reacciones adversos graves:----------

1. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos garantizará la existencia de un sistema para notificar, registrar y transmitir información sobre reacciones y acontecimientos adversos graves relacionados con la obtención, verificación, procesamiento, almacenamiento,

distribución, desecho y trasplante de células y tejidos humanos.----------

2. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos establecerá el procedimiento para notificar las reacciones y acontecimientos adversos.----------

3. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos notificará al Ministerio de Salud Pública la información referida a reacciones y acontecimientos adversos graves.--------

CAPÍTULO III

SELECCIÓN Y EVALUACIÓN DE LOS DONANTES

Artículo 12°.- Principios de la donación de células y tejidos:--------

1. Las leyes de trasplante vigentes en el país – Nº 14.005 del 17 de agosto de 1971 y Nº 17.668 del 15 de julio de 2003 - exige que la donación sea de carácter voluntario y no remunerado.----------

2. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos tomarán todas las medidas necesarias para garantizar que cualquier actividad de promoción y publicidad en apoyo de la donación de células y tejidos cuente con la autorización previa, en aras de velar por la precisión y seriedad

del mensaje a difundir. Estará prohibida la publicidad de la necesidad de células y tejidos o la posesión de los mismos con el objetivo de ofrecer o de tratar de obtener un beneficio económico o una ventaja comparable. ----------

3. El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos se esforzarán por garantizar que la obtención de células y tejidos se efectúe sin ánimo de lucro.----------

Artículo 13°.- Consentimiento:----------

1. El consentimiento deberá concederse libremente y de forma expresa, por escrito, antes de la donación.-

2. Solamente se autorizará la obtención de células y tejidos humanos cuando se hayan cumplido todos los requisitos sobre consentimiento informado obligatorio.----------

3.El Ministerio de Salud Pública y el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos tomarán las medidas necesarias para garantizar que los receptores, los donantes o sus familias reciban la información necesaria de acuerdo a lo mencionado en el Anexo III del presente Decreto.----------

4. El documento de consentimiento informado será archivado en el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos. El centro conservará un duplicado del mismo.----------

Artículo 14°.- Protección de datos y confidencialidad:----------

1. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos tomará las medidas necesarias para exigir y garantizar que todos los datos recogidos dentro del ámbito de aplicación de la presente normativa, incluida la información genética, a los que terceros tengan acceso, se hayan convertido en anónimos, a fin de que el donante y el receptor ya no sean identificables.----------

2. A tal fin, velarán por que:----------

a) se adopten medidas de protección de los datos y medidas de seguridad para evitar adiciones, supresiones o modificaciones no autorizadas de las fichas de los receptores y donantes, así como cualquier transferencia de información;----------

b) se establezcan procedimientos para solucionar las divergencias de datos; ----------

c) se impida la revelación no autorizada de dicha información, garantizando al mismo tiempo la

trazabilidad de las donaciones de acuerdo a Ley N° 17668 de 15 de julio de 2003;----------

3. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos tomará todas las medidas necesarias para garantizar que no se revele la identidad del receptor o receptores al donante o a su familia y viceversa, sin perjuicio de la comunicación de la información en caso de que el donante esté relacionado biológicamente con el receptor (Ley N° 17.668 de 15 de julio de 2003).------

Artículo 15°.- Selección, evaluación y obtención:----------

1. Se documentarán los resultados de la evaluación del donante y de los procedimientos de verificación y se comunicará al donante cualquier resultado anómalo pertinente.----------

2. En caso de donación autóloga, el médico responsable del paciente establecerá y documentará los criterios de adecuación, según la historia y las indicaciones terapéuticas de conformidad a las pautas establecidas.----------

3. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos velará por que todas las actividades relacionadas con la obtención de células

y tejidos se efectúen de conformidad con los requisitos mencionados en la presente norma.--------

CAPÍTULO IV

DISPOSICIONES RELATIVAS A LA CALIDAD Y LA SEGURIDAD DE LAS CÉLULAS Y TEJIDOS

Artículo 16°.- Gestión de la calidad:----------

1. Cada centro de obtención, procesamiento y trasplante de células y tejidos implantará un sistema de gestión de calidad.----------

2. Los centros tomarán todas las medidas necesarias a fin de garantizar que el sistema de gestión de calidad incluya como mínimo la documentación siguiente:----------

- Procedimientos de trabajo normalizados.----------
- Directivas.----------
- Manuales de formación.----------
- Formularios de transmisión de información.--------
- Registro de procedimientos.----------

3. Los equipos tomarán todas las medidas necesarias para garantizar que esta documentación esté accesible para inspecciones oficiales.----------

4. Los centros deberán mantener registros de los donantes durante 20 años. Los datos también se podrán almacenar de forma electrónica.----------

Artículo 17°.- Persona responsable:----------

1. Los centros deben designar a un responsable. Esta persona deberá poseer las calificaciones básicas:----------

- Poseer el título de Médico.----------
- Poseer una experiencia práctica de un mínimo de dos años en los ámbitos pertinentes.----------

2. La persona designada será responsable de lo siguiente:----------

a) Garantizar que cada unidad de células y/o tejidos sea procesada de conformidad con la legislación vigente.----------

b) Trasmitir al Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos la información pertinente a la obtención, procesado, almacenado, utilizado de células y/o tejidos.----------

c) Aplicar los requisitos establecidos en los artículos 15 al 22 inclusive del presente Decreto.----------

3. Los centros de obtención, procesamiento y trasplante de células y tejidos notificarán a las autoridades competentes el nombre del responsable mencionado en el numeral 1. Cuando se sustituya de forma permanente o temporal a esta persona, el centro comunicará inmediatamente a las

autoridades competente el nombre del nuevo responsable y la fecha en que asumirá sus funciones.----------

Artículo 18°.- Personal:----------

El personal de los centros directamente implicado en las actividades relacionadas con la obtención, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos deberá disponer de la calificación necesaria para efectuar estas tareas y deberá recibir la formación pertinente.

Artículo 19°.- Recepción de células y tejidos:----------

1. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos velará por que todas las donaciones de células y tejidos humanos sean sometidas a pruebas de laboratorio conforme a los requisitos establecidos en la presente norma y por que la selección y aceptación de las células y tejidos cumplan los requisitos establecidos en ésta.---------

2. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos velará por que la documentación relacionada a las células y tejidos humanos cumplan los requisitos mencionados en la presente norma.----------

3. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos verificará que las condiciones de acondicionamiento de las células y tejidos humanos recibidos de centros nacionales e internacionales se ajustan a los requisitos establecidos y registrará este hecho. Todas las células y tejidos que no cumplan estas disposiciones deberán rechazarse.----------

4. Deberá documentarse la aceptación o el rechazo de las células y tejidos recibidos.----------

5. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos velará por que las células y tejidos humanos estén correctamente identificados en todo momento. Deberá asignarse un código de identificación a cada entrega o partida de células o tejidos.----------

6. Algunas células y los tejidos se mantendrán en cuarentena hasta que se cumplan los requisitos en materia de examen y de información del donante.----

Artículo 20°.- Procesamiento de células y tejidos:----------

1. El centro incluirá en sus manuales de procedimiento todo proceso que afecte a la calidad y la seguridad, y velará por que se lleve a cabo bajo condiciones controladas. Verificará que el equipo

utilizado, el entorno de trabajo y la concepción, la validación y las condiciones de control de los procesos se ajusten a los requisitos contemplados en Anexo IV del presente Decreto.----------

2. Cualquier modificación de los procesos utilizados en la preparación de las células y tejidos también deberá cumplir los criterios establecidos en el numeral 1.----------

3. El centro deberá incluir disposiciones especiales en sus manuales de procedimiento relativos a la manipulación de las células y tejidos que vayan a desecharse a fin de evitar la contaminación de otras células y tejidos, del entorno del procesamiento y del personal.----------

Artículo 21°.- Condiciones de almacenamiento de las células y los tejidos:----------

1. Los centros velarán por que todos los procedimientos asociados con el almacenamiento de células y tejidos estén documentados en los manuales de procedimientos y por que las condiciones de dicho almacenamiento, se ajusten a los requisitos contemplados en esta norma.----------

2. Los centros velarán por que todos los procesos de almacenamiento se desarrollen en condiciones controladas.----------

3. Los centros establecerán y aplicarán procedimientos de control de las áreas de acondicionamiento y almacenamiento a fin de evitar cualquier situación que pudiera afectar negativamente a la funcionalidad o la integridad de las células y tejidos.----------

4. Las células o tejidos tratados no serán distribuidos mientras no se cumplan todos los requisitos establecidos por la presente norma.--------

5. El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos garantizará que los centros de almacenamiento de células y tejidos dispongan de acuerdos y procedimientos que garanticen que, en caso de cese de actividad por cualquier razón, las células y los tejidos almacenados sean transferidos, previa autorización correspondiente, a otros centros habilitados, designados, autorizados y/o acreditados.----------

Artículo 22°- Etiquetado, documentación y acondicionamiento:----

Los centros velarán por que el etiquetado, la documentación y el acondicionamiento se ajusten a los requisitos contemplados en la presente norma.--

Artículo 23°.- Distribución:----------

El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos velará por la calidad de las células y tejidos durante la distribución. Las condiciones de distribución deberán ajustarse a los requisitos contemplados en esta norma.----------

Artículo 24°.- Relaciones entre centros y terceros:----------

1. Los centros celebrarán contratos por escrito con terceros cada vez que tenga lugar una actividad exterior que influya en la calidad y en la seguridad de células y tejidos procesados en cooperación con terceros. En particular, esto será de aplicación en los casos siguientes:----------

a) cuando el centro confíe a un tercero la responsabilidad de una fase de la obtención, y/o procesamiento de las células o tejidos;----------

b) cuando un tercero suministre bienes y preste servicios que afecten a la garantía de la calidad y a la seguridad de las células o tejidos, incluida su distribución;----------

c) cuando un centro preste servicios a otro que no esté autorizado y acreditado;----------

2. Los centros evaluarán y seleccionarán a terceros en función de su capacidad para cumplir las normas establecidas en la presente norma.----------

3. Los centros elaborarán una lista exhaustiva de los acuerdos contemplados en el numeral 1 que hayan celebrado con terceros.----------

4. En los acuerdos entre el centro y terceros deberán especificarse las responsabilidades que corresponden al tercero y detallarse los procedimientos.----------

5. Los centros transmitirán copias de sus acuerdos con terceros cuando lo exija el Ministerio de Salud Pública o el Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos.----------

CAPÍTULO V

INTERCAMBIO DE INFORMACIÓN, INFORMES Y SANCIONES

Artículo 25°.- Codificación de la información:----------

El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos establecerá un sistema para la identificación de las células y tejidos humanos, con el fin de garantizar su trazabilidad.

Artículo 26°.- Sanciones:----------

El Ministerio de Salud Pública aplicará sanciones por concepto de infracciones a las disposiciones adoptadas en la presente norma, entre un mínimo de U.R. 30 (treinta unidades reajustables) y un máximo de 1.000 (mil unidades reajustables), de acuerdo a lo dispuesto en el Decreto del Poder Ejecutivo N° 137/006 de 15 de mayo de 2006.--------

Estas sanciones serán eficaces, proporcionadas y disuasorias. ----------

CAPÍTULO VI

CONSULTA DE LOS COMITÉS

Artículo 27°.- Requisitos técnicos y su adaptación al progreso técnico y científico:----------

Los requisitos técnicos que se enumeran a continuación y su adaptación al progreso técnico y científico se decidirán de conformidad con la Ley N° 14.005, la Ley N° 17.668, el presente Decreto y el procedimiento descripto en el artículo 28:----------

a) requisitos para la habilitación, acreditación, designación o autorización del centro y del programa

b) requisitos para la obtención de células y tejidos humanos;----------

c) sistema de calidad, incluida la formación;----------

d) criterios para la selección del donante de células o tejidos;----------

e) pruebas de laboratorio general requeridas para los donantes;----------

f) pruebas de histotipificación requerida para donantes y receptores.----------

g) procedimientos de obtención de células y tejidos y recepción en el centro;----------

h) procedimiento de obtención de residuos quirúrgicos y recepción en el centro de procesamiento.----------

i) requisitos del método de preparación de células y tejidos;----------

j) procesamiento, almacenamiento y distribución de células y tejidos;----------

k) requisitos para la asignación y distribución al receptor de células y tejidos específicos.----------

Artículo 28°.- Consulta de uno o varios comités científicos:----------

El Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos podrá consultar al comité o comités científicos competentes al definir o adaptar al progreso científico y técnico los requisitos técnicos contemplados en la presente norma.---------

Artículo 29°.- Intégrase al presente Decreto los Anexos I, II, III y IV que se adjuntan y forma parte del mismo.----------

Artículo 30°.- Comuníquese. Publíquese.----------

Decreto N°

Decreto Diario Oficial N°

Ref. N°

Dr. Tabaré Vázquez
Presidente de la República

ANEXO I

REQUISITOS PARA LA OBTENCIÓN DE CELULAS Y TEJIDOS

El centro encargado de la obtención de celulas y tejidos deberá garantizar ciertos requisitos mínimos y otras condiciones.

a) tener un equipo médico especializado en la obtención de células y tejidos y disponer del personal con la formación y experiencia necesarias para realizar este trabajo.

b) disponer de los documentos que especificarán las condiciones de la actividad y los protocolos que deberán seguirse.

c) contar con procedimientos de trabajo normalizados para la extracción, el empaquetado, la conservación y el desecho de las células o los tejidos.

d) instalar un sistema de gestión de la calidad.

e) garantizar que se lleven a cabo los estudios apropiados para evitar la presencia de enfermedades transmisibles.

f) disponer de las instalaciones y los recursos materiales necesarios para la extracción, el empaquetado, la conservación , y el desecho de las células.

g) garantizar que los procedimientos para la extracción, el empaquetado, la conservación , y el desecho de las células o tejidos se lleven a cabo conforme a lo establecido en el Programa correspondiente .

i) garantizar la trazabilidad adecuada de las células o tejidos extraídos, trasplantados , entregados o desechados, mediante un documento único por donante.

ANEXO II

REQUISITOS DE IDENTIFICACIÓN PARA LAS CÉLULAS Y TEJIDOS

ETIQUETADO DE LAS CÉLULAS O LOS TEJIDOS

El etiquetado de cada envase de células o tejidos deberá contener al menos la siguiente información:

a) número o código de identificación del donante.

b) tipo de células o tejido.

c) fecha de obtención.

d) centro de obtención

e) lote y cantidad

ETIQUETADO DEL CONTENEDOR DE ENVÍO

Cuando se envíen células o tejidos, cada contenedor deberá llevar una etiqueta en la que figuren al menos los siguientes datos:

a) identificación de las células o los tejidos;

b) identificación del centro de obtención (dirección y número de teléfono), y de la persona encargada de la entrega;
c) identificación del centro de destino (dirección y número de teléfono) y de la persona encargada de la recepción en el punto de destino.

DATOS QUE DEBERÁN REGISTRARSE EN EL CENTRO DE OBTENCION

Los datos que deberán quedar registrados en el centro de obtención son los siguientes:

a) duplicado del consentimiento;
b) identificación y características del donante: tipo de donante, edad, sexo y presencia de factores de riesgo;
c) revisión de los datos clínicos conforme a los criterios de selección de donantes;
d) resultados del examen clínico, de las pruebas de laboratorio y de otras pruebas
e) fecha y hora de la obtención y centro en el que se lleva a cabo;
f) equipo que la realiza y persona encargada de ella.
g) información sobre las soluciones de conservación utilizadas durante la obtención, incluida la composición, el lote, la fecha de

expiración, la temperatura, la cantidad, la concentración y el método de preparación;

h) material obtenido y características pertinentes;

i) incidentes notables ocurridos antes, durante y después de la obtención;

j) destino de las células;

k) método de conservación de las células y 3 años de conservación obligatorio.

ANEXO III

INFORMACIÓN QUE SE HA DE FACILITAR SOBRE LA DONACIÓN DE CÉLULAS Y TEJIDOS

A. DONANTES VIVOS

1. La persona encargada del proceso de donación garantizará que se haya informado adecuadamente al donante de, como mínimo, aquellos aspectos relacionados con la donación y el proceso de obtención. La información deberá facilitarse antes de la obtención.

2. La información deberá ser facilitada por una persona competente, capaz de transmitirla de manera adecuada y clara, utilizando términos fácilmente comprensibles por el donante.

3. La información deberá cubrir: el objetivo y la naturaleza de la obtención, sus consecuencias y riesgos, pruebas analíticas, si se realizan; registro y protección de los datos del donante, confidencialidad médica, fines terapéuticos y beneficios potenciales, así como información sobre las salvaguardas aplicadas para proteger al donante.

4. El donante deberá ser informado de que tiene derecho a recibir los resultados confirmados de las pruebas de laboratorio, explicados claramente.

5. Deberá informarse sobre la necesidad de exigir el consentimiento y la autorización obligatorios aplicables para que pueda llevarse a cabo el procesamiento de células y/o tejidos.

B. DONANTES FALLECIDOS

1. Toda la información deberá facilitarse y todos los consentimientos y autorizaciones deberán obtenerse de conformidad con la Ley 14005 de 17 de agosto de 1971 y la Ley 17668 de 15 de julio de 2003.

2. Los resultados confirmados de la evaluación del donante deberán comunicarse y explicarse claramente a las personas interesadas, de conformidad con la legislación vigente.

ANEXO IV

PROCESAMIENTO, ALMACENAMIENTO Y DISTRIBUCIÓN DE CÉLULAS Y TEJIDOS.

PROCESAMIENTO

Cada instalación de procesamiento de células o tejidos deberá tener un sistema adecuado de control de procesos.

Cuando los procedimientos técnicos no puedan verificarse en cualquier momento concreto durante el proceso, deberán ser controlados continuamente para garantizar que se cumplan los procedimientos de trabajo normalizados establecidos.

Cuando se aplique un procedimiento de inactivación microbiana a las células o tejidos, este deberá ser especificado, documentado y validado.

Cuando un tercero lleve a cabo cualquier paso del proceso, deberán recogerse en un acuerdo por escrito las especificaciones requeridas en lo que se refiere a la ejecución y la validación.

Los procesos deberán ser sometidos a una evaluación periódica crítica para garantizar que siguen alcanzando los resultados previstos.

Antes de introducir nuevos procesos estos deberán ser validados para demostrar que darán como resultado, células o tejidos que cumplan los procedimientos de trabajo normalizados del Programa.

Cuando en el procesamiento intervenga cualquier cambio importante, que implique equipo nuevo o modificado, reajustes importantes o cambios de localización, dichas etapas de validación deberán repetirse y documentarse.

Los entornos en los que se procesen las células o tejidos deberán ser adecuadamente controlados para minimizar o evitar las posibilidades de contaminación.

ALMACENAMIENTO

Deberán definirse las condiciones de almacenamiento necesarias (incluidos parámetros importantes como la temperatura) para mantener las propiedades requeridas de las células o los tejidos.

Los parámetros deberán ser controlados, vigilados y registrados para demostrar el cumplimiento de las condiciones especificadas.

Para cada tipo de condición de almacenamiento deberá especificarse el tiempo mínimo de almacenamiento de acuerdo a las pautas establecidas por los Comité de expertos correspondientes.

El periodo seleccionado deberá tener en cuenta el posible deterioro de las propiedades requeridas de las células o los tejidos, la evolución de los criterios de selección y examen del donante a lo largo del tiempo y la disponibilidad de otros tratamientos.

DISTRIBUCIÓN

1. Deberán definirse las condiciones de transporte necesarias (incluidos parámetros importantes como la temperatura) para mantener las propiedades requeridas de las células o los tejidos.

2. El empaquetado deberá garantizar que las células o los tejidos se mantienen en las condiciones establecidas en los procedimientos de trabajo normalizados.

3. Si se encargara de la distribución un tercero mediante contrato, deberá contarse con un acuerdo por escrito para garantizar que se mantengan las condiciones requeridas.

REPUBLIQUE DU BENIN

Loi N° 2010-40 DU 08 DECEMBRE 2010

portant code d'éthique et de déontologie pour la recherche en santé en République du Bénin.

L'Assemblée Nationale a délibéré et adopté en sa séance du 14 octobre 2010,

Suite à la Décision de conformité à la Constitution DCC 10-141 du 23 novembre 2010 de la Cour Constitutionnelle,

Le Président de la République promulgue la loi dont la teneur suit :

TITRE PREMIER :

DES DISPOSITIONS GENERALES

CHAPITRE PREMIER

DE L'OBJET, DU CHAMP D'APPLICATION ET DES PERSONNES CHARGEES DE LA RECHERCHE EN SANTE

Article 1er : Toute recherche entreprise en République du Bénin en vue du développement des connaissances en santé est régie par les dispositions de la présente loi.

Article 2 : La recherche en santé a pour objet de :

- Mettre au point des outils pour prévenir et soigner la maladie ou en atténuer les effets ;
- concevoir des approches plus efficaces pour la prestation des soins de santé tant à l'individu qu'à la communauté ;
- contribuer à mieux outiller les professionnels de la santé à des fins de prévention de la maladie, de restauration de la santé et de réadaptation.

Article 3 : Toute personne physique ou morale qui prend l'initiative d'une recherche en santé à la qualité de promoteur.

Lorsque plusieurs personnes physiques ou morales prennent l'initiative d'une même recherche, elles désignent en leur sein une personne qui fait office de promoteur et assume les obligations correspondantes.

Article 4 : Toute personne physique ou morale qui prend l'initiative d'une recherche en santé a la qualité de promoteur

Article 5 : Lorsque le promoteur confie la mise en oeuvre d'une recherche à une équipe de chercheurs, il désigne parmi eux un chercheur principal.

Lorsque la recherche est entreprise par plusieurs équipes, celles-ci désignent en leur sein un coordonnateur.

CHAPITRE II

DES PRINCIPES D'ETHIQUE DE LA RECHERCHE EN SANTE

Article 6 : Toute recherche impliquant des sujets humains doit être exécutée dans le respect des principes ci-après :

- la dignité humaine et les droits de l'homme ;
- la vulnérabilité humaine et l'intégrité personnelle ;
- l'anonymat ;
- la confidentialité ;
- les croyances et les pratiques socio-culturelles ;
- l'innocuité ;
- l'action bénéfique de la recherche ;
- l'équité de la recherche ;
- la restitution des résultats aux personnes concernées ;
- les règles de diffusion et d'utilisation des résultats ;
- le partage des bienfaits de la recherche.

Article 7 : L'implication d'êtres humains, en tant qu'objets de recherche, doit être subordonnée à la possibilité pour eux d'y consentir librement et en toute connaissance de cause.

Ces personnes ont la latitude de se soustraire du programme de recherche à n'importe quel moment sans crainte ni menace.

Article 8 : La recherche clinique et/ou la recherche biomédicale ne peut s'effectuer sur une personne en état de mort cérébrale qu'avec son consentement ou celui de sa famille, préalablement exprimé par écrit.

Article 9 : L'utilisation des cadavres humains à des fins de recherche doit se faire conformément aux textes en vigueur.

Article 10 : L'utilisation d'animaux à des fins de recherche doit se faire dans le respect des textes en vigueur.

TITRE II

DU DOMAINE DE LA RECHERCHE EN SANTE

CHAPITRE PREMIER

DU CHAMP D'APPLICATION ET DES COMPOSANTES DE LA RECHERCHE EN SANTE

Article 11 : La recherche épidémiologique, la recherche clinique, la recherche biomédicale, la recherche en médecine traditionnelle et la recherche sur les systèmes de santé sont les différentes composantes régies par la présente loi.

Article 12 : La recherche épidémiologique est toute étude qui vise à mesurer les facteurs déterminant ou influençant la survenue ou la persistance d'un problème de santé dans une population donnée.

Article 13 : La recherche clinique et la recherche biomédicale désignent les diagnostics, les essais ou expérimentations organisés et pratiqués directement sur l'être humain et/ou l'animal en vue du développement des connaissances médicales et pharmaceutiques.

Article 14 : La recherche en médecine traditionnelle est celle qui s'intéresse aux pratiques de soins de santé employées par des individus, des groupes et par une communauté, selon des traditions le plus souvent orales.

Article 15 : La recherche sur les systèmes de santé est celle qui porte sur les dispositions législatives et réglementaires relatives à la prévention des maladies et aux soins aux malades ainsi que sur les administrations, les personnes et les équipements qui y contribuent.

CHAPITRE II

DES MODALITES DE LA RECHERCHE EN SANTE

Article 16 : La recherche épidémiologique s'intéresse à l'état de santé des populations et à ses variations dans le temps et dans l'espace.

Elle peut être descriptive, analytique, évaluative, expérimentale, prospective, rétrospective et/ou théorique.

Article 17 : La recherche clinique et la recherche biomédicale sont avec ou sans bénéfice individuel direct.

Elles sont dénommées recherches clinique et biomédicale avec bénéfice individuel direct, lorsqu'il en est attendu un bénéfice direct pour la personne qui s'y prête.

Toutes les autres recherches clinique et biomédicale, qu'elles portent sur des personnes malades ou non, sont dénommées sans bénéfice individuel direct.

Article 18 : La recherche en médecine traditionnelle vise à :

- valider les propriétés thérapeutiques des plantes médicinales et extraits d'animaux et minéraux ainsi que leurs utilisations dans le traitement des différentes affections ;
- œuvrer efficacement pour la mise au point des produits de la médecine traditionnelle qui ont déjà fait leurs preuves thérapeutiques, tout en veillant à leur conditionnement hygiénique et à leur bonne conservation, en vue d'une utilisation à l'échelle nationale, régionale et internationale.

Article 19 : La recherche sur les systèmes de santé a pour but de favoriser la prise de décision rationnelle pour la gestion optimale des établissements et structures du système de santé.

Cette gestion vise à assurer, à moindre coût et avec une qualité meilleure de service, la promotion de la santé et la prestation de soins préventifs, curatifs, réadaptatifs et promotionnels aux différents niveaux du système.

TITRE III

DES CONDITIONS D'EXECUTION DE LA RECHERCHE EN SANTE

CHAPITRE PREMIER

DE LA RECHERCHE EPIDEMIOLOGIQUE

Article 20 : Toute recherche épidémiologique appliquée à un groupe d'individus ou à une communauté doit requérir l'accord préalable de ses représentants légaux.

Lorsqu'un groupe d'individus ou une communauté sur lequel porte l'étude doit être représenté par une personne mandatée, le chercheur doit s'assurer de l'authenticité de son mandat.

Article 21 : Le consentement éclairé à titre individuel des personnes participant à toute recherche épidémiologique est obligatoire.

Le consentement est dit éclairé lorsque la personne sollicitée comprend le but et la nature de la recherche, les obligations qu'implique sa participation à celle-ci ainsi que les risques et les avantages qui peuvent en découler.

Le refus d'une participation individuelle à une telle recherche doit être libre et respecté.

Article 22 : Lorsque des groupes d'individus sont constitués à des fins d'une recherche épidémiologique et qu'il n'est pas possible d'identifier leur représentant, le chercheur doit obtenir le consentement éclairé et libre de chacune des personnes appelées à participer à cette recherche.

Article 23 : Le consentement éclairé n'est pas exigé dans le cas où :

- il est impossible de localiser des personnes participant à toute recherche dont les dossiers seront examinés ;

- il existe un risque de biais dans les résultats de certaines recherches où les personnes participant à une recherche sont susceptibles de modifier leurs comportements.

CHAPITRE II

DES RECHERCHES CLINIQUE ET BIOMEDICALE

Article 24 : Les recherches clinique et biomédicale doivent être effectuées :

- sous la direction d'un chercheur qualifié, au cas où il n'est pas médecin, il doit être assisté d'un médecin justifiant d'une expérience d'au moins cinq (05) ans dans le domaine concerné ;
- dans des conditions matérielles et techniques adaptées à l'étude et compatibles avec les impératifs de rigueur scientifique et de sécurité des personnes qui se prêtent à ces recherches.

Article 25 : Toute recherche clinique et/ou biomédicale sur l'être humain doit :

- se fonder sur le dernier état des connaissances scientifiques et sur une expérimentation pré-clinique suffisante ;
- procurer aux personnes concernées un bénéfice largement supérieur au risque prévisible encouru ;
- viser à étendre les connaissances scientifiques sur l'être humain et les moyens susceptibles de maintenir ou d'améliorer son état de santé.

Article 26 : Préalablement à la réalisation d'une recherche clinique et/ou biomédicale sur une personne, le consentement libre, éclairé et exprès de celle-ci doit être recueilli après que le chercheur lui a fait connaître :

- l'objectif de la recherche, sa méthodologie et sa durée ;

- les résultats attendus, les contraintes et les risques prévisibles, même en cas d'arrêt de la recherche avant son terme ;

- l'avis du Comité national d'éthique pour la recherche en santé (CNERS) prévu aux articles 43 et suivants de la présente loi.

Le chercheur informe la personne dont le consentement est sollicité de son droit de refuser de participer à la recherche ou de retirer son adhésion à tout moment sans encourir aucune menace.

Le consentement est donné par écrit ou, en cas d'impossibilité, attesté par un tiers. Ce dernier doit être totalement indépendant du chercheur et du promoteur.

Article 27 : Les mineurs et les majeurs protégés par la loi admis dans un établissement sanitaire ou social ne peuvent être sollicités pour une recherche clinique et/ou biomédicale que si l'on peut en attendre un bénéfice direct pour leur santé et après avis du père et/ou de la mère, du tuteur ou du curateur.

Toutefois, ils peuvent être l'objet de recherches sans bénéfice individuel direct au cas où celles-ci remplissent les conditions suivantes :

- ne présenter aucun risque sérieux prévisible pour leur santé ;

- être utiles à des personnes présentant les mêmes caractéristiques d'âge, de sexe et d'état de santé ;

- ne pas pouvoir être réalisées autrement.

Article 28 : Lorsqu'une recherche clinique et/ou biomédicale est effectuée sur des mineurs ou des majeurs protégés par la loi, le consentement doit être donné par :

- les titulaires de l'exercice de l'autorité parentale, pour les mineurs non émancipés ;
- le représentant légal, pour les recherches avec bénéfice individuel direct ne présentant pas de risque prévisible sérieux, pour les mineurs ou les majeurs protégés par la loi ;
- le tuteur autorisé par le conseil de famille ou le juge des tutelles, dans les autres cas.

Article 29 : La recherche clinique et/ou biomédicale exige la souscription préalable par son promoteur, d'une assurance garantissant sa responsabilité civile et celle de tout intervenant, indépendamment de la nature des liens existant entre les intervenants et le promoteur.

Article 30 : La recherche clinique et/ou biomédicale ne donne lieu à aucune contrepartie financière directe ou indirecte pour les personnes qui s'y prêtent, hormis le remboursement des frais auxquels elles sont exposées et sous réserve de dispositions particulières prises par le Comité national d'éthique pour la recherche en santé.

Article 31 : La recherche clinique et/ou biomédicale avec ou sans bénéfice individuel direct ne doit comporter aucun risque prévisible sérieux pour la santé des personnes qui s'y prêtent.

Elle doit être précédée d'un examen médical des personnes concernées, effectué par un médecin désigné par le chercheur principal ou

le coordonnateur parmi les médecins agréés par le Comité national d'éthique pour la recherche en santé. Les résultats de cet examen leur sont communiqués par l'intermédiaire du médecin de leur choix, avant l'expression de leur consentement éclairé.

Article 32 : Nul ne peut se prêter simultanément à plusieurs recherches cliniques ou biomédicales sans bénéfice individuel direct.

Avant de soumettre une personne à une recherche clinique et/ou biomédicale, le chercheur a l'obligation de vérifier si elle n'est déjà impliquée dans une autre recherche en cours.

Pour chaque recherche sans bénéfice individuel direct, le protocole soumis à l'avis du Comité national d'éthique pour la recherche en santé détermine une période d'exclusion au cours de laquelle la personne qui s'y prête ne peut participer à une autre recherche sans finalité thérapeutique directe. La durée de cette période varie en fonction de la nature de la recherche.

Article 33 : La recherche clinique et/ou biomédicale sans bénéfice individuel direct doit être réalisée dans un lieu équipé de moyens matériels et techniques appropriés à la recherche et compatibles avec les impératifs de sécurité des personnes qui s'y prêtent. Le site de recherche ainsi défini doit être validé par le ministre en charge de la santé, après avis du Comité national d'éthique pour la recherche en santé.

Article 34 : Toute recherche clinique et/ou biomédicale avec ou sans bénéfice individuel direct sur les femmes enceintes, les parturientes et les mères qui allaitent doit remplir les conditions suivantes :

- être dénuée de tout risque sérieux prévisible pour la santé de la mère et/ou de l'enfant ;
- être utile à la connaissance des phénomènes de la grossesse, de l'accouchement ou de l'allaitement ;
- ne pouvoir être réalisée autrement.

Article 35 : L'utilisation à des fins thérapeutiques d'organes, de tissus ou de cellules d'origine animale qui ne sont ni des dispositifs médicaux, ni destinés à des thérapies géniques ou cellulaires, n'est possible que dans le cadre de recherches clinique et/ou biomédicale soumises aux dispositions de la présente loi.

Article 36 : Par dérogation aux dispositions de la présente loi, les recherches cliniques et/ou biomédicales portant sur l'utilisation thérapeutique de tels organes, tissus ou cellules chez l'être humain ne peuvent être mises en œuvre qu'après autorisation du ministre en charge de la santé, sur avis conforme du Comité national d'éthique pour la recherche en santé.

L'autorisation peut être assortie de conditions particulières portant notamment sur la surveillance à long terme des patients.

Article 37 : Des règles de bonnes pratiques relatives au prélèvement, à la conservation, à la transformation, au transport et à l'utilisation des organes, tissus et cellules des animaux, sont fixées conjointement par les ministres en charge de la santé et de l'élevage, sur proposition du Comité national d'éthique pour la recherche en santé.

Article 38 : Des arrêtés conjoints des ministres en charge de la santé et de l'élevage fixent :

- les règles de bonnes pratiques relatives à la sélection, à la production et à l'élevage des animaux ;

- les conditions sanitaires auxquelles doivent répondre les animaux desquels proviennent les organes, tissus et cellules utilisés ;

- les règles d'identification de ces animaux, organes, tissus et cellules permettant d'assurer la traçabilité des produits obtenus.

Article 39 : En cas de recherche clinique et/ou biomédicale à mettre en œuvre dans des situations d'urgence qui ne permettent pas de recueillir le consentement préalable de la personne qui y sera soumise, le protocole présenté à l'avis du Comité national d'éthique pour la recherche en santé peut prévoir que le consentement de cette personne ne sera pas recherché et que seul sera sollicité, celui des membres de sa famille dans les conditions prévues à l'article 26 de la présente loi. L'intéressé en sera informé, dès que possible, et son consentement lui sera demandé pour la poursuite éventuelle de la recherche.

CHAPITRE III

DE LA RECHERCHE EN MEDECINE TRADITIONNELLE

Article 40 : La recherche en médecine traditionnelle doit être effectuée :

- sous la direction d'un chercheur qualifié et, au cas où il n'est pas médecin, assisté d'un médecin et/ou d'un pharmacien justifiant d'une expérience d'au moins cinq (05) ans dans le domaine concerné et d'un praticien de la médecine traditionnelle, sur la base d'une collaboration préalable matérialisée par un accord écrit ;

- dans des conditions matérielles et techniques adaptées à la recherche et compatibles avec les impératifs de rigueur scientifique et de sécurité des personnes qui se prêtent à cette recherche.

Article 41 : Toute recherche en médecine traditionnelle sur l'être humain doit :

- se fonder sur une étude ethnomédicale ;

- se fonder sur la confirmation par le médecin du diagnostic et du résultat thérapeutique ;

- procurer aux personnes concernées un bénéfice largement supérieur au risque prévisible encouru ;

- viser à étendre les connaissances scientifiques sur l'être humain et les moyens susceptibles de maintenir ou d'améliorer son état de santé ;

- requérir l'accord préalable du Comité national d'éthique pour la recherche en santé.

CHAPITRE IV

DE LA RECHERCHE SUR LES SYSTEMES DE SANTE

Article 42 : Toute recherche sur les systèmes de santé doit requérir :

- la participation active des professionnels de la santé et des gestionnaires du système de santé ;

- l'accord et la participation des individus, des groupes et des communautés concernés ;

- l'accord préalable du Comité national d'éthique pour la recherche en santé.

TITRE IV

DU CONTROLE DE LA RECHERCHE EN SANTE

CHAPITRE PREMIER

DE L'ORGANE DE CONTROLE

Article 43 : Il est créé le Comité national d'éthique pour la recherche en santé (CNERS) ci-après dénommé : **" le Comité "**.

Le Comité est l'organe de contrôle de la recherche en santé en République du Bénin.

Il est chargé d'examiner les protocoles de recherche et de valider les compétences d'un chercheur qualifié.

Article 44 : Un décret pris en conseil des ministres, sur proposition du ministre en charge de la santé, détermine la composition, les attributions et les modalités de fonctionnement du Comité.

Article 45 : Le Comité est placé sous la tutelle du ministre en charge de la santé.

CHAPITRE II

DE LA MISE EN ŒUVRE DU CONTROLE

Article 46 : L'examen de tout protocole de recherche épidémiologique exigeant la présence de groupes témoins doit s'assurer que :

- les avantages, les risques, les contraintes et l'efficacité de la nouvelle méthode sont évalués par comparaison avec les meilleures méthodes diagnostiques, thérapeutiques ou de prévention en usage ;

- le groupe témoin ne reçoit de placebo que lorsqu'il n'existe pas de traitement éprouvé contre la maladie visée ; toutefois, même s'il existe un traitement éprouvé, les essais avec témoins sous placebo peuvent être éthiquement acceptables dans les conditions suivantes :

* lorsque, pour des raisons méthodologiques impérieuses et scientifiquement solides, il n'existe pas d'autres moyens qui permettent de déterminer l'efficacité ou l'innocuité de la nouvelle méthode prophylactique, diagnostique ou thérapeutique ;

* lorsqu'une méthode prophylactique, diagnostique ou thérapeutique est mise à l'essai pour une affection bénigne et que la participation à l'essai n'expose pas à des risques supplémentaires de dommages significatifs ou durables.

- si l'efficacité du traitement testé sur le groupe expérimental est supérieure à celle du traitement habituellement utilisé, tous les participants à l'essai en bénéficient immédiatement.

Article 47 : Lorsque la proposition de recherche est initiée de l'extérieur du Bénin par une personne physique ou morale, elle doit être accompagnée de l'avis du Comité d'éthique du pays initiateur ou de toute autre structure en tenant lieu, avant son examen par le Comité.

TITRE V

DES INFRACTIONS ET DES SANCTIONS

Article 48 : Le fait de pratiquer ou de faire pratiquer sur une personne une recherche clinique et/ou biomédicale ou une recherche en médecine traditionnelle sans avoir recueilli le consentement libre, éclairé et exprès de l'intéressé, des titulaires de l'autorité parentale ou du tuteur dans les cas prévus par les dispositions de la présente loi, est puni d'un emprisonnement de six (06) mois à douze (12)) mois et d'une amende de un million (1 000 000) à cinq millions (5 000 000) de francs ou de l'une de ces deux peines seulement.

Les mêmes peines sont applicables lorsque le consentement a été retiré avant qu'il ne soit procédé à la recherche.

La peine encourue lorsqu'il s'agit d'une personne morale est une amende de cinq millions (5 000 000) à quinze millions (15 000 000) de francs.

Article 49 : Le fait de pratiquer ou de faire pratiquer une recherche clinique et/ou biomédicale ou en médecine traditionnelle en infraction aux dispositions des articles 26 à 28 de la présente loi, est puni d'un emprisonnement de six (06) mois à un (01) an et d'une amende de un million

(1 000 000) à cinq millions (5 000 000) de francs lorsque le coupable est une personne physique.

Article 50 : Outre les peines prévues à l'article 49 ci-dessus, le coupable encourt les sanctions suivantes :

- l'interdiction à temps des droits civiques, civils et de famille suivant les dispositions du code pénal ;

- l'interdiction pour une durée de deux (02) ans à cinq (05) ans, d'exercer l'activité professionnelle ou sociale à l'occasion de laquelle ou dans l'exercice de laquelle l'infraction a été commise ;

- la confiscation du corps du délit ;

- l'exclusion de la soumission aux appels d'offres pour l'attribution des marchés publics pour une durée de cinq (05) ans à dix (10) ans.

La peine encourue lorsqu'il s'agit d'une personne morale est une amende de cinq millions (5 000 000) à quinze millions (15 000 000) de francs. Elle est également passible des sanctions prévues aux 2ème, 3ème et 4ème tirets de l'alinéa précédent.

Article 51 : Est puni d'un emprisonnement de six (06) mois à douze (12) mois et d'une amende de un million (1 000 000) à cinq millions (5 000 000) de francs ou de l'une de ces deux peines seulement :

- quiconque aura pratiqué ou fait pratiquer une recherche clinique et/ou biomédicale et une recherche en médecine traditionnelle en violation du respect de la confidentialité prévu à l'article 6 de la présente loi ;

- quiconque aura pratiqué ou fait pratiquer une recherche clinique et/ou biomédicale et une recherche en médecine traditionnelle sans avoir obtenu l'avis préalable prévu par les articles 26, 41 et 42 de la présente loi ;

- quiconque aura pratiqué ou fait pratiquer, continué de pratiquer ou de faire pratiquer une recherche clinique et/ou biomédicale et ou une recherche en médecine traditionnelle dont la réalisation a été interdite ou suspendue par le ministre en charge de la santé.

Article 52 : Le promoteur dont la responsabilité civile n'est pas garantie par l'assurance prévue à l'article 29 de la présente loi est puni d'un emprisonnement de six (06) mois à douze (12) mois et d'une amende de un million (1 000 000) à cinq millions (5 000 000) de francs ou de l'une de ces deux peines seulement.

Article 53 : Le fait de pratiquer ou de faire pratiquer sur une personne une recherche clinique et/ou biomédicale et une recherche en médecine traditionnelle autorisées mais ayant entraîné un homicide involontaire par maladresse, imprudence, inattention, négligence ou inobservation des règlements est puni d'un emprisonnement de six (06) mois à deux (02) ans et d'une amende de cinq cent mille (500 000) francs à un million (1 000 000) de francs ou de l'une de ces deux peines seulement.

Article 54 : Le fait de pratiquer ou de faire pratiquer sur une personne une recherche clinique et biomédicale et/ou une recherche en médecine traditionnelle autorisée mais ayant causé des blessures involontaires ou une maladie ayant entraîné par défaut d'adresse ou de précaution une incapacité temporaire de travail pour le sujet est puni d'un emprisonnement d'un (01) mois à douze (12) mois et d'une amende de cinquante mille (50 000) francs à deux cent cinquante mille (250 000) francs ou de l'une de ces deux peines seulement.

Article 55 : Quiconque aura pratiqué ou fait pratiquer sans le consentement du sujet ou sans l'avis du Comité une recherche clinique et/ou biomédicale et une recherche en médecine traditionnelle ayant entraîné la mort du sujet sera puni d'une réclusion criminelle à temps de cinq (05) ans à dix (10) ans.

S'il y a une incapacité de travail de vingt et-un (21) jours, la peine sera un emprisonnement de six (06) mois à deux (02) ans et une amende de cinq cent mille (500 000) francs à un million (1 000 000) francs.

Si l'incapacité temporaire de travail est de moins de vingt et un (21) jours, la peine sera un emprisonnement de six (06) mois à dix huit (18) mois et une amende de cinq cent mille (500 000) francs à un million (1 000.000) francs ou l'une de ces deux peines seulement.

TITRE VI

DES DISPOSITIONS FINALES

Article 56 : La présente loi qui abroge toutes dispositions antérieures contraires, sera exécutée comme loi de l'Etat.

Fait à Cotonou, le 08 décembre 2010.

Par le Président de la République,
Chef de l'Etat, Chef du Gouvernement,

Dr BONI YAYI.-

Le Ministre d'Etat Chargé de la Prospective, du Développement, de l'Evaluation des Politiques Publiques et de la Coordination de l'Action Gouvernementale,

Pascal Irénée KOUPAKI

Le Ministre de la Santé,

Issifou TAKPARA .-

Le Garde des Sceaux, Ministre de la de la Législation et des Droits de l'Homme,

Grégroire AKOFODJI

AMPLIATIONS : PR 6 AN 4 CS 2 CC 2 CES 2 HAAC 2 HCJ 2 MECPDEPPCAG 4 GS/MJLDH 4 MS 4 AUTRES MINISTERES 27 SGG 4 SMTP 2 DGAE-DGCPE 2 DGBM-DCF-DGTCP-DGID-DGDDI 5 BN-DAN-DLC- 3 GCONB-DGCST-INSAE 3 BCP-CSM-IGAA 3 BCP-CSM-IGAA 3 UAC-ENAM-FADESP 3 UNIPAR-FDSP 2 JO 1

REPUBLIQUE DE GUINEE

Travail - Justice - Solidarité

CODE DE LA SANTE PUBLIQUE

L'ASSEMBLEE NATIONALE DE LA REPUBLIQUE DE GUINEE.

VU LES DISPOSITIONS DE LA LOI FONDAMENTALE NOTAMMENT EN SES ARTICLES 59 ET 77.

APRES EN AVOIR DELIBERE, ADOPTE :

LE PRESIDENT DE LA REPUBLIQUE PROMULGUE LA LOI DONT LA TENEUR SUIT :

LIVRE PREMIER : DE LA NATION GENERALE DE SANTE PUBLIQUE

CHAPITRE I : DES PRINCIPES ET DISPOSITIONS FONDAMENTAUX

Article 1er : La présente Loi assure la protection et la promotion de la Santé, les droits et les obligations de l'individu, de la famille et de la Collectivité sur l'ensemble du Territoire de la République de Guinée.

Les objectifs essentiels qui concourent à l'amélioration de la Santé visent à procurer à l'individu, la famille et à la Collectivité les conditions sanitaires minimales leur permettant de mener une vie sociale et économiquement productive.

La mise en œuvre de ces objectifs est subordonnée à l'élaboration d'une carte sanitaire nationale définissant la sphère de compétence territoriale ou devra s 'appliquer le système médico-sanitaire guinéen.

Article 2 : La carte sanitaire nationale sera réglementée par un acte pris par le Ministre chargé de la Santé publique qui en assure l'application.

Article 3 : L'individu, la famille et la Collectivité jouissent de la protection médico-sanitaire contre les maladies endémo-épidémiques par l'amélioration constante et suivie des conditions de vie et de travail essentiellement par :

- La vaccination obligatoire pour l'ensemble de la Collectivité ;
- L'établissement des services de santé adéquats ;
- La lutte contre les endémies ;
- La protection des conditions alimentaires et nutritionnelles ;
- La formation des personnels de Santé ;
- La promotion et l'émulation de la recherche biomédicale, la recherche bioéthique, en génie génétique et en d'autres technologies médicales nouvelles.

Article 4 : La politique nationale de Santé de la République en Guinée se définit comme la totalité des activités inhérentes à la promotion et à la protection médico-sanitaire de l'individu, de la famille et de la collectivité en conformité avec les dispositions de l'article 3 de la présente Loi.

Cette politique nationale de Santé se caractérise par la prise en charge des soins conformément à l'aliéna 2 de l'article 1er de la présente Loi en assurant l'émulation des soins de Santé primaires.

Cette politique nationale de santé devra prendre en compte le développement du secteur privé.

ARTICLE 5 : Toutefois la Politique Nationale de Santé se base essentiellement sur les considérations normatives suivants :

- Le développement du secteur public et sa prévalence sur le secteur privé qui en est un complément ;
- Le renforcement de la complémentarité entre différents secteurs concourant à l'émulation de la Santé ;
- La planification, la recherche qui s'intègrent dans le cadre général de développement socio-économique ;
- La collaboration intersectorielle et multidisciplinaire dans la mise en œuvre des programmes de Santé ;
- La mobilisation des ressources humaines, matérielles, financières, budgétaires et extrabudgétaire en vue d'appuyer les programmes élaborés ;
- L'intégration des activités de prévention, de réhabilitation et de réadaptation ;
- La décentralisation et la hiérarchisation des Services de Santé ;
- L'auto-responsabilité de l'individu, de la famille et de la Collectivité, leur participation effective à la planification, à l'organisation, à l'application et à l'évaluation idoine des Services et programmes de Santé.

LIVRE DEUXIEME : DE LA SANTE PUBLIQUE

CHAPITRE I : DES MESURES APPLICABLES EN MATIERES DE GENIE SANITAIRE ET D'HYGIENNE PUBLIQUE

SECTION 1 : DES EAUX DESTINEES A LA CONSOMMATION HUMAIN

Article 6 : Par eau potable destinée à la consommation humaine, on entend une eau qui ne rend pas malade et qui est bonne à boire.

Article 7 : On distingue en principe les eaux préparées provenant des stations de traitement, des eaux naturelles souterraines provenant des captages, des eaux superficielles qui sont celles des rivières, fleuves, lacs, étangs et les eaux atmosphériques constituées par les eaux de pluies.

Article 8 : Les récipients de collecte, de stockage, de relevage, de distribution doivent être conçus dans des matériaux ne pouvant altérer la qualité de l'eau de l'industrie et de l'Energie avant leur mise en œuvre.

Article 9 : Les matériaux utilisables, au terme de l'article 8 susvisé doivent requérir l'avis favorable et compétent des Ministères chargés de la Santé publique, de l'Industrie et de l'Energie avant leur mise en œuvre.

Article 10 : Les matériaux à l'article 8 ne devront recevoir aucun revêtement susceptible de se désagréger, de réagir au contact de l'eau et altérer ainsi la qualité de l'eau destinée à la consommation.
Article 11 : Les matériaux utilisés conçus de telle sorte qu'ils ne doivent favoriser le retournement d'eau en cours afin qu'elles soient exemptes de toute contamination.

Ces équipements ne doivent pas entraîner une élévation permanente ou intermittente de l'eau.

Article 12 : Les ouvrages de captage, de traitement, de stockage, de distribution doivent être munis de dispositifs de protection ; ceux-ci doivent être approuvés par le service de Prévention du Ministère chargé de la Santé Publique.

Article 13 : Les ouvrages : puits, sources de captage, citerne, reconnus non conformes à la Réglementation relative à l'eau de consommation humaine devront subir un réaménagement de conformité ;

Article 14 : Les ouvrages de traitement e l'eau destinée à la consommation humaine ne doivent être conçus que dans des matériaux prévus par les dispositions de l'article 8 de la présente loi.

La conception doit permettre:

- Un échantillonnage en amont et en aval au niveau des équipements utilisés ;
- Un arrêt de tout traitement qui s'aère non conforme à la Réglementation relative au traitement des eaux ;
- Une dépollution active ou une déviation des eaux ;
- Une dépollution active ou une déviation des eaux polluées en cas d'accidents ou à des moments saisonniers de fortes pollutions.

Article 15 : Les produits utilisés pour le traitement des eaux doivent recevoir obligatoirement l'avis favorable du Service de Prévention du Ministère chargé de la Santé publique.

Article 16 : L'eau distribuée en tout point d'un immeuble ou dans un lieu public doit être une eau potable.

Article 17 : Afin d'éviter la dis-connexion de retour d'eau dans le réseau, l'on peut avoir recours à un autre procédé techniquement valable pour l'installation d'un tel dispositif idoine.

Article 18 : Une pression convenable fixé par les autorités chargées de la Santé publique doit être assurée à tous les points élevés des immeubles et lieux publics.

Article 19 : Dans les ouvrages de production d'eau chaude et d'eau froide, il ne doit jamais se produire un mélange entre l'eau du réseau et le fluide du vecteur utilisé.

Article 20 : Les appareils et ménagers, les équipements d'arrosage et lavage doivent être installés de manière à éviter toute contamination de l'eau du réseau et comporter de ce fait dispositifs de protection.

SECTION 2 : DES EAUX DE BAIGNADE

Article 21 : Les eaux de baignade doivent répondre à des critères de qualité caractérisés par des paramètres dont les valeurs admissibles sont fixées par les normes en vigueur.

Article 22 : Les eaux de piscine doivent obligatoirement être traitées à l'aide des produits autorisés par les Services chargés de l'hygiène publique, hormis les piscines alimentées en continue sans recyclage.

Article 23 : Toute piscine ouverte au public doit disposer de pédicures dont le nombre est fonction de la capacité d'accueil.

Article 24 : Les eaux de pédicule doivent être traitées d'une manière permanente.

Article 25 : Les abords des piscines doivent être régulièrement entretenus, lavés et désinfectés.

Article 26 : Les produits utilisés pour les traitements spéciaux de piscine doivent être soumis à l'avis préalable des services compétents du Ministère chargé de la Santé publique.

Article 27 : Tout lieu de baignade doit faire l'objet d'un contrôle périodique de qualité par les Services compétents du Ministère chargé de la Santé publique.

En conséquence les structures destinées aux eaux récréatives doivent être conformes aux normes des conceptions.

Article 28 : Aucune structure destinée à la baignade ne saurait communiquer d'une manière ou d'une autre, directement avec le réseau d'eau potable.

SECTION 3 : DE LA POLLUTION DES EAUX

Article 29 : Au terme de la présente Loi, la pollution des eaux peut se définir comme pollution chimique, organique ou nucléaire ou celle déterminée par la Réglementation internationale.

Cette pollution chimique suppose un apport des éléments susceptibles d'affecter la qualité de l'eau en modifiant le taux organique et biologique de celle-ci.

Tandis que la pollution nucléaire sous entend un apport d'éléments radioactifs nucléaires toxiques.

Article 30 : Autour des ouvrages de captage d'eau destinée à la consommation humaine doivent être aménagés un périmètre immédiat et un périmètre approché de protection.

Article 31 : Il est fait interdiction de mener toute activité susceptible d'induire la pollution des eaux dans le périmètre approché.

Article 32 : Tout déversement ou enfouissement des produits toxiques des déchets organiques, chimiques ou nucléaires sous quelque forme que ce soit dans le périmètre approché est formellement interdit sous peine de sanctions prévues par la loi en vigueur.

Article 33 : Tout déversement ou enfouissement des produits toxiques des déchets organiques, chimiques ou radioactifs dans le lit d'un cours d'eau (rivière, lac, étang, fleuve) et dans la mer, est prohibé sous peine des sanctions prévues par la Loi en vigueur.

Article 34 : Toute eau de surface est considérée comme eau polluée.

Article 35 : Une enquête devra être diligentée dans la société dans le cas d'utilisation de l'eau de surface par les services compétents du Ministère chargé de la Santé Publique, pour déterminer :

- Si le niveau et la nature de pollution seraient susceptibles d'être corrigés par les traitements à proposer ;

- S'il n'existe pas une cause de pollution permanente en amont de la prise d'eau ; l'enquête requiert par conséquent l'avis des autorités compétentes pour la réalisation ou non de l'ouvrage.

SECTION 4 : DE LA SURVEILLANCE HYGIENIQUE DES EAUX DESTINEES A LA CONSOMMATION HUMAINE

Article 36 : Il est procédé à une surveillance sanitaire de la qualité des eaux afin de suivre les variations de qualité à des moments donnés et en des points choisis pour prévenir toute altération de leur qualité. Les normes définies étant celles des Règlements sanitaires en vigueur.

Article 37 : Tout ouvrage, canalisation neuve ou ancienne doit subir, soit avant la mise en service, soit périodiquement, un rinçage et une désinfection.

La mise en service d'un réseau, collectif public ou privé ne peut effectuée qu'après délivrance d'un Certificat de conformité par les Services compétents du Ministère chargé de la Santé Publique.

Article 38 : La surveillance et le contrôle de la qualité des eaux destinées à la consommation humaine sont assurés par la Division Prévention et le Laboratoire National de Santé publique du Ministère chargé de la Santé Publique.

SECTION 5 : DU LABORATOIRE DE CONTROLE DE L'EAU

Article 39 : Le laboratoire de contrôle de l'eau fait partie de l'unité hydrologie - bromatologie du Département Chimie Pharmaceutique et Alimentaire de l'Institut National de Santé Publique.

Il est le laboratoire de référence pour le contrôle des eaux sur toute l'étendue du Territoire National.

Article 40 : Ce laboratoire a pour mission essentielle :

- Le contrôle de l'eau de boisson et destinée à d'autres usages pour le compte du Ministère chargé de la Santé dans l'intérêt de la Santé publique ;

- Vérifier le respect des normes OMS relatives à la qualité de l'eau en Guinée ;

- Recueillir auprès des services compétents les données de base (hydrogéologie, physique) des points d'eau en Guinée ;

- Proposer des normes de qualité concernant la production, l'importation et la commercialisation de l'eau en Guinée.

Article 41 : Le laboratoire est dirigé par un cadre pharmacien ou un ingénieur sanitaire ou un médecin ayant une compétence complémentaire dans les analyses bactériologiques et chimiques de l'eau.

SECTION 6 : DE L'EVACUATION DES EXCRETA ET DES EAUX USEE DOMESTIQUES ET INDUSTRIELLES

Article 42 : Sont considérées comme eaux usées au titre du présent Chapitre :

- Les eaux usées domestiques ;
- Des eaux ménagères (eaux de lavage de linge, cuisine, douche) ;
- Des eaux vannes (eaux industrielles constituées de tous les rejets liquides provenant des industries).

Article 43 : L'écoulement ou le développement des eaux usées domestiques dans le milieu naturel ou sur les voies publiques est formellement interdit aux termes de la présente Loi.

Article 44 : Toute concession doit être dotée d'ouvrages sanitaires destinés à la collecte et au traitement des fèces.

A cet effet:

- Toute défécation en plein air est interdite ;
- Tout enfouissement d'excréta dans le milieu naturel est formellement proscrit.

Article 45 : Les eaux usées domestiques doivent subir un traitement préalable dans des ouvrages sanitaires avant tout rejet.

Le rejet des effluents d'ouvrages ne peut s'effectuer que sur l'autorisation des Services compétents du Ministère chargé de la Santé publique, après avoir constaté q'une telle opération est techniquement admise.

Article 46 : Le Ministère chargé de la Santé Publique définit les modalités d'implantation et de conception des ouvrages sanitaires.

Article 47 : Les eaux d'égout doivent obligatoirement subir un traitement préalable dans une station d'épuration avant tout rejet. Cependant le rejet des effluents de station d'épuration dans le milieu naturel ne peut être admis d'après avis des Ministères chargés de la Santé publique et de l'Environnement.

Article 48 : Tout rejet des eaux usées industrielles brutes dans la mer, les cours d'eau, les étangs, les lacs, les caniveaux ou les égout publics est formellement interdit.

Article 49 : Les eaux usées industrielles, avant tout rejet, doivent obligatoirement subir un ou des traitements conformément à la Réglementation en vigueur.

Article 50 : Avant tout rejet, les eaux usées traitées doivent répondre à des critères de qualité physique, chimique, et bactériologique garantissant l'équilibre du milieu récepteur.

Article 51 : Les critères de qualité des effluents traités en fonction des milieux récepteurs sont généralement consignés dans les directives techniques conçues par les Services techniques compétents du Ministère chargé de la Santé publique et du Ministère chargé de l'Environnement.

SECTION 7 : DE L'ELIMINATION DES DECHETS SOLIDES MENAGERS ET INDUSTRIELS

Article 52 : Les déchets toxiques d'industrie et les déchets spéciaux d'hôpitaux sont éliminés impérativement conformément aux dispositions réglementaires.

Article 53 : Les déchets toxiques d'industrie et les déchets spéciaux d'hôpitaux sont éliminés impérativement conformément aux dispositions réglementaires.

Article 54 : Toute décharge brute de déchets et de quelque nature que ce soit est strictement interdite.

Article 55 : Toute production de déchets solides, soit au niveau des autorités publiques, soit des responsables privés, la mise en place de systèmes adéquats de traitement de déchets soumis à l'approbation des Services compétents du Ministère chargé de la Santé publique.

Article 56 : Les boues de vidange d'ouvrages sanitaires et les boues de stations d'épandage doivent obligatoirement subir un ou plusieurs traitements autorisés par les Services compétents des Ministères chargés de la Santé publique et de l'Environnement avant la mise en décharge ou une éventuelle réutilisation.

SECTION 8 : L'USAGE DES PESTICIDES DANS LA LUTTE ANTIECTORIELLE

Article 57 : Les secteurs public et privé devront concourir à l'établissement régulier des normes réglementant la distribution et l'utilisation des pesticides conformément aux dispositions des Conventions internationales.

Article 58 : Par pesticides on entend toute substance ou association de substances qui est destinée à repousser, détruire ou combattre les ravageurs y compris les vecteurs des maladies humaines ou animales et espèces indésirables de plantes ou d'animaux causant des maladies humaines ou animales et espèces indésirables durant la production, la transformation, le stockage, le transport ou la commercialisation des denrées alimentaires, des produits agricoles, du bois et des produits ligneux ou des aliments pour animaux, ou qui peut être administrée aux produits ligneux ou des aliments pour animaux, ou qui peut être administrée aux animaux pour combattre les insectes, les arachnides et les autres endo ou hecto parasites.

Le terme comprend des substances destinées à être utilisées comme régulateurs de croissance des plantes comme défoliants, comme agents de dessiccation comme agents d'éclaircissage des fruits ou pour empêcher la chute prématurées des fruits ainsi que les substances appliquées sur la culture soit avant, soit après la récolte, pour protéger les produits contre la détérioration durant d'entreposage et le transport.

Article 59 : Par industrie de pesticides, on entend tos les organismes et toutes les personnes s'occupant de la fabrication, de la formulation ou de la commercialisation des pesticides et des produits pesticides.

Article 60 : Par poison provenant des pesticides, on entend toute substance qui, absorbée en quantité relativement minime par les êtres humains, les plantes

ou les animaux, peut causer des troubles organiques ou fonctionnels, générateurs de lésions même mortelles.

Article 61 : Par homologation des pesticides, on entend le processus par lequel les autorités compétentes approuvent la vente et l'utilisation de d'un pesticide après examen des données scientifiques complètes montrant que le produit en cause est efficace pour les usages prévus et ne présente pas de risque excessifs pour la santé humaine ou animale ou pour l'environnement.

Article 62 : Il est interdit en République de Guinée tout pesticide pour lequel toutes les utilisations homologuées sont prohibées par les Services de Santé et de l'Environnement ou les demandes d'homologation ou autres actions équivalentes pour toute utilisation, lorsque celles-ci ont été rejetées pour des motifs touchant la Santé publique ou à la protection de l'environnement.

Article 63 : Toute infraction aux présentes dispositions en l'usage des pesticides sera punie d'un emprisonnement de 2 à 5 ans et d'une amende de 100.000 à 2 millions de francs guinéens sans préjudice de l'application des dispositions du Code pénal.

CHAPITRE II: DE L'HYGIENE ALIMENTAIRE

Article 64 : On entend par hygiène alimentaire, l'hygiène des établissements alimentation et de l'hygiène des denrées alimentaires.

Article 65 : Aux termes de la présente Loi, les magasins de vente de denrées alimentaires doivent être obligatoirement aérés, pourvus de ventilateurs, suffisamment éclairés et le sol en matériaux durs et lavables.

Article 66 : Les comptoirs de vente et les matériels en contact avec les denrées alimentaires ne doivent entraîner aucune contamination de celles-ci. En conformité avec l'article 65, des mesures énoncées par voie réglementaire détermineront les conditions d'aménagement et d'exploitation desdits comptoirs de vente, en vue de placer ces denrées alimentaires à l'abri de toute contamination, soit pendant la manipulation, soit pendant stockage.

Article 67 : Les magasins d'entreposage destinés à stocker de telles denrées sont également soumis aux dispositions des articles 69 et 70 ci-dessous.

Article 68 : Tout lieu de vente de denrées alimentaires devra être maintenu dans un état de salubrité constant.

Article 69 : Les moyens de transport utilisés pour les denrées alimentaires ne devront pas servir également au transport des hommes, des animaux ou des marchandises pouvant altérer ou contaminer ces denrées.

Article 70 : Les conditions d'aménagement et de fonctionnement des abattoirs publics et privés doivent être définies selon les directives techniques et sanitaires requises.

Article 71 : Les fabriques et laboratoires de préparation des aliments doivent être conformes aux normes de construction d'entretien et d'hygiène prescrites par la Réglementation en vigueur.

SECTION 1 : DES BOISSONS AUTRES QUE LE LAIT

Article 72 : Toute eau destinée à la préparation des boissons, l'entretien ou d'autres opérations doit résulter de l'eau distribuée par le réseau public, hormis les mesures formelles édictées par les directives de l'autorité compétente justifiant de sa potabilité.

Article 73 : Les matériaux utilisés en vue du conditionnement, du bouchage tels que : capsules, rondelles, lièges doivent être neufs et dans un état de propreté susceptibles d'empêcher toute contamination du liquide.

Les machines, les appareils et récipients utilisés devront être constamment nettoyés, rincés et désinfectés.

Les emballages utilisés telles que bouteilles en verre, doivent être abandonnés dès que le niveau d'usure est assez avancé.

SECTION 2 : DE LA GLACE ALIMENTAIRE

Article 74 : Toute fabrication de glace alimentaire n'excluant pas le contact avec le fluide réfrigérant est formellement interdite.

Section 75 : Le lait et les produits laitiers destinés à la consommation humaine doivent être maintenus à l'abri de toute altération température élevée, de même que leurs emballages d'origine doivent être conformes aux normes en vigueur.

Article 76 : Il est formellement interdit l'usage des additifs alimentaires, en l'occurrence, stabilisants, colorants, parfumants et conservateurs. Les aliments qui dispositions du Codex alimentarus de l'OMS/FAO.

SECTION 4 : DES VIANDES – DES VOLAILLES ET DES Œufs

Article 77 : Conformément aux Ordonnances n° 075/PRG/SGG/89 et n° 022/PRG/SGG/90 relatives à la Police sanitaire des animaux en République de Guinée, à la Réglementation de l'Inspection et de l'Hygiène des denrées alimentaires d'origine animale fixant des règles applicables à la vente, au stockage des denrées alimentaires sur les marchés, les normes suivantes seront obligatoirement observées :

- L'animal destiné à l'abattage doit faire l'objet d'un examen sur pied avec présentation d'un Certificat sanitaire dans les 24 heures qui précèdent d'opération ;
- Tout animal suspect ou présentant des signes évidents de maladie ne peut être abattu, que conformément aux mesures qu'énonceront le Ministre chargé de l'Elevage définissant les modalités et les conséquences de l'examen anté-mortem :
- L'abattage doit être effectué dans de bonnes conditions d'hygiène, évitant toute souillure et toute contamination de carcasse tout en limitant la souffrance de l'animal.

D'une manière générale, les mesures prévues par l'Ordonnance n° 022/PRG /SGG/90 précitée et dont les normes régissent l'abattage d'animal y seront appliquées.

Article 78 : Les dépilage et le déplumage seront effectués de manière à éviter toute contamination du gibier ou de la volaille.

Par conséquent, le gibier dépilé ou la volaille déplumée sera placé dans un emballage conformément aux normes du codex alimentarus de l'OMS/FAO.

Article 79 : Il es formellement interdit d'utiliser des produits chimiques, exceptés les conservateurs et stabilisants dûment autorisés par la Réglementation du codex alimentarus de l'OMS/FAO.

Article 80 : Les œufs destinés à la consommation seront entreposés à l'abri de tout contact susceptible de les altérer. Ils seront placés dans des plateaux vendus. Les coquilles doivent être indemnes de tout traumatisme.

Article 81 : Les qualités comestibles des denrées destinées à la consommation humaine devront être conformes aux normes du codex alimentarus de l'OMS/FAO et aux mesures énoncées par les autorités compétentes chargés de l'Hygiène publique.

SECTION 5 : DES PRODUITS DE MER ET D'EAU DOUCE

Article 82 : Les produits de mer et d'eau douce fraîchement péchés seront étendus sur des étagères recouvertes de matériaux inaltérables facilement lavables et désinfectables.

Toutefois, la conservation desdits produits se fera au moyen de fumage, de la congélation ou de la surcongélation.

L'utilisation de produits chimiques à cet effet est formellement interdite.

Sont également interdits:

- L'arrosage et le trempage des huîtres n eau de mer ;
- Le rafraîchissement avec la glace non alimentaire ou au moyen des feuillages, d'herbes ou de tissus imbibés d'eau non potable, la vente de lots non munis de l'étiquette de salubrité délivrée par l'autorité compétente ;
- L'ouverture des huîtres et coquillages non destinés à la consommation immédiate.

Article 83 : Il sera assuré un contrôle du traitement, du stockage, de la manutention et de la distribution du poisson, des cuirassés, des conserves et denrées alimentaires congelées par les Services compétents.

SECTION 6 : DE L'ALIMENTATION ANIMALE OU VAGETALE

Article 84 : L'enfouissement, le dépôt ou le déversement des déchets solides, industriels, de boues des stations, d'épuration non traitées sur des terrains cultivés de fruits et légumes pouvant être consommés crus sont formellement interdits

Article 85 : Les autorités compétentes procéderont à une enquête préalable avant toute implantation d'une aire de culture maraîchère. L'on prendra en considération, le périmètre de protection immédiat et la nature de protection, la qualité de l'eau utilisée.

Il est formellement interdit l'arrosage des jardins potagers par des eaux polluées.

Article 86 : Toute importation d'aliments d'origine animale ou végétale requiert l'autorisation e le contrôle des autorités compétentes.

Article 87 : Les aliments non traditionnels obtenus à partir de matières animales ou végétales ou des produits alimentaires comme les farines, la levure, les isolats de protéines, ne peuvent être vendus qu'après avis des Ministres chargés de la Santé Publique, de l'Elevage et de l'Agriculture.

Article 88 : Toute infraction commise en violation des dispositions des articles 84, 85, 86, 87 ci-dessus, sera condamnée à un emprisonnement de
6 mois à 1 an et d'une amende de 200.000 à 500.000 francs guinéens ou de l'une de ces deux peines seulement sans préjudice de l'application des dispositions du Code pénal.

SECTION 7 : DE LA RESTAURATION COLLECIVE

Article 89 : Un restaurant doit obligatoirement répondre aux normes et critères suivants :

- Les mûrs, parois, et sols seront maintenus dans un état de propreté ;
- L'établissement devra disposer d'installations sanitaires conformes aux normes d'hygiène ;
- L'établissement doit être suffisamment aéré et éclairé ;
- Les tables doivent être constamment propres, les couverts, carafes d'eau et matériels utilisés à l'usage de la cuisine doivent être tenus dans un constant état de propriété.

Article 90 : Les grillages de la restauration collective devront répondre obligatoirement aux normes et critères ci-après :

- Le stockage de denrées à préparer sera assuré à l'aide de congélateur ;
- La congélation des denrées à préparer sera assurée à l'aide de congélateur ;
- La congélation des denrées devra se faire dans des récipients propres recouverts pour les poissons et sur des tringles en parfait état de propriété pour la viande qui sera emballée dans un sac en plastique réglementaire dans lequel s'écoulera le jus et qui en assure la protection ;
- Le découpage sera effectué sur une surface lisse, lavable et facilement désinfectable, l'aide de matériels constamment nettoyés et maintenus propres ;
- Les grilles doivent être nettoyées et lavées après chaque usage ;
- L'établissement doit être desservi en eau par le réseau public ou être alimenté en eau reconnue potable par le Laboratoire National de Santé publique.

Article 91 : Toute infraction aux dispositions des articles 89 et 90 de la présente Loi sera punie d'un emprisonnement de 6 mois à 1 an et d'une amende de 50.000 à 500.000 francs guinéens ou de l'une de ces deux peines seulement, sans préjudice de l'application des dispositions su code de l'Environnement.

SECTION 8 : DE L'HYGIENE DES PLATS ET DES CUISINES

Article 92 : Les plats chauds doivent être apportés directement de la cuisine au consommateur.

- Les plats chauds cuisinés, pour être consommé chauds ou non, doivent répondre aux dispositions du Codex-alimentarus de l'OMS/FAO ;
- Les plats préparés le jour même de leur consommation, doivent être entreposés dans une enceinte réfrigérée à plus de 3° C dans l'attente du service ;
- Dans les établissements dits « libre service », le service individuel doit être contrôlé et les plats présentés protégés pour éviter toute souillure ou contamination des denrées.

SECTION 9 : DE L'HYGIENE DU PERSONNEL

Article 93 : Le personnel des restaurants doit subir régulièrement une visite médicale.

Chaque employé doit disposer de trois blouses ou tabliers.

Tout employé atteint d'une maladie contagieuse doit être libéré pour subir des soins médicaux. Il ne pourra retrouver son emploi qu'après guérison complète, et ce, conformément aux dispositions du Code du Travail.

CHAPITRE III : DE LA SOLUBRITE DES EDIFICES, BATIMENTS D'HABITATION ET DES PROJETS D'AMENAGEMENT

SECTION 1 : DE LA SALUBRITE DES EDIFICES ET BATIMENTS

Article 94 : Tous projets d'aménagement des édifices et de bâtiments d'habitation doivent être conformes aux dispositions du Décret n° 199/PRG /SGG/89.

L'on devra également tenir obligatoirement compte de la liste des travaux et ouvrages conformément à l'annexe dudit Décret.

Article 95 : Toutefois ces édifices et bâtiments seront dotés de poubelles servant à la collecte des ordures produites par les bureaux et les habitations.

Ces ordures seront ensuite transportées en bordure de route pour être ramassées par les Agents des Voiries.

Article 96 : Le déversement d'eaux résiduelles dans les caniveaux conçus à usage des eaux de ruissellement, conformément à l'article 30 du Code de l'Environnement, est formellement interdit.

Article 97 : Toute infraction aux dispositions des articles 95 et 96 de la présente Loi sera punie d'un emprisonnement de 6 mois à 1 an et d'une amende de 50.000 à 1.000.000 de francs guinéens ou de l'une de ces deux peines seulement sans préjudice de l'application des dispositions du Code de l'Environnement.

SECTION 2 : DES PROJETS D'AMENAGEMENT

Article 98 : Une concertation préalable des Ministères chargés de l'industrie, de la Santé publique, de l'Environnement et des Travaux Publics est obligatoire en vue de l'élaboration de tout projet d'aménagement. Auquel cas, des avis techniques seront nécessairement requis avant toute exécution des travaux de génies. Une autorisation officielle sera alors délivrée avant les travaux.

Article 99 : La décision définitive en matière d'aménagement est du ressort du Comité interministériel pour l'action sanitaire et sociale.

Article 100 : La décision prise devra nécessairement comporter une étude de faisabilité faisant mention des effets nuisibles du projet sur la santé des populations concernées et des mêmes effets sur l'équilibre du milieu naturel.

Article 101 : Toute infraction aux dispositions des articles 98, 99 et 100 de la présente Loi entraîne la démolition de ces ouvrages aménagés et l'auteur sera puni d'une amende de 300.000 à 1.000.000 de francs guinéens et d'un emprisonnement de 3 mois à 1 an ou de l'une de ces deux peines seulement sans préjudice de l'application des dispositions du Code pénal.

Article 102 : Par aménagement aux termes des dispositions des articles 98, 99 et 100 de la présente Loi, on entend les travaux infrastructurels, susceptibles de causer des préjudices à l'environnement et les activités utilitaires pouvant générer des déchets susceptibles d'affecter la Santé publique.

SECTION 3 : DES DECHETS SOLIDES, LIQUIDES ET INDUSTRIELS

Article 103 : Conformément aux normes prescrites par le Code de l'Environnement, les Services des Voiries de chaque localité détermineront les conditions de collecte et d'élimination des déchets solides, liquides et industriels.

Article 104 : Les particuliers de chaque localité prévue à l'article 103 se conformeront aux conditions et aux modalités fixées par les Services des Voiries quant à la fréquence des collectes d'élimination des déchets liquides et solides.

Les Ministères chargés de la Santé Publique et de l'Environnement déterminent par voie réglementaire les normes relatives à l'élimination de ces déchets, soit par incinération ou par enfouissement.

Article 105 : Il est obligatoire d'aménager dans chaque localité une ou plusieurs décharges destinées à la collecte des déchets solides.

Ces décharges aménagées dans les lieux convenablement choisis en tenant compte de la géologie, seront entretenus par les Services des Voiries.

Ces décharges devront être gérés selon les normes techniques d'élimination des déchets et de la protection du milieu naturel des nuisances susceptibles d'être préjudiciables à la Santé publique et à l'environnement.

Article 106 : Tous les établissements industriels doivent obligatoirement déclarer la nature des déchets résultant de l'exploitation de leurs industries et envisager avec les Services des Voiries les conditions de leur élimination.

SECTION 4 : DU BRUIT

Article 107 : Les nuisances résultant du bruit sont préjudiciables à la Santé publique. Les normes techniques appropriées seront obligatoirement appliquées pour l'élimination du bruit.

Ces normes doivent être observées tant dans les locaux à usage d'habitation, sur les lieux de travail que des artères des localités.

Des dispositions réglementaires seront prises en tant que de besoin en vue de déterminer les conditions d'élimination du bruit dans les ateliers, les locaux à usage d'habitation et commercial.

SECTION 5 : DES SUBSTANCES RADIOACTIVES, TOXIQUE ET NUCLEAIRES

Article 108 : La manipulation des substances radioactives et toxiques peut comporter les risques préjudiciables à la Santé publique.

Ainsi, le transport, le stockage et l'enfouissement desdites substances nécessitent certaines précautions techniques qui seront fixées par voie réglementaire en ayant recours à un cahier de charge.

Article 109 : Les risques et l'intérêt que procurent les rayonnements ionisants aux plans diagnostique et thérapeutique nécessitent une réglementation visant à déterminer formellement le recours au procédé de métier nucléaire.

Article 110 : Lorsqu'il sera établi que les substances radioactives ou toute source de rayonnement ionisant sont susceptibles de mettre en danger la Santé publique, le Ministère chargé de la Santé publique en collaboration avec les Ministères concernés pourraient prendre des dispositions préventives destinées à écarter tous risque de contamination.

Article 111 : Sera punie d'une amende de 20.000.000 à 100.000.000 de francs guinéens et d'une emprisonnement de 5 à 20 ans ou de l'une de ces deux peines seulement sans préjudice de l'application du Code de l'Environnement, toute personne qui aura manipulé, déposé, stocké et enfoui des substances radioactives, toxiques et nucléaires sur le milieu naturel.

CHAPITRE IV : DES MORGUES, OPERATIONS MORTUAIRES ET CIMETIERES

Article 112 : Tout projet d'aménagement de cimetière requiert nécessairement l'autorisation préalable du Ministère chargé de la Santé publique, lequel examinera si la demande formulée est conforme aux exigences concernant la distance entre le cimetière et les localités à usage d'habitation et les sources d'approvisionnement en eau, aux conditions d'inhumation, d'exhumation, du transport et d'embaumement du corps humain.

Article 113 : Toute incinération de corps ne saurait avoir lieu sans l'autorisation de l'Officier de l'état civil.

Les conditions d'incinération seront fixées par le Ministère chargé de la Santé publique.

SECTION 1 : DES MORGUES HOSPITALIERES

Article 114 : Il doit être créé dans chaque Hôpital, après avis préalable des Ministères chargés de la Santé Publique, de l'Intérieur, de l'Equipement, une morgue hospitalière.

Article 115 : le corps d'une personne décédée ne sera admis dans une morgue qu sous conditions résolutoires en l'occurrence d'un Certificat de décès ou sur réquisition de la Police.

Article 116 : L'admission dans une morgue hospitalière a lieu dans un délai de 24 heures après le décès, conformément aux dispositions de l'article 115 de la présente Loi.

Toutefois elle sera subordonnée le cas échéant à la déclaration des nom, prénoms, âge, sexe, profession et domicile du défunt.

SECTION 2 : DE L'INHUMATION

Article 117 : Sur le territoire d'une localité où existe une autorité d'état-civil, l'inhumation dans le cimetière local d'une personne décédée est autorisée par la personnalité administrative compétente, selon le cas après avoir rempli la procédure habituelle conformément à la Loi.

Article 118 : Toute inhumation hors d'un cimetière est formellement interdite hormis l'autorisation expresse du Ministère chargé de la Santé publique déterminant le lieu de sépulture qui devra nécessairement se situer à une distance minimum de 500 mètres de l'habitation la plus proche.

Cette autorisation est individuelle.

Article 119 : Quelque soit le lieu d'inhumation, les autorités administratives compétentes seront responsables de la bonne exécution des opérations funéraires du territoire de leurs localités.

Article 120 : Le permis d'inhumation prévu par les textes en vigueur tient lieu d'autorisation de transfert de corps du lieu de décès jusqu'à celui de l'inhumation qui a lieu en dehors de la localité où le décès est survenu.

Article 121 : Par dérogation aux dispositions du précédent article, en cas de décès survenu en un endroit ouvert au public, le défunt sera transféré immédiatement, sur simple réquisition de la Police soit à son domicile, soit au dépositoire public agrée le plus proche selon le cas, à condition que ce domicile ou ce dépositoire soit situé à la limite de la localité considérée.

Article 122 : Hormis le cas visé à l'article 125, le transfert d'une dépouille mortuaire de la République de Guinée à l'étranger ne pourrait se faire qu'après avoir été au préalable placée dans un cercueil approprié.

Article 123 : Est formellement interdit tout transfert de corps dans les véhicules de transport en commun notamment autocar, autobus, taxi, ambulance ou véhicules destinés aux transports des denrées alimentaires.

Des véhicules spéciaux seront aménagés à cet effet de manière à soustraire le corps de la vue du public.

Article 124 : Tout transfert d'un corps en transit ou vers une localité en vue d'inhumation en dehors des limites de la localité où le décès est survenu peut être autorisé :

- Par les personnalités administratives compétentes dès lors que le décès et l'inhumation ont lieu dans des localités autres que celles de la Préfecture ;
- Par des personnalités administratives au lieu du décès avec l'accord préalable de l'autorité administrative du lieu d'inhumation, selon les circonstances lorsque le décès et l'inhumation ont lieu dans des localités différentes.

Article 125 : Dans l'hypothèse d'un transfert de corps à l'étranger, l'autorité compétente du pays de réintégration et sous réserve que soit observée la Réglementation fixée par la Convention Internationale de Berlin du 10 février 1937 à laquelle la République de Guinée a souscrit.

Article 126 : Les dossiers de demande de transfert de corps seront déposés auprès des autorités administratives compétentes.

Les demandes seront formulées par les plus proches parents du défunt et doivent comporter les nom et prénoms du défunt et accompagnées des pièces ci-après :

- Un permis d'inhumer délivré par les autorités administratives compétentes ;
- Un Certificat médical attestant la cause du décès résultant si possible de l'une des maladies suivantes : choléra, charbon, lèpre, peste, fièvre jaune, méningite cérébro-spinale, infection typho-paratyphoïdique, dysenterie, trypanosomiase ;
- Un Certificat de mise en bière en conformité avec les stipulations conventionnelles, l'engagement de supporter les frais qu'entraînera la translation de l'inhumation du corps.

Article 127 : Tout transfert de corps humain hors des limites territoriales d'un pays où le décès est survenu à un autre subordonné aux exigences suivantes sous réserve de l'application des articles 124, 125, 126 ci-dessus :

1. Le corps devra être déposé dans un cercueil hermétique muni d'un dispositif filtrant :
   a) - Si la distance à parcourir excède 200 km quelle que soit la durée prévue du transfert ;
   b) - Si la date du transfert est évaluée à plus de 24h quelle que soit la distance à parcourir ;

c) - Si le décès est consécutif à l'une des maladies énumérée à l'article 126 alinéa 2 ;
d) - Si le transfert est effectué par voie aérienne ferroviaire ou maritime, quelles que soient la distance et la durée du trajet ;
e) - Dans tous les cas, on devra quérir la décision du Ministère chargé de la Santé ;
f) - S'il s'agit du transfert de restes mortels provenant d'un corps inhumé même depuis plus de 5 ans à moins qu'il s'agisse de restes réduits à l'état d'ossements ; ainsi donc le cercueil hermétique peut, par décision de l'autorité administrative compétente, après avis motivé du Médecin, ne pas être exigé ;
g) - Si le corps est embaumé dans les conditions prévues par la Réglementation en vigueur, le cercueil hermétique ne sera pas obligatoire si la distance est inférieure à 300 km et la durée du transport évaluée à moins de 24h ;

2. Dans tous les autres cas, le corps sera placé dans un cercueil en bois dur ou tout autre appareil similaire offrant une résistance au moins équivalente, doublée, d'une garniture étanche d'un modèle accepté par le Ministère chargé de la Santé publique.

Quel que soit le modèle accepté, le cercueil hermétique sera ajusté, de manière à ne pouvoir se mouvoir, dans une bière en bois dur on tout autre matériel ayant une résistance au moins équivalente dont les parois doivent avoir 0,020 m au maximum.

Il sera muni d'un appareil filtrant accepté par le Ministère chargé de la Santé publique, susceptible d'assurer la réduction des gaz de putréfaction de même que l'épuration.

Article 128 : L'autorité administrative compétente assurera la surveillance des mesures d'hygiène, de salubrité fixées dans l'article 127.

Article 129 : Tout corps humain arrivant dans une localité conformément à l'article 127 inhumé, doit être présenté à l'autorité administrative de la localité. Celles-ci vérifie les scellés du cercueil en s'assurant que le corps est accompagné de l'autorisation régulière de circulation et celle-ci assiste à son inhumation. Ensuite elle dresse le procès-verbal de ces opérations et le transmet à l'autorité hiérarchique compétente.

SECTION 3 : DE L'EXHUMATION

Article 130 : Toute exhumation d'un corps humain devra obligatoirement résulter de l'une des deux conditions suivantes :

- Du Procureur de la République : Lorsqu'il s'agit de la manifestation de la vérité ;
- D'un proche parent de la personne décédée : Dans cette dernière hypothèse, le demandeur devra nécessairement indiquer les motifs, la destination prévue pour les restes à exhumer avec mention du lieu et de la date de ré - inhumation. C'est alors que la signature sera légalisée après la justification de la demande formulée.

Article 131 : Toute exhumation de personne décédée à la suite de l'une des maladies énumérées à l'article 126, ne pourra être autorisée qu'après un délai de trois ans, malgré les précautions d'usage observées lors de l'inhumation.

Ce délai sera réduit lorsque la personne est décédée à la suite de l'une des maladies ci-après : Coqueluche, diphtérie, rougeole, infections puerpérales.

Article 132 : S'il apparaît qu'au moment de l'exhumation, le cercueil est en parfait état, on ne pourrait l'ouvrir que si un délai de cinq ans s'est écoulé après l'inhumation.

Mais si le cercueil est détérioré, le corps sera alors placé dans un autre cercueil, le cas échéant, dans une boite à ossements.

Avant toute manipulation usuelle, les cercueils extraits de la fosse seront abondamment arrosés d'un liquide désinfectant notamment, la solution d'hypochlorite de chaux ou l'eau de Javel.

Article 133 : Les personnes chargées de procéder aux opérations d'exhumation doivent obligatoirement porter des gants spéciaux qui seront ensuite désinfectés de même que leurs chaussures. Elles subiront un nettoyage antiseptique de la paume des mains et les parties du corps non protégées.

Article 134 : En vue d'assurer la bonne pratique d'exhumation, la présence d'un Officier de Police Judiciaire chargé de faire le constat des opérations exhumatoires s'avère obligatoires.

SECTION 4 : DE L'EMBAUMEMENT ET DE LA THANATOPRAXIE

Article 135 : Toute opération visant la conservation des corps par action directe sur les tissus, par injection sous cutanée ou intramusculaire, par perfusion artérielle ou veineuse de même que par des inventions de nature anatomique ne pourrait être pratiquée moins de 6 heures à la suite du décès que sous autorisation de l'autorité compétente.

L'on devra nécessairement produire les documents suivants :

1. Une demande d'un membre de la famille ou d'un ayant droit ou ayant cause ;
2. Une déclaration spécifiant le procédé que l'on se propose d'employer ainsi que l'endroit et l'heure de l'opération ;
3. Un Certificat délivré par le Médecin traitant indiquant que la mort est survenue d'une cause naturelle et autorisant l'embaumement.

Dans l'hypothèse d'une mort suspecte ou survenue par suite d'un accident, le dossier à produire sera subordonné à une déclaration expresse de l'autorité judiciaire compétente attestant que l'opération n'est pas de nature à faire obstacle à la manifestation de la vérité.

Article 136 : Seuls les produits solides ou fluides dont la composition est acceptée par le Ministère chargé de la Santé publique seront utilisés pour la réalisation des opérations prévues à l'article 135.

Article 137 : Etant donné le niveau technologique élevé des opérations, celles-ci ne seront pratiquées que par un Médecin ou un membre de l'Association de la Thanatopraxie officiellement agréé ou toute personne dûment habilitée.

Seuls les Médecins et diplômés en thanatopraxie sont autorisés à délivrer des pièces ou Certificats relatifs à ces opérations.

L'opération sera accompagnée d'un Certificat de Médecin établissant que les signes de décomposition rendent l'opération nécessaire avec l'expiration des 6 heures, l'autorité administrative compétente pourrait alors autoriser l'opération sans attendre l'expiration du délai prescrit.

Toutefois le Ministère chargé de la Santé publique peut autoriser après avis du Médecin Chef de Service que pour des objectifs scientifiques ou thérapeutiques l'autopsie ou les prélèvements à défaut de l'accord de la famille peuvent être pratiqués sans délai.

A ce sujet, le décès fera l'objet d'un constat par deux Médecins assermentés pour s'assurer de la validité de la mort. Ils signeront le procès-verbal du constat de décès en mentionnant l'heure et la date de la survenance.

En conséquence, le Médecin-Chef dresse un procès-verbal énumérant les motifs et les circonstances de l'opération et notification sera faite à la famille du défunt.

SECTION 5 : DE L'AUTOPSIE ET DU MOULAGE

Article 138 : Toute demande de moulage ou d'autopsie d'un cadavre peut provenir de l'autorité judiciaire en accord avec l'autorité compétente du lieu de la survenance du décès.

L'autorisation en cause ne sera demandée qu'après un délai de six heures suivant la déclaration du décès auprès de l'autorité compétente. Par ailleurs, cette demande sera accompagnée d'un Certificat du Médecin légiste attestant que les signes de décomposition rendent l'opération nécessaire avant l'expiration du délai réglementaire.

Article 139 : Le corps d'une personne décédée dans un établissement hospitalier qui n'a pas été réclamé pendant le délai de quarante cinq jours, pourrait être mis à la disposition de la Faculté de Médecine ou d'un laboratoire de dissection à condition que la mort résulte d'une cause naturelle et non de l'une des maladies énumérées à l'article 126 de la présente Loi.

L'organisme dépositaire est chargé d'en assurer la conservation ou l'inhumation.

SECTION 6 : DES POMPES FUNEBRES ET DE LA THANATOPRAXIE

Article 140 : Les pompes funèbres et la thanatopraxie s'attellent aux tâches funéraires ainsi qu'il suit :

- Assurer le transport des corps d'un point à un autre, d'une localité à l'exception des transits ordinaires sans cérémonie ni inhumation sur un lieu de la localité considérée ;
- Vendre des linceuls, des cercueils et des couronnes ;
- Fournir et poser toute teinture ou décoration à caractère funéraire dans des lieux ouverts au public ou en bordure de la voie publique ;
- Assurer les prestations et la fourniture des soins d'hygiène, de toilette et la conservation des corps en conformité avec les normes de la présente Loi et les coutumes de la République de Guinée.

Article 141 : Le Service des pompes funèbres et de la thanatopraxie sera assuré par des Collectivité locales chargées d'organiser de telles activités ou d'octroyer la concession à un particulier.

Les prestations prévues par l'article 136 pourront générer de taxes dont le montant fera l'objet d'une décision réglementaire de l'autorité compétente.

Le matériel fourni par les localités devra être constitué pour répondre aux besoins des Collectivités.

Article 142 : Dans les localités où le Service prévu dans l'article 136 est laissé à l'initiative privée, l'autorité administrative compétente est habilitée à édicter les règles d'hygiènes régissant les opérations mortuaires de même qu'elle fera respecter les prescriptions énoncées par la présente Loi en matière funèbre.

SECTION 7 : DES CIMETIERE ET DES LIEUX DE SEPULTURE

Article 143 : Tout projet d'aménagement d'un cimetière requiert nécessairement l'autorisation du Ministère chargé de la Santé publique, lequel déterminera en collaboration avec les autres Départements Ministériels compétents, la distance entre le cimetière et les habitations, entre le cimetière et les sources d'approvisionnement en eau, les conditions d'inhumation, les règles régissant l'exhumation, le transport des corps et l'embaumement.

Article 144 : Toutefois, lorsque les localités sont pourvues d'une adduction d'eau potable, la distance entre le cimetière et les habitations pourra, à titre exceptionnel, être réduite ou supprimée par voie réglementaire.

Dans le cas contraire, la distance entre le cimetière et les habitations d'une part, entre le cimetière et les sources d'eau d'autres part, sera de 500 mètres au minimum.

Article 145 : Lorsqu'un cimetière ne répond plus aux critères définis pour recevoir les inhumations, l'autorité administrative compétente pourra alors procéder à la fermeture définitive de celui-ci. Dès lors qu'il est devenu un lieu sacré, de culte, l'autorité administrative compétente pourvoira à son entretien et à son aménagement.

A ce titre, le cimetière doit être protégé par une clôture empêchant ainsi la divagation des animaux domestiques et sauvages en conformité avec les règles de la domanialité publique.

Ainsi donc, l'eau provenant des points d'eau (puits, sources, rivières) situés à moins de 100 mètres de cette clôture sera formellement interdite à la consommation.

Article 146 : La sépulture dans le cimetière d'une localité est obligatoire pour :

- Les personnes décédées ou dont les cadavres auront été trouvés sur le territoire quel que soit leur domicile ;
- Les personnes domiciliées sur le territoire alors même qu'elles seraient décédées dans une autre localité ;
- Les personnes non domiciliées dans la localité mais ayant droit à une sépulture de famille ou rituelle.

Article 147 : Les inhumations en terrain gratuit auront lieu, soit en fosse individuelle, soit en tranchée, les corps étant, dans ce dernier cas, placés côte à côte et à une distance de 20 cm les uns des autres.
Quelque soit le genre de fosses utilisées, elle devront être établies de telle sorte que la hauteur de comblement comprise entre le corps et la surface de sol soit égale au moins à 1,5 m.

Article 148 : Au risque d'entraîner leurs renouvellements plus ou moins rapprochés, exception faite d'une exhumation aux fins de ré-inhumation définitive dans une sépulture autre que la première conformément à la Loi, l'ouverture des fosses destinées aux nouvelles sépultures ne pourrait se produire qu'après 5 ans au minimum des précédentes inhumations.

L'autorité administrative d'une localité pourrait alors augmenter ce délai en tenant compte de la nature propre du terrain de chaque cimetière.

En effet, les terrains affectés aux sépultures, constitueront au minimum au tant de fois nécessaire, en vue d'y enterrer le nombre annuel présumé de morts, en tenant dûment compte du délai de renouvellement fixé par Loi en vigueur.

Article 149 : Dans l'hypothèse où l'espace du terrain le permettra les localités destinées à l'inhumation des personnes désireuses de posséder une place distincte et séparée pour y fonder leurs sépultures et celles de leurs parents ou de toute autre personne, une décision de l'autorité administrative compétente pourrait fixer les modalités d'acquisition d'une telle sépulture.

Article 150 : A cet effet, les terrains destinés aux inhumations seront concédés à titre onéreux : tarifs desdits terrains seront fixés par une fourchette globale déterminée dans un acte réglementaire.

Article 151 : Chaque personne peut indistinctement placer sur la fosse d'un proche parent une pierre sépulture ou tout autre signe caractéristique à condition que ces stèles démonstratives ne portent nullement préjudice à la superficie du terrain octroyé ou non destiné à chacune des fosses.

Article 152 : Dans l'hypothèse de la création des concessions destinées à y fonder des sépultures familiales aucun ayant droit du concessionnaire ne saurait se prévaloir de renouvellement fait par lui pour revendiquer la pleine et entière jouissance des droits inhérents à la concession.

Article 153 : Toute décision de l 'autorité administrative compétente ayant pour objet la suppression des droits antérieurement concédés à une personne ou à

une famille fera l'objet d'une publication par voie d'affiche ou de notification individuelle.

En effet, ces actes de publication seront obligatoirement inscrits sur le registre de la localité où la décision a été prise.

Article 154 : Une décision prise par l'autorité administrative locale pourrait affecter définitivement dans un cimetière un ossuaire convenablement aménagé ou seraient ré-inhumées gratuitement les personnes dont les concessions ont été reprises.

Article 155 : Les terrains des cimetières ne sauraient faire l'objet d'une transaction commerciale.

Article 156 : Les infractions commises en violation des dispositions du Chapitre IV de la présente Loi seront punies d'une amende de 200.000 à 1.000.000 de francs guinéens et d'un emprisonnement de 6 mois à 5 ans, ou de l'une de ces deux peines seulement sans préjudice de l'application des dispositions du Code pénal et des autres normes en vigueur.

CHAPITRE V : DE LA PREVENTION ET DE LA LUTTE CONTRE LES MALADIES TRANSMISSIBLES

Article 157 : La liste des maladies transmissibles susceptibles de constituer un danger pour la santé des populations de la République de Guinée est établie par le Ministère chargé de la Santé publique et fixée par voie réglementaire.

Cette liste est renouvelable lorsque les circonstances l'exigent.

Article 158 : Tout Médecin ayant constaté l'existence d'une maladie transmissible pouvant se propager rapidement est obligatoirement tenu d'en aviser sans délai les autorités supérieures dont il dépend sous peine de sanctions disciplinaire ou pénale.

A ce titre, tout Médecin de nationalité Guinéenne ou étrangère exerçant dans le cadre de la coopération qui serait au courant de l'apparition d'une maladie transmissible, doit en informer exclusivement et à titre confidentiel les autorités hiérarchiques directes.

Il ne peut en aucun cas transmettre ces informations en dehors de la structure administrative où il exerce ses fonctions.

A cet égard, tout retard ou négligence constatés dans la transmission de l'information reçue est possible de sanctions disciplinaires ou pénales prévues à l'alinéa 1er du présent article.

Article 159 : Toute personne atteinte d'une maladie transmissible susceptible de propagation, recevra impérativement un traitement hospitalier ou ambulatoire. Cependant, les sujets contacts feront l'objet d'un contrôle médico-sanitaire conformément à la Loi.

Toutefois, un plan d'action d'urgence sera établi aux fins de lutter contre les épidémies. A cet effet, le Ministère chargé de la santé publique soumettra les populations de toute localité atteinte aux mesures préventives appropriées.

Seront obligatoires, la vaccination et la revaccination contre les maladies transmissibles que le Ministère chargé de la Santé aura spécifiées.

SECTION 1 : DES CONDITIONS D'HYGIENE

Article 160 : Conformément aux mesures fixées dans le cadre de l'environnement, des mesures d'évacuation des ordures et excrété seront prises par l'autorité administrative de la localité.

Article 161 : Les Services chargés de l'hygiène et de la protection de l'environnement assureront la surveillance et le contrôle de la qualité des eaux utilisées pour la boisson et les usages domestiques et industriels, de l'air ambiant, de même que les denrées alimentaires sur toute l'étendue du Territoire de la République de Guinée.

SECTION 2 : DES CAS D'EPIDEMIE

Article 162 : Seul le Ministère chargé de la Santé Publique est habilité à faire la déclaration relative à l'existence d'une épidémie et prescrire des mesures de quarantaine en conformité avec les dispositions des articles 21 et 22 de la constitution de l'Organisation Mondiale de la Santé (OMS).

Dans ces conditions, les mesures exceptionnelles seront prises :

- Restriction de la circulation des personnes et des biens ;
- Fermeture des lieux publics et privés ;
- Interdiction de la vente des denrées alimentaires et des boissons ;
- Destruction des objets souillés susceptibles de contagion.

Article 163 : Les Services chargés des maladies transmissibles prendront toutes les mesures nécessaires de contrôle afin d'éviter la propagation de la maladie d'une localité à l'autre.

Article 164 : Toute infraction aux dispositions des articles 158 à 163 de la présente Loi sera punie d'une amende de 50.000 à 1.000.000 de francs guinéens et d'un emprisonnement de 6 mois à 5 ans ou de l'une de ces deux peines seulement sans préjudice de l'application des dispositions du Code pénal et du Code de l'Environnement.

CHAPITRE VI : DU CONTROLE SANITAIRE DES FRONTIERES

Article 165 : Le contrôle sanitaire aux frontière a pour objet de prévenir conformément aux dispositions de la présente Loi, l'introduction en République de Guinée ou la propagation à l'étranger des maladies au moyen de transports aériens, fluviaux, maritimes ou terrestres, des personnes, des animaux, des marchandises infectées ou présumées infectées, susceptibles de véhiculer la contagion.

Article 166 : Le contrôle sanitaire de routine aux frontières sera effectué à des endroits déterminés par le Ministère chargé de la Santé publique.

Ces postes de contrôle relèvent de la compétence exclusive de ce Département.

Article 167 : Les Médecins et les agents assermentés des services de contrôle sanitaire aux frontières établiront un procès-verbal des faits ou maladies constatés susceptibles d'entraîner la contagion, et en informeront immédiatement les autorités sanitaires du pays.

Article 168 : Les Médecins et les Agents assermentés des Services de contrôle sanitaire aux frontières doivent obligatoirement soumettre à un examen, les personnes et les moyens de transport en provenance d'une zone infectée par une maladie transmissible, et prendre le cas échéant, toute les mesures qui s'imposent aux fins d'en prévenir la propagation et d'assurer la destruction des substances et objets souillés. Il va de soi que de telles mesures ne donnent lieu à aucune indemnisation.

Article 169 : Toute infraction aux dispositions des articles 165 à 168 sera punie d'une amende de 50.000 à 1.000.000 de francs guinéens et d'un emprisonnement de 6 mois à 2 ans ou de l'une de ces deux peines seulement sans préjudice de l'application des dispositions du Code pénal et des dispositions conventionnelles souscrites par la République de Guinée.

CHAPITRE VII : DE LA PREVENTION ET DE LA LUTTE CONTRE LES LEAUX SOCIAUX

Article 170 : Conformément à la présente Loi, des mesures efficaces et efficientes doivent être prises par toute la Société Guinéenne en vue d'enrayer constamment les maladies non transmissibles en l'occurrence l'alcoolisme, le tabagisme et la toxicomanie.

La lutte sera menée efficacement et principalement contre les stupéfiants conformément aux dispositions des conventions internationales souscrites par la République de Guinée.

Article 171 : Les Ministères chargés de la Santé Publique et des Affaires Sociales procéderont au recensement des maladies non transmissibles au niveau national et prendront toutes les mesures adéquates en vue du traitement approprié, l'adaptation et la réinsertion sociale des personnes atteintes.

Article 172 : Dans le but de protéger la société contre les risques inhérents à certains fléaux sociaux, les personnes atteintes seront astreintes à un traitement approprié.

Article 173 : La vente du tabac et de ses produits dérivés sera subordonnée à l'apposition sur l'emballage d'une étiquette portant la mention « La consommation du tabac est nocive pour la Santé ».

D'autres mesures ultérieures seront énoncées par voie réglementaire, destinées à mettre en garde certains groupes de la population notamment les femmes enceintes, les adolescents, les personnes atteintes d'affections cardio-vasculaires ou respiratoires contre les risques encourus par la consommation du tabac.

Article 174 : Les mesures et les exigences relatives à la délimitation des normes applications à la publicité en faveur des boissons alcooliques et du tabac feront l'objet d'une réglementation ultérieure.

article 175 : La production, la transformation ou l'extraction, la préparation, la détention, l'offre, la distribution, l'achat, la vente, l'importation, l'exportation, la consommation des substances considérées comme stupéfiantes notamment l'opium brut ou officinal , l'extrait d'opium, la morphine et les autres alcaloïdes de l'opium à l'exception de la codéine, leurs sels dérivés, le chanvre indien, le kat ou la participation de quelque manière que ce soit à l'une de ces opérations seront punis conformément aux dispositions de la Législation en vigueur.

CHAPITRE VIII : DELA SAN TE BUCCO-DENTAIRE

Article 176 : Le Ministère chargé de la Santé Publique garantit la promotion et la préservation des soins bucco-dentaires, prendra des mesures curatives et préventives par le truchement de programmes élaborés en la matière dans l'intérêt de la population selon l es priorités qu'il aura fixées.

CHAPITRE IX : DE LA SANTE MATERNELLE ET INFANTILE

Article 177 : Le concept de Santé Maternelle et Infantile (SMI) est étroitement lié aux soins de Santé, la prévention et le traitement des maladies ainsi que les soins de réadaptations dispensés à la mère et à l'enfant.

Article 178 : A ce titre, les soins de santé maternelle et infantile visent à réduire la mortalité et la morbidité maternelles, péri natales et à promouvoir l'hygiène en matière de reproduction ainsi que le développement physique et psychosocial de l'enfant et de l'adolescent au sein de la famille.

Article 179 : La santé maternelle et infantile est étroitement liée à la Santé générale de la société et directement influencée par les conditions socio-économiques. A ce titre, son amélioration nécessite l'établissement d'un programme multi - sectoriel.

Article 180 : Toutes prestations des soins de Santé en matière de Santé Maternelle et Infantile seront dispensées conformément aux lignes directrices suivantes :

- Elaboration des stratégies nationales et locales destinées à assurer à chaque groupe de population un module de SMI correspondant à ses desiderata ;
- Utilisation souple et rationnelle des ressources humaines, matérielles et financières concourant à l'amélioration de la couverture de soins de SMI dans le cadre des soins de santé primaires de même que le recours à la participation active de la Société ;
- Approche intersectorielle reliant les activités sanitaires en faveur de la mère et de l'enfant aux activités connexes menées dans d'autres secteurs, cela à tous les échelons depuis le groupe familial jusqu'au niveau de planification ;
- Réorientation de toutes les autres activités socio-sanitaires au bénéfice des soins de Santé intégrés mettant l'accent sur les besoins spécifiques de la mère et de l'enfant.

Article 181 : Toute femme enceinte subira des examens médicaux nécessités par son état dans une formation sanitaire de son choix.

En conséquence les autorités sanitaires locales mettront en places des moyens appropriés en vue de procéder à l'éducation de la future mère.

En effet, toute femme occupant un emploi salarié ou travaillant dans la Fonction Publique, sera soumise au Statut de la Fonction Publique, au Code du Travail en ce qui concerne la fixation de la durée et de la période de congé de maternité.

Article 182 : La Planification Familiale revêt un caractère prioritaire. Ainsi les services offerts dans ce domaine permettront à toute personne d'exercer son droit de décider librement, de façon responsable et informée du nombre et de l'espacement de ses enfants sans qu'il soit porté la moindre atteinte à sa dignité.

Article 183 : Conformément aux dispositions du Code pénal, l'avortement thérapeutique a uniquement pour but de sauver la vie de la femme gravement menacée.

Il sera autorisé par un Collège de Médecins spécialistes, lequel consignera sa décision dans un procès-verbal justifiant les raisons de celui-ci.

Article 184 : La surveillance médicale, la prévention, la vaccination, l'éducation pour la Santé et les soins dispensés aux enfants dès leur naissance jusqu'à l'âge de 6 ans seront fixés par une Décision du Ministère chargé de la Santé publique.

Article 185 : L'alimentation des jeunes enfants fera l'objet d'une surveillance particulière à la charge de l'autorité sanitaire locale, laquelle élaborera un programme d'éducation sanitaire de la mère.

Article 186 : Le Ministère chargé de la Santé Publique déterminera les vaccinations obligatoires et en fixera le calendrier.

Article 187 : Tout nouveau-né doit bénéficier de l'allaitement maternel exclusif de la naissance à 6 mois au moins.

A cet égard l'usage des biberons et des substituts du lait maternel fera l'objet d'une décision du Ministère chargé de la Santé Publique.

Il est formellement interdit de faire la publicité des substituts du lait maternel à travers les médias et d'utiliser les affiches promotionnelles sur toutes l'étendue du territoire national.

Il est fait obligation de respecter scrupuleusement les dispositions du Code International sur la Commercialisation des substituts du lait maternel approuvé par l'Assemblée Mondiale de la Santé en 1981.

La surveillance de la croissance et du développement psychomoteur de l'enfant se fera dans les centres de Santé Maternelle et Infantile (SMI) et tous les événements survenus de la naissance à l'âge de 3 ans seront rigoureusement portés dans le dossier de l'enfant.

Toute vaccination contre les maladies infantiles infectieuses demeure obligatoire conformément à la réglementation en vigueur.

A chaque consultation du nourrisson, il sera fait mention du tracé de la courbe du poids de l'enfant jusqu'à l'âge de 5 ans en présence des parents.

Article 188 : Il est obligatoire d'établir la surveillance des enfants à risque notamment les enfants drépanocytaires, prématurés, malnutris, les enfants issus de mères diabétiques, sidéennes, syphilitiques, cardiopathes graves, cancéreuses, par des consultations périodiques.

Article 189 : Seuls les documents sanitaires délivrés par les Services sanitaires sont valables sur toute l'étendue du territoire.

Quant aux établissements en mission éducative, ils devront nécessairement avoir un pédiatre ou un médecin autorisé et un psychologue.

Article 190 : Il est obligatoire de nommer un personnel compétent chargé des crèches, haltes-garderies, jardins d'enfants et de les doter d'un matériel de travail adéquat.

Article 191 : Les produits locaux seront nécessaires à la fabrication des aliments destinés aux jeunes enfants. On devra familiariser les mères à leur meilleure utilisation.

Article 192 : La pratique de l'hygiène doit être effectuée par tous les établissements scolaires du pays et les moyens appropriés doivent être dégagés à cet effet.

SECTION 2 : DE LA PROTECTION DE LA SANTE DES ENFANTS D'AGE SCOLAIRE ET DES ADOLESCENTS

Article 193 : Les autorités sanitaires locales chargées d'organiser la protection des enfants d'âge scolaire se conformeront aux modalités programmatiques élaborées par le Ministère chargé de la Santé Publique.

Elles devront élaborer un programme de la surveillance médicale des élèves et des étudiants selon les modalités définies par le Ministère chargé de la Santé Publique.

Les formations sanitaires devront mettre à la disposition des enfants et des adolescents les moyens de prévention, d'immunisation et de surveillance médicale appropriées.

Article 194 : Le programme de la surveillance sanitaire des adolescents est du ressort des Ministères chargés de la Santé Publique, de l'Education Nationale, de la Jeunesse et sera mis en œuvre dans chaque établissement.

Article 195 : Une visite médicale annuelle sera systématiquement organisée dans tous les établissements primaires et secondaires pour chaque enfant à qui sera délivré un Certificat qu'il présentera à ses parents :

- L'enseignement de l'éducation sexuelle, de l'éducation à la vie familiale, des notions de nutrition et d'hygiène sera dispensé ;
- L'éducation pour la santé sera orientée vers la conscientisation des enfants et des adolescents sur les méfaits du tabac, de l'alcool et de la drogue.

SECTION 3 : DES VISITES ET EXAMENS PRENUPTIAUX

ARTICLE 196 : Avant le mariage, des examens de laboratoires et une visite systématique des futurs conjoints doivent être obligatoires.

L'Officier de l'état-civil doit exiger les pièces les attestant.

Article 197 : Les visites et examens prénuptiaux sont destinés à ceux qui ont l'intention de fonder un foyer.

Article 198 : Les visites et examens prénuptiaux sont faits dans un délai d'un mois avant le mariage et leur validité n'excède pas trois mois à compter de la date de délivrance du Certificat qui les atteste.

Article 199 : Les visites et examens prénuptiaux portent sur la recherche d'anomalies ou de maladies pouvant compromettre la procréation. Il s'agit notamment de :

- Certaines malformations congénitales ou non qui rendent impossible l'accouplement ;
- Les maladies sexuellement transmissibles y compris le SIDA ;
- L'incompatibilité des groupes sanguins.

Article 200 : Les Certificats sont délivrés par les Services de Santé compétents du Ministère chargé de la Santé Publique et permettront aux futurs conjoints de connaître leur état de santé.

CHAPITRE X : DE LA MEDECINE DU TRAVAIL

Article 201 : En conformité avec les dispositions du Code de Travail de la République de Guinée relatives à la protection de la Santé des travailleurs, des mesures préventives doivent être prises en vue de protéger la Santé des travailleurs dans les entreprises, les industries, l'agriculture et dans tous les secteurs d'activités professionnelles et artisanales.

Article 203 : Le Ministère chargé de la Santé Publique agissant conjointement avec le Ministère chargé du Travail détermineront les normes d'hygiène et de sécurité nécessaires applicables dans les établissements, en vue d'assurer la protection de la Santé des travailleurs contre les dangers et les nuisances pouvant résulter des déchets liquides, solides et gazeux.

Section 1 : Des visites médicales systématiques

Article 204 : Des mesures sanitaires adéquates seront énoncées en vue d'assurer la protection de la Santé au travail dans les entreprises et secteurs d'activités économiques, chez les travailleurs indépendants, dans le secteur informel et chez les artisans.

Ces mesures seront matérialisées par des visites médicales d'embauche, périodiques, spontanées, de reprise de travail après une longue absence des travailleurs, la dotation en médicaments de première nécessité, en personnel médical compétent et en matériel médicochirurgical, les mesures générales d'hygiène, de sécurité de travail.

Article 205 : Tous les Services de santé installés ou devant être installés dans une entreprise, une industrie, secteur informel ne peuvent avoir l'autorisation de mise en exploitation qu'en vertu d'une Décision du Ministère chargé de la Santé Publique après avis de l'Inspection Générale de la Santé Publique.

Un contrôle périodique sera effectué par l'Inspection Générale de la Santé Publique dans tous les Services de santé ayant obtenu l'autorisation de mise en exploitation.

Un procès-verbal sera alors dressé à l'occasion de chaque mission d'inspection à l'intention du Ministre chargé de la Santé Publique.

Article 206 : En conformité avec les dispositions du Titre III du Livre II du Code de Travail de la République de Guinée toutes les mesures de portée sanitaire concernant les entreprises, les industries, les secteurs informels relèveront de la compétence exclusive du Ministère chargé de la Santé Publique qui, en prenant toutes décisions de nature médico-sanitaire pourrait quérir les avis des secteurs concernés.

Section 2 : De la salubrité et de l'hygiène des lieux de travail

Article 207 : Les établissements industriels seront regroupés en différentes catégories selon la nature des risques qu'ils peuvent faire encourir à la Société et à l'environnement.

Dans ces conditions le Ministère chargé de la Santé Publique de concert avec les Départements concernés s'assurera de toutes mesures techniques appropriées, destinées à autoriser l'exploitation de tels établissements ou leur fermeture pure et simple.

Dans l'hypothèse ou un établissement offrant toutes les garanties de commodité et de salubrité est répertorié, un Certificat de conformité lui sera alors délivré en conséquence.

Article 208 : Toute infraction aux dispositions de l'article 207 de la présente Loi sera punie d'une amende de 500.000 à 2.000.000 de francs guinéens et d'un emprisonnement de 1 à 5 ans ou l'une de ces peines seulement sans préjudice de l'application des dispositions du Code de l'Environnement.

CHAPITRE XL : DE LA SANTE MENTALE

Article 209 : Le Ministère chargé de la Santé Publique édictera des mesures permettant d'assurer :

- Des Services préventifs dans le domaine de la Santé mentale aux différentes étapes de la croissance du citoyen de la naissance jusqu'à la vieillesse ;

- La protection nécessaire et le traitement approprié en cas d'aliénation mentale et d'épilepsie.

Les autres départements ministériels concourent également à la réalisation des objectifs ci-dessus énumérés.

Article 210 : La prévention des maladies mentales revêt un caractère prioritaire, en ce qu'elle est fondée sur la connaissance des facteurs ayant une incidence sur la santé mentale, des causes diverses découlant de modifications comportementales et des méthodes de prévention idoines.

De ce point de vue, le Ministère chargé de la Santé Publique en coordination avec les Départements concernés encouragera et soutiendra :

- Le développement des activités éducatives, socioculturelles et récréatives contribuant au renforcement de la santé mentale en faveur des enfants et des adolescents ;

- La réalisation des programmes de prévention et de l'utilisation des substances psychotropes, des différents stupéfiants et autres substances pouvant provoquer des troubles mentaux.

Article 211 : Les mesures visant à assurer le placement de personnes atteintes de maladies mentales dans des établissements conçus à cet effet obéiront nécessairement et obligatoirement aux principes d'éthique sociaux ainsi qu'aux conditions scientifiques et juridiques que déterminera le Ministère chargé de la Santé Publique.

Article 212 : Le Ministère chargé de la Santé Publique établira de concert avec les autorités judiciaires, administratives, etc. ; de la République de Guinée des normes techniques applicables au régime de dispensation des soins destinés aux malades mentaux incarcérés ou détenus dans des établissements qui ne sont pas spécialisés en Santé mentale.

Article 213 :L'admission dans un établissement psychiatrique d'une personne présumée atteinte d'une maladie mentale ne pourra se faire que sur une base volontaire conformément à la réglementation en vigueur.

Article 214 : Toute personne atteinte de troubles mentaux qui constitue une menace ou un danger pour elle-même ou pour autrui sera hospitalisée d'office même si le consentement de sa famille ou de son représentant légal n'a pas été requis.

Article 215 : Toute demande de placement volontaire sera établie :

- Par le malade lui-même ;

- Par sa famille ou son représentant dûment mandaté, lorsqu'il est mineur ou incapable ;

- Par toute personne désignée pour exercer les fonctions de curateur ou de tuteur du malade.

Article 216 : La sortie à la suite d'une hospitalisation ne pourra avoir lieu que sur instruction d'un Médecin ainsi qu'à la demande du malade.

Dans ces conditions, le Directeur de l'Hôpital doit avoir la conviction que celui-ci pourra vivre en dehors de l'hôpital sans risque grave pour lui-même et pour autrui.

Article 217 : La décision d'hospitalisation d'office sur une base administrative ou judiciaire est prise sur requête dûment motivée lorsque le danger estimé imminent est encouru du fait de la maladie par le malade lui-même ou pour autrui.

Article 218 : Nul ne pourra prendre la décision d'hospitalisation d'office d'un parent ascendant ou descendant, d'un conjoint, d'un collatéral frère ou sœur, d'un oncle, d'une tante ou de leurs conjoints respectifs.

Toutefois, l'hospitalisation d'office peut à tout moment, sur requête du Médecin de l'hôpital psychiatrique, être transformée en internement volontaire. En outre la sortie d'une personne hospitalisée sur une base administrative ne pourrait être autorisée que par une décision du Directeur de l'Hôpital à la suite d'une demande des parents ou des représentants légaux du malade lorsque ceux-ci assument la responsabilité de son comportement à son domicile.

Article 219 : La sortie à la suite d'une hospitalisation sur une base judiciaire ne pourrait être autorisée que par le Tribunal ayant ordonné l'hospitalisation.

Toutefois, dans chaque établissement où sera créé un Service d'examen psychiatrique d'office, de mise en observation, d'internement volontaire et d'hospitalisation d'office, il sera ouvert un registre dans lequel doivent être consignées toutes les indications nécessaires.

Article 220 : Les enfants et adolescents, âgés de moins de 16 ans pourront faire l'objet d'examen psychiatrique d'office.

Ils ne feront l'objet ni d'internement volontaire, ni d'hospitalisation d'office.

Quant aux personnes âgées dont l'affaiblissement des facultés mentales constitue l'essentiel de la maladie, elles ne seront pas assujetties à un examen psychiatrique d'office ni à un examen volontaire, ni à l'hospitalisation d'office.

Dans tous les cas, les dossiers des malades mentaux seront confidentiels hormis les renseignements recherchés par les autorités judiciaires.

Article 221 : Seul le Directeur de l'Hôpital est autorisé à faire délivrer un Certificat de séjour des malades mentaux mentionnant la nature de leurs maladies et toutes les autres questions liées à leur hospitalisation.

Cependant, seul le malade, son représentant légal et l'autorité judiciaire peuvent prendre connaissance dudit Certificat.

Toutes les décisions prévues au présent Chapitre pourront faire l'objet de recours devant les Tribunaux ou devant les autorités sanitaires compétentes en l'occurrence le Médecin légiste ou tout spécialiste assermenté.

CHAPITRE XII : DES SOINS AUX PERSONNES AGEES ET AUX HANDICAPES

Article 222 : Le Ministère chargé de la Santé Publique s'occupe de la promotion des personnes âgées en élaborant un système de prestations, de prévention des maladies, de traitement et d'entretien fonctionnel permettant aux personnes âgées d'avoir accès aux soins ambulatoires et hospitaliers destinés à protéger leur santé adaptés à leurs âges de même qu'à leur état mental et physique.

Article 223 : Est considérée comme handicapée, toute personne physique dont les possibilités de réinsertion éducative, professionnelle ou sociale sont déficientes, congénitales ou non à caractère permanent, affectant ses capacités physiques, mentales ou sensorielles.

Article 224 : La prévention des incapacités constitue un droit et une obligation de la société dans son ensemble en ce qu'elle est partie intégrante de l'une des obligations prioritaires de la République de Guinée en matière de Santé publique et de la protection sociale.

Article 225 : Le régime de soins, de réadaptation et de réinsertion socioprofessionnelle est fixé par des textes connexes des Départements ministériels obéissant au droit commun en matière de protection sanitaire et sociale.

Quant aux personnes âgées, leur régime de soins médicaux sera fixé par un acte réglementaire.

Article 226 : La Médecine traditionnelle guinéenne est l'ensemble des connaissances techniques de préparation et l'utilisation des substances, mesures et pratiques en usage, explicables ou non à l'état actuel de la science, résultant des fondements socioculturel et religieux des collectivités guinéenne, qui s'appuient sur les expériences vécues et les traditions transmises à la postérité, oralement ou par écrit et qui servent à diagnostique, prévenir ou éliminer un déséquilibre du bien être physique, mental, social ou spirituel.

Article 227 : l'exercice de la médecine traditionnelle est juridiquement autorisé. Cet exercice est reconnu à toute personnes physique ou morale, à titre

individuel ou en association, dans les conditions fixées par les dispositions en vigueur.

Article 228 : Est tradi-praticien de Santé, toute personne reconnue compétente par la collectivité dans laquelle elle vit pour diagnostiquer, pratiquer les soins ou activités selon les techniques et méthodes se référant aux fondements socioculturels et concourant à la santé, au bien-être physique, mental, social et spirituel des membres de ladite localité.

Article 229 : Le terme de tradi-praticien de santé au sens de la présente Loi s'applique notamment aux catégories professionnelles suivantes :

- Tradi-thérapeute;
- Accoucheuses traditionnelles;
- Médico-droguistes.

Un tradi-thérapeute est celui qui est reconnu par sa localité comme compétent pour diagnostiquer et dispenser des soins de Santé basée sur les concepts de la maladie et des invalidités prévalant dans ladite localité.

Est accoucheuse traditionnelle, la personne reconnue compétente pour prodiguer à une femme et à un nouveau - né, avant, pendant et après l'accouchement des soins de santé basée sur des concepts prévalant dans sa localité.

Est médecin-droguiste, celui qui a les connaissances des usages et vend les substances médicales, autres que les plantes, d'origine animale ou minérale.

Article 230 : La pratique de la Médecine traditionnelle s'étend aux actes de consultations, de diagnostic et de soins utilisant exclusivement les méthodes traditionnelles.

CHAPITRE XIV. DES SECOURS D'URGENCE

Article 231 : En vue de pallier aux problèmes médico-sanitaires posés ou que pourront soulever les catastrophes naturelles et les désastres d'origine humaine, il est créé un Service de gestion des urgences rattaché à la Direction chargée de la Prévention.

Ce Service devra collaborer étroitement et efficacement avec tous les secteurs du Ministère chargé de la Santé Publique dans le processus de la gestion des urgences.

Il devra entreprendre des études et élaborer un programme ayant pour objectifs de :

- Planifier, organiser et développer le secours d'urgence sur l'ensemble du Territoire de la République de Guinée en coordination avec l'ensemble des autres services concernés ;

- Assurer le ramassage, le transport et l'évacuation sur les formations sanitaires des victimes du sinistre ou de toutes les personnes dont l'état nécessite des soins urgents indispensables à leur survie ;

- Dispenser aux personnes visées ci-dessus les premiers soins nécessaires à leur état ;

- Définir les modalités d'enseignement en matière de prévention et de recherche.

Article 232 : Des mesures doivent être prises pour doter tous les hôpitaux sur l'ensemble du territoire de la République de Guinée des équipements susceptibles de concourir à la bonne gestion des urgences.

La capacité opérationnelle optimale de l'hôpital sera renforcée en équipements et autres ressources destinées à dispenser des soins intensifs.

Article 233 :L'on devra élaborer des mesures de coordination régionale chargées d'assurer des soins intensifs et des soins intermédiaires, tandis que les Centres de Santé, dispensaires et les cliniques privées seront responsables des traitements légers et ambulatoires.

Article 234 :L'étude de planification des urgences devra nécessairement tenir compte de certains facteurs contingents comme l'étendue, la gravité, l'extension et éventuellement la dimension des problèmes devant nécessiter une gestion efficace et efficiente d'une situation spécifique.

Article 235 : Une étude intersectorielle de la gestion des urgences devra comporter des éléments de coordination étroite avec les études épidémiologiques des activités médico-sanitaires de la République de Guinée notamment l'évaluation, la planification et les données prévisionnelles en matière de situations d'urgences y compris les épidémies.

Article 236 : La situation des urgences est susceptible d'affecter plusieurs secteurs organisationnels en matière de secours.

Le Comité interministériel pour la concertation sanitaire et sociale pourra élaborer un mécanisme harmonieux et uniformisé dont l'objectif consistera à équiper outre les secteurs de secours, l'équipe médico-sanitaire en matériels techniques indispensables à la dispensation des soins.

LIVRE TROISIEME : DE L'ETHIQUE POUR LA RECHERCHE EN SANTE

CHAPITRE 1 : DISPOSITIONS GENERALES

Section 1 : Des principes

Article 237 : Toute recherche impliquant des sujets humains doit être exécutée en conformité avec les principes essentiels d'éthique :

- Le principe du respect de la personne ;
- Le principe de bienfaisance sous ses deux aspects : éviter de nuire et promouvoir un bien ;
- Le principe de Justice ;
- Le principe de la qualité de la recherche.

Article 238 : Le principe du respect de la personne implique :

- Que les personnes autonomes c'est-à-dire capables du choix de leurs propres objectifs soient traitées avec le respect dû à leur capacité d'autodétermination ;
- Que les personnes dépendantes ou vulnérables c'est-à-dire dont l'autonomie est atteinte ou diminuée soient protégées de tout abus ou préjudice.

Article 239 : Le principe de bienfaisance implique :

- L'évaluation des avantages escomptés et des risques possibles de la recherche ;
- L'obligation de maximiser les avantages éventuels en minimisant les possibilités de nuisance ou ;
- La préservation des sujets étudiés de tout mal évitable lié au sujet.

Article 240 : Le principe de justice implique :

- La non-discrimination à l'endroit d'individus ou de groupes ;
- La non exploitation en particulier de personnes vulnérables.

Article 241 : Le principe de qualité de la recherche implique :

- La qualification du chercheur ;

- La validité scientifique du projet ;

- Un protocole détaillé comportant : les pré requis justifiant le passage à la recherche sur l'homme, l'objectif de la recherche, la méthodologie, la population cible, les contraintes et les risques éventuels pour les sujets étudiés, les modalités de leur consentement, les modalités d'analyse des données, les modalités de publication des résultats, le suivi des personnes à leur sortie de l'essai.

Section 2 : Du consentement

Article 242 : En règle générale, toute recherche en santé impliquant la participation d'êtres humains en tant que sujets est subordonnée à leur consentement. Le consentement doit être éclairé, libre et matérialisé par un document.

Article 243 : Le consentement est dit éclairé lorsque la personne consentante comprend le but et la nature de l'enquête, les obligations qu'implique sa participation à celle-ci ainsi que les risques et les avantages qui peuvent en découler.

Pour ce faire, le chercheur a l'obligation d'informer honnêtement le sujet, de s'assurer qu'il a bien compris et de répondre aux questions.

Article 244 : Le consentement est dit libre lorsque le sujet est en possession de toutes ses facultés mentales et qu'il ne subit ni pression, ni coercition.

De plus, il doit savoir qu'il est libre de s'abstenir ou de revenir sur sa décision.

Article 245 : Le consentement est matérialisé par un document qui résume les objectifs de l'étude et qu'elle implique pour le sujet. S'il est d'accord, le sujet signe ce document devant un témoin indépendant du chercheur.

Article 246 : Des exceptions à la règle du consentement sont admissibles dans le cas où :

- La recherche est faite sur dossiers ou sur échantillons biologiques et qu'il est impossible de localiser les sujets ;

- Il existe un risque de dénaturer les objectifs de certaines enquêtes par exemple lorsque les sujets choisis sont susceptibles de modifier leur comportement que l'on se propose d'étudier.

- Dans les deux cas, l'accord du Comité National d'Éthique pour la Recherche en santé est indispensable.

Section 3 : De la protection des personnes particulièrement vulnérables

Article 247 : Par personne particulièrement vulnérable, on entend une personne qui, du fait de sa situation ou de son état mental, ne peut pas donner un consentement entièrement libre ou éclairé.

C'est le cas notamment pour :

- Les enfants mineurs ;
- Les prisonniers ;
- Les malades et déficients mentaux ;
- Les personnes dont l'état nécessite des soins d'urgence ou de réanimation ;
- Les femmes enceintes ou allaitantes du fait de leurs états sont considérées comme faisant partie des personnes particulièrement vulnérables.

Article 248 : La recherche sur les personnes particulièrement vulnérables nécessite des mesures de protection et leur consentement, s'il est possible, doit obéir à des règles particulières.

Article 249 : Le consentement personnel de l'enfant doit être demandé lorsque son âge lui permet de comprendre l'objectif de la recherche, les risques et inconvénients liés à cette recherche ainsi que ce qu'on attend de sa participation.

Dans tous les cas, le consentement de l'enfant doit être complété par le consentement éclairé du parent ou du tuteur légal.

En cas de désaccord entre la volonté des parents et celle de l'enfant, c'est le refus qui prévaut.

Article 250 : Il ne peut être proposé à l'enfant et à ses parents que des recherches portant sur des maladies de l'enfance ou des pathologies auxquelles les enfants sont particulièrement vulnérables, et à condition que les mêmes recherches ne puissent pas être effectuées sur d'autres adultes.

Article 251 : Le consentement éclairé de la femme enceinte ou de la mère allaitante est, dans tous les cas, requis.

Il ne peut leur être proposé que des recherches visant à :

- Améliorer la santé de la mère sans préjudice pour le fœtus ou le nourrisson ;
- Augmenter la viabilité du fœtus ;
- Favoriser le bon développement du nourrisson ou l'aptitude de la mère à le nourrir.

Article 252 : Toute recherche favorisant l'interruption de la grossesse tel que prévu à l'article 269 du Code pénal est interdite.

Article 253 : Il ne peut être proposé aucune participation à des recherches biomédicales à des personnes détenues en prison ou privées de toute leur liberté.

Article 254 : Dans le cas où un sujet malade est placé sous la responsabilité de l'autorité judiciaire, l'accord de celle-ci est requis en complément du consentement éclairé du sujet.

Article 255 : Dans la mesure du possible, le malade doit être informé des recherches pour lesquelles sa participation est envisagée et son consentement doit être sollicité.

Article 256 : Le déficient mental doit être informé des recherches pour lesquelles sa participation est envisagée. Le refus du déficient mental doit toujours être respecté.

En outre est requis le consentement éclairé du parent ou du tuteur. Le refus du malade mental doit toujours être respecté.

Article 257 : On ne peut se proposer d'entreprendre sur des malades ou déficients mentaux que des recherches intéressant la pathologie dont ils sont atteints et ne pouvant être conduites sur des sujets sains.

Article 258 : Dans les situations d'urgences, lorsque la personne n'est pas en état de donner un consentement éclairé pour une recherche, on sollicite le consentement d'un proche.

Section 4 : De la non nuisance

Article 259 : Le chercheur est responsable de la sécurité des personnes soumises à la recherche.

En particulier, il doit prévoir les risques auxquels elles sont exposées et les protéger de ces risques.

Article 260 : L'évaluation d'un risque comporte une appréciation de sa probabilité et de sa gravité.

Article 261 : Les risques encourus du fait de la recherche peuvent être des risques non mineurs. Les personnes particulièrement vulnérables ne peuvent être exposées dans le cadre d'une recherche qu'à des risques mineurs.

Article 262 : Un risque est dit mineur si, du fait de sa probabilité ou de sa faible gravité, il est d'un niveau comparable aux risques quotidiennement encourus par les personnes concernées.

Article 263 : Des risques un peu plus élevés que des risques mineurs ne sont pas admissibles dans le cadre de la recherche que pour les personnes capables de donner un consentement entièrement libre et éclairé.

Article 264 : Tout préjudice lié à la recherche doit être indemnisé.

Article 265 : En aucun cas, le consentement des sujets ne décharge de leurs responsabilités, le promoteur et l'investigateur de la recherche.

Article 266 : Le promoteur est la personne ou l'institution commanditaire de la recherche. Le promoteur est responsable des accidents liés à l'application du protocole.

Article 267 : L'investigateur est la personne qui conduit la recherche. Il est responsable en cas d'accident dû à une faute qu'il a commise personnellement.

CHAPITRE II : DISPOSITIONS APPLICABLES A LA RECHERCHE EPIDEMIOLOGIQUE

Article 268 : On entend par recherche épidémiologique, des enquêtes ou des essais d'intervention effectués sur des populations dans le but d'acquérir des connaissances sur les facteurs qui influencent leur état de santé.

Section 2 : De la pression injustifiée et de l'incitation à participer

Article 269 : Il est interdit à toute personne d'exercer une contrainte sur un sujet pour l'amener à participer à une enquête épidémiologique.

Article 270 : Le chercheur ne doit pas rester anonyme ; il est tenu de s'identifier auprès des sujets invités à participer à l'enquête.

Article 271 : Il appartient au chercheur de s'assurer que l'individu qui participe à une enquête ne subit pas des influences indues.

Article 272 : Des avantages individuels ou collectifs peuvent être attribués en compensation de la participation de la collectivité à la recherche.

Ces avantages sont négociés avec le représentant de la collectivité et en aucun cas, ils ne peuvent constituer pour le représentant une source d'enrichissement personnel.

En cas de violation de cette prescription, l'article 339 du Code pénal s'applique.

Article 273 : L'accord individuel ou collectif doit être indépendant des avantages que l'individu ou la collectivité peuvent tirer de la recherche.

Article 274 : Le remboursement des frais encourus comme les voyages, l'hébergement, la nourriture ainsi que la compensation des dommages ne sont pas considérés comme étant des avantages tels que stipulés à l'article 272.

Section 3 : Du respect des valeurs et habitudes sociales

Article 275 ; Le chercheur est tenu, avant d'appliquer toute enquête épidémiologique sur une collectivité ou un groupe d'individus, de recueillir tous les renseignements utiles sur leur composition et mode de vie et de respecter leurs droits, leurs croyances et leurs habitudes.

Article 276 : Des enquêtes peuvent contribuer au changement de certaines habitudes ou de certains comportements de façon à modifier les attitudes en faveur de la santé. Sur le plan de l'éthique, sans vouloir imposer un bienfait que la collectivité n'a pas sollicité, de telles enquêtes doivent être considérées comme acceptables et exemptes de préjudice. Toutefois, le chercheur ne doit pas surévaluer leurs avantages.

Article 277 : Tout chercheur étranger menant des enquêtes en Guinée est tenu de se conformer aux normes éthiques de son propre pays ainsi que celles de la Guinée et de respecter les valeurs culturelles des collectivités faisant l'objet de ces enquêtes.

De même, le chercheur guinéen appelé à mener des enquêtes à l'extérieur du pays, doit respecter les normes éthiques guinéennes tout en respectant les valeurs culturelles du pays hôte.

Section 4 : De la diffusion de l'information et de la confidentialité des résultats

Article 278 : Il est formellement interdit de procéder à la divulgation d'informations identifiantes liées à des enquêtes épidémiologiques. Une

information est dite identifiante si elle permet d'identifier la ou les personnes ayant fait l'objet de ces enquêtes.

Article 279 : Les communautés, les groupes et les individus ayant participer à une enquête doivent être correctement informés des résultats de ces enquêtes. L'information doit tenir compte du niveau d'instruction et de compréhension des communautés concernées.

Toutefois, si la connaissance de ces résultats peut avoir des conséquences défavorables pour cette communauté, leur divulgation n'est pas requise.

Article 280 : Au cas où les résultats de l'enquête peuvent améliorer la santé communautaire, le chercheur est tenu d'en informer les autorités sanitaires compétentes.

Article 281 : Lorsque, au cours d'une enquête, le chercheur découvre qu'un sujet est atteint d'une maladie ou d'un état pathologique et qu'il ne peut informer le sujet, il est tenu de faire comprendre au sujet que cette absence d'information ne signifie pas qu'il est exempt de la maladie ou de l'état pathologique. Le chercheur doit aviser /p. 57/ le sujet des moyens d'obtenir un diagnostic personnel en vue d'un traitement adéquat.

Article 282 : Lorsqu'il n'est pas possible d'aviser individuellement les sujets enquêtés de la nécessité de recevoir des soins, le chercheur devra néanmoins communiquer à la communauté les avis appropriés sur les soins de santé à appliquer.

Article 283 : Le chercheur est dans l'obligation de publier les renseignements d'intérêt général résultant de ses enquêtes même si cela est contraire à l'avis des services publics ou de tous autres organismes.

Article 284 : Le chercheur ne doit pas publier des résultats de recherche dans le but de tirer des conclusions favorables à des intérêts particuliers.

Article 285 ; Le chercheur ne doit pas présenter comme des faits reconnus de simples interprétations, suggestions, théories ou hypothèses.

Article 286 : Lorsque le chercheur estime que la divulgation d'informations sensibles risque d'exposer un groupe à des critiques ou à un traitement indésirable, il doit faire preuve de retenue dans la communication et l'interprétation de ses conclusions. Une information est dite sensible lorsqu'elle risque d'entraîner pour la personne ou le groupe concerné, une discrimination sociale.

Article 287 : Toutefois lorsque la compréhension des résultats exige que soient connus les circonstances et les lieux de l'enquête, le chercheur doit envisager des mesures de protection pour éviter au groupe concerné tout préjudice ou inconvénient.

Article 288 : Lorsqu'un antagonisme apparaît entre d'une part, l'obligation de ne causer aucun tort, et d'autre part le fait de dire la vérité et de présenter publiquement des conclusions scientifiques, le chercheur doit atténuer ces inconvénients en interprétant les données de manière à protéger les intérêts des personnes à risque sans pour autant nuire à l'intégrité scientifique.

CHAPITRE III : DISPOSITIONS APPLICABLES A LA RECHERCHE CLINIQUE ET BIOLOGIQUE

Article 289 : On entend par Recherche Clinique et Biologique, la recherche portant sur des individus humains dans le but d'acquérir des connaissances sur le fonctionnement de l'organisme et le traitement des maladies.

Section 1 : De la recherche clinique et biologique associée avec des soins médicaux

Article 290 : Lorsqu'une recherche est associée avec des soins médicaux, le malade doit être clairement informé de ce qui relève du traitement de sa maladie.

Article 291 : La recherche associée avec des soins médicaux doit se faire dans le respect de la dignité de la personne malade.

Article 292 : L'association de la recherche biomédicale avec des soins médicaux en vue de l'acquisition des connaissances médicales nouvelles ne peut se faire que si cette recherche est justifiée par une utilité diagnostique et thérapeutique relative à la maladie dont la personne est atteinte.

Article 293 : Lorsqu'un protocole de recherche est appliqué à un malade hospitalisé et que le promoteur de la recherche n'est pas l'institution d'accueil, une convention doit être passée entre cette institution et le promoteur.

Article 294 : Lorsqu'un malade hospitalisé participe à une recherche, cette participation peut lui donner un avantage financier sur le coût du traitement ou de la prise en charge.

Section 2 : De la recherche clinique et biologique non associée avec des soins médicaux

Article 295 : Dans toute recherche biomédicale non associée avec des soins médicaux, le bien être du sujet doit toujours prévaloir sur les intérêts de la science et de la société.

Le chercheur est tenu de protéger la vie et la santé du sujet lors d'expériences entreprises à des fins purement scientifiques. L'expérience doit être arrêtée si sa poursuite s'avère dangereuse pour le sujet.

Article 296 : La recherche biomédicale à visée non thérapeutique ne peut être entreprise que sur des sujets volontaires en bonne santé, ou exceptionnellement sur des malades volontaires atteints d'une affection étrangère à l'étude, si on est assuré que leur consentement est entièrement libre et éclairé.

Section 3 : De la recherche en médecine traditionnelle

Article 297 : Les recherches traditionnelles en santé font partie du patrimoine culturel guinéen. Le patrimoine culturel doit être protégé aussi bien que le patrimoine national (environnement). Il n'est pas éthique de laisser se perdre le secret d'une recette. Celui qui connaît une recette doit veiller à ce qu'elle soit recueillie.

Article 298 : Lorsqu'un chercheur recueille une recette traditionnelle il doit mentionner sa source.

Si le chercheur tire de la recette un profit, ce profit doit être partagé avec celui auprès de qui la recette a été recueillie.

Article 299 : Lorsqu'un médecin chercheur participe à une recherche préclassique ou clinique sur la médecine traditionnelle, il est légitime qu'il ne modifie pas les recettes de celles-ci sauf s'il juge que le malade est en danger et qu'il a les moyens d'intervenir efficacement dans le cadre du système de soins de santé moderne.

Article 300 : Les dispositions qui s'appliquent à la recherche clinique et biologique s'appliquent aussi à l'évaluation d'une recette traditionnelle par les méthodes modernes.

Section 4 : De l'indemnisation en cas de préjudice accidentel

Article 301 : Toute personne soumise à des recherches biomédicales, qui par la suite présenterait de ce fait une lésion, a droit à une indemnisation entière de toute incapacité temporaire ou permanente.

En cas de décès, les personnes en charge ont droit à une indemnisation appropriée.

Article 302 : En aucun cas le chercheur ne doit exiger des sujets de l'expérimentation qu'ils renoncent à leur droit d'indemnisation en cas d'accident ou qu'ils soient tenus de faire la preuve qu'il y a eu négligence ou incompétence de la part du chercheur.

CHAPITRE IV : DE L'EXAMEN ETHIQUE

Article 303 : Tout projet de recherche en santé impliquant des sujets humains doit être soumis avant son exécution à l'appréciation du Comité National d'Éthique pour la Recherche en Santé (CNERS) qui se prononce en toute indépendance. En aucun cas, l'avis du CNERS ne décharge le promoteur ou l'investigateur de ses responsabilités éthiques et scientifiques.

Article 304 ; L'examen éthique vise à :

- Assurer que la valeur scientifique du projet de recherche a été approuvée par le Comité Consultatif comme stipulé à l'article 241 du présent Code ;

- Vérifier que toutes les expériences et enquêtes proposées ont été préalablement évaluées et jugées suffisamment sûres pour être menées sur des sujets humains ;

- S'assurer que les modalités prévues dans les dispositions du présent Livre pour le consentement des sujets sont respectées (Chapitre I, Section 2 ; Chapitre II, Section 1) ;

- S'assurer que tout autre problème éthique découlant du projet a reçu une solution satisfaisante au plan des principes comme de la pratique.

Article 305 : Lorsque les recherches portent sur une épidémie ou une calamité, il est impératif que le CNERS soit informé dès le début des travaux. Le protocole de recherche doit lui être soumis dans un délai n'excédant pas trente jours.

Malgré le caractère d'urgence, le chercheur est tenu de respecter les droits des sujets à savoir leur liberté, leur vie privée et la confidentialité des opérations.

Article 306 : Tout protocole de recherche doit comporter les éléments suivants :

- L'identité du promoteur de la recherche ;

- L'identité du ou des investigateurs ;

- Un exposé précis des objectifs et hypothèses de recherche ainsi que de leur justification eu égard à l'état actuel des connaissances ;

- Une présentation précise de la méthodologie et de son adéquation aux objectifs. Cette présentation doit inclure entre autres une description précise de toutes les interventions pratiquées sur le sujet ;

- Le calcul du nombre de sujets nécessaires à l'étude et la méthode d'analyse des données ;

- Les critères choisis pour décider du terme de l'enquête ;

- Les critères déterminant l'inclusion ou l'exclusion de sujets individuels ;

- Les risques encourus par les sujets soumis à la recherche ;

- Les modalités de recueil du consentement des sujets en indiquant quels sont les moyens et la documentation que l'on se propose d'utiliser pour obtenir le consentement éclairé ou lorsque cela n'est pas possible en indiquant les autres moyens retenus pour obtenir une autorisation, ainsi que les moyens de protection des droits, et de sauvegarde du confort, des sujets enquêtés.

Le protocole doit également :

- Comprendre des informations permettant d'établir la sécurité de chaque projet de procédure et d'intervention et également de tout médicament, vaccin ou dispositif qui doit être à l'essai en se fondant notamment sur les résultats des travaux pertinents de recherche en laboratoire et sur l'animal ;

- Apporter la preuve que le chercheur possède les qualifications nécessaires ou dans le cas contraire qu'il travaille sous la surveillance d'une personne compétente ;

- Apporter la preuve que le chercheur dispose de moyens appropriés lui permettant de conduire ses recherches de manière sûre et efficace ;

- Décrire les moyens proposés pour protéger la vie et préserver la confidentialité des données identifiantes pendant l'enquête et lors de la publication des résultats ;

- Mentionner toutes considérations d'ordre éthique qui pourraient être retenues.

Article 307 : L'examen éthique d'un protocole qui prévoit la nécessité d'un groupe témoin ou d'un groupe recevant un placebo doit s'assurer :

- Que le groupe témoin choisi dans le cas de l'étude d'un état morbide susceptible d'entraîner une issue fatale, une incapacité ou d'autres inconvénients sérieux, recevra des soins conformes à la thérapie en usage et

- Que s'il s'avère que le mode de traitement à l'essai est supérieur à celui habituellement utilisé, tous les membres du groupe témoin en bénéficieront dès la fin de l'essai.

De telles enquêtes doivent prévoir un dispositif d'arrêt, et être arrêtées avant la date prévue si on observe dans le groupe traité une toxicité inacceptable du produit à l'essai.

Article 308 : Lorsque le protocole prévoit une randomisation (tirage au sort), l'examen éthique doit veiller à ce que cette randomisation soit justifiée par l'incertitude qui subsiste quant à la différence de résultats entre les deux stratégies thérapeutiques comparées dans l'essai.

Tous les sujets doivent êtres informés à la fois sur l'incertitude qui subsiste quant à la différence de valeur entre les deux stratégies thérapeutiques et sur le fait que l'objectif de l'essai est de déterminer quelle est la stratégie thérapeutique la meilleure.

Article 309 : Lorsque le chercheur est convaincu que la recherche comporte des risques pour les individus ou les groupes cibles, il est tenu d'informer le CNERS ainsi que les sujets retenus des groupes avérés et des possibilités de prévenir ou d'atténuer ces risques.

Article 310 : Le CNERS doit donner son avis sur tout projet de recherche qui lui est soumis dans un délai maximum ne dépassant pas soixante jours à compter de la date de dépôt du projet.

Article 311 : Le chercheur est tenu de soumettre son projet de recherche au CNERS au moins quatre-vingt-dix jours avant la date prévue pour la mise en œuvre du projet.

Article 312 : Lorsqu'un membre du CNERS est directement concerné par un projet de recherche, sa participation aux séances d'examen de ce projet est interdite.

Article 313 : Le chercheur est tenu d'informer le CNERS des problèmes rencontrés lors du déroulement de la recherche.

Le CNERS peut demander à tout moment l'interruption d'une recherche lorsqu'il se rend compte de l'existence de problèmes éthiques nouveaux ou ayant échappé à son appréciation antérieure.

Article 314 : Le rejet définitif d'un projet de recherche pour des raisons liées à l'éthique ne peut avoir lieu que dans la mesure où le chercheur n'est pas arrivé à résoudre les problèmes éthiques qui lui sont signalés par le comité.

Article 315 : Le CNERS peut faire appel à des experts sur des points particuliers pour apprécier la qualité du protocole sur les plans scientifique et éthique.

En aucun cas le protocole ne peut être communiqué à des personnes extérieures au CNERS.

Dans tous les cas, il n'appartient qu'au seul CNERS de prendre une décision.

Article 316 : Les membres du CNERS sont tenus à une stricte confidentialité sur le contenu des protocoles et sur leurs délibérations

CHAPITRE V : DES DISPOSITIONS DIVERSES

Article 317 : Des dispositions réglementaires seront prises en tant que besoin pour la mise en application effective des différentes mesures fixées par la présente Loi.

Article 318 : La présente Loi sera enregistrée, publiée au Journal Officiel de la République et exécutée comme Loi de l'État.

Conakry, le 19 juin 1997

- GENERAL LANSANA CONTE -

LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

GUIDELINE FOR APPLICATION TO CONDUCT OF CLINICAL TRIALS IN LIBERIA

Date: February 2014

THIS GUIDELINE WAS PROMULGATED UNDER PART IV SECTION 2 (1 j & n) OF THE LIBERIA MEDICINES AND HEALTH PRODUCTS REGULATORY AUTHORITY ACT OF 2010

First Edition

February 2014

GUIDELINE FOR APPLICATION TO CONDUCT CLINICAL TRIALS IN LIBERIA

Foreword

This is the first edition of the guideline for application to conduct clinical trials in Liberia which has been drafted by a committee constituted by the Liberia Medicines and Health Products Regulatory Authority (LMHRA). The guideline has been made under Part IV Section 2(1 j & n) of the Liberia Medicines and Health Products Regulatory Authority Act, 2010. The edition is the first on the process of Clinical Trials in Liberia to have been drafted and to be implemented under the LMHRA's Act of 2010. The Authority has a legal responsibility of ensuring that all clinical trials obtain a written authorization from the LMHRA prior to commencement of study of any kind in Liberia.

It is therefore anticipated that all those who will be intending to conduct clinical trials in Liberia will herein oblige themselves with the aforementioned legal provisions and follow the procedures and requirements as set out in this guideline. The review process had evolved through drafting the guideline and consultation with stakeholders from various institutions before final approval by the LMHRA Management. The guideline therefore provides an up-to-date guidance on application requirements and standards of Good Clinical Practices (GCP) to be followed by all those who have interests in clinical trials in the country, to include research institutions, Medicines and Health Products Ethics Committee (MHEC), researchers, Contract Research Organizations (CROs), trial participants, trial applicants, Principal Investigators (PIs) and Sponsors alike.

It is the expectation of the LMHRA that the guideline will enable consistent and uniform documentation of applications and make it easier for the Authority to evaluate all clinical trials and make decisions on approval/non-approval based on clear and transparent outlined criteria. The Authority has also adopted for use the International Conference on Harmonization (ICH) of Technical requirements for Registration of Pharmaceuticals for Human Use - Tripartite Guideline for Good Clinical Practice (GCP). Applicants are therefore required to follow the LMHRA guideline along with the current GCP guideline when generating clinical trials data. As clinical trials are complex in nature and since review of technical guidelines in any scientific spectrum is unavoidable in order to keep pace and benefit from developments in science and technology, the LMHRA shall always welcome new ideas, opinions, and suggestions in this context that will assist in improvement of this guideline.

David Sumo (Pharm.)

MANAGING DIRECTOR

LMHRA

Acknowledgements

I am grateful to the hard working committee for their tireless effort in the draft of this policy document to guide all medicines and health products related clinical trials in the Republic of Liberia. This guideline has been drafted to outline application requirements and procedures for clinical trials.

The process to draft the guideline started in August, 2013 with a seven-man committee that worked along with the Department of Pharmacovigilance and Medicines Information of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) to produce the first draft. The drafting team relied on their experiences, knowledge on clinical trials and available literatures (WHO, ICH-GCP, NIH, School of Pharmacy-University of Liberia, etc.).

I would like to express my profound gratitude to the Drafting Committee members, Pharm. Ezekiel F. Hallie, Pharm. Joseph N. Somwarbi, Pharm. Nathaniel Borley Comehn, Pharm. James D. K. Goteh, Pharm. Juwe D. Kercula and Mr. Theophilus Ndorbor, for the level of hard work and resources exerted in a timely development of this first draft. I would also like to express my sincere thanks and appreciation to all persons and institutions for their support.

David Sumo, Pharm.
Managing Director
LMHRA

Acronyms

ADRs	:	Adverse Drug Reactions
AEs	:	Adverse Events
API	:	Active Pharmaceutical Ingredient
BSE	:	Bovine spongiform encephalopathy
BUCHS	:	Bugando University College of Health Sciences
CoA	:	Certificate of Analysis
CRF	:	Case Report Form
CRO	:	Contract Research Organization
CTA	:	Clinical Trial Application Form
CTC	:	Clinical Trial Model Certificate
DMC	:	Data Monitoring Committee
DSMB	:	Data and Safety Monitoring Board
IEC	:	Independent Ethics Committee
GCLP	:	Good Clinical and Laboratory Practices
GCP	:	Good Clinical Practice
GMP	:	Good Manufacturing Practice
IB	:	Investigator's Brochure
ICH		International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDMC	:	Independent Data Monitoring Committee
IMP	:	Investigational Medicinal Product
IP	:	Investigational Product
IRB	:	Institutional Review Board
LMHRA	:	Liberia Medicines & Health Products Regulatory Authority

LPB	**:**	Liberia Pharmacy Board
MOH/SW	:	Ministry of Health & Social Welfare
MTA	:	Material Transfer Agreement
NEC	:	National Ethics Committee
NF	**:**	National Formulary
PI	:	Principal Investigator
PIL	:	Principal Investigator List
QA	:	Quality Assurance
QC	:	Quality Control
REC	**:**	Research Ethics Committees (Independent /Institutional)
SAE	:	Serious Adverse Event
SUSARs	:	Suspected Unexpected Serious Adverse Reactions
SOPs	:	Standard Operating Procedures
TFDA	:	Tanzania Food and Drugs Authority
TSE	:	Transmissible Spongiform Encephalopathy
USP	:	United States Pharmacopoeia
WHO	:	World Health Organization
WMA	:	World Medical Assembly

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1.0 Introduction

Clinical trials are organized research studies directed on prospective human participants expected to determine the safety and effectiveness of new or unverified treatments. They are specifically designed to find better ways to treat, cure, prevent or diagnose diseases and/or conditions and to answer scientific questions.

The Liberia Medicines and Health Products Regulatory Authority Act of 2010, provides for the regulation and control of clinical trials in the country. **Part V Section 5(1)** of the Act prohibits any person/organization to conduct a clinical trial on any medicines and health products without a written authorization from the Authority. **Section 5(2)** provides that the conditions for authorization of such Clinical Trial shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such authorizations. In this regard, any person wishing to conduct a clinical trial of a medicines and health products shall submit to the Authority an application in prescribed form signed by him/her and accompanied with prescribed fees, an Ethical Clearance Certificate issued by any approved institute for clinical research and any other relevant information as required by the LMHRA. This guideline has therefore been developed so as to provide guidance on current minimum standards required for authorization to conduct clinical trials involving medicines and health products in Liberia. It articulates among other things, including application procedures, good clinical practice (GCP) requirements and ethical principles for clinical research involving human participants. Ethics are as important as scientific considerations when reviewing clinical protocols for research, this is an important aspect emphasized in this document.

The LMHRA has requirements for qualifications and responsibilities of investigators and monitors. It also has requirements concerning informed consent and procedures for trial amendments. Other requirements include reporting of Serious Adverse Events (SAEs)/Suspected Unexpected Serious Adverse drug Reactions (SUSARs), requirements concerning Data Safety Monitoring Board (DSMB) or alternatively known as Data Monitoring Committee (DMC), as well as the regular submission of progress reports, procedures for termination of clinical trials and a snapshot on inspection of trial sites. Various forms and tools have also been attached as appendices to aid in the application process. These shall be filled in and submitted together with the documentation as specified in the guideline.

1.1 Relevance of this Guideline

The relevance of this guideline is to provide Liberia with clearly expressed standards of good clinical practice in clinical study that are also applicable to local realities and contexts and to

ascertain that clinical trial carried out on human participants are designed and conducted according to strict scientific and ethical principles within the basis of good clinical practice. Compliance with these standards provides the public with assurance that the rights, safety and well-being of trial participants are safeguarded and that clinical trial data are trustworthy.

1.2 Definition of terms

In the context of this guideline the following words/phrases are defined as adopted from WHO:

The Act - The Liberia Medicines and Health Products Regulatory Authority Act of 2010 and regulations relating to clinical trials made under the Act.
Adverse Drug Reactions - All noxious and unintended responses to a clinical trial medicinal product related to any dose or all unintended noxious responses to a registered medicinal product which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function.
Adverse Event -Any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product and which does not necessarily have a usual relationship with the treatment. An adverse event (AE) can therefore beany unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of an investigational medicinal product (IMP), whether or not related to the IMP.
Applicant - A person applying to conduct a clinical trial which may include a sponsor, contract research organization or in the case of investigator-initiated academic research studies, research institution or principal investigator.
Audit of a trial - A systematic examination, carried out independently of those directly involved in the trial, to determine whether the conduct of a trial complies with the agreed protocol and whether the data reported are consistent with the records on site, e.g. whether data reported or recorded in the case-report forms are consonant with those found in hospital files and other original records.
Audit Certificate - A declaration of confirmation by the auditor that an audit has taken place
Audit Report - A written evaluation by the sponsor's auditor of the results of the audit
Authority– Liberia Medicines and Health Products Regulatory Authority (LMHRA)
Blinding/Masking - A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the study participant(s) being unaware and double-blinding usually refers to the study participant(s), investigator(s), monitor, and in some cases, data analyst(s) being unaware of the treatment assignment(s).
Case Report Form - A document that is used to record data on each trial subject during the course of the trial, as defined by the protocol. The data should be collected by procedures which guarantee preservation, retention and retrieval of information and allow easy access for verification, audit and inspection.

Clinical Trial/Study - A systematic study on medicinal product(s) in human participants (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety. Clinical trials are generally classified into four phases.
A brief description of the individual phases, based on their purposes as related to clinical development of medicinal products, is given below:

Phase I - These are the first trials of a new active ingredient or new formulations in man, often carried out in healthy volunteers. Their purpose is to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a pharmacodynamic profile of the active ingredient in humans.

Phase II - These trials are performed in a limited number of study participants and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and to assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials.

Phase III - Trials in larger (and possibly varied) patient groups with the purpose of determining the short and long-term safety/efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g. clinically-relevant drug interactions, factors leading to differences in effect such as age). These trials should preferably be of a randomized double-blind design, but other designs may be acceptable, e.g. long-term safety studies. Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use.

Phase IV - Studies performed after marketing of the medicinal product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of post marketing surveillance, or assessment of therapeutic value or treatment strategies.
Although methods may differ, these studies should use the same scientific and ethical standards as applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new medicinal products.
Clinical Trial/Study Report - A clear and accurate written description of a trial/study of any therapeutic or prophylactic agent conducted in human study participants in which the clinical and statistical description, presentations and analyses are fully integrated into a single report.

Comparator Product - A medicinal or marketed product (i.e. active control), or placebo, used as a reference in a clinical trial.

Confidentiality -Maintenance of the privacy of trial participants including their personal identity and all personal medical information.

Contract- A written, dated and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Coordinating Committee - A committee that a sponsor may organize to coordinate the conduct of a multi-center trial.

Coordinating Investigator - An investigator assigned the responsibility for the coordination of investigators at the different centers participating in a multi-center trial.

Contract Research Organization - A person or an organization (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Data and Safety Monitoring Board - An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data and the critical efficacy endpoints and to recommend to the sponsor whether to continue, modify, or stop a trial.

Direct Access - Permission to examine, analyze, verify and reproduce any records and reports that are important to evaluation of a clinical trial. LMHRA inspectors with direct access should take all reasonable precautions to maintain the confidentiality of study participants' identities and sponsor’s proprietary information.

Documentation - All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Essential Documents - Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Ethical Clearance - An authorization to conduct a clinical trial issued by the Medicines and Health Products Ethics Committee based on ethical issues related to trials involving human participants in Liberia.

Good Clinical Practice - A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial study participants are protected.

Good Manufacturing Practice - That part of quality assurance which ensures that investigational products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. In these guidelines, GMP refers to the current LMHRA GMP Guideline.

Impartial Witness - A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the

study participant or the study participant's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the study participant.

Independent Ethics Committee - An independent body (a review board or a committee, institutional, regional or national), constituted of medical professionals and non-medical members, whose responsibility is to verify that the safety, integrity and human rights of participants in a particular trial are protected and to consider the general ethics of the trial, thereby providing public reassurance. Ethics committees should be constituted and operated so that their tasks can be executed free from bias and from any influence of those who are conducting the trial.

Informed Consent - A participant's voluntary confirmation of willingness to participate in a particular trial, and the documentation thereof. This consent should only be sought after all appropriate information has been given about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki (see Appendix 11).

Inspection - The act of conducting an official review of documents, facilities, records, and any other resources that are deemed necessary by LMHRA to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or CRO's facilities or at other establishments deemed appropriate by LMHRA.

Interim Clinical Trial/Study Report - A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

Investigational medicinal Product - A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator - A physician, dentist or other qualified person who conducts a clinical trial at a trial site. See also Sub-investigator.

Investigator's Brochure - A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human study participants.

Legally Acceptable Representative - An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective study participant, to the study participant's participation in the clinical trial.

Material Transfer Agreement - A written agreement entered into by a provider and a recipient of research material. The purpose of the MTA is to protect the intellectual and other property rights of the provider while permitting research with the material to proceed.

Monitor- A person appointed by, and responsible to, the sponsor or Contract Research Organization (CRO) for the monitoring and reporting of progress of the trial and for verification of data.

Monitoring Report - A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

Multi-center Trial - A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

Pre-clinical Studies - Biomedical studies not performed on human study participants.

Principle Investigator - A person responsible for the conduct of the clinical trial at a trial site who is a pharmacist, physician, dentist or other qualified person, and a member of good standing of a professional health association. If a trial is conducted by a team of individuals at a trial site, the principle investigator is the responsible leader of the team. See also Sub-investigator.

Protocol - A document which states the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the investigator, the institution involved and the sponsor. It can also function as a contract.

Protocol Amendment - A written description of change(s) to or formal clarification of a protocol.

Quality Assurance - All those planned and systematic actions that are established to ensure that the trial is performed and the credible data are generated, documented (recorded), and reported incompliance with LMHRA requirement(s).

Quality Control - The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

Randomization - The process of assigning trial study participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Serious Adverse Event - or Serious Adverse Drug Reactions (Serious ADR)

Any untoward medical occurrence that at any dose: a) that results in death, b) that is life threatening, c) that requires hospitalization or prolongation of existing hospitalization, d) that results in persistent or significant disability/incapacity, or e) that is a congenital anomaly/birth defect.

Source Data - All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the construction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents - Original documents, data and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, study participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives,

microfilm or magnetic media, x-rays, study participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Sponsor - An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.

Sponsor-Investigator- An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a study participant. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard Operating Procedures - Detailed written instructions to achieve uniformity of the performance of a specific function.

Sub-investigator - Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or make important trial-related decisions (e.g. associates, residents, research fellows).

Trial participant- An individual who participates in a clinical trial either as a recipient of the investigational medicinal product(s) or as a control.

Study participant Identification Code - A unique identifier assigned by the investigator to each trial study participant to protect the study participant's identity and used in lieu of the study participant's name when the investigator reports adverse events and/or other trial related data.

Trial Site - The location(s) where trial-related activities are actually conducted.

Unexpected Adverse Drug Reaction - An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

Vulnerable Study participants - Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such a medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable study participants include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

2.0 Application Procedure

An application to conduct a clinical trial is required for the following categories of medicines:

1. Unregistered medicines
2. Registered medicines where the proposed clinical trials are outside the conditions of approval. These may include changes to:
   a. Indications and clinical use
   b. Target patient population(s)
   c. Routes of administration
   d. Dosage
3. An application must be made by completing an application form (Appendix 1) accompanied by a fee as prescribed in Appendix 11. Any application that will not be accompanied by proof of payment will not be accepted.
   a. Fees may be paid directly to the LMHRA's account or by bank transfer to:
      Liberia Medicines and Health Products Regulatory Authority (LMHRA)
      Bank: **ECOBANK, Liberia Ltd**
      Account number: **001-113472105440**

4. Approval by LMHRA to conduct post-marketing clinical trials of a registered medicine within the approved conditions of registration of such a medicine is not required.
5. 2.4.1 The application shall be submitted in the English Language, both electronic and hard copy. Processing of application shall only begin upon receipt of the hard copies. Four copies word formatted, Times New Roman, font size 12, shall be submitted in sealed envelope.

6. Applications should be submitted to the following address:
   Liberia Medicine and Health products Regulatory Authority (LMHRA)
   VP Road, Tubman Boulevard
   Old Road, Sinkor
   1000 Monrovia, 10 Liberia
   West Africa

7. An application to conduct a clinical trial shall include:
   Cover letter, duly filled in, signed and stamped application form (Appendix 1)
8. General investigational plan
9. Capacity building plans including training and updating of staff that will be involved in the clinical trial
10. Protocol (study protocol and investigators, copies or description of CRFs to be used, facilities and IEC data, informed consent forms and information given to participants)
11. Investigator's Brochure or prescribing information data sheet

12. Declarations by sponsor, investigators and monitor(s) in prescribed format (Appendices 2-4)
13. Financial declaration by Sponsor and/or Principal investigator in prescribed format (Appendix 5)
14. Certified copy of insurance of study participants
15. Ethical clearance or a copy of acknowledgement of submission of study protocol from the Medicines and Health Products Ethics Committee
16. Curriculum vitae (CV) of investigator(s) (see Appendix 6 for recommended format)
17. Investigational medicinal product dossier
18. An application to conduct a clinical trial may be made by a sponsor or the sponsor's agent who must also submit a power of attorney attesting that he is a duly appointed agent.
19. A statement by the applicant must be provided indicating that all information contained therein, or referenced by the application is complete, accurate and not misleading.
20. In the case of multi-center trials, a coordinating investigator must also sign the application form.
21. If the trial is part of an international study, information regarding the other Participating countries must be provided including the part of the trial that will be carried out locally.
22. LMHRA will only process an application upon receipt of a completed application together with the prescribed fees.
23. Processing of application shall take a period of five (5) months upon receipt of submission whereby the outcome of the application shall be communicated to the applicant within this period.

3.0 Qualifications and Responsibilities of Sponsors, Investigators and Monitors:

1. Sponsors, investigators and monitors should assume responsibilities as provided in the GCP guidelines.
2. The principal investigator (PI) engaged in clinical trials must have a university degree in pharmacy, pharmacology, toxicology, biochemistry or medicines and related fields and must be competent with practical experience within the relevant professional area. The principal investigator must have had previous experience as a co-investigator in at least two trials in the relevant professional area and shall be responsible for the conduct of the clinical trial at a clinical trial site.
3. In case of multi-center studies where the PI is not a resident of Liberia, the appointed national principal investigator must be the resident and shall assume full responsibilities for all local clinical trial sites.
4. All investigators in a clinical trial as well as the trial monitor must have had formal training in Good Clinical and Laboratory Practices (GCLP) within the last two years. Evidence of attending GCLP course should also be submitted.

4.0 Study Protocol

The clinical trial study protocol shall have at least the following:

4.1 General Information

1. Protocol title, identification number and date. Any amendment(s) shall also bear the amendment number(s) and date(s).
2. Name and address of the sponsor and monitor (if other than the sponsor).
3. Name, title and contact details of the sponsor's medical expert (or dentist when appropriate) for the trial.
4. Name, title and contact details of the investigator (s) who is (are) responsible for conducting the trial, and the contact details of the trial site (s).
5. Name, title and contact details of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).
6. Name(s) and address (es) of the clinical laboratory (ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

4.2 Background Information

1. Name and description of the investigational product (s).
2. A summary of findings from pre-clinical studies that potentially have clinical significance and from clinical trials (if investigated elsewhere) that are relevant to the trial.
3. Summary of the known and potential risks and benefits of the studied product as observed in both animal and human testing.
4. Description of and justification for the route of administration, dosage, dosage regimen, and duration of treatment period(s).
5. A statement that the trial shall be conducted in compliance with the study protocol, GCP and LMHRA requirement(s).
6. Description of the population to be studied (e.g. age group and sex).
7. Reference literatures and data that are relevant to the trial that provide background for the trial.

4.3 Trial Objectives and Purpose

A detailed description of the objectives and the purpose of the trial shall be provided as to convince the Authority.

4.4 Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

1. A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.
2. A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.
3. A description of the measures taken to minimize/avoid bias, including:
    a. Randomization.
    b. Blinding.
4. A description of the trial treatment(s), dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labeling of the investigational product(s).
5. The expected duration of subject participation, a description of the sequence and duration of the trial periods, including follow-ups, if any.
6. A description of the "stopping rules" or "discontinuation criteria" for individual subjects, at any/all parts of the trial.
7. Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
8. Maintenance of trial treatment randomization codes and procedures for breaking codes.
9. The identification of any data to be recorded directly on the case report forms (CRFs) (i.e. no prior written or electronic record of data), and to be considered as source data.

4.5 Selection and withdrawal of study participants

1. Provide participants' inclusion criteria.
2. Provide participants' exclusion criteria.
3. Provide participants' withdrawal criteria (i.e. terminating investigational product trial treatment) and procedures specifying:
    a. When and how to withdraw participants from the trial/investigational product treatment.
    b. The type and timing of the data to be collected for withdrawn participants.
    c. Whether and how participants are to be replaced.

4.6 Treatment of study participants

During the participation of all subjects in the trial, the below documentations are required:

1. The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and duration including follow-up period(s) for participants for each investigational product trial treatment.
2. Medication(s)/treatment(s) permitted (including rescue medications) and those not permitted before and/or during the trial.
3. Procedures for monitoring participants' compliance.

4.7 Assessment of Efficacy

The below required documentations should be provided:

1. Specifications of the efficacy parameters.
2. Methods and timing for assessing, recording, and analyzing of efficacy parameters.

4.8 Assessment of Safety

1. Specification of safety parameters.
2. The methods and timing for assessing, recording, and analyzing safety monitoring arameters.
3. Procedures for eliciting reports of and for recording and reporting adverse events and inter-current illnesses.
4. The type and duration of the follow-up of subjects after adverse events.

4.9 Statistics

1. A description of the statistical methods to be employed, including timing of any planned interim analysis(es).
2. The number of subjects planned to be enrolled. In multi-center trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
3. The level of significance to be used.
4. Criteria for the termination of the trial.

5. Procedure for accounting for missing, unused and spurious data.
6. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
7. The selection of study participants to be included in the analyses (e.g. all randomized participants, all dosed participants, all eligible participants, evaluable participants).

4.10 Direct Access to Source Data/Documents

The sponsor shall ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit LMHRA inspection(s), providing direct access to source data/documents.

4.11 Quality Control and Quality Assurance

There should be mechanism for good quality control and quality assurance.

4.12 Pharmaceutical and Health products Ethics

Description of ethical considerations relating to the trial shall include the following issues:

1. Choice of investigators
2. Monitors and monitoring plan
3. Indicate how additional staff (monitors, pharmacists, nursing staff, etc.) will maintain patient confidentiality, follow the protocol, and abide by ethical and LMHRA requirements
4. Indemnity measures for the participants
5. Patient Information leaflets and Informed Consent forms for any proposed archiving of biological specimens for later research or for genetics research.
6. Treatment and/or management of participants and their disease condition(s) after completion of trial
7. Institutional ethics committee capacity to monitor site and conduct of trial
8. Provide an explanation if minimum recommended compensation for a participant is not being provided.
9. Follow-up of trial study participants after the conclusion of the trial
10. In case of transfer of materials, provide Material Transfer Agreement
11. (MTA) highlighting among other things, the following:
    a. Identification of the provider and recipient
    b. Identification of the material and the volume of material

c. Definition of the trial and how the material will and will not be used.
d. Maintenance of confidentiality of background or supporting data or information, if any
e. Indemnification and warranties (where applicable)

12. Data handling and record keeping should be done in conformity with WHO guidelines

4.14 Publication Policy

Publication policy, if not addressed in a separate agreement.

5.0 The Investigator's Brochure

The investigator's brochure must contain at least the following information in respect to the investigational medicinal product:

1. The physical, chemical and pharmaceutical properties
2. The pharmacological aspects including its metabolites in all animal species tested
3. The pharmacokinetics and metabolism including its biological transformation in all animal species tested
4. Toxicological effects in any animal species tested under a single dose study, a repeated dose study or a special study
5. Results of clinical pharmacokinetic studies
6. Information regarding safety, pharmacodynamics, efficacy and dose responses that were obtained from previous clinical trials in humans if available. More details could be found in WHO-GCP guidelines and may be followed when compiling information on this part.

6.0 Requirements concerning Informed Consent

1. In obtaining and documenting informed consent, the investigator shall comply with Medicines and Health Products Ethics Committee (MHEC) requirement(s) and adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki (Appendix 11).
   Prior to the beginning of the trial, the investigator should obtain Ethical Clearance from MHEC and LMHRA approval.
2. Informed consent to study participants shall be administered in English and all information to be given to study participants both oral and written must be in English. The consent form together with the accompanying information shall be in English.
3. The written informed consent form and any other written information to be provided to participants shall be revised whenever important new information becomes available that may be relevant to the participant's consent. Any revised written informed consent form, and written information should receive MHEC and LMHRA approval in advance of use. The participant or the participant's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the participant's willingness to continue participation in the trial. The communication of this information shall be documented.
4. Neither the investigator, nor the trial staff, shall coerce or unduly influence a participant to participate or to continue to participate in a trial.
5. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the participant or the participant's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.
6. The investigator, or a person designated by the investigator, shall fully inform the participant or, if the participant is unable to provide informed consent, the participant's legally acceptable representative, of all pertinent aspects of the trial including the written information and the MHEC and LMHRA approval.
7. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the participant or the participant's legally acceptable representative and the impartial witness, where applicable.
8. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the participant or the participant's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the participant or the participant's legally acceptable representative.

9. Prior to participation in the trial, the written informed consent form shall be signed and personally dated by the participant or by the participant's legally acceptable representative, and by the person who conducted the informed consent discussion.
10. If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness shall be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to participant, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to participate in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness shall sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.
11. Both the informed consent discussion and the written informed consent form and any other written information to be provided to participants shall include explanations of the following:
    a. That the trial involves research.
    b. The purpose of the trial.
    c. The trial treatment(s) and the probability for random assignment to each treatment.
    d. The trial procedures to be followed, including all invasive procedures.
    e. The participant's responsibilities.
    f. Those aspects of the trial that are experimental.
    g. The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.
    h. The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.
    i. The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.
    j. The compensation and/or treatment available to the participant in the event of trial-related injury.
    k. The anticipated prorated payment, if any, to the participant for participating in the trial.
    l. The anticipated expenses, if any, to the participant for participating in the trial.
    m. That the participation in the trial is voluntary and that the participant may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.

n. That the LMHRA will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by LMHRA and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorizing such access.

o. That records identifying the participant will be kept confidential and will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.

p. That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participating in the trial.

q. The person(s) to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.

r. The foreseeable circumstances and/or reasons under which the participation in the trial may be terminated.

s. The expected duration of participating in the trial.

t. The approximate number of participants involved in the trial.

12. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the participants. During participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to participants.
13. When a clinical trial includes participants who can only be enrolled in the trial with the consent of the participant's legally acceptable representative (e.g., minors, or patients with severe dementia), the participant should be informed about the trial to the extent compatible with the participant's understanding and, if capable, the participant should sign and personally date the written informed consent.
14. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent of the participant is not possible, and the participant's legally acceptable representative is not available, enrolment of the participant should require measures described in the protocol and/or elsewhere, with documented LMHRA approval to protect the rights, safety and well-being of the participant and to ensure compliance with MHEC and LMHRA requirements. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.

7.0 Investigational Medicinal Product (IMP) Dossiers

1. Clinical trial investigational medicinal products must be manufactured in accordance with Good Manufacturing Practices (GMP). This implies that the manufacture of the investigational product may be subject to control and inspection in the same way as in the case of marketed medicinal products.
2. Chemistry and manufacturing information for IMP(s) which have not been registered by LMHRA should be presented in a concise manner and shall include the following:

7.1 Active Pharmaceutical Ingredients (API)

1. Nomenclature
2. Name and address of the manufacturer
3. Physicochemical properties
4. Route of synthesis and manufacturing process
5. Documented evidence of structure and stereochemistry
6. Characterization of impurities
7. Specifications and their justifications
8. Batch analyses
9. Validation of analytical procedures
10. Container closure system
11. Stability studies

7.2 Investigational Medicinal Product (IMP)

1. Name, strength and dosage form
2. Description and composition
3. Name and address of the manufacturer
4. Pharmaceutical development
5. Description of manufacturing process including flow diagram and process validation.
6. Manufacturing information for novel excipients.
7. Specifications and their justifications (including excipients)
8. Batch analyses
9. Validation of analytical procedures
10. Characterization of impurities
11. Certificates of analysis (CoAs) and Bovine spongiform encephalopathy (BSE) /transmissible spongiform encephalopathy (TSE) certificates for excipients of human or animal origin

12. Stability studies
13. Container closure system
14. If the pharmaceutical or chemical properties of the IMP have been altered compared to those in use during animal testing or previous clinical trials, such alterations must be described and justified.
15. Pharmaceutical and/or chemical alterations in the IMP that are used in an ongoing clinical trial and that may affect the quality, safety and/or efficacy of the IMP must immediately be reported and justified to LMHRA.
16. In cases where an extension of shelf life for the IMP is desired, an application for this must be submitted to LMHRA. In such cases stability data and certificates of analysis (CoAs) from reanalysis of the relevant batches must be submitted.
17. In case of IMP(s) which have been registered by LMHRA, a cross reference to the part of the dossier containing chemistry and manufacturing information should be declared.
18. Information on preclinical pharmacology and toxicology studies done must be submitted. In case information on preclinical studies was submitted in phase I study application, a summary of preclinical studies for the late phase trials (i.e. phase II and III) should be submitted.
19. Information on human experience data and previous clinical studies done mustbe submitted and in accordance with applicable GCP guidelines.
20. Labeling
21. Investigational medicinal products (including registered products) used in clinical trials must be properly labeled and contain the following minimum information:
22. Statement indicating that the product is for “clinical trial purpose only”
23. Name, number or identifying mark
24. Recommended storage conditions
25. Manufacturer’s address
26. Protocol code or identification
27. Re-labeling of any remaining IMP from previously manufactured batches must be performed in accordance with established written procedures and GMP principles.

8.0 Clinical Trial Amendments

1. Application for amendment(s) to a previously authorized clinical trial shall be made in forms (Appendices 6 and 7), whichever is applicable, and shall be accompanied with amendment fees as prescribed in the Fees and Charges Regulations enforced at the time of application.
2. The applicant must submit the description of the proposed amendment including reasons thereof.
3. Original wording, revised wording and rationale for the change(s) including a copy of complete protocol incorporating all amendments should also be submitted, where applicable.
4. The applicant must also submit supporting data for the amendment, including:
   a. Updated overall risk-benefit assessment
   b. Possible consequences for participants already in the trial
   c. Possible consequences for the assessment of trial results summaries of data
5. LMHRA approval must be obtained for the following amendments:
   a. Changes that affect patient selection and monitoring
   b. Changes that affect clinical efficacy and safety requirements (e.g. dosage adjustments, study procedures, etc.)
   c. Changes that affect patient discontinuation
   d. Addition/deletion of an investigational site
   e. Change of principal investigator
   f. Changes that result in the extension of duration of a trial
   g. Changes that relate to the chemistry and manufacturing information that may affect drug safety and quality (For example: specifications for the IMP where limits of the test are relaxed or deleted; where a new impurity or degradation product has been identified; and addition of new raw materials, solvents, reagents, catalysts or any other materials used in the manufacture of the API).
6. The application for amendment(s) shall be accompanied by Ethical Clearance or authorization from the MHEC.

9.0 Reporting of Serious Adverse Events (SAEs)/Suspected Unexpected Serious Adverse Reactions (SUSARs)

1. All serious adverse events (SAEs) including suspected unexpected serious adverse reactions (SUSARs) should be reported to LMHRA within 8 working days and for fatal ones within 24 hours of their occurrence.
2. Form attached (Appendix 9) should be used when reporting, followed by detailed written reports. When completing the form, the application number and/or protocol number should be included.
3. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should also be reported.
4. For reported deaths, additional information (e.g., autopsy reports and terminal medical reports) should be submitted.
5. The relationship between SAE(s)/SUSARs and the IMP must be established, evaluated, clarified and submitted to LMHRA for further assessment.

10.0 Requirements concerning Data and Safety Monitoring Board (DSMB)/Data Monitoring Committee (DMC)

For trials that will involve Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) to monitor trials, the following issues related to DSMB/DMC must be submitted:

1. A broad statement of the aims and objectives of the DSMB/DMC
2. Terms of Reference
3. Composition of the DSMB/DMC
4. Qualifications of the DSMB/DMC members
5. Specific roles including responsibilities of statisticians
6. The role of statistical stopping rules
7. Relationship with the principal investigators and trial management team
8. Clarification of the decision-making powers
9. How DSMB/DMC meetings will be organize.
10. Whether the DSMB/DMC will be blinded to treatment
11. What options a DSMB/DMC can recommend
12. In what form and to whom decisions shall be conveyed
13. Who the DSMB/DMC will report to
14. The role of the DSMB/DMC in the publication of results
15. Disclosure of competing interests of DSMB/DMC members

11.0 Submission of Progress Reports

The sponsor and/or PI must submit progress reports to LMHRA on a quarterly basis depending on the duration of the clinical trial from the date of initiation of the clinical trial.

12.0 Termination of Clinical Trial

12.1 Premature termination

If a clinical trial is terminated by the principal investigator or sponsor in its entirety, the principal investigator or sponsor must inform LMHRA not later than 15 days after the date of the termination; and must:

1. Provide LMHRA with the reason(s) for the termination and its impact on the proposed or ongoing clinical trials in respect of the investigational medicinal product including issues related to accountability and disposal of investigational products as well as maintenance of records.
2. As soon as possible, inform all co-investigators of the termination and of the reasons for the termination and advice them in writing of potential risks to the health of clinical study participants or other persons including ensuring that patients continue to receive medical care.

12.2 Revoking of LMHRA's Clinical Trial Approval

LMHRA may revoke the authorization to conduct a clinical trial if the Authority is of the opinion that the safety of the study participants in the trial is compromised or that the scientific reasons for conducting the trial have changed.

12.3 End of trial (Study closeout)

1. After the trial has been conducted and closed, the sponsor and/or principal investigator shall submit a closing report within 30 working days. This should be followed by a final study report within six months after trial closure unless otherwise justified. The structure and content of the final study report should be acceptable to LMHRA in line with the guidelines.
2. Any unexpected safety issue that changes the risks-benefit analysis and is likely to have an impact on trial participants should be reported together with proposed actions to be taken.

13.0 Inspection of Clinical Trial Sites

1. The Authority may inspect clinical trial (investigator) sites, sponsor's office, data management center, contract research organization (CRO) or any other establishment related to the trial as it will be deemed appropriate by the Authority to ensure that the generally accepted principles and/or requirements of GCP and LMHRA are met.
2. The objectives of inspection will be to ensure that participants are not Subjected to undue risks, to validate the quality of data generated and/or to Investigate complaints.
3. The Authority may use the information collected as a result of the inspections to ensure compliance with regulatory requirements and may take enforcement action where necessary.

14.0 Appeals

As provided in Part VIII Section 1 (5 XI bi) Liberia Medicines and Health Products Regulatory Authority Act of 2010, any person who is aggrieved by a decision of the Authority of not granting authorization for the conduct of any specified activity may make his/her representation within thirty days to the Authority and shall be accorded administrative hearing. If no such representation is submitted by the applicant within the said period or if after consideration of any comments so submitted the Authority is still not satisfied it shall reject the application.

15.0 References

Department of Health. (2000). Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa, DoH, Johannesburg.
European Union (EU) Clinical Trials Directive 2001/20/EC

General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). ICH - Tripartite Guideline, Guideline for Good Clinical Practice, Recommended for Adoption at Step 4 of the ICH Process on 1 May 1996 by the ICH Steering Committee.

Southern Africa Development Community. (2004). Draft Guideline on Regulating the Conduct of Clinical Trials in Human Participants, SADC, Gaborone.

Tanzania Food and Drug Administration (TFDA) (February, 2009), Guidelines for Conducting Clinical Trials in Tanzania

World Health Organization. (1995). Guidelines for good clinical practice (ICH-GCP) for trials on pharmaceutical products, Technical Report Series No. 850, Annex 3,WHO, Geneva.

World Medical Association (2000). Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Study participants, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964. Amended by the 29th WMA

16.0 Appendixes

Appendix 1: Format for Clinical Trial Application Form (CTA)

Applicant's letterhead
To be completed by Applicants for all Clinical Trials
Study Title:
Protocol No:
Version No:
Date of protocol:
Investigational medicinal product's name, number or identifying mark
Comparator product (if applicable):
Concomitant medications (if applicable):
Applicant
Sponsor's name, signature and stamp
Sponsor's agent,
Contact Person:
Address:
Telephone Number:
Fax Number:
E-mail address:

FOR OFFICIAL USE ONLY
Date original application received:
Application/Reference No.:
Application Fee paid:
Signature:
Date:

(All future communications to LMHRA regarding the application should quote the above application/reference number).

Acknowledgement of Receipt of Application (To be completed by LMHRA receiving officer). Cover sheet to be sent to the applicant once details above are completed.
Receipt of the application is hereby acknowledged.
Name:
Signature:
Date: Stamp:

SECTION 1: FORMAT FOR CHECKLIST AND TABLE OF CONTENTS (indicate pages)

1. Covering letter
2. Completed application form
3. General investigational plan
4. Capacity building plans including training and updating of staff involved in the clinical trial
5. Investigator's Brochure or prescribing information data sheet
6. Protocols (study protocol and investigators, facilities and IEC data, informed consent forms and information given to participants}
7. Declarations by Sponsor, monitors and investigators in prescribed format
8. Financial joint declaration by Sponsor and Principal investigator
9. Certified copy of indemnity of study participants
10. Investigational medicinal product dossier:
    - Chemistry, manufacturing and quality control data of active ingredient and finished product/dosage form
    - Pharmacology and toxicology data
    - Previous human experience data
    - Prototype product label

Note: Incomplete applications shall not be processed

SECTION 2: ADMINISTRATIVE AND SUPPLEMENTARY DETAILS

Title of the Study:
Protocol Number/Identification:
Version number
Date of final protocol:

Part 1: CONTACT DETAILS (Name/Address/Tel/Mobile/Fax/E-Mail)

1.1 Applicant:
1.2 Sponsor:
1.3 Local contact person:
1.4 National principal investigator:
1.5 International principal investigator: (if applicable)
1.6 Monitor:
1.7 Study coordinator:

Part 2: DETAILS OF INVESTIGATIONAL MEDICINAL PRODUCT(S)

2.1 Name(s) and details of IMP to be used in trial:

[A summary of the chemistry and manufacturing data, formulation, composition, excipients and strength should be provided. Complete chemistry and manufacturing data should be included in the investigator's brochure. Product(s) registration number(s) and date(s) of registration, if applicable,
shall be included]

2.2 Name(s) and details (as above) of comparator product(s) and product registration number(s) and date(s) of registration if applicable: [As in 2.1, where applicable. Prescribing information sheet for registered comparator products should be included]

2.3 Name(s) and details (as above) of concomitant medication(s) including rescue medications which are required in the protocol, and product registration number(s) if applicable [As in 2.1, where applicable. Prescribing information sheet for registered products should be included]

2.4 If any of the above products are marketed locally, explain whether locally sourced products will be used in the trial:

2.5 Details of packaging, storage conditions and shelf-life of IMP:

2.6 Registration status of IMP, for the indication to be tested in this trial, in other countries [i.e. Country: date registered / date applied for / date registration refused / date registration withdrawn by applicant / date registration cancelled by regulatory authority) [Attach as an appendix if necessary]

Part 3: DETAILS OF INVESTIGATORS AND TRIAL SITE(S)

3.1 Details of investigator(s):

[Designation and title of principal investigators/investigators) Include
Name/Address/Tel/Mobile/Fax/E-Mail]

3.2 Current work-load of investigator(s):i

[Number of studies currently undertaken by investigators as principal and/or
co- or sub-investigator, and the total number of patients represented by these studies. Time-commitments of researcher(s) in relation to clinical trial work and non-trial work]

3.3 Details of Trial Site(s):

[Name of site, physical address, contact details, contact person, etc]

3.4 Capacity of Trial Site(s):

[Number of staff, names, qualifications, experience -- including study coordinators, site facilities, emergency facilities, other relevant infrastructure]

Part 4: TRIAL STUDY PARTICIPANTS

4.1 Number of local participants:

4.2 Total number of participants worldwide (where applicable):
4.3 Total enrolment in each local site/centre: [If competitive enrolment, state minimum and maximum number per site.]
4.4 Volunteer base from which local participants will be drawn
4.5 Retrospective data indicating potential of each site to recruit required number of participants within envisaged duration of trial: [Attach as an appendix if necessary]

Part 5: OTHER DETAILS

5.1 Provide an explanation if the trial is to be conducted locally only and not in the host country of the applicant / sponsor:
5.2 Estimated duration of trial:
5.3 Details of other Regulatory Authorities to which applications to conduct this trial have been submitted, but approval has not yet been granted. Include date(s) of application:
5.4 Details of other Regulatory Authorities which have approved this trial. Include date(s) of approval and number of sites per country:
5.5 Details of other Regulatory Authorities or Research Ethics Committees which have rejected this trial, if applicable, and provide reasons for the rejection:
5.6 Details of and reasons for this trial having been suspended at any stage by other Regulatory Authorities, if applicable:
5.8 If any sub-studies are proposed as part of this protocol, indicate whether these will also be conducted locally. If not, please explain:

Part 6: ETHICS

6.1 Ethics Committee responsible for each site, date of approval or date of application:
6.2 Attach copy of response(s) positive or negative made by, and/or conditions required by Ethics Committee(s) [if available]
6.3 Details of capacity building component of the trial, if any:
6.4 Details of GCP training of investigators, monitors, study co-coordinators in terms of conducting this trial:
6.5 Detailed monitoring plan for each site: [Attach as an appendix if necessary]
6.6 Details of trial indemnity: [e.g. insurer, policy holder, policy number, insurance cover, period of validity]
6.7 Details of possible conflict of interest of any person(s)/organization(s) who/which will be involved in the trial:
6.8 Remuneration/compensation to be received by investigators, trial participants or others: [Indicate breakdown of costs to be covered, if applicable. Indicate compensation to be received by participants for travel and incidental expenses. This is subject to discussion and agreement with the Authority.]

SECTION 3: DECLARATION BY THE APPLICANT

Title of the Study:
Protocol No:
Version No:
Date of Protocol:
Study investigational medicinal product:
I/We, the undersigned have submitted all requested and required documentations, and have disclosed all information which may influence the approval of this application.

I/We, hereby declare that all information contained therein, or referenced by, this application is complete and accurate and is not false or misleading.
I/We, agree to ensure that if the above said clinical trial is approved, it will be conducted according to the submitted protocol and all applicable legal, ethical and regulatory requirements.

Applicant: _____ Date: _____

National Principal Investigator: _____ Date: _____

National Co-coordinator/Other: _____Date: _____

Appendix 2: Declaration by Principal Investigator

Name:
Title of the study:
Protocol and site:
I, the undersigned, declare that:
1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and understand the responsibilities and obligations of the
Principle Investigator (PI) within the context of this study.

2. I have notified the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of any aspects of the study with which I do not/am unable to, comply. (If applicable, this may be attached to this declaration.)

3. I have thoroughly read, understood, and critically analyzed the protocol and all applicable accompanying documentation, including the investigator's brochure, patient information leaflet(s) and informed consent form(s).

4. I will conduct the trial as specified in the protocol and in accordance with LMHRA requirements and ICH – GCP principles.

5. To the best of my knowledge, I have the potential at the site(s) I am responsible for, recruit the required number of suitable participants within the stipulated time.

6. I shall not commence the trial before written authorization from the Medicines and Health Products Ethics Committee and the LMHRA unless it has been obtained.

7. I will obtain informed consent from all participants or if their legal representatives.

8. I will ensure that every participant (or other involved persons), shall at all times be treated in a dignified manner and with respect.

9. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. [Conflict of interest exists when an investigator (or the investigator's institution), has financial or personal associations with other persons or organizations that may inappropriately influence (bias) his or her actions].

10. I have*/have not (delete as applicable) previously been the principal investigator at a site which has been closed due to failure to comply with ICH-GCP (*Attach details).

11. I have*/have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices. (*Attach details).

11. I will submit all required reports within the stipulated time-frames.

Signature: …… Date: ……..

Witness: …….. Date: ……

Appendix 3: Declaration by Co- and Sub-Investigator

Name:
Title of the study:
Protocol number:
Principal Investigator's Name:
Site:
I, the undersigned, declare that:
1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and understand the responsibilities and obligations of the Investigator within the context of this study.

2. I will carry out my role in the trial as specified in the protocol and in accordance with Good Clinical Practice (ICH - GCP).

3. I will not commence with my role in the trial before written authorization from Medicines and Health Products Ethics Committee and the LMHRA unless it has been obtained.

4. If applicable to my role in the trial, I will ensure that informed consent has been obtained from all participants or their legal representatives.

5. I will ensure that every participant (or other involved persons, such as relatives) shall at all times be treated in a dignified manner and with respect.

6. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. [Conflict of interest exists when an investigator (or the investigator's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions).

7. I have not previously been involved in a trial which has been closed due to failure to comply with Good Clinical Practice.

8. I will submit all required reports within the stipulated time-frames.

Signature: …….. Date: ……

Witness: ……. Date: ……

Appendix 4: Declaration by Monitor

Name:
Title of the study:
Protocol number:
Site:
I, the undersigned, declare that:
1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH - GCP) and understand the responsibilities and obligations of the clinical trial monitor within the context of this study.

2. I have notified LMHRA of any aspects of the above with which I do not/am unable to comply. (If applicable, this may be attached to this declaration.)

3. I will carry out my responsibilities as specified in the trial protocol and in accordance with LMHRA requirements and ICH–GCP.

4. I declare that I have no financial or personal relationship(s) which may inappropriately influence me in monitoring this clinical trial.

5. I have*/have not (delete as applicable) previously been the monitor at a site which has been closed due to failure to comply with GCP. (*Attach details.).
6. I have*/have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices. (*Attach details).

7. I will submit all required reports when needed.

Signature: …… Date: ……

Witness: ……. Date: ……

Appendix 5: Joint Declaration by Sponsor (or Representative) and

Principal Investigator (or National Principal Investigator)

Concerning Sufficient Funds to complete the Study
Title of the study:
Protocol:

I, _____ (sponsor/sponsor's agent) and I, _____ (Principal Investigator/National Principal Investigator) do hereby declare that sufficient funds have been made available to complete the above mentioned study.

Signed: …… Date: …….
SPONSOR (or Agent)

Address:

Contact details:

Signed: ……. Date: ……

PRINCIPAL INVESTIGATOR (or National PI)

Address:

Contact details:

Appendix 6: Application for Clinical Trial Protocol Amendment

APPLICATION FOR APPROVAL OF:
PROTOCOL AMENDMENT
INCREASE IN NUMBER OF STUDY PARTICIPANTS
CHANGES IN DOSE/REGIMEN OF INVESTIGATIONAL MEDICINAL PRODUCT

Title of the study:

Protocol Number:

Date:

1. APPLICANT
1.1 Name:
1.2 Address:
1.3 Telephone:
1.4 Email:

2. **TRIAL PARTICULARS** (original application)
2.1 Trial Approval Number:
2.2 Date of Approval of original protocol:
2.3 Principal Investigator(s) approved for this trial:
Number of local sites approved for this trial:
Number of participants approved for this trial:

3. AMENDMENT PARTICULARS(Please list requests for approval)
3.1 Does the applicant wish to increase the number of local study participants participating in this trial? Yes, No
3.2 Does the applicant wish to change the dose/regimen of the investigational medicinal product? Yes, No
3.3 Does this amendment request require a new consent form to be signed by the participant? Yes, No
If "Yes" please submit new Principal Investigators List (PIL) together with this application.
Protocol Amendment Number:
Version Number and Date of Protocol Amendment (for each document submitted):
General motivation for the proposed amendment: [List all of the issues included in the amendment and provide the rationale for each amendment]
Details of the proposed protocol amendment: [For each amendment, provide reasons for amendment and clearly highlight changes to the original protocol; this can be done either as "old text" replaced with "new text" or with the old text deleted with a line through it and the new text in bold and underlined]
3.4 Will this amendment apply to all approved site(s)? Yes, No
If No: Specify the investigator(s)/site(s) for which the amendment will apply:

4. **ETHICS COMMITTEE APPROVAL**

4.1 Have the Research Ethics Committee(s) responsible for each center to which this amendment applies been notified? Yes, No
4.2 Research Ethics Committee(s) responsible:
4.3 Date of application to Ethics Committee:
4.4 Date of approval by Ethics Committee:

I/We, the undersigned, agree to conduct/manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility shall sign this form).

Applicant:_____ Date:_____

Appendix 7: Application for Additional Investigator(s), Change of Investigator(s) or Additional Clinical Trial Site(s)

APPLICATION FOR APPROVAL OF:
CHANGES IN INVESTIGATOR(S) AT APPROVED SITE (includes additional investigators)
ADDITIONAL SITE(S)

Title of the study:
Protocol number:
Date:

1. APPLICANT
Name:
Address:
Telephone:
Email:

2. **TRIAL PARTICULARS (original application)**

Trial approval number:
Date of approval of original protocol:
Principal investigator(s) approved for this trial:
Number of local sites approved for this trial:
Number of participants approved for this trial:

3. **INVESTIGATOR'S DETAILS**

3.1 Name and address of additional Investigator(s)/Changes to Investigators: [Proof of ICH - GCP training must be provided for investigators who have not previously participated in clinical trials]
3.2 Summarize other ongoing/planned studies at the site involving the investigator:
[Provide details of studies, including numbers of study participants, whether the investigator is involved in research in a full-time or part-time capacity, and any other details that may affect the capacity of the site at any one time]
3.3 Date of application to Ethics Committee:
3.4 Date of approval by Ethics Committee:
3.5 Is CV for the additional investigator(s) attached? Yes, No
3.6 Is the declaration of Intent attached? Yes, No(If yes, attach declaration)

4. **CAPACITY OF THE SITE**

Describe how the site is structured so as to be able to take on the work for which this application is being made: [Give details of support staff, facilities, back-up and any other relevant infrastructure].

5. **RATIONALE FOR APPLICATION**

5.1 Briefly explain the reason for the new investigator/s or site(s):

I/We, the undersigned, agree to conduct/manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility should sign this form).

Applicant: ……. Date: …….

Appendix 8: SAE Reporting Form (refer to ADR reporting form)

Study Sponsor Notification by Investigator

A serious adverse event must be reported to the study sponsor by telephone within 24 hours of the event. A Serious Adverse Event (SAE) form must be completed by the investigator and faxed to the study sponsor within 24 hours. The investigator will keep a copy of this SAE form on file at the study site. Report serious adverse events by phone and facsimile to:

At the time of the initial report, the following information should be provided:

- Study identifier
- Study Center
- Subject number
- A description of the event
- Date of onset
- Current status
- Whether study treatment was discontinued
- The reason why the event is classified as serious
- Investigator assessment of the association between the event and study treatment

Within the following 48 hours, the investigator must provide further information on the serious adverse event in the form of a written narrative. This should include a copy of the completed Serious Adverse Event form or ADR form, and any other diagnostic information that will assist the understanding of the event. Significant new information on ongoing serious adverse events should be provided promptly to the study sponsor.

Appendix 9: Good Clinical Practice (GCP) Principles (adopted from ICH-GCP)

1. Applicants must be able to demonstrate that clinical trials are conducted according to generally accepted principles of good clinical practice.
2. Trials must be conducted in accordance with the applicable regulatory requirement(s).

3. Before a trial is initiated, foreseeable risks and inconveniences must be weighed against the anticipated benefit for the individual trial study participant and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
4. The rights, safety, and wellbeing of the trial study participants are the most important considerations and must prevail over interests of science and society.
5. The available non-clinical and clinical information on an investigational medicinal product must be adequate to support the proposed clinical trial.
6. Clinical trials must be scientifically sound, and described in a clear, detailed protocol.
7. A trial must be conducted in compliance with a protocol that has received regulatory and ethics approval prior to initiation.
8. The medical care given to, and medical decisions made on behalf of, study participants must always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
9. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
10. Freely given informed consent must be obtained from every study participant prior to clinical trial participation.
11. All clinical trial information must be recorded, handled, and stored in a way that enables its accurate reporting, interpretation and verification.
12. The confidentiality of records that could identify study participants must be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
13. Investigational medicinal product must be manufactured, handled, and stored in accordance with applicable good manufacturing practices (GMP) and must be used in accordance with the approved protocol.
14. Systems with procedures that assure the quality of every aspect of the trial must be implemented.

Appendix 10: World Medical Association (WMA) Declaration of Helsinki (Ethical principles for medical research involving human study participants)

As adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996and the52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of clarification on paragraph 29 added by the WMA General Assembly,
Washington 2002

A. Introduction

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principle to provide guidance to physicians and other participants in medical research involving human study participants. Medical research involving human study participants includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.
3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, " A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human study participants.
5. In medical research on human study participants, considerations related to the well-being of the human study participant should take precedence over the interests of science and society.
6. The primary purpose of medical research involving human study participants is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the a etiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research population is vulnerable and need special

protection. The particular needs of the economically and medically disadvantaged must be recognized. Special
attention is also required for those who cannot give or refuse consent for themselves, for those who may be study participant to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research investigators should be aware of the ethical, legal and regulatory requirements for research on human study participants in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirements should be allowed to reduce or eliminate any of the protections for human study participants set forth in this Declaration.
B. Basic Principles for all Medical Research
10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human study participant.
11. Medical research involving human study participants must conform to general accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animal used for research must be respected.
13. The design and performance of each experimental procedure involving human study participants should be clearly formulated in an experimental protocol.
This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is
performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for study participants.
14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
15. Medical human research involving study participants should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human study participant must always rest with a medically qualified person and never rest on the study participant of the research, even though the study participant has given consent.
16. Every medical research project involving human study participant should be preceded by careful assessment of predictable risk and burdens in comparison with foreseeable benefits to the

study participant or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
17. Physicians should abstain from engaging in research project involving human study participants unless they are confident that the risk involved has been adequately assessed and can be satisfactorily managed. Physicians should cease any investigations if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human study participants should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the study participant. This is especially important when the human study participants are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the result of the research.

20. The study participants must be volunteers and informed participants in the research project.

21. The right of research study participants to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the study participant, the confidentiality of every patient's information and to minimize the impact of the study on the study participant's physical and mental integrity and on the personality of the study participant.

22. In research of human beings, each potential study participant must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The study participant should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the study participant has understood the information, the physician should then obtain the study participant's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the study participant is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24. For a research study participant who is legally incompetent, physically or mental incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the

population represented and this research cannot instead be performed on legally competent persons.

25. When a study participant deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reason for involving research study participants with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligation. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicity available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principle laid down in this Declaration should not be acceptable for publication.

C. Additional Principles for Medical Research Combined with Medical Care

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to patients who are research study participants.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgment it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.
Footnote: Note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:
Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be study participant to any additional risk of serious or irreversible harm.
All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Appendix 11: Fees for Clinical Trials in Liberia

No.	Service	Cost
1	Application to conduct Clinical Trial (LMHRA)	US$3,000.00
2	Application to conduct clinical trial (Ethics Committee Review)	US $ 2, 000.00
3	Fast track for clinical trial application (time shortens by half)	Double the cost for registration and analysis for the application
4	Amendments for major changes in clinical trials	US500.00

5	Amendments for minor changes in clinical trials	US$250.00

LIBERIA INSTITUTE OF BIOMEDICAL RESEARCH/ NATIONAL HEALTH SCIENCE RESEARCH (LIBR/NHSR) Ethics Committee Guidelines:

Procedures for Researchers

September 23, 2011

I. Administrative Procedures

1.1 FREQUENCY OF MEETINGS

The Liberia Institute of Biomedical Research/National Health Science Research Ethics Committee (LIBR/NHSREC) shall meet bi-monthly, on the third Friday of the month. These dates shall be made public or can be seen on the LIBR/NHSREC website. However, there shall be called meetings as necessary.

1.2 ATTENDANCE AT MEETINGS

All members of the ethics committee are required to be at each meeting.

1.2.1 QUORUM

A quorum of a meeting is a third of the members of the LIBR/NHSREC.

1.2.2 SUBMISSION OF COMMENTS

Where a member cannot attend a meeting he/she should advise the Committee Secretary one (1) week before the committee meeting on their views/concerns on the items tabled for consideration.

1.2.3 MEMBERS WHO WILL NOT BE IN ATTENDANCE

Members who for some unforeseen reason cannot attend a meeting should inform the Secretary one day before the meeting

1.3 AGENDA

Agenda and research protocols shall be distributed by the LIBR Administration to committee members no later than four weeks before the meeting. The papers shall be distributed by post or by courier, or by email if necessary, to ensure timely delivery. Receipt of agenda papers shall be confirmed by each member prior to the meeting...

Agenda papers shall include:

1. Minutes of Previous Meeting;
2. New Proposals
3. Re-submission/Revised Proposals/Protocol changes;
4. Out of Session Considerations
5. Progress/Final Reports on approved proposals
6. Any other business

1.4 MINUTES

Minutes of the previous meeting shall be written and distributed to all members four weeks to the next meeting. The minutes shall be read and adopted at the subsequent meeting. The Chair signs the approved minutes.

1.5 Timely consideration

All proposals submitted by the deadline shall be reviewed at the next bi-monthly meeting. If additional information is required from the researcher, he/she shall be contacted by written communication(letter, fax, email) to provide more information. Researchers(PI and Co-PI) and occasionally sponsors, may be asked to make themselves available for contact during the meeting if answers to relatively simple questions are sought.

1.6 METHOD OF DECISION MAKING

The LIBR/NHSREC shall endeavor to reach decisions by general agreement. However, all decisions shall be based on the LIBR/NHSREC SOPs.

The Committee may seek advice and assistance from experts to consider a particular research protocol, as long as the experts have no conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome, or involvement with competing research.

1.7 Notification of Decision

The Principal Investigator(PI) and, where applicable, the Project Sponsor or other relevant contact shall be notified in writing of the Committee's decision at least one month after the meeting at which the protocol is reviewed.

1.8 Decision Types

Approved – the submission satisfies all requirements in accordance with LIBR/NHSREC SOPs and GCP.
Not Approved – the submission has failed to satisfy all requirements accordance with LIBR/NHSREC SOPs and GCP.

Approved Under Condition– "Partially Endorsed" - does not equate to approval. Specified matters must be resolved to the satisfaction of the Committee prior to commencement/continuation of the study.

1.9 Expedited Review for Minimal Risk Research

On receipt of a study protocol that initially appears to be of minimal risk, clarification may be sought from the Chair to decide whether the protocol requires consideration by the whole Committee or a subcommittee of two or more LIBR/NHSREC members. Any decisions made in this manner will be confirmed at the next full meeting of the Committee.

A study is qualified for expedited review according to the following criteria:

- Modification/ amendment of protocol
- Proposals involve interviewing of a non-confidential nature, not likely to harm the status or interests of the individual and not likely to offend the sensibilities of the people involved
- Those that involve collection of small amounts of blood samples(and not too frequent), e.g. by finger, heel or ear stick.

- Those that involve the collection of biological specimens for research purposes by non-invasive means (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner)
- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have already been approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However, procedures involving the use of X-rays or microwaves are NOT recommended for expedited review.
- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis
- Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and no additional risks have been identified.
- Biomedical programme review/evaluation

1.10. Fees

The LIBR/NHSREC shall charge a minimum fee for the consideration of research proposals as follows:

- A minimum fee of 3% of a research budget shall be levied for review and deliberation on all research proposals other than academic ones;
- A minimum fee of 1% of the budget shall be levied on all research proposals fulfilling academic requirements.

1.11. Monitoring

The LIBR/NHSREC shall, as a condition of approval of each protocol, require researchers to report on a Three –monthly basis from the date of approval. Researchers are to immediately report anything that may warrant a review of the protocol including:

1. serious and unexpected adverse effects on participants;
2. proposed changes to the protocol; and
3. Unforeseen events that might affect continued ethical acceptability of the project.

1.12. Complaints Procedure

Whenever a complaint about a researcher raises the possibility of ‘research misconduct’ the matter will be handled in accordance with the ‘research misconduct’ processes specified in the LIBR/NHSREC STANDARD OPERATING PROCEDURES. Where a complaint about a researcher alleges serious misconduct that falls outside the range of ‘research misconduct’ as described in the LIBR/NHSREC STANDARD OPERATING PROCEDURES, the matter will be dealt with under governmental processes for dealing with other forms of misconduct.

1.13. **Confidentiality of Protocols**

LIBR/NHSREC documents and protocols are to be maintained in a secure environment. All documents distributed to Committee members must be securely stored. Committee files are to be kept in locked cabinets and accessed only by authorized individuals

2. **Researchers**

2.1. **Researchers' Responsibilities**

Researchers are expected to be aware of the values and principles of ethical and responsible conduct of human research, including appropriate consideration of:

1. research merit and integrity;
2. justice;
3. beneficence; and
4. respect.

This should be reflected in any proposal put to the LIBR/NHSREC for consideration.

2.2. **Conflict of Interest**

Researchers should establish transparent processes to identify and manage actual and potential conflicts of interest.

A conflict of interest in the context of research exists where:

• a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or

• an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

the institution or researcher's influence/association has possible propensity to compromise the objectivity and outcome of the research.

While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.
A researcher with a conflict of interest bearing on research should immediately inform the LIBR/NHSREC about the conflict.

2.3. Submission Types

New Submission – a research proposal NOT considered by LIBR/NHSREC previously;

Re-Submission – a submission on an **unapproved** research proposal that has been considered by LIBR/NHSREC previously. The submission could be a revised proposal, provision of further information or a response to specified matters of conditional approval;

Protocol Change – only on previously **approved** research proposals where there is a change in protocol relating to methodology. A change in rationale need not require LIBR/NHSREC approval but should be assessed before reaching that decision.

2.4. **New Submissions**

All submissions must be typed, dated, signed and presented to the LIBR/NHSREC electronically or by hard copies.

New submissions must also include all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation and internet content. All participant information sheets should include a signature block. Researchers should also include the name of the principal investigator, sponsor or sponsors, and contact information.

All submissions must be received by the LIBR/NHSREC by no later than the close off for submissions, usually 6 weeks prior to each meeting.

The Principal Researcher or his/her representative should be available for comments and clarifications at anytime the Committee request such presence.

2.5. **Declaration of Funding Sources**

A researcher is required to disclose the amounts, sources or potential sources of funding in any research proposal and, following approval of the proposal, any subsequent funding sources.

2.6. **Payments for Participants**

It is generally unacceptable to LIBR/NHSREC to pay participants for their involvement in research. A payment, gift, reward or any other inducement that is likely to encourage participants to take risks is ethically unacceptable.

Reimbursement of direct costs to participants taking part in research, including costs such as travel, accommodation and parking shall be permitted.

2.7. **Complaints/Adverse Occurrences**

Participants shall be advised of the first point of contact for complaints. The consent form signed by participants shall include the name and telephone number of this contact.

The first instance of a complaint shall be directed to the LIBR/NHSREC ethics committee VIA THE ADDRESS BELOW:
LIBR/NHSREC
Charlesville, Margibi County
Email: director.libr@gmail.com

2.8. Student Research

In considering approval of PhD or other student research, the LIBR/NHSREC shall consider the merit and integrity of the proposed study, including whether:

- the potential benefit of the research will outweigh any possible harm to participants;
- the results of the research will create new knowledge or be a slight revision of other research;
- the design and methodology of the research is appropriate to achieving desired aims;
- the research will be closely supervised by a person or team with experience, qualifications and competence appropriate to the research;

• the research will be conducted using facilities and resources appropriate to the research;
• the research will be carried out using the recognized principles of research conduct.

All correspondence from the (student) researcher - especially to participants - should be on university stationery, clearly identifying the status of the Researcher within the University. *Information to Participants* shall also identify the Supervisor in such a way that indicates their professional oversight of, and responsibility for, the research activity.
Students must ensure secure storage and, where necessary, destruction of data. Research files are to be kept in locked cabinets at the university responsible for the research, and accessed only by authorized individuals.

2.9. **Presentation of Research Protocols**

The LIBR/NHSREC encourages researchers to make themselves available for contact, including attendance, at the meeting when their project is being considered in order to answer any questions that may arise. It may be reasonable in some instances for the Sponsor to attend on behalf of the Researcher.

When facilities are available during LIBR/NHSREC meetings for conference call, connection with researchers shall normally be sufficient. The LIBR/NHSREC Secretariat will contact researchers prior to the meeting to make appropriate arrangements.

2.10. **Change to Protocol**

Principal researchers are required to advise the LIBR/NHSREC in writing if their research protocol, as approved by LIBR/NHSREC, changes before the study commences or at any time during the study. The LIBR/NHSREC will then reassess the proposal and reach a decision based on the revised protocol. It is preferable that significant protocol changes on studies which have not yet commenced be shown as changes on the original approved proposal

2.11. **Reporting Requirements**

Principal researchers are requested to provide the LIBR/NHREC with progress reports every three months, for studies covering a period of one year or longer. The Committee shall receive a copy of the final report. Shorter-term studies are required to submit a final report within three months after completion of the study.
Progress reports should be designed to assure the Committee that the research protocol as approved has not changed, and that the project is progressing satisfactorily. While there is no specific format for a progress or final report, researchers must in the very least ensure they provide advice as to:

• progress to date, or outcome in the case of completed or discontinued research;
• any events of significance that have occurred during the study, particularly in relation to adverse outcomes;
• maintenance and security of records;
• compliance with the approved proposal and protocol; and
• compliance with any conditions of approval.

2.12. **DISCONTINUED Research**

Researchers are required to advise the LIBR/NHSREC if and why an approved project is discontinued before the expected completion date.

2.13. **Withdrawal of Approval**

If the LIBR/NHSREC becomes aware that a research project is not being conducted in accordance with the approved protocol and the welfare and rights of participants are not protected, the LIBR/NHSREC shall withdraw its approval and advice the researcher/ organization or institution of such withdrawal. The LIBR/NHSREC shall suspend such a project immediately.

Approved: _____

Chairman, LIBR/NHSRC

National Commission for Science and Technology

THE FRAMEWORK OF GUIDELINES FOR RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES IN MALAWI

Issued with Legislative Anchorage to the Science and Technology Act No.16 of 2003

30th May, 2011

National Commission for Science and Technology

THE FRAMEWORK OF GUIDELINES FOR RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES IN MALAWI

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The National Commission for Science and Technology remains indebted to a cross-section of stakeholders who discussed and vetted this Framework at various stages of development including all those who participated at the national stakeholders' consultative meeting on 30th May, 2011. The NCST gratefully acknowledges the use of and reference made to various guidelines and codes of ethics of other local and international institutions as listed in the section on source materials. Lastly, I declare with gratitude that funding for the development of this Framework was provided by the Government of Malawi under the stewardship of the NCST Board.

Anthony Muyepa
DIRECTOR GENERAL

1.0 INTRODUCTION

Researchers in the fields of social sciences and humanities work within a variety of economic, cultural, legal and political settings that influence the emphasis of their disciplines involving their own techniques, procedures and ethical approaches. Even within the same setting and discipline, individuals may have different moral precepts that guide their work. No declaration could successfully impose a rigid set of rules to which social and humanities researchers everywhere should be expected to adhere. For this reason this document is referred to as *The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi*, herein referred to as the *framework*.

The framework contains a preamble; value of research in the social sciences and humanities; ethical principles and obligations; and sections on autonomous implementation of the framework; research communication; appropriate research environment; monitoring system; application; affiliation and clearance, and acknowledgements.

The purpose of the framework is to provide individuals and institutions with guidelines for making ethical choices in the conduct of social sciences and humanities research in Malawi. Its aim is to enable the social and humanities researchers make individual ethical judgments and decisions informed by shared ethics, principles, values and experiences that are not imposed by their professions. This is a mere framework given that the specific disciplines in the social sciences and humanities can present researchers with many and different complex situations. It shall be adapted by researchers according to the situations they encounter.

The framework is designed to be informative and descriptive rather than being authoritarian or rigidly prescriptive, and is applicable as far as possible to different disciplines in the social sciences and humanities. Its informative and descriptive nature, however, reflects the minimum standards and requirements that should be followed by stakeholders. Its provisions are fairly broadly drawn. However, it will require periodic updating and amendment as deemed necessary by the National Commission for Science and Technology (NCST).

2.0 PREAMBLE

Noting the steady growth of social sciences and humanities research in Malawi, the NCST developed this framework to guide the conduct of research in the Social Sciences and Humanities in conformity with national policies, laws and international standards.

Most research in the social sciences and humanities has direct impact on individuals' privacy and security. Without ethical commitment and guidelines, the credibility and quality of the research work being done, the autonomy and rights of the research participants, the integrity of researchers, and public confidence in research are adversely affected. This framework shall therefore guide the co-ordination, procedure, and ethical conduct of research in the social sciences and humanities in Malawi.

The National Committee on Research in the Social Sciences and Humanities and any NCST approved and registered institutional research and ethics committee shall be key structures to facilitate observance and to promote adherence to what has been provided in this framework. The National Committee on Research in the Social Sciences and Humanities in Malawi is a technical committee established within the institutional set up of the NCST as provided for in Part III, Section 11, Sub-section 1-3 of the Science and Technology Act No. 16 of 2003.

3.0 VALUE OF RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES

The ultimate goal of research in the social sciences and humanities is to improve human life in the physical, material, moral, emotional and intellectual forms. The collection and use of research data in the various disciplines that fall in the categories of the social sciences and humanities, therefore, have direct bearings on people. Data are collected from human research participants, for use by individuals or groups of individuals, to meet individual or collective needs.

Researchers in the social sciences and humanities, therefore, have obligations to: their sources of research data, those whose lives will be

affected by the research findings, other interested parties and end-users of the research data, as well as themselves and their colleagues. Such obligations raise issues related to values, ethics, professional conduct, and moral commitment.

The framework provided herein is premised on the values of:

i. service and benefit to humanity,
ii. respect for the rights, worth and dignity of research participants.
iii. promotion of innovation and creativity in research,
iv. excellence and professionalism,
v. collegiality,
vi. continuous transfer of skills and knowledge,
vii. encouragement of collective participation in matters of human development, and
viii. transparency and accountability at all levels of the research continuum.

4.0 ETHICAL PRINCIPLES AND OBLIGATIONS

This framework forms the basis for the ethical design and conduct of research in the social sciences and humanities.

4.1. Informed Consent

All persons have the right to individual autonomy and self determination. Some of them are vulnerable in the sense that they have a compromised autonomy related to decisions about research participation to a degree that would violate the principle of respect for persons. Therefore, any individual who is invited to participate in a research study shall be given an adequate description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process is designed to provide potential participants with readily understandable information in an amount and timing appropriate to achieve the participant's understanding. Consent shall be obtained from each research participant who is legally, mentally and physically able. For those that are not, including minors, permission shall be sought from parents or legal guardians or any of their legally authorized representatives as the situation may apply. The following are examples of the exceptional

circumstances under which research can be approved by a research ethics committee without parental permission;

i. If the research ethics committee determines that a research protocol is designed for conditions or for a subject population for which permission is not a reasonable requirement to protect the research participants (for example, neglected or abused children), provided an appropriate mechanism for protecting the children who will participate in the research is adequately substituted, and provided further that the waiver **is not inconsistent** with any of the relevant local laws.
ii. Research on adolescents involving their access to contraceptives; or research on adolescents that aims at describing sexually transmitted diseases treatment seeking behaviours, provided the waiver **is not inconsistent** with any of the relevant local laws.

4.1.1. Written Consent

Consent shall be in writing unless an NCST -recognized research ethics review committee finds that written documentation of informed consent may be waived. Consent forms and other informational documents like information sheets shall be written in simple language so as to be easily understood by potential participants and any persons without technical background in the field. The standard consent form and/or information sheet must include the following elements which are considered the most important information to be given out to the research participants;

- ***Research purpose and procedures***: a statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, a description of procedures to be followed, and identification of any procedures which are experimental;
- ***Risks and discomforts of the research study***: a description of any reasonably foreseeable risks or discomforts to the research participants;

- ***Potential benefit of the research study***: a description of any benefits to the research subjects or to others or to the country as a whole that may reasonably be expected from the research;
- ***Alternative procedures***: a disclosure of appropriate alternative procedures, if any, that might be advantageous to the research participants;
- ***Provisions for confidentiality***: a statement describing the extent to which confidentiality of records identifying the research participant will be maintained;
- ***Research related injury***: for research involving more than minimal risk, an explanation as to whether any compensation is available and if so, what it consists of and how it will be provided;
- ***Voluntariness in participation and the right to discontinue participation without penalty***: a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- ***Contacts for additional information***: an explanation of whom to contact for answers to pertinent questions about the research and research participants rights, and whom to contact in the event of the research related injury (i.e. contacts of the principal investigator and the chair of the research and ethics committee reviewing and approving a particular study for additional information on the research and rights of participants, respectively);

4.1.2. Oral or Verbal Consent

Any NCST-recognized research ethics review committee may allow an oral or verbal consent in the case of all those that do not read or write or do not understand the language of the written consent form. However, the script or information sheet to be read to the potential participants must be approved by the NCST-recognized research ethics review committee and be signed for by their parents or legal guardians or any

of the legally authorized representatives. The consent form or information sheet to be read out shall, however, contain the elements described in **4.1.1**.

4.1.3 *Consent for protected sites*

For research related to intangible cultural heritage (as per definition contained in the convention for the safeguarding of the intangible cultural heritage), heritage sites and graveyards/cemetery, consent/permission (be of entry) shall be obtained from the relevant custodians and/or offices or legal representatives.

4.1.4 Use of Language

No consent form or information sheet, whether written or oral, shall include intimidatory, threatening, or deceptive language through which the subject or the subject's authorized representative is made to lose or waive any of the subject's legal rights, or releases or appears to release the investigator or sponsor from liability for negligence or any harmful consequences originating from participating in the research.

4.1.5 Requirement

The standard requirement is that all participants shall sign in person a consent document or form or information sheet containing adequate elements of a consent document. Those who cannot sign, due to illiteracy, will provide a thumb print under a witness who shall also sign for witnessing. For those who cannot legally, mentally and physically give consent, their parents or legal guardians or authorized legal representatives will be required to sign or thumbprint.

4.1.6 Assent

Researchers shall obtain assent from minors who are capable of assenting. In determining whether children are capable of assenting, an ethics review committee and the researchers shall take into account the ages, maturity and psychological state of the children involved. However, minors must assent in tandem with parental permission. An

assent needs to be tailored to the level of comprehension of the prospective participants. A research ethics review committee is granted wide discretion in determining whether a child is capable of assenting and can waive the requirement for child assent under the following circumstances;

- If a child is not capable of assent
- If the research offers a prospect of direct benefit not available outside of the research(thus falling under the scope of parental authority in overriding a child's desires)
- Or given the same conditions under which parental permission can be waived (as stated above in 4.1)

4.1.7 Consent from Emancipated Minors

Emancipated minors may include those that society may regard as mature minors by law, those legally married, or students under a defined Malawian adult age. Assent from such minors may be regarded as an informed consent.

4.1.8 Protection for Vulnerable Populations

Vulnerable persons are those who have a compromised autonomy related to decisions about research participation to a degree that would violate the principle of respect for persons. Researchers to involve such persons shall be required to obtain extra protections or safeguards for their safety and welfare. Examples of vulnerable populations include pregnant women, prisoners, orphans, people living with HIV and AIDS, refugees, persons with mental disabilities, the illiterate, and women and men who, in some settings, may have to ask their spouses before consenting to participate in a research. .

4.2 Privacy and Confidentiality

i. Researchers shall be required to take precautionary measures to ensure that sensitive research information is not attributed to specific individuals that provided it and is collected in a manner that does not invade the privacy of the participants.
ii. Researchers shall respect individuals' right to privacy.
iii. Researchers shall ensure that sensitive, identifiable information is collected for research purposes and access to such

information is limited to a well defined group such as the research team, the research ethics committee or the research regulatory authority.

4.3 Rights of Participants

i. Research participants have the right to know the benefits and risks of their participation in a research study
ii. Research participants have the right to withdraw from participating in a research study without any penalty for their voluntary withdraw.
iii. Research participants or communities from which research participants come have the right to feedback from researchers.

4.4 Accountability and Transparency

Researchers shall be committed to research that is fair, honest and transparent. They shall be accountable to their profession, research participants, and the wider society, and shall make arrangements to have their research data preserved for a reasonable period of time for posterity.

4.5 Obligations to others

Researchers shall promote social relations based on the principle of non-exploitation, collaboration, and mentorship. They shall strive to establish working relationships that benefit other researchers and participants, and have primary ethical obligations to the people they study. They shall respect the dignity and well-being of all people involved in their research. Their research shall not unnecessarily consume the time of participants or make them incur undue loss of property and income. Research shall not expose research participants to risks due to their participation in the research.

4.6 Responsibility to the public

Social and humanities research shall be done to benefit society and groups and individuals within it by making the research appropriately available to sponsors, students, decision makers, other researchers and research participants. Above all, researchers shall conduct their work responsibly and in light of the moral and legal order of the society in which they practice. They shall be truthful and be responsible for the

factual content of their statements and must consider the wider implications of the information that they disseminate. They shall make sure that the information presented is well understood, properly contextualized and responsibly utilized.

4.7 Responsibility to colleagues and fellow researchers

Social and humanities researchers shall maintain standards and appropriate professional behaviour that are shared amongst the professional research community. Without compromising obligations to funders, employers, subjects or society at large, this requires methods, procedures and findings to be open to collegial review and dissemination of findings to the scientific and scholarly community.

Where junior researchers work with their senior colleagues the aims shall be to: transfer professional skills, mentor, and build capacity in them.

4.8 Responsibility to students and trainees

Where researchers use students, the following guidelines shall apply:

i. Research and teaching shall be conducted in such a way that does not discriminate on the basis of gender, marital status, race, social class, political convictions, religion, ethnicity, nationality, age or any other criterion irrelevant to academic performance;
ii. Ensure improvement in teaching and training techniques, and being available to the needs and interests of the students;
iii. Impress on students the ethical challenges involved in stages of social and humanities research;
iv. Teachers shall publicly acknowledge student assistance in research and preparation of their work; and
v. Wherever students are used in the research the aim shall be to transfer professional skills and to build capacity in them.

4.9 Non-discrimination

Researchers shall avoid discrimination against others on the basis of sex, race, religion, ethnicity, culture, or other social and human categories that are not related to their scientific competence and integrity.

4.10 Avoidance of conflict of interest

Researchers and members serving on research ethics review committees shall avoid conflict of interests. In this case, conflict of interests shall include but not limited to:

i. researchers and members of any research ethics review committee who serve as an investigator on research under consideration by the same committee;
ii. researchers and members who hold a significant financial interest in a body that funds or sponsors research or promotes products or services on which the research is being done;
iii. a member whose spouse or close relative has a research under review by the committee;
iv. researchers and members who have any special form of relationship with the sponsor of the research under consideration if such relationship is likely to influence decision of the committee;
v. any person who receives a bribe or inducement to do research that compromises objectivity.

Insider dealing shall not be allowed in the research review process, and award of research grants. In a case where conflict of interest is likely to occur, a member of the committee or researcher shall be required to declare the nature of the conflict of interest and provide relevant information. Such a member shall not participate in the review of a particular protocol in which such a member has a conflict of interest. Such a member shall recuse oneself and move out of the meeting room to allow the committee freely deliberates on the protocol in which a member has declared conflict of interest. Such a member shall only be recalled into the meeting room after decision on that protocol had been made. The declaration and recusal shall have to be properly reflected in the minutes of that meeting.

4.11 Objectivity

Researchers shall strive to avoid bias or deception in the design of methods, data analysis, and data interpretation of their research. They shall serve rather than threaten the interests of society in which they

operate. For this reason they shall be aware of the fact that their assumptions may have an impact upon society. Hence, their duty is, on the one hand, to keep an unbiased attitude as far as possible, while, on the other hand, to acknowledge the tentative and relative character of the results of their research and not to conceal their own ideological position(s). No social sciences and humanities assumptions shall be presented as indisputable truths. Researchers shall need to clear misconceptions and misinterpretations about their research.

4.12 Integrity

Social science and humanities researchers bear responsibility for the integrity and reputation of their disciplines of scholarship and of science in general. Researchers shall not deceive or knowingly misrepresent (i.e. fabricate evidence or results, falsify, plagiarize), or attempt to prevent reporting of misconduct in any way, or obstruct the scientific or scholarly research of others. Researchers shall also allow others to have access to their research data and other research materials for purposes of their own work.

4.13 Coercion and Undue Influence

Coercion and undue influence shall not be allowed. Coercion refers to a situation in which a person to some degree is forced, or at least strongly pushed, to do something that is not good for him or her to do. Its interchangeable term is undue influence. If individuals are put in a position where there is undue influence to participate in research, then their ability to control their own destiny has been compromised. It shall be noted that undue influence and inducement amount to coercion.

5.0 AUTONOMOUS IMPLEMENTATION OF THE FRAMEWORK

This framework is of a general application, but academic and other institutions are encouraged to develop their own frameworks in line with it. Such institutional frameworks/guidelines shall, however, be required to be endorsed by the NCST.

6.0 RESEARCH COMMUNICATION

Research communication entails popularization of research results. Researchers in the social sciences and humanities shall ensure that

scientific knowledge is communicated to a wider audience beyond the research community. Reporting of research and its results shall be the responsibility of every researcher and the research institution. The responsibility may be delegated to either the sponsor or any individual upon mutual agreement and expressed commitment to publish or disseminate the results within a specified period.

6.1. Authorship

As a rule, research results shall be published whether they support or contradict the expected outcome. When publishing, the following authorship guidelines shall apply:

i. Authorship shall be based on the level of contribution made in terms of ideas, conceptualization, and actual performance of the research, analysis and writing of the report or any other publications based on the research.
ii. Co-authorship and its sequence should not be based on the status of an individual in the institution or elsewhere.
iii. All other persons not meeting the criteria for authorship but contributed to the conduct and completion of research or publication shall be properly acknowledged.
iv. Students shall be listed as principal authors on any multiple authored publications that considerably originate from their dissertations.
v. Appropriate acknowledgment shall be given where data or information from other studies or publication is quoted or otherwise included.

6.2. Research Dissemination

Researchers bear a special responsibility to convey research results in a comprehensive and responsible manner. Researchers may disseminate preliminary results of their research before being peer-reviewed or published in recognized journals. When such results are being disseminated through the popular media, great care shall be taken to ensure that the media people, not specifically trained in social science and humanities issues and research, are able to understand the limitations and implications of research results to avoid distortions.

It is incumbent upon research institutions to promote multifaceted and comprehensive research communication, characterized by high quality and relevance. Institutions conducting social science and humanities research shall establish committees responsible for dissemination of research results to ensure that the results reach end-users. The committees shall also be charged with the responsibility of publishing circulars and organizing events for specific dissemination of results.

All funded research shall have a component on dissemination of results. Institutions shall be required to establish budget lines for dissemination of research results and organize theme specific conferences or symposia.

Institutions shall establish research data banks and repositories from which they shall develop research indicators in the social sciences and humanities and compile annual inventories of research and to facilitate availability and access by other users.

7.0 APPROPRIATE RESEARCH ENVIRONMENTS

Researchers shall establish and maintain sound and appropriate research environments in which research can be conducted. Researchers shall actively participate in the initiatives and efforts to improve the quality of research environments in their communities and institutions, and to promote public involvement in these.

8.0 AFFILIATION AND RESEARCH CLEARANCE

As a matter of policy, it remains a fundamental requirement that all foreign based researchers intending to conduct research in Malawi should be affiliated to local research related institutions and government departments. The affiliating institutions' role shall be to aide such researchers to conduct research in Malawi according to the applicable regulatory requirements.

In considering affiliation, fees and MoUs may be required depending on procedures and policies of the affiliating local institutions.

Researchers in Civil Society Organisations/NGOs and other related institutions shall be required of their research to be reviewed and approved by an NCST authorized research and ethics review committee.

9.0 FORMAT FOR RESEARCH PROPOSALS

Research proposals/protocols shall be prepared according to the following general or specific format;

9.1 General Format

This format shall apply where a research and ethics review committee has not specified a format.

i. Proposal title
ii. Names of investigator(s) and qualifications (their CVs should be appended)
iii. Institution of affiliation (local and/or international)
iv. Summary
v. Introduction/literature review
vi. Problem Statement/Justification
vii. Main and specific objectives
viii. Methodology/Materials and methods
    - This should include a description of details of the study design and methods to be used. The description should include study site(s)/location(s); study participants; sampling

methods; sample size; data collection instruments; and data management and analysis methods.

- Data collection instruments, where appropriate, must be translated into the appropriate local language and should be attached in the annex and be appropriately referred to.

ix. Ethics

- This should include a description of strategies and/or processes that will be followed to guarantee the protection of the rights and welfare of the research subjects/communities as required and described under **section 4.0,** while taking into cognizance of the nature and design of a particular study.
- Consent/assent forms or information sheets in English and in an appropriately translated local language should be attached in the annex and be appropriately referred to.

x. Work plan (where appropriate, roles and responsibilities of collaborators, should be stated clearly)

xi. Expected outcomes of the study

xii. Strategies of dissemination of research results

xiii. Budget

xiv. Declaration of source of funding (if already available or proposed)

xv. Reference

9.2 Specific Format

i. Some funding agencies may have different requirements which researchers shall be required to follow in soliciting funding.

ii. In submitting for research and ethical review to the **National Committee on Research in the Social Sciences and Humanities** as mentioned **under section 10,** researchers shall be **generally** required to;

- follow the format that is defined in **section 9.1;**
- submit both **an <u>electronic copy</u> and <u>two</u> hard copies** of the research proposal/protocol; and to

- enquire from the secretariat on the other specific requirements and procedures for submission of a protocol for review by this committee which are not described herein.

iii. Institutional research and ethics committees shall specify their own formats that shall, however, be modeled on the general format.

10.0 MONITORING SYSTEM

Once misconduct during research has been reported, a proper process of investigation shall be set up. All relevant facts for investigation shall be gathered without taking sides and the findings shall be made public for purposes of preserving the integrity of the research community. The regulatory research authority shall impose strict measures in the case of fabrication, falsification, fraud, or plagiarism or any form of serious violation of this framework. All those that report any forms of misconduct shall be protected.

All records of research approved by institutional research ethics review committees shall be submitted to the NCST for record keeping and for creating research data base of all research taking place in the country. **In the event that there are no institutional research and ethics review committees, researchers shall be required to seek approval from the National Committee on Research in the Social Sciences and Humanities whose secretariat is at the NCST**.

11.0 APPLICATION OF THE FRAMEWORK

The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi shall apply to all researchers and research institutions in the social sciences and humanities doing research in Malawi. The guidelines give due consideration to prevent research activity from becoming unduly constricted, and limiting of academic or scientific freedom but placing emphasis that such freedom should occur within the framework of ethical principles set forth in this document as minimum standards. Nonetheless, all institutional and subject or discipline specific guidelines are subject to this framework

and other relevant laws and national policies for conducting research in Malawi.

12.0 SOURCE MATERIALS

The International Sociological Association Code of Ethics (2001), United Kingdom
Republic of Malawi Constitution (1995)
The Social Sciences and Humanities Research Ethics Board (SSH REB) (2005), United Kingdom
The Science Council of Japan Code of Conduct for Scientists (2006), Japan
National Committee for Research Ethics, Guidelines for Research Ethics in the Social Sciences, Law and the Humanities (2006), Norway
Human Sciences Research Council Code of Research Ethics, South Africa
National Research Council of Malawi, *Procedures and Guidelines for the Conduct of Research in Malawi* (2002), Malawi
Ethical Guidelines for Social Sciences Research in Health, India
The National Health Sciences Research Committee, *National Guidelines for the Conduct of Health Research in Malawi (2007),* Malawi
The American Anthropological Association Code of Ethics, USA
Social Research Association Ethical Guidelines, (2003), (UK)
HIV/AIDS Research Strategy for Malawi (2005-2007), Malawi
Institutional Review Board Member Handbook (2003) by Robert Amdur
Government of Malawi, (2003), Science and Technology Act No. 16 of 2003
National Advisory Board on Research Ethics (2009) Helsinki
Economic and Social Research Council Research Ethics Framework

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What is the National Regulatory Requirement and Position on Accessing, Collection, Storage and Use of Human Biological Specimen for Research in Malawi?

- **Regulatory requirement and position**

The Government of Malawi has been embracing a State practice and a national regulatory position on the accessing, collection, storage and use of human biological specimen for research from the time of the establishment and existence of the then National Research Council of Malawi in 1974 to the present time of the existence of the National Commission for Science and Technology that has the legal mandate to nationally promote, co-ordinate and regulate research, science and technology as empowered by the S&T Act No.16 of 2003. The national regulatory requirement and position of State practice is defined in a number of instruments. **Sections 3.4.7 and 3.4.8** of the National Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi (2012) stipulate non permissible areas and forms of research actions related to collection, storage and use of human biological specimens in Malawi. Specifically, section 3.4.7 states that *"all forms of studies and testing aimed at collecting and storing human biological samples for future unspecified genetic research/analyses including any scientific retrospective analyses"* is **non permissible.** Similarly, section 3.4.8 stipulates that *"plans, attempts and requests for obtaining human biological/genetic material for future research"* is also non permissible. Within the regulatory ambit of the national jurisdictional mandate of the NHSRC, it is specifically stipulated in section 10 of the General Guidelines on Health Research in Malawi (2007) that *"researchers should not collect biological specimens that are not required to address the study objectives; tests on biological specimens should only be as described in the approved proposal; and specimens collected for a particular purpose should not be used for other purposes"*

The regulatory requirement on access, collection and use of human biological samples for research has a legislative anchorage as lawfully made under **sections 18 and 48** of the said S&T Act. Stakeholders including researchers are obliged to adhere to this regulatory requirement without let or hindrance.

- **Regulatory interpretation, application and guidance**

The regulatory requirement stated above is self-explanatory. The regulatory requirement permits the access, collection, storage and use of biological samples **but only for a presently defined research study whose protocol clearly describes the study objectives, methodologies and other testing procedures after obtaining an informed consent. Thus, human biological samples/specimens are only allowed to be accessed, collected and used for tests/analyses necessary and required to answer objective(s) of a particular research study which has presently been approved. It is not permitted in Malawi to consent participants to collection, use and storage of specimens for future use, be it for future research or any other purposes.**

Similarly, specimens collected for one clearly defined and approved study are not allowed to be used for another research study nor for any other research purpose other than for tests/analyses required to answer objectives of a particular presently intended study for which initial approval is made. Thus, researchers are only **allowed** to administer consent to participants to collect specimens for purposes of only answering the study objectives of a presently intended study that has been clearly defined and for which approval is being sought. In the case of accessing and collecting cadaveric tissues/samples **for a presently clearly defined research study**, the relevant provisions contained in the Anatomy Act (1991) must be adhered to.

Any samples to which participants had been consented for future use remain **null and void** because an action to request potential participants to consent to storage for future use is a regulatory violation, and no committee must have approved such a consent form. Such samples are to be discarded and destroyed.

- **Period of storage**

Depending on the nature of the approved research study, samples can spontaneously be analysed or can be stored for analysis at a later date. Samples that can be stored for testing/analysis at a later date for purposes of answering study objectives of the presently approved study protocol can be kept for the maximum of the initial five year period during which all tests/analyses approved for that particular study should be concluded. In the case of certain studies that may require storage of samples longer than the initial five year period in order to perform the analyses/tests for which a particular study was authorised, approval from the ethics committee that originally approved that study shall be sought for renewal of storage for a further equal period, following a sound justification by the researcher that an ethics committee may consider, **otherwise specimens are required to be discarded and safely destroyed immediately after all the tests/analyses aimed at answering the objectives of a particular study are done.**

- **Material Transfer Agreement (MTA)**

Primarily, testing/analysis of samples in order to answer the objectives of a clearly and presently defined study for which the samples have been collected is required to be done locally within Malawi so as to promote local capacity building and transfer of technology. There are, however, restricted circumstances and reasons where there might be a justifiable need to perform analyses/tests beyond the Malawi borders. Such circumstances would necessitate the transfer/exportation of the samples, subject to the provisions of any national relevant law. In which case, the researcher shall be required to apply for such a transfer under a material transfer agreement that shall be reviewed and approved by the committee undertaking the review. Exportation of specimens is considered a last resort. Thus, it is permissible in exceptional circumstances to export specimens especially where there is no technology available in Malawi to conduct the desired tests and such technology can not be imported into Malawi, or where further tests to adequately answer the study objectives are necessary to confirm the results. Under any allowable circumstances, the researcher shall be required to provide an adequate justification for material transfer under a MTA Form that is available within the approved SOPs of COMREC.

Cinquante unième Année | Numéro 03 | 15 Janvier 2010

JOURNAL OFFICIEL

DE LA

REPUBLIQUE DU MALI

TARIFS DES ABONNEMENTS			TARIFS DES INSERTIONS	OBSERVATIONS
	Un an	6 mois	La ligne.....400 F	Prix au numéro de l'année courante.....500F Prix au numéro des années précédentes.....600F
Mali .....20.000 F		10.000 F	Chaque annonce répétée.....moitié prix	Les demandes d'abonnement et les annonces doivent être adressées au Sécrétariat Général du Gouvernement-D.J.O.D.I.J
Afrique.....35.000 F		17.500 F	Il n'est jamais compté moins de 2.000 F pour les annonces.	Les abonnements prendront effet à compter de la date de paiement de leur montant. Les abonnements sont payables d'avance.
Europe.....38.000 F		19.000 F		
Frais d'expédition.....13.000 F				

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ACTES DE LA REPUBLIQUE DU MALI

PRESIDENCE DE LA REPUBLIQUE

LOIS

LOI N°09-059/ DU 28 DECEMBRE 2009 REGISSANT LA RECHERCHE BIOMEDICALE SUR L'ETRE HUMAIN

L'Assemblée Nationale a délibéré et adopté en sa séance du 15 décembre 2009 ;

Le Président de la République promulgue la loi dont la teneur suit :

TITRE I : DES DISPOSITIONS GÉNÉRALES

CHAPITRE I : DE L'OBJET ET DU CHAMP D'APPLICATION

ARTICLE 1ER : La présente loi régit la recherche biomédicale sur l'être humain.

Les dispositions de la présente loi s'appliquent aux recherches sur les personnes vivantes, les embryons et fœtus, le matériau biologique d'origine humaine, les renseignements personnels identifiables, les cadavres, les embryons ou fœtus issus d'interruptions de grossesses ou d'avortement spontanés et les enfants mort-nés.

CHAPITRE II : DES DÉFINITIONS

ARTICLE 2 : Au sens de la présente loi, on entend par :

Comité de recherche : Un centre agréé par le Ministre en charge de la santé pour un ou plusieurs types de recherche biomédicale.

Comité institutionnel d'éthique : Comité d'éthique prévu dans les textes organiques d'une institution nationale de recherche.

Comité national d'éthique : Comité créé au niveau national ayant pour missions d'instruire les dossiers de recherche biomédicale sur le plan éthique, sur sa propre initiative, sur demande du Président de la République, du Premier ministre, d'un membre du Gouvernement, des Présidents d'institutions ou des Présidents des fondations et ONG reconnues d'utilité publique et des investigateurs de recherche.

Coordinateur de recherche : Personne physique ayant la charge de coordonner les actions des investigateurs travaillant sur le même projet et dans des centres différents.

Institution de recherche : Toute structure spécialisée, disposant de la personnalité morale, dont la mission est de promouvoir et de conduire la recherche biomédicale.

Investigateur de recherche : Personne physique ayant la charge de diriger et de surveiller la réalisation du projet de recherche du Promoteur, qui est habilitée en vertu de la loi malienne. Il faut un investigateur principal par projet de recherche.

Promoteur : Personne physique ou morale, établissement ou organisme qui initie et finance un projet de recherche sur l'être humain.

Recherche biomédicale : Tout essai ou expérimentation clinique, biologique ou chirurgical organisé et pratiqué sur l'être humain en vue du développement des connaissances biologiques ou médicales.

Recherche avec bénéfice direct : Recherche censée apporter un bénéfice direct à la personne qui s'y prête. Elle est aussi appelée recherche à finalité directe.

Recherche sans bénéfice direct : Recherche censée n'apporter aucun bénéfice direct à la personne qui s'y prête. Elle est aussi appelée recherche sans finalité directe. Elle peut augmenter les connaissances dans un domaine biomédical, avec une possibilité d'application à moyen et long terme.

Renseignements personnels identifiables : Les renseignements relatifs à une personne qui permettent de l'identifier ou de la réidentifier par une combinaison d'identificateurs indirects (tels que la date de naissance, le domicile ou des caractéristiques personnelles uniques).

TITRE II : DES CONDITIONS DE LA RECHERCHE BIOMÉDICALE SUR L'ÊTRE HUMAIN

ARTICLE 3 : Aucune recherche biomédicale ne peut être effectuée sur l'être humain à moins que les conditions suivantes soient réunies :

- la recherche est fondée sur le plan scientifique et est clairement décrite dans un protocole ;

- les renseignements disponibles d'ordre préclinique et clinique sont suffisants pour justifier la tenue de la recherche projetée ;

- le risque prévisible encouru par les personnes qui se prêtent à la recherche est hors de proportion avec le bénéfice escompté pour ces personnes ou l'intérêt de cette recherche ;

- elle vise à étendre la connaissance scientifique de l'être humain et les moyens susceptibles d'améliorer sa condition ;

- elle est autorisée sous le régime de la présente loi.

ARTICLE 4 : Les recherches biomédicales ne peuvent être effectuées que :

- sous la direction et sous la surveillance d'un investigateur justifiant une formation et d'une expérience appropriée ;

- dans des conditions matérielles et techniques adaptées à l'étude et compatibles avec les impératifs de rigueur scientifique et de sécurité des personnes qui se prêtent à ces recherches.

ARTICLE 5 : Les recherches sans bénéfice individuel direct sur les femmes enceintes ou qui allaitent ne sont admises que si elles présentent un équilibre des avantages et des préjudices favorables pour la femme et son embryon, son fœtus ou son enfant.

ARTICLE 6 : Les personnes privées de liberté ne peuvent être sollicitées pour se prêter à des recherches biomédicales que s'il en est attendu un bénéfice direct et majeur pour leur santé.

ARTICLE 7 : Les mineurs, les majeurs sous tutelle, les personnes séjournant dans un établissement sanitaire ou social et les malades en situation d'urgence ne peuvent être sollicités pour une recherche biomédicale que s'ils peuvent en profiter individuellement ou collectivement.

Toutefois, les recherches sans bénéfice individuel direct sont admises si les trois conditions suivantes sont remplies :

- ne présenter aucun risque sérieux prévisible sur leur santé ;

- être utiles à des personnes présentant les mêmes caractéristiques d'âge, de maladie ou de handicap ;

- résultats ne pouvant être réalisés autrement.

ARTICLE 8 : Pour les recherches biomédicales sans bénéfice individuel direct, le promoteur assume, même sans faute, l'indemnisation des conséquences dommageables de la recherche pour la personne qui s'y prête, sans que puisse être opposé le fait d'un tiers ou le retrait volontaire de la personne qui avait initialement consenti à se prêter à la recherche.

Pour les recherches biomédicales avec bénéfice individuel direct, le promoteur assume l'indemnisation des conséquences dommageables de la recherche pour la personne qui s'y prête, sauf preuve à sa décharge que le dommage n'est pas imputable à sa faute ou à celle de tout intervenant sans que puisse être opposé le fait d'un tiers ou le retrait volontaire de la personne qui avait initialement consenti à se prêter à la recherche.

Pour toute recherche biomédicale sur l'être humain, le promoteur souscrit une assurance garantissant sa responsabilité civile telle qu'elle résulte du présent article et celle de tout intervenant, indépendamment de la nature des liens existant entre les intervenants et le promoteur.

Les dispositions du présent article sont d'ordre public.

ARTICLE 9 : La recherche biomédicale ne donne lieu à aucune contrepartie financière directe ou indirecte pour les personnes qui s'y prête, hormis le remboursement des frais exposés et sous réserve de dispositions particulières prévues.

Toutefois, en cas de bénéfice commercial d'une recherche, des ristournes doivent être négociées pour la communauté objet de l'étude.

TITRE III : DES MODALITES ET PROCEDURES DE RECHERCHE BIOMEDICALE

ARTICLE 10 : Préalablement à la réalisation d'une recherche biomédicale sur une personne, le consentement libre, éclairé et exprès de celle-ci doit être recueilli après que l'investigateur, ou le médecine qui le représente, lui ait fait connaître :

- l'objectif de la recherche, sa méthodologie et sa durée ;

- les bénéfices attendus, les contraintes et les risques prévisibles, y compris en cas d'arrêt de la recherche avant son terme ;

- l'avis d'un comité d'éthique agréé.

Il informe la personne dont le consentement est sollicité de son droit de refuser ou de participer, à une recherche ou de retirer son consentement à tout moment sans encourir aucune responsabilité, sans nuire à la qualité scientifique globale des résultats.

A titre exceptionnel, lorsque dans l'intérêt d'une personne malade, le diagnostic de sa maladie n'a pu lui être révélé, l'investigateur peut, dans le respect de la confidentialité et de l'anonymat, réserver certaines informations liées à ce diagnostic.

Dans ce cas, le protocole de la recherche doit mentionner cette éventualité. Les informations communiquées sont résumées dans un document écrit remis à la personne dont le consentement est sollicité.

Le consentement est donné par écrit, ou en cas d'impossibilité, attesté par un tiers.
Ce dernier doit être totalement indépendant de l'investigateur et du promoteur.

Le consentement peut aussi être enregistré ou filmé.

ARTICLE 11 : En cas de recherche biomédicale à mettre en œuvre dans des situations d'urgence qui ne permettent pas de recueillir le consentement préalable de la personne qui y sera soumise, le protocole présenté à l'avis d'un comité d'éthique agréé peut prévoir que le consentement de cette personne ne sera recherché et que seul sera sollicité celui de ses proches, s'ils sont présents, dans les conditions prévues ci-dessus.

L'intéressé sera informé dés que possible et son consentement lui sera demandé pour la poursuite éventuelle de cette recherche.

ARTICLE 12 : Lorsqu'une recherche biomédicale est effectuée sur des mineurs ou sur des majeurs interdits avec bénéfice individuel direct ou sans bénéfice individuel direct, ne présentant pas de risque prévisible sérieux, le consentement doit être donné par leurs représentants légaux.

ARTICLE 13 : Avant de réaliser une recherche sur l'être humain, tout investigateur est tenu d'en soumettre le projet à l'avis d'un comité scientifique et d'un comité d'éthique agréé.

Le Comité scientifique donne son avis sur la validité scientifique du protocole de recherche.

Le Comité d'éthique donne son avis sur les conditions de validité de la recherche, notamment la protection des participants, leur information et les modalités de recueil de leur consentement, les compensations éventuellement dues, la pertinence générale du projet et l'adéquation entre les objectifs poursuivis et les moyens mis en œuvre ainsi que la qualification du ou des investigateurs. Il communique au Ministre chargé de la santé tout avis favorable ou défavorable donné à un projet de recherche en fonction du niveau de la recherche et de l'intérêt national.

Avant sa mise en œuvre, le promoteur ou l'investigateur principal transmet au Ministre chargé de la santé une demande décrivant les données essentielles de la recherche, accompagnée de l'avis du ou des comités consultés. Cet avis ne le dégage pas de sa responsabilité.

Lorsque la recherche doit se dérouler dans un ou plusieurs établissements publics ou privés, le promoteur ou l'investigateur principal en informe le ou les directeurs de ces établissements avant que cette recherche ne soit mise en œuvre.

Le promoteur informe, dès qu'il en a connaissance, le Comité national d'éthique, le ministre chargé de la santé, de tout effet ayant pu contribuer à la survenue d'un décès, provoqué une hospitalisation ou entraîné des séquelles organiques ou fonctionnelles durables et susceptibles d'être dues à la recherche. Il l'informe également de tout arrêt prématuré de la recherche en indiquant le motif de cet arrêt.

ARTICLE 14 : Sous réserve de toute obligation éthique ou juridique de divulguer des renseignements confidentiels, les membres des comités, les personnes appelées à collaborer à leurs travaux et les agents de l'Etat qui en sont dépositaires sont tenus de garder secrètes les informations dont ils peuvent avoir connaissance en raison de leurs fonctions et qui sont relatives à la nature des recherches, aux personnes qui les organisent ou qui s'y prêtent ou aux produits, objets ou méthodes expérimentés.

Ne peuvent valablement participer à une délibération les personnes qui ne sont pas indépendantes du promoteur et de l'investigateur de la recherche examinée.
Les chercheurs doivent préserver la confidentialité des renseignements personnels concernant les participants à la recherche, sous réserve de toute obligation d'ordre éthique ou juridique de divulguer des renseignements confidentiels.

ARTICLE 15 : Les recherches biomédicales sans bénéfice individuel direct ne doivent comporter aucun risque prévisible sérieux pour la santé des personnes qui s'y prêtent. Elles doivent être précédées d'un examen médical des personnes concernées. Les résultats de cet examen leur sont communiqués par l'intermédiaire de l'investigateur principal.

ARTICLE 16 : Dans le cas d'une recherche sans bénéfice individuel direct à l'égard des personnes qui s'y prêtent, le promoteur verse à ces personnes une indemnité en compensation des contraintes subies. Le montant total des compensations qu'une personne peut percevoir au cours d'une même année est limité à un maximum fixé par le comité d'éthique agréé.

ARTICLE 17 : Les inspecteurs de la santé, la Direction de la Pharmacie et du Médicament et les membres du comité d'éthique agréé, ont qualité pour veiller au respect des dispositions de la présente loi et des textes règlementaires pris pour son application.

ARTICLE 18 : Les renseignements relatifs à la recherche doivent être consignés dans des registres, traités et conservés de façon à permettre la présentation de rapports complets et exacts sur la recherche ainsi que son interprétation et sa vérification.

Ces renseignements doivent être disponibles chez l'organisme qui a commandité la recherche et chez le chercheur.

TITRE IV : DES INTERDICTIONS ET SANCTIONS

ARTICLE 19 : Nul ne peut se prêter simultanément à plusieurs recherches biomédicales qui pourraient nuire à sa santé ou aux résultats de la recherche.

Pour chaque recherche, le protocole soumis à l'avis consultatif du comité scientifique et du comité d'éthique agréé détermine une période d'exclusion au cours de laquelle la personne qui s'y prête ne peut participer à une autre recherche. La durée de cette période varie en fonction de la nature de la recherche.

ARTICLE 20 : Les recherches biomédicales ne peuvent être réalisées que par une équipe compétente, dans un lieu équipé de moyens matériels et techniques adaptés à la recherche et compatibles avec les impératifs de sécurité des personnes qui s'y prêtent.

ARTICLE 21 : Le fait de pratiquer ou de faire pratiquer sur une personne, une recherche biomédicale sans avoir accueilli le consentement de la personne ou de ses représentants légaux dans les conditions prévues par la présente loi est puni de :

- Un (01) à trois (03) ans d'emprisonnement et de 300 000 à 1 000 000 de francs d'amende ou de l'une des deux peines seulement et l'interdiction, pour une durée de cinq ans au plus, d'exercer l'activité professionnelle ou sociale à l'occasion de laquelle ou dans l'exercice de laquelle l'infraction a été commise pourra être prononcée.

- S'il en est résulté une mutilation, amputation, privation de l'usage d'un membre ou d'un sens, perte de l'œil ou autres infirmités ou maladie, la peine sera de cinq à dix ans de réclusion criminelle et l'interdiction d'exercer l'activité professionnelle ou sociale à l'occasion de laquelle l'infraction a été commise pourra être prononcée.

- En cas de décès le coupable sera puni de la réclusion criminelle à vie et l'interdiction d'exercer l'activité professionnelle ou sociale à l'occasion de laquelle l'infraction a été commise doit être prononcée.

Les dispositions du Code Pénal sont applicables s'agissant de la complicité, de récidive et des circonstances atténuantes.

ARTICLE 22 : Quiconque entreprend une recherche sans autorisation du Ministre de la Santé est puni de cinq à dix ans d'emprisonnement, sans préjudice de la fermeture temporaire ou définitive de l'établissement de recherche.

ARTICLE 23 : Le promoteur dont la responsabilité civile n'est pas garantie par l'assurance prévue à l'article 8 de la présente loi est puni d'un emprisonnement de un à six mois et d'une amende de 300 000 à 1 000 000 de francs ou de l'une de ces deux peines seulement.

Le promoteur qui réalise ou fait réaliser une recherche biomédicale sans avoir transmis au Ministre chargé de la santé la demande prévue à l'article 13 de la présente loi est puni des mêmes peines.

ARTICLE 24 : Le Ministre chargé de la santé peut, à tout moment, en cas de risque pour la santé publique ou de non respect des dispositions de la présente loi, suspendre ou interdire une recherche biomédicale.

TITRE V : DES DISPOSITIONS FINALES

ARTICLE 25 : Un décret pris en Conseil des Ministres fixe les modalités d'application de la présente loi.

Bamako, le 28 décembre 2009

Le Président de la République,
Amadou Toumani TOURE

LOI N°09-060/DU 28 DECEMBRE 2009 PORTANT MODIFICATION DE LA LOI N°08-051 DU 29 DECEMBRE 2008 PORTANT LOI DE FINANCES POUR L'EXERCICE 2009.

L'ASSEMBLÉE NATIONALE A DÉLIBÉRÉ ET ADOPTÉ EN SA SÉANCE DU 16 DÉCEMBRE 2009 ;

LE PRÉSIDENT DE LA RÉPUBLIQUE PROMULGUE LA LOI DONT LA TENEUR SUIT :

ARTICLE UNIQUE : Les dispositions des articles 3, 4, 5, 6, 7, 12, 14, 28 et 33 de la Loi N°08-051 du 29 décembre 2008susvisée sont modifiée ainsi qu'il suit :

CHAPITRE I : LES RESSOURCES

ARTICLE 3 (Nouveau) : Les ressources du Budget de l'Etat sont évaluées comme suit :

Budget Général	1 014 542 104 000
* Budget National	701 271 000 000
* Budget Spécial d'Investissement	257 629 000 000
* Appui budgétaire	55 642 104 000

CHAPITRE III : CONDITIONS GENERALES DE L'EQUILIBRE FINANCIER

ARTICLE 12 (Nouveau) : Le montant du déficit s'élève à CENT VINGT SEPT MILLIARDS TROIS CENT TROIS MILLIONS NEUF CENT VINGT ET UN MILLE (127 303 921 000) FCFA. Et

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GUIDELINES OF ETHICS FOR HEALTH RESEARCH IN TANZANIA

Prepared by the National Health Research Ethics Committee

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DEDICATION

This work is dedicated to all persons and animals that have been involved and will continue to be involved in health research either as human subjects or as experimental animals in the search for new knowledge for the better care of mankind.

FOREWORD

Guidelines on Ethics for Health Research in Tanzania
(Second Edition, 2009)

FOREWORD

Once again, Professor Yohana Mashalla is to be congratulated for the commendable work that he has done in revising and upgrading this very important document relating to health research, the Guidelines on Ethics for Health Research in Tanzania. Among the most useful additions to the First (and very popular) Version of 2001 is the inclusion of sections on i) a wide range of important Definitions of Health Research Terminologies, ii) Socio-cultural Factors in Health Research, and iii) the increasing number of categories of Vulnerable People in the community, with a timely caution on undue reliance on research protocols emanating from developed countries for 'exclusive' use in developing countries.

May I also take this opportunity to extend our appreciation to other members of the TANHER Forum Ethics Editorial Task Force, Dr Andrew Kitua and Dr Godwin Ndossi, and others, for their valuable inputs that have helped to enrich this document, since it was first published in 2001.

As with the first version of the Ethical Guidelines, I have no hesitation in warmly recommending this Second Version to all its users, ranging from health researchers themselves to health trainees and practitioners and also to health policy makers and administrators at all levels.

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PREFACE

This is the first publication of guidelines on research ethics by the National Health Research Ethics Committee. It aims at providing health researcher in Tanzania with guidelines that will assist them to carry out health research in accordance with accepted ethical standards and norms.

Health research has in recent years become a subject of great interest and attracts funding from both local as well as international collaborators. There is a growing trend for health research in developing counties to rely on protocols that have been developed elsewhere. Researchers in these countries have sometimes engaged themselves in researches over which they have no control, and the utilization of which have no relevance to their own countries. Such reseats have triggered concern in the sense of physical or psychological harm. With increasing categories of vulnerable people in the community e.g. pregnant women, street children, prisoners, orphans and detainees, refuges, PLWA and AIDS patient, the need for guidelines on health research has become even more pressing.

In preparing these Guidelines, special attention was given to socio-cultural factors that are pertinent to Tanzania. At the same time the Editorial Board wisely decided not to re-invent the wheel. Therefore, cross-reference was made to a number of excellent reports; Special gratitude is given to the Royal College of Physicians of London, the BMA, CMA, MAT CIOMS, WMA, the SAMRC and the Code of Federal Regulations ICH Guidelines whose publications formed the basis for these guidelines. It is anticipated that the guidelines will find a place in research and training institutions, as well as the hospitals, in Tanzania. The process of establishing useful ethical guidelines is dynamic and requires more inputs so that it can continuously be tailored to fit the needs of a dynamic environment. In this edition, the scope and descriptions have been expanded to make the document much more reader friendly.

It is now my privilege to thank all members of the National Health Research Ethics Committee, as well as member of the special Forum Editorial Task Force for their dedication and hard work. Without their commitment, this exercise would not have been possible.

A very special word of thanks goes to members of the Editorial Board, the National Institute for Medical Research, Tanzania Food and Nutrition Centre and the Tanzania Commission for Science and Technology for their continued support. I sincerely also wish to thank those whose thoughts have in one way or another enriched this document, many thanks to all of you. Finally, my sincere appreciation are directed to EDCTP for providing financial support which enabled the revision of the previous national guidelines into the current state.

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
BMA	British Medical Association
CIOMS	Council for International Organizations of Medical Sciences
CMA	Commonwealth Medical Association
COHRED	Council on Health Research for Development
COSTECH	Commission for Science and Technology
EDCTP	European and Developing Countries Clinical Trial Programme
FRCS	Fellow of the Royal College of Surgeons
GMC	General Medical Council
HIV	Human Immunodeficiency Virus
HRUTF	Health Research Users Trust Fund
ICRIA	Institutional Committee for Research Involving Animals
IREC	Institutional Research Ethics Committee
MAT	Medical Association of Tanzania
MB ChB	Bachelor of Medicine and Bachelor of Surgery
MD	Doctor of Medicine
MRCC	Medical Research Coordinating Committee
NHRCC	National Health Research Coordinating
NHREC	National Health Research Ethics Committee
NIMR	National Institute of Medical Research
PhD	Doctor of Philosophy
PLWA	People Living with AIDS
RCT	Randomized Controlled Trials
SAMRC	South African Medical Research Council
TANHER	Forum Tanzania National Health Research Forum
TDR	Special Programme for Research and Training in Tropical Diseases
TFNC	Tanzania Food and Nutrition Centre
WMA	World Medical Assembly

DEFINITIONS

The primary objective of this section is to introduce readers, researches and the general populations to the meaning of the terms as well as providing a common understanding for easy communication and reference. In this document, unless stated otherwise:

(i) Adverse event

Is an untoward medical occurrence in a participant in a clinical trial administered a pharmaceutical product and that does not necessarily have a causal relationship with the treatment. An Adverse event can therefore be any unfavourable and unintended sign, symptom or disease temporarily associated with the use of a pharmaceutical product, whether or not related to the pharmaceutical product.

(ii) Applicable regulatory requirement(s)

Applicable regulatory requirement(s) is any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products of the jurisdiction where trial is conducted.

(iii) Biomedical Research

Biomedical research may be defined as activities involving subjects undertaken with the prime objectives of testing a hypothesis and permitting conclusion to be drawn for the purpose of contributing to medical knowledge. The spectrum of biomedical research is such that on one end it consists of studies of analysis of identifiable or non-identifiable data without any subject/ patient contact, or change in medication. On the other end of spectrum, there are studies that involve changing a patient from a proven treatment to a different regime but the benefit and risks of which are not fully known. Biomedical research may either be "Therapeutic" or "Non-therapeutic" in nature.

(iv) Children

Children means persons who have not attained the legal age for consent to treatments or procedures involved in clinical trials, under the applicable law of the jurisdiction in which the clinical trial will not be conducted.

(v) Clinical trial

Clinical trial means any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmaco-dynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the primary objective of ascertaining its safety and/or efficacy. In most cases the terms clinical trial and clinical study are used interchangeably.

(vi) Closed system

Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic documents that are on the system.

(vii) Confidentiality

Confidentiality is the prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

(viii) Digital signature

Digital signature means an electronic signature based upon cryptographic method of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

(ix) Data Safety and Monitoring Board

Data Safety and Monitoring Board is an independent Board or Committee that may be established by the sponsor to assess at intervals the progress of implementation of

a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a clinical trial.

(x) Electronic document/record

An electronic document/record means any combination of text, graphic, data, audio, pictorial or other information representation in digital form that is created, modified, archived, retrieved or distributed by a computer systems.

(xi) Electronic signature

An electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(xii) Flawed research

Flawed research is defined as an imperfect research that contains mistakes either in the design, planning implementation, interpretation or dissemination of the research results.

(xiii) Foetus

Foetus means the product of conception from implantation until delivery. A nonviable foetus means a neonate after delivery that although living, is NOT viable. A viable neonate however, means, a foetus after delivery being able to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beats and respiration.

(xiv) Guardian

Guardian means an individual who is authorized under applicable local law to consent on behalf of a child to general medical care when general medical care includes participation in research. It also means an individual authorized to consent on behalf of a child to participate in a clinical trial or research.

(xv) Hand written signature

Hand written signature means the scripted name or legal mark of an individual hand written by that individual and executed or adopted with the present intention to authenticate writing in a permanent form. The act of signing with a writing or marking instrument, such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(xvi) Healthy volunteers

"Healthy volunteers" are defined as individuals who do not suffer from any significant illness relevant to the proposed study. Individuals who are temporarily "healthy" but they are only on a remission from a relapsing condition cannot be considered healthy volunteers for a study related to that condition.

(xvii) Human subject

A human subject is an individual who is or becomes a participant in research, either as a recipient of the test product or as a control. A subject may either be a healthy human or a patient.

(xviii) Informed consent

Is a process by which an individual voluntarily confirms his or her willingness to participate in particular trial, after having been informed of all aspects of the research that are relevant to the individual's decision to participate. Informed consent is documented by means of a written, signed and dated consent form.

(xix) Innovative Treatment

Is a procedure where for specific reasons pertinent to a specific patient, the clinician digresses from what is accepted as normal practice. The primary objective of innovative treatment is to provide alternative treatment to the patient.

The responsibility for deciding and employing, innovative treatment lies entirely on the clinician. When the digression is small and designed merely to deal either the

particular circumstances of an individual patient, it is wise to consider an extension of the treatment. However, when a major digression is being considered for regular use, while it has not been approved for medial practice, the innovation should become subject of formal research so that its true worth can be evaluated. In the eyes of may people, therefore, innovative treatment straddle the gap between research and medical practice.

(xx) Institution

An institution means any public or private entity or agency or medical, dental or non-medical or dental facility where clinical trials or health research are conducted.

(xxi) Institutional Ethics Review Committee

An Institutional Ethics Review Committee means a board or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. In these guidelines, the term carries the same meaning as Institutional Review Board.

(xxii) Investigator/researcher

The investigator/researcher means an individual who actually conducts an investigation i.e. under whose immediate direction the test product is administered or dispensed to, or used involving, a subject, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(xxiii) Legally acceptable Representative

A legally acceptable representative is an individual or juridical or other body authorized under applicable law(s) to consent on behalf of a prospective subject, to the subject's participation in a clinical trial or any other health research.

(xxiv) Medical practice

Medical practice means the practice of physicians in the course for diagnosis, prescription of, and administration treatment of patients or non-sick individuals in clinics and bedside.

(xxv) Minimal risk

Minimal risk mean that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or investigations.

(xxvi) Monitoring

Monitoring is the process of overseeing the progress of implementation of a clinical trial or health research and of ensuring that it is conducted, recorded and reported in accordance with the approved protocol/proposal, standard operating procedures (SOPs), and the applicable regulatory requirement(s).

(xxvii) Multi-centre trial

Is a clinical trial or any other health research conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator and institutions.

(xxviii) Neonate

A neonate means a newborn.

(xxix) Non-therapeutic research

Is defined as activities or treatment whose prime objective is to extend knowledge about a particular condition in such a manner that the benefits are for the future. It may either involve healthy volunteers or patient and is carried out with the purpose of testing a hypothesis and contributing to the knowledge.

(xxx) Open system

An open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic documents/records that are not on the system.

(xxxi) Patients

"Patient" in the research context is defined as individuals with a known illness and has been recruited in the research study because of any of the following:

- Have sought medical attention,
- Have a known illness or disability of interest to the research,
- Form a control group of subject suffering from an illness which is not of interest to the proposed study.

(xxxii) Permission

Permission in the context of the guidelines means the agreement of parent(s) or guardian to the participation of their child in clinical trial.

(xxxiii) Pregnancy

Pregnancy encompasses the period of time from implantation until delivery. A woman shall be considered to be pregnant if she exhibits any pertinent presumptive signs of pregnancy, such as missed menses, until the results of al pregnancy test are negative or until delivery.

(xxxiv) Prisoner

Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to include individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentence.

(xxxv) Protocol

A protocol is a document that describes the summary (abstract), background, rationale, objective(s), design, methodology, statistical considerations, and organization of a clinical trial or health research. Occasionally the terms protocol and proposal are used interchangeably.

(xxxvi) Protocol/proposal amendment

Protocol/proposal amendment is a written description of a change or changes made to or formal clarification of the original protocol or proposal(s).

(xxxvii) Randomization

Randomization is a process of assigning trial/research subjects to treatment or control groups by using an element of chance to determine the assignment in order to reduce bias.

(xxxviii)Sponsor

Sponsor means a person who initiates a clinical trial, but who does not actually conduct the investigation, i.e. the test product is administered or dispensed to or used involving, a subject under the immediate direction of another individual.

(xxxix) Standard Operating Procedures (SOPs)

Standard Operating Procedures are detailed, written instructions aimed at achieving uniformity in the performance of a specific function.

(xl) Student

A student is defined as a pupil or any person admitted to a primary or secondary school, tertiary institution, college or university for the purpose of acquiring primary, secondary, technical or university education in Tanzania or any other institution to which a researcher has direct or indirect control.

(xli) Test product

A test product means any drug (including a biological product for human use), medical device for human use, human food additive, colour additive, electronic product, or any other product subject to TFDA Act.

(xlii) ***Therapeutic research***

The world Medial association first published its Code of Ethics on Human experimentation the Helsinki Declaration in 1964 and modified it in 1975. *The Ethical Code states that;* "In the field of biomedical research a fundamental distinction must be recognized between medical researches in which the aim is essentially diagnosis or therapeutic for a patient, and medical research, the essential object of which is purely, scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research". Therefore, therapeutic research means research intended to benefit a subject by establishing diagnosis and treatment.

(xliii) Vulnerable subjects

Vulnerable subjects in health research are individuals whose capacity and willingness to volunteer in a clinical trial or health research may be unduly influenced by the expectation(s), whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in the case of refusal to participate (e.g. student, military, subordinate staff, persons with incurable diseases, unemployed, patients in emergency situations, refugees, minors, impoverished persons and those incapable of giving consent).

(xliv) Well-being

The well-being of the trial subjects means the physical and metal integrity of the subjects participating in a clinical trial.

INTRODUCTION

Research or experimentation connotes a set of activities undertaken to test a particular hypothesis with the intention of drawing conclusions about a given unknown situation. Medical research specifically refers to the scientific investigations carried out for the purpose of contributing to medical knowledge. It is the means by which 'scientists discover new knowledge that may lead to the prevention or treatment or even elimination of certain categories of disease and disability' (CIOMS, 1993).

Confusion sometimes arises from the wide range of procedures covered under the term 'medical research'. In defining medical research, a distinction has to be made between research that consist of analysis of identifiable or non-identifiable data without any patient contact or change of medication, and research that involves changing a patient from one regimen of known benefits (efficacy) to one the benefit and risks of which are not fully known. With increasing diversity in the health profession and involvement of social scientists in health related studies, the term 'Health Research' is now increasingly becoming more acceptable than "medical" or "biomedical research"

The history of human experimentation is ancient and for centuries, society's attitude to medical research had been very positive. In the 18th century, convicted prisoners of Newgate jail volunteered for medical experimentation in exchange for their freedom. In recent years people living with HIV/AIDS (PLWA), women, homosexuals, cigarette smokers and other groups have sought to be included in medical studies mostly in anticipation of finding relief of suffering, prolongation of life, getting cured from their disease conditions and/ or, in a few cases, simply to contribute to the advancement of medical knowledge.

However, this positive attitude changed following the Second World War, when it became clear that Nazi research physicians committed atrocities in the concentration

camps in the name of medical research. This raised serious world concern and led to the formulation of the first international code of ethics, the Nuremberg Code, for research involving human subjects. Subsequently two other guidelines namely, the Declaration of Helsinki (Declaration) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Guidelines) have been formulated and implemented worldwide. The Declaration was formulated by the World Medical Assembly (WMA) while the Guidelines were formulated by the Council for International Organizations of Medical Sciences (CIOMS). The CIOMS guidelines specifically related to the application of the Declaration, particularly in developing countries. In addition, many counties including developing countries have formulated country specific guidelines on ethics of biomedical research taking into account the country's, unique socio-cultural, political, economic, religious and moral factors.

Another development in the formulation of guidelines was the publication of a report in London in 1986 by the Royal College of Physicians on Research on Healthy Volunteers. The publication defined "healthy volunteers" and also described the risks associated with biomedical research and the possible safeguards for the volunteers, sponsors and Research Ethics Committee. Further development was made in 1990 when the London Royal College of Physicians published guidelines on Research Involving Patients. Development of such guidelines was pivotal to the future understanding of this importance of maintaining ethical standards in research involving human subject. The fundamental principle in all of the guidelines in the value placed on human life and the protection of the rights and welfare of all human subjects who participate in scientific experimentation.

Apart from medical students and nurses, the vast majority of health research or human experimentation are carried out in lay people who, as is the case in many developing counties are poor, illiterate and lack awareness of both civil and consumer rights. Moreover, the doctor-patient or researcher-subject relationship is still skewed in favour of the former. In Tanzania, the attitudes about the relation are

changing and research subjects and patients rightly expect both information and support. The fact that this is not easy for either side is well described by Faulder [7].

"Doctors do not like to confess about their own doubts and worries; indeed they regard such revelations as a sign of weakness, a threat to the patient's morale and a major offence against the canon of trust in the patient-doctor relationship. But who has established this canon of trust? And why is it that trust is almost uniquely in terms of patient's confidence in the doctors? Seldom do we hear about doctors trusting their patient. Trust between two people, if it is to mean anything must be reciprocal"

The sentiment expressed above underscore the importance of mutual between the health professionals and patients or research subjects who in may cases, will not accept to participate in research if they feel suspicious about consent. Veracity is therefore, an essential element especially in the complex undertaking involving human experimentation. The problems associated with telling truth include that of undermining the subject's morale and confidence, or introducing difficult decision at a vulnerable time. On the other hand, evidence suggests that uniformed subjects may also be alarmed, anxious and subject to considerable stress, balance between these two opposing feelings is crucial in cultivating trust between researcher and the human subject.

Tanzania has a number of training and research institutions that carry out research on a variety of national health research priority areas. Due to the phenomenon of globalization and given the pace at which medical science and technology is changing, health researchers are constantly exposed to new ethical dilemmas, and in some cases, those dilemmas are in direct conflict with their professional ethics. It is the opinion of the National Health Research Forum that researchers of today in Tanzania need to be thoroughly grounded and guided in the health related components of human rights and ethics for them to be able to analyze the complex issues raised by the political, socio-economic and cultural changes in society. The

purpose of the National Health Research Ethic Guidelines is to provide guidance to researchers and other stakeholders on how to balance between the rights of individuals and the need of the society within the context of health research.

CHAPTER ONE

1.1 RATIONALE FOR HEALTH RESEARCH GUIDELINES

As earlier stated, Tanzania is one of the poor countries in the world still fighting poverty, illiteracy and diseases. Unlike in the developed world, the Tanzania people still have communicable diseases contributing significantly to the burden of diseases. Currently, unlike in the past, there is an increasing trend of non-communicable diseases. The prevalence of diabetes, cardiovascular accidents, hypertension, occupational diseases etc are more than a decade ago. Care must therefore be taken to ensure that such vulnerability is not exploited.

The need for research involving human subjects has for years been beyond argument. This is because researches on human subjects provide knowledge on the physiology and psychology of disease pattern. In addition, there are situations where there is no evidence of studies and results from experimental animals, the drugs need to be tested in human subjects to determine efficacy and safety.

Research in healthy volunteers has advantages in that physiological variations are likely to be minimal and the response more uniform. However, research in the patients must be carried out in the best interest of the patient although the individual patient may not benefit from the research. The society on the other hand may in the future benefit from the research results.

It is now generally accepted that it is unethical to use healthy individuals on a trial of a drugs with known side effects within therapeutic closed. However, in trials involving drugs with known side effects, it is better that the drug is tried first in patients suffering from a known illness, who are more likely to benefit from the trial.

In addition, since WMA prescribed guidelines on Biomedical Research; there has always been good concern for flawed research involving human subjects because flawed researches have continued to be reported even in recent years. Therefore,

there is a need for any country to put in place guidelines and regulations that will safeguard the interests of research participants during research.

The need for achieving good standards has prompted many countries to develop guidelines and regulation for safeguarding the interests of research participants. This stems from the fact that the apprehension of patient and societies about biomedical research is justified. Therefore, society and professionals must concentrate on building an ethical framework that will permit research activities to progress, but at the same time, maintain public confidence that individual autonomy is respected.

1.2 Machinery for approving and monitoring health research

A pre-requisite to achieving good standards is by ensuring that there is a well functioning and efficient system of regulating and monitoring the conduct of research, and reporting, is in place at all levels.

1.2.1 Research Ethics Committees

Worldwide, National, Institutional or Local Research Ethics Committees exist and have the responsibilities of monitoring the research conduct and approving health research proposals for ethical clearance. In Tanzania, most institutions that engage in health research have established Institutional Research Ethics Committee (IRECs). The IRECS are appointed by Appointing Authorities in the institutions and the sizes of the committees vary significantly. A sizable committee consisting of up to twelve members would be most appropriate. The WHO Guideline, (2000) stipulates that a minimum should be five members. Unfortunately, most IRECS are challenged by a number of problems making them unable to function according to their terms of reference. The problems facing IRECS range from lack of funds, training, competence, independence to practice, clear job description and the more serious lack of legal backing. In 1983, the BMA drew up guidelines on what was to be considered in ideal composition of Local Research Ethics Committees. There was general agreement that committees should have:

(i) Gender balance so that both men and women are well represented;
(ii) Senior as well as junior members of the profession;
(iii) Representative from the nursing profession;
(iv) A Pharmacologist;
(v) A Pharmacist or Pathologist;
(vi) A Lay member to represent the views of the community in general; and
(vii) A Chairman who is appointed from among committee members or in some cases appointed from among researchers in the institutions and holding the post for duration determined by the institution.

Subsequent studies in England have shown that most IRECs were dominated by doctors, while women and lay members of the society were under-represented. The general view should be that IRECs should have a separate panel of experts who could be co-opted when required to obviate the imbalances.

1.2.2 Institutional Ethics Research Committees (IRECs)

In 1991, the London Royal College of Physicians described the Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects. The primary objectives of the IRECs are to ensure that:

(i) Ethical standards in research are maintained;
(ii) Research subjects and research workers are protected from harm and any form of exploitation;
(iii) The rights and autonomy of research subjects are preserved;
(iv) The public is reassured that the research is being conducted in an acceptable manner and in the best interests of the community.

1.2.3 Function of IRECs

All research involving human subject must be subjected to IRECs for peer review. In reviewing the protocols, consideration should always be given to the following:

(i) Scientific quality of the protocol should be critically assessed. The proposed study should be designed with a view of obtaining what is considered to be the problem for study by involving as few as possible people who will be exposed to minimal risks as much as possible. It should be borne in mind that a poorly designed study, which might not yield scientifically desirable results, is unethical;

(ii) The objectives of the proposed study should be directed at advancing biomedical knowledge and in line with the prevailing community interests;

(iii) Competence of the investigator in terms of qualification, knowledge and experience in the area of the proposed study. Similarly, the competence in handling proposed research equipment and procedures and in ensuring that research subjects are protected from harm;

(iv) For all research proposals, there is adequate literature review on the proposed subject and that risks have been studied and measures for preventing risks have been clearly defined. A thorough literature review is essential to avoid duplication of what may have been studied already;

(v) Determine whether efforts have been made to ensure that prospective research subjects will adequately be provided with information on the aims, the methods, benefits and risks they are likely to be subjected to by agreeing to participate in the study;

(vi) Assess whether the procedure for seeking consent from prospective research subjects are adequately detailed and non-ambiguous. Also determine whether appropriate safeguard have been made to ensure that the rights of the participating subjects would not be abused;

(vii) Assess the proposed provisions for storage and handling of data and how subject-identifiable information will be used. Appropriate measures should be proposed to ensure confidentiality of all data generated in the course of the research;

(viii) Investigate research fraud and take appropriate or recommended to relevant authorities for immediate action where scientific fraud has been suspected or proved;

(ix) Offer Class Approvals to investigators who conduct multiple projects, which pose no, risks e.g. some projects in epidemiology or training. This will reduce repetitive submissions from the same researchers;

For effective operations, IRECs should hold meeting as frequently as possible as a strategy to facilitate fast ethical clearance and minimize complaints of delays; the Chairman may be given powers to approve minor matters on behalf of the Committee, but ensure that the papers are made available to the rest of the members of IREC at the next meeting; and The committees should have powers to co-opt professional or lay members for particular or specific signed where necessary.

1.2.4 Criteria for IREC approval of research

In order to approve research covered by these guidelines, the IREC shall determine all of the following requirements are satisfied:

(i) Risks to subjects are minimized:

(a) By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk; and

(b) Whenever appropriate, by using procedures already being used on the subjects for diagnostic or treatment purposes.

(ii) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, IREC should consider only those risks and benefits that may result from the research. The IREC should not consider possible long range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

(iii) Selection of subjects is equitable. In making this assessment IREC should take into account the purposes of the research and the setting in which the research

will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations.

(iv) Informed consent will be sought from each subject or the subject's legally authorized representative.

(v) Informed consent will be appropriately documented.

(vi) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.

(vii) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality.

(viii) When some or all of the subjects such as children, pregnant women, prisoners, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons are likely to be vulnerable to coercion

1.2.5 The Roles of Health Research Ethics Committees

(i) The national and institutional ethical committee have the duty to ensure that the dignity, rights, safety and well being of all actual and potential research participants are safeguarded during the process of conducting research. These roles are in accordance with the operational guidelines of ethics committees that review biomedical research, developed by the World Health Organization (TDR/PRD/Ethics/2000.1).

(ii) The committees must be composed of competent individuals in reviewing research work that must always be independent of any political, religious, or financial pressures while reviewing the relevant proposals. If at any time a member of the committee should have any conflict of interest in a particular proposal including authorship, then such a member should not participate in reviewing the particular proposals but should be replaced by any other person with similar competence but who has no such conflict of interest.

(iii) It shall be the responsibility of every member of the committee to sign a form declaring no conflict of interest before reviewing any proposal.

(iv) The health research committees should be multidisciplinary and multi-sectoral in composition, and taking into consideration gender representation. It must perform its duties of reviewing proposals in the interest of actual and potential research participants and concerned communities. In performing their work, the committees have to pay due attention to the requirements of the relevant regulatory agencies and applicable laws of Tanzania.

1.2.6 Safeguards for children in clinical investigations

Research Ethics Committee at all levels shall in addition to other responsibilities and guidelines contained in this document review critically clinical investigations involving children and approve only those clinical investigations that satisfy the conditions described below:

(i) Clinical investigations not involving greater than minimal risks

IREC may approve any clinical investigation involving children only as subjects in which no greater than minimal risk to children is presented; and only if IREC finds and documents that adequate provisions have been provided for soliciting the assent of children and the permission of their parents.

(ii) Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects

Any clinical investigation in which no more than minimal risk to children is presented by an intervention procedure that holds out the potential of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may involve children as subjects only if IREC finds and documents that:

(a) The risk is justified by the anticipated benefits to the subject;

(b) The relation of the anticipated benefit to the risk is at least as favourable to the subjects as presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of their children and permission of their parents or guardians.

(iii) Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalisable knowledge about subjects' disorder or condition

Any clinical investigation in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if IREC finds and documents that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;

(c) The intervention or procedure is likely to yield generaisable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition; and

(d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

(iv) Clinical investigations not otherwise approved that present an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children

If an IREC or NHREC does not believe that a clinical investigation involving children only as subjects does not meet the requirement in ***(i)***, ***(ii)*** and ***(iii)*** above, the clinical investigation may be approved ONLY if:

(a) The IREC or NHREC finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children; and

(b) The TFDA after consultation with experts in pertinent disciplines, and following opportunity for public review and comment, determines either:

- That the clinical investigation in facts, satisfies the conditions under this section; or
- That the following conditions are met:
  - (i) The clinical investigation presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children;
  - (ii) The clinical investigation will be conducted in accordance with sound ethical principles; and
  - (iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

(v) Requirements for permission by parents or guardians and for assent by children

In addition to the determinations required under this section, IREC or NHREC:

(a) Must determine that adequate provisions are made for soliciting the assent of the children when in the judgement of the IREC the children are capable of providing assent;

(b) In determining whether children are capable of providing assent, the IREC or NHREC must take into account the ages, maturity and the psychological state of the children involved. This judgement may be made for all children to be involved in clinical investigations under a particular protocol or for each children, as the Ethics Committee deems appropriate;

(c) The assent of children is not a necessary condition for proceeding with the clinical investigation if IREC determines:

  (i) That the capacity of some or all the children is so limited that they cannot reasonably be consulted;

  (ii) That the intervention or procedure involved in the clinical investigation holds prospect of direct benefit that is important to the

health or well-being of the children and is available only in the context of the clinical investigation.

(d) Even when it is established that the subjects are capable of assenting, IREC or NHREC may still waive the assent requirement if it finds and documents that:
   (i) The clinical investigation involves no more than minimal risk to the subjects;
   (ii) The waiver will not adversely affect the rights and welfare of the subjects;
   (iii) The clinical investigation could not particularly be carried out without the waiver; and

(e) Whenever appropriate, the subjects will be provided with additional pertinent information after participation;

(f) In addition to the determinations required under this section, the IREC or NHREC must determine that the permission of each child's parents or guardian is granted; and

(g) Where parental permission is to be obtained, IREC or NHREC may find that the permission of one parent is sufficient if consistent with the Laws of the country;

(h) Where the clinical investigation requires obtaining parental permission, both parents must give their permission unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child;

(i) Permission by parents or guardians must be documents in accordance with and to the extent described under Chapter 3 (3.5); and

(j) When IREC or NHREC determines that assent is required, it must also determine whether and how assent must be documented.

1.2.7 Electronic records and electronic signatures

1.2.7.1 General consideration

Advances in science and technology have made life easier and transmission, storage and retrieval of records is now much more efficient. It is common practice now for Institutional Research Ethics Committee to receive electronic documents which contain electronic signatures. Therefore, there is a need to provide guidelines on the use of electronic documents and electronic signatures. This section therefore, describes the criteria under which IRECs will consider electronic records, electronic signatures, and handwritten signatures executed to electronic documents to be trustworthy, reliable and generally equivalent to paper records and handwritten signatures executed on paper. This section applies to records in electronic form that are created, modified, maintained, archived or transmitted under any record requirement set forth by IRECs or NHREC.

Where electronic signatures and their associated electronic records meet the requirement of this section, IREC or NHREC will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by IREC/NHREC.

Implementation of the guidelines on electronic records and signature will depend on how advanced are the receiving units at the respective IRECs and NHREC. As a general rule, for records submitted to the Committee, researchers and persons at the receiving units may use electronic record in lieu of paper records or electronic signatures in lieu of traditional handwritten signatures, in whole or part, provided that:

(i) The requirements of this section are met;

(ii) The document or parts of the document to be submitted have been identified by IREC/NHREC as being the type of submission the committee accepts in electronic form;

(iii) Documents submitted to receiving units at IREC or NHREC not meeting the above condition shall not be considered as official if they are submitted in an electronic form.

1.2.7.2 Controls for electronic documents

There are two forms of controls for electronic documents (records); i.e. controls for closed systems and controls for open systems. The definition of each term has been provided under definitions.

(a) Controls for closed systems

Staff of IREC and NHREC who will be using closed systems to create, modify, maintain, or transmit electronic documents shall be required to employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic document, and to ensure that the signer cannot be repudiate the signed document as not genuine. Such procedure and controls shall include the following:

(i) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered documents;

(ii) The ability to generate accurate and complete copies of documents in both human readable and electronic form suitable for inspection, review, and copying by IREC/NHREC;

(iii) Protection of documents to enable their accurate and ready retrieval throughout the document retention period;

(iv) Limiting systems access to authorized persons only;

(v) Use of operational system checks to enforce permitted sequencing or steps and events as appropriate;

(vi) Use of authority checks to ensure that only authorized persons can use the system, electronically sign documents, access the operation or computer system input or output device, alter a record or perform the operation at hand;

(vii) Determination that persons who develop, maintain or use electronic records and/or electronic signature systems have the education, training and experience to perform assigned tasks; and

(viii) Use of appropriate controls over systems documentation including:

- Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance;
- Revision and change control procedures to maintain an audit trial that documents time-sequenced development and modification of systems documentation.

(b) Controls for open systems

Persons who use open systems to create, modify, maintain or transmit electronic documents shall apply similar to those for closed systems to ensure authenticity, integrity, and confidentiality from the point of creation to the point of receipt. In addition, additional guidelines such as ensuring document encryption and use of appropriate digital signature standards to ensure record authenticity, integrity and confidentiality.

1.2.7.3 Electronic signature manifestation

(a) General requirements

(i) Signed electronic documents shall contain information associated with the signing that clearly indicates all of the following:

(a) The printed name of the signer;

(b) The date and time when the signature was executed; and

(c) The meaning (such as review, approval, responsibility or authorship) associated with the signature.

(ii) The items identified under (i) of this section shall be subject to the same controls as for electronic documents and shall be included as part of human readable form of the electronic record.

(b) Electronic signature/document linking

Electronic signatures and handwritten signatures executed to electronic documents shall be linked to their respective electronic documents to ensure that the signatures

cannot be excised, copied, or otherwise transferred to falsify an electronic document by ordinary means.

1.2.7.4 Electronic signature general requirements

(i) Each electronic signature shall be unique to one individual and shall not be reused, by or reassigned to anyone else;

(ii) Before an IREC/NHRC establishes, assigns certifies, or otherwise sanctions an individual's electronic signature, the Committee shall verify the identity of the individual;

(iii) Persons using electronic signatures shall, prior to or at the time of such use, certify to IREC/NHREC that the electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures; provided that:

   (a) The certification shall be submitted in a paper form signed with a traditional handwritten signature;

   (b) Persons using electronic signatures shall, upon IREC/NHREC request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

1.2.7.5 National Health Research Ethics Committee (NHREC)

Upon realizing the level of vulnerability of its communities, Tanzania felt the need to have a system of ensuring that health research is coordinated and conducted in a more transparent way and observing ethical and human rights standards that will protect the community. The TANHER Forum was also established in 1991 to among other things, address matters related to ethics of research in the country. The National Health Research Ethics Committee was formed as an arm of the Forum.

1.2.7.6 Composition of National health Research Ethics Committee

The National Health Research Ethics Committee is an advisory body to TANHER Forum, and its composition shall include:

(i) The Chairman

(ii) The Secretary

(iii) Representatives from health research institutions, religious group, the legal profession, and a lay member.

(iv) The Chairman and Secretary of the TANHER Forum as Ex-Officials.

1.2.7.7 Functions of the NHREC

For practical purposes, NHREC shall have the following functions:

(i) Prepare and revise national guidelines on health research in Tanzania;

(ii) To grant accreditation to other ethics committees, which conform to satisfactory standards of evaluation and supervision of health research;

(iii) To monitor and coordinate activities of other accredited research ethics committees which conduct or supervise research that is funded by NIMR HRUTF and TANHER forum;

(iv) To advise national and international research collaborators on matters related to the ethics of health research in Tanzania;

(v) To participate in national and international discussions on the ethics of health research; and

(vi) To enhance health research ethics, standards and discussion on the health researchers issues in Tanzania.

CHAPTER TWO

2.1 PRINCIPLES OF HEALTH RESEARCH

It is essential that health research is conducted in order to develop new knowledge for the better care of mankind. However, as earlier stated, health research may be associated with risks and the possibility of exploitation of the individual subjects or the community in which the study is to be carried out. Poverty, ill health, lack of resources and certain in communities increase the likelihood of exploitation especially in developing countries where community expectations on research are high. Therefore, in the field of health research selection of research subjects must take into account whether the study is carried out among healthy subjects, patients, children, women etc. Where relevant, the research protocol must describe the social contexts of a proposed research population, e.g. country or community that create conditions for possible exploitation or increased vulnerability among potential research subjects, and strategies that will be taken to overcome these conditions and protect the dignity, safely and welfare of the participants.

Further fundamental distinction must be recognized between health research the primary aim of which is diagnostic or therapeutic for the patient, and that which is purely scientific. The distinction is important and influences the approach and the conduct of the research.

The WMA has recognized the need to establish standards to guide research involving human subject and recommended that, the guidelines to researchers involved in health research should from time to time be reviewed. Furthermore, WMA cautions that researchers in health research are not relieved form criminal, civil and ethical responsibilities under the laws of their respective countries.

2.2 The basic principles of health research

While health research may be significantly influenced by the law of the country, institution, multinational and international agencies, there are fundamental principles that cut across any health research. These include:

Health research must be scientifically sound and should at all times conform to scientific principles and evidence based scientific knowledge. In order to conduct a research in a scientifically acceptable manners research protocol should have the following provisions:

(i) Be scientifically appropriate;

(ii) The outcomes of the research should benefit the population from which the research participants are drawn;

(iii) Have justification for the selected population; and

(iv) Address particular needs of the proposed research population.

(v) Health research must be supported by a well thought out protocol detailing the experimental procedures, which, before implementation, must have been submitted to qualified independent reviewers for consideration, comments and guidance;

(vi) The quality of researchers in health research must be qualified and competent to carry out the proposed study. At no time should health research be left in the hands of incompetent persons. While, in recent years, a multi-disciplinary approach to health research has been given emphasis, in dealing with patients, attention must be directed at ensuring that health research involving patients rests in the hands of qualified and competent personnel;

(vii) The risk-benefit of the proposed study must be considered, and be established that the benefits of the research findings outweighs the associated risks, The research must:

   (a) Establish safeguards for the protection of research subjects from potential harm.

   (b) Be carefully monitored and whenever there are observable risks to research subjects, researchers should immediately discontinue such experiments.

(viii) The privacy and integrity of research subjects must always be observed, and at all times, precaution must be taken to preserve and respect the privacy of individual research subjects;

(ix) The right to information entails that research subjects must be provided with the necessary information related to the study in which they are going to participate. The information must include reason for the study, procedures, techniques, advantages, disadvantages and the right for research subjects to decline participation or discontinue from the study without consequences. The right to information is essential and fundamental in establishing trust between researches and research subjects;

(x) Accuracy of the results must be maintained, and should reflect what was done and what was observed. Fictitious and fabricated results should not be accepted for publication under any circumstances;

(xi) Matters related to handling of research outputs must be clearly detailed. The communities where the study was carried out have the right to information on the research outputs. This must be prepared, repackaged and given in a simple language that the community understands;

(xii) Capacity building must be given emphasis so that the research must bring and leave behind improvement in the way of life in terms of capacity buildings;

(xiii) What happens after the research has come to an end is becoming a major subject for discussion and there should be clear plans on what will happen when the study comes to an end; and

(xiv) As health research may carry physical, mental, and/ or psychological risks, health research protocols must therefore, detail the ethical issues and the strategies to counter or minimize effects.

2.1 Conclusion

These basic principles of health research must be followed because they are fundamental in advancing health sciences, knowledge and search for new cures and

care of humankind. Researchers are being directed to familiarize themselves with these principles and apply them. Adherence to the principles will minimize the duration of processing research protocols by either NREC or IRECs. Further details on the basic principles of health research are provided in the Helsinki Declarations (Appendix One)

CHAPTER THREE

3 CONSENT

3.1 Background

There is sufficient evidence that many forms of health research carry the risks of causing physical as well as psychological to the participating subjects or the society where it is being carried. To ensure that research participants are well protected, the Nuremberg Code of Ethics stressed that all subjects involved in the research should have a legal capacity to consent and researchers should ensure that:

(i) Each healthy volunteer or patient participating in the research must have provided valid consent;

(ii) Consent if freely given after the individual participant in the research must have received as full an explanation, as the research thinks appropriate;

(iii) The subject may decline to participate without giving any reasons or incurring displeasure or penalty;

(iv) Due regard should be given to the individual needs of the patients or participating research subjects;

(v) Patients or healthy individual participating in the research must be well informed about the potential risks and benefits of the procedure(s), and why it is proposed and the significance in terms of advancing knowledge and the researcher's own sake in proposing the procedures;

(vi) Where options are provided, the participating subjects in the research must be told about the alternatives; and when a clinical trial is being proposed, they need to know about the advantages and disadvantages of conventional regimes as well as options in the trial;

(vii) Research subjects should be told that they are free to withdraw from the study at any stage without conditions; and

(viii) The information obtained should be treated confidentially.

3.2 General requirements for informed consent

Consent is an important component of research involving human subject and in accordance with these Guidelines, no investigator shall involve a human subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such informed consent only under the circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in a language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or representative is made to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents the liability for negligence.

Care however, must also be observed in obtaining consent in societies where elders and community leaders have final say in matters related to the family, clan or tribe. It is not uncommon for women to rely on their husbands for consent. Researchers must ensure that in such circumstances, consent is given in the best interest of the participating subject.

3.3 Types of consent

Consent may be explicit or implicit. In practice however, implicit is more common than explicit consent e.g. in the process of measuring blood pressure or venepuncture, the researcher assumes that consent has been given by the subject extending the forearm. Consent may be given either orally or it may be written down. In biomedical research it is common practice to have a written down consent popularly referred to as informed consent. Written consent however, is not in any

way superior to verbally given consent especially in circumstances where illiteracy rates are high.

The consent form was originally introduced to protect surgeons from allegations of assault by patients who came to regret the surgical interventions, which, had been carried out upon them. This is still seen by some researchers as the function of the consent form. With regards to the consent form an eminent judge has said: "There seem to be some confusion in the minds of some as to the purpose of seeking consent from a patient. It has two purposes, the one clinical and the other legal. The clinical purposes stem from the fact that in many instances the cooperation of the patient and the patient's faith or at least confidence in the efficiency of treatment is a major factor contributing to the treatment's success. Failure to obtain such consent will not only deprive the patient and medical staff of this advantage, but will usually make it more difficult to administer the treatment. The legal purpose is quite different. It is to provide those concerned in the treatment with a defence to a criminal charge of assault or better or civil claim for damage for trespass to the person. For written consent to be valid:

(i) The consent form should be simple but carrying the necessary and relevant message on the proposed study;
(ii) Participating subjects should realize that they are taking part in the research willingly;
(iii) The consent form must be submitted to an Ethical Clearance Committee for approval before it can be used.

3.4. Elements of informed consent

For all practical purposes, and in seeking informed consent, the following information shall be provided to each participating subject:

(i) A statement that the trial involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a

description of the procedures to be followed, and identification of any procedures which are experimental;

(ii) A description of any reasonably foreseeable risks or discomforts to the subject;

(iii) A description of any benefits to the subject or others which may reasonably be expected from the research;

(iv) A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject;

(v) A statement describing the extent, if any, to which confidentiality of records identifying subjects will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records;

(vi) For research involving more than minimal risks, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if any injury occurs and, if so, what they consist of, or where further information may be obtained;

(vii) A description of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(viii) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

(ix) When appropriate one or more of the following elements of information shall also be provided to each subject:

(a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant) which are currently unforeseeable;

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(c) Any additional costs to the subjects that may result from participation in the research;

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(f) The approximate number of subjects involved in the research.

3.5. Documentation of informed consent

Informed consent shall for practical purposes be documented by the use of a written consent form approved by the IREC and signed and dated by the subject or subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form. The consent may be either of the following:

(i) A written consent document that embodies the elements of informed consent described under 3.4. This form may be read to the subject or subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed;

(ii) A short form written consent document stating that the elements of the informed consent have been presented orally to the subject or subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also the IREC shall approve a written summary of what is said to signed by the subject or subject's representative;

(iii) However, the representative shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary; and

(iv) A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

3.6. Witnessed consent

Witnessed consent is an alternative to written consent. It is useful for individuals who have intellectual or cultural difficult to understand or in speech, capable to

consent. In that case, a third party which may be a technician, doctor, nurse or any other persons may sign the document stating that at the time the investigator was explaining the methods and the purposes of the study to the research candidate, the witness was present, and that witness's option was given freely and with understanding.

3.7. Consent from vulnerable groups in the society

There are circumstances where prospective candidates are unable to freely consent to research procedures for one reason or another. They include children, mentally handicapped, prisoners, detainees, refugees, severely ill or unconscious patients and the elderly. Research that can be carried out on subjects who can consent should not be carried out on individuals who have no capacity to understand, or freedom to refuse is limited. It has always been argued that it is unethical to include in a study individuals whose capacity to consent is limited. However, there are those who have argued that excluding the entire groups of such people from a study of the basis of limited capacity to consent is unethical, discriminatory, and it means there is failure in the system to seek measure to improve their conditions. It is however, generally accepted that carrying out research in groups of people with limited capacity to consent is not unethical as long as it is governed by strict safeguards including:

(i) Critical review by IRECs or NREC;
(ii) The research should not be contrary to the interests of the subject;
(iii) The research should not pose risks to the subjects or pose minimal risk;
(iv) The research must be impossible to carry out in subjects with capacity to consent; and
(v) Must be designed to have maximum benefits to other in the same category as the subject.

3.8. Consent for research involving minors

The British Paediatrics Association draws attention to the fact that many children are vulnerable, easily bewildered and frightened and unable to express their needs. In

law, parents or guardians cannot consent to any treatment or procedures, which are contrary to the child's interests. This has been expressed as guidance that; "Those acting for the child can only legally give their consent provided that the intervention is for the benefit of the child. If they are responsible for allowing the child to be subject to any risk (other than one so insignificant as to be negligible) which is not for the benefit of the child, it could be said that they were acting illegally". A research worker must therefore be able to recognize when a child is very upset by a procedure and accept that as genuine dissent from their being involved. However, as part of the society, researches in children have to be carried out. Researches involving minor must fulfil the following:

(i) Must have identifiable benefit to minors in the same category;
(ii) The procedures should have first been tested on consenting adults before they are carried out in children;
(iii) The child may consent independently; and
(iv) Where the child understanding is thought to be doubtful it may be a matter of good practice to seek the child's permission to explain the research proposals to parents, and if the minor objects, the objection should be given weight.

3.9. Consent involving the mentally disordered persons

The mentally disordered persons have been defined as including the mentally ill, mentally handicapped, demented and the unconscious. In these categories or persons, some will never have the capacity, to some will have it at times and not others and some will lose it irrevocably. However, many people with a mental disorder are able to consent as long as adequate time is taken to explain the procedures. Nonetheless, care should be taken not to exert undue pressure to any of the following categories:

3.9.1. Consent for research on mentally ill persons

(i) Apart from patients suffering from severe conditions such as dementia, most patients will be able to give consent to therapeutic trials; and

(ii) Non-therapeutic trial should not be carried out on mentally ill persons;

3.9.2. Consent for research on demented and unconscious patients

It is very unlikely that there is any justification in carrying out research on this category of patients. However;

(i) Research may be carried out only if it not contrary to the interests of the patient. If it carries minimal risk as to be said to be negligible,

(ii) May be potentially of benefit to the category of such patients, and;

(iii) Should have been scrutinized and satisfied the Research Ethics Committee.

3.9.3. Consent for research involving people with learning disabilities

Research involving this category of patients may only be approved where;

(i) The research is not contrary to the interests of people with learning disabilities;

(ii) It exposes them to no risk or minimal risk as to be said to be negligible; and

(iii) The research may potentially benefit others in the same category.

3.10 Consent for research in the elderly

The elderly constitute a special group of people in the community who are great consumers of pharmaceutical products and a number of drugs are targeting elderly people. In many societies, the numbers of elderly people is growing and studies in elderly people are therefore important if we are to understand the drug interaction in the elderly people whose physiology may have changed with age. It should however, be borne in mind that the elderly are more prone to exploitation because of their dependence on others or institutions in which they are living. While most elderly people may be considered to have capacity to consent, it is important that:

(i) When considering inclusion of elderly patients in the research, special care must be exercised when involving elderly who have stayed long in the hospital or residential homes because of their vulnerability to suggestions and dependence to others;

(ii) Research with potential benefits to individual and others in the same category should be discussed in the presence of an independent but caring observer (e.g. a senior nurse). The observer should be satisfied that the researcher explained the aims, procedures, benefit and risks if any to the patient and that the elderly person understood the intended research activities and agreed.

3.11 Protections for pregnant women, human foetuses and neonates

3.11.1 Research in pregnant women or foetuses

Pregnant women or foetuses may be involved in research if all of the following conditions are met:

(i) Research among pregnant women should only be carried out if the pregnancy forms an essential part of the proposed research;

(ii) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provided data for assessing potential risks to the pregnant women and foetuses;

(iii) The risk to the foetus is caused primarily by interventions or procedures that holdout the prospect of direct benefit for the woman or the foetus; or, if there is no such prospect of benefit, the risk to the foetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(iv) Any risk is the least possible for achieving the objectives of the research;

(v) If the research holds out the prospect of direct benefit to the pregnant woman, and the foetus, or no prospect of benefit for the woman nor foetus is not greater than minimal and the purpose of the research is development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart (a) of this section, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;

(vi) Each individual providing consent under paragraphs (iv) and (v) of this section is fully informed regarding the reasonably foreseeable impact of the research on the foetus or neonate;

(vii) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(viii) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(ix) Individuals engaged in the research will have part in determining the viability of a neonate.

3.11.2 Research involving neonates

(a) General considerations

In research involving neonates, attention should be directed at ensuring distinction between neonates of uncertain viability from nonviable neonates. Generally, neonates of uncertain viability and nonviable neonates may be involved in research only if all of the following conditions are fulfilled:

(i) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

(ii) Each individual providing consent under paragraph (a)(2) or (b)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate;

(iii) Individuals engaged in the research will have no part determining the viability of a neonate;

(iv) The requirements of paragraphs of (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability

Until such time that it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following conditions have been fully met:

1. *The IREC or NHREC determines that:*

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

2. *Legally informed consent*

Legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is obtained, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates

After delivery, nonviable neonates may not be involved in research covered under this subpart unless the following additional conditions have been fulfilled:

(i) Vital functions of the neonate will not be artificially maintained;

(ii) The research will not terminate the heart beat or respiration of the neonate;

(iii) There will be no added risk to the neonate resulting from the research;

(iv) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;

(v) Legally effective informed consent of both parents of the neonates is obtained.

(d) Viable neonates

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirements of subparts of this section.

3.11.3 Research involving after delivery, the placenta, the dead foetus or foetal material

Often researchers have shown interests to research on the placenta, dead foetus and foetal materials. As a general rule:

(i) Research involving after delivery, the placenta, dead foetus, macerated foetal material, or cells, tissues, or organs excised from a dead foetus, shall be conducted only in accordance with national laws and regulations regarding such activities;

(ii) If information associated with materials described in the paragraph (i) of this section is recorded for research purpose in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this section are applicable.

3.12 Consent for research in prisoners and people in detention

Imprisonment or detention deprives individuals of their rights and autonomy. A detained person is less likely to give a free consent and may be restricted in terms of privacy. Prisoners and people living in detention are vulnerable in the sense that they are vulnerable to suggestions especially where hope for freedom has been advanced. It is however, not unethical to carry out research on prisoners or detained people as long as:

(i) The research output would benefit the individual or others people in the same category, and

(ii) The consent to participate in the research will be given without undue pressure, coercion including any impression that their participation in the research will result in a reduction in the sentence.

3.13 Consent of students in research

The student community has been involved in a number of research studies and their participation has been central in a number of researches involving healthy

volunteers. However, it should be born in the mind that students are a vulnerable group especially where the training institution is carrying out the research. It is however, not unethical to conduct research on students as long as:

(i) The tutor involving in the tuition of the student should not be recruitment and other negotiations on the terms and research conditions;

(ii) The informed consent should clearly state that the students might, wish at any stage of the research to withdraw from the study without any undue consequences;

(iii) An impression should not be created that acceptance to participate in the study will benefit the student in the passing of their examinations;

(iv) An impression should not be created that non-acceptance will result in discrimination and consequences on the studies; and

(v) There should not be any form of coercion, pressure or financial inducement other that that proposed as fees for participants.

Similar considerations might be taken where research is being considered to involve junior staff in the department from which the Principal Investigators belong. Over enthusiasm aimed at impressing the senior member and fear for not participating might have significant influence on the consent of the junior staff. Junior staff may be included in the study as ling as there is no any form of coercion pressure of inducement other than that proposed for all participants in the research.

3.14 Consent of Community

Ethical issue regarding consent of community are described in detail in Section 6.2 of Chapter Six.

3.15 Research without the consent of the patient

It is generally accepted that under no circumstances research should be conducted without the consent of the prospective research subject or any authorized person on his/her behalf; and IRECs or the NRECs should be consulted well in advance and should scrutinize such proposals.

3.16 Exceptions from general requirements

Though rare and efforts should be made to ensure that informed consent is obtained, there are few exceptions from the general requirements. The obtaining of informed consent shall be deemed feasible unless, before use of the test product, both the investigator and practicing physician who is not otherwise participating in the clinical trial certify in writing the following:

(i) The human subject is confronted by a life-threatening situation necessitating the use of the test product;
(ii) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject;
(iii) Time is not sufficient to obtain consent from the subject's legal representative;
(iv) There is no available alternative approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject;
(v) If immediate use of the test product is, in the opinion of the investigator, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination in paragraph (i) above in advance of using the test product, the determinations of the clinical investigator shall be made and, within five (5) working days after the use of the test product, be reviewed and evaluated in writing by an independent practicing physician who is not participating in the clinical trial; and
(vi) The documentations required under paragraphs (i) and (ii) above shall be submitted to the Institutional Review Committee within five (5) working days after the use of the test product.

3.17 Exception from informed consent requirements for emergence research

Generally, there are rare cases where exception from informed consent requirements may be considered by an Institutional Review Committee for approval e.g. under emergency. In this case IREC may approve a clinical trial without requiring that informed consent of research subjects to be obtained provided that:

(i) The human subjects are in a life threatening situation, and available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled trial, is necessary to determine the safety and effectiveness of the particular interventions;

(ii) Obtaining informed consent is not feasible because of the following:

(a) The subject will not be able to give informed consent as a result of the medical condition;

(b) The intervention under investigation must be administered before consent from the subjects' legally authorized representative is feasible; and

(c) There is no reasonable way to identify prospectively the individual likely to become eligible for participation in the clinical trial;

(iii) Participation in the trial holds prospects of direct benefits to the subject because:

(a) The subjects are facing a life threatening situation that necessitate intervention;

(b) Appropriate animal and other pre-clinical studies have been conducted, and the information derived from the studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects,

(c) The risks associated with the trial are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of a standard therapy, if any, and what is known about the risks and benefits of the proposed intervention.

(iv) The clinical trial could not reasonably be carried out without the waiver;

(v) The proposed trial activity plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for consent within the prescribed window rather than proceeding without consent;

(vi) The IREC has reviewed and approved informed consent procedures. The procedures and informed consent documents are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible; and

(vii) The IREC has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical trial.

3.18 The duration of consent

There has been concern in research circles on the length of time for which the given consent can still be considered valid. In practice, this is not at question since consent is an evolving matter and not a once and for all decision. The given consent is clearly only valid until such time as the person who had given consent expresses a change of mind. Therefore, researchers should take necessary precaution not to act on information on consent that cannot revolve and be confirmed.

3.19 Conclusion

Some countries or communities often described as "developing" have been perceived as inappropriate participants for some phases of clinical trials researches due to perceived increased level of vulnerability to exploitation or harm. It is therefore more useful to identify the particular aspect of the selected study community that create conditions for exploitation or increase vulnerability for the selected population group. Some factors to be considered include:

(a) Governmental, institutional or social stigmatization or discrimination.

(b) Social and legal marginalization of population segments.

(c) Limited availability, accessibility and suitability of health care.

(d) Limited ability of individual or group in the community to understand the research process.

(e) Limited ability of individuals to be able to give freely their informed consent in the light of prevailing class, gender and other social and legal factors.

(f) Lack of meaningful IRECs and review committees.

CHAPTER FOUR

4 CONFIDENTIALITY

4.1. Introduction

Privacy is a basic right which permits individuals to decide the manners, and extent to which information concerning them should be shared with others. Confidentiality is a central issue in the doctor-patient and researcher-research subject relationship and is based on trust. Information obtained in the researcher/research subject relationship must be regarded as strictly confidential. Any breach of confidentiality threatens that relationship.

However, there are occasions when public interest may be seen to override the privacy of an individual, but in such circumstances, the facts must be subject to close scrutiny as to whether there is genuine ground for disclosure. Arriving at a decision may be a dilemma as in the following examples:

(i) In a study, a researcher discovers that a male research subject is sero-positive for HIV, but the sero-status of his partner who is not a research subjects is not known. The ethical dilemma includes whether the researcher should disclose the information to the partner.

(ii) In a study among prison workers, a researcher discovers that a fellow physician, as an employee of the prison participates in cruel and inhuman practices. Ethical issues to be considered are whether the researcher should disclose this information to the Medical Licensing Authority or keep the information confidential. In either way, there are ethical implications to the profession as well as to the community.

(iii) There are concerns that high level care provided during research might constitute undue incentives and inducement for communities to participate in subsequent studies.

(iv) In a study among school children, the researcher discovers that a school child is on drugs. The child however, pleads that the information should not be disclosed to teachers and parents.

In all these cases, a decision has to be made in the best interest of the research subjects and society. In general, in order to safeguard confidentiality:

(a) Identify of research subjects should be confidential.

(b) The investigator must take all necessary precautions to ensure that information collected is handled and kept confidentially.

(c) Investigators must be aware of the consequences that might result from the disclosure of information without the consent of the individual or any other person legally capable of consenting on that individual's behalf.

4.2. Confidentiality and medical records

Confidentiality with regard to the use of medical records is a controversial issue. Some have argued that it would be impractical to demand that research obtain individual consent from the patient. It has in some cases been proposed that each time a patient is attending a clinical trial? for the first time, he/ she should sign a form saying he/ she is willing or unwilling to allow information pertaining to their condition to be used in research. As a matter of principle:

(i) Where the medical record is given in a form that does not able individuals to be identified, no breach of confidentiality will arise.

(ii) Where the disclosure would enable one or more individuals to be identified, the person concerned or those who may legally give permission on their behalf must be made aware.

(iii) Where the person or persons concerned have been identified, they should be made aware that they are at liberty at any stage, to withhold their consent to disclosure.

(iv) In the case where a researcher requires information from records of patients attending a particular physician, it is the responsibility of the attending

physician to provide the required information without divulging the identity of his patients.

(v) Any research, which will involve access to personal records, should have the approval of IREC.

(vi) Information derived from medical records should be stored securely, and if possible, encoded so that the identity of the subjects is unidentifiable.

CHAPTER FIVE

5. ETHICAL ISSUE REGARDING RANDOMIZED CONTROLLED TRIALS

5.1 Introduction

Sir Austin Bradord Hill introduced Randomized Control Trials (RCTs) into medical research in 1946, in the trial of streptomycin in the treatment of tuberculosis. The pre-requisite for randomizing is embodied in the maxim "only randomize if uncertain principle". Alternatively, the doctor may be described as being in "equipoise". There is an ethical imperative to ascertain that the treatments doctors give are effective. Therefore:

(i) Randomization is only ethical if there is substantial uncertainty about the best treatment for the patient;

(ii) If the doctor considers that one of the treatments in the study is appropriate or inappropriate for the patient, then randomization would be unethical;

(iii) To be "equipoise", the doctor should be indifferent to the choice of treatment because he/she has no knowledge to indicate that one drug option is better than the other;

(iv) Once there is unequivocal evidence of superiority of one drug over the other, it is unethical to deprive a patient of that treatment;

(v) Randomized Controlled Trials are ethical when the trial subjects are provided with adequate information, counselling and support at all stages of the trial;

(vi) At any stage of the trial subjects must have the option to withdraw and should be supported if that is their choice; and

(vii) Where the product is known to have adverse effects, the proposal should carry provisions to indicate how such effects will be detected and minimized in the event they occur in a research subject.

5.2 Double-blind controlled trials

One major problem inherent with controlled trials is the introduction of bias by the doctor or researchers. Randomization therefore can be accompanied with "double-blind" procedures. This eliminates the subjective preferences of the doctor or researchers by keeping the assignee treatment secret to both the investigators and trial subjects. The current designs for double-blind trials have been refined such that the possibility if unintentional bias affecting the outcomes has been considerably reduced.

5.3 Ethical issues related to controlled trials

Practical problems may arise if the doctor considers that the appropriate drug for the patient is the new drug only available in a trial since randomizations would deprive the patient of the product. Problems might also arise if at the end of the trial a patient may beneficial but is no longer available or not licensed for general use. In such circumstances:

(i) An investigator who has proved beyond reasonable doubt that one treatment is superior to the other is ethically unable to carry out controlled trials;

(ii) Withholding a product that has shown to be beneficial for a time or given period should only be done after scrutiny and approval of the proposal by the IRECs or other relevant authorities;

(iii) The proposal should indicate well in advance any provisions for continued supply of products at the end of the trials. In exceptional cases where the product has not been licensed, treatment can be provided on a "named patient" basis or by means of a doctor's exemption certificate from the Medical Control Agency; and

(iv) Where benefits have been observed in the trial sufficient to be of general use, the trial must be stopped and arrangements be made for those not on the product to be provided with the drug.

5.4 Consent in randomized controlled trials

Consent in randomized controlled trials has been a subject of discussion on whether consent may be given before or after randomization. As general guideline:

(i) The allocation of the treatment should be conducted after the patient has consented to participate in the study. This is a precaution because knowledge of the treatment that will be given to a particular group might influence the research outcomes; and

(ii) Any randomization of the treatment without the research patient consenting is unethical. Exceptional cases are where there is an argument for not telling the patient the truth, and must be subject of IRECs.

(iii) Randomization before seeking consent should be discouraged because of the coercion and over emphasized advantages for research subjects participating in the study.

5.6 Phases of vaccine and drug development

5.6.1. Vaccine development

(i) Phase I, refers to the first introduction of a candidate vaccine into a human population for initial determination of its safety and biological effects, including immunogenicity. This phase may include studies of dose and route of administration, and usually shall involve fewer than 100 volunteers;

(ii) Phase II refers to the initial trials examining effectiveness in limited number of volunteers (usually between 200 and 500). The focus of this phase is immunogenicity; and

(iii) Phase III, trials are intended for a more completed assessment of safety and effectiveness in the prevention of diseases, involving a larger number of volunteers in a multi-centre adequately controlled study.

5.6.2 Drug development

There are defined phases which must be followed in the development of any drug for use on humans. The specific phases include the following:

(i) **Phase I** refers to the first introduction of a drug into humans. Normal volunteer subjects are usually studied to determine levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness.

(ii) **Phase II** investigation consists of controlled clinical trials designed to demonstrate effectiveness and relative safety. Normally, these are performed on a limited number of closely monitored patients.

(iii) **Phase III** trials are performed after a reasonable probability of effectiveness of a drug has been established and are intended to gather additional evidence of effectiveness for specific indications and more precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies.

(iv) **Phase IV** trials are conducted after the national drug registration authority has approved a drug for distribution or marketing. These trials may include research designed to explore a pharmacological effect, to establish the incidence of adverse reactions, or to determine the effects of long-term administration of a drug in a populations not studied adequately in the pre-marketing phases (such as children or elderly) or to establish a new clinical indication for a drug. Such research is to be distinguished from marketing research, sales promotion studies, and routine post-marketing surveillance for adverse drug reactions in that these categories ordinarily need be reviewed by ethical committee.

In general practice and in accordance with these Guidelines, Phase I drug trials, and Phase I as well as Phase II vaccine trials shall be conducted according to the Articles of the Declaration of Helsinki that refer to non-clinical research. However, some exception can be justified. For example, it is customary and ethically justifiable to conduct Phase I studies of highly toxic chemotherapies of cancer in patients with cancer, rather than in normal volunteers as prescribed in the Declaration of Helsinki,

Article III 2. Similarly, it may be ethically justifiable to involve HIV-seropositive individuals as subjects in Phase II trials of candidate vaccines.

Phase II and **Phase III** drug trial shall in accordance with these Guidelines be conducted according to the Articles of the Declaration of Helsinki that refer to "Medical Research Combined with Professional Care (clinical research)". However, the Declaration does not provide for controlled trials. Rather, it assures the freedom of the physician "to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope for saving life, re-establishing health or alleviating suffering" (Article II.1). Also in regard to Phase II and Phase III drug trials there are customary and ethically justified exceptions to the requirements of the Declaration of Helsinki. A placebo given to a control group, for example, cannot be justified by its "potential diagnostic or therapeutic value for the patient", as Article II.6 of the Declaration of Helsinki prescribes.

Many other interventions and procedures characteristic of late-phase development have no possible diagnostic or therapeutic value of the patients and thus must be justified in other groups; usually such justification consist of a reasonable expectation that they carry little or nor risk and that they will contribute materially to the achievement of the goals of the research.

Phase III trials of vaccines do not use "a new diagnostic and therapeutic measure" that offers "hope of saving life, re-establishing health or alleviating suffering" (clinical researcher). Yet administration of the vaccine is intended to be a benefit to the subject rather than "the purely scientific application of medical research carried out on a human being" (non-clinical biomedical research). Thus Phase III vaccine trials do not conform to either of the categories defined in the Declaration of Helsinki.

5.7 Clinical trial protocol/proposal and protocol amendment

Institutional and the National Research Ethics Committees are currently receiving several clinical trials protocols/proposals for evaluation. Therefore there is a need for clear guidelines to be given to enable IREC and the NHREC to ensure standards for clinical trials is enhanced. The contents of a clinical trial should generally include items described below. However, site specific information may be provided on separate proposal pages or addressed in a separate agreement. IREC and the NHREC should scrutinize clinical trial protocols/proposals for the following:

5.7.1 General information

(i) Proposal title, identification number and date. Any amendments should also bear the amendment number(s) and dates;

(ii) Name and address of the sponsor and monitor (if other than the sponsor);

(iii) Name and title of the person(s) authorized to sign the proposal and proposal amendment(s) for the sponsor;

(iv) Name, title, address, telephone and fax contacts, and email address of the sponsor's medical expert(s) for the trial;

(v) Name, and title of the investigator(s) who is(are) responsible for conducting the trial, and the physical address, telephone and fax contacts and email address;

(vi) Name, title, address and telephone and fax contacts of the qualified physician(s) who is(are) responsible for all trial sites related to medical decisions, if other than the investigator;

(vii) Name(s) and addresses) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

5.7.2 Background information

(i) Name and description of the investigational product(s);

(ii) A summary of findings from non-clinical studies that potentially have clinical significance and from clinical trials that is relevant to the trial;

(iv) Abstract of known and potential risks and benefits if any to human subjects;

(v) Description of and justification for the route of administration, dosage, dosage regimes and treatment period(s);

(vi) A statement that the trial will be conducted in compliance with the proposal and applicable regulatory requirements;

(vii) A description of the population to be studied;

(viii) Reference to literature and data that are relevant to the trial and that provide background for the trial.

5.7.3 Trial objectives

A clinical trial proposal should contain a detailed description of the objectives and the purpose of the trial.

5.7.4 Trial design

A scientifically sound design of the proposal is a pre-requisite for scientific integrity and credibility of the data from any clinical trial. Therefore a description of a clinical trial design should include the following:

(i) A specific statement of the measurable primary endpoints and the secondary endpoints;

(ii) A brief description of the design of the trial to be conducted (e.g. double blind, placebo controlled, parallel design) and a schematic presentation of the trial design showing stages;

(iii) A brief description of strategies for minimizing bias due to randomization and blinding;

(iv) A description of the trial treatment(s), dosages and dosage regimes including dosage form, packaging, and labelling of the trial drug(s);

(v) Projected duration of participation, the sequence and duration of trial periods including follow-up if any;

(vi) A full description of criteria for discontinuation of participants from the trial as well as end of the trial;

(vii) Maintenance of trial treatment randomization, codes and procedures for breaking the code; and

(viii) Accountability procedures for the trial product(s) including the placebo(s) and comparator(s) if any.

5.7.5 Selection and withdrawal of research participants

Any clinical trial proposal submitted for ethical review, IREC should scrutinize the proposal for the following:

(i) A full description of the inclusion criteria;
(ii) A full description of the exclusion criteria;
(iii) A description of the withdraw criteria i.e. terminating trial product, and procedures specifying:
    (i) When and how to withdraw subjects from the trial;
    (ii) Type and timing of the data to be collected for withdrawn subjects;
    (iii) Whether and how subjects will be replaced, if needed;
    (iv) How withdrawn subjects will be followed-up.

5.7.6 Treatment of research participants on clinical trial

IREC/NHREC are required to scrutinize all clinical trial proposals for procedures for treatment of research participants, medication(s) permitted including rescue medication as well as procedures for monitoring compliance to treatment(s).

5.7.7 Assessment of efficacy

All clinical trial proposals must be scrutinized by IREC/NHREC for a description of assessment of efficacy, specifying:

(i) Specification of the efficacy measurable indicators; and
(ii) Methods and timing for assessing, recording and analyzing efficacy parameters.

5.7.8 Assessment of safety

It shall be the responsibility of IREC/NHREC to establish in all clinical trial proposals assessment of safety, specifying:

(ii) Specification of the safety measurable indicators;

(iii) Methods and timing for assessing, recording and analyzing safety parameters;

(iv) Procedures for eliciting reports of and for recording and reporting adverse event and inter-current illnesses;

(v) The type and duration of the follow-up of subjects after adverse events have occurred.

5.7.9 Statistical analysis

All clinical trial proposals must provide a description on statistical analysis specifying:

(i) A description of the statistical methods to be employed, including timing of any planned interim analysis;

(ii) The number of subjects planned to be enrolled;

(iii) For multi-centre studies, the proposal should specify the number of enrolled subjects projected for each trial site;

(iv) Sample size, reason for the choice of sample size including reflections on calculations of, the power of the trial and clinical justification should clearly be specified;

(v) The level of significance to be used;

(vi) Criteria for the termination of the trial;

(vii) Procedures for accounting for missing, unused and spurious data;

(viii) Procedures for reporting any deviation(s) from the original plan and justification for deviation in the proposal and or report;

(ix) The selection of subjects to be included in the analyses e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects.

5.7.10 Ethical issues

IREC/NHREC should scrutinize all submitted clinical trial proposals for adequate description of ethical issues and how they will be addressed during implementation of the trial.

5.7.11 Publication policy

Publications of research results have raised concerns among researchers in the developing countries. Weakness in signed contracts, supervision and lack of intellectual property rights are among reasons for researchers in developing countries feeling of being marginalized. It shall be the responsibility of IREC/NHREC to ensure that all submitted clinical trial proposals provide a description of how publication of research results will be addressed equitably.

5.7.12 Financing and insurance

Financing and insurance issues must be clearly described in all clinical trial proposals and it shall be the responsibility of IRECs/NHREC to determine the adequacy of the financing and insurance framework in line with institutional and laws of Tanzania.

5.7.13 Direct access to source date and documents

It shall be the responsibility of the IREC/NHREC to ensure that all clinical trial proposal contain a description to the effect that the sponsor specifies in the proposal or other written contract/agreement that the researcher(s) and or the responsible institution(s) shall permit trial-related monitoring, audits, IREC/NHREC review, and regulatory inspection(s) by providing direct access to source data and documents.

5.8 Investigator's Brochure

The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical information in the investigational product(s) that are relevant to the study of the trial product in human subjects. The Investigator's Brochure serves the purpose of providing IRECs, NHREC, researchers and other stakeholders in the trial with information to empower them to understand the rationale for, and their compliance with many key features of the proposal, including doses, dose frequency or intervals, routes of administration and safety monitoring procedures. Generally, the

sponsor is responsible for ensuring that an up-to date Investigator's Brochure is made available to researchers who are responsible for providing the up-to-date IB to the responsible IREC or NHREC. It shall be the responsibility of the IREC or NHRE to ensure that Investigator's Brochure:

(i) Contains information presented in a concise, simple, objective, balanced and non-promotional;

(ii) Contains a title page specifying the sponsor's name, identity of each research product, chemical or approved generic name, trade name(s) and the release date;

(iii) Confidentiality statement instructing researchers to treat the Investigator's Brochure as a confidential document;

(iv) A brief introduction statement that contains the chemical name, all active ingredients in the trial product, pharmacological class, the rationale for carrying out the trial, anticipated prophylactic, therapeutic, or diagnostic indications and approach to be followed in evaluating the trial product;

(vi) A description of the trial product substance(s), and the relevant physical, chemical and pharmaceutical properties of the trial product;

(vii) IRECs and NHREC should scrutinize Investigator's Brochure for all relevant non-clinical pharmacology, toxicology, pharmacokinetic and metabolism summarized. The summary should provide information on the methodology used, the results, and a discussion of the relevance of the findings to the investigated trial product and the possible unfavourable and unintended effects in humans;

(viii) A thorough discussion of the known effects of the trial product(s) in human subjects should be provided including information on pharmacokinetics, metabolism pharmaco-dynamics, dose response, safety, efficacy and other pharmacological activities related to the trial product(s);

(ix) A description on marketing experience including countries where the trial product has been marketed or approved. All significant information arising from the marketed use should be summarized in the Investigator's Brochure.

5.9 Data Safety Monitoring Committee (Board)

For all clinical trial proposals it shall be the responsibility of IREC or NHREC to establish that the there is full description of establishment of a Data Safety Monitoring Committee or Board (DSMB) to periodically assess the progress of implementation of a clinical trial, the safety data and the efficacy endpoints, and to recommend to the sponsor and IREC or NHREC whether to continue, modify or terminate a trial. In assessing the DSMB, the IREC or NHREC shall ascertain the following:

(i) Composition of the Committee/Board;

(ii) Qualification and competence of members of the Board;

(iii) Experience in assessing clinical trial;

(iv) Affiliation of members;

(v) Terms of reference to members; and

(vi) Reporting framework.

CHAPTER SIX

6. ETHICAL ISSUES REGARDING EPIDEMIOLOGICAL STUDIES

6.1 Definition

Epidemiology is the study of geographical trends and determinants of health-related conditions or events in a given populations of study. Studies of epidemiology have in the recent years contributed significantly to the understanding of physiological processes, behavioural and physical changes that have influence on the health of communities. Epidemiological studies have also enhanced understanding of the burden of diseases in difference communities, efficacy and effectiveness of proposed intervention strategies and formulation of policy on resource deployment, storage and allocation.

6.2 Observational epidemiological studies

Observational epidemiological studies include cross-sectional, case-control and cohort studies. They involve use of questionnaires, performing physical or laboratory investigations and do not involve interventions.

6.3 Experimental epidemiological studies

Experimental epidemiological studies on the other hand involve studies where the investigators alter one or more variables under control and studies the effects of such alterations. They also include randomized controlled studies whereby randomization is aimed at reducing 'bias' attributable to individual or group influence. Results from the categories are then compared. Epidemiological studies of that nature usually raise ethical issues; and are generally unethical except where genuine reasons have been advanced to convince IREC to grant ethical clearance.

6.4 Potential for physical and psychological damage

Epidemiological studies have been shown to have potential physical and psychological damage. The potential may arise from data and specimen collection, storage and utilization of the results. The emergence of HIV/AIDS and large number

of People Living with AIDS (PLWA) in communities has to a greater extent increased the community's concern on damage. Therefore in all forms of epidemiological studies special consideration should be given to the rights of individual participants, communities and the researchers.

6.5 Existing guidelines on epidemiological studies

Guidelines on epidemiological studies now exist (e.g. the CIOMS). The guidelines are aimed at enhancing sensitivity of researchers and IRECs to ethical issues, adoption of standards ethics starting from the designing of the epidemiological studies, and encourage high professional standards, humane attitudes and high quality research.

It is however, unfortunate that the guidelines do no answer all the questions related to dilemmas that arise when applying them in different communities with difference social-cultural backgrounds. Therefore, in reviewing proposals on epidemiological studies, special attention should be given to ensure that:

(i) Research proposal provides adequate process of ensuring that consent is obtained;
(ii) Respect for persons is considered;
(iii) Beneficence is considered;
(iv) The study will do no harm (Non – maleficence); and
(v) There will be justice in sharing the benefits and risks.

6.6 Guidelines for informed consent in epidemiological studies

Cases have been reported where informed consent in epidemiological studies have been challenged. In accordance with these Guidelines informed consent shall be obtained from all subjects recruited for the study. Studies that propose not to seek informed consent should be critically scrutinized and the principal investigators of the proposals should be directed to provide satisfactory reasons to IRECs as to why the proposal should be granted ethical clearance in absence of informed consent. However, where subjects to be recruited in the study are well informed through the

media that is generally an acceptable practice that personal data is made available for epidemiological studies, informed consent may not necessarily be required.

6.7 Consent of the community

There are circumstances where it may not be feasible to obtain informed consent from individual subjects recruited for epidemiological studies. In such situation:

(i) An agreement of the community representation may have to be sought from the community where the planned study is to take place;

(ii) Selection of the representative should be carried in a manner that conforms with the traditions and culture of the community;

(iii) Approval proved for by the community has to be assessed and to conform with ethical norms;

(iv) There may be need to establish the authenticity of the community approval; and

(v) Individual refusal to participate in the study must be respected regardless of the community consent.

6.8 Inducement and pressure to subjects

Community concern has been expressed on the use of inducement and pressure during recruitment of subjects for epidemiological studies. The common question asked is whether a person who has authority over the individual or the community should make recruitment of subjects into the study. For example a member of the parliament recruiting study subjects in his/ her constituency, schoolteacher on students, army officer recruiting research subjects etc.

Emergence of vulnerable groups in communities including pregnant women, children, HIV infected persons, the sick, prisoners, adolescents, disabled and physically challenged individuals are strong points for instituting strict measure on ethical consideration. It should be the responsibility of the researcher using the expected outcomes and benefits to convince subjects to participate in the study

without necessarily having to exert pressure or suggest inducements. In accordance with these Guidelines, Institutional Research Ethics Committees or Board are required to:

(i) Critically review the proposal on the recruitment procedures;
(ii) Recruiting officers should be scrutinized to ascertain their influences on the community;
(iii) Subjects or communities should not be subjected to pressure during recruitment; and
(iv) Scrutinize the proposal for any clues of inappropriate inducement or promises.

6.9 Provision of health care to community under study

In Tanzania, like in many developing countries, the health system has, between late 1970s to the 1990s, been affected by a declining economy, poverty, emerging new diseases, re-emerging diseases and rapidly growing population. Health facilities are faced with shortages of essential supplies and materials as well as trained human resources. Carrying research studies in such communities may create a sense of relief and expectations that the community will be provided with health care during the period of study and in some cases even after the study has come to an end. In accordance with these Guidelines and where possible:

(i) Arrangements should be made to provide the care that the community needs; and
(ii) Provision for a referral system should be established.

6.10 Training and support to local personnel

Health knowledge has from the beginning of the 20th century been growing rapidly and health personnel in developing countries have found difficult to keep pace. Economic crisis has contributed to lack of current reading materials in libraries etc., and health personnel especially those in rural areas are left far behind. Health

research in communities brings along with it knowledge, skills and capacity building in terms of hardware, materials and supplies which should be optimized during the study. Research studies proposed to be carried out to such communities should:

(i) Include in the protocol aspects of imparting knowledge to local personnel; and
(ii) Provide opportunity to train local health personnel in skills which can be used after the study has come to an end.

6.11 Multi-centre research

Multi-centre research involves studies of the same nature carried out at different station in more than one country. Studies are required where global results are pooled and analyzed to provide a global view of a health condition e.g. WHO Cardiac Study which involves about sixty countries of the world. Research in Multi-centre studies has in some countries faced difficulties in obtaining ethical clearance because of absence of a national body to approval the protocol. To avoid delays in implementing multi-centre study:

(i) A single IREC with a good range of expertise may examine the protocol in depth and share its views with other IRECs;
(ii) A mechanism whereby one committee is selected to analyze the ethics of the protocol, leaving the other IRECs to concentrate on local aspects e.g. suitability of the investigators etc;
(iii) The principal investigator should be well informed of the procedures and running of the research; and
(iv) At all times, the interest of research subjects must be given priority.

CHAPTER SEVEN

7. GUIDELINES ON RESEARCH OUTPUT

7.1 Introduction

The primary objective of health research is to search for cure, better management of health conditions and advancing knowledge and skills in health. Research information should therefore be made available to stakeholders including the community where the study was carried. Because of the community concern on research involving human subjects, the commonest question asked include who owns research results?

It is now generally accepted that the research sponsor has the right to receive the full results of the research, and in studies involving close and sustained cooperation with patients or research subjects, both the sponsor and the research subjects should be informed of the results. Problems arise when the sponsor owns the results and dissemination of research results was not part of the research protocol. Results from such research may not be published and may not be available to medical library. This is serious especially where research protocol was prepared from outside and local personnel were only involved in data collection and linkages between local and outside research are not assured of sustainability. It should be the responsibility of the IREC to scrutinize the protocols and ensure that:

(i) Research protocol contains procedures for information dissemination to stakeholders, including communities where research subjects were recruited;
(ii) Research is free from commercial bias;
(iii) Research results with proven advantages are widely disseminated and be put to use; and
(iv) The protocol contains provisions to ensure that in the cause of dissemination of research results, confidentiality of third party is not compromised.

7.2 Receiving gifts and hospitality in health research

The growing research interest of researchers from developed world to developing countries may bring along with financial or other packages that might influence research. Bearing in mind that a number of researchers in developing countries are lowly paid, gifts and hospitality might be inducement for researchers to engage in researcher that do not conform with internationally accepted standards. The CMA as well as MAT has provided guidelines, and a joint advice has been issued by the BMA and other on subjects such as 'Clinical Trials in General Practice' and "Post Marketing Surveillance". The views of the GMC are that.

"*It may be improper for a doctor to accepted per capita or other payments from a pharmaceutical firm in relation to a research project such as the clinical trial of a new product, unless the payment have been specified in a protocol for the project which has been approved by the relevant national or local ethical committee. It may be improper for a doctor to accept per capita or other payments under arrangements for recording clinical assessments of a medicinal product, whereby he is asked to report reactions which he has observed in patients for whom he has prescribed the product, unless the payments have been approved by the relevant national or local ethical committee. It is improper for a doctor to accept payment in money or kind which could influence his professional assessment of the therapeutic value of the new product*".

While this seems to be directed at the doctor, the principle is equally applicable to non-medical researchers as long as they are carrying out research involving human subjects. Therefore:

(i) Researchers should be transparent by indicating in their protocols gifts and other forms that would be associated with their carrying out the study;

(ii) IRECs should assess the per capita payment which should not exceed a reasonable estimate of the cost of studying a subject plus any legitimate profit; and

(iii) IRECs should provide guidance on what constitutes legitimate profit on the basis of acceptable practice.

7.3 Compensation (No fault)

As earlier stated, research may be cause of harm to research subjects in the physical or psychological sense. The risks are however, minimal but cannot be completely neglected. The question that is commonly asked is whether there are guidelines on the form acceptable for compensation. It should be stressed that motives driving research subjects to participate in the research may be variable. However, there is agreement that the benefits that society stands to gain outweigh the risks. Therefore, research subjects who develop illness as a result of participating in a research project are only legally entitled to compensation if they can show evidence of negligence on the part of:

(i) Investigator;
(ii) The host institution;
(iii) The sponsor of the research; or
(iv) Respective staff.

From the preceding paragraph, it can be concluded that research subjects have no legal right if they are unable to demonstrate negligence, a concept that raises questions of justice to research subjects. The BMA considers this lack of automatic compensation measure unacceptable and has called for more consideration especially where;

(i) The research protocol carries high risks because it involves invasive procedures; and
(ii) There is sufficient evidence that the procedures carry risks, arrangements for compensation should be made regardless of whether there may or may not have been negligence.

In Tanzania there are provisions in the Insurance Act of the necessity for compensation to research participants who develop illness as a result of participating to a research project. The Act clearly states that the insurance cover should be in accordance with local laws and regulations. In 2007, the Ministry of Health and Social Welfare through the Tanzania Food and Drug Authority directed full implementation of the provisions. Therefore in accordance with these Guidelines, it shall be required that:

(iv) All clinical trial proposals shall provide statements on how participants will be compensated in the event of adverse effects;

(v) The name(s) of insurance companies or brokers be provided in the proposal;

(vi) The terms of compensation shall be clearly stated in the proposal; and

(vii) The mode of compensation shall be clearly stated.

CHAPTER EIGHT

8. ETHICAL ISSUES UPON COMPLETION OF A STUDY

8.1 Introduction

It has become apparent that there are ethical issues involved when research on human subjects comes to an end, and the matter has attracted attention of researchers in many scientific fora. The questions often asked include post research obligations to:

(i) Research subjects and researchers.

(ii) Communities

(iii) Institutions.

(iv) Sponsors

Also commonly asked is "who should bear the responsibility"? Experience in developed countries has shown that more often the responsibility rests with the researchers, sponsors and the health authorities, taking into consideration for the benefits of communities or those with the studied condition. Similarly, the contribution of market forces in collaboration with health professionals and others have been recognized as those factors which make the outcomes of the study reasonably available to all stakeholders. Experience in the developing countries on the other hand is different, as in many cases consideration of what happens when the study comes to an end is often left un-addressed.

8.2. Guidelines on what to do at the end of a study

8.2.1 The CIOMS Guidelines

CIOMS recognizes the need for guidelines on this issue, and Guideline 15 states:

"*As a general rule, the sponsoring agency should agree in advance of the research that any products developed through such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing*".

CIOMS further stresses capacity building of the host country and requires that external research sponsors should help develop the host countries capacity to be able to carry out similar studies independently, including the review process.

8.2.2 US National Bioethics Advisory Commission

The US National Bioethics Advisory Commission recommends that "*Arrangements should be put in place to continue to provide to all participants (including members of a controlled group) any research intervention that was proven successful along the research, and the agreed upon details regarding post-trial treatment must be included in the informed consent process*".

However, other schools of thought argue against this and advocate that such conditions should not in any way constitute general requirements of health research in developing countries because they are unrealistic and generally not achievable.

In the case of Tanzania, it is in accordance with these Guidelines recommended that arrangements regarding post-study treatment are included in the proposal and informed consent form to the extent that available resources allow.

8.2.3 Ethical issues related to the post-study period

There are numerous ethical issues to be considered after the trial has come to an end which when not addressed carefully constitute dilemmas in health research. For example researchers have encountered dilemma on deciding who should be informed of the results and in what order. As a general rule:

(i) Research results should be disseminated to stakeholders including individuals, communities, and policy and decision makers;

(ii) Research results should be repackaged and disseminated in a manner and language that stakeholders regardless of education and cultural background will understand.

8.4 What to do with the human resources involved in the study?

More often in Tanzania, staffs are recruited from either institutions or communities hosting the study. At the end of the study it is uncommon that staff from institutions return to their routine work while those from local communities where the studies were carried out are left on their own. This has in many cases caused anxiety and in the long run may erode the trust on research and compromise future results.

In accordance with these Guidelines and as a matter of principle research protocols should provide capacity buildings of staff involved in the study to enable them to be able to carry out similar studies independently. This may be in the form of training, faculties and continuing education.

8.5 Sustainability of health improvement

Often health research is associated with health improvement, which may not be easily sustained after the study has come to an end. As a general rule, research protocols should provide strategies to sustain the health of the research subjects.

8.6 Disposal of residual resources

Researches bring to the host communities large pools of resources including vehicles, equipment, supplies, chemicals and pharmaceutical products, etc. Questions arise on appropriate disposal of such resource at the end of the study. As general guidelines:

(i) Prior consideration should be given to resources that may be beneficial to the host communities.

(ii) Research protocols should detail how residual resources will be disposed of;

(iii) Contract agreement should be entered between researchers and host communities on the disposal of residual resources.

(iv) Disposal should aim at capacity building; and

(v) National legal regulations on such disposal of residual resources should be taken into account.

8.7 Availability of products

Health research in patients may involve provision of therapeutic products. Researchers may encounter dilemmas where a trial product has proven benefits to the studied subjects. In this regard:

(i) Research protocols should provide details on how to handle research subjects on a product if it proves to benefit the patients;

(ii) Contract agreement should be drawn to ensure that a product with proven beneficial effect is made available to the community as soon as possible, at an affordable price.

(iii) Agreement should be made to ensure that a product, which has been shown to be effective, is made available to all research subjects as well as to other population at risk.

8.8 Archived specimens

Often researchers store specimen long after the study has come to an end. Ethical issues related to archived specimens like blood, organs, tissues, etc, are becoming subjects of discussion. The questions often asked include whether researchers may use archived specimens for studies other than the study consented to by the research subjects. It is important to note that consent is provided for the intended study, and it is unethical to use specimens for purposes other than those consented for. As general guidelines on this matter:

(i) Research protocols should detail the purpose and use of research specimens; and

(ii) Archived specimens should be commitment that if the specimens will be required in another experiment, researchers must provide a new protocol;

8.9 Patient rights and sharing of benefits

Researchers in developing countries, including Tanzania, have in recent years complained of research piracy by researchers from developed countries. As a result, Intellectual Property Rights and the sharing of benefits from commercial products are raising ethical issues. For example, an ethno-botanical study has demonstrated a

pharmacological effect of a product. However, because of lack of facilities for further product development, collaborators from overseas went ahead to isolate the active ingredient, patented and later commercialized in without the involvement of the local collaborators. It is therefore, recommended that local researchers involved in collaborative health research with external researchers should draw contract agreement detailing:

(i) How intellectual property rights matters shall be dealt with;

(ii) Anticipated benefits and risks that may have to be shared;

(iii) How benefits and risks shall be shared between researchers, sponsors and society;

(iv) The contributions of each researchers; and

(v) The methods of dissemination of research result, including publication.

8.10 Capacity building

There in need to ensure that all forms of research funding should include provision for capacity building of the host institution. Strategies for capacity building should be developed so as to include:

(i) Early involvement of the study community in the design, development and implementation processes;

(ii) Scientific exchange, knowledge and skills transfer;

(iii) Support for development of local ethical review capacity;

(iv) Support for education, information technology; and

(v) Support for consensus building.

8.11 Community participation

Involvement of community representatives should neither be seen a single encounter, not as one-directional. The orientation of community involvement in research should be one of partnership towards mutual education and consensus building regarding all aspects of the research. To ensure the ethical and scientific quality of the proposed research, its relevance to the community and its acceptance

by the study population, community representatives should be involved in an early and sustained manners in the:

(i) Design of the study

(ii) Development and implementation stages

(iii) Dissemination of research results.

8.12 Conclusion

In this chapter an attempt has been made to address what should be done when the research has come to an end and the dilemmas that researchers, research subjects and communities are likely to encounter. The list however, is not exhaustive and researchers are advised to update themselves on their experiences. Clear approaches and frequent exchange of ideas between researchers and other stakeholders are essential and will enrich our understanding of the intricacies and ethical matters related to what should happen when the research has some to an end.

CHAPTER NINE

9. ETHICAL ISSUES REGARDING ANIMAL EXPERIMENTATION

9.1. Introduction

The role of animals in advancing health science has long been established. Animal experimentation has provided knowledge on the understanding of human physiology and pathophysiologic basic of diseases. Similarly, animal experimentation has in numerous ways provided models for training and others scientific knowledge. It is important therefore, that animals involved in research should be respected and cared for. Good care improves the welfare of the animals and consequently will yield better, dependable and reproducible results than animals that are poorly kept or suffer from diseases. Experimental animals are any non-human living vertebrates or any other animal which according to the National Ethics Committee for Research on Animals has a nervous system which is so sophisticated that the animals is capable of experiencing pain in much the same way that any vertebrate might experience. An animal experiment therefore, is any procedure or procedures whereby a live animal or animals are used for the purpose of testing a hypothesis, answering research questions, collecting information for purpose of advancing knowledge or teaching or registering the effects of a certain procedure on an animal.

9.2. The National Health Research Ethics Committee recommendation

With respect to ethical issues in research involving laboratory animals, the National Health Research Ethics Committee wishes to:

(i) Recognize the contribution of animals to knowledge and that future use of animals are necessary;

(ii) Urge researchers to exercise humane care to animals during experimentation;

(iii) Stress that during animals experimentation, care must be exercised to ensure as much as possible that the animal is free from pain, stress, and discomfort, suffering and permanent damage; and

(iv) Stress that any institution carrying out animal experiments should establish Committee for Research Involving Animals (ICRIA) or Animal Use and Care Committees.

9.3 Composition of ICRIA

The size of the committee must not be too large or too small but should consist of members with the following qualities:

(i) Researchers with long experience in animal experiments;

(ii) One member representing a recognized organization involving in monitoring animal welfare in Tanzania but not involved in the proposed research;

(iii) One member representing veterinary sector (a registered veterinarian) but not involved in the proposed research;

(iv) One lay member vested with interest in research, but not involved in the proposed research.

9.4. Appointment of members of ICRIA

The management of the institution should make appointment of membership to ICRIA, and the functions of ICRIA should include:

(i) To prepare institutional guidelines on the conduct of animal experiment and clinical care within the institution;

(ii) To keep register of the variety of animal species used for experiments;

(iii) To ensure that the animals are well fed, kept and free from discomfort, suffering of diseases by making frequent examinations;

(iv) To ensures that procedures for experiments conform to acceptable standards;

(v) To ensure that experimental procedures are done by competent persons;

(vi) To ensure that decisions made by the Committee are complied upon by researchers;

(vii) To hold regular meetings aimed at reviewing suitability of submitted proposal for clearance; and

(viii) To make regular reports to the management of the institution.

9.5 Shipment of drugs for investigational use in laboratory animals

There are cases where laboratory animals in Tanzania are and or will be used in investigation of a trial product (drug). The drugs will in most cases be shipped from outside the country. It is important that such information be contained in the submitted protocol for review by IREC or NHREC. IRECs and NHREC must ensure that a person:

(i) May ship into Tanzania a drug intended solely for tests *in vitro* or laboratory animals if it is labelled as follows:

- **CAUTION:** Contains a new drug for research use only in laboratory animals, or for test *in vitro*. **Not For Use in Humans**.

(ii) May ship a biological product for research *in vitro* diagnostic use if it is labelled as follows:

- **CAUTION:** Contains a biological product for research *in vitro* diagnostic tests only.

(iii) Shipping into Tanzania a drug under paragraph (i) of this section shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new drug will actually be used for tests *in vitro* or animal used only for laboratory research;

(iv) Shipping a drug under paragraph (i) of this section shall maintain adequate records showing the name and post office address of thee expert to whom the drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery. The records of shipment and deliveries shall be maintained for period not less than **TWO** Years.

9.6 Disposition of unused drugs

As a matter of principle the person who ships into Tanzania:

(i) Drugs under section 9.5 of this chapter shall assure the return of all unused supplies of the drug(s) from individual investigators whenever the research discontinues or is terminated.

(ii) Drugs, may authorize alternative disposition of unused supplies of the drug or drugs provided that the alternative disposition does not expose humans to risks from the drug(s), either directly or indirectly, and the shipper shall maintain record of the alternative disposition.

CHAPTER TEN

10. PROCEDURES FOR CONDUCTING HEALTH RESEARCH IN TANZANIA

10.1 Role of the National Institute for Medical Research (NIMR)

The responsibility for controlling, coordinating, conducting and promoting the conduct of health research and dissemination of research results in Tanzania is vested upon NIMR by the Act of Parliament No.23 of 1979 (Appendix III). It follows therefore that in order to conduct health research in Tanzania permission must be sought from NIMR and under no circumstances can any research involving human beings be conducted or initiated in Tanzania without the permission of NIMR. This permission is given in the form of research clearance certificate signed by or on behalf of the Director General of NIMR who is the chairman of the Medical Research Coordinating Committee (MRCC). The same certificate will, as from August 2001, also carry the approval of the Ministry of Health to conduct the research by NIMR in health facilities of the Ministry of Health and in communities under the national health authorities in Tanzania, signed by or on behalf of the Chief Medical Officer.

10.2 The Medical Research Coordinating Committee (MRCC)

The MRCC of NIMR is the National Health Research Clearance body responsible for receiving, reviewing and granting research clearance to all health research proposals, submitted for the purpose of conducting research in Tanzania or elsewhere but for the benefit of Tanzania citizens (Appendix III). Once the Committee is satisfied with the scientific and ethical considerations of a research proposal, and has issued an Ethics Clearance Certificate, it will be co-signed by the Director General of the NIMR (as MRCC Chairperson), and the Chief Medical Officer of the Ministry of Health and Social Welfare. In case the research involves Tanzanians. For non Tanzanian after getting Ethical clearance they proceed to Tanzania Commission for Science and Technology (COSTECH) to get further approvals.

10.3 Tanzania Commission for Science and Technology

The Tanzania Commission for Science and Technology is a body mandated to issue research permit and research clearance to conduct research in the country, for all foreign researchers seeking to conduct or collaborate in conducting research in Tanzania. In order to issue any such permit for the conduct of health research, the commission requires the confirmation by NIMR that the research has been cleared and hence scientifically and ethically sound.

In order to enhance efficiency and reduce delays in issuing the clearance certificates, NIMR has authorized institutions mandated to conduct health research, to form Institutional Health Research Ethics Review Committee whose function will be to review research proposals for health research intended to be conducted within or by the institution and which will be conducted by a research team which involves only Tanzania nationals. Any research, whose team either involves foreign nationals or has the intention of conducting the research in collaboration with external individuals or institutions, has to be submitted to NIMR for clearance, unless the institution has been mandated to control and monitor such research by the Tanzania Government. It is emphasized that Institutional Committees of Health Research in Tanzania may issues research permits only for research proposals which do not involve foreigners. All copies of research proposals reviewed and cleared by the Institutional Health Research Committees must be submitted to NIMR for scrutiny and for record keeping. NIMR charges US $ 300 for clearance of a research proposal. This charge is currently applicable only to research proposals involving external collaboration.

10.4 Functions of the different institutions involving in health research clearance

10.4.1 Tanzania Commission for Science and Technology (COSTECH)

(i) The body that coordinates all research in Tanzania;

(ii) The only institution that may provide research permits to foreign research after ascertaining that the research has been cleared by NIMR;

(iii) Receives copies of the clearance certificates and corresponding proposals of health research proposal that have been cleared by NIMR.

10.4.2 *The National Institute for Medical Research (NIMR)*

(i) The body mandated to control and monitor health research conducted in Tanzania.

(ii) Receives health research proposals from individuals and institutions for ethical clearance.

(iii) Reviews the proposals and issues clearance certificate, demands modification of proposals before clearance or denies clearance if not satisfied with the scientific and ethical soundness of the proposal.

(iv) Sends clearance certificated to the Ministry of Health for permission to conduct research within the premises of the facilities of the Ministry of Health.

(v) Sends copies of the clearance proposals and corresponding certificates to COSTECH for the issuance of research permits to foreign researchers or collaborators.

(vi) Monitors the conduct of research according to protocol.

10.4.3 *Other Health Research and Academic Institutions*

(i) Receive research proposals.

(ii) Review the proposal and issues research clearance to proposals from its staffs, which do not involve foreign researchers or collaborators.

(iii) Submit all research proposals involving foreign researchers or collaborators to NIMR for national ethical clearance.

(iv) May review research proposal involving foreign researchers or collaborators but can not issue research clearance and must therefore submit the proposal and reviewers comments to NIMR for clearance.

If mandated by law to issue clearance to research proposals involving foreign researchers or collaborators, the institutions must send a copy of such proposals and

corresponding clearance certificates to NIMR for records and for further scrutiny. In any case NIMR may revoke such a clearance certificate or demand necessary amendments to the proposal before it is conducted in Tanzania, if it is not satisfied with the scientific and ethical integrity of the proposal.

CHAPTER ELEVEN

11. THE TANZANIA NATIONAL HEALTH RESEARCH FORUM

11.1 Background

The Tanzania National Health Research Forum is a forum of partner institutions involved in health research and their representatives. It is an inclusive body which ensures that each partner has a clearly defined role, is considered an asset and share in the ownership of the mechanism. It functions are based on the Essential National Research (ENHR) strategy, which ensures that evidence based information, is utilized correctly in the policy and decision making process, enhancing the provision of better and equitable health to the population.

The Forum is a consultative and advisory body to policy and decision makers as regards to health research coordination, undertaking collaboration, dissemination of health research and enhancing the utilization of research results for policy and decision making. It is a non-political, non-religious, voluntary body dealing only with issues of health research and development in the country.

11.2 The genesis of TANHER Forum

The genesis of the TANHER Forum may be traced to:

(i) 1985, the Health System Research Unit was established in the MoH with the support of the World Health Organization;

(ii) 1991, the Essential National Health Research Strategy was developed, and was supported by MoH, NIMR and COHRED;

(iii) 1996, The National Health User's Trust Fund was established under the support of MoH, NIMR and Swiss Agency for Development Cooperation.

(iv) 1998:

  (a) Ghana held ENHR Conference under the support of COHRED and National Health Research Forum was first proposed as a mechanism for WNHR.

  (b) Proposal for NHRF was approved by the NIMR Council.

(c) ENHR Strategy Workshop was held and an interim NHRF Chairman was appointed.

(v) 1999, ENHR Priority Setting Workshop was held using the Three Pronged Approach. It was during the workshop that elections for the NHRF Chairman, Secretary and the Secretariat were made;

(vi) The NHRF was launched officially be the Minister for Health on 26th February, 1999;

(vi) The NHRF Secretary became the Council Member of the Global Forum for Health Research in March 1999; and

(vii) The NHRF held its First Annual Meeting on February 2000.

11.3 The terms of reference of the Forum include:

(i) To discuss and recommended a mechanism for National Health Research (NHR) priority setting;

(ii) To establish and revise periodically NHR Priorities;

(iii) To receive and approve the report of the NHRCC;

(iv) To receive and approve the report of the NHREC.

(vii) To recommend to the MoH for approval of ethical guidelines for scientific content and ethics of health research in Tanzania.

(viii) To promote the establishment of networking and coordinating between centres and institutions.

(ix) To advise policy and decision makers on the allocation of funds for NHR activities; and

(x) To provide guidelines for partnership in health research.

The forum is therefore an independent body, which supports NIMR in its role in health research coordination and ethics review without actually taking these functions away from NIMR. Its functions are with respect to defining policies and guidelines for the conduct of health research and making it possible that all stakeholders actively participate in the formulation of such guidelines.

It ensures that harmonization of guidelines for the conduct of health research in Tanzania and the review process including the health research review guidelines. It also provides checks and balances in the processes and outputs of research monitoring bodies like NIMR, functions towards ensuring the development and maintenance of health research priorities in Tanzania, as well as that funds are made available for financing of such health research priorities.

In addition, the Forum works to enhance the translation of health research results into action. The approach is to set strategies for enhancing the utilization of such results by policy and decision makers, and stimulate the application of such strategies. In this regard, the Forum acts as a catalyst for the reactions of all stakeholders in this process, ensuring participation and ownership of the processes by the stakeholders themselves. The Forum is therefore an essential organ for strengthening the conduct of health research in Tanzania, and as a stimulant for development of research capacities.

11.4 Mode of operation

Depending on the mandate, each partner institution is a vehicle for passing on the Forum recommendations to policy and decision makers for policy and decision-making. It is the aim of the Forum to develop better strategies for research coordination, ensuring the maintenance of quality research and setting priorities for national research activities.

11.5 Conclusion

This booklet is the first national initiative in providing guidelines to health researchers and other stakeholders for the conduct of health research involving human subjects has been necessitated by the concern of the Tanzania society. It is intended to increase the level of awareness of all stakeholders on the need to comply with ethical standards in health research.

It is now accepted that health research carries the potential to cause physical and/ or psychological harm. This work draws the attention of researchers on ethical issues that have to be given consideration before, during, and after the study period. This however, is by no means exhaustive. Several issue, which are due to recent advancements in medical science and technology, which though important, may not have been included in this work. Such areas include the ethics of gene therapy, embryo research, the use of radiation in research. These important areas will nevertheless have to be addressed in the future.

In preparing these guidelines, emphasis was directed at ensuring that the interest of individual research subjects must always come first and be respected. In recruiting subjects into the study, adequate information on the aims methods, anticipated benefits; potential hazard and any discomfort that the research may entail must be given to all subjects in a manner that will empower them to make informed consent.

The rights if individual subjects to refuse participation in the study and or withdraw from the study at any stage of the study must be respected. In the process of obtaining consent, the consent will only be valid if it is given freely, and without undue pressure or inducements. No research which could equally be carried out on competent persons with their consent should be allowed to be carried out on people who cannot give valid consent.

To enable monitoring of health research in Tanzania, institutions engaged in research and training of health personnel must establish Research Ethics Committees (IREC). The composition of IRECs should include competent people in their areas of specialization, but also people from outside with the capacity to contribute towards enhancing ethical consideration in health research. The functions of the IRECs include receiving and scrutinizing research protocols, monitoring the research processes and keeping the records of research outputs. IRECs will be expected to provide advice and guidance to authors on the scientific and ethical soundness of their research proposals.

For smooth running and proper record keeping on the trends of health research in Tanzania, the NHREC should establish stronger linkages with collaborating institutions. The composition of the NHREC should be optimal and lay people should be included and encouraged to participate in activities of the NHERC.

These guidelines should be considered in line with acceptable community socio-cultural norms so as to avoid transgressing societal value. Where in doubt, existing guidelines e.g. the guiding principles and those earlier cited should be consulted.

APPENDIX ONE

DECLARATION OF HELSINKI

Human experimentation

In 1964, the WMA drew up a code on human experimentation. This code is since then known as the Declaration of Helsinki, as amended by the 29th World Medical Assembly, Tokyo, Japan, in 1975, the 35th World Medical Assembly, Venice, Italy, in 1983, 41st World Medical Assembly, Hong Kong, 1989 and the General Assembly, Somerset West, Durban, South Africa, in 1996 reads:

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge of conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration", and the International code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of aetiology and pathogenesis of disease.

In current medical practice, most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially in biomedical research.

Medical progress is based on research, which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aims is essentially diagnostic or therapeutic for a patient, and medical research, the

essential object of which is purely scientific and without implying directed diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research, which may affect the experiment, and the welfare of animals used for research must be respected. Because it is essential that the results of laboratory experiments must be applied to human beings to further scientific knowledge and to help suffering humanity, the WMA has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

1. Basic Principles

(a) Biomedical research involving human subjects must conform to the generally scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

(b) The design and performance of each experiment procedure involving human subjects should be clearly formulated in an experimental protocol, which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

(c) Biomedical research involving human subjects should be conducted only by scientifically qualified persons under the supervision of a clinically competent medical person. The responsibility for human subjects must always rest with the medically qualified person and never rest on the subject of research, even though the subject has given his or her consent.

(d) Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

(e) Every biomedical research involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable to the subject or to others. Concern for the interest of the subject must always prevail over the interest of science and society.

(f) The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

(g) Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazard involved is believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefit.

(h) In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results.

(i) In any research on human being, each potential subject must be adequately informed of the aims, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdrawn his or her consent to participation at any time. The physician should then obtain the subject's free-given consent, preferably in writing.

(j) When obtaining informed consent for the research project the physician particularly should be cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

(k) In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtained informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor

child is in fact able to give consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

(l) The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

2. Medical research combined with professional care (Clinical Research)

(a) In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.

(b) The potential benefits, hazard and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

(c) In any medical study, every patient including those of a control group, if any should be assured of the best-proven diagnostic and therapeutic method.

(d) The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

(e) If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.

(f) The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

3. Non-therapeutic biomedical research involving human subjects (Non-clinical biomedical research)

(a) In the purely scientific of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

(b) The subjects should be volunteers; either healthy persons or patients for whom the experimental design are not related to the patient's illness.

(c) The investigator or investigating team should discontinue the research if in his or her judgment it may; if continued, be harmful to the individual.

(d) In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject.

APPENDIX TWO

SCIENTIFIC AND ETHICAL REVIEW GUIDELINES

The guidelines have been drawn to provide as a checklist which would assist IRECs to review proposals submitted for ethical clearance. The checklist also serves as a standard for harmonizing proposal review. On reviewing the proposal the review committee should look for the following:

1. Title

1.1. Is there a title for the proposed study?

1.2. Is the title clear and explains the intended research?

1.3. Should not be too long?

2. Authors and Institutional Affiliations

2.1. Who are the authors?

2.2. Are they qualified for the intended research?

2.3. Any previous experience in research of similar nature?

2.4. Adequacy of the research team for the proposed study?

2.5. Is multi-disciplinary approach addressed?

2.6. To which institutions are they affiliated?

3. Summary

3.1. Does the proposal carry a summary?

3.2. Adequacy of the summary in providing important elements of the study (Background, Rationale, Objectives, Methodology, Timeframe and Total Budget)?

4. Background and literature review

4.1. Has the subject of research been adequately reviewed?

4.2. Will the proposed study bring new knowledge?

5. Problems statement

5.1. Is there a problem warranting the study?

5.2. What research questions would the study answer?

5.3. What hypothesis is being tested?

5.4. What is to be gained from the study?

5.5. Will the study design provide answers to the raised question?

6. Objectives of the study

6.1. Are objectives clear and address the problem to be researched?

6.2. Will the objectives attempt to answer the raised research questions?

6.3. Are objectives realizable?

7. Study area and population

7.1. Where is the study going to be carried out?

7.2. Is the selected study area and population appropriate for the proposed study?

7.3. Given the available capacities, is it feasible to carry out the study in the selected area and population?

7.4. Is the study population well defined?

7.5. What sampling methods have been proposed for selecting study population?

7.6. Would the selected population be representative of the community from which the sample has been selected?

8. Methodology

8.1. Are proposed methods clearly explained?

8.2. Will the proposed methods provide answers to the research question?

8.3. Are there advantages of using one method over the other or combination of methods?

8.4. How will collected data be handled?

8.5. Does the proposal address issues of capacity building of local collaborator (s)?

9. Ethical consideration

9.1. Is it ethical to carry out the proposed study?

9.2. Have ethical issues related to the study been considered?

9.3. Have the risks to benefit been considered?

9.4. Are social and cultural factors that may transgress individual privacy been considered?

9.5. Is the procedure for seeking consent clear?

9.6. Has autonomy of research subjects been considered?

9.7. Are the necessary instruments available?

10. Compensation

In case of clinical trials:

10.1 Is there a description of how research participants will be compensated?

10.2 What are the levels of compensation?

10.3 To what extent compensation is in accordance with local laws?

10.4 Which company(ies) will be involved in providing insurance cover?

11. Safety data monitoring

In the case of clinical trials, establish:

1.1 Is there a Data Safety Monitoring Board proposed?

1.2 Have the functions of the DSMB clearly defined?

1.3 Has at least one member from Tanzania been included?

12. Constraints

12.1. Are there constraints that might require social attention?

12.2. What strategies have been proposed to address the constraints?

12.3. Is there assurance that the effects of the constraints on the study output will be minimal?

13. Dissemination

13.1. Are there proposals of how the research results will be disseminated?

13.2. Do the proposed dissemination strategies target stakeholders?

14. Budget

14.1. Is the budget realistic?

14.2. Is a budget justification satisfactory?

14.3. Is there balance on how funds will be shared between collaborating institutions?

14.4. are the potential participants been considered for their time and travel

14.5. Is the payment appropriate for their circumstances

APPENDIX THREE

Research provisions of the National Institute for Medical Research Act No. 23 of 1979

1. The National Institute for Medical Research (NIMR) was established by Act of Parliament No. 23 of 1979. Section 4 (1) of the NIMR Principal Act prescribes the NIMR functions relevant to research to include among other things:

(i) To carry out, and promote the carrying out of, medical research designed to alleviate disease among the people of Tanzania.

(ii) In collaboration with the Government of any person or body of persons, to promote, or provide facilities for, the training of local personnel for carrying out scientific research into medical problems.

(iii) To carry out, and promote the carrying out of research into various aspects of local traditional medical practices for the purpose of facilitating the development and application of herbal medicine.

(iv) To monitor, control and co-ordinate medical research carried out within Tanzania, or elsewhere on behalf of or for the benefit of the Government of Tanzania, and evaluate the findings of that research.

(v) To establish a system for the registration of, and to register, the finding of medical research carried out within Tanzania, and promote the practical application of those findings for the purpose of improving or advance the health and general welfare of the people of Tanzania.

(vi) To establish and operate a system of documentation and dissemination of information on any aspect of the medical research carried out by or on behalf of the Institute.

2. Section 4 (2) further stresses that, in particular, but without prejudice to the generality of Subsection (1) NIMR may:

(i) Carry out, and promote the carrying out of, research and investigation into the cause, and the ways of controlling and preventing the occurrence in Tanzania of particular diseases or a category of them.

(ii) In co-operation with the Government or any person or body of persons, carry out and promote the carrying out of, basic, applied and operational research designated to provide effective measure for the control of disease endemic in Tanzania.

3. The Act. No, 23 of 1979 further mandates NIMR, under Section 11, to require in writing any hospital, health centre, dispensary or other medical establishment or category of them to furnish to its such information relating to such disease or disease as the Institute may specify.

4. Further, Section 12 empowers NIMR to call for information on medical research by requiring every person or body of persons engaged in medical or other allied scientific research within Tanzania to furnish to it such information relating to medical or other allied scientific research as the Institute may specify. The section spells out condition to be complied that, every person or body of persons required to furnish information under Section 12 (1) shall comply with the requirement and any person or body or persons, who refuses or fails to comply with that requirement shall be guilty of an offence.

In conclusion, NIMR is the National Institute with mandate to carry out, promote and monitor the conduct of health research in Tanzania. In order to enhance smooth operations and research environment in Tanzania, institutions with mandates to carry out health research in Tanzania should therefore, familiarize themselves with the relevant provisions of the NIMR Act.

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TITLE 10

PREVIOUS CHAPTER

Chapter 10:22
RESEARCH ACT

Acts 5/1986, 2/1988, 18/1989 (s. 40, s. 43), 11/1991 (s. 29), 2/1998, 22/2001.

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SCHEDULE: Powers of Council.

AN ACT to establish the Research Council of Zimbabwe and to confer on the Council functions and powers relating to the promotion, direction, supervision and co-ordination of research; to provide for the establishment of research councils and research institutes and for the control of such research councils and research institutes by the Council; to provide for the control of research conducted by bodies or persons in terms of any Act; to provide for the registration of foreign researchers; and to provide for matters connected with or incidental to the foregoing.

[Date of commencement: 1st October, 1986.]

PART I

PRELIMINARY

1 Short title

This Act may be cited as the Research Act [Chapter 10:22].

2 Interpretation

In this Act—

"Council" means the Research Council of Zimbabwe established by section three;

"financial year", in relation to the Council, means the financial year of the Council referred to in section nineteen;

"member" means a member of the Council;

"Minister" means a Vice-President or any Minister to whom the President may, from time to time, assign the administration of this Act;

"Minister responsible", in relation to any matter for which a research council or research institute is to be or has been established, means—

(a) any Minister who is empowered or required by any law to exercise any function in respect of such matter; or

(b) a Vice-President, where that Vice-President is empowered or required by any law to exercise any function in relation to such matter;

"potentially harmful research or undertaking"—

(a) means any form of research or undertaking which, in the Council's opinion, poses or is likely to pose a danger to persons, animals or plants or to the environment generally;

(b) in relation to a safety board which has been appointed to ensure the safety of a particular class of research or undertaking referred to in paragraph (a), means that class of research or undertaking;

"repealed Act" means the Research Act [Chapter 336 of 1974];

"research" means any systematic, critical or scientific study of, or inquiry into, any subject or matter for the extension of knowledge;

"research council" means a research council established in terms of this Act to conduct research, and includes, where the context so requires or admits, a research council established in terms of the repealed Act;

"research institute" means a research institute established in terms of this Act to conduct research;

"safety board" means a safety board established by the Council in terms of subsection (1) of section twenty-eight B.

PART II

RESEARCH COUNCIL OF ZIMBABWE

3 Establishment of Council

There is hereby established a council, to be known as the Research Council of Zimbabwe, which shall be a body corporate and shall be capable of suing and being sued in its corporate name and, subject to this Act, of performing all such acts as a body corporate may by law perform.

4 Composition of Council

(1) The Council shall consist of such members as the Minister shall appoint, not being less than ten or more than fifteen in number, as the Minister may from time to time determine.

(2) The Minister shall appoint one member as chairman of the Council and one other member as vice-chairman of the Council and the vice-chairman shall exercise the functions of the chairman during any period that the chairman is unable to exercise his functions.

5 Disqualifications for appointment to Council

The Minister shall not appoint a person as a member, and no person shall be qualified to hold office as a member who—

(a) has, in terms of a law in force in any country—

(i) been adjudged or otherwise declared insolvent or bankrupt and has not been rehabilitated or discharged; or

(ii) made an assignment to or arrangement or composition with his creditors which has not been rescinded or set aside; or

(b) has, within the period of five years immediately preceding the date of his proposed appointment, been sentenced in any country to a term of imprisonment imposed without the option of a fine for an offence involving fraud or dishonesty; or

(c) is a member of Parliament or was, at any time during the period of twelve months ending on the date of his proposed appointment as a member, a member of Parliament.

6 Tenure and conditions of office of members of Council

(1) A member shall, subject to this Part, hold office for such period, not exceeding three years, as the Minister may fix on his appointment, and shall, upon the expiry of his term of office, be eligible for reappointment as a member.

(2) Subject to this Act, a member shall hold office on such conditions as the Minister may fix for members generally.

7 Vacation of office by member and suspension of member of Council

(1) A member shall vacate his office and his office shall become vacant—

(a) one month after the date he gives notice in writing to the Minister of his intention to resign his office or after the expiry of such other period as he and the Minister may agree; or

(b) on the date he begins to serve a sentence of imprisonment imposed in any country; or

(c) if he becomes disqualified to hold office as a member in terms of paragraph (a) or (c) of section five; or

(d) if he is required in terms of subsection (2) to vacate his office; or

(e) if he is absent from three consecutive meetings of the Council of which he has had notice without the permission of the Council.

(2) The Minister may require a member to vacate his office if that member—

(a) is guilty of any conduct that renders him unsuitable to continue to hold office as a member; or

(b) has failed to comply with any of the conditions of his office fixed by the Minister in terms of subsection (2) of section six; or

(c) is mentally or physically incapable of efficiently carrying out his functions as a member.

(3) The Minister may suspend a member against whom criminal proceedings have

been instituted for an offence in respect of which a sentence of imprisonment without the option of a fine may be imposed and, while that member is so suspended, he shall not carry out any functions as a member.

8 Filling of vacancies on Council

On the death of, or the vacation of office by, a member, the Minister shall appoint a person to fill the vacancy until the expiry of the period during which the member would, but for his death or the vacation of his office, have continued in office:

Provided that, if, but for his death or the vacation of his office, the member would have continued to hold office for less than three months the Minister need not appoint a person to fill the vacancy.

9 Meetings and procedure of Council

(1) The Council shall hold its first meeting on such date and at such place as the Minister may specify and thereafter the Council shall meet for the transaction of business and adjourn, close and otherwise regulate its meetings and proceedings as it thinks fit:

Provided that a meeting of the Council shall be held not less than three times in each year.

(2) The chairman of the Council may at any time, and shall, at the request in writing of at least three other members, convene a special meeting of the Council.

(3) A notice convening a special meeting of the Council shall specify the purpose for which the meeting is to be convened.

(4) If the chairman of the Council is prevented by any cause from exercising his functions in relation to the Council and the vice-chairman notifies the Minister in writing that he is unable to exercise the functions of the chairman as is provided in subsection (2) of section four, the Minister may appoint a member, other than the vice-chairman, to act as chairman of the Council and the member so appointed shall exercise the functions of the chairman.

(5) If at a meeting of the Council the chairman and the vice-chairman are absent and an acting chairman has not been appointed in terms of subsection (4), the members present may elect one of their number to preside as chairman at that meeting.

(6) Not less than one-half of all members shall form a quorum at a meeting of the Council.

(7) All acts, matters or things authorized or required to be done by the Council may be decided by a majority vote at a meeting of the Council at which a quorum is present.

(8) At all meetings of the Council each member shall have one vote on a question before the Council and, in the event of an equality of votes, the chairman of the Council, the vice-chairman of the Council, an acting chairman or any other member presiding at the meeting, as the case may be, shall have a casting vote in addition to his deliberative vote.

10 Transaction of business of urgent nature

(1) If it is not practicable to hold a meeting of the Council for the transaction of business of an urgent nature, the chairman shall, after consulting such other members as is practicable in the circumstances, deal with the business himself, and as soon as may be thereafter give to the Council full particulars of the nature and extent of the urgency of the business and the circumstances in which the urgency arose and of the action taken by him in the matter.

(2) Any proposal circulated among all members and agreed to in writing by a majority of all members shall have the same effect as a resolution passed at a duly constituted meeting of the Council and shall be incorporated in the minutes of the next following meeting of the Council:

Provided that if a member requires that such proposal be placed before a meeting of the Council this subsection shall not apply to such proposal.

11 Committees of Council and observers

(1) For the better exercise of its functions the Council may establish one or more

committees in which may be vested such of the functions of the Council as the Council may direct:
Provided that the vesting in a committee of any such functions shall not divest the Council of such functions and the Council may, in the exercise of its functions, amend or rescind any decision of any such committee.
(2) On the establishment of a committee of the Council in terms of subsection (1), the Council—
(a) subject to subsection (3), may appoint as members of that committee persons who are not members of the Council; and
(b) shall appoint to that committee at least one member of the Council and shall appoint that member or, in the event that there are two or more members on the committee, one of those members, as the case may be, to be chairman of the committee.
(3) The Council shall not appoint a person to be a member of a committee if he is disqualified in terms of section five from appointment as a member of the Council.
(4) A member of a committee of the Council shall vacate his office—
(a) in the case of a member who is a member of the Council, upon his ceasing to be a member of the Council;
(b) in the case of a member who is not a member of the Council—
(i) if his appointment is terminated by the Council; or
(ii) if he would be required in terms of section seven to vacate his office had that section and paragraphs (a) and (c) of section five applied to him.
(5) Subject to this section and section fifteen, members of committees of the Council shall hold office on such conditions as the Council may fix for members of committees generally.
(6) Subject to section twelve, the procedure to be followed at any meeting of a committee of the Council and the quorum at such meeting shall be determined by the Council.
(7) The chairman of the Council may at any time and place convene a meeting of a committee of the Council.
(8) No decision or act of a committee of the Council or act done under the authority of a committee of the Council shall be invalid solely on the ground that—
(a) the committee consisted of fewer than the number, if any, fixed by the Council as constituting the membership of the committee; or
(b) a disqualified person purported to act as a member of the committee at the time the decision was taken or the act was done or authorized.
(9) For the better exercise of the functions of the Council, the chairman of the Council or of a committee of the Council may, with the approval of the Council, invite to attend any meeting of the Council or of a committee of the Council, as the case may be, any person who, in the opinion of the chairman of the Council or of the committee, has special knowledge or experience that is relevant to the matter to be considered by the Council or the committee, as the case may be, at that meeting.
(10) A person invited to attend a meeting of the Council or of a committee in terms of subsection (9) may take part in the proceedings of the Council or of the committee as if he were a member thereof but shall not have a vote on any question before the Council or committee, as the case may be.
12 Minutes of proceedings of Council and committees
(1) The Council shall cause minutes of all proceedings of and decisions taken all meetings of the Council and of every committee of the Council and safety board to be entered in books kept for the purpose.
(2) Any minutes referred to in subsection (1) which purport to be signed by the chairman of the meeting to which the minutes relate or by the chairman of the next following meeting of the Council or of the committee or safety board concerned, as the case may be, shall be accepted for all purposes as prima facie evidence of the proceedings of and decisions taken at the meeting concerned.

13 Validity of decisions and acts of Council

No decision or act of the Council or act done under the authority of the Council shall be invalid solely on the ground that—

(a) the Council consisted of fewer than the minimum number of members for which provision is made in subsection (1) of section four; or

(b) there was a vacancy in the membership of the Council; or

(c) a disqualified person purported to act as a member at the time the decision was taken or the act was done or authorized.

14 Execution of contracts and instruments by Council

An agreement, contract or instrument approved by the Council may be entered into or executed on behalf of the Council by any person or persons generally or specially authorized by the Council for that purpose.

15 Remuneration and allowances of members of Council and committees

A member of the Council or of a committee of the Council or a safety board shall be paid from the funds of the Council—

(a) such remuneration, if any, as the Minister, with the approval of the Minister responsible for finance, may from time to time fix for such members generally; and

(b) such allowances, if any, as the Minister, with the approval of the Minister responsible for finance, may from time to time fix to meet any reasonable expenses incurred by such members in connection with the business of the Council or of the committee or safety board concerned, as the case may be.

PART III

FUNCTIONS AND POWERS OF COUNCIL

16 Functions of Council

(1) The Council shall generally be responsible for the promotion, direction, supervision and co-ordination of research with particular reference to the interests of Zimbabwe and shall, in appropriate cases, discharge its responsibilities—

(a) by exercising the power of control conferred upon it by or under this Act over research councils and research institutes; and

(b) by making donations or grants and awarding fellowships or any other similar awards for specific research; and

(c) by promoting, assisting and encouraging research in Zimbabwe and co-operating with individuals, organizations and institutions in the co-ordination of research in Zimbabwe; and

(c1) by ensuring that persons, animals, plants and the environment generally are protected from the effects of potentially harmful research or undertakings;

(d) by making recommendations to the Minister in relation to—

(i) the grant to an individual, the holder of an office or post, a body, unit, corporation or other association of persons of an honour or award for outstanding achievement, invention or discovery in the field of research; and

(ii) the payment of a reward or gratuity to the recipient of an honour or award referred to in subparagraph (i) from moneys appropriated for the purpose by Act of Parliament; and

(e) by co-operating with persons, organizations or institutions in any other part of the world in matters of research; and

(f) by securing full use in the public interest of the results of research by the collection and dissemination of information and by the giving of advice in relation thereto; and

(g) by making recommendations to the Minister in relation to—

(i) the formulation and implementation by the Government of a national science policy; and

(ii) the research needs of Zimbabwe and the priorities to be observed in the allocation of funds and other resources for purposes of meeting such needs; and

(iii) the establishment of research councils or research institutes to conduct research; and

(iv) the constitution under which a research council or research institute shall be established in terms of this Act or the constitution under which a research council was established in terms of the repealed Act; and

(v) the assignment of responsibilities to the Minister responsible in respect of any research council or research institute established in terms of this Act or any research council established in terms of the repealed Act; and

(vi) subject to section twenty-seven, the approval and monitoring of research conducted in Zimbabwe by scholars and other persons who are not citizens or residents of Zimbabwe; and

(vii) all such other things, and the steps to be taken, as fall within the functions of the Council in terms of this Act; and

(h) by tendering advice to the Minister on the overall management of research programmes and the allocation of funds and other resources for research.

(2) Without prejudice to subsection (1), the Council may, after consultation with the Minister responsible and subject to subsection (3), exercise the powers and functions conferred upon it by or under this Act over research conducted by any person or body in terms of any Act.

(3) Where the Council intends to exercise the powers and functions referred to in subsection (2) it shall, by notice in writing, advise the person or body concerned that with effect from such date as may be specified in the notice, the Council intends to exercise its powers over that person or body and, where such notice is given, with effect from the date specified therein, sections twenty-six and twenty-eight shall, notwithstanding the provisions of the Act concerned apply, mutatis mutandis, to the person or body as though such person or body were a research council or a research institute referred to in those provisions.

17 Powers of Council

(1) The Council shall have power to do all or any of the matters or things specified in the Schedule.

(2) The Minister, after consultation with the Council, may from time to time, by statutory instrument, make amendments to the Schedule.

PART IV

FINANCIAL PROVISIONS

18 Funds of Council

The funds of the Council shall consist of—

(a) such moneys as may be payable to the Council from moneys appropriated for the purpose by Act of Parliament; and

(b) such other moneys or assets as may vest in or accrue to the Council in the course of its operations or otherwise.

19 Financial year of Council

The first financial year of the Council shall be the period ending on the 30th June immediately following the date of the commencement of its operations or on such other date as the Minister may direct and thereafter the financial year of the Council shall be the period of twelve months ending on the 30th June in each year or on such other date as the Minister may direct.

20 Accounts of Council

(1) The Council shall keep proper accounts and other records relating thereto in respect of all its operations, undertakings and property, including such particular accounts and records as the Minister may direct.

(2) The Council shall prepare and submit to the Minister in accordance with subsection (4) of section twenty-one, a statement of accounts in respect of each financial year or such other period as the Minister may direct.

21 Appointment of auditors and audit of accounts of Council

(1) The Council shall annually appoint as auditors one or more persons approved by

the Minister who are registered as public auditors in terms of the Public Accountants and Auditors Act [Chapter 27:12].
(2) The accounts of the Council kept in terms of subsection (1) of section twenty shall be examined by the auditors appointed in terms of subsection (1).
(3) The auditors shall make a report to the Council on the accounts examined by them and on the statement of accounts prepared in terms of subsection (2) of section twenty and such report shall include a statement showing—

(a) whether or not they have obtained all the information and the explanations they have required; and

(b) whether, in their opinion, such statement of accounts is properly drawn up so as to exhibit a true and fair view of the state of affairs of the Council according to their best information and the explanations given to them and as shown by the books of the Council.

(4) As soon as the accounts of the Council have been audited, the Council shall submit to the Minister its statement of accounts referred to in subsection (2) of section twenty, together with a copy of the report of the auditors referred to in subsection (3).
(5) In addition to the report of the auditors referred to in subsection (3), the Minister may require the Council to obtain from the auditors such other reports, statements or explanations in connection with the operations, undertakings and property of the Council as the Minister may consider expedient.
(6) If, in the opinion of the auditors—

(a) they have not obtained the information and explanations they require; or

(b) the accounts and records relating thereto have not been properly kept; or

(c) the Council has not complied with this Part;

the auditors shall include in the report made in terms of subsection (3) or (5), as the case may be, statements to that effect.

22 Powers of auditors

(1) The auditors appointed in terms of subsection (1) of section twenty-one shall have the right of access at all reasonable times to the books, accounts and vouchers of the Council and other records relating thereto kept by the Council and shall be entitled to require from any member, employee or agent of the Council such information and explanations as in their opinion are necessary for the purposes of their audit.
(2) Any member, employee or agent of the Council who fails without just cause to comply with a requirement of an auditor in terms of subsection (1) shall be guilty of an offence and liable to a fine not exceeding five hundred dollars or to imprisonment for a period not exceeding three months or to both such fine and such imprisonment.

23 Reports by Council

(1) In addition to any annual report which the Council may be required to submit to the Minister in terms of the Audit and Exchequer Act [Chapter 22:03], the Council—

(a) shall submit to the Minister such other reports as the Minister may require;

(b) may submit to the Minister such other reports as the Council considers desirable.

(2) The Council shall give to the Minister all such information relating to the operations and undertakings of the Council as the Minister may at any time require.
(3) The Minister may lay before Parliament a report submitted to him by the Council in terms of subsection (1).

PART V

RESEARCH COUNCILS AND RESEARCH INSTITUTES

24 Establishment of research councils and research institutes

(1) Whenever the Minister responsible considers it necessary or desirable to establish a research council or research institute for the purposes of facilitating the carrying out

of research, he shall submit his proposal to the Council and shall include the suggested constitution of the research council or research institute concerned.
(2) The Council shall consider any proposal received by it in terms of subsection (1) and shall thereafter submit its own recommendations thereon to the Minister.
(3) Where the Minister has received any proposal and the recommendations of the Council in terms of subsection (2), he may—

(a) approve the proposal with or without such qualifications or amendments as he may direct in writing; or

(b) decline to approve the proposal.

(4) Where the Minister has approved a proposal in terms of subsection (3), the Minister responsible may establish the research council or research institute concerned in accordance with the approval granted by the Minister and shall cause notice of the establishment of the research council or research institute to be given in the Gazette.

25 Provisions to be contained in constitution of research council or research institute

(1) The constitution of a research council or research institute which is intended to be a body corporate shall contain provision for the following matters—

(a) the name of the research council or research institute;

(b) the composition of the research council or research institute and the tenure and conditions of office of members thereof;

(c) the disqualifications for appointment as a member of the research council or research institute;

(d) the circumstances in which the Minister responsible may require a member of the research council or research institute to vacate his office and in which the Minister responsible may suspend such member from the exercise of his functions as a member;

(e) the circumstances in which a member of the research council or research institute shall vacate his office;

(f) the filling of vacancies on the research council or research institute;

(g) meetings and the procedure at meetings of the research council or research institute;

(h) minutes of proceedings of the research council or research institute;

(i) the transaction of business of an urgent nature by the research council or research institute;

(j) the validity of the decisions and acts of the research council or research institute;

(k) the execution of contracts and instruments by the research council or research institute;

(l) the appointment of an executive committee and other committees of the research council or research institute and the powers to delegate functions to such committees;

(m) the funds of the research council or research institute;

(n) the keeping of accounts, audit and reports of the research council or research institute;

(o) the corporate powers which shall be exercised by the research council or research institute and the conditions or limitations upon which or within which such corporate powers shall be exercised;

(p) the nature and scope of the research to be carried out by the research council or research institute;

(q) the dissolution of the research council or research institute and the proper and effective winding-up of its affairs, including the transfer of employees, if any, and the disposition of any assets and liabilities;

(r) such other matters as may be considered necessary or desirable.

(2) The Minister responsible may, after consultation with the Council and with the

approval of the Minister, amend the constitution of a research council or research institute.

26 Functions and research programmes of research council or research institute

(1) Subject to section twenty-eight, the functions of a research council or research institute shall be to carry out research within Zimbabwe in accordance with its constitution and a research programme approved by the Council in terms of subsection (1) of section twenty-eight.

(2) A research council or research institute, as the case may be, shall, as often as the Council may direct, prepare and submit to the Council—

(a) a research programme showing its proposals with respect to—

(i) the research to be carried out by the research council or research institute, as the case may be; and

(ii) the priorities to be observed in carrying out such research; and

(iii) such other matters as the Council may require; and

(b) reports on the implementation by it of research programmes approved or funded, whether wholly or in part, by the Council.

27 Registration in relation to foreign research with Council

(1) Any person—

(a) who wishes to conduct research in Zimbabwe on behalf of a foreign institution, foreign organization or other foreign person, whether as an employee or otherwise; or

(b) other than a citizen of or a person ordinarily resident in Zimbabwe, who wishes to conduct research in Zimbabwe;

shall, before conducting such research, register with the Council in the form and manner to be determined by the Council and shall tender to the Council the appropriate registration fee.

(2) The Council may, with the approval of the Minister, fix a fee for the registration and in so doing may fix different fees for the registration of different classes of persons.

(3) The Council may, before registering a person referred to in subsection (1), request that person to furnish it with such relevant information as it may require.

(4) The Council shall, on registering a person in terms of subsection (1), issue to that person a certificate of registration.

(5) Where there has been a substantial or material change in the particulars of research conducted by a person who has been registered in terms of subsection (1), such person shall as soon as possible advise the Council of such change.

(6) A person who has been registered in terms of subsection (1) shall—

(a) at such time as the Council may request, submit an interim report relating to his research;

(b) on completion of his research, submit a final report on the results or other findings of his research to the Council.

28 Control of research councils and research institutes by Council

(1) The Council—

(a) shall consider the research programme submitted to it from time to time by a research council or research institute in terms of subsection (2) of section twenty-six and may, subject to such modifications as the Council thinks fit, approve the research programme to be carried out by the research council or research institute, as the case may be; and

(b) shall exercise general supervision and control of the research council or research institute concerned and ensure that the research council or research institute, as the case may be, observes the provisions of this Act and of its constitution and the research programme as approved or amended by the Council from time to time; and

(c) may, after consultation with the research council or research institute concerned, give the research council or research institute, as the case may be, general

directions on matters of policy.
(2) The Council may, after consultation with a research council or research institute, as the case may be, make such amendments to the approved research programme of that research council or research institute as the Council thinks fit.
(3) Every research council and research institute shall permit the Council and any person appointed by the Council to make inspections and examinations of its operations, records and accounts, and shall comply with any directions given to it by the Council under the provisions of this Act.
28A Access to research facilities
(1) Subject to this section and to any directions given to it by the Council, a research Council or research institute may permit any person to utilize research facilities owned or controlled by the research council or institution for the purpose of conducting any form of research or undertaking.
(2) A person who utilizes any research facilities in accordance with subsection (1) shall pay the research council or research institute concerned—
(a) such fee as may be agreed between him and the research council or research institute; or
(b) a reasonable fee determined by the Council, where he and the research council or research institute have been unable to agree on a fee.
(3) The research council or institute may vary any of the terms or conditions upon which it has permitted a person to utilize its facilities in terms of subsection (1):
Provided that before doing so the research council or institute shall give the person concerned an adequate opportunity to make representations in the matter.
PART VA
MEASURES TO ENSURE SAFETY OF RESEARCH
28B Safety boards
(1) Subject to this Part, the Council may establish one or more boards for the purpose of ensuring the safety of potentially harmful research or undertakings generally or any class of potentially harmful research or undertakings.
(2) Where the Council has established a safety board, it shall publish notice of that fact in the Gazette.
(3) A safety board shall consist of such number of members appointed by the Council as the Council may from time to time determine.
(4) The Council may appoint persons who are not members of the Council to be members of a safety board.
(5) Subsections (3) to (10) of section eleven shall apply, mutatis mutandis, in respect of safety boards and their members.
28C Functions of safety boards
(1) Subject to subsection (3), the functions of a safety board shall be-
(a) to monitor and supervise potentially harmful research or undertakings; and
(b) to formulate and additionally or alternatively, to implement measures to protect persons, animals and the environment generally from dangers that may arise from potentially harmful research or undertakings; and
(c) to make recommendations to the Council in regard to the control and regulation of, and the policy to be adopted towards, potentially harmful research or undertakings; and
(d) to publish information regarding potentially harmful research or undertakings;
(e) to perform such other functions in regard to potentially harmful research or undertakings as may be prescribed.
(2) The Council may vest in a safety board such of the Council's functions, in so far as they relate to potentially harmful research or undertakings, as the Council may think fit:
Provided that the vesting of such a function in a safety board shall not divest the

Council of that function, and the Council may amend or rescind any decision the safety board may have made in the exercise of that function.

PART VI

GENERAL

29 Discoveries and inventions by officers of Council, research council or research institute.

(1) Subject to section thirty the rights in all discoveries and inventions and in all improvements in respect of processes, articles, substances, materials, machinery or apparatus made in the course of their employment by officers of the Council or a research council or research institute or persons holding research fellowships or other similar awards granted by the Council or a research council or research institute shall be vested in the Council or the research council or research institute, as the case may be, and such discoveries, inventions and improvements shall be made available for use in the public interest subject to such conditions and the payment of such fees or royalties as the Council or the research council or research institute, as the case may be, may, in accordance with regulations made by the Minister, determine.

(2) The Council or a research council or research institute may, out of its funds, pay the discoverer or inventor working as an officer of the Council or the research council or research institute, as the case may be, or as a person holding a research fellowship or other similar award granted by the Council or the research council or research institute, as the case may be, such bonus, or make provision for such financial participation in the profits derived from the relevant discovery or invention as the Minister or the Minister responsible, as the case may be, in consultation with the Minister responsible for finance, may determine.

(3) The Council, a research council or research institute may apply for a patent in respect of any discovery, invention or improvement referred to in subsection (1) and shall, for the purposes of the Patents Act [Chapter 26:03], be regarded as the assignee of the discoverer or inventor.

30 Special investigations at request of person with a specific object of making discoveries, inventions or improvements

(1) Subject to the approval of the Minister or the Minister responsible, as the case may be, the Council, a research council or research institute may, at the request of any person and at such place and subject to such conditions and the payment of such charges as may be agreed upon, carry out or cause to be carried out through its officers or through persons holding research fellowships or other similar awards granted by it or to whom special grants were made by it special investigations with the object of the discovery or invention of or the improvements in respect of any process, article, substance, material, machinery or apparatus.

(2) The rights in any discovery, invention or improvement so made shall be vested in the Council or the research council or research institute concerned, as the case may be, or the person who made the discovery, invention or improvement if he is a person to whom a special grant is made by the Council or the research council or research institute, as may be provided by a written agreement entered into by the parties concerned prior to the investigation.

(3) Any discoveries, inventions or improvements, the rights to which are vested in the Council, a research council or research institute in pursuance of an agreement referred to in subsection (2), shall be made available for use in the public interest and the Council, the research council or research institute concerned may apply for a patent in respect thereof, as if they were discoveries, inventions or improvements referred to in subsection (1) of section twenty-nine.

(4) If the rights to any discovery, invention or improvement are, in pursuance of an agreement referred to in subsection (2), vested in any person other than the Council, the research council or research institute concerned, that discovery, invention or improvement shall be used or made available for use in the public interest subject to such conditions as may be provided by the agreement.

31 Minister may give Council directions in pubic interest

The Minister may from time to time give the Council such directions of a general character relating to the exercise of its functions as appear to the Minister to be requisite in the public interest and the Council shall be bound to comply with any such directions.

31A Exemption from liability

No liability shall attach to the Council, any committee of the Council or a safety board, or to any member or employee of the Council a committee of the Council or a safety board, in respect of loss or damage sustained by any person as a result of the bona fide exercise or performance by the Council, committee, safety board, member or employee concerned of any function conferred or imposed upon it or him, as the case may be by or under this Act:

Provided that this section shall not be construed so as to prevent any person from recovering damages or compensation for any loss or damage sustained by him which was caused by negligence or breach of contract.

32 Regulations

(1) The Minister, after consultation with the Council, may make regulations prescribing anything which in terms of this Act is permitted or required to be prescribed or which, in his opinion, is necessary or convenient to be prescribed for the better carrying out of or giving effect to the provisions of this Act.

(2) Regulations made in terms of subsection (1) may provided for—

(a) the terms and conditions under which persons may utilize research facilities in terms of section twenty-eight A;

(b) the prohibition, regulation and control of potentially harmful research or undertakings;

(c) precautions to be taken by persons carrying on potentially harmful research or undertakings in order to prevent or minimize danger to persons, animals or plants or to the environment generally;

(d) the functions of safety boards in regard to potentially harmful research or undertakings;

(e) the inspection of any premises or place where it is known or suspected on reasonable grounds that any potentially harmful research or undertaking is being or will be carried on;

(f) returns and other information to be supplied by persons who carry on potentially harmful research or undertakings.

(3) Regulations made in terms of subsection (1) may provide penalties for contraventions thereof, but no such penalty shall exceed a fine of level fourteen or imprisonment for a period of one year or both such fine and such imprisonment.

[amended by Act 22 of 2001, with effect from the 10th September, 2002.]

PART VII

TRANSITIONAL PROVISIONS

33 Transitional provisions

Where, prior to the 1st October, 1986, a research council has been established in terms of the Research Act [Chapter 336 of 1974] and is operating on the 1st October, 1986, date in accordance with its constitution—

(a) subject to paragraph (b), that research council shall continue in existence and shall be deemed to have been established in terms of section twenty-four; and

(b) the constitution of that research council shall be deemed to have been drawn up in terms of sections twenty-four and twenty-five and may be amended in accordance with of those sections; and

(c) that research council shall continue to operate subject to this Act and of its constitution, as may be amended from time to time.

SCHEDULE (Section 17 (1))

POWERS OF COUNCIL

1. To employ, upon such terms and conditions as may be determined by the Council and approved by the Minister, such professional, technical, administrative and other staff as may be necessary for conducting the affairs of the Council, and to suspend or discharge such staff.

2. To pay any person in its employment such salary, wages or other remuneration as may be determined by the Council and approved by the Minister, and to grant him such leave as the Council may consider appropriate.

3. To provide for persons in its employment or their dependants, by means of insurance, a pension fund or provident fund or by any other means whatsoever, pecuniary benefits upon retirement, death or termination of service or in the event of sickness or injury.

4. Subject to the Audit and Exchequer Act [Chapter 22:03], to raise moneys by way of loan, bank overdraft or otherwise in such amounts and for such purposes as the Minister may approve:

Provided that, if the power specified in the this paragraph is conferred on a research council or research institute in terms of its constitution, the Minister or the Minister responsible, as the case may be, shall not give his approval until he has consulted the Council.

5. To purchase, take on lease or in exchange, hire or otherwise acquire any movable or immovable property, and any rights, including patent rights or privileges, which the Council considers necessary or expedient for the purpose of performing its functions.

6. To construct, maintain, alter and improve any of its buildings, works, machinery and plant necessary or expedient for the purpose of performing its functions.

7. To work or otherwise beneficially use and to exchange, let, sell or mortgage any of the property, rights or privileges acquired or constructed under paragraph 5 or 6:

Provided that the Council or, where the power specified in this paragraph is conferred on a research council or research institute in terms of its constitution, a research council or research institute shall not sell any of its immovable property except with the consent of the Minister or the Minister responsible, as the case may be.

8. Subject to the Audit and Exchequer Act [Chapter 22:03], to invest and deal with any of its moneys not immediately required in such securities and in such manner as the Council may consider appropriate, and to vary or realize such investments.

9. To invite and receive donations from any person towards its expenses and to grant fellowships and other similar awards and make donations and grants in such amounts and for such purposes as the Minister may approve.

10. With the approval of the Minister, to enter into agreements to facilitate the voluntary transfer of professional, technical or other staff between the Council and any other person.

11. For the better performance of its functions—

(a) to co-operate with Ministries and departments of the State, universities, technical colleges and persons conducting research in Zimbabwe; and

(b) with the approval of the Minister, to co-operate with persons and organizations engaged in research in other countries.

12. Subject to the approval of the Minister, to have charge of, and direction and supervision over, the research which may be undertaken under conditions to be determined in each case by or for single industrial firms, or by such organizations or persons as may desire to avail themselves of the facilities for this purpose.

13. Subject to the approval of the Minister, to publish from time to time such information as the Council may consider necessary.

14. To do all things incidental or conducive to the exercise or enjoyment of the rights, interests and powers conferred upon the Council and the performance of the obligations imposed upon it by this Act.

Go To Top Page **NEXT CHAPTER**

Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality, 2017

Prepared by the Task Force on Re-envisioning the Multicultural Guidelines for the 21st Century

Adopted by the APA Council of Representatives in August 2017

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Acknowledgements

Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality, 2017 is an update of the *2002 Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists (Multicultural Guidelines).*

The ***2017 Guidelines*** were developed by a five-member *Task Force on Re-envisioning the Multicultural Guidelines for the 21st Century*, appointed by the Board for the Advancement of Psychology in the Public Interest (BAPPI), and adopted by the Council of Representatives in August 2017.

Members of the Task Force included: Caroline S. Clauss-Ehlers, Rutgers, The State University of New Jersey (Chair); David A. Chiriboga, University of South Florida; Scott J. Hunter, University of Chicago; Gargi Roysircar-Sodowsky, Antioch University New England; and Pratyusha Tummala-Narra, Boston College.

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This document will expire as APA policy in 10 years (2027). Correspondence regarding the *2017 Multicultural Guidelines* should be addressed to the American Psychological Association, Public Interest Directorate, 750 First Street, NE, Washington, 20002-4242

Overall List of Multicultural Guidelines

Guideline 1. Psychologists seek to recognize and understand that identity and self-definition are fluid and complex and that the interaction between the two is dynamic. To this end, psychologists appreciate that intersectionality is shaped by the multiplicity of the individual's social contexts.

Guideline 2. Psychologists aspire to recognize and understand that as cultural beings, they hold attitudes and beliefs that can influence their perceptions of and interactions with others as well as their clinical and empirical conceptualizations. As such, psychologists strive to move beyond conceptualizations rooted in categorical assumptions, biases, and/or formulations based on limited knowledge about individuals and communities.

Guideline 3. Psychologists strive to recognize and understand the role of language and communication through engagement that is sensitive to the lived experience of the individual, couple, family, group, community, and/or organizations with whom they interact. Psychologists also seek to understand how they bring their own language and communication to these interactions.

Guideline 4. Psychologists endeavor to be aware of the role of the social and physical environment in the lives of clients, students, research participants, and/or consultees.

Guideline 5. Psychologists aspire to recognize and understand historical and contemporary experiences with power, privilege, and oppression. As such, they seek to address institutional barriers and related inequities, disproportionalities, and disparities of law enforcement, administration of criminal justice, educational, mental health, and other systems as they seek to promote justice, human rights, and access to quality and equitable mental and behavioral health services.

Guideline 6. Psychologists seek to promote culturally adaptive interventions and advocacy within and across systems, including prevention, early intervention, and recovery.

Guideline 7. Psychologists endeavor to examine the profession's assumptions and practices within an international context, whether domestically or internationally based, and consider how this globalization has an impact on the psychologist's self-definition, purpose, role, and function.

Guideline 8. Psychologists seek awareness and understanding of how developmental stages and life transitions intersect with the larger biosociocultural context, how identity evolves as a function of such intersections, and how these different socialization and maturation experiences influence worldview and identity.

Guideline 9. Psychologists strive to conduct culturally appropriate and informed research, teaching, supervision, consultation, assessment, interpretation, diagnosis, dissemination, and evaluation of efficacy as they address the first four levels of the *Layered Ecological Model of the Multicultural Guidelines*.

Guideline 10. Psychologists actively strive to take a strength-based approach when working with individuals, families, groups, communities, and organizations that seeks to build resilience and decrease trauma within the sociocultural context.

I. Introduction

Since the initial version of the *Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists* (APA, 2002) was released, there has been significant growth in research and theory regarding multicultural contexts. The guidelines were passed by the American Psychological Association (APA) Council of Representatives at the 2002 annual conference and were posted on the APA website. The attention given to these guidelines, including their publication in the *American Psychologist* (2003), speaks to the profession's recognition of the important role that diversity and multiculturalism play, both in terms of how individuals and groups define themselves, and how they approach others within the United States (U.S.) and globally (APA, 2002).

The current *Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality, 2017* (i.e., *Multicultural Guidelines*) are conceptualized from a need to reconsider diversity and multicultural practice within professional psychology at a different period in time, with intersectionality as its primary purview. The 2017 version of the *Multicultural Guidelines* encourages psychologists to consider how knowledge and understanding of identity develops from and is disseminated within professional psychological practice. Endemic to this understanding is an approach that incorporates developmental and contextual antecedents of identity and how they can be acknowledged, addressed, and embraced to engender more effective models of professional engagement. The *Multicultural Guidelines* incorporate broad reference group identities (e.g., Black/African American/Black American, White/White American, and Asian/Asian American/Pacific Islander) to acknowledge within-group differences and the role of self-definition in identity.

With the *Multicultural Guidelines*, APA and its members are presented with an opportunity to participate directly, as professional psychologists, in engaging a fuller understanding of diversity and its considerations within practice, research, consultation, and education (including supervision) to directly address how development unfolds across time and intersectional experiences and identities; and to recognize the highly diverse nature of individuals and communities in their defining characteristics, despite also sharing many similarities by virtue of being human. Our conscious awareness of what it means to think, feel, regulate, behave, and create meaning has been enhanced by advances in research and clinical

scholarship affording us a contemporary consideration of psychology that incorporates human differences across their varied elements.

II. Need: Scope of Work

The *Multicultural Guidelines* developed out of the need to update the guidelines published in 2003 (APA, 2003). Per APA recommendations, approved *Multicultural Guidelines* are to be updated every 10 years, to remain current with scientific evidence and models of professional practice. In August 2015, APA developed two task forces: the *Task Force on Re-envisioning the Multicultural Guidelines for the 21st Century* and the *Task Force on Guidelines Focused on Race/Ethnicity*. The guidelines written by each Task Force group are considered partner documents. The stated reason for the appointment of two groups by the Board for the Advancement of Psychology in the Public Interest (BAPPI) was that:

> In the intervening years, there has been enormous domestic and global change affecting the lives of individuals, communities, countries and society at large, as well as the development of substantial new multicultural conceptual and empirical scholarship. BAPPI has determined that the wealth of scholarship specific to race/ethnicity as well as the scholarship focused on other identity groups warrants splitting the *2002 Multicultural Guidelines* into two sets of guidelines going forward: one focused on "pan" or "umbrella" multicultural guidelines that captures universal concepts based on the scholarly literature across a broad cross-section of identity groups (e.g., age, disability, race, ethnicity, gender, religion/spirituality, sexual orientation and gender diversity, social class, language, immigration status), and the other focused specifically on the race/ethnicity-related scholarly developments since the *2002 Multicultural Guidelines* were adopted (APA, 2015a).

III. Purpose

The purpose of the *Multicultural Guidelines* is to provide psychologists with a framework from which to consider evolving parameters for the provision of multiculturally competent services. Services include practice, research, consultation, and education, all of which benefit from an *appreciation for*, *understanding of,* and *willingness to learn about* the multicultural

backgrounds of individuals, families, couples, groups, research participants, organizations, and communities. To simplify the presentations that follow, the *Multicultural Guidelines* often refer to the client when in fact speaking not only of the recipient of clinical services, but also the student, research participant, or consultee. With the exception of the case studies presented in Appendix B, the guidelines use nonbinary pronouns. The current *Multicultural Guidelines* also advocate for a more diverse and inclusive population of psychologists.

This version of the *Multicultural Guidelines* marks a significant extension from the initial *Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists* (APA, 2002). The latter focused on race and ethnicity as the salient variables in multicultural practice. The 2002 version states: ". . . in these Guidelines, we will use the term multicultural rather narrowly, to connote interactions between racial/ethnic groups in the U.S. and the implications for education, training, research, practice, and organizational change" (p. 10). The goal of this new version is to regard the term multicultural more fully—to consider it in its broadest conceptualization. The broadening of our understanding within the *Multicultural Guidelines* reflects current trends in the literature that consider contextual factors and intersectionality among and between reference group identities, including culture, language, gender, race, ethnicity, ability status, sexual orientation, age, gender identity, socioeconomic status, religion, spirituality, immigration status, education, and employment, among other variables (APA, 2002).

These variables are considered within the context of domestic and international climates as well as human rights. It is important to note that, for the purposes of the *Multicultural Guidelines*, cultural competence does not refer to a process that ends simply because the psychologist is deemed competent. Rather, cultural competence incorporates the role of cultural humility whereby cultural competence is considered a lifelong process of reflection and commitment (Hook & Watkins, 2015; Waters & Asbill, 2013). This current iteration of the *Multicultural Guidelines* also recognizes the contributions of other culturally competent models of practice such as the American Counseling Association's (ACA) *Multicultural and Social Justice Counseling Competencies: Guidelines for the Counseling Profession* (Ratts, Singh, Nassar-McMillan, Butler, & McCullough, 2016); the American Psychiatric Association's *Cultural Formulation Interview* (American Psychiatric Association, 2013); and the *Standards*

and Indicators for Cultural Competence in Social Work Practice (National Association of Social Workers, 2015).

Conceptual framework. The model developed by the Multicultural Guidelines Task Force is called a *Layered Ecological Model of the Multicultural Guidelines*. This framework incorporates Bronfenbrenner's (1977, 1979) ecological model that proposes five concentric circles: (1) the *microsystem* of immediate family, friends, teachers, and institutions that have direct influence on the individual; (2) the *mesosystem* that refers to interrelations of various social entities found in the microsystem that affect a person's life (e.g., home, school, community); (3) the *exosystem* that deals with societal and cultural forces acting upon the individual without necessarily having a direct link to individual experience; (4) the *macrosystem* that corresponds with the cultural context in which the individual lives, such as cultural values and norms, as well as laws and governmental influences; and (5) the *chronosystem* that deals with the influence of the passage of time, historical trends and transitions, and the historical context that surrounds individual experience.

The *Layered Ecological Model of the Multicultural Guidelines* comprises dynamic, nested systems that transact over time (see Figure 1). Psychologists are informed by an understanding of such transactions among individuals, microsystems, exosystems, and macrosystems. At the intrapersonal system level, psychologists who are clinicians treat an individual client's anxiety, trauma, depression, suicidal ideation, family problems, employment insecurities, alcohol and other substance abuse, aggression, and disruptions in the achievement and trajectory of identities and career as well as lifetime goals and roles. More broadly, in their service to individuals, psychologists address microsystems that affect an individual's resilience, such as interactions with schools, family, peers, place of worship, workplace, and community health clinics.

In a consulting role, psychologists may engage more directly with exosystems and macrosystems. Psychologists as advocates may address how disparities and inequities in criminal justice, law enforcement, educational policy, health, and mental health care may have an adverse effect on the individual. Psychologists are encouraged to analyze the effects of variables within macrosystems such as cultural norms, developing bioscientific knowledge, politics, the media, human development, and reference group identities on human experience. Finally, psychologists

are encouraged to be aware of the chronosystem, or historical incidents, trends, and transitions that influence the individual.

IV. Layered Ecological Model of the Multicultural Guidelines

Description of the current model. The model includes two central circles (see Figure 1). One circle represents the self-definition of the individual that refers to respective roles as client, student, research participant, or consultee. The second circle represents the self-definition of the individual that refers to the clinician, educator, researcher, or consultant. The bidirectional arrows pointing between the two circles represent the dynamic interactions between these two individuals and their respective roles (e.g., interactions between clinician and client; educator and student; researcher and research participant; consultant and consultee).

These two bidirectional circles (Level 1) are layered with four surrounding circles (Levels 2–5) that represent successively expanding sources of influence. These are labeled on Figure 1 as: Bidirectional Model of Self-Definition and Relationships (Level 1) ; Community, School, and Family Context (Level 2); Institutional Impact on Engagement (Level 3); Domestic and International Climate (Level 4); and Outcomes (Level 5). These influences are reciprocal, in that while the outer layers can affect the inner layers, the reverse is also true. A description of the five levels follows.

Level 1: Bidirectional Model of Self-Definition and Relationships. The two inner circles capture a bidirectional model of self-definition and relationships. Specifically, the circle on the left represents the *individual's self-definition* in the roles of client, student, research participant, or consultee. The circle on the right represents the *individual's self-definition* in the roles of clinician, educator, researcher, or consultant (these may also involve more than two people, for example, if the client is a couple, family, or group). The bidirectional arrow that intersects the two circles represents the bidirectional relationships considered within the model.

Level 2: Community, School, and Family Context. The inner circles of the individual's self-definition are surrounded by the model's second layer: the *community, school, and family context*. Specific areas considered at this juncture of the model include family, community, school, neighborhood, workplace, place of worship, and physical space. The context represented by Level 2 has direct influence on the bidirectional relationships described in Level 1.

Level 3: Institutional Impact on Engagement. Levels 1 (individual's self-definition) and 2 (community, school, and family context) function within Level 3, the *institutional context* that considers the influence of local, state, and federal governments; medical systems; legal systems (including law enforcement); mental and behavioral health systems; and educational systems. Level 3 examines the effects of institutional context on how clients and psychologists experience the community, school, and family contexts (Level 2) and how this experience influences both the individual's self-definition and relationships with one another (i.e., client, student, consultee, research participant and clinician, educator, researcher, consultant, Level 1).

Level 4: Domestic and International Climate. The model now broadens to a fourth level that captures *domestic climate* (on the circle's left-hand side) and *international climate* (on the circle's right-hand side). Like previous circles, this layer encompasses Levels 1–3. At the top of this fourth circle is consideration of the *larger societal context* and at the bottom is consideration of *human rights*.

The psychologist is encouraged to identify and understand the ways in which the larger societal context affects the individual's self-definition and bidirectional relationships, whether as someone engaged in psychological services, the classroom, the life of an organization, or a research project. The larger societal context is also characterized by human rights concerns. The psychologist is encouraged to consider whether human rights are being compromised due to domestic and international climates. Within the context of a bidirectional relationship, the psychologist is encouraged to consider and explore the extent to which human rights are protected or threatened in work with clients, students, research participants, and consultees.

Level 5: Outcomes. The fifth layer surrounds all the model's prior levels with a focus on *outcomes*. Outcomes refer to those results, both positive and negative, that are derived from the bidirectional transactions between the client, student, research participant, and consultee and the clinician, educator, researcher, and consultant. Outcomes are influenced by interactions and experiences with Level 1 (bidirectional model of self-definition and relationships), Level 2 (community, school, and family context), Level 3 (institutional impact on engagement), and Level 4 (domestic and international climate). The psychologist is encouraged to consider how the transactions across layers in the ecological model result in a range of outcomes for the client, student, research participant, or consultee. The psychologist can also strive to understand which

level or levels in the model have directly (or indirectly) contributed to specific outcomes and consider ways to improve them.

Three Processes that Drive the *Layered Ecological Model of the Multicultural Guidelines*. Three dynamic processes influence the model: *power/privilege*, *tensions*, and *fluidity*. They are located on the dotted line that creates a circle (or another layer) around Levels 1–5 to show that they drive the ecological model. *Power/privilege* represents a continuum of power and privilege that can be experienced by participants engaged in psychological endeavors as well as by the psychologists providing services. Psychologists are encouraged to consider the social power and privilege they have in their bidirectional relationships with clients. Psychologists strive to listen and learn about the dynamics of power and privilege as experienced by those with whom they work. Through this awareness, psychologists seek to promote ways for individuals, families, couples, groups, and organizations to identify, own, and respond to their experiences.

The second process refers to the *tensions* between and among Levels 1–5. Tensions may arise between concentric circles or within bidirectional relationships. Psychologists are encouraged to recognize that these tensions are dynamic and contextual and may result not solely from issues occurring at one level of the model, but rather, through the multiple intersections and interactions between and among various levels. Psychologists are encouraged to work with the client, student, research participant, or consultee to identify tensions as they relate to interactions among systems rather than keeping the sole focus at an individual level.

Fluidity is the third dynamic process. Fluidity refers to the dynamic interaction between and among the concentric circles and shifts within the concentric circles. The transactions between the psychologists and participants engaged in psychological endeavors are constantly shifting based on the changes that occur within and between the ecological model's five levels and three dynamics. Psychologists are encouraged to consider changes in relationship patterns, life events and transitions, contextual influences, the passage of time, and the influence of internal experience on themselves as well as in work with clients, students, research participants, and consultees.

Finally, on the far left of Figure 1 is an upward facing arrow labeled "resilience." To the far right, is a downward facing arrow labeled "trauma." Through professional relationships that

promote healing, learning, knowledge gained through research participants, and collaborations built through consultation, the goal is to increase resilience and decrease trauma.

V. Documentation of Need/Distinction between Standards and Guidelines

When using these *Multicultural Guidelines*, psychologists should be aware that APA has made an important distinction between standards and guidelines (Reed, McLaughlin, & Newman, 2002; APA, 2015c). Standards are mandates to which all psychologists must adhere (e.g., the *Ethical Principles of Psychologists and Code of Conduct*, APA, 2010), whereas guidelines are aspirational and informative regarding practice considerations; APA has indicated that experience and training of professionals also allows for effective interpretation and application of guidelines. Psychologists are encouraged to use these *Multicultural Guidelines* in tandem with the *Ethical Principles of Psychologists and Code of Conduct*, and should be aware that state and federal laws may override these *Guidelines* (APA, 2010; 2015c); where this does occur, federal and state laws will take precedence.

In addition, these *Multicultural Guidelines* refer to psychological practice (e.g., clinical work, consultation, education, research, and training) rather than treatment. Practice guidelines are practitioner-focused and provide guidance for professionals in areas such as clinical practice, education, research, and consultation. Treatment guidelines are client-focused and address intervention-specific recommendations for clinical populations or conditions (Reed, McLaughlin, & Newman, 2002). The current guidelines are intended to complement treatment and other practice efforts by professional psychologists. The practice components for each guideline consider work with individuals from diverse sociocultural backgrounds who are seeking mental and behavioral health services, as well as training and supervision with students. Research components consider scientific inquiry and the generation of knowledge from within a multicultural biopsychosocial framework. Consultation refers to being responsive to considerations regarding diversity within organizations. Education, along with practice, refers to the inclusion of multicultural curricula in psychology programs, modeling cultural competence for students, and providing training and supervisory experiences in diverse community contexts.

Compatibility

These guidelines are consistent with the *APA Ethical Principles of Psychologists and Code of Conduct* (APA, 2010) and the *Standards of Accreditation for Health Service Psychology* (APA, 2015c; APA/COA, 2015).

Multicultural Guidelines Development Process

The original *Multicultural Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change* (APA, 2002) were based on the work of Sue and colleagues (1982) who presented a model of multicultural counseling competencies (MCCs). Yet the history of the decision making regarding a need for these guidelines is much older. As discussed in the *Report of the Task Force on the Implementation of the Multicultural Guidelines* (APA, 2008), "[t]he origins of the *Multicultural Guidelines* are rooted in various social, historical, and political events and inspired by a number of professional developments in the field of psychology" (p. 4), and within APA itself, over the past 50 years.

Multiple conversations, both within the field at large and within the APA directly, have taken place to address how psychology in the United States has been inattentive regarding diversity and multicultural practice, while the field at large has worked to move forward to address cultural plurality. Since the publication of the guidelines in the *American Psychologist* in 2003, multicultural competence research and specific guidelines rooted in this research have expanded to areas of immigration, sexual orientation, gender identity, social class, religion, and spirituality (APA, 2012a; APA, 2012b; APA, 2015b; Smith, 2010). Models of cultural competence have directed increasing attention to social injustice and global factors as they relate to psychological well-being and intervention (Ratts et al., 2016). The 2003 *Multicultural Guidelines* document helped operationalize psychology, which has been enhanced by collaboration across social science domains. The purpose of revisiting the original *Multicultural Guidelines* is to promote the application of multicultural knowledge to contemporary psychological practice, education, research, and consultation. The educational aspect of the *Multicultural Guidelines* is valuable; it serves to guide and inform the training and practice of professional psychology. The research aspect suggests that there are diverse research methods that can be used to generate new knowledge.

In Spring 2015 the Board for the Advancement of Psychology in the Public Interest (BAPPI) put forth a call for nominations for two task forces: the *Task Force on Re-envisioning the Multicultural Guidelines for the 21st Century* and the *Task Force on Guidelines Focused on Race/Ethnicity*. The BAPPI Advisory Group for Recommending Appointments to the Task Force on Re-envisioning the Multicultural Guidelines for the 21st Century and the Task Force on Guidelines Focused on Race/Ethnicity helped select task force members who were appointed after an application and review process. The *Task Force on Re-envisioning the Multicultural Guidelines for the 21st Century* included five members, one of whom served as Task Force Chair. Members reflected a range of research, writing, clinical work, teaching, and consultation within linguistically and culturally diverse communities.

Each guideline includes three sections: (a) Introduction/Rationale (that links the guideline to the overall model and incorporates a discussion of its relevance); (b) Applications to Practice, Research, and Consultation (that illustrates how the guideline can apply to practice, research, and consultation roles); and (c) one or more relevant case illustrations. While the application section is divided into practice, research, and consultation subsections for organizational purposes, there is some overlap among these areas. Appendix A includes relevant definitions; Appendix B includes case illustrations that depict each level of the model and illustrate various guidelines; and Appendix C includes references. Case illustrations reflect the core value of demonstrating the applicability of the *Multicultural Guidelines* in professional settings.

V. Guidelines

A. Level 1: Bidirectional Model of Self-Definition and Relationships

Connection to the model. The first level encompasses the mutual influence of self-definition and relationships/interactions with others across varying contexts within the microsystem, mesosystem, exosystem, and macrosystem. Identity is complex, fluid, and intersectional, and individuals' experiences and definition of their identities may not be reflected or mirrored by assumptions or categorical thinking occurring in interactions with others. At the same time, the messages that they receive from others influence their self-definition and life outcomes as these can either promote or constrict psychological and social well-being.

Guideline 1. Psychologists seek to recognize and understand that identity and self-definition are fluid and complex and that the interaction between the two is dynamic. To this end, psychologists appreciate that intersectionality is shaped by the multiplicity of the individual's social contexts.

Introduction/Rationale

Psychologists are encouraged to consider the relationship between various layers of an individual's ecological contexts and identity development and the implications of this relationship for experiences of privilege and oppression, well-being, access to resources, and barriers from and access to appropriate, quality care.

Psychologists strive to recognize the need to move beyond stereotypes when working with clients, research participants, students, and consultees. They seek to avoid overgeneralized or simplistic categories and labels of sociocultural groups. Such categorization has been described through the concept of *ethnic gloss,* that refers to an illusion of homogeneity among diverse groups that minimizes important distinctions among ethnic groups within a broader racial category; for example, American Indian, Latino/Hispanic/Latinx, Asian/Asian American/Pacific Islander, Black/African American/Black American, and White/White American (Trimble & Dickson, 2005).

Psychologists strive to understand the need to become acquainted with aspects of identity, as well as which aspects of identity are especially relevant to the presenting problem or issue. Identity is a construct that has been central to theories of psychological development. Identity reflects both individual and collective features of emotional and cognitive experience, and develops within interpersonal and structural contexts. Identity has also been conceptualized as an internal experience of "subjective self-sameness" that facilitates emotional experiences and behaviors that reflect an individual's actual or true self (Erikson, 1950; Mann, 2006). Identity has been thought to develop across contexts and time, and is shaped by cultural influences including age, generation, gender, ethnicity, race, religion, spirituality, language, sexual orientation, gender identity, social class, ability/disability status, national origin, immigration status, and historical as well as ongoing experiences of marginalization, among other variables (Comas-Díaz, 2012; Crenshaw, 1989; Greene, 2013; Hays, 2016; Olkin, 2002; Roysircar-Sodowsky & Maestas, 2000).

Similarly, group identity or social identity, which refers to one's affiliation with and feelings about one's connection with other members of a particular sociocultural group as well as having an awareness of group status as compared with other groups, shifts over the course of time and across generations as determined by social, cultural, economic, and political factors (Oyserman, 2007; Tajfel, 1981). Various dimensions of identity associated with sociocultural contexts, such as racial identity, multiracial identity, biracial identity, ethnic identity, gender identities, religious identity, and sexual orientation, have been described in psychological theories (Cross, 1991; Helms & Cook, 1999; Phinney, 1996; Rockquemore, Brunsma, & Delgado, 2009). For example, racial identity has been described as a sense of collective identity rooted in individuals' perception that they share a common heritage with a specific racial group (Helms & Cook, 1999), and ethnic identity has been defined as the extent to which individuals identify as members of their ethnic group(s) (Phinney, 1996). Biracial identity and multiracial identity have been described as involving a sense of "border crossing," where many individuals interact within and shift across different racial and cultural contexts and experience hybridity as a reference point for identity (Root, 2003; Rockquemore et al., 2009).

Research indicates that identity varies across different cultural groups as well as within such groups (Comas-Díaz, 2012; Hays, 2016; La Roche, 2013; Sue & Sue, 2016; Tummala-Narra, 2016). It is important to consider how developmental stages inform identity and a redefinition of self. Self-definition and identity labels often contribute to individuals' relationships with others and to their psychological well-being (Kiang, 2008). For example, while some individuals prefer not to define themselves along a hyphenated identity, others do describe themselves with a hyphenated identity (e.g. Mexican-American, Vietnamese-American, and Haitian-American) that may offer a sense of connection and belonging within multiple sociocultural contexts. The experience of the bicultural identity further involves the salience of one particular aspect of identity over others owing to the influence of the specific context within which an individual interacts (Sirin & Fine, 2008). Research and clinical literature also suggest differences in cultural worldviews of immigrant parents and children and youth, with parents espousing beliefs and expectations congruent with the culture of origin to a greater extent than children, contributing to varying challenges with identity and intergenerational dynamics within immigrant families (Birman & Simon, 2014; Hwang & Ting, 2008; Qin, 2009).

Generational differences within communities are also evident in the experiences of lesbian, gay, bisexual, transgender, gender nonconforming, queer (and/or questioning), and intersex (LGBTQ+) individuals. Studies with LGBTQ+ populations note that cohort and age have significant influence on identity development (APA, 2012b; APA, 2015b). Specifically, the historical period of time and context in which an individual has been raised and has engaged in a coming out process has important implications for gender identity, identity labels, disclosure of sexual orientation and identity to others, and parenting (APA, 2012b). For example, the coming out process for an older adult in contemporary U.S. society may be markedly different from that of a young adult, and older adults may experience ageism within LGBTQ+ communities, which has implications for identity, self-definition, and disclosure (APA, 2012b). Generational differences can reflect how a society at different periods of time may experience marked shifts in societal attitudes toward sexual orientation and gender identities, religious and spiritual attitudes, social justice–oriented movements (e.g., women's, gay, and civil rights movements), changing conceptualizations of family, reproductive technologies, and legislation concerning marriage equality (APA, 2012b; Drescher, 2009).

It is important to recognize that language describing identity (e.g., identity labels) conveys perceptions of and feelings about a particular group. Additionally, conceptualizations of identity labels vary with respect to the meanings they convey. For example, some scholars in the area of physical disabilities have advocated for person-first language (e.g., people with disabilities) in an effort to reduce stigma and stereotyping, whereas other scholars have supported the use of identity-first language (e.g., disabled people) to help individuals value and take pride in disability (Dunn & Andrews, 2015; Olkin, 2002).

Language concerning diverse gender identities has received growing attention over the past decade. Gender identity has been redefined as a nonbinary construct, and refers to an individual's "deeply felt, inherent sense of being a girl, woman, or female; a boy, a man, or male; a blend of male or female; or an alternative gender" (APA, 2015b, p. 834; Bethea & McCollum, 2013; Bockting, 2014). This conceptualization allows for a broader realm of possible identities and new nonbinary gender-based language. It also highlights the significance of self-definition and fluidity of identity. The use of pronouns among people with nonbinary gender identities, such as *zie*, instead of *she* or *he*, moves us away from misgendered, inaccurate perceptions and conceptualizations of gender experiences (Mizock, Harrison, & Russinova,

2014). Further, third-person plural pronouns “they,” “them,” and “their” in some instances indicate third-person singular pronouns, avoiding the use of gendered pronouns (APA, 2015b). Identity development is dynamic and fluid, influenced by structural and interpersonal factors. Individuals and groups, for example, are influenced by structural oppression and privilege, historical trauma, migration, and dislocation. People of color, for example, may develop identity in the context of racism and stereotyping, which may constrain possibilities of self-definition. A Chinese American adolescent who has internalized the model minority stereotype, or the notion that all Asian/Asian American/Pacific Islanders are academically successful, may struggle with feeling isolated while struggling with academic work. First-generation college students from a poor background who have viewed themselves as competent and successful in high school may face class-based discrimination on campus, diminishing the ability to develop a sense of social and academic competence.

Psychologists are encouraged to attend to intersecting sociological and neurobiological contexts that contribute to diverse identities of an individual. Intersectionality, by its broadest definition, incorporates the vast array of cultural, structural, sociobiological, economic, and social contexts by which individuals are shaped and with which they identify (Howard & Renfrow, 2014). Individuals are located within a range of social groups whose structural inequalities result in marginalized identities. Unlike unidimensional identity models, intersectionality addresses “the vexed dynamics of difference and the solidarity of sameness” (Cho, Crenshaw, & McCall, 2013, p. 787).

For example, Black/African American/Black American lesbian women may have some similarities to and differences from other oppressed groups in the meanings that are assigned to their multiple positionalities. Black/African American/Black American women may identify with the oppressive and discriminatory experiences of White/White American women as well as Black/African American/Black American men. Conversely, Black/African American/Black American lesbian women’s experiences may not be equivalent to those of these groups. They may experience discrimination as Black/African American/Black American women who are lesbian. This experience does not necessarily reflect the sum of oppressions of racism, sexism, and heteronormativity (i.e., race + sex + heterosexism), but rather unique identities and social locations as Black/African American/Black American lesbian women that are not based in or

driven by the perspectives of White/White American women or of Black/African American/Black American men (Bowleg, 2008; Crenshaw, 1989).

Intersectional identities also include experiences of privileged contexts that intersect with those of oppression. An older White/White American gay man from an upper middle class background is discriminated against because of his sexual orientation, but is privileged because of his dominant racial, gender, and social class statuses. An Alaska Native college student may experience privilege relative to family and friends who don't have access to higher education, and at the same time may face discrimination based on the intersectional oppressions of race, gender, and social class on the college campus. A Laotian immigrant woman with a disability may experience a sense of safety and privilege due to her legal immigration status in the United States, but can experience discrimination and a lack of access to appropriate resources within and outside of her family and ethnic community based on her disability status. A Jewish American adolescent may experience privilege as a result of being perceived as White, but is the target of anti-Semitic slurs at school and in social media.

Thus, individuals' perspectives are shaped by the multiplicity of identities and contexts to which they belong, some oppressed and some privileged. Aspects of identity such as race, gender, and class work dynamically. The intersections of multiple identities transform the oppression and privilege aspects of layered interlocking identities. A possible transformation occurs when marginalized individuals practice self-empowerment and social justice advocacy for others.

Intersectionality stands in contrast to linear, discrete, or "single axis" variables assumed to cause between-group differences that encourage deriving knowledge from the notion that all members of a structural category, for example, immigrant generation status, have essentially the same experience (Grzanka, 2014). Thus, intersectionality captures the vast within-group differences in identities found among members of marginalized and dominant groups. Intersectionality theory argues that focusing solely on the effect of one or two reference group identities (e.g., interaction of race and age studied through covariate analyses) on overall identity fails to consider the multiple social and cultural identities that intersect within an individual's life.

By recognizing that an individual's identity is derived from interacting systemic effects, psychologists strive to understand associated human biases informed by systems of power,

privilege, oppression, social dictates, constraints, values, and negative perceptions of marginalized societies. On the other hand, applying a linear approach keeps invisible the forces of patriarchy, cisgenderism, heteronormativity (i.e., meaning that heterosexuality is the norm, and sexual relations are only fitting between people of different sexes), class oppression, ableism, and other forms of institutionalized oppression (Shin, 2015).

Applications to Practice, Research, and Consultation

Practice. Psychologists understand that identity and self-definition are fluid and dynamic. Psychologists are also encouraged to strive toward attunement to life experiences, transitions, and identity labels, and how identity experience may change over time and context (Akhtar, 2011; Sue & Sue, 2016; Tsai, Chentsova-Dutton, & Wong, 2002). Educators' and supervisors' modeling of culturally competent practices plays an important role in helping students develop cultural competence. Psychologists who are educators are also encouraged to provide coursework focused on the multidimensional nature of identity.

Attunement to an individual's self-definition requires careful listening to self-defined narratives (Seeley, 2000; Tummala-Narra, 2016). Some scholars have emphasized the importance of the therapist's cultural humility (Gallardo, 2014; Owen, et al., 2016; Tervalon & Murray-García, 1998). Cultural humility has been defined as a "lifelong process of self-reflection, self-critique, continual assessment of power imbalances, and the development of mutually respectful relationships and partnerships" (Gallardo, 2014, p. 3; Morse, García, & Trimble, in press; Tervalon & Murray-García, 1998). The concept of cultural humility has also been referred to as "an other-oriented stance, which is marked by openness, curiosity, lack of arrogance, and genuine desire to understand clients' cultural identities" (Owen et al., 2016, p. 31). Studies have indicated that clients' perceptions of therapists' cultural humility is associated with improved therapeutic outcomes. In addition, evidence indicates that the therapist's attention to clients' identifications of what is salient concerning their identity statuses rather than relying on the therapist's assumptions is an important factor in therapeutic processes and outcomes (Owen, et al., 2014; Owen et al., 2016).

It is also important that clinicians, researchers, and consultants attend to their own lack of knowledge and/or training concerning language that is affirming of an individual's or group's actual identity experiences. For example, psychologists may not be exposed to language that

affirms an individual's sexual orientation, gender identity, racial identity, religious identity, or disability (APA, 2015b; Bockting, 2014; Comas-Díaz, 2012; Drescher, 2009; Mustanski, Kuper, & Greene, 2014; Olkin, 2002). With regard to assessment and psychotherapy, clinicians can invite clients to describe their identities and labels, rather than relying on preconceived conceptualizations. While therapeutic outcomes are not determined solely through matching therapeutic dyads based on sociocultural similarities (Sue & Sue, 2016), the therapist's willingness to engage with sociocultural issues is critical for clients' feelings of safety and comfort in disclosing and exploring painful experiences related to their sociocultural identities and/or experiences of oppression. Therefore, psychologists engage in actively listening for the various layers of the client's identity and consider the structural, contextual, and interpersonal nature of identity development.

Through a focus on how contexts of identities inform biases, psychologists strive to develop a formulation of a client's surrounding world and also recognize how their own range of identities interacts with those of the client, thus engaging differences as well as commonalities that have an impact on and influence their work together. An intersectional framework encourages a depth of curiosity to learn from diverse perspectives for a holistic understanding of the psychologist's self as well as the person of the client.

The psychologist's analysis of power that deconstructs, for example, class dynamics, can translate to both social change and a psychotherapeutic change process (Cho, Crenshaw, & McCall, 2013), merging macro upstream levels and micro downstream levels of analysis and change (See definitions in research section below; Howard & Renfrow, 2014). Because of their personal level of social privilege owing to their professional identity (Roysircar, 2008), psychologists carry the power of being agents of social justice in their respective occupations. For instance, some intersectionality scholars have become activists through efforts to identify social justice interventions for subjugated social groups and to lead coalitions against systemic operations of power and privilege (Clough & Fine, 2007; Grabe & Else-Cole, 2012). Intersectionality scholars practice self-reflection and are constantly engaged in the critique of their own work and refinement of their ideas and practices (Clough & Fine, 2007).

One illustration of a training model focused on intersectionality, GRACES, consolidates potential identities into social categories (gender, geography, race, religion, age, ability, appearance, class, culture, ethnicity, education, employment, gender identity, sexuality, sexual

orientation, and spirituality), providing a scaffold from which to consider power, oppression, strength, and connection in the world of clients, therapists, and therapy (Butler, 2015). One way to explore practitioner biases is to insert various hypothetical clients with different intersecting identities into the same case study (Butler, 2015). Practitioners may find that they react differently to a case depending on the client's intersecting identities. Practitioners may reflect that they are drawn toward areas of difference that they feel most comfortable in addressing and that are most pertinent to them and avoid differences that they feel they know less about. As such, practitioners may need to work to take risks in exploring controversial aspects of difference.

Self-disclosing and exploring intersecting identities requires some level of vulnerability for both the psychologist and the client. The relationship-building process provides both the psychologist and the client time to gain some comfort in having identity conversations. Psychologists also strive to understand that the task of self-disclosure may be difficult or uncomfortable for the client. Strategies such as clinician authenticity, tone, spontaneity, therapist self-reflection, practice, patience with stumbling, supervision, and consultation can be implemented to make the client feel comfortable in identity self-disclosure (Dee Watts-Jones, 2010). The conversation on intersecting identities can open the relational environment to discuss differences and share common experiences, strengthen the working alliance, and foster broader routes toward change (Dee Watts-Jones, 2010).

Research. Cole (2009) made a useful distinction between looking "downstream" for causes (that is, in individual behavior that may be associated with a social category membership) and "upstream" at macro societal processes that define systems of social inequality, such as laws, cultural mores, institutional practices, and public policies. Currently, intersectional researchers (cf., Bowleg, 2008; Cole, 2009; Sirin & Fine, 2008) have demonstrated that scholars can attend to structural dynamics resulting in social identities through the use of qualitative and quantitative research designs as well as interdisciplinary research teams (e.g., comprising psychologists, sociologists, political scientists, women studies faculty, ethnic studies faculty, legal scholars).

Qualitative methods and/or mixed methods have proven more sensitive to social complexities and personal subjectivities than demographic questionnaires that rely on preexisting frameworks to place social groups in nominal, ordinal, or frequency order and count individual experiences as an additive aggregate (Grzanka, 2014). The additive approach that posits that

social inequality increases with each additional stigmatized identity is antithetical to the theoretical fidelity of intersectionality because people's experiences are not conceptualized as discrete, independent, and summative (Bowleg, 2008).

Questions on intersectionality focus on meaningful constructs like minority stress, voluntary integration of diverse cultural groups, equality versus inequity, homophobia, sexism, cisgenderism, classism, ableism, and racism (Grzanka, 2014). Rather than looking for orthogonality in constructs, this approach has investigated interdependence, multidimensionality, and mutually constitutive relationships (Crenshaw, 1989; Greene, 2013).

Some examples of self-reflective "scholar-activism" have been described by Clough and Fine (2007). These researchers have described their respective experiences of working as academic researchers with incarcerated women of color and people leaving prison after incarceration. They shared deeply personal stories of how their positions of privilege became highlighted and intensified during the research process. They also questioned the politics and efficacy of participatory action research and other forms of scholar-activism that do more for those on the scholar side of the equation than for those being studied, e.g., the individuals and groups under the social scientific microscope.

Although the issue of intersectionality has gained increased attention in psychology, research concerning the experiences of people facing multiple forms of marginality is still emerging (Fine, 2010). In conducting research, psychologists are encouraged to include open-ended questions related to identity in both quantitative and qualitative studies. The ability for research participants to describe their identities provides more accurate demographic data.

For example, surveys that do not allow for self-identification, but rather require checking broad categorical self-designations, such as those related to race ("Asian," "American Indian," "Hispanic" "Alaska Native," "Black," "White"), limit the researcher's understanding of how participants may experience and define identity (Trimble & Dickson, 2005). Researchers can then investigate within- and across-group differences concerning various dimensions of identity (e.g., age, gender, race, ethnicity, language, immigration status, religion, spirituality, sexual orientation, social class, disability status). Identity-related research can also incorporate longitudinal investigations focused on shifts in identity, and their implications for psychological development and mental health. Further, psychological research can promote a more nuanced understanding of intersectional identities through more collaboration with individuals and

communities who can provide their self-descriptions of individual and group identity; this has been a core foundation of modern socioneurobiological approaches to cross-cultural research regarding identity and affiliation (cf., Decety & Ickes, 2009).

Additionally, researchers are encouraged to study groups belonging to multiple subordinated groups (Cole, 2009); for instance, the category of Black/African American/Black American women needs to include women of different nationalities, immigration statuses, social classes, gender identities, and sexualities. Cole (2009) argues that who is included within an intersectional category involves more than just being inclusive. It also improves psychologists' ability to theorize and empirically investigate the ways various social categories (e.g., classes, sexualities) structure individual and social life across the board. Cole (2009) further states that intersectional researchers seek sites of commonality across differences; however, this does not mean defining homogenous groups. The shift to the possibility of finding a common ground between groups deemed to be fundamentally different opens up opportunities to build coalitions among diverse groups who are disadvantaged by public policy.

At the same time, it is critically important from an intersectional standpoint that in recognizing similarities, researchers remain sensitive to nuanced differences across groups, even when similarities are found. For example, middle class Black/African American/Black American men and working class White/White American men may both experience job stressors, but their experiences of stress are not equivalent or identical (Roysircar, Thompson, & Boudreau, 2017).

Consultation. Consultants aim to address organizational issues that may stem from a lack of understanding related to identity (Ainslie, 2009; Fine, 2010). For example, a consultant who is guiding the development of a community-based intervention in the aftermath of a hate-based crime is encouraged to carefully assess the historical and ongoing structural factors that contributed to the traumatic stress experienced by the particular community, and how the event shaped individual and collective identities.

Consultants are also responsible for educating and collaborating with their clients (e.g., individuals, groups, communities) about the importance of respecting their own and others' self-definitions of identity. Consultants can also inform educational institutions that intersectional identities comprise both a personal agentic process of self-definition (e.g., this is how I choose to identify myself) and structural institutional dynamics and labels (e.g., this is how others, including the institution, identify me). Psychologists can point to intersectional oppression when

explaining the complexities of identity and self-definition. Readers are encouraged to consult *Case A: Tuan: Identity Transformation and Intersectionality over the Lifespan* and *Case B: An Example of Inclusive Research* in Appendix B, that illustrate key concepts presented in Guideline 1.

Guideline 2. Psychologists aspire to recognize and understand that as cultural beings, they hold attitudes and beliefs that can influence their perceptions of and interactions with others as well as their clinical and empirical conceptualizations. As such, psychologists strive to move beyond conceptualizations rooted in categorical assumptions, biases, and/or formulations based on limited knowledge about individuals and communities.

Introduction/Rationale

Psychologists' worldviews are rooted in their professional knowledge, personal life experiences, and interactions with others across their ecological contexts, and these worldviews influence their empirical and clinical conceptualizations and approaches. Multicultural and feminist scholars have emphasized that people are cultural beings whose beliefs, attitudes, and life histories influence their clinical and research conceptualizations (APA, 2003; Arredondo et al., 1996; Brown, 2010; Fouad & Brown, 2000; Jernigan, Green, Helms, Perez-Gualdron, & Henze, 2010; Kelly & Greene, 2010; Sue & Sue, 2016). Socialization concerning age, sex, gender, race, ethnicity, sexual orientation, religion and spirituality, social class, and disability has important implications for psychologists' conscious and unconscious preferences and inclinations when formulating diagnoses, analyzing and interpreting research data, and planning interventions (Greenwald & Banaji, 1995; Saewyc, 2011; Sue, Arredondo, & McDavis, 1992).

Psychotherapy research indicates that therapists' attitudes, cultural empathy, and cultural humility predict therapist's self-reported cultural competence in practice and client's perceptions of therapist's cultural competence (Lee & Tracey, 2008; Owen et al., 2016; Tummala-Narra, Singer, Li, Esposito, & Ash, 2012b). Further, clients' perceptions of the therapist's multicultural orientation and ability to address multicultural issues effectively in psychotherapy are related to

clinical processes, such as the working alliance, that have important implications for improved psychological functioning (Maxie, Arnold, & Stephenson, 2006; Owen, Tao, Leach, & Rodolfa, 2011; Worthington, Soth-McNett, & Moreno, 2007; Tao, Owen, Pace, & Imel, 2015). It is important to consider that clients' ratings of therapists' multicultural competence and therapists' self-perceived multicultural competence have been found to be discrepant. Therapists' multicultural competence may also vary from client to client within the same caseload. As such, multicultural competence can be context driven and multiply determined by therapist characteristics and client-therapist dynamics (Worthington & Dillon, 2011). Specifically, studies indicate that multicultural competence is associated with improved psychological well-being for clients who report higher levels of therapists' multicultural competence relative to other clients being seen by the same therapist (Dillon, et al., 2016).

Psychologists' pre-existing beliefs and assumptions influence the ways in which they respond to clinical and research data. Both conscious and unconscious factors may lead psychologists toward unwarranted assumptions about the client or data. In a clinical setting, an example of cultural conflict occurs when a clinician assumes that the client is enmeshed with a parent, or in other words, has a pathological relationship with the parent, without carefully assessing the client's cultural worldview concerning family relationships. In fact, psychological understandings of what constitutes childhood, adolescence, adulthood, and older adulthood are to some extent culturally constructed and context-dependent, where a particular behavior of a parent or of a child is considered normative in one context, but considered maladaptive or pathological in another. An example of cultural conflict that can manifest in the research process is when researchers analyze interview data without attending to reflexivity, or being actively aware of how their own perspectives and life experiences may affect the interpretation of the participant's narrative.

While categorizing individuals is a way of organizing information, particularly when meeting people whose experiences are unfamiliar, there is significant risk of misunderstanding, misinterpretation, and misdiagnosis (Foddy, Platow, & Yamagishi, 2009; Macrae, Milne, & Bodenhausen, 2005). Over the past decade, scholars have documented the prevalent negative conscious and unconscious (e.g., implicit, aversive) stereotyping of and bias against women, racial and ethnic minorities, sexual minorities, religious minorities, transgender and gender nonconforming individuals, older adults, people with disabilities, and people from low income

backgrounds, and their negative effects on mental health outcomes and health disparities (Allen, 2016; Bockting, 2014; Chalfin, 2014; Dovidio, 2009; García Coll & Marks, 2012; Greene, 2010; Helms, 2008; Lamont, Swift, & Abrams, 2015; Rostosky, Riggle, Horne, & Miller, 2009; Smith, 2013; Saewyc, 2011; Steele, 2010). Specifically, both subtle and explicit forms of discrimination are associated with mental health problems such as depression, anxiety, substance abuse, and suicidal ideation and behavior (Alvarez, Juang, & Liang, 2006; Blume, Lovato, Thyken, & Denny, 2012; Helms, Nicolas, & Green, 2010; Lamont et al., 2015; Sellers, Copeland-Linder, Martin, & Lewis, 2006; Tummala-Narra, Alegría, & Chen, 2012a). The internalization of stereotypes, both "positive" (e.g., model minority stereotype) and negative, may perpetuate privilege for some and has been associated with mental health problems, such as depression and individual and collective self-esteem (Fryberg, Markus, Oyserman, & Stone, 2008; Goodley & Runswick-Cole, 2011; Szymanski, Kashubeck-West, & Meyer, 2008; Yoo, Burrola, & Steger 2010).

Studies have indicated that color-blind racial ideology and individuals taking on a "color-blind" approach, wherein people's sociocultural identities and experiences are minimized and the universal dimensions of human experience are solely emphasized, is not effective for therapeutic process or outcome (Helms, 2008; Johnson & Williams, 2015). In fact, scholars have suggested that such an approach based on color-blind racial ideology contributes to disengagement from the negative or painful affect that accompanies discussions about sociocultural issues to the detriment of clients (Neville, Awad, Brooks, Flores, & Bluenel, 2013). The denial or minimization of sociocultural differences and similarities can have important implications for how psychologists understand not only the client's experience but also the dynamics between the therapist and client, as these dynamics often involve mutual influence of the therapist's and the client's sociocultural histories and experiences (Altman, 2010; Burkard, Knox, Clarke, Phelps, & Inman, 2014; Miville et al., 1999; Owen et al., 2016; Tummala-Narra, 2016).

Studies have noted a strong association between a clinician's personal exploration and investment in issues of diversity and professional practices related to issues of sociocultural diversity (Gallardo, 2014; Miville, Romans, Johnson, & Lone, 2004; Ruth, 2012; Tummala-Narra et al., 2012b) Specifically, psychologists who examine their beliefs about their own and others' worldviews on an ongoing basis are less likely to impose their beliefs in their professional work (Stuart, 2004; Sue & Sue, 2016). Therapist's knowledge of cultural norms,

beliefs, and values of clients, and sociopolitical influences such as racism, xenophobia, anti-Muslim prejudice and discrimination, anti-Semitism, sexism, transphobia, cisgenderism, homophobia, heterosexism, classism, and ableism, all of which influence the therapeutic relationship, has been considered a critical part of culturally competent practice (Atkinson & Hackett, 1995; Maxie et al., 2006). Although it is not possible to gain a thorough understanding of every cultural group, routine engagement with and curiosity regarding issues of diversity allows psychologists to develop their attunement and challenge preexisting stereotypes and assumptions (Fields, 2010). It is important to recognize that psychologists address their own resistances in addressing issues of diversity as a way of coping with anxiety, sadness, or other uncomfortable, difficult emotions, or as a way of avoiding the tasks involved with challenging the status quo (Hays, 2016; Tummala-Narra, 2016). For example, a therapist who has religious beliefs that consider homosexuality to be a sin may feel uncomfortable exploring a client's sexual orientation. A therapist who believes that clients who live in poverty only want to discuss their struggles with gaining access to resources may not explore other significant challenges faced by their clients, such as traumatic loss or the ending of a relationship (Smith, 2013).

Psychologists' recognition of their own assumptions and stereotypes are further connected with their theoretical and empirical formulations. Significant research has informed us of the limitations of models that have been developed within a Western, White/White American, male, middle class, heterosexual, cisgender framework when addressing health and behavioral concerns of individuals across diverse sociocultural backgrounds (Harding, 2006; Alvares, 2011; Mateo, Cabanis, Cruz de Echeverría Loebell, & Krach, 2012; Mertens, 2014). Psychologists are encouraged to apply their knowledge to determine when models and theories are most applicable and suitable to the individuals, communities, and organizations with which they interact. As has been suggested by Mays (2015), given "our divergent positionalities, [psychologists have] the capacity to reorient, to 'concoct sense' away from dominance" (p. 227) when that position of understanding has been shown to diminish personhood or the capacity to engage across cultural understandings. A focus on intersectionality has increased the capacity psychologists have for considering the multitude of positions and components of identity and personhood that exist within the array of communities, individuals, educational settings, and organizations. As such, psychologists are encouraged to become aware of the ways in which theoretical models of

understanding of domains such as development and mental health are shaped by the social, economic, and political contexts under which they were developed and ultimately presented.

To first appreciate and then engage with the similarities and differences they encounter when working with different communities and cultures, psychologists strive to undergo training that utilizes a variety of theoretical models, from which they are able to organize and conceptualize the information they are presented with as part of their interactions with diverse individuals in the varied settings and contexts in which they practice (Leong & Lee, 2006). The theoretical approaches that are available for organizing and interpreting experience and data are diverse themselves (e.g., systems, cognitive-behavioral, psychodynamic, humanistic, feminist, integrative), although at their best, they are tied to solid sources of empirical validation and remain open to ongoing testing with regard to their validity and reliability across contexts, identities, and cultural concerns. There have, in fact, been various developments in the integration of multicultural issues in various theories of psychotherapy over the past two decades (Hays, 2016; Quinn, 2012; Tummala-Narra, 2016; Wachtel, 2009).

Cole (2009) has outlined three specific questions psychologists might ask when they are considering the applicability of a particular theoretical model of approach to their working with diverse communities and individuals in research (although it has been argued that this applies more universally across psychological practice; cf., Grzanka, 2014). Cole's (2009) questions include the following: "1. Who is included in this category [being investigated]? 2. What role does inequality play? and 3. Where are the similarities [across and within social categories under consideration]?" Through appreciating the historical and current foundations of a specific model, and its constraints with regard to how it is best applied, psychologists strive to conduct practice that is informed by an understanding of the differential power dynamics that exist within the relationships they form professionally. They also practice with an awareness of the implicit heterogeneity of the groups they counsel, teach, or consult with, or with whom they are working as part of a study. This highlights the need for psychologists to "take seriously the cultural and political history of groups, as well as the ways these socially constructed categories depend on one another for meaning and are jointly associated with outcomes" (Cole, 2009, p. 178).

It is important to note that psychologists may consciously or unconsciously choose theoretical formulations and/or therapeutic approaches that offer the ease of relying on categorization rather than critically approaching issues of identity, development, and social

context with complexity and nuance, as the latter requires modifying existing assumptions and theories, as well as approaches to practice, research, consultation, and education. Thus, psychologists strive toward in-depth and ongoing examination and reflection concerning their own cultural worldviews, experiences, and theoretical conceptualizations, and their impact on practice, research, consultation, and education.

Applications to Practice, Research, and Consultation

Practice. Psychologists are encouraged to approach practice, research, consultation, and education with attention to self-examination and self-reflection concerning their attitudes, beliefs, values, and assumptions about individuals from cultural groups and sociocultural backgrounds similar to and different from their own. Psychologists consider the role of their own worldviews and sociocultural histories on clinical observations in assessment, interpretation of psychological tests, and formulation of diagnoses. Additionally, psychologists seek to become well informed regarding the strengths of a particular theoretical orientation while also considering challenges, given varied cultural considerations and difficulties with applicability, when evidence about the use of this model across cultures is lacking.

Psychologists can engage in personal reflection on multicultural issues through ongoing reading; dialogue with colleagues, friends, and family members; and their own psychotherapy experiences (McWilliams, 2014; Tummala-Narra, 2016). Psychologists working with students in educational and supervisory roles are encouraged to model culturally competent practice to support student development in this area.

It is important that psychologists pursue continuing education and ongoing training and consult with colleagues regarding multicultural and diversity issues (Hansen et al., 2006; Lee & Tracey, 2008; Maxie et al., 2006; Worthington, Soth-McNett, & Moreno, 2007). Effective diversity trainings consider the experiences of clinicians and how their sociocultural backgrounds may influence their receptivity to and engagement with such trainings (Dickson, Argus-Calvo, & Tafoya, 2010). Further, psychologists engage in consultation with peers and colleagues to develop awareness of their assumptions about culture and context. They strive to engage in reflective processes concerning cultural awareness throughout the course of their professional lives.

Psychologists are encouraged not to base their understandings of a cultural group on limited knowledge and exposure to that cultural group. For example, it is not acceptable for researchers to assume that they understand the "Latino/Hispanic/Latinx" culture because they conducted a project in Mexico. Overgeneralizations and stereotypic thinking may lead to engaging in inaccurate assessment and misdiagnosis, inappropriate treatment, and microaggressions in research and clinical settings (Pierce, Carew, Pierce-Gonzalez, & Willis,1978; Sue et al., 2007).

Sue and colleagues (2007) defined racial microaggressions as "brief and commonplace daily verbal, behavioral and environmental indignities, whether intentional or unintentional, that communicate hostile, derogatory, or negative racial slights and insults to the target person or group" (Sue et al., 2007, p. 273). Microaggressions further involve a sense of ambiguity and subtlety, in contrast with more explicit forms of discrimination (Owen, Tao, Imel, Wampold, & Rodolfa, 2014; Sue et al., 2007). Microaggressions are often experienced in everyday life by people of minority status (e.g., people of color, LGBTQ+ individuals, religious minorities, people with disabilities), and their cumulative effects have been associated with various forms of psychological stress (e.g., anxiety) (Blume et al., 2012; Owen et al., 2014).

Research. Researchers attend to how design, methodology (including sampling and instrumentation), and data analysis are potentially shaped by their worldviews and assumptions. A collaborative approach that values the perspectives and sociocultural locations and identities of research participants, and the self-reflexivity of the researcher(s) is a hallmark of culturally informed empirical studies. Research concerning interactive aspects of cultural worldviews and experiences can provide a better understanding of psychologists' role as cultural beings in their work.

For example, researchers of psychotherapy process have documented that microaggressions have a negative impact on the working alliance (Owen et al., 2014). A clinician who assumes that most people with physical disabilities are marginalized initiates a conversation in the first session with a client about his physical disability and states, "I'm sure it's been really hard to deal with people's reactions to your disability." While the clinician's intention is to connect and empathize with the client, the clinician has not yet adequately explored the client's experiences with disability, which may be distinct from those of other people with disabilities. It is also possible that the client wishes to focus on a different aspect of

identity. As such, researchers and clinicians strive toward complex understandings of clients' identities and self-definitions (as mentioned in Guideline 1) to avoid categorizing and overgeneralizing experiences, that can contribute to misinterpretation of data.

Consultation. The power dynamics inherent in clinical, research, supervisory, and consulting relationships may contribute to categorical thinking. It is important that supervisors create a space that offers a basic sense of respect, where they initiate discussion with the supervisee about the supervisee's experience of the supervision. It would also be helpful for supervisors to consult with colleagues who can help them to work through any conflictual or painful emotions. While this type of situation requires the ability to withstand and explore painful affective experiences, modeling such exploration is critical for effective supervision and training, which does not operate through simple, categorical thinking.

A critical part of psychologists' self-examination entails conscious and deliberate attention to privilege and its influence in their everyday work. It is important that researchers, clinicians, educators, and consultants consider the effects of privilege on their interactions with participants, clients, students, and consultees, and that privileged identities (e.g., White/White American, male, heterosexual, middle class, cisgender, and able-bodied) often remain invisible to others and to themselves and are therefore assumed to be normative (McIntosh, 2015). The issue of privilege is connected with systemic issues in training that contribute to challenges associated with engaging in a dialogue concerning multicultural issues.

While courses focused specifically on multicultural issues are critical to education in psychology, a model that includes multicultural considerations across the lifespan throughout the curriculum is encouraged. Relatedly, multicultural education is not intended to be provided solely by faculty who identify as minorities (e.g., racial, gender, or sexual), as this contributes to the problem of categorization and marginalization within psychology, and it dismisses the importance of faculty from all sociocultural backgrounds investing their time and resources to examining and addressing the influence of their beliefs, attitudes, and assumptions on education and training. Readers are encouraged to consult *Case C: Marcus: Exploring Stereotypes and Microaggressions* and *Case D: Melissa: Training Experiences as a Practicum Student* in Appendix B, that illustrate key concepts presented in Guideline 2.

B. Level 2: Community/School/Family Context

Connection to the model. The model's second level examines clinical, educational, consultative, and research interactions(s) within the context of community, school, and family. Within this level, the psychologist seeks to understand the client's experience from a multicultural framework that considers the impact of community, school, workplace, social determinants, and family contexts. Two general issues to be addressed at this level include consideration of: (1) the role of language in community, school, workplace, and family contexts; and (2) the role of social and physical environments on the lives of clients.

Guideline 3. Psychologists strive to recognize and understand the role of language and communication through engagement that is sensitive to the lived experience of the individual, couple, family, group, community, and/or organizations with whom they interact. Psychologists also seek to understand how they bring their own language and communication to these interactions.

Introduction/Rationale

Psychologists are encouraged to consider the role of language in their professional relationships as well as within the context of the client's experience within school, work, family, and community contexts. Language refers to the verbal and nonverbal symbols used to communicate with others (Guo et al., 2009; Javier, 2007). Through language, the individual, group, couple, family, community, and/or organization share an aspect of self and experience with someone else. Language embodies the culture and values in which is it spoken (Chen, 2015). For instance, in Spanish the word "yo" means "I" but is not capitalized as in the English language (Clauss-Ehlers, 2006). This difference reflects the focus on the collective or the larger group in many Spanish-speaking countries. This is in contrast to the frequent focus on the individual as reflected in many English-speaking cultures.

One question of language, in the context of guidelines for practice, is to consider who has ownership of language. For instance, what is the language or terminology that individuals, couples, families, groups, communities, and/or organizations want to use to define themselves? Further, who determines the terminology used and how identities are defined? For those who speak more than one language, how is the language of the psychological interaction decided

upon (Villate, Villate, & Hayes, 2016; Wong, Yin, O'Brien, 2016)? These questions underscore the complexity of language for individuals, families, communities, organizations, and helping professionals. One rationale for engaged sensitivity on the part of the psychologist is to recognize that the role of language and communication for the individual, couple, family, group, community, and/or organization relates to the fact that in language's intrinsic connection to culture, it also reflects social identity (Chiu & Chen, 2004).

On the other side of the language equation, psychologists also bring language and communication styles (both verbal and nonverbal) that reflect their lived experiences. The psychologist's language may reflect a professional culture that may or may not be responsive to the client's/student's/participant's/organization's perspective. In their work implementing evidence-based mental health interventions in post-conflict areas, Murray et al. (2014) found that conducting qualitative studies to understand the best and most appropriate local terminology related to mental health was critical in stigma reduction efforts. This resulted in adapting language in the mental and behavioral health setting "that is least stigmatising within the local setting" (Murray et al., 2014, p. 102).

The interchange of multiple contexts and cultures as reflected by language and communication are at dynamic interplay in the exchange between individual, couple, family, group, community, and/or organizations and the psychologist. It is important that the psychologist strives to recognize this nonlinear interplay, and is sensitive to its complexity. Psychologists can seek to recognize the cognitive and affective components of bilingualism and multilingualism, psychological meanings associated with each language, and the connection between cultural values and identity associated with each language (Akhtar, 2011). Linguistic terminology and its meanings can change over time and context with sociopolitical shifts (e.g., the increased use of technology, specifically social media, as a global means of communication).

Psychologists are encouraged to understand the cultural experience and reality expressed by the client as represented by language. To this end, psychologists may also engage in code-switching, engaging both professional and personal language to more fully enter and participate in the client's world (Javier, 2007). Intergenerational communication is one such example that "applies to interactions involving individuals who are from different age cohorts or age groups" (Hummert, 2015, p. 273). Intergenerational communication can be examined within the context

of intergenerational interaction and communication throughout the lifespan (Williams & Nussbaum, 2001).

Psychologists are encouraged to be aware of intergenerational language strategies, intergenerational relationships, and intergenerational conflicts that influence communication within a societal and cultural context (Williams & Nussbaum, 2001). Relatedly, psychologists strive to be aware of how language varies according to developmental stage and the impact this variability has on clinical, educational, research, and consultative interactions (Eskildsen, 2015).

Another example is language and communication through engagement between people who identify as cisgender and people who identify as transgender and gender nonconforming (APA, 2015b). Recent literature has called for the intercultural communication field to "address the lives of transgender persons and the (inter)discipline of transgender studies to develop our theorizing about gender and intersectionality and intervene in the violence against trans* persons" (Johnson, 2013, p. 135). Psychologists are encouraged to be aware of communication between cisgender and transgender and gender nonconforming individuals.

Applications to Practice, Research, and Consultation

Practice. Given that much of the psychologist's role involves communication with others in diverse professional contexts (e.g., clinical consultation, teaching, research, organizational consultation; community outreach), awareness of and sensitivity to language is encouraged in psychological practice. Services that psychologists provide for people and communities call for an understanding of the language and communication style used within a specific context. Psychologists strive to engage in developmentally appropriate communication efforts that seek to understand how people, communities, and organizations self-identify and subsequently follow the lead presented by that individual or group's identification (Wong et al., 2016). Included in communication efforts is an awareness of and responsiveness to nonverbal forms of communication (Weiste & Peräkylä, 2014).

Where language is a key concern, psychologists also strive to be aware of the use of interpreter guidelines when not versed in the language of the client. Psychologists are encouraged to use interpretation in situations where it is difficult to match on language, while recognizing the implicit challenges that occur, specifically in both assessment and clinical work where language variances can challenge effective communication (Cofresi & Gorman, 2004).

Aspirations for psychologists working with interpreters are to form a collaborative partnership that promotes an understanding of the client's experience (Costa, 2016).

Other psychologists may reflect the same language background as the client, whether it is a monolingual, bilingual/bicultural, or multilingual/multicultural experience. Psychologists are encouraged not to assume sameness between themselves and the client, but rather to understand that language and culture may be experienced differently even when a shared language exists (Javier, 2007). Just as psychologists are encouraged to follow the self-definition and use of terminology selected by the client, psychologists who share language capabilities with their clients make an effort to follow the client's lead in choice of language being spoken during the session. It is also important that psychologists reflect on the impact of their own linguistic heritage and monolingualism, bilingualism, or multilingualism on their interactions and communications to clients (Akhtar, 2011).

Substantial literature documents the notion of events being encoded in the specific language spoken when they were experienced (Javier, 2007). This literature highlights how the events that occur within a specific language environment may have a level of emotion attached to them when shared in the language in which they are experienced (Javier, 2007; Schmidt, 2012). Alternatively, evidence suggests that for some clients, speaking in the language in which the experience was not encoded may serve as a distancing mechanism (Clauss-Ehlers, 2006, Javier, 2007).

By following the client's lead in this domain, the psychologist considers the complexity associated with code-switching in psychological practice. One such example includes consideration of the use of slang or informal language that may be used in a particular context or during a particular developmental stage. For instance, adolescents may use slang to describe their experiences. Here the psychologist is encouraged to seek out an understanding of what the slang means as needed. Given that psychologists bring their own linguistic context to clinical and research interactions, they are encouraged to consider the appropriateness of using slang themselves and if motivations are driven by a desire to "look cool" in the eyes of the client, student, research participant, or organization.

Using standardized assessment tools in linguistically and culturally diverse communities evokes another area of significant consideration (Stolk, 2009). Knowledge about efficacious approaches to assessment, diagnosis, and treatment are key elements of appropriate multicultural

practice (Ferraro, 2010; Mindt, Byrd, Saez, & Manly, 2010; United States Department of Health and Human Services (USDHHS), 2001). Understanding the limitations and lack of potential applicability of a measure commonly utilized when differences in language and cultural experience are present is an important example of how psychologists may apply their knowledge. Consideration of the appropriateness of an assessment measure is a first step to be taken by the psychologist, who is then tasked to determine whether there are other standardized measures available to conduct an assessment of the client's cognitive and behavioral status (i.e., where making use of a less culturally biased measure would be helpful).

Issues with the application of standardized assessments to linguistically and culturally diverse communities include norms not being developed in the language of or for the population in which the assessment is being administered. As a result, it is often the expectation that an individual will take a test in English (as assessments are often available only in English), even though English may be a second language for the examinee; this may compromise both interpretation of findings and applicability. Further, test items may reflect the dominant culture in which the assessment is being administered rather than the examinee's heritage culture. For example, within neuropsychological assessment, many measures have been created within an English-speaking context; efforts to apply such measures to individuals where English is not the dominant language can compromise an understanding of proposed relationships between brain and behavior for the examinee. It has been strongly advised to consider matching on language whenever possible when conducting formal diagnostic evaluations, to better support an understanding of functional status, given already challenging comparisons due to normative sample absences (Díaz-Santos & Hough, 2015).

Research. Language and communication within a sociocultural context are relevant to the research enterprise. A comparison of research measures across cultures can introduce problems and fail to capture the nuances associated with the participating culture and community (Clauss-Ehlers, Serpell, & Weist, 2013; Wagner, Hansen, & Kronberger, 2014). Similar to practice considerations when conducting assessments, Wagner et al. (2014) contend that simple translations of interview questions for qualitative research may fail to represent the same semantic meaning. The use of cultural metrics to conduct linguistically and culturally sensitive research can be operationalized through several strategies (Wagner et al., 2014). The use of a bundled variable strategy is recommended for quantitative research. This approach looks at

statistical interactions between multiple variables rather than focusing on one dependent variable (Wagner et al., 2014). Thus, instead of looking at the effect of one variable across many cultures, different variables are examined across multiple cultures.

Research practice informed by multicultural considerations allows psychologists an opportunity to more directly consider and then account for sources of variance (Marshall & Batten, 2004). Communications regarding study design, implementation, analysis, and interpretation can directly and openly consider that participants will vary in their understanding of and approach to the measures and conditions. The research psychologist is encouraged to incorporate local terms or phrases in the research protocol to make the research more reflective of the participant's experience (Jacquez, Vaughn, & Wagner, 2013). In turn, greater relevance of research measures may lead to participant responses that capture experiences more readily. Psychologists are encouraged to address these challenges by acknowledging limitations and to address multiple factors with regard to self-identification and understanding. As an example, Hoare, Levy and Robinson (1993) have encouraged researchers to incorporate the community in empirical investigation. They state: "… participation de-mystifies the research process. Understanding the research process equips community members to be advocates of change" (Hoare, et al., 1993, pp. 53-54). Research psychologists are encouraged to consult with consumer engagement groups about the language and terminology being used in the research process and within relevant research measures (Green, et al., 2014). In addition, psychologists are encouraged to be aware of the role of language and informed consent to participate in research. Here, for instance, it is important that psychologists provide informed consent documents that are written in the research participant's primary language. For those participants with low literacy or who are unable to read, the research psychologist or interpreter can read the consent form in the research participant's primary language.

Consultation. As with practice and research domains, the application of sensitivity to language and communication within the consultation sphere involves understanding the culture of the entity with whom the psychologist is working. Language within the consultation arena can be an indication of the organization's cultural context. Psychologists are encouraged to be attentive to the language(s) of the organization as communicated by multiple constituencies. In this way, psychologists strive to develop a broad understanding of organizational issues. The psychologist is also encouraged to use a theoretical approach informed by intersectionality and

multicultural identity to effectively respond to existing patterns of communication, self-identity, and understanding of self within the organization that may contribute to the organization's successes and challenges (Leong & Huang, 2008; Sue, 2008; Thomas, 2008).

Psychologists can also use their professional language to engage multiple constituencies. Where relevant, psychologists may promote communication across organizational constituencies that may not be fully hearing or understanding one another. In this way, the psychologist acts as a convener, bringing groups together to express their experiences within the organization, considering how they may be similar and how they may differ. Through an engendered conversation, the psychologist is encouraged to promote organizational change. Readers are encouraged to consult *Case E. Dr. Enrique: Culturally and Linguistically Responsive Consultation* in Appendix B, that illustrates key concepts presented in Guideline 3.

Guideline 4. Psychologists endeavor to be aware of the role of the social and physical environment in the lives of clients, students, research participants, and/or consultees.

Introduction/Rationale

The psychologist is aware that the resources available in the immediate environment provide many of the tools by which individuals can build their lives. These resources combine into what is sometimes called social capital, and include factors such as the overall wealth and safety of the neighborhood, the quality of schools, pollution and other environmental hazards, the quality and accessibility of healthcare and transportation systems, and the availability of nutritious food. A resource-rich environment can maximize the potential for a quality life, while a resource-poor environment can create barriers to self-actualization. Unfortunately, individuals from disadvantaged backgrounds are disproportionately represented in resource-poor environments (Krieger et al., 2016; Olkin, 2002; Reardon, Fox, & Townsend, 2015). The psychologist may therefore wish to pay special attention to resources available to clients, including barriers to healthcare services, the quality of such services, and other social and physical environmental factors that might either impede or facilitate interventions. In the healthcare community, the term "social determinants of health" has been defined by Healthy People 2020 (2017) to include neighborhood and built environment, health and health care, social and community context, education, and economic stability.

Psychologists are encouraged to recognize that these environmental factors do not detract from the importance to be placed on the client's personal and perceived world. Rather, they call attention to the fact that life plays out in the context of the social and physical environments where the client lives. For example, a client with a physical disability who lives alone in a rural area with few social supports may encounter great difficulty accessing mental health and behavioral health services. Conversely, a live-alone client with a similar physical disability who lives in central New York City may encounter little difficulty in accessing both transportation and health services. As another example, a student who identifies as LGBTQ+ and attends a very conservative university may encounter hostility from peers and even faculty and staff when seeking help with marital problems, as well as a lack of qualified counselors.

Research on the importance of resources has been facilitated by the inclusion, beginning with the 2000 U.S. Census and in other regional databases, of objective information down to the census block level of data on the sociodemographic characteristics of residents—not only racial and ethnic characteristics but also information on income levels, home ownership, car ownership, and other variables. The location of schools, police departments, clinics, hospitals, and even grocery and department stores—all of which represent elements of the so-called "built" environment (Opotow, 2016)—can also be accessed, as can crime statistics. Combined with the client's own perceptions of the general neighborhood, this information provides a wealth of information about the neighborhood in which a client lives. The psychologist may also wish to explore the involvement and influence of a relatively new form of the environment, that posed by social media, that may be particularly salient in the lives of those with intersectional identities (McInroy, 2016).

Applications to Practice, Research, and Consultation

Practice. When considering the many factors that may influence an individual and the effectiveness of interventions, the psychologist seeks to understand the immediate social and environmental context. The neighborhood in which a client lives can inform the psychologist about the availability of resources, as well as potential problems that may interfere with any intervention. This information may also be helpful to the client. LGBTQ+ adolescents facing harassment and bullying at school and rejection at home, for example, may be unaware of helpful resources (Tucker, et al., 2016). Safety concerns or lack of adequate public

transportation are barriers to access and may also increase the risk of dropout from treatment among clients facing poverty or with limited resources (Glaeser, Kahn, & Rappaport, 2008; Kanter, 2015).

One general finding is that clients from low-resource neighborhoods may present not only with mental health and behavioral health problems but also with problems exacerbated by living in neighborhoods characterized by poverty, poor health care, lack of access to health care, high crime rates that lead to chronic fears for personal safety, few public spaces, and inadequate staffing and resources in the public schools (Krieger et al., 2016; Reardon, Fox, & Townsend, 2015). Neighborhood safety has implications for health behaviors for individuals of all ages. For instance, unsafe neighborhoods prevent children from playing outside and older adults might feel like vulnerable targets. As noted, lack of or inadequate public transportation can be a particular problem for clients living in poverty or with limited economic resources, creating barriers to healthcare or to participation in research and/or education. Attention solely to the immediate behavioral health problems of a client, without regard to the socioenvironmental context, may result in attrition and generally poor outcomes, regardless of the quality of practice. The psychologist is therefore encouraged to consider implications of a client's social and built environments. Advocacy in the form of involvement in local and regional efforts to improve the infrastructure of communities is also recommended.

The second of the two general findings from studies of environmental influence is that individuals living in low-resource environments, including not only those from historically disadvantaged and discriminated groups but also the more mainstream, may have a greater likelihood of receiving lower-quality care from health services and greater barriers to access (Jha, Orav, & Epstein, 2011; Schoen, et al., 2013). This broad spread of effect is tempered by the fact that low-income and discriminated groups, and even middle-income individuals from those same groups, are more likely than low-income Whites/White Americans to live in low-resource areas. This means that the vulnerabilities created by life in low-resource environments are much more likely to affect disadvantaged and discriminated identity groups (Williams & Jackson, 2005). The greater exposure to crime and violence and limited access to quality school systems creates additional and often lifelong vulnerabilities for diverse populations.

The psychologist also recognizes that among those most affected by living in a low-resource environment are persons who have physical or intellectual disabilities (Freedman,

Grafova, Schoeni, & Rogowski, 2008; Goodley & Runswick-Cole, 2011; Kramer, Olsen, Mermelstein, Balcells, & Liljenquist, 2012; Olkin, 2002). Challenges to mobility, including those arising from cognitive issues, can make individuals more dependent on the resources available in their immediate environment. Individuals living in impoverished environments may generally find it difficult to leave their homes due to concerns about safety, the lack of social cohesion, and problems with transportation (Butler et al., 2016; Spivock, Gauvin, Riva, & Brodeur, 2008). Even when they do not have mobility impairments, these concerns may prevent clients from seeking and/or accessing help from mental health professionals. Despite the need, research on approaches to assuring cultural competence in meeting the needs of persons with disabilities is sparse and has yielded mixed results. Of particular concern is that there are remarkably few studies that examine the intersection of disabilities with membership in marginalized populations. As Butler and colleagues (2016, p. 29) note, "there is not a sufficient evidence base to conclude whether interventions used to promote racial and ethnic provider cultural competence will produce reductions in disparities when used to promote provider cultural competence for people with disabilities." Nevertheless, it is well noted in the literature that people with disabilities face barriers to appropriate care and resources, including discrimination and prejudice in clinical and educational settings, similar to other underserved individuals and communities (Goodley & Runswick-Cole, 2011; Olkin, 2002).

According to Berkman (2009) and others, the impact of the environmental context can be divided into three basic ways that reflect the presence of critical periods in the exposure to adverse environments. The first category deals with early exposure that leads either immediately or later to negative health consequences. Being born to a mother who herself abuses or is addicted to substances (e.g., alcohol, nicotine, narcotics, and opioids) can lead to a heightened risk for a child, particularly during adolescence, exhibiting adaptive problems and even increased risk of mortality (e.g., Borelli, Luthar, & Suchman, 2010; Mayes, & Suchman, 2006). The second category encompasses a cumulative history of exposure to problems such as pollution, high levels of crime, or inadequate educational resources. The third category involves a social trajectory where earlier exposure to adverse environments, such as high crime rates or impoverished educational experiences, may create barriers or opportunities later in life.

Research. Much of the research on social and built environments has focused on the physical health consequences of living in low-resource environments, but more remains to be

done. Already mentioned is the host of physical health problems disproportionately represented among persons living in low-resource neighborhoods, including all-cause mortality, cardiovascular disease, diabetes, asthma, and obesity (Beck, Simmons, Huang, & Kahn, 2012; Krieger, et al., 2016; Roux & Mair, 2010). The reasons for these disparities, however, are clearly complex, and deserve attention with respect to the development of effective interventions. For example, how can barriers to health care resulting from safety and other socioenvironmental factors be minimized for those with mobility impairments? Similarly, recognizing that greater obesity in children living in low-income neighborhoods may partly result from more fast food availability (Kumanyika, & Grier, 2006; Reitzel et al., 2014), what interventions are feasible? While rarely studied, higher levels of depressive symptomatology have also been reported in low-income areas (e.g., Echeverría, Diez-Roux, Shea, Borrell, & Jackson, 2008; Ostir, Eschbach, Markides, & Goodwin, 2003; Roux & Mair, 2010), as has the disproportionate numbers of LGBTQ+ youth in the juvenile justice system (e.g., Allen, Ruiz, & O'Rourke, 2016). Even more rare are studies that focus on life span issues. In sum, Lewin's (1946) call for community action research and practice still has relevance in light of continuing inequities.

Consultation. What Berkman (2009) referred to as the "social trajectory" is of particular interest to consulting psychologists. While health problems that result from early or cumulative exposure to adverse environments may be difficult to resolve, those that result from social trajectories may be more amenable to environmental interventions. Some examples include efforts to reduce crime or gun violence or to improve educational or healthcare systems. Consider an adolescent identifying as LGBTQ+ who is exposed to harassment and abuse in school and from peers, and is unable to perform according to academic potential in school. The adolescent's life trajectory, without the influence of informed interventions, may contribute to a lifetime of unrewarding and unfulfilling jobs and relationships with others. One such intervention might draw from community resources, since there is evidence that LGBTQ+ youth may build resilience from the support of family and friends (Gray, Mendelsohn, & Omoto, 2015; Shilo, Antebi, & Mor, 2015).

Once again, the research highlights the importance for psychologists of attending to policy at a societal level, in addition to treatment at the individual level. From a policy perspective, the literature underscores the value to the field of psychology, as well as to

individual psychologists, of serving as advocates for improvements in the quality of care and related services in local areas. Helping a client is only the beginning, as it helps only one individual. Helping the community—the second level of the model adopted for these guidelines—gain resources critical for health helps all. Readers are encouraged to consult *Case F. Yasmin: Bridging Different Worlds; Case G. Anthony: Having an Identity That Extends Beyond One's Disability;* and *Case H. Jung: Access to Culturally Relevant Treatment* in Appendix B, that illustrate key concepts presented in Guideline 4.

C. Level 3: Institutional Impact on Engagement

Connection to the model. The influences in Level 3 consider how the forces described in Levels 1–2 interact within a larger institutional, systemic context. The nature of engagement at the institutional level must also be considered. While psychologists may focus on the individual nature of problems presented at Level 1, three additional areas are to be considered within the multicultural framework presented: (1) the ways in which power, oppression, and privilege affect institutional influence and engagement; (2) the ongoing impact of inequities and disparities; and (3) the role of advocacy in institutional engagement.

Guideline 5. Psychologists aspire to recognize and understand historical and contemporary experiences with power, privilege, and oppression. As such, they seek to address institutional barriers and related inequities, disproportionalities, and disparities of law enforcement, administration of criminal justice, educational, mental health, and other systems as they seek to promote justice, human rights, and access to quality and equitable mental and behavioral health services.

Introduction/Rationale

At the macro level, oppression (Essed, 2002) in its various forms such as racism (Du Bois, 1903/1996; Franklin, 2004); cultural imperialism (Mohawk, 2004; Speight, 2007); classism (Liu, 2012); ableism (Goodley & Runswick-Cole, 2011; Olkin & Pledger, 2003); ageism (Lamont et al., 2015); English-only injunction (Lynch, 2006); and stigma about minority status (Hatzenbuehler, 2016; Meyer, 2003) hinder access to societal resources, which results in disparities. Ample research has indicated that people from oppressed groups experience limited

access to, less utilization of, and diminished quality of health care (Institute of Medicine, 2003; USDHHS, 2011).

If psychologists focus only on individual functioning, they may not include in their understanding structural oppression embedded in institutional practices that produce inequities and disproportionalities, resulting in negative psychosocial outcomes for underserved individuals, couples, families, and communities (Aldarondo, 2007; Liu, Pickett, & Ivey, 2007). With regard to racism, psychologists are encouraged to challenge their color-blind racial attitudes and beliefs that the world is just and fair (cf., Neville, et al., 2013). Psychologists are also encouraged to observe an ongoing self-reflective process of their own social position, exploring and owning their privilege when interacting with clients and the possibility of their clients' less privileged position (Ancis & Szymanski, 2001; Roysircar, 2004b, 2008).

With regard to the range of social and political challenges that have emerged across the world, and their potential to influence psychologists' concerns for social justice, psychologists are encouraged to advocate for accessibility and pursue treatment with social responsibility, inherent to the elements of social justice within the field of psychology. All people, including racial, ethnic, linguistic, religious, and LGBTQ+ minorities, prison inmates, immigrants and refugees, the poor, and people with disabilities have a right to equitable treatment, allocation of societal resources, and decision making.

"Citizen psychologists" have a specific focus on policy, political advocacy, and use of structural resources. In addition, they give voice to people by employing psychological knowledge and expertise in best practices in an array of civic settings from the local to the national level (Daniel, 2017). Thus, citizen psychologists aspire to understand power differentials, power dynamics, and privilege lying at the core of multicultural tensions in the United States and the impact of these on societal structures and institutionalized forms of oppression. Psychologists endeavor to promote advocacy beyond the direct support of clients to include public policy decisions, advances in human welfare services, public health, systems of care, training and education, consultation, research, funding, and issues that affect the well-being of the public at large.

Oppression is a structural phenomenon that is grounded in the culture and norms of a society, and, therefore, influences its institutional operations (Young, 1990). Understanding oppression as a structural phenomenon highlights the similarities across different types of

subjugation, such as ethnocentrism, cultural encapsulation, sexism, heterosexism, cisgendersim, homophobia, and Islamophobia. To determine whether a particular group is oppressed, Young (1990) delineated, among others, categories such as marginalization (i.e., exclusion from contributing to social life, for example, civic functions and events), powerlessness (i.e., lacking authority to be active agents of political life, such as easy access to voting), cultural imperialism (i.e., privileging the dominant group's perspectives over those of others, such as about mental health), and violence (i.e., directing destructive forces systemically at particular groups, such as American Indians, Alaska Natives (AI/AN), Native Hawaiians, Blacks/African Americans/Black Americans, Japanese Americans, and undocumented immigrants). These categories of oppression can be experienced separately or intersectionally. Traumas from intersectional oppression, it has been noted, is transmitted collectively across generations of American Indians/Alaska Natives, Native Hawaiians, and Blacks/African Americans/Black Americans (cf., Brave Heart, Chase, Elkins, & Altschul, 2011; Gone, 2013; Leary, 2005; Turner & Pope, 2009).

Disparities in the legal system. There are significant disparities in equitable treatment across the legal system. Racial profiling by the police targets individuals for suspicion of crime based on an individual's race, ethnicity, religion, or national origin, resulting in people of color being disproportionately likely to be stopped, questioned, and ultimately arrested. Racial profiling results from stereotypes that are fixed, overgeneralized beliefs about a particular group of people.

One such example is Arizona's SB 1070, that invites racial profiling against people presumed to be "foreign" based on how they look or sound and who are suspected of being in the country unlawfully; this law was ultimately upheld by the U.S. Supreme Court. Following fatal police shootings of Black/African American/Black American males in 2014 and 2015, groups such as Black Lives Matter accused law enforcement officers of being too quick to use lethal force against unarmed Blacks/African Americans/Black Americans.

Overall in 2015, about 25% of the Blacks/African Americans/Black Americans killed were unarmed, compared with 17% of White/White American people. Those who were killed were twice as likely not to have a weapon as to have one (Reese, 2015). A study in 2016 confirmed that Black/African American/Black American men and women are treated differently in the hands of law enforcement (Fryer, 2016). This study found that Black/African

American/Black American men and women are more likely to be touched, handcuffed, pushed to the ground or pepper sprayed by a police officer, even after accounting for how, where, and when they encountered the police. But when it came to police shootings, however, the study found no racial bias. The study examined more than 1,000 shootings in 10 major police departments in Texas, Florida, and California. This finding by Fryer (2016) contradicted the image of police shootings that many Americans hold after some killings have been captured on video and shown in the media. The study did not say whether the most egregious examples—those at the heart of the nation's debate on police shootings—are free of racial bias. Instead, it examined a larger pool of shootings, including nonfatal ones.

There are disparities and disproportionalities in incarceration rates by race such that Black/African American/Black American individuals were incarcerated at a rate 5.1 times greater than their White/White American counterparts (The Sentencing Project, 2015). Scholars attribute these disparities to disparate criminal justice policy as well as implicit racism in decision-making among law enforcement and justice officials (Mauer, 2011).

Poverty and homelessness, particularly in conjunction with mental illness, lead to heightened law enforcement intervention as individuals who lack housing are forced to live in public spaces and are more vulnerable to arrest for trespassing, loitering, and disorderly conduct; in addition, they may be incarcerated for long periods of time for offenses that often receive no jail time for other people (The Sentencing Project, 2015). Further, what few mental health services may be available in a jail or prison are generally not accessible to people with speech and hearing disabilities (who are entitled to them under current law and the Americans with Disabilities Act [ADA]) as well as for immigrants with low English proficiency because of the lack of language interpreters (Leigh & Vernon, 2007). For prison management, importance is placed on keeping the area safe, orderly, and escape-proof, while also making sure that appropriate programs designed to change offensive behavior and provide rehabilitation are included. Oftentimes, programs targeted at mental health receive less attention when striving to keep this balance (Jordan, 2011).

This disparity is especially problematic because there is a significant link between lack of adequate mental healthcare in prison and an increase in suicide risk and psychiatric symptoms, decompensated medical conditions, and relapse to drug use and overdose (Binswanger et al., 2011). Imprisonment without appropriate mental health care is seen to have a null or slight

criminogenic effect on subsequent criminal behavior and can also be related to recidivism (Visher & O'Connell, 2012). Psychologists are encouraged to advocate for alternatives to incarceration, such as immediate mental health and substance abuse treatment and transitional homes after release. Both the person who has been incarcerated and the community are better served when treatment barriers are removed.

Many homeless people interact with both police officers and paramedics. However, the level of trust directed toward those two professions varies greatly in the homeless community. A study showed that 92% of a polled homeless population reported that they would be willing to call paramedics in an emergency but only 69% would call the police in an emergency, even when they had no interactions with the police over the past year (Zakrison, Hamel, & Hwang, 2004). This lack of desire to call the police is detrimental for some individuals who are homeless because of their potential inability to escape or remove themselves from a dangerous or threatening situation.

Disparities in education. After World War II, some metropolitan-based psychologists began to apply their science to examine disparity or disproportionality in education. In New York City, Mamie Clark and Kenneth Clark researched the inappropriate placement of Black/African American/Black American children in classes for students with intellectual disabilities (Clark & Clark, 1939). The Clarks tested the children and found that many were above average in intelligence. This prompted a long battle with the New York Board of Education in which the Clarks fought for a change in school board policies. Owing to the Clarks' (1939) research findings on Black/African American/Black American children, the Supreme Court ruled in 1954 that segregation in public schools by race was unconstitutional (Benjamin & Crouse, 2002; Guthrie, 2003). Steele and colleagues' work on stereotype threat (Steele, 1997), a situational predicament in which people are at risk of conforming to stereotypes about their social group, has led to an increasing recognition that negative labeling of minority communities could cause a self-fulfilling prophecy and limit academic and job success. In recent studies among Black/African American/Black American college students and adults, higher levels of internalized racial oppression were associated with lesser valuing of higher education (Brown, Rosnick, & Segrist, 2016) and lower career aspirations (Brown & Segrist, 2016).

While legal segregation ended 60 years ago, schools are socially segregated by race, ethnicity, and class. Urban schools are marked by class segregation that intersects with ethnicity

and low English proficiency (National Center for Education Statistics [NCES], 2016). Latino/Hispanic//Latinx, Asian/Asian American/Pacific Islander, and English-language-learner students have increased in number, while Black/African American/Black American students have had no change and White/White American students have declined in number. Forty percent of urban students attend high poverty schools (defined as schools with more than 40% of students receiving free or reduced price lunch), whereas 10% of suburban students and 25% of rural students do so. A high concentration of students living in poverty is related to less desirable student performance. In addition, urban students—who already have less access to regular health care—are more likely to be exposed to safety and health risks that place their health and well-being in jeopardy. Student behavior problems—particularly student absenteeism, classroom discipline, weapons possession, and student pregnancy—are more common in urban schools than in other schools. Teacher absenteeism, an indicator of morale, is more of a problem in urban schools than in suburban or rural schools. Students in urban schools are less likely than most other groups to attend gifted and talented programs. However, the use of alcohol is less of a problem in urban schools than in rural schools (NCES, 2016). The general perception is that urban students achieve less in school, attain less education, and encounter less success in the labor market later in life.

The McKinney-Vento Homeless Assistance Act of 1987 has provisions to help transport homeless children to school and improve physical access to education. However, it has been seen to place disproportionate emphasis on physical access and not enough on enhancing the instructional opportunities for the children (Stone & Uretsky, 2016) or their readiness to engage in available opportunities once they are at school. Stress arises for homeless children whose families are on the brink of breakup, sometimes necessitating the choice between maintaining a stable family as a support system and the child receiving an education (Kozoll, Osborne, & García, 2003). Though the special education system has shown to greatly increase access, various schools' financial barriers, problems with screening, and bureaucratic issues can impede education for children with disabilities. Thus, the freedom to choose which school is best for a child to attend may not be available to children who come from poor families or who have disabilities.

Class inequality also occurs in college access and intersects with racial and ethnic disparities or disproportionalities in universities ranked high by the *U.S. News and World*

Report. A college degree affects a person's future income, occupation, and social relationships. Blacks/African Americans/Black Americans and Latino/Hispanic/Latinx students may attend lower-status broad-access college institutions that have fewer resources and provide lower economic payoffs, such as future earnings. Selective universities are resource rich and invest in education that keeps them competitive, including investing in students who have strong academic qualifications and can pay high tuition. Universities that are both public and selective and ranked among the top institutions of higher education may have undergraduate student bodies that are majority middle class, White/White American, and pay high in-state tuition (Berrey, 2015). These state universities' emphasis on high standardized test scores and GPA places students from poor as well as racial and ethnic minority backgrounds at a disadvantage because such academic outcomes have been correlated with high family income.

Disparities in mental health care. Economic disparities, often due to under- or unemployment, have been linked to poorer psychological well-being (Goodman, Pugach, Skolnik, & Smith, 2013; USDHHS, 2001). Among people of color, Alaska Native and American Indian populations (9.9%) and Black/African American/Black American Americans (9.6%) have the highest rates of unemployment, that far exceed that of their White/White American counterparts' (4.6%; U.S. Bureau of Labor Statistics, 2015). Using data from two nationally representative samples, the National Comorbidity Survey Replication (NCS-R) and the National Latino and Asian American Study (NLAAS), researchers found that long-term unemployment predicted large, negative effects on mental health, that were larger for Blacks/African Americans/Black Americans and Latino/Hispanic/Latinx Americans (Diette, Goldsmith, Hamilton, & Darity, 2012). Similarly, income gap between immigrants and nonimmigrants was a bigger indicator of health status than actual income, with new immigrants and refugees reporting higher unemployment than nonimmigrants (Mawani, 2014). Relatedly, 17.7 % of newly immigrated Asian Indian immigrants who were unemployed and underemployed were found to have depression, but suitably employed Asian Indians were 90.9% less likely to experience depression (Leung, Cheung, & Tsui, 2011).

Immigrant and refugee care inequality. The barriers to the use of mental health services among immigrant populations can be characterized by the examination of two distinct prevalent phenomena: that of dropping out of treatment and that of not seeking assistance or treatment for mental health difficulties until syndromes become dysfunctional enough to be significantly

debilitating (Dow, 2011). Potential reasons include a cultural disconnect with Western medicine and treatment, language barriers, and misdiagnosis, the latter of which may be seen as a particularly salient concern in the context of treatment (Dow, 2011). Even when treatment is provided, it can be disparate. In a study on outpatient services, for instance, Latino/Hispanic/Latinx, and Asian Pacific Islander immigrant youth with externalization problems (e.g., aggression, anger) were twice as likely to receive services when compared to Latino/Hispanic/Latinx children with internalization problems (e.g., low self-esteem, depression); another disparity was that internalization problems were addressed more often in nonimmigrant families (Gudiño, Lau, & Hough, 2008).

Additionally, Latino/Hispanic/Latinx immigrants who were poor often did not have access to Medicaid specialty services, received poor quality of mental health care that led them to resort to natural healers and social support systems (íía et al., 2002), and could often not afford the cost of treatment and private insurance coverage (Thomas & Snowden 2002). Chinese immigrants reported that cost, time, language barriers, credibility of treatment, and logistical concerns affected access to mental health care (Kung, 2003). The mental health system's low responsiveness to the frequent and primary use of social as opposed to professional resources may contribute to the isolation of immigrant families and their systemic concealment of mental illness in family members (Dow, 2011).

Other factors related to underutilization. Fear of institutions can often limit the use of mental health services. About one third of refugees and asylees reported that they had both physical and mental health concerns, but many avoided public programs and assistance, despite eligibility, because of the fear that participation would affect their legal status (Edberg, Cleary, & Vyas, 2011). However, the underrepresentation of people of color in mental and behavioral health services cannot be solely explained by access. Even when economic factors are not a barrier to mental health service for people of color, differences in service utilization persist. For instance, clients from diverse racial and ethnic backgrounds with similar levels of health insurance still receive fewer services than their White/White American counterparts (Smedley, Stith, & Nelson, 2003). This disparity or disproportionality in service utilization has been explained by other variables: prior mistreatment in health settings resulting in cultural mistrust (Alegría et al., 2008; Whaley, 2001); linguistic difference between providers and clients (Kim et al., 2011); failure by the clinician to understand the needs of people of color (Breaux & Ryujin,

1999); underdetection by both providers and families (Alegría et al., 2008); clients' perceptions of their therapists' understanding of racial differences (Chang & Yoon, 2011); lack of psychoeducation for people of color about mental health as well as distrust of Western treatment (Li & Seidman, 2010); and lack of multicultural competence among clinicians (Daniel, Roysircar, Abeles, & Boyd, 2004; Hernandez, Nesman, Mowery, Acevedo-Polakovich, & Callejas, 2015). It is also important to note that while there are many religious organizations serving refugees and asylum seekers, LGBTQ+ refugee and asylum seekers may not have their needs met through these organizations if their intersecting identities are not acknowledged and respected.

When those in a minority group do receive treatment, they are more likely to drop out in comparison to their White/White American counterparts (Owen, Imel, Adelson, & Rodolfa, 2012). Barriers of cultural disconnect may be apparent across domains of response from practitioner body language to the pursuit of inappropriate or inapplicable interventions. Interventions can focus on building trust into the accessibility of integrated mental and behavioral health services within communities. Such intervention can promote community psychoeducation to reduce service utilization limitations and seek to increase the cultural attunement of service providers (Dow, 2011).

With regard to misdiagnosis, cases of abuse have been either overlooked or wrongly emphasized as a result of language barriers, child-rearing norms, other cultural contexts, therapist bias, or therapist lack of knowledge (Aday, 2002). Practitioners' lack of ability to attune to cultural characteristics has led to the overpathologizing of psychotic symptoms, which in the context of certain cultures may present as within an appropriate range of stress responses (Dow, 2011). The prevalence of disparity in diagnoses confirms the Surgeon General's report on culture and mental health (USDHHS, 2001), that states, " . . . cultural misunderstanding or communication problems between clients and therapists may prevent minority group members from using services and receiving appropriate care" (p. 42).

Stigmatization by the dominant society about minority mental health (resulting in overdiagnosis or underdiagnosis), cultural stigmatization (shaming) by one's cultural group, and an individual's internalization of both dominant and minority societies' stigma interact with each other, resulting in underutilization. Research has shown, for instance, that immigrants from countries with high rates of political violence have a strong likelihood of trauma symptomology,

however Latino/Hispanic/Latinx men were less likely to seek treatment after political violence (Fortuna, Porche, & Alegría, 2008). Asian Indians were found to regard mental illness within the cultural views of karmic punishment, supernatural associations, or somato-medical explanations (Li & Seidman, 2010), and utilized services in ways unrelated to identified psychopathology (Kim, DeCoster, Huang, & Chiriboga, 2011). Similarly, Chinese immigrants were found to practice self-denial of need for services, fearing stigmatization by their society, as well as personal loss of self-respect or identity (Kung, 2003). Koreans between the ages of 60 and 74 were also likely to have stigmatized perceptions of mental illness and utilization of services (Park et al., 2015).

Acculturation issues. Acculturation has proven to be a significant variable in determining attitudes toward therapy, help-seeking behaviors, and utilization of help resources by Asian immigrant groups (Frey & Roysircar, 2006). Psychologists may find it facilitative to understand help-seeking attitudes of Asians/Asian Americans/Pacific Islanders that are determined by high versus low acculturation. When working with a less acculturated client, a psychologist can play the role of adviser, advocate, facilitator of indigenous support systems, and facilitator of indigenous healing systems (Atkinson, Thompson, & Grant, 1993). Even those with bicultural identities may have trouble relating under a fully Western framework, though they may have a stronger sense of self-assurance than less acculturated Asians/Asian Americans/Pacific Islanders (Omizo, Kim, & Abel, 2008; Roland, 2006; Roysircar-Sodowsky & Maestas, 2002).

Upon entering the United States, many immigrants face prejudice and discrimination based on both their immigrant status and ethnicity. U.S. citizens have expressed a fear that immigrants take jobs away from them, and there are pervasive negative stereotypes about immigrants being lazy and criminal in their conduct. In an effort to curb undocumented immigration, certain states have passed propositions that limit undocumented immigrants' access to health care, welfare, and higher education. Prejudicial attitudes like these create an unwelcoming environment for immigrants, both legal and undocumented, and add to their acculturation adaptation difficulties and psychological distress.

Nonmainstream religions. When health disparities are discussed, oftentimes religion is neglected. As a Western society, religion is typically not a part of current health practices. However, for many individuals, health can be very much entwined with their religious or spiritual leanings. Religion can give rise to different values and practices that intersect with other

social categories, such as race, gender, sexual orientation, gender identity, or class status. Furthermore, religion can often influence the ways in which individuals seek assistance for their illnesses (Padela & Curlin, 2013).

For example, many Muslims view illness as a "trial from God" (Mitchum, 2011; Padela, Gunter, & Killawi, 2011, p. 12). When conceptualized in this way, it is not appropriate to solely treat the underlying medical condition; spiritual healing is also needed. Conversely, some religions prohibit certain medical interventions. For instance, Muslims are not allowed to consume pork, but some vaccines and medicines are derived from pig products (Padela, et al., 2011; Mitchum, 2012). If a Muslim client presents with an illness, making sure that the agreed-upon medicine does not contain certain substances, like pig products, is needed. Having knowledge about what healthcare practices go with or against religious identity is important (Roysircar, 2003). In some cases, the individual may not know details about the medicine or treatment. Here the practitioner strives to be knowledgeable to best inform and care for their clients. This knowledge would likely improve the therapeutic relationship by creating honesty, dialogue, and trust (Roysircar, 2003).

Applications to Practice, Research, and Consultation

Practice. By incorporating a critical understanding of contextual factors, psychologists are likely to obtain a comprehensive understanding of clients' concerns. With classroom and supervisory settings, psychologists as educators are encouraged to consider how issues of power and privilege affect clinical supervision and classroom dynamics, particularly as they relate to coursework focused on multicultural issues in psychology.

Psychologists might be mindful of Terrell and Terrell's (1984) concept of cultural mistrust, which is the idea that targets of oppression bring a justifiable skepticism to medical, mental health, and research settings due to prior exploitation. Validating clients' cultural mistrust and demonstrating cultural humility and a willingness to engage in open processing of racial issues can strengthen the therapeutic alliance and ultimately enhance treatment outcomes (Ward, 2002).

For many Asians/Asian Americans/Pacific Islanders and Hispanic/Latino/Latinx Americans, symptomology may need to be reframed as reactions to family or interpersonal issues. In certain collectivist cultures, well-being is tied to how well the family is functioning

and how committed the family is to health improvement. Within such a communal context, including families and addressing both the individual's and the family's motivation to continue treatment can be crucial to productive therapy (Li & Seidman, 2010). Attention is also needed for Latino/Hispanic/Latinx populations who would be using resources if not for limited English proficiency. Language assistance policies alone resulted in greater utilization in all Asian immigrant samples surveyed (Snowden, Masland, Peng, Lou, & Wallace 2011). In addition to the words being used, correct methods of verbal and nonverbal communication can be sought. Norms of address (titles, greetings) can be extremely important factors in a group setting and in couple or family therapy (Hudson, Adams, & Lauderdale, 2016).

It is recommended that diagnoses and assessment are culturally tailored and ecologically relevant. If a client refuses to talk about something in an interview, it could reflect how traumatizing that event was. However, if the topic in question is a subject that is not spoken of in this individual's culture (i.e., an issue of stigma), declining to talk about the subject might not be indicative of severe trauma. Rather, the avoidance might simply reflect a certain society's belief that speaking about a certain topic makes it worse. On the other hand, the inability to address a topic might result from it not being culturally appropriate to discuss as well as being extremely traumatizing (e.g., a type of "double trauma," as in the case of a Muslim woman who is raped). Here, not imposing the values of Western therapy, such as self-disclosure and implicit trust in the therapist (a stranger, a paid helper), on the client with an immigration experience is important.

In addition, being aware of the terminology that a particular culture uses (e.g., "fuku," a Dominican word for an intergenerational family curse; Roysircar & Pignatiello, 2015) can reduce potential confusion on the part of the practitioner or the client. Assessment includes pre-immigration vulnerabilities, such as religious persecution, torture, rape, flight, and relocation camps, as well as their exacerbation by post-immigration stressors, such as under- or unemployment, absence of network support, rejection by the host society, identity conflicts, and acculturative stress (Mawani, 2014; Roysircar, 2004a). It is important to realize that refugees who have been resettled are likely grieving multiple losses: loss of community, loss of an established role in that community, loss of supports, and the inability to use certain coping mechanisms that may have been helpful in the past. In addition to the personal loss experience, it is important to be aware of the potential intergenerational trauma that might be affecting the

individual. This may be particularly relevant for older immigrants who are valued as elders in their culture of origin but then marginalized in the United States. Increasing recognition of empowerment and social capital by providing specific resources such as support groups, language classes, and vocational training is critical to immigrants in the process of adapting to their host society (Agnew, 2009).

Research. Many studies on refugee and immigrant mental health focus on specialist services, like inpatient care, and do not address the whole range of service sectors where mental health care is provided. With regard to such research, methodological diversity is crucial. For example, investigators could complement quantitative methods with qualitative (Hill, et al., 2005), discovery-oriented (Smith, Flowers, & Larkin, 2009), and community-based participatory approaches (Mertens, 2014). Sue (1999) raised a crucial point that psychological research has emphasized internal validity of well-controlled studies over external validity (i.e., generalizable to varied populations and circumstances in the outside world), which has had negative implications for communities that have been excluded from many research studies of empirically supported treatments (cf., Wampold & Bhati, 2004). It will become increasingly important for researchers to establish relationships with community partners to collect and analyze data with and from those communities (Hill, Pace, & Robbins, 2010; Huynh & Roysircar, 2006).

Scholars have conceptualized the phenomenon of lateral violence, an interpersonal consequence of internalized oppression, whereby targets, unable to challenge oppressive systems, displace destructive feelings and actions onto members of their own or another underrepresented social group (Maracle, 1996). Research is needed to better understand the precise links between internalized forms of oppression and expressions of lateral violence. In the past and at present times, many refugees have been children, but there is very limited information on the help-seeking and service utilization of refugee and immigrant children. Research is also needed on how adult refugees and immigrants may be affected psychologically by the lack of recognition of their skill level (formerly they may have been doctors, educators, executives in the country of origin), and how unhealthy psychosocial and physical environments accompanying low-skill jobs have a negative impact on refugee well-being. Another area of research could be on how inequalities in exposure to environmental contaminants (e.g., lead, poor sanitation, crowded and unhygienic living conditions) can have long-term mental and

physical health consequences for farm laborers, refugees, and immigrants that are sometimes intergenerational.

Though meta-analysis has focused on developing a broad understanding of barriers to treatment for minority populations (cf., Griner & Smith, 2006), such research has not yet been established in the context of immigrant or refugee status minority groups. However, since the Surgeon General's report, more importance has been placed on documenting and understanding why disparities occur, such as this *Multicultural Guideline*'s objective (USHDDS, 2001) . Due to significant advances in research on mental health disparities for Latino/Hispanic/Latinx communities, encouraging developments have been made with regard to lessening disparities in mental health care for this particular ethnic group (Alegría et al., 2007). These same advances are necessary for the vast diversity of populations who have not received such focus in the clinical research domain.

Integrated health care. In the era of integrated health care, more focus is needed on the integrative aspects of health care, including the interface between mental and physical health services (Reiss-Brennan, et al., 2016). Such research could be dynamically focused on the multiple arenas of health care and service delivery, including access to and awareness of healthcare options; utilization of such options; sensitivity to multicultural differences in healthcare missions; immigrant and refugee perceptions on the quality of obtainable healthcare options; and healthcare treatment outcomes. Most studies have either exclusively focused on physical healthcare services (e.g., Avila & Bramlett, 2013; Alang, McCreedy, & McAlpine, 2015; Calvo & Hawkins, 2015; Kan, Choi, & Davis, 2016) or on mental healthcare services (e.g., Chong, Lee, & Victorino, 2014; Rousseau, Measham, & Nadeau, 2013), but not the integration of the two, as is becoming commonplace in a variety of community health centers, outpatient practices, and hospitals. Such a focus would help bridge the gap between physical health disparities and mental health disparities for immigrant and refugee populations, while also aiding in our considerations of stigma as it relates to specialty aspects of health care, such as mental health stigma.

Comparative research. The majority of the existing literature on immigrant mental health care focuses exclusively on target groups (Huang, Calzada, Cheng, & Brotman, 2012; Li & Seidman, 2010; Roberts, Mann, & Montgomery, 2016; Tsai & Thompson, 2013).

Comparative studies can be utilized to better understand the differences in mental health care that exist between dominant and nondominant help-seeking individuals. Similar studies have been conducted in international settings (e.g., Hollander, Bruce, Burstrom, & Ekblad, 2011), and significant findings from such studies uncover not only disparities of race or refugee status, but also, for example, disparities of gender, age, and socioeconomic status intersectionalities. These help identify unique demographic patterns that correlate with more notable mental health disparities than other demographic configurations.

Consultation. Psychologists can consult with nongovernmental organizations and community groups (e.g., Catholic Charities, Save the Children, Doctors Without Borders, and Partners in Health; ethnic community support groups of Cambodians, Vietnamese, Bhutanese, Korean church groups, and Islamic mosque groups; and human rights groups) to identify the specific problems to be solved that reflect inequitable access and then work with policymakers to develop policy options and alternatives. For instance, psychologists can consult with community and neighborhood health centers to increase access beyond hospital outpatient services.

Psychoeducation for clients, providers, and communities is a major intervention to reduce limitations on accessibility. Addressing stigma is central to increasing access for marginalized populations. Stigma that is addressed through talks on mental health by individuals who have mental disorders and through films could increase service utilization. Underutilization of treatment services warrants consultation on language matching, affordability, and location. Matching refugees and immigrants with providers of the same race or cultural background is possibly an advantage, but such matching also limits accessibility. Therefore, psychologists receiving education in a particular mental health problem, such as refugee trauma, is important. Self-reflection on social privilege is especially important in a group stetting, where a less-privileged individual in the group may be stereotyped. The psychologist consulting with a group that is having interpersonal difficulties can facilitate a discussion about the effects of a structurally imposed disparity, such as the educated middle class versus the working class or the powerful versus the disenfranchised, and facilitate consciousness of how group dynamics may reflect power dynamics in the larger society (Roysircar, 2008). Psychologists can help underrepresented groups and individuals find their voice, create cross-group relationships, and benefit from equity in resource allocations, in addition to experiencing equality.

Readers are encouraged to consult *Case I. Aiden: Struggling with Loss, Grief, and Inequity* in Appendix B, that illustrates key concepts presented in Guideline 5.

Guideline 6. Psychologists seek to promote culturally adaptive interventions and advocacy within and across systems, including prevention, early intervention, and recovery.

Introduction/Rationale

Psychologists endeavor to recognize that culture's relevance to mental health treatment, intervention, prevention, and service delivery is well established (Bernal & Sáez-Santiago, 2006). With this recognition comes the need to understand the multicultural aspects of personal and organizational experience. The term "culture-centered interventions" (APA, 2003; Pederson, 1997) refers to those intervention efforts that view the integration of culture and language as central to the delivery of services. Culture-centered interventions commonly exhibit an awareness of culture; knowledge concerning cultural aspects of an individual, group, couple, family, community, or organizational experience; an understanding of the difference between culture and pathology; and an ability to integrate the aforementioned points within the context of service delivery (Zayas, Torres, Malcolm, & DesRosiers, 1996).

Related work has considered the role of the culturally centered psychologist as a tool in the provision of culturally and linguistically relevant clinical services (Aldarondo, 2007; Hall, Ibaraki, Huang, Marti, & Stice, 2016); the development of rapport from a cross-cultural framework (Hays, 2016; Toporek, Gerstein, Fouad, Roysircar, & Israel, 2006); and social justice efforts to decrease health disparities through the provision of culturally centered service delivery and development of more culturally competent infrastructures. Perception and acceptance of help seeking is likely to vary across cultures. Research has found significant differences across communities in terms of access and utilization of services (USDHHS, 2001). The role of mental health stigma may be a factor that decreases help-seeking behavior. For instance, research has identified a relationship between stigma and low functioning among patients with bipolar disorder who were recruited from Latin America (Vázquez et al., 2011). Stigma can also affect the individual's decision to continue to engage in ongoing care.

Advocacy. Psychologists are encouraged to identify ways in which they may serve as advocates for system change. Systemic mental health advocacy refers to "a social movement that

seeks to change the disadvantageous policies and practices of legal, government, and health systems from within to develop a more inclusive community for people with mental disorders (also known as collective mental health advocacy; Stringfellow & Muscari, 2003)" (Gee, McGarty, & Banfield, 2015, p. 1). Several key advocacy movements include the United Kingdom's Consumer and Psychiatric Survivor Movement, the deinstitutionalization of mental health systems in the United States, Australia, and Canada during the 1960s and 1970s, and consumers and ex-consumers of mental health services prompting a change in services during the 1980s and 1990s (Gee et al., 2015).

Advocacy on behalf of persons from disadvantaged and discriminated populations has a long history in behavioral health. Since the early 1800s, systemic mental health advocacy has developed around the world through consumer-run organizations and groups, many receiving political recognition for consumer participation. Peer support specialists can talk about their experiences with mental health issues with those who face decisions about their own treatment (Stylianos & Kehyayan, 2012). Civil rights leaders have shared how their experiences in the Civil Rights Movement advocated for people with mental illnesses and underrepresented communities (Clauss-Ehlers & Parham, 2016; Parham & Clauss-Ehlers, 2016). Many of these efforts sought to address segregation practices influenced by referrals, residence, and insurance status (Smith, 2005).

Recent research has identified five critical themes that reflect the work of advocates and advocacy: "building consumer and career participation, voice and recognition for consumers and careers, influencing and improving mental health systems, effective collaboration and partnerships, and building organizational strength" (Gee et al., 2015, p. 1). These themes reflect a focus on involvement from constituencies that include people engaged in mental and behavioral health services and their caregivers. They also speak to the importance of having stronger systems of care for consumers and those involved with their care. Here psychologists act as part of a "cooperative community" working alongside consumers, colleagues, and other mental health professionals to promote mental health concerns as an important aspect of health (Gee et al., 2015, p. 2). In their model of advocacy, Stylianos and Kehyayan (2012) underscore the importance of "trust, empowerment, and choice" as factors that can influence and engage with services and may have an impact on outcomes (p. 117).

Areas of advocacy. While addressing the scope of advocacy that psychologists engage in globally is beyond the parameters of the *Multicultural Guidelines*, current literature demonstrates a range of advocacy areas in which psychologists are involved. These include, but are not limited to, advocacy efforts in response to risk behaviors such as substance abuse, sexual activity, and adolescent suicidal and homicidal ideation (Latkin, German, Vlahov, & Galea, 2013; Michael, et al., 2015); advocates for social justice in the school context (Espelage & Poteat, 2012); advocates for LGBT youth in school settings (McCabe & Rubinson, 2008); advocates for children living in foster care and their foster parents (Mainwaring, 2014); and responding to human rights issues (Kakkad, 2005). Two additional areas in which psychologists are involved include prevention and early intervention.

Prevention and early intervention. Multiculturally informed intervention and advocacy enhances prevention and early intervention services. Primary prevention efforts are of particular relevance to the psychologist because they are designed to prevent the development of issues. Prevention interventions have been developed to address specific issues such as school violence (Thakore et al., 2015); anxiety disorders among children and adolescents; and internalizing/externalizing mental health problems in response to divorce (Michael et al., 2015), among many other content areas. Community psychology has contributed to an understanding of prevention and early intervention through work that develops community partnerships to address service use disparities (Pickard, Kilgore, & Ingersoll, 2016). Psychologists are encouraged to be aware of the specific sociocultural context in which prevention programs are delivered. Effective prevention programs are informed by the contextual needs of the community they are designed to serve (Stanley, Ellis, Farrelly, Hollinghurst, & Downe, 2015). Early intervention (Shonkoff & Meisels, 2000) refers to:

> Multidisciplinary services provided for children from birth to 5 years of age to promote child health and well-being, enhance emerging competencies, minimize developmental delays, remediate existing or emerging disabilities, prevent functional deterioration, and promote adaptive parenting and overall family functioning. These goals are accomplished by providing individualized developmental, educational, and therapeutic services for children in conjunction with mutually planned support for their families (pp. xvii–xviii).

In their study of early interventionist's perceptions of family-centered care, cultural diversity, and cultural sensitivity, Gardiner and French (2011) found that, while interventionists understood family-centered care and early intervention, they were less able to conceptualize culturally sensitive intervention approaches appropriate for work with diverse families in terms of race, ethnicity, language, sexual orientation, socioeconomic status, couple and family composition, work, and religion. Rather, interventionists shared that they lacked training in cultural sensitivity and often did not have resources such as interpreters to address language barriers. The researchers concluded that training in cultural sensitivity is imperative for successful primary prevention and early intervention (Gardiner & French, 2011).

Applications to Practice, Research, and Consultation

Practice. Psychologists are encouraged to be aware of cultural differences in perceptions of mental health, stigma, and help-seeking behavior (Turner, et al., 2016). Psychologists strive to adapt their understanding of these terms in work with individuals, families, and groups so that interventions incorporate the perspective of those with whom they are working. By having an understanding of the differing worldviews through which individuals, families, and groups may approach mental health, stigma, and help seeking, it is thought that psychologists become more aware of barriers to access and utilization, providing better care as a result. Psychologists are encouraged to consult the science of prevention and intervention, especially with respect to evidence-based support for culture-centered interventions (Gardiner & French, 2011).

Psychologists also engage in advocacy efforts within the context of clinical practice. Relationship-centered advocacy is one approach used in clinical practice that emphasizes developing a mutually collaborative relationship based on a social justice framework (Weintraub & Goodman, 2010). Through advocacy efforts, psychologists participate in a "cooperative community" (Gee et al., 2015, p. 2) that seeks to improve the lives of those struggling with mental health issues.

Research. Psychologists who conduct research are encouraged to engage in efforts to foster the development of the science of culture-centered interventions. Psychologists strive to seek research participants who are diverse across multicultural variables so that findings reflect

the needs of specific populations. Psychologists can also respond to gaps in the literature by developing or applying research measures that address multicultural contexts (Gardiner & French, 2011). Testing and development of measures in different languages and among diverse cultures is critical to the development of the literature on culture-centered interventions and measures with culturally sound psychometric findings.

In addition, Bernal, Jiménez-Chafey, and Domenech Rodríguez (2009) discuss how culture and context have critical influence across diagnosis and treatment. At the same time, they reiterate concerns about the fidelity of evidence-based treatments (EBTs) that may have been developed within a different cultural and linguistic context. Bernal et al. (2009) favor what they call "cultural compatibility and universalistic hypotheses (p. 362)." Increasingly, the application and adaptation of EBTs to culturally and linguistically diverse contexts and relevant outcomes are being documented in the literature (Bernal et al., 2009).

Consultation. Psychologists are encouraged to engage in consultation that furthers the development and implementation of culture-centered interventions (APA, 2003; Pederson, 1997). Consultation may focus on the development of culture-centered services, including prevention and early intervention, through the training of linguistically and culturally aware staff. Consultation may also involve conducting a needs assessment to determine that services reflect the diversity of the surrounding community in which they are offered. The psychologist as consultant can support systemic mental and behavioral health advocacy through efforts designed to support access to care, decrease stigma, and further develop a cultural-centered mental health infrastructure. Readers are encouraged to consult *Case J. Dr. Amy: Multiculturally Informed Advocacy* in Appendix B, that illustrates key concepts presented in Guideline 6.

D. Level 4: Domestic and International Climate

Connection to the model. The influences of Levels 1 to 3 come together in the model's fourth level, that considers the impact of domestic and international climates on client experiences. Technological and transportation advances lead to a more immediate connectivity on both the domestic front and also at the international level. The growing importance to clients of global events and context, including the increase within the United States of persons born in other countries, not only suggests that psychologists strive to understand their clients within an international context, it also emphasizes generational and cohort differences in experience. Two

areas to be addressed are: (1) the psychology profession's assumptions regarding work within an international context; and (2) the role of developmental stage within historical time. Guidelines 7 and 8 address these areas.

Guideline 7. Psychologists endeavor to examine the profession's assumptions and practices within an international context, whether domestically or internationally based, and consider how this globalization has an impact on the psychologist's self-definition, purpose, role, and function.

Introduction/Rationale

Globalization, international geopolitics, and digital technologies have drawn the United States into a global satellite, where a complexity of social, business, and military encounters and ensuing intersectional identities are experienced at individual, local, and universal levels. A resultant dynamic interaction of local, national, and cross-national psychologies enhances understanding of indigenous, culture-specific, and common, as well as unique, aspects of behavior and identity development. Multilateral and horizontal dialogues among psychology professionals working collaboratively on cross-national projects can address the question of what it means to be human, universal, local, indigenous, communal, and individualistic so that psychology can be practiced broadly in global contexts. In addition, psychologists, as upholders of social justice, strive to develop coalition building with practitioners across nationalities to stop oppression, disempowerment, and crimes against humanity.

One traumatic event in one city in one part of the world, such as the violence of domestic terrorists in London or Paris, reverberates across the globe to the United States, and thus psychologists, while acting locally, aspire to think globally and understand human conditions in broad contexts. By recognizing that international psychology represents a postmodern form of consciousness, psychologists can theorize about universal conditions of trauma, resilience, oppression, empowerment, and human rights and dignity, while also operationalizing culture-specific manifestations of a universal experience.

At the present time, the U.S.' corporate and military power has much control of the world's economic, social, and political activities. United States' free trade policy, transactions, capital, and investment movements around the world have kept its economy open, dynamic, and

competitive, and have helped to ensure that the United States continues to be among the most profitable places in the world to do business (Office of the United States Trade Representative, 2016). However, the very quick connectivity of the world's economies, cultures, and Internet communications in the past 20 years has left imbalances and inequities for urban communities, manufacturers, and tradespeople within and outside the United States, causing vocational crises.

Despite recently closing hundreds of bases in Iraq and Afghanistan, the U.S. military covers 75% of the world's nations and is deployed in more than 150 countries, with over 130,000 active-duty personnel; other personnel deployed are part of peacekeeping missions, military attachés, or embassy and consulate security (Vine, 2015). The United States still maintains nearly 800 military bases in more than 70 countries and territories abroad (Time Magazine Graphics, 2016). The total cost of U.S. bases and troops in war zones is $160 to $200 billion (Vine, 2015). Britain, France, and Russia, by contrast, have approximately 30 foreign bases combined. The huge U.S. international engagement has heightened debates such as: What effect does the U.S. presence have socially, culturally, and environmentally around the world and on various worldviews of nations? What effects do U.S. international corporate powers and the Department of Homeland Security's "levels of threat" have on those living in the U.S.? Does the U.S. military presence after declaring The Global War on Terrorism make the United States and its allies safer? How are American Muslims affected by the U.S. travel ban on certain Muslim nations? Are hostile interactions with Syria and North Korea predictive of additional U.S. military engagements internationally? These debates are being held by social, political, peace, and trauma psychologists, policymakers, political scientists, economists, environmental scientists, sociologists, journalists, anthropologists, and U.S. citizens, among others.

U.S. wars (e.g., Operation Iraqi Freedom, Operation New Dawn in Iraq, and Operation Enduring Freedom) have made post-traumatic stress disorder (PTSD) and traumatic brain injuries (TBIs) top-priority illnesses for the Department of Defense due to the thousands of soldiers and millions of family members who have been affected by the conflicts; moreover, billions of dollars have been spent each year for research and treatment of these disorders (Moore & Penk, 2011). Approximately 17% of active-duty soldiers had PTSD 3 to 6 months after deploying to Iraq and Afghanistan (Milliken, Auchterlonie, & Hoge, 2007). The prevalence of PTSD resulting from these two wars ranged from 4% to 45% (Shen, Arkes, Kwan, Tan, & Williams, 2010). Military suicide rates increased to the highest levels in history, soaring

to 29.7 deaths per 100,000, well above the rate of 25.1 per 100,000 for civilians (Luxton et al., 2010). Approximately 51% of United States Department of Veterans Affairs (VA)-enrolled service members have received one or more psychological diagnoses, the most common being PTSD (United States, 2015). Included in the stressors of war are the negative perceptions of many American soldiers, veterans, and civilians alike of Muslims societies outside and within the United States.

With regard to education, the number of international students at American colleges and universities grew by 7.1% to over one million in the 2015–2016 academic year. China was the largest sender of students to the U.S. during the 2015/16 academic year (e.g., 328,547); followed by India (e.g., 165,918); Saudi Arabia (e.g., 61,287); and South Korea (e.g., 61,007). Business, engineering, computer science, and math majors are among the most popular among international students, who report that they chose to study in the United States because of both access and the quality of its higher education (Open Doors, 2016). Meanwhile, the number of American students studying abroad for academic credit continues to increase. It is estimated that approximately 10% of all American undergraduates and approximately 15% of those studying for a bachelor's degree (as opposed to an associate's degree) study abroad at some point during their program (Open Doors, 2016).

International students coming from more than 200 countries contributed about $32.8 billion into the U.S. economy in 2015–2016 and supported more than 400,000 jobs (NAFSA: National Association of International Educators, 2016). The current chilling U.S. climate for foreign nationals may reduce the number of international students on university campuses in the near future. In the 21st century, as internationalization intensifies in its influence around the world, U.S. psychologists consulting with the military, businesses, and educational institutions are encouraged to move beyond White/White American-centric theories and simultaneously increase their understanding of psychology from the perspectives of other cultures (Pederson, Draguns, Lonner, & Trimble, 2008).

Psychologists are encouraged to be aware of their own cultural perspectives and avoid imposing them as this may have a negative impact on the well-being of clients from different nationalities. A lack of openness and accommodation can interfere with psychologists' understanding of diverse experiences of the individuals with whom they may engage professionally. For instance, Fanon (1952) articulated the concept of double identity in the

context of colonial domination in Algeria. He contended that the colonized will often internalize the foreign ruler's idea of their own inferiority and emulate the colonizer through cultural assimilation, thus leading to alienation from their true identities (cf., David & Okazaki, 2006). As a result, myriad psychological troubles result from colonialism: misrecognition, dehumanization, depersonalization, inferiority, shame, helplessness, and a diminished sense of belonging (Fanon, 1952; Freire, 1970). In the new millennium, the impact of mass trauma has been experienced around the globe: terrorism, natural disasters, ethnic and religious cleansing, 9/11 trauma and the ensuing War on Terror, Syrian genocide and refugee crisis, continuing conflict in the Middle East, economic crises in Europe and North America, and globally, the trafficking of children, women, and child soldiers. These international events, made visible by media coverage, have great complexity and arouse confusion for many cultures grappling with their national challenges. Clearly, fast-paced and momentous events and transitions challenge psychologists' understanding of individual and mass trauma within systemic contexts, and their application of this understanding to inform research and practice (APA, 2012a; Roysircar, Podkova, & Pignatiello, 2013).

Clients, families, students, and their local communities and organizations across the globe, are likely to present stresses and illnesses in many ways. As such, proponents of psychological theories are encouraged to investigate conceptual holes in certain U.S. originating theories, fill these gaps with cultural constructs relevant to a particular population, and then adapt their theories to culture-specific representations, while also investigating the outcomes of such cultural adaptations (Hwang, 2016). Psychologists can also strive to examine their purpose, roles, and functions, be reflective about the consequence of uncritically exporting therapy models, and affirm the importance of respecting and incorporating local or culture-specific healing practices (Gerstein, Heppner, Aegisdottir, Leung, & Norsworthy, 2009). Miike (2012) recommends engaging in cultural humility and learning *from* cultures rather than learning *about* cultures.

Among the many cultural barriers for psychologists in international practice, the use of the English language is a complex issue. Draguns (2001) argued that a great many psychological ideas and knowledge of therapy methods are lost as a result of the dominance of English in the one-way flow of information (see also Hwang, 2016; Roysircar, 2013b). He thus suggested that psychologists listen to practitioners use their own languages and mental health terms, and seek to

become “receptive to the absorption of outside influences” (p. 1020), “avoid the pitfalls of encapsulation and homogenization,” and do all this “through communication and cooperation” (p. 1026).

Transnationalism can be experienced by U.S. expatriates living abroad, such as children of military families, missionaries, professionals, and business employees living overseas. Arnett (2002) suggested that globalization has an impact on social identity, with local identity losing salience. As adolescents develop into adults outside their birth country, they may favor a global identity. Furthermore, they may identify with more than one ethnic, racial, cultural, religious, and national identity, rendering complexity in social identity formation and in the cognitive-emotional processing of “Who am I.” Ethnic and racial identity has been a significant predictor of wellness among U.S. ethnic and racial minority adolescents, while governmental bureaucracy (e.g., census, passport, sojourner vs. native status, citizenship) demands single identification with one group. Such research and government approaches are based on the presupposition that a single ethnic, racial, or cultural identity is normative and positive.

It is important to note variations in experiences of transnationalism among immigrants, both legal and undocumented, in the United States. For example, transnational immigrants include people who as young adults migrated to the United States and then as older adults reside in their birth country and in the United States at different periods. They can also include older adults who relocate to the United States to help care for their grandchildren, but maintain their home in their birth country (APA, 2012a). A growing community of transnational immigrants includes “parachute kids.” This refers to children and adolescents who arrive without their parents or primary caregivers (Ying, 2001). They are known as parachute kids because they have been dropped off in a new country to live alone or with a caregiver. Undocumented children crossing the borders by foot or boat to enter the United States can be likened to parachute kids.

There are important differences between second-generation immigrant-origin youth and parachute kids, as the latter tend to live with relatives or family friends or attend boarding schools, or live in housing in groups without the supervision of adults (Chiang-Hom, 2004; Lee & Friedlander, 2014). These children and youth may be ill prepared for their international journey and adjustment to a foreign sociocultural context (Kuo & Roysircar, 2006). Further, they face the expectation of academic excellence in a new school and corresponding cultural and linguistic environments. Due to a lack of parental support and supervision, they may be at risk

for depression, substance abuse, gang involvement, and communication problems as well as interpersonal conflicts with family members (Kuo & Roysircar, 2006; Lee & Friedlander, 2014).

Transnationalism covers another child and youth population, Third Culture Kids (TCKs). In the current global economy, millions of U.S. children and adolescents are being raised in countries other than their passport country, which is referred to as their adoptive/second or amalgamated/expatriate third culture. Many TCKs will eventually return to their passport country either for school or when their parents complete employment overseas; however, a number will in many ways be citizens of the world because of their multiple experiences in international educational settings and temporary residences. Recognizing and understanding the causes of integration problems for TCKs who return to their birth/first culture may help reduce trauma from cultural marginalization pain, social isolation, relationship difficulties, low self-esteem, and work or school performance problems, as well as experiences of not identifying or interacting with the new home culture (Pollock & Van Reken, 2009). In anecdotes, many TCKs, upon returning to the United States, report feeling a profound sense of loss of their TCK lifestyle, culture, and sense of identity (Zilber, 2009). Pollock and Van Reken (2009) spoke of a delayed adolescence where once highly independent and mature TCK individuals resort back to more immature activities.

Living in a diaspora, foreign-born immigrants and refugees' transnational identities are distinguished by perpetual transformations determined by federal, state, and local institutions (green card status, asylum visa, driver's license, relocation settlements, English language requirements, deportation laws, and absence of citizenship privileges). Transnational identities of immigrants comprise both a personal agentic process (i.e., this is how I choose to identify myself) and structural institutional dynamics (i.e., this is how others, including the institution, identify me).

Psychologists strive to explain the complexities of transnational feminists by avoiding imposing U.S. women's narratives and assumptions on immigrants' lives and identities. Psychologists suggest caution when an immigrant is asked, "When did you last go home?" or "Have you gone home?" For immigrants, what is the meaning of home? Is it their birthplace? Where they grew up? Where their parents live? Where they currently live and work as adults? Who are an immigrant's community? Is home a geographic space, a historical space, an emotional space, or wherever the immigrant makes home in the second culture? How one

understands and defines home is a profoundly political question. An international student or new immigrant may not wish to be called a person of color, just as a Muslim woman may not wish to be unveiled because her hijab/burka or head covering is her femininity and not a result of societal oppression. Psychologists seek to understand that for immigrants, their home, community, and identity all fall somewhere between the histories they have inherited, their current choices, and access with regard to employment, community affiliations, neighborhoods, nonfamilial friendships, and English language acquisition.

Indeed, confronted by endless possibilities of communicating across the globe through the Internet, social networking sites allow people to continue in their pursuit of connections and attachments with "the other," so that the quest for discovery of new lands and people can easily shift from fantasy to reality and vice versa. Yet the growing need for interconnectedness between people around the world with regard to social, political, economic, technological, and cultural forms of exchange cannot be met solely via today's advanced technologies (e.g., social media). There is a need for both physically present engagement and the broader exposures that interactions with others across boundaries can happen while online. On the downside, the engagement with global diversity and the expectation that it can create a sense of closeness and intimacy with "the other" has led many to also be fearful and anxious of "the other."

Applications to Practice, Research, and Consultation

Practice. While U.S. psychologists have responded to trauma, PTSD, depression, anxiety, and other nomenclatures of psychopathology as health service providers, culture provides the context in which personality and mental disorders can be understood. Culture defines adaptation and maladaptation, resilience, vulnerability, and coping (Roysircar, Colvin, Afolayan, Thompson, & Robertson, 2017; Yamada & Marsella, 2013). The scoring and interpretation of assessments aims to reflect variables that are culturally important for the identification of problems in living (Dana, 2000). With regard to understanding psychological processes and behaviors, it is important for psychologists to seek to understand that individualism, self-reliance, self-efficacy, self-actualization, and self-care do not connote the only model in which human development and positive functioning can occur. In many cultures, self-psychology and group and interpersonal processes are interpreted differently (Roland, 2006).

Because of diverse nationalities' openness to Western understanding and practice, U.S. psychologists aspire to prevent the colonization of indigenous or culture-specific systems of health. They do this, first, by striving to learn to integrate Western and indigenous interventions. Second, they train local stakeholders and mental health workers to implement this Western culture-specific integrated model of care so they do not play the role of the primary interventionists (James, Noel, Favorite, & Jean, 2012). When engaged in therapy, psychologists are encouraged to export cultural empathy, described as ". . . the attitude and skill to bridge the cultural gap between the clinician and client," which is steeped in a sense of mutuality, openness, and deep empathic attunement (Dyche & Zayas, 2001, p. 246).

Hwang (2016) suggests that a surface structure strategy of providing culturally similar therapists, conducting therapy in the client's language, and creating office decorations that are culturally appropriate falls short of what he calls deep structure adaptations. Hwang (2016) referred to the former as a "top-down" psychotherapy adaptation and modification framework (PAMF). As a contrast, he developed a "bottom-up" formative method of adapting psychotherapy (FMAP). Hwang's work has been in Chinese communities in San Francisco that are culturally segregated and insular. His work involved a strong collaboration with stakeholders that were (a) Asian/Asian American/Pacific Islander-focused community health centers, (b) regular mental health providers, (c) traditional Chinese medicine practitioners, (d) Buddhist monks and nuns, and (e) local Taoist masters. Hwang (2016) recognized that Chinese-oriented practices and ideologies would be invaluable for informing mental health practice. The first step of the strategy was generating knowledge with the stakeholders of Chinese communities. The second step was integrating that knowledge with U.S. theoretical and empirical clinical knowledge. With the stakeholders, the third step was to create initial culturally adapted interventions. The fourth step was to test these interventions through evaluation studies. In the final step, the interventions were revised. Feedback, which Hwang (2016) considered as essential, was held off on until the clients gained more familiarity with what was going on.

An upfront psychiatric diagnosis carries with it the stigma of abnormality. Instead, Hwang (2016) placed psychological symptoms in one column on a chart and corresponding physical symptoms in another column, helping to foster a sense of balance of psychological-somatization presentation. Metaphors and Chinese proverbs were immensely helpful in communicating the relationship between symptoms and cognitive-behavioral treatment, and

Hwang's team was able to make the resulting interventions effective. When Hwang (2016) and his team assembled the final therapy manual, they searched through many *chengyu* or Chinese phrases. What they finally put on the cover of the manual was translated as, "If a mountain is obstructing your path, then find a way around it. If there is no road around it, then you need to find or make a path of your own. If you can't find a way around it or create a path, then you need to change the way you think and feel about the problem" (Hwang, 2016, p. 298).

Within the United States, it is anticipated that psychologists of the future will be asked to interact with clients from a potentially limitless range of immigrant backgrounds. For example, in 2012, two thirds of the students in New York City's public school system came from immigrant and underrepresented cultures. Consequently, psychologists in the average New York City public school are encouraged to be prepared to work with students whose parents have arrived in New York City from an estimated 40 nations across the globe (Roysircar, 2012). Exposure to the literature on practices in mental health, case conceptualization, and treatment in different cultures (cf., Moodley, Lengyell, Wu, & Geilen, 2015; Poyrazili & Thompson, 2013) is preparation for the central practice task of grasping what the world may look like from the vantage point of student-clients, as well as their extended families, neighborhood friends, and peers.

According to a study conducted by Whiteford and colleagues (2013) "Overall, mental and substance use disorders were the fifth leading disorder category of global DALYs" (e.g., disability-adjusted life years, p. 5); psychologists' behavioral health and psychosocial interventions will play a crucial part in preventing and treating these health problems worldwide (Council for Training in Evidence-Based Behavioral Health Practice, 2008). Partnerships between primary healthcare systems of other nations and U.S. behavioral health practices are needed for integrated treatment and increased human resources. Because hospital inpatient care is limited and costly in other nations, the demand for mental and behavioral health care in primary care medical facilities in different nations becomes critical (Souza, Yasuda, & Cristofani, 2009).

The need to proactively address the care-need gap from a practical approach has been repeatedly identified by the World Health Organization (World Health Organization [WHO], 2006). For instance, U.S. psychologists in international primary care settings can broadly address in a limited number of short sessions a wide array of problems that include medical,

physical, neurological, psychosomatic, relational, interpersonal, familial, financial, unemployed status, anxiety stressors, and culture-bound syndromes (Roysircar, et al., 2015). Research has also substantiated that it is feasible to deliver psychosocial/counseling interventions in nonspecialized, primary care healthcare settings in international locations (WHO, 2006).

Research. Research on the nature and status of the mental health professions in different countries can ask a series of questions with respect to the nature of a possible global helping paradigm that would link psychology, psychotherapy, and indigenous healing across national boundaries. Such questions include: How do perceptions of health and illness vary across cultures? How do help-seeking attitudes and behaviors vary across cultures? How does self-disclosure differ across cultures? How do models of helping vary across cultures? What is the relationship between indigenous healing and psychology? What constitutes ethical practice across cultures (Ruth, 2015)? While studies answering these questions will involve comparative cross-cultural research, within-group differences can be studied by applying the question to only one international setting and gaining in-depth knowledge of one society as a result.

Recent research has begun to address the relationship between structural forms of stigma and the impact on individual-level stigma processes. One particular example has focused on sexual orientation stigmatization across countries to determine the ways in which the combination of national legislation and social attitudes are linked to specific stigmatization processes at community and individual levels for sexual minority individuals. Results of a study (Pachankis et al., 2015) demonstrated that sexual minority men were more likely to conceal or hide their sexual orientation and/or gender identities in countries that were determined to have high levels of structural stigma as compared to those in low stigma countries.

With regard to the adaptation of transcultural adolescents, a question that psychologists may ask is: Are there interventions that may help reduce the severity or duration of integration difficulties in TCKs once they are detected? The answer may be found in research that compares findings on TCKs' adaptation to the new home society with research on immigrants adjusting to a new culture, as well as on sojourners or international students who are temporarily working, living, or studying in a country other than their own. Culturally appropriate skills in testing can take into consideration the English language in which a test has been normed and administered (AERA/APA/NCME, 2014). When administering a test in an international setting, a researcher is encouraged to consult with local language experts, healing practitioners, stakeholders, health

providers, and trained translators. Back translation that includes cultural translation is recommended for measures that are used for research. Internationally skilled psychologists, in addition to their expertise in traditional testing and its technical aspects, also strive to be aware of the cultural limitations of the tests they administer (AERA/APA/NCME, 2014).

Conducting research in nonindustrialized nations raises ethical concerns. Although U.S. psychologists obtain approval for their research from their institutions' human subject committee/institutional review board, the international communities in which they conduct their work may have no regulatory standards, even at the governmental level. Psychologists are encouraged to consult with local non-governmental organizations (NGOs), health clinics, and stakeholders to develop local regulatory standards for their research. In this way, psychologists can abide by both local and U.S. standards for research.

As an important example, transnational feminist researchers emphasize the importance of country and culture in the psychology of women. Three considerations are offered to argue for the value of the transnational feminist approach. First, evaluating a woman's well-being based on Western scholarship is not necessarily logical in its application to the rest of the world. Second, violence against women in the United States can be seen as a health issue that may reinforce internationally macro-level structures that perpetuate gender inequality. Third, a respectful discussion of strategies that draws on international knowledge rather than applying decisions made in the United States may be more empowering to the local sensibility. The effects of this intersectional approach, that seeks to strengthen local identity, may lead to respectful negotiations and improved use of funds for international research. A critical dialogue is posed by Grabe and Else-Quest (2012) to highlight the moral at hand for feminist scholars: "When we speak, write, and publish our findings, who are we accountable to? For us, our commitment is first and foremost to the women and girls with whom we work, whether in Nicaragua, Tanzania, California, or Philadelphia" (p. 161).

Consultation. Psychologists are encouraged to consult about accessible, equitable, and effective global mental and behavioral health care. Available mental healthcare resources are inequitably distributed, with low- and middle-income countries showing significantly fewer resources in comparison to high-income countries. Psychologists are encouraged to proactively address this care-need gap identified by WHO (2004). Given that there is currently no global practice blueprint to achieve universal mental and behavioral health care, psychologists are

encouraged to devise and consult on how to match effective strategies to a country's unique sociocultural, sociopolitical, and socioeconomic situation.

As an example, owing in part to the globalization of the manufacturing trade, members of the working class in the United States may have suffered unemployment, underemployment, or stagnant wages. Psychologists consulting on the impact of globalization are encouraged to be empathic about the painful reality of affected working class U.S. Americans' dispossession. They may be in a position to give voice to their pain in an effort to guide a leveling of the playing field. Psychologists in consultation regarding how to best understand a range of social and cultural experiences may also strive to identify ways that they can approach and discuss religion with their clients and students, and to assist others to consider how religion for many can be viewed as a vehicle for good, while recognizing that others may see it only as a representation of power (O'Grady & Orton, 2016; Pargament, Smith, Koenig, & Perez, 1998). Readers are encouraged to consult *Case K. Michael: Identity and Refugee Status,* that illustrates key concepts presented in Guideline 7.

Guideline 8. Psychologists seek awareness and understanding of how developmental stages and life transitions intersect with the larger biosociocultural context, how identity evolves as a function of such intersections, and how these different socialization and maturation experiences influence worldview and identity.

Introduction/Rationale

The life cycle of individuals is heavily influenced not only by the immediate social and physical environment but also by current societal trends and the historical period. For example, wars and economic depressions affect the life cycle at all levels. The psychologist seeks ways to remain aware of how a client's personal experience and development has been influenced by these dynamic forces.

As discussed in several other guidelines, people often have multiple identifications. These identifications may have their own developmental cycles, as well as emerging and engaging across the full developmental cycle of the individuals psychologists consult with and treat. An individual who identified as a Black/African American/Black American activist and champion of the poor at one stage of life may transition into the Chief Executive Officer (CEO)

position of a large corporation at another. A multiracial person may identify with a singular, multiple, or no racial category (Rockquemore, Brunsma, & Delgado, 2009), and these identifications may change from childhood through older adulthood. A gay preadolescent with myotonic muscular dystrophy may transition to a community activist leading the fight for disability rights upon entry to adulthood. The historical period one lives through may also affect how individuals perceive themselves. Growing up during the Great Depression had a lifelong effect on the lives of those in later adolescence at the time, but only a minimal effect on those who were younger (Elder, 1974, 1998). Some historical periods have a lasting influence, such as the continuing impact of America's period of slavery and the infamous Tuskegee experiments. For these reasons, psychologists seek to develop and sustain an awareness of how an individual's identity has changed over time and how their identities, and the importance of each, are affected by the historical period, and the concurrent immediate developmental, social, and familial contexts in which the individual is situated.

To date, only minimal attention has been paid to considering intersectionality from the perspective of developmental stage and historical time, but the available literature supports the necessity of doing so. In a relatively early acknowledgment that identities are transformative and unique to the individual, Satcher (USDHHS, 2001) noted, "not all members that society groups into a given category will share the same culture. Many may identify with other social groups to which they feel a stronger cultural tie such as a Mexican American who identifies primarily as being Catholic, gay, Texan, or teenager" (p. 9). Implicit in Satcher's reference to the teenage developmental period as being a potentially critical aspect of identity is the relatively unexplored issue of how intersectional identities evolve. When does a child become aware that she is a Catholic, or Texan, or a teenager or lesbian; when does this identity begin to matter? For instance, a Mexican-born teenager may not appreciate the nature of one's identity and upbringing until moving to Boston and trying to fit in. Vespa (2009) notes that societal expectations of an individual are often based on a confluence of both gender and race, although depending on life stage, one or the other may be more influential in driving that individual's self-identity. Societal expectations may also change as a function of the historical period and immediate social context (Vespa, 2009).

Life cycle perspectives on behavioral problems. The psychologist dealing with diverse populations faces many challenges rarely anticipated in a homogenous caseload or research

project. The ten guidelines identified by this APA task force testify to the complexity of these challenges, and to the importance of understanding that clients comprise diverse intersectional identities, and present with characteristics and issues that can differ dramatically from those associated with middle- to upper-class non-Latino/Hispanic/Latinx, White/White American clients. Guideline 8 emphasizes the need to consider diverse clients within a developmental perspective, since their lives have proceeded along trajectories that reflect their unique confluence of culture, race, and social context. It is also important to avoid labeling departures from cisgendered, heteronormative, majority group behaviors or stages as reflecting cultural deviancy or deficits as opposed to variations that may result from the life experiences and cultural heritage of the client, research participant, or consultee (Jamil, Harper, & Bruce, 2013; McLoyd, 2006).

Before reviewing some of the unique characteristics of developmental stages and transitions experienced by racial/ethnic and other identity groups, it is important to recognize that the literature has identified characteristics of stages and transitions that represent general turning points and issues strongly influenced by the socioenvironmental context that may be expressed in unique ways . For instance, the developmental transition into retirement comes in many forms. Psychologists have long sought to understand how developmental stages, and indeed the entire life course, affect behavioral health. Each life stage has what Havighurst (1956; see also Seiffge-Krenke & Gelhaar, 2008) long ago referred to as "developmental tasks" and what Erikson (1950; Sokol, 2009) referred to as epigenetic psychosocial stages of development. Both theorists felt that how one deals with the tasks and challenges at each stage is a central issue. Struggling with one's personal gender identity for example is part of the issue of identity versus ego diffusion described by Erikson, and the task of learning one's gender role as described by Havighurst (1956). Important not only in general, but also to studies of identity groups, is that successful resolution of personal identity provides the individual with a greater advantage in facing the tasks of succeeding stages. In contrast, unsuccessful or only partially successful resolution can create potential problems not only in the present but also in the future. The timing and resolution of turning points may vary according to an individual's intersectional identities and is a topic rarely addressed in the literature.

With respect to members from underrepresented groups, many of the latter face challenges atypical of the more advantaged even if the overall developmental task remains the

same, and may therefore face a greater chance of failure or have problems in resolution (Arnett, 2014; Cohler, & Michaels, 2012). Consider, for example, young male Hmong refugees who arrived in the United States without an education or employable skills, and who as a result faced unique challenges to developing a sense of personal autonomy and self-worth (Cerhan, 1990). Compounding the problem, economic stresses faced by minority parents can themselves have a lasting impact on a child's socioemotional development (McLoyd, 2006).

Successful resolution of each task or developmental stage has adaptive—or negative—implications for each successive life stage. In a study of over 7,000 persons followed over a 50-year period in England, Takizawa, Maughan, and Arseneault (2014) found that childhood experiences with bullying had effects on behavioral health that lasted for decades. As another example, for adolescents, one step toward achieving independence from parents is to obtain a driver's license. For the child of undocumented parents, or from economically challenged families, however, obtaining a driver's license may be difficult if not impossible.

In like manner, for an older person, the loss of driving privileges may pose challenges to personal autonomy, potentially making the individual not only more dependent on their immediate environment (see Guideline 4), including peers and family, but also leading to questions about self-worth and efficacy (Meuser, 2015). In dealing with clients and consultees across all stages—the psychologist would do well to consider the tasks and challenges facing individuals, their context, and their resolution of tasks in the past.

With regard to the LGBTQ+ community, D'Augelli (1994) noted that most conceptualizations of life span development are predicated on heterosexuality as the norm, and concluded that existing theories of development were inadequate when considering those with differing sexual identities. While few have worked on a revision or replacement for this model, there is at least a beginning. Roseborough (2004) studied conceptualizations of life span development among a small group of gay men. Applying Eriksonian stages to the study of LGBTQ+ adolescents transitioning into adulthood, Cohler and Michaels (2012) also examined how early life experiences influence progress along the life course. For both Roseborough (2004) and Cohler and Michaels (2012), the central point is that the developmental stages of diverse groups may vary widely in timing and critical points from what the psychologist may expect for clients of the same overt gender and age. Progress through stages may also exhibit

greater complexity. In a qualitative study of LGBTQ+ adolescents, for example, Jamil, Harper and Fernandez (2009) found that ethnic and sexual identities developed along dual tracks.

Applications to Practice, Research, and Consultation

Practice. When seeking to better understand a client, the psychologist may explore the developmental trajectory of the intersectional identities expressed by the client including factors that may have acted as barriers or those that promoted identity achievement. For example, scholars examining experiences of biracial identity and multiracial identity have adopted an ecological approach to racial identity by emphasizing that mixed-race people develop racial identities through interactions within multiple contexts and that there are no predictable stages of identity development or a single adaptive outcome or endpoint (Rockquemore & Laszloffy, 2003; Rockquemore et al., 2009). With regard to ethnic identity, Fuller-Rowell, Ong, and Phinney (2013) found that among Latino/Hispanic/Latinx college students, the progression toward a more mature ethnic identity may be negatively influenced by discrimination. In a small qualitative study, Vargas, Park-Taylor, Harris, and Ponterotto (2016) found that the developmental trajectories of boys from mother-only households reflected barriers and challenges not found in more traditional family units.

Another area that has received relatively little attention concerns issues faced by those in the deaf community (David & Werner, 2016; Humphries, 2014). In addition to race, gender, LGBTQ+ status and other identities, the psychologist may encounter other aspects of intersectional identity when working with clients from the deaf community. Several important statistics deserve special emphasis with such clients, students, organizations, and/or research participants as described by the National Institute on Deafness and Other Communication Disorders (NIDOCD, 2016). The first is that the majority of children with profound hearing loss are born to parents without hearing loss. Without exposure to information about the implications of this loss, a parent may not understand the needs of their hearing-impaired child. This includes, for example, awareness of the bicultural, bilingual nature of the deaf experience (e.g., Grosjean, 2010), and appreciation of American Sign Language as not only a language experience but a cultural experience as well (see Glickman, & Harvey, 2013).

The second statistic is that nearly 60,000 children in the United States had received cochlear implants by 2012. Such implants have been a point of controversy in the deaf

community, since many activists feel that a hearing "impairment" is not in fact an impairment or disability, and for this reason look unfavorably on implants (Sparrow, 2005). This can be a sensitive topic that the psychologist is encouraged to identify and understand.

The third statistic to consider is the role of generational differences in the life experiences of people with hearing loss. For example, a distinct deaf culture exists that may be of particular importance and meaningfulness, especially for older generations who have lived their entire lives as part of the deaf community. During the 20th century a vibrant deaf culture emerged, with deaf clubs, social gatherings, and a sense of community and shared experience (Burch, 2002; Holcomb, 2013). This culture has been threatened by the growing presence of technologies such as the previously mentioned cochlear implants, which are increasingly recommended for children and adults with profound hearing impairment. Differing opinions about technologies and the erosion of deaf culture across generations may generate conflict between parents and children (Sparrow, 2005).

Another factor the psychologist is encouraged to consider is that some individuals experience hearing loss only in later life. These are people who may not have had previous experience with hearing loss. Such individuals may have very different psychological issues to face than people with earlier onset. For example, many may feel that wearing a hearing aid is a stigma that sets them apart (David & Werner, 2016).

Research. Going beyond standard formulations of the life course, several researchers have studied identity formation in minority groups (e.g., Aboud, & Amato, 2001; Atkinson, Thompson, & Grant, 1993; Cross, 1978). Most of the work has focused on racial/ethnic groups, and therefore the implications for other identity groups, and especially those with complex intersectional identities, are unclear. One of the leaders in developmental studies of ethnic/racial identity, Phinney (1989), was influenced by Erickson's (1968) theory. Phinney (1989; 1993; Phinney, Ong, & Madden, 2000) proposed an ethnic identity status model with stages that reflect an individual's progress toward identity: unexamined ethnic identity that can include identity diffusion (marked by a relative lack of thought about ethnic identity) and identity foreclosure (marked by an uncritical acceptance of existing views about one's ethnic identity); ethnic identity search/moratorium (marked by active exploration of one's ethnic identity); and ethnic identity achievement (characterized by exploration and commitment to one's ethnic identity). The psychologist is encouraged to recognize various models of identity (e.g., Dirkes, Hughes,

Ramirez-Valles, Johnson, & Bostwick, 2016; Hamilton, Samek, Keyes, Mque, & Iacono, 2015). More research is clearly needed on the multidimensional aspects of ethnic identity, and developmental influences on individuals' intersectional identities (Smith & Silva, 2011).

In light of the generally underdeveloped nature of such research, psychologists may wish to incorporate qualitative research strategies as a means of discovering the full range of issues. Online strategies may have particular appeal since they have the potential to reach difficult to access populations (e.g., McInroy, 2016). It is also important that, when conducting research, psychologists seek to pay close attention to and inform themselves of the intersectional considerations participants present, and how these influence interpretations of findings regarding self, identity, group membership, and the consistency of presentation across groups of a psychological phenomenon or concept.

Consultation. Psychologists are encouraged to recognize the multiple and often unique factors underlying how well individuals thrive and meet goals during different stages of the life course. In addition to the historical period within which individuals develop, birth cohort and generation exert an influence (Baltes, Cornelius, & Nesselroade, 1979; Takizawa, Maughan, & Arseneault, 2014). The problem is compounded by what has been described as "invisible intersectionality," (see Purdie-Vaughns, & Eibach, 2008) that refers to the fact that often the various identities of an individual are not readily discernible to an uninformed observer. Moreover, intersectionality may create ambiguity for an individual when encountering prejudicial and discriminatory behavior, since it may be unclear which identities are eliciting the discriminatory behavior (Mohr & Purdie-Vaughns, 2015; Sedlovskaya, et al., 2013). For these reasons the psychologist strives to not take it for granted that problems arise only from the more obvious identity differences and ambiguities. Readers are encouraged to consult *Case L. Mary: A Focus on the Interpersonal Instead of the Contextual,* that illustrates key concepts presented in Guideline 8.

E. Level 5: Outcomes

Connection to the model. The influences of all levels of the model come together in the form of outcomes. As noted in the introduction, outcomes refer to the positive and negative consequences of activities engaged in by both clients and psychologists, and as influenced by forces in Levels 2–4. While psychologists are most often focused on behavioral health

problems, and how to attend to these problems from a multicultural framework, there are two general issues that can be addressed: (1) the ways in which to address and assess the various identities of participants, and (2) the enduring impact of disadvantage and associated trauma on what might be called the resilience of participants. The last two guidelines deal with these two general issues.

Guideline 9. Psychologists strive to conduct culturally appropriate and informed research, teaching, supervision, consultation, assessment, interpretation, diagnosis, dissemination, and evaluation of efficacy as they address the first four levels of the *Layered Ecological Model of the Multicultural Guidelines*.

Introduction/Rationale

The several levels of the model that inform the present guidelines all exert an influence on both the client and the psychologist. When dealing with clients and research participants who present with complex intersectional identities, these multiple lines of influence add to the usual challenges faced by the psychologist engaged in assessment, selection of appropriate intervention strategies, and research and consultation.

The psychologist therefore recognizes that assessment tools, and nearly all clinical interventions, have the potential to mischaracterize or even miss the behavioral health needs of racial/ethnic and other identity groups. The reasons include cultural and regional differences, stigma, literacy (including health literacy), the unique presentation of symptoms, explanations of psychological distress, distrust of providers and authority in general, and many other factors (Sue & Sue, 2016). When the fit of a particular therapy or assessment tool to a particular group is unclear, further research may be called for. In that case, focus groups and community involvement are forms of qualitative research that may be most helpful in the early stages of cultural adaptation (Hall, Yip, & Zárate, 2016; Ramos & Alegría, 2014).

The problem has not gone unnoticed. Since 2000 the U.S. Department of Health and Human Services, through its Office of Minority Health (2001, 2013), has published and subsequently revised a list of 15 standards designed to improve services for diverse groups in all realms, including behavioral health. Entitled the *Culturally and Linguistically Appropriate Services (CLAS*) standards (Office of Minority Health, 2013), they provide a blueprint for

appropriate care, research and evaluation. Psychologists working within hospitals may be interested in similar guidelines created by the Joint Commission (2010). Of the 15 standards, the first deals with the overarching need to deliver services appropriate to the individual's diverse needs. It states that health professionals (Office of Minority Health, 2013, p. 1): "Provide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs." Part of providing effective care and service is research into what represents appropriate client care. While randomized clinical trials (RCTs) are the gold standard in service research, they are costly and often fail to recruit the number from any specific identity group that would allow assessment of intervention effectiveness (Burlew, et al., 2011).

Psychologists also recognize that they do not work in isolation from the community: from an organizational perspective, there is a responsibility to ensure sufficient outreach to allow community feedback and monitoring of services, as well as to ensure that providers are well versed in the practice of multicultural competence, and that community members themselves have had educational opportunities designed to inform them of signs and symptoms of behavioral health problems and how to access services (Carrizales, Zahradnik, & Silverio, 2016; Chiriboga & Hernandez, 2015; Office of Minority Health, 2013).

Applications to Practice, Research, and Consultation

Practice. Psychologists are aware that members of diverse groups are less likely to seek help from mental health providers, just as they are less likely to participate in research and interventions. They are also less likely to continue in therapy or research once enrolled. Dropout rates among persons of color recruited for studies or participating in interventions are generally higher than those found among non-Latino/Hispanic/Latinx, White/White American clients and participants (e.g., Delphin-Rittmon, et al., 2015; Haan, Boon, Jong, Geluk, & Vermeiren, 2014; Jiang, et al., 2015; Thompson-Brenner et al., 2013).

Among the reasons are problems with the development of a therapeutic or research alliance, distrust, or a feeling that the intervention or research lacks relevance to the individual's life and circumstances (Griner & Smith, 2006). Others may be reluctant to participate in research or seek therapy due to their legal status, stigma associated with mental health disorders, gender identity, and unfamiliarity with the idea of research or with the healthcare system (Kim, et al.,

2011). The psychologist recognizes these barriers and seeks opportunities to improve rapport. Failure to do so may lead to therapeutic failure or systematic sample attrition. Compounding the problem is a lack of research on attrition in diverse groups other than those defined by race and ethnicity (Huey & Polo, 2008).

Yet another issue is fear of unequal treatment or mistreatment. The infamous Tuskegee study in which Black/African American/Black American men with syphilis were left untreated has helped create this perception. A lesser-known experiment conducted in Guatemala in the middle to late 1940s involved infecting men and women with syphilis without their consent or knowledge (Presidential Commission for the Study of Bioethical Issues, 2011). The historical period and generation can play a strong role in how members of diverse populations view researchers and practitioners, since societal views on individuals from diverse and discriminated groups change over time. Olson and colleagues (2015; see also Kimmel, Hinrichs, & Fisher, 2015) found that previous generations of children with a transgender identity were subjected to blatant discrimination, whereas during the past few years there has been growing acceptance of transgender and gender nonconforming identity, even in young children. Perhaps in consequence, Olson and colleagues (2015) found little evidence of distress in their recent national study of community-resident children.

Research. Given their reliance on primarily non-Latino/Hispanic/Latinx, White/White American samples, psychologists strive to recognize that the often-limited generalizability of randomized controlled trials (RCTs) may reduce the effectiveness of resulting evidence-based treatments (EBTs) with diverse groups (Southam-Gerow, Rodríguez, Chorpita, & Daleiden, 2012). In a review of 79 articles dealing with interventions and trials related to serious mental illness (SMI), for example, Evans, Berkman, Brown, Gaynes, and Weber (2016) found that no study addressed efficacy with respect to persons who self-reported as LGBTQ+, or for whom English was a second language, and only one focused on older adults.

On the other hand, culturally adapted interventions have had demonstrated efficacy (Bernal & Domenech Rodríguez, 2012; Hall, Ibaraki, Huang, Marti, & Stice, 2016; Smith & Trimble, 2016; Zane, Kim, Bernal, & Gotuaco, 2016). One general conclusion: there is a need for establishing the effectiveness of EBTs for specific groups with a history of discrimination and systematic disadvantage. In short, the frequent mixing together of reference identity groups can lead to results that are not equally appropriate to all groups.

Choice of assessment tool can also be a problem when studying diverse populations. Applying standard tools can lead to erroneous conclusions when the individual client or participant belongs to a group or groups that face nonstandard problems or when there are errors in translation of instruments. For example, some populations, including Latino/Hispanic/Latinx elders in particular, but also older adults in general, are more likely to express somatic symptoms that are indicative of depression (Blazer, 2002; Liefland, Roberts, Ford, & Stevens, 2014). Assessment tools that omit somatic symptoms may therefore have the potential for underestimation of depression.

The psychologist seeks to understand that assessment tools may function very differently in different populations. For example, Chakawa, Butler and Shapiro (2015) found that only one of six items revealed different outcomes in a comparison of Black/African American/Black American and White/White American adults who completed a measure of ethnic identity. In contrast, Kim and colleagues (2009, 2011) found differential item functioning in 80% of items on a depression scale when comparing Mexican American and White/White American elders, but, like Chakawa and colleagues (2015), they found that 10% of items displayed differential responses when Blacks/African Americans/Black Americans and White/White Americans were compared. While the significance of differential item responses is ambiguous, the differences raise the possibility that instrument scores may not reflect underlying problems across different groups (Janssen, 2011). This is particularly true for less studied groups, such as the LGBTQ+ and refugee communities. Investigating prior use of the instrument with the target audience can be informative.

One strategy to deal with the potential misfit of RCTs and EBTs is to adapt them to the needs of the target population. The danger of EBT adaptation is that the resulting intervention is no longer evidence-based, unless additional research specific to the adaptation is conducted (Morales & Norcross, 2010). Hence the psychologist strives to review culturally adapted interventions for evidence of fidelity to the original approach. Critically, the psychologist strives to balance fidelity with fit of the intervention to the client's needs. It deserves mention that culturally adapted research and intervention is a hallmark of community-based participatory research (CBPR; Frerichs, Hassmiller Lich, Dave, & Corbie-Smith, 2015; Jernigan, Jacob, the Tribal Community Research Team, & Styne, 2016; Lichtveld, Goldstein, Grattan, & Mundorf, 2016). The latter is a form of community-engaged research (Perez et al., 2016; Santilli, Carroll-

Scott, & Ickovics, 2016). CBPR and other community-engaged research approaches, involve working closely with community members as partners and stakeholders, and have the potential to improve recruitment of diverse groups, resolve potential problems of trust or interest on the part of the community, reduce attrition, and improve cultural appropriateness.

Consultation. Glover and Friedman (2015) contend that when consulting with persons from diverse cultural groups, consulting psychologists are encouraged to check their "cultural baggage" (p. 149). At issue is viewing clients/organizations from their own perspective. This can be a challenge, since it requires psychologists to first understand their own culturally influenced perspectives and then consider how those perspectives influence how others are viewed (Sue & Sue, 2016). Despite the many problems associated with service to disadvantaged or discriminated groups there is an ethical responsibility to provide the most appropriate and effective care available (Sue & Sue, 2016; Trimble, Scharrón-del Río, & Hill, 2012). The psychologist recognizes that one cannot take the value and effectiveness of research or interventions for granted when working with clients and research participants from racial and ethnic minority and other minority groups. One barrier to effective consultation is the lack of data, especially data concerning individuals whose core identities may not be immediately evident, such as members of LGBTQ+ communities and other individuals with multiple sociocultural identities (Purdie-Vaughns & Eibach, 2008). Here, the consultant may wish to encourage the use of mixed methodologies that allow more qualitative strategies to inform investigators of the validity of more quantitative results (Del Toro & Yoshikawa, 2016).

Translation adequacy is another area where the consulting psychologist can make a difference—and an area that psychologists strive to consider when evaluating assessment tools. Since rigorous translations that achieve measurement equivalence require considerable time and effort (Bracken & Barona, 1991; Drasgow & Probst, 2005; Gile, Hansen, & Pokorn, 2010), the psychologist is encouraged to pay attention to the work that went into creating the translation, and the ongoing work that can be done. While many researchers employ an in-house "do it yourself" approach to translation, there is an informal gold standard that dates back to Brislin's (1970) early work on translation methodology. According to Brislin (1970; see also Koller, et al., 2007), it is critical to have different individuals prepare a translation from source material and to back translate the material into the language of the original source. It is also important to consider the target audience for which the translation was created, and whether the translation is

couched at the level of sophistication appropriate for that audience. The factorial structure of any translation can also be compared to that of the original, to help ensure that the translated version captures the original intent (Kim, Chiriboga, & Jang, 2009). Readers are encouraged to consult *Case M. Community-Based Research,* that illustrates key concepts presented in Guideline 9.

Guideline 10. Psychologists actively strive to take a strength-based approach when working with individuals, families, groups, communities, and organizations that seeks to build resilience and decrease trauma within the sociocultural context.

Introduction/Rationale

The Level 5 focus on outcomes as the ultimate component of the model encourages the psychologist to consider desired results in the context of the professional relationship. A strength-based approach seeks to consider and incorporate the positive attributes that diverse individuals, families, groups, and organizations bring to their experiences. This approach differs from more traditional models of practice that may have viewed deficits and pathology as the central focus (Clauss-Ehlers & Weist, 2004). With a strength-based approach, the psychologist operates from a perspective that acknowledges challenges while also identifying positive ways in which diverse individuals, families, groups, communities, and organizations address life experiences.

Resilience is one aspect of the strength-based approach. Resilience refers to the "process, capacity or outcome of successful adaptation despite challenges or threatening circumstances . . . good outcomes despite high risk status, sustained competence under threat and recovery from trauma" (Masten, Best, & Garmezy, 1990, p. 426). The concept of resilience has been deeply considered throughout the psychological literature (Masten, 2014), with a research and practice trajectory largely influenced by Rutter's study of how children cope with adversity (Cicchetti, 2013; Garmezy, 1991; Luthar, 2006; Rutter, 1985).

A focus on human strengths and resilience is found in positive psychology. Positive psychology is a framework that emphasizes mental health, adaptive functioning, and human strengths (Chang, Downey, Hirsch, & Lin, 2016). The focus shifts from exploring psychopathology to understanding how human beings achieve optimal well-being (Seligman &

Csikszentmihalyi, 2000). Positive psychology emphasizes individual qualities such as hope and optimism, capacity for love and vocation, perseverance, and courage over external and contextual sources of resilience. While it is important for psychologists to recognize the role of individual factors that determine resilience, psychologists are also encouraged to consider the role of contextual level factors and how they intersect with individual level factors in resilience.

In particular, although dispositional traits, such as the commitment to finding the meaning of life and a belief that one can influence the surroundings that are associated with pathways to resilience outcomes (Bonanno, 2004), resilience is also promoted by external resources, sociocultural factors, and affirming systems. In their study of first- and second-generation students who participated in a summer Educational Opportunity Fund (EOF) program to gain college entrance, Clauss-Ehlers and Wibrowski (2007) found the EOF academic institute acted as a resilience-promoting community that enhanced access to a college education. Hence, findings indicated that program participation related to significant increases in resilience and social support from peers and program staff among student participants. In another example, Theron, Theron, and Malindi (2012) studied South African adults' perceptions of a South African child's resilience. The adults reported a resilient South African child would show interrelated intrapersonal and interpersonal strengths. Intrapersonal strengths included a resilient personality, a future orientation, educational progress, value adherence, and equanimity. Interpersonal strengths included being actively supported in multiple systems. Theron et al. (2012) noted that the focus on intrapersonal and interpersonal strengths reflects the idea that resilience is a culturally congruent, bidirectional process between children and their environment.

More recent frameworks of resilience have considered a strength-based approach for understanding child and adolescent development, with attention to positive contextual, social, and individual factors that disrupt the negative effects of risk factors, and promote healthy development (Zimmerman & Brenner, 2010). Recent models have also incorporated sociocultural context into our understanding of resilience, and how social position factors such as race, gender, and social class can either promote or inhibit positive development (Clauss-Ehlers, 2008; García Coll & Marks, 2012; Kirmayer, Dandeneau, Marshall, Phillips, & Williamson, 2011; Suárez-Orozco, Suárez-Orozco, & Todorova, 2008). Many of these models consider how the larger sociocultural context influences resilience processes among diverse

communities. How cultural constructs dynamically influence coping and the ability to respond to adversity is also emphasized. The term cultural resilience refers to the extent to which the individual, family, group, or organization's culture promotes coping. The culturally focused resilient adaptation model has been described as "a dynamic, interactive process in which the individual negotiates stress through a combination of character traits, cultural background, cultural values, and facilitating factors in the sociocultural environment" (Clauss-Ehlers, 2004, p. 36).

Empirical evidence supports the notion that the sociocultural context be considered when examining resilience among diverse constituencies. Research has found, for instance, that cultural values, the relational context, and a sense of something larger than oneself promote resilience (Clauss-Ehlers, 2008). Consistent with ecological theory, responses of 131 Haitian children and adolescents, studied qualitatively and quantitatively in a complementary manner, indicated that resilience was derived from systems of home life and familial relationships, reflections on self-other interactions, interpersonal relationships, and connectedness with the natural and social environments, and that vulnerability was derived from living without external systemic support, placing a child at risk for an intrapersonal life of negative representation of self, self in relation to others, and personal-social attitudes (Roysircar, Colvin, Afolayan, Thompson, & Robertson, 2017).

In their study of 10- to 12-year-old Black/African American/Black American girls, Belgrave, Chase-Vaughn, Gray, Addison, and Cherry (2000) found that the girls who experienced a culture- and gender-specific intervention had significantly higher scores on a scale that measured Afrocentric values, racial identity, and physical appearance in comparison to the control group. In a study that examined the relationship between resilience and stress among a diverse group of college women, Clauss-Ehlers, Yang, and Chen (2006) found ethnic and gender identities were associated with greater resilience. In response to women who reported experiencing significant stressors, those who reported an androgynous gender identity (i.e., a gender identity that incorporated both feminine and masculine qualities) reported significantly higher resilience. Further, women who reported involvement in learning about their ethnic traditions also reported greater resilience.

Sociocultural considerations of resilience complement an expanding literature that seeks to understand the cultural underpinnings of trauma (Buse, Burker, & Bernacchio, 2013; Pole & Triffleman, 2010). Herman (1992) defines psychological trauma as:

> …an affiliation of the powerless. . . . Traumatic events overwhelm the ordinary systems of care that give people a sense of control, connection, and meaning. . . . Traumatic events are extraordinary, not because they occur rarely, but rather because they overwhelm the ordinary human adaptations to life. Unlike commonplace misfortunes, traumatic events generally involve threats to life or bodily integrity, or a close personal encounter with violence and death. They confront human beings with the extremities of helplessness and terror, and evoke the responses of catastrophe (p. 33).

Trauma is understood as a "global phenomenon" that characterizes the human condition (Buse et al., 2013, p. 15). While trauma is a universal experience, psychologists are encouraged to consider the cultural context in which traumatic events unfold (Wilson, 2007). Cultural considerations of trauma examine how the cultural context influences interpretation of and response to the traumatic event. For instance, the interpretation of and response to trauma may be shaped by cultural constructs such as societal norms focused on individualism versus collectivism (i.e., a focus on the individual vs. a focus on the group), religion and spirituality, body and mind (i.e., connections between the mind and the body), social roles, and overarching cultural values (Buse et al., 2013).

Understanding trauma from a multicultural perspective means that psychologists are aware that experiences and interpretations of traumatic events are influenced by the individual, couple, family, group, community, and organization's cultural perspectives. For instance, in their exploration of the applicability of cognitive processing therapy to post-traumatic stress disorder among Latino/Hispanic/Latinx and non-Latino/Hispanic/Latinx clients, Marques and colleagues (2016) found it was important for professionals to recognize how family, religion, violence exposure, and poverty shaped client beliefs and emotional responses to trauma. They conclude:

> We recognize that it can be challenging to talk with clients about their values and experiences with contextual factors, including marginalization and discrimination.

Nonetheless, talking with clients about these aspects of identity may help clients and clinicians identify and challenge stuck points, the central goal in CPT (p. 105).

Additionally, sociocultural context shapes how resilience is conceptualized and experienced in the face of traumatic stress. Harvey (2007) has argued that resilience is influenced by individuals' and communities' complex and dynamic contexts, and as such, resilience in the process of trauma recovery entails the negotiation of multiple domains of functioning (e.g., safety, attachment, self-cohesion) within these contexts. It is also important to recognize that resilience in the face of trauma is shaped by cultural beliefs and understandings (Tummala-Narra, 2007). Specifically, a behavior thought to reflect resilience in one cultural context may be considered undesirable in another cultural context. For example, survivors of intimate partner violence who view resilience as encompassing the ability to maintain a family unit and children's connections with parents may not consider the possibility of leaving an abusive partner or spouse. A different survivor of intimate partner violence, whose cultural beliefs emphasize the ability to secure independence from the abusive partner or spouse, may be more likely to consider leaving the partner or spouse.

Applications to Practice, Research, and Consultation

Practice. Culturally informed clinical and community-based interventions consider the role of historical and ongoing experiences of trauma and social injustice, as experienced and narrated by survivors (Brown, 2010; Bryant-Davis, 2007; Comas-Díaz, 2000). From a multicultural approach, practitioners recognize that resilience may be defined in distinct ways across sociocultural contexts, and that resilience and coping may be expressed in individual and collective forms (Clauss-Ehlers, 2008; Comas-Díaz, 2012; Franklin, 2004; Harvey & Tummala-Narra, 2007). Practitioners may be faced with dilemmas concerning the assessment of resilience and pathology in the aftermath of traumatic exposure. Often these dilemmas stem in part from the practitioner's cultural worldviews.

Attending to trauma and resilience in psychological practice further involves a consideration of traumatic exposure that is not currently recognized as a precipitant to PTSD in existing psychiatric diagnostic manuals. Specifically, traumatic stress rooted in exposure to violence based on sexism, racism, xenophobia, religious discrimination, poverty, heterosexism,

homophobia, transphobia, social class discrimination, and ableism, is conceptualized from a multicultural perspective as a key problem that negatively affects individuals' and communities' psychological well-being (Bryant-Davis, 2007; Comas-Díaz, 2000; Daniel, 2000; Franklin, 2004; Greene, 2013; Nagata & Cheng, 2003; Olkin, 2002; Smith, 2010; Tummala-Narra, 2005). There is ample research and clinical literature indicating that stress rooted in social injustice is associated with mental health issues, such as depression and anxiety (Bryant-Davis, 2007; Herman, 1992; Smith, 2010; Sue, 2009; Tummala-Narra, et al., 2012a). Psychologists in practice settings can inquire about individuals' and communities' experiences with social and political injustice and trauma, and their impact on psychological health and access to appropriate care and resources (Carter, 2007). Relatedly, psychologists can promote individual and collective resilience and coping in collaboration with individuals and communities such that core cultural beliefs and values are respected. It is also important to note that the role of traumatic stress is sometimes overlooked among individuals with serious mental illness.

Psychologists are encouraged to examine the sociopolitical contexts of traumatic experiences on a full range of mental health symptoms, and foster clients' understandings of the role of social injustice and trauma on their mental health. Traumatic experience and traumatic stress occur in the context of social injustice and violence, and trauma recovery occurs in the context of affirming communities and systems. Psychologists play a critical role in promoting resilience at the macro level by engaging in advocacy and collaboration with legal, medical, housing, educational, and other resources and systems of care that help survivors heal from injustices imposed on them (Goodman & Epstein, 2008; Harvey & Tummala-Narra, 2007; Herman, 1992).

Research. Exploration of resilience and trauma from a multicultural perspective has implications for empirical investigation. Research is needed on the local definitions of resilience, such as religious precepts (Roysircar, 2013a; 2013b) and political processes of nationalism and patriotism (Nuttman-Shwartz, Huss, & Altman, 2010) to provide evidence for the concept of cultural resilience. Here, research can encourage scientific inquiry to incorporate a strength-based approach. For instance, over 50% of Haitian children had higher resilience scores than vulnerability scores in their individual assessment profiles, despite continuous trauma experiences (Roysircar et al., 2015), a result that was consistent with the findings of researchers who have studied dispositional resilience (Seligman & Csikszentmihalyi, 2000), person-

environment interactional competency (Masten & Narayan, 2012), and cultural resilience (Clauss-Ehlers, Yang, & Chen, 2006; Nicolas, DeSilva, Grey, & Gonzalez-Eastep, 2006). Girls and women experience many systemic and relational forms of oppression, but it is important to note that findings about sex and gender differences in children's reactions to mass trauma are mixed (Kerig, Chaplo, Bennett, & Modrowski, 2016). Gender and sex roles may vary in cultures with different religions and culture-specific experiences of social disorder.

Researchers are encouraged to be familiar with gender and sex roles in a culture to understand nuanced resilience and vulnerability responses of boys and girls, as well as men and women, in that culture, particularly with regard to the type of adversity (e.g., natural disasters, human-made disasters, political or religious violence, or a combination of all three ecological crises; Cohen-Louck & Ben-David, 2017; Tekin et al., 2016). While existing research provides important knowledge about understanding trauma and resilience from a multicultural perspective, additional study is needed to build upon the evidence base (Marques et al., 2016). Future research can also incorporate samples that represent diverse demographic and developmental variables. The application of qualitative and quantitative approaches will present diverse ways to explore relevant constructs (Chang et al., 2016). Additionally, research can explore the cumulative effects of various factors across the ecological context and in response to social injustice to better understand the complexity of trauma, mental health, and resilience (Harvey, 2007; Zimmerman & Brenner, 2010).

Research can also consider the development of appropriate measures of trauma and resilience that integrate a multicultural context (Clauss-Ehlers, 2008). Recent assessment measures have explored the concept of resilience from a sociocultural perspective. Other efforts have assessed resilience in the aftermath of traumatic exposure (Harvey, 2007). Instruments that examine resilience and trauma from a multicultural perspective can provide helpful tools for researchers and clinicians to assess strengths and challenges associated with resilience and trauma. Additional work is needed to develop assessment measures that incorporate larger contextual factors (e.g., race, ethnicity, language, gender, social class, sexual orientation, disability) in the measurement of trauma and resilience. Such scales will also benefit from psychometric data based on diverse samples.

Consultation. Consultation across research, practice, and educational settings can integrate existing knowledge concerning the role of sociocultural issues in resilience and trauma.

Specifically, research and practice consultants can help individuals and organizations consider the impact of historical and ongoing violence experienced by vulnerable populations (e.g., women and men coping with sexual violence; survivors of intimate partner violence; older adults enduring a lifetime of neighborhood violence; children coping with physical, sexual, and/or emotional abuse and neglect; and survivors of political violence, racial violence, hate-based violence, and terrorism) on individuals' psychological well-being and intergroup relations. They can also encourage individuals and organizations to assess resilience among individuals and communities as defined along unique sociocultural contexts (Tummala-Narra, 2013). Psychologists involved with training and education are encouraged to include sociocultural understandings of trauma, traumatic stress, resilience, and coping in their curricula.

Further, clinical supervisors often hold key roles in how knowledge concerning multicultural conceptualizations of trauma and resilience are translated to practice. It is important that graduate-level psychology students are exposed to research and applications related to trauma and resilience that provide an opportunity to examine and discuss the influence of sociocultural issues in conducting research and implementing interventions with trauma survivors from diverse sociocultural backgrounds. Consultation also encompasses attention to secondary traumatic stress and vicarious traumatization as experienced by researchers, practitioners, and educators (Baird & Kracen, 2006; Yassen, 1995). This is particularly important as psychologists at any phase of their training and careers may experience stress from either a personal history of trauma or repeated exposure to traumatic material that may have a negative impact on their work and ultimately, on the well-being of clients, students, research participants, and consultees.

Knowledge of individual and community trauma and resilience has implications for policymakers serving vulnerable communities. Resilience appears to be the outcome of how a person's attitudes/skills interact productively with family, natural, physical, economic, cultural, religious, and social environments. The wider people's reach for resources and the greater the security and nurturance of their environment, the more resilience outcomes they will manifest. Systemic factors of resilience would include larger societal interventions, such as reductions of disparity in health and psychological care. Readers are encouraged to consult *Case N. The Oregano Family: Working with Mental Health and Faith-Based Communities in Clinical*

Training and *Case O. Lucy: Fear about a Marriage Ending,* that illustrate key concepts presented in Guideline 10.

Conclusion

The goal of the *Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality, 2017* is to present practice guidelines to help the practitioner, educator, researcher, and consultant strive to identify, understand, and respond to multicultural content in a helpful, professional way. The *Layered Ecological Model of the Multicultural Guidelines* presents a framework to understand multiculturally focused practice, education, research, and consultation. The model's five layers, Bidirectional Model of Self-Definition and Relationships, Community, School, and Family Context, Institutional Impact on Engagement, Domestic and International Climate, and Outcomes, present an ecological framework from which psychologists can consider and apply the *Multicultural Guidelines*.

Figure 1. Layered Ecological Model of the Multicultural Guidelines

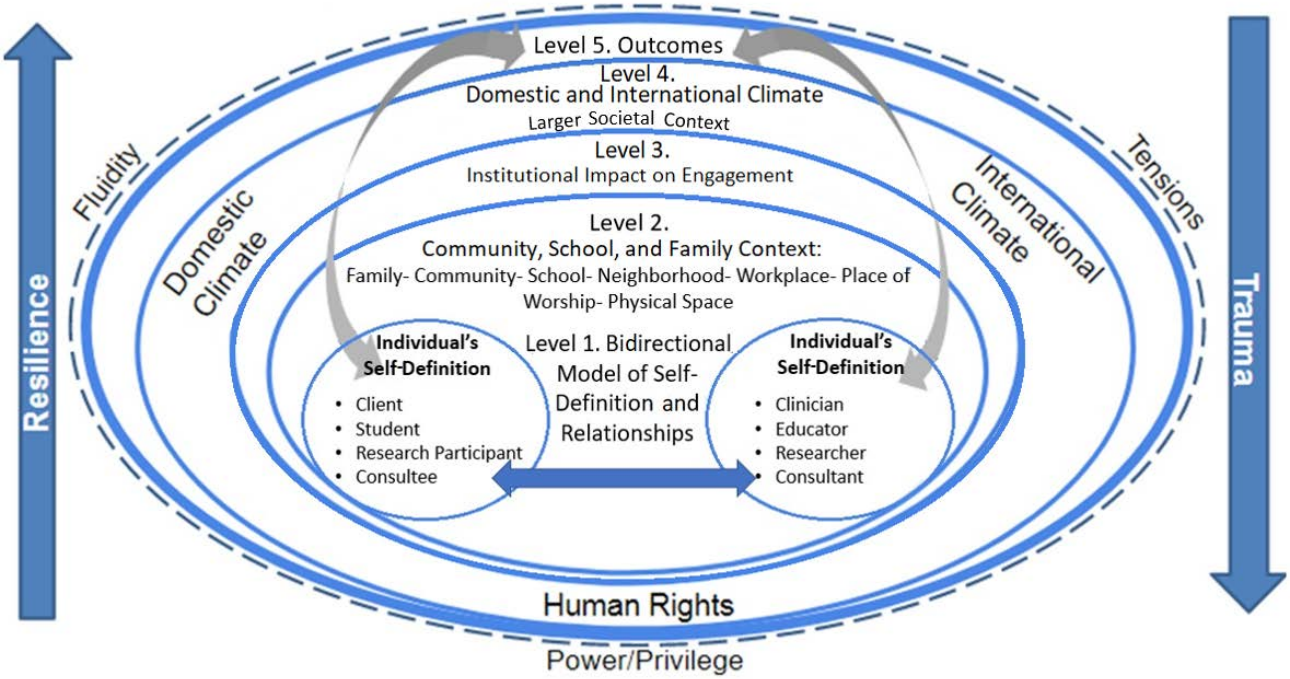

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Appendix A: Definitions

Advocacy: Refers to the psychologists' role in promoting mental and behavioral health and well-being among those with whom they work. Advocacy in mental health extends beyond individual and group counseling into systems-level change and may involve policy work on local, state, federal, and international levels. Psychologists who serve as advocates become part of a cooperative community, working with clients, colleagues, mental health professionals, and interested supportive others to promote systems of care.

Culture: Belief systems and value orientations that influence customs, norms, practices, and social institutions, including psychological processes (language, care-taking practices, media, educational systems) and organizations (media, educational systems). Culture has been described as the embodiment of a worldview through learned and transmitted beliefs, values, and practices, including religious and spiritual traditions. It also encompasses a way of living informed by the historical, economic, ecological, and political forces on a group.

Disparities: Differences in domains such as health, wealth, income, education, incarceration, employment, and housing, across social identity groups. Health disparities refer to differences in access, utilization, and quality of care. Disparities are linked to structural forms of oppression and may exist with regard to racial or ethnic group, gender, sexual orientation, gender identity, or other identifying considerations, both across and within social groups.

Disproportionalities: Over- or underrepresentation of a given population that may be defined by racial and ethnic background, socioeconomic status, national origin, English proficiency, sexual orientation, and educational needs, among other variables, in a specific category.

Diversity: The definition of diversity is complex, given the array of contexts in which the word is used. It is, within the realm of psychology (and sociopolitical and legal consideration), most often associated with a recognition of a range of identities and personal attributes, across the population of individuals inhabiting a particular setting or environment, such as an educational program, or a country's citizenry, or when discussing the world at large. To be diverse is to be made up of a broad range of individuals representing the multitude of races, creeds, religious or social identifiers, or genders that comprise humanity (or the array of potential identifiers associated with an attribute of nature). It is strongly associated with the concepts of difference, tolerance, and multicultural engagement.

Human rights: The United Nations defines human rights as universal legal rights that protect individuals and groups from those behaviors that interfere with freedom and human dignity (Min, n.d..). Key aspects of human rights are that they are recognized internationally, legally protected, and concerned with human dignity; are universal and

interdependent; cannot be taken away; protect individuals and groups; and are obligations of the State and State leaders (Min, n.d.).

Implicit racism: Implicit racism refers to an individual's utilization of unconscious biased attitudes when making judgments about people from different racial and ethnic groups. Implicit racism is an automatic negative reaction when a person is faced with race-related triggers, including phenotypic, cultural, class, and/or speech/accent differences. Since this type of racism lies beyond the awareness of individuals, they may report that they do not hold racist ideologies and yet display implicit racism in their everyday interactions. Implicit attitudes influence "responses that are more difficult to monitor and control… [e.g., eye movements, blinking] or responses that people do not view as an indication of their attitude and thus do not try to control" (Dovidio, Kawakami, & Gaertner, 2002, p. 62).

Internationalization of psychology: A process by which psychologists demonstrate awareness of the globalization of psychology. Psychologists recognize that their assumptions, values, and biases reference their national history and culture. Internationalization entails recognizing and appreciating global variations in human behaviors, norms, explanatory systems, thought processes, religion, spirituality, and styles of social communication and interaction.

Intersectionality: A paradigm that addresses the multiple dimensions of identity and social systems as they intersect with one another and relate to inequality, such as racism, genderism, heterosexism, ageism, and classism, among other variables. Intersectionality is organized around the location of self within a set of co-constructed social identities (e.g., Black/African American/Black American, gay, older adult, male), and proposes ways to identify, challenge, and resist various forms of oppression. The study of intersectionality has been a significant paradigm within women's studies and is becoming a focus for psychologists who do research and engage in activism regarding historical and contemporary social injustices.

Language: Those symbols, both verbal and nonverbal, that an individual uses to express their ideas and knowledge. Language embodies culture; a society's language reflects its cultural values. For instance, in Spanish the word "I" is "yo," and is written in lowercase rather than uppercase as is found in North America (Clauss-Ehlers, 2006). This reflects the collective aspect of many Latin American countries where the group is more important than the individual.

Macroaggressions: Best defined as potential large-scale or overt acts of aggression and disrespect that are directed toward those of a different race, culture, gender, religion, or other sociocultural identity. Macroaggressions include direct and indirect acts of bias that are broadly engaged toward diverse individuals or groups, and are typically readily identifiable given their presentation. One example of a macroaggression would be recent actions taken to diminish the power in the statement "Black Lives Matter," through

efforts to dismiss clear differences in actions taken by political and legal structures against one group specifically (e.g., the promotion of the campaign stating "All Lives Matter," where specific and necessary efforts to emphasize the importance of speaking out in support of African Americans and their challenges within the historical and current culture are challenged by statements made by predominantly White/White Americans that no one group of individuals is due any greater regard than any other, thereby attempting to negate the consideration of aggressions toward a specific group as important and necessary). Macroaggressions can be contrasted with microaggressions, which are perhaps more covert and insidious.

Microaggressions: Lately, the discourse on racism has shifted from overt exo-level manifestations like legal segregation or Jim Crow laws to subtle or indirect discriminatory behaviors and expressions of bias at the interpersonal level, called microaggressions. Microaggressions are: "Brief and commonplace daily, verbal, behavioral, and environmental indignities, whether intentional or unintentional, that communicate hostile, derogatory, or negative racial slights and insults to the target person or group" (Sue et al., 2007, p. 273). Microaggressions are likely to emerge not when behavior would look prejudicial, but when other rationales could be offered. Many microaggressions have become conditioned, with people not realizing that they are engaging in them. In this interpersonal dilemma of unintentional and/or invisible prejudice, there is a question as to whether a racial incident actually happened, resulting in a clash of realities for the actor and the target.

Multicultural: The coexistence of diverse cultures that reflect varying reference group identities. Multicultural can embody the coexistence of cultures within an individual, family, group, or organization.

Prevention: Efforts that aim to avert the development of a challenge, disease, or concern related to mental health, health, or safety, among other areas. Prevention is often divided into three categories: primary prevention seeks to restrict or diminish the onset of an issue or disease through reduction of risk; secondary prevention aims to reduce or end disease progression through the identification and treatment of a condition before it becomes symptomatic; tertiary prevention refers to efforts that decrease the impact of a disease or concern once it has been treated. In education policy, early intervention refers to services provided for children from birth to age 3. These services seek to promote health and well-being, respond to any existing developmental delays, decrease developmental delays, enhance educational skills and competence, and support the parental role.

Privilege: Unearned special rights, immunities, and societal advantages that are granted on the basis of membership in a dominant social identity group. Privilege represents an expression of power. Through cultural norms and values, privilege oftentimes is invisible to those who possess it.

Oppression: Superiority exercised by the dominant group over other groups through laws, policies, cultural norms, and everyday practices that produce and reproduce societal inequities. Structural forms of oppression inhibit the ability to develop one's full potential and may result in negative physical, psychological, and social outcomes.

Resilience: The ability to overcome structural and individual challenges through a combination of character traits, cultural background, cultural values, and environmental supports. As such, resilience is considered an ability to overcome challenges given both individual and contextual strengths.

Self-definition: An individual's description of one's identity and identifications with one or more cultural groups or communities. A person's self-definition can shift across time, context, and life transitions, and has implications for identity labels. Self-definition is linked to a sense of agency and control over one's own life. Due to internalized forms of oppression, self-definition might reflect distorted perceptions of cultural groups produced through stereotypes and prejudice.

Social justice: Full and equal participation of all groups in a society that is mutually shaped to meet their needs. Social justice includes a vision of society in which the distribution of resources is equitable and all members are physically and psychologically safe and secure (Bell, 1997).

Stereotypes: Fixed, overgeneralized beliefs about a group or community. These beliefs can relate to different aspects of diversity such as age, gender, race, ethnicity, national origin, sexual orientation, ability status, language, religion, and social class. Stereotypes shape attitudes and behaviors toward various sociocultural groups and contribute to discrimination.

Strength-based approach: Focuses psychological practice toward recognition of the inherent strengths of individuals, families, groups, and organizations. It developed as a response to more traditional deficit-based models of pathology and intervention, and instead guides professionals in assisting clients and consultees to use personal strengths as a means of attaining recovery and empowerment. This approach views health and well-being holistically, by engaging assets to identify and achieve positive outcomes.

Trauma: Experiences of extraordinary, terrifying events such as accidents, natural disasters, interpersonal violence, political violence, and war. Recent conceptualizations of traumatic experiences include hate-based victimization (e.g., violence against racial groups and LGBTQ+ communities). Responses to traumatic events involve an array of psychological and physical concerns such as nightmares, flashbacks, hypervigilance,

difficulty regulating affect, headaches, difficulty concentrating on tasks, loss of trust in others, and relational challenges.

Appendix B: Case Studies That Illustrate the *Layered Ecological Model of the Multicultural Guidelines**

Case studies are presented to help illustrate the applied aspect of *Re-envisioning the Multicultural Guidelines*. Cases represent clinical, educational, research, and consultation scenarios. Please note that while cases strive to reflect intersectionality across a range of diverse backgrounds and experiences, it is beyond the scope of this project to portray all dimensions of diversity. As such, case studies seek to address a range of multicultural scenarios that might be found in clinical, educational, research, and consultative arenas. Case studies can be used as teaching and training tools.

* Names and identifying data have been changed to protect confidentiality. Some cases are composite cases, incorporating various experiences; others are fictional.

Level 1 Case Illustrations: Bidirectional Model of Self-Definition and Relationships

Guideline 1. Psychologists seek to recognize and understand that identity and self-definition are fluid and complex and that the interaction between the two is dynamic. To this end, psychologists appreciate that intersectionality is shaped by the multiplicity of the individual's social contexts.

A. Tuan: Identity Transformation and Intersectionality over the Life Span

Tuan is a 48-year-old cisgender Vietnamese American bilingual man who has sought help from a psychologist to address his depressed mood and isolation. In the initial session of psychotherapy, Tuan told the therapist that he identifies as Vietnamese American. When asked by the therapist about whether he was in a relationship, he responded, "I'm not in a relationship. I'm not sure what my sexual orientation is."

Tuan was born in a large city in Vietnam and arrived to a rural area in the United States with his parents when he was 10 years old. While in Vietnam, his family faced financial struggles and had hoped for improved living conditions in the United States. He reported growing up in a middle-class home with parents who worked hard in a small business. He lived in a neighborhood and attended school where there was little racial and cultural diversity. At home, he spoke Vietnamese with his parents, and outside of home, he spoke English. He often felt different and "on the outside" at school, but did develop a few close friendships. In describing his school experiences, Tuan spoke about how he had always thought he felt different due to his racial and ethnic backgrounds, but that in recent years, he realized that he also felt different because of his sexual orientation. Tuan recalled that he was attracted to boys and girls while in school and college, but never believed he could talk openly with anyone about his feelings.

Tuan later married a second-generation Vietnamese American heterosexual woman. The marriage ended after 3 years, when he disclosed to his wife that he was sexually attracted

to both men and women. Following their divorce, Tuan began exploring his attraction to men but dated infrequently. About one year prior to seeking psychotherapy, Tuan disclosed his sexual orientation to his parents. To his disappointment, Tuan's parents said he was "dishonorable" and they would not accept his sexual orientation. Tuan had few supports and confided in one friend. His friend, while sympathetic to Tuan's painful experience of coming out, was unsure of how to support him. Tuan increasingly felt like a burden to his friend and parents, and wished that he no longer had to feel the pain and anguish of living a secret life. He felt as though no one could understand his conflicts. He coped with his sadness through working more hours and staying isolated.

Over time and as he explored his sexual orientation, Tuan felt more disconnected with his Vietnamese heritage and language. In psychotherapy, Tuan struggled with how to come to terms with what he has known about himself for a long time, and how others can accept his sexual identity. He reported feeling as though he could not be the "right type" of Vietnamese person in his parents' view, nor could he be the "out" bisexual man to non-Vietnamese American and non-Asian American friends who did not understand why he couldn't just "be himself." Tuan told his therapist that he could not fully be himself in any situation, always having to hide some aspect of self to connect with others.

Questions for Discussion:

1. Are there aspects of Tuan's identity that feel difficult to address in psychotherapy or counseling? Do you have a sense of why?
2. For what reasons might Tuan feel uncomfortable or reluctant to describe his challenges within and outside of his family with a therapist?
3. How can therapists help clients explore the multiple dimensions and fluidity of their identities?
4. How might you explore the complex nature of Tuan's identity in an empirical study?

B. An Example of Inclusive Research

A research team at Alphabeta University developed a study of sleep and cognition that ultimately involved the assessment of over 1,000 children between the ages of 7 and 9 years of age, who were recruited from urban and suburban communities in two U.S. cities. The goals of the study were to assess the impact of snoring and sleep disordered breathing (SDB) on the youths' cognitive and behavioral development. Given concerns about the role that racial and cultural factors may play in the interaction between development and this medical condition, the researchers made a decision to emphasize a predominantly underserved population across a range of socioeconomic and cultural backgrounds consistent with the cities being used for the study (i.e., Chicago, Illinois, and Chapel Hill, North Carolina), as well as the general population of children and their families being seen in respective sleep clinics.

Children who participated were evaluated across a number of variables addressing their sleep status and the arousals they experienced secondary to their SDB. This was done

using standardized approaches to sleep assessment, including completion of a polysomnographic study while the child slept overnight (with a parent accompanying them) in the clinical research laboratory. The children also underwent comprehensive assessments of their cognitive and behavioral status, including completion of a set of neuropsychological measures such as IQ and educational attainment, but also attention, problem solving, and memory tasks; parent reports about their development and sleep profiles; questionnaires regarding emotional and behavioral regulation; and an assessment of their sleep efficiency.

The study aimed to apply specific theoretical approaches to address the potential relationships between SDB and cognitive inefficiency, as well as behavioral difficulties that are often seen as a result of sleep problems and sometimes misdiagnosed as a disorder such as Attention-Deficit/Hyperactivity Disorder (ADHD). Because substantial prior research has focused most directly on children representative of a White/White American suburban middle-class background, the research team determined that, with their approach, the study required being more directly inclusive of a wider range of children across cultures and socioeconomic status backgrounds.

The principal investigators expressed a particular concern about the possible variability that might be found, given educational differences across cultural and racial groups, socioeconomic differences the families experience, and differences secondary to gender that all contribute to health challenges that underlie snoring and SDB. As a result, they developed the study as a comparison across groups recruited both within and across the settings in which recruitment took place (e.g., families coming to an urban hospital that was situated within a more diverse section of the city, such that Latino/Hispanic/Latinx and Black/African American/Black American children were readily able to be included, versus children from a setting that was more suburban and less diverse in terms of socioeconomic and cultural groups recruited).

The researchers discussed with their statistician the need to focus on multiple potential moderating variables, including race and ethnicity, but also parental education and income, type of educational setting, availability of physical activities for recreation, and resources such as a local grocery store with an affordable range of healthy food choices. One particular consideration for the research team was potential vulnerability to SDB; the study's Principal Investigator (PI) in particular was concerned that, based on previous studies, it was known that obesity contributes to a greater likelihood of developing SDB, and children of Latino/Hispanic/Latinx and Black/African American/Black American backgrounds were more prone to being identified as obese.

Results from the study were particularly informative; they highlighted a number of potential effects, such as the strong influence of SDB on neuropsychological profiles in the attention and executive functioning domains, and less successful grade profiles. More importantly, however, the researchers identified that differences in socioeconomic background were a significant moderator of these effects. Specifically, children with lower available financial resources appeared to show a greater impact of SDB on their learning and skill development. To better address these concerns, the team turned to their

statistician to utilize a set of analytic approaches to the data. These approaches more effectively allowed for matching subjects across the range of variables identified as showing cultural and racial differences to better explore and address these important factors. They also felt that this allowed for a greater emphasis on multicultural factors in the onset and expression of a challenging health concern. In turn, it was thought that this approach would more effectively engage the public and guide physicians to pay closer attention to sleep in their patients.

Questions for Discussion:

1. When addressing the prevalence and impact of sleep disordered breathing in their subject populations, what were the important factors requiring attention, given differences regarding a range of cultural and racial/ethnic factors?
2. When conducting research regarding the interaction between physical and psychological concerns, like sleep and cognition, what would you highlight as an important set of considerations to develop an appropriate study sample and ensure appropriate statistical considerations?
3. Because factors such as race and sociocultural status intersect, how can a research team effectively parse the potential impact of these factors on study design and analysis?

Guideline 2. Psychologists aspire to recognize and understand that as cultural beings, they hold attitudes and beliefs that can influence their perceptions of and interactions with others as well as their clinical and empirical conceptualizations. As such, psychologists strive to move beyond conceptualizations rooted in categorical assumptions, biases, and/or formulations based on limited knowledge about individuals and communities.

C. Marcus: Exploring Stereotypes and Microaggressions

Marcus is a 40-year-old cisgender, heterosexual African American man who has been coping with anxiety and panic attacks since he was in his early 20s. He worked with a therapist previously for a few sessions, but did not find this experience helpful. He reported that his previous therapist appeared uncomfortable and unsympathetic with his concerns about the challenges he faced at his workplace. As the intensity of his anxiety symptoms increased over the past year, he decided to seek help from another therapist. In his first session with this new therapist, Marcus disclosed that he felt overwhelmed by work-related pressures, and that he felt as though he was always looking over his shoulder to be sure that he could maintain his position.

Marcus grew up in a low-income neighborhood where he struggled with traumatic events on a regular basis. He described his relationship with his parents and his older sister as close, but reported that the family coped with stress related to long work hours for his parents, and with ongoing violence in their neighborhood and schools. Marcus would frequently hear shots being fired or learn about people being robbed.

Marcus received scholarships to attend a high school far away from home, and subsequently to college, where he studied engineering. He described his experience of leaving home as "confusing and difficult," as he missed his family and friends, and the predominantly White institutions he attended felt unfamiliar. Marcus's focus and drive to excel academically brought new economic opportunities, and he was able to help his family financially. However, Marcus remained feeling "like an outsider" at school and later at work. He has also dreaded being around extended family since he left for college as several family members have commented that he acts as though he "is above them." Marcus noted that he had experienced anxiety throughout his life, first due to the violence near his home, and later due to a lack of safety and belonging when living away from his family home.

Marcus shared with the therapist that he continues to feel as though he constantly has to work harder than anyone in his workplace to maintain the managerial level position he has achieved. Marcus also told his therapist that his co-workers, none of whom are African American, assume that he has always been wealthy given his educational opportunities, and yet, on the other hand, project stereotypes about African American men as being lazy and aggressive. He struggles with others' perceptions of him, feeling as if they "box" him into ideas about who he should be, rather than reflecting who he really is. Marcus indicates to the therapist that he does not want to be put in a "box" or category. His experience of being stereotyped and categorized has taken a significant toll on Marcus's psychological well-being, as evidenced in his anxiety and panic attacks. Sometimes, he even wonders if his success is due to affirmative action rather than his own ability, and whether or not he can continue to be successful.

Questions for Discussion:

1. What reactions and feelings come up for you as you read about Marcus and his therapist? How might these feelings influence the way you might interact with Marcus?
2. How does your current knowledge or understanding of African American men's racial and social class experiences inform how you might conceptualize Marcus's concerns?
3. Have you had the experience of feeling "boxed in" or categorized by others based on their understanding of people from racial or sociocultural backgrounds with whom you identify?
4. How have you tried to help clients cope with isolation related to stereotyping or discrimination? What types of resources outside of counseling or psychotherapy have been helpful to your clients in addressing stereotyping and discrimination?

D. Melissa: Training Experiences as a Practicum Student

A 22-year-old, gender non-conforming psychology practicum student training on an inpatient unit shadowed a male psychologist. Dr. Samuel, an older, cisgender, heterosexual person, was a practicing evangelical Christian who integrated his deeply held beliefs with his approach to clinical and professional practice.

Shortly after beginning practicum, Melissa, who requested the pronoun "they"/"them" rather than "she"/"her" when others referred to Melissa, had a conversation with Dr. Samuel, who discussed Biblical verses to frame a point being made. For instance, Dr. Samuel presented Melissa with a video to watch that discussed the importance of a Biblical framework for explaining human nature, and Melissa hesitantly obliged. However, Melissa identified as secular and feminist, and in actuality felt offended by Dr. Samuel's request. Given the power differential and role of a practicum student on an inpatient unit, Melissa felt obligated to converse with Dr. Samuel about his Christian beliefs and values within the context of his supervision of their work.

While Melissa never witnessed Dr. Samuel discussing his religion with his clients, they observed several ways in which they believed his religious orientation influenced how he dealt with female versus male patients on the unit. It appeared to Melissa that Dr. Samuel was often more dismissive toward his female patients by having shorter meetings with them and being more directive regarding how to progress with treatment, in comparison with their observations of his interactions with male patients. They also observed that Dr. Samuel would address his White patients differently than patients of color and those who spoke a primary language other than English. They noticed that Dr. Samuel was quick to diagnose patients of color and those less proficient in English, and he was often more dismissive of their communications with him. On the other hand, he appeared to spend more time trying to understand his White, English-speaking patients of different ethnicities and cultures. Melissa soon got the impression that many of the female patients and patients of color would rather work with the other psychologists on the unit.

Aside from patient-therapist interactions, Melissa also noticed that Dr. Samuel interacted differently with his coworkers. Notably, most of the professionals on the unit were women, and Dr. Samuel never shook hands with or made direct eye contact with these female colleagues; this was quite different from his interactions with male colleagues on the unit. Dr. Samuel's behaviors with both his colleagues and his patients made an impact on how he was often viewed by women coworkers on the unit, and Melissa overheard many conversations between staff members sharing the viewpoint that Dr. Samuel was disrespectful with them.

Questions for Discussion:

1. Discuss how stereotypes can be held by almost all individuals, no matter their ethnic, racial, religious, age, sexual orientation, and gender identity statuses, and the intersectionality of these backgrounds.
2. Discuss how unconscious beliefs and attitudes of both psychologists and student trainees can have an impact on clinical relationships with clients as well as coworkers. While clinicians and trainees may not intentionally react to clients and fellow professionals in a harmful or stereotypical way, discuss how they may hold implicit biases that drive reactions to clients or coworkers.
3. Could the given case be superimposed on a professional who is a fundamentalist Muslim; a conservative Brahman Hindu; a traditional Catholic; or an Orthodox Jew? Could the case be superimposed on a psychology practicum trainee of diverse self-definitions and identities, such as an international student, an immigrant, someone with

refugee status, someone whose second language was English; someone with a gay, lesbian, or bisexual orientation; someone with a non-Western religious or spiritual affiliation; or someone from an upper socioeconomic class?

4. What are your views about "color-blind democracy" in the theory, research, and practice of psychology?

Level 2 Case Illustrations: Community, School, and Family Context

Guideline 3. Psychologists strive to recognize and understand the role of language and communication through engagement that is sensitive to the lived experience of the individual, couple, family, group, community, and/or organizations with whom they interact. Psychologists also seek to understand how they bring their own language and communication to these interactions.

E. Dr. Enrique: Culturally and Linguistically Responsive Consultation

Dr. Enrique is a licensed Latino/Hispanic/Latinx male psychologist who has been contacted by the principal of a local Catholic school to consult with them about parent involvement. The school serves students in the elementary school years and is located in a low-resource neighborhood in the heart of a large metropolitan city. The student body is primarily Latino/Hispanic/Latinx with most children speaking Spanish at home. While instruction at the school is primarily taught in English, most of the students' parents are monolingual Spanish speakers.

When the principal contacts Dr. Enrique, she says that the teachers are very concerned about the lack of parent involvement. The school staff shares the belief that parent involvement is critical to the academic success of their students. Further, while the school has reached out and invited parents to events, the turnout has been low. The principal explains how the teachers interpret the lack of parent involvement as parents not caring about their children's academic success. Teachers are frustrated with the lack of response on behalf of the parents. The principal senses low morale among teachers and is concerned that this will have a negative effect on interactions between the school and students/families.

Dr. Enrique is motivated to learn more about the current situation and how to respond. First, Dr. Enrique reaches out to the teachers. He hears their concerns about the lack of parental involvement and participation. Dr. Enrique inquires about the events with no parent participation. He learns that they were advertised in English because the school did not have a translator. He also learns that the events were scheduled during the day at a time when many parents may have been working or taking care of young children.

Dr. Enrique suggests that the school plan another event. He reaches out to the principal, stating the invitation must come from the head of the school, and then trickle down through the teachers. Flyers are sent home in Spanish. The event is scheduled during the evening in hopes that parents will not be working. The flyer clearly states that child care will be offered and refreshments served. The flyer is sent out two weeks prior to the

event, and then subsequently sent home in children's backpacks once a week for the following two weeks.

The night of the event approaches. Teachers and the principal are present, as are other administrators. Volunteers help watch the children as needed and a buffet dinner has been organized. Slowly parents begin to circle into the main hallway where the event is held. The room begins to fill to the point that there are more parents than teachers. Dr. Enrique opens the conversation in Spanish and English—welcoming everyone to the event.

As the conversation continues, he shares that the school invites parents to be more involved in the day-to-day life of the school. Teachers talk about specific ways that parents can come to school and participate in various activities. Parents share that their lack of engagement reflected their sense that it would be disrespectful to the school, specifically to the teachers, if they came in. They share that in their cultures, *respeto*, or having a sense of respect for others, is of utmost importance. Not participating in the life of the school is born out of concern that their participation would be viewed as a lack of *respeto*. Parents didn't want their children's teachers to think that they did not respect their role by being present at the school. They shared that in their cultures, parents tend not to get involved as an indication that they have the utmost trust in the teachers and their decisions.

Through communication of the two perspectives, the teachers can clearly share with the parents that they want them to be involved in the life of the school. They talk about how their school in the United States truly wants to build working partnerships with parents. Hearing the invitation, parents commit to greater involvement. It is as though having the teachers' permission prompts them to feel more comfortable with participating more fully.

Questions for Discussion:

1. What is your view of the consultant's role within a multicultural context?
2. How can the consultant understand and incorporate cultural values and perspectives in work with organizations?
3. How did Dr. Enrique respond to each of the constituencies involved in the school? How did his response encourage collaboration among constituencies?
4. How does Dr. Enrique's example inform your own work as an organizational consultant working within a multicultural context?

Guideline 4. Psychologists endeavor to be aware of the role of the social and physical environment in the lives of clients, students, research participants, and/or consultees.

F. Yasmin: Bridging Different Worlds

Yasmin is a 28-year-old Muslim, immigrant, cisgender woman from Pakistan. She continues to experience the loss of her husband who was killed in the September 11, 2001 collapse of the World Trade Center, where he worked in a small business. Yasmin has experienced numerous acts of racially motivated verbal and physical aggression since 9/11. She has also experienced the challenging demands of raising her son who was born with multiple disabilities.

After her husband's death, Yasmin's parents and parents-in-law came from Pakistan, taking turns living with her, supporting her, and helping her with child care. Their eventual departure was very difficult for her. For the past 5 years Yasmin has lived by herself.

Yasmin mourned for her husband for several years. She eventually entered into a relationship with another Pakistani man. This relationship helped Yasmin express herself in ways that helped her to be less conservative than previously. While romantic, this was not a sexual relationship. However, due to disagreements about the care of her son, Yasmin decided to end the relationship.

Yasmin was very close to her father until he passed away a few years ago. Between her father, husband, and former male companion, she always had a strong male figure in her life. When Yasmin decided to end the relationship with her companion, it was the first time that she was without close male guidance. Yasmin had to live independently. She struggled to pursue a career in retail, take care of herself, and meet the particularly challenging demands of her son who was completely dependent on her. Yasmin chose to stop wearing her hijab (a veil/head covering that often covers the head and chest) partly for her own protection from being stared or shouted at in public transportation, or in large stores. Nonetheless, she continues to face prejudice because of her accent and speech, physical appearance, behavioral differences, and gender practices. However, Yasmin has made friends, Pakistani as well as American, who have helped her in ways that she needed following the passing of her husband. However, Yasmin does not have the familial and communal support that she would have if she were in Pakistan. Despite these challenges, Yasmin is taking online courses to improve her career standing. Her perseverance through struggles attests to her resilience.

Yasmin is now dating a White/White American male whom she met at work. While this man is good to her son and Yasmin likes many aspects of an egalitarian relationship, she is bothered by his sexual advances. She likens his amorous behaviors to sexual assault and believes she is at risk for rape. Because of her Muslim faith and cultural gender role, Yasmin believes that intercourse should occur only after marriage. She feels immodest, thinking she is sexually provocative. Sometimes she thinks she is a sinner. Yasmin is filled with shame, thinking that she is letting down her mother, sisters, and mother-in-law, who had advised her to return home to them in Pakistan for her protection, sexual purity, and for the preservation of her conservative values and practices. Yasmin also feels guilt, thinking she will be unfaithful to her dead husband if she has sex.

Questions for Discussion:

1. Describe practitioners' self-reflections about a dominant society's use of oppression, privilege, and power over religious minority groups and individuals; their reflective self-examination of their own biases and stereotypes about Islam and its followers; their ever-present awareness of their multiple social identities as well as those of others; the biases that exist because of such identities; and how their interactions with others are based on these identities.
2. How would a psychologist incorporate trauma and resilience when working with a culturally diverse person who has suffered continuous life stressors including racism, discrimination, and societal hatred? How would a psychologist evaluate theoretical adaptations to demonstrate evidence-based practice?
3. Discuss practitioners' need to understand Islamic tenets and the differences between Muslim culture and that of the United States. Discuss an understanding of how much a particular Muslim immigrant is committed to such ideals and how difficult it may be to remain committed to one's faith in the United States; how it might be common for Muslim women living in the United States to struggle with the difference in women's roles in the United States versus those in an Islamic culture; and how such underlying gender roles may make clients uncomfortable with a practitioner.
4. How would Yasmin define self, community, and their relationship with each other?
5. Describe Yasmin's challenges as she adapts to life in a highly individualistic environment as opposed to the collectivist family culture she was used to.

G. Anthony: Having an Identity That Extends Beyond One's Disability

Anthony, a 25-year-old, cisgender, biracial/multi-ethnic (Black/African American/Black American, White/White American, Latino/Hispanic/Latinx) male, was referred for individual psychotherapy in conjunction with his participation in ongoing vocational rehabilitation programming. He presented with a history of mild intellectual disability that was acquired secondary to a traumatic brain injury (TBI) he sustained during early adolescence when he was in a motor vehicle accident with his family. Of note, Anthony and his brother were the only members of their family to survive the accident, and both sustained significant TBI's.

Anthony was fifteen at the time of the accident, and he had been highly functioning prior to his TBI. Before sustaining his injury, Anthony had been enrolled in a college prep high school program and was active in both athletics and extracurricular activities, including chess and computer design clubs. He and his brother, who is three years younger than Anthony, were the middle children in a large family of six boys and two girls. Anthony lost both his parents and two of his siblings in the accident. Two older siblings (males), both of whom were adults and living on their own at the time of the accident, now serve as guardians for Anthony and his brother. The two youngest siblings (one male, one female), were also not in the car at the time of the accident. Subsequent to the accident they were raised by an aunt who lived in a nearby city. Anthony visits these two younger siblings during the holidays and at family gatherings.

Anthony's case manager, when discussing current concerns with the psychologist, indicated that Anthony had been struggling of late with impulse control, particularly around select peers, both male and female. This led to difficulties both at his residence, a group home program for young men who have neurodevelopmental challenges, and in the sheltered employment program Anthony participates in weekly. The case manager indicated that she suspected some of his impulsivity, which has included inappropriate language and touching, was related to Anthony's desire to be more like his typical peers who are in relationships. She shared that she and the staff working with Anthony were seeking guidance on how to best support him in making better behavioral choices, particularly around his romantic and sexual feelings. The case manager also shared that they were looking to provide Anthony with an opportunity to more directly address his feelings of difference that appear to have an impact on his mood.

At first, therapeutic work with Anthony focused on helping him share his current experience of himself as a man with an acquired neurodevelopmental disorder as well as to gain an understanding of how his viewpoint about himself had changed. This work was done in a context of Anthony's awareness of who he had been prior to the accident and what was different for him as a consequence of his injuries and the loss of some capabilities. It was clear from early on that Anthony's tendency to act and speak impulsively were primary consequences of his TBI. He sustained injuries to his developing executive skills, such that challenges were noted with flexibility, thinking strategically, and impulsivity, including saying inappropriate things as they came to mind. It also became evident that Anthony's recent behavioral difficulties, where he impulsively sought out more intimate interactions with male and female peers, were associated with efforts to be "more of who I used to be, someone who went on dates and had friends, who had people in my life who wanted to be around me."

Anthony shared that he often felt dismayed that he was now seen as "ugly" and "stupid" by other men and women he saw daily. He brought in a photo of himself, taken during adolescence and prior to his accident. Anthony actively compared what was different for him then with now; he focused specifically on the scar he had because of his neurosurgeries for his TBI; his loss of gross and fine motor skill, such as his inability to ambulate independently; and his altered growth, that made him much shorter than peers. Anthony began to talk more directly about what he had lost cognitively and emotionally because of the accident; sharing that he had been a budding wrestler and a good student before his TBI, and that he had many friends then too. Since then, his path had changed significantly, with many associated losses in terms of opportunities and expected outcomes. Anthony shared that he was most often reminded of these losses, including the fact that he had just been able to start dating shortly before the car accident, when he saw perceived neurotypical peers outside of his program and residence.

Anthony experienced significant and understandable sadness about these losses. He was able to identify that this led him to want to "change stuff" by making his life "normal." However, Anthony also admitted that some things could not easily be changed, like his inability to ambulate without a walker, and that he needed to use a wheelchair when

required to go long distances. Anthony shared how this was a substantial limitation on his ability to ask a peer out on a date, or to spend time with a peer without adult supervision.

As treatment continued, discussions focused on Anthony's experience of these losses and their impact on his ability to see the possibility of a life that was more layered and optimistic. With regard to his impulsive actions, the therapist helped Anthony better understand his range of feelings regarding intimacy and sexuality. The therapist and Anthony took into account that he had physical and cognitive differences secondary to his TBI that affected how Anthony could share, verbally and through touch, his attraction to someone. As a man who was hampered in his mobility and capacity for physical contact across a variety of situations and settings, it was important for the therapist to help Anthony and his support team address how he, a young man with many typical wishes and desires both in terms of love and physical interest, could address these within home and work environments.

One important step forward occurred when Anthony was able to meet a wider range of peers, both for friendship and potential dating, and to work directly on how to discriminate between an interest in intimacy and frank sexual desires. Therapy additionally helped Anthony become more comfortable with how he could express and address his physical desires. This was accomplished in part through a better understanding of his own body and learning how to address feelings in a socially appropriate manner. Social scripts were developed, with coaching provided within treatment as well as with the teams at work and in the residence. This allowed Anthony to more effectively inhibit immediate wishes to connect through touching, that were often perceived as intrusive and inappropriate. Instead Anthony could work toward initiating interactions verbally, allowing boundaries to be established.

Anthony worked to recognize himself as not only someone with a disability, but also as a member of a wider array of communities, where his strengths and differences could be better appreciated. His beliefs of himself as "damaged" and "ugly" were challenged through opportunities to ask both how others perceived him, and through frank discussions about how this allied with and differed from his own expectations and perceptions. Anthony was supported in more directly mourning the trauma and losses he experienced, so that he could begin to conceptualize himself as both a survivor and as resilient. This led to two important changes: One, Anthony began to see himself as moving forward on a new trajectory, which, while different from his path prior to the accident, was still valid and open to many successes. Two, Anthony came to recognize that he himself could play a more active role in decision making. These changes led Anthony to seek out new opportunities within his vocational program and to open himself up to the interest a fellow peer had expressed with regard to dating him.

Questions for Discussion:

1. Describe practitioners' considerations regarding cognitive and physical disability, and how these are conceptualized within the dominant society's continued emphasis on privilege, oppression, and capability.

2. How would psychologists adapt trauma theory to address the challenges experienced by Anthony, a biracial/multi-ethnic man, who has lost both family and his experience of himself as a functional member of the community? How would they evaluate theoretical adaptations to demonstrate evidence-based practice?
3. What is required of practitioners so they can have an understanding of how disability is experienced within the United States? What can promote an understanding of how individuals with cognitive and physical challenges experience daily life that can subsequently facilitate more effective problem solving within supportive treatments?
4. How can a therapist consider disability across multiple levels of identity? What are the implications of these considerations for understanding intersectionality?

H. Jung: Access to Culturally Relevant Treatment

Jung is a 70-year-old Korean woman who married an American soldier and came back to the United States with him when he left the service. They lived in a rural area of northern Maine, where her husband was a fisherman until his death five years ago. Jung's English proficiency is minimal and she suffers from left-sided paralysis secondary to a stroke. Since her husband's death, Jung has become increasingly depressed because there are no Koreans living nearby and her disability limits travel. Jung has become increasingly isolated, her only social contact being a friendly postman and the grocery store clerk who delivers her food.

Jung's primary care doctor realizes there is a problem but Jung's limited ability to speak English and reticence to talk about mental health issues interfere with any care beyond medication. A search of local mental health providers revealed there is no one within 100 miles who speaks even limited Korean. Jung shuts down when the doctor encourages her to try a telephone interpreting service. In desperation, the doctor contacted the Korean Consulate and spoke with staffers working in a facility in Nova Scotia, the closest to Jung's home. The consulate arranged for a psychologist fluent in the Korean language to speak with Jung via the Internet on a monthly basis while she is at the doctor's office.

Questions for Discussion:

1. How could Jung's relationships with the delivery person and the grocery clerk be incorporated into achieving her treatment goals to help her feel less isolated?
2. How could local resources, in addition to the postman and clerk, help in providing a more beneficial environment for Jung?

Level 3 Case Illustrations: Institutional Impact on Engagement

Guideline 5. Psychologists aspire to recognize and understand historical and contemporary experiences with power, privilege, and oppression. As such, they seek to

address institutional barriers and related inequities, disproportionalities, and disparities of law enforcement, administration of criminal justice, educational, mental health, and other systems as they seek to promote justice, human rights, and access to quality and equitable mental and behavioral health services.

I. Aiden: Struggling with Loss, Grief, and Inequity

Aiden is a 10-year-old, White/White American boy of Irish descent, who was referred to a psychologist by his school counselor. Aiden has been struggling with completing his schoolwork and concentrating on tasks. According to his teachers, he has been disruptive in class and unable to complete homework on a regular basis. His grades have declined over the course of several marking periods. While the school recommended an evaluation, the process was delayed due to Aiden's father's hesitancy to engage in the testing process. Rather, Aiden's father repeatedly shared that his son didn't have psychological issues, stating that his behavior was just reflective of his being a kid. He continued to encourage Aiden to focus on his schoolwork and not let feelings "get in the way" of academic success.

It was when Aiden's grades dropped substantially that his father finally agreed to the evaluation process. Aiden was evaluated for a learning disability. Testing results indicated that he did not have a learning disability, but rather, issues of grief and loss were affecting his academic life. The evaluator recommended that Aiden be referred for psychotherapy.

After some hesitation, Aiden's father agreed; however, the start of therapy was further delayed by the family's lack of health insurance coverage for treatment. The school was eventually able to connect the family with a community-based mental health center that could work with Aiden at a reduced fee. Aiden lives with his father, who works long hours in two different grocery stores to support his family. Aiden's mother died of ovarian cancer when he was 7 years old. Aiden and his father were devastated by her illness, which progressed quite quickly and led to her death just 7 months after initial diagnosis. No other family members were living near Aiden and his father. Aiden's father had struggled with maintaining stable employment, and was overwhelmed with grief over his wife's death. Aiden's mother was also the primary household earner and her death resulted in additional economic challenges for her husband and son, who lost their health insurance.

While Aiden's father eventually agreed to therapy for his son at the community-based mental health center, he underestimated the impact of their traumatic loss on both of them. He also doubted whether someone he considered to be a "professional person" would be able to understand the loss and poverty that he and his son were experiencing. Aiden's father feels unable to fully support his son emotionally, given his tremendous responsibilities securing money for food and rent. A salient source of support became the Catholic Church that Aiden and his father attended on most Sundays. A few people from the church offered emotional support but later expressed their feelings of inadequacy related to providing academic support.

Questions for Discussion:

1. How does the role of stigma affect Aiden's access to treatment?
2. How does a lack of resources influence the family's access to treatment and health care?
3. What role does cultural mistrust play in Aiden's father's willingness to have his son engage in treatment?
4. In your role as a psychologist, how have you engaged in trauma-informed practice?

Guideline 6. Psychologists seek to promote culturally adaptive interventions and advocacy within and across systems, including prevention, early intervention, and recovery.

J. Dr. Amy: Multiculturally Informed Advocacy

Dr. Amy has been asked to consult with a community advocacy group to help develop and implement a parenting program for families with young children. The advocacy group is very connected to the diverse community in which it is housed. As such, there is a history of relationships between the organization and the surrounding neighborhood. Dr. Amy's task is to help staff plan, market, and implement a parenting program for parents with young children from birth to age 3. The group's decision to develop such a program stems from an awareness of the increasing number of young families moving into the neighborhood along with the number of parents referred to the clinic by child protective services.

The parenting program's advocacy goal is to provide parents of infants and toddlers a place to go—at no cost—where they can learn parenting skills and interact with one another. The parenting program is geared primarily toward early intervention, since eligible parents must have children from birth to age 3. The preventive aspect of the program aims to encourage learning and parent interactions before a crisis occurs, rather than during or afterwards.

To ensure the program reflects the community's demographic composition, Dr. Amy and parenting center staff walk throughout the neighborhood to talk with parents about their interest. Through these informal conversations, they learn that many parents have felt isolated since having a child. Several mothers share that they are the only parent raising their child. They talk about the lack of a social support network and feeling that they lack a voice in their communities. Some parents talk about being depressed since the birth of their child. They talk about feeling overwhelmed to the point of waking up in the morning wondering how they are going to live up to their parental responsibilities throughout the day. These conversations help Dr. Amy and her colleagues recognize that the parent program should be a safe haven where parents can interact with one another in addition to staff.

A series of workshops are organized that aim to be responsive to the struggles shared by the parents with whom they spoke. Topics such as "father involvement," "post-partum depression," "parenting style," "work/family balance," and "stress management" are all key concerns. Workshops are also responsive to the neighborhood's linguistic and cultural diversity. Written information and workshops are presented in the languages spoken within the surrounding community. The program also works to develop collaborative relationships with parents in the community. As parents enroll, they are encouraged to recommend topics of discussion that reflect what they are experiencing. Parents enjoy coming in with their babies and toddlers. They learn about community resources and talk about shared challenges. Over time, the number of referrals from child protective services decreases.

Questions for Discussion:

1. How did Dr. Amy effectively engage in advocacy efforts that supported the community?
2. In what culturally responsive ways can psychologists engage in advocacy efforts?
3. What are some of the barriers to effective community-based advocacy? How can these barriers be addressed?
4. In your role as a practicing psychologist, are there ways that prevention and early intervention can promote positive outcomes?

Level 4 Case Illustrations: Domestic and International Climate

Guideline 7. Psychologists endeavor to examine the profession's assumptions and practices within an international context, whether domestically or internationally based, and consider how this globalization has an impact on the psychologist's self-definition, purpose, role, and function.

K. Michael: Identity and Refugee Status

Michael is a 24-year-old African refugee in the United States who was born and raised in Ethiopia. He identifies as cisgender male, heterosexual, and being poor. Michael came to the United States via Uganda where he took part in a struggle to overthrow a post-colonial military regime. Michael traveled to the United States on a student visa; however, the visa was a means of escape from Africa and he was not registered as a student in the United States. This visa has long expired and he is presently undocumented. While Michael was not his birth name; it was the name of his Ugandan friend who arranged for Michael to travel to the United States in his place. The issue of names and identity is central to Michael's life.

One of Michael's first acts upon leaving Ethiopia was to abandon his thirteen names, each taken from a preceding generation in his family. With this symbolic erasure of his past, Michael believed that he had entered the world with a blank slate, and could define his identity anew. Michael found Uganda in the midst of its own nationalistic identity

crisis, trying to fill the void left by British colonists. This country, with its abundance of revolutionary sentiment, was the perfect place for Michael to redefine himself. Michael and his friend, the original Michael, organized groups at a university where they were both pretending to be students, to protest human rights violations by the military government. However, the activism became armed revolution, and Michael felt lost and conflicted. He believed in liberation but could not be the violent radical that a nationalistic context now esteemed.

Some time later, Michael travelled to a Midwestern college town in the United States where he encountered a new set of dynamics around identity. In Uganda, Michael was an outsider enamored with a revolution but not willing to kill. In the United States, as an African, he was expected to accept his social position as a second-class, invisible person of color. Two different structural systems invited two opposing identities. The result was that Michael saw himself as a traitor, abandoning his African compatriots and beloved friends, including his namesake, who lost his life fighting for freedom. At the same time, Michael experienced himself as a maladjusted acquiescent person who accepted a subordinate identity enforced by a racist and classist society.

Questions for Discussion:

1. What are some practitioners' self-reflections regarding their values, beliefs, and assumptions about refugees coming to the United States from countries with civil strife; and about their knowledge of political uprisings, dictatorships, and religious and ethnic cleansing in African, Arabic, and/or Middle Eastern nations?
2. How would a psychologist do a structured intake on personal and family history with Michael, who is a reticent and distrusting interviewee?
3. Describe Michael's various cultural and social identities and their intersectionality. Which are dictated externally and have developed into an existential problem of a lack of self-knowledge?
4. Describe a community-based intervention that may help Michael incorporate and internalize a revolutionary aspect into his identity.

Guideline 8. Psychologists seek awareness and understanding of how developmental stages and life transitions intersect with the larger biosociocultural context, how identity evolves as a function of such intersections, and how these different socialization and maturation experiences influence worldview and identity.

L. Mary: A Focus on the Interpersonal Instead of the Contextual

Mary is a 17-year-old Japanese American–born teenager raised in the United States. She is currently facing the prospect of taking the SAT and other national exams required to apply for college. While a bright student with a straight A average in high school, Mary has become increasingly anxious about taking the exams. As a result, she refuses to take the step of actually signing up to take them. Her parents, who were born in Japan, are bewildered about her refusal and anxiety, and what they increasingly see as self-destructive behavior.

Since early childhood, Mary's parents have enrolled her in afterschool educational support activities, similar to the *juku*, or private educational organizations that provide additional academic experiences outside the school setting in Japan. Mary's mother stopped working after she was born so she could devote herself to her daughter's development.

On some level, she feels that Mary's current struggles must reflect a failure on her part. On another level, Mary's mother feels frustrated that the sacrifice she made with regard to giving up her career to raise her daughter has not been rewarded by a motivation on her daughter's part to attend college.

After consultation with Mary's pediatrician, her parents have taken the step of having her see a psychologist. The latter is a non-Latino/Hispanic/Latinx White/White American professional who views Mary's behavior as simply acting out and resisting parental authority. He is unaware of the significance with which national exams are often viewed in Japan. He is also unaware of the trend to engage children in outside academic activities starting at a very young age that is a tradition for this family. Mary's parents tell the psychologist that they are devastated by what they perceive as a lack of motivation, especially given the overarching importance they have placed on these exams throughout her adolescence. The psychologist continues to frame the issue as one that reflects adolescent development and resistance to authority. As a result, he employs a CBT approach designed to address parent-child relations and issues of adolescent development instead of the generational and cultural conflict at play.

Questions for Discussion:

1. In what ways can the psychologist incorporate a multicultural framework in working with Mary and her family?
2. What are some of the intergenerational issues that affect family relationships and functioning?
3. As a psychologist taking a systemic approach, in what ways can you be responsive to the concerns of both Mary and her parents?
4. What are some of the developmental issues that may currently have an impact on Mary's experience, as well as that of her parents?

Level 5 Case Illustrations: Outcomes

***Guideline 9. Psychologists strive to conduct culturally appropriate and informed research, teaching, supervision, consultation, assessment, interpretation, diagnosis, dissemination, and evaluation of efficacy as they address the first four levels of the* Layered Ecological Model of the Multicultural Guidelines**.

M. Community-Based Research

A research psychologist new to the local university was interested in assessing depressive symptomatology among American Indian residents of a nearby tribal reservation. She approached the local tribal council and asked for their help in recruiting subjects. After a week of deliberation, the council firmly refused to grant her request. When the disappointed psychologist asked for an explanation, the head of the council initially said that it didn't seem like the project would benefit local members of his tribe. When pressed, he admitted that her university had a long history of doing research in the town without informing anyone of the results or working with the community. As a result, community leaders had become united in rejecting any proposed research by university faculty.

The psychologist expressed her disappointment but said she understood the concerns and would do her best to demonstrate her commitment to the community. For the next three years she worked closely with the town's tribal council on a number of projects that they initiated and participated in several activities designed to assist tribal members. When she finally revisited the possibility of research on depression, the council members wrote letters of support and actively assisted in recruitment.

Questions for Discussion:

1. As psychologists conducting community-based research, what are some considerations for building relationships in the community?
2. How can research psychologists be aware of the experiences of the communities in which they are conducting research?
3. How does this case reflect your own experiences conducting community-based research?
4. In what ways can research psychologists give back to the communities where their research is being conducted?

Guideline 10. Psychologists actively strive to take a strength-based approach when working with individuals, families, groups, communities, and organizations that seeks to build resilience and decrease trauma within the sociocultural context.

N. The Oregano Family: Working with Mental Health and Faith-Based Communities in Clinical Training

Six weeks prior to being seen at the university counseling center, the Oregano family suffered a devastating tragedy when Mr. Oregano, the husband and father of three children, was in a fatal plane crash. Traveling back home on a consumer airline, sudden lightening caused an electrical outage that led to the crash. Mrs. Oregano and her three

children, ages 4, 10, and 16, come to counseling presenting symptoms of post-traumatic stress. Understandably, the 4-year-old continues to ask when his father is going to return home.

The service provider is a doctoral student who is supervised by a licensed psychologist. The doctoral student is working with the Oregano family as part of a clinical practicum experience. From the beginning of their work together, Mrs. Oregano has expressed concern about the status of her late husband's afterlife. A devout Roman Catholic, she shares that the family has no body to bury, something profoundly important to someone whose faith believes in resurrection of the body. She expresses her concern to the trainee, sharing that a formal burial will help the family and future generations remember her late husband, while also respecting the saints. She shares with the trainee the teachings of her priest and is overwhelmed with grief related not only to loss, but also to concerns about her late husband's afterlife.

The trainee focuses on the symptoms Mrs. Oregano and her children are experiencing. Uncertain how to address the role of religion for this family, the trainee avoids it, minimizing family concerns in this area, focusing solely on the post-traumatic stress symptoms. The family begins to attend psychotherapy sporadically, which the trainee interprets as resistance to dealing with the loss.

The supervisor encourages the trainee to ask the family about their faith and the concerns the lack of a burial presents. Treatment seems to shift as Mrs. Oregano and her oldest child talk about their visits with their priest and the solace they get from the church. The supervisor increasingly encourages the trainee to incorporate the "voice" of the priest in sessions. In other words, the trainee is to ask about what the priest would say in response to current struggles and stresses. In this way, the supervisor invites the trainee to consider the importance of both mental health and faith. The Oregano family can approach their loss through an integration of both perspectives, rather than feeling they have to choose one over the other.

Questions for Discussion:

1. What does the supervisor encourage the trainee to understand when taking a culturally informed approach to education and training?
2. What are the goals of supervision that takes a culturally informed approach?
3. What are some of the challenges that might emerge for supervisor and supervisee in the context of supervision that takes this approach?
4. How can using an awareness of internal and contextual biases reduce or remove potential tensions in supervision?

O. Lucy: Fear about a Marriage Ending

Lucy is a 36-year-old White/White American transgender woman who has sought help from a psychologist to cope with her anxiety related to her relationship with her wife. Lucy has been employed in a pharmaceutical company for over eight years. She has grown increasingly anxious about the stability of her marriage, as she suspects that her

wife may be romantically involved with someone else. Lucy sometimes experiences panic symptoms, and feels overwhelmed by the prospect of her marriage ending.

Lucy grew up in a home in a rural area of the United States with her two siblings, parents, and grandparents. She describes her parents as "progressive and accepting," and as supportive when, in her teens, she told them that she was a girl. Her parents encouraged Lucy to work with a therapist at this time, which was an important source of support for her. However, Lucy was severely bullied by peers who verbally and physically attacked her in and out of school. She coped with these traumatic experiences through the use of substances such as alcohol and marijuana. Lucy described this time of her life as "most painful and depressing" and often thought of ending her life. She decided to attend college in a city far from her family home to escape the trauma she endured as an adolescent. While Lucy had not worked with a therapist since high school, she connected with a transgender community in college, and continued to form friendships with people she experienced as supportive and caring toward her. Soon after college, she met a cisgender woman whom she dated for several years and later married. Lucy feels that her wife has been a central figure in her life and someone who has advocated for her. This has been especially important in circumstances at work when Lucy has faced transphobic and heterosexist comments from coworkers.

Lucy has done hormone replacement therapy for several years, and more recently, has been considering sexual reassignment surgery (SRS). However, she feels confused about whether to pursue this, as her wife is against the idea of surgery, and has told Lucy that she "passes" as a woman without it. Lucy has felt hurt by these comments and wonders whether her wife truly understands what it means for her to be a transgender woman. At the same time, Lucy believes that her wife has been the one person she has relied on to help her cope with hostility based on her gender identity and sexual orientation. Their tension has escalated over the past year, and increasingly, Lucy has suspected that her wife is losing interest in being with her. Lucy worries that these conflicts may lead to separation or divorce. She is terrified of this potential loss and worries that she may cope with her anxiety by using substances or hurting herself in some other way.

Questions for Discussion:

1. What reactions do you have after reading about Lucy's experiences? What experience have you had in working with transgender clients?
2. How would you conceptualize the role of trauma in Lucy's life?
3. How would you approach helping Lucy with her anxiety, considering her past history of substance use, depression, and suicidal ideation?
4. In what ways do others' perceptions of Lucy's gender identity and sexual orientation affect her identity and relationships?

Appendix B: Case Studies That Illustrate the *Layered Ecological Model of the Multicultural Guidelines**

Case studies are presented to help illustrate the applied aspect of *Re-envisioning the Multicultural Guidelines*. Cases represent clinical, educational, research, and consultation scenarios. Please note that while cases strive to reflect intersectionality across a range of diverse backgrounds and experiences, it is beyond the scope of this project to portray all dimensions of diversity. As such, case studies seek to address a range of multicultural scenarios that might be found in clinical, educational, research, and consultative arenas. Case studies can be used as teaching and training tools.

* Names and identifying data have been changed to protect confidentiality. Some cases are composite cases, incorporating various experiences; others are fictional.

Level 1 Case Illustrations: Bidirectional Model of Self-Definition and Relationships

Guideline 1. Psychologists seek to recognize and understand that identity and self-definition are fluid and complex and that the interaction between the two is dynamic. To this end, psychologists appreciate that intersectionality is shaped by the multiplicity of the individual's social contexts.

A. Tuan: Identity Transformation and Intersectionality over the Life Span

Tuan is a 48-year-old cisgender Vietnamese American bilingual man who has sought help from a psychologist to address his depressed mood and isolation. In the initial session of psychotherapy, Tuan told the therapist that he identifies as Vietnamese American. When asked by the therapist about whether he was in a relationship, he responded, "I'm not in a relationship. I'm not sure what my sexual orientation is."

Tuan was born in a large city in Vietnam and arrived to a rural area in the United States with his parents when he was 10 years old. While in Vietnam, his family faced financial struggles and had hoped for improved living conditions in the United States. He reported growing up in a middle-class home with parents who worked hard in a small business. He lived in a neighborhood and attended school where there was little racial and cultural diversity. At home, he spoke Vietnamese with his parents, and outside of home, he spoke English. He often felt different and "on the outside" at school, but did develop a few close friendships. In describing his school experiences, Tuan spoke about how he had always thought he felt different due to his racial and ethnic backgrounds, but that in recent years, he realized that he also felt different because of his sexual orientation. Tuan recalled that he was attracted to boys and girls while in school and college, but never believed he could talk openly with anyone about his feelings.

Tuan later married a second-generation Vietnamese American heterosexual woman. The marriage ended after 3 years, when he disclosed to his wife that he was sexually attracted to both men and women. Following their divorce, Tuan began exploring his attraction to men but dated infrequently. About one year prior to seeking psychotherapy, Tuan

disclosed his sexual orientation to his parents. To his disappointment, Tuan's parents said he was "dishonorable" and they would not accept his sexual orientation. Tuan had few supports and confided in one friend. His friend, while sympathetic to Tuan's painful experience of coming out, was unsure of how to support him. Tuan increasingly felt like a burden to his friend and parents, and wished that he no longer had to feel the pain and anguish of living a secret life. He felt as though no one could understand his conflicts. He coped with his sadness through working more hours and staying isolated.

Over time and as he explored his sexual orientation, Tuan felt more disconnected with his Vietnamese heritage and language. In psychotherapy, Tuan struggled with how to come to terms with what he has known about himself for a long time, and how others can accept his sexual identity. He reported feeling as though he could not be the "right type" of Vietnamese person in his parents' view, nor could he be the "out" bisexual man to non-Vietnamese American and non-Asian American friends who did not understand why he couldn't just "be himself." Tuan told his therapist that he could not fully be himself in any situation, always having to hide some aspect of self to connect with others.

Questions for Discussion:

5. Are there aspects of Tuan's identity that feel difficult to address in psychotherapy or counseling? Do you have a sense of why?
6. For what reasons might Tuan feel uncomfortable or reluctant to describe his challenges within and outside of his family with a therapist?
7. How can therapists help clients explore the multiple dimensions and fluidity of their identities?
8. How might you explore the complex nature of Tuan's identity in an empirical study?

C. An Example of Inclusive Research

A research team at Alphabeta University developed a study of sleep and cognition that ultimately involved the assessment of over 1,000 children between the ages of 7 and 9 years of age, who were recruited from urban and suburban communities in two U.S. cities. The goals of the study were to assess the impact of snoring and sleep disordered breathing (SDB) on the youths' cognitive and behavioral development. Given concerns about the role that racial and cultural factors may play in the interaction between development and this medical condition, the researchers made a decision to emphasize a predominantly underserved population across a range of socioeconomic and cultural backgrounds consistent with the cities being used for the study (i.e., Chicago, Illinois, and Chapel Hill, North Carolina), as well as the general population of children and their families being seen in respective sleep clinics.

Children who participated were evaluated across a number of variables addressing their sleep status and the arousals they experienced secondary to their SDB. This was done using standardized approaches to sleep assessment, including completion of a polysomnographic study while the child slept overnight (with a parent accompanying

them) in the clinical research laboratory. The children also underwent comprehensive assessments of their cognitive and behavioral status, including completion of a set of neuropsychological measures such as IQ and educational attainment, but also attention, problem solving, and memory tasks; parent reports about their development and sleep profiles; questionnaires regarding emotional and behavioral regulation; and an assessment of their sleep efficiency.

The study aimed to apply specific theoretical approaches to address the potential relationships between SDB and cognitive inefficiency, as well as behavioral difficulties that are often seen as a result of sleep problems and sometimes misdiagnosed as a disorder such as Attention-Deficit/Hyperactivity Disorder (ADHD). Because substantial prior research has focused most directly on children representative of a White/White American suburban middle-class background, the research team determined that, with their approach, the study required being more directly inclusive of a wider range of children across cultures and socioeconomic status backgrounds.

The principal investigators expressed a particular concern about the possible variability that might be found, given educational differences across cultural and racial groups, socioeconomic differences the families experience, and differences secondary to gender that all contribute to health challenges that underlie snoring and SDB. As a result, they developed the study as a comparison across groups recruited both within and across the settings in which recruitment took place (e.g., families coming to an urban hospital that was situated within a more diverse section of the city, such that Latino/Hispanic/Latinx and Black/African American/Black American children were readily able to be included, versus children from a setting that was more suburban and less diverse in terms of socioeconomic and cultural groups recruited).

The researchers discussed with their statistician the need to focus on multiple potential moderating variables, including race and ethnicity, but also parental education and income, type of educational setting, availability of physical activities for recreation, and resources such as a local grocery store with an affordable range of healthy food choices. One particular consideration for the research team was potential vulnerability to SDB; the study's Principal Investigator (PI) in particular was concerned that, based on previous studies, it was known that obesity contributes to a greater likelihood of developing SDB, and children of Latino/Hispanic/Latinx and Black/African American/Black American backgrounds were more prone to being identified as obese.

Results from the study were particularly informative; they highlighted a number of potential effects, such as the strong influence of SDB on neuropsychological profiles in the attention and executive functioning domains, and less successful grade profiles. More importantly, however, the researchers identified that differences in socioeconomic background were a significant moderator of these effects. Specifically, children with lower available financial resources appeared to show a greater impact of SDB on their learning and skill development. To better address these concerns, the team turned to their statistician to utilize a set of analytic approaches to the data. These approaches more effectively allowed for matching subjects across the range of variables identified as

showing cultural and racial differences to better explore and address these important factors. They also felt that this allowed for a greater emphasis on multicultural factors in the onset and expression of a challenging health concern. In turn, it was thought that this approach would more effectively engage the public and guide physicians to pay closer attention to sleep in their patients.

Questions for Discussion:

4. When addressing the prevalence and impact of sleep disordered breathing in their subject populations, what were the important factors requiring attention, given differences regarding a range of cultural and racial/ethnic factors?
5. When conducting research regarding the interaction between physical and psychological concerns, like sleep and cognition, what would you highlight as an important set of considerations to develop an appropriate study sample and ensure appropriate statistical considerations?
6. Because factors such as race and sociocultural status intersect, how can a research team effectively parse the potential impact of these factors on study design and analysis?

Guideline 2. Psychologists aspire to recognize and understand that as cultural beings, they hold attitudes and beliefs that can influence their perceptions of and interactions with others as well as their clinical and empirical conceptualizations. As such, psychologists strive to move beyond conceptualizations rooted in categorical assumptions, biases, and/or formulations based on limited knowledge about individuals and communities.

C. Marcus: Exploring Stereotypes and Microaggressions

Marcus is a 40-year-old cisgender, heterosexual African American man who has been coping with anxiety and panic attacks since he was in his early 20s. He worked with a therapist previously for a few sessions, but did not find this experience helpful. He reported that his previous therapist appeared uncomfortable and unsympathetic with his concerns about the challenges he faced at his workplace. As the intensity of his anxiety symptoms increased over the past year, he decided to seek help from another therapist. In his first session with this new therapist, Marcus disclosed that he felt overwhelmed by work-related pressures, and that he felt as though he was always looking over his shoulder to be sure that he could maintain his position.

Marcus grew up in a low-income neighborhood where he struggled with traumatic events on a regular basis. He described his relationship with his parents and his older sister as close, but reported that the family coped with stress related to long work hours for his parents, and with ongoing violence in their neighborhood and schools. Marcus would frequently hear shots being fired or learn about people being robbed.

Marcus received scholarships to attend a high school far away from home, and subsequently to college, where he studied engineering. He described his experience of

leaving home as "confusing and difficult," as he missed his family and friends, and the predominantly White institutions he attended felt unfamiliar. Marcus's focus and drive to excel academically brought new economic opportunities, and he was able to help his family financially. However, Marcus remained feeling "like an outsider" at school and later at work. He has also dreaded being around extended family since he left for college as several family members have commented that he acts as though he "is above them." Marcus noted that he had experienced anxiety throughout his life, first due to the violence near his home, and later due to a lack of safety and belonging when living away from his family home.

Marcus shared with the therapist that he continues to feel as though he constantly has to work harder than anyone in his workplace to maintain the managerial level position he has achieved. Marcus also told his therapist that his co-workers, none of whom are African American, assume that he has always been wealthy given his educational opportunities, and yet, on the other hand, project stereotypes about African American men as being lazy and aggressive. He struggles with others' perceptions of him, feeling as if they "box" him into ideas about who he should be, rather than reflecting who he really is. Marcus indicates to the therapist that he does not want to be put in a "box" or category. His experience of being stereotyped and categorized has taken a significant toll on Marcus's psychological well-being, as evidenced in his anxiety and panic attacks. Sometimes, he even wonders if his success is due to affirmative action rather than his own ability, and whether or not he can continue to be successful.

Questions for Discussion:

5. What reactions and feelings come up for you as you read about Marcus and his therapist? How might these feelings influence the way you might interact with Marcus?
6. How does your current knowledge or understanding of African American men's racial and social class experiences inform how you might conceptualize Marcus's concerns?
7. Have you had the experience of feeling "boxed in" or categorized by others based on their understanding of people from racial or sociocultural backgrounds with whom you identify?
8. How have you tried to help clients cope with isolation related to stereotyping or discrimination? What types of resources outside of counseling or psychotherapy have been helpful to your clients in addressing stereotyping and discrimination?

D. Melissa: Training Experiences as a Practicum Student

A 22-year-old, gender non-conforming psychology practicum student training on an inpatient unit shadowed a male psychologist. Dr. Samuel, an older, cisgender, heterosexual person, was a practicing evangelical Christian who integrated his deeply held beliefs with his approach to clinical and professional practice.

Shortly after beginning practicum, Melissa, who requested the pronoun "they"/"them" rather than "she"/"her" when others referred to Melissa, had a conversation with Dr.

Samuel, who discussed Biblical verses to frame a point being made. For instance, Dr. Samuel presented Melissa with a video to watch that discussed the importance of a Biblical framework for explaining human nature, and Melissa hesitantly obliged. However, Melissa identified as secular and feminist, and in actuality felt offended by Dr. Samuel's request. Given the power differential and role of a practicum student on an inpatient unit, Melissa felt obligated to converse with Dr. Samuel about his Christian beliefs and values within the context of his supervision of their work.

While Melissa never witnessed Dr. Samuel discussing his religion with his clients, they observed several ways in which they believed his religious orientation influenced how he dealt with female versus male patients on the unit. It appeared to Melissa that Dr. Samuel was often more dismissive toward his female patients by having shorter meetings with them and being more directive regarding how to progress with treatment, in comparison with their observations of his interactions with male patients. They also observed that Dr. Samuel would address his White patients differently than patients of color and those who spoke a primary language other than English. They noticed that Dr. Samuel was quick to diagnose patients of color and those less proficient in English, and he was often more dismissive of their communications with him. On the other hand, he appeared to spend more time trying to understand his White, English-speaking patients of different ethnicities and cultures. Melissa soon got the impression that many of the female patients and patients of color would rather work with the other psychologists on the unit.

Aside from patient-therapist interactions, Melissa also noticed that Dr. Samuel interacted differently with his coworkers. Notably, most of the professionals on the unit were women, and Dr. Samuel never shook hands with or made direct eye contact with these female colleagues; this was quite different from his interactions with male colleagues on the unit. Dr. Samuel's behaviors with both his colleagues and his patients made an impact on how he was often viewed by women coworkers on the unit, and Melissa overheard many conversations between staff members sharing the viewpoint that Dr. Samuel was disrespectful with them.

Questions for Discussion:

5. Discuss how stereotypes can be held by almost all individuals, no matter their ethnic, racial, religious, age, sexual orientation, and gender identity statuses, and the intersectionality of these backgrounds.
6. Discuss how unconscious beliefs and attitudes of both psychologists and student trainees can have an impact on clinical relationships with clients as well as coworkers. While clinicians and trainees may not intentionally react to clients and fellow professionals in a harmful or stereotypical way, discuss how they may hold implicit biases that drive reactions to clients or coworkers.
7. Could the given case be superimposed on a professional who is a fundamentalist Muslim; a conservative Brahman Hindu; a traditional Catholic; or an Orthodox Jew? Could the case be superimposed on a psychology practicum trainee of diverse self-definitions and identities, such as an international student, an immigrant, someone with refugee status, someone whose second language was English; someone with a gay, lesbian, or bisexual orientation; someone with a non-Western religious or spiritual

affiliation; or someone from an upper socioeconomic class?
8. What are your views about "color-blind democracy" in the theory, research, and practice of psychology?

Level 2 Case Illustrations: Community, School, and Family Context

Guideline 3. Psychologists strive to recognize and understand the role of language and communication through engagement that is sensitive to the lived experience of the individual, couple, family, group, community, and/or organizations with whom they interact. Psychologists also seek to understand how they bring their own language and communication to these interactions.

E. Dr. Enrique: Culturally and Linguistically Responsive Consultation

Dr. Enrique is a licensed Latino/Hispanic/Latinx male psychologist who has been contacted by the principal of a local Catholic school to consult with them about parent involvement. The school serves students in the elementary school years and is located in a low-resource neighborhood in the heart of a large metropolitan city. The student body is primarily Latino/Hispanic/Latinx with most children speaking Spanish at home. While instruction at the school is primarily taught in English, most of the students' parents are monolingual Spanish speakers.

When the principal contacts Dr. Enrique, she says that the teachers are very concerned about the lack of parent involvement. The school staff shares the belief that parent involvement is critical to the academic success of their students. Further, while the school has reached out and invited parents to events, the turnout has been low. The principal explains how the teachers interpret the lack of parent involvement as parents not caring about their children's academic success. Teachers are frustrated with the lack of response on behalf of the parents. The principal senses low morale among teachers and is concerned that this will have a negative effect on interactions between the school and students/families.

Dr. Enrique is motivated to learn more about the current situation and how to respond. First, Dr. Enrique reaches out to the teachers. He hears their concerns about the lack of parental involvement and participation. Dr. Enrique inquires about the events with no parent participation. He learns that they were advertised in English because the school did not have a translator. He also learns that the events were scheduled during the day at a time when many parents may have been working or taking care of young children.

Dr. Enrique suggests that the school plan another event. He reaches out to the principal, stating the invitation must come from the head of the school, and then trickle down through the teachers. Flyers are sent home in Spanish. The event is scheduled during the evening in hopes that parents will not be working. The flyer clearly states that child care will be offered and refreshments served. The flyer is sent out two weeks prior to the event, and then subsequently sent home in children's backpacks once a week for the following two weeks.

The night of the event approaches. Teachers and the principal are present, as are other administrators. Volunteers help watch the children as needed and a buffet dinner has been organized. Slowly parents begin to circle into the main hallway where the event is held. The room begins to fill to the point that there are more parents than teachers. Dr. Enrique opens the conversation in Spanish and English—welcoming everyone to the event.

As the conversation continues, he shares that the school invites parents to be more involved in the day-to-day life of the school. Teachers talk about specific ways that parents can come to school and participate in various activities. Parents share that their lack of engagement reflected their sense that it would be disrespectful to the school, specifically to the teachers, if they came in. They share that in their cultures, *respeto*, or having a sense of respect for others, is of utmost importance. Not participating in the life of the school is born out of concern that their participation would be viewed as a lack of *respeto*. Parents didn't want their children's teachers to think that they did not respect their role by being present at the school. They shared that in their cultures, parents tend not to get involved as an indication that they have the utmost trust in the teachers and their decisions.

Through communication of the two perspectives, the teachers can clearly share with the parents that they want them to be involved in the life of the school. They talk about how their school in the United States truly wants to build working partnerships with parents. Hearing the invitation, parents commit to greater involvement. It is as though having the teachers' permission prompts them to feel more comfortable with participating more fully.

Questions for Discussion:

5. What is your view of the consultant's role within a multicultural context?
6. How can the consultant understand and incorporate cultural values and perspectives in work with organizations?
7. How did Dr. Enrique respond to each of the constituencies involved in the school? How did his response encourage collaboration among constituencies?
8. How does Dr. Enrique's example inform your own work as an organizational consultant working within a multicultural context?

Guideline 4. Psychologists endeavor to be aware of the role of the social and physical environment in the lives of clients, students, research participants, and/or consultees.

F. Yasmin: Bridging Different Worlds

Yasmin is a 28-year-old Muslim, immigrant, cisgender woman from Pakistan. She continues to experience the loss of her husband who was killed in the September 11,

2001 collapse of the World Trade Center, where he worked in a small business. Yasmin has experienced numerous acts of racially motivated verbal and physical aggression since 9/11. She has also experienced the challenging demands of raising her son who was born with multiple disabilities.

After her husband's death, Yasmin's parents and parents-in-law came from Pakistan, taking turns living with her, supporting her, and helping her with child care. Their eventual departure was very difficult for her. For the past 5 years Yasmin has lived by herself.

Yasmin mourned for her husband for several years. She eventually entered into a relationship with another Pakistani man. This relationship helped Yasmin express herself in ways that helped her to be less conservative than previously. While romantic, this was not a sexual relationship. However, due to disagreements about the care of her son, Yasmin decided to end the relationship.

Yasmin was very close to her father until he passed away a few years ago. Between her father, husband, and former male companion, she always had a strong male figure in her life. When Yasmin decided to end the relationship with her companion, it was the first time that she was without close male guidance. Yasmin had to live independently. She struggled to pursue a career in retail, take care of herself, and meet the particularly challenging demands of her son who was completely dependent on her. Yasmin chose to stop wearing her hijab (a veil/head covering that often covers the head and chest) partly for her own protection from being stared or shouted at in public transportation, or in large stores. Nonetheless, she continues to face prejudice because of her accent and speech, physical appearance, behavioral differences, and gender practices. However, Yasmin has made friends, Pakistani as well as American, who have helped her in ways that she needed following the passing of her husband. However, Yasmin does not have the familial and communal support that she would have if she were in Pakistan. Despite these challenges, Yasmin is taking online courses to improve her career standing. Her perseverance through struggles attests to her resilience.

Yasmin is now dating a White/White American male whom she met at work. While this man is good to her son and Yasmin likes many aspects of an egalitarian relationship, she is bothered by his sexual advances. She likens his amorous behaviors to sexual assault and believes she is at risk for rape. Because of her Muslim faith and cultural gender role, Yasmin believes that intercourse should occur only after marriage. She feels immodest, thinking she is sexually provocative. Sometimes she thinks she is a sinner. Yasmin is filled with shame, thinking that she is letting down her mother, sisters, and mother-in-law, who had advised her to return home to them in Pakistan for her protection, sexual purity, and for the preservation of her conservative values and practices. Yasmin also feels guilt, thinking she will be unfaithful to her dead husband if she has sex.

Questions for Discussion:

6. Describe practitioners' self-reflections about a dominant society's use of oppression, privilege, and power over religious minority groups and individuals; their

reflective self-examination of their own biases and stereotypes about Islam and its followers; their ever-present awareness of their multiple social identities as well as those of others; the biases that exist because of such identities; and how their interactions with others are based on these identities.

7. How would a psychologist incorporate trauma and resilience when working with a culturally diverse person who has suffered continuous life stressors including racism, discrimination, and societal hatred? How would a psychologist evaluate theoretical adaptations to demonstrate evidence-based practice?

8. Discuss practitioners' need to understand Islamic tenets and the differences between Muslim culture and that of the United States. Discuss an understanding of how much a particular Muslim immigrant is committed to such ideals and how difficult it may be to remain committed to one's faith in the United States; how it might be common for Muslim women living in the United States to struggle with the difference in women's roles in the United States versus those in an Islamic culture; and how such underlying gender roles may make clients uncomfortable with a practitioner.

9. How would Yasmin define self, community, and their relationship with each other?

10. Describe Yasmin's challenges as she adapts to life in a highly individualistic environment as opposed to the collectivist family culture she was used to.

N. Anthony: Having an Identity That Extends Beyond One's Disability

Anthony, a 25-year-old, cisgender, biracial/multi-ethnic (Black/African American/Black American, White/White American, Latino/Hispanic/Latinx) male, was referred for individual psychotherapy in conjunction with his participation in ongoing vocational rehabilitation programming. He presented with a history of mild intellectual disability that was acquired secondary to a traumatic brain injury (TBI) he sustained during early adolescence when he was in a motor vehicle accident with his family. Of note, Anthony and his brother were the only members of their family to survive the accident, and both sustained significant TBI's.

Anthony was fifteen at the time of the accident, and he had been highly functioning prior to his TBI. Before sustaining his injury, Anthony had been enrolled in a college prep high school program and was active in both athletics and extracurricular activities, including chess and computer design clubs. He and his brother, who is three years younger than Anthony, were the middle children in a large family of six boys and two girls. Anthony lost both his parents and two of his siblings in the accident. Two older siblings (males), both of whom were adults and living on their own at the time of the accident, now serve as guardians for Anthony and his brother. The two youngest siblings (one male, one female), were also not in the car at the time of the accident. Subsequent to the accident they were raised by an aunt who lived in a nearby city. Anthony visits these two younger siblings during the holidays and at family gatherings.

Anthony's case manager, when discussing current concerns with the psychologist, indicated that Anthony had been struggling of late with impulse control, particularly around select peers, both male and female. This led to difficulties both at his residence, a

group home program for young men who have neurodevelopmental challenges, and in the sheltered employment program Anthony participates in weekly. The case manager indicated that she suspected some of his impulsivity, which has included inappropriate language and touching, was related to Anthony's desire to be more like his typical peers who are in relationships. She shared that she and the staff working with Anthony were seeking guidance on how to best support him in making better behavioral choices, particularly around his romantic and sexual feelings. The case manager also shared that they were looking to provide Anthony with an opportunity to more directly address his feelings of difference that appear to have an impact on his mood.

At first, therapeutic work with Anthony focused on helping him share his current experience of himself as a man with an acquired neurodevelopmental disorder as well as to gain an understanding of how his viewpoint about himself had changed. This work was done in a context of Anthony's awareness of who he had been prior to the accident and what was different for him as a consequence of his injuries and the loss of some capabilities. It was clear from early on that Anthony's tendency to act and speak impulsively were primary consequences of his TBI. He sustained injuries to his developing executive skills, such that challenges were noted with flexibility, thinking strategically, and impulsivity, including saying inappropriate things as they came to mind. It also became evident that Anthony's recent behavioral difficulties, where he impulsively sought out more intimate interactions with male and female peers, were associated with efforts to be "more of who I used to be, someone who went on dates and had friends, who had people in my life who wanted to be around me."

Anthony shared that he often felt dismayed that he was now seen as "ugly" and "stupid" by other men and women he saw daily. He brought in a photo of himself, taken during adolescence and prior to his accident. Anthony actively compared what was different for him then with now; he focused specifically on the scar he had because of his neurosurgeries for his TBI; his loss of gross and fine motor skill, such as his inability to ambulate independently; and his altered growth, that made him much shorter than peers. Anthony began to talk more directly about what he had lost cognitively and emotionally because of the accident; sharing that he had been a budding wrestler and a good student before his TBI, and that he had many friends then too. Since then, his path had changed significantly, with many associated losses in terms of opportunities and expected outcomes. Anthony shared that he was most often reminded of these losses, including the fact that he had just been able to start dating shortly before the car accident, when he saw perceived neurotypical peers outside of his program and residence.

Anthony experienced significant and understandable sadness about these losses. He was able to identify that this led him to want to "change stuff" by making his life "normal." However, Anthony also admitted that some things could not easily be changed, like his inability to ambulate without a walker, and that he needed to use a wheelchair when required to go long distances. Anthony shared how this was a substantial limitation on his ability to ask a peer out on a date, or to spend time with a peer without adult supervision.

As treatment continued, discussions focused on Anthony's experience of these losses and their impact on his ability to see the possibility of a life that was more layered and optimistic. With regard to his impulsive actions, the therapist helped Anthony better understand his range of feelings regarding intimacy and sexuality. The therapist and Anthony took into account that he had physical and cognitive differences secondary to his TBI that affected how Anthony could share, verbally and through touch, his attraction to someone. As a man who was hampered in his mobility and capacity for physical contact across a variety of situations and settings, it was important for the therapist to help Anthony and his support team address how he, a young man with many typical wishes and desires both in terms of love and physical interest, could address these within home and work environments.

One important step forward occurred when Anthony was able to meet a wider range of peers, both for friendship and potential dating, and to work directly on how to discriminate between an interest in intimacy and frank sexual desires. Therapy additionally helped Anthony become more comfortable with how he could express and address his physical desires. This was accomplished in part through a better understanding of his own body and learning how to address feelings in a socially appropriate manner. Social scripts were developed, with coaching provided within treatment as well as with the teams at work and in the residence. This allowed Anthony to more effectively inhibit immediate wishes to connect through touching, that were often perceived as intrusive and inappropriate. Instead Anthony could work toward initiating interactions verbally, allowing boundaries to be established.

Anthony worked to recognize himself as not only someone with a disability, but also as a member of a wider array of communities, where his strengths and differences could be better appreciated. His beliefs of himself as "damaged" and "ugly" were challenged through opportunities to ask both how others perceived him, and through frank discussions about how this allied with and differed from his own expectations and perceptions. Anthony was supported in more directly mourning the trauma and losses he experienced, so that he could begin to conceptualize himself as both a survivor and as resilient. This led to two important changes: One, Anthony began to see himself as moving forward on a new trajectory, which, while different from his path prior to the accident, was still valid and open to many successes. Two, Anthony came to recognize that he himself could play a more active role in decision making. These changes led Anthony to seek out new opportunities within his vocational program and to open himself up to the interest a fellow peer had expressed with regard to dating him.

Questions for Discussion:

1. Describe practitioners' considerations regarding cognitive and physical disability, and how these are conceptualized within the dominant society's continued emphasis on privilege, oppression, and capability.
2. How would psychologists adapt trauma theory to address the challenges experienced by Anthony, a biracial/multi-ethnic man, who has lost both family and his

experience of himself as a functional member of the community? How would they evaluate theoretical adaptations to demonstrate evidence-based practice?

3. What is required of practitioners so they can have an understanding of how disability is experienced within the United States? What can promote an understanding of how individuals with cognitive and physical challenges experience daily life that can subsequently facilitate more effective problem solving within supportive treatments?

4. How can a therapist consider disability across multiple levels of identity? What are the implications of these considerations for understanding intersectionality?

O. Jung: Access to Culturally Relevant Treatment

Jung is a 70-year-old Korean woman who married an American soldier and came back to the United States with him when he left the service. They lived in a rural area of northern Maine, where her husband was a fisherman until his death five years ago. Jung's English proficiency is minimal and she suffers from left-sided paralysis secondary to a stroke. Since her husband's death, Jung has become increasingly depressed because there are no Koreans living nearby and her disability limits travel. Jung has become increasingly isolated, her only social contact being a friendly postman and the grocery store clerk who delivers her food.

Jung's primary care doctor realizes there is a problem but Jung's limited ability to speak English and reticence to talk about mental health issues interfere with any care beyond medication. A search of local mental health providers revealed there is no one within 100 miles who speaks even limited Korean. Jung shuts down when the doctor encourages her to try a telephone interpreting service. In desperation, the doctor contacted the Korean Consulate and spoke with staffers working in a facility in Nova Scotia, the closest to Jung's home. The consulate arranged for a psychologist fluent in the Korean language to speak with Jung via the Internet on a monthly basis while she is at the doctor's office.

Questions for Discussion:

3. How could Jung's relationships with the delivery person and the grocery clerk be incorporated into achieving her treatment goals to help her feel less isolated?

4. How could local resources, in addition to the postman and clerk, help in providing a more beneficial environment for Jung?

Level 3 Case Illustrations: Institutional Impact on Engagement

Guideline 5. Psychologists aspire to recognize and understand historical and contemporary experiences with power, privilege, and oppression. As such, they seek to address institutional barriers and related inequities, disproportionalities, and disparities of law enforcement, administration of criminal justice, educational, mental

health, and other systems as they seek to promote justice, human rights, and access to quality and equitable mental and behavioral health services.

P. Aiden: Struggling with Loss, Grief, and Inequity

Aiden is a 10-year-old, White/White American boy of Irish descent, who was referred to a psychologist by his school counselor. Aiden has been struggling with completing his schoolwork and concentrating on tasks. According to his teachers, he has been disruptive in class and unable to complete homework on a regular basis. His grades have declined over the course of several marking periods. While the school recommended an evaluation, the process was delayed due to Aiden's father's hesitancy to engage in the testing process. Rather, Aiden's father repeatedly shared that his son didn't have psychological issues, stating that his behavior was just reflective of his being a kid. He continued to encourage Aiden to focus on his schoolwork and not let feelings "get in the way" of academic success.

It was when Aiden's grades dropped substantially that his father finally agreed to the evaluation process. Aiden was evaluated for a learning disability. Testing results indicated that he did not have a learning disability, but rather, issues of grief and loss were affecting his academic life. The evaluator recommended that Aiden be referred for psychotherapy.

After some hesitation, Aiden's father agreed; however, the start of therapy was further delayed by the family's lack of health insurance coverage for treatment. The school was eventually able to connect the family with a community-based mental health center that could work with Aiden at a reduced fee. Aiden lives with his father, who works long hours in two different grocery stores to support his family. Aiden's mother died of ovarian cancer when he was 7 years old. Aiden and his father were devastated by her illness, which progressed quite quickly and led to her death just 7 months after initial diagnosis. No other family members were living near Aiden and his father. Aiden's father had struggled with maintaining stable employment, and was overwhelmed with grief over his wife's death. Aiden's mother was also the primary household earner and her death resulted in additional economic challenges for her husband and son, who lost their health insurance.

While Aiden's father eventually agreed to therapy for his son at the community-based mental health center, he underestimated the impact of their traumatic loss on both of them. He also doubted whether someone he considered to be a "professional person" would be able to understand the loss and poverty that he and his son were experiencing. Aiden's father feels unable to fully support his son emotionally, given his tremendous responsibilities securing money for food and rent. A salient source of support became the Catholic Church that Aiden and his father attended on most Sundays. A few people from the church offered emotional support but later expressed their feelings of inadequacy related to providing academic support.

Questions for Discussion:

5. How does the role of stigma affect Aiden's access to treatment?
6. How does a lack of resources influence the family's access to treatment and health care?
7. What role does cultural mistrust play in Aiden's father's willingness to have his son engage in treatment?
8. In your role as a psychologist, how have you engaged in trauma-informed practice?

Guideline 6. Psychologists seek to promote culturally adaptive interventions and advocacy within and across systems, including prevention, early intervention, and recovery.

Q. Dr. Amy: Multiculturally Informed Advocacy

Dr. Amy has been asked to consult with a community advocacy group to help develop and implement a parenting program for families with young children. The advocacy group is very connected to the diverse community in which it is housed. As such, there is a history of relationships between the organization and the surrounding neighborhood. Dr. Amy's task is to help staff plan, market, and implement a parenting program for parents with young children from birth to age 3. The group's decision to develop such a program stems from an awareness of the increasing number of young families moving into the neighborhood along with the number of parents referred to the clinic by child protective services.

The parenting program's advocacy goal is to provide parents of infants and toddlers a place to go—at no cost—where they can learn parenting skills and interact with one another. The parenting program is geared primarily toward early intervention, since eligible parents must have children from birth to age 3. The preventive aspect of the program aims to encourage learning and parent interactions before a crisis occurs, rather than during or afterwards.

To ensure the program reflects the community's demographic composition, Dr. Amy and parenting center staff walk throughout the neighborhood to talk with parents about their interest. Through these informal conversations, they learn that many parents have felt isolated since having a child. Several mothers share that they are the only parent raising their child. They talk about the lack of a social support network and feeling that they lack a voice in their communities. Some parents talk about being depressed since the birth of their child. They talk about feeling overwhelmed to the point of waking up in the morning wondering how they are going to live up to their parental responsibilities throughout the day. These conversations help Dr. Amy and her colleagues recognize that the parent program should be a safe haven where parents can interact with one another in addition to staff.

A series of workshops are organized that aim to be responsive to the struggles shared by the parents with whom they spoke. Topics such as "father involvement," "post-partum depression," "parenting style," "work/family balance," and "stress management" are all key concerns. Workshops are also responsive to the neighborhood's linguistic and cultural diversity. Written information and workshops are presented in the languages spoken within the surrounding community. The program also works to develop collaborative relationships with parents in the community. As parents enroll, they are encouraged to recommend topics of discussion that reflect what they are experiencing. Parents enjoy coming in with their babies and toddlers. They learn about community resources and talk about shared challenges. Over time, the number of referrals from child protective services decreases.

Questions for Discussion:

5. How did Dr. Amy effectively engage in advocacy efforts that supported the community?
6. In what culturally responsive ways can psychologists engage in advocacy efforts?
7. What are some of the barriers to effective community-based advocacy? How can these barriers be addressed?
8. In your role as a practicing psychologist, are there ways that prevention and early intervention can promote positive outcomes?

Level 4 Case Illustrations: Domestic and International Climate

Guideline 7. Psychologists endeavor to examine the profession's assumptions and practices within an international context, whether domestically or internationally based, and consider how this globalization has an impact on the psychologist's self-definition, purpose, role, and function.

R. Michael: Identity and Refugee Status

Michael is a 24-year-old African refugee in the United States who was born and raised in Ethiopia. He identifies as cisgender male, heterosexual, and being poor. Michael came to the United States via Uganda where he took part in a struggle to overthrow a post-colonial military regime. Michael traveled to the United States on a student visa; however, the visa was a means of escape from Africa and he was not registered as a student in the United States. This visa has long expired and he is presently undocumented. While Michael was not his birth name; it was the name of his Ugandan friend who arranged for Michael to travel to the United States in his place. The issue of names and identity is central to Michael's life.

One of Michael's first acts upon leaving Ethiopia was to abandon his thirteen names, each taken from a preceding generation in his family. With this symbolic erasure of his past, Michael believed that he had entered the world with a blank slate, and could define his identity anew. Michael found Uganda in the midst of its own nationalistic identity crisis, trying to fill the void left by British colonists. This country, with its abundance of

revolutionary sentiment, was the perfect place for Michael to redefine himself. Michael and his friend, the original Michael, organized groups at a university where they were both pretending to be students, to protest human rights violations by the military government. However, the activism became armed revolution, and Michael felt lost and conflicted. He believed in liberation but could not be the violent radical that a nationalistic context now esteemed.

Some time later, Michael travelled to a Midwestern college town in the United States where he encountered a new set of dynamics around identity. In Uganda, Michael was an outsider enamored with a revolution but not willing to kill. In the United States, as an African, he was expected to accept his social position as a second-class, invisible person of color. Two different structural systems invited two opposing identities. The result was that Michael saw himself as a traitor, abandoning his African compatriots and beloved friends, including his namesake, who lost his life fighting for freedom. At the same time, Michael experienced himself as a maladjusted acquiescent person who accepted a subordinate identity enforced by a racist and classist society.

Questions for Discussion:

5. What are some practitioners' self-reflections regarding their values, beliefs, and assumptions about refugees coming to the United States from countries with civil strife; and about their knowledge of political uprisings, dictatorships, and religious and ethnic cleansing in African, Arabic, and/or Middle Eastern nations?
6. How would a psychologist do a structured intake on personal and family history with Michael, who is a reticent and distrusting interviewee?
7. Describe Michael's various cultural and social identities and their intersectionality. Which are dictated externally and have developed into an existential problem of a lack of self-knowledge?
8. Describe a community-based intervention that may help Michael incorporate and internalize a revolutionary aspect into his identity.

Guideline 8. Psychologists seek awareness and understanding of how developmental stages and life transitions intersect with the larger biosociocultural context, how identity evolves as a function of such intersections, and how these different socialization and maturation experiences influence worldview and identity.

S. Mary: A Focus on the Interpersonal Instead of the Contextual

Mary is a 17-year-old Japanese American–born teenager raised in the United States. She is currently facing the prospect of taking the SAT and other national exams required to apply for college. While a bright student with a straight A average in high school, Mary has become increasingly anxious about taking the exams. As a result, she refuses to take the step of actually signing up to take them. Her parents, who were born in Japan, are bewildered about her refusal and anxiety, and what they increasingly see as self-destructive behavior.

Since early childhood, Mary's parents have enrolled her in afterschool educational support activities, similar to the *juku*, or private educational organizations that provide additional academic experiences outside the school setting in Japan. Mary's mother stopped working after she was born so she could devote herself to her daughter's development.

On some level, she feels that Mary's current struggles must reflect a failure on her part. On another level, Mary's mother feels frustrated that the sacrifice she made with regard to giving up her career to raise her daughter has not been rewarded by a motivation on her daughter's part to attend college.

After consultation with Mary's pediatrician, her parents have taken the step of having her see a psychologist. The latter is a non-Latino/Hispanic/Latinx White/White American professional who views Mary's behavior as simply acting out and resisting parental authority. He is unaware of the significance with which national exams are often viewed in Japan. He is also unaware of the trend to engage children in outside academic activities starting at a very young age that is a tradition for this family. Mary's parents tell the psychologist that they are devastated by what they perceive as a lack of motivation, especially given the overarching importance they have placed on these exams throughout her adolescence. The psychologist continues to frame the issue as one that reflects adolescent development and resistance to authority. As a result, he employs a CBT approach designed to address parent-child relations and issues of adolescent development instead of the generational and cultural conflict at play.

Questions for Discussion:

5. In what ways can the psychologist incorporate a multicultural framework in working with Mary and her family?
6. What are some of the intergenerational issues that affect family relationships and functioning?
7. As a psychologist taking a systemic approach, in what ways can you be responsive to the concerns of both Mary and her parents?
8. What are some of the developmental issues that may currently have an impact on Mary's experience, as well as that of her parents?

Level 5 Case Illustrations: Outcomes

Guideline 9. Psychologists strive to conduct culturally appropriate and informed research, teaching, supervision, consultation, assessment, interpretation, diagnosis,

***dissemination, and evaluation of efficacy as they address the first four levels of the* Layered Ecological Model of the Multicultural Guidelines**.

T. Community-Based Research

A research psychologist new to the local university was interested in assessing depressive symptomatology among American Indian residents of a nearby tribal reservation. She approached the local tribal council and asked for their help in recruiting subjects. After a week of deliberation, the council firmly refused to grant her request. When the disappointed psychologist asked for an explanation, the head of the council initially said that it didn't seem like the project would benefit local members of his tribe. When pressed, he admitted that her university had a long history of doing research in the town without informing anyone of the results or working with the community. As a result, community leaders had become united in rejecting any proposed research by university faculty.

The psychologist expressed her disappointment but said she understood the concerns and would do her best to demonstrate her commitment to the community. For the next three years she worked closely with the town's tribal council on a number of projects that they initiated and participated in several activities designed to assist tribal members. When she finally revisited the possibility of research on depression, the council members wrote letters of support and actively assisted in recruitment.

Questions for Discussion:

5. As psychologists conducting community-based research, what are some considerations for building relationships in the community?
6. How can research psychologists be aware of the experiences of the communities in which they are conducting research?
7. How does this case reflect your own experiences conducting community-based research?
8. In what ways can research psychologists give back to the communities where their research is being conducted?

Guideline 10. Psychologists actively strive to take a strength-based approach when working with individuals, families, groups, communities, and organizations that seeks to build resilience and decrease trauma within the sociocultural context.

N. The Oregano Family: Working with Mental Health and Faith-Based Communities in Clinical Training

Six weeks prior to being seen at the university counseling center, the Oregano family suffered a devastating tragedy when Mr. Oregano, the husband and father of three children, was in a fatal plane crash. Traveling back home on a consumer airline, sudden lightening caused an electrical outage that led to the crash. Mrs. Oregano and her three children, ages 4, 10, and 16, come to counseling presenting symptoms of post-traumatic

stress. Understandably, the 4-year-old continues to ask when his father is going to return home.

The service provider is a doctoral student who is supervised by a licensed psychologist. The doctoral student is working with the Oregano family as part of a clinical practicum experience. From the beginning of their work together, Mrs. Oregano has expressed concern about the status of her late husband's afterlife. A devout Roman Catholic, she shares that the family has no body to bury, something profoundly important to someone whose faith believes in resurrection of the body. She expresses her concern to the trainee, sharing that a formal burial will help the family and future generations remember her late husband, while also respecting the saints. She shares with the trainee the teachings of her priest and is overwhelmed with grief related not only to loss, but also to concerns about her late husband's afterlife.

The trainee focuses on the symptoms Mrs. Oregano and her children are experiencing. Uncertain how to address the role of religion for this family, the trainee avoids it, minimizing family concerns in this area, focusing solely on the post-traumatic stress symptoms. The family begins to attend psychotherapy sporadically, which the trainee interprets as resistance to dealing with the loss.

The supervisor encourages the trainee to ask the family about their faith and the concerns the lack of a burial presents. Treatment seems to shift as Mrs. Oregano and her oldest child talk about their visits with their priest and the solace they get from the church. The supervisor increasingly encourages the trainee to incorporate the "voice" of the priest in sessions. In other words, the trainee is to ask about what the priest would say in response to current struggles and stresses. In this way, the supervisor invites the trainee to consider the importance of both mental health and faith. The Oregano family can approach their loss through an integration of both perspectives, rather than feeling they have to choose one over the other.

Questions for Discussion:

5. What does the supervisor encourage the trainee to understand when taking a culturally informed approach to education and training?
6. What are the goals of supervision that takes a culturally informed approach?
7. What are some of the challenges that might emerge for supervisor and supervisee in the context of supervision that takes this approach?
8. How can using an awareness of internal and contextual biases reduce or remove potential tensions in supervision?

O. Lucy: Fear about a Marriage Ending

Lucy is a 36-year-old White/White American transgender woman who has sought help from a psychologist to cope with her anxiety related to her relationship with her wife. Lucy has been employed in a pharmaceutical company for over eight years. She has grown increasingly anxious about the stability of her marriage, as she suspects that her

wife may be romantically involved with someone else. Lucy sometimes experiences panic symptoms, and feels overwhelmed by the prospect of her marriage ending.

Lucy grew up in a home in a rural area of the United States with her two siblings, parents, and grandparents. She describes her parents as "progressive and accepting," and as supportive when, in her teens, she told them that she was a girl. Her parents encouraged Lucy to work with a therapist at this time, which was an important source of support for her. However, Lucy was severely bullied by peers who verbally and physically attacked her in and out of school. She coped with these traumatic experiences through the use of substances such as alcohol and marijuana. Lucy described this time of her life as "most painful and depressing" and often thought of ending her life. She decided to attend college in a city far from her family home to escape the trauma she endured as an adolescent. While Lucy had not worked with a therapist since high school, she connected with a transgender community in college, and continued to form friendships with people she experienced as supportive and caring toward her. Soon after college, she met a cisgender woman whom she dated for several years and later married. Lucy feels that her wife has been a central figure in her life and someone who has advocated for her. This has been especially important in circumstances at work when Lucy has faced transphobic and heterosexist comments from coworkers.

Lucy has done hormone replacement therapy for several years, and more recently, has been considering sexual reassignment surgery (SRS). However, she feels confused about whether to pursue this, as her wife is against the idea of surgery, and has told Lucy that she "passes" as a woman without it. Lucy has felt hurt by these comments and wonders whether her wife truly understands what it means for her to be a transgender woman. At the same time, Lucy believes that her wife has been the one person she has relied on to help her cope with hostility based on her gender identity and sexual orientation. Their tension has escalated over the past year, and increasingly, Lucy has suspected that her wife is losing interest in being with her. Lucy worries that these conflicts may lead to separation or divorce. She is terrified of this potential loss and worries that she may cope with her anxiety by using substances or hurting herself in some other way.

Questions for Discussion:

5. What reactions do you have after reading about Lucy's experiences? What experience have you had in working with transgender clients?
6. How would you conceptualize the role of trauma in Lucy's life?
7. How would you approach helping Lucy with her anxiety, considering her past history of substance use, depression, and suicidal ideation?
8. In what ways do others' perceptions of Lucy's gender identity and sexual orientation affect her identity and relationships

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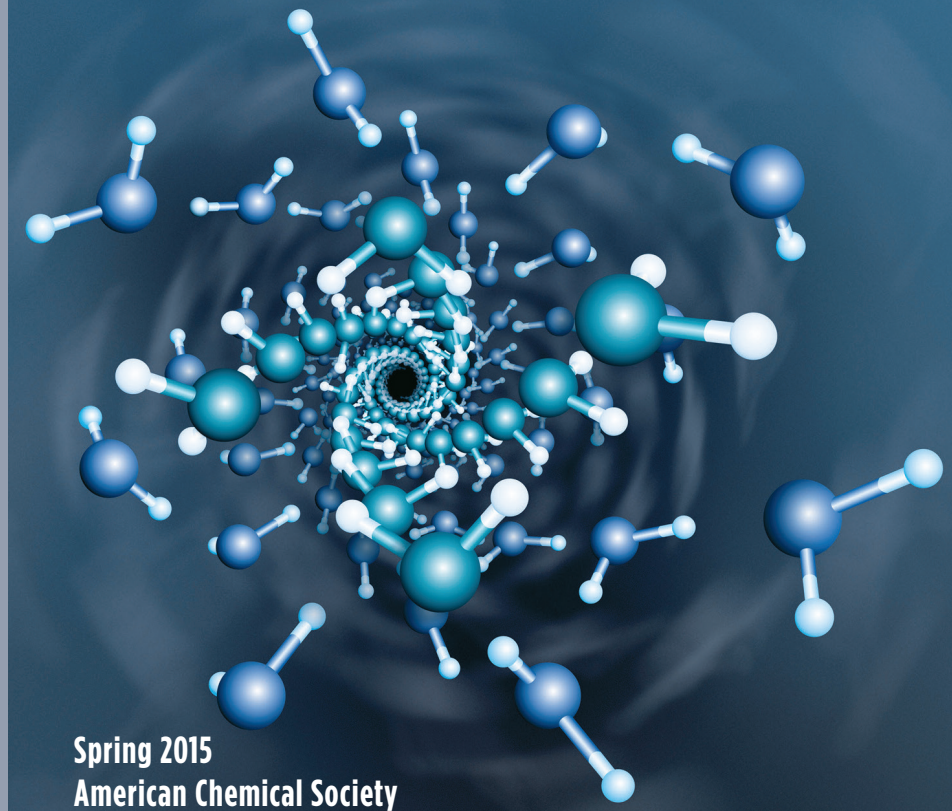

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ACS recognizes that the chemistry program would make appropriate accommodations for students with temporary or permanent disabilities to allow them to complete degree and certification requirements.

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I. GUIDELINES FOR PROGRAM APPROVAL AND STUDENT CERTIFICATION

1. Goals of Program Approval and Student Certification

Chemistry is central to intellectual and technological advances in many areas of science. The traditional boundaries between chemistry subdisciplines are blurring, and chemistry increasingly overlaps with other sciences. Unchanged, however, is the molecular perspective that lies at the heart of chemistry. Chemistry programs have the responsibility to communicate this molecular view to their students and to teach the skills necessary for their students to apply this perspective.

The American Chemical Society (ACS) promotes excellence in chemistry education for undergraduate students through approval of baccalaureate chemistry programs. ACS has charged the Committee on Professional Training (CPT) with the development and administration of guidelines for this purpose. ***ACS, through CPT, approves chemistry programs*** meeting the ACS guidelines. Approved programs offer their students a broad-based and rigorous chemistry education that provides them with the intellectual, experimental, and communication skills necessary to become successful scientific professionals. Offering such a rigorous program requires an energetic and accomplished faculty, a modern and well-maintained infrastructure, and a coherent chemistry curriculum that develops content knowledge and broader skills through the utilization of effective pedagogical approaches. ACS recognizes that the diversity of institutions and students is a strength in higher education. Thus, these guidelines provide approved programs with opportunities to develop chemistry degree tracks that are appropriate to the educational missions of their institutions.

ACS authorizes the chair of the ACS-approved program to certify graduating students who complete a bachelor's degree meeting the ACS guidelines. Graduates who attain a certified degree must complete requirements that may in fact exceed those of the degree-granting institution, but this comprehensive undergraduate experience provides an excellent foundation for a career in the molecular sciences. An ACS-certified degree signifies that a student has completed an integrated, rigorous program including introductory and foundational course work in chemistry and in-depth course work in chemistry or chemistry-related fields. The certified degree also

emphasizes laboratory experience and the development of professional skills needed to be an effective chemist. Certification gives a student an identity as a chemist and helps in the transition from undergraduate studies to professional studies or employment.

ACS approval publicly recognizes the excellent chemistry education opportunities provided by an institution to its students. It also provides standards for a chemistry curriculum based on broad community expectations that are useful for a program when designing its curriculum or acquiring resources. The approval process provides a mechanism for faculty to evaluate their programs, identify areas of strength and opportunities for change, and leverage support from their institutions and external agencies. Faculty benefit from the commitment to professional development required of approved programs. Students benefit from taking chemistry courses from a program that meets the high standards of ACS approval, and ACS-certified graduates benefit from their broad, rigorous education in chemistry and the recognition associated with their degree.

2. Institutional Environment

An approved chemistry program requires a substantial institutional commitment to an environment that supports long-term excellence. Because the approved program exists in the context of the institutional mission, it must support the needs, career goals, and interests of the institution's students. Competitive policies should be implemented regarding faculty salaries, duties, promotions, and tenure decisions. Similarly, in order to support a viable and sustainable chemistry program, the institutional environment must provide the attributes described in this section.

2.1 Institutional Accreditation. The institution must be accredited by the regional accrediting body. Such accreditation ensures broad institutional support in areas such as mathematics, related sciences, and the humanities.

2.2 Program Organization. The administration of the approved program should rest in a chemistry department organized as an independent unit with control over an adequate budget, faculty selection and promotion, curriculum development, and assignment of teaching responsibilities. If the program is

part of a larger unit, the chemistry faculty must have reasonable autonomy over these functions.

2.3 Program Budget. An approved chemistry program requires continuing and stable financial support. The institution must have the ability and will to make such a commitment at a reasonable level that is consistent with the resources of the institution and its educational mission. Adequate support enables a program to have

- a chemistry faculty with the scientific breadth to offer the educational experiences described in these guidelines,
- nonacademic staff and resources for administrative support services, stockroom administration, and instrument and equipment maintenance,
- a physical plant that meets modern safety standards with adequate waste-handling and disposal facilities,
- resources for capital equipment acquisition and replacement along with the expendable supplies required for high-quality laboratory instruction,
- modern chemical information resources,
- support for maintaining and updating instructional technology,
- research resources for faculty and students,
- personnel support to assist with the acquisition and administration of external funding,
- support for faculty and student travel to professional meetings, and
- opportunities for professional development and scholarly growth by the faculty, including sabbatical leaves.

2.4 Minimum Number of Graduates. Initial and continuing approval requires that the program award an average of at least two chemistry degrees per year during any six-year period. There is no required minimum number of certified graduates.

3. Faculty and Staff

Faculty members are responsible for defining and executing the overall goals of the undergraduate program. The faculty facilitates student learning of content knowledge and development of professional skills that constitute an undergraduate chemistry education. An energetic and accomplished faculty is

essential to an excellent undergraduate program. An approved program therefore has mechanisms in place to maintain the professional competence of its faculty, provide faculty development and mentoring opportunities, and provide regular feedback regarding faculty performance.

3.1 Faculty. The faculty of an approved program should have a range of educational backgrounds and the expertise to provide a sustainable, robust, and engaging environment in which to educate students. In addition:

- There must be at least five full-time permanent faculty members wholly committed to the chemistry program. Most vigorous and sustainable approved programs have a larger number. Currently approved programs with fewer than five permanent faculty will have until 2025 to meet this requirement. In cases where faculty contracts are renewed on a regular basis, the individuals in these positions should hold the expectation for both long-term and full-time employment.
- At least 75% of the permanent chemistry faculty members must hold the Ph.D. or an equivalent research degree.

The collective expertise of the faculty should reflect the breadth of the major areas of modern chemistry. Because faculty members serve as important professional role models, an ACS-approved program should have a faculty that is diverse in gender, race, and ethnic background.

3.2 Adjunct, Temporary, and Part-Time Faculty. Courses leading to student certification in an approved program should be taught by permanent faculty. Programs may occasionally engage highly qualified individuals outside the regular faculty to deliver special courses or to replace permanent faculty members who are on sabbatical or other leaves of absence. The Committee strongly discourages excessive reliance on temporary or part-time faculty by an ACS-approved program and carefully reviews such situations.

3.3 Teaching Contact Hours. Contact hours are the actual time spent by faculty and instructional staff in the direct supervision of students in a classroom (face-to-face or online) or laboratory. Online activities that are developed as substitutes for classroom instruction should be assigned at least the same contact hour value as equivalent face-to-face classroom experiences. The institution's policies about teaching contact hours should provide all faculty and instructional staff adequate time for professional development, regular curriculum assessment and improvement, contact with

students outside of class, and when appropriate, supervision of research. For the purpose of these guidelines, the following two groups of faculty and instructional staff are identified, based on their teaching responsibilities:

Group A. For faculty and instructional staff who teach only in the classroom or in both the classroom and laboratory, the number of contact hours *must not exceed 15 total hours per week.* Fifteen contact hours is an upper limit, and a significantly smaller number should be the normal teaching obligation, particularly for faculty supervising undergraduate research.

Group B. For faculty and instructional staff who teach exclusively laboratory courses, the number of contact hours *must not exceed 16 total hours per week.*

In any given academic year, exceptions may be made for up to two individuals in Group A and two individuals in Group B above, provided that:

- The average for each individual in Group A does not exceed 15 contact hours per week during the academic year and the average for each individual in Group B does not exceed 16 contact hours per week.
- The maximum for each individual does not exceed 18 contact hours in any semester or quarter.
- The maximum contact hours for each individual are exceeded in only one quarter or semester of the academic year.

3.4 Professional Development. Institutional policies and practices should provide opportunity and resources for scholarly activities that allow faculty and instructional staff to stay current in both their research specialties and modern pedagogy in order to teach most effectively.

- The institution should provide opportunities for renewal and professional development through sabbaticals, participation in professional meetings, and other professional activities. Faculty and instructional staff should use these opportunities for improvement of instructional and research programs. Institutions should provide resources to ensure program continuity during sabbaticals and other leaves.
- Excellent programs provide formal mechanisms by which established faculty mentor junior colleagues. Proper mentoring integrates all members of the faculty and instructional staff into the culture of their particular academic unit, institution, and the chemistry profession, ensuring the stability and vitality of the program.

3.5 Support Staff. A sustainable and robust program requires an adequate number of administrative personnel, stockroom staff, and technical staff, such as instrument technicians, machinists, and chemical hygiene officers. The number of support staff should be sufficient to allow faculty members to devote their time and effort to academic responsibilities and scholarly activities.

3.6 Student Teaching Assistants. The participation of upper-class chemistry undergraduates and graduate students in the instructional program as teaching assistants both helps them reinforce their knowledge of chemistry and provides a greater level of educational support for students they supervise. If undergraduate or graduate students serve as teaching assistants, they must be properly trained and supervised.

4. Infrastructure

A modern and comprehensive infrastructure is essential to a vigorous undergraduate program. Program infrastructure must receive strong institutional support to provide sustainability through inevitable changes in faculty, leadership, and funding levels.

4.1 Physical Plant. An approved program should have classroom, teaching laboratory, research, office, and common space that is safe, modern, well-equipped, and properly maintained.

- Chemistry classrooms and faculty offices should be reasonably close to instructional and research laboratories. Classrooms should adhere to modern standards for lighting, ventilation, and comfort and have proper demonstration facilities, projection capabilities, and internet access.
- Laboratories for research and instruction in the chemical sciences must be suitable for their purpose and must meet applicable government regulations. Properly functioning and appropriate fume hoods, safety showers, eyewashes, first aid kits, and fire extinguishers must be readily available. Construction or renovation of laboratory facilities must conform to Occupational Safety and Health Administration (OSHA), national, and state regulations.
- The number of students supervised by a faculty member or by a teaching assistant in an instructional lab should not exceed 25. Many laboratories require smaller numbers for safe and effective instruction.
- Faculty and student research laboratories should have dedicated facilities appropriate for the type of work conducted in them. These facilities should permit experiments to be maintained for extended periods of time during ongoing research projects.
- The program should have access to support facilities such as machine, electronic, and glass fabrication shops to support both teaching and research.

4.2 Instrumentation. Characterization and analysis of chemical systems require an appropriate suite of modern, high quality, and properly maintained instrumentation and specialized laboratory equipment that are utilized in undergraduate instruction and research.

Approved programs must have a functioning NMR spectrometer on site that undergraduates use. The field strength and capabilities of the NMR instrumentation should support the instructional and research needs of the program. If the on-site instrument does not meet all of the program's research needs, stable arrangements must be made with proximal sites to provide ready access to appropriate NMR instrumentation.

In addition, instruments from at least four of the following five categories must be on site and used by undergraduates:

- optical molecular spectroscopy (e.g., FT-IR, fluorescence, Raman, UV-Vis)
- optical atomic spectroscopy (e.g., atomic absorption, ICP-atomic emission)
- mass spectrometry (e.g., MS, GC-MS, LC-MS)
- chromatography and separations (e.g., GC, GPC, HPLC, ion chromatography, capillary electrophoresis, SEC)
- electrochemistry (e.g., potentiometry, amperometry, coulometry, voltammetry)

Programs must maintain an additional complement of instrumentation that is adequate to support the curriculum, including undergraduate research. For example, programs might have multiple instruments from one or more of the categories listed above or additional supplemental instrumentation, which might include vacuum and inert-atmosphere systems (e.g., Schlenk line, dry box), thermal analysis (e.g., DSC, TGA), x-ray diffraction, or imaging and microscopy methods (e.g., electron microscopy, scanning probe microscopy, confocal microscopy), or biochemical instrumentation (e.g., thermocyclers,

centrifuges, gel electrophoretic systems).

In all cases, the institution must maintain the instrumentation in adequate operating condition.

4.3 Computational Capabilities and Software. The ability to compute chemical properties and phenomena complements experimental work by enhancing understanding and providing predictive power. Students should have access to computing facilities and use computational chemistry software.

4.4 Chemical Information Resources. A broad range of the peer-reviewed chemical literature must be readily accessible to both faculty and students.

- An approved program must provide immediate institutional access to no fewer than 14 current and archival, peer-reviewed journals whose subject matter spans the chemical sciences. At least three of the journals must have a general focus (for example, *Science, JACS, Angewandte Chemie International Edition, Chemistry – A European Journal, Chemical Communications,* etc.), and at least one must come from each area of analytical chemistry, biochemistry, inorganic chemistry, organic chemistry, physical chemistry, and chemistry education. In addition, the library must provide timely access to journal articles that are not available on site by a mechanism such as interlibrary loan or a document delivery service.
- Students must have access to technical databases and other resources that enable development of skills in searching the literature, including structure-based searching, and support research and instructional activities.

4.5 Laboratory Safety Resources. The program must be conducted in a safe environment that is consistent with the following features:

- There must be a written chemical hygiene plan consistent with OSHA and state standards. A mechanism for harmonizing this plan with the teaching and research activities of the program is required for the establishment of a safety culture.

- Laboratory safety plans need to recognize hazards encountered in the instructional and research activities in the program. Common hazards include chemical hazards (health, physical, and environmental), extreme temperatures, high pressures and voltages, ionizing and non-ionizing radiation, and intense light sources.
- For materials and equipment that present particular hazards, specific standard operating procedures (SOPs) should be developed and incorporated into the chemical hygiene and chemical safety plans of the program.
- Hazardous waste management must be part of the chemical hygiene plan and adhere to institutional, federal, and state regulations regarding hazardous waste management and laboratory safety. This includes maintenance of proper facilities for chemical waste disposal and personnel to address this task.
- Safety information and reference materials, such as Safety Data Sheets, should be accessible from or available in the laboratories.
- Appropriate personal protective equipment must be readily available to students, staff, and faculty.
- Regularly tested and inspected eyewash and shower stations must be located in all laboratories in which such safety devices are mandated.
- Regularly tested and inspected fume hoods must be present in all laboratories that involve the use of potentially hazardous materials.
- The chemistry program must promote a safety culture by coordinating safety inspections of laboratories, receiving and analyzing accident reports, receiving emergency response training and assuring that everyone working in instructional and research laboratories is properly educated on safety issues. The mechanism for promoting a safety culture, which will often include a safety committee or safety officer, should be a collaborative endeavor with the institutional environmental health and safety office (if one exists) and the chemical hygiene officer.

4.6 Support and Resources for Transfer Students. Many students transfer among institutions during their undergraduate education, including those who start their course work at community colleges. Approved programs should be aware of the educational backgrounds and unique challenges facing transfer students. Programs should provide an advisor to assist transfer students with orientation, academic advising, and successful integration into their new institution. They should also engage in activities to encourage and ease transfer student matriculation and provide a vibrant, supportive framework for their success.

5. Curriculum

The curriculum of an approved program provides both a broad background in chemical principles and in-depth study of chemistry or chemistry-related areas that build on this background. These guidelines describe the chemistry curriculum in terms of content and development of student skills. The content areas encompass five of the traditional subdisciplines of chemistry: analytical, biochemistry, inorganic, organic, and physical, and include both small molecules and macromolecules. Student learning progresses from beginner to expert knowledge and comprises introductory, foundation, and in-depth experiences. Beyond the *introductory* chemistry experience, *foundation* experiences provide breadth of coverage across the traditional subdisciplines. Rigorous *in-depth* experiences build upon the foundation. Furthermore, because chemistry is an experimental science, substantial laboratory work is integral to these three levels of experience. Programs have the opportunity to design innovative curricula that meet the needs and interests of their students by defining degree tracks or concentrations requiring specified in-depth course work. The curriculum must also include experiences that develop student skills essential for their effective performance as scientific professionals (see Section 7).

5.1 Content Requirements. To provide students with an intellectual framework that covers the breadth of modern chemistry, the foundation experience of the curriculum must cover the five subdisciplines listed above. Student laboratory experiences must include at least four of the five subdisciplines.

Recognizing that the synthesis, analysis, and physical properties of small molecules give an incomplete picture of the higher order interactions that occur in macromolecular, supramolecular, mesoscale, and nanoscale systems, the principles that govern these systems must be part of the curriculum required for certified graduates. This instruction must cover the preparation, characterization, and physical properties of such systems. At least two of the following four types of systems must be covered: synthetic polymers, biological macromolecules, supramolecular aggregates, meso- or nanoscale materials. Coverage of these topics may be distributed across multiple courses, in which case it should constitute the equivalent of approximately one-fourth of a standard semester course.

5.2 Introductory or General Chemistry. The introductory or general chemistry experience plays a vital role in educating all students. The purpose of

introductory chemistry course work for those students pursuing a degree in chemistry is preparation for the foundation course work. This introduction provides students with basic chemical concepts such as stoichiometry, states of matter, atomic structure, molecular structure and bonding, thermodynamics, equilibria, and kinetics. The diversity of institutions and students requires a variety of approaches for teaching general or introductory chemistry. Possible approaches range from a full-year course to a one-semester course to waiving the introductory course requirement for very well-prepared students. To accommodate all these situations, these guidelines focus on the requirements and characteristics of experiences beyond the introductory level.

To prepare students properly for the foundation laboratories, laboratories in introductory or general chemistry courses must be primarily hands-on, supervised laboratory experiences. Students need to be instructed in basic laboratory skills such as safe practices, keeping a notebook, use of electronic balances and volumetric glassware, preparation of solutions, chemical measurements using pH electrodes and spectrophotometers, data analysis, and report writing.

5.3 Foundation Course Work. Foundation course work provides breadth and lays the groundwork for the in-depth course work. Certified graduates must have instruction equivalent to a one-semester course of at least three semester credit hours in each of the five traditional subdisciplines of chemistry: analytical chemistry, biochemistry, inorganic chemistry, organic chemistry, and physical chemistry. Programs operating on the quarter system can achieve this breadth with at least eight three-credit one-quarter courses that include the equivalent of at least one quarter of coverage in each of the five areas.

Foundation course work builds on the introductory chemistry experience. Foundation course work uses specialized books or materials that serve as an introduction to each field, rather than a general chemistry textbook. Exam questions should cover concepts in greater detail than in an introductory or general chemistry course. A student completing a foundation course should have mastered the vocabulary, concepts, and skills required to pursue in-depth study in that area.

Some areas, particularly organic and physical chemistry, have traditionally been taught as year-long courses. In these cases, the first-semester course in the sequence can be used as a foundation course and the second-semester course as an in-depth course. Integrated foundation course work may provide

exposure to multiple foundation areas of chemistry or a group of topics organized by overarching themes (for example, synthesis, characterization, and reactivity) rather than by the traditional organization of chemistry subdisciplines.

5.4 In-Depth Course Work. The curriculum required for certification must also include a minimum of the equivalent of four one-semester or six one-quarter in-depth courses and correspond to at least 12 semester or 18 quarter credit hours. Because in-depth courses build on prerequisite foundation course work, the goals of in-depth courses are both to integrate topics introduced in the foundation courses and to investigate these topics more thoroughly. Exams and other assignments associated with in-depth courses should require critical thinking and problem-solving skills. The second semester in a two-semester course sequence such as organic or physical chemistry can be considered an in-depth course.

In-depth course work could focus on content that increases a student's understanding of one or more of the foundation areas. It could also include courses that support a specialized degree track (see Section 5.8). One or more of the in-depth courses may be taught in another department, but they must contain significant chemistry or chemistry-related content at a level beyond the foundation. The Committee encourages programs to integrate modern topics in chemistry such as catalysis, environmental chemistry, green/sustainable chemistry, materials science, and toxicology into the in-depth courses.

Laboratory courses provide an important aspect of in-depth course work for certified graduates. In general, associated classroom and laboratory courses (e.g., the second semester of organic chemistry lecture and laboratory) count as a single course in satisfying the requirement for four in-depth courses even if they have separate course numbers. Likewise, a laboratory that represents the first laboratory exposure to a foundational area is not considered an in-depth course. For a laboratory course to be considered as one of the four in-depth courses required for certification, it must represent an advanced laboratory experience that includes the integration of student skills and builds on the foundation laboratory experiences. In-depth laboratory experiences involve experiment design, execution, data analysis, and use of the chemical literature. In these courses, students are typically in the laboratory for at least six hours per week. Such courses may have an accompanying classroom component. No single laboratory or lecture course can be used to satisfy both foundation and in-depth requirements.

5.5 Frequency of Course Offerings. The most effective programs teach five foundation courses annually. Approved programs must teach at least four foundation courses annually, covering at least four of the five foundation areas. For programs on the quarter system, this requirement translates to teaching at least six of eight foundation courses every year. Each foundation course must be taught at least once in any two-year period. If any foundation courses are not taught annually, the program must make arrangements to ensure that students can complete the requirements for certification in four years.

While permanent full-time chemistry faculty usually teach all of the foundation courses, in some cases it may be appropriate to include courses taught by faculty outside the chemistry department. For example, a student might obtain a foundation biochemistry experience through a course taught in a biochemistry or biology department. In cases where course work in one of the foundation areas is taught by another department, the chemistry faculty must teach all of the remaining foundation courses annually.

Because in-depth courses determine the rigor of the undergraduate experience, the chemistry faculty must teach at least four semester-long or six quarter-long in-depth courses annually, exclusive of research. These courses must correspond to at least twelve semester or 18 quarter hours. The frequency of the in-depth course offerings must allow students to complete the requirements for a certified chemistry degree in four years. Although courses taken outside the chemistry program may be used to satisfy an individual student's in-depth course requirements, the program is still required to teach at least four in-depth semester (six quarter-long) courses, as defined in Section 5.4, in each academic year.

5.6 Laboratory Experience. The certified graduate must have 400 hours of laboratory experience beyond the introductory chemistry laboratory. Laboratory course work must cover at least four of the five traditional chemistry subdisciplines and may be distributed between the foundation and in-depth levels. Laboratory course work is an ideal place in the curriculum to develop the student skills described in Section 7. The laboratory experience must include synthesis of molecules, measurement of chemical properties, determination of structures, hands-on experience with modern instrumentation such as that listed in Section 4.2, data analysis, and computational modeling. Laboratory experiences should be designed to teach students to understand the operation and theory of modern instruments and use them to solve chemical problems. In

a computational chemistry laboratory experience, the students would be expected to use the same principles of experiment design, execution, and data analysis characteristic of hands-on laboratory experiences. In contrast, virtual laboratory experiences that replace activities that are traditionally performed hands-on cannot be used as part of the 400 laboratory hours.

5.7 Cognate Courses. Certified graduates must complete course work equivalent to two semesters of calculus and two semesters of physics with laboratory. The Committee strongly recommends a calculus-based physics curriculum and study of multivariable calculus, linear algebra, and differential equations.

5.8 Degree Tracks or Concentrations. A degree track used to certify graduates is a specialized, faculty-designed curriculum meeting the foundation, in-depth, and laboratory requirements. Degree tracks offer the opportunity to incorporate emerging areas of chemistry, make use of local expertise, and align with faculty and student interests. The faculty is responsible for defining degree tracks for its program. While the ACS approves chemistry programs, it does not approve specific degree tracks developed by individual chemistry programs. Consequently, if programs develop additional degree tracks, they may certify graduates from these tracks so long as the students meet the requirements for certification.

A degree track can broadly cover the field of chemistry or focus on a specific chemistry subdiscipline or chemistry-related multidisciplinary area. A chemistry degree track might require the second semesters of organic and physical chemistry, along with the equivalent of two semesters of in-depth electives (which can include undergraduate research). More specialized tracks might provide greater depth of instruction focused on a chemistry area such as advanced organic synthesis, computational chemistry, biochemistry, or chemical measurement science. Examples of multidisciplinary tracks include chemical education, chemical physics, environmental chemistry, forensic chemistry, materials science, medicinal chemistry, polymer chemistry, or other specialties. Degree tracks might also require additional courses, either within the chemistry program or offered in another department, which would not count as in-depth courses because they do not have sufficient chemistry content that builds on the foundation course work.

5.9 Pedagogy. An approved program should use effective pedagogies in classroom and laboratory course work. Programs should teach their courses in a challenging, engaging, and inclusive manner that accommodates a variety of learning styles. Additionally, a program should provide opportunities for faculty to maintain their knowledge of effective practices in chemistry education and modern theories of learning and cognition in science. An approved program should regularly review its pedagogical approaches to ensure that they promote student learning and build the skills needed to be an effective professional.

Faculty should incorporate pedagogies that have been shown to be effective in undergraduate chemistry education. Examples include problem- or inquiry-based learning, peer-led instruction, learning communities, and technology-aided instruction such as the use of personal response systems and flipped or hybrid classes. Laboratory work provides a particularly attractive opportunity for inquiry-driven and open-ended investigations that promote independent thinking, critical thinking and reasoning, and a perspective of chemistry as a scientific process of discovery.

5.10 Capstone Experiences. Certified graduates should be provided with an integrative experience that requires them to synthesize the knowledge and skills introduced across the curriculum. Such experiences provide a bridge between the students' academic and future professional activities. These experiences can take many different forms. An important aspect of this integrative experience is the opportunity it provides programs to assess the ability of students to integrate knowledge, use the chemical literature, and demonstrate effective communication skills. Such assessments typically involve some combination of written or oral exams, required presentations, and written reports.

These integrative experiences could be provided in an existing upper-level, designated capstone course (e.g., senior seminar) or distributed among several courses taught in the chemistry department. Typically, a stand-alone capstone course could not be used to fulfill the in-depth course requirement. Mentored teaching also provides an excellent opportunity for students to integrate their knowledge and skills, as does an independent research experience that also requires a research report and presentation of the student's results.

5.11 Online and Virtual Instruction. Classes taught partially or wholly online should provide at least the same skill development and content as the corresponding wholly face-to-face experience. Programs should ensure that

students in such courses have adequate access to faculty and instructors and opportunities for collaboration with peers. Faculty contact-hour credit for virtual and online instruction should be at least equivalent to the corresponding classroom experience.

Chemistry is an empirical science that requires the safe and effective physical manipulation of materials, equipment, and instrumentation. This hands-on expertise cannot be developed through virtual laboratory exercises. Virtual labs may supplement hands-on laboratory exercises, but they must not replace them (see also Section 5.6).

6. Undergraduate Research

Undergraduate research allows students to integrate and reinforce chemistry knowledge from their formal course work, develop their scientific and professional skills, and create new scientific knowledge. A vigorous research program is also an effective means of keeping faculty current in their fields and provides a basis for acquiring modern instrumentation. Original research culminating in a comprehensive written report provides an effective means for integrating undergraduate learning experiences and allows students to participate in the advancement of science.

Conducting undergraduate research with a faculty advisor allows the student to draw on faculty expertise and encourages a student-faculty mentor relationship. The research project should be envisioned as a component of a publication in a peer-reviewed journal. It should be well-defined, stand a reasonable chance of completion in the available time, apply and develop an understanding of in-depth concepts, use a variety of instrumentation, promote awareness of advanced safety practices, and be grounded in the primary chemical literature.

Research can satisfy up to four semester credit hours or six quarter credit hours of the in-depth course requirement for student certification and can account for up to 180 of the required 400 laboratory hours. A student using research to meet the ACS-certification requirements must prepare a well-written, comprehensive, and well-documented research report, including safety considerations where appropriate. Thorough and current references to peer-reviewed literature play a critical role in establishing the overall scholarship of the report. Although oral presentations, poster presentations, and journal

article co-authorship are valuable, they do not substitute for the student writing a comprehensive report.

Research performed during the summer or performed off-campus, even though it might not receive academic credit, may count toward student certification. In such cases, the student must prepare a comprehensive written report that a faculty member of the home institution evaluates and approves.

7. Development of Student Skills

In order to prepare students to enter the workforce or postgraduate education, programs must provide experiences that go beyond chemistry content knowledge to develop competence in other critical skills necessary for a professional chemist. Faculty mentoring is another key component of student development because it helps students gain confidence and provides guidance about career planning and networking. Approved programs should have an established process by which they assess the development of student skills. A capstone experience (as described in Section 5.10) provides an excellent opportunity for this assessment. In addition, either dedicated courses or integration of learning opportunities throughout the curriculum can be used to develop and assess student skills.

7.1 Problem Solving Skills. An important goal of chemistry education is to provide students with the tools to solve problems. Students should be taught how to define problems clearly, develop testable hypotheses, design and execute experiments, analyze data using appropriate statistical methods, understand the fundamental uncertainties in experimental measurements, and draw appropriate conclusions. Throughout the curriculum, students should be challenged to apply their understanding of all chemistry subdisciplines and use appropriate laboratory skills and instrumentation to solve problems.

7.2 Chemical Literature and Information Management Skills. Essential student skills include the ability to retrieve information efficiently and effectively by searching the chemical literature, evaluate technical articles critically, and manage many types of chemical information. Students must be instructed in effective methods for performing and assessing the quality of searches using keywords, authors, abstracts, citations, patents, and structures/substructures.

The program should provide ready access to technical databases with sufficient depth and breadth of the chemical literature for effective searching. Students' ability to read, analyze, interpret, and cite the chemical literature as applied to answering chemical questions should be assessed throughout the curriculum. Instruction should also be provided in data management and archiving, record keeping (electronic and otherwise), and managing citations and related information. This includes notebooks, data storage, information and bibliographic management and formatting. Undergraduate research and/or individual or group projects provide excellent opportunities for development and assessment of literature searching and information management skills. A stand-alone course can be an effective means of imparting information-retrieval skills, though such a course usually would not qualify as an in-depth course.

7.3 Laboratory Safety Skills. Programs must instruct students in the aspects of modern chemical safety appropriate to their educational level and scientific needs. Approved programs need to promote a safety-conscious culture in which students demonstrate and apply their understanding of the concepts of safe laboratory practices. The promotion of safety awareness and skills must begin during the first laboratory experience and should be incorporated into each lab experience thereafter. Students must undergo general safety instruction as well as lab-specific instruction before beginning undergraduate research. Classroom and laboratory discussions need to stress safe practices and should actively engage students in the evaluation and assessment of safety risks associated with laboratory experiences. Safety understanding and skills must be developed and assessed throughout the curriculum.

Programs should provide students with training that allows them to

- carry out responsible disposal techniques
- comply with safety regulations
- properly use personal protective equipment to minimize exposure to hazards
- understand the categories of hazards associated with chemicals (health, physical, and environmental)
- use Safety Data Sheets (SDSs) and other standard printed and online safety reference materials

- recognize chemical and physical hazards in laboratories, assess the risks from these hazards, know how to minimize the risks, and prepare for emergencies.

7.4 Communication Skills. Effective communication is vital to all professional chemists. Speech and English composition courses alone rarely give students sufficient experience in oral and written communication of technical information. The chemistry curriculum should include critically evaluated writing and speaking opportunities so students learn to present information in a clear and organized manner, write well-organized and concise reports in a scientifically appropriate style, and use relevant technology in their communications. Because chemistry is a global enterprise, knowledge of one or more foreign languages or an international experience can be a valuable asset to chemistry students and add greatly to a student's ability to communicate with other chemists worldwide.

7.5 Team Skills. Solving scientific problems often involves multidisciplinary teams. The ability to work in such teams is essential for a professional chemist. Programs should incorporate team experiences into classroom and laboratory components of the chemistry curriculum, thus providing opportunities for students to learn to interact effectively in a group to solve scientific problems and work productively with a diverse group of peers. Effective group experiences provide students with the opportunity to develop both leadership and team skills.

7.6 Ethics. Ethics should be an intentional part of the instruction in a chemistry program. Students should be trained in the responsible treatment of data, proper citation of others' work, and the standards related to plagiarism and the publication of scientific results. The curriculum should expose students to the role of chemistry in contemporary societal and global issues, including areas such as sustainability and green chemistry. As role models, faculty should exemplify responsible conduct in their teaching, research, and all other professional activities.

8. Program Self-Evaluation

An approved program should regularly evaluate its curriculum and pedagogy, faculty development opportunities, and infrastructure needs relative to the program's teaching and research mission. Self-evaluation is a continual process that enables programs to both introduce change in a deliberate way and improve overall effectiveness. Steps in the self-evaluation process include identifying the goals of the program, collecting and analyzing data to determine if these goals are being met, implementing changes as needed to meet the program goals, and then, after an appropriate period of time, beginning the process anew. Thoughtful and thorough self-evaluation can lead to improved or modernized course content or pedagogy, identification of areas in which the curriculum may be strengthened and student outcomes improved, and increased support for professional development and scholarly activities of faculty. Such evaluation can also provide a strong infrastructure to support the educational and scientific missions of the program.

9. Certification of Graduates

The chair of an approved program certifies those graduates receiving a baccalaureate degree consistent with these guidelines. Students usually receive certification when they complete the baccalaureate degree. It is also possible to certify students who initially obtain a non-certified baccalaureate degree from an approved program and subsequently complete additional study in an ACS-approved program to qualify for certification. The Office of Professional Training provides certificates for certified graduates.

II. APPROVAL PROCESS AND REVIEW PROCEDURES

1. Membership of the Committee

The CPT has 17 members. The ACS Board of Directors and the president of the Society with the advice of the ACS Committee on Committees jointly appoint 16 voting members. There is also one nonvoting staff Secretary. One voting member serves as an appointed chair and one serves as an elected vice chair. Initial appointments are usually for a three-year term, and reappointment for up to a total of three 3-year terms of service is possible. The Committee typically retains one or more former members or appoints individuals with special expertise as nonvoting consultants. Members of CPT are experienced educators and scientists from all areas of the country, chosen to represent different fields of chemistry and reflect much of the breadth of the chemistry community. The Secretary communicates the results of all reviews conducted by CPT and consults with faculty and administrators about guidelines and procedures related to ACS approval.

2. Costs Associated with the CPT and the Approval Program

The Society does not charge academic institutions for the evaluation of the chemistry program, including site visits by Visiting Associates of CPT (Section 8).

3. Initial Approval Process

The ACS, through CPT, establishes the recommendations and requirements for approval of bachelor's degree programs in chemistry and policies for administering the approval process. The chemistry faculty should conduct a self-study to determine the program's readiness to begin the approval process. The following flowchart summarizes the steps of the initial approval process, and the accompanying text describes each of the steps in the flowchart.

Initial Approval Process Flowchart

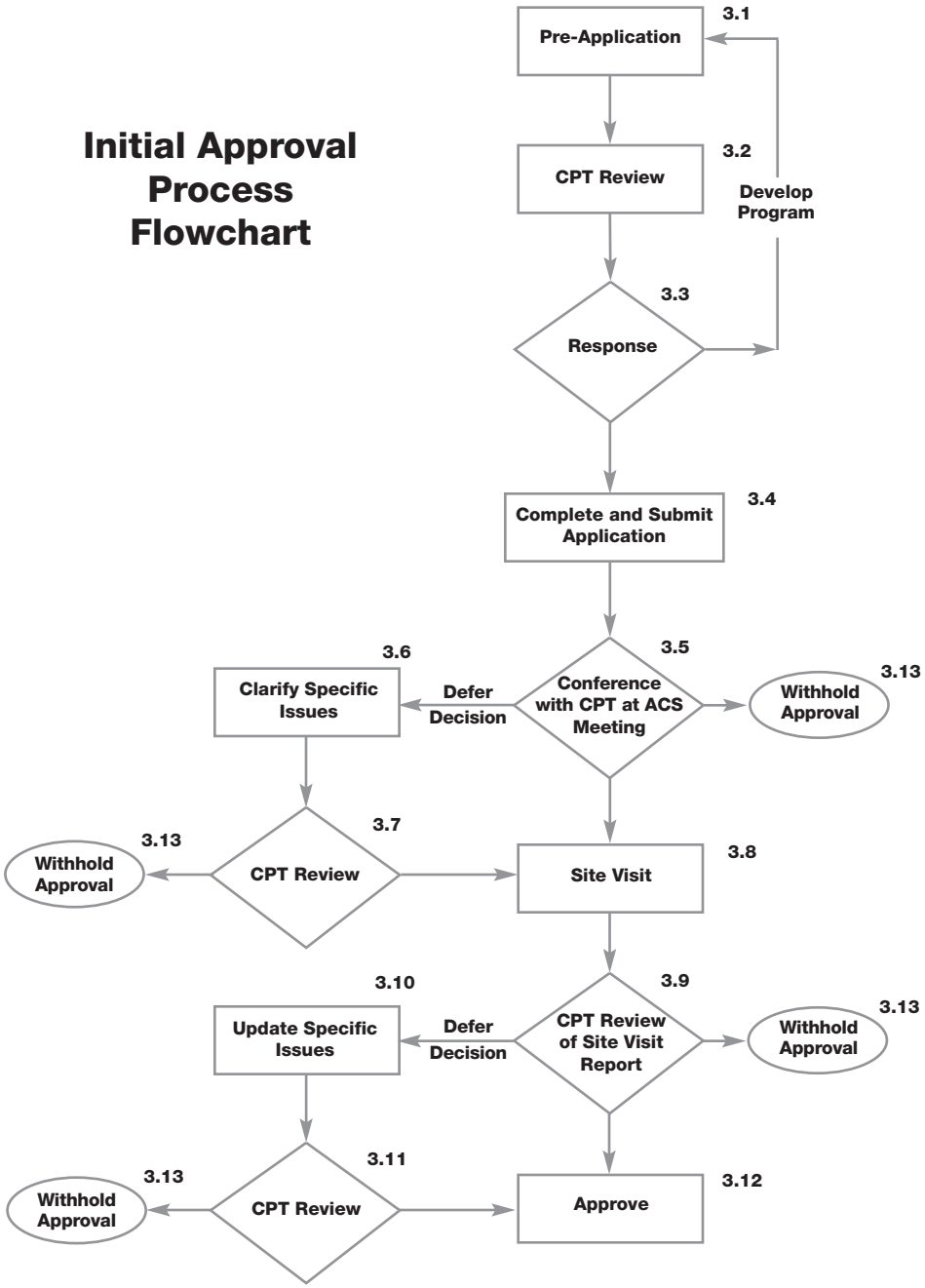

3.1 Pre-Application. The chemistry program completes a pre-application form, which is available on the CPT website, and submits it during the time periods identified on the pre-application web page.

3.2 CPT Review. The Committee reviews the pre-application form within two months of the submission deadline.

3.3 Response. The Secretary of the Committee reports the outcome of the review to the department chair by letter. Two outcomes are possible.

1) *The program does not meet* the requirements for ACS approval that are covered by the pre-application form. The letter identifies the deficiencies and instructs the program to submit a new pre-application form after addressing the areas of noncompliance.
2) *The program meets* the requirements for ACS approval covered by the pre-application form. The Committee invites the department to submit a full application package.

3.4 Complete and Submit Application Package. The program completes a comprehensive self-study questionnaire and provides supporting documentation including course syllabi, examinations, and student research reports (when research is required). The ACS staff check the package for completeness and assign the application for review by the Committee at the next ACS national meeting.

3.5 Conference with CPT. The chair of the department applying for approval is expected to meet with the Committee to discuss the chemistry program and answer questions about certain aspects of the application package. If the chair of a combined department is not a chemist, a chemistry faculty member must attend the conference. Additional chemistry faculty members or administrators may also meet with the Committee. The Secretary of CPT communicates the outcome of CPT's review to the chair of the department that administers the chemistry program. Three outcomes are possible.

1) *The Committee agrees that the program is ready for a site visit* (Section 3.8) by Visiting Associates. (Section 8)
2) *The Committee defers a decision* pending clarification of certain aspects of the application. (Sections 3.6, 3.7)
3) *The Committee withholds approval of the program.* (Section 3.13)

3.6 Clarify Specific Issues. The program must clarify the specific issues identified in the letter from the Secretary of CPT and submit a response by the deadline given in the letter. This step may only be taken once following submission of an application for approval.

3.7 CPT Review. ACS staff verifies that the information submitted by the applicant is complete and schedules the application for review at the next regular CPT meeting. Two outcomes are possible.

1) *The Committee agrees that the program is ready for a site visit* (Section 3.8) by Visiting Associates. (Section 8)
2) *The Committee withholds approval of the program.* (Section 3.13)

3.8 Site Visit. The Secretary of CPT reports the decision to proceed with a site visit by letter to the chair of the department that administers the chemistry program. The president (or chief administrative officer) of the institution must then invite ACS to make a site visit. Two Visiting Associates will make the site visit, which typically is spread over two days. The ACS pays all expenses of the site visitors. ACS staff provide the site visitors with background information and instructions from the Committee. The president or chief administrative officer of the institution must be available to meet with the site visitors. The site visitors submit a written report to the Secretary of CPT within one month following the visit. For more information on Visiting Associates, see Section 8.

3.9 CPT Review of Site Visit Report. CPT reviews the written report on the site visit at the first regular meeting after it is received. Three decisions are possible after this review.

1) *The Committee approves the chemistry program.* (Section 3.12)
2) *The Committee requests additional or updated information.* (Sections 3.10, 3.11)
3) *The Committee withholds approval of the program.* (Section 3.13)

3.10 Update Specific Issues. The program must clarify or update the specific issues identified in the letter from the Secretary of CPT to the chair of the department administering the chemistry program and submit a response by the deadline given in the letter. This is not an iterative step and occurs only once following the site visit.

3.11 CPT Review. CPT reviews the program's report describing the resolution of the specific issues. Two decisions are possible after this review.

1) *The Committee approves the chemistry program.* (Section 3.12)
2) *The Committee withholds approval of the program.* (Section 3.13)

3.12 Approve. The Secretary of CPT writes to the president of the institution and the chair of the department that administers the chemistry program to report this decision. The Committee will post the name of the institution on the list of ACS-approved programs on the ACS website. An approved program must satisfy the reporting requirements described in Sections 4 and 5. Failure to comply with the annual and periodic review requirements will lead to probationary action. (Section 6)

3.13 Withhold Approval. The letter from the Secretary of CPT describes the areas of noncompliance. This letter is sent to the chair of the department administering the chemistry program with a copy to the president or chief administrative officer. After addressing these concerns, the program returns to the pre-application step of the approval process. The institution may appeal this decision as described in Section 7.

4. Annual Review

Approved programs must report annually to the Committee on the number of degrees granted by the chemistry program, information on graduates at all degree levels, the certification status of the baccalaureate graduates, and supplemental information on the curriculum and faculty. The Family Educational Rights and Privacy Act (FERPA) allows institutions to provide the names, gender, and graduation dates of all graduates to CPT. The Committee reviews the report for completeness and consistency with the guidelines and may request additional information from the program. The Committee summarizes and publishes the statistical information about the numbers of graduates at the various degree levels each year.

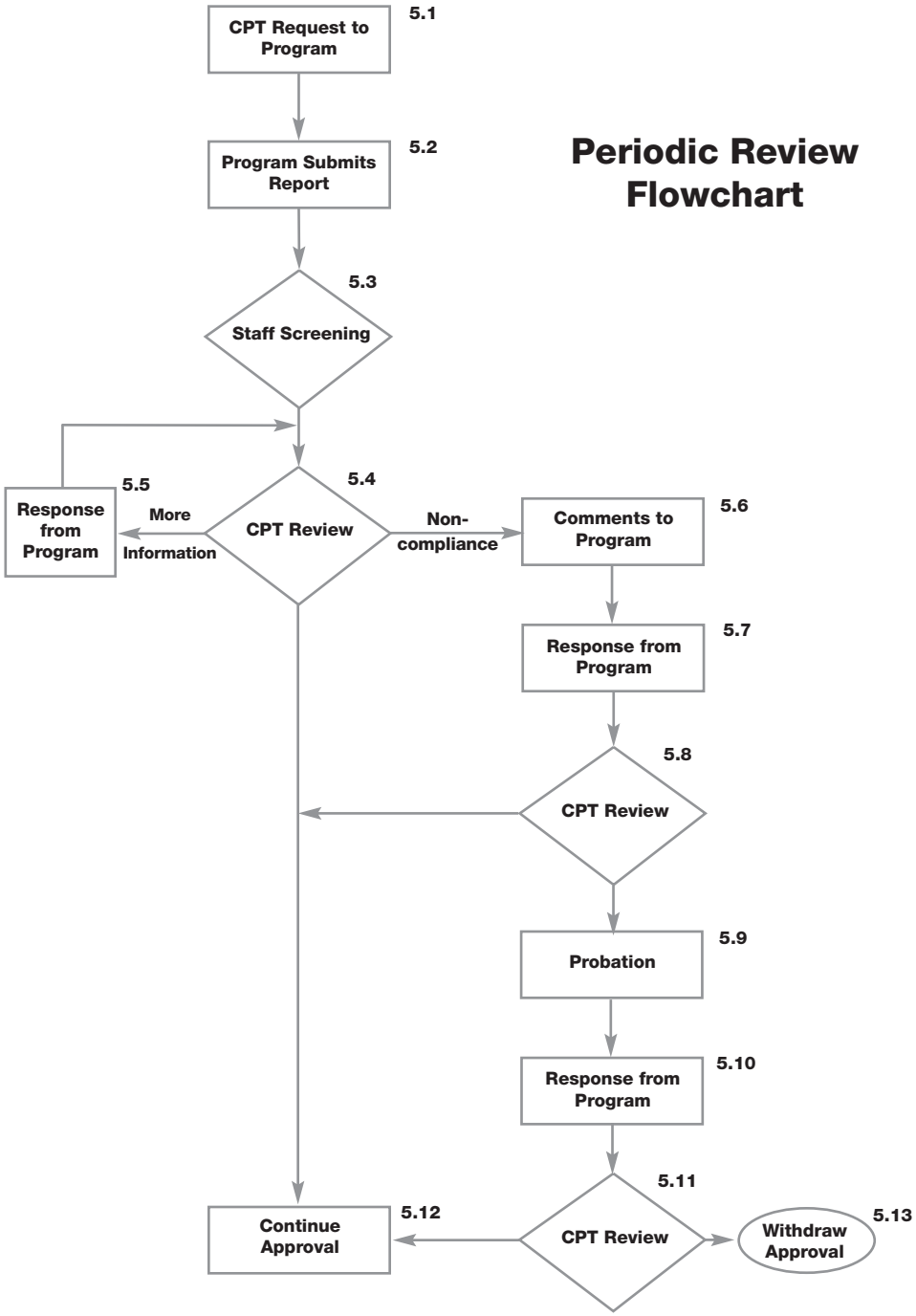

5. Periodic Review

To ensure compliance with the ACS guidelines, approved programs must submit a periodic report about their program using a form provided by CPT. The adjacent flowchart summarizes the steps of the review process, and the accompanying text describes each of the steps in the flowchart.

5.1 Request for Periodic Report. The Secretary of CPT contacts the chair of the department that administers the ACS-approved chemistry program with instructions for completing the report. A report form with questions on all components of the ACS guidelines, a checklist of supporting documents to be submitted, and a copy of the letter reporting the final outcome of the previous review will be provided. Among the supporting documents that may be requested are copies of specific course syllabi, examinations, and student research reports. Approved programs must submit a periodic report at least every six years. In cases where programs have been given an extended period of time to address significant issues, the next periodic report will be requested no sooner than 12 months after the outcome of the previous review has been communicated to the chair of the department.

5.2 Program Submits Report. The program must respond by the deadline provided in the letter from the Secretary.

5.3 Staff Screening. An ACS staff member checks the periodic report package for completeness and corresponds with the department chair to obtain any missing or other information as authorized by CPT.

5.4 CPT Review. The Committee reviews the periodic report at one of its three yearly meetings. Three outcomes are possible.

1) *The Committee requests more information.* This is not an iterative step and may occur only once following the initial submission of the periodic report. (Section 5.5)
2) *The Committee determines that the chemistry program is not in compliance* with the requirements specified in the guidelines or has not adequately addressed the recommendations from the previous periodic review. (Section 5.6)
3) *The Committee continues approval.* (Section 5.12)

5.5 Request more information. The CPT members may find that essential information is missing from the report package or clarification of ambiguous information is needed. The response is returned to CPT for review and a decision of continue approval or noncompliance is made.

5.6 Comments to Program. The Secretary of CPT identifies the area(s) of noncompliance in a letter to the chair of the department, including a reasonable timeframe for response as established by the Committee.

5.7 Response from Program. The program must report to CPT on the measures taken to address the deficiencies by the deadline provided in the letter from the Secretary.

5.8 CPT Review. The Committee reviews the program's response at the first possible meeting after receiving it. Two outcomes are possible.

1) *Continue approval.* (Section 5.12)
2) *Probation.* (Section 5.9)

5.9 Probation. If the deficiencies have not been corrected, CPT places the chemistry program on probation. The Secretary of CPT communicates this decision and the areas of noncompliance in a letter to the president (or chief administrative officer) of the institution and the chair of the department that administers the chemistry program. The probation decision is confidential between CPT and the institution. During probation, the institution remains on the list of ACS-approved schools, and the department chair may continue to certify graduates who have satisfied the requirements as specified in the guidelines.

5.10 Response from Program. The probationary period normally lasts from 12 to 18 months. The institution must provide a written report that describes how it has corrected all of the areas of noncompliance, including supporting documentation as appropriate. Either the chair of the department administering the chemistry program or a member of the administration may submit the response to the Secretary of CPT before the end of the probationary period.

5.11 CPT Review. The Committee reviews the program's response at the first regular meeting after receiving it. In some circumstances, CPT may request a site visit by Visiting Associates (Section 8). Two outcomes are possible.

1) *Continue approval.* (Section 5.12)
2) *Withdraw approval.* (Section 5.13)

5.12 Continue Approval. If CPT determines that the chemistry program meets all of the requirements for ACS approval and the spirit of the guidelines, the Committee continues approval of the program. The Secretary of CPT reports this outcome in a letter to the chair of the department responsible for administering the ACS-approved chemistry program, with a copy to the president (or chief administrative officer) of the institution. The Committee may identify aspects of the program that must be addressed as part of the next periodic review. Failure to respond adequately may lead to a determination of noncompliance in the future. The letter may also contain CPT's suggestions for further development of the chemistry program. Under certain circumstances, CPT may request a shorter review cycle.

5.13 Withdraw Approval. If the program does not meet all of the requirements for ACS approval by the end of the probationary period, CPT withdraws approval of the chemistry program. The Secretary of CPT reports this outcome in a letter to the president (or chief administrative officer) of the institution and the chair of the department responsible for administering the chemistry program. The institution may appeal this decision as described in Section 7. The name of the institution will be removed from the published list of ACS-approved schools, and the chair may no longer certify graduates after the period for submitting an appeal has elapsed.

If a previously approved program wishes to re-apply for ACS approval within 12 months following the letter withdrawing approval, the program is not required to follow the regular application procedure. The program must submit a request for reinstatement to the Committee accompanied by a completed periodic report package for the current year. The possible outcomes of this review will be approval or withhold approval. The normal appeal procedure will still apply. (See Section 7)

In cases where a chemistry program submits a request to have ACS approval withdrawn, CPT will act to withdraw approval at the next regular meeting of the Committee. No probation period will be imposed. The normal appeal procedure will still apply. (See Section 7)

6. Administrative Probation

The Committee may place an ACS-approved program on probation if it does not comply with any of the following administrative requirements for maintaining approval:

- Submission of a periodic review report by the deadline.
- Submission of additional information requested during CPT review of a periodic report.
- Completion of an annual report by the deadline.

The chair of the department responsible for administering the chemistry program receives two warnings that the program has missed the deadline before the Secretary of CPT contacts the president (or chief administrative officer) of the institution. The Secretary of CPT notifies the president that the chemistry program does not comply with the requirements for maintaining approval and allows 30 days to correct the situation before placing the program on administrative probation. Administrative probation lasts no longer than 60 days. During administrative probation, programs retain approval and may certify graduates. The Committee withdraws approval of any program that fails to submit the required report or information within the 60-day period.

7. Appeal of an Adverse Decision

An institution may petition for review of an adverse decision (withhold or withdrawal of approval) if it believes that the Committee did not have access to all of the necessary evidence, has not adhered to its own established policies and procedures, or has failed to consider all of the evidence and documentation presented during the evaluation. The petition must reach the Committee within 60 days following the date of the letter advising the institution of the adverse decision. Following the Committee's review of the petition, the institution must provide any additional information and documents in support of the petition by the provided deadline, typically no more than six months. After receiving the petition and supporting information, the Committee reviews the matter at its next regular meeting, which may include a conference with representatives of the institution if desired by either the institution or the Committee. After the meeting and deliberation, the Secretary of CPT reports the Committee's findings to the president of the institution and the chair of the department that administers the chemistry program.

Any action of any Society unit is always subject to review by the Society's Board of Directors, which has full legal responsibility for all Society activities.

7.1 Appeal of Withdraw Approval. A program undergoing its periodic review may follow the procedures described above to appeal this decision. Two outcomes of the appeal are possible.

1) The Committee continues approval. (Section 5.12)
2) The Committee affirms the decision to withdraw approval. (Section 7.3)

7.2 Appeal of Withhold Approval. A program applying for approval may follow the procedures described above to appeal this decision. Three outcomes of the appeal are possible.

1) The Committee approves the chemistry program. (Section 3.12)
2) The Committee agrees that the program is ready for a site visit (Section 3.8) *by Visiting Associates.* (Section 8)
*3) The Committee affirms the decision to withhold approval. (*Section 7.3)

7.3 Independent Appeals Board. Every institution has the right to appeal the Committee's final decision to an independent Appeals Board convened for that purpose. The Society's president and the chair of its Board of Directors will appoint an Appeals Board, consisting of three individuals who are not members of the Committee, to hear the appeal. No further appeal is available after the action of the Appeals Board.

8. Visiting Associates

The Committee selects Visiting Associates who are experienced educators and scientists familiar with the ACS guidelines and the administrative and technical aspects of conducting a successful chemistry program. In the selection of the Visiting Associates, the Committee makes every effort to eliminate any possibility of bias or conflict of interest. The Committee periodically holds meetings with Visiting Associates to brief them on guidelines policy and evaluation procedures. Visiting Associates receive comprehensive and detailed instructions on CPT's expectations for the site visit that also are sent to the chair of the department to aid in preparation for the visit. In addition, the Associates receive confidential comments from CPT that describe

aspects of the program that should receive careful attention during the site visit and in the site visit report. Finally, Visiting Associates serve as fact-finders for CPT and do not fill the role of external consultants who might advise the faculty on the development of the chemistry program.

9. Confidentiality

The information provided to the Committee and all related discussions and correspondence between the Committee and an institution are solely for the confidential use of the Committee. In the event that an institution appeals a Committee decision, the Committee provides the information necessary for the proper conduct of the appeal to the Appeals Board.

The Committee communicates all decisions to the chair of the department that administers the chemistry program. In the case of initial approval, continued approval, report on a site visit, probation, withdrawal of approval, and appeals, the Committee also informs the president (or chief administrative officer) of the institution. These communications summarize the reasons for the decisions made by the Committee.

In its annual published reports, the Committee identifies those institutions whose programs are currently approved as meeting the ACS guidelines for undergraduate professional education in chemistry. These annual reports also summarize statistical information provided by each institution about its chemistry graduates. Otherwise, the Committee does not publish any additional information about a particular program or evaluation.

10. Complaints

Any administrative official of an institution, department chair, faculty member, student, or other person who disagrees with one or more of the policies, procedures, or activities of the Committee and who wishes to present a complaint should do so in an appropriately documented letter to the Committee Secretary. The same procedure is to be followed should the complaint allege failure of an approved institution to adhere to the ACS guidelines or allege that there is a situation tending to jeopardize the quality and vitality of a program at an approved institution. In both cases, the Committee will evaluate the matter and take actions where appropriate.

APPENDIXES

A. The Formal Mandate of the Committee on Professional Training

A resolution of the ACS Council established the Committee on Professional Training in 1936, and the Committee published the first edition of the guidelines for approval of undergraduate programs in 1939. In 1968, the Committee became a Joint Committee of the ACS Board and Council, reporting to both. In 1979, the Society codified the responsibilities of the CPT in ACS Bylaw III,3,(h):

1) The SOCIETY shall sponsor an activity for the approval of undergraduate professional programs in chemistry. The Committee on Professional Training, constituted as an Other Joint Board-Council Committee under this Bylaw, shall act for the Board and Council in the formulation and implementation of the approval program with published criteria and/or guidelines, as well as published evaluation policies and procedures.

2) The goals of the approval program shall be *inter alia:*

a. promoting and assisting in the development of high standards of excellence in all aspects of postsecondary chemical education, and undertaking studies important to their maintenance,
b. collecting and making available information concerning trends and developments in modern chemical education, and
c. cooperating with the SOCIETY and other professional and educational groups having mutual interests and concerns.

3) Institutions may petition for review of adverse evaluation decisions to an established Appeals Board consisting of three members of the SOCIETY, not members of the Committee, appointed jointly by the President and the Chair of the Board.

B. Members of the Committee on Professional Training

CPT Members – 2015

Dr. Edgar A. Arriaga, *University of Minnesota-Twin Cities*

Dr. Ronald Brisbois, *Macalester College*

Dr. Michelle O. Claville, *Hampton University*

Dr. Ron W. Darbeau, *McNeese State University, Vice Chair 2013*

Dr. Steven A. Fleming, *Temple University (Committee Associate)*

Dr. Suzanne Harris, *University of Wyoming, Vice Chair 2009 (Consultant)*

Dr. Bob A. Howell, *Central Michigan University*

Dr. Jeffrey N. Johnston, *Vanderbilt University*

Dr. Kerry K. Karukstis, *Harvey Mudd College*

Dr. Laura L. Kosbar, *IBM T.J. Watson Research Center*

Dr. Clark R. Landis, *University of Wisconsin-Madison, Vice Chair 2015*

Dr. Cynthia K. Larive, *University of California, Riverside, Vice Chair 2007-08, Chair 2009-11 (Consultant)*

Dr. Stephen Lee, *Cornell University*

Dr. Anne B. McCoy, *The Ohio State University, Vice Chair 2011, Chair 2012-14*

Dr. Lisa McElwee-White, *University of Florida*

Dr. Christopher R. Meyer, *California State University, Fullerton*

Dr. Lee Y. Park, *Williams College, Vice Chair 2010 (Consultant)*

Dr. Richard W. Schwenz, *University of Northern Colorado*

Dr. Joel I. Shulman, *University of Cincinnati (Consultant)*

Dr. Greg M. Swain, *Michigan State University*

Dr. Thomas J. Wenzel, *Bates College, Vice Chair 2014, Chair 2015*

Dr. George S. Wilson, *University of Kansas (Consultant)*

Former CPT Members Who Participated in the Development of the Guidelines

Dr. Ron C. Estler, *Fort Lewis College, Vice Chair 2012*

Dr. Joseph S. Francisco, *University of Nebraska-Lincoln*

Dr. Carlos G. Gutierrez, *California State University, Los Angeles*

Dr. Scott C. Hartsel, *University of Wisconsin-Eau Claire*

Dr. John W. Kozarich, *ActivX Biosciences*

Dr. Nancy S. Mills, *Trinity University*

Dr. Jeanne E. Pemberton, *University of Arizona, Chair 2000-02*

Dr. William F. Polik, *Hope College, Vice Chair 2005, Chair 2006-08*

Dr. Barbara A. Sawrey, *University of California, San Diego*

Dr. Maria da Graca H. Vicente, *Louisiana State University*

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IMPACT

APA AND APA SERVICES, INC. STRATEGIC PLAN

AMERICAN PSYCHOLOGICAL ASSOCIATION

AMERICAN PSYCHOLOGICAL ASSOCIATION SERVICES, INC.

I am very proud to be a psychologist. Most in psychology chose this field for the pursuit of knowledge and to make an impact, and I've seen firsthand how psychology affects practically every aspect of our society. We live in a world that is constantly changing, and psychology is at the heart of solving some of the world's most seemingly intractable problems. How will psychology impact the future? And how will the future impact psychology?

As the leading scientific and professional organization representing psychology in the United States, the American Psychological Association is positioning our field to play a leading role in addressing the grand challenges of today and the future. Approved by APA's Council of Representatives, this new strategic plan enables us to focus the association's efforts toward maximizing the impact we can have on complex issues facing the field of psychology and broader society.

The plan was built on a strong belief that a new vision for the association should be co-created. Our more than 118,000 members were invited to provide input into a transformative path forward that addresses the needs and interests of the different segments that make up the field. For example, applied psychologists expressed a need for outreach that helps people understand their contributions to a variety of settings. Educators and trainers cited the need to strengthen support for graduate education and diversify the psychology pipeline. Clinical practitioners voiced their needs related to reimbursement and scope of practice. Scientists highlighted their need for more research funding and effective channels for disseminating their findings. And many psychologists across work settings emphasized the need to apply psychological knowledge to address large societal challenges, like the opioid crisis.

I am immensely proud of the new strategic plan that our APA/APA Services, Inc. has co-created and believe that APA is positioned to have a truly significant impact in benefiting society and improving lives. Our implementation of the plan will be transformational for APA, with the association realigning itself and refocusing its work in concert with its companion organization and the new strategic priorities. Working together, we can ensure that psychology realizes its true potential as a force for a better world.

Arthur C. Evans Jr., PhD
Chief Executive Officer and Executive Vice President
American Psychological Association and APA Services, Inc.

VISION

The change APA aspires to create in the world.

A strong, diverse, and unified psychology that enhances knowledge and improves the human condition.

MISSION

APA's unique role in creating that change.

To promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives.

GUIDING PRINCIPLES

The core values that must inform and infuse everything APA does. They apply equally across all areas of psychology including practice, basic and applied research, applied psychology, and education and training.

- **Build on a foundation of science.** Ensure that the best available psychological science informs policies, programs, products, and services.
- **Advocate for psychology and psychologists.** Demonstrate an unwavering commitment to promoting the field while supporting and unifying those who make it their profession.
- **Champion diversity and inclusion.** Further the understanding and appreciation of differences and be inclusive in everything we do.
- **Respect and promote human rights.** Focus on human rights, fairness, and dignity for all segments of society.
- **Engage with and deliver value to members.** Provide resources, opportunities, and networks that help all members at every stage of their careers.
- **Lead by example.** Serve others, model integrity, and demonstrate the highest ethical standards in all our actions.

OPERATING PRINCIPLES

How all parts of APA will work together to execute the plan.

- **Make an impact.** Focus on efforts with the scale and scope to significantly advance the interests of the public, the field, and psychology professionals.
- **Embrace a global perspective.** Advance psychology globally through international engagement, association efforts, and meaningful collaborations.
- **Build a stronger association.** Collaborate across APA to align resources, decision-making, and the contributions of governance, advisory groups, staff, and the broader membership with the strategic plan.
- **Increase organizational effectiveness.** Focus on the future, make data-informed decisions, invest in strategic priorities, create capacity for new initiatives, and emphasize outcomes.

STRATEGIC GOALS AND OBJECTIVES

Goals are the high-level descriptions of what APA must achieve to be successful. To some degree, they are aspirational in that they are wide-ranging, complex, and ongoing. Objectives are more specific and address the component pieces of each goal.

Utilize psychology to make a positive impact on critical societal issues.

- Employ psychology to improve population health, increase access to services, and reduce disparities.
- Promote the application of psychological science to the development and adaptive use of new technologies that affect people's lives.
- Use psychology to improve the functioning of public and private institutions, organizations, systems, and communities.
- Increase the influence of psychology on policy decisions at the international, national, state, and local levels.
- Foster the advancement of human rights, fairness, diversity, and inclusion through the application of psychological science.

Elevate the public's understanding of, regard for, and use of psychology.

- Expand the public's perception of psychology to accurately reflect the full breadth of the field.
- Influence educational systems to foster lifelong appreciation and application of psychology.
- Make psychological science accessible and understandable to the public and key decision makers.
- Distinguish psychology's unique contributions in health, health care, and human welfare.
- Become a go-to organization for the public regarding the quality and effectiveness of psychology-related products and services.

Prepare the discipline and profession of psychology for the future.

- Attract, diversify, develop, and support the next generation of psychology professionals.
- Protect and increase funding for applied psychology, education, practice, basic, applied, and clinical research, and training.
- Facilitate greater alignment between the science and practice of psychology.
- Promote the adoption of new technologies and methodologies in psychology and guide their integration into the discipline and profession.
- Ensure that psychology functions as a hub of interdisciplinary collaboration.

Strengthen APA's standing as an authoritative voice for psychology.

- Expand APA's position as a premier provider of science, practice, education, and career resources for psychology.
- Establish, uphold, and embody the ethical standards for the profession and discipline nationally.
- Increase the impact of APA's legislative, regulatory, marketplace, and social welfare advocacy.
- Serve as a leading resource for standards and evidence-based guidelines for the field.

8 focus groups

EVERY APA MEMBER was invited to take the strategic plan survey

425 invited for interviews

COMPLETED 195 phone interviews WITH GOVERNANCE MEMBERS

20+ *hours spent* engaging major boards and select committees

10K surveys received from members and nonmembers

700 responses received during public comment period

DEVELOPMENT PROCESS

As an organization that represents the entire field of psychology, APA must focus on overarching issues that affect the discipline and profession and engage in activities that have broad impact.

APA's new strategic plan—only the second in the association's 126-year history—is a three-to-five-year blueprint that reflects the best thinking of its governance, members, collaborators, and staff on how to succeed in the current environment and thrive in the coming years.

It is intended to be a living document that is flexible and responsive to the emerging needs of society, as well as APA's diverse constituencies. Rather than being an endpoint, the plan is the first step in a process designed to ensure that APA becomes an even more relevant, effective, and sustainable voice for psychology.

From the outset, the development of APA's new strategic plan has been driven by the idea that, in order for the association to be successful, the plan itself must be co-created by its members and staff, with input from the broader psychological community. To achieve this dynamic, APA intentionally sought the input of every member of the association.

In practice, this meant that APA invited every member of Council and its Board of Directors, as well as all division presidents, board and committee chairs, APA past presidents, and presidents and executive directors of affiliated state, provincial, and territorial psychological associations to participate in phone interviews to discuss the key issues and opportunities facing the organization.

APA also conducted eight focus groups with APA/APA Services, Inc. members and non-members and conducted a survey completed by over 10,000 members and non-members. APA solicited staff input through focus groups, surveys, and town hall meetings.

In addition to gathering information from stakeholders, APA interviewed leaders of nonprofit and commercial organizations to glean insight into how these organizations handle a variety of issues ranging from strategic planning to diversity and inclusion. APA also analyzed trends across key areas including research funding, health policy, and emerging technologies, to better understand the environment the association will be operating in over the life of the plan.

Based on this feedback, APA developed draft versions of the strategic plan, which were shared with the APA/APA Services, Inc. Board of Directors, Board of Scientific Affairs, Board for the Advancement of Psychology in the Public Interest, Board of Educational Affairs, Board of Professional Affairs, Membership Board, Policy and Planning Board, Council Leadership Team and an ad-hoc advisory group made up of members from across the association. Feedback from these groups was also incorporated into the plan.

APA staff then presented the plan to members and governance groups, including the Council, through a series of webinars. Further adjustments were made to the plan to reflect their comments.

APA posted the plan for public comment from December 19, 2018, through January 19, 2019. APA received more than 700 responses, the clear majority of which supported the plan as written.

The plan was adopted by the APA Council of Representatives on February 15, 2019, with an overwhelming 96.3 percent supporting the motion. This vote marks the start of a new chapter in APA's history.

The implementation process of the plan will be transformative and comprehensive, with the association realigning itself and refocusing its work in concert with the new strategic priorities. During the implementation stage, APA will again seek input and feedback from APA members and stakeholders on defining the programs and activities the association undertakes, as well as concrete outcomes within each set of goals and objectives.

AMERICAN
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AMERICAN PSYCHOLOGICAL ASSOCIATION

Role of Psychology and the American Psychological Association in Dismantling Systemic Racism Against People of Color in the United States

OCTOBER 2021

Historically, racism has been used to divide the public, fuel racial violence, and reduce support for health care, economic, and education policy that would benefit the well-being of society (Blacksher & Valles, 2021; Cui & Worrell, 2019; McGhee, 2021). American psychology, including APA, has been complicit in actions that have perpetuated racism. Therefore, an important aspect of APA's continued work in understanding how psychology can meaningfully contribute to disarming and dismantling individual and systemic racism, is to first acknowledge that racism has had a historical underpinning in White supremacy and in supporting structures of White privilege institutionally and structurally for centuries.

The purpose of this resolution is to identify psychology's role in helping to expose, understand, and ultimately dismantle racism that is operating across all levels in each of the following systems of society – education, science, health care, work and economic opportunities, criminal justice, early childhood development, and government and public policy, as addressed below, while acknowledging that systemic racism also has impact beyond these sectors.

For the first time, APA and American psychology are systematically and intentionally examining, acknowledging, and charting a path forward to address their roles in racism. At the same time, this is an insufficient response with respect to both psychology's responsibility and its potential to heal. In short, this resolution is in itself necessary but not sufficient. The resolution possesses moral legitimacy only as one step in an ongoing process, not as an endpoint. Not later than the Council of Representatives' second meeting of 2022, and with advice from the Task Force on Strategies to Eradicate Racism, Discrimination, and Hate and other subject matter experts within and outside the Association, APA's CEO will develop a plan to prioritize, operationalize, and ensure accountability for achieving the goals of the resolutions set forth below.

This resolution also acknowledges the complexity of ethnoracial dialogues, especially in the United States (U.S.). While the limited and forced federal categorization and definition of ethnicity and race exist, the minoritized experiences of individuals and communities facing systemic racism cannot be easily and plainly described. For this reason, in this resolution, "ethnic and racial minorities," "ethnically and racially diverse individuals," "people of color," and other terms are interchangeably used while also mentioning specific ethnic and racial groups. Terms such as "people of color" are also used as inclusive language for biracial and multiracial individuals who must navigate multiple race-related systemic challenges. The resolution also warns that a monolithic approach to understanding ethnically and racially categorized people without appreciating the diversity-within factors and intersectional identities in itself is a form of systemic racism that denies various unique challenges and strengths that exist within each ethnic and racial group.

EDUCATION

WHEREAS, Racism at every level permeates the landscape of education in the United States (U.S.), from housing and policies that determine where children are zoned to attend school in prekindergarten through postsecondary and lifelong learning, to the detriment of the academic achievement, self-concept, persistence, and success of students of color (Baumgartner & Johnson-Bailey, 2010; Burt et al., 2018; Sosina & Weathers, 2019; Voight et al., 2015; Wong et al., 2003);

WHEREAS, Access to quality education, affirming and safe education environments, and positive academic support impact not only people of color but also the larger society, given that attainment of education positively influences economic, vocational, physical health, psychological health, community, and social well-being (Gage et al., 2019; Krezmien et al., 2006; Sullivan et al, 2014);

WHEREAS, Education holds the promise of personal and communal well-being for students of color (Worrell et al., 2020), but that the history of racism has consistently led to defunding, under-resourcing, and police presence in schools, specifically depriving people of color and affecting their job procurement, job experiences, and other educational outcomes (Freeman, 2021; Metzl, 2019);

WHEREAS, teachers of color continue to be underrepresented in U.S. K-12 schools, which can negatively impact the self-image of students of color in predominantly White educational spaces (Clark & Clark, 1947; Gaias et al., 2021; Jordan & Hernandez-Reif, 2009; Kohli, 2008; Mabokela & Madeson, 2003; Okonofua et al., 2021);

WHEREAS, Students of color are increasingly enrolled in majority-underserved, high-poverty schools and school segregation is associated with significant racial disparities in a) per-pupil school funding, b)teacher qualifications and experience, c) access to honors and Advanced Placement courses, and d) access to health and mental health services in schools, among other disparities, and therefore represents a structural form of racism that is foundational to racial and ethnic inequities in educational attainment (Graves & Blake, 2016; Sosina & Weathers, 2019; Teranishi, 2010);

WHEREAS, Asian American and Pacific Islander children in educational settings are harmed by the "model minority" myth, which suggests that these students do not experience educational or mental health challenges and homogenizes very diverse Asian American populations (Leong & Lau, 2001; Luther et al., 2021). In addition, increased racism and xenophobia directed against Asian American and Pacific Islander children may negatively impact their self-image and mental health, potentially impairing their educational attainment. Immigrant Asian American and Pacific Islander children may have also experienced trauma due to war and conflict in their countries of origin, which may also affect their educational attainment (American Psychological Association, 2009, 2013);

WHEREAS, Previously unexamined ethnocentric curricular and co-curricular activities need to be carefully reviewed and addressed for the perpetuation of systemically racist beliefs in education policies (Brown & Brown, 2010; Harper, 2012; Hyland, 2005);

WHEREAS, individual interactions and everyday experiences of students of color with their peers and educators should be respected, and not considered a cultural enrichment to White educators and students (Lewis, 2003; Modica, 2015; Perez Huber & Cueva, 2012; Sera & Wall, 2021; Sue et al., 2007; Young, 2011);

WHEREAS, Educators should strive to provide inclusive learning experiences for all students, but they may fail to see the impacts of negative linguistic stereotyping and biases toward students of color, in contrast to affirmation of White students from Western and European backgrounds when both groups experience English-proficiency challenges and present with accents (Blanchard & Muller, 2015; Byrnes et al., 1997; Palmer & Eun-Young, 2005). Such discrepancies of treatment and reactions toward certain heritage languages can lead to a sense of shame and an expectation to assimilate to the White American norm, further systematically oppressing students of color with linguistic diversities (Flores et al., 2015; Gándara et al., 2004; Lippi-Green, 1997; Matthews & López, 2019; Ready & Wright, 2011; Tatum, 1987);

WHEREAS, Discriminatory policies and practices (forms of institutional racism), the inappropriate application of psychometric tests and assessment instruments, and teacher biases have prevailed in the overrepresentation of children of color classified in: special education; identified with behavioral problems; subjected to suspensions, expulsions, and placements in alternative schools; and associated with low graduation rates (Downey & Pribesh, 2004; Fulks et al., 2020; Gilliam et al., 2016; Girvan et al., 2019; Losen & Martinez, 2013);

WHEREAS, Education has been used as a weapon of oppression against people of color within the U.S. domestic context, including boarding schools designed to strip Indigenous Americans of their language and culture, and segregated schools that provided inferior education and opportunity (Mohatt et al., 2014; Family and Children's Trust Fund of Virginia, 2019), and international students of color whose families settle in the U.S. with refugee, asylee, immigrant, and/or undocumented statuses face additional layers of systemic racialized oppression (Chen & Rhoads, 2016; Gildersleeve & Vigil, 2015; Merriam et al., 2001; Suárez-Orozco et al., 2015; Teranishi et al., 2015);

WHEREAS, Interlocking systems of oppression negatively affect students marginalized by their intersectional identities. For example, Black female students with a disability—such that they experience exclusionary discipline at significantly higher rates than their White peers, leading to school pushout (Gage et al., 2019; Krezmien et al., 2006; Sullivan et al., 2014). In addition, for girls and women of color, systemic racism and systemic sexism are intersecting oppressive factors in education (Crenshaw, 1991; Eaton et al., 2020);

WHEREAS, Because of the disproportionate concentration of students of color in lower economic strata resulting from racism, students of color seeking higher and graduate education are often in a disadvantaged economic position, which necessitates increased reliance on student loans, in turn leading to further systemic disadvantage on the basis of race (Jiménez & Glater, 2020; Lantz & Davis, 2017; Wilcox et al., 2021a, 2021b);

WHEREAS, Assessments of the impacts of systemic racism in education often center around what negative and hurtful experiences students face, but what remains lacking are institutional/school-level conversations and actions to intervene and address systemic oppression that educators of color face. Educators of color, often being the only or one of the few in educational spaces, are expected to navigate White norms set by their peers and administrators but also students (and their families) without adequate support and resources, and with an additional, disproportionate, and often under-appreciated role in advancing institutional diversity, equity, and inclusion agendas (Alger, 2000; Gonzalez, 1995; Jackson & Phelps, 2004; Jimenez et al., 2019; Perna, 2003; Turner et al., 2008);

WHEREAS, Although education is intended to liberate and enlighten, it has too often oppressed and silenced the voices of people of color who know and have experienced a different history. Psychological education comes from a White, Western European and ethnocentric perspective that has distorted the lives of people of color, omitted their contributions in history, and portrayed them in pathological and stereotypical ways. The detrimental impact to people of color is demeaning, and it provides those with power and

privilege a false reality that allows them to oppress and pass racist policies in innocence and naivete (Cross, 2005; Huber et al., 2006);

WHEREAS, The use of standardized test scores in the admissions process are viewed inappropriately by some as a barometer of applicants' academic merit, when in fact they "do not measure the full range of abilities that are needed in higher education, nor were they designed to . . . tests are therefore best viewed as imprecise estimates of how students might be expected to perform" (Institute of Medicine, 2004, p. 6; Worrell, 2009); and

WHEREAS, The climate for diversity in higher education and graduate psychology programs can encourage or suppress underrepresented racial and ethnic group participation (Worrell, 2011); in education, students of color are subjected to more negative racial experiences, and their racial and ethnic backgrounds are often portrayed in a stereotypical and demeaning fashion (Cheryan & Monin, 2005; Maton et al., 2011; Mendoza-Denton et al., 2002);

THEREFORE, BE IT RESOLVED that APA reaffirms its commitment to combating every level of racism throughout the education system, from prekindergarten through postsecondary education and lifelong learning, for its devastating effects on the academic, physical, psychological, and economic well-being of people and communities of color;

THEREFORE, BE IT RESOLVED that APA will advocate for rigorous education policy in order to create equity across learning environments that will positively impact students of color and the larger society, fostering educational attainment that will reverberate across social determinants of health, complemented with population-specific policies to redress the history of violence and inequity disenfranchising Indigenous American, Latinx, Black, Middle Eastern and North African, Asian American and Pacific Islander, and biracial and multiracial communities;

THEREFORE, BE IT RESOLVED that APA affirms the importance of teaching the history of racism in the U.S. and will continue to provide resources to support the teaching of this history to prepare all students to think critically about identity, community, and civics, fostering both educational success and solidarity to build a more just future;

THEREFORE, BE IT RESOLVED that APA will advocate for evidence-based pre-service and in-service training for teachers to raise awareness of and mitigate against biases, both explicit and implicit, that negatively affect learning and development among students of color;

THEREFORE, BE IT RESOLVED that APA will support school desegregation efforts to achieve a better balance across schools to reflect the diversity of the communities that public schools serve while ensuring that resources are adequately advocated for historically minoritized and marginalized students;

THEREFORE, BE IT RESOLVED that APA urges all schools and school districts to review student disciplinary policies and collect and monitor demographic data on students under disciplinary action, ensuring that these policies do not disproportionately affect students of color;

THEREFORE, BE IT RESOLVED that APA further urges all schools and school districts to provide culturally responsive and age-appropriate mental health services and supports to students, particularly historically minoritized and marginalized students at risk for behavioral, academic, or other psychosocial challenges that may affect student learning;

THEREFORE, BE IT RESOLVED that through appropriate mechanisms, APA will encourage higher education admissions policies that require a comprehensive, holistic review of each applicant, including an assessment of applicants' attributes that support the mission of the institution, and balance quantitative data with these qualitative characteristics. Further, APA will encourage programs to consider interview processes that are not cost-prohibitive to applicants of color and do not disadvantage applicants who cannot travel;

THEREFORE, BE IT RESOLVED that APA will advocate for Public Service Loan Forgiveness and college affordability in order to promote equitable access to higher and graduate education for students of color;

THEREFORE, BE IT RESOLVED that APA calls on psychology departments and programs to engage in sustainable and systemic antiracist efforts, and actively work to change educational environments that are ethnoracially discriminatory and oppressive;

THEREFORE, BE IT RESOLVED that APA will encourage higher education institutions and graduate psychology training and internship programs to develop and regularly evaluate the climate for equity and inclusion; regularly train students, faculty, and staff regarding institutional antiracism and anti-racist policies and expectations; and establish confidential mediation processes for students and faculty who experience racism and/or racism;

THEREFORE, BE IT RESOLVED that through appropriate mechanisms, APA will support and lead efforts to encourage undergraduate and graduate departments and programs of psychology to systematically review instructional materials and goals, and incorporate greater attention to psychology's historical role in perpetuating racism;

THEREFORE, BE IT RESOLVED that through appropriate mechanisms, APA will encourage Health Service Psychology graduate programs to establish explicit policies regarding the value of culturally competent care pursuant to the APA Multicultural Guidelines and the role of institutional diversity in achieving this goal;

THEREFORE, BE IT RESOLVED that APA will support and lead research, advocacy, prevention, and program development efforts that seek to ameliorate the antecedents and consequences of all levels of racism throughout the education system through psychological science and practice;

THEREFORE, BE IT RESOLVED that APA calls on all psychologists to actively engage in antiracist efforts to address the causes and effects of all levels of racism in the education system; advocate for changes to policies and procedures that contribute to racist practices and outcomes; engage in antiracist practice through an intersectional lens; develop preventive and intervention efforts to promote racial justice; and promote racial justice through their research, teaching, practice, and advocacy; and

THEREFORE, BE IT RESOLVED that because racism in criminal justice, employment, housing, health care, and other systems both causes and is caused by racism in the education system, APA will support and lead research, advocacy, prevention, and program development efforts that seek to address systemic racism at the intersection of education and other systems.

SCIENCE

WHEREAS, Stereotypes, insufficient education and information, and structural biases and barriers have limited the access and interest of populations of color to the field of psychological science (e.g., Buchanan et al., in press; Roberts et al., 2020);

WHEREAS, Structural biases and barriers, such as a lack of appreciation for qualitative and mixed-methods research, have limited the research on historically marginalized groups and from diverse scholars (Chavez et al., 2008; Howard & Hoffman, 2018);

WHEREAS, Structural biases and barriers, such as biases toward research with White comparison groups, have created inequities in the review processes used to evaluate research based on theories and methods relevant to the study of diverse populations (Buchanan et al., in press; Hall & Maramba, 2001);

WHEREAS, Convenience sampling has maintained a "White-default" approach to the reporting of findings in psychological science, which also reproduces Whiteness as the standard against which outcomes for marginalized populations are measured (Buchanan et al., in press);

WHEREAS, Epistemological biases and the devaluation of all but those epistemologies most closely aligned with Whiteness have limited sampling designs, research designs, and methodological approaches that, in turn, stand to limit our understanding of the qualitative and quantitative characteristics and experiences of underrepresented and historically marginalized groups within the scientific literature (Cokley & Awad, 2008, 2013; Grzanka & Moradi, 2021);

WHEREAS, The boundaries of psychological science have often been controlled to define "good" psychological science as that which centers "objectivity," an extension of well-established literatures despite the historic marginalization of scholars and communities of color from those literatures, is quantitative in nature, and is rooted in paradigms most closely aligned with Whiteness, thereby equating "good" psychological science with the reproduction of systemic and structural barriers to antiracist scholarship (Grzanka & Cole, in press);

WHEREAS, Scholarly structures pertaining to the propagation, dissemination, and recognition of research, such as impact factors and citation counts, have created disparate opportunities, processes, and outcomes for scholars from racial/ethnic and intersecting marginalized backgrounds. This has implications for their retention and recruitment into the field, provision of mentoring tailored to the needs of junior faculty of color, and their prospects for professional development, such as procuring tenure in departments of psychology and related fields (Buchanan et al., in press);

WHEREAS, The devaluing of contributions of scientists of color has resulted in their marginalization from full participation in the field of psychology, including APA governance groups, journal editorial and peer review positions, and tenured and tenure-track university positions, in turn harming the scope of scientific progress (Roberts et al., 2020);

WHEREAS, Research training has inadequately prepared new cohorts of psychological scientists to identify, understand, and correct systemic inequities, such as the lack of recruitment of diverse and underrepresented participants, the use of measurement tools normed for White populations and the underuse of participatory approaches that emphasize collaboration with community stakeholders, thereby continuing to perpetuate inequity in psychological science (Helms et al., 2005); and,

WHEREAS, Psychological science has focused predominantly on examining and changing individuals rather than examining and changing the institutions that result in psychological detriment, such as the harms caused by systems of racism to people of color, and its diversity efforts have centered on the comparison of people of color to White people rather than seeking to critique and dismantle racism (Buchanan & Wiklund, 2020; Grzanka & Miles, 2016; Grzanka & Cole, in press);

THEREFORE, BE IT RESOLVED that APA reaffirms its commitment to combating every level of racism throughout psychological science, from education and training, support for scholars of color, addressing the marginalization of those methods and epistemologies less aligned with Whiteness, enhancing expectations in the reporting of psychological science, to working to ensure that the future of psychological science atones for its historical misuse that has resulted in academic, physical, psychological, and economic harm for individuals and communities of color;

THEREFORE, BE IT RESOLVED that APA will invest in the training of scientists to ensure all can identify, understand, and address the historical and contemporary rootedness of much psychological science in White socio-cultural norms; and to develop a psychological science that helps to dismantle systemic and structural racism that has disproportionally excluded perspectives, scholars, and samples of people of color from psychological research;

THEREFORE, BE IT RESOLVED that APA affirms that scholars strive for samples that take a more careful approach to representative sampling in quantitative research, so that research results are applicable beyond merely White, middle class, college-educated populations, and that genuinely and thoroughly integrates intersectionality;

THEREFORE, BE IT RESOLVED that APA affirms that the body of psychological science must be comprised of rigorous research conducted across the epistemological continuum, to include not only those positivist and postpositivist paradigms that most closely align with Whiteness, but also constructivist, critical-ideological, and other critical paradigms; that no one methodological approach is "better," but rather, each may be conducted with or without appropriate scientific rigor and with or without appropriate applicability to the research question(s). High-quality psychological science includes quantitative, qualitative, mixed-methods, and participatory approaches conducted in accordance with the standards of rigor unique to each approach, and conclusions informed by the totality of the high-quality psychological science that spans these methods which are more likely to be racially just;

THEREFORE, BE IT RESOLVED that APA affirms and will encourage psychological scientists to conduct and report research within APA journals in a manner that better incorporates samples that are more inclusive of participants of color relevant to their psychological research, as appropriate, to increase the diversity of the samples examined and reported in psychological research. This includes engaging representatives of communities of color in planning, conducting, interpreting, and communicating about such research to help ensure that their human rights are respected and protected, and to promote the objectivity of scientific inquiry by considering historical, cultural, and political contexts;

THEREFORE, BE IT RESOLVED that APA will adopt practices and collect data to ensure accountability, reflected in metrics such as the proportion of papers including racially diverse samples sent for peer review, commensurate practices in manuscript titling, and monitoring of discriminatory or racist comments within the reviewing and editorial process;

THEREFORE, BE IT RESOLVED that APA will create resources to guide scientific departments in addressing inequities in review, promotion and tenure criteria (and critically evaluate publication impact metrics) to place a value on the work of scholars of color, provide career resources, mentoring, and reinforcement for research that adopts practices that promote standards for how research is conducted, reported, and disseminated that are less rooted in Whiteness;

THEREFORE, BE IT RESOLVED that APA will advocate for increased research funding and opportunities for scholars of color to expand the foundation of knowledge that informs diagnosis and intervention and other aspects of psychological practice;

THEREFORE, BE IT RESOLVED that APA re-affirms its commitment to Evidence-Based Practice as the standard of science-informed treatment, including a commitment to promote the need for and support of research questions being answered by a body of methodologically and epistemologically diverse, high-quality psychological science;

THEREFORE, BE IT RESOLVED that APA will strive to ensure that scholars of color are represented on APA and other peer review panels, editorial boards, and governance groups and in leadership positions that shape practices and policies (which may be enhanced by mentoring and guidance for early career scientists of color); and

THEREFORE, BE IT RESOLVED that APA will systematically evaluate the policies and practices used to review psychological science (e.g., grant proposals, publications, and reports) and evaluate the progress of scholars of color, as well as among researchers studying individuals and communities of color, to dismantle all forms of racism within psychological science and engage in reform and redesign of policies and practices to assure equity and move toward an antiracist psychological science.

HEALTH CARE

WHEREAS, Health care in the U.S. reflects the history of racism denying communities of color access to care, resulting in an inequitable and inaccessible health care system for all (American Psychological Association, 2021b; Bailey et al., 2021; Gee & Ontniano Verissimo, 2016; James, 2017; Krieger, 2021);

WHEREAS, The dominant health care model informing education, training, and practice interventions has largely been derived from White and Western populations and professionals without systematic inclusion of other perspectives, resulting in systems and practices that do not acknowledge or incorporate non-White, non-Western knowledge and perspectives (Interlandi, 2019);

WHEREAS, The traditional "medical model" of health care pathologizes cultural difference, driving underutilization by marginalized communities due to stigma and creating barriers to a population health approach, which aims to provide access to primary, secondary, and tertiary levels of prevention and intervention services for historically minoritized communities (Bailey et al., 2021);

WHEREAS, The failure to understand how the role of power, combined with the systematic exclusion of vital cultural and psychological knowledge and resources and inadequate cultural competency of providers to work with people of color, results in the application and misapplication of diagnoses and therapeutic interventions less well-suited to those who are not White and Western (American Psychological Association, 2021c);

WHEREAS, This misapplication can reinforce inaccurate theories, models, and interventions and stigmatization, which result in inadequate, inappropriate, potentially harmful and fundamentally poor health care for people of color (American Psychological Association, 2021c);

WHEREAS, The history of oppression suffered by people of color has resulted in intergenerational trauma that calls for a developmental, culturally responsive, and race conscious, trauma-informed, and lifespan approach to treatment (Comas-Diaz, Hall & Neville 2019; Mohatt et al., 2014);

WHEREAS, The COVID-19 pandemic has magnified the profound existing socioeconomic, racial/ethnic, and intersectional inequities in access to diagnostic assessment and behavioral health services to address anxiety, depression, and grief, among other mental health concerns (Evans & Bufka, 2020); and

WHEREAS, Many people of color experience multiple barriers to accessing needed behavioral health services, including cultural and linguistic barriers, the high cost of care, limited or challenging insurance options, unaffordable or not easily accessible transportation, and a paucity of appropriately trained and culturally responsive providers in communities of color (American Psychological Association, 2017).

THEREFORE, BE IT RESOLVED that APA will strongly encourage educators and trainers of health care providers to address the limitations of knowledge derived primarily from White and Western populations, and will promote education and training structures across the professional lifespan that are inclusive of diverse perspectives to improve the knowledge and cultural responsiveness of professionals;

THEREFORE, BE IT RESOLVED that APA affirms that psychological practice needs to adopt culturally responsive, evidence-based prevention, early intervention, and recovery frameworks based on a population health approach to dismantle power structures in the behavioral health care system that serve to create barriers to effective and quality care to people of color;

THEREFORE, BE IT RESOLVED that through continuing education policies, as appropriate, APA will encourage psychologists and other providers to seek further education and training on implicit bias, microaggressions, and the necessity of a developmentally, culturally sensitive and race conscious, trauma-informed, and lifespan approach to treatment when working with populations with histories of oppression and intergenerational trauma;

THEREFORE, BE IT RESOLVED that APA will partner in interprofessional and interdisciplinary program development, consultation, and advocacy efforts in support of culturally derived, informed, and adapted evidence-based and practice-based evidence, assessments, and interventions that reflect the knowledge, experience, and inclusion of intersectional communities of color;

THEREFORE, BE IT RESOLVED that APA will continue to advocate for greater federal investment and funding in training of psychologists from underrepresented groups and to expand incentives for psychologists and other mental health professionals to work in underserved communities (e.g., through expansion of federal Health Resources and Services Administration's programs, such as the National Health Service Corps);

THEREFORE, BE IT RESOLVED that APA will continue to advocate for the availability and accessibility of and payment for culturally responsive telehealth practices, such as audio-only telemental health services and interjurisdictional practice, that reduce barriers to access for all populations, especially those in rural and remote areas, without access to significant technology, and to those with disabilities, and thereby reduce geographic, cultural, functional and linguistic barriers to accessing care;

THEREFORE, BE IT RESOLVED that APA will continue to develop and advocate for access to Current Procedural Terminology (CPT) codes and reimbursement models to capture the ways in which psychologists practice across diverse groups in addressing mental health, physical health, and social determinants of health;

THEREFORE, BE IT RESOLVED that when advancing a population health approach, APA will also promote quality measurement that captures disparities across diverse groups, such as poor quality care, and advance the development and implementation of quality and trusted services that eliminate ethnic and racial disparities in care; and

THEREFORE, BE IT RESOLVED that APA will continue to advocate for equitable health care for all, including comprehensive health care for communities of color at federal and state levels, and stronger enforcement of mental health parity laws to ensure that behavioral health treatments are adequately covered by insurance plans.

WORK AND ECONOMIC OPPORTUNITIES

WHEREAS, Work is integral to adult life and human identity, a critical source of economic opportunity, and a key contributor to the welfare of families, communities, and society at large (Katz & Kahn, 1978), yet ample research evidence demonstrates how racism at all levels can powerfully undermine equal access and

equal outcomes at work and in the workforce (Avery et al., 2018; Avery & Ruggs, 2020);

WHEREAS, The history of the U.S. includes the use of racism to divide the workforce, facilitate unsafe and racist workplaces, and justify low wages especially for workers of color (Gee & Ford, 2011);

WHEREAS, Both work and racism interact with one another to profoundly affect the world of work, including disempowering multiracial labor unions, facilitating deindustrialization's disproportionate impact on communities of color, and promoting the "wages of Whiteness" privileging White workers and marginalizing immigrant workers and workers of color (Roediger, 1999);

WHEREAS, Technological advances (e.g. artificial intelligence, automation) in a globalized world worsen racial and economic inequities across the globe, fueling survival immigration and anti-immigrant sentiment (Matamoros-Fernández, 2017);

WHEREAS, Racism diminishes workforce training and development opportunities for people and communities of color, contributing to higher levels of unemployment, poverty, crime, community violence, and problems for the re-entry population securing jobs;

WHEREAS, Employers will perpetuate systemic racism in their work environment whenever they fail to adopt a lens of equity, diversity, and inclusion, thereby risking the creation of discriminatory policies and practices that uphold a broader climate and culture rife with biases, both explicit and unintentional;

WHEREAS, Ethnic and cultural diversity yields a substantial positive financial return for U.S. companies, especially for diversity at the executive level (Hunt et al., 2015; Roberson & Park, 2007) and may lead to other valued organizational outcomes when implemented well from the top and integrated into organizational policy and practice, including increased profitability and increased employee motivation, commitment, and productivity (Peterson & Mann, 2020); and

WHEREAS, Applied psychology has developed evidence-based interventions for addressing racism in the workplace as a systemic problem requiring multimodal solutions prior to, during, and subsequent to entering the workforce, including congenial and productive intergroup contact in the workplace.

THEREFORE, BE IT RESOLVED that APA will collaborate through consultation and policy with private and public sectors at local and national levels to meaningfully increase representation of people of color at all levels in the workforce by helping to ensure equal access and opportunity along all critical educational and training pathways showing evidence for a more diverse and robust workforce applicant pool;

THEREFORE, BE IT RESOLVED that APA will advocate for organizational and policy solutions with robust equity, diversity, and inclusion initiatives across public and private sectors, along with comprehensive health care and a broad parental leave and daycare program, all of which will benefit communities of color, and thus the good of all families, communities, and the nation;

THEREFORE, BE IT RESOLVED that APA will encourage employers to use reliable, valid, and fair employment testing and personnel selection practices that minimize bias, reduce adverse impact, and comply with professional standards, legal requirements, and ethical guidelines (Equal Employment Opportunity Commission [EEOC], 1978; EEOC 2012; Hough et al., 2001; Morelli, 2019; Ployhart & Holtz, 2008; Schmidt & Hunter, 1998; Society for Industrial and Organizational Psychology [SIOP], 2018). Such practices require continuous evaluation and investment in personnel selection systems to maintain their high quality and reflect their commitment to providing people of color applying to jobs with fair and equitable hiring opportunities (Jones et al., 2017; SIOP, 2018);

THEREFORE, BE IT RESOLVED that APA will urge all organizations to examine, redefine, and improve organizational culture to fully include and support employees of color at all levels. This requires a systematic examination of policies and practices including but not limited to performance management, training, compensation, and changes to organizational climate;

THEREFORE, BE IT RESOLVED that APA will advocate—within and outside the discipline—for top-down organizational cultural change implemented with employees and cultivated through leadership, teamwork, and day-to-day individual behaviors that contribute to productive intergroup contact. This should include feedback structures and processes that facilitate bottom-up, assessment, and change in the form of organizational diversity, equity, and inclusion committees and multiracial labor unions; and

THEREFORE, BE IT RESOLVED that APA will advocate—within and outside the discipline—for specific support structures, mentorship, professional development, and retention and recruitment of employees of color in leadership and upper management positions, especially given the additional burdens such employees face due to intersecting marginalization.

CRIMINAL AND JUVENILE JUSTICE

WHEREAS, The U.S. criminal justice system originated in laws, policies, and practices that criminalized and punished Indigenous and African people for resisting colonization and slavery, and has evolved to require or incentivize the oppression of people of color through convict leasing; the Jim Crow era; the wars on crime and drugs; broken-windows, zero-tolerance, and quality-of-life policing; mass incarceration; and the criminalization of immigrants (Chavez-Dueñas et al., 2019; Cunneen & Tauri, 2019; Hinton & Cook, 2021; Muhammed, 2019);

WHEREAS, The criminal justice system produces glaring racial and ethnic disparities for people of color, compared to White people, through more aggressive policing and prosecution, increasing the likelihood that people of color plead guilty and are convicted by judges and juries, are detained and imprisoned for longer periods of time (Kovera, 2019), and experience a host of negative educational, economic, health, and mental health consequences as a result (Bor et al., 2018; Bryant-Davis et al., 2017; Burke et al., under contract; Stevenson et al., 2020);

WHEREAS, Bias and discrimination can have cumulatively worse impacts at each juncture within the criminal and juvenile justice systems (Hunt, 2015; Kovera, 2019; Stevenson et al., 2020) and are especially pronounced against individuals who hold multiple marginalized identities (Ritchie, 2017); and

WHEREAS, Decades of psychological science have yielded incontrovertible evidence that negative criminal and juvenile justice outcomes for people of color are facilitated by (a) structural racism in the system that generates bias and discrimination (Muhammed, 2019); (b) institutional racism in policies and practices, including professional socialization into subcultures of social control and intolerance (Hall et al., 2016; Stoughton, 2015) and chronic situational conditions that are known to intensify bias (Pryor et al., 2020; Swencionis & Goff, 2017); and (c) interpersonal racism arising from stereotypes and attitudes among criminal and juvenile justice professionals, both explicit and implicit, that dehumanize people of color and associate them with criminality and threat (Andretta et al., 2019; Eberhardt, 2019; Willis-Esqueda, 2020), all of which threatens the perceived legitimacy of criminal and juvenile justice actors and undermines the system as a whole (Trinkner & Goff, 2019; Tyler, 2017);

THEREFORE, BE IT RESOLVED that APA will advocate for the development of empirically rooted, culturally informed policies, programs, and practices that seek to eliminate the disproportionate criminalization and punishment of people of color by reducing opportunities for discriminatory outcomes, such as discouraging law enforcement actions that overpolice communities of color; addressing factors known to relate to increased risk of bias in criminal justice professionals' decision-making, such as racial bias, serious mental illness, and substance use; and instituting services that match both momentary and long-term needs, including responding to individuals' mental health crises or disabilities with appropriately trained behavioral health professionals and community-based programs, and supporting successful rehabilitation of people of color who enter the system and reintegrate into their community (Goff & Rau, 2020; Klukoff et al., 2021; Kovera, 2019; Primm et al., 2005; Pryor et al., 2020; Thompson et al., 2016);

THEREFORE, BE IT RESOLVED that APA will work to address the harms inflicted upon people of color by the criminal and juvenile justice system by advancing historically and culturally informed programs, policies and practices that foster educational, economic, physical, and psychological well-being and resilience among people, families, and communities of color (Arditti & Johnson, 2020; Fine & Cross, 2016);

THEREFORE, BE IT RESOLVED that APA will promote partnerships between psychologists and criminal and juvenile justice agencies to foster research and development related to the use of rigorous, diversity-science informed methods that facilitate measurement, analysis, and identification of racial and ethnic disparities throughout the criminal and juvenile justice system and support data-driven changes to laws, policies, practices, and multicomponent interventions that will eliminate structural racism, dismantle institutional racism, and facilitate the democratic ideal of equal justice for all (Boxer et al., 2021; Miller et al., 2019); and

THEREFORE, BE IT RESOLVED that APA will support criminal and juvenile justice agencies as they build antiracist values into their organizational policies and practices, including encouraging administrators and supervisors to endorse antiracist principles through the execution of evidence-based reforms that eradicate bias and discrimination; adopt effective interventions that raise awareness of the conditions that produce racial and ethnic disparities at every level of the criminal justice system (Brannon et al., 2018; Neville & Spanierman, 2012); and implement recruitment, hiring, and promotion practices that attract, retain, and advance racially and ethnically diverse people who understand the lives and perspectives of people of color as well as people who are committed to equity and justice (Ba et al., 2021; Ward et al., 2009).

EARLY CHILDHOOD DEVELOPMENT

WHEREAS, Attitudes toward race are learned very early in life, through modeling within the family and within cultural contextual experiences. These socialization experiences may begin as parent-led processes but may become more peer-led during adolescence (Hu et al., 2017);

WHEREAS, Interpersonal and internalized racism develop through direct methods of transmitting race-related messages, such as educational conversations with parents, or through indirect socialization experiences, such as observation of parental attitudes and behaviors, which produce the development of attitudes and biases towards oneself and others (Boykin & Toms, 1985; Hughes & Chen, 1997; Hughes et al., 2006; Liu et al., 2019);

WHEREAS, Research on racism and implicit bias has shown that anti-Black racism and discrimination relates to parental discipline and occurs from toddlerhood throughout adolescence. Racism may be more likely to be indirectly communicated through parents' negative attitudes towards people of color (Brown et al., 2007; Lesane-Brown et al., 2010; Xu et al., 2014);

WHEREAS, Disparities in school discipline grow from racism of school staff as well as policing in schools and the influence of

the norms of White sociocultural norms consequently impacting Black, Indigenous, and other students of color (Anyon et al., 2016; Sevon et al., 2021; Skiba et al., 2002);

WHEREAS, Research suggests that implicit biases may be reduced through interventions designed to either address biases directly or increase teachers' empathy for children of color (Gilliam et al., 2016);

WHEREAS, Systems and structures of racism affect youth of color even prenatally through such mechanisms as maternal health care, stressors associated with experiencing racism, and disparities in access to resources and opportunity, and continue to affect youth of color throughout the lifespan (APA 2021);

WHEREAS, Racist attitudes that often begin in early childhood have been linked to racial inequity (Kovera, 2019) and negative group outcomes (Dovidio et al., 2002; Greenwald et al., 2009);

WHEREAS, Significant adversity in life such as exposure to racism can undermine the foundations of healthy development (Shonkoff et al., 2021);

WHEREAS, Parents of color are more likely to be in low-wage jobs and paid less compared to White counterparts and to experience erratic work hours, and are less likely to have employment benefits like paid time off or parental leave. These challenges are often exacerbated for women of color. While evidence suggests that parents of color tend to spend more time with their children despite long and inconsistent work hours, this comes at the cost of overall well-being, with implications for childcare and ultimately child/adolescent mental health (Moorman, 2021);

WHEREAS, Children of all backgrounds who learn about their own culture and that of other ethnoracial identities yield more optimal psychosocial outcomes (Priest et al., 2014); and

WHEREAS, Increased contact between youth and people of different ethnoracial identities yields reduced racial conflict in the organization or environment (Dovidio et al., 2017);

THEREFORE, BE IT RESOLVED that all APA antiracism efforts should consider a developmental approach to how racism is socialized across the lifespan and include consideration of protective factors in the prevention of both interpersonal and internalized racist attitudes;

THEREFORE, BE IT RESOLVED that APA will support the development and implementation of interventions designed to address the prevention of racism and promotion of antiracism that are developmentally appropriate beginning in very early childhood;

THEREFORE, BE IT RESOLVED that to improve children's positive racial and ethnic socialization, APA will advocate for strategies to improve cross-racial experiences before children attend school, and increase contact with peers before age six, when they typically become a part of a school group. The adults in close contact with children need skills and guidance to provide environments that appreciate diversity and inclusion and reject racism and discrimination. Such adults include family members, caretakers, educators, and professionals serving children;

THEREFORE, BE IT RESOLVED that APA will advocate for increased research on racism that includes not only race-related outcomes but also childhood racism socialization processes, as well as support for the development of standardized effective measurement tools that quantify both direct and indirect racism socialization methods. This information will then help in the development of policies, practices and recommendations for promoting antiracism within and across generations;

THEREFORE, BE IT RESOLVED that APA will update materials developed for the public to be inclusive of cultural differences and current experiences of all communities, including citizens of diverse races and ethnic origins and more recent migrant groups;

THEREFORE, BE IT RESOLVED that APA will increase dissemination to the public of educational information addressing the prevention of racism and the promotion of antiracism in early childhood by engaging subject matter experts in opportunities to communicate via television, social media, audio and other visual formats, and other venues as available;

THEREFORE, BE IT RESOLVED that APA will advocate for learning environments (e.g., school, extracurricular activities) that are culturally diverse and antiracist; and

THEREFORE, BE IT RESOLVED that APA will promote alliances with other health professionals, educators, and community groups committed to children's well-being and concerned with systemic racism.

GOVERNMENT AND PUBLIC POLICY

WHEREAS, Public policy at all levels plays an inextricable role in perpetuating and eradicating racism through policy changes in areas including, but not limited to, education, health care, science, criminal justice, and employment;

WHEREAS, Racism, especially its institutional and structural forms, cannot be dismantled without effective public policy, as existing or absent public policy pertaining to (but not limited to) education, health care, science, criminal justice, and employment is rooted in both historical and contemporary racism;

WHEREAS, Psychology is uniquely positioned, and has a responsibility to inform antiracist and equity-driven public policy through psychological science and practice;

THEREFORE BE IT RESOLVED that APA reaffirms its commitment to promoting comprehensive strategies to address systemic racism, as well as actively taking steps to eradicate racism in U.S. governmentwide programs;

THEREFORE BE IT RESOLVED that APA is committed to the education and training of psychologists who are well-versed in both public policy as well as systemic and social determinants of health, including racism; and

THEREFORE BE IT RESOLVED that as Congress and state legislatures consider legislation concerning race and racism, APA will consider and apply psychological science in determining how best to educate, support, and/or oppose such proposals.

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APA Presidential Task Force on Enhancing Diversity

Final Report

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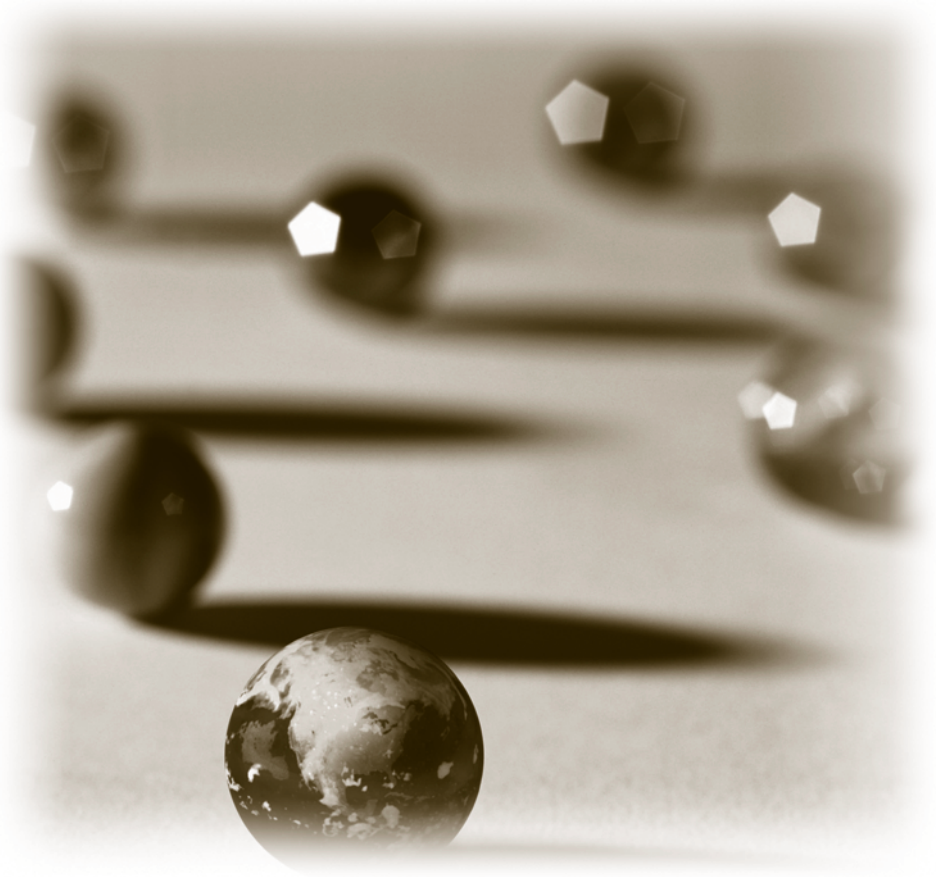

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Charge to the Task Force on Enhancing Diversity

To develop a report with recommendations for APA action on:

- Increasing APA's welcomeness to diverse groups
- Developing a conceptual model for reconciling differences between diverse groups

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*Dr. Haldeman was unable to attend the Task Force's meeting; Dr. Greene attended in his place.

[1] Biosketches of the task force members are provided in Appendix A.

American Psychological Association

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Final Report of the Task Force on Enhancing Diversity (TFED)

Preface

The following is a statement by 2005 APA President Ronald F. Levant, EdD, MBA, ABPP, of his vision in creating this Presidential Task Force on Enhancing Diversity Within APA.

I applaud the American Psychological Association's efforts to attract ethnic minority psychologists, notably through its Commission on Ethnic Minority Recruitment, Retention, and Training (CEMRRAT) and through other actions within the APA governance and central offices directed at other dimensions of diversity. Nevertheless, I believe that we are not doing everything we can to make APA a comfortable place for psychologists who are members of marginalized minority groups. As a White heterosexual able-bodied male, I understand that to make APA more welcoming to marginalized minorities, some resources may have to be reallocated, which may be perceived as threatening to members of the dominant majority group. However, I believe that it is in the interest of everyone—the majority and the minorities—to address this problem. By taking effective action to welcome diverse groups, APA's reputation as a welcoming place will grow, and that will lead to attracting and retaining more members. Furthermore, this will enable APA to evolve to more accurately reflect the changing demographics in American society. Moreover, by APA's becoming more welcoming and bringing in more diverse members, the level of creativity and productivity will increase because our deliberations will be enriched by having the benefit of multiple perspectives. Thus, APA will better serve marginalized groups in its clinical, research, education, and training cAPAcities.

I have appointed former APA President Richard M. Suinn, PhD, to chair a task force composed of APA leaders with expertise in a number of dimensions of diversity, including ethnicity, race, disability status, sexual orientation, aging, religion, and gender. The charge of the Task Force on EnhancingDiversity (TFED) was to develop a report with recommendations for APA action in these two areas: Increasing the sense of being welcome in APA for marginalized minorities, and developing a conceptual model for how to reconcile differences when they occur among diverse groups.

> *"...I have had numerous experiences over many years in APA wherein a lack of sensitivity or downright rudeness was in evidence in interactions between members of dominant groups and minorities..."*

I have chosen as the first goal of this task force developing recommendations for how APA can increase the sense of being welcome in APA for marginalized minorities because I have had numerous experiences over many years in APA wherein a lack of sensitivity or downright rudeness was inevidence in interactions between members of dominant groups and minorities (based on all of the dimensions of diversity, including race, ethnicity, culture, gender, sexual orientation, age, and disability status) at the interpersonal or small informal group level all the way up to the formal organizational level (e.g., the Council of Representatives). I think this constitutes institutionalized racism, sexism, heterosexism, ageism, and able-bodyism (and other

biases against those with disabilities), which flies in the face of the mission of APA, which is to "advance psychology as a science and a profession, and as a means of promoting health, education, and human welfare." I have asked that the task force document the marginalization of minorities in APA and develop a plan to at least enable APA to act upon its own stated mission by mainstreaming all of its members. I anticipate that this plan would be presented for adoption by the APA Council of Representatives with a plan for implementation by all aspects of our association.

I have chosen as the second goal of this task force developing a conceptual model and processes for how to reconcile differences when they occur among diverse groups. This goal derives partly from my recognition of the consequences when APA's majority culture fails to address the groups that are marginalized within APA—a major consequence is conflict between the majority and the marginalized. Some examples will be identified later in this report. Such conflicts may be overt or covert, intentional or unintentional. However, conflict situations do not simply occur between the majority and the marginalized. Conflicts can also occur among marginalized groups themselves. I think it is especially unfortunate when members of marginalized and oppressed groups in society conflict with each other, rather than collaborate on addressing the marginalization and oppression of all groups in our society.

"It is my vision that the task force will provide a foundation that documents and illustrates issues within APA regarding marginalization."

When I think of examples of this, I have in mind conflicts such as occurred between feminist women and African Americans during the O. J. Simpson double murder trial, or that happened at the National Multicultural Summit between an African American male minister and a lesbian. These conflicts between majority and marginalized groups or among marginalized groups are, of course, not unique to psychology, but run throughout our society. As psychologists we can provide conceptual models, applied practices, and leadership for how these conflicts can be dealt with in our profession and in society. As an example of a conceptual model (and by no means the only one), I have developed the "General Role Strain Model," which articulates the process whereby social roles, imbedded in power hierarchies and communicated by ideologies, create strain for marginalized subgroups within our society. This model can be applied to various dimensions of diversity, such as race/ethnicity, gender role, sexual orientation, social class, age, and disability (Levant, 2003).

As an example of an applied practice, interest-based bargaining has been used to mediate conflicts between APA divisions and state, provincial, and territorial psychological associations regarding their relative representation on the APA Council of Representatives. Interest-based bargaining enabled the development of the "wild-card" plan for determining representation on Council.

With regard to leadership, APA's *Multicultural Guidelines* (2003) state that: "Psychologists are in a position to provide leadership as agents of prosocial change, advocacy, and social justice, thereby promoting societal understanding, affirmation, and appreciation of multiculturalism against the damaging effects of individual, institutional, and societal racism, prejudice, and all forms of oppression based on stereotyping and discrimination" (p. 382).

Introduction

It is my vision that the task force will provide a foundation that documents and illustrates issues within APA regarding marginalization. It is also my goal that the task force members, as persons with multiple areas of expertise, help us to straightforwardly confront examples of how APA can be and is "unwelcoming," and offer ways that will enable all parts of APA to progress toward true integration of all members for mutual enrichment. I also ask that all members within our association, all parts of our governance, all members of our Central Office accept responsibility for implementation of the aspirations and recommendations from the task force so we can truly accomplish the mission of APA.

Overview of the Task Force and Its Report

The American Psychological Association (APA) Presidential Task Force on Enhancing Diversity (TFED) was constituted by persons who were representatives and possessed expert knowledge of at least one defined marginalized constituency. Task force members were expected to bring to task force deliberations the concerns and experiences of marginalization of their constituency including, but not limited to, the constituencies of: African Americans, American Indians, Asian Americans/Pacific Islanders, Hispanics/Latinas/Latinos, persons with disabilities, older persons, gay/lesbian/bisexual/transgender persons, Muslims/marginalized religions, and women.

The task force was funded to have one meeting, which took place in San Diego, CA, January 13-16, 2005. The work at this meeting was preceded and followed by a number of structured assignments, which members completed by electronic mail. A draft report was written and distributed for review at the Spring 2005 APA consolidated boards/committees meeting where feedback was received at an open forum and governance groups were invited to send additional feedback in writing. For those APA boards and committees not in attendance at that meeting, copies of the draft report were provided to staff liaisons for distribution to these governance units.

All comments received from governance groups were compiled by the task force's staff liaisons and forwarded to the task force chair, who coordinated the drafting of appropriate responses to each comment and the related revision of the task force report. The TFED staff liaisons subsequently added these responses to the compiled comments, and edited and formatted the revised TFED report and its accompanying resolution. The revised report (including its

prioritized recommendations) and resolution along with the Summaries of Comments and Responses documents subsequently were forwarded to all APA governance groups for a second round of review and comments. Comments from this second round of feedback were then reviewed, and again appropriate responses were developed and integrated into the final draft of the TFED report, its recommendations, and the Resolution on Diversity.[2]

This report seeks to respond affirmatively to the task force's charge and addresses the following issues and concerns.

- Describes the past history and current record of diversity in APA
- Identifies change toward greater organizational diversity/inclusion as the report's overarching concern and articulates major principles that can guide change within APA
- Identifies specific benefits that are expected to be associated with change and that should be expected to accrue to APA, its majority group members, and its minority group members
- Describes aspects of APA that were identified by TFED members based on their expertise as frequently perceived and/or experienced as "unwelcoming" by various marginalized groups
- Describes various conceptual models for effecting changes within APA
- Presents specific recommendations for effecting change within APA that will make it more welcoming
- Describes specific models for conceptualizing change
- Provides references related to the report's findings/recommendations.

This final report also incorporates suggestions received from those boards and committees that reviewed the prior two drafts.

A Caveat on Diversity and Science

A reader might consider the *TFED Final Report* as interesting, as it reflects some people's observations, but too irrelevant to be seriously considered by the association. Such a person may argue that APA has made great strides toward being a model of acceptance of all groups, and that there are several concrete examples of such goodwill. Perhaps most telling, this person might well ask, "This is all well and good, but the observations are no more than perceptions, and the members of APA have already dedicated themselves to being welcoming to all its members, whether from marginalized groups or not. If the task force claims that such a well-intentioned, conscious commitment is insufficient, then where is the science that supports this claim?"

From the very beginning, this *TFED Final Report* accepts the view that APA members do not intentionally or consciously practice exclusionary policies. The report also acknowledges that APA has made overt efforts to be attentive to many groups marginalized by society—and a brief review of such efforts is presented in a later section. However, the task force and its focus on APA actually might be viewed as a microcosm of what U.S. President Clinton envisioned when he created his initiative on race. This initiative involved "looking at America through the eyes of others," that is, marginalized groups *(President's Initiative on Race*, 1998, p. 36). The ensuing report to the President "advocated fostering a constructive dialogue on race…searching for common values and goals shared by all groups,

[2] The specific suggestions and the task force's responses are described in two separate documents: "Summary of Comments and Responses to the Draft Report of the APA Task Force on Enhancing Diversity (2005)" and "Summary of Comments and Responses to the 2nd Draft Report of the APA Task Force on Enhancing Diversity (2005)," which are available from the APA Office of Ethnic Minority Affairs.

and developing and institutionalizing promising practices that would allow for equal access and opportunity." (Bingham, Porché-Burke, James, Sue, & Vasquez, 2002, p. 76). The task force wishes to make it known that our attitude is not simply a request for equal access: We want to come to APA to contribute our talents, not to feel out of place; to be of value to APA and its membership, not to take away from anyone. We seek all APA members to be allies with us to serve the association in ways that will be mutually beneficial.

In a similar fashion to that of former President Clinton, APA President Ronald Levant specifically charged the APA task force with providing an honest appraisal of how APA and its members can be very exclusionary and very "unwelcoming," while at the same time be consciously and intentionally dedicated to being inclusive and attentive.

So what evidence is there that people can be simultaneously exclusionary and inclusive? There is in fact hard, empirical evidence that goodwill and good intentions and conscious commitments are insufficient to prevent the occurrence of marginalizing behaviors. Dr. Derald Wing Sue, in his division presidential address, observed that modern racism continues to exist to such a degree as to be considered "normative" (Sue, 2005, p. 106). He was not speaking about dramatic or extreme attitudes or behaviors, but rather the invisible and hidden attitudes among well-meaning, well-intentioned persons who would aggressively disclaim that they are racist—what Dovidio, Gaertner, Kawakami, and Hodson (2002) refer to as "contemporary bias" (p. 89).

"...empirical evidence that goodwill and good intentions and conscious commitments are insufficient to prevent the occurrence of marginalizing behaviors."

The *TFED Final Report* is a quiet but firm call for all members of the association and all structures within the association to consider the scientific evidence, and then to re-read the plea of the task force to contribute to APA's being a better place for all people.

Recently, Dovidio et al. (2002) organized an oustanding review of the scientific evidence in an article entitled "Why Can't We Just Get Along? Interpersonal Biases and Interracial Distrust." In this article, evidence from a series of empirical studies makes the point that one's current conscious attitudes do not assure behaving in a nonracist fashion. The authors recognize that "dual attitudes" can and do coexist—more specifically, a past attitude may be replaced by a new, oppositional attitude, yet both continue to remain, and both can influence current behaviors. The authors refer to the older, now unconscious, replaced attitude as "implicit attitude" andthe new conscious attitude as "explicit attitude."

They confirmed that a person's past implicit negative or stereotyped attitudes still have the power to influence a well-intentioned person's current judgment and behaviors, such as an individual's spontaneous, nonverbal behaviors intended to convey friendliness. In one study, participants' current, explicit nonracist attitudes were influential in determining deliberative behaviors such as verbal attempts to convey friendliness, but participants' implicit prior racist attitudes still showed up in more subtle, nonverbal behaviors. Among the interesting findings of this scientific research was the greater ability of the ethnic minority

recipient of the covert unconscious negative attitude to be aware of this attitude, compared to the White person in the dyad. In fact, during Black and White dyadic conversation, the Black person could see the interaction as unpleasant, whereas the White person believed that a friendly exchange had taken place. Dovidio et al. conclude that a consequence is severe disruption in communications and ability to mutually problem solve (Dovidio et al., 2004; Dovidio et al., 2002).

So the science is there, and the task force has sought to honestly share its perceptions, with the view that APA as an organization can benefit by implementing the recommendations of this report. Our assumption is that the dynamics identified by Dovidio et al. (2002) are likely to occur in the dyads made up of White persons and persons of other marginalized groups, for example, women, older persons, persons with disabilities, gay/lesbian/bisexual/transgendered persons, and those whose religion may be different. The task force members also truly believe that working to make APA a welcoming place for marginalized groups today will be to the benefit of all APA members tomorrow. We therefore ask that every individual APA member, every APA governance unit, every APA staff member, and every APA directorate commit to the implementation of the recommendations and step forth to be held accountable.

The Past History and Current Record of APA and Diversity

We have stated several times that APA has made significant efforts to recognize and promote diversity. To set this context, this section offers a brief, selected historical review of APA activities.

Where We Have Been

APA was founded in 1892 by 26 Euro American men. It was not until 1971 that members elected the first ethnic minority person as APA president—Kenneth B. Clark, PhD. Some interest in ethnic issues did occur earlier. In 1963 the APA Board of Directors established the Ad Hoc Committee on Equality of Opportunity in Psychology "to explore the possible problems encountered in training and employment in psychology as a consequence of race" (American Psychological Association, 1963). Five years later, a "petition of concerns to the APA Council of Representatives" was presented raising issues of importance to Black psychologists, including the inadequate representation of Blacks in the APA governance. In 1973, the Vail Conference formed a task group that recommended that APA create an Office and Board of Ethnic Minority Affairs. In 1978, APA and the National Institute of Mental Health (NIMH) sponsored the Dulles Conference on Expanding the Role of Culturally Diverse People in Psychology, which also recommended that APA establish an Office and a Board of Ethnic Minority Affairs. This office was finally established in 1979, and the Board of Ethnic Minority Affairs was approved by a vote of membership in 1980. Meanwhile, in 1986 Logan Wright, PhD, a Native American, was elected APA president—15 years after Kenneth Clark. It was another 13 years before another persons of color was elected to the APA presidency—Richard M. Suinn, PhD, (Holliday & Holmes 2003). Also in 1973, the Committee of Women in Psychology was established after several women conducted a "storming of Council of Representatives" to convey dissatisfaction with the lack of attention to women's issues in the association.

Several APA divisions were formed over the years with a special focus on diverse and marginalized groups: In 1945, Division 20—originally named "the Division on Adulthood and Old Age"; in 1958, Division 22, named initially the "National Council on Psychological Aspects of Disability—a Division of the APA"; in 1973, Division 35, the "Psychology of Women"; in 1976, Division 36, named "Psychologists Interested in Religious Issues"; in 1985, Division 44, "The Society for the Psychological Study of Lesbian and Gay Issues"; and in 1986, the "Society for the Psychological Study of Ethnic Minority Issues."

Where We Are Today

APA has supported diversity in a number of ways that are noticeable today. The current CEO of APA is an ethnic minority person. There is an Office on Aging; a Disability Issues in Psychology Office; an Office of Ethnic Minority Affairs; a Lesbian, Gay, and Bisexual Concerns Office; and a Women's Program Office. There is a Committee on Disability Issues in Psychology; a Committee on Ethnic Minority Affairs; a Committee on Lesbian, Gay, and Bisexual Concerns; a Committee on Aging; and a Committee on Women in Psychology. The previously cited divisions are still in existence and viable. Division 35 publishes *Psychology of Women Quarterly,* and Division 45 publishes *Cultural Diversity and Ethnic Minority Psychology.*

In 1997, APA President Ronald Fox, PhD, organized the Commission on Ethnic Minority Recruitment, Retention, and Training (CEMRRAT), which continues to have influence through its successor, the CEMRRAT2 Task Force. In 1998, the APA Board of Directors and Council of Representatives set aside $27,000 emphasizing recruitment and retention activities of ethnic minority psychologists. These funds were increased annually through the year 2004, when the total reached $100,000. In 1999, funds from

CEMRRAT and the Committee for the Advancement of Professional Practice (CAPP) enabled the establishment of the Committee on State Leaders' Diversity Initiative, which seeks to involve more ethnic minority psychologists in governance and leadership positions in state psychological associations. These funds have supported ethnic minority delegates annually to the APA State Leadership Conference. At least four Diversity Delegates have gone on to be elected presidents at state psychological associations.

In 2001, the APA Council of Representatives (C/R) also set aside funds for travel support for any ethnic minority representatives of divisions or state psychological associations who were elected to the Council for the years 2000–2004. The Council renewed this commitment in 2004 for those elected during 2005–2007. In 2005, diversity training was provided to members of the C/R.

The above offers one context regarding the increasingly positive attitude of APA and its leadership over the years toward diversity. Another perspective can be seen by examining APA participation data. Although the number of women psychologists who join APA has shown an increase (from 45% of the membership in 1995 to 52% in 2004), the percentage of ethnic minority persons has remained constant during the same span (at about 5.5%). The percentage of psychologists over the age of 60 who are members has increased from 16% to 25%. Lesbian, gay, and bisexual members increased from 3.6% in 1995 to 6.3% in 2004, but it is not known if these numbers are accurate or possibly underreported due to concerns about self-identification (APA Research Office, 2004b). An important context is the diversity picture of the APA governance boards and committees and C/R for 2004. Women comprise 51% of all governance positions (N = 160 of 339); ethnic minorities compose 21% (N = 71); persons over the age of 60 comprise 25% (N = 85); persons with disabilities are 8.6% (N = 29); and lesbian, gay, and bisexual members are 7.7% (N = 26) of governance positions (APA Research Office 2004a). In general, compared to the composition of the overall APA membership, these groups are overrepresented in governance.

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A similar picture is seen when looking only at the APA Council of Representatives membership. The percentage of women increased from 40% in 2000 to 47% in 2004; ethnic minorities rose from 7% in 2002 to 20% in 2004; persons with disabilities showed an increase from 2% to 7%, self-identifiedgay/lesbian/bisexual members increased from 5% to 6%, and members age 61 and older went up from 31% to 34% over the sam time period.

When the APA Board of Directors or the position of APA President is examined, the data become inconsistent depending on the year of analyses. For instance there have been only four ethnic minority persons (two males and two females) directly elected to the APA Board of Directors since the establishment of APA to 2005. Of the

111 APA Presidents to date, only 10 have been women and only three have been men of color. In terms of participation in the APA journal editorial process, recent data from the Publications and Communications Board show the rates of ethnic minority participation in 2004 as:
(a) 6.44% of ad hoc reviewers, i.e., 493 ethnic minority reviewers out of a total of 7650;
(b) 9.75% of members of editorial boards, i.e., 125 ethnic minorities out of a total of 1282, and (c) 12.21% of associate editors, i.e., 16 out of 131, with the last being more than double the percentage of ethnic minorities in APA membership. When comparing changes from 2000 to 2004, the number of ethnic minorities serving as ad hoc reviewers increased 71%, while ethnic minorities on editorial boards increased by 215%, and ethnic minority associate editors increased by 400%.

Although there had been no ethnic minorities who were editors of APA journals in 2000, in 2004 the number increased to two, one being the CEO as editor of the *American Psychologist.* No data were provided by the Publications and Communications Board related to the participation of other marginalized groups in the editorial process.

Still another type of data is derived from examination of convention programming, journal articles, and awards. Regarding APA convention programs, from 1983–1989, the number of programs on ethnic minority issues hovered around 40–50 programs. It was not until 1991—the year before APA's centennial—that the number reached 100. In 2004, the number dropped to about 82 programs (R. M. Suinn, personal communication, February 2005).[3]

Regarding publications, Arredondo (2005) conducted a 10-year analysis of articles in the *American Psychologist.* She found that less than 8% of publications in that journal addressed cultural and multicultural issues. Regarding APA awards, again for the 10-year period from 1993–2002, Arredondo evaluated the awards given annually by the association.[4] Of 208 recipients, results indicated that only 32.7% were female, and only 18 were ethnic minority psychologists, leading to a ratio of Euro Americans to ethnic minorities of more than 11:1.

Within the above context of APA governance, the trend has been for APA to progressively do more in support of diversity, including increasing the presence of diverse persons in governance. Because the data are not readily available on the total numbers of psychologists from various diverse groups in the nation that could be joining APA, we are unable to determine if the percentage-of-membership figures are representative of the total pool of ethnic minority psychologists. Within the context of publications in the *American Psychologist* and APA awards—at least during the period 1993–2002—the picture may appear less positive. As more detailed reporting of data becomes available, more accurate interpretation of the numbers reported in this report can be made regarding the climate within APA.[5]

[3] These data were counts taken from the APA program books' indicies, which classified each program.

[4] The awards evaluated include the Distinguished Scientific Early Career Contributions to Psychology, Distinguished Scientific Contributions, Distinguished Contributions to the Public Interest, Distinguished Career Contributions to Education and Training, Distinguished Contributions to the International Advancement of Psychology, Distinguished Professional Contributions to Public Service, Distinguished Professional Contributions to Knowledge, Distinguished Scientific Applications of Psychology, Distinguished Contributions to Research in Public Policy, Distinguished Contributions to Applied Psychology as Professional Practice, Distinguished Contributions of Applications of Psychology to Education and Training, and International Humanitarian Awards. Also included in the study were the American Psychological Foundation Gold Medal Awards and certain awards for graduate students. For detailed information on the study, contact Dr. Patricia Arredondo at Arizona State University.

[5] A major recommendation of this report is for APA to conduct a climate study (see Recommendation 2).

It also should be acknowledged that several of our task force recommendations have already been addressed by various APA governance groups.[6]

Hence, depending upon the context, these data confirm the view that APA has been evolving as an organization that seeks to be welcoming to diversity, and that there is converging interest across the association regarding the goal of enhancing diversity within APA. Attitudes have gradually changed from neglect and passive inattention in the very early years of APA, to years where such neglect represented a more active disinterest, to more recent years in which many areas of diversity have been receiving more active attention and support. As attitudes have progressed positively, actions have eventually followed, although not always rapidly or consistently. Leadership has made a difference, as has the development of an essential mass of concerned APA members, large enough to make change happen. The recommendations of this report are aimed to further enhance APA's progress toward being supportive for diversity.

"...these data confirm the view that APA has been evolving as an organization that seeks to be welcoming to diversity, and that there is converging interest across the association regarding the goal of enhancing diversity within APA."

[6] The Task Force is grateful to the various boards/committees that provided updated information on their activities and accomplishments relevant to our recommendations. For example the Committee on Disability Issues in Psychology (CDIP) shared information on actions related to disability issues: Its guidelines for speakers, its training manual for accreditation site visitors, and nominations of persons with disabilities for governance and awards. Also, CDIP reports that steps are in place for the establishment of a division on disabilities, a grant proposal has been submitted for a barriers/obstacles study, and a newsletter is under development. Similarly, the Publications and Communications Board called attention to its prior development of a database for use in identifying ethnic minority reviewers and also indicated that editors are already authorized to and have included students in the editorial review process. BCA reports that there are already lists of places of worship at the APA information booths.

Principles of Change

The members of the Task Force on Enhancing Diversity (TFED) quickly recognized that to be effective, this report must lead to change. Any progress that might occur within APA deriving from the work of this Task Force will necessarily involve change of some sort. In recognition of this, the Task Force identified the following Principles of Change.

Principle 1: APA's Leadership Role
APA has demonstrated significant progress toward making APA welcoming for members of various marginalized groups over the last 3 decades. However, we believe that the Association and its members can do more. We are all in a position to reaffirm the values of the American Psychological Association as reflected in our mission statement and in various policies and to provide leadership against the damages of prejudice, stigma, and discrimination against all marginalized groups. Psychology should not reflect the ills of society, but rather, be a model for what society should be—a place where diversity is mainstreamed and where mutual appreciation exists for the contributions of all.

"Psychology should not reflect the ills of society, but rather, be a model for what society should be—a place where diversity is mainstreamed..."

Principle 2: Documenting Inclusion Within APA Structures
A significant step toward integration of diversity within APA is getting diverse groups to the (leadership) table and noting increases in the number of members of marginalized groups who are being invited or elected to sit at the table. We need to examine the numbers of ethnic minority positions in APA governance, the number of persons who are gay/lesbian/bisexual/transgendered on editorial boards, the number of women in leadership roles, etc. These data are becoming available and should be supported as important indices of APA's progress. However, such numbers are not the end goal, but rather the means to an end. We must also understand how change happens. For example, during the APA's first 80 years, two women held the presidency; in the last 30 years, eight women have been elected. How did that happen? What are the effects of the women's presence as APA president? What difference have they made? These forms of analysis are critical. Counting, however, has its place. The absence of data on certain groups is itself indicative of inattention to certain groups and the relative invisibility of those groups.

Further, certain marginalized groups may never yield great numbers within APA (e.g., American Indians, persons with disabilities). Thus, although counting may be a necessary step, it is not a sufficient step. Attention to diversity must be a part of all individuals and entities within APA, and this attention is reflected in more than just numbers.

The doctrine of separate is not equal has been a bedrock of civil rights since the 1954 Supreme Court decision (*Brown v. the Board of Education of Topeka, Kansas*). However, we note that this doctrine does not apply equally to all marginalized groups, especially persons with disabilities, who routinely have separate entrances, seating areas, transportation, drinking fountains, bathrooms, classrooms, procedures, etc. Acceptance of this segregation is a powerful contributor to marginalization of people with disabilities.

Table 1 Stages of Change
Stage 1 *Intolerance/exclusion* Absent, ostracized
Status quo
Stage 2 *Tolerance* At the table; Allowance for representation
First-order change
Stage 3 *Acceptance* Inclusion
First-order change
Stage 4 *Celebration/Collaboration/ Mutual Enrichment* Beyond inclusion to integration Synergy Leadership roles Mutual enrichment Redefining psychology
Second-order change

Principle 3: Stages of Change

We recognize change as a process that is difficult, especially when it is imposed on us and when it requires that we examine our own "isms." It is not our intent to impose change, but to provide impetus and vehicles for real and meaningful change within APA. We have conceptualized the change process in Table 1. This stage model can be applied to both individuals and organizations such as APA. In Stage 1, individuals viewed as different, are ostracized and not valued. Often, they are absent from committees or groups, precluding representation of diversity. On the other end of the continuum is Stage 4 Celebration/Collaboration/Mutual Enrichment. The behavior at this stage is about collaboration, acceptance of differences, and a willingness to redefine psychology from diverse perspectives.

Principle 4: Involvement of All APA Entities and Functions

APA has numerous entities and operations, and evidence of marginalization or being "unwelcoming" may occur in various ways. It will be important to determine if changes need to be studied within the context of each organizational entity. The domains or organizational practices of APA include but are not limited to its: (a) annual convention, (b) divisions, (c) staff activities, (d) governance structure, (e) newsletters, (f) journals, (g) editorships and editorial boards, (h) other publications, (i) accreditation process for programs and internships. The governance structure (i.e., APA's Council of Representatives, Board of Directors, boards, and committees) can unintentionally perpetuate conflicts and exclusion. In addition, we believe the four directorates (Practice, Education, Public Interest, and Science) are at different places in their trajectory toward greater integration of marginalized groups. Those entities, operations, and structures that have been successful should be commended, and the reasons for their success shared with those still struggling.

Principle 5: The Importance of Language

We raise three issues with regard to language:[7] specificity, power, and specialness.

Specificity is required to make clear which of the diverse groups is under discussion. For the purposes of this report, "diversity" or

[7] Where persons from international heritage are involved, such persons might associate different connotations or meanings with language terms or behaviors displayed. To be welcoming would require sensitivity to such differences.

"marginalized groups" refers collectively to ethnicity, gender, sexual orientation, disability, religion, and older age.

Power refers to the ability of words, whether spoken or written, to convey tremendous emotive content. Although not wanting to insist on political correctness for its own sake, we are cognizant of the different impact of words such as African American or Black, sex or gender, handicapped or disabled, homosexual or gay, etc. We also acknowledge that words can be attached to actions (e.g., derogatory terms associated with violence). Nonetheless, we may err in our judgment of which words to use in this report; we wish to be respectful, and apologize in advance for any misjudgments.

Specialness refers to how we often conceptualize the needs of marginalized groups as special or out of the ordinary (e.g., children with "special needs" tend to therefore be placed in special classes). We take issue with this perspective and underscore that integration is not only for the benefit of marginalized groups but for all groups, and that integration is not a special need.

Principle 6: The Significance of History
We recognize that it is not productive to debate which of the marginalized groups are more marginalized than others. At the same time, we acknowledge that different marginalized groups are at different points in their collective history, their civil rights development, and their roles and recognition within APA. In recognition of these facts, we refer to marginalized groups collectively when possible, and to more specific groups when warranted. Those marginalized groups that have not progressed as far can learn from the histories of other groups, and we make some recommendations based on what has worked for one group and can be more generally applied.

Principle 7: The Public Face of Marginalized Groups
Both the "lived experience" and the expertise about marginalization are important. We hold as self-evident that persons within a marginalized group have the lived experience and thus possess unique knowledge about their group. This does not deny that persons outside the specific group can be experts and powerful allies, and that they must be a part of—and even leaders of—the process of change. However it is of value to include the voices of persons from the marginalized group under review or inspection. In short, the public face of diversity should itself be diverse.

Principle 8: Responsibility
The Preface to this report calls on each entity and individual within APA to take responsibility for the enactment of this report's recommendations. Everyone shares in this responsibility, and likewise is part of the history of "unwelcoming" acts and atmosphere. Nonetheless, we do not mean to place blame or undue responsibility in the hands of any single person or persons. Unconscious prejudice and discrimination occur for every single one of us, whether we are members of majority groups or marginalized groups.

Principle 9: The Aftermath of Change: Backlash, Private Dialogues, and Mutual Benefits
We recognize that change in APA's efforts to promote diversity often evokes a backlash, both public and private, and it is possible that this report may evoke such a reaction. That is, there are private dialogues, from which persons from marginalized groups are excluded, that undermine diverse representation and inclusion. We recognize that individuals struggle with change that is uncomfortable. In addition, there are public examples of backlash, found in letters to the editor of the *APA Monitor on Psychology,* threatened

resignations from the APA, etc. We can only continue to try to point to the mutual benefits for all when second-order changes occur, such as described in the model in Principle 3. In addition, we can continue to work to confront the private dialogue that we understand exists. Where backlash exists, we seek reconciliation and movement toward mutual understanding with all our APA colleagues.

Principle 10: Allowance for Mistakes

One of the consequences of perceived backlash and other related reactions is that some persons from marginalized groups experience pressure to perform perfectly. These persons are under the microscope and do not enjoy the benefit of the doubt as do others not from marginalized groups. We must proceed with the unambivalent belief in our capabilities to rise to the occasion, and forgive mistakes and imperfections in ourselves as much as we do for others.

"There are private dialogues, from which persons from marginalized groups are excluded, that undermine diverse representation and inclusion."

The Benefits of Change

A major viewpoint of the Task Force for Enhancing Diversity, which is emphasized by President Ronald Levant in his Preface, is that changing APA to be more welcoming benefits not only marginalized groups, but APA itself. The next sections identify the specific forms of value-added benefits that would be expected to accrue to APA as an organization of majority members, but also the specific benefits that would accrue to its marginalized groups.

Benefits to APA and Majority Group Members

Making changes toward inclusiveness can have benefits for APA and for majority group members. Some examples are listed below.

- Overall APA membership would increase as individuals who previously felt unwelcomed see APA reaching out and recognizing their needs and interests. New membership, renewal of memberships, lower resignation rates could all occur as APA shows its broader appeal. Financial gains will accrue through dues, attendance at conventions, journal and book subscriptions, and even potential donations and bequests.

- Attention to diverse people with diverse needs can stimulate new approaches that benefit all peoples. For instance, when awareness about differences in learning styles occurs, new approaches to teaching are developed, and such new approaches can enhance the education of majority students. Data from the University of Michigan has confirmed that the presence of ethnic minority students led to improving the development of majority students. Women's involvement in nontraditional fields led to innovations. For example, Lillian Moller Gilbreth (1878-1972)—engineer, management consultant, psychologist, and professor—focused her attention on domestic engineering and helped design modern kitchens to make housework more efficient. She also adapted and developed devices and techniques for persons with disabilities

- As the nation's demographics continue to change, all members of APA eventually will be coming into regular contact with members of marginalized groups. By increasing exposure to diversity within APA and striving for inclusiveness, members in the current mainstream of APA would strengthen their competencies and ability to work with a diverse national population that is growing rapidly in numbers and strength.

- By increasing the number of diverse APA members, including in various leadership roles, APA would enable such members to provide new perspectives and beliefs that are useful in the expansion of professional and scientific skills for all members.

- By being inclusive rather than exclusive in its approach, APA can develop resources directly relevant to diverse groups, including resources for working with women or persons with disabilities or from different cultures or diverse religious beliefs. Such resources can then be the foundation for growth of training programs, internships, and postdoctoral training sites as such programs and sites begin to expand culturally competent training derived from APA resources.

- Fully embracing diversity would make *Psychology* more available to a broader audience, facilitate the enrichment of society, and would form the next logical evolutionary step for the field. It also would increase the

opportunities to promote the mission of APA, to make psychology a household word, to give psychology away, and to contribute to improving the human condition. By actively engaging in promoting social justice and prosocial behaviors, APA and its members can experience increased professional pride in such leadership.

- Attending to marginalized groups would enhance the international visibility of APA and may increase international participation in APA-sponsored events, including conferences, conventions, and publications.

Benefits to Currently Marginalized Groups

Making changes toward inclusiveness can have benefits for marginalized group members. Some examples are listed below.

- Opportunities would be enhanced for increased representation in training and participation in APA governance, thereby empowering members of marginalized groups who previously have had limited opportunities in the arena of organized psychology.

- Students of the next generation representing these groups would feel more welcomed into the field, and thereby expand their involvement in advancing psychology.

- Attracting diverse students today is important to preparing candidates for the leadership roles in the APA of tomorrow.

- Those members of the national ethnic minorty psychological associations (i.e., Association of Black Psychologists, Asian American Psychological Association, National Latina/(o) Psychological Association, Society of Indian Psychologists) who may not currently view APA as relevant, may feel more welcomed and join APA, bringing fresh, new perspectives and increasing the cross-fertilization of ideas and professional practices among groups.

The Need for Change: APA as an "Unwelcoming" Environment

The Task Force could have focused solely on recognizing the efforts and achievements within the association to promote a welcoming environment and proceeded to suggesting recommendations for further future progress in this direction. However, President Levant's own initial comments briefly cite his view that APA still shows evidence of being unwelcoming. Further he charged the Task Force with discussing specific ways in which groups are marginalized. Hence the Task Force allocated time during its meeting to make more specific how marginalization might appear. Concrete illustrations were therefore identified and appear in the sections to follow. The Task Force acknowledges that these experiences that convey an unwelcome environment might not appear in all contexts or for all persons in their individual environments. Further, some sources of the experiences may not be under the direct immediate control of APA groups. However, by listing examples and suggesting remedies, the Task Force is hopeful that the increased sensitivity this brings will foster a climate that can even further the nature of welcoming that APA has achieved to date.

The previously described data in the sections "Where We Have Been . . . Where We Are Today" offer some confirmation that APA has achieved significant progress toward being overtly supportive to some aspects of diversity. The following is therefore written in anticipation that APA will continue and extend such momentum. Sometimes progress is slowed because individuals or groups assume that everything that has to be done is already done based on prior accomplishments. What may be readily overlooked are other elements essential for true mainstreaming, true integration, and true collaboration of interests. While recognizing the progress made within APA, this section shares observations suggesting that APA has more work ahead to be a comprehensively welcoming body.

Inclusiveness, Exclusiveness, and Marginality in Psychology

Despite its progress toward being a more inclusive organization, APA is still perceived by some members of marginalized groups as "unwelcoming." As marginalized groups and their members differ in their characteristics, needs, and levels of representation and involvement, APA may be perceived differently by different groups and their members. We acknowledge that not all marginalized groups are marginalized equally or in the same manner. However, the task force members and President Levant observed sufficient consistent evidence of unwelcomeness and marginalization within APA to indicate the need for these topics to be confronted rather than denied.[8]

In spite of a visible presence of many marginalized group members, APA is still primarily representative of the dominant group in our society and its worldview. If APA's dominant group were to be identified, it would overwhelmingly include persons who are Euro American, upper middle class, able-bodied, and Judeo-Christian in belief and/or perspective. Among leadership positions, the dominant gender is still typically male. Decision making is still a process that is primarily in the hands of dominant-group members. The results are

[8] There may be some dispute regarding whether the TFED report provides convincing evidence that APA has been unwelcoming. The report's section "The Past History and Current Record of APA and Diversity" presents data that can be interpreted to suggest an environment that has at the least been slow in opening itself to marginalized groups. In addition, the presidentially appointed task force is constituted by members of APA with experience in marginalized groups, direct contact with other persons belonging to such groups, and experiences within APA and governance. TFED members also include scientists and practitioners whose professional activities involve topics within the report. Hence their perceptions should carry some validity. In fact the perception of APA being unwelcoming to marginalized groups was strong enough as to have motivated APA President Levant to form the task force. A major recommendation proposed by TFED is the conduct of a climate survey, which could provide clarity regarding how widespread the perception of APA's being unwelcoming is. Regardless, the TFED recommendations address the goal of enabling APA to enhance its diversity and be more welcoming—a goal with its own singular value.

decisions that consciously or unconsciously establish standards, methods of inquiry, intellectual paradigms, performance criteria, and policies that view dominant- group behavior and values as normative. The majority society's definition of heterosexual orientation as normative is one example.

Consequently, strengths, contributions, competencies, needs, and interests of smaller and/or marginalized groups may not be recognized. This failure to include marginalized groups in decisions, such as the design of methods of inquiry, is consistent with the dominant epistemology, which is linear, controlled, and quantitative. By using the norms of the dominant group, the behaviors of marginalized groups tend to be interpreted as pathological (because of not fitting the "norm"), or in ways that blame the victim, or as deficit-oriented. In other words, psychology continues to typically view differences, disabilities, and diversities as problematic. In addition, the subjective influences of the White majority culture on the scientific domain are ignored or denied.

As a result, initiatives such as the *APA Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists* are viewed as though they are relevant perhaps to psychological practice but not to psychological science, because practice involves service delivery to marginalized persons, while scientific methodology/research design/ statistical methods are "universal" and "culture free." The influences of culture and worldviews on research paradigms, decisions about methodologies, data collection, and interpretation of data are both denied and ignored.

The dominant epistemology, culture, and worldview may also influence interpersonal, intergroup, and organizational behaviors involving marginalized group members. For example:

- Rules for appropriate social behavior and interaction in the dominant group are based on Western standards, which are then used to interpret behaviors, such as the lack of eye contact, expression of emotions, or even physical distancing. Thus, using only the Western definition of norms, an observer would fail to understand the respect that no eye contact represents in some cultures, even though it could mean disrespect in the Western environment. Also, whereas emotional expressiveness might be interpreted as aggressiveness in one culture, the same behaviors can communicate engagement and involvement in another culture. Physical distance/proximity to another person of the same/opposite sex might follow rules for "normal" distance in one culture that are quite different from the rules in another culture. Finally, a Western culture will measure success by the achievement of individuality and independence, yet in other world cultures, interdependency is considered essential, and group connectedness is valued.

- The Western worldview facilitates a disposition toward gatekeeping as a process designed to operate in ways that keep people out rather than inviting them in with a spirit of mutual enrichment. In contrast, the spirit of mutual enrichment assumes that diverse people can make diverse contributions. Their diverse contributions create the opportunity to generate and entertain a wider range of potential solutions to problems. For example, blind students may be rejected for admission to graduate programs if the training requires the administration and interpretation of tests that require being sighted. But if a spirit of collaboration and inclusiveness is adopted, the focus shifts to determining how the student can be included rather than excluded, and

what conditions can be changed to enable the student to perform successfully. One potential solution might include having someone else administer and interpret the tests and report the findings, while the blind student integrates the data and uses the materials in counseling or consulting. In fact, many professional psychologists, not just those who are blind, do not directly engage in test administration and interpretation.

- Another example involves the use of tests of all kinds as a gatekeeping function. Many have held the expectation that women cannot perform psychology's scientific endeavors well because they have less aptitude in the associated subject matters and procedures. The measure of aptitude and the distribution of scores on IQ, GREs, etc., are to a large extent, a matter of how the tests are constructed. Women and men do perform differently on various questions, but the overall score depends on the balance of questions in the particular test. For example, there are many different IQ tests, on which women originally scored higher than men, but these have been adjusted to eliminate any female superiority. As psychologists, we know that aptitude tests are not as independent of past experience and social position as is often claimed (Rogers, 2001).

- When dominant cultural views prevail, members of marginalized groups can be pigeonholed or viewed only as a representative of a single characteristic, such as their race/ethnicity, gender, sexual orientation, physical characteristic, age, or religious orientation. Or alternatively, those characteristics that form the basis for their marginalized status are completely ignored. This can occur in regard to both the conceptual paradigms that govern research and the participation of diverse people in APA governance. Most people, including marginalized individuals, have more than one identity that is salient to them. These identities may or may not be the ones most salient to dominant-group members. In fact, the members of marginalized groups hold multiple identities and competencies, some of which are derived from creating adaptive survival strategies as a marginalized person.

- Ethnic minority members tend to be considered by nominating bodies only when the search is for a "minority person," and that person is then expected to be the expert on ethnic minority issues. But this person may simultaneously be an expert in neuropsychology and not simply with regard to ethnic minority persons, or an expert in industrial/organizational consulting and not simply with regard to affirmative action, or an expert in advanced quantitative statistical analyses and not simply with regard to qualitative analyses. On the other hand, if the primary goal of the Task Force is achieved, that is, of mainstreaming marginalized groups into the entire APA structure, then the multiple identities and expertise of the members of such groups will gain greater prominence. As a result, these persons would be given tasks that recognize their broader talents, thereby bringing greater contributions to the association.

We acknowledge that "unwelcoming" behavior can also occur among marginalized groups in their attempt to compete for what appear to be limited resources. However, the decisions about the allocation of resources typically are made by majority culture persons. For example, convention time and space have been reduced leaving everyone vying for the smaller amount of allocated time.

Behaviors That Convey an "Unwelcoming" Environment

Several behaviors serve as examples of dominant members' creating an environment of being "unwelcoming." Such behaviors may be well intentioned, or are displayed by individuals without their being aware of the message being conveyed. Nevertheless, such behaviors should not be condoned—especially if APA members are striving to have APA become an equally welcoming place for all its current and potential members.

- *Language that is not respectful but is stigmatizing or marginalizing.* Language such as the "Chinese fire drill," or saying to an older psychologist "Are you still working?" may be viewed as disrespectful. Members of marginalized groups have the right to determine how they will be referred to without being viewed as needlessly sensitive about something that does not matter in the same way to majority group members, as is suggested by the question, "Are we going to have to be politically correct again?"

- *Patronizing behavior on the part of dominant-group members is another form of behavior that makes marginalized group members feel unwelcomed.* This might be conveyed by comments such as, "Perhaps your people might be too sensitive to my calling it the way it is...," or "We can understand that minority issues are important for practitioners, but basic science is color-blind," or "It's difficult to understand the complaint; after all APA already has a division for ethnic people, Council has elected minorities to seats, and APA has an entire office devoted to ethnic minority affairs. You have enough concessions to keep you happy for a century."

- *Refusing to listen to marginalized group members' feedback about the effects of how they are being treated or requests for change suggests that those group members and their interests are unimportant.* Sometimes this failure to be interested is expressed in the phrase, "I thought we already addressed that issue," or expressed concerns may be put aside by the comment, "If we open the door to this group...or by this action, then we have opened the door to a long list of others who will want the same treatment."

- *Dominant-group individuals conversing with one another while ignoring the marginalized person sitting in between them makes the marginalized person feel invisible and irrelevant.* A similar example is the inclination of majority group members to cluster together in social gatherings, ignoring newcomers who are dissimilar to the group.

  For persons with a disability, the isolating factor can be the locale selected for the social gathering, such as places that are inaccessible to people with disabilities because of structural barriers or crowding. Such behavior might be laughingly labeled as "benign neglect" but does convey an isolating, a marginalizing, a lack of welcoming, and worse, a sense that other people are not valued in any way.

- *The tendency for marginalized group members to have one minority member who is viewed by dominant culture persons as the representative for the entire group, serves to ignore the diversity within the group.* This lumping of groups together ignores that there are significant subcultural differences within certain groups. Similarly, the impairments associated with disability can be profoundly different, yet the differences not recognized when disability is included in research, clinical intervention, education, and training. This tendency to assume that one member of a marginalized group is by nature a representa-

tive of all members of his/her group might be called the "homogenization error."

- *A variant, on the "homogenization" error, however, can occur when the majority member possesses a stereotype image of how the marginalized group should look or act.* For instance, phenotype may be used as the marker of ethnic or cultural credibility. Consequently, there is sometimes a misperception that in order to be a "real Indian," the individual in question should have a complexion expected of a stereotypical American Indian, the darker the better. Thus a non-Indian will listen more intently to a darker complexion Indian person speaking on Indian issues than to one who has lighter skin, hair, and eyes, etc. Likewise, persons with hidden disabilities are sometimes seen as more acceptable to the majority than are persons with readily apparent disabilities. Yet, at other times one must have the "right" disability to "authoritatively" speak about the disability experience. In still another variant, if a woman fails to endorse all of the components of a feminist position, she may be considered less authentic and less representative of women. While Western women may view wearing a head scarf as a symbol of male oppression, Muslim women may not uniformly experience it as such and may resent being told how they should view their freedom and oppression based on Western standards. Similarly, among ethnic minority groups, members may be alternately viewed as "too ethnic" or "inauthentic" depending on the issue and context.

- *Setting a higher standard for marginalized persons to meet is another action that contributes to discomfort and feeling marginalized.* For instance, a mishap by a majority member might not be noticed, but the same event is critically evaluated if evidenced by a marginalized person. Often marginalized groups feel they are defined by their weaknesses rather than by their strengths.

- *Another stumbling block for marginalized groups is what happens when such groups face barriers to their progress or ability to achieve.* Often the dominant group expects the members of the marginalized group to develop the solutions, rather than engaging in more collaborative ways of problem solving. This may take the form of, "Stop complaining—you need to be part of the solution rather than being the problem," or "Tell us what you want us to do, and we'll do it."

"Unwelcoming" Actions Found in Research Reporting and Editing Activities

The previously mentioned tendency for the dominant worldview to have broad consequences may be seen in the typical format of research reports. The study of White persons has been so historically normative that it required serious advocacy to point out that data based only on White populations are not routinely valid for ethnic minorities, or even that research studies on non-White populations is good science. Fortunately, progress has been achieved such that research on marginalized populations is gradually and routinely appearing in some major APA journals. Still, the absence of such articles in other APA journals raises the question of whether some editorial policies remain unchanged and whether studies of marginalized groups are still unwelcomed.[9]

[9] On the other hand, consider the message of mainstreaming communicated by a journal that has the following research articles in one issue: "Toward an Understanding of Jewish Identity: A Phenomenological Study," "Development, Reliability, and Validity of the Lesbian, Gay, and Bisexual Knowledge and Attitudes Scale for Heterosexuals (LGB-KASH)" and "Resilience AgainstDiscrimination: Ethnic Identity and Other Group Orientation as Protective Factors for Korean Americans." Likewise, consider the reaction upon seeing an article "Islam 101: Understanding the Religion and Therapy Implications" given equal space in the same journal issue as an article on "Developing Evidence-Based Practice: The Role of Case Base Research." These examples are from two actual APA journals that are not dedicated to only minority/marginalized group studies.

Despite the APA mandates regarding representative sampling, many research reports are released that have few or no members of marginalized groups in their study sample, yet do not have discussions about limitations; or have methodology sections that fail to reflect that the research is really a study of dominant-group persons. These omissions reinforce the notion that dominant-group behavior is normative and that discussion about groups that are omitted is unwarranted. Study methods may unwittingly preclude participation by people with disabilities (e.g., paper and pencil tests or surveys not available in alternate formats), without mention of this as a limitation of a study.

Furthermore, the articles themselves rarely offer any analysis of the implications of the absence of marginalized group members on the research outcomes or interpretation of results. For example, research on couples often contains samples that are completely heterosexual or White. But, the title of such research fails to mention this, and the study does not discuss the limitations of findings that do not take gender and cultural factors into account in ways that are methodologically warranted. The failure to pursue inquiries about the effects of such omissions in research leaves marginalized group members feeling as though there is no real interest in doing so. These examples might raise editorial issues that are difficult to solve, such as limitations on space. Hence, the point to be made is that historical values of a dominant group can surface in a variety of ways and can be subject to interpretation by marginalized individuals.

Finally, there has been a perception that a lack of diversity permeates the editorial boards of APA journals. In a number of journals, there is a lack of presence of editors and editorial board members reflecting diversity. Also databases have not in the past increased the use of ethnic minorities as ad hoc reviewers. Similarly, although it would be valuable to develop a mentoring system, widespread acceptance or implementation of such an approach has been slow at best. Once more the message seems to be "exclusion" instead of "inclusion" and "resisting" rather than "enabling." One way to overcome or change such perceptions is for data to be obtained and publicized widely. For instance, the Publications and Communications (P&C) Board has recently shared the following regarding increases in ethnic minority editorial participation during the period of 2000-2004: Ad hoc reviewers have increased 71% (from 288 to 493 reviewers); editorial board members by 215% (from 58 to 125), associate editors by 400% (from 4 to 16), and the number of editors of APA journals went from none to two. Such documentation goes a long way to developing accurate and balanced perceptions.[10]

An "Unwelcoming" Aspect of APA Convention Activities

There are often complaints that convention programming that is of direct interest to marginalized group members is, itself, marginalized: Such programs are often scheduled opposite one another, scheduled opposite some major APA event; scheduled on the last day after even the booksellers have left, in an out-of-the-way room. The latter makes it difficult for majority and marginalized members to attend such programming and events.[11]

It is often explained that attention is given to avoiding these types of conflicts, and that various interest groups have their programs rotated to earlier times in the convention week. Perhaps this is accurate, but if such difficulties are experienced even a few times within the context of a number of other "unwelcoming" experiences, then such events will add one more confirmation of a perception that APA is insensitive and "unwelcoming."

[10] The P&C Board indicates a readiness to support an article presenting the data on ethnic minority participation in the APA editorial process.

[11] According to BCA: "Some scheduling is organized by divisional program chairpersons and not under the direct control of BCA. BCA will work with these program chairpersons in the future, and will continue its attempts to avoid conflicts from scheduling of programs under BCA control."

Models of Change and Conflict Resolution/Reconciliation Strategies

Overview

The task force believes that the type of organizational change called for by this report can best be managed when organization leaders and members are guided by some conceptual model(s) of change and collaboration. Change in the direction of power sharing and greater inclusion of previously underrepresented members in governance undoubtedly will be met by resistance among members who prefer the status quo. Unspoken attitudes, unwillingness to share power or resources, resistance to movement from the status quo, and lack of experience with some of APA's underrepresented members (e.g., persons with disabilities) can be undercurrents that lead to organizational barriers of exclusion. Dynamics of "we-they" or "our wishes versus your demands" can lead to impasses in the process of conducting the business of APA. As more systematic plans for change occur as a result of APA leadership and the input of different constituencies on behalf of marginalized members of the association, responsible action will involve anticipating the need for models and proven practices to manage processes of conflict and change and movement toward greater inclusion, collaboration, and mutual interest. To address such processes in the future, the task force was charged with identifying conflict resolutions models and procedures that have wide applicability appropriate for use throughout APA.

"Unspoken attitudes, unwillingness to share power or resources, resistance to movement from the status quo, and lack of experience with some of APA's underrepresented members (e.g., persons with disabilities) can be undercurrents that lead to organizational barriers of exclusion."

Organizational change, particularly change that focuses on diversity, typically has engendered fears and concerns that an organization will lower or change its norms and that the underrepresented individuals will somehow want to take APA away from its mission. In the preparation of recent guidelines on behalf of gays, lesbians, and bisexuals, older adults, and women, and multicultural populations, there were numerous negative anecdotal comments about whether such guidelines are really needed. The occurrence of such remarks further strengthens the argument about the necessity to anticipate resistance to a focus on diversity and multiculturalism. The messages that each APA president promulgates must affirm how inclusion of underrepresented members at the level of policy making is value-added and a win-win approach that will make APA relevant for all of its members. Some past APA presidents, Ronald Levant as the current president, and Gerald Koocher as the 2006 president have provided such affirmations.

Anticipating that even planned change can create dissonance in an organization, several models that address ways to resolve differences or to reach reconciliation are identified in the next section. The value of such models is in their applicability to various problem-solving activities, even where the focal issue involves topics other than diversity. Therefore, these models can be useful resources or reference points that APA governance and other entities of organized psychology can refer to when blocks occur in the process of conducting their-business and seeking greater inclusion of varying points of view.

Models for Reconciliation, Conflict Resolution, Collaboration for Mutual Interest[12]

The task force recommended several models that address change, reconciliation, and conflict resolution. Although these models have been used for varying reasons and in varying contexts, there are elements in all of them that can assist organizational leaders at different phases of the change management process. These elements include:

- Proactive strategies to create mutual understanding;
- Win-win desired outcomes;
- Recognition of power differential among the different parties;
- Attention to the cognitive, emotional, and behavioral dynamics introduced by the participants; and
- In most cases a social justice orientation that encourages respect for individuals regardless of their role and power in society.

For readers interested in possible procedures to use for their problem-solving/reconciliation/conflict resolution efforts, the following models would be appropriate to consider: the gender role strain model (cited by Levant in his preface); the interest-based bargaining model (Fisher & Ury, 1981; Peterson & Levant, 2000); the multiethnic, multiracial, multicultural conflict model (Henderson, 2002); and the normative-re-educative model of change (Chin & Benne, 1985).

[12] The task force is appreciative of those governance groups that recommended a reconciliation model as a meaningful fit to the theme of the report.

Recommendations for Enhancing Diversity

The following are specific actions/recommendations for enhancing diversity in APA, which the Task Force proposes for implementation at multiple levels throughout APA. The recommendations require a strategic change process with accountability for tasks throughout APA. The task force members recognize that organizational change is a long-term process requiring accountability. Thus, the prescriptive statements that follow are comprehensive in breadth and depth. The recommendations are organized by three levels of priority (immediate, medium-term, and long-term), with estimated implementation timelines and costs provided for the immediate and medium-term priorities. These recommendations are the bases for the Resolution on Enhancing Diversity in APA (Appendix B).

TFED Immediate Priorities

	Recommendation	Time Required	Estimated Costs	
1.	The APA Council of Representatives (C/R) formulate and adopt an anti-discrimination policy resolution (or if one is already being proposed at the time of this report, then this recommendation is that the Council move quickly to adopt such a resolution).	12 months or fewer		$0
2.	The Policy and Planning Board in collaboration with the Committee on Ethnic Minority Affairs (CEMA); the Committee on Disability Issues in Psychology (CDIP); the Committee on Aging (CONA); the Committee on Women in Psychology (CWP); the Committee on Early Career Psychologists (CECP); and the Committee on Lesbian, Gay, and Bisexual Concerns (CLGBC) take responsibility for organizing a "climate study" within all APA governance entities regarding members' experiences, comfort/discomfort, and positive/negative attitudes/opinions/policies affecting or about members of diverse groups. Such a study might include examination of possible systemic factors that act as obstacles toward increasing diversity. Individual assessments would be collapsed for reporting purposes to initially provide baseline data on the climate that might be later repeated to obtain information on change over time. Thus the initial goal of this study is to provide a baseline against which to consider whether actions derived from other Task Force recommendations have had an impact over time.	2-3 years	Planning via conference call and e-mail Staff support (survey development and dissemintion, follow-up, and analysis) $15,000/year x 2 years	$0 $30,000

TFED Immediate Priorities—*continued*

	Recommendation	Time Required	Estimated Costs	
3.	The CEO of APA direct the executive directors of APA directorates to collaborate on projects related to enhancing diversity. For example, they might write joint columns for the *APA Monitor on Psychology* that explore ways in which diversity intersects with other issues pertinent to practice, education, and science in psychology and the best ways to address diversity issues within the organization.	Initiate within 1 year		$0
4.	The Publications and Communications Board, and as appropriate, the Council of Editors, adopt the policy of incorporating the language and/or principles from the *APA Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists;* the *APA Guidelines for Psychotherapy With Lesbian, Gay, and Bisexual Clients;* and the *APA Guidelines for Psychological Practice With Older Adults* into publication and editorial policies/procedures.[1]	18 months		$0
5.	The Publication and Communications Board expand its database of ethnic minority psychologists to include other marginalized groups who have expertise to serve as ad hoc reviewers or on editorial boards. To expand the database to identify APA members whose group identity is not available in existing APA membership databases, the APA membership office, the APA research office, and the APA management information systems department should collaborate on mechanisms to survey APA members regarding their identity related to the various marginalized groups. The CEO of APA should direct the APA publisher to annually report on the number and percentages (total and by journal titles) of ad hoc reviewers, editorial board members, associate editors, and editors who are ethnic minorities and women . . . and when data become available, for members of other marginalized groups. Such an annual report should be reported as an information item to the APA Board of Directors and the Council of Representatives.[2]	Expansion of database = 1 year Begin annual report within 2 years	Staff assistance re update of database = 1/4 FTE Staff assistance re: annual report and database maintenance	$10,000 $8,000/ year

[1] P & C has indicated it actively reviewed the APA Publication Manual at its May 2005 meeting to ensure that the manual is consistent with the APA Guidelines on Multicultural Education. TFED endorses any future steps by P & C to further respond to the broader goal of the recommendation relating to other editorial policy/procedural documents as appropriate.

[2] The P & C Board recently released data on the success of the improved ethnic minority database in increasing the numbers of ethnic minorities in the editorial process. TFED's recommendation is for continued use of and expansion of the database.

TFED Immediate Priorities—*continued*

	Recommendation	Time Required	Estimated Costs	
6.	BAPPI and the Office of Ethnic Minority Affairs coordinate the collection of feedback from relevant APA and other relevant groups, e.g., COGDOP, CEMA, CLGBC, CDIP, CONA, CWP, and appropriate divisions regarding the most appropriate strategies for assessing the relationship between a training program's adherence to Domain D's requirements and accreditations decisions. Recommendations will be provided to CoA for its consideration.	18 months	Part-time intern	$5000
7.	BAPPI work with BSA to develop a mechanism (e.g., Advanced Training Institute) for training researchers in skills needed to design, conduct, and evaluate research with diverse populations, such as research design approaches with ethnic minority populations.[3]	2 years	Planning Conduct of institute training	$0 $10,000 /year
8.	BCA take actions that recognize the needs of marginalized groups such as women and religious groups. Such needs include, for Muslims as an example, access to a prayer room at certain times, and for other groups, lists of area synagogues, churches, mosques, etc. BCA should also consider reinstating child care for those with small children at convention.[4]	18 months		$0
9.	BAPPI seek to increase opportunities for recognizing programmatic/institutional efforts related to diversity achievements similar to the criteria for the Suinn Minority Achievement Award. An example might be the creation of an award for "Outstanding Commitment to the Multicultural Guidelines" or "Outstanding Commitment to the Gay/Lesbian/Bisexual Guidelines." BAPPI should strive to have such awards be established and supported by APA governance groups other than those staffed by the Public Interest Directorate, and by divisions other than Divisions 35, 44, or 45. In doing so, the principal message is that diversity needs to be mainstreamed across all of the APA structure.	2 years	Awards	$5,000 /year

[3] One example of a useful resource is the forthcoming APA book edited by Fisher and Trimble on designing and conducting research with diverse populations (Fisher & Trimble, in press) and the article by Olkin (2004) "Making Research Accessible to Participants With Disabilities."

[4] BCA has offered to work with local hotels to provide lists of places of worship and also noted the lack of available space for prayer room assignment. BCA also noted that child care by APA was discontinued because of low usage and high financial cost.

TFED Immediate Priorities—*continued*

	Recommendation	Time Required	Estimated Costs	
10.	The Membership Committee along with the APA Office of Public Information evaluate all APA promotional materials regarding the extent such materials expressly state interest in and welcoming of diverse groups. Also, such materials should be evaluated in terms of their accessibility (e.g., availability in large print, on disk, or on the Web at a site compatible with most major screen readers).	18 months		$0
11.	C/R and B/D encourage and support the establishment of a new APA Division on Disability Studies should such a new division be formally proposed in the future.	Unknown		$0
12.	CDIP in collaboration with BEA conduct a study of barriers/obstacles that students with disabilities face within training programs with the intent that these data subsequently be used in establishing formal suggestions for enabling the training of students with disabilities. These suggestions would include ones related to training students with disabilities (especially those with visual and auditory limitations) in testing and assessment procedures.[5]	2 years	Staff assistance of 1/4 FTE	$10,000
13.	CDIP and the Office of Disability Issues publish a newsletter (perhaps on the Web) that promulgates awareness of and sensitivity to disability issues.	1 years	Intern @ 7.5 hours/wk	$4,500/ year
		TOTAL	One-Time Costs:	$55,000
			Recurring Costs	$27,500/ year

[5] CDIP indicates that the Disability Issues in Psychology Office has already initiated this study and the Office and CDIP are therefore commended on their work. It is TFED's hope that the information can prompt the next step, whereby formal suggestions for further action are derived from the data.

TFED Medium-Term Priorities

	Recommendation	Time Required	Estimated Costs	
14.	The APA Chief Executive Officer (CEO), Board of Directors (B/D), and Council of Representatives (C/R) consider developing mechanisms for enhancing diversity and addressing recommendations cited in this report. One possible mechanism might be the development of an Office of Diversity Enhancement as a staff office in APA to monitor diversity recommendations and outcome(s). A study should be conducted to define the roles and responsibilities of this office versus those of the Office of Ethnic Minority Affairs and the Equal Employment Opportunity Commission Office to avoid overlap. Furthermore, the actual name of this office should reflect the roles and responsibilities as these are defined, such as the "Office of Diversity Enhancement." The primary mission of this office would be to promote and oversee activities that enhance diversity within APA, such as the recommendations in this Task Force report.	1 year of advanced planning	Costs depend on whether functions are assigned to an existing office/program or become a new self-standing office/program.	$40,000-$80,000/year
15.	Chairpersons of APA Boards and Committees place on their agenda a discussion on having joint meetings that could lead to identifying common interests, foster better understanding, promote collaboration, and reduce biases and barriers. Discussion would include identifying a timeline for continuation of such joint meetings.	18 months		$0
16.	BSA develop strategies to encourage and to support research training programs and research conferences that have the goal of increasing the number of ethnic minority and lesbian, gay, bisexual, transgender, and other marginalized graduate students and early career psychologists entering research careers. Other goals of such programs and conferences might include student outreach, seeking increased awareness of private research funding opportunities, and developing lesson plans for innovations in teaching practices. Lesson plans might discuss how research evidence using diversity as the variable, expands the knowledge base in psychology—such as how being from a marginalized group influences psychological development.	18-24 months of advanced planning	Staff assistance of 1/4 FTE Training grants, conferences, and materials	$10,000/year $20,000/year

TFED Medium-Term Priorities

	Recommendation	Time Required	Estimated Costs
17.	The Publications and Communications Board and its Council of Editors expand the editorial review mentoring approach to graduate students representing marginalized groups from the departments of members of editorial boards of each journal. BEA and the Council of Editors could also collaborate on activities for encouraging psychology programs to add this type of mentoring to research methodology course content.	2 years of advance planning	Costs depend on how program is structured and the nature of student activities, e.g., student participants may volunteer or be paid part- time editorial assistants. **$0-$10,000 per student per year**
18.	The CEO of APA should take steps to ensure that all APA materials (including this report) that are in print and on the Web are accessible to persons with visual impairments.	12 months to review existing material	Intern @ 250 hours **$3,000**
19.	BAPPI and the Office of Ethnic Minority Affairs, in consultation with relevant APA groups, i.e., CEMA, the Office of Disability Issues, CDIP, CONA, and appropriate divisions, will coordinate a project to develop site visitor training materials relevant to the assessment of *APA Guidelines and Principles of Accreditation*, Domain D, for consideration by the Committee on Accreditation.	2 years	Most planning will involve e-mail and teleconferencing. **$0-$5,000** Some consultant costs may be required. **$20,000** Some material development costs may be required. **$10,000** Some additional staff assistance may be required. **Total $35,000**

TFED Medium-Term Priorities

	Recommendation	Time Required	Estimated Costs	
20.	BCA in cooperation with Division 36 develop a document offering suggestions on how to be sensitive to religious/cultural differences in terms of food/beverages offered at social events. Such a document would be distributed to individuals and groups that plan events at the annual APA convention (such as hospitality hours, social hours) and arrange food service during Divisional Executive Board meetings, etc. These resource materials should be made available for planning other APA meetings, such as C/R, Consolidated, task force, etc., meetings.	12 months	Intern Document	$3,000 $2,000
21.	The Membership Committee in consultation with the CONA develop recommendations regarding the retention of older members in APA.	12 months		$0
22.	The Membership Committee conduct a survey of psychologists who do not join APA to determine their reasons for nonaffiliation. Such a survey might be accomplished through collaboration with COGDOP, CUDCP, NCSPP, SPAs, AAPA, ABPsi, NLPA; SIP, other national or international organizations of psychologists, and/or the APA Committee on Early Career Psychologists as appropriate. The intent would be to identify factors that might be important in increasing new membership in APA or retaining existing members.	2 years	Staff assistance @ 1/4 FTE	$10,000
23.	The editor of the *APA Monitor on Psychology* consider a series focused on "International and Current Issues Regarding Marginalized Groups."	1 year		$0
24.	BSA and BAPPI develop strategies to ensure that students with visual impairments have access to necessary materials to achieve appropriate competence in understanding test and assessment results as necessary for graduating and passing licensing exams. This would include efforts to bring pressure to bear on test and assessment publishers to make their materials available in alternate formats.	2 years		$0

TFED Medium-Term Priorities

	Recommendation	Time Required	Estimated Costs	
25.	CDIP review and update current resource information provided by the APA Convention Resource Room for attendees with disabilities.[6]	1 year	Document development	$1,000
26.	The Office of Disability Issues, CDIP, and BCA should continue to periodically update the fact sheet/brochure on *Guidelines for APA Conference Speakers* that describes procedures for increasing accessibility or presentations to audience members with disabilities, and ensure that conference speakers are aware of and adhere to these guidelines.[7]	12-18 months	Document development	$1,000
27.	The APA CEO add weight to the criterion that, in evaluating candidates for future directors of APA offices involved with marginalized/underrepresented groups, consideration should include persons with first-hand experience as a member of such groups.	6 months		$0
28.	BCA consider proposing to B/D and C/R adoption of a policy to boycott holding conferences or meetings in states with oppressive legislation targeting marginalized groups, such as states banning gay marriages or having discriminatory legislation that creates a harmful environment for lesbian/gay/bisexual individuals, or any setting that is inaccessible for persons of disability regardless of whether a person with a disability is in attendance or not.	1 years		$0
		TOTAL	One-Time Costs:	$55,000
			Recurring Costs	$75,000–$125,000/year

[6] CDIP reports that this action has already been in place as part of CDIP's services. Future periodic reviews of the resource information would be desirable.

[7] BCA, CDIP, and the Disability Issues in Psychology Office confirm that they already have worked on the information for speakers as part of their continuing work. Future periodic updating of the brochure and its use by speakers would be desirable.

TFED Long-Term Priorities

	Recommendation	Time Required	Estimated Costs
29.	The chairpersons and/or presidents of APA governance groups, divisions, and state psychological associations formulate plans and policies derived from a self-study related to increasing membership, activity, and representation of individuals from marginalized groups in their respective organizations. When formulated, these plans should be presented as a written report to the B/D and C/R. Such plans might include examination of possible systemic factors that act as obstacles toward increasing diversity, such as the nature of nomination-election-appointment procedures required for participation. Those groups that have histories of success might highlight their procedures as possible models. The self-study might also include identifying ways to enhance diversity goals that fit into their group's own goals and activities. We also encourage boards and committees to consider including student representatives/monitors/liaisons as appropriate. When the topic is striving to attract new diverse members to APA or SPA groups, it is important to ensure that new members feel welcomed, valued, motivated to continue their membership, and perhaps even desirous of getting involved in governance. As APA and SPA groups consider the topic, the following suggestions might be worth considering: (a) a personal phone call to new members; (b) assigning a "sponsor" who is a similar minority to new members; (c) sending personalized invitations to events at the next APA annual conference, including small teas or gatherings with the president and or chief administrative officer; (d) APA's asking the new Committee on Early Career Psychologists to reach out to new members personally; (e) providing a forum for new members to give information about their own work and interests; (f) listing new members in the *APA Monitor on Psychology* or newsletters; (g) inviting columns for the *APA Monitor* or newsletters to be written by new members about their experience as a minority in the organization, why they joined, what they wish for, what suggestions they have; (h) having a follow-up personal phone call 1 year after membership initiation to ask for feedback from new members.	2 years	To Be Determined

TFED Long-Term Priorities

	Recommendation	Time Required	Estimated Costs
30.	BAPPI in collaboration with Division 36 develop a working paper regarding how Muslims, Jews, and members of other marginalized religions can increase their involvement and/or representation in APA governance activities. Further, this working paper would address the issue of how to increase the importance of training psychologists to work with clients or students whose religious beliefs are associated with a cultural belief or behavioral system that differs from the current dominant Christian culture.	2 years	To Be Determined
31.	Conduct an analysis and feasibility study on the need and demand for, and the cost of translating into other languages and publishing both psychological non-English research and key original U.S. works and/or adding these to the APA Web site. This study should also include consideration of establishing a Spanish language Web site for key APA works and ways to encourage members to develop second language skills, such as speaking Spanish.	1 year 2 years	To Be Determined
32.	BSA develop strategies for encouraging research interests or skills among ethnic minority high school students.[8]	12-18 months	To Be Determined
33.	BSA collaborate with the American Psychological Society on a joint agenda aimed at developing mechanisms to provide training for researchers to conduct research with ethnic minority populations and to increase the number of ethnic minorities and women who enter research careers.	24-36 months	To Be Determined
34.	BCA review and update current information by the Disability Issues in Psychology Office regarding convention programming logistics (in terms of rooms assigned: location, size, accessibility), timing of diversity-related events (i.e., competing with major events or each other), and allocation of convention hours for diversity-related events.[9]	12-18 months	To Be Determined

[8] TOPSS, PT@CC, the Membership Committee, the Education Directorate, and OEMA have initiated a grassroots program to increase the interest of ethnic minority high school students in psychology, including research careers. TOPSS is continuing this valuable project.

[9] BCA has indicated that such collaboration with the Disabilities Issues in Psychology Office routinely occurs. TFED acknowledges this achievement and encourages such collaboration to continue as future updates are planned. In the future, use might be made of such resources as guidelines of the Society for Disability Studies (SDS) and the Association for Higher Education and Disability (AHEAD). It is noted that BCA also attempts to avoid conflicts among diversity programming schedules, but has no direct control over programming scheduled by divisional program chairs. However, BCA will work with divisional program chairs toward the goal of avoiding such conflicts due to divisional programming.

TFED Long-Term Priorities

	Recommendation	Time Required	Estimated Costs
35.	BAPPI take action to ensure there is greater representation in terms of diversity among awardee pools for awards being implemented by any unit within the APA governance through reviewing annual reports from the appropriate central office providing data on award recipients for the year. Any unit of APA that administers an award should seek to constitute selection committees with participants from diverse groups.	2 years	To Be Determined
36.	The appropriate directorates establish awards for service, research, education, training, and supervision related to disability issues and by persons with disabilities.		To Be Determined
37.	The Membership Committee evaluate the possibility of membership dues exemptions or waivers where there is financial hardship. The committee might consider determining whether marginalized groups, such as persons with disabilities, might need such exemptions.	12-24 months	To Be Determined
38.	The Membership Committee evaluate the possibility of reduced dues for members of national ethnic minority organizations.	12-24 months	To Be Determined
39.	CIRP coordinate efforts to identify a model of the effects of catastrophic disaster as a situational cause of marginalization of groups. For instance, what is it like to grow up Muslim in America after 9/11; or what was the effect of the tsunami on world perceptions of various groups seeking relief; or what effect does the AIDS crises in Africa have on worldviews regarding the needs of persons in Africa. CIRP and CYF might also formulate models applicable for understanding how such international events affect the psychological development of children.[10]		To Be Determined
40.	CIRP identify and reach out to other international psychology-related organizations, such as those in the Middle East and Africa, to develop joint activities related to convention, training, practice, and research efforts.[11]	24-36 months	To Be Determined

[10] CIRP has indicated that this assignment would be outside the scope of its mission. However, CIRP repeats its stated willingness to take the lead in developing a bibliography of research on the issue.

[11] CIRP has provided information regarding the limits of its international mission, which do not include training or practice, although other TFED recommendations do fit. Hence, implementing actions outside the scope of CIRP will need to be reassigned to the appropriate group by the APA CEO.

TFED Long-Term Priorities

	Recommendation	Time Required	Estimated Costs
41.	CIRP pursue collaboration with international training programs, such as those currently being developed in many Muslim nations, regarding training issues.[12]	24-36 months	To Be Determined
42.	CDIP and the Office of Disability Issues develop steps to increase the number of persons with disabilities serving in APA governance. This might be through recommending that APA boards and committees create a slate for people with disabilities with CDIP providing a database of nominees with expertise relevant to such governance groups.	12-24 months	To Be Determined
43.	CDIP and the Office of Disability Issues design a strategy for making "valuing diversity" a household value. An example of such a step might be to submit articles to popular magazines regarding psychologists who are blind working as psychotherapists.	12-24 months	To Be Determined
44.	C/R and B/D consider the development of leadership mentoring programs within APA directed to graduate, undergraduate, and high school students from marginalized groups.	24-36 months	To Be Determined
45.	BSA develop strategies to encourage and support research training programs and research conferences to attract, retain, and graduate doctoral students and early career professionals with disabilities. Examples might include dissertation awards, travel funds for presentations and attendance at conferences, and other financial support targeted to graduate students with disabilities.		To Be Determined

[12] CIRP has provided information regarding the limits of its international mission, which do not include training, although other TFED recommendations do fit. Hence, implementing actions outside the scope of CIRP will need to be reassigned to the appropriate group by the APA CEO.

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Appendix A: Biosketches of Task Force Members

Norman Abeles, PhD, is Professor of Psychology at Michigan State University. He and his students are involved in research dealing with mood and memory concerns of older adults. He was the 1997 President of the American Psychological Association and helped to establish the APA Committee on Aging (CONA). He will be a delegate to the 2005 White House Conference on Aging. He currently serves on the APA Ethics Committee and the American Psychological Foundation and is President of Division 52, International Psychology.

Patricia Arredondo, EdD, is Associate Vice President and Senior Advisor for Academic Initiatives and Professor of Counseling Psychology at Arizona State University. Professor Arredondo will serve as President of the American Counseling Association (ACA) in 2005-2006. She was recognized as a "Living Legend" by the ACA for her contributions to the development of multicultural counseling competencies, dedication to Latina/o issues, and her leadership in promoting organizational change through a focus on diversity. She is Past-President of the National Latina/o Psychological Association and Division 45 of the American Psychological Association (APA). She is a Fellow of Divisions 17 & 45.

Beverly Greene, PhD, ABPP, is a Professor of Psychology at St. John's University and a Clinical Psychologist in independent practice in New York City. A Fellow of APA, the Academy of Clinical Psychology, and the American Orthopsychiatric Association, she has a Diplomate in Clinical Psychology from the American Board of Professional Psychology. Dr. Greene is the recipient of numerous national awards that include the 1996 CLGBC Outstanding Leadership Award, 2003 Committee on Women in Psychology's Distinguished Leadership Award, and Division 45's 2004 Distinguished Senior Career Contributions to Ethnic Minority Research Award. She is also the recipient of the Psychotherapy With Women Research Award (1995, 1996, 2000), the Distinguished Publication Award (1995, 2001), and the Women of Color Psychologies Publication Award (1991, 1995, 2000) for distinguished contributions to the psychological literature.

Douglas C. Haldeman, PhD, has been a Counseling Psychologist in independent practice in Seattle for more than 20 years. He serves on the clinical faculty of the psychology department at the University of Washington. His clinical and research interests focus on the ethical treatment of lesbian, gay, bisexual, and transgendered (LGBT) clients in psychotherapy. Dr. Haldeman is the author of numerous journal articles and book chapters on a wide range of issues pertinent to the psychology of gay men. He has maintained a special focus on sexual orientation conversion therapy and is coauthor of the American Psychological Association's Guidelines for Psychotherapy with Lesbian, Gay, and Bisexual Clients, as well as the APA's Resolution on Appropriate Therapeutic Responses to Sexual Orientation. He has lectured and conducted training workshops for professionals on working with LGBT clients all over North America and Europe. Dr. Haldeman resides in Seattle with his life partner of 25 years and their 11 Samoyeds.

Zari Hedayat-Diba, PhD, MFT, is a licensed Marriage and Family Therapist in private practice in Los Angeles. She wrote her dissertation on the "Selfobject functions of the Koran" and has several professional publications on the topic of Islam. She is adjunct faculty at Antioch University, where she currently teaches a course on cross-cultural infant observation.

J. (Doug) McDonald, PhD, is a Professor of Psychology at the University of North Dakota (UND). He is a member of Oglala Lakota Sioux tribe. He earned his PhD (Clinical Psychology, 1992) from the University of South Dakota. His research interests include cross-cultural psychology, masculinity, and ethics. He directs UND's Indians Into Psychology (InPsyDE) program. Dr. McDonald was twice President of the Society of Indian Psychologists and served on APA's Board for the Advancement of Psychology in the Public Interest and Board of Educational Affairs. He is also currently treasurer for Division 45. He lives in Grand Forks with his children, Alex and Rosie.

Jill Oliveira-Berry, PhD, received her PhD in clinical psychology from the University of Hawaii at Manoa. She completed a postdoctoral fellowship in health

psychology at Tripler Army Medical Center and continues to serve on staff as a supervisor for Native Hawaiian postdoctoral trainees at Tripler. She is also Director of the Behavioral Health Program at Na Pu`uwai, Native Hawaiian Health Systems Clinic. She has produced a series of videotapes and professional presentations in the area of multicultural skills training and culture-centered psychotherapeutic interventions. Her research interests include the evaluation of traditional native Hawaiian healing approaches to elicit positive changes in psychosocial issues affecting chronic disease.

Rhoda Olkin, PhD, is a Distinguished Professor of clinical psychology at the California School of Professional Psychology, San Francisco Bay Campus. She received her doctorate from the University of California, Santa Barbara, and her BA in psychology from Stanford University. A licensed psychologist, she is the author of the well-received *What Psychotherapists Should Know About Disability* (1999, Guilford Publications) and numerous articles on disability. She chaired the American Psychological Association's Committee on Disability Issues in Psychology and conducts a private practice and expert witness work in the San Francisco East Bay Area.

Richard M. Suinn, PhD, ABPP, is emeritus professor, Colorado State University, where he headed the psychology department for 20 years. He was Mayor of the city of Ft. Collins, CO, and Team Psychologist for U.S. Olympians. He was the 1999 President of APA. He received APA's Raymond Fowler Award, Division 45's Lifetime Contribution to Ethnic Minority Issues, and Asian American Psychological Association's Lifetime Contribution to Asian American Psychology Award. Born in Hawaii, he has his doctorate from Stanford and an honorary doctorate from the California School of Professional Psychology. He has authored 150 articles, eight books, and five psychological tests, including the Suinn-Lew Asian Self-Identity Acculturation Scale.

Melba J. T. Vasquez, PhD, is in independent practice in Austin, TX. She is coauthor of E*thics in Psychotherapy & Counseling: A Practical Guide for Psychologists,* 1998 (2nd ed.) (with Ken Pope) and of *How To Survive and Thrive as a Therapist: Information, Ideas, and Resources for Psychologists in Practice,* 2005, also with Ken Pope. She is a Past-President of APA Division 35, Society for the Psychology of Women, and of Division 17, Society of Counseling Psychology. She was elected to serve as President of the Texas Psychological Association in 2006 and serves on the Council of Representatives for APA Division 42, Independent Practice, for 2004-2007.

Joseph L. White, PhD, has enjoyed for the past 44 years a distinguished career in the field of psychology and mental health as a teacher, mentor, administrator, clinical supervisor, writer, consultant, and practicing psychologist. He is currently Professor Emeritus of Psychology and Psychiatry at the University of California, Irvine, where he spent most of his career as a teacher, supervising psychologist, mentor, and director of ethnic studies and cross-cultural programs. Dr. White received his PhD in clinical psychology from Michigan State University in 1961. Dr. White is the author of several papers and three books: *The Psychology of Blacks: An African-American Perspective* (1990; 1984); The Troubled Adolescent (1989); *Black Man Emerging: Facing the Past and Seizing a Future in America* (1998). He was a pioneer in the field of Black psychology and is affectionately referred to as the "Godfather" of Black psychology. His seminal article in Ebony magazine in 1970, "Toward a Black Psychology," was instrumental in beginning the modern era of African American and ethnic psychology. He is currently a member of the Board of Trustees of the Menninger Foundation in Topeka, KS.

Appendix B: APA Resolution and Justification Statement

Resolution on Enhancing Diversity in APA

(Adopted by the APA Council of Representatives on 08/17/05)

WHEREAS in 2005 the President of the American Psychological Association (APA), Ronald F. Levant, EdD, MBA, appointed a Task Force on Enhancing Diversity to suggest ways that APA can be a more welcoming place for psychologists who are members of marginalized groups—more specifically, members who are African American/Black, American Indian/Alaska Native, Asian American/Pacific Islander, Hispanic/Latino(a); lesbian, gay, bisexual, or transgendered; persons with disabilities; older persons; Muslims and others of nondominant religious orientation or heritage; and women; and

WHEREAS conflicts occur not only between the majority and the marginalized groups, but among marginalized groups; and

WHEREAS one charge of the task force was to identify conceptual models for use in reconciling differences when they occur among diverse groups and between majority groups and specific marginalized groups; and

WHEREAS this task force also was charged to develop recommendations for how the American Psychological Association can become more welcoming to its many diverse constituent members; and

WHEREAS many of the task force members and the members they represent have reported that interactions between members of dominant groups and the marginalized groups identified above sometimes exhibited insensitivity, an appearance of invisibility, or outright rudeness; and

WHEREAS the task force has completed its final report, which provides the basis for this resolution by: (a) presenting the past history and current record of APA and diversity, (b) describing 10 major principles of change, (c) identifying the benefits of change to APA and its majority and marginalized group members, (d) explaining through use of examples the need for change in APA, (e) outlining specific models of change and specific conflict resolution/reconciliation strategies, (f) recommending prioritized actions for enhancing diversity in APA, and (g) providing reference citations of the report's major concepts and models;

THEREFORE, BE IT RESOLVED, THAT enhancing diversity and increasing the sense of being welcome in APA by diverse groups are top priorities for APA; and

BE IT FURTHER RESOLVED, THAT APA's Council of Representatives directs APA's Chief Executive Officer (CEO) to develop a Diversity Implementation Plan to ensure that diversity is an integral part of APA structures and activities. In developing this plan, the CEO should consider, among other things the Immediate, Medium-Term, and Long-Range Recommendations outlined by the Task Force on Enhancing Diversity in APA that are included as the Appendix to this resolution; and

BE IT FURTHER RESOLVED, THAT $10,000 be budgeted in 2005, and $25,000 in 2006 to facilitate the development of the Diversity Implementation Plan and that beginning in 2007, a specific line item appear in the annual APA budget to operationalize the Diversity Implementation Plan in an amount recommended annually by the CEO.

The APA President's Task Force on Enhancing Diversity in APA: Immediate, Medium-Term, and Long-Range Recommendations

Immediate Recommendations

(a) Supporting an antidiscrimination policy
(b) Surveying all governance entities as to "climate" (e.g. current level of participation, relative level of comfort) of members of diverse groups
(c) Enhancing inter-directorate collaboration through joint columns in the *APA Monitor on Psychology* and other collaborative projects
(d) Adopting the policy of incorporating language and principles from the *APA Guidelines on Multicultural Education, Training, Research, Practice, and Organizational Change for Psychologists;* the *APA Guidelines for Psychotherapy With Lesbian, Gay, and Bisexual Clients;* and the *APA Guidelines for*

Psychological Practice With Older Adults into publication and editorial policies/procedures
(e) Expanding the editorial/publications pipeline with respect to greater inclusion of diverse persons
(f) Obtaining relevant governance groups' feedback to the Office of Accreditation and Program Consultation for its consideration in supporting more effective implementation of Domain D of the *APA Guidelines and Principles for Accreditation of Programs in Professional Psychology*
(g) Developing a training mechanism for psychological researchers in skills, knowledge, and attitudes requisite for conducting research with diverse populations
(h) Recognizing the needs of APA meeting and convention attendees who are from various marginalized religious groups
(i) Increasing attentiveness to diversity issues in areas such as awards and the content of membership promotional materials
(j) Providing favorable consideration of a new Division on Disability
(k) Conducting a study of barriers students with disabilities face
(l) Developing a newsletter from the Office of Disability Issues

Medium-Term Recommendations

(a) Planning mechanisms for diversity enhancement within the Association
(b) All governance groups organizing discussions of having joint meetings to promote collaboration with other governance groups
(c) Developing experiences and activities to encourage diverse marginalized students and early career psychologists to enter research careers and APA governance/leadership
(d) Opening opportunities for students from marginalized groups to be mentored as ad hoc journal reviewers
(e) Developing site visitor training materials relevant to the assessment of *APA Guidelines and Principles for Accreditation of Programs in Professional Psychology,* Domain D, for consideration by the APA Committee on Accreditation
(f) Providing educational materials to increase awareness at meetings to diverse religions' food restrictions
(g) Developing strategies for recruiting and retaining members from marginalized groups
(h) Initiating an APA Monitor on Psychology series on international issues
(i) Improving attention and commitment to issues facing persons with disabilities such as access, resource materials, and representation among staff
(j) Examining states' laws and positions that may be oppressive to marginalized groups or insensitive to persons with disabilities relative to decisions about locations of APA meetings

Long-Range Recommendations

(a) All governance groups formulating plans for increasing representation of individuals from marginalized groups
(b) Developing ideas for increasing APA's involvement with international psychological organizations
(c) Initiating non-English translations of key APA publications
(d) Encouraging increased attention to tolerance and understanding of religious, sexual orientation, and disability issues, especially in psychology education and training
(e) Expanding efforts related to increasing research training to marginalized students at a all levels of the educational pipeline
(f) Evaluating the value of reduced dues for marginalized groups
(g) Increasing the Association's understanding of and commitment to persons with disabilities
(h) Developing leadership mentoring opportunities for marginalized students at all levels of the educational pipeline

Justification Statement

1. *The resolution's relevance to psychology and psychologists and importance to psychology or to society as a whole.*
The proposed resolution speaks to the need to improve APA's organizational climate or "welcomeness" for those psychologists who represent a major

and ever-growing segment of the U.S. population, yet who are marginalized in society and in the American Psychological Association (APA). To confirm that these groups form a major part of our society, here are some exemplary figures: Latinas/os number 39.9 million, over 13% of the U.S. population and are the fastest growingracial/ethnic group in the United States; regarding the elderly, current projections suggest that by 2030 one in three Americans will be 55 years old or older; and persons with disabilities comprise about 15% of the U.S. population. Despite the national demographics of these and other marginalized groups, the representation of such groups remains low within membership of the APA. For instance, only 6% of members identify themselves as ethnic minorities, while only 1% of APA membership identifies as having a disability.

Among members of the APA Council of Representatives (C/Rs), only 6% self-identified as gay, lesbian, or bisexual (Salazar, 2004). It should be noted that the numbers of such groups actually in APA governance has increased, such that task force members were selected from a pool of APA members experienced in APA who could see the progress but also view the lapses.

APA President Ronald F. Levant, EdD, MBA, charged the task force with identifying ways in which the APA climate is unwelcoming to marginalized groups. Therefore, the task force resolution focuses on the climate within the APA as it affects membership recruitment and retention; representation in governance, in the professional literature, and as awardees; the development of future leaders within the association and the discipline; and other related areas of organizational functioning.

As a leading national association speaking to societal issues, APA has significant impact on society as a whole, and, therefore, so would the recommendations associated with the resolution. Any implementation steps accepted by APA will serve as a model for similar progress in other organizations and institutions. To the degree that APA influences the education, science, and practice of psychology nationally, positive change within APA will benefit psychology as a whole.

2. Quality and quantity of psychological data and conceptualization relevant to the proposed resolution
The Final Report of the Task Force on Enhancing Diversity in APA forms the core background of the resolution by providing conceptual formulations and principles for guiding organizational change. The report's specific recommendations and associated resolution derive from the report's findings and data including those of: the U.S. Census Bureau; U.S. President William J. Clinton's Initiative on Race report; and the psychological literature on ethnic minorities, feminism, persons with disabilities, elderly persons, gay/lesbian/bisexual issues, and relevant literature on religious diversity. In addition, task force members are researchers, educators, and service providers with extensive knowledge of the empirical and theoretical literature in their areas of expertise. Thus, concrete illustrations regarding the climate within APA, recommendations relating to conflict resolution and reconciliation strategies, and conceptualizations of the process of change were derived from related psychological and organizational behavior literatures and represent the best views of the task force members, who were appointed by APA President Ronald F. Levant, PhD, MBA, in recognition of their various areas of expertise.

Task force members have extensive backgrounds in APA governance and state leadership; in formal conflict resolution consultation, including collective bargaining; and in education/research/administration/service delivery activities. Furthermore, in his "Introduction" to the task force report, President Levant, himself, states his own personal observations regarding the need for APA to consider how it is unwelcoming and the importance of developing strategies for changing this.

3. Likely degree of consensus among APA constituents
In addition to their various areas of expertise, the task force members have credibility among the various constituencies they represented: ethnic minorities, persons with disabilities, lesbian/gay/bisexual persons, Muslim/marginalized religions, older persons, and women. Task force members also have been deeply involved in the appropriate APA divisions and

also active in APA governance such as the Board of Directors, the Council of Representatives, and various boards and committees. Indeed they were appointed by President Levant for their visibility as leaders, their first-hand knowledge regarding marginalized groups, their long experience within APA, and their constructive approaches. Such credibility and experience should serve to galvanize consensus about the need for the task force report and its recommendations and resolution.

4. Likelihood of the resolution having a constructive impact on public opinion/policy, assessment, consultation, and training

The underlying message of the resolution is that changes in climate toward greater inclusiveness and "welcomeness" have multiple positive outcomes for all participants in an organization. For instance, as the climate becomes more positive and welcoming, membership size increases; as membership increases, the financial condition of the organization becomes more favorable. As the funding becomes more positive, the nature of services can be expanded so as to increase outreach, improve development of resource materials and valuable education, training, and mentoring of future psychologists and APA members. Industrial/organizational psychologists and consultants will verify that a positive climate is indeed essential to an organization or institution remaining viable and successful.

The task force members were charged with making recommendations for ways to enhance diversity and improve the climate for groups within APA. By taking those actions suggested by the report and its recommendations, APA should not only increase its welcomeness to marginalized groups, but also provide a model for change toward greater inclusiveness and effectiveness that can be used by other associations, organizations, and institutions. As a result, APA and Psychology are enabled to influence more persons and social institutions while facilitating the enrichment of society

Experiences in Developing and Implementing a Capstone Course in Information Technology Management

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Executive Summary

With business and technology complexity increasing rapidly, information technology management departments are attempting to deal with the challenge in a variety of ways. One approach is through the deployment of a nonstandard, comprehensive, finishing course, a so-called capstone information technology management (ITM) course. This paper describes the experiences of faculty members at Christian Brothers University in developing and implementing a capstone course in information technology management. In addition, the paper presents the rationale on which the course is based and reviews how other similar information technology departments have addressed the issue.

Beginning with a brief introduction to the importance of Information Technology Management in today's world, the paper presents a compelling case for why this course is needed. The discussion includes statements of support by industry leaders as well as factual studies pointing out the lack (and often, the failure) of proper emphasis being placed in this area by business schools. The conclusion of this investigation is that a capstone course in Information Technology is not only required but central to successful preparation of ITM graduates for their future role in the workplace.

The paper then documents the efforts of the ITM faculty at our school, as they set about to design, develop, implement, measure and incorporate a capstone course on Information Technology Management into their ITM curriculum. Significant detail is provided on the design concepts and how they were carefully chosen to incorporate ISCC recognized guidelines into the course. The approach was to ensure that students completing it would be well prepared for their ITM career choices and for pursuing advanced degrees. The paper presents conclusions in a tabular form to highlight the goals, design objectives, and the deficiencies these objectives and goals are designed to correct.

Implementation is discussed along with two methods of implementation deployed by different faculty members at CBU to accomplish those design goals. Along with the implementation strategies, the pitfalls and problems are discussed as an aid to others interesting in developing this type course. Included in this discussion are measurement methods deployed and their success/failure aspects. The issue of a final core competency exam is explored along with a final discussion of early results comparing the exam to the project approach as a method for evaluation of student performance.

In conclusion the paper summarizes what has been learned by the faculty at CBU during the development of this capstone course and how other universities have attempted to resolve this issue. A table of different approaches by a variety of other colleges and universities is presented to aid the reader in developing a better understanding of the complexity of this type of course development. While this paper is not a panacea to cure all

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the ills of course development in this area, it does offer one perspective on why it should be done, how it was designed, measured, and the results which were achieved. The premise is: *this should better prepare the reader to understand the issues and the practical side of development of an Information Technology Management capstone course for their institution.*

Keywords: ITM, Capstone, Senior, Course, Undergraduate, Learning, Comprehensive, Project

Introduction

The signs are all around us.

- "Hailed as a savior when he arrived at AT&T three years ago, CEO C. Michael Armstrong quickly made $120 billion worth of acquisitions to position the company for the digital era. Now, amid a steep decline in its share price, Armstrong is separating the company into four pieces." (Rosenbush, 2001)
- "I guarantee that if you were a fly on the wall at almost any board meeting, you'd hear the same kinds of questions: 'I wonder how we can do more business over the Internet? What kind of intranet will best serve our needs? How can we better communicate with and manage our suppliers? How can we get closer to our customers?'" (Maruca, 2000)
- In 2000, Wipro Industries increased their profits by more than 100% over 1999 and has recently won contracts with General Electric, Home Depot, and Nokia. According to Vivek Paul, Wipro's CEO, their goal is to challenge IBM Global Consulting, Accenture, and Electronic Data Services as a major player in the business/information systems consulting industry. What makes this claim significant is that Wipro is based in Bangladesh, India. (Einhorn, 2001)

It's a new game with new rules.

IT challenges are both growing and changing. Global organizations, supplier-to-customer supply chain connectivity, mergers, acquisitions, divestitures, outsourcing, and major e-business components are all standard fare in today's business environment. Information technology has become strategic to many businesses and essential to virtually all businesses. The need is clear. Never has there been a better time to be an information technology management major. However, a number of studies have questioned whether or not graduates of information technology management undergraduate programs possess the proper balance of technical, business, and interpersonal skills to allow them to immediately contribute after moving into today's business environment. (Chow et. al., 1994; Alexander, 1996; Coffee, 1998)

In fact, there is evidence that formal undergraduate information technology education is coming up short. According to a survey of 1,250 IT users, 78% of those interviewed thought encouraging people to study IT full-time was the best way to deal with the IT problem. Ironically, despite this response, only 20% of the IT managers interviewed "thought undergraduates were equipped for work." (Kennedy, 1998) Other studies have found a similar lack of preparation on the part of information technology graduates. (McGee, 1998; Buckingham, 1987)

According to a study sponsored by the National Science Foundation (NSF), "Large software and hardware systems continue to fail despite rapid advances in information technology… [and] the problem is even deeper than reported. Failures of complex information systems are generally not reported by industry. Within the companies where these failures occur, the valuable lessons to be learned by these failures rarely are reported or examined. In academe, exploring the reasons for these failures is not addressed. Graduates are not prepared to cope with the complexity of medium to large systems… Something is amiss in the nation's ability to generate well prepared new graduates in the information systems-centric

disciplines." (Lidtke, 1999) The NSF-sponsored study identified several skill deficiencies: (1) inability to solve problems relating to medium and large computing systems; (2) inability to apply systemic thinking to complex computing systems; (3) deficiencies in business case preparation and assessment in computing systems applications work; and, (4) inadequate written, verbal, group and listening skills.

The NSF study also identified three categories of industry-defined attributes an IT graduate should possess: (1) personal skills, including problem-solving and critical-thinking skills, persistence, and curiosity; (2) interpersonal skills, including collaborative and communication skills (verbal, written, listening, group); and, (3) technical knowledge and skills, including systems development skills and application capabilities. Gupta identified a similar list and added a fourth category: business functional knowledge, including the ability to interpret business problems, develop appropriate technical solutions, and understand the business environment. (Gupta, 1998)

This paper deals with one aspect of a potential solution: the capstone ITM course. More specifically, the paper describes the capstone course (ITM 455) developed and implemented by faculty members in the Information Technology Management Department at Christian Brothers University. While ITM 455 is intended as the IT capstone course, it is nevertheless only one course in the ITM curriculum. The ITM curriculum offers students a combination of both core business courses (Economics, Statistics, Accounting, Management, Marketing, Law, Ethics) and computer science courses. (It is worth noting that (1) ITM is only one specialization at the bachelor degree level in the School of Business at Christian Brothers University and (2) all bachelor degree students, including those in ITM, take Business Policy, the School of Business "capstone course.") In this paper, the components of ITM 455, the logic behind its development, and the issues encountered in delivering it are presented. In addition, an overview of how other ITM-type departments have addressed the same question is included.

Background

The idea of including a capstone course in a degree program is, of course, not new; nor is the idea of a capstone course in the ITM or MIS specialization area. The value of a capstone course for a degree program (such as a BSBA) has been evaluated, tried, and generally recommended. (Magner, 1990; Magner, 1992; Boyer, 1998; Thomas, 1998; Gardner, 1998; Heinemann, 1997; Jessup, 1995) A number of journal articles and conference proceedings have addressed this topic as it relates to more technical curricula, such as computer science or computer engineering. (Merts, 1997; Magney, 1996; Codespoti, 1994) However, considerably less literature has addressed issues related to a capstone course in a combination business and technology setting. (Novitzki, 1998; Gupta, 1998; O'Neil, 1998) It is in this latter area, a combined business and information technology environment, that this paper is focused.

Design

Christian Brothers University's Information Technology Management (i.e., CBU ITM) curriculum is based somewhat on the National Science Foundation sponsored "Information Systems-Centric Curriculum (ISCC) Program Guidelines" (Lidtke, 1999), although a course-by-course match is clearly not exact. Table 1 below shows a comparison.

The CBU Information Technology Management curriculum also includes several other technical courses appropriate for today's professional information technology environment: ITM 152 – Introduction to Information Technology, ITM 153 - Basic IT Applications (word processing, spreadsheet, presentation), and a choice from several electives including: ITM 280 – Operating Systems, ITM 457 – Internet Programming, ITM 456 – Java Programming, and ITM 492 – Advanced Communications Networks.

ISCC Program Guideline	CBU ITM Course
ISCC 41 - Database	ITM 451 - Database Design
ISCC 42 - Computer Interaction Methods	ITM 255 - C/C++ Programming
ISCC 43 - Telecommunications/Networks	ITM 291 & 292 – Telecommunications /Networks
ISCC 44 - Dynamics of Change	No single course, although covered to some degree in multiple courses
ISCC 45 - Applications of Artificial Intelligence	ITM 480 - Decision Support Systems (which includes artificial intelligence and expert systems)
ISCC 51 - Distributed Systems	Covered in ITM 351 - Systems Analysis & Design and ITM 451 - Database Design
ISCC 52 - Computer Ethics	Covered in ITM 250 - Introduction to Information Technology and ITM 455 - Information Systems Management (capstone)
ISCC 53 - Enterprise Systems	Covered in ITM 351 - Systems Analysis & Design, ITM 451 - Database Design, and ITM 455 - Information Systems Mgmt
ISCC 61 - Comprehensive Project	ITM 455 - Information Systems Mgmt (capstone)

Table 1. ISCC Program Guidelines versus CBU ITM Courses

For a "capstone course," ISCC Guidelines present "ISCC 61: Comprehensive Collaborative Project" as the concluding course in its sequence. The ISCC 61 description states, "This course will provide a summative experience for the student… will require … participation in a team activity producing working systems from real world specifications … [and] ideally … will be done in collaboration with an industry system development team working on a complex systems development project." In line with these guidelines, the ITM Department faculty designed its capstone course (ITM 455) to explore and put to practical use the entire body of knowledge gained in previous ITM courses. ITM 455 was formulated around the following educational outcomes:

1. Competency in relating business and ITM, including the ability to assess potential business problems and, if appropriate, propose/develop solutions supported by information technology.
2. Competency in the core disciplines of ITM, including systems analysis/design, database, application development, and telecommunications for the resolution of business issues.
3. Competency in important supporting areas, including creativity/critical thinking, writing, presenting, and the ability to work as part of a team.

Clearly defining a course at the conceptual level, however, is a far cry from implementing one successfully.

Approach

As an overview statement, ITM 455 is focused first on business issues as they relate to IT, plus IT leadership and management preparation. The CBU course differs from the ISCC 61 course in that it is not a development course, but rather a professional-life-in-IT preparation course. In line with this perspective, students taking the IT capstone course are expected to exhibit a different, more business-like perspective and atypical student behavior patterns (e.g., punctuality, professional decorum, and active participation in class discussions). As one ITM faculty member stated with regard to the course and the professional world senior ITM students are about to enter, "We aren't in the business of perpetrating myths."

Table 2 presents the major course components of ITM 455, the goals addressed by each component, the approaches taken to address these goals, and the NSF-identified deficiencies each goal addresses. By design, ITM 455 is unique. Its emphasis is not on technology or techniques, but instead focuses on major IT issues and the business environment where much of IT takes place.

Emphasis	Goal	Approaches	Deficiency Addressed
Business & IT Issues and Trends	Increased knowledge of business and IT reality (e.g., realities of managing IT globally)	• MBA level IT/business textbook • Discussion of current business and IT events • Speakers from local business	• Deficiency 1: Increased awareness of actual medium and large-scale information technology and business problems
Business Case Studies	Ability to analyze specific business and IT challenges (e.g., implementation of ERP system)	• Numerous case studies, essentially one per IT/business topic	• Deficiencies 2 and 3: Opportunity to employ systemic thinking to complex computing questions and practice in business case preparation and assessment
Written Assignments	Ability to create professional written documentation (e.g., executive summary)	• Case study summaries • Project descriptions • By-weekly project updates • Final project report	• Deficiency 4: Opportunity to address deficiencies in written, verbal, group, and listening skills
Verbal Reporting	Ability to make professional verbal presentations – with or without slides	• Facilitation of case study discussion • Project updates • Project presentations.	• Deficiency 4: Opportunity to address deficiencies in verbal skills

Discussion Participation	Ability to engage in group discussions without definitive answers (e.g., outsourcing)	• Case study discussion • Discussion with guest speakers • Feedback to other students	• Deficiencies 2, 3, and 4: Opportunity to employ systemic thinking to complex computing questions, opportunity to practice business case preparation and assessment, and opportunity to address deficiencies in written, verbal, group, and listening skills
Team Assignments	Ability to build consensus and play a meaningful role in joint efforts	• Case study preparation • Possibly, project assignment	• Deficiency 4: Opportunity to address inadequate group skills
Capstone Project Assignment	Ability to grapple with real business/IT dilemmas, successfully analyze situations, and propose real solutions	• Select appropriate business situation • Involvement with business organization, problem discovery, development, and presentation of business solution approach	• Deficiencies 1, 2, and 4: Opportunity to evaluate actual medium-size computing problem, opportunity to employ systemic thinking to the problem's complex computing issues, and opportunity to address deficiencies in written, verbal, group, and listening skills

Table 2. ITM 455: CBU's ITM Capstone Course Design Components

Implementation

Once the course's initial design and approach were solidified, the implementation details were developed. A decision was made to select a graduate level, business/IT textbook that emphasizes the use of business cases as the primary teaching method. Lectures would be used to simply introduce and reenforce fundamental principles of information technology management. The selected cases would emphasize the practical application of these principles to a diverse set of business related situations. Students would be challenged to explore alternatives and participate in classroom discussions with their peers. The instructor would serve primarily as a moderator and discussion guide. At the conclusion of each case discussion, the instructor would be expected to summarize the key points made, the case lessons, and the principles applied. Most of the class time would be spent in this case discussion mode, with frequent references and tie-ins to the student projects and reading materials. Examinations would be used to test student comprehension of key principles learned in class lectures, reading assignments, and case discussions. Finally, a comprehensive research project would be used to give each student an opportunity to work individually and in a team setting to develop a meaningful analysis and proposed solution to a real world problem on a topic approved by the instructor.

While ITM 455 is still in its early development stage, several approaches to final projects have been used in an attempt to create this required outcome. In one approach, teams were formed consisting of 2 or 3 students. Each team met, selected an industry, and proposed a study, which was then reviewed and approved by the instructor. Each individual team member then selected one company in that industry

and developed a comprehensive research report on that company. Each report focused on the web presence of the company. Comprehensive analysis of the company's web site was required. Students were expected to determine the mission of the company, its organizational style and the purposes of its web presence (i.e., whether it was e-commerce, institutional, investment oriented, informational, employment oriented, etc.). The critical review was also expected to assess the web site's applicability to corporate mission and purpose, its complementary themes, the quality of information provided, its ease of use, the audience intended, and other key characteristics. Bi-weekly team meetings were required to ensure progress throughout the semester and to simulate a real-world project situation. Individual reports had a minimum length requirement of 16 pages.

Once the individual and team reports were complete, the teams would reconvene to present their research to the other teams. The combining of presentations of individual student research with team research has produced some interesting outcomes, not the least of which is that students learn (sometimes reluctantly) that with effort they are able to work successfully both as an individual and as a team member, and that the team can accomplish the research project objectives.

As a next step, each team was required to jointly develop a presentation for a "virtual" company in the team's chosen industry, with the virtual company expected to embody the best features of the companies surveyed. The "development" of the virtual company included creation of a mission statement, "realistic" company financial statements, a web-page design, a description of the web site's target audience, a justification for the company's web design model, and the development of a prototype web site. As a concluding activity, each team was required to present its web site and accompanying organizational description to the entire class.

While this approach to project work has several positive aspects, there are also challenges.

- Expectations: One challenge is the need to set proper student expectations for both the work effort required and an acceptable outcome. This has typically been accomplished with a minimum expenditure of class time by bringing high-quality project reports from prior semesters to class and allowing a 15-minute "lab time" in which current student teams are allowed to review the reports. Current-semester students are not allowed to copy the reports or take them out of the classroom.
- Teamwork: A second challenge is that of teamwork. How must assignments be structured to ensure that all individual students contribute in the team setting? One method that has been employed to aid this process is the requirement that each team submit a minimum of three team progress reports, with each team member responsible for at least one report. The reports (which can be submitted by email) must show the team's meeting dates, as well as listing the members present and absent, along with the reasons for the absences. In addition, the report must show each meeting's agenda, individual project assignments and accomplishments, and must provide an overall project status update.

An alternative project approach required students to develop IT-business focused case studies based on slightly modified versions of actual business situations faced by local companies. In summary, course instructors are aware of the challenge required to develop meaningful project assignments and are continuing to evaluate reasonable project-oriented alternatives. It is quite possible that no one model will ever be specified. On a practical note, using multiple models discourages passing along class notes and solutions to upcoming students and encourages original thinking.

Core Competency Exam

In addition to the course requirements for ITM 455 mentioned earlier, the ITM Department also administers a Core Competency Exam at the conclusion of ITM 455. The exam is voluntary and has no grade impact on the individual student. The purpose of this exam is to assess ITM graduating senior competency in key subject areas. The exam is a 50-question, multiple-choice exam. Questions are taken from

sample questions included in the CCP (Certified Computing Professional) and ACP (Associate Computing Professional) Review Outlines published by the ICCP (Institute for Certification of Computing Professionals). The results of this examination are tabulated by academic subject areas and then used as indicators of departmental and school strengths and weaknesses. Thus, currently, the ITM 455 Final Project and the ITM 455 Competency Examination are the two "objective" methods of evaluating the effectiveness of the curriculum and associated core business courses. The ITM Department recognizes that it is in the early, formative stage of developing evaluation tools capable of measuring effectiveness.

Early Results

On the positive side, even during the first year of the course's existence, several important goals were achieved. Students are: (1) demonstrating an awareness of current business and IT issues and trends, (2) regularly preparing and presenting written and verbal reports, (3) participating in teams to complete some assignments, (4) engaging in class discussions on controversial IT issues, and (5) doing meaningful capstone IT/business related projects.

However, reality differs considerably from the original ITM faculty vision in several important ways. Students: (1) often regard the course's requirements as outside their true interests; (2) question the value of some verbal, written, and team assignments as being make-work situations; (3) tend to fight the experience, are uncomfortable with the change in typical classroom venue, and only partially embrace the learning opportunity; (4) often reluctantly engage in classroom discussions on topics that range outside known facts and into less definitive areas (e.g., strategy); and, (5) have trouble equating regular class attendance, punctuality, on-time and professionally-prepared assignments, and engaged participation in class discussions with expected professional decorum.

Our ITM students often state a desire to remain very narrowly focused. This is especially true of those students who are strongly technical in their orientation. They often neither understand nor appreciate the effect that company mission and goals, culture, organizational structure, strategic planning, management style, and other management-oriented business components have upon the successful implementation of information systems. One implicit goal is to expose such students to those subjects and their importance at some point during the capstone course experience.

Other Approaches

There is clearly no single way to handle a capstone course in information technology. Gupta presented a number of interesting approaches to be used within the capstone IT course, including "targeted assignments." One example was to have each student interview both a business functional area manager and an IT executive about the role of IT in the organization and then contrast their views. He also suggested guidelines for course success, including planning and organizing the course well in advance to ensure meaningful timing of assignments and instructional materials, expecting and planning for student frustrations, building an atmosphere of trust and mutual respect between faculty and students and among fellow students, and insisting on verbal project progress reports during class time as a means of coping with project management and client issues.

In another example of a capstone course the students completed a major project with a selected company in an IT related industry. This approach consisted of a class organized into teams who were then allowed to select from several alternatives a team project for their course work during the semester. The selected team project became the primary focus of the course for that semester. During the initial class meeting students were allowed to select an appropriate project from a list of potential projects. Next, the faculty "class manager" formed teams matching the students with each other consistent with an assessment of their skill level and experience. (Novitzki, 1998) This approach certainly offers tremendous benefit to

the student. However, it requires extensive project management time on the part of the faculty. Extensive outside the classroom time is required to coordinate and recruit those companies willing to participate each semester. This approach was not considered due to our required class teaching load and the number of faculty in our ITM Department.

Capstone courses seem to be focused around the following approaches: (1) actual IT design and development project, (2) conceptual IT design project, (3) IT research project, and (4) IT design philosophies. Table 3 presents a sampling of business-school IT programs and describes how each one addresses the IT capstone course question.

University	**Course***	**Description**
Arkansas, University of	Business Application System Development (CISQ 4363)	System design, development, and implementation of real life project
California State University (Sacramento)	System Development Life Cycle II (MIS 161)	Second in two-course system analysis, design, and development sequence
Louisiana State University	Analysis and Design of Management Information Systems (ISDS 4125)	Design philosophies and techniques for the creation of information systems; conceptual design of actual systems
Miami University (Ohio)	Capstone in Management Information Systems (MIS 495)	Extensive research, reading, writing, and discussion; independent research project on topic and company from management MIS perspective
Minnesota, University of	Information Services Management (IDSc 4204)	IT functions, roles, and organizational structures, including IT planning, strategy, operations, outsourcing, acquisition, and user support
Texas, University of	Business System Development (MIS 374)	Full range of development is covered; real world client projects
** Courses listed are "last courses" in IT curricula, apparently (though not necessarily) capstone IT courses; among those listed, only Miami University (Ohio) has an explicitly stated capstone IT course; survey based on review of online catalog descriptions*		

Table 3. Capstone IT Courses at Selected Universities

Summary

The challenges of developing and implementing a successful IT capstone course are nearly as numerous as the challenges of successfully deploying IT in a business environment. At CBU, the challenge is still relatively new, but no less formidable. While the current CBU approach has been described (see Table 2), one part of the ongoing question deals with how the course should be structured. Gupta described an approach utilizing a team-teaching methodology and questioned whether or not the development project should be extended over two semesters (see California State University, Table 3). The answers to such questions are not simple. CBU faculty considered combining the course with a concurrent intern assignment and with blending the course with assignments based on learning a "small" ERP system that

would be implemented on our department's server. (Note: A business internship course is already available as BUS 400.)

A second part of the question deals with how the course should be conducted. ITM 455 faculty members have begun to accept that this course will probably not ever be "smooth." Students come to the end of their undergraduate studies with too much variety in their backgrounds and in their career goals and expectations for that to occur. Departmental goals for the course, however, are far beyond achieving smooth sailing. The objective is to create a challenging, stretching, truly meaningful, summary learning experience for the graduating Information Technology Management student, to force students to expand her or his perspective at least in part by changing the approach. Felder described the difficulties of moving from the classical learning model to an active learning environment. (Felder, 1995) After changing to an approach that placed more of the responsibility for active learning on the student, Felder observed resistance to change that led him to conclude that students passed through the traditional stages of grief and trauma as they moved to the new learning environment (i.e., shock, denial, strong emotion, resistance/withdrawal, surrender/acceptance, struggle/exploration, return to confidence, and integration/success). Similar responses must be expected of ITM capstone class students as well.

A third part of the question deals with metrics. Is the course really working? Are Christian Brothers University's ITM graduates well equipped to compete in today's business environment? What parts of the curriculum can be changed to better equip the next group of students for the challenges ahead? Gupta stated, "Information systems academic programs must continually monitor industry to ensure that graduates can acquire the mix of skills necessary to perform competitively in the job market. Further, academic institutions offering IS programs must assure the hiring firms that their IS graduates have competencies to support the firm's organizational initiatives." Because the needs of business continue to change, so must business IT curricula. The measurement approaches associated with ITM 455 to date represent a minimal beginning. While they have been helpful in focusing attention on internal strengths and shortcomings, they do not address external realities. It may be that these are best measured by the achievements of our graduates that can only be measured by observation over time. Regardless, ongoing curriculum and learning experience review, including regular interaction with business and IT leaders, will always be an important part of the improvement process.

A fourth part of the question deals with intangibles. Years ago, a trusted colleague succinctly stated, "The problem we teachers have is that we spend too much time answering questions the students don't have." A major challenge in today's educational environment is that, because the questions have changed so much – and so fast, "we teachers" no longer <u>have</u> the answers. Like the students, teachers also struggle with the environment and the growing complexity of the questions. Yet the challenge remains. How do undergraduate information technology management programs best equip students to face an uncertain "real" world? How do teachers meaningfully interact with – "teach" – students in a world whose rules and boundaries are often uncertain and beyond anyone's understanding? An evolving capstone ITM course provides a setting for meaningful dialogue and opportunities for nonstandard learning.

These are challenging times. It is apparent that the relative academic and business stability of times past are just that, historical. As such, approaches to education must be meaningful, continually revised, and no less "dated" than today's news. The alternative is obsolescence, irrelevance, and extinction. The ITM capstone course represents the last opportunity ITM faculty members have to contribute in a creative way to the ITM major's undergraduate career. By its last-course placement, the capstone course will always be fraught with considerable challenge. Nevertheless, regardless of how it is structured, conducted, and measured, the course should serve as a final reminder for the soon-to-be graduate. "This is what you've learned. This is what it's all about. Go out with confidence. You are ready. Good luck."

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Biographies

Dr. Daniel Brandon is an Associate Professor and Department Chairperson in the Information Technology Management (ITM) Department at Christian Brothers University (CBU) in Memphis, TN. His education includes a BS in Engineering from Case Western University, MS in Engineering from the University of Connecticut, and a Ph.D. from the University of Connecticut specializing in computer control and simulation. He also has the PMP (Project Management Professional) certification.

In addition to his seven years at CBU, Dr. Brandon has over twenty years experience in the information systems industry including experience in management, operations, research, and development. He was the Director of Information Systems for the Prime Technical Contractor at the NASA Stennis Space Center for six years, MIS manager for Film Transit Corporation in Memphis for ten years, and affiliated with Control Data Corporation in Minneapolis for six years in several positions including Manager of Applications Development. He has also been an independent consultant and software developer in a several industries including: Medical, Transportation/Logistics, Finance, Law, and Entertainment.

Dr. James M. Pruett is currently working with a University of Tennessee College of Nursing research team in Memphis, Tennessee. His education includes a B.S. in Industrial Engineering from Louisiana Tech University and an M.S. and Ph.D., with an emphasis in Industrial Engineering, from the University of Arkansas.

Prior to spending one year as a Visiting Professor in the Information Technology Management Department at Christian Brothers University (during which time this article was written), Dr. Pruett served as a faculty member and administrator for over 20 years in the Industrial Engineering and Information Systems & Decision Sciences Departments at Louisiana State University and for over six years as a manager and consultant in the information technology area with International Paper.

Jim S. Wade currently holds a tenured position as Associate Professor in the Information Technology Management Department at Christian Brothers University in Memphis, Tennessee. He has been at CBU for twelve years.

Prior to coming to CBU, he was a Vice-President of Econocom International, a computer leasing company headquartered in Memphis, Tennessee. He retired from IBM with 30 years service in 1986. At IBM he held various marketing positions including Branch Manager, Senior Education Manager, and Large Accounts Marketing Manager. He has a BS Degree from the University of Florida and an MS Degree in Telecommunications Management from Christian Brothers University.

This document has been moved. The new hyperlink is now:

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

Please update your bookmarks accordingly.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

Research and Innovation Actions (RIA)

Innovation Actions (IA)

Administrative forms (Part A)
Research proposal (Part B)

Version 1.4
21 May 2015

Disclaimer
This document is aimed at informing potential applicants for Horizon 2020 funding. It serves only as an example. The actual Web forms and templates, provided in the online proposal submission system under the Participant Portal, might differ from this example. Proposals must be prepared and submitted .via the online proposal submission system under the Participant Portal.

Research and Innovation

History of changes

Version	Date	Change	Page
1.1	27.02.2014	▪ Information on Evaluation added - scoring of proposals as they were submitted, rather than on their potential if certain changes to be made (Part B)	1
1.2	04.04.2014	▪ In section 3.3, the number of the template section referred to for exploitation measures is corrected.	7
1.3	04.12.2014	▪ Reference added to Part B on compliance with any minimum requirements linked to participation for first stage proposals	1
1.4	21.05.2015	▪ Typographical correction: separation of required bullet points under section 2.1 "Expected impacts" (PartB)	3

Horizon 2020
Call:
Topic:
Type of action:
Proposal number:
Proposal acronym:

Example, not to complete

Table of contents

Section	*Title*	*Action*
1	General information	
2	Participants & contacts	
3	Budget	
4	Ethics	
5	Call-specific questions	

How to fill in the forms

The administrative forms must be filled in for each proposal using the templates available in the submission system. Some data fields in the administrative forms are pre-filled based on the previous steps in the submission wizard.

1 - General information

Topic		Type of action	
Call identifier		Acronym	
Proposal title*	*Max 200 characters (with spaces). Must be understandable for non-specialists in your field.*		
Duration in months	*Estimated duration of the project in full months.*		
Fixed keyword 1		Add	
Free keywords	*Enter any words you think give extra detail of the scope of your proposal (max 200 characters with spaces).*		

Abstract

Short summary (max. 2,000 characters, with spaces) to clearly explain:

- *the objectives of the proposal*
- *how they will be achieved*
- *their relevance to the work programme.*

Will be used as the short description of the proposal in the evaluation process and in communications with the programme management committees and other interested parties .

- *Do not include any confidential information.*
- *Use plain typed text, avoiding formulae and other special characters.*

If the proposal is written in a language other than English, please include an English version of this abstract in the "Technical Annex" section.

Remaining characters 2000

Has this proposal (or a very similar one) been submitted in the past 2 years in response to a call for proposals under the 7th Framework Programme, Horizon 2020 or any other EU programme(s)?

Please give the proposal reference or contract number.	

Example, not to complete

Declarations

1) The coordinator declares to have the explicit consent of all applicants on their participation and on the content of this proposal.*	☐
2) The information contained in this proposal is correct and complete.	☐
3) This proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).	☐

4) The coordinator confirms:

- to have carried out the self-check of the financial capacity of the organisation on https://ec.europa.eu/research/participants/portal4/desktop/en/organisations/lfv.html. Where the result was "weak" or "insufficient", the coordinator confirms being aware of the measures that may be imposed in accordance with the H2020 Grants Manual (Chapter on Financial capacity check); or	☐
- is exempt from the financial capacity check being a public body including international organisations, higher or secondary education establishment or a legal entity, whose viability is guaranteed by a Member State or associated country, as defined in the H2020 Grants Manual (Chapter on Financial capacity check); or	☐
- as sole participant in the proposal is exempt from the financial capacity check.	☐

5) The coordinator hereby declares that each applicant has confirmed:

- they are fully eligible in accordance with the criteria set out in the specific call for proposals; and	☐
- they have the financial and operational capacity to carry out the proposed action.	☐
The coordinator is only responsible for the correctness of the information relating to his/her own organisation. Each applicant remains responsible for the correctness of the information related to him and declared above. Where the proposal to be retained for EU funding, the coordinator and each beneficiary applicant will be required to present a formal declaration in this respect.	

According to Article 131 of the Financial Regulation of 25 October 2012 on the financial rules applicable to the general budget of the Union (Official Journal L 298 of 26.10.2012, p.1) and Article 145 of its Rules of Application (Official Journal L 362, 31.12.2012, p.1) applicants found guilty of misrepresentation may be subject to administrative and financial penalties under certain conditions.

Personal data protection

Your reply to the grant application will involve the recording and processing of personal data (such as your name, address and CV), which will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions in this form and any personal data requested are required to assess your grant application in accordance with the specifications of the call for proposals and will be processed solely for that purpose. Details concerning the processing of your personal data are available on the privacy statement. Applicants may lodge a complaint about the processing of their personal data with the European Data Protection Supervisor at any time.

Your personal data may be registered in the Early Warning System (EWS) only or both in the EWS and Central Exclusion Database (CED) by the Accounting Officer of the Commission, should you be in one of the situations mentioned in:
-the Commission Decision 2008/969 of 16.12.2008 on the Early Warning System (for more information see the Privacy Statement), or
-the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database (for more information see the Privacy Statement) .

Example, not to complete

2 - Administrative data of participating organisations

PIC	Legal name

Short name:

Address of the Organisation

Street

City

Postcode

Country

Webpage

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... no

Non-profit ..... no

International organisation ..... no

International organisation of European interest ..... no

Secondary or Higher education establishment ..... no

Research organisation ..... no

Small and Medium-sized Enterprises (SMEs) ..... no

Academic Sector ..... no

Legal person .....

Nace code

Example, not to complete

Departments carrying out the proposed work

Department 1

Department name

☐ Same as organisation address

Street

Town

Postcode

Country

Dependencies with other proposal participants

Character of dependence	Participant	

Example, not to complete

Proposal ID	*Acronym*	*Participant*

Person in charge of the proposal

Title

Sex ◯ Male ◯ Female

First name

Family name

E-Mail

Position in org. *Please indicate the position of the Contact Point above in the organisation.*

Department *Please indicate the position of the Contact Point above in the organisation.*

Street

☐ Same as organisation address

Town

Post code

Country

Website

Phone *+xxx xxxxxxxxx*

Phone 2 *+xxx xxxxxxxxx*

Fax *+xxx xxxxxxxxx*

Other contact persons

First Name	***Last Name***	***E-mail***	***Phone***

Example, not to complete

Proposal ID *Acronym*

3 - Budget for the proposal

Participant	Country	(A) Direct personnel costs/€	(B) Other direct costs/€	(C) Direct costs of sub-contracting /€	(D) Direct costs of providing financial support to third parties/€	(E) Costs of inkind contributions not used on the beneficiary's premises/€	(F) Indirect Costs/€ (=0.25(A+B-E))	(G) Special unit costs covering direct & indirect costs	(H) Total estimated eligible costs/€ (=A+B+C+D+F+G)	(I) Reimburse-ment rate	(J) Max. grant / € (=H*I)	(K) Requested grant / €
		0	0	0	0	0	0	0	0	100	0	0
Total		0	0	0	0	0	0	0	0		0	0

Example, not to complete

For Stage 1 proposals
only the Total requested amount has to be filled in.

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES i		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	◯ Yes ◉ No	
Does your research involve the use of human embryos?	◯ Yes ◉ No	
Does your research involve the use of human foetal tissues / cells?	◯ Yes ◉ No	
2. HUMANS		**Page**
Does your research involve human participants?	◯ Yes ◉ No	
Does your research involve physical interventions on the study participants?	◯ Yes ◉ No	
Does it involve invasive techniques?	◯ Yes ◉ No	
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues? If your research involves human embryos/foetuses, please also complete the section "Human Embryos/Foetuses" [Box 1].	◯ Yes ◉ No	
4. PROTECTION OF PERSONAL DATA ii		**Page**
Does your research involve personal data collection and/or processing?	◯ Yes ◉ No	
Does your research involve further processing of previously collected personal data (secondary use)?	◯ Yes ◉ No	
5. ANIMALS iii		**Page**
Does your research involve animals?	◯ Yes ◉ No	

Example, not to complete

Not required for stage 1

6. NON-EU COUNTRIES		Page
Does your research involve non-EU countries?	◯ Yes ◉ No	
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	◯ Yes ◉ No	
Do you plan to import any material - including personal data - from non-EU countries into the EU? If you consider importing data, please also complete the section "Protection of Personal Data" [Box 4].	◯ Yes ◉ No	
Do you plan to export any material - including personal data -from the EU to non-EU countries? If you consider exporting data, please also complete the section "Protection of Personal Data" [Box 4].	◯ Yes ◉ No	
If your research involves low and/or lower middle income countries, are benefits-sharing measures foreseen?	◯ Yes ◉ No	
Could the situation in the country put the individuals taking part in the research at risk?	◯ Yes ◉ No	
7. ENVIRONMENT PROTECTION vi Directive 2001/18/EC - vii Directive 2009/41/EC - viii Regulation EC No 1946/2003 - ix Directive 2008/56/EC x Council Directive 92/43/EEC -xi Council Directive 79/409/EEC - xii Council Regulation EC No 338/97		Page
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	◯ Yes ◉ No	
Does your research deal with endangered fauna and/or flora and/or protected areas?	◯ Yes ◉ No	
Does your research involve the use of elements that may cause harm to humans, including research staff?	◯ Yes ◉ No	
8. DUAL USE xiii		Page
Does your research have the potential for military applications?	◯ Yes ◉ No	
9. MISUSE		Page
Does your research have the potential for malevolent/criminal/terrorist abuse?	◯ Yes ◉ No	
10. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration? Please specify	◯ Yes ◉ No	

I confirm that I have taken into account all ethics issues described above and if any ethics issues apply, I have attached the required documents. ☐ Legal Info

Not required for stage 1

Example, not to complete

5 - Call specific questions

Please note that this section will be updated at a later stage. In order to view the new content you will have to open the administrative form again. Once the form is final, this warning message will disappear.

Example, not to complete

Calls/topics may include additional questions, which are not shown in the general template

Validation result

Section	Description
	The form has not yet been validated, click "Validate Form" to do so!

Example, not to complete

Proposal template
(technical annex)

Research and Innovation actions
Innovation actions

Example, not to complete

Please follow the structure of this template when preparing your proposal. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the evaluation criteria. Sections 1, 2 and 3 each correspond to an evaluation criterion for a full proposal.

Please be aware that proposals will be evaluated as they were submitted, rather than on their potential if certain changes were to be made. This means that only proposals that successfully address all the required aspects will have a chance of being funded. There will be no possibility for significant changes to content, budget and consortium composition during grant preparation.

⚠ **First stage proposals**: In two-stage submission schemes, at the first stage you only need to complete the parts indicated by a bracket (i.e. }). These are in the cover page, and sections 1 and 2.

⚠ **Page limit:** For full proposals, the cover page, and sections 1, 2 and 3, together should not be longer than 70 pages. All tables in these sections must be included within this limit. The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).

The page limit for a first stage proposal is 15 pages.

If you attempt to upload a proposal longer than the specified limit, before the deadline you will receive an automatic warning, and will be advised to shorten and re-upload the proposal. After the deadline, any excess pages will be overprinted with a 'watermark', indicating to evaluators that these pages must be disregarded.

Please do not consider the page limit as a target! It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long proposals in a positive light.

COVER PAGE

Title of Proposal

List of participants

Participant No *	**Participant organisation name**	**Country**
1 (Coordinator)		
2		
3		

* Please use the same participant numbering as that used in the administrative proposal forms. (Not applicable in the case of stage-1 proposals in two stage schemes.)

For first stage proposals, please note that this table will be used to check whether or not you comply with any minimum requirements linked to participation as set out in the eligibility criteria of the relevant work programme.

Table of Contents

Example, not to complete

1. Excellence

Your proposal must address a work programme topic for this call for proposals.

⚠ ***This section of your proposal will be assessed only to the extent that it is relevant to that topic.***

1.1 Objectives

- Describe the specific objectives for the project[1], which should be clear, measurable, realistic and achievable within the duration of the project. Objectives should be consistent with the expected exploitation and impact of the project (see section 2).

1.2 Relation to the work programme

- Indicate the work programme topic to which your proposal relates, and explain how your proposal addresses the specific challenge and scope of that topic, as set out in the work programme.

1.3 Concept and approach

- Describe and explain the overall concept underpinning the project. Describe the main ideas, models or assumptions involved. Identify any trans-disciplinary considerations;
- Describe the positioning of the project e.g. where it is situated in the spectrum from 'idea to application', or from 'lab to market'. Refer to Technology Readiness Levels where relevant. (See General Annex G of the work programme);
- Describe any national or international research and innovation activities which will be linked with the project, especially where the outputs from these will feed into the project;
- Describe and explain the overall approach and methodology, distinguishing, as appropriate, activities indicated in the relevant section of the work programme, e.g. for research, demonstration, piloting, first market replication, etc;
- Where relevant, describe how sex and/or gender analysis is taken into account in the project's content.

⚠ *Sex and gender refer to biological characteristics and social/cultural factors respectively. For guidance on methods of sex / gender analysis and the issues to be taken into account, please refer to http://ec.europa.eu/research/science-society/gendered-innovations/index_en.cfm*

1.4 Ambition

- Describe the advance your proposal would provide beyond the state-of-the-art, and the extent the proposed work is ambitious. Your answer could refer to the ground-breaking nature of the objectives, concepts involved, issues and problems to be addressed, and approaches and methods to be used.
- Describe the innovation potential which the proposal represents. Where relevant, refer to products and services already available on the market. Please refer to the results of any patent search carried out.

[1] The term 'project' used in this template equates to an 'action' in certain other Horizon 2020 documentation.

2. Impact

2.1 Expected impacts

⚠ *Please be specific, and provide only information that applies to the proposal and its objectives. Wherever possible, use quantified indicators and targets.*

- Describe how your project will contribute to:
  - the expected impacts set out in the work programme, under the relevant topic;
  - improving innovation capacity and the integration of new knowledge
  - strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets;
  - any other environmental and socially important impacts (if not already covered above).
- Describe any barriers/obstacles, and any framework conditions (such as regulation and standards), that may determine whether and to what extent the expected impacts will be achieved. (This should not include any risk factors concerning implementation, as covered in section 3.2.)

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

- Provide a draft 'plan for the dissemination and exploitation of the project's results' (unless the work programme topic explicitly states that such a plan is not required). For innovation actions describe a credible path to deliver the innovations to the market. The plan, which should be proportionate to the scale of the project, should contain measures to be implemented both during and after the project.

  ⚠ *Dissemination and exploitation measures should address the full range of potential users and uses including research, commercial, investment, social, environmental, policy making, setting standards, skills and educational training.*

  ⚠ *The approach to innovation should be as comprehensive as possible, and must be tailored to the specific technical, market and organisational issues to be addressed.*

- Explain how the proposed measures will help to achieve the expected impact of the project. Include a business plan where relevant.
- Where relevant, include information on how the participants will manage the research data generated and/or collected during the project, in particular addressing the following issues:[2]
  - What types of data will the project generate/collect?

[2] For further guidance on research data management, please refer to the H2020 Online Manual on the Participant Portal.

Example, not to complete

- What standards will be used?
- How will this data be exploited and/or shared/made accessible for verification and re-use? If data cannot be made available, explain why.
- How will this data be curated and preserved?

⚠ *You will need an appropriate consortium agreement to manage (amongst other things) the ownership and access to key knowledge (IPR, data etc.). Where relevant, these will allow you, collectively and individually, to pursue market opportunities arising from the project's results.*

⚠ *The appropriate structure of the consortium to support exploitation is addressed in section 3.3.*

- Outline the strategy for knowledge management and protection. Include measures to provide open access (free on-line access, such as the 'green' or 'gold' model) to peer-reviewed scientific publications which might result from the project[3].

⚠ *Open access publishing (also called 'gold' open access) means that an article is immediately provided in open access mode by the scientific publisher. The associated costs are usually shifted away from readers, and instead (for example) to the university or research institute to which the researcher is affiliated, or to the funding agency supporting the research.*

⚠ *Self-archiving (also called 'green' open access) means that the published article or the final peer-reviewed manuscript is archived by the researcher - or a representative - in an online repository before, after or alongside its publication. Access to this article is often - but not necessarily - delayed ('embargo period'), as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download/view fees during an exclusivity period.*

b) Communication activities

- Describe the proposed communication measures for promoting the project and its findings during the period of the grant. Measures should be proportionate to the scale of the project, with clear objectives. They should be tailored to the needs of various audiences, including groups beyond the project's own community. Where relevant, include measures for public/societal engagement on issues related to the project.

Example, not to complete

3. Implementation

3.1 Work plan — Work packages, deliverables and milestones

Please provide the following:

- brief presentation of the overall structure of the work plan;

[3] Open access must be granted to all scientific publications resulting from Horizon 2020 actions. Further guidance on open access is available in the H2020 Online Manual on the Participant Portal.

- timing of the different work packages and their components (Gantt chart or similar);
- detailed work description, i.e.:
    - a description of each work package (table 3.1a);
    - a list of work packages (table 3.1b);
    - a list of major deliverables (table 3.1c);
- graphical presentation of the components showing how they inter-relate (Pert chart or similar).

⚠ *Give full details. Base your account on the logical structure of the project and the stages in which it is to be carried out. Include details of the resources to be allocated to each work package. The number of work packages should be proportionate to the scale and complexity of the project.*

⚠ *You should give enough detail in each work package to justify the proposed resources to be allocated and also quantified information so that progress can be monitored, including by the Commission.*

⚠ *You are advised to include a distinct work package on 'management' (see section 3.2) and to give due visibility in the work plan to 'dissemination and exploitation' and 'communication activities', either with distinct tasks or distinct work packages.*

⚠ *You will be required to include an updated (or confirmed) 'plan for the dissemination and exploitation of results' in both the periodic and final reports. (This does not apply to topics where a draft plan was not required.) This should include a record of activities related to dissemination and exploitation that have been undertaken and those still planned. A report of completed and planned communication activities will also be required.*

⚠ *If your project is taking part in the Pilot on Open Research Data[4], you must include a 'data management plan' as a distinct deliverable within the first 6 months of the project. A template for such a plan is given in the guidelines on data management in the H2020 Online Manual. This deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management.*

Definitions:

'Work package' means a major sub-division of the proposed project.

'Deliverable' means a distinct output of the project, meaningful in terms of the project's overall objectives and constituted by a report, a document, a technical diagram, a software etc.

'Milestones' means control points in the project that help to chart progress. Milestones may correspond to the completion of a key deliverable, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development.

Example, not to complete

[4] Certain actions under Horizon 2020 participate in the 'Pilot on Open Research Data in Horizon 2020'. All other actions can participate on a voluntary basis to this pilot. Further guidance is available in the H2020 Online Manual on the Participant Portal.

3.2 Management structure and procedures

- Describe the organisational structure and the decision-making (including a list of milestones (table 3.2a))
- Explain why the organisational structure and decision-making mechanisms are appropriate to the complexity and scale of the project.
- Describe, where relevant, how effective innovation management will be addressed in the management structure and work plan.

  ⚠ *Innovation management is a process which requires an understanding of both market and technical problems, with a goal of successfully implementing appropriate creative ideas. A new or improved product, service or process is its typical output. It also allows a consortium to respond to an external or internal opportunity.*

- Describe any critical risks, relating to project implementation, that the stated project's objectives may not be achieved. Detail any risk mitigation measures. Please provide a table with critical risks identified and mitigating actions (table 3.2b)

3.3 Consortium as a whole

⚠ *The individual members of the consortium are described in a separate section 4. There is no need to repeat that information here.*

- Describe the consortium. How will it match the project's objectives? How do the members complement one another (and cover the value chain, where appropriate)? In what way does each of them contribute to the project? How will they be able to work effectively together?
- If applicable, describe the industrial/commercial involvement in the project to ensure exploitation of the results and explain why this is consistent with and will help to achieve the specific measures which are proposed for exploitation of the results of the project (see section 2.2).
- **Other countries**: If one or more of the participants requesting EU funding is based in a country that is not automatically eligible for such funding (entities from Member States of the EU, from Associated Countries and from one of the countries in the exhaustive list included in General Annex A of the work programme are automatically eligible for EU funding), explain why the participation of the entity in question is essential to carrying out the project

3.4 Resources to be committed

⚠ *Please make sure the information in this section matches the costs as stated in the budget table in section 3 of the administrative proposal forms, and the number of person/months, shown in the detailed work package descriptions.*

Please provide the following:

- a table showing number of person/months required (table 3.4a)
- a table showing 'other direct costs' (table 3.4b) for participants where those costs exceed 15% of the personnel costs (according to the budget table in section 3 of the administrative proposal forms)

Example, not to complete

Table 3.1a: Work package description

For each work package:

Work package number		**Start Date or Starting Event**					
Work package title							
Participant number							
Short name of participant							
Person/months per participant:							

Objectives

Description of work (where appropriate, broken down into tasks), lead partner and role of participants

Deliverables (brief description and month of delivery)

Example, not to complete

Table 3.1b: List of work packages

Work package No	Work Package Title	Lead Participant No	Lead Participant Short Name	Person-Months	Start Month	End month
				Total months		

Example, not to complete

Table 3.1c: List of Deliverables[5]

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Type	Dissemination level	Delivery date

KEY

Deliverable numbers in order of delivery dates. Please use the numbering convention <WP number>.<number of deliverable within that WP>.

For example, deliverable 4.2 would be the second deliverable from work package 4.

Type:
Use one of the following codes:

R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
OTHER: Software, technical diagram, etc.

Dissemination level:
Use one of the following codes:

PU = Public, fully open, e.g. web
CO = Confidential, restricted under conditions set out in Model Grant Agreement
CI = Classified, information as referred to in Commission Decision 2001/844/EC.

Delivery date
Measured in months from the project start date (month 1)

Example Complete

[5] If your action taking part in the Pilot on Open Research Data, you must include a data management plan as a distinct deliverable within the first 6 months of the project. This deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management. A template for such a plan is available on the Participant Portal (Guide on Data Management).

Table 3.2a: List of milestones

Milestone number	Milestone name	Related work package(s)	Estimated date	Means of verification

KEY

Estimated date
Measured in months from the project start date (month 1)

Means of verification
Show how you will confirm that the milestone has been attained. Refer to indicators if appropriate. For example: a laboratory prototype that is 'up and running'; software released and validated by a user group; field survey complete and data quality validated.

Table 3.2b: Critical risks for implementation

Description of risk	Work package(s) involved	Proposed risk-mitigation measures

Example, not to c te

Table 3.4a: Summary of staff effort

Please indicate the number of person/months over the whole duration of the planned work, for each work package, for each participant. Identify the work-package leader for each WP by showing the relevant person-month figure in bold.

	WPn	WPn+1	WPn+2	Total Person/ Months per Participant
Participant Number/Short Name				
ParticipantNumber/ Short Name				
Participant Number/ Short Name				
Total Person/Months				

Table 3.4b: 'Other direct cost' items (travel, equipment, other goods and services, large research infrastructure)

Please complete the table below for each participant if the sum of the costs for' travel', 'equipment', and 'goods and services' exceeds 15% of the personnel costs for that participant (according to the budget table in section 3 of the proposal administrative forms).

Participant Number/Short Name	Cost (€)	Justification
Travel		
Equipment		
Other goods and services		
Total		

Please complete the table below for all participants that would like to declare costs of large research infrastructure under Article 6.2 of the General Model Agreement[6], irrespective of the percentage of personnel costs. Please indicate (in the justification) if the beneficiary's methodology for declaring the costs for large research infrastructure has already been positively assessed by the Commission.

Participant Number/Short Name	Cost (€)	Justification
Large research infrastructure		

[6] Large research infrastructure means research infrastructure of a total value of at least EUR 20 million, for a beneficiary. More information and further guidance on the direct costing for the large research infrastructure is available in the H2020 Online Manual on the Participant Portal.

Example, not to com

Section 4: Members of the consortium

⚠ *This section is not covered by the page limit.*

⚠ *The information provided here will be used to judge the operational capacity.*

4.1. Participants (applicants)

Please provide, for each participant, the following (if available):

- a description of the legal entity and its main tasks, with an explanation of how its profile matches the tasks in the proposal;
- a curriculum vitae or description of the profile of the persons, including their gender, who will be primarily responsible for carrying out the proposed research and/or innovation activities;
- a list of up to 5 relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content;
- a list of up to 5 relevant previous projects or activities, connected to the subject of this proposal;
- a description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work;
- [any other supporting documents specified in the work programme for this call.]

4.2. Third parties involved in the project (including use of third party resources)

Please complete, for each participant, the following table (or simply state "No third parties involved", if applicable):

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y/N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties[1]	Y/N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	Y/N
If yes, please describe the third party and their contributions	

[1] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Example, not to complete

Section 5: Ethics and Security

⚠ *This section is not covered by the page limit.*

5.1 Ethics

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use , etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

  ⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

  ⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*

5.2 Security[2]

Please indicate if your project will involve:

- activities or results raising security issues: (YES/NO)
- 'EU-classified information' as background or results: (YES/NO)

Example, not to complete

[2] Article 37.1 of the Model Grant Agreement: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the Commission/Agency.* Article 37.2: *Activities related to 'classified deliverables' must comply with the 'security requirements' until they are declassified. Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the Commission/Agency. The beneficiaries must inform the coordinator — which must immediately inform the Commission/Agency — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).*

CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION

(2000/C 364/01)

PROCLAMACIÓN SOLEMNE

HØJTIDELIG PROKLAMATION

FEIERLICHE PROKLAMATION

ΠΑΝΗΓΥΡΙΚΗ ΔΙΑΚΗΡΥΞΗ

SOLEMN PROCLAMATION

PROCLAMATION SOLENNELLE

FORÓGRA SOLLÚNTA

PROCLAMAZIONE SOLENNE

PLECHTIGE AFKONDIGING

PROCLAMAÇÃO SOLENE

JUHLALLINEN JULISTUS

HÖGTIDLIG PROKLAMATION

El Parlamento Europeo, el Consejo y la Comisión proclaman solemnemente en tanto que Carta de los Derechos Fundamentales de la Unión Europea el texto que figura a continuación.

Europa-Parlamentet, Rådet og Kommissionen proklamerer højtideligt den tekst, der følger nedenfor, som Den Europæiske Unions charter om grundlæggende rettigheder.

Das Europäische Parlament, der Rat und die Kommission proklamieren feierlich den nachstehenden Text als Charta der Grundrechte der Europäischen Union.

Το Ευρωπαϊκό Κοινοβούλιο, το Συμβούλιο και η Επιτροπή διακηρύσσουν πανηγυρικά, ως Χάρτη Θεμελιωδών Δικαιωμάτων της Ευρωπαϊκής Ένωσης, το κείμενο που ακολουθεί.

The European Parliament, the Council and the Commission solemnly proclaim the text below as the Charter of fundamental rights of the European Union.

Le Parlement européen, le Conseil et la Commission proclament solennellement en tant que Charte des droits fondamentaux de l'Union européenne le texte repris ci-après.

Forógraíonn Parlaimint na hEorpa, an Chomhairle agus an Coimisiún go sollúnta an téacs thíos mar an Chairt um Chearta Bunúsacha den Aontas Eorpach.

Il Parlamento europeo, il Consiglio e la Commissione proclamano solennemente quale Carta dei diritti fondamentali dell'Unione europea il testo riportato in appresso.

Het Europees Parlement, de Raad en de Commissie kondigen plechtig als Handvest van de grondrechten van de Europese Unie de hierna opgenomen tekst af.

O Parlamento Europeu, o Conselho e a Comissão proclamam solenemente, enquanto Carta dos Direitos Fundamentais da União Europeia, o texto a seguir transcrito.

Euroopan parlamentti, neuvosto ja komissio juhlallisesti julistavat jäljempänä esitetyn tekstin Euroopan unionin perusoikeuskirjaksi.

Europaparlamentet, rådet och kommissionen tillkännager högtidligt denna text såsom stadga om de grundläggande rättigheterna i Europeiska unionen.

Hecho en Niza, el siete de diciembre del año dos mil.

Udfærdiget i Nice den syvende december to tusind.

Geschehen zu Nizza am siebten Dezember zweitausend.

Έγινε στη Νίκαια, στις επτά Δεκεμβρίου δύο χιλιάδες.

Done at Nice on the seventh day of December in the year two thousand.

Fait à Nice, le sept décembre deux mille.

Arna dhéanamh i Nice, an seachtú lá de Nollaig sa bhliain dhá mhíle.

Fatto a Nizza, addì sette dicembre duemila.

Gedaan te Nice, de zevende december tweeduizend.

Feito em Nice, em sete de Dezembro de dois mil.

Tehty Nizzassa seitsemäntenä päivänä joulukuuta vuonna kaksituhatta.

Som skedde i Nice den sjunde december tjugohundra.

Por el Parlamento Europeo
For Europa-Parlamentet
Für das Europäische Parlament
Για το Ευρωπαϊκό Κοινοβούλιο
For the European Parliament
Pour le Parlement européen
Thar ceann Pharlaimint na hEorpa
Per il Parlamento europeo
Voor het Europees Parlement
Pelo Parlamento Europeu
Euroopan parlamentin puolesta
För Europaparlamentet

Por el Consejo de la Unión Europea
For Rådet for Den Europæiske Union
Für den Rat der Europäischen Union
Για το Συμβούλιο της Ευρωπαϊκής Ένωσης
For the Council of the European Union
Pour le Conseil de l'Union européenne
Thar ceann Chomhairle an Aontais Eorpaigh
Per il Consiglio dell'Unione europea
Voor de Raad van de Europese Unie
Pelo Conselho da União Europeia
Euroopan unionin neuvoston puolesta
För Europeiska unionens råd

Por la Comisión Europea
For Europa-kommissionen
Für die Europäische Kommission
Για την Ευρωπαϊκή Επιτροπή
For the European Commission
Pour la Commission européenne
Thar ceann an Choimisiúin Eorpaigh
Per la Commissione europea
Voor de Europese Commissie
Pela Comissão Europeia
Euroopan komission puolesta
För Europeiska kommissionen

PREAMBLE

The peoples of Europe, in creating an ever closer union among them, are resolved to share a peaceful future based on common values.

Conscious of its spiritual and moral heritage, the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity; it is based on the principles of democracy and the rule of law. It places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security and justice.

The Union contributes to the preservation and to the development of these common values while respecting the diversity of the cultures and traditions of the peoples of Europe as well as the national identities of the Member States and the organisation of their public authorities at national, regional and local levels; it seeks to promote balanced and sustainable development and ensures free movement of persons, goods, services and capital, and the freedom of establishment.

To this end, it is necessary to strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments by making those rights more visible in a Charter.

This Charter reaffirms, with due regard for the powers and tasks of the Community and the Union and the principle of subsidiarity, the rights as they result, in particular, from the constitutional traditions and international obligations common to the Member States, the Treaty on European Union, the Community Treaties, the European Convention for the Protection of Human Rights and Fundamental Freedoms, the Social Charters adopted by the Community and by the Council of Europe and the case-law of the Court of Justice of the European Communities and of the European Court of Human Rights.

Enjoyment of these rights entails responsibilities and duties with regard to other persons, to the human community and to future generations.

The Union therefore recognises the rights, freedoms and principles set out hereafter.

CHAPTER I

DIGNITY

Article 1

Human dignity

Human dignity is inviolable. It must be respected and protected.

Article 2

Right to life

1. Everyone has the right to life.

2. No one shall be condemned to the death penalty, or executed.

Article 3

Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.

2. In the fields of medicine and biology, the following must be respected in particular:

— the free and informed consent of the person concerned, according to the procedures laid down by law,

— the prohibition of eugenic practices, in particular those aiming at the selection of persons,

— the prohibition on making the human body and its parts as such a source of financial gain,

— the prohibition of the reproductive cloning of human beings.

Article 4

Prohibition of torture and inhuman or degrading treatment or punishment

No one shall be subjected to torture or to inhuman or degrading treatment or punishment.

Article 5

Prohibition of slavery and forced labour

1. No one shall be held in slavery or servitude.

2. No one shall be required to perform forced or compulsory labour.

3. Trafficking in human beings is prohibited.

CHAPTER II

FREEDOMS

Article 6

Right to liberty and security

Everyone has the right to liberty and security of person.

Article 7

Respect for private and family life

Everyone has the right to respect for his or her private and family life, home and communications.

Article 8

Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.

2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

3. Compliance with these rules shall be subject to control by an independent authority.

Article 9

Right to marry and right to found a family

The right to marry and the right to found a family shall be guaranteed in accordance with the national laws governing the exercise of these rights.

Article 10

Freedom of thought, conscience and religion

1. Everyone has the right to freedom of thought, conscience and religion. This right includes freedom to change religion or belief and freedom, either alone or in community with others and in public or in private, to manifest religion or belief, in worship, teaching, practice and observance.

2. The right to conscientious objection is recognised, in accordance with the national laws governing the exercise of this right.

Article 11

Freedom of expression and information

1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers.

2. The freedom and pluralism of the media shall be respected.

Article 12

Freedom of assembly and of association

1. Everyone has the right to freedom of peaceful assembly and to freedom of association at all levels, in particular in political, trade union and civic matters, which implies the right of everyone to form and to join trade unions for the protection of his or her interests.

2. Political parties at Union level contribute to expressing the political will of the citizens of the Union.

Article 13

Freedom of the arts and sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

Article 14

Right to education

1. Everyone has the right to education and to have access to vocational and continuing training.

2. This right includes the possibility to receive free compulsory education.

3. The freedom to found educational establishments with due respect for democratic principles and the right of parents to ensure the education and teaching of their children in conformity with their religious, philosophical and pedagogical convictions shall be respected, in accordance with the national laws governing the exercise of such freedom and right.

Article 15

Freedom to choose an occupation and right to engage in work

1. Everyone has the right to engage in work and to pursue a freely chosen or accepted occupation.

2. Every citizen of the Union has the freedom to seek employment, to work, to exercise the right of establishment and to provide services in any Member State.

3. Nationals of third countries who are authorised to work in the territories of the Member States are entitled to working conditions equivalent to those of citizens of the Union.

Article 16

Freedom to conduct a business

The freedom to conduct a business in accordance with Community law and national laws and practices is recognised.

Article 17

Right to property

1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.

2. Intellectual property shall be protected.

Article 18

Right to asylum

The right to asylum shall be guaranteed with due respect for the rules of the Geneva Convention of 28 July 1951 and the Protocol of 31 January 1967 relating to the status of refugees and in accordance with the Treaty establishing the European Community.

Article 19

Protection in the event of removal, expulsion or extradition

1. Collective expulsions are prohibited.

2. No one may be removed, expelled or extradited to a State where there is a serious risk that he or she would be subjected to the death penalty, torture or other inhuman or degrading treatment or punishment.

CHAPTER III

EQUALITY

Article 20

Equality before the law

Everyone is equal before the law.

Article 21

Non-discrimination

1. Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.

2. Within the scope of application of the Treaty establishing the European Community and of the Treaty on European Union, and without prejudice to the special provisions of those Treaties, any discrimination on grounds of nationality shall be prohibited.

Article 22

Cultural, religious and linguistic diversity

The Union shall respect cultural, religious and linguistic diversity.

Article 23

Equality between men and women

Equality between men and women must be ensured in all areas, including employment, work and pay.

The principle of equality shall not prevent the maintenance or adoption of measures providing for specific advantages in favour of the under-represented sex.

Article 24

The rights of the child

1. Children shall have the right to such protection and care as is necessary for their well-being. They may express their views freely. Such views shall be taken into consideration on matters which concern them in accordance with their age and maturity.

2. In all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration.

3. Every child shall have the right to maintain on a regular basis a personal relationship and direct contact with both his or her parents, unless that is contrary to his or her interests.

Article 25

The rights of the elderly

The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.

Article 26

Integration of persons with disabilities

The Union recognises and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community.

CHAPTER IV

SOLIDARITY

Article 27

Workers' right to information and consultation within the undertaking

Workers or their representatives must, at the appropriate levels, be guaranteed information and consultation in good time in the cases and under the conditions provided for by Community law and national laws and practices.

Article 28

Right of collective bargaining and action

Workers and employers, or their respective organisations, have, in accordance with Community law and national laws and practices, the right to negotiate and conclude collective agreements at the appropriate levels and, in cases of conflicts of interest, to take collective action to defend their interests, including strike action.

Article 29

Right of access to placement services

Everyone has the right of access to a free placement service.

Article 30

Protection in the event of unjustified dismissal

Every worker has the right to protection against unjustified dismissal, in accordance with Community law and national laws and practices.

Article 31

Fair and just working conditions

1. Every worker has the right to working conditions which respect his or her health, safety and dignity.

2. Every worker has the right to limitation of maximum working hours, to daily and weekly rest periods and to an annual period of paid leave.

Article 32

Prohibition of child labour and protection of young people at work

The employment of children is prohibited. The minimum age of admission to employment may not be lower than the minimum school-leaving age, without prejudice to such rules as may be more favourable to young people and except for limited derogations.

Young people admitted to work must have working conditions appropriate to their age and be protected against economic exploitation and any work likely to harm their safety, health or physical, mental, moral or social development or to interfere with their education.

Article 33

Family and professional life

1. The family shall enjoy legal, economic and social protection.

2. To reconcile family and professional life, everyone shall have the right to protection from dismissal for a reason connected with maternity and the right to paid maternity leave and to parental leave following the birth or adoption of a child.

Article 34

Social security and social assistance

1. The Union recognises and respects the entitlement to social security benefits and social services providing protection in cases such as maternity, illness, industrial accidents, dependency or old age, and in the case of loss of employment, in accordance with the rules laid down by Community law and national laws and practices.

2. Everyone residing and moving legally within the European Union is entitled to social security benefits and social advantages in accordance with Community law and national laws and practices.

3. In order to combat social exclusion and poverty, the Union recognises and respects the right to social and housing assistance so as to ensure a decent existence for all those who lack sufficient resources, in accordance with the rules laid down by Community law and national laws and practices.

Article 35

Health care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Article 36

Access to services of general economic interest

The Union recognises and respects access to services of general economic interest as provided for in national laws and practices, in accordance with the Treaty establishing the European Community, in order to promote the social and territorial cohesion of the Union.

Article 37

Environmental protection

A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development.

Article 38

Consumer protection

Union policies shall ensure a high level of consumer protection.

CHAPTER V

CITIZENS' RIGHTS

Article 39

Right to vote and to stand as a candidate at elections to the European Parliament

1. Every citizen of the Union has the right to vote and to stand as a candidate at elections to the European Parliament in the Member State in which he or she resides, under the same conditions as nationals of that State.

2. Members of the European Parliament shall be elected by direct universal suffrage in a free and secret ballot.

Article 40

Right to vote and to stand as a candidate at municipal elections

Every citizen of the Union has the right to vote and to stand as a candidate at municipal elections in the Member State in which he or she resides under the same conditions as nationals of that State.

Article 41

Right to good administration

1. Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union.

2. This right includes:

— the right of every person to be heard, before any individual measure which would affect him or her adversely is taken;

— the right of every person to have access to his or her file, while respecting the legitimate interests of confidentiality and of professional and business secrecy;

— the obligation of the administration to give reasons for its decisions.

3. Every person has the right to have the Community make good any damage caused by its institutions or by its servants in the performance of their duties, in accordance with the general principles common to the laws of the Member States.

4. Every person may write to the institutions of the Union in one of the languages of the Treaties and must have an answer in the same language.

Article 42

Right of access to documents

Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to European Parliament, Council and Commission documents.

Article 43

Ombudsman

Any citizen of the Union and any natural or legal person residing or having its registered office in a Member State has the right to refer to the Ombudsman of the Union cases of maladministration in the activities of the Community institutions or bodies, with the exception of the Court of Justice and the Court of First Instance acting in their judicial role.

Article 44

Right to petition

Any citizen of the Union and any natural or legal person residing or having its registered office in a Member State has the right to petition the European Parliament.

Article 45

Freedom of movement and of residence

1. Every citizen of the Union has the right to move and reside freely within the territory of the Member States.

2. Freedom of movement and residence may be granted, in accordance with the Treaty establishing the European Community, to nationals of third countries legally resident in the territory of a Member State.

Article 46

Diplomatic and consular protection

Every citizen of the Union shall, in the territory of a third country in which the Member State of which he or she is a national is not represented, be entitled to protection by the diplomatic or consular authorities of any Member State, on the same conditions as the nationals of that Member State.

CHAPTER VI

JUSTICE

Article 47

Right to an effective remedy and to a fair trial

Everyone whose rights and freedoms guaranteed by the law of the Union are violated has the right to an effective remedy before a tribunal in compliance with the conditions laid down in this Article.

Everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal previously established by law. Everyone shall have the possibility of being advised, defended and represented.

Legal aid shall be made available to those who lack sufficient resources in so far as such aid is necessary to ensure effective access to justice.

Article 48

Presumption of innocence and right of defence

1. Everyone who has been charged shall be presumed innocent until proved guilty according to law.

2. Respect for the rights of the defence of anyone who has been charged shall be guaranteed.

Article 49

Principles of legality and proportionality of criminal offences and penalties

1. No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence under national law or international law at the time when it was committed. Nor shall a heavier penalty be imposed than that which was applicable at the time the criminal offence was committed. If, subsequent to the commission of a criminal offence, the law provides for a lighter penalty, that penalty shall be applicable.

2. This Article shall not prejudice the trial and punishment of any person for any act or omission which, at the time when it was committed, was criminal according to the general principles recognised by the community of nations.

3. The severity of penalties must not be disproportionate to the criminal offence.

Article 50

Right not to be tried or punished twice in criminal proceedings for the same criminal offence

No one shall be liable to be tried or punished again in criminal proceedings for an offence for which he or she has already been finally acquitted or convicted within the Union in accordance with the law.

CHAPTER VII

GENERAL PROVISIONS

Article 51

Scope

1. The provisions of this Charter are addressed to the institutions and bodies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers.

2. This Charter does not establish any new power or task for the Community or the Union, or modify powers and tasks defined by the Treaties.

Article 52

Scope of guaranteed rights

1. Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

2. Rights recognised by this Charter which are based on the Community Treaties or the Treaty on European Union shall be exercised under the conditions and within the limits defined by those Treaties.

3. In so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. This provision shall not prevent Union law providing more extensive protection.

Article 53

Level of protection

Nothing in this Charter shall be interpreted as restricting or adversely affecting human rights and fundamental freedoms as recognised, in their respective fields of application, by Union law and international law and by international agreements to which the Union, the Community or all the Member States are party, including the European Convention for the Protection of Human Rights and Fundamental Freedoms, and by the Member States' constitutions.

Article 54

Prohibition of abuse of rights

Nothing in this Charter shall be interpreted as implying any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms recognised in this Charter or at their limitation to a greater extent than is provided for herein.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2014
Information and Communications Technology

How to search the EU Clinical Trials Register

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1. Searching the EU Clinical Trials Register

The EU Clinical Trials Register search engine allows free-text searches of the information entered into the EU clinical trials database, EudraCT.

Access the EU Clinical Trials Register here: https://www.clinicaltrialsregister.eu/

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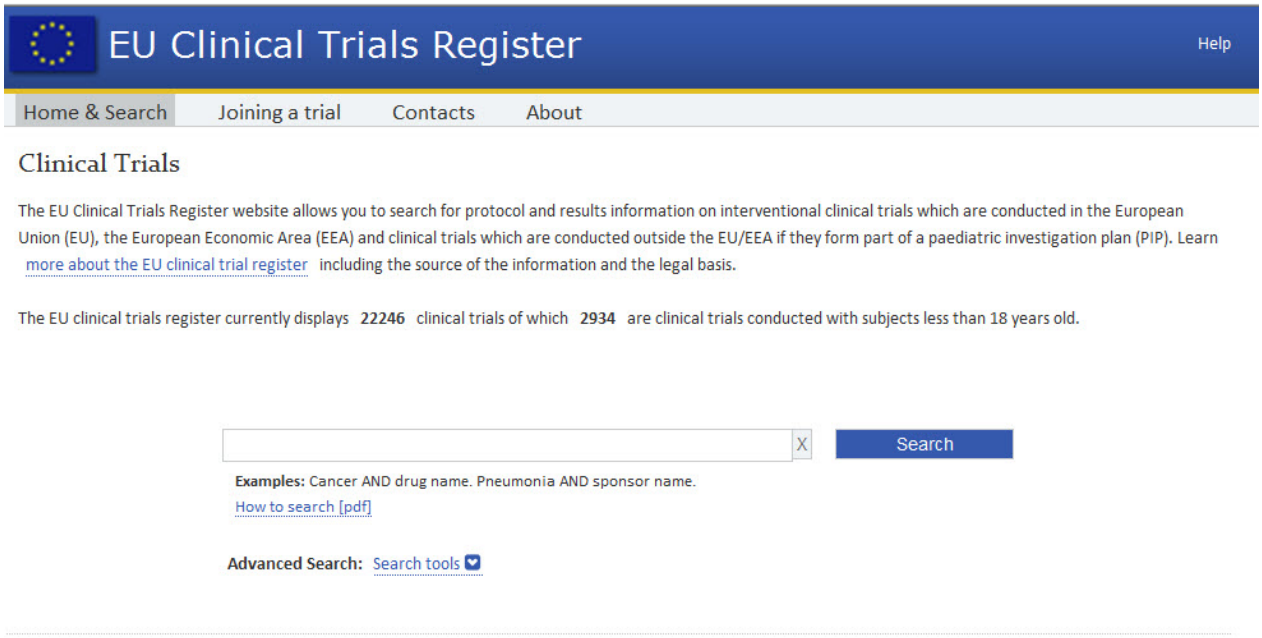

Note: The EU Clinical Trials Register user interface (UI) currently only supports English.

1.1. Basic search

Click in the search field and enter a word or phrase. For example enter `cancer` and `chemotherapy` and click Search. Your query will be matched against any instance of the words in any part of each trial record. The search results will be displayed below the search window and ordered by relevance.

Note: If you enter two words in the search field without using search operators, such as `cancer neoplasm`, the `OR` operator is automatically included (see information about search operators below).

The EU Clinical Trials Register makes use of thesaurus-enabled searching. This means that search queries look both for specified search terms and their synonyms in order to provide improved search results. A synonym is a different word with almost identical or similar meaning. For example, a search query for `high blood pressure` returns records containing more technical/medical terms, such as `hypertension`, in addition to records containing `high blood pressure`.

To clear the search field, click **X**.

1.2. Search operators

If you cannot find what you are searching for, try a search operator to narrow down your search results. Some of these operators are explained below. Search for either word (OR operator)

Enter `OR` (all upper case) between the words if you want to search for trial records that may contain just one of several words.

For example, a search for `cancer OR neoplasm` returns all trial records containing either word.

1.3. Search for multiple words (AND operator)

Enter `AND` (in upper case) between the words if you want to search for trial records that contain all of several words.

For example, a search for `cancer AND neoplasm` returns all trial records containing both words.

1.4. Search for required words (+ operator)

Enter **+** immediately before a word to specify that all search results must contain that word.

For example, a search for `+cancer chemotherapy` returns all trial records containing `cancer` that *may* contain `chemotherapy`. This search would not return trial records containing `chemotherapy` which do not also contain `cancer`.

1.5. Search for an exact phrase (quotation marks operator)

Use quotation marks (`"`), if you want to search for trial records containing an exact phrase or set of words.

For example, a search for `"fallopian tube cancer"` returns all trial records containing this exact phrase.

Note: The quotation marks operator can be combined with the other operators described. For example: `"HIV infections" AND pneumonia`.

1.6. Search for one word whilst excluding another word (NOT operator)

Enter `NOT` (in upper case) between the words if you want to search for trial records that do not contain the word after the `NOT`, but contain the first word.

For example, a search for `"HIV infections" NOT hepatitis` returns all the trial records containing `"HIV infections"`, where no reference to `hepatitis` is made.

Note: An exclamation mark (`!`) may be used in place of `NOT` for equivalent functionality.

1.7. Advanced search

The advanced search allows you to choose one or more filters to modify the results you see. To use the advanced search options, click Search tools. The following search filters will be displayed:

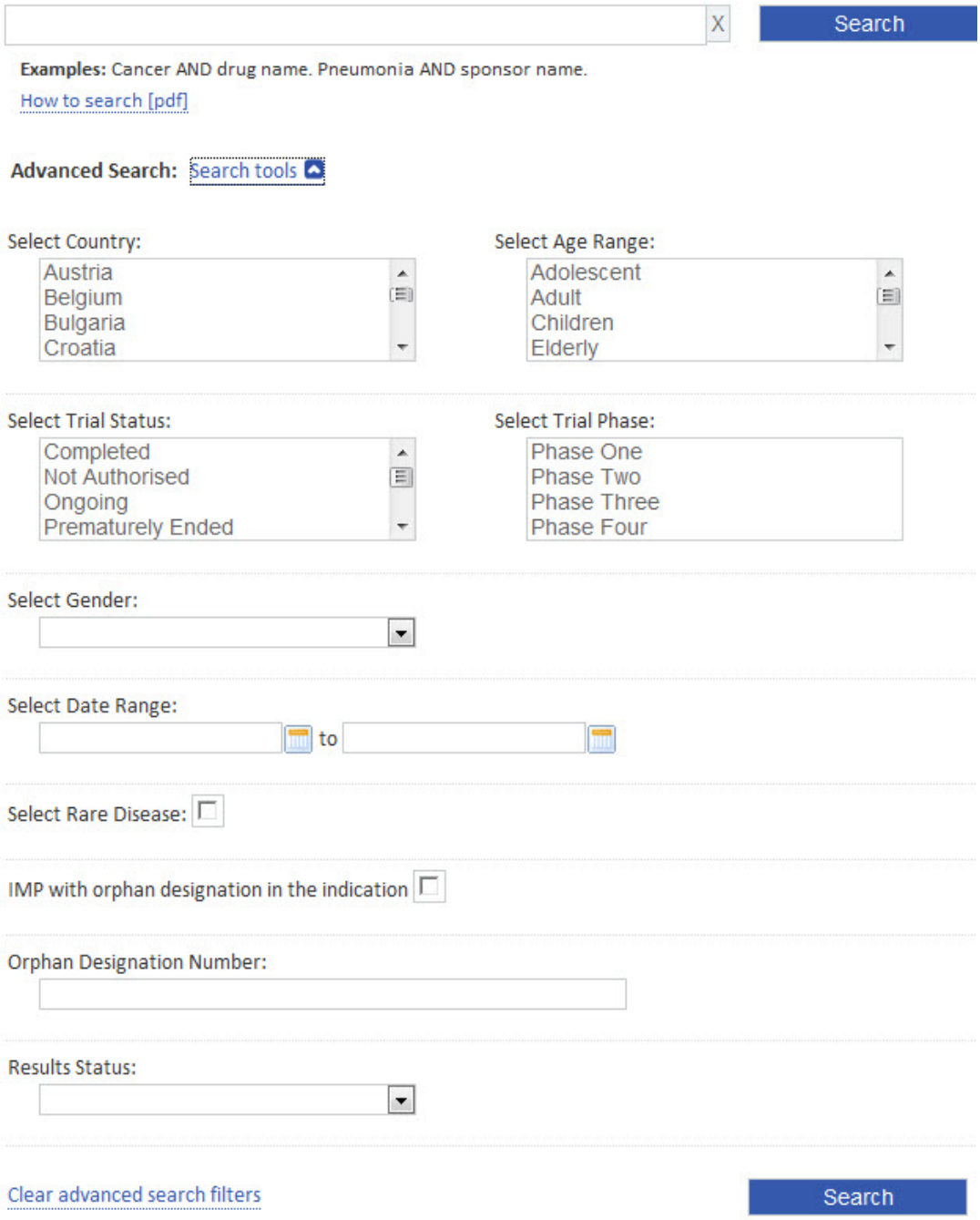

Advanced search filters:

Field	Description
Select Country	A search filter based on the location of the trial. This includes the European Union Member States as well as the European Economic Area countries (Norway, Iceland and Liechtenstein). Select the country that interests you. Leave this selection blank to run the query against ALL countries. • CTRL + click to make multiple selections.
Select Age Range	A search filter based on a specified age range of trial subjects. Select the age range(s) that interest you. Leave this selection

Field	Description
	blank to run the query against ALL age ranges. • CTRL + click to make multiple selections.
Select Trial Status	A search filter based on trial status. Leave this selection blank to run the query against ALL trial statuses. Please see Annex below for trial status definitions. • CTRL + click to make multiple selections.
Select Trial Phase	A search filter based on trials that include at least one of the specified phases. Leave blank to run the query against ALL trial phases. Please see below for trial phase definitions. • CTRL + click to make multiple selections.
Select Gender	A search filter based on the sex of the participants in a study. Include male or female participants ONLY, or BOTH to retrieve records with trials including both sexes. Leave blank to run the query against ALL gender selections. • Click the drop-down arrow to select a single option.
Select Date Range:	A search filter based on the date when the trial was first entered into the EudraCT database by a national competent authority or a third country data provider. • Click the calendars to select a date range to search the register. Please note – Clicking the **Done** button will close the calendar window.
Select Rare Disease	Check this box to restrict your query to trials concerning rare diseases.
IMP with Orphan Designation in the indication:	Check this box to restrict your query to trials concerning investigational medicinal products with orphan designation. That is, potential medicines for rare diseases which have yet to reach the market, but which have already been issued an 'orphan designation' by a regulatory authority, such as the European Medicines Agency.
Orphan Designation Number:	If known, you can restrict your search to a particular orphan designation number.
Results Status	A search filter based on the presence or absence of trial results. Select either clinical trials with results, or clinical trials without results. Leave this selection blank to run the query against ALL results statuses.
Clear advanced search filters	Click Clear advanced search filters to reset all search filters.

Note: You can combine different search filters or combine a basic search with advanced search filters.

Once the search query has been specified, click **Search.**

If the search does not return any results, a statement is displayed at the top of the page.

If matches to your search query are found, these are displayed below the search window. See Search Explained.

2. Search Results Explained

A list of search results is displayed in a summary view. The total number of clinical trials found is displayed at the top of the page.

The view is divided into two tabs, one for trials with a EudraCT protocol, and another for paediatric studies in scope of Article 45 of the Paediatric Regulation, which do not have a EudraCT protocol.

2.1. Trials with a EudraCT protocol

The summary view lists the clinical trials that correspond to the search.

For each clinical trial:

- To see a detailed view of a clinical trial conducted in the named country, click on the Country ISO code. In the example below, it is HU. The protocol-related data can be accessed by clicking on the country code.
- To see the trial results (if available); click on "View results"

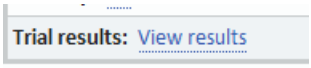

Note that the statement "no results available" is displayed when results have not yet been published.

Note that multiple pages of search results can be accessed using the navigation bar above the summary of results.

EudraCT Number: 2004-001452-36 **Sponsor Protocol Number:** XM02-02-INT **Start Date*:** 2004-06-30

Sponsor Name: BioGeneriX

Full Title: Efficacy and Safety of XM 02 compared to Filgrastim in patients with breast cancer receiving chemotherapy. Multinational, multicentre, randomised, controlled study

Medical condition: Patients with breast cancer high risk stage II or stage III/IV (classification according to American Joint Committee on Cancer [AJCC] receiving chemotherapy and developing Neutropenia due to chemot...

Disease:

Population Age: Adults, Elderly **Gender:** Male, Female

Country: HU *(Completed)* LT *(Completed)*

Trial results: *(No results available)*

EudraCT Number: 2013-001484-23 **Sponsor Protocol Number:** Triple-B **Start Date*:** 2013-05-24

Sponsor Name: BOOG Study Center

Full Title: Biomarker discovery randomized phase IIb trial with carboplatin-cyclophosphamide versus Paclitaxel with or without Bevacizumab as first-line treatment in advanced triple negative Breast cancer (Tri...

Medical condition: Metastatic breast cancer

Disease:	Version	SOC Term	Classification Code	Term	Level
	14.1	100000004864	10027475	Metastatic breast cancer	LLT

Subscribe to this Search

To subscribe to the RSS feed for this search click here. This will provide an RSS feed for Clinical Trials matching your search that have been added or updated in the last 7 days.

Download Options:

Number of Trials to download: Trials shown on current page

Download Content: Summary Details

Download Format: Plain Text

Download

Note, where multi-state trials are shown in search results, selecting "Full Trial details" will download full information for each of the member states/countries involved in the trial.

The clinical trial overview record has the following fields:

Field	Description
EudraCT Number	When registered, each trial is issued with a unique EudraCT number, which identifies the protocol and trial throughout its lifespan.
Sponsor Protocol Number	This is the unique identifier number for the Protocol e.g. Sponsor acronym and numbering system (UCL 07/095).
Sponsor Name	The individual, company, institution, or organisation that takes responsibility for the initiation, management or financing of a clinical trial.
Full Title	The full title of the clinical trial as specified in the study protocol and other documents submitted as part of the Clinical Trial Application.
Start Date	The date upon which the clinical trial commenced within the European Economic Area (EEA). **Note:** Outside the EU/EEA (i.e. paediatric investigation plans), the start date is actually date the study was submitted into the EudraCT database, **which may not be the actual start date of the study**.
Medical condition	Medical condition or disease under investigation. Description of intended indication for the product under development.
Disease	The MedDRA classification, including the version of MedDRA, its classification code, the term and its level in the MedDRA terminology hierarchy. **Key to MedDRA hierarchical levels (highest to lowest):** SOC

Field	Description
	(System Organ Class) HLGT (High Level Group Term) HLT (High Level Term) PT (Preferred Term) LLT (Lowest Level Term). See MedDRA website for more information.
Population age	The age range(s) of those taking part in the study.
Gender	The gender(s) of those taking part in the study.
Country	The countries in which the study is based. Click on the ISO country code to view full details of the clinical trial. ISO two letter Country Codes (also known as ISO 3166-1-alpha-2 code) are used in the EudraCT database to record all country references. See the ISO website for the complete list.
Trial results	The summary results of the trial. Click on the link "view results" if available to review the results of the trial. Note that the statement "no results available" is displayed when results have not yet been published.

2.1.1. Protocol records

For a given clinical trial there may be several protocol records (Clinical Trial Applications (CTAs), third country files) according to the number of countries where the trial was authorised. By default, the summary view displays information of the oldest record. This is the record first entered in the EudraCT system.

Some fields may appear to be blank or carry a default value 'Information not present in EudraCT'. For more information refer to the FAQ, which are also accessible under the About section of the EU Clinical Trials Register website.

2.1.2. Results records

For a given clinical trial, there may be several versions of results available which correspond to the versions published by the sponsor over time. View each version by clicking on the Results version number field.

Summary	
EudraCT number	2004-001443-29
Trial protocol	ES
Global end of trial date	11 Dec 2013

Results information	
Results version number	v1(current)
This version publication date	12 Dec 2013
First version publication date	12 Dec 2013
Other versions	

Trial Information
Subject Disposition
Baseline Characteristics
End Points
Adverse Events
More Information

The results related summary section has the following fields:

Summary	
EudraCT number	The unique reference given to each trial which identifies the protocol and trial throughout its lifespan
Trial protocol	Links to the protocol records of the trial.
Global end of trial date	The date the trial ended globally.
Results information	
Results version number	The version number for this set of results
This version publication date	The date this version of results was published.
First version publication date	The date the first version of results was published.
Other versions	Links to the other versions of results of the trial.

Each set of trial results is divided into the following sections:

Section	**Description**
Trial information	Details of the trial (e.g. full title of the trial, study identifier, sponsor details, population of the trial). Additionally it also shows details on the results analysis stage.
Subject Disposition	A summary of the progress of subjects through each stage of the trial.
Baseline Characteristics	Data collected at the beginning of the trial for all subjects and for each arm or comparison group. These data include demographics, such as age and gender, and study-specific characteristics.
End Points	Planned measurements described in the protocol that are used to determine the effect of interventions on subjects in a clinical trial.

Adverse Events	A summary of unfavourable changes in the health of subjects that happen during a clinical trial or within a certain time period after the trial is over.
More Information	Additional information about the trial.

Note that for older trials the legislation allows summary attachments to be posted instead of the full dataset. In such case, the sponsor may have provided only an attachment as a mean to provide summary results and the full data sets would not be available.

2.2. Paediatric studies in scope of Article 45 of the Paediatric Regulation

Paediatric studies that were completed by 26 January 2007 in respect of products covered by an EU marketing authorisation (Article 45 of Regulation (EC) No 1901/2006) are presented in a dedicated tab in the user interface due to their data format being different from other trial records included in the register.

The study overview record has the following fields:

Field	Description
Study title	The full title of the study as specified in the study protocol.
Active substance	Active substance(s) studied.
Study summary document link (including results)	Links to a document containing a summary of the study results (e.g. copy of a medical journal article or a synopsis in accordance with Annex I to the ICH Topic E 3 guidance). ***Note*** *that this link is only provided if the sponsor / marketing-authorisation holder has submitted such a document.*
View full study document link	Provides further basic information about the study, such as therapeutic area, brand name(s) and population of study subjects.
Document reference	A reference number automatically assigned by the EMA.

3. Download search results

Note: This functionality is only available for trials with a EudraCT protocol, but not for paediatric studies in scope of Article 45 of the Paediatric Regulation.

Once a successful search has been run the search results can be downloaded in plain text format.

Using the menu below you can select the options to download by using the drop-down menus

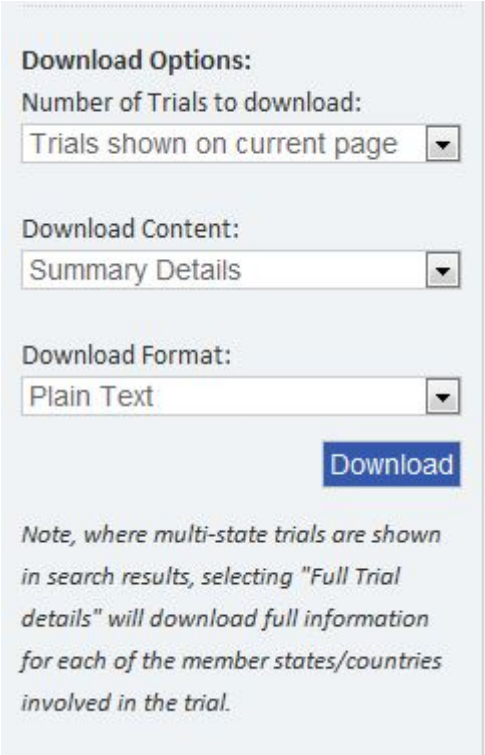

The Download Options menu has the following fields:

Field	Description
Number of Trials to download	Choose 'Trials shown on current page' in order to download all the trials shown on the page you are currently viewing. Choose 'Selected Trials only' and then click the check box beside each result that you are interested in in order to download only selected trials. (Please see screenshot below.) **Note:** This option is only available on a page by page basis.
Download Content	Select from the drop-down list to select a précis of the information (summary details) or the entire record of the study (full trial details).
Download Format	Currently, only a plain text output is provided (.txt file extension)
Download	Click the Download button when you have selected your download options.

If you choose to download 'Selected Trials only', you may select trials (by ticking the EudraCT Number) on the page you are currently viewing

EudraCT Number: 2004-001452-36	Sponsor Protocol Number: XM02-02-INT	Start Date*: 2004-06-30
Sponsor Name: BioGeneriX		
Full Title: Efficacy and Safety of XM 02 compared to Filgrastim in patients with breast cancer receiving chemotherapy. Multinational, multicentre, randomised, controlled study		
Medical condition: Patients with breast cancer high risk stage II or stage III/IV (classification according to American Joint Committee on Cancer [AJCC] receiving chemotherapy and developing Neutropenia due to chemot...		
Disease:		
Population Age: Adults, Elderly		Gender: Male, Female
Country: HU *(Completed)* LT *(Completed)*		
Trial results: *(No results available)*		

Click the **Download** button when you have selected the trials to download. Open the file or save it locally.

4. Subscribe to a search

Note: This functionality is only available for trials with a EudraCT protocol, but not for paediatric studies in scope of Article 45 of the Paediatric Regulation.

The EU Clinical Trials Register offers the option to save a specific search (or an advanced search) query as a Really Simple Syndication (RSS) 'feed'.

- Once a search query is subscribed, you will be notified in your RSS reader if the search query returns new results.
- The method of subscribing to an RSS feed varies between browsers, but involves no more than a couple of mouse clicks.

Note: If you are interested in this feature, and are not sure whether your browser supports RSS feeds, please refer to your browser's Help, which is accessible through the browser's options bar. The following are instructions for subscribing to a search in Internet Explorer 8.

Subscribe to search feed in IE8:

1. Click the word 'here' from the Subscribe to this Search menu:

Subscribe to this Search
To subscribe to the RSS feed for this search click here. This will provide an RSS feed for Clinical Trials matching your search that have been added or updated in the last 7 days.

2. The following screen is displayed:

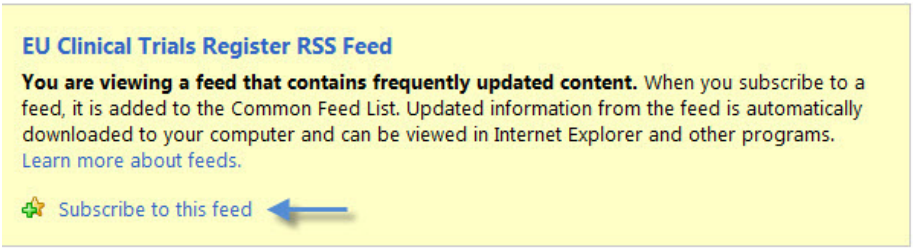

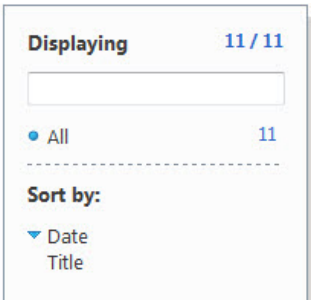

3. Click Subscribe to this feed:

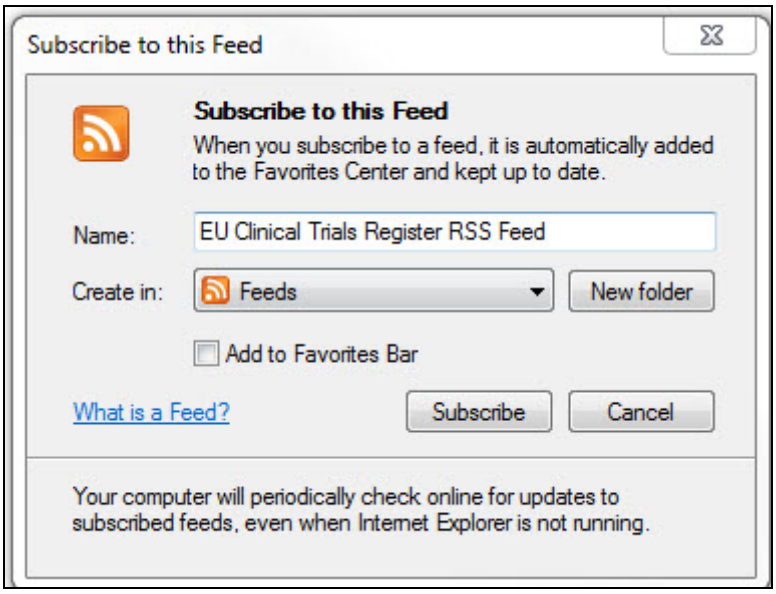

Once a search query has been created, click **Subscribe**.

If additional records matching your search query are added to the database, the RSS feed will indicate that additional results are available to view. Click the link to view the latest results summary in the EU Clinical Trials Register.

Click Subscribe and the search is added to your RSS feeds:

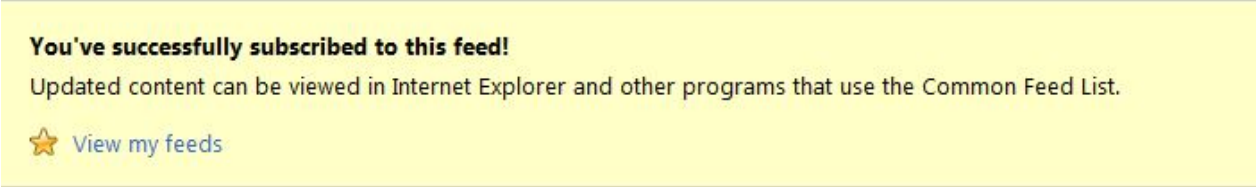

5. Annex

The Annex contains definitions of clinical trial phases and statuses. You may also find the EU Clinical Trials Register glossary useful to explain other unfamiliar terms and acronyms that may be encountered when viewing clinical-trial records.

Clinical trial phase definitions

Phase	Description
Phase I	Phase I is the first stage in the clinical development of a medicinal product. It is to ensure a treatment is safe for people to take, rather than

Phase	Description
	to try to treat a condition. These trials are very small, (typically around 30 people), and usually involve healthy volunteers or sometimes patients.
Phase II	Phase II aims to investigate the safety and effectiveness of a potential therapy. Usually between 100 and 300 people will be enlisted to take part with the aim of determining whether the treatment will be safe and effective to treat a condition.
Phase III	If previous trials have indicated a treatment is safe and that it also shows promise in being able to treat a condition, phase III clinical trials begin. These involve large numbers of participants, usually from several hundred to several thousand subjects, and are often spread between different hospitals and countries. If these trials show that a drug is safe and effective, the manufacturers can apply for a marketing authorisation.
Phase IV	Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Clinical trial status definitions

Phase	Description
On-going	A trial that has received a positive opinion of an ethics committee and authorisation from a competent authority in the Member State(s) concerned and has not ended or is being interrupted.
Not Authorised	In the European Clinical Trials Register, all trials displayed have an authorisation from a competent authority. However, paediatric trials for which a negative ethics committee opinion was issued are also displayed. Since a trial with a negative ethics committee opinion cannot proceed, these are labelled as not authorised.
Temporarily Halted	A trial that has been temporarily interrupted. Reasons for such an interruption are varied, ranging from an interruption in supply of an investigational medicinal product, to the need to await the authorisation of a substantial amendment to the protocol.
Restarted	A trial that was temporarily halted or suspended and has subsequently been restarted.
Prematurely Ended	A trial that has ended without completing all events described in the protocol. Reasons for a premature end can be related to lack of safety or efficacy of a product, or lack of feasibility of the trial.
Completed	A trial that has been completed in accordance with the full requirements of the protocol.
Prohibited by National Competent Authority	A trial whose conduct a national competent authority has prohibited. Reasons may be related to lack of safety or efficacy of a product, or to

Phase	Description
	non-compliance by some of the people involved.
Suspended by National Competent Authority	A trial whose conduct a national competent authority has suspended. Reasons may be related to lack of safety or efficacy of a product, or to non-compliance by some of the people involved. A suspended trial can be restarted.

P. b. b. Verlagspostamt 1030 Wien GZ 02Z034232 M

BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

Jahrgang 2002 **Ausgegeben am 9. August 2002** **Teil I**

120. Bundesgesetz: Universitätsgesetz 2002 sowie Änderung des Bundesgesetzes über die Organisation der Universitäten und des Bundesgesetzes über die Organisation der Universitäten der Künste (NR: GP XXI RV 1134 AB 1224 S. 111. BR: 6697 AB 6717 S. 690.)

120. Bundesgesetz über die Organisation der Universitäten und ihre Studien (Universitätsgesetz 2002) sowie Änderung des Bundesgesetzes über die Organisation der Universitäten und des Bundesgesetzes über die Organisation der Universitäten der Künste

Der Nationalrat hat beschlossen:

Artikel I

Bundesgesetz über die Organisation der Universitäten und ihre Studien (Universitätsgesetz 2002)

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1. Unterabschnitt
Grundsätze, Aufgaben und Geltungsbereich

Ziele

§ 1. Die Universitäten sind berufen, der wissenschaftlichen Forschung und Lehre, der Entwicklung und der Erschließung der Künste sowie der Lehre der Kunst zu dienen und hiedurch auch verantwortlich

zur Lösung der Probleme des Menschen sowie zur gedeihlichen Entwicklung der Gesellschaft und der natürlichen Umwelt beizutragen. Universitäten sind Bildungseinrichtungen des öffentlichen Rechts, die in Forschung und in forschungsgeleiteter akademischer Lehre auf die Hervorbringung neuer wissenschaftlicher Erkenntnisse sowie auf die Erschließung neuer Zugänge zu den Künsten ausgerichtet sind. Im gemeinsamen Wirken von Lehrenden und Studierenden wird in einer aufgeklärten Wissensgesellschaft das Streben nach Bildung und Autonomie des Individuums durch Wissenschaft vollzogen. Die Förderung des wissenschaftlichen Nachwuchses geht mit der Erarbeitung von Fähigkeiten und Qualifikationen sowohl im Bereich der wissenschaftlichen und künstlerischen Inhalte als auch im Bereich der methodischen Fertigkeiten mit dem Ziel einher, zur Bewältigung der gesellschaftlichen Herausforderungen in einer sich wandelnden humanen und geschlechtergerechten Gesellschaft beizutragen. Um den sich ständig wandelnden Erfordernissen organisatorisch, studien- und personalrechtlich Rechnung zu tragen, konstituieren sich die Universitäten und ihre Organe in größtmöglicher Autonomie und Selbstverwaltung.

Leitende Grundsätze

§ 2. Die leitenden Grundsätze für die Universitäten bei der Erfüllung ihrer Aufgaben sind:

1. Freiheit der Wissenschaften und ihrer Lehre (Art. 17 des Staatsgrundgesetzes über die allgemeinen Rechte der Staatsbürger, RGBl. Nr. 142/1867) und Freiheit des wissenschaftlichen und des künstlerischen Schaffens, der Vermittlung von Kunst und ihrer Lehre (Art. 17a des Staatsgrundgesetzes über die allgemeinen Rechte der Staatsbürger);
2. Verbindung von Forschung und Lehre, Verbindung der Entwicklung und Erschließung der Künste und ihrer Lehre sowie Verbindung von Wissenschaft und Kunst;
3. Vielfalt wissenschaftlicher und künstlerischer Theorien, Methoden und Lehrmeinungen;
4. Lernfreiheit;
5. Berücksichtigung der Erfordernisse der Berufszugänge;
6. Mitsprache der Studierenden, insbesondere bei Studienangelegenheiten, bei der Qualitätssicherung der Lehre und der Verwendung der Studienbeiträge;
7. nationale und internationale Mobilität der Studierenden, der Absolventinnen und Absolventen sowie des wissenschaftlichen und künstlerischen Universitätspersonals;
8. Zusammenwirken der Universitätsangehörigen;
9. Gleichstellung von Frauen und Männern;
10. soziale Chancengleichheit;
11. besondere Berücksichtigung der Erfordernisse von behinderten Menschen;
12. Wirtschaftlichkeit, Sparsamkeit und Zweckmäßigkeit der Gebarung.

Aufgaben

§ 3. Die Universitäten erfüllen im Rahmen ihres Wirkungsbereichs folgende Aufgaben:

1. Entwicklung der Wissenschaften (Forschung und Lehre), Entwicklung und Erschließung der Kunst sowie Lehre der Kunst;
2. Bildung durch Wissenschaft und durch die Entwicklung und Erschließung der Künste;
3. wissenschaftliche, künstlerische, künstlerisch-pädagogische und künstlerisch-wissenschaftliche Berufsvorbildung, Qualifizierung für berufliche Tätigkeiten, die eine Anwendung wissenschaftlicher Erkenntnisse und Methoden erfordern, sowie Ausbildung der künstlerischen und wissenschaftlichen Fähigkeiten bis zur höchsten Stufe;
4. Heranbildung und Förderung des wissenschaftlichen und künstlerischen Nachwuchses;
5. Weiterbildung, insbesondere der Absolventinnen und Absolventen von Universitäten;
6. Koordinierung der wissenschaftlichen Forschung (Entwicklung und Erschließung der Künste) und der Lehre innerhalb der Universität;
7. Unterstützung der nationalen und internationalen Zusammenarbeit im Bereich der wissenschaftlichen Forschung und Lehre sowie der Kunst;
8. Unterstützung der Nutzung und Umsetzung ihrer Forschungsergebnisse in der Praxis und Unterstützung der gesellschaftlichen Einbindung von Ergebnissen der Entwicklung und Erschließung der Künste;
9. Gleichstellung von Frauen und Männern und Frauenförderung;
10. Pflege der Kontakte zu den Absolventinnen und Absolventen;
11. Information der Öffentlichkeit über die Erfüllung der Aufgaben der Universitäten.

Rechtsform

§ 4. Die Universitäten sind juristische Personen des öffentlichen Rechts.

Weisungsfreiheit und Satzungsfreiheit

§ 5. Die Universitäten erfüllen ihre Aufgaben gemäß § 3 im Rahmen der Gesetze und Verordnungen nach Maßgabe des § 2 Abs. 2 des Bundesgesetzes über die Organisation der Universitäten (UOG 1993), BGBl. Nr. 805/1993, oder des § 2 Abs. 2 des Bundesgesetzes über die Organisation der Universitäten der Künste (KUOG), BGBl. I Nr. 130/1998, weisungsfrei und geben sich ihre Satzung im Rahmen der Gesetze (§ 7 Abs. 1 UOG 1993 und § 8 Abs. 1 KUOG).

Geltungsbereich

§ 6. Dieses Bundesgesetz gilt für folgende Universitäten:

1. Universität Wien;
2. Universität Graz;
3. Universität Innsbruck;
4. Medizinische Universität Wien;
5. Medizinische Universität Graz;
6. Medizinische Universität Innsbruck;
7. Universität Salzburg;
8. Technische Universität Wien;
9. Technische Universität Graz;
10. Montanuniversität Leoben;
11. Universität für Bodenkultur Wien;
12. Veterinärmedizinische Universität Wien;
13. Wirtschaftsuniversität Wien;
14. Universität Linz;
15. Universität Klagenfurt;
16. Universität für angewandte Kunst Wien;
17. Universität für Musik und darstellende Kunst Wien;
18. Universität Mozarteum Salzburg;
19. Universität für Musik und darstellende Kunst Graz;
20. Universität für künstlerische und industrielle Gestaltung Linz;
21. Akademie der bildenden Künste Wien.

Wirkungsbereich der Universitäten

§ 7. (1) Der Wirkungsbereich der Universitäten gemäß § 6 Z 1 bis 3 und 7 bis 21 ergibt sich, soweit nicht Abs. 2 anderes bestimmt, aus den am Tag vor dem In-Kraft-Treten dieses Bundesgesetzes an den gleichnamigen Universitäten eingerichteten Studien und Forschungseinrichtungen.

(2) Der Wirkungsbereich der Medizinischen Universitäten Wien, Graz und Innsbruck ergibt sich aus den am Tag vor dem In-Kraft-Treten dieses Bundesgesetzes an den Medizinischen Fakultäten der Universitäten Wien, Graz und Innsbruck eingerichteten Studien und Forschungseinrichtungen.

(3) Änderungen der Wirkungsbereiche der Universitäten sind nur im Wege der Leistungsvereinbarungen gemäß § 13 oder durch Verordnung der Bundesregierung gemäß § 8 zulässig.

Sicherung von Forschungs- und Lehrbereichen

§ 8. Die Bundesregierung kann auf Vorschlag der Bundesministerin oder des Bundesministers einer Universität oder mehreren Universitäten durch Verordnung die Einrichtung eines Studiums auftragen, wenn dies aus übergeordneten bildungspolitischen oder wissenschaftspolitischen Gründen erforderlich ist und keine diesbezügliche Einigung im Rahmen einer Leistungsvereinbarung erfolgt.

Rechtsaufsicht

§ 9. Die Universitäten unterliegen der Aufsicht des Bundes. Diese umfasst die Aufsicht über die Einhaltung der Gesetze und Verordnungen einschließlich der Satzung (Rechtsaufsicht).

Gesellschaften, Stiftungen, Vereine

§ 10. Jede Universität ist berechtigt, Gesellschaften, Stiftungen und Vereine zu gründen und sich daran zu beteiligen, sofern diese Gründung oder Beteiligung der Erfüllung der Aufgaben der Universität dient und insbesondere die Forschung (Entwicklung oder Erschließung der Künste) und die Lehre dadurch nicht beeinträchtigt werden.

Universitätsbericht

§ 11. Die Bundesministerin oder der Bundesminister hat dem Nationalrat ab dem Jahr 2005 auf der Grundlage der Leistungsberichte der Universitäten mindestens alle drei Jahre einen Bericht über die bisherige Entwicklung und die künftige Ausrichtung der Universitäten vorzulegen. Dabei ist auch auf die Nachwuchsförderung, auf die Entwicklung der Personalstruktur der Universitäten und auf die Lage der Studierenden einzugehen.

2. Unterabschnitt

Finanzierung, Leistungsvereinbarung und Qualitätssicherung

Universitätsfinanzierung aus Bundesmitteln

§ 12. (1) Die Universitäten sind vom Bund zu finanzieren. Dabei sind die finanziellen Leistungsmöglichkeiten des Bundes, seine Anforderungen an die Universitäten und die Aufgabenerfüllung der Universitäten zu berücksichtigen.

(2) Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen bis spätestens Ende des zweiten Jahres jeder Leistungsvereinbarungsperiode gemäß § 13 den für die nächste Leistungsvereinbarungsperiode zur Finanzierung der Universitäten zur Verfügung stehenden Gesamtbetrag festzusetzen und darüber das Einvernehmen gemäß § 45 des Bundeshaushaltsgesetzes, BGBl. Nr. 213/1986, herzustellen.

(3) Der Betrag gemäß Abs. 2 erhöht sich um die in den einzelnen Jahren der jeweiligen Leistungsvereinbarungsperiode anfallenden Aufwendungen der Universitäten aus den allgemeinen Bezugserhöhungen für das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an den Universitäten vorhandene Bundespersonal, soweit es in diesem Zeitraum in einem Arbeitsverhältnis zur Universität oder in einem Bundesdienstverhältnis, in einem besonderen öffentlich-rechtlichen Rechtsverhältnis oder Ausbildungsverhältnis zum Bund steht und der Universität zugewiesen ist. Die Erhöhung darf jenen Hundertsatz nicht überschreiten, um den die veranschlagten Personalausgaben des Bundes gegenüber dem Bundesvoranschlag für das vorhergehende Kalenderjahr gestiegen sind.

(4) Die Erhöhung gemäß Abs. 3 ist mit jenem Betrag begrenzt, der erforderlich wäre, wenn das von dieser Bestimmung erfasste Universitätspersonal noch in einem Dienst-, Ausbildungs- oder besonderen öffentlich-rechtlichen Rechtsverhältnis zum Bund stünde.

(5) Die Bundesministerin oder der Bundesminister kann bis zu 1 vH des jährlichen Betrags gemäß Abs. 2 und 3 für besondere Finanzierungserfordernisse zur Ergänzung von Leistungsvereinbarungen gemäß § 13 einbehalten.

(6) Der gemäß Abs. 2 und 3 zur Verfügung stehende Gesamtbetrag wird auf einen Teilbetrag für die Grundbudgets gemäß § 13 und einen Teilbetrag für die formelgebundenen Budgets gemäß Abs. 8 aufgeteilt.

(7) Die Universitäten erhalten jeweils ein Globalbudget, das für die dreijährige Periode im Voraus festgelegt wird. Es setzt sich aus dem jeweiligen Grundbudget und dem jeweiligen formelgebundenen Budget zusammen. Die Universitäten können im Rahmen ihrer Aufgaben und der Leistungsvereinbarungen frei über den Einsatz der Globalbudgets verfügen. Eine allfällige Reduktion des Globalbudgets einer Universität beträgt im ersten Jahr der dreijährigen Periode höchstens 2 vH, im zweiten Jahr höchstens 4 vH und im dritten Jahr höchstens 6 vH eines Drittels des für die vorangegangene dreijährige Periode festgesetzten Globalbudgets.

(8) Der Teilbetrag für die formelgebundenen Budgets beträgt 20 vH des gemäß Abs. 2 und 3 zur Verfügung stehenden Gesamtbetrags. Die auf die einzelnen Universitäten entfallenden Anteile werden anhand von qualitäts- und quantitätsbezogenen Indikatoren bemessen. Diese beziehen sich auf die Bereiche Lehre, Forschung oder Entwicklung und Erschließung der Künste sowie gesellschaftliche Zielsetzungen.

(9) Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen nach Anhörung der Universitäten die Indikatoren gemäß Abs. 8

und die Art der Berechnung der formelgebundenen Budgets bis 31. Dezember 2005 durch Verordnung festzusetzen.

(10) Einnahmen aus Drittmitteln und Erträge, die Universitäten aus Veranlagungen erzielen, sind auszuweisen. Sie verbleiben in der Verfügung der Universitäten und reduzieren nicht die Höhe der staatlichen Zuweisungen.

(11) Die Zuteilungen der Mittel erfolgen monatlich aliquot. Die monatlichen Zuweisungen können entsprechend den universitären Erfordernissen im Rahmen der zur Verfügung stehenden Globalbudgets verändert werden.

Leistungsvereinbarung

§ 13. (1) Die Leistungsvereinbarung ist ein öffentlich-rechtlicher Vertrag. Sie ist zwischen den einzelnen Universitäten und dem Bund im Rahmen der Gesetze für jeweils drei Jahre abzuschließen.

(2) Inhalt der Leistungsvereinbarung ist insbesondere:

1. die von der Universität zu erbringenden Leistungen, die entsprechend den Zielen, leitenden Grundsätzen und Aufgaben der Universität in folgenden Bereichen festzulegen sind:
   a) strategische Ziele, Profilbildung, Universitäts- und Personalentwicklung:
   Die langfristigen und die innerhalb der Leistungsvereinbarungsperiode zu erreichenden Ziele sind festzulegen. Die Universität hat ihre besonderen Schwerpunkte und Stärken und den daraus abgeleiteten und zur Zielerreichung vorgesehenen Ressourceneinsatz bekannt zu geben. Es ist anzugeben, welche Fördermaßnahmen und Anreize zur Erreichung der Ziele in der Personalentwicklung erforderlich sind und welche Beiträge die Angehörigen der Universität leisten sollen.
   b) Forschung sowie Entwicklung und Erschließung der Künste:
   Die Universität hat insbesondere die geplanten und die weiterzuführenden Forschungsprojekte und Forschungsprogramme sowie die Vorhaben zur Entwicklung und Erschließung der Künste bekannt zu geben.
   c) Studien und Weiterbildung:
   Die Angaben zum Studienbetrieb und zu den Weiterbildungsaktivitäten sind durch entsprechende Statistiken über die quantitative Entwicklung in diesen Bereichen und mittels der Ergebnisse der Auswertung der Lehrveranstaltungsbeurteilungen nach Studien zu belegen. Auf dieser Basis sind die Vorhaben im Studien- und Weiterbildungsbereich sowie bei der Heranbildung von besonders qualifizierten Doktoranden und Postgraduierten zu bezeichnen und allfällige Änderungen der Lehr- und Lernorganisation zu definieren, mit denen den anzustrebenden Qualifikationsprofilen der Studierenden und der Forscherinnen und Forscher entsprochen werden soll.
   d) gesellschaftliche Zielsetzungen:
   Die Universität hat ihren Beitrag zur Entwicklung der Gesellschaft zu formulieren. Dazu zählen unter anderem Maßnahmen zur Erhöhung des Frauenanteils in leitenden Funktionen der Universität, Angebote für berufstätige Studierende, der Ausbau von gesellschaftlich relevanten Kunst-, Kultur- und Forschungsbereichen sowie der Wissens- und Technologietransfer.
   e) Erhöhung der Internationalität und Mobilität:
   Aktivitäten und Vorhaben in diesem Bereich beziehen sich insbesondere auf mehrjährige internationale Kooperationen mit Universitäten, mit anderen Forschungseinrichtungen und Institutionen aus dem Kunst- und Kulturbereich, auf gemeinsame Studien- und Austauschprogramme für Studierende, für das wissenschaftliche und künstlerische Personal sowie auf die Erhöhung des Anteils der ausländischen Studierenden und Postgraduierten.
   f) interuniversitäre Kooperationen:
   Die Universität hat ihre Aktivitäten zur gemeinsamen Nutzung von Organisationseinheiten und Leistungsangeboten mit anderen Universitäten zu bestimmen. Dabei sind Informationen über die Bereiche, das Ausmaß und die Auswirkungen der Kooperationen mit anderen österreichischen Universitäten zu liefern.
2. die Leistungsverpflichtung des Bundes:
   Zuteilung des Grundbudgets, unter Berücksichtigung der Kriterien für das Grundbudget;
3. Inhalt, Ausmaß und Umfang der Ziele sowie Zeitpunkt der Zielerreichung;
4. Aufteilung der Zuweisung des Grundbudgets auf das Budgetjahr;
5. Maßnahmen im Falle der Nichterfüllung der Leistungsvereinbarung;
6. Berichtswesen und Rechenschaftslegung.

(3) Die Leistungsvereinbarung kann bei gravierenden Veränderungen der ihr zugrunde liegenden Rahmenbedingungen einvernehmlich abgeändert werden.

(4) Das Grundbudget wird als Grundfinanzierung auf Grund der Leistungsvereinbarung festgelegt. Folgende Kategorien bilden die Basis für die Verhandlung und sind für die Bemessung des Grundbudgets maßgebend:

a) Bedarf,

b) Nachfrage,

c) Leistung,

d) gesellschaftliche Zielsetzungen.

Die vier Kriterien sind unter Bedachtnahme auf die §§ 2 und 3 in der Leistungsvereinbarung zu konkretisieren.

(5) Die Universität hat der Bundesministerin oder dem Bundesminister bis 30. April jeden Jahres einen auf der Basis der Leistungsvereinbarung zu erstellenden Leistungsbericht vorzulegen. Nach dem zweiten Budgetjahr hat der Leistungsbericht überdies eine Prognose über die zu erwartenden Leistungsergebnisse und die finanzielle Situation der Universität für das dritte Jahr zu beinhalten.

(6) Jede Universität hat der Bundesministerin oder dem Bundesminister im Wege des Universitätsrats jeweils bis 30. April eine Wissensbilanz über das abgelaufene Kalenderjahr vorzulegen. Gesondert darzustellen sind zumindest:

1. der Wirkungsbereich, gesellschaftliche Zielsetzungen sowie selbst definierte Ziele und Strategien;
2. das intellektuelle Vermögen, differenziert in Human-, Struktur- und Beziehungskapital;
3. die in der Leistungsvereinbarung definierten Leistungsprozesse mit ihren Outputgrößen und Wirkungen.

Die Bundesministerin oder der Bundesminister hat durch Verordnung Richtlinien für den Aufbau und die Gestaltung der Wissensbilanz zu erlassen.

(7) Im dritten Jahr einer Leistungsperiode hat die Universität der Bundesministerin oder dem Bundesminister bis 30. April einen Entwurf für die nächste Leistungsvereinbarung vorzulegen. Die Bundesministerin oder der Bundesminister hat bis 31. August dazu Stellung zu nehmen. Die Verhandlungen über die Leistungsvereinbarung sind bis 31. Dezember abzuschließen.

(8) Kommt eine Leistungsvereinbarung nicht rechtzeitig zustande, haben die Bundesministerin oder der Bundesminister und der Senat der Universität je eine fachlich geeignete Person in eine Schlichtungskommission zu entsenden. Diese beiden Mitglieder haben unverzüglich ein drittes Mitglied zu bestellen. Bei Nichteinigung innerhalb von vier Wochen hat der Präsident der Österreichischen Akademie der Wissenschaften dieses dritte Mitglied zu nominieren. Die Schlichtungskommission hat bei den Verhandlungspartnern innerhalb von sechs Wochen ab der Bestellung des dritten Mitglieds auf einen Abschluss der Leistungsvereinbarung hinzuwirken.

(9) Wird innerhalb dieser sechswöchigen Frist keine Einigung über eine Leistungsvereinbarung erzielt, erhält die betreffende Universität bis zum Abschluss einer neuen Leistungsvereinbarung im ersten, zweiten und dritten Jahr jeweils 98 vH eines Drittels des für die vorangegangene Leistungsvereinbarung festgesetzten Grundbudgets.

Evaluierung und Qualitätssicherung

§ 14. (1) Die Universitäten haben zur Qualitäts- und Leistungssicherung ein eigenes Qualitätsmanagementsystem aufzubauen.

(2) Gegenstand der Evaluierung sind die Aufgaben und das gesamte Leistungsspektrum der Universität.

(3) Evaluierungen haben nach fachbezogenen internationalen Evaluierungsstandards zu erfolgen. Die zu evaluierenden Bereiche des universitären Leistungsspektrums sind für jene Evaluierungen, die sich nur auf eine Universität beziehen, in der Leistungsvereinbarung festzulegen.

(4) Universitätsinterne Evaluierungen sind nach Maßgabe der Satzung kontinuierlich durchzuführen.

(5) Externe Evaluierungen sind, wenn sie

1. eine einzelne Universität betreffen, auf Veranlassung des Universitätsrats, des Rektorats oder der Bundesministerin oder des Bundesministers,

2. mehrere Universitäten betreffen, auf Veranlassung der Universitätsräte, der Rektorate der betreffenden Universitäten oder der Bundesministerin oder des Bundesministers

durchzuführen.

(6) Die betreffenden Universitäten und ihre Organe haben die für die Evaluierungen erforderlichen Daten und Informationen zur Verfügung zu stellen und sind zur Mitwirkung verpflichtet.

(7) Die Leistungen der Universitätsprofessorinnen und Universitätsprofessoren sowie der Universitätsdozentinnen und Universitätsdozenten und der wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb sind regelmäßig, zumindest aber alle fünf Jahre, zu evaluieren. Die näheren Bestimmungen trifft die Satzung.

(8) Die Ergebnisse aller Evaluierungen sind den Entscheidungen der Universitätsorgane zugrunde zu legen. Die Beurteilung der Lehre durch die Studierenden ist bei den Leistungsvereinbarungen zu berücksichtigen.

(9) Der Aufwand für von der Bundesministerin oder vom Bundesminister veranlasste Evaluierungen ist vom Bund zu tragen.

3. Unterabschnitt
Gebarung und Rechnungswesen
Gebarung

§ 15. (1) Das Rektorat hat die Gebarung der Universität nach den Grundsätzen der Rechtmäßigkeit, Wirtschaftlichkeit, Zweckmäßigkeit, Sparsamkeit und Transparenz zu gestalten und den Haushalt der Universität mit entsprechender Sorgfalt zu führen.

(2) Die Universitäten können über ihre Einnahmen frei verfügen, sofern gesetzlich nicht anderes bestimmt ist. Allfällige Zweckwidmungen sind zu berücksichtigen.

(3) Die Gebarung der Universitäten erfolgt im eigenen Namen und auf eigene Rechnung.

(4) Die Begründung von Verbindlichkeiten, die über die laufende Geschäftstätigkeit der Universität hinausgehen, bedarf der Zustimmung des Universitätsrats. Dieser kann das Rektorat ermächtigen, Verbindlichkeiten bis zu einer bestimmten Höhe ohne seine vorherige Zustimmung einzugehen.

(5) Für Verbindlichkeiten der Universitäten trifft den Bund keine Haftung, sofern gesetzlich nicht anderes bestimmt ist.

(6) Die Gebarung der Universitäten unterliegt der Prüfung durch den Rechnungshof.

Rechnungswesen und Berichte

§ 16. (1) An jeder Universität ist unter der Verantwortung und Leitung des Rektorats ein Rechnungswesen, einschließlich einer Kosten- und Leistungsrechnung, sowie ein Berichtswesen einzurichten, die den Aufgaben der Universität entsprechen. Für das Rechnungswesen ist der erste Abschnitt des dritten Buches des Handelsgesetzbuches sinngemäß anzuwenden.

(2) Jede Universität kann darüber hinaus weitere Abschnitte des dritten Buches des Handelsgesetzbuches anwenden, um damit ihrer Verpflichtung zur Rechnungslegung bei Wahrung der Vergleichbarkeit mit den anderen Universitäten nachzukommen. Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen durch Verordnung die erforderlichen Regelungen, Anpassungen und Ergänzungen für die Gliederung des Rechnungsabschlusses, bestehend aus Bilanz sowie Gewinn- und Verlustrechnung, für die Bewertung der Vermögensgegenstände und Schulden, für die Anwendung von Bewertungsvereinfachungsverfahren, für die Prüfung des Rechnungsabschlusses, für die Aufnahme entsprechender Erläuterungen und für eine einheitliche Anwendung dieser Grundsätze festzulegen.

(3) Das Rechnungsjahr der Universitäten entspricht dem Kalenderjahr, soweit nicht in der Verordnung gemäß Abs. 2 etwas anderes angeordnet wird.

(4) Das Rektorat hat dem Universitätsrat bis 30. April einen Leistungsbericht und einen Rechnungsabschluss über das abgelaufene Rechnungsjahr zusammen mit einem Bericht einer Abschlussprüferin oder eines Abschlussprüfers vorzulegen. Die Abschlussprüferin oder der Abschlussprüfer ist vom Universitätsrat längstens sechs Monate vor Ablauf des Rechnungsjahres mit der Prüfung des Rechnungswesens und des Rechnungsabschlusses zu beauftragen. Die Abschlussprüferin oder der Abschlussprüfer muss eine von der Universität unabhängige beeidete Wirtschaftsprüferin und Steuerberaterin oder ein von der Universität unabhängiger beeideter Wirtschaftsprüfer und Steuerberater, eine beeidete Buchprüferin und

Steuerberaterin oder ein beeideter Buchprüfer und Steuerberater, eine Wirtschaftsprüfungs- und Steuerberatungsgesellschaft oder Buchprüfungs- und Steuerberatungsgesellschaft sein.

(5) Der Universitätsrat hat den vom Rektorat vorgelegten Leistungsbericht und den Rechnungsabschluss innerhalb von vier Wochen zu genehmigen und an die Bundesministerin oder den Bundesminister weiterzuleiten. Erfolgt bis zu diesem Zeitpunkt keine Genehmigung, sind der Leistungsbericht und der Rechnungsabschluss mit einer entsprechenden Stellungnahme dennoch weiterzuleiten.

(6) Die Bundesministerin oder der Bundesminister kann durch Verordnung festlegen, dass die Universitäten ihr oder ihm laufend automationsunterstützt und in technisch geeigneter Form den Zugang zu den für die Planung, die Steuerung und die Statistik benötigten standardisierten Daten, insbesondere für die Berechnung der Indikatoren gemäß § 12 Abs. 8, ermöglichen.

Inanspruchnahme von Dienstleistungen

§ 17. (1) Die Bundesrechenzentrum GmbH hat die Universitäten auf deren Verlangen und gegen Entgelt bei der Einrichtung, Fortentwicklung und beim Betrieb der IT-Verfahren zu unterstützen, die für ein Rechnungswesen gemäß § 16 und eine Personalverwaltung gemäß §§ 125 ff erforderlich sind.

(2) Für die Personalverrechnung der Beamtinnen und Beamten sind die von der Bundesrechenzentrum GmbH betriebenen diesbezüglichen IT-Verfahren jedenfalls in Anspruch zu nehmen.

Gewerbe- und abgabenrechtliche Stellung der Universitäten

§ 18. (1) Bei der Erfüllung ihrer Aufgaben unterliegen die Universitäten nicht den Bestimmungen der Gewerbeordnung 1994 (GewO 1994), BGBl. Nr. 194/1994.

(2) Alle dem Bund auf Grund bundesgesetzlicher Bestimmungen eingeräumten abgaben- und gebührenrechtlichen Begünstigungen finden auch auf die Universitäten Anwendung, soweit diese in Erfüllung ihrer gesetzlichen Aufgaben tätig werden.

2. Abschnitt
Leitung und innerer Aufbau der Universität
1. Unterabschnitt
Bestimmungen für alle Universitäten

Satzung

§ 19. (1) Jede Universität erlässt durch Verordnung (Satzung) die erforderlichen Ordnungsvorschriften im Rahmen der Gesetze und Verordnungen selbst. Die Satzung ist vom Senat auf Vorschlag des Rektorats mit einfacher Mehrheit zu beschließen.

(2) In der Satzung sind insbesondere folgende Angelegenheiten zu regeln:

1. Wahlordnung für die Wahl der Mitglieder des Universitätsrats, des Rektorats, des Senats und anderer Organe;
2. Einrichtung eines für die Vollziehung der studienrechtlichen Bestimmungen in erster Instanz zuständigen monokratischen Organs;
3. generelle Richtlinien für die Durchführung, Veröffentlichung und Umsetzung von Evaluierungen;
4. studienrechtliche Bestimmungen nach Maßgabe des II. Teils dieses Bundesgesetzes;
5. Zusammensetzung des Arbeitskreises für Gleichbehandlungsfragen (§ 42 Abs. 2);
6. Erlassung eines Frauenförderungsplans;
7. Einrichtung einer Organisationseinheit zur Koordination der Aufgaben der Gleichstellung, der Frauenförderung sowie der Geschlechterforschung;
8. Richtlinien für akademische Ehrungen;
9. Art und Ausmaß der Einbindung der Absolventinnen und Absolventen der Universität.

(3) Wahlen sind geheim durchzuführen, das Wahlrecht ist persönlich und unmittelbar auszuüben.

Leitung und innere Organisation

§ 20. (1) Die obersten Organe der Universität sind der Universitätsrat, das Rektorat, die Rektorin oder der Rektor und der Senat.

(2) Die Mitgliedschaft in mehr als einem der obersten Organe der Universität ist unzulässig.

(3) Die Mitglieder von Kollegialorganen sind bei der Ausübung dieser Funktion an keine Weisungen oder Aufträge gebunden (§ 13 Abs. 2 UOG 1993 und § 14 Abs. 2 KUOG). Sie haben mit einfacher Stimmenmehrheit eine Vorsitzende oder einen Vorsitzenden zu wählen. Kommt eine zur Wahl, Entsendung oder Nominierung von Vertreterinnen und Vertretern in ein Kollegialorgan der Universität berufene Personengruppe dieser Verpflichtung nicht zeitgerecht nach, hat der Universitätsrat dieser Personengruppe eine einmalige Nachfrist zur Nachholung der Wahl, Entsendung oder Nominierung zu setzen. Kommt der Senat seiner Verpflichtung zur Wahl der Mitglieder des Universitätsrats gemäß § 21 Abs. 6 Z 1 oder Abs. 7 nicht zeitgerecht nach, hat die Bundesministerin oder der Bundesminister dem Senat eine einmalige Nachfrist zur Nachholung der Wahl zu setzen. Verstreicht diese Frist ergebnislos, gilt das Kollegialorgan auch ohne Vertreterinnen und Vertreter dieser Personengruppe als gesetzmäßig zusammengesetzt.

(4) Das Rektorat hat nach Stellungnahme des Senats einen Organisationsplan zu erstellen, der der Genehmigung des Universitätsrats bedarf. Bei der Einrichtung von Organisationseinheiten (Departments, Fakultäten, Institute oder andere Organisationseinheiten) ist auf eine zweckmäßige Zusammenfassung nach den Gesichtspunkten von Forschung, Entwicklung und Erschließung der Künste, Lehre und Lernen sowie Verwaltung zu achten. Das Rektorat hat sicherzustellen, dass den Organisationseinheiten die zur Erfüllung ihrer Aufgaben erforderlichen Ressourcen zugewiesen werden.

(5) Zur Leiterin oder zum Leiter einer Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst ist vom Rektorat auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren der betreffenden Organisationseinheit eine Universitätsprofessorin oder ein Universitätsprofessor zu bestellen. Diese Leiterinnen und Leiter haben mit den der betreffenden Organisationseinheit zugeordneten Angehörigen der Universität Zielvereinbarungen über die Leistungen in Forschung oder Entwicklung und Erschließung der Künste sowie in der Lehre abzuschließen, die von diesen Angehörigen zu erbringen sind. Dabei ist auf die Freiheit der Wissenschaft und der Künste und auf einen entsprechenden Freiraum der einzelnen Wissenschafterinnen und Wissenschafter sowie Künstlerinnen und Künstler in der Forschung oder bei der Entwicklung und Erschließung der Künste sowie in der Lehre Bedacht zu nehmen. Nähere Bestimmungen sind in der Satzung festzulegen.

(6) Jede Universität hat ein Mitteilungsblatt herauszugeben und im Internet auf der Homepage der Universität öffentlich zugänglich zu machen. Im Mitteilungsblatt sind insbesondere kundzumachen:

1. Satzung, Entwicklungsplan und Organisationsplan einschließlich der Personalzuordnung;
2. Eröffnungsbilanz;
3. Leistungsvereinbarung, Rechnungsabschluss, Leistungsbericht, Wissensbilanz;
4. Verordnungen und Geschäftsordnungen von Organen;
5. Richtlinien der Leitungsorgane;
6. Curricula;
7. von der Universität zu verleihende akademische Grade sowie Bezeichnungen für die Absolventinnen und Absolventen von Universitätslehrgängen;
8. Mitteilungen an die Studierenden sowie sonstige Verlautbarungen von allgemeinem Interesse;
9. Ausschreibung und Ergebnisse von Wahlen;
10. Ausschreibung von Stellen und Leitungsfunktionen;
11. Mitglieder der Leitungsorgane;
12. Verleihung von Lehrbefugnissen;
13. Berechtigungen und erteilte Bevollmächtigungen;
14. Verwendung der Studienbeiträge.

Universitätsrat

§ 21. (1) Der Universitätsrat hat folgende Aufgaben:

1. Genehmigung des Entwicklungsplans, des Organisationsplans und des Entwurfs der Leistungsvereinbarung der Universität sowie der Geschäftsordnung des Rektorats;
2. Stellungnahme zur Ausschreibung der Funktion der Rektorin oder des Rektors durch den Senat;
3. Wahl der Rektorin oder des Rektors aus dem Dreiervorschlag des Senats sowie Wahl der Vizerektorinnen und Vizerektoren auf Grund eines Vorschlags der Rektorin oder des Rektors und nach Stellungnahme des Senats;

4. Abschluss des Arbeitsvertrages und der Zielvereinbarung mit der Rektorin oder dem Rektor;
5. Abberufung der Rektorin oder des Rektors und der Vizerektorinnen und Vizerektoren;
6. Nominierung eines weiblichen und eines männlichen Mitglieds für die Schiedskommission;
7. Stellungnahme zu den Curricula und zu den Studienangeboten außerhalb der Leistungsvereinbarung;
8. Genehmigung der Gründung von Gesellschaften und Stiftungen;
9. Genehmigung der Richtlinien für die Gebarung sowie Genehmigung des Rechnungsabschlusses, des Leistungsberichts des Rektorats und der Wissensbilanz und Weiterleitung an die Bundesministerin oder den Bundesminister;
10. Bestellung einer Abschlussprüferin oder eines Abschlussprüfers zur Prüfung des Rechnungsabschlusses der Universität;
11. Zustimmung zur Begründung von Verbindlichkeiten, die über die laufende Geschäftstätigkeit der Universität hinausgehen, sowie Ermächtigung des Rektorats, solche Verbindlichkeiten bis zu einer bestimmten Höhe ohne vorherige Einholung der Zustimmung des Universitätsrats einzugehen;
12. Berichtspflicht an die Bundesministerin oder den Bundesminister bei schwerwiegenden Rechtsverstößen von Universitätsorganen sowie bei Gefahr eines schweren wirtschaftlichen Schadens;
13. Genehmigung von Richtlinien des Rektorats für die Bevollmächtigung von Arbeitnehmerinnen und Arbeitnehmern gemäß § 28 Abs. 1.

(2) Der Universitätsrat ist berechtigt, sich über alle Angelegenheiten der Universität zu informieren. Die Universitätsorgane sind verpflichtet, dem Universitätsrat alle zweckdienlichen Auskünfte zu erteilen, Geschäftsstücke und Unterlagen über die vom Universitätsrat bezeichneten Gegenstände vorzulegen, von ihm angeordnete Erhebungen anzustellen und Überprüfungen an Ort und Stelle vornehmen zu lassen.

(3) Der Universitätsrat besteht aus fünf, sieben oder neun Mitgliedern, die in verantwortungsvollen Positionen in der Gesellschaft, insbesondere der Wissenschaft, Kultur oder Wirtschaft, tätig sind oder waren und auf Grund ihrer hervorragenden Kenntnisse und Erfahrungen einen Beitrag zur Erreichung der Ziele und Aufgaben der Universität leisten können. Die Größe des ersten Universitätsrats legt der Gründungskonvent fest (§ 121 Abs. 4). Über eine Änderung der Größe des Universitätsrats entscheidet der Senat mit Zweidrittelmehrheit.

(4) Dem Universitätsrat dürfen Mitglieder der Bundesregierung oder einer Landesregierung, Mitglieder des Nationalrats, des Bundesrats oder eines sonstigen allgemeinen Vertretungskörpers und Funktionäre einer politischen Partei sowie Personen nicht angehören, die eine dieser Funktionen in den letzten vier Jahren ausgeübt haben.

(5) Die Mitglieder des Universitätsrats dürfen keine Universitätsangehörigen gemäß §§ 125, 132 und 133, keine Arbeitnehmerinnen und Arbeitnehmer der Universität und keine Mitarbeiterinnen oder Mitarbeiter des für die Angelegenheiten der Universitäten zuständigen Bundesministeriums sein. Die Mitgliedschaft in mehr als einem Universitätsrat ist unzulässig.

(6) Dem Universitätsrat gehören nach Maßgabe des Abs. 3 folgende fünf, sieben oder neun Mitglieder an:

1. zwei, drei oder vier Mitglieder, die vom Senat gewählt werden;
2. zwei, drei oder vier Mitglieder, die von der Bundesregierung auf Vorschlag der Bundesministerin oder des Bundesministers bestellt werden;
3. ein weiteres Mitglied, das von den unter Z 1 und 2 genannten Mitgliedern einvernehmlich bestellt wird.

Der Senat und die Bundesregierung haben gleich viele Mitglieder zu bestellen, die Bestellung der Mitglieder gemäß Z 2 hat nach der Wahl der Mitglieder gemäß Z 1 zu erfolgen.

(7) Kommt es innerhalb von drei Monaten nach der Bestellung der Mitglieder gemäß Abs. 6 Z 1 und 2 zu keiner einvernehmlichen Bestellung des weiteren Mitglieds gemäß Abs. 6 Z 3, hat die Bundesministerin oder der Bundesminister eine angemessene Nachfrist zu setzen. Verstreicht diese ergebnislos, ist dieses Mitglied des Universitätsrats vom Senat aus einem Dreiervorschlag der Akademie der Wissenschaften auszuwählen.

(8) Die Funktionsperiode der Mitglieder beträgt fünf Jahre. Eine Wiederwahl oder Wiederbestellung für die unmittelbar folgende Funktionsperiode ist nur einmal zulässig. Bei vorzeitigem Ausscheiden eines Mitglieds des Universitätsrats ist für den Rest der Funktionsperiode ein neues Mitglied auf dieselbe Art wie das ausgeschiedene Mitglied zu wählen oder zu bestellen.

(9) Die oder der Vorsitzende des Universitätsrats wird vom Universitätsrat aus dem Kreis der Mitglieder mit einfacher Mehrheit gewählt.

(10) Die Mitglieder des Universitätsrats sind bei ihrer Tätigkeit zu entsprechender Sorgfalt verpflichtet.

(11) Die Mitglieder des Universitätsrats erhalten für ihre Tätigkeit eine Vergütung, die vom Universitätsrat festzusetzen ist.

(12) Der Universitätsrat ist beschlussfähig, wenn wenigstens die Hälfte der Mitglieder persönlich anwesend ist. Stimmübertragungen sind unzulässig. Der Universitätsrat entscheidet mit Stimmenmehrheit, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(13) Die Mitgliedschaft im Universitätsrat endet

1. durch Ablauf der Funktionsperiode;
2. durch Verzicht;
3. durch Abberufung;
4. durch Tod.

(14) Die Bundesministerin oder der Bundesminister kann ein Mitglied des Universitätsrats wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung oder wegen mangelnder körperlicher oder geistiger Eignung mit Bescheid von seiner Funktion abberufen. Eine Abberufung setzt übereinstimmende Beschlüsse des Senats und des Rektorats voraus, die beide einer Zweidrittelmehrheit bedürfen.

(15) Das Rektorat, die Vorsitzende oder der Vorsitzende des Senats, die oder der Vorsitzende des Arbeitskreises für Gleichbehandlungsfragen und die oder der Vorsitzende der Hochschülerschaft an der betreffenden Universität haben das Recht, in den Sitzungen des Universitätsrats zu Tagesordnungspunkten angehört zu werden, die ihren Aufgabenbereich betreffen. Die Vorsitzenden der Betriebsräte sind zu allen Sitzungen des Universitätsrats einzuladen und sind im Rahmen der ihnen nach dem Arbeitsverfassungsgesetz, BGBl. Nr. 22/1974, zukommenden Aufgaben anzuhören.

Rektorat

§ 22. (1) Das Rektorat leitet die Universität und vertritt diese nach außen. Es hat alle Aufgaben wahrzunehmen, die durch dieses Bundesgesetz nicht einem anderen Organ zugewiesen sind. Zu seinen Aufgaben zählen insbesondere:

1. Erstellung eines Entwurfs der Satzung zur Vorlage an den Senat;
2. Erstellung eines Entwicklungsplans der Universität zur Vorlage an den Senat und an den Universitätsrat;
3. Erstellung eines Organisationsplans der Universität zur Vorlage an den Senat und an den Universitätsrat;
4. Erstellung eines Entwurfs der Leistungsvereinbarung zur Vorlage an den Universitätsrat;
5. Bestellung der Leiterinnen und Leiter von Organisationseinheiten;
6. Abschluss von Zielvereinbarungen mit den Leiterinnen und Leitern der Organisationseinheiten;
7. Zuordnung der Universitätsangehörigen (§ 94 Abs. 1 Z 2 bis 6) zu den einzelnen Organisationseinheiten;
8. Aufnahme der Studierenden;
9. Einhebung der Studienbeiträge in der gesetzlich festgelegten Höhe;
10. Veranlassung von Evaluierungen und der Veröffentlichung von Evaluierungsergebnissen;
11. Erteilung der Lehrbefugnis (venia docendi);
12. Stellungnahme zu den Curricula;
13. Einrichtung eines Rechnungs- und Berichtswesens;
14. Budgetzuteilung;
15. Erstellung des jährlichen Leistungsberichts, des Rechnungsabschlusses und der Wissensbilanz;
16. Erlassung von Richtlinien für die Bevollmächtigung von Arbeitnehmerinnen und Arbeitnehmern der Universität gemäß § 28 Abs. 1.

(2) Dem Rektorat unterstehen alle Einrichtungen der Universität. Das Rektorat kann Entscheidungen anderer Organe mit Ausnahme der Beschlüsse des Universitätsrats zurückverweisen, wenn diese Entscheidungen nach Auffassung des Rektorats im Widerspruch zu Gesetzen und Verordnungen einschließlich der Satzung stehen. Der Universitätsrat ist in schwerwiegenden Fällen zu informieren.

(3) Das Rektorat besteht aus der Rektorin oder dem Rektor und bis zu vier Vizerektorinnen oder Vizerektoren. Bei der Zusammensetzung des Rektorats ist sicherzustellen, dass dieses über entsprechende Kompetenzen im Bereich der Wissenschaft sowie Management- und Verwaltungsführungskompetenzen verfügt.

(4) Die Rektorin oder der Rektor ist Vorsitzende oder Vorsitzender des Rektorats und dessen Sprecherin oder Sprecher.

(5) Das Rektorat entscheidet mit Stimmenmehrheit, sofern in der Geschäftsordnung nicht anderes bestimmt ist. Bei Stimmengleichheit gibt die Stimme der Rektorin oder des Rektors den Ausschlag.

(6) Das Rektorat hat eine Geschäftsordnung zu erlassen, die der Genehmigung des Universitätsrats bedarf und im Mitteilungsblatt zu verlautbaren ist. In der Geschäftsordnung ist festzulegen, welche Agenden gemäß Abs. 1 den einzelnen Mitgliedern des Rektorats allein zukommen, welche Agenden von zwei Mitgliedern des Rektorats und welche von allen Mitgliedern gemeinsam wahrzunehmen sind. Entscheidungen in wirtschaftlichen Angelegenheiten sind jedenfalls von mindestens zwei Mitgliedern des Rektorats zu treffen. In der Geschäftsordnung ist auch die Vertretungsbefugnis festzulegen.

(7) Die Mitglieder des Rektorats sind in dieser Funktion an keine Weisungen oder Aufträge gebunden (§ 13 Abs. 2 UOG 1993 und § 14 Abs. 2 KUOG); die Vizerektorinnen und Vizerektoren sind in dieser Funktion auch an keine Weisungen oder Aufträge der Rektorin oder des Rektors gebunden. Die Mitglieder des Rektorats sind bei ihrer Tätigkeit zu entsprechender Sorgfalt verpflichtet.

Rektorin oder Rektor

§ 23. (1) Die Rektorin oder der Rektor hat folgende Aufgaben:

1. Vorsitzende oder Vorsitzender sowie Sprecherin oder Sprecher des Rektorats;
2. Erstellung eines Vorschlags für die Wahl der Vizerektorinnen und Vizerektoren;
3. Leitung des Amts der Universität;
4. Verhandlung und Abschluss der Leistungsvereinbarungen mit der Bundesministerin oder dem Bundesminister;
5. Ausübung der Funktion der oder des obersten Vorgesetzten des gesamten Universitätspersonals;
6. Abschluss des Arbeitsvertrages mit den Vizerektorinnen und Vizerektoren;
7. Auswahlentscheidung aus Besetzungsvorschlägen der Berufungskommissionen für Universitätsprofessorinnen und Universitätsprofessoren;
8. Führung von Berufungsverhandlungen;
9. Abschluss von Arbeits- und Werkverträgen;
10. Erteilung von Vollmachten gemäß § 28 Abs. 1.

(2) Die Funktion der Rektorin oder des Rektors ist vom Senat nach Einholung einer Stellungnahme des Universitätsrats öffentlich auszuschreiben. Zur Rektorin oder zum Rektor kann nur eine Person mit internationaler Erfahrung und der Fähigkeit zur organisatorischen und wirtschaftlichen Leitung einer Universität gewählt werden.

(3) Die Rektorin oder der Rektor ist vom Universitätsrat aus einem Dreiervorschlag des Senats für eine Funktionsperiode von vier Jahren zu wählen. Eine Wiederwahl ist zulässig.

(4) Der Arbeitsvertrag und die Zielvereinbarung mit der Rektorin oder dem Rektor wird vom Universitätsrat abgeschlossen.

(5) Die Rektorin oder der Rektor kann vom Universitätsrat wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder körperlicher oder geistiger Eignung oder wegen eines begründeten Vertrauensverlusts von der Funktion abberufen werden. Die Abberufung kann auf Antrag des Senats oder von Amts wegen durch den Universitätsrat erfolgen. Im ersten Fall ist in beiden Organen jeweils die einfache Mehrheit aller Mitglieder erforderlich; im zweiten Fall bedarf der Beschluss im Universitätsrat der Zweidrittelmehrheit aller Mitglieder, der Senat ist anzuhören. Mit der Wirksamkeit der Abberufung endet das Arbeitsverhältnis der Rektorin oder des Rektors zur Universität.

Vizerektorinnen und Vizerektoren

§ 24. (1) Die Rektorin oder der Rektor bestimmt die Zahl und das Beschäftigungsausmaß der Vizerektorinnen und Vizerektoren. Dem Senat kommt ein Recht zur Stellungnahme zu.

(2) Die Vizerektorinnen und Vizerektoren sind vom Universitätsrat auf Vorschlag der Rektorin oder des Rektors und nach Anhörung des Senats für eine Funktionsperiode zu wählen, die jener der Rektorin oder des Rektors entspricht. Eine Wiederwahl ist zulässig.

(3) Scheidet die Rektorin oder der Rektor vor Ablauf der Funktionsperiode aus dem Amt aus, endet die Funktion der Vizerektorinnen und Vizerektoren mit dem Zeitpunkt des Amtsantritts der auf Vorschlag der neuen Rektorin oder des neuen Rektors gewählten Vizerektorinnen und Vizerektoren.

(4) Eine Vizerektorin oder ein Vizerektor kann vom Universitätsrat wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung, wegen mangelnder körperlicher oder geistiger Eignung oder wegen eines begründeten Vertrauensverlusts von der Funktion abberufen werden. Die Rektorin oder der Rektor kann die Abberufung einer Vizerektorin oder eines Vizerektors beim Universitätsrat anregen. Die Abberufung bedarf der Zweidrittelmehrheit aller Mitglieder des Universitätsrats, der Senat ist anzuhören. Mit der Wirksamkeit der Abberufung endet das Arbeitsverhältnis der Vizerektorin oder des Vizerektors zur Universität.

Senat

§ 25. (1) Der Senat hat folgende Aufgaben:

1. Erlassung und Änderung der Satzung;
2. Zustimmung zu dem vom Rektorat erstellten Entwurf des Entwicklungsplans innerhalb von zwei Monaten; stimmt der Senat nicht fristgerecht zu, ist der Entwicklungsplan dennoch an den Universitätsrat weiterzuleiten;
3. Zustimmung zu dem vom Rektorat beschlossenen Entwurf des Organisationsplans innerhalb von zwei Monaten; stimmt der Senat nicht fristgerecht zu, ist der Organisationsplan dennoch an den Universitätsrat weiterzuleiten;
4. Änderung der Größe des Universitätsrats und Wahl von Mitgliedern des Universitätsrats (§ 21 Abs. 6 Z 1 und Abs. 7);
5. Ausschreibung der Funktion der Rektorin oder des Rektors und Erstellung eines Dreiervorschlags für die Wahl der Rektorin oder des Rektors an den Universitätsrat;
6. Stellungnahme zu den Vorschlägen der Rektorin oder des Rektors bezüglich der Vizerektorinnen und Vizerektoren (Anzahl, Beschäftigungsausmaß und Wahlvorschlag);
7. Mitwirkung bei der Abberufung von Mitgliedern des Universitätsrats, der Rektorin oder des Rektors sowie von Vizerektorinnen und Vizerektoren;
8. Mitwirkung an Habilitationsverfahren;
9. Mitwirkung an Berufungsverfahren;
10. Erlassung der Curricula für ordentliche Studien und Lehrgänge (§§ 56 und 57);
11. Festlegung von akademischen Graden und Bezeichnungen für die Absolventinnen und Absolventen von Universitätslehrgängen;
12. Entscheidungen in zweiter Instanz in Studienangelegenheiten;
13. Festlegung der Kategorien für die Zweckwidmung der Studienbeiträge durch die Studierenden;
14. Einsetzung von Kollegialorganen mit und ohne Entscheidungsbefugnis (Abs. 7 und 8);
15. Erlassung von Richtlinien für die Tätigkeit von Kollegialorganen;
16. Genehmigung der Durchführung von Beschlüssen der entscheidungsbefugten Kollegialorgane;
17. Stellungnahme an das Rektorat vor der Zuordnung von Personen zu den einzelnen Organisationseinheiten durch das Rektorat;
18. Einrichtung eines Arbeitskreises für Gleichbehandlungsfragen;
19. Nominierung eines weiblichen und eines männlichen Mitglieds für die Schiedskommission;
20. Entsendung eines Mitglieds für die Schlichtungskommission.

(2) Der Senat besteht aus zwölf bis vierundzwanzig Mitgliedern. Die Anzahl der Mitglieder des ersten Senats ist vom Gründungskonvent (§ 120) festzulegen. Über eine Änderung der Größe des Senats entscheidet der Senat mit Zweidrittelmehrheit.

(3) Dem Senat gehören Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren, der im § 94 Abs. 2 Z 2 genannten Gruppe, des allgemeinen Universitätspersonals und der Studierenden an. Die Anzahl der Vertreterinnen und Vertreter dieser Gruppen wird vom Universitätsrat bestimmt, wobei jedenfalls die in Abs. 4 Z 1 genannten Vertreterinnen und Vertreter die absolute Mehrheit haben und die in Abs. 4 Z 4 genannten Vertreterinnen und Vertreter 25 vH der Mitglieder des Senats stellen müssen.

(4) Die Mitglieder und Ersatzmitglieder des Senats sind folgendermaßen zu bestellen:

1. Die Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren sind von allen Universitätsprofessorinnen und Universitätsprofessoren (§ 97) zu wählen.
2. Die Vertreterinnen und Vertreter der in § 94 Abs. 2 Z 2 genannten Gruppe sind von allen Universitätsdozentinnen und Universitätsdozenten (§ 122 Abs. 3) sowie den wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeitern im Forschungs-, Kunst- und Lehrbetrieb zu wählen. An den Universitäten gemäß § 6 Z 1 bis 15 muss den Gewählten zumindest eine Person mit Lehrbefugnis (venia docendi) angehören.
3. Die Vertreterinnen und Vertreter des allgemeinen Universitätspersonals sind von allen Angehörigen des allgemeinen Universitätspersonals zu wählen.
4. Die Vertreterinnen und Vertreter der Studierenden sind zu wählen.

(5) Die Funktionsperiode des Senats beträgt drei Jahre.

(6) Der Senat ist beschlussfähig, wenn wenigstens die Hälfte der Mitglieder anwesend ist. Er entscheidet mit Stimmenmehrheit, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(7) Vom Senat können zur Beratung oder Entscheidung einzelner seiner Aufgaben Kollegialorgane eingerichtet werden.

(8) Für folgende Angelegenheiten sind entscheidungsbefugte Kollegialorgane einzusetzen:

1. Habilitationsverfahren (§ 103),
2. Berufungsverfahren (§ 98),
3. Studienangelegenheiten gemäß § 25 Abs. 1 Z 10.

(9) Die Zahl der Mitglieder der Kollegialorgane gemäß Abs. 8 darf die Hälfte der Zahl der Senatsmitglieder nicht überschreiten. In den Kollegialorganen gemäß Abs. 8 Z 3 stellen die Studierenden mindestens ein Viertel der Mitglieder. Die Kollegialorgane gemäß Abs. 7 haben in ihrer Zusammensetzung der Relation der Vertreterinnen und Vertreter der einzelnen Gruppen im Senat zu entsprechen.

(10) Die Kollegialorgane gemäß Abs. 7 und Abs. 8 Z 3 sind längstens für die Dauer der Funktionsperiode des Senats einzurichten. Diese Kollegialorgane sind an die Richtlinien des Senats gebunden und entscheiden in dessen Namen. Der Senat kann eine gemäß Abs. 7 erteilte Entscheidungsvollmacht jederzeit widerrufen. Die Beschlüsse der Kollegialorgane gemäß Abs. 7 und Abs. 8 Z 3 bedürfen der Genehmigung des Senats.

(11) Bei der Festlegung der Kategorien für die Zweckwidmung der Studienbeiträge durch die Studierenden gemäß Abs. 1 Z 13 hat der Senat jedenfalls eine von den Vertreterinnen und Vertretern der Studierenden im Senat bestimmte Kategorie zu berücksichtigen.

2. Unterabschnitt

Forschungsförderung, Auftragsforschung und Vollmachten

Forschungsförderung und Auftragsforschung

§ 26. (1) Die Angehörigen des wissenschaftlichen und künstlerischen Universitätspersonals sind berechtigt, in ihrem Fach auch Forschungsvorhaben oder künstlerische Arbeiten an der Universität durchzuführen, die nicht aus dem Budget der Universität, sondern aus Forschungsaufträgen Dritter, aus Mitteln der Forschungsförderung oder aus anderen Zuwendungen Dritter finanziert werden. Die Durchführung solcher Vorhaben zählt zur Universitätsforschung.

(2) Voraussetzung für die Durchführung eines Vorhabens gemäß Abs. 1 an der Universität ist, dass

1. die Erfüllung der Pflichten aus dem Arbeitsverhältnis,
2. die Erfüllung der Aufgaben der betreffenden Organisationseinheit der Universität in der Forschung oder in der Entwicklung und Erschließung der Künste sowie im Lehrbetrieb und
3. die Rechte und Pflichten anderer Universitätsangehöriger

nicht beeinträchtigt werden.

(3) Für die Inanspruchnahme von Personal und Sachmitteln der Universität zur Durchführung von Forschungsaufträgen oder künstlerischen Arbeiten im Auftrag Dritter ist voller Kostenersatz an die Universität zu leisten. Über die Verwendung dieses Kostenersatzes entscheidet das Rektorat.

(4) Ein Vorhaben gemäß Abs. 1 ist dem Rektorat von der Projektleiterin oder vom Projektleiter vor der beabsichtigten Übernahme und Durchführung zu melden. Es ist nur zu untersagen, wenn die Voraussetzungen des Abs. 2 nicht erfüllt sind oder keine Vereinbarung über den vollen Kostenersatz vorliegt.

(5) Über die Verwendung der Projektmittel entscheidet die Projektleiterin oder der Projektleiter. Die Mittel für Vorhaben gemäß Abs. 1 sind von der Universität zu verwalten und ausschließlich auf Anweisung der Projektleiterin oder des Projektleiters zu verwenden.

(6) Mitarbeiterinnen und Mitarbeiter an einem Vorhaben gemäß Abs. 1 sind auf Vorschlag der oder des Universitätsangehörigen, die oder der dieses Vorhaben durchführt, gegen Ersatz der Personalkosten in ein zeitlich befristetes Arbeitsverhältnis zur Universität aufzunehmen.

Vollmachten

§ 27. (1) Jede Leiterin und jeder Leiter einer Organisationseinheit ist berechtigt, im Namen der Universität und im Zusammenhang mit deren Aufgaben

1. durch unentgeltliche Rechtsgeschäfte Vermögen und Rechte zu erwerben;
2. Förderungen anderer Rechtsträger entgegenzunehmen;
3. Verträge über die Durchführung wissenschaftlicher oder künstlerischer Arbeiten sowie über Untersuchungen und Befundungen im Auftrag Dritter abzuschließen, soweit sie der wissenschaftlichen Forschung (Entwicklung und Erschließung der Künste) dienen;
4. staatlich autorisierte technische Prüf- und Gutachtertätigkeiten durchzuführen, sofern die betreffende Universitätseinrichtung als staatlich autorisierte Prüfanstalt anerkannt ist;
5. von Vermögen und Rechten, die aus Rechtsgeschäften gemäß Z 1 bis 4 erworben werden, zur Erfüllung der Zwecke der Organisationseinheit Gebrauch zu machen.

Bei Missbrauch kann diese Berechtigung vom Rektorat entzogen werden.

(2) Jede oder jeder mit der Erfüllung von Verträgen gemäß Abs. 1 Z 3 verantwortlich betraute Universitätsangehörige (Projektleiterin oder Projektleiter) ist zum Abschluss der für die Vertragserfüllung erforderlichen Rechtsgeschäfte und zur Verfügung über die Geldmittel im Rahmen der Einnahmen aus diesem Vertrag zu ermächtigen. Diese Bevollmächtigungen sind im Mitteilungsblatt der Universität zu verlautbaren.

(3) Für die Inanspruchnahme von Personal und Sachmitteln der Universität zur Durchführung von Aufträgen Dritter (Abs. 1 Z 3 und 4) ist voller Kostenersatz an die Universität zu leisten. Über die Verwendung dieses Kostenersatzes entscheidet das Rektorat.

(4) Die der Universität auf Grund von Tätigkeiten gemäß Abs. 1 zufließenden Drittmittel sind, sofern keine Zweckwidmung vorliegt, für Zwecke jener Organisationseinheit zu verwenden, der die zeichnungsbefugte Arbeitnehmerin oder der zeichnungsbefugte Arbeitnehmer der Universität zugeordnet ist. Zur Erfüllung von Verpflichtungen der Universität auf Grund von Rechtsgeschäften gemäß Abs. 1 sind zunächst die Mittel heranzuziehen, die für die betreffende Organisationseinheit zweckgewidmet sind.

(5) Die gemäß Abs. 1 berechtigten oder gemäß Abs. 2 bevollmächtigten Universitätsangehörigen haben dem Rektorat über die Durchführung der von ihnen abgeschlossenen Rechtsgeschäfte zu berichten.

§ 28. (1) Die Rektorin oder der Rektor kann unter Beachtung der vom Rektorat erlassenen Richtlinien festlegen, welche Arbeitnehmerinnen und Arbeitnehmer der Universität Rechtsgeschäfte im Namen der Universität abschließen dürfen. Diese Bevollmächtigungen sind im Mitteilungsblatt der Universität zu verlautbaren.

(2) § 27 Abs. 4 und 5 gelten sinngemäß.

3. Unterabschnitt

Sonderbestimmungen für die Klinischen Bereiche der Medizinischen Universitäten

Organisation

§ 29. (1) Die Medizinischen Universitäten gemäß § 6 Z 4 bis 6 erfüllen ihre Forschungs- und Lehraufgaben im Klinischen Bereich auch im Zusammenwirken mit öffentlichen Krankenanstalten.

(2) Die organisatorische Gliederung des Klinischen Bereichs der Medizinischen Universität und der Krankenanstalt sind aufeinander abzustimmen. Dabei sind auch jene Einrichtungen der Medizinischen Universität festzulegen, die zur Unterstützung der Lehr- und Forschungsaufgaben des Klinischen Bereichs erforderlich sind. Vor der Erstellung des Organisationsplans für den Klinischen Bereich hat das

Rektorat daher das Einvernehmen mit dem Träger der Krankenanstalt herzustellen. Der Organisationsplan für den Klinischen Bereich bedarf der Zustimmung der Bundesministerin oder des Bundesministers.

(3) Die Medizinische Universität ist berechtigt, sich an einer Gesellschaft zur Führung des Betriebs der Krankenanstalt zu beteiligen.

(4) Die Medizinische Universität hat folgende Verpflichtungen:

1. Sie hat ihre in ärztlicher oder zahnärztlicher Verwendung stehenden Arbeitnehmerinnen und Arbeitnehmer mit der Mitwirkung an der Erfüllung der Aufgaben der Organisationseinheiten des Klinischen Bereichs als Einrichtungen der Krankenanstalt zu beauftragen. Diese Mitwirkung ist dem Rechtsträger dieser Krankenanstalt und nicht der Universität zuzurechnen. Ein Arbeitsverhältnis zum Rechtsträger der Krankenanstalt wird dadurch nicht begründet.
2. Sie hat die notwendigen Daten und Informationen aller Organisationseinheiten über die Erfordernisse von Forschung und Lehre zur Ermittlung und Abwicklung des Klinischen Mehraufwandes nach betriebswirtschaftlichen Kriterien zu erheben, zu dokumentieren und zu bewerten. Die Medizinische Universität hat ab 1. Jänner 2007 das Ergebnis ihrer Ermittlung der Leistung des Kostenersatzes gemäß § 55 des Krankenanstaltengesetzes zu Grunde zu legen, sofern nicht in einer Verordnung gemäß § 56 des Krankenanstaltengesetzes oder in einer Vereinbarung gemäß Abs. 5 eine andere Regelung getroffen wird.
3. Sie hat eine mittelfristige Planung für sämtliche Anlagen zu erstellen, die ganz oder teilweise dem Bedarf von Forschung und Lehre dienen und zu Mehrkosten im Sinne des § 55 Krankenanstaltengesetz führen. Diese Planung sowie Neuanschaffungen sind nach Maßgabe des Bedarfs für Forschung und Lehre unter Beachtung der Grundsätze der Sparsamkeit, Wirtschaftlichkeit und Zweckmäßigkeit sowie in Abstimmung mit den sonstigen Einrichtungen und Anschaffungen der Krankenanstalt vorzunehmen.

(5) Die Medizinische Universität hat mit dem Rechtsträger der Krankenanstalt nach Zustimmung der Bundesministerin oder des Bundesministers unter Bedachtnahme auf die Leistungsvereinbarung gemäß § 13 eine Vereinbarung über die Zusammenarbeit beim Betrieb der einzelnen zum Klinischen Bereich der Medizinischen Universität gehörenden und gleichzeitig einen Teil der öffentlichen Krankenanstalt bildenden Organisationseinheiten zu treffen, die auch die wechselseitigen Leistungen und deren Bewertung enthält.

(6) Den Organisationseinheiten einer Medizinischen Universität können gegen Ersatz der Kosten auch Aufgaben des öffentlichen Gesundheitswesens übertragen werden.

(7) Die Leiterin oder der Leiter der Universitätsklinik für Zahn-, Mund- und Kieferheilkunde der Medizinischen Universität Wien ist berechtigt, im Namen der Medizinischen Universität Wien Verträge über die Erbringung zahnärztlicher Leistungen abzuschließen.

(8) Die Wahrnehmung der Aufgaben im Rahmen einer öffentlichen Krankenanstalt und der allfälligen Aufgaben im Rahmen des Gesundheitswesens ist von der autonomen Besorgung durch die Universität ausgenommen (§ 61 Abs. 3 UOG 1993).

Ethikkommission

§ 30. (1) An jeder Medizinischen Universität ist vom Senat zur Beurteilung klinischer Prüfungen von Arzneimitteln und Medizinprodukten, der Anwendung neuer medizinischer Methoden und angewandter medizinischer Forschung an Menschen eine Ethikkommission einzurichten.

(2) Die Ethikkommissionen haben jedenfalls den Erfordernissen des § 8c Abs. 1 bis 5 und 7 des Krankenanstaltengesetzes, BGBl. Nr. 1/1957, zu entsprechen.

(3) Die Ethikkommission hat sich eine Geschäftsordnung zu geben. Diese ist dem Universitätsrat und dem Rechtsträger der Krankenanstalt im Wege der Rektorin oder des Rektors zur Kenntnis zu bringen.

(4) Die Mitglieder der Ethikkommission unterliegen in dieser Funktion weder Weisungen der Organe der Krankenanstalt noch Weisungen der Organe der Universität.

Gliederung des Klinischen Bereichs

§ 31. (1) Der Klinische Bereich einer Medizinischen Universität umfasst jene Einrichtungen, die funktionell gleichzeitig Organisationseinheiten einer öffentlichen Krankenanstalt sind.

(2) Die Organisationseinheiten einer Medizinischen Universität, in denen im Rahmen einer Krankenanstalt neben Forschungs- und Lehraufgaben auch ärztliche oder zahnärztliche Leistungen unmittelbar am Menschen erbracht werden, führen die Bezeichnung „Universitätsklinik“.

(3) Die Organisationseinheiten einer Medizinischen Universität, in denen im Rahmen einer Krankenanstalt neben Forschungs- und Lehraufgaben auch ärztliche Leistungen mittelbar für den Menschen erbracht werden, führen die Bezeichnung „Klinisches Institut“.

Leitungsfunktionen im Klinischen Bereich

§ 32. (1) Zur Leiterin oder zum Leiter einer Organisationseinheit einer Medizinischen Universität, die gleichzeitig die Funktion einer Krankenabteilung oder einer gleichzuwertenden Einrichtung einer öffentlichen Krankenanstalt (§ 7 Abs. 4 und § 7a Krankenanstaltengesetz) hat, darf nur eine Universitätsprofessorin oder ein Universitätsprofessor mit einschlägiger Facharzt- oder Zahnarztqualifikation bestellt werden. Zur Stellvertreterin oder zum Stellvertreter der Leiterin oder des Leiters darf nur eine Universitätsangehörige oder ein Universitätsangehöriger mit entsprechender Qualifikation als Fachärztin oder Facharzt oder als Zahnärztin oder Zahnarzt bestellt werden. Vor der Bestellung ist dem Rechtsträger der Krankenanstalt Gelegenheit zur Stellungnahme zu geben.

(2) Die Bestellung zur Leiterin oder zum Leiter sowie zur Stellvertreterin oder zum Stellvertreter der Leiterin oder des Leiters einer im Abs. 1 genannten Organisationseinheit hat zunächst zeitlich befristet zu erfolgen.

Kostenersatz an den Krankenanstaltenträger

§ 33. Die Medizinischen Universitäten sind verpflichtet, die Kostenersätze gemäß § 55 des Krankenanstaltengesetzes namens des Bundes an den jeweiligen Rechtsträger der Krankenanstalt zu leisten. Ausgenommen davon sind die Kostenersätze des Bundes für Klinikneubauten und Klinikumbauten sowie für die Ersteinrichtung dieser Gebäude.

Vertreterinnen und Vertreter der Ärzte und Zahnärzte

§ 34. Die im Klinischen Bereich einer Medizinischen Universität tätigen Ärztinnen und Ärzte sowie Zahnärztinnen und Zahnärzte mit Ausnahme der Leiterinnen und Leiter von Organisationseinheiten (§ 32) haben zur Wahrnehmung der Aufgaben gemäß § 3 Abs. 3 des Krankenanstalten-Arbeitszeitgesetzes, BGBl. I Nr. 8/1997, aus ihrer Mitte fünf Vertreterinnen oder Vertreter zu wählen.

Lehrkrankenhaus

§ 35. Abteilungen von Krankenanstalten, die nicht zum Klinischen Bereich einer Medizinischen Universität gehören, können von den Medizinischen Universitäten mit Zustimmung des Rechtsträgers der Krankenanstalt zur Verbesserung und Intensivierung des praktisch-medizinischen Unterrichts herangezogen werden. Werden mehrere Abteilungen einer solchen Krankenanstalt zu diesem Zweck ständig herangezogen, kann dieser Krankenanstalt von der betreffenden Medizinischen Universität die Bezeichnung „Lehrkrankenhaus“ verliehen werden.

4. Unterabschnitt
Sonderbestimmungen für die Veterinärmedizinische Universität Wien

Tierspital

§ 36. (1) Die Organisationseinheiten der Veterinärmedizinischen Universität Wien, die neben ihren Lehr- und Forschungsaufgaben auch tierärztliche Leistungen unmittelbar an lebenden Tieren zu erbringen haben, führen die Bezeichnung „Universitätsklinik“ und bilden gemeinsam organisatorisch das „Tierspital“.

(2) Für das Tierspital ist vom Rektorat durch Verordnung eine Anstaltsordnung zu erlassen, die der Genehmigung des Universitätsrats bedarf.

(3) Zu Leiterinnen und Leitern der Organisationseinheiten des Tierspitals dürfen nur Personen mit facheinschlägiger Qualifikation bestellt werden.

(4) Das den Organisationseinheiten des Tierspitals zugeordnete Personal hat an der Erfüllung der Aufgaben mitzuwirken, die dem Tierspital im Rahmen der Untersuchung und Behandlung von Tieren obliegen.

(5) Die Leiterinnen und Leiter der Organisationseinheiten des Tierspitals sind berechtigt, im Namen der Veterinärmedizinischen Universität Wien Verträge über die Erbringung tierärztlicher Leistungen abzuschließen.

(6) Die Wahrnehmung der tierärztlichen Aufgaben im Rahmen des Tierspitals ist von der autonomen Besorgung durch die Universität gemäß § 5 ausgenommen (§ 70 Abs. 4 UOG 1993).

Veterinärmedizinische Lehrinstitute und Organisationseinheit für Wildtierkunde und Ökologie

§ 37. (1) Tierkliniken, die nicht zur Veterinärmedizinischen Universität Wien gehören, und Tierarztpraxen können vom Rektorat mit Zustimmung der Betreiberin oder des Betreibers der Tierklinik oder der Tierarztpraxis zur Verbesserung und Intensivierung des praktisch-veterinärmedizinischen Unterrichts herangezogen werden. Wird eine Tierklinik oder eine Tierarztpraxis ständig zu diesem Zweck herangezogen, kann dieser die Bezeichnung „Veterinärmedizinisches Lehrinstitut“ verliehen werden.

(2) An der Veterinärmedizinischen Universität Wien ist eine Organisationseinheit mit der Bezeichnung „Forschungsinstitut für Wildtierkunde und Ökologie“ einzurichten.

(3) Die im Abs. 2 genannte Organisationseinheit ist in der Leistungsvereinbarung und im Rechnungsabschluss sowie im Leistungsbericht gesondert auszuweisen.

5. Unterabschnitt

Sonderbestimmungen für die Katholische und die Evangelische Theologie

§ 38. (1) Die Universitäten, deren Wirkungsbereich sich auch auf Studien der Katholischen Theologie erstreckt, haben bei der Gestaltung ihrer inneren Organisation und der Studienvorschriften sowie bei der Sicherstellung des Lehr- und Forschungsbetriebs das Konkordat zwischen dem Heiligen Stuhle und der Republik Österreich, BGBl. II Nr. 2/1934, zu beachten. Die Verpflichtung zur Einholung der Zustimmung gemäß Art. V § 3 und zu einer allfälligen Enthebung von der Ausübung der Lehrbefugnis gemäß Art. V § 4 obliegt der Rektorin oder dem Rektor.

(2) Die Universität, deren Wirkungsbereich sich auch auf Studien der Evangelischen Theologie erstreckt, hat bei der Gestaltung ihrer internen Organisation und der Studienvorschriften sowie bei der Sicherstellung des Lehr- und Forschungsbetriebs § 15 des Bundesgesetzes über äußere Rechtsverhältnisse der Evangelischen Kirche, BGBl. Nr. 182/1961, zu beachten. Die Verpflichtung, gemäß § 15 Abs. 4 des Bundesgesetzes über äußere Rechtsverhältnisse der Evangelischen Kirche vor der Auswahl aus dem Besetzungsvorschlag mit der Evangelischen Kirche Kontakt aufzunehmen, obliegt der Rektorin oder dem Rektor.

6. Unterabschnitt

Sonderbestimmungen für die Akademie der bildenden Künste Wien

Gemäldegalerie und Kupferstichkabinett

§ 39. (1) An der Akademie der bildenden Künste Wien sind folgende Organisationseinheiten einzurichten:

1. die „Gemäldegalerie der Akademie der bildenden Künste Wien“, der eine Glyptothek eingegliedert ist;
2. das „Kupferstichkabinett“.

Bei der Organisation dieser beiden Einrichtungen sind die Aufgaben und die besondere Stellung dieser Einrichtungen zu berücksichtigen.

(2) Die Gemäldegalerie ist eine durch eine Stiftung geschaffene Einrichtung. Sie hat die Aufgaben der gleichnamigen Einrichtung gemäß § 46 des Bundesgesetzes über die Organisation der Universitäten der Künste (KUOG) weiterzuführen. Sie hat durch ständige Schausammlungen und zusätzliche Ausstellungen für eine Darbietung ausgewählter Objekte ihrer Sammlungen für die Öffentlichkeit zu sorgen.

(3) Das Kupferstichkabinett hat die Aufgaben der gleichnamigen Einrichtung gemäß § 65 KUOG weiterzuführen. Es hat ausgewählte Objekte seiner Sammlung der Öffentlichkeit darzubieten.

(4) Zu Leiterinnen oder zu Leitern der Gemäldegalerie und des Kupferstichkabinetts dürfen nur Personen mit einschlägiger Ausbildung und entsprechend hoher fachlicher Qualifikation bestellt werden. Die Leiterin oder der Leiter der Gemäldegalerie trägt die Funktionsbezeichnung „Direktorin“ oder „Direktor“.

(5) Die Gemäldegalerie und das Kupferstichkabinett sind in der Leistungsvereinbarung und im Rechnungsabschluss sowie im Leistungsbericht der Akademie der bildenden Künste Wien gesondert auszuweisen.

7. Unterabschnitt

Sonderbestimmungen für den Universitätssport

§ 40. (1) An den Universitäten gemäß § 6 Z 1, 2, 3, 7, 10, 14 und 15 sind Universitäts-Sportinstitute eingerichtet, die den Studierenden, den Absolventinnen und Absolventen und dem Personal der Universitäten sowie der Fachhochschul-Studiengänge des Universitätsstandortes für sportliche Tätigkeiten und Wettkämpfe zur Verfügung stehen.

(2) Die Universitäts-Sportinstitute sind in der Leistungsvereinbarung und im Rechnungsabschluss sowie im Leistungsbericht der betreffenden Universität gesondert auszuweisen.

(3) Mittel, die dem Universitäts-Sportinstitut aus dem universitären Sportbetrieb und aus dem Betrieb von Universitätssportanlagen zufließen, sind für die Zwecke des Universitätssportes zu verwenden.

(4) Zur Leiterin oder zum Leiter eines Universitäts-Sportinstituts darf nur eine Person mit einschlägiger Ausbildung und entsprechender fachlicher Qualifikation bestellt werden.

3. Abschnitt

Gleichstellung von Frauen und Männern

Frauenfördergebot

§ 41. Alle Organe der Universität haben darauf hinzuwirken, dass in allen universitären Arbeitsbereichen ein ausgewogenes Zahlenverhältnis zwischen den an der Universität tätigen Frauen und Männern erreicht wird. Die Erreichung dieses Ziels ist durch geeignete Maßnahmen, insbesondere durch die Erlassung und Umsetzung eines Frauenförderungsplans, anzustreben.

Arbeitskreis für Gleichbehandlungsfragen

§ 42. (1) An jeder Universität ist vom Senat ein Arbeitskreis für Gleichbehandlungsfragen einzurichten, dessen Aufgabe es ist, Diskriminierungen durch Universitätsorgane auf Grund des Geschlechts entgegenzuwirken und die Angehörigen und Organe der Universität in Fragen der Gleichstellung von Frauen und Männern sowie der Frauenförderung zu beraten und zu unterstützen.

(2) Die Anzahl der Mitglieder des Arbeitskreises für Gleichbehandlungsfragen sowie deren Funktionsdauer ist in der Satzung festzulegen. Die im Senat vertretenen Gruppen von Universitätsangehörigen sind berechtigt, Mitglieder in einem in der Satzung festgelegten Verhältnis in den Arbeitskreis zu entsenden. Aus dem Kreis der Mitglieder des Arbeitskreises ist eine Vorsitzende oder ein Vorsitzender zu wählen.

(3) Die Mitglieder des Arbeitskreises für Gleichbehandlungsfragen sind bei der Ausübung ihrer Funktion an keine Weisungen oder Aufträge gebunden (§ 13 Abs. 2 UOG 1993 in Verbindung mit § 40 Abs. 7 UOG 1993, § 14 Abs. 2 in Verbindung mit § 40 Abs. 7 KUOG). Sie dürfen bei der Ausübung ihrer Befugnisse nicht behindert und wegen dieser Tätigkeit in ihrem beruflichen Fortkommen nicht benachteiligt werden.

(4) Den Mitgliedern des Arbeitskreises ist vom Rektorat in allen inneruniversitären Angelegenheiten Auskunft zu erteilen sowie Einsicht in die Geschäftsstücke, Unterlagen und in die automationsunterstützt aufgezeichneten Daten über das Personal der Universität zu geben, deren Kenntnis zur Erfüllung der Aufgaben des Arbeitskreises erforderlich ist. Auf Verlangen ist die Herstellung von Fotokopien dieser Unterlagen zu gestatten. Einsicht in die Personalakten ist nur mit Genehmigung der Betroffenen zulässig.

(5) Werden vom Arbeitskreis für Gleichbehandlungsfragen zur Vorbereitung seiner Beschlüsse Gutachten und Stellungnahmen facheinschlägiger Expertinnen oder Experten sowie Auskünfte eingeholt, dürfen diesen Expertinnen oder Experten die dafür erforderlichen Unterlagen zur Verfügung gestellt werden. Diese Expertinnen oder Experten sind zur Verschwiegenheit verpflichtet.

(6) Dem Arbeitskreis für Gleichbehandlungsfragen sind insbesondere unverzüglich zur Kenntnis zu bringen:

1. alle Ausschreibungstexte für die Besetzung von Stellen und Funktionen;
2. die Liste der eingelangten Bewerbungen;
3. die Liste der zu Aufnahmegesprächen eingeladenen Bewerberinnen und Bewerber.

(7) Das Rektorat hat gleichzeitig mit der Information des zuständigen Betriebsrats den Arbeitskreis für Gleichbehandlungsfragen darüber in Kenntnis zu setzen, mit welcher Bewerberin oder mit welchem

Bewerber ein Arbeitsvertrag abgeschlossen werden soll. Arbeitsverträge, die ohne vorherige Verständigung des Arbeitskreises oder vor Ablauf der Frist gemäß Abs. 8 abgeschlossen werden, sind unwirksam.

(8) Hat der Arbeitskreis für Gleichbehandlungsfragen Grund zur Annahme, dass die Entscheidung eines Universitätsorgans eine Diskriminierung von Personen auf Grund ihres Geschlechts darstellt, ist er berechtigt, innerhalb von zwei Wochen die Schiedskommission anzurufen.

(9) Betrifft die Beschwerde des Arbeitskreises für Gleichbehandlungsfragen eine Entscheidung über die Begründung, eine wesentliche Veränderung oder die Beendigung eines Arbeits- oder Ausbildungsverhältnisses, ist die Vollziehung der Entscheidung des Universitätsorgans bis zur Entscheidung der Schiedskommission unzulässig.

(10) Dem Universitätsrat und dem Rektorat ist jährlich ein Tätigkeitsbericht des Arbeitskreises zu übermitteln.

Schiedskommission

§ 43. (1) An jeder Universität ist eine Schiedskommission einzurichten. Zu ihren Aufgaben zählen:

1. die Vermittlung in Streitfällen von Angehörigen der Universität;
2. die Entscheidung über Beschwerden des Arbeitskreises für Gleichbehandlungsfragen wegen einer Diskriminierung auf Grund des Geschlechts durch die Entscheidung eines Universitätsorgans.

(2) Angelegenheiten, die einem Rechtszug unterliegen, und Leistungsbeurteilungen sind von der Prüfung durch die Schiedskommission ausgenommen.

(3) Die Schiedskommission hat bei der Erfüllung ihrer Aufgaben auf ein Einvernehmen zwischen den Beteiligten hinzuwirken.

(4) Alle Organe und Angehörigen der Universität sind verpflichtet, den Mitgliedern der Schiedskommission Auskünfte in der Sache zu erteilen und an Kontaktgesprächen teilzunehmen.

(5) Kann kein Einvernehmen erzielt werden, hat die Schiedskommission in den Angelegenheiten gemäß Abs. 1 Z 2, welche die Entscheidung über die Begründung, eine wesentliche Veränderung oder die Beendigung eines Arbeits- oder Ausbildungsverhältnisses betreffen, innerhalb von vier Wochen mit Bescheid darüber abzusprechen, ob durch die beabsichtigte Entscheidung des Universitätsorgans eine Diskriminierung auf Grund des Geschlechts vorliegt.

(6) Bejaht die Schiedskommission in den Fällen des Abs. 1 Z 2 das Vorliegen einer Diskriminierung auf Grund des Geschlechts, hat das Universitätsorgan eine neue Personalentscheidung unter Beachtung der Rechtsauffassung der Schiedskommission zu treffen.

(7) Gegen den Bescheid der Schiedskommission ist kein ordentliches Rechtsmittel zulässig. Der Arbeitskreis für Gleichbehandlungsfragen und das betroffene Universitätsorgan haben das Recht, gegen den das Verfahren abschließenden Bescheid vor dem Verwaltungsgerichtshof Beschwerde zu führen.

(8) Arbeitsverträge, die von der Rektorin oder vom Rektor während eines anhängigen Verfahrens vor der Schiedskommission oder trotz eines negativen Bescheids der Schiedskommission abgeschlossen werden, sind unwirksam.

(9) Die Schiedskommission besteht aus sechs Mitgliedern, die keine Angehörigen der betreffenden Universität sein müssen. Je ein männliches und ein weibliches Mitglied sind vom Senat, vom Universitätsrat und vom Arbeitskreis für Gleichbehandlungsfragen für eine Funktionsperiode von zwei Jahren zu nominieren. Zwei der Mitglieder müssen rechtskundig sein.

(10) Die Mitglieder der Schiedskommission sind bei der Ausübung dieser Funktion an keine Weisungen oder Aufträge gebunden (§ 13 Abs. 2 UOG 1993 und § 14 Abs. 2 KUOG).

(11) Die Schiedskommission entscheidet mit einfacher Mehrheit. Bei Stimmengleichheit gibt die Stimme der oder des Vorsitzenden den Ausschlag.

(12) Dem Universitätsrat und dem Rektorat ist jährlich ein Tätigkeitsbericht der Schiedskommission zu übermitteln.

Anwendung des Bundes-Gleichbehandlungsgesetzes

§ 44. Auf alle Angehörigen der Universität sowie auf die Bewerberinnen und Bewerber um Aufnahme in ein Arbeitsverhältnis zur Universität oder um Aufnahme als Studierende ist das Bundes-Gleichbehandlungsgesetz, BGBl. Nr. 100/1993, mit Ausnahme des vierten und fünften Abschnitts des dritten Teils und des § 50 mit der Maßgabe anzuwenden, dass die Universität als Dienststelle und als

Zentralstelle (§ 2 Abs. 1 und 2 B-GBG) gilt und sie die Pflicht zur Leistung von Schadenersatz gemäß § 10 Abs. 1 B-GBG trifft. Das Recht zur Erstellung eines Vorschlags für den Frauenförderungsplan (§ 41 Abs. 1 B-GBG) steht dem Arbeitskreis für Gleichbehandlungsfragen zu.

4. Abschnitt
Verfahren
Aufsicht

§ 45. (1) Die Universitäten unterliegen der Aufsicht des Bundes. Diese umfasst die Einhaltung der Gesetze und Verordnungen einschließlich der Satzung (Rechtsaufsicht).

(2) Die zuständigen Organe der Universität haben der Bundesministerin oder dem Bundesminister im Wege des Universitätsrats auf Verlangen unverzüglich alle zur Erfüllung ihrer oder seiner Aufgaben erforderlichen Auskünfte zu erteilen und alle erforderlichen Unterlagen zu übermitteln.

(3) Die Bundesministerin oder der Bundesminister hat mit Bescheid Entscheidungen von Universitätsorganen aufzuheben, wenn die betreffende Entscheidung im Widerspruch zu geltenden Gesetzen oder Verordnungen einschließlich der Satzung steht. Im Falle einer Verletzung von Verfahrensvorschriften hat eine Aufhebung nur dann zu erfolgen, wenn das Organ bei deren Einhaltung zu einem anderen Ergebnis hätte kommen können.

(4) Die Bundesministerin oder der Bundesminister hat mit Bescheid Wahlen, die im Widerspruch zu geltenden Gesetzen oder Verordnungen einschließlich der Satzung stehen, aufzuheben.

(5) Ab der formellen Einleitung eines aufsichtsbehördlichen Verfahrens durch das aufsichtsführende Organ ist die Durchführung der diesem Verfahren zu Grunde liegenden Beschlüsse bis zum Abschluss des Verfahrens unzulässig. Ein in diesem Zeitraum oder nach der aufsichtsbehördlichen Aufhebung des betreffenden Beschlusses dennoch ergangener Bescheid leidet an einem gemäß § 68 Abs. 4 Z 4 AVG mit Nichtigkeit bedrohten Fehler.

(6) Die Universitätsorgane sind im Fall der Abs. 3 und 4 verpflichtet, den der Rechtsanschauung der Bundesministerin oder des Bundesministers entsprechenden Rechtszustand unverzüglich herzustellen.

(7) Im aufsichtsbehördlichen Verfahren haben die Universitätsorgane Parteistellung sowie das Recht, gegen den das Verfahren abschließenden Bescheid vor dem Verwaltungsgerichtshof Beschwerde zu führen.

Verfahren in behördlichen Angelegenheiten

§ 46. (1) Die Universitätsorgane haben in allen behördlichen Angelegenheiten das Allgemeine Verwaltungsverfahrensgesetz 1991, BGBl. Nr. 51/1991, anzuwenden.

(2) In Studienangelegenheiten endet der administrative Instanzenzug in behördlichen Verfahren beim Senat.

(3) In Studienangelegenheiten sind auch die Organe der gesetzlichen Vertretung der Studierenden zur Einbringung von Rechtsmitteln berechtigt, sofern die betroffenen Studierenden nicht ausdrücklich die Zustimmung verweigern.

Säumnis von Organen

§ 47. (1) Kommt ein nicht zu den Leitungsorganen zählendes Organ einer Universität einer ihm nach diesem Bundesgesetz obliegenden Aufgabe nicht innerhalb angemessener Zeit nach, hat das Rektorat auf Antrag einer oder eines davon betroffenen Angehörigen der Universität oder von Amts wegen eine Frist von vier Wochen zu setzen, innerhalb der das säumige Organ die zu erfüllende Aufgabe nachzuholen hat. Lässt dieses die Frist verstreichen, ist die zu erfüllende Aufgabe vom Rektorat durchzuführen (Ersatzvornahme). Dies gilt nicht im Anwendungsbereich des § 73 des Allgemeinen Verwaltungsverfahrensgesetzes 1991.

(2) Ist der Senat, das Rektorat oder die Rektorin oder der Rektor im Sinne des Abs. 1 säumig, hat der Universitätsrat auf Antrag einer oder eines davon betroffenen Angehörigen der Universität oder von Amts wegen die Maßnahmen gemäß Abs. 1 zu setzen.

(3) Ist der Universitätsrat im Sinne des Abs. 2 oder in einer Angelegenheit des § 21 Abs. 1 säumig, hat die Bundesministerin oder der Bundesminister die Ersatzvornahme vorzunehmen.

Verschwiegenheitspflicht

§ 48. Die Mitglieder von Kollegialorganen und andere Universitätsorgane sind zur Amtsverschwiegenheit verpflichtet (Art. 20 Abs. 3 B-VG).

Haftung

§ 49. (1) Die Universität kann für sich Rechte und Pflichten begründen. Für Verbindlichkeiten, die daraus entstehen, trifft den Bund keine Haftung.

(2) Für den von Organen oder Arbeitnehmerinnen oder Arbeitnehmern der Universität oder von anderen Personen im Auftrag der Universität auf Grund dieses Bundesgesetzes in Wahrnehmung der hoheitlichen Aufgaben wem immer schuldhaft zugefügten Schaden haftet der Bund nach den Bestimmungen des Amtshaftungsgesetzes, BGBl. Nr. 20/1949. Der Bund hat in diesem Fall derjenigen oder demjenigen, die oder den sie für den Rückersatzanspruch für haftbar erachtet, den Streit zu verkünden (§ 21 Zivilprozessordnung, RGBl. Nr. 113/1895). Diese oder dieser kann dem Rechtsstreit als Nebenintervenientin oder Nebenintervenient beitreten (§ 17 Zivilprozessordnung). Die Universität und diejenige oder derjenige, die oder der den Schaden zugefügt hat, haften der oder dem Geschädigten nicht.

(3) Hat der Bund der oder dem Geschädigten gemäß Abs. 2 den Schaden ersetzt, ist er berechtigt, nach Maßgabe der §§ 3, 5 und 6 Abs. 2 des Amtshaftungsgesetzes von derjenigen oder demjenigen, die oder den sie für den Rückersatzanspruch für haftbar erachtet, Rückersatz zu fordern. In diesem Verfahren sind die zum Rückersatz herangezogenen Personen von der Verschwiegenheitspflicht befreit.

(4) Für die von Organen oder Arbeitnehmerinnen oder Arbeitnehmern der Universität oder von anderen Personen im Auftrag der Universität in Wahrnehmung der hoheitlichen Aufgaben dem Bund schuldhaft unmittelbar zugefügten Schäden haften diese Organe dem Bund nach den Bestimmungen des Organhaftpflichtgesetzes, BGBl. Nr. 181/1967, mit der Maßgabe, dass die zur Haftung herangezogenen Personen von der Verschwiegenheitspflicht befreit sind.

Rechtsvertretung

§ 50. Die Universität sowie Gesellschaften, deren Geschäftsanteile die Universität mittelbar oder unmittelbar zu mehr als 50 vH hält, sind berechtigt, sich von der Finanzprokuratur gemäß dem Prokuraturgesetz, StGBl. Nr. 172/1945, gegen Entgelt rechtlich beraten und vertreten zu lassen.

II. Teil
Studienrecht

1. Abschnitt
Allgemeine Bestimmungen

Begriffsbestimmungen

§ 51. (1) In Vollziehung der Studienvorschriften werden die Universitäten im Rahmen der Hoheitsverwaltung tätig.

(2) Im Geltungsbereich dieses Bundesgesetzes gelten folgende Begriffsbestimmungen:

1. Anerkannte postsekundäre Bildungseinrichtungen sind die Bildungseinrichtungen, die Studien im Ausmaß von mindestens sechs Semestern durchführen, bei denen die Zulassung die allgemeine Universitätsreife im Sinne dieses Bundesgesetzes oder bei künstlerischen Studien den Nachweis der künstlerischen Eignung voraussetzt und die auf Grund der Rechtsvorschriften des Staates, in dem sie ihren Sitz haben, als Bildungseinrichtungen im Sinne dieser Begriffsbestimmung anerkannt sind.
2. Ordentliche Studien sind die Diplomstudien, die Bakkalaureatsstudien, die Magisterstudien und die Doktoratsstudien.
3. Diplomstudien sind die ordentlichen Studien, die sowohl der wissenschaftlichen und künstlerischen Berufsvorbildung und der Qualifizierung für berufliche Tätigkeiten, welche die Anwendung wissenschaftlicher und künstlerischer Erkenntnisse und Methoden erfordern, als auch deren Vertiefung und Ergänzung dienen. Diese Studien erfüllen die Anforderungen der Richtlinie 89/48/EWG des Rates vom 21. Dezember 1988 über eine allgemeine Regelung zur Anerkennung der Hochschuldiplome, die eine mindestens dreijährige Berufsausbildung abschließen, Amtsblatt Nr. L 019 vom 24. Jänner 1989.
4. Bakkalaureatsstudien sind die ordentlichen Studien, die der wissenschaftlichen und künstlerischen Berufsvorbildung und der Qualifizierung für berufliche Tätigkeiten dienen, welche die Anwendung wissenschaftlicher und künstlerischer Erkenntnisse und Methoden erfordern. Diese Studien erfüllen die Anforderungen der Richtlinie 89/48/EWG des Rates vom 21. Dezember 1988 über eine allgemeine Regelung zur Anerkennung der Hochschuldiplome, die eine mindestens dreijährige Berufsausbildung abschließen.

5. Magisterstudien sind die ordentlichen Studien, die der Vertiefung und Ergänzung der wissenschaftlichen und künstlerischen Berufsvorbildung auf der Grundlage von Bakkalaureatsstudien dienen.
6. Studieneingangsphase ist das Angebot von Lehrveranstaltungen aus den das jeweilige Diplom- oder Bakkalaureatsstudium besonders kennzeichnenden Fächern, das der Information und der Orientierung der Studienanfängerinnen und Studienanfänger dient.
7. Bakkalaureatsarbeiten sind die im Bakkalaureatsstudium anzufertigenden eigenständigen schriftlichen Arbeiten, die im Rahmen von Lehrveranstaltungen abzufassen sind.
8. Diplom- und Magisterarbeiten sind die wissenschaftlichen Arbeiten in den Diplom- und Magisterstudien, die dem Nachweis der Befähigung dienen, wissenschaftliche Themen selbstständig sowie inhaltlich und methodisch vertretbar zu bearbeiten.
9. Künstlerische Diplom- und Magisterarbeiten sind künstlerische Arbeiten, die dem Nachweis der Befähigung dienen, im Hinblick auf das Studienziel des Studiums selbstständig und wissenschaftlich fundiert künstlerisch arbeiten zu können.
10. Bakkalaureatsgrade sind die akademischen Grade, die nach dem Abschluss der Bakkalaureatsstudien verliehen werden.
11. Magistergrade sind die akademischen Grade, die nach dem Abschluss der Magisterstudien verliehen werden.
12. Doktoratsstudien sind die ordentlichen Studien, die der Weiterentwicklung der Befähigung zu selbstständiger wissenschaftlicher Arbeit sowie der Heranbildung und Förderung des wissenschaftlichen Nachwuchses auf der Grundlage von Diplom- und Magisterstudien dienen.
13. Dissertationen sind die wissenschaftlichen Arbeiten, die anders als die Diplom- und Magisterarbeiten dem Nachweis der Befähigung zur selbstständigen Bewältigung wissenschaftlicher Fragestellungen dienen.
14. Doktorgrade sind die akademischen Grade, die nach dem Abschluss der Doktoratsstudien verliehen werden. Sie lauten „Doktorin …“ oder „Doktor …“, abgekürzt „Dr. …“, mit einem im Curriculum festzulegenden Zusatz.
15. Ordentliche Studierende sind die Studierenden, die zu den ordentlichen Studien zugelassen sind.
16. Allgemeine Universitätsreife ist jener Ausbildungsstand, der einer Person die Fähigkeit und das Recht vermittelt, bei Erfüllung allfälliger ergänzender studienspezifischer Erfordernisse zu einem ordentlichen Studium an einer Universität zugelassen zu werden.
17. Besondere Universitätsreife ist die Erfüllung ergänzender studienspezifischer Voraussetzungen für die Zulassung zu einem bestimmten ordentlichen Studium.
18. Ergänzungsprüfungen sind die Prüfungen zur Erlangung der allgemeinen Universitätsreife oder für den Nachweis der Kenntnis der deutschen Sprache oder der körperlich-motorischen Eignung.
19. Zulassungsprüfungen sind die Prüfungen, die unter Berücksichtigung der Vorbildungsmöglichkeiten dem Nachweis der künstlerischen Eignung für die künstlerischen Studien dienen.
20. Außerordentliche Studien sind die Universitätslehrgänge und der Besuch einzelner Lehrveranstaltungen aus wissenschaftlichen Fächern.
21. Universitätslehrgänge dienen der Weiterbildung. Die Einrichtung von Universitätslehrgängen zur Vorbereitung auf ein künstlerisches Bakkalaureats- oder Diplomstudium ist zulässig.
22. Außerordentliche Studierende sind die Studierenden, die zu den außerordentlichen Studien zugelassen sind.
23. Mastergrade sind die akademischen Grade, die für die Absolventinnen und Absolventen jener Universitätslehrgänge festgelegt werden, deren Zugangsbedingungen, Umfang und Anforderungen mit Zugangsbedingungen, Umfang und Anforderungen entsprechender ausländischer Masterstudien vergleichbar sind.
24. Curriculum ist die Verordnung, mit der das Qualifikationsprofil, der Inhalt und der Aufbau eines Studiums und die Prüfungsordnung festgelegt werden.
25. Prüfungsordnung ist der Teil des Curriculums, der die Arten der Prüfungen, die Festlegung der Prüfungsmethode und nähere Bestimmungen für das Prüfungsverfahren enthält.
26. Der Umfang der Studien ist im Sinne des Europäischen Systems zur Anrechnung von Studienleistungen (European Credit Transfer System – ECTS, 253/2000/EG, Amtsblatt Nr. L 28 vom 3. Februar 2000) in ECTS-Anrechnungspunkten anzugeben. Mit diesen Anrechnungspunkten ist der relative Anteil des mit den einzelnen Studienleistungen verbundenen Arbeitspensums zu bestimmen, wobei das Arbeitspensum eines Jahres 1 500 Echtstunden zu betragen hat und diesem Arbeitspensum 60 Anrechnungspunkte zugeteilt werden.

27. Doppeldiplom-Programme sind ordentliche Studien, die auf Grund von Vereinbarungen zwischen einer oder mehreren österreichischen Universitäten und einer oder mehreren ausländischen anerkannten postsekundären Bildungseinrichtungen gemeinsam durchgeführt werden, wobei in diesen Vereinbarungen festgelegt sein muss, welche Leistungen die betreffenden Studierenden an den beteiligten Institutionen zu erbringen haben.
28. Nostrifizierung ist die Anerkennung eines ausländischen Studienabschlusses als Abschluss eines inländischen ordentlichen Studiums.

(3) Studierende sind die nach den Bestimmungen dieses Bundesgesetzes durch das Rektorat zum Studium an der Universität zugelassenen Personen.

(4) Das Recht, als Vertreterin oder als Vertreter der Studierenden in Kollegialorganen tätig zu werden, richtet sich nach dem Hochschülerschaftsgesetz 1998, BGBl. I Nr. 22/1999.

Einteilung des Studienjahres

§ 52. Das Studienjahr besteht aus dem Wintersemester, dem Sommersemester und der lehrveranstaltungsfreien Zeit. Es beginnt am 1. Oktober und endet am 30. September des folgenden Jahres. Der Senat hat nähere Bestimmungen über Beginn und Ende der Semester und der lehrveranstaltungsfreien Zeit zu erlassen.

Fernstudien

§ 53. (1) In jedem Studium dürfen Fernstudieneinheiten festgelegt werden. Dabei ist die Erreichung des Lehrzieles durch die planmäßige Abfolge von unterrichtlicher Betreuung und Selbststudium der Teilnehmerinnen und Teilnehmer mittels geeigneter Lernmaterialien sicherzustellen.

(2) Die Aufgliederung der vorgesehenen Unterrichtseinheiten auf unterrichtliche Betreuung und Selbststudium, das Lehrangebot und die vorgesehenen Lernmaterialien sind den Studierenden vor Beginn der Fernstudieneinheit in geeigneter Weise bekannt zu machen.

2. Abschnitt
Studien

Bakkalaureats-, Magister-, Diplom- und Doktoratsstudien

§ 54. (1) Die Universitäten sind berechtigt, Diplom-, Bakkalaureats-, Magister- und Doktoratsstudien einzurichten, wobei folgende Bakkalaureats- und Magisterstudien angeboten werden dürfen:

1. Geistes- und kulturwissenschaftliche Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Philosophie“ bzw. „Bakkalaureus der Philosophie“, abgekürzt jeweils „Bakk. phil.“,
   Magistergrad: „Magistra der Philosophie“ bzw. „Magister der Philosophie“, abgekürzt jeweils „Mag. phil.“.
2. Ingenieurwissenschaftliche Studien:
   Bakkalaureatsgrad: „Bakkalaurea der technischen Wissenschaften“ bzw. „Bakkalaureus der technischen Wissenschaften“, abgekürzt jeweils „Bakk. techn.“,
   Magistergrad: „Diplom-Ingenieurin“ bzw. „Diplom-Ingenieur“, abgekürzt jeweils „Dipl.-Ing.“ oder „DI“.
3. Künstlerische Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Künste“ bzw. „Bakkalaureus der Künste“, abgekürzt jeweils „Bakk. art.“,
   Magistergrad: „Magistra der Künste“ bzw. „Magister der Künste“, abgekürzt jeweils „Mag. art.“.
4. Veterinärmedizinische Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Veterinärmedizin“ bzw. „Bakkalaureus der Veterinärmedizin“, abgekürzt jeweils „Bakk. med. vet.“,
   Magistergrad: „Magistra der Veterinärmedizin“ bzw. „Magister der Veterinärmedizin“, abgekürzt jeweils „Mag. med. vet.“.
5. Naturwissenschaftliche Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Naturwissenschaften“ bzw. „Bakkalaureus der Naturwissenschaften“, abgekürzt jeweils „Bakk. rer. nat.“,
   Magistergrad: „Magistra der Naturwissenschaften“ bzw. „Magister der Naturwissenschaften“, abgekürzt jeweils „Mag. rer. nat.“.

6. Rechtswissenschaftliche Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Rechtswissenschaften“ bzw. „Bakkalaureus der Rechtswissenschaften“, abgekürzt jeweils „Bakk. iur.“,
   Magistergrad: „Magistra der Rechtswissenschaften“ bzw. „Magister der Rechtswissenschaften“, abgekürzt jeweils „Mag. iur.“.
7. Sozial- und wirtschaftswissenschaftliche Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Sozial- und Wirtschaftswissenschaften“ bzw. „Bakkalaureus der Sozial- und Wirtschaftswissenschaften“, abgekürzt jeweils „Bakk. rer. soc. oec.“,
   Magistergrad: „Magistra der Sozial- und Wirtschaftswissenschaften“ bzw. „Magister der Sozial- und Wirtschaftswissenschaften“, abgekürzt jeweils „Mag. rer. soc. oec.“.
8. Theologische Studien:
   Bakkalaureatsgrad: „Bakkalaurea der Theologie“ bzw. „Bakkalaureus der Theologie“, abgekürzt jeweils „Bakk. theol.“,
   Magistergrad: „Magistra der Theologie“ bzw. „Magister der Theologie“, abgekürzt jeweils „Mag. theol.“.

(2) Neu einzurichtende Studien dürfen grundsätzlich nur als Bakkalaureats- und Magisterstudien eingerichtet werden. Die am 31. Dezember 2003 in der Anlage 1 zum Universitäts-Studiengesetz (UniStG), BGBl. I Nr. 48/1997, genannten Studien dürfen als Diplomstudien neu eingerichtet werden. Lehramtsstudien und Humanmedizinische Studien sowie Zahnmedizinische Studien dürfen nur in Form von Diplomstudien angeboten werden. Für die Diplomstudien sind jeweils die in der Anlage 1 zum UniStG genannten akademischen Grade festzulegen.

(3) Der Arbeitsaufwand für Bakkalaureatsstudien hat 180 ECTS-Anrechnungspunkte und für Magisterstudien mindestens 120 ECTS-Anrechnungspunkte zu betragen.

(4) Der Arbeitsaufwand für Doktoratsstudien hat mindestens 120 ECTS-Anrechnungspunkte zu betragen. Beträgt der Arbeitsaufwand mindestens 240 ECTS-Anrechnungspunkte, so darf das Studium als „Doctor of Philosophy“-Doktoratsstudium bezeichnet und der akademische Grad „Doctor of Philosophy“, abgekürzt „PhD“, verliehen werden.

(5) Curricula sind vor der Beschlussfassung dem Rektorat und dem Universitätsrat, Curricula theologischer Studien auch den zuständigen kirchlichen Stellen zur Stellungnahme zuzuleiten.

(6) Für die pädagogische und fachdidaktische Ausbildung in Lehramtsstudien sind in den Curricula unbeschadet der schulpraktischen Ausbildung 20 bis 25 vH des gesamten Arbeitspensums für das jeweilige Unterrichtsfach vorzusehen.

(7) Im Curriculum darf als Voraussetzung für die Anmeldung zu Lehrveranstaltungen, deren Verständnis besondere Vorkenntnisse erfordert, der Nachweis dieser Vorkenntnisse durch die positive Beurteilung bei einer oder mehreren Prüfungen oder in anderer zweckmäßiger Form festgelegt werden. Diese Festlegungen gelten auch für Studierende, die sich zu der betreffenden Lehrveranstaltung im Rahmen der Nutzung des Lehrangebotes oder eines individuellen Studiums anmelden.

(8) Im Curriculum ist für Lehrveranstaltungen mit einer beschränkten Zahl von Teilnehmerinnen und Teilnehmern die Anzahl der möglichen Teilnehmerinnen und Teilnehmer sowie das Verfahren zur Vergabe der Plätze festzulegen. Dabei ist zu beachten, dass den bei einer Anmeldung zurückgestellten Studierenden daraus keine Verlängerung der Studienzeit erwächst. Im Bedarfsfall sind überdies Parallellehrveranstaltungen, allenfalls auch während der sonst lehrveranstaltungsfreien Zeit, anzubieten.

(9) Studien dürfen auch gemeinsam mit anderen Universitäten durchgeführt werden.

(10) Die Universitäten sind auch berechtigt, Doppeldiplom-Programme durchzuführen.

Individuelles Studium

§ 55. (1) Fächer aus verschiedenen Diplom-, Bakkalaureats- oder Magisterstudien dürfen zu einem individuellen Diplom-, Bakkalaureats- oder Magisterstudium verbunden werden. Der Antrag auf Zulassung zu einem individuellen Studium ist an jener Universität einzubringen, an welcher der Schwerpunkt des geplanten Studiums liegen soll.

(2) Der Antrag hat jedenfalls zu enthalten:

1. die Bezeichnung des Studiums;
2. ein Curriculum einschließlich Qualifikationsprofil;
3. den Umfang in ECTS-Anrechnungspunkten;

4. wenn das Studium an mehreren Universitäten durchgeführt werden soll, die Zuordnung der Fächer zu den beteiligten Universitäten.

(3) Der Antrag ist vom für die Organisation der Studien zuständigen Organ bescheidmäßig zu genehmigen, wenn das beantragte Studium einem facheinschlägigen Studium gleichwertig ist. In der Genehmigung ist der Zeitpunkt der Zulassung zum individuellen Studium festzulegen.

(4) Absolventinnen und Absolventen individueller Bakkalaureatsstudien ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ jener Universität, an welcher der Schwerpunkt des Studiums gelegen ist, der akademische Grad „Bakkalaurea“ bzw. „Bakkalaureus“, abgekürzt jeweils „Bakk.“, Absolventinnen und Absolventen individueller Diplom- oder Magisterstudien ist der akademische Grad „Magistra“ bzw. „Magister“, abgekürzt jeweils „Mag.“, zu verleihen. Überwiegen in einem individuellen Diplom- oder Magisterstudium die Fächer aus ingenieurwissenschaftlichen Studien, ist den Absolventinnen und Absolventen der akademische Grad „Diplom-Ingenieurin“ bzw. „Diplom-Ingenieur“, abgekürzt jeweils „Dipl.-Ing.“ oder „DI“, zu verleihen.

Universitätslehrgänge

§ 56. Die Universitäten sind berechtigt, Universitätslehrgänge einzurichten. Die Universitätslehrgänge dürfen auch während der sonst lehrveranstaltungsfreien Zeit sowie zur wirtschaftlichen und organisatorischen Unterstützung in Zusammenarbeit mit anderen Rechtsträgern durchgeführt werden.

Vorbereitungslehrgänge

§ 57. Die Universitäten gemäß § 6 Z 16 bis 21 sind berechtigt, Vorbereitungslehrgänge zur Vorbereitung auf ein künstlerisches Bakkalaureats- oder Diplomstudium einzurichten.

Akademischer Grad und Bezeichnung für die Absolventinnen und Absolventen von Universitätslehrgängen

§ 58. (1) Im Curriculum eines Universitätslehrgangs dürfen im jeweiligen Fach international gebräuchliche Mastergrade festgelegt werden, die den Absolventinnen und Absolventen jener Universitätslehrgänge zu verleihen sind, deren Zugangsbedingungen, Umfang und Anforderungen mit Zugangsbedingungen, Umfang und Anforderungen entsprechender ausländischer Masterstudien vergleichbar sind.

(2) Wenn Abs. 1 nicht zur Anwendung kommt, darf die Bezeichnung „Akademische …“ bzw. „Akademischer …“ mit einem die Inhalte des jeweiligen Universitätslehrganges charakterisierenden Zusatz festgelegt werden, die den Absolventinnen und Absolventen jener Universitätslehrgänge zu verleihen ist, die mindestens 60 ECTS-Anrechnungspunkte umfassen.

(3) Den Urkunden über die Verleihung der Bezeichnung dürfen fremdsprachige Übersetzungen angeschlossen werden, wobei die Benennung der Universität und des ausstellenden Organs sowie die Bezeichnung selbst nicht zu übersetzen sind.

3. Abschnitt
Studierende

Rechte und Pflichten der Studierenden

§ 59. (1) Den Studierenden steht nach Maßgabe der gesetzlichen Bestimmungen Lernfreiheit zu. Sie umfasst insbesondere das Recht,

1. sowohl an der Universität, an der sie zum Studium zugelassen wurden, als auch an anderen Universitäten die Zulassung für andere Studien zu erlangen;
2. nach Maßgabe des Lehrangebotes und nach Maßgabe der Curricula zwischen dem Lehrpersonal auszuwählen;
3. neben einem ordentlichen Studium an der Universität der Zulassung oder anderen Universitäten das Lehrangebot zu nutzen, für welches die Studierenden die in den Curricula festgelegten Anmeldungsvoraussetzungen erfüllen;
4. die facheinschlägigen Lehr- und Forschungseinrichtungen und die Bibliothek an der Universität, an der sie zum Studium zugelassen wurden, nach Maßgabe der Benützungsordnungen zu benützen;

5. als ordentliche Studierende eines Diplom- oder Magisterstudiums das Thema ihrer Diplom- oder Magisterarbeit oder das Thema ihrer künstlerischen Diplom- oder Magisterarbeit nach Maßgabe der universitären Vorschriften vorzuschlagen oder aus einer Anzahl von Vorschlägen auszuwählen;
6. als ordentliche Studierende eines Doktoratsstudiums das Thema ihrer Dissertation nach Maßgabe der universitären Vorschriften vorzuschlagen oder aus einer Anzahl von Vorschlägen auszuwählen;
7. wissenschaftliche Arbeiten in einer Fremdsprache abzufassen, wenn die Betreuerin oder der Betreuer zustimmt;
8. als ordentliche Studierende nach Maßgabe der universitären Vorschriften Prüfungen abzulegen;
9. nach Erbringung der in den Curricula vorgeschriebenen Leistungen akademische Grade verliehen zu erhalten;
10. als außerordentliche Studierende an den betreffenden Universitätslehrgängen teilzunehmen und die darin vorgeschriebenen Prüfungen abzulegen;
11. als außerordentliche Studierende, die nur zum Besuch von Lehrveranstaltungen zugelassen sind, Lehrveranstaltungen zu besuchen, für welche sie die in den Curricula festgelegten Anmeldungsvoraussetzungen erfüllen, sowie nach Maßgabe der universitären Vorschriften Prüfungen abzulegen;
12. auf eine abweichende Prüfungsmethode, wenn die oder der Studierende eine länger andauernde Behinderung nachweist, die ihr oder ihm die Ablegung der Prüfung in der vorgeschriebenen Methode unmöglich macht, und der Inhalt und die Anforderungen der Prüfung durch eine abweichende Methode nicht beeinträchtigt werden;
13. auf Anträge hinsichtlich der Person der Prüferinnen oder Prüfer. Diese Anträge sind nach Möglichkeit zu berücksichtigen. Bei der zweiten Wiederholung einer Prüfung ist dem Antrag auf eine bestimmte Prüferin oder einen bestimmten Prüfer der Universität der Zulassung zum Studium, in dem die Prüfung abzulegen ist, jedenfalls zu entsprechen; und
14. nach Maßgabe des § 78 auf Anerkennung erbrachter, den Universitätsstudien gleichwertiger Vorleistungen zur Verkürzung der Studienzeit.

(2) Die Studierenden haben

1. der Universität, an der eine Zulassung zum Studium besteht, Namens- und Adressenänderungen unverzüglich bekannt zu geben;
2. die Fortsetzung des Studiums der Universität, an der die Zulassung zu einem Studium besteht, jedes Semester während der allgemeinen Zulassungsfrist oder der Nachfrist zu melden;
3. sich bei vorhersehbarer Studieninaktivität zeitgerecht vom Studium abzumelden;
4. sich zu den Prüfungen fristgerecht an- und abzumelden und
5. anlässlich der Verleihung des akademischen Grades je ein Exemplar ihrer Diplom- oder Magisterarbeit oder künstlerischen Diplom- oder Magisterarbeit oder Dissertation oder eine Dokumentation ihrer künstlerischen Diplom- oder Magisterarbeit an die Universitätsbibliothek und je ein Exemplar der Dissertation an die Österreichische Nationalbibliothek abzuliefern.

(3) Prüfungstermine sind jedenfalls für den Anfang, für die Mitte und für das Ende jeden Semesters anzusetzen.

(4) Die berufstätigen Studierenden und die Studierenden mit Kinderbetreuungspflichten oder anderen gleichartigen Betreuungspflichten, die somit nicht Vollzeit studieren, sondern nur einen Teil ihrer Zeit dem Studium widmen können, sind berechtigt zu melden, zu welchen Tageszeiten sie einen besonderen Bedarf nach Lehr- und Prüfungsangeboten haben. Die Universitäten haben diesen besonderen Bedarf auf Grund der Meldeergebnisse bei der Gestaltung ihres Lehr- und Prüfungsangebotes nach Möglichkeit zu berücksichtigen. Bereits anlässlich der Zulassung zu einem Studium hat die Antragstellerin oder der Antragsteller das Recht, diesen Bedarf zu melden.

(5) Als Information über den Titel, die Art, die Zeit und den Ort der Abhaltung der Lehrveranstaltungen jedes Semesters ist ein Verzeichnis der Lehrveranstaltungen mindestens einmal im Studienjahr zu veröffentlichen.

(6) Die Leiterinnen und Leiter der Lehrveranstaltungen haben vor Beginn jedes Semesters die Studierenden in geeigneter Weise über die Ziele, die Inhalte und die Methoden ihrer Lehrveranstaltungen sowie über die Inhalte, die Methoden, die Beurteilungskriterien und die Beurteilungsmaßstäbe der Lehrveranstaltungsprüfungen zu informieren.

Verfahren der Zulassung zum Studium

§ 60. (1) Das Rektorat hat Personen, welche die Zulassungsvoraussetzungen erfüllen, auf Grund ihres Antrages mit Bescheid zum jeweiligen Studium an dieser Universität zuzulassen.

(2) Soweit zur Beurteilung der Erfüllung der Zulassungsvoraussetzungen fremdsprachige Urkunden vorgelegt werden, hat die Antragstellerin oder der Antragsteller autorisierte Übersetzungen anfertigen zu lassen.

(3) Das Rektorat ist berechtigt, die Verpflichtung zur Vorlage einzelner Unterlagen nachzusehen, wenn glaubhaft gemacht wird, dass deren Beibringung innerhalb einer angemessenen Frist unmöglich oder mit übergroßen Schwierigkeiten verbunden ist, und die vorgelegten Unterlagen für eine Entscheidung ausreichen.

(4) Mit der Zulassung wird die Antragstellerin oder der Antragsteller als ordentliche oder außerordentliche Studierende oder ordentlicher oder außerordentlicher Studierender Angehörige oder Angehöriger dieser Universität. Dies ist durch die Ausstellung eines Ausweises zu beurkunden, der als Lichtbildausweis ausgestaltet sein kann. Der Ausweis hat zumindest Namen, Geburtsdatum und Matrikelnummer der oder des Studierenden und die Gültigkeitsdauer zu enthalten.

(5) Einer Antragstellerin oder einem Antragsteller, die oder der noch an keiner Universität zugelassen war, hat die Universität anlässlich der erstmaligen Zulassung eine Matrikelnummer zuzuordnen. Diese ist für alle weiteren Studienzulassungen der oder des betreffenden Studierenden beizubehalten. Die näheren Bestimmungen über Bildung und Vergabe von Matrikelnummern sind durch Verordnung der Bundesministerin oder des Bundesministers zu treffen.

(6) Universitäten gemäß § 6 Z 1 bis 15 stellen ausländischen Antragstellerinnen und Antragstellern, die zur sichtvermerksfreien Einreise berechtigt sind oder über einen gültigen Aufenthaltstitel verfügen, den Zulassungsbescheid direkt zu. Langen an österreichischen Berufsvertretungsbehörden Anträge anderer ausländischer Antragstellerinnen und Antragsteller auf Zulassung zum Studium zur Weiterleitung an die zuständige Universität ein, können die Berufsvertretungsbehörden auf die Vollständigkeit und Schlüssigkeit des Antrags sowie darauf hinwirken, dass die Zulassung zum Studium und der Erstaufenthaltstitel zeitgleich zugestellt werden können. Hiebei ist der Antragstellerin oder dem Antragsteller Gelegeheit zu geben, auf ihre oder seine Kosten Ergänzungen und Klarstellungen vorzunehmen.

Zulassungsfristen

§ 61. (1) Das Rektorat hat nach Anhörung des Senates für jedes Semester die allgemeine Zulassungsfrist festzulegen. Dies ist der Zeitraum, in dem die in Abs. 3 bezeichneten Personen ihre Anträge auf Zulassung einzubringen und den Studienbeitrag zu entrichten haben. Die allgemeine Zulassungsfrist hat mindestens vier Wochen zu betragen und spätestens vier Wochen nach Beginn des Semesters zu enden.

(2) Mit Ablauf der allgemeinen Zulassungsfrist beginnt die Nachfrist, die im Wintersemester am 30. November, im Sommersemester am 30. April endet. Innerhalb der Nachfrist ist die Zulassung und die Meldung der Fortsetzung des Studiums zulässig, wenn der erhöhte Studienbeitrag einbezahlt wird.

(3) Die allgemeine Zulassungsfrist gilt für:

1. österreichische Staatsangehörige;
2. Staatsangehörige einer anderen Vertragspartei des EU-Beitrittsvertrages, BGBl. Nr. 45/1995, oder einer anderen Vertragspartei des Abkommens über den Europäischen Wirtschaftsraum, BGBl. Nr. 909/1993;
3. andere ausländische Staatsangehörige und Staatenlose, die eine auf höchstens zwei Semester befristete Zulassung zum Studium in Österreich entweder auf Grund transnationaler EU-, staatlicher oder universitärer Mobilitätsprogramme, einschließlich Doppeldiplom-Programme, oder nach Absolvierung ausländischer Studien in einem der ersten Diplomprüfung des gewählten Diplomstudiums oder einem Bakkalaureatsstudium entsprechenden Umfang anstreben;
4. Personengruppen, welche die Bundesministerin oder der Bundesminister auf Grund deren besonderer persönlicher Nahebeziehungen zu Österreich oder deren Tätigkeit im Auftrag der Republik Österreich durch Verordnung festlegt;
5. alle Antragstellerinnen und Antragsteller auf Zulassung zu einem Studium an den Universitäten gemäß § 6 Z 16 bis 21.

(4) Für alle anderen ausländischen Staatsangehörigen und Staatenlosen gilt die besondere Zulassungsfrist. Sie endet bei Antragstellung für das Wintersemester am 1. September, bei Antragstellung für

das Sommersemester am 1. Februar jedes Kalenderjahres. Die Anträge müssen vor dem Ende dieser Frist vollständig in der gewählten Universität einlangen.

(5) Das Rektorat ist unter Berücksichtigung der Dauer und des Durchführungszeitraumes berechtigt, für die Zulassung zu Universitätslehrgängen und für die Zulassung zu ordentlichen Studien im Rahmen transnationaler EU-, staatlicher oder universitärer Mobilitätsprogramme, einschließlich Doppeldiplom-Programme, eine abweichende Regelung für die allgemeine Zulassungsfrist zu treffen.

Meldung der Fortsetzung des Studiums

§ 62. (1) Die Studierenden sind verpflichtet, innerhalb der allgemeinen Zulassungsfrist oder der Nachfrist jedes Semesters der Universität, an der eine Zulassung zum Studium besteht, die Fortsetzung des Studiums zu melden.

(2) Die Meldung der Fortsetzung des Studiums ist unwirksam,

1. solange die allfälligen Studienbeiträge nicht eingelangt sind;
2. solange eine Zusatzprüfung, die gemäß der Universitätsberechtigungsverordnung – UBVO 1998, BGBl. II Nr. 44, im Verlauf des Studiums abzulegen ist, nicht fristgerecht nachgewiesen wird.

(3) Die Wirkung der Meldung der Fortsetzung des Studiums für ein Semester erstreckt sich bis zum Ende der Nachfrist des unmittelbar darauf folgenden Semesters, sofern die Zulassung zum Studium noch nicht erloschen ist.

(4) Über die Meldung der Fortsetzung des Studiums hat die Universität den Studierenden Studienbestätigungen auszustellen. Diese müssen jedenfalls Namen, Geburtsdatum, Matrikelnummer und Sozialversicherungsnummer der oder des Studierenden sowie den Studierendenstatus, das Studium und das Semester enthalten.

Zulassung zu ordentlichen Studien

§ 63. (1) Die Zulassung zu einem ordentlichen Studium setzt voraus:

1. die allgemeine Universitätsreife;
2. die besondere Universitätsreife für das gewählte Studium;
3. die Kenntnis der deutschen Sprache;
4. die künstlerische Eignung für die Studien an den Universitäten gemäß § 6 Z 16 bis 21 und
5. die körperlich-motorische Eignung für das Lehramtsstudium im Unterrichtsfach Leibeserziehung und das Studium der Sportwissenschaften.

(2) Personen, die zu dem Studium, für das die Zulassung beantragt wird, bereits an einer anderen inländischen Universität zugelassen waren, haben mit dem Antrag auf Zulassung die Abgangsbescheinigung dieser Universität vorzulegen.

(3) Bei Nachweis der allgemeinen und der besonderen Universitätsreife sind unbefristet zuzulassen:

1. österreichische Staatsangehörige;
2. Staatsangehörige einer anderen Vertragspartei des EU-Beitrittsvertrages oder einer anderen Vertragspartei des Abkommens über den Europäischen Wirtschaftsraum;
3. andere ausländische Staatsangehörige und Staatenlose, wenn im betreffenden Studium vertretbare Studienbedingungen (Abs. 4) bestehen;
4. Personengruppen, welche die Bundesministerin oder der Bundesminister auf Grund deren besonderer persönlicher Nahebeziehungen zu Österreich oder deren Tätigkeit im Auftrag der Republik Österreich durch Verordnung festlegt.

(4) Der Senat ist berechtigt, auf Grund der Verhältniszahl zwischen Lehrenden und Studierenden in einem Studium Studienbedingungen festzustellen, die durch die weitere Zulassung von ausländischen Staatsangehörigen und Staatenlosen gemäß Abs. 3 Z 3 unvertretbar würden. In diesem Fall hat der Senat festzulegen, wie viele dieser Personen jedes Semester zugelassen werden können, ohne dass unvertretbare Studienbedingungen entstehen, und nach welchen Kriterien die allenfalls zahlenmäßig beschränkte Zulassung erfolgt. Es ist dabei zulässig, eine bevorzugte Zulassung von Antragstellerinnen oder Antragstellern aus Entwicklungsländern zu beschließen. Diese Festlegungen sind im Mitteilungsblatt der Universität zu verlautbaren.

(5) Bei Nachweis der allgemeinen und der besonderen Universitätsreife sind ohne Berücksichtigung allfälliger Beschlüsse gemäß Abs. 4 befristet zuzulassen:

1. Personen, die an universitären Mobilitätsprogrammen, einschließlich Doppeldiplom-Programmen, teilnehmen, für die Dauer der bewilligten Programmteilnahme;

2. Personen, die ausschließlich Fernstudienangebote auf der Grundlage von Kooperationsverträgen nützen wollen, für höchstens zwei Semester;
3. ausländische Staatsangehörige und Staatenlose gemäß Abs. 3 Z 3, die nach Absolvierung ausländischer Studien in einem der ersten Diplomprüfung des gewählten Diplomstudiums oder einem Bakkalaureatsstudium entsprechenden Umfang eine Zulassung zum Studium in Österreich anstreben, für höchstens zwei Semester.

Die Verlängerung der jeweiligen Befristung ist unzulässig.

(6) Die befristete Zulassung gemäß Abs. 5 Z 1 und 2 setzt voraus, dass ein Kooperationsvertrag zwischen den beteiligten Universitäten besteht, der die Bedingungen für die Zusammenarbeit, den Austausch der Studierenden und die Durchführung näher regelt. Mit der Nominierung durch die Partneruniversität gelten die allgemeine und die besondere Universitätsreife als nachgewiesen.

(7) Nach dem Erlöschen der Zulassung wegen der negativen Beurteilung bei der letzten zulässigen Wiederholung einer Prüfung ist die neuerliche Zulassung für dieses Studium an der Universität, an der die letzte zulässige Wiederholung der Prüfung nicht bestanden wurde, ausgeschlossen.

(8) Die gleichzeitige Zulassung für dasselbe Studium an mehr als einer Universität in Österreich ist unzulässig. Weitere Zulassungen für dasselbe Studium an anderen Universitäten leiden im Sinne des § 68 Abs. 4 Z 4 AVG an einem mit Nichtigkeit bedrohten Fehler und sind von der Bundesministerin oder dem Bundesminister von Amts wegen für nichtig zu erklären.

(9) Die Ablegung von Prüfungen für ein Studium an einer anderen als der Universität der Zulassung ist nur zulässig, wenn

1. das Curriculum eines gemeinsam mit einer anderen Universität eingerichteten Studiums dies vorsieht;
2. das für die studienrechtlichen Angelegenheiten zuständige Organ die Ablegung der Prüfung an der anderen Universität im Voraus genehmigt, weil die Ablegung der betreffenden Prüfung an der Universität, an der die oder der Studierende für dieses Studium zugelassen ist, nicht möglich ist, oder
3. es sich um Prüfungen auf der Grundlage neuer Medien, insbesondere von On-line-Studienangeboten handelt.

(10) Personen, deren Muttersprache nicht Deutsch ist, haben die Kenntnis der deutschen Sprache, sofern und soweit diese für einen erfolgreichen Studienfortgang erforderlich ist, nachzuweisen. Der Nachweis wird insbesondere durch ein Reifezeugnis auf Grund des Unterrichts in deutscher Sprache erbracht.

(11) Kann der Nachweis der deutschen Sprache nicht erbracht werden, so hat das Rektorat die Ablegung einer Ergänzungsprüfung vorzuschreiben, die vor der Zulassung abzulegen ist. In den künstlerischen Studien kann im Curriculum festgelegt werden, dass die Ablegung der Ergänzungsprüfung spätestens vor der Meldung der Fortsetzung des Studiums für das dritte Semester nachzuweisen ist.

Allgemeine Universitätsreife

§ 64. (1) Die allgemeine Universitätsreife ist durch eine der folgenden Urkunden nachzuweisen:

1. österreichisches Reifezeugnis einschließlich eines Zeugnisses über die Berufsreifeprüfung;
2. anderes österreichisches Zeugnis über die Zuerkennung der Studienberechtigung für ein bestimmtes Studium an einer Universität;
3. ausländisches Zeugnis, das einem dieser österreichischen Zeugnisse auf Grund einer völkerrechtlichen Vereinbarung oder auf Grund einer Nostrifikation oder auf Grund der Entscheidung des Rektorats im Einzelfall gleichwertig ist;
4. Urkunde über den Abschluss eines mindestens dreijährigen Studiums an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung;
5. in den künstlerischen Studien die Bestätigung über die positiv beurteilte Zulassungsprüfung;
6. Urkunde über den Abschluss eines mindestens dreijährigen Lehrganges universitären Charakters.

(2) Ist die Gleichwertigkeit ausländischer Zeugnisse im Hinblick auf die Inhalte und die Anforderungen einer österreichischen Reifeprüfung nicht gegeben, so sind vom Rektorat die Ergänzungsprüfungen vorzuschreiben, die für die Herstellung der Gleichwertigkeit mit einer inländischen Reifeprüfung erforderlich und vor der Zulassung abzulegen sind.

(3) Für die in Österreich ausgestellten Reifezeugnisse ist die Ablegung jener Zusatzprüfungen zur Reifeprüfung vorzuschreiben, die gemäß UBVO 1998 im Verlaufe des Studiums nachzuweisen sind.

(4) Der Nachweis der allgemeinen Universitätsreife für die Zulassung zu Doktoratsstudien gilt jedenfalls durch den Nachweis des Abschlusses eines fachlich in Frage kommenden Diplomstudiums oder

Magisterstudiums, eines fachlich in Frage kommenden Fachhochschul-Diplomstudienganges oder Fachhochschul-Magisterstudienganges oder eines anderen gleichwertigen Studiums an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung als erbracht. Wenn die Gleichwertigkeit grundsätzlich gegeben ist und nur einzelne Ergänzungen auf die volle Gleichwertigkeit fehlen, ist das Rektorat berechtigt, die Feststellung der Gleichwertigkeit mit der Auflage von Prüfungen zu verbinden, die während des jeweiligen Doktoratsstudiums abzulegen sind.

(5) Die Zulassung zu einem Magisterstudium setzt den Abschluss eines fachlich in Frage kommenden Bakkalaureatsstudiums oder eines fachlich in Frage kommenden Fachhochschul-Bakkalaureatsstudienganges oder eines anderen gleichwertigen Studiums an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung voraus. Der Nachweis der allgemeinen Universitätsreife gilt durch den Nachweis dieser Zulassungsvoraussetzung jedenfalls als erbracht.

Besondere Universitätsreife

§ 65. (1) Zusätzlich zur allgemeinen Universitätsreife ist die Erfüllung der studienspezifischen Zulassungsvoraussetzungen einschließlich des Rechts zur unmittelbaren Zulassung zum Studium nachzuweisen, die im Ausstellungsstaat der Urkunde, mit der die allgemeine Universitätsreife nachgewiesen wird, bestehen. Der Nachweis eines Studienplatzes ist nicht zu fordern.

(2) Für die in Österreich ausgestellten Reifezeugnisse handelt es sich um jene Zusatzprüfungen zur Reifeprüfung, deren Ablegung auf Grund der UBVO 1998 vor der Zulassung zum Studium vorgeschrieben ist.

(3) Ist das in Österreich angestrebte Studium im Ausstellungsstaat der Urkunde nicht eingerichtet, sind die studienspezifischen Zulassungsvoraussetzungen in Bezug auf ein im Ausstellungsstaat der Urkunde eingerichtetes, mit dem in Österreich angestrebten Studium fachlich am nächsten verwandtes Studium zu erfüllen.

(4) Die Bundesministerin oder der Bundesminister ist berechtigt, durch Verordnung Personengruppen festzulegen, deren Reifezeugnis auf Grund deren besonderer persönlicher Nahebeziehungen zu Österreich oder deren Tätigkeit im Auftrag der Republik Österreich für die Ermittlung des Vorliegens der besonderen Universitätsreife als in Österreich ausgestellt gilt.

(5) Auf Grund der für den Nachweis der allgemeinen Universitätsreife vorgelegten Urkunde ist das Vorliegen der besonderen Universitätsreife im Hinblick auf das gewählte Studium zu prüfen.

Studieneingangsphase

§ 66. (1) In den Diplom- und Bakkalaureatsstudien ist im Curriculum eine Studieneingangsphase für die Studienanfängerinnen und Studienanfänger zu gestalten, in die Lehrveranstaltungen aus den einführenden und das Studium besonders kennzeichnenden Fächern einzubeziehen sind.

(2) Zur studienvorbereitenden Beratung ist für die Abhaltung von Orientierungsveranstaltungen zu sorgen.

(3) Anlässlich der Zulassung zum Diplom- oder Bakkalaureatsstudium sind die Studierenden in geeigneter Form über die wesentlichen Bestimmungen des Universitätsrechts und des Studienförderungsrechts, die studentische Mitbestimmung in den Organen der Universität, die Rechtsgrundlagen der Frauenförderung und den gesetzlichen Diskriminierungsschutz, das Curriculum, das Qualifikationsprofil der Absolventinnen und der Absolventen, die Studieneingangsphase, das empfohlene Lehrangebot in den ersten beiden Semestern sowie insbesondere über die Zahl der Studierenden im Studium, die durchschnittliche Studiendauer, die Studienerfolgsstatistik und die Beschäftigungsstatistik zu informieren.

(4) Zur studienbegleitenden Beratung sind Anfängerinnen- und Anfängertutorien einzurichten, welche die Studierenden bei der Bewältigung der leistungsmäßigen, organisatorischen und sozialen Anforderungen des ersten Studienjahres unterstützen sollen und von den Studierenden besucht werden können. Es ist zulässig, diese Anfängerinnen- und Anfängertutorien auch im Zusammenwirken mit anderen Rechtsträgern, insbesondere mit der Österreichischen Hochschülerschaft zu veranstalten.

Beurlaubung

§ 67. (1) Die Universitäten haben festzulegen, dass Studierende auf Antrag für höchstens zwei Semester je Anlassfall, insbesondere wegen Ableistung eines Präsenz- oder Zivildienstes, wegen Schwangerschaft oder wegen Betreuung eigener Kinder, bescheidmäßig zu beurlauben sind. Näheres ist in der Satzung festzulegen.

(2) Während der Beurlaubung bleibt die Zulassung zum Studium aufrecht. Die Teilnahme an Lehrveranstaltungen, die Ablegung von Prüfungen sowie die Einreichung und Beurteilung wissenschaftlicher Arbeiten sowie künstlerischer Magister- und Diplomarbeiten ist unzulässig.

Erlöschen der Zulassung zu ordentlichen Studien

§ 68. (1) Die Zulassung zu einem Studium erlischt, wenn die oder der Studierende

1. sich vom Studium abmeldet;
2. die Meldung der Fortsetzung des Studiums unterlässt, ohne beurlaubt zu sein;
3. bei einer für ihr oder sein Studium vorgeschriebenen Prüfung auch bei der letzten zulässigen Wiederholung negativ beurteilt wurde, wobei sich die Zahl der zulässigen Wiederholungen nach den Prüfungsantritten an der jeweiligen Universität in den facheinschlägigen Studien bemisst;
4. das Recht auf unmittelbare Zulassung für dieses Studium oder auf Fortsetzung des Studiums im Ausstellungsstaat der Urkunde, mit der die allgemeine Universitätsreife nachgewiesen wurde, verloren hat, weil sie oder er eine hiefür erforderliche Prüfung nicht rechtzeitig abgelegt hat;
5. im Falle der befristeten Zulassung das Teilstudium im Befristungsausmaß absolviert hat oder
6. das Studium durch die positive Beurteilung bei der letzten vorgeschriebenen Prüfung abgeschlossen hat.

(2) An den Universitäten gemäß § 6 Z 16 bis 21 kann in der Satzung vorgesehen werden, dass die Zulassung zum Studium erlischt, wenn mehr als drei Semester während der gesamten Studiendauer das jeweilige Lehrangebot aus dem zentralen künstlerischen Fach nicht besucht wird.

(3) Das Erlöschen der Zulassung zu einem Studium ist zu beurkunden. Insbesondere im Fall des Abs. 1 Z 4 hat das Rektorat auf Antrag einen Feststellungsbescheid zu erlassen.

Abgangsbescheinigung

§ 69. (1) Beendet die oder der Studierende ein Studium an einer Universität, so ist auf Antrag eine Abgangsbescheinigung auszustellen. Diese hat alle Prüfungen, zu denen die oder der Studierende in diesem Studium an dieser Universität angetreten ist, und deren Beurteilungen anzugeben. Hinsichtlich der positiv beurteilten Prüfungen ist nur die positive Beurteilung anzugeben. Zur Unterstützung der internationalen Mobilität der Studierenden ist der Anschluss einer fremdsprachigen Übersetzung zulässig, wobei die Benennung der Universität und des ausstellenden Organs nicht zu übersetzen sind.

(2) Zur Unterstützung der internationalen Mobilität der Studierenden sowie der Absolventinnen und Absolventen hat die Bundesministerin oder der Bundesminister durch Verordnung festzulegen, in welcher Form der Anhang zum Diplom („Diploma Supplement“) gemäß Art. IX.3 des Übereinkommens über die Anerkennung von Qualifikationen im Hochschulbereich in der europäischen Region, BGBl. III Nr. 71/1999, auszustellen ist.

Zulassung zu außerordentlichen Studien

§ 70. (1) Die Zulassung zu den außerordentlichen Studien setzt den Nachweis der allfälligen im Curriculum eines Universitätslehrganges geforderten Voraussetzungen voraus.

(2) Die Zulassung zu den Vorbereitungslehrgängen ist längstens bis zur Vollendung des 20. Lebensjahres möglich. Darüber hinaus sind die Universitäten gemäß § 6 Z 16 bis 21 berechtigt, im Curriculum für einen Vorbereitungslehrgang ein Zulassungsalter bis zur Vollendung des 25. Lebensjahres vorzusehen, wenn dies auf Grund der Studieninhalte erforderlich ist.

(3) Nach dem Erlöschen der Zulassung wegen der negativen Beurteilung bei der letzten zulässigen Wiederholung einer Prüfung ist die neuerliche Zulassung für diesen Universitätslehrgang ausgeschlossen.

Erlöschen der Zulassung zu außerordentlichen Studien

§ 71. (1) Die Zulassung erlischt, wenn die oder der Studierende

1. sich vom Studium abmeldet,
2. die Meldung der Fortsetzung des Studiums unterlässt,
3. bei einer für ihr oder sein Studium vorgeschriebenen Prüfung bei der letzten zulässigen Wiederholung negativ beurteilt wurde oder
4. den Universitätslehrgang durch die positive Beurteilung bei der letzten vorgeschriebenen Prüfung abgeschlossen hat.

(2) Das Erlöschen der Zulassung ist zu beurkunden. Das Rektorat hat auf Antrag einen Feststellungsbescheid zu erlassen.

4. Abschnitt

Prüfungen

Feststellung des Studienerfolgs

§ 72. Der Studienerfolg ist durch die Prüfungen und die Beurteilung wissenschaftlicher Arbeiten (Diplomarbeiten, Magisterarbeiten und Dissertationen) und künstlerischer Diplom- und Magisterarbeiten festzustellen.

Beurteilung des Studienerfolgs

§ 73. (1) Der positive Erfolg von Prüfungen und wissenschaftlichen Arbeiten und künstlerischen Diplom- und Magisterarbeiten ist mit „sehr gut“ (1), „gut“ (2), „befriedigend“ (3) oder „genügend“ (4), der negative Erfolg ist mit „nicht genügend“ (5) zu beurteilen. Zwischenbeurteilungen sind unzulässig. Wenn diese Form der Beurteilung unmöglich oder unzweckmäßig ist, hat die positive Beurteilung „mit Erfolg teilgenommen“, die negative Beurteilung „ohne Erfolg teilgenommen“ zu lauten.

(2) Prüfungen, die aus mehreren Fächern oder Teilen bestehen, sind nur dann positiv zu beurteilen, wenn jedes Fach oder jeder Teil positiv beurteilt wurde.

(3) Bei studienabschließenden Prüfungen, die mehr als ein Fach umfassen, ist zusätzlich zu den Beurteilungen für die einzelnen Fächer eine Gesamtbeurteilung zu vergeben. Diese hat „bestanden“ zu lauten, wenn jedes Fach positiv beurteilt wurde, anderenfalls hat sie „nicht bestanden“ zu lauten. Die Gesamtbeurteilung hat „mit Auszeichnung bestanden“ zu lauten, wenn in keinem Fach eine schlechtere Beurteilung als „gut“ und in mindestens der Hälfte der Fächer die Beurteilung „sehr gut“ erteilt wurde. In den künstlerischen Studien hat bei studienabschließenden Prüfungen, die nur ein zentrales künstlerisches Fach umfassen, an die Stelle der Beurteilung „sehr gut“ die Beurteilung „mit Auszeichnung bestanden“ zu treten.

Nichtigerklärung von Beurteilungen

§ 74. (1) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat die Beurteilung einer Prüfung mit Bescheid für nichtig zu erklären, wenn die Anmeldung zu dieser Prüfung erschlichen wurde.

(2) Überdies ist die Beurteilung einer Prüfung, einer wissenschaftlichen Arbeit oder einer künstlerischen Magister- oder Diplomarbeit mit Bescheid für nichtig zu erklären, wenn diese Beurteilung, insbesondere durch die Verwendung unerlaubter Hilfsmittel, erschlichen wurde.

(3) Die Prüfung, deren Beurteilung für nichtig erklärt wurde, ist auf die Gesamtzahl der Wiederholungen anzurechnen.

(4) Prüfungen, die außerhalb des Wirkungsbereiches einer Fortsetzungsmeldung abgelegt wurden, und Beurteilungen wissenschaftlicher Arbeiten sowie künstlerischer Magister- und Diplomarbeiten, die außerhalb des Wirkungsbereiches einer Fortsetzungsmeldung erfolgten, sind absolut nichtig. Eine Anrechnung auf die Gesamtzahl der Wiederholungen erfolgt nicht.

Zeugnisse

§ 75. (1) Die Beurteilung der Prüfungen, wissenschaftlichen Arbeiten und künstlerischen Magister- oder Diplomarbeiten ist jeweils durch ein Zeugnis zu beurkunden. Sammelzeugnisse sind zulässig.

(2) Die Zeugnisse sind vom Senat festzulegen und haben jedenfalls folgende Angaben zu enthalten:

1. die ausstellende Universität und die Bezeichnung des Zeugnisses;
2. die Matrikelnummer;
3. den Familiennamen und die Vornamen;
4. das Geburtsdatum;
5. die Bezeichnung des Studiums;
6. die Bezeichnung der Prüfung oder das Fach und die erfolgte Beurteilung sowie die ECTS-Anrechnungspunkte;
7. den Namen der Prüferin oder des Prüfers, das Prüfungsdatum und die Beurteilung;
8. den Namen der Ausstellerin oder des Ausstellers.

Bei Zeugnissen über die Beurteilung wissenschaftlicher Arbeiten sowie künstlerischer Magister- und Diplomarbeiten ist das Thema anzugeben.

(3) Zeugnisse über Prüfungen vor Einzelprüferinnen oder Einzelprüfern hat die Prüferin oder der Prüfer, Zeugnisse über die Beurteilung wissenschaftlicher Arbeiten sowie künstlerischer Magister- und Diplomarbeiten hat die Beurteilerin oder der Beurteiler, Zeugnisse über kommissionelle Prüfungen hat die oder der Vorsitzende des Prüfungssenates, Zeugnisse über Studienabschlüsse hat das für die studienrechtlichen Angelegenheiten zuständige Organ auszustellen.

(4) Die Zeugnisse sind unverzüglich, längstens jedoch innerhalb von vier Wochen nach Erbringung der zu beurteilenden Leistung auszustellen. Zur Unterstützung der internationalen Mobilität der Studierenden ist der Anschluss einer fremdsprachigen Übersetzung zulässig, wobei die Benennung der Universität und des ausstellenden Organs nicht zu übersetzen sind.

(5) Die Ausstellung von Zeugnissen mittels automationsunterstützter Datenverarbeitung ist zulässig. Wenn keine eigenhändige Fertigung erfolgt, ist eine Beglaubigung nur bei studienabschließenden Zeugnissen erforderlich.

(6) Die Universität hat einer oder einem ausländischen Studierenden ab dem zweiten Studienjahr auf Antrag der oder des Studierenden einen Studienerfolgsnachweis auszustellen, sofern sie oder er im vorausgegangenen Studienjahr positiv beurteilte Prüfungen im Umfang von mindestens 16 ECTS-Anrechnungspunkten (8 Semesterstunden) abgelegt hat.

Zulassungs- und Ergänzungsprüfungen

§ 76. (1) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat fachlich geeignete Prüferinnen oder Prüfer für die Zulassungs- und Ergänzungsprüfungen heranzuziehen, die Prüfungsmethode zu bestimmen und festzulegen, ob die Prüfung als Einzelprüfung oder als kommissionelle Prüfung abzulegen ist.

(2) Im Curriculum für das Lehramtsstudium aus dem Unterrichtsfach Leibeserziehung und für das Studium Sportwissenschaften ist festzulegen, in welcher Weise die Ergänzungsprüfung für den Nachweis der körperlich-motorischen Eignung abzulegen ist.

(3) Wird zur Vorbereitung auf eine Ergänzungsprüfung ein Universitätslehrgang eingerichtet, gilt dessen positiver Abschluss als Ergänzungsprüfung.

(4) In den Curricula für künstlerische Studien ist festzulegen, in welcher Weise die Zulassungsprüfung für den Nachweis der künstlerischen Eignung abzulegen ist.

Wiederholung von Prüfungen

§ 77. (1) Die Studierenden sind berechtigt, positiv beurteilte Prüfungen bis sechs Monate nach der Ablegung, jedoch längstens bis zum Abschluss des betreffenden Studienabschnittes oder bis zum Abschluss des betreffenden Studiums einmal zu wiederholen. Die positiv beurteilte Prüfung wird mit dem Antreten zur Wiederholungsprüfung nichtig. An den Universitäten gemäß § 6 Z 16 bis 21 dürfen zwei positiv beurteilte Lehrveranstaltungsprüfungen aus dem zentralen künstlerischen Fach während der gesamten Studiendauer je einmal wiederholt werden.

(2) Die Studierenden sind berechtigt, negativ beurteilte Prüfungen dreimal zu wiederholen. Auf die Zahl der zulässigen Prüfungsantritte sind alle Antritte für dasselbe Prüfungsfach in allen facheinschlägigen Studien an derselben Universität anzurechnen. In der Satzung ist festzulegen, ob und wie viele weitere Prüfungswiederholungen zulässig sind.

(3) Die dritte Wiederholung einer Prüfung ist kommissionell abzuhalten, wenn die Prüfung in Form eines einzigen Prüfungsvorganges durchgeführt wird. Auf Antrag der oder des Studierenden gilt dies auch für die zweite Wiederholung.

(4) Die Festlegung von Fristen und die Verpflichtung zur Ablegung von Lehrveranstaltungsprüfungen als Voraussetzung für die Wiederholung von Prüfungen sind unzulässig.

(5) Die Zulassungsprüfung für den Nachweis der künstlerischen Eignung sowie die Ergänzungsprüfung für den Nachweis der körperlich-motorischen Eignung sind unbeschränkt wiederholbar.

Anerkennung von Prüfungen

§ 78. (1) Positiv beurteilte Prüfungen, die ordentliche Studierende an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung, einer berufsbildenden höheren Schule, einer Höheren Anstalt für Lehrer- und Erzieherbildung, in Studien an anerkannten inländischen Bildungseinrichtungen, deren Zugang die allgemeine Universitätsreife erfordert, oder in einem Lehrgang universitären Charakters abgelegt haben, sind auf Antrag der oder des ordentlichen Studierenden vom für die studienrechtlichen Angelegenheiten zuständigen Organ bescheidmäßig anzuerkennen, soweit sie den im Curriculum vorgeschriebenen Prüfungen gleichwertig sind. Die an einer inländischen Universität oder an einer Universität der Europäischen Union oder des Europäischen Wirtschaftsraumes für ein Fach abgelegten Prüfungen sind für das gleiche Fach im weiteren Studium desselben Studiums an einer anderen inländischen Universität jedenfalls anzuerkennen, wenn die ECTS-Anrechnungspunkte gleich sind oder nur

geringfügig abweichen. Solche Anerkennungen können im Curriculum generell festgelegt werden. Die Anerkennung von Prüfungen, die entgegen der Bestimmungen des § 63 Abs. 8 und 9 an einer anderen Universität abgelegt wurden, ist ausgeschlossen.

(2) Die an österreichischen Konservatorien mit Öffentlichkeitsrecht abgelegten Prüfungen sind auf Antrag der oder des ordentlichen Studierenden bescheidmäßig anzuerkennen, soweit sie den im Curriculum vorgeschriebenen Prüfungen gleichwertig sind. Solche Anerkennungen können im Curriculum generell festgelegt werden.

(3) Die wissenschaftliche Tätigkeit in Betrieben oder außeruniversitären Forschungseinrichtungen, die eine wissenschaftliche Berufsvorbildung vermitteln können, sind entsprechend der Art der Forschungstätigkeit und der Forschungsprojekte der betreffenden Einrichtung sowie nach Art und Umfang der Mitwirkung oder Tätigkeit der oder des Studierenden nach Maßgabe der Gleichwertigkeit auf Antrag der oder des ordentlichen Studierenden bescheidmäßig als Prüfung anzuerkennen.

(4) Die künstlerische Tätigkeit an Institutionen außerhalb der Universität, die eine künstlerische Berufsvorbildung vermitteln können, kann entsprechend der Art der künstlerischen Tätigkeit sowie nach Art und Umfang der Mitwirkung oder Tätigkeit der oder des Studierenden nach Maßgabe der Gleichwertigkeit auf Antrag der oder des ordentlichen Studierenden bescheidmäßig als Prüfung anerkannt werden.

(5) Auf Antrag ordentlicher Studierender, die Teile ihres Studiums im Ausland durchführen wollen, ist bescheidmäßig festzustellen, welche der geplanten Prüfungen den im Curriculum vorgeschriebenen Prüfungen gleichwertig sind. Die für die Beurteilung notwendigen Unterlagen sind von der Antragstellerin oder dem Antragsteller vorzulegen.

(6) Die Anerkennung einer Prüfung gilt als Prüfungsantritt und positive Beurteilung der entsprechenden im Curriculum vorgeschriebenen Prüfung in dem Studium, für welches die Prüfung anerkannt wird.

(7) Positiv beurteilte Prüfungen, die außerordentliche Studierende abgelegt haben, sind für ordentliche Studien nur insoweit anerkennbar, als sie im Rahmen von Universitätslehrgängen oder vor der vollständigen Ablegung der Reifeprüfung oder der Studienberechtigungsprüfung oder der Ergänzungsprüfung für den Nachweis der körperlich-motorischen Eignung oder der Zulassungsprüfung für den Nachweis der künstlerischen Eignung für das Studium, für welches die Prüfung anerkannt werden soll, abgelegt wurden.

(8) Über Anerkennungsanträge in erster Instanz ist abweichend von § 73 AVG spätestens zwei Monate nach Einlangen des Antrages bescheidmäßig zu entscheiden.

Rechtsschutz bei Prüfungen

§ 79. (1) Die Berufung gegen die Beurteilung einer Prüfung ist unzulässig. Wenn die Durchführung einer negativ beurteilten Prüfung einen schweren Mangel aufweist, hat das für die studienrechtlichen Angelegenheiten zuständige Organ diese Prüfung auf Antrag der oder des Studierenden mit Bescheid aufzuheben. Die oder der Studierende hat den Antrag innerhalb von zwei Wochen ab der Bekanntgabe der Beurteilung einzubringen und den schweren Mangel glaubhaft zu machen. Der Antritt zu der Prüfung, die aufgehoben wurde, ist nicht auf die zulässige Zahl der Prüfungsantritte anzurechnen.

(2) Mündliche Prüfungen sind öffentlich. Es ist zulässig, den Zutritt erforderlichenfalls auf eine den räumlichen Verhältnissen entsprechende Anzahl von Personen zu beschränken. Bei kommissionellen mündlichen Prüfungen hat jedes Mitglied des Prüfungssenates während der gesamten Prüfungszeit anwesend zu sein. Das Ergebnis einer mündlichen Prüfung ist unmittelbar nach der Prüfung der oder dem Studierenden bekannt zu geben. Wurde die Prüfung negativ beurteilt, sind die Gründe dafür der oder dem Studierenden zu erläutern.

(3) Wenn die Beurteilungsunterlagen (insbesondere Gutachten, Korrekturen schriftlicher Prüfungen und Prüfungsarbeiten) den Studierenden nicht ausgehändigt werden, ist sicherzustellen, dass diese mindestens sechs Monate ab der Bekanntgabe der Beurteilung aufbewahrt werden.

(4) Die Prüferin oder der Prüfer oder die oder der Vorsitzende des Prüfungssenats hat für den geordneten Ablauf der Prüfung zu sorgen und das Prüfungsprotokoll zu führen. In das Protokoll sind der Prüfungsgegenstand, der Ort und die Zeit der Prüfung, die Namen der Prüferin oder des Prüfers oder die Namen der Mitglieder des Prüfungssenats, die Namen der oder des Studierenden, die gestellten Fragen, die erteilten Beurteilungen, die Gründe für die negative Beurteilung sowie allfällige besondere Vorkommnisse aufzunehmen. Die Gründe für die negative Beurteilung sind der oder dem Studierenden auf Antrag schriftlich mitzuteilen. Das Prüfungsprotokoll ist mindestens ein Jahr ab der Bekanntgabe der Beurteilung aufzubewahren.

(5) Der oder dem Studierenden ist Einsicht in die Beurteilungsunterlagen und in die Prüfungsprotokolle zu gewähren, wenn sie oder er dies innerhalb von sechs Monaten ab Bekanntgabe der Beurteilung verlangt. Die oder der Studierende ist berechtigt, von diesen Unterlagen Fotokopien anzufertigen.

5. Abschnitt

Bakkalaureatsarbeiten, Diplom- und Magisterarbeiten sowie Dissertationen

Bakkalaureatsarbeiten

§ 80. (1) Im Bakkalaureatsstudium sind im Rahmen von Lehrveranstaltungen Bakkalaureatsarbeiten abzufassen. Nähere Bestimmungen über Bakkalaureatsarbeiten sind im jeweiligen Curriculum festzulegen.

(2) Bei der Bearbeitung des Themas und der Betreuung der Studierenden sind die Bestimmungen des Urheberrechtsgesetzes, BGBl. Nr. 111/1936, zu beachten.

Diplom- und Magisterarbeiten

§ 81. (1) Im Diplom- oder Magisterstudium ist eine Diplom- oder Magisterarbeit abzufassen. In besonders berufsorientierten Studien ist es zulässig, im Curriculum anstelle der Diplom- oder Magisterarbeit einen anderen gleichwertigen Nachweis vorzusehen. Die Abfassung als Klausurarbeit ist unzulässig. Nähere Bestimmungen über Betreuung und Beurteilung von Diplom- oder Magisterarbeiten sind in der Satzung, nähere Bestimmungen über das Thema der Diplom- oder Magisterarbeit sind im jeweiligen Curriculum festzulegen.

(2) Die Aufgabenstellung der Diplom- oder Magisterarbeit ist so zu wählen, dass für eine Studierende oder einen Studierenden die Bearbeitung innerhalb von sechs Monaten möglich und zumutbar ist.

(3) Die gemeinsame Bearbeitung eines Themas durch mehrere Studierende ist zulässig, wenn die Leistungen der einzelnen Studierenden gesondert beurteilbar bleiben. Erfordert die Bearbeitung eines Themas die Verwendung der Geld- oder Sachmittel von Einrichtungen der Universität, so ist die Vergabe nur zulässig, wenn die Leiterin oder der Leiter dieser Einrichtung über die beabsichtigte Vergabe informiert wurde und diese nicht binnen eines Monats wegen einer wesentlichen Beeinträchtigung des Lehr- und Forschungsbetriebes untersagt hat.

(4) § 80 Abs. 2 gilt auch für Diplom- und Magisterarbeiten.

Dissertationen

§ 82. (1) Im Doktoratsstudium ist eine Dissertation abzufassen. Nähere Bestimmungen über Betreuung und Beurteilung von Dissertationen sind in der Satzung, nähere Bestimmungen über das Thema der Dissertation sind im jeweiligen Curriculum festzulegen.

(2) § 80 Abs. 2 und § 81 Abs. 3 gelten auch für Dissertationen.

Künstlerische Diplom- und Magisterarbeiten

§ 83. (1) In künstlerischen Studien ist eine künstlerische Diplom- oder Magisterarbeit zu schaffen. Die Studierenden sind berechtigt, anstelle der künstlerischen Diplom- oder Magisterarbeit eine Diplom- oder Magisterarbeit aus einem im Curriculum festgelegten wissenschaftlichen Prüfungsfach zu verfassen.

(2) Die künstlerische Diplom- oder Magisterarbeit hat neben einem künstlerischen Teil, der den Schwerpunkt bildet, auch einen schriftlichen Teil zu umfassen. Dieser hat den künstlerischen Teil zu erläutern. Nähere Bestimmungen über Betreuung und Beurteilung von künstlerischen Diplom- und Magisterarbeiten sind in der Satzung, nähere Bestimmungen über das Thema der künstlerischen Diplom- und Magisterarbeit sind im jeweiligen Curriculum festzulegen.

(3) § 80 Abs. 2 und § 81 Abs. 3 gelten auch für künstlerische Diplom- und Magisterarbeiten.

Einsicht in die Beurteilungsunterlagen

§ 84. (1) Wenn die Beurteilungsunterlagen (insbesondere Gutachten und Korrekturen von künstlerischen Arbeiten) den Studierenden nicht ausgehändigt werden, hat das für die studienrechtlichen Angelegenheiten zuständige Organ sicherzustellen, dass diese mindestens sechs Monate ab der Bekanntgabe der Beurteilung aufbewahrt werden.

(2) Der oder dem Studierenden ist Einsicht in die Beurteilungsunterlagen zu gewähren, wenn sie oder er dies innerhalb von sechs Monaten ab Bekanntgabe der Beurteilung beantragt. Die oder der Studierende ist berechtigt, von diesen Unterlagen Fotokopien anzufertigen.

Anerkennung von Diplom- und Magisterarbeiten, künstlerischen Diplom- und Magisterarbeiten sowie Dissertationen

§ 85. Diplom- oder Magisterarbeiten, künstlerische Diplom- oder Magisterarbeiten oder Dissertationen, die an einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung positiv beurteilt wurden, sind vom für die studienrechtlichen Angelegenheiten zuständigen Organ auf Antrag anzuerkennen, wenn sie den Anforderungen einer Diplom- oder Magisterarbeit, künstlerischen Diplom- oder Magisterarbeit oder einer Dissertation entsprechen.

Veröffentlichungspflicht

§ 86. (1) Die Absolventin oder der Absolvent hat die positiv beurteilte Diplom- oder Magisterarbeit, Dissertation oder künstlerische Diplom- oder Magisterarbeit oder die Dokumentation der künstlerischen Diplom- oder Magisterarbeit durch Übergabe an die Bibliothek der Universität, an welcher der akademische Grad verliehen wird, zu veröffentlichen. Die Absolventin oder der Absolvent hat vor der Verleihung des akademischen Grades jeweils ein vollständiges Exemplar der positiv beurteilten Diplom- oder Magisterarbeit, Dissertation oder künstlerischen Diplom- oder Magisterarbeit oder die Dokumentation der künstlerischen Diplom- oder Magisterarbeit abzuliefern. Von der Veröffentlichungspflicht ausgenommen sind die wissenschaftlichen Arbeiten oder deren Teile, die einer Massenvervielfältigung nicht zugänglich sind. Die positiv beurteilte Dissertation ist überdies durch Übergabe an die Österreichische Nationalbibliothek zu veröffentlichen.

(2) Anlässlich der Ablieferung einer wissenschaftlichen oder künstlerischen Arbeit ist die Verfasserin oder der Verfasser berechtigt, den Ausschluss der Benützung der abgelieferten Exemplare für längstens fünf Jahre nach der Ablieferung zu beantragen. Dem Antrag ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ stattzugeben, wenn die oder der Studierende glaubhaft macht, dass wichtige rechtliche oder wirtschaftliche Interessen der oder des Studierenden gefährdet sind.

6. Abschnitt
Akademische Grade

Verleihung akademischer Grade

§ 87. (1) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat den Absolventinnen und Absolventen der ordentlichen Studien nach der positiven Beurteilung aller im jeweiligen Curriculum vorgeschriebenen Prüfungen und in den Diplom-, Magister- und Doktoratsstudien nach der Ablieferung der positiv beurteilten wissenschaftlichen Arbeit oder künstlerischen Diplom- oder Magisterarbeit oder der Dokumentation der künstlerischen Diplom- oder Magisterarbeit den festgelegten akademischen Grad durch einen schriftlichen Bescheid unverzüglich, jedoch spätestens einen Monat nach der Erfüllung aller Voraussetzungen von Amts wegen zu verleihen.

(2) Das für die studienrechtlichen Angelegenheiten zuständige Organ hat den Absolventinnen und Absolventen der Universitätslehrgänge nach der positiven Beurteilung aller im jeweiligen Curriculum vorgeschriebenen Prüfungen den festgelegten akademischen Grad durch einen schriftlichen Bescheid unverzüglich, jedoch spätestens einen Monat nach der Erfüllung aller Voraussetzungen von Amts wegen zu verleihen.

(3) Zur Unterstützung der internationalen Mobilität der Studierenden ist dem Verleihungsbescheid eine englischsprachige Übersetzung anzuschließen, wobei die Benennung der Universität und des ausstellenden Organs sowie der akademische Grad nicht zu übersetzen sind. Der Verleihungsbescheid hat jedenfalls folgende Angaben zu enthalten:

1. den Familiennamen und die Vornamen, allenfalls den Geburtsnamen;
2. das Geburtsdatum und die Staatsangehörigkeit;
3. das abgeschlossene Studium;
4. den verliehenen akademischen Grad.

(4) Werden die Voraussetzungen für einen akademischen Grad mit demselben Wortlaut mehr als einmal erbracht, so ist derselbe akademische Grad auch mehrfach zu verleihen.

(5) Wird ein ordentliches Studium auf Grund eines Doppeldiplom-Programms abgeschlossen, bei dessen Durchführung bei einem Studienumfang von bis zu 120 ECTS-Anrechnungspunkten jeweils mindestens 30 ECTS-Anrechnungspunkte, bei einer Studiendauer von mehr als 120 ECTS-Anrechnungspunkten jeweils mindestens 60 ECTS-Anrechnungspunkte unter der Verantwortung einer ausländischen Partnerinstitution erbracht wurden, ist es zulässig, die Verleihung des akademischen Grades durch eine gemeinsame Urkunde mit dieser Partnereinrichtung oder diesen Partnereinrichtungen vorzunehmen.

Führung akademischer Grade

§ 88. (1) Personen, denen von einer anerkannten inländischen oder ausländischen postsekundären Bildungseinrichtung ein akademischer Grad verliehen wurde, haben das Recht, diesen in der in der Verleihungsurkunde festgelegten Form zu führen. Dazu gehört auch das Recht, die Eintragung eines von einer inländischen postsekundären Bildungseinrichtung oder einer anerkannten postsekundären Einrichtung einer anderen Vertragspartei des EU-Beitrittsvertrages oder einer anderen Vertragspartei des Abkommens über den Europäischen Wirtschaftsraum verliehenen akademischen Grades in abgekürzter Form in öffentliche Urkunden zu verlangen.

(2) „Mag.“, „Dr.“ und „Dipl.-Ing.“ („DI“) sind im Falle der Führung dem Namen voranzustellen, die übrigen akademischen Grade sind dem Namen nachzustellen.

Widerruf inländischer akademischer Grade

§ 89. Der Verleihungsbescheid ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ aufzuheben und einzuziehen, wenn sich nachträglich ergibt, dass der akademische Grad insbesondere durch gefälschte Zeugnisse erschlichen worden ist.

7. Abschnitt
Nostrifizierung

§ 90. (1) Die Antragstellung betreffend die Anerkennung eines ausländischen Studienabschlusses als Abschluss eines inländischen ordentlichen Studiums (Nostrifizierung) setzt den Nachweis voraus, dass die Nostrifizierung zwingend für die Berufsausübung oder die Fortsetzung der Ausbildung der Antragstellerin oder des Antragstellers in Österreich erforderlich ist. Nähere Bestimmungen sind in der Satzung festzulegen.

(2) Der Antrag ist an einer Universität einzubringen, an der das entsprechende inländische Studium eingerichtet ist. Es ist unzulässig, denselben Nostrifizierungsantrag gleichzeitig oder nach der Zurückziehung an einer anderen Universität einzubringen.

(3) Die Nostrifizierung ist vom für die studienrechtlichen Angelegenheiten zuständigen Organ mit Bescheid auszusprechen. Im Bescheid ist festzulegen, welchem inländischen Studienabschluss der ausländische Studienabschluss entspricht und welchen inländischen akademischen Grad die Antragstellerin oder der Antragsteller an Stelle des ausländischen akademischen Grades auf Grund der Nostrifizierung zu führen berechtigt ist. Die Ausfertigung des Bescheides ist auf der Urkunde, die als Nachweis des ausländischen Studienabschlusses vorgelegt wurde, zu vermerken.

(4) Die Nostrifizierung ist bescheidmäßig zu widerrufen, wenn sie insbesondere durch gefälschte Zeugnisse erschlichen worden ist.

(5) Die Taxe für die Nostrifizierung eines ausländischen Studienabschlusses beträgt 150 Euro. Die Taxe ist im Voraus zu entrichten. Sie verfällt, wenn der Antrag auf Nostrifizierung abgewiesen oder zurückgezogen wird.

8. Abschnitt
Studienbeitrag

§ 91. (1) Studierende, welche die österreichische Staatsbürgerschaft besitzen oder denen Österreich auf Grund eines völkerrechtlichen Vertrages dieselben Rechte für den Berufszugang zu gewähren hat wie Inländern, haben jedes Semester einen Studienbeitrag in der Höhe von 363,36 Euro zu entrichten. Der Studienbeitrag erhöht sich bei Entrichtung innerhalb der Nachfrist um 10 vH.

(2) Studierende, die nicht die österreichische Staatsbürgerschaft besitzen und auf die kein völkerrechtlicher Vertrag gemäß Abs. 1 anzuwenden ist, haben jedes Semester einen Studienbeitrag in der Höhe von 726,72 Euro zu entrichten. Der Studienbeitrag erhöht sich bei Entrichtung innerhalb der Nachfrist um 10 vH.

(3) Studierende, die zu mehreren Studien, auch an mehreren Universitäten, zugelassen sind, haben den Studienbeitrag nur einmal zu entrichten.

(4) Der Studienbeitrag ist für jedes Semester im Voraus zu entrichten. Zur Sicherstellung der Einhebung des Studienbeitrages sind der Bundesministerin oder dem Bundesminister von den Universitäten folgende Daten der Studierenden zu übermitteln:

1. die Matrikelnummer;
2. die Namen einschließlich allfälliger akademischer Grade und das Geschlecht;
3. die Staatsangehörigkeit;
4. der Beitragsstatus;
5. die Anschrift am Studienort und am Heimatort.

Nähere Bestimmungen zur Einhebung des Studienbeitrages sind durch die Bundesministerin oder den Bundesminister durch Verordnung festzulegen.

(5) Die Studienbeiträge verbleiben der jeweiligen Universität.

(6) Der Studienbeitrag von Studierenden, die ein von mehreren Universitäten gemeinsam eingerichtetes Studium betreiben oder die zu mehreren Studien an verschiedenen Universitäten zugelassen sind, ist unter den beteiligten Universitäten aufzuteilen.

(7) Für den Besuch von Universitätslehrgängen haben die Teilnehmerinnen und Teilnehmer einen Lehrgangsbeitrag zu entrichten. Er ist unter Berücksichtigung der tatsächlichen Kosten des Universitätslehrgangs festzusetzen. Ordentlichen Studierenden, die eine Studienbeihilfe beziehen, ist auf Antrag unter Bedachtnahme auf ihre Leistungsfähigkeit eine Ermäßigung des Lehrgangsbeitrags zu gewähren. Der Lehrgangsbeitrag ist vom Senat festzusetzen. Außerordentliche Studierende, die ausschließlich zum Studium eines Universitätslehrganges zugelassen sind, haben den Lehrgangsbeitrag und keinen Studienbeitrag zu entrichten. Für Vorbereitungslehrgänge ist kein Lehrgangsbeitrag und kein Studienbeitrag einzuheben.

(8) Anlässlich der Entrichtung des Studienbeitrages sind die Studierenden berechtigt, zwischen den vom Senat gemäß § 25 Abs. 1 Z 13 festgelegten Möglichkeiten der Zweckwidmung der Studienbeiträge zu wählen.

Erlass und Rückerstattung des Studienbeitrages

§ 92. (1) Der Studienbeitrag ist insbesondere zu erlassen

1. Studierenden für die Semester, in denen sie nachweislich Studien oder Praxiszeiten im Rahmen von transnationalen EU-, staatlichen oder universitären Mobilitätsprogrammen absolvieren werden;
2. Studierenden für die Semester, in denen sie auf Grund verpflichtender Bestimmungen im Curriculum Studien im Ausland absolvieren werden;
3. ausländischen Studierenden, deren Heimatstaat oder deren dort zuletzt besuchte Universität Studierenden österreichischer Staatsbürgerschaft ebenfalls den Erlass des Studienbeitrages gewährt;
4. Konventionsflüchtlingen.

(2) Über den Antrag auf Erlass des Studienbeitrages entscheidet das Rektorat.

(3) Dem Antrag sind die für den Erlass des Studienbeitrages erforderlichen Nachweise beizufügen.

(4) Die Entscheidung der Universität ist in geeigneter Form zu dokumentieren.

(5) Studierende, denen gemäß Abs. 1 Z 1 und 2 der Studienbeitrag erlassen wurde und die in diesem Semester keine Studien oder Praxiszeiten im Sinne dieser Bestimmungen im Ausland absolviert haben, müssen den Studienbeitrag nachträglich entrichten. Dies hat das Rektorat bescheidmäßig zu verfügen.

(6) Sofern Studierende den Erlass des Studienbeitrages durch unvollständige oder unwahre Angaben maßgebender Tatsachen schuldhaft veranlasst oder erschlichen haben, haben sie unbeschadet strafrechtlicher Verantwortlichkeit den doppelten Studienbeitrag zu entrichten. Dies hat das Rektorat bescheidmäßig zu verfügen.

(7) Studierende, die beurlaubt sind, haben keinen Studienbeitrag zu entrichten.

(8) Gegen Bescheide des Rektorats ist die Berufung an den Senat zulässig.

(9) Die Bundesministerin oder der Bundesminister ist berechtigt, entsprechend den Schwerpunktsetzungen Österreichs bei den Maßnahmen zur Unterstützung und Förderung der wirtschaftlichen und sozialen Entwicklung der Entwicklungsländer sowie der Unterstützung der Reformländer Zentral- und Osteuropas durch Verordnung Staaten festzulegen, deren Angehörigen der Studienbeitrag erstattet werden kann.

(10) Die Erstattung erfolgt im Rahmen der Privatwirtschaftsverwaltung auf Grund von Anträgen der Studierenden. Die Erstattung hat binnen vier Wochen ab Antragstellung auf Erstattung zu erfolgen. Auf die Erstattung besteht kein Rechtsanspruch.

9. Abschnitt
Sonderbestimmungen

Sonderbestimmungen für die Katholische Theologie

§ 93. (1) Bei einem Übertritt von Studierenden von einer kirchlichen theologischen Lehranstalt (Art. V § 1 des Konkordates zwischen dem Heiligen Stuhle und der Republik Österreich) an eine Organisationseinheit einer Universität, deren Wirkungsbereich sich auf die Katholische Theologie bezieht, gelten folgende besondere Bestimmungen:

1. Die Prüfungen, die an diesen Lehranstalten abgelegt wurden, sind als Ergänzungsprüfungen anzuerkennen, wenn die von der Lehranstalt namhaft gemachte Prüferin oder der von der Lehranstalt namhaft gemachte Prüfer
   a) die Lehrbefugnis (venia docendi) für das betreffende Fach besitzt oder
   b) von einer Organisationseinheit einer Universität, deren Wirkungsbereich sich auf die Katholische Theologie bezieht, zur Abnahme der Ergänzungsprüfungen für die Dauer von jeweils drei Jahren bevollmächtigt wurde.
2. Die Prüfungen, die an diesen Lehranstalten abgelegt wurden, sind anzuerkennen, wenn sie vor
   a) einer für ein Fach der Katholischen Theologie hiezu bestellten Universitätsprofessorin oder einem für ein Fach der Katholischen Theologie hiezu bestellten Universitätsprofessor oder
   b) einer oder einem sonst von einer Organisationseinheit einer Universität, deren Wirkungsbereich sich auf die Katholische Theologie bezieht, hiezu Bevollmächtigten abgelegt wurden. Zu der in angemessener Frist vorzunehmenden Bevollmächtigung ist der kirchlichen theologischen Lehranstalt Gelegenheit zur Stellungnahme zu geben.
3. Absolventinnen und Absolventen dieser kirchlichen theologischen Lehranstalten ist der jeweilige für das Studium vorgesehene akademische Grad zu verleihen, wenn die abgelegten Prüfungen gemäß den oben genannten Bestimmungen anerkannt wurden und die wissenschaftliche Arbeit von einer für ein Fach der Katholischen Theologie bestellten Universitätsprofessorin oder einem für ein Fach der Katholischen Theologie bestellten Universitätsprofessor positiv beurteilt oder von einer fachzuständigen Person mit Lehrbefugnis (venia docendi) an der betreffenden Lehranstalt betreut und positiv beurteilt wurde.

(2) Für die Verleihung des akademischen Grades ist diesfalls die Zulassung zum Studium an der Universität nicht erforderlich.

III. Teil
Angehörige der Universität

1. Abschnitt
Einteilung

§ 94. (1) Zu den Angehörigen der Universität zählen:

1. die Studierenden (§ 51 Abs. 3);
2. die Forschungsstipendiatinnen und Forschungsstipendiaten;
3. die Ärztinnen und Ärzte in Facharztausbildung;
4. das wissenschaftliche und das künstlerische Universitätspersonal;
5. das allgemeine Universitätspersonal;
6. die Privatdozentinnen und Privatdozenten (§ 102);
7. die emeritierten Universitätsprofessorinnen und Universitätsprofessoren;
8. die Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand.

(2) Zum wissenschaftlichen und künstlerischen Universitätspersonal gehören:

1. die Universitätsprofessorinnen und Universitätsprofessoren;
2. die Universitätsdozentinnen und Universitätsdozenten sowie die wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb.

(3) Zum allgemeinen Universitätspersonal gehören:

1. das administrative Personal;
2. das technische Personal;

3. das Bibliothekspersonal;
4. das Krankenpflegepersonal;
5. die Ärztinnen und Ärzte zur ausschließlichen Erfüllung von Aufgaben im Rahmen einer öffentlichen Krankenanstalt.

2. Abschnitt

Forschungsstipendiatinnen und Forschungsstipendiaten sowie Ärztinnen und Ärzte in Facharztausbildung

Forschungsstipendiatinnen und Forschungsstipendiaten

§ 95. Forschungsstipendiatinnen und Forschungsstipendiaten sind Studierende oder Absolventinnen und Absolventen eines Doktoratsstudiums (post docs), die an der Universität im Rahmen eines Stipendiums an einem Forschungsprojekt arbeiten. Durch die Zuerkennung des Stipendiums wird kein Arbeitsverhältnis zur Universität begründet und ein bestehendes Arbeitsverhältnis nicht verändert.

Ärztinnen und Ärzte in Facharztausbildung

§ 96. Ärztinnen und Ärzte in Ausbildung zur Fachärztin oder zum Facharzt stehen für die Dauer ihrer Ausbildung in einem zeitlich befristeten Ausbildungsverhältnis zur Universität. Ihre Aufgaben ergeben sich aus den ärzterechtlichen Ausbildungsvorschriften.

3. Abschnitt

Wissenschaftliches und künstlerisches Universitätspersonal

Universitätsprofessorinnen und Universitätsprofessoren

§ 97. (1) Die Universitätsprofessorinnen und Universitätsprofessoren sind für die Forschung oder die Entwicklung und Erschließung der Künste sowie für die Lehre in ihrem Fachgebiet verantwortlich und stehen in einem befristeten oder unbefristeten Arbeitsverhältnis zur Universität. Sie sind Vollzeit- oder Teilzeitbeschäftigte.

(2) Zu Universitätsprofessorinnen und Universitätsprofessoren können in- oder ausländische Wissenschafterinnen und Wissenschafter oder Künstlerinnen und Künstler mit einer entsprechend hohen wissenschaftlichen oder künstlerischen und beruflichen Qualifikation für das Fach bestellt werden, das der zu besetzenden Stelle entspricht.

(3) Universitätsprofessorinnen und Universitätsprofessoren werden von der Rektorin oder vom Rektor nach Durchführung eines Berufungsverfahrens gemäß § 98 oder § 99 bestellt.

Berufungsverfahren für Universitätsprofessorinnen und Universitätsprofessoren

§ 98. (1) Die fachliche Widmung einer unbefristet oder länger als drei Jahre befristet zu besetzenden Stelle einer Universitätsprofessorin oder eines Universitätsprofessors ist im Entwicklungsplan festzulegen.

(2) Jede Stelle ist vom Rektorat im In- und Ausland öffentlich auszuschreiben. In das Berufungsverfahren können mit ihrer Zustimmung auch Wissenschafterinnen und Wissenschafter oder Künstlerinnen und Künstler, die sich nicht beworben haben, als Kandidatinnen und Kandidaten einbezogen werden.

(3) Die im Senat vertretenen Universitätsprofessorinnen und Universitätsprofessoren haben auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs vier – davon zwei externe – Gutachterinnen oder Gutachter zu bestellen. Sie können diese Aufgabe aber auch an die Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs und des fachlich nahe stehenden Bereichs übertragen.

(4) Der Senat hat eine entscheidungsbevollmächtigte Berufungskommission einzusetzen. Die Universitätsprofessorinnen und Universitätsprofessoren stellen mehr als die Hälfte der Mitglieder und die Studierenden mindestens ein Mitglied. Die Gutachterinnen und Gutachter gemäß Abs. 3 sind im selben Verfahren von der Mitgliedschaft in der Berufungskommission ausgeschlossen.

(5) Die vier Gutachterinnen und Gutachter haben die Eignung der Bewerberinnen und Bewerber für die ausgeschriebene Professorenstelle zu beurteilen.

(6) Die Rektorin oder der Rektor hat allen geeigneten Kandidatinnen und Kandidaten Gelegenheit zu geben, sich in angemessener Weise zumindest dem Fachbereich und dem fachlich nahe stehenden Bereich zu präsentieren.

(7) Die Berufungskommission erstellt auf Grund der Gutachten und Stellungnahmen einen begründeten Besetzungsvorschlag, der die drei für die Besetzung der ausgeschriebenen Stelle am besten geeigneten Kandidatinnen und Kandidaten zu enthalten hat. Ein Vorschlag mit weniger als drei Kandidatinnen und Kandidaten ist besonders zu begründen.

(8) Die Rektorin oder der Rektor hat die Auswahlentscheidung aus dem Besetzungsvorschlag zu treffen oder den Besetzungsvorschlag an die Berufungskommission zurückzuverweisen, wenn dieser nicht die am besten geeigneten Kandidatinnen und Kandidaten enthält.

(9) Die Rektorin oder der Rektor hat ihre oder seine Auswahlentscheidung dem Arbeitskreis für Gleichbehandlungsfragen vor Aufnahme der Berufungsverhandlungen bekannt zu geben. Der Arbeitskreis hat das Recht, innerhalb von zwei Wochen Beschwerde zu erheben. Über diese entscheidet die Schiedskommission mit Bescheid.

(10) Weist die Schiedskommission die Beschwerde ab, kann die Rektorin oder der Rektor die Berufungsverhandlungen aufnehmen. Gibt die Schiedskommission der Beschwerde statt, wird die Auswahlentscheidung unwirksam. Eine neue Auswahlentscheidung ist unter Beachtung der von der Schiedskommission vertretenen Rechtsanschauung zu treffen.

(11) Die Rektorin oder der Rektor führt die Berufungsverhandlungen und schließt mit der ausgewählten Kandidatin oder dem ausgewählten Kandidaten den Arbeitsvertrag.

(12) Die Universitätsprofessorin oder der Universitätsprofessor erwirbt mit dem Abschluss des Arbeitsvertrages mit der Universität die Lehrbefugnis (venia docendi) für das Fach, für das sie oder er berufen ist. Eine allenfalls früher erworbene Lehrbefugnis wird hievon nicht berührt.

(13) Die Lehrbefugnis (venia docendi) einer Universitätsprofessorin oder eines Universitätsprofessors in einem zeitlich befristeten Arbeitsverhältnis erlischt mit dem Ende des Arbeitsverhältnisses.

Abgekürztes Berufungsverfahren für Universitätsprofessorinnen und Universitätsprofessoren

§ 99. (1) Soll eine Universitätsprofessorin oder ein Universitätsprofessor für einen Zeitraum bis zu zwei Jahren aufgenommen werden, ist § 98 Abs. 1 und 3 bis 8 nicht anzuwenden. Eine Verlängerung der Bestellung ist nur nach Durchführung eines Berufungsverfahrens gemäß § 98 zulässig.

(2) Die Rektorin oder der Rektor hat die Kandidatin oder den Kandidaten für die zu besetzende Stelle auf Vorschlag oder nach Anhörung der Universitätsprofessorinnen und Universitätsprofessoren des fachlichen Bereichs der Universität auszuwählen, dem die Stelle zugeordnet ist.

Wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb

§ 100. (1) Die wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb müssen eine für die vorgesehene Verwendung in Betracht kommende angemessene Qualifikation aufweisen. Sie haben in ihrem Fach an der Erfüllung der Aufgaben der Universität in der Forschung oder bei der Entwicklung und Erschließung der Künste und in der Lehre mitzuarbeiten. Sie stehen in einem Arbeitsverhältnis zur Universität und sind Vollzeit- oder Teilzeitbeschäftigte.

(2) Die Universität hat die berufliche Weiterbildung der Mitarbeiterinnen und Mitarbeiter gemäß Abs. 1 zu fördern.

4. Abschnitt
Allgemeines Universitätspersonal

§ 101. (1) Die Angehörigen des allgemeinen Universitätspersonals haben die zur Erfüllung ihrer Aufgaben erforderlichen fachlichen Qualifikationen aufzuweisen. Sie stehen in einem Arbeitsverhältnis zur Universität und sind Vollzeit- oder Teilzeitbeschäftigte.

(2) Die Universität hat die berufliche Weiterbildung der Mitarbeiterinnen und Mitarbeiter gemäß Abs. 1 zu fördern.

(3) Für das Bibliothekspersonal aller Universitäten ist eine einheitliche Ausbildung aus dem Bereich Bibliotheks-, Informations- und Dokumentationswesen vorzusehen.

5. Abschnitt

Privatdozentinnen und Privatdozenten, Habilitation, emeritierte Universitätsprofessorinnen und Universitätsprofessoren sowie Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand

Privatdozentinnen und Privatdozenten

§ 102. Privatdozentinnen und Privatdozenten sind Personen, denen auf Grund ihrer wissenschaftlichen oder künstlerischen Qualifikation von der Universität die Lehrbefugnis (venia docendi) für ein wissenschaftliches oder künstlerisches Fach verliehen wurde. Sie stehen in dieser Funktion in keinem Arbeitsverhältnis zur Universität.

Habilitation

§ 103. (1) Das Rektorat hat das Recht, auf Antrag die Lehrbefugnis (venia docendi) für ein ganzes wissenschaftliches oder künstlerisches Fach zu erteilen. Die beantragte Lehrbefugnis muss in den Wirkungsbereich der Universität fallen oder diesen sinnvoll ergänzen. Mit der Erteilung der Lehrbefugnis ist das Recht verbunden, die wissenschaftliche oder künstlerische Lehre an dieser Universität mittels deren Einrichtungen frei auszuüben sowie wissenschaftliche oder künstlerische Arbeiten (§§ 81 bis 83, § 124) zu betreuen und zu beurteilen.

(2) Voraussetzung für die Erteilung der Lehrbefugnis ist der Nachweis einer hervorragenden wissenschaftlichen oder künstlerischen Qualifikation sowie der didaktischen Fähigkeiten der Bewerberin oder des Bewerbers.

(3) Die vorgelegten schriftlichen Arbeiten müssen

1. methodisch einwandfrei durchgeführt sein,
2. neue wissenschaftliche Ergebnisse enthalten und
3. die wissenschaftliche Beherrschung des Habilitationsfaches und die Fähigkeit zu seiner Förderung beweisen.

Die vorgelegten künstlerischen Arbeiten müssen die Fähigkeit zur Vertretung des künstlerischen Faches im Umfang der beantragten Lehrbefugnis beweisen.

(4) Der Antrag auf Erteilung der Lehrbefugnis ist an das Rektorat zu richten. Dieses hat den Antrag, sofern er nicht mangels Zuständigkeit der Universität zurückzuweisen ist, an den Senat weiterzuleiten.

(5) Die Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren im Senat haben auf Vorschlag der Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs vier Vertreterinnen oder Vertreter des angestrebten Habilitationsfaches, darunter zwei externe, als Gutachterinnen oder Gutachter über die vorgelegten wissenschaftlichen oder künstlerischen Arbeiten zu bestellen. Sie können diese Aufgabe aber auch an die Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs und des fachlich nahe stehenden Bereichs übertragen.

(6) Die Universitätsprofessorinnen und Universitätsprofessoren des Fachbereichs und des fachlich nahe stehenden Bereichs haben das Recht, Stellungnahmen zu den Gutachten abzugeben.

(7) Der Senat hat eine entscheidungsbevollmächtigte Habilitationskommission einzusetzen. Die Universitätsprofessorinnen und Universitätsprofessoren stellen mehr als die Hälfte der Mitglieder der Habilitationskommission, die Studierenden mindestens ein Mitglied. Die Gutachterinnen und Gutachter gemäß Abs. 5 sind im selben Verfahren von der Mitgliedschaft in der Habilitationskommission ausgeschlossen.

(8) Die Habilitationskommission entscheidet auf Grund der Gutachten und Stellungnahmen.

(9) Das Rektorat erlässt auf Grund des Beschlusses der Habilitationskommission den Bescheid über den Antrag auf Erteilung der Lehrbefugnis. Gegen diesen Bescheid ist kein ordentliches Rechtsmittel zulässig.

(10) Das Rektorat hat einen Beschluss der Habilitationskommission zurückzuverweisen, wenn wesentliche Grundsätze des Verfahrens verletzt wurden.

(11) Durch die Erteilung der Lehrbefugnis (venia docendi) wird weder ein Arbeitsverhältnis begründet, noch ein bestehendes Arbeitsverhältnis zur Universität verändert (Privatdozentin oder Privatdozent).

Emeritierte Universitätsprofessorinnen und Universitätsprofessoren sowie Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand

§ 104. (1) Emeritierte Universitätsprofessorinnen und Universitätsprofessoren sowie Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand stehen in keinem aktiven Arbeitsverhältnis zum Bund oder zur Universität.

(2) Sie haben das Recht, ihre Lehrbefugnis (venia docendi) an der Universität, an der sie vor ihrer Emeritierung oder vor ihrem Übertritt oder ihrer Versetzung in den Ruhestand in einem aktiven Arbeitsverhältnis tätig waren, weiter auszuüben und im Rahmen ihrer Lehrbefugnis Lehrveranstaltungen und Prüfungen abzuhalten.

6. Abschnitt
Allgemeine Bestimmungen

Gewissensfreiheit und Forschungsfreiheit

§ 105. Keine Universitätsangehörige und kein Universitätsangehöriger darf gegen ihr oder sein Gewissen zur Mitwirkung bei einzelnen wissenschaftlichen oder künstlerischen Arbeiten verhalten werden. Aus einer Weigerung zur Mitwirkung darf ihr oder ihm kein Nachteil erwachsen. Die oder der betroffene Universitätsangehörige hat jedoch ihre oder seine Vorgesetzte oder ihren oder seinen Vorgesetzten von ihrer oder seiner Weigerung schriftlich zu informieren.

Verwertung von geistigem Eigentum

§ 106. (1) Jede oder jeder Universitätsangehörige hat das Recht, eigene wissenschaftliche oder künstlerische Arbeiten selbstständig zu veröffentlichen. Bei der Veröffentlichung der Ergebnisse der Forschung oder der Entwicklung und Erschließung der Künste sind Universitätsangehörige, die einen eigenen wissenschaftlichen oder künstlerischen Beitrag zu dieser Arbeit geleistet haben, als Mitautorinnen oder Mitautoren zu nennen.

(2) Auf Diensterfindungen gemäß § 7 Abs. 3 Patentgesetz, BGBl. Nr. 259/1970, die an einer Universität im Rahmen eines öffentlich-rechtlichen oder privatrechtlichen Dienst- oder Ausbildungsverhältnisses zum Bund oder im Rahmen eines Arbeits- oder Ausbildungsverhältnisses zur Universität gemacht werden, ist das Patentgesetz mit der Maßgabe anzuwenden, dass die Universität als Dienstgeber gemäß § 7 Abs. 2 Patentgesetz gilt.

(3) Jede Diensterfindung ist dem Rektorat unverzüglich zur Kenntnis zu bringen. Will die Universität die Diensterfindung zur Gänze oder ein Benützungsrecht daran für sich in Anspruch nehmen, hat das Rektorat dies der Erfinderin oder dem Erfinder innerhalb von drei Monaten mitzuteilen. Andernfalls steht dieses Recht der Erfinderin oder dem Erfinder zu.

IV. Teil
Personalrecht

Ausschreibung und Aufnahme

§ 107. (1) Alle zur Besetzung offen stehenden Stellen sind vom Rektorat öffentlich auszuschreiben. Die Ausschreibungsfrist hat zumindest drei Wochen zu betragen.

(2) In folgenden Fällen kann von einer Ausschreibung abgesehen werden:

1. bei der Besetzung von Stellen, die ausschließlich für Aufgaben in der Lehre und mit geringem Stundenausmaß (Lehrauftrag) vorgesehen sind, und
2. bei Stellen für zeitlich befristete Drittmittelprojekte, denen ein qualifiziertes Auswahlverfahren vorausgegangen ist, wenn die Bestimmungen des Geldgebers dem nicht entgegenstehen.

(3) Arbeitsverträge sind von der Rektorin oder vom Rektor auf Vorschlag oder nach Anhörung der Leiterin oder des Leiters der Organisationseinheit und der oder des unmittelbaren Vorgesetzten, der oder dem die zu besetzende Stelle zugeordnet ist, abzuschließen.

(4) Arbeitsverträge für Mitarbeiterinnen und Mitarbeiter an Vorhaben gemäß § 27 Abs. 1 Z 3 sowie für Mitarbeiterinnen und Mitarbeiter, die aus zweckgebundenen Mitteln der Forschungsförderung finanziert werden, sind von der Rektorin oder vom Rektor auf Vorschlag der oder des unmittelbaren Vorgesetzten, der oder dem die zu besetzende Stelle zugeordnet ist, abzuschließen.

(5) Arbeitsverträge von Universitätsprofessorinnen und Universitätsprofessoren sind von der Rektorin oder vom Rektor nach Durchführung des Berufungsverfahrens gemäß §§ 98 oder 99 abzuschließen.

Rechtsgrundlagen der Arbeitsverhältnisse

§ 108. (1) Auf Arbeitsverhältnisse zur Universität ist, soweit gesetzlich nicht anderes bestimmt ist, das Angestelltengesetz, BGBl. Nr. 292/1921, anzuwenden.

(2) Die Universitäten bilden gemeinsam den Dachverband der Universitäten, in den das Rektorat jeder Universität eine Vertreterin oder einen Vertreter zu entsenden hat. Der Dachverband beschließt eine Geschäftsordnung und wählt mit Stimmenmehrheit eine Vorsitzende oder einen Vorsitzenden.

(3) Der Dachverband ist für die ihm angehörenden Universitäten auf Arbeitgeberseite kollektivvertragsfähig im Sinne des Arbeitsverfassungsgesetzes, BGBl. Nr. 22/1974. Ein vom Dachverband abgeschlossener Kollektivvertrag gilt für die Arbeitnehmerinnen und Arbeitnehmer der im Dachverband zusammengefassten Universitäten.

(4) Der Kollektivvertragsfähigkeit des Dachverbandes kommt im Verhältnis zur Kollektivvertragsfähigkeit anderer Interessenvertretungen oder Berufsvereinigungen der Arbeitgeberinnen und Arbeitgeber Vorrang zu.

(5) Zum Zweck der eindeutigen Identifikation in dienstlichen Belangen darf eine aus der ZMR-Zahl (§ 16 Abs. 4 des Meldegesetzes 1991, BGBl. Nr. 9/1992) durch bereichsspezifische Verschlüsselung abgeleitete Personenkennzeichnung des Universitätspersonals verwendet werden.

Dauer der Arbeitsverhältnisse

§ 109. (1) Arbeitsverhältnisse können auf unbestimmte oder bestimmte Zeit abgeschlossen werden. Arbeitsverhältnisse auf bestimmte Zeit sind bei sonstiger Rechtsunwirksamkeit des Arbeitsvertrags auf höchstens sechs Jahre zu befristen, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(2) Eine mehrmalige unmittelbar aufeinanderfolgende Befristung ist nur bei Arbeitnehmerinnen und Arbeitnehmern, die im Rahmen von Drittmittelprojekten oder Forschungsprojekten beschäftigt werden, bei ausschließlich in der Lehre verwendetem Personal sowie bei Ersatzkräften zulässig. Die Gesamtdauer solcher unmittelbar aufeinanderfolgender Arbeitsverhältnisse einer Arbeitnehmerin oder eines Arbeitnehmers darf sechs Jahre, im Fall der Teilzeitbeschäftigung acht Jahre nicht überschreiten.

Gesetzliche Sonderregelungen zur Arbeitszeit und Arbeitsruhe für das wissenschaftliche und künstlerische Universitätspersonal

§ 110. (1) Anstelle der Bestimmungen des Arbeitszeitgesetzes, BGBl. Nr. 461/1969, und des Arbeitsruhegesetzes, BGBl. Nr. 144/1983, gelten für das wissenschaftliche und künstlerische Personal der Universitäten die nachfolgenden Bestimmungen. Ausgenommen sind das wissenschaftliche Personal, auf das das Krankenanstalten-Arbeitszeitgesetz anzuwenden ist, sowie leitende Angestellte der Universitäten, denen maßgebliche Führungsaufgaben selbstverantwortlich übertragen sind.

(2) Im Sinne dieser Bestimmung ist:

1. Arbeitszeit: die Zeit vom Beginn bis zum Ende der Arbeit ohne die Ruhepausen und die Ruhezeiten, sie umfasst die Normalarbeitszeit und die Überstundenarbeit;
2. Tagesarbeitszeit: die Arbeitszeit innerhalb eines ununterbrochenen Zeitraumes von 24 Stunden;
3. Wochenarbeitszeit: die Arbeitszeit innerhalb des Zeitraumes von Montag bis einschließlich Sonntag;
4. Nacht: der Zeitraum zwischen 22 Uhr und 6 Uhr;
5. Nachtarbeitnehmerin oder Nachtarbeitnehmer: eine Arbeitnehmerin oder ein Arbeitnehmer, die oder der regelmäßig oder, sofern der Kollektivvertrag nichts anderes vorsieht, in mindestens 48 Nächten im Kalenderjahr während der Nacht mindestens drei Stunden arbeitet.

(2a) Die wöchentliche Normalarbeitszeit beträgt 40 Stunden, soweit nicht durch Kollektivvertrag abweichende Regelungen getroffen werden.

(3) Die Tagesarbeitszeit darf 13 Stunden nicht überschreiten. Die Wochenarbeitszeit darf innerhalb eines Durchrechnungszeitraumes von bis zu 17 Wochen im Durchschnitt 48 Stunden und in den einzelnen Wochen des Durchrechnungszeitraumes 60 Stunden nicht überschreiten.

(4) Die Tagesarbeitszeit von Nachtarbeitnehmerinnen und Nachtarbeitnehmern darf innerhalb eines Durchrechnungszeitraumes von 17 Wochen im Durchschnitt acht Stunden nicht überschreiten.

(5) Beträgt die Gesamtdauer der Arbeitszeit mehr als sechs Stunden, ist die Arbeitszeit durch eine Ruhepause von mindestens 30 Minuten zu unterbrechen.

(6) Nach Beendigung der Tagesarbeitszeit ist den Arbeitnehmerinnen und Arbeitnehmern eine ununterbrochene Ruhezeit von mindestens elf Stunden zu gewähren.

(7) Innerhalb eines Zeitraumes von Montag bis einschließlich Sonntag ist den Arbeitnehmerinnen und Arbeitnehmern eine ununterbrochene Ruhezeit von 36 Stunden zu gewähren. Das Ausmaß der wöchentlichen Ruhezeit kann auf 24 Stunden gekürzt werden, wenn der Arbeitnehmerin oder dem Arbeit-

nehmer innerhalb von 14 Tagen eine durchschnittliche wöchentliche Ruhezeit von 36 Stunden gesichert ist.

(7a) Soweit betriebliche Erfordernisse nicht entgegenstehen, sind Sonntage und gesetzliche Feiertage (§ 7 Abs. 2 und 3 des Arbeitsruhegesetzes) arbeitsfrei zu halten.

(8) Nachtarbeitnehmerinnen und Nachtarbeitnehmer sind auf ihr Verlangen auf eine Arbeitsstelle mit Tagesarbeit zu versetzen, wenn sie durch die Nachtarbeit nachweislich in ihrer Gesundheit beeinträchtigt sind und eine Versetzung auf eine Arbeitsstelle mit Tagesarbeit aus betrieblichen Gründen möglich ist.

(9) Nachtarbeitnehmerinnen und Nachtarbeitnehmer haben Anspruch auf unentgeltliche Untersuchungen ihres Gesundheitszustands vor Aufnahme der Tätigkeit und danach in regelmäßigen Zeitabständen. Diese Untersuchungen sind besondere Untersuchungen gemäß § 51 des ArbeitnehmerInnenschutzgesetzes (ASchG), BGBl. Nr. 450/1994.

(10) Durch Kollektivvertrag kann die ununterbrochene Ruhezeit gemäß Abs. 6 bis auf acht Stunden verkürzt werden. Solche Verkürzungen der Ruhezeit sind innerhalb der nächsten zwei Wochen durch entsprechende Verlängerung einer anderen täglichen oder wöchentlichen Ruhezeit auszugleichen. Überdies kann durch Kollektivvertrag der Durchrechnungszeitraum für die wöchentliche Arbeitszeit gemäß Abs. 3 bis auf zwölf Monate und für die wöchentliche Ruhezeit gemäß Abs. 7 bis auf zwei Monate ausgedehnt werden. Abweichungen durch Kollektivvertrag sind nur dann zulässig, wenn den betroffenen Arbeitnehmerinnen und Arbeitnehmern gleichwertige Ausgleichruhezeiten gewährt werden.

(11) Der Arbeitgeber ist, sofern die Tat nicht nach anderen Vorschriften einer strengeren Strafe unterliegt, von der Bezirksverwaltungsbehörde mit einer Geldstrafe von 36 Euro bis zu 1 500 Euro zu bestrafen, wenn

1. Arbeitnehmerinnen oder Arbeitnehmer vom Arbeitgeber über die Höchstgrenzen der täglichen oder wöchentlichen Arbeitszeit gemäß Abs. 3 oder 4 hinaus eingesetzt werden,
2. ihnen Ruhepausen gemäß Abs. 5 oder die tägliche oder wöchentliche Ruhezeit gemäß Abs. 6 oder 7 nicht gewährt wird,
3. der Gesundheitszustand von Nachtarbeitnehmerinnen oder Nachtarbeitnehmern nicht entsprechend den Bestimmungen des Abs. 9 untersucht wird.

Gesetzliche Sonderregelungen zur Arbeitsruhe für das allgemeine Universitätspersonal

§ 111. Das allgemeine Universitätspersonal, dessen Mitarbeit zur Unterstützung und Aufrechterhaltung des Lehrbetriebs oder des Forschungs- oder Kunstbetriebs unbedingt erforderlich ist, darf während der Wochenend- und Feiertagsruhe gemäß §§ 3 und 7 Arbeitsruhegesetz beschäftigt werden.

Arbeitsinspektion

§ 112. (1) Das Arbeitsinspektionsgesetz 1993 – ArbIG, BGBl. Nr. 27/1993, gilt mit der Maßgabe, dass das Arbeitsinspektorat bei der Festlegung einer Frist zur Herstellung des rechtmäßigen Zustandes gemäß § 9 Abs. 1 ArbIG bestehende Generalsanierungspläne zu berücksichtigen hat.

(2) Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit den Universitäten bis Ende 2004 den erforderlichen Aufwand für den Generalsanierungsbedarf zu erheben.

Erweiterter Kündigungs- und Entlassungsschutz

§ 113. Eine Kündigung oder Entlassung einer oder eines Angehörigen des wissenschaftlichen oder künstlerischen Universitätspersonals ist unwirksam, wenn die Kündigung wegen einer von ihr oder ihm in Forschung (Entwicklung und Erschließung der Künste) oder Lehre vertretenen Auffassung oder Methode erfolgt.

Übernahme von öffentlichen Ämtern

§ 114. (1) Die Übernahme eines öffentlichen Amtes bedarf keiner Bewilligung durch die Universität, ist jedoch dem Rektorat unverzüglich zu melden.

(2) Ist eine Ausübung des öffentlichen Amtes neben der Erfüllung der Pflichten aus dem Arbeitsverhältnis zur Universität nicht möglich, ist die Arbeitnehmerin oder der Arbeitnehmer auf Antrag gänzlich oder teilweise bei entsprechender Kürzung oder Entfall des Entgelts freizustellen.

Pensionskassensystem

§ 115. Durch Kollektivvertrag ist jedenfalls für das wissenschaftliche und künstlerische Universitätspersonal eine Pensionskassenzusage im Sinne des Betriebspensionsgesetzes, BGBl. Nr. 282/1990, zu erteilen.

V. Teil
Strafbestimmungen

§ 116. (1) Wer vorsätzlich

1. eine dem inländischen oder ausländischen Hochschulwesen eigentümliche Bezeichnung oder
2. einen oder mehrere inländische akademische Grade oder
3. eine den inländischen oder ausländischen akademischen Graden oder Titeln gleiche oder ähnliche Bezeichnung unberechtigt verleiht, vermittelt oder führt,

begeht, wenn die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet oder nach anderen Verwaltungsbestimmungen mit strengerer Strafe bedroht ist, eine Verwaltungsübertretung, die von der örtlich zuständigen Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 15 000 Euro zu bestrafen ist.

(2) Unberechtigt ist die Verleihung, Vermittlung oder Führung insbesondere dann, wenn der akademische Grad oder die gleiche oder ähnliche Bezeichnung

1. von einer Einrichtung stammt, die einer postsekundären Bildungseinrichtung nicht gleichrangig ist;
2. von einer Einrichtung stammt, die vom Sitzstaat nicht als postsekundäre Bildungseinrichtung anerkannt ist;
3. nicht auf Grund entsprechender Studien- und Prüfungsleistungen oder wissenschaftlicher oder künstlerischer Leistungen erworben wurde;
4. nicht auf Grund des wegen wissenschaftlicher oder künstlerischer Leistungen hohen Ansehens in Fachkreisen oder wegen hervorragender Verdienste für die wissenschaftlichen oder kulturellen Aufgaben der postsekundären Bildungseinrichtung ehrenhalber verliehen wurde.

VI. Teil
Liegenschaften, Bauwerke, Räumlichkeiten

Raumnutzung

§ 117. Die Universitäten sind insbesondere im Rahmen ihrer Mietrechte verpflichtet, für eine optimale Raumnutzung zu universitären Zwecken zu sorgen.

Mietrechte an Objekten der BIG und anderer Eigentümer

§ 118. Von der BIG oder von anderen Dritten angemietete Liegenschaften, Bauwerke und Räumlichkeiten, die kurzfristig nicht zu universitären Zwecken benötigt werden, dürfen an Dritte weitergegeben werden, soweit dies auf Grund des Mietvertrags und des Mietrechtsgesetzes zulässig ist.

VII. Teil
Wissenschaftsrat

§ 119. (1) Der Wissenschaftsrat ist eine Einrichtung des Bundes. Er unterliegt der Aufsicht durch die Bundesministerin oder den Bundesminister gemäß § 45.

(2) Die Aufgaben des Wissenschaftsrats sind:

1. Beratung der Bundesministerin oder des Bundesministers, der gesetzgebenden Körperschaften und der Universitäten in den Angelegenheiten der Universitäten und in Fragen der Wissenschaftspolitik und der Kunst;
2. Beobachtung und Analyse des österreichischen Universitäts- und Wissenschaftssystems unter Bedachtnahme auf europäische und internationale Entwicklungen sowie Erarbeitung von Vorschlägen zu dessen Weiterentwicklung.

(3) Die Beschlüsse, Stellungnahmen und Empfehlungen des Wissenschaftsrats sind zu veröffentlichen.

(4) Der Wissenschaftsrat hat dem Nationalrat ab 2004 zumindest alle drei Jahre im Wege der Bundesminsterin oder des Bundesministers einen Tätigkeitsbericht vorzulegen. Dieser Bericht hat auch Empfehlungen über die Grundausrichtung der Leistungsvereinbarungen mit den Universitäten unter Bedachtnahme auf die Standortentwicklung zu enthalten.

(5) Der Wissenschaftsrat besteht aus zwölf Mitgliedern aus unterschiedlichen Bereichen der Gesellschaft, insbesondere der Wissenschaft und der Kunst, die von der Bundesregierung auf Vorschlag der Bundesministerin oder des Bundesministers bestellt werden. Dabei sind Frauen in entsprechender Anzahl zu berücksichtigen.

(6) Von der Mitgliedschaft im Wissenschaftsrat ausgeschlossen sind:

1. akademische Funktionärinnen und Funktionäre der Universitäten gemäß § 6 sowie der in Österreich gemäß Universitäts-Akkreditierungsgesetz, BGBl. I Nr. 168/1999, akkreditierten Privatuniversitäten;
2. Mitarbeiterinnen und Mitarbeiter des für die Universitäten zuständigen Bundesministeriums sowie
3. Mitglieder der Bundesregierung oder einer Landesregierung, Mitglieder des Nationalrats, des Bundesrats oder sonst eines allgemeinen Vertretungskörpers, Funktionäre einer politischen Partei sowie Personen, die eine dieser Funktionen in den letzten vier Jahren ausgeübt haben.

(7) Die Bundesregierung hat zunächst vier Personen zu Mitgliedern des Wissenschaftsrats zu bestellen. Diese erstatten der Bundesministerin oder dem Bundesminister Vorschläge für die Nominierung der acht weiteren Mitglieder.

(8) Die Funktionsperiode der Mitglieder des Wissenschaftsrats ist von der Bundesregierung mit drei oder sechs Jahren festzusetzen und beginnt mit der konstituierenden Sitzung des Wissenschaftsrats. Eine einmalige Wiederbestellung ist zulässig. Bei vorzeitigem Ausscheiden eines Mitglieds des Wissenschaftsrats ist für den Rest der Funktionsperiode des ausgeschiedenen Mitglieds ein neues Mitglied zu bestellen.

(9) Die Mitgliedschaft im Wissenschaftsrat endet

1. durch Ablauf der Funktionsperiode,
2. durch Verzicht,
3. durch Abberufung,
4. durch Tod.

(10) Die Bundesministerin oder der Bundesminister beruft die konstituierende Sitzung des Wissenschaftsrats ein. Die oder der Vorsitzende wird aus dem Kreis der Mitglieder mit Stimmenmehrheit gewählt. Der Wissenschaftsrat gibt sich eine Geschäftsordnung.

(11) Die Bundesregierung kann ein Mitglied des Wissenschaftsrats auf Antrag der Bundesministerin oder des Bundesministers oder auf Antrag der Mehrheit der Mitglieder des Wissenschaftsrats wegen einer schweren Pflichtverletzung, einer strafgerichtlichen Verurteilung oder wegen mangelnder körperlicher oder geistiger Eignung mit Bescheid von seiner Funktion abberufen.

(12) Der Wissenschaftsrat ist beschlussfähig, wenn wenigstens die Hälfte der Mitglieder persönlich anwesend ist. Stimmübertragungen sind unzulässig.

(13) Der Wissenschaftsrat ist berechtigt, in- und ausländische Expertinnen und Experten zu den Sitzungen einzuladen und Arbeitsgruppen einzurichten.

(14) Die Mitglieder des Wissenschaftsrats erhalten für ihre Tätigkeit eine Vergütung, die von der Bundesministerin oder vom Bundesminister festzusetzen ist.

(15) Die Bundesministerin oder der Bundesminister hat dem Wissenschaftsrat die zur Erfüllung seiner Aufgaben erforderliche räumliche, technische und personelle Ausstattung zur Verfügung zu stellen.

VIII. Teil
Übergangs- und Schlussbestimmungen

1. Abschnitt
Implementierung der neuen Organisation

Gründungskonvent

§ 120. (1) An jeder der in § 6 Z 1 bis 21 vorgesehenen Universitäten ist unverzüglich nach der Kundmachung dieses Bundesgesetzes ein Gründungskonvent einzurichten, der aus zwölf Mitgliedern besteht.

(2) Dem Gründungskonvent gehören Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren, der im § 94 Abs. 2 Z 2 genannten Gruppe, des allgemeinen Universitätspersonals und der Studierenden der gleichnamigen Universität gemäß UOG 1993 oder KUOG an.

(3) Abweichend von Abs. 2 sind die Angehörigen einer Medizinischen Fakultät nur für den Gründungskonvent jener Medizinischen Universität aktiv und passiv wahlberechtigt oder entsendungsfähig, die gemäß § 136 Abs. 2 die Gesamtrechtsnachfolgerin der betreffenden Medizinischen Fakultät ist.

(4) Angehörige von Interuniversitären Einrichtungen sind für den Gründungskonvent jener Universität aktiv und passiv wahlberechtigt, welche gemäß § 136 Abs. 4 bis 11 die Nachfolgeeinrichtung der jeweiligen Interuniversitären Einrichtung ist.

(5) Die im Amt befindlichen Rektorinnen und Rektoren, Vizerektorinnen und Vizerektoren gemäß UOG 1993 und KUOG sind passiv nicht wahlberechtigt.

(6) Die Bundesministerin oder der Bundesminister hat durch Verordnung eine Wahlordnung für die Gründungskonvente aller Universitäten nach den Grundsätzen des gleichen, unmittelbaren, geheimen und persönlichen Verhältniswahlrechts zu erlassen.

(7) Die Mitglieder und Ersatzmitglieder des Gründungskonvents sind folgendermaßen zu bestellen:

1. Sieben Vertreterinnen und Vertreter der Universitätsprofessorinnen und Universitätsprofessoren sind von allen Universitätsprofessorinnen und Universitätsprofessoren (§ 97) zu wählen.
2. Zwei Vertreterinnen und Vertreter der im § 94 Abs. 2 Z 2 genannten Gruppe sind von allen Universitätsdozentinnen und Universitätsdozenten (§ 122 Abs. 3) sowie den wissenschaftlichen und künstlerischen Mitarbeiterinnen und Mitarbeitern im Forschungs-, Kunst- und Lehrbetrieb zu wählen. Den Gewählten muss zumindest eine Person mit Lehrbefugnis (venia docendi) angehören.
3. Eine Vertreterin oder ein Vertreter des allgemeinen Universitätspersonals ist von allen Angehörigen des allgemeinen Universitätspersonals zu wählen.
4. Zwei Vertreterinnen und Vertreter der Studierenden sind durch die gesetzliche Vertretung der Studierenden zu entsenden.

(8) Die oder der Vorsitzende des Dienststellenausschusses der Universitätslehrer sowie die oder der Vorsitzende des Dienststellenausschusses für die Bediensteten mit Ausnahme der Universitätslehrer, die oder der Vorsitzende des Arbeitskreises für Gleichbehandlungsfragen, die Bibliotheksdirektorin oder der Bibliotheksdirektor, die Universitätsdirektorin oder der Universitätsdirektor, die Leiterin oder der Leiter des zentralen Informatikdienstes sowie die oder der Vorsitzende der Hochschülerschaft an der betreffenden Universität gehören dem Gründungskonvent mit beratender Stimme an.

(9) Der Gründungskonvent ist beschlussfähig, wenn wenigstens die Hälfte der stimmberechtigten Mitglieder persönlich anwesend oder durch ein Ersatzmitglied vertreten ist. Die Beschlüsse werden mit Stimmenmehrheit gefasst, sofern in diesem Bundesgesetz nicht anderes bestimmt ist.

(10) Die im Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes im Amt befindliche Rektorin oder der im Amt befindliche Rektor hat die Wahlen in den Gründungskonvent auszuschreiben, die konstituierende Sitzung bis längstens 30. November 2002 einzuberufen und bis zur Wahl der oder des Vorsitzenden zu leiten. Für den Gründungskonvent einer Medizinischen Universität kommt diese Aufgabe der Dekanin oder dem Dekan der Medizinischen Fakultät zu, deren Nachfolgeeinrichtung die Medizinische Universität ist.

(11) Der Gründungskonvent hat die im § 121 vorgesehenen Maßnahmen zur Implementierung vorzubereiten und durchzuführen, soweit gesetzlich nicht ausdrücklich anderes bestimmt ist.

(12) Die Funktion des Gründungskonvents endet mit Ablauf des 31. Dezember 2003.

Implementierungsschritte

§ 121. (1) Die Bestimmungen des UOG 1993 und des KUOG sind an den Universitäten und an den Universitäten der Künste bis 31. Dezember 2003 anzuwenden.

(2) Die zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes im Amt befindlichen Rektorinnen und Rektoren, Vizerektorinnen und Vizerektoren üben ihr Amt bis zur Funktionsübernahme des Rektorats nach diesem Bundesgesetz aus.

(3) Der Gründungskonvent hat die Größe des Senats gemäß § 25 Abs. 2 festzulegen, eine provisorische Satzung einschließlich einer Wahlordnung für den Senat zu beschließen und die erforderlichen wei-

teren Schritte der Überleitung zu veranlassen, soweit hiefür gesetzlich keine anderen Maßnahmen vorgesehen sind. Die Wahlordnung hat den Grundsätzen gemäß § 120 Abs. 6 zu entsprechen.

(4) Der Gründungskonvent hat die Größe des Universitätsrats mit fünf, sieben oder neun Mitgliedern festzulegen und unverzüglich zwei, drei oder vier Mitglieder des Universitätsrats zu wählen. Kommt der Gründungskonvent einer Universität bis 31. Jänner 2003 dieser Aufgabe nicht nach, bestellt die Bundesministerin oder der Bundesminister auch die Mitglieder, die vom Gründungskonvent zu wählen gewesen wären.

(5) Die Bundesregierung hat bis 28. Februar 2003 auf Antrag der Bundesministerin oder des Bundesministers nach Maßgabe des Abs. 4 zwei, drei oder vier Mitglieder für jeden Universitätsrat zu bestellen.

(6) Der Universitätsrat hat sich unverzüglich zu konstituieren und längstens bis 31. März 2003 das weitere Mitglied (§ 21 Abs. 6 Z 3) zu wählen.

(7) Der Gründungskonvent hat unverzüglich die Wahl der Rektorin oder des Rektors auszuschreiben und einen Vorschlag für die Wahl der Rektorin oder des Rektors zu erstellen. Die Wahl der Rektorin oder des Rektors durch den Universitätsrat hat bis spätestens 30. Juni 2003 zu erfolgen.

(8) Die gewählten Rektorinnen oder Rektoren haben nach Anhörung des Gründungskonvents unverzüglich die Zahl der Vizerektorinnen und Vizerektoren sowie deren Beschäftigungsausmaß festzulegen und einen Wahlvorschlag vorzulegen. Die Wahl der Vizerektorinnen und Vizerektoren hat spätestens acht Wochen nach der Rektorswahl stattzufinden.

(9) Die Mitglieder des Rektorats haben am 1. Oktober 2003 ihr Amt anzutreten.

(10) Das Rektorat hat unverzüglich einen provisorischen Organisationsplan zu erlassen und die provisorischen Leiterinnen und Leiter der einzelnen Organisationseinheiten zu bestellen. Dieser provisorische Organisationsplan ist mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität in Kraft zu setzen.

(11) Die Rektorin oder der Rektor hat unverzüglich die Wahlen für den Senat auszuschreiben und die Sitzung bis zur Wahl der oder des Vorsitzenden zu leiten. Die Wahlen zum Senat haben bis 31. Oktober 2003, die konstituierende Sitzung des Senats und die Wahl des Vorsitzenden bis 30. November 2003 stattzufinden.

(12) Die Geschäftsordnung des Rektorats ist bis 31. Oktober 2003 kundzumachen.

(13) Bis spätestens 31. Dezember 2003 ist dem Universitätsrat die endgültige Organisationsform der Universität (Organisationsplan) und dem Senat der Vorschlag für die Satzung zur Beschlussfassung vorzulegen.

(14) Unverzüglich nach der Genehmigung des Organisationsplans sind die Leiterinnen und Leiter der Organisationseinheiten zu bestellen.

(15) Die gemäß UOG 1993 errichteten Universitätskliniken und Klinischen Institute der Medizinischen Fakultäten bleiben bis zum Wirksamwerden eines neuen Organisationsplans der betreffenden Medizinischen Universität bestehen und die bestellten Leiterinnen und Leiter im Amt. Diese Einrichtungen gelten ab 1. Jänner 2004 als Organisationseinheiten des Klinischen Bereichs dieser Medizinischen Universität.

(16) Die Universität hat der Bundesministerin oder dem Bundesminister jeweils bis zum 30. April 2005, 2006 und 2007 zusätzlich zum Rechnungsabschluss einen Tätigkeitsbericht vorzulegen, der sich auf das gesamte Leistungsspektrum der Universität zu beziehen hat.

(17) Die Bundesministerin oder der Bundesminister hat im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Finanzen bis spätestens Ende des Jahres 2005 den für die erste Leistungsvereinbarungsperiode zur Finanzierung der Universitäten zur Verfügung stehenden Gesamtbetrag festzusetzen und darüber das Einvernehmen gemäß § 45 des Bundeshaushaltsgesetzes herzustellen. Die Universität hat der Bundesministerin oder dem Bundesminister bis 30. April 2006 den Entwurf der ersten Leistungsvereinbarung für die Jahre 2007 bis 2009 vorzulegen.

(18) Jede Universität hat bis zum Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes ein Bestandsverzeichnis zu erstellen. Dieses Verzeichnis hat das bisher der Universität gewidmete bewegliche und unbewegliche Vermögen, Verbindlichkeiten der Universität gegenüber Dritten, insbesondere aus Kreditaufnahmen, sowie alle Bankkonten inklusive der Wertpapierbestände und die Drittmittel der Institute (Kliniken) anzuführen. Diesem Verzeichnis ist auch eine Aufstellung des am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität beschäftigten Personals beizufügen.

(19) Die Bundesministerin oder der Bundesminister hat bis 30. September 2006 einen Bericht über die Nachwuchsförderung und die Entwicklung der Personalstruktur der Universitäten vorzulegen.

(20) Der Gründungskonvent jeder Universität hat bis spätestens 31. Dezember 2002 eine Vertreterin oder einen Vertreter in den Dachverband der Universitäten zu entsenden. Die Funktionsperiode dieser Vertreterin oder dieses Vertreters endet mit der Entsendung einer neuen Vertreterin oder eines neuen Vertreters durch das Rektorat der betreffenden Universität (§ 108 Abs. 2).

(21) Die Rektorin oder der Rektor der Universität Wien hat die konstituierende Sitzung des Dachverbandes der Universitäten (§ 108) einzuberufen und diese Sitzung bis zur Wahl der oder des Vorsitzenden zu leiten.

(22) Erfolgen die zur Implementierung erforderlichen Schritte nicht rechtzeitig, können die notwendigen Maßnahmen ohne Setzung einer Nachfrist durch die Bundesministerin oder den Bundesminister im Wege der Ersatzvornahme vorgenommen werden.

(23) Legt eine Universität den Entwurf einer ersten Leistungsvereinbarung der Bundesministerin oder dem Bundesminister nicht rechtzeitig vor, beträgt das Budget für das betreffende Jahr 98 vH des Budgets des Vorjahres.

(24) Die Fakultätsvertretungen gemäß § 15 des Hochschülerschaftsgesetzes 1998 an den Medizinischen Fakultäten der Universitäten Wien, Graz und Innsbruck für die Studienrichtungen Medizin, Humanmedizin, Zahnmedizin und das Doktoratsstudium der medizinischen Wissenschaft üben bezüglich der Vollziehung der Bestimmungen des Universitätsgesetzes 2002 bis 31. Dezember 2003 auch die Funktion der Universitätsvertretungen der Studierenden gemäß § 13 des Hochschülerschaftsgesetzes 1998 an den Medizinischen Universitäten Wien, Graz und Innsbruck aus und gelten ab 1. Jänner 2004 als diese Universitätsvertretungen.

(25) Die Bestimmungen dieses Bundesgesetzes werden an den Universitäten mit 1. Jänner 2004 voll wirksam.

2. Abschnitt
Organisation
Überleitung der Universitätsangehörigen gemäß UOG 1993 und KUOG

§ 122. (1) Alle zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes in einem Dienstverhältnis, Arbeitsverhältnis oder in einem sonstigen Rechtsverhältnis stehenden oder im Zeitraum zwischen dem In-Kraft-Treten und dem vollen Wirksamwerden dieses Bundesgesetzes neu in ein Dienst-, Arbeits- oder sonstiges Rechtsverhältnis aufgenommenen Universitätsangehörigen haben Rechte und Aufgaben nach Maßgabe dieses Bundesgesetzes.

(2) Im Übrigen gilt Folgendes:

1. Universitätsprofessorinnen und Universitätsprofessoren gemäß § 21 UOG 1993 oder § 22 KUOG gelten organisationsrechtlich als Universitätsprofessorinnen und Universitätsprofessoren gemäß § 97 dieses Bundesgesetzes;
2. emeritierte Universitätsprofessorinnen und Universitätsprofessoren und Universitätsprofessorinnen oder Universitätsprofessoren im Ruhestand gemäß § 24 UOG 1993 oder § 25 KUOG gelten organisationsrechtlich als emeritierte Universitätsprofessorinnen und Universitätsprofessoren oder Universitätsprofessorinnen und Universitätsprofessoren im Ruhestand gemäß § 104 dieses Bundesgesetzes;
3. Gastprofessorinnen und Gastprofessoren gemäß § 25 UOG 1993 oder § 26 KUOG gelten organisationsrechtlich als Universitätsprofessorinnen und Universitätsprofessoren gemäß § 97 dieses Bundesgesetzes;
4. Universitätsdozentinnen und Universitätsdozenten gemäß § 27 Abs. 3 UOG 1993 oder § 28 Abs. 3 KUOG (Amtstitel: Außerordentliche Universitätsprofessorin oder Außerordentlicher Universitätsprofessor) gelten organisationsrechtlich als Universitätsdozentinnen und Universitätsdozenten gemäß § 94 Abs. 2 Z 2 dieses Bundesgesetzes;
5. Universitätsassistentinnen und Universitätsassistenten gemäß § 29 UOG 1993 oder § 30 KUOG gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;
6. Wissenschaftliche Mitarbeiterinnen und Mitarbeiter im Forschungs- und Lehrbetrieb gemäß § 32 UOG 1993 und Mitarbeiterinnen und Mitarbeiter im Kunst-, Forschungs- und Lehrbetrieb gemäß § 33 KUOG gelten, soweit sie nicht arbeitsrechtlich zur Gruppe der Wissenschaftlichen und

Künstlerischen Mitarbeiterinnen und Mitarbeiter (in Ausbildung) gemäß § 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, gehören, organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;

7. Studienassistentinnen und Studienassistenten gemäß § 34 UOG 1993 oder § 34 KUOG gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;
8. Lehrbeauftragte gemäß § 30 UOG 1993 oder § 31 KUOG gelten organisationsrechtlich als wissenschaftliche und künstlerische Mitarbeiterinnen und Mitarbeiter im Forschungs-, Kunst- und Lehrbetrieb gemäß § 100 dieses Bundesgesetzes;
9. die Wissenschaftlichen Mitarbeiterinnen und Mitarbeiter im Forschungs- und Lehrbetrieb gemäß § 19 Abs. 2 Z 2 UOG 1993 sind, soweit sie arbeitsrechtlich zur Gruppe der Wissenschaftlichen und Künstlerischen Mitarbeiterinnen und Mitarbeiter (in Ausbildung) gemäß § 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, gehören, organisationsrechtlich den Forschungsstipendiatinnen und Forschungsstipendiaten gemäß § 96 dieses Bundesgesetzes gleichgestellt;
10. die Mitarbeiterinnen und Mitarbeiter im Kunst-, Forschungs- und Lehrbetrieb gemäß § 20 Abs. 2 Z 2 KUOG sind, soweit sie arbeitsrechtlich zur Gruppe der Wissenschaftlichen und Künstlerischen Mitarbeiter (in Ausbildung) gemäß § 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, gehören, organisationsrechtlich den Forschungsstipendiatinnen und Forschungsstipendiaten gemäß § 96 dieses Bundesgesetzes gleichgestellt;
11. Ärztinnen und Ärzte in Ausbildung zur Fachärztin oder zum Facharzt gemäß § 33 Abs. 1 Z 3 UOG 1993 in Verbindung mit § 19 Abs. 2 Z 3 UOG 1993 oder gemäß § 33 Abs. 1 Z 1 UOG 1993 in Verbindung mit § 19 Abs. 2 Z 1 lit. f UOG 1993 (Universitätsassistenten) gelten organisationsrechtlich als Ärztinnen und Ärzte in Facharztausbildung gemäß § 94 Abs. 1 Z 3 dieses Bundesgesetzes;
12. Ärztinnen und Ärzte gemäß § 33 Abs. 2 UOG 1993 gelten organisationsrechtlich als allgemeines Universitätspersonal gemäß § 101 dieses Bundesgesetzes;
13. Allgemeine Universitätsbedienstete gemäß § 35 UOG 1993 oder gemäß § 35 KUOG gelten organisationsrechtlich als allgemeines Universitätspersonal gemäß § 101 dieses Bundesgesetzes;
14. Universitätsdozentinnen und Universitätsdozenten gemäß § 27 UOG 1993 oder gemäß § 28 KUOG, die als solche in keinem Dienstverhältnis (§ 170 BDG 1979, § 55 Vertragsbedienstetengesetz 1948) stehen, gelten organisationsrechtlich als Privatdozentinnen und Privatdozenten gemäß § 102 dieses Bundesgesetzes;
15. Honorarprofessorinnen und Honorarprofessoren gemäß § 26 UOG 1993 oder § 27 KUOG gelten organisationsrechtlich als Privatdozentinnen und Privatdozenten gemäß § 102 dieses Bundesgesetzes.

(3) Universitätsdozentinnen und Universitätsdozenten (Amtstitel: Ao. Universitätsprofessorinnen und Universitätsprofessoren) gemäß Abs. 2 Z 4 bleibt das Recht gewahrt, die wissenschaftliche oder künstlerische Lehre in ihrem Fach an der Universität, die ihnen die Lehrbefugnis (venia docendi) verliehen hat, mittels der Einrichtungen der Universität frei auszuüben, die Einrichtungen dieser Universität für wissenschaftliche oder künstlerische Arbeiten zu benützen und wissenschaftliche oder künstlerische Arbeiten (§§ 81 bis 83, § 124) zu betreuen und zu beurteilen. Darüber hinaus haben sie das Recht, auf dem Gebiet ihrer Lehrbefugnis Lehrveranstaltungen auch an anderen Universitäten, zu deren Wirkungsbereich das Fachgebiet ihrer Lehrbefugnis gehört, anzukündigen und nach Maßgabe der räumlichen Möglichkeiten abzuhalten.

(4) Die im Abs. 3 genannten Universitätsdozentinnen und Universitätsdozenten haben folgende Aufgaben verantwortlich wahrzunehmen:

1. Forschungstätigkeit (Entwicklung und Erschließung der Künste);
2. Durchführung von Lehrveranstaltungen, insbesondere der Pflichtlehrveranstaltungen, in Vertretung ihres Faches, nach Maßgabe des Bedarfs, unter Berücksichtigung der Studienvorschriften;
3. Durchführung von Prüfungen;
4. Betreuung von Studierenden;
5. Heranbildung und Förderung des wissenschaftlichen oder künstlerischen Nachwuchses;

6. Mitwirkung an Organisations-, Verwaltungs- und Managementaufgaben;
7. Mitwirkung bei Evaluierungsmaßnahmen.

(5) Auf Vorschlag der Mehrheit der Universitätsprofessorinnen und Universitätsprofessoren einer Organisationseinheit mit Forschungs- und Lehraufgaben oder Aufgaben der Entwicklung und Erschließung der Künste und der Lehre der Kunst können die im Abs. 3 genannten Universitätsdozentinnen und Universitätsdozenten vom Rektorat abweichend von § 20 Abs. 5 mit der Leitung dieser Organisationseinheit betraut werden.

(6) Hinsichtlich der Wahl in Kollegialorgane gehören die in Abs. 3 genannten Universitätsdozentinnen und Universitätsdozenten zu der im § 94 Abs. 2 Z 2 genannten Gruppe.

(7) Universitätsdozentinnen und Universitätsdozenten gemäß Abs. 2 Z 14 sowie Honorarprofessorinnen und Honorarprofessoren gemäß Abs. 2 Z 15 bleibt das Recht gewahrt, die wissenschaftliche oder künstlerische Lehre in ihrem Fach an der Universität, die ihnen die Lehrbefugnis verliehen hat, mittels der Einrichtungen der Universität frei auszuüben sowie wissenschaftliche oder künstlerische Arbeiten (§§ 81 bis 83, § 124) zu betreuen und zu beurteilen. Darüber hinaus haben sie das Recht, auf dem Gebiet ihrer Lehrbefugnis Lehrveranstaltungen auch an anderen Universitäten, zu deren Wirkungsbereich das Fachgebiet ihrer Lehrbefugnis gehört, anzukündigen und nach Maßgabe der räumlichen Möglichkeiten abzuhalten.

Übergangsbestimmungen für Berufungskommissionen, Habilitationskommissionen und besondere Habilitationskommissionen

§ 123. Berufungskommissionen, Habilitationskommissionen und besondere Habilitationskommissionen, die vor dem vollen Wirksamwerden dieses Bundesgesetzes an der betreffenden Universität oder Universität der Künste konstituiert wurden und ihre Tätigkeit bereits aufgenommen haben, haben das Verfahren in ihrer bisherigen Zusammensetzung und nach den bisherigen Bestimmungen durchzuführen.

3. Abschnitt
Studienrecht

§ 124. (1) Die an den Universitäten am 1. Oktober 2003 eingerichteten Diplom-, Bakkalaureats-, Magister- und Doktoratsstudien bleiben an diesen Universitäten, solange keine entgegenstehenden Entscheidungen gemäß § 54 dieses Bundesgesetzes getroffen werden, weiterhin eingerichtet. Auf diese Studien sind die jeweiligen Studienpläne in der am 1. Oktober 2003 geltenden Fassung weiterhin anzuwenden und diese Studienpläne dürfen gemäß § 25 Abs. 1 Z 10 auch abgeändert werden. An Absolventinnen und Absolventen dieser Diplomstudien sowie dieser Bakkalaureats- oder Magisterstudien sind jeweils jene akademischen Grade zu verleihen, die am 1. Oktober 2003 für die jeweiligen Studien vorgesehen sind. § 80 bis § 80b UniStG sind sinngemäß anzuwenden. Werden an Stelle bestehender Studien gemäß § 54 Abs. 1 Bakkalaureats-, Magister- oder Doktoratsstudien eingerichtet, so sind in den Curricula den § 80 Abs. 2 und § 80a Abs. 2 UniStG entsprechende Übergangsbestimmungen vorzusehen.

(2) Die Studienkommissionen haben bis zum 1. Juli 2003 allen gemäß UniStG erlassenen Studienplänen ECTS-Anrechnungspunkte im Sinne des § 13 Abs. 4 Z 9 und § 19 Abs. 4 UniStG zuzuteilen.

(3) Die an den Universitäten am 31. Dezember 2003 gemäß UniStG eingerichteten Universitätslehrgänge und Vorbereitungslehrgänge bleiben an den Universitäten weiterhin eingerichtet. Auf diese Studien sind die jeweiligen Studienpläne in der am 31. Dezember 2003 geltenden Fassung weiterhin anzuwenden.

(4) § 77 ist ab dem 1. Oktober 2003 anzuwenden. Für die Wiederholung von Prüfungen, die vor dem 1. Oktober 2003 negativ beurteilt wurden, ist statt § 77 dieses Bundesgesetzes der § 58 Abs. 1 bis Abs. 6 UniStG, in der zuletzt geltenden Fassung, anzuwenden.

(5) Wird zu einem gemäß Abs. 1 eingerichteten Diplomstudium dieses Studium auch als Bakkalaureats- und Magisterstudien eingerichtet, so darf eine Zulassung zum Diplomstudium nicht mehr erfolgen. Die Übergangsbestimmungen dürfen für das Weiterstudium auf Grund der alten Vorschriften eine Übergangsfrist vorsehen, die höchstens der durchschnittlichen Studiendauer für dieses Diplomstudium entspricht.

(6) Auf Anträge gemäß den §§ 27 und 28 UniStG, die vor dem 1. Jänner 2004 anhängig gemacht wurden, sind die §§ 27 und 28 UniStG, in der zuletzt geltenden Fassung, anzuwenden.

(7) Auf jene Nostrifizierungsverfahren, die an den Universitäten gemäß § 6 Z 16 bis 21 vor dem 1. August 1998 anhängig gemacht wurden, ist statt § 90 dieses Bundesgesetzes § 49 KHStG anzuwenden. Auf jene Nostrifizierungsverfahren, die an den Universitäten gemäß § 6 Z 1 bis 15 vor dem 1. August

1997 anhängig gemacht wurden, ist statt § 90 dieses Bundesgesetzes § 40 AHStG anzuwenden. Auf jene Nostrifizierungsverfahren, die an den Universitäten bis zum 31. Dezember 2003 anhängig gemacht werden, sind statt § 90 dieses Bundesgesetzes die §§ 70 bis 73 UniStG anzuwenden.

(8) Auf ordentliche Studierende, die an den Universitäten vor dem 1. Jänner 2004 zu einem individuellen Diplomstudium zugelassen wurden, ist § 17 UniStG weiterhin anzuwenden.

(9) § 64 Abs. 1 Z 6 und § 78 Abs. 1 sind nur für jene Lehrgänge universitären Charakters anzuwenden, denen die Berechtigung zur Bezeichnung nach dem 1. September 2001 verliehen wurde.

4. Abschnitt
Überleitung des Personals
Beamtinnen und Beamte des Bundes

§ 125. (1) Für den Bereich jeder Universität wird ein „Amt der Universität …“ eingerichtet, das in seiner Bezeichnung den Namen der betreffenden Universität zu führen hat. Das „Amt der Universität …“ ist der Bundesministerin oder dem Bundesminister unmittelbar nachgeordnet und wird von der Rektorin oder dem Rektor dieser Universität geleitet. Diese oder dieser ist in dieser Funktion an die Weisungen der Bundesministerin oder des Bundesministers gebunden. Das „Amt der Universität …“ ist Dienstbehörde erster Instanz. In Dienstrechtsverfahren hat die Rektorin oder der Rektor als Leiterin oder Leiter des „Amts der Universität …“ das Dienstrechtsverfahrensgesetz 1984, BGBl. Nr. 29/1984, anzuwenden. Über Berufungen gegen Bescheide des „Amts der Universität …“ entscheidet die Bundesministerin oder der Bundesminister.

(2) Beamtinnen oder Beamte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität im Planstellenbereich Universitäten oder Universitäten der Künste ernannt sind, gehören ab dem auf diesen Zeitpunkt folgenden Tag (Stichtag) für die Dauer ihres Dienststandes dem Amt jener Universität an, deren Aufgaben sie überwiegend besorgt haben, und sind dieser Universität zur dauernden Dienstleistung zugewiesen, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(3) Beamtinnen und Beamte, die in einem anderen Planstellenbereich ernannt und der Universität zur Dienstleistung zugewiesen sind, gelten bei entsprechendem Bedarf ab dem Stichtag weiterhin der Universität zur Dienstleistung zugewiesen.

(4) Beamtinnen oder Beamte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität im Planstellenbereich Universitäten ernannt und einer Einrichtung einer Medizinischen Fakultät zugeordnet sind, gehören ab dem auf diesen Zeitpunkt folgenden Tag (Stichtag) für die Dauer ihres Dienststandes dem Amt jener Medizinischen Universität an, welche die Nachfolgeeinrichtung der betreffenden Medizinischen Fakultät ist, und sind dieser Medizinischen Universität zur dauernden Dienstleistung zugewiesen, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(5) Beamtinnen oder Beamte, die zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes einer Interuniversitären Einrichtung zugeordnet sind oder in der Zeit danach zugeordnet werden, gelten mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität, welche die Nachfolgeeinrichtung der betreffenden Interuniversitären Einrichtung ist, als dieser Universität zugeordnet, solange sie nicht zu einer anderen Bundesdienststelle versetzt werden.

(6) Die in den Abs. 2 bis 5 genannten und in einem definitiven Bundesdienstverhältnis stehenden Beamtinnen und Beamten sind den Arbeitnehmerinnen und Arbeitnehmern der Universität in einem unbefristeten Arbeitsverhältnis organisationsrechtlich gleichgestellt.

(7) Die Verwendung der Beamtinnen und Beamten gemäß Abs. 2 bis 5 in einer Gesellschaft, an der die Universität mehrheitlich beteiligt ist, ist unter Beachtung der Art. 17 und 17a StGG zulässig.

(8) Dem „Amt der Universität …“ zugewiesene Beamtinnen und Beamte gemäß Abs. 2, 4 und 5 in einem definitiven Dienstverhältnis haben, wenn sie innerhalb von drei Jahren ab dem Stichtag ihren Austritt aus dem Bundesdienst erklären, mit Wirksamkeit von dem auf den Austritt folgenden Monatsersten Anspruch auf Aufnahme in ein Arbeitsverhältnis zur betreffenden Universität zu den zu diesem Zeitpunkt für neu eintretende Arbeitnehmerinnen und Arbeitnehmer geltenden Bestimmungen.

(9) Dem „Amt der Universität …“ zugewiesene Beamtinnen und Beamte gemäß Abs. 2, 4 und 5, die sich zum Stichtag im provisorischen Dienstverhältnis (§§ 10 und 177 BDG 1979) befinden, haben, wenn sie innerhalb von drei Jahren ab ihrer Definitivstellung ihren Austritt aus dem Bundesdienst erklären, mit Wirksamkeit von dem auf den Austritt folgenden Monatsersten Anspruch auf Aufnahme in ein Arbeitsverhältnis zur betreffenden Universität zu den zu diesem Zeitpunkt für neu eintretende Arbeitnehmerinnen und Arbeitnehmer geltenden Bestimmungen.

(10) Die beim Bund zurückgelegte Dienstzeit ist in den Fällen der Abs. 8 und 9 für alle zeitabhängigen Ansprüche anzurechnen. Forderungen des Bundes gegenüber diesen Bediensteten aus ihrem öffentlich-rechtlichen Dienstverhältnis, die bis zum Austritt entstanden sind, gehen bei Begründung eines Arbeitsverhältnisses zur Universität auf die Universität über und sind von dieser dem Bund zu refundieren.

(11) Eine Beamtin oder ein Beamter, die oder der in ein Arbeitsverhältnis zur Universität übertritt, hat keinen Anspruch auf Abfertigung gemäß § 26 und § 54 des Gehaltsgesetzes 1956, BGBl. Nr. 54. Wird eine Beamtin oder ein Beamter, die oder der gemäß § 21 BDG 1979 in Verbindung mit § 26 Abs. 3 Gehaltsgesetz 1956 aus dem Dienstverhältnis ausgetreten ist, innerhalb von sechs Monaten nach Beendigung dieses Dienstverhältnisses in ein Arbeitsverhältnis zur Universität aufgenommen, hat sie oder er der Universität die anlässlich der Beendigung des bisherigen Dienstverhältnisses gemäß § 26 Abs. 3 Gehaltsgesetz 1956 erhaltene Abfertigung zu erstatten.

(12) Für dem „Amt der Universität …“ zugewiesene Beamtinnen und Beamten hat die Universität dem Bund den gesamten Aktivitätsaufwand samt Nebenkosten zu ersetzen und einen Beitrag zur Deckung des Pensionsaufwands zu leisten. Dieser Beitrag beträgt 31,8 vH des Aufwandes an Aktivbezügen. Als Aktivbezüge gelten alle Geldleistungen, von denen ein Pensionsbeitrag zu entrichten ist. Die von den Beamtinnen und Beamten einzubehaltenden Pensionsbeiträge sind anzurechnen. Im Falle einer künftigen Änderung der Höhe des Pensionsbeitrages der Bundesbeamtinnen und Bundesbeamten gemäß § 22 Gehaltsgesetz 1956 ändert sich der Prozentsatz des Deckungsbeitrages im gleichen Ausmaß. Ab 1. Jänner 2004 geleistete besondere Pensionsbeiträge und Überweisungsbeträge sind umgehend und in voller Höhe an den Bund zu überweisen. Die sonstigen Zahlungen an den Bund sind jeweils am 10. des betreffenden Monats fällig.

(13) Für Beamtinnen und Beamte an den Universitäten gilt das ArbeitnehmerInnenschutzgesetz, BGBl. Nr. 450/1994.

Vertragsbedienstete des Bundes

§ 126. (1) Bedienstete des Bundes, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität zu Lasten einer Planstelle der Planstellenbereiche Universitäten oder Universitäten der Künste in einem vertraglichen Dienstverhältnis stehen, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer jener Universität, deren Aufgaben sie überwiegend besorgt haben.

(2) Vertragsbedienstete, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an einer Universität zu Lasten einer Planstelle der Planstellenbereiche Universitäten in einem vertraglichen Dienstverhältnis stehen und einer Einrichtung einer Medizinischen Fakultät zugeordnet sind, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer jener Medizinischen Universität, welche die Nachfolgeeinrichtung der Medizinischen Fakultät ist.

(3) Vertragsbedienstete, die zum Zeitpunkt des In-Kraft-Tretens dieses Bundesgesetzes einer Interuniversitären Einrichtung zugeordnet sind oder in der Zeit danach zugeordnet werden, werden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität, welche die Nachfolgeeinrichtung der betreffenden Interuniversitären Einrichtung ist, Arbeitnehmerinnen oder Arbeitnehmer dieser Universität.

(4) Hinsichtlich einer allfälligen zeitlichen Befristung des Arbeitsverhältnisses tritt keine Änderung ein. Die Universität setzt die Rechte und Pflichten des Bundes gegenüber diesen Arbeitnehmerinnen und Arbeitnehmern fort. Das Vertragsbedienstetengesetz 1948, BGBl. Nr. 86, in der jeweils geltenden Fassung, gilt hinsichtlich der ihm zum Stichtag unterliegenden Arbeitnehmerinnen und Arbeitnehmer als Inhalt des Arbeitsvertrags mit der Universität. Der Abschluss von Sonderverträgen gemäß § 36 Vertragsbedienstetengesetz 1948 ist nicht mehr zulässig. Innerhalb von zwei Jahren ab dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität ist eine Kündigung aus einem der im § 32 Abs. 4 des Vertragsbedienstetengesetzes 1948 angeführten Gründe nicht zulässig.

(5) Die Arbeitnehmerinnen und Arbeitnehmer gemäß Abs. 1 bis 3 können innerhalb von drei Jahren nach dem Wirksamwerden des für neu eintretende Arbeitnehmerinnen und Arbeitnehmer abgeschlossenen Kollektivvertrags ihre Bereitschaft zum Übertritt in diesen Kollektivvertrag erklären. Ihre Arbeitsverträge sind mit Wirksamkeit des auf die Erklärung folgenden Monatsersten entsprechend anzupassen.

(6) Auf Vertragsassistentinnen und Vertragsassistenten in einem Dienstverhältnis gemäß § 52a des Vertragsbedienstetengesetzes 1948 ist § 52b des Vertragsbedienstetengesetzes 1948 mit der Maßgabe anzuwenden, dass an die Stelle der Bundesministerin oder des Bundesministers (§ 52b Abs. 1 Z 2) das Rektorat tritt.

(7) Arbeitnehmerinnen und Arbeitnehmer gemäß Abs. 6 können innerhalb von drei Jahren nach dem Wirksamwerden des für neu eintretende Arbeitnehmerinnen und Arbeitnehmer abgeschlossenen Kollek-

tivvertrags, frühestens jedoch nach der Verlängerung des Arbeitsverhältnisses auf unbestimmte Zeit gemäß § 52b des Vertragsbedienstetengesetzes 1948, ihre Bereitschaft zum Übertritt in diesen Kollektivvertrag erklären. Ihre Arbeitsverträge sind mit Wirksamkeit des auf die Erklärung folgenden Monatsersten entsprechend anzupassen.

(8) Aus Anlass des Ausscheidens aus dem Bundesdienstverhältnis gemäß Abs. 1 bis 3 und des Übertritts gemäß Abs. 5 oder 7 gebührt keine Abfertigung gemäß § 35 des Vertragsbedienstetengesetzes 1948. Die im vorangegangenen Dienstverhältnis zurückgelegte Dienstzeit ist für alle zeitabhängigen Rechte zu berücksichtigen.

Lehrlinge des Bundes

§ 127. Hinsichtlich der Rechtsstellung der Lehrlinge des Bundes, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem Ausbildungsverhältnis gemäß Berufsausbildungsgesetz, BGBl. Nr. 142/1969, stehen, tritt nach dem Stichtag keine Änderung ein. Die Universität tritt in die Ausbildungsverpflichtung des Bundes ein.

Neuaufnahmen

§ 128. Für ab dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität neu aufgenommene Arbeitnehmerinnen und Arbeitnehmer gilt bis zum In-Kraft-Treten eines Kollektivvertrags gemäß § 108 Abs. 3 das Vertragsbedienstetengesetz 1948 mit Ausnahme der §§ 4, 32 und 34 als Inhalt des Arbeitsvertrags mit der Universität.

Haftungen des Bundes

§ 129. (1) Zur Sicherung der bezugsrechtlichen Ansprüche der Beamtinnen und Beamten, die nach dem Stichtag in ein Arbeitsverhältnis zur Universität überwechseln, und der Vertragsbediensteten sowie der Lehrlinge, die in ein Arbeits- oder Ausbildungsverhältnis zur Universität übergeführt werden, haftet der Bund wie ein Ausfallsbürge (§ 1356 des Allgemeinen Bürgerlichen Gesetzbuches). Die Höhe der Haftung ist mit jenem Betrag begrenzt, der sich am Tag vor dem Ausscheiden der Bediensteten aus dem Bundesdienst aus der für die genannten Bediensteten maßgeblich gewesenen besoldungsrechtlichen Stellung unter Berücksichtigung ihrer Verwendung zu diesem Zeitpunkt ergibt, zuzüglich der nach diesem Zeitpunkt zurückgelegten Dienstzeit, der vorgesehenen regelmäßigen Vorrückungen und der allgemeinen Gehaltserhöhungen.

(2) Anwartschaften auf Abfertigungen und Jubiläumszuwendungen von Arbeitnehmerinnen und Arbeitnehmern gemäß Abs. 1 werden von der Universität übernommen.

Forderungen des Bundes gegenüber den Bediensteten

§ 130. Die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität bestehenden Forderungen des Bundes aus dem Titel gewährter Vorschüsse sowie allfällige Rückersatzansprüche nach dem Amtshaftungsgesetz, BGBl. Nr. 20/1949, Organhaftpflichtgesetz, BGBl. Nr. 181/1967, oder Dienstnehmerhaftpflichtgesetz, BGBl. Nr. 80/1965, gegenüber Arbeitnehmerinnen und Arbeitnehmern der Universität, die aus einem Beamtendienstverhältnis in ein Arbeitsverhältnis zur Universität überwechseln oder aus einem Dienstverhältnis als Vertragsbedienstete oder Vertragsbediensteter in ein Arbeitsverhältnis zur Universität übergeführt werden, gehen mit dem Entstehen dieser Arbeitnehmerschaft auf die Universität über und sind von dieser dem Bund zu refundieren.

Übergang der Dienst- und Naturalwohnungen

§ 131. Beamtinnen oder Beamte, die in ein Arbeitsverhältnis zur Universität überwechseln, und Vertragsbedienstete, die in ein Arbeitsverhältnis zur Universität überführt werden, sind hinsichtlich der Nutzung von Dienst- oder Naturalwohnungen so zu behandeln, als ob sie Bundesbedienstete wären. Dadurch wird kein Bestandsverhältnis an der Wohnung begründet, die Bestimmungen des § 80 des Beamten-Dienstrechtsgesetzes 1979, BGBl. Nr. 333, und der §§ 24a bis 24c des Gehaltsgesetzes 1956, BGBl. Nr. 54, finden weiterhin sinngemäß Anwendung. Die Rechte des Dienstgebers im Sinne des § 80 des Beamten-Dienstrechtsgesetzes 1979 nimmt die Bundesministerin oder der Bundesminister wahr.

Wissenschaftliche (Künstlerische) Mitarbeiterinnen und Mitarbeiter (in Ausbildung)

§ 132. (1) Hinsichtlich der Rechtsstellung der Wissenschaftlichen (Künstlerischen) Mitarbeiterinnen und Mitarbeiter (in Ausbildung) (§ 6 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974), die am

Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem Ausbildungsverhältnis zum Bund stehen, tritt nach dem Stichtag keine Änderung ein. Sie gelten ab dem Stichtag als der Universität oder der Medizinischen Universität zugeordnet, welche die Nachfolgeeinrichtung der Universität oder der Medizinischen Fakultät ist, deren Aufgaben sie überwiegend besorgt haben. Die Universität tritt in die Ausbildungsverpflichtung des Bundes ein. Das Rechtsverhältnis endet aus den im § 6e des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste genannten Gründen oder durch Aufnahme in ein Arbeitsverhältnis zu einer Universität oder einer Medizinischen Universität.

(2) Die §§ 6 bis 6g und 7 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, sind auf die im Abs. 1 genannten Mitarbeiterinnen und Mitarbeiter bis zum Ablauf ihres Ausbildungsverhältnisses weiter anzuwenden.

Personen in einem besonderen Rechtsverhältnis zum Bund

§ 133. (1) Hinsichtlich des Rechtsverhältnisses von Personen, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem besonderen Rechtsverhältnis zum Bund (Tutoren gemäß § 1a, Studienassistenten und Demonstratoren gemäß § 1b, Lehrbeauftragte gemäß § 1 Abs. 2 und § 2 sowie Gastprofessorinnen und Gastprofessoren gemäß § 3 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste) stehen, tritt nach dem Stichtag keine Änderung ein. Sie gelten ab dem Stichtag als der Universität oder der Medizinischen Universität zugeordnet, welche die Nachfolgeeinrichtung der Universität oder Medizinischen Fakultät ist, deren Aufgaben sie überwiegend besorgt haben. Das Rechtsverhältnis endet mit Zeitablauf.

(2) Der Abschluss oder die Verlängerung eines solchen besonderen Rechtsverhältnisses zum Bund durch die Universität ist mit Wirksamkeit ab dem Stichtag unzulässig.

(3) Die §§ 1, 1a, 1b, 2, 2a, 3 und 7 des Bundesgesetzes über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste sind auf die im Abs. 1 genannten Personen bis zum Ablauf ihres besonderen Rechtsverhältnisses weiter anzuwenden.

Angestellte im Rahmen der Teilrechtsfähigkeit

§ 134. (1) Angestellte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an der Universität in einem Arbeitsverhältnis zu einer teilrechtsfähigen Einrichtung der Universität stehen, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer dieser Universität. Ab diesem Zeitpunkt setzt die Universität als Arbeitgeberin die Rechte und Pflichten der teilrechtsfähigen Einrichtung der Universität fort. Ein im Rahmen der Teilrechtsfähigkeit befristet abgeschlossenes Arbeitsverhältnis endet mit Zeitablauf.

(2) Angestellte, die am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an einer Medizinischen Fakultät in einem Arbeitsverhältnis zu einer teilrechtsfähigen Einrichtung dieser Medizinischen Fakultät stehen, werden mit dem folgenden Tag (Stichtag) Arbeitnehmerinnen oder Arbeitnehmer der Medizinischen Universität, welche die Nachfolgeeinrichtung der Medizinischen Fakultät ist. Ab diesem Zeitpunkt setzt die Medizinische Universität als Arbeitgeberin die Rechte und Pflichten der teilrechtsfähigen Einrichtung der Medizinischen Fakultät fort. Ein im Rahmen der Teilrechtsfähigkeit befristet abgeschlossenes Arbeitsverhältnis endet mit Zeitablauf.

(3) Angestellte, die in einem Arbeitsverhältnis zu einer teilrechtsfähigen Interuniversitären Einrichtung stehen, werden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an jener Universität, welche die Nachfolgeeinrichtung dieser Interuniversitären Einrichtung ist, zu deren Arbeitnehmerinnen oder Arbeitnehmern. Ab diesem Zeitpunkt setzt diese Universität als Arbeitgeberin die Rechte und Pflichten der teilrechtsfähigen Interuniversitären Einrichtung fort. Ein im Rahmen der Teilrechtsfähigkeit befristet abgeschlossenes Arbeitsverhältnis endet mit Zeitablauf.

Interessenvertretung der Arbeitnehmerinnen und Arbeitnehmer der Universität

§ 135. (1) Für alle Arbeitnehmerinnen und Arbeitnehmer der Universität gilt das Arbeitsverfassungsgesetz, BGBl. Nr. 22/1974.

(2) Die Universität gilt als Betrieb im Sinne des § 34 ArbVG.

(3) An jeder der in § 6 Z 1 bis 21 genannten Universitäten ist je ein Betriebsrat für das wissenschaftliche und künstlerische sowie für das allgemeine Universitätspersonal nach den Bestimmungen der

§§ 50 ff ArbVG zu wählen. Die Ärztinnen und Ärzte in Facharztausbildung sowie die Ärztinnen und Ärzte gemäß § 94 Abs. 3 Z 5 sind zum Betriebsrat für das wissenschaftliche und künstlerische Personal aktiv und passiv wahlberechtigt. Gemäß § 22a des Behinderteneinstellungsgesetzes (BEinstG), BGBl. Nr. 92/1970, sind Behindertenvertrauenspersonen zu wählen.

(4) Der am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an den Universitäten gemäß § 6 Z 1 bis 3 und 7 bis 21 eingerichtete Dienststellenausschuss für die Universitätslehrer bleibt bis zum Ablauf der am Stichtag noch laufenden Funktionsperiode bestehen. Ab dem Stichtag obliegt dem bestehenden Dienststellenausschuss für die Universitätslehrer die Funktion des Betriebsrats für das wissenschaftliche und künstlerische Personal im Sinne des Arbeitsverfassungsgesetzes.

(5) Der am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes an den Universitäten gemäß § 6 Z 1 bis 3 und 7 bis 21 eingerichtete Dienststellenausschuss für die Bediensteten mit Ausnahme der Universitätslehrer bleibt bis zum Ablauf der am Stichtag noch laufenden Funktionsperiode bestehen. Ab dem Stichtag obliegt dem bestehenden Dienststellenausschuss für die Bediensteten mit Ausnahme der Universitätslehrer die Funktion des Betriebsrats für das allgemeine Universitätspersonal im Sinne des Arbeitsverfassungsgesetzes.

(6) Die Dienststellenausschüsse für die Universitätslehrer und die Dienststellenausschüsse für die Bediensteten mit Ausnahme der Universitätslehrer an den Universitäten gemäß § 6 Z 1 bis 3 haben ab dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes auch die Funktion des entsprechenden Dienststellenausschusses an der Medizinischen Universität desselben Standorts wahrzunehmen.

(7) Die bestehenden Personalvertretungsorgane haben vor Ablauf ihrer Funktionsperiode für die rechtzeitige Ausschreibung von Betriebsratswahlen zu sorgen.

(8) Im Übrigen gelten für die Universitäten die Bestimmungen des Arbeitsverfassungsgesetzes mit folgender Maßgabe:

1. Eine Unterteilung in Arbeiter- und Angestelltenbetriebsrat findet nicht statt.
2. Für die zur Dienstleistung zugewiesenen Beamtinnen und Beamten hat der Betriebsrat gleichzeitig die Funktion des Dienststellenausschusses im Sinne des § 9 des Bundes-Personalvertretungsgesetzes, BGBl. Nr. 133/1967, wahrzunehmen. Die der Universität zugewiesenen Beamtinnen und Beamten gehören darüber hinaus weiterhin dem Wirkungsbereich des zuständigen Zentralausschusses beim Bundesministerium für Bildung, Wissenschaft und Kultur an.

(9) Der beim Bundesministerium eingerichtete Zentralausschuss für die Universitätslehrer und der Zentralausschuss für die Bediensteten mit Ausnahme der Universitätslehrer bleiben bis zum Ende der am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes laufenden Funktionsperiode bestehen, § 23 Abs. 2 lit. a und c des Bundes-Personalvertretungsgesetzes sind nicht anzuwenden.

5. Abschnitt
Übertragung von Rechten und Vermögen
Nachfolgeeinrichtungen

§ 136. (1) Die im § 6 Z 1 bis 3 angeführten Universitäten werden mit dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität Gesamtrechtsnachfolgerinnen der jeweiligen gleichnamigen Universität (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) gemäß § 5 UOG 1993. Diese Universitäten werden einerseits in ihre gleichnamige Nachfolgeuniversität und andererseits in die Medizinische Universität aufgespalten.

(2) Die im § 6 Z 4 bis 6 angeführten Medizinischen Universitäten Wien, Graz und Innsbruck sind Gesamtrechtsnachfolgerinnen der Medizinischen Fakultät (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) der Universität des jeweiligen Standorts.

(3) Die im § 6 Z 7 bis 21 angeführten Universitäten sind Gesamtrechtsnachfolgerinnen der jeweiligen gleichnamigen Universität (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) gemäß § 5 UOG 1993 oder Universität der Künste (einschließlich ihrer teilrechtsfähigen Organisationseinheiten) gemäß § 6 Z 1 bis 6 KUOG.

(4) Die Universität Klagenfurt ist die Gesamtrechtsnachfolgerin des Instituts für Interdisziplinäre Forschung und Fortbildung der Universitäten Klagenfurt, Wien, Innsbruck und Graz – IFF.

(5) Die Universität für Bodenkultur Wien ist die Gesamtrechtsnachfolgerin des Interuniversitären Forschungsinstituts für Agrarbiotechnologie Tulln. Die an dieser Interuniversitären Einrichtung beteilig-

ten Universitäten haben bis spätestens 31. Dezember 2003 basierend auf ihrer Zusammenarbeit und ihren daraus resultierenden Rechten und Pflichten mit Wirksamkeit vom 1. Jänner 2004 einen Vertrag über die weitere Zusammenarbeit auf diesem Fachgebiet abzuschließen. Kommt dieser Vertrag nicht zeitgerecht zustande, ist das Vermögen der Interuniversitären Einrichtung mit 1. Jänner 2004 entsprechend den von den beteiligten Universitäten bis zum 31. Dezember 2003 eingebrachten Ressourcen aufzuteilen.

(6) Die Universität Linz ist die Gesamtrechtsnachfolgerin des Interuniversitären Instituts für Informationssysteme zur Unterstützung sehgeschädigter Studierender.

(7) Die Technische Universität Wien ist die Gesamtrechtsnachfolgerin des Interuniversitären Instituts für Technologie Management (ITM).

(8) Die Universität Graz ist die Gesamtrechtsnachfolgerin der Interuniversitären Koordinationsstelle für Frauen- und Geschlechterforschung Graz.

(9) Die Universität Wien ist die Gesamtrechtsnachfolgerin der Österreichischen Zentralbibliothek für Physik.

(10) Die Medizinische Universität Wien ist die Gesamtrechtsnachfolgerin der Österreichischen Zentralbibliothek Medizin.

(11) Die Universität Graz ist die Gesamtrechtsnachfolgerin des Interuniversitären Universitäts-Sportinstituts in Graz.

Übergang von Mietrechten an Liegenschaften, Bauwerken und Räumlichkeiten

§ 137. (1) Die Mietrechte an den vom Bund, einer Universität oder einer teilrechtsfähigen Organisationseinheit einer Universität angemieteten Liegenschaften, Bauwerken und Räumlichkeiten gehen mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Universität (Stichtag) unter Ausschluss der Rechtsfolgen der §§ 12a und 46a des Mietrechtsgesetzes im Wege der Gesamtrechtsnachfolge auf die am Tag vor dem Stichtag nutzende Universität oder Medizinische Fakultät über.

(2) Zu dem im Abs. 1 genannten Stichtag tritt die Universität auch als Verpächterin oder Leihgeberin an Stelle des Bundes in die bestehenden Pacht- und Leihverträge ein.

Rechtsnachfolge bei gemeinsam genutzten Liegenschaften, Bauwerken und Räumlichkeiten

§ 138. Das Mietrecht geht auf jene Universität über, der die Liegenschaft, das Gebäude oder die einzelnen Räumlichkeiten am Tag vor dem Stichtag zur ausschließlichen und dauerhaften Nutzung zugeordnet war oder waren. Ist eine Liegenschaft, ein Bauwerk oder sind einzelne Räumlichkeiten mehreren Universitäten zur gemeinsamen dauerhaften Nutzung überlassen, geht das Mietrecht auf jene Universität über, die das Objekt im Beobachtungszeitraum zwischen 1. Jänner 2001 und 30. September 2003 überwiegend genutzt hat. Für die Medizinischen Universitäten gelten für diesen Beobachtungszeitraum die Nutzungen der jeweiligen Medizinischen Fakultät. Ist eine Liegenschaft, ein Bauwerk oder sind einzelne Räumlichkeiten mehreren Universitäten zur gemeinsamen dauerhaften Nutzung überlassen, wird jener Universität das Hauptmietrecht eingeräumt, die das Objekt im Beobachtungszeitraum zwischen dem 1. Jänner 2001 und dem 30. September 2003 überwiegend genutzt hat. Die anderen Universitäten erhalten ein Untermietrecht und bezahlen einen Untermietzins in der Höhe des Hauptmietzinses.

Übertragung der im Eigentum des Bundes stehenden Mobilien auf die Universitäten

§ 139. (1) Das Eigentumsrecht an dem beweglichen Vermögen des Bundes, das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes den Universitäten und Universitäten der Künste zur Nutzung überlassen ist, geht einschließlich aller zugehörenden Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem folgenden Tag (Stichtag) im Wege der Gesamtrechtsnachfolge auf die nutzende Universität über. Die Gesamtrechtsnachfolge ist im Mitteilungsblatt der Universität kundzumachen (§ 20 Abs. 6).

(2) Das Eigentumsrecht an dem beweglichen Vermögen des Bundes, das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes einer Medizinischen Fakultät oder einer ihrer Organisationseinheiten zur Nutzung überlassen ist, geht einschließlich aller zugehörenden Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem folgenden Tag (Stichtag) im Wege der Gesamtrechtsnachfolge auf jene Medizinische Universität über, welche die Gesamtrechtsnachfolgerin der Medizinischen Fakultät ist. Die Gesamtrechtsnachfolge ist im Mitteilungsblatt der Universität kundzumachen.

(3) Das Eigentumsrecht an dem beweglichen Vermögen des Bundes, das am Tag vor dem vollen Wirksamwerden dieses Bundesgesetzes einer Interuniversitären Einrichtung gemäß § 136 Abs. 4 bis 11 zur Nutzung überlassen ist, geht einschließlich aller zugehörenden Rechte und Rechtsverhältnisse, Forde-

rungen und Schulden mit dem folgenden Tag (Stichtag) im Wege der Gesamtrechtsnachfolge auf die in diesen Gesetzesstellen jeweils genannte Universität über. Die Gesamtrechtsnachfolge ist im Mitteilungsblatt der Universität kundzumachen. Diese Vermögenswerte sind von den als Nachfolgeeinrichtungen bestimmten Universitäten zur Weiterführung der Aufgaben der bisherigen Interuniversitären Einrichtungen zu verwenden.

(4) Abweichend von Abs. 1 bis 3 verbleiben die Bestände der Universitätsbibliotheken, die aus geschichtlichem, künstlerischem und sonstigem kulturellen oder wissenschaftlichen Zusammenhang ein Ganzes bilden, im Eigentum des Bundes. Weiters verbleiben die Mobilien im Eigentum des Bundes, die einzelnen Universitäten insbesondere zu Zwecken zur Repräsentation oder zur künstlerischen Ausgestaltung leihweise vorübergehend zur Nutzung überlassen worden sind. Jede Universität hat bis 30. September 2003 ein Verzeichnis dieser Bestände anzulegen.

(5) Hinsichtlich des Eigentums an den Sammlungen der Gemäldegalerie und des Kupferstichkabinetts der Akademie der bildenden Künste Wien tritt abweichend von Abs. 1 bis 3 keine Änderung ein.

Übertragung der im Eigentum teilrechtsfähiger Einrichtungen der Universitäten und Universitäten der Künste stehenden Immobilien, Mobilien und Rechte auf die Universitäten

§ 140. (1) Das Eigentumsrecht am beweglichen und unbeweglichen Vermögen der teilrechtsfähigen Einrichtungen der Universitäten und Universitäten der Künste geht einschließlich aller zugehörigen Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der betreffenden Universität im Wege der Gesamtrechtsnachfolge auf die jeweilige Universität über.

(2) Das Eigentumsrecht am beweglichen und unbeweglichen Vermögen einer teilrechtsfähigen Medizinischen Fakultät oder einer ihrer teilrechtsfähigen Einrichtungen geht einschließlich aller zugehörigen Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes an der Medizinischen Universität im Wege der Gesamtrechtsnachfolge auf die Medizinische Universität über, welche die Nachfolgeeinrichtung der betreffenden Medizinischen Fakultät ist.

(3) Das Eigentumsrecht am beweglichen und unbeweglichen Vermögen der teilrechtsfähigen Interuniversitären Einrichtungen gemäß § 136 Abs. 4 bis 11 geht einschließlich aller zugehörigen Rechte und Rechtsverhältnisse, Forderungen und Schulden mit dem Tag des vollen Wirksamwerdens dieses Bundesgesetzes im Wege der Gesamtrechtsnachfolge auf die in diesen Gesetzesstellen jeweils genannte Universität über.

(4) Die Universitäten haben dafür zu sorgen, dass bestehenden Auflagen, Bedingungen und Widmungen bestmöglich entsprochen wird. Eine interne personenbezogene Drittmittel-Zuweisung des damit verbundenen Vermögenswertes ist dadurch nicht ausgeschlossen.

6. Abschnitt
Budget

§ 141. (1) Der Bund leistet den Universitäten für die Aufwendungen, die ihnen in Erfüllung ihrer Aufgaben gemäß § 3 entstehen, ab dem 1. Jänner 2004 für die Jahre 2004 bis 2006 einen jährlichen Globalbetrag in der Höhe von 1 660 866 000 Euro. Für die folgenden Jahre bemisst sich das Budget der Universität gemäß der jeweiligen Leistungsvereinbarung.

(2) Der Betrag gemäß Abs. 1 erhöht sich jeweils um die im betreffenden Jahr anfallenden Aufwendungen der Universitäten aus

1. Bezugserhöhungen der Beamten, Vertragsbediensteten und der Personen, die von ihrem Optionsrecht (§ 125 Abs. 8 oder 9, § 126 Abs. 5 oder 7) Gebrauch machen;
2. Mietaufwendungen aus bis 28. Februar 2002 abgeschlossenen Verträgen mit der BIG, die ab 2003 finanziell wirksam werden, für das Jahr 2004 um 5 204 000 Euro und für die Jahre 2005 und 2006 um jeweils 6 213 000 Euro;
3. den finanziellen Verpflichtungen aus bestehenden Vereinbarungen im Rahmen der Hochschulraumbeschaffung für folgende Objekte:
   a) Universität Wien – Altes AKH, Mietzinszahlungen bis einschließlich 2013;
   b) Universität Wien, Fakultät für Wirtschaftswissenschaften und Informatik, Brünner Straße 72, bis einschließlich 2005;
   c) Universität Graz, Institutsgebäude Merangasse, bis einschließlich 2004;

d) Universität für Bodenkultur Wien, Institutsgebäude Muthgasse II, bis einschließlich 2006;

e) Universität für Bodenkultur Wien, Peter-Jordanstraße 65, bis einschließlich 2011;

f) Universitätszentrum Althanstraße: Verpflichtungen aus dem bestehenden Mietvertrag mit der Universitätszentrum Althanstraße Erweiterungsgesellschaft mbH bis einschließlich 2011 bzw. im Fall des Erwerbs der Liegenschaft durch die BIG die Mietaufwendungen ab 2004;

4. den Kostenersätzen des Bundes gemäß § 55 Z 2 und 3 des Krankenanstaltengesetzes, die den Universitäten gemäß § 6 Z 4 bis 6 zusätzlich zum jährlichen Globalbetrag für die Jahre 2004 bis 2006 zur Verfügung zu stellen sind.

(3) Für die erste Leistungsvereinbarungsperiode (§ 121 Abs. 17) gilt § 12 Abs. 7 mit der Maßgabe, dass der auf die Universität entfallende Anteil des Globalbetrags gemäß § 141 Abs. 1 und 2 an die Stelle eines Drittels des Globalbudgets tritt. § 13 Abs. 9 gilt mit der Maßgabe, dass 80 vH dieses Anteils an die Stelle des Drittels des Globalbudgets tritt.

(4) Zusätzlich zu den Leistungen des Bundes gemäß Abs. 1 und 2 wird den Universitäten für das Jahr 2004 einmalig ein Betrag von 11 000 000 Euro und ab diesem Jahr ein jährlicher Betrag von 4 000 000 Euro zur Finanzierung der durch die Implementierung dieses Bundesgesetzes verursachten Aufwendungen zur Verfügung gestellt.

(5) Zur Finanzierung von Anreizen für die erfolgreiche Umstrukturierung der Organisation und des Studienbereichs der Universitäten im Sinne der Profilentwicklung werden von der Bundesministerin oder vom Bundesminister vom Globalbudget jeder Universität für das Jahr 2005 0,4 vH und für das Jahr 2006 0,8 vH einbehalten.

(6) Den Universitäten sind mit dem Zeitpunkt des vollen Wirksamwerdens dieses Bundesgesetzes die jeweils bestehenden Rücklagen gemäß § 53 Abs. 2 des Bundeshaushaltsgesetzes zur Verfügung zu stellen. Dies gilt auch für veranlagte Mittel.

7. Abschnitt
In-Kraft-Treten und Vollziehung

Verweisungen

§ 142. (1) Die Bezeichnungen „Bundesministerin“ oder „Bundesminister“ in diesem Bundesgesetz beziehen sich, soweit nicht ausdrücklich anderes angeführt ist, auf die Bundesministerin oder den Bundesminister, die oder der für die Angelegenheiten der Universitäten zuständig ist.

(2) Soweit in diesem Bundesgesetz auf andere Bundesgesetze verwiesen wird, sind diese Bundesgesetze in der jeweils geltenden Fassung anzuwenden.

(3) Wird in anderen Bundesgesetzen auf Bestimmungen verwiesen, an deren Stelle mit dem In-Kraft-Treten dieses Bundesgesetzes neue Bestimmungen wirksam werden, sind diese Verweisungen auf die entsprechenden neuen Bestimmungen zu beziehen.

In-Kraft-Treten und Außer-Kraft-Treten von Rechtsvorschriften

§ 143. (1) Die Bestimmungen dieses Bundesgesetzes treten mit 1. Oktober 2002 in Kraft, soweit im Folgenden nicht anderes bestimmt ist.

(2) Der II. Teil dieses Bundesgesetzes tritt mit 1. Jänner 2004 in Kraft.

(3) Die §§ 120 bis 122 treten mit dem auf die Kundmachung folgenden Tag in Kraft.

(4) Die Bestimmungen des UOG 1993 mit Ausnahme der Verfassungsbestimmungen treten mit Ablauf des 31. Dezember 2003 außer Kraft.

(5) Die Bestimmungen des KUOG mit Ausnahme der Verfassungsbestimmungen treten mit Ablauf des 31. Dezember 2003 außer Kraft.

(6) Das Bundesgesetz über die Abgeltung von wissenschaftlichen und künstlerischen Tätigkeiten an Universitäten und Universitäten der Künste, BGBl. Nr. 463/1974, tritt, soweit nicht die §§ 132 Abs. 2 und 133 Abs. 3 anderes bestimmen, mit Ablauf des 31. Dezember 2003 außer Kraft.

(7) Das Hochschul-Taxengesetz 1972, BGBl. Nr. 76/1972, tritt mit Ablauf des 31. Dezember 2003 außer Kraft.

(8) § 112 tritt mit 1. Oktober 2013 außer Kraft.

(9) Die Bestimmungen des Universitäts-Studiengesetzes (UniStG) mit Ausnahme der Verfassungsbestimmungen treten mit Ablauf des 31. Dezember 2003 außer Kraft.

Vollziehung

§ 144. Mit der Vollziehung dieses Bundesgesetzes sind betraut:

1. hinsichtlich des § 17 die Bundesministerin oder der Bundesminister für Finanzen;
2. hinsichtlich der §§ 137 und 139 die Bundesministerin oder der Bundesminister für Finanzen im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Bildung, Wissenschaft und Kultur;
3. hinsichtlich der §§ 12 Abs. 2 und 9, 16 Abs. 2, 121 Abs. 17 und § 141 die Bundesministerin oder der Bundesminister für Bildung, Wissenschaft und Kultur im Einvernehmen mit der Bundesministerin oder mit dem Bundesminister für Finanzen;
4. hinsichtlich des § 18 Abs. 2 die Bundesministerin oder der Bundesminister für Justiz, soweit Gerichts- und Justizverwaltungsgebühren betroffen sind, im übrigen die Bundesministerin oder der Bundesminister für Finanzen;
5. hinsichtlich des § 29 Abs. 6 die Bundesministerin oder der Bundesminister für soziale Sicherheit und Generationen im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Bildung, Wissenschaft und Kultur;
6. hinsichtlich des § 44 die Bundesministerin oder der Bundesminister für soziale Sicherheit und Generationen;
7. hinsichtlich der §§ 106 Abs. 2 und 3, 108 Abs. 1, 3 und 4, 109 bis 113, 115 sowie 135 die Bundesministerin oder der Bundesminister für Wirtschaft und Arbeit im Einvernehmen mit der Bundesministerin oder dem Bundesminister für Bildung, Wissenschaft und Kultur;
8. hinsichtlich der §§ 8 und 21 Abs. 6 Z 2 die Bundesregierung;
9. im Übrigen die Bundesministerin oder der Bundesminister für Bildung, Wissenschaft und Kultur.

Artikel II
Änderung des UOG 1993

Das Bundesgesetz über die Organisation der Universitäten (UOG 1993), BGBl. Nr. 805/1993, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 13/2001, wird wie folgt geändert:

Nach § 88 wird folgender § 88a eingefügt:

„§ 88a. Die Funktionsperiode eines Universitätsorgans gemäß diesem Bundesgesetz, die nach dem 31. Juli 2002 ablaufen würde, kann durch Beschluss des obersten Kollegialorgans um die Dauer einer weiteren Funktionsperiode verlängert werden.“

Artikel III
Änderung des KUOG

Das Bundesgesetz über die Organisation der Universitäten der Künste (KUOG), BGBl. I Nr. 130/1998, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 13/2001, wird wie folgt geändert:

Nach § 77 wird folgender § 77a eingefügt:

„§ 77a. Die Funktionsperiode eines Universitätsorgans gemäß diesem Bundesgesetz, die nach dem 31. Juli 2002 ablaufen würde, kann durch Beschluss des obersten Kollegialorgans um die Dauer einer weiteren Funktionsperiode verlängert werden.“

Klestil

Schüssel

P. b. b. Erscheinungsort Wien, Verlagspostamt 1030 Wien

BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

Jahrgang 1969 Ausgegeben am 31. Dezember 1969 114. Stück

461. Bundesgesetz: Arbeitszeitgesetz
462. Bundesgesetz: Abänderung und Ergänzung von Arbeitszeitvorschriften
463. Bundesgesetz: Landarbeitsgesetz-Novelle 1969
464. Bundesgesetz: 16. Vertragsbedienstetengesetz-Novelle
465. Bundesgesetz: Neuerliche Abänderung des Dorotheums-Bedienstetengesetzes
466. Bundesgesetz: Abänderung der Bundesforste-Dienstordnung
467. Verordnung: Zuweisung der Dienstbeurteilung für bestimmte Beamte der Personalstände „Bibliotheksdienst" und „Bibliotheken" gemäß § 15 Abs. 5 der Dienstpragmatik
468. Verordnung: Erhöhung der Wertgrenze für die Entrichtung von Hundertsatzgebühren in Stempelmarken
469. Verordnung: Änderung der Sprengel der Bezirksgerichte Stockerau und Hollabrunn
470. Verordnung: Änderung der Sprengel der Bezirksgerichte Mistelbach, Laa an der Thaya, Stockerau und Korneuburg
471. Verordnung: Änderung der Sprengel der Bezirksgerichte Horn und Eggenburg
472. Verordnung: Zuweisung der Dienstbeurteilung für Beamte der Generalprokuratur, der Justizanstalten, der Arbeitsbetriebe — Betriebsähnliche Verwaltungszweige und der Bewährungshilfe gemäß § 15 Abs. 5 der Dienstpragmatik
473. Verordnung: Zuweisung von Disziplinarsachen bestimmter Beamter an andere Disziplinarkommissionen gemäß § 100 Abs. 2 der Dienstpragmatik
474. Verordnung: 31. Änderung der Arzneitaxe
475. Verordnung: Änderung der Verordnung, mit der wohnbaustatistische Erhebungen angeordnet werden
476. Kundmachung: Ausschreibung der Wahl zum Nationalrat, die Festsetzung des Wahltages und des Stichtages
477. Kundmachung: Verlautbarung des Beschlusses Nr. 13/1969 des Rates der Europäischen Freihandelsassoziation
478. Kundmachung: Verlautbarung des Beschlusses Nr. 7/1969 des Gemeinsamen Rates, gefaßt auf Grund des Übereinkommens zur Schaffung einer Assoziierung zwischen den Mitgliedstaaten der Europäischen Freihandelsassoziation und der Republik Finnland
479. Protokoll betreffend die steuerliche Behandlung des grenzüberschreitenden Straßenverkehrs zwischen der Republik Österreich und dem Fürstentum Liechtenstein

461. Bundesgesetz vom 11. Dezember 1969 über die Regelung der Arbeitszeit (Arbeitszeitgesetz)

Der Nationalrat hat beschlossen:

ABSCHNITT 1

Geltungsbereich

§ 1. (1) Die Bestimmungen dieses Bundesgesetzes gelten für die Beschäftigung von Arbeitnehmern (Lehrlingen), die das 18. Lebensjahr vollendet haben.

(2) Ausgenommen vom Geltungsbereich dieses Bundesgesetzes sind:

1. Arbeitnehmer, die in einem Arbeitsverhältnis zu einer Gebietskörperschaft, zu einer Stiftung, zu einem Fonds oder zu einer Anstalt stehen, sofern diese Einrichtungen von Organen einer Gebietskörperschaft oder von Personen verwaltet werden, die hiezu von Organen einer Gebietskörperschaft bestellt sind; die Bestimmungen dieses Bundesgesetzes gelten jedoch für Arbeitnehmer, die nicht im Bereich der Hoheitsverwal-

tung tätig sind, sofern für ihr Arbeitsverhältnis ein Kollektivvertrag wirksam ist;

2. Arbeitnehmer, für die die Vorschriften des Landarbeitsgesetzes, BGBl. Nr. 140/1948, gelten;

3. Arbeitnehmer, für die die Vorschriften des Bäckereiarbeitergesetzes, BGBl. Nr. 69/1955, gelten;

4. Arbeitnehmer, für die die Vorschriften des Hausgehilfen- und Hausangestelltengesetzes, BGBl. Nr. 235/1962, gelten;

5. Arbeitnehmer, für die die Vorschriften der Hausbesorgerordnung 1957, BGBl. Nr. 154, gelten;

6. Lehr- und Erziehungskräfte an Unterrichts- und Erziehungsanstalten, soweit sie nicht unter Z. 1 fallen;

7. Arbeitnehmer, die im Rahmen des Bordpersonals von Luftverkehrsunternehmungen tätig sind;

8. leitende Angestellte, denen maßgebliche Führungsaufgaben selbstverantwortlich übertragen sind;

9. Heimarbeiter im Sinne des Heimarbeitsgesetzes 1960, BGBl. Nr. 105/1961.

ABSCHNITT 2

Arbeitszeit

Begriff der Arbeitszeit

§ 2. (1) Im Sinne dieses Bundesgesetzes ist:

1. Arbeitszeit die Zeit vom Beginn bis zum Ende der Arbeit ohne die Ruhepausen;

2. Tagesarbeitszeit die Arbeitszeit innerhalb eines ununterbrochenen Zeitraumes von vierundzwanzig Stunden;

3. Wochenarbeitszeit die Arbeitszeit innerhalb des Zeitraumes von Montag bis einschließlich Sonntag.

(2) Arbeitszeit im Sinne des Abs. 1 Z. 1 ist auch die Zeit, während der ein im übrigen im Betrieb Beschäftigter in seiner eigenen Wohnung oder Werkstätte oder sonst außerhalb des Betriebes beschäftigt wird. Werden Arbeitnehmer von mehreren Arbeitgebern beschäftigt, so dürfen die einzelnen Beschäftigungen zusammen die gesetzliche Höchstgrenze der Arbeitszeit nicht überschreiten.

Normalarbeitszeit

§ 3. (1) Die Tagesarbeitszeit darf acht Stunden, die Wochenarbeitszeit dreiundvierzig Stunden nicht überschreiten, soweit im folgenden nicht anderes bestimmt wird.

(2) An Stelle der in Abs. 1 festgelegten Wochenarbeitszeit von dreiundvierzig Stunden tritt ab 3. Jänner 1972 eine solche von zweiundvierzig Stunden und ab 6. Jänner 1975 eine solche von vierzig Stunden.

(3) Eine von Abs. 1 und 2 abweichende Wochenarbeitszeit kann durch Kollektivvertrag zugelassen werden, sofern dieser eine vor dem Inkrafttreten dieses Bundesgesetzes zulässige Wochenarbeitszeit auf Grund eines Arbeitszeitverkürzungsplanes so verkürzt, daß die Wochenarbeitszeit spätestens ab 6. Jänner 1975 vierzig Stunden nicht überschreitet. Die nach einem solchen Arbeitszeitverkürzungsplan festgelegte Wochenarbeitszeit gilt als Wochenarbeitszeit im Sinne dieses Bundesgesetzes.

(4) Aus Anlaß der mit dem Inkrafttreten dieses Bundesgesetzes sowie der gemäß Abs. 2 oder 3 eintretenden Arbeitszeitverkürzung darf das Entgelt der betroffenen Arbeitnehmer nicht gekürzt werden (Lohnausgleich). Ein nach Stunden bemessenes Entgelt ist dabei in dem gleichen Verhältnis zu erhöhen, in dem die Arbeitszeit verkürzt wird. Akkord-, Stück- und Gedinglöhne sowie auf Grund anderer Leistunglohnarten festgelegte Löhne sind entsprechend zu berichtigen. Durch Kollektivvertrag kann eine andere Regelung des Lohnausgleiches vereinbart werden.

Andere Verteilung der Normalarbeitszeit

§ 4. (1) Die nach § 3 zulässige Wochenarbeitszeit kann nach Maßgabe der folgenden Absätze abweichend von der nach § 3 Abs. 1 zulässigen Tagesarbeitszeit verteilt werden.

(2) Zur Erreichung einer längeren Freizeit, die entweder mit der Wochenruhe oder mit einer Ruhezeit gemäß § 12 zusammenhängen muß, kann die Arbeitszeit an einzelnen Tagen regelmäßig gekürzt und die ausfallende Arbeitszeit auf die übrigen Tage der Woche verteilt werden.

(3) Fällt in Verbindung mit Feiertagen die Arbeitszeit an Werktagen aus, um den Arbeitnehmern eine längere zusammenhängende Freizeit zu ermöglichen, so kann die ausfallende Arbeitszeit auf die Werktage von höchstens sieben zusammenhängenden, die Ausfalltage einschließenden Wochen verteilt werden.

(4) Das Arbeitsinspektorat kann eine ungleichmäßige Verteilung der Arbeitszeit innerhalb der Woche zulassen, soweit dies die Art des Betriebes erfordert.

(5) Die Wochenarbeitszeit des Personals von Verkaufsstellen im Sinne des Ladenschlußgesetzes, BGBl. Nr. 157/1958, und sonstiger Arbeitnehmer des Handels kann in den einzelnen Wochen eines Durchrechnungszeitraumes von vier Wochen bis zu sechsundvierzig Stunden und ab 6. Jänner 1975 bis zu vierundvierzig Stunden ausgedehnt werden, wenn innerhalb dieses Zeitraumes die durch-

schnittliche Wochenarbeitszeit die nach § 3 zulässige Dauer nicht überschreitet.

(6) Der zur Erreichung der durchschnittlichen Arbeitszeit nach Abs. 5 im Durchrechnungszeitraum erforderliche Zeitausgleich ist unter Berücksichtigung der jeweiligen Betriebserfordernisse zusammenhängend zu gewähren. Ein Zeitausgleich von mehr als vier Stunden kann in zwei Teilen gewährt werden, wobei ein Teil mindestens vier Stunden zu betragen hat.

(7) Für Lenker und Beifahrer von Kraftfahrzeugen sowie Kutscher gelten, soweit nicht durch Kollektivvertrag etwas anderes bestimmt wird, die Abs. 5 und 6 mit der Maßgabe, daß der Durchrechnungszeitraum nur zwei Wochen beträgt.

(8) Bei mehrschichtiger Arbeitsweise ist ein Schichtplan zu erstellen. Innerhalb des Schichtturnus darf die Wochenarbeitszeit im wöchentlichen Durchschnitt die nach § 3 zulässige Dauer nicht überschreiten.

(9) Für Arbeitnehmer, auf welche die Bestimmungen der Abs. 5 bis 8 keine Anwendung finden, kann durch Kollektivvertrag zugelassen werden, daß die Arbeitszeit innerhalb eines mehrwöchigen Zeitraumes so verteilt wird, daß sie im wöchentlichen Durchschnitt die nach § 3 zulässige Dauer nicht überschreitet.

(10) Im Falle einer anderen Verteilung der Arbeitszeit nach Abs. 2 bis 5 und 7 bis 9 darf die Tagesarbeitszeit zehn Stunden nicht überschreiten. Für männliche Arbeitnehmer darf bei Arbeiten, die werktags und sonntags einen ununterbrochenen Fortgang mit Schichtwechsel erfordern, die Tagesarbeitszeit zehn Stunden nur insoweit überschreiten, als dies zur Ermöglichung des Schichtwechsels erforderlich ist; hiebei darf die Tagesarbeitszeit die Dauer von zwei Schichten nicht überschreiten.

Verlängerung der Normalarbeitszeit in den Fällen der Arbeitsbereitschaft

§ 5. (1) Wenn in die Arbeitszeit regelmäßig und in erheblichem Umfang Arbeitsbereitschaft fällt, kann durch Kollektivvertrag zugelassen werden, daß die nach § 3 zulässige Wochenarbeitszeit um höchstens zwanzig Stunden verlängert wird. Die Tagesarbeitszeit darf in solchen Fällen zwölf, für Arbeitnehmerinnen zehn Stunden nicht überschreiten.

(2) Das Arbeitsinspektorat kann für Betriebe, Betriebsabteilungen oder für bestimmte Arbeiten, sofern hiefür kein Branchenkollektivvertrag wirksam ist, bei Vorliegen der in Abs. 1 genannten Voraussetzungen eine Verlängerung der Arbeitszeit nach Maßgabe des Abs. 1 zulassen.

(3) Durch Kollektivvertrag kann zugelassen werden, daß die Wochenarbeitszeit über die nach Abs. 1 zulässige Dauer hinaus für die Zeit bis längstens 5. Jänner 1975 verlängert wird, sofern die bisherige kollektivvertragliche Wochenarbeitszeit mehr als sechzig Stunden betrug.

Überstundenarbeit

§ 6. (1) Überstundenarbeit liegt vor, wenn entweder

a) die Grenzen der nach den §§ 3 oder 5 zulässigen Wochenarbeitszeit überschritten werden oder

b) die Tagesarbeitszeit überschritten wird, die sich auf Grund der Verteilung dieser Wochenarbeitszeit gemäß den §§ 3 bis 5 und 18 Abs. 2 ergibt.

(2) Arbeitnehmer dürfen zur Überstundenarbeit nur dann herangezogen werden, wenn diese nach den Bestimmungen dieses Bundesgesetzes zugelassen ist und berücksichtigungswürdige Interessen des Arbeitnehmers der Überstundenarbeit nicht entgegenstehen.

Verlängerung der Arbeitszeit bei Vorliegen eines erhöhten Arbeitsbedarfes

§ 7. (1) Bei Vorliegen eines erhöhten Arbeitsbedarfes kann die Arbeitszeit unbeschadet der Bestimmungen des § 8 über die nach den §§ 3 bis 5 zulässige Dauer um fünf Überstunden in der einzelnen Woche und darüber hinaus um höchstens sechzig Überstunden innerhalb eines Kalenderjahres verlängert werden. Wöchentlich sind jedoch nicht mehr als zehn Überstunden zulässig. Die Tagesarbeitszeit darf zehn Stunden nicht überschreiten.

(2) Unbeschadet der nach Abs. 1 erster Satz zulässigen Überstunden können durch Kollektivvertrag bis zu fünf weitere Überstunden, für Lenker und Beifahrer von Kraftfahrzeugen sowie Kutscher, für Arbeitnehmer im Gast-, Schank- und Beherbergungsgewerbe, im Verkehrswesen sowie in bestimmten Arten oder Gruppen von Betrieben, in denen ähnlich gelagerte Verhältnisse vorliegen, jedoch bis zu zehn weitere Überstunden wöchentlich zugelassen werden. Dabei kann das Ausmaß der wöchentlichen Überstunden abweichend von Abs. 1 zweiter Satz festgelegt werden.

(3) Wenn in den Fällen des § 5 von der dort vorgesehenen Möglichkeit einer kollektivvertraglichen Verlängerung der Wochenarbeitszeit nicht oder nur zum Teil Gebrauch gemacht wurde, kann durch Kollektivvertrag ein höheres als das nach Abs. 1 zulässige Ausmaß an Überstunden zugelassen werden. Die Tagesarbeitszeit darf in diesen Fällen jedoch dreizehn, für Arbeitnehme-

rinnen zehn Stunden, und die Wochenarbeitszeit sechzig Stunden nicht überschreiten.

(4) Wurde die Wochenarbeitszeit auf Grund einer Bewilligung des Arbeitsinspektorates gemäß § 5 Abs. 2 verlängert, so sind die nach Abs. 1 in Betracht kommenden Überstunden nur insoweit zulässig, als die Tagesarbeitszeit dreizehn, für Arbeitnehmerinnen zehn Stunden, und die Wochenarbeitszeit sechzig Stunden nicht überschreitet.

(5) Das Arbeitsinspektorat kann bei Nachweis eines dringenden Bedürfnisses auf Antrag des Arbeitgebers nach Anhörung der gesetzlichen Interessenvertretungen der Arbeitgeber und der Arbeitnehmer eine über das Ausmaß der Abs. 1 bis 3 hinausgehende Arbeitszeitverlängerung bewilligen. Eine Tagesarbeitszeit über zehn Stunden kann das Arbeitsinspektorat jedoch nur zulassen, wenn dies im öffentlichen Interesse erforderlich ist.

Verlängerung der Arbeitszeit zur Vornahme von Vor- und Abschlußarbeiten

§ 8. (1) Die für den Betrieb oder eine Betriebsabteilung zulässige Dauer der Arbeitszeit darf um eine halbe Stunde täglich, jedoch höchstens bis zu zehn Stunden täglich in folgenden Fällen ausgedehnt werden:

a) bei Arbeiten zur Reinigung und Instandhaltung, soweit sich diese Arbeiten während des regelmäßigen Betriebes nicht ohne Unterbrechung oder erhebliche Störung ausführen lassen,

b) bei Arbeiten, von denen die Wiederaufnahme oder Aufrechterhaltung des vollen Betriebes arbeitstechnisch abhängt,

c) bei Arbeiten zur abschließenden Kundenbedienung einschließlich der damit zusammenhängenden notwendigen Aufräumungsarbeiten.

(2) Die Arbeitszeit darf in den Fällen des Abs. 1 für männliche Arbeitnehmer über zehn Stunden täglich verlängert werden, wenn eine Vertretung des Arbeitnehmers durch andere Arbeitnehmer nicht möglich ist und dem Arbeitgeber die Heranziehung betriebsfremder Personen nicht zugemutet werden kann.

(3) Durch Kollektivvertrag kann näher bestimmt werden, welche Arbeiten als Vor- und Abschlußarbeiten gelten.

(4) Das Arbeitsinspektorat kann feststellen, ob bestimmte Arbeiten als Vor- und Abschlußarbeiten gelten.

Höchstgrenze für Arbeitszeitverlängerungen

§ 9. Abgesehen von den Bestimmungen des § 4 Abs. 10 zweiter Satz, § 5, § 7 Abs. 2 bis 4 und Abs. 5 zweiter Satz, § 8 Abs. 2 sowie der §§ 16, 18 bis 20 und 23 darf die Arbeitszeit auch beim Zusammentreffen mehrerer Arbeitszeitverlängerungen zehn Stunden täglich nicht überschreiten und die sich aus § 3 ergebende Wochenarbeitszeit um nicht mehr als zehn Stunden wöchentlich überschreiten.

Überstundenvergütung

§ 10. (1) Sofern durch Kollektivvertrag nicht anderes bestimmt wird, gebührt für die ersten vier Überstunden, ab 6. Jänner 1975 für die ersten fünf Überstunden in einer Arbeitswoche ein Zuschlag von 25 v. H., für weitere Überstunden ein Zuschlag von 50 v. H.

(2) In den Fällen des § 4 Abs. 5, 7 und 9 gebührt der Zuschlag von 25 v. H. für das dem Durchrechnungszeitraum entsprechende Vielfache von vier bzw. fünf Überstunden.

(3) Der Berechnung des Zuschlages nach Abs. 1 und 2 ist der auf die einzelne Arbeitsstunde entfallende Normallohn zugrunde zu legen. Bei Akkord-, Stück- und Gedinglöhnen ist dieser nach dem Durchschnitt der letzten dreizehn Wochen zu bemessen. Durch Kollektivvertrag kann auch eine andere Berechnungsart vereinbart werden.

ABSCHNITT 3

Ruhepausen und Ruhezeiten

Ruhepausen

§ 11. (1) Beträgt die Gesamtdauer der Tagesarbeitszeit mehr als sechs Stunden, so ist die Arbeitszeit durch eine Ruhepause von mindestens einer halben Stunde zu unterbrechen. Wenn es im Interesse der Arbeitnehmer des Betriebes gelegen oder aus betrieblichen Gründen notwendig ist, können an Stelle einer halbstündigen Ruhepause zwei Ruhepausen von je einer Viertelstunde oder drei Ruhepausen von je zehn Minuten gewährt werden.

(2) Eine Pausenregelung gemäß Abs. 1 zweiter Satz kann, sofern eine gesetzliche Betriebsvertretung besteht, nur mit deren Zustimmung getroffen werden.

(3) Bei Arbeiten, die werktags und sonntags einen ununterbrochenen Fortgang erfordern, sind den in Wechselschichten beschäftigten Arbeitnehmern an Stelle der Pausen im Sinne des Abs. 1 Kurzpausen von angemessener Dauer zu gewähren. Eine derartige Pausenregelung kann auch bei sonstiger durchlaufender mehrschichtiger Arbeitsweise getroffen werden.

(4) Das Arbeitsinspektorat kann, wenn es im Interesse der Arbeitnehmer des Betriebes gelegen oder aus betrieblichen Gründen notwendig ist, eine von Abs. 1 abweichende Pausenregelung zulassen.

(5) Das Arbeitsinspektorat kann ferner für Betriebe, Betriebsabteilungen oder für bestimmte Arbeiten (zum Beispiel Fließbandarbeiten) über die Bestimmungen des Abs. 1 hinausgehende Ruhepausen anordnen, wenn die Schwere der Arbeit oder der sonstige Einfluß der Arbeit auf die Gesundheit der Arbeitnehmer dies erfordert.

(6) Kurzpausen im Sinne des Abs. 3 und Ruhepausen im Sinne des Abs. 5 gelten, soweit sie das Ausmaß nach Abs. 1 überschreiten, als Arbeitszeit.

Ruhezeiten

§ 12. (1) Nach Beendigung der Tagesarbeitszeit ist den Arbeitnehmern eine ununterbrochene Ruhezeit von mindestens elf Stunden zu gewähren. Durch Kollektivvertrag kann zugelassen werden, daß die ununterbrochene Ruhezeit für männliche Arbeitnehmer nur zehn Stunden beträgt.

(2) Das Arbeitsinspektorat kann beim Nachweis eines dringenden Bedürfnisses Ausnahmen zulassen, wenn die Erholung des Arbeitnehmers durch andere Maßnahmen gesichert ist.

(3) Den Arbeitnehmern gebührt wöchentlich eine ununterbrochene Wochenruhe von mindestens sechsunddreißig Stunden. Hievon kann in den Fällen der Schichtarbeit gemäß § 11 Abs. 3 nur insoweit abgewichen werden, als dies zur Ermöglichung des Schichtwechsels erforderlich ist.

(4) Wenn es aus betrieblichen Gründen notwendig ist, können durch Verordnung für bestimmte Arten oder Gruppen von Betrieben oder im Einzelfall durch Bewilligung des Arbeitsinspektorates Ausnahmen von der Bestimmung des Abs. 3 zugelassen werden.

ABSCHNITT 4

Sonderbestimmungen für Lenker und Beifahrer von Kraftfahrzeugen

§ 13. Für Lenker und Beifahrer von Kraftfahrzeugen gelten die Bestimmungen der Abschnitte 2 und 3 mit den in den §§ 14 und 16 enthaltenen Abänderungen.

Arbeitszeit und Lenkzeit

§ 14. (1) Die Arbeitszeit für Lenker und Beifahrer von Kraftfahrzeugen umfaßt unbeschadet des § 2 die Lenkzeiten, die Zeiten für sonstige Arbeitsleistungen und Zeiten der Arbeitsbereitschaft.

(2) Innerhalb der nach Abschnitt 2 zulässigen Arbeitszeit darf die gesamte Lenkzeit zwischen zwei Ruhezeiten acht Stunden und innerhalb einer Woche achtundvierzig Stunden nicht überschreiten. Durch Kollektivvertrag oder in Einzelfällen durch das Arbeitsinspektorat kann zugelassen werden, daß die Lenkzeit höchstens zweimal in der Woche auf neun Stunden erhöht werden kann, wenn

a) ein der Personenbeförderung dienendes Kraftfahrzeug ohne Anhänger oder mit einem Anhänger gelenkt wird, dessen Gesamtgewicht fünf Tonnen nicht überschreitet, oder

b) ein der Güterbeförderung dienendes Kraftfahrzeug ohne Anhänger oder mit einem Anhänger oder Sattelanhänger gelenkt wird, sofern das höchste zulässige Gesamtgewicht des Kraftfahrzeuges (Sattelkraftfahrzeuges) zwanzig Tonnen nicht überschreitet.

(3) Das Arbeitsinspektorat kann in Einzelfällen über Abs. 2 hinaus nach Anhörung der gesetzlichen Interessenvertretungen der Arbeitgeber und der Arbeitnehmer Ausnahmen zulassen, wobei auf die Bestimmungen des § 16 Bedacht zu nehmen ist.

Lenkpausen

§ 15. (1) Nach einer ununterbrochenen Lenkzeit von höchstens vier Stunden ist eine Lenkpause einzulegen. Die Lenkzeit gilt auch dann als ununterbrochen, wenn sie durch kürzere Zeiträume unterbrochen wird, als sie nach den Abs. 2 und 3 für Lenkpausen vorgesehen sind.

(2) Beim Lenken der in § 14 Abs. 2 lit. a und b genannten Kraftfahrzeuge hat die Lenkpause mindestens eine halbe Stunde zu betragen.

(3) Beim Lenken von anderen als den in § 14 Abs. 2 lit. a und b genannten Kraftfahrzeugen hat die Lenkpause mindestens eine Stunde zu betragen. Durch Kollektivvertrag kann zugelassen werden, daß diese Lenkpause durch zwei Lenkpausen von mindestens je einer halben Stunde ersetzt wird, von denen die erste innerhalb der ersten vier Stunden der Lenkzeit, die zweite innerhalb der restlichen Lenkzeit einzuhalten ist.

(4) Für den Kraftfahrlinienverkehr können, soweit es für die Erstellung der Fahrpläne erforderlich ist, durch Verordnung oder im Einzelfall durch Bewilligung des zuständigen Bundesministeriums von Abs. 1 bis 3 abweichende Pausenregelungen zugelassen werden.

Einsatzzeit

§ 16. (1) Die Einsatzzeit von Lenkern und Beifahrern umfaßt die zwischen zwei Ruhezeiten anfallende Arbeitszeit, die Ruhepausen und Lenkpausen.

(2) Die Einsatzzeit darf, soweit in den Abs. 3 und 4 nicht anderes bestimmt wird, zwölf Stunden nicht überschreiten.

(3) Durch Kollektivvertrag kann in den Fällen der Arbeitsbereitschaft (§ 5) abweichend von

§ 7 Abs. 3 zugelassen werden, daß die Einsatzzeit bis zu vierzehn Stunden betragen darf.

(4) Befinden sich zwei Lenker im Fahrzeug, so kann durch Kollektivvertrag in den Fällen der Arbeitsbereitschaft (§ 5) abweichend von § 7 Abs. 3 zugelassen werden, daß die Einsatzzeit bis zu siebzehn Stunden betragen darf.

(5) Das Arbeitsinspektorat kann nach Anhörung der gesetzlichen Interessenvertretungen der Arbeitgeber und der Arbeitnehmer in Einzelfällen Ausnahmen im Sinne der Abs. 3 und 4 zulassen.

Die Tagesarbeitszeit von Arbeitnehmerinnen darf auch in den Fällen der Abs. 2 bis 5 zehn Stunden nicht überschreiten.

(7) Für den Kraftfahrlinienverkehr können, soweit es für die Erstellung der Fahrpläne erforderlich ist, durch Verordnung oder im Einzelfall durch Bewilligung des zuständigen Bundesministeriums von § 12 Abs. 1 abweichende Ruhezeitenregelungen zugelassen werden.

Fahrtenbuch

§ 17. (1) Lenker und Beifahrer, die nicht im Kraftfahrlinienverkehr eingesetzt sind, haben während der Fahrt ein persönliches Fahrtenbuch mit sich zu führen, in welches laufend die Angaben über die Dauer der Lenkzeit, sonstiger Arbeitsleistungen, der Arbeitsbereitschaft, der Ruhepausen und der Ruhezeiten, nach Arbeitstagen getrennt, einzutragen sind. Das Fahrtenbuch ist den zur Kontrolle Berechtigten über deren Verlangen vorzuweisen.

(2) Dem Arbeitgeber obliegt die Ausgabe der persönlichen Fahrtenbücher. Nach deren Abschluß sind diese vom Arbeitgeber mindestens ein Jahr lang aufzubewahren.

(3) Nähere Bestimmungen über Form und Inhalt des Fahrtenbuches sind durch Verordnung zu treffen. Ferner können durch Verordnung Ausnahmen und Erleichterungen in der Führung der Fahrtenbücher gestattet werden, wenn die Überwachung der Einhaltung der Arbeitszeitregelungen auf andere Weise hinlänglich sichergestellt ist.

ABSCHNITT 5

Sonderbestimmungen für Arbeitnehmer in Betrieben des öffentlichen Verkehrs

§ 18. (1) Für Arbeitnehmer, die in den dem öffentlichen Verkehr dienenden Haupt- oder Nebenbahnbetrieben, in Straßenbahn- oder Oberleitungsomnibusbetrieben, im Schiffsdienst von Schiffahrtsunternehmungen und von Hafenbetrieben sowie in Betrieben der Luftfahrt tätig sind, gelten, soweit § 1 Abs. 2 nicht anderes bestimmt, die Bestimmungen der Abschnitte 2 und 3 nach Maßgabe der folgenden Absätze.

(2) Durch Kollektivvertrag kann zugelassen werden, daß die nach den §§ 3 oder 5 zulässige Wochenarbeitszeit abweichend von § 4 und abweichend von der nach § 3 Abs. 1 zulässigen Tagesarbeitszeit innerhalb eines mehrwöchigen Durchrechnungszeitraumes so verteilt wird, daß im wöchentlichen Durchschnitt die nach den §§ 3 oder 5 zulässige Wochenarbeitszeit nicht überschritten wird. Dabei, sowie in den Fällen der Überstundenarbeit abweichend von § 7 Abs. 1 und 2, darf die Tagesarbeitszeit zehn Stunden, in den Fällen des § 5 jedoch zwölf Stunden, insoweit überschreiten, als dies die Aufrechterhaltung des Verkehrs erfordert.

(3) Für Arbeitnehmer, deren Arbeitsleistung Warte- und Bereitschaftszeiten einschließt, können durch Kollektivvertrag abweichend von den §§ 2 und 3 besondere Regelungen über das Ausmaß der Wochenarbeitsleistung, über die Bewertung der Warte- und Bereitschaftszeiten als Arbeitszeit sowie über die Art und Höhe der Abgeltung dieser Zeiten getroffen werden.

(4) Durch Kollektivvertrag kann eine von den §§ 11 und 12 abweichende Regelung zugelassen werden, wenn es im Interesse der Arbeitnehmer des Betriebes gelegen oder aus betrieblichen Gründen notwendig ist.

ABSCHNITT 6

Sonderbestimmungen für bestimmte Arbeitnehmer in Heil- und Pflegeanstalten (Krankenanstalten) und Kuranstalten

§ 19. (1) Für Arbeitnehmer, die in Heil- und Pflegeanstalten (Krankenanstalten) sowie Kuranstalten als Angehörige von Gesundheitsberufen tätig sind oder die sonst zur Aufrechterhaltung des Betriebes in solchen Anstalten unumgänglich notwendig sind, gelten, soweit § 1 Abs. 2 nicht anderes bestimmt, die Bestimmungen der Abschnitte 2 und 3 nach Maßgabe der folgenden Absätze.

(2) Unbeschadet der nach § 7 Abs. 1 erster Satz zulässigen Überstunden können durch Kollektivvertrag abweichend von § 7 Abs. 2 bis zu fünfzehn weitere Überstunden wöchentlich zugelassen werden. Die Tagesarbeitszeit darf in diesen Fällen jedoch dreizehn und die Wochenarbeitszeit sechzig Stunden nicht überschreiten.

(3) Das Arbeitsinspektorat kann für Betriebe, Betriebsabteilungen oder für bestimmte Arbeiten, sofern hiefür kein Branchenkollektivvertrag wirksam ist, eine Verlängerung der Arbeitszeit nach Maßgabe des Abs. 2 zulassen.

(4) Für Arbeitnehmer im Sinne des Abs. 1 darf bis zum Inkrafttreten der Bestimmung des § 3 die wöchentliche Normalarbeitszeit fünfundvierzig Stunden nicht überschreiten.

ABSCHNITT 7

Ausnahmen

Außergewöhnliche Fälle

§ 20. (1) In außergewöhnlichen Fällen finden die Bestimmungen der §§ 3 bis 5, 7, 8, 9, 11, 12, 14 bis 16, 18 und 19 keine Anwendung auf vorübergehende und unaufschiebbare Arbeiten, die

a) zur Abwendung einer unmittelbaren Gefahr für die Sicherheit des Lebens oder für die Gesundheit von Menschen oder bei Notstand sofort vorgenommen werden müssen, oder

b) zur Behebung einer Betriebsstörung oder zur Verhütung des Verderbens von Gütern oder eines sonstigen unverhältnismäßigen wirtschaftlichen Sachschadens erforderlich sind, wenn unvorhergesehene und nicht zu verhindernde Gründe vorliegen und andere zumutbare Maßnahmen zur Erreichung dieses Zweckes nicht getroffen werden können.

(2) Der Arbeitgeber hat die Vornahme von Arbeiten auf Grund des Abs. 1 ehestens, längstens jedoch binnen vier Tagen nach Beginn der Arbeiten dem Arbeitsinspektorat schriftlich anzuzeigen. Die Anzeige hat die Gründe der Arbeitszeitverlängerung sowie die Anzahl der zur Mehrarbeit herangezogenen Arbeitnehmer zu enthalten. Die Aufgabe der Mitteilung bei der Post gilt als Erstattung der Anzeige.

Verkürzung der Arbeitszeit und Verlängerung der Ruhezeit bei gefährlichen Arbeiten

§ 21. Für Arbeitnehmer, die bei Arbeiten beschäftigt werden, die mit einer besonderen Gefährdung der Gesundheit verbunden sind, kann durch Verordnung eine kürzere als die nach § 3 zulässige Dauer der Arbeitszeit oder die Einhaltung längerer Ruhepausen oder Ruhezeiten als in den §§ 11 und 12 vorgesehen, angeordnet werden. Insoweit Ruhepausen über das im § 11 Abs. 1 vorgesehene Ausmaß hinausgehen, gelten sie als Arbeitszeit.

Arbeitszeit bei Reparaturarbeiten in heißen Öfen von Eisen- oder Stahlhüttenbetrieben oder Kokereien

§ 22. (1) Bei Reparaturarbeiten (Zustellungen), die in Eisen- oder Stahlhüttenbetrieben in heißen Siemens-Martin-Öfen, heißen Schmelz-, Glüh-, Aufheiz- oder Brennöfen sowie in heißen Konvertern oder in Kokereien in heißen Kokereiöfen vorgenommen werden, darf die Wochenarbeitszeit vierzig Stunden nicht überschreiten. Wird die Arbeitszeit an einzelnen Werktagen regelmäßig verkürzt, so darf sie an den übrigen Tagen der Woche acht Stunden nicht überschreiten.

(2) Nimmt die Beschäftigung mit den im Abs. 1 genannten Arbeiten nicht eine volle Woche in Anspruch, so sind Arbeitszeiten in den im Abs. 1 angeführten heißen Öfen oder heißen Konvertern mit einem Zuschlag von 7·5 v. H. zu bewerten. Eine Arbeitsstunde ist daher mit 64½ Minuten in Anschlag zu bringen, jedoch darf die nach § 3 zulässige Dauer der Wochenarbeitszeit nicht überschritten werden.

(3) Als heiße Öfen oder heiße Konverter im Sinne der Abs. 1 und 2 gelten solche, bei denen die Innentemperatur mehr als 30° C beträgt.

(4) Die Bestimmungen der Abs. 1 und 2 gelten auch für Reparaturarbeiten (Zustellungen) in Hochöfen, soweit mit Kohlenstoffsteinen gearbeitet wird.

(5) Bei Einführung einer Wochenarbeitszeit von zweiundvierzig Stunden tritt an Stelle des im Abs. 2 genannten Zuschlages von 7·5 v. H. ein solcher von 5 v. H. Eine Arbeitsstunde ist daher dann mit 63 Minuten in Anschlag zu bringen.

Ausnahmen im öffentlichen Interesse

§ 23. Wenn es das öffentliche Interesse infolge besonders schwerwiegender Umstände erfordert, können durch Verordnung für einzelne Arten oder Gruppen von Betrieben Ausnahmen von den Bestimmungen der §§ 3, 4, 9, 11, 12, 14 bis 16, 18 und 19 zugelassen oder abweichende Regelungen hinsichtlich der Dauer der Ruhepausen getroffen werden.

ABSCHNITT 8

Gemeinsame Vorschriften

Auflegen des Gesetzes

§ 24. Jeder Arbeitgeber hat einen Abdruck dieses Bundesgesetzes im Betrieb an geeigneter, für die Arbeitnehmer leicht zugänglicher Stelle aufzulegen.

Aushang der betrieblichen Arbeitszeit- und Ruhezeitenregelung

§ 25. In Betrieben, in denen keine Arbeitsordnung gemäß § 21 des Kollektivvertragsgesetzes, BGBl. Nr. 76/1947, oder Dienstordnung gemäß § 200 des Allgemeinen Berggesetzes, RGBl. Nr. 146/1854, erlassen wurde oder zu erlassen ist, muß vom Arbeitgeber an einer für die Arbeitnehmer des Betriebes leicht zugänglichen Stelle ein Aushang über den Beginn und das Ende der Normalarbeitszeit und der Ruhe-

pausen sowie über die Dauer der Wochenruhe gut sichtbar angebracht werden.

Auskunftspflicht

§ 26. (1) Die Arbeitgeber haben zur Überwachung der Einhaltung der in diesem Bundesgesetz geregelten Angelegenheiten Aufzeichnungen über die geleisteten Arbeitsstunden und deren Entlohnung zu führen.

(2) Die Arbeitgeber haben der Arbeitsinspektion und deren Organen die erforderlichen Auskünfte zu erteilen und auf Verlangen Einsicht in die Aufzeichnungen über die geleisteten Arbeitsstunden und deren Entlohnung zu geben.

Behördenzuständigkeit und Verfahrensvorschriften

§ 27. (1) Die nach den Bestimmungen dieses Bundesgesetzes den Arbeitsinspektoraten zustehenden Aufgaben und Befugnisse sind in den vom Wirkungsbereich der Arbeitsinspektion ausgenommenen Betrieben von den zur Wahrung des Arbeitnehmerschutzes sonst berufenen Behörden wahrzunehmen.

(2) Bescheide gemäß § 4 Abs. 4, § 5 Abs. 2, § 7 Abs. 5, § 11 Abs. 4, § 12 Abs. 2 und 4, § 14 Abs. 2 und 3, § 15 Abs. 4, § 16 Abs. 5 und 7 und § 19 Abs. 3 sind zu befristen, wobei die Bewilligung über das Kalenderjahr nicht hinausgehen darf.

(3) Berufungen gegen Bescheide gemäß § 8 Abs. 4 kommt keine aufschiebende Wirkung zu.

(4) Über Berufungen gegen Bescheide der Arbeitsinspektorate entscheidet das Bundesministerium für soziale Verwaltung, soweit es sich jedoch um Bescheide einer Berghauptmannschaft handelt, das Bundesministerium für Handel, Gewerbe und Industrie.

(5) Die den Arbeitsinspektoraten nach den Bestimmungen dieses Bundesgesetzes zustehenden Befugnisse sind für Fälle, die sich über den Wirkungsbereich eines Arbeitsinspektorates hinaus erstrecken, vom Bundesministerium für soziale Verwaltung, für Fälle, die sich über den Wirkungsbereich einer Berghauptmannschaft hinaus erstrecken, vom Bundesministerium für Handel, Gewerbe und Industrie wahrzunehmen.

(6) Anzeigen gemäß § 20 Abs. 2 sind von Stempel- und Rechtsgebühren des Bundes befreit.

Strafbestimmungen

§ 28. (1) Arbeitgeber und deren Bevollmächtigte, die den Bestimmungen dieses Bundesgesetzes zuwiderhandeln, sind, sofern die Tat nicht nach anderen Vorschriften einer strengeren Strafe unterliegt, von der Bezirksverwaltungsbehörde, im Bergbau von der Berghauptmannschaft, mit einer Geldstrafe von 300 S bis 6000 S oder mit Arrest von drei Tagen bis zu sechs Wochen zu bestrafen.

(2) Abs. 1 ist nicht anzuwenden, wenn die Zuwiderhandlung von Organen einer Gebietskörperschaft begangen wurde. Besteht bei einer Bezirksverwaltungsbehörde der Verdacht einer Zuwiderhandlung durch ein solches Organ, so hat sie, wenn es sich um ein Organ des Bundes oder eines Landes handelt, eine Anzeige an das oberste Organ, dem das der Zuwiderhandlung verdächtige Organ untersteht (Art. 20 Abs. 1 erster Satz des Bundes-Verfassungsgesetzes in der Fassung von 1929), in allen anderen Fällen aber eine Anzeige an die Aufsichtsbehörde zu erstatten.

Weitergelten von Regelungen

§ 29. (1) Soweit Kollektivverträge, Arbeitsordnungen oder Betriebsvereinbarungen für die Arbeitnehmer günstigere Bestimmungen vorsehen oder in Betrieben günstigere Regelungen bestehen, als sich nach den Bestimmungen dieses Bundesgesetzes ergibt, werden diese durch die Bestimmungen dieses Bundesgesetzes nicht berührt.

(2) Im Zeitpunkt des Inkrafttretens dieses Bundesgesetzes bestehende kollektivvertragliche Vereinbarungen in Angelegenheiten, in denen nach den Bestimmungen der §§ 3 Abs. 3 und 4, § 4 Abs. 7 und 9, § 5 Abs. 1 und 3, § 7 Abs. 2 und 3, § 10 Abs. 1 und 3, § 12 Abs. 1, § 14 Abs. 2, § 15 Abs. 3, § 16 Abs. 3 und 4, § 18 Abs. 2 bis 4 und § 19 Abs. 2 dieses Bundesgesetzes abweichende Regelungen durch Kollektivvertrag zugelassen sind, gelten als solche Regelungen, insoweit sie den vorgenannten Bestimmungen entsprechen.

ABSCHNITT 9

Schluß- und Übergangsbestimmungen

Aufhebung von Rechtsvorschriften

§ 30. (1) Mit dem Inkrafttreten dieses Bundesgesetzes treten für dessen Geltungsbereich alle mit den Bestimmungen dieses Bundesgesetzes in Widerspruch stehenden Vorschriften, soweit sie noch in Geltung stehen und soweit § 32 nicht anderes bestimmt, außer Kraft. Insbesondere verlieren ihre Wirksamkeit:

1. Arbeitszeitordnung vom 30. April 1938, Deutsches RGBl. I S. 447 (GBl. f. d. L. Ö. Nr. 231/1939), mit Ausnahme des § 16,
2. Ausführungsverordnung zur Arbeitszeitordnung vom 12. Dezember 1938, Deutsches RGBl. I S. 1799 (GBl. f. d. L. Ö. Nr. 667/1939), mit Ausnahme der Nr. 20,

3. Verordnung über die Arbeitszeit in Kokereien und Hochofenwerken vom 20. Jänner 1925, Deutsches RGBl. I S. 5 (GBl. f. d. L. Ö. Nr. 231/1939),

4. Verordnung über die Arbeitszeit in Gaswerken vom 9. Februar 1927, Deutsches RGBl. I S. 59 (GBl. f. d. L. Ö. Nr. 231/1939),

5. Verordnung über die Arbeitszeit in Metallhütten vom 9. Februar 1927, Deutsches RGBl. I S. 59 (GBl. f. d. L. Ö. Nr. 231/1939),

6. Verordnung über die Arbeitszeit in Stahlwerken, Walzwerken und anderen Anlagen der Großeisenindustrie vom 16. Juli 1927, Deutsches RGBl. I S. 221 (GBl. f. d. L. Ö. Nr. 231/1939),

7. Verordnung über die Arbeitszeit in der Zementindustrie vom 26. März 1929, Deutsches RGBl. I S. 82 (GBl. f. d. L. Ö. Nr. 231/1939),

8. Zweite Anordnung vom 15. Februar 1939, welche die Arbeitszeit auf Baustellen betrifft, Deutscher Reichsanzeiger und Preußischer Staatsanzeiger Nr. 45 (GBl. f. d. L. Ö. Nr. 271/1939),

9. Verordnung über die Arbeitszeit in Krankenpflegeanstalten vom 13. Februar 1924, Deutsches RGBl. I S. 66, berichtigt im Deutschen RGBl. I S. 154/1924 (GBl. f. d. L. Ö. Nr. 25/1940),

10. Anordnung über Arbeitszeitverkürzung für Frauen, Schwerbeschädigte und minderleistungsfähige Personen (Freizeitanordnung) vom 22. Oktober 1943, RABl. I S. 508,

11. Abschnitt III, §§ 4 bis 7 der Verordnung zur Abänderung und Ergänzung von Vorschriften auf dem Gebiete des Arbeitsrechtes vom 1. September 1939, Deutsches RGBl. I S. 1683 (GBl. f. d. L. Ö. Nr. 1217/1939),

12. Verordnung über den Arbeitsschutz vom 12. Dezember 1939, Deutsches RGBl. I S. 2403,

13. Verordnung über die Sechzigstundenwoche vom 31. August 1944, Deutsches RGBl. I S. 191,

14. Verordnung des Bundesministeriums für soziale Verwaltung vom 22. Juni 1956, BGBl. Nr. 126, in der Fassung der Verordnung BGBl. Nr. 124/1959, über die Regelung der Arbeitszeit bei Reparaturarbeiten in heißen Öfen von Eisen- und Stahlhüttenbetrieben,

15. Verordnung des Bundesministeriums für soziale Verwaltung vom 25. September 1956, BGBl. Nr. 195, in der Fassung der Kundmachung vom 31. März 1966, BGBl. Nr. 49, betreffend die Zulassung von Arbeitszeitverlängerungen beim Nachweis eines dringenden Bedürfnisses.

(2) Weiters treten außer Kraft:

1. Erste Anordnung über die Vereinfachung der Lohn- und Gehaltsabrechnung vom 12. Juli 1944, Deutsches RGBl. I S. 166,

2. Zweite Anordnung über die Vereinfachung der Lohn- und Gehaltsabrechnung vom 2. September 1944, Deutsches RGBl. I S. 196,

3. Anordnung gegen Arbeitsvertragsbruch und Abwerbung sowie das Fordern unverhältnismäßig hoher Arbeitsentgelte in der privaten Wirtschaft vom 20. Juli 1942, RABl. I S. 341,

4. Anordnung über die Mehrarbeitsvergütung von Angestellten in der privaten Wirtschaft während der Kriegszeit vom 15. Oktober 1942, RABl. I S. 477,

5. Anordnung zur Regelung der Vergütung von zusätzlicher Sonn- und Feiertagsarbeit der kaufmännischen und technischen Angestellten der Industrie, des Handwerks und des Handels vom 14. März 1942, RABl. I S. 168,

6. Anordnung des Reichstreuhänders der Arbeit Wien vom 24. November 1944 über die Entlohnung der aus Anlaß einer Lastenminderung der Gas- und Elektrizitätswerke geleisteten Nachtarbeitsstunden sowie der Arbeitsleistungen an Samstagnachmittagen und Sonntagen, Amtliche Mitteilungen des Präsidenten der Gauarbeitsämter und der Reichstreuhänder der Arbeit in den Donau- und Alpengauen, S. 284/1944,

7. Anordnung über die Aufhebung arbeitsfreier Tage außerhalb der gesetzlichen Sonn- und Feiertage vom 3. Mai 1944, RABl. I S. 184,

8. Anordnung Nr. 13 zur Sicherung der Ordnung in den Betrieben vom 1. November 1943, RABl. I S. 543,

9. Zweite Anordnung zur Sicherung der Ordnung in den Betrieben vom 23. September 1944, RABl. I S. 359,

10. Anordnung zur Änderung der Anordnung Nr. 13 zur Sicherung der Ordnung in den Betrieben vom 1. November 1943, RABl. I S. 415/1944.

Außerkrafttreten von Ausnahmegenehmigungen

§ 31. Bescheide, die auf Grund von durch dieses Bundesgesetz außer Kraft gesetzten Arbeitszeitvorschriften erlassen wurden, verlieren spätestens mit dem Ablauf von drei Monaten nach dem Inkrafttreten dieses Bundesgesetzes ihre Wirksamkeit.

Weitergelten von Arbeitnehmerschutzvorschriften

§ 32. (1) Soweit § 33 Abs. 2 Z. 4 des Bundesgesetzes über die Beschäftigung von Kindern und Jugendlichen, BGBl. Nr. 146/1948, nicht anderes bestimmt, bleiben die im Zeitpunkt des Inkrafttretens dieses Bundesgesetzes geltenden Bestimmungen der

a) Glashüttenverordnung vom 23. Dezember 1938, Deutsches RGBl. I S. 1961 (GBl. f. d. L. Ö. Nr. 1003/1939), in der Fassung der Verordnung vom 13. September 1940, Deutsches RGBl. I S. 1246,

b) Verordnung über die Herstellung, Verpackung, Lagerung und Einfuhr von Thomasmehl vom 30. Jänner 1931, Deutsches RGBl. I S. 17, in der Fassung der Verordnung vom 30. September 1931, Deutsches RGBl. I S. 525 (GBl. f. d. L. Ö. Nr. 1436/1939),

als Bundesgesetze vorläufig in Geltung. Die unter lit. a und lit. b genannten Vorschriften treten je mit dem Zeitpunkt außer Kraft, zu dem die darin geregelten Angelegenheiten auf Grund bestehender bundesgesetzlicher Vorschriften durch Verordnung geregelt werden. Die betreffenden Verordnungen haben das Außerkrafttreten der unter lit. a und lit. b bezeichneten Vorschriften festzustellen.

(2) Die Bestimmungen der Nr. 54 erster bis dritter Satz der Ausführungsverordnung zur Arbeitszeitordnung vom 12. Dezember 1938, Deutsches RGBl. I S. 1799 (GBl. f. d. L. Ö. Nr. 667/1939), bleiben als Bundesgesetz bis zu dem Zeitpunkt vorläufig in Geltung, in dem die betreffende Angelegenheit durch Verordnung gemäß § 17 Abs. 4 dieses Bundesgesetzes geregelt worden ist. Diese Verordnung hat das Außerkrafttreten der angeführten Bestimmungen der Nr. 54 der Ausführungsverordnung festzustellen.

Inkrafttreten und Vollziehung

§ 33. (1) Dieses Bundesgesetz tritt, soweit Abs. 2 und 3 nicht anderes bestimmen, am 5. Jänner 1970 in Kraft.

(2) Die Bestimmungen des § 12 Abs. 3 betreffend die ununterbrochene Wochenruhe und des § 17 betreffend das Fahrtenbuch treten jeweils mit den gemäß § 12 Abs. 4 bzw. den gemäß § 17 Abs. 3 zu erlassenden Verordnungen in Kraft. Weiters werden für die im Kraftfahrlinienverkehr tätigen Arbeitnehmer die Bestimmungen der §§ 15 und 16 jeweils mit den gemäß § 15 Abs. 4 bzw. gemäß § 16 Abs. 7 zu erlassenden Verordnungen wirksam.

(3) Die Bestimmungen des § 3 werden für Arbeitnehmer, auf die die Sonderbestimmungen des Abschnittes 6 Anwendung finden, wirksam, wenn eine Arbeitszeitverkürzung für den überwiegenden Teil der Arbeitnehmer in öffentlichen Heil- und Pflegeanstalten (Krankenanstalten) der Gebietskörperschaften erfolgt ist. Dieser Zeitpunkt ist durch Kundmachung des Bundesministers für soziale Verwaltung festzustellen.

(4) Mit der Vollziehung dieses Bundesgesetzes sind betraut:

a) hinsichtlich der Arbeitnehmer in Betrieben, die der bergbehördlichen Aufsicht unterstehen, der Bundesminister für Handel, Gewerbe und Industrie im Einvernehmen mit dem Bundesminister für soziale Verwaltung;

b) hinsichtlich der Arbeitnehmer in Betrieben, die dem Verkehrs-Arbeitsinspektionsgesetz unterliegen, der Bundesminister für Verkehr und verstaatlichte Unternehmungen im Einvernehmen mit dem Bundesminister für soziale Verwaltung;

c) hinsichtlich aller anderen Arbeitnehmer der Bundesminister für soziale Verwaltung;

d) hinsichtlich des § 27 Abs. 6 der Bundesminister für Finanzen.

Jonas

Klaus **Rehor**

Koren **Mitterer** **Weiß**

462. Bundesgesetz vom 11. Dezember 1969, mit dem Arbeitszeitvorschriften abgeändert und ergänzt werden

Der Nationalrat hat beschlossen:

Artikel I

Abänderung des Bundesgesetzes über die Beschäftigung von Kindern und Jugendlichen

Das Bundesgesetz über die Beschäftigung von Kindern und Jugendlichen, BGBl. Nr. 146/1948, in der Fassung der Bundesgesetze BGBl. Nr. 45/1952, 70/1955, 113/1962 und 103/1969, wird abgeändert wie folgt:

1. a) § 11 Abs. 1 und 2 haben zu lauten:

„§ 11. (1) Die tägliche Arbeitszeit der Jugendlichen darf acht Stunden, ihre Wochenarbeitszeit dreiundvierzig Stunden nicht überschreiten, soweit im folgenden nicht anderes bestimmt wird.

(2) An Stelle der in Abs. 1 festgelegten Wochenarbeitszeit von dreiundvierzig Stunden tritt ab 3. Jänner 1972 eine solche von zweiundvierzig Stunden und ab 6. Jänner 1975 eine solche von vierzig Stunden."

b) Nach Abs. 2 sind folgende Abs. 3 und 4 einzufügen:

„(3) Eine von Abs. 1 und 2 abweichende Wochenarbeitszeit kann durch Kollektivvertrag zugelassen werden, sofern dieser eine vor dem Inkrafttreten dieses Bundesgesetzes zulässige Wochenarbeitszeit auf Grund eines Arbeitszeitverkürzungsplanes so verkürzt, daß die Wochenarbeitszeit spätestens ab 6. Jänner 1975 vierzig Stunden nicht überschreitet. Die nach einem solchen Arbeitszeitverkürzungsplan festgelegte Wochenarbeitszeit gilt als Wochenarbeitszeit im Sinne dieses Bundesgesetzes.

(4) Aus Anlaß der mit dem Inkrafttreten dieses Bundesgesetzes sowie der gemäß Abs. 2 oder 3 eintretenden Arbeitszeitverkürzung darf das Entgelt der betroffenen Arbeitnehmer nicht verkürzt werden (Lohnausgleich). Ein nach Stunden bemessenes Entgelt ist dabei in dem gleichen Verhältnis zu erhöhen, in dem die Arbeitszeit verkürzt wird. Akkord-, Stück- und Gedinglöhne sowie auf Grund anderer Leistungslohnarten festgelegte Löhne sind entsprechend zu berichtigen. Durch Kollektivvertrag kann eine andere Regelung des Lohnausgleiches vereinbart werden."

c) Die bisherigen Abs. 3, 4 und 5 erhalten die Bezeichnung 5, 6 und 7.

d) Der nunmehrige Abs. 5 hat zu lauten:

„(5) Durch Kollektivvertrag kann zugelassen werden, daß die Wochenarbeitszeit auf die Werktage abweichend von den Bestimmungen des Abs. 1, 2 oder 3 über die tägliche Arbeitszeit aufgeteilt wird. Durch Kollektivvertrag kann ferner zugelassen werden, daß die Wochenarbeitszeit innerhalb eines mehrwöchigen Zeitraumes so verteilt wird, daß sie im wöchentlichen Durchschnitt die nach Abs. 1, 2 oder 3 zulässige Dauer nicht übersteigt. Die tägliche Arbeitszeit darf jedoch keinesfalls zehn Stunden überschreiten."

2. § 12 Abs. 3 hat zu lauten:

„(3) Die Dauer der Mehrarbeitsleistungen nach Abs. 2 darf insgesamt drei Stunden in der Woche nicht überschreiten."

3. § 13 hat zu entfallen.

4. § 14 Abs. 1 hat zu lauten:

„§ 14. (1) Als Mehrarbeit gilt jede Arbeitsleistung, die über die nach § 11 Abs. 1, 2 oder 3 festgelegte Wochenarbeitszeit hinausgeht."

Artikel II

Abänderung des Hausgehilfen- und Hausangestelltengesetzes

Das Hausgehilfen- und Hausangestelltengesetz, BGBl. Nr. 235/1962, in der Fassung der Bundesgesetze BGBl. Nr. 104/1965 und 94/1969, wird abgeändert wie folgt:

§ 5 Abs. 1 hat zu lauten:

„§ 5. (1) Die Arbeitszeit einschließlich der Zeit, während der sich der Dienstnehmer zur Erbringung seiner Dienstleistung bereithalten muß, darf in zwei Kalenderwochen folgendes Ausmaß nicht überschreiten:

1. Für die in die Hausgemeinschaft des Dienstgebers aufgenommenen Dienstnehmer
   a) die das 18. Lebensjahr noch nicht vollendet haben
      ab 5. 1. 1970 ..... 106 Stunden,
      ab 3. 1. 1972 ..... 104 Stunden,
      ab 6. 1. 1975 ..... 100 Stunden;
   b) die das 18. Lebensjahr vollendet haben
      ab 5. 1. 1970 ..... 116 Stunden,
      ab 3. 1. 1972 ..... 114 Stunden,
      ab 6. 1. 1975 ..... 110 Stunden.

2. Für die nicht in die Hausgemeinschaft des Dienstgebers aufgenommenen Dienstnehmer
   a) die das 18. Lebensjahr noch nicht vollendet haben
      ab 5. 1. 1970 ..... 84 Stunden,
      ab 3. 1. 1972 ..... 82 Stunden,
      ab 6. 1. 1975 ..... 80 Stunden;
   b) die das 18. Lebensjahr vollendet haben
      ab 5. 1. 1970 ..... 92 Stunden,
      ab 3. 1. 1972 ..... 90 Stunden,
      ab 6. 1. 1975 ..... 86 Stunden.

Das Entgelt der Dienstnehmer darf aus Anlaß der gemäß den vorstehenden Z. 1 oder 2 eintretenden Arbeitszeitverkürzung nicht verkürzt werden (Lohnausgleich)."

Artikel III

Abänderung des Mutterschutzgesetzes

Das Mutterschutzgesetz, BGBl. Nr. 76/1957, in der Fassung der Bundesgesetze BGBl. Nr. 92/1959, 240/1960, 68/1961, 9/1962, 199/1963 und 281/1968, wird abgeändert wie folgt:

§ 8 hat zu lauten:

„§ 8. (1) Werdende und stillende Mütter dürfen über die auf Grund gesetzlicher Vorschriften oder kollektivvertraglicher Regelungen festgesetzte tägliche Arbeitszeit hinaus nicht beschäftigt werden; keinesfalls darf die wöchentliche Arbeitszeit dreiundvierzig Stunden übersteigen.

(2) An Stelle der in Abs. 1 festgelegten Wochenarbeitszeit von dreiundvierzig Stunden tritt ab 3. Jänner 1972 eine solche von zweiundvierzig Stunden und ab 6. Jänner 1975 eine solche von vierzig Stunden.

(3) Eine von Abs. 1 und 2 abweichende Wochenarbeitszeit kann durch Kollektivvertrag zugelassen werden, sofern dieser eine vor dem Inkrafttreten dieses Bundesgesetzes zulässige Wochenarbeitszeit auf Grund eines Arbeitszeitverkürzungsplanes so verkürzt, daß die Wochenarbeitszeit spätestens ab 6. Jänner 1975 vierzig Stunden nicht überschreitet. Die nach einem solchen Arbeitszeitverkürzungsplan festgelegte Wochenarbeitszeit gilt als Wochenarbeitszeit im Sinne dieses Bundesgesetzes."

Artikel IV

Abänderung des Schauspielergesetzes

Das Schauspielergesetz, BGBl. Nr. 441/1922, in der Fassung des Bundesgesetzes BGBl. Nr. 108/1958, wird abgeändert wie folgt:

§ 20 Abs. 3 hat zu lauten:

„(3) In der Zeit vom Beginne der Abendvorstellung bis zum Beginne der Abendvorstellung am nächsten Tage (Arbeitstag) darf das Mitglied nicht länger als acht Stunden beschäftigt werden. Im übrigen gelten die Bestimmungen des Arbeitszeitgesetzes, BGBl. Nr. 461/1969."

Artikel V

Inkrafttreten und Vollziehung

(1) Dieses Bundesgesetz tritt am 5. Jänner 1970 in Kraft.

(2) Mit der Vollziehung dieses Bundesgesetzes sind betraut:

a) hinsichtlich der Dienstnehmer, auf deren Dienstverhältnis das Bundesgesetz über die Beschäftigung von Kindern und Jugendlichen oder das Hausgehilfen- und Hausangestelltengesetz oder das Schauspielergesetz Anwendung finden, die Bundesminister für soziale Verwaltung, für Handel, Gewerbe und Industrie und für Justiz nach Maßgabe des § 34 Abs. 2 des Bundesgesetzes über die Beschäftigung von Kindern und Jugendlichen, des § 27 Abs. 2 des Hausgehilfen- und Hausangestelltengesetzes und des § 53 Abs. 3 des Schauspielergesetzes;

b) hinsichtlich der Dienstnehmerinnen und Heimarbeiterinnen, auf deren Beschäftigung das Mutterschutzgesetz Anwendung findet, der Bundesminister für soziale Verwaltung.

Jonas

Klaus Rehor Klecatsky Mitterer

463. Bundesgesetz vom 11. Dezember 1969, mit dem das Landarbeitsgesetz neuerlich abgeändert wird (Landarbeitsgesetz-Novelle 1969)

Der Nationalrat hat beschlossen:

Artikel I

Die im Landarbeitsgesetz, BGBl. Nr. 140/1948, in der Fassung der Bundesgesetze BGBl. Nr. 279/1957, 241/1960, 97/1961, 10/1962, 194/1964, 238/1965, 265/1967 und 283/1968, für die Regelung des Arbeitsrechtes in der Land- und Forstwirtschaft gemäß Artikel 12 Abs. 1 Z. 4 des Bundes-Verfassungsgesetzes in der Fassung von 1929 aufgestellten Grundsätze werden wie folgt geändert:

1. § 23 Abs. 2 lit. e hat zu lauten:

„e) Vorladung vor Gerichte, sonstige Behörden und öffentliche Ämter, sofern der Dienstnehmer keinen Anspruch auf Ersatz des Verdienstentganges hat;".

2. § 39 wird aufgehoben. Die Überschrift zu § 39 hat zu entfallen.

3. Die §§ 56 bis 59 haben zu lauten:

„§ 56. (1) Die regelmäßige Wochenarbeitszeit darf, soweit im folgenden nicht anderes bestimmt wird,

ab 5. 1. 1970 ..... 43 Stunden,
ab 3. 1. 1972 ..... 42 Stunden,
ab 6. 1. 1975 ..... 40 Stunden

nicht überschreiten.

(2) Für die mit dem Dienstgeber in Hausgemeinschaft lebenden Dienstnehmer mit freier Station darf die regelmäßige Wochenarbeitszeit

ab 5. 1. 1970 ..... 47 Stunden,
ab 3. 1. 1972 ..... 45 Stunden,
ab 6. 1. 1975 ..... 44 Stunden,
ab 5. 1. 1976 ..... 43 Stunden

nicht überschreiten.

(3) Wenn in die Arbeitszeit regelmäßig und in erheblichem Umfang Arbeitsbereitschaft fällt, kann die regelmäßige Wochenarbeitszeit durch Kollektivvertrag auf höchstens sechzig Stunden verlängert werden.

§ 57. (1) Während der Arbeitsspitzen darf die regelmäßige Wochenarbeitszeit in der Landwirtschaft um sechs Stunden verlängert werden; sie ist in der arbeitsschwachen Zeit so zu verkürzen, daß die im § 56 festgelegte regelmäßige Wochenarbeitszeit im Jahresdurchschnitt nicht überschritten wird.

(2) Die Verteilung der regelmäßigen Wochenarbeitszeit auf die Zeiten der Arbeitsspitzen kann

durch Kollektivvertrag bestimmt werden. Die Ausführungsgesetze haben über diese Verteilung Bestimmungen vorzusehen für den Fall, daß eine kollektivvertragliche Regelung fehlt oder für bestimmte Dienstverhältnisse nicht Geltung hat.

§ 58. (1) Die Auf Grund ihres Dienstverhältnisses neben ihrer übrigen Tätigkeit auch mit Viehpflege, Melkung oder mit regelmäßigen Verrichtungen im Haushalt beschäftigten Dienstnehmer haben diese Arbeiten auch über die Wochenarbeitszeit (§§ 56 und 57) hinaus bis zu einem Ausmaß von sechs Stunden wöchentlich zu verrichten. Hiefür gebührt ihnen ein Freizeitausgleich im Verhältnis 1 : 1 innerhalb eines Monates. Über dieses Ausmaß hinaus geleistete Arbeiten unterliegen den Bestimmungen des § 59.

(2) Wenn ein Freizeitausgleich nicht gewährt wird, ist für die Mehrarbeiten im Sinne des Abs. 1 eine besondere Vergütung zu leisten, deren Ausmaß durch Kollektivvertrag bestimmt werden kann.

§ 59. (1) An einem Wochentag dürfen von einem Dienstnehmer höchstens zwei, an einem sonst arbeitsfreien Samstag höchstens acht, in einer Arbeitswoche jedoch nicht mehr als zwölf Überstunden verlangt werden.

(2) Die Leistung von Überstunden über die normale Arbeitszeit darf nicht verweigert werden, wenn außergewöhnliche Umstände wie drohende Wetterschläge und sonstige Elementarereignisse, ferner Gefahren für das Vieh oder drohendes Verderben der Produkte sowie Gefährdung des Waldbestandes eine Verlängerung der Arbeitszeit dringend notwendig machen.

(3) Die üblichen Früh- und Abendarbeiten, die zu den vertragsmäßigen Verrichtungen eines Dienstnehmers gehören, gelten nicht als Überstunden."

4. § 61 hat zu lauten:

„**§ 61.** Dem Dienstnehmer sind während der Arbeitszeit für die Einnahme der Mahlzeiten angemessene Arbeitspausen im Gesamtausmaß von mindestens einer Stunde täglich zu gewähren. Die Arbeitspausen werden in die Arbeitszeit nicht eingerechnet."

5. § 62 Abs. 3 hat zu lauten:

„**§ 62.** (3) Viehpflege, Melkung und unaufschiebbare Arbeiten im Haushalt sind von den hiezu bestimmten Dienstnehmern auch an Sonn- und Feiertagen nach Maßgabe der nachstehenden Bestimmungen zu leisten, wobei jedoch ein Sonn- oder gesetzlicher Feiertag im Monat arbeitsfrei zu sein hat:

a) Den im § 58 Abs. 1 genannten Dienstnehmern gebührt für Arbeiten an einem Sonn- oder gesetzlichen Feiertag bis zu zwei Stunden ein Freizeitausgleich im Verhältnis 1 : 1·5 innerhalb eines Monates. Wenn dieser Freizeitausgleich nicht gewährt wird, ist für diese Mehrarbeiten eine besondere Vergütung zu leisten, deren Ausmaß durch Kollektivvertrag bestimmt werden kann.

b) Den ausschließlich mit der Viehpflege, Melkung und regelmäßigen Verrichtungen im Haushalt beschäftigten Dienstnehmern gebührt für jeden Sonn- und gesetzlichen Feiertag, an dem sie diese Arbeiten verrichtet haben, ein freier Werktag."

6. § 65 Abs. 1 hat zu lauten:

„**§ 65.** (1) Dem Dienstnehmer gebührt in jedem Dienstjahr ein ununterbrochener Urlaub von 18 Werktagen. Das Urlaubsausmaß erhöht sich auf 24 Werktage, wenn das Dienstverhältnis ohne Unterbrechung 15 Jahre, und auf 30 Werktage, wenn das Dienstverhältnis ohne Unterbrechung 25 Jahre gedauert hat."

7. § 68 Abs. 3 hat zu lauten:

„**§ 68.** (3) Die Abfindung der Anwartschaft auf Urlaub (Abs. 1) beträgt für jede Woche seit Beginn des Dienstverhältnisses $^1/_{52}$ des auf drei Wochen, für Jugendliche bis zum Ende des Kalenderjahres, in dem sie das 18. Lebensjahr vollenden, $^1/_{52}$ des auf vier Wochen entfallenden Engeltes (§ 8 Abs. 2)."

8. § 74 hat zu lauten:

„**§ 74.** (1) Weibliche Dienstnehmer, die einen eigenen Haushalt führen, sind ohne Schmälerung des Entgeltes von der Pflicht zur Leistung von Arbeiten an Sonn- und Feiertagen sowie an den Vortagen vor Weihnachten, Ostern und Pfingsten befreit. Allein die bei der Viehpflege und Melkung notwendigen Arbeiten müssen von ihnen auch an diesen Tagen verrichtet werden.

(2) Die im Abs. 1 genannten Dienstnehmer erhalten in jedem Monat, in dem sie voll beschäftigt sind

bis zum 31. 12. 1971 ..... einen Tag,
bis zum 31. 12. 1974 ..... einen halben Tag

arbeitsfrei ohne Schmälerung des Entgeltes.

(3) Für die im Abs. 1 genannten Dienstnehmer wird die tägliche Arbeitspause

bis zum 31. 12. 1971 um 45 Minuten,
bis zum 31. 12. 1974 um 30 Minuten

ohne Schmälerung des Entgeltes verlängert."

9. § 76 Abs. 3 hat zu lauten:

„**§ 76.** (3) Die regelmäßige Wochenarbeitszeit der Jugendlichen bis zum vollendeten 18. Lebens-

jahr darf die im § 56 Abs. 1 festgelegte Stundenzahl nicht überschreiten. § 57 gilt sinngemäß."

Artikel II

Aus Anlaß der Arbeitszeitverkürzung (Art. I) darf das Entgelt der betroffenen Dienstnehmer nicht verkürzt werden (Entgeltausgleich). Ein nach Stunden bemessenes Entgelt ist in dem gleichen Verhältnis zu erhöhen, in dem die Arbeitszeit verkürzt wird. Akkord-, Stück- und Gedinglöhne sowie auf Grund anderer Leistungsentgeltarten festgelegte Entgelte sind entsprechend zu berichtigen. Durch Kollektivvertrag kann eine andere Regelung des Entgeltausgleiches vereinbart werden.

Artikel III

Die Ausführungsgesetze der Bundesländer zu den Grundsätzen der Art. I und II sind binnen drei Monaten, vom Tage der Kundmachung dieses Bundesgesetzes an gerechnet, zu erlassen.

Artikel IV

Mit der Wahrnehmung der dem Bunde gemäß Art. 15 Abs. 8 des Bundes-Verfassungsgesetzes in der Fassung von 1929 zustehenden Rechte ist der Bundesminister für Land- und Forstwirtschaft betraut.

Jonas

Klaus Schleinzer

464. Bundesgesetz vom 11. Dezember 1969, mit dem das Vertragsbedienstetengesetz 1948 neuerlich abgeändert wird (16. Vertragsbedienstetengesetz-Novelle)

Der Nationalrat hat beschlossen:

Artikel I

Das Vertragsbedienstetengesetz 1948, BGBl. Nr. 86, in der Fassung der Bundesgesetze BGBl. Nr. 174/1959, 282/1960, 165/1961, 186/1962, 117/1963, 173/1963, 313/1963, 154/1964, 126/1965, 191/1965, 110/1966, 18/1967, 237/1967, 260/1968 und 199/1969, wird geändert wie folgt:

1. § 14 Abs. 4 lautet:

„(4) Für eine Wochentagsarbeitsstunde gebührt der 186ste Teil des Monatsentgeltes."

2. § 20 Abs. 1 lautet:

„(1) Dem Monatsentgelt des vollbeschäftigten Vertragsbediensteten des Entlohnungsschemas II liegt eine 43stündige Wochendienstleistung zugrunde."

3. § 20 Abs. 4 lautet:

„(4) Über die tägliche Arbeitszeit hinaus auf Anordnung geleistete Überstunden sind, soweit dadurch eine 43stündige Wochendienstleistung überschritten wird, von der 44. Stunde an bei Wochentagsarbeit mit dem Eineinviertelfachen, bei Feiertagsarbeit von der neunten Stunde an mit dem Zweifachen und bei Sonntagsarbeit von der neunten Stunde an mit dem Dreifachen des auf eine Wochentagsarbeitsstunde entfallenden Teiles des Monatsentgeltes zu entlohnen; die Zeit des Arbeitsausfalles an gesetzlichen Feiertagen, Urlaubstagen oder sonstigen Tagen einer gerechtfertigten Abwesenheit vom Dienst ist in die 43stündige Wochendienstleistung einzurechnen. Die Bundesregierung kann zur Anpassung an die außerhalb des öffentlichen Dienstes bestehenden Regelungen über die Entschädigung für Überstunden durch Verordnung bestimmen, daß die Entlohnung für Wochentagsüberstunden, durch die eine 47stündige Wochendienstleistung überschritten wird, auf das Eineinhalbfache, sowie für Überstunden, die in die Nachtzeit (22 Uhr bis 6 Uhr) fallen, auf das Zweifache des auf eine Wochentagsarbeitsstunde entfallenden Teiles des Monatsentgeltes erhöht wird. Wochentagsüberstunden können innerhalb eines Monates durch Freizeit ausgeglichen werden."

Artikel II

(1) Hat ein Vertragsbediensteter aus dem Anlaß der Anrechnung von Vordienstzeiten für die Vorrückung dem Bund eine Abfertigung erstattet, die er seinerzeit aus öffentlichen Mitteln erhalten hat, so ist ihm der Erstattungsbetrag auf Antrag zurückzugeben.

(2) In den Fällen, in denen Zeiträume, die der seinerzeitigen Abfertigung zugrunde gelegt wurden, nach dem 27. April 1945 zur Berechnung einer nicht erstatteten Abfertigung herangezogen wurden, ist nur der Unterschiedsbetrag zwischen dem Betrag zurückzugeben, den der Vertragsbedienstete auf Grund der Auflösung des seinerzeitigen Dienstverhältnisses als Abfertigung erhalten hat, und dem Betrag, den der Vertragsbedienstete aus Anlaß der Anrechnung von Vordienstzeiten dem Bunde tatsächlich erstattet hat.

(3) Dem Vertragsbediensteten sind ferner auf Antrag jene Abfertigungsbeträge auszuzahlen, auf die er nach dem 27. April 1945 anläßlich der Beendigung eines Bundesdienstverhältnisses verzichtet hat, wenn er binnen drei Monaten nach Beendigung dieses Dienstverhältnisses ein anderes Bundesdienstverhältnis eingegangen ist und die erstgenannte Bundesdienstzeit nicht der Bemessung einer später ausgezahlten Abfertigung zugrunde gelegt wurde.

Artikel III

(1) Die Bestimmungen des Art. I treten mit 5. Jänner 1970 in Kraft.

(2) Mit der Vollziehung dieses Bundesgesetzes ist, soweit darin nichts anderes bestimmt wird, die Bundesregierung, in Angelegenheiten jedoch, die nur den Wirkungsbereich eines Bundesministers betreffen, dieser Bundesminister betraut.

Jonas

Klaus Withalm Soronics Klecatsky
Mock Rehor Koren Schleinzer
Mitterer Weiß Prader Waldheim Kotzina

465. Bundesgesetz vom 11. Dezember 1969, mit dem das Dorotheums-Bedienstetengesetz neuerlich abgeändert wird

Der Nationalrat hat beschlossen:

Artikel I

Das Dorotheums-Bedienstetengesetz, BGBl. Nr. 194/1968, in der Fassung der Bundesgesetze BGBl. Nr. 29/1969 und 228/1969, wird abgeändert wie folgt:

Im § 2 Abs. 3 hat der zweite Satz zu lauten:

„Für eine Wochentagsarbeitsstunde gebührt ab 5. Jänner 1970 der 186ste Teil des Monatsbezuges."

Artikel II

Mit der Vollziehung dieses Bundesgesetzes ist der Bundesminister für Inneres betraut.

Jonas

Klaus Soronics

466. Bundesgesetz vom 11. Dezember 1969, mit dem die Bundesforste-Dienstordnung abgeändert wird

Der Nationalrat hat beschlossen:

Artikel I

§ 12 Abs. 2 erster Satz der Bundesforste-Dienstordnung, BGBl. Nr. 201/1969, lautet:

„Soweit dies nicht der Fall ist, insbesondere für den ausschließlichen Bürodienst, sind die Dienststunden von der Generaldirektion unter Zugrundelegung einer wöchentlich 43stündigen Arbeitszeit zu bestimmen."

Artikel II

(1) Dieses Bundesgesetz tritt am 5. Jänner 1970 in Kraft.

(2) Mit der Vollziehung dieses Bundesgesetzes ist, soweit darin nichts anderes bestimmt ist, der Bundesminister für Land- und Forstwirtschaft betraut.

Jonas

Klaus Schleinzer

467. Verordnung des Bundesministers für Unterricht vom 30. November 1969 über die Zuweisung der Dienstbeurteilung für bestimmte Beamte der Personalstände „Bibliotheksdienst" und „Bibliotheken" gemäß § 15 Abs. 5 der Dienstpragmatik

Auf Grund des § 15 Abs. 5 der Dienstpragmatik, RGBl. Nr. 15/1914, in der Fassung der Dienstpragmatik-Novelle 1969, BGBl. Nr. 148, wird verordnet:

§ 1. Die Dienstbeurteilung der dem Personalstand des Bibliotheksdienstes angehörenden, außerhalb des Dienstbereiches der Österreichischen Nationalbibliothek verwendeten Beamten, ausgenommen die im § 2 genannten Beamten, wird der Dienstbeurteilungskommission bei der Österreichischen Nationalbibliothek zugewiesen, sofern nicht gemäß § 15 Abs. 7 und 8 der Dienstpragmatik die Zuständigkeit der Dienstbeurteilungskommission beim Bundesministerium für Unterricht gegeben ist.

§ 2. Die Dienstbeurteilung sämtlicher dem Personalstand des Bibliotheksdienstes angehörenden Beamten, die am Ende des Jahres, für das die Dienstbeurteilung gilt, den Zentralleitungen der Zentralstellen dienstzugeteilt waren, wird der Dienstbeurteilungskommission beim Bundesministerium für Unterricht zugewiesen.

§ 3. Die Dienstbeurteilung der dem Personalstand der Bibliotheken angehörenden Beamten der Universitätsbibliotheken in Wien, Graz, Innsbruck und Salzburg, der Bundesstaatlichen Studienbibliotheken in Klagenfurt und Linz, der Bibliotheken der Technischen Hochschulen in Graz und Wien, der Bibliothek der Montanistischen Hochschule in Leoben, der Bibliothek der Hochschule für Bodenkultur in Wien, der Bibliothek der Tierärztlichen Hochschule in Wien, der Bibliothek der Hochschule für Welthandel in Wien, der Bibliothek der Hochschule für Sozial- und Wirtschaftswissenschaften in Linz und der Österreichischen Phonothek wird der Dienstbeurteilungskommission bei der Österreichischen Nationalbibliothek zugewiesen, sofern nicht gemäß § 15 Abs. 7 und 8 der Dienstpragmatik die Zuständigkeit der Dienstbeurteilungskommission beim Bundesministerium für Unterricht gegeben ist.

Mock

468. Verordnung des Bundesministers für Finanzen vom 12. Dezember 1969 betreffend die Erhöhung der Wertgrenze für die Entrichtung von Hundertsatzgebühren in Stempelmarken

Auf Grund des § 3 Abs. 3 des Gebührengesetzes 1957, BGBl. Nr. 267/1957, wird verordnet:

§ 1. Der im § 3 Abs. 3 des Gebührengesetzes 1957 festgelegte Höchstbetrag für die Entrichtung der Hundertsatzgebühren in Stempelmarken wird auf 300 S erhöht.

§ 2. Diese Verordnung ist auf alle Vorgänge anzuwenden, für welche die Gebührenschuld nach dem 31. Dezember 1969 entsteht.

Koren

469. Verordnung der Bundesregierung vom 16. Dezember 1969, mit der die Sprengel der Bezirksgerichte Stockerau und Hollabrunn geändert werden

Auf Grund des § 8 Abs. 5 lit. d des Übergangsgesetzes vom 1. Oktober 1920 in der Fassung des BGBl. Nr. 368 vom Jahre 1925 wird mit Zustimmung der Niederösterreichischen Landesregierung verordnet:

§ 1. (1) Die Gemeinden Niederrußbach und Oberrußbach scheiden aus dem Sprengel des Bezirksgerichtes Stockerau aus. Die Gemeinde Stranzendorf scheidet aus dem Sprengel des Bezirksgerichtes Hollabrunn aus.

(2) Die mit den übereinstimmenden Gemeinderatsbeschlüssen der im Absatz 1 genannten Gemeinden mit Genehmigung der Niederösterreichischen Landesregierung und mit Zustimmung der Bundesregierung neu errichtete Gemeinde Rußbach im politischen Bezirk Korneuburg wird dem Sprengel des Bezirksgerichtes Stockerau zugewiesen.

§ 2. Diese Verordnung tritt mit 1. Jänner 1970 in Kraft.

Klaus	**Withalm**	**Soronics**	**Klecatsky**
Mock	**Rehor**	**Koren**	**Schleinzer**
Mitterer	**Prader**	**Waldheim**	**Kotzina**

470. Verordnung der Bundesregierung vom 16. Dezember 1969, mit der die Sprengel der Bezirksgerichte Mistelbach, Laa an der Thaya, Stockerau und Korneuburg geändert werden

Auf Grund des § 8 Abs. 5 lit. d des Übergangsgesetzes vom 1. Oktober 1920 in der Fassung des BGBl. Nr. 368 vom Jahre 1925 wird mit Zustimmung der Niederösterreichischen Landesregierung verordnet:

§ 1. (1) Die Gemeinde Ernstbrunn scheidet aus dem Sprengel des Bezirksgerichtes Mistelbach aus. Die Gemeinde Klement scheidet aus dem Sprengel des Bezirksgerichtes Laa an der Thaya aus. Die Gemeinde Merkersdorf scheidet aus dem Sprengel des Bezirksgerichtes Stockerau aus. Die Gemeinden Naglern, Simonsfeld und Lachsfeld scheiden aus dem Sprengel des Bezirksgerichtes Korneuburg aus.

(2) Die mit den übereinstimmenden Gemeinderatsbeschlüssen der im Absatz 1 genannten Gemeinden mit Genehmigung der Niederösterreichischen Landesregierung und mit Zustimmung der Bundesregierung neu errichtete Marktgemeinde Ernstbrunn im politischen Bezirk Korneuburg wird dem Sprengel des Bezirksgerichtes Korneuburg zugewiesen.

§ 2. Diese Verordnung tritt mit 1. Jänner 1970 in Kraft.

Klaus	**Withalm**	**Soronics**	**Klecatsky**
Mock	**Rehor**	**Koren**	**Schleinzer**
Mitterer	**Prader**	**Waldheim**	**Kotzina**

471. Verordnung der Bundesregierung vom 16. Dezember 1969, mit der die Sprengel der Bezirksgerichte Horn und Eggenburg geändert werden

Auf Grund des § 8 Abs. 5 lit. d des Übergangsgesetzes vom 1. Oktober 1920 in der Fassung des BGBl. Nr. 368 vom Jahre 1925 wird mit Zustimmung der Niederösterreichischen Landesregierung verordnet:

§ 1. (1) Die Gemeinden Weitersfeld und Oberhöflein scheiden aus dem Sprengel des Bezirksgerichtes Horn aus. Die Gemeinden Obermixnitz und Untermixnitz scheiden aus dem Sprengel des Bezirksgerichtes Eggenburg aus.

(2) Die mit den übereinstimmenden Gemeinderatsbeschlüssen der im Absatz 1 genannten Gemeinden mit Genehmigung der Niederösterreichischen Landesregierung und mit Zustimmung der Bundesregierung neu errichtete Marktgemeinde Weitersfeld im politischen Bezirk Horn wird dem Sprengel des Bezirksgerichtes Horn zugewiesen.

§ 2. Diese Verordnung tritt mit 1. Jänner 1970 in Kraft.

Klaus	**Withalm**	**Soronics**	**Klecatsky**
Mock	**Rehor**	**Koren**	**Schleinzer**
Mitterer	**Prader**	**Waldheim**	**Kotzina**

472. Verordnung des Bundesministers für Justiz vom 17. Dezember 1969 über die Zuweisung der Dienstbeurteilung für Beamte der Generalprokuratur, der Justizanstalten, der Arbeitsbetriebe — Betriebsähnliche Verwaltungszweige und der Bewährungshilfe gemäß § 15 Abs. 5 der Dienstpragmatik

Auf Grund des § 15 Abs. 5 der Dienstpragmatik, RGBl. Nr. 15/1914, in der Fassung der Dienstpragmatik-Novelle 1969, BGBl. Nr. 148, wird verordnet:

§ 1. Die Dienstbeurteilung der dem Personalstand der Generalprokuratur angehörenden Beamten und jener Beamten und Richter, die am Ende des Jahres, für das die Dienstbeurteilung gilt, der Generalprokuratur dienstzugeteilt waren, wird der Dienstbeurteilungskommission beim Bundesministerium für Justiz zugewiesen, sofern nicht schon gemäß § 15 Abs. 7 und 8 der Dienstpragmatik die Zuständigkeit dieser Dienstbeurteilungskommission gegeben ist.

§ 2. Die Dienstbeurteilung der dem Personalstand der Justizanstalten, der Arbeitsbetriebe — Betriebsähnliche Verwaltungszweige und der Bewährungshilfe angehörenden Beamten, und zwar

a) der Beamten der allgemeinen Verwaltung der Verwendungsgruppen A und B, der Justizwachebeamten und der Jugenderzieher der Verwendungsgruppen W 1 und W 2, Dienststufe 2 und 3,
b) sämtlicher Beamten der Justizwachschule, der Wiener Jugendgerichtshilfe, der Bundesanstalt für Erziehungsbedürftige Wiener Neudorf und der gemäß § 26 des Bewährungshilfegesetzes, BGBl. Nr. 146/1969, Geschäftsstellen der Bewährungshilfen zugeteilten Beamten und
c) sämtlicher Beamten, die am Ende des Jahres, für das die Dienstbeurteilung gilt, dem Bundesministerium für Justiz dienstzugeteilt waren,

wird der Dienstbeurteilungskommission beim Bundesministerium für Justiz (Justizanstalten) zugewiesen, sofern nicht schon gemäß § 15 Abs. 7 und 8 der Dienstpragmatik die Zuständigkeit dieser Dienstbeurteilungskommission gegeben ist.

Klecatsky

473. Verordnung des Bundesministers für Justiz vom 17. Dezember 1969 über die Zuweisung von Disziplinarsachen bestimmter Beamter an andere Disziplinarkommissionen gemäß § 100 Abs. 2 der Dienstpragmatik

Auf Grund des § 100 Abs. 2 der Dienstpragmatik, RGBl. Nr. 15/1914, wird verordnet:

Die Disziplinarsachen der dem Personalstand der Justizanstalten, der Arbeitsbetriebe — Betriebsähnliche Verwaltungszweige und der Bewährungshilfe angehörenden Beamten werden der Disziplinarkommission des Oberlandesgerichtes zugewiesen, in dessen Sprengel sie verwendet werden, sofern nicht gemäß § 102 Abs. 1 lit. b der Dienstpragmatik in der Fassung der Dienstpragmatik-Novelle 1969, BGBl. Nr. 148, die Zuständigkeit der Disziplinaroberkommission beim Bundesministerium für Justiz gegeben ist.

Klecatsky

474. Verordnung des Bundesministers für soziale Verwaltung vom 17. Dezember 1969, mit der die Österreichische Arzneitaxe 1962 neuerlich geändert wird (31. Änderung der Arzneitaxe)

Auf Grund des § 7 des Gesetzes vom 18. Dezember 1906, RGBl. Nr. 5/1907, betreffend die Regelung des Apothekenwesens wird verordnet:

Artikel I

Die Österreichische Arzneitaxe 1962, BGBl. Nr. 128, in der Fassung der Verordnung BGBl. Nr. 281/1969, wird geändert wie folgt:

In der Anlage B werden die Preisansätze der nachstehend angeführten Arzneimittel und Gefäße wie folgt festgesetzt:

I. Arzneimittel:

	Gramm	Groschen
Acetonum	10	30
• Acidum citricum	10	70
Acidum oxalicum (Ergb. 6)	10	170
• Acidum salicylicum	10	140
Acidum sulfosalicylicum (Ergb. 6)	1	70
• Aether	10	140
Aetheroleum Chenopodii	1	260
• Aetheroleum Juniperi ligni pro usu externo (Erg. 6)	10	160
Aetheroleum Myristicae	1	230
Aetheroleum Rosmarini	1	60
Aetheroleum Salviae (Ergb. 6)	1	100
• Aetheroleum Spicae (Ergb. 6)	1	100
• Aetheroleum Terebinthinae rectificatum	10	90
Aetheroleum Thymi	1	50
• Agar (pulv.)	10	790
Aluminium sulfuricum	10	80
Ammonium bromatum	10	150
Ammonium sulfuricum *)	10	110

	Gramm	Groschen
Balsamum peruvianum	1	50
• Benzinum	100	260
• Benzolum	10	40
Bismutylum nitricum	1	120
• Calcaria usta (DAB 6)	100	680
Camphora	10	250
Carboxymethylcellulosi Natrium	10	220
Cera Lanae	10	120
• Cera Lanae cum Aqua	10	150
• Ceratum Cetacei (Ergb. 6)	10	210
Chinidinum sulfuricum	1	960
Chininum bisulfuricum	1	500
Cholesterolum	1	140
• Collodium	10	110
• Collodium elasticum	10	110
Cortex Cascarillae (Ergb. 6)	10	320
• Cortex Frangulae (pulv.)	10	90
Cortex Quillajae	10	130
Creolinum *)	10	70
Cuprum aceticum (Ergb. 6)	1	40
Dextrinum	10	120
• Emulsio ammoniata	100	1520
Emulsio Calcis	100	1760
Eugenolum (Ergb. 6)	1	150
Extr. Aloes (DAB. 6)	1	60
Extr. Chamomillae fluidum	10	2160
Extr. Chinae fluidum	10	1360
• Extr. Liquiritiae fluidum	10	310
Extr. Rhei	1	100
Extr. Secalis cornuti fluidum (DAB. 6)	10	1350
Extr. Valerianae fluidum (Ergb. 6)	10	480
• Faex medicinalis siccata zur Pillenbereitung	10	80
Ferrum-III-chloratum	10	50
• Ferrum oxydatum saccharatum	10	90
Ferrum sulfuricum	10	80
• Flos Aurantii matura *)	10	160
• Flos Cyani (Ergb. 6)	10	720
• Flos Lamii albi (Ergb. 6)	10	410
• Flos Stoechados (Ergb. 6)	10	110
Folium Bucco (Ergb. 6)	10	870
Folium Digitalis purpureae titratum	1	170
• Folium Malvae	10	80
• Folium Melissae	10	200
• Folium Theae nigrae *)	10	150
• Folium Thymi	10	150
• Folium Uvae-ursi Herba Herniariae āā *)	10	90
Fructosum	10	320
• Fructus Cassiae Fistulae (Ph. A. VIII)	10	70
• Fructus Cynosbati sine seminibus (Ergb. 6)	10	80
Fructus Piperis nigri	10	130
Fungus Laricis (pulv.) (Ergb. 6)	10	300
• Gelatina alba	10	220
Glucosum ad injectionem	10	190
Guarana (pulv.) (Ergb. 6)	1	30
Herba Abrotani *)	10	110
• Herba Asperulae (odoratae) (Ergb. 6)	10	90
• Herba Capilli Veneris (Ergb. 6)	10	100
• Herba Cardui benedicti	10	30
• Herba Grindeliae (Ergb. 6)	10	170
• Herba Herniariae	10	120
• Herba Hyperici (Ergb. 6)	10	40
• Herba Verbenae (Ergb. 6)	10	40
∴ Hydrargyrum chloratum amidatum	1	290
Jodoformium	1	110
Kalium chloratum	10	60
Kalium citricum (Ergb. 6)	1	10
∴ Kalium cyanatum (Ergb. 6)	1	50
Kalium guajacolsulfonicum	10	390
• Kalium permanganicum	10	100
• Lignum Juniperi (Ergb. 6)	10	60
Linimentum contra Scabiem (DAB. 6)	10	300
• Lycopodium	10	1240
• Magnesium carbonicum praecipitatum	10	70
Magnesium chloratum (Ergb. 6)	10	50
• Magnesium oxydatum	10	120
Magnesium stearicum	10	120
Maltose (Ergb. 6)	1	110
• Mel depuratum (DAB. 6)	10	130
Methylenditannin *)	1	120
• Mixtura pro potu acido (Ph. A. VIII El.)	100	590
Natrium nitrosum	10	130
Oleum ad injectionem (Amygdalae)	10	280
• Oleum Amygdalae	10	180
• Oleum Arachidis	10	60
Oleum Arachidis hydrogenatum	10	80
Oleum camphoratum (DAB. 6)	10	140
Oleum Cedri ligni *)	10	570
• Oleum Chloroformii (DAB. 6)	10	70
Oleum Hyoscyami (DAB. 6)	10	250
• Oleum Jecoris Aselli	10	50
	100	410
• Oleum Juglandis coctum *)	10	220
• Oleum Lauri	10	230
• Oleum Lini	10	70
Oleum Lini sulfuratum (Ergb. 6)	10	210

	Gramm	Groschen
• Oleum phenolatum (2%) (Ergb. 6)	10	90
• Oleum Rapae (DAB. 6)	10	70
• Oleum Sesami	10	110
• Paraffinum liquidum	10	40
	100	330
Pix betulina (DAB. 6)	10	60
Pix Fagi	10	50
Pix Juniperi (DAB. 6)	10	160
Plumbum carbonicum	10	150
Podophyllinum	1	1140
Polyaethylenglycola	10	150
Propylenglycolum	10	60
• Radix Bardanae (Ergb. 6)	10	60
• Radix Petroselini (Ergb. 6)	10	170
• Radix Pimpinellae (DAB. 6)	10	220
Radix Ratanhiae	10	110
• Radix Taraxaci *)	10	120
Radix Veratri (DAB. 6)	10	130
• Radix Zingiberis	10	170
• Sapo kalinus	10	50
∴ Scopolaminum hydrochloricum (Ergb. 6)	0,01	140
• Sebum ovile (DAB. 6)	10	60
• Sebum salicylatum (DAB. 6)	10	120
Semen Myristicae (Ergb. 6)	1	30
• Semen Quercus tostum (pulv.) (Ergb. 6)	10	110
• Sirupus Rubi Idaei	10	60
Solutio Acidi formicici spirituosa	10	100
• Solutio Aluminii acetico-tartarici	100	500
• Solutio Calcii hydroxydati	100	130
• Solutio Calcii sulfurati	100	250
• Solutio Dakajodini *)	100	200
• Solutio Ferri aromatica	100	710
• Solutio Ferri-III-chlorati	10	40
• Solutio Formaldehydi	10	20
• Solutio Formaldehydi saponata	100	690
• Solutio Masticis composita	10	400
Solutio Picis Lithanthracis	10	270
Solutio Saponis kalini spirituosa	100	1030
• Species urologicae	10	80
Spiritus Cornu Cervi rectificatus *)	100	460
• Spiritus e Vino	10	240
• Spuma maris (pulv.) *)	10	370
Sulfadimidini Natrium	1	60
Syngulin (R) fluidum	1	—
Terebinthina (DAB. 6)	10	90
Terebinthina laricina (Ergb. 6)	10	240
Tinct. Belladonnae	10	220
Tinct. Convallariae	10	620
Tinct. Digitalis lanatae	10	470
Tinct. Digitalis purpureae	10	490
Tinct. Ferri chlorati aetherea (DAB. 6)	10	70
Tinct. Ipecacuanhae	10	830
Tinct. Lobeliae	10	290
Tinct. odontalgica (Ph. A. VIII El.)	10	330
Tinct. Opii	10	1080
Tinct. Opii benzoica (DAB. 6)	10	120
Tinct. Primulae	10	210
Tinct. Strophanthi (DAB. 6)	10	1980
Tinct. Strychni	10	280
Toluolum (Ergb. 6)	10	40
Turiones Pini (Ergb. 6)	10	110
• Ung. camphoratum (Ergb. 6)	10	180
Ung. Lauri compositum (Ergb. 6)	10	190
• Ung. leniens (DAB. 6)	10	190
Ung. Terebinthinae (Ergb. 6)	10	180
• Vaselinum album	10	30
Vinum Chinae	100	1400
Vinum Chinae ferratum	100	1150
Vinum Condurango	100	840
Vinum dulce (album)	100	580
Vinum meridianum dulce	100	780
Xylolum (Ergb. 6)	10	90
Zincum oxydatum	10	70
• Zincum oxydatum cum Talco (1+1) *)	100	490

II. Gefäße:

	Groschen
I. h) Pappschachteln ohne Falz bis 20 g Inhalt, das Stück	390
von mehr als	
20 g bis 50 g Inhalt, das Stück	410
50 g bis 100 g Inhalt, das Stück	470
100 g bis 200 g Inhalt, das Stück	560
solche von mehr als 200 g für je 100 g des Inhaltes, das Stück mehr	210
j) Pulverkästchen zur Aufnahme von 1—6 Pulvern, das Stück	400
von mehr als	
6 bis 12 Pulvern, das Stück	420
solche von mehr als 12 Pulvern, das Stück	500
k) Suppositorienkästchen zur Aufnahme von 6 Suppositorien, das Stück	530
von mehr als	
6 bis 12 Suppositorien, das Stück	630
von mehr als	
12 Suppositorien für je 12 Suppositorien, das Stück mehr	180

Artikel II

Die Verordnung tritt mit 1. Jänner 1970 in Kraft.

Rehor

475. Verordnung des Bundesministers für Bauten und Technik vom 18. Dezember 1969, über eine Änderung der Verordnung, mit der wohnbaustatistische Erhebungen angeordnet werden

Auf Grund der §§ 2 Abs. 2 und 3, 4 Abs. 1 und 2, 7 Abs. 1 und 7 sowie des § 8 des Bundesstatistikgesetzes 1965, BGBl. Nr. 91, wird — hinsichtlich des § 5 Abs. 2 dieser Verordnung im Einvernehmen mit dem Bundesministerium für Finanzen — verordnet:

Die Verordnung vom 17. Dezember 1965, BGBl. Nr. 3/1966, mit der wohnbaustatistische Erhebungen angeordnet werden, wird abgeändert wie folgt:

1. Dem § 2 Abs. 2 ist nachstehender Satz anzufügen:

„Ab 1. Jänner 1970 sind die Anlagen 3 (Zählblatt C) und 7 (Liste zur Erfassung des Baufortschrittes) in der neuen Fassung zu verwenden."

2. Der § 5 Abs. 2 hat zu lauten:

„(2) Die Pauschalabfindung beträgt:

a) bei der Fertigstellung von Gebäuden mit einer oder zwei Wohnungen oder bei endgültiger Einstellung solcher Bauten bis 31. Dezember 1969 ..... S 17·00
im Jahre 1970 ..... S 18·70
im Jahre 1971 ..... S 20·40
ab 1. Jänner 1972 ..... S 25·50

b) bei der Fertigstellung von Gebäuden mit drei und mehr Wohnungen sowie bei der Fertigstellung von baulichen Maßnahmen an bestehenden Gebäuden oder bei endgültiger Einstellung solcher Bauten oder baulicher Maßnahmen bis 31. Dezember 1969 ..... S 19·00
im Jahre 1970 ..... S 20·90
im Jahre 1971 ..... S 22·80
ab 1. Jänner 1972 ..... S 28·50
und

c) beim Abbruch (Abgang) von Gebäuden mit mindestens einer Wohnung ..... S 5·00

Bei der Berechnung der Pauschalabfindung ist der Bezug von teilfertiggestellten Ein- und Zweifamilienhäusern der Fertigstellung gleichzuhalten."

Kotzina

Anlage 3

Bitte vor Ausfüllung des Zählblattes die Anleitung lesen!

Von der Gemeinde einzutragen!

Geschäftszahl aus dem Baufortschrittsverzeichnis: .....

Datum und Zahl der Baubewilligung: .....

Dient nur statistischen Zwecken!
Alle Angaben werden geheimgehalten!

Abzugeben beim Gemeindeamt innerhalb von **4 Wochen** nach **Baubeginn!**

WOHNBAUSTATISTIK

ZÄHLBLATT C

Hier sind für **Neubauten** und **sonstige Baumaßnahmen** (ausgenommen Abbrüche) das Datum des **Baubeginnes** und die voraussichtliche Baudauer anzugeben.

Anleitung: Der Baubeginn ist der Zeitpunkt des Einsetzens der tatsächlichen Baumaßnahmen an der Baustelle. Anlieferung und Lagerung von Baustoffen allein gilt hingegen nicht als Baubeginn.

Lage der Baustelle: ..... (Bundesland) ..... (Politischer Bezirk) ..... (Gemeinde)

..... (Ortschaft) ..... (Straße, Gasse, Platz) Nr. ..... (Orientier.-Nr. (wenn nicht vorhanden: Konskript.-Nr.)

..... (Katastralgemeinde) ..... (Einlagezahl) ..... (Grundstücknummer)

Bauherr: ..... (Name und Wohnanschrift)

Bevollmächtigter Vertreter: ..... (Name und Anschrift)

Baubeginn:

Mit dem Bau wurde begonnen am: ..... 19.....

Anzahl der Wohnungen des Bauvorhabens: .....

Wer in diesem Erhebungsformular wissentlich unvollständige oder wahrheitswidrige Angaben macht, wird nach den Bestimmungen des § 11 des Bundesstatistikgesetzes vom 1. April 1965, BGBl. Nr. 91, bestraft.

Datum und Unterschrift des Bauherrn (bzw. bevollmächtigten Vertreters):

Für die Gemeinde (Datum und Unterschrift):

.....

.....

Bitte nicht ausfüllen!

Papier grün

Anlage 7

Bundesland: .....

Politischer Bezirk: .....

Gemeinde: .....

WOHNBAUSTATISTIK

Baufortschrittsverzeichnis der Gemeinde

Dieses Verzeichnis ist von der Gemeinde für **bauliche Maßnahmen im Sinne der Zählblätter A und B** anläßlich der Erteilung der Baubewilligung anzulegen und darin der Baufortschritt einzutragen. Das Verzeichnis ist am Jahresende auf den letzten Stand zu bringen.

Geschäftszahl (Laufende Nummer)	Datum und Zahl der Baubewilligung	Anschrift der Baustelle	Name und Wohnanschrift des Bauherrn (bzw. Name und Anschrift des bevollmächtigten Vertreters)	Anzahl der Wohnungen des Bauvorhabens	Das Bauvorhaben war Ende 19....., ..., ..., ...			Das Bauvorhaben wurde endgültig eingestellt [1])
					noch nicht begonnen	begonnen, noch nicht fertiggestellt	fertiggestellt oder bezogen	
					Zutreffende Spalten ankreuzen und Jahreszahl der Überprüfung hinzufügen (z. B.: x 69)			

[1]) Unter Einstellung ist nicht eine vorübergehende Unterbrechung der Bautätigkeit, sondern die endgültige Einstellung des Baues zu verstehen, desgleichen die Nichtausnützung einer erteilten Baubewilligung, deren Gültigkeitsdauer abgelaufen ist, wenn sie nicht mehr verlängert wurde.

476. Kundmachung der Bundesregierung vom 25. November 1969 über die Ausschreibung der Wahl zum Nationalrat, die Festsetzung des Wahltages und des Stichtages

(1) Auf Grund des § 1 Abs. 2 der Nationalrats-Wahlordnung 1962, BGBl. Nr. 246, in der Fassung der Bundesgesetze BGBl. Nr. 70/1967 und 413/1968, wird hiemit die Wahl für den Nationalrat ausgeschrieben.

(2) Im Einvernehmen mit dem Hauptausschuß des Nationalrates wird als Wahltag der 1. März 1970 festgesetzt.

(3) Als Tag, der als Stichtag gilt, wird der 1. Jänner 1970 bestimmt.

Klaus	Withalm	Soronics	Klecatsky
Mock	Rehor	Koren	Schleinzer
Mitterer	Weiß	Prader	Waldheim
		Kotzina	

477. Kundmachung des Bundeskanzlers vom 4. Dezember 1969, womit der Beschluß Nr. 13/1969 des Rates der Europäischen Freihandelsassoziation, gefaßt auf Grund des Übereinkommens zur Errichtung der Europäischen Freihandelsassoziation (BGBl. Nr. 100/1960, in der Fassung der Kundmachung BGBl. Nr. 367/1969), verlautbart wird

EUROPEAN FREE TRADE ASSOCIATION

EFTA/DC 13/69

DECISION OF THE COUNCIL No. 13 OF 1969

(Adopted at the 31st Simultaneous Meeting on 23rd October 1969)

INCREASE IN VALUE LIMITS REGARDING CONSIGNMENTS OF SMALL VALUE

THE COUNCIL,

Having regard to paragraph 5 of Article 4 of the Convention,

Having regard to paragraph 3 of Article 7 of the Convention,

DECIDES:

1. The amounts set out in paragraph 3 of Decision of the Council No. 21 of 1961, as amended by paragraph 1 of Decision of the Council No. 2 of 1968, are again amended to read as follows:

„Austria	ÖS	3,100
Denmark	D. Kr.	900
Norway	N. Kr.	850
Portugal	Escudos	3,500
Sweden	Sw. Kr.	620
Switzerland	S. Fr.	520
United Kingdom	£	50“

2. The amounts referred to in sub-paragraph 1 (b) of Rule 12 of Annex B to the Convention are amended to read:

(Übersetzung)

EUROPÄISCHE FREIHANDELS-ASSOZIATION

EFTA/DC 13/69

BESCHLUSS DES RATES Nr. 13/1969

(In der 31. gemeinsamen Sitzung am 23. Oktober 1969 gefaßt)

ERHÖHUNG DER WERTGRENZEN FÜR SENDUNGEN GERINGEN WERTES

DER RAT hat,

gestützt auf Artikel 4, Absatz 5 des EFTA-Übereinkommens,

gestützt auf Artikel 7, Absatz 3 des EFTA-Übereinkommens,

BESCHLOSSEN:

1. Die Wertgrenzen gemäß Absatz 3 des Beschlusses des Rates Nr. 21/1961, abgeändert durch Beschluß des Rates Nr. 2/1968, werden abermals wie folgt abgeändert:

„Österreich	3.100	Österreichische Schilling
Dänemark	900	Dänische Kronen
Norwegen	850	Norwegische Kronen
Portugal	3.500	Escudos
Schweden	620	Schwedische Kronen
Schweiz	520	Schweizer Franken
Vereinigtes Königreich	50	Englische Pfund“.

2. Die Wertgrenzen, auf die in Absatz 1 lit. b der Regel 12 des Anhanges B des EFTA-Übereinkommens Bezug genommen wird, haben folgendermaßen zu lauten:

(English)

„Austria	ÖS	3,100
Denmark	D. Kr.	900
Norway	N. Kr.	850
Portugal	Escudos	3,500
Sweden	Sw. Kr.	620
Switzerland	S. Fr.	520
United Kingdom	£	50".

(French)

„en Autriche	3,100	schillings autrichiens
au Danemark	900	couronnes danoises
en Norvège	850	couronnes norvégiennes
au Portugal	3,500	escudos
en Suède	620	couronnes suédoises
en Suisse	520	francs suisses
au Royaume-Uni	50	livres sterling".

3. This Decision shall enter into force on 1st January 1970.

4. The Secretary-General shall deposit the text of this Decision with the Government of Sweden.

„Österreich	3.100	Österreichische Schilling
Dänemark	900	Dänische Kronen
Norwegen	850	Norwegische Kronen
Portugal	3.500	Escudos
Schweden	620	Schwedische Kronen
Schweiz	520	Schweizer Franken
Vereinigtes Königreich	50	Englische Pfund".

3. Dieser Beschluß tritt am 1. Jänner 1970 in Kraft.

4. Der Generalsekretär wird den Text dieses Beschlusses bei der Regierung Schwedens hinterlegen.

Klaus

478. Kundmachung des Bundeskanzlers vom 4. Dezember 1969, womit der Beschluß Nr. 7/1969 des Gemeinsamen Rates, gefaßt auf Grund des Übereinkommens zur Schaffung einer Assoziierung zwischen den Mitgliedstaaten der Europäischen Freihandelsassoziation und der Republik Finnland (BGBl. Nr. 193/1961, in der Fassung der Kundmachung BGBl. Nr. 396/1969), verlautbart wird

FINLAND-EFTA ASSOCIATION

FINEFTA/DJC 7/69

DECISION OF THE JOINT COUNCIL No. 7 OF 1969

(Adopted at the 31st Simultaneous Meeting on 23rd October 1969)

INCREASE IN VALUE LIMITS REGARDING CONSIGNMENTS OF SMALL VALUE

THE JOINT COUNCIL,

Having regard to paragraph 5 of Article 4 and paragraph 3 of Article 7 of the Convention,

Having regard to Article 2 and paragraph 3 of Article 6 of the Agreement,

(Übersetzung)

FINNLAND-EFTA ASSOZIIERUNG

FINEFTA/DJC 7/69

BESCHLUSS DES GEMEINSAMEN RATES Nr. 7/1969

(In der 31. gemeinsamen Sitzung am 23. Oktober 1969 gefaßt)

ERHÖHUNG DER WERTGRENZEN FÜR SENDUNGEN GERINGEN WERTES

DER GEMEINSAME RAT hat,

gestützt auf Artikel 4 Absatz 5 und Artikel 7 Absatz 3 des EFTA-Übereinkommens,

gestützt auf Artikel 2 und Artikel 6 Absatz 3 des Assoziierungs-Übereinkommens,

DECIDES:

1. The amount of Finnish Markkas referred to in paragraph 1 of Decision of the Joint Council No. 12 of 1967 and in sub-paragraphs 2 (a) and 2 (b) of Decision of the Joint Council No. 13 of 1967 shall read:

„500"

2. This Decision shall enter into force on 1st January 1970.

3. The Secretary-General of the European Free Trade Association shall deposit the text of this Decision with the Government of Sweden.

BESCHLOSSEN:

1. Der in Absatz 1 des Beschlusses des Gemeinsamen Rates Nr. 12/1967 [1]) und in den Absätzen 2 lit. a und 2 lit. b des Beschlusses des Gemeinsamen Rates Nr. 13/1967 [2]) erwähnte Betrag in Finnischen Mark hat zu lauten:

„500"

2. Dieser Beschluß tritt am 1. Jänner 1970 in Kraft.

3. Der Generalsekretär der Europäischen Freihandelsassoziation wird den Text dieses Beschlusses bei der Regierung Schwedens hinterlegen.

---

[1]) Der Beschluß des Gemeinsamen Rates Nr. 12/1967 ist unter BGBl. Nr. 88/1968 verlautbart.

[2]) Der Beschluß des Gemeinsamen Rates Nr. 13/1967 ist unter BGBl. Nr. 89/1968 verlautbart.

Klaus

479.

Protokoll

betreffend die steuerliche Behandlung des grenzüberschreitenden Straßenverkehrs zwischen der Republik Österreich und dem Fürstentum Liechtenstein

In der Zeit vom 4. bis 6. November 1969 haben zwischen einer österreichischen Delegation unter der Leitung des Sektionschefs im Bundesministerium für Finanzen, Dr. Josef Hammerschmidt, und einer liechtensteinischen Delegation unter der Leitung des Regierungschefs des Fürstentums Liechtenstein, Dr. Gerard Batliner, Besprechungen über die Besteuerung des grenzüberschreitenden Straßenverkehrs zwischen der Republik Österreich und dem Fürstentum Liechtenstein stattgefunden, die zu folgendem Ergebnis geführt haben:

I. Kraftfahrzeugsteuer

Kraftfahrzeugen, die in einem der beiden Staaten zum Verkehr zugelassen sind, wird im andern Staat Befreiung von der Kraftfahrzeugsteuer gewährt, wenn der vorübergehende Aufenthalt im andern Staat ein Jahr, von jedem Grenzübertritt an gerechnet, nicht übersteigt.

Diese Bestimmung tritt am 1. Jänner 1970 in Kraft.

II. Beförderungssteuer

In Anbetracht der Tatsache, daß im Fürstentum Liechtenstein derzeit eine der österreichischen Beförderungssteuer gleichkommende Abgabe nicht erhoben wird, erklärt sich die österreichische Delegation bereit, daß liechtensteinische Beförderungsunternehmer im grenzüberschreitenden Verkehr die Beförderungssteuer nach Maßgabe der folgenden Regeln entrichten:

1. Grenzüberschreitender Personenverkehr auf der Straße:

In Liechtenstein ansässige Beförderungsunternehmer, die im grenzüberschreitenden Verkehr auf der Straße mit in Liechtenstein zum Verkehr zugelassenen Kraftfahrzeugen Personenbeförderungen gegen Entgelt durchführen, sind in Österreich ab 1. Jänner 1970 von der Beförderungssteuer befreit.

2. Grenzüberschreitender Güterverkehr auf der Straße:

In Liechtenstein ansässige Beförderungsunternehmer, die mit in Liechtenstein zum Verkehr zugelassenen Kraftfahrzeugen im grenzüberschreitenden Güterverkehr auf der Straße Beförderungen von Gütern durchführen, entrichten ab 1. Jänner 1970 die Beförderungssteuer in Österreich für jede Fahrt auf österreichischem Gebiet wie folgt:

Für jede Tonne Rohgewicht der beförderten Güter und jeden Kilometer (Tonnenkilometer) von den auf einer Fahrt auf österreichischem Gebiet zurückgelegten

ersten 30 km	10 g
vom 31. km bis zum einschließlich 50. km	60 g
vom 51. km bis zum einschließlich 80. km	50 g
vom 81. km bis zum einschließlich 90. km	40 g
vom 91. km bis zum einschließlich 110. km	30 g
vom 111. km bis zum einschließlich 190. km	20 g
und vom 191. km an	5 g

Als eine Fahrt gilt die Beförderungsstrecke von der Grenzübertrittstelle bis zu dem von ihr am weitesten entfernten Zielpunkt. Diese Bestimmung findet auf Beförderungen bei der Rückfahrt sinngemäß Anwendung.

Für Strecken, welche Kraftfahrzeuge ohne Ladung zurücklegen (Leerfahrten), wird keine Beförderungssteuer erhoben.

Die vorstehende Regelung kann jederzeit unter Einhaltung einer einmonatigen Frist gekündigt werden; sie verliert ihre Wirksamkeit mit Ablauf der Kündigungsfrist.

Vaduz, am 6. November 1969.

Für die Österreichische Delegation:

Hammerschmidt m. p.

Für die Liechtensteinische Delegation:

Batliner m. p.

Klaus

BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

Der Bezugspreis des Bundesgesetzblattes für die Republik Österreich beträgt vorbehaltlich allfälliger Preiserhöhungen infolge unvorhergesehener Steigerung der Herstellungskosten bis zu einem Jahresumfang von 1800 Seiten S 168·— für Inlands- und S 216·— für Auslandsabonnements. Für den Fall, daß dieser Umfang überschritten wird, bleibt für den Mehrumfang eine entsprechende Neuberechnung vorbehalten. Der Bezugspreis kann auch in zwei gleichen Teilbeträgen zum 1. Jänner und 1. Juli entrichtet werden.

Einzelne Stücke des Bundesgesetzblattes sind erhältlich gegen Entrichtung des Verschleißpreises von 40 g für das Blatt = 2 Seiten, jedoch mindestens S 1·50 für das Stück, bei der Manz'schen Verlags- und Universitätsbuchhandlung in Wien I, Kohlmarkt 16 (Postleitzahl 1010), Telephon 63 17 85 Serie, sowie in der Verkaufsstelle der Österreichischen Staatsdruckerei — Wiener Zeitung, Wien I, Wollzeile 27 a (Postleitzahl 1037), Telephon 52 43 42.

Bezugsanmeldungen werden von der Abonnementstelle der Österreichischen Staatsdruckerei — Wiener Zeitung in Wien III, Rennweg 12 a (Postleitzahl 1037), entgegengenommen.

Als Bezugsanmeldung gilt auch die Überweisung des Bezugspreises oder seines ersten Teilbetrages auf das Postsparkassenkonto Wien Nr. 178. Die Bezugsanmeldung gilt bis zu einem allfälligen schriftlichen Widerruf. Der Widerruf ist nur mit Wirkung für das Ende des Kalenderjahres möglich. Er muß, um wirksam zu sein, spätestens am 15. Dezember bei der Abonnementstelle der Österreichischen Staatsdruckerei — Wiener Zeitung, Rennweg 12a, 1037 Wien, einlangen.

Die Zustellung des Bundesgesetzblattes erfolgt erst nach Entrichtung des Bezugspreises. Die Bezieher werden, um keine Verzögerung in der Zustellung eintreten zu lassen, eingeladen, den Bezugspreis umgehend zu überweisen.

Ersätze für abgängige oder mangelhaft zugekommene Stücke des Bundesgesetzblattes sind binnen drei Monaten nach dem Erscheinen unmittelbar bei der Abonnementstelle der Österreichischen Staatsdruckerei — Wiener Zeitung, Wien III, Rennweg 12 a (Postleitzahl 1037), anzufordern. Nach Ablauf dieses Zeitraumes werden Stücke des Bundesgesetzblattes ausnahmslos nur gegen Entrichtung des Verschleißpreises abgegeben.

Druck der Österreichischen Staatsdruckerei

P. b. b. Erscheinungsort Wien, Verlagspostamt 1030 Wien

BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

Jahrgang 1983 Ausgegeben am 8. März 1983 59. Stück

144. Bundesgesetz: Arbeitsruhegesetz — ARG
(NR: GP XV RV 1289 AB 1444 und Zu 1444 S. 145. BR: AB 2672 S. 432.)

144. Bundesgesetz vom 3. Feber 1983 über die wöchentliche Ruhezeit und die Arbeitsruhe an Feiertagen (Arbeitsruhegesetz — ARG)

Der Nationalrat hat beschlossen:

1. ABSCHNITT

Geltungsbereich

§ 1. (1) Dieses Bundesgesetz gilt für Arbeitnehmer aller Art, soweit im folgenden nicht anderes bestimmt wird.

(2) Ausgenommen sind:

1. Arbeitnehmer, die in einem Arbeitsverhältnis zu einer Gebietskörperschaft oder zu einem Gemeindeverband stehen, soweit sie nicht
   a) in Betrieben eines Landes, einer Gemeinde oder eines Gemeindeverbandes beschäftigt sind,
   b) in Betrieben des Bundes beschäftigt sind;
2. Arbeitnehmer der Post- und Telegraphenverwaltung und des Wirtschaftskörpers Österreichische Bundesbahnen, von weiteren Haupt- und Nebenbahnen im Sinne des § 1 I Z 1 Eisenbahngesetz 1957, BGBl. Nr. 60, und von Kraftfahrlinienunternehmungen im Sinne des Kraftfahrliniengesetzes 1952, BGBl. Nr. 84, soweit für diese Arbeitnehmer zwingende dienstrechtliche Vorschriften über die wöchentliche Ruhezeit gelten;
3. Arbeitnehmer von Schiffahrtsunternehmungen im Sinne des § 1 Abs. 1 Z 1 Binnen-Schiffahrts-Konzessionsgesetz 1978, BGBl. Nr. 533, sowie Arbeitnehmer von Luftverkehrsunternehmungen im Sinne des § 101 lit. a Luftfahrtgesetz 1957, BGBl. Nr. 253, soweit diese Unternehmungen im internationalen Verkehr tätig sind und für die in diesen Unternehmungen beschäftigten Arbeitnehmer kollektivvertragliche Regelungen über die wöchentliche Ruhezeit gelten;
4. Lehr- und Erziehungskräfte an Unterrichts- und Erziehungsanstalten, soweit sie nicht bereits unter Z 1 fallen;
5. leitende Angestellte, denen maßgebliche Führungsaufgaben selbstverantwortlich übertragen sind;
6. Arbeitnehmer, für die folgende Vorschriften gelten:
   a) das Hausbesorgergesetz, BGBl. Nr. 16/1970;
   b) das Hausgehilfen- und Hausangestelltengesetz, BGBl. Nr. 235/1962;
   c) das Bundesgesetz über die Beschäftigung von Kindern und Jugendlichen, BGBl. Nr. 146/1948;
   d) das Landarbeitsgesetz, BGBl. Nr. 140/1948;
   e) das Seeschiffahrtsgesetz, BGBl. Nr. 174/1981;
7. Arbeitnehmer, die dem Bäckereiarbeitergesetz, BGBl. Nr. 69/1955, unterliegen, soweit auf sie nicht § 11 Abs. 4 Bäckereiarbeitergesetz Anwendung findet;
8. Arbeitnehmer, die in Theaterbetrieben im Sinne des § 1 Abs. 2 Schauspielergesetz, BGBl. Nr. 441/1922, beschäftigt sind;
9. Heimarbeiter, auf die das Heimarbeitsgesetz 1960, BGBl. Nr. 105/1961, anzuwenden ist.

(3) Auf Arbeitnehmer gesetzlich anerkannter Kirchen und Religionsgesellschaften, die nicht in Betrieben beschäftigt sind, findet dieses Gesetz Anwendung, wenn keine gleichwertige interne Regelung besteht.

2. ABSCHNITT

Wochenendruhe, Wochenruhe, Ersatzruhe und Feiertagsruhe

Begriff der Ruhezeit

§ 2. (1) Im Sinne dieses Bundesgesetzes ist

1. Wochenendruhe eine ununterbrochene Ruhezeit von 36 Stunden, in die der Sonntag fällt (§ 3);
2. Wochenruhe eine ununterbrochene Ruhezeit von 36 Stunden in der Kalenderwoche (§ 4);
3. wöchentliche Ruhezeit sowohl die Wochenendruhe als auch die Wochenruhe;
4. Ersatzruhe eine ununterbrochene Ruhezeit, die als Abgeltung für die während der wöchentlichen Ruhezeit geleistete Arbeit zusteht (§ 6);
5. Feiertagsruhe eine ununterbrochene Ruhezeit von 24 Stunden, die frühestens um 0 Uhr und spätestens um 6 Uhr des gesetzlichen Feiertages beginnt (§ 7).

(2) Während der Wochenend- und Feiertagsruhe darf im Rahmen der §§ 10 bis 18 nur die unumgänglich notwendige Anzahl von Arbeitnehmern beschäftigt werden.

Wochenendruhe

§ 3. (1) Der Arbeitnehmer hat in jeder Kalenderwoche Anspruch auf eine ununterbrochene Ruhezeit von 36 Stunden, in die der Sonntag zu fallen hat (Wochenendruhe). Während dieser Zeit darf der Arbeitnehmer nur beschäftigt werden, wenn dies auf Grund der §§ 2 Abs. 2, 10 bis 18 zulässig ist.

(2) Die Wochenendruhe hat für alle Arbeitnehmer spätestens Samstag um 13 Uhr, für Arbeitnehmer, die mit unbedingt notwendigen Abschluß-, Reinigungs-, Instandhaltungs- oder Instandsetzungsarbeiten beschäftigt sind, spätestens Samstag um 15 Uhr zu beginnen.

(3) In Betrieben mit einer werktags durchlaufenden mehrschichtigen Arbeitsweise hat die Wochenendruhe spätestens mit Ende der Nachtschicht zum Sonntag zu beginnen und darf frühestens mit Beginn der Nachtschicht zum Montag enden.

(4) Wird in Verbindung mit Feiertagen eingearbeitet und die ausfallende Arbeitszeit auf die Werktage der die Ausfallstage einschließenden Wochen verteilt (§ 4 Abs. 3 des Arbeitszeitgesetzes, BGBl. Nr. 461/1969), so kann der Beginn der Wochenendruhe bis spätestens Samstag 18 Uhr aufgeschoben werden.

Wochenruhe

§ 4. Der Arbeitnehmer, der nach der für ihn geltenden Arbeitszeiteinteilung während der Zeit der Wochenendruhe beschäftigt wird, hat in jeder Kalenderwoche an Stelle der Wochenendruhe Anspruch auf eine ununterbrochene Ruhezeit von 36 Stunden (Wochenruhe). Die Wochenruhe hat einen ganzen Wochentag einzuschließen.

Abweichende Regelung der wöchentlichen Ruhezeit

§ 5. (1) Zur Ermöglichung der Schichtarbeit kann im Schichtplan die wöchentliche Ruhezeit abweichend von den §§ 3 und 4 geregelt werden.

(2) Das Ausmaß der wöchentlichen Ruhezeit kann in den Fällen des Abs. 1 bis auf 24 Stunden gekürzt werden. In einem Durchrechnungszeitraum von vier Wochen muß dem Arbeitnehmer jedoch eine durchschnittliche wöchentliche Ruhezeit von 36 Stunden gesichert sein. Zur Berechnung dürfen nur mindestens 24stündige Ruhezeiten herangezogen werden.

(3) Der Bundesminister für soziale Verwaltung — für Betriebe, die der bergbehördlichen Aufsicht unterliegen, der Bundesminister für Handel, Gewerbe und Industrie — kann auf Antrag des Arbeitgebers nach Anhörung der gesetzlichen Interessenvertretungen der Arbeitgeber und Arbeitnehmer abweichend von Abs. 2 Schichtpläne zulassen. Sie können die wöchentliche Ruhezeit von mindestens 24 Stunden unterschreiten oder den vierwöchigen Durchrechnungszeitraum überschreiten, wenn dies aus wichtigen Gründen erforderlich und mit den Interessen der Arbeitnehmer vereinbar ist. Solche Schichtpläne können befristet werden.

(4) Der Bundesminister für soziale Verwaltung — für Betriebe, die der bergbehördlichen Aufsicht unterliegen, der Bundesminister für Handel, Gewerbe und Industrie — hat Ausnahmen gemäß Abs. 3 von Amts wegen oder auf Antrag einer der gesetzlichen Interessenvertretungen der Arbeitgeber oder Arbeitnehmer, des Arbeitgebers oder von Organen der Arbeitnehmerschaft des Betriebes abzuändern oder zu widerrufen, wenn die Voraussetzungen des Abs. 3 nicht mehr vorliegen.

(5) Für Arbeitnehmer, die auf im öffentlichen Interesse betriebenen Großbaustellen oder auf Baustellen der Wildbach- und Lawinenverbauung in Gebirgsregionen beschäftigt sind, kann durch Kollektivvertrag die wöchentliche Ruhezeit abweichend von den §§ 3 und 4 geregelt werden. Die wöchentliche Ruhezeit kann für einzelne Wochen gekürzt werden oder zur Gänze entfallen, wenn in einem vierwöchigen Durchrechnungszeitraum eine durchschnittliche wöchentliche Ruhezeit von 36 Stunden gesichert ist. Abs. 2 dritter Satz gilt sinngemäß.

(6) Für Arbeitnehmer, die bei der Herstellung oder beim Vertrieb von Tageszeitungen und Montagfrühblättern beschäftigt sind, kann durch Kollektivvertrag die wöchentliche Ruhezeit abweichend von den §§ 3 und 4 geregelt werden. Die wöchentliche Ruhezeit kann bis auf 24 Stunden gekürzt werden, wenn in einem vierwöchigen Durchrechnungszeitraum eine durchschnittliche wöchentliche Ruhezeit von 36 Stunden gesichert ist. Abs. 2 dritter Satz gilt sinngemäß.

Ersatzruhe

§ 6. (1) Der Arbeitnehmer, der während seiner wöchentlichen Ruhezeit (§ 2 Abs. 1 Z 3) beschäftigt wird, hat in der folgenden Arbeitswoche Anspruch auf Ersatzruhe, die auf seine Wochenarbeitszeit anzurechnen ist. Die Ersatzruhe ist im Ausmaß der während der wöchentlichen Ruhezeit geleisteten Arbeit zu gewähren, die innerhalb von 36 Stunden vor dem Arbeitsbeginn in der nächsten Arbeitswoche erbracht wurde.

(2) Während der Ersatzruhe nach Abs. 1 dürfen Arbeitnehmer nur im Rahmen der §§ 11 oder 14 beschäftigt werden.

(3) Wird ein Arbeitnehmer während der Ersatzruhe gemäß Abs. 1 beschäftigt, so ist diese Ersatzruhe im entsprechenden Ausmaß zu einer anderen, einvernehmlich festgesetzten Zeit nachzuholen.

(4) Während der Ersatzruhe nach Abs. 3 dürfen Arbeitnehmer nur zur Abwendung einer unmittelbaren Gefahr für die Sicherheit des Lebens oder für

die Gesundheit von Menschen oder bei Notstand beschäftigt werden. Hiefür gebührt keine weitere Ersatzruhe.

(5) Die Ersatzruhe hat unmittelbar vor dem Beginn der folgenden wöchentlichen Ruhezeit zu liegen, soweit vor Antritt der Arbeit, für die Ersatzruhe gebührt, nicht anderes vereinbart wurde.

Feiertagsruhe

§ 7. (1) Der Arbeitnehmer hat an Feiertagen Anspruch auf eine ununterbrochene Ruhezeit von mindestens 24 Stunden, die frühestens um 0 Uhr und spätestens um 6 Uhr des Feiertages beginnen muß.

(2) Feiertage im Sinne dieses Bundesgesetzes sind:

1. Jänner (Neujahr), 6. Jänner (Heilige Drei Könige), Ostermontag, 1. Mai (Staatsfeiertag), Christi Himmelfahrt, Pfingstmontag, Fronleichnam, 15. August (Mariä Himmelfahrt), 26. Oktober (Nationalfeiertag), 1. November (Allerheiligen), 8. Dezember (Mariä Empfängnis), 25. Dezember (Weihnachten), 26. Dezember (Stephanstag).

(3) Für Angehörige der evangelischen Kirchen AB und HB, der Altkatholischen Kirche und der Methodistenkirche ist auch der Karfreitag ein Feiertag.

(4) Feiertage dürfen auf die wöchentliche Ruhezeit nur angerechnet werden, soweit sie in die Zeit der wöchentlichen Ruhezeit fallen.

(5) In Betrieben mit einer werktags durchlaufenden mehrschichtigen Arbeitsweise hat die Feiertagsruhe spätestens mit Ende der Nachtschicht zum Feiertag zu beginnen und darf frühestens mit Beginn der Nachtschicht am nächsten Werktag enden.

(6) Ist für die Normalarbeitszeit (§ 3 Arbeitszeitgesetz) an Feiertagen Zeitausgleich vereinbart, so muß dieser mindestens einen Kalendertag oder 36 Stunden umfassen.

(7) Fällt ein Feiertag auf einen Sonntag, so sind die §§ 3 bis 5 anzuwenden.

Freizeit zur Erfüllung der religiösen Pflichten

§ 8. (1) Der Arbeitnehmer, der während der Wochenend- oder Feiertagsruhe beschäftigt wird, hat auf Verlangen Anspruch auf die zur Erfüllung seiner religiösen Pflichten notwendige Freizeit, wenn diese Pflichten nicht außerhalb der Arbeitszeit erfüllt werden können und die Freistellung von der Arbeit mit den Erfordernissen des Betriebes vereinbar ist.

(2) Der Arbeitnehmer hat diesen Anspruch bei Vereinbarung der Wochenend- oder Feiertagsarbeit, spätestens jedoch zwei Tage vorher, bei späterer Vereinbarung sofort, dem Arbeitgeber gegenüber geltend zu machen.

Entgelt für Feiertage und Ersatzruhe

§ 9. (1) Der Arbeitnehmer behält für die infolge eines Feiertages oder der Ersatzruhe (§ 6) ausgefallene Arbeit seinen Anspruch auf Entgelt.

(2) Dem Arbeitnehmer gebührt jenes Entgelt, das er erhalten hätte, wenn die Arbeit nicht aus den im Abs. 1 genannten Gründen ausgefallen wäre.

(3) Bei Akkord-, Stück- oder Gedinglöhnen, akkordähnlichen oder sonstigen leistungsbezogenen Prämien oder Entgelten ist das fortzuzahlende Entgelt nach dem Durchschnitt der letzten 13 voll gearbeiteten Wochen unter Ausscheidung nur ausnahmsweise geleisteter Arbeiten zu berechnen. Hat der Arbeitnehmer nach Antritt des Arbeitsverhältnisses noch keine 13 Wochen voll gearbeitet, so ist das Entgelt nach dem Durchschnitt der seit Antritt des Arbeitsverhältnisses voll gearbeiteten Zeiten zu berechnen.

(4) Durch Kollektivvertrag im Sinne des § 18 Abs. 4 Arbeitsverfassungsgesetz, BGBl. Nr. 22/1974, kann geregelt werden, welche Leistungen des Arbeitgebers als Entgelt anzusehen sind. Die Berechnungsart für die Ermittlung der Höhe des Entgelts kann durch Kollektivvertrag abweichend von Abs. 2 und 3 geregelt werden.

(5) Der Arbeitnehmer, der während der Feiertagsruhe beschäftigt wird, hat außer dem Entgelt nach Abs. 1 Anspruch auf das für die geleistete Arbeit gebührende Entgelt, es sei denn, es wird Zeitausgleich im Sinne des § 7 Abs. 6 vereinbart.

3. ABSCHNITT

Ausnahmen von der Wochenend- und Feiertagsruhe

Ausnahmen für bestimmte Tätigkeiten

§ 10. (1) Während der Wochenend- und Feiertagsruhe dürfen Arbeitnehmer nur beschäftigt werden mit:

1. der Reinigung, Instandhaltung oder Instandsetzung, soweit sich solche Arbeiten während des regelmäßigen Arbeitsablaufes nicht ohne Unterbrechung oder erhebliche Störung ausführen lassen und infolge ihres Umfanges nicht bis spätestens Samstag 15 Uhr abgeschlossen werden können;
2. der Bewachung oder Wartung von Betriebsanlagen einschließlich Bergbauanlagen oder Wartung von Tieren;
3. Arbeiten, die dem Brandschutz dienen;
4. der gesundheitlichen Betreuung oder Versorgung mit Speisen und Getränken derjenigen Arbeitnehmer, die auf Grund der Ausnahmebestimmungen dieses Bundesgesetzes während der Wochenend- oder Feiertagsruhe beschäftigt werden dürfen;

5. der Beförderung der während der Wochenend- oder Feiertagsruhe beschäftigten Arbeitnehmer zu und von der Arbeitsstelle;
6. der Be- und Entlüftung, Beheizung oder Kühlung der Arbeitsräume;
7. Umbauarbeiten an Betriebsanlagen einschließlich Bergbauanlagen, wenn diese aus technischen Gründen nur während des Betriebsstillstandes durchgeführt werden können und ein Betriebsstillstand außerhalb der Ruhezeiten mit einem erheblichen Schaden verbunden wäre;
8. der Betreuung, Beaufsichtigung und Versorgung mit Speisen und Getränken in Internaten und Heimen, wenn diese Internate und Heime auch während der Wochenend- oder Feiertagsruhe betrieben werden.

(2) Der Arbeitgeber hat die nach Abs. 1 zulässigen Arbeiten dem Arbeitsinspektorat binnen vier Tagen nach ihrem erstmaligen Beginn schriftlich anzuzeigen. Die Anzeige hat die Gründe für die Arbeiten, die Anzahl der zur Arbeitsleistung benötigten Arbeitnehmer und den Zeitraum ihrer Durchführung zu enthalten. Entfallen die Gründe für diese Arbeiten, so hat dies der Arbeitgeber binnen vier Tagen schriftlich dem Arbeitsinspektorat anzuzeigen.

Ausnahmen in außergewöhnlichen Fällen

§ 11. (1) Während der Wochenend- und Feiertagsruhe dürfen Arbeitnehmer in außergewöhnlichen Fällen mit vorübergehenden und unaufschiebbaren Arbeiten beschäftigt werden, soweit diese
1. zur Abwendung einer unmittelbaren Gefahr für die Sicherheit des Lebens oder die Gesundheit von Menschen oder bei Notstand sofort vorzunehmen sind oder
2. zur Behebung einer Betriebsstörung oder zur Verhütung des Verderbens von Gütern oder eines sonstigen unverhältnismäßigen wirtschaftlichen Schadens erforderlich sind, wenn unvorhergesehene und nicht zu verhindernde Gründe vorliegen und andere zumutbare Maßnahmen zu diesem Zweck nicht möglich sind.

(2) Der Arbeitgeber hat die in Abs. 1 angeführten Arbeiten dem Arbeitsinspektorat binnen vier Tagen nach Beginn der Arbeiten schriftlich anzuzeigen. Die Anzeige hat die Gründe für die Arbeiten sowie die Anzahl der zur Arbeitsleistung benötigten Arbeitnehmer zu enthalten.

(3) Zur Sicherstellung der nach Abs. 1 notwendigen Arbeiten können Bereitschaftsdienste oder Rufbereitschaften eingerichtet werden.

(4) Der Arbeitgeber hat die Einrichtung von Bereitschaftsdiensten im Sinne des Abs. 3 unter Angabe von Gründen und der erforderlichen Anzahl der Arbeitnehmer dem Arbeitsinspektorat vorher schriftlich anzuzeigen. Entfallen die Gründe, die für die Einrichtung maßgebend waren, so hat er dies binnen vier Tagen dem Arbeitsinspektorat schriftlich anzuzeigen.

Ausnahmen durch Verordnung für bestimmte Tätigkeiten

§ 12. (1) Durch Verordnung sind für Arbeitnehmer in bestimmten Betrieben Ausnahmen von der Wochenend- und Feiertagsruhe für Arbeiten zuzulassen, wenn diese
1. zur Befriedigung dringender Lebensbedürfnisse notwendig sind;
2. im Hinblick auf während der Wochenend- oder Feiertagsruhe hervortretende Freizeit- und Erholungsbedürfnisse und Erfordernisse des Fremdenverkehrs notwendig sind;
3. zur Bewältigung des Verkehrs notwendig sind;
4. aus technologischen Gründen einen ununterbrochenen Fortgang erfordern;
5. im Bergbau aus technologischen oder naturbedingten Gründen oder aus Gründen der Sicherheit einen ununterbrochenen Fortgang erfordern;
6. wegen der Gefahr des Mißlingens von Arbeitserzeugnissen nicht aufgeschoben werden können, soweit diese Gefahr nicht durch andere Maßnahmen abgewendet werden kann oder
7. wegen der Gefahr des raschen Verderbens von Rohstoffen nicht aufgeschoben werden können und nach der Art des Betriebes auf einen bestimmten Zeitraum beschränkt sind.

(2) Soweit dies nach der Art der Tätigkeit zweckmäßig ist, hat die Verordnung die nach Abs. 1 zulässigen Arbeiten einzeln anzuführen und das für die Durchführung notwendige Zeitausmaß festzulegen. Arbeiten, die im unmittelbaren Zusammenhang mit den nach Abs. 1 zulässigen Arbeiten stehen oder ohne die diese nicht durchführbar wären, sind zuzulassen, soweit sie nicht vor oder nach der Wochenend- oder Feiertagsruhe vorgenommen werden können.

(3) Werden auf Grund einer Verordnung im Sinne der Abs. 1 und 2 Bauarbeiten im öffentlichen Interesse während der Wochenend- und Feiertagsruhe durchgeführt, so hat das bauausführende Unternehmen diese dem Arbeitsinspektorat unter Bekanntgabe der sachlichen Gründe und der erforderlichen Anzahl der Arbeitnehmer anzuzeigen. Eine Abschrift der Anzeige ist den zuständigen kollektivvertragsfähigen Interessenvertretungen der Arbeitgeber und Arbeitnehmer zu übermitteln. Die Anzeige hat innerhalb von 21 Tagen nach Bekanntwerden der Umstände zu erfolgen, welche die Arbeiten während der Wochenend- oder Feiertagsruhe erfordern.

Ausnahmen durch Verordnung des Landeshauptmannes

§ 13. (1) Der Landeshauptmann kann neben den gemäß § 12 Abs. 1 und 2 zulässigen Ausnahmen nach Anhörung der zuständigen gesetzlichen Interessenvertretungen der Arbeitgeber und Arbeitnehmer durch Verordnung weitere Ausnahmen zulassen, wenn

1. nicht bereits eine Ausnahme im Sinne dieses Bundesgesetzes, insbesondere durch den Ausnahmenkatalog gemäß § 12 Abs. 1, für den zu regelnden Bereich besteht und
2. ein außergewöhnlicher regionaler Bedarf für Versorgungsleistungen gegeben ist.

(2) Verordnungen im Sinne des Abs. 1 haben den örtlichen Geltungsbereich, die Tätigkeiten, die Zeiträume und das maximale Zeitausmaß, während dem die Beschäftigung von Arbeitnehmern zulässig ist, genau zu bezeichnen. Arbeiten, die im unmittelbaren Zusammenhang mit den nach Abs. 1 zulässigen Arbeiten stehen oder ohne die diese nicht durchführbar wären, sind zuzulassen, soweit sie nicht vor oder nach der Wochenend- oder Feiertagsruhe vorgenommen werden können.

(3) Verordnungen gemäß Abs. 1 sind dem Bundesminister für soziale Verwaltung jeweils zur Kenntnis zu bringen.

Ausnahmen durch Verordnung im öffentlichen Interesse

§ 14. Durch Verordnung sind Ausnahmen von der Wochenend- oder Feiertagsruhe für die Arbeitnehmer bestimmter Betriebe zuzulassen, wenn es das öffentliche Interesse infolge besonders schwerwiegender Umstände erfordert.

Ausnahmen in Einzelfällen

§ 15. (1) Der Bundesminister für soziale Verwaltung hat auf Antrag des Arbeitgebers nach Anhörung der gesetzlichen Interessenvertretungen der Arbeitgeber und Arbeitnehmer für bestimmte Arbeitnehmer eines Betriebes eine Ausnahme von der Wochenend- und Feiertagsruhe zuzulassen, wenn dies im Einzelfall infolge der Neuerrichtung oder Änderung einer Betriebsanlage oder der Einführung eines neuen Verfahrens aus den im § 12 Abs. 1 Z 4, 6 und 7 genannten Gründen erforderlich ist.

(2) Der Bundesminister für Handel, Gewerbe und Industrie hat auf Antrag des Arbeitgebers nach Anhörung der gesetzlichen Interessenvertretungen der Arbeitgeber und Arbeitnehmer für bestimmte Arbeitnehmer eines Bergbaubetriebes eine Ausnahme von den Bestimmungen der Wochenend- und Feiertagsruhe zuzulassen, wenn dies

1. infolge der Neuerrichtung oder Änderung einer Bergbauanlage oder der Einführung eines neuen Verfahrens aus technologischen Gründen,
2. infolge von Betriebsunterbrechungen durch außergewöhnliche Ereignisse,
3. durch besondere Witterungseinflüsse bis zum Ausgleich entstandener Folgen,
4. zur Überbrückung von Versorgungsengpässen oder
5. unverzüglich zur Sicherstellung der Versorgung mit mineralischen Rohstoffen

erforderlich ist.

4. ABSCHNITT

Sonderbestimmungen für Märkte und Messen

Märkte und marktähnliche Veranstaltungen

§ 16. Finden Märkte oder marktähnliche Veranstaltungen (§§ 324 bis 332 GewO 1973) auf Grund gewerberechtlicher Bewilligung während der Wochenend- oder Feiertagsruhe statt, so ist die Beschäftigung von Arbeitnehmern nur im örtlich und zeitlich bewilligten Rahmen dieser Veranstaltung und im unbedingt notwendigen Ausmaß zulässig.

Messen und messeähnliche Veranstaltungen

§ 17. (1) Werden Messen oder messeähnliche Veranstaltungen durchgeführt, dürfen Arbeitnehmer auch während der Wochenend- und Feiertagsruhe mit Arbeiten beschäftigt werden, die

1. innerhalb der letzten zwei Wochen vor Beginn zur Vorbereitung der Veranstaltung, wie zum Aufbau der Ausstellungseinrichtung und zur Anlieferung des Messegutes,
2. zur Durchführung der Veranstaltung,
3. zur Betreuung und Beratung der Besucher,
4. zur Erfüllung der Aufgaben als Beauftragter der beruflich berührten Besucherkreise oder
5. für den Abbau und Abtransport des Messegutes, der Ausstellungseinrichtungen und sonstigen Abschlußarbeiten

notwendig sind. In den Fällen der Z 1, 4 und 5 sind Arbeiten jedoch nur dann zulässig, wenn ihre Durchführung nicht durch zumutbare organisatorische Maßnahmen außerhalb der Ruhezeiten möglich ist.

(2) Werbe- und Verkaufsveranstaltungen, die die Voraussetzungen der Abs. 3 bis 5 erfüllen, gelten als Messen oder messeähnliche Veranstaltungen.

(3) Als Messe im Sinne dieses Bundesgesetzes ist eine zeitlich begrenzte, im allgemeinen regelmäßig wiederkehrende Veranstaltung zu verstehen, in deren Rahmen eine Vielzahl von Ausstellern ein umfassendes Angebot eines oder mehrerer Wirtschaftszweige ausstellt und überwiegend nach Muster vor allem an gewerbliche Wiederverkäufer, gewerbliche Verbraucher oder Großabnehmer vertreibt.

(4) Veranstaltungen, die nur einmal oder jedenfalls ohne Regelmäßigkeit durchgeführt werden

oder die die wirtschaftliche Leistungsfähigkeit von bestimmten Gewerbezweigen oder Regionen darstellen sollen (Handwerksausstellungen, Leistungsschauen und dergleichen), bei welchen der Informationszweck gegenüber der Absicht des Warenvertriebes überwiegt, gelten als messeähnliche Veranstaltungen im Sinne dieses Bundesgesetzes.

(5) Als Messen und messeähnliche Veranstaltungen gelten Veranstaltungen jedoch nur dann, wenn infolge der großen Zahl der Aussteller und Besucher die Organisation der Durchführung von den Ausstellern nicht selbst bewältigt werden kann und die Veranstaltungen außerhalb jener Betriebsstätten durchgeführt werden, in denen der normale Geschäftsbetrieb der Aussteller stattfindet.

Verkaufsstellen in Bahnhöfen und Autobusbahnhöfen, auf Flugplätzen und Schiffslandeplätzen, Zollfreiläden

§ 18. (1) Für den Verkauf von Reiseproviant, Reiseandenken und notwendigem Reisebedarf (insbesondere Reiselektüre, Schreibmaterialien, Blumen, Reise-Toiletteartikel, Filme) und Artikel des Trafiksortiments dürfen Arbeitnehmer auch während der Wochenend- und Feiertagsruhe in Verkaufsstellen unmittelbar in Bahnhöfen und Autobusbahnhöfen, auf Flugplätzen und an Schiffslandeplätzen beschäftigt werden.

(2) Für den Verkauf des Sortiments von Zollfreiläden auf Flughäfen dürfen Arbeitnehmer auch während der Wochenend- und Feiertagsruhe beschäftigt werden.

5. ABSCHNITT

Sonderbestimmungen

Sonderbestimmungen für Arbeitnehmer in Verkehrsbetrieben

§ 19. (1) Für Arbeitnehmer

1. in Verkehrsbetrieben im Sinne des
   a) Eisenbahngesetzes 1957, BGBl. Nr. 60,
   b) Kraftfahrliniengesetzes 1952, BGBl. Nr. 84,
   c) Luftfahrtgesetzes, BGBl. Nr. 253/1957,
   d) Binnenschiffahrts-Konzessionsgesetzes, BGBl. Nr. 533/1978,
   e) Schiffahrtsanlagengesetzes, BGBl. Nr. 12/1973,
   f) Gelegenheitsverkehrsgesetzes, BGBl. Nr. 85/1952,
   g) § 179 Gewerbeordnung 1973 (Schlepplifte), BGBl. Nr. 50/1974, sowie
2. in Schlaf-, Liege- und Speisewagenunternehmungen im Rahmen des fahrenden Betriebes der Eisenbahnen

kann durch Kollektivvertrag die wöchentliche Ruhezeit und die Ruhezeit an Feiertagen abweichend von den §§ 3, 4 und 7 geregelt werden, soweit diese Arbeitnehmer nicht gemäß § 1 Abs. 2 Z 2 und 3 vom Geltungsbereich ausgenommen sind.

(2)

1. Die wöchentliche Ruhezeit darf in einzelnen Wochen 36 Stunden unterschreiten oder ganz unterbleiben, wenn in einem kollektivvertraglich festgelegten Zeitraum eine durchschnittliche Ruhezeit von 36 Stunden erreicht wird. Zur Berechnung dürfen nur mindestens 24stündige Ruhezeiten herangezogen werden.
2. Die Lage der Ersatzruhe kann abweichend von § 6 festgelegt werden.
3. In Fällen des besonderen Bedarfes kann zur Aufrechterhaltung des Verkehrs durch Betriebe im Sinne des Abs. 1 eine finanzielle Abgeltung der Ersatzruhe vorgesehen werden.

(3) In Betrieben von Gebietskörperschaften können dienstrechtliche Vorschriften, die den wesentlichen Inhalt des Arbeitsverhältnisses zwingend festlegen, Regelungen im Sinne der Abs. 1 und 2 treffen.

Sonderbestimmungen für Arbeitnehmer in Heil- und Pflegeanstalten (Krankenanstalten) und Kuranstalten

§ 20. (1) Für Arbeitnehmer in Heil- und Pflegeanstalten (Krankenanstalten) und in Kuranstalten,

1. die in Gesundheitsberufen tätig sind oder
2. deren Beschäftigung zur Aufrechterhaltung des Betriebes in solchen Anstalten unumgänglich notwendig ist,

kann durch Kollektivvertrag die wöchentliche Ruhezeit und die Ruhezeit an Feiertagen abweichend von den §§ 3, 4 und 7 geregelt werden.

(2)

1. Die wöchentliche Ruhezeit darf in einzelnen Wochen 36 Stunden unterschreiten oder ganz unterbleiben, wenn in einem kollektivvertraglich festgelegten Zeitraum eine durchschnittliche Ruhezeit von 36 Stunden erreicht wird. Zur Berechnung dürfen nur mindestens 24stündige Ruhezeiten herangezogen werden.
2. Die Lage der Ersatzruhe kann abweichend von § 6 festgelegt werden.
3. In Ausnahmefällen kann zur Aufrechterhaltung des Anstaltsbetriebes eine finanzielle Abgeltung der Ersatzruhe vorgesehen werden.

(3) In Betrieben (Anstalten) von Gebietskörperschaften und sonstigen juristischen Personen des öffentlichen Rechts können dienstrechtliche Vorschriften, die den wesentlichen Inhalt des Arbeitsverhältnisses zwingend festlegen, Regelungen im Sinne der Abs. 1 und 2 treffen.

Sonderbestimmungen für bestimmte Arbeitnehmer in öffentlichen Apotheken und Anstaltsapotheken

§ 21. (1) Für angestellte Apothekenleiter und pharmazeutische Fachkräfte in öffentlichen Apo-

theken oder Anstaltsapotheken kann durch Kollektivvertrag die wöchentliche Ruhezeit und die Ruhezeit an Feiertagen abweichend von den §§ 3, 4 und 7 geregelt werden.

(2)
1. Die wöchentliche Ruhezeit darf in einzelnen Wochen 36 Stunden unterschreiten oder ganz unterbleiben, wenn in einem kollektivvertraglich festgelegten Zeitraum eine durchschnittliche Ruhezeit von 36 Stunden erreicht wird. Zur Berechnung dürfen nur mindestens 24stündige Ruhezeiten herangezogen werden.
2. Die Lage der Ersatzruhe kann abweichend von § 6 festgelegt werden.
3. In Ausnahmefällen kann zur Aufrechterhaltung der Arzneimittelversorgung eine finanzielle Abgeltung der Ersatzruhe vorgesehen werden.

(3) In Betrieben von Gebietskörperschaften können dienstrechtliche Vorschriften, welche den wesentlichen Inhalt des Arbeitsverhältnisses zwingend regeln, Regelungen im Sinne der Abs. 1 und 2 treffen.

Sonderbestimmungen für Arbeitnehmer in Betrieben des Bewachungsgewerbes

§ 22. (1) Für Arbeitnehmer in Betrieben des Bewachungsgewerbes im Sinne des § 318 Gewerbeordnung 1973 kann durch Kollektivvertrag die wöchentliche Ruhezeit und die Ruhezeit an Feiertagen abweichend von den §§ 3, 4 und 7 geregelt werden.

(2)
1. Die wöchentliche Ruhezeit darf in einzelnen Wochen 36 Stunden unterschreiten oder ganz unterbleiben, wenn in einem kollektivvertraglich festgelegten Zeitraum eine durchschnittliche Ruhezeit von 36 Stunden erreicht wird. Zur Berechnung dürfen nur mindestens 24stündige Ruhezeiten herangezogen werden.
2. Die Lage der Ersatzruhe kann abweichend von § 6 festgelegt werden.
3. Zur Aufrechterhaltung der ordnungsgemäßen Bewachung kann eine finanzielle Abgeltung der Ersatzruhe vorgesehen werden.

6. ABSCHNITT

Allgemeine Vorschriften

Auflage des Gesetzes

§ 23. Der Arbeitgeber hat einen Abdruck dieses Bundesgesetzes und der auf Grund dieses Bundesgesetzes erlassenen Verordnungen, soweit sie für den Betrieb in Betracht kommen, sowie eine Abschrift der für den Betrieb allenfalls ergangenen Bescheide an geeigneter, für die Arbeitnehmer leicht zugänglicher Stelle aufzulegen.

Aushang der Ruhezeitenregelung

§ 24. Der Arbeitgeber hat an einer für die Arbeitnehmer des Betriebes leicht zugänglichen Stelle einen Aushang über den Beginn und das Ende der wöchentlichen Ruhezeit gut sichtbar anzubringen.

Aufzeichnungen und Auskunftspflicht

§ 25. (1) Der Arbeitgeber hat zur Überwachung der Einhaltung der Ruhezeiten Aufzeichnungen über Ort, Dauer und Art der Beschäftigung aller während der Wochenend-, Wochen-, Ersatz- oder Feiertagsruhe beschäftigten Arbeitnehmer und deren Entlohnung sowie über die gemäß § 6 gewährte Ersatzruhe zu führen.

(2) Der Arbeitgeber hat der Arbeitsinspektion und ihren Organen die erforderlichen Auskünfte zu erteilen und auf Verlangen die gemäß Abs. 1 zu führenden Aufzeichnungen zur Einsicht vorzulegen.

Behördenzuständigkeit und Verfahrensvorschriften

§ 26. (1) Die nach diesem Bundesgesetz den Arbeitsinspektoraten zustehenden Aufgaben und Befugnisse sind in den vom Wirkungsbereich der Arbeitsinspektion ausgenommenen Betrieben von den zur Wahrung des Arbeitnehmerschutzes sonst berufenen Behörden wahrzunehmen.

(2) Über Berufungen gegen Bescheide der Arbeitsinspektorate entscheidet der Bundesminister für soziale Verwaltung, soweit es sich um Bescheide einer Berghauptmannschaft handelt, der Bundesminister für Handel, Gewerbe und Industrie.

(3) Die den Arbeitsinspektoraten nach diesem Bundesgesetz zustehenden Aufgaben und Befugnisse, die sich über den Wirkungsbereich eines Arbeitsinspektorates hinaus erstrecken, sind vom Bundesminister für soziale Verwaltung, die sich über den Wirkungsbereich einer Berghauptmannschaft hinaus erstrecken, vom Bundesminister für Handel, Gewerbe und Industrie wahrzunehmen.

(4) Anzeigen gemäß § 10 Abs. 2, § 11 Abs. 2 und 4 und § 12 Abs. 3 sind von Stempel- und Rechtsgebühren des Bundes befreit.

Strafbestimmungen

§ 27. (1) Arbeitgeber oder deren gesetzliche Vertreter, die den §§ 3, 4, 5 Abs. 1 und 2, §§ 6, 7, 8 und 9 Abs. 1 bis 3 und 5 und den §§ 10 bis 18 und 23 bis 25 zuwiderhandeln, sind, sofern die Tat nicht nach anderen Vorschriften einer strengeren Strafe unterliegt, von der Bezirksverwaltungsbehörde, soweit es sich um Betriebe handelt, die der bergbehördlichen Aufsicht unterstehen, von der Berghauptmannschaft mit einer Geldstrafe von 500 S bis 30 000 S zu bestrafen.

(2) Besteht bei einer Bezirksverwaltungsbehörde (Berghauptmannschaft) der Verdacht einer Zuwiderhandlung durch ein Organ einer Gebietskörperschaft, so hat die Behörde, wenn es sich um ein Organ des Bundes oder eines Landes handelt, eine Anzeige an das oberste Organ, welchem das der Zuwiderhandlung verdächtigte Organ untersteht, in allen anderen Fällen aber eine Anzeige an die Aufsichtsbehörde zu erstatten.

Weitergelten von Regelungen

§ 28. (1) Bei Inkrafttreten dieses Bundesgesetzes bestehende für die Arbeitnehmer günstigere Regelungen in Kollektivverträgen, Arbeits-(Dienst-) Ordnungen, Betriebsvereinbarungen oder Arbeitsverträgen werden durch dieses Bundesgesetz nicht berührt.

(2) Bei Inkrafttreten dieses Bundesgesetzes bestehende Bestimmungen in Kollektivverträgen in Angelegenheiten, die durch Kollektivvertrag abweichend geregelt werden können, gelten als solche abweichende Regelungen. Bestehende kollektivvertragliche Ansprüche können auf Ansprüche gemäß § 19 Abs. 2 Z 3, § 20 Abs. 2 Z 3, § 21 Abs. 2 Z 3 und § 22 Abs. 2 Z 3 nur insoweit angerechnet werden, als dadurch die Belastung der Arbeit während der wöchentlichen Ruhezeit nicht aber Mehrarbeit oder andere Arbeitserschwernisse abgegolten werden.

(3) Bestehende kollektivvertragliche Ansprüche können auf Ansprüche gemäß § 9 Abs. 5 nur insoweit angerechnet werden, als dadurch die Belastung der Feiertagsarbeit nicht aber Mehrarbeit oder andere Arbeitserschwernisse abgegolten werden.

7. ABSCHNITT

Übergangs- und Schlußbestimmungen

Außerkrafttreten von Ausnahmegenehmigungen

§ 29. Bescheide, mit Ausnahme der Strafbescheide, die auf Grund von Vorschriften erlassen worden sind, die durch dieses Bundesgesetz außer Kraft gesetzt werden, verlieren spätestens mit Ablauf von sechs Monaten nach Inkrafttreten dieses Bundesgesetzes ihre Wirksamkeit, wenn nicht innerhalb dieser Frist um eine Ausnahmegenehmigung nach diesem Bundesgesetz angesucht wird.

Anhängige Verfahren

§ 30. (1) Auf die im Zeitpunkt des Inkrafttretens dieses Bundesgesetzes anhängigen Verwaltungsverfahren ist an Stelle der aufgehobenen Vorschriften dieses Bundesgesetz anzuwenden.

(2) Die Bestimmungen dieses Bundesgesetzes sind auch auf strafbare Handlungen oder Unterlassungen anzuwenden, die vor seinem Inkrafttreten begangen worden sind, sofern diese dadurch nicht einer strengeren Strafe unterliegen als nach den bisher geltenden Vorschriften.

Aufhebung von Rechtsvorschriften

§ 31. (1) Mit Inkrafttreten dieses Bundesgesetzes treten außer Kraft:

1. Das Gesetz vom 28. Juli 1902, RGBl. Nr. 156, betreffend die Regelung des Arbeitsverhältnisses der bei Regiebauten von Eisenbahnen und in den Hilfsanstalten derselben verwendeten Arbeiter, in der Fassung des Gesetzes StGBl. Nr. 42/1919 und der Bundesgesetze BGBl. Nr. 191/1928, 50/1948 und 234/1972;
2. § 3 des Privat-Kraftwagenführergesetzes, BGBl. Nr. 359/1928, in der Fassung der Bundesgesetze BGBl. Nr. 174/1946, 50/1948, 313/1964, 317/1971 und 390/1976;
3. Artikel VI des Angestelltengesetzes, BGBl. Nr. 292/1921, in der Fassung der Bundesgesetze BGBl. Nr. 229/1937, 174/1946, 159/1947, 108/1958, 253/1959, 292/1971, 317/1971, 418/1975, 390/1976 und 107/1979;
4. die Verordnung des Justizministers im Einvernehmen mit dem Minister des Inneren und dem Leiter des Handelsministeriums vom 30. Juni 1911, RGBl. Nr. 129, über die Einhaltung der Sonn- und Feiertagsruhe in den Kanzleien der Rechtsanwälte und Notare, in der Fassung des Gesetzes StGBl. Nr. 95/1919 und der Vollzugsanweisung StGBl. Nr. 124/1920;
5. die Vollzugsanweisung des Staatsamtes für Handel und Gewerbe, Industrie und Bauten im Einvernehmen mit den beteiligten Staatsämtern vom 24. Juni 1919, StGBl. Nr. 326, über die Sonntagsruhe in den Kanzleien der Patentanwälte;
6. die Verordnung des Bundesministers für Handel und Verkehr vom 6. April 1933, BGBl. Nr. 166, betreffend die Bewilligung von Ausnahmen von der Feiertagsruhe für den Bergbau;
7. das Gesetz vom 16. Jänner 1895, RGBl. Nr. 21, betreffend die Regelung der Sonn- und Feiertagsruhe im Gewerbebetriebe, in der Fassung der Gesetze RGBl. Nr. 125/1905 und StGBl. Nr. 282/1919 sowie der Bundesgesetze BGBl. II Nr. 421/1934, BGBl. Nr. 548/1935, 194/1947 und 156/1958 hinsichtlich seiner arbeitsrechtlichen Bestimmungen;
8. das Gesetz vom 15. Mai 1919, StGBl. Nr. 282, über die Mindestruhezeit, den Ladenschluß und die Sonntagsruhe in Handelsgewerben und anderen Betrieben, in der Fassung des Bundesgesetztes BGBl. Nr. 50/1974;

9. § 2 Abs. 1 Z 2, 4, 6 und 7 und § 5 des Feiertagsruhegesetzes 1957, BGBl. Nr. 153, in der Fassung des Bundesgesetzes BGBl. Nr. 264/1967;
10. die §§ 9, 10 und 12 Abs. 1 des Bergarbeitergesetzes, StGBl. Nr. 406/1919, in der Fassung des Bundesgesetzes BGBl. Nr. 190/1928, der Verordnung BGBl. Nr. 209/1933 und des Bundesgesetzes BGBl. Nr. 50/1948;
11. die Verordnung des Bundesministers für soziale Verwaltung im Einvernehmen mit den Bundesministern für Handel und Verkehr und für Unterricht vom 26. Juni 1933, BGBl. Nr. 261, betreffend Ausnahmen von der Arbeitsruhe an Feiertagen (Ruhe- und Festtagen);
12. die Verordnung der Bundesregierung vom 28. Juni 1933, BGBl. Nr. 262, betreffend Ausnahmen von der Arbeitsruhe an Feiertagen (Ruhe- und Festtagen) in der Fassung des Bundesgesetzes BGBl. Nr. 455/1937;
13. die Verordnung des Handelsministers im Einvernehmen mit dem Minister des Inneren und dem Minister für Kultus und Unterricht vom 24. April 1895, RGBl. Nr. 58, womit in Durchführung des Gesetzes vom 16. Jänner 1895, RGBl. Nr. 21, betreffend die Regelung der Sonn- und Feiertagsruhe im Gewerbebetriebe, die gewerbliche Arbeit an Sonntagen bei einzelnen Kategorien von Gewerben gestattet wird, in der Fassung der Verordnungen RGBl. Nr. 125/1895, 97/1897, 76/1898, 35/1904, 99/1904, 97/1906, 186/1912, 208/1913, BGBl. Nr. 98/1924, 44/1926, 313/1927, 156/1929, 403/1935, 273/1959 und 369/1967;
14. die Verordnung des Handelsministeriums, des Ministeriums für Inneres, des Ministeriums für Kultus und Unterricht, des Finanzministeriums und des Ministeriums für Landesverteidigung im Einvernehmen mit dem k. u. k. Reichskriegsministerium vom 18. Jänner 1897 betreffend die Einhaltung der Sonntagsruhe beim Pulververschleiße, RGBl. Nr. 26;
15. die Verordnungen der Landeshauptleute, die auf Grund des § 7 der Durchführungsverordnung zum Sonntagsruhegesetz, RGBl. Nr. 58/1895, erlassen wurden;
16. § 376 Z 47 Abs. 2 lit. b bis d der GewO 1973, BGBl. Nr. 50/1974;
17. Verordnung des Landeshauptmannes von Wien vom 18. Feber 1982, LGBl. Nr. 10, betreffend Ausnahmen von der Sonn- und Feiertagsruhe im Gewerbe der Blumenbinder in Verkaufsstellen auf Bahnhöfen.

(2) Mit Inkrafttreten dieses Bundesgesetzes treten für Arbeitnehmer, die unter den Geltungsbereich dieses Bundesgesetzes fallen, folgende Rechtsvorschriften außer Kraft:

1. das Feiertagsruhegesetz 1957, BGBl. Nr. 153, in der Fassung des Bundesgesetzes BGBl. Nr. 264/1967;
2. die Verordnung des Staatsamtes für soziale Verwaltung vom 29. Oktober 1945, StGBl. Nr. 212, über die Lohnzahlung an Feiertagen, in der Fassung des Bundesgesetzes BGBl. Nr. 105/1961;
3. § 12 Abs. 3 und 4 des Arbeitszeitgesetzes, BGBl. Nr. 461/1969, in der Fassung der Bundesgesetze BGBl. Nr. 238/1971, 2/1975 und 354/1981.

Weitergelten von Rechtsvorschriften

§ 32. Verordnungen, die der Landeshauptmann auf Grund des § 1 Artikel VII oder IX des Gesetzes vom 16. Jänner 1895, RGBl. Nr. 21, betreffend die Regelung der Sonn- und Feiertagsruhe im Gewerbebetriebe, in der Fassung der Gesetze RGBl. Nr. 125/1905, StGBl. Nr. 282/1919 und BGBl. II Nr. 421/1934, BGBl. Nr. 548/1935, 194/1947 und 156/1958 erlassen hat und welche die Beschäftigung von Arbeitnehmern während der Wochenend- und Feiertagsruhe zulassen, gelten nach Inkrafttreten dieses Bundesgesetzes als bundesgesetzliche Regelung. Sie treten mit Neuerlassung der Verordnung des Landeshauptmannes, spätestens jedoch 18 Monate nach Inkrafttreten dieses Bundesgesetzes außer Kraft.

Inkrafttreten

§ 33. (1) Dieses Bundesgesetz tritt mit 1. Juli 1984 in Kraft.

(2) Verordnungen auf Grund dieses Bundesgesetzes können bereits von dem seiner Kundmachung folgenden Tag an erlassen werden. Diese Verordnungen dürfen frühestens mit dem im Abs. 1 bezeichneten Tag in Kraft gesetzt werden.

Vollziehung

§ 34. Mit der Vollziehung dieses Bundesgesetzes sind betraut:

1. der Bundeskanzler im Einvernehmen mit dem Bundesminister für soziale Verwaltung hinsichtlich der Arbeitnehmer in Betrieben des Bundes; soweit finanzielle Angelegenheiten berührt sind, auch im Einvernehmen mit dem Bundesminister für Finanzen;
2. der Bundesminister für Handel, Gewerbe und Industrie im Einvernehmen mit dem Bundesminister für soziale Verwaltung hinsichtlich der Arbeitnehmer in Betrieben, die der bergbehördlichen Aufsicht unterstehen;

3. der Bundesminister für Verkehr im Einvernehmen mit dem Bundesminister für soziale Verwaltung hinsichtlich der Arbeitnehmer in Betrieben, die dem Verkehrs-Arbeitsinspektorat unterstehen;
4. der Bundesminister für Finanzen hinsichtlich des § 26 Abs. 4;
5. der Bundesminister für Handel, Gewerbe und Industrie für Arbeitnehmer in Betrieben, die der bergbehördlichen Aufsicht unterliegen hinsichtlich der §§ 5 Abs. 3 und 4, 15 Abs. 2, 26 Abs. 2 und 3 und 27;
6. im übrigen der Bundesminister für soziale Verwaltung
   a) im Einvernehmen mit dem Bundeskanzler hinsichtlich der Arbeitnehmer in Betrieben der Länder, Gemeinden und Gemeindeverbände, soweit finanzielle Angelegenheiten berührt sind auch im Einvernehmen mit dem Bundesminister für Finanzen;
   b) im Einvernehmen mit dem Bundesminister für Handel, Gewerbe und Industrie hinsichtlich der §§ 12, 14 bis 17;
7. der Bundesminister für soziale Verwaltung hinsichtlich aller anderen Arbeitnehmer.

Kirchschläger

Kreisky

BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

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BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

Jahrgang 1999 **Ausgegeben am 17. August 1999** **Teil I**

165. Bundesgesetz: Datenschutzgesetz 2000 – DSG 2000
(NR: GP XX RV 1613 AB 2028 S. 179. BR: 5992 AB 6034 S. 657.)
[CELEX-Nr.: 395L0046]

165. Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz 2000 – DSG 2000)

Der Nationalrat hat beschlossen:

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Artikel 1
(Verfassungsbestimmung)
Grundrecht auf Datenschutz

§ 1. (1) Jedermann hat, insbesondere auch im Hinblick auf die Achtung seines Privat- und Familienlebens, Anspruch auf Geheimhaltung der ihn betreffenden personenbezogenen Daten, soweit ein schutzwürdiges Interesse daran besteht. Das Bestehen eines solchen Interesses ist ausgeschlossen, wenn Daten infolge ihrer allgemeinen Verfügbarkeit oder wegen ihrer mangelnden Rückführbarkeit auf den Betroffenen einem Geheimhaltungsanspruch nicht zugänglich sind.

(2) Soweit die Verwendung von personenbezogenen Daten nicht im lebenswichtigen Interesse des Betroffenen oder mit seiner Zustimmung erfolgt, sind Beschränkungen des Anspruchs auf Geheimhaltung nur zur Wahrung überwiegender berechtigter Interessen eines anderen zulässig, und zwar bei Eingriffen einer staatlichen Behörde nur auf Grund von Gesetzen, die aus den in Art. 8 Abs. 2 der Europäischen

Konvention zum Schutze der Menschenrechte und Grundfreiheiten (EMRK), BGBl. Nr. 210/1958, genannten Gründen notwendig sind. Derartige Gesetze dürfen die Verwendung von Daten, die ihrer Art nach besonders schutzwürdig sind, nur zur Wahrung wichtiger öffentlicher Interessen vorsehen und müssen gleichzeitig angemessene Garantien für den Schutz der Geheimhaltungsinteressen der Betroffenen festlegen. Auch im Falle zulässiger Beschränkungen darf der Eingriff in das Grundrecht jeweils nur in der gelindesten, zum Ziel führenden Art vorgenommen werden.

(3) Jedermann hat, soweit ihn betreffende personenbezogene Daten zur automationsunterstützten Verarbeitung oder zur Verarbeitung in manuell, dh. ohne Automationsunterstützung geführten Dateien bestimmt sind, nach Maßgabe gesetzlicher Bestimmungen

1. das Recht auf Auskunft darüber, wer welche Daten über ihn verarbeitet, woher die Daten stammen, und wozu sie verwendet werden, insbesondere auch, an wen sie übermittelt werden;
2. das Recht auf Richtigstellung unrichtiger Daten und das Recht auf Löschung unzulässigerweise verarbeiteter Daten.

(4) Beschränkungen der Rechte nach Abs. 3 sind nur unter den in Abs. 2 genannten Voraussetzungen zulässig.

(5) Gegen Rechtsträger, die in Formen des Privatrechts eingerichtet sind, ist, soweit sie nicht in Vollziehung der Gesetze tätig werden, das Grundrecht auf Datenschutz mit Ausnahme des Rechtes auf Auskunft auf dem Zivilrechtsweg geltend zu machen. In allen übrigen Fällen ist die Datenschutzkommission zur Entscheidung zuständig, es sei denn, daß Akte der Gesetzgebung oder der Gerichtsbarkeit betroffen sind.

Zuständigkeit

§ 2. (1) Bundessache ist die Gesetzgebung in Angelegenheiten des Schutzes personenbezogener Daten im automationsunterstützten Datenverkehr.

(2) Die Vollziehung solcher Bundesgesetze steht dem Bund zu. Soweit solche Daten von einem Land, im Auftrag eines Landes, von oder im Auftrag von juristischen Personen, die durch Gesetz eingerichtet sind und deren Einrichtung hinsichtlich der Vollziehung in die Zuständigkeit der Länder fällt, verwendet werden, sind diese Bundesgesetze von den Ländern zu vollziehen, soweit nicht durch Bundesgesetz die Datenschutzkommission, der Datenschutzrat oder Gerichte mit der Vollziehung betraut werden.

Räumlicher Anwendungsbereich

§ 3. (1) Die Bestimmungen dieses Bundesgesetzes sind auf die Verwendung von personenbezogenen Daten im Inland anzuwenden. Darüber hinaus ist dieses Bundesgesetz auf die Verwendung von Daten im Ausland anzuwenden, soweit diese Verwendung in anderen Mitgliedstaaten der Europäischen Union für Zwecke einer in Österreich gelegenen Haupt- oder Zweigniederlassung (§ 4 Z 15) eines Auftraggebers (§ 4 Z 4) geschieht.

(2) Abweichend von Abs. 1 ist das Recht des Sitzstaates des Auftraggebers auf eine Datenverarbeitung im Inland anzuwenden, wenn ein Auftraggeber des privaten Bereichs (§ 5 Abs. 3) mit Sitz in einem anderen Mitgliedstaat der Europäischen Union personenbezogene Daten in Österreich zu einem Zweck verwendet, der keiner in Österreich gelegenen Niederlassung dieses Auftraggebers zuzurechnen ist.

(3) Weiters ist dieses Bundesgesetz nicht anzuwenden, soweit personenbezogene Daten durch das Inland nur durchgeführt werden.

(4) Von den Abs. 1 bis 3 abweichende gesetzliche Regelungen sind nur in Angelegenheiten zulässig, die nicht dem Recht der Europäischen Gemeinschaften unterliegen.

Artikel 2

1. Abschnitt

Allgemeines

Definitionen

§ 4. Im Sinne der folgenden Bestimmungen dieses Bundesgesetzes bedeuten die Begriffe:

1. „Daten“ („personenbezogene Daten“): Angaben über Betroffene (Z 3), deren Identität bestimmt oder bestimmbar ist; „nur indirekt personenbezogen“ sind Daten für einen Auftraggeber (Z 4), Dienstleister (Z 5) oder Empfänger einer Übermittlung (Z 12) dann, wenn der Personenbezug der

Daten derart ist, daß dieser Auftraggeber, Dienstleister oder Übermittlungsempfänger die Identität des Betroffenen mit rechtlich zulässigen Mitteln nicht bestimmen kann;

2. „sensible Daten“ („besonders schutzwürdige Daten“): Daten natürlicher Personen über ihre rassische und ethnische Herkunft, politische Meinung, Gewerkschaftszugehörigkeit, religiöse oder philosophische Überzeugung, Gesundheit oder ihr Sexualleben;
3. „Betroffener“: jede vom Auftraggeber (Z 4) verschiedene natürliche oder juristische Person oder Personengemeinschaft, deren Daten verwendet (Z 8) werden;
4. „Auftraggeber“: natürliche oder juristische Personen, Personengemeinschaften oder Organe einer Gebietskörperschaft beziehungsweise die Geschäftsapparate solcher Organe, wenn sie allein oder gemeinsam mit anderen die Entscheidung getroffen haben, Daten für einen bestimmten Zweck zu verarbeiten (Z 9), und zwar unabhängig davon, ob sie die Verarbeitung selbst durchführen oder hiezu einen anderen heranziehen. Als Auftraggeber gelten die genannten Personen, Personengemeinschaften und Einrichtungen auch dann, wenn sie einem anderen Daten zur Herstellung eines von ihnen aufgetragenen Werkes überlassen und der Auftragnehmer die Entscheidung trifft, diese Daten zu verarbeiten. Wurde jedoch dem Auftragnehmer anläßlich der Auftragserteilung die Verarbeitung der überlassenen Daten ausdrücklich untersagt oder hat der Auftragnehmer die Entscheidung über die Art und Weise der Verwendung, insbesondere die Vornahme einer Verarbeitung der überlassenen Daten, auf Grund von Rechtsvorschriften, Standesregeln oder Verhaltensregeln gemäß § 6 Abs. 4 eigenverantwortlich zu treffen, so gilt der mit der Herstellung des Werkes Betraute als datenschutzrechtlicher Auftraggeber;
5. „Dienstleister“: natürliche oder juristische Personen, Personengemeinschaften oder Organe einer Gebietskörperschaft beziehungsweise die Geschäftsapparate solcher Organe, wenn sie Daten, die ihnen zur Herstellung eines aufgetragenen Werkes überlassen wurden, verwenden (Z 8);
6. „Datei“: strukturierte Sammlung von Daten, die nach mindestens einem Suchkriterium zugänglich sind;
7. „Datenanwendung“ (früher: „Datenverarbeitung“): die Summe der in ihrem Ablauf logisch verbundenen Verwendungsschritte (Z 8), die zur Erreichung eines inhaltlich bestimmten Ergebnisses (des Zweckes der Datenanwendung) geordnet sind und zur Gänze oder auch nur teilweise automationsunterstützt, also maschinell und programmgesteuert, erfolgen (automationsunterstützte Datenanwendung);
8. „Verwenden von Daten“: jede Art der Handhabung von Daten einer Datenanwendung, also sowohl das Verarbeiten (Z 9) als auch das Übermitteln (Z 12) von Daten;
9. „Verarbeiten von Daten“: das Ermitteln, Erfassen, Speichern, Aufbewahren, Ordnen, Vergleichen, Verändern, Verknüpfen, Vervielfältigen, Abfragen, Ausgeben, Benützen, Überlassen (Z 11), Sperren, Löschen, Vernichten oder jede andere Art der Handhabung von Daten einer Datenanwendung durch den Auftraggeber oder Dienstleister mit Ausnahme des Übermittelns (Z 12) von Daten;
10. „Ermitteln von Daten“: das Erheben von Daten in der Absicht, sie in einer Datenanwendung zu verwenden;
11. „Überlassen von Daten“: die Weitergabe von Daten vom Auftraggeber an einen Dienstleister;
12. „Übermitteln von Daten“: die Weitergabe von Daten einer Datenanwendung an andere Empfänger als den Betroffenen, den Auftraggeber oder einen Dienstleister, insbesondere auch das Veröffentlichen solcher Daten; darüber hinaus auch die Verwendung von Daten für ein anderes Aufgabengebiet des Auftraggebers;
13. „Informationsverbundsystem“: die gemeinsame Verarbeitung von Daten in einer Datenanwendung durch mehrere Auftraggeber und die gemeinsame Benützung der Daten in der Art, daß jeder Auftraggeber auch auf jene Daten im System Zugriff hat, die von den anderen Auftraggebern dem System zur Verfügung gestellt wurden;
14. „Zustimmung“: die gültige, insbesondere ohne Zwang abgegebene Willenserklärung des Betroffenen, daß er in Kenntnis der Sachlage für den konkreten Fall in die Verwendung seiner Daten einwilligt;
15. „Niederlassung“: jede durch feste Einrichtungen an einem bestimmten Ort räumlich und funktional abgegrenzte Organisationseinheit mit oder ohne Rechtspersönlichkeit, die am Ort ihrer Einrichtung auch tatsächlich Tätigkeiten ausübt.

Öffentlicher und privater Bereich

§ 5. (1) Datenanwendungen sind dem öffentlichen Bereich im Sinne dieses Bundesgesetzes zuzurechnen, wenn sie für Zwecke eines Auftraggebers des öffentlichen Bereichs (Abs. 2) durchgeführt werden.

(2) Auftraggeber des öffentlichen Bereichs sind alle Auftraggeber,

1. die in Formen des öffentlichen Rechts eingerichtet sind, insbesondere auch als Organ einer Gebietskörperschaft, oder
2. soweit sie trotz ihrer Einrichtung in Formen des Privatrechts in Vollziehung der Gesetze tätig sind.

(3) Die dem Abs. 2 nicht unterliegenden Auftraggeber gelten als Auftraggeber des privaten Bereichs im Sinne dieses Bundesgesetzes.

2. Abschnitt

Verwendung von Daten

Grundsätze

§ 6. (1) Daten dürfen nur

1. nach Treu und Glauben und auf rechtmäßige Weise verwendet werden;
2. für festgelegte, eindeutige und rechtmäßige Zwecke ermittelt und nicht in einer mit diesen Zwecken unvereinbaren Weise weiterverwendet werden; die Weiterverwendung für wissenschaftliche oder statistische Zwecke ist nach Maßgabe der §§ 46 und 47 zulässig;
3. soweit sie für den Zweck der Datenanwendung wesentlich sind, verwendet werden und über diesen Zweck nicht hinausgehen;
4. so verwendet werden, daß sie im Hinblick auf den Verwendungszweck im Ergebnis sachlich richtig und, wenn nötig, auf den neuesten Stand gebracht sind;
5. solange in personenbezogener Form aufbewahrt werden, als dies für die Erreichung der Zwecke, für die sie ermittelt wurden, erforderlich ist; eine längere Aufbewahrungsdauer kann sich aus besonderen gesetzlichen, insbesondere archivrechtlichen Vorschriften ergeben.

(2) Der Auftraggeber trägt bei jeder seiner Datenanwendungen die Verantwortung für die Einhaltung der in Abs. 1 genannten Grundsätze; dies gilt auch dann, wenn er für die Datenanwendung Dienstleister heranzieht.

(3) Der Auftraggeber einer diesem Bundesgesetz unterliegenden Datenanwendung hat, wenn er nicht im Gebiet der Europäischen Union niedergelassen ist, einen in Österreich ansässigen Vertreter zu benennen, der unbeschadet der Möglichkeit eines Vorgehens gegen den Auftraggeber selbst namens des Auftraggebers verantwortlich gemacht werden kann.

(4) Zur näheren Festlegung dessen, was in einzelnen Bereichen als Verwendung von Daten nach Treu und Glauben anzusehen ist, können für den privaten Bereich die gesetzlichen Interessenvertretungen, sonstige Berufsverbände und vergleichbare Einrichtungen Verhaltensregeln ausarbeiten. Solche Verhaltensregeln dürfen nur veröffentlicht werden, nachdem sie dem Bundeskanzler zur Begutachtung vorgelegt wurden und dieser ihre Übereinstimmung mit den Bestimmungen dieses Bundesgesetzes begutachtet und als gegeben erachtet hat.

Zulässigkeit der Verwendung von Daten

§ 7. (1) Daten dürfen nur verarbeitet werden, soweit Zweck und Inhalt der Datenanwendung von den gesetzlichen Zuständigkeiten oder rechtlichen Befugnissen des jeweiligen Auftraggebers gedeckt sind und die schutzwürdigen Geheimhaltungsinteressen der Betroffenen nicht verletzen.

(2) Daten dürfen nur übermittelt werden, wenn

1. sie aus einer gemäß Abs. 1 zulässigen Datenanwendung stammen und
2. der Empfänger dem Übermittelnden seine ausreichende gesetzliche Zuständigkeit oder rechtliche Befugnis – soweit diese nicht außer Zweifel steht – im Hinblick auf den Übermittlungszweck glaubhaft gemacht hat und
3. durch Zweck und Inhalt der Übermittlung die schutzwürdigen Geheimhaltungsinteressen des Betroffenen nicht verletzt werden.

(3) Die Zulässigkeit einer Datenverwendung setzt voraus, daß die dadurch verursachten Eingriffe in das Grundrecht auf Datenschutz nur im erforderlichen Ausmaß und mit den gelindesten zur Verfügung stehenden Mitteln erfolgen und daß die Grundsätze des § 6 eingehalten werden.

Schutzwürdige Geheimhaltungsinteressen bei Verwendung nicht-sensibler Daten

§ 8. (1) Gemäß § 1 Abs. 1 bestehende schutzwürdige Geheimhaltungsinteressen sind bei Verwendung nicht-sensibler Daten dann nicht verletzt, wenn

1. eine ausdrückliche gesetzliche Ermächtigung oder Verpflichtung zur Verwendung der Daten besteht oder

2. der Betroffene der Verwendung seiner Daten zugestimmt hat, wobei ein Widerruf jederzeit möglich ist und die Unzulässigkeit der weiteren Verwendung der Daten bewirkt, oder
3. lebenswichtige Interessen des Betroffenen die Verwendung erfordern oder
4. überwiegende berechtigte Interessen des Auftraggebers oder eines Dritten die Verwendung erfordern.

(2) Bei der Verwendung von zulässigerweise veröffentlichten Daten oder von nur indirekt personenbezogenen Daten gelten schutzwürdige Geheimhaltungsinteressen als nicht verletzt. Das Recht, gegen die Verwendung solcher Daten gemäß § 28 Widerspruch zu erheben, bleibt unberührt.

(3) Schutzwürdige Geheimhaltungsinteressen sind aus dem Grunde des Abs. 1 Z 4 insbesondere dann nicht verletzt, wenn die Verwendung der Daten

1. für einen Auftraggeber des öffentlichen Bereichs eine wesentliche Voraussetzung für die Wahrnehmung einer ihm gesetzlich übertragenen Aufgabe ist oder
2. durch Auftraggeber des öffentlichen Bereichs in Erfüllung der Verpflichtung zur Amtshilfe geschieht oder
3. zur Wahrung lebenswichtiger Interessen eines Dritten erforderlich ist oder
4. zur Erfüllung einer vertraglichen Verpflichtung zwischen Auftraggeber und Betroffenem erforderlich ist oder
5. zur Geltendmachung, Ausübung oder Verteidigung von Rechtsansprüchen des Auftraggebers vor einer Behörde notwendig ist und die Daten rechtmäßig ermittelt wurden oder
6. ausschließlich die Ausübung einer öffentlichen Funktion durch den Betroffenen zum Gegenstand hat.

(4) Die Verwendung von Daten über gerichtlich oder verwaltungsbehördlich strafbare Handlungen oder Unterlassungen, insbesondere auch über den Verdacht der Begehung von Straftaten, sowie über strafrechtliche Verurteilungen oder vorbeugende Maßnahmen verstößt – unbeschadet der Bestimmungen des Abs. 2 – nur dann nicht gegen schutzwürdige Geheimhaltungsinteressen des Betroffenen, wenn

1. eine ausdrückliche gesetzliche Ermächtigung oder Verpflichtung zur Verwendung solcher Daten besteht oder
2. die Verwendung derartiger Daten für Auftraggeber des öffentlichen Bereichs eine wesentliche Voraussetzung zur Wahrnehmung einer ihnen gesetzlich übertragenen Aufgabe ist oder
3. sich sonst die Zulässigkeit der Verwendung dieser Daten aus gesetzlichen Sorgfaltspflichten oder sonstigen, die schutzwürdigen Geheimhaltungsinteressen des Betroffenen überwiegenden berechtigten Interessen des Auftraggebers ergibt und die Art und Weise, in der die Datenanwendung vorgenommen wird, die Wahrung der Interessen der Betroffenen nach diesem Bundesgesetz gewährleistet.

Schutzwürdige Geheimhaltungsinteressen bei Verwendung sensibler Daten

§ 9. Schutzwürdige Geheimhaltungsinteressen werden bei der Verwendung sensibler Daten ausschließlich dann nicht verletzt, wenn

1. der Betroffene die Daten offenkundig selbst öffentlich gemacht hat oder
2. die Daten in nur indirekt personenbezogener Form verwendet werden oder
3. sich die Ermächtigung oder Verpflichtung zur Verwendung aus gesetzlichen Vorschriften ergibt, soweit diese der Wahrung eines wichtigen öffentlichen Interesses dienen, oder
4. die Verwendung durch Auftraggeber des öffentlichen Bereichs in Erfüllung ihrer Verpflichtung zur Amtshilfe geschieht oder
5. Daten verwendet werden, die ausschließlich die Ausübung einer öffentlichen Funktion durch den Betroffenen zum Gegenstand haben, oder
6. der Betroffene seine Zustimmung zur Verwendung der Daten ausdrücklich erteilt hat, wobei ein Widerruf jederzeit möglich ist und die Unzulässigkeit der weiteren Verwendung der Daten bewirkt, oder
7. die Verarbeitung oder Übermittlung zur Wahrung lebenswichtiger Interessen des Betroffenen notwendig ist und seine Zustimmung nicht rechtzeitig eingeholt werden kann oder
8. die Verwendung der Daten zur Wahrung lebenswichtiger Interessen eines anderen notwendig ist oder
9. die Verwendung zur Geltendmachung, Ausübung oder Verteidigung von Rechtsansprüchen des Auftraggebers vor einer Behörde notwendig ist und die Daten rechtmäßig ermittelt wurden oder
10. Daten für private Zwecke gemäß § 45 oder für wissenschaftliche Forschung oder Statistik gemäß § 46 oder zur Benachrichtigung oder Befragung des Betroffenen gemäß § 47 verwendet werden oder

11. die Verwendung erforderlich ist, um den Rechten und Pflichten des Auftraggebers auf dem Gebiet des Arbeits- oder Dienstrechts Rechnung zu tragen, und sie nach besonderen Rechtsvorschriften zulässig ist, wobei die dem Betriebsrat nach dem Arbeitsverfassungsgesetz zustehenden Befugnisse im Hinblick auf die Datenverwendung unberührt bleiben, oder
12. die Daten zum Zweck der Gesundheitsvorsorge, der medizinischen Diagnostik, der Gesundheitsversorgung oder -behandlung oder für die Verwaltung von Gesundheitsdiensten erforderlich ist, und die Verwendung dieser Daten durch ärztliches Personal oder sonstige Personen erfolgt, die einer entsprechenden Geheimhaltungspflicht unterliegen, oder
13. nicht auf Gewinn gerichtete Vereinigungen mit politischem, philosophischem, religiösem oder gewerkschaftlichem Tätigkeitszweck Daten, die Rückschlüsse auf die politische Meinung oder weltanschauliche Überzeugung natürlicher Personen zulassen, im Rahmen ihrer erlaubten Tätigkeit verarbeiten und es sich hiebei um Daten von Mitgliedern, Förderern oder sonstigen Personen handelt, die regelmäßig ihr Interesse für den Tätigkeitszweck der Vereinigung bekundet haben; diese Daten dürfen, sofern sich aus gesetzlichen Vorschriften nichts anderes ergibt, nur mit Zustimmung der Betroffenen an Dritte weitergegeben werden.

Zulässigkeit der Überlassung von Daten zur Erbringung von Dienstleistungen

§ 10. (1) Auftraggeber dürfen bei ihren Datenanwendungen Dienstleister in Anspruch nehmen, wenn diese ausreichende Gewähr für eine rechtmäßige und sichere Datenverwendung bieten. Der Auftraggeber hat mit dem Dienstleister die hiefür notwendigen Vereinbarungen zu treffen und sich von ihrer Einhaltung durch Einholung der erforderlichen Informationen über die vom Dienstleister tatsächlich getroffenen Maßnahmen zu überzeugen.

(2) Die beabsichtigte Heranziehung eines Dienstleisters durch einen Auftraggeber des öffentlichen Bereichs im Rahmen einer Datenanwendung, die der Vorabkontrolle gemäß § 18 Abs. 2 unterliegt, ist der Datenschutzkommission mitzuteilen, es sei denn, daß die Inanspruchnahme des Dienstleisters auf Grund ausdrücklicher gesetzlicher Ermächtigung erfolgt oder als Dienstleister eine Organisationseinheit tätig wird, die mit dem Auftraggeber oder einem diesem übergeordneten Organ in einem Über- oder Unterordnungsverhältnis steht. Kommt die Datenschutzkommission zur Auffassung, daß die geplante Inanspruchnahme eines Dienstleisters geeignet ist, schutzwürdige Geheimhaltungsinteressen der Betroffenen zu gefährden, so hat sie dies dem Auftraggeber unverzüglich mitzuteilen. Im übrigen gilt § 30 Abs. 6 Z 4.

Pflichten des Dienstleisters

§ 11. (1) Unabhängig von allfälligen vertraglichen Vereinbarungen haben Dienstleister bei der Verwendung von Daten für den Auftraggeber jedenfalls folgende Pflichten:

1. die Daten ausschließlich im Rahmen der Aufträge des Auftraggebers zu verwenden; insbesondere ist die Übermittlung der verwendeten Daten ohne Auftrag des Auftraggebers verboten;
2. alle gemäß § 14 erforderlichen Datensicherheitsmaßnahmen zu treffen; insbesondere dürfen für die Dienstleistung nur solche Mitarbeiter herangezogen werden, die sich dem Dienstleister gegenüber zur Einhaltung des Datengeheimnisses verpflichtet haben oder einer gesetzlichen Verschwiegenheitspflicht unterliegen;
3. weitere Dienstleister nur mit Billigung des Auftraggebers heranzuziehen und deshalb den Auftraggeber von der beabsichtigten Heranziehung eines weiteren Dienstleisters so rechtzeitig zu verständigen, daß er dies allenfalls untersagen kann;
4. – sofern dies nach der Art der Dienstleistung in Frage kommt – im Einvernehmen mit dem Auftraggeber die notwendigen technischen und organisatorischen Voraussetzungen für die Erfüllung der Auskunfts-, Richtigstellungs- und Löschungspflicht des Auftraggebers zu schaffen;
5. nach Beendigung der Dienstleistung alle Verarbeitungsergebnisse und Unterlagen, die Daten enthalten, dem Auftraggeber zu übergeben oder in dessen Auftrag für ihn weiter aufzubewahren oder zu vernichten;
6. dem Auftraggeber jene Informationen zur Verfügung zu stellen, die zur Kontrolle der Einhaltung der unter Z 1 bis 5 genannten Verpflichtungen notwendig sind.

(2) Vereinbarungen zwischen dem Auftraggeber und dem Dienstleister über die nähere Ausgestaltung der in Abs. 1 genannten Pflichten sind zum Zweck der Beweissicherung schriftlich festzuhalten.

Genehmigungsfreie Übermittlung und Überlassung von Daten in das Ausland

§ 12. (1) Die Übermittlung und Überlassung von Daten an Empfänger in Mitgliedstaaten der Europäischen Union ist keinen Beschränkungen im Sinne des § 13 unterworfen. Dies gilt nicht für den

Datenverkehr zwischen Auftraggebern des öffentlichen Bereichs in Angelegenheiten, die nicht dem Recht der Europäischen Gemeinschaften unterliegen.

(2) Keiner Genehmigung gemäß § 13 bedarf weiters der Datenverkehr mit Empfängern in Drittstaaten mit angemessenem Datenschutz. Welche Drittstaaten angemessenen Datenschutz gewährleisten, wird unter Beachtung des § 55 Z 1 durch Verordnung des Bundeskanzlers festgestellt. Maßgebend für die Angemessenheit des Schutzes ist die Ausgestaltung der Grundsätze des § 6 Abs. 1 in der ausländischen Rechtsordnung und das Vorhandensein wirksamer Garantien für ihre Durchsetzung.

(3) Darüberhinaus ist der Datenverkehr ins Ausland dann genehmigungsfrei, wenn

1. die Daten im Inland zulässigerweise veröffentlicht wurden oder
2. Daten, die für den Empfänger nur indirekt personenbezogen sind, übermittelt oder überlassen werden oder
3. die Übermittlung oder Überlassung von Daten ins Ausland in Rechtsvorschriften vorgesehen ist, die im innerstaatlichen Recht den Rang eines Gesetzes haben und unmittelbar anwendbar sind, oder
4. Daten aus Datenanwendungen für private Zwecke (§ 45) oder für publizistische Tätigkeit (§ 48) übermittelt werden oder
5. der Betroffene ohne jeden Zweifel seine Zustimmung zur Übermittlung oder Überlassung seiner Daten ins Ausland gegeben hat oder
6. ein vom Auftraggeber mit dem Betroffenen oder mit einem Dritten eindeutig im Interesse des Betroffenen abgeschlossener Vertrag nicht anders als durch Übermittlung der Daten ins Ausland erfüllt werden kann oder
7. die Übermittlung zur Geltendmachung, Ausübung oder Verteidigung von Rechtsansprüchen vor ausländischen Behörden erforderlich ist und die Daten rechtmäßig ermittelt wurden, oder
8. die Übermittlung oder Überlassung in einer Standardverordnung (§ 17 Abs. 2 Z 6) oder Musterverordnung (§ 19 Abs. 2) ausdrücklich angeführt ist oder
9. es sich um Datenverkehr mit österreichischen Dienststellen im Ausland handelt oder
10. Übermittlungen oder Überlassungen aus Datenanwendungen erfolgen, die gemäß § 17 Abs. 3 von der Meldepflicht ausgenommen sind.

(4) Wenn eine Übermittlung oder Überlassung von Daten ins Ausland in Fällen, die von den vorstehenden Absätzen nicht erfaßt sind,

1. zur Wahrung eines wichtigen öffentlichen Interesses oder
2. zur Wahrung eines lebenswichtigen Interesses einer Person

notwendig und so dringlich ist, daß die gemäß § 13 erforderliche Genehmigung der Datenschutzkommission nicht eingeholt werden kann, ohne die genannten Interessen zu gefährden, darf sie ohne Genehmigung vorgenommen werden, muß aber der Datenschutzkommission umgehend mitgeteilt werden.

(5) Voraussetzung für die Zulässigkeit jeder Übermittlung oder Überlassung in das Ausland ist die Rechtmäßigkeit der Datenanwendung im Inland gemäß § 7. Bei Überlassungen ins Ausland muß darüber hinaus die schriftliche Zusage des ausländischen Dienstleisters an den inländischen Auftraggeber – oder in den Fällen des § 13 Abs. 5 an den inländischen Dienstleister – vorliegen, daß er die Dienstleisterpflichten gemäß § 11 Abs. 1 einhalten werde. Dies entfällt, wenn die Dienstleistung im Ausland in Rechtsvorschriften vorgesehen ist, die im innerstaatlichen Recht den Rang eines Gesetzes haben und unmittelbar anwendbar sind.

Genehmigungspflichtige Übermittlung und Überlassung von Daten ins Ausland

§ 13. (1) Soweit der Datenverkehr mit dem Ausland nicht gemäß § 12 genehmigungsfrei ist, hat der Auftraggeber vor der Übermittlung oder Überlassung von Daten in das Ausland eine Genehmigung der Datenschutzkommission (§§ 35 ff) einzuholen. Die Datenschutzkommission kann die Genehmigung an die Erfüllung von Bedingungen und Auflagen binden.

(2) Die Genehmigung ist unter Beachtung der gemäß § 55 Z 2 ergangenen Kundmachungen zu erteilen, wenn die Voraussetzungen des § 12 Abs. 5 vorliegen und wenn, ungeachtet des Fehlens eines im Empfängerstaat generell geltenden angemessenen Datenschutzniveaus,

1. für die im Genehmigungsantrag angeführte Übermittlung oder Überlassung im konkreten Einzelfall angemessener Datenschutz besteht; dies ist unter Berücksichtigung aller Umstände zu beurteilen, die bei der Datenverwendung eine Rolle spielen, wie insbesondere die Art der verwendeten Daten, die Zweckbestimmung sowie die Dauer der geplanten Verwendung, das Herkunfts- und das Endbestimmungsland und die in dem betreffenden Drittland geltenden allgemeinen oder sektoriellen Rechtsnormen, Standesregeln und Sicherheitsstandards; oder

2. der Auftraggeber glaubhaft macht, daß die schutzwürdigen Geheimhaltungsinteressen der vom geplanten Datenverkehr Betroffenen auch im Ausland ausreichend gewahrt werden. Hiefür können insbesondere auch vertragliche Zusicherungen des Empfängers an den Antragsteller über die näheren Umstände der Datenverwendung im Ausland von Bedeutung sein.

(3) Im Genehmigungsverfahren haben Auftraggeber des öffentlichen Bereichs auch hinsichtlich der Datenanwendungen, die sie in Vollziehung der Gesetze durchführen, Parteistellung.

(4) Bei meldepflichtigen Datenanwendungen hat die Datenschutzkommission eine Ausfertigung jedes Bescheides, mit dem eine Übermittlung oder Überlassung von Daten in das Ausland genehmigt wurde, zum Registrierungsakt zu nehmen und die Erteilung der Genehmigung im Datenverarbeitungsregister (§ 16) anzumerken.

(5) Abweichend von Abs. 1 kann auch ein inländischer Dienstleister die Genehmigung beantragen, wenn er zur Erfüllung seiner vertraglichen Verpflichtungen gegenüber mehreren Auftraggebern jeweils einen bestimmten weiteren Dienstleister im Ausland heranziehen will. Die tatsächliche Überlassung darf jeweils nur mit Zustimmung des Auftraggebers erfolgen. Der Auftraggeber hat der Datenschutzkommission mitzuteilen, aus welcher seiner meldepflichtigen Datenanwendungen die dem Dienstleister genehmigte Überlassung erfolgen soll; dies ist im Datenverarbeitungsregister anzumerken.

(6) Die Übermittlung von Daten an ausländische Vertretungsbehörden oder zwischenstaatliche Einrichtungen in Österreich gilt hinsichtlich der Pflicht zur Einholung von Genehmigungen nach Abs. 1 als Datenverkehr mit dem Ausland.

(7) Hat der Bundeskanzler trotz Fehlens eines im Empfängerstaat generell geltenden angemessenen Schutzniveaus durch Verordnung festgestellt, daß für bestimmte Kategorien des Datenverkehrs mit diesem Empfängerstaat die Voraussetzungen gemäß Abs. 2 Z 1 zutreffen, tritt an die Stelle der Verpflichtung zur Einholung einer Genehmigung die Pflicht zur Anzeige an die Datenschutzkommission. Die Datenschutzkommission hat binnen sechs Wochen ab Einlangen der Anzeige mit Bescheid den angezeigten Datenverkehr zu untersagen, wenn er keiner der in der Verordnung geregelten Kategorien zuzurechnen ist oder den Voraussetzungen gemäß § 12 Abs. 5 nicht entspricht; andernfalls ist die Übermittlung oder Überlassung der Daten in das Ausland zulässig.

3. Abschnitt

Datensicherheit

Datensicherheitsmaßnahmen

§ 14. (1) Für alle Organisationseinheiten eines Auftraggebers oder Dienstleisters, die Daten verwenden, sind Maßnahmen zur Gewährleistung der Datensicherheit zu treffen. Dabei ist je nach der Art der verwendeten Daten und nach Umfang und Zweck der Verwendung sowie unter Bedachtnahme auf den Stand der technischen Möglichkeiten und auf die wirtschaftliche Vertretbarkeit sicherzustellen, daß die Daten vor zufälliger oder unrechtmäßiger Zerstörung und vor Verlust geschützt sind, daß ihre Verwendung ordnungsgemäß erfolgt und daß die Daten Unbefugten nicht zugänglich sind.

(2) Insbesondere ist, soweit dies im Hinblick auf Abs. 1 letzter Satz erforderlich ist,

1. die Aufgabenverteilung bei der Datenverwendung zwischen den Organisationseinheiten und zwischen den Mitarbeitern ausdrücklich festzulegen,
2. die Verwendung von Daten an das Vorliegen gültiger Aufträge der anordnungsbefugten Organisationseinheiten und Mitarbeiter zu binden,
3. jeder Mitarbeiter über seine nach diesem Bundesgesetz und nach innerorganisatorischen Datenschutzvorschriften einschließlich der Datensicherheitsvorschriften bestehenden Pflichten zu belehren,
4. die Zutrittsberechtigung zu den Räumlichkeiten des Auftraggebers oder Dienstleisters zu regeln,
5. die Zugriffsberechtigung auf Daten und Programme und der Schutz der Datenträger vor der Einsicht und Verwendung durch Unbefugte zu regeln,
6. die Berechtigung zum Betrieb der Datenverarbeitungsgeräte festzulegen und jedes Gerät durch Vorkehrungen bei den eingesetzten Maschinen oder Programmen gegen die unbefugte Inbetriebnahme abzusichern,
7. Protokoll zu führen, damit tatsächlich durchgeführte Verwendungsvorgänge, wie insbesondere Änderungen, Abfragen und Übermittlungen, im Hinblick auf ihre Zulässigkeit im notwendigen Ausmaß nachvollzogen werden können,
8. eine Dokumentation über die nach Z 1 bis 7 getroffenen Maßnahmen zu führen, um die Kontrolle und Beweissicherung zu erleichtern.

Diese Maßnahmen müssen unter Berücksichtigung des Standes der Technik und der bei der Durchführung erwachsenden Kosten ein Schutzniveau gewährleisten, das den von der Verwendung ausgehenden Risiken und der Art der zu schützenden Daten angemessen ist.

(3) Nicht registrierte Übermittlungen aus Datenanwendungen, die einer Verpflichtung zur Auskunftserteilung gemäß § 26 unterliegen, sind so zu protokollieren, daß dem Betroffenen Auskunft gemäß § 26 gegeben werden kann. In der Standardverordnung (§ 17 Abs. 2 Z 6) oder in der Musterverordnung (§ 19 Abs. 2) vorgesehene Übermittlungen bedürfen keiner Protokollierung.

(4) Protokoll- und Dokumentationsdaten dürfen nicht für Zwecke verwendet werden, die mit ihrem Ermittlungszweck – das ist die Kontrolle der Zulässigkeit der Verwendung des protokollierten oder dokumentierten Datenbestandes – unvereinbar sind. Unvereinbar ist insbesondere die Weiterverwendung zum Zweck der Kontrolle von Betroffenen, deren Daten im protokollierten Datenbestand enthalten sind, oder zum Zweck der Kontrolle jener Personen, die auf den protokollierten Datenbestand zugegriffen haben, aus einem anderen Grund als jenem der Prüfung ihrer Zugriffsberechtigung, es sei denn, daß es sich um die Verwendung zum Zweck der Verhinderung oder Verfolgung eines Verbrechens nach § 278a StGB (kriminelle Organisation) oder eines Verbrechens mit einer Freiheitsstrafe, deren Höchstmaß fünf Jahre übersteigt, handelt.

(5) Sofern gesetzlich nicht ausdrücklich anderes angeordnet ist, sind Protokoll- und Dokumentationsdaten drei Jahre lang aufzubewahren. Davon darf in jenem Ausmaß abgewichen werden, als der von der Protokollierung oder Dokumentation betroffene Datenbestand zulässigerweise früher gelöscht oder länger aufbewahrt wird.

(6) Datensicherheitsvorschriften sind so zu erlassen und zur Verfügung zu halten, daß sich die Mitarbeiter über die für sie geltenden Regelungen jederzeit informieren können.

Datengeheimnis

§ 15. (1) Auftraggeber, Dienstleister und ihre Mitarbeiter – das sind Arbeitnehmer (Dienstnehmer) und Personen in einem arbeitnehmerähnlichen (dienstnehmerähnlichen) Verhältnis – haben Daten aus Datenanwendungen, die ihnen ausschließlich auf Grund ihrer berufsmäßigen Beschäftigung anvertraut wurden oder zugänglich geworden sind, unbeschadet sonstiger gesetzlicher Verschwiegenheitspflichten, geheim zu halten, soweit kein rechtlich zulässiger Grund für eine Übermittlung der anvertrauten oder zugänglich gewordenen Daten besteht (Datengeheimnis).

(2) Mitarbeiter dürfen Daten nur auf Grund einer ausdrücklichen Anordnung ihres Arbeitgebers (Dienstgebers) übermitteln. Auftraggeber und Dienstleister haben, sofern eine solche Verpflichtung ihrer Mitarbeiter nicht schon kraft Gesetzes besteht, diese vertraglich zu verpflichten, daß sie Daten aus Datenanwendungen nur auf Grund von Anordnungen übermitteln und das Datengeheimnis auch nach Beendigung des Arbeits(Dienst)verhältnisses zum Auftraggeber oder Dienstleister einhalten werden.

(3) Auftraggeber und Dienstleister dürfen Anordnungen zur Übermittlung von Daten nur erteilen, wenn dies nach den Bestimmungen dieses Bundesgesetzes zulässig ist. Sie haben die von der Anordnung betroffenen Mitarbeiter über die für sie geltenden Übermittlungsanordnungen und über die Folgen einer Verletzung des Datengeheimnisses zu belehren.

(4) Unbeschadet des verfassungsrechtlichen Weisungsrechts darf einem Mitarbeiter aus der Verweigerung der Befolgung einer Anordnung zur Datenübermittlung wegen Verstoßes gegen die Bestimmungen dieses Bundesgesetzes kein Nachteil erwachsen.

4. Abschnitt

Publizität der Datenanwendungen

Datenverarbeitungsregister

§ 16. (1) Bei der Datenschutzkommission ist ein Register der Datenanwendungen zum Zweck der Prüfung ihrer Rechtmäßigkeit und zum Zweck der Information der Betroffenen eingerichtet.

(2) Jedermann kann in das Register Einsicht nehmen. In den Registrierungsakt einschließlich darin allenfalls enthaltener Genehmigungsbescheide ist Einsicht zu gewähren, wenn der Einsichtswerber glaubhaft macht, daß er Betroffener ist, und soweit nicht überwiegende schutzwürdige Geheimhaltungsinteressen des Auftraggebers oder anderer Personen entgegenstehen.

(3) Der Bundeskanzler hat die näheren Bestimmungen über die Führung des Registers durch Verordnung zu erlassen. Dabei ist auf die Richtigkeit und Vollständigkeit des Registers, die Übersichtlichkeit und Aussagekraft der Eintragungen und die Einfachheit der Einsichtnahme Bedacht zu nehmen. Es ist die Möglichkeit vorzusehen, eine Meldung (§§ 17 und 19) auf automationsunterstütztem Wege vorzunehmen.

Meldepflicht des Auftraggebers

§ 17. (1) Jeder Auftraggeber hat, soweit in den Abs. 2 und 3 nicht anderes bestimmt ist, vor Aufnahme einer Datenanwendung eine Meldung an die Datenschutzkommission mit dem in § 19 festgelegten Inhalt zum Zweck der Registrierung im Datenverarbeitungsregister zu erstatten. Diese Meldepflicht gilt auch für Umstände, die nachträglich die Unrichtigkeit und Unvollständigkeit einer Meldung bewirken.

(2) Nicht meldepflichtig sind Datenanwendungen, die

1. ausschließlich veröffentlichte Daten enthalten oder
2. die Führung von Registern oder Verzeichnissen zum Inhalt haben, die von Gesetzes wegen öffentlich einsehbar sind, sei es auch nur bei Nachweis eines berechtigten Interesses oder
3. nur indirekt personenbezogene Daten enthalten oder
4. von natürlichen Personen ausschließlich für persönliche oder familiäre Tätigkeiten vorgenommen werden (§ 45) oder
5. für publizistische Tätigkeit gemäß § 48 vorgenommen werden oder
6. einer Standardanwendung entsprechen: Der Bundeskanzler kann durch Verordnung Typen von Datenanwendungen und Übermittlungen aus diesen zu Standardanwendungen erklären, wenn sie von einer großen Anzahl von Auftraggebern in gleichartiger Weise vorgenommen werden und angesichts des Verwendungszwecks und der verarbeiteten Datenarten die Gefährdung schutzwürdiger Geheimhaltungsinteressen der Betroffenen unwahrscheinlich ist. In der Verordnung sind für jede Standardanwendung die zulässigen Datenarten, die Betroffenen- und Empfängerkreise und die Höchstdauer der zulässigen Datenaufbewahrung festzulegen.

(3) Weiters sind Datenanwendungen für Zwecke

1. des Schutzes der verfassungsmäßigen Einrichtungen der Republik Österreich oder
2. der Sicherung der Einsatzbereitschaft des Bundesheeres oder
3. der Sicherstellung der Interessen der umfassenden Landesverteidigung oder
4. des Schutzes wichtiger außenpolitischer, wirtschaftlicher oder finanzieller Interessen der Republik Österreich oder der Europäischen Union oder
5. der Vorbeugung, Verhinderung oder Verfolgung von Straftaten

von der Meldepflicht ausgenommen, soweit dies zur Verwirklichung des Zweckes der Datenanwendung notwendig ist.

Aufnahme der Verarbeitung

§ 18. (1) Der Vollbetrieb einer meldepflichtigen Datenanwendung darf – außer in den Fällen des Abs. 2 – unmittelbar nach Abgabe der Meldung aufgenommen werden.

(2) Meldepflichtige Datenanwendungen, die weder einer Musteranwendung nach § 19 Abs. 2 entsprechen noch innere Angelegenheiten der anerkannten Kirchen und Religionsgesellschaften betreffen, dürfen, wenn sie

1. sensible Daten enthalten oder
2. strafrechtlich relevante Daten im Sinne des § 8 Abs. 4 enthalten oder
3. die Auskunftserteilung über die Kreditwürdigkeit der Betroffenen zum Zweck haben oder
4. in Form eines Informationsverbundsystems durchgeführt werden sollen,

erst nach ihrer Prüfung (Vorabkontrolle) durch die Datenschutzkommission nach den näheren Bestimmungen des § 20 aufgenommen werden.

Notwendiger Inhalt der Meldung

§ 19. (1) Eine Meldung im Sinne des § 17 hat zu enthalten:

1. den Namen (die sonstige Bezeichnung) und die Anschrift des Auftraggebers sowie eines allfälligen Vertreters gemäß § 6 Abs. 3 oder eines Betreibers gemäß § 50 Abs. 1, weiters die Registernummer des Auftraggebers, sofern ihm eine solche bereits zugeteilt wurde, und
2. den Nachweis der gesetzlichen Zuständigkeit oder der rechtlichen Befugnis für die erlaubte Ausübung der Tätigkeit des Auftraggebers, soweit dies erforderlich ist, und
3. den Zweck der zu registrierenden Datenanwendung und ihre Rechtsgrundlagen, soweit sich diese nicht bereits aus den Angaben nach Z 2 ergeben, und
4. die Kreise der von der Datenanwendung Betroffenen und die über sie verarbeiteten Datenarten und
5. die Kreise der von beabsichtigten Übermittlungen Betroffenen, die zu übermittelnden Datenarten und die zugehörigen Empfängerkreise – einschließlich allfälliger ausländischer Empfängerstaaten – sowie die Rechtsgrundlagen der Übermittlung und

6. – soweit eine Genehmigung der Datenschutzkommission notwendig ist – die Geschäftszahl der Genehmigung durch die Datenschutzkommission sowie
7. allgemeine Angaben über die getroffenen Datensicherheitsmaßnahmen im Sinne des § 14, die eine vorläufige Beurteilung der Angemessenheit der Sicherheitsvorkehrungen erlauben.

(2) Wenn eine größere Anzahl von Auftraggebern gleichartige Datenanwendungen vorzunehmen hat und die Voraussetzungen für die Erklärung zur Standardanwendung nicht vorliegen, kann der Bundeskanzler durch Verordnung Musteranwendungen festlegen. Meldungen über Datenanwendungen, die inhaltlich einer Musteranwendung entsprechen, müssen nur folgendes enthalten:

1. die Bezeichnung der Datenanwendung gemäß der Musterverordnung und
2. die Bezeichnung und Anschrift des Auftraggebers sowie den Nachweis seiner gesetzlichen Zuständigkeit oder seiner rechtlichen Befugnis, soweit dies erforderlich ist, und
3. die Registernummer des Auftraggebers, sofern ihm eine solche bereits zugeteilt wurde.

(3) Eine Meldung ist mangelhaft, wenn Angaben fehlen, offenbar unrichtig, unstimmig oder so unzureichend sind, daß Einsichtnehmer im Hinblick auf die Wahrnehmung ihrer Rechte nach diesem Bundesgesetz keine hinreichende Information darüber gewinnen können, ob durch die Datenanwendung ihre schutzwürdigen Geheimhaltungsinteressen verletzt sein könnten. Unstimmigkeit liegt insbesondere auch dann vor, wenn der Inhalt einer gemeldeten Datenanwendung durch die gemeldeten Rechtsgrundlagen nicht gedeckt ist.

Prüfungs- und Verbesserungsverfahren

§ 20. (1) Die Datenschutzkommission hat alle Meldungen binnen zwei Monaten zu prüfen. Kommt sie hiebei zur Auffassung, daß eine Meldung im Sinne des § 19 Abs. 3 mangelhaft ist, so ist dem Auftraggeber längstens innerhalb von zwei Monaten nach Einlangen der Meldung die Verbesserung des Mangels unter Setzung einer Frist aufzutragen.

(2) Liegt wegen wesentlicher Gefährdung schutzwürdiger Geheimhaltungsinteressen der Betroffenen durch die gemeldete Datenanwendung Gefahr im Verzug vor, so hat die Datenschutzkommission die Weiterführung der Datenanwendung mit Bescheid gemäß § 57 Abs. 1 AVG vorläufig zu untersagen.

(3) Bei Datenanwendungen, die gemäß § 18 Abs. 2 der Vorabkontrolle unterliegen, ist gleichzeitig mit einem allfälligen Auftrag zur Verbesserung darüber abzusprechen, ob die Verarbeitung bereits aufgenommen werden darf oder ob dies mangels Nachweises ausreichender Rechtsgrundlagen für die gemeldete Datenanwendung nicht zulässig ist.

(4) Wird einem Verbesserungsauftrag nicht fristgerecht entsprochen, so hat die Datenschutzkommission die Registrierung mit Bescheid abzulehnen; andernfalls gilt die Meldung als ursprünglich richtig eingebracht.

(5) Wird innerhalb von zwei Monaten nach Erstattung der Meldung kein Auftrag zur Verbesserung erteilt, gilt die Meldepflicht als erfüllt. Bei Datenanwendungen, die der Vorabkontrolle gemäß § 18 Abs. 2 unterliegen, darf die Verarbeitung aufgenommen werden.

(6) Im Registrierungsverfahren haben Auftraggeber des öffentlichen Bereichs auch hinsichtlich der Datenanwendungen, die sie in Vollziehung der Gesetze durchführen, Parteistellung.

Registrierung

§ 21. (1) Meldungen gemäß § 19 sind in das Datenverarbeitungsregister einzutragen, wenn

1. das Prüfungsverfahren die Zulässigkeit der Registrierung ergeben hat oder
2. zwei Monate nach Einlangung der Meldung bei der Datenschutzkommission verstrichen sind, ohne daß ein Verbesserungsauftrag gemäß § 20 Abs. 1 erteilt wurde oder
3. der Auftraggeber die verlangten Verbesserungen fristgerecht vorgenommen hat.

Die in der Meldung enthaltenen Angaben über Datensicherheitsmaßnahmen sind im Register nicht ersichtlich zu machen.

(2) Bei Datenanwendungen, die gemäß § 18 Abs. 2 der Vorabkontrolle unterliegen, können auf Grund der Ergebnisse des Prüfungsverfahrens dem Auftraggeber Auflagen für die Vornahme der Datenanwendung durch Bescheid erteilt werden, soweit dies zur Wahrung der durch dieses Bundesgesetz geschützten Interessen der Betroffenen notwendig ist.

(3) Dem Auftraggeber ist die Durchführung der Registrierung schriftlich in Form eines Registerauszuges mitzuteilen.

(4) Jedem Auftraggeber ist bei der erstmaligen Registrierung eine Registernummer zuzuteilen.

Richtigstellung des Registers

§ 22. (1) Streichungen und Änderungen im Datenverarbeitungsregister sind auf Antrag des Eingetragenen oder in den Fällen der Abs. 2 und 4 von Amts wegen durchzuführen.

(2) Gelangen der Datenschutzkommission aus amtlichen Verlautbarungen Änderungen in der Bezeichnung oder der Anschrift des Auftraggebers zur Kenntnis, so sind die Eintragungen von Amts wegen zu berichtigen. Ergibt sich aus einer amtlichen Verlautbarung der Wegfall der Rechtsgrundlage des Auftraggebers, ist von Amts wegen die Streichung aus dem Register anzuordnen.

(3) Änderungen oder Streichungen nach Abs. 2 sind ohne weiteres Ermittlungsverfahren durch Bescheid zu verfügen.

(4) Werden der Datenschutzkommission andere als die in Abs. 2 bezeichneten Umstände bekannt, die den Verdacht der Mangelhaftigkeit einer Registrierung im Sinne des § 19 Abs. 3 oder der rechtswidrigen Unterlassung einer Meldung begründen, so hat die Datenschutzkommission ein Verfahren zur Feststellung des für die Erfüllung der Meldepflicht erheblichen Sachverhalts einzuleiten und das Datenverarbeitungsregister entsprechend dem Ergebnis des Verfahrens zu berichtigen.

Pflicht zur Offenlegung nicht-meldepflichtiger Datenanwendungen

§ 23. (1) Auftraggeber einer Standardanwendung haben jedermann auf Anfrage mitzuteilen, welche Standardanwendungen sie tatsächlich vornehmen.

(2) Nicht-meldepflichtige Datenanwendungen sind der Datenschutzkommission bei Ausübung ihrer Kontrollaufgaben gemäß § 30 offenzulegen.

Informationspflicht des Auftraggebers

§ 24. (1) Der Auftraggeber einer Datenanwendung hat aus Anlaß der Ermittlung von Daten die Betroffenen in geeigneter Weise

1. über den Zweck der Datenanwendung, für die die Daten ermittelt werden, und
2. über Namen und Adresse des Auftraggebers,

zu informieren, sofern diese Informationen dem Betroffenen nach den Umständen des Falles nicht bereits vorliegen.

(2) Über Abs. 1 hinausgehende Informationen sind in geeigneter Weise zu geben, wenn dies für eine Verarbeitung nach Treu und Glauben erforderlich ist; dies gilt insbesondere dann, wenn

1. gegen eine beabsichtigte Verarbeitung oder Übermittlung von Daten ein Widerspruchsrecht des Betroffenen gemäß § 28 besteht oder
2. es für den Betroffenen nach den Umständen des Falles nicht klar erkennbar ist, ob er zur Beantwortung der an ihn gestellten Fragen rechtlich verpflichtet ist, oder
3. Daten in einem Informationsverbundsystem verarbeitet werden sollen, ohne daß dies gesetzlich vorgesehen ist.

(3) Werden Daten nicht durch Befragung des Betroffenen, sondern durch Übermittlung von Daten aus anderen Aufgabengebieten desselben Auftraggebers oder aus Anwendungen anderer Auftraggeber ermittelt, darf die Information gemäß Abs. 1 entfallen, wenn

1. die Datenverwendung durch Gesetz oder Verordnung vorgesehen ist oder
2. die Information im Hinblick auf die mangelnde Erreichbarkeit von Betroffenen unmöglich ist oder
3. wenn sie angesichts der Unwahrscheinlichkeit einer Beeinträchtigung der Betroffenenrechte einerseits und der Kosten der Information aller Betroffenen andererseits einen unverhältnismäßigen Aufwand erfordert. Dies liegt insbesondere dann vor, wenn Daten für Zwecke der wissenschaftlichen Forschung oder Statistik gemäß § 46 oder Adreßdaten im Rahmen des § 47 ermittelt werden und die Information des Betroffenen in diesen Bestimmungen nicht ausdrücklich vorgeschrieben ist. Der Bundeskanzler kann durch Verordnung weitere Fälle festlegen, in welchen die Pflicht zur Information entfällt.

(4) Keine Informationspflicht besteht bei jenen Datenanwendungen, die gemäß § 17 Abs. 2 und 3 nicht meldepflichtig sind.

Pflicht zur Offenlegung der Identität des Auftraggebers

§ 25. (1) Bei Übermittlungen und bei Mitteilungen an Betroffene hat der Auftraggeber seine Identität in geeigneter Weise offenzulegen, sodaß den Betroffenen die Verfolgung ihrer Rechte möglich ist. Bei meldepflichtigen Datenanwendungen ist in Mitteilungen an Betroffene die Registernummer des Auftraggebers anzuführen.

(2) Werden Daten aus einer Datenanwendung für Zwecke einer vom Auftraggeber verschiedenen Person verwendet, ohne daß diese ihrerseits ein Verfügungsrecht über die verwendeten Daten und damit die Eigenschaft eines Auftraggebers in Bezug auf die Daten erlangt, dann ist bei Mitteilungen an den Betroffenen neben der Identität der Person, für deren Zwecke die Daten verwendet werden, auch die Identität des Auftraggebers anzugeben, aus dessen Datenanwendung die Daten stammen. Handelt es sich hiebei um eine meldepflichtige Datenanwendung, ist die Registernummer des Auftraggebers beizufügen. Diese Pflicht trifft sowohl den Auftraggeber als auch denjenigen, in dessen Namen die Mitteilung an den Betroffenen erfolgt.

5. Abschnitt

Die Rechte des Betroffenen

Auskunftsrecht

§ 26. (1) Der Auftraggeber hat dem Betroffenen Auskunft über die zu seiner Person verarbeiteten Daten zu geben, wenn der Betroffene dies schriftlich verlangt und seine Identität in geeigneter Form nachweist. Mit Zustimmung des Auftraggebers kann das Auskunftsbegehren auch mündlich gestellt werden. Die Auskunft hat die verarbeiteten Daten, die verfügbaren Informationen über ihre Herkunft, allfällige Empfänger oder Empfängerkreise von Übermittlungen, den Zweck der Datenverwendung sowie die Rechtsgrundlagen hiefür in allgemein verständlicher Form anzuführen. Auf Verlangen des Betroffenen sind auch Namen und Adresse von Dienstleistern bekannt zu geben, falls sie mit der Verarbeitung seiner Daten beauftragt sind. Mit Zustimmung des Betroffenen kann anstelle der schriftlichen Auskunft auch eine mündliche Auskunft mit der Möglichkeit der Einsichtnahme und der Abschrift oder Ablichtung gegeben werden.

(2) Die Auskunft ist nicht zu erteilen, soweit dies zum Schutz des Betroffenen aus besonderen Gründen notwendig ist oder soweit überwiegende berechtigte Interessen des Auftraggebers oder eines Dritten, insbesondere auch überwiegende öffentliche Interessen, der Auskunftserteilung entgegenstehen. Überwiegende öffentliche Interessen können sich hiebei aus der Notwendigkeit

1. des Schutzes der verfassungsmäßigen Einrichtungen der Republik Österreich oder
2. der Sicherung der Einsatzbereitschaft des Bundesheeres oder
3. der Sicherung der Interessen der umfassenden Landesverteidigung oder
4. des Schutzes wichtiger außenpolitischer, wirtschaftlicher oder finanzieller Interessen der Republik Österreich oder der Europäischen Union oder
5. der Vorbeugung, Verhinderung oder Verfolgung von Straftaten

ergeben. Die Zulässigkeit der Auskunftsverweigerung aus den Gründen der Z 1 bis 5 unterliegt der Kontrolle durch die Datenschutzkommission nach § 30 Abs. 3 und dem besonderen Beschwerdeverfahren vor der Datenschutzkommission gemäß § 31 Abs. 4.

(3) Der Betroffene hat am Auskunftsverfahren über Befragung in dem ihm zumutbaren Ausmaß mitzuwirken, um ungerechtfertigten und unverhältnismäßigen Aufwand beim Auftraggeber zu vermeiden.

(4) Innerhalb von acht Wochen nach Einlangen des Begehrens ist die Auskunft zu erteilen oder schriftlich zu begründen, warum sie nicht oder nicht vollständig erteilt wird. Von der Erteilung der Auskunft kann auch deshalb abgesehen werden, weil der Betroffene am Verfahren nicht gemäß Abs. 3 mitgewirkt oder weil er den Kostenersatz nicht geleistet hat.

(5) In jenen Bereichen der Vollziehung, die mit der Wahrnehmung der in Abs. 2 Z 1 bis 5 bezeichneten Aufgaben betraut sind, ist, soweit dies zum Schutz jener öffentlichen Interessen notwendig ist, die eine Auskunftsverweigerung erfordert, folgendermaßen vorzugehen: Es ist in allen Fällen, in welchen keine Auskunft erteilt wird – also auch weil tatsächlich keine Daten verwendet werden –, anstelle einer inhaltlichen Begründung der Hinweis zu geben, daß keine der Auskunftspflicht unterliegenden Daten über den Betroffenen verwendet werden. Die Zulässigkeit dieser Vorgangsweise unterliegt der Kontrolle durch die Datenschutzkommission nach § 30 Abs. 3 und dem besonderen Beschwerdeverfahren vor der Datenschutzkommission nach § 31 Abs. 4.

(6) Die Auskunft ist unentgeltlich zu erteilen, wenn sie den aktuellen Datenbestand einer Datenanwendung betrifft und wenn der Betroffene im laufenden Jahr noch kein Auskunftsersuchen an den Auftraggeber zum selben Aufgabengebiet gestellt hat. In allen anderen Fällen kann ein pauschalierter Kostenersatz von 260 S verlangt werden, von dem wegen tatsächlich erwachsender höherer Kosten abgewichen werden darf. Ein etwa geleisteter Kostenersatz ist ungeachtet allfälliger Schadenersatzansprüche zurückzuerstatten, wenn Daten rechtswidrig verwendet wurden oder wenn die Auskunft sonst zu einer Richtigstellung geführt hat.

(7) Ab dem Zeitpunkt der Kenntnis von einem Auskunftsverlangen darf der Auftraggeber Daten über den Betroffenen innerhalb eines Zeitraums von vier Monaten und im Falle der Erhebung einer Beschwerde gemäß § 31 an die Datenschutzkommission bis zum rechtskräftigen Abschluß des Verfahrens nicht vernichten.

(8) Soweit Datenanwendungen von Gesetzes wegen öffentlich einsehbar sind, hat der Betroffene ein Recht auf Auskunft in dem Umfang, in dem ein Einsichtsrecht besteht. Für das Verfahren der Einsichtnahme gelten die näheren Regelungen der das öffentliche Buch oder Register einrichtenden Gesetze.

(9) Für Auskünfte aus dem Strafregister gelten die besonderen Bestimmungen des Strafregistergesetzes 1968 über Strafregisterbescheinigungen.

(10) Im Falle der auf Grund von Rechtsvorschriften, Standesregeln oder Verhaltensregeln gemäß § 6 Abs. 4 eigenverantwortlichen Entscheidung über die Durchführung einer Datenanwendung durch einen Auftragnehmer gemäß § 4 Z 4, dritter Satz, kann der Betroffene sein Auskunftsbegehren zunächst auch an denjenigen richten, der die Herstellung des Werkes aufgetragen hat. Dieser hat dem Betroffenen, soweit dies nicht ohnehin bekannt ist, binnen zwei Wochen unentgeltlich Namen und Adresse des eigenverantwortlichen Auftragnehmers mitzuteilen, damit der Betroffene sein Auskunftsrecht gemäß Abs. 1 gegen diesen geltend machen kann.

Recht auf Richtigstellung oder Löschung

§ 27. (1) Jeder Auftraggeber hat unrichtige oder entgegen den Bestimmungen dieses Bundesgesetzes verarbeitete Daten richtigzustellen oder zu löschen, und zwar

1. aus eigenem, sobald ihm die Unrichtigkeit von Daten oder die Unzulässigkeit ihrer Verarbeitung bekannt geworden ist, oder
2. auf begründeten Antrag des Betroffenen.

Der Pflicht zur Richtigstellung nach Z 1 unterliegen nur solche Daten, deren Richtigkeit für den Zweck der Datenanwendung von Bedeutung ist. Die Unvollständigkeit verwendeter Daten bewirkt nur dann einen Berichtigungsanspruch, wenn sich aus der Unvollständigkeit im Hinblick auf den Zweck der Datenanwendung die Unrichtigkeit der Gesamtinformation ergibt. Sobald Daten für den Zweck der Datenanwendung nicht mehr benötigt werden, gelten sie als unzulässig verarbeitete Daten und sind zu löschen, es sei denn, daß ihre Archivierung rechtlich zulässig ist und daß der Zugang zu diesen Daten besonders geschützt ist. Die Weiterverwendung von Daten für einen anderen Zweck ist nur zulässig, wenn eine Übermittlung der Daten für diesen Zweck zulässig ist; die Zulässigkeit der Weiterverwendung für wissenschaftliche oder statistische Zwecke ergibt sich aus den §§ 46 und 47.

(2) Der Beweis der Richtigkeit der Daten obliegt – sofern gesetzlich nicht ausdrücklich anderes angeordnet ist – dem Auftraggeber, soweit die Daten nicht ausschließlich auf Grund von Angaben des Betroffenen ermittelt wurden.

(3) Eine Richtigstellung oder Löschung von Daten ist ausgeschlossen, soweit der Dokumentationszweck einer Datenanwendung nachträgliche Änderungen nicht zuläßt. Die erforderlichen Richtigstellungen sind diesfalls durch entsprechende zusätzliche Anmerkungen zu bewirken.

(4) Innerhalb von acht Wochen nach Einlangen eines Antrags auf Richtigstellung oder Löschung ist dem Antrag zu entsprechen und dem Betroffenen davon Mitteilung zu machen oder schriftlich zu begründen, warum die verlangte Löschung oder Richtigstellung nicht vorgenommen wird.

(5) In jenen Bereichen der Vollziehung, die mit der Wahrnehmung der in § 26 Abs. 2 Z 1 bis 5 bezeichneten Aufgaben betraut sind, ist, soweit dies zum Schutz jener öffentlichen Interessen notwendig ist, die eine Geheimhaltung erfordern, mit einem Richtigstellungs- oder Löschungsantrag folgendermaßen zu verfahren: Die Richtigstellung oder Löschung ist vorzunehmen, wenn das Begehren des Betroffenen nach Auffassung des Auftraggebers berechtigt ist. Die gemäß Abs. 4 erforderliche Mitteilung an den Betroffenen hat in allen Fällen dahingehend zu lauten, daß die Überprüfung der Datenbestände des Auftraggebers im Hinblick auf das Richtigstellungs- oder Löschungsbegehren durchgeführt wurde. Die Zulässigkeit dieser Vorgangsweise unterliegt der Kontrolle durch die Datenschutzkommission nach § 30 Abs. 3 und dem besonderen Beschwerdeverfahren vor der Datenschutzkommission nach § 31 Abs. 4.

(6) Wenn die Löschung oder Richtigstellung von Daten auf ausschließlich automationsunterstützt lesbaren Datenträgern aus Gründen der Wirtschaftlichkeit nur zu bestimmten Zeitpunkten vorgenommen werden kann, sind bis dahin die zu löschenden Daten für den Zugriff zu sperren und die zu berichtigenden Daten mit einer berichtigenden Anmerkung zu versehen.

(7) Werden Daten verwendet, deren Richtigkeit der Betroffene bestreitet, und läßt sich weder ihre Richtigkeit noch ihre Unrichtigkeit feststellen, so ist auf Verlangen des Betroffenen ein Vermerk über die

Bestreitung beizufügen. Der Bestreitungsvermerk darf nur mit Zustimmung des Betroffenen oder auf Grund einer Entscheidung des zuständigen Gerichtes oder der Datenschutzkommission gelöscht werden.

(8) Wurden im Sinne des Abs. 1 richtiggestellte oder gelöschte Daten vor der Richtigstellung oder Löschung übermittelt, so hat der Auftraggeber die Empfänger dieser Daten hievon in geeigneter Weise zu verständigen, sofern dies keinen unverhältnismäßigen Aufwand, insbesondere im Hinblick auf das Vorhandensein eines berechtigten Interesses an der Verständigung, bedeutet und die Empfänger noch feststellbar sind.

(9) Die Regelungen der Abs. 1 bis 8 gelten für das gemäß Strafregistergesetz 1968 geführte Strafregister sowie für öffentliche Bücher und Register, die von Auftraggebern des öffentlichen Bereichs geführt werden, nur insoweit als für

1. die Verpflichtung zur Richtigstellung und Löschung von Amts wegen oder
2. das Verfahren der Durchsetzung und die Zuständigkeit zur Entscheidung über Berichtigungs- und Löschungsanträge von Betroffenen

durch Bundesgesetz nicht anderes bestimmt ist.

Widerspruchsrecht

§ 28. (1) Sofern die Verwendung von Daten nicht gesetzlich vorgesehen ist, hat jeder Betroffene das Recht, gegen die Verwendung seiner Daten wegen Verletzung überwiegender schutzwürdiger Geheimhaltungsinteressen, die sich aus seiner besonderen Situation ergeben, beim Auftraggeber der Datenanwendung Widerspruch zu erheben. Der Auftraggeber hat bei Vorliegen dieser Voraussetzungen die Daten des Betroffenen binnen acht Wochen aus seiner Datenanwendung zu löschen und allfällige Übermittlungen zu unterlassen.

(2) Gegen eine nicht gesetzlich angeordnete Aufnahme in eine öffentlich zugängliche Datei kann der Betroffene jederzeit auch ohne Begründung seines Begehrens Widerspruch erheben. Die Daten sind binnen acht Wochen zu löschen.

Die Rechte des Betroffenen bei der Verwendung nur indirekt personenbezogener Daten

§ 29. Die durch die §§ 26 bis 28 gewährten Rechte können nicht geltend gemacht werden, soweit nur indirekt personenbezogene Daten verwendet werden.

6. Abschnitt

Rechtsschutz

Kontrollbefugnisse der Datenschutzkommission

§ 30. (1) Jedermann kann sich wegen einer behaupteten Verletzung seiner Rechte oder ihn betreffender Pflichten eines Auftraggebers oder Dienstleisters nach diesem Bundesgesetz mit einer Eingabe an die Datenschutzkommission wenden.

(2) Die Datenschutzkommission kann im Fall eines begründeten Verdachtes auf Verletzung der im Abs. 1 genannten Rechte und Pflichten Datenanwendungen überprüfen. Hiebei kann sie vom Auftraggeber oder Dienstleister der überprüften Datenanwendung insbesondere alle notwendigen Aufklärungen verlangen und Einschau in Datenanwendungen und diesbezügliche Unterlagen begehren.

(3) Datenanwendungen, die der Vorabkontrolle gemäß § 18 Abs. 2 unterliegen, dürfen auch ohne Vorliegen eines Verdachts auf rechtswidrige Datenverwendung überprüft werden. Dies gilt auch für jene Bereiche der Vollziehung, in welchen ein Auftraggeber des öffentlichen Bereichs die grundsätzliche Anwendbarkeit der §§ 26 Abs. 5 und 27 Abs. 5 in Anspruch nimmt.

(4) Zum Zweck der Einschau ist die Datenschutzkommission nach Verständigung des Inhabers der Räumlichkeiten und des Auftraggebers (Dienstleisters) berechtigt, Räume, in welchen Datenanwendungen vorgenommen werden, zu betreten, Datenverarbeitungsanlagen in Betrieb zu setzen, die zu überprüfenden Verarbeitungen durchzuführen sowie Kopien von Datenträgern in dem für die Ausübung der Kontrollbefugnisse unbedingt erforderlichen Ausmaß herzustellen. Der Auftraggeber (Dienstleister) hat die für die Einschau notwendige Unterstützung zu leisten. Die Kontrolltätigkeit ist unter möglichster Schonung der Rechte des Auftraggebers (Dienstleisters) und Dritter auszuüben.

(5) Informationen, die der Datenschutzkommission oder ihren Beauftragten bei der Kontrolltätigkeit zukommen, dürfen ausschließlich für die Kontrolle im Rahmen der Vollziehung datenschutzrechtlicher Vorschriften verwendet werden. Die Pflicht zur Verschwiegenheit besteht auch gegenüber Gerichten und Verwaltungsbehörden, insbesondere Abgabenbehörden; dies allerdings mit der Maßgabe, daß dann, wenn die Einschau den Verdacht einer strafbaren Handlung nach den §§ 51 oder 52 dieses Bundesgesetzes oder eines Verbrechens nach § 278a StGB (kriminelle Organisation) oder eines Verbrechens mit einer Frei-

heitsstrafe, deren Höchstmaß fünf Jahre übersteigt, ergibt, Anzeige zu erstatten ist und hinsichtlich solcher Verbrechen und Vergehen auch dem Ersuchen der Strafgerichte nach § 26 StPO zu entsprechen ist.

(6) Zur Herstellung des rechtmäßigen Zustandes kann die Datenschutzkommission Empfehlungen aussprechen, für deren Befolgung erforderlichenfalls eine angemessene Frist zu setzen ist. Wird einer solchen Empfehlung innerhalb der gesetzten Frist nicht entsprochen, so kann die Datenschutzkommission je nach der Art des Verstoßes von Amts wegen insbesondere

1. ein Verfahren zur Überprüfung der Registrierung gemäß § 22 Abs. 4 einleiten, oder
2. Strafanzeige nach §§ 51 oder 52 erstatten, oder
3. bei schwerwiegenden Verstößen durch Auftraggeber des privaten Bereichs Klage vor dem zuständigen Gericht gemäß § 32 Abs. 5 erheben, oder
4. bei Verstößen von Auftraggebern, die Organe einer Gebietskörperschaft sind, das zuständige oberste Organ befassen. Dieses Organ hat innerhalb einer angemessenen, jedoch zwölf Wochen nicht überschreitenden Frist entweder dafür Sorge zu tragen, daß der Empfehlung der Datenschutzkommission entsprochen wird, oder der Datenschutzkommission mitzuteilen, warum der Empfehlung nicht entsprochen wurde. Die Begründung darf von der Datenschutzkommission der Öffentlichkeit in geeigneter Weise zur Kenntnis gebracht werden, soweit dem nicht die Amtsverschwiegenheit entgegensteht.

(7) Der Einschreiter ist darüber zu informieren, wie mit seiner Eingabe verfahren wurde.

Beschwerde an die Datenschutzkommission

§ 31. (1) Die Datenschutzkommission erkennt auf Antrag des Betroffenen über behauptete Verletzungen des Rechtes auf Auskunft gemäß § 26 durch den Auftraggeber einer Datenanwendung, soweit sich das Auskunftsbegehren nicht auf die Verwendung von Daten für Akte der Gesetzgebung oder der Gerichtsbarkeit bezieht.

(2) Zur Entscheidung über behauptete Verletzungen der Rechte eines Betroffenen auf Geheimhaltung, auf Richtigstellung oder auf Löschung nach diesem Bundesgesetz ist die Datenschutzkommission dann zuständig, wenn der Betroffene seine Beschwerde gegen einen Auftraggeber des öffentlichen Bereichs richtet, der nicht als Organ der Gesetzgebung oder der Gerichtsbarkeit tätig ist.

(3) Bei Gefahr im Verzug kann die Datenschutzkommission im Zuge der Behandlung einer Beschwerde nach Abs. 2 die weitere Verwendung von Daten zur Gänze oder teilweise untersagen oder auch – bei Streitigkeiten über die Richtigkeit von Daten – dem Auftraggeber die Anbringung eines Bestreitungsvermerks auftragen.

(4) Beruft sich ein Auftraggeber des öffentlichen Bereichs bei einer Beschwerde wegen Verletzung des Auskunfts-, Richtigstellungs- oder Löschungsrechts gegenüber der Datenschutzkommission auf die §§ 26 Abs. 5 oder 27 Abs. 5, so hat diese nach Überprüfung der Notwendigkeit der Geheimhaltung die geschützten öffentlichen Interessen in ihrem Verfahren zu wahren. Kommt sie zur Auffassung, daß die Geheimhaltung von verarbeiteten Daten gegenüber dem Betroffenen nicht gerechtfertigt war, ist die Offenlegung der Daten mit Bescheid aufzutragen. Gegen diese Entscheidung der Datenschutzkommission kann die belangte Behörde Beschwerde an den Verwaltungsgerichtshof erheben. Wurde keine derartige Beschwerde eingebracht und wird dem Bescheid der Datenschutzkommission binnen acht Wochen nicht entsprochen, so hat die Datenschutzkommission die Offenlegung der Daten gegenüber dem Betroffenen selbst vorzunehmen und ihm die verlangte Auskunft zu erteilen oder ihm mitzuteilen, welche Daten bereits berichtigt oder gelöscht wurden.

Anrufung der Gerichte

§ 32. (1) Ansprüche gegen Auftraggeber des privaten Bereichs wegen Verletzung der Rechte des Betroffenen auf Geheimhaltung, auf Richtigstellung oder auf Löschung sind vom Betroffenen auf dem Zivilrechtsweg geltend zu machen.

(2) Sind Daten entgegen den Bestimmungen dieses Bundesgesetzes verwendet worden, so hat der Betroffene Anspruch auf Unterlassung und Beseitigung des diesem Bundesgesetz widerstreitenden Zustandes.

(3) Zur Sicherung der auf dieses Bundesgesetz gestützten Ansprüche auf Unterlassung können einstweilige Verfügungen erlassen werden, auch wenn die in § 381 EO bezeichneten Voraussetzungen nicht zutreffen. Dies gilt auch für Verfügungen über die Verpflichtung zur Anbringung eines Bestreitungsvermerks.

(4) Für Klagen und Anträge auf Erlassung einer einstweiligen Verfügung nach diesem Bundesgesetz ist in erster Instanz das mit der Ausübung der Gerichtsbarkeit in bürgerlichen Rechtssachen betraute Landesgericht zuständig, in dessen Sprengel der Betroffene seinen gewöhnlichen Aufenthalt oder Sitz hat. Klagen des Betroffenen können aber auch bei dem Landesgericht erhoben werden, in dessen Sprengel der Auftraggeber oder der Dienstleister seinen gewöhnlichen Aufenthalt oder Sitz hat.

(5) Die Datenschutzkommission hat in Fällen, in welchen der begründete Verdacht einer schwerwiegenden Datenschutzverletzung durch einen Auftraggeber des privaten Bereichs besteht, gegen diesen eine Feststellungsklage (§ 228 ZPO) bei dem gemäß Abs. 4 zweiter Satz zuständigen Gericht zu erheben.

(6) Die Datenschutzkommission hat, wenn ein Betroffener es verlangt und es zur Wahrung der nach diesem Bundesgesetz geschützten Interessen einer größeren Zahl von Betroffenen geboten ist, einem Rechtsstreit auf Seiten des Betroffenen als Nebenintervenient (§§ 17 ff ZPO) beizutreten.

Schadenersatz

§ 33. (1) Ein Auftraggeber oder Dienstleister, der Daten schuldhaft entgegen den Bestimmungen dieses Bundesgesetzes verwendet, hat dem Betroffenen den erlittenen Schaden nach den allgemeinen Bestimmungen des bürgerlichen Rechts zu ersetzen. Werden durch die öffentlich zugängliche Verwendung der in § 18 Abs. 2 Z 1 bis 3 genannten Datenarten schutzwürdige Geheimhaltungsinteressen eines Betroffenen in einer Weise verletzt, die einer Eignung zur Bloßstellung gemäß § 7 Abs. 1 des Mediengesetzes, BGBl. Nr. 314/1981, gleichkommt, so gilt diese Bestimmung auch in Fällen, in welchen die öffentlich zugängliche Verwendung nicht in Form der Veröffentlichung in einem Medium geschieht. Der Anspruch auf angemessene Entschädigung für die erlittene Kränkung ist gegen den Auftraggeber der Datenverwendung geltend zu machen.

(2) Der Auftraggeber und der Dienstleister haften auch für das Verschulden ihrer Leute, soweit deren Tätigkeit für den Schaden ursächlich war.

(3) Der Auftraggeber kann sich von seiner Haftung befreien, wenn er nachweist, daß der Umstand, durch den der Schaden eingetreten ist, ihm und seinen Leuten (Abs. 2) nicht zur Last gelegt werden kann. Dasselbe gilt für die Haftungsbefreiung des Dienstleisters. Für den Fall eines Mitverschuldens des Geschädigten oder einer Person, deren Verhalten er zu vertreten hat, gilt § 1304 ABGB.

(4) Die Zuständigkeit für Klagen nach Abs. 1 richtet sich nach § 32 Abs. 4.

Gemeinsame Bestimmungen

§ 34. (1) Der Anspruch auf Behandlung einer Eingabe nach § 30, einer Beschwerde nach § 31 oder einer Klage nach § 32 erlischt, wenn der Einschreiter sie nicht binnen eines Jahres, nachdem er Kenntnis von dem beschwerenden Ereignis erlangt hat, längstens aber binnen drei Jahren, nachdem das Ereignis behauptetermaßen stattgefunden hat, einbringt. Dies ist dem Einschreiter im Falle einer verspäteten Eingabe gemäß § 30 mitzuteilen; verspätete Beschwerden nach § 31 und Klagen nach § 32 sind abzuweisen.

(2) Eingaben nach § 30, Beschwerden nach § 31, Klagen nach § 32 sowie Schadenersatzansprüche nach § 33 können nicht nur auf die Verletzung der Vorschriften dieses Bundesgesetzes, sondern auch auf die Verletzung von datenschutzrechtlichen Vorschriften eines anderen Mitgliedstaates der Europäischen Union gegründet werden, soweit solche Vorschriften gemäß § 3 im Inland anzuwenden sind.

(3) Ist die vermutete Verletzung schutzwürdiger Geheimhaltungsinteressen eines Betroffenen im Inland gemäß § 3 nach der Rechtsordnung eines anderen Mitgliedstaats der Europäischen Union zu beurteilen, so kann die Datenschutzkommission im Falle ihrer Befassung die zuständige ausländische Datenschutzkontrollstelle um Unterstützung ersuchen.

(4) Die Datenschutzkommission hat den Unabhängigen Datenschutzkontrollstellen der anderen Mitgliedstaaten der Europäischen Union über Ersuchen Amtshilfe zu leisten.

7. Abschnitt
Kontrollorgane

Datenschutzkommission und Datenschutzrat

§ 35. (1) Zur Wahrung des Datenschutzes sind nach den näheren Bestimmungen dieses Bundesgesetzes – unbeschadet der Zuständigkeit des Bundeskanzlers und der ordentlichen Gerichte – die Datenschutzkommission und der Datenschutzrat berufen.

(2) **(Verfassungsbestimmung)** Die Datenschutzkommission übt ihre Befugnisse auch gegenüber den in Art. 19 B-VG bezeichneten obersten Organen der Vollziehung aus.

Zusammensetzung der Datenschutzkommission

§ 36. (1) Die Datenschutzkommission besteht aus sechs Mitgliedern, die auf Vorschlag der Bundesregierung vom Bundespräsidenten für die Dauer von fünf Jahren bestellt werden. Wiederbestellungen sind zulässig. Die Mitglieder müssen rechtskundig sein. Ein Mitglied muß dem Richterstand angehören.

(2) Die Vorbereitung des Vorschlages der Bundesregierung für die Bestellung der Mitglieder der Datenschutzkommission obliegt dem Bundeskanzler. Er hat dabei Bedacht zu nehmen auf:

1. einen Dreiervorschlag des Präsidenten des Obersten Gerichtshofs für das richterliche Mitglied,
2. einen Vorschlag der Länder für zwei Mitglieder,
3. einen Dreiervorschlag der Bundeskammer für Arbeiter und Angestellte für ein Mitglied,
4. einen Dreiervorschlag der Wirtschaftskammer Österreich für ein Mitglied.

Alle vorgeschlagenen Personen sollen Erfahrung auf dem Gebiet des Datenschutzes besitzen.

(3) Ein Mitglied ist aus dem Kreise der rechtskundigen Bundesbeamten vorzuschlagen.

(4) Für jedes Mitglied ist ein Ersatzmitglied zu bestellen. Das Ersatzmitglied tritt bei Verhinderung des Mitglieds an dessen Stelle. Die Funktionsperiode des Ersatzmitglieds endet mit der Funktionsperiode des Mitglieds; für den Fall der vorzeitigen Beendigung der Funktionsperiode des Mitglieds gilt Abs. 8.

(5) Der Datenschutzkommission können nicht angehören:

1. Mitglieder der Bundesregierung oder einer Landesregierung sowie Staatssekretäre;
2. Personen, die zum Nationalrat nicht wählbar sind.

(6) Hat ein Mitglied der Datenschutzkommission Einladungen zu drei aufeinanderfolgenden Sitzungen ohne genügende Entschuldigung keine Folge geleistet oder tritt bei einem Mitglied ein Ausschließungsgrund des Abs. 5 nachträglich ein, so hat dies nach seiner Anhörung die Datenschutzkommission festzustellen. Diese Feststellung hat den Verlust der Mitgliedschaft zur Folge. Im übrigen kann ein Mitglied der Datenschutzkommission nur aus einem schwerwiegenden Grund durch Beschluß der Datenschutzkommission, dem mindestens drei ihrer Mitglieder zustimmen müssen, seines Amtes für verlustig erklärt werden. Die Mitgliedschaft endet auch, wenn das Mitglied seine Funktion durch schriftliche Erklärung an den Bundeskanzler zurücklegt.

(7) Auf die Ersatzmitglieder sind die Abs. 2, 3, 5 und 6 wie auf Mitglieder anzuwenden.

(8) Scheidet ein Mitglied wegen Todes, freiwillig oder gemäß Abs. 6 vorzeitig aus, so wird das betreffende Ersatzmitglied (Abs. 4) Mitglied der Datenschutzkommission bis zum Ablauf der Funktionsperiode des ausgeschiedenen Mitglieds. Unter Anwendung der Abs. 2 und 3 ist für diese Zeit ein neues Ersatzmitglied zu bestellen. Scheidet ein Ersatzmitglied vorzeitig aus, ist unverzüglich ein neues Ersatzmitglied zu bestellen.

(9) Die Mitglieder und Ersatzmitglieder der Datenschutzkommission haben Anspruch auf Ersatz der Reisekosten (Gebührenstufe 3) nach Maßgabe der für Bundesbeamte geltenden Rechtsvorschriften. Sie haben ferner Anspruch auf eine dem Zeit- und Arbeitsaufwand entsprechende Vergütung, die auf Antrag des Bundeskanzlers von der Bundesregierung durch Verordnung festzusetzen ist.

Weisungsfreiheit der Datenschutzkommission (Verfassungsbestimmung)

§ 37. (1) Die Mitglieder der Datenschutzkommission sind in Ausübung ihres Amtes unabhängig und an keine Weisungen gebunden.

(2) Die in der Geschäftsstelle der Datenschutzkommission tätigen Bediensteten unterstehen fachlich nur den Weisungen des Vorsitzenden oder des geschäftsführenden Mitglieds der Datenschutzkommission.

Organisation und Geschäftsführung der Datenschutzkommission

§ 38. (1) **(Verfassungsbestimmung)** Die Datenschutzkommission hat sich eine Geschäftsordnung zu geben, in der eines ihrer Mitglieder mit der Führung der laufenden Geschäfte zu betrauen ist (geschäftsführendes Mitglied). Diese Betrauung umfaßt auch die Erlassung von verfahrensrechtlichen Bescheiden und von Mandatsbescheiden im Registrierungsverfahren gemäß § 20 Abs. 2 oder § 22 Abs. 3. Inwieweit einzelne fachlich geeignete Bedienstete der Geschäftsstelle der Datenschutzkommission zum Handeln für die Datenschutzkommission oder das geschäftsführende Mitglied ermächtigt werden, bestimmt die Geschäftsordnung.

(2) Für die Unterstützung in der Geschäftsführung der Datenschutzkommission hat der Bundeskanzler eine Geschäftsstelle einzurichten und die notwendige Sach- und Personalausstattung bereitzustellen.

(3) Die Datenschutzkommission ist vor Erlassung von Verordnungen anzuhören, die auf der Grundlage dieses Bundesgesetzes ergehen oder sonst wesentliche Fragen des Datenschutzes unmittelbar betreffen.

(4) Die Datenschutzkommission hat spätestens alle zwei Jahre einen Bericht über ihre Tätigkeit zu erstellen und in geeigneter Weise zu veröffentlichen. Der Bericht ist dem Bundeskanzler zur Kenntnis zu übermitteln.

Beschlüsse der Datenschutzkommission

§ 39. (1) Die Datenschutzkommission ist bei Anwesenheit aller sechs Mitglieder beschlußfähig. Für den Fall der Verhinderung eines Mitglieds gilt § 36 Abs. 4.

(2) Das richterliche Mitglied führt den Vorsitz.

(3) Für einen gültigen Beschluß der Datenschutzkommission ist die Zustimmung der Mehrheit der abgegebenen Stimmen notwendig. Bei Stimmengleichheit gibt die Stimme des Vorsitzenden den Ausschlag. Stimmenthaltung ist unzulässig.

(4) Entscheidungen der Datenschutzkommission von grundsätzlicher Bedeutung für die Allgemeinheit sind von der Datenschutzkommission unter Beachtung der Erfordernisse der Amtsverschwiegenheit in geeigneter Weise zu veröffentlichen.

Wirkung von Bescheiden der Datenschutzkommission und des geschäftsführenden Mitglieds

§ 40. (1) Gegen Bescheide, die das geschäftsführende Mitglied der Datenschutzkommission gemäß § 20 Abs. 2 oder § 22 Abs. 3 in Verbindung mit § 38 Abs. 1 erlassen hat, ist die Vorstellung an die Datenschutzkommission gemäß § 57 Abs. 2 AVG zulässig. Eine Vorstellung gegen einen gemäß § 22 Abs. 3 ergangenen Bescheid hat aufschiebende Wirkung.

(2) Gegen Bescheide der Datenschutzkommission ist kein Rechtsmittel zulässig. Sie unterliegen nicht der Aufhebung oder Abänderung im Verwaltungsweg. Die Anrufung des Verwaltungsgerichtshofes durch die Parteien des Verfahrens ist außer in den Fällen des Abs. 1 zulässig. Dies gilt auch für die in Vollziehung der Gesetze tätigen Auftraggeber des öffentlichen Bereichs in jenen Fällen, in welchen ihnen gemäß § 13 Abs. 3 oder § 20 Abs. 6 Parteistellung zukommt oder durch Gesetz ausdrücklich ein Beschwerderecht an den Verwaltungsgerichtshof eingeräumt wurde.

(3) Bescheide, mit welchen gemäß § 13 Übermittlungen oder Überlassungen von Daten ins Ausland genehmigt wurden, sind zu widerrufen, wenn die rechtlichen und tatsächlichen Voraussetzungen für die Erteilung der Genehmigung, insbesondere auch infolge einer gemäß § 55 ergangenen Kundmachung des Bundeskanzlers, nicht mehr bestehen.

(4) Wenn die Datenschutzkommission eine Verletzung von Bestimmungen dieses Bundesgesetzes durch einen Auftraggeber des öffentlichen Bereichs festgestellt hat, so hat dieser mit den ihm zu Gebote stehenden rechtlichen Mitteln unverzüglich den der Rechtsanschauung der Datenschutzkommission entsprechenden Zustand herzustellen.

Einrichtung und Aufgaben des Datenschutzrates

§ 41. (1) Beim Bundeskanzleramt ist ein Datenschutzrat eingerichtet.

(2) Der Datenschutzrat berät die Bundesregierung und die Landesregierungen auf deren Ersuchen in rechtspolitischen Fragen des Datenschutzes. Zur Erfüllung dieser Aufgabe

1. kann der Datenschutzrat Fragen von grundsätzlicher Bedeutung für den Datenschutz in Beratung ziehen;
2. ist dem Datenschutzrat Gelegenheit zur Stellungnahme zu Gesetzesentwürfen der Bundesministerien zu geben, soweit diese datenschutzrechtlich von Bedeutung sind;
3. haben Auftraggeber des öffentlichen Bereichs ihre Vorhaben dem Datenschutzrat zur Stellungnahme zuzuleiten, soweit diese datenschutzrechtlich von Bedeutung sind;
4. hat der Datenschutzrat das Recht, von Auftraggebern des öffentlichen Bereichs Auskünfte und Berichte sowie die Einsicht in Unterlagen zu verlangen, soweit dies zur datenschutzrechtlichen Beurteilung von Vorhaben mit wesentlichen Auswirkungen auf den Datenschutz in Österreich notwendig ist;
5. kann der Datenschutzrat Auftraggeber des privaten Bereichs oder auch ihre gesetzliche Interessenvertretung zur Stellungnahme zu Entwicklungen von allgemeiner Bedeutung auffordern, die aus datenschutzrechtlicher Sicht Anlaß zu Bedenken, zumindest aber Anlaß zur Beobachtung geben;

6. kann der Datenschutzrat seine Beobachtungen, Bedenken und allfälligen Anregungen zur Verbesserung des Datenschutzes in Österreich der Bundesregierung und den Landesregierungen mitteilen, sowie über Vermittlung dieser Organe den gesetzgebenden Körperschaften zur Kenntnis bringen.

(3) Abs. 2 Z 3 und 4 gilt nicht, soweit innere Angelegenheiten der anerkannten Kirchen und Religionsgesellschaften betroffen sind.

Zusammensetzung des Datenschutzrates

§ 42. (1) Dem Datenschutzrat gehören an:

1. Vertreter der politischen Parteien: Von der im Hauptausschuß des Nationalrates am stärksten vertretenen Partei sind vier Vertreter, von der am zweitstärksten vertretenen Partei sind drei Vertreter und von jeder anderen im Hauptausschuß des Nationalrates vertretenen Partei ist ein Vertreter in den Datenschutzrat zu entsenden. Bei Mandatsgleichheit der beiden im Nationalrat am stärksten vertretenen Parteien entsendet jede dieser Parteien drei Vertreter;
2. je ein Vertreter der Bundeskammer für Arbeiter und Angestellte und der Wirtschaftskammer Österreich;
3. zwei Vertreter der Länder;
4. je ein Vertreter des Gemeindebundes und des Städtebundes;
5. ein vom Bundeskanzler zu ernennender Vertreter des Bundes.

(2) Die in Abs. 1 Z 3, 4 und 5 genannten Vertreter sollen berufliche Erfahrung auf dem Gebiet der Informatik und des Datenschutzes haben.

(3) Für jedes Mitglied ist ein Ersatzmitglied namhaft zu machen.

(4) Dem Datenschutzrat können Mitglieder der Bundesregierung oder einer Landesregierung sowie Staatssekretäre und weiters Personen, die zum Nationalrat nicht wählbar sind, nicht angehören.

(5) Die Mitglieder gehören dem Datenschutzrat solange an, bis sie dem Bundeskanzler schriftlich ihr Ausscheiden mitteilen oder, mangels einer solchen Mitteilung, von der entsendenden Stelle (Abs. 1) dem Bundeskanzler ein anderer Vertreter namhaft gemacht wird.

(6) Die Tätigkeit der Mitglieder des Datenschutzrates ist ehrenamtlich. Mitglieder des Datenschutzrates, die außerhalb von Wien wohnen, haben im Fall der Teilnahme an Sitzungen des Datenschutzrates Anspruch auf Ersatz der Reisekosten (Gebührenstufe 3) nach Maßgabe der für Bundesbeamte geltenden Rechtsvorschriften.

Vorsitz und Geschäftsführung des Datenschutzrates

§ 43. (1) Der Datenschutzrat gibt sich mit Beschluß eine Geschäftsordnung.

(2) Der Datenschutzrat hat aus seiner Mitte einen Vorsitzenden und zwei stellvertretende Vorsitzende zu wählen. Die Funktionsperiode des Vorsitzenden und der stellvertretenden Vorsitzenden dauert – unbeschadet des § 42 Abs. 5 – fünf Jahre. Wiederbestellungen sind zulässig.

(3) Die Geschäftsführung des Datenschutzrates obliegt dem Bundeskanzleramt. Der Bundeskanzler hat das hiefür notwendige Personal zur Verfügung zu stellen. Bei ihrer Tätigkeit für den Datenschutzrat sind die Bediensteten des Bundeskanzleramtes fachlich an die Weisungen des Vorsitzenden des Datenschutzrates gebunden.

Sitzungen und Beschlußfassung des Datenschutzrates

§ 44. (1) Die Sitzungen des Datenschutzrates werden vom Vorsitzenden nach Bedarf einberufen. Begehrt ein Mitglied die Einberufung einer Sitzung, so hat der Vorsitzende die Sitzung so einzuberufen, daß sie binnen vier Wochen stattfinden kann.

(2) Zu den Sitzungen kann der Vorsitzende nach Bedarf Sachverständige zuziehen.

(3) Für Beratungen und Beschlußfassungen im Datenschutzrat ist die Anwesenheit von mehr als der Hälfte seiner Mitglieder erforderlich. Zur Beschlußfassung genügt die einfache Mehrheit der abgegebenen Stimmen. Bei Stimmengleichheit gibt die Stimme des Vorsitzenden den Ausschlag. Stimmenthaltung ist unzulässig. Die Beifügung von Minderheitenvoten ist zulässig.

(4) Der Datenschutzrat kann aus seiner Mitte ständige oder nichtständige Arbeitsausschüsse bilden, denen er die Vorbereitung, Begutachtung und Bearbeitung einzelner Angelegenheiten übertragen kann. Er ist auch berechtigt, die Geschäftsführung, Vorbegutachtung und die Bearbeitung einzelner Angelegenheiten einem einzelnen Mitglied (Berichterstatter) zu übertragen.

(5) Jedes Mitglied des Datenschutzrates ist verpflichtet, an den Sitzungen – außer im Fall der gerechtfertigten Verhinderung – teilzunehmen. Ist ein Mitglied an der Teilnahme verhindert, hat es hievon unverzüglich das Ersatzmitglied zu verständigen.

(6) Mitglieder der Datenschutzkommission, die dem Datenschutzrat nicht angehören, sind berechtigt, an den Sitzungen des Datenschutzrates oder seiner Arbeitsausschüsse teilzunehmen. Ein Stimmrecht steht ihnen nicht zu.

(7) Die Beratungen in der Sitzung des Datenschutzrates sind, soweit er nicht selbst anderes beschließt, vertraulich.

(8) Die Mitglieder des Datenschutzrates, die anwesenden Mitglieder der Datenschutzkommission und die zur Sitzung gemäß Abs. 2 zugezogenen Sachverständigen sind zur Verschwiegenheit über alle ihnen ausschließlich aus ihrer Tätigkeit im Datenschutzrat bekanntgewordenen Tatsachen verpflichtet, sofern die Geheimhaltung im öffentlichen Interesse oder im Interesse einer Partei geboten ist.

8. Abschnitt

Besondere Verwendungszwecke von Daten

Private Zwecke

§ 45. (1) Für ausschließlich persönliche oder familiäre Tätigkeiten dürfen natürliche Personen Daten verarbeiten, wenn sie ihnen vom Betroffenen selbst mitgeteilt wurden oder ihnen sonst rechtmäßigerweise, insbesondere in Übereinstimmung mit § 7 Abs. 2, zugekommen sind.

(2) Daten, die eine natürliche Person für ausschließlich persönliche oder familiäre Tätigkeiten verarbeitet, dürfen, soweit gesetzlich nicht ausdrücklich anderes vorgesehen ist, für andere Zwecke nur mit Zustimmung des Betroffenen übermittelt werden.

Wissenschaftliche Forschung und Statistik

§ 46. (1) Für Zwecke wissenschaftlicher oder statistischer Untersuchungen, die keine personenbezogenen Ergebnisse zum Ziel haben, darf der Auftraggeber der Untersuchung alle Daten verwenden, die

1. öffentlich zugänglich sind oder
2. der Auftraggeber für andere Untersuchungen oder auch andere Zwecke zulässigerweise ermittelt hat oder
3. für den Auftraggeber nur indirekt personenbezogen sind.

Andere Daten dürfen nur unter den Voraussetzungen des Abs. 2 Z 1 bis 3 verwendet werden.

(2) Bei Datenanwendungen für Zwecke wissenschaftlicher Forschung und Statistik, die nicht unter Abs. 1 fallen, dürfen Daten, die nicht öffentlich zugänglich sind, nur

1. gemäß besonderen gesetzlichen Vorschriften oder
2. mit Zustimmung des Betroffenen oder
3. mit Genehmigung der Datenschutzkommission gemäß Abs. 3

verwendet werden.

(3) Eine Genehmigung der Datenschutzkommission für die Verwendung von Daten für Zwecke der wissenschaftlichen Forschung oder Statistik ist zu erteilen, wenn

1. die Einholung der Zustimmung der Betroffenen mangels ihrer Erreichbarkeit unmöglich ist oder sonst einen unverhältnismäßigen Aufwand bedeutet und
2. ein öffentliches Interesse an der beantragten Verwendung besteht und
3. die fachliche Eignung des Antragstellers glaubhaft gemacht wird.

Sollen sensible Daten übermittelt werden, muß ein wichtiges öffentliches Interesse an der Untersuchung vorliegen; weiters muß gewährleistet sein, daß die Daten beim Empfänger nur von Personen verwendet werden, die hinsichtlich des Gegenstandes der Untersuchung einer gesetzlichen Verschwiegenheitspflicht unterliegen oder deren diesbezügliche Verläßlichkeit sonst glaubhaft ist. Die Datenschutzkommission kann die Genehmigung an die Erfüllung von Bedingungen und Auflagen knüpfen, soweit dies zur Wahrung der schutzwürdigen Interessen der Betroffenen, insbesondere bei der Verwendung sensibler Daten, notwendig ist.

(4) Rechtliche Beschränkungen der Zulässigkeit der Benützung von Daten aus anderen, insbesondere urheberrechtlichen Gründen bleiben unberührt.

(5) Auch in jenen Fällen, in welchen gemäß den vorstehenden Bestimmungen die Verwendung von Daten für Zwecke der wissenschaftlichen Forschung oder Statistik in personenbezogener Form zulässig ist, ist der direkte Personsbezug unverzüglich zu verschlüsseln, wenn in einzelnen Phasen der

wissenschaftlichen oder statistischen Arbeit mit nur indirekt personenbezogenen Daten das Auslangen gefunden werden kann. Sofern gesetzlich nicht ausdrücklich anderes vorgesehen ist, ist der Personsbezug der Daten gänzlich zu beseitigen, sobald er für die wissenschaftliche oder statistische Arbeit nicht mehr notwendig ist.

Zurverfügungstellung von Adressen zur Benachrichtigung und Befragung von Betroffenen

§ 47. (1) Soweit gesetzlich nicht ausdrücklich anderes bestimmt ist, bedarf die Übermittlung von Adreßdaten eines bestimmten Kreises von Betroffenen zum Zweck ihrer Benachrichtigung oder Befragung der Zustimmung der Betroffenen.

(2) Wenn allerdings angesichts der Auswahlkriterien für den Betroffenenkreis und des Gegenstands der Benachrichtigung oder Befragung eine Beeinträchtigung der Geheimhaltungsinteressen der Betroffenen unwahrscheinlich ist, bedarf es keiner Zustimmung, wenn

1. Daten desselben Auftraggebers verwendet werden oder
2. bei einer beabsichtigten Übermittlung der Adreßdaten an Dritte
   a) an der Benachrichtigung oder Befragung auch ein öffentliches Interesse besteht oder
   b) der Betroffene nach entsprechender Information über Anlaß und Inhalt der Übermittlung innerhalb angemessener Frist keinen Widerspruch gegen die Übermittlung erhoben hat.

(3) Liegen die Voraussetzungen des Abs. 2 nicht vor und würde die Einholung der Zustimmung der Betroffenen gemäß Abs. 1 einen unverhältnismäßigen Aufwand erfordern, ist die Übermittlung der Adreßdaten mit Genehmigung der Datenschutzkommission gemäß Abs. 4 zulässig, falls die Übermittlung an Dritte

1. zum Zweck der Benachrichtigung oder Befragung aus einem wichtigen Interesse des Betroffenen selbst oder
2. aus einem wichtigen öffentlichen Benachrichtigungs- oder Befragungsinteresse oder
3. zur Befragung der Betroffenen für wissenschaftliche oder statistische Zwecke

erfolgen soll.

(4) Die Datenschutzkommission hat die Genehmigung zur Übermittlung zu erteilen, wenn der Antragsteller das Vorliegen der in Abs. 3 genannten Voraussetzungen glaubhaft macht und überwiegende schutzwürdige Geheimhaltungsinteressen der Betroffenen der Übermittlung nicht entgegenstehen. Die Datenschutzkommission kann die Genehmigung an die Erfüllung von Bedingungen und Auflagen knüpfen, soweit dies zur Wahrung der schutzwürdigen Interessen der Betroffenen, insbesondere bei der Verwendung sensibler Daten als Auswahlkriterium, notwendig ist.

(5) Die übermittelten Adreßdaten dürfen ausschließlich für den genehmigten Zweck verwendet werden und sind zu löschen, sobald sie für die Benachrichtigung oder Befragung nicht mehr benötigt werden.

(6) In jenen Fällen, in welchen es gemäß den vorstehenden Bestimmungen zulässig ist, Namen und Adresse von Personen, die einem bestimmten Betroffenenkreis angehören, zu übermitteln, dürfen auch die zum Zweck der Auswahl der zu übermittelnden Adreßdaten notwendigen Verarbeitungen vorgenommen werden.

Publizistische Tätigkeit

§ 48. (1) Soweit Medienunternehmen, Mediendienste oder ihre Mitarbeiter Daten unmittelbar für ihre publizistische Tätigkeit im Sinne des Mediengesetzes verwenden, sind von den einfachgesetzlichen Bestimmungen des vorliegenden Bundesgesetzes nur die §§ 4 bis 6, 10, 11, 14 und 15 anzuwenden.

(2) Die Verwendung von Daten für Tätigkeiten nach Abs. 1 ist insoweit zulässig, als dies zur Erfüllung der Informationsaufgabe der Medienunternehmer, Mediendienste und ihrer Mitarbeiter in Ausübung des Grundrechtes auf freie Meinungsäußerung gemäß Art. 10 Abs. 1 EMRK erforderlich ist.

(3) Im übrigen gelten die Bestimmungen des Mediengesetzes, insbesondere seines dritten Abschnitts über den Persönlichkeitsschutz.

9. Abschnitt

Besondere Verwendungsarten von Daten

Automatisierte Einzelentscheidungen

§ 49. (1) Niemand darf einer für ihn rechtliche Folgen nach sich ziehenden oder einer ihn erheblich beeinträchtigenden Entscheidung unterworfen werden, die ausschließlich auf Grund einer automationsunterstützten Verarbeitung von Daten zum Zweck der Bewertung einzelner Aspekte seiner Person ergeht,

wie beispielsweise seiner beruflichen Leistungsfähigkeit, seiner Kreditwürdigkeit, seiner Zuverlässigkeit oder seines Verhaltens.

(2) Abweichend von Abs. 1 darf eine Person einer ausschließlich automationsunterstützt erzeugten Entscheidung unterworfen werden, wenn

1. dies gesetzlich ausdrücklich vorgesehen ist oder
2. die Entscheidung im Rahmen des Abschlusses oder der Erfüllung eines Vertrages ergeht und dem Ersuchen des Betroffenen auf Abschluß oder Erfüllung des Vertrages stattgegeben wurde oder
3. die Wahrung der berechtigten Interessen des Betroffenen durch geeignete Maßnahmen – beispielsweise die Möglichkeit, seinen Standpunkt geltend zu machen – garantiert wird.

(3) Dem Betroffenen ist bei automatisierten Einzelentscheidungen auf Antrag der logische Ablauf der automatisierten Entscheidungsfindung in allgemein verständlicher Form darzulegen.

Informationsverbundsysteme

§ 50. (1) Die Auftraggeber eines Informationsverbundsystems haben, soweit dies nicht bereits durch Gesetz geregelt ist, einen geeigneten Betreiber für das System zu bestellen. Name (Bezeichnung) und Anschrift des Betreibers sind in der Meldung zwecks Eintragung in das Datenverarbeitungsregister bekannt zu geben. Unbeschadet des Rechtes des Betroffenen auf Auskunft nach § 26 hat der Betreiber jedem Betroffenen auf Antrag binnen zwölf Wochen alle Auskünfte zu geben, die notwendig sind, um den für die Verarbeitung seiner Daten im System verantwortlichen Auftraggeber festzustellen; in Fällen, in welchen der Auftraggeber gemäß § 26 Abs. 5 vorzugehen hätte, hat der Betreiber mitzuteilen, daß kein der Pflicht zur Auskunftserteilung unterliegender Auftraggeber benannt werden kann. Die Unterstützungspflicht des Betreibers gilt auch bei Anfragen von Behörden. Den Betreiber trifft überdies die Verantwortung für die notwendigen Maßnahmen der Datensicherheit (§ 14) im Informationsverbundsystem. Von der Haftung für diese Verantwortung kann sich der Betreiber unter den gleichen Voraussetzungen, wie sie in § 33 Abs. 3 vorgesehen sind, befreien. Wird ein Informationsverbundsystem geführt, ohne daß eine entsprechende Meldung an die Datenschutzkommission unter Angabe eines Betreibers erfolgt ist, treffen jeden einzelnen Auftraggeber die Pflichten des Betreibers.

(2) Durch entsprechenden Rechtsakt können auch weitere Auftraggeberpflichten auf den Betreiber übertragen werden. Soweit dies nicht durch Gesetz geschehen ist, ist dieser Pflichtenübergang gegenüber den Betroffenen und den für die Vollziehung dieses Bundesgesetzes zuständigen Behörden nur wirksam, wenn er – auf Grund einer entsprechenden Meldung an die Datenschutzkommission – aus der Registrierung im Datenverarbeitungsregister ersichtlich ist.

(3) Die Bestimmungen der Abs. 1 und 2 gelten nicht, soweit infolge der besonderen, insbesondere internationalen Struktur eines bestimmten Informationsverbundsystems gesetzlich ausdrücklich anderes vorgesehen ist.

10. Abschnitt

Strafbestimmungen

Datenverwendung in Gewinn- oder Schädigungsabsicht

§ 51. (1) Wer in der Absicht, sich einen Vermögensvorteil zu verschaffen oder einem anderen einen Nachteil zuzufügen, personenbezogene Daten, die ihm ausschließlich auf Grund seiner berufsmäßigen Beschäftigung anvertraut oder zugänglich geworden sind oder die er sich widerrechtlich verschafft hat, selbst benützt, einem anderen zugänglich macht oder veröffentlicht, obwohl der Betroffene an diesen Daten ein schutzwürdiges Geheimhaltungsinteresse hat, ist, wenn die Tat nicht nach einer anderen Bestimmung mit strengerer Strafe bedroht ist, vom Gericht mit Freiheitsstrafe bis zu einem Jahr zu bestrafen.

(2) Der Täter ist nur mit Ermächtigung des Verletzten zu verfolgen.

Verwaltungsstrafbestimmung

§ 52. (1) Sofern die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet oder nach anderen Verwaltungsstrafbestimmungen mit strengerer Strafe bedroht ist, begeht eine Verwaltungsübertretung, die mit Geldstrafe bis zu 260 000 S zu ahnden ist, wer

1. sich vorsätzlich widerrechtlichen Zugang zu einer Datenanwendung verschafft oder einen erkennbar widerrechtlichen Zugang vorsätzlich aufrechterhält oder
2. Daten vorsätzlich in Verletzung des Datengeheimnisses (§ 15) übermittelt, insbesondere Daten, die ihm gemäß §§ 46 oder 47 anvertraut wurden, vorsätzlich für andere Zwecke verwendet oder
3. Daten entgegen einem rechtskräftigen Urteil oder Bescheid verwendet, nicht beauskunftet, nicht richtigstellt oder nicht löscht oder
4. Daten vorsätzlich entgegen § 26 Abs. 7 löscht.

(2) Sofern die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet, begeht eine Verwaltungsübertretung, die mit Geldstrafe bis zu 130 000 S zu ahnden ist, wer

1. Daten ermittelt, verarbeitet oder übermittelt, ohne seine Meldepflicht gemäß § 17 erfüllt zu haben oder
2. Daten ins Ausland übermittelt oder überläßt, ohne die erforderliche Genehmigung der Datenschutzkommission gemäß § 13 eingeholt zu haben oder
3. seine Offenlegungs- oder Informationspflichten gemäß den §§ 23, 24 oder 25 verletzt oder
4. die gemäß § 14 erforderlichen Sicherheitsmaßnahmen gröblich außer Acht läßt.

(3) Der Versuch ist strafbar.

(4) Die Strafe des Verfalls von Datenträgern und Programmen kann ausgesprochen werden (§§ 10, 17 und 18 VStG), wenn diese Gegenstände mit einer Verwaltungsübertretung nach Abs. 1 oder 2 in Zusammenhang stehen.

(5) Zuständig für Entscheidungen nach Abs. 1 bis 4 ist die Bezirksverwaltungsbehörde, in deren Sprengel der Auftraggeber (Dienstleister) seinen gewöhnlichen Aufenthalt oder Sitz hat. Falls ein solcher im Inland nicht gegeben ist, ist die am Sitz der Datenschutzkommission eingerichtete Bezirksverwaltungsbehörde zuständig.

11. Abschnitt

Übergangs- und Schlußbestimmungen

Befreiung von Gebühren, Abgaben und vom Kostenersatz

§ 53. (1) Die durch dieses Bundesgesetz unmittelbar veranlaßten Eingaben der Betroffenen zur Wahrung ihrer Interessen sowie die Eingaben im Registrierungsverfahren und die gemäß § 21 Abs. 3 zu erstellenden Registerauszüge sind von den Stempelgebühren und von den Verwaltungsabgaben des Bundes befreit.

(2) Für Abschriften aus dem Datenverarbeitungsregister, die ein Betroffener zur Verfolgung seiner Rechte benötigt, ist kein Kostenersatz zu verlangen.

Mitteilungen an die Europäische Kommission und an die anderen Mitgliedstaaten der Europäischen Union

§ 54. (1) Von der Erlassung eines Bundesgesetzes, das die Zulässigkeit der Verarbeitung sensibler Daten betrifft, hat der Bundeskanzler anläßlich der Kundmachung des Gesetzes im Bundesgesetzblatt der Europäischen Kommission Mitteilung zu machen.

(2) Die Datenschutzkommission hat den anderen Mitgliedstaaten der Europäischen Union und der Europäischen Kommission mitzuteilen, in welchen Fällen

1. keine Genehmigung für den Datenverkehr in ein Drittland erteilt wurde, weil die Voraussetzungen des § 13 Abs. 2 Z 1 nicht als gegeben erachtet wurden;
2. der Datenverkehr in ein Drittland ohne angemessenes Datenschutzniveau genehmigt wurde, weil die Voraussetzungen des § 13 Abs. 2 Z 2 als gegeben erachtet wurden.

Feststellungen der Europäischen Kommission

§ 55. Der Inhalt der in einem Verfahren gemäß Art. 31 Abs. 2 der Richtlinie 95/46/EG des Europäischen Parlaments und des Rates vom 24. Oktober 1995 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten und zum freien Datenverkehr, ABl. Nr. L 281 vom 23. November 1995, S. 31, getroffenen Feststellungen der Europäischen Kommission über

1. das Vorliegen oder Nichtvorliegen eines angemessenen Datenschutzniveaus in einem Drittland oder
2. die Eignung bestimmter Standardvertragsklauseln oder Verpflichtungserklärungen zur Gewährleistung eines ausreichenden Schutzes der Datenverwendung in einem Drittland

ist vom Bundeskanzler im Bundesgesetzblatt gemäß § 2 Abs. 3 BGBlG, BGBl. Nr. 660/1996, kundzumachen.

Verwaltungsangelegenheiten gemäß Art. 30 B-VG

§ 56. Der Präsident des Nationalrats ist Auftraggeber jener Datenanwendungen, die für Zwecke der ihm gemäß Art. 30 B-VG übertragenen Angelegenheiten durchgeführt werden. Übermittlungen von Daten aus solchen Datenanwendungen dürfen nur über Auftrag des Präsidenten des Nationalrats vorgenommen werden. Der Präsident trifft Vorsorge dafür, daß im Falle eines Übermittlungsauftrags die Voraus-

setzungen des § 7 Abs. 2 vorliegen und insbesondere die Zustimmung des Betroffenen in jenen Fällen eingeholt wird, in welchen dies gemäß § 7 Abs. 2 mangels einer anderen Rechtsgrundlage für die Übermittlung notwendig ist.

Sprachliche Gleichbehandlung

§ 57. Soweit in diesem Artikel auf natürliche Personen bezogene Bezeichnungen nur in männlicher Form angeführt sind, beziehen sie sich auf Frauen und Männer in gleicher Weise. Bei der Anwendung der Bezeichnungen auf bestimmte natürliche Personen ist die jeweils geschlechtsspezifische Form zu verwenden.

Manuelle Dateien

§ 58. Soweit manuell, dh. ohne Automationsunterstützung geführte Dateien für Zwecke solcher Angelegenheiten bestehen, in denen die Zuständigkeit zur Gesetzgebung Bundessache ist, gelten sie als Datenanwendungen im Sinne des § 4 Z 7. § 17 gilt mit der Maßgabe, daß die Meldepflicht nur für solche Dateien besteht, deren Inhalt gemäß § 18 Abs. 2 der Vorabkontrolle unterliegt.

Umsetzungshinweis

§ 59. Mit diesem Bundesgesetz wird die Richtlinie 95/46/EG des Europäischen Parlaments und des Rates vom 24. Oktober 1995 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten und zum freien Datenverkehr, ABl. Nr. L 281 vom 23. November 1995, S 31, umgesetzt.

Inkrafttreten

§ 60. (1) **(Verfassungsbestimmung)** Die Verfassungsbestimmungen des Art. 1, der §§ 35 Abs. 2, 37, 38 Abs. 1 und 61 Abs. 4 und 7 treten mit 1. Jänner 2000 in Kraft. Mit dem Inkrafttreten dieses Bundesgesetzes tritt das Datenschutzgesetz, BGBl. Nr. 565/1978 in der geltenden Fassung, außer Kraft.

(2) Die übrigen Bestimmungen dieses Bundesgesetzes treten ebenfalls mit 1. Jänner 2000 in Kraft.

Übergangsbestimmungen

§ 61. (1) Meldungen, die vor Inkrafttreten dieses Bundesgesetzes an das Datenverarbeitungsregister erstattet wurden, gelten als Meldungen im Sinne des § 17, soweit sie nicht im Hinblick auf das Entfallen von Meldepflichten gemäß § 17 Abs. 2 oder 3 gegenstandslos geworden sind. Desgleichen gelten vor Inkrafttreten dieses Bundesgesetzes durchgeführte Registrierungen als Registrierungen im Sinne des § 21.

(2) Soweit nach der neuen Rechtslage eine Genehmigung für die Übermittlung von Daten ins Ausland erforderlich ist, muß für Übermittlungen, für die eine Genehmigung vor Inkrafttreten dieses Bundesgesetzes erteilt wurde, eine Genehmigung vor dem 1. Jänner 2003 neu beantragt werden. Wird der Antrag rechtzeitig gestellt, dürfen solche Übermittlungen bis zur rechtskräftigen Entscheidung über den Genehmigungsantrag fortgeführt werden.

(3) Datenschutzverletzungen, die vor dem Inkrafttreten dieses Bundesgesetzes stattgefunden haben, sind, soweit es sich um die Feststellung der Rechtmäßigkeit oder Rechtswidrigkeit eines Sachverhalts handelt, nach der Rechtslage zum Zeitpunkt der Verwirklichung des Sachverhalts zu beurteilen; soweit es sich um die Verpflichtung zu einer Leistung oder Unterlassung handelt, ist die Rechtslage im Zeitpunkt der Entscheidung in erster Instanz zugrundezulegen. Ein strafbarer Tatbestand ist nach jener Rechtslage zu beurteilen, die für den Täter in ihrer Gesamtauswirkung günstiger ist; dies gilt auch für das Rechtsmittelverfahren.

(4) **(Verfassungsbestimmung)** Datenanwendungen, die für die in § 17 Abs. 3 genannten Zwecke notwendig sind, dürfen auch bei Fehlen einer im Sinne des § 1 Abs. 2 ausreichenden gesetzlichen Grundlage bis 31. Dezember 2007 vorgenommen werden, in den Fällen des § 17 Abs. 3 Z 1 bis 3 jedoch bis zur Erlassung von bundesgesetzlichen Regelungen über die Aufgaben und Befugnisse in diesen Bereichen.

(5) Manuelle Datenanwendungen, die gemäß § 58 der Meldepflicht unterliegen, sind, soweit sie schon im Zeitpunkt des Inkrafttretens dieses Bundesgesetzes bestanden haben, dem Datenverarbeitungsregister bis spätestens 1. Jänner 2003 zu melden. Dasselbe gilt für automationsunterstützte Datenanwendungen gemäß § 17 Abs. 3, für die durch die nunmehr geltende Rechtslage die Meldepflicht neu eingeführt wurde.

(6) Die zum Zeitpunkt des Inkrafttretens dieses Gesetzes im Amt befindliche Datenschutzkommission übernimmt für den Zeitraum von sechs Monaten ab Inkrafttreten dieses Gesetzes die Funktion der Datenschutzkommission gemäß § 35.

(7) **(Verfassungsbestimmung)** Soweit in einzelnen Vorschriften Verweise auf das Datenschutzgesetz, BGBl. Nr. 565/1978, enthalten sind, gelten diese bis zu ihrer Anpassung an dieses Bundesgesetz sinngemäß weiter.

Verordnungserlassung

§ 62. Verordnungen auf Grund dieses Bundesgesetzes in seiner jeweiligen Fassung dürfen bereits von dem Tag an erlassen werden, der der Kundmachung der durchzuführenden Gesetzesbestimmungen folgt; sie dürfen jedoch nicht vor den durchzuführenden Gesetzesbestimmungen in Kraft treten.

Verweisungen

§ 63. Soweit in diesem Bundesgesetz auf Bestimmungen anderer Bundesgesetze verwiesen wird, sind diese in ihrer jeweils geltenden Fassung anzuwenden.

Vollziehung

§ 64. Mit der Vollziehung dieses Bundesgesetzes sind, soweit sie nicht der Bundesregierung oder den Landesregierungen obliegt, der Bundeskanzler und die anderen Bundesminister im Rahmen ihres Wirkungsbereiches betraut.

Klestil

Klima

P. b. b. Verlagspostamt 1030 Wien 01Z023000K

BUNDESGESETZBLATT

FÜR DIE REPUBLIK ÖSTERREICH

Jahrgang 2001 Ausgegeben am 27. November 2001 Teil I

136. Bundesgesetz: 2. Euro-Umstellungsgesetz – Bund
(NR: GP XXI RV 742 AB 824 S. 81. BR: 6458 AB 6459 S. 681.)

136. Bundesgesetz, mit dem das Verfassungsgerichtshofgesetz 1953, das Verwaltungsgerichtshofgesetz 1985, das Datenschutzgesetz 2000, das Parteiengesetz, das Mediengesetz, das Privatradiogesetz, das Fernsehsignalgesetz, das Bundesstatistikgesetz 2000, das Bundesgesetz über die Neuorganisation der Bundestheater, das Künstler-Sozialversicherungsfondsgesetz und das Bundesvergabegesetz 1997 geändert werden (Euro-Umstellungsgesetz für den Wirkungsbereich des Bundeskanzleramtes); mit dem das Fachhochschul-Studiengesetz, das Forschungsorganisationsgesetz, das Studienberechtigungsgesetz und das Tierversuchsgesetz geändert werden; mit dem das Bundes-Jugendförderungsgesetz, das Bundes-Jugendvertretungsgesetz und das Krankenanstaltengesetz geändert werden; mit dem das Außenhandelsgesetz 1995, das Handelsstatistische Gesetz 1995, das Chemiewaffenkonvention-Durchführungsgesetz, das Sicherheitskontrollgesetz 1991, das Akkreditierungsgesetz, das Bauproduktegesetz, das Beschussgesetz, das Dampfkesselbetriebsgesetz, das Elektrotechnikgesetz 1992, das ERP-Fonds-Gesetz, das Kesselgesetz, das Luftreinhaltegesetz für Kesselanlagen, das Maß- und Eichgesetz, das Normengesetz 1971, das Vermessungsgesetz, das Arbeitskräfteüberlassungsgesetz, das Arbeitsmarktförderungsgesetz, das Jugendausbildungs-Sicherungsgesetz, das Ausländerbeschäftigungsgesetz, das Arbeitsinspektionsgesetz 1993, das ArbeitnehmerInnenschutzgesetz, das Bauarbeitenkoordinationsgesetz, das Ziviltechnikergesetz 1993, das Ziviltechnikerkammergesetz 1993, das Ingenieurgesetz 1990, die Gewerbeordnung 1994, das Sonn- und Feiertags-Betriebszeitengesetz, das Bundesgesetz zur Verbesserung der Nahversorgung und der Wettbewerbsbedingungen, das Bundesgesetz gegen den unlauteren Wettbewerb 1984, das EU-Wettbewerbsgesetz, das Euro-Währungsangabengesetz, das Wohnungsgemeinnützigkeitsgesetz, das Heizkostenabrechnungsgesetz, das Stadterneuerungsgesetz, das Wohnhaus-Wiederaufbaugesetz, das Gaswirtschaftsgesetz, das Starkstromwegegesetz 1968, das Preistransparenzgesetz, das Berufsausbildungsgesetz, das Bundesgesetz über das Grubenwehrehrenzeichen, das Lagerstättengesetz und das Allgemeine österreichische Berggesetz geändert werden (2. Euro-Umstellungsgesetz – Bund)

Der Nationalrat hat beschlossen:

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1. Abschnitt

Bundeskanzleramt
(Euro-Umstellungsgesetz für den Wirkungsbereich des Bundeskanzleramtes)

Artikel 1

Änderung des Verfassungsgerichtshofgesetzes 1953

Das Verfassungsgerichtshofgesetz 1953, BGBl. Nr. 85, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 86/2001, wird wie folgt geändert:

1. Der Titel lautet:

„Verfassungsgerichtshofgesetz 1953 – VfGG“

2. § 17a lautet:

„§ 17a. (1) Für Anträge gemäß § 15 Abs. 1 einschließlich der Beilagen ist eine Eingabengebühr von 180 Euro zu entrichten. Gebietskörperschaften sind von der Entrichtung der Eingabengebühr befreit. Die Gebührenschuld entsteht im Zeitpunkt der Überreichung der Eingabe; die Gebühr wird mit diesem Zeitpunkt fällig. Die Gebühr ist zu entrichten, indem sie mit Erlagschein unter Angabe des Verwendungszwecks auf ein entsprechendes Konto des Finanzamtes für Gebühren und Verkehrsteuern in Wien eingezahlt wird. Der postamtlich bestätigte Nachweis der Erlagscheineinzahlung ist der Eingabe anzuschließen und dem Antragsteller von der Einlaufstelle auf Verlangen zurückzugeben; zuvor ist auf dem Zahlschein ein deutlicher Sichtvermerk anzubringen und auf der im Akt verbleibenden Ausfertigung der Eingabe zu bestätigen, dass die Gebührenentrichtung durch Vorlage des Erlagscheines nachgewiesen wurde. Für die Erhebung der Eingabengebühr ist das Finanzamt für Gebühren und Verkehrsteuern in Wien in erster Instanz zuständig. Im Übrigen gelten für die Eingabengebühr die Bestimmungen des Gebührengesetzes 1957, BGBl. Nr. 267, über Eingaben mit Ausnahme des § 11 Z 1 und des § 14 sowie die §§ 74, 203 und 241 Abs. 2 und 3 der Bundesabgabenordnung 1961, BGBl. Nr. 194.

(2) Der Bundeskanzler und der Bundesminister für Finanzen sind ermächtigt, die Eingabengebühr im Einvernehmen mit dem Hauptausschuss des Nationalrates durch Verordnung neu festzusetzen, sobald und soweit sich der von der Bundesanstalt „Statistik Österreich“ verlautbarte Verbraucherpreisindex 1996 oder ein an dessen Stelle tretender Index gegenüber der für Jänner 1997 verlautbarten und in der Folge gegenüber der der letzten Festsetzung zugrunde gelegten Indexzahl um mehr als 10 vH geändert hat. Der neue Betrag ist aus dem im Abs. 1 genannten Betrag im Verhältnis der Veränderung der für Jänner 1997 verlautbarten Indexzahl zu der für die Neufestsetzung maßgebenden Indexzahl zu berechnen, jedoch auf ganze Euro abzurunden.“

3. In § 28 Abs. 1 wird der Betrag „500 S“ *durch den Betrag* „36 Euro“ *ersetzt.*

4. In § 28 Abs. 2 wird der Betrag „1 500 S“ *durch den Betrag* „109 Euro“ *ersetzt.*

5. § 89 wird folgender Abs. 14 angefügt:

„(14) Der Titel und die §§ 17a, 28 Abs. 1 und 2 und 91 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

6. Nach § 90 wird folgender § 91 angefügt:

„§ 91. Soweit in diesem Bundesgesetz auf Bestimmungen anderer Bundesgesetze verwiesen wird, sind diese in ihrer jeweils geltenden Fassung anzuwenden.“

Artikel 2

Änderung des Verwaltungsgerichtshofgesetzes 1985

Das Verwaltungsgerichtshofgesetz 1985, BGBl. Nr. 10, zuletzt geändert durch die Kundmachung BGBl. I Nr. 31/2000, wird wie folgt geändert:

1. § 24 Abs. 3 und 4 lautet:

„(3) Für folgende Eingaben einschließlich der Beilagen ist eine Eingabengebühr von 180 Euro zu entrichten:

1. für Beschwerden, Anträge auf Wiederaufnahme des Verfahrens und Anträge auf Wiedereinsetzung in den vorigen Stand;
2. unbeschadet der Pflicht zur Entrichtung der Eingabengebühr gemäß § 17a des Verfassungsgerichtshofgesetzes 1953, BGBl. Nr. 85, für Beschwerden gemäß Art. 144 Abs. 1 B-VG, die dem Verwaltungsgerichtshof gemäß Art. 144 Abs. 3 B-VG zur Entscheidung abgetreten worden sind.

Gebietskörperschaften sind von der Entrichtung der Eingabengebühr befreit. Die Gebührenschuld entsteht im Fall der Z 1 im Zeitpunkt der Überreichung der Eingabe, im Fall der Z 2 im Zeitpunkt des Einlangens der Beschwerde beim Verwaltungsgerichtshof; die Gebühr wird mit diesen Zeitpunkten fällig. Die Gebühr ist zu entrichten, indem sie mit Erlagschein unter Angabe des Verwendungszwecks auf ein entsprechendes Konto des Finanzamtes für Gebühren und Verkehrsteuern in Wien eingezahlt wird. Der postamtlich bestätigte Nachweis der Erlagscheineinzahlung ist im Fall der Z 1 der Eingabe anzuschließen, im Fall der Z 2 dem Verwaltungsgerichtshof gesondert vorzulegen. Der postamtlich bestätigte Nachweis der Erlagscheineinzahlung ist der Partei von der Einlaufstelle auf Verlangen zurückzugeben; zuvor ist auf dem Zahlschein ein deutlicher Sichtvermerk anzubringen und auf der im Akt verbleibenden Ausfertigung der Eingabe zu bestätigen, dass die Gebührenentrichtung durch Vorlage des Erlagscheines nachgewiesen wurde. Für die Erhebung der Eingabengebühr ist das Finanzamt für Gebühren und Verkehrsteuern in Wien in erster Instanz zuständig. Im Übrigen gelten für die Eingabengebühr die Bestimmungen des Gebührengesetzes 1957, BGBl. Nr. 267, über Eingaben mit Ausnahme des § 11 Z 1 und des § 14 sowie die §§ 74, 203 und 241 Abs. 2 und 3 der Bundesabgabenordnung 1961, BGBl. Nr. 194.

(4) Der Bundeskanzler und der Bundesminister für Finanzen sind ermächtigt, die Eingabengebühr im Einvernehmen mit dem Hauptausschuss des Nationalrates durch Verordnung neu festzusetzen, sobald und soweit sich der von der Bundesanstalt „Statistik Österreich“ verlautbarte Verbraucherpreisindex 1996 oder ein an dessen Stelle tretender Index gegenüber der für Jänner 1997 verlautbarten und in der Folge gegenüber der der letzten Festsetzung zugrunde gelegten Indexzahl um mehr als 10 vH geändert hat. Der neue Betrag ist aus dem im Abs. 1 genannten Betrag im Verhältnis der Veränderung der für Jänner 1997 verlautbarten Indexzahl zu der für die Neufestsetzung maßgebenden Indexzahl zu berechnen, jedoch auf ganze Euro abzurunden.“

2. In § 33a wird der Betrag „10 000 S“ *durch den Betrag* „726 Euro“ *ersetzt.*

3. § 73 wird folgender Abs. 4 angefügt:

„(4) Die §§ 24 Abs. 3 und 4, 33a und 74 samt Überschrift in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

4. Nach § 73 wird folgender § 74 samt Überschrift angefügt:

„Verweisungen

§ 74. Soweit in diesem Bundesgesetz auf Bestimmungen anderer Bundesgesetze verwiesen wird, sind diese in ihrer jeweils geltenden Fassung anzuwenden.“

Artikel 3
Änderung des Datenschutzgesetzes 2000

Das Datenschutzgesetz 2000 (DSG), BGBl. I Nr. 165/1999, wird wie folgt geändert:

1. In § 26 Abs. 6 wird der Ausdruck „260 S“ *durch* „18,89 Euro“ *ersetzt.*

2. In § 52 Abs. 1 wird der Ausdruck „260 000 S“ *durch* „18 890 Euro“ *ersetzt.*

3. In § 52 Abs. 2 wird der Ausdruck „130 000 S“ *durch* „9 445 Euro“ *ersetzt.*

4. § 60 wird folgender Abs. 3 angefügt:

„(3) §§ 26 Abs. 6 und 52 Abs. 1 und 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 4
Änderung des Parteiengesetzes

Das Bundesgesetz über die Aufgaben, Finanzierung und Wahlwerbung politischer Parteien (Parteiengesetz – PartG), BGBl. Nr. 404/1975, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 130/2000, wird wie folgt geändert:

1. In § 2 Abs. 2 lit. a wird der Betrag von „drei Millionen Schilling“ *durch* „218 019 Euro“ *ersetzt.*

2. § 2 Abs. 3 erster Satz lautet:

„Die Zuwendungen gemäß Abs. 2 betragen 14 010 294 Euro.“

3. § 2a Abs. 2 erster Satz lautet:

„Die Summe der gemäß Abs. 1 gebührenden Förderungsmittel wird berechnet, indem die Zahl der bei der jeweiligen Nationalratswahl Wahlberechtigten mit einem Betrag von 1,4535 Euro multipliziert wird.“

4. § 4 Abs. 6 Z 11 lautet:

„11. sonstige Aufwandsarten, wobei solche über 72 672 Euro gesondert auszuweisen sind.“

5. In § 4 Abs. 7 wird der Betrag von „100 000 S“ *durch* „7 260 Euro“ *ersetzt.*

6. Dem § 15 wird folgender Abs. 6 angefügt:

„(6) § 2 Abs. 2 und 3, § 2a Abs. 2, § 4 Abs. 6 Z 11 und § 4 Abs. 7 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 5

Änderung des Mediengesetzes

Das Bundesgesetz über die Presse und andere publizistische Medien (Mediengesetz), BGBl. Nr. 314/1981, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 75/2000, wird wie folgt geändert:

1. In § 27 Abs. 1 wird der Betrag von „30 000 S“ *durch* „2 180 Euro“ *ersetzt.*

2. In § 44 Abs. 3 wird der Betrag von „2 000 S“ *durch* „145 Euro“ *ersetzt.*

3. In § 44 Abs. 4 erster und dritter Satz wird jeweils der Betrag von „1 000 S“ *durch* „72 Euro“ *ersetzt.*

4. In § 45 Abs. 2, § 46 Abs. 4 und § 49 wird jeweils der Betrag von „30 000 S“ *durch* „2 180 Euro“ *ersetzt.*

5. Der bisherige Text des Art. VIa erhält die Bezeichnung „(1)“ *und folgender Abs. 2 wird angefügt:*

„(2) Art. I § 27 Abs. 1, § 44 Abs. 3 und 4, § 45 Abs. 2, § 46 Abs. 4, § 49 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 6

Änderung des Privatradiogesetzes

Das Bundesgesetz, mit dem Bestimmungen für privaten Hörfunk erlassen werden (Privatradiogesetz – PrR-G), BGBl. I Nr. 20/2001, wird wie folgt geändert:

1. In § 27 Abs. 1 wird der Betrag von „30 000 S“ *durch* „2 180 Euro“ *ersetzt.*

2. In § 27 Abs. 2 wird der Betrag von „50 000 S“ *durch* „3 600 Euro“ *ersetzt.*

3. In § 27 Abs. 3 wird der Betrag von „100 000 S“ *durch* „7 260 Euro“ *ersetzt.*

4. Dem § 33 wird folgender Abs. 3 angefügt:

„(3) § 27 Abs. 1 bis 3 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 7

Änderung des Fernsehsignalgesetzes

Das Bundesgesetz über die Anwendung von Normen von Fernsehsignalen (F-SG), BGBl. I Nr. 50/2000, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 32/2001, wird wie folgt geändert:

1. In § 8 wird der Betrag von „100 000 S“ *durch* „7 260 Euro“ *ersetzt.*

2. Der bisherige Text des § 10 erhält die Bezeichnung „(1)“; *folgender Abs. 2 wird angefügt:*

„(2) § 8 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 8

Änderung des Bundesstatistikgesetzes 2000

Das Bundesgesetz über die Bundesstatistik (Bundesstatistikgesetz 2000), BGBl. I Nr. 163/1999, wird wie folgt geändert:

1. In § 32 Abs. 5 wird der Betrag „693,4 Millionen Schilling“ *durch den Betrag* „50,391 Millionen Euro“ *und in Abs. 6 Z 3 der Betrag* „20 Millionen Schilling“ *durch den Betrag* „1,453 Millionen Euro“ *ersetzt.*

2. In § 66 Abs. 1 wird der Betrag „30 000 Schilling“ *durch den Betrag* „2 180 Euro“ *ersetzt.*

3. § 73 wird durch folgenden Abs. 9 ergänzt:

„(9) § 32 Abs. 5 und Abs. 6 Z 3 sowie § 66 Abs. 1 in der Fassung BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 9

Änderung des Bundesgesetzes über die Neuorganisation der Bundestheater

Das Bundesgesetz über die Neuorganisation der Bundestheater (Bundestheaterorganisationsgesetz – BThOG), BGBl. I Nr. 108/1998, wird wie folgt geändert:

1. In § 7 Abs. 2 wird der Betrag „1 839 Millionen Schilling“ *durch den Betrag* „133,645 Millionen Euro“ *ersetzt.*

2. Nach § 31 wird folgender § 31a eingefügt:

„**§ 31a.** § 7 Abs. 2 in der Fassung BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 10

Änderung des Künstler-Sozialversicherungsfondsgesetzes

Das Bundesgesetz über die Errichtung eines Fonds zur Förderung der Beiträge der selbstständigen Künstler zur gesetzlichen Sozialversicherung (Künstler-Sozialversicherungsfondsgesetz – K-SVFG), BGBl. I Nr. 131/2000, wird wie folgt geändert:

1. In § 18 Abs. 1 wird der Betrag „12 000 S“ *durch den Betrag* „872 Euro“ *ersetzt.*

2. § 30 wird durch folgenden Abs. 3 ergänzt:

„(3) § 18 Abs. 1 in der Fassung BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 11

Änderung des Bundesvergabegesetzes 1997

Das Bundesvergabegesetz 1997 (BVergG), BGBl. I Nr. 56/1997, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 125/2000, wird wie folgt geändert:

1. § 10 Abs. 1 lautet:

„(1) Der Bundeskanzler hat den Gegenwert der in SZR festgesetzten Schwellenwerte in Euro kundzumachen. Der Gegenwert der in SZR festgesetzten Schwellenwerte in Euro ergibt sich aus der entsprechenden Veröffentlichung der Kommission der Europäischen Gemeinschaft (Kommission) im Amtsblatt der Europäischen Gemeinschaften.“

2. § 14 Abs. 1 Z 1 bis 3 lauten:

„1. bei Liefer- und Dienstleistungsaufträgen gemäß §§ 1 und 3 70 000 Euro ohne Umsatzsteuer,
2. bei Bau- und Baukonzessionsaufträgen gemäß § 2 Abs. 1 Z 2 und 3 und Abs. 2 sowie § 11 Abs. 3 1 Million Euro ohne Umsatzsteuer,
3. bei Bau- und Baukonzessionsaufträgen gemäß § 2 Abs. 1 Z 1 500 000 Euro ohne Umsatzsteuer.“

3. § 37 Abs. 3 Z 4 lautet:

„4. der Haftungsrücklass in der Regel 3 vH nicht überschreiten soll und – wenn er 2 000 Euro unterschreitet – nicht einbehalten werden muss,“.

4. § 42 Abs. 2 lautet:

„(2) Sofern in den Ausschreibungsunterlagen nicht ausdrücklich anderes zugelassen wird, ist das Angebot in deutscher Sprache und in Euro zu erstellen.“

5. In den §§ 62 Abs. 1 Z 1 bis 3, 80, 86 Abs. 6 und 7, 88 Abs. 1 Z 1 bis 3 und 91 Z 2 lit. a und b wird der Ausdruck „ECU“ *durch* „Euro“ *ersetzt.*

6. In § 89 Abs. 3 Z 7 lit. e wird der Ausdruck „§ 4“ *durch* „§ 9“ *ersetzt.*

7. In § 98 Abs. 6 hat der Ausdruck „50 000 S“ *zu lauten* „3 600 Euro“.

8. § 109 Abs. 3 zweiter Satz lautet:

„Ein solches Ersuchen ist nur zulässig, wenn der Wert eines Auftrages – beurteilt nach dem arithmetischen Mittel der Gesamtpreise der Angebote – mindestens 15 Millionen Euro beträgt.“

9. § 118 Abs. 3 lautet:

„(3) Im Nachprüfungsverfahren beträgt die Höchstgrenze für Mutwillensstrafen (§ 35 AVG) ein Prozent des geschätzten Auftragswertes, höchstens jedoch 60 000 Euro.“

10. In § 127 Abs. 1 hat der Ausdruck „50 000 S“ *zu lauten* „3 600 Euro“.

11. § 128 wird folgender Abs. 7 angefügt:

„(7) Die §§ 10 Abs. 1, 14 Abs. 1 Z 1 bis 3, 37 Abs. 3 Z 4, 42 Abs. 2, 62 Abs. 1 Z 1 bis 3, 80, 86 Abs. 6 und 7, 88 Abs. 1 Z 1 bis 3, 91 Z 2 lit. a und b, 89 Abs. 3 Z 7 lit. e, 98 Abs. 6, 109 Abs. 3 zweiter Satz, § 118 Abs. 3 und § 127 Abs. 1 treten mit 1. Jänner 2002 in Kraft.“

2. Abschnitt

Bundesministerium für Bildung, Wissenschaft und Kultur

Artikel 12

Änderung des Fachhochschul-Studiengesetzes

Das Bundesgesetz über Fachhochschul-Studiengänge (Fachhochschul-Studiengesetz – FHStG), BGBl. Nr. 340/1993, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 72/1998, wird wie folgt geändert:

1. In § 18 wird die Betragsangabe „500 000 S“ *durch die Betragsangabe* „36 300 Euro“ *ersetzt.*

2. Dem § 20 wird folgender Abs. 3 angefügt:

„(3) § 18 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 13

Änderung des Forschungsorganisationsgesetzes

Das Forschungsorganisationsgesetz, BGBl. Nr. 341/1981, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 47/2000, wird wie folgt geändert:

1. § 15 Abs. 2 fünfter Satz lautet:

„Wenn die zu vereinbarende Tätigkeit voraussichtlich länger als sechs Monate dauern wird oder das zu vereinbarende Gesamtentgelt eines derartigen Vertrages 363 364 Euro übersteigt, bedarf der Vertragsabschluss der vorherigen Genehmigung des Bundesministers für Bildung, Wissenschaft und Kultur.“

2. § 38 Abs. 3 lautet:

„(3) § 15 Abs. 2 fünfter Satz in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

3. § 38 wird folgender Abs. 4 angefügt:

„(4) § 30a tritt mit Ablauf des 31. Dezember 2000 außer Kraft.“

Artikel 14

Änderung des Studienberechtigungsgesetzes

Das Bundesgesetz über die Erlangung studienrichtungsbezogener Studienberechtigungen an Universitäten und Hochschulen künstlerischer Richtung (Studienberechtigungsgesetz – StudBerG), BGBl. Nr. 292/1985, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 620/1994, wird wie folgt geändert:

1. In § 17 Abs. 3 wird die Betragsangabe „30 000 S“ *durch die Betragsangabe* „2 200 Euro“ *ersetzt.*

2. Dem § 19 wird folgender Abs. 8 angefügt:

„(8) § 17 Abs. 3 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 15

Änderung des Tierversuchsgesetzes

Das Tierversuchsgesetz, BGBl. Nr. 501/1989, in der Fassung des Bundesgesetzes BGBl. I Nr. 169/1999 wird wie folgt geändert:

1. In § 18 wird die Betragsangabe „100 000 S“ *durch die Betragsangabe* „7 260 Euro“, *die Betragsangabe* „50 000 S“ *durch die Betragsangabe* „3 600 Euro“ *und die Betragsangabe* „25 000 S“ *durch die Betragsangabe* „1 800 Euro“ *ersetzt.*

2. Dem § 20 wird folgender Abs. 5 angefügt:

„(5) § 18 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

3. Abschnitt

Bundesministerium für soziale Sicherheit und Generationen

Artikel 16

Änderung des Bundes-Jugendförderungsgesetzes

Das Bundes-Jugendförderungsgesetz, BGBl. I Nr. 126/2000, wird wie folgt geändert:

1. Im § 7 Abs. 2 wird die Betragsangabe „700 000 S“ *durch die Betragsangabe* „50 871 Euro“ *und die Betragsangabe* „100 000 S“ *durch die Betragsangabe* „7 267,3 Euro“ *ersetzt.*

2. Im § 7 Abs. 3 wird die Betragsangabe „200 000 S“ *durch die Betragsangabe* „14 534,6 Euro“, *die Betragsangabe* „500 000 S“ *durch die Betragsangabe* „36 336,4 Euro“, *die Betragsangabe* „1 000 000 S“ *durch die Betragsangabe* „72 672,8 Euro“ *und die Betragsangabe* „2 000 000 S“ *durch die Betragsangabe* „145 345,7 Euro“ *ersetzt.*

3. Im § 7 Abs. 4 wird die Betragsangabe „100 000 S“ *durch die Betragsangabe* „7 267,3 Euro“ *ersetzt.*

4. Dem § 12 erster Satz wird die Absatzbezeichnung „(1)“ *vorangestellt und folgender Abs. 2 angefügt:*

„(2) § 7 Abs. 2, 3 und 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 17

Änderung des Bundes-Jugendvertretungsgesetzes

Das Bundes-Jugendvertretungsgesetz, BGBl. I Nr. 127/2000, wird wie folgt geändert:

1. Im § 6 Z 4 lit. f wird die Betragsangabe „200 000 S“ *durch die Betragsangabe* „14 534,6 Euro“ *ersetzt.*

2. Dem § 13 erster Satz wird die Absatzbezeichnung „(1)“ *vorangestellt und folgender Abs. 2 angefügt:*

„(2) § 6 Z 4 lit. f in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 18

Änderung des Krankenanstaltengesetzes

Das Krankenanstaltengesetz, BGBl. Nr. 1/1957, zuletzt geändert durch die Bundesgesetze BGBl. I Nr. 135/2000 und BGBl. I Nr. 5/2001, wird wie folgt geändert:

1. Titel
(Grundsatzbestimmungen)

1. In § 27a Abs. 1 wird die Betragsangabe „50 S“ *durch die Betragsangabe* „3,63 Euro“ *ersetzt.*

2. In § 27a Abs. 2 wird die Betragsangabe „20 S“ *durch die Betragsangabe* „1,45 Euro“ *ersetzt.*

3. In § 27a Abs. 4 entfällt die Wendung „wobei auf volle Schilling zu runden ist“.

4. In § 27a Abs. 5 wird die Betragsangabe „10 S“ *durch die Betragsangabe* „0,73 Euro“ *ersetzt.*

5. § 28 Abs. 1 lautet:

„(1) Der Eurowert je LKF-Punkt als Grundlage für die Ermittlung der LKF-Gebühren, die Pflegegebühren und allfälligen Sondergebühren (§ 27 Abs. 4) sind vom Rechtsträger der Krankenanstalt für die Voranschläge und für die Rechnungsabschlüsse unter Bedachtnahme auf § 27 Abs. 3 kostendeckend zu ermitteln. Die LKF-Gebühren ermitteln sich als Produkt der für den einzelnen Pflegling ermittelten LKF-Punkte mit dem von der Landesregierung festgelegten Eurowert je LKF-Punkt. Gelangen LKF-Gebühren zur Verrechnung, ist das österreichweit einheitliche System der leistungsorientierten Diagnosenfallgruppen einschließlich des Bepunktungssystems in geeigneter Weise kundzumachen. Der für die LKF-Gebühren zur Verrechnung gelangende Eurowert je LKF-Punkt, die Pflegegebühren und Sondergebühren sind von der Landesregierung unter Bedachtnahme auf die Ausstattung und Einrichtung, wie sie durch die Funktion der Krankenanstalt erforderlich sind, und die ordnungsgemäße und wirtschaftliche Gebarung festzusetzen und im Landesgesetzblatt kundzumachen. In diese Kundmachung sind auch der kostendeckend ermittelte Eurowert, die kostendeckend ermittelten Pflegegebühren und Sondergebühren aufzunehmen.“

2. Titel
(Unmittelbar anwendbares Bundesrecht)

1. § 57 lautet:

„**§ 57.** (1) Der Bund hat dem Strukturfonds gemäß § 56a jährlich die folgenden Mittel für die Finanzierung von öffentlichen Krankenanstalten gemäß § 2 Abs. 1 Z 1 und 2 mit Ausnahme der Pflegeabteilungen in öffentlichen Krankenanstalten für Psychiatrie und private Krankenanstalten der im § 2 Abs. 1 Z 1 bezeichneten Art, die gemäß § 16 gemeinnützig geführte Krankenanstalten sind, zu gewähren:

1. 1,416 vH des Aufkommens an der Umsatzsteuer im betreffenden Jahr nach Abzug des im § 9 Abs. 2 Z 1 des Finanzausgleichsgesetzes 2001 genannten Betrages;
2. 31 249 318,69 Euro;
3. 127 177 459,79 Euro.

(2) Der Hauptverband der österreichischen Sozialversicherungsträger leistet für Rechnung der in ihm zusammengefassten Sozialversicherungsträger an den Strukturfonds gemäß § 56a jährlich Mittel in der Höhe von 83 573 759,29 Euro.

(3) Der Strukturfonds leistet an die Länder (Landesfonds) zur Finanzierung der in Abs. 1 genannten Krankenanstalten jährlich folgende Beiträge:

1. 1,416 vH des Aufkommens an der Umsatzsteuer im betreffenden Jahr nach Abzug des im § 9 Abs. 2 Z 1 des Finanzausgleichsgesetzes 2001 genannten Betrages;
2. 23 982 035,28 Euro;
3. 90 841 042,71 Euro;
4. 127 177 459,79 Euro nach Maßgabe des § 59d und nach Abzug der Mittel zur Förderung des Transplantationswesens, der Mittel für die Finanzierung von Planungen und Strukturreformen und allfälliger Mittel für die Anstaltspflege österreichischer PatientInnen im Ausland.“

2. § 59 Abs. 6 Z 1 und 2 lauten:

„(6) Die Mittel des Strukturfonds gemäß § 57 Abs. 3 Z 4 sind gemäß der nachfolgenden Bestimmungen aufzuteilen:

1. Zunächst sind von den 127 177 459,79 Euro jährlich Vorweganteile abzuziehen und folgendermaßen zu verteilen:
   a) 3 633 641,71 Euro für das Bundesland (den Landesfonds) Oberösterreich,
   b) 4 360 370,05 Euro für das Bundesland (den Landesfonds) Steiermark,
   c) 3 633 641,71 Euro für das Bundesland (den Landesfonds) Tirol.
2. Sodann sind von den verbleibenden 115 549 806,32 Euro die Mittel zur Förderung des Transplantationswesens im Ausmaß von 2 906 913,37 Euro jährlich, die Mittel für die Finanzierung von Planungen und Strukturreformen im Ausmaß von 2 180 185,03 Euro jährlich, bei einem Mehrbedarf jedoch bis zu höchstens 3 633 641,71 Euro jährlich, abzuziehen und vom Strukturfonds einzubehalten und gemäß § 59d und § 59e zu verwenden. Von dem sodann verbleibenden Betrag sind weiters allfällige für Anstaltspflege im Ausland aufzuwendende Mittel jährlich abzuziehen und gemäß Art. 32 Abs. 3 der Vereinbarung gemäß Art. 15a B-VG über die Neustrukturierung des Gesundheitswesens und der Krankenanstaltenfinanzierung zu verwenden.“

3. Titel
(Grundsatzbestimmungen)

1. In § 27a Abs. 1 wird die Betragsangabe „50 S“ *durch die Betragsangabe* „3,63 Euro“ *ersetzt.*

2. In § 27a Abs. 2 wird die Betragsangabe „20 S“ *durch die Betragsangabe* „1,45 Euro“ *ersetzt.*

3. In § 27a Abs. 4 entfällt die Wendung „wobei auf volle Schilling zu runden ist“.

4. Titel

(1) Die Landesgesetzgebung hat die Ausführungsbestimmungen zum 1. Titel innerhalb von sechs Monaten zu erlassen und mit 1. Jänner 2002 in Kraft zu setzen.

(2) Die Landesgesetzgebung hat die Ausführungsbestimmungen zum 3. Titel innerhalb eines Jahres zu erlassen.

(3) Die Wahrnehmung der Rechte des Bundes gemäß Art. 15 Abs. 8 B-VG hinsichtlich des 1. und des 3. Titels steht dem Bundesminister für soziale Sicherheit und Generationen zu.

(4) Der 2. Titel tritt mit 1. Jänner 2002 in Kraft.

(5) Der 1. und der 2. Titel treten mit Ablauf des 31. Dezember 2004 außer Kraft.

(6) Der 3. Titel tritt mit 1. Jänner 2005 in Kraft.

(7) Mit der Vollziehung des 2. Titels ist der Bundesminister für soziale Sicherheit und Generationen im Einvernehmen mit dem Bundesminister für Finanzen betraut.“

4. Abschnitt

Bundesministerium für Wirtschaft und Arbeit

Artikel 19

Änderung des Außenhandelsgesetzes 1995

Das Außenhandelsgesetz 1995 (AußHG 1995), BGBl. Nr. 172/1995, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 429/1996, wird wie folgt geändert:

1. Im § 4 Z 3 wird die Betragsangabe „11 500 S“ *durch die Betragsangabe* „840 €“ *ersetzt.*

2. Im § 4 Z 4 lit. a wird die Betragsangabe „3 500 S“ *durch die Betragsangabe* „255 €“ *ersetzt.*

3. Im § 4 Z 4 lit. b wird die Betragsangabe „500 S“ *durch die Betragsangabe* „37 €“ *ersetzt.*

4. Im § 4 Z 10 wird die Betragsangabe „40 000 S“ *durch die Betragsangabe* „2 910 €“ *ersetzt.*

5. Im § 4 Z 17 wird die Betragsangabe „11 500 S“ *durch die Betragsangabe* „840 €“ *ersetzt.*

6. Im § 4 Z 18 lit. a wird die Betragsangabe „5 000 S“ *durch die Betragsangabe* „365 €“ *ersetzt.*

7. Im § 17 Abs. 5 wird die Betragsangabe „500 000 S“ *durch die Betragsangabe* „36 300 €“ *ersetzt.*

8. Im § 18 Abs. 1 Z 1 und im § 19 Abs. 1 Z 1 wird die Betragsangabe „eine Million Schilling“ *oder* „einer Million Schilling“ *jeweils durch die Betragsangabe* „75 000 €“ *ersetzt.*

9. Im § 18 Abs. 1 wird die Betragsangabe „zwei Millionen Schilling“ *durch die Betragsangabe* „145 200 €“ *ersetzt.*

10. Im § 19 Abs. 1 am Ende des ersten Satzes und im § 19 Abs. 2 wird die Betragsangabe „einer Million Schilling“ *jeweils durch die Betragsangabe* „72 600 €“ *ersetzt.“*

11. Dem § 23 Abs. 2 wird folgender Abs. 3 angefügt:

„(3) § 4 Z 3, Z 4 lit. a und b, Z 10, Z 17 und Z 18 lit. a, § 17 Abs. 5, § 18 Abs. 1 sowie § 19 Abs. 1 und 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 20

Änderung des Handelsstatistischen Gesetzes 1995

Das Handelsstatistische Gesetz 1995 (HStG 1995), BGBl. Nr. 173/1995, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 180/1998, wird wie folgt geändert:

1. Im § 23 Abs. 1 wird die Betragsangabe „15 000 S“ *durch die Betragsangabe* „1 090 €“ *ersetzt.*

2. Dem § 26 Abs. 3 wird folgender Abs. 4 angefügt:

„(4) § 23 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 21

Änderung des Chemiewaffenkonvention-Durchführungsgesetzes

Das Chemiewaffenkonvention-Durchführungsgesetz – CWKG, BGBl. I Nr. 24/1997, wird wie folgt geändert:

1. Im § 11 Abs. 1 wird die Betragsangabe „500 000 S“ *durch die Betragsangabe* „36 300 €“ *ersetzt.*

2. Im § 11 Abs. 2 wird die Betragsangabe „300 000 S“ *durch die Betragsangabe* „21 800 €“ *ersetzt.*

3. Dem § 13 Abs. 3 wird folgender Abs. 4 angefügt:

„(4) § 11 Abs. 1 und Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 22

Änderung des Sicherheitskontrollgesetzes 1991

Das Sicherheitskontrollgesetz 1991, BGBl. Nr. 415/1992, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 762/1996, wird wie folgt geändert:

1. Im § 18 wird die Betragsangabe „500 000 S“ *durch die Betragsangabe* „36 300 €“ *ersetzt.*

2. Der bisherige Text des § 19 erhält die Absatzbezeichnung „(1)“ *und es wird folgender Abs. 2 angefügt:*

„(2) § 18 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 23

Änderung des Akkreditierungsgesetzes

Das Bundesgesetz über die Akkreditierung von Prüf-, Überwachungs- und Zertifizierungsstellen (Akkreditierungsgesetz), BGBl. Nr. 468/1992, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 430/1996, wird wie folgt geändert:

1. In § 37 Z 2 wird der Ausdruck „100 000 S“ *durch den Ausdruck* „7 260 €“ *ersetzt.*

2. Dem Artikel V wird folgender Abs. 5 angefügt:

„(5) § 37 Z 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 24

Änderung des Bauproduktegesetzes

Das Bundesgesetz über das In-Verkehr-Bringen von Bauprodukten und den freien Warenverkehr mit diesen (Bauproduktegesetz), BGBl. I Nr. 55/1997, wird wie folgt geändert:

1. In § 15 Abs. 1 wird der Ausdruck „500 000 S“ *durch den Ausdruck* „36 300 €“ *und der Ausdruck* „300 000 S“ *durch den Ausdruck* „21 800 €“ *ersetzt.*

2. Nach § 17 wird folgender § 18 angefügt:

„**§ 18.** § 15 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 25

Änderung des Beschussgesetzes

Das Bundesgesetz über die obligatorische Erprobung aller Handfeuerwaffen und Patronen (Beschussgesetz), BGBl. Nr. 141/1951, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 233/1984, wird wie folgt geändert:

1. In § 18 Abs. 1 wird der Ausdruck „3 000 S“ *durch den Ausdruck* „218 €“ *ersetzt.*

2. Nach § 23 wird folgender § 24 angefügt:

„**§ 24.** § 18 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 26

Änderung des Dampfkesselbetriebsgesetzes

Das Bundesgesetz über den Betrieb von Dampfkesseln und Wärmekraftmaschinen (Dampfkesselbetriebsgesetz), BGBl. Nr. 212/1992, wird wie folgt geändert:

1. In § 11 wird der Ausdruck „100 000 S“ *durch den Ausdruck* „7 260 €“ *und der Ausdruck* „30 000 S“ *durch den Ausdruck* „2 180 €“ *ersetzt.*

2. Dem § 13 wird folgender Abs. 3 angefügt:

„(3) § 11 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 27

Änderung des Elektrotechnikgesetzes 1992

Das Bundesgesetz über die Sicherheitsmaßnahmen, Normalisierung und Typisierung auf dem Gebiete der Elektrotechnik (Elektrotechnikgesetz 1992), BGBl. Nr. 106/1993, wird wie folgt geändert:

1. In § 17 Abs. 1 wird der Ausdruck „350 000 S“ *durch den Ausdruck* „25 435 €“, *der Ausdruck* „200 000 S“ *durch den Ausdruck* „14 530 €“ *und der Ausdruck* „100 000 S“ *durch den Ausdruck* „7 260 €“ *ersetzt.*

2. Dem § 19 wird folgender Abs. 5 angefügt:

„(5) § 17 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 28

Änderung des ERP-Fonds-Gesetzes

Das Bundesgesetz über die Verwaltung der ERP-Counterpart-Mittel (ERP-Fonds-Gesetz), BGBl. Nr. 207/1962, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 1105/1994, wird wie folgt geändert:

1. In § 3 Abs. 2 wird der Ausdruck „4.705,404.000 Schilling“ *durch den Ausdruck* „341 955 045 €“ *ersetzt.*

2. In § 5 Abs. 1 wird der Ausdruck „fünfhunderttausend Schilling“ *durch den Ausdruck* „36 340 €“, *der Ausdruck* „hunderttausend bis fünfhunderttausend Schilling“ *durch den Ausdruck* „7 270 € bis 36 340 €“ *und der Ausdruck* „zehntausend bis hunderttausend Schilling“ *durch den Ausdruck* „730 € bis 7 270 €“ *ersetzt.*

3. In § 20 Abs. 2 wird der Ausdruck „fünfhunderttausend Schilling“ *durch den Ausdruck* „36 340 €“ *ersetzt.*

4. Dem § 28 wird folgender Abs. 6 angefügt:

„(6) § 3 Abs. 2, § 5 Abs. 1 und § 20 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 29

Änderung des Kesselgesetzes

Das Bundesgesetz über Sicherheitsmaßnahmen für Dampfkessel, Druckbehälter, Versandbehälter und Rohrleitungen (Kesselgesetz), BGBl. Nr. 211/1992, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 468/1992, wird wie folgt geändert:

1. In § 31 wird der Ausdruck „25 000 S“ *durch den Ausdruck* „1 800 €“, *der Ausdruck* „100 000 S“ *durch den Ausdruck* „7 260 €“ *und der Ausdruck* „300 000 S“ *durch den Ausdruck* „21 800 €“ *ersetzt.*

2. Dem § 34 wird folgender Abs. 5 angefügt:

„(5) § 31 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 30

Änderung des Luftreinhaltegesetzes für Kesselanlagen

Das Bundesgesetz zur Begrenzung der von Dampfkesselanlagen ausgehenden Luftverunreinigungen (Luftreinhaltegesetz für Kesselanlagen), BGBl. Nr. 380/1988, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 115/1997, wird wie folgt geändert:

1. In § 15 Abs. 1 wird der Ausdruck „10 000 S“ *durch den Ausdruck* „726 €“, *der Ausdruck* „100 000 S“ *durch den Ausdruck* „7 260 €“ *und der Ausdruck* „500 000 S“ *durch den Ausdruck* „36 300 €“ *ersetzt.*

2. Dem § 16 wird folgender Abs. 5 angefügt:

„(5) § 15 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 31

Änderung des Maß- und Eichgesetzes

Das Bundesgesetz über das Maß- und Eichwesen (Maß- und Eichgesetz), BGBl. Nr. 152/1950, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 657/1996, wird wie folgt geändert:

1. In § 63 wird der Ausdruck „150 000 S“ *durch den Ausdruck* „10 900 €“ *ersetzt.*

2. Nach § 70 wird folgender § 71 angefügt:

„**§ 71.** § 63 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 32

Änderung des Normengesetzes 1971

Das Bundesgesetz über das Normenwesen (Normengesetz 1971), BGBl. Nr. 240/1971, wird wie folgt geändert:

1. In § 8 Abs. 1 wird der Ausdruck „30 000 S“ *durch den Ausdruck* „2 180 €“ *ersetzt.*

2. Dem § 10 wird folgender Abs. 3 angefügt:

„(3) § 8 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 33

Änderung des Vermessungsgesetzes

Das Bundesgesetz über die Landesvermessung und den Grenzkataster (Vermessungsgesetz), BGBl. Nr. 306/1968, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 30/1997, wird wie folgt geändert:

1. In § 51 Abs. 1 wird der Ausdruck „5 000 S“ *durch den Ausdruck* „360 €“ *und in § 51 Abs. 2 der Ausdruck* „500 S“ *durch den Ausdruck* „36 €“ *ersetzt.*

2. Dem § 57 wird folgender Abs. 4 angefügt:

„(4) § 51 Abs. 1 und 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 34

Änderung des Arbeitskräfteüberlassungsgesetzes

Das Arbeitskräfteüberlassungsgesetz (AÜG), BGBl. Nr. 196/1988, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 44/2000, wird wie folgt geändert:

1. Im § 22 Abs. 1 Z 1 wird der Ausdruck „mit Geldstrafe von 10 000 S bis 50 000 S, im Wiederholungsfall von 20 000 S bis 100 000 S“ *durch den Ausdruck* „mit Geldstrafe von 726 € bis zu 3 600 €, im Wiederholungsfall von 1 450 € bis zu 7 260 €“ *ersetzt.*

2. Im § 22 Abs. 1 Z 2 und Z 3 wird der Ausdruck „mit Geldstrafe bis zu 10 000 S, im Wiederholungsfall von 5 000 S bis 20 000 S“ *jeweils durch den Ausdruck* „mit Geldstrafe bis zu 726 €, im Wiederholungsfall von 360 € bis zu 1 450 €“ *ersetzt.*

3. § 23 lautet:

„**§ 23.** (1) Dieses Bundesgesetz tritt mit 1. Juli 1988 in Kraft.

(2) § 1 Abs. 4 in der Fassung des Bundesgesetzes BGBl. Nr. 460/1993 tritt mit 1. Juli 1993 in Kraft.

(3) Die §§ 1 Abs. 3, 13 Abs. 4 und 5, 15, 17, 18 Abs. 1, 19 Abs. 1 bis 3, 20 Abs. 1, 21 Abs. 1 und 22 Abs. 3 in der Fassung des Bundesgesetzes BGBl. Nr. 314/1994 treten mit 1. Juli 1994 in Kraft. Bis zum In-Kraft-Treten des § 5 Z 1 lit. b des Bundessozialämtergesetzes (Art. 33 des Arbeitsmarktservice-Begleitgesetzes, BGBl. Nr. 314/1994) obliegen die Aufgaben und Befugnisse der Bundesämter für Soziales und Behindertenwesen den jeweiligen Landesgeschäftsstellen des Arbeitsmarktservice.

(4) Die §§ 1, 10a, 12a, 13, 16a und 17 in der Fassung des Bundesgesetzes BGBl. I Nr. 120/1999 treten mit 1. Oktober 1999 in Kraft und sind auf Sachverhalte anzuwenden, die sich nach dem 30. September 1999 ereignen.

(5) § 11 Abs. 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 44/2000 tritt mit 1. Juli 2000 in Kraft.

(6) § 22 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 35

Änderung des Arbeitsmarktförderungsgesetzes

Das Arbeitsmarktförderungsgesetz, BGBl. Nr. 31/1969, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 142/2000, wird wie folgt geändert:

1. In den §§ 34 Abs. 1 und 39 Abs. 1 wird der Ausdruck „drei Millionen Schilling“ *jeweils durch den Ausdruck* „220 000 €“ *ersetzt.*

2. Im § 48 Abs. 1 wird der Ausdruck „mit einer Geldstrafe von 10 000 S bis 50 000 S, im Wiederholungsfall von 20 000 S bis 100 000 S“ *durch den Ausdruck* „mit Geldstrafe von 726 € bis zu 3 600 €, im Wiederholungsfall von 1 450 € bis zu 7 260 €“ *ersetzt.*

3. Dem § 53 wird folgender Abs. 13 angefügt:

„(13) Die §§ 34 Abs. 1, 39 Abs. 1 und 48 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 36

Änderung des Jugendausbildungs-Sicherungsgesetzes

Das Jugendausbildungs-Sicherungsgesetz, BGBl. I Nr. 91/1998, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 142/2000, wird wie folgt geändert:

1. Im § 3 Abs. 5 wird der Ausdruck „2 000 Schilling“ *durch den Ausdruck* „150 €“ *ersetzt.*

2. Im § 4 Abs. 4 wird der Ausdruck „2 985 Schilling“ *durch den Ausdruck* „220 €“ *ersetzt.*

3. Dem § 8 wird folgender Abs. 5 angefügt:

„(5) § 3 Abs. 5 und § 4 Abs. 4 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 37

Änderung des Ausländerbeschäftigungsgesetzes

Das Ausländerbeschäftigungsgesetz, BGBl. Nr. 218/1975, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 120/1999, wird wie folgt geändert:

1. Im § 28 Abs. 1 werden ersetzt:

a) in Z 1 die Wortfolge „bei unberechtigter Beschäftigung von höchstens drei Ausländern für jeden unberechtigt beschäftigten Ausländer mit Geldstrafe von 10 000 S bis 60 000 S, im Falle der erstmaligen und weiteren Wiederholung von 20 000 S bis zu 120 000 S, bei unberechtigter Beschäftigung von mehr als drei Ausländern für jeden unberechtigt beschäftigten Ausländer mit Geldstrafe von 20 000 S bis zu 120 000 S, im Falle der erstmaligen und weiteren Wiederholung von 40 000 S bis zu 240 000 S“ *durch die Wortfolge* „bei unberechtigter Beschäftigung von höchstens drei Ausländern für jeden unberechtigt beschäftigten Ausländer mit Geldstrafe von 726 € bis 4 360 €, im Falle der erstmaligen und weiteren Wiederholung von 1 450 € bis 8 710 €, bei unberechtigter Beschäftigung von mehr als drei Ausländern für jeden unberechtigten beschäftigten Ausländer mit Geldstrafe von 1 450 € bis 8 710 €, im Falle der erstmaligen und weiteren Wiederholung von 2 900 € bis 17 430 €“,

b) in Z 2 der Ausdruck „mit Geldstrafe von 2 000 S bis zu 30 000 S, im Falle der lit. c bis f von 30 000 S bis 50 000 S“ *durch den Ausdruck* „mit Geldstrafe von 145 € bis 2 180 €, im Falle der lit. c bis f von 2 180 € bis 3 600 €“,

c) in Z 3 der Ausdruck „mit einer Geldstrafe von 5 000 S bis 30 000 S“ *durch den Ausdruck* „mit Geldstrafe von 360 € bis 2 180 €“,

d) in Z 4 der Ausdruck „mit Geldstrafe bis zu 10 000 S“ *durch den Ausdruck* „mit Geldstrafe bis zu 726 €“,

e) in Z 5 der Ausdruck „mit Geldstrafe bis zu 15 000 S“ *durch den Ausdruck* „mit Geldstrafe bis zu 1 090 €“.

2. Dem § 34 wird folgender Abs. 21 angefügt:

„(21) § 28 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 38

Änderung des Arbeitsinspektionsgesetzes 1993

Das Bundesgesetz über die Arbeitsinspektion (Arbeitsinspektionsgesetz 1993 – ArbIG, BGBl. Nr. 27/1993, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 38/1999, wird wie folgt geändert:

1. In § 24 Abs. 1 wird die Wortfolge „mit Geldstrafe von 500 S bis 50 000 S, im Wiederholungsfall mit Geldstrafe von 1 000 S bis 50 000 S“ *ersetzt durch die Wortfolge* „mit Geldstrafe von 36 € bis 3 600 €, im Wiederholungsfall mit Geldstrafe von 72 € bis 3 600 €“.

2. Dem § 25 wird folgender Abs. 3 angefügt:

„(3) § 24 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 39

Änderung des ArbeitnehmerInnenschutzgesetzes

Das Bundesgesetz über Sicherheit und Gesundheitsschutz bei der Arbeit (ArbeitnehmerInnenschutzgesetz – ASchG), BGBl. Nr. 450/1994, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 70/1999, wird wie folgt geändert:

1. In § 130 Abs. 1, 2, 3, 5 und 6 wird die Wortfolge „mit Geldstrafe von 2 000 S bis 100 000 S, im Wiederholungsfall mit Geldstrafe von 4 000 S bis 200 000 S“ *ersetzt durch die Wortfolge* „mit Geldstrafe von 145 € bis 7 260 €, im Wiederholungsfall mit Geldstrafe von 290 € bis 14 530 €“.

2. In § 130 Abs. 4 wird die Wortfolge „mit Geldstrafe bis 3 000 S, im Wiederholungsfall mit Geldstrafe bis 5 000 S“ *ersetzt durch die Wortfolge* „mit Geldstrafe bis 218 €, im Wiederholungsfall mit Geldstrafe bis 360 €“.

3. Dem § 131 wird folgender Abs. 6 angefügt:

„(6) § 130 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 40

Änderung des Bauarbeitenkoordinationsgesetzes

Das Bundesgesetz über die Koordination bei Bauarbeiten (Bauarbeitenkoordinationsgesetz – BauKG), BGBl. I Nr. 37/1999, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 85/1999, wird wie folgt geändert:

1. In § 10 Abs. 1 wird die Wortfolge „mit Geldstrafe von 2 000 S bis 100 000 S, im Wiederholungsfall mit Geldstrafe von 4 000 S bis 200 000 S“ *durch die Wortfolge* „mit Geldstrafe von 145 € bis 7 260 €, im Wiederholungsfall mit Geldstrafe von 290 € bis 14 530 €“ *ersetzt.*

2. Dem § 11 wird folgender Abs. 3 angefügt:

„(3) § 10 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 41

Änderung des Ziviltechnikergesetzes 1993

Das Ziviltechnikergesetz 1993, BGBl. Nr. 156/1994, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 86/1997, wird wie folgt geändert:

1. § 31 Z 2 lautet:

„2. unberechtigt die im § 30 angeführten Bezeichnungen führt oder seiner Firma beifügt, begeht, sofern die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung bildet oder nach anderen Verwaltungsstrafbestimmungen mit strengerer Strafe bedroht ist, eine Verwaltungsübertretung und ist mit einer Geldstrafe bis 7 260 € zu bestrafen. Die Dauer der im Falle der Uneinbringlichkeit der Geldstrafe zu bestimmenden Ersatzfreiheitsstrafe darf 14 Tage nicht übersteigen.“

2. Der bisherige Text des § 33 erhält die Absatzbezeichnung „(1)“ *und es wird folgender Abs. 2 angefügt:*

„(2) § 31 Z 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 42

Änderung des Ziviltechnikerkammergesetzes 1993

Das Ziviltechnikerkammergesetz 1993, BGBl. Nr. 157/1994, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 56/2000, wird wie folgt geändert:

1. § 35 lautet:

„**§ 35.** Die Führung der Bezeichnung „Architekten- und Ingenieurkonsulentenkammer“ sowie der Bezeichnung „Kammer“ mit einem auf das Architekten-, Ingenieurkonsulenten- oder Ziviltechnikerwesen hinweisenden Zusatz durch andere als die nach diesem Bundesgesetz bestehenden Körperschaften ist als Verwaltungsübertretung mit Geldstrafe bis zu 7 260 € zu bestrafen. Die Dauer der für den Fall der Uneinbringlichkeit der Geldstrafe zu bestimmenden Ersatzfreiheitsstrafe darf 14 Tage nicht übersteigen.“

2. § 56 Abs. 1 Z 2 lautet:

„2. Geldstrafen bis zur Höhe von 18 150 €;“.

3. Dem § 77 wird folgender Abs. 4 angefügt:

„(4) § 35 und § 56 Abs. 1 Z 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 43

Änderung des Ingenieurgesetzes 1990

Das Ingenieurgesetz 1990, BGBl. Nr. 461, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 512/1994, wird wie folgt geändert:

1. § 12 lautet:

„**§ 12.** Wer die Standesbezeichnung „Ingenieur“, auch in Wortgruppen oder Wortverbindungen, seinem Namen beifügt, ohne dazu berechtigt zu sein, begeht eine Verwaltungsübertretung und ist von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 1 450 € zu bestrafen. Gleiches gilt für Übertretungen des § 3.“

2. § 20 lautet:

„**§ 20.** Wer die Bezeichnung „Diplom-HTL-Ingenieur“ oder „Diplom-HLFL-Ingenieur“ führt, ohne dazu berechtigt zu sein, oder so führt, dass damit die Berechtigung zur Führung eines akademischen Grades vorgetäuscht wird, begeht eine Verwaltungsübertretung und ist von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 7 260 Euro zu bestrafen.“

3. § 21 Abs. 2 erster Satz lautet:

„(2) Für die Verleihung ist eine Verwaltungsabgabe in der Höhe von 109 € zu entrichten.“

4. Dem § 13 wird folgender Abs. 5 angefügt:

„(5) § 12, § 20 und § 21 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 44

Änderung der Gewerbeordnung 1994

Die Gewerbeordnung 1994, BGBl. Nr. 194, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 121/2000, wird wie folgt geändert:

1. Im § 13 Abs. 2 wird der Betrag „10 000 S“ *durch den Betrag* „726 €“ *ersetzt.*

2. Im § 173a wird die Wortfolge „einer Million Schilling“ *durch den Betrag* „72 670 €“ *ersetzt.*

3. Im § 284e wird der Ausdruck „Schilling-“ *durch den Ausdruck* „Euro-“ *ersetzt.*

4. Im § 338 Abs. 3 wird der Betrag „500 S“ *durch den Betrag* „36 €“ *ersetzt.*

5. Die Einleitung zu § 366 Abs. 1 lautet wie folgt:

„Eine Verwaltungsübertretung, die mit Geldstrafe bis zu 3 600 € zu bestrafen ist, begeht, wer“.

6. Die Einleitung zu § 367 lautet wie folgt:

„Eine Verwaltungsübertretung, die mit Geldstrafe bis zu 2 180 € zu bestrafen ist, begeht, wer“.

7. Die Einleitung zu § 368 lautet wie folgt:

„Eine Verwaltungsübertretung, die mit einer Geldstrafe bis zu 1 090 € zu bestrafen ist, begeht, wer“.

8. Im § 376 Z 3 Abs. 9 wird der Betrag „20 000 S“ *durch den Betrag* „1 450 €“ *ersetzt.*

9. Im § 376 Z 28 Abs. 2 wird der Betrag „30 000 S“ *durch den Betrag* „2 180 €“ *ersetzt.*

10. Im § 376 Z 41 Abs. 2 wird der Betrag „20 000 S“ *durch den Betrag* „1 450 €“ *ersetzt.*

11. Im § 376 Z 47 Abs. 3 wird der Betrag „30 000 S“ *durch den Betrag* „2 180 €“ *ersetzt.*

12. Im § 377 Abs. 10 wird der Betrag „30 000 S“ *durch den Betrag* „2 180 €“ *ersetzt.*

13. In den § 382 wird nach Abs. 7 folgender Abs. 7a eingefügt:

„(7a) § 13 Abs. 2, § 173a, § 284e, § 338 Abs. 3, § 366 Abs. 1, § 367, § 368, § 376 Z 3 Abs. 9, § 376 Z 28 Abs. 2, § 376 Z 41 Abs. 2, § 376 Z 47 Abs. 3 und § 377 Abs. 10 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 45

Änderung des Sonn- und Feiertags-Betriebszeitengesetzes

Das Sonn- und Feiertagsbetriebszeitengesetz, BGBl. Nr. 129/1984, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 804/1995, wird wie folgt geändert:

1. Im § 4 Abs. 1 wird der Betrag „10 000 S“ *durch den Betrag* „726 €“ *ersetzt.*

2. Dem § 7 wird folgender Abs. 3 angefügt:

„(3) § 4 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 46

Änderung des Bundesgesetzes zur Verbesserung der Nahversorgung und der Wettbewerbsbedingungen

Das Bundesgesetz zur Verbesserung der Nahversorgung und der Wettbewerbsbedingungen, BGBl. Nr. 392/1977, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 693/1993, wird wie folgt geändert:

1. Im § 8 Abs. 1 wird der Betrag „30 000 S“ *durch den Betrag* „2 180 €“ *ersetzt.*

2. Der bisherige Text des § 11 erhält die Absatzbezeichnung „(1)“ *und es wird folgender Abs. 2 angefügt:*

„(2) § 8 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 47

Änderung des Bundesgesetzes gegen den unlauteren Wettbewerb 1984

Das Bundesgesetz gegen den unlauteren Wettbewerb 1984, BGBl. Nr. 448/1984, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 55/2000, wird wie folgt geändert:

1. In § 9a Abs. 2 Z 8 wird die Betragsangabe „5 S“ *durch die Betragsangabe* „0,36 €“ *und die Betragsangabe* „300 000 S“ *durch die Betragsangabe* „21 600 €“ *ersetzt.*

2. In § 29 Abs. 2, § 30 Abs. 2, § 31 Abs. 3, § 33 Abs. 1 und § 33f wird die Betragsangabe „40 000 S“ *jeweils durch die Betragsangabe* „2 900 €“ *ersetzt.*

3. § 44 Abs. 4 wird folgender Abs. 5 angefügt:

„(5) Die §§ 9a Abs. 2 Z 8, 29 Abs. 2, 30 Abs. 2, 31 Abs. 3, 33 Abs. 1 und 33f in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 48

Änderung des EU-Wettbewerbsgesetzes

Das Bundesgesetz über die Durchführung der Wettbewerbsregeln in der Europäischen Union (EU-Wettbewerbsgesetz/EU-WBG), BGBl. Nr. 125/1993, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 175/1995, wird wie folgt geändert:

1. In § 4 Abs. 4 wird der Ausdruck „Unvernehmensverbände“ *durch* „Unternehmensverbände“ *ersetzt.*

2. In § 5 Abs. 2 wird die Betragsangabe „75 000 S“ *durch die Betragsangabe* „5 445 €“ *und die Betragsangabe* „15 000 S“ *durch die Betragsangabe* „1 090 €“ *ersetzt.*

3. Der bisherige Text des § 7 erhält die Absatzbezeichnung „(1)“ *und es wird folgender Abs. 2 angefügt:*

„(2) § 5 Abs. 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 49

Änderung des Euro-Währungsangabengesetzes

Das Bundesgesetz, mit dem Regelungen über die doppelte Preisauszeichnung und andere Angaben von Geldbeträgen erlassen werden (Euro-Währungsangabengesetz – EWAG), BGBl. I Nr. 110/1999, wird wie folgt geändert:

1. In § 23 wird die Betragsangabe „20 000 S“ *durch die Betragsangabe* „1 450 €“ *ersetzt.*

2. In § 24 Abs. 1 wird die Betragsangabe „100 000 S“ *durch die Betragsangabe* „7 260 €“ *und die Betragsangabe* „200 000 S“ *durch die Betragsangabe* „14 530 €“ *ersetzt.*

3. Nach § 29 wird folgender § 29a samt Überschrift eingefügt:

„In-Kraft-Treten

§ 29a. Die §§ 23 und 24 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 50

Änderung des Wohnungsgemeinnützigkeitsgesetzes

Das Bundesgesetz über die Gemeinnützigkeit im Wohnungswesen, BGBl. Nr. 139/1979, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 142/2000, wird wie folgt geändert:

1. In § 6 Abs. 1 erster Satz wird die Betragsangabe „3 000 S“ *durch die Betragsangabe* „218 €“ *ersetzt.*

2. In § 6 Abs. 2 erster Satz wird die Betragsangabe „zehn Millionen Schilling“ *durch die Betragsangabe* „726 700 €“ *ersetzt.*

3. In § 14d Abs. 2 Z 1 wird die Betragsangabe „14,80 S“ *durch die Betragsangabe* „1,0755 €“ *ersetzt.*

4. In § 38 Abs. 1 wird die Betragsangabe „100 000 S“ *durch die Betragsangabe* „7 260 €“ *ersetzt.*

5. In Art. IV wird folgender Abs. 1g eingefügt:

„(1g) § 6 Abs. 1 und 2, § 14d Abs. 2 Z 1 und § 38 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 51

Änderung des Heizkostenabrechnungsgesetzes

Das Bundesgesetz über die sparsamere Nutzung von Energie durch verbrauchsabhängige Abrechnung der Heiz- und Warmwasserkosten (Heizkostenabrechnungsgesetz – HeizKG), BGBl. Nr. 827/1992, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 36/2000, wird wie folgt geändert:

1. In § 20 wird die Betragsangabe „80 000 S“ *durch die Betragsangabe* „5 800 €“ *ersetzt.*

2. In § 29 wird folgender Abs. 1b eingefügt:

„(1b) § 20 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 52

Änderung des Stadterneuerungsgesetzes

Das Bundesgesetz betreffend die Assanierung von Wohngebieten (Stadterneuerungsgesetz), BGBl. Nr. 287/1974, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 421/1992, wird wie folgt geändert:

1. In § 6 Abs. 6 Z 2 wird die Betragsangabe „30 000 S“ *durch die Betragsangabe* „2 180 €“ *ersetzt.*

2. Die Überschrift zu Artikel III § 1 lautet:

„Aufhebung geltender bundesgesetzlicher Vorschriften, In-Kraft-Treten“.

3. Der bisherige Artikel III § 1 erhält die Bezeichnung „§ 1 (1)“. *Nach § 1 Abs. 1 wird folgender Abs. 2 angefügt:*

„(2) § 6 Abs. 6 Z 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 53

Änderung des Wohnhaus-Wiederaufbaugesetzes

Das Bundesgesetz betreffend die Wiederherstellung der durch Kriegseinwirkung beschädigten oder zerstörten Wohnhäuser und den Ersatz des zerstörten Hausrates (Wohnhaus-Wiederaufbaugesetz – WWG), BGBl. Nr. 130/1948, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 917/1993, wird wie folgt geändert:

1. In § 24 Abs. 1 wird die Betragsangabe „30 000 S“ *durch die Betragsangabe* „2 180 €“ *ersetzt.*

2. Der bisherige Text des § 34a erhält die Absatzbezeichnung „(1)“ *und es wird folgender Abs. 2 angefügt:*

„(2) § 24 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 54

Änderung des Gaswirtschaftsgesetzes

Das Bundesgesetz, mit dem Neuregelungen auf dem Gebiet der Erdgaswirtschaft erlassen werden, BGBl. I Nr. 121/2000, wird wie folgt geändert:

1. § 7 Abs. 4 lautet:

„(4) Im Anhang zum Jahresabschluss sind Geschäfte, deren Leistung, Entgelt oder sonstiger wirtschaftlicher Vorteil einen Wert von 727 000 € übersteigt und die mit verbundenen Unternehmen (§ 6 Z 25) getätigt worden sind, gesondert aufzuführen.“

2. § 66 Abs. 1 lautet:

„(1) Für nach diesem Bundesgesetz auf Antrag eingeleitete Preisverfahren ist, ausgenommen in den Fällen des § 21 Abs. 4, ein Kostenbeitrag von mindestens 72 € und höchstens 3 600 € zu leisten.“

3. Dem § 81 wird folgender Abs. 4 angefügt:

„(4) § 7 Abs. 4 und § 66 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 treten mit 1. Jänner 2002 in Kraft.“

Artikel 55

Änderung des Starkstromwegegesetzes 1968

Das Bundesgesetz vom 6. Februar 1968, BGBl. Nr. 70/1968, über elektrische Leitungsanlagen, die sich auf zwei oder mehrere Bundesländer erstrecken (StarkstromwegeG 1968), zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 144/1998, wird wie folgt geändert:

1. § 26 Abs. 1 und 2 lauten:

„(1) Wer vorsätzlich oder grobfahrlässig der Bestimmung des § 3 zuwiderhandelt, begeht, sofern die Tat nicht nach anderen Vorschriften einer strengeren Strafe unterliegt, eine Verwaltungsübertretung. Diese ist von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis 2 180 € oder mit Arrest bis zu sechs Wochen zu ahnden.

(2) Wer vorsätzlich oder grobfahrlässig den Bestimmungen der §§ 8 und 9 Abs. 1 und 4 sowie des auf Grund des § 7 ergangenen Bescheides zuwiderhandelt, begeht, sofern die Tat nicht nach anderen Vorschriften einer strengeren Strafe unterliegt, eine Verwaltungsübertretung. Diese ist von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 726 € oder mit Arrest bis zu zwei Wochen zu ahnden.“

2. Dem § 29 wird folgender Abs. 4 angefügt:

„(4) § 26 Abs. 1 und 2 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft.“

Artikel 56

Änderung des Preistransparenzgesetzes

Das Preistransparenzgesetz, BGBl. Nr. 761/1992, zuletzt geändert durch das Bundesgesetz BGBl. Nr. 174/1995, wird wie folgt geändert:

1. § 10 lautet:

„**§ 10.** Wer

1. einer auf Grund des § 1 Abs. 2, des § 2 Abs. 2 oder des § 7 Abs. 1 erlassenen Verordnung,
2. den Bestimmungen des § 7 Abs. 1 über die Pflicht zur Führung von Aufzeichnungen und zur Gewährung der Einsichtnahme in diese oder
3. der Auskunftspflicht gemäß § 7 Abs. 2

zuwiderhandelt, begeht, sofern die Tat nicht den Tatbestand einer in die Zuständigkeit der Gerichte fallenden strafbaren Handlung erfüllt, eine Verwaltungsübertretung und ist hiefür von der Bezirksverwaltungsbehörde mit Geldstrafe bis zu 2 180 €, im Wiederholungsfall mit Geldstrafe bis zu 7 260 € zu bestrafen."

2. In § 12 wird nach dem Abs. 1 folgender Abs. 1a eingefügt:

„(1a) § 10 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft."

Artikel 57

Änderung des Berufsausbildungsgesetzes

Das Berufsausbildungsgesetz, BGBl. Nr. 142/1969, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 83/2000, wird wie folgt geändert:

1. Im § 32 Abs. 1 wird der Betrag „15 000 S" *durch* „1 090 €", *der Betrag* „2000 S" *durch* „145 €" *sowie der Ausdruck* „4 500 S bis 30 000 S" *durch* „327 € bis 2 180 €" *ersetzt.*

2. Im § 32 Abs. 2 wird der Betrag „45 000 S" *durch* „3 270 €" *ersetzt.*

3. Im § 32 Abs. 3 wird der Betrag „30 000 S" *durch* „2 180 €" *ersetzt.*

4. Dem § 36 wird folgender Satz angefügt:

„§ 32 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft."

Artikel 58

Änderung des Bundesgesetzes über das Grubenwehrehrenzeichen

Das Bundesgesetz über das Grubenwehrehrenzeichen, BGBl. Nr. 63/1954, wird wie folgt geändert:

1. In § 5 wird der Betrag „300 S" *durch den Betrag* „21 €" *ersetzt.*

2. Der bisherige Text des § 6 erhält die Absatzbezeichnung „(1)" *und es wird folgender Abs. 2 angefügt:*

„(2) § 5 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft."

Artikel 59

Änderung des Lagerstättengesetzes

Das Bundesgesetz über die Durchforschung des Bundesgebietes nach nutzbaren Mineralien (Lagerstättengesetz), BGBl. Nr. 246/1947, wird wie folgt geändert:

1. In § 7 wird der Betrag „20 000 S" *durch den Betrag* „1 450 €" *ersetzt.*

2. Der bisherige Text des § 8 erhält die Absatzbezeichnung „(1)" *und es wird folgender Abs. 2 angefügt:*

„(2) § 7 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft."

Artikel 60

Änderung des Allgemeinen österreichischen Berggesetzes

Das Kaiserliche Patent, womit für den ganzen Umfang der Monarchie ein allgemeines Berggesetz erlassen wird (Allgemeines österreichisches Berggesetz), RGBl. Nr. 146/1854, zuletzt geändert durch das Bundesgesetz BGBl. I Nr. 191/1999, wird wie folgt geändert:

1. In § 248 wird der Betrag „2 000 S" *durch den Betrag* „145 €" *ersetzt.*

2. Der bisherige Text des § 248 erhält die Absatzbezeichnung „(1)" *und es wird folgender Abs. 2 angefügt:*

„(2) § 248 Abs. 1 in der Fassung des Bundesgesetzes BGBl. I Nr. 136/2001 tritt mit 1. Jänner 2002 in Kraft."

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and

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Standards of Accreditation for Programs in Health Service Psychology

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I. SCOPE OF ACCREDITATION

The accreditation process promotes consistent quality and excellence in education and training in health service psychology. Education and training provides tangible benefits for prospective students; for the local, national, and international publics that are consumers of psychological services; and the discipline of psychology itself.

For the purposes of accreditation by the American Psychological Association (APA) Commission on Accreditation (CoA) *health service psychology* is defined as the integration of psychological science and practice in order to facilitate human development and functioning. Health service psychology includes the generation, application, and promulgation of knowledge and practices that encompass a wide range of professional activities relevant to health promotion, prevention, consultation, assessment, and treatment for psychological and other health-related disorders.

Programs that are accredited to provide training in health service psychology prepare individuals to work in diverse settings with diverse populations. Programs that are accredited to provide training in health service psychology train individuals to be eligible to pursue licensure and/or relevant credentials.

The CoA reviews programs for accreditation at the master's, doctoral, internship, and postdoctoral levels.

A. Scope of Accreditation for Doctoral Programs

The CoA reviews doctoral programs in psychology that provide in-depth, integrative, broad, and general training in scientific psychology and practice in health service psychology. Practice areas include clinical psychology, counseling psychology, school psychology, and other developed practice areas. The CoA also reviews programs that combine two or more of the above-listed practice areas.

B. Scope of Accreditation for Internship Programs

The CoA reviews internship training programs in practice areas in health service psychology, including clinical psychology, counseling psychology, school psychology, and other developed practice areas.

C. Scope of Accreditation for Postdoctoral Residency Programs

The CoA reviews postdoctoral residency programs providing education and training in preparation for health service psychology practice at an advanced level of competency in: (a) the

developed practice areas that have been defined within the scope of accreditation at the doctoral level; (b) a focus area that promotes attainment of advanced competencies in a content within one or more of the developed practice areas that have been defined within the scope of accreditation at the doctoral level; and/or (c) in a recognized specialty practice area in health service psychology.

II. GUIDING PRINCIPLES OF ACCREDITATION

The accreditation standards and procedures are guided by the following principles and practical concerns.

A. The Purpose and Practice of Accreditation

Accreditation is a voluntary, nongovernmental process of self-study and external review intended to evaluate, enhance, and publicly recognize quality in institutions and in programs of higher education. As such, it serves:

1. General, liberal education;
2. Technical, vocational education and training; and
3. Education and training for the professions.

Accreditation of programs in health service psychology is intended to protect the interests of students, benefit the public, and improve the quality of teaching, learning, research, and practice. Through its standards, the accrediting body promotes both attainment of a common level of professional competency and ongoing improvement of educational institutions and training programs through sound educational experimentation and constructive innovation.

The accreditation process involves judging the degree to which a program has achieved (a) its educational aims, (b) the standards described in this document, and (c) minimum levels of both discipline-specific knowledge and profession-wide competencies among its students/trainees and graduates. The CoA does not explicitly prescribe the processes by which competencies should be reached; rather, it considers the degree to which a program's processes produce educational and training outcomes consistent with its aims and the *Standards of Accreditation*.

Thus, accreditation in psychology is intended to "achieve general agreement on the goals of training ... encourage experimentation on methods of achieving those goals and ... suggest ways of establishing high standards in a setting of flexibility and reasonable freedom."[1]

B. Professional Values

1. There are certain principles and values that are at the core of the profession and impact the way in which the CoA functions and the decisions it makes. The following overarching values govern the policies, standards, and procedures of the CoA.
   a. **Quality.** The primary goal of the accreditation process is to ensure quality in the education of psychologists, and to ensure that students/trainees receive the requisite knowledge, skills, attitudes, and values required for competent and safe practice. The focus on quality ensures that those most vulnerable in the educational process, students/trainees, and the public to whom students/trainees and future psychologists will provide services, are adequately protected.
   b. **Transparency.** As part of its commitment to accountability, the CoA is transparent regarding the policies, standards, and procedures by which it operates. It is open to, and values, input regarding these from the public, students, faculty, and practitioners. The CoA is also committed to transparency regarding its decisions within the limits imposed by the confidentiality of the information it receives from programs as part of their application process.
   c. **Peer Review.** Peer-review is fundamental to the decision making of the CoA. This process ensures that the education students/trainees receive is assessed by peers nominated for their expertise in health service psychology. Peer review, following carefully developed policies, standards, and procedures, further ensures that the program review process will be fair and objective. A goal of the peer-review process is to promote trust and credibility of the process and outcomes of program review.
2. In addition to the principles and values that regulate the functions of the CoA, the following five principles guide accreditation decisions, such that programs whose policies and procedures violate them would not be accredited.
   a. **Commitment to Cultural and Individual Differences and Diversity.** The CoA is committed to a broad definition of cultural and individual differences and diversity that includes, but is not limited to, age, disability, ethnicity, gender, gender identity, language, national origin, race, religion, culture, sexual orientation, and socioeconomic status.
   b. **Preparation for Entry-Level Practice.** Education and training in preparation for entry-level practice in health service psychology at the doctoral level (including internship) should be general in its orientation rather than narrow and specialized. This preparation should be based on the existing and evolving body of knowledge, skills, and competencies that define the declared substantive practice area(s) and should be well grounded in the broad theoretical and scientific foundations of the discipline and field of psychology in general.

      Education in health service psychology is on a continuum: ranging from in-depth, integrative, broad, and general preparation at the doctoral and internship levels, to advanced preparation at the postdoctoral level in a focus area and/or recognized specialty.
   c. **Advanced Preparation for Practice at the Postdoctoral Level in a Focus Area and/or Recognized Specialty.** Postdoctoral residency education and training in health

[1] The APA Committee on Training in Clinical Psychology (1947). First report of the new accreditation process in psychology. *American Psychologist*, 2, 539-558.

service psychology reflects advanced and focused knowledge of the science and practice of psychology. It builds upon the breadth of knowledge attained in doctoral and internship education to ensure competence in health service psychology and is of sufficient depth and focus to ensure advanced competence in the practice area for which the residents are being prepared. This preparation should be based on the existing and evolving body of knowledge, skills, and competencies that define the practice area(s) and should be well integrated with the broad theoretical and scientific foundations of the discipline and field of psychology in general.

d. **Science and Practice.** The competent practice of psychology requires attention to the empirical basis for all methods involved in psychological practice, including a scientific orientation toward psychological knowledge and methods. Therefore, education and training at all levels should be based on the existing and evolving body of general knowledge and methods in the science and practice of psychology, whether in preparation for entry-level practice or in preparation for advanced-level practice in a substantive traditional or specialty practice area. General knowledge in the discipline of psychology is foundational to, and should be well integrated with, the specific knowledge, skills, attitudes, and values that define a particular area of interest in health service psychology. The relative emphasis a particular program places on science and practice should be consistent with its training aims and the intended career path of its students/trainees. However, all programs should enable their students to understand the value of science for the practice of psychology and the value of practice for the science of psychology.

e. **Program Aims and Student/Trainee Competencies.** A program or institution will be evaluated considering its educational aims and the educational principles described above, the demonstrated competencies of its students/trainees, and the career paths of its graduates. There are certain educational aims that are accepted by the profession as necessary, including adequate mastery by students/trainees of the discipline-specific knowledge in psychology and the profession-wide competencies.

The program should be consistent with the stated aims, its policies, and with the standards of the CoA described herein. Consistent with these parameters, a program should have a clear, coherent, and well-articulated description of the principles underlying its aims, as well as a clear description of the resources, methods, and processes by which it proposes to attain its desired training outcomes. A program may describe program-specific competencies in addition to profession-wide competencies. Such program-specific competencies should be consistent with the stated aims of the program and with the general requirements of accreditation and should include clear demonstration by students/trainees of attainment of discipline-specific knowledge and profession-wide competencies.

The program's aims and desired training outcomes should be consistent with that of its parent or sponsor institution's mission. The program should also address the validity and consistency of its aims and mission in relation to current professional standards and regional and national needs.

C. Outcome-Oriented Evaluation Focus

The accreditation review process places great emphasis on the outcomes of a program's training efforts. The accreditation process reviews resources and processes to ensure that they are adequate to meet the program's aims and the scope of accreditation. However these evaluations are not meant to discourage experimentation, innovation, or modernization regarding the delivery of education.

Consistent with this outcomes-oriented approach, the accreditation standards do not contain a "checklist" of criteria. Rather, they identify and describe the profession-wide competencies and the discipline-specific knowledge that all programs must address as well as general areas that are considered essential to the success of any training program in health service psychology. Programs are expected to document their record of achievements in these areas (in the case of already accredited programs), or their potential for success (in the case of applicant programs).

It is assumed that, with reasonable guidance about the kind of information needed by the CoA, programs can decide how best to present their aims, competencies, and outcomes.

Similarly, it is assumed that with adequate information from a program, the CoA can reach an informed, fair, and reasonable decision about that program without relying solely on highly restrictive lists of specific criteria.

Protection of the interests of the program and the public are ensured by the CoA using fair and reasonable evaluative methods to assess:

1. The clarity of program aims and outcomes and their consistency with accreditation standards;
2. The sufficiency of resources and adequacy of processes to support the accomplishment of the program's aims;
3. The effectiveness of a program in achieving its aims and outcomes; and
4. The likelihood that such outcomes can be maintained or improved over time.

D. Function of the CoA: Professional Judgment

This document reflects shared assumptions about the attributes of high-quality education. It assumes that the CoA will use these shared assumptions, the collective professional judgment of its members, and the accreditation standards to reach an informed, fair, and reasonable decision about a program's readiness for accreditation review and/or its accreditation.

The CoA, in representing a broad array of constituencies, has the authority to adopt implementing regulations that elucidate, interpret, and operationally define its standards, principles, and procedures. The

implementing regulations are meant to convey to programs and the public the criteria used by the CoA in determining a program's compliance with a standard, while recognizing that application of these criteria and standards requires the exercise of professional judgment. The CoA may in its decision-making processes refer to or adopt definitions, aims, practices, and principles developed by certain health service psychology training communities or reference groups. By creating procedures that use fair and reasonable evaluative methods designed to assess program compliance with accreditation standards, the CoA seeks to ensure protection of the interests of the program and the public.

DOCTORAL

I. INSTITUTIONAL AND PROGRAM CONTEXT

A. Type of Program

1. **Health Service Psychology.** The program offers broad and general doctoral education and training that includes preparation in health service psychology (HSP). A doctoral program that is accredited in health service psychology must demonstrate that it contains the following elements:
   a. Integration of empirical evidence and practice: Practice is evidence-based, and evidence is practice-informed.
   b. Training is cumulative, graded in complexity, and designed to prepare students for practice or further organized training.
   c. The program engages in actions that indicate respect for and understanding of cultural and individual differences and diversity.
   d. Training in discipline-specific knowledge and across the profession-wide competencies includes integrative in-depth education in the underlying assumptions and philosophies of the theories and methods of science and practice.
2. **Practice Area.** Health service psychology includes several practice areas in which an accredited program may focus, including the areas of clinical psychology, counseling psychology, school psychology, combinations of these areas, and other developed practice areas.

B. Institutional and Administrative Structure

1. **Administrative Structure.** The program's purpose must be pursued in an institutional setting appropriate for doctoral education and training in health service psychology. The institution must have a clear administrative structure and commitment to the doctoral program.
   a. The sponsoring institution of higher education must be authorized under applicable law or other acceptable authority to provide a program of postsecondary education and have appropriate graduate degree-granting authority. This includes state authorization and accreditation of the institution by a nationally recognized institutional accrediting body in the United States.

b. The program is an integral part of the mission of the academic department, college, school, or institution in which it resides. It is represented in the institution's operating budget and plans in a manner that supports the training mission of the program. Funding and resources are stable and enable the program to achieve its aims.

2. **Administrative Responsibilities Related to Equity, Diversity, and Inclusion.** The program recognizes the importance of cultural and individual differences and diversity in the training of psychologists. The CoA defines cultural and individual differences and diversity as including, but not limited to, age, disability, ethnicity, gender, gender identity, language, national origin, race, religion, culture, sexual orientation, and socioeconomic status. The program has made systematic, coherent, and long-term efforts to attract and retain students and faculty from diverse backgrounds into the program. Consistent with such efforts, it acts to ensure a supportive and encouraging learning environment appropriate for the training of individuals who are diverse and the provision of training opportunities for a broad spectrum of individuals. Further, the program avoids any actions that would restrict program access on grounds that are irrelevant to success in graduate training, either directly or by imposing significant and disproportionate burdens on the basis of the personal and demographic characteristics set forth in the definition of cultural diversity. Because of the United States' rich, diverse higher education landscape, training can take place in both secular and faith-based settings. Thus, this requirement does not exclude programs from having a religious affiliation or purpose and adopting and applying admission and employment policies that directly relate to this affiliation or purpose, so long as public notice of these policies has been made to applicants, students, faculty, and staff before their application or affiliation with the program. These policies may provide a preference for persons adhering to the religious purpose or affiliation of the program, but they shall not be used to preclude the admission, hiring, or retention of individuals because of the personal and demographic characteristics set forth under the definition of cultural diversity. This provision is intended to permit religious policies as to admission, retention, and employment only to the extent that they are protected by the U.S. Constitution. This provision will be administered as if the U.S. Constitution governed its application. Notwithstanding the above, and regardless of a program's setting, the program may not constrain academic freedom or otherwise alter the requirements of these standards. Finally, compelling pedagogical interests require that each program prepare graduates to navigate cultural and individual differences in research and practice, including those that may produce value conflicts or other tensions arising from the intersection of different areas of diversity.

C. Program Context and Resources

1. **Program Administration and Structure**

   a. **Program Leadership.** The program has consistent and stable leadership with a designated leader who is a doctoral-level psychologist and a member of the core faculty. The program leader's credentials and expertise must be in an area covered by HSP accreditation and must be consistent with the program's aims. This leadership position may be held by more than one individual.

   b. **Program Administration.** The program has designated procedures and personnel responsible for making decisions about the program, including curriculum, student selection and evaluation, and program maintenance and improvement. The program's decision-making procedures, including who is involved in decision making, must be consistent with the missions of the institution and department, and with the program's aims. The program ensures a stable educational environment through its personnel and faculty leadership.

2. **Length of Degree and Residency.** The program has policies regarding program length and residency that permit faculty, training staff, supervisors, and administrators to execute their professional, ethical, and potentially legal obligations to promote student development, socialization and peer interaction, faculty role modeling, and the development and assessment of student competencies. Residency provides students with mentoring and supervision regarding their development and socialization into the profession, as well as continuous monitoring and assessment of student development through live face-to-face, in-person interaction with faculty and students. These obligations cannot be met in programs that are substantially or completely online. At a minimum, the program must require that each student successfully complete:

   a. a minimum of 3 full-time academic years of graduate study (or the equivalent thereof) plus an internship prior to receiving the doctoral degree;

   b. at least 2 of the 3 academic training years (or the equivalent thereof) within the program from which the doctoral degree is granted; and

   c. at least 1 year of which must be in full-time residence (or the equivalent thereof) at that same program. Programs seeking to satisfy the requirement of 1 year of full-time residency based on "the equivalent thereof" must demonstrate how the proposed equivalence achieves all the purposes of the residency requirement.

3. **Partnerships/Consortia.** A graduate program may consist of, or be located under, a single administrative entity (e.g., institution, agency, school, or department) or in a partnership or consortium among separate administrative entities. A consortium is comprised of multiple independently administered entities that have, in writing, formally agreed to pool resources to conduct a training or education program.

4. **Resources.** The program has, and appropriately uses, the resources it needs to achieve its training aims, including student acquisition and demonstration of competencies. The program works with its academic unit and/or the administration of the sponsor institution to develop a plan for the acquisition of additional resources that may be necessary for program maintenance and development. The resources should include the following:

   a. financial support for training and educational activities;

b. clerical, technical, and electronic support;

c. training materials and equipment;

d. physical facilities;

e. services to support students with academic, financial, health, and personal issues; and

f. sufficient and appropriate practicum experiences to allow a program to effectively achieve the program's training aims.

D. Program Policies and Procedures

1. **Areas of Coverage.** The program has and adheres to formal written policies and procedures that govern students as they enter, progress through, and matriculate from the program. These must include policies relevant to:

   a. academic recruitment and admissions, including general recruitment/admissions and recruitment of students who are diverse;

   b. degree requirements;

   c. administrative and financial assistance;

   d. student performance evaluation, feedback, advisement, retention, and termination decisions;

   e. due process and grievance procedures;

   f. student rights, responsibilities, and professional development; and

   g. nondiscrimination. The program must document non-discrimination policies and operating conditions and avoidance of any actions that would restrict program access or completion on grounds that are irrelevant to success in graduate training or the profession.

2. **Implementation.** All policies and procedures used by the program must be consistent with the profession's current ethics code and must adhere to their sponsor institution's regulations and local, state, and federal statutes regarding due process and fair treatment. If the program uses policies developed at another level (e.g., department or institution), it must describe how it implements these policies at the program level.

3. **Availability of Policies and Procedures.** The program makes the formal written policies and procedures available to all interested parties. By the time of matriculation, the program provides students with written policies and procedures regarding program and institution requirements and expectations regarding students' performance and continuance in the program and procedures for the termination of students.

4. **Record Keeping.** The program is responsible for keeping information and records related to student training and complaints/grievances against the program. Records must be maintained in accord with federal, state, and institution policies regarding record keeping and privacy. The CoA will examine student records and programs' records of student complaints as part of its periodic review of programs.

   a. **Student Records.** The program must document and maintain accurate records of each student's education and training experiences and evaluations for evidence of the student's progression through the program, as well as for future reference and credentialing purposes. The program should inform students of its records retention policies.

   b. **Complaints/Grievances.** The program must keep records of all formal complaints and grievances of which it is aware that have been submitted or filed against the program and/or against individuals associated with the program since its last accreditation site visit. The CoA will examine a program's records of student complaints as part of its periodic review of the program.

II. AIMS, COMPETENCIES, CURRICULUM, AND OUTCOMES

A. Aims of the Program

1. The program must provide information on the aims of its training program that are consistent with health service psychology as defined by these standards, the program's area of psychology, and the degree conferred.

2. These aims should reflect the program's approach to training and the outcomes the program targets for its graduates, including the range of targeted career paths.

B. Discipline-Specific Knowledge, Profession-Wide Competencies, and Learning/Curriculum Elements Required by the Profession

1. **Discipline-Specific Knowledge and Profession-Wide Competencies.** Discipline-specific knowledge serves as a cornerstone for the establishment of identity in and orientation to health services psychology. Thus, all students in accredited programs should acquire a general knowledge base in the field of psychology, broadly construed, to serve as a foundation for further training in the practice of health service psychology.

   a. Discipline-specific knowledge represents the requisite core knowledge of psychology an individual must have to attain the profession-wide competencies. Programs may elect to demonstrate discipline-specific knowledge of students by:

      i. Using student selection criteria that involve standardized assessments of a foundational knowledge base. In this case, the program must describe how the curriculum builds upon this foundational knowledge to enable students to demonstrate graduate level discipline-specific knowledge.

      ii. Providing students with broad exposure to discipline-specific knowledge. In this case, the program is not required to demonstrate that students have specific foundational knowledge at entry but must describe how the program's curriculum enables students to demonstrate discipline-specific knowledge.

b. Profession-wide competencies include certain competencies required for all students who graduate from programs accredited in health service psychology. Programs must provide opportunities for all of their students to achieve and demonstrate each required profession-wide competency. Although in general, the competencies appearing at or near the top of the following list serve as foundations upon which later competencies are built, each competency is considered critical for graduates in programs accredited in health service psychology. The specific requirements for each competency are articulated in the CoA's *Implementing Regulations*. Because science is at the core of health service psychology, programs must demonstrate that they rely on the current evidence base when training students in the following competency areas:

i. research;

ii. ethical and legal standards;

iii. individual and cultural diversity;

iv. professional values, attitudes, and behaviors;

v. communication and interpersonal skills;

vi. assessment;

vii. intervention;

viii. supervision ; and

ix. consultation and interprofessional/interdisciplinary skills.

2. **Learning/Curriculum Elements Related to the Program's Aims.** The program must describe the process by which students attain discipline-specific knowledge and each profession-wide competency (i.e., the program's curriculum) and provide a description of how the curriculum is consistent with professional standards and the program's aims.

3. **Required Practicum Training Elements**

a. Practicum must include supervised experience working with diverse individuals with a variety of presenting problems, diagnoses, and issues. The purpose of practicum is to develop the requisite knowledge and skills for graduates to be able to demonstrate the competencies defined above. The doctoral program needs to demonstrate that it provides a training plan applied and documented at the individual level, appropriate to the student's current skills and ability, which ensures that by the time the student applies for internship the student has attained the requisite level of competency.

b. Programs must place students in settings that are (a) committed to training, (b) provide experiences that are consistent with health service psychology and the program's aims, and (c) enable students to attain and demonstrate appropriate competencies.

c. Supervision must be provided by appropriately trained and credentialed individuals.

d. As part of a program's ongoing commitment to ensuring the quality of their graduates, each practicum evaluation must be based in part on direct observation of the practicum student's developing skills (either live or electronically).

4. **Required Internship Training Elements.** The program must demonstrate that all students complete a 1-year full-time or 2-year part-time internship.

a. **Accredited Internships.** Students are expected to apply for, and to the extent possible, complete internship training programs that are either APA- or CPA-accredited. For students who attend accredited internships, the doctoral program is required to provide only the specific name of the internship.

b. **Unaccredited Internships.** When a student attends an unaccredited internship, it is the responsibility of the doctoral program to provide evidence demonstrating quality and adequacy of the internship experience. This must include information on the following:

i. the nature and appropriateness of the training activities;

ii. frequency and quality of supervision;

iii. credentials of the supervisors;

iv. how the internship evaluates student performance;

v. how interns demonstrate competency at the appropriate level; and

vi. documentation of the evaluation of its students in its student files.

C. Program-Specific Elements—Degree Type, Competencies, and Related Curriculum

1. **Degree Type.** All accredited doctoral programs in health service psychology support the development of disciplinary knowledge and core competencies associated with the profession, and support the acquisition and integration of knowledge, skills, and attitudes from two major domains within the discipline: research and evidence-based practice. Programs are accredited either to offer the PhD degree or to offer the PsyD degree. Other doctoral degree designations that meet these general parameters may be eligible for consideration as appropriate. Although all doctoral degrees contain all the required elements common to programs accredited in HSP, they differ in the balance among, and relative emphasis on, program components, based on specific training aims or likely career paths of their graduates.

In general, PhD programs place relatively greater emphasis upon training related to research, and PsyD programs place relatively greater emphasis on training for engaging in professional practice. Graduates of each type of program or other doctoral degree designations, however, must demonstrate a fundamental understanding of, and competency, in both research/scholarly activities and evidence-based professional practice.

Programs that confer the PhD must have a substantial proportion of faculty who conduct empirical research in the discipline (or related disciplines and fields) and a substantial proportion of faculty who have been trained for the practice of psychology.

Thus, students in PhD programs are trained to both create and disseminate the scholarly research upon which science and practice are built, as well as use such research to engage in evidence-based practice.

Programs that confer the PsyD must have a substantial proportion of faculty who engage in scholarship and/or empirical research in the discipline (or related disciplines and fields) and a substantial proportion of faculty who have been trained for the practice of psychology. Thus, students in PsyD programs are trained to engage in evidence-based practice, as well as in scientific inquiry and evaluation.

2. **Program-Specific Competencies and Related Curriculum.** Doctoral programs accredited in health service psychology may require that students attain additional competencies specific to the program.
   a. If the program requires additional competencies of its students, it must describe the competencies, how they are consistent with the program's aims, and the process by which students attain each (i.e., curriculum).
   b. Additional competencies must be consistent with the ethics of the profession.

D. Evaluation of Students and Program

1. **Evaluation of Students' Competencies**
   a. The program must evaluate students' competencies in both profession-defined and program-defined areas. By the time of degree completion, each student must demonstrate achievement of both the profession-wide competencies and those required by the program. Thus, for each competency, the program must:
      i. Specify how it evaluates student performance, and the minimum level of achievement or performance required of the student to demonstrate competency. Programs must demonstrate how their evaluation methods and minimum levels of achievement are appropriate for the measurement of each competency. The level of achievement expected should reflect the current standards for the profession.
      ii. Provide outcome data that clearly demonstrate that by the time of degree completion, all students have reached the appropriate level of achievement in each profession-wide competency as well as in each program-defined competency. While the program has flexibility in deciding what outcome data to present, the data should reflect assessment that is consistent with best practices in student competency evaluation.
      iii. Present formative and summative evaluations linked to exit criteria, as well as data demonstrating achievement of competencies, for each student in the program.
   b. For program graduates, the program must provide distal evidence of students' competencies and program effectiveness and must evaluate graduates' career paths in health service psychology after they have left the program.
      i. Two years after graduation, the program must provide data on how well the program prepared students in each profession-wide and program-specific competency. The program must also provide data on students' job placement and licensure rates.
      ii. At 5 years post-graduation, the program must provide data on graduates, including data on graduates' licensure (as appropriate for their current job duties) and their scholarly/research contributions (as consistent with the program's aims).

2. **Evaluation of Program Effectiveness and Quality Improvement Efforts**
   a. The program must demonstrate a commitment to ensure competence in health service psychology through ongoing self-evaluation to monitor its performance and contribution to the fulfilment of its sponsor institution's mission.
   b. The program must document mechanisms for engaging in regular, ongoing self-assessment that:
      i. Involves program stakeholders, including faculty, students, graduates, and others involved in the training program.
      ii. Evaluates its effectiveness in training students who, by the time of graduation, demonstrate the competencies required by the profession and the program, and who after graduation can engage in professional activities consistent with health service psychology and with the program's aims.
      iii. Evaluates the currency and appropriateness of its aims, curriculum, and policies and procedures with respect to the following: its sponsor institution's mission and goals; local, state, regional, and national needs for psychological services; national standards for health service psychology; and the evolving evidence base of the profession.
      iv. Identifies potential areas for improvement.

3. **Documenting and Achieving Outcomes Demonstrating Program's Effectiveness.** All accredited doctoral programs are expected to document student achievement while in the program and to look at post-graduation outcomes. Accredited programs are also expected to prepare students for internship training and document that by the time of graduation all students are prepared for entry-level practice. The program's achievement of this should be reflected in student success in achieving licensure after completion of the program.
   a. The outcomes of program graduates including licensure rate and other proximal and distal outcomes of program graduates shall be evaluated within the context of the requirement that all accredited doctoral programs prepare students for entry-level practice; each program's expressed and implied educational aims and competencies; and statements made by the program to the public.

b. Doctoral programs' specific educational aims and required competencies may differ from one another; therefore, there is no specified licensure rate. Instead, the CoA shall use its professional judgment to determine if the program's licensure rate, in combination with other factors, such as attrition of students from the program and their time to degree, demonstrates students' successful preparation for entry-level practice in health service psychology.

III. STUDENTS

A. Student Selection Processes and Criteria

1. The program has an identifiable body of students at different levels of matriculation who:
   a. constitute a number that allows opportunities for meaningful peer interaction, support, and socialization.
   b. are reflective of a systematic, multi-year plan, implemented and sustained over time, designed to attract students from a range of diverse perspectives and backgrounds as outlined in I.B.2.
      i. The program must implement specific activities, approaches, and initiatives to increase diversity among its students. It may participate in institutional-level initiatives aimed toward achieving diversity, but these alone are not sufficient.
      ii. The program should document the concrete actions it is taking to achieve diversity, identifying the areas of diversity recruitment in which it excels as well as the areas in which it is working to improve. The program should demonstrate that it examines the effectiveness of its efforts to attract students who are diverse and document any steps needed to revise/enhance its strategies.
   c. have demonstrated by prior achievement, students' appropriate competency for the program's aims as well as expectations for a doctoral program.
      i. If the program has criteria for selection that involve demonstration of prior knowledge, the program must discuss how these criteria influence program requirements, are appropriate for the aims of the program, and maximize student success.
      ii. If the program has broad entrance criteria (e.g., undergraduate or graduate GPA), the program must address how students will be prepared for advanced education and training in psychology, how the curriculum is structured in accord with the goal of graduate-level competency, and how the criteria relative to the curriculum maximize student success.
   d. are prepared, by interest and aptitude, to meet the program's aims.
   e. reflect, through their intellectual and professional development and intended career paths, the program's aims and philosophy.

B. Supportive Learning Environment

1. Program faculty are accessible to students and provide them with guidance and supervision. They serve as appropriate professional role models and engage in actions that promote the students' acquisition of knowledge, skills, and competencies consistent with the program's training aims.
2. The program recognizes the rights of students and faculty to be treated with courtesy and respect. To maximize the quality and effectiveness of students' learning experiences, all interactions among students, faculty, and staff should be collegial and conducted in a manner that reflects the highest standards of the scholarly community and of the profession (see the current *APA Ethical Principles of Psychologists and Code of Conduct*). The program has an obligation to inform students of these principles, put procedures in place to promote productive interactions, and inform students of avenues of recourse should problems arise.
3. To ensure a supportive and encouraging learning environment for students who are diverse, the program must avoid any actions that would restrict program access on grounds that are irrelevant to success in graduate training.

C. Plans to Maximize Student Success

1. Program faculty engage in and document actions and procedures that actively encourage timely completion of the program and maximize student success. The program minimizes preventable causes of attrition (e.g., flawed admission procedures or unsupportive learning environments) and engages in tailored retention/completion efforts as appropriate (e.g., accommodation of student needs and special circumstances).
2. **Program Engagement.** The program engages in specific activities, approaches, and initiatives to implement and maintain diversity and ensure a supportive learning environment for all students. The program may participate in institutional-level initiatives aimed toward retaining students who are diverse, but these alone are not sufficient. Concrete program-level actions to retain students who are diverse should be integrated across key aspects of the program and should be documented. The program should also demonstrate that it examines the effectiveness of its efforts to retain students who are diverse and document any steps needed to revise/enhance its strategies.
3. **Feedback and Remediation.** Students receive, at least annually and as the need is observed for it, written feedback on the extent to which they are meeting the program's requirements and performance expectations. Such feedback should include:
   a. timely, written notification of any problems that have been noted and the opportunity to discuss them;
   b. guidance regarding steps to remediate any problems (if remediable); and

c. substantive, written feedback on the extent to which corrective actions have or have not been successful in addressing the issues of concern.

IV. FACULTY

A. Program Leadership, Administration, and Management

1. Leadership of the program is stable. There is a designated leader who is a doctoral-level psychologist and a member of the core faculty. The program leader's credentials and expertise are consistent with the program's mission and aims and with the substantive area of health service psychology in which the program provides training. More than one individual can hold this leadership position.

2. The program leader(s) together with program core faculty have primary responsibility for the design, implementation, and evaluation of the program's administrative activities (e.g., policies and procedures for student admissions, student evaluations, and arrangement of practicum experiences) and for its educational offerings (e.g., coursework, practicum experiences, and research training).

B. Faculty Qualifications and Role Modeling

1. **Core Faculty.** The program has an identifiable core faculty responsible for the program's activities, educational offerings, and quality, members of which:
   a. function as an integral part of the academic unit of which the program is an element;
   b. are sufficient in number for their academic and professional responsibilities;
   c. have theoretical perspectives and academic and applied experiences appropriate to the program's aims;
   d. demonstrate substantial competence and have recognized credentials in those areas that are at the core of the program's aims; and
   e. are available to function as appropriate role models for students in their learning and socialization into the discipline and profession.

2. **Additional Core Faculty Professional Characteristics**
   a. Core faculty must comprise individuals whose education, training, and/or experience are consistent with their roles in the program considering the substantive area in which the program seeks accreditation.
   b. Core faculty must comprise individuals whose primary professional employment (50% or more) is at the institution where the program is housed, and to whom the institution has demonstrated a multiyear commitment. At least 50% of core faculty professional time must be devoted to program-related activities.
   c. Core faculty must be identified with the program and centrally involved in program development, decision making, and student training. "Identified with the program" means that each faculty member is included in public and departmental documents as such, views themself as core faculty, and is seen as core faculty by the students.
   d. Core faculty activities directly related to the doctoral program must include program-related teaching, research, scholarship, and/or professional activities; supervising students' research, students' dissertations, and students' teaching activities; mentoring students' professional development; providing clinical supervision; monitoring student outcomes; teaching in a master's degree program that is an integral part of the doctoral program; and developing, evaluating, and maintaining the program.
   e. Core faculty activities not directly related to the doctoral program and not seen as aspects of the core faculty role must include undergraduate teaching in general and related activities; teaching and related activities in terminal master's or other graduate programs; and clinical work or independent practice not directly associated with training, such as at a counselling center.

3. **Associated and Adjunct Faculty.** In addition to core faculty, programs may also have associated program faculty, contributing faculty, and adjunct (visiting, auxiliary, or "other") faculty. Associated program faculty do not meet the criteria for core faculty. They are not centrally involved in program development and decision making, but they still make a substantial contribution to the program and take on some of the tasks often associated with core faculty. Adjunct faculty are hired on an ad hoc basis to teach one or two courses, provide supervision, etc.

4. **Faculty Sufficiency**
   a. Consistent with the program's model, the program faculty, and in particular the core faculty, needs to be large enough to advise and supervise students' research and practice, conduct research and/or engage in scholarly activity, attend to administrative duties, serve on institutional or program committees, provide a sense of program continuity, provide appropriate class sizes and sufficient course offerings to meet program aims, and monitor and evaluate practicum facilities, internship settings, and student progress.
   b. The program faculty, and in particular the core faculty, must be large enough to support student engagement and success within the program, from admissions, to matriculation, to timely completion of program requirements and graduation.
   c. At least one member of the core faculty must hold professional licensure as a psychologist to practice in the jurisdiction in which the program is located.
   d. The program faculty must themselves be engaged in activities demonstrating the skills they are endeavoring to teach their students, such as delivering psychological services, conducting psychological research, publishing scholarly

work, presenting professional work at conferences/meetings, teaching classes/workshops, and supervising the professional work of others.

5. **Cultural and Individual Differences and Diversity**

   a. **Recruitment of Faculty Who Are Diverse.** Each accredited program is responsible for making systematic, coherent, and long-term efforts to attract (i.e., recruit) and retain faculty from differing backgrounds. The program has developed a systematic, long-term plan to attract faculty from a range of diverse backgrounds and implemented it when possible (i.e., when there have been faculty openings). The program may participate in institutional-level initiatives aimed toward achieving diversity, but these alone are not sufficient. The program should document concrete actions it has taken to achieve diversity, addressing the areas of diversity recruitment in which it excels as well as the areas in which it is working to improve. It should demonstrate that it examines the effectiveness of its efforts to attract faculty who are diverse and document any steps needed to revise/enhance its strategies.

   b. **Retention of Faculty Who Are Diverse.** The program has program specific activities, approaches, and initiatives it implements to maintain diversity among its faculty. A program may include institutional-level initiatives aimed toward retaining faculty who are diverse, but these alone are not sufficient. The program demonstrates that it examines the effectiveness of its efforts to maintain faculty who are diverse and documents any steps needed to revise/enhance its strategies.

V. COMMUNICATION PRACTICES

A. Public Disclosure

1. **General Disclosures**

   a. The program demonstrates its commitment to public disclosure by providing clearly presented written materials and other communications that appropriately represent it to all relevant publics. At a minimum, this includes general program information pertaining to its aims, required curriculum sequence, and the expected outcomes in terms of its graduates' careers, as well as data on achievement of those expected and actual outcomes.

   b. The program must disclose its status regarding accreditation, including the specific academic program covered by that status, and the name, address, and telephone number of the CoA. The program should make available, as appropriate through its sponsor institution, such reports or other materials as pertain to the program's accreditation status.

2. **Communication with Prospective and Current Students**

   a. All communications with potential students should be informative, accurate, and transparent.

   b. The program must be described accurately and completely in documents that are available to current students, prospective students, and other publics. This information should be presented in a manner that allows applicants to make informed decisions about entering the program. Program descriptions should be updated regularly as new cohorts begin and complete the program.

   c. Descriptions of the program include information about its requirements for admission and graduation; tuition and other costs; curriculum; time to completion; faculty, students, facilities, and other resources, including distance learning technologies; administrative policies and procedures; the kinds of research, practicum, and internship experiences it provides; and its education and training outcomes.

      i. If the program has criteria for selection that involve competence-based assessments, it must describe how those criteria are appropriate for the aims of the program, how the curriculum is structured in terms of students' initial assessed competency at entry to the program, and how the criteria maximize student success.

      ii. If the program has broad entrance criteria (e.g., undergraduate or graduate GPA), it must address how students will be prepared for advanced education and training in psychology, how the curriculum is structured in accord with the goal of graduate-level competency, and how the criteria relative to the curriculum maximize student success.

   d. The program must provide reasonable notice to its current students of changes to its aims, curriculum, program resources, and administrative policies and procedures, as well as any other program transitions that may impact its educational quality.

3. **Communication Between Doctoral and Doctoral Internship Programs**

   a. Throughout the internship year, communication between the doctoral program and the internship should be maintained. This ongoing interaction can remain largely informal, depending on the needs of the program and the trainee. The doctoral program should initiate this contact at the start of the training year.

   b. Any formal, written internship evaluations must be retained in student files and used to evaluate the student competencies required for degree completion.

B. Communication and Relationship with the Accrediting Body

The program must demonstrate its commitment to the accreditation process through:

1. **Adherence.** The program must abide by the accrediting body's published policies and procedures as they pertain to its recognition as an accredited program. The program must respond in a com-

plete and timely manner to all requests for communication from the accrediting body, including completing all required reports and responding to all questions.

a. **Standard Reporting.** The program must respond to regular, recurring information requests (e.g., annual reports and narrative reports) as required by the accrediting body's policies and procedures.

b. **Nonstandard Reporting.** The program must submit timely responses to any additional information requests from the accrediting body.

c. **Fees.** The program must be in good standing with the accrediting body in terms of payment of fees associated with the maintenance of its accredited status.

2. **Communication.** The program must inform the accrediting body in a timely manner of changes in its environment, plans, resources, or operations that could alter the program's quality. This includes notification of any potential substantive changes in the program, such as changes in practice area or degree conferred or changes in faculty or administration.

DOCTORAL INTERNSHIP

I. INSTITUTIONAL AND PROGRAM CONTEXT

A. Type of Program

1. **Sponsoring Institution.** The program is sponsored by an institution or agency that provides service to a population sufficient in number and variability to give interns adequate experiential exposure to meet training purposes, aims, and competencies.

2. **Length of Program.** Accredited internships may be structured as full-time or part-time. The program requires interns to have the equivalent of 1 year of full-time training to be completed in no fewer than 12 months (or 10 months for school psychology internships), or the equivalent of half-time training to be completed within 24 months. The sponsoring doctoral program, internship program, and intern must have a clear understanding of the intern's plan if internship time is to be divided among two or more agencies for half-time training.

3. **Location.** Programs can be single-site or multiple sites.

B. Institutional and Program Setting and Resources

1. **Description.** Internship program setting descriptions must include:
   a. a description of the sponsoring institution/agency;
   b. a description of the training setting and how it is appropriate for the aims/purposes of the training program;
   c. a description of how the setting functions primarily as a service provider;
   d. information on required hours.

2. **Administrative Structure.** The program offers internship education and training in psychology that prepares interns for the practice of health service psychology.
   a. The program is an integral part of the mission of the institution in which it resides.
   b. The administrative structure and processes facilitate systematic coordination, control, direction, and organization of the training activity and resources.

3. **Administrative Responsibilities Related to Cultural and Individual Differences and Diversity.** The program recognizes the importance of cultural and individual differences and diversity in the training of psychologists. The CoA defines cultural and individual

differences and diversity as including, but not limited to, age, disability, ethnicity, gender, gender identity, language, national origin, race, religion, culture, sexual orientation, and socioeconomic status. The program has made systematic, coherent, and long-term efforts to attract and retain interns and faculty/staff from diverse backgrounds into the program. Consistent with such efforts, it acts to ensure a supportive and encouraging learning environment appropriate for the training of diverse individuals and the provision of training opportunities for a broad spectrum of individuals. Further, the program avoids any actions that would restrict program access on grounds that are irrelevant to success in graduate training, either directly or by imposing significant and disproportionate burdens on the basis of the personal and demographic characteristics set forth in the definition of cultural diversity. Because of the United States' rich, diverse higher-education landscape, training can take place in both secular and faith-based settings. Thus, this requirement does not exclude programs from having a religious affiliation or purpose and adopting and applying admission and employment policies that directly relate to this affiliation or purpose, so long as public notice of these policies has been made to applicants, interns, faculty, and staff before their application or affiliation with the program. These policies may provide a preference for persons adhering to the religious purpose or affiliation of the program, but they shall not be used to preclude the admission, hiring, or retention of individuals because of the personal and demographic characteristics set forth under the definition of cultural diversity. This provision is intended to permit religious policies as to admission, retention, and employment only to the extent that they are protected by the U.S. Constitution. This provision will be administered as if the U.S. Constitution governed its application. Notwithstanding the above, and regardless of a program's setting, the program may not constrain academic freedom or otherwise alter the requirements of these standards. Finally, compelling pedagogical interests require that each program prepares interns to navigate cultural and individual differences in research and practice, including those that may produce value conflicts or other tensions arising from the intersection of different areas of diversity

4. **Funding and Budget**
   a. Interns are provided financial support. Financial support should be set at a level that is representative and fair in relationship to both the geographic location and clinical setting of the training site.
   b. The program must have financial support for faculty/staff and sufficient and dependable training activities for the duration of the year or years of the contract with interns.
   c. Funding for the program should be represented in the institution's operating budget and plans in a manner that enables the program to achieve its training aims.

5. **Training Resources and Support Services.** The program must demonstrate adequacy of its educational and training resources, including:
   a. clerical, technical, and electronic support sufficient to meet the program's needs;
   b. training materials, equipment, and access to the current knowledge base in the profession, including access to appropriate technology and resources to stay current with the scholarly literature; and
   c. physical facilities

C. Program Policies and Procedures

1. **Areas of Coverage.** The program has and adheres to, and makes available to all interested parties, formal written policies and procedures that govern interns as they enter and complete the program. These must include policies relevant to:
   a. intern recruitment and selection;
   b. any required prior doctoral program preparation and experiences;
   c. administrative and financial assistance;
   d. requirements for successful internship performance (including required competencies and minimal levels of achievement for completion);
   e. intern performance evaluation, feedback, retention, and termination decisions;
   f. identification and remediation of insufficient competence and/or problematic behavior, which shall include necessary due process steps of notice, hearing, and appeal;
   g. grievance procedures for interns including due process;
   h. supervision requirements;
   i. maintenance of records; and
   j. documentation of non-discrimination policies and operating conditions and avoidance of any actions that would restrict program access or completion on grounds that are irrelevant to success in graduate training or the profession.

2. **Implementation.** All policies and procedures used by the program must be consistent with the profession's current ethics code and must adhere to the sponsor institution's regulations and local, state, and federal statutes regarding due process and fair treatment. The program must describe how it incorporates and implements departmental and institutional policies at the program level, whenever such policies impact the program specifically.

3. **Availability of Policies and Procedures.** At the start of internship, the program must provide interns with written or electronic policies and procedures regarding program and institution requirements and expectations regarding interns' performance and continuance in the program and procedures for the termination of interns.

4. **Record Keeping**
   a. **Intern Performance.** The program must document and permanently maintain accurate records of the interns' training experiences, evaluations, and certificates of internship completion for evidence of the interns' progress through the program as well as for future reference and credentialing purposes. The program should inform interns of

its records retention policies.

b. **Complaints and Grievances.** The program must keep information and records of all formal complaints and grievances of which it is aware that have been submitted or filed against the program and/or against individuals associated with the program since its last accreditation site visit. The CoA will examine a program's records of intern complaints as part of its periodic review of the program.

D. Program Climate

1. **Cultural and Individual Differences and Diversity.** The program ensures a welcoming, supportive, and encouraging learning environment for all interns, including interns from diverse and underrepresented communities.

   a. Program climate is reflected in the recruitment, retention, and development of training supervisors and interns, as well as in didactic and experiential training that fosters an understanding of cultural and individual differences and diversity as it relates to professional psychology.

   b. The program conducts periodic self-assessment of its training climate in regard to diversity and takes steps to maintain an atmosphere that promotes the success of all interns.

2. **Supportive Learning Environment**

   a. The program recognizes the rights of interns and faculty/staff to be treated with courtesy and respect. To maximize the quality and effectiveness of the interns' learning experiences, all interactions among interns, training supervisors, and faculty/staff should be collegial and conducted in a manner that reflects the highest standards of the profession. (See the current *APA Ethical Principles of Psychologists and Code of Conduct*.) The program has an obligation to inform interns of these principles and of their avenues of recourse should problems arise.

   b. Program faculty/staff are accessible to interns and provides them with a level of guidance and supervision that encourages successful completion of the internship. Faculty/staff members serve as appropriate professional role models and engage in actions that promote interns' acquisition of knowledge, skills, and competencies consistent with the program's training aims.

II. AIMS, TRAINING, COMPETENCIES, AND OUTCOMES

A. Required Profession-Wide Competencies

1. Certain competencies are required for all interns who graduate from programs accredited in health service psychology. Programs must provide opportunities for all their interns to achieve and demonstrate that each required profession-wide competency has been met.

2. The role of the internship is to build upon a trainee's competencies in all the competency areas. Because science is at the core of health service psychology, programs must demonstrate that they rely on the current evidence base when training and assessing interns in the competency areas. Interns must demonstrate competence in:

   a. research;

   b. ethical and legal standards;

   c. individual and cultural diversity;

   d. professional values, attitudes, and behaviors;

   e. communication and interpersonal skills;

   f. assessment;

   g. intervention;

   h. supervision; and

   i. consultation and interprofessional/interdisciplinary skills.

B. Program-Specific Aims and Competencies

1. **Specific Aims of the Training Program.** Consistent with profession-wide competencies required of all programs, the program must provide information on the specific aims of the training program. The program's aims should align with the program's training activities and intended outcomes.

2. **Program-Specific Competencies.** While internship programs accredited in health service psychology must encompass profession-wide competencies required of all programs, they may also elect to demonstrate program-specific competencies.

   a. The program must specify if its intended training outcomes will place special emphasis on the development of any competencies in addition to those expected for all psychology interns or to a greater degree of achievement than might be expected for all psychology interns.

   b. Additional competencies, if any, must be current and consistent with the definition of health service psychology, ethics of the profession, and aims of the program.

C. Learning Elements to Develop Competencies

1. **Educational Activities.** It is the responsibility of the program to have a clear and coherent plan for educational activities that support interns' achievement of both profession-wide and any program-specific competencies.

2. **Learning Elements**

   a. The program's primary training method must be experiential (i.e. service delivery in direct contact with service recipients) and include sufficient observation and supervision by psychologists to facilitate interns' readiness to enter the general practice of psychology on training completion.

   b. The program must follow a logical training sequence that builds on the skills and competencies acquired during doctoral training.

   c. Training for practice must be cumulative, graded in complexity, and designed to prepare interns for practice or further organized training in a manner consistent with the

program's training structure.

d. The program must describe how intern service delivery tasks and duties are primarily learning-oriented and training considerations take precedence over service delivery and revenue generation.

3. **Supervision**

a. Supervision is regularly scheduled.

b. Interns receive at least 4 hours of supervision per week.

c. One or more doctoral level psychologists, who are appropriately trained and licensed, are involved in ongoing supervisory relationships with an intern and have primary professional responsibility for the cases on which supervision is provided. The supervisor(s) must conduct a total of at least 2 hours per week of individual supervision with the intern during the year.

d. Supervisory hours beyond the 2 hours of individual supervision may be provided in an individual or group format and must be:

i. characterized as an interactive educational experience between the intern and supervisor. The relationship between supervisor and intern must be evaluative and hierarchical, must extend over time, and must have the simultaneous purposes of enhancing the professional functioning of the more junior person, monitoring the quality of professional services offered, and serving as a gatekeeper for those who are to enter the profession.

ii. provided by health care professionals who are appropriately credentialed for their role/contribution to the program.

e. Interns should have access to consultation and supervision during times they are providing clinical services.

f. The doctoral-level licensed psychologist supervisors maintain overall responsibility for all supervision, including oversight and integration of supervision provided by other professionals.

D. Outcomes and Program Effectiveness

1. **Evaluation of Interns' Competencies**

a. **Current Interns.** As part of its ongoing commitment to ensuring the quality of its graduates, the program must evaluate interns in both profession-wide competencies and any program-defined competencies. By the end of the internship, each intern must demonstrate achievement of both the profession-wide competencies and any additional competencies required by the program at the level of independent entry-level practice. For each competency, the program must:

i. specify how it evaluates intern performance;

ii. identify the minimum level of achievement or performance required of the intern to demonstrate competency;

iii. provide outcome data that clearly demonstrate all interns successfully completing the program have attained the minimal level of achievement of both the profession-wide and any program-specific competencies;

iv. base each intern evaluation in part on direct observation (either live or electronic) of the intern; and

v. present outcome data (with the program having the flexibility to decide which) that reflects assessment that is consistent with professionally accepted practices in intern competencies evaluation.

b. **Internship Program Alumni.** The program must evaluate the functioning of alumni in terms of their career paths in health service psychology. Each program must provide data on how well the program prepared interns in each of the profession-wide and any of the program-specific competencies. The program must also provide data on interns' job placement and licensure status.

2. **Evaluation of Program Effectiveness and Quality Improvement Efforts**

a. The program must demonstrate ongoing self-evaluation to monitor its performance to ensure competence in health service psychology and contribute to fulfilment of its sponsor institution's mission.

b. The program must document mechanisms for engaging in regular, ongoing self-assessment that:

i. involves program stakeholders, including training faculty/staff, interns, program graduates, and others involved in the training program;

ii. evaluates its effectiveness in training interns who, by the completion of the internship, demonstrate competencies required by the profession and the program, and who can engage in professional activities consistent with health service psychology and with the program's aims;

iii. has procedures in place to use proximal and distal data to monitor, make changes in, and improve the program;

iv. provides resources and/or opportunities to enhance the quality of its training and supervision faculty/staff through continual professional development; and

v. evaluates the currency and appropriateness of its aims, educational activities, policies, and procedures with respect to its sponsor institution's mission and goals; local, state, regional, and national needs for psychological services; national standards for health service psychology; and the evolving evidence base of the profession.

III. INTERNS

A. Intern Selection Process and Criteria

1. **Identifiable Body of Interns.** The program has an identifiable body of interns who are qualified to begin doctoral internship training.
   a. They are currently enrolled in a doctoral program accredited by an accrediting body recognized by the U.S. Secretary of Education or by the Canadian Psychological Association. If the internship accepts an intern from an unaccredited program, the program must discuss how the intern is appropriate for the internship program.
   b. Interns have interests, aptitudes, and prior academic and practicum experiences that are appropriate for the internship's training aims and competencies.
   c. Adequate and appropriate supervised practicum training for the internship program must include face-to-face delivery of health service psychological services.
2. **Recruitment of Interns Who Are Diverse**
   a. The program has made and continues to make systematic, coherent, and long-term efforts to attract interns from different ethnic, racial, gender, and personal backgrounds into the program.
   b. Consistent with such efforts, the program acts to ensure the provision of training opportunities appropriate for the training of diverse individuals. It reviews its success with these efforts and makes changes as appropriate.
3. **Intern Sufficiency**

The program has a sufficient number of interns who:

   a. are provided with opportunities that ensure appropriate peer interaction, support, and socialization;
   b. are provided with opportunities for socialization and interaction with professional colleagues in a manner consistent with the program's training structure;
   c. understand the program's, aims, and required competencies; and
   d. have a training status at the site that is officially recognized in the form of a title or designation such as "psychology intern" (consistent with the licensing laws of the jurisdiction in which the internship is located and with the sponsoring institution).

B. Feedback to Interns

1. Interns receive, at least semi-annually and as the need is observed for it, written feedback on the extent to which they are meeting stipulated performance requirements. Feedback is linked to the program's expected minimal levels of achievement for profession-wide competencies and any program-specific competencies.
2. Such feedback should include:
   a. timely written notification of all problems that have been noted and the opportunity to discuss them;
   b. guidance regarding steps to remediate all problems (if remediable);
   c. substantive written feedback on the extent to which corrective actions are or are not successful in addressing the issues of concern; and
   d. documentation that the intern evaluation was reviewed and discussed by the intern and the supervisor.

IV. SUPERVISOR/FACULTY/ STAFF LEADERSHIP

A. Program Leadership

1. **Internship Program Director**
   a. The program director is primarily responsible for directing the training program and has administrative authority commensurate with that responsibility.
   b. The director should have appropriate administrative skills to ensure the success of the program and serve as a role model for the interns.
   c. The director must be a psychologist, appropriately trained and credentialed (i.e., licensed, registered, or certified) to practice psychology in the jurisdiction in which the program is located.
   d. The director's credentials and expertise must be consistent with the program's aims and the required competencies of its interns.
2. **Administrative and Program Leadership Structure.** The program's administrative structure and processes facilitate appropriate review and continuous program improvement to ensure the program achieves its aims and provides the training environment needed for interns to attain all competencies. The program must describe how faculty/staff and interns contribute to the planning and implementation of the training program.
3. **Intern Training Supervisors**
   a. Supervisors function as an integral part of the site where the program is housed and have primary responsibility for professional service delivery.
   b. The program must have a sufficient number of supervisors to accomplish the program's service delivery and to supervise training activities and program aims. An accredited internship program must have a minimum of two doctoral-level psychologists.
   c. Supervisors are doctoral-level psychologists who have primary professional responsibility for the cases that they provide supervision and are appropriately trained and credentialed (i.e., licensed, registered, or certified) to practice psychology in the jurisdiction in which the internship is located.
      i. When supervision services are conducted in a con-

text where a state or territory credential is required for practice, the supervisor holds that required credential.

ii. When supervision services are conducted in a federal jurisdiction (e.g., the VA or Bureau of Prisons), the credentialing rules pertaining to practice in a federal setting apply.

iii. Supervision requirements of school settings are governed by Federal general education and special education laws.

d. Supervisors are responsible for reviewing with the interns the relevant scientific and empirical bases for the professional services delivered by the interns.

e. Supervisors participate actively in the program's planning, implementation, and evaluation and serve as professional role models to the interns consistent with the program's training aims and required competencies.

f. Other professionals who are appropriately credentialed can participate in the training program. These individuals may augment and expand interns' training experiences if they are integrated into the program and are held to standards of competence appropriate to their role/contribution within the program.

B. Faculty/Staff Diversity

The program must demonstrate systematic and long-term efforts to recruit and retain faculty/staff who are from diverse backgrounds.

V. COMMUNICATION PRACTICES

A. Public Disclosure

1. **General Disclosures**

a. The program demonstrates its commitment to public disclosure by providing clearly presented written materials and other communications that appropriately represent it to all relevant publics. At a minimum this includes general program information pertaining to its aims, required training sequence, any program-specific competencies, and expected outcomes in terms of its interns' careers.

b. The program also demonstrates commitment to public disclosure by providing current information on its use of distance education technologies for training and supervision.

c. The program articulates its commitment to attracting and training diverse interns.

d. The program provides its status regarding accreditation, including the specific training program covered by that status, and the name, address, and telephone number of the CoA. The program should make available, as appropriate through its sponsor institution, such reports or other materials that pertain to the program's accreditation status.

2. **Communication With Prospective and Current Interns**

a. All communications with potential interns should be informative, accurate, and transparent.

b. The program is described accurately and completely in documents that are available to current interns, prospective interns, and other publics. This information should be presented in a manner that allows applicants to make informed decisions about entering the program. Program descriptions should be updated regularly as new cohorts begin and complete the program.

c. The program describes its aims; requirements for admission and completion; curriculum; training supervisors, facilities, and other resources; administrative policies and procedures, including leave policies; the kinds of experiences it provides; anticipated workload requirements; and training outcomes in documents available to current interns, prospective interns, and other publics.

d. The program provides reasonable notice to its current interns of changes to its aims, didactics, program resources, and administrative policies and procedures, as well as any other program transitions that may impact its training quality.

e. The program issues a certificate of completion to all interns who have successfully met all program requirements. The certificate of completion must include a statement about the program's scope of accreditation (e.g., Internship in Health Service Psychology).

3. **Communication Between Doctoral and Internship Programs**

a. Throughout the internship year, there should be communication between the doctoral program and the internship program. The nature and frequency of this communication will depend on needs. Communication must take place when problems arise with interns.

b. The internship should send formal written intern evaluations to the doctoral program at or near the midpoint of the training year and again at internship completion.

B. Communication and Relationship With Accrediting Body

The program demonstrates its commitment to the accreditation process through:

1. **Adherence.** The program abides by the accrediting body's published policies and procedures as they pertain to its recognition as an accredited program, and the program responds in a complete and timely manner to all requests for communication from the accrediting body, including completing all required reports and responding to questions from the accrediting body.

a. **Standard Reporting.** The program responds to regular recurring information requests (e.g., annual reports and narrative reports) as identified by the accrediting body's policies and procedures.

b. **Nonstandard Reporting.** The program submits timely responses to any additional information requests from the accrediting body consistent with its policies and

procedures.

c. **Fees.** The program is in good standing with the accrediting body in terms of payment of fees associated with the maintenance of its accredited status.

2. **Communication.** The program informs the accrediting body in a timely manner of changes in its environment, plans, resources, or operations that could alter the program's quality. This includes notification of any potential substantive changes in the program, such as changes in sequence of experiential training, faculty changes, and changes in administration.

POSTDOCTORAL RESIDENCY

I. INSTITUTIONAL AND PROGRAM CONTEXT

A. Program Type and Structure

1. **Areas of Postdoctoral Accreditation.** Programs providing training in health service psychology (HSP) may be accredited in one or more areas:
   a. An area that promotes attainment of advanced competencies in one or more of the major areas of training in health service psychology that are recognized within the scope of accreditation (i.e., clinical, counseling, school, and other developed practice areas).
   b. Specialty practice areas in health service psychology. If accreditation is sought in a recognized specialty practice area, the specialty practice area must meet at least two of the following requirements:
      i. The specialty is recognized by the Commission on the Recognition of Specialties and Proficiencies in Professional Psychology (CRSPPP) of the APA or by the American Board of Professional Psychology (ABPP).
      ii. The specialty is recognized by and holds membership on the Council of Specialties (CoS).
      iii. The specialty has provided the CoA with specialty-specific postdoctoral educational and training guidelines endorsed by the Council of Specialties.
2. **Length of Program.** Each resident must complete a minimum of 1 year of full-time training in no less than 12 months (10 months for school psychology postdoctoral training programs), or 2 years of half-time training in no less than 24 months. Specialty practice residencies may require longer training periods, as described by the CoA.
3. **Direct Service Delivery.** This is a required element of training that promotes advanced competencies in health service psychology. Programs must allocate sufficient time to direct service delivery to ensure achievement of all required advanced competencies.

4. **Learning**. Learning must take precedence over service delivery. The program must demonstrate that residents' service delivery activities are primarily learning-oriented and that training considerations take precedence over service needs and revenue generation.

B. Institutional and Program Setting, Structure, and Resources

1. **Training Setting.** The setting must be appropriate for the program's aims and the development of residents' advanced competencies. Resources to support training must be sufficient to meet the program's aims and various expected learning outcomes. The service population must be appropriate and sufficient to meet the direct service activities that foster development of advanced competencies.

2. **Administrative Structure**

   a. The program's aims are consistent with the mission of the larger institution in which it resides. The program is represented in the institution's operating budget and plans in a manner that enables it to achieve its aims.

   b. The administrative structure and processes facilitate systematic coordination, control, direction, and organization of the training activity and resources.

   c. A postdoctoral training program may consist of, or be located under, a single administrative entity (e.g., institution, agency, school, or department) or may take the form of a consortium.

3. **Administrative Responsibilities Related to Cultural and Individual Differences and Diversity.** The program recognizes the importance of cultural and individual differences and diversity in the training of psychologists. The CoA defines cultural and individual differences and diversity as including, but not limited to, age, disability, ethnicity, gender, gender identity, language, national origin, race, religion, culture, sexual orientation, and socioeconomic status. The program has made systematic, coherent, and long-term efforts to attract and retain residents and faculty/staff from diverse backgrounds into the program. Consistent with such efforts, it acts to ensure a supportive and encouraging learning environment appropriate for the training of individuals who are diverse and the provision of training opportunities for a broad spectrum of individuals. Further, the program avoids any actions that would restrict program access on grounds that are irrelevant to success in postdoctoral training, either directly or by imposing significant and disproportionate burdens on the basis of the personal and demographic characteristics set forth in the definition of cultural diversity. Because of the United States' rich, diverse higher education landscape, training can take place in both secular and faith-based settings. Thus this requirement does not exclude programs from having a religious affiliation or purpose and adopting and applying admission and employment policies that directly relate to this affiliation or purpose, so long as public notice of these policies has been made to applicants, residents, and faculty/staff before their application or affiliation with the program. These policies may provide a preference for persons adhering to the religious purpose or affiliation of the program, but they shall not be used to preclude the admission, hiring, or retention of individuals because of the personal and demographic characteristics set forth under the definition of cultural diversity. This provision is intended to permit religious policies as to admission, retention, and employment only to the extent that they are protected by the U.S. Constitution. This provision will be administered as if the U.S. Constitution governed its application. Notwithstanding the above, and regardless of a program's setting, the program may not constrain academic freedom or otherwise alter the requirements of these standards. Finally, compelling pedagogical interests require that each program prepare residents to navigate cultural and individual differences in research and practice, including those that may produce value conflicts or other tensions arising from the intersection of different areas of diversity.

4. **Funding and Budget Sources**

   a. A program must have ongoing stable and sufficient funding to conduct the training necessary to meet its aims which is reflected in the institution's operating budget.

   b. All residents must be financially supported at a level consistent with comparable postdoctoral-level professionals in training at the same site or in the region.

5. **Training Resources, Facilities, and Support Services**

   a. The program provides sufficient and appropriate resources to fulfill the aims of the program (e.g., office space, supplies, computers, clerical support, library, and test equipment).

   b. These resources and facilities must be accessible to all residents when the resident is working.

C. Program Policies and Procedures

1. **Administrative**

   a. **Resident Recruitment and Selection**

      i. The program has procedures for resident selection that ensure residents are appropriately prepared for the advanced training offered.

      ii. At the initiation of training, residents must have completed all requirements for the doctoral degree including an internship. Training should be in programs accredited by an accrediting body recognized by the U.S. Secretary of Education or by the Canadian Psychological Association. If the program accepts residents who attended unaccredited programs, the residency must describe how the program ensures that selected residents are otherwise qualified and appropriately prepared for advanced training in the residency program.

   b. **Program Policies and Procedures.** The program has and adheres to, and makes available to all interested parties, formal written policies and procedures that govern residents as they enter and complete the program. These must include policies relevant to:

      i. resident recruitment and selection;

      ii. any required prior doctoral program and internship

preparation and experiences;

iii. administrative and financial assistance;

iv. requirements for successful resident performance (including required competencies and minimal levels of achievement for completion);

v. resident performance evaluation, feedback, retention, and termination decisions;

vi. identification and remediation of insufficient competence and/or problematic behavior, which shall include necessary due process steps of notice, hearing and appeal

vii. grievance procedures for residents including due process;

viii. supervision requirements;

ix. maintenance of records; and

x. documentation of non-discrimination policies and operating conditions and avoidance of any actions that would restrict program access or completion on grounds that are irrelevant to success in post-doctoral training or the profession.

2. **Resident Evaluation.** Residents must receive written feedback on the extent to which they are meeting performance requirements at least semi-annually (or more often as the need arises).

3. **Implementation.** All policies and procedures used by the program must be consistent with the profession's current ethics code and must adhere to the sponsor institution's regulations and local, state, and federal statutes regarding due process and fair treatment. The program must describe how it incorporates and implements departmental and institutional policies at the program level, whenever such policies specifically impact the program.

4. **Availability of Policies and Procedures.** At the start of residency, the program must provide residents with written or electronic copies of policies and procedures regarding program and institution requirements and expectations regarding residents' performance and continuance in the program and procedures for the termination of resident training.

5. **Record Keeping**

   a. **Resident Performance.** The program documents and permanently maintains accurate records of the residents' supervised training experiences and evaluations for future reference, certification, licensing, and credentialing purposes.

   b. **Complaints and Grievances.** Each program is responsible for maintaining records of all formal complaints and grievances against the program of which it is aware that have been submitted or filed against the program and/or against individuals associated with the program since its last accreditation site visit. The CoA will examine a program's records of residents' complaints as part of its periodic review of the program.

D. Program Climate

1. **Cultural and Individual Differences and Diversity.** The program ensures a welcoming, supportive, and encouraging learning environment for all residents, including residents from diverse and underrepresented communities.

   a. Program climate is reflected in the recruitment, retention, and development of training supervisors and residents, as well as in didactic and experiential training that fosters an understanding of cultural and individual diversity as it relates to professional psychology.

   b. The program conducts periodic self-assessment of its training climate in regards to diversity and takes steps to maintain an atmosphere that promotes the success of all residents.

2. **Resident/Faculty/Staff Relationship Climate**

   a. The program recognizes the rights of residents and training supervisors to be treated with courtesy and respect. To maximize the quality and effectiveness of residents' learning experiences, interactions among residents, training supervisors, and program staff should be collegial and conducted in a manner that reflects the highest standards of the profession. (See the current *APA Ethical Principles of Psychologists and Code of Conduct*.) The program has an obligation to inform residents of these principles and of their avenues of recourse should problems arise.

   b. Program faculty/staff are accessible to residents and provide them with a level of guidance and supervision that encourages successful completion of the postdoctoral residency. Faculty/staff members serve as appropriate professional role models and engage in actions that promote residents' acquisition of knowledge, skills, and competencies consistent with the program's training aims.

   c. The program provides opportunities for socialization into the profession.

   d. The program encourages peer interaction, and residents are provided with opportunities for appropriate peer interaction, support, and learning.

   e. Residents are provided with opportunities for collegial interaction with professionals and/or trainees in other disciplines.

II. AIMS, COMPETENCIES, TRAINING, AND OUTCOMES

A. Aims of the Program

The program must describe its aims in residency training (i.e., the overall, long-term expected outcome of the residency program).

B. Competencies

Postdoctoral programs ensure that residents attain advanced competencies relevant to the program's specialty or area of focus. Because science is at the core of health service psychology, programs must demonstrate that they rely on the current scientific evidence base when training and assessing residents in the competency areas. All programs provide experiences to promote advanced competencies fundamental to health service psychology (Level 1). Additionally, programs ensure that residents attain advanced competencies relevant to the program's aims or area of focus, **if any** (Level 2), or that are consistent with the program's designated specialty (Level 3).

1. **Level 1—Advanced Competency Areas Required of All Programs at the Postdoctoral Level**
   a. **Integration of Science and Practice**. This includes the influence of science on practice and of practice on science.
   b. **Individual and Cultural Diversity.** This includes issues of cultural and individual diversity relevant to advanced practice, as appropriate to the setting, the population served, and the focus or specialty area.
   c. **Ethical and Legal.** This includes professional conduct, ethics and law, and professional standards for providers of psychological services relevant to advanced practice, as appropriate to the setting, the population served, and the focus or specialty area.
2. **Level 2—Program-Specific or Area of Focus Competencies.** Programs accredited in traditional practice areas (clinical, counseling and/or school) must include one or more Level 2 competencies. The program specifies the relevant expected learning outcomes appropriate and relevant for any optional level 2 competencies.
3. **Level 3—Specialty Competencies.** To be accredited in a specialty practice area, the program must fulfill the standards for accreditation in relation to the specialty competencies established by CoA for that specialty practice area.

C. Learning Experiences That Promote the Development of Advanced Competencies

1. **Training Plan.** A formal, goal-directed, individualized training plan describing planned training experiences must be developed for each resident. The individualized training plan should include the resident's level of competence at entry in planning for how they will successfully attain the program's exit criteria. Educational activities may occur in an interprofessional context or may make use of existing didactics occurring in the setting if they are appropriate for achieving an advanced level of competence in health service psychology.
2. **Educational Activities**. The program must describe how structured educational activities (e.g., didactics, clinical conferences, grand rounds, group supervision) complement experiential training and how they are linked to competencies in Levels 1–3 above.
3. **Clinical Activities.** The program must provide supervised service delivery experiences in an appropriate setting that promotes the development of the advanced competencies identified in Levels 1–3.
4. **Individual Supervision**
   a. At least 2 hours per week of individual supervision focused on resident professional activities must be conducted by an appropriately trained and licensed doctoral-level psychologist. Individual supervision must have the following characteristics:
      i. It is an interactive educational experience between the resident and supervisor. The relationship between supervisor and resident must be evaluative and hierarchical, must extend over time, and must have the simultaneous purposes of enhancing the professional functioning of the more junior person, monitoring the quality of professional services offered, and serving as a gatekeeper for those who are to enter the profession.
      ii. It is provided by licensed/credentialed health care professionals who are appropriately trained and credentialed for their role/contribution to the program and area in which the program is accredited.
   b. Supervisors must maintain an ongoing supervisory relationship with the resident and have primary professional clinical responsibility for the cases for which they provide supervision.
   c. A resident must have an appropriately trained and licensed doctoral-level psychologist serving as primary supervisor in order to ensure continuity of the training plan.
   d. The primary supervisor must maintain overall responsibility for all supervision, including oversight and integration of supervision provided by other health professionals.
   e. Program required supervisory hours beyond the two hours of individual supervision noted above can be provided in an individual or group format and must be:
      i. Characterized as an interactive educational experience between the resident and supervisor. The relationship between supervisor and resident must be evaluative and hierarchical, must extend over time, and must have the simultaneous purposes of enhancing the professional functioning of the more junior person, monitoring the quality of professional services offered, and serving as a gatekeeper for those who are to enter the profession.
      ii. Provided by licensed/credentialed health care professionals who are appropriately trained and

credentialed for their role/contribution to the program and area in which the program is accredited.

D. Evaluation

1. **Evaluation of Resident Competencies**
   a. An evaluation must be made of the resident's progress toward satisfactory attainment of the program's required competencies, as reflected in the attainment of the program's stated minimum levels of achievement and other program requirements.
   b. Data on residents' competencies must include competency-based assessments of residents as they progress through, and at completion of, the program (proximal data), as well as graduates' evaluations of the specific contributions of program training in the attainment of all required competencies (distal data).
      i. Proximal data must, at the least, include evaluations of residents by knowledgeable others (i.e., supervisors or trainers). The evaluation process and assessment forms must parallel the program's required competencies. These evaluations include the feedback provided to residents as required in Standard I.C.1(d).
      ii. At each evaluation interval, the evaluation must be based in part on direct observation of the competencies evaluated.
      iii. Distal data must reflect the program's effectiveness in achieving its aims.
      iv. Distal data typically include information obtained from alumni surveys assessing former residents' perception of the degree to which the program contributed to their achievement of program aims, including preparing them in advanced competencies.
2. **Quality Improvement of the Program.** The program must demonstrate continuous self-evaluation, ensuring that its aims are met, that the quality of its professional education and training is enhanced, and that it contributes to the fulfillment of its host institution's mission.
   a. The program, with appropriate involvement of its training supervisors, residents, and former residents, engages in ongoing self-evaluation that addresses:
      i. its expectations for the quality and quantity of the resident's preparation and performance in the program;
      ii. its effectiveness in achieving program aims for residents, including responsiveness to outcome data (while residents are in the program and after completion) that takes into account the residents' views regarding the quality of the training experiences and the program as appropriate;
      iii. its procedures to maintain current achievements or to make changes as necessary; and
      iv. its aims and expected outcomes as they relate to local, regional, state, and national needs, as well as advances in the knowledge base of the profession and the practice area in which the program provides its training.
   b. The program provides resources and/or opportunities to enhance the quality of its training and supervising staff through continued professional development.
   c. The program and its host institution value and recognize the importance of resident training and of the supervisors' training and supervisory efforts and demonstrate this in tangible ways.
   d. The program describes how it uses proximal and distal data to monitor and improve the program.

III. PROGRAM RESIDENTS

A. Resident Selection Processes and Criteria

1. **Resident Selection.** As evidence that residents meet the program's entry requirements, the program ensures that its residents:
   a. have completed appropriate doctoral education and training in health service psychology, including the completion of an appropriate internship as described in Postdoctoral Residency §I.C.1.a.ii; and
   b. have interests and abilities that are appropriate for the postdoctoral training program's aims and required competencies.
2. **Postdoctoral Psychology Residents.** The program has one or more postdoctoral psychology residents who:
   a. understand the program's aims and required competencies;
   b. have meaningful involvement in those activities and decisions that serve to enhance resident training and education; and
   c. have a title commensurate with the title used in that setting by other professionals in training who have comparable responsibility, education, and training, consistent with the laws of the jurisdiction in which the program is located.
3. **Resident Diversity.** The program has made systematic and sustained efforts to attract residents from diverse backgrounds into the program.
   a. Consistent with such efforts, it acts to provide a supportive and encouraging learning environment for all residents, including those with diverse backgrounds, and to provide learning opportunities appropriate for the training of diverse individuals.

B. Feedback to Residents

1. Residents receive, at least semi-annually and as the need is observed, written feedback on the extent to which they are meet-

ing stipulated performance requirements. Feedback is linked to the program's expected minimal levels of achievement.

2. Such feedback should include:
   a. timely written notification of all problems that have been noted and the opportunity to discuss them;
   b. guidance regarding steps to remediate all problems (if remediable);
   c. substantive written feedback on the extent to which corrective actions are or are not successful in addressing the issues of concern; and
   d. documentation that the resident evaluation was reviewed and discussed by the resident and the supervisor.

C. Program Activities, Resources, and Processes

These are designed to maximize the likelihood of all residents' success in completing the program. The program must provide professional mentoring to residents in addition to supervision.

IV. PROGRAM FACULTY/STAFF

A. Program Leadership

1. **Program Leadership**
   a. The program has a designated director who is a psychologist, appropriately trained and credentialed (i.e., licensed, registered, or certified) to practice psychology in the jurisdiction in which the program is located, who is primarily responsible for directing the training program, and who has administrative authority commensurate with those responsibilities.
   b. The program director's credentials and expertise must be consistent with the program's aims.
   c. For programs that include a recognized specialty practice area, the individual providing leadership of that area must have appropriate expertise and credentials in that specialty.
2. **Program Leadership Structure.** The program must describe how faculty/staff and residents contribute to the planning and implementation of the training program.
3. **Administrative and Program Leadership Structure.** The program's administrative structure and processes facilitate appropriate review and continuous program improvement to ensure the program achieves its aims and provides the training environment needed for residents to attain all competencies. The program must describe how faculty/staff and residents contribute to the planning and implementation of the training program.

B. Faculty/Staff

1. **Supervisor Sufficiency.** The formally designated supervisors include at least two psychologists, who:
   a. deliver services in the setting and practice area in which postdoctoral training occurs;
   b. function as an integral part of the program at the site where the program is housed;
   c. have primary professional and clinical responsibility for the cases on which they provide supervision;
   d. are appropriately trained and credentialed (i.e., licensed, registered, or certified) to practice psychology in the jurisdiction in which the program is located;
      i. When supervision services are conducted in a context where a state or territory credential is required for practice, the supervisor holds that required credential.
      ii. When supervision services are conducted in a federal jurisdiction (e.g., the VA or Bureau of Prisons), the credentialing rules pertaining to practice in a federal setting apply.
      iii. Supervision requirements of school settings are governed by federal general education and special education laws.
   e. are of appropriate quality for the program's aims and have appropriate qualifications for advanced training in the focus area or specialty;
   f. participate actively in the program's planning, its implementation, and its evaluation; and
   g. serve as professional role models for the residents.
2. **Recruitment and Retention of Diverse Faculty/Staff**
   a. The program makes systematic and sustained efforts to attract and retain faculty/staff from diverse backgrounds into the program.
   b. Consistent with such efforts, it acts to ensure a supportive and encouraging learning environment and the provision of continuing educational opportunities appropriate for a broad spectrum of professionals.
   c. The program avoids any actions that would restrict program access on grounds that are irrelevant to a career in health service psychology.

C. Ancillary Faculty/Staff

1. The program may use ancillary faculty/staff in achieving its aims and competencies.
2. The program must describe how any ancillary faculty/staff are appropriate and sufficient to achieve the program's aims and ensure attainment of appropriate advanced competencies by the residents.

V. COMMUNICATION PRACTICES

A. Public Disclosure

1. **General Disclosures**

a. The program demonstrates its commitment to public disclosure by providing accurate and complete written materials and other communications that appropriately represent it to all relevant publics. At a minimum, this includes general program information pertaining to its aims, recruitment and selection, implementation of strategies to ensure resident cohorts that are diverse, required training experiences, use of distance education technologies for training and supervision, and expected training outcomes.

b. The program also demonstrates commitment to public disclosure by providing current information on its use of distance education technologies for training and supervision.

c. The program provides its status regarding accreditation, including the specific training program covered by that status, and the name, address, and telephone number of the CoA. The program makes available, as appropriate through its sponsor institution, such reports or other materials that pertain to the program's accreditation status.

2. **Communication With Prospective and Current Residents**

a. All communications with potential residents should be informative, accurate, and transparent.

b. The program provides current information on relevant training outcomes.

c. The program is described accurately and completely in documents available to current residents, prospective residents, and other publics. This information should be presented in a manner that allows applicants to make informed decisions about entering the program. At a minimum, descriptions of the program should include the licensure status, employment status, and advanced certifications residents can expect to obtain. Program descriptions should be updated regularly as new cohorts begin and complete the program.

d. The program describes its aims; requirements for admission and completion; curriculum; training supervisors, facilities, and other resources; administrative policies and procedures, including leave policies; the kinds of experiences it provides; anticipated workload requirements; and training outcomes in documents available to current interns, prospective interns, and other publics.

e. The program provides reasonable notice to its current residents of changes to its aims, didactics, program resources, and administrative policies and procedures, as well as any program transitions that may impact training quality.

f. The program issues a certificate of completion to residents who successfully attain the required competencies and complete the contracted learning period. The certificate of completion must include a statement about the program's type and scope of accreditation.

B. Communication and Relationship with Accrediting Body

The program demonstrates its commitment to the accreditation process through:

1. **Adherence.** The program abides by the accrediting body's published policies and procedures as they pertain to its recognition as an accredited program. The program responds in a complete and timely manner to all requests for communication from the accrediting body, including completing all required reports and responding to questions from the accrediting body.

a. **Standard Reporting.** The program responds to regular recurring information requests (e.g., annual reports and narrative reports) as identified by the accrediting body's policies and procedures.

b. **Nonstandard Reporting.** The program submits timely responses to information requests from the accrediting body consistent with the accrediting body's policies and procedures.

c. **Payment of Fees.** The program remains in good standing with the accrediting body in terms of payment of fees.

2. **Communication.** The program informs the accrediting body in a timely manner of any changes in its environment, plans, resources, or operations that could alter the program's quality. This includes notification of any potential substantive changes in the program, such as changes in sequence of experiential training, faculty/staff changes, or changes in administration.

Accreditation Operating Procedures of the Commission on Accreditation

APPROVED JUNE 2015

REVISIONS APPROVED AUGUST 2017, JUNE 2018, NOVEMBER 2019, MARCH 2022

GENERAL OPERATING PROCEDURES

1. REAFFIRMATION FOR CONTINUED ACCREDITATION

Accredited programs are reviewed annually by written report and by the data provided annually to the Commission on Accreditation (CoA). Accredited programs are also assessed an annual fee. In addition, each accredited program undergoes a more extensive periodic review that involves a self-study report and a site visit.

Immediately following the site visit, the program is assessed a site visit fee. Instructions for preparing annual reports and the periodic self-study reports are sent to programs by the Office of Program Consultation and Accreditation, in accordance with the CoA directions.

1.1 Annual Review (Reaffirmation)

Annual reaffirmation of a program's accredited status is based on the CoA's review of any narrative annual report information requested and the data provided in the Annual Report Online, as well as a signed assurance of the program's continued adherence to the Standards of Accreditation (SoA). If the program does not provide assurance of adherence to the SoA, if the Annual Report Online is incomplete or missing, or if any information provided by the program raises questions about the program's continued consistency with the SoA (including any information or actions that may have been taken by regional accrediting bodies or state agencies regarding the institution's accreditation and/or authority to grant degrees), the CoA may, at any time, request additional information or an invitation for a special site visit. The CoA's request for a special site visit will state the explicit reasons why a site visit is needed, although any subsequent review by the CoA may not be limited to these issues.

1.2 Periodic Review

The CoA schedules the year of the next site visit for accredited programs at the time an accreditation decision is made. In preparation for that review, programs are expected to prepare a self-study report demonstrating their continued consistency with the SoA.

Upon receipt of a self-study report in anticipation of the periodic review, the staff will

review the self-study report to determine the extent to which the materials include information responsive to the self-study instructions and take one of the following actions:

a. Authorize a site visit;

b. Postpone approval for a site visit, pending receipt of additional information from the program; or

c. Refer to the CoA for full review. Following this review, the CoA may choose among the following decision options:

   1. Authorize a site visit (questions may be provided to the program and to the site visitors for consideration during the site visit); or

   2. Defer authorization pending receipt of additional information and/or clarification of the self-study materials.

Specific information is provided for the review processes at each level of accreditation in the *Accreditation Operating Procedures* by level.

1.3 Withdrawal From Accredited Status

A program may request to voluntarily withdraw from accredited status at any time by advising the CoA of its intent in writing in advance of the requested withdrawal date. Programs requesting voluntary withdrawal will be placed on the next CoA agenda for official vote of the program's change in accredited status.

In addition, the CoA has the authority to delete a program from the list of accredited programs when the CoA concludes that the program is no longer in existence. In such instances, the program will receive prior notification of the pending action.

Furthermore, accredited programs assume the responsibility and obligation to provide certain information and payments to the CoA in a timely manner as set forth in the SoA and these *Accreditation Operating Procedures*. An accredited program will be deemed to have decided to voluntarily withdraw from accreditation, thereby terminating its accredited status, if it fails to satisfy any of the following requirements:

a. Providing a self-study by the designated due date (see Section 8 D; 8 I; and 8 P);

b. Scheduling a site visit to allow completion of the periodic review before the end of the program's accreditation review cycle as designated by the CoA (see Section 7 D; 7 I; and 7 P);

c. Submitting its annual report by the designated due date (see Section 1.1);

d. Submitting payment of its annual fee by the designated due date; or

e. Failing to submit information requested in the course of program review by the designated due date (see Section 8 D; 8 I; and 8 P).

If delay in meeting these requirements is based on exceptional circumstances beyond the control of the program that preclude the program from meeting its accreditation responsibilities, the chief executive officer or the president of the institution in which the program is located may apply to the CoA (or its Executive Committee[1] if authorized by the CoA) with supporting evidence for an extension of the deadline.

The CoA will confirm the withdrawal of a program in writing no later than 30 days in advance of the effective date of the program's withdrawal from accreditation. The program will have a final chance to respond to this correspondence. The effective date of withdrawal will be deemed as no more than 60 days after the program has withdrawn from accreditation by failing to meet its obligations as an accredited program. The CoA will notify the public of the change in status. A program that has withdrawn under this provision retains the right to reapply subsequently as an applicant.

2. APPEAL OF A DECISION

2.1 Appealable Decisions

The Board of Educational Affairs (BEA) of the APA serves as the appeal agent for CoA decisions.

The following decisions may be appealed:

a. Denial of a site visit upon application for "accredited, on contingency" or initial "full accreditation"

b. Denial of "accredited, on contingency" status

c. Denial of "full accreditation"

d. Accredited, on probation

e. Revocation of accreditation

f. Withdrawal, based on lack of adherence to the provisions of Section 1.3

2.2 Filing an Appeal

The chief executive officer of a doctoral program's host institution or the responsible administrative officer of an internship or postdoctoral residency program may challenge an appealable decision within 30 days of receipt of written notice of the CoA decision. The written notice must identify the specific grounds upon which the appeal is made, which must be either a procedural violation or substantive errors by the CoA in its review of the program consistency with the SoA. The appeal should be addressed to the president of the APA. A nonrefundable appeal fee will be charged to the appellant program, such fee to be submitted with the program's letter of appeal.

2.3 Appointment of Appeal Panel

Within 30 days of receipt of the program's letter of appeal, the APA Board of Educational Affairs will provide the program with a list of six potential appeal panel candidates, none of whom will have had affiliation with the program filing the appeal or with the accreditation process related to the program. The Office of Program Consultation and Accreditation will determine the willingness of the potential panel members to serve and notify the program to that effect. Within 15 days, the program will select three panel members from this list to serve as

1 Throughout this document, CoA may refer to the Commission on Accreditation in its entirety, the CoA Executive Committee, or its duly authorized representative(s).

its appeal panel, one of whom will be a public member. If the program does not notify the Office of Program Consultation and Accreditation of its selection within 15 days, the Board of Educational Affairs will designate three members to serve on the appeal panel. Consistent with policies adopted by the Board of Educational Affairs, the program and the CoA will have an opportunity to participate in a voir dire of the panel and to challenge any of the designated panelists for due cause (e.g., conflict of interest, bias, or other prejudicial infirmity).

2.4 Scope and Conduct of Appeal

An appeal is not a *de novo* hearing, but a challenge of the decision of the CoA based on the evidence before the CoA at the time of its decision. The CoA's decision should not be reversed by the appeal panel without sufficient evidence that the CoA's decision was plainly wrong or without evidence to support it.

Accordingly, the appeal panel should not substitute its judgment for that of the CoA merely because it would have reached a different decision had it heard the matter originally.

The procedural and substantive issues addressed by the appeal panel will be limited to those stated in the program's appeal letter. If an issue requires a legal interpretation of the Commission on Accreditation's procedures or otherwise raises a legal issue, the issue may be resolved by APA legal counsel instead of the appeal panel.

Only the facts or materials before the CoA at the time of its final decision may be considered by the panel. The panel will be provided with only those documents reviewed by the CoA in making its decision, the letter that notified the program of the CoA decision, the letter of appeal, written briefs submitted by the program, and reply briefs submitted by the CoA. The letter of appeal and written briefs shall not refer to facts or materials that were not before the CoA. Deliberative and other internal documents prepared for purposes of CoA's review are not part of the record and shall not be considered on appeal.

The program will be provided a final listing of the record before the CoA and a copy of the record at least 30 days before the date of the appeal hearing. If the program objects to the record or wishes to refer to any fact or material not included in that record, it must notify the Office of Program Consultation and Accreditation at least 15 days prior to the hearing so that the issue can be resolved by APA's legal counsel.

The appeal panel will convene a hearing at APA during one of three prescheduled appeal panel hearing dates. In addition to the three members of the appeal panel, the appeal hearing will be attended by one or more program representatives, one or more representatives of the CoA, and staff of the Office of Program Consultation and Accreditation. Separate legal counsel may also accompany either party, the program, or the CoA.

When legal counsel attends and participates in the hearing, it is with the understanding they recognize the proceedings are not a judicial forum, but a forum to review the CoA's decision in terms of procedural violations or substantive error.

APA's legal counsel will also attend the hearing. In addition to advising APA, counsel has responsibility to assure compliance with the *Accreditation Operating Procedures* and may resolve legal or procedural issues or can advise the panel regarding those issues.

2.5 Decision and Report of Appeal Panel

The CoA's decision should be affirmed unless (a) there was a procedural error and adherence to the proper procedures would dictate a different decision; or (b) based on the record before it, the CoA's decision was plainly wrong or without evidence to support it. The appeal panel has the options of (a) upholding the CoA decision, (b) amending the CoA decision, or (c) remanding the matter to the CoA to address specific designated issues before final action.

The report of the appeal panel will state its decision and the basis of that decision based on the record before the panel. The report of the panel will be addressed to the president of the APA and sent within 30 days of the hearing. Copies will be provided to the chief executive officer of the doctoral program's host institution or to the responsible administrative officer of an internship or postdoctoral residency program, the chair of the CoA, the chair of the Board of Educational Affairs, and the Office of Program Consultation and Accreditation.

2.6 Review of Adverse Action Based Solely on Financial Deficiencies

Where an adverse CoA decision is based solely on failure of the program to meet an agency standard pertaining to finances, the program will have one opportunity to seek review of new information by the Commission. The CoA will undertake such a review only where the program can establish, to the CoA's satisfaction, that there is new financial information that (a) was unavailable to the program until after the CoA reached its decision and (b) is significant and bears materially on the financial deficiencies identified by the CoA as the reason for the adverse action. Such a request for review must be received prior to the adverse action becoming final or any appeal hearing, whichever is earlier. A program may seek the review of new financial information as described above only once. Any determination by the CoA made with respect to review requested under this provision does not provide a basis for appeal.

3. COMPLAINTS

3.1 Complaint Against an Accredited Program

The procedures for handling complaints against accredited programs are intended to deal only with complaints based on purported lack of program consistency with the *Standards of Accreditation for Health Service Psychology* (SoA). It is not a mechanism for adjudication of disputes between individuals and programs. The CoA cannot, for instance, direct a program to change a grade, readmit a student, or reinstate a faculty member. For resolution of these disputes, complainants are encouraged to follow their institution's due process and grievance procedures.

3.1.1 Filing a Complaint

For timely resolution, complainants are encouraged to file their complaints as soon as possible after the alleged noncompliance comes to their attention. When inquiries are received by the Office of Program Consultation and Accreditation, copies of the SoA, *Accreditation*

Operating Procedures, and a complaint summary form will be sent to the person making the inquiry. To be processed, all complaints must:

a. Be written and signed;

b. Identify the individual, group, or legal entity making the complaint;

c. Present evidence that the subject program is not consistent with one or more of the SoA's components;

d. Describe the status of legal action, if any, related to the complaint; and

e. Grant permission to send the complaint, in its entirety, to the program.

3.1.2 Timelines for Filing a Complaint

For students, interns, postdoctoral residents, or individuals complaining on their behalf, complaints must be filed in writing within 18 months of leaving their program (either through withdrawal, termination, or graduation/completion). Complaints filed by individuals not included above must be filed in writing within one year from the time that the alleged noncompliance occurred.

3.1.3 Processing of a Complaint

Receipt of a complaint meeting these requirements will be acknowledged in writing by the Office of Program Consultation and Accreditation within 30 days of receipt and sent to the program at the same time that acknowledgment of receipt is forwarded to the complainant. The program will be given 30 days to respond.

Complainants are encouraged to submit all available supporting information at the time the complaint is filed, rather than providing supplemental information at a later date. The program's response must be from the program itself and not from any third party acting for the program. The complainant may be asked to respond to information provided by the program but will not receive a copy of materials provided by the program.

3.1.4 CoA Action

The CoA will review the complaint at its first regularly scheduled meeting held after the receipt of the program's response. After review, the CoA may act upon the complaint or defer action pending receipt of additional information. The CoA may act upon the complaint in any of the following ways:

a. Request an invitation for a special site visit to investigate the complaint;

b. Request additional information from the program;

c. Send an informative letter to the program, the complainant, or both;

d. Notify the program that no action is required by the program; or

e. Such other action as, in the judgment of the CoA, is appropriate under the circumstances.

The CoA will communicate its action on the complaint, in writing, to the complainant and the program.

3.2 Complaint Against Accreditation Site Visitor(s)

The procedures for handling complaints against site visitors are intended to deal with complaints based on purported inappropriate actions of site visitors related to the site visit.

3.2.1 Filing a Complaint

The director of training of a program, with notice to the chief executive officer of a doctoral program's host institution or the responsible administrative officer of an internship or postdoctoral residency program, may file a complaint regarding the actions of site visitors.

The director of training must notify the Office of Program Consultation and Accreditation of the institution's or program's intent to file a complaint within 30 days after the completion of the site visit.

Subsequently, the complaint must:

a. Be written and signed;

b. Be sent to the Office of Program Consultation and Accreditation before the host institution has received the written report from the site visit team and within 30 days after completion of the site visit;

c. Provide a clear description of the critical incident(s) in question; and

d. Grant permission to send the complaint, in its entirety, to the site visit team.

3.2.2 Processing of a Complaint

Receipt of a complaint meeting these requirements will be acknowledged by the Office of Program Consultation and Accreditation and held until the site visit team's report is received by the Office. The complaint will be sent to all members of the site visit team with request for comment within 30 days. At the same time, the site visit report will be sent to the program for comment. The program will be asked to explain in its response whether and how the complained of conduct may have influenced the content of the site visit report.

3.2.3 CoA Action

In no case will the CoA decision regarding the program's consistency with the SoA be made until the complaint has been disposed of by the CoA. Based upon its review of the complaint and response, the CoA may make the following decisions:

a. Dismiss the complaint;

b. Reprimand the site visitor(s), which may include deletion from the list of potential site visitors maintained in the Office of Program Consultation and Accreditation;

c. Pursue the matter further, either by further inquiry of the parties involved or by means of a special fact-finding subcommission of the CoA, to provide additional information upon which to base a decision; or

d. Take other action as, in the judgment of the CoA, is appropriate under the circumstances.

After acting on the complaint, the CoA must then determine whether the critical incident(s) influenced the content of the site visit report. If the incident is determined to have influenced the site visit report, the CoA will void the site visit report and request from the host institution an invitation to revisit at APA expense. If the incident

is determined not to have influenced the site visit report, the CoA will proceed with its review of the program.

The CoA will communicate the disposition of the complaint, in writing, to the program and to the site visitors.

3.3 Complaint Against the Commission on Accreditation

There may be instances in which a party or parties desire to formally express dissatisfaction with actions of the Commission on Accreditation. These concerns may be expressed through the following avenues where the CoA action at issue is not subject to appeal per Section 2 (Appeal of a Decision):

a. When the CoA has completed a periodic review, with a resulting decision to deny an initial site visit, deny or revoke accreditation, or grant "accredited, on probation" status, the affected program may formally appeal the decision as set forth in Section 2 of the *Accreditation Operating Procedures*.

b. Individuals, groups, or programs may wish to make a complaint or to raise issues regarding CoA activities, operations, or policies. This may be accomplished by:

   1. Expressing the concern or issue through APA governance, including the Board of Educational Affairs (BEA), the Board of Directors, and/or the Council of Representatives; or
   2. Written communication with the CoA through the Office of Program Consultation and Accreditation.

If the complaint is directed to the CoA, the CoA will take action on such written communication in the same manner in which it processes complaints against the actions of accredited programs, as specified in Section 3.1 of the *Accreditation Operating Procedures*, to the extent relevant. If the complaint is directed to an APA governance group other than the BEA, the matter will be referred to BEA for handling. The BEA will be responsible for resolving the complaint. BEA will provide CoA an opportunity to respond to the complaint before acting on the complaint, and will seek additional information from the complainant or the CoA.

c. Parties also have the option of filing third-party testimony with regard to the CoA's petition for continued recognition by the U.S. Secretary of Education at such time as a petition is reviewed. Those desiring to do so should contact the U.S. Department of Education's Office of Accreditation and State Liaison.

4. THIRD-PARTY COMMENT/TESTIMONY—PROVISION OF THIRD-PARTY TESTIMONY RELATED TO INITIAL OR PERIODIC REVIEW FOR ACCREDITATION

The U.S. Secretary of Education's criteria for recognition activities states: "In providing public notice that an institution or program subject to its jurisdiction is being considered for accreditation or preaccreditation, the agency must provide an opportunity for third party comment concerning the institution's or program's qualifications for accreditation or preaccreditation." The following section outlines the steps that will be taken by the CoA, consistent with the Secretary's requirements.

4.1 Provision of Third-Party Comment

a. The CoA will provide public notice of all programs scheduled for initial or periodic review prior to the beginning of each review year.

   1. In the case of programs applying for continued accreditation, such notice will appear in the APA *Monitor on Psychology* and/or on the Commission on Accreditation website and will include a summary of the accreditation guidelines, along with instructions that questions regarding testimony be directed to the Office of Program Consultation and Accreditation. Such notice may also appear on related web pages with information for students/interns/residents.
   2. In the case of programs applying for initial accreditation (whether "full" or "contingent"), the CoA will provide public notice of all programs that have submitted initial application materials. Such notice will appear on the Commission on Accreditation website, and may appear on related web pages with information for students/interns/residents.

b. Deadlines for receipt of third-party testimony will be given in the notice. The deadlines will be determined according to the following formula: the due date of self-study reports for programs in each review cycle, plus 5 additional working days.

c. All third-party testimony must state the name of the person(s) or the party(ies) represented by the testimony. Issues addressed in the testimony must be limited to a program's consistency with the SoA. All testimony must be in writing and is limited to 10 pages.

d. All third-party testimony made on a program will be incorporated into the preliminary review process, as governed by Sections 6 D, 6 I, and 6 P of the *Accreditation Operating Procedures*. The testimony provided will be forwarded to the program, which will be given the opportunity to comment in writing no later than 1 month prior to the meeting during which the review will occur. Should no comments be received from the program during this time, the CoA will consider the testimony to be undisputed.

e. The CoA will consider all third-party testimony and program comments part of the record for purposes of program review and decision. Consideration of the testimony will be governed by Section 4 of the *Accreditation Operating Procedures*.

f. Third-party testimony is not to be confused with the complaint process. Although both deal with a program's consistency with the SoA, the complaint process differs in many respects:

   1. The process and actions to be taken with the CoA in the review of a complaint are governed by Section 3.1.3 of the *Accreditation Operating Procedures*;
   2. Complaints may be filed only against the operations of an accredited program and not against those reviewed for initial accreditation;
   3. Submission of third-party testimony can be made only in the context of a program's review for initial or continued accreditation, as appropriate;

4. Third-party testimony may be filed on behalf of a program as well as against it; and
5. A program has the option of declining to respond to third-party testimony.

Attention will be invited to the existence of the complaint process, with instructions to contact the Office of Program Consultation and Accreditation should questions arise.

4.2 Provision of Third-Party Information for the Identification of Incorrect/Misleading Information Released by an Accredited or Applicant Program

a. The CoA provides for the public correction of incorrect or misleading information released by an accredited or applicant program about:
   1. The program's accreditation status;
   2. The contents of reports of site team visitors; and
   3. The CoA's accrediting actions with respect to the program.

b. The procedure for providing such correction is as follows:
   1. All third-party testimony must state the name of the person(s) or the party(ies) represented by the testimony. Issues addressed in the testimony must identify the incorrect/misleading information alleged to have been provided by the program. All testimony must be in writing and is limited to 10 pages. If the information appeared in print form, a copy of the document in question should accompany the testimony.
   2. The third-party testimony will be forwarded to the program alleged to have supplied the information, and the program will have the opportunity to comment in writing no later than one month from the program's receipt of the CoA's letter. Should no comments be received from the program during this time, the CoA will consider the testimony to be undisputed.
   3. Upon receipt of a response from the program or in the absence of a response, one month after the program's receipt of the CoA's letter, the CoA will review the testimony and any program response. If a misleading instance is verified, the program will be informed by the CoA, in writing, that the program's actions are not consistent with the SoA. The CoA reserves the right to take further action with regard to the program, consistent with the *Accreditation Operating Procedures*, as may be appropriate under the circumstances.
   4. In those instances in which incorrect/misleading information has been verified, the CoA will provide public correction of such information via its website and/or the APA *Monitor on Psychology*. This public announcement will include a summary of the information released by the program, accompanied by the CoA's clarification/correction of the information (subject to its procedures regarding confidentiality and public disclosure of information).

5. CONFIDENTIALITY AND PUBLIC DISCLOSURE OF INFORMATION

An up-to-date listing of all applicant programs will be regularly available on the Office of Program Consultation and Accreditation website. Included in all published materials will be the identity of programs whose accreditation has been denied, or revoked, as well as those voluntarily withdrawing from accredited status. The CoA will make public notice of all accreditation decisions no later than 30 days following the CoA meeting at which the decisions were made. In the case of programs for which appealable decisions have been reached, and appeal has been filed, the CoA will note that the decision is under appeal.

CoA decisions including accreditation actions, deferrals, and adverse actions, and a list of any standards to which a program is required to respond, will be disclosed in the directory of accredited programs on the accreditation website. The CoA will share the accreditation status of programs with regional and specialized accrediting bodies as appropriate. All other information, and the records used in accreditation decisions, will be kept confidential by the CoA.

The Commission will identify and make public, as appropriate, all applicant programs applying for initial review by the CoA for "accredited, on contingency" or "full accreditation" to allow for third-party comment.

The CoA will notify the Department of Education of any accredited program that the CoA has reason to believe is failing to comply with financial aid responsibilities as outlined in Title IV of the Higher Education Act, or any purported fraud and abuse by accredited programs, and its reasons for such concern. The CoA also will take action to correct in a timely manner any incorrect or misleading information released by an accredited program about the accreditation status of the program and the CoA's accrediting actions with respect to the program.

In addition, the Office of Program Consultation and Accreditation will make disclosure as required by the U.S. Department of Education and in those instances when the CoA is legally required to disclose such information.

DOCTORAL ACCREDITATION OPERATING PROCEDURES

6.D DOCTORAL APPLICATION FOR INITIAL ACCREDITATION

6.1 D Doctoral Application

Intent to Apply—Guidelines for programs seeking acknowledgment of "intent" to obtain accreditation are provided in the Self-Study Instructions available under separate cover from the APA Office of Program Consultation and Accreditation. The review process is initiated by the program that wishes to submit itself for review, and the burden of proof for consistency with the SoA rests with the applicant.

All programs can seek review of "intent to apply" status and "accredited, on contingency" prior to seeking full accreditation. The application for acknowledgment of "intent" includes documentation related to key standards of accreditation. Review for this status is a document review only. The review is conducted to verify that the essential elements are in place to begin a program and as such is not an accredited status and does not provide the public with a judgment regarding the quality of the program. Rather, if a program is approved as "intent" for accreditation, it serves as a notice to the public that the program will be seeking accreditation in the near future.

Doctoral programs seeking "accredited, on contingency" must be reviewed on all aspects of the SoA, which involves submission of a self-study and a site visit. "Accredited, on contingency" is granted to a doctoral program when the program demonstrates initial evidence of educational quality consistent with the SoA and the capacity to meet all accreditation standards in the designated time frame. Review for this status requires matriculation of students, clinical evaluations of students in practicum, evidence of the integration of science and practice, and significant resource allocation. To move from "accredited, on contingency" status to "fully accredited," the doctoral program must submit a new self-study for a second site visit within 5 years of being granted "contingent" accreditation.

Applicants for initial accreditation begin the process by submitting a self-study report or, in the case of a program seeking public notice of "intent to apply," the appropriate required

sections of the self-study. Instructions for preparing the report are provided by the Office of Program Consultation and Accreditation.

Applications may be submitted to the Office of Program Consultation and Accreditation at any time during the year and must be accompanied by a nonrefundable application fee.

6.2 D Review for Initial Site Visit

Upon receipt of an initial application for "intent to apply," "accredited, on contingency," or "full accreditation" status, the Office of Program Consultation and Accreditation will confirm receipt of the required application fee.

For programs seeking public notification of "intent to apply," the staff will ascertain that the "intent" application has provided the information responsive to the eligibility instructions. Following this review, the staff will forward the "intent" application to the Commission for review.

The accreditation process for "accredited, on contingency" or "full accreditation" begins with a review by staff of the application in terms of the extent to which the materials include information responsive to the self-study instructions.

Following review of the application for "accredited, on contingency" or "full accreditation," one of the following actions will be taken:

a. Authorize a site visit after approval by CoA reviewers;

b. Defer authorization pending receipt of any missing self-study materials;

c. Refer to the full CoA for review. Following this review, the CoA may choose among the following decision options:

   1. Authorize a site visit (questions may be provided to the program and to the site visitors for consideration during the site visit);

   2. Defer authorization pending receipt of additional information and/or clarification of the self-study materials; or

   3. Deny a site visit (see Section 2.1).

The CoA is solely responsible for selecting among the above actions in response to the review of the application.

6.3 D Withdrawal of Application for Accreditation

A program may withdraw its application without prejudice at any time before the CoA makes an accreditation decision.

7.D DOCTORAL SITE VISIT

Site visits are conducted as part of the review for initial "accredited, on contingency" or initial "full accreditation" of a doctoral program and as part of the periodic review of an accredited program. For accredited doctoral programs, the CoA will request an invitation to schedule a site visit from the chief executive officer of the institution in which a doctoral program is housed.

For accredited programs, the submission of a self-study serves as the formal invitation to site visit the program and conduct an accreditation review. For applicant programs, the accreditation application serves as the formal invitation to site visit the program and conduct an accreditation review.

If a site visit is not arranged within the assigned review cycle and thus precludes the program from meeting its accreditation responsibilities, the program will be deemed to have withdrawn from accredited status at the end of the review cycle (in accordance with Section 1.3).

Within the calendar year in which they are scheduled for a periodic review by the CoA, accredited doctoral programs will be assigned randomly to one of two review cycles for their site visits. The specific dates of the site visit within the cycle are chosen by the program. A change of cycle may be requested by the program in writing to the chair of the CoA for exceptional circumstances only.

Programs that have received authorization for an initial accreditation site visit will be assigned to the next available review cycle.

7.1 D Site Visit Team

The Office of Program Consultation and Accreditation will maintain a database of potential site visitors appointed by the CoA. Training will be provided for site visitors, and their performance will be evaluated by the CoA regularly, based on information from programs and other relevant sources.

The CoA is responsible for assigning site visitors, but will give notice to the program and provide an opportunity for the program to communicate its views and any objections regarding site visitor selection.

7.1.1 D Special Site Visit

The Commission on Accreditation may vote to conduct a special site visit in lieu of or in addition to a regular site visit to the program in keeping with its mandate to protect the public and maintain program quality. The special site visit is viewed by the Commission as an opportunity to interact directly with the program. It affords the Commission the opportunity to collect information as to the program's operation and to address questions that are not fully answered by the record before the Commission. In that regard, special site visits are intended to be beneficial to both the Commission and the program. A special site visit team may include one or more members of the Commission or other individuals selected by the Commission.

7.2 D Site Visit Report and Program Response

Within 30 days of the completion of the visit, the site visit team will deliver to the Office of Program Consultation and Accreditation a report in a format prescribed by the CoA. The report will address the program's consistency with the SoA and address any questions posed by the CoA prior to the visit. The site visit team may, at its discretion, provide the CoA with evaluative comments related to the program's strengths and weaknesses and overall consistency with the SoA but should not make a specific accreditation recommendation. It should be clear to the program, however, that evaluative comments represent the opinions of the site visitors and do not represent an accreditation

decision.

After the site visit report is submitted, any communications between the site visit team and the program regarding the site visit must be conducted through the Office of Program Consultation and Accreditation rather than directly between the site visit team and the program.

A copy of the site visit report will be provided to the program. The program should confirm that it has received the report. The program may also provide written comment or response to any aspect of the report. Such response must be delivered to the Office of Program Consultation and Accreditation within 30 days of receipt of the report by the program or its host institution. Upon written request by the program, the period for responding may be extended by the chair of the CoA for an additional period not to exceed 30 days. The CoA will proceed with the review of a program once it has received the program's response. In the absence of a response from the program within the allotted time, the CoA will proceed with the review of the program.

In its response to the site visit report, the program should correct any errors of fact and provide evidence to counter anything in the report with which the program does not concur. Any statements of fact in the report that are not challenged in the program's response may be considered by the CoA to be undisputed. The CoA will review the site visit report and all other relevant documents that it has received, and after considering all elements of the program review, will accept sole responsibility for the accreditation decision.

8.D PERIODIC REVIEW BY THE COA

A periodic review by the CoA is one in which a decision may be made about a program's accreditation status. The periodic review follows submission of (a) a self-study report by the program, (b) site visit report, and (c) the program's response to the site visit report. These requirements apply equally to programs making initial application for accreditation and those seeking continuation of accredited status.

8.1 D Guiding Principles of the Periodic Review

In all reviews, the CoA will be guided by the following general principles:

a. Should a member of the CoA be in actual or potential conflict of interest with respect to a program scheduled for review, that member will be recused during discussion and decision making on that program;

b. A high degree of professional judgment will be exercised by the CoA as to whether the program is fulfilling acceptable, publicly stated objectives, consistent with the SoA.

Before making an accreditation decision, the CoA will review the program's most recent self-study report, the most recent site visit report, the program's response to that report, and any other records of relevance that the program has submitted and any third-party comments and responses to those comments that have been received (consistent with Section 4 of these procedures).

In making a decision, the CoA will also consider the program's outcomes in light of the program's stated educational aims and the importance of ensuring that students are adequately prepared for entry into practice.

8.2 D Accreditation Statuses and Decision Options

The following decisions are available to the CoA with respect to the accredited status of a doctoral program:

a. Public notice of "intent to apply" is not an accredited status. Rather, it designates a doctoral program that has made known its intent to seek accreditation once it has students in place; programs can be listed publicly **once** for up to 3 years.

b. "Accredited, on contingency" is an accredited status that designates a doctoral program that, in the professional judgment of the CoA, is consistent, substantively and procedurally, with the SoA in terms of the commitment to a program of study for all students with demonstrated support of the administration, evidence that there is capacity to ensure that all students demonstrate appropriate discipline-based knowledge, and that the program has appropriate and adequate resources for all students to become competent in the profession-wide competencies. Thus, the doctoral program must have a sequence of training and a curriculum map in place, including syllabi for required courses. A doctoral program that is "accredited, on contingency" must provide outcome data for students in the program within 3 years of receiving "accredited, on contingency" status. Failure to do so will lead to the program being deemed to have withdrawn from accreditation. The maximum amount of time a doctoral program can be on "accredited, on contingency" is 5 years in total.

c. "Accredited" (or "fully accredited") designates a program that, in the professional judgment of the CoA, is consistent, substantively and procedurally, with the SoA. Accredited programs are scheduled for periodic review at intervals of up to 10 years.

d. "Accredited, inactive" designates a doctoral program that has not admitted students for 2 successive academic years or has provided the CoA with notice that it has decided to phase out and close the program.

   Requests for inactive status are granted by the CoA for one year at a time. Request for renewal of inactive status must be done prior to the beginning of the academic/training year. Programs not granted renewal of inactive status are given notice that they are no longer compliant with the provisions of accreditation and then may be placed on probation.

e. "Accredited, on probation" serves as notice to the program, its students, and the public that in the professional judgment of the CoA, the accredited program is not currently consistent with the SoA and may have its accreditation revoked.

   Prior to this decision, the program will be given an opportunity to *show cause* why it should not be placed on probation by providing a written response to the issues of concern. The program's show cause response will be reviewed two CoA meetings after the program was provided the show cause notice. Programs that are still not in compliance at the time of the CoA's review are then placed on "accredited, on probation" status.

Following placement on "accredited, on probation" status, the program is given a time by which to comply with the issues identified by the CoA in the probation decision. Doctoral programs must provide a response to the issues within four CoA meetings after the probation decision was reached.

f. "Revocation of accreditation" is considered by the CoA to be an adverse action. It designates a program that has previously been placed on "accredited, on probation" status and for which the CoA has evidence that the program continues to be substantively inconsistent with the SoA at the time of its review of the program's response to the probation. A decision to revoke a program's accreditation reflects the CoA's determination that the program will not become consistent with the SoA within a reasonable time.

g. "Denial of accreditation" is considered by the CoA to be an adverse action. It designates an applicant program which, in the professional judgment of the CoA, is substantively inconsistent with the SoA. Prior to this decision, the program is given an opportunity to show cause why it should not be denied accreditation through a written response to the issues of concern.

h. "Denial of a site visit" is considered by the CoA to be an adverse action. It designates an applicant program that, in the professional judgment of the CoA, is not ready for a site visit. Prior to this decision, the program is given an opportunity to show cause why it should not be denied a site visit through a written response to the issues of concern.

8.3 D Decision Process

A quorum of the CoA, two-thirds of its members, must be present at a scheduled meeting to make an accreditation decision on a program. If a CoA member has recused him/herself from a portion of the meeting because of a conflict or perceived conflict of interest, that person will not be counted in determining a quorum. Accreditation decisions reflect the majority view of CoA members.

In the case of a program initially applying for accreditation (either "full" or "contingent"), the CoA will determine whether to grant or deny the program accreditation. In the case of an accredited program, the CoA will determine whether to reaffirm the program's present status. When a program's current accredited status is not renewed, it will automatically become a program whose status is "accredited, on probation."

In the case of an accredited program that has been placed on probation, the CoA will determine whether to restore the program's status from "accredited, on probation" to "accredited" or revoke accreditation. A program returned to accredited status will have a self-study due one year after receipt of the decision for a full review and site visit. A program that does not have its status restored to "accredited" will have its accreditation revoked. In extraordinary circumstances, if the CoA determines that the program has made significant progress on most of the probation issues but needs additional time to implement changes, the CoA may vote to continue a program on probation for good cause. The length of the extension will be determined by the CoA depending on the program's circumstances for coming into full compliance, but may not exceed one year. A program may not be continued on probation more than once in a single review cycle.

Deferral for information: Whenever it deems appropriate, the CoA may defer making a decision about a program in order to obtain more information. Further, when in the CoA's judgment, significant disparity exists between the site visit report and information provided in the program's response to that report, the CoA will defer making a decision and seek additional information to resolve the difference. Further, the Commission may seek additional information through a request for an invitation to conduct a special site visit. When a decision is deferred for information, the CoA will notify the program in writing and specify what additional information is needed to determine the program's consistency with the SoA. The CoA may also write to the chair of the site visit team to identify issues in need of clarification, and a copy of this correspondence will be provided to the program. The program will be provided the opportunity to respond to any new information provided by the site visit team chair, prior to final review of the program by the CoA.

Deferral for cause: When the CoA has concerns that may result in a decision to deny a site visit or deny accreditation to an applicant program or place an accredited program on probation, it will defer its final decision, give written notice to the program of its concerns, and thereby provide an opportunity to supplement the record before a decision is made. The CoA will assume that materials and information provided by the program before the final decision is made by the CoA represent the full and complete basis on which the program wishes its accreditation status to be determined.

8.4 D Site Visit Interval

At the time of making a decision for "full accreditation," the CoA will also decide the year in which to schedule the program's next periodic review. For all accredited programs, a period of up to 10 years between site visits will be designated. Programs returned to accredited status from probationary status will be given one year from receipt of the decision in which to provide a new self-study in preparation for the next site visit and full review.

An accredited program may always request to submit a self-study and schedule a site visit earlier than scheduled. Such a request should be provided in writing to the CoA along with the rationale for requesting an earlier review. In addition, the CoA reserves the right to schedule an earlier visit for any accredited program if it has evidence to suggest concerns about the program's consistency with the SoA.

8.5 D Communication of Decision to Program

Within 30 days following any decision, the CoA will give written notice of the outcome of its review to the chief executive officer of the institution housing a doctoral program or the appropriate administrative officer of the institution housing an internship or postdoctoral residency program. The decision will contain a statement of the bases for the decision. The CoA's decision also may alert the program to SoA-related areas of concern, requesting that the program address its attention to these in subsequent narrative reports or in the next self- study.

8.6 D Effective Date of a Decision

Award of "accreditation" (either "on contingency" or "full") and other nonappealable accreditation decisions are effective on the final day

of the site visit preceding the CoA decision. Appealable decisions (as defined in Section 2.1) that are not appealed by the program are effective 30 days after receipt of the CoA's decision.

If a program elects to appeal a decision of "accredited, on probation," and the decision is upheld, the effective date of probation remains as 30 days after receipt of the CoA's decision, and the program must respond to the issues of probation in the same time frame as indicated in the CoA's decision.

If a program elects to appeal any decision other than probation, and the decision is upheld, the original CoA decision will take effect 30 days after the appeal panel hearing date.

For any appeal in which the decision is amended or reversed by the appeal panel, the new decision will be effective 30 days after the end ofthe appeal hearing.

8.7 D Failure to Meet Accreditation Responsibilities

Changes in a program's accreditation status by the CoA may result from a program's failure to meet the following responsibilities:

a. Abiding by the CoA's published policies and procedures; or

b. Informing the CoA in a timely manner of changes in its environment, plans, resources, or operations that could diminish the program's quality.

Before a change in accreditation status is made for any of these reasons, the program will be notified in writing by the CoA and given 30 days in which to respond. Based on the program's response, the CoA will determine appropriate action.

This section involves the substantive review of program materials and responses in determining whether the CoA should change a program's accredited status, unlike Section 1.3 wherein a program is deemed to have withdrawn by its failure to meet its procedural obligations as an accredited program.

INTERNSHIP ACCREDITATION OPERATING PROCEDURES

6.I INTERNSHIP APPLICATION FOR INITIAL ACCREDITATION

6.1 I Internship Application

Information for programs seeking public notification of their "intent to apply" for accreditation are provided in the Self-Study Instructions available under separate cover from the APA Office of Program Consultation and Accreditation. The accreditation process is initiated by the program that wishes to submit itself for review, and the burden of proof for consistency with the SoA rests with the applicant.

All programs can seek public notification of "intent to apply" and "accredited, on contingency" prior to seeking full accreditation. The application for public notification of intent includes documentation related to key standards of the SoA. This review is a document review only. The review is conducted to verify that the essential elements are in place to begin a program and as such is not an accredited status and does not provide the public with a judgment regarding the quality of the program. Rather, if approved, this serves as public notice of the program's intent to seek accreditation in the near future.

Internship programs seeking "accredited, on contingency" must be reviewed on all aspects of the SoA. "Accredited, on contingency" is an accredited status and is granted if and only if the program meets all standards except for the inclusion of all required outcome data on interns in the program and after program completion. To move from "accredited, on contingency" status to "fully accredited," the program must provide the required data by the time two cohorts have completed the program within a 2-year time frame. The program may be granted a second term of "accredited, on contingent" under exceptional circumstances of no more than 2 years.

Applicants for initial accreditation begin the process by submitting a self-study report, or in the case of a program seeking public notification of "intent to apply" the appropriate required sections of the self-study. Instructions for preparing the report are provided by the Office of Program Consultation and Accreditation. Applications may be submitted to the Office of Program

Consultation and Accreditation at any time during the year and must be accompanied by a nonrefundable application fee.

6.2 I Review for Initial Site Visit

Upon receipt of an application for public notification of "intent to apply," "accredited, on contingency," or "full accreditation," the Office of Program Consultation and Accreditation will confirm receipt of the required application fee.

For internship programs seeking public notice of "intent to apply," the staff will ascertain that the application has provided the information responsive to the instructions. Following this review, the staff will forward the "intent" application to the Commission for review.

The accreditation process for "accredited, on contingency" or "full accreditation" begins with a review by staff of the application in terms of the extent to which the materials include information responsive to the self-study instructions.

Following review of the application for "accredited, on contingency" or "full accreditation," one of the following actions will be taken:

a. Authorize a site visit after approval by CoA reviewers;

b. Defer authorization pending receipt of any missing self-study materials;

c. Refer to the CoA for review. Following this review, the CoA may choose among the following decision options:

   1. Authorize a site visit (questions may be provided to the program and to the site visitors for consideration during the site visit);
   2. Defer authorization pending receipt of additional information and/or clarification of the self-study materials; or
   3. Deny a site visit (see Section 2.1).

The CoA is solely responsible for selecting among the above actions in response to the review of the application.

6.3 I Withdrawal of Application for Accreditation

A program may withdraw its application without prejudice at any time before the CoA makes an accreditation decision.

7.I INTERNSHIP SITE VISIT

Site visits are conducted as part of the review for initial "accredited, on contingency" or initial "full accreditation" of an internship program and as part of the periodic review of an accredited program. For accredited internship programs, the CoA will request an invitation to schedule a site visit from the appropriate administrative officer of the agency in which the internship is housed.

For accredited internship programs, the submission of a self-study serves as the formal invitation to site visit the program and conduct an accreditation review. For applicant programs, the accreditation application serves as the formal invitation to site visit the program and conduct an accreditation review.

If a site visit is not arranged within the assigned review cycle and thus precludes the program from meeting its accreditation responsibilities, the program will be deemed to have withdrawn from accredited status at the end of the review cycle (in accordance with Section 1.3).

Within the year in which they are scheduled for a periodic review by the CoA, accredited internship programs will be assigned randomly to one of two cycles for their site visits. The specific dates of the site visit within the cycle are chosen by the program. A change of cycle may be requested by the program in writing to the chair of the CoA for exceptional circumstances only.

Programs that have received authorization for an initial accreditation site visit will be assigned to the next available review cycle.

7.1 I Site Visit Team

The Office of Program Consultation and Accreditation will maintain a database of potential site visitors appointed by the CoA. Training will be provided for site visitors, and their performance will be evaluated by the CoA regularly, based on information from programs and other relevant sources.

The CoA is responsible for assigning site visitors, but will give notice to the program and provide an opportunity for the program to communicate its views and any objections regarding site visitor selection.

7.1.1 I Special Site Visit

The Commission on Accreditation may vote to conduct a special site visit in lieu of or in addition to a regular site visit to the program in keeping with its mandate to protect the public and maintain program quality. The special site visit is viewed by the Commission as an opportunity to interact directly with the program. It affords the Commission the opportunity to collect information as to the program's operation and to address questions that are not fully answered by the record before the Commission. In that regard, special site visits are intended to be beneficial to both the Commission and the program. A special site visit team may include one or more members of the Commission, or other individuals selected by the Commission.

7.2 I Site Visit Report and Program Response

Within 30 days of the completion of the visit, the site visit team will submit the report to the Office of Program Consultation and Accreditation in a format prescribed by the CoA. The report will address the program's consistency with the SoA and address any questions posed by the CoA prior to the visit. The site visit team may, at its discretion, provide the CoA with evaluative comments related to the program's strengths and weaknesses and overall consistency with the SoA but should not make a specific accreditation recommendation. It should be clear to the program, however, that evaluative comments represent the opinions of the site visitors and do not represent an accreditation decision.

After the site visit report is submitted, any communications between the site visit team and the program regarding the site visit must be conducted through the Office of Program Consultation and Accreditation rather than directly between the site visit team and the program.

A copy of the site visit report will be provided to the program. The program should confirm that it has received the report. The program may also provide written comment or response to any aspect of the report. Such response must be submitted to the Office of Program Consultation and Accreditation within 30 days of receipt of the report by the program or its host institution. Upon written request by the program, the period for responding may be extended by the chair of the CoA for an additional period not to exceed 30 days. The CoA will proceed with the review of a program once it has received the program's response. In the absence of a response from the program within the allotted time, the CoA will proceed with the review of the program.

In its response to the site visit report, the program should correct any errors of fact and provide evidence to counter anything in the report with which the program does not concur. Any statements of fact in the report which are not challenged in the program's response may be considered by the CoA to be undisputed. The CoA will review the site visit report and all other relevant documents that it has received, and after considering all elements of the program review, will accept sole responsibility for the accreditation decision.

8.I PERIODIC REVIEW BY THE COA

A periodic review by the CoA is one in which a decision may be made about a program's accreditation status. The periodic review follows submission of (a) a self-study report by the program, (b) site visit report, and (c) the program's response to the site visit report. These requirements apply equally to programs making initial application for accreditation and those seeking continuation of accredited status.

8.1 I Guiding Principles of the Periodic Review

In all reviews, the CoA will be guided by the following general principles:

a. Should a member of the CoA be in actual or potential conflict of interest with respect to a program scheduled for review, that member will be recused during discussion and decision making on that program;

b. A high degree of professional judgment will be exercised by the CoA as to whether the program is fulfilling acceptable, publicly stated objectives, consistent with the SoA.

Before making an accreditation decision, the CoA will review the program's most recent self-study report, the most recent site visit report, the program's response to that report, and any other records of relevance that the program has submitted and any third-party comments and responses to those comments that have been received (consistent with Section 4 of these procedures).

In making a decision, the CoA will also consider the program's outcomes in light of the program's stated aims and the importance of ensuring that interns are adequately prepared for entry into practice.

8.2 I Accreditation Statuses and Decision Options

The following decisions are available to the CoA with respect to the accredited status of an internship program:

a. Public notice of "intent to apply" is not an accredited status. Rather, it designates an internship program that has made known its intent to seek accreditation once it has interns in place; programs can be approved **once** for such listing for up to 2 years.

b. "Accredited, on contingency" is an accredited status and designates an internship program that, in the professional judgment of the CoA, is consistent, substantively and procedurally, with the SoA with the exception of the provision of adequate and appropriate proximal and distal outcome data. A program that is "accredited, on contingency" must provide outcome data for trainees in the program and program graduates by the time two cohorts have completed the program. At a maximum this will be 2 years for full-time internship. Failure to do so will lead to the program being deemed to have withdrawn from accreditation, following completion of the program by the interns currently on-site at the program. Programs that are "accredited, on contingency" may be eligible for a second term of "accredited, on contingency" only under extenuating circumstances.

c. "Fully accredited" designates a program which, in the professional judgment of the CoA, is consistent, substantively and procedurally, with the SoA. Accredited programs are scheduled for periodic review at intervals of up to 10 years. Programs that were previously "accredited on contingency" are eligible for 3 years of initial "full accreditation" following receipt of adequate and appropriate outcome data.

d. "Accredited, inactive" designates a one-year internship program that will not be accepting funded interns for a given training year. In the case of an internship program that takes 2 years to complete, the program may be designated as "accredited, inactive" if the program undergoes a period of 2 successive years with no funded interns.

Requests for inactive status are granted by the CoA for one year at a time. Request for renewal of inactive status must be done prior to the beginning of the training year. An internship program is expected to make such a request in writing as soon as it has determined whether it will be accepting interns. Programs not granted renewal of inactive status are given notice that they are no longer compliant with the provisions of accreditation and then may be placed on probation.

e. "Accredited, on probation" serves as notice to the program, its interns, and the public that in the professional judgment of the CoA, the accredited program is not currently consistent with the SoA and may have its accreditation revoked. Prior to this decision, the program will be given an opportunity to *show cause* why it should not be placed on probation by providing a written response to the issues of concern. The program's show cause response will be reviewed two CoA meetings after the program was provided the show cause notice. Programs that are still not in compliance at the time of the CoA's review are then placed on "accredited, on probation" status.

Following placement on "accredited, on probation" status, the program is given a time certain in which to come into compliance with the issues identified by the CoA in the probation decision. Internship programs must provide a response to the issues within two CoA meetings after the probation decision was reached. In the

case of a school psychology internship program that is 10 months in length, the program must provide a response within one CoA meeting after the probation decision was reached.

f. "Revocation of accreditation" is considered by the CoA to be an adverse action. It designates a program that has previously been placed on "accredited, on probation" status and for which the CoA has evidence that the program continues to be substantively inconsistent with the SoA at the time of its review of the program's response to the probation. A decision to revoke a program's accreditation reflects the CoA's determination that the program will not become consistent with the SoA within a reasonable time.

g. "Denial of accredited, on contingency" as well as "denial of accreditation" are considered by the CoA to be adverse actions. It designates an applicant program which, in the professional judgment of the CoA, is substantively inconsistent with the SoA. Prior to this decision, the program is given an opportunity to show cause why it should not be denied accreditation through a written response to the issues of concern.

h. "Denial of a site visit" is considered by the CoA to be an adverse action. It designates an applicant program which, in the professional judgment of the CoA, is not ready for a site visit. Prior to this decision, the program is given an opportunity to show cause why it should not be denied a site visit through a written response to the issues of concern.

8.3 I Decision Process

A quorum of the CoA, two-thirds of its members, must be present at a scheduled meeting to make an accreditation decision on a program. If a CoA member has recused him/herself from a portion of the meeting because of a conflict or perceived conflict of interest, that person will not be counted in determining a quorum. Accreditation decisions reflect the majority view of CoA members.

In the case of a program initially applying for accreditation, the CoA will determine whether to grant or deny the program accreditation. In the case of an accredited program, the CoA will determine whether to reaffirm the program's present status. When a program's current accredited status is not renewed, it will automatically become a program whose status is "accredited, on probation."

In the case of an accredited program that has been placed on probation, the CoA will determine whether to restore the program's status from "accredited, on probation" to "accredited" or revoke accreditation. A program returned to accredited status will have a self-study due one year after receipt of the decision for a full review and site visit. A program that does not have its status restored to "accredited" will have its accreditation revoked. In extraordinary circumstances, if the CoA determines that the program has made significant progress on most of the probation issues but needs additional time to implement changes, the CoA may vote to continue a program on probation for good cause. The length of the extension will be determined by the CoA depending on the program's circumstances for coming into full compliance, but may not exceed one year. A program may not be continued on probation more than once in a single review cycle.

Deferral for information: Whenever it deems appropriate, the CoA may defer making a decision about a program in order to obtain more information. Further, when in the CoA's judgment, significant disparity exists between the site visit report and information provided in the program's response to that report, the CoA will defer making a decision and seek additional information to resolve the difference. Further, the Commission may seek additional information through a request for an invitation to conduct a special site visit. When a decision is deferred for information, the CoA will notify the program in writing and specify what additional information is needed to determine the program's consistency with the SoA. The CoA may also write to the chair of the site visit team to identify issues in need of clarification, and a copy of this correspondence will be provided to the program. The program will be provided the opportunity to respond to any new information provided by the site visit team chair, prior to final review of the program by the CoA.

Deferral for cause: When the CoA has concerns which may result in a decision to deny a site visit or deny accreditation to an applicant program or place an accredited program on probation, it will defer its final decision, give written notice to the program of its concerns, and thereby provide an opportunity to supplement the record before a decision is made. The CoA will assume that materials and information provided by the program before the final decision is made by the CoA represent the full and complete basis on which the program wishes its accreditation status to be determined.

8.4 I Site Visit Interval

At the time of making a decision for "full accreditation," the CoA will also decide the year in which to schedule the program's next periodic review. For all accredited programs, a period of up to 10 years between site visits will be designated depending upon the program's stage of development and the stability of program outcomes. Programs returned to accredited status from probationary status will be given one year from receipt of the decision in which to provide a new self-study in preparation for the next site visit and full review.

An accredited program may always request to submit a self-study and schedule a site visit earlier than scheduled. Such a request should be provided in writing to the CoA along with the rationale for requesting an earlier review. In addition, the CoA reserves the right to schedule an earlier visit for any accredited program if it has evidence to suggest concerns about the program's consistency with the SoA.

8.5 I Communication of Decision to Program

Within 30 days following any decision, the CoA will give written notice of the outcome of its review to the chief executive officer of the institution or the appropriate administrative officer of the institution housing an internship program. The decision will contain a statement of the bases for the decision. The CoA's decision also may alert the program to SoA-related areas of concern, requesting that the program address its attention to these in subsequent reports or in the next self-study.

8.6 I Effective Date of a Decision

Award of "accreditation" (either "contingent" or "full") and other non-appealable accreditation decisions are effective on the final day of the site visit preceding the CoA decision. Appealable decisions (as defined

in Section 2.1) that are not appealed by the program are effective 30 days after receipt of the CoA's decision.

If a program elects to appeal a decision of "accredited, on probation," and the decision is upheld, the effective date of probation remains as 30 days after receipt of the CoA's decision, and the program must respond to the issues of probation in the same time frame as indicated in the CoA's decision.

If a program elects to appeal any decision other than probation, and the decision is upheld, the original CoA decision will take effect 30 days after the appeal panel hearing date.

For any appeal in which the decision is amended or reversed by the appeal panel, the new decision will be effective 30 days after the end of the appeal hearing.

8.7 | Failure to Meet Accreditation Responsibilities

Changes in a program's accreditation status by the CoA may result from a program's failure to meet the following responsibilities:

a. Abiding by the CoA's published policies and procedures; or

b. Informing the CoA in a timely manner of changes in its environment, plans, resources, or operations that could diminish the program's quality.

Before a change in accreditation status is made for any of these reasons, the program will be notified in writing by the CoA and given 30 days in which to respond. Based on the program's response, the CoA will determine appropriate action.

This section involves the substantive review of program materials and responses in determining whether the CoA should change a program's accredited status, unlike Section 1.3 wherein a program is deemed to have withdrawn by its failure to meet its procedural obligations as an accredited program.

POSTDOCTORAL RESIDENCY ACCREDITATION OPERATING PROCEDURES

6.P POSTDOCTORAL RESIDENCY APPLICATION FOR INITIAL ACCREDITATION

6.1 P Postdoctoral Residency Application

Upon receipt of an application for public notification of "intent to apply," "accredited, on contingency," or initial "full accreditation," the Office of Program Consultation and Accreditation will confirm receipt of the required application fee.

For postdoctoral residency programs seeking public notice of "intent to apply," the staff will ascertain that the application has provided the information responsive to the instructions. Following this review, the staff will forward the "intent to apply" application to the Commission for review.

All programs can seek public notification of "intent to apply" and "accredited, on contingency" prior to seeking "full accreditation." Review for public notice of "intent to apply" is a document review only. The review is conducted to verify that the essential elements are in place to begin a program and as such is not an accredited status and does not provide the public with a judgment regarding the quality of the program. Rather, if it is approved, it serves as a notice to the public that the program will be seeking accreditation in the near future.

Programs seeking "accredited, on contingency" must be reviewed on all aspects of the SoA. "Accredited, on contingency" is an accredited status and is granted if and only if the postdoctoral residency program meets all standards except for the inclusion of all required outcome data on residents in the program and after program completion. To move from "accredited, on contingency" status to "fully accredited," the program must provide the required data by the time two cohorts have completed the program. At a maximum, this will be 4 years for full-time residency programs that are more than 1 year in duration.

Applicants for initial accreditation begin the process by submitting a self-study report, or in the case of a program seeking notice of "intent to apply" status or "accredited, on contingency" status, the appropriate required sections of the self-study. Instructions for preparing the report are provided by the Office of Program Consultation and Accreditation. Applications may be submitted to the Office of Program Consultation and Accreditation at any time during the year and must be accompanied by a nonrefundable application fee.

6.2 P Review for Initial Site Visit

The accreditation process for "accredited, on contingency" or "full accreditation" begins with a review by staff of the application in terms of the extent to which the materials include information responsive to the self-study instructions.

Following review of the application for "accredited, on contingency" or accreditation, one of the following actions will be taken:

a. Authorize a site visit after approval by CoA reviewers;

b. Defer authorization pending receipt of any missing self-study materials;

c. Refer to the CoA for full review. Following this review, the CoA may choose among the following decision options:

   1. Authorize a site visit (questions may be provided to the program and to the site visitors for consideration during the site visit);
   2. Defer authorization pending receipt of additional information and/or clarification of the self-study materials; or
   3. Deny a site visit (see Section 2.1 [f]).

The CoA is solely responsible for selecting among the above actions in response to the review of the application.

6.3 P Withdrawal of Application for Accreditation

A program may withdraw its application without prejudice at any time before the CoA makes an accreditation decision.

7.P POSTDOCTORAL RESIDENCY SITE VISIT

Site visits are conducted as part of the review for initial "accredited, on contingency" or initial "full accreditation" of a postdoctoral residency program and as part of the periodic review of an accredited program. For accredited postdoctoral residency programs, the CoA will request an invitation to schedule a site visit from the appropriate administrative officer of the agency in which the postdoctoral residency program is housed.

For accredited programs, the submission of the self-study serves as the formal invitation to site visit the program and conduct an accreditation review. For applicant programs, the accreditation application and the signed self-study serves as the formal invitation to site visit the program and conduct an accreditation review.

If a site visit is not arranged within the assigned review cycle and thus precludes the program from meeting its accreditation responsibilities, the program will be deemed to have withdrawn from accredited status at the end of the review cycle (in accordance with Section 1.3).

Within the year in which they are scheduled for a periodic review by the CoA, accredited postdoctoral residencies will be assigned randomly to one of two cycles for their site visits. The specific dates of the site visit within the cycle are chosen by the program. A change of cycle may be requested by the program in writing to the chair of the CoA for exceptional circumstances only.

Programs that have received authorization for an initial accreditation site visit will be assigned to the next available review cycle.

7.1 P Site Visit Team

The Office of Program Consultation and Accreditation will maintain a database of potential site visitors appointed by the CoA. The CoA will prepare lists of site visitors from this database. Training will be provided for site visitors, and their performance will be evaluated by the CoA regularly, based on information from programs and other relevant sources.

The CoA is responsible for assigning site visitors, but will give notice to the program and provide an opportunity for the program to communicate its views and any objections regarding site visitor selection.

7.1.1 P Special Site Visit

The Commission on Accreditation may vote to conduct a special site visit in lieu of or in addition to a regular site visit to the program in keeping with its mandate to protect the public and maintain program quality. The special site visit is viewed by the Commission as an opportunity to interact directly with the program. It affords the Commission the opportunity to collect information as to the program's operation and to address questions that are not fully answered by the record before the Commission. In that regard, special site visits are intended to be beneficial to both the Commission and the program. A special site visit team may include one or more members of the Commission, or other individuals selected by the Commission.

7.2 P Site Visit Report and Program Response

Within 30 days of the completion of the visit, the site visit team will deliver to the Office of Program Consultation and Accreditation a report in a format prescribed by the CoA. The report will address the program's consistency with the SoA and address any questions posed by the CoA prior to the visit. The site visit team may, at its discretion, provide the CoA with evaluative comments related to the program's strengths and weaknesses and overall consistency with the SoA but should not make a specific accreditation recommendation. It should be clear to the program, however, that evaluative comments represent the opinions of the site visitors and do not represent an accreditation decision.

After the site visit report is submitted, any communications between the site visit team and the program regarding the site visit must be conducted through the Office of Program Consultation and Accreditation rather than directly between the site visit team and the program.

A copy of the site visit report will be provided to the program. The program should confirm that it has received the report. The pro-

gram may also provide written comment or response to any aspect of the report. Such response must be delivered to the Office of Program Consultation and Accreditation within 30 days of receipt of the report by the program or its host institution. Upon written request by the program, the period for responding may be extended by the chair of the CoA for an additional period not to exceed 30 days. The CoA will proceed with the review of a program once it has received the program's response. In the absence of a response from the program within the allotted time, the CoA will proceed with the review of the program.

In its response to the site visit report, the program should correct any errors of fact and provide evidence to counter anything in the report with which the program does not concur. Any statements of fact in the report that are not challenged in the program's response may be considered by the CoA to be undisputed. The CoA will review the site visit report and all other relevant documents it has received, and after considering all elements of the program review, accept sole responsibility for the accreditation decision.

8.P PERIODIC REVIEW BY THE COA

A periodic review by the CoA is one in which a decision may be made about a program's accreditation status. The periodic review follows submission of (a) a self-study report by the program, (b) site visit report, and (c) the program's response to the site visit report. These requirements apply equally to programs making initial application for accreditation and those seeking continuation of accredited status.

8.1 P Guiding Principles of the Periodic Review

In all reviews, the CoA will be guided by the following general principles:

a. Should a member of the CoA be in actual or potential conflict of interest with respect to a program scheduled for review, that member will be recused during discussion and decision making on that program;

b. A high degree of professional judgment will be exercised by the CoA as to whether the program is fulfilling acceptable, publicly stated objectives, consistent with the SoA.

Before making an accreditation decision, the CoA will review the program's most recent self-study report, the most recent site visit report, the program's response to that report, and any other records of relevance that the program has submitted and any third-party comments and responses to those comments that have been received (consistent with Section 4 of these procedures).

In making a decision, the CoA will also consider the program's outcomes in light of the program's aims and as appropriate, the specialty area guidelines if the program is in a recognized specialty area. Further, the CoA will consider the importance of ensuring that residents are adequately prepared for advanced general or specialty area practice.

8.2 P Accreditation Statuses and Decision Options

The following decisions are available to the CoA with respect to the accredited status of a postdoctoral residency program:

a. Public notice of "intent to apply" is not an accredited status, but rather designates a postdoctoral program that has made known its intent to seek accreditation once it has residents in place; programs can be approved **once** for such listing for up to 2 years.

b. "Accredited, on contingency" is an accredited status and designates a postdoctoral residency program that, in the professional judgment of the CoA, is consistent, substantively and procedurally, with the SoA with the exception of the provision of adequate and appropriate proximal and distal outcome data. A program that is "accredited, on contingency" must provide outcome data for trainees in the program and program graduates by the time two cohorts have completed the program. At a maximum this will be 2 years for full-time 1-year postdoctoral residency programs and 4 years for full-time residency programs that are more than 1 year in duration. Failure to do so will lead to the program being deemed to have withdrawn from accreditation, following completion of the program by the interns currently on-site at the program. Programs that are "accredited, on contingency" may be eligible for a second term of "accredited, on contingency" only under extenuating circumstances.

c. "Fully accredited" designates a program which, in the professional judgment of the CoA, is consistent, substantively and procedurally, with the SoA. Accredited programs are scheduled for periodic review at intervals of up 10 to years. Programs that were previously "accredited on contingency" are eligible for 3 years of initial "full accreditation" following receipt of adequate and appropriate outcome data.

d. "Accredited, inactive" designates a one-year postdoctoral residency program that will not be accepting funded interns for a given training year. In the case of a postdoctoral residency program that takes 2 years to complete, the program may be designated as "accredited, inactive" if the program undergoes a period of 2 successive years with no funded interns/residents.

   Requests for inactive status are granted by the CoA for one year at a time. Request for renewal of inactive status must be done prior to the beginning of the academic/training year. Programs not granted renewal of inactive status are given notice that they are no longer compliant with the provisions of accreditation and then may be placed on probation.

e. "Accredited, on probation" serves as notice to the program, its residents, and the public that in the professional judgment of the CoA, the accredited program is not currently consistent with the SoA and may have its accreditation revoked. Prior to this decision, the program will be given an opportunity to *show cause* why it should not be placed on probation by providing a written response to the issues of concern. The program's show cause response will be reviewed two CoA meetings after the program was provided the show cause notice. Programs that are still not in compliance at the time of the CoA's review are then placed on "accredited, on probation" status.

   Following placement on "accredited, on probation" status, the program is given a time certain in which to come into compliance with the issues identified by the CoA in the probation decision. Postdoctoral residency programs must provide a response to

the issues within two CoA meetings after the probation decision was reached.

f. "Revocation of accreditation" is considered by the CoA to be an adverse action. It designates a program that has previously been placed on "accredited, on probation" status and for which the CoA has evidence that the program continues to be substantively inconsistent with the SoA at the time of its review of the program's response to the probation. A decision to revoke a program's accreditation reflects the CoA's determination that the program will not become consistent with the SoA within a reasonable time.

g. "Denial of accredited, on contingency" as well as "denial of accreditation" are considered by the CoA to be adverse actions. It designates an applicant program that, in the professional judgment of the CoA, is substantively inconsistent with the SoA. Prior to this decision, the program is given an opportunity to show cause why it should not be denied accreditation through a written response to the issues of concern.

h. "Denial of a site visit" is considered by the CoA to be an adverse action. It designates an applicant program that, in the professional judgment of the CoA, is not ready for a site visit. Prior to this decision, the program is given an opportunity to show cause why it should not be denied a site visit through a written response to the issues of concern.

8.3 P Decision Process

A quorum of the CoA, two-thirds of its members, must be present at a scheduled meeting to make an accreditation decision on a program. If a CoA member has recused him/herself from a portion of the meeting because of a conflict or perceived conflict of interest, that person will not be counted in determining a quorum. Accreditation decisions reflect the majority view of CoA members.

In the case of a program initially applying for accreditation, the CoA will determine whether to grant or deny the program accreditation. In the case of an accredited program, the CoA will determine whether to reaffirm the program's present status. When a program's current accredited status is not renewed, it will automatically become a program whose status is "accredited, on probation."

In the case of an accredited program that has been placed on probation, the CoA will determine whether to restore the program's status from "accredited, on probation" to "accredited" or revoke accreditation. A program returned to accredited status will have a self-study due one year after receipt of the decision for a full review and site visit. A program that does not have its status restored to "accredited" will have its accreditation revoked. In extraordinary circumstances, if the CoA determines that the program has made significant progress on most of the probation issues but needs additional time to implement changes, the CoA may vote to continue a program on probation for good cause. The length of the extension will be determined by the CoA depending on the program's circumstances for coming into full compliance, but may not exceed one year. A program may not be continued on probation more than once in a single review cycle.

Deferral for information: Whenever it deems appropriate, the CoA may defer making a decision about a program in order to obtain more information. Further, when in the CoA's judgment, significant disparity exists between the site visit report and information provided in the program's response to that report, the CoA will defer making a decision and seek additional information to resolve the difference. Further, the Commission may seek additional information through a request for an invitation to conduct a special site visit. When a decision is deferred for information, the CoA will notify the program in writing and specify what additional information is needed to determine the program's consistency with the SoA. The CoA may also write to the chair of the site visit team to identify issues in need of clarification, and a copy of this correspondence will be provided to the program. The program will be provided the opportunity to respond to any new information provided by the site visit team chair prior to final review of the program by the CoA.

Deferral for cause: When the CoA has concerns that may result in a decision to deny a site visit or deny accreditation to an applicant program or place an accredited program on probation, it will defer its final decision, give written notice to the program of its concerns, and thereby provide an opportunity to supplement the record before a decision is made. The CoA will assume that materials and information provided by the program before the final decision is made by the CoA represent the full and complete basis on which the program wishes its accreditation status to be determined.

8.4 P Site Visit Interval

At the time of making a decision for "full accreditation," the CoA will also decide the year in which to schedule the program's next periodic review. For all accredited programs, a period of up to 10 years between site visits will be designated depending upon the program's stage of development and the stability of program outcomes. Programs returned to accredited status from probationary status will be given one year from receipt of the decision in which to provide a new self-study in preparation for the next site visit and full review.

An accredited program may always request to submit a self-study and schedule a site visit earlier than scheduled. Such a request should be provided in writing to the CoA along with the rationale for requesting an earlier review. In addition, the CoA reserves the right to schedule an earlier visit for any accredited program if it has evidence to suggest concerns about the program's consistency with the SoA.

8.5 P Communication of Decision to Program

Within 30 days following any decision, the CoA will give written notice of the outcome of its review to the chief executive officer or the appropriate administrative officer of the institution housing the postdoctoral residency program. The decision will contain a statement of the bases for the decision. The CoA's decision also may alert the program to SoA-related areas of concern, requesting that the program address its attention to these in subsequent reports or in the next self-study.

8.6 P Effective Date of a Decision

Award of "accreditation" (either "contingent" or "full") and other non-appealable accreditation decisions are effective on the final day of the site visit preceding the CoA decision. Appealable decisions (as defined in Section 2.1) that are not appealed by the program are effective 30

days after receipt of the CoA's decision.

If a program elects to appeal a decision of "accredited, on probation," and the decision is upheld, the effective date of probation remains as 30 days after receipt of the CoA's decision, and the program must respond to the issues of probation in the same time frame as indicated in the CoA's decision.

If a program elects to appeal any decision other than probation, and the decision is upheld, the original CoA decision will take effect 30 days after the appeal panel hearing date.

For any appeal in which the decision is amended or reversed by the appeal panel, the new decision will be effective 30 days after the end of the appeal hearing.

8.7 P Failure to Meet Accreditation Responsibilities

Changes in a program's accreditation status by the CoA may result from a program's failure to meet the following responsibilities:

a. Abiding by the CoA's published policies and procedures; or

b. Informing the CoA in a timely manner of changes in its environment, plans, resources, or operations that could diminish the program's quality.

Before a change in accreditation status is made for any of these reasons, the program will be notified in writing by the CoA and given 30 days in which to respond. Based on the program's response, the CoA will determine appropriate action.

This section involves the substantive review of program materials and responses in determining whether the CoA should change a program's accredited status, unlike Section 1.3 wherein a program is deemed to have withdrawn by its failure to meet its procedural obligations as an accredited program.

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G. Technology readiness levels (TRL)

Where a topic description refers to a TRL, the following definitions apply, unless otherwise specified:

- TRL 1 – basic principles observed
- TRL 2 – technology concept formulated
- TRL 3 – experimental proof of concept
- TRL 4 – technology validated in lab
- TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 7 – system prototype demonstration in operational environment
- TRL 8 – system complete and qualified
- TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

A.List of countries, and applicable rules for funding

Legal entities established in the following countries and territories will be eligible to receive funding through Horizon 2020:

- The Member States of the European Union, including their overseas departments;
- The Overseas Countries and Territories (OCT) linked to the Member States[1]:
  - Anguilla, Aruba, Bermuda, Bonaire, British Virgin Islands, Cayman Islands, Curaçao, Falkland Islands, French Polynesia, Greenland, Montserrat, New Caledonia, Pitcairn Islands, Saba, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, Turks and Caicos Islands, Wallis and Futuna..
- The Countries Associated to Horizon 20202: the latest information on which countries are associated, or in the process of association to Horizon 2020 can be found in the online manual[3].
- The following countries, except where this is explicitly excluded in the call text

  Afghanistan, Albania, Algeria, American Samoa, Angola, Argentina, Armenia, Azerbaijan, Bangladesh, Belarus, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Chile, Colombia, Comoros, Congo (Democratic People's Republic), Congo (Republic), Costa Rica, Côte d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Eritrea, Ethiopia, Fiji, Gabon, Gambia, Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Buissau, Guyana, Haiti, Honduras, Indonesia, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Korea (Democratic Republic), Kosovo*, Kyrgyz Republic, Lao, Lebanon, Lesotho, Liberia, Libya, former Yugoslav Republic of Macedonia, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Micronesia, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Palau, Palestine, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Rwanda, Samoa, Sao Tome and Principe, Senegal, Serbia, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sudan, Suriname, Swaziland, Syrian Arab Republic, Tajikistan, Tanzania, Thailand, Timor-Leste, Togo, Tonga, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, Uzbekistan, Vanuatu, Uruguay, Venezuela, Vietnam, , Yemen, Zambia, Zimbabwe.

(* This designation is without prejudice to positions on status and is in line with UNSCR 1244/99 and the ICJ Opinion on the Kosovo declaration of independence).

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[1] Entities from Overseas Countries and Territories (OCT) are eligible for funding under the same conditions as entities from the Member States to which the OCT in question is linked

[2] Signed an agreement with the Union as identified in Article 7 of the Horizon 2020 Regulation.

[3] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/international-cooperation_en.htm

International European interest organisations[4] will also be eligible to receive funding from Horizon 2020.

Legal entities established in countries not listed above will be eligible for funding when such funding is explicitly foreseen in the relevant call text.

In addition, legal entities established in countries not listed above and international organisations will be eligible for funding:

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and an international organisation or a third country:
- When the Commission deems participation of the entity essential for carrying out the action funded through Horizon 2020.

[4] These are international organisations, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Horizon 2020 Programme

Guidance

How to complete your ethics self-assessment

Version 6.1
4 February 2019

IMPORTANT NOTICE

These guidelines are designed to help **applicants** in **getting your proposal 'ethics-ready' for Horizon 2020 funding** (i.e. to identify and deal correctly with any ethics issues that may arise from it). They provide help both with the ethics issues table in Part A and the ethics self-assessment in Part B of your proposal *(see the* proposal templates *on the Participant Portal).*

This document is however **no more than a 'how to' guide.** It covers most of the ethics issues arising in research projects and gives advice on dealing with classic cases. Cases that are not covered must therefore be dealt with outside this guide.

The **ethics self-assessment** will become part of your **grant agreement** (in Annex 1, as description of the action, ethics requirements, etc.) and may thus give rise to binding obligations that may later on be checked **through ethics checks, reviews** or **audits**.

This means the time you invest in this self-assessment is not wasted. It will actually improve your research results and:

your proposed research will be in line with applicable international, EU and national law

your proposal will be processed more easily during the Horizon 2020 proposal selection procedure

the results of your research can be published more easily in internationally refereed journals

you will contribute to the responsible conduct of research, thereby increasing its social acceptance.

Consider that ethics issues arise in many areas of research. Apart from the obvious example, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. may involve the voluntary participation of research subjects and the collection of data that might be considered as personal. You must protect your volunteers, yourself and your researcher colleagues.

Start thinking about ethics while designing your research protocols. Don't wait until the last minute to seek advice or check requirements under national and EU law. Use the ethics by design methodology *(see section 11)*.

Ethics also matter for scholarly publication. Major scientific journals in many areas will increasingly require ethics committee approval before publishing research articles. Thus, you should be prepared for ethics procedures even if your research is funded by sources other than Horizon 2020.

Your first source should always be at your institution. We would ask you to seek advice from colleagues with expertise in the ethics of research, such as:

specialised ethics departments

relevant managers in your university/research organisation

hospital research ethics committees

ethics advisers in your company

data protection officers.

They will be able to provide you with information appropriate to your specific needs and legal environment.

Consider involving/appointing an ethics adviser/advisory board. From the beginning of your project, an ethics adviser can help you deal with ethical issues and put in place the procedures to handle them appropriately. If your research includes several ethical concerns or involves several significant or complex ethical issues *(such as participation of children from developing countries, 'non-human primates (NHPs)', potential misuse or vulnerable populations)* we suggest you appoint an ethics adviser or an ethics advisory board comprising several experts from different backgrounds. The Commission/Agency may also make this an ethics requirement during the selection procedure.

Other information

For a broader overview of how Horizon 2020 grants work, see the Participant Portal Online Manual. For detailed information, see the Horizon 2020 AGA — Annotated Grant Agreement.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found on Participant Portal Reference Documents.

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
5.0	15.03.2016	▪ Document revised by DGT editors
5.1	01.06.2016	▪ Reparation of hyperlinks ▪ Reference to new Data Protection Regulation ▪ Adapt instructions on providing of documents to new MGA provisions.
5.2	12.07.2016	▪ Insert link to new guidance note on research on refugees, asylum seekers and migrants ▪ Correction in ethics issues table in section 7.2
5.3	21.02.2018	▪ H2020 is written as Horizon 2020 throughout the document.
6.0	23.07.2018	▪ A new reference document is added in section 6 on Non-EU countries. ▪ Adaptation of the section 4 on personal data further to the application of the new GDPR.
6.1	04.02.2019	▪ Modification of the Important Notice to refer to the ethics by design methodology ▪ Modification of the section 11 to cover ethics by design and add a reference on AI ▪ Replace the reference to the FP7 guidance note on social sciences by the new one (with the link to the document in the Portal)

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1. Human embryos & foetuses

This section covers research on human embryos and foetuses (mainly human embryonic stem cells (hESC)).

⚠ The following fields of research **are not eligible for funding** under Horizon 2020 and cannot therefore be included in proposals):

- research activities directed at human cloning for reproductive purposes
- research activity intended to modify the genetic make-up of human beings that could make such changes heritable (apart from research relating to cancer treatment of the gonads, which may be financed)
- research activities intended to create human embryos solely for the purposes of research or stem cell procurement, including the technique of somatic cell nuclear transfer[1]
- research that leads to the destruction of human embryos.

⚠ Research on human stem cells (both adult and embryonic) may be financed — depending on both the content of the scientific proposal and the laws of the Member States involved. No funding will be granted for research activities that are prohibited in all Member States. No activity will be funded in a Member State where such activity is forbidden.[2]

1.1 Ethics issues checklist

Section 1: HUMAN EMBRYOS/ FOETUSES		YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐			
If **YES:**	- Will they be directly derived from embryos within this project?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
	- Are they previously established cells lines?	☐	☐		1) Origin and line of cells. 2) Details of the licensing and control measures by the competent authorities of the Member States involved.	1) Copies of Ethics Approval. 2) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and

[1] *See Article 19(3) of the Horizon 2020 Framework Programme Regulation (EU) No 1291/2013.*

[2] *See also Article 19(4) of the Horizon 2020 Framework Programme Regulation (EU) No 1291/2013.*

						human-induced pluripotent stem cell (hiPSC) lines. 3) Declaration confirming that the 6 specific conditions *(see below)* for research activities involving human embryonic stem cells are met.
Does your research involve the use of human embryos?		☐	☐		1) Origin of embryos. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Confirm that informed consent has been obtained.	1) Copies of ethics approval. 2) Informed Consent Forms + Information Sheets.
If **YES:**	- Will the research lead to their destruction?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
Does your research involve the use of human foetal tissues / cells?		☐	☐		1) Origin of human foetal tissues/cells. 2) Details of the informed consent procedures. 3) Confirm that informed consent has been obtained.	1) Copies of ethics approval. 2) Informed Consent Forms + Information Sheets.

1.2 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the Statement of the Commission related to research activities involving human embryonic stem cells[3]).

For research activities involving **human embryonic stem cells (hESC)**, this means you must make sure that:

- cells were NOT derived from embryos specially created for research or by somatic cell nuclear transfer
- the project uses existing cultured cell lines only
- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation

[3] *See Article 19(1) of the Horizon 2020 Framework Programme Regulation (EU) No 1291/2013.*

- informed consent has been obtained for using donated embryos for the derivation of the cell lines
- personal data and privacy of donors of embryos for the derivation of the cells are protected
- NO financial inducements were provided for the donation of embryos used for derivation of the cell lines.

Moreover, under national law, research on human embryonic stem cells (hESC) is normally subject to strict licensing and control.[4]

⚠ You must provide the Commission/Agency with a declaration confirming compliance with these conditions (as part of your proposal).

For research on **human embryos (hE)**, you must obtain the donors' free and fully informed consent.

⚠ Your research may NOT:

- create human embryos solely for the purpose of research or for the purpose of stem cell procurement (including by means of somatic cell nuclear transfer)
- destroy human embryos *(e.g. to obtain stem cells)*.

1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your proposal must include the **information** referred to in the ethics issues checklist and any **documents** that are already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Statement of the Commission related to research activities involving human embryonic stem cells.

FP7: Recommendations on the ethical review of hESC FP7 research projects (Opinion 22), European Group on Ethics in Science and New Technologies.

FP7 guidance: Research on Human embryos/foetus.

[4] *See also Article 13(2) of the Rules for Participation Regulation (EU) No 1290/2013.*

2. Human beings

This section refers to any research involving work with humans beings ('research or study participants'), regardless of its nature or topic.

> ***Examples:*** *collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites, etc.*

2.1 Ethics issues checklist

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human participants?		☐	☐		1) Confirm that informed consent has been obtained.	1) Informed Consent Forms + Information Sheets.
If **YES:**	- Are they volunteers for social or human sciences research?	☐	☐		1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Copies of ethics approvals (if required).
	- Are they persons unable to give informed consent (including children/minors)?	☐	☐		1) Details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors. 2) What steps will you take to ensure that participants are not subjected to any form of coercion?	1) Copies of ethics approvals.
	- Are they vulnerable individuals or groups?	☐	☐		1) Details of the type of vulnerability. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.	1) Copies of ethics approvals.
	- Are they children/minors?	☐	☐		1) Details of the age range. 2) What are your assent	1) Copies of ethics approvals.

					procedures and parental consent for children and other minors? 3) What steps will you take to ensure the welfare of the child or other minor? 4) What justification is there for involving minors?	
	- Are they patients?	☐	☐		1) What disease/condition /disability do they have? 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) What is your policy on incidental findings?	1) Copies of ethics approvals.
	- Are they healthy volunteers for medical studies?	☐	☐			1) Copies of ethics approvals.
Does your research involve physical interventions on the study participants?		☐	☐			
If **YES:**	- Does it involve invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)*?	☐	☐		1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.
	- Does it involve collection of biological samples?	☐	☐		1) What type of samples will be collected? 2) What are your procedures for collecting biological samples?	1) Copies of ethics approvals.
For research involving processing of genetic information, see also section 4.						

2.3 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law.

This implies that you must ensure respect for people and for human **dignity** and fair distribution of the **benefits and burden of research,** and that you must protect the **values**, **rights** and **interests** of the research participants.

Moreover, you must obtain:

- the necessary ethics approvals (if required)
- free and fully **informed consent** of the research participants.

Informed consent

Participation must be entirely voluntary and you must obtain and clearly document participants' informed consent in advance.

⚠ No consent is required if national law provides for an exception (e.g. in the public interest).

Participants must be given an **informed consent form** and detailed **information sheets** that:

- are written in a language and in terms they can fully understand
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- state how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
- state what procedures will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).

You must ensure that potential participants have fully understood the information and do not feel pressured or coerced into giving consent.

Participants must normally give their consent in writing (e.g. by signing the **informed consent form** and **information sheets**).

If consent cannot be given in writing, for example because of illiteracy, non-written consent must be formally documented and independently witnessed.

Specific cases

Research involving children (or other persons unable to give consent, *e.g. certain elderly populations, persons judged as lacking mental capacity***)** — You must obtain informed consent from the legally authorised representative and ensure that they have sufficient information to enable them to provide this on behalf and in the best interests of the participants. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents or legal representatives. Participants must be asked for consent if they reach the age of majority in the course

You must also ensure that your research methodologies do not result in discriminatory practices or unfair treatment.

⚠ General principle — **maximise benefits** and **minimise risks/harm.**

In addition, when conducting surveys, interviews or focus groups where personal information is gathered and stored, you must also pay attention to:

- privacy

- data protection
- data management *(see also section 4)*
- the health and safety of participants *(see section 7.2)*.

Specific cases

Research involving children (or other persons unable to give consent) — should be carried out only if:

- studies with consenting adults would not be effective
- participants are subject to only a minimal risk and burden
- the results of the research will benefit the individual or group represented by the participant.

Social science and humanities research — often involves working with human participants and particular methodological tools *(e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and sometimes physical interventions)*.

You must therefore clarify the ethical implications of the chosen methodologies.

Example:

Describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable given the methodology, what action should be taken to mitigate them?

For your grant proposal, you should also provide an assessment of risks, stating explicitly what kinds of harm *(psychological, social, legal, economic, environmental, etc.)* might occur, the likelihood of subjects actually incurring such harm, and the steps that you will take to minimise them.

Research entailing more than minimal risk typically involves:

- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation
- deception
- risks to researcher safety or
- seeking respondents through the internet/social media *(e.g. using identifiable visual images or discussing sensitive issues)*.

Particular attention must be paid to vulnerable categories of individuals such as children, patients, people subject to discrimination, minorities, people unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc.

If your research involves children or other individuals unable to make decisions for themselves, you must maintain an active relationship with their legal guardians and/or carers; you must not only seek their consent, but also allow them to monitor the research.

⚠ Ensure that data are kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity.

In rare cases, there may be a need to override agreements on confidentiality and anonymity *(e.g. if maintaining confidentiality facilitates illegal behaviour such as drug dealing, child abuse, etc. that has come to light in the course of the research)*. In such circumstances, you must carefully consider disclosure to the appropriate authorities. You must inform the participants or their guardians of your intentions and the reasons for disclosure, unless this makes disclosure impracticable. You should also consider the technical aspects of collecting and storing your research data.

Data collection using electronic encoding tools (digital recorders or cameras) should be given special attention *(see also section 4)*. You should also discuss these issues with your organisation's data protection officer.

Medical research —is specifically addressed by the Declaration of Helsinki.

Your grant proposal must also comply with:

- the principles laid down in the Oviedo Bioethics Convention and
- EU Regulation No 536/2014 on clinical trials on medicinal products for human use.

2.4 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Informed consent

FP7 guidance: Informed consent

Medical research

WMA Declaration of Helsinki

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997) (Oviedo Bioethics Convention)

EU Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use as well as the requirements for authorization of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13)

EU Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC (OJ L 158, 27.5.2014)

Functional Magnetic Resonance Imaging

Social science research

Social sciences and humanities

Research Ethics in Ethnography/Anthropology

Guidance note — Research on refugees, asylum seekers & migrants

Ethics in Social Science and Humanities

Research on children

FP7 guidance: Ethics for Clinical Trials on Medicinal Products Conducted with Paediatric Population

3. Human cells or tissues

This section refers to research using, producing or collecting human cells or tissues.

You may obtain cells or tissues:

- from commercial sources
- as part of this research project
- from another research project, laboratory or institution
- from a biobank.

3.1 Ethics issues checklist

Section 3: HUMAN CELLS / TISSUES		YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, *see section 1*)**?**		☐	☐		1) Details of the cells or tissue types.	1) Copies of relevant ethics approvals. 2) Copies of accreditation /designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required)**.**
If **YES:**	- Are they available commercially?	☐	☐		1) Details of the provider (company or other).	1) Copies of import licences (if relevant).
	- Are they obtained within this project?	☐	☐		1) Details of the source of the material, the amount to be collected and the procedure for collection. 2) Details of the duration of storage and what you will do with the material at the end of the research. 3) Confirm that informed consent has been obtained.	1) Informed Consent Forms + Information Sheets.
	- Are they obtained from another project, laboratory or institution?	☐	☐		1) Country where the material is stored. 2) Details of the legislation under which material is stored. 3) How long will the material be stored and what will you do with it at the end of the research project?	1) Copies of import licences (if relevant). 2) Statement of laboratory/institution that informed consent has been obtained.

					4) Name of the laboratory/institution. 5) Country where the laboratory/institution is located. 6) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	
	- Are they obtained from a biobank?	☐	☐		1) Name of the biobank. 2) Country where the biobank is located. 3) Details of the legislation under which material is stored. 4) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

3.2 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2004/23/EC).

  Under this Directive, the handling of cells and tissues is subject to specific rules *(in particular, concerning donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries)*.

The main obligations are to:

- keep track of the **origin** of the cells and tissues you use, produce or collect

and to obtain:

- the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues
- free and fully informed consent of the donors.

Specific cases

Cells or tissues from clinical practice (secondary use) — For human cells or tissues which you or others have derived from clinical practice *(e.g. waste material from surgery or other operations*) provide evidence *(e.g. copies of examples of informed consent documentation)* that the donors have given informed consent for the use of their waste cells or tissues (either specifically for the research or generally, for any secondary use).

If, for the purposes of your research, you intend to collect more **additional material** than would normally be collected during the standard clinical procedure *(e.g. a larger than normal tissue sample or a sample that includes some additional adjacent material)*, you must ensure that informed consent has also been given for collecting additional material. You must also explain the need for such material in your grant proposal and show that you have obtained appropriate ethics approvals.

Secondary use for future research — If you intend to store the material for future use in other projects, you must:

- confirm that you have obtained the donor's consent for such secondary use
- state the legislation under which the material will be stored
- state how long it will be stored and what you will do with it at the end of the research.

Biobanking — Biobanks raise significant ethical issues concerning informed consent and data privacy.

'Biobanks' are repositories for the storage of biological samples (usually human) and play a significant role in biomedical research. These 'libraries' provide researchers with access to large numbers of tissue samples, genetic material and associated data.

If your project has the aim or effect of setting up a biobank, you must ensure that there is strict compliance with appropriate European and national ethical standards (in particular, regarding data privacy; *see section 4*).

You must confirm that informed consent has been obtained and show that you have obtained all necessary ethics approvals (or that you are exempted under national law).

⚠ No samples/data may be placed in the biobank before all appropriate consents and ethics approvals have been obtained

You will need to make a report on key aspects of the biobank's activities, including in particular:

- information on which donors will be excluded/included *(e.g. competent adults, children and minors, adults unable to provide informed consent, individuals in an emergency setting, etc.)*
- details of the material that will be 'banked', including:
  - personal (coded or fully identifiable) biosamples
  - personal information associated with a sample *(e.g. name/code, gender, age, etc.)*
  - personal data resulting from analysis of a sample *(e.g. analysis of genetic material or a genome)*
  - anonymised biosamples
  - anonymised data resulting from analysis of a sample (from which individuals could be identified) and
  - epidemiological (population level) data
- information on the standard procedures for:
  - accepting material into the biobank,
  - processes and standards for sample-quality assurance and ensuring accuracy of data and information
  - handling requests for release of samples/data from the biobank *(including fair and just financial arrangements and benefit-sharing for third countries)*.

Genetic testing — For using or storing human cells or tissues for genetic testing, you must obtain the donor's informed consent for the genetic testing, and show that you have obtained approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from non-EU countries — If your research project involves the transfer of cells and tissues from/to non-EU countries, you must comply with the specific provisions on import/export under Directive 2004/23/EC *(see also section 6)*.

Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to non-EU countries *(see section 4)*.

3.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** that are already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

EU Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p.48).

4. Personal data

This section concerns research which involves processing of personal data, regardless of the method used *(e.g. interviews, questionnaires, direct online retrieval etc.)*.

'Personal data' means information relating to an identified or identifiable natural person.

An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person *(art. 2(a) EU General Data Protection Regulation (GDPR)*.

Examples: *name, address, identification number, pseudonym, occupation, e-mail, CV, location data, Internet Protocol (IP) address, cookie ID, phone number, data provided by smart meters, data held by a hospital or doctor*.

⚠ Individuals are not considered 'identifiable' if identifying them requires excessive effort.

Completely anonymised data does not fall under the data privacy rules (as from the moment it has been completely anonymised).

'Processing of personal data' means any operation (or set of operations) performed on personal data, either manually or by automatic means. This includes:

- collection (digital audio recording, digital video caption, etc.)
- recording
- organisation, structuring & storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, appification, etc.)
- retrieval & consultation
- use
- disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)
- alignment or combination
- restriction, erasure or destruction.

Examples: *access to/consultation of a database containing personal data; managing of the database; posting/putting a photo of a person on a website; storing IP addresses or MAC addresses*; *video recording (CCTV); creating a mailing list or a list of participants.*

⚠ Processing normally covers **any** action that uses data for research purposes (even if interviewees, human volunteers, patients, etc. are *not* actively included in the research).

Personal data may come from any type of research activity *(ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.), lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking and domicile information, etc.)*.

4.1 Ethics issues checklist

Section 4: PROTECTION OF PERSONAL DATA		YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve processing of personal data?		☐	☐		1) Details of the technical and organisational measures to safeguard the rights of the research participants. For instance: For organisations that must appoint a DPO under the GDPR: Involvement of the data protection officer (DPO) and disclosure of the contact details to the research participants. For all other organisations: Details of the data protection policy for the project (i.e. project-specific, not general). 2) Details of the informed consent procedures. 3) Details of the security measures to prevent unauthorised access to personal data. 4) How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)? Explain. 5) Details of the anonymisation /pseudonymisation techniques. 6) Justification of why research data will not be anonymised/ pseudonymised (if relevant). 7) Details of the data transfers (type of data transferred and country to which it is transferred – for both EU and non-EU countries).	1) Informed Consent Forms + Information Sheets used (if relevant).
If **YES:**	- Does it involve the processing of special categories of personal data *(e.g. genetic, health, sexual lifestyle,*	☐	☐		1) Justification for the processing of special categories of personal data. 2) Why can the research objectives not be reached by processing anonymised/ pseudonymised data (if applicable)?	

	ethnicity, political opinion, religious or philosophical conviction.)?					
	- Does it involve processing of genetic, biometric or health data?	☐	☐			1) Declaration confirming compliance with the laws of the country where the data was collected.
	- Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing *(such as, tracking, surveillance, audio and video recording, geo-location tracking etc.)* or any other data processing operation that may result in high risk to the rights and freedoms of the research participants*?*	☐	☐		1) Details of the methods used for tracking, surveillance or observation of participants. 2) Details of the methods used for profiling. 3) Risk assessment for the data processing activities. 4) How will harm be prevented and the rights of the research participants safeguarded? Explain. 5) Details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.	1) Opinion of the data controller on the need for a data protection impact assessment (art.35 GDPR) (if relevant).
Does your research involve further processing of previously collected personal data *(including use of pre-existing data sets or sources, merging existing data sets)***?**		☐	☐		1) Details of the database used or of the source of the data. 2) Details of the data processing operations. 3) How will the rights of the research participants be safeguarded? Explain. 4) How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)? Explain. 5) Justification of why the research data will not be	1) Declaration confirming lawful basis for the data processing. 2) Permission by the owner/manager of the data sets *(e.g. social media databases)* (if applicable). 3) Informed Consent Forms + Information Sheets + other consent documents *(opt in processes, etc.)*. (if

				anonymised/ pseudonymised (if relevant).	applicable).
Does your research involve publicly available data?	☐	☐		1) Confirm that the data used in the project is publicly available and can be freely used for the project.	1) Permission by the owner/manager of the data sets *(e.g. social media databases)* (if applicable).
Is it planned to export personal data from the EU to non-EU countries? *Specify the type of personal data and countries involved*	☐	☐		Details of the types of personal data to be exported. How will the rights of the research participants be safeguarded? Explain.	1) Declaration of confirming compliance with Chapter V of the GDPR.
Is it planned to import personal data from non-EU countries into the EU? *Specify the type of personal data and countries involved*	☐	☐		1) Details of the types of personal data to be imported.	1) Declaration confirming compliance with the laws of the country in which the data was collected.

4.2 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the GDPR, national data protection laws and other relevant legislation, *such as on clinical trials*).

Under these rules, personal data must be processed in accordance with certain principles and conditions that aim to **limit** the negative **impact** on the persons concerned and ensure **fairness**, **transparency** and **accountability** of the data processing, **data quality** and **confidentiality**.

This implies the following main obligations:

- Data processing should be subject to appropriate safeguards (see table above).
- Data should wherever possible be processed in anonymised or pseudonymised form.

- Data processing is subject to free and fully informed consent of the persons concerned (unless already covered by another legal basis, *e.g. legitimate or public interest*).

- Data processing must NOT be performed in secret and research participants must be made aware that they take part in a research project and be informed of their rights and the potential risks that the data processing may bring.

- Data may be processed ONLY if it is really adequate, relevant and limited to what is necessary for your research ('data minimisation principle').

  ⚠ Collecting personal data *(e.g. on religion, sexual orientation, race, ethnicity, etc.)* that is not essential to your research may expose you to allegations of 'hidden objectives' or 'mission creep' (i.e. collecting information with permission for one purpose and using it/making it available — online or otherwise — for another reason, without additional permission).

- Data processing operations which are more intrusive and likely to raise higher ethics risks must be subject to higher safeguards.

- For complex, sensitive or large-scale data processing or data transfers outside of the EU, you should consult your data protection officer (DPO), if you have one, or a suitably qualified expert.

- The level of data security must be appropriate to the risks for the research participants occurring in case of unauthorized access or disclosure, accidental deletion or destruction of the data.

- You are responsible for any partners, contractors or service providers that process research data at your request or on your behalf.

Generally, one of the best ways how to avoid/limit data protection issues for your project is to use **anonymised** or **pseudonymised** data.

⚠ Pseudonymisation and anonymisation are not the same thing.

'Anonymised' means that the data has been rendered anonymous in such a way that the data subject can no longer be identified (and therefore is no longer personal data and thus outside the scope of data protection law).

'Pseudonymised' means to divide the data from its direct identifiers so that linkage to a person is only possible with additional information that is held separately. The additional information must be kept separately and securely from processed data to ensure non-attribution.

Moreover, if you have a **data protection officer** (DPO), it is generally recommended to involve them in all stages of your project, whenever it comes to data privacy issues, since this will help your proposal and grant agreement implementation (EU grants are subject to full compliance with data privacy rules).

⚠ Be aware that even if you solve all privacy-related issues, research data may still raise other ethics issues, such as the potential misuse of the research methodology/ findings or ethics harms to specific groups.

4.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

General

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1)

Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89)

Guidelines on Consent under Regulation 2016/679 (wp259rev.01), Article 29 Working Party

Guidelines on Transparency under Regulation 2016/679 (wp260rev.01), Article 29 Working Party

Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679(wp251rev.01), Article 29 Working Party

Council of Europe Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data, CM/Inf (2018)15-final

Handbook on European data protection law (2018 edition), European Union Agency for Fundamental Rights and Council of Europe, European Court of Human Rights, European Data Protection supervisor

Data transfers outside the EU - International data transfers using model contracts

Electronic communications

EU Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

EU Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks

5. Animals

This section refers to research involving animals.

5.1 Ethics issues checklist

Section 5: ANIMALS		YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve animals?		☐	☐		1) Details of the species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. 2) Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used.	
If **YES**:	- Are they vertebrates?	☐	☐			
	- Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	☐	☐		1) Why are NHPs the only research subjects suitable for achieving your scientific objectives? Explain. 2) What is the purpose of the animal testing? Give details. 3) Where do the animals come from? Give details.	1) Personal history file of NHP.
	- Are they genetically modified?	☐	☐		1) Details of the phenotype and any inherent suffering expected. 2) What scientific justification is there for producing such animals? Give details. 3) What measures will you take to minimise suffering in breeding, maintaining the colony and using the GM animals? Give details.	1) Copies of GMO authorisations.
	- Are they cloned farm animals?	☐	☐		1) Details of the phenotype and any inherent suffering expected. 2) What scientific justification is there for	1) Copies of authorisations for cloning (if required).

					producing such animals? Give details. 3) What measures will you take to minimise suffering in breeding, maintaining the colony and using of the GM animals? Give details.	
	- Are they an endangered species?	☐	☐		1) Why is there no alternative to using this species? Give details. 2) What is the purpose of the research? Give details.	1) Copies of authorisations for supply of endangered animal species (including CITES).

5.2 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2010/63/EU).

  This Directive is designed to limiting the use of animal testing for scientific purposes. It sets out EU-wide animal welfare standards (including authorisations, restrictions on the use of certain kinds of animals, standards for procedures, minimum requirements for personnel, recording and traceability, care and accommodation).

  ⚠ Some EU Member States have stricter rules.

This means that you must choose alternatives to animal use where possible and implement the principles of **replacement**, **reduction** and **refinement** ('**three Rs**').

Replacement — replacing animal use by an alternative method or testing strategy (without use of live animals).

Examples

'Higher' animals can be replaced by 'lower' animals: microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals.

Live animals may be replaced by non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audio-visual aids, or in vitro modelling.

Reduction — reducing the number of animals used.

Refinement — improving the breeding, accommodation and care of animals and the methods used to minimise pain, suffering, distress or lasting harm to animals.

Moreover, you must obtain:

- the necessary authorisations for the supply of animals and the animal experiments (and other specific authorisations, if applicable).

⚠ You must obtain all relevant national authorisations before you can start to use animals.

Specific cases

Non-human primates (NHPs) — Since non-human primates are so close to human beings, their use in experiments raises particular ethics concerns. Directive 2010/63/EU sets strict limits to their use: They may be used only for specific research purposes (of primary importance) and only if there is no alternative *(art. 8)*. Moreover, only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used *(art. 10)*.

⚠ The use of great apes requires very exceptional justification and must be specifically authorised by the Commission/Agency.

Endangered species — Endangered species cannot be used, except for very important research purposes and where there is no alternative non-endangered species that will meet the scientific objective *(art. 7 Directive 2010/63/EU)*.

In this case, you should follow agreed international practices (CITES).

5.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

General

EU Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

The ARRIVE Guidelines — Animal Research: Reporting In Vivo Experiments. Festing MFW, Overend P, Gaines Das R, Cortina Borja M, Berdoy M (2002), *The design of animal experiments: reducing the number of animals in research through better experimental design*, Laboratory Animal Handbooks Series, 14. London: Royal Society of Medicine Press.

Hooijmans C. *et al*. (2010), *A gold standard publication checklist to improve the quality of animal studies, to fully integrate the Three Rs, and to make a systematic review more feasible*, ATLA 38: 167-182.

For alternatives to animal testing, refer to the following website: http://ecvam.jrc.it/

Research on animals

Research on animals

Endangered species

CITES

6. Non-EU countries

This section concerns research involving non-EU countries.

This is the case where:

- research activities are conducted, partially or wholly, in a non-EU country
- participants or resources come from a non-EU country
- material is imported from or exported to a non-EU country.

Being outside the reach of European laws and standards, such research can raise specific ethical issues (particularly in developing countries), such as:

- exploitation of research participants
- exploitation of local resources
- risks to researchers & staff
- research that is prohibited in the EU.

⚠ Horizon 2020 funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States.[5]

6.1 Ethics issues checklist

Section 6: THIRD COUNTRIES	YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? *Specify the countries involved:*	☐	☐		1) Risk-benefit analysis. 2) What activities are carried out in non-EU countries? Give details.	1) Copies of ethics approvals and other authorisations or notifications (if required). 2) Confirmation that the activity could have been legally carried out in an EU country (for instance, an opinion from an appropriate ethics structure in an EU country).
Is it planned to use local resources *(e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)***?**	☐	☐		1) What type of local resources will be used and how exactly? Give details.	1) For human resources: copies of ethics approvals. For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the *UN*

[5] *See Article 19(4) of the Horizon 2020 Framework Programme Regulation (EU) No 1291/2013.*

					Convention on Biological Diversity (e.g. access permit and benefit sharing agreement).
Is it planned to import any material from non-EU countries into the EU? *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.*	☐	☐		1) What type of materials will you import? Give details.	1) Copies of import licences.
If **YES:** *Specify the materials and countries involved:*					
Is it planned to export any material from the EU to non-EU countries? *For data exports, see section 4.*	☐	☐		1) Details of the type of materials to be exported.	1) Copies of export licences.
If **YES:** *Specify material and countries involved:*					
In case research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?	☐	☐		1) Details of the benefit sharing measures. 2) Details of the responsiveness to local research needs. 3) Details of the procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the research at risk?	☐	☐		1) Details of the safety measures you intend to take, including training for staff and insurance cover.	

6.2 How do I deal with the issues?

Specific cases

Research carried out in a non-EU country — For activities carried out outside the EU, it is not enough for that the activity to be accepted and comply with the legal obligations of a non-EU country; the activities must ALSO be allowed in at least one Member State (*see art. 19 H2020 Programme Regulation No 1291/2013).*

⚠ Beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

Resources from a non-EU country — Any use of local resources (especially animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, fossils) must show respect for cultural traditions and share benefits (i.e. also benefit local participants and their communities, involve local researchers – as equal partners – and respond to local research needs).

This is particularly important for **low income and lower-middle income countries** *(see Convention on Biological Diversity and Declaration of Helsinki and follow the Global code of conduct for research in resource-poor settings)*.

For access to **genetic resources**, you must also comply with the Nagoya Protocol on Access and Benefit Sharing and EU Regulation (EU) No 511/2014 which implements this Protocol.

Import/export of material — If genetic resources are transferred across borders, it may be mandatory under the law of the provider country to obtain an authorisation for the transfer. In addition, you must use an agreement which describes the conditions for the export and the terms of utilisation and, if applicable, relevant benefit-sharing measures.

ℹ For transfers of human cells or tissues, *see section 3.*

ℹ For data transfers, *see section 4.*

Sending researchers to a non-EU country — Non-EU countries are not necessarily less safe than EU countries. Nevertheless, a risk assessment must be undertaken when sending researchers abroad and appropriate safety measures must be taken. These may include insurance cover or health and safety measures, *such as no lone working, contact points via phone, counselling support, etc. (see also section 7.2)*.

6.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Human resources

Declaration of Helsinki

Flora & fauna

Convention on Biological Diversity

Genetic resources

Nagoya Protocol on Access and Benefit Sharing

EU Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing of benefits arising from their utilization in the Union (ABS Regulation) (OJ L 150, 20.5.2014, p. 59)

Commission Implementing Regulation (EU) No 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices (OJ L 275, 20.10.2015, p. 4)

Developing countries and lower income settings

FP 7 guidance: Developing countries

Global code of conduct for research in resource-poor settings

7. Environment, health & safety

This section concerns research that may adversely affect:

- the environment or
- the health & safety of the researchers involved.

This may be due to any of the following:

- the experimental design of the research itself
- undesirable side-effects of the technologies used.

7.1 Environment

7.1.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH AND SAFETY	YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? *For research involving animal experiments, see section 5.*	☐	☐		1) Risk-benefit analysis. 2) Show how you apply the precautionary principle (if relevant). 3) What safety measures will you take? Give details.	1) Safety classification of laboratory. 2) Copy of GMO and other authorisations (if required).
Does your research deal with endangered fauna and/or flora /protected areas?	☐	☐			1) Specific authorisations (if required).

7.1.2 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the precautionary principle and legislation on nature conservation and pollution control).

The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must prove that a new technology will not harm the environment.

The legislation on nature conservation and pollution control includes the EU Habitats Directive 92/43/EEC, the EU Wild Birds Directive 79/409/EEC, EU Regulation (EC) No 338/97 on protection of wild fauna, the EU GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety.

This means you must assess potential risks to the environment and avoid or minimise such risks.

Moreover, you must obtain:

- the necessary environmental authorisations (if applicable).

⚠ You must obtain all relevant national authorisations before you can start your research.

7.1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

7.2 Health & safety

The health and safety of all human participants in research - as subjects, investigators or uninvolved third parties, must be a priority in all research studies.

The kinds of risk to researcher safety vary according to the nature of the discipline, the topic and the research site. Only the 'researcher in the field' can fully assess safety concerns and/or their willingness to tolerate risks.

However, research in both familiar and unfamiliar settings can involve added safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks.

Moreover, in certain types of research, the risk of harm to the researcher is caused by the topic of study or by the actions of the researchers themselves. Lack of caution or failure to obey standard procedures may lead to physical or psychological harm.

⚠ Improved safety practices may impose additional cost burdens, which can be included in your estimated budget.

7.2.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve the use of elements that may cause harm to humans, including research staff? *For research involving human participants, see section 2.*	☐	☐	1) Details of the health and safety procedures.	1) Safety classification of laboratory.

7.2.2 How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the legislation on public-health control *(e.g. regulating conduct in animal epidemics, food imports, consumer protection, etc.)* and safety at work *(e.g. Directive 2006/25/EC)*).

This means you must warn and advise researchers. In some cases you must even remove them from dangerous situations.

Moreover, you should establish and follow a set of safety checks and procedures (or a more in-depth risk assessment) for each project they conduct.

You must also obtain:

- the necessary health and safety authorisations (if applicable).

Specific cases

Toxic chemicals and/or **explosives** — Staff should have adequate training in storing, handling and disposing of such substances. If new substances and/or formulations *(e.g. nanomaterials)* are developed, you must provide adequate risk assessments.

Radioactive material — Clear legislation exists in all EU countries on the storage, handling and disposal of radioactive materials.

The release of radioactive material into the environment is allowed only if you can show that use of alternatives (e.g. non-radioactive stable isotopes, simulants etc.) is not possible.

Research 'in the field' — Establish and abide by recognised procedures to help keep researchers and subjects safe. These should include:

- keeping careful notes of all research engagements
- ensuring projects are adequately staffed
- using mobile phones to keep in touch with the research base
- conducting full risk assessments of fieldwork sites

- formally notifying authorities of research being conducted in an area
- carrying authorised identification
- researcher preparation & training covering techniques for handling conflict, threats, abuse or compromising situations
- debriefing after field research with an assessment of fieldwork safety and
- reporting any health & safety incidents.

7.2.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the Technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

General environment

EU Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7)

EU Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (OJ L 103, 25.4.1979, p.1)

EU Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 103, 25.4.1979, p.1)

Cartagena Protocol on Biosafety

EU Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)

EU Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)

GMOs

EU Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1)

EU Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75)

Public health & consumer protection

Consumer safety

Health & safety at work

EU Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of the workers to risks arising from physical agents (OJ L 114, 27.4.2006, p.38)

A Code of Practice for the Safety of Social Researchers

8. Dual use

This section concerns research involving goods, software and technologies covered by the EU Export Control Regulation No 482/2009. These **dual-use items** are normally used for civilian purposes but may have military applications, or may contribute to the proliferation of weapons of mass destruction.

8.1 Ethics issues checklist

Section 8: DUAL USE	YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	☐	☐		1) What goods and information used and produced in your research will need export licences? 2) How exactly will you ensure compliance? 3) How exactly will you avoid negative implications?	1) Copies of export licences.

8.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the EU Export Control Regulation No 428/2009).

⚠ In certain exceptional cases, publication of research findings (*e.g. a scientific article in a journal published both outside or inside the EU*) may be classed as an intangible technology transfer (ITT) and may require an authorisation (which is not always granted).

Specific cases

Cross-border transfers — For cross-border transfers of dual-use materials, technologies and information, you must observe the EU Export Control Regulation No 428/2009. If you have any doubts, you should consult the relevant national export control authority to clarify whether transfer licences are needed.

Research that may affect ethics standards — If international non-proliferation laws or international humanitarian laws *may have a bearing on your research (e.g. in the case of pathogen-related research, development of autonomous robotics, drones and certain laser technologies),* you must comply with the relevant international law (in particular, the Biological and Toxin Weapons Convention).

⚠ You may also want to appoint an independent ethics adviser/ethics board, with relevant ethics and security expertise, to carry out a risk-benefit analysis of the intended research and to suggest appropriate safeguards to cover security risks (during and beyond the lifetime of the project) and training for researchers.

8.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the technical Annex) and fill in the **critical risk table** Part B in section 3, in which you describe what action you would take if the national authorities do not grant the required authorisation(s)/license(s).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Guidance note — Research involving dual use items

EU Regulation No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items

EU Charter of Fundamental Rights

Biological and Toxin Weapons Convention

UN Security Council Resolution 1540

9. Exclusive focus on civil applications

This section explains the exact meaning of the 'exclusive focus on civil applications'.

⚠ Only research that has an exclusive focus on civil applications is eligible for funding.[6]

However, this does not rule out the participation of military partners or the development of generic technologies, products or knowledge that may meet the needs of both civil and military end-users (known as 'dual-use' goods or technologies), provided that the research itself has a clear focus on civil applications.

9.1 Ethics issues checklist

Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Could your research raise concerns regarding the exclusive focus on civil applications?	☐	☐		1) Explain the exclusive civilian focus of your research. 2) Justify inclusion of military partners or military technologies (i.e. explain how they relate to civilian applications, e.*g. in the context of law enforcement activities*).	

9.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular Horizon 2020 Regulation No 1291/2013) which limits funding of research to activities having an exclusive focus on civil applications).

⚠ Research activities aimed at the development or improvement of dual-use technologies or goods can be financed through Horizon 2020, provided that the research is fully motivated by, and limited to civil applications.

9.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the technical Annex).

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[6] *See Article 19(2) of the Horizon 2020 Framework Programme Regulation (EU) No 1291/2013.*

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Guidance note — Research focusing exclusively on civil applications

10. Potential misuse of research results

This section concerns research involving or generating materials, methods, technologies or knowledge that could be misused for unethical purposes. Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals or the environment.

10.1 Ethics issues checklist

Section 10: MISUSE	YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research have a potential for misuse of research results?	☐	☐		1) Risk-assessment. 2) Details of the applicable legal requirements. 3) Details of the measures to prevent misuse.	1) Copies of authorisations (if required). 2) Copies of security clearances (if applicable). 3) Copies of ethics approvals (if applicable).

10.2 How do I deal with the issues?

Some questions that could be used to identify potential misuse are:

- Could the materials/methods/technologies and knowledge involved or generated harm humans, animals or the environment if they were modified or enhanced?
- What would happen if the materials/methods/technologies and knowledge involved or generated ended up in the wrong hands?
- Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical?

You must conduct a risk-assessment and take appropriate steps to avoid misuse.

You must also comply with the numerous international, EU and national laws that address concerns relating to potential misuse of materials, technologies and information *(see list below)*.

Specific cases

Biological, chemical, radiological and nuclear security-sensitive materials and explosives (CBRNE) — To avoid misuse, take appropriate measures to provide adequate security for the facility used, personnel, transfer and information. Further possible safeguards are:

- including security expertise in your research *(e.g. by appointing an independent adviser)*

- limiting the dissemination of research results
- training all staff appropriately.

In many cases, overlaps between safety and security measures will exist, but gaps need to be identified and addressed. The most frequent issue relates to research involving pathogens and the need to implement adequate biosecurity measures.

Research with a potential impact on human rights — Concerns in this field relate primarily to research on surveillance technologies, new data-gathering and data-merging technologies *(e.g. in the context of big data)*. However, social or genetic research that could lead to discrimination or stigmatisation is also affected.

Risk mitigation measures may include:

- a human rights impact assessment
- involving human rights experts in your research
- training personnel and/or technological safeguards
- caution when publishing or otherwise disseminating results *(e.g. through privacy by design)*
- adapting the research design *(e.g. using dummy data)*.

Research that has other potential misuses — Although anything could ultimately be used for malevolent purposes, research in this category is that which provides terrorists or criminals with information or technologies that would have *substantial direct impacts* on the security of individuals, groups or states.

Examples: *infrastructural vulnerability studies, cyber-security-related research*

In many cases, researchers outside the security domain are not familiar with security safeguards. In such situations, researchers should consult experts familiar with security ethics and/or human rights. If security or human rights abuse concerns exist, you should arrange for:

- training on this issue
- the appointment of an ethics adviser/ethics advisory board.

10.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the technical Annex).

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Guidance note — Potential misuse of research results

FP7 guidance: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU-funded research

Council Common Position 2003/805/CFSP on the universalisation and reinforcement of multilateral agreements in the field of non-proliferation of weapons of mass destruction and means of delivery

EU Regulation No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items

EU Regulation No 2913/92 establishing the Community Customs Code

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

UN Security Council Resolution 1540

Treaty on the Non-Proliferation of Nuclear Weapons (NPT)

Chemical Weapons Convention

Responsible life sciences research for global health security: A guidance document

Biorisk management: Laboratory biosecurity guidance

11. Other ethics issues

Ethics issues checklist

Section 10: OTHER ETHICS ISSUES	YES/	NO	Page	Information to be provided	Documents to be provided/kept on file
Are there any other ethics issues that should be taken into consideration? *Please specify:*	☐	☐		1) Any relevant information.	1) Any relevant document.

Other ethics issues?

Since Horizon 2020 intends to support ground-breaking and innovative research, it may be that your research raises **new ethical issues and concerns** that are currently not (fully) covered by the Ethics Issue Table *(e.g. new developments in the fields of neurobiology, man-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, etc.)*.

If you **know** of any such other ethically relevant issues that apply to your project, describe them in this section and explain how you intend to address them. This allows you to alert the Commission/Agency in time and get appropriate assistance for addressing them. It also avoids the problems you would have if such issues were found out only later (in the context of an audit or investigation).

For highly innovative research, use the ethics by design methodology (in particular in the area of artificial intelligence; *see guidance in the background documents section below*).

If, ethical issues arise **unexpectedly during your research**, contact us immediately via your Participant Portal account and provide detailed information on the issue and how you intend to handle it. We will ensure that you receive appropriate help and guidance.

Ethics advisers/advisory boards

A suitably experienced *ethics adviser* can help you to deal with ethical issues and putting into place the procedures to handle these appropriately if your research includes several ethical concerns.

If your research involves several significant or complex ethical issues, you should appoint an *ethics advisory board* with several experts with varied expertise.

If you appoint an ethics adviser/advisory board, it is important that they are:

- external to the project and to the host institution
- totally independent and
- free from any conflict of interest.

Your university or institution (or members of your consortium) may have experience with an ethics adviser or members of an ethics advisory board and may be in a position to suggest potential candidates.

The ethics adviser or ethics advisory board should maintain an overview of the work throughout the whole course of your project and help you to think ahead about possible problems that might arise and how they can be addressed. Their experience will help you check for compliance with ethical standards within the relevant research fields. They will also be responsible for reporting to you and to the Commission/Agency, on a regular basis, on ethics concerns as they arise and the continuing probity of your studies.

If you appoint an ethics adviser or set up an ethics advisory board, you should work with them on a regular basis throughout your project. Their oversight role should be fully integrated into your research activities and they should work closely with you and your colleagues so they are fully aware of all the developments as your research progresses. Your ethics advisers/ethics advisory board should be an essential element in your project management structure.

What do you need to provide?

You must provide:

- the name and contact information for persons suggested
- the terms of reference for their involvement and the deliverables expected
- their declarations of no conflict of interest.

Background documents & further reading

General information on ethics

Ethics for Researchers

European Textbook on Ethics in Research (2010)

Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

Food-related research

FP7 guidance: Guidance Note — Ethics and Food-Related Research

Research related to artificial intelligence (AI)

High-Level Expert Group on Artificial Intelligence: Draft Ethics guidelines for trustworthy AI

RESEARCH ON HUMAN EMBRYOS/FOETUS

When involving the use of hESC in their research project, researchers should take into account and specify:

- → That the proposal does not include research activities which destroys embryos including for the procurement of stem cells;
- → Whether the consortium has taken into account the legislation, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place, including the procedures for obtaining informed consent
- → The source of the hESC;
- → The measures taken to protect personal data, including genetic data, and privacy;
- → The nature of financial inducements, if any

A positive opinion from a Regulatory Committee constituted by Member States' representatives is required.

Participants in research projects must seek the approval of the relevant national or local ethics committees prior to the start of the research activities.

In conclusion, each research proposal involving the use of hESC, which is supported within FP7, is assessed by at least **two independent ethical reviews**: one **in the country itself where** the research will be carried out, and one **at the EU level**.* **No System in the world offers a higher guarantee regarding the respect of fundamental ethical principles.**

* If the research raising ethical issues is performed in more than one country (i.e. n countries), **it implies that more than two ethical reviews will be performed (i.e. in fact n+1 ethical reviews)**

GUIDANCE FOR APPLICANTS

INFORMED CONSENT

For the purposes of the Ethics Review process, the definition of Informed Consent given in the *Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use* is adopted. The principle of "informed and free decision" remains valid for any other kind of research.

"Informed Consent is the decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation."

The Informed consent form must contain adequate information to meet the necessary requirements. In most cases, an information sheet should be attached. It is recommended that drafts of the consent form and the information sheet are submitted to the Commission with the application. In almost all cases the above drafts have to be available when applying for local ethics committee opinion and approval from national competent authorities, prior to the start of the proposed research.

In which cases do researchers need to make use and provide an informed consent form?

An informed consent form is required in the following cases:

When the research involves:
Patients
Children
Incompetent/Incapacitated persons
Healthy volunteers
Immigrants
Others (i.e.prisoners)
When the research uses/collects:
Human Genetic Material
Biological samples
Personal data

What type of information should be provided to the research subject:

General information:

A statement that the study involves research subjects and an **explanation of the purposes** of the research.
The **expected duration** of the subject's participation.
A **description of the procedures** to be followed/ of the **medicine** that is going to be tested, and an identification of any procedures which are experimental.
A statement that participation is **voluntary**.
Information about who is organising and funding the research.
A description of any reasonably **foreseeable risk, discomfort or disadvantages**.
A description of any **benefits to the subject or to others** which may reasonably be expected from the research avoiding inappropriate expectations.
A disclosure of appropriate **alternative procedures for treatment/diagnosis** if any, that might be advantageous to the subject.

A statement describing the procedures adopted for ensuring **data protection/confidentiality/privacy** including duration of storage of personal data.
A description of how **incidental findings are handled**.
A description of any planned **genetic tests**.
For research involving more than minimal risk, an explanation as to whether there are any **treatments or compensation if injury occurs** and, if so, what they consist of, or where further information may be obtained. Insurance coverage should be mentioned.
A reference to **whom to contact for answers** to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
A statement offering the subject the **opportunity to ask questions and to withdraw at any time** from the research without consequences.
An explanation of what will happen with the **data or samples at the end of the research** period and if the data/ samples are retained or sent/sold to a third party for further research.
Information about what will happen to the **results** of the research.

SPECIFIC INFORMATION:

1. Projects involving children:

Informed consent of parents/legal representative* must be obtained, but also, when the child is able to give assent, the investigator must also obtain that assent.
*The definition of legal representative should be in accordance with the legislation of the host country.

In long-term studies, where the child reaches the age of majority, the research team should obtain his/her consent to continue the study and/or for the use of samples already obtained.

A child's refusal to participate or continue participating in the research should always be respected.

Researchers should avoid exerting any pressure against the child/his-her parents that will lead to the participation of the child to the research.

Informed Consent and Information sheets are comprehensive and **separate for parents/legal representative and for children.**	
Information sheets must be in accordance to **the age of children**:	
• Information for children five years and under should be predominantly pictorial.	
• For pre-adolescent (aged up to 16) information sheets should explain briefly and in simple terms the background and aim of the study, so the child can consider assent. It also should contain an explanation that their parents will be asked for consent.	
• If an adolescent aged 16 to 18 is no longer a minor as defined in national law, or is an "emancipated minor", then written informed consent is required from these individuals.	
Assent of the child who is able to give must be required.	
Information sheets should **indicate how the study will affect the child** at home, school or other activities.	

2. Projects involving imaging procedures:

The level of invasiveness of the different diagnosis/treatment imaging procedures depends on the type of equipment, intensity of dose, repetition of exposures, subject conditions, etc. Informed consent should thus contain also information about:

Type of exposure (intensity, duration, eventual repetition) and on the eventual long-term effects.	
Use of **contrast fluid** and the eventual toxicity.	
The information sheet must include questions about patient/volunteer's **medical information**: previous treatments, presence of implants, asthma, allergy, renal failure, hypertension, claustrophobia.	

3. Projects involving incapacitated adults not able to give informed consent:

In principle, only persons able to freely understand and question, should consent. Vulnerable persons like mentally-deficient persons, severely-injured patients, etc should be excluded. However, in order to safeguard the participation of these specific groups, a special legal framework has been established. The Principle **"the interests of the patient always prevail over those of science and society,"** must be followed at all times.

In the case of clinical trials, conditions listed in the Article 5 of the *Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of*

clinical trials on medicinal products for human use, and the principles of the *Oviedo Convention* must be followed.

The informed consent must be obtained from the legal representative* if:

Consent represents the **subject's presumed will**.	
The person not able to give informed legal consent has received **information according to his/her capacit**y of understanding.	
The research is **essential** to validate data obtained in clinical trials on persons able to give informed consent or by other research methods.	
The research **relates directly to a life-threatening or debilitating clinical condition** from which the incapacitated adult concerned suffers.	
There are grounds for expecting that administering the medicinal product to be tested will produce **a benefit to the patient** outweighing the risks or produce no risk at all.	

*The definition of legal representative should be in accordance with the legislation of the host country.

In addition, all relevant requirements listed for persons capable of giving such consent shall apply.

4. Projects involving illiterate populations

When clinical trials are conducted in developing countries or communities with poor resources in developed countries, additional measures may often be needed to ensure that the objectives of informed consent are met. These measures are related to the researcher's knowledge of the local ethos. For example, in certain cases it may be appropriate to seek the agreement of a person(s) invested with a certain authority within the community.

However, **free and informed consent always has to be given by each individual involved in a trial/research**.

Where formal written informed consent from the participant is not possible, the following strategies should be used:

- Presence of a community representative trained by the scientific team.
- Witnessing the oral approval by a trained and independent community representative. He/She will verify that the purpose of the research has been explained to the participant and he/she has understood what is proposed.

WHO SHOULD GIVE THE INFORMATION? / HOW TO INFORM?

The information must be given by a physician or by other individuals with appropriate scientific training and qualifications. This point is also remarked in the Declaration of Helsinki (paragraph 14): *"After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent."*

Information must be given in lay terms and under no circumstances pressure of any kind should be exercised on the individual participant nor her/his family/legal custodian. The communication/information dissemination means used should be adjusted to the particularities of situation/research subject at hand.

Consent should be a **continuing process**, especially in long-term trials or projects, researchers should foster a continuous dialogue with participants and inform them of anything new related to the trial.

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Functional Magnetic Resonance Imaging

2013

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Directorate General for Research and Innovation
Ethics Sector

Functional Magnetic Resonance Imaging

Understanding the technique and addressing its ethical concerns with a future perspective

European Commission
2013

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“With the fMRI results in the very early nineties, MRI itself took on an entirely new direction. Rather than MRI providing only anatomic and some basic physiologic information, it now could produce dynamic brain activation maps quickly, non-invasively, and with relatively high resolution. Many MRI technicians, industry engineers, marketing people, radiologists, scientists and others of the MRI establishment were nonplussed as researchers started having healthy volunteers, in the name of brain activation, doing all kinds of odd things in the magnet other than simply lying perfectly still with eyes closed — then producing highly processed and wildly colored maps rather than the standard gray scale. A revolution had begun. We could now look into the human brain as never before — and we were leveraging mostly established technology to do it.”

Peter A. Bandettini, fMRI pioneer, 2012

Foreword

Functional magnetic resonance imaging (fMRI) has revolutionized the study of the human brain functions *in vivo*. Due to the rapid implementation, particularly in neuroscience research, and complexity of this imaging method, its development and use has not been always adequately supported by ethics. It was the aim of this document to provide a reflective assessment of the ethical issues that are raised by fMRI and propose solutions, not separating this assessment from a sound background on the history, functioning, limits, safety, applications and future of the technology.

Daniela Seixas
Chair of the Working Party

Objectives

To explain the functioning, risks and limits of the technique of functional magnetic resonance imaging (fMRI), in the context of its history and future perspectives.

To identify and consider the ethical issues that arise from the use of fMRI to study the human brain in clinical practice and in research, and in non-medical and non-research settings.

To produce recommendations on ethics useful for research, policy, governance and public engagement.

Abbreviation List

ACR – American College of Radiology

AD – Alzheimer's disease

ADNI – Alzheimer's Disease Neuroimaging Initiative

BOLD – blood oxygenation level dependent contrast

CPT – current procedural terminology

DBS – deep brain stimulation

DMN – default mode network

EEG – electroencephalography

FDA – U.S. Food and Drug Administration

fMRI – functional magnetic resonance imaging

FMRIB – Oxford Centre for Functional Magnetic Resonance Imaging of the Brain

IF – incidental findings

MEG – magnetoencephalography

MRI – magnetic resonance imaging

NMR – nuclear magnetic resonance

PET – positron emission tomography

phMRI – pharmacologic MRI

RF – radiofrequency

SAR – specific absorption rate

SMF – static magnetic field

SPECT – single-photon emission computed tomography

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Part One

Introduction

Introduction

The brain is the most complex organ in humans and is responsible for controlling the body. Since time immemorial, it has been an object of fascination. Although the brain is related to the mind, still today the mechanisms by which it gives rise to thought and consciousness are not completely understood.
Magnetic resonance imaging (MRI) is a non-invasive and relatively safe imaging method that allows the visualization of the structure and many of the pathologies of the human brain in vivo, and that more recently is able to study the brain functions. MRI came into clinical use in the early 1980s, a few years before the first successful functional magnetic resonance imaging (fMRI) experiment in 1991 (Bandettini, 2012).

The availability of MRI scanners has increased rapidly in most European countries over the past two decades (OECD, 2012). For example in the Netherlands, the number of MRI units *per capita* increased tenfold between 1990 and 2010 (OECD, 2012). Similarly, in Italy, the number of MRI scanners *per capita* increased by nearly six times between 1997 and 2010 (OECD, 2012). The success of fMRI is believed to be a result of the good accessibility to MRI scanners, the parallel development of computing power and the advances on brain physiology and MRI signal knowledge (Bandettini, 2012).

1.1 Historical perspective

The phenomenon of nuclear magnetic resonance (NMR) was intensively investigated in the twentieth century. NMR in a solid was first described in 1946 by the research teams of Felix Bloch and Edward Purcell, together awarded the Nobel Prize for physics in 1952. They explained that if a group of atoms whose nuclei have a magnetic moment (the force that a magnet can exert on electric currents and the torque that a magnetic field will exert on it) is placed in a magnetic field, their nuclei can be regarded as magnetic dipoles precessing (changing the orientation of their rotational axis) about this field at a certain frequency, which is defined by the multiple of a constant that is unique to those atoms and the magnitude of the field. If these dipoles (closed circulations of electric current) are simultaneously affected by an electromagnetic radiofrequency (RF) field of a frequency matching in resonance that of their precession, they will interact

with that field. Physically, this means that these nuclei will absorb energy from the RF field and change their nuclear state. These fundamental principles together with other technical and analytical developments led to modern MRI. Paul Lauterbur, working in the United States, conceived a technique to noninvasively map NMR differences in different tissues of the body (Lauterbur, 1986), and Peter Mansfield, working in the United Kingdom, developed a mathematical process to obtain MRI images in less than one second (Mansfield and Maudsley, 1977), making blood oxygenation measurement possible in humans as explained below. For their contributions they were jointly awarded the 2003 Nobel Prize in Physiology or Medicine.

Functional MRI is an MRI technique little more than twenty years old, based as well on the behaviour of biological tissues under the influence of magnetic fields, but relying specifically on an NMR method for measuring blood oxygenation. Linus Pauling reported already in 1936 that the magnetic susceptibility of blood haemoglobin (iron-containing protein for oxygen transport found in the red blood cells) changed as a function of whether it was bound to oxygen or not (Pauling and Coryell, 1936). In 1990, the extravascular effect of intravascular blood was described in the brains of rats at the high field of 7 T (tesla is a unit of magnetic field strength), and the term blood oxygenation level dependent contrast (BOLD) entered the fMRI lexicon (Ogawa et al, 1990a; Ogawa et al, 1990b). BOLD is the process of oxygenation by which oxygen is reversibly bound to the ferrous ion of haemoglobin in red blood cells; Ogawa sagaciously hypothesized that the BOLD effect was related to functional states of the brain (Ogawa et al, 1990a; Ogawa et al, 1990b).

Although the first successful fMRI experiment, which studied brain visual areas in 1991, did not use the BOLD effect (but an exogenous source of contrast, not haemoglobin), it heralded the beginning of the use of MRI to map human brain functions (Belliveau et al, 1991). The application of the BOLD technique to human neuroimaging was soon reported by others (Bandettini et al, 1992; Kwong et al, 1992; Ogawa et al, 1992). It deserves mention that positron emission tomography (PET) studies contributed to the understanding of the BOLD effect. Fox and colleagues, using PET, described that with brain activation, oxygen extraction decreased, implying an increase in blood oxygenation, predicting that the BOLD signal should increase with activation (Fox and Raichle, 1986).

Since the early 1990s, the advances in fMRI have consisted of developments in hardware, imaging methods, image processing and display software, and paradigm design (manner of stimulating the brain in order to obtain meaningful information). These methods and technologies are still evolving, as fMRI users demand increasingly more spatial and temporal resolution, specificity, sensitivity and robustness (Bandettini, 2012).

1.2 Understanding fMRI

Using a static magnetic field (SMF) that typically ranges from 0.5 T to 3 T (3 T is about 50,000 times greater than the magnetic field of the Earth), and much weaker varying magnetic fields, MRI makes use of the NMR phenomenon. MRI, conventionally used to reveal the structure of an anatomic region of interest, exploits the magnetic properties displayed by the atomic nuclei of the molecules of the human body, particularly hydrogen because of its abundance in the water and fat of the tissues.
Functional MRI also takes advantage of the magnetic properties of the biological molecules, in this case, haemoglobin. The different magnetic susceptibilities of haemoglobin in its different oxygenation states explains the mechanism that underlies BOLD contrast used in fMRI (Thulborn, 2012). When we speak, move or think (and when we are even at rest) certain areas of our brains become involved in these tasks. The neurons involved in the process demand more energy locally, consequently increasing regional blood flow and, relatively, the amount of oxyhaemoglobin (magnetically more inactive than deoxyhaemoglobin), which in turn locally increases the MRI signal. By structurally sampling the brain every few seconds, fMRI is able to provide temporal data of the MRI signal in each image voxel (or volume-pixel, the smallest distinguishable cube-shaped part of a three-dimensional image).

Functional MRI may have slightly lower spatial resolution than anatomical MRI because a sample of the whole brain is needed every few seconds (while a conventional structural scan takes minutes to acquire), but is better than other techniques that study brain function, such as PET or electroencephalography (EEG). On the other hand, because of the nature of the method (dependent on blood flow to indirectly measure neural activity) and of the time needed to sample the whole brain, fMRI has lower temporal resolution than techniques that directly measure the electrical activity of the brain, namely EEG or magnetoencephalography (MEG). Other fMRI techniques were

developed (Williams et al, 1992), but are not widely used because they are generally limited in sensitivity, brain coverage and temporal resolution relative to BOLD contrast approaches (Bandettini, 2012).

To illustrate the technique, an example of a simple fMRI study with a motor task is given. After a safety screening for entering the strong magnetic field of the MRI scanner, the subject lies inside the magnet tunnel during the functional scan, while alternating 30-second periods of opening and closing movements of the hand with rest. A second structural MRI sequence of high spatial resolution of the brain is also obtained for image registration purposes (functional and anatomical image alignment). Although depending on the task and the purpose of the scan (clinical or research), most studies can be completed within approximately 20 to 40 minutes. Complex image processing is then needed to detect the activity in each brain image voxel and is defined as how closely the time-course of the MRI signal from each voxel matches the expected time-course (the alternating 30-second periods). Voxels whose signals correspond are given a high activation score, voxels showing no correlation have a low score and voxels showing deactivation are given a negative score. These can then be translated into activation maps that are, in fact, statistical maps that may represent for example a t-test, or in other cases, an ANOVA or a non-parametric statistical test.

In the fMRI field, a task paradigm is the manner (timing, duration and magnitude) in which a stimulus is presented to the subject being scanned in order to activate certain brain regions. The stimulus used depends on which brain functions need to be studied, and may be for example motor (as illustrated above), sensorial, language or cognitive. The most commonly used paradigm designs are block design and event-related design (Figure 1).

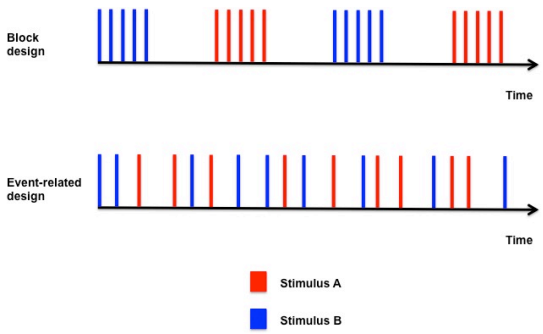

Figure 1. Common fMRI paradigm designs: block and event-related.

Block design was adapted from PET experiments that had lower temporal resolution; it usually consists of alternating periods of 20-30 seconds of two (sometimes three) conditions, for example stimulus and rest, to determine the differences between these conditions. In *event-related* fMRI, on the other hand, the presentation of the individual stimuli usually lasts only a few seconds, is randomized and the time between the stimuli can vary (Buckner et al, 1996). This technique is ideal for cognitive tasks, attempting to model the change in MRI signal in response to neural events associated with behavioural trials. A *mixed* block design and event-related approach is also possible (Visscher et al, 2003).

An innovation in paradigm design (Spiers and Maguire, 2007) that is re-emerging is the *free-behaviour* design, closer to the real world, yet still amenable to experimental control (Maguire, 2012). Non-constrained paradigms have been important in memory research (Cabeza and St Jacques, 2007). An example of free-behaviour design for the study of memory would be to show participants short film clips before scanning and then asking them to recall the clips during the fMRI session (Maguire, 2012).

Resting state fMRI is a paradigm design in that there is no external input to induce brain activity. It relies on spontaneous ongoing brain activity that translates in signal fluctuations that are correlated between functionally related brain structures (Figure 2). Although now it is an established methodology, much of the early research work was dedicated to demonstrating that the effect was neuronally based and functional in nature and did not correspond to noise of the MRI data (Lowe, 2012).

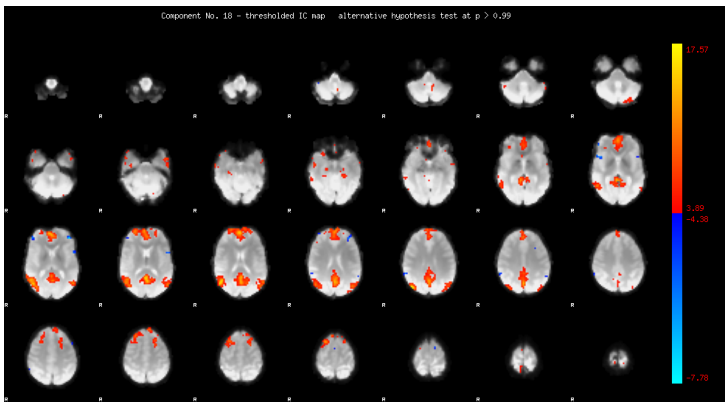

Figure 2. Default-mode network (DMN) brain map obtained with resting fMRI (it does not use a task to investigate brain functions). The DMN deactivates during demanding cognitive tasks and is involved in internal modes of cognition; it seems to be important in planning the future and in social interactions. Maps of other neural networks functionally connected during rest may be collected, for example sensory-motor, visual and auditory networks.

Real-time fMRI allows immediate access to functional brain imaging results by allowing the analysis of data as they are being acquired. This almost immediate availability of results is useful for quality control or fast functional localization (Weiskopf, 2012), which may be important for example in studies for presurgical planning of brain lesions in non-cooperative patients. Real-time fMRI has been used as a brain-computer interface for neurofeedback, to train self-regulation of the local BOLD response and to study consequential behavioural effects such as modulation of pain, reaction time, linguistic or emotional processing (Weiskopf, 2012).

1.3 Limits of the technique

Several limitations of fMRI have been identified, and include limitations associated with the neurovascular coupling phenomenon, the experimental design, reliability and validity of paradigms, head motion, physiological noise, structural changes in the brain, image registration, spatial and temporal resolution, field strength, image statistics (false positives and false negatives, correction for multiple comparisons, power calculation, sample size, region-of-interest analysis, inferences to the population), influence of cultural and anthropological frameworks in data interpretation, hardware and software diversity, and lack of normative procedures (Logothetis, 2008; Seixas and Ayres-Basto, 2008; Seixas and Lima, 2011). Many of these issues converge in fundamental questions concerning the interpretation of fMRI data, and conclusions drawn from results often ignore the actual limitations of the method, including those imposed by the particular circuitry and functional organization of the brain (Logothetis, 2008).

Robert Savoy, reflecting on the fMRI education for researchers, states that data interpretation is the most challenging aspect, and requires a long apprenticeship and extensive practice of data analysis (Savoy, 2012). Moreover, fMRI veterans recognize that expertise in fMRI requires knowledge in a wide array of domains and that training programs have to deal with the challenge of teaching researchers from a variety of backgrounds. This situation is now changing, with most researchers having previous fMRI experience (Savoy, 2012). In Europe, the Oxford Centre for Functional Magnetic Resonance Imaging of the Brain (FMRIB, http://www.fmrib.ox.ac.uk/) and the Wellcome Trust Centre for Neuroimaging of the University College London (http://www.fil.ion.ucl.ac.uk/) are multi-disciplinary neuroimaging research facilities,

which focus on the use of MRI for neuroscience research, brain imaging data analysis software development and fMRI education.
There are new educational challenges, related to the growing list of technologies now used to study human brain function in combination with fMRI (for example EEG, taking advantage of its high temporal resolution). Another overwhelming challenge is that of educating consumers of fMRI claims as the technique becomes more influential in society (Savoy, 2012).

In spite of the complexity of the technique, as seen before, and its relative newness, a lot appears to already have been done in trying to further understand its physiological mechanisms and its limitations, particularly with respect to MRI sequence development, experimental design and image processing methods and statistics (Bandettini, 2012). Taking the example of resting state fMRI, nearly 10 years passed before the controversy about its meaning and interpretation subsided in the specialized literature and it was accepted as a valid scientific method to study the functional connectivity of the brain (Biswal et al, 1995; Lowe, 2012). As a recent article celebrating the 20 years of fMRI stated,

> "In the past twenty years there has existed a dynamic tension between those moments when we have been stunned by what fMRI has revealed and those moments when we have been cautioned of real or perceived fMRI limits or problems. While of absolute limits exist with regard to imaging technology, sensitivity, resolution, and how much we can actually infer about neuronal activity from the haemodynamic response, I don't think that we will truly bump up against them any time soon. At this point in time, I think that the community is still well within the steep part of the learning curve with regard to figuring out how best to extract, use, and interpret the fMRI signal" (Bandettini, 2012).

1.4 Safety issues

The risks of an fMRI scan do not differ much from those of a conventional MRI exam, with the possible exception of eventual risks or discomfort for the subject related to stimulus presentation. Also, in longer fMRI acquisitions and due to certain type of sequences commonly used, or at ultra-high magnetic fields, the discomfort related to

time-varying field and the SMF may be more noticeable, as explained below. In a study quantifying adverse events associated with fMRI and real-time MRI, 641 imaging scans of 114 patients participating in a clinical trial were not associated with an increase in adverse event number or severity (Hawkinson et al, 2012).

Patients and volunteers undergoing MRI examinations are exposed to SMF and time-varying magnetic fields (gradient fields and RF fields):

1.4.1 Static magnetic field

The biological effects most likely to occur in patients and volunteers undergoing MRI procedures are vertigo-like transient symptoms, particularly induced by movement in the strong SMF of the MRI scanner. Moving patients slowly into the magnet tunnel may avoid these sensations. In addition, the accumulated experience of MRI procedures in clinical situations, where exposures to fields of 3 T are becoming increasingly common, does not suggest that any obvious detrimental field-related effects occur, especially in the short term (Health Protection Agency, 2008).

Much less is known about the effects of the ultra-high field MRI scanners, with a magnetic field strength of more or equal to 7 T. According to current knowledge, it is not expected that exposure of human subjects to magnetic fields of this magnitude implies specific risks, provided that known contraindications to MRI are observed (Moller and von Cramon, 2008). However, transient phenomena such as vertigo, nausea, metallic taste or flashes of light are more frequently observed comparing to weaker magnetic fields of 1.5 T (Heilmaier et al, 2011; Moller and von Cramon, 2008).

Similarly, little is known about the effects of SMFs on growth and behavioural development of fetuses and infants, suggesting caution is warranted concerning their imaging (Health Protection Agency, 2008). Kok and colleagues looked at 35 children who were exposed to a field of 1.5 T during MRI exams in the third trimester of pregnancy, and found no adverse effects on eye or ear functions, or on reproductive outcome (Kok et al, 2004). Of notice is the emerging field of fetal fMRI, with the potential to provide insight into early brain function (Schopf et al, 2012).

Regarding potential long-term effects of MRI, the overall evidence from epidemiological studies does not suggest adverse health effects from exposure to SMFs; however,

evidence is limited (Health Protection Agency, 2008). Additionally, there are no published studies of mortality or cancer incidence among subjects undergoing MRI procedures (Health Protection Agency, 2008).

There is also risk of displacement, vibration or damage of electronic or electronically conductive implants or metals, especially those containing ferromagnetic matter, under the SMFs, and in general MRI exams are contraindicated for patients with such materials. Because of the importance for clinical medicine of MRI, more and more medical devices nowadays are being produced to be MRI compatible. The Journal of the American Medical Association reported the first MRI-safe pacemaker to receive conditional approval from U.S. Food and Drug Administration (FDA) in 2011 (Mitka, 2011). All persons to enter an MRI scanner room, including patients, healthy volunteers and staff must be screened for implants or metals and other potential safety concerns (Expert Panel on MR Safety et al, 2013). The website www.mrisafety.com maintained by Frank G. Shellock is an online updated information resource for MRI safety and bioeffects (http://www.mrisafety.com/).
A particular concern is the safety of MRI in patients with deep brain stimulation (DBS) devices. Tagliati and colleagues performed a survey in 42 centres on MRI use and DBS, and in one case MRI was associated with failure of the pulse generator without neurological sequelae after the replacement of this DBS component (Tagliati et al, 2009).

1.4.2 Gradient magnetic fields

Gradient coils are used to produce deliberate variations in the main SMF. There are usually three sets of gradient coils, one for each direction of space. The gradient magnetic fields are involved in selecting image plane and slice and spatial encoding of detected MRI signal, being important for image quality. They change rapidly during the imaging process both in amplitude and polarity and may induce currents in conductive materials associated with implants (with consequent heating or vibration and eventual damage of devices or heating of the body) and within the body (originating peripheral nerve and muscle stimulation) (Health Protection Agency, 2008). The rapidly changing fields induced by the gradient coils will preferentially stimulate the myelinated nerves, but its thresholds are well below those able to induce ventricular fibrillation (Health Protection Agency, 2008). However, people with epilepsy or taking drugs that lower seizure threshold may exhibit increased sensitivity to stimulation by the electric fields induced in the central nervous system, and these people should be imaged with

caution (Health Protection Agency, 2008). The effects are minimized by avoiding crossing hands or ankles and avoiding wire loops touching the subject.

Time-varying magnetic fields associated with gradients are responsible as well for acoustic noise (vibration of the coils working in the SMF) that is more intense the better the performance of the gradients and the stronger the static field (Health Protection Agency, 2008). Although there is little risk of a permanent threshold shift in hearing in those exposed to MRI-associated noise, certain scans may be uncomfortable, particularly for sensitive individuals (Health Protection Agency, 2008). Patients or volunteers should be adequately protected with earplugs.

1.4.3 Radiofrequency fields

Radiofrequency coils behave as the antennae of the MRI system that broadcasts the RF signal to the subject and/or receives the return signal. The head of the subject is normally placed inside a coil that resembles a birdcage, commonly used for brain imaging. The birdcage coil provides the best RF homogeneity of all the RF coils. Exposure to RF energies may result in heating of the human tissues or eventual implanted devices. Exposure to RF fields of sufficient intensity can induce heating in biological tissue, while effects in the absence of heating remain controversial (Health Protection Agency, 2008). There are restrictions in place for exposure to RF fields during MRI procedures to limit potential body heating. There are uncertainties concerning effects of increased heat loads on infants and pregnant women, and on people with impaired thermoregulatory ability as a result of age, disease or the use of medications (Health Protection Agency, 2008). These people should be imaged with caution.

1.4.4 Other considerations

There are no published studies of mortality or cancer incidence among either patients or volunteers undergoing MRI procedures. However, there have been many epidemiological studies undertaken on people exposed either to power frequency magnetic fields or to RF fields in non-MRI situations. Taken as a whole, the scientific evidence has not clearly demonstrated adverse health effects, although there is evidence of an association between long-term exposure to residential power frequency magnetic fields and a raised risk of childhood leukaemia (National Radiological Protection Board, 2001; International Agency for Research on Cancer, 2002).

Reproductive and developmental outcomes in relation to the use of MRI have been examined in a number of studies. For example, a cross-sectional postal survey conducted in 1990 examined reproductive health among women employed at most of the clinical MRI facilities in the USA (Evans et al, 1993). Based on 287 pregnancies that occurred while working at an MRI unit, as compared with 964 pregnancies that occurred during work in another job, the relative risks for various reproductive outcomes (delayed conception in planned pregnancies, miscarriage, delivery before 39 weeks, low birth weight and sex ratio of babies) were all close to one and none of the differences was statistically significant (Evans et al, 1993).

1.5 Applications of the technique

Functional MRI has achieved a scientific impact comparable to other important biomedical discoveries (Rosen and Savoy, 2012). It is better implemented in neuroscience research, in particular in cognitive neuroscience, than in the clinical practice. It has contributed remarkably, for example, to our understanding of memory, reward circuitry, brain plasticity, resting state networks and social behaviour (Rosen and Savoy, 2012). In the clinical setting, fMRI is mostly used for planning of neurosurgical interventions, although it is not still widely adopted (Bullmore, 2012). Moreover, in spite of its considerable impact in the comprehension of neurological and psychiatric diseases, it does not yet have a relevant role in the diagnosis of these pathologies (Rosen and Savoy, 2012).

The fMRI field has also extended to areas that pose more complicated ethical and philosophical dilemmas, like the research on conscience, moral cognition, decision-making and free-will (Greene et al, 2004; Owen et al, 2006; Soon et al, 2008). And, in recent years, there is a growing interest in complex human faculties for which there are no adequate animal models (Hasson and Honey, 2012), such as music perception (Hannon and Trainor, 2007), neuroaesthetics (Cela-Conde et al, 2011), and the perception of art (Ishizu and Zeki, 2011).

There are many challenges associated with the translation of functional brain imaging research to applications in the broader social arena. For example, Jones and colleagues identified areas where neuroimaging is already having an impact on legal practice: third-party judging, lie detection, determination of mental states, memory, adolescent brain development and culpability of conduct and brain-based appeals

(Jones et al, 2009). Other controversial applications of fMRI technology are neuromarketing (Ariely and Berns, 2010) and politics (Knutson et al, 2006), among others.

1.6 Future of fMRI

The future of fMRI, as seen by Russell Poldrack, will have more methodological rigor (Poldrack, 2012), because many of the limits of fMRI, as previously discussed, are the limits of its own analytic methods. Bennett and colleagues scanned a dead salmon using a social cognition task (!) and found activation when using a threshold not corrected for multiple comparisons (Bennett et al, 2010). Unfortunately, a minority of papers is still published using methods that are improperly corrected for chance, considering the enormous number of tests conducted when analysing an fMRI experiment, and therefore with a high risk of false positives (Bennett et al, 2010).
Among the expected directions in the fMRI field is a greater focus on selective inference, powered by open large fMRI databases and increased use of computational models to describe brain processes. Additionally, instead of concentrating on localization of brain function, increasing focus will be put on understanding connectivity between brain regions, and patterns of activations (Poldrack, 2012).
An ongoing project that likely will produce extraordinary evidence for the understanding of the brain in the coming years is the Human Connectome Project (http://www.humanconnectomeproject.org; van Essen and Ugurbil, 2012). It aims to chart human brain functional and structural connectivity in a large population using cutting-edge neuroimaging techniques, including task fMRI and resting state fMRI. The resultant datasets are being made freely available via an online platform (http://www.humanconnectomeproject.org).

Functional MRI may play a more important role in clinical medicine in the future (Bullmore, 2012). Compared to task fMRI (used today for the planning of neurosurgery of intracranial lesions that are close to cortical eloquent areas), resting state fMRI as a potential clinical tool has several advantages. It does not require patients to perform challenging paradigms, and acquisition takes no more time than a conventional MRI sequence. Brain function can thus be measured in unconscious patients, in patients with dementia or with other important neurological impairment. Also, with a single

scanning session multiple brain networks can be studied at the same time and image interpretation is not influenced by task performance. Moreover, many brain disorders already being investigated with resting state fMRI are expected to have fMRI phenotypes at the level of large-scale brain networks, possibly useful for clinical diagnosis and prognosis (Bullmore, 2012).

Another fMRI application that may be of relevance for clinical medicine for drug discovery and development is pharmacologic MRI (phMRI) (Jenkins, 2012). It possible to elicit neuronal activity using various pharmacological agents as stimuli, including challenges with cholinergics, serotonergics, cannabinoids or opioids. Likewise it is possible to use drugs as a means of modifying the response to other fMRI stimulus, such as cognitive tasks (Dodds et al, 2009).

In the clinical setting it is expected that MRI systems with field strengths higher than 3 T will be adopted because they allow better spatial resolution, which can be important for the study of common diseases like multiple sclerosis (Tallantyre et al, 2010) or epilepsy (Henry et al, 2011). Ultra-high fields are important as well for studies based in magnetic susceptibility contrast, like BOLD imaging, increasing sensitivity, specificity and resolution (capable of working at the level of cortical columns) (Duyn, 2012; Yacoub et al, 2008). Moreover, they allow the use of new contrasts for structural and functional imaging (Duyn, 2012; Yacoub et al, 2008). There are however drawbacks of increasing field strength for fMRI, related to physiological noise (Kruger and Glover, 2001), and economic, technological and biological limitations (higher risk of tissue heating and sensory stimulation) (Duyn, 2012).

Imaging genetics is a research approach in which genetic information and fMRI data in the same subjects are combined to define neural mechanisms associated with genetic variation (Hariri and Weinberger, 2003). This relatively recent research area has had an important role in understanding neuropsychiatric phenotypes (Meyer-Lindenberg, 2012). Initial studies investigated single genetic variants or small deletions, but the field is moving to investigate the full complexity of the genome, making large-scale collaborative work essential (Meyer-Lindenberg, 2012).

1.7 Neuroethics and fMRI

Neuroethics addresses ethical, legal and social implications of neuroscience clinical practice and research findings and with the nature of the research itself (Illes and Bird, 2006). From the discussion above, it is clear that fMRI as a neurotechnology raises numerous ethical challenges, some unique to the field and others not significantly different from other issues encountered in bioethics. Challenges arise from the fMRI technique itself, and concerns that derive from functional imaging research findings, which enhance our understanding of the neural mechanisms of conscience, emotions, personality and social behaviour (Roskies, 2002).

Although a review of the literature from 1989 to 2005 reported a steady increase in the number of articles published on neuroethics, in this period only seven European countries (Belgium, Italy, France, Netherlands, UK, Germany and Spain) published more than five articles (Lombera and Illes, 2009). Moreover, few articles were reported that discussed both fMRI and ethical, legal, or social implications, and even fewer direct citations between the two literatures were identified (Garnett et al, 2011).

In Part Two of this document we pinpoint the ethical issues associated with fMRI in an integrated view, and propose recommendations to address these challenges that may be of use for all stakeholders involved in the field. A list of references is also suggested for a general overview of the problems in question. Furthermore, we hope this document contributes to raising awareness to ethical concerns related to functional neuroimaging in the European context.

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Part Two

Recognizing and Addressing fMRI Ethical Concerns

Recognising and Addressing fMRI Ethical Concerns

2.1 Limits, validity and interpretation of fMRI studies

Ethical use of fMRI requires understanding of the limits of the technique and the factors influencing its validity and interpretation. Functional magnetic resonance imaging does not measure neuronal activity directly, but the consequential changes in blood flow and oxygenation. The phenomenon of neurovascular coupling is also well studied, although there is some debate about this in the literature (Attwell and Iadecola, 2002). Other methods of measuring brain activity, such as EEG, are more closely related to the electrical activity of neurons and hence have better temporal resolution than MRI, however they are not true three-dimensional imaging modalities. Compared to PET, fMRI has superior temporal and spatial resolution. An understanding of the measurement of these mechanisms and the underlying assumptions are key in the planning of an fMRI experiment, as well as for the correct interpretation of a result.

Many other factors can influence fMRI validity and image interpretation. These include the manner of stimulating the brain in order to obtain meaningful information (paradigm design), magnetic field strength, MRI acquisition parameters including study length, subject collaboration and head movement (particularly task-correlated motion), presence of non-trivial structural changes in the brain, and image processing methods and statistics (Bell and Racine, 2009; Seixas and Ayres-Basto, 2008; Seixas and Lima, 2011). Moreover, interpretation of data depends not only on scientific frameworks (it is to be noted that a normal reference of brain function, with respect to fMRI, does not yet exist), but also on the cultural and social context (Illes and Racine, 2005). Considering the potential for variability, comparison of fMRI data across research centres is also problematic.

A distinction also needs to be made between fMRI research experiments, which are more focused on group data and in making inferences for the population, and fMRI as used in clinical neuroimaging (for example for planning the surgical removal of a brain lesion) that is focused on results from the individual patient (Desmond and Annabel Chen, 2002). Comparing analysis of fMRI data of a single subject with fMRI group analysis is a good exercise in order to understand some of the problems related to the

validity and interpretation of the technique.

Statistical methods developed for fMRI are usually designed to detect activation rather than characterize it. In single patient clinical studies, the extension of the statistical maps is of importance for the surgeon to better plan an intervention, where in research fMRI, detection is often sufficient. Moreover, in individual subject studies false negatives are critical, to ensure that the absence of activation does not have a deleterious consequence for the patient (e.g. the potential injury of a brain region following surgery, which is not involved in an eloquent function such as language or vision), and so lower statistical thresholds may be desirable. Methods of correction for multiple comparisons have been developed for fMRI group analysis, and are mostly concerned in the reduction of false positives. Stringent alpha-correction levels are also often used to reduce false positives, but this strategy limits statistical power that is key for single subject analysis (Yarkoni, 2009). Increasing sample size (in the case of group studies), scanning time or the number of sessions also increases statistical sensitivity (Loring et al, 2002).

Functional MRI is a complex technique, which requires expertise in several domains. Interpretation of results at times may be speculative, and there is a tendency toward localizing and modularizing brain functions (Hardcastle and Stewart, 2002). On the other hand, the brain may exhibit complex patterns of activation, but not all of the activations may be necessary for performance.

There is sometimes unwarranted anticipation surrounding new or expected uses and there should be caution with respect to premature translation to the market, the legal system or the classroom. Functional MRI imaging is being used non-clinically in the study of cognitive processes such as memory, language acquisition, antisocial behaviour, gender differences behaviour, spiritual experiences, decision-making, lie detection, legal testimony. Indiscriminate and uncontrolled use of this technique can lead to data protection issues and ethical implications for possible discrimination and stigmatization, as well as resulting possible dual use. It can lead to children being streamed pre-emptively into educational programs, with no possibility of bettering their development and low selfesteem (Meyer-Lindenberg A, 2012).

2.1.1 Recommendations

- The adequate method of study of the brain functions to answer specific clinical or research questions (fMRI, PET, EEG or other), should be selected taking into account these techniques relative advantages and limitations, and not just based on accessibility, costs or novelty. Sometimes more than one method may be necessary to better inform on a particular scientific or clinical problem.

- Conclusions about the role of a particular brain region in specific situations should be based on a convergence of information, not just a single fMRI experiment. Integrated views of the brain functioning should be encouraged.

- Validation and development of standardized paradigms/tasks, scanning procedures, and analysis methods for fMRI should be stimulated, whenever possible. The field should look for normative patient and healthy subject data. Organised cooperative efforts across research and clinical centres are recommended, which aim at standardization and creation of large fMRI databases (and of other types of data) (van Essen and Ugurbil, 2012). Such data will be of major importance in the advancement of neurobiological knowledge and imaging methods and in optimising resources. Examples include The Human Connectome Project (http://www.humanconnectomeproject.org/), The Alzheimer's Disease Neuroimaging Initiative (http://www.adni-info.org/) and the UK Biobank (http://www.ukbiobank.ac.uk/).

- It would be useful in the fMRI field to develop a standard code, as for example Current Procedural Terminology (CPT) that is a listing of descriptive terms and identifying codes for reporting medical services and procedures (American Medical Association, 2007). The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and thereby serves as an effective means for reliable nationwide communication among physicians, and other healthcare providers, patients, and third parties (coders, accreditation organizations, medical insurance companies, etc.). This would increase inter-use reliability of fMRI.

- It must be insured that researchers and clinicians, and other relevant stakeholders, involved in the fMRI field have sufficient expertise in the different

competences required, understand fMRI limitations and are able to correctly and clearly communicate results. It is important that particularly the non-specialists are taught about the interpretation, limitations and possible misuse of fMRI results. This should be carried out by means of training of ethical standards within the relevant professions rather than imposition through external regulatory processes (Fenton et al, 2009).

- Patient and healthy volunteers' consent forms should reflect uncertainties related with the technique (Rosen and Gur, 2002).

- Heightened awareness of fMRI challenges and limitations should prevent premature uses of the technique (Racine et al, 2005). These are of concern mostly in the applications of the technique in new areas of research or outside the medical research and clinical environments. At the same time, open-minded and multidisciplinary approaches to new applications of fMRI should be supported, in order not to constrain advancement of knowledge in the field.

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2.2 Safety and ethics

Increasing involvement of fMRI technology and its extension to neuroscientific non-clinical research applications must recognize ethical issues in terms of acceptability of safety issues, particularly in case of high magnetic field equipment of 3 T and above. Partly, ethical acceptability depends on adequate protection of the safety of participants, both patients and healthy volunteers.

There is definitely a need for standardized guidance to assist applicants for ethical approvals in reviewing the issues posed by fMRI research in terms of safety and protection of participants. One of the major goals of this workgroup is the protection of human participants by developing a list of "points to consider" for investigators undertaking fMRI research. Given the rapid evolvement of the technology such a list should be updated regularly.

2.2.1 Recommendations

This section is organized in steps which consider the successive stages of organization of a safety strategy for an MRI environment, including safety measures to control access to the MRI facility, training of personnel and operating procedures, emergency procedures in clinical and non-clinical settings, screening procedures of participants and accompanying persons, MRI exclusion criteria, screening for pregnancy, procedures in place for ensuring safety during scanning.

2.2.1.1 Safety measures to control access to the fMRI facility

- Facilities, clinical and non-clinical, must organize a standard zoning system to regulate access to the fMRI facility safety purposes (zone 4 to zone 1).

- *Zone 4* is housing the MRI scanner and must fall within zone 3. Zone 4 pertains to the risks due the magnetic forces of the SMF of the magnet (with a risk to induce metallic projectiles) and the effects of the time-varying gradient and RF fields when imaging procedures are in progress. At the entry to zone 4 a sign must clearly indicate the presence of the magnetic field and its potential danger.

- *Zone 3* surrounds zone 4, and includes all areas that potentially pose a risk. Typically zone 3 includes the console of the scanner, equipment rooms, and preparatory areas. Rooms within zone 3 may or may not fall within the fringe

fields of the magnet: the “five Gauss line” (1 Tesla = 10,000 Gauss). The boundaries of the 5 G line must be clearly marked: usually with a red line on the floor and with signs reminding the presence of the magnetic field and its risks. This applies particularly to fMRI facilities in non-clinical settings. In addition, appropriate signs must clearly remind that "The magnet is always on" and that persons with pacemakers or prostheses are at risk for accidents. No unscreened non-MR personnel are allowed access to zone 3. Access should be restricted with key locks, pass key locking systems, excluding combination locks. Zone 3 may possibly involve areas of the surrounding building that fall outside of the scanning facility: these additional areas and the risks they present must be marked clearly.

- *Zone 2* is the interface between the freely accessible zone 1 and the strictly controlled zones 3 and 4, which pose a risk. Passage from zone 2 to zone 3 must be impossible for participants not accompanied by qualified MR personnel. Zone 2 may be used for first contact and screening procedures.

- *Zone 1* is freely accessible to the general public, for example waiting rooms. Zone 1 is definitely outside the environment in which the magnetic field constitutes a possible risk.

2.2.1.2 Training procedures for personnel

- MRI facilities present serious potential dangers to untrained or improperly screened personnel, be it clinicians, scientists or radiographers. Also there is a definite need for appropriate training for all individuals who operate the equipment. Certified training procedures, including didactic training in the field, must be organized for each level of authorization. Applicants must clearly document procedures for training and certifying personnel at all levels and keeping certifications current.

- *Level I* personnel are authorized to have unsupervised access to the MRI suite, but may never operate the equipment, including anesthetists, maintenance and transportation staff. They are able to screen themselves and are familiar with safety procedures for entering the MRI suite and are familiar with basic emergency procedures.

- *Level II* personnel are those who, in addition to Level I certification, are also certified to operate the MR equipment, as well as to screen others for entry into zones 3 and 4. Training must include in depth knowledge of MRI safety issues including the safety of different materials. Whenever relevant, training will include elements of RF thermal safety issues and use of contrast agents and their side effects. They must be familiar with safety aspects of claustrophobia and panic state management.

- *Level III* personnel are senior staff members who are fully certified to train and certify Level I and Level II personnel. Such personnel must have knowledge and experience to run a safe MRI environment. The designated safety officer must be a senior level III staff member.

- All researchers should adhere to an accepted national standard of care consistent with safety provisions, similar to those of the American College of Radiology (ACR) (Expert Panel on MR Safety, 2013). Final responsibility for the safety of the MRI examination will at all times rest with the principal investigator or the radiologist (respectively in a research or clinical setting), the safety officer and the MRI facility director.

2.2.1.3 Adequate procedures for dealing with emergencies

- Facilities must at all times be ready to anticipate potential emergencies and to ensure the availability of highly competent personnel coverage. This implies the continuous presence of at least two trained staff members whenever a participant or accompanying person is present in zones 3 or 4.

- A duly licensed physician must be on site to deal with any medical issue, e.g., management of panic states, cardiac problems, acute psychiatric symptoms, etc. Especially for all cases in which an MR contrast is administered (although it is rarely used in the context of an fMRI scan), a physician must be on site to handle possible adverse reactions to the administered contrast.

- Personnel involved in the scan session must be made aware of the designated safety officer: it is important that a single Level II individual is in charge of safety

issues in order to avoid ambiguity or diffusion of responsibility during an emergency prior to entry into the facility.

- Procedures for dealing with emergencies are of utmost importance to maintain staff readiness to deal with emergencies, both in medical settings as in non-medical settings. Knowledge of urgent contact procedures with emergency resources in the facility and community is very important. The staff must be regularly trained in urgent removal and evacuation of a participant from the scanner. The radiographer must be aware when and how to quench urgently the magnetic field.

- If participants have pre-existing medical conditions or are from a vulnerable population, e.g. psychiatric patients, then a qualified member from the research team, who is trained in responding to these conditions, must be in attendance during the MRI scan.

- Note that for scans performed in non-medical settings, it must be made clear to participants in advance that emergency medical services are not readily available onsite.

- The relevant services (such as ambulance and fire departments) should be made aware of the special circumstances that apply when entering a MRI facility. Meetings with such services must be regularly organized in order to familiarize them with safety considerations and for updating their emergency procedures.

- Facility's risk management reporting process includes systematic reporting of all incidents and all adverse events associated with MRI in order to improve safety. All near-accidents revealing breaches of safety procedures and other safety-related incidents should be reported, as they might reveal weaknesses in safety procedures.

2.2.1.4 MRI safety screening procedures for personnel and of participants

- It is important to underline the necessity of routine careful screening of all individuals who enter the MRI facility, i.e., all radiographers, all accompanying caretakers and participants who enter the MRI facility.

- It is good practice to use standard screening forms for example the MR Safe Practice Guidelines to be obtained from the ACR (Expert Panel on MR Safety et al, 2013) or to be downloaded from www.mrisafety.com or www.IMRSER.org. A qualified interviewer must review the screening form with the participant item by item to make sure that the participant has fully understood each item and that there are no contraindications to scanning. It is advocated to include a second approach to screening to provide redundancy and increase safety. Thereby is must be double-checked that participant is free of surface metallic objects that may be unsafe for MRI: jewellery, coins or other metals.

- In fMRI experiments that involve a task to be performed by the subject during the scanning session (for example a motor task), before entering the equipment participants should be trained in performing the necessary task, when possible. A mock scanner may be useful to familiarize them with performing complex fMRI tasks in this particular environment.

- The participants' ability to comply with the MRI procedures should be evaluated in terms of sufficient comprehension, eventual mental impairments, and ability to remain focused. When there are concerns about the participant's comprehension, it may be needed to obtain the necessary safety information from the legal caretaker. In these cases it may also be desirable that the caretaker accompanies the participant during the scanning session. Informed consent procedures of vulnerable subjects for fMRI experiments will be covered in sections 2.4 and 2.6.

- Also, the final responsibility for ensuring that it is safe for the participant and/or accompanying persons to enter the MRI environment rests with the research facility an the scientific investigator who have the authority to deny or authorize entry into the MRI facility.

Notes: Availability of a high strength magnet (1000 G or more) as a supplement to screening may be useful but should not replace the screening interview, given the risk of false negatives. Ferromagnetic detectors such as hand-held, wall-mounted and walk-through models constitute a potentially useful supplement. However, such devices should be systematically validated and, at this stage, should not replace thorough interviewing procedures.

2.2.1.5 MRI exclusion criteria

- Cardiac pacemakers, aneurysm clips, cochlear / retinal implants, hearing aids, permanent eye lining, tattoos, metal plates / pins / screws on bones / deep brain and other stimulation devices: these devices or materials may sometimes preclude an MRI exam. Checking procedures for verifying the safety of implanted devices are mandatory and include contact with the manufacturer, published information, web-searches and educated opinions of qualified safety experts. MR safety information may be less readily available for field strengths higher than 3 T.

- Patients or volunteers that were exposed to metallic flakes and/or that had a metallic injury cannot have a MRI scan unless they have an X-ray showing absence of embedded metal in the body. Permission for screening with ionizing radiation (X-rays) needs to be obtained in advance.

- Persons suffering from real claustrophobia or those who feel uncomfortable in small, enclosed spaces, like the MRI tunnel, should not be scanned for scientific reasons. For clinical purposes sedation may be indicated, although it can alter fMRI results. The use of sedatives for an MRI study only for scientific reasons is not ethically acceptable. Similarly, it is also not ethically acceptable to sedate patients/healthy volunteers to prevent small movements during the scanning session. For subjects who feel uncomfortable in enclosed spaces it may be of help for them to visualize the scanner room and/or to watch a film about the normal MRI procedures before the study.

2.2.1.6 Screening for pregnancy in women of child-bearing age

- Ethical acceptability – or not – of exposing pregnant mothers and fetuses to MRI scanning without compelling clinical indications, will be discussed in a separate chapter. In any case, there is an absolute need to put in place an appropriate screening program to exclude pregnant participants. Thereby the usual ethical issues are raised in terms of confidentiality.

- Some recruitment procedures merely ask during the consent/assent process if there is a possibility she may be pregnant and note the date of the last menstrual period and/or whether there has been unprotected sexual activity. Other centres test routinely for pregnancy in all females of child-bearing age. However, routine pregnancy testing raises a number of ethical issues as the testing holds implications for the disclosure of such results. For example,
    - Having the parents first learn of an adolescent's sexual activity;
    - Cultural influences – the screening process may be harmful for the adolescent female and/or her family;
    - Accidental disclosures of pregnancy to accompanying persons.

- Applicants must fully document the strategy on how to deal with pregnancy as incidental finding. In any case, screening involving pregnancy testing must be in compliance with the local applicable law. To avoid these ethical issues, pregnancy might be mentioned as a reason not to volunteer at the time of recruitment.

2.2.1.7 Standard procedures in place for ensuring safety during scanning

- It is important that the participant is visible to and in hearing contact with the MRI operator at all times. The possibility to voluntarily terminate a study at any time during scanning must be foreseen in accordance with the Declaration of Helsinki (World Medical Association, 2013).

- Earplugs or other hearing protection should be used during scanning to attenuate noise levels. Acoustic noise levels during scanning indeed reach more than 120 dB, depending on pulse sequence, field strength, etc. Risks will vary given single versus repeated exposures and scan duration. Hearing protection typically lowers these exposures by about 20 dB, depending on the type of

protection. Even with optimal hearing protection, a weighted root mean square sound pressure level greater than 99 dB poses a significant risk. For participants that already suffered a noise-induced hearing loss, caution must be taken to avoid further damage. The following FDA document is relevant for guidance on this subject: "Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices", dated July 14, 2003 (U.S. Food and Drug Administration, 2013).

- For adults, children, and infants greater than one month of age, field strengths greater than 8T are presently considered to pose a potential significant risk. Specific neurocognitive domains were proven to be affected by movement-induced time-varying magnetic fields within a SMF of a 7T MRI scanner. Domains that were affected included attention/concentration and visuospatial orientation. Especially attention and concentration were negatively affected when exposed to time-varying magnetic fields within a SMF varying from 5.0% to 21.1% *per* Tesla exposure ($p<0.05$), particular in situations were high working memory performance was required. In addition, visuospatial orientation was affected after exposure (46.7% *per* Tesla exposure, $p=0.05$). These side effects are distressing and may challenge the ethical acceptability to use these fields of 7T and higher in patients/volunteers. More studies are needed to investigate secondary effects of ultra-high magnetic fields and their duration, particularly cognitive effects that are more difficult to measure and less likely to be spontaneously reported by the patients or healthy volunteers.

- The *specific absorption rate* (SAR) is the RF power absorbed *per* unit of mass of an object and is expressed in watts *per* kilogram. The SAR describes the potential for heating of the subject's tissues due to the application of the RF energy necessary to produce the MRI signal. The SAR increases with field strength. The SAR limits vary from country to country, but in most countries standard MRI systems are limited to a maximum SAR of 4 W/kg. The following limits were proposed by the FDA (U.S. Food and Drug Administration, 2013):
    - Whole body average dose over 15 or more minutes: 4 W/kg;
    - Head average dose over 10 or more minutes: 3 W/kg;
    - Head or torso dose per gram of tissue over 5 or more minutes: 8 W/kg;
    - Extremities dose per gram of tissue over 15 or more minutes: 12 W/kg.

- Any rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation is considered a significant risk.

2.2.1.8 Other risks and discomfort associated with fMRI experiments

- As seen above, the risks and safety issues of an fMRI scan are identical to those of a conventional structural MRI exam. But an fMRI experiment may include a stimulus that can pose eventual risks or discomfort to the subject, beyond the actual scanning procedure. Examples are fMRI experiments investigating visceral pain, in which an inflating balloon may be inserted in the oesophagus or the rectum of the patient or healthy volunteer to elicit pain or other visceral sensations (Bonaz et al, 2002; Hojo et al, 2012).

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2.3 fMRI in pregnancy: safety issues and ethical considerations

Magnetic resonance imaging is generally considered safe during pregnancy, as magnetic energy has been shown not to be harmful for the developing fetus (Shellock and Crues, 2004). However, there is still a paucity of published data from studies evaluating the long-term safety of MRI examinations in pregnancy (de Wilde et al, 2005). A small number of animal studies pointed to possible teratogenic effects of MRI exposure in early pregnancy. A reduction in crown-rump length was seen in mice exposed to MRI in mid-gestation (Heinrichs et al, 1986). Exposure to the electromagnetic fields simulating a clinical study caused eye malformations in a genetically predisposed mouse strain (Tyndall and Sulik, 1991). Several hours of exposure of chick embryos within the first 48 hours of life to a strong SMF and rapid electromagnetic gradient fluctuations resulted in an excess number of dead or abnormal chick embryos, when examined at day 5 (Yip et al, 1994).

Although not directly applicable to humans, these findings provide some cause for concern regarding fetal MRI in the first trimester. From there, it is generally recommended as a measure of prevention to screen females of reproductive age for pregnancy before permitting them access to MRI environments. Also, the guidelines of the UK National Radiological Protection Board stated that "it might be prudent to exclude pregnant women (patients and volunteers) during the first three months of pregnancy" (National Radiological Protection Board, 1991).

Though permitted to work in and around the magnetic resonance environment, pregnant health care practitioners are requested not to remain within the scanner bore or zone 4 during actual data acquisition or scanning.
In addition, one must also consider that in case of MRI scanning in early pregnancy, patients may blame the procedure if later a fetal malformation is detected. The relatively high rate of spontaneous abortion in the first trimester is also a reason for concern. An MRI study could be coincidentally followed by a spontaneous abortion, but might give rise to parental culpability feelings regarding causal effect.

Precautions should be taken to avoid scanning in pregnancy and practitioners should reassess the potential risks versus benefits of the scanning. It is highly recommended to postpone the MRI examination to the end of the pregnancy, if possible. Pregnant

patients should only undergo MRI scans, at any stage of pregnancy, when it is not prudent to wait until the patient is no longer pregnant.

Paramagnetic MRI contrast agents should not be injected into pregnant patients. Indeed, part of the gadolinium-based MRI contrast agents readily enters the fetal circulation. They will be excreted by the fetal kidneys into the amniotic fluid. Gadolinium-chelated molecules will remain in the amniotic fluid for an indeterminate amount of time. The fact that chelated molecules remain in the amniotic fluid is worrying as the dissociation of the potentially toxic gadolinium ion from its ligand increases with time. It is unclear what impact such free gadolinium ions might have on the fetus. It must thereby be reminded that animal studies have already demonstrated increased rates of spontaneous abortion, skeletal abnormalities, and visceral abnormalities when given at 2–7 times the recommended human dose (U.S. Pharmacopeia, 2004).

Moreover, the decision to administer a gadolinium-based contrast agent to pregnant patients can only be decided after a very thoughtful risk/benefit analysis. Paramagnetic agents are not recommended in pregnancy by FDA because they cross the placenta and their long-term effects are unknown (Kanal et al, 2007). European Society of Radiology guidelines state that gadolinium-based contrast agents are probably safe in pregnancy, but they should only be considered when absolutely necessary (Webb et al, 2005).

2.3.1 Recommendations

- From the safety data and ethical considerations outlined above, one must exclude pregnant women (patients and volunteers) during the first three months of pregnancy from participation in projects using fMRI.

- An ethically acceptable screening process must be put in place to detect pregnancy in participant women of child-bearing age.

- Given the possibility of spontaneous abortions or fetal malformations, applicants should exclude participants that are likely to develop culpability feelings regarding a possible causal effect.

- Administration of gadolinium-based contrast products merely for scientific reasons is considered to be non-ethical given the principle of precaution.

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2.4 fMRI in children and the fetus: ethical acceptability?

Since little is known about the effects of SMFs on growth and behavioural development of fetuses and infants, and hence a minimal-risk standard is difficult to define, caution is suggested concerning the use of fMRI in these scenarios (Fenton et al, 2009; Health Protection Agency, 2008; Hinton, 2002). The physical and psychological risks of the MRI procedure, explained in the previous section, may not exceed minimal risk in pediatric imaging (Davidson et al, 2003; Matthias et al, 2011; Rosen and Gur, 2002; Rosenberg et al, 1997). However, the sedation and contrast enhancement that are sometimes associated with MRI research (but rarely in the more specific context of fMRI) seem to exceed the level of risk encountered by typical, healthy children in their everyday experiences.

Five specific scenarios can be considered:

- Children in good health, too young to give their assent;
- Healthy school-aged children and adolescents able to give their assent that are invited to participate in scientific studies on cognitive brain physiology;
- Sick children that need anyhow MRI or fMRI scans for diagnostic or follow-up reasons in which additional scanning is planned for clinical scientific reasons;
- Children who suffer from mental, psychiatric or neurological conditions, who do not need to undergo fMRI for diagnostic reasons, but are asked to participate for clinical science reasons. These patients might eventually benefit from the studies: early or improved diagnosis, guided neurosurgery or drug treatment;
- The fetus, usually imaged with MRI to rule out or to confirm suspicious findings on fetal ultrasound.

Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research (World Medical Association, 2013). Injection of a contrast agent for MRI examination carries a small but real risk of allergic reaction, and the risk of local and minor systemic reactions from MRI contrast agents varies from 4 percent to 6 percent. Therefore, it is our opinion that MRI with contrast enhancement does not meet the minimal-risk standard for research with healthy children or healthy adolescents.

With respect to the possibility of psychological harm, in studies of children aged 10 to 18 years old who had MRI scans, 12 percent said they felt disturbed by the confined space, 16 percent said they were bothered by the noise, and 1.2 percent could not complete their MRI scan due to claustrophobia. A number of articles have reported that children experience greater anxiety or fear during MRI scanning than do adults. Other authors claimed that there were no significant differences between children and adults in measures of physical comfort, emotional comfort or perception of performance (Thomason, 2009).

One of the greatest challenges to participating in fMRI research is for patients to remain still for the duration of the scan. This is an impossible demand for young children and keeping older children for a prolonged period in this situation is ethically unacceptable due to the excessive physical discomfort they will experience. Sedation to overcome the psychological and physical stress merely for scientific research is unacceptable.
Preventive sedation in MRI protocols can result in added risk for side effects such as gastrointestinal complaints (18 percent to 37 percent) and motor imbalance and transient ataxia (66 percent to 85 percent). In addition, sedation administered purely for scientific reasons does not meet the minimal-risk standard and is ethically very questionable. In children that must anyhow have sedation for clinically justified investigations, the extension of fMRI techniques may be acceptable.
Use of injectable sedatives for panic states or claustrophobia attacks usually causes more severe side effects, and scanning of sensitive children must be avoided at all costs.

All this must be kept into perspective since some studies e.g. that by Schopf and colleagues, have advocated that combined structural and functional data for all gestational ages would allow more specific insight into the developmental processes of the fetal brain (Schopf et al, 2012). While this scientific objective is sound, it is important to consider whether it is ethically acceptable to prolong MRI fetal exams in order to pursue such results.

2.4.1 Recommendations

- It seems ethically unacceptable to perform fMRI in young healthy children that are unable to give their assent as the whole procedure carries a significant risk of inducing anxiety and unacceptable physical discomfort.

- It seems ethically acceptable to recruit children older than 12 years who are able to give their written assent after being fully informed. Indeed, children that do not have the legal capacity to consent to participate in research, may be recruited if they are able to assent, i.e. being capable of having a study explained to them and capable of reading a simple form about it, and giving verbal or written agreement. Parents or legal guardians' permission remains mandatory.

- Investigators must describe how they plan to minimize implicit pressure on such children to participate. As with all consent and assent forms, the freedom to decline participation, without penalty, should be made clear. Children may never be rushed to take their decision during a first meeting. Parents and children must take time to discuss at home whether or not they would like to participate in the study.

- The ethical acceptability for financial incentives that might benefit parents remains highly questionable.

- Most young healthy research volunteers are unlikely to have had previous experience of being scanned. When assent/consent is being sought for participation in research studies, all should be given detailed information about what the scanning process involves and its potential risks. Showing teaching videos and using mock scanners might be helpful in this respect. The mock scanner typically includes recorded MRI sounds, a screen for stimulus presentation/movie viewing, supine positioning of the child on a moving table and button box for the child to key in responses.

- Administration of contrast agent to an MRI increases the odds of harm and makes them unacceptably high when scans are performed solely for scientific reasons.

- Administration of sedatives, especially injections, seems unacceptable when the scans are performed solely for scientific reasons. The risks and benefits should be fully considered in such scenarios.

- Additional MRI and fMRI scans, performed in sick children who need to undergo these procedures for clinical reasons, seem ethically acceptable as the patient's might directly or indirectly benefit from these investigations. In these circumstances contrast administration and sedation seem ethically acceptable.

- Sick children who are or can be involved in the information process must receive verbal explanations of what will happen to him/her and the opportunity for discussion should always be provided. It is always preferable to seek the child's written assent, even when it is not legally required. Parents or caretakers' permission is mandatory.

When planning a research study that will involve children, the applicants must consider four main issues:

- Document rationale for including children. Address the unique outcomes and benefits of studying children. Indicate if the study addresses a medical condition that particularly affects children: e.g. a condition uniquely affecting/manifesting in children. Indicate if the research concerns an area of neuropsychology specifically related to children: e.g. adolescent depression; stages of brain development.
- Document fully the risk level. Indicate the relevant regulations.
- Justify the ethical acceptability to deviate from standard of care for the subjects.
- Fully document the consent procedure, i.e. permission and assent requirements for the study. Indicate the strategies to obtain assent from the child and permissions from parents or caretakers.

- The local institution's Research Boards and/or Ethic's Committees will determine if adequate provisions are made for obtaining the assent of children and evaluate whether the children are capable of providing assent. In determining which children are capable of assenting, they should take into account the ages, maturity, and psychological state of the children. This

judgment may be made for all children as a group under a particular protocol, or for each child individually as the committee deems appropriate.

- At the moment, this working party cannot recommend fetal fMRI, in particular as a routine procedure, because there is no sufficient specific fMRI technical expertise for the fetus, and because in fetal medicine there is a lot of uncertainty on the meaning and prognosis even of structural abnormal findings.

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2.5 Incidental findings

An incidental finding (IF) is defined, according to Wolf and colleagues, as having "…potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study" (Wolf et al, 2008). In fMRI studies, these can be abnormalities found in the structural scans obtained for registration purposes, or unexpected neural activations.

Incidental findings are common with the use of brain MRI and are more problematic in the research setting, where they fall out of the scope of the investigation and many times are discovered outside of a clinical environment by a non-physician. This is even more so if there is the possibility of false positive findings, which may result in unnecessary worries, medical investigations and costs.

In a retrospective study of brain MRI scans of 1000 volunteers who participated as control subjects for various research protocols 18% demonstrated incidental abnormal findings, of which 15.1% required no referral, 1.8% required routine referral and 1.1%, required urgent referral (Katzman et al, 1999). A recent meta-analysis described a prevalence of 0.7% neoplastic brain IFs, and this prevalence seems to increase with age (Morris et al, 2009).

The issue of IFs is being recognized increasingly and many research centres have already in place strategies to deal with them, but no consensus exists regarding the ideal strategy. For example, neuroradiology reviews of research scans are perceived as time-consuming and expensive and potentially exposing institutions to risk (Shoemaker et al, 2011). In addition, there are concerns that receiving a radiology report may cause unnecessary anxiety among research participants, unfairly burden those who are uninsured or cause insurance problems (Shoemaker et al, 2011). Conversely, neuroimaging IFs may have medical importance, and a large majority of research participants seem to prefer to be informed of their radiology review (Shoemaker et al, 2011). However, it is unclear whether these study participants have been duly informed on the potential detrimental social consequences such information can have due to the pre-contractual disclosure duty when applying for example to private life insurance, professional disability insurance etc.

2.5.1 Recommendations

It is important that participants know that an fMRI study is usually not suitable for diagnosis, and whether the research team includes a radiologist trained in reading brain images. They should also be informed that an abnormality may be detected, the clinical significance of which may not be readily clear. The participants must be informed about the path that will be taken in the event that such IF is discovered provided the study participant has given written informed consent to receiving such information and has not decided to make use of his right not to know. The protocol must identify a qualified physician to report such findings to a participant who has consented to receiving such information, and offer support and guidance.

Guidelines on how to handle IFs are needed, and the following recommendations represent the authors' suggestions. Concerning IFs, two research contexts must be distinguished: the therapeutic research context and the non-therapeutic and non-medical research context. It is also of relevance to address the different possible study populations separately: patients, healthy volunteers and vulnerable patients/volunteers (i.e. study participants who are not able to give informed consent).

2.5.1.1 Therapeutic research context

Before fMRI scans are performed in a therapeutic research context where new drugs and/or medical devices/procedures are tested:

- The patient should be duly informed that through the fMRI IFs could occur indicating diseases which could either be handled within the current treatment regime or would make necessary a new or additional treatment regime(s). Since the patient is under treatment and has through this decision shown his willingness to improve/restore his/her health it can be presumed that the patient would like to know about these findings especially in cases where immediate action is needed. Nevertheless in order to respect the patient's autonomy, he/she should be asked whether he/she wants to receive such information.

- There also can be IFs, which indicate diseases for which no treatment yet exists. The patient should be given the opportunity to decide whether he/she wants to be informed about such findings. If the patient wants such information to be given, a specific counselling policy must be developed to help the patient bear the implications of such findings.

- Healthy volunteers should be duly informed that through the fMRI IFs could occur indicating diseases for which efficient treatments already exist. The healthy volunteers should be asked before participation whether they want to be informed about such findings. There could be reasons on the side of the study participant not to be informed about such findings.

- The healthy volunteers should also be asked whether they want to be informed about incidental IFs related to diseases for which no treatment yet exists. If the study participant wants such information to be given, a specific counselling policy must be developed to help the study participant bear the implications of such findings.

- Persons not able to give informed consent should only be included if there is either a clear potential benefit for them personally or the group of patients affected by the same disease, and if the burden imposed on them is minimal, and if they cannot be replaced for study reasons by persons able to give informed consent.

- With respect to this vulnerable population, informed consent has to be provided by the legal representatives. The legal representatives should be duly informed about the procedures to be performed and the possibility of IFs, which indicate diseases for which efficient treatments already exist. They should also be informed that IFs could occur which indicate diseases for which no treatment yet exists. In case such information is provided to the legal representatives, a specific counselling policy must be developed to help the legal representatives and the patient to tackle the implications of such findings.

2.5.1.2 Non-therapeutic and non-medical research context

Before fMRI scans are performed in a non-therapeutic/non-medical research context:

- Patients should be duly informed that through the fMRI IFs could occur indicating diseases for which efficient treatments already exist.

- In order to respect patients' autonomy, they should be asked before participation whether they want to be informed about such findings. There could be reasons on the side of the study participant not to be informed about such findings, though this may rarely occur.

- The patients should also be asked whether he/she wants to be informed about IFs related to diseases for which no treatment yet exists. If the study participant wants such information to be given, a specific counselling policy must be developed to help the study participant bear the implications of such findings.

- Healthy volunteers should be duly informed that through the fMRI IFs could occur indicating diseases for which efficient treatments already exist.

- The healthy volunteers should be asked before participation whether they want to be informed about such findings. There could be reasons on the side of the study participant not to be informed about such findings, though this may rarely occur.

- The healthy volunteer should also be asked whether he/she wants to be informed about IFs related to diseases for which no treatment yet exists. If the study participant wants such information to be given, a specific counselling policy must be developed to help the study participant bear the implications of such findings.

- Persons not able to give informed consent should only be included if the burden imposed on them is minimal, and if they cannot be replaced for study reasons by persons able to give informed consent. Furthermore, this group should stand to benefit from the knowledge, practices or interventions that result from the research. With respect to this vulnerable population, informed consent has to be provided by the legal representatives.

- The legal representatives should be duly informed about the procedures to be performed and the possibility of IFs, which indicate diseases for which efficient treatments already exist. They should also be informed that IFs could occur which indicate diseases for which no treatment yet exists. In case such information is provided to the legal representatives, a specific counselling policy must be developed to help the legal representatives and the patient to tackle the implications of such findings.

- For all volunteers who, prior to participation, choose not to be informed of IFs, researchers should refrain from interpreting scans beyond the scope of the research protocol. It also follows that for these volunteers, absent consent, researchers should not document and/or store any information that exceeds the research scope. This is consistent with data protection laws, and will help minimize potential harms to these volunteers.

2.5.1.3 Insurance

- Study participants undergoing fMRI should be duly informed that IFs, may they be such for which efficient treatments already exist, or such for which no treatment yet exists, have to be disclosed to private insurance companies if requested, for example in case the study participant plans to obtain, or is in the process of applying for, private health insurance, private life insurance or professional disability insurance (pre-contractual disclosure duty).

2.5.1.4. Collaborative databases

- At this moment, recommendations for unexpected neural activations (functional IFs) are difficult to produce because there are no normative data; effort for collaborative databases is encouraged. This is to increase our knowledge on such IFs in health and disease, how to identify them and their meaning.

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2.6 fMRI in the context of neurodegenerative and psychiatric diseases

Functional magnetic resonance imaging has a huge potential in the study of conditions which cannot be understood through brain structural abnormalities alone, including psychiatric diseases, neurodegenerative diseases and unconscious states, for example pre-symptomatic diagnosis of diseases such as schizophrenia, addictive behaviours, dementia, understanding of autism and to distinguish between patients in a minimally conscious state from patients in a persistent vegetative state. It might also be useful in monitoring treatment as in children with attention deficit hyperactivity disorder or dyslexia. This has huge implications for the inclusion of vulnerable persons in such research, from the consent process to long-term consequences from the results of these investigations (Fenton et al, 2009).

Competence and voluntariness of persons undergoing fMRI are key considerations especially for children, elderly and persons with disabilities who have impaired or not yet developed full mental capacity to make full-informed decisions. These persons may be unable to comprehend the full implications of the results from such investigations (Fenton et al, 2009). In these patients, competence cannot be presumed, complicating

recruitment and consent procedures (Anderson et al, 2012). These are issues of consent and capacity and patient's personal and environmental conditions (psychological status, education, expectations, and social support) should drive the physician to partial or full diagnostic disclosure, or delay communication. Furthermore, the results from fMRI investigations may lead to discrimination in provision of health insurance, life insurance, future employment, and education, which can result in discrimination and stigmatization and health care disparities (Meyer-Lindenberg, 2012).

Neuroimaging approaches may also identify factors important in psychopathology such as structural abnormalities, dysfunctional metabolism or activation patterns. This may have implications for the detention of individuals who have not yet committed a crime, but are deemed a potential threat to public safety and some countries, such as UK, is monitoring the data collected in such cases in order to address possible gaps in legislations (Health & Social Care Information Centre, 2013). Such individuals could, for example, be diagnosed with ''Dangerous Severe Personality Disorder'' or DSPD, a term without defined or sanctioned legal or medical status, creating an ethical conflict about the public's right to safety versus the individual's right to freedom (Canli and Amin, 2002).

The claustrophobic nature of the fMRI apparatus may lead vulnerable and impaired persons to experience unnecessary fear, stress and anxiety, leading to the use of physical or drug induced sedation procedures to reduce movement. With careful screening and safety procedures, the long term effects of exposure to the magnetic field are believed to be negligible; however, emotional and physical responses to the stress of prolonged immobility and confined environment must be considered when testing cognitively and emotionally disabled individuals. Presently, performing competent brain imaging requires intensive time commitment and institutional support (Rosen and Gur, 2002).

The field of fMRI is evolving into data-intensive, big data endeavor with large databases and masses of data being shared around the world. At the same time, ultra-high field MRI scanners are now available producing data at previously unobtainable quality and quantity. Both aspects are leading to changes in fMRI data analysis methodology (Lohmann et al, 2013). Moreover, imaging genetics, a research approach in which genetic information and fMRI data are combined to investigate neuromechanisms linked

to genetic variation (Hariri and Weinberger, 2003), is trying to incorporate new sources of biological information such as whole genome sequencing, proteomic, lipidomic and expression profiles, ultimately hoping to improve and create therapeutic options for psychiatric and neurological disorders (Meyer-Lindenberg, 2012). Challenges of big data include data storage, search, analysis, sharing and transfer. Shared databases among neuroimaging consortia can lead to data banks that require specific security and de-identification measures, due to the level of complexity, quantity and quality of the data obtained of individuals and populations and since some cranial features acquired during imaging could possibly be used to re-identify volunteers as well as for example particular genetic profiles. Risks related to the crossing of information and the limits of de-identification and anonymization are considerable, even if the most effective methods are used. Further complicating the issue of brain databases is the discovery of incidental findings on secondary analysis of the data. Lessons learnt from ethical considerations of genetic studies can be used (Illes et al, 2007).

A model example of the ethical implications of fMRI in the context of neurodegenerative and psychiatric diseases is Alzheimer's disease (AD). This has been the subject of extensive reviews and reports, for example from the Alzheimer's Association (www.alz.org) and the Alzheimer's Disease Neuroimaging Initiative (ADNI) (http://www.loni.ucla.edu/ADNI). Functional MRI has been used to increase the sensitivity and specificity in diagnosing AD, predicting who is likely to develop AD, and development alternative surrogate markers. Ethical issues have been organised thus: the medical and social consequences of predicting AD using functional neuroimaging, e.g. new meaning of the disease, and differentiating different clinical subtypes of AD; scanning protocols and modalities; research and clinical ethics issues, and stigma; key issues for education, counselling, and communication.

The screening of patients will vary depending on whether fMRI is effective at diagnosing the progression of AD or can result in the selection of a possible treatment, which can actually reverse the pathologic changes and cure patients. National and international laws and guidelines for research need to be carefully considered in the research design, especially since there may be a negative risk-benefit for individual AD volunteers often recruited from the pool of vulnerable subjects (e.g., mentally disabled persons). Autonomy, cognitive privacy, and cultural sensitivity should also be considered as highlighted in the Belmont Report (Illes et al, 2007).

2.6.1 Recommendations

Results from fMRI imaging can lead to tension between academic and medical investigators on the one hand, and commercial service providers and their customers on the other:

- Members of the neuroimaging community should be engaged with ethical issues when they undertake fMRI research, particularly in the context of neurodegenerative and psychiatric diseases. Across various cultures, values differ in terms of what defines benefit and risk, who will benefit and who is at risk, what methods must be in place to assure the maximum safety, comfort, and protection of subjects and patients, and educational and policy needs. Researchers should be motivated by ensuring public understanding, external forces, requirements, values, and press and public.

- Potential barriers should also be acknowledged: lack of resources, administrative burden, relevance to the research, and lack of interest.

- It is always important to consider fMRI in context, i.e. fMRI markers must be correlated to other biomarkers of underlying cellular and molecular mechanisms. It is important to consider translational fMRI in the connectivity paradigm, and clinical decision support, especially in drug response prediction (Bullmore, 2012).

- Persons with neurodegenerative and psychiatric diseases should also be engaged in discussing the potential role of fMRI in mitigating stigma. This can be done by supporting explanations of mental illness as an imbalance of brain chemistry; legitimising psychiatric symptoms, which may have previously been de-legitimised since they lacked objective representation (Buchman et al, 2013).

- It is also important to consider two norms: ethical transparency and ethical reproducibility, i.e. transparent reporting concerning the ethics methods, i.e., design elements related to ethics concerns undertaken in a study and critical engagement with, and learning from, the ethics practices of other investigators (Eijkholt et al, 2012).

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2.7 Implications of fMRI research

Philosophically, fMRI is a biomedical model of health that focuses primarily on biological processes. It is based on a positivistic and individualistic worldview, for example the risk of disease for an individual can be measured and predicted through an objective scientific method (positivism) and the individual has an explicit right to make use of, and personally benefit from, his or her genetic material (individualism). This is consistent with ideas of neuroessentialism: the brain is considered the ''self-defining essence of a person''. Neurogenetics and fMRI is constructed, ultimately, as the key for the blueprint (genetics) to understanding the self (Brief and Illes, 2010).
Yet positivism and individualism are predominant mostly within the context of Western ideas of consent, ownership, confidentiality, and benefit. In research with indigenous peoples or other groups with non-Western cultural practices or moral philosophies, it is thus important to link neurogenetic research with community-based participatory approaches, which consider holistic, rather than reductionist, views on health and wellness.

Reciprocally, fMRI studies have the potential to contribute to philosophical problems. Research using fMRI has been conducted investigating moral reasoning (Chiong et al, 2013), social emotions (Immordino-Yang et al, 2009) and conscience (Monti et al, 2010). Studies investigating conscience with fMRI methods are focus of much debate. A recent fMRI study reported awareness in four out of 23 patients (one in six) by wilfully modulating their brain activity through mental imagery, for example by imagining playing a tennis game, who had been diagnosed as being in a vegetative state (Monti et al, 2010). Functional MRI cannot provide any direct measure about conscious awareness, but can be used to provide diagnostic information about the severity of the patient's functional impairment, based on topological changes of functional brain networks, and this may allow a more accurate prediction of the clinical outcome in the future. Thus there must be careful consideration of technical and methodological limitations with respect to potential patient benefit and burden (Schwarzbauer and Schafer, 2011).

A pragmatic approach to neuroethics in fMRI should also address the challenges and ethical implications from the perspective of patients. Self-identity may be affected by fMRI results, for example in autism. Patient accounts of the experience of living with autism have revealed a view of autism that stands in stark opposition to the biomedical model, since they have unique ways of experiencing the world. To illustrate, Temple Grandin once stated, "If I could snap my fingers and be nonautistic, I would not – because then I wouldn't be me. Autism is part of who I am." The importance of such personal accounts allows us to measure whether researcher and/or clinician priorities are in line with the priorities and preferences of the individuals themselves.

To best serve these particular populations of individuals and their families questions need to be asked, such as what aspects of a person's identity, integrity, and sense of personhood would the results from such imaging techniques bring about? What, if any, level of change is ethically appropriate (Racine et al, 2011)? Functional MRI is posing some serious challenges to our conceptions of free will and moral responsibility.

2.7.1 Recommendations

- The inclusion of different patient cultural perspectives in the conduct of research will help ground research within a concerted and collaborative framework to respect values and social diversity (Racine et al, 2011).

- The understanding of complex, fundamental problems like consciousness benefits from multidisciplinary approaches.

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2.8 Science communication and the power of images

In order to fully appreciate the nature of at least some of the ethical issues that arise from the use of fMRI, a discussion of the power of images and pictures and what they convey will be helpful. Particularly where fMRI is used outside the clinical or neuroscience research setting, i.e., beyond the reach and interpretative expertise of neuroimagers, the reactions these images may elicit within the lay public need to be understood by those using the technique. Brain images, in particular, are arguably more potent than images involving other body organs given the brain's centrality in Western culture and the irresistible inclination humans have to seek simple explanations to even the most complex questions. The media often exacerbate this tendency by oversimplifying the explanatory value of images in neuroscience. (Indeed, neuroscientists may also do this, although likely inadvertently). Even neuroscience itself can confer an aura of credibility when invoked by the press (Kulynych, 2002).

Much has been written about the power of images to persuade. Indeed, there are some images that are so iconic that we can picture them mentally by a mere description of the image. For instance, there are likely few Westerners who would not immediately conjure the correct image at the mention of Leonardo da Vinci's "Mona Lisa." An even more powerful category of images, photographs, have a sort of evidentiary persuasiveness that other types of images lack (Meskin and Cohen, 2008). And it is our reaction to and interaction with photographs that is most at play in fMRI, because brain images have been the preferred media to communicate fMRI science. The lay public, scientists, science communicators in general and the media all play roles in how fMRI

images are perceived and discussed. However this first needs to be understood with respect to the significance of photographs in general.

"Seeing is believing"

From the earliest days of photography, we have been accustomed to understanding photographic images as two-dimensional visual representations of the objects they depict[1]. While not completely literal (due the lack of a third dimension), photos can reveal fundamental information about the characteristics of the subject of the photo. Further, with the exception of photorealist art (e.g., some of the early works of artist Chuck Close), we do not confuse photographs with paintings – we recognize, and give more credence to, photographs. Indeed, in the era of cell phone cameras, Instagram, Pintrest, Facebook, Twitter, etc., we have become ever more receptive to documenting and sharing visual representations of ourselves and/or the things around us. We value photographs as the next best thing to "being there." There is a marked difference in how we react to hearing about devastating natural events (earthquakes, tsunamis, hurricanes, typhoons, etc.) and seeing photographs or film footage of the devastation. In this case, we are more inclined to believe what we see. Invariably, however, we often confer validity to a photograph, which may or may not be justified by the circumstances.

Our penchant for investing evidentiary weight into what we see carries over into other realms, including viewing images associated with medical tests and procedures. For instance, an x-ray of a hairline fracture can provide the documentary evidence of an injury sustained in a fall – an injury that might not be obvious absent that imaging. But unlike x-rays, the images from which are relatively straightforward given even a rudimentary understanding of human anatomy, brain imaging (i.e., fMRI, SPECT, and PET) presents a host of challenges and idiosyncrasies that defy simple extrapolation.

With respect to fMRI, while the final images produced may resemble a photograph (especially to the uninitiated), they are not photographs. In fact, the data garnered through fMRI are far removed from final image of an object that looks like a brain with variously colored blotches. One commentator refers to this as "inferential distance" –

[1]Interestingly, from the beginning of photography, manipulation of images, either through technical means or through the staging of a photo's subject, was also a part of the craft of photography. For instance, U.S. Civil War photographer Matthew T. Brady occasionally rearranged dead soldiers' bodies on the battlefield for his photos, either for a more dramatic effect or for a more cohesive visual narrative of the nature of the war.

the difference between the image resulting from the fMRI and the neural activity from which the image is constructed (Roskies, 2008). Because fMRI images retain basic spatial information, and show some structures of the brain, if only in a rudimentary way, fMRI images may be assumed to be as evidentiary as photographs. Certainly the public and the media are unlikely to appreciate that fMRI is the result of correlates of neural activity, blood oxygenation levels, and statistical calculations. For the most part, they are inclined to see the brain-like image and attach the same credibility they would to a photograph. This inclination is reinforced by popular media, where fMRI has been portrayed as a "real time" process on at least one popular U.S. television show.

An additional potential complication to public understanding of fMRI comes from an interesting study conducted in 2008, which sought to demonstrate what the authors referred to as the "allure of neuroscience explanations" (Weisberg et al, 2008). The study found that non-experts in neuroscience (i.e., the lay public and students in an introductory neuroscience course) were more satisfied with explanations of psychological phenomena when they contained logically irrelevant neuroscience information than they were by the same explanations absent that irrelevant neuroscience information. This phenomenon suggests that persons who have limited understanding of neuroscience may well be more vulnerable to arguments that rely on these types of explanations when deciding whether to participate in research or undergo clinical procedures.

Limited public understanding of the process of producing neuroimages partly underlies another trend: commercializing neuroimaging scanning. While most of these operations (in the U.S.) involve single-photon emission computed tomography (SPECT), there are a few relying on fMRI, which purport to be the next generation of lie detectors. These companies all rely on the power of images to draw in potential customers. Used in a courtroom proceeding, a "photograph" of a brain with brightly colored spots that claim to represent a diagnosis, a proclivity, or a prediction of some aberrant behaviour could be more compelling than oral testimony. In popular culture, the entire notion of marketing and advertising are predicated on the power of images (and words) to persuade people to behave in the desired way – i.e., to purchase a specific product or service. Indeed, the relatively new field of neuromarketing is a testament to the strength of the association, and to deterministic thinking.

2.8.1 Recommendations

- The neuroscience community, science communicators in general and the media have an ethical responsibility to be mindful of the fact that the lay public will attach a lot of power to the images resulting from fMRI. The misunderstanding of what these images represent can inevitably lead to misuse of these images.

- The use of fMRI, particularly outside neuroclinical or neuroscientific environments, including other areas of scientific research, marketing, legal, employment, education, and military, where misinterpretation and over-interpretation of fMRI brain images is more likely to happen, should always be supported by objective neuroscience.

- In some situations the power of fMRI images may be responsibly used, for example in explaining diagnosis or prognosis in the context of psychiatric or neurodegenerative diseases or in planning a brain intervention (Farah and Gillihan, 2012).

- It is important to always bear in mind that fMRI is not intended as a standalone technique, whether in use in research, in the clinic, or beyond.

- It is a responsibility of scientists to clearly explain not only fMRI findings, but also the conventions and the meaning of fMRI brain images, the methodology behind the study and its limitations and societal impact of research. Sometimes statistical brain maps are not the best method to represent fMRI results, and the most appropriate science representation method should be chosen over the most appealing (Logothetis, 2008).

- Science communication and techniques of representation of fMRI results should be part of the curricula of fMRI teaching programmes.

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Research Ethics in Ethnography/Anthropology

by

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SUMMARY

- There is great variety in research methods in the social sciences and humanities (SSH), yet there are some fundamental ethical principles that are recognised by all. Some methodologies are complex and/or unconventional in their approach and so give rise to difficult ethical decision taking.

- Anthropology is the study of all aspects of human culture. Ethnography is a field-based research method – not unique to anthropology – employing observation and interviewing to investigate social practices and the meanings behind social interaction. Ethnology involves the systematic comparison of different cultures using ethnographic research methods to compare and contrast different cultures. The data produced tend to be descriptive and so require qualitative data analysis.

- In order to 'understand' human behaviour these approaches examine social processes in as natural a way as possible, using several connected research methods that focus on social interaction and communications. A reflexive awareness by the researcher of their effects on the people being studied is encouraged – usually through the use of a reflective journal written by the researcher.

- The basic ethical principles to be maintained include doing good, not doing harm and protecting the autonomy, wellbeing, safety and dignity of all research participants. Researchers should be as objective as possible and avoid ethnocentricity. Any deception of participants should be fully justified. They should not knowingly misrepresent or attempt to prevent reporting of misconduct, or obstruct the scientific research of others.

- The contribution that can be made to advancing human knowledge by the SSH disciplines may be obstructed or undermined if inappropriate ethical review criteria are applied to research proposals. Ethical review should be well informed, fair and transparent while seeking full justification for the proposed research.

- Ethical review should protect researchers, subjects and institutions in field sites from harm. Research ethics committees should ask: who is doing the research, what are they doing it for and how are they doing it? They should help in estimating risks of harm to participants, researchers and organisations and balance those against benefits that might accrue to society as outcomes of the research. Committees should strive to be consistent in their judgments and in the advice they offer to researchers.

They should be as objective and transparent as possible and 'independent' of institutional and professional biases and any form of vested interest.

- Research proposals should never be rejected as a consequence of methodological ignorance, prejudice or the desire to manage a research institution's corporate image. Above all ethical review must recognise that ethical decision making is not a static, one-off exercise. Only the field researcher truly confronts the unanticipated aspects of research as it occurs spontaneously while the project is ongoing.

- Given the intrusive nature of ethnography and anthropology in people's lives there must be 'good reasons' for conducting the research. Managing the 'trust' relationship between researchers and researched is vital. Ethnography is extremely skilled work and so requires competent, well-trained researchers, capable of making reasonable ethical judgments during the research. Researchers have a responsibility to each other and to prevent doing harm that will undermine future research work.

- Ethical codes have to be 'interpreted' and put into practice by the researcher in light of the substantive research topic and methodology employed.

- The manner in which research is commissioned, by whom and how the relationship between researchers and commissioners is managed is a key determinant of ethical practice. Poorly designed research is unethical since it wastes researchers' and subjects' time and energy.

- Concern for the rights and well-being of research participants lies at the root of ethical research. Vulnerability is a prime concern and the very young and the very old, together with those with learning difficulties are seen to be worthy of special attention in most societies.

- In qualitative research it may be impossible to maintain a neat distinction between covert and overt research. Settings are often more complex and changeable than can be anticipated.

- In ethnographic research samples are more likely to be small, purposive and/or theoretical. It would be inappropriate to require a method of sampling more suited to other research styles.

- A clearly written protocol is usually the first indicator of rigorous research but this is much harder to set out in advance in ethnography. The need for flexibility in approach has to be written in to the proposal and fully

understood by reviewers. Anthropologists are frequently engaged in longitudinal studies of their chosen communities and frequently seek return projects in order to investigate changes in the community.

- Anthropologists and ethnographers have to be aware of the range of ways their activities can cause distress to others. Ways of showing respect for research subjects can be embedded in both the content of research questions and the manner in which they are delivered.

- Researchers should detail the steps taken to minimise harm and to maximise benefits. Some overall judgement will then have to be made about the anticipated benefits of the project outweighing the *estimated* potential for harm.

- Anthropologists have to be highly attuned to who the gatekeepers are in different communities. Awareness of the balance of power between researcher and researched is vital. Ensuring participants have, and perceive themselves to have, adequate power to determine their role in the research is seen as ethically necessary. The ultimate test of the enhanced power of research subjects lies in their knowing that they have the ability to withdraw from the study at any point.

- Gaining consent cannot easily be separated from the giving of information. Subjects should be able to choose 'freely' to participate in research. They should have been given enough information about the research for them to know what their participation involves. In anthropological studies participants' consent may have to be treated as ongoing throughout the research engagement. Consent should be gained in the most convenient, least disturbing manner for both researcher and researched. If confidentiality and/or anonymity have been promised then the steps taken to ensure this should be outlined.

- Incomplete disclosure of research aims and methods may be justified if it can be adequately demonstrated that participants should not be told too much. This should only be considered if risks to the subjects are minimal.

- The monitoring of physical safety may be considered during ethical scrutiny – any potential risks to safety for subjects and researchers need to be addressed.

- Research should be conducted in accordance with the principles of the applicable country-specific national data protection legislation.

- Research subjects can act as more active 'participants'. They can become full collaborators or co-researchers, but allowing subjects an active research role is not ethically 'compulsory'. The wisdom of participant involvement very much depends upon the substance of the research, its aims, the proposed design, the methods to be employed and the anticipated consequences for the participants of too active an involvement.

- How to disseminate findings is also an ethical concern. Before dissemination it is important to judge whether or not the information released has benefits or contains the potential for harm. Thought must be given to what to publish, how to release findings and via which media.

- Even at the point of dissemination questions remain about the ownership of the findings and of the source data.

- New social media have given rise to innovative methodological approaches for ethnographers and anthropologists. These have given rise to new forms of community and personal identity for people that pose real challenges to the key ethical research principles of consenting, voluntary participation, and vulnerability. With this interconnectivity, understanding of *public* and *private* space has become more complicated.

- The EC's established and monitored ethical review systems can protect people being researched and help advance research standards globally. Anthropologists who conduct their research in a range of different countries and cultures, while upholding these values are, at the same, time promoting them globally.

- As multi-site, interdisciplinary and cross-national studies grow due to larger corporate commissioning the issues of ethical review become even more complex. Knowledge transfer requires partnership arrangements that may lead to aspects of joint research programmes being beyond the control of any single partner.

Background

This Report was prepared for the Ethics Unit B6, DG Research and Innovation of the European Commission (EC). The primary audience for this Report are ethics review committees or panels who might not be so directly familiar with the methods regularly adopted by ethnographers and anthropologists. There is nothing new here for practitioners of those disciplines, but it is hoped anyone with an interest in ethics review in ethnography/anthropology may also find the information contained here useful. Although there are some fundamental core ethical principles that can be applied to all human subjects research, the operationalisation of those principles varies according to the methodology adopted. A wide variety of research methods can be found within the social sciences and humanities (SSH) – for this reason the contribution that can be made to advancing human knowledge and scientific understanding from the SSH disciplines may be obstructed or undermined if inappropriate review criteria are applied to research proposals. Ethical review should be informed by the underlying theoretical and methodological assumptions of the discipline which frames the research proposal. This requires the provision of a full justification of the research approach from the research proposer, together with a properly constituted and competent review panel and a robust, fair and transparent review process.

Section 1 in this paper deals with basic theoretical assumptions and methodology. Sections 2 and 3 establish the ethical principles by which all scientific research should be assessed. In section 4 those general ethical principles are applied to the 'special consideration' that needs to be given to given to ethnographic and anthropological research, given the nature of its theoretical assumptions and primary research methods. This paper draws on previously published material – Iphofen (2011), Iphofen, Krayer and Robinson (2009). I am grateful for the comments made by a range of experts to improve upon the first draft of this Report and particularly wish to acknowledge the constructive contributions to this final version made by Prof. Robert Dingwall.

1 Terms, Concepts and Definitions:

Disciplines and Method

Anthropology is a long-established 'discipline' with some sub-disciplines. For the purpose of SSH in the European Commission our focus is on what is called social anthropology (for most of Europe) or cultural anthropology (in the USA) or ethnology (in some European countries). It is the study of culture within human populations, and is methodologically based predominantly on ethnography. Ethnography is a field-based/grounded, inductive method that employs forms of observation and interviewing to investigate social practices and the meanings behind social interaction. Since it is a method used in many social sciences in varied ways there needs to be consistency of approach in review.

Social anthropology covers kinship and domestic/family structure, social, economic and political organization, law and conflict resolution, patterns of consumption and exchange, material culture, technology, gender relations, ethnicity, child rearing and socialization, religion, myth, symbols, values, etiquette, worldviews, sports, music, nutrition, recreation, games, food, festivals, and language.

Ethnography entails the study of a group through direct contact with its culture and social interactions. Ethnology involves the systematic comparison of different cultures using a range of ethnographic research methods to compare and contrast patterns within and between different cultures. In addition to covering similar topics to anthropology, ethnology is interested in notions of cultural invariants, universal taboos and concepts of 'human nature'. The topics and fields remain contested.

The discipline of anthropology and the research 'style' of ethnography present one of the more complex methodological and theoretical approaches within SSH. This is due to the range of theoretical assumptions that can inform the different directions research can take, and the multiplicity of methods that can be adopted to conduct the research. This has given rise to considerable disagreement even between researchers and theorists who are operating in these fields.

Ethnography can be simply defined as "…the observation, description, depiction and/or representation of lived social experience." Ethnographic approaches lay stress on the language and meanings that people apply to their own actions in given social settings and processes, assuming that subjects are accurately and authentically observed in their normal social settings when behaving in routine ways. Ethnography is a way of studying peoples' behaviour – language, culture, values, meanings and social organization – in everyday, natural settings rather than in formal research settings. It is best understood as a 'style' of research requiring the observation and description of people in their normal social context. It can entail large costs in time, money and energy but it represents the highest standards in qualitative research only replaced by interviews when resources are considered excessive. So ethical review should seek to prefer ethnography wherever possible.

Researchers vary in the degree to which they choose to participate in these social settings, from joining the groups under study, to observing them in a more covert, detached manner – thus adjusting how 'intrusive' they are in their subjects' lives. The researcher more often plays some part in the ordinary conversations and activities of people being researched, rather than conducting a separate more formal research interview. As a research 'style' it can make use of a variety of different research 'methods' – direct observation, interview, survey, secondary analysis of archival material (such as diaries and letters), focus groups and so on.

Ethnographic research may focus on a single case study, a group or sometimes even on the activity of a single person. This approach can highlight aspects of life patterns that are unique, particular, changing and new for different people and groups. It may allow research to be less dominated by the researcher's own preconceptions and perspectives at the expense of the views of the subjects being studied. This is particularly useful for studying a social group in ways that allow members' perspectives to be seen as "reasonable" or "understandable in their context". In complex societies it can also be useful for discovering *alternative* processes that may explain the apparently unusual behaviour of marginalized or deviant sub-groups in society. Ethnography can also serve to highlight the differences between what people say they do and what they actually do. By observing what people do and not just taking them at their word, we can find out more about the actions that they take, why they take them, and how they interpret their own actions in relation to the actions of others.

The data produced are frequently descriptive and tend to be subject to qualitative data analysis. The numbers of subjects studied depend upon the size of the group or community being studied and the numbers of researchers available to conduct the study. Ethnography tends to be conducted by small numbers of researchers for pragmatic reasons. The prime goal here is the attempt to access authentically produced data – to allow the data to emerge naturally and in an unforced way.

Ethnographic research 'styles' can be contrasted with other research activities that aim to uncover what is general, constant, or predictable for all human beings or members of a general population. Thus the *survey* approach asks fairly large samples of people questions about themselves and the *experimental* style attempts to systematically control social situations and their participants. Surveys are seeking greater generalization about a larger population, experiments seek to identify causal phenomena. But these fundamentally different styles can be used to complement one another and when used together may offer cumulative perspectives and insights into social phenomena.

The broad theoretical assumptions of ethnography

These are sometimes referred to as the "special commitments" that are attached to the use of ethnography:

1) **Understanding and interpretation.** The *verstehen* tradition in the human sciences argues that all human actions are socially constructed and meaningfully intended. People do things for specific reasons and to attain specific outcomes. They are thinking, purposeful creatures communicating their intentions in a variety of ways.

2) **Social events are processual.** Social meanings are generated in a dynamic process of negotiation; this is not a static phenomenon. Human beings are engaged in movement and change – they sometimes initiate it and always have to respond to it. So meanings and intentions have to be actively established and maintained. (A good example of this is to be seen in the importance of the perception of the passage of time. Most people organise their world and their actions in it in terms of their perception of time. There are negotiations about time and its use.)

3) **Naturalism.** It is assumed that the artificial manipulation and control of subjects should be avoided – for accuracy and authenticity it is vital to observe them doing what they do 'naturally'.

4) **Holism.** Along with naturalism the inauthentic fragmentation of social life should be avoided. Scientific analysis sometimes segments peoples' actions and thoughts in ways which take them out of context. Attitudes and behaviour are to be seen as elements in a whole cultural context. Often actions and thoughts can only be understood in terms of the social network that individuals belong to.

5**)** **Multiple perspectives.** A fundamental theoretical assumption is that there is always more than one way of looking at or talking about things. This implies the avoidance of any 'dominant hierarchy' perspective. This requires guarding against assuming the necessary superiority of any one scientific perspective or any one 'worldview'. People hold different perspectives according to their particular social situation. This might mean different people holding different perspectives on the same situation or event. It also means the same people holding different perspectives when in different contexts or at different points in time. It suggests a kind of 'relativity' about how we understand the world. It is does not assume that there is only one, rational, efficient, or correct way to do things – attitudes, values and behaviour depend upon social and cultural circumstances.

Ethnographic research methods

The authenticity and humanism of the ethnographic method relies on adopting a research approach which resembles an extension of what we do in ordinary everyday life. The difference is that the researcher is self-conscious and preserves a permanent retrievable record of their observations and activities.

a) **Multiple methods** are used. Mostly these are different forms of participant observation. There will be a 'sampling' of time, people and events since the researcher cannot be everywhere and with everyone. This is not the kind of sampling 'frame' employed in quantitative data analysis – it is still the basis for controlled, systematic data collection. **Triangulation** is often advocated in which a range of different methods are systematically used to avoid the threats to validity which may be embodied in any one method – thus interview, unobtrusive measures, documentary sources and, even, a survey may be employed. This requires full understanding of what it means to adopt a 'multi-methods' or 'mixed methods' approach and there is an extensive and growing literature on the complications of mixing and/or multiplying methods.

b) **Progressive focusing** takes place whereby one begins with broad ideas or observes general spheres of interest. Sensitising concepts may be developed which illustrate general or specific problems within the group. Significant persons and/or significant events are noted. Several 'hypotheses' about what people are doing or why they are doing it may be 'tested' in a speculative sense rather than via a formal statistical probability test. It is more like estimating whether a particular explanation seems to 'work' or be adequate for understanding what is going on. A similar approach is also used in the natural sciences – such as with 'critical' experiments in chemistry.

c) **Reflexivity** is required in which the researcher maintains self-awareness. The researcher must be aware of the consequences of their presence for what may be found out. The findings may be influenced by the researcher's presence either by producing thoughts or actions which are not normally engaged in, or by discouraging people from revealing as much as they normally would.

d) **Establishing a role** which is acceptable in the research setting is essential. The researcher can even be an 'acceptable incompetent' – someone who lacks expertise and knowledge about those being studied but is still treated considerately. The more a researcher participates with a group, the more they will have to confront problems of role conflict. Being both a researcher and a member of the group requires careful management of social interactions. While establishing a role the field of research has to be 'cased'. Casing the field requires establishing the suitability of setting and informants, the feasibility of research, tactics to be adopted, access (to key informants and via gatekeepers), and mapping of the range of social settings in the field.

e) **Theoretical sampling** takes place in which appropriate conceptual categories are discovered and developed. These might be samples of behaviour or of conversation or of disclosed attitudes and so on. Those are chosen which are most likely to permit the development of 'theory' – that is, good explanations for the behaviour being studied. Theory involves moving from the first order generalizations that account for the specific observations to more abstract second order generalizations that allow those conclusions to be translated to other settings removed in time and/or space.

Cases are analysed until new categories and properties no longer appear – when *theoretical saturation* is reached. Theory is more often generated during the research process rather than anticipated beforehand and 'tested' by the research. (Such an approach is inductive rather than deductive – starting from observation and working towards a theory, rather than beginning with the theory and testing it by observation. Of course this does not preclude hypothetico-deductive work where a series of case studies have developed a second-order statement that can be tested under different conditions to determine whether it remains true.)

This is the key to explanation in ethnography. Generally, although the 'causal' power of experimental or statistical control methods is lost, the explanatory power of ethnography lies in the use of a comparative method called **analytic induction** this entails:

1) starting from a rough description
2) developing a hypothetical explanation
3) studying a number of cases from the same or different comparable settings - searching for both 'typical' and for 'critical' cases
4) if the initial hypothesis does not explain, it is reformulated or replaced
5) possible negative cases are continually sought
6) this proceeds until no new counter examples are found either in the field or by referring to other case study reports and integration into the broader published literature.

……

In summary these disciplines and this research method is necessarily processual, dynamic, and usually fairly longitudinal and may employ a range of standard research methods (observations – participant and non-participant/overt or covert, interviews, focus groups, surveys, field 'experiments' etc.) singly or in combination.

2 Basic Principles of Research Ethics:

Codes and guidelines

As with other fields of study in SSH, anthropologists may follow a range of ethical codes and/or guidelines. Adherence to *codes* tends to be treated as a professional requirement that could lead to expulsion from some professional associations if they are transgressed. *Guidelines* are regarded as educative or advisory without institutional sanction but are intended to be used by researchers in support of their own resolution of ethical dilemmas. In all cases they are seen as 'frameworks' within which to consider the frequent conflict and tensions inherent in ethical decision-making.

Most ethical codes/guides are structured in terms of sets of responsibilities or obligations to different sectors of societies or communities. Typically professional anthropological institutions suggest these include the following categories. Responsibilities to…
…those being studied (subjects – human and/or animal – individuals, groups, communities),
…scholarship and science (colleagues within the discipline or profession),
…the public (society at large),
…funders/research commissioners,
…researchers' own and 'host' governments.

Ethical Principles

Underlying these frameworks are some basic ethical principles. These include doing good (beneficence), avoiding doing harm (non-malificence), and protecting the autonomy, wellbeing, safety and dignity of all research participants. This means that anthropologists should ensure that their research does not harm the safety, dignity, or privacy of the people with whom they work, conduct research on, or with whom they perform other professional activities. They must seek to ensure the psychological wellbeing, or even the survival of those they are studying, carefully and respectfully negotiating the limits of the relationship between researchers and those being researched. They should maintain as objective as possible a comparative analytical stance and avoid ethnocentricity. They should not normally deceive their subjects without good reason. Nor should they knowingly misrepresent (i.e., fabricate evidence, falsify, plagiarize), or attempt to prevent the reporting of misconduct, or obstruct the scientific/scholarly research of others. There is an obligation to make use of the results of their work in an 'appropriate' fashion. Individual researchers may choose to move beyond disseminating research results to a position of advocacy on behalf of their subjects. Dissemination and reporting of research findings must be done with a view to the basic principles of beneficence and non-malificence. (See the American Anthropological Association, and the Association of Social Anthropologists of the UK and Commonwealth.)

3 Formal ethical review criteria:

Formal ethical review exists in order to protect researchers, subjects and institutions from any harm that may be consequent on a research engagement. In simple terms research ethics committees (RECs) should be asking: who is doing the research, what are they doing it for and how are they doing it? When incorrectly administered ethical review can obstruct or inhibit research and, at worst, has been charged with being anti-democratic and restrictive of academic freedom. To protect research review against these charges there needs to be enhanced professional involvement in it to ensure it becomes facilitative of research and in the raising of ethical awareness amongst researchers. It is especially important that any ethical review committee balances expertise, independence and 'lay' representation so it should contain experts in the research methodology/discipline that is being proposed, representatives of other research disciplines with methodological and ethical expertise, lay members (who might be considered representative of communities being studied) and independent experts in law and ethics. This may be difficult to achieve in anthropology, especially as expatriates or 'leaders' may have agendas of their own which they wish to promote. The committee should be aware of the relevant European legislation and the legislation of the host country or countries in which the research is to be conducted.

Ethical scrutiny can also be seen as crucial in attempting to prevent or reduce fraudulent scientific research. Real damage can be done to an entire field of study from even just a few highly publicised cases of research misconduct. Ethical decisions must be reached in a transparent manner – researchers must be seen to behave ethically for the sake of the goals of the discipline and of the profession of social research. Formalised ethical scrutiny is intended to assist researchers in estimating and balancing risks of harm to participants, researchers and organisations and considering what benefits might accrue to society, groups, individuals, organisations and so on. Ethical review might include the requirement that a full risk assessment has been conducted to ensure the safety of researchers. It can also be a means for clarifying lines of accountability – about who takes decisions, on what grounds and who is responsible for errors and misjudgements. It offers external, independent and collegial mentorship/advice. And, to aid transparency, it provides the means for retaining a systematic record of what decisions were taken and the reasoning behind them. It should also look at procedures for handling complaints and the redress of grievances against researchers and research organisations.

Responsible researchers have to be aware of the process of ethical scrutiny that is required for certain topics, in certain organisations, with certain categories of people and/or in certain geographic locations. Some countries have established genuinely systematic procedural operations through which all researchers must go to gain public funding – but this is by no means universal and presents particular problems for anthropologists operating in communities in which moral values and norms can differ from those of the originating researcher. Similarly legislation might be applied to varying degrees in geographical locations review committees might not be fully versed in.

Committees should strive to be consistent in their judgments and in the advice they offer to researchers. Their judgments should be as objective and transparent as possible and 'independent' of institutional and professional biases and any form of vested interest. Research proposals should never be rejected as a consequence of methodological ignorance or prejudice. A peer supportive collegial dialogue between researchers and ethics committees is necessary. Ethics is about balancing harms and benefits and so the probability estimate should have to do with the chances of harm coming to individuals balanced against the chances of such harm outweighing the potential benefits. This represents an attempt to ensure harm is minimised or avoided and that benefit is maximised. Time-consuming delays due to administrative complexity can be addressed by establishing appropriate procedural mechanisms (such as the availability of self-completed, online review application forms; recommended proformas for consent letters; standardised participant information sheets; and so on). But it is particularly vital in anthropological/ehtnographic research that such mechanisms should not restrict the flexibility of researchers in adopting and introducing novel procedures for giving information and/or gaining consent that might be more appropriate to the people they are studying.

Above all ethical review must recognise that ethical decision making is not a static, one-off exercise. Only the field researcher truly confronts the unanticipated aspects of ethical research as it occurs in a dynamic, spontaneous manner. Ethnography in particular is all about building relationships in the field with people and so it is hard to anticipate what ethical issues might arise at the commencement of a study – they can crop up continually and surprisingly throughout the project. So to be inclusive and reasonable ethical scrutiny needs to allow for such variation in methodological approach.

Good review requires addressing ethical issues at all stages of the research process – from specification, through tender, the ongoing monitoring of a project in action and its final dissemination. But the requirement for review should be proportionate to risk. Some projects clearly present little risk to any of the participants – in which case some form of 'expedited' procedure is advised. This might include allowing the Chairperson to take action alone or offering appropriate review by a sub-committee. As the 'repository of knowledge' held by ethics committees grows – either in formal recorded decision notes or simply through members' experience, so too grows awareness of minimally problematic methods and techniques – in such cases more expedited reviews could be conducted and fuller consideration reserved for evidently more ethically complex projects.

Similarly we expect a great deal from RECs when we expect them to be adequately comprehensive in their judgments when, increasingly, research projects address complex questions drawing upon multidisciplinary perspectives and multi-professional teams of researchers. In practice what we seek from RECs is a balancing of responsibilities between individuals (field researcher and research manager) and institutions (employing organisation and professional association) – thereby achieving a form of distributed collective

responsibility. Ethical research practice becomes a mutual accomplishment of all participants – research subjects, researchers, commissioners, funders and managers (Iphofen, 2011: Ch 13).

4 Ethical Decision Making with reference to Ethnographic and Anthropological Research:

The following sections are drawn from Iphofen (2011) but applied specifically to ethnographic and anthropological research. References have been sought from international professional associations guidelines and 'novel' ethnographic research that makes use of the Internet:

a Justifiable 'interventions'

Given the nature of the 'intrusiveness' that ethnographic approaches normally adopt, good reasons have to be given for 'interfering' in people's lives to such an extent. The question "Is this research really necessary?" is essentially an ethical one. Primary anthropological research is likely to take up considerable amounts of participants' time, entail a fair amount of intimate questioning and/or observation of their behaviour and attitudes. For these sorts of reasons a full rationale would have to be offered for the research being conducted with those particular people, at the chosen site, with the specified forms of research engagement (research 'instruments' or methods) and for the proposed length of time. Providing such a rationale offers an opportunity to clarify the benefits accruing to the research participants or the communities or groups to which they belong – this is usually termed 'benefit sharing' (e.g. see Peterson 2001, Diniz 2008).

The 'trust' relationship

The focus upon qualitative data that ethnographic research entails implies a different form of relationship with research participants. This relationship can be summarised under the concept of 'trust' and tends to be of a more humanistic nature than research that produces quantitative data (Miles and Huberman 1994: 292). Quantitative data analysis is at one remove from the human nature of the subject from whom it was generated. Qualitative data remain methodologically closer to the values, meaning, intentions, aspirations and goals of the human subject. In that sense this is a more 'personal' kind of research. But this does not mean that those engaged in quantitative data analysis are immune from the need to consider their trust relationship with society and those from whom the data they are analysing were generated. Nor does it mean that qualitative data made available for secondary analysis removes the mutual 'trust' obligations implied in primary research engagements. Thus personal biographies (even if posthumously conducted and published) raise similar ethical considerations as biographical data gathering from live individuals (Roberts 2002).

Researchers have advocated making a very clear statement of the relationship between researcher and researched such that the goals and anticipated consequences of research for those being studied should be clearly stated at the

outset. Howard Becker (1967) argued that it is not that we shouldn't take sides – we inevitably will – what matters is that we make it clear, to ourselves and to others, whose side we are on (see also Hammersley 2000). Some ethical guidelines for research with children in the developing world even suggest that if the proposed research does not directly benefit the children involved or their community then it should not proceed (Schenk and Williamson 2005: 15).

Funders' motives

Who is funding the research and what they wish to do with the findings has long been a key professional issue within anthropology and now concerns the trend toward 'evidence based' policy making. While researchers want to claim benefits for their activity, they are rarely in control of the use to which their findings may be put. Researchers have complained about being commissioned to conduct 'unnecessary' research which a government wishes to have conducted to support its policies – and when the research fails to support a favoured policy it might even be suppressed (Tombs and Whyte 2003, Dingwall 2010). Moreover many researchers take the knowledge of their accumulated research evidence with them when they accept roles on governmental advisory committees. To assume that such evidence is necessarily 'counted' when it fails to fall congruent with government policy is naïve to say the least.

The wide range of theoretical perspectives available to anthropologists, and variations in perspective can influence research design. Consequently the particular theoretical perspective that informs the researchers' work should be made explicit from the start of the project. This need not be rigidly observed of course, since theoretical positions may change as empirical data emerge and some ethnographers will insist that they hold no rigid theoretical position.

b Researchers' competence

Ethnography is extremely skilled work – balancing being a member of the group as well as collecting data can be quite complex. Researchers should demonstrate that they either have these skills or provision is made for them to acquire them through training and practice. This is particularly important in anthropological studies since the individual researcher has high responsibility for the correct moral behaviour being adopted since only they in practice know the detail about what is going on and where the research is taking them. They will be the first to notice if harm is being done or if there is a potential for harm to be done as the research progresses. Qualitative data gathering, in particular, is a 'coalface' or 'street level' activity. Often the individual researcher is involved in a direct relationship with the respondent or individual or group under study – either in observing them, asking questions or participating in their daily lives in some way. This is an extension of the 'trust' relationship mentioned earlier.

Judgements 'in the field'

Field researchers engaged in collecting and analysing data will be aware of any 'filtering' or 'data reduction' principles they are applying. They will also be aware of whether or not they are putting some pressure on subjects to participate and the kinds of pressure being applied. Furthermore it may be only as they are interrogating data that makes connections between various data sources that

something is disclosed about an individual that might not have been apparent from each of the sources alone. Ethical choices and moral dilemmas may arise at any point during the research process and to attempt to pass the problem on to a supervisor, or any other agency, is to evade it. The researcher 'in the field' and/or data analyst has an insight into the effects of the research process that may not be available to anyone else (Dingwall 1980). Moreover moral views are judgements that change over and through time. What was acceptable behaviour in any one group, community or society some time ago may not be acceptable now. Only the field researcher is actively aware of the implications of such change.

The field researcher's problem is to make a 'live' estimate whether an acceptable balance of harm and benefit is being achieved. And the judgement of the balance of harm and benefit frequently has to be taken in a dynamic, changing situation. A subject of a biographical case study, for example, initially might be flattered to be asked lots of questions about their life. But as questioning persists it might become more of a burden than they had anticipated – and this might present a particular problem for someone who may already be burdened by psychological or relationship problems, an illness, excessive physical pain or disability or, as can be the case in anthropology, is stigmatized or ostracized by the rest of the community for their involvement in the research.

Fluid and flexible decision-making

It is a fundamental assumption of ethnography that people experience life as an ongoing social process and it continues to be so even while they are being researched. What may have seemed straightforward and morally uncomplicated at the outset may turn out to be fraught with difficulty once a project is underway. Qualitative research is particularly characterized by '…fluidity and inductive uncertainty' (Mauthner *et al.* 2002: 2). Whether in surveys, focus groups or one-to-one interviews, unanticipated harm (and benefit of course) can emerge during a study when the only ethical decision-taker available is the researcher themselves. Only they can assess whether a particular set of questions is disturbing a respondent to such an extent that they cannot justifiably continue to ask them.

Of course researchers should not feel alone in coming to ethical decisions. They require the support of their employing organization, their professional associations and the mentoring of the REC that conducted ethical review. Lines of accountability and grievance procedures can offer further support and protection.

Contaminating the field

There has been a longstanding awareness in anthropology that getting ethical decisions 'wrong' can lead to a contamination of the field which has consequences for all other anthropological research. So the moral 'virtue' of researchers must be established and maintained. Researchers have a responsibility to each other, and to ensure their own continuing career and integrity as a researcher, to prevent doing harm that will undermine future research work. It is not that they can always be expected to not make mistakes –

but that genuine errors are admitted, remedied and avoided in future. Contamination of the field diminishes public trust in the act of research and in the actions of other researchers thereby effectively hindering future access to respondents and undermining the value of any knowledge produced.

Codes and guidelines

Similarly professional associations can offer ethical codes and/or research guidelines in the form of generic principles that will have to be 'interpreted' and put into practice by the researcher in light of the substantive research topic and methodology employed. Pragmatic codes necessitate a form of ethical pluralism that reflects and assists 'real world research' (Robson 1993). At base all codes recognise the central dilemma of ethical research – the balancing of the potential benefits to be gained with the potential for causing harm. Most codes address questions such as: what sorts of benefits are we talking about and who actually gains? What sort of harm could be caused and who might be harmed?

For methodological as well as ethical reasons, the use of a reflective research journal or diary has had a long tradition within anthropology. It acts as a retrospective check on reliability and validity but can also aid the researcher in active ethical decision making. By keeping a diary researchers will necessarily reflect on their actions and consequences for research participants.

A major debate within the professional associations has always been about how sanctionable ethical codes or guidelines can (or should) be. What powers of exclusion, reprimand or proscription can be applied by the professional association to any member who transgresses? Some associations have constituted disciplinary committees which can exclude or punish members who bring the association into disrepute. Others believe that ethical guidelines function better in an aspirational manner or as 'educative' prescriptions – advising the researcher on proper behaviour, assisting their judgments, but ultimately leaving the individual researcher to make their own ethical choices.

Professional training

Novice and/or student researchers can represent a threat to the professional standing of social researchers if they are released into the field without adequate guidance, support and preparatory training. The increasing complexity of ethical scrutiny and research governance has led some higher education institutions to prevent students from conducting live research projects – instead rehearsing with families, friends and fellow students. Internship could allow students to accompany trained researchers on their projects and be closely supervised in specific research tasks. Without profound awareness of 'correct' behaviour in some communities, people can be irretrievably offended and research discontinued. This remains a particular concern of anthropological researchers and why they need to spend so much time 'getting to know' the people they plan to study and their customs and values.

A more systematic maintenance of ethical standards would recommend that researchers should be required to attend training courses and continuous professional development in ethical decision-making. At the very least this could

offer a way of ensuring that they have read and considered the available professional guidelines. Training would need to take place at a range of levels of experience – novices may not be able to anticipate all the kinds of things that could go wrong but more experienced researchers may suffer from complacency, the assumption that they are prepared for all eventualities and/or ignorance of the implications of new legislation. Anthropologists returning to communities they have studied for some time may not be fully aware of changes that have taken place since their last visit.

Relationship to research commissioners

Individual researchers can do a great deal to establish their own integrity while in the field and/or when publishing their findings. But the public image of the profession of anthropology as a whole is a much more difficult thing to control. Government agencies have frequently recruited scholars and intellectuals for diplomatic and security services, but there is little doubt that, if known about, this can compromise professional integrity. For example, the CIA has recruited from the American Association of Anthropology (AAA) on the grounds that such professionals would possess vital linguistic and cultural insights into the communities and societies for which 'intelligence' is deemed 'vital to national security'. A US professor of anthropology, Felix Moos, has long advocated the importance of anthropologists supplying state agencies with information about other communities and societies to provide valuable insight into their language and culture. A programme (PRISP) was even set up to sponsor students who would subsequently work for the security agencies (see debate in *Anthropology Today* 2004/5.) This was discontinued when the Association realised that such plans '…threaten to compromise the ethical foundations of the discipline' (See *The Times Higher* December 16 2005: 10).

In 2006 the UK Foreign and Commonwealth Office (FCO) funded a project for the Economic and Social Research Council entitled "Combating Terrorism by Countering Radicalism" which drew letters of protest from major professional research associations on the grounds of endangering both the lives of researchers and future potential field studies. It looked as if researchers were being recruited to act as spies for British intelligence in countries identified by MI5's anti terror unit. As a consequence of the complaints the project was withdrawn but re-launched the following year as: "New Security Challenges: 'Radicalisation' and Violence - A Critical Reassessment", The FCO said it would withdraw its proportion of the funding for the project if the places and topics specified in the first project were not covered - "if its interests (were) not met by the selected projects". (ESRC 'ignores' danger fears, *The Times Higher* 20 JULY 2007 http://www.timeshighereducation.co.uk/news/esrc-ignores-danger-fears/209666.article.)

The US military employed anthropologists during the conflict in Iraq to map what they call the 'human terrain system' (HTS) and to advise commanders on local culture and social networks. Those anthropologists who support such collaboration argue that the military can do its job better – even if that means that they are assisted in targeting the insurgents better. Others complain that this merely means supporting the US Government in conducting a bad mission

better. The AAA recently formally discouraged its members from taking part (Jacobsen 2008). But the temptation is the offer of secure employment and some may even be motivated by a sense of patriotism. The overall US governmental research budget for social science, influenced by the Pentagon, has increased substantially. The risk is of a public perception of all social scientists as potential spies and supporters of armed aggression (See for further detail: Price 2004, 2008, 2011).

So the final determinant of the trust that can be accorded to a researcher and/or their research project is related to who is funding the exercise. The responsible identity and moral worth of a researcher is certainly compromised in the eyes of the public and research subjects if their work is being financed by an 'untrustworthy' commissioner. Such a perception is certainly in the eyes of the beholder. For example, those opposed to smoking will distrust the motives of any research funded by tobacco companies, in spite of claims to its objectivity. Whatever one's moral judgement on the examples of military-inspired funding offered above they at least relate to funding sources within a country linked to that nation's own goals in international policy. Interesting dilemmas have to be confronted when researchers accept funding from internationally proscribed regimes on the grounds that they should be allowed the 'freedom' to choose research appropriate to their own professional and theoretical interests. For example, the School of Oriental and African Studies, within the University of London, has received funding in the past both from the military dictatorship in Burma and the ultra-conservative Iranian regime (Baty 2000). The manner in which research is commissioned, by whom, and how the relationship between researchers and commissioners is managed is a key determinant of ethical practice.

c Research Quality and Design

It is generally accepted that poorly designed research is inherently unethical since it wastes researchers' and subjects' time and energy if the results are less than useful. It may produce more disbenefits such as a contamination of the field by discouraging participants from future research engagements which may be of better quality. Concerns for quality represent an attention to the 'scientific' standards of the project. Undoubtedly there are overlaps between scientific quality, methodology and research ethics.

Authentic qualitative data

Qualitative data gathering necessarily 'sacrifices' control over potentially influential variables in favour of accessing the authentic and natural behaviour and attitudes of those being studied. This means methodologically seeking not to deprive participants of their power to act as they would even if they were not being studied. Fortunately, this is consistent with the broader ethical purpose of seeking not to take away power from subjects, to preserve their autonomy and to behave as democratically as possible in the conduct of the research. But it would be dishonest to imply that the qualitative researcher needs no power to direct the research. They will choose to adopt methods or practices that are intended to help seek answers to the set research questions and, therefore, entail some form of intervention into and direction of the lives of the people being studied.

Assessing 'vulnerability'

Concern for the rights and well being of research participants lies at the root of ethical review. Vulnerability is a prime concern and the very young and the very old, together with those with learning difficulties are seen to be worthy of special attention in most societies. Vulnerability is linked to the problem of routinely socially excluded participants and one might ask whether or not the potential for social exclusion in research was an ethical or methodological concern (or both). If we exclude individuals or groups from research we are limiting their access to 'normal' social relations, customs and activities that the majority of the population enjoy (i.e. they should have as good a chance of any other member of a target population of being included in research). So a 'right to participate' might be accorded to individuals/groups to avoid 'disprivileging' them. However if by including them we increase their vulnerability and expose them to risks they would not otherwise have experienced then we would be morally right to exclude them. So to reduce risks to the vulnerable we may intentionally exclude them. This is a particular problem for anthropologists studying societies with clear, rigid social hierarchies. The 'vulnerable' sector might be low down on the social hierarchy and the researcher may be tacitly challenging the social structure when taking vulnerable groups into consideration – and so not regarded as behaving 'objectively'. Balancing a 'right to participate' against a 'right to be excluded' illustrates, as most of these points do, the implicit paternalism of much ethics review. The ethical point is to have good reason for inclusion/exclusion and not to forget, ignore or exclude them only for research convenience or because it would be too difficult to find ways to include them.

Covert observation

When methods are compared there does seem to be a view amongst some observers that there are inherently unethical procedures. Covert observation is seen by some as particularly problematic since it necessarily implies deception – yet to let people know they were being observed might result in an alteration of their behaviour. In qualitative research it may be impossible to maintain a neat distinction between covert and overt research. Settings are often more complex and changeable than can be anticipated (Murphy and Dingwall 2001: 342).

Sampling

Asking whether a design is appropriate is the overarching research quality question since it incorporates most of all the other elements that go into making up a 'do-able' research project. This requires clearly stated research questions and clarification of the aims and objectives of the research. So the techniques of data collection, sampling and so on must be clearly appropriate to the methods adopted. To illustrate: one question that is invariably asked to test the rigour of a research design is the size of the population sample and how it will be selected. There is often an implicit status judgement that random samples are superior to convenience samples due to the level of inference and the assumed quality of the statistic that can be employed with different forms of sample selection. But all samples are 'samples of convenience' – the issue has to do with preventing the 'inconveniences' of sampling from impeding the collection of the appropriate data. Thus a street social survey taking a random sample must, once the

randomising criterion has been established (every 'nth' person being questioned) not choose to avoid the 'nth' person if they happen to be disabled (see Iphofen, 2009: Ch.10). Similarly it makes no sense to randomise a sample for a phenomenological study of what it means to be disabled – the design should ensure that the rationale for a 'purposive' selection of disabled people fitting a theoretically-justified category is made. In ethnographic research samples are more likely to be small and purposively sampled. Sampling design does depend on the budget and the research question – so random sampling is not necessarily 'excluded' in anthropological research. The point is that it would suggest ignorance of qualitative research methodology on the part of reviewers to insist upon forms of sampling more appropriate to other research styles.

Previous research

All research, whether primary or secondary, must demonstrate the ways in which it builds upon or adds to existing research findings. Only by doing this can the rationale for conducting the current project be justified. Primarily for reasons of 'quality' then researchers must demonstrate that, by conducting an 'adequate' exploration of the literature, they can show the need for conducting the current study and the remaining research questions that it is worth seeking the answers to and the ways the current proposal will add to the present state of knowledge. To replicate unnecessarily existing studies would be wasteful of time, money and energy. It does not mean that replication is never justified – the grounds for doing so must be made clear such as changes in the situational context leading to the existing data being outdated, or errors in the existing research subsequently coming to light or the need to replicate the research in successive historical periods, or alternative geographical or cultural locations for comparative and/or longitudinal analysis. Anthropologists are frequently engaged in longitudinal studies of their chosen communities and frequently seek return projects in order to investigate changes in language, values and norms and the external and internal factors leading to change.

Threats of non-completion

As a quality measure of insight into their design and methods researchers are usually asked to show ability to anticipate the threats to successful completion of a proposed project. Budgetary omissions represent such a threat and key items in a budget should be seen as clearly essential to the design. Costs of travel, subsistence and accommodation are vital to ethnographic studies since they can last for some time and may require repeat visits for reliability checks. An additional cost of anthropological research might be culturally expected 'gifts' to significant community members to secure participation or even allowing the researcher to be resident in a community. The same can be said of realistic timescales. A researcher that claims completion within an evidently difficult to achieve time is as suspect as one who underfunds the project. Establishing realistic project timetables requires demonstrable skills in project management. Evidence of this quality may be provided by a skilled design and the application of conventionally applied project management charts and programmes of study. This may be difficult to anticipate with anthropological research, especially if access to a community proves more difficult than originally anticipated.

Subjects reacting to research
All SSH research is now acutely aware of the 'Hawthorne effect' deriving from a series of studies conducted in the late 1920s and 1930s. The special lesson from this work for ethical anthropological research is related to how the subjects' awareness of being observed affected their behaviour. The information they received lead to such a degree of 'subject reactivity' that their behaviour could not be considered 'normal' – which undermined the value of the research. Another major criticism was of the developing friendship and therapeutic relationships between researchers and subjects. This was something actually encouraged within the project team on ethical grounds, and in terms of the quality of the responses they received. From the 1940s to the 1960s however this was perceived as lacking rigour and a source of empirical error. Interestingly the growth of ethnographic feminist research methodologies from the 1980s has led to a re-thinking of the value of sustained researcher/researched relationships – albeit as part of a critique of more *experimental* research styles (See Madge 1965, Oakley 2000 Ch.11).

The most noted example from anthropology is that of Margaret Mead's study – *Coming of Age in Samoa*. Under the influence of the eminent anthropologist Frans Boas, Mead had been led into offering the example of adolescence in Samoa as an example of a "negative instance" which could disconfirm the growing biological determinism of the day and which had fuelled the eugenics movement. She made some crucial methodological and interpretive errors in her investigations and subsequent analyses. Primary among them was not realising that the adolescents she had gathered data from had invented some outrageous sexual fantasies due to their own boredom and her obsessive interest in their behaviour. This essentially combines the error of too dominant a theoretical perspective with a Hawthorne effect leading her to 'discover' just what she was looking for (see Freeman 1983). In scientific research this is generally referred to as 'confirmation bias' or 'motivated reasoning'.

A clear protocol
Most ethical review committees will deem a clearly written protocol as the first indicator of rigorous research. They will seek to find the stages in the research project clearly flagged together with the precise ways in which each of the elements in the research question are to be addressed. Such protocols contain clear justifications for the steps and actions, for the time taken to achieve each of the essential tasks, when the 'deliverables' might be expected and in what form they will appear.

All this is much harder to set out in advance in ethnographic research. The particular skills required in seeking qualitative data include balancing the control necessary for systematic and rigorous observation against allowing genuine attitudes to be revealed and the behaviour of interest to occur naturally. In this instance what is assumed within so-called qualitative theoretical perspectives neatly meets ethical requirements – it requires that researchers don't interfere too much! The problem is how to do that in practice and ensure that the required data are actually generated – researchers cannot wait around forever for people to authentically reveal their views and/or spontaneously

engage in the behaviour of interest. Many research methods are precisely designed for the attitudes, knowledge and behaviour to be generated when researchers are around to collect them. Anthropology is not like that. One of my first supervisors told me of his work in studying the Sami people (Lapps) of sub-Arctic Northern Europe. He thought he had acquired a key position in the group when they appointed him chief reindeer herdsman. Unfortunately the reindeer and the tribe parted company for nine months of the year as the herd travelled the tundra. He learned a great deal about reindeer but much less about the Laplanders. So a carefully written research protocol in ethnography needs to clarify the areas of uncertainty as well as those that can be reasonably anticipated. Most importantly the need for flexibility in approach has to be written in to the proposal and fully understood by reviewers.

In all cases the 'quality' researcher is one that can judge the best balance between the data it is necessary to generate in order to properly answer the research questions against the prospect that the gathering and reporting of such data could result in 'measurable' harm to the research subjects. Justifiable design adjustments to minimise the potential for harm can still produce high quality research – but it takes a competent researcher to do that.

d Minimising Harm, Maximising Benefit

The heart of ethical scrutiny is the attempt to balance the risk of harm against the potential for benefits that can accrue to individuals, groups, communities, organisations and even societies from research participation. Consideration has to be given to the different kinds of harm, the likelihood of their occurrence and the ways in which they can be minimised. Concurrently ways of maximising both short and long-term benefits have to be explored.

Researcher/subject relationships

Roger Sapsford (1999: 41) quotes the feminist scholar Shulamit Reinharz who likened conventional research to the process of rape by their intrusion '…into their subject's privacy, disrupt their perceptions, utilise false pretences, manipulate the relationship and give little or nothing in return. When the needs of the researchers are satisfied they break off contact with the subject' (Reinharz 1979: 95). In part this may be due to an attitudinal problem with researchers and how they reveal that to their subjects. In brief encounters field researchers may have to collect a rapid response from many subjects – but they could still adopt a demeanour that leaves the respondent feeling valued. In longer term encounters the researcher may wish to go back to their office to add the data and continue their analysis, while the subject may need some 'closure' time and some opportunity to come to terms with a relationship that appeared to have friendship at its core but was, in fact, highly instrumental.

Forms of distress

Researchers have to be aware of the range of ways their activities can cause distress to others – even in ways that might seem surprising to themselves. To seek someone's opinions in a community merely because they fit a category of 'marginalised person' could lead to their lowered self-esteem. One can never anticipate the emotional effects an apparently innocent question can have and

which might even catch the respondent by surprise. Again questions which a researcher considers harmless or uncontroversial may cause embarrassment to a respondent – particularly so if they were not expecting such a question. Questions carelessly framed subtly show disrespect for respondents by placing them in embarrassing situations.

Misperceiving the purpose of the research could raise false expectations about something being done, say, to 'solve' a problem facing a community. This might be connected to subjects failing to understand how research evidence becomes the property of a commissioning or funding body – it might not be in the interests of such agencies to effect the change the respondents might have been hoping for. Hence there is a responsibility on the part of the researcher to make clear the limits on action that can be taken as a consequence of conducting the research.

Psychological distress might be more likely to be a consequence of social research than physical harm or illness but the dangers of physical exertion in, for example, standing too long to answer questions must be considered. Sometimes it is equally difficult to identify the social harm that might be consequent on participating in research. Some communities might ostracise or even physically harm an individual who had taken part in research which they might perceive to have put the rest of the community at risk. Other social harms are much more diffuse. For example merely by deciding to research some topics and subsequently reporting them brings them into public prominence and either encourages the 'spread' of the practices being investigated or produces an adverse societal reaction to a marginal group who wished to be quietly allowed to get on with their marginal or socially deviant activity since it was doing no harm to others.

Material harm

The most common economic deprivation to be suffered by research participants is their giving of 'free' time. This is frequently compensated for with gifts or other material rewards – all of which may have consequences in the larger community. Participants' very livelihood could even be put at risk.

The legal consequences of research participation are likely to inhere in the respondents offering information that implicates them in illegal activity or discloses their involvement in criminality.

All of these harms can arise out of participation while others may be consequent on certain categories of people being excluded. If a research project fails to explore the situation of illegal immigrants in employment, for example, by excluding such subjects on the grounds of protecting their anonymity and fearing legal obligations to disclose their identity, the true facts of their situation may fail to be disclosed and the production of policies designed to resolve their situation thereby hampered.

Having research subjects participate in the research design and in advising about the dissemination of findings may protect researchers from the charge of not adequately attempting to anticipate the harms that may come to them as a

consequence of participation. That in itself is no guarantee of their subjects' protection since subjects are no more able to anticipate some harms than researchers are able to do.

But risk of harm can be reduced by thinking through the consequences of the varieties of distress listed above. Psychological distress can be minimised by debriefing subjects after the research is completed to reassure them about the value of their contribution and also acquainting them with appropriate ongoing support. For physical damages or discomfort the possibility of reparation via insurance indemnity schemes should be prepared for. Both of these eventualities are unlikely to apply in more remote communities so researchers would need to think of alternative appropriate forms of compensation.

Respecting the subject

Ways of showing respect for research subjects can be subtly embedded in both the content of research questions and the manner in which they are delivered. The potential for social distress can be minimised by controlling the dissemination of research findings in ways that do not lead to community concerns about the contributions made by individual participants. Careful selection and use of language while conducting the research, ethnic and gender matching between researchers and subjects can all contribute to minimising communal consequences for individuals. Individuals might be just as culturally sensitive as they are personally so similar care should be taken over cultural differences – this in itself requires considerable awareness for what such cultural sensitivities might be and in anthropological research careful pre-knowledge of the community becomes vital.

Tacit benefits cannot be assumed to be understood and accepted by all. They might have to be indicated anew with each project proposal and for each new scrutiny committee. Benefits from social research accrue differentially to individuals, groups, organisations and society. Currently there appears to be general cultural acceptance that enhanced knowledge can contribute to the community and society if the accumulated evidence is sensibly applied. The generic pursuit of valued 'scientific progress' can be claimed and clarified to gain the support required and the understanding of the general public. While this might be evident in 'high income' societies, it may not be so in the kinds of low-income societies frequently studied by anthropologists. Indeed some kinds of 'knowledge' might even be seen as challenging existing forms of authority within the community and so disruptive of ordinary social life.

It is a researcher's responsibility to detail the steps taken to avoid or minimise harm and to maximise benefits. Some overall judgement will then have to be made about the anticipated benefits of the project outweighing the *estimated* potential for harm. If ways of reducing the potential for harm and/or maximising the benefit cannot be identified then doubts as to whether to continue the project have to be raised. Similarly if the balance of harms over benefits is seen to increase during the lifetime of the project the ethical researcher should consider discontinuing the work. (This might not be inevitable since the discontinuance itself devalues the contributions already made by the research

subjects. Discontinuing could be wasteful of resources, energy and commitment and so could be unethical.)

The only realistic way for researchers to conduct an assessment of this balance is to adopt a continual reflexive stance in order to conduct an ongoing estimate of harms and benefits and make both research and personal action judgements accordingly (Gokah 2006).

e Selecting, Recruiting, Retaining and Releasing Participants

The relationship with research subjects must be carefully managed and controlled at each stage of the research process. This means thinking about how subjects are chosen and encouraged to join a research project, how they are encouraged to remain in the project for the duration and how their withdrawal from a project is facilitated. The key questions include the equitable selection of subjects, resisting placing undue pressure on them to join and, equally, avoiding undue pressure in discouraging them from leaving. Awareness of systematic inclusion and exclusion of specific socio-demographic categories for reasons that are not linked to research design must be maintained and such systematic distortions avoided. The designed research focus may allow for the exclusion of certain categories of respondent – if so this must be achieved in as open and transparent a manner as possible. There may be explicit benefits accruing from being included in a research project, and these should be made clear at the outset – just as warning about disbenefits is essential.

Targeting the subjects

'Who' to access is largely a problem of choosing the most appropriate sample from the population and so is predominantly a methodological issue. All samples are, in fact, chosen more or less for convenience and/or purposively – even when randomized as discussed earlier. But 'how' people are accessed for research purposes remains both a practical and an ethical problem. It is hard to separate issues associated with accessing participants in the first place, re-accessing them as part of a continuing study, and remaining unimpeded in that access from 'gatekeepers' who may seek to control what participants may actually contribute to the study.

Anthropologists have to be highly attuned to who the gatekeepers are in different communities. Sometimes they can be formal authority figures and at other times appear to lack 'official' status but turn out to be the most influential member of the community. Such distributions of authority can operate entirely independently of matrilineality/patrilineality (sex-related inheritance lines) or matrifocality/patrifocality (power distributed according to gender) or other forms of social or economic structure.

Balance of power

Awareness of the balance of power between researcher and researched is vital. This may be even less clear in qualitative research studies (Murphy and Dingwall 2001: 344). When subjects make themselves available for study there is an implied loss of power in even allowing a researcher into one's life. The focus of the relationship is determined by the researcher's criteria, not by the research

subject – otherwise the relationship would not exist. By their interpretation and re-presentation of their subjects' lives, researchers are necessarily maintaining or challenging those subjects' location in the social hierarchy (Becker 1967).

To some extent exploitation of the subject is inevitable. People, opportunities, situations and meaningful spaces are all exploited to derive the 'rich, deep data' that is sought in qualitative research (Birch and Miller 2002). The establishment of rapport is an accomplished research skill and even friendship can be faked as part of the management of consent and the encouraging of continued participation. There is also a danger that researchers may expose themselves to unwanted personal consequences if they disclose too much about themselves as a rapport-generating strategy (Duncombe and Jessop 2002: 118-9). However, while there is a sense in which friendship is necessarily implied in the establishment of rapport and the development of trust, it is important to remember that the relationship is one of 'formal informality'. In all likelihood the relationship would not have existed without the need for one party to secure a research goal. There is a danger in the researcher seeking to avoid exploiting the subject to such an extent that no research goals are accomplished – that would be a waste of everybody's time!

Ensuring participants have, and perceive themselves to have, adequate power to determine their role in the research is seen as ethically necessary. This is a particular problem for children, old people, marginalized groups, or those with learning difficulties – all who may perceive themselves as possessing less power in ordinary relationships anyway.

In fact many research respondents assume that researchers are necessarily agents of 'the authorities' and may only reveal such information as they wish those presumed authorities to know. So researchers who are actually conducting projects on behalf of such authorities have a tricky balance to maintain. They have to gather the required information without being 'duped' by the subject or without misleading the subject as to the potential value of the research.

Finding and securing respondents, participants and interviewees for research projects raises the primary ethical concern of 'compliance'. Did subjects feel obliged to participate in any way? Were deceptive or unreasonable methods adopted to ensure a reasonable response rate? If subjects are reluctant to participate, what can legitimately be done to encourage their response? Many research ethics codes and guidelines warn against applying 'undue pressure' to recruit and to retain subjects. There is though an ethical judgement to be made about how much pressure is 'undue'. In some respects it might be best if the subject could be the final arbiter of that, however, if they were able to be so, then the pressure can hardly be said to be excessive – one more dilemma in the moral minefield.

Establishing rapport

Researchers are often trained in appropriate language for securing compliance. Anthropologists commonly have to learn an entirely new language to secure participation of their subjects and enhance the value of any information gained.

Using an interpreter is seen to merely add at worst another 'gatekeeper' and at best 'filters' the data in translation. But it is not enough to gain literal competence in the research subjects' language – the researcher also requires colloquial and idiomatic skills. Such skills largely rely upon a combination of verbal/rhetorical techniques together with more subtle non-verbal communicative resources. Having an interviewer attempt to 'persuade' a subject to answer questions in a face-to-face setting cannot in itself be regarded as coercion. Indeed standard interviewer instructions will offer guidance on how to convert an initially reluctant subject into becoming a respondent, plus standard practice on re-accessing some refusals for possible conversion into a response. The legitimacy of such approaches can only be called into question when the subject 'feels' forced into compliance. So mechanisms need to be available for a subject to report such concerns. It might be a testimony to the compliance skills of a researcher to secure a high response rate – and without excessive complaints being made we would never know if they were too 'forceful'. If research subjects strongly do not want make themselves 'accessible' then there is little a researcher can do about it.

The problem is that research subjects may not value a project as much as the researcher themselves does. The researcher might then attempt various methods of gentle persuasion – by offering a range of good reasons for them being involved. One could demonstrate the specific gains to their community from involvement – which could range from direct payment to the provision of external services to meet community needs. Familiarity and trust are essential compliance criteria, so researchers may occasionally use agencies already embedded in the community to effect an introduction to research subjects.

Inclusion and exclusion

While elements of the research design may allow the systematic exclusion of certain categories of research subject, it would be unethical for such groups to be left out simply because it would be inconvenient to include them. If there are genuine benefits to be sought for research participation, then it would be unfair if only those who were easily available were consistently to be chosen. One legitimate ground for exclusion would be that participants should not be selected from groups unlikely to be among the beneficiaries of subsequent applications of the research. In the same way subjects ought not to be systematically selected from groups for reasons not directly related to the research focus of study – again that they are easily available, in some sort of compromised position (such as prisoners or other captive populations) or that they are particularly manipulable. In all cases 'convenience' and 'inconvenience' should neither count as a methodological nor an ethical criterion.

The ultimate test of the enhanced power of research subjects lies in their knowing that they have the ability to withdraw from the study at any point. No matter how inconvenient this may be to the researcher, they will have fulfilled their ethical obligations if they not only permit such withdrawal when it is sought, but facilitate it in terms of ensuring no harm comes to the subjects as a consequence of their withdrawal from the study. This may mean going out of

one's way to ensure they receive the same treatment, attitudes and services they would have done had they not taken part in the study in the first place.

f Giving Information and Seeking Consent

The use of the phrase 'informed consent' makes it clear that gaining consent cannot easily be separated from the giving of information. The phrase 'voluntary informed consent' implies that subjects should be able to choose 'freely' to consent to participate in research. The notion of 'voluntary' participation assumes the individual has the competence or mental capacity to make such a judgment. It also assumes they have been given enough information about the research and that they can understand what that information implies for their involvement.

Formal consent

Research ethics committees often seek proof of consent having been properly sought and given by requiring the completion of a written, possibly signed and, in some cases, independently witnessed form. Such a highly formalised requirement seems sensible when a risk of harm to the participants may be anticipated. But it is also clear that such formality could alienate some potential participants who might fear the researcher is a representative of 'officialdom' and who might be wary of such engagements. Indeed some anthropologists complain that they are aware that asking for a signature would be seen as offensive in the communities they study. In such communities it implies that the respondent is not trusted. While formal consenting may protect the researcher against any future charge of not giving adequate information, it is by no means legally binding and might not even guarantee the respondent's continued participation in a project.

There is considerable 'fluidity' in consenting – it is not an event, it is a process. Particularly in anthropological studies consenting may have to be treated as ongoing throughout the research engagement. This has consequences both for the nature and flow of information as well as the potential for changes in the subject's capacity to consent. Both the amount of information provided in an ongoing research project and the relationship between researcher and researched is liable to fluctuate – and so too might the subject's view of their consenting.

Relationships between researcher and subject will vary in duration, intensity, tone and depth. A fundamental change in the relationship, and therefore the informed and voluntary nature of consent, occurs when some high-risk intervention is proposed and/or the subject's capacity to consent changes. In SSH research the questioning in an open-ended interview might begin to touch upon topics the interviewee did not expect, was not warned about and which they might regard as sensitive. When that happens consent must be amendable or, if necessary, removed by the participant. If they fear harm may come to them from continuing the study they should be able to easily withdraw. The ongoing consenting process may best be seen as episodic with distinctive 'markers' throughout – only one of which may be a signed, witnessed, written consent

form – but this requirement so alters the research design in ethnographic work that it should not be deemed essential.

Implicit contracts

Thinking about informed consent leads on to thinking about the vulnerability of research participants, the use of deception, the degree of disclosure of information, human rights, and the flexible nature of the relationship between researchers and researched. In some ways the information provided by the researcher is like an informal contract between researcher and subject. This is why it is important that the researcher and the organization(s) they work for is seen to be 'safe' or 'worthy' by their research subjects. Subjects may know little about funding organisations so the researcher may have to inform them. RECs put great store in giving information leaflets to participants – but this assumes a lot about how best to communicate information to people. Not all communities have adequate literacy levels, some prefer messages in the form of pictures while others put more store in face-to-face communications. Anthropological work necessarily requires good understanding of how the different communities being studied prefer to receive information.

It is also vital to be clear about why a particular participant was selected for the research. Power hierarchies in some societies might be such that trying to explain the importance of a random selection or a quota sample might simply be unacceptable. Powerful and influential members of a community might be offended at not being selected – somehow their exclusion being interpreted as a form of 'dishonour'. Snowball sampling could be seen as a more common sense rationale. When subjects are selected more purposively this has to be fully explained and trust in the researcher's honesty and intentions incrementally established. The statement that only 'they' have the answers to the questions the researcher is interested in could elevate their status. In such cases researchers have to be aware of disturbing the existing balance of power within the community.

Consequently an appropriate explanation of the aims or purpose of study will justify the researcher's need to derive information from them. Similarly subjects are entitled to know just what will be expected of them if they agree to take part. The nature of the research process, what form it will take and how long it will last, are all essential elements within informed consent. If any risks or potential harm or discomfort is anticipated it is at this stage that the subjects should be informed. But this should also be balanced against the judgment of anticipated benefits. Subjects might be willing to take known risks if they too perceive the benefits to be worthwhile – even if not to them but to their community in general.

Right to withdraw

Given that all research contains some element of risk, no matter how minimal, subjects do need to know the conditions under which a study may be discontinued or how they may withdraw if anything concerns them or some untoward event occurs. This emphasizes the voluntary nature of consent – they should be made aware of their ability to refuse to participate, that they can

withdraw at any time and this will have no adverse consequences for how they will subsequently be treated by anyone involved in the study.

Maintaining confidentiality and anonymity

If confidentiality and/or anonymity have been promised then the steps taken to ensure this should be outlined. If there are any limits to confidentiality/anonymity or threats to their maintenance, these should be disclosed. In particular subjects should be clearly informed about how the data will be reported and the study findings released. Targeted feedback to participants is a way of demonstrating both the value of subjects and a concern for their wellbeing. This can vary widely in the kinds of communities anthropologists study – from highly 'advanced' to much less literate and lower income communities. Feedback has varied from 'executive summary' type reports, to photographic essays or videos. But participants should also be informed of the other avenues through which the research will be disseminated. In advanced societies the provision of researcher and institutional contact names and numbers acts as a form of reassurance that the subject has alternative routes through which to have questions answered, to make complaints, announce withdrawal or resolve a grievance. In less advanced societies such contacts are less likely to be available but some opportunity to air any grievances could easily be offered by researchers re-visiting the community and listening to any concerns in a face-to-face setting.

The importance given to gaining consent and supplying subjects with information can vary greatly. Ethnography draws on extensive comparative anthropological experience across cultures and so tends to be highly ethically aware. But even ethnographers can resent subjects being resistant to taking part in their study: 'Further problems for ethnography can be related to the *illegitimate* and *private* character of observed activities and the possibilities for local members to *hide* such activities, or for gate-keepers to prevent or obstruct observations in various ways, especially by *denying access* to the field' (ten Have 2004: 132). The giving of oral consent in a face-to-face situation does appear more natural and consequently more consistent with the ethos of qualitative enquiry so, to ensure that as much information as necessary/possible can be demonstrated to have been given, researchers have taken to audiotape recording the consenting process.

With high-risk projects the signed and witnessed consent form may be the only way of establishing the correct contractual relationship between researchers and researched. The less separation between the giving of information, say in a leaflet, and the taking of consent then the more certain the researcher can be that consent was informed and voluntary. But key decisions have to be made about the design and content of consent forms and information leaflets to ensure the details are presented clearly and in a format suited to the subject's needs and abilities.

Flexibility and adaptability

It is hard to be too prescriptive about both consenting and information-giving since how they are done will depend upon the combination of the topic of the

research, the nature of the subjects and the chosen research methods and instruments. Offering no absolute prescription does not mean that there is no 'right way' to do it – the correct procedure requires the provision of 'adequate' information and 'adequate' consent – what constitutes adequacy being very much dependent on the nature of the researcher-researched relationship.

Capacity to consent

Judging that a subject has the capacity to consent is to make an assessment of their cognitive and communicative competence. The researcher is being asked to assess that, assuming full and clear information has been given, the subject has the ability to understand, retain and analyse that information, come to an independent decision, and express that decision clearly and effectively to the researcher seeking consent. It should be immediately evident how difficult a judgment that must be. While we generally assume such cognitive competence in adults, we tend to assume it to be diminished in the very young, the very old and those self-evidently disabled in mental function as judged, usually, by their behaviour.

Evidently judging the capacity to consent is a contentious area. There are two basic problems here – it assumes that only some (i.e. let's say mentally disabled) people lack the capacity to consent when more of us lack this capacity than we care to admit. We cannot all know or anticipate what precisely we are consenting to – sometimes the researchers do not know either! Secondly it assumes that those with 'less capacity' do not wish to be free to choose themselves whether to participate in research – once again we patronise in making their decisions for them and assume that their disability limits their engagement with the world (in this case in research) that they may wish to be free to choose to engage in. We cannot and perhaps should not protect everyone 'from themselves'. The point is not that we should not judge capacity to consent – we should only have to recognise that we have to make a judgement and that we could be wrong. Anthropologists face the added challenge that in some cultures the very notion of 'research' itself is an alien concept.

The general principles should be that consent should be gained in the most convenient, least disturbing manner for both researcher and researched. This also implies that it should be accomplished competently; which, in turn, suggests that researchers should be fully trained in taking consent. Errors in consenting could account for a considerable degree of disenchantment with the research experience and thereby contaminate the field for future research.

Ongoing management of informed consent

However consent is gained initially it must be managed and negotiated in an ongoing manner throughout the course of a research project. Gaining their consent to taking part is only one of the ways in which harm to participants can be avoided on the assumption that they too must participate in the anticipation and recognition of its potential. If they are to be able to consent they need to know fully what their participation entails. They will need information but here the ethical concern may conflict with a methodological one: How much information should they be given and in what form?

Too much information could act as a disincentive to participation by implying an excessive commitment of time or an inhibiting amount of emotional investment. Or it may be too 'leading' in revealing too much about the researcher's interests. Too little information could be seen as deceptive and result in participants' early withdrawal from the study when they find out more about it.

A greater difficulty with gathering qualitative data in particular is that while the participant might not fully know what they are agreeing to, the researchers may know only a little more since the research can be allowed, or even encouraged, to move in directions that only become appropriate when the research is under way. This means that consent has to be ongoing, and information-giving conceived as dynamically integrated into the life of the project (see, for example, Miller and Bell 2002).

Managing the consenting process can become even more complicated if third parties or gatekeepers are involved. In some cases, for example when researching children under the legal age of consent, consent will need to be taken from both the child subject and the parent/guardian, or in highly authoritarian communities consent to interview a subordinate may be needed form a superior – in both cases a major problem arises if the former consents and the latter objects. The researcher will probably have little choice but to respect the parent/superior's objection and there may be a reasonable assumption that the parent/superior is acting in what they perceive to be the child/subordinate's best interests. But there are real complications to sustaining consent throughout the project if matters of concern arise to either and not both of the consenting parties. Hence the need for a researcher to be a skilled diplomat and negotiator in ensuring the fairest outcome to all stakeholders – and, in order to maintain transparency, able to record fully the rationale upon which the decision was based. Similar complications can befall gatekeepers acting on behalf of, say, subjects with learning difficulties or older people who are residents of care homes. In both cases the agents responsible for their care might have their own reason for the discontinuation of a project which is not necessarily congruent with the interests of the subjects.

Chih Hoong Sin's (2005) work studying dementia across a range of different ethnic groups, with a mixed methods approach and a large team of researchers illustrates the difficulties involved in the complex management of a multi-level and repeated consenting process. He challenges the formulaic requirements of ethical review committees: 'The fluidity of consent demands a more reflexive approach to its engagement' (Sin 2005: 277).

Restricting informed consent

There may be times when information about the full nature of a study may have to be restricted in order to comply with a particular research design. This is particularly likely to occur with covert observational studies or ethnographic field research in which the researcher's role is not fully disclosed – also known as immersive fieldwork. To seek consent in such a situation would nullify the research method and the rationale for its adoption. But any exemptions to

seeking consent must be detailed together with an explanation of why they have occurred. Thus there may be broad methodological justifications and more specific, strategic reasons to do with the safety of researchers and/or research subjects.

Incomplete disclosure may be justified if it can be demonstrated that participants should not be told too much – or anything – in order to accomplish the research goals. This could only be considered if it entailed minimal risks to the subjects, also if some way of debriefing them could be made available, and, perhaps, if there were a way to provide for the appropriate dissemination of findings to subjects. In fact it may be the case that subjects could suffer from 'information overload' if they are told too much. After all they are not the professionals whose careers are dependent upon satisfactory outcomes.

Observational studies in which the participants are not aware that they are being observed offers the best examples of exceptions to fully informed consent. There have been many such 'classic' ethnographic studies in the history of SSH research and they usually cover the fringe areas of society – criminality, social deviance, the sex industry, terrorist groups and religious cults. Moser and Kalton describe observation as '…the classic method of scientific enquiry' (1971: 244) and express surprise at the relatively infrequent use of observational methods by social scientists when one reflects that '…they are literally surrounded by their subject matter'. However, they exhort that: 'The method must be suitable for investigating the problem in which the social scientist is interested; it must be appropriate to the populations and samples he (*sic)* wishes to study; and it should be reasonably reliable and objective' (Moser and Kalton 1971: 244). Of course, observation entails the direct focus upon behaviour un-mediated by the 'subject's' views on and potential distortions of that behaviour. Instead the potential for bias rests with the observer's recording skills and their interpretations of the meanings or intentions behind the behaviour. Thus it is not necessarily any more 'objective' than any other method of social enquiry in that:
'…observers are so much part of their subject matter that they may fail to see it objectively; …their vision may be distorted by what they are used to seeing or what they expect to see; and …they may find it hard to present a report in which observation is satisfactorily distinguished from inference and interpretation' (Moser and Kalton 1971: 253).

Covert studies

A recent example is the work of Sidhir Venkatesh who could not have conducted his research on hustlers, prostitutes and drug dealers in any detail if they had been aware of his status as a researcher. His analysis of a drug dealing gang's accounts demonstrated how it adopted a business model successfully employed by many other modern businesses – such as McDonald's (see Levitt and Dubner 2005, Ch. 3.) What Venkatesh explains well is how inappropriate and ineffective conventional research instruments, such as questionnaires and interview schedules, can be in such an environment, in fact, how self-defeating they are in trying to learn about the lives of poor and marginalised communities. He came to see how just as his research subjects were 'hustling' for money, drugs, sexual favours etc., he was also hustling for the data that he saw as vital to his research

goals. He had to become imaginative and devious in gaining information – otherwise he would be seen as an agent of the authorities and a threat to his respondents' access to services (Venkatesh 2008).

Occasionally research ethics committees have accused SSH researchers of adopting inherently immoral methodologies. These include covert observation – participant or otherwise – and research designs in which some form of deception is employed. But the use of deception should not be necessarily ruled out as inherently morally unacceptable. The use of deception has been more than comprehensively debated throughout the social sciences for many years (see Bok 1979: ChXIII). And I would argue that there is nothing inherently 'wrong' with deception since it is ubiquitous in modern life (Feldman 2010). In research terms deception is routinely employed in a mundane fashion in the blind randomised control trial in biomedicine now seen as almost 'ethically secure'. The question facing an ethics committee should not be: 'Is deception wrong?' To answer that in the affirmative would be to deny practices that are central to human civilisation. Rather the committee should ask: 'Would the form of deception proposed here harm the research participants, the researchers and/or society in general in any way?' This is not an easy question to answer since that would have to be balanced against the benefits accruing to all of those constituent groups if the research was conducted successfully. As Robert Rosenthal has pointed out: '…the…researcher whose study might reduce violence or racism or sexism, but who refuses to do the study because it involves deception, has not solved an ethical problem but only traded it in for another' (cited in Bok 1979: 192).

The key question about deception has to do with whether or not it damages the trust the general public (and so future potential research participants) have in researchers. If deception leads to an undermining of trust and so a reluctance to participate in research, there is then a risk to the success of future research projects (Bok 1979: 205 *et seq.*). The benefits to society of future research are thereby equally harmed. 'Thus, we are always confronted with a conflict of values. If we regard the acquisition of knowledge about human behaviour as a positive value, and if an experiment using deception constitutes a significant contribution to such knowledge which could not be very well achieved by other means, then we cannot unequivocally rule out this experiment. The question for us is not simply whether it does or does not use deception, but whether the amount and type of deception are justified by the significance of the study and the unavailability of alternative (that is, deception-free) procedures' (Kelman 1967 in Bynner and Stribley 1979: 190).

Another way of addressing this is to consider it alongside the issues of consent and vulnerability. Thus if the form of deception proposed in a research project minimises the research subjects' capacity to consent and makes them more vulnerable to harm without substantially contributing to societal benefit then it becomes harder to ethically justify it going ahead. It is a complex question – but not simply dealt with by suggesting that deception in research is inherently wrong.

Intrusiveness

Finally, ethical review committees often ask whether a piece of research is likely to be excessively intrusive and so 'disturbing' the subjects' normal life routines. Of course research is inevitably intrusive, but that intrusiveness is variable – dependent upon how much of the respondents' time, energy and so on it takes up. It also needs to be balanced against the concerns addressed above – thus, ironically, the more covert a piece of research, the less intrusive in ordinary lives it is likely to be. It might become more intrusive depending upon how and where research findings are published – but that merely raises another set of ethical concerns.

RECs have been criticized in the past on the grounds of the lack of sophisticated understanding of the balance of ethics with appropriate methodologies. That critique is certainly justified when review committees fail to think through the moral complexities that are routinely a part of human life in any case and charge SSH with lacking moral awareness. As was made clear earlier, they fail in their duties if they seem happy to mechanically insist upon the provision to research subjects of an information leaflet and a written, signed (possibly witnessed) consent form. That represents a complete failure to recognise that consent can never be simply given or 'gained' it has to be managed and negotiated in a continuous fashion – whatever the research design. Some of the concerns of ethics reviewers may be met if a promise is made that retrospective consent will be sought. But even this must be carefully considered. If subjects remain ignorant of the research having taken place, and no harm came to them during the process, then more harm than good could be done by subsequently informing them that they have been the subjects of research of which they had no knowledge. They may merely be upset at their activities having been 'secretly' observed, or disturbed by the researcher's findings about and reflections upon their actions. They may not like the idea that their ostensibly 'private' behaviour has been assumed to be 'public' and open to a stranger's gaze. But if such work were excluded social science would lose the advantage of such classic insights gained from, say, the ethological studies of how people behave in public found in the work Erving Goffman (e.g. Goffman 1971) or Jack Douglas (e.g. Douglas 1977) or the kind of semiology conducted by Roland Barthes (1972).

Addressing consent and capacity together shows the extent to which they overlap. Thus we judge those lacking the capacity to consent as being more vulnerable. But that is only our perception – our subjects certainly may not see it that way and we may be doing them more harm by making the assumption that they are made vulnerable by consenting to participate. It is disingenuous to ever claim fully informed consent when even the researcher may not, indeed cannot, be fully informed. They cannot anticipate all the things that could go wrong in research so how can the research subjects be expected to? Even to get the subject to be 'as informed as' the researcher would theoretically require that they be educated/trained to the same level of competence. So the requirement ought to be that the subject is as informed as is necessary to ensure they remain as free as possible in making their own judgements about how engaged in the research they wish to be – from 'not at all' to 'fully', with no obstructions to their discontinuance in the research that could harm them.

g Monitoring Safety

The monitoring of physical safety should not be separated from ethical scrutiny – any potential risks to safety need to be assessed and if the researcher feels unsafe or anticipates risk of harm to themselves or the potential for harm to their subjects this concern must be addressed. The safety both of participants and field researchers has to be monitored since there may be some mutual dependence – in terms of environmental threats or changed local conditions.

An awareness of the risks (physical and emotional) to field researchers is **both** an ethical and a practical managerial concern to do with danger on the job (Lee 1995). Dangers in research may arise from interviewing or observing in potentially threatening locations such as in hostile crowds, where a high degree of militancy is present or from the discussion of topics emerging which the researcher had not anticipated in interviewing in domestic environments, or in foreign urban environments or unfamiliar districts at night (Lee-Treweek and Linkogle 2000). While there might be some degree of professional 'duty' to accept some personal risk in the interests of science, there is now awareness that consideration for the safety of subjects should be matched by a consideration for those doing the 'subjecting' (See Craig, Corden and Thornton 2001). In any case while a researcher might accept risks in the pursuit of their science, there may be a reciprocal harm to subjects/participants arising from researchers that do not take enough care of themselves. For example, a researcher studying active conflict might put themselves at risk of violence which a participant might feel they have to protect them from – thereby increasing their own potential for harm. Any ethics review that saw a potential for harm and said nothing about it would surely be not behaving in an ethical manner.

Illegal activity

In certain types of research the risk of harm to the researcher is occasioned by the topic of study and the actions of the researchers themselves. This is the case for those carrying out covert participant observation in fields where the committal of criminal offences is the norm for the participants and might be expected of the researchers in order to protect their covert identity. It might be argued that the maintenance of 'normal appearances' requires the participation in illegal activity and if the researcher were not to comply they might then be subjecting themselves to the risk of physical harm. On the other hand there is a risk of a distortion of the field in that the researcher has become so active in the activity being researched that they are, in part, only studying themselves. Ethnographic studies of football hooliganism offer illustrative cases. The difficulties in gaining and maintaining access in such spheres are used to excuse the researcher's participation in violent and potentially criminal conduct. It is hard to see how such research could ever be conducted without allowing the researcher to operate their own judgment about whether to engage in the research and to conduct their own assessment of the risk to permit judgment about its continuance (see for example Pearson 2007).

The nature of anthropological field research is such that it probably poses the greatest danger primarily to the researcher, but also potentially to the subjects

being studied. More often than not anthropologists are studying different, 'alien' or strange cultures – ones with value systems and moral orders vastly different to the anthropologist's. They are faced with moral dilemmas when, for example, marginalised members of the society they are studying are threatened with violence and/or death during their field observations. Their scientific objectivity is certainly compromised if they intervene and there is an assumption of moral superiority by doing so. Examples include the ways in which some societies treat females as inferior citizens or societies in which AIDS is rampant blame certain individuals for the spread of the disease as sorcerers or witches. Intervention to prevent mistreatment of such individuals becomes a political and ethical act which cannot be methodologically justified and so any claimed 'objectivity' for the research project becomes undermined. Researchers expose themselves to danger if they record such maltreatment (for instance by photography) or attempt to bring it to some kind of formal/legal resolution. On the other had to stand by and merely observe may appear to condone such actions and, by doing so, may even increase the conviction of the perpetrators that it is justified. An anthropologist working with the US military in Iraq was killed 'incidentally' by a roadside bomb (Jacobsen 2008). Both action and inaction, as always, can have moral, even fatal, consequences.

'Scoping' for danger

One of the great advantages of the Internet and the World Wide Web is the ability to check on safety issues worldwide quite quickly and which tend to be fairly up-to-date. One of my Nigerian postgraduate students planned to conduct a study in the village in Nigeria where her family comes from – a quick check by her supervisor was made on the Internet only to discover there had been some recent local violence in that region over oil rights. Prior to conducting the study she was able to ascertain how serious the situation was and whether or not it had subsided.

Researchers cannot always ascertain in advance where and what the risks might be – even when conducting research in their home country. Recent localised events can alter the character and ambience of a district and its attitudes to 'strangers'. So the first lesson is to be forewarned, the next is to be prepared. Research managers and the researchers themselves have a responsibility to anticipate risks and benefits to field researchers for participating in the activity, together with meeting any study-specific needs for researchers. Managers should establish and follow a set of safety checks or a full risk assessment in preparation for each project they conduct. Some concerns are generic and apply to all projects while others will be study-specific.

Police checks might be advisable to ensure in the first place that researchers pose no perceivable threat to their subjects. The fact that police checks are conducted may also offer respondents further reassurance about promises of privacy and data protection. (On the other hand sub-groups engaged in illegal activities might be even more suspicious of researchers who have been 'cleared' by the police. And in many communities the police may be distrusted due to corruption fears.) In order to protect researchers, provision must be made for monitoring their safety throughout a project, together with awareness of any

threats to subjects and researchers that might arise out of their specific research engagement. Reviewing some of the following issues might lead to advising that a project should not go ahead – not only should such consideration be seen to be an ethical one but it ensures a degree of methodological rigour. One might have cause to doubt the validity and reliability of data secured from an insecure setting or relationship.

Careful record keeping

Keeping careful notes of all engagements (if they can be audio- or video-recorded then that is even more helpful), in order to record what happened and what was said by all parties can offer some protection against subsequent charges. The practice of maintaining a reflective research journal or diary could be seen as a professional 'standard' which helps secure the researcher's integrity to some degree since it might include the researcher's perspective on a difficult situation or problematic respondent.

The safety of social researchers is of particular concern for those conducting research in the field on their own and in unfamiliar surroundings. But some of these concerns apply also in familiar surroundings where surprising things can happen. Professional bodies hold some responsibility for ensuring awareness of risks to researchers and do offer guidance to their members on their conduct in potentially unsafe surroundings. But research funders, employers, research managers and researchers themselves carrying out fieldwork should pay attention to these concerns – indeed they may even have a legal obligation to do so.

There are many sorts of threats to the safety of social researchers when gathering data that require proximate social interaction. There is the straightforward risk of physical violence and/or verbal abuse. This might be linked to the characteristics of the subject or the nature of the topic of the research or the subject's perception of threat from a researcher; it may even be provoked by something unexpected emerging from the research. The researcher's safety may be threatened not by actual violence but by the threat of it – causing some psychological trauma.

Safety checklist

The following list of procedures that can be adopted to establish minimal protection:

- ensure projects are adequately staffed (this might mean having another researcher accompany the primary researcher for safety, researchers could work in pairs or shadow each other);
- keep regular communications with a research base monitoring the researchers' activities and whereabouts;
- accommodation away from the researchers' homes should be vetted for security and convenience to location;
- careful attention paid to the time allowed for interviews etc. to ensure researchers are not overstressed and so remain alert to risks;
- conduct risk assessment of the fieldwork site – travel facilities, pedestrian environment (well-lit and 'defensible' spaces) including routes in and out

of densely populated areas, local 'escape' rendezvous for researchers, check police authorities' and community groups' views of risks, check specific local tensions such as religious, cultural or racial divisions, any public health issues, possible language support needed, study maps of the area to enhance geographical familiarity and so on;
- formally notify relevant groups of the researchers' presence in the area;
- avoid cold-calling in areas where proper reconnoitring has not been accomplished;
- do not enter houses when the number and nature of residents is unknown;
- dress in an inconspicuous and culturally sensitive manner;
- keep valuable equipment out of sight;
- take particular care in buildings where security staffing is unknown;
- carry a personal alarm;
- stay in public rooms in houses avoid private locations to avoid the risk of being in a compromising situation, or in which there might be accusations of improper behaviour and/or where one's person could be at risk;
- carry authorised identification;
- inherently dangerous research methods/sites/topics/times/respondents should not be imposed on researchers;
- risks in any of the latter areas need to be addressed in project proposals and by prior risk assessment of respondents and research sites;
- brief field researchers on local cultural and gender norms in behavioural interaction and forms of language use and appropriate dress;
- researcher preparation and training should include techniques for handling conflict, threats, abuse or compromising situations;
- debriefing after field research should include an assessment of fieldwork safety and any incidents recorded with violent incidents reported to the employer's health and safety officer and to the local police force if necessary and advisable.

Research organisations and researchers themselves should seek to remain up-to-date on emerging safety risks and be prepared to amend protocols accordingly (Kenyon and Hawker 1999, Paterson *et al.* 1999). Despite all of these precautions it will never be possible to fully predict where risk might arise for researchers, so it is vital to be alert to possible danger in all fieldwork encounters. And while a full background risk assessment can help, researchers should also avoid making stigmatising assumptions about a research site or a community that could equally prejudice their fieldwork (Ritchie and Lewis 2003: 70).

'Dangers to fieldworkers come in all shapes and sizes. Probably more common than physical risk is the danger of emotional damage as one mingles – and empathizes – with research participants in sometimes desperate and distressing circumstances. Researchers may find themselves victimized or harassed because of their gender or perhaps their ethnic status. The heavy demands of fieldwork can cause problems with partners and with family. Like any other work, fieldwork can damage your health if it's not conducted thoughtfully.' (Bloor and Fincham 2006: 19)

h Privacy and Confidentiality (strategies)

There are ethical tensions even in what appears at first sight to be an uncontentious area – that is, protecting the privacy of research subjects and keeping any information they provide as confidential. It is also here that the risks to a research organisation are heightened as a consequence of growing legal requirements to protect the data held on research subjects. Striving for anonymity and confidentiality adds complications since they are neither mutually exclusive nor necessarily entirely congruent. In offering both anonymity and confidentiality the amount of useful data that can be disclosed might be severely limited. Moreover one might be able to retain anonymity while not treating information given as confidential; but breaches of confidentiality are also likely to undermine attempts at anonymity. This area of debate also challenges us to think more clearly about the ethical implications of the difference between the public and private spheres of social life and how concerns for privacy limit the critical insights that social research offers in democratic societies. This could mean that it might not always be in the public interest to maintain the privacy of research subjects when matters of public policy are being investigated.

Confidentiality

One can think of confidentiality as a variable dimension: it can be 'high' or 'low' with some information being treated as a mundane matter while others so 'private' that the research subject might request it being treated highly confidentially. A researcher might choose to use and/or disclose only some of the information gained and this might be done in concert with research subjects. They might ask for certain parts of the data to be ignored or kept secret. Of course, confidentiality could never be 'complete' since it would be hard to know what useful data could be collected from a subject if everything they say or do has to be kept secret.

Anonymity

Anonymity cannot be seen as a continuous variable, it is dichotomous – one either keeps an identity secret or one does not. It is true, of course, that controlling anonymity depends upon factors beyond the researcher's control. A determined enquirer could, usually by a process of elimination, guess at or even discover the identity of research subjects if enough geographical and/or biographical information is available in the published research report. Indeed modern data mining techniques make this a much more problematic topic.

The researcher's responsibility is to bear all of these considerations in mind and do their best, in terms of their agreement with the research subjects, commissioners and other relevant stakeholders, not to compromise pre-agreed levels of confidentiality and anonymity. They have an obligation to remove, as far as possible, the opportunities for others to deduce identities from the compiled data. Confidentiality must be 'contracted' for in the initial encounter between researcher and subject(s) and, as indicated earlier, this is more likely to be a verbal agreement in anthropological studies. Researchers must also strive to operate within the constraints of the law (originating country, local law and

maybe even international law) on how data on private individuals are to be held, managed and, if required by law, disclosed to the appropriate authorities. This latter requirement may, of course, be resisted on moral grounds – such as when 'protecting' the individuals or communities being studied from corrupt official agencies.

Protecting data

Signing a consent form immediately compromises anonymity and, possibly, confidentiality. In order to formalise the agreement to a research engagement and, theoretically, protect both parties signed consent forms set up a contradiction between consent and anonymity. What this means is, simply, that one cannot assume that signed consent is always ethically both necessary and desirable.

These issues also have to be considered in light of the current data protection legislation of the country in which the researcher is operating – that is, in the research site where the data is being collected and, if elsewhere, where the data is being analysed and stored. Since this is such a complex problem most large-scale research organisations will have a data protection officer whose responsibility it is to advise researchers on what is possible and what must be achieved within the law. They are also likely to have a data protection management policy which all researchers should be trained in and subscribe to. No claims for the maintenance of confidentiality and/or anonymity can be sustained if primary source data are not adequately protected and kept secure.

[Extensive information on data protection policies and regulations across Europe can be found on the RESPECT project website: www.respect.org]

Information that might enable data to be linked to individuals has to be kept in a secure locked file with restricted users, in a specific location and with access restricted to named, accountable members of the research group. If held in a computer the same criteria should apply – the key file must be password protected. Preferably the data must be encrypted restricting access to only those with the requisite codes.

Separate identifiers

An immediate problem is revealed here in the 'portability' of computerised data files. They can be e-mailed, transferred to disc or flash drive or, even, left on the hard drive of a laptop computer. Either way their physical nature enables them to be lost, mislaid or stolen and the information contained accessible to others. The first principle of anonymity and confidentiality with generic data is the need to separate identifiers from responses – the identity of the respondents being separated from the information they have provided. So the data in themselves must not reveal the link to whoever provided them. Thus cases are often assigned numbers and the numbers linked to the originating individual is stored separately and securely. The temporary suspension of this requirement may be allowed for the identification of responses for subject matching in the short term and for the necessary reliability checks from the generalised analysis to the raw data – thus it may be necessary to keep the data linked to the 'case' (i.e.

individual) to which it applies for the sake of the integrity of the data. This would also be necessary, again in the short term, in order to track response rates. But this is a precarious period of the data gathering process during which data could be linked to specific individuals and both anonymity and confidentiality compromised. Consequently data security measures must be heightened during this period. Moreover it is necessary to have a policy about how identifiers are to be destroyed if confidentiality is under threat.

Given the growth of collaborative international research it is possible that identifying information could be further separated from raw data by being kept in a different country. (One would have to bear in mind the vulnerability of such data in different countries where alternative legislation might apply.)

Pseudonyms or names?

Of course another way of separating identifiers from responses is the application of pseudonyms or aliases to link data from the same source. For the smaller data sets typical of qualitative research the assignment of a pseudonym sustains the humanising nature of this research style. There may be a temptation to select pseudonyms that appear particularly well suited to some of the characteristics of the research participant in ethnographic studies. If anonymity is to be successfully retained, no matter how appealing, this temptation should be resisted as it may offer subtle and latent clues to a respondent's identity.

In ethnographic studies, as long as there is some pre-agreement, the disclosure of the identities of the research participants in their cultural contexts might not only be seen as apt but as vital to the insights gained from the research. This might not be free from risks. For example, after being released after five months imprisonment in Indonesia for violating her tourist visa and conspiring with separatists, the anthropologist Lesley McCulloch admitted she lied during her trial to protect her contacts in the Aceh separatist movement in Sumatra. At her trial she claimed she had been ambushed by separatists and forced at gunpoint to go with them. She later admitted that she had gone to South Aceh to do research and collect information for her studies of the Indonesian military, their human rights abuses and illegal businesses in Aceh. 'The story we gave [during the trial] was to protect our sources, not so much ourselves, but those who'd set up the trip for us and arranged the meetings.' Although her fellow prisoners regularly bribed the guards to be allowed home for the night, neither she nor her lawyers ever handed over any money in return for favours. McCulloch was not banned from returning to Indonesia (Aglionby 2003).

This case raises several issues. The researcher did not respect the laws of the country nor the system of justice in operation. She even lied – claiming to be a tourist – to gain entry to the country. However without such deception it is unlikely she could gather the material necessary to investigate injustices, corruption, violence, bribery and so on. Ironically it appears she is not even banned from returning to Sumatra – one wonders whether or not, no matter how vital the data, the researcher would be wise to take a chance on returning.

Deceiving to protect
More importantly the researcher has contravened some basic ethical principles. By lying to achieve her research goals she has 'contaminated the field'. Thus, if she can lie to gain access to her research subjects, why should we assume she will not lie about her research findings or in her concluding report? If she is capable of lying once, might she not be capable of lying again in order to 'colour' her research in a direction favourable to her perspectives, opinions and research career? So who can trust her now? Her anthropological colleagues, the Sumatran authorities or, even, her research subjects – the people she claims to be wishing to help? The problem with such deception is that outside observers cannot know the moral limits the researcher has set herself – whatever her claimed intentions, doubt has been cast on her real motives. Even if we share her view of the corruption of the Sumatran authorities, can we trust anyone who has chosen to be corrupt to achieve her research goals? The claim that no attempt to bribe the prison guards to achieve special favours might either be disbelieved or even suspected to be a deliberate ruse to persuade external observers of her moral integrity. It is a classic ethical and logical dilemma – once the lie has been told, and the observer knows that, nothing the liar says can be treated as truth.

Of course, one could argue that the only mistake she made was to admit to the lie – a really good and seasoned liar without honourable intentions would know not to do that and could continue in their deceptions while claiming good intent. Thus supporting the view that good liars succeed and honourable people are condemned for their moral naivety. Once again, though, we must take care not to rush to judgement in condemning the lie and liars. As was touched upon earlier deception is neither an artificial, deviant nor even dispensable feature of social life. It holds a key place in history and can even be seen as a productive element in human success and intellectual enlightenment (Campbell 2001).

The research report itself may be designed in such a way as to deflect anyone seeking to identify participants. Thus key information in reports (such as precise geographical locations or detailed descriptions of buildings or people) may be changed to avoid inadvertent identification. While it is a challenge to accuracy, such information might not be vital to the report's conclusions but preserves the privacy of respondents. Similarly the reporting of research information in an aggregate form helps minimise the chances of unwanted identification.

Threats to anonymity
A major problem for ethnography and anthropology is that neither researchers nor their subjects are always in a position to know what the threats to the maintenance of anonymity and confidentiality may be and, therefore, how they could be anticipated. Whatever precautions they take themselves could be circumvented by the actions of determined others.

Thus researchers can only <u>strive</u> to protect their respondent's identity and do their best to hold the information given 'in confidence'. To take another example, if a subject subsequently accidentally or intentionally chooses to reveal their participation in a study there is little the researcher can do about it and so they

cannot be held responsible for such action. If a subject wishes their identity to be disclosed as part of the research report the researcher then has some dilemmas – principally the effect this might have on other subjects of their research (knowing the identity of one participant might help identify others who desire continued anonymity). Some subjects may wish their identities to be disclosed in order to maintain some link to or 'ownership' of the data while gatekeepers to more vulnerable subjects might seek identification to 'charismatise' the data donors (Grinyer 2002). The researcher should resist requests for the identity disclosure of any subject when such disclosure could lead to the failure to preserve the anonymity of other subjects who had requested that their identities not be disclosed. Either way the researcher still has a responsibility to anticipate the potential disadvantages of removing anonymity and may warn the subjects of such pitfalls.

It is interesting that subjects may not be as concerned as researchers have to be about these issues. Recent studies have suggested that most subjects are not fully aware of what they are consenting to when they agree to participate in research (Graham *et al.* 2005). One might argue that often researchers cannot anticipate all the things that could go wrong so they too are not in a position to warn subjects of all the dangers of participation. To help in making their decision to consent we need more insight into what subjects' understanding is of their participation – do they understand what it means to give consent? Do they fully understand what is being promised when confidentiality and/or anonymity is offered?

The Graham *et al*. study demonstrated the centrality of the relationship between 'interviewer' (the field researcher) and 'interviewee' (research subject). This is the key to participants' motivation to comply with researcher requests, to see the project through to completion, and to sustain a commitment to providing accurate responses. These sorts of gatekeeping issues become even more important when dealing with subjects who are assumed to have less 'capacity to consent' such as children. That seems to mean that they might not fully understand what they are consenting to – much as adults don't but perhaps to a different degree. The main tension here is between the rights of children to decide for themselves and the parental right of control. This is usually legally enshrined but UK law for one is not entirely clear in helping resolve this tension for the purposes of research. Of course in ethnographic work with communities those lacking capacity to consent might not be immediately evident to a researcher new to the terrain.

Threats to confidentiality

While confidentiality is also a matter of obeying the law on data protection, the information given by those being researched is, by definition, introduced into a more 'public' domain by virtue of its disclosure to the researcher. The researcher has to try to make clear to the respondent precisely what this sharing of confidences might imply for the respondent. After all these *data* are 'given things' or 'donations' – given to the researcher. In a qualitative research interview the apparent friendship established between interviewer and interviewee might lead to the disclosure of more information than the

interviewee first intended and there may be regret that so much has been disclosed and a need to address the social and emotional consequences of that.

The duty of confidentiality is owed on the basis of a contractual (formal or informal) understanding between researcher and researched. But that duty can be breached by either party to the contract if, say, police authorities request data which is relevant to a case they are investigating or a court issues a *subpoena* which demands the data be disclosed. If criminal activity is disclosed the researcher has to choose between obedience to the law and a breach of any confidentiality and anonymity originally promised. The researcher's moral integrity only remains intact if this is clearly understood by the respondent prior to the commencement of the research. Yet making that clear may have methodological consequences in producing a tendency to minimal disclosure by the respondent as a safety precaution. Once more though, it takes a cautious respondent to always bear in mind the sensitivity of their own information once released into a more public domain.

One device is to randomise the reporting of responses in order to disguise potentially incriminating information. In that way researchers could not subsequently be required to disclose identities.

Public and private space

It should not be assumed necessarily that the assurance and guarantee of anonymity is an ethical prerequisite. Nor should it be assumed that the allocation of pseudonyms offers ethical reassurance to participants. Sometimes participants reject anonymity in order to retain 'ownership of the data' that they have 'donated' to the researcher (Grinyer, 2001, 2002). Grinyer and Thomas (2001) advise collecting sensitive data in a sensitive manner with any information to be imparted by their respondents about their own experiences '…on their own terms and in their own time' (2001: 162). The method they adopted was via narrative correspondence. They made a public appeal through a variety of different media to seek people willing to 'tell their story' – either by writing or tape-recording an account 'of their own' – according to their own dimensions of relevance and not to answer particular questions set by the researcher(s). In fact two thirds of their respondents refused anonymity, however it was decided only to use subjects' Christian names in order to preserve some degree of anonymity – thereby protecting the subjects from unanticipated risks as a consequence of identity disclosure. Evidently how important this is seen to be will vary according to the topic of the research – it might be more problematic for research in emotionally sensitive and personal areas. But the lesson is not to assume the necessity for anonymity, and not to assume that all forms of identity disguise are acceptable and that participants will not change their minds.

As with all other such situations the researcher in the field might find themselves balancing morality with the law in attempting to make the right decisions about disclosures. The prime dilemma is to balance the moral stance of confidentiality, with the legal position, while also judging the 'seriousness' of any reported

offence and balancing that against the potential danger to 'as yet unknown' others who could be harmed by non-reporting.

Researchers' main concern here has to do with what might be considered to constitute 'public space'. Obvious challenges to our understanding of what constitutes 'public space' occur in direct (participant or non-participant) observation studies. Where social and/or individual behaviour is being observed without the subjects' knowledge, researchers must take care not to infringe what may be referred to as the 'private space' of an individual or group. The problem is that this varies between cultures and subcultures. Some societies and sub-cultures establish very clear demarcations between what is considered personal and, therefore, private space, and what is made more generally visible for others. This is something anthropological researchers would have to be very sensitised to.

The most notorious transgressors of such rules are the paparazzi who follow the rich and famous hoping to catch evidence of some private indiscretion which they decide should be made available for public consumption. The only check on their behaviour is litigation. Researchers cannot afford such contamination of their field so, where it is practicable, they should attempt to obtain consent after the event. At the very least they could interpret behaviour patterns that appear deliberately to make observation difficult as a tacit refusal of permission to be observed. (Those very actions might themselves be of social scientific interest, but there would have to be very good justification for disobeying the tacit refusal of consent in order, for example, to better understand how people manage their public/private space and so enable the continuing development of even more ethical observational research.)

The social scientist as an intuitively interested observer of human social interaction observes some noteworthy pattern of behaviour and writes about it. It is perhaps only different in depth of analysis and theoretical background to the kind of human interest writing that columnists for newspapers and magazines publish. It would not be expected that retrospective consent for such commentary should (or even could) be sought. Other examples are vox pops or vignettes – overhearing a comment by a passer-by and using it, or finding oneself engaged in really insightful discussion that highlights a particular phenomenon of interest. To neglect to report it might mean the loss of a valuable insight into the human condition from which we all might learn. But it must be employed with care and sensitivity to the individual's awareness that their accounts and behaviour might be 'collectable' and reportable in a research study. Once again what lies behind all these reflections are ideas for accomplishing the best way of respecting the rights of others – even in unconsented observational studies.

A major threat to confidentiality and anonymity lies in data retained after the completion of a project and/or preserved in a data archive for some future analytical purpose (secondary research). In the UK there is a legal obligation implicit in case law which prohibits researchers from passing on information to a third party without the explicit consent of the research subject – and only the research subject can decide which of their data can be considered confidential.

The general principle is that consent should be sought for all uses of data for secondary purposes – thus if data has even only the potential to be passed on or made available for further analysis this should be clarified to respondents. It again illustrates the importance of a clear consenting process and the provision of adequate information. If the data are required to be retained and archived for subsequent study, the subject's permission must be gained in advance (Backhouse 2002). There are added data protection problems associated with the secondary analysis of qualitative data collected for some other purpose. It is essential that the archiving principles adopted are declared and understood by both participants and researchers.

To illustrate, the policies for qualitative research in the UK can be found at the major archive sites:
http://www.qualidata.essex.ac.uk
http://www.dipex.org.uk

Information about the UK Data Archive licence with depositors, plus a download option for the form can be found at:
http://www.data-archive.ac.uk/depositingData/LicenceAgreement.asp

In general, good practice suggests that research should be conducted in accordance with the principles of the applicable country-specific national data protection legislation. But care should be taken not to confuse the 'protection' of the data with privacy/confidentiality. Protected data may still be made publicly available – its protection may relate to its integrity (i.e. its link to context and to subject).

Accountability

In business, management and public policy research it is quite common to reveal the identity of organisations involved in research and to identify individual key informants – at least those assumed to be less vulnerable at the more elite hierarchical levels. That would best be accomplished as part of a preliminary agreement ideally with the problem being addressed in open discussion with research subjects with the aim of obtaining some degree of informed consent to a potential disclosure. In cases where disclosure of the identity of a subject (whether an individual or an organisation) is central and relevant to the research neither confidentiality nor anonymity can be guaranteed. Indeed the disclosure of unanticipated but serious public accountability issues is ethically justified. There is more of an expectation that not preserving anonymity is both methodologically essential and in the public interest – enhancing the presumed public benefits to research. The full value of such research may depend upon researchers' skills in report-writing and the medium chosen for dissemination and the quality of its content. Seeking a deliberately salacious outlet may boost a researcher's notoriety and their short-term public visibility but it might not help in securing further commissioned projects for management or public organisations.

It has to be acknowledged that some risk of unintended disclosure is always present in any project. Researchers should be able to demonstrate that, where

agreed, they have taken all reasonable steps to prevent the disclosure of identities and, where not agreed, they have very good reasons for allowing the disclosure.

i Dealing with Vulnerability

The perception of subjects as vulnerable is likely to be influenced by diverse cultural preconceptions and so regulated differentially by localised legislation. It is likely to be one of the areas where researchers need extra vigilance to ensure compliance with local laws and customs. Some vulnerabilities may not even be obvious until research is actually being conducted. There may be a popular consensus that some members of a society are visibly (or understood to be) more vulnerable than others.

Clearly that is a social judgement and we may be in danger of patronising some individuals or sectors of society who wish to be seen as 'strong enough' to make their own decisions about their presumed vulnerability. Evident/visible physical disability leads to presumed vulnerability, but to be 'precious' about the disabled may lead to their social exclusion and the lack of adequate representation of their views and experiences in research studies. Even this should not be simply assumed – children can be very wise, mentally disabled people astute on some specific matters and the physically disabled extremely wary of repetitive research engagements. Between cultures and societies views of vulnerability can differ markedly. Researchers cannot predict everyone's vulnerability, nor can they cater for it comprehensively – but researchers can attempt to minimise the more obvious vulnerabilities by careful phrasing of questions and considering what to do if there is an evident emotional response.

So the key question for ethical review is: 'Are these subjects made any more vulnerable than they might ordinarily be in their daily lives as a result of their participation in this research?'

Protection from harm

Researchers have a duty to attempt to protect all participants in a study from any harmful consequences that may arise out of their participation. This is even more the case when those groups or individuals are less able to protect themselves. Children are seen as particularly vulnerable, while older people may be both vulnerable and marginalized. Children may lack the sophistication to perceive when a study is not in their interests or when disclosure is damaging to them (Alderson 1995). Older people may be excluded from most studies due to their lessened economic and political importance in their society. The ethical researcher has to guard against all these 'disprivileging' possibilities. Feminist research in particular has highlighted and made public the traditionally private worlds of females, families and households (Cotterill 1992). That, in itself, is not without ethical concern – how those worlds are made public and the consequences for the people in the study may then lie outside of their control.

More recently researchers have become concerned about the potential for harm to groups or individuals who may be typically 'excluded' from studies as a consequence of their socio-cultural location. Such exclusion might mean that

their interests are inadequately represented in a study and the researcher's (necessarily) limited perspective on the world cannot guarantee the inclusion of all groups. While 'who' to include is primarily a methodological problem, ethical concerns arise when routine exclusion perpetuates or exacerbates an individual's or a group's lowered status in society.

Some threats to vulnerability are so subtle that they may be hard to recognise. Researchers are ever more accustomed to being cautious about communication across cultures and to avoiding gendered or racist language. But some of the ways in which offence can be caused are so deeply embedded in our language use they may not be easily recognised (Karpf 2006: Ch 12). If it is the case that men and women have fundamentally different linguistic schemata that reflect different dimensions of relevance and cognitive structures then the choice of question phrasing is anything but methodologically and ethically trivial (Tannen 1994, 1995). This is not just a question of gender differentiation in language, there are subtle meta-communicative 'frames' that hide implicit assumptions about relationships and similarly tacit mechanisms for checking and asserting hierarchical relationships that can seriously impair the validity and reliability of research interactions – quite apart from the unintended 'offence' they might cause. Sometimes these may be no more than the inappropriate employment of terms of endearment – such as, in the UK, calling someone 'dear' or 'love' (see Tannen 1992: Chs 5, 6). All we can do is seek to improve our knowledge about how such mechanisms operate and to gain skills in the more sensitive employment of language. The added problem for the anthropologist entails working in a second language or a regional dialect within their second language when subtle messages about vulnerability and dependence are not fully acquired and/or understood. Even anthropologists studying sub-cultures within their own society can miss subtle forms of idiom and jargon. Such a researcher of communicative forms within the European Commission would have to be well versed in acronyms to understand fully the social interaction involved.

Research with children

Children are frequently assumed to be one of the most vulnerable groups in most societies so extra care has to be taken when they are the subjects of a research project or if they are otherwise involved in a larger study of a community. The seeking of both the child's and parental consent and the screening of interviewees is often advised. But the extent to which this has to be accomplished appears dependent upon the age of the child, the location of questioning/interviewing, the presence of a parent or guardian as chaperone and the length of time spent with an interviewer. All of these factors have to be balanced against methodological accuracy and the guaranteeing of confidentiality and/or anonymity, if requested, for the child's response (Alderson & Morrow 2004).

The problem with research with children has increasingly become one of protecting their rights, ensuring their participation is free and informed and that the protections guaranteed by the law are routinely observed. But how does one protect the rights of a child to choose freely to participate in a research activity while still observing the parents' rights to decide, on their child's behalf, whether

or not it is in their interests to participate? Researchers have to balance the maintenance of confidentiality with care for the rights of the child.

While a great deal of energy has been expended on the ethics of research with children, very little has been done to find out children's own perspectives on ethical issues associated with their participation in research. Using fairly innovative, 'user-friendly' techniques for accessing children's views a NatCen team in the UK found that the interviewer has such a key role to play in ensuring that children understand their participation rights in research that it is vital they are well-trained, and that they are accorded some flexibility – using their own judgement – in both information-giving and in the consenting process. What counted as 'sensitive' or personal topics varied considerably between the children interviewed – making it difficult to predict which areas of discussion required more careful approaches. But ultimately they were unable to conclusively answer a key question: just how much do children comprehend what is being asked of them and what research may be for? Hence it remains difficult to assess just what 'capacity' for consent children do actually possess (Reeves *et al.* 2007). Nonetheless the UK National Children's Bureau has been very keen to avoid patronising children and advocating ways in which they can actively participate in research – contributing to and critiquing research in which they are the 'subjects' (see for example, Shaw, Brady and Davey 2011).

Research with people with disabilities

Research can contribute toward the achievement of human rights and social justice for people with disabilities; but, equally, if not conducted properly it can obstruct those very aspirations (United Nations 1993). Guidance on the ethics of research with people with disabilities has been offered by the National Disability Authority (Ireland) (NDA 2004). They outline a set of overarching 'core values' such as respect for the human rights, dignity, equality and diversity of all involved in research. They promote social justice, well-being and the avoidance of harm, together with facilitating participation so that no groups – the disabled in particular – are systematically excluded from research for reasons of ignorance or avoidance. They advocate the maintenance of high professional research standards and the fulfilment of legal responsibilities.

Guidelines for 'good practice' for anthropological research with any group or community include the following:

- *Plan for inclusion*: ensure the representation of all groups in the community. Different forms of participation at different stages of the research process may have to be considered, as well as the implications of the appropriateness of different research methodologies to people with different abilities. In anthropological work this can, of course, lead to challenges to existing power structures.
- *Anticipate diversity*: do not assume necessary homogeneity within any group. Cultural heterogeneity might be discovered and explored. Varied appropriate methods of communication, access and participation will be required to cater for diversity in sexual orientation, ethnicity and other social situational factors.

- *Minimise harm*: ensure the research will not damage the established rights or limit the legitimate entitlements of all people in the group. It may be necessary to consider ways in which people can be empowered to participate in research, and the ways in which they can become disempowered both by the research or during the research.
- *Avoid 'over-researching'*: some groups and some individuals are researched more frequently on the grounds of their ability to articulate their situation or they might be more politically active and so make themselves more accessible than others. To over-research is both methodologically unsound as a 'sampling' strategy and may be harmful in terms of making excessive demands on the time and physical energy of the disabled group/person.
- *Collaborate with those being studied*: include participants in research planning and design, as active participants/researchers themselves and/or as members of advisory groups.
- *Make use of 'consultants'*: consider ways in which the expertise of those who have previous knowledge of the study group can be used in an advisory capacity before and during research projects. Recognise the value of accumulated knowledge and experience. Researchers who have worked previously with a particular ethnic group or in a specific community can help guard against major errors of engagement.
- *Facilitate research accessibility*: by using accessible and appropriate language and being sensitive to the use of language. This not only means employing the standard 'intelligent layperson' forms of language in interviews, questionnaires, proposals and reports, it also means avoiding insensitive uses of terminology. Research findings could be available to and 'readable' by members of the population – in particular when such research has direct implications for their lives. If the participants lack literacy skills then information could be provided using pictures.
- *Exercise caution with the use of gatekeepers and proxies*: Gatekeepers control access to research subjects while proxies are presumed to speak on their behalf. In all cases this must be treated as 'indirect' evidence and it might be hard to avoid. For example in some communities older people, or people with disability may be unable to speak for themselves and may need the services of an advocate and/or interpreter. But the researcher must be aware that this necessarily changes the dynamic of the relationship between researcher and researched. In some cases the person with disability may be unable to prevent the intervention of a gatekeeper since they may be dependent upon them for their care. Use of proxies, gatekeepers and so on certainly has implications for the status of the evidence produced by such means. Particular care over the consenting process is required when any form of proxy is involved.
- *Consider budgetary implications and project timeframes*: specialist research materials, translation facilities, production of additional reports and discussion papers all have cost implications for research budgets.

Dealing with prejudice

Anthropologists have to be particularly sensitive to sources of vulnerability in different societies and the variations can be immense. Sexism and ageism offer

the most common examples of institutionalized vulnerability. In many societies women may be considered particularly vulnerable as subordinate members of the community. The main problem with older people as vulnerable subjects is their assumed physical and mental deterioration. Such assumptions lead to stereotypical attitudes toward them and expectations about them. It might be advisable with older people and other distinct population categories that researchers add some extra ethical principles that take account of systematic variations in treatment of those sectors of the population while allowing that they should be accorded at least the same 'research rights' as all members of the population. Such guiding principles have been suggested by Tom Kitwood under the umbrella notion of 'personhood' (Kitwood 1997). They include recognition, respect and trust. More recently the guiding principle of 'dignity' has also been proposed in a major EU study (Tad 2005). If all subjects were accorded consideration under these principles, then no special positive discriminatory action need be taken for older people *per se*.

In practical terms then, to maintain the dignity and personhood of research subjects one would have to anticipate the potential limitations to their participation in research and adjust methodologies accordingly. So, perhaps paradoxically, given the condemnation of covert research in some circles, it could be argued that observation could be the least intrusive way of researching aspects of the lives of vulnerable people since it is less likely to challenge them emotionally and physically. A range of naturalistic observation methods could be employed for which in some cases they need not be made aware and, in others, might be positively enjoyed (Clark 2007).

Establishing trust

Being there, being interested, listening and hearing remains a *sine qua non* of qualitative research. Research subjects often have a way of knowing – as we all do as ordinary human beings – if this is being accomplished authentically. More than that there is an inherently long-term expectation of involvement between researcher and researched that is implied in any relationship of trust (Duncombe and Jessop 2002). Honest and immediate responses to potential breaches of trust have to be made. This can be as apparently trivial as requiring more time and energy investment of the participant than was originally implied. And this can happen in qualitative research when repeat visits are deemed necessary to enhance validity or as a check on the reliability of data gathered. The ongoing development of the research relationship provides insight into potential for increasing a participant's vulnerability.

By consenting to participation the respondent has already to some degree allowed the researcher into their life. The degree to which that involvement is to be continued or deepened has to be continuously negotiated. The precise nature of the mutual expectations of researcher and researched will have to be continuously clarified for methodological as well as for ethical reasons. It is vital that, given their presumed vulnerable status at the outset of the research, the process and outcomes of the project does nothing to exacerbate that vulnerability.

There may be a limit to the degree to which participants can remain truly involved which depends upon the conceptual level or the detailed technical language adopted within research reports. The researcher comes from a professional and disciplinary tradition which the participants may not share. To ensure participants' continued understanding of how their contribution extends theoretical knowledge it might be necessary to 'translate' the research products for their benefit. There is clearly a danger of either demeaning the participants or of limiting the nature of their contribution by the inaccessibility of the terminology.

Here, again, the potential for conflict between researcher and professional (carer, civil servant, welfare officer etc.) roles can emerge. 'Being listened to' is something many clients often plead for. Ironically, more time may be spent with and listening to a 'patient as a subject' within the context of a research project than in routine therapeutic engagements; or in interviews with a young offender than they might spend in their encounters with the police. While the researcher who is also, say, a health professional may cope with that personally, a problem of appropriate disengagement from a research relationship which has therapeutic implications can arise. Preparations for that disengagement could be made both with researched clients and health or social service colleagues.

j Involving Subjects in Research

In recent years there has been a considerable move in SSH research towards incorporating research subjects as more active 'participants'. In some research traditions they can become full collaborators or co-researchers, while in anthropology their status has varied throughout the history of the development of the discipline.

This topic illustrates a tension between methodology and ethics that runs throughout SSH. Do we need passive, compliant subjects who merely accept the things we do *to* them or say *about* them? Or should we only do research *with* them and show that we prefer knowledgeable participants who can be constructively and actively involved – but who may at times be recalcitrant and hold very strong views of their own about how the research should proceed?

It is not always possible or methodologically desirable to allow subjects too active a research role and should by no means be seen as ethically 'compulsory'. The wisdom of participant involvement very much depends upon the substance of the research, its aims, the proposed design, the methods to be employed and the anticipated consequences for the participants of too active an involvement. However participant involvement can offer insights to problems and anticipate harms that external researchers might not have thought of.

Communities can vary in their capacity to make judgments about the benefits of research to themselves and/or to their society at large. People in more 'advanced' societies may understand the importance of and value scientific knowledge and sustain this interest in popular news media. Less advanced groups might not value research in the same way and might not have access to

popular news media. In either case, by participating in research individuals gain knowledge and experience that they might otherwise have missed or information and insights that could enhance their life style and opportunities. Or they may gain personally and more directly from having opportunity to air their concerns or even the potential catharsis that comes from sharing problems with independent observers. But that is no guarantee that active participation in research design and/or data gathering and analysis is to their benefit – nor is it necessarily to the benefit of the researcher.

More actively-oriented research participants might value the opportunity that research affords for improving any services delivered by their larger society. If a research study enhances the provision of services to the community then study participants may gain both directly and indirectly. Research which reflects the needs and perspectives of service users may even be more likely to produce successful policy and practice recommendations. It remains vital, on ethical grounds, that those being studied should be able to freely decide for themselves, with advocacy support if needed, if they wish to be involved more actively than merely being the 'objects' of study.

Participatory research

A key question is how to ensure the most effective contribution to research from participants. They cannot be assumed to be passive and/or acquiescent, nor that they may not be knowledgeable about how they wish to participate in the research. Groups may possess acute political awareness, may be articulate and forceful in their own interests and researchers need to be prepared for such empowerment. Once the decision is taken to involve subjects then it also has to be decided within which of the stages in the research cycle they can be best employed. They can be involved in selecting and prioritising the topics to be studied, in helping to design and manage the research, as active researchers themselves (in data collection and analysis), and finally in the writing of reports and the dissemination and evaluation of the research. Probably the most subject-inclusive research method is participant action research (PAR) which suggests a variety of strategies for incorporating subjects effectively. (See, for example, Whyte 1991, Reason 1994.) But the 'objectivity' of some research designs would be seriously compromised by excessive contribution from the subject population.

A major concern is the selection of the primary goals of the research. Any research which establishes alliances with participants may find that the research goals may have to compete with the action-oriented aims of the subjects. Researchers will carry theoretical as well as potentially ideological assumptions into the field. Thus methodological and policy/practice ideologies may lie in tension with each other, with the danger that one set of concerns dominates the other (Ruano 1991). The participant's commitment may be more to social reform than to methodological purity – in which case the researcher's pursuit of objectivity is tainted (Ruano 1991: 216). So while '…this means that the researcher must be willing to relinquish the unilateral control that the professional researcher has traditionally maintained over the research process. This does not mean that the professional researcher must accept every idea put

forward by key practitioner collaborators' (Whyte 1991: 241). But Whyte does go on to suggest that researchers have to use '…rational discourse and powers of persuasion in planning and implementing PAR'. In which case I wonder what that suggests about the true balance of power in the relationship.

In some cases the need to access participants, the nature of the topic under study and the chosen methodology can 'impel' researchers toward a participatory approach. The personal concerns of the participants can compromise the professional concerns of the researcher – to say nothing of the danger that the nature of such personal relationships could directly affect the personal concerns of the researcher. Compromises with funding and commissioning agencies can impede the full pursuit of participants' interests and concerns. And, ethically, perhaps it could be argued that should be the case since they are paying!

Balancing 'stakeholder' interests

Moreover the initiating methodology and design might have elements of the professional researcher's vested interests, while the data to be collected might have been directed by the commissioner's information needs and not those of the co-researchers. (This being a particular concern if, say, the research is being funded by state intelligence agencies as discussed earlier.) Budgets for participatory research can be difficult to estimate given the variable time that may need to be spent on addressing group dynamics, interpersonal relationships and any specific research skills training that participants might need. Roles have to be established and the balance between 'leadership' and 'facilitation' remains uneasy in participatory research. Collaboration, co-operation and partnership each imply different models of group research engagement, and different implications for the balance of power between co-researchers. Given all of these complex and variable influences Peter Reason suggests that there is no one method of collaborative inquiry and that '…those who want to use collaborative methods…should study what others have done, explore the range of methods that is available, and then invent their own form which is suitable for the project they wish to undertake' (Reason 1994: 201).

The effectiveness of subject participation in research can be enhanced if the experience of interest groups operating in this field is drawn upon. On the other hand interest groups will have vested interests that may distort the research. So the balance of power between researcher and researched requires attention since specific interest or pressure groups will have accumulated a range of political skills and persuasive powers from their lobbying activities to such an extent that the researcher may find themselves, and the methodology, dominated by participants with 'too much' experience.

Some of the above concerns can be met if research participants are selected from groups likely to be among the beneficiaries of subsequent applications of the research. For some commentators on participation the starting point is the principle that ethical research is research that is of benefit to those being studied. Care must still be taken to ensure participants are not systematically selected from groups for reasons not directly related to the research focus of study such as the fact that they may be easily available and so accessible, or that

they have little choice but to participate, or might be considered relatively easy to manipulate. Correspondingly participants must not be systematically excluded for reasons of inconvenience that are not related to the research focus of study.

There may be an assumption that including subjects as participants extends the duration of the study – however, it may equally be the case that subjects are better able to move quickly to answer the research questions as a consequence of their contacts and insights. On the other hand since the 'subject as researcher' adopts multiple roles – researcher, practitioner, subject and principal disseminator – there is a great deal of tension in which of the roles take primacy at any one time. Investigating a 'problem' in one's community does not necessarily lead to its solution. By problematising a situation the researcher may undermine their own ability to continue behaving 'normally' in their community. Research into one's own life and behaviour can lead to serious ethical conflict which might be difficult to resolve – examples include: a police officer researching into policing organizations, prison officers investigating the prisoner's experiences, teachers exploring the educational system, health professionals conducting research on their own patients (see Sapsford 1999: 41, Iphofen 2005).

Given that ethical decision making is a particularly dynamic process for ethnographic approaches, it is even more so when subjects are extensively and intensively involved – hence it will be more demanding of consideration on the part of researchers and subjects alike. While some ethical consequences can be anticipated, not all can and the subjects become even more implicated in those decisions than if the study was being conducted *on* and not *with* them: it will be even more necessary '…to negotiate in practice the ethics discussed in principle when the group was forming' (Treleaven 1994: 158).

The implicit assumption that subject involvement is of benefit to the participant and empowering should be guarded against. Any researcher's desire to incorporate their subjects into their cherished project might not be matched by any sensed need in the members of the community they seek to include. Subjects do not have a 'right' to be included so the view that they ought to be granted such a right is a political act that endows participation with a form of democratic 'value'. To feel obliged or persuaded to participate is coercive and so cannot be regarded as necessarily empowering or emancipatory. To put such pressure on potentially vulnerable community members may even exacerbate their vulnerability – and they might not be the best judge of that happening. Even by allowing the subjects a 'taste' of empowerment while collaborating on a project could prove frustrating when they find themselves back in their own culture – their sensed relative deprivation could even be exacerbated by the experience. On the other hand a 'right' to be not unreasonably excluded might justifiably be accorded to subjects – a complementary example is offered in the suggestion that 'representatives' of women and minorities (of age and ethnicity) should be included in all relevant clinical trials – otherwise the results cannot be assumed to be applicable to such populations.

In the research setting – whether that be in the most well-intentioned action research or merely collaborative – since it is a research project the balance of power (in skills, knowledge, experience and resources) still lies with the researcher. There are many devices for attempting to even out this power differential but it is difficult to demonstrate clearly that a redistribution of power has been accomplished, that the participant had freely chosen to join the project and that no additional distress or harm was suffered. There may indeed be a subtle tyranny to participatory research in which people feel 'obliged' to be involved (see for example Cooke and Kothari 2001). The ethical challenges of community-based participatory research were considered by a Community Research Team in Durham University and reported in 2012. A set of principles and illustrative case studies offer examples of good practice. (See Durham Community Research Team 2012)

k Disseminating Findings

There is a surprising range of ethical issues associated with the dissemination and reporting of project findings. The series of questions that need to be addressed about publication include those contained in the classic mass communication formula: what is communicated, to whom, how, when and why?

It need not be seen as ethically inevitable to publish. All, a part or nothing of the findings (i.e. embargoing them) could be published, largely depending on judgements about the harm and benefits that might accrue from this 'knowledge transfer'. Once an appropriate audience for the work has been decided upon, next the form in which the information might best be released for maximum benefit can be chosen. Potential harms arising out of dissemination must be anticipated, and intellectual property rights assigned where they are due, with all recognisable sources of information acknowledged and referenced. In fact it might not be a bad idea to consider dissemination issues at the start of research, even though these might change during the life of the project.

Audiences for the report

Audiences for anthropological findings are wide-ranging and also include those who may be considered to be 'users' of the research. It could include: the general public, the research participants who donated their time, insights and information, the academic/professional audience of other researchers in similar and/or related fields, the government and policy makers at all levels, those who might be affected by policy changes consequent on the research, interest groups, journalists and others involved in mass media who rely upon research for interesting/challenging news stories and so on.

The first ethical concern to these constituencies is to judge whether or not the information released will benefit them or contains the potential for harm. The greatest loss of disseminatory control is to journalists who pick up research outputs and 'interpret' them according to their news values – seeking conflict and controversy since that makes for more saleable newspapers. Learning to prepare press releases and to be interviewed for radio and television is one of the vital skills of all SSH researchers. They have to become quite skilled in resisting a news reporter's 'drive' towards the opposing view. This becomes

especially difficult if the interpretation of findings is complex and subtle – especially so if there is no 'opposing view', since they may feel the need to create one!

On the other hand researchers' major complaint is when their findings are not so broadly disseminated and their publications infrequently cited. The greatest dissatisfaction is with reports that merely 'sit on a shelf' or articles in journals read by only a few people and do nothing to justify the researchers', participants' and/or funders' efforts. Hence articles in more 'intellectually-oriented' but more broadly read periodicals are often sought to explain the findings more fully and, hopefully, help to ensure that key policy recommendations are not merely ignored. For anthropological research outlets such as *National Geographic* command popular interest about other cultures, other periodicals and more general newspapers will be keen for more 'sensational' reports and may tend to select such elements from a fuller press release about the research. So anthropologists may have to exercise a little more care in press releases so as not to distort impressions of the culture or group they have been studying.

Without publishing findings the charge could be made that all stakeholders' time had been wasted – that is clearly an ethical concern. To produce 'results' and then keep them to oneself might seem a scholarly indulgence or may even be further grounds arousing suspicions about funders' motives. But few researchers have easy access to popular commercial outlets and fewer still will find they can control how their work is treated in such media.

However it is also the case that researchers should not assume the general public to lack the ability to read and discern with some degree of technical sophistication a fuller account of the work done. Given the more easy availability of the internet and cheap costs of publishing information on the World Wide Web, there is really little excuse for researchers not offering a more careful, detailed account in such a form. They may have to encounter dialogue with an informed and intelligent public – but that is something that increasingly researchers should consider as part of the justification for continued public support of their work. It could be assumed that researchers will have much more control over their formal reports to funders and commissioners and in their outlets in scholarly journals. Even here the process of peer review may 'force' alterations in reported findings in order to secure publication. Peer review is a highly flawed procedure which is heavily reliant upon trust and so raises many ethical concerns. It is a '…subjective and therefore inconsistent process' (Smith 2006: 179). There are plenty of examples of fraud and misconduct in peer review with plagiarism occurring in some cases and rejection due to prejudice against particular authors' work and/or their favoured methodologies.

The central problem is focussed on who can be legitimately counted as an authoritative yet independent peer. Such an individual would need at least equivalent, if not more, knowledge of the field and background in profession, discipline and methodology than the author. It is hard to come to an objective judgement that peer review is effective in actually accomplishing what it claims to do – filter the dissemination of knowledge and information so that only the

best gets through and the 'truth' emerges. Systematic review of the process suggests that there is only a belief that this is the case – no good evidence – and that peer review is no better at detecting fraud and error than could be achieved by chance (Jefferson *et al.* 2002). The best that researchers can do is to hold the peer review process itself under review, participate in it (be willing to review others' work) and when it is being applied to one's own work ensure that the system operating within the chosen journal outlet is as fair and transparent as possible.

Ownership of the findings

Even at the dissemination stage questions remain relating to who owns this information. When researchers collect data it is assumed that they have been 'given' to them and so can be treated as a gift. It might not mean that they fully 'own' it since the data donor might claim rights to it in retrospect. Once analysed however the data become 'findings' and if the research subject had no part to play in the analysis it is hard to see how they can claim ownership of the knowledge thereby produced. The study of poverty and inequality in different societies offers some interesting challenges to the problem of data ownership and its use. For example it has been charged that researchers could be regarded as 'stealing' from the poor by holding on to data about poverty captured from many data sources over a series of years: in so doing they slow the understanding of poverty and hamper poverty-reduction efforts. Leading analysts in research institutes in Europe and the US hold the monopoly over some quantitative datasets for extended periods, making them available to policy makers in advanced countries while limiting access to poverty researchers in developing nations. In some South Asian countries official statistical agencies refuse to place officially collected data in the public domain until they have secured enough income from private companies willing to pay for access to it. Even qualitative researchers hold on to vital life history and experiential accounts in order to enhance their own career prospects by publishing first and delay archiving or making the accounts publicly available for analysis. Good practice would require datasets to be made more publicly available on research organisations' websites once they had been 'cleaned' for purposes of anonymity and confidentiality (Hulme 2003a, 2003b).

When research participants are involved in the dissemination of research findings their criteria of relevance may differ from those of the researcher. In such cases researchers have to guard against influences of that kind compromising their impartiality otherwise the primary claim to be acting in society's interests would be jeopardised. This does not mean that researchers cannot 'take sides' – but that if they do they should make this clear and they should clarify the grounds on which they believe it reasonable to do so. The same rationale should apply to policy makers, government departments and/or professionals who may be concerned that they might be expected to become committed to implementing the 'best options' emerging from the project.

Howard Becker's overview of this problem some years ago offers a useful set of grounds for judging how researchers should assess the consequences of reporting their work: '…it is that one should refrain from publishing items of fact or conclusions that are not necessary to one's argument or that would cause suffering out of proportion to the scientific gain of making them public. …Even though the statement as it stands cannot determine a clear line of action for any given situation …it suggests …that the scientist must be able to give himself good reasons for including potentially harmful material …(and)…it guards him against either an overly formal or an overly sentimental view of the harm those he studies may suffer…(and)…it insists that he know enough about the situation he has studied to know whether the suffering will in any sense be proportional to gains science may expect from publication of his findings' (Becker 1964).

Becker's conclusions were drawn after an overview of studies that chose to report socially damaging information about a community whose members could be fairly easily identified, a decision to report confidential information about an interest group whose members were deemed 'unlikely to read' the outlet in which the information about them was reported and studies of proscribed organisations who, as a consequence of their activities, had placed themselves so far beyond the moral community that any research reporting their 'secret' activities could be deemed legitimate (Becker 1964).

The 'gift' of data

The source material for qualitative research is unlikely to be anonymous data. It is more usually a person's account, story, imagery, considered responses and, in that sense at least, is primarily owned by them and given by them. Since data are literally 'given things', the subjects' agreement to participation in research entails 'gifting' their experiences to the researcher as data. It is likely in the first instance to be their 're-presentation' of a personal experience and has, therefore, a precious, human quality. If a respondent talks about their experience of an illness or disease, or their domestic arrangements, for example, they will be disclosing intimacies – something that reveals a quality associated with the nature of their existence as a human social being and members of a specific community. Indeed all data generated from human responses is, in essence, 'gifted' even if it is nothing more than a superficial counting procedure or behavioural actions.

Then, as a necessary part of the research process, the researcher manipulates this data in some way by coding, classifying, re-interpreting it and, ultimately, by disseminating it in a form accessible to interested others. The researcher's ethical responsibility is then associated with how that shared gift is cared for (whether or not the data continue to be treated as 'precious' as they are analysed, transformed and reproduced as new knowledge) and how the person who shared the data is cared for as a consequence of that data being delivered – albeit in a different form – to a larger audience.

Part of the problem here is that an essential element of the researcher's task is inevitably to select from those data enough of them to permit the description, understanding, explanation and so on that are part of the purposes of the

research – the production of this 'new' knowledge. Conventionally this is known as 'data reduction' and is inevitable since the full richness of the person's unique and individual original experience can never be captured. Nor can it be fully reproduced. One of the researcher's tasks is to help convey that experience authentically and in a way that might be useful for purposes of explanation, policy-making or practice. So there is always something of the researcher themselves that must be included in the re-presentation since they were party to the mediated reproduction of the experience. Thus the anthropological researcher has to maintain a reflexive position, gauge how much of what emerges is dependent on or independent of them and consistently hold themselves accountable for the knowledge produced (Holland 1999).

Acknowledging all sources and careful and comprehensive referencing is essential to giving credit where it is due. It is a first principle in establishing rights to intellectual property. But the current pressure to publish and to claim the ownership of knowledge can lead to dishonourable behaviour and, even, to scientific fraud. The temptations to cheat are many and varied, and more effort must be put in to understanding the causes and consequences of scientific fraud. In the complex interrelationship between ethical review, publication and intellectual property, even governmental research councils have been found to 'misbehave' as the following example illustrates: A student who had participated in a field trial on a small municipality's drinking water found his name appearing on two academic journal articles of which he had no knowledge. Both papers neglected to report any negative results from the trials which in fact had been terminated prematurely when residents complained of laundry being bleached, the water smelling of chlorine and small pets dying during the trials. The Canadian Natural Sciences and Engineering Research Council (NSERC) had sponsored the trial which was part-funded by the company that had patented the alternative water-purifying technique being tested. The student was threatened with an action for defamation when he complained to the journal editors (one of which later retracted the article), but the NSERC failed to respond to the accusation that it had failed to maintain research standards (Fine 2006). Since commissioning/funding councils are equally capable of engaging in unethical behaviour it is even more vital that both individual researchers, with the support of their professional associations, disclose actions of this nature and work together to maintain and espouse professional standards that can help expose and remove corrupt research practices.

l Implications of internet and e-research for ethnography and anthropology

Changes in communications technology offer considerable opportunities for innovative methodological approaches for professional ethnographers and anthropologists. But this technology has also permitted a tremendous growth in 'amateur ethnographers'. Ordinary members of the online and 'digitally-armed' public are key gatherers of new data using developed communications technologies. The potential for digital video ethnography has expanded rapidly with the cheap availability of highly portable audiovisual recording devices with large memory capacity. There are even iphone apps for recording observations.

Ordinary personal phones can record enormous amounts of data and transfer and disseminate them instantly and broadly.

Social media networking

With the new social media (Facebook, Linkedin, Twitter etc.) come new forms of social contact and new forms of community, some say even new forms of identity for people as well as for groups and organisations. YouTube, for example, offers entirely new possibilities for participant observation. People are linked in ways never seen before and, given previous developments, future ways of linking and interacting are difficult to anticipate. Identity can be 'managed' in new ways and communities formed on a range of disparate and even unrelated values and practices. Barry Wellman (2004) calls this 'networked individualism' – moving from communities based on place to communities based on persons. Early mass communication developments such as radio and television challenged traditional forms of community based on locality and were, in many respects, disconnecting; new forms of media are re-connecting. Both the form of the community and the way individuals relate to it pose real challenges to the key ethical research principles of consenting, voluntary participation, and vulnerability.

With this interconnectivity understanding of public and private space has become more complicated. Participant observation studies of online communities are easy to conduct and 'consenting' may be easily sidestepped by the assumption of the availability of 'subjects' (respondents, participants and non-professional 'co-researchers') in the public domain. Pressures to produce research less expensively may lead to unwarranted assumptions about the populations such online communities can be considered representative of. To illustrate, one online market research company (Everydaylives) points to having access to "55,000 people in 30 markets" willing to video their own and/or their friends' lifestyles. (For example they may be asked to film their fridge and talk about it; show examples of their worst possible day or their indulgences; or film their mealtime routines.) These video ethnographies are treated as cross-national panel studies in ways that raise many methodological questions quite apart from the ethical issues of consent, privacy, confidentiality and so on.

Different examples show the many ways research activity may be conducted with varying degrees of openness. Patricia Lange's YouTube channel "AnthroVlog" (http://anthrovlog.wordpress.com) has a clear research purpose – the study of people via their video-logs (vlogs). Mike Wesch offers an educational course and engages his novice students in digital ethnography (http://mediatedcultures.net/ksudigg/). And while 'authenticity' has always been a problem for ethnography and anthropology, the potential for 'faking' is heightened via new media. (A notorious example was the "lonely girl 15" vlog that turned out to be entirely scripted as a 'developmental narrative' by three experienced scriptwriters and 'acted' by a young woman.) From a SSH perspective populations and samples have to be seen as self-selecting, data (videos, audio and text) are generated, filtered, organised and distributed by 'users' who vary greatly in technical capacity and accessibility. But there is no doubt these are 'communities' and social researchers have to exercise ethical caution in engaging with them. These are not 'amoral' communities, yet one has

to be attuned to how 'morality' can be applied in new communities. For example, when almost 250,000 Germans requested that Google blur pictures of their homes on their Street View service, home-owners in Essen who opted out of service were victimised by anti-privacy vandals, having their homes pelted with eggs and had 'Google's cool' notices pinned to their doors.

In a period of austerity it is important to resist the temptation of online panels offering cheap, quick, but possibly unreliable findings. There will be pressure from commissioners to use Internet surveys since they can rapidly access target groups and re-contacting is cheap and easy via e-mail. The major problem is that panels necessarily have to be 'opt-in'. More importantly little is known about the structure and demographics of the online community and how it compares to the 'offline' community. The American Association for Public Opinion Research (AAPOR) reported in 2010 on nonprobability online panels suggesting they cannot estimate accurately estimate population characteristics. (http://www.aapor.org/Home.htm)

Such work is not necessarily methodologically or ethically unsound – but its implications are certainly not yet fully understood. Charles Ess's (2002) work raises some core ethical principles that remain applicable despite rapid technological and social developments across the Internet and the Web.

5 Conclusion

Much of this discussion is predicated on an assumption of values that are fairly commonly held internationally. One of the central tenets of ethical scrutiny at European Commission level is that there is a certain degree of 'universality' to principles of research ethics. Not to accept such principles is rather like suggesting that certain standards in human rights only apply to certain geographical regions. It is up to countries (and the EC) that have established and monitored systems intended to protect people being researched to advance those standards globally. Research fields cannot only be contaminated locally in an increasingly global world. How willing would we be to learn from research conducted in what we would regard as an unethical manner on human subjects in one of these developing countries? Could our beneficence, our knowledge-gain, be regarded as properly generated in this way – in fact, might we not have grounds for epistemological doubts for knowledge gained from a range of improper practices? Thus anthropologists who conduct their research in a range of different countries and cultures, while upholding these values are, at the same, time promoting them globally.

As multi-site, interdisciplinary and cross-national studies grow due to larger corporate commissioning – European Commission research funding being a case in point – the issues of ethical review become even more complex. Knowledge transfer requires partnership arrangements that may lead to aspects of joint research programmes being beyond the control of any single partner. There can be no easy guarantee that standards and values are necessarily shared across institutions. (In the UK the Association for University Research and Industry Links (AURIL) has, for example, recently seen the need to establish its own ethics code to cover collaborative knowledge exchange.)

The balance between the right to privacy and the public interest is challenged daily with the power of modern communications technology – the surprisingly easy access to and disclosure of 'secret' government documents and diplomatic cables via Wikileaks, and the hacking into personal communications between climate scientists offer illustrative examples. As a consequence some commentators have suggested that social research is less 'privileged' even than investigative journalism when it comes to sacrificing some core ethical principles – such as confidentiality, anonymity and informed consent – when democratic values and the public interest are at stake.

Of course this all depends upon who is conducting the research, why they are conducting it and who 'benefits' from findings. 'Context' is always vital for ethical judgment – different rationales for reward incentives may be proffered from the different social research sectors – private, academic and/or government-sponsored. Intent also remains a fundamental criterion. Journalists need to 'sell' a story and the more contentious and conflict-ridden, the better. If researchers act in that way their integrity comes into question and their field of study permanently contaminated. Ultimately the judgment call in such situations comes down to one's estimate of the potential damage to the 'public interest', balanced against the potential damage to 'private' individuals and the research professions. And it is impossible to regulate that balance in general terms – it very much depends upon the specific case. So it remains vital for SSH researchers to continue to think things through and come to their own, often personal but well-informed, conclusions when confronted by the challenge of ethics.

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Glossary of Terms

Analytic induction: an ongoing process of systematically searching for evidence that challenges (falsifies) the emerging explanation – a way of 'testing' that the theory being developed does indeed offer a valid explanation of the behavior observed.

Anonymity: not disclosing the identity of research subjects.

Confidentiality: not showing data from a research project in a form which will allow the subject to be identified.

Consent: when a subject gives the researchers permission to study them.

Contamination of the field: actions by a researcher that alters the behaviour of those being studied and/or upsets them making them reluctant to help researchers in the future.

Debriefing: offering the opportunity to discuss the research after completion for the purpose of advice, counseling or even complaint.

Deduction (deductive method): procedures which use a set of logical rules to infer from some basic assumptions that certain conclusions will follow. This usually requires starting from a theory which gives rise to specific hypotheses which then must be tested by observation to check if the theory is correct.

Ethical review: the formal review of a research proposal in terms of the balance of harms and benefits that could be anticipated as consequences of the research.

Ethnography: the study of groups of people and their social interactions with a focus on the meanings lying behind those interactions. It uses a wide range of data collection methods – including observation, depth interviewing and documentary analysis.

Gatekeeper: someone who controls access to research subjects.

Holism: the assumption that individual actions can only be understood in terms of the total social context in which they occur.

Induction: a process of explanation which starts from specific observations, proceeds to generalizations about what those observations might mean and then to the building of a more comprehensive theory about behaviour.

Naturalism: studying people in their normal or natural setting without undue interference by the researcher.

Participant observation: a researcher joins a group in order to study them

more closely – observing, asking questions and making notes.

Proxy: someone who acts on behalf of or 'represents' a research subject.

Purposive sampling: selecting a sample of subjects from the population with a specific focus of interest – such all figure of 'authority', or all mothers and so on.

Reflexivity: continuous monitoring by the researcher of their own actions and thoughts and how these might influence their findings.

Retrospective consent: seeking permission from a research subject after the study has been conducted.

Sampling: taking a small selection from a larger group in order to draw inferences about that larger group.

Snowball sampling: selecting participants on the recommendations of a previous research subject. As a snowball gathers more snow when rolling down a hill – so extra subjects are 'collected' and added to the sample.

Theoretical sampling: is a flexible form of sampling that is conducted as the research progresses – cases being selected in order to test out categories and build a theory that explains what is going on. It stops when no new categories emerge.

Triangulation: the use of a range of different methods to offer different angles on the same problem.

Verstehen: explanation by 'understanding' people's meanings – the attempt to 'interpret' the motives and intentions behind subjects' behaviour in social settings.

Vulnerability: a source of weakness in a research subject that can increase the risk of them coming to harm.

EUROPEAN COMMISSION
Directorate-General for Research and Innovation

Guidance note — Research on refugees, asylum seekers & migrants

Research on refugees, asylum seekers and migrants concerns a **particularly vulnerable group** which needs **particular safeguards** in terms of research ethics.

This note provides some guidelines to help you make your research ethics compliant.

General principles

To account for their particular vulnerability, you should apply the following principles whenever your research involves such participants:

- treat them with **care** and **sensitivity**
- be **objective** and **transparent**
- avoid **ethnocentricity**: show respect for their ethnicity, language, religion, gender and sexual orientation
- rigorously safeguard the dignity, wellbeing, autonomy, safety and security of their **family & friends**
- respect their **values** and right to **make their own decisions**
- give special protection to participants with diminished autonomy, such as **unaccompanied minors** — for example, by involving NGOs or national authorities *(e.g. National Refugee Councils)* with relevant experience, to provide legal advice, psychological support, language interpreting and/or legally appointed supervision.

What to include in your ethics self-assessment

Information on the participants' **legal status** and any details regarding their specific **vulnerability** due to their status.

Confirmation that your research:

- is **relevant to the communities involved** (both source and host)
- has objectives that are **not harmful or prejudicial** to participants

A detailed **strategy document** describing:

- the procedures you will implement to protect participants' best interests and ensure their involvement will not jeopardise safety or increase vulnerability
- how the criterion of relevancy will be satisfied (e.g. by prior consultation with the community itself or a cultural insider)

Specific concerns

Recruitment of researchers

Consider including researchers with a **refugee or migrant background**, or from the same culture. This may mitigate potential risks of coercion or power differentials between researchers and participants.

⚠ Be aware that such people could also act as gatekeepers or could even amplify power differentials.

What to include in your ethics self-assessment

Details on recruitment, inclusion and exclusion criteria for researchers:

- **justify** your **interactions with vulnerable groups**

  The reasons may vary but there are common principles: give a rationale for your methodology, including the research subject, choice of research sites, participants and researchers; how you plan to establish a trust relationship with participants; how you will be transparent about future use of findings and their potential harm/benefit for vulnerable groups.
- do **not create unjustified expectations** in participants about:
  - future residence in the EU or the determination of their refugee status by any national authorities
  - how the research will help to improve the situation of their group and how participants will be recognized or rewarded (make sure to avoid undue inducement)
- justify why **certain volunteers cannot be recruited**, to avoid concerns about favouritism and unfair exclusion.

Informed consent

Demonstrate appropriate efforts to **ensure participants fully understand** the implications of being involved in your research.

Issues

Informed consent procedures may **discourage participants** from participating in research projects:

- signing consent forms may **jeopardise their anonymity** — important to people fearing persecution in their home country or capture by host country law enforcement agencies
- complex and legalistic consent **forms can be difficult to translate** into multiple languages in a comprehensible style, particularly where participants have low levels of literacy

Alternatives to consent forms

You may use less formalised procedures for giving information and obtaining consent, such as:

- including a **cultural insider** in the process

- working with a recognised **NGO**
- using **oral consent** (only with the knowledge and approval of a competent Research Ethics Committee).

⚠ For particularly vulnerable groups (participants in refugee **camps** (closed, waiting or detention camps) and unaccompanied **minors** consider having in all cases an experienced NGO member (with relevant and acknowledged credentials) or a cultural insider present during informed consent procedures.

Participation by such groups might be less genuinely voluntary, especially in research sponsored by powerful organisations.

> ***What to include in your ethics self-assessment***
>
> Details on any less formalised procedures for giving information and obtaining consent (alternatives to consent forms).

Incidental findings

You must handle appropriately any information you **discover unintentionally** that is not related to your research aims, such as:

- human rights violations (on or by the participants)
- human and sexual trafficking
- domestic violence
- forced marriage
- female genital mutilation
- trading in human organs
- child pornography.

> ***What to include in your ethics self-assessment***
>
> A **strategic plan** for helping participants in these situations, *e.g. by informing the responsible national authorities, NGOs or other agencies with relevant expertise*. This plan must be **approved** by a competent national research ethics committee.

Rehousing, relocation & safe passage

Research on participants should not influence housing, resettlement, relocation or status determination procedures.

Protection of personal data

To protect participants' safety (as stated above) and prevent possible stigmatisation, social exclusion or racism.

Act as follows:

- Be extremely careful about which **type of information** you collect. Only gather data that is essential for your specific research aims. Do not collect names, addresses or specific locations and exact dates unless absolutely essential.
- **Store all data safely**: password-protected where appropriate and separate from any other personal or communication data, such as meeting points or mobile numbers (*pseudonymisation*).
- Keep **completely anonymous** any information that participants wish to hide for reasons of personal safety or privacy.

What to include in your ethics self-assessment

A **detailed strategy** to ensure all personal data collected will be kept confidential and anonymous. Explain this thoroughly to the participants in the Information Sheets or orally (if approved by a competent national research ethics committee).

Your **procedures** for data collection, storage, protection, retention, transfer, destruction or re-use (including: collection methodology, digital recording, picture, etc.), exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data merging or exchange plan, commercial exploitation of data sets etc.

Your **data safety procedures** (protective measures to avoid unforeseen usage or disclosure, including mosaic effect, i.e. enabling identification by merging multiple sources).

The specific procedures that you will implement to ensure the confidentiality and **anonymisation/pseudonymisation** of personal data about the relocation of participants (especially for participants defecting or leaving their country for political reasons).

Explicit confirmation of **compliance** with national and EU legislation, (in particular, EU Directive 95/46/EC).

> ⚠ The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

Measures to ensure that responsible adults or legally appointed supervisors provide consent for any collection of data or material (e.g. genetic material) involving **minors**.

Details of any information on participants processed by NGOs or other organisations involved in **programmes to relocate refugees**.

Observing, researching or interviewing refugees in such programmes should only take place if:

- authorised by the national or EU authorities responsible
- the use of the information is limited in scope, so guaranteeing effective data protection.

Protocols describing **confidentiality** and **limitations on use** of personal data that you have obtained from the NGOs, if information collected by them can be used in your research.

Details of how **health data** gathered during participants' entry into the EU will be handled with special care.

Confirmation that any **publication** of participants' data (e.g. social networking, webpages) will always comply fully with EU data protection rules.

Confirmation that any **audio and visual material** will have the full informed consent of the participants involved.

Justification for using audio and visual material from **minors** or **deceased participants**.

Details of the strategy you will implement if you observe any **adverse incidents** (e.g. racist or sexual abuse, human trafficking, terrorism).

Misuse

This means **disclosing data** that may **endanger the safety** of participants, family, friends or associates.

Act as follows:

- when publishing or disseminating findings, **take into account possible negative consequences** for participants (stigmatisation, discrimination, intimidation, xenophobic practices)
- do not disclose information that may lead to **criminalisation**, incite **racism** or jeopardise participants' **social assimilation**
- your research should not influence **resettlement and relocation** procedures or **status determination** procedures
- since your findings on participants could impact their wellbeing and be misused in public or political dialogue, **be sensitive to wording**. Use terms and apply methods accurately and precisely, to avoid misuse or intentional misinterpretation of your findings
- pay particular attention to the **use of official statistics** (approximate numbers) and how they are interpreted
- formulate a specific policy on publishing **incidental findings**

What to include in your ethics self-assessment

A detailed description of the **precautions** you will take **to prevent disclosure** of such information.

Confirm you will report to the authorities any **emerging information** in your research that might lead to threats or endanger the safety and wellbeing of others.

HISTORY OF CHANGES		
VERSION	PUBLICATION DATE	CHANGE
1.0	06.07.2016	Initial version
1.1	07.01.2020	Updated to VM4.0 / insertion of header

H2020 Programme

AGA – Annotated Model Grant Agreement

Version 5.2
26 June 2019

Disclaimer
This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the Executive Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	▪ Initial version following adoption of the grant agreement v.1.0. Article 6.
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to H2020 Work Programme (section 3 MSCA) (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement v.2.0, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSCA ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles
2.0	30.03.2015	▪ Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. ▪ Clickable cross-references (Articles) ▪ New table explaining the treatment of the different types of work contracts (under Article 6.2.A). ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. ▪ Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 ▪ Other minor corrections and clarifications
2.0.1	18.05.2015	▪ Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants

2.1	30.10.2015	▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47, 50, 55 and 56. ▪ New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses ▪ New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Ph1 Lump Sum: Article 5; – SME Instrument Ph2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. ▪ Other minor corrections and clarifications.
2.1.1	01.07.2016	▪ Update of the explanations on Article 18 regarding time records; including a model of time-sheet with the minimum requirements.
2.2	25.11.2016	▪ Updates due to the amendment of the model grant agreement v.3.0, in particular Articles 4.2, 5, 6.2.A, 10, 13, 16, 20, 34, 37, 41, 42, 43, 45, 46, 48, 49, 50 and 55 ▪ New annotations on Articles 29.2 and 29.3. ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6, 6.1, 6.2, 6.5 and 18. ▪ Updates in the annotations to specific model grant agreements: - ERC: Preamble, Articles 6, 29 and 56a - MSCA: Preamble ITN, Articles 4, 5, 6, 8, 18, 19 and 32; IF Articles 2, 4, 6, 8, 18, 32 and 56a; RISE Articles 4, 6, 8, 18, 19, 31 and 32; COFUND Articles 4, 6, 8, 15 and 18. - ERA-NET Co-fund: Articles 2, 19 and 21 - PCP-PPI: Articles 5 and 13 - EJP Co-fund: Articles 5, 6.F and 20 ▪ Synchronised presentation for grounds for Chapter 6 measures, security obligations and information obligations. ▪ Other minor corrections and clarifications ▪ Update in Section I.3 'List of issues applicable to particular countries' New rules that apply in principle only for grant agreements signed with version 3.0 are marked with 3.0 » (This version refers to MGA v3.0 to align it no AGA v3.0 was created)
4.0	21.04.2017	▪ Updates due to the amendment of the model grant agreement v.4.0, in particular Articles 5, 6 and 52 ▪ New annotations on Article 14a following the introduction of this Article in the revised model grant agreements v.4.0 ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6 and 18. ▪ Updates in the annotations to specific model grant agreements: ERC, MSCA, PCP-PPI and FPA/SGA ▪ Other minor corrections and clarifications New rules that apply in principle only for grant agreements signed with version 4.0 are marked with 4.0 »
4.0.1	20.06.2017	▪ Addition of index at the bottom of the pages
4.1	26.10.2017	▪ New explanations and examples, in particular in Articles, 6.2.F, 18,

		50 and 55 of the general MGA ▪ Corrigendum of annotations on Article 6 of the MSCA-ITN, IF, Cofund and the MSCA-RISE grants ▪ Corrigendum of annotation on Article 6.2.F of the EJP Cofund grant ▪ Update in Section I.3 'List of issues applicable to particular countries' ▪ Other minor corrections and clarifications
5.0	03.07.2018	▪ Updates due to the amendment of the model grant agreement v.5.0, in particular Articles 29.3 and 34 ▪ New presentation of calculations for payments and recoveries, now compiled under Article 21 ▪ Updates due to the adoption of the Guide on grant reductions ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 6.2.A, 6.2.D, 11, 14a, 43, 44, 48, 49, 50.3, 51, 55 and 57.2. ▪ Annotations on the new Lump Sum Pilot model grant agreement ▪ Annotations on the new MSCA Special Needs model grant agreement ▪ New annotations and updates in the specific model grant agreements: – ERC: Articles 18, 29 and 32 – MSCA: ITN Articles 6.2.a, 6.2.B, 32; IF Articles 6.2.A, 6.2.B, 18, 32, 55.1, 56a; RISE Articles 6.2.A, 32 and Co-fund Articles 6.2.A and 15 – SME Phase 1: Article 8 – PCP/PPI: Article 8 – SGA: Article 3 – General lump sum: preamble, Articles 8 and 18 ▪ Other minor corrections and clarifications
5.1	06.12.2018	▪ Updates in the annotations of Articles 6.1, 8, 20, 22.1.3, 41.4 and 55 ▪ Annotations on the new ERC Lump Sum Pilot PoC model grant agreement ▪ New annotations and updates in the specific model grant agreements: - ERC: Article 56a - MSCA: IF Articles 38, 49.1.1 and 56a, ITN Article 8, RISE Article 8 - Lump sum pilot: Article 4
5.2	26.06.2019	▪ Updates in the annotations of Articles 6.2.D.5, 6.2.F, 16.2, 20, 29, 31, 37, 55 ▪ New annotations and updates in the specific model grant agreements: - MSCA: IF Article 6.2.B, ITN Articles 6.2.B and 32, RISE Article 6.2.A - ERA-NET Cofund: Preamble and Articles 5, 8, 15 - EJP Cofund: Articles 3, 6.2.F For easy identification, paragraphs, indents or sections with new explanations or changes are marked with the symbol ■ on the left

IMPORTANT NOTICE

The **AGA — Annotated Model Grant Agreement** is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement (General MGA) and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020 (H2020).

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and eligibility conditions of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

   New rules that do not apply to all signed grant agreements (but instead only to those signed after a certain version, e.g. version 3.0), will be marked with: 3.0 and 3.0

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the H2020 MGAs. For a more general overview of how H2020 grants work, *see the Funding & Tenders Portal Online Manual*.

A comprehensive list of all H2020 reference documents (including legislation, work programme and templates) can be found on Participant Portal Reference Documents.

H2020 terms are explained in the Glossary.

If necessary, you can also contact the Research Enquiry Service.

Legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

⚠ Please note that Regulation (EC, Euratom) No 966/2012 has been replaced by Regulation (EU, Euratom) 2018/1046 (with effect from 2 August 2018).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

⚠ Please note that Delegated Regulation (EC,Euratom) No 1268/2012 has been replaced by Regulation (EU, Euratom) 2018/1046 (with effect from 2 August 2018). The rules of the RAP are now included in the new Financial Regulation.

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1 'Health, Demographic Change and Wellbeing', etc.*

⚠ **Specific MGAs —** The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**] established in [official **address** in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full]* ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]* *as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

Beneficiaries means the legal entities who have signed the grant agreement (GA) with the Commission/Agency (i.e. participate in a project supported by an EU grant).

The term **participant** is used in this document in a wider meaning than in the definition of Article 1.1(15) of the Rules for Participation Regulation No 1290/2013. It covers normally beneficiaries and linked third parties (and sometimes also other third parties involved in the action).

The **coordinator** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the

action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 (technical implementation) and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including **linked third parties**, international partners, subcontractors, third parties giving in-kind contributions, etc.) are considered as **third parties involved in the action** (for the definitions and conditions, *see Articles 8 and 9-14a*).

Their involvement in the action varies depending on the role.

Since there is no formal contractual link with them, they are formally speaking not bound by the terms and conditions of the GA. However, by participating in the action and via the obligations on their beneficiary, they are indirectly bound to most of the GA obligations.

⚠ The consortium set-up must follow the roles of the GA. Participants should be attributed their roles according to their real contribution to the project. The main actors should be the beneficiaries. All other roles (third parties) should perform secondary tasks.

This means for instance that:

- linked third parties — are allowed to *fully* participate in the action, like the beneficiary they are linked to; they will therefore be treated for many issues (including cost eligibility; *see Article 6.3*) like beneficiaries
- subcontracting — beneficiaries/linked third parties may NOT subcontract tasks to other beneficiaries/linked third parties *(see Article 13)*
- coordinator tasks — the key coordinator tasks listed in the GA may NOT be subcontracted or delegated to any other beneficiary or linked third party (except, under certain circumstances, to an entity with 'authorisation to administer'; *see Article 41.2*)
- in-kind contributions between beneficiaries/linked third parties — if beneficiaries/linked third parties give in-kind contributions to other beneficiaries/linked third parties, their cost should normally simply be declared by the contributing beneficiary/linked third party (if the contributions are particularly important for the project, it may however be advisable to specifically mention them in the description of the action).

For an overview on the different types of third parties and their GA roles, rights and obligations, *see the table in Article 8*.

⚠ If you are a 'sole beneficiary' (Article 187(2) Financial Regulation No 2018/1046, *e.g. European Economic Interest Grouping (EEIG) or joint venture*) or a 'beneficiary without legal personality' (Article 197(2)(c) Financial Regulation No 2018/1046; *e.g. association*) and will implement the project with the help of your members, you should make sure that the members participate as linked third parties, so that they will be able to charge their costs to the project.

2. Name and address — Legal entity data

The legal entity data (legal name, address, legal representatives, etc.) of the beneficiaries comes from the Funding & Tenders Portal Participant Register (former Beneficiary Register).

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries (via their **legal entity appointed representative (LEAR)**) must keep their **data** in the Funding & Tenders Portal up-to-date at all times including after the end of the grant (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[1]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[2]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[3].

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1 More information on the types of action can be found on the General Annexes to the Work Programme.

2 For the definition, *see Article 2.1(6) of the Rules for Participation Regulation No 1290/2013:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

3 For the definition, *see Article 2.1(7) of the Rules for Participation Regulation No 1290/2013:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new

⚠ The term **action** comes from the Financial Regulation No 966/2012 and **means project**. (Previous EU Research Framework Programmes used project.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of Horizon 2020 *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

For more information on RIA, IA and CSA actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

2. Complementary grants

'Complementary grants' are different EU grants which are linked by the work programme/calls by identifying them as complementary actions.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written **collaboration agreement** regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a non-associated third country (i.e. a third country not associated to Horizon 2020) or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[4]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 of the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a **coordination agreement** *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

For guidance on coordination agreements, *see How to draw up your coordination agreement.*

infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

[4] *See Article 12 of the Rules for Participation Regulation No 1290/2013.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The action starting date is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties (retroactive)

  Example: *GA signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium requests a fixed starting date before the entry into force of the GA, it assumes the risks implied by starting the action before the GA is signed (in particular not being reimbursed for the costs incurred, *e.g. if the proposal is not successful or that the GA is not signed*).

  The action starting date can **NEVER** be **before** the **submission** of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The action duration is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the ***action tasks*** (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as project closure or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2: Moreover, *lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding and costs of international partners will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9 and Article 14a)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and cost declarations (i.e. financial statements; Article 20 and Annex 4).

⚠ Costs for personnel, equipment, goods or services that are in-kind contributions by a third party (for free or against payment) can in practice simply be added to the budget category they correspond to (i.e. personnel costs or other direct costs) — if they comply with the eligibility rules set out in Articles 6 and 11 and 12.

3. Budget transfers (budget flexibility)

The budget in Annex 2 is an estimation.

⚠ **Budget flexibility** — The budget is in principle flexible (with the exceptions set out below).

Be however aware that the budget table will be used for the calculation of grant reductions *(see Article 43)*.

Beneficiaries may transfer budget among themselves, between linked third parties or between budget categories (without requesting an amendment; *see Article 55*) and — at the time of reporting — declare costs that are different from the estimated budget.

⚠ The maximum grant amount *(see Article 5.1)* can however **NOT** be **increased**.

What? If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example: *The estimated budget includes personnel costs of EUR 60 000 for beneficiary A and EUR 75 000 for beneficiary B. However, at the end of the action, the actual personnel costs of beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not? The GA allows transfers of budget, NOT of **tasks**.

Moreover, a beneficiary can NOT transfer budget to a **form of costs** that it did not set out **in its estimated budget** — except within the personnel costs category and to costs of internally invoiced goods and services (*Article 6.2.D.5*).

Example (allowed transfer): *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is acceptable without an amendment of the GA.*

Example (not allowed transfer): *A beneficiary budgets all its costs as 'actual costs' in the estimated budget. However, at the end of the first reporting period, the beneficiary wants to declare part of the costs by using a specific unit cost allowed in the call (e.g. unit cost for clinical studies). This is NOT possible without an amendment of the GA.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work ('action tasks') of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %*** *of the action's eligible costs]* ***[OPTION 2 for innovation actions (IA)***[7]***: 100%*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[8] *and* ***70%*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]* ***[OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA: […%]*** *of the action's eligible costs]* ***[OPTION B for IA: […%]*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[9] *and* ***[…%]*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[10]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[12]: **[OPTION 1 to be used if Article 15 applies:** as actually incurred costs (**actual costs**);]* ***[OPTION 2****: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[13]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[14]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a[16] ('**unit costs**').]*

***[OPTION** 1b **for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION 2: specific cost category(ies):** not applicable.]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

10 To be used only if option in Point (f) is used.

11 To be used only if option in Point (f) is used.

12 To be used only if option in Point (f) is used.

13 To be used only if option in Point (f) is used.

14 To be used only if option in Point (f) is used.

15 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

16 Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount will **NOT** be **increased** — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA and CSA actions is normally **100%** of the total *eligible* costs[5]; for IA actions it is normally **70%** of the total eligible costs[6].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[7].

5 *See Article 28(4) of the Rules for Participation Regulation No 1290/2013.*

6 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rate of a beneficiary does NOT condition the reimbursement rate of its linked third parties.

Example: *The beneficiary is entitled to 70 % but it has a linked third party entitled to 100 %. The linked third party will have a reimbursement rate of 100 % — despite the lower reimbursement rate of the beneficiary to which it is linked.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

⚠ The grant can **NEVER** reimburse **more** than the maximum grant amount fixed in Article 5.1.

3. Cost forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump sum costs)[9]. In practice, they are currently all used, except for lump sums.

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - **personnel** costs (— unless declared as unit cost; *see below*)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs** (— unless declared as unit cost; *see below*)

    Example: *EUR 2 000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - personnel costs of **SME owners/natural persons** not receiving a salary[10]
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)[11]
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices

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7 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

8 *See Article 28(6) of the Rules for Participation Regulation No 1290/2013.*

9 *See Articles 123, 124 of the Financial Regulation No 966/2012.*

10 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

11 *See Article 33(2) of the Rules for Participation Regulation No 1290/2013.*

- specific unit costs for:
  - costs for **energy efficiency measures** in buildings[12]
  - **access costs** for providing trans-national access to research infrastructure[13]
  - **access costs** for providing *virtual* access to research infrastructure[14]
  - costs for **clinical studies**[15]
- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[16]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

Example: *EUR 150 000 to carry out a study within an action*

The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	Budget categories					
	Direct personnel costs	Direct costs of sub-contracting	Direct costs of financial support to third parties (option used if Article 15 applies)	Other direct costs	Indirect costs	Specific cost categories (option used if Article 6.2 (F) applies)
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: - costs established according to the usual cost accounting	NO	NO	YES, only for: costs of internally invoice	NO	YES, only if foreseen by Commission Decision

[12] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[13] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

[14] Decision of 6 February 2019 authorising the use of unit costs for the actions involving virtual access under the Research Infrastructures Part of the Horizon 2020 Framework Programme Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_virtual-access_infra.pdf

[15] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[16] *See Article 29(1) of the Rules for Participation Regulation No 1290/2013.*

	practices of the beneficiary - costs of SME owners and natural persons not receiving a salary			goods and services		
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the **errors, irregularities or fraud** or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action— as part of the calculation of the payment of the balance.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex 1

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 of the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

The procedure for the final payment and detailed calculations are described in Article 21.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, substantial errors, irregularities or fraud or serious breach of obligations (and therefore **rejects costs** and/or **reduces the grant**), it will revise the final grant amount, for the beneficiary concerned and, if needed, make a recovery.

The detailed calculations are described in Article 21.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only** reimburse **eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Cost eligibility is NOT the same as beneficiary/action eligibility. The latter are normally checked upstream (before Grant Agreement/Amendment signature) in order to make sure that only eligible beneficiaries/actions are selected for a grant. Loss of eligibility during an ongoing grant normally leads to termination or change of status *(see Articles 50 and 55)*; costs become automatically ineligible as from the date of loss of eligibility.

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Article 6.1 refers to general eligibility conditions, applicable per cost form *(see Article 5)*.

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action

duration. By contrast, costs of services or equipment supplied after the end of the action (or after GA termination) are not eligible.

Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

  ⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

Examples:

1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

3. *Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible, if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements (CFS) required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

Personnel costs for ERA chairs — Are eligible even if the salary is above national salaries, provided that it does not go beyond normal EU/international salaries for similar positions (since the ERA chairs aim to incentivise international mobility for internationally outstanding researchers and research managers. When the level of remuneration of the ERA Chair is indicated in Annex 1, this will be duly taken into account in case of checks, audits or reviews.

Costs to allow for the participation of disabled people *(e.g. costs for sign language interpreters required for dissemination events organised under the action)* — May be eligible if they fulfil the general and specific eligibility conditions listed under Articles 6.1 and 6.2. The beneficiaries must keep records *(see Article 18)* to prove in case of an audit, check or review the actual costs incurred and that they were necessary for the implementation of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced

(e.g. number of square meters for energy efficiency in buildings) **by** the **amount per unit**

> ***Example:*** *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2a.*

- the **number of units** must be **necessary** for the action
- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

> ***Example:*** *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Costs declared on the basis of the usual accounting practices— For two budget categories (A. personnel costs and D.5 costs of internally invoiced goods and services), costs may be declared not as a fixed unit cost, but on the basis of the beneficiary's usual cost accounting practices. In this case,:

- the beneficiary:
  - must calculate the costs according to its usual accounting practices
  - must budget and declare a total amount (not the units used)
- the amount per unit is not fixed in Annex 2a.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency and set out in Annex 2a of the GA *(see Article 5.2)*.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR 30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION 1 for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)[16]]***[*OPTION 2:*** *not applicable***]**.

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to **specific eligibility** conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

– either costs that have been caused in full by the activities of the action

- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action can NOT be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a **25% fixed flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[*A.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual** costs (i.e. budget categories A.1, A.2, A.3 [*and A.6*]): the hourly rate is calculated per full financial year, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories A.1, A.2, A.4, A.5 [*and A.6*]): the hourly rate is one of the following:

(ii) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

1. Direct personnel costs (A.): Types of costs — Forms — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Employees (or equivalent) (A.1)

1.1.1 What? Personnel costs for employees or equivalent (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) that worked in the action.

⚠ '**Equivalent appointing act**' means the appointing acts of civil servants (who do not sign employment contracts but receive official nominations for their posts).

⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Reliable time records will normally be sufficient proof of the assignment to the action — unless there is other contradicting evidence *(e.g. the employment contract indicates that the person was hired to work on another project)*

It covers (and is limited to):

- **basic remuneration** (i.e. the payments for the employee's normal work and participation in projects — up to what is the beneficiary's usual remuneration practice for national projects)

and, in addition:

- for non-profit legal entities: **additional remuneration** (i.e. extra payments made for the participation in projects — above the beneficiary's usual remuneration practice for national projects).

⚠ **National projects** are to be understood in the large sense, meaning all types of projects funded under any type of national (public or private) funding scheme (including projects co-financed by EU funds that are managed by the Member States, *e.g. regional funds, agricultural and fisheries funds*).

Projects from EU programmes directly managed by the Commission/Agencies or their funding bodies *(e.g. LIFE, ERASMUS, Health, etc.)* do not, however, qualify as national projects (but as EU/international projects).

Both basic remuneration and additional remuneration do not only cover the payment itself (salary or bonus), but also the social security contributions *(mandatory employer and employee contributions)*, taxes included in the remuneration *(e.g. income tax)* and other costs and payments included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee).*

What not? Cost of persons who work for the beneficiary, but NOT with an employment contract or equivalent appointing act *(e.g. staff provided by a temporary work agency, seconded staff, self-employed persons with a direct contract with the beneficiary)*.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions *(e.g. best value for money and no conflict of interest; see Articles 10 and 13)*.

Seconded staff and **self-employed persons with a direct contract —** Can also be declared under other categories within the personnel costs *(see below, points 1.2 and 1.3)*.

1.1.2 Costs for employees (or equivalent) must be **declared** as:

- **actual personnel costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.1.3 The costs for employees (or equivalent) must comply with the following **eligibility conditions**:

For basic remuneration:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are NOT eligible under *Article 6.5(a)(i)*. However, bonuses based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted, if they fulfil the conditions set out below, i.e. as part of the usual remuneration practices for national projects and thus eligible as basic remuneration.

  Examples (positive):

  If the profit of the company at the end of the year is more that x € (or more than x %), each employee will receive a bonus of z % of his/her basic remuneration (or a fixed bonus of x € more as part of the gross salary).

  Examples (negative):

  If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.

  Any part of the remuneration which is based on commercial targets or fund raising targets is NOT eligible (because neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation).

  ***Examples**: x € for reaching a sales target; x % on sales; x € premium per externally funded project gained; x % of the external funding gained*

- be paid in accordance with national law, the collective labour agreement and the employment contract/equivalent appointing act

  Examples:

  ***1.** The collective labour agreement establishes that all researchers may receive a bonus between EUR 100 and EUR 200 per month based on their seniority.*

  ***2.** The national law authorises public universities to pay a bonus based on merit of the employees.*

  ***3.** The contract fixes a premium of EUR 1 000 for each research paper published in peer-reviewed international research journals.*

- **exclude arbitrary bonuses** (i.e. bonuses which are not part of the beneficiary's usual remuneration practices and/or which are not based on objective conditions).

For additional remuneration (in addition to the conditions above):

- be a **non-profit legal entity**

- be paid for the performance of **additional work** or **different expertise** than his/her usual tasks

  This is usually the case, since additional remuneration aims precisely to reimburse the additional work/expertise that is required for EU and international projects.

- be **consistently applied** whenever the same kind of work or expertise is required and **regardless of the source of funding** used

  The additional remuneration may not differ according to *where* the funds come from. In particular, it cannot be set up for actions funded by a specific donor; additional remuneration schemes that are applicable only to EU projects are not acceptable.

  ***Example (not acceptable):** All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

  Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

However, the additional remuneration does not have to be the *same* for all persons working in the same project (provided that objective criteria are used to determine the differences).

⚠ **8000 EUR ceiling —** Additional remuneration is eligible **ONLY up to** a ceiling of **8000 EUR** annual costs; *see point 1.1.4*).

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Teleworking — Remuneration costs of personnel not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible, if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of quasi-financial benefits *(e.g. costs of lunch vouchers)* may be accepted as eligible, if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally NOT eligible as direct costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action, the related costs would be considered part of the entity's normal indirect costs, which are covered by the 25 % flat-rate.

Costs for students, PhDs and other researchers under scholarship, internship or similar agreements (not employees) — Costs of students that work for the beneficiary can be accepted, if the agreement is work-oriented (not training-oriented: i.e. not aimed at helping the student to acquire professional skills).

PhD agreements will be considered work-oriented. However, time for training, if any, may NOT be charged to the action.

Fellowships/scholarships/stipends — Can be charged to the action (as personnel costs), if they fulfil the conditions set out Article 6.1 and 6.2.A.2, and in particular:

- the remuneration complies with the application national law on taxes, labour and social security
- the assignment of tasks respects the laws in force in the country of the beneficiary
- the students have the necessary qualifications to carry out the tasks allocated to them under the action.

Cost for exemptions from academic fees — The fees (or part of them) are eligible as personnel cost, if the student's contract includes the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic remuneration only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible).

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts for participation in projects (whatever their form) are acceptable if it is the beneficiary's usual practice and compatible with national law. The remuneration will be qualified as basic or additional remuneration, depending on the scope (national

OR EU/international) and amount (above, equal or below usual remuneration practices for national projects).

1.1.4 The **costs** must be **calculated** as follows:

In general, personnel costs for H2020 actions are calculated (for each person assigned to the action, including persons working exclusively on the action) as follows:

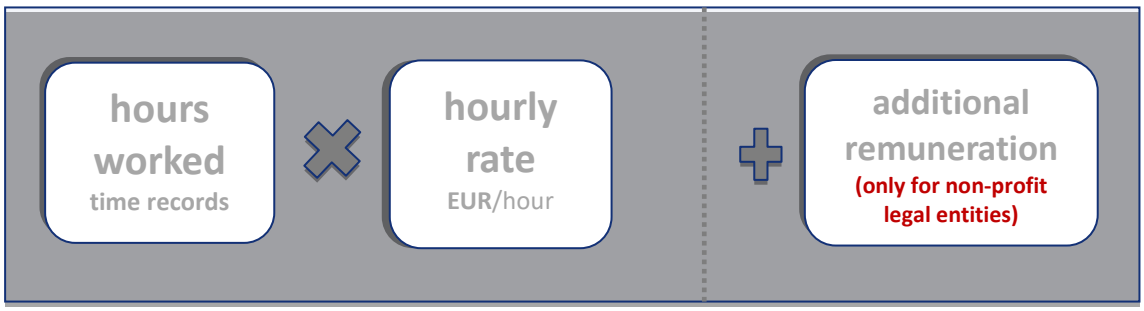

In practice, the calculation will differ (per type of beneficiary/employee) depending on the remuneration practices of the beneficiary:

Case 1: beneficiaries declaring personnel costs as actual costs

Case 1A: employee whose remuneration is not project-based (i.e. same remuneration, regardless if they are involved or not in specific projects)

Case 1B: employee whose remuneration is project-based (i.e. different remuneration levels, depending on whether they work in specific projects or not)

Examples:

1. *The beneficiary and the researcher sign a separate employment contract for the work of the person in the Horizon 2020 action. The hourly rate resulting from that additional employment contract is different from the hourly rate of the other employment contract of the person with the beneficiary.*

2. *The beneficiary has a remuneration scheme which includes the payment of a bonus for work in specific projects. The bonus is paid as part of the total salary of the person in addition to the basic salary and other general bonuses.*

3. *The employment contract of the person fixes a specific hourly rate to be paid for work in specific projects. This hourly rate replaces the standard salary of the person while it works in those projects.*

Case 2: beneficiaries declaring personnel costs as unit costs in accordance with the usual cost accounting practices (average personnel costs).

Additional remuneration is in practice an issue ONLY for case 1B beneficiaries. All other beneficiaries will automatically fall under 'basic remuneration only' and therefore are not concerned by the provisions on additional remuneration.

Case 1B beneficiaries need to differentiate between payments that are basic remuneration and payments that are additional remuneration. For them, the hourly rate charged to the action must be calculated using only basic remuneration (i.e. excluding any part that qualifies as additional remuneration). Additional remuneration may be charged (separately and on top), if the beneficiary is a non-profit entity, if that remuneration is eligible and only up to a ceiling of 8000 EUR per year.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ **Double ceiling —** Beneficiaries must ensure that:

- the **total number of hours** worked **declared** in EU and Euratom grants for a person for a year is NOT higher than the number of **annual productive hours** used for the calculation of the hourly rate *(see below)*

  Example: *Beneficiary using 1 720 as annual productive hours. According to the time-records, during the financial year 2017 employee Z worked 900 hours in a H2020 action and 900 hours in another EU project. The total hours worked for EU projects by employee Z would therefore be 1 800 (900 + 900). However, the beneficiary cannot declare more than 1 720 hours, since this is the number of annual productive hours it used for the calculation of the hourly rate. Therefore, for 2017, the beneficiary can only charge 820 hours to the H2020 action (i.e. 1 720 – 900 hours declared to other EU grant), even if the person worked 900 hours in the action.*

- the **total** amount of **personnel costs declared** (for reimbursement as actual costs) in EU and Euratom grants for a person for a year is NOT higher than the total personnel costs recorded in the **beneficiary's accounts** (for that person for that year).

  Example: *The total personnel costs recorded in the 2017 accounts of the beneficiary for employee Z is EUR 18 000. The beneficiary already declared EUR 9 000 to the other EU grant. The hourly rate for employee Z according to the formula in the H2020 Grant Agreement is 11 EUR/hour and employee Z worked 900 hours for the action in 2017. The eligible personnel costs for the H2020 action would therefore be: 11 EUR/hour x 900 hours = EUR 9 900. However, since the beneficiary already declared EUR 9 000 to the other EU grant, the maximum that it can declare to the H2020 action is: EUR 18 000 (total personnel costs for employee Z) – EUR 9 000 (already declared to other EU grant) = EUR 9 000. The beneficiary can therefore declare only EUR 9 000, even if the result of the formula for personnel costs would be EUR 9 900.*

How to calculate direct personnel costs for employees (or equivalent):

For case 1A beneficiaries (actual costs, not project-based remuneration): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary must calculate, for each employee, the hourly rate to be charged to the action by using one of the following methods:

- **per full financial year** (main method): single hourly rate for each person for each full financial year
- **per month** (alternative method): one hourly rate for each person for each month (i.e. 12 hourly rates per person for each financial year).

Each beneficiary may choose any of the two options. However, the option chosen must be applied during the full financial year to all its personnel in all H2020 grants. If the beneficiary wants to change option, it can do so for the next financial year (— again for all its personnel in all its H2020 grants).

⚠ **Recalculations & adjustments of financial statements (exceptional) —** To benefit from this new option (i.e. hourly rate per month) beneficiaries may apply it retroactively for all grants on-going (i.e. for which the final report has not been submitted) on 20 July 2016 (i.e. date of adoption of the H2020 MGA version 3.0). The beneficiary may re-calculate costs already declared on the basis the full financial year by using the monthly calculation method. However, in that case it must do the recalculation for ALL personnel costs declared for that/those financial year(s) in ALL on-going H2020 grants. The beneficiary must declare the differences, either positive or negative, as adjustments in the next reporting period.

⚠ The grant agreement **formulas for the hourly rates are mandatory**. Those formulas may lead to minor/temporary differences with the personnel cost recorded in the accounts. Those differences have no impact on the eligibility of the costs, provided that the formula has been correctly applied and that the *double ceiling* explained above has been respected.

Calculation of the hourly rate *per full financial year*

Annual hourly rates must be calculated as follows:

for each person:

{actual **annual personnel costs** for the person
divided by
number of **annual productive hours**}.

The rate must be calculated by ***full financial* year** (i.e. the 12-month period covered by the annual accounts of the entity).

Example: *When the financial year matches the* ***calendar year****, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance with the GA is available at the end of the reporting period. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate. The method must however be consistently applied and can NOT be changed within the same grant.

⚠ **Recalculations & adjustments of financial statements (exceptional)** — Adjustments to the hourly rate are normally allowed ONLY for mistakes *(e.g. incorrect accounting information; error in the calculation; etc.)* and must be done using the hourly rate which would have had to be used at the end of the reporting period concerned.

Examples:

1. *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

2. *Reporting period 1 runs from 1 January 2016 to 30 June 2017. The beneficiary used the hourly rate 2016 for the entire period (i.e. also for the part from 01/01/2017 – 30/06/2017) because the financial year 2017 was still on-going at the end of the reporting period. In 2018, the beneficiary realises that the 2016 hourly rate was incorrectly calculated and that it has to declare an adjustment for reporting period 1. To calculate the adjustment, the beneficiary must use the correct hourly rate for 2016 for the whole reporting period 1, including the period from January to June 2017.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed (even if a recalculation of the hourly rate after the closure of the financial year would give another result).

The **annual personnel costs** may include only eligible personnel costs.

Any part of the remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 2:** the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option (1, 2 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, same cost-centre, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed ad-hoc for specific employees)*.

The beneficiary must keep the same option(s) for *the full financial year*. It can only change its option(s) for the next financial year.

⚠ **Absences & overtime —**

Absences: the three options treat absences (leave) in different ways:

- under option 1 (1720 fixed): ONLY actual time spent on parental leave (maternity and parental leave) may be deducted from the 1720 fixed hours. NO other leave *(e.g. sick leave, special leave, annual leave, etc.)* can be deducted.
- under option 2 (individual): the beneficiary must deduct all leaves (i.e. *actual time* on sick leave, parental leave or special leave, etc.) to calculate the annual productive hours.

  ⚠ In order to calculate the annual workable hours, the beneficiary has to deduct the annual leave entitlement (see example in the *table of options*). However, if the employment contract allows end-of-year transfers for leave entitlements (i.e. the days not taken one year can be taken the next one; days not taken are not paid out), the beneficiary may opt for deducting instead *actual time* of annual leave (if this is done consistently throughout the years).
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard time of absence in the organisation. However, the beneficiary may deduct on top the actual time spent on parental leave (maternity and parental leave) by the individual employee.

Overtime: all three options include potential overtime in the annual productive hours, either implicitly (options 1 and 3) or explicitly (option 2):

- under option 1 (1720 fixed): NO overtime may be added to the 1720 fixed hours
- under option 2 (individual): all overtime worked (paid or unpaid) must be added to the annual workable hours to calculate the annual productive hours
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard overtime hours in the organisation (if any).

⚠ **No impact on the hours worked —** The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding can NOT be charged to the action (they must be capped at the ceilings).

Calculation of the hourly rate *per month*

Monthly hourly rates must be calculated as follows:

for each person:

{actual **monthly personnel costs**
divided by
{number of **annual productive hours/12**}**}**.

The rate must be calculated **for each month**.

The **monthly personnel costs** may include only eligible personnel costs.

If a part of the remuneration is generated over a period longer than a month *(e.g. the thirteenth salary)*, only the entitlement generated in the month can be included in the monthly personnel costs (— irrespectively of how much is actually paid in that month).

Example:

In accordance with the collective labour agreement, Ms T is entitled to a thirteenth salary (another full month salary in addition to her 12 monthly salaries) to be paid in July each year. The monthly salary of MS T is EUR 3 000.

The monthly personnel costs in July will be:

EUR 3 000 + {EUR 3 000 / 12} = 3 000 + 250 = EUR 3 250

The beneficiary can therefore NOT include the total of the thirteenth salary in the personnel costs for July, but must distribute it over the months in which it was generated (in this example 1/12 per month). Otherwise, the hours of July would be incorrectly priced at the double of the hours worked in normal months.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** If a later event *(e.g. the unexpected leave of the employee)* means that the payments made for the employee are actually lower (i.e. that the monthly hourly rates were overstated) the beneficiary must recalculate the hourly rates with the correct amount. If some of the related personnel costs were already declared, the beneficiary must declare the difference as adjustment in the next reporting period.

If the monthly entitlement of an extra salary is not known in advance *(for example for an annual merit pay whose amount is decided in December — if eligible as basic remuneration —)* the beneficiary cannot take into account the extra salary until the amount is known. It may therefore recalculate the hourly rates at that moment and, if needed, declare the difference as adjustment in the next reporting period.

For calculating the **annual productive hours**, the beneficiary must use one of the following two options *(see the table of options above for the details on each option)*:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ Option 2 can NOT be used for monthly hourly rates because the individual annual productive hours — and thus also the monthly hours, i.e. 1/12 of the annual — are known only at the end of the financial year. It would be therefore impossible to calculate the hourly rates at the end of each month.

In principle, the same option (1 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must keep the same option(s) *during the entire financial year*. It can only change its option(s) for the next financial year.

⚠ **Absences & overtime —**

The same rules on the treatment of absences and overtime apply as for annual hourly rates, except that time spent on parental leave can NOT be deducted from the annual productive hours.

However, beneficiaries may charge to the action the *costs* incurred for parental leave (as personnel costs) in proportion to the time the person worked for the action during the financial year (time worked on the action over total productive hours for the year). This must be done separately and on top of the personnel costs declared by multiplying the hours worked for the action by the monthly hourly rates.

Example:

In 2015 Ms T has been five months in parental leave. During that time the social security reimbursed to the beneficiary 50 % of her salary. Her monthly salary was EUR 3 000 (reimbursement EUR 1 500). The beneficiary used option 1 (1720 fixed hours) for the annual productive hours and Ms T worked in 2015 320 hours on the H2020 action.

Personnel costs incurred during parental leave= {EUR 3 000 x 5} - {EUR 1 500 x 5} = 15 000 – 7 500 = EUR 7 500

(Note: amounts reimbursed to the beneficiary by the social security are not actual costs for it and, therefore, must be deducted)

Proportion of time worked for the action in 2015 = Time worked for the action / Total productive hours excluding the parental leave = 320 / {1720 - {1 720 x 5/12}} = 320 / {1 720 – 716,7} = 320 / 1 003,3 = 31,89 %

Cost of parental leave for the H2020 action = EUR 7 500 x 31,89 % = EUR 2 391,75

⚠ **No impact on the hours worked —** The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding can NOT be charged to the action (they must be capped at the ceilings). The ceilings apply per full financial year, not per month.

However, do not forget that your personnel costs must comply with national labour law.

Example:

If the national law provides for a prohibition for employees to work more than 48 hours per week, it is not possible to charge to the H2020 action 250 hours in a month for an employee.

Step 2 — **Multiplying the hourly rates by the hours worked on the action**

The hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

For case 1B beneficiaries (actual costs, project-based remuneration): 4 steps

Step 1 — **Checking the nature of the remuneration (basic or additional) for each employee)**

The beneficiary must first find out, for each employee, if the remuneration it is paying is all basic remuneration or contains also additional remuneration.

To do this, the beneficiary must calculate **two reference hourly rates**:

- reference rate for the work on the H2020 action ('**action reference**')

and

- reference rate for the usual remuneration practice for national projects ('**national projects reference**').

If the action reference is *equal or below* the national projects reference, the remuneration is all basic remuneration. If it is *higher*, the exceeding part is additional

remuneration and must be taken out for the calculation of the hourly rate to be charged to the action.

Step 1a — **Calculation of the reference hourly rates**

For the **action reference**: the beneficiary must calculate an hourly rate (either *annual* or *monthly*) based on the remuneration paid to the employee for his/her work in the H2020 action.

For *annual* reference rates:

{annual personnel costs for the person for his/her work in the action

divided by

number of hours worked for the action in the financial year}.

If the reporting period ends before the end of the financial year, the beneficiary must use the personnel costs and the hours from the beginning of the year until the end of the reporting period.

For *monthly* reference rates:

{monthly personnel costs for the person for his/her work on the action

divided by

number of hours worked for the action in the month}.

For the **national projects reference**: the beneficiary must calculate an hourly rate based on either:

- regulatory requirements *(e.g. national law or collective labour agreements)* setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The national law establishes that the maximum monthly salary of engineers acceptable for national grants is EUR 4 000. Beneficiary A has paid that salary to its engineers while working in national grants. Beneficiary B has signed a collective labour agreement whereby the monthly salary to be paid for work under national grants is fixed at EUR 3 500. Beneficiary B has paid that salary to its engineers working in national grants.*

  Maximum amount acceptable as basic remuneration for beneficiary A = EUR 4 000/month for a person working full-time. If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

  Maximum amount acceptable as basic remuneration for beneficiary B = EUR 3 500/month for a person working full-time. If the remuneration of the person for the work in the H2020 action was more than this ceiling, the excess will qualify as additional remuneration.

- internal rules setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The internal rules of University Z provide that a professor working in externally-funded projects may get an extra salary of up to 50 % for the time its works for those projects. The maximum extra salary University Z has actually paid for work in national projects was 30 %.*

  Maximum amount acceptable as basic remuneration = salary of the person + 30 % (for the time worked in the H2020 action). If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

or

- if none of these are available or if the beneficiary never had any national projects before the submission of the H2020 proposal: the average remuneration of the employee in the previous financial year.

The hourly rate of the national project reference must be calculated using 1720 fixed annual productive hours (unless there is an hourly rate directly set in the law, collective labour agreement or internal rules).

For the average remuneration of the employee, the beneficiary must moreover exclude remuneration that came from H2020 actions; i.e.:

{total annual personnel costs* for the person for year n-1 excluding remuneration paid for work in H2020 actions

divided by

1720** minus hours worked in H2020 actions in year n-1}

* The total annual personnel costs include all remuneration paid by the beneficiary to the person for work, irrespectively of the tasks of the person and the projects for which the person was working; but excludes all remuneration paid for work in H2020 actions. If the remuneration included ineligible items *(e.g. profit distribution)* those must also be removed.

** 1720 is the fixed number of annual productive hours. The beneficiary must remove from those annual productive hours the hours worked in H2020 actions. If in year n-1 the person worked exclusively in H2020 actions, the beneficiary must use the average salary of the last year in which the person did not work exclusively in H2020 actions *(e.g. year n-2 or year n-3)*. If in year n-1 the person was on long-term sick leave, the beneficiary may use the average of year n-2 (instead of n-1).

If the national law or the internal rules set up different levels of remuneration for different categories of staff, the reference will be the one of the category to which the person belongs.

If the national law or the internal rules set up different remuneration levels for different types of national projects (or for different work within the projects), the reference will be the one applicable to the type of project/work that is closest to the H2020 action.

Example: *The internal rules of University Z provide that a professor working in basic research projects will receive 10 % extra salary; while a professor working in applied research projects will receive 15 % extra salary. Both extra salaries are systematically paid also for projects funded by national schemes. The H2020 action is an innovation action. The reference that would apply in this case is the extra salary for applied research projects (15 %) as the type of project is closer to the H2020 innovation action than basic research projects.*

The beneficiary must keep appropriate and sufficient evidence to support the action and national project references used *(see Article 18)*.

Example: *If the beneficiary uses the internal rules it must keep documental evidence of the internal rules applied, the category of the person (if applicable), and the payslip and payment documents proving that such remuneration was paid at least once prior to the submission of the proposal.*

Step 1b — **Comparing the action reference with the national project reference**

If the action reference is *higher* than the national project reference, the exceeding part is additional remuneration:

{total additional remuneration = difference between the two reference rates * number of hours worked on the action}

{total basic remuneration = national project reference rate * number of hours worked on the action}

If the action reference is *equal or lower* than the national project reference, there is no additional remuneration; the remuneration paid to the employee is all basic remuneration.

Example personnel costs with additional remuneration (Part 1 of 3):

1. *Ms R is employed full-time as professor at University X. She has a basic annual gross salary of EUR 24 000. The internal rules of the university provide that professors involved in research projects financed by external funders can get up to EUR 6 000 per month of full dedication to the project. However, due to budgetary restrictions the maximum that has been paid to any professor in a national project was EUR 4 800. Ms R worked in 2017 for the H2020 action 200 hours. For those hours she received an extra salary of EUR 6 500. She also participated in other projects*

generating other extras for her. So, her total gross annual salary was EUR 36 000. The hourly rate for the H2020 action is as follows:

The salary of Ms R varies depending on her participation in certain projects. Therefore, the beneficiary must assess if any part of that salary qualifies as additional remuneration. For that, it must compare the action reference with the national project reference:

Action reference rate = basic salary corresponding to the 200 hours worked for the action ((24 000 / 1720) x 200 = 2 790,70 €) + bonus paid for the action (6 500 €) = 9 290,70 € / 200 (hours worked in the action) = 46,45 €/hour (hourly rate)

National project reference rate (in this example based on the internal rules of the university applicable to national projects) = maximum salary paid for any professor working in a national project in accordance with the internal rules = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

The Action reference (i.e. 46,45) is higher than the national project reference (i.e. 33,49). The excess (46,45 – 33,49 = 12,96 €/hour) qualifies as additional remuneration. Therefore:

The total basic remuneration = 33,49 €/hour x 200 (hours worked in the action) = 6 698 €

The total additional remuneration = 12,96 €/hour x 200 (hours worked in the action) = 2 592 €

(This example continues here for the calculation of the hourly rate)

***2.** Same situation as above, but in this case the work in the action has been done under a supplementary employment contract covering additional working hours (on top of the full-time contract of the professor).*

Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour

National project reference rate = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary is NOT paying additional remuneration.

The total basic remuneration = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 2 — **Calculation of the hourly rate (for each employee; on the basis of basic remuneration)**

The beneficiary must then calculate the hourly rate to be charged to the action for the employee:

- **If** there is **additional remuneration**, the beneficiary must calculate the hourly rate using only the basic remuneration. In practice, this will be the action reference, capped at the national project reference (i.e. the hourly rate will normally be equal to the national project reference rate).

  Example personnel costs with additional remuneration (Part 2 of 3):

  ***1.** Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of 9 290,70 €. In the calculations made in part 1 of the example we identified that 2 592 € qualify as additional remuneration.*

  The hourly rate applicable to the action will be, therefore:

  (Actual annual personnel costs for the action - additional remuneration) / hours worked in the action over the year = (9 290,70 € - 2 592 €) / 200 = 33,49 €/hour.

  Personnel costs resulting from the hourly rate = 33,49 €/hour x 200 = 6 698 €.

  (This example continues here for the eligibility of additional remuneration)

- **If** there is **NO additional remuneration** (i.e. all is basic remuneration), the beneficiary can simply use the action reference as hourly rate to charge to the H2020 action.

  Example personnel costs without additional remuneration (Part 2 of 3):
  Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of EUR 6 500 through an additional contract.
  Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour
  National project reference rate = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour
  In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary must use the action reference as hourly rate to charge to the H2020 action:
  Total personnel costs to be declared = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 3 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount of basic remuneration that can be charged to the action *(see examples in Step 2 above)*.

Step 4 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the beneficiary is a non-profit entity and the payments that are additional remuneration are eligible, it may also declare them to the action.

If the resulting amount (for the year) is above the **8000 EUR ceiling**, it must be capped:

Occupation	Contract	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional payment (bonus) but also the additional taxes, costs and social security contributions triggered by the additional payment.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0,8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0,25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0,25 * 0,80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} \times \text{hours worked by the employee for the action over the year}$$

Example personnel costs with additional remuneration (Part 3 of 3):

1. *Ms R worked 200 hours over the financial year. For that work she received 6 698 € of basic remuneration and 2 592 € of additional remuneration.*

If the beneficiary is a for-profit legal entity, the 2 592 € of additional remuneration would be automatically ineligible. The personnel costs which the beneficiary can charge to the action would be therefore 6 698 €.

If the beneficiary is a non-profit legal entity, additional remuneration may be eligible up to the ceiling. To calculate the eligibly part, you need to determine the pro-rata of the cap which corresponds to the 200 hours worked for the action:

(8 000 / 1 720) x 200 = 930,23 €

Although the beneficiary paid 2 592 € of additional remuneration, only 930,23 € are eligible. The difference (2 592 – 930, 23 = 1 661,77 €) is ineligible, since it exceeds the ceiling.

Therefore, the personnel costs which the beneficiary could charge to the action would be: 6 698 € of basic remuneration + 930,23 € of additional remuneration = 7 628,23 €.

For case 2 beneficiaries (unit costs in accordance with the usual cost accounting practices): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary can use the hourly rate(s) that it uses normally (usual cost accounting practices) as average personnel costs, provided that:

- the cost accounting practices are applied in a **consistent** manner, based on objective criteria, regardless of the source of funding
- the hourly rate is calculated using the **actual personnel costs recorded** in the beneficiary's **accounts**, excluding any ineligible cost or costs already included in other budget categories and
- the hourly rate is calculated using one of the **three options** provided in the MGA for the number of **annual productive hours** *(e.g. option 3 'standard annual productive hours')*.

The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

This does not mean that cost accounting practices must be the *same* for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

If necessary, the hourly rate must be adjusted to remove:

- cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the hourly rate).

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

- costs that are already included in other budget categories (double funding of the same costs;

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020*

actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.

Budgeted or estimated elements used to calculate the hourly rate can only be accepted if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way (i.e. do not play a major role in calculating the hourly rate)
- correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

Beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A (as chosen by the beneficiary) applies.

Since there is no obligation to keep time-sheets for periods covered by a declaration on exclusive work, beneficiaries should report:

- for annual hourly rates: a pro-rata of the annual productive hours corresponding to the period covered by the declaration (at the annual hourly rate)
- for monthly hourly rates: 1/12 of the annual productive hours for each month actually worked for the action in the period covered by the declaration (at the monthly hourly rate).

Example:

1a *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours and calculates annual hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate		*Hours worked for the project*	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

1b *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its monthly personnel cost were 2 666,66 EUR in 2014, 2 860 EUR from January 2015 until October 2015 and 2 900 EUR from then on. The beneficiary applies 1720 as annual productive hours and calculates monthly hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*x*	*Hours worked for the project =*		*Total*
2014➔					
October	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 666*
November	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 666*
December	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 666*
				Total	*= 8 000**
2015 ➔					
January	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
February	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
March	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
April	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
Mai	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
June	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
July	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
August	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
September	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
October	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
November	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
December	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
				Total	*= 34 400*
2016➔					
January	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
February	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
March	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
				Total	*= 8 700*
				TOTAL	*= 51 100*

* *Decimals have been rounded*

If the declaration covers months in which the person was **absent** for more than half of the working days those months can NOT be taken into account to calculate the hours worked in the action (— unless the absence is linked to annual leave AND the duration does not exceed the pro-rata of annual leave entitlements corresponding to the period covered by the declaration).

Example:

1. *Researcher Y worked exclusively in the action from1 July 2014 to 31 October 2014. In August it took three weeks of holidays and in September it was 10 days on sick leave. The beneficiary applies 1720 as annual productive hours*

Number of hours that can be charged to the action based on the declaration = 3 months (July, September and October) x (1720 / 12) = 3 x 143,33 = 430 hours

August is not taken into account because the person was absent more than half of the working days, since s/he took three weeks of holidays.

2. *The person has the right to two working days of annual leave per month worked. The period covered by the declaration is from January to September (i.e. 9 months). Therefore, the leave entitlement of the person for that period is 9 x 2 = 18 working days. The person takes 3 weeks of annual leave in August. August could also be counted because the leave taken (i.e. 15 working days) is less that the leave entitlement for that period (i.e. 18 working days).*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the annual hourly rate can only be calculated on the basis of the personnel costs incurred during the ongoing financial year.

Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if option 1 - 1 720 fixed hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 286,66; if option 2 -individual annual productive hours- is used, the productive hours for the period February-March would be the actual productive hours for the period February-March; if option 3 – standard annual productive hours - is used, the productive hours for the period February-March would be the standard annual productive hours/12*2)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the indemnity in the reporting period in which the employee's contract ends — but outside the hourly rate (i.e. separately and on top of the personnel costs declared on the basis of the hourly rate) AND only for the part that corresponds to the time worked by the person on the action (i.e. pro-rata of the total time during which the entitlement was generated).

Moreover, the indemnity can be accepted ONLY if it:

- arises from the applicable national labour law and
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Employment contract remunerated per hour — For employment contracts that do not establish a fixed salary and a number of hours to be worked but only an amount to be paid for each hour worked by the employee, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the individual annual productive hours can be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

This summary table explains the three **different options** for **annual productive hours (for case 1A and case 2 beneficiaries)**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full time equivalent (FTE) covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the GA {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by

		minus
		
		absences (such as sick leave and special leave)}
		
		– the 'annual workable hours' are established according to one of the following:
		
		  – employment contract of the person concerned
		
		  – applicable collective labour agreement
		
		  – national law on working time.
		
		  Example: *contract stipulating 35 hours of work per week*
		
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		
		Example for calculation of individual annual workable hours:
		
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus 8 days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for 5 days.
		
		The individual annual workable hours would therefore be:
		
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		
		Individual annual productive hours for Researcher X:
		
		Annual workable hours = 1 848
		
		+ overtime (hours) = 29
		
		- annual sick leave (5 days x 8 hours) = 40
		
		➔ *individual annual productive hours for Researcher X = 1 837*
		
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
		
		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.
			applying option 2 to all persons concerned, where possible.
			
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow to determine the number of individual annual workable hours: the auditors will apply option 1.
			
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example for calculation of standard annual workable hours:*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would*	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation method consistently applied) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive

		therefore be: *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	hours to the higher number. – If the standard annual productive hours is 90 % of the standard annual workable hours the auditor will not challenge that amount if the amount is in accordance with the usual cost accounting practices of the beneficiary and the calculation method is consistently applied.

		This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 fixed hours).*	

1.2 Direct personnel costs: Natural persons with direct contract (A.2)

1.2.1 **What?** This budget category **covers** typically the costs of **in-house consultants** and similar persons (i.e. **self-employed *natural* persons**) that worked on the action for the beneficiary under conditions similar to those of an employee, but under a contract which is NOT legally the same as for employees. It regards, in particular, contracts qualified as quasi-subordinate work contracts under national law when the conditions under which the work is carried out are similar to those of an employee.

What not? Staff provided by another entity against a price, including staff provided by a temporary work agency (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

> **Staff provided by a temporary work agency —** A contract with a temporary work agency qualifies typically as purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency),* even if that third party is a one-person company.
- the person must work **under conditions similar to those of an employee,** in particular:

> ⚠ **Similar does not mean equal —** The working conditions of the person do NOT have to be exactly the same that those of an employee, but overall similar.

  - the beneficiary must organise and supervise the work of the person in a way similar to that of its employees

    Example (acceptable):

    The beneficiary's project leader and the person discuss regularly the work to be carried out for the action. The project leader decides the tasks and timing of the work and instructs the person accordingly.

    Example (not acceptable):

    The beneficiary's project leader and the person meet only once a month or irregularly, for updates on the state of play of the entrusted work. If changes are needed, they have to be agreed by the person and may lead to a change of the amount charged to the beneficiary.

  - the beneficiary must be able to ensure reliable time recording (for the hours that the person works for the action)

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

– the person is subject to similar presence requirements as the employees.

Examples (acceptable):

The person works physically at the beneficiary's premises, following a time schedule similar to that of the employees (e.g. the beneficiary authorises up to two days of teleworking per week to its personnel and the person has chosen to benefit from this regime, i.e. works 2 days in teleworking and 3 days physically at the beneficiary's premises).

Example (not acceptable):

The entity authorises up to two days of teleworking per week. However, the person works four days in teleworking and only one day at the beneficiary's premises.

- the **result** of the work carried out (including patents or copyright) must in principle **belong to** the **beneficiary**

  If (exceptionally) they belong to the person, the beneficiary must (just like for employees) obtain the necessary rights from the person (transfer, licences or other), in order to be able to respect its obligations under the GA *(see Article 26.3)*.

- **not** be **significantly different** from costs for employees performing similar tasks

  The remuneration must be based on working time, rather than on delivering specific outputs/products.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **rules** as explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, for the **actual costs hourly rate**, the beneficiaries must use one of the following options:

– if the contract specifies an hourly rate: this hourly rate must be used

– if the contract states a fixed amount for the work and the number of hours to be worked: the global amount for the work must be divided by the number of hours to be worked

– if the contract states a fixed amount for the work but does not specify the number of hours to be worked: the global amount for the work must be divided by the pro-rata of 1 720 annual productive hours which corresponds to the duration of the contract over the financial year.

Example: *The contract provides that the person will work at the beneficiary's premises for assisting in research tasks. The contract is for 6 months starting on 1 January 2017 and ending on 30 June 2017. According to its time records, the person worked 500 hours in the H2020 action over that period. The contract sets a monthly payment of EUR 3 000 but does not explicitly establish the number of hours to be worked.*

Personnel costs for the action = hourly rate x 500 (hours worked in the action)

Hourly rate = annual personnel costs / annual productive hours = (3 000 € x 6 months) / (1 720 hours x (6 months/12 months)) = 18 000 € / (1 720 x 0,5) = 18 000 € / 860 hours = 20,93 €/hour

Personnel costs for the action = 20,93 x 500 = 10 465 €.

Social security contributions which are mandatory under national law may be included in the calculation of the hourly rate.

For the **unit costs** hourly rate (average personnel costs), the rules in point 1.1.4 apply without any changes.

This summary table explains how to treat **different types of work contracts** for declaring costs under H2020[17]:

Characteristics of the contract	**Contract remunerating time** *(e.g. the contract establishes that the person must work for the beneficiary 40 hours per week)*	**Contract not specifying the working time conditions** *(e.g. the contract establishes the tasks, but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4); however: ➔ Only option 1 (i.e. 1720 fixed annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. ***Example:*** *Contract from 01.01.2015 to 31.03.2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430*
Other contract (i.e. not an employment contract)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared in category A.2 'natural persons with direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A. 'personnel costs'. They must be treated like CASE D1.	**CASE D1:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

[17] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

		CASE D2: the costs fulfil the conditions of Article 6.2.A.2. The costs can be declared in category A 'personnel costs'. They must be calculated as described in Article 6.2.A. Calculation (point 1.2.4); however: ➔ Only option 1 (i.e. 1720 fixed annual productive hours) can be used to calculate the hourly rate. ➔ If the contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720.

1.3 Direct personnel costs: Seconded personnel (against payment) (A.3)

1.3.1 **What?** This budget category **covers** the costs of persons that worked on the action and that were **seconded** by a third party as an in-kind contribution ***against payment*** *(see Article 11)*.

What not? Persons provided by a temporary work agency, secondment of staff between beneficiaries (or linked third parties) in the same grant or secondment by a third party free of charge.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

Secondment of staff between beneficiaries (or linked third parties) — Is allowed, but it is the beneficiary/third party who employs the person who has to declare its costs (NOT the beneficiary/third party to whom the person has been seconded). The costs declared must be supported by reliable time records of the number of hours the person worked for the action. Those time records must be produced under the responsibility of the beneficiary/third party to whom the person is seconded

Persons seconded free of charge — Costs for persons seconded free of charge (i.e. the third party's costs) can be declared as personnel costs by the beneficiary, if they fulfil the conditions of Articles 6.4 and 12.

> For information on in-kind contributions provided by third parties *free of charge, see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared** ONLY as **actual costs**.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.3.4 There is no specific **calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1*).

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the seconded person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.4 Direct personnel costs: SMEs owners & natural persons not receiving a salary (A.4 & A.5)

1.4.1 **What?** These budget categories **cover** the costs of SME owners (direct owners or co-owners of the SME which is a beneficiary of the grant) and beneficiaries that are natural persons which work on the action, but **don't receive a salary**.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts/other non-employment contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

1.4.2 These costs must be **declared as** the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4 650 or 4 880* /143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *H2020 Work Programme (section 3 MSCA)*[19] in force at the time of the call.

*EUR 4 650 for calls under Work Programmes 2014-2015 and 2016-2017 and EUR 4 880 for calls under Work Programme 2018-2020.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*

*EUR 4 650/143 * 98.8% = EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **SME owner/beneficiary that is natural person**, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf
[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ **Ceiling** — The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than 1 720.

1.5 Direct personnel costs: Access to research infrastructure personnel costs (A.6)

1.5.1 **What?** This budget category **covers** the personnel costs for access to infrastructure activities, i.e. normally:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons with direct contract and
- costs of seconded personnel (against payment).

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs) *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.5.4 The same **calculation rules** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting (B.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing trans-national or virtual access to research infrastructure: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (subcontracting costs (B.)):

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency may exceptionally have to be declared under category B 'subcontracting' (instead of category D.3 'other goods and services') if the temporary work agency carries out directly some task of the action (provided they comply with the eligibility conditions).

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)]***

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

1. Direct costs of providing financial support to third parties (C.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category (together with the corresponding *Article 15* and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances (D.1): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs relate to the personnel of the beneficiaries. They may also relate to experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if:

- the experts' participation is foreseen in Annex 1 or
- their participation is specifically justified in the periodic technical report and the Commission/Agency approved it without formally amending the GA (simplified approval procedure).

The beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly). There is no distinction between travelling in- or outside Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

***Example*:**

Beneficiary A declares the cost of a business class airplane ticket for one of its employees.

If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or subsistence allowances as a lump sum/*per diem* payment, it is the lump sum/*per diem* amount that is considered an eligible cost, NOT the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these lump sum/per diem costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (travel costs (D.1)):

Combination with personal travels or travels for other purposes — The costs of a combined travel can be charged to the action — but ONLY up to the cost that would have been incurred if the travel would have been made exclusively for the action AND if:

- it is the usual practice of the beneficiary to pay for such travels *(e.g. travels combining professional and personal reasons)*
- it has been an actual cost for the beneficiary.

***Example*:**

The researcher flies from Madrid, where the beneficiary is established, to Prague for a project meeting. After the meeting, instead of flying back to Madrid, the researcher flies directly to New York to participate in an event not related to the action.
The beneficiary may charge to the action:

- *the cost of the flight from Madrid to Prague, and*
- *the part of the flight back from New York to Madrid up to the cost that it would have incurred for a flight back from Prague to Madrid after the end of the project meeting.*

⚠ **Record-keeping —** The beneficiary must keep evidence not only of the actual cost of the flight back, but also of the cost of the flight that the person would have taken if it would have returned directly after the end of the work for the action.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).]*

***[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.2): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs (D.2): Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

- if the beneficiary does not use the equipment exclusively for the action, only the portion used on the action may be charged. The amount of use must be auditable

  Example: *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*

  Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

- the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

  Example: *A microscope was bought on 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs (D.2)):

Low-value assets — The full cost of a low value asset may be eligible in the year when it is purchased if:

- the full cost is recorded in the accounts of the entity as expenditure of that year (i.e. NOT recorded as an asset subject to depreciation)

and

- the cost of the asset is below the low-value ceiling as defined under national law (e.g. *national tax legislation)* or other objective reference compatible with the materiality principle

and

- the item is used exclusively for the action in the year of purchase.

  If the item is not used exclusively for the action in the year of purchase, only the portion used on the action may be charged.

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that correspond to the part of the equipment's use for the action. Declaring its *full* price in one single year would be considered either as not compliant with the international accounting standards or as an excessive cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, a piece of equipment bought in January 2013 has a depreciation period of 48 months.
If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that corresponds to the part of the equipment's use for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year, the beneficiary can NOT charge the full price in one single year (— even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year).

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plants constructed by the beneficiary as part of the action tasks — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

However, (full) direct costs for construction of a prototype or pilot plant may exceptionally be eligible, if all of the following apply:

- building the prototype or pilot plant is (one of) the main action task(s) as described in Annex 1 of the GA.
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the eligibility conditions of Articles 6.1 and 6.2 are met.

  If the beneficiary records the construction costs directly under a fixed assets account in the balance sheet rather than as expenses of the year, those costs will normally be considered as compliant with Article 6.1(a)(v) provided that:

  - it is in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices,
  - there is no double charging of costs (in particular, no charging of depreciation costs for the prototype or pilot plant to another EU or Euratom grant).

1.2 Equipment costs (D.2): Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs (D.2): Costs of renting or leasing equipment

1.3.1 **What?** This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:

  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are not higher than the depreciation costs of similar equipment).

1.4 Equipment costs (D.2): Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services (D.3): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access to peer-reviewed scientific publications*, e.g. article processing or equivalent charges*, costs related to open access to research data and related costs, *such as data maintenance or storage and conference fees for presenting project-related research*)
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4 or the certificate was submitted not for the final report but before*).
- translation costs *(if translation is necessary for the action's implementation, is justified, etc.)*.

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services (D.3)):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are fulfilled *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are fulfilled *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the plan for the exploitation and dissemination of the results are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access to peer-reviewed scientific publications and research data are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Self-produced consumables with an accounting value in the inventory of the beneficiary (i.e. not internally invoiced costs for goods and services) — Consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price; the cost of production for the beneficiary is however normally recorded in the accounts of the beneficiary (as part of the *inventory)*. Therefore, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

> ⚠ Beneficiaries can **NOT** charge the **commercial price** for self-produced consumables.

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.
The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency are eligible normally under category D.3 'other goods and services' if they comply with the eligibility conditions (and unless the temporary work agency carries out directly some task of the action, in which case it can be considered as subcontracting and should be declared under category B 'subcontracting').

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[20]);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure (D.4): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of Horizon 2020 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in

[20] *See also International Financial Reporting Standard No 16.*

particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure to calculate the EUR 20 million threshold *(see below)* and therefore declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

[21] *See Article 126 of the Financial Regulation No 966/2012.*

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure (LRI)

Beneficiaries can declare capitalised and operating costs for **large research infrastructure**, if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a **research infrastructure** in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a **grouping of costs** (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any GA (by ticking the LRI box either in the Participant Register or during grant preparation).

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Participant Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) ex-ante assessment report will be issued.

⚠ Although the ex-ante assessment is granted at entity level, it does not necessarily mean that it covers the entire legal entity from the beginning of H2020. It may cover only some departments, cost centres or even individual infrastructures of the beneficiary, possibly with different starting dates.

In that case, the beneficiary may use budget category D.4 only for cost items that are covered by the positive assessment (i.e. that use the methodology and comply with the conditions of the approval).

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs in category D.4 'large research infrastructure'.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) before signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

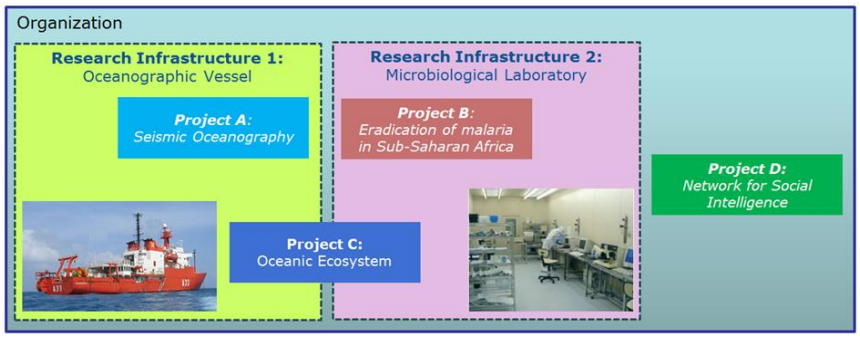

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU/Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU/Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the H2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the H2020 grant, even if they belong to the same action.

> ⚠ **Combining H2020 & other EU grants —** The terminologies under the different EU funds/funding programmes may differ *(e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).*

4.4 Costs must be directly measured

Costs can be claimed as direct costs in category D.4 'Large research infrastructure' only if they are **directly measured** (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[24] *See Article 129(1) of the Financial Regulation No 966/2012.*

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (**project time**) and therefore require reliable time recording (through time-sheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No *1290/2013*

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. This data must be regularly updated.

  Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints *(e.g. opening hours)*, but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

D.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

1. Costs of internally invoiced goods and services (D.5): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 **What?** This budget category covers the costs for goods and services which the beneficiary itself produced or provided for the action. They include (non-exhaustive list):

- self-produced consumables *(e.g. electronic wafers, chemicals)*
- use of specific research devices or research facilities *(e.g. clean room, wind tunnel, supercomputer facilities, electronic microscope)*
- specialised premises for hosting the research specimens used for the action *(e.g. animal house, greenhouse, aquarium)*
- standardised testing or research processes *(e.g. genomic test, mass spectrometry analysis)*
- hosting services for visiting researchers participating in the action *(e.g. housing, canteen*).

What not? Costs of goods of services purchased and costs of goods or services internally invoiced which are not directly used for the action *(e.g. supporting services like cleaning, general accountancy, administrative support, etc.)*.

1.2 Costs of internally invoiced goods and services must be **declared as** unit costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following cumulative **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. used during the action duration, necessary for the action, identifiable and verifiable, etc.; *see Article 6.1(b)*)

⚠ It is NOT necessary to have a document called 'internal invoice' to support these costs, but the beneficiary should have a documented methodology how to determine them (such a methodology must be part of its usual costs accounting practices). The beneficiary must also keep supporting evidence of the use of the good or service for the action.

- be in line with the beneficiary's **usual cost accounting practices**

  It must be the usual practice of the beneficiary to calculate a unit cost for that good or service (i.e. an internal cost per unit invoiced to other departments of the same entity – not prices charged in the context of commercial sales or grants from other fund providers).

- the cost accounting practices must have been applied in a **consistent** manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  Example: *if the beneficiary sets up a new unit cost which applies only to EU actions, the internally invoiced costs based on that new unit cost would be ineligible.*

- the amount per unit must have been **calculated** using the actual costs recorded in the beneficiary's accounts, excluding any ineligible costs or costs already included in other budget categories

  If necessary, the unit cost must be adjusted to remove:

  - cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the unit cost for its internal invoices)

    Example: *The beneficiary uses internal invoices for the use of an electronic microscope based on a unit cost per hour of use. The methodology to calculate the unit cost includes costs of capital (e.g. interest charged by the bank for a loan used to buy the microscope). Those costs are ineligible under the GA (see Article 6.5) and must therefore be removed. The unit cost must be recalculated without them.*

    ⚠ A beneficiary can NOT simply apply an estimated percentage of deduction on the amount of its internal invoices to remove ineligible costs. It has to ensure that the internal invoice does not include any ineligible costs under the GA.

  - costs of resources that do not belong to the beneficiary and which it uses free of charge *(e.g. personnel or equipment of a third party provided free of charge)*, because they are not in its accounts *(see Article 6.1(a)(v))*

    As an exception, if the resource for which the unit cost is calculated is co-owned by the beneficiary and a third party, the costs registered in the accounts of the third party for the co-owned resource do not need to be removed if:

    - the third party is mentioned in the grant *(e.g. as third party providing in-kind contributions in Annex 1)* and

    - the costs fulfil the other eligibility conditions of this Article *(e.g. directly linked to the resource, exclude ineligible costs, etc.)*.

  - costs that are already included in other budget categories (double funding of the same costs, *see Article 6.1(a)(i)*).

    Example: *The beneficiary uses internal invoices for water chemistry analyses, based on a unit cost per water sample analysed. The methodology to calculate the unit cost includes the cost of the staff carrying out the analysis. However, the costs for those persons are already charged to the*

action under direct personnel costs (category A.1). The cost of the staff must therefore be removed and the unit cost must be recalculated without them.

- if budgeted or estimated elements were used to calculate the amount per unit, those elements must:
  - be relevant (i.e. clearly related to invoiced item)
  - be used in a reasonable way (i.e. do not play major role in calculating the unit cost)
  - correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)
- the amount per unit must have been calculated using only costs of items which were **directly linked** to the production of the internally invoiced goods or services *(e.g. staff, equipment, raw materials, etc.)*

  If a cost item is not used exclusively for the internally invoiced good or service, only the share used for the good or service may be counted (the percentage taken must be substantiated by persuasive evidence).

  Example: ***Shared staff —*** *Among the persons operating the beneficiary's wind tunnel, there is one person that is assigned only part-time to that wind tunnel; the rest of the time it works in another department. If the beneficiary includes the costs of this person at the rate of 50 %, it must be able to justify the reality of that percentage, for example, by any of the following:*
  - *reliable time recording system*
  - *a statistic survey performed in the past based on actual data*
  - *detailed calculations based on technical specifications or other scientific and technical requirements of the equipment or infrastructure allowing to reconcile the time spent by the person for the functioning of the wind tunnel*

  or
  - *a combination of these methods.*

  ⚠ **Ceiling** — The (share of the) working time of a person which is included in the calculation of the unit cost reduces the number of hours that the person can charge over the year to EU/Euratom grants *(see Article 6.2.A. Calculation)*. The same hours of the person cannot be charged twice to the grant, once embedded in the unit cost and again as direct personnel costs.

  If necessary, the unit cost must be adjusted to remove costs elements allocated to the unit cost indirectly; i.e. through cost drivers/allocation keys based on other cost items included in the unit cost *(e.g. for a clean room: the costs of the of the human resources department charged to the unit cost as a fixed amount per employee assigned to the clean room; or power supply costs allocated to the clean room on the basis of the square meters it occupies)*.

  Example: *Costs for an animal housing facility*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. keepers, veterinarians and other persons directly assigned to run the animal house)* – *consumables used for the animal housing (e.g. animal food, bedding)* – *depreciation of cages and other equipment directly linked to the housing of the animals* – *generic supplies like electricity or water — BUT only if the consumption of the facility*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the animal house facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the animal housing is part of a main building of the beneficiary)*

has been directly measured (so that the cost can be accurately determined) – *maintenance and cleaning of the animal house facility — BUT only if the cost is directly identifiable (e.g. a separate invoice for the cleaning of the cages)*	– *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

Example: *Wind tunnel*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. technicians, engineers and other persons directly assigned to the functioning of the wind tunnel)* – *depreciation of the equipment, including specific software and hardware necessary for the functioning of the wind tunnel* – *generic supplies like electricity — BUT only if the consumption of the facility has been directly measured (so the cost can be accurately determined)* – *insurance — BUT only if the cost is directly identifiable (e.g. a separate invoice for the insurance of the facility)* – *maintenance and cleaning of the wind tunnel equipment (e.g. air cooling system) — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)* – *calibration/metrology tests — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the building where the installation is located is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

1.1.4 They must be **calculated** according to the rules set out above (point 1.1.3).

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Article 6.2. Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) *[**OPTION 1 to be used if Article 15 applies:** costs of providing financial support to third parties[and][;]][**OPTION 2**: not applicable;]*

(d) *[**OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:** [unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION 2:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (E.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared as** a fixed flat-rate (*see Article 5.2(e)*; ⚠ new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

⚠ The pre-filled amount may NOT be changed (except in case of a parallel operating grant, *see below*).

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation, etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying the 25 % flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

***Example:** subcontracting of opinion surveys*

The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises
- costs of providing financial support to third parties (if option applies)
- costs from specific cost categories (unit or lump sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a GA and has incurred the following costs:

- *EUR 100 000 personnel costs (EUR 7 000 of which are an in-kind contribution in the form of a laboratory technician who carries out work for the action from his/her laboratory in a public research centre)*
- *EUR 20 000 subcontracting costs,*
- *EUR 10 000 other direct costs (consumables).*

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

⚠ **Combining different EU grants —** Beneficiaries that have **action grants** and **operating grants** may claim indirect costs in their action grants ONLY if they are able to demonstrate cost separation (i.e. that their operating grants do not cover any costs which are covered by their action grants).

Operating grants are annual grants to finance the operation and running costs of an entity *(e.g. call COMM-C2/01-2013 under the Europe for Citizens programme)*.

Example: *Entity A receives an operating grant under the Europe for Citizens programme for the financial year 2016 (i.e. from 01.01.2016 until 31.12.2016) The operating grant is not renewed in 2017. On 01.04.2016, entity A signs an H2020 action grant with one reporting period of 18 months (01.04.2016 – 31.12.2017). Beneficiary A may declare the indirect costs in the H2020 action grant as follows:*

- *from 01.04.2016 to 31.12.2016 ONLY IF it can demonstrate that the operating grant does not cover any costs of the action (see beow);*
- *from 01.01.2017 – 31.12.2017 under the normal H2020 rules (i.e 25% of the direct eligible costs since there is no operating grant covering the 2017 financial year).*

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grants may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be full operating grants)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant activities or the operating grant activities)
- the beneficiary must record:
  - all real costs incurred for the activities that are covered by their operating grants (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all real costs incurred for the activities that are covered by their action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that **cannot fulfil these conditions** must EITHER:

- not sign/terminate the operating grants, in order to be able to claim indirect costs in the action grants
- keep the operating grants, but sign the action grants *without* indirect costs or request no indirect costs at reporting stage (i.e. lower the pre-filled amount in the indirect cost column of the financial statement).

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of overlapping EU action and operating grants, the beneficiary should immediately contact the Commission/Agency (via the Funding & Tenders Portal). Be aware that operating grants are not always easy to identify. They exist under various labels (operating grants; financial contributions/support to the functioning/operation of entities; etc.). Check your call text.

H2020 > Chapter 3 > Article 6.2.F

F. [OPTION 1: [Insert name of specific cost category(ies)[22]]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION** 1a **for** specific unit costs **(if unit cost foreseen by Commission decision and applicable to the grant):** [**insert name of specific cost category**] are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category]** are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]

[same for each specific cost category]

[OPTION 2:** Not applicable**]

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit/lump sum costs, i.e. currently:

- actions under Part III of Horizon 2020, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: **costs for energy efficiency measures in buildings**

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': **access costs for providing trans-national or virtual access to research infrastructure**

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': **costs for clinical studies**

  The unit cost applies ONLY to actions with clinical studies.

⚠ **Double funding risk —** Costs that are declared as a specific unit or lump sum cost may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Example: *The unit cost for efficiency energy measures in buildings covers subcontracting costs related to the energy efficiency measures. These cannot be declared as subcontracting costs. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

1.1 Specific cost category — costs for energy efficiency measures in buildings (F.2)

1.1.1 **What?** This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared as** the unit cost set out in Commission *Decision C(2013) 8196*[26] and set out in Annexes 2 and 2a of the GA.

The precise unit cost ('amount per unit', i.e. EUR/m2 of eligible conditioned gross floor area) is not pre-fixed by the Decision; it must be calculated for each beneficiary/linked third party — before signature of the GA — using the following table:

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

The formula for calculating the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) is:

Amount per unit = {EUR 0,1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

The use of the unit cost is mandatory. The beneficiaries/linked third parties cannot choose between unit and actual costs.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m² of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1 EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0,1 EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 Specific cost category — access costs for providing *trans-national* access to research infrastructure (F.2)

1.2.1 **What?** This budget category **covers** direct and indirect access costs for providing trans-national access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.

Beneficiaries that use budget category F.2 'access costs for providing trans-national access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, in category D.1 'travel'; *see Article 6.2.D.1 and Article 16*.)

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing trans-national access to research infrastructure'), the costs must be **declared as** the unit cost calculated in accordance with Commission Decision C(2013) 8199[27] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/unit of access) is not pre-fixed by the Decision; it must be calculated for each access provider and installation, using the calculation table provided on the call page and then summarised in the following table:

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The formula for calculating the 'amount per unit of access' (EUR/unit of access) is:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{28}\text{)}}{\text{average annual total quantity of access (over past two years}^{29}\text{)}}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs (in Part B of their proposal).

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed under previous EU grants, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the user's research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)
  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[29] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation); those costs are not eligible; *see also Article 6.2.D.2*
- travel and subsistence costs for users
- ineligible costs as referred to in Article 6.5.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5 900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800 000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6 100, 5 900) = 6 000

Unit cost = average (3 200 000, 2 800 000) / average (6 100, 5 900) = 3 000 000 /6 000 = 500 €

The detailed calculation tables (one for each installation) must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annex 1; the summary table must be included in Annex 2a.

The proposal and Annex 1 should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. One cost form per installation.

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 Specific cost category — costs for clinical studies (F.2)

1.3.1 **What?** This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
- costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
- indirect costs for the study.

What not? Travel and subsistence costs of study participants and horizontal tasks *(e.g. study monitoring, study coordination)* are not covered by the clinical studies unit cost. (These costs can be reimbursed separately, *e.g. in categories A. 'personnel', D.1 'travel' and D.3 'other goods and services'; see Articles 6.2.A, 6.2.D.1, 6.2.D.3*.)

1.3.2 If they are declared under this budget category (i.e. F.2 'costs for clinical studies'), the costs must be **declared as** the unit cost set out in Commission Decision C(2016) 7553[30] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/study participant) is not pre-fixed by the Decision; it must be calculated for each study/study sequence *(see below)* and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — using the following table:

Task, Direct cost categories	Resource per patient	Costs year N-1 Beneficiary 1 [short name]	Costs year N-1 Linked third party 1a [short name]	Costs year N-1 Beneficiary 2 [short name]	Costs year N-1 Linked third party 2a [short name]	Costs year N-1 Third party giving in-kind contributions 1 [short name]
Sequence No. 1						
Task No. 1 Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR

[30] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

	technician), 15 minutes					
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1 XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						

…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

⚠ Where the nature of the clinical study allows it, it can be split into sequences, *e.g. treatment cycles*. The number of sequences should be limited to the necessary minimum *(e.g. 3 sequences)*.

Separating the unit cost table into sequences will allow you to declare unit costs for study participants that dropped out during the study, but finalised the tasks of a sequence. Thus, the sequence unit cost can be charged for the participant, for the completed sequence(s).

Each beneficiary/linked third party/third party must calculate its unit cost on the basis of its historical data (estimated costs of the components per task and study participant). Historical cost reference data should be taken from the last closed financial year at the time of submission of the grant proposal (certified or auditable profit and loss account for 'year N-1').

Beneficiaries can choose whether to include *all* the cost components in their unit cost or only *some*, but they may NOT add any other cost categories.

They may choose whether to include personnel costs or not, but if they do, *all* the study-related personnel costs must be included (they cannot choose for individual persons/types of personnel). Moreover, this choice must be applied to all the tasks and sequences of the study. If personnel costs are included, they must moreover use one of the three available categories: doctors, other medical personnel or technical personnel (no other categories, *e.g. nurses must be included in 'other medical personnel').*

For consumables, medical equipment and services, there is more flexibility. They can choose for each individual cost items, if they would like to include it in their unit cost (or declare them as actual costs).

The choice (whether to include a cost component in the unit cost or not) is made by adding the costs into the table (or leaving it blank). All blank cost components are outside the unit cost (and can normally be declared as actual costs, if all the eligibility conditions are met).

The beneficiaries/linked third parties/third parties may therefore (for the same study/sequence) not only obtain completely different amounts per unit, but also include different components into their calculation.

Example:

Beneficiary No 1 decided to claim:

- *personnel costs as unit costs*
- *all consumables for sequence 1 as actual costs, all consumables in sequence 2 as unit cost and consumables in sequence 3 partially as actual, partially as unit costs*
- *medical equipment partially as actual, partially as unit cost (e.g. cost of a standard MRI scan — part of the study protocol sequence 2 task 3 — as unit costs and the costs for the use of an novel imaging tool — also sequence 2 task 3 — as actual costs, for instance because the historical data is not fully available)*
- *all services as unit costs.*

Beneficiary No 2 decided to claim all study costs as unit costs.

Linked third party 2a decided not to use the unit cost for any of the study costs (all costs as actual costs).

The formulas for calculating the individual cost components are:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

{certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full time equivalent for doctors for year N-1}
multiplied by
estimated number of hours to be worked by doctors for the task (per participant)**}**

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full time equivalent for other medical personnel for year N-1}
multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)**}**

For personnel costs of technical personnel: 'average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full time equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1
total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)**}**

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}
total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1
total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1**}**

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}**}**

multiplied by

25%**}**

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

This table must already be part of the proposal *(see the proposal templates and the template for essential information to be provided for proposals including clinical studies provided on the call pages)* and be included in Annex 1 and 2a of the GA.

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs components not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*.

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently (and for the different cost components/cost items) whether to be reimbursed on the basis of unit costs or of costs actually incurred.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

⚠ Amendment requests to change the unit cost calculation will be accepted ONLY if there was a change in the study protocol *(e.g. due to requests from competent authorities, regulatory agencies or ethics committees)* or if there was an error in the calculation.

⚠ The maximum grant amount *(see Article 5.1)* will NOT be increased.

⚠ In case of an amendment, it is still the historical costs of the last closed financial year at the time of submission of the grant proposal that must be used to re-calculate the unit cost.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

- amount per unit *(see Annex 2a GA)* **x** the number of study participants

1.4 Specific cost category — access costs for providing *virtual* access to research infrastructure (F.2)

1.2.1 What? This budget category **covers** direct and indirect costs for providing virtual access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including costs for preparatory and closing activities that may be necessary to provide the requested access services).

> ⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.
>
> Beneficiaries that use budget category F.2 'access costs for providing virtual access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Contributions to the capital investment of the infrastructure (including rental, lease or depreciation costs of buildings, as well as depreciation and lease of instrumentation), unless otherwise specificed in the work programme/call. In the latter case, only the portion used to provide virtual access under the action can be eligible.

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing virtual access to research infrastructure'), the costs must be **declared as** the unit cost calculated in accordance with Decision of 6 February 2019[31] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/unit of access) is not pre-fixed by the Decision; it must be calculated for each access provider and installation, using the calculation table provided on the call page and then summarised in the following table:

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The formula for calculating the 'amount per unit of access' (EUR/unit of access) is:

$$\text{Amount per unit} = \frac{\text{total virtual access costs to the installation over last year}}{\text{total quantity of virtual access to the installation provided over the last year}}$$

The total virtual access costs must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices, and
- excluding periods when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost lower than the one calculated on the basis of their historical costs (in Part B of their proposal).

[31] Availabel at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_virtual-access_infra.pdf

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed under previous EU grants, if any.

The 'total virtual access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the ' total quantity of virtual access to the installation provided over the last year', as recorded in the certified or auditable profit-and-loss accounts of the reference period (year N-1) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water specifically supplied for the installation
  - costs of software licence, internet connection or other electronic services for data management and computing supplied specifically for the installation when they are needed to provide virtual access services
  - costs of specific scientific services included in the access provided or needed for the provision of virtual access by the installation.

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation) unless otherwise specificed in the Work Programme.
- ineligible costs as referred to in Article 6.5.

The detailed calculation tables (one for each installation) must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annex 1; the summary table must be included in Annex 2a.

The proposal and Annex 1 should describe both the access services provided and the logistical, technological and scientific support needed to enable the virtual use of the installation by users, as well as any conditions that users must meet to have virtual access to the installation.

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. One cost form per installation.

The use of unit costs for virtual access activities is optional, i.e. each virtual acess provider (beneficiary/third party) can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing virtual access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

1. Costs of linked third parties (A-F)

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility) like beneficiaries.

The same rules apply, but with the changes needed to render them applicable to linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 14.1.1.

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared in category A.1 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions by third parties free of charge (A-F)

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared in category D.2 'equipment' (Article 6.2.D.2).*

In-kind contributions *free of charge* must be **distinguished** from **in-kind contributions *against payment*** *(see Article 11)*.

In-kind contributions *against payment* are costs *of* the beneficiary (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. Their costs (i.e. the payment) must be declared under those specific budget categories.

Examples:

1. *The cost of personnel seconded against payment must be declared in category A.3 'seconded personnel (against payment)' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

The costs of in-kind contributions free of charge (i.e. the costs of the third party offering them) can be assimilated to beneficiary costs and must be declared in the budget category that the beneficiary would have used.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action [;][.]

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

– **debt and debt service charges**

'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

> ***Example:*** *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

– **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

Conversely, if VAT is NOT deductible, it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction

between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*
  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
  - if a beneficiary is receiving an operating grant[32] from the EU/Euratom, then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied — unless it can demonstrate that the operating grant does not cover any costs of the action *(see Article 6.2.E)*.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

If a beneficiary **declares ineligible costs**, they will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Specific cases (ineligible costs):

Non-identifiable VAT (in foreign invoices) — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts if it is not possible to deduct the VAT. That VAT would therefore be eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

Duties — The eligibility of duties depends on the eligibility of the cost item to which they are linked (i.e. in whose price they are included). If the item is eligible, the duty is also eligible.

[32] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the applicable national law.*

⚠ Normally, the beneficiaries must comply **BOTH** with the national law of the **country** in which they are **established** AND that of the country where the **action** is **implemented**.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA). However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Examples (acceptable):

1. *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

2. *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action. They may also call on international partners to carry out work under the action without receiving EU funding (see Article 14a) (**third parties involved in the action**).

Suppliers of goods, works or services and third parties providing in-kind contributions (against payment or free of charge) do not implement action tasks themselves, but only make resources available to the beneficiary, whereas subcontractors, linked third parties and international partners implement action tasks.

⚠ Beneficiaries using third parties remain **fully responsible** for them under the GA.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues like beneficiaries.

Third parties involved in the action do NOT sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 Contracts to purchase goods, works or services	Article 13 Subcontracts
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 Contracts and subcontracts	Article 14 Implementation by linked third parties
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks. They must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme). ℹ For more information on conditions for participation and funding, *see the Funding & Tenders Portal Online Manual.*

The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 Contracts	Article 11 In-kind contributions against payment
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the government (the ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the ministry/government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

This table gives an **overview** of the different kinds of **third parties**:

TYPE	CHARACTERISTICS						
	Works on action tasks?	Provides resources or services for action?	What is eligible?	Must be indicated in Annex 1?	Indirect costs?	Selecting the third party	GA articles
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link and be eligible for funding	Article 14
International partners	**YES**	**NO**	**N/A**	**YES**	**N/A**	Must not be eligible for funding	Article 14a
Subcontractor	**YES**	**NO**	**Price**	**YES**	**NO**	Must be best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contribution	**NO**	**YES**	**Costs**	**YES**	**YES**	May not be used to circumvent the rules	Articles 11 and 12
Contractor (selling, equipment, good or service)	**NO**	**YES**	**Price**	**NO**	**YES**	Must be best value for money, avoid conflict of interest	Article 10
Third parties receiving financial support[33]	The third parties participate in the action as recipients.		**Amount of support given**	**YES**	**NO**	According to the conditions in Annex 1	Article 15

[33] Only if allowed in the work programme/call.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

*[****additional OPTION for beneficiaries requesting zero funding****: If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION 2:** Not applicable]*

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

Beneficiaries not receiving EU funding — They participate in the action as beneficiaries, but NOT with EU funding. They must carry out the work under the action and comply with the GA (although not with *all* its obligations; the financial obligations and some IPR obligations do not apply for them).

'**Beneficiaries not receiving EU funding**' are either:

- 'beneficiaries **not eligible** for funding', i.e. beneficiaries which:
  - are NOT from an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme AND
  - were NOT granted exceptional EU funding by the Commission/Agency (during the selection procedure)

For more information on third country participants, *see the Funding & Tenders Portal Online Manual (international cooperation).*

Beneficiaries that (exceptionally) become eligible for funding during the action, may in principle request funding (as from their eligibility), if the grant agreement is amended to change Articles 9, 57 and Annex 2 (*see Article 55*).

Since the maximum grant amount will NOT be increased *(see Article 5.1)*, this would only be possible if the consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY as from the date of eligibility for funding and if they comply with all the obligations under the GA *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

- 'beneficiaries **requesting zero funding**', i.e. beneficiaries that are eligible for funding, but decided not to request any funding.

Beneficiaries requesting zero funding may in principle request funding later on, if the GA is amended (to change Article 9 and Annex 2; *see Article 55*).

Since the maximum grant amount will NOT be increased *(see Article 5.1), this would only be possible if the* consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY if they comply with all the obligations under the GA retroactively *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate as beneficiaries in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on their role in the grant and if the beneficiary has linked third parties that receive EU funding or not).

This table shows the **GA obligations** that do **NOT apply** to beneficiaries not receiving EU funding (marked by X under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Articles 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of **breach** of any **of** their **obligations**, their participation may be terminated and any of the other Chapter 6 measures (except for rejection of costs or recovery) may be taken.

Examples:

1. *A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

2. *In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).*

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […][23]**]

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EU)[25] or 'contracting entities' within the meaning of Directive 2004/17/EC[26] (or 2014/25/EU)[27] must **comply** with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

⚠ **Purchases —** For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the purchasing context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, *such as technical quality, etc.*), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the grant amount). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules which the European Commission applies for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional cost eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[34] must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 4 of Directive 2014/25/EU)*.

Specific cases (purchases):

Purchases between beneficiaries — Are in principle not accepted. If a beneficiary needs supplies from another beneficiary, it is the latter beneficiary that should charge them to the action. (Otherwise there is the risk that the grant is used to charge commercial profit margins.) Purchases between beneficiaries will only be accepted in exceptional and properly justified cases *(e.g. beneficiary A is the usual supplier of beneficiary B for a generic consumable that beneficiary B needs for the action)*.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[34] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the measures described in Chapter 6.

1. In-kind contributions by third parties against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example (in-kind contributions against payment): *medical equipment provided by a hospital (against a fee) to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2; e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

If the amount paid by the beneficiary is lower than the cost incurred by the third party, the beneficiary may in addition declare the difference as in-kind contributions free of charge (see Article 12). If it decides to do so, it may have to declare that difference also as receipt (*see Article 5.3.3*).

For the upper limit (third party's costs), normally only the *direct* costs *actually* incurred by the third party will be taken into account.

The following costs may however be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[35] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the GA (alternative to actual costs; *see Article 6.2.F*).

The actual costs must be identifiable and verifiable in the third party's accounts.

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used on the beneficiary's premises

or

- taken into account: if the in-kind contributions are NOT used on the beneficiary's premises (*but, for instance, on the third party's premises*).

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

[35] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

3. Additional cost eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1 (*see Article 55*). Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA (**simplified approval procedure**).

Example (approval): *A new researcher is brought into a team working during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

Specific cases (in-kind contributions):

Foundations, spin-off companies, etc., created in order to manage the administrative tasks of the beneficiary and which are paid directly by the coordinator — These are typically legal entities (third parties) created or controlled by the beneficiary (usually a public body like a university/ministry) which handle the financial and administrative aspects of the beneficiaries' involvement in research projects.

Their tasks may include, among others, the employment of personnel, purchase of equipment or consumables that the third party puts at disposal of the beneficiary to carry out the work of the project.

Sometimes they also include the handling of the EU contribution (which means that the beneficiary will use the bank account of the third party and that all payments made to that account count for the beneficiary).

The contributions made by these entities are usually qualified as in-kind contributions against payment. If the costs for the services are not recorded in the accounts of the beneficiary *(e.g. there is no invoice from the entity)*:

- the beneficiary has to prove that such practice is in line with national law and applicable accounting standards
- the costs must be recorded in the accounts of the third party.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The beneficiaries may declare **costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions by third parties free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary itself makes no payment and there is therefore NO cost incurred by the beneficiary. However, the GA provides that it may charge the costs incurred by the third party for its in-kind contribution *(see also Article 6.4)*.

Examples (in-kind contributions free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the ministry/government).

Article 12 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in *Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs *actually* incurred by the third party may be declared.

The following costs may however (alternatively) be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[36] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the GA (alternative to actual costs; *see Article 6.2.F*).

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used in the beneficiary's premises

or

- taken into account: if the in-kind contributions are used on the third party's premises.

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs; but the beneficiary may NOT include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional cost eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1 (*see Article 55)*. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA (**simplified approval procedure**; for details, *see Article 11*).

[36] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[28]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]*.**]***

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be **set out in Annex 1** and the total estimated costs of subcontracting per beneficiary must be **set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) **must comply** with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ **Subcontractors —** Subcontractors participate in the action by carrying out action tasks *for* the beneficiary. They are NOT beneficiaries and therefore have no direct obligations under the grant agreement (but their beneficiaries must ensure that they comply with certain key obligations).

Subcontract — For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on business conditions

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from linked third parties; *see Article 14*).
- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2).*
- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work.
- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary.

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.
- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

The beneficiaries must make special arrangements regarding **results** produced by the subcontractors (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

⚠ **Security obligations —** Stricter rules apply for action tasks that involve information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37).*

ⓘ For more information on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Funding & Tenders Portal Online Manual.*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts either on the best value for money (considering the quality of the service proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the subcontracting context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional cost eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI).

⚠ This concerns research and innovation actions or innovation actions *with* a PCP or PPI.
This should NOT be confused with PCP/PPI action (separate type of action, which use a different model grant agreement and whose *main* action task is the implementation of the PCP or PPI).

The additional rules mirror the key obligations for PCP/PPI actions from the H2020 MGA PCP/PPI.

4. Additional cost eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the **name** of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the subcontract (or the subcontracting costs). For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2 (*see Article 55*). Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA (**simplified approval procedure**).

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

The approval is at the full discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

5. Additional cost eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 4 of Directive 2014/25/EU)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* **—** Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts —** Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[37] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[30] and **third parties with a legal link to a beneficiary**[31] (**'linked third parties'**) may implement the action tasks attributed to them **in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

*The linked third parties may declare as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

*The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their linked third parties.*

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

⚠ **Linked third parties —** Linked third parties are allowed to participate in the action, like the beneficiary they are linked to. They are NOT beneficiaries, but they are allowed to participate fully in the action and receive EU funding; they will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries and their beneficiaries must ensure that they comply with certain key obligations.

⚠ **Combining H2020 & other EU grants —** The terminologies under different EU funds/funding programmes may differ *(e.g. 'linked third parties' under H2020 are the SAME as 'affiliated entities' under the Financial Regulation, while 'affiliated entities' under H2020 is NARROWER than 'affiliated entities' under the Financial Regulation (see Articles 2.1(2) and 23(5) of the Rules for Participation Regulation No 1290/2013 and Article 122 of the Financial Regulation No 966/2012).*

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks.
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission/Agency as reimbursement of costs for their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises.
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only **affiliated entities** or **entities with a legal link to a beneficiary** can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; ad hoc collaboration agreements or contracts to carry out work in the action are NOT covered. In this latter case, both legal entities should be beneficiaries.

AND

– a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

– under the direct or indirect control of the beneficiary or

- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

1. Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research)* ***—*** *They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

2. Associations, foundations *or* ***other legal entities composed of members —*** *That entity is generally the beneficiary and the members are the linked third parties.*

Examples (affiliated entities):

1. *Company A established in France holding 20% of the shares in Company B established in Italy. However, with 20% of the shares it has 60% of the voting rights in company B. Therefore, company A controls company B and both companies may be linked third parties in a H2020 GA.*

2. *Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.*

Linked third parties must fulfil the same **conditions for participation** and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme).[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an US company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country that is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.*

For more information on conditions for participation and funding, *see the Funding & Tenders Portal Online Manual*.

They must be **named** in Article 14 and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the linked third party is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the linked third parties (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial capacity of a beneficiary is 'weak' and
- the beneficiary mainly coordinates the work of its linked third party.

[38] *See Articles 9 and 10 of the Rules for Participation Regulation No 1290/2013.*

Examples:

1. *The financially weak beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The financially weak beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

3. *The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.*

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery), who must upload it (as a scanned PDF copy) in the system.

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files.

The liability is for any amount owned by the beneficiary under the GA, and up to the linked third party's maximum EU contribution in Annex 2.

ℹ For more information on the financial capacity check, *see the Funding & Tenders Portal Online Manual*.

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. *Entities specifically established for the purpose of implementing the action (e.g. EEIGs).*

2. *National research associations established according to the national law in order to carry out research not limited to the action.*

3. *A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.*

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional cost eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO simplified approval procedure.

3. Additional cost eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* (since linked third parties cannot sign them in the IT system; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary.

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Each linked third party has to provide its own ***certificate* on the financial statements** (**CFS**; *see Article 20.4*).

The threshold of EUR 325 000 applies to each linked third party (independently of its beneficiary).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

4. Additional cost eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. 'Other obligation': Extension of obligations under the GA to linked third parties

The beneficiaries must ensure that the linked third parties comply with certain obligations under the GA.

Obligations that must be extended to linked third parties:

- Record-keeping obligations *(see Article 18)*
- Reporting *(see Article 20)*

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties.

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following **international partners**[37] may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

– *will not be reimbursed and*

– *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36 and 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary braches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION 2:** Not applicable**]

[37] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

1. International partners

4.0 This optional Article (together with the corresponding options in Article 4) will be inserted into the GA if the action is implemented with international partners. It was introduced with GA version 4.0 and does NOT automatically apply to older grant agreements (however beneficiaries with older GAs may ask for an amendment to introduce international partners *see Article 55*).

International partners — International partners are allowed to participate in the action without EU funding. They are NOT beneficiaries and do NOT receive EU funding; they therefore have no direct obligations under the grant agreement (but their beneficiaries must to ensure that they comply with certain key obligations).

Characteristics of implementation by international partners:

- International partners perform their action tasks directly. They do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the action tasks performed by its international partner.

- International partners perform their action tasks without receiving EU funding, i.e. their costs are NOT eligible for reimbursement under the grant. Therefore, they will not be subject to financial checks, reviews or audits.

  The costs of the international partners are estimated in Annex 2 (to get an overview of the overall project budget). But this is for information purposes only, the international partners are not required to report on their costs.

International partners do NOT need to have a (capital or legal) link to the beneficiary (but they may have one).

They must NOT be eligible for funding, i.e. be:

- a legal entity established in a third country not listed in General Annex A to the H2020 Work Programme or

  Example: *A consortium of legal entities from EU Member States, H2020 associated countries and third countries listed in General Annex A to the H2020 Work Programme wants to work with a legal entity established in New Zealand. Since the New Zealand entity would like to be involved in the action without requesting EU funding and without becoming a beneficiary, one of the beneficiaries may decide to list the New Zealand entity as its international partner and attribute certain action tasks to it (provided that the international partner agrees to the action tasks and the related obligations under the GA).*

- an international organisation other than international European interest organisations[39].

They may be used to implement any of the action tasks.

They must be **named** in Article 14a and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the international partner is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the international partners (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

Although they are not beneficiaries and do not receive EU funding, their beneficiaries must ensure that they comply with certain key (non-financial) obligations:

Thus, they must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 to verify the proper implementation of the action tasks and that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

Moreover, they must extend the following obligations under the GA to the international partners:

Obligations that must be extended to international partners:

- Record-keeping obligations (on the scientific and technical implementation; *see Article 18.1.1*)
- Technical reporting (in the required language; *see Article 20.3(a), 20.4(a) and 20.7)*
- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38).*

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the international partners.

[39] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013*: **'international European interest organisation'** means an international organisation, the majority of whose members are

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving financial support.*

15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving financial support.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties ONLY where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*.)

Examples:

1. *An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.*

2. *One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.*

Member States or associated countries, and whose principle objective is to promote scientific and technological cooperation in Europe.

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving a prize.*

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving a prize.****]***

[OPTION 2: *Not applicable****]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

***Access** for user groups with a majority of users not working in a EU or associated country[34] is **limited** to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) procedure and criteria for **selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: […]*[35]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

(a) advertise widely, including on a dedicated website, the access offered under the Agreement;

(b) promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;

*(c) ensure that users **comply** with the terms and conditions of the Agreement;*

*(d) ensure that its obligations under Articles 35, 36, 38 and 46 **also apply** to the users.*

[OPTION 2:** Not applicable**]

[32] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[34] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[35] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the H2020 Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[40] or installation[41] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

The access costs may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 of the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

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[40] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[41] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

⚠ **Record-keeping —** The beneficiaries must keep appropriate records and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional cost eligibility condition: Access which must be provided

Trans-national access can be either:

- **in person** (hands-on), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional cost eligibility condition: Categories of users that may have access — Limited access for special user groups

For trans-national access, user groups in which all or most users work in non-associated **third countries** may ONLY have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional cost eligibility condition: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. 'Other obligation': Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to users

The beneficiaries must also ensure that the users comply with certain obligations under the GA.

Obligations that must be extended to users:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users.

16.2 Rules for providing virtual access to research infrastructure

[OPTION 1 for virtual access to research infrastructure: *'**Access providers**'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION 1 to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable**]***

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e. actions under Part I of Horizon 2020, 'Research infrastructures'.

Grants for this type of actions usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the installation during the course of the action and costs related to technological and scientific support for users access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*

– costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 3)*.

As from the Work Programme 2020, the access costs may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed — unless provided for in the work programme/call. In this case only the portion used to provide virtual access under the project is eligible.

Virtual access may or may not be **measured**. If measured, the GA will specify a unit of access.

When the research infrastructure access policy requires the identification of users, the EU financial support to virtual access will cover the access costs incurred by the infrastructure or installation for the provision of access under the grant to the identified users. The proposal can also define eligibility criteria (e.g. affiliation to a research or academic institution) for the users to whom access will be provided under the grant

When access is provided without identifying users, the research infrastructures virtual services to be supported by the EU must be *widely* used by the European research community[42].

The beneficiaries must provide detailed information on the provision of access activity in the **periodic technical reports** including, when access is provided without identifying users,statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*

Access must be open to all users; users are not selected.

3. Additional cost eligibility condition: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

[42] Under the H2020-INFRAEOSC-2018-2020 call, other communities could be considered in order to widen the user base.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request the information for **any purpose** *(e.g. checks for monitoring the action or assessing reports and requests for payment; reviews; audits; investigations; evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission/Agency may request the information at **any time**, either during the action or afterwards.

Examples:

1. *In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid (see Article 22).*

2. *The Commission may request information from the beneficiaries in order to evaluate the action's impact up to five years after the balance is paid (see Article 23).*

3. *The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.*

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information is sent via the Funding & Tenders Portal. Afterwards, information requests may have to be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Participant Register

Each beneficiary must keep its information in the Participant Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form *(e.g. private limited liability company, public law body, S.A., S.L.)*
- organisation type *(e.g. SME, secondary or higher education establishment, etc.)*.

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, *see the Funding & Tenders Portal Online Manual*.

3. Information likely to delay or affect the action or EU financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU financial interests.

> ***Examples (situation likely to significantly affect or delay the action's implementation or affect the EU financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Participant Register *(see above)*, the beneficiary must **update** the Participant Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.).*

Best practice: It is recommended that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the Funding & Tenders Portal
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (for linked third parties, *see point 10*) must keep appropriate and sufficient evidence to **prove** the eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[43]

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

[43] International Standard on Auditing ISA 500 'Audit Evidence'.

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Commission/Agency.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission/Agency will accept any document considered an original under national law.

Examples:

1. *The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.*

2. *The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.*

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

1. *For costs declared in category A.1 (employees or equivalent): the costs must be detailed for each person carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).*

2. *For costs declared in category D.1, D.2, D.3 and D.4 (other direct costs): the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.). It should be able to provide details of individual transactions for each type of cost. For depreciation, it must be able to provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).*

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For costs declared in accordance with their usual cost accounting practices (**average personnel** costs and costs of **internally invoiced goods and services**), the beneficiaries must keep detailed records and other supporting documents to:

- show that the costs used to calculate the unit cost match the actual costs as recorded in the statutory accounts

  Examples:

  1. *For personnel costs: accounting records; financial statement extracts; labour contracts; collective labour agreements; applicable tax, labour and social security laws; pay slips; bank statements showing salary payments; classification of employees (based on experience, qualifications, salary, department, etc.).*

  2. *For internally invoiced goods and services: accounting records; financial statement extracts; time records (or other records) for the share of personnel costs included in the unit costs; invoices or contracts for maintenance costs, cleaning costs, other services, showing that the cost are directly identifiable.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost is free of ineligible cost components

  Examples:

  1. *For personnel costs: records that show that the hourly rate does not include an indirect cost component (already covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (they should be claimed under category D.1 'travel').*

  2. *For internally invoiced goods and services: evidence that shows that there is no profit/margin/mark-up included in the internally invoiced goods and services (e.g. different rates: one for billing the activity, with mark-up, and another one for internal costing, free of any mark-up); lists of accounts/cost centres that were excluded from the calculation of internally invoiced goods and services — because already included in the costs claimed under another budget categories (e.g. LRI costs, indirect costs, in-kind contributions, etc.).*

- assess the acceptability of budgeted and estimated elements

  Examples:

  1. *For personnel costs: records that show the method for calculating the annual salary increases (e.g. consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases).*

  2. *For internally invoiced goods and services: traceable data used to determine the budgeted/ estimated elements; records on the nature and frequency of the updates of the budgeted and estimated elements; etc.*

- for personnel costs: verify the number of productive hours used to calculate the unit cost (hourly rate)

– for internally invoiced goods and services: verify that the cost items used for the calculation of the unit cost were directly linked to the production of the invoiced good or service.

Examples (not acceptable):

1. *Maintenance which goes beyond than the maintenance of the infrastructure/facilities used to produce the good/service (e.g. maintenance costs for all the beneficiary's cleanrooms; maintenance costs for an entire building, while the cleanroom used for the good/service occupies only a part of the building).*

2. *Generic supplies for which there is no evidence that they were directly linked to the infrastructure/facilities used to produce the good/service (e.g. electricity costs when there is no electricity counter or technical specifications to measure the consumption).*

By contrast, it is NOT necessary to keep records on the actual costs incurred (per person/good or service) — unless they are needed to document the usual cost accounting practices (as just described).

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary/linked third party may request that the Commission/Agency confirms that its cost accounting practices for personnel costs comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared *before* the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificate is NOT valid for H2020.)

When? Beneficiaries may in principle submit their requests for approval at **any time** — before or during the grant.

Best practice: In order to ensure that the auditor has enough information to get assurance on the methodology, it is recommended to request it only *after* the first reporting period has passed.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

⚠ If the beneficiary declares personnel costs according to the changed cost accounting practices *before* the new certificate is approved, it bears the **full risk** of non-approval and cost rejection by the Commission/Agency.

How? The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 of the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump sum costs

For lump sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

⚠ For H2020, exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, monthly or per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a declaration on exclusive work for the action [ODT format] (one per reporting period), to confirm that the person worked exclusively for the action, either:

  - during the whole reporting period

  or

  - during an uninterrupted time-period, covering at least a full calendar month within the reporting period.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

'Exclusive work' means that the person carried out NO OTHER activities for the beneficiary than those of the action.

Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration. If a person worked randomly for the action after an

uninterrupted time-period covered by a declaration, time-sheets are needed for the period of random work.

> ***Example:*** *The person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

If a person worked under different regimes during the reporting period (exclusive and non-exclusive), the declaration may be used ONLY for a period of exclusive work. The other months must be recorded with time-sheets.

If there were several periods of exclusive work during one reporting period, the beneficiary may choose to use the declaration for the longest one (and use the monthly time-sheets for the others).

The declaration must be **dated** and **signed** by the person concerned AND her/his supervisor.

– keep **time records**.

Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

– show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

Time records should include, as a minimum:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record
- the supervisor's full name and signature
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template [ODT format] for time-sheets with these minimum requirements is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept **alternative evidence** if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has full discretion to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the **full risk** of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned

Criterion 2 is met – the project is identified as XYZ

Criterion 3 is met – the time is quantified: two weeks

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown

Criterion 2 is not met: the project name is not mentioned

Criterion 3 is not met – the time is not quantified

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Example: *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

1. *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*

2. *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

For **international partners,** beneficiaries must keep appropriate and sufficient evidence ONLY on scientific and technical implementation of the action. Beneficiaries are not required to prove the costs of the international partners, since the latter do not receive EU funding (*see Article 14a*).

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When? The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

> 'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).
>
> 'Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points.

The deliverables that must be produced are listed in Annex 1 of the GA.

> ***Example:*** *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

For deliverables that are not in writing *(e.g. cell line or prototype)*, the beneficiaries must submit a short written description.

How? The coordinator must upload them directly in the Funding & Tenders Portal.

Security obligations — If the deliverables contain **EU classified information**, the coordinator must first contact the Commission/Agency to discuss how to submit them (approval needed; *see Article 37*).

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Funding & Tenders Portal Online Manual.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1] to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2 : *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

What & When? In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of the action (reporting).

> These reports must be **distinguished** from **deliverables** (that are part of Annex 1; see Article 19) and milestones (part of Annex 1, but not covered by Article 19 or 20).

The coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Each report should be seen as a single package, composed of several parts, i.e.:

- a **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically generated by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (CFS; one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

If the coordinator **breaches** its **obligation** to submit the reports, the Commission/Agency may suspend the payment deadline and — if not remedied after a written reminder — terminate the GA or take any of the other Chapter 6 measures *(e.g. cost rejection, grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50).*

> The GA will not be terminated if the breach concerns the last reporting period (because the action duration is already over).

How? The report(s) must be **prepared** by the **coordinator** and the other **beneficiaries together** (directly in the Funding & Tenders Portal Continuous and Periodic Reporting Modules).

List of documents for the periodic reports:

- explanation of the work carried out (periodic reporting - part B technical report)
- overview of the progress (periodic reporting - part B technical report)
- updated plan for the exploitation and dissemination of results (if necessary) (periodic reporting - part B technical report)
- summary for publication (continuous reporting)
- answers to the questionnaire (continuous reporting)

- individual financial statements for each beneficiary and linked party (periodic reporting - financial report)
- explanation of the use of resources (periodic reporting - financial report)
- summary financial statement (generated automatically by the IT system)
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication (generated automatically by the IT system)
- final summary financial statement (generated automatically by the IT system)
- certificates on the financial statements (CFS) (if necessary).

Generally, they can be **prepared together** (i.e. by several users from different beneficiaries), via the Funding & Tenders Portal Continuous and Periodic Reporting Modules. The parts in the **continuous reporting** can be filled out at any moment in time (continuously open) and are then automatically added into the periodic report by the IT system *(part A of the technical report with the questionnaire and the summary for publication; consolidated financial statement*). Other parts are opened only at **periodic reporting** *(part B of the technical report, individual financial statements, explanation of the use of resources)*. Data is cross-linked to avoid duplication of data input *(e.g. the financial statement and the explanation on the use of resources are linked: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense, if necessary; the final report is completely automatized: assembled on the basis of elements from the periodic report).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (directly in the Funding & Tenders Portal).

This includes the **coordinator**, who must also submit the individual financial statement for itself.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (since the linked third parties cannot sign them in the IT system).

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must ensure that the data encoded is correct (i.e. identical to the signed paper version).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

If a beneficiary cannot submit its individual financial statement on time, the report can be **submitted without this financial statement**. The costs will be considered zero for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned.

⚠ **Record-keeping —** The beneficiary must keep the originals for itself and its linked third parties in its files *(see Article 18.1.2)*.

When all parts are ready, the report(s) are assembled automatically by the IT system and must be **submitted** by the coordinator (as a single package; **single submission**).

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator, as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) (**suspension of the payment deadline**). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified (**single re-submission**).

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

⚠ **Adjustments of financial statements (exceptional) —** If the beneficiaries notice a mistake *(e.g. incorrect accounting information; error in the calculation; etc)*, they can make an adjustment (positive or negative) in the following reporting period to the financial statements for any previous reporting period.

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed *(e.g. to take into account of a different hourly rate after the closure of the financial year)*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated **plan for the exploitation and dissemination of the results** (if such a plan is foreseen in Annex 1).

3.0 For grants signed after GA version 3.0, the overview of the progress must also indicate the communication activities carried out by the consortium *(see also Article 38.1)*.

> ⚠ **Security obligations —** Technical reports may NOT contain any information that has been **EU-classified** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Funding & Tenders Portal Online Manual.*

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an easy-to-read way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential (or EU-classified) information.

For the last reporting period: The summary should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact (because it will be directly re-used for the final report).

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the H2020 Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the H2020 Specific Programme)
- information to monitor the implementation of H2020 on cross–cutting issues *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Financial report: Individual financial statements — Explanation of the use of resources — Summary financial statement — Certificates on the financial statements (CFS)

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 (**cost overruns**). The grant will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

⚠ **Combining different EU grants —** Beneficiaries that have **action grants** and **operating grants** may claim indirect costs in their action grants ONLY if they are able to demonstrate cost separation (i.e. that their operating grants do not cover any costs which are covered by their action grants).

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grants may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be full operating grants)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant activities or the operating grant activities)
- the beneficiary must record:
  - all real costs incurred for the activities that are covered by their operating grants (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all real costs incurred for the activities that are covered by their action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that **cannot fulfil these conditions** must EITHER:

- not sign/terminate the operating grants, in order to be able to claim indirect costs in the action grants
- keep the operating grants, but sign the action grants *without* indirect costs or request no indirect costs at reporting stage (i.e. lower the pre-filled amount in the indirect cost column of the financial statement).

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of overlapping EU action and operating grants, the beneficiary should immediately contact the Commission/Agency (via the Funding & Tenders Portal). Be aware that operating grants are not always easy to identify. They exist under various labels (operating grants; financial contributions/support to the functioning/operation of entities; etc.). Check your call text.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

For the final reporting period, some beneficiaries/linked third parties will also have to submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and unit costs calculated according to its usual accounting practices (average personnel costs and costs for internally invoiced goods and services).

This means that costs based on lump sums, flat-rates (*e.g. indirect costs*) or unit costs (other than those for personnel costs and costs for internally invoiced goods and services calculated according to the beneficiary's usual cost accounting practices) are NOT counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in an action which declared the following total eligible costs for the action:

- *personnel costs according to usual accounting practices = EUR 250 000*
- *subcontracting costs = EUR 40 000*
- *depreciation costs of equipment used to carry out the action = EUR 60 000*
- *indirect costs (25 % flat rate) = EUR 77 500*
- *total eligible costs claimed by A = EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and personnel costs according to usual accounting practices incurred by A (and hence the requested financial contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or unit costs calculated according to usual accounting practices must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency are NOT counted for the EUR 325 000 threshold and they do not need to be covered (again) by the certificate).

Linked third parties must submit a certificate if it reaches (on its own, without its beneficiary) the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

The certificate(s) may be submitted ONLY **with** the ***final*** **financial report**. Certificates submitted at any other moment will NOT be accepted (and costs incurred for them will be considered ineligible, because not necessary).

Costs for partial certificates (i.e. one certificate per reporting period) will be accepted ONLY in the last reporting period and ONLY if:

- a CFS is mandatory (i.e. the threshold is reached at the end of the action) and
- the total costs of the partial certificates is similar to the cost that would have been incurred for a single certificate.

The certificate must be issued by an **external auditor**, using the template in Annex 5 of the GA.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[44] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

The **summary financial statement** is generated automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

For the final reporting period, the IT system will also generate a **final summary financial statement** (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a non-EU country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in non-EU countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

5. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants above EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

A template is available and must be submitted via the Funding & Tenders Portal Continuous Reporting Module.

6. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

[44] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    For cost adjustments to previous periods ('adjustment financial statements'), the exchange rate to be used is the one for the reporting period in which the costs adjusted were incurred.

    For eligibile cost related to drafting and submitting the final reports incurred after the action duration, the exchange rate to be used is the one for the last reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[45].

    How to calculate the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[46].

    Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16,.7531 for EUR 1. The university will report costs of EUR 29 845,22 (MDL 500 000 / MDL 16,.7531 * EUR 1).*

7. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

[45] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[46] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments to be made

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts before)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or an(other) executive agency — without the consent of the beneficiary concerned and up to the beneficiary's maximum grant amount in Annex 2 *(see also Article 44)*.

All payments are subject to a **payment deadline** (i.e. number of days within which the Commission/Agency has to pay the consortium — after having received the payment request). The deadline depends on the type of payment:

- for pre-financing: 30 days
- for interim payments and payment of the balance: 90 days *(see Article 21)*.

If there are issues with the payment request or with the costs declared which make it impossible to comply with the payment deadline, the Commission/Agency will **suspend the deadline** *(see Article 47)*.

The pre-financing payment is automatic, while for interim and final payments the Commission/Agency must first:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs
- calculate the amount to be paid
- approve the payment request and authorise the payment.

This is not an in-depth verification and therefore no guarantee for eligibility or correctness. The costs may still have to be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

The payments are made **to the coordinator**; the beneficiaries are NOT paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only if the coordinator is terminated that the Commission/Agency (and especially the Guarantee Fund) will intervene; *see Article 50*).

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

The shares for the Commission's **Joint Research Centre (JRC)** will always be kept back and not be paid out to the coordinator (the JRC is a Commission DG and the amounts are therefore cleared internally).

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) is kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 - EUR 52 500 = EUR 297 500

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing amount does not depend on any financial statement. It is a float that is fixed in each GA and automatically paid at the beginning of the action.

How to calculate the pre-financing payment:

Step 1 — **Pre-financing amount**

The amount of pre-financing is fixed in the GA.

There is no standard amount (or percentage) for the pre-financing payment. For H2020 grants, it will normally be (depending on the availability of EU budget credits) 100 % of the average EU funding per reporting period (i.e. maximum grant amount set out in Article 5.1 / number of periods). For actions with only one reporting period, it will however be less, since 100 % would mean the totality of the grant amount.

Step 2 — **Deduction of the Guarantee Fund contribution**

At the moment of the pre-financing, an amount that corresponds to 5 % of the maximum grant amount *(see Article 5.1)* is deducted from the pre-financing payment and transferred to the Guarantee Fund. (The Guarantee Fund is a Fund that covers defaulting beneficiaries).

Step 3 — **Pre-financing payment letter**

The Commission/Agency will inform the coordinator about the amount due (pre-financing payment letter).

Pre-financing funds remain **EU property** until the payment of the balance — when they are cleared against the eligible costs accepted by the Commission/Agency.

Example for calculating the pre-financing payment:

Action with 3 reporting periods of 18 months.

Maximum grant amount: EUR 1 000 000.

Reimbursement rate: 100 %.

Guarantee Fund contribution: 5% of EUR 1 000 000 = EUR 50 000.

Pre-financing amount & deduction of Guarantee Fund contribution:

Pre-financing amount: EUR 333 334.

Amount to be paid out to the consortium as pre-financing: EUR 333 334 - EUR 50 000 = EUR 283 334.

Payment at beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Commission/Agency on the basis of the termination report, the payments already made and the report on the distribution of payments *(see also Articles 44.1.1, 50.2.2 and 50.3.3)*.

⚠ The **amount due** is used to determine whether the terminated beneficiary received too much from the consortium (and should pay it back to them) and will then flow into the calculation of the next interim and final payments in order to cap that beneficiary's accepted EU contribution.

⚠ The terminated beneficiary's share of the final grant amount (beneficiary's final grant share) will be calculated only at the end of the project (payment of the balance), together with the rest of the consortium.

⚠ If the terminated beneficiary is audited during the ongoing project, its amount due will be re-calculated. If the terminated beneficiary is audited after the end of the project, the recovery will follow the standard rules (revised final grant amount calculated on the basis of the final grant share).

How to calculate the amount due at beneficiary termination:

Amount due

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rate to the eligible costs)**

In order to calculate the amount of accepted EU contribution for the beneficiary concerned, the Commission/Agency will calculate the accepted costs for the beneficiary and each of its linked third parties (i.e. eligible/not rejected costs declared in the interim and termination reports; *see Articles 6 and 42*), apply the reimbursement rate(s) and sum them up to a total amount for the beneficiary.

Only costs incurred *(see Article 6.1(a))* by the beneficiary concerned until termination takes effect are eligible (except for costs for the termination report). Costs relating to contracts due for execution (i.e. delivery) only after termination are NOT eligible.

If the coordinator fails to submit the termination report (within the 30 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. The Commission/Agency will NOT send a written reminder and will not extend the deadline.

If the beneficiary requested less than the maximum EU contribution, the accepted EU contribution will be this lower requested amount.

➔ Amount resulting from Step 1.

Step 2 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions, the Commission/Agency will calculate the grant reductions for the beneficiary concerned and its linked third parties (if any; see *Article 43*) and then sum them up to a total amount for the beneficiary.

This total amount of grant reductions is then deducted from the pro rata temporis part of the beneficiary's and linked third parties' maximum grant amounts (Annex 2) — pro rata temporis corresponding to their period of participation (i.e. until termination).

ℹ For more guidance on grant reductions, *see the Guidance on grant reductions*.

➔ Amount resulting from Step 2.

The **amount due** is the lower of the two (amount resulting from Step 1 and amount resulting from Step 2).

Beneficiary balance

Step 3 — **Calculation of the beneficiary balance**

In order to establish if the beneficiary received excess funding, the Commission/Agency will deduct the total amount of pre-financing and interim payments made (according to the report on the distribution of payments) from the amount due.

If the amount due is *higher* than the payments already made, the difference will be paid by the Commission/Agency to the coordinator at the next interim/final payment.

If the amount due is *lower* than the payments made, the beneficiary must repay the difference (to the consortium; NOT to the Commission/Agency). If the beneficiary doesn't, the Commission/Agency will intervene, by activating the Guarantee Fund to pay the money to the consortium and then recovering it from the beneficiary in the name of the Guarantee Fund *(see below*).

If the coordinator does not submit the report on the distribution of payments, the terminated beneficiary will NOT have to repay any amounts to the consortium. If there are issues, the consortium will have to deal with them internally.

Step 4 — **Beneficiary calculation letter**

The Commission/Agency will inform the beneficiary about the balance, i.e. the amounts that are owed to the consortium or to the beneficiary concerned (beneficiary termination calculation letter).

If the closure involves grant reduction or recovery (refund to the consortium), there will be two letters: a pre-information letter (opening a contradictory procedure) and confirmation letter *(see Articles 43 and 44)*.

Recovery (if any)

Step 5 — **Beneficiary recovery letter & debit note**

If the beneficiary does not repay the consortium by the date specified in the confirmation letter, the Commission/Agency will activate the Guarantee Fund (to pay the consortium) and claim back the money paid by the Guarantee Fund from the beneficiary, (beneficiary recovery letter; *see Articles 44 and 50*).

Step 6 — **Enforced recovery**

If the beneficiary does not honour the debit note within the deadline, the Commission/Agency will enforce its claim, by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**
- taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
- adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Example for calculating the amount due at beneficiary termination:

Grant with three beneficiaries (A, B and C) and two reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100 %.

Pre-financing: EUR 200 000.

Amount due:

Beneficiary A goes bankrupt in the middle of the action and is terminated at month 18 (of 36), just before the end of RP1.

Costs declared by beneficiary A in termination report: EUR 50 000 (direct costs) + EUR 12 500 (25 % flat rate for indirect costs) = EUR 62 500.

Costs rejected for beneficiary A following audit: EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Accepted costs beneficiary A: EUR 62 500 – EUR 12 500 = EUR 50 000.

Application of reimbursement rate: EUR 50 000 (total accepted EU contribution).

Amount resulting from Step 1: EUR 50 000.

10% grant reduction beneficiary A due to breach of obligations: 10% of {{18/36} x EUR 200 000} = 10% of EUR 100 000 = EUR 10 000.

Amount resulting from Step 2: 100 000 – 10 000 = EUR 90 000.

Lower amount of the two: EUR 50 000.

Beneficiary A amount due: EUR 50 000.

Beneficiary balance:

Payments received by beneficiary A (according to the report on the distribution of payments): EUR 60 000.

Beneficiary A balance: EUR 50 000 (amount due) - EUR 60 000 (payments received) = EUR -10 000 (excess payments of EUR 10 000).

Recovery:

Amount to be recovered from beneficiary A: EUR 10 000 (negative balance of EUR 10 000 must be returned to the consortium; otherwise Commission/Agency will start a recovery procedure).

Interim payments

How much? The amount of the interim payments will be calculated by the Commission/Agency on the basis of the financial statements and the payments already made.

How to calculate interim payments:

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rates to the eligible costs)**

In order to calculate the amount of accepted EU contribution, the Commission/Agency will, for each beneficiary and linked third party, calculate the accepted costs (i.e. eligible/not rejected costs declared in the financial statement; *see Articles 6 and 42*), apply the reimbursement rate(s) and then sum them up to a total amount for the consortium.

If a beneficiary/linked third party requested in the financial statements less than the EU contribution, the accepted EU contribution will be this lower requested amount.

Step 2 — **Limit to 90% of the maximum grant amount**

If the total for the consortium is more than 90 % of the maximum grant amount minus pre-financing and previous interim payments, it will be capped.

Step 3 — **Interim payment letter**

The Commission/Agency will inform the coordinator about the amount due (interim payment letter).

Examples for calculating interim payments:

Case 1:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Interim payment RP1:

Costs declared by the consortium for RP1: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = EUR 625 000.

After checking the reports EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are considered not eligible and rejected. The Commission/Agency therefore rejects EUR 32 000 direct costs + EUR 8 000 (25% flat rate for indirect costs) = EUR 40 000.

Total accepted costs RP1: EUR 585 000.

Application of reimbursement rate: 100% = EUR 585 000 (total accepted EU contribution).

Limit to 90% of the maximum grant amount minus pre-financing = EUR 900 000 – EUR 333 334 = EUR 566 666.

Amount to be paid out to the consortium as interim payment for RP1: EUR 566 666.

Interim payment RP 2:

Total accepted costs RP2: EUR 162 500.

Amount to be paid out to the consortium as interim payment for RP2: EUR 0 (the 90% limit has already been reached in RP1: 333 334 + 566 666 = 900 000).

Case 2 (grant with terminated beneficiary):

Grant with three beneficiaries (A, B and C) and two reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Pre-financing: EUR 200 000.

Beneficiary A was terminated before the end of RP1 and the amount due was its accepted costs :EUR 62 500 EUR (no grant reductions applied).

Interim payment RP1:

Costs declared by beneficiary A for RP1: EUR 50 000 (direct costs) + EUR 12 500 (25% flat rate for indirect costs) = EUR 62 500.

Costs declared by beneficiary B for RP1: EUR 115 000 (direct costs) + EUR 28 750 (25% flat rate for indirect costs) = EUR 143 750.

Costs declared by beneficiary C for RP1: EUR 90 000 (direct costs) + EUR 22 500 (25% flat rate for indirect costs) = EUR 112 500.

Total costs declared RP1: EUR 62 500 + EUR 143 750 + EUR 112 500 = EUR 318 750.

Costs of beneficiary A are not capped since there were no grant reductions at beneficiary termination.

Some direct costs declared by beneficiary B are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total accepted costs RP 1: EUR 318 750– EUR 12 500 = EUR 306 250.

Application of the reimbursement rate 100%: EUR 306 250 (total accepted EU contribution).

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000 – EUR 200 000 = EUR 250 000.

Amount to be paid out to the consortium as interim payment for RP1: EUR 250 000.

Case 3:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Pre-financing: EUR 200 000.

Interim payment RP1:

Costs declared by beneficiary A for RP1: EUR 95 000 (direct costs) + EUR 23 750 (25% flat rate for indirect costs) = EUR 118 750.

Costs declared by beneficiary B for RP1: EUR 115 000 (direct costs) + EUR 28 750 (25% flat rate for indirect costs) = EUR 143 750.

Costs declared by beneficiary C for RP1: EUR 90 000 (direct costs) + EUR 22 500 (25% flat rate for indirect costs) = EUR 112 500.

Total costs declared RP1: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total accepted costs RP 1: EUR 375 000 – EUR 12 500 = EUR 362 500.

Application of the reimbursement rate 100%: EUR 362 500 (total accepted EU contribution).

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000 – EUR 200 000 = EUR 250 000.

Amount to be paid out to the consortium as interim payment for RP1: EUR 250 000.

Interim payment RP2:

Costs declared by beneficiary A for RP2: EUR 20 000 (direct costs) + EUR 5 000 (25% flat rate for indirect costs) = EUR 25 000.

Costs declared by beneficiary B for RP2: EUR 30 000 (direct costs) + EUR 7 500 (25% flat rate for indirect costs) = EUR 37 500.

Costs declared by beneficiary C for RP2: EUR 30 000 (direct costs) +EUR 7 500 (25% flat rate for indirect costs) = EUR 37 500.

Total costs declared RP2: EUR 25 000 + EUR 37 500 + EUR 37 500 = EUR 100 000.

Costs rejected for beneficiary B at RP2: EUR 10 000 (direct costs) + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.

Costs rejected for beneficiary C at RP2: 5 000 (direct costs) + 1 250 (25% flat rate for indirect costs) = EUR 6 250.

Total accepted costs RP2 = EUR 81 250.

Application of the reimbursement rate 100%: EUR 81 250 (total accepted EU contribution).

Amount to be paid out to the consortium as interim payment for RP2: EUR 0 (the 90% limit has already been reached in RP1: EUR 200 000 + EUR 250 000 = EUR 450 000).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Commission/Agency on the basis of the financial statements, the final grant amount, the payments already made and the report on the distribution of payments *(see also Articles 5.3 and 44.1.2)*.

If the final grant amount is *higher* than the payments already made, the balance will take the form of a *payment*; if the final grant amount is *lower* than the payments made, the balance will take the form of a *recovery*.

How to calculate the payment of the balance:

Final grant amount

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rates to the eligible costs)**

In order to calculate the amount of accepted EU contribution, the Commission/Agency will, for each beneficiary/linked third party, calculate the accepted costs (i.e. eligible/not rejected costs declared in the financial statements; *see Articles 6 and 42*), apply the reimbursement rate(s) and then sum them up to a total amount for the consortium.

If a beneficiary/linked third party requested less than the maximum EU contribution, the accepted EU contribution will be this lower requested amount.

Step 2 — **Limit to the maximum grant amount**

If the total for the consortium is more than the maximum grant amount for the action *(see Article 5.1)*, it will be capped at that amount

Step 3 — **Calculation of receipts & deduction of profit (no-profit rule)**

From this amount, the Commission/Agency will deduct any profit made due to receipts.

Thus, the total accepted EU contribution + receipts are capped at the total accepted costs; the amount resulting from Steps 1 and 2 plus receipts cannot exceed the accepted costs.

If grant amount + receipts > total accepted costs ➔ deduction of profit

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The amounts taken into account are the total accepted EU contribution (following Steps 1 and 2), the total receipts and the total accepted costs.

The **receipts** that must be taken into account are receipts which have been, during the action duration *(see Article 3)*:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation).

The following **are** considered **receipts**:

- income generated by the action *(i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)*

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped at the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action *(i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for being used for the action)*

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs *(i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action)*

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

  Receipts due to free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered **receipts**:

- in-kind contributions given by a **third party (donor)** free of charge — if they were not given specifically to be used for the action

  Example: *A university professor whose costs are charged by the beneficiary university in the GA, but whose salary is paid by the ministry and not reimbursed by the university: This in-kind contribution from a third party (the ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions given by a third party (donor) specifically to be used for the action — if they may be used according to the donor's rules to cover also costs *other* than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

- financial contributions made **by one beneficiary to another** within the same action — since receipts are only contributions from *third parties*

  Conversely, such a financial contribution cannot either be declared as cost for the action.

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

– income generated by exploiting the results of the project *(e.g. the IPR)* — since successfully exploiting the results is one of the main objectives of the action

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance *(i.e. the final payment at the end of the action)*. They must be declared in the final report.

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

➔ Amount resulting from Steps 1-3.

Step 4 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions (if any), the Commission/Agency will, for each beneficiary/linked third party, calculate the grant reductions at their level, add any reductions that must be made at action-level and then sum them up to a total amount for the consortium *(see Article 43)*.

This total amount of grant reductions for the consortium is then deducted from the maximum grant amount for the action set out in *Article 5.1*.

ℹ For more guidance on grant reductions, *see the Guidance on grant reductions*.

➔ Amount resulting from Step 4.

The **final grant amount** is the lower of the 2 (amount resulting from Steps 1-3 and amount resulting from Step 4).

Balance

Step 5 — **Calculation of the balance & Guarantee Fund release**

In order to calculate the balance, the Commission/Agency will deduct the total amount of pre-financing and interim payments made from the final grant amount.

If the final grant amount is *higher* than the payments already made, the balance will take the form of a payment. In addition, the Guarantee Fund contribution (5% that were kept from the pre-financing) will be released with a separate payment.

If the final grant amount is *lower* than the payments made, the balance will take the form of a recovery (amount overpaid needs to be paid back to the Commission/Agency; *see Article 44*). In this case, the amount to be paid back will be directly compensated against the Guarantee Fund release and if this amount is sufficient to cover the debt, the recovery process ends (instead the consortium will be paid the remainder of the Guarantee Fund contribution, if any is left). If the Guarantee Fund amount is not sufficient, further steps will be taken to recover the rest *(see below)*.

Step 6 — **Payment of the balance letter & debit note**

The Commission/Agency will inform the coordinator about the amount due to the consortium or the amount that needs to be paid back (payment of the balance letter).

If the final payment involves a grant reduction or recovery, there will be two letters: a pre-information letter (opening a contradictory procedure) and a confirmation letter *(see Articles 43 and 44)*.

If there is still an amount to be recovered after compensation with the Guarantee Fund release, the confirmation letter will include a debit note to the coordinator for the amount and the division of final grant amount table *(see below)*.

Recovery (if any)

Step 7a — **Recovery from the coordinator**

If the coordinator pays the debt by the date specified in the debit note, the recovery process ends.

If the coordinator does NOT repay the Commission/Agency by the date specified AND if it has NOT submitted the report on the distribution of payments, the Commission/Agency will pursue recovery against the coordinator alone (enforced recovery, *see below*).

Step 7b — **Recovery from the beneficiaries**

If the coordinator does NOT repay the Commission/Agency by the date specified, BUT has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

Step 7ba — **Identifying the beneficiaries with excess funding**

In order to identify the beneficiaries that received excess funding, the Commission/Agency will compare the amount each beneficiary *actually* received (report on the distribution of payments) with its *share of the final grant amount* (beneficiary's accepted EU contribution divided by total accepted EU contribution and obtained percentage then applied to final grant amount).

Beneficiary's final grant share formula:

{{{beneficiary's accepted costs

multiplied by

reimbursement rate}

divided by

accepted EU contribution calculated under Step 1}

multiplied by

final grant amount for the action}

This means that the final grant amount is redistributed between the beneficiaries in proportion to their accepted costs (especially important for overspent grants, i.e. where the consortium declared costs *above* the maximum grant amount limit and each beneficiary's accepted EU contribution must therefore be adjusted to bring it into line with the maximum grant amount) and then compared to the amounts they received from the coordinator.

Recovery will be pursued only against the beneficiaries with a negative result (i.e. excess of payments received over final grant amount share).

Step 7bb — **Division of the debt**

In order to calculate the amount each of those beneficiaries has to pay back, the Commission/Agency will split the amount to be recovered between them (in proportion to their relative share of the total payments in excess; division of final grant amount table).

Step 7bc — **Beneficiary recovery letter & debit note**

The Commission/Agency will cancel the debit note sent to the coordinator and inform the beneficiaries concerned about the amounts to be paid back, together with a debit note for each beneficiary (beneficiary recovery letter).

Step 8 — **Enforced recovery**

If the coordinator/beneficiaries do not honour the debit note within the deadline, the Commission/Agency will enforce its claim(s) by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- by drawing on the Guarantee Fund and then follow it up with a **debit note on behalf of** the **Guarantee Fund**, to continue the recovery procedure by:
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Examples for calculating the payment of the balance:

Case 1 (payment):

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000.

Reimbursement rate: 100%.

Payments made (pre-financing and interim): EUR 900 000 (limit of 90% of the maximum grant amount).

Guarantee Fund contribution: 5% of EUR 1 000 000 = EUR 50 000.

Payments received: EUR 900 000 – EUR 50 000 = EUR 850 000.

Final grant amount:

Total accepted costs: EUR 1 045 000.

Application of the reimbursement rate: 100 % = EUR 1 045 000 (total accepted EU contribution).

Limit to the maximum grant amount: EUR 1 000 000.

No receipts/profit.

No grant reductions.

Final grant amount: EUR 1 000 000.

Balance & Guarantee Fund release:

Payments made: EUR 900 000.

Balance: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments made) = EUR +100 000 (positive balance to be paid to the consortium).

Release of Guarantee Fund: EUR 50 000 (to be paid to consortium).

Amounts to be paid out to the consortium: EUR 100 000 (positive balance) + EUR 50 000 (Guarantee Fund release)

Case 2 (grant with terminated beneficiary):

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Beneficiary A was terminated before the end of RP1 and the amount due calculated was EUR 62 500 EUR.

Payments made (pre-financing and interim): EUR 450 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 500 000 = EUR 25 000.

Payments received: EUR 450 000 - EUR 25 000 = EUR 425 000.

Final grant amount:

Total accepted costs: EUR 362 500.

Application of the reimbursement rate: 100% = EUR 362 500 (total accepted EU contribution).

Limit to maximum grant amount: EUR 362 500 (no limitation; costs below maximum grant amount).

No receipts/profit.

Amount resulting from Steps 1 to 3: EUR 362 500.

10% grant reduction beneficiary B: 10% of EUR 200 000 = EUR 20 000.

No other grant reductions.

Amount resulting from Step 4: 500 000 – 20 000 = EUR 480 000.

Lower amount of the two: EUR 362 500.

Final grant amount: EUR 362 500.

Balance & Guarantee Fund release:

Payments made: EUR 450 000.

Balance: EUR 362 500 (final grant amount) - EUR 450 000 (payments made) = EUR -87 500 (excess payments of EUR 87 500).

Offsetting against Guarantee Fund release: EUR 87 500 – EUR 25 000 = EUR -62 500.

Payment:

Amount to recovered from the consortium: EUR 62 500.

Case 3 (recovery – underspent grant):

Grant with four beneficiaries: A, B, C, D.

Maximum grant amount: EUR 3 000 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 800 000; B= EUR 1 200 000; C= EUR 600 000; D= EUR 400 000).

Reimbursement rate: 100 %.

Payments made (pre-financing and interim): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 3 000 000 = EUR 150 000.

Payments received: EUR 2 700 000 - EUR 150 000 = EUR 2 550 000.

Final grant amount:

Total accepted costs: EUR 2 430 000.

Application of the reimbursement rate: 100% = EUR 2 430 000 (total accepted EU contribution).

Limit to maximum grant amount: EUR 2 430 000 (no limitation; costs below maximum grant amount).

No receipts/profit.

Amount resulting from Steps 1 to 3: EUR 2 430 000.

10% grant reduction beneficiary B: 10% of EUR 1 200 000 = EUR 120 000.

No other grant reductions.

Amount resulting from Step 4: 3 000 000 - 120 000 = EUR 2 880 000.

Lower amount of the two: EUR 2 430 000.

Final grant amount: EUR 2 430 000 (underspent grant ➔ beneficiary shares: A= EUR 600 000; B= EUR 1 100 000; C= EUR 400 000; D= EUR 330 000).

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 430 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR -270 000 (excess payments of EUR 270 000).

Offsetting against Guarantee Fund release: EUR 270 000 – EUR 150 000 = EUR 120 000.

Recovery:

Amount to be recovered from the consortium: EUR 120 000 (negative balance of EUR 120 000 must be paid back by coordinator, otherwise Commission/Agency will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from coordinator:

The coordinator does not reimburse the Commission/Agency and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 400 000; B= EUR 1 200 000; C= EUR 600 000; D= EUR 350 000).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

A: EUR 600 000 (final grant share) - EUR 400 000 (payments received) = EUR 200 000 (no payment in excess)

B: EUR 1 100 000 (final grant share) - EUR 1 200 000 (payments received) = EUR -100 000 (excess payment of EUR 100 000)

C: EUR 400 000 (final grant share) - EUR 600 000 (payments received) = EUR -200 000 (excess payment of EUR 200 000)

D: EUR 330 000 (final grant share) - EUR 350 000 (payments received) = EUR -20 000 (excess payment of EUR 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission/Agency.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 320 000.

B: 100 000/320 000 = 31.25 %.

C: 200 000/320 000 = 62.5 %.

D: 20 000/320 000 = 6.25 %.

Total to be recovered: EUR 120 000.

B: 31.25 % x 120 000 = EUR 37 500

C: 62.5 % x 120 000 = EUR 75 000

D: 6.25 % x 120 000 = EUR 7 500.

Case 4 (recovery – overspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 3 000 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 1 000 000; B= EUR 1 500 000; C= EUR 500 000)

Reimbursement rate: 100%.

Payments made (pre-financing and interim): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 3 000 000 = EUR 150 000.

Payments received: EUR 2 700 000 - EUR 150 000 = EUR 2 550 000.

Receipts:

Beneficiary A was sponsored for this project by a private company with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher.

Beneficiary B (a university) received as in-kind contribution from its government the secondment of a scientist specifically assigned to the project. The salary of this seconded scientist (EUR 80 000) was declared as cost by this beneficiary, even if paid by the government.

Final grant amount:

Total accepted costs: EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000.

Application of the reimbursement rate: 100% = EUR 3 075 000 (total accepted EU contribution).

Limit to maximum grant amount: EUR 3 000 000.

Calculation of receipts and deduction of profit: Profit: EUR 3 140 000 (total accepted EU contribution + receipts : EUR 3 000 000 + EUR 60 000 + EUR 80 000) – EUR 3 075 000 (total accepted costs) = EUR 65 000

Amount after deducting profit: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Amount resulting from Steps 1 to 3: EUR 2 935 000.

10% grant reduction beneficiary A: 10% of EUR 1 000 000 = EUR 100 000.

No other grant reductions.

Amount resulting from Step 4: 3 000 000 - 100 000 = EUR 2 900 000.

Lower amount of the two: EUR 2 900 000.

Final grant amount: EUR 2 900 000.

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 900 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR +200 000 (positive balance to be paid to the consortium).

Release of Guarantee Fund: EUR 150 000 (to be paid to consortium).

Amounts to be paid out to the consortium: EUR 200 000 (positive balance) + EUR 150 000 (Guarantee Fund release)

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Commission/Agency on the basis of the final grant amount and the revised final grant amount *(see also Articles 5.4 and 44.1.3)*.

If the revised final grant amount is *lower* than the beneficiary's share of the final grant amount (beneficiary final grant share), the difference will be recovered.

How to calculate recoveries after payment of the balance:

Revised final grant amount

Step 1 — **Re-calculation of the accepted EU contribution**

In order to calculate the revised amount of accepted EU contribution for the beneficiary concerned, the Commission/Agency will calculate the revised amount of accepted costs for the beneficiary (i.e. eligible/not rejected costs declared in the financial statements; *see Articles 6 and 42*) and apply the reimbursement rate.

If the audit concerns a linked third party, the revised final grant amount will be calculated for its beneficiary.

➔ Amount resulting from Step 1.

Step 2 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions, the Commission/Agency will calculate the grant reduction for the beneficiary concerned (if any; see *Article 43*).

This amount of grant reduction is then deducted from the beneficiary's maximum grant amount set out in Annex 2.

If the audit concerns a linked third party, the grant reduction will be calculated for the linked third party (i.e. deducted from its maximum grant amount), but the revised final grant amount will be calculated at beneficiary-level.

For beneficiaries that overspent (i.e. declared more costs at payment of the balance than their maximum grant amount), the reduction rate (percentage) will be applied directly to their share of the final grant amount and the resulting amount will be recovered (—short cut to ensure a proportionate result for beneficiaries that contributed more to the action than initially planned in the estimated budget; avoids disproportionate grant reductions compared to the real project participation; *see also Article 4.2*).

> For more guidance on grant reductions, *see the Guidance on grant reductions*.

➔ Amount resulting from Step 2.

The revised final grant amount is the lower of the two (amount resulting from Step 1 and amount resulting from Step 2).

Balance & recovery (if any)

Step 3 — **Calculation of the beneficiary balance**

In order to calculate if the beneficiary has to pay back any amounts, the Commission/Agency will compare the beneficiary's revised final grant amount with its final grant share *(see above)*.

Beneficiary's final grant share formula:

{{{beneficiary's accepted costs

multiplied by

reimbursement rate}

divided by

accepted EU contribution calculated under Step 1}

multiplied by

final grant amount for the action}

If the revised final grant amount is *lower* than its final grant share, the difference will be recovered.

If exceptionally the audit (or check, review or investigation) showed that the beneficiary made errors resulting in less cost declared than its eligible costs, there will be no recovery. Instead, the beneficiary will be allowed to submit corrected financial statements to claim the difference.

Step 4 — **Audit implementation letters & debit note**

The Commission/Agency will inform the beneficiary about the amounts put in question (audit implementation letter).

If the audit implementation involves a grant reduction or recovery (generally the case), there will be two letters: a pre-information letter (opening a contradictory procedure) and a confirmation letter *(see Articles 43 and 44)*.

If there is an amount to be recovered, the confirmation letter will include a debit note for the amount.

⚠ In case of European Court of Auditor audits, OLAF investigations and Member State judgments with a financial impact on the grant, similar procedures and letters will be used.

Step 5 — **Enforced recovery**

If the beneficiary does not honour the debit note within the deadline, the Commission/Agency will enforce its claim by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- by drawing on the Guarantee Fund and then follow it up with a **debit note on behalf of** the **Guarantee Fund**, to continue the recovery procedure by:
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Examples for calculating recoveries after payment of the balance:

Case 1 (recovery – underspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100 %.

Final grant amount:

Total accepted costs: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

A: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

B: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

C: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Application of the reimbursement rate: 100% = EUR 493 750 (total accepted EU contribution).

Limit to maximum grant amount: EUR 493 750 (no limitation; costs below maximum grant amount).

No receipts/profit.

No grant reductions

Final grant amount: EUR 493 750 (underspent grant ➔ beneficiary shares: A= 187 500 EUR; B= EUR 156 250; C= EUR 150 000).

Beneficiary revised final grant amount:

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000 and that there were issues with the visibility of EU funding and IPR.

Re-calculation of accepted EU contribution for beneficiary A: EUR 150 000 (direct costs) — EUR 30 000 (rejected direct costs) = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

Application of the reimbursement rate: 100% = EUR 150 000.

Amount resulting from Step 1: EUR 150 000.

10% grant reduction for beneficiary A: 10% of 200 000 = EUR 20 000.

Amount resulting from Step 2: 200 000 – 20 000 = EUR 180 000.

Lower amount of the two: EUR 150 000.

Beneficiary A revised final grant amount: EUR 150 000.

The other beneficiaries final grant amounts (i.e. their final grant shares) remain unchanged.

Beneficiary balance:

Balance: EUR 150 000 (revised final grant amount) - EUR 187 500 (final grant share) = EUR –37 500 (excess of EUR 37 500).

Recovery:

Amount to be recovered from beneficiary A: EUR 37 500 (negative balance of EUR 37 500 must be paid back by the beneficiary).

Case 2 (recovery – overspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 100 000; C= EUR 200 000).

Reimbursement rate: 100%.

Final grant amount:

Total accepted costs: EUR 200 000 + EUR 150 000 + EUR 250 000 = EUR 600 000

A: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) = EUR 200 000

B: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) = EUR 150 000

C: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) = EUR 250 000.

Application of the reimbursement rate: 100% = EUR 600 000 (total accepted EU contribution).

Limit to the maximum grant amount: EUR 500 000.

Final grant amount = EUR 500 000.

Beneficiary revised final grant amounts:

An audit concluded that direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs of beneficiary C were not eligible for an amount of EUR 20 000 and that there were issues with the confidentiality obligations.

Calculation of the beneficiaries final grant shares:

A: (200 000/600 000) x 500 000 = EUR 166 667

B: (150 000/600 000) x 500 000 = EUR 125 000

C: (250 000/600 000) x 500 000 = EUR 208 333.

Beneficiary A:

Re-calculation of accepted EU contribution for beneficiary A: EUR 160 000 (direct costs) – EUR 30 000 (rejected costs) = EUR 130 000 + EUR 32 500 (25% flat rate for indirect costs) = EUR 162 500.

Application of the reimbursement rate: 100% = EUR 162 500.

No grant reductions

Beneficiary A revised final grant amount: EUR 162 500.

Beneficiary C:

Re-calculation of accepted EU contribution for beneficiary C: EUR 200 000 (direct costs) – 20 000 (rejected costs) = EUR 180 000 + EUR 45 000 ((25% flat rate for indirect costs) = EUR 225 000.

Application of the reimbursement rate: 100% = EUR 225 000.

Amount resulting from Step 1: EUR 225 000.

10% grant reduction beneficiary C: 10% of 200 000 = EUR 20 000.

Amount resulting from Step 2: 200 000 – 20 000 = EUR 180 000.

Lower amount of the two: EUR 180 000.

Beneficiary C revised final grant amount: EUR 180 000.

Beneficiary B's final grant amounts (i.e. its final grant amount share) remains unchanged.

Beneficiary balance:

Beneficiary A:

Balance: EUR 162 500 (revised final grant amount) - EUR 166 667 (final grant share) = EUR –4 167 (excess of EUR 4 167).

Beneficiary C:

Balance: EUR 180 000 (revised final grant amount) - EUR 208 333 (final grant share) = EUR -28 333 (excess of EUR 4 167).

Recovery:

Amount to be recovered from beneficiary A: EUR 4 167 (negative balance of EUR 4 167 must be paid back by the beneficiary).

Amount to be recovered from beneficiary C:

In principle: EUR 28 333 (negative balance according to normal calculation).

However, since normal calculation leads to disproportionate grant reductions for beneficiaries that overspent at payment of the balance: shortcut calculation (see above): 10% of EUR 208 333 = EUR 20 833.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Agency performs a plagiarism check on documents submitted by the consortium.*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in EU actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The checks itself are **internal**. They may however have external effects, since the Commission/Agency may lead to a **request for information** *(see Article 17.1)* or it may take Chapter 6 measures in view of the results.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date.*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. In this case, the Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

If the check shows **ineligible costs** or serious **breach of obligations**, it may lead to cost rejection or grant reduction and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission/Agency may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Project reviews

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA and may exceptionally also concern issues related to only one specific beneficiary.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows **ineligible costs** or **substantial errors, irregularities or fraud** or serious **breach of obligations** (including non- or improper implementation of the action as described in Annex 1), it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (or, exceptionally, the beneficiary concerned) via the Funding & Tenders Portal.

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or a **review meeting** (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a **review report**.

> The review report together with the Commission/Agency comments will be notified to the coordinator (or, exceptionally, the beneficiary concerned) for comments within 30 days (**contradictory review procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The Commission/Agency operational services (authorising officers) will analyse the comments received and decide on the follow-up, if any.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Record-keeping — Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including cost rejection, grant reduction, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit **third parties providing in-kind contributions** (free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to:*

- *see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest)*
- *see if payments made under the contract/subcontract match the costs declared by the beneficiary*
- *assess the technical work carried out by the subcontractor.*

The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to check the contractors'/subcontractors' costs or accounts, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).

4. *The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 of the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and, in very serious cases, to exclusion and/or financial penalties *(see Article 45)*. In some cases, findings may result in the **acceptance** of additional costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the Funding & Tenders Portal or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation 2018/1725 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an **audit report**.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days (**contradictory audit procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the **final audit report** and the **letter of audit conclusions** (LoC) — and the file will then be passed on to the Commission/Agency operational services (authorising officers) for the follow-up, if any.

If there are cost adjustments in favour of the EU budget to be made on the basis of the audit, please do not take any immediate action (do NOT deduct them from the next financial statement). If needed, the adjustments will be done by the Commission/Agency and you will be informed about them in the payment letter or audit implementation pre-information letter (with the possibility to take position).

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[41] and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. OLAF investigations

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the outcome of the investigation to the Commission/Agency, who will then decide how to proceed.

If an OLAF investigation shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)*, to exclusion and/or financial penalties *(see Article 45)*, as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. ECA checks and audits

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

If an ECA check or audit shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, this may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION 2:** Not applicable.]*

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

⚠ Checks, reviews, audits and investigations must however respect the privileges and immunities accorded to an international organisation by its constituent documents or international law.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the **findings concern substantial errors, irregularities or fraud or serious breach of obligations,** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings (rejection and grant reduction)

If the Commission/Agency finds (typically in a review, audit or OLAF investigation) **substantial errors, irregularities or fraud** or serious **breach of obligations** which are **systemic** or **recurrent**, it may make a correction (cost rejection or grant reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed (extension of the findings)
- other grants of the beneficiary (extension of the findings).

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; the beneficiary set up a fraudulent network to overcharge personnel costs .*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

Findings may be extended to all other EU or Euratom grants awarded under similar conditions.

⚠ Findings will normally be extended only within one programme *(e.g. findings in an H2020 audit to all H2020 grants)* but they may exceptionally also be extended to similar programmes *(e.g. if justified by the nature of the findings and the similarity of the applicable grant agreements or in case of serious irregularities or fraud).*

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings also impact other EU/Euratom grants, the audit/review procedure will be followed by an extension procedure, to fix the list of impacted grants and ask the beneficiary's views on the method for correction. In order to minimise the administrative burden, this procedure is usually centralised.

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure (**letter of audit conclusions**), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for cost rejection:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (if the beneficiary does not submit revised financial statements)
  - the conditions for external counter-audits to propose an alternative correction method *(see below)*
- for grant reduction: the proposed flat-rate for the correction.

The correction rate for cost rejection will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The flat-rate for grant reductions will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept the alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for cost rejection: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for grant reduction: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

The beneficiary must choose one method for the entire extension procedure, i.e. submit for all grants either revised financial statements or an alternative correction method.

The Commission/Agency has **full discretion** to accept or refuse the alternative correction method proposed by the beneficiary; there is NO entitlement to it.

After the extension procedure is completed, the list of grants and beneficiary position is handed to the operational services which are in charge of managing the concerned grants. They will decide on the actions to be taken in their grants.

The implementation will be done on the basis of the:

- revised financial statements — if the beneficiary sent revised statements and they were approved
- initially notified correction rate for extrapolation — if the beneficiary did not send any revised statements or they could not be approved
- alternative correction method — if the beneficiary sent an alternative method and it was accepted.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:** five]**[OPTION 2 for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the H2020 Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the H2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of H2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[47] annexed to the EU Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[47] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

Best practice: Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[48]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[48] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background before providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or ‘**associated country**’[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

Access rights are therefore normally limited to other beneficiaries and certain affiliated entities of other beneficiaries, unless otherwise agreed.

Example: *Beneficiary A used background from beneficiary B to generate its results. Beneficiary A would like to use its affiliated entity A established in a MS to exploit the results. For this, affiliated entity A needs access rights to beneficiary B's background.*

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Record-keeping

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. subcontractors, linked third parties, international partners, employees, etc.)*.

> ***Examples (third parties that may claim rights):*** *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action (if they have rights under national law or their contract); beneficiaries for which linked third parties carry out a significant part of the work.*
>
> ***Examples (arrangements):*** *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

> **Best practice:** Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is impossible under EU or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.)*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Standard forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

1. *For an invention: e.g. patent, confidential information.*

2. *For the design of a technology: e.g. industrial design, copyright.*

3. *For a website: e.g. industrial design, copyright, trademark.*

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example (better not to protect for the moment): *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*. Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (using the text of the GA language version available on Funding & Tenders Portal Reference Documents).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the plan for the exploitation and dissemination of the results.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

For more guidance on dissemination and exploitation, *see the Funding & Tenders Portal Online Manual.*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018'];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1a for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) **[OPTION A for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme: data** which is **relevant for addressing a public health emergency**, if specifically requested by the [Commission][Agency] and within the deadline specified in the request]**[OPTION B**: not applicable];*

*(iii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

[additional OPTION for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme:** As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.]**]

***[OPTION 1b for health actions that do NOT participate in the Open Research Data Pilot, if foreseen in the work programme:** The [Commission][Agency] may require beneficiaries to:*

(a) deposit digital research data, which is generated in the action and relevant for addressing a public health emergency, in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user

(b) give specific access rights to third parties that need the digital research data to address the public health emergency (including the right to access, mine, exploit ad reproduce the data free of charge)

within the deadline specified in the [Commission][Agency]'s request.

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

[OPTION 1c for health actions targeting public health emergencies, if foreseen in the work programme: *The beneficiaries must deposit the digital research data generated in the action in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user, at the latest within 30 days after it has been generated.*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access, if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.**]***

[OPTION 2**: Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) before filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security obligations, etc.)*.

Security obligations — Dissemination may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

Results that contain **EU-classified information**, can be disclosed only after approval by the Commission/Agency *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Funding & Tenders Portal Online Manual.*

The beneficiaries may choose the **form** for disseminating their results.

Standard forms of dissemination:

- website
- presentation at a scientific conference
- peer-reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination — unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the

interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

For more guidance on dissemination and exploitation, *see the Funding & Tenders Portal Online Manual.*

2. Open access to scientific publications

What? Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals).*

Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

The requirement of Horizon 2020 for open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets requirements that must be fulfilled *if* they do decide to publish them.

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications, a publication platform or publisher site.

Best practice: In order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights, such as the right to copy, distribute, search, link, crawl and mine.

Beneficiaries/authors are encouraged to retain copyright and grant appropriate licences to publishers. They are encouraged to use Creative Commons (CC) or similar licenses. CC BY is a good legal tool for providing open access in its broadest sense.

Open access can be provided through:

a) **publishing in open access ('gold' open access) '**

Publishing in open access' means that open access is provided immediately via the publication venues, at the time that an article is published (i.e. in open access journals/platforms or in 'hybrid' journals combining subscription access and open access to individual articles).

Some publishers levy author processing charges for open access publishing. These costs are eligible *(see Article 6.2.D.3)*, if incurred before the end of the action and if all other eligibility conditions are fulfilled.

Although publishing in open access already ensures access via the publisher, the beneficiaries must still deposit their publication in a repository *(see below)*, in order to ensure the long-term preservation and availability of the publication. This is part of the open access requirement.

b) **self-archiving ('green' open access) '**

Self-archiving' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in a repository and made available in open access through that repository.

A 'repository for scientific publications' is an online archive, where researchers deposit research publications, research data and other scientific outputs and can provide open access to them. Repositories help preserve, manage and provide access to scientific outputs. They collect and disseminate digital research outputs from individual research organisations (institutional repositories, *e.g. the repository of University X*) or specific research communities (thematic/disciplinary repositories, *e.g. Europe PMC for life sciences including biomedicine and health or arXiv for physics, mathematics, computer science, quantitative biology, quantitative finance and statistics*). They can also be centralised repositories, *such as for example Zenodo, developed by CERN*.

Best practice: Identify the repository that suits your need in the Directory of Open Access Repositories (OpenDOAR). The Open Access Infrastructure for Research in Europe (OpenAIRE) can help you to find such repositories. We recommend that you use a repository that is compliant with the requirements of OpenAIRE and that you use the OpenAIRE database as a point of departure. OpenAIRE also offers support services for researchers, by providing information on open access requirements, a general Helpdesk and country-specific helpdesks (National Open Access Desks) that answer questions on open access and Horizon 2020 .

Beneficiaries without institutional/thematic repositories may deposit their publications in Zenodo, at no cost to them.

Beneficiaries should NOT use a repository with rules which could conflict with open access.

A *template* for an **open access clause** addendum which can be added to **publishing agreements** to enable open access through self-archiving in repositories is available on the Funding & Tenders Portal.

How? Open access to scientific publications involves four actions:

1) **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication, author's version).

   This must be done at the latest on publication (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*).

   'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

   Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

2) Provide **open access** to the scientific **publication** — either via open access publishing (i.e. via the publication venue AND via the repository) or as self-archiving (i.e. via the repository only).

   Open access must be given:

   – in case of 'open access publishing': at the latest on publication

   – in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

3) Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

   This is needed for visibility, traceability and monitoring.

   It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and 'Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and
- a persistent identifier *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

Best practice: For ease of tracking, beneficiaries should also include the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601) in the funding acknowledgement field in their metadata.

The metadata compliance of the repository can be checked using *OpenAIRE*.

4) Aim to **deposit** at the same time with action 1, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

ℹ For more guidance on open access, *see the Funding & Tenders Portal Online Manual.*

3. Open access to research data (Extended Open Research Data Pilot)

What? Beneficiaries of actions that participate in the Open Research Data Pilot (ORDP) must:

- develop a d**ata management plan (DMP)** as a deliverable of the project and
- give **open, free-of-charge access** to the end-user to **digital research data** generated during the action.

The purpose of the ORDP is therefore twofold: research data management and open access.

⚠ As of the Work Programme 2017, the Open Research Data pilot has been extended to all thematic areas of Horizon 2020 (except ERC PoC actions, SME instrument Ph1 actions, ERA-NET Cofund actions that do not produce data, EJP Cofund actions, and prizes).

Participation is therefore now in principle **the default**. However, actions may **opt out** at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55*) —, if:

- participation is incompatible with the obligation to protect results *(see Article 27)*
- participation is incompatible with the security obligations *(see Article 37)*
- participation is incompatible with rules on protection of personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate/collect any research data or
- there are other legitimate reasons not to take part.

Open access to digital research data means taking measures to make it possible for end-users to **access, mine, exploit, reproduce** and **disseminate** the data via a research data repository without any charges for them.

'Digital research data' are information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Only data that are generated by beneficiaries in the course of the action or reused digitally *in the action* are concerned. Actions are encouraged to digitise any other data and provide open access to them, but they are not obliged to do so.

The pilot applies to **2 types** of digital research **data**:

- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data and associated metadata, as specified by the beneficiaries themselves in their data management plan.

Examples: *curated data not directly attributable to a publication or raw data*

⚠ Beneficiaries participating in the ORPD should NOT provide open access to specific datasets if this would go against other GA obligations *(e.g. to protect results or personal data)* or if the action's main objective, as described in Annex 1, would be jeopardised by giving open access to those specific datasets. In this case, the reasons must be explained in the data management plan, which is a deliverable for projects participating in the ORDP, *see below*).

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories *(Re3data)* and the Core Trust Seal certified repositories. One key entry point for accessing and depositing related data and tools is Zenodo. For further details on general and discipline-specific repositories visit the EUDAT Collaborative Data Infrastructure.

Actions participating in the pilot must moreover develop a **data management plan (DMP)** as a deliverable of the project within the first 6 months of the project implementation.

The DMP must support the management life-cycle for all data that will be collected, processed or generated by the action. It must cover how to make data findable, accessible, interoperable and re-usable (FAIR), including:

- the handling of data during and after the project
- what data will be generated or reused
- what methodology and standards will be applied
- whether data will be shared / made open access (and how) and, if any, what data will not be shared / made open access (and why) and
- how data will be curated and preserved.

The DMP should be updated (and become more precise) as the project evolves. New versions should be created whenever important changes to the project occur *(e.g. new data sets, changes in consortium policies, etc.),* at least as part of the mid-term review (if any) and at the end of the project.

Best practice: FAIRsharing provides a curated and searchable portal of data standards, databases, and policies in the life sciences and other scientific disciplines. For more information on disciplinary metadata standards, visit Digital Curation Centre and Research Data Alliance Metadata Directory. Additional information on DMPs, repositories and the FAIR principles can be found in this Practical Guide.

For more guidance on data management plans (and a template), *see also the H2020 proposal forms and the Funding & Tenders Portal Online Manual.*

Costs related to the implementation of the ORDP *(e.g. costs for providing open access, related research data management costs, data curation and data storage costs)* are eligible if incurred before the end of the action and if all the other eligibility conditions are fulfilled *(see Article 6.2.D.3)*.

How? Open access to digital research data involves 3 actions:

1) Develop a **data management plan (DMP)** by month six of the project as a deliverable. The DMP is a 'living document' to be revised as appropriate in the duration of the project

2) **Deposit** the digital research data, preferably in a research data repository.

3) Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. for databases: by attaching an appropriate creative commons licence (CC-BY or CC0 tool) to the data; if the access/use is not subject to any rights: by indicating that no licence is needed)*.

   Open access must not necessarily be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

4) Provide **information**, via the repository, about **tools and instruments** for validating the results.

   Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.).*

For more guidance on the research data pilot, see *the Funding & Tenders Portal Online Manual.*

4. Data sharing for public health emergencies

If foreseen in the work programme/call, grant agreements for health actions will include specific contractual provisions concerning the sharing of research data for public health emergencies.

Public health emergencies are for instance:

- public health emergencies of international concern ('PHEIC') according to the World Health Organisation, or
- public health emergencies under Decision 1082/2013/EU, or
- public health emergencies under applicable national frameworks and regulations.

What? The data-sharing obligations for public health emergencies refer to any type of quality-controlled digital research data *(see point 3)* and associated metadata which is generated in the action and is relevant for the response to the public health emergency.

Personal data must be processed in accordance with applicable EU and national law (including international practices and standards; *see Article 39.2*).

For H2020 actions *targeting* public health emergencies, the beneficiaries must moreover:

– provide a data management plan (DMP) preferably with the proposal or at the latest before grant signature

  The data management plan should address the relevant aspects of making the data findable, accessible, interoperable and re-usable (FAIR), including:

- what data the project will generate
- whether and how the data will be made accessible for verification and re-use and
- how it will be circulated and preserved.

For more guidance on data management plans (and a template), *see the H2020 proposal forms and the Funding & Tenders Portal Online Manual.*

- for relevant data (as agreed with the Commission/Agency): provide open access within 30 days after it has been generated
- for other data: provide open access as soon as possible.

If agreed with the Commission/Agency, the open access obligation can exceptionally be replaced by special access rights to specific third parties that need the data to address the public health emergency.

In this case, the access rights must include the right to access, mine, exploit and reproduce the data free of charge (as further specified by the Commission/Agency, if needed) — but they may be used only for the access needed and only for addressing the public health emergency (i.e. limited both in scope and in time). Sub-licensing is only allowed if the beneficiary agrees.

For *other* H2020 actions, the special open access obligation (or the special access rights to specific third parties) is linked to a specific request by the Commission/Agency and limited to datasets agreed with the Commission/Agency.

5. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38*).

Best practice: Where possible, beneficiaries should make this reference in the language of the dissemination activity (using the text of the GA language version available on Funding & Tenders Portal Reference Documents).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

Combining H2020 & other EU grants — If the outputs were developed in another EU-funded action (funded not by H2020, but another EU programme, including Structural Funds/ESIF Funds), do NOT forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION 2 for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results.

> ⚠ **Security obligations —** Transfer may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Funding & Tenders Portal Online Manual.*

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a global authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, the beneficiary must **formally notify in advance** (via the Funding & Tenders Portal) any transfer to a specifically-identified third party established in a non-associated third country — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — Common legal structures (CLS) (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights and other access rights are preserved, *(e.g. the access rights of the EU, Member States and third parties; see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a non-associated third country.

> ⚠ As of the Work Programme 2018, the calls will normally already indicate if this option will be activated in the GAs. The option may however still be activated (without such indication):
>
> – for calls which do not fix the type of research and innovation activities ("bottom-up" calls, such as FET Open or MSCA) or
>
> – in other calls, exceptionally, if justified by the nature of the research and innovation activities or other action-related reasons.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiary must **formally notify** the Commission/Agency **in advance** (via the Funding & Tenders Portal) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

A notification before the results are generated is allowed, if the specific results concerned (and the details of the transfer/licence) can already be identified.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).]

***[OPTION 2 for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION 3 for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[47], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION 1b for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION 1d for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION 2:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When? The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity of another beneficiary (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

***1.** If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).*

***2.** If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.*

How? Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries who left the action before the end, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free
- for the exploitation of results: under fair and reasonable conditions

  'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

Fair and reasonable conditions includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicensing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

1. *A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.*

2. *In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.*

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)

  The additional access rights to results for complementary grant agreements apply ONLY if (and to the extent that) the access is needed for the purposes of the complementary grant (i.e. the access is needed for implementing the action tasks under the complementary grant or for exploiting the results of the beneficiaries in the complementary grant).

- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [48], in particular regarding:

- **working conditions**;
- transparent **recruitment** processes based on merit, and
- **career development**.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[49] and the Code of Conduct for their Recruitment.[50]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[51] and of the Code of Conduct[52] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[53])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[53] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

For more guidance on researcher rights, *see the Human Resources Strategy for Researchers tool.*

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more guidance on gender in research, *see the Funding & Tenders Portal Online Manual.*

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following fundamental principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries

- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the **H2020 ethics appraisal scheme** (i.e. the H2020 policy on ethics issues in research), which includes all of the following:

- ethics *self*-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more guidance on ethics, *see How to complete your ethics self-assessment, Research involving dual use items, Research focusing exclusively on civil applications, Potential misuse of research results and more generally, the Funding & Tenders Portal Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State.

The beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that the research results cannot peripherally be useful in a military context. Research related to *dual-use* products or technologies (usually used for civilian purposes but with possible military applications) is not prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

In order to ensure the necessary level of research integrity, the beneficiaries must follow principles listed in this Article and ensure that the persons carrying out research tasks comply with the European Code of Conduct for Research Integrity[54] (i.e. follow the good research practices listed in this Code and refrain from any research integrity violations it describes).

Fundamental research integrity principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources

[54] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment
- **accountability** for the research from the idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

The Code constitutes a general reference framework and takes into account the legitimate interests of the beneficiaries (i.e. regarding IPRs and data sharing).

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply. In addition, beneficiaries should rely on local, national or discipline-specific guidelines, if such documents exist and are not contrary to the Code.

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define **ethics requirements** and include them as **deliverables** in Annex 1 of the GA.

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

Examples (ethics deliverables): *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

Examples (other ethics requirements): *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

Best practice: When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18).*

The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

If the documents are not in English, the beneficiary may be asked to provide an English summary.

This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.

Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

The Commission/Agency may carry out **ethics checks, reviews or audits**, to ensure that the beneficiaries have properly implemented the ethics requirements and obtained the opinions/notifications/authorisations *(see Article 22)*.

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

Activities that involve human embryos (hE) or human embryonic stem cells (hESC) can only be funded, if:

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[55] (in particular, do NOT result in the destruction of human embryos)

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

[55] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A ‘conflict of interests’ exists if **shared interests**:

- influenced the contract’s/subcontract’s selection/award procedure
- influenced the contract’s/subcontract’s price and this does not correspond to the market price or
- affected the action’s performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  1. *A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.*

  2. *A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.*

  3. *A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).*

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits*.

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  1. *If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.*

  2. *If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.*

  3. *If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.*

If there is a **(risk of) a conflict of interests**, the coordinator must **inform** the Commission/Agency (via the Funding & Tenders Portal), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Security obligations — Stricter confidentiality obligations apply for information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Funding & Tenders Portal Online Manual.*

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2: *Not applicable**]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[51] — until it is declassified.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].**[OPTION 2:*** *Not applicable.**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable.**]***

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

1. Results with a security recommendation — EU-classified information

If the GA provides for (one of) these options, the beneficiaries must comply with the **security obligations** set out in this Article, in Annex 1 and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises security issues and must be subject to a security recommendation and/or EU-classification under Decision No 2015/444[56].

⚠ Be aware that national/third country security requirements *(national/third country security classification, etc)* may affect the project implementation (and even put it at risk). It is your responsibility to avoid this and to keep your project free of such restrictions (either by adapting your project or by obtaining all necessary authorisations to be able to comply with your obligations under the GA). Any potential security issues should immediately be notified to the Commission/Agency.

ℹ For more guidance on security obligations, *see the Guidelines for the classification of information in research projects, Potential misuse of research results* and, *more generally, the Funding & Tenders Portal Online Manual.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[57].

Moreover, the coordinator must — before the start of the activity for which it is needed — submit a **copy** of any **export** or **transfer licence**.

⚠ Be aware that national/third country security requirements *(technology transfer restrictions, etc)* may affect the project implementation (and even put it at risk). It is your responsibility to avoid this and to keep your project free of such restrictions (either by adapting your project or by obtaining all necessary authorisations to be able to comply with your obligations under the GA). Any potential security issues should immediately be notified to the Commission/Agency.

ℹ For more guidance on dual use goods, *see How to complete your ethics self-assessment* and *Research involving dual use items.*

[56] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[57] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and] Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is] [are]* not responsible for any use that may be made of the information it contains.

1. Communication activities (consortium) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[58].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a beneficiary in a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to **multiple audiences** (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a **major media impact** (i.e. media coverage *(online and printed press, broadcast media, social media, etc.)* that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ **Security obligations —** Information given may NOT include **EU-classified information** or information on results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the classification of information in research projects and, more generally, the Funding & Tenders Portal Online Manual.*

[58] For the definition of 'communication activities', *see the Glossary.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the H2020 proposal templates*) and be included in Annex 1 and 2.

For guidance on promoting the action, *see the Social media guide for EU funded R&I actions and the Funding & Tenders Portal Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the **EU emblem**

AND

- including the **reference to EU funding** set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity or, for infrastructure, equipment or major results, the official language(s) of the country where they are located (using the text of the GA language version available on Funding & Tenders Portal Reference Documents).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object).

Examples: *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency; the]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of *[the Agency or]* the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency and the]* Commission will insert the following information:

> "© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the measures described in Chapter 6.

1. Communication activities (EU)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material):*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (EU)

The Commission/Agency will process personal data in compliance with Regulation 2018/1725 and as set out in its Funding & Tenders Portal privacy statements.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligibility of costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the EU financial interests).

⚠ When the Commission/Agency collects and processes personal data under the GA, national data protection law is NOT applicable and will NOT be accepted as a pretext for not complying with obligations under the GA.

Disclosure of staff data under the GA *(e.g. data requested by the Commission/Agency project officer or auditors)* is automatically justified under Article 5(c) of Regulation 45/2001.

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[59] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

Persons whose data is being processed (data subjects) can contact the data controller or the DPO (via the contact information in the privacy statement), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

[59] Available at http://ec.europa.eu/dpo-register/search.htm.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (consortium)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[60] and the corresponding national law).

⚠ The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [61]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc*.

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage

[60] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[61] *See Article 8 of Directive 95/46/EC*.

- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[62]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the relevant Funding & Tenders Portal privacy statements).

Examples:

1. *Before encoding staff data in the Participant Register or into a proposal, the beneficiary must provide the staff concerned with the privacy statement.*

2. *If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the privacy statement.*

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[62] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What? The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How? Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

1. *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.*

2. *Assignment for the benefit of creditors in a bankruptcy procedure.*

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

[OPTION to be used when the beneficiary is an European Research Infrastructure Consortium (ERIC)*[54] *without own resources: *As an exception, the beneficiary delegates the tasks set out above to [insert name of member of the ERIC]. The beneficiary retains sole responsibility for compliance with the obligations under the Agreement.]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is NOT responsible for the implementation of the action and has NO responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them **withdraws**, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless the Commission/Agency expressly agrees otherwise (exceptional; only for specific reasons). They will have to do this without any additional funding (although — in case of beneficiary termination — the Guarantee Fund may intervene for the defaulting beneficiary; *see Article 50*).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% contribution to the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

Specific cases (beneficiaries' responsibilities):

ERIC (European Research Infrastructure Consortium)[63]: If the beneficiary is an ERIC which does not have its own resources, it may exceptionally delegate the following responsibilities to one of its members:

- monitor that the action is implemented properly *(see Article 7)*
- inform about events or circumstances likely to affect significantly or delay the action

[63] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1).

implementation *(see Article 17.2)*
- submit deliverables and reports *(see Articles 19 and 20)*
- submit documents or information required

⚠ An ERIC using one of its members remains **fully responsible** for it under the GA.

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION 1 for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION 2: *Not applicable****]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly *(see Article 22)*.

Example:

In case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can normally NOT be subcontracted or outsourced to a third party (including linked third parties). They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use linked third parties for *other* tasks; *see Articles 13, 14*).

Specific cases (coordinator's responsibilities):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- they must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs (and those must include receiving and administering EU funds).

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

ERICs (European Research Infrastructure Consortia)[64] — Beneficiaries that are ERICs and do not have their own resources may exceptionally delegate the following coordination tasks to one of its members:

- monitor that the action is implemented properly *(see Article 7)*;
- act as intermediary for communications *(see Article 17)*;
- request and review documents or information required and verify completeness and correctness;
- submit deliverables and reports *(see Articles 19 and 20)*;

⚠ ERICs using one of their members remain **fully responsible** for it under the GA.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article, *e.g. scientific coordination of the action*) can be carried out by any beneficiary.

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it will however NOT be considered the action's coordinator (but one of the other beneficiaries).

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

> **Best practice:** In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

[64] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1)

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

> **Best practice:** The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see How to draw up your consortium agreement and the Funding & Tenders Portal Online Manual*.

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted ONLY for complementary actions *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

The beneficiaries of complementary grants must — through the collaboration agreement — create and participate in common boards and advisory structures, to decide on collaboration and synchronisation of the activities. These boards and advisory structures complement the governance of the project; they do not replace the consortium and other project governance mechanisms (if any).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted ONLY for jointly funded actions *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the GA and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see How to draw up your coordination agreement and the Funding & Tenders Portal Online Manual.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Cost rejection

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

Cost rejections will be made for **violations of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Grounds for cost rejection (EU):

- **Costs** do **not comply with** the GA **eligibility rules (in this grant)**

  The Commission/Agency will reject costs, if they do not comply with the eligibility rules set out in Articles 6 and 8-16.

- **Costs** do **not comply with** the GA **eligibility rules (in other grants)**

  The Commission/Agency may also reject costs, if such ineligibility was found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the ineligibility is:
    - systemic or recurrent and
    - has a material impact on this grant.

Rejection of costs can take place at any moment — at the time of beneficiary termination, interim payment, payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if cost rejection leads to a recovery: there will be an *ex ante* **contradictory procedure**
- if cost rejection does NOT lead to a recovery: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection (**payment review procedure**).

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post payment review procedure allows the

Commission/Agency however to pay quickly without having to suspend the payment deadline (by postponing the discussion on the disputed costs).

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Payment review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out (**notification of amounts due**; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections.

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for rejections at the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after beneficiary termination and after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

If the Commission/Agency rejects costs at **beneficiary termination**, it will deduct the rejected amount from the costs the beneficiary declared in the termination report and calculate the amount due to the beneficiary. If the amount is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will recover the difference *(see Articles 44 and 50)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

If the Commission/Agency rejects costs at the moment of an **interim payment** or the **payment of the balance**, it will deduct them and calculate the amount to be paid accordingly *(see Articles 5.3 and 21)*.

If ineligible costs are found **in-between payments**, the Commission/Agency will reject them at the next payment (i.e. deduct the amount rejected from the costs declared in the next financial statement and calculate the amount to be paid accordingly; *see Article 21*).

If the Commission/Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the costs accepted for the beneficiary at the payment of the balance and calculate a **revised grant amount**. If the revised grant amount is lower than its share of the final grant amount, the Commission/Agency will **recover** the difference *(see Articles 5.4 and Article 44)*.

The detailed calculations for all cases are described in Article 21.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **redu**ces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Grant reduction

If the Commission/Agency finds *(in particular following a check, audit, extension of audit findings, review or OLAF investigation)* **substantial errors, irregularities or fraud** or **breach of obligations** under the GA or during the award procedure *(e.g. the action has not been properly implemented)*, it may reduce the grant in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations.

Grant reductions will be made (at beneficiary termination, at the end of the action or after the payment of the balance) for substantial errors, irregularities or fraud or serious breach of obligations, in proportion to the seriousness of the error, irregularity, fraud or breach *(e.g. in case of fraud the reduction may be up to a 100%)*.

If the issues are found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

Grounds for grant reduction (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may make a grant reduction if a beneficiary has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Serious breach of obligations covers all kinds of non-compliance with GA obligations (including obligations during the award procedure).

  Example: *false declarations in the proposal form, in order to obtain EU funding*

  In practice, the most frequent breach is improper implementation of the action/non-compliance with Annex 1 GA (i.e. if the work performed does not correspond to the activities described in Annex 1). This will normally be examined on the basis of the periodic and final technical reports and, if needed, a project review.

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also make a grant reduction, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

3.0 Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol[65]).

Grant reduction can take place:

- at beneficiary termination
- at the payment of the balance or

[65] See judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128.

– after the payment of the balance.

3.0 Reduction at beneficiary termination was introduced explicitly with GA version 3.0. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination is possible for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 *(see above)*.

For more guidance on grant reductions, *see the Guidance on grant reductions*.

2. Procedure

The Commission/Agency will follow a **contradictory procedure.**

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Depending on the moment the reduction takes place, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

– for reductions at beneficiary termination: normally with the beneficiary concerned

– for reductions at payment of the balance: normally the coordinator

– for reductions after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

If the Commission/Agency reduces the grant at **beneficiary termination**, it will calculate the reduction at beneficiary-level and calculate the amount due to the beneficiary. If the amount is lower than the (pre-financing and interim) payments received by the beneficiary, the beneficiary will have to pay back the difference *(see Articles 44 and 50)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

If the Commission/Agency reduces the grant at the **payment of the balance**, it will calculate the reductions for each beneficiary and for the action (if any) and calculate the balance to be paid to the consortium (i.e. final grant amount) accordingly *(see Articles 5.3 and 21)*.

If the Commission/Agency reduces the grant **after the payment of the balance**, it will calculate the reduction for the beneficiary and compare the revised grant amount with its share of the final grant amount. If the revised grant amount is lower, the Commission/Agency will recover the difference *(see Articles 5.4 and 44)*.

The detailed calculations for all cases are described in Article 21.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION 2:** not applicable**];***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**]** **[OPTION 2:** not applicable**]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to early termination, cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to its maximum grant amount in Annex 2.

Grounds for recovery (EU):

- Commission/Agency **paid too much**

  The Commission/Agency will make a recovery, if the amounts paid out exceed the amounts that are due for the grant.

Recovery normally takes place only at **payment of the balance** or **afterwards**. Exceptionally, it can take place before, if a **beneficiary's participation is terminated**.

The Commission/Agency will recover after beneficiary termination if the beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

The Commission/Agency will recover at the payment of the balance if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Articles 5.3 and 21)*.

The Commission/Agency will recover after payment of the balance if — due to cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid in excess (or that the coordinator did not distribute the payments received; *see Article 5.4*).

The detailed calculations for all cases are described in *Article 21*.

2. Procedure

The basic procedure for recovery is almost always the same: After a **contradictory procedure**, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)* and issues a debit note.

Enforced recovery:

If the coordinator/beneficiary concerned does not pay by the date set out in the debit note, the Commission or the Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[66]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

  ⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

  For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 TFEU action, arbitration, etc.; *see Article 57.2*).

  Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission or the Agency may offset before this date, in order to safeguard the EU financial interests.[67]

  If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. The interest is normally offset first, before the principal amount.

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or

    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU[68].[69]

      The decision describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      ⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

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66 *See Article 80(1) of the Financial Regulation No 966/2012.*

67 *See Article 87 of the Rules of Application Regulation No 1268/2012.*

68 *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

69 *See Article 79(2) of the Financial Regulation No 966/2012.*

This decision — duly endorsed with the order for enforcement issued by the competent authority in the Member State concerned — allows to have the debtor's **assets seized**.

The contradictory procedure will normally be **combined** with the **contradictory procedure** for cost rejection and/or grant reduction (if any).

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

1. Administrative sanctions

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary is in an exclusion situation under Article 106(1) of the Financial Regulation No 966/2012, it may impose administrative sanctions (— in proportion to the seriousness of the misconduct).

Administrative sanctions (financial penalties and/or exclusion from future procurement contracts, grants and expert contracts) are **public law measures** (i.e. taken directly on the basis of Articles 106 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(substantial errors, irregularities or fraud, serious breach of obligations, bankruptcy, non-compliance with tax or social security obligations, grave professional misconduct, fraud, corruption, or criminal/illegal activity).*

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum sanctions** are as follows:

- for exclusion: up to **5 years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the sanction and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again, the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget (Annex 2) — depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again, the rate may be increased to between **4%** and **20%**.

The decision to apply an administrative sanction may be **published** on the Commission/Agency websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU financial interest and image)
- the time that has elapsed since it took place
- the duration and recurrence of the misconduct

- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

The Commission/Agency will follow the procedures set out in 106 of the Financial Regulation No 966/2012 (i.e. **contradictory procedure, panel, decision)**.

If the Commission/Agency imposes a financial penalty, it will also issue a debit note to **recover** the amount.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

However, there is NO:

- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

Specific case (administrative sanctions):

International organisations — Decisions on administrative sanctions (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability for damages (EU)

The Commission/Agency can NOT be held liable if — in implementing the GA — its own services cause damage (to a beneficiary or third party).

Moreover, the Commission/Agency can NOT be held liable if — in implementing the GA — a beneficiary or third party involved in the action causes damage (to another beneficiary or third party).

Examples:

1. *An experiment carried out by a beneficiary leads to an accidental escape of pollutants into the local river.*

2. *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the action.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third parties involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

1. Liability for damages (consortium)

If a beneficiary causes damage to the Commission/Agency (in implementing the action), the Commission/Agency may claim compensation).

Examples:

1. *Costs of legal proceedings borne by the Commission.*

2. *At a meeting on Commission premises, a beneficiary smokes and causes a fire.*

2. Procedure

The Commission/Agency will follow the normal procedure for damages claims (i.e. bringing an action for contractual damages before the European Court of Justice; not direct claim via a debit note).

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The Commission/Agency may stop the clock (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

Suspension of the payment deadline must be **distinguished** from **suspension of payments** *(see Article 48)*. Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary which is, for example, suspected of serious misconducts.

Grounds for suspension of the payment deadline (EU):

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

In practice, suspension is needed if there are issues with the payment request or with the costs declared which make it impossible for the Commission/Agency to comply with the **payment deadline** (i.e. for interim payments and payment of the balance: 90 days after payment request; *see Article 21*).

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

Late payment without suspension of the payment deadline gives rise to late-payment interest for the beneficiaries *(see Article 21.11)*.

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why.

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

Suspension will normally last until it is possible to make all the necessary checks and verifications that are needed for the payment (*e.g. analysis of technical reports and financial statements, eligibility of claimed costs, calculation of amount to be paid, approval and authorisation of payment*).

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (EU)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more or for all beneficiaries), on the grounds listed in this Article.

Suspension of payments has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systemic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend all outstanding payments for the audited beneficiary until the issue is resolved.*

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may also decide to:

- suspend the GA *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure**.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of suspension, this procedure will be directed either at the coordinator or the beneficiary concerned:

- suspension linked to the consortium: normally the coordinator

- suspension linked to a beneficiary *(e.g. simultaneous suspension of payments in several grants after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must make sure that the other members of the consortium are informed and ask for their comments.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned with the periodic reports (except with the report for the last reporting period).

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted. They must be included in the periodic report for the last reporting period (— even if suspension is still ongoing).

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May:	*the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May:	*the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June:	*the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July:	*the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August:	*the Commission pays for all beneficiaries except B.*
25 October:	*the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

If payments for one (or some) of the beneficiaries are still suspended at the end of the action, the Commission/Agency will make a partial payment of the balance for the amount that is not suspended (— but ONLY after having received all the necessary information for the final calculations for ALL consortium members, i.e. including the suspended beneficiaries).

The partial final payment is NOT the payment that closes the action. That payment will be made only after the payment suspensions are lifted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. GA suspension (consortium)

The beneficiaries may suspend the action (in full or in part), on the ground set out in this Article.

GA suspension may be used exceptionally if it is necessary to stop the action implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for GA suspension (consortium):

- **Action can no longer be implemented (or becomes excessively difficult)**

  The beneficiaries may suspend the action (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment after resumption).

Information obligation — Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g. **inform** the Commission/Agency under Article 17.2; **notify** a situation of force majeure under Article 51)*.

2. Procedure

The coordinator must immediately **formally notify** the Commission/Agency (via the Funding & Tenders Portal).

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must notify it to the Commission/Agency by requesting an amendment to the GA.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

It sets the resumption date and adapts the grant to the new situation *(e.g. by extending the action duration, modifying Annexes 1 and 2, updating the reporting periods)*.

If the Commission/Agency approves the amendment, the suspension is lifted and will be resumed as from the **resumption date** set out in the amendment. The resumption date can be retroactive (i.e. back to the date when the problem stopped/issue was clarified).

Example: *The action was suspended on 24.03.2016 due to weather conditions. Once the conditions improve, the coordinator requests and amendment to lift the suspension (e.g. after 60 days, on 22.05.2016). Therefore, in accordance with Article 54 of the GA, the action will be resumed as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the budget must be lowered in the amendment, to adapt the action to the new situation).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **can NOT be continued** (or the Commission/Agency does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the GA termination. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities, or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 <u>Procedure</u>

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (EU)

The Commission/Agency may suspend the action (in full or in part), on the grounds listed in this Article.

Grounds for GA suspension (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend the audited beneficiary's part of the action until the issue is resolved.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** 5 days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the GA, the Commission/Agency will follow a **contradictory procedure**.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of suspension, this procedure will be directed either at the coordinator or the beneficiary concerned:

- suspension linked to the consortium: normally the coordinator
- suspension linked to a beneficiary *(e.g. simultaneous suspension of several grants after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must make sure that the other members of the consortium are informed and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform the coordinator later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If possible, the Commission/Agency will give an estimation of how long the suspension will be needed.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once the action is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator (together with the suspension **end date**).

The suspension can be lifted retroactively (i.e. back to the date when the problem stopped/issue was clarified).

The coordinator must then request an amendment to the GA *(see Article 55)*, to set the **resumption date** in the tools and adapt the grant to the new situation *(e.g. by extending the action duration modifying Annexes 1 and 2, updating the reporting periods)*.

If the **action** (or part of it) **can NOT be continued**, the GA (or the beneficiary concerned) may be terminated.

If the suspension leads to the GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the GA termination.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The beneficiaries have the right to terminate the GA.

GA termination should be a last-resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA, but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Grounds for GA termination (consortium):

- **Any ground** that **justifies** early termination of the action

  The beneficiaries may terminate the GA in principle on any ground — as long as there is a good reason *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

  Examples:

  1. *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

  2*. The consortium requests termination because the action was finished ahead of schedule.*

  If there are no legitimate reasons for discontinuing the action, the Commission/Agency **can NOT oppose**, but termination will be considered **improper**.

  Improper termination of the GA may lead to a grant reduction (see *(see Articles 5.3 and 43*).

  This will be the case, for instance, if:

  - the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
  - the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
  - implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

  Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a grant reduction.*

2. Procedure

The coordinator must **formally notify** the Commission/Agency (via the Funding & Tenders Portal) of the termination — on behalf of the other beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. generating event before the termination date; *see Article 6.1(a)*) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. The Commission/Agency will NOT send a reminder and will NOT extend the deadline.

The detailed calculations are described in Article 21.

Termination has NO effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the security obligations (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*
- Chapter 6 measures (i.e. rejection of costs *(see Article 42)*, grant reduction *(see Article 43)*, recovery *(see Article 44)*.

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Beneficiary termination (consortium)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must inform the beneficiary concerned, request the beneficiary's opinion in writing and provide it to the Commission/Agency (or — if the beneficiary didn't reply — provide proof that the beneficiary's opinion has been requested in writing).

Grounds for beneficiary termination (consortium):

- **Any ground** that **justifies** termination of the participation of the beneficiary

  The beneficiaries may terminate the participation of one of their consortium members in principle on any ground — as long as there is a good reason *(e.g. withdrawal by a beneficiary because due to a change in ownership; the beneficiary cannot implement its tasks in the same way; bankruptcy)*.

  For beneficiaries that are involved in **several EU GAs,** withdrawal from one GA does NOT necessarily imply that it has to also withdraw from the others.

  Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

  If there are no legitimate reasons, the Commission/Agency **can NOT oppose** beneficiary termination, but it will be considered **improper**.

  Improper termination of the participation of a beneficiary may lead to GA termination *(see Article 50.3.1(c))* and/or to a grant reduction at the payment of the balance *(see Articles 5.3 and 43)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT continue participating in the action.

> ⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in actions, like beneficiaries.
> Linked third parties can NOT however do more than the beneficiary they are linked to: If their beneficiary is terminated, they must also leave the action.

2. Procedure

The coordinator must **formally notify** the Commission/Agency of the termination (via the Funding & Tenders Portal). At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Since for beneficiary termination the notification is combined with an amendment request, they must be submitted and signed by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3)*.

NO amendment is needed if the termination takes effect after the end of the action — unless it concerns the coordinator (since the coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants), the GA may be terminated.

> ***Example:*** *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional funding to do so) — unless the Commission/Agency expressly agrees otherwise.

The coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

In case of coordinator termination, the reports must be submitted by the new coordinator (to avoid problems with the payment). If the nomination of the new coordinator takes more time, the 30 days deadline may be extended.

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the terminated beneficiary:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes, those amounts must be paid back to the consortium.

Only **costs** incurred before termination (i.e. generating event before the termination date *see Article 6.1(a)*) are eligible — except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. The Commission/Agency will NOT send a written reminder and will not extend the deadline.

If the coordinator fails to submit the *report on the distribution of payments*, the terminated beneficiary whose participation was terminated will NOT have to repay any amounts.

The detailed calculations are described in *Article 21*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (beneficiary termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*) and the reports must be submitted by the new coordinator (to avoid problems with the payment). If needed, the 30 days deadline for submission of the reports can be extended *(see above)*.

Coordinator in bankruptcy/liquidation/administration (or similar) — In principle the coordinator must be changed. If the coordinator can no longer submit the request, the same procedure as for coordinator termination without its agreement should be used *(see above and Article 55)*.

Exceptionally, at the end of the action it may not be necessary to change the coordinator, but only its bank account if the administrator/liquidator accepts to do the final transfers of amounts.

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable];*

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**); see Article 22.5.2;

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks****][OPTION 2:*** *not applicable]*.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. GA or beneficiary termination (EU)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

⚠ Beneficiary termination may lead to **GA termination**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

⚠ The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

Grounds for termination (EU):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the GA termination; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or if the consortium no longer complies with the eligibility conditions set out General Annexes A and C to the H2020 Work Programme *(e.g. the rules regarding the minimum number of beneficiaries, their legal situation, or their place of establishment)*. [70]

  Examples:

  1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

  2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there has been a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Such changes can be of any kind and can be triggered by the beneficiary itself or outside circumstances.

  Examples:

  1. *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

  2. *The country in which one of the beneficiaries is established ceases to be an EU Member State. This means that the beneficiary is no longer eligible for funding and that the decision to award the grant is called into question. The Commission may decide to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

  ⚠ Costs become automatically ineligible as from the date of loss of eligibility *(see Article 6)*.

- **GA cannot be amended after termination** of a beneficiary's participation

[70] *See also Article 8 of the Rules for Participation Regulation No 1290/2013.*

The Commission/Agency may terminate the GA, if it cannot be amended after termination of a beneficiary's participation because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example:

1. *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

2. *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify beneficiary termination because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when a national investigation uncovers that it falsified the results of its clinical studies.*

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material*

contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.

- **Specific grounds for joint actions**

  For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

  - the third country/IO action does not start by the date specified in Annex 1

    In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission/Agency in full.

  - the third country/IO action is terminated

  - the third country/IO action can no longer contribute to the subject of the GA.

    Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity.

  Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have participated in large-scale drug trafficking.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may terminate the GA or the participation of a beneficiary, if a beneficiary (or one of its representatives) has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding; coordinator does not transfer payments to the other beneficiaries, but uses them for itself; coordinator does not submit the reports (despite a reminder); consortium does not inform the Commission/Agency about the receipt of a second grant for the same/similar proposal; review shows that action does not achieve its critical objectives and is way behind schedule and consortium submits a short-term implementation plan that is not acceptable; audit shows that beneficiary declared costs based on fake invoices; consortium does not provide requested information (despite a reminder); a check shows that scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism); consortium does not submit an amendment request after beneficiary termination.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also terminate the GA or the participation of a beneficiary, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and

  - the substantial errors, irregularities or fraud or serious breach of obligations are:

    - systemic or recurrent and

    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that appear intentional and also affect all other GAs signed by the audited beneficiary. The Commission may terminate the participation of the audited beneficiary in the GA.*

- **Non-removal of a linked third party/international partner**

  The Commission/Agency may terminate the participation of a beneficiary if it refuses to remove one of its linked third parties or an international partner which is in one of the following situations:

  - bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings;

- professional misconduct
- non-compliance with tax or social security obligations
- fraud, corruption or other criminal activities
- substantial errors, irregularities or fraud or serious breach of obligations (in this grant or other grants).

3.0 This termination ground was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, beneficiary termination/linked third party removal was however already implicitly included in the different grounds of Article 50.3.3 (given that linked third parties have to fulfil the same conditions as the beneficiaries for participating in the action).

Before terminating (GA or beneficiary), the Commission/Agency may first suspend the GA *(see Article 49.2)*, to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before GA or beneficiary termination, the Commission/Agency will follow a **contradictory procedure**

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of termination, this procedure will be directed either at the coordinator or the beneficiary concerned:

- terminations linked to the consortium *(e.g. GA termination after a negative project review)*: normally the coordinator
- terminations linked to a beneficiary *(e.g. beneficiary termination or simultaneous termination of GAs after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If a beneficiary is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy or similar), the Commission/Agency will also contact the liquidator/administrator (— as soon as possible after the termination is confirmed).

If it confirms termination, the Commission/Agency will specify the date on which termination will take effect **(termination date)**.

This date will be a date after the notification: Terminations can**not** be **retroactive** (notably to ensure the fulfilment of obligations and deadlines after termination; *see point 3*).

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of **GA termination** are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. generating event before the termination date; *see Article 6.1(a)*) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

The effects of **beneficiary termination** are the same as when the beneficiaries terminate one of their partners *(see Article 50.2.2)*.

The detailed calculations are described in Article 21.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific case:

Termination of the coordinator — The amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*) and the reports must be submitted by the new coordinator. If needed, the 60 days deadline for submission of the reports can be extended.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What? In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Personal reasons *(e.g. sickness)* or internal instructions are in general NOT considered as cases of force majeure.

If force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

⚠ New in Horizon 2020: If a task could not be executed due to a situation of force majeure but certain costs were incurred for that task and could not have been avoided, those costs may still be eligible. This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

Force majeure may lead to GA suspension *(see Article 49)* or GA termination *(see Article 50)*.

How? The coordinator must immediately **formally notify** the Commission/Agency (via the Funding & Tenders Portal).

The beneficiary concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal electronic exchange system and using the forms and templates provided there.

If — after the payment of the balance — the [Commission][Agency] finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

1. Communication between the parties — Funding & Tenders Portal electronic exchange system

All communication between the consortium and the Commission/Agency – before and after the payment of the balance – must be in electronic form **via** the **Funding & Tenders Portal**.

Beneficiaries will receive Funding & Tender Portal notifications even after the end of the action (and the LEARs are obliged to keep beneficiary contact data up to date, in order to ensure that the communication channels remain active).

The responsibility for opening notifications in time is with the beneficiaries.

Formal notifications are normally considered to have been **accessed 10 days after** they have been **sent** (— even not actually opened by recipient, *e.g. refusal of reception or omission*). Deadlines that are counted from the date of receipt are counted as of day eleven.

The same is in principle valid for formal notifications **after the payment of the balance** — except that the Commission/Agency will check that the notification has *actually* been accessed by the beneficiary (at any time, before or after the 10 days deadline). If it was not accessed, the Commission/Agency will send a second notification, this time on paper by registered post with proof of delivery. In that case, the deadlines will start to run from the date of receipt of the second notification.

4.0 The communication via the Funding & Tenders Portal was extended to after the payment of the balance with GA version 4.0. For older grant agreements, it is in principle on paper, unless the beneficiary agrees to accept communication via the Funding & Tenders Portal.

The Funding & Tenders Portal offers different **functions**:

- viewing and changing the legal entity data in the Participant Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the Funding & Tenders Portal project file (with date and time).

Formal notifications are also recorded (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation and access are linked to the user role *(e.g. LEAR, PLSIGN or PFSIGN*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator. They cannot submit information directly to the Commission/Agency.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission/Agency.*

For more guidance on access and roles in the Funding & Tenders Portal*, see the Portal Online Manual.*

In principle, all communications from/to the Commission/Agency must normally go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations No 883/2013 and No 2185/2996)*.

Specific cases (PP access rights):

Beneficiaries in bankruptcy — If during a beneficiary goes bankrupt during the action, the liquidator may be granted the necessary access rights in the Funding & Tenders Portal, in order to complete the beneficiaries' obligations. If exceptionally necessary, the Commission/Agency can also agree to communication outside the Funding & Tenders Portal electronic exchange system (i.e. via registered post or e-mails).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means intergovernmental organisations (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the applicable legal texts provide otherwise), public law decisions cannot be applied to international organisations; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions (i.e. exclusion or financial penalties; *see Article 45*).

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration *(see Article 57.2)*. The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are **calendar days**.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*
The action is divided into the following reporting periods:
RP1: from 1 March 2015 to 31 August 2016
RP2: from 1 September 2016 to 28 February 2017
Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.
The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What? An amendment is necessary whenever there is a need to **change** the GA (i.e. the core agreement and/or the Annexes).

⚠ The cases where an amendment is necessary are called 'amendment types' (AT); the amendment clauses are called 'AT clauses'.

⚠ The general terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to set its 'end date of participation'.*

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and have an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

⚠ **Information obligation — Changes** in the **name, address, legal form** and **organisation type** AND changes in the **legal, financial, technical, organisational** or **ownership situation** may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary terminate its participation and to amend the GA.*

2. *Beneficiary B moves from Europe to Australia during the action. The change of address implies that the beneficiary becomes not eligible for EU funding, so the GA will have to be amended to make it a 'beneficiary not receiving EU funding'.*

3. *Beneficiary C participates in an innovation action (IA) and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Participant Register is sufficient; no amendment is needed.*

2. *Beneficiary E participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Characteristics of amendments:

- Can only be done in writing — an oral agreement is not binding on the parties.
- Enters into force after the signature by the coordinator and the Commission/Agency through an exchange of letters.
- Takes effect on the date agreed by the parties (retroactive or in the future); if no date specified, on the date of the second party approves (not retroactive).
- Can only be implemented after the entry into force of the GA and before the final payment is made.
- Must normally be requested before the end of the project; in exceptional cases amendment clauses are also open after the end of the project *(e.g. change of coordinator or change of coordinator's bank account, in order to be able to make the final payment)*.

- Has to be signed by persons having the same capacity to represent the legal entity as those who signed the initial GA.
- Leaves all the other provisions of the GA which are not affected unchanged and to continue to have full effect.
- Forms an integral part of the GA.
- Has to be in line with the rules applicable to the GA (applicable law and EU law), with the other provisions of the GA and with the applicable model grant agreement.
- Cannot have the purpose or effect of making changes to the GA which might call into question the decision awarding the grant or result in unequal treatment of beneficiaries or applicants.

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation was terminated** due to **non-accession** to the GA or non-provision of the requested declaration on **joint and several liability** (**AT1**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary that never became part of the GA.

  How? The amendment is normally triggered by the beneficiaries.

  In case of beneficiary termination (by the consortium), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  The changes will be made ex tunc (i.e. since the beginning) since the beneficiary never participated in the grant.

  If the beneficiary was participating with linked third parties/international partners, they will automatically be removed.

  GA options for the beneficiary (and its linked third parties/international partners) are automatically removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Removal of a beneficiary whose participation was terminated** for **other reasons** (**AT2**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary during the action.

  What not? There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator AND the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  How? The amendment is normally triggered by the beneficiaries.

  In case of beneficiary termination (by the consortium), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the request for amendment, the same procedure as for coordinator change without its agreement should be used.

Changes will be made ex nunc (because the beneficiary participated in the grant up until termination and, moreover, many obligations are applicable after termination).

The termination date will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

If the beneficiary was participating with linked third parties/international partners, they will also have to be removed (with effect from the same date) and the end date of participation will be added to Article 14/Article 14a (AT5a/5b).

By contrast, the GA options for the beneficiary (and its linked third parties/international partners) will NOT be removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will normally have to be changed (AT21 and AT31).

- **Adding a new beneficiary** (**AT3**; *see Article 56.2*)

  What? Addition of a new beneficiary during the action.

  How? The amendment is normally triggered by the beneficiaries.

  The new beneficiary must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

  The accession date will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

  The date must be selected in the Accession Form (attached to the amendment request). It is possible to choose between:

  - the date of signature of the Accession Form
  - the date of entry into force of the amendment

  OR

  - a fixed date:
    - retroactive (before signature of the Accession Form)

    OR

    - future (after signature of the Accession Form — this should be an exceptional case with a justification).

  Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

  Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

  If the new beneficiary is participating with linked third parties/international partners, they will also have to be added (with effect from the same date) and the starting date of participation will be added to Article 14/Article 14a (AT6a/6b).

  The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change of beneficiary due to partial takeover** (**AT4**; called 'partial transfer of rights and obligations' in FP7)

  ⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination *(see Article 50)* or addition of a new beneficiary *(see Article 56)*.

  This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment clause for addition of a new beneficiary (AT3).

What? Transfer due to partial takeover.

'Partial takeover' means that a part of the business of the beneficiary — including the GA — is taken over by (one or more) other entity(ies) (transfer of a business unit as a going concern, *e.g. partial acquisition, distribution of a business unit after dissolution/liquidation, division/demerger, etc.*).

'Partial acquisition' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, *some* of the rights and obligations (and contracts) of the original entity are transferred to the new entity. Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'Distribution of a business unit on dissolution/liquidation' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entities purchase a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only *some* of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'Division/demerger' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has an ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two partial takeovers: one to company E and one to company O.*

What not? Simple sale of (one or more) assets of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary.

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Funding & Tenders Portal messaging function).

NO amendment is necessary for universal takeovers *(see below)*.

How? The amendment is normally triggered by the beneficiaries; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as new beneficiary).

'New beneficiary' is used here only for the purpose of the amendment; it can be either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

⚠The new beneficiary(ies) will (each) be fully **jointly and severally liable** with the former beneficiary for recoveries under Article 44. (By contrast: NO joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular:

- explain the financial liability of the former beneficiary
- cite the applicable rules (with hyperlinks to the texts, if possible), and
- provide a copy of the takeover contract.

Best practice: In order to avoid multiple submission of documents, beneficiaries are recommended to upload the takeover contract in the Participant Register (via My Organisation page) and specify in the amendment request that the legal documents are available in the Funding & Tenders Portal. This is particularly useful if several EU grant agreements or contracts are affected by a partial takeover.

The transfer date will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.

If the former beneficiary was participating with linked third parties/international partners, the new beneficiary will have to determine which of the former beneficiary's linked third parties/international partners stay on as linked third parties/international partners of the new beneficiary (AT6a/6b) — all other linked third parties/international partners will be automatically removed.

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

The former beneficiary does NOT need to submit any reports to the Commission/Agency. The financial statement for the open reporting period until transfer must be uploaded with the next periodic report either by the former beneficiary (for the time it was a beneficiary) or by the new one together with its own financial statement.

- **Removing a linked third party/international partner** (**AT5a/5b**; *see Articles 14 and 14a*)

What? Removal of a linked third party/international partner during the action.

How? The amendment is normally triggered by the beneficiaries.

If requested by the Commission/Agency *(e.g. because of audit results or an OLAF investigation)*, the consortium MUST submit an amendment to remove a linked third party/international partner.

⚠ If the consortium does not follow-up this request, the Commission/Agency may **terminate** the participation of the *beneficiary* (and thereby also remove the linked third party/international partner).

NO termination notification — Linked third parties/international partners can be removed by the consortium by simple amendment; no formal termination notification is required (termination notification applies only to beneficiaries; *see Article 50.2*)

Changes will be made ex nunc (because the linked third party/international partner participated in the grant up until removal and, moreover, many obligations are applicable after termination).

The end date of participation will be added to Article 14/14a.

The date must be selected in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

The GA options for the linked third party/international partner will normally NOT be removed/changed/become not applicable.

Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Adding a linked third party/international partner** (**AT6a/6b**; *see Articles 14 and 14a*)

What? Addition of a new linked third party/international partner during the action.

How? The amendment is normally triggered by the beneficiaries.

The new linked third party/international partner must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

The name of the linked third party/international partner and the starting date of participation will be added to Article 14/14a.

The date must be selected in the amendment request. It is possible to choose between a fixed date or the 'date of entry into force of the amendment'. If the linked third party/international partner joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

The GA options for the linked third party/international partner will be added/changed/become applicable.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'** (**AT7a**; *see Article 9*)

What? If a beneficiary/linked third party — exceptionally — becomes eligible/not eligible for receiving EU funding during the action *(e.g. due to a change of establishment or a country changing eligibility status)* OR if it suddenly requests funding/zero funding, this change will normally require an amendment (to change Annex 1, Annex 2 and the options in Articles 9 and 57).

Examples:

1. *Beneficiary R moves from Europe to Australia and thus is no longer eligible for receiving EU funding. The GA must be amended. If R is participating with a linked third party M established in France, M will continue being eligible for funding.*

2. *The country in which beneficiary X is established leaves the EU (without an agreement ensuring continued eligibility). The beneficiary is therefore no longer eligible for funding and the GA may have to be amended (or terminated; see Article 50).*

3. *Beneficiary Y is eligible but signed the grant with zero funding. During the action the responsibilities within the consortium are shifted and beneficiary Y takes on a bigger role involving more costs. The other consortium members agree to adapt the budget and renounce to some funding in order to allow beneficiary Y to claim funding.*

Costs become automatically ineligible as from the date of loss of eligibility *(see Article 6)*.

How? This amendment can normally be triggered only by the Commission/Agency.

- **Change of coordinator (AT8)**

What? Replacement of the coordinator during the action *(e.g. because of financial difficulties)*.

Exceptionally, an amendment remains possible and necessary *after* the end of the action *(see Article 3)* — until the payment of the balance is paid out and distributed.

Coordinator in bankruptcy/liquidation/administration (or similar) — After the end of the action, if the coordinator can continue its participation with the bank account of the administrator/liquidator (i.e. termination and coordinator change not really needed), it is therefore exceptionally sufficient to change the bank account (AT40) without changing the coordinator.

What not? There is NO need to request an amendment for a change of the *person* in charge of the coordination of the project (since the person's name is not mentioned in the GA).

> ⚠ **Information obligation** — In case of a **change of person in charge of coordination**, the coordinator must — in addition to updating the data in the Funding & Tenders Portal inform the Commission/Agency under Article 17.2).

How? The amendment is normally triggered by the beneficiaries.

If the new coordinator is not already a beneficiary of the GA, it must first accede to the GA as a new beneficiary (AT3).

The former coordinator may continue to participate in the action as a normal beneficiary or may terminate its participation (AT2).

Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the amendment request, the same procedure as for coordinator change without its agreement should be used.

The handover date will be added to the Preamble of the GA.

The date must be selected in the amendment request (fixed date or date of entry into force of the amendment).

The date the former coordinator stops acting as coordinator should normally be the date the new coordinator takes over the coordination tasks (handover date). If there was a gap (former coordinator leaves before new coordinator starts; *e.g. coordinator is in bankrupcy*) there will be two different dates: the one for the former coordinator (when it stopped doing coordinator tasks — must be at the latest its termination date) and the one for the new coordinator (when it took over the coordinator tasks — must be after its accession date).

- **Change of the coordinator's bank account for payments (AT40)**

What? An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

What not? NO amendment is necessary for a change of the name of the bank or name of the account holder; a change of the bank account data (and validation) in the Funding & Tenders Portal Participant Register is sufficient.

How? The bank account data must first be updated in the Participant Register (and be validated).

- **Change of the starting date, action duration or reporting periods (AT23, AT24, AT25)**

What? Change of the action's schedule (starting date, action duration or reporting periods).

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

> ⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

How? An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

- **Changes to Annex 1 (description of the action) (AT21)**

What? Changes to the description of the action, in particular:

- significant change of the action tasks *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
- changes concerning in-kind contributions provided by third parties (against payment or free of charge) or subcontracts

  Such changes could in principle also be made via simplified approval procedure *(see Articles 11, 12 and 13)*; however, if the beneficiary requests an amendment, it will immediately know if the Commission/Agency agrees (or not). Without amendment, this decision is left for later and the Commission/Agency may reject the costs as ineligible later on (at the moment of the payment).
- changes concerning the tasks to be carried out by linked third parties and related costs (including if a linked third party is removed)
- significant changes to the plan for exploitation and dissemination (unless Annex 1 already foresees an update to be submitted with the periodic report)
- changes concerning GA options (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2)*
- significant changes concerning deliverables *(e.g. changes of ethics requirements to align to ethical principles and legislation; adding/removing deliverables; changes in substance of a project output which is reflected in a deliverable, etc.)*.

What not? Changes to the due date of a deliverable normally do not require an amendment (except for certain deliverables, where timeliness is key)

- **Changes to Annex 2 and Annex 2a (estimated budget) or specific unit costs (AT31 and AT36)**

  What? Changes to the estimated budget, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which are linked to a significant change in the action's work (i.e. Annex 1)
  - a budget transfer to a form of costs that is not used by the beneficiary (i.e. with 0 EUR costs in Annex 2) — except for transfer of amounts within the budget category A 'personnel costs' and for transfers to the budget category 'costs of internally invoiced goods and services'.

    Example:

    During the action implementation, the beneficiary decides to use the access costs for transnational access to research infrastructure unit cost. This requires an amendment to fix the unit cost and to move budget to budget category F.2.

  What not? There is NO need to request an amendment for changes covered by the budget transfers rule in Article 4.2 *(e.g. budget transfers within the personnel cost; see also below)*.

  How? The amendment is normally triggered by the beneficiaries.

  Best practice: If Annex 2a or specific unit costs need to be changed, the beneficiaries should contact the Commission/Agency (via the Funding & Tenders Portal messaging function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment, provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

  Budget transfers within the personnel cost category and budget transfers to costs of internally invoiced goods and services are possible without having to amend the GA.

  Examples:

  1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices (average personnel costs).*

2. *An SME joins an on-going GA. The SME owner does not have a salary but incorrectly budgets its costs as actual personnel costs (category A.1). He realises the mistake and then switches to the unit costs for SME owners (category A.4).*

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is normally sufficient.

Linked third parties/international partners — Since they normally do not have direct access to the Participant Register, linked third parties/international partners must inform their beneficiary who must inform the Commission/Agency. The data will then be updated by the Commission/Agency (and validated).

If (exceptionally) the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator (and instruct it to request an amendment or trigger itself an amendment, if needed).

Example: Company R moves from Europe to Australia and this implies that the beneficiary is no longer eligible for EU funding. In such a case, the Commission will make an amendment to the GA to change the beneficiary status into 'beneficiary not receiving EU funding'.

Short names have no legal value and only serve as easy identifiers in the GA. If needed, they can be changed in the context of an amendment initiated on other grounds.

A change of the person that represent the coordinator for the purposes of signing the GA requires NO follow-up at all (not even a change in the Participant Register — since this name is only relevant at the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

Transfers of the GA linked to a universal takeover (i.e. where the original entity is replaced by one new entity and all the rights and obligations — including the GA — are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is normally sufficient.

Example: *Beneficiary X merges with another existing entity Y by:*

- *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
- *establishing a new separate legal entity (X and Y are together known as 'Z').*

If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator (and instruct it to request an amendment, if needed).

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information (AT40).*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going innovation actions (IAs). The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% (but only to a reimbursement rate of 70%). The GA must be amended to change the reimbursement rate (AT33) and the estimated budget (AT31).*
For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

Information obligation — In case of a **universal takeover**, the beneficiary must — in addition to updating the data in the Participant Register— inform the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the Funding & Tenders Portal) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Funding & Tenders Portal Online Manual.*

2. Procedure

How? Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) directly in the Funding & Tenders Portal.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Funding & Tenders Portal messaging function), to discuss the amendment.

Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Participant Register.

Examples:

1. *A new beneficiary must be validated (legal entity validation). This means that the new beneficiary will first have to register in the Participant Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Funding & Tenders Portal.*

2. *Validation of the new bank account, to change the bank account.*

The amendment request must include the necessary information and supporting documents. A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications or additional information/documents.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Portal Online Manual.*

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action; *see Article 3*). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases *(e.g. change of bank account, change of coordinator to make the payment of the balance)*.

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Termination of the coordinator without its agreement — For change of coordinator without its agreement a special procedure applies: The other beneficiaries must nominate one of them to act on their behalf to notify termination and request the amendment. The nominated beneficiary must name a contact person responsible for the amendment.

Before it has been accepted or rejected, an amendment request may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The other party must — within **45 days** — **agree or disagree**.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If **accepted** it will be **counter-signed** by the receiving party directly in the Funding & Tenders Portal (for the consortium: by the PLSIGN of the coordinator).

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Funding & Tenders Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

1. *Where a new beneficiary is added to the GA (AT3), it must assume the rights and obligations from the accession date specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).*

2. *Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment (AT26). This date may be before the date on which the amendment enters into force (see Article 49.2.2).*

3. *If the amendment intends to correct an error (AT60), the change will be made with effect from entry into force of the GA (i.e. from the beginning).*

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* directly in the Funding & Tenders Portal. They must do this **within 30 days** after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on **joint and several liability** *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, before signing the Accession Form.

Without the declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Linked third parties do not become parties to the GA and therefore do NOT need to sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (new in Horizon 2020). All documents are available in the Funding & Tenders Portal project file.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries (amendment)

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How? The new beneficiary must:

- register in the Participant Register and be validated — unless it already has a validated participant identification code (PIC)
- sign the Accession Form (directly in Funding & Tenders Portal)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the **accession date**. It must be either:

- the date of signature of the Accession Form
- the date of entry into force of the Amendment

OR

- a fixed date:
  - either retroactive (i.e. before signature of the Accession Form)

  OR
  - future (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that both can incur costs for a certain period.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned].****]***

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations:

Situation	Applicable law
For international organisations that do NOT accept any applicable law clause	No reference to any applicable law[71]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of

[71] *See Article 180(1) of the Rules of Application Regulation No 1268/2012.*

	international organisations and the rules of general international law.
For international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law)	The international organisation can choose any of the following combinations of applicable laws: – only EU law – only Belgian law – only other MS or EFTA country law – only general principles governing law of IOs + rules of general international law – EU law + MS or EFTA country law (except Belgium) – EU law + general principles governing law of IOs + rules of general international law – EU law + Belgian law + general principles governing law of IOs + rules of general international law – EU law + other MS or EFTA country law + general principles governing law of IOs + rules of general international law – Belgian law + general principles governing law of IOs + rules of general international law – other MS or EFTA country law + general principles governing law of IOs + rules of general international law

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not eligible for EU funding, which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. [OPTION for Agency grants: Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).]

1. Dispute settlement

As a general rule, H2020 GAs contain an Article 272 TFEU arbitration clause — referring **contractual disputes** (i.e. disputes on the interpretation, application or validity of the GA) to the European Court of Justice.

> An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against confirmation letters, debit notes, etc.; NOT against audit reports, audit letters, pre-information letters, etc.).
>
> For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency (information is available both in the Preamble of your GA and in SyGMa).

For disputes of public law nature (i.e. which concern **administrative sanctions**, **offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions must be brought before the European Court of Justice under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ **Public law measures** must ALWAYS be brought to the European Court of Justice under Article 263 TFEU (including actions brought by non-EU beneficiaries or beneficiaries not receiving EU funding).

⚠ All procedures are organised in a way that the beneficiaries will always be **informed** about what they can do if they disagree (**means of redress** information in the letters).

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, contractual disputes are normally referred to the courts of Brussels, Belgium. They can NOT choose another forum. (So far NONE of the H2020 association agreements provides for the sole jurisdiction of the European Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Beneficiaries not receiving EU funding — Beneficiaries not receiving EU funding which are not eligible (meaning from a third country not eligible for funding; *see Article 9*) are treated like non-EU beneficiaries (i.e. courts of Brussels), unless their national law explicitly provides that they cannot be subject to the jurisdiction of the Belgian courts. In this latter case (very exceptional), contractual disputes are referred to the Permanent Court of Arbitration.

Disputes of public law nature remain before the European Court of Justice.

International organisations — For international organisations, contractual disputes are referred to the Permanent Court of Arbitration (in line, for instance, with their PAGODA agreement, e.g. for the United Nations, the Financial and Administrative Framework Agreement (FAFA) with the United Nations[72]).

Disputes of public law will normally not arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

For this reason, the Commission/Agency will normally NOT adopt enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions *(see Article 45).*

Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (NOT as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[72] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

For countries for which it has carried out a formal assessment of specific situations or their legal framework, the Commission will keep record of its official position.

See the List of issues applicable to particular countries.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC), i.e.:
  - ERC PoC
  - ERC PoC Lump Sum Pilot
- ERC Low Value grants.

Frontier research actions use the H2020 ERC MGA. For ERC PoC, there are two specific MGAs: the standard ERC PoC MGA (based on actual costs reimbursement) and the ERC PoC Lump Sum Pilot MGA with a pre-fixed amount of EUR 150 000. A specific MGA also exists for ERC Low Value grants. Other ERC actions (coordination and support actions (CSA)) use the H2020 General MGA.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)

- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The H2020 ERC MGA PoC Lump Sum Pilot deviates from the General MGA as follows:

- Preamble
- Article 4.2 (estimated lump sum breakdown and transfers)
- Article 5 (grant amount and form of grant
- Article 6 (not applicable)
- Article 7.1 (reference to PI supervision)
- Article 8 (resources to implement the action)
- Articles 9-12and 14a-16 (not applicable)
- Articles 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to single reporting/final report)
- Article 13 (subcontracting)
- Article 18 (keeping records)
- Articles 20 and 21 (specific reporting and payment provisions; only final report, no interim payments)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 22 (specific procedure for extension of audit findings)
- Article 41.3 (Provisions on internal arrangements)
- Article 42 (not applicable)
- Article 47 (specific provision for suspension of payment deadline)
- Article 49 (specific provision for suspension of the action)
- Article 50 (specific provisions for termination)
- Article 56.3 (GA transfer for mono-MGAs)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

For the ERC PoC Lump Sum Pilot MGA, the Articles where the only difference is the removal of references to eligibility of costs *(e.g. Article 14, 17.1, 22.5, 41.2 – removal of CFS —)* or rejection of costs *(e.g. Articles 14.2, 18.2, 22.6)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the standard ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the standard ERC PoC MGA will be limited to major differences from the ERC MGA.

For the ERC PoC Lump Sum Pilot MGA, the annotations will focus mainly on differences arising from the cost models (lump sum versus actual costs reimbursement).

The annotations (for all three MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal. For ERC PoC Lump Sum Pilot, there is a single MGA for both mono- and multi-beneficiary actions.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

***[OPTION by default:** 'principal investigator':[4]*

*- [**Name**][Date and place of birth]]*[5]

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

*- [**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**] established in [official address in full] *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]*

[same for each beneficiary]

***[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*:* ***and other ERC grants with more than one principal investigator****: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Participants: Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The '**host institution (HI)**' is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**' for at least the duration of the action.

2. Participants: Principal investigator(s)

For ERC grants, the main researcher (i.e. the **principal investigator (PI)**) is named in the GA.

PIs can be of any **nationality**, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted (and usually engaged) by a host institution that is based in an EU Member State or H2020 associated country.

Due to the key role of the PI, s/he can NOT be replaced by any other researcher during the action. Requests for amendments to change the PI will be rejected.

PI time commitments — The PI must comply with certain minimum requirements regarding working time on the action (fixed in Annex 1 and 2) and working time in an EU Member State or H2020 associated country (set out in the work programme/call).

The Agency must be informed before any change in employment or location of the PI.

Should the PI move to another host institution (in an EU Member State or H2020 associated country), the GA can be transferred to the new host institution (**portability**; *see Article 56a*). If the PI moves to an institution established in a non-associated third country, the GA may be terminated *(see Article 50.1 H2020 General MGA)*.

In case of breach, the Agency may terminate the GA or take any of the other Chapter 6 measures *(e.g. grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50 H2020 General MGA).*

PIs do not become party to the GA, but they are the key actors in charge of the research activities. However, it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary.

Examples:

1. A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium. The engagement of the team follows the rules of the beneficiary and its country.

2. PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the action), PIs and their host institutions must sign a **supplementary agreement (SA)** *(see Article 32)*. The supplementary agreement can NOT replace the employment/engagement contract and is not sufficient by itself.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party (from an EU Member State or H2020 associated country), i.e.:

- a third party that provides the PI as in-kind contribution or
- a linked third party *(see Article 8)*.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution AND the third party.

Retired PI — The PI may be retired.

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)] [and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
  - costs of internally invoiced goods and services
- indirect costs.

Thus, the ERC MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure
- direct costs of providing financial support to third parties
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices (average personnel costs), the unit costs for SME owners and beneficiaries that are natural persons without salary, the unit costs for internally invoiced goods and services and the flat-rate of 25% for indirect costs.[73]

It does NOT use the unit costs of category F 'specific cost categories' of the General MGA.

[73] See *Article 29(1) and 33(2) of the Rules for Participation Regulation No 1290/2013 and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* — with the exception of categories C. 'financial support to third parties' and F 'specific cost categories'.

The same **eligibility conditions** and **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the following **specificities**:

– for category A 'personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: under budget category A.1 'costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: under budget category A.3 'seconded persons' (Article 6.2.A.3)).

– for category D 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs', even for the unsuccessful candidates (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs) and to research data are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[74]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

[74] See http://erc.europa.eu/implementing-arrangements

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

Combining H2020 & other EU grants — ERC grants do NOT prevent **PIs** from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

For more information on how to combine EU funding from different programmes, *see the Funding & Tenders Portal Online Manual (links to Regional funding).*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record-keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(a) ***[OPTION 1 if the JRC is a beneficiary**: information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC)*;*]**[OPTION 2**: not applicable;**]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2.

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC actions, the principal beneficiary must submit both:

- a **periodic scientific report** after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a **final scientific report** at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a **financial report** at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a breakdown of direct costs table and a budget follow-up table
- an individual financial statement
- a summary financial statement, created automatically by the IT system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a certificate on the financial statements (CFS).

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted directly in the Funding & Tenders Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA. Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in **the data management plan**;*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2: *Not applicable**]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

> 'Peer-reviewed publications' means publications that have been evaluated by other scholars.
>
> Monographs, book chapters and other long-text publications are considered to be peer-reviewed, if the following conditions are fulfilled:
>
> – at least one independent expert (i.e. external to the publishing house) has reviewed the manuscript before acceptance for publication. For monographs in the strict sense (i.e. not edited collections), external review of a substantial part of the work is sufficient to be considered peer-reviewed
>
> – the external reviewer must not be a scientific series editor or a commercial editor related to the publication in question. For edited collections, it must not be the editor of the collection
>
> – PhD theses and habilitations for professorial degrees are considered peer-reviewed if they are formally published (because the review by external experts is generally part of the assessment of the candidate's research work for the PhD degree or the 'venia legendi').

⚠ Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

ERC grants have however the following **specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

– for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)

– for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org). For monographs, book chapters and other long-text publications, the recommended repository is the OAPEN Library (http://oapen.org).

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Moreover, for publications after the end of the action, if beneficiaries cannot provide open access within the time limits set by Article 29.2 without incurring additional costs for gold open access,

they may choose green open access with an extended embargo period which goes beyond six/twelve months.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a digital object identifier (DOI)[75] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable). For ease of tracking, beneficiaries should include the digital object identifier for the 'European Research Council' (http://dx.doi.org/10.13039/501100000781) in the funding acknowledgement field in their metadata, in addition to the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601).

For more guidance, *see Open Access on the ERC website, the ERCEA Implementation Guidelines and the ERC Scientific Council's Open Access Guidelines for research results funded by the ERC.*

2. Open access to research data

This option will be inserted in the GA for ERC frontier research actions that participate in the Open Research Data Pilot (in line with provisions in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the following **specificities**:

The data management plan (DMP) must address the following issues (the use of the ERC template is strongly recommended but not mandatory):

1. Making data Findable
2. Making data openly Accessible
3. Making data Interoperable
4. Increase data Re-use
5. Allocations of resources and data security

Moreover the DMP can provide justification for NOT ensuring open access to specific parts of the research data. For ERC actions, the exception allowing beneficiaries not to give access to specific parts of their research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives.)

For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does NOT need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

A first version of the data management plan must be submitted within the first 6 months of the project implementation and should then be updated during the lifetime of the project, as needed.

The beneficiaries may **opt out** of the pilot at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55 H2020 General MGA)*. No reasons have to be provided for opting out. By opting out, they free themselves retroactively from the obligations associated with taking part in the pilot.

[75] For more information, *see http://www.doi.org/.*

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow and facilitate the transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action

The PI must ensure a sufficient time commitment and presence throughout the course of the project to guarantee its proper execution.

The two time commitment obligations are as follows:

- % of working time that the PI must work on the action
- % of working time that the PI must work in an EU Member State or H2020 associated country.

To be operational, these two percentages must be translated into working hours, i.e.:

- minimum number of hours that the PI must work in the action over its duration
- minimum number of hours that the PI must work in an EU Member State or H2020 associated country over the duration of the action.

The calculation should be done as follows:

Step 1 — For each year of the action, the percentages of PI commitment are applied to:

a) either the annual hours of a standard full time equivalent at the host institution, or

b) 1720 annual hours (this option must be used in all cases when it is not possible to determine the number of hours of a full time equivalent at the host institution).

The standard full time equivalent (or 1720 annual hours) works as a ceiling: they apply even if the PI works in total *more* hours (i.e. has other parallel affiliations, freelance activities or work-related obligations or works more hours on the action). In this case, the time commitment is capped at 100% and the hours are calculated on the standard full time equivalent (or 1720 annual hours).

By contrast, if the PI works in total *less* hours than the standard full time equivalent (or 1720 annual hours), the time commitment obligation will be reduced proportionally.

To do so, the percentage of PI commitment will be applied to the total work of the PI (instead of to options a) or b) above).

The total work of the PI will be determined by adding up all her/his hours of remunerated work, including under contracts with entities other than the host institution.

Example: *The % of PI commitment to the ERC action is 50%. The PI works 60 % part time at the host institution and has another contract with a different entity to work 350 hours over the year. A full time equivalent at the host institution works 1750 hours per year. The hours that the PI works in total are = 60 % of 1750 + 350 = 1 050 + 350 = 1 400. Since this amount is lower than the full time equivalent, the time commitment obligation will be: 1 400 x 50 % = 700*

Step 2 — Sum up the results for each year of Step 1 to get the total number of hours over the action duration.

The percentages must be reached for the overall action duration (NOT annually or per reporting period).

The PI's time commitments obligations must be fulfilled even if no personnel costs are charged for him/her to the project.

- Applying the host institution's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**

- Upholding the **intellectual property rights** of the host institution

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it if s/he becomes aware of any violations.

  Example: *The PI reads a research article and discovers a violation of the host institution's project IPRs. S/he is obliged to inform the host institution.*

- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the host institution and the PI, to set out their internal arrangements for implementing the grant.

It is **purely internal**; the EU/Euratom is NOT party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must remain in place at least for the action duration *(see Article 3)* (— without any interruptions, even if the PI works only part-time on the ERC project).

It must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

It must be concluded **before GA signature** (or in case of portability before submission of the amendment request) and a copy must be sent to the Agency.

A template [ODT format] for a model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution *(see Article 56a)*, a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The new agreement must take effect from the grant transfer date (or before). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make **specific reference to the European Research Council (ERC)**. Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC home page*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION 1:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION 2:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****]***.

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG and other ERC grants with more than one principal investigator: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new host institution ('new beneficiary') — at any time during the action.

⚠ **Transfer** — The rights and obligations under the GA are transferred from the host institution to a new host institution — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former host institution remains fully responsible until the Agency has approved the amendment.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution ('former beneficiary') may **oppose** a transfer only if it is not allowed under national law. It may however **negotiate** transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the views of the PI.

2. Procedure

The PI should first contact the host institution that signed the GA (i.e. the former host institution).

> ⚠ **Record-keeping**
> **Best practice:** Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

> The date must be selected in the amendment request. If the new host institution joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new host institution (signed directly in the Funding & Tenders Portal), the PI's justification letter and a supplementary agreement signed between the new host institution and the PI

The **financial reporting periods** will be automatically adapted to match the transfer date (unless the transfer date coincides with the end of a financial reporting period). **Scientific reporting** periods will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

> ℹ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Funding & Tenders Portal Online Manual.*

3. Effects

The principal beneficiary must — within 60 days from either the transfer date or the date of signature of the amendment, whichever is the latest — submit:

- a financial report to the Agency (for the open period until transfer)
- a report on the distribution of payments (only in case of multi-beneficiary GA)
- if the costs reach the threshold set out in Article 20:, a certificate on the financial statement (CFS) (— even if this is not the last reporting period).

These documents will be used for calculating the interim payment due to the former beneficiary. The Agency will moreover instruct the former host institution to transfer the remaining pre-financing to the new host institution.

If the PI requests it, the Agency may require the former host institution to **transfer equipment** that was purchased and used exclusively for the action.

> The former host institution may oppose this only if it is not possible under national law. It may however negotiate transfer conditions with the new host institution, taking into account the views of the PI.
>
> Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may declare the costs of this reimbursement (and any other related costs, i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, while the PI moves to a new host institution, the GA is transferred and changed into a multi-beneficiary grant agreement (allowing both the former host institution and the new host institution to participate in the grant). The former host institution stays on as beneficiary, the organisation that hosts and engages the PI is the new host institution. If the former host institution remains only for a limited time *(e.g. to ensure a smooth handover)*, it can then be terminated at a later stage, via a beneficiary termination *(see Article 50.2 H2020 General MGA)*.

II.3 H2020 ERC PoC MGA: Annotations

The H2020 ERC PoC MGA is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability *(Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION 1 by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION A if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION B:*** *not applicable;****]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).****]***

[OPTION 2 for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION A if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION B:** not applicable;**]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC PoC actions, the principal beneficiary must submit **periodic reports** — only one if there is one reporting period, otherwise one at the end of each reporting period.

The report(s) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a summary financial statement, which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a certificate on the financial statements (CFS) will have to be added (if necessary).

How? All reports must be prepared and submitted directly in the Funding & Tenders Portal *(see Article 20 H2020 General MGA*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

II.4 H2020 ERC PoC Lump Sum Pilot MGA: Annotations

Like the H2020 ERC PoC MGA, the H2020 ERC PoC Lump Sum Pilot MGA is very similar to the H2020 ERC MGA.

As the ERC frontier research grants, the ERC PoC Lump Sum Pilot grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team, and there is no supplementary agreement *(Article 32 H2020 ERC MGA).* Furthermore, there is no right of the PI to portability of the grant *(Article 56a H2020 ERC MGA*) (although for mono-beneficiary grants there is the possibility, in duly justified cases, to transfer the grant to a new beneficiary; *see Article 56.3*).

Also, under the ERC PoC Lump Sum Pilot MGA the grant payment is based on pre-fixed lump sum amount and not on actual costs reimbursement.

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

ERC PoC Lump Sum Pilot funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC Lump Sum Pilot grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC Lump Sum Pilot grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC Lump Sum Pilot actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC PoC Lump Sum Pilot actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2019-PoC)*.

For more information on ERC actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The 'estimated lump sum breakdown' for the action is set out in Annex 2.

It contains the lump sum shares for the work per beneficiary *[and linked third party]*.

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiaries. It shows the amounts that the Agency commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 can be adjusted by transfers of amounts between the beneficiaries, but only via an amendment (see Article 55).

1. Estimated lump sum breakdown

Differently from the ERC frontier research grants and the standard ERC PoC, the ERC PoC Lump Sum Pilot grants do not have any budget categories. Instead, they have a lump sum (for multi-beneficiary grants, broken down per beneficiary).

For multi-beneficiary grants, the breakdown is used to determine:

- the share of the lump sum to which each beneficiary is entitled for the work
- the maximum amount for which each beneficiary is liable in case of improper implementation of the work.

Example: *On a grant involving three beneficiaries, the Agency carries out a review after the payment of the balance. The review concludes that 50% of the work attributed to beneficiary A was not implemented as indicated in Annex 1. On those grounds, the Agency decides to reduce the grant. According to Annex 2, EUR 50 000 was allocated to beneficiary A. Therefore, beneficiary A will be liable in proportion to its tasks or parts of the action not implemented (i.e. in case of a 50% reduction, beneficiary A will be liable for EUR 25 000).*

2. Lump sum share transfers

Unlike in the General MGA, transfers of ERC PoC Lump Sum Pilot shares are only possible via a formal amendment (i.e. increasing the share of a beneficiary and decreasing the share of another under a multi-beneficiary action).

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 150.000** (one hundred and fifty thousand euros).

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The ERC PoC Lump Sum Pilot MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant** *(see Decision C(2018) 5960)*.

The use of the lump sum will be set out in the ERC Work Programme.

The lump sum is a fixed amount of EUR 150 000 for each grant. This amount takes already into account the H2020 ERC funding rate.

There are no cost eligibility conditions. If the action is correctly implemented (in line with the description in Annex 1), the beneficiaries are entitled to receive the fixed lump sum amount.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** for the action and it can NOT be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum for the approved work and reduction for non-approved work

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum for the approved work and reduction for non-approved work

The amount of the lump sum corresponds to the lump sum shares (see Annex 2) declared by the beneficiaries *[and linked third parties]* for the approved work in the financial statement at the payment of the balance (see Article 20.4).

The grant is reduced (see Article 43) for the part of the work that has not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For ERC PoC Lump Sum Pilot grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation; see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For ERC PoC Lump Sum Pilot grants, the rules on the revised final grant amount are in principle the same as for the General MGA *(see Article 5.4 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services;
- use in-kind contributions provided by third parties against payment;
- use in-kind contributions provided by third parties free of charge;
- call upon subcontractors to implement action tasks described in Annex 1;
- call upon linked third parties to implement action tasks described in Annex 1;
- call upon international partners to implement action tasks described in Annex 1

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the ERC PoC Lump Sum Pilot MGA.

The General MGA rules on third party involvement are limited in PoC Lump Sum Pilot actions to subcontracting (*Article 13*) and linked third parties (*Article 14*).

The articles for purchases *(Article 10)* and in-kind contributions *(Articles 11* and *12)* are not applicable to the PoC Lump Sum MGA. Beneficiaries may make purchases and use any in-kind contributions from third parties following their internal practices but not subject to other rules (as long as they are needed to carry out the work of the action).

⚠ For all types of third party involvement (purchases, in-kind contributions, subcontracts and linked third parties), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Specific rules for subcontracting action tasks

Subcontracting may cover only a limited part of the action.

The tasks to be implemented for each subcontract must be set out in Annex 1. The Agency may however approve subcontracts not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the final report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).***]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for ERC PoC Lump Sum Pilot actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The ERC PoC Lump Sum Pilot MGA has however the following **specificities**:

The estimated subcontracting costs do NOT need to be included in Annex 1 or shown in the table of estimated costs in Annex 2 (there is no such table for the ERC PoC Lump Sum Pilot; Annex 2 is not the budget, but the estimated lump sum for mono-beneficiary grants/lump sum breakdown for multi-beneficiary grants). By contrast, the tasks to be subcontracted must still be indicated in Annex 1, as it happens in the General MGA.

The principles of best value for money and no conflict of interest are not explicitly mentioned in Article 13. Nonetheless, they must still be complied with and confirmed by the beneficiaries at proposal stage.

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations which occurred at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *[OPTION 1 by default*: five*][OPTION 2 for low value grants*: three*]* years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

Records and other supporting documentation on the scientific and technical implementation of the action must be in line with the accepted standards in the respective field.

The beneficiaries do not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For ERC PoC Lump Sum Pilot actions, beneficiaries do not need to keep records on their actual costs; they only need to keep appropriate and sufficient evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 5 years after the balance is paid or longer if there are ongoing procedures (*such as audits, investigations or litigation)*. In this case, the evidence must be kept until the end of the respective procedure.

The records and supporting documentation must:

- refer to the implementation of the action, in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and
- prove that the tasks or part of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs actually incurred are NOT needed.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the final report set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action has one '**reporting period**':

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The principal beneficiary must submit — within 60 days following the end of the reporting period —the final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a **summary** for publication by the Agency.

(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out.

(c) a '**breakdown of direct cost table**': not applicable

(d) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and each linked third party]*, for the reporting period.

The individual financial statement must declare the lump sum share indicated in Annex 2, for the work that was completed in the reporting period.

The beneficiaries may exceptionally also declare a partial lump sum share for the part of the work that was not completed (e.g. due to scientific or technical reasons), if agreed by the Agency.

Lump sum shares which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiaries *[and each linked third party]* must **certify** that:

– the information provided is full, reliable and true;

– the work has been completed and that the action in general has been properly implemented (see Article 7);

– the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(e) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the request for payment of the balance;

(g) a 'certificate **on the financial statements**': not applicable

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

Financial statements must be drafted in euro.

20.7 Language of reports

The final report (including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the final report submitted does not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the report and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC PoC Lump Sum Pilot actions, the principal beneficiary must submit a **final report** at the end of the action.

The report must include the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be fit for publication and written in an easy to read language for a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of the results towards the action's objectives

- an individual financial statement.

The final report includes the completed work and the corresponding lump sum shares per beneficiary.

In principle, lump sum shares should be claimed only for work fully accomplished as described in Annex 1. However, if agreed by the Agency, the beneficiary may exceptionally declare partial lump sum shares for work not completed, for example, due to technical reasons.

Best practice: In case of doubt, the beneficiary should contact the Agency about work partially accomplished.

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that a new research methodology made the planned methodology obsolete. The new methodology could have been accepted via an amendment.*

- non-implementation linked to financial reasons

  Example: *The in-depth market study turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

How? The final report must be **prepared** by the **principal beneficiary** and the other **beneficiaries together**, directly in the Funding & Tenders Portal).

In practice, the following steps will apply:

Step 1 — The principal beneficiary will indicate in the Funding & Tenders Portal if the work foreseen in Annex 1 has been fully accomplished during the action duration.

Step 2 — The beneficiaries will have to sign individual financial statements to confirm proper implementation of their parts of the work and submit them to the principal beneficiary. All of them will be part of the final report.

Step 3 — The principal beneficiary will submit the final report to the Agency.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the 'Guarantee Fund'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)]) is not paid to the principal beneficiary, but kept by the Agency for the JRC.]*

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the lump sum for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares for the work declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The part of the work that has not been delivered or cannot be approved at the payment of the balance will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for the beneficiary, in the estimated lump sum breakdown (see Annex 2).

1. Payments to be made

ERC PoC Lump Sum Pilot actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid on approval of the final report.

2. Payment calculations — Amounts due — Recoveries

Beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Agency on the basis of the termination report, the payments already made and the report on the distribution of payments.

The rules follow those of the General MGA *(see Articles 21.3, 44.1.1, 50.2.2 and 50.3.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply takes into account the lump sum share for the beneficiary's accepted work.

Exceptionally, the Commission/Agency may accept also *part* of a lump sum share for work partially accomplished by the beneficiary.

Example for calculating the amount due at beneficiary termination:

Grant with three beneficiaries (A, B and C).
Maximum grant amount: EUR 150 000.
Lump sum share breakdown per beneficiary (Annex 2):

	Lump sum shares for the work	Total EU contribution
Beneficiary A	50 000	50 000
Beneficiary B	70 000	70 000
Beneficiary C	30 000	30 000
Total	150 000	150 000

The participation of beneficiary B is terminated before the end of the project. The reason for terminating its participation is the non-availability anymore of a biosafety level 4 laboratory which has been damaged by a fire during the course of the action and where proof of concept activities for the second virus should have been also performed. Therefore, this beneficiary cannot complete its tasks due to force majeure (see Article 51 H2020 General MGA). On those grounds, the Agency decides to accept for that beneficiary a part of the lump sum shares proportionate to the tasks carried out by the beneficiary in the action (e.g. 50%). According to the distribution of payment, the principal beneficiary had transferred EUR 50 000 as pre-financing to beneficiary B.

Amount due:

Lump sum shares for partly accepted work = EUR 70 000 – 50% of EUR 70 000 = EUR 35 000

Beneficiary B amount due: EUR 35 000.

Beneficiary balance:

Payments received by beneficiary B (according to the report on the distribution of payment): EUR 50 000.

Beneficiary B balance: EUR 35 000 (amount due) - EUR 50 000 (payment received) = - EUR 15 000

Since the payment received by Beneficiary B exceeds the amount of the lump sum share is entitled for its part of the work it has fully accomplished, there is a recovery of EUR 15 000 (see Article 50).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Agency on the basis of the financial statements, the final grant amount and the payment already made.

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares of the beneficiaries for the accepted work. Work partially accomplished due to scientific or technical reasons may exceptionally be accepted by the Agency.

⚠ The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

Example: *The beneficiary argues that a new research methodology made the planned methodology obsolete. The new methodology could have been accepted via an amendment.*

- non-implementation linked to financial reasons

Example: *The in-depth market study turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

Step 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to ERC PoC Lump Sum Pilot grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Example for calculating the payment of the balance:

Grant with three beneficiaries (A, B and C).

Beneficiary A is in charge of scaling-up activities, beneficiary B is in charge of health and safety testing activities and beneficiary C is in charge of additional screening of target molecules as well as in charge of establishing a worldwide patent landscape mapping and an IPR strategy accordingly.

Maximum grant amount: EUR 150 000.

Lump sum share breakdown per beneficiary (Annex 2):

	Lump sum shares for the work	Total EU contribution
Beneficiary A	100 000	100 000
Beneficiary B	20 000	20 000
Beneficiary C	30 000	30 000
Total	150 000	150 000

Case 1:

At the end of the action, it appears that beneficiaries A and B fully completed their tasks. However beneficiary C completed only its tasks related to health and safety testing while it failed to establish a worldwide patent landscape mapping. The Agency decides to reduce by 10 % the lump sum share of beneficiary C corresponding to the proportion of the undelivered part of its work. In addition, the consortium breached its obligation to promote the action and its results under Article 38. The Agency decides to reduce the maximum grant amount by 10 % for that reason.

Final grant amount:

Lump sum share for accepted work of beneficiary A + Lump sum share for accepted work of beneficiary B + partial lump sum share for partly accepted work of beneficiary C = 100 000 + 20 000 + (30 000 – 10% of 30 000)

Amount resulting from Step 1: EUR 147 000

Grant reduction for other breaches: 10% grant reduction for the action = maximum grant amount – 10 % (reduction) = 150 000 – 15 000 = EUR 135 000.

Amount resulting from Step 2: EUR 135 000.

Lower amount of the two: EUR 135 000

Final grant amount: = EUR 135 000.

Case 2:

Work of beneficiary B and work of beneficiary C were not carried out (i.e. representing a total lump sum shares of EUR 50 000) and therefore the Agency reduced the grant accordingly.

Final grant amount:

Lump sum shares for accepted work: EUR 100 000

No grant reductions for other breaches.

Final grant amount: EUR 100 000 (➔ beneficiary shares: A = EUR 100 000; B = EUR 0; C = EUR 0)

Balance & Guarantee Fund release:

Payments made: EUR 127 500.

Balance: EUR 100 000 (final grant amount) - EUR 127 500 (payments made) = EUR - 27 500 (excess payments of EUR 27 500).

Offsetting against Guarantee Fund release: EUR 27 500 - EUR 7 500 (i.e. 5% of EUR 150 000) = EUR 20 000

Recovery:

Amount to be recovered from the consortium: EUR 20 000 (negative balance of EUR 20 000 must be paid back by the principal beneficiary, otherwise the Agency will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from the principal beneficiary:

The principal beneficiary does not reimburse the Agency and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 75 000; B= EUR 25 000; C = 27 500).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

*A: {(EUR 100 000 / (100 000 + 0) * 100 000 = EUR 100 000 (share in the final grant)} - EUR 75 000 (payments received) = EUR 25 000 (no payment in excess)*

*B: {0 / (100 000 + 0 + 0) * 100 000 = EUR 0 (share in the final grant)} - EUR 25 000 (payments received) = EUR – 25 000 (excess payment of EUR 25 000)*

*C: {0 / (100 000 + 0 + 0) * 100 000 = EUR 0 (share in the final grant)} - EUR 27 500 (payments received) = EUR – 27 500 (excess payment of EUR 27 500)*

Beneficiaries B and C received payment in excess of its EU contribution and will have to reimburse the Agency.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 52 500.

B: 25 000 /52 500 = 47.62 %.

C: 27 500 / 52 500 = 52.38 %.

Total to be recovered: EUR 20 000.

B: 47.62 % x 20 000 = EUR 9 524

C: 52.38 % x 20 000 = EUR 10 476

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 2 (Grant reductions) applies.

All other steps follow the General MGA *(see for the calculations Article 21 H2020 General MGA)*.

Examples for calculating recoveries after payment of the balance:

Case 1:

Grant with three beneficiaries (A, B, C).

Beneficiary A is in charge of scaling-up activities, beneficiary B is in charge of health and safety testing activities on 50 samples and beneficiary C is in charge of identifying application domains and establishing a market deployment strategy accordingly.

Maximum grant amount: EUR 150 000.

Lump sum share breakdown per beneficiary (Annex 2):

	Lump sum shares for the work	Total EU contribution
Beneficiary A	100 000	100 000
Beneficiary B	40 000	40 000
Beneficiary C	10 000	10 000
Total	150 000	150 000

Final grant amount:

Final grant amount: EUR 100 000 + EUR 40 000 + EUR 10 000 = EUR 150 000.

The Agency carries out a review on the action and finds out that beneficiary B carried out its health and safety testing activities on half of the number of samples foreseen (i.e. 25 out 50). The Agency therefore reduces the lump sum share of beneficiary B in proportion of the non-implemented work, i.e. 50% of EUR 40 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 40 000 (accepted lump sum shares) — EUR 20 000 (rejected lump sum shares) = EUR 20 000

Beneficiary B revised final grant amount: EUR 20 000.

The other beneficiaries final grant amounts (i.e. their final grant amount shares) remain unchanged.

Beneficiary balance:

The share of beneficiary B in the final grant amount = EUR 40 000 / 150 000 x 150 000 = EUR 40 000.

Balance: EUR 20 000 (revised final grant amount) – EUR 40 000 (final grant share) = EUR -20 000 (excess of EUR 20 000).

Recovery:

Amount to be recovered from beneficiary B: EUR 20 000 (negative balance of EUR 20 000 must be paid back by the beneficiary).

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

[…]

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

[…]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since (differently from ERC frontier research grants and the standard ERC PoC grants), ERC PoC Lump Sum Pilot grants do not use actual costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since beneficiaries have no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the implementation of the action (in particular full accomplishment of the work as described in Annex 1 of the GA), or on other aspects of the grant agreement, *such as promoting the action, visibility of EU funding, dissemination and exploitation of results, management of intellectual property, etc.*

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Agency or the Commission may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiaries that were audited.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **after termination of a beneficiary's participation, at the payment of the balance or afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** (including undue amounts paid by the Agency for lump sum shares declared by its linked third parties)***]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum grant amount indicated, for the linked third party, in the estimated lump sum breakdown (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter'** to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's approved lump sum share

[plus

its linked third parties' approved lump sum shares]},

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for the approved work calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

[…]

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{beneficiary's approved lump sum share

[plus

its linked third parties' approved lump sum shares]}

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for the approved work calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

[...]

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for ERC PoC Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(d) it does not comply with the provisions of the Agreement (see Article 20);

(e) the final report has not been submitted or is not complete or additional information is needed, or

(f) there is doubt about amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the final report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA *(see Article 47 H2020 General MGA)*.

The ERC PoC Lump Sum Pilot MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for ERC PoC Lump Sum Pilot grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work implementation).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

[…]

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20.4).

If the Agency does not receive the report within the deadline (see above), the lump sum will not be paid.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the report submitted and compliance with other obligations under the Agreement. Only part of the work completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

[…]

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the final report (see Article 20.4).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the payments received by the beneficiary exceed this amount.

Step 1 — Calculation of the lump sum share for the approved part of the work

If the beneficiary's part of the work is approved, the grant amount for the beneficiary corresponds to its lump sum share (see Annex 2) for the approved work declared in the termination report.

Only the part of the work completed by the beneficiary before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

[…]

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the report (see Articles 20.8 and 50.3.1(l)), the principal beneficiary may not submit any report after termination.If the Agency does not receive the report within the deadline (see above), the lump sum will not be paid.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the report submitted and compliance with other obligations under the Agreement. Only part of the work completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(a) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated lump sum breakdown (see Annexes 1and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the final report Article 20.4).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

The Agency will — on the basis of the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the pre-financing payment received by the beneficiary exceeds this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum share for the approved part of the work

If the beneficiary's part of the work is approved, the grant amount for the beneficiary corresponds to its lump sum share (see Annex 2) for the approved work declared in the termination report.

Only the part of the work completed by the beneficiary before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

1. GA termination (consortium or EU)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for ERC PoC Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21*).

2. Beneficiary termination (consortium or EU)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for ERC PoC Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the Agency has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

[…]

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added to a mono-beneficiary grant, the grant becomes a multi-beneficiary grant and the provisions will be applied accordingly.

Article 56.3 Transfer to a new beneficiary

In justified cases, the beneficiary of a mono-beneficiary grant may request the transfer of the action to a new beneficiary, provided that this would not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

The new beneficiary must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Transfer of the GA

In justified cases, ERC PoC Lump Sum Pilot mono-beneficiary grants can be **transferred** to a new beneficiary.

Transfer — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (*Article 50*) or addition of a new beneficiary (*Article 56.2*).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains fully responsible until the Agency has approved the amendment.

The transfer may NOT entail changes to the GA which would call into question the decision to award the ERC PoC Lump Sum Pilot grant.

Example: *The Agency will not accept the transfer to a host institution established in a third country.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new beneficiary (signed directly in the Funding & Tenders Portal) and the PI's justification letter.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Funding & Tenders Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 60 days from the transfer date or the date of signature of the amendment, whichever is the latest — a transfer report, with information on:

- the progress of the work and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to decide on how to split the lump sum share and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must also be uploaded later on with the final report (by the new beneficiary, together with its own financial statement).

The lump sum share will be split between the former beneficiary and the new beneficiary — on the basis of the part performed by the former beneficiary and the remaining part to be given to the new beneficiary. If the pre-financing received by the former beneficiary (see *Article 21*) exceeds the amount of its accepted lump sum share, the Agency will request the former beneficiary to transfer the difference to the new beneficiary.

The former and the new beneficiary must agree on arrangements, where necessary, concerning the transfer of the equipment, materials and/or services purchased for the principal investigator.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowska-Curie Actions (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE
- MSCA-COFUND and
- MSCA-SNLS.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MSCA-ITN MGA deviates from the General MGA — Multi as follows:

- Article 4.2 (MSCA-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-IF MGA deviates from the General MGA — Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 9-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSCA-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSCA-IF specific conditions for termination)
- Article 55 (MSCA-IF specific conditions for amendments)
- Article 56a (MSCA-IF portability)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-RISE MGA deviates from the General MGA — Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9 - 16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSCA-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (MSCA specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-COFUND MGA deviates from the General MGA — Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of a programme)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)

The H2020 MSCA-SNLS MGA deviates from the General MGA — Mono as follows:

- Article 1 (linked grant)
- Article 4 (estimated lump sum breakdown, lump sum share transfers)
- Article 5 (maximum grant amount and form of grant)
- Article 6 (not applicable)
- Articles 9-16 (not applicable)
- Article 18 (special provisions for record-keeping)
- Articles 20, 21 (specific provisions for reporting and payments)
- Articles 23a-34 (not applicable)
- Article 37 (not applicable)
- Article 42 (not applicable)
- Article 44 (specific provisions for calculation of recoveries)
- Article 56 (not applicable)
- Article 56a (portability)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement
- Annexes 5 and 6 Not applicable

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 9-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND; MSCA-SNLS)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories; MSCA-SNLS estimated lump sum breakdown and lump sum share transfers)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement; MSCA-SNLS rules on third party involvement)

III.2 H2020 MSCA-ITN MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-ITN actions

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by networks of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN takes the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries.

This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[OPTION for all actions except EID with only two beneficiaries: *However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.****]***

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NOT** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment *(see Article 55)* is required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID with only two beneficiaries: a maximum of 40 % of the budget may be allocated to beneficiaries established in the same country (or to the same international European interest organisation or international organisation).

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In an action with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (= 40%). If the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes (*e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes (*e.g. to increase the salary of a researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

For MSCA-ITN, the maximum grant amount is limited to a maximum unit cost equivalent of 540 person-months (and for EID with only two beneficiaries: 180 person-months).

2. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the H2020 Work Programme (section 3 MSCA))*.

3. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[76].

For MSCA-ITN, these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if applicable)

[76] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they can NOT be changed.

The eligibility conditions are set out in *Article 6*.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5 H2020 General MGA*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(iv) ***[OPTION for EID:** if spent on inter-sectorial mobility between academic and non-academic beneficiaries (i.e. not partner organisations): are international (i.e. spent between beneficiaries established in different countries).]*

(v) ***[OPTION for EJD:** are, for at least two-thirds of the recruited researchers, spent in a joint, multiple or double degree programme with two or more beneficiaries or partner organisations stablished in EU Member States or associated countries.]*

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country) – unless as part of a procedure for obtaining refugee status under the Geneva Convention[6].

For beneficiaries that are international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately before the recruitment date.

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for 1 EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree in at least one EU Member State or associated country [;][.]**]***

(viii) ***[OPTION for 2 EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

[6] 1951 Refugee Convention and the 1967 Protocol.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)
- a monthly mobility allowance (A.2) — to cover costs related to their mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by budget category B.1 'research, training and networking costs')

AND

- a monthly family allowance (A.3) — for researchers with family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

Example: *Costs for student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.*

1.2 The costs must be **declared** as the unit costs fixed by Decision C(2017) 6855[77] and set out in Annex 2 and 2a of the GA.

This is currently:

– for the living allowance: **EUR 3 270** per researcher per month (person-month)

To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

The list of coefficients is published in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does NOT change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action).

– for the mobility allowance: **EUR 600** per person-month

– for the family allowance: **EUR 500** per person-month.

For the latest information on the amounts and the country correction coefficients, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first 4 years (full time equivalent research experience) of their research career)

    '**Date of recruitment**' means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    Example: *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as recruitment date.*

[77] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

Years of '**research career**' are counted from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:
  - sickness, parental, unemployment and invalidity benefits
  - pension rights and
  - benefits for accidents at work and occupational diseases.

  If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:
  - sickness, parental and invalidity benefits and
  - benefits for accidents at work and occupational diseases.

  In this case, the living allowance will be reduced by 50%.

  The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

  Staff provided by a temporary work agency — Beneficiaries must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:
  - subject to prior approval by the Agency
  - on personal or family grounds only (i.e. not for professional reasons) and
  - if limited to a maximum of 50% of the time spent under the action.

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  ⚠ While it is not possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities (and must be set out in Annex 1 of the GA).

- are supported for **at least 3 months**

  Person-months linked to shorter contracts will not be eligible.

  However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. If the contract is set out for a longer duration, but

the training is interrupted within the first three months for reasons not linked to the beneficiary *(e.g. because the researcher resigns)*, the costs may still be claimed.

- comply — at the date of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (— unless the beneficiary is an 'international European interest organisation'[78] or international organisation, for whom the mobility rule is limited to time spent *with* them)

  The mobility rule applies only to the **first recruitment** under the action. For instance, it does not apply to beneficiaries or partner organisations to which the researcher is sent or seconded afterwards.

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[79] are NOT counted.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  For EJD:

  - the PhD-programme must lead to the award of:

    - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or

    - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

    in at least one EU Member State or H2020 associated country

  and

  - at least two-thirds of the recruited researchers must be enrolled in a joint, double or multiple degree programme within Europe, i.e. between two or more beneficiaries or partner organisations established in EU Member States or Horizon 2020 associated countries.

  The degree must not necessarily be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researchers (gross amount).

[78] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[79] 1951 Refugee Convention and the 1967 Protocol.

MSCA-ITN researchers must NOT be requested to pay tuition fees for their research training and/or PhD degree programme (neither from their own funds, nor from the researcher unit cost). The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* can be reimbursed under category B 'institutional costs'.

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as*:

- *part of his/her salary*
- *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
- *rental costs, directly paid or reimbursed by the beneficiary.*

Any form is acceptable, provided that:

- both sides agree
- it is allowed under national law

AND

- there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1 100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[80]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[81].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a*

[80] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html.
[81] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm.

payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers who have — at the date of the recruitment — a family, i.e.:
  - persons linked to them by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ Beneficiaries may declare a **maximum** of **36 person-months** per researcher. Person-months exceeding this number will be rejected by the Agency.

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector.

This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations/entities with a capital or legal link. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary, *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 50% rule.

Inter-sectoral mobility between beneficiaries must be international (i.e. spent between beneficiaries established in different countries).

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence).*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - costs for visa-related fees (even if incurred before the recruitment date) and travel expenses
  - additional costs arising from each secondment of 6 months or less which require mobility from the place of residence *(e.g. travel and accommodation costs)*

    Example: *A researcher does doctoral research at a beneficiary in Italy for 36 months. During this time, she goes on a 4-month secondment to Poland. The beneficiary must cover her travel and accommodation costs in Poland for this 4-month period with the research, training and networking costs category.*
- management and indirect[82] costs (B.2) — for the beneficiary's additional costs in connection with the action.

⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.

⚠ **Budget flexibility** — There is some flexibility as regards the *use* of the amounts received:
- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of a researcher or to organise additional training activities, to cover travel and accommodation costs for secondments of more than 6 months in line with the consortium internal arrangements)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of a researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[83] and set out in Annex 2 and 2a of the GA.

[82] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

This is currently:

- for research, training and networking costs: **EUR 1 800** per researcher per month (person-month)

- for management and indirect costs: **EUR 1 200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[84] in the same period: only management costs, i.e. EUR 600 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for recruited researchers'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for budget category A 'costs for recruited researchers' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

[83] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[84] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon **entities with a capital or legal link** to the beneficiaries[7], to implement certain action tasks described in Annex 1 (i.e. hosting and training of researchers);
- call upon **partner organisations** to implement certain action tasks described in Annex 1 (i.e. hosting and training researchers during secondments).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[7] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-ITN allows the beneficiaries to use:

– entities with a capital or legal link to them

and

– partner organisations

to carry out work under the action (**third parties involved in the action**).

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-ITN grant (i.e. recruits the researchers), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-ITN action as entity with a capital or legal link implementing the research training activities, while the foundation or subsidiary participates as beneficiary (because it can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-ITN action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and training of researchers (including during secondments) — and can even implement ALL those activities under the action. But they can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary, tasks to be carried out and time spent with them).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme).

For more information on conditions for participation and funding, *see the H2020 Work Programme (section 3 MSCA).*

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers, but only during **secondments**.

Secondments — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country) in order to further enrich the training experience of the researchers.

They are limited to a **maximum of 30%** of the time that is declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out and time spent with them).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations can be established anywhere (EU Member State, H2020 associated country or non-associated third country).

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term meeting**' between the beneficiaries, entities with a capital or legal link, partner organisations and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of each researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — within 30 days after the first year of the action — send to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Funding & Tenders Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

> **Best practice:** It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** after the recruitment date.

> It is important to give correct and complete information in the researcher declaration since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Funding & Tenders Portal.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA):*

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[16] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or other entity mentioned in Annex 1);

(j) ensure that the researchers do not have to bear any costs for the implementation of the action as described in Annex 1;

(k) host the researchers at their premises (or at the premises of an entity with a capital or legal link);

(l) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(m) ensure that the researchers are adequately supervised;

(n) ensure that a career development plan is established and support its implementation;

(o) ensure an appropriate exposure to the non-academic sector;

(p) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective recruitment procedures and best possible working conditions.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[85]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises (or those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or ensure that this is provided by the entity with a capital or legal link).

[85] Available at http://ec.europa.eu/euraxess/

If the Agency finds that a beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**
- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Ensure that **secondments** are **limited** to a **maximum** of **30 %** of the months declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD, provided that it is in line with the proposal description and in compliance with the conditions set out in the call.

> ⚠ **Secondments** — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country), in order to further enrich the training experience of the researchers *(see Article 8)*.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

- Ensure that the researchers do NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Ensure that the researchers do NOT have to bear **any costs** for the implementation of the action as described in Annex 1

  Recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training and/or PhD degree programme (*e.g. student registration,, access to student services (e.g. library, computing, etc.), teaching, supervision, examination and graduation)* neither from their own funds, nor from the researcher unit cost.
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[86].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[87].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Funding & Tenders Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities (including during secondments with other beneficiaries and/or partner organisations).

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration

[86] Available at https://www.iprhelpdesk.eu/.
[87] Available at http://ec.europa.eu/euraxess/.

– the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2 H2020 General MGA).*

The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (consortium) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the

Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MSCA-IF MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-IF actions

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include three additional funding strands: the 'Career Restart Panel', the 'Reintegration Panel' and the 'Society & Enterprise Panel'.

The MSCA-IF annotations are equally applicable to the Widening Fellowships *(see H2020 Work Programme (section 15 Spreading Excellence and Widening Participation))*.

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION 3 if needed for the action:** [insert date]]*[4] ('**starting date of the action**').

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the actual starting date must be *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, there will be a **maximum deadline for notification** set out in Article 3 for both starting the action and notifying this to the Agency (normally 12 months from the entry into force of the GA).

The notification must be done directly in the Funding & Tenders Portal.

Late notification will delay the pre-financing payment *(see Article 21.2 H2020 General MGA)*.

If the action does not start or the starting date is not notified in time, the Agency may terminate the GA *(see Article 50 H2020 General MGA)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researcher (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

⚠ **Budget flexibility** — There is however some flexibility as regards the *use* of the amounts received:

- The institutional unit cost should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (*including for GF outgoing phase; see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the H2020 Work Programme (section 3 MSCA))*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[88].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[88] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[**OPTION 1 by default:** 24] [**OPTION 2 for EF-CAR**: 36] [**OPTION 3 for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including periods of secondment to **'partner organisations'**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for professional, personal or family reasons (see Article 55), and

(iii) be working exclusively for the action.

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory

deductions under national law, *such as employer/employee social security contributions and direct taxes*)

- a monthly mobility allowance (A.2) — to cover costs related to his/her mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by category B.1 'research, training and networking costs').

AND

- a monthly family allowance (A.3) — if the researcher has family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiary are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017)6855 [89] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 4 880** for the researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the H2020 Work Programme (section 3 MSCA) in force at the time of the call and according to the country of recruitment (i.e. the country of the beneficiary).

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

ℹ For the latest information on the amounts and the country correction coefficients, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[89] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the date of the call deadline — an **experienced researcher** (i.e. have a doctoral degree OR have at least four years (full time equivalent research experience) of research career).

    Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases

    If national law prevents it from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

    The social security coverage must be guaranteed for the entire action (i.e. also during optional secondments, if any, and for the GF outgoing phase).

    For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent coverage during the stay in the third country.

    Example: *A German university recruits the fellow for the total duration of the action (i.e. provides the main employment contract under the action) and sends him/her to a US university. Continuing the German social security during the stay in the US would be so expensive, that the beneficiary asks the US partner organisation to conclude an additional employment contract, in order to insure the researcher in the US.*

    Staff provided by a temporary work agency — The beneficiary must always recruit the researcher directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency
    - on personal and family grounds

– on professional grounds (except during the outgoing phase for GF) in agreement with the beneficiary

– if limited to a maximum of 50% of the time spent under the action

Part-time employment for professional reasons can be requested in order to pursue supplementary activities, *such as creating a company, pursuing another research project, engaging in advanced studies not related to the MSCA grant, etc.* It cannot be requested in order to participate in another MSCA grant at the same time.

When part-time employment for professional reasons is accepted, the beneficiary must ensure reliable **time records** *(e.g. timesheets)* either on paper or in a computer-based time recording system.

In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ If NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is NOT allowed (**—** unless part-time for professional reasons was approved). Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must not jeopardise the research activities (and must be set out in Annex 1 of the GA).

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researcher (gross amount).

  The mobility and family allowances are due to the researchers for each month worked.

  Mobility and family allowances can be paid to the researcher in various ways, *for example as:*

  – *part of his/her salary*

  – *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*

  – *rental costs paid or reimbursed by the beneficiary, etc.*

  Any form is acceptable, provided that:

  - both sides agree

  – it is allowed under national law

  AND

  – there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1 100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[90]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[91].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0,9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0,87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the date of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the 3 years immediately before to the call deadline (— unless the beneficiary is an 'international European interest organisations' or international organisations, for whom the mobility rule is limited to time spent *with* them)

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) are NOT counted.

  For EF Career Restart Panel, Reintegration Panel and Society & Enterprise Panel: specific mobility rule — not more than 3 years in the 5 years immediately before the call deadline

  For GF: the mobility rule is checked for the country of the partner organisation, not for the country of the beneficiary (i.e. where the outgoing phase takes place, not where the return phase takes place).
- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a EU Member State or an H2020 associated country.

  'Long-term resident' means a period of legal and continuous residence in a EU Member States or H2020 associated countries for 5 or more consecutive years. Periods outside these countries will be taken into account if shorter than 6 consecutive months and all in all not more than 10 months.

[90] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[91] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

For EF Reintegration Panel: The long-term residence requirement will not apply to researchers who have obtained refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) in a EU Member State or H2020 associated country.

- for EF Career Restart Panel: not have been **active** in research for at least 12 months immediately before the call deadline

  'Active in research' means being employed or holding a scholarship. Parental leaves and unpaid leaves of absence will not be counted as periods of active engagement in research, even if a formal employment relationship exists during these periods. Publication activities or mere association to a university are not taken into account either.

- for the family allowance: have a **family**, i.e.
  - persons linked to the researcher by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs for the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ The beneficiary may declare a **maximum** of **24 person-months** for the researcher (or **36 months** for GF and EF Career Restart Panel). Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by requesting an amendment to suspend the action; *see Article 49.1.1.2*).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence) and the action must be suspended.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.1): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - costs for visa-related fees (even if incurred before the recruitment date) and travel expenses
  - additional costs arising from secondments *(e.g. travel costs and accommodation costs for optional secondments)*
- management and indirect[92] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (including for GF outgoing phase; *see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[93] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 800** for the researcher per month (person-month)

[92] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[93] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for management and indirect costs: **EUR 650** per person-month (if the beneficiary already receives an EU/Euratom operating grant[94] in the same period: only management costs, i.e. EUR 325 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for the recruited researcher'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for budget category A 'costs for the recruited researcher' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for the recruited researcher:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[94] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon entities with a capital or legal link to the beneficiary[5], to implement certain action tasks described in Annex 1 (i.e. hosting and training of the researcher);
- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. hosting and training the researcher during secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

[5] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-IF allows the beneficiary to use:

– entities with a capital or legal link to it

and

– partner organisations

to carry out work under the action (**third parties involved in the action**).

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to the beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-IF grant (i.e. recruits the researcher), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation or subsidiary participates as beneficiary (because it is can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and research training of researchers (including during a secondment) — and can even implement ALL those activities under the action. But they can NOT recruit the researcher (only the beneficiary can recruit the researcher).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of link with the beneficiary and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary (for instance, be established in an EU Member State or H2020 associated country).

Example: *For the EF Society & Enterprise Panel, the entities with a capital or legal link must also be from the non-academic sector.*

For more information on conditions for participation and funding, *see the H2020 Work Programme (section 3 MSCA).*

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers, but only during **a secondment**.

Secondments — For MSCA-IF, secondments are either:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country).

Optional secondments are limited to a **maximum of 3 months** (for actions with duration of up to 18 months) and **6 months** (for actions with duration of more than 18 months).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researcher (only the beneficiary can recruit the researcher).

For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent social security coverage during the stay in the third country *(see Article 6)*.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations for optional secondments must be established in an EU Member State or H2020 associated country; partner organisations for GF outgoing phase must be established in a non-associated third country.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher
  - in case of part-time for professional reasons, the work for the action has been reliably recorded *(through time-sheets, logbooks, counters etc.)*.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** and **entities with a capital or legal link** (if any) give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[12] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(g) ensure that the researcher does not have to bear any costs for the implementation of the action as described in Annex 1;

(h) host the researcher at its premises (or at the premises of an entity with a capital or legal link);

(i) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(j) ensure that the researcher is adequately supervised;

(k) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(l) support the secondment of the researcher to a partner organisation in a Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

*(m) **[OPTION for GF:** support a maximum of 3 months spent by the researcher with the beneficiary (or an entity with a capital or legal link and/or a partner organisation) before the outgoing phase and the return of the researcher to the beneficiary (or an entity with a capital or legal link) to carry out a mandatory return period of 12 months.**]***

[…]

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises (or at those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or to ensure that this is provided by the entity with a capital or legal link).

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- **Support secondments** of the researcher (if any) and ensure that they are **limited** to a **maximum** of **3 months** (for actions of up to 18 months) or **6 months** (for actions of more than 18 months)

⚠ **Secondments —** For MSCA-IF, secondments can be:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

and/or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country) *(see Article 8)*

For GF: Also support time spent by the researcher with the beneficiary (or an entity with a capital or legal link and/or a partner organisation) before the outgoing phase (limited to a maximum of 3 months) and the researcher's return (mandatory return-period must always be 12 months)

- Ensure that the researcher does NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

- Ensure that the researcher does NOT have to bear **any costs** for the implementation of the action as described in Annex 1

  The recruited researcher must NOT be requested to pay visa-related fees or tuition fees for the research training neither from his/her own funds, nor from the researcher unit cost.

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[95].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[96].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Funding & Tenders Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during optional secondments/GF outgoing phase with partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

[95] Available at https://www.iprhelpdesk.eu/.
[96] Available at http://ec.europa.eu/euraxess/.

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

  This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment — unless part-time employment for professional reasons has been approved (see Article 55). Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the MSCA-IF beneficiary (in all actions except MSCA-IF Widening Fellowships) must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave).

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. GA suspension — Additional grounds for suspension: Professional, personal or family reasons (beneficiary)

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, the beneficiary in MSCA-IF actions may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave, long-term sick leave or another professional opportunity)*.

Suspension must be requested if the researcher is absent for more than 30 consecutive days (for reasons other than normal annual leave).

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and (planned) end date of the suspension and
- the (planned) resumption date when the action will be resumed (i.e. automatically end date +1 day).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are NOT eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for professional, personal or family reasons (including parental leave).

[…]

1. Amendments — Additional ground for amendments: Change to part-time employment (beneficiary)

What? For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time) — on professional, personal or family grounds (including parental leave).

⚠ If NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

How? The amendment should be requested immediately (retroactive change is possible, if justified; *see Article 55 H2020 General MGA*).

The action duration will be automatically adapted (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months, so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working time; AT23 clause) and the reporting periods will be changed (to adapt them to the new action duration; AT25 clause).

ℹ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Funding & Tenders Portal Online Manual.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains **fully responsible** until the Agency has approved the amendment.

The transfer may be based on any **ground** that is linked to the beneficiary and affects objectives of the action (i.e. implementing the research training activities).

Examples: *Internal reorganisation affecting implementation of the action; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher *(e.g. other professional opportunities, personal or family commitments)* are NOT considered valid grounds for transferring the GA to a new beneficiary. These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*.

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility conditions or does not have sufficient financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The 'transfer date' should normally be the date the researcher starts working with the new beneficiary. In order to allow for full synchronisation of dates, chose the entry into force of the amendment (i.e. not a fixed date) as transfer date and put this date also as starting date in the employment contract for the researcher. If there is a gap in employment (between transfer date and employment starting date at the new beneficiary), request an amendment to suspend the action (AT82; must be done before the end of the action).

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed directly in the Funding & Tenders Portal).

The **maximum grant amount/action duration** will be adapted to take into account the country correction coefficient of the new beneficiary.

⚠ The maximum grant amount *(see Article 5)* will **NOT** be **increased**.

If the new beneficiary is in a country with a lower country correction coefficient, the maximum grant amount *(see Article 5.1) will be lowered*.

If the new beneficiary is in a country with a higher country correction coefficient, the action duration will normally be adapted, so that the maximum grant amount can stay the same. If (exceptionally) the action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new correction coefficient *(using e.g. the management and indirect costs or own funding)*.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Funding & Tenders Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date or the date of signature of the amendment, whichever is the latest — a transfer report, with information on:

- the progress and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to check the eligible costs and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must also be uploaded later on with the next periodic report (by the new beneficiary, together with its own financial statement).

The maximum grant amount will be split between the former beneficiary and the new beneficiary — on the basis of the researcher months already spent with the former beneficiary.

The former and the new beneficiary must agree on arrangements, where necessary, concerning intellectual property and other issues.

III.4 H2020 MSCA-RISE MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-RISE actions

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

For more information on MSCA-RISE, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries.

This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NOT** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment is required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the seconded staff (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs a staff member, to organise additional training activities or horizontal networking events)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs**).

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the H2020 Work Programme (section 3 MSCA)).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[97].

For MSCA-RISE, these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[97] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for seconded staff members</u> are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 1 month at the sending:

- beneficiary (or entity with a capital or legal link[6] to it and located in the same country), or
- partner organisation (or entity with a capital or legal link to it and located in the same country).

(c) the secondments comply with the following conditions:

(i) last at least 1 month and no longer than 12 months (per secondment);

(ii) be between different countries;

(iii) for secondments within the EU (or associated countries)[7]: be between different sectors (academic and non-academic)[8];

(iv) for secondments from EU (or associated countries): be from a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country) to a partner organisation (or entity with a capital or legal link) established in a non-EU Member State (or non-associated country), and

(v) for secondments to EU (or associated countries): be from a partner organisation (or entity with a capital or legal link) established in a country listed in General Annex A of the Main Work Programme to a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country).

[6] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] For secondments for entities with a capital link or legal link to the beneficiaries or partner organisations: only the sector (academic or non-academic) of the beneficiary counts; the entity will be considered to belong to the same sector as their beneficiary.

1. Seconded staff costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members, by providing for:

- a monthly top-up allowance (A) — for travel, accommodation and subsistence costs relating to the secondment.

> ⚠ **Budget flexibility —** There is NO flexibility as regards the *use* of the seconded staff unit costs (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
>
> ⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

What not? Research, training and networking costs and management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared as** the unit cost fixed by Decision C(2017) 6855[98] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the top-up allowance: **EUR 2 100** per seconded staff member per month (person-month).

> ℹ For the latest information on the amount, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - **early stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full time equivalent research experience) of their research career)
    - **experienced researchers** (i.e. have a doctoral degree OR at least four years (full time equivalent research experience) of research career), or

[98] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

- **administrative, managerial** or **technical staff supporting research and innovation activities** (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

  Examples (not eligible administrative, managerial or technical staff):

  1. *Ms B, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

  2. *Mr Y, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

  Years of '**research career**' are counted from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited or from where s/he is seconded) — even if a doctorate was never started or envisaged.

- have already been actively **engaged** in or **linked** to research and innovation activities at the premises of the sending beneficiary/partner organisation/entity with a capital or legal link, continuously for at least **1 month** (full time equivalent)

  Examples:

  1. *Mr Y is employed by/has a fellowship with/is a registered PhD candidate of beneficiary Y as from 1 January 2014; Mr Y will not be eligible for a secondment from 1 January 2014 but would be eligible for secondment as from 1 February 2014.*

  2. *Ms X is employed 50% part-time by beneficiary X as from 1 January 2014. Ms X will not be eligible for a secondment from 1 February 2014, but would be eligible for secondment as from 1 March 2014.*

  The type of relationship (employment contract, fellowship or other) is NOT relevant — as long as it:

  - complies with national law
  - complies with internal practices and
  - during the secondment: confers to the sending beneficiary/partner organisation/entity with a capital or legal link the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

    If this is not the case, the beneficiary/partner organisation/entity with a capital or legal link must conclude a contract which allows this (or a supplementary agreement) — before the secondment.

    Example: *A PhD-candidate can be seconded if s/he: has a contract allowing him/her to work full-time on the R&I activities of the action during the secondment under the instructions of the sending beneficiary/partner organisation/entity with a capital or legal link.*

- be incurred for secondments:

  - that last at **least 1 month** and **no longer than 12 months**

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

    For the minimum duration, only splits within *secondments of* same staff, from same sending beneficiary/partner organisation to same hosting beneficiary/partner organisation can be added. Secondments from/to entities with a capital or legal link

will be counted as secondments from/to the beneficiaries/partner organisations they are linked to.

Example: *Two secondments of two weeks of the same staff member to different beneficiaries are not eligible since the minimum duration of 1 month is not reached.*

For the maximum duration, all secondments (and all splits) for the *same staff member* must be added.

- that are one of the following three:
  - secondments **between beneficiaries/entities with a capital or legal link** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in **different** EU Member States or H2020 associated **countries** AND **different sectors** (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations for whom one of the main objectives is to pursue research or technological development or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country) **to** a **partner organisation/entity with a capital or legal link** in a third country

  OR

  - secondments **from** a **partner organisation/entity with a capital or legal link** in a third country listed in General Annex A to the H2020 Work Programme **to** a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country).

  Secondments from/to branches/departments of beneficiaries/partner organisations which are not separate legal entities are NOT eligible, if they are located in countries other than the country of their beneficiary/partner organisation.

Examples:

A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the H2020 Work Programme.*
A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the H2020 Work Programme.*
A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
They may each claim 120 person-months (for their own staff).

If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded *from* both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation *to* two or more participating organisations in a RISE project — as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('implemented person-months')

⚠ Beneficiaries may declare a **maximum** of **12 person-months** per seconded staff member. Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert 5.47 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[99] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility —There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[100] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1 800** per researcher per month (person-month)
- for management and indirect costs: **EUR 700** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[101] in the same period: only management costs, i.e. EUR 350 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

[99] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[100] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[101] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for seconded staff members'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for seconded staff members.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the seconded staff members are met. Person-months which are not eligible for budget category A 'costs for seconded staff members' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]*]*.*

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff);
- call upon entities with a capital or legal link to the beneficiaries or to partner organisations[9], to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[9] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-RISE allows the beneficiaries to use:

– partner organisations

and

– entities with a capital or legal link to a beneficiary or a partner organisation

to carry out work under the action (**third parties involved in the action**).

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them.)

Partner organisations are third parties involved in the action without a (capital or legal) link to a beneficiary.

They may participate in the exchanges by seconding and hosting staff.

⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action. They can be between beneficiaries/entities with a capital or legal link OR between beneficiaries/entities with a capital or legal link and partner organisations (from a third country).

They must have a **minimum** duration of **1 month** and a **maximum** duration of **12 months** (per seconded staff member).

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations must be established in a non-associated third country (i.e. not EU Member State or H2020 associated country).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary or a partner organisation — which is neither limited to the action nor established for the sole purpose of its implementation).

They may participate in the exchanges by seconding and hosting staff.

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary/partner organisation and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary/partner organisation they are linked to (for instance, if linked to a beneficiary: be established in an EU Member State or H2020 associated country; if linked to a partner organisation: be established in a non-associated third country AND be established in the same country as their beneficiary/partner organisation.

Examples (eligible entities with capital or legal link):

1. *University X (established in France) is part of a Joint Research Unit (JRU) with beneficiary Y (also established in France). Mr. X is employed by university X and is to be sent on a secondment to beneficiary Z. University X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

2. *SME X (established in Portugal) is a subsidiary of beneficiary Y (also established in Portugal). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. SME X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Ms. X.*

3. *Mr. X is formally employed by foundation X (established in Spain) which does the HR management for beneficiary Y (also established in Spain). Mr. X actually works with beneficiary Y and should be sent on a secondment to beneficiary Z. Foundation X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

Examples (ineligible entities with capital or legal link):

1. *SME X (established in Germany) is a subsidiary of applicant Y (established in Greece). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. Since SME X is not established in the same country as applicant Y, it cannot act as entity with a capital or legal link for the purposes of a MSCA-RISE grant. Therefore, Ms X cannot be seconded.*

2. *University X (validated as academic; established in Sweden) is member of an association of universities (applicant Y; validated as non-academic). Mr. X is employed by university X and is to be sent on a secondment to applicant Z (validated as academic). University X cannot act as entity with a capital or legal link of applicant Y for the purposes of the MSCA-RISE grant because this would circumvent the inter-sector mobility rules (mix of academic and non-academic).*

ℹ For more information on conditions for participation and funding, *see the Main H2020 Work Programme (section 3 MSCA).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities)*

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until these procedures end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents bear the **full risk** of cost rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must keep the documents for the staff of the partner organisation/entity with a capital or legal link.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term meeting**' between the beneficiaries, partner organisations, entities with a capital or legal link and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — after each year except if a periodic report is due (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Funding & Tenders Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a 'researcher declaration' for each seconded staff member — within **20 days** from the start of the secondment.

It is important to give correct and complete information in the researcher declaration, since this information will be used to determine the eligibility of the person-months that are declared.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — and indicate each split.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment, indicating the split. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (within 20 days from the start date of each secondment). Secondments to entities with a capital or legal link will be counted as secondments to the beneficiary/partner organisation they are linked to and must therefore be covered by the same researcher declaration.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declarations must be prepared and submitted directly in the Funding & Tenders Portal.

Specific case (deliverables):

Researcher declaration for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must submit the researcher declarations.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the seconded staff members **access** to both **background** AND **results** necessary for their research and innovation activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[17] and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

(k) ensure that the seconded staff members do not have to bear any costs for the implementation of the action as described in Annex 1.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[17] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time.**

  For part-time staff members this may require a change of their relationship (i.e. conclude a contract or a supplementary agreement), to allow the secondment to be implemented on a full-time basis.

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

  Beneficiaries and partner organisations must:

  – not penalise the staff members or reduce their rights due to the participation in the action and

  – in particular, since their normal remuneration is not covered by the grant (which is only a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are of course accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary/partner organisation/entity with a capital or legal link) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[102].

[102] Available at https://www.iprhelpdesk.eu/.

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*
- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.
- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

  They can be:
  - paid directly to the seconded staff member in advance or via different instalments or
  - managed centrally by the beneficiary according to the specific needs of the secondment.
- Ensure that the seconded staff members do not have to bear **any costs** for the implementation of the action as described in Annex 1.

  The seconded staff members must NOT be requested to pay tuition fees for their research and innovation training neither from their own funds, nor from the staff member unit cost.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract (or fellowship or other relationship), some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA grant in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (consortium) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MSCA-COFUND MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-COFUND actions

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in a programme implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**');

(b) for **costs of providing financial support to costs for researchers in a programme implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the H2020 Work Programme (section 3 MSCA))*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[103].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[103] Commission Decision C(2017) 6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced maximum grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in a programme implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in a programme implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme), by providing for:

- a monthly living allowance (A.1 or A.2) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*).

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit cost (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs of the beneficiary are not covered. Management costs are covered under budget category B 'management costs' *(see Article 6.2.B)*. Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are NOT eligible under the grant; they may be funded through other sources (including other EU programmes).

Combining H2020 & other EU grants — A MSCA-COFUND grant does NOT prevent the beneficiary or partner organisations from applying for further (non-H2020) EU funding for their programme — for costs that are not eligible (or not declared) under the MSCA-COFUND grant.

For more information on how to combine EU funding from different programmes, *see the Funding & Tenders Portal Online Manual (links to Regional funding).*

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[104] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance:
  - for early-stage researchers in doctoral programmes: EUR 3 870 per researcher per month (person-month)

[104] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for experienced researchers in fellowship programmes: EUR 5 480 per person-month.

⚠ The unit cost that the beneficiary receives is however **EUR 1 935** and **EUR 2 740** respectively (because of the MSCA COFUND reimbursement rate).

ⓘ For the latest information on the amounts, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence)*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** only the:

- management costs (B) — for direct costs of managing the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER sources (including other EU programmes).

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2017) 6855[105] and set out in Annex 2 and 2a of the GA.

This is currently:

- for management costs: EUR 650 per researcher per month (person-month).

The unit cost that the beneficiary receives is however **EUR 325** (because of the MSCA COFUND reimbursement rate).

For the latest information on the amount, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher costs.

1.3 The **eligibility** of the management costs is directly linked to (and conditional on) the eligibility of the costs for researchers.

Management costs are eligible only if ALL the eligibility conditions for the researchers are met. Person-months which are not eligible for budget category A 'costs for researchers' are also not eligible for budget category B 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

[105] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

– for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. implementing a doctoral or fellowship programme including recruiting researchers or hosting and training researchers during a secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do not apply.

Instead, MSCA-COFUND allows the beneficiary to use:

- partner organisations

to carry out work under the action (**third parties involved in the action**).

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to:

- implement a doctoral or fellowship programme (i.e. recruit the researchers)
- provide training and hosting of researchers during a secondment *(see Article 15)*.

⚠ **Secondments —** For MSCA-COFUND, secondments can be:

- (optional) additional periods of research training with a partner organisation, in order to further enrich the training experience of the researchers

and/or

- for fellowship programmes similar to MSCA-IF GF: (mandatory) outgoing phase with a partner organisation (from a third country).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during secondments.

Partner organisations can recruit the researchers (and MUST do so if it is the partner organisation that implements the doctoral or fellowship programme; *see Article 15.1.1(b)*).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations that implement a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *H2020 Work Programme*. Partner organisations hosting secondments can be established anywhere.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

15.1 Rules for providing financial support to or implementation of a *[doctoral][fellowship]* programme

15.1.1 The beneficiary must ensure that the ***[doctoral][fellowship]* programme** (implemented by itself or a partner organisation) complies with the following conditions:

(a) **types of programme**:

[OPTION 1 for DPs: *The programme must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programme**');**]***

[OPTION 2 for FPs: *The programme must concern fellowships for research training activities for recruited researchers ('**fellowship programme**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country[5], the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programme:

[OPTION 1 for DPs: *The doctoral programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately before the call deadline or recruitment — unless:*
  - *otherwise specified in Annex 1 for existing programme or*
  - *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[6];*
- *are nationals or long-term residents of an EU Member State or associated country[7], in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION 2 for FPs: *The fellowship programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*

- *show* **transnational mobility** *by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than [**OPTION A by default:** 12 months in the 3][**OPTION B for actions with activities similar to the MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel:** 3 years in the 5] years immediately before to the call deadline or recruitment — unless:*

  - *otherwise specified in Annex 1 for existing programmes or;*

  - *this time was part of a procedure for obtaining refugee status under the Geneva Convention[8];*

- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*

- *fulfil any additional conditions set out in Annex 1.]*

Researchers that are already permanently employed by the entity where the research training activities take place may not be supported.

(c) **procedure and criteria for selecting researchers** in the programme:

[OPTION 1 for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency and must indicate the minimum gross salary to be offered to the researches, as set out in Annex 1).**]***

[OPTION 2 for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

The selection committee(s) must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

There must be no more than 4 deadlines or cut-off dates per year.

*The calls must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.**]***

(d) **conditions for the recruitment** of researchers under the programme:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION 1 for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 709.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 354.50;**]***

- ***[OPTION 2** for **FPs:** for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 836;**]**.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 918.**]***

- researchers should not have to bear any costs for the implementation of the action as described in Annex 1.

15.1.2 In addition, the beneficiary must:

- for programmes implemented by itself:
  - take measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[9] and ensure that the researchers are aware or them;
  - ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;
  - ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);
  - ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;
  - ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
  - ensure that researchers work exclusively on the research training activities;
  - ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
  - ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
  - ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of results, promoting the action) — during the research training activities and afterwards;
  - inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — a follow-up questionnaire provided by the Agency;
  - ***[OPTIONS for DPs:** ensure a fair gender representation in the recruited researchers (by promoting genuine equal access opportunities between men and women throughout the recruitment process);*

- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

- for programmes implemented by a partner organisation:

  - ensure that the partner organisation complies with the obligations set out in this Article and

  - ensure that the partner organisation allows that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[5] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[6] 1951 Refugee Convention and the 1967 Protocol.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] 1951 Refugee Convention and the 1967 Protocol.

[9] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing a doctoral/fellowship programme

MSCA-COFUND can provide support both for a programme implemented by the beneficiary itself or for a programme of a partner organisation (which the beneficiary funds by providing financial support).

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisation that implements the doctoral/fellowship programme (also called 'cascade funding').

Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Types of programme — Categories of persons

The beneficiary/partner organisation must implement one of the following **types of** research training **programme** supporting transnational mobility:

- doctoral programme (DP), i.e. a programme with research training activities for recruited early-stage researchers that leads to the award of a doctoral degree

  The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programme (FP), i.e. a programme with fellowships for recruited experienced researchers.

The **researchers** must — at the date of the call deadline or recruitment —:

- be one of the following two:

  - **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time-equivalent research experience) of their research career) or

  - **experienced researchers** (i.e. have a doctoral degree OR have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than:

  - for fellowship programmes similar to MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel: 3 years in the 5 years immediately before the recruitment date or call deadline

  - for all other programmes (doctoral programmes and other fellowship programmes): 12 months in the 3 years immediately before the recruitment date or call deadline

  — unless Annex 1 of the GA specifies otherwise for an already existing programme or the beneficiary/partner organisation is an 'international European interest organisation'[106], for whom the mobility rule is limited to time spent *with* them.

  Exceptions in Annex 1 are only possible for existing programmes (NO exceptions for new programmes).

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[107] are NOT counted.

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

- if the programme is implemented by a partner organisation established in a **third country** (only third countries listed in General Annex A to the H2020 Work Programme) or if a secondment to a partner organisation in a non-associated third country constitutes the ***main* part** of the research training activities: be nationals or **long-term residents** of a EU Member State or H2020 associated country.

[106] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[107] 1951 Refugee Convention and the 1967 Protocol.

'Long-term resident' normally means a period of legal and continuous residence in EU Member States or H2020 associated countries for 5 or more consecutive years. Periods outside these countries will be taken into account if shorter than 6 consecutive months and all in all not more than 10 months.

For fellowship programmes similar to MSCA-IF EF Reintegration Panel: The long-term residence requirement will not apply to researchers who have obtained refugee status under the Geneva Convention[108] in a EU Member State or H2020 associated country.

NO other restrictions on researcher nationality or researcher origin or destination allowed.

3. Additional cost eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs[109])*.

Vacancies must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a **maximum** of **4** fixed deadlines or regular cut-off dates **per year**) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

The calls must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.

4. Additional cost eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits

[108] 1951 Refugee Convention and the 1967 Protocol.
[109] Available at http://ec.europa.eu/euraxess/.

- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, the beneficiary/partner organisation may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — The beneficiary/partner organisation must always recruit researchers directly. Recruitments via other means *(e.g. temporary* work *agency)* are NOT allowed.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum remuneration —** monthly **living allowance** (i.e. gross amount including salary, social security contributions, taxes and other costs included in the remuneration) and, if applicable, a single mobility allowance for the researcher to take up the doctoral or fellowship programme (to be funded through other sources) **—** of:

- for early-stage researchers (doctoral programmes): EUR 2 709
- for experienced researchers (fellowship programmes): EUR 3 836.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 354,50; for experienced researchers EUR 1 918).

Lower payments are considered as underpayment.

⚠ Since the MSCA-COFUND grant reimburses 50% of the researcher unit cost (i.e. EUR 1 935 and EUR 2 740 respectively), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 774** or **EUR 1096** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

The total cost of the doctoral/fellowship programme, in particular the amounts to be provided for the benefit of the researchers and for the hosting organisation, must be specified in Annex 1.

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral/fellowship programme — the average monthly allowance (over the duration of the programme) respects the above-mentioned minimum.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the

average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[110]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[111].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

Recruited researchers should not have to bear **any costs** for the implementation of the action as described in Annex 1.

For doctoral programmes: recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training and/or PhD programme *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* neither from their own funds, nor from the researcher unit cost.

For fellowship programmes: the recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training neither from their own funds, nor from the researcher unit cost.

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**, unless duly justified for reasons associated with personal or family reasons.

    This also means that a researcher can NOT benefit from two MSCA grants at the same time.

    Part-time employment can be accepted:
    - subject to prior approval by the Agency
    - on personal and family grounds only (i.e. NOT for professional reasons) and
    - if limited to a maximum of 50% of the time spent under the action.

    In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

    Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

    ⚠ While it is not possible to request part-time employment for **professional reasons**, the beneficiary may — in exceptional cases — request an interruption of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

[110] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html.
[111] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm.

  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities.

  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency

- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[112].

- for doctoral programmes: the beneficiary/partner organisation must:

  - ensure **gender balance** regarding the recruited researchers

  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career development plan.

[112] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas, documents relating to selection procedure)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the minimum remuneration was paid to the researchers.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents bear the full risk of cost rejection by the Agency.

Specific case (record-keeping):

Documents for a programme implemented by a partner organisation — For a programme implemented by a partner organisation, it is the beneficiary that must keep the documents also for the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must

- submit a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- organise a **'mid-term meeting'** with the Agency;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** of the start of the research training activities of the researcher.

It is important to give correct and complete information in the researcher declaration since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Funding & Tenders Portal.

2. Deliverable: Mid-term meeting

What & When? The beneficiary must organise a mid-term meeting with the Agency to present the implementation of the action in the light of the schedule in Annex 1.

Best practice: Please contact the Agency for the timing.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researchers in MSCA-COFUND, the MSCA-COFUND MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** (if any) give similar access.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,*

addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.6 H2020 MSCA-SNLS MGA: Annotations

ARTICLE 1 — SUBJECT OF THE GRANT AGREEMENT

ARTICLE 1 – SUBJECT OF THE AGREEMENT

[…] This grant is **linked** to another MSCA **grant** (number [insert number] — [insert acronym]).

1. Linked grant

MSCA-SNLS grants are always linked to another MSCA grant of the beneficiary (main grant – IF, ITN, RISE or Cofund).

The MSCA-SNLS provides support only to researchers or staff members with disabilities who are eligible under the linked MSCA GA.

Moreover, the MSCA-SNLS grant shares the fate of the main grant *(e.g. if the main grant is suspended or terminated, the MSCA-SNLS grant may also be suspended or terminated; see Articles 49.2 and 50.3)*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the acquisition of the special needs items or services described in Annex 1, which are needed to allow the concerned researcher or staff member to participate in the linked grant ('**action**').

2. Action: MSCA-SNLS

What? MSCA-SNLS grants fund additional costs that MSCA researchers and staff members with disabilities face due to the increased costs of their mobility during another MSCA action (main grant).

MSCA-SNLS is awarded for the acquisition of special needs items or services *(e.g. assistance by third persons, adaptation of work environment, additional travel/transportation costs)* to allow the recruited or seconded researcher/staff member to participate in the main MSCA action.

What not? Additional costs entailed by the recruited or seconded researcher/staff member but already covered by another source *(e.g. social security or health insurance)* cannot be funded under the MSCA-SNLS.

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The '**estimated lump sum breakdown**' for the action is set out in Annex 2.

It contains the lump sum shares, per work package (i.e. special needs items or services).

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiary. It shows the amounts that the Agency commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 cannot be adjusted by transfers of amounts between work packages (not even via an amendment; see Article 55).

1. Estimated lump sum breakdown

Since MSCA-SNLS grants do not use eligible costs, the MSCA-SNLS MGA does not have any budget categories. Instead, it has either a single lump sum or, if several special needs items or services are needed, a lump sum breakdown.

For technical reasons, each item or service must be considered a separate work package.

The breakdown is used to determine:

- the share of the lump sum to which the beneficiary is entitled for each work package.
- the maximum amount of grant reduction that can be applied for improper implementation of a work package.

Example: *Annex 2 sets out EUR 10 000 for work package 1 (WP1) – Special assistance services for the entire action duration (12 months). The Agency carries out a review on the grant and concludes that WP1 was not properly implemented because only part of the activities of that work package were actually carried out (i.e. assistance was provided for 11 months instead of 12 months). The Agency will reduce the grant in proportion to the improper implementation of WP1 up to a maximum of EUR 10 000 (the share of the lump sum allocated to that work package).*

2. Lump sum share transfers

Given that MSCA-SNLS is a mono-beneficiary action, there is NO redistribution between *beneficiaries*.

Transfers between *work packages* are NOT possible, because the lump sum shares have been fixed for each special needs item or service.

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)].

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The MSCA-SNLS MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum is set out in the H2020 Work Programme (section 3 MSCA).

The lump sum will be fixed taking into account the H2020 MSCA funding rates. This means that the lump sum fixed in Article 5 does not have to be multiplied again by the funding rate; it is already the net maximum EU funding.

The lump sum is one amount for the entire action. It will be limited to a maximum of EUR 60 000 per researcher/staff member and will be available as of 2019.

There are no cost eligibility conditions. If the action is correctly implemented, the beneficiary is entitled to receive the lump sum fixed in the GA.

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs and cannot be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary are added together.

The grant is reduced (see Article 43) for all other work packages (i.e. all work packages that have not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For MSCA-SNLS grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation); see Article 43), it will calculate the '**revised final grant amount**'.

This amount is calculated by the Agency by reducing the grant in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For MSCA-SNLS grants, the rules on the revised final grant amount are also in principle the same as for the General MGA (see *Article 5.4 H2020 General MGA*).

However, since there is no reporting of costs, the calculations are different (see *Article 21*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services ;
- call upon subcontractors to implement action tasks described in Annex 1;

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Third parties involved in the action

For MSCA-SNLS actions, NEITHER the rules from the General MGA NOR from the MSCA main grant for third party involvement apply.

There are NO special rules for purchases or subcontracting. The beneficiary may make purchases or subcontract tasks if this is needed for the special needs items or services.

For all types of third party involvement (purchases and/or subcontracts), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiary must — for a period of three years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

Records and other supporting documentation on the implementation of the action must be in line with the accepted standards in the respective filed.

The beneficiary does not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For MSCA-SNLS actions, the beneficiary does not need to keep full records on its actual costs; it only needs to keep appropriate and sufficient evidence (documentation, records) that the special needs items or services were provided to the researcher/staff member as described in Annex 1.

The records and supporting documentation must also prove that:

- the eligibility conditions for the researcher/staff member as per MSCA main grant were complied with
- the special need(s) of the researcher/staff member was certified by a competent national authority.

By contrast, timesheets or invoices are NOT needed. The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 3 years (because not above 60 000 EUR) after the balance is paid or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit — within 60 days following the end of the reporting period — a final report.

The **final report** must include the following:

(a) a '**final technical report**' containing:

(i) an **overview of the results**.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

(ii) a summary for publication by the Agency: not applicable;

(iii) the answers to the '**questionnaire**': not applicable;

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4) which includes the **request for payment of the balance**.

The financial statement must declare the lump sum shares indicated in Annex 2, for the **work packages** that were completed.

If agreed by the Agency, the beneficiary may exceptionally also declare work packages that were not completed.

Lump sum shares which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the work packages have been completed and that the action in general has been properly implemented (see Article 7);

- the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Reports

What & When? For MSCA-SNLS actions, the beneficiary must submit a **final periodic report** at the end of the action.

Each report is composed of a technical and a financial report, however, the financial report is not to declare costs but completed work packages and corresponding lump sum shares (one or more, depending on the number of special needs items or services which are covered by the grant).

In principle, lump sum shares should be claimed only for special needs items and services that were fully provided to the researcher/staff member concerned. However, if agreed by the Agency, the beneficiary may exceptionally declare partial lump sum shares for work packages that were not completed, for example, due to technical reasons or reasons related to the researcher/staff member.

Best practice: In case of doubt, the beneficiary should contact the Agency about partial work packages.

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that it did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the beneficiary to have enough time.*

- non-implementation linked to financial reasons

  Example: *The special needs service turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].*

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3) whichever is the latest.

*An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.**]***

[OPTION 2 if the JRC is the beneficiary: *The Agency will make a pre-financing payment of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)], within 30 days from the submission of a debit note from the JRC after the signature of the 'Arrangement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the Agency to the Guarantee Fund.**]***

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining lump sum shares for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Incomplete work packages, and work packages that have not been delivered or cannot be approved will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for the beneficiary, in the estimated lump sum breakdown (see Annex 2).

[…]

1. Payments to be made

MSCA-SNLS actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Agency on the basis of the financial statement, the final grant amount and the payments already made.

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares for the accepted work packages. Partial work packages can exceptionally be accepted (i.e. shares for work packages that were not

completed, for example due to technical reasons or reasons related to the researcher/staff member).

Examples:

1. *The beneficiary of an ongoing MSCA-SNLS GA cannot complete the pending work packages because the person providing assistance to the MSCA-RISE staff member with special mobility needs is no longer able to provide the service and the staff member in question does not want to replace his/her assistant. Therefore, the beneficiary requests termination of the MSCA-SNLS GA. The Agency decides to accept part of the lump sum shares for the uncompleted work packages that is proportionate to the tasks already carried out under the MSCA-SNLS action.*

2. *The participation of an early-stage researcher (ESR) with physical impairment has been terminated in the linked MSCA-ITN GA due to personal circumstances of the researcher (e.g. another professional opportunity). Given that the grounds for termination of the MSCA-SNLS are not linked to the beneficiary, the Agency decides to exceptionally accept partial work packages that were initiated but could not be fully completed. The Agency will however verify if the reported lump sum shares for the uncompleted work packages are proportionate to the tasks carried out.*

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that it did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the beneficiary to have enough time.*

- non-implementation linked to financial reasons

  Example: *The special needs service turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

Steps 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to MSCA-SNLS grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 4 (Grant reductions) applies.

All other steps follow the General MGA.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued relevance of the action.

[…]

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

[…]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since MSCA-SNLS grants do not use eligible costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since the beneficiary has no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the *technical* implementation of the action (in particular whether the special needs items and services have been provided to the researcher/staff member as described in Annex 1 of the GA).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of the beneficiary to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiary.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[12] applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for MSCA-SNLS grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial report has not been submitted or is not complete or additional information is needed, or

(c) there is doubt about the amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA (see *Article 47 H2020 General MGA*).

The MSCA-SNLS MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for MSCA-SNLS grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work package implementation).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiary

49.1.1 Conditions

The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) the beneficiary or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2);

(c) not applicable;

(d) the action implementation of the linked grant (see Article 2) is suspended.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiary may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA (see *Article 49 H2020 General MGA*).

For *full* GA suspension (action is entirely suspended), all on-going work packages (i.e. special needs items or services) must be interrupted and no new work packages may be started.

For *partial* GA suspensions (suspension of specific work package(s)),, other work packages may be continued and new work packages may be started.

2. GA suspension — Additional ground for suspension: Suspension of main grant (EU)

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, the Agency may suspend the MSCA-SNLS action if the main grant (to which the MSCA-SNLS grant is linked) is suspended.

> ***Example:*** *The beneficiary of an ongoing MSCA-IF grant has requested GA suspension for family grounds of the recruited researcher with visual impairment. The beneficiary has already fully adapted the main work environment but the adaptation of a small laboratory is still missing. The Agency will suspend the MSCA-SNLS GA until the MSCA-IF action will be resumed.*

ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

[…]

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no lump sum shares will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21) on the basis of the report submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiary's obligations (in particular Article 20, 22, 23, 36, 38, 40, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary’s legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

If the Agency does not receive the report within the deadline (see above), no lump sum shares will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21) on the basis of the report submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 43 and 44) continue to apply.

1. GA termination

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for MSCA-SNLS grants there is no reporting of costs, the calculations are different *(see Article 21)*.

2. GA termination — Additional ground for termination: Termination of main grant or researcher/staff member's participation in main grant (EU)

In addition to the normal grounds for GA termination *(see Article 50.3 H2020 General MGA)*, the Agency may terminate the MSCA-SNLS action if the main grant or the researcher/staff member's participation in the main grant (to which the MSCA-SNLS grant is linked) is terminated.

Example: *The beneficiary of MSCA-COFUND grant has committed substantial errors and irregularities and the Agency has decided to terminate the GA. The MSCA-COFUND GA is linked to MSCA-SNLS GA which foresees the construction of multiple ramps at the premises of the beneficiary to create an accessible work environment. The termination of the MSCA-COFUND GA serves as a ground for termination of the MSCA-SNLS GA by the Agency.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

The rules for amendments are the same as in the General MGA *(see Article 55 H2020 General MGA)*.

Given the parallelism of the MSCA-SNLS grants and the main grant, there may be a need to amend both in a synchronised manner.

> ***Example:*** *If the time spent by the researcher or staff member on the linked MSCA action is changed (e.g. for MSCA-IF from full-time to part-time), the duration of the MSCA-SNLS action may also have to be adapted accordingly.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

If the linked grant (see Article 1) is transferred to a new beneficiary, the beneficiary may also request the transfer of this action.

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher or staff member;
- a proposal for the necessary changes, including the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The lump sum will be split between the former beneficiary and the new beneficiary, on the basis of the part performed by the former beneficiary and the remaining part to be given by the new beneficiary. If the pre-financing received by the former beneficiary (see Article 21) exceeds the amount of the lump sum recalculated for the former beneficiary, the Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing received in excess.

Where necessary, the former and the new beneficiary must agree on arrangements concerning the transfer of any equipment, materials and/or services purchased and used for the researcher or staff member concerned. The former beneficiary may object only on the basis that the transfer is technically not possible or not possible under national law.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-SNLS grant can be **transferred** to a new beneficiary if the main grant (MSCA-IF, MSCA-ITN, MSCA-RISE or MSCA-COFUND) is transferred to it.

Transfer of the main grant agreement may cover:

- 'transfer' in the sense of Article 56a MSCA-IF MGA
- change of beneficiary due to 'partial takeover'
- addition of a new beneficiary to the main grant, which will host the researcher/staff member with special needs.

Transfer — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (*Article 50*) or addition of a new beneficiary (*Article 56*).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains fully responsible until the Agency has approved the amendment.

The transfer may NOT entail changes to the GA which would call into question the decision to award the MSCA-SNLS grant.

Example: *The transfer will not be accepted if the special needs item or service is eligible for funding by another source in the country of the new beneficiary (e.g. social security or health insurance system).*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new beneficiary (signed directly in the Funding & Tenders Portal).

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Funding & Tenders Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress of the work and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to decide on how to split the lump sum and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must be also uploaded with the final report (by the new beneficiary, together with its own financial statement).

The lump sum will be split between the former beneficiary and the new beneficiary — on the basis of the part performed by the former beneficiary and the remaining part to be given to the new beneficiary. If the pre-financing received by the former beneficiary (see *Article 21*) exceeds the amount of the lump sum recalculated for the former beneficiary, the Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing received in excess.

The former and the new beneficiary must agree on arrangements, where necessary, concerning the transfer of the equipment, materials and/or services purchased for the researcher/staff member.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1 Lump Sum
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 SME Ph1 Lump Sum MGA deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 SME Ph2 MGA deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 SME Ph1 Lump Sum MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1 Lump Sum:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 SME Ph1 Lump Sum MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (**'action'**), as described in Annex 1.

1. SME Instrument Ph1 Lump Sum actions

What? SME Instrument Ph1 Lump Sum funds:

- the feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above*; see General Annex G to the H2020 Work Programme*).

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, 'Innovation in SMEs' (*e.g. H2020-SMEINST-01-2016-2017)*.

For more information on SME Instrument Ph1 actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph1 Lump Sum MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 Lump Sum MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph1 Lump Sum MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Decision C(2013) 8198[113].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

[113] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME Instrument Phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, for SME Ph1 Lump Sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to grant *reduction*). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the feasibility study (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Decision C(2013) 8198[114] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

[114] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

For SME Ph1 Lump Sum grants, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to grant *reduction*, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the SME Ph1 Lump Sum MGA.

The special rules from the General MGA on third party involvement are limited in SME Ph1 actions to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs of purchases and subcontracts are **ALL covered** by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) or international partners (Article 14a) are NOT allowed (since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are in principle the same as in the General MGA *(see Article 10 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[115] or 2009/81/EC and the national legislation implementing them.

Moreover, the obligations in Article 10.1 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[115] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the following **specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated subcontracting costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[116] or 2009/81/EC and the national legislation implementing them.

[116] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Finally, the obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations'*. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

Examples: *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Reports

What & When? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a **final periodic report**, containing a technical and a financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

Payment of the balance

How much? The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The Agency may disclose confidential information also to its staff, other EU institutions and bodies.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency and Commission responsibility — Agency and the Commission right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (consortium) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submiting the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submiting to the Agency in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(iii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iv) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the Agency will formally notify the beneficiary of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a **recovery**, the Agency will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for SME Ph1 Lump Sum grants the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*, improper implementation leads to the *ineligibility* of the costs (NOT grant *reduction*; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ Cost rejections will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide required information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for SME Ph1 Lump Sum grants 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*, the grant can be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the following **specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (‘**extension of findings from other grants to this grant**’; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (‘**extension of findings from other grants to this grant**’; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Beneficiary termination (consortium)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the following **specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. GA or beneficiary termination (EU)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the following **specificities**:

The request for amendment (which the coordinator must send 60 days after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 SME Ph2 MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through Phase 1 or another means.

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above; *see General Annex G to the H2020 Work Programme*).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-05-2016-2017)*.

For more information on SME Instrument Ph2 actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **if the beneficiary is a natural person** not receiving a salary (see Article 6.2, points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific costs category(ies)**: not applicable.

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the H2020 Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are by definition NO non-profit legal entities, they can NOT declare additional remuneration (under budget category A 'personnel costs'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules [...][11].]*

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement." ***]***

[OPTION 1 only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[12] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[24].***]**

[OPTION 2 only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*

- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).]*

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[11] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[12] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[13] See Articles 28 and 31(2)(a) of Directive 2004/18 replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the following **specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Funding & Tenders Portal messaging function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage)

OR

- refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the simplified approval procedure: there is NO assessment (and the beneficiary therefore bears the **full risk**).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as in the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be shorter and more frequent than in other H2020 actions.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 ERA-NET Cofund MGA deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 ERA-NET Cofund MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***
	[OPTION if the JRC participates: *3b Administrative Arrangement****]***
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

ERA-NET Cofund uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities participating financially to the co-funded joint call for proposals MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8*).

> ⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

New beneficiaries may be added to ERA-NET Cofund actions during grant preparation or later on with an amendment to the grant agreement, however:

- new partners contributing to the co-funded joint call should not join later than the launch of the call; all partners participating in the call have to be members in the consortium or linked third parties
- beneficiaries joining *after* the launch of the call can ONLY execute the payments of the financial support to the third parties (except in case of transfer of rights and obligations; *see Article 55 H2020 General MGA*).

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. ERA-NET Cofund actions

What? ERA-NET Cofund co-funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the H2020 Work Programme*).

  These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the H2020 Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of Horizon 2020 *(e.g. FETPROACT-02-2017; SC5-33-2017)*.

For more information on ERA-NET Cofund actions*, see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action**: [insert date]]*[7] ('starting date of the action').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55 H2020 General MGA*). Normally, the duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs.

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**:

- for costs of internally invoiced goods and services: on the basis of an mount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

Best practice: If the amendment concerns a very limited share of the budget, beneficiaries are invited to first consult the Commission/Agency to verify if the amendment is needed.

2. Reimbursement rate

How much? For ERA-NET Cofund, the reimbursement rate is currently set at **33 %** *(see General Annex D to the H2020 Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - **personnel** costs for implementing the trans-national projects (— unless declared as unit cost, *see below*)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects (— unless declared as unit cost, *see below*)
- **unit costs** for:
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices
  - **coordination costs** for additional activities[117]
- **flat-rate costs** for:
  - **indirect costs**.

[117] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects (‘**costs for employees (or equivalent)**’). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary’s usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.2.1.1,A.2.1.2 and A.2.1.3) : the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or

- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.2.1.1 and A.2.1.2) **calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION 1 by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

A.2.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:***:***

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Costs for trans-national projects (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as direct costs related to trans-national projects:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment

- other goods and services
- costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc.) or for additional coordination and networking activities of beneficiaries implementing trans-national project themselves. Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs must normally be **declared as** actual costs *(see Article 5.2(b))*.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

1.3 In principle, the same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the following **specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities

Direct coordination costs for additional activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Additional coordination costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the direct costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8200[118] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the **additional coordination activities** described in Annex 1.

Costs for additional coordination activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare any additional coordination costs.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the H2020 Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[118] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (C.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing to the joint call for proposals can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action).

Linked third parties may participate in all activities under the action. Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is ONLY allowed for beneficiaries/linked third parties that **implement trans-national projects** (NOT for beneficiaries that only provide financial support to third parties — with the exception of third parties with authorisation to administer described in the specific cases below)).

Specific cases (third parties involved in the action):

Authorisation to administer — Beneficiaries providing financial support to third parties may exceptionally delegate administrative tasks (such as the administration of payments to the final recipients) to other legal entities (third parties) which they created or control and to which they have granted an 'authorisation to administer' (i.e. to handle their administrative affairs).

Sometimes this also includes the handling of the EU contribution. In this case, the beneficiary will use the bank account of the third party and all payments made to that account will count for the beneficiary. Moreover, the third party will then pass on the EU contribution to thefinal recipientsand those payments will be registered in the accounts of the third party).

The services rendered by these third party are usually qualified as in-kind contributions against payment. If the costs are not recorded in the accounts of the beneficiary *(e.g. there is no invoice from the entity)*:

- the beneficiary has to prove that such practice in line with national law and applicable accounting standards
- the costs must be recorded in the accounts of the third party.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be **trans-national projects**, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.2a);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

A core part of ERA-NET Cofund actions is to provide financial support to third parties (i.e. pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing the financial support, while it is the final recipients (third parties) that actually implement the trans-national research and/or innovation projects.

⚠ Beneficiaries can in principle NOT also be final recipient (since that is not the purpose of a cascading grant).

However, there are cases where exceptions are permitted (i.e. where the call can be opened also for other beneficiaries of the EU grant or other departments of the same beneficiary).

In this case, the consortium will be asked during grant preparation to:

- identify the beneficiaries which can apply for funding under the co-funded call for proposals
- explain the measures to mitigate (potential) conflict of interest or unequal treatment of applicants and
- reflect this fully in their description of the action (Annex 1 to the GA), both in the context of the description of the co-funded call and in relation to the monitoring of the trans-national projects.

Moreover, beneficiaries must set up information barriers ('Chinese walls') to prevent exchanges or communication that could lead to conflicts of interest or unequal treatment of applicants and ensure independent and fair complaints procedures.

Costs can be declared ONLY by the beneficiary providing the financial support, NOT by the final recipient receiving the financial support (even if it is at the same time beneficiary of the grant and can therefore declare other costs).

If the call is NOT open other beneficiaries of the EU grant or other departments of the same beneficiary, this should also be explicitly mentioned in the description of the action (Annex 1 to the GA).

ERA-NET grants can however also include actions which are implemented by the beneficiaries themselves, if foreseen in the work programme.

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Trans-national projects

The projects must be trans-national (i.e. they must involve at least two independent entities from two different EU Member States or H2020 associated countries), both in case of:

- financial support to third parties and
- implementation of the projects by the beneficiaries themselves.

Note that additional eligibility conditions may apply in specific cases concerning the minimum number of independent entities (including entities from third countries).

3. Additional cost eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

4. Additional cost eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

5. Additional cost eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection (**joint selection list**) on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

6. Additional cost eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

7. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION 1 by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Information on each selected project — Information on each implemented project

What & When? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

Example: *data on each participant and abstracts of the proposals*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

Example: *data on each participant and an overview of the results*

How? The information must be uploaded directly in the Funding & Tenders Portal

2. Deliverable: Information on cumulative expenditure incurred

What & When? The coordinator must submit to the Commission/Agency — on a yearly basis — information on the cumulative expenditure incurred by the consortium

How? In practice, this mandatory declaration for ERA-NET Cofund *(see Article 20.5)* is handled as deliverable and must be uploaded directly in the Funding & Tenders Portal.

It does NOT need to be set out in Annex 1 (since legally speaking the obligation is not based on Article 19 but on Article 20.5).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.2a Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

(a) a ***periodic technical report*** *(see point (a) above) and*

(b) a ***statement on the use of the second pre-financing payment*** *(see Annex 8), including the* ***request for a third pre-financing payment****.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.3 Request for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4), from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

What & When? For ERA-NET Cofund actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- ranking list of the projects
- observer report on the evaluation

- joint selection list
- commitment on availability of funds (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8).

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 8*).

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Funding & Tenders Portal).

2. Reporting periods

ERA-NET Cofund actions are normally divided into 2 reporting periods with 2 pre-financing payments (or exceptionally 3 reporting periods with 3 pre-financing payments, if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

The declaration is normally handled as deliverable *(see Article 19)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments to be made — No interim payments

ERA-NET Cofund actions normally are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because the Commission/Agency does not have sufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since ERA-NET Cofund pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- for the first pre-financing payment: between 10% and 30 % of the maximum grant amount
- for the second pre-financing payment: between 60 % and 80% of the maximum grant amount.

If the GA provides for a 3 pre-financing payments, then the amount is divided as follows:

- 30 % for the first pre-financing payment
- 30 % for the second pre-financing payment
- 30 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP/PPI MGA

VI.1 Background information and approach

The PCP/PPI Model Grant Agreement is used for PCP/PPI actions only.

The PCP/PPI MGA follows the General MGA for numbering and content, except for:

The H2020 PCP-PPI MGA deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI specific payment provisions)
- Article 23 (PCP-PPI specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of resources
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP/PPI actions are added:

- Article 2 (PCP/PPI actions)
- Article 4.1 (PCP/PPI budget categories)
- Article 8 (PCP/PPI rules on third party involvement).

VI.2 H2020 PCP/PPI MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties]*
	[OPTION if the JRC participates: *3b Administrative Arrangement]*
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

PCP/PPI uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities contributing financially to the PCP or PPI procurement budget MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8)*. They form the buyers group.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI actions

What? PCP/PPI funds:

- one single joint public procurement of research and development (R&D) services (PCP) or one joint or several coordinated public procurements for innovative solutions (PPI)

AND

- related additional coordination and networking activities.

For PCP actions, it must be only one PCP per GA; for PPI actions, it can be one joint or several coordinated PPIs per GA.

The additional activities must relate to the joint call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the H2020 Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP/PPI grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the H2020 Work Programme)*.

PCP/PPI actions are funded in all Parts of Horizon 2020 *(e.g. SEC-09-FCT-2017).*

The possibility to have several coordinated PPIs was introduced with GA version 4.0 but is also open to older grant agreements.

For more information on PCP/PPI actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14 a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP/PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP/PPI MGA uses its **own budget categories**.

Budget categories of the PCP/PPI MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare PCP/PPI subcontracting costs. Who actually pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP/PPI MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **[…%]** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION 1 for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2a*[13] ***(unit costs).]***

[OPTION 2: specific cost category(ies): *not applicable.**]***

[…]

8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
13 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The PCP/PPI, normally uses the same reimbursement rates as the General MGA (**100%** for research and innovation actions (RIA) and **70% or 100%** for innovation actions (IA) actions; *see Article 5 H2020 General MGA*), unless the call provides exceptionally for another rate.

2. Cost forms

The PCP/PPI MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The PCP/PPI MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs of *[PCP]/[PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. PCP/PPI subcontracting costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP/PPI actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **PCP/PPI subcontracting** described in Annex 1
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[14]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[15] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed;

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agree otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories B.1.1, B.1.2, B.1.3 [and B.1.6]): the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of annual productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or option (iii) above, i.e.:

-fixed number of hours;

-standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for during each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories B.1.1, B.1.2, B.1.4, B.1.5 [*and B.1.6*]): the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[16]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[17] ***[OPTION 1 by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[18]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable****.]***

B.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]*[***OPTION 2***: *not applicable*]***]***.

Beneficiaries receiving an operating grant[19] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

B.5 ***[OPTION 1: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION *1a* ***for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *[**Insert name of specific cost category**[20]] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units, [and if [insert additional eligibility conditions, if any]].***]***

[*same for each specific cost category****]***

[OPTION 2: *Not applicable****]***

[…]

[14] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[15] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[16] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[17] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[18] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[19] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[20] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Additional coordination and networking costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as costs for additional coordination and networking activities related to the joint call for tender:

- direct personnel costs for additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for additional coordination and networking activities
- other direct costs for additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs must normally be **declared as** actual costs.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary MUST be declared as the unit cost fixed by Decision C(2013) 8197[119] and set out in Annex 2 and 2a of the GA.

This concerns only *beneficiaries* that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI MGA has however the following **specificities**:

[119] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the joint call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

1. *The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.*

2. *Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).*

3. *Costs for validation and testing of solutions provided by the subcontractors*.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the H2020 Work Programme, the costs of additional coordination and networking activities are eligible up to a maximum amount of 30% (for PCP)/50% (for PPI) of the total requested grant amount. For each GA, this ceiling is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

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The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP/PPI actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing financially to the joint procurement budget can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action). They form the buyers group.

Moreover, certain **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12)) are ONLY allowed for **additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, **subcontracting** (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities.

Linked third parties (Article 14) may participate in all activities under the action.

In addition, PCP/PPI actions often have **other interested third parties** (preferred partners), which are neither lead procurer nor part of the buyers group nor linked third parties nor third parties providing in-kind contributions, but which have a special interest in closely following the PCP and may therefore be mentioned in Annex 1 (e.g. entities involved in the related additional networking activities; other potential buyers for the solutions that have expressed a special interest in the PCP/PPI).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

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13.1 ***[OPTION 1 for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[26];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

(c) *For the '****contract implementation stage****':*

(i) *monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;*

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) *ensure payment of the subcontractors.*

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[26] See Article 16(f) of Directive 2004/18/EC replaced by Article 14 of Directive 2014/24/EU, and Article 24(e) of Directive 2004/17/EC replaced by Article 32 of Directive 2014/25/EU..

1. PCP subcontracting

In PCP actions, the beneficiaries award PCP subcontracts for research and development services that are necessary to address a common challenge set out in Annex 1 (PCP R&D services). 'PCP

subcontract' thus means a contract for the purchase of R&D services (identified in Annex 1 as action task).

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries and linked third parties (buyers group), with a joint procurement in 3 phases

  The **buyers group** is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[120])

    Any entity that fits the definition of a contracting authority or contracting entity as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI actions.*

  – that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the H2020 Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the H2020 Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

[120] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is split in **3 phases** (solution design, prototyping, original development and testing of a limited set of 'first' products or services) which are implemented via 3 different specific contracts (under the overall PCP framework agreement).

The buyers group must select multiple competing subcontractors (with a minimum of 3 subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum 2 subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a **common challenge** (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

  The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

  If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

  The procurement must be for an R&D services contract (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the H2020 Work Programme*).

  If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

  Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

  This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[121]).

  Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement (**common jointly-committed budget**)

  This budget is based on the financial commitments of the beneficiaries and linked third parties in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

[121] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary (**lead procurer**)

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is NOT part of the buyers group).

  Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[122].

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors (PCP implementation)

- **Subcontractors** are **paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP actions).

There can only be one PCP per PCP action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

[122] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

For PCP subcontracting, there is NO simplified approval procedure (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 and phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must normally be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

- the procurement must be preceded by an **open market consultation**

  This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[123].

  A prior information notice (PIN) must be published in the Official Journal of European Union (OJEU) and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

- the procurement must be based on **common procurement specifications** prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more guidance and templates for the tender documents, *see the PCP procurement documents [ODT format].*

5. Additional cost eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase

[123] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the H2020 Work Programme)*
  - the obligation of the subcontractors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries (place of performance obligation)
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the H2020 Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions and without the right to sub-licence

    This right serves as a safeguard to ensure a competitive supply chain (during or after the PCP action) in case of problems. It does NOT mean that every subcontractor will always and automatically be obliged to grant non-exclusive licenses to third parties to exploit its results.

    Examples (licences needed): *other providers working for the buyers group need access to the IPR to work for the buyers group; a PCP subcontractor abuses its monopoly situation*

  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the H2020 Work Programme)*

    This right serves as a safeguard to ensure commercial exploitation in the public interest, in case the subcontractors fail to do so themselves. It will be for exceptional cases.
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2014/24/EU, 2014/25/EU[124] and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[125]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[126]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[124] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[125] *See Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.*

[126] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

[OPTION 2 for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint (or several coordinated) procurement procedure(s) by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and, 2004/17/EC (or 2014/25/EU).

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint (or coordinated) PPI procurement(s) ('**joint procurement agreement**');*

*(ii) **[OPTION 1 for PPI actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION 2:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION 1 for PPI actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) '**contract notice**'(s), which:*

- *are published by the lead procurer (or beneficiary) in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specify a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call(s) for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allow for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *are promoted and advertised widely;*
- *indicate how potential tenderers can obtain the tender documentation and the 'PPI request(s) for tenders';*

*and the **tender documentation** and **PPI request for tenders**.*

*(ii) **Step 2**: make one (or several) **evaluation(s) of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make one (or several) '**contract award notice**'(s), which are published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION 2 for PPI actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) **request(s) for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25//EU)[271] —:*

- *use technical specifications that are functional or performance based;*
- *avoid selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specify award criteria based on best value for money*

- *describe the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describe the arrangements for intellectual property rights*
- *describe the arrangements for liability for damages;*

(iv) ***Step 2:*** *make one (or several)* ***evaluation(s) of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24/EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[27] See Articles 28 and 31(2)(a) of Directive 2004/18/EU replaced by Article 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. PPI subcontracting

For PPI actions, beneficiaries award PPI subcontracts for procuring the innovative solutions that are necessary to address the common challenge set out in Annex 1 (PPI innovative solution(s)). 'PPI subcontract' thus means a contract for the purchase of innovative solutions (identified in Annex 1 as an action task).

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the following **specificities**:

The PPI procurement covers 2 phases (deployment and operational validation) — but there is no requirement to split the PPI procurement for those 2 phases in different contracts.

The beneficiaries may choose between implementing *one single* or *several coordinated* PPI procurements.

> For joint procurements, there is one joint PPI call for tender launched by the lead procurer and one joint evaluation of offers.
>
> For coordinated procurements, there are several separate PPI procurements carried out individually by the different procurers in the buyers group.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer (early adopter) of innovative solutions that are not yet available on a large-scale commercial basis.

> PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.
>
> Each PPI action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them together (i.e. the core functionality and performance characteristics must be the same; there may be additional local functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement (**common jointly-committed budget**) only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

> The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).
>
> For joint procurements:
>
> - the buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts
> - if there is no mandate, the general rule is that:
> - framework agreement(s) must be signed by all members of the buyers group together
> - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI actions).

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PPI subcontracting, there is NO simplified approval procedure (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an **open market consultation** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[127].

[127] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).

A prior information notice (PIN) must be published in the Official Journal of the European Union and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

The PIN must contain information on:

- the expected launch date for the call for tender

  This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP action) is sufficient.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

For more guidance and templates for the tender documents, *see the PPI procurement documents [ODT format].*

4. Additional cost eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions *(e.g. regarding access to background, licensing etc.)* if these:
    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and

– price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2014/24/EU, 2014/25/EU[128] and 2009/81/EC normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2014/24/EU and 2014/25/EU[129]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[128] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[129] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[28]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24//EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
  - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - ***[OPTION for PCP: an assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP)****]****;*
- ***[OPTION 1 by default (two pre-financing payments):*** *the coordinator must submit in month [**Y**] a progress report containing:*
  - *a '**periodic summary technical report**' for publication by the [Commission][Agency];*
  - *an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each subcontract financed by the procurement**, including data on each contractor that participated in the procurement, and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[**OPTION 1 for PCP:** at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[**OPTION 2 for PPI:** at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed — Assessment of the results

What & When? For PCP/PPI actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after the evaluation for each PCP phase) — submit to the Commission/Agency information on:

- the total number of bids received
- the evaluation of tenders and
- the winning tenderer(s) and abstracts of the winning tenders (using the following template [ODT])

The information must be complemented by the coordinator at the end of the action (and, for PCP actions, also at the end of each PCP phase) by submitting an assessment of the results and conclusions (using the following template [ODT]).

How? The information must be submitted via the Funding & Tenders Portal Continuous Reporting Module.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[38]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[39]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.2a <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities[.][;]

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment**, including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.3 Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

[…]

[38] Month X should be the end of the preparation phase and submission of second pre-financing request.
[39] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

What & When? For PCP/PPI actions, the coordinator must submit a periodic report after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress

- summary for publication
- questionnaire (i.e. the structured information requested)
- call for tender documents (including contract notice, invitation to tender and procurement contracts)
- report on outcome of the preparation phase *(e.g. open market consultation)*
- commitment on availability of funds (Annex 7)

  This ensures that the PCP/PPI subcontracting costs are covered.
- statement on the use of the previous pre-financing instalment (Annex 8)

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 7*)

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Funding & Tenders Portal).

2. Reporting periods

Normally, PCP/PPI actions are divided into 2 reporting periods (with 2 pre-financing payments; *see Article 21*). The first reporting period corresponds to the preparation of the joint procurement; the second reporting period corresponds to the implementation and follow-up of the joint procurement.

Actions will exceptionally be divided into 3 reporting periods (with 3 pre-financing payments), if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments to be made — No interim payments

Normally, PCP/PPI actions are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since PCP/PPI pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for PCP/PPI actions are as follows:

- for the first pre-financing payment: the percentage of the maximum grant amount foreseen for the additional networking and coordination activities related to the preparation of the call for tender
- for the second pre-financing payment: if needed, up to 100% of the remaining part of the grant (minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP/PPI actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 EJP Cofund MGA deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing payment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 EJP Cofund MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the H2020 Work Programme)*.

EJP Cofund actions are funded in all Parts of Horizon 2020 and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Funding & Tenders Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[7] (‘**starting date of the action**’).

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). The duration can however NOT exceed 84 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a].]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

For the FEJP action, there are moreover 3 additional specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Thus, the EJP Cofund MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION 2**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1 **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] *(**unit costs**).]***

[OPTION 2: specific cost category(ies)**: not applicable.]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.

[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[130].

2. Cost forms

For EJP Cofund actions, the **cost forms** are in principle the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however 3 specific unit costs for category F 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [131]

[130] *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

[131] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[16]***]][OPTION 2: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[16] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, EJP grants have the following **specificities**:

- for category A 'personnel costs'

  Costs of students, PhDs and other researchers (under scholarship, internship or similar agreement) — Are eligible even if the agreement is training-oriented (or work-oriented but with a non-negligeable training component), the costs fulfil the eligibility conditions set out in Article 6 and Annex 1 explicitly includes the training activities.

- for category D.2 'equipment costs'

  There is a special cost category for the FEJP action: full purchase cost for JET equipment *(see below)*.

- for category F 'specific cost categories'

There are special cost categories for the FEJP action: specific cost categories *(see below)*.

The annotations below will be limited to these special cost categories for the FEJP action (and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated).

D. Other direct costs ***[(not covered by Point F)]***

[…]

D.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]: *The* ***costs of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018*: The* ***costs of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand)* ***to be included in the JET facilities*** *are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** under category D.2 'equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional** cost eligibility **conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. ***[OPTION 1: [Insert name of specific cost category(ies)]][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION 1a for specific unit costs (if unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[22]] *are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION 2: *not applicable]*

[…]

[22] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the Fusion programme EJP Cofund action (FEJP), there are however 3 additional specific cost categories set out in Decision C(2013) 8201[132] available:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Double funding risk — Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 Specific cost category – costs for mobility of personnel (F.2)

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (irrespective of their duration) to another research institution, in a location other than their normal place of employment, by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance.

[132] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party, but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. category A 'personnel costs' or D.3 'other goods and services'; *see Article 6.2.A, 6.2.D.3*).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; Article 6.2.E).

1.1.2.1 Until 31 December 2018, the costs had to be **declared as** the unit costs fixed by Decision C(2013) 8201[133] and set out in Annexes 2 and 2a of the GA.

This was:

– for the daily subsistence allowance: **EUR 127,65**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[134]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106,4	Italy	104,2
Bulgaria	58,4	*Italy Varese*	93,4
Croatia	80,0	Latvia	77,6
Cyprus	84,1	Lithuania	71,5
Czech Rep.	80,6	Malta	83,3
Denmark	135,3	Netherlands	105,3
Estonia	77,6	Poland	74,2
Finland	122,1	Portugal	83,5
France	117,7	Romania	68,8
Germany	95,8	Slovakia	79,7
Germany Bonn	94,1	Slovenia	85,3
Germany Karlsruhe	93,8	Spain	97,1
Germany Munich	106,4	Sweden	131,9
Greece	90,5	*Switzerland Geneva*	124,6
Hungary	78,3	*Switzerland Berne*	123,3
Ireland	110,6	United Kingdom	147,8
		UK Culham	112.5

[133] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

[134] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) were applied as from 1 January 2016:

Country/place	Coefficient	Country/place	Coefficient
Austria	105,9 %	Italy	99,4 %
Bulgaria	52,1 %	*Italy Varese*	92,2 %
Croatia	74,6 %	Latvia	74,2 %
Cyprus	77,3 %	Lithuania	69,0 %
Czech Rep.	73,4 %	Malta	84,5 %
Denmark	131,8 %	Netherlands	107,8 %
Estonia	78,0 %	Poland	71,8 %
Finland	119,7 %	Portugal	79,2 %
France	114,6 %	Romania	64,8 %
Germany	96,6 %	Slovakia	76,4 %
Germany Bonn	93,4 %	Slovenia	81,2 %
Germany Karlsruhe	93,8 %	Spain	90,2 %
Germany Munich	106,0 %	Sweden	127,9 %
Greece	79,9 %	*Switzerland*	142,4 %
Hungary	69,0 %		
Ireland	116,6 %	United Kingdom	166,9 %
		UK Culham	127,7 %

– for the monthly subsistence allowance: between **EUR 0 and 720,27**, per individual per month **—** depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82,05**
> 300	**145,86**
> 500	**237,05**
> 800	**382,92**
> 1 300	**601,73**
> 2 000	**720,27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 252,81**, per dependent child per month).

The European Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this case, the FEJP GA will be **amended** (and the Annotated MGA will be revised accordingly).

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. category D.1 'travel'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.2.2 From 1 January 2019 onward, the costs must be **declared as** the unit costs fixed by Decision 30 January 2019[135] and set out in Annexes 2 and 2a of the GA.

This is:

– for the daily subsistence allowance: **EUR 138,15**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 January 2019) (Belgium and Luxembourg = 100)[136]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.3	Italy	97.3
Bulgaria	53.4	*Italy Varese*	90.9
Croatia	74.9	Latvia	74.9
Cyprus	74.4	Lithuania	74.3
Czech Rep.	78.3	Malta	86.5
Denmark	133.9	Netherlands	108.3
Estonia	80.3	Poland	70.6
Finland	119.9	Portugal	82.4
France	114.8	Romania	63.9
Germany	97.5	Slovakia	77.3
Germany Bonn	93.9	Slovenia	81.5
Germany Karlsruhe	94.6	Spain	88.7
Germany Munich	107.5	Sweden	127.9
Greece	79.9	*Switzerland*	127.8
Hungary	74.5		
Ireland	119.8	United Kingdom *UK Culham*	133.5 100.5

– for the monthly subsistence allowance: between **EUR 0 and 779,52**, per individual per month — depending on the distance between the place where the individual was working before and the place of secondment

[135] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion19-20_en.pdf

[136] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**88.80**
> 300	**157.86**
> 500	**256.55**
> 800	**414.42**
> 1300	**651.23**
> 2000	**779.52**

– for the family allowance: **EUR 273,60**, per dependent child per month).

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and
  - one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation
    - another beneficiary, the ITER Organization or the European Joint Undertaking for ITER and the Development of Fusion Energy (Fusion for Energy)[137], where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127,65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

[137] ITER and and Fusion for Energy were added by decision of 06/12/2018

- the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment
- to this amount, add the following for each leg of the journey (outward and return):
  - for train travel: a maximum of 30 minutes for each leg
  - for air travel: a maximum of 2 hours for each leg.

  NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

- for the monthly subsistence allowance:

  amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

- for the family allowance:

  amount per unit (EUR 252,81) **x** number of actual months of secondment **x** number of dependent children

  The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

  '**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

  A full month can be one of the following two:

  - a **calendar month** *(e.g. 1 to 31 July inclusive)* or
  - a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

  If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127,65 = EUR 77 738,85*

*Monthly subsistence allowance: 20 months * EUR 382,92 (800< distance >1 300) = EUR 7 658,40*

Subtotal = EUR 85 697,25

** correction coefficient (2016) of 106.0 % (Germany Munich) = EUR 90 839,09*

*Family allowance: 20 months * EUR 252,81 = EUR 5 056,20*

Total declared unit costs: EUR 95 895,29

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127,65 = EUR 382,95*

** correction coefficient (2016) of 127,7 % (Culham, UK) = EUR 489,03*

Total declared unit costs: EUR 489,03

1.2 Specific cost category – costs for fellowships for researchers (F.2)

1.2.1 **What?** This budget category **covers** direct costs for FEJP researcher fellowships, by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility.

⚠ The unit cost for fellowships for researchers was applicable ONLY until 31 December 2018. It has been discontinued since then.

What not? This budget category does not cover direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; *see Article 6.2.E*).

1.2.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[138] and set out in Annexes 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [139]:

Country	Coefficient	Country	Coefficient
Austria	104,8%	Italy	106,7%
Belgium	100,0%	Lithuania	73,1%
Bulgaria	71,5%	Luxembourg	100,0%
Cyprus	91,8%	Latvia	75,9%
Czech Republic	83,8%	Malta	89,6%
Germany	98,8%	Netherlands	104,3%
Denmark	135,3%	Poland	76,4%
Estonia	78,3%	Portugal	89,1%
Greece	92,7%	Romania	68,3%
Spain	97,6%	Sweden	111,7%
Finland	116,6%	Slovenia	86,1%
France	111,0%	Slovakia	82,6%

[138] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.
[139] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Croatia	97,5%	United Kingdom	120,3%
Hungary	76,2%	Switzerland	113,1%
Ireland	113,5%		

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[140]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.
- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)
- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

These are calculated per individual per complete month (NO *pro-rata* payments).

[140] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 Specific cost category – access costs for research infrastructure (F.2)

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

> ⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4 H2020 General MGA)*. FEJP beneficiaries that that have obtained a positive ex-ante assessment may opt between declaring costs under:
>
> – category D.4 'capitalised and operating costs of large research infrastructure'
>
> or
>
> – category F.2 'access cost for research infrastructure'.

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, under category D.1 'travel'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be **declared as** the unit cost calculated in accordance with Decision C(2013) 8201[141] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{142})}{\text{average annual total quantity of access (over past two years}^{143})}$$

The averages must be based on:

– the beneficiary's certified or auditable historical data

– costs allocated to the installation according to the beneficiary's usual cost accounting practices and

[141] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

[142] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[143] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 of the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

As already mentioned above, access costs for installations contributed in-kind must be declared as actual costs under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

What & When? For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission/Agency (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How? The annual work plan must be uploaded directly in the Funding & Tenders Portal.

2. Deliverable: Summary progress report

What & When? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the explanation of the work carried out and the overview of the progress; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION 1 in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing payment****' (see Annex 8).****]***

[OPTION 2: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports for each reporting period (including the final one), with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **5** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing payment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a statement on the use of the first pre-financing payment *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a *[first]* **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a *[first]* pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to *[**OPTION 1 in case of a single pre-financing payment:** 5%][**OPTION 2 in case of two pre-financing payments:** 2,5%]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

***[OPTION in case of a second pre-financing payment:** The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 = net payment of EUR 3 250 000*

1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU budget credits)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

'**Framework partnerships**' are long-term co-operations that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)) and for PCP/PPI actions. Framework partnerships are currently not (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

4.0 As from GA 4.0 FPA/SGAs are also possible for PCP/PPI actions. This does NOT apply to older grant agreements.

> ⚠ The FPA/SGA therefore now covers both research and innovation actions or innovation actions *with* a PCP or PPI and PCP/PPI actions (separate type of action with PCP/PPI as *main* action task).

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP	3		
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PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING	33		27
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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement)
- Article 63.2 (FPA/SGA rules on dispute settlement).

For more guidance on framework partnerships, *see the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name** (**short name**)**]**, established in [official address in full] ***[OPTION for partners with VAT**: VAT number [insert number],] [**OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding (see Article 14),]* represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] (**short name)**], established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number],]*

*[**OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not receiving EU funding (see Article 14),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties have agreed to enter into the framework partnership under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Participants: Coordinator — Partners — Linked third parties — Third parties involved in the action

In FPAs and SGAs the beneficiaries are called '**partners**' (because technically speaking they become beneficiaries only once an SGA is signed).

⚠ **Same partners at FPA and SGA level** — Partners must generally be the same at FPA and SGA level. However, partners/linked third parties that do not want to actively participate in a specific action, may participate as **partners not carrying out action tasks** and will not have to comply with most of the obligations under that SGA *(see Preamble SGA).*

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed directly in Funding & Tenders Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as **third parties involved in the partnership**.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions (**third parties involved in the specific actions**).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION 1 by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION 2 if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across partners of different framework partnerships]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and the Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions (**action plan**).

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all Parts of Horizon 2020.

4.0 Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2)* and PCP- PPI actions; Framework partnerships are currently NOT (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options were inserted in the FPA):

- **with competition (calls for proposals):**
  - **open to all partners** for which this type of activity is included in the FPA action plan

    Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

    Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

  - **open to all applicants** meeting the criteria

Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **without competition**:
  - **invitations to submit a proposal**

    Such invitations can only be issued in one of the following cases:

    - in monopoly situations or where partners are designated in the basic act
    - if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
    - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals
  - **submission** of a proposal **by a certain date**

    This option can be included in the FPA only if it is provided for in the work programme/call.

    The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 Rules of Application Regulation No 1268/2012).

1. Framework partnership starting date

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA.

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Framework partnership duration

The framework partnership duration may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Programme)*.

The FPA duration can NOT be extended (i.e. it is not possible to request an amendment extending the duration). The duration of an FPA only determines the moment up to which SGAs can be signed. The SGAs can still be implemented after the end of the framework partnership.

All SGAs must be signed before the end of the FPA.

⚠ Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA has ended.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

[OPTION 2:** Not applicable**]

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

⚠ If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — **specific consortium agreements for each SGA**. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the framework partnership implementation is suspended, all specific actions are also suspended (see Article 55) — from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to GA suspension *(see Article 49 H2020 General MGA)*.

FPA suspension automatically supends all on-going specific actions.

Amendments (to resume the action) after a suspension can NOT have the effect of extending the FPA duration set out in Article 3 FPA.). The duration of an FPA only determines the moment up to which SGAs can be signed An SGA can be implemented *after* the end of the framework partnership.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. FPA termination

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ FPA termination has NO effect on ongoing SGAs (— unless they are also terminated; *see Article 56 FPA and Article 20 SGA*). Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA is terminated.

2. Beneficiary termination

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ **Different partners at FPA and SGA level (exceptional)** — Beneficiary termination may lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners/linked third parties can participate as partners not carrying out action tasks for certain specific actions.

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also shows, if applicable, the estimated costs of the partners not receiving EU funding, if applicable (see Article 7 SGA) and of the international partners (see Article 12a SGA).

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and* ***forms of costs*** *of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions, applicable per budget category, are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **eligibility conditions** and **calculation rules**.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, eligibility conditions and calculation rules of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

Linked third parties must already be identified in the FPA *(see Article 19 FPA)*. Their specific activities must then be set out in the specific actions.

Examples:

1. *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

2. *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like the partner they are linked to.

Linked third parties can NOT however do more than their partners: If a linked third party wants to participate in a specific action, its partner must also be active in that action (i.e. NOT be partner not carrying out action tasks). If the partner does not want to, the linked third party could itself become a partner of the FPA and SGA (— after the consortium composition is changed).

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the Agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the Agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must first submit a request for the FPA amendment (which will automatically include the change in the consortium composition for the SGAs — the new beneficiary is added (automatically) as 'inactive' to all signed SGAs under that FPA).

The coordinator must then request for each SGA a separate amendment to activate the new beneficiary *(e.g. to change Annex 1, Annex 2)*.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

63.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Framework Partnership Agreement or a Specific Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU partners (except partners established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU partner(s) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for partners not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: As an exception, *for the following partners:*

- *[insert name of international organisation or partner not eligible for EU funding]*
- *[insert name of international organisation or partner not eligible for EU funding]*

[same for other partners that are international organisations or partner not eligible for EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Framework Partnership Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 50, 51 and 52), the partners must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must always be brought against the Commission (not against the Agency — even in Agency specific grants).

1. Dispute settlement

The rules on dispute settlement are similar to those of the General MGA *(see Article 57.2 H2020 General MGA)*.

However for FPAs, the Commission/Agency will determine already at FPA-level which partners must participate as 'beneficiaries not receiving EU funding' — because of a general issue with the jurisdiction clause (i.e. Belgian courts). Those beneficiaries can NEVER receive EU funding.

All other partners' status will be determined at SGA-level. Thus, partners from eligible countries (EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme) may participate as normal partners or as 'partners not receiving EU funding'. Partners from non-eligible countries may participate as 'partners not receiving EU funding' or — exceptionally — be granted funding.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name** (**short name**)],established in [official address in full], *[**OPTION for partners with VAT:** VAT number [insert number]], [**OPTION for coordinators not receiving EU funding:** as 'partner not receiving EU funding' (see Article 7),]* represented for the purposes of signing the Specific Agreement by [function, forename and surname],

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 FPA and Article 62 FPA):

2. [**full official name**] (**short name**)], established in[official address in full], *[**OPTION FOR partners with VAT:** VAT number [insert number]],*

***[OPTION for partners not carrying out action tasks under this SGA**: X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not carrying out action tasks',]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT :** VAT number [insert number]], as 'partner not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 5)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Additional information on the estimated budget

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[OPTION if the JRC participates: *Annex 5: Administrative Arrangement]*

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Partners — Partners not carrying out action tasks under the SGA — Linked third parties

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

⚠ **Same partners at FPA and SGA level** — Partners must generally be the same at FPA and SGA level. An entity that is not partner/linked third party in the FPA cannot become party in the SGA. Conversely, all partners/linked third parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners (and linked third parties) who do NOT actively participate in a specific action are **partners not carrying out action tasks** under that Specific Agreement (and must be identified as such in the preamble to the SGA).

⚠ **Partners not carrying out action tasks —** They formally participate in the action as partners, but NOT with any action tasks or EU funding. In practice, most of the obligations therefore do not apply to them for that specific action.

Linked third parties — If a partner participates as not carrying out action tasks, its **linked third parties** get the same status. They can NOT actively participate in the specific action (— unless they themselves become partners of the FPA and SGA).

These partners are formally part of the consortium for the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will be identified in Annex 1 as 'partners not carrying action tasks' (as they do not carry out any action tasks). Moreover, they will also be mentioned in Annex 2 with zero costs.

Formally, the rights and obligations under the FPA and SGA fully apply to them. In practice however, many of them *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, financial or technical audits or reviews, IPR results, access to background and results of others, etc.)* are NOT applicable because these partners do not carry out action tasks and do not receive any EU funding. Other obligations remain relevant *(e.g. checks, information obligations, confidentiality)*.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed directly in the Funding & Tenders Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including **linked third parties**) are considered as **third parties involved in the specific action**.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the specific action will be [insert number] months as of *[OPTION 1 by default: the first day of the month following the date the Specific Agreement enters into force (see Article 21)] [OPTION 2 if needed for the action: insert date]* ('starting date of the action').

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.Normally, the SGA starting date should also be after the entry into force of the FPA (because one presumes the other). However, in justified cases, it is possible to exceptionally fix an SGA starting date before the entry into force of the FPA (i.e. retroactive).

If the consortium requests a starting date before the entry into force of the FPA, it assumes the risks implied by starting the action before the FPA and SGA are signed (in particular not being reimbursed for the costs incurred, *e.g. if the proposal is not successful or that the FPA/SGA are not signed*).

⚠ The SGA action starting date can in any case **NEVER** be **before** the **submission** of the SGA proposal.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

Same partners at FPA and SGA level — If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump Sum MGAs

IX.1 Background information and approach

The General Lump Sum Model Grant Agreement (H2020 General Lump Sum MGA) is used mainly for coordination and support actions (CSA) and, exceptionally, for research and innovation actions (RIA) and innovation actions (IA) — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5*

The Lump Sum Pilot Model Grant Agreement (H2020 Lump Sum Pilot MGA) is used in a limited number of cases provided for in the work programme/call.

Example: *Specific call within the Nanotechnologies, Advance Materials, Biotechnology and Advance Manufacturing and Processing topic DT-NMBP-20-2018*

The General Lump Sum MGA follows the General MGA for numbering and content, except for:

The H2020 General Lump Sum MGA deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The MGA Lump Sum Pilot follows the General MGA for numbering and content, except for:

The H2020 Lump Sum Pilot MGA deviates from the General MGA as follows:

- Article 4 (estimated lump sum breakdown and transfers)
- Article 5 (grant amount and form of grant)
- Article 6 (not applicable)
- Article 8 (resources to implement the action)
- Articles 10, 11, 12 (not applicable)
- Article 13 (subcontracting)
- Article 15 (financial support to third parties)
- Article 18 (keeping records)

- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 22 (specific procedure for extension of audit findings)
- Article 42 (not applicable)
- Article 47 (specific provision for suspension of payment deadline)
- Article 49 (specific provision for suspension of the action)
- Article 50 (specific provisions for termination)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement

The main difference between the General Lump Sum MGA and the Lump Sum Pilot MGA lies in the grant implementation mechanisms: the General Lump Sum MGA works with eligible costs and pre-financing payments (instead of interim payments); the Lump Sum Pilot MGA works with lump sum shares per work package and beneficiary (instead of eligible costs) and interim payments based on accomplished work packages.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply *(Articles 6, 10, 11, 12, 42 Lump Sum Pilot MGA)* or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5 General Lump Sum MGA, Article 43.3 Lump Sum Pilot MGA, Annexes)* will not be shown.

For the Lump Sum Pilot MGA, the Articles where the only difference is the removal of references to eligibility of costs *(e.g. Article 14, 14a, 17.1, 22.5, 41.2 – removal of CFS —)* or rejection of costs *(e.g. Articles 14.2, 15.3, 16.3, 18.2, 22.6)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 Lump Sum MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. General Lump Sum actions

What? General Lump Sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for it.

> For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Funding & Tenders Portal Online Manual and the H2020 grants fact sheets.*

CSA, RIA and IA Lump Sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of Horizon 2020 *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The General Lump Sum MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the General Lump Sum MGA:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA): 70%** of the action's eligible costs]*[8]*[**OPTION 3 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The General Lump Sum MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the EU reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The eligibility conditions are set out in *Article 6*. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For General Lump Sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For General Lump Sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, for General Lump Sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The General Lump Sum MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the action (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs' **covers** the (direct and indirect) costs for the action.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice, the declaration of costs for General Lump Sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

For General Lump Sum grants, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

⚠ If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the General Lump Sum MGA.

The special rules from the General MGA on third party involvement are limited in General Lump Sum actions to purchases (*Article 10*), subcontracting (*Article 13*), linked third parties (*Article 14*) and international partners (*Article 14a*).

By contrast, there are NO special rules for in-kind contributions (Articles 11 and 12). Beneficiaries may use any in-kind contributions from third parties if they are needed to carry out the work of the action.

⚠ For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[9] (or 2014/24/EU)[10] or 'contracting entities' within the meaning of Directive 2004/17/EC[11] (or 2014/25/EU)[12] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).
[10] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).
[11] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).
[12] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for General Lump Sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for General Lump Sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The General Lump Sum MGA has however the following **specificities**:

The estimated subcontracting costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[18]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For General Lump Sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the actions tasks (as described in Annex 1) were properly carried out.

The records and supporting documentation must:

- refer to the technical implementation of the action in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and

- prove that the tasks or parts of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs incurred are NOT needed.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.2a Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**statement on the use of the previous pre-financing instalment**', including the **request for a further pre-financing payment** (Annex 7).

20.3. Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2 :*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For General Lump Sum actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes the request for further pre-financing payments; *see Article 7*).

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Funding & Tenders Portal).

2. Reporting periods

General Lump Sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- a *[first]* **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- *[same for more pre-financing payments]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2a if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

General Lump Sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing instead of an interim payment).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

> The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.
>
> The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:
>
> – if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
>
> – if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.
>
> ***Example:***
>
> *Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.*
> *90% limit of the maximum grant amount: EUR 360 000.*
> *3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.*
> *Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.*
> *2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;*
> *3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;*
> *Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
> *70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
> *Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000*
> *3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.*

Payment of the balance

How much? The amount of the payment of the balance depends on the overall financial situation at the end of the action, and in particular:

- the amount of pre-financing(s) already paid *(see Article 21 H2020 General MGA)*
- cost rejections (improper implementation of the action; *see Article 42)*
- grant reduction (other serious breaches or substantial errors, irregularities or fraud *see Article 43)*.

ARTICLE 41 — BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Agency][Commission]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for General Lump Sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs does not lead to a **recovery,** *[Commission][Agency]* will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for General Lump Sum grants the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*, improper implementation leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ 'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide requested information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for General Lump Sum grants 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*, the grant can be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Agency or the]* Commission*]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION 2 :*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or*** **[OPTION 2:** *not applicable;*** **]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The General Lump Sum multi-beneficiary MGA has, however, the following **specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide requested information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Article 43 and Article 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA (see *Article 49 H2020 General MGA)*.

The General Lump Sum MGA has, however, the following **specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION 2:** not applicable]*;

(j) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION 2:** not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2).

*(n) [**OPTION 1**: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][**OPTION 2**: not applicable].*

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n)above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the [Commission][Agency]

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) ***[OPTION 1****: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks]****[OPTION 2****: not applicable].*

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or to beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The rules on GA termination are the same as in the General MGA *(see Article 50 H2020 General MGA)*.

2. Beneficiary termination (consortium)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the General Lump Sum multi-beneficiary MGA has the following **specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. GA or beneficiary termination (EU)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the General Lump Sum multi-beneficiary MGA has the following **specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IX.3 H2020 Lump Sum Pilot MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled [**insert title of the action**] — [**insert acronym**] ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation): *The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. Lump Sum Pilot actions

What? Lump Sum Pilot grants are used in a limited number of cases provided for in the work programme/call. They can be research and **innovation actions (RIA)**, **innovation actions (IA)** or **coordination and support actions (CSA)**.

Examples: *Specific call within the Nanotechnologies, Advance Materials, Biotechnology and Advance Manufacturing and Processing topic DT-NMBP-20-2018, some R&I activities in the rail sector (e.g. topics S2R-CFM-IP5-01-2018 and S2R-CFM-CCA-01-2018).*

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The '**estimated lump sum breakdown**' for the action is set out in Annex 2.

It contains the lump sum shares, per work package and beneficiary *[and linked third party]*.

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiaries. It shows the amounts that the *[Commission][Agency]* commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 can be adjusted by transfers of amounts between beneficiaries and/or work packages, via an amendment (see Article 55).

Transfers between work packages are however possible only if:

- the work packages are not already completed (and declared in a financial statement);
- the transfers are justified by the technical and scientific implementation of the action and
- a review in accordance with Article 22.1.2 confirms that the amendment does not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

1. Estimated lump sum breakdown

Since Lump Sum Pilot grants do not use eligible costs, the Lump Sum Pilot MGA does not have any budget categories. Instead, it has a breakdown of the lump sum, per work package and beneficiary.

The breakdown is used to determine:

- the share of the lump sum to which each beneficiary is entitled for each work package

  Example: *Annex 2 sets out EUR 200 000 for work package 1 (WP1). The consortium completed WP1 in the first reporting period as described in Annex 1. Therefore, the consortium declares EUR 200 000 for WP1 in the periodic reports of period 1. If the Commission confirms that the WP1 was completed as described in Annex 1, it will include EUR 200 000 in the periodic payment.*

- the maximum amount for which each beneficiary is liable (grant reduction) in case of improper implementation of a work package

  Example: *In the example above, the Commission carries out a review on the grant in the last reporting period. The review concludes that WP1 was not properly implemented because only part of the activities of that work package were actually carried out. The Commission will reduce the grant in proportion to the improper implementation of WP1 up to a maximum of EUR 200 000 (the share of the lump sum allocated to that work package).*

- the maximum amount for which each beneficiary is liable in case of improper implementation of a work package.

Example: *In the example above, the Commission carries out a technical audit on the grant after the payment of the balance. The audit concludes that WP2 (value also EUR 200 000) was not implemented as indicated in Annex 1. On those grounds, the Commission decides to reduce the grant. Beneficiaries A and B were together responsible for carrying out WP2 (according to Annex 2 beneficiary A for EUR 150 000 and beneficiary B for EUR 50 000). Therefore, each beneficiary will be liable for their proportion of the work package (e.g. in case of a 50% reduction, beneficiary A for EUR 75 000 and Beneficiary B for EUR 25 000).*

2. Lump sum share transfers

Unlike in the General MGA, transfers of Lump Sum Pilot shares are only possible via a formal amendment.

The transfer may be:

- within the same work package (i.e. increasing the share of a beneficiary and decreasing the share of another)
- between work packages (i.e. increasing the share allocated to a work package and decreasing the share of another).

Transfers between work packages can only be accepted in exceptional circumstances, if duly justified and after a project review .

Transfers from or to a work package which the consortium has already declared as completed in a reporting period are NOT allowed.

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR** [**insert amount** (insert amount in words)].

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The Lump Sum Pilot MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant** *(see Decisions C(2017)7149 and C(2017)7151)*.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be fixed taking into account the H2020 funding rates. This means that the lump sum fixed in Article 5 does not have to be multiplied again by the funding rate; it is already the net maximum EU funding.

The lump sum is one amount for the entire consortium.

There are no cost eligibility conditions. If the action is correctly implemented (in line with the description in Annex 1), the beneficiaries are entitled to receive the fixed lump sum amount.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** for the action and it can NOT be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiaries *[and linked third parties]* are added together.

The grant is reduced (see Article 43) for all other work packages (i.e. all work packages that have not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For Lump Sum Pilot grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation; see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For Lump Sum Pilot grants, the rules on the revised final grant amount are in principle the same as for the General MGA *(see Article 5.4 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services;
- use in-kind contributions provided by third parties against payment;
- use in-kind contributions provided by third parties free of charge;
- call upon subcontractors to implement action tasks described in Annex 1;
- call upon linked third parties to implement action tasks described in Annex 1;
- call upon international partners to implement action tasks described in Annex 1

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources —Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the Lump Sum Pilot MGA.

The General MGA rules on third party involvement are limited in Lump Sum Pilot actions to subcontracting (*Article 13*), linked third parties (*Article 14*) and international partners (*Article 14a*).

The articles for purchases (*Article 10*) and in-kind contributions (*Articles 11* and *12*) are not applicable to the Lump Sum Pilot MGA. Beneficiaries may make purchases and use any in-kind contributions from third parties following their internal practices but not subject to other rules (as long as they are needed to carry out the work of the action).

⚠ For all types of third party involvement (purchases, in-kind contributions, subcontracts, linked third parties and international partners), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Specific rules for subcontracting action tasks

Subcontracting may cover only a limited part of the action.

The tasks to be implemented for each subcontract must be set out in Annex 1. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

***[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for Lump Sum Pilot actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The Lump Sum Pilot MGA has however the following **specificities**:

The estimated subcontracting costs do NOT need to be included in Annex 1 or shown in the table of estimated costs in Annex 2 (there is no such table for the Lump Sum Pilot; Annex 2 is not the budget, but the estimated lump sum breakdown). By contrast, the tasks to be subcontracted must still be indicated in Annex 1, as it happens in the General MGA

The principles of best value for money and no conflict of interest are not explicitly mentioned in Article 13. Nonetheless, they must still be complied with and confirmed by the beneficiaries at proposal stage.

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations which occurred at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.*

*The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION 2: *Not applicable**]***

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.*

*The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION 2: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable**]***

1. Financial support to third parties

The rules for financial support to third parties in Lump Sum Pilot actions are in principle the same as in the General MGA *(see Article 15 H2020 General MGA)*.

Thus, although the minimum conditions for granting financial support are not explicitly listed in Article 15 of the Lump Sum Pilot MGA, they must still be complied with (and confirmed by the beneficiaries at proposal stage).

Moreover, like under General MGA, the proposal must fix the criteria that the beneficiaries intend to apply for their cascading grants (i.e. no more than EUR 60 000 maximum amount per recipient, the criteria for determining the exact amount of support, the types of activities, the categories of recipients and the conditions for giving support) and this description will also become part of Annex 1 of the GA.

The obligations in Article 15.1 and 15.2 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants:*** *three]* years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

Records and other supporting documentation on the scientific and technical implementation of the action must be in line with the accepted standards in the respective field.

The beneficiaries do not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For Lump Sum Pilot actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep appropriate and sufficient evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

The records and supporting documentation must:

- refer to the technical implementation of the action, in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and
- prove that the tasks or part of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs actually incurred are NOT needed.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

[…]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including work packages, milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must declare the lump sum shares indicated in Annex 2, for the **work packages** that were completed in the reporting period.

For the last reporting period, the beneficiaries may exceptionally also declare partial lump sum shares for work packages that were not completed (e.g. due to scientific or technical reasons), if agreed by the *[Commission][Agency]*.

Lump sum shares which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the work packages have been completed and that the action in general has been properly implemented (see Article 7);
- the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) an **explanation of the use of resources**: not applicable;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action.

(b) a '**final financial report**' containing a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the financial statements for all reporting periods and including the **request for payment of the balance**.

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

Financial statements must be drafted in euro.

[…]

1. Reports

What & When? For Lump Sum Pilot actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Each report is composed of a technical and a financial report (like in the General MGA). However, unlike in the General MGA, beneficiaries do not declare costs but their lump sum shares (as set out in Annex 2), for the work packages completed during that reporting period.

Work packages can be declared only once fully completed (as described in Annex 1). If a work package is carried out by several beneficiaries, they cannot declare it until all of them have completed it.

Example:

Grant for a consortium with a maximum grant amount of EUR 3 000 000 and the following breakdown per work package and beneficiary:

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Annex 1 of the grant agreement indicates that at the end of the first reporting period WP1, WP2 and WP3 should have been completed. WP4 and WP5 should have been initiated.

At the end of the first reporting period (RP1) the actual situation is as follows:

	WP1	WP2	WP3	WP4	WP5
Beneficiary A	Completed			Initiated	Initiated
Beneficiary B		Completed	Completed	Not initiated	
Beneficiary C	Completed	Initiated		Initiated	
Beneficiary D		Completed		Completed	

Since the beneficiaries can only declare completed work packages, they can only declare the amounts for WP1 and WP3. They cannot declare any amount for the WP2, WP4 or WP5, even if they are initiated, because they are not completed.

Partial work packages are allowed only in the following two situations:

- beneficiary termination — terminated beneficiaries may declare (in the termination report) shares for on-going work packages, provided that their part was completed in accordance with Annex 1 *(see Article 50)*.

- last reporting period — at the end of the action, beneficiaries may exceptionally also declare partial shares for work packages that were not completed, for example due to technical reasons.

Best practice: In case of doubt, the coordinator should contact the Commission/Agency about partial work packages.

The Commission/Agency will **NOT** accept partial lump sum shares in the last reporting period if:

- the situation could have been solved via an amendment

  Example: *The consortium argues that they did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the consortium to have enough time.*

- non-implementation is linked to financial reasons

  Example: *The project resulted to be more expensive than initially expected and the consortium decided to stop the work in some WPs.*

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Funding & Tenders Portal).

In practice, the following steps will apply for the financial part:

Step 1 — The coordinator will indicate in the Funding & Tenders Portal which work packages have been fully accomplished during the reporting period.

Step 2 — The beneficiaries will have to sign individual financial statements to confirm proper implementation of those work package(s) and submit them to the coordinator. All of them will be part of the financial report for the reporting period concerned.

Step 3 — The coordinator will submit both the technical and the financial report to the Commission/Agency.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.3 Interim payments — Amount — Calculation

Interim payments pay the lump sum shares for work packages completed during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Work packages that have not been completed in time or cannot be approved at the time of an interim payment may be submitted (again) for the next reporting period (or any other future reporting period, after they have been completed).

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiaries *[and linked third parties]* for the concerned reporting period are added together.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining lump sum shares for the implementation of the action.

If the total amount of earlier payments is greater than the **final grant amount** (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Incomplete work packages and work packages that have not been delivered or cannot be approved at the payment of the balance will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for that beneficiary, in the estimated lump sum breakdown (see Annex 2).

[…]

1. Payments to be made

The rules on payments are in principle the same as in the General MGA (one pre-financing payment, interim payments at the end of each reporting period, and a final payment of the balance).

2. Payment calculations — Amounts due — Recoveries?

Interim payments

How much? The amount of the interim payments will be calculated by the Commission/Agency on the basis of the financial statements and the payments already made.

The rules follow those of the General MGA *(see Article 21.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up the lump sum shares for the accepted work packages for this reporting period (the lump sum shares in Annex 2 already take into account the reimbursement rate; no need to apply it again). Partial work packages will NOT be accepted; the entire work package (i.e. work of all beneficiaries) needs to be done.

Beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Commission/Agency on the basis of the termination report, the payments already made and the report on the distribution of payments.

The rules follow those of the General MGA *(see Articles 21.3, 44.1.1, 50.2.2 and 50.3.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares for the beneficiary's accepted work packages. Partial work packages can be accepted (i.e. shares for work packages where the beneficiary's part is completed).

Exceptionally, the Commission/Agency may accept also *part* of a lump sum share for a work package in which the beneficiary has not carried out all its tasks.

> ***Example:*** *The beneficiary requests terminating its participation in the action because a fire devastated its laboratory where most of the technical equipment and computers used for the action were located. Therefore, the beneficiary cannot complete its tasks in the on-going work packages due to force majeure (see Article 51 H2020 General MGA). On those grounds, the Commission decides to accept for that beneficiary a part of the lump sum shares for the on-going work packages proportionate to the tasks carried out by the beneficiary in those work packages.*

Not completed work packages (or not completed parts of them) can be finished and declared later on.

Example for calculating the amount due at beneficiary termination:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

The participation of beneficiary B is terminated before the end of the first reporting period. At the time when the termination takes effect beneficiary B had fully completed its tasks for WP2 and WP3 and initiated its tasks for WP4. The coordinator had transferred EUR 650 000 as pre-financing to beneficiary B.

Amount due:

Lump sum shares for accepted work packages: WP2 + WP3 = EUR 600 000.

Beneficiary B amount due: EUR 600 000.

Beneficiary balance:

Payments received by beneficiary B (according to the report on the distribution of payments): EUR 650 000.

Beneficiary B balance: EUR 600 000 (amount due) - EUR 650 000 (payments received) = EUR -50 000 (excess payments of EUR 50 000).

Recovery:

Amount to be recovered from beneficiary B: EUR 50 000 (negative balance of EUR 50 000 must be returned to the consortium; otherwise Commission/Agency will start a recovery procedure).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Commission/Agency on the basis of the financial statements, the final grant amount, the payments already made and the report on the distribution of payments

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs but simply sums up all the lump sum shares for the accepted work packages. Partial work packages can exceptionally be accepted (i.e. shares for work packages that were not completed, for example due to technical reasons).

The Commission/Agency will **NOT** accept partial lump sum shares in the last reporting period if:

- the situation could have been solved via an amendment

  Example: *The consortium argues that they did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the consortium to have enough time.*
- non-implementation is linked to financial reasons

  Example: *The project resulted to be more expensive than initially expected and the consortium decided to stop the work in some WPs.*

Steps 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to Lump Sum Pilot grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Example for calculating the payment of the balance:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Case 1:

At the end of the action, WP7 was not completed as described in Annex 1. The Commission decides to reduce 50 % of WP7, corresponding to the proportion of the undelivered part of that work package. All other work packages were completed as described in Annex 1. In addition, the consortium breached an important confidentiality obligation under Article 36. The Commission decides to reduce the maximum grant amount by 10 % for that reason.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP2 + WP3 + WP4 + WP5 + WP6 + 50 % WP7 + WP8 = EUR 2 900 000.

Amount resulting from Step 1: EUR 2 900 000.

Grant reduction for other breaches: 10% grant reduction for the action = maximum grant amount – 10 % (reduction) = 3 000 000 – 300 000 = EUR 2 700 000.

Amount resulting from Step 2: EUR 2 700 000.

Lower amount of the two: EUR 2 700 000.

Final grant amount: = EUR 2 700 000.

Case 2:

The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable. The termination takes effect before the end of the first reporting period. At the moment of termination the state of play of each work package is as follows:

	WP1	WP2	WP3	WP4	WP5	WP6, WP7, WP8
Beneficiary A	**Completed**			Initiated	Initiated	Not initiated
Beneficiary B		**Completed**	**Completed**	Not initiated		Not initiated
Beneficiary C	**Completed**	Not initiated		Not initiated		Not initiated
Beneficiary D		**Completed**		**Completed**		Not initiated

In the reports, the consortium justifies that for WP2 the work of beneficiary B and beneficiary D were fully accomplished in accordance with Annex 1, that the work of beneficiary C in this work package was ancillary and that beneficiary C stopped in fact collaborating in the action. On those grounds, the Commission accepts exceptionally 370 000 EUR for WP2.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP2 (part) + WP3 = 350 000 + 370 000 + 350 000 = EUR 1 070 000

No grant reductions for other breaches.

Final grant amount: EUR 1 070 000.

Case 3:

Work package 2 was not carried out (i.e. representing a total lump sum share of EUR 470 000) and therefore the Commission reduced the grant accordingly.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP3 + WP4 + WP5 + WP6 + WP7 + WP8 = EUR 2 530 000.

No grant reductions for other breaches.

Final grant amount: EUR 2 530 000 (➔ beneficiary shares: A = EUR 1 150 000; B = EUR 650 000; C = EUR 430 000; D = EUR 300 000).

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 530 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR -170 000 (excess payments of EUR 170 000).

Offsetting against Guarantee Fund release: EUR 170 000 - EUR 150 000 = EUR 20 000

Recovery:

Amount to be recovered from the consortium: EUR 20 000 (negative balance of EUR 20 000 must be paid back by coordinator, otherwise Commission will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from coordinator:

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 977 500; B= EUR 765 000; C = EUR 450 500; D= EUR 357 000).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

*A: {(EUR 1 150 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 1 150 000 (share in the final grant)} - EUR 977 500 (payments received) = EUR 172 500 (no payment in excess)*

*B: {(EUR 650 000 / (1 150 000 + 650 000 + 430 000 +300 000)) * 2 530 000 = EUR 650 000 (share in the final grant)} - EUR 765 000 (payments received) = EUR -115 000 (excess payment of EUR 115 000)*

*C: {(430 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 430 000 (share in the final grant)} - EUR 450 500 (payments received) = EUR -20 500 (excess payment of 20 500)*

*D: {(300 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 300 000 (share in the final grant)} - EUR 357 000 (payments received) = EUR -57 000 (excess payment of EUR 57 000).*

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 192 500.

B: 115 000/192 500 = 59.74 %.

C: 20 500 /192 500 = 10.65 %.

D: 57 000/192 500 = 29.61 %.

Total to be recovered: EUR 20 000.

B: 59.74 % x 20 000 = EUR 11 948

C: 10.65 % x 20 000 = EUR 2 130

D: 29.61 % x 20 000 = EUR 5 922

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Commission/Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 2 (Grant reductions) applies.

All other steps follow the General MGA *(see for the calculations Article 21 H2020 General MGA)*.

Example for calculating recoveries after payment of the balance:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Case 1:

Final grant amount:

Final grant amount: EUR 1 150 000 + EUR 900 000 + EUR 530 000 + EUR 420 000 = EUR 3 000 000.

The Commission carries out a technical audit on the action and finds out that beneficiary B did not carry out its activities under the work package 4 (lump sum share EUR 50 000). The Commission therefore reduces the grant by EUR 50 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 900 000 (accepted lump sum shares) — EUR 50 000 (rejected lump sum shares) = EUR 850 000
Beneficiary B revised final grant amount: EUR 850 000.
The other beneficiaries final grant amounts (i.e. their final grant amount shares) remain unchanged.

Beneficiary balance:
The share of beneficiary B in the final grant amount = EUR 900 000 / 3 000 000 x 3 000 000 = EUR 900 000.
Balance: EUR 850 000 (revised final grant amount) – EUR 900 000 (final grant share) = EUR -50 000 (excess of EUR 50 000).
Recovery:
Amount to be recovered from beneficiary B: EUR 50 000 (negative balance of EUR 50 000 must be paid back by the beneficiary).

Case 2:

Same example as above, but in this case a reduction of the maximum grant amount had been performed at the time of the payment of the balance as follows: the consortium breached a confidentiality obligation under Article 36 and the Commission reduced the maximum grant amount by 10 % for that reason (i.e. EUR 3 000 000 – 10 % = EUR 2 700 000).

Final grant amount:

Final grant amount: = EUR 2 700 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 900 000 (accepted lump sum shares) — EUR 50 000 (rejected lump sum shares) = EUR 850 000.

Beneficiary B revised final grant amount: EUR 850 000.

Beneficiary balance:

The share of beneficiary B in the final grant amount = EUR 900 000 / EUR 3 000 000 x EUR 2 700 000 = EUR 810 000.

Balance: EUR 850 000 (revised final grant amount) – EUR 810 000 (final grant share) = EUR 40 000 (no excess).

Recovery:
No recovery.

Case 3:

Final grant amount:

Final grant amount: EUR 1 150 000 + EUR 900 000 + EUR 530 000 + EUR 420 000 = EUR 3 000 000.

The Commission carries out a technical audit on the action and finds out that work package 8 (EUR 600 000) has not been implemented as described in Annex 1 and decides to reject it.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for the consortium & revised final grant amount:

Beneficiary A: 1 150 000 – 300 000 = EUR 850 000.

Beneficiary B: 900 000 – 150 000= EUR 750 000.

Beneficiary D: 420 000 - 150 000= EUR 270 000.

The EU contributions of beneficiary C remain unchanged.

Beneficiary balance:

The share of beneficiary A in the final grant amount = EUR 1 150 000.

The share of beneficiary B in the final grant amount = EUR 900 000.

The share of beneficiary D in the final grant amount = EUR 420 000.

Balance:

A: EUR 850 000 (revised final grant amount) - EUR 1 150 000 (final grant share) = EUR -300 000.

B: EUR 750 000 (revised final grant amount) - EUR 900 000 (final grant share) = EUR -150 000.

D: EUR 270 000 (revised final grant amount) - EUR 420 000 (final grant share) = EUR -150 000.

Recovery:

Amount to be recovered from beneficiary A: EUR 300 000 (negative balance of EUR 300 000 must be paid back by the beneficiary).

Amount to be recovered from beneficiary B: EUR 150 000 (negative balance of EUR 150 000 must be paid back by the beneficiary).

Amount to be recovered from beneficiary D: EUR 150 000 (negative balance of EUR 150 000 must be paid back by the beneficiary).

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

[…]

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement. […]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since Lump Sum Pilot grants do not use eligible costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since beneficiaries have no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the *technical* implementation of the action (in particular full accomplishment of the work packages as described in Annex 1 of the GA), or on other aspects of the grant agreement, *such as promoting the action, visibility of EU funding, ethics and research integrity, dissemination and exploitation of results, management of intellectual property, etc.*

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiaries that were audited.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — **after termination of a beneficiary's participation, at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for lump sum shares declared by its linked third parties)****]****,* except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(d) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(e) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum grant amount indicated, for the linked third party, in the estimated lump sum breakdown (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(f) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[34] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments, the *[Commission][Agency]* will:

(c) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's approved lump sum shares

[plus

its linked third parties' approved lump sum shares]},

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for approved work packages calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(d) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

[…]

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{beneficiary's approved lump sum shares

[plus

its linked third parties' approved lump sum shares]}

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for approved work packages calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

[...]

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial report has not been submitted or is not complete or additional information is needed, or

(c) there is doubt about amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will take effect the day notification is sent by the [Commission][Agency] (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be lifted — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the [Commission][Agency] if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the [Commission][Agency] may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA *(see Article 47 H2020 General MGA)*.

The Lump Sum Pilot MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for Lump Sum Pilot grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work package implementation).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the [*Commission*][*Agency*] the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiaries may not claim damages due to suspension by the *[Commission] [Agency]* (see Article 46).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA *(see Article 49 H2020 General MGA)*.

For *full* GA suspension (action is entirely suspended), all on-going work packages must be interrupted and NO new work packages may be started.

For *partial* GA suspensions other work packages may be continued and new work packages may be started(except for those covered by the suspension).

However, partial suspensions may have an indirect effect on other work packages, in the sense that it might not be possible to fully complete them (and thus not be possible to declare them for the reporting period — unless it is already the end of the action; *see Articles 20 and 21*).

Example: *A fire caused some damage to an equipment of a beneficiary which is used for a set of chemical 3D-analyses (large part of WP2) which are then needed for further experiments in WP4 and WP5. The consortium therefore requests that the part of the action that is affected (WP3) is suspended until the equipment is restored. The other beneficiaries may continue to work on the other work packages (WP4 and WP5). However, if these work packages cannot be fully completed at the end of the reporting period because the WP3 continues to be suspended, the lump sum shares for WP4 and WP5 cannot be declared by the beneficiaries.*

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

[…]

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), only lump sum shares included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21.4), on the basis of the reports submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

[…]

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages

The grant amount for the beneficiary is calculated by adding the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary *[and its linked third parties]* in the termination report.

Only lump sum shares for work packages fully completed by the beneficiary before termination will be approved — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the *[Commission][Agency]*

[…]

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), only lump sum shares included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4), on the basis of the reports submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(iv) a report on the distribution of payments to the beneficiary concerned;

(v) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated lump sum breakdown (see Annexes 1and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator, and

(vi) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work

The grant amount for the beneficiary is calculated by adding the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary *[and its linked third parties]* in the termination report.

Only lump sum shares for work packages fully completed by the beneficiary before termination will be approved — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

1. GA termination (consortium or EU)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21*).

2. Beneficiary termination (consortium or EU)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

Ethics in Social Science and Humanities

October 2018

Disclaimer
This document has been drafted by a panel of experts at the request of the European Commission (DG Research and Innovation) and aims at raising awareness in the scientific community, and in particular with beneficiaries of EU research and innovation projects. It does not constitute official EU guidance. Neither the European Commission nor any person acting on their behalf can be made responsible for the use made of it.

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1. Introduction

This document aims to help researchers in social sciences and humanities (SSH) identify and address ethical dimensions when involved in research and innovation actions financed by the EU Framework Programme. It is also designed to help the wider research community deal with the ethical issues that may arise in interdisciplinary research using SSH methodology. Used together with other guidance documents provided by the European Commission, it should help you integrate research ethics in your proposal and your research.1

Rapid technological development and political upheavals in recent years have raised new research ethics concerns, requiring sensitivity to identify ethically problematic areas in SSH research. Increasing use of the internet and social media data in research methodology is a case in point. Crises outside the Europe Union (EU), coupled with migration, have given rise to new, socially important issues, requiring the involvement of new, potentially vulnerable groups of people in research, but also calling for social science research in crisis areas.2 The many important topics to be addressed by SSH research demand attention to research ethics. It is important to guarantee safe conditions for research participation for people who may benefit from research, but also for researchers themselves.

Much of the advice below is widely available in various literature and guidance documents published by funding bodies, communities of SSH researchers, learned societies and professional organisations. Their role continues to be central for SSH researchers. This document is designed to give practical advice on integrating ethics into the planned research by providing, wherever possible, checklists for points at which a pause is needed to reflect and plan the action to be taken.
While this document focuses on more formal aspects of research ethics compliance associated with SSH research, it also draws attention to ethics in research practice and day-to-day research work, and identifies ways to integrate ethical conduct in your research. Hence, it highlights two ethical dimensions of research:

'procedural ethics', pertaining to the aspects of compliance in performing research, and 'ethics in practice', the everyday ethical issues that arise while doing research.3
According to the European Charter for Researchers,

Researchers should focus their research for the good of mankind and for expanding the frontiers of scientific knowledge, while enjoying the freedom of thought and expression, and the freedom to identify methods by which problems are solved, according to recognised ethical principles and practices.4

Indeed, perhaps more than any other professionals, academic researchers enjoy great freedom to explore their professional interests, investigate a wide range of phenomena and set their own research agenda. In fact, respect for academic freedom is stipulated in Article 13 of the Charter of Fundamental Rights of the European Union5 (2000), which is legally binding on EU member states.
Academic freedom has its limits, however, and a researcher has considerable responsibility to

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[1] This text is a revised version of a Guidance Note written in 2010 to address the needs of applicants and evaluators under the 7th Framework Programme.
[2] For research involving refugees, please refer to the Guidance Note – Research on refugees, asylum seekers & migrants. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-refugees-migrants_en.pdf
[3] Marilys Guillemin & Lynn Gillam. (2004). 'Ethics, Reflexivity, and 'Ethically Important Moments' in Research. Qualitative Inquiry 10, p. 263.
[4] European Charter for Researchers. (2000). Available at: https://euraxess.ec.europa.eu/jobs/charter/european-charter
[5] Charter of Fundamental Rights of the European Union (2000). Available at: http://www.europarl.europa.eu/charter/pdf/text_en.pdf

- the people involved in the research and their rights, safety, well-being and interests (or dignity, integrity, rights, and autonomy)
- communities that are engaged and involved in the research; and
- society at large, in terms of the contributions research can make in effecting socially useful and valued development and change, but also in terms of avoiding potential misuse or unintended consequences of research results.

The European Charter for Researchers, moreover, calls attention to limitations to academic freedom that may arise through particular research circumstances (including supervision, guidance, management) or operational constraints, e.g. for budgetary or infrastructural reasons. The Charter reminds us that '*[s]uch limitations should not, however, contravene recognised ethical principles and practices, to which researchers have to adhere*.'

By acknowledging their responsibilities, social scientists help build and maintain the trust of various social groupings – whether research participants, collaborators, members of the public, or funding bodies – that is necessary to conduct social science research in the first place.

Social scientists commonly face ethical problems, and although ethics can be considered an everyday aspect of research practice, they are becoming more complex.[6] SSH research is dynamic, progressive and developmental, raising new issues and concerns as new foci for research evolve and new ways to collect and analyse data become possible. There is a need for ethically sensitive decisions at all stages of the research process. As a researcher, you are therefore encouraged to engage in continued reflection on any new ethical concerns that emerge while performing your work and on their potential implications for your own work, your research participants, communities and society in general. Moreover, you are encouraged to document and share such concerns within your project and your community of researchers.

Objectives of SSH research

Ethics review of all scientific projects start with the question of whether the research objectives raise any ethical questions. From the scientific point of view, every research proposal must address the question of why the planned research needs to be conducted, whether there is any new knowledge to be gained, and whether it is worth spending the time and money to obtain it. Justifying the conduct of any proposed research project means demonstrating that it will offer benefits to scientific understanding, to policy and/or to practice, or to social actors in general, thus making the resources spent on research worthwhile.[7]

2. General principles/underlying ethical principles

As a researcher you have an over-riding obligation to protect participants' welfare and safety and to ensure they are treated fairly and with respect.

Research participants' rights are anchored in fundamental human rights and the fundamental ethical principles that govern all scientific research. In the context of research funded by the European Commission, the key sources of EU and international law are the ***Charter of Fundamental Rights of the European Union*** and the ***European Convention on Human Rights (ECHR)*** and its Protocols (for other texts). Other important sources are the ***UN Declaration of Human Rights*** and the ***UN Convention on the Rights of Persons with Disabilities (UN CRPD)***. Additional central policies and widely accepted declarations that codify principles of research ethics and ethical treatment of

[6] Israel, Ibid., p.4.

[7] Ron Iphofen (2009). *Ethical Decision-Making in Social Research. A Practical Guide*, London: Palgrave Macmillan, p. 19. See also, Paul Ransome (2013). *Ethics & Social Values*, Palgrave Macmillan, pp. 30-32.

research participants include the ***Nuremberg Code***, the ***Helsinki Declaration***, and the ***Belmont Report***. Although these codes originate in the biomedical field, they encompass the central principles that apply to all human research. In addition, you are obliged to follow the national legislation of the jurisdiction/country where you plan to conduct your research and the overall principles of EU-funded research.

The basic ethical principles that have evolved to protect human participants from harm, which have their origin in clinical research, apply to all fields of research in which humans participate by contributing time, effort, insights and personal data for researchers' use. These overarching ethical principles in the context of EU-funded research include:

- respecting human dignity and integrity
- ensuring honesty and transparency towards research subjects
- respecting individual autonomy and obtaining free and informed consent (as well as assent whenever relevant)
- protecting vulnerable individuals
- ensuring privacy and confidentiality
- promoting justice and inclusiveness
- minimising harm and maximising benefit
- sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- respecting and protecting the environment and future generations.[8]

3. Ethical dimensions of research methodology

In general, all scientists must consider whether the methodology they have chosen tallies with their objectives and whether the expected benefits outweigh the potential risks. It must be made clear to prospective research participants that they are free to decide whether or not to take part in the research, and whether any data collected from and about them is included in analysis. In most cases, this is secured through obtaining informed consent.

In some rare cases, the anticipated social benefits of the research are so significant that certain individual interests carry less relative weight by comparison. However, these are exceptions in social science research, and strong justification must always be provided.

SSH research is diverse and relies on a multitude of research methods, all of which need specific attention to ethics. The section below briefly introduces methodologies that need particular attention from the perspective of research ethics. The focus is on methods the use (and justification) of which frequently occupy *Ethics Panels* in the screening and review process of proposals. These include:

- use of deception in research
- covert research
- internet research and social media data in research

[8] For a more detailed account of ethical principles in H2020, please refer to the Annotated Model Grant Agreement, Version 4.1., 26 October 2017, 258

3.1 Use of deception

Use of deception in research means that researchers deliberately lie or trick the participants in the research setting so that the true purpose of the study remains unknown to them (until it is revealed in a debriefing once participation is finished). Researchers include deception in the design of the study if disclosing its real purpose would lead participants to modify their behaviour, thereby distorting the research objective.

Use of deception as part of SSH research has been subject to controversy and debate. It violates the principle of informed consent and, it has been argued, can harm participants, researchers, research professions and society overall.[9] Nevertheless, learned societies for social research argue that there are exceptional, justified uses of deception, as in cases where the study addresses important matters and is expected to reveal something of social significance, which cannot be discovered in any other way.

In general, strong justification must always be provided for having recourse to deception, and any study relying on deception must be so designed as to protect participants' dignity and autonomy, despite the method used.

Information for participants may be withheld from them only when the need to preserve the integrity of the research outweighs the participants' interests, or if it is shown to be in the public interest. If information has been withheld from participants, they will be appropriately informed *after* their participation in such a manner and to such an extent that, to their judgment, the informed consent remains intact. Uses of deception are limited and a study must not rely on deception unless the use of such techniques can be justified by the likelihood that the study will have a significant scientific or applied value, and there is no other way to collect the data.

⚠ In the case of procedures that can cause **physical or mental harm**, information must not be withheld, and no deception must be used.[10] Risk management and harm alleviation strategies must be in place.

- ***If your research design includes deception,***
- ***provide strong justification for the choice of method by showing the importance of the research objective and demonstrating that your research cannot be conducted in any other way***
- ***describe how you will debrief your participants and retrospectively obtain their informed consent***
- ***show that the use of deception will not harm your participants socially, emotionally or psychologically and that revealing the real nature of the research will not lead to any discomfort, anger or objections on their part, and finally***
- ***obtain local ethics committee approval for your study before it gets under way.***

[9] Israel, p. 96, referring to Hegtvedt (2007).
[10] Code of Conduct Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants. (2018).

3.2 Covert research

Another method that goes against the requirements of informed consent and that can invade participants' privacy is *covert research*. This type of secret or disguised research is rare and should be the exception rather than the rule.[11] Like deception, covert research requires strong justification and a demonstration of clear benefits of the chosen method over any other approach. Matters of social significance must be addressed in the research. Covert research should be avoided in principle, unless it is the only method by which information can be gathered, and/or when access to the usual sources of information is obstructed by those in power.[12]

Circumstances that *may* lend support to using covert methods include settings where research participants change their behaviour because they know they are being studied.[13]

Participant or non-participant observation in non-public spaces or experimental manipulation of research participants without their knowledge should be resorted to only where it is impossible to use other methods to obtain essential data.[14] Informed consent should be sought after the event wherever possible. Here the risk researchers face is, of course, that some participants may not give their consent retrospectively, which would mean that some or all of the data collected could not be used.[15]

- Covert research may be used in settings that pose no particular risk to participants or researchers if the anonymity of those being observed is safeguarded. Observing fully public settings may therefore not require consent. Such research must be conducted with respect for privacy:

- no personal data are collected (data are fully anonymised at the point and time of collection)
- data are collected unobtrusively and in accordance with local cultural values, and
- data are collected only in situations where people being studied can reasonably expect to be observed by strangers.[16]

Researchers, however, enter risky terrain if they intend to observe illegal activities where covert investigations by appropriate authorities may already be under way (as when drug cartels or human trafficking are under investigation or paramilitary groups, terrorists or organised gangs are under surveillance). By accident, a researcher may become a witness of or even an indirect accomplice to criminal activity and may eventually be involved in obstructing justice if they fail to report illegal activities to authorities.

[11] Swedish Research Council. (2017). Good Research Practice.
[12] International Sociological Association. (2001). Code of Ethics.
[13] See for example, British Sociological Association. (2017). Statement of Ethical Practice, Item 14, p. 6.
[14] BSA. Ibid., Item 15, p.5
[15] Ransome. Ibid, p. 46.
[16] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants. (2018).

If you plan to engage in covert research

- *consult the legal department and the data protection officer (DPO) at your host institution to find out about the legal basis of your research and whether your research design poses any risk of breaking the law;*
- *abroad, ensure that you obtain local ethics approval from your host country as well and make sure the methodology you employ is compatible with the local legislation;*
- *remember that if you are working in non-EU countries, the proposed research must be legal at least in one EU member state;*
- *keep in mind that there are positive disclosure obligations in many EU member states that you must be aware of if you intend to conduct research involving terrorism or other criminal activities, for example;*
- *remember that safeguarding the anonymity of research participants is central. Ideally, where informed consent has not been obtained prior to the research, it should be obtained afterwards.*[1]

3.3 Internet research and social media data in research

The internet has been described as a social phenomenon, a tool and also a (field) site for research.[17] *When processing large amounts of data in your research, bear in mind that all big data research on social, medical, psychological, and economic phenomena engages with human subjects; all these data are people. As a researcher you have the ethical responsibility to minimise potential harm to them.*[18]

Social media have been characterised as web-based and mobile-based internet applications that allow the creation, access and exchange of user-generated content that is ubiquitously accessible. Analysing social media data, in particular Twitter feeds for sentiment analysis, has become a major research and business activity, given the easy availability of web-based application programming interfaces (APIs) provided by Twitter, Facebook and News services. There has been explosive growth in data services and software tools for scraping and sentiment analysis and in social media analytics platforms. [19] In turn, the use of such tools in social science research has become increasingly widespread.

A number of issues have been raised in research that is internet-mediated and/or uses social media data. These relate, among others, to:

[17] Annette Markham & Elizabeth Buchanan. Ethical Decision-Making and Internet Research. Recommendations from the AoIR Ethics Working Committee (Version 2), p.3. Available at: http://www.aoir.org/reports/ethics2.pdf

[18] Matthew Zook et al. (2017). Ten simple rules for responsible big data research. Editorial. Plos Computational Biology, March 30, 2017, p.1. Available at: http://journals.plos.org/ploscompbiol/article/file?id=10.1371/journal.pcbi.1005399&type=printable

[19] Bogdan Batrinca & Philip C. Treleaven. Social media analytics: a survey of techniques, tools and platforms. AI & Soc (2015) 30:89–116

- whether all data that are available are also public and whether it is fair to use them in research
- meeting conditions of free and voluntary informed consent in the context of social media research
- anonymity
- risk of harm through tracing or exposing the social media user's identity and profile
- uncertainty about whether some users being studied are children or belong to other vulnerable groups.[20]

In using social media data in your research, bear in mind that even data sets comprising thousands of tweets involve human beings who could be directly or indirectly affected by research. There is considerable evidence that even anonymised data sets may make individuals identifiable if they contain enough personal information.[21] Research with anonymised data sets may cause harm to a group through, for instance, discrimination against or stigmatisation of entire populations. Consider the 'm*osaic effect', if you plan to combine large amounts of data from various sources that appear not to be attributable to particular individuals in isolation. While they may look relatively harmless in their own right, there is a chance that they may cause a breach of privacy when combined.*[22] *Through availability of government data sets and their machine readability the effect is also relevant in social research, as there is a risk that disparate threads can be easily combined in a way that yields private information or information that could be harmful to individuals* if placed in a new context.[23] *Linking diverse sources of social media data can produce the same effect.*

If, on assessing the risks, you anticipate any risk of harm to individuals whose data you are using, you must:

- paraphrase all data that will be republished (to prevent others being led to the individual's online profile),
- seek informed consent from people whose data you intend to use in its original form in research outputs, or
- consider a more traditional research approach that better ensures consent and confidentiality.[24]

Remember that just because data is publicly accessible, that does not mean that it can be processed by anyone for any purpose. When ascertaining whether data is open for use or is to be considered private, bear in mind the online environment where it is posted and the *reasonable expectations of privacy* which the user may have.[25] Password-protected profiles and closed group discussions are obviously intended by their users to be private.

When processing social media platform data:

- make sure you are sensitive to the issues raised
- comply with the EU General Data Protection Regulation (GDPR)

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[20] Leanne Townsend & Claire Wallace. Social Media Research: A Guide to Ethics. University of Aberdeen. Available from: https://www.gla.ac.uk/media/media_487729_en.pdf
[21] Markham & Buchanan. Ibid., p. 7.
[22] David E. Pozen (2005.) The Mosaic Theory, National Security, and the Freedom of Information Act. The Yale Law Journal 115:3, Dec 2005, pp. 628-679. Available at: https://www.yalelawjournal.org/note/the-mosaic-theory-national-security-and-the-freedom-of-information-act
[23] See, for example, Adam Mazmanian (2014). The mosaic effect and big data. The Business of Federal Technology, May 13, 2014. Available at: https://fcw.com/articles/2014/05/13/fose-mosaic.aspx
[24] Townsend & Wallace. Ibid., p. 11.
[25] Albena Kuyumdzhieva. (2018). Data Ethics and Ethics Review Process. Ethics compliance under GDPR. Presentation.

- consult your host institution's data protection officer and/or ethics advisor, and
- find out if you need to obtain ethical approval for collecting data.

For more information, please refer to the document Ethics and Data Protection (Section: The use of previously collected data ('secondary use').

Consider the following if you plan to use social media data in your research:

- *Remember that the data you process is about real people.*
- *Consult the relevant terms and conditions of the platforms you will be using to obtain your data.*
- *Appreciate that open source does not mean that it is open for use.*
- *Ascertain whether the data you intend to access is really public (open platforms vs password-protected fora); if the forum is closed, contact the site or group administrator). Seemingly public data may not be available for research.*
- *Take all relevant precautions to avoid collecting data from children or vulnerable adults through social media and online questionnaires without appropriate authorisations.*
- *Consider the potential sensitivity of the data and whether users could be harmed if their data are exposed to new audiences. Sensitive data postings relate to criminal offences, use of illegal drugs, financial problems, mental issues and suicidal feelings, extramarital sexual activity, controversial political opinions and activism.*
- *Closed groups and fora: if there is an expectation of privacy, seek permission from users to use the data and obtain their informed consent.*
- *Consider the user's reasonable expectation of privacy.*
- *For all details, consult the document* Ethics and Data Protection.

The GDPR includes specific safeguards related to automated processing or profiling of personal data. Please refer to the document Ethics and Data Protection for more information.

3.4 Research participation

No-one is obliged to participate in research. You need to justify why human participation in your planned work is necessary in the first place.
Anyone who considers participating in your research must have a fair chance to judge whether it is worthwhile taking the time and making the effort to share information with you. Usually this is safeguarded through participants giving their informed consent to participation as part of negotiating the terms of the relationship with the research team.
Your research involves human participants if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and/or implement appropriate safeguards.

- *In your self-assessment, provide clear descriptions of your recruitment policy: who you intend to recruit; where and how you will reach your target group; your criteria for inclusion/exclusion.*
- *Enter 'human participation' in your ethics form if you collect data through online questionnaires, paper questionnaires, interviews, focus groups, observations or workshops – in other words, through any activity in which you interact with research participants and collect their data for your analysis.*

3.5 Vulnerable participants

If you involve vulnerable participants, you must provide justification for doing so. The obvious question to address is: can the research results be obtained by involving another, less vulnerable, group? Explain how you ensure that the individuals you involve will not be stigmatised, re-traumatised or otherwise harmed through their participation in your research.

Note that some groups are always vulnerable. These include children, people with cognitive impairments, and those who are unable to give informed consent. Other vulnerability is likely to be context-dependent. This means you and your fellow-researchers need to give some thought to whether a particular group is vulnerable, and for what reason.

In general, groups considered vulnerable because of their circumstances may include:

- children
- refugees
- irregular migrants
- sex workers
- people with cognitive impairments
- dissidents
- traumatised people at risk of re-traumatisation (e.g. people from conflict areas, victims of crime and/or violence); and
- people in dependent relationships with the researcher or the research team (e.g. students doing course work with researchers).

Make sure you do not exacerbate people's vulnerability through your research or research participation. In some countries you may need to show evidence of competence and certification in order to work with children and vulnerable adults.

If you plan to involve refugees in your research, please refer to the *Guidance note — Research on refugees, asylum seekers & migrants.*

Individuals who cannot consent to research participation are sometimes needed as research participants. Check national laws on research involvement of people who cannot consent, as they are likely to differ from country to country.

If you plan to involve vulnerable individuals in research, describe the risk of exposure to harm to participants (e.g. social, psychological, physical, reputational, economic or emotional).

- *Be clear about the possible benefits and/or the lack of benefits of research participation: avoid raising unfounded expectations.*
- *Make sure people can opt out of research, e.g. when involving students. If participation is seen as part of course work, meaningful alternatives must be offered. Do not involve participants who are in any way dependent on you or your staff.*
- *If participation in research has the potential to re-traumatise people, take steps to minimise the risk and ensure that your team includes people with the appropriate expertise and skills.*
- *If there is a risk of stigmatisation, take active steps to minimise this risk.*
- *If there is a risk that the research may make participants vulnerable to physical or psychological abuse, take active steps to minimise such risks.*

3.6 Children in research

Due justification must be provided for involving children's in research. In addition, you must obtain their assent and the informed consent of their parents or guardians. When involving young children in research, you must monitor their assent for any verbal or non-verbal clues that they may actually disagree or wish to stop participating.

The age at which children can give their informed consent to research participation varies from country to country. You must abide by the relevant laws of the country where you collect the data. See the *documents* *Ethics and Data Protection* for additional information.

Depending on national laws, you may require official vetting and authorisation to work with children.

Depending on national/regional/local laws, conducting research in kindergartens and schools may require special authorisation from municipal social services, boards of education, or similar.

4 Informed consent

Most social science research endeavours are such that human participation requires evidence of the voluntary, free, and informed consent of those who contribute their time, insights, effort and data for the use of researchers. Informed consent, whether in writing (as is most usual) or given orally, is thus the default option. Obtaining informed consent, however, does not in itself guarantee ethical research. In some research settings, this very act and the aim of safeguarding participants' rights and well-being in the research setting may place them at risk of harm in their social context (rather than affording them protection).

There may also be situations in which standard procedures for obtaining written informed consent are culturally or contextually inappropriate to the participants. In such cases, explain how you plan to obtain and document consent by other means (e.g. orally).

If you have concerns that obtaining written informed consent from participants could expose them to harm, consider other ways for them to document their agreement to participate. These options can be explored together with the prospective participants. In such cases, you must justify your decision and your alternative procedure for obtaining consent in:

- *your ethics self-assessment*
- *your application for ethics approval.*

When preparing information sheets and consent forms, the following checklist may be helpful:

- Give participants a clear explanation of the aims, overall purpose, methods and implications of the research.
- Explain that participation is voluntary.
- Remind participants that they have a right to withdraw their consent at any time without any consequences.
- Explain the degree of benefit, risks, burden or discomfort involved in participation. Give an estimate of the time and effort expected of participants.
- Explain precautions to ensure participants' safety and provide information on insurance, if there is any.[26]
- Explain who is funding the research and for what purpose.
- Disclose who will benefit from the research.
- Give a firm commitment to protecting respondents' anonymity and privacy (provided that this can genuinely be guaranteed).
- Make a clear commitment to treating personal and sensitive information confidentially.
- Reassure participants that there are secure procedures for analysing any data gathered.
- Explain clearly who will have access to any data that participants provide.
- Consider any unintended/unexpected/incidental findings and explain how you intend to deal with such findings.

[26] Modified list based on a checklist in Paul Ransome's *Ethics & Values in Social Research* (2013, Palgrave Macmillan, p. 43).

- Explain briefly where research findings will be published.
- Offer to provide respondents with further information about research if they ask for it.
- Give the name and contact details of the contact person who can answer any queries participants may have.
- Clarify possible uses to which data may be put in future (if this is envisaged) and clarify whether participants will be asked for consent again if this is the case. Cover any issues relating to copyright of data and other materials used in the research.

Whenever you are collecting personal data directly from research participants, you must seek their informed consent using a procedure that meets the minimum standards of the GDPR[27]. This requires consent to be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to them.[28] This may take the form of a written statement, which may be collected by electronic means, or of an oral statement. For additional details, see the documents Ethics and Data Protection.

5 Findings outside the scope of the research: 'unintended/unexpected/incidental' findings

Social science and humanities research relies on methods that may unintentionally produce findings outside the scope of the original research questions. Fieldwork, observations and interviews can yield information that goes beyond the scope of the research design, thus presenting the researcher with a dilemma: whether to preserve confidentiality or to disclose the information to relevant authorities or services.

Unintended/unexpected/incidental findings may include indications of criminal activity, human trafficking, abuse, domestic violence or bullying. Researchers must inform the participants, or their guardians or other responsible people, of their intentions and reasons for disclosure, provided that doing so does not undermine the act of disclosure. A characteristic of incidental/unexpected findings is that they require the researcher to take some form of action.

As a rule, criminal activity witnessed or uncovered in the course of research must be reported to the responsible and appropriate authorities, even if this means overriding commitments to participants to maintain confidentiality and anonymity. There may be a legal obligation to report criminal activity. In some research settings (for example when working with refugees), it may be more appropriate to contact relevant NGOs or agencies with appropriate expertise rather than the authorities.

For guidance on research involving refugees, see the Guidance note – Research on refugees, asylum seekers & migrants

[27] For research involving clinical trials, the processing of data should also comply with the requirements established in the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[28] See further Article 7, GDPR and 'Guidelines on Consent under Regulation 2016/679', European Commission Article 29 Working Party, adopted on 28 November 2017.

Incidental findings

- *Plan ahead by drafting a policy for dealing with unintended, unexpected, or incidental findings that are not harmless.*
- *Inform participants about the limits of the confidentiality that you can offer (the information sheet should cover incidental findings policy). See the Guidance Note on Informed Consent.*
- *Be aware of the legal context in which you conduct your research and consult your host institution's legal department (see also covert research, above) to ensure that your research design is within legal limits.*
- *Include in your work plan a structure for discussing unexpected or incidental findings within your consortium.*

6 Data protection and privacy

The main risk faced by a SSH research participant is disclosure of identity and insufficient protection of their private information, associated with discrimination and stigmatisation. Safeguarding privacy and appropriate measures for processing, handling, and storing data are thus central at all stages of research and beyond.

Data protection is both an integral issue for research ethics in Europe and a fundamental human right. It is closely linked to human dignity and the principle that everyone should be valued and respected. If this principle is to guide the development of today's 'information societies', it must be rigorously applied by the research community.

The right to data protection is guaranteed by the **EU Charter of Fundamental Rights** and the **Treaty on the Functioning of the European Union**. It gives effect to the right to privacy by providing individuals with autonomy and control over the way information about them is collected and used.[29] In research settings, data protection creates obligations on researchers to provide research subjects with detailed information about what will happen to the personal data that they collect from them. It also requires the organisations processing the data to ensure it is properly protected, 'minimised' and destroyed when no longer needed.

All individual EU-funded research projects that process personal data must comply with:

- EU and national data protection laws
- ethical considerations
- the values and principles underpinning the EU.

Particular attention should be paid to research involving profiling, automated decision-making, data mining, big-data analytics and artificial intelligence, as these may pose higher risks to the rights and freedoms of data subjects. The increasing impact of these and other forms of ICT on social and material life is reflected in the letter and spirit of the EU GDPR.[30]

Now that large-scale data collection enabled by internet-mediated research and mobile devices is a reality, the onus is still on researchers and the research data infrastructure at their host institutes to discharge their ethical responsibilities.
For further details of data protection, see the document Ethics and Data Protection.

[29] Article 8, EU Charter of Fundamental Rights.
[30] EU Regulation 2016/679.

7 Sites of research

Knowledge and understanding based on social science research has the potential to improve people's lives, both in diverse communities within the EU and in non-EU countries. Research is thus necessary and it is often conducted in contexts and geographical areas where the conditions for research work may be risky as regards the safety of participants and researchers themselves. Examples include:

- non-EU countries or regions within them where economic, political, environmental and health conditions may pose risks to volunteers participating in research and/or research staff
- conflict regions
- regions with non-democratic regimes.

Obviously, milieus that pose risks to social scientists can be found in the EU countries as well. Studying criminal activity in all its facets and research in troubled neighbourhoods are a case in point.

If you plan research in countries considered resource poor, provide details of benefit-sharing measures, such as responsiveness to local research needs and procedures to facilitate effective capacity-building. Please refer to the Global Code of Conduct in Resource Poor Settings for more information.[31]

If your research site is located in an area that poses relatively high risks to you or your potential participants, provide clear strategies for keeping your research participants/informants, your research staff and yourself safe. A risk assessment needs to be made in which you should include details of safety measures you intend to take, including training for staff and insurance cover.

When conducting research outside the EU

- *your research must comply with the rules governing EU-funded research and the host country's laws*
- *consult and notify relevant bodies in the country where you are to conduct your research;*
- *apply for formal ethics approval for your research if this is required by national law. Any research you intend to conduct outside the EU must be permissible and legal in at least one EU country.*

[31] Global Code of Conduct available at: http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf

Research in regions of higher risk

List of overall considerations to apply to research projects in resource poor countries:

- *Make sure your research is responsive to the needs of the country where it is carried out (e.g. the study has value for the welfare of the intended participants, their community, and/or their country). This issue is of critical relevance for emerging and developing countries.*
- *Where applicable, apply for local authorisation for conducting your research.*
- *Be sensitive to local conditions. Explain how your research proposal fits into local customs and practices.*
- *Show how the results of your research can be applied in low and/or lower middle-income countries.*
- *Show how you are helping build local capacities by conducting research in resource poor countries and how benefits will be shared.*
- *If appropriate, state that you are planning to discuss in advance the planned research and dissemination of the results with relevant parties in the community.*
- *Make sure that your research complies with the rules for EU-funded research and ethics requirements and that it also abides by relevant local, national, international and EU laws and guidelines.*
- *Confirm that the research you plan to conduct outside the EU is legal in at least one EU country.*
- *Find out how to obtain ethics approval in your host country, so that the ethical acceptability of your research is appropriately assessed against customs and traditions at your study site.*
- *Consider the safety of participants and staff, especially if you plan to address sensitive topics (e.g. political views, sexual orientation, religion, trade union membership) or involve marginalised groups. Provide a risk analysis and mitigation strategy.*
- *Research in conflict areas can be justified. If you intend to collect data in a troubled region, devise a strategy for keeping researchers, informants and their associates safe.*

7.1 Risks, harm and risk assessment

A particular characteristic of SSH research is that the methodologies are dynamic, progressive and developmental. This means that anticipating *all* risks relating to a research endeavour at the proposal stage may be very difficult. Nevertheless, you need to devote time to thinking through your research design and making a risk assessment that considers risks from the perspective of the individual and society. Risk assessment is a continuous activity in a project, and your risk assessment document will respond to changes in methodology and, more generally, in the circumstances of the research setting.

While much social science research can be classed as posing minimal or low risks, some such research has the potential for heightened risk.

7.2 Risks and harm in SSH

The likely risks and harms in SSH research may differ from those in clinical research It is important to understand their nature and likelihood in order to set up appropriate collaboration with participants and measures for their protection. As a rule, the potential harm associated with participation in social science research is multifaceted. Addressing such harm appropriately requires care.

Participants in social science studies are seldom exposed to physical harm, although they may sometimes experience transient psychological discomfort or even harm as a result of the research activity itself.[32] Research may be disruptive and damaging to research participants as individuals or to whole communities or categories of people, such as those with HIV infection. Risks can be non-material, including '*risk to a participant's personal social standing, privacy, personal values and beliefs, their links to family and the wider community, and their position within occupational settings, as well as the adverse effects of revealing information that relates to illegal, sexual or deviant behaviour.*'[33]

One of the main risks faced by a SSH research participant, then, is disclosure of identity and insufficient protection of their private information, leading to discrimination and stigmatisation. Safeguarding privacy and appropriate measures for processing, handling, and storing data are thus central at all stages of research and beyond. When engaging in large-scale data collection enabled by internet-mediated research and mobile devices, the onus is still on researchers and the research data infrastructure at their host institutes to discharge their ethical responsibilities.

Participation in research involving risks that have not been appropriately managed may cause harm of various kinds: emotional, psychological, economic, reputational, and legal.[34] Such damage can, at worst, be longstanding and even irreparable.

In assessing risks, bear in mind that some groups are more vulnerable if the confidential private information they provide is linked with them or traced back to them.
They include: victims and witnesses of violence, in particular domestic violence; sex workers; in some contexts, members of minority groups; irregular migrants; refugees; LGBTI persons; patients; disabled people; HIV-positive people.
When planning research in a cultural context different from your own, carefully assess the risks facing a potential research participant (and yourself).

[32] Guidance Note 2010.
[33] ESRC Framework for Research Ethics. Updated January 2015.
[34] See Guidance Note 2010, and Joan E. Sieber. *Risk and Harm*. (2004).

Research ethics issues in SSH research are diverse and sometimes very complex. The risks are varied and need to be systematically addressed according to the research and ethics issues associated with each project. The responsibilities incumbent on the research teams to identify and prevent potential harm can be significant.

7.3 Risk assessment

The notion of minimal risk is used to denote research in which the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research ethics committees (RECs) sometimes use the threshold of minimal risk as a criterion for requiring a full ethics review.

The following list provides examples of research that entail **more than minimal risk** according to the *Economic and Social Research Council* (ESRC):

- Research involving potentially vulnerable groups and people unable to consent;
- Research involving sensitive topics and those which might cause psychological stress, anxiety or humiliation;
- Research involving potentially sensitive topics, such as participants' sexual behaviour; illegal or political behaviour; experience of violence, abuse or exploitation; mental health; participants' personal or family lives; or their gender or ethnic status. Elite interviews[35] may also fall into this category.
- Individuals or groups in cases where a gatekeeper is normally required to give permission for initial or continued access to participants. This includes research involving gatekeepers such as adult professionals (e.g. those working with children or the elderly), or research in communities (within or outside the EU) where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community leader, and research where participants are in a dependent relationship with the gatekeeper (e.g. employees recruited through their workplace). Permission for access to other groups, for example participants in a long term cohort study, may also need to be requested from a data producer who controls access to the group.
- Research involving justified deception without participants' valid and informed consent at the time the research is carried out;
- Intrusive interventions or data collection methods, such as the administration of substances; vigorous physical exercise; or techniques where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life. Also research which would or might induce psychological stress, anxiety or humiliation, or cause more than minimal distress.
- Research where the safety of the researcher may be in question;
- Research involving respondents through the internet, in particular where visual images are used, and where sensitive issues are discussed or where participants and other individuals may be identifiable in the visual images used or generated.
- Social media and participants recruited or identified through the internet, especially if the understanding of privacy in these settings is contentious when sensitive issues are discussed - for example in 'closed' discussion groups where there is potential for quotes to be identifiable, and including those where visual images are used.
- Any research where biological samples are collected and/or medical imaging technologies are used as part of SSH research.

[35] Interviews where an interview partner is chosen on the basis of their position or status, not randomly.

Risk assessment

- *Provide a clear and adequate assessment of risks in your ethics self-assessment, stating explicitly what kinds of harm might occur and the likelihood of participants experiencing such harm. Be explicit about how you intend to manage risks and mitigate harm. Provide sufficient detail in your risk assessment and justify the choices made.*
- *Remember that any involvement or intervention may involve a risk to the participant and that the onus is on you to establish that there is no risk, that the risk is minimal and justifiable, and that appropriate risk management structures are in place.*

7.4 Checklist for higher-risk SSH research

Use the table below to check whether your planned work could potentially involve a higher than minimal risk/increased sensitivity.

Participants	*Children, vulnerable groups (e.g. persons unable to consent, minorities, marginalised people, migrants, refugees, victims of abuse and violence)*
Sites of research	*Conflict regions, sites of historical value to indigenous people, troubled neighbourhoods, non-EU countries or regions within them where the economic, political, environmental and health conditions may pose risks.*
Sensitive areas of research	*Risk of exposure to harm to participants, researchers;* *potentially sensitive topics, such as participants' sexual behaviour; illegal or political activities; experience of violence, abuse or exploitation; mental health; participants' personal or family lives; or their gender or ethnic status. Research into criminal activity.*
Methodology	*Deception, covert research, invasive methods (fMRI for children) as part of interdisciplinary research, profiling and web-crawling*
Data processing, sensitive data	*Data collection and processing to be implemented – risk of traceability and re-identification through small groups of participants, linking of large amounts of data from different sources; uncertainty whether children are participating; sensitive data*
Consequences of research	*Potential for misuse of findings (see section 10)*

If your work involves any of the above, you must:

- *provide a clear justification in your ethics self-assessment for choosing an approach that involves higher risk;*
- *explain why alternative approaches are not possible (if they are not);*
- *identify the risks, and show how you plan to mitigate and manage the risks (risk mitigation plan).*

8 Misuse of research

Some research involves materials, methods or technologies or generates knowledge that could be used for unethical ends. Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals or the environment, or society.

Although the risk of misuse of research can never be eliminated, it can be minimised by identifying risks in good time and taking the right precautions.

Professional codes remind social scientists of their responsibility to protect the interests and welfare of groups and individuals with whom and on whom they work, or who are involved in their research efforts. Social scientists must be accurate and truthful when sharing their analyses and reporting their findings. They also need to consider the effects of their involvements and the consequences of their work or its misuse for those they study and other interested parties.[36]

When designing a proposal, consider not only the immediate aims and intended applications of the activities you plan, but also whether your research could serve unethical purposes. An example of this would be a study involving a minority or vulnerable groups or research which develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.
Questions to identify potential misuse include:

- Could the materials/methods/technologies and knowledge concerned harm people, animals or the environment if modified or enhanced?
- What would happen if they ended up in the wrong hands, e.g. among criminals or terrorists, or were used to curtail human rights or civil liberties?
- Could they serve any purposes other than the intended ones? If so, would that be unethical?

Research which could have an impact on human rights concerns includes research on surveillance technologies, new data gathering and data merging technologies (e.g. in the context of big data). However, social research that could lead to discrimination or stigmatisation is also relevant. Risk mitigation measures may include:

- human rights impact assessment, involving human rights experts in your research
- training personnel and/or technological safeguards
- caution when publishing or otherwise disseminating results (e.g. through privacy by design)
- adapting the research design (e.g. using dummy data)[37].

[36] See, for example, ISA and BSA. Ibid.
[37] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

If you are planning research that may give rise to concerns about potential misuse, in preparing your proposal:

- *provide a risk assessment in part B, detailing the risks and how they will be mitigated in order to prevent misuse*
- *provide a risk mitigation strategy*
- *if required, attach copies of authorisations, security clearances and ethics approval*
- *describe in the risk table in the management section what action you would take if the national authorities did not grant authorisation.*

For full details concerning misuse, see the *Guidance note — Potential misuse of research*.

9 Ethics approval in SSH research

A number of EU member states, associated countries, and countries where EU-funded research takes place have established structures for research ethics approval for all research involving humans, regardless of discipline. In some countries, however, formal research ethics approval is required and provided only for clinical studies involving humans. Such research ethics committees are often not well-suited to assessing the ethical dimensions of SSH research.

Before submitting your application, check your institutional, local/regional and national requirements concerning ethics approval and availability of research ethics committees for social science research. Including this information in your ethics self-assessment may save you valuable time and effort when the Grant Agreement is drawn up.

If your institutional/national framework makes no provision for a research ethics committee which you can approach to obtain authorisation or approval for the SSH research you intend to perform, you can consider the following options.

An **ethics opinion** may be given, for example, by:

- the coordinator's institutional research ethics committee
- the institutional research ethics committee of another research partner, or
- a relevant authority in the country (if applicable), which may give its approval.

If it is not possible to obtain ethics approval, explain why not (your explanation must be backed up by documentary evidence) and show clearly how you will make sure your research meets all ethical and legal requirements.

⚠ **As a researcher, you must act ethically, regardless of whether you obtain ethics approval.** You are responsible for ensuring that any research you conduct protects the physical, social and psychological well-being of research participants, regardless of the type of approval procedure your research undergoes.

10 Management of ethics issues

If your work raises ethics issues, particularly if more than a minimal risk or increased sensitivity are at stake, make sure you set up adequate ethics monitoring structures. These must be clearly identifiable in your work plan and your ethics self-assessment. Make sure that ethical considerations are integrated into the project from the outset, so that they are part of every relevant interaction and will continue to be addressed even after your research has been completed.

Link your self-assessment to your work plan and demonstrate how you integrate research ethics into your work and how you facilitate the identification and discussion of ethical concerns. For example:

- indicate where ethical issues are addressed in specific tasks in relevant work packages
- include an ethics deliverable, and
- define ethics-related milestones where relevant.

Allocate ethics resources in your description of your work and the budget. Bear in mind that you are the main person responsible for handling ethics issues in your project. You must therefore avoid handing over the task (and responsibility) of addressing ethics to anyone else, especially anyone outside your consortium.

If you decide to seek further guidance from an independent ethics advisor (or an ethics advisory board) with relevant experience in research ethics in the area of your research, give them meaningful opportunities to interact in your project by providing sufficient resources (including budget and meeting time). Keep the advisor and/or advisory board abreast of your work and your reporting schedule and make sure they are fully integrated into your project, so you can include their reports and advice in your periodic reports.

For additional information on involving and collaborating with ethics advisors and advisory boards, see the guidance in *Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects.*

11 Other issues

SSH research as part of multidisciplinary and interdisciplinary research

SSH research methods are often used as part of multidisciplinary or interdisciplinary research, for example, in technology innovation, human computer interaction research and robotics. When using SSH methods in such research, SSH studies – like any other SSH research – should be conducted using the best available knowledge in the field. Social researchers and research assistants hired to conduct interviews and perform other tasks bringing them into direct contact with participants are required to be competent to carry out SSH research.[38] Respondents and participants have the right to expect competent SSH researchers as collaboration partners.

If your project's main focus is not on SSH, but you plan to use SSH methods and involve participants, you are encouraged to involve people with sufficient SSH expertise and experience in the relevant work to conduct responsible and competent social science research.

In some study designs, physical interventions in research participants are integrated into interdisciplinary SSH research. If a study affects subjects' physical integrity, this part of the research must also comply with the guidelines governing medical research.

[38] Ransome, Ibid., p.32-33, 41.

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GLOBAL CODE OF CONDUCT
FOR RESEARCH IN RESOURCE-POOR SETTINGS

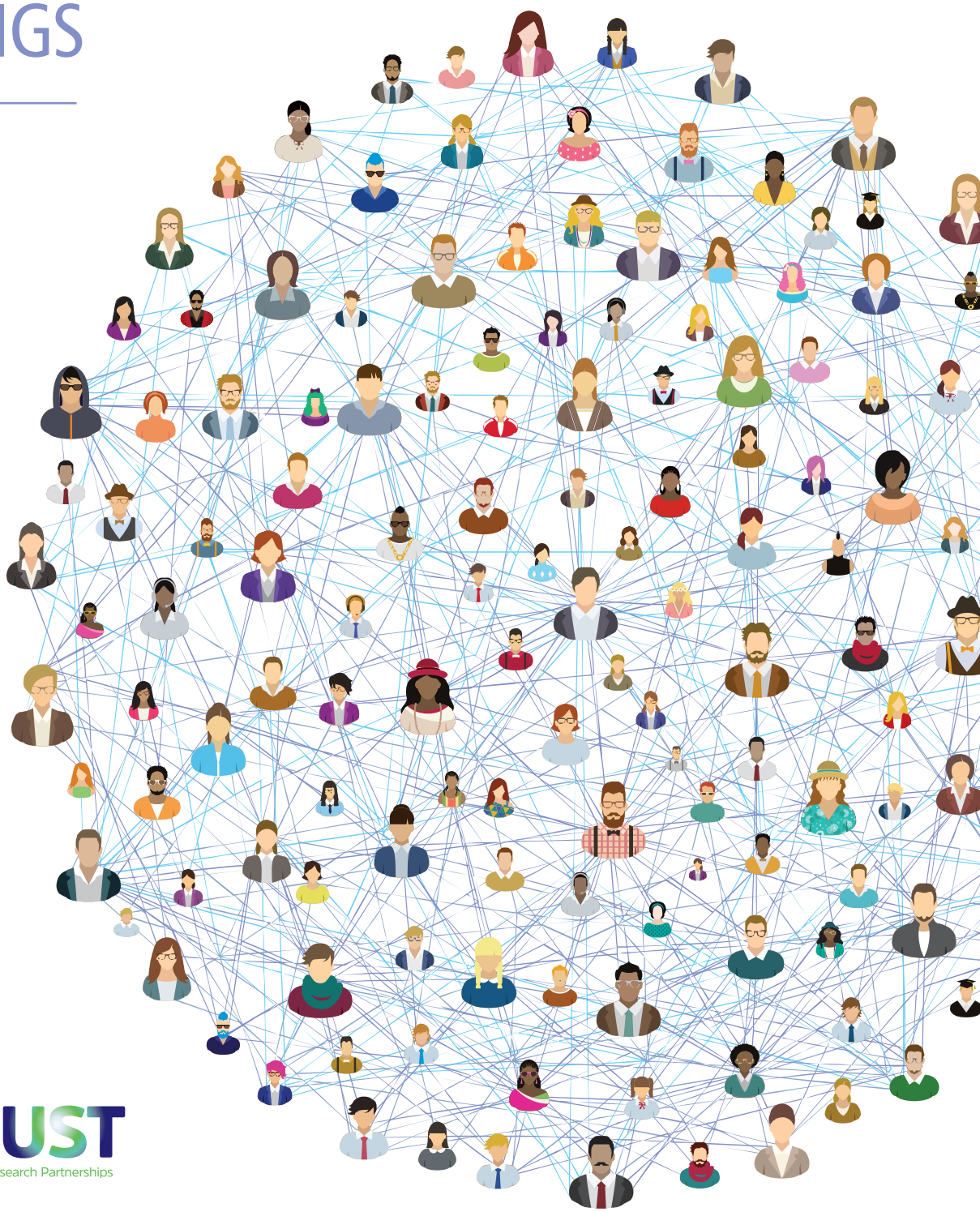

TRUST
Equitable Research Partnerships

www.globalcodeofconduct.org/

GLOBAL CODE OF CONDUCT FOR RESEARCH IN RESOURCE-POOR SETTINGS

Research partnerships between high-income and lower-income settings can be highly advantageous for both parties. Or they can lead to ethics dumping, the practice of exporting unethical research practices to lower-income settings.

This Global Code of Conduct for Research in Resource-Poor Settings counters ethics dumping by:

- Providing guidance across all research disciplines
- presenting clear, short statements in simple language to achieve the highest possible accessibility
- focusing on research collaborations that entail considerable imbalances of power, resources and knowledge
- using a new framework based on the values of fairness, respect, care and honesty
- offering a wide range of learning materials and affiliated information to support the Code, and
- complementing the European Code of Conduct for Research Integrity through a particular focus on research in resource-poor settings.

Those applying the Code oppose double standards in research and support long-term equitable research relationships between partners in lower-income and high-income settings based on fairness, respect, care and honesty.

FAIRNESS

ARTICLE 1
Local relevance of research is essential and should be determined in collaboration with local partners. Research that is not relevant in the location where it is undertaken imposes burdens without benefits.

ARTICLE 2
Local communities and research participants should be included throughout the research process, wherever possible, from planning through to post-study feedback and evaluation, to ensure that their perspectives are fairly represented. This approach represents Good Participatory Practice.

ARTICLE 3
Feedback about the findings of the research must be given to local communities and research participants. It should be provided in a way that is meaningful, appropriate and readily comprehended.

ARTICLE 4
Local researchers should be included, wherever possible, throughout the research process, including in study design, study implementation, data ownership, intellectual property and authorship of publications.

ARTICLE 5
Access by researchers to any biological or agricultural resources, human biological materials, traditional knowledge, cultural artefacts or non-renewable resources such as minerals should be subject to the free and prior informed consent of the owners or custodians. Formal agreements should govern the transfer of any material or knowledge to researchers, on terms that are co-developed with resource custodians or knowledge holders.

ARTICLE 6
Any research that uses biological materials and associated information such as traditional knowledge or genetic sequence data should clarify to participants the potential monetary and non-monetary benefits that might arise. A culturally appropriate plan to share benefits should be agreed to by all relevant stakeholders, and reviewed regularly as the research evolves. Researchers from high-income settings need to be aware of the power and resource differentials in benefit-sharing discussions, with sustained efforts to bring lower-capacity parties into the dialogue.

ARTICLE 7
It is essential to compensate local research support systems, for instance translators, interpreters or local coordinators, fairly for their contribution to research projects.

RESPECT

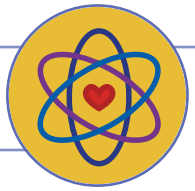

ARTICLE 8
Potential cultural sensitivities should be explored in advance of research with local communities, research participants and local researchers to avoid violating customary practices. Research is a voluntary exercise for research participants. It is not a mission-driven exercise to impose different ethical values. If researchers from high-income settings cannot agree on a way of undertaking the research that is acceptable to local stakeholders, it should not take place.

ARTICLE 9
Community assent should be obtained through recognized local structures, if required locally. While individual consent must not be compromised, assent from the community may be an ethical prerequisite and a sign of respect for the entire community. It is the responsibility of the researcher to find out local requirements.

ARTICLE 10
Local ethics review should be sought wherever possible. It is of vital importance that research projects are approved by a research ethics committee in the host country, wherever this exists, even if ethics approval has already been obtained in the high-income setting.

ARTICLE 11
Researchers from high-income settings should show respect to host country research ethics committees.

CARE

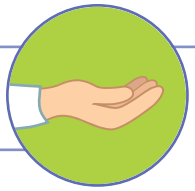

ARTICLE 12
Informed consent procedures should be tailored to local requirements to achieve genuine understanding and well-founded decision-making.

ARTICLE 13
A clear procedure for feedback, complaints or allegations of misconduct must be offered that gives genuine and appropriate access to all research participants and local partners to express any concerns they may have with the research process. This procedure must be agreed with local partners at the outset of the research.

ARTICLE 14
Research that would be severely restricted or prohibited in a high-income setting should not be carried out in a lower-income setting. Exceptions might be permissible in the context of specific local conditions (e.g. diseases not prevalent in high-income countries). If and when such exceptions are dealt with, the internationally acknowledged compliance commandment "comply or explain" must be used, i.e. exceptions agreed upon by the local stakeholders and researchers must be explicitly and transparently justified and made easily accessible to interested parties.

ARTICLE 15
Where research involvement could lead to stigmatization (e.g. research on sexually transmitted diseases), incrimination (e.g. sex work), discrimination or indeterminate personal risk (e.g. research on political beliefs), special measures to ensure the safety and wellbeing of research participants need to be agreed with local partners.

ARTICLE 16
Ahead of the research it should be determined whether local resources will be depleted to provide staff or other resources for the new project (e.g. nurses or laboratory staff). If so, the implications should be discussed in detail with local communities, partners and authorities and monitored during the study.

ARTICLE 17
In situations where animal welfare regulations are inadequate or non-existent in the local setting compared with the country of origin of the researcher, animal experimentation should always be undertaken in line with the higher standards of protection for animals.

ARTICLE 18
In situations where environmental protection and biorisk-related regulations are inadequate or non-existent in the local setting compared with the country of origin of the researcher, research should always be undertaken in line with the higher standards of environmental protection.

ARTICLE 19
Where research may involve health, safety or security risks for researchers or expose researchers to conflicts of conscience, tailored risk management plans should be agreed in advance of the research between the research team, local partners and employers.

HONESTY

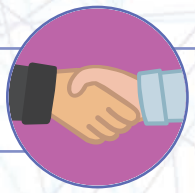

ARTICLE 20
A clear understanding should be reached among collaborators with regard to their roles, responsibilities and conduct throughout the research cycle, from study design through to study implementation, review and dissemination. Capacity-building plans for local researchers should be part of these discussions.

ARTICLE 21
Lower educational standards, illiteracy or language barriers can never be an excuse for hiding information or providing it incompletely. Information must always be presented honestly and as clearly as possible. Plain language and a non-patronising style in the appropriate local languages should be adopted in communication with research participants who may have difficulties comprehending the research process and requirements.

ARTICLE 22
Corruption and bribery of any kind cannot be accepted or supported by researchers from any countries.

ARTICLE 23
Lower local data protection standards or compliance procedures can never be an excuse to tolerate the potential for privacy breaches. Special attention must be paid to research participants who are at risk of stigmatization, discrimination or incrimination through the research participation.

The code was drafted by the TRUST project under the leadership of Prof. Doris Schroeder. Existing guidelines have played an important role in formulating the code.

Please see the website for those we have taken substantial inspiration from and for further information on authorship and global engagement activities: **http://www.globalcodeofconduct.org**.

The Ethics and Research Integrity Sector, Directorate General for Research and Innovation, European Commission will propose the Code as a reference document for funding applications in the Framework Programme.

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"Ethics in research and international cooperation"

PREAMBLE

The document aims at providing research applicants with guidance when dealing with specific **ethical issues** that can arise when an FP funded research project involves research activities in **developing countries** or **countries with emerging economies**.

What is particular about developing and emerging economy- countries?

Developing and emerging economy-countries face a very wide, and constantly changing variety of situations. Many of the ethical issues that are specific to research projects carried out in these countries originate from the potential vulnerability of local people, such as:

- Potential 'vulnerability' of study participants that may affect their ability to give individual informed consent (i.e. right to deny their participation to a study without prejudice) because of their lack of access to healthcare services, the low level of education and the limited knowledge of their own legal rights, etc…
- Potential vulnerability of the local research team or of the local Ethics Review Committee, both of which may have difficulty challenging the study design or the proposed research methodologies from an ethical perspective especially if the proposed study would result in a financial investment that would improve the local research infrastructure.

Fundamental ethical considerations

Three overall considerations should apply to **all** research projects involving these countries. The proposed research must:

1. be responsive to the needs of the country where research is carried out (e.g. the study must be of added value for the health and welfare of the intended participants, their community, and/or their country).
2. be scientifically sound (although not within the scope of the ethical review),
3. abide by relevant EU/national legislation as well as by the relevant international guidelines.

Specific issues to address in the ethical review process

Applicable legislation

Sponsors and researchers **must** comply with the relevant EU legislation in addition to the legislation of the host and funding countries. They **should** also comply with internationally accepted guidance documents, such as the Declaration of Helsinki.

How does the research comply with the relevant **EU legislation**?	
How does the research comply with the relevant **national legislation**?	
Does the research comply with relevant internationally accepted guidance documents? **If no**, please explain why.	

Benefit sharing

International research projects must provide benefits to all stakeholders, with particular emphasis on benefits for research participants and their community, but also for local researchers. It should be assessed whether and how the research might impact on the local health system. As part of benefit sharing, post-study clinical or other research commitments must be addressed in the research proposal.

Will the research contribute to the development of **local expertise**?	
Does the research provide **benefits of participation** for the involved stakeholders (e.g. development of research infrastructure, distribution of results, publications, access to data, intellectual property, technology transfer).?	
May the research lead to the diversion of **local resources** in a way that could be detrimental to the local community (e.g. diversion of local human resources, equipments, etc.)? **If yes**, please justify steps taken to minimize impact.	
Do **post-study commitments** address the issue of access of the research participants, their communities and their country to research-proven interventions and research outcomes?	

Healthy volunteers

As healthy volunteers can represent a particularly vulnerable population in emerging economy- and developing countries, specific attention should be paid to ensure that they are able to provide genuine informed consent, and to ensure their safety.

Are the potential **risks and benefits** that relate to the proposed research adequately presented within the informed consent procedure?	
Are there any mechanisms in place, which can ensure that participants cannot be also enrolled in **several similar research projects** at the same time or within a short time period from the planned research?	

Standard of care

The revised Helsinki Declaration states that "the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention." It is expected that within the framework of the Seventh Framework Programme (FP7), this recommendation is followed.

Does the standard of care provided to the research participants comply with the relevant international rules and recommendations? **If not**, please justify.	

Ethical review process

The relevant local independent Ethical Review Committee (ERC) from which an authorisation is planned to be requested) must be identified in the submitted documents. International guidelines require approval by two ERCs, one local (i.e. located in the country where the study is planned to be conducted) and one in the country where the sponsor is based.

Is the relevant **local independent relevant ERC** identified in the proposal?	
Will there be a **double ethics review** by the local ERC and the ERC of the sponsor's country. **If not**, please justify.	

Informed consent / assent

A special CORDIS document on informed consent specifies the requirements of the appropriate proper informed consent procedure [1] In emerging economy-and developing countries, because of particular cultural or environmental factors, a participant's informed consent/assent **may** involve other community figures and/or family members.

Independent of the cultural particularities that may require a slight modification of the standard procedures, the **principle of Informed Consent** — individual, comprehensible and fully documented — **is fundamental.** It must be adhered to in all circumstances without exposing the individual to discrimination or danger simply because the procedure does not fully comply with the local cultural settings. It is also important to ensure that the participants will not face any risk that relates to their refusal to participate in the planned study, and are offered actual alternative options.

Are **the principles of an individual informed consent / assent** well-documented (in writing) and followed ?	
Does the research involve **particularly vulnerable populations** (e.g. orphans, migrants, sex workers, etc.)? **If yes**, are adequate provisions in place to ensure adherence to the principles of an individual informed consent/assent?	
Are actual and potential **risks** clearly spelt out in the information documents and proposed verbal explanations if the local population has developed a non-written culture?	
Are the potential **benefits** presented in a balanced and objective way and in a locally accessible form?	
Do the inducement **rewards or participation-related compensation** provided for participating in the research, threatens or challenges the ability of research human subjects to provide genuine informed consent?	
Does the designed informed consent process appropriately explain the alternatives provided to the participants in case they do not wish to enrol in the research?	

[1] http://cordis.europa.eu/fp7/ethics_en.html

Data protection

Data protection and privacy must be ensured, in compliance with EU/national legislation. The research must describe in detail how, for how long and by whom study data will be handled, protected, stored. If cross-country transmission is anticipated, a formal legal agreement, such as a Material Transfer Agreement or a Memorandum of Understanding is recommended so as to safeguard the rights of developing countries, but also those of the stakeholders of the developed country.

Does the research involve the processing of **personal data?**	
Does the research involve the processing of **genetic information or sensitive personal data** (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	
Is **Data Protection and Privacy** ensured, in compliance with the relevant EU and/or national legislation?	
Does the proposed research appropriately address **data** ownership, storage and access?	
Does the research appropriately address **biological samples** ownership, storage and access?	
If cross-country transfer of **biological samples** is considered, is a Material Transfer Agreement or a Memorandum of Understanding available? **If not**, justify.	

Animal welfare

Research projects must comply with the applicable EU/national legislation governing animal experimentation. The proposed research should also contribute to the building of capacity (e.g. in terms of training on animal experiments and/or facilities).

Does the research project comply with the **applicable EU/national legislation** governing animal experimentation?	
Will the research be evaluated by an appropriate ERC?	
Does the experiment involve **endangered animal species**?	
Does the research help in **building local capacity** for humane conduct of animal experimentation?	

SOME USEFUL REFERENCES

1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. OJ L 121, 1.5.2001.

2. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ 23 November 1995 No L. 281 pp. 0031-0050.

3. Directive 86/609/EC of the European Parliament and of the Council of 24 November 1986 on the protection of animals used for experimental and other scientific purposes. OJ L 358 , 18/12/1986 P. 0001 – 0028.

4. World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Available from: http://www.wma.net

5. Ethical aspects of Clinical Research in Developing Countries. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, 2003.

6. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organizations of Medical Sciences (CIOMS) ISBN 92 9036 075 5. Available from: http://www.cioms.ch/frame_guidelines_nov_2002.htm

7. Universal Declaration on Bioethics and Human Rights. Available from: http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

8. International Convention on Biological Diversity. Available from: http://www.cbd.int/

9. JR Mc Millan, C. Conlon (2004). The ethics of research related to healthcare in developing countries. J Med Ethics. 30. 204-206.

10. Wendler D, Emanuel EJ, Lie RK (2004). The standard of care debate: can research in developing countries be both ethical and responsive to those countries' health needs. Am J Public Health. 94-6:923-928.

EUROPEAN COMMISSION
Directorate-General for Migration and Home Affairs
Directorate-General for Research and Innovation
Directorate-General for Trade

Guidance note — Research involving dual-use items

Exporting certain goods/technologies can be a security threat, especially in terms of WMD (Weapons of Mass Destruction) proliferation.

Transactions involving such **dual-use items** can be subject to certain **restrictions**, which may affect your research project.

All H2020-funded projects must comply with the relevant national, international and EU laws on dual-use items.

This note explains what requirements may apply to research involving dual-use items.

Identifying dual-use concerns

Check carefully if your research, develops, produces or uses any dual-use items, technology or software.

What are dual-use items?

- *Definition: items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices - Article 2(1) of Regulation No 428/2009*
- *List of items concerned – Annex I of Regulation No 428/2009*

Addressing dual-use concerns

If it does, you will have to comply with the following controls and/or requirements:

- Export authorisations – usually granted by the authorities of the EU country where the exporter is based.
- Brokering authorisations – from the same source (*these are needed if you are carrying out brokering services for dual-use items – Article 5(1) of Regulation 428/2009*).

- Additional restrictions – required by some EU countries. Check with the relevant national authorities.
- Intangible technology transfers (ITTs) – you may require an authorisation to publish your research findings (e.g. in a scientific article in a journal from outside the EU) if they concern technology that could be used to develop, produce or use dual-use items.
- Transit restrictions – some countries may prohibit the transit through their territory of non-EU dual-use items (*whether listed or not in Annex I of Regulation 428/2009*).

If your planned research could involve, develop, produce or use dual-use items, software or technologies, you will need to do the following when preparing your proposal:

- tick the box in the ethics table in part A
- clearly state in part B which items could come under the dual-use rules, and how you will make sure your research complies with the rules
- describe in the risk table in the **management section** what action you would take if the national authorities do not grant authorisation.

If your proposal involves the exportation dual-use items, you will need check the rules governing this in your country and, if necessary, apply to the relevant national authorities for authorisation.

Sample situations

Example 1 — Authorisation required for transferring equipment

A project was planning some testing activities in an EU accessing country. The tests needed an item classified as dual-use under Regulation 428/2009 and so authorisation was needed.

However, because the beneficiary failed to submit its licence application on time to the authorities in the 'exporting' country, the authorisation was not granted in time for the test. The project could not export the equipment and had to choose between:

(i) rescheduling the testing in another EU country at the beneficiary's own cost, or

(ii) buying new equipment locally.

Example 2 — Authorisation required to publish research

One EU country, invoking Article 3 of Regulation 428/2009, required a prominent virologist to obtain an export licence before publishing the results of his research on a certain virus, as the research could be construed as contributing to the proliferation of biological weapons.

The researcher challenged the requirement before the national court, arguing that his work did not fall within the scope of the article and claiming that the requirement would hamper scientific progress and create legal inequality between different countries.

The court ruled that the authorisation requirement was justified, explaining that any exceptions should be interpreted strictly given the importance of non-proliferation.

Further information

Guidance — How to complete your ethics self-assessment

Dual use on the Europa website

Guidance note — Research with an exclusive focus on civil applications

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EUROPEAN COMMISSION
Directorate-General for Migration and Home Affairs
Directorate-General for Research and Innovation
Directorate-General for Trade

Guidance note — Research with an exclusive focus on civil applications

Only research and innovation **activities** focusing on **civil applications** are **eligible for funding** under Horizon 2020. Research intended to be used in military applications, cannot be funded under this framework programme.

This note provides some guidelines to help you determine whether or not your research meets this criterion.

How to determine if your research has an exclusive focus on civil applications?

If your research is intended to be used in military application or aims to serve military purposes, it cannot be funded under Horizon 2020.

As long as your research is intended for non-military activities, it could be eligible for funding.

Projects involving the defence industry or military organisations are not automatically excluded from funding. Research on defence related subjects may still qualify for funding, as long as its aims are exclusively focused on civil applications.

Examples of previously funded projects which complied with the exclusive focus on civil applications criterion:

Projects involving the defence industry or military organisations such as: the UK Defence Science and Technology Laboratory (Dstl) the Swedish Defence Research Agency (FOI) and the Norwegian Defence Research Establishment (FFI).

Projects on defence related subjects such as: explosives, chemical, biological, radiological and nuclear defence or counter-terrorism.

A considerable number of technologies and products are generic and can address the needs of both civil and military users. They are called 'dual-use goods or technologies'. If your research is intended to develop or improve dual-use technologies or goods, it may still qualify for funding, as long as the goods or technologies are intended for civil applications.

How to address the exclusive focus on civil applications criterion in your proposal?

If your planned research has an exclusive focus on civil applications, you will need to do the following when preparing your proposal:

- tick the box in the ethics table in part A
- clearly state in part B how your research will focus exclusively on civil applications.

Further information

Guidance — How to complete your ethics self-assessment

Guidance note — Research involving dual use items

Article 19(2) of the Horizon 2020 Framework Programme Regulation No 1291/2013

Commission Communication: Towards a more competitive and efficient defence and security sector

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EUROPEAN COMMISSION
Directorate-General for Migration and Home Affairs
Directorate-General for Research and Innovation

Guidance note — Potential misuse of research

Some research involves materials, methods or technologies or generates knowledge that could be **misused for unethical purposes**. Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals or the environment.

Although the risk of **misuse of research** can never be eliminated, it can be minimised by recognising risks in good time and taking the right precautions.

All H2020-funded projects must avoid such misuse and comply with the numerous international, EU and national laws that address concerns relating to potential misuse of materials, technologies and information. If beneficiaries breach any of their obligations under the Grant Agreement, the grant may be reduced or terminated.

This note helps to identify and address potential misuse of research.

⚠ This note does not cover research misconduct *(e.g. falsification of research results, fabrication of scientific evidence and plagiarism)*.

Identifying potential misuse

To identify any possible misuse, start by considering the risks associated with the research you plan and any unethical ways in which the materials, methods, technologies and knowledge involved could be used.

The research most vulnerable to misuse is research that:

- provides knowledge, materials and technologies that could be channelled into crime or terrorism
- could result in chemical, biological, radiological or nuclear weapons and the means for their delivery
- involves developing surveillance technologies that could curtail human rights and civil liberties
- involves minority or vulnerable groups or develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.

When designing a proposal, consider not only the immediate aims and intended applications of the activities you plan, but also whether your research could serve unethical purposes.

You should also examine whether there are any risks that will outlast the project itself.

Questions to identify potential misuse include:

- Could the materials/methods/technologies and knowledge concerned harm people, animals or the environment if modified or enhanced?
- What would happen if they ended up in the wrong hands?
- Could they serve any purposes other than the intended ones? If so, would that be unethical?

Sample situations

Example 1 — Research into biological agents

A research lab successfully reconstitutes an extinct virus. Although this is a scientific breakthrough, releasing the virus – whether accidentally or on purpose – would jeopardise public health and safety and might result in millions of deaths.

Example 2 — Vulnerability studies in the field of airport security

To improve airport security in Europe, a team of researchers conducts a series of vulnerability assessments to identify shortcomings in the security systems of certain airports. Their findings could help make airports less vulnerable to threats. However, if such findings end up in the wrong hands, they could be used to plan an attack on these particular airports.

Addressing potential misuse

There are various ways to mitigate risk. Depending on the activity planned and the potential misuse, applicants may choose to:

- take additional security measures, *e.g. physical security measures, classification of certain deliverables, compulsory security clearance for those involved in the project*
- take additional safety measures, *e.g. compulsory safety training for staff*
- adjust the research design, *e.g. use dummy data*
- limit dissemination, *e.g. by publishing only part of the research results, regulating export, etc.*

You may also consider appointing an independent ethics advisor or an ethics board with experts from different backgrounds who are not involved in managing the project's research activities.

If you are planning research that may give rise to concerns about potential misuse, you will need to do the following when preparing your proposal:

- tick the box in the ethics table in part A
- provide a risk-assessment in part B and explain how you will prevent misuse
- if required, attach copies of authorisations, security clearances and ethics approvals

describe in the risk table in the management section what action you would take if the national authorities do not grant authorisation.

Further information

Guidance — How to complete your ethics self-assessment

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Research Ethics:

A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research

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A. EXECUTIVE SUMMARY

The following Report titled "**A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research**" is based on discussions among 51 Ethics Experts with previous experience in EU Ethics Screening, Review and Audit and was chaired by Johannes Rath. The discussions took place from December 2009 to March 2010 via the SINAPSE system and concluded that:

Research misconduct and potential misuse constitute an ethical issue in the context of EU funded research and should be systematically addressed in EU Ethic's oversight (Screening, Review and Audit).

In defining the scope of this ethical issue the following definitions were used as guidelines:

A. **"Potential misuse of research"** in the context of this document is defined as: **Research involving or generating materials, methods or knowledge that could be misused for unethical purposes.**

   The **main areas of concern regarding potential misuse** are:
   - Research involving agents or equipment that could be directly misused for criminal, terrorist or unethical military purposes;
   - Research which creates knowledge that could be used for criminal, terrorist and unethical military purposes;
   - Research which can result in stigmatization and discrimination;
   - Application and development of surveillance technologies;
   - Data mining and profiling technologies.

B. **"Research misconduct"** in the context of this document is defined as: **fabrication, falsification and plagiarism.**

   Falsification is defined as the misrepresentation of results.
   Fabrication is defined as the reporting on experiments never performed.
   Plagiarism is defined as taking the writings or ideas of another and representing them as one's own.

Aim of this report: The aim of this document is to provide a comprehensive strategy on how to safeguard EU funded research against misconduct and misuse. In a comprehensive approach the potential role and proposed actions of relevant stakeholders are addressed:

1. The EU Commission and its subsidiary institutions;
2. EU Ethics Screeners, Reviewers and Auditors;
3. Research project applicants, host institutions and national contact points.

B. INTRODUCTION

The **potential misuse of research** has received substantial attention in recent years due to the dramatic impacts such misuse has had in the general public. The Amerithrax case in the United States in year 2001 has not only cost the lives of 5 persons but also created an economic damage estimated to be in the area of 1 billion Dollars (1). The need to safeguard against such misuse has led to numerous legislative initiatives in various countries (2, 3). It has also stimulated the discussion among scientists, scientific institutions and publishers to establish and implement codes of conduct to minimize the risks of misuse of research (4, 5). Several funding institutions have developed and established such oversight mechanisms to ensure that the risks for such misuse are minimized (6). Such as, in the European Union the EU presidency has presented Ethics as the key oversight mechanism to ensure that EU funded research is not misused in the context of bio-warfare or bioterrorism (7).

In addition to the context of terrorist and unethical military use of research other areas of potential misuse have created concerns in recent times. Stigmatization and discrimination of individuals or groups of individuals is one example. National legislators in several countries, for example, have introduced new legislation safeguarding against such misuse in the context of genetic data (8,9).

Another example is the potential misuse of modern Information and Communication Technologies (ICT) for unethical purposes which has been the driving force for legislators to continuously update and develop new legislation mainly in the context of personal data protection to safeguard against such misuse. However, as research progresses sophisticated new tools are developed, that may allow the re-personalization of previously anonymous data (e.g. deep mining, image reconstruction technologies). To balance the needs between security and the risks to privacy for such technologies will remain a continuous challenge for ethics reviewers as well as legislators.

As an ever growing number of people today are working in research so has the number of individuals having access to research materials, technologies or knowledge suitable for misuse. Furthermore, science today is progressing in areas where misuse could have substantial and widespread impacts (e.g. security related research, synthetic biology, nanotechnology) to humans, animals, plants or economies (10).

Potential misuse of research could be addressed at all levels of EU Ethics oversight**. Screening** should ensure that proposals having misuse capabilities are forwarded to the **Ethics Review** in order to define and ensure adequate safeguards. An **Audit** process could verify that safeguards are adequately implemented by the project investigator and any risks that would arise during the course of the project are addressed.

Cases of research **misconduct** are frequently discussed in leading scientific journals and have gained substantial public interest as even highly regarded scientists have been involved in such misconducts recently (11). Such misconduct is not only diminishing scientific integrity but also public acceptance of science. Various institutions have set up mechanisms to counter research misconduct (12, 13, 14). Three areas of scientific misconduct are usually identified in these mechanisms which are falsification, fabrication, and plagiarism.

Within the EU ethics oversight regime auditing could be used to address research misconduct. Such an assessment could have substantial implications to the scientist therefore clear procedures would need to be established. Such procedures do not exist yet and would need to be developed.

EU ethics oversight can substantially contribute to safeguard EU funded research against misconduct and potential misuse by complementing partially existing institutional, national and international mechanisms.

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C. ROLE OF THE EU COMMISSION AND ITS SUBSIDIARY INSTITUTIONS

The EU Commission, together with its subsidiary institutions, play a central role in safeguarding EU funded research against misconduct and potential misuse by defining the framework and organizing Ethics Screening, Review and Audit. Actions that could be taken by the Commission to minimize the risks of research misconduct and misuse are summarized in detail in Table1.

It is anticipated that the implementation of the actions would benefit:

- Awareness of this ethical issue among applicants and ethics experts;
- Consistency of the assessment in ethics screening, review and audit;
- Scientific integrity.

Table 1: Suggested actions for the EU Commission and its subsidiary institutions

ACTION 1: Increase the awareness among applicants:

- Replace the current " Dual-Use" box/ or add as a new box on the **Ethical issues table** the following ethical issue:

  "Can materials, technologies or knowledge used or generated during the project be misused for unethical purposes?
  Examples:
  a. *Materials and technologies that could be used in weapons production, operation or dissemination (e.g. pathogens, toxic chemicals, nuclear material, explosives specific software systems, special robot systems);*
  b. *Information that could be misused for criminal, terrorist or unethical military activities (e.g. vulnerability studies, how to increase harmful consequences of weapons for example antibiotic resistance studies);*
  c. *Information that could result in stigmatization or discrimination of individuals or groups of individuals;*
  d. *Application or development of surveillance technologies that could be misused for unethical purpose ;*
  e. *Data mining and profiling technologies that could be misused for unethical purposes ."*

- Develop a specific guidance document for applicants, which should include potential misuse case studies on and a list of potential consequences in case of research misconduct.

ACTION 2: Increase expertise, awareness and common understanding of this ethical issue among Screeners, Reviewers and Auditors by:

- Providing this document to all Screeners, Reviewers and Auditors;
- Ensuring representation of relevant experts in Screening, Review and Audit panels;
- Providing training to all Ethics Experts participating in Screening, Review and Audit on this ethical issue;
- Establishing an open SINAPSE discussion platform for an informal exchange of experiences and views.

ACTION 3: Ensuring scientific integrity by investigating alleged research misconduct:

- Establish an Ombudsman system where concerns about misconduct in EU funded research could be filed confidentially;
- Establish a standard operating procedure and carry out trial runs on how to investigate and assess research misconduct in the context of EU financed research (e.g. within Ethics Audit);
- Establish a team trained in dealing with alleged research misconduct.

ACTION 4: Review and update current guidance document regularly to enhance practicability and ensure adequate representation of emerging issues

D. ROLE OF THE EU ETHICS SCREENERS, REVIEWERS AND AUDITORS

By carrying out Ethics screening, review and audit, EU Ethics experts play a key role in ensuring that EU funded research is in-line with the current EU standards in ethics. Table 2 of this document provides an overview on what types of research are of key concern with regards to potential misuses; it also provides concepts on how to safeguard such research during Ethics Review. Thereby it shall enhance a common understanding of this ethical issue and improve consistency of evaluation outcomes in the future.

Safeguards should be proportionate to risks resulting from potential misuse. In case the proposed research can not be safeguarded adequately and the risks of misuse outweigh the expected benefits the experts may consider recommending to the EU Commission not to fund the particular work programme or project as a whole.

The list provided is non-exhaustive and should not limit the inclusion of other areas of research that could be misused for unethical purposes.

Ethics Screening should ensure that all relevant proposals enter Ethics Review. Ethics Audit could be used to verify that all safeguards expressed as Requirements are implemented adequately.

Table 2: Key areas of concern, examples and potential requirements

Research activities of concern	Examples	Potential Requirements
a. Research involving human, animal and plant pathogens, toxic chemicals, and radioactive material that when misused could cause severe harm to humans, animals, plants or the environment.	**Agents: Pathogen species, toxic substances**, for examples see COUNCIL REGULATION (EC) No 428/2009 Annex 1	• Any weaponization of such agents needs to be checked for its legitimacy in relation to relevant international conventions and on a national level. • Provide national approvals (e.g. handling of pathogens at biosafety level 3 and above, radioactive substances, toxic chemicals, export licences). • Keep inventories. • Restrict access to locked rooms, locked cabinets. • Require training in bio-security. • Require special training on safety and security for persons handling such substances should receive. • All agents must be inactivated after the project or the applicant must ensure that no unauthorized access to such agents occurs after the end of the project.
	Special manipulations Examples: Disrupting immunity or the effectiveness of an immunization, conferring to a biological agent or toxin, resistance to prophylactic or therapeutic interventions against that agent or toxin facilitate their ability to evade detection methodologies; increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin.	
b. Research involving other types of materials that when misused could cause severe harm to humans, animals, plants or the environment.	Explosives, conventional weapons, small arms	• Provide national approval for the handling of such materials. • Provide export licences if international movement of agents listed in Annex 1 of Council Regulation 428/2009 is carried out.

		• Access should be restricted (locked rooms, locked cabinets). • Persons handling such materials should receive special training. • After the project such materials should be destroyed or the applicant must ensure that no unauthorized access to such materials will occur.
c. Research that, based on current understanding, can be reasonably anticipated to provide knowledge, which could be misused for criminal, terrorist or unethical military purposes	Knowledge on how to enhance the harmful consequences of weapons, infrastructural vulnerabilities, autonomous robots with self organizing computing and networking capabilities Weapons support systems (e.g. software in the context of the EU dual use directive);	• Include Security Experts in Advisory functions. • Restrict access of such information to key stakeholders. • Ensure adequate data protection during the course of project. • Workpackage on security impacts of the generated knowledge and potential safeguards.
d. Research involving ICT and surveillance with the potential for misuse	Personal data protection (e.g. data mining and profiling technologies); Surveillance technologies with the potential to violate core spheres of privacy (e.g. family communication).	• Ensure EU standards on data protection are met by Non-EU applicants. • Ensure that technical and/or organisational safeguards are introduced so that results can only be employed in an EU ethics standards compliant manner. • Ensure that technical personnel (e.g. IT service provider) is also bound by confidentiality.
e. Research with the potential for stigmatization and discrimination	Genetic or other (e.g. social, medical) studies creating information that could be misused for stigmatization and discrimination (e.g. insurance, employment).	• Require local ethical approval Ensure personal data protection at EU standards. • Verify national legislations exists to prohibit discrimination in the context of genetic information life • Establish a project advisory group on this issue. • Include minority representatives in the project management/advisory group. • Provide copies of national approvals in case the relevant jurisdiction foresees such approvals. • Ensure adequate data protection to avoid illegitimate access by third parties. • Ensure that research subjects are well informed about this potential misuse during informed consent.

E. ROLE OF THE RESEARCHER (PROJECT APPLICANTS), NATIONAL CONTACT POINTS AND HOST INSTITUTIONS

Researchers creating risks to the society have a responsibility to safeguard their research against such risks. No oversight system can fully compensate for this responsibility. Awareness of this issue among researchers has increased however; practical arrangements to address misuse or to incorporate safeguards in their work are often missing (e.g. biosecurity). Applicants should be assisted through expertise provided by their respective national contact points and host institutions in identifying relevant existing national and international safeguards and, if needed, develop project specific safeguards to ensure potential misuse is minimized.
The following checklist (Table 3) provides some ideas on what elements should be addressed.

Table 3: Potential misuse of research: CHECKLIST FOR APPLICANTS, HOST INSTITUTIONS AND NATIONAL CONTACT POINTS

1. Do you foresee any potential misuse for unethical purposes that could result from this research project?

2. Does your project involve any of the following key areas of concern:
    a. Agents and technologies that could be misused in weapons context (e.g. pathogens, toxic chemicals, nuclear material, explosives, software robotic systems)
    b. Information that could be misused for criminal, terrorist or unethical military activities (e.g. vulnerability studies, how to increase harmful consequences of weapons for example antibiotic resistance studies)
    c. Information that could result in stigmatization or discrimination of individuals or groups of individuals
    d. Surveillance technologies that could be misused for unethical purposes
    e. Data mining and profiling technologies that could be misused for unethical purposes

If so:
1. Tick relevant box on “Ethical Issues Table”
2. Provide an assessment of this misuse potential in the “Ethical Issues” section of the application
3. Provide information on safeguards on how to minimize the potential for misuse. Such safeguards could be for example
    a. existing national legislation and approvals (e.g. Dual-Use export import legislation, work in contained environments, etc)
    b. incorporation of adequate advisory boards into the project management
    c. access restrictions
    d. transfer restrictions

F. CONCLUSION

In conclusion, the discussion group **clearly identified misconduct and the potential misuse of research as an ethical issue**. Adequately safeguarding against such risks will not only protect individuals and the society as a whole, but also scientific integrity and the scientists.

This document provides a comprehensive framework for such action by proposing an integrated mechanism involving funding institutions, ethics experts and researchers. It identifies the scope of the ethical issue, provides safeguarding ideas and describes the roles relevant stakeholders could play. The framework which is clearly laid out in three tables is not only comprehensive; it is also practical and can be utilized in the context of EU Ethics oversight as a tool with immediate results.
To ensure and further enhance practicability the concepts outlined in this document should be evaluated on a regular basis for their relevance and efficiency, and amended as necessary.

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Ethics

for researchers

Facilitating Research Excellence in FP7

Research and Innovation

EUROPEAN COMMISSION

Directorate-General for Research and Innovation
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Directorate-General for Research and Innovation
Science in society /Capacities FP7

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Introduction

Designed for all researchers who are preparing an application to receive funding from the European Union for their research, this document describes the most important aspects of research ethics and indicates the main points of attention for the Ethics Review procedure as a part of the 7th Framework Programme (FP7). For research funded by the European Union, ethics is an integral part of research from beginning to end and ethical compliance is pivotal to achieve real research excellence.

After a briefly explaining the history and legal basis of research ethics (Chapter 1) it is illustrated how exactly the Ethics Review procedure is integrated in the application and evaluation process. (Chapter 2) Chapter 3 will help you to understand the core subjects of research ethics and provides a practical roadmap to help with the preparation of your proposal.

SCIENTIFIC MISCONDUCT

Scientific misconduct includes (negligent or intended) fabrication (making up data or results), falsification (changing or misreporting research data or improper manipulation of experiments) and plagiarism (using ideas or words without accurate reference).

These practices go against all scientific values and can undermine the scientific progress. Even more, it can cause harm.

The European Commission condemns all forms of scientific misconduct. There is no place for these practices in research funded by the European Union.

Chapter I: Research Ethics

True Research Excellence

Ethical research conduct implies the application of fundamental ethical principles to scientific research. All possible domains of scientific research can raise ethical issues. Ethics is not just about the theories and the complex philosophical reasoning. Ethics is everywhere. In everything we do there can be an ethical component. When conducting research, there is clear need to make a thorough ethical evaluation.

Ethics is often misunderstood by researchers as hindering the scientific progress. While it is true that research ethics intends to put boundaries to what is and is not possible (under a certain perspective), it does not intend to regulate research or go against research freedom. The way research ethics is interpreted at the European Commission, aims to be collaborative and constructive. Also, by considering ethics at the conceptual stage of the proposal, the quality of the research is enhanced.

The Nuremberg Code[1]

The Nuremberg Code is one of the most important documents in the history of research ethics. The Code was formulated in 1947 in Nuremberg, Germany, by the American judges of the Nuremberg Tribunal, who had to judge doctors of the Nazi-regime accused of murderous and torturous human experiments. The Nuremberg Code, with principal focus on medical research, consists of only 10 rules, indicating the most basic and fundamental principles. Consent, proportionality, necessity and the right to withdraw are at the core of this document. Although the Nuremberg Code has never officially been adopted as law, it has had a major influence on human rights law and medical ethics. Previous ethics codes focussed on the obligations of the investigator towards the research subjects. The Nuremberg Code reverses that logic: The rights are directly awarded to the research subjects. This was, at that time, a fundamentally different view on research ethics.

History and Legal Basis of Research Ethics

For a good understanding of the field, it is important to take a look at the history of research ethics. Research ethics is most developed as a concept in medical research, but the general principles apply for all fields of research. Informed consent and confidentiality are as important for a sociological study as they are for clinical research.

As a reaction to malpractices that were revealed during the Nuremberg trials, the World Medical Association (established in Paris in 1947) adopted a declaration on research ethics in 1964, in Helsinki, Finland.[2] Since, *the Declaration of Helsinki* has been reviewed for several times, but the general focus and core ideas remain the same.[3] The *Declaration of Helsinki* sets forward ethical principles for the conduct of medical research on human subjects, including research on identifiable human material and data. The basic principle behind the declaration is that, for all research, the well-being of the individual research subject must take precedence over all other interests. The declaration sets principles for the conduct of medical research and additional principles for medical research combined with medical care.[4]

Although research ethics is most developed within the context of medical research, research ethics is of crucial importance for **all scientific domains**. Professional and academic associations have often provided guidance documents and ethics codes, adapted to the specificities of their research domains. Good examples are the *Code of Ethics* from the International Sociological Association, The

Code of Ethics and Conduct from the British Psychological Society and the ethics guidelines from the British Educational Research Association.[5]

There is a strong connection between **research ethics and human rights**. Both fields influence each other and there are significant overlaps. This is illustrated by the *Convention on Human Rights and Biomedicine* or the *Oviedo Convention*, adopted by the Ministers of the Council of Europe in 1996.[6] This convention is meant to address the ethical issues raised by research within the framework of the protection of human rights and sets common standards for all members of the Council of Europe.[7] The convention sets out the general fundamental principles, additional protocols provide standards for more specific types of research. These principles include the primacy of the interest and welfare of the human being, informed consent and privacy.[8] The *Oviedo Convention* also sets standards for the use of the human genome and research on human embryos.[9] The *Additional Protocol Concerning Biomedical Research*, signed by most members of the Council of Europe but only ratified by a few[10], confirms the general principles and provides more specific rules for the role of ethics committees in research, the conditions for adequate informed consent, confidentiality and the right to information.[11] Other important international declarations and conventions are the UNESCO's *Universal Declaration on Bioethics and Human Rights* and the Council for International Organizations of Medical Sciences' (CIOMS*) International Ethical Guidelines for Biomedical Research Involving Human Subjects*[12]

Within the European regulatory framework, research ethics is based on the explicit European commitment to human rights. Firmly enshrined in the treaties[13], compliance with human rights is pivotal for all European policy domains. To further strengthen this commitment, the European Union adopted its own human rights legislation, the *European Charter of Fundamental Rights.*

THE EUROPEAN CHARTER OF FUNDAMENTAL RIGHTS[14]

Taking into account the ethical aspects of research practices has a particular significance in the European legal framework as the European Union is founded on a common ground of shared values laid out in the European Charter of Fundamental Rights. The Charter recognises a range of personal, civil, political, economic and social rights. The Cologne European Council of June 1999 entrusted the task of drafting a charter to a convention. The Lisbon Treaty incorporates the Charter into the Treaty on the European Union, giving the charter an equal legal effect, and states that all European legislation needs to conform to the principles of the Charter. Consequently, this also applies to the European research policy. The European Charter of Fundamental Rights contains several principles which can be relevant in the context of research. These principles form the basis of important ethics guidelines but also support the conduct of research.

Article 3 – Right to the integrity of the person

Everyone has the right to respect for his or her physical and mental integrity.

In the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law;
- the prohibition of eugenic practices, in particular those aiming at the selection of persons;
- the prohibition on making the human body and its parts as such a source of financial gain;
- the prohibition of the reproductive cloning of human beings.

Article 7 – Respect for private and family life

Everyone has the right to respect for his or her private and family life, home and communications.

Article 8 – Protection of Personal Data

Everyone has the right to the protection of personal data concerning him or her.

Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

Compliance with these rules shall be subject to control by an independent authority.

Article 13 – Freedom of the Arts and Sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

Chapter II: The 7th Framework Programme: The Ethics Review Procedure

Ethics Reviews are an integral component of the research proposal evaluation procedure undertaken by the European Commission. The purpose of these Ethics Reviews is to ensure that all research activities carried out under the 7th Framework Programme are conducted in compliance with fundamental ethical principles.

The 7th Framework Programme is a significant source of public funding dedicated to supporting a sound research community for a better future for Europe. Through the Ethics Review, some concerns the public might have relating to scientific research, are represented and addressed. The 7th Framework Programme legislation explains in more detail the most important aspects for the Ethics Review at the European level.

The 7th Framework Programme: Article 6 – Ethical Principles

In compliance with the general obligations from the Treaties, the *7th Framework Programme Legislation*[15] sets general standards for all research funded by the programme. Article 6 of the decision comprises the applicable ethical principles:

1. *All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.*

2. *The following fields of research shall not be financed under this Framework Programme:*

   - *research activity aiming at human cloning for reproductive purposes,*

   - *research activity intended to modify the genetic heritage of human beings which could make such changes heritable,*

   - *research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.*

3. *Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved.*

   Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided.

   As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved.

The Ethics Review Procedure

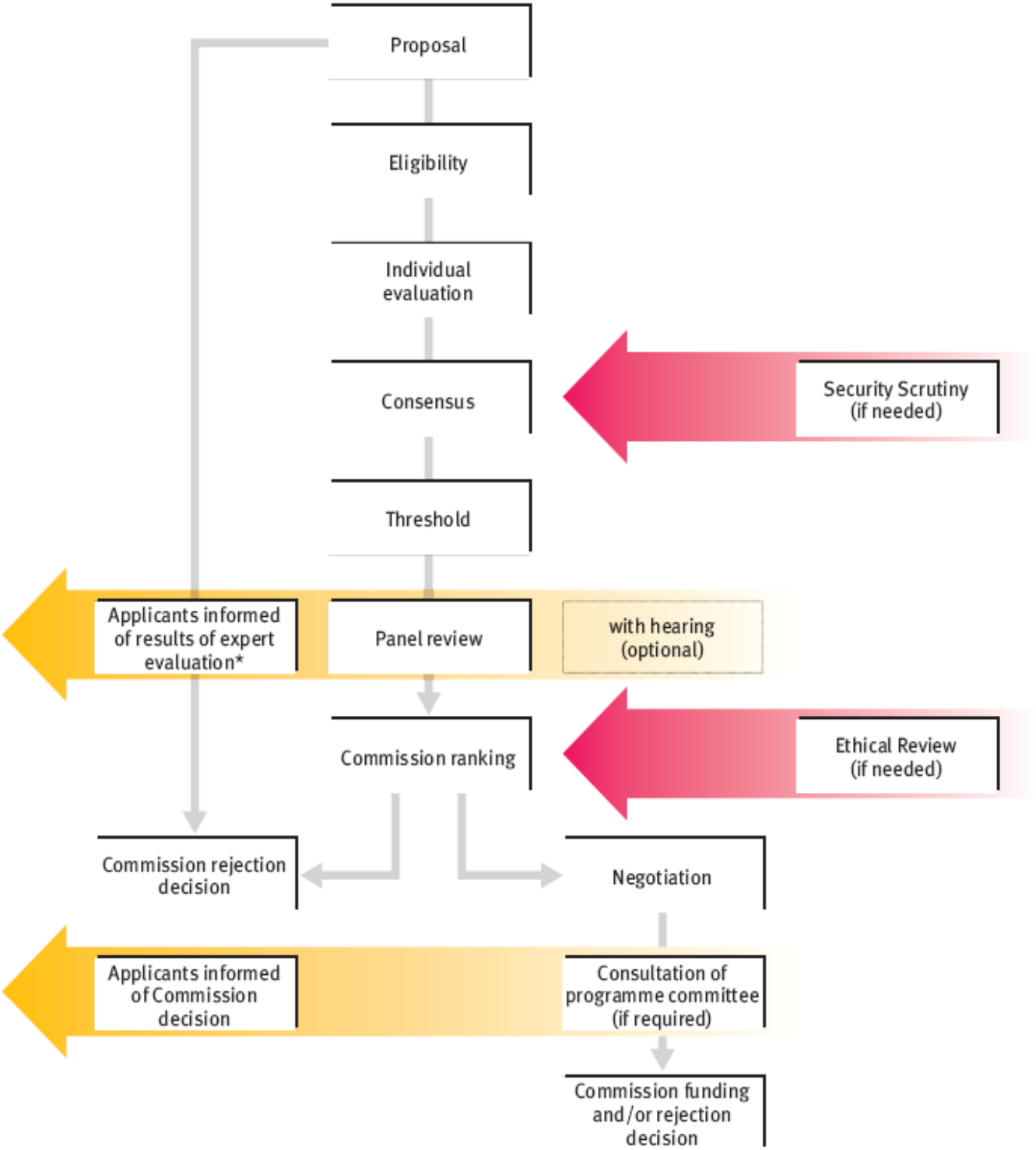

Ethics Requirements

Both after the Ethics Screening and the Ethics Review, the experts can formulate recommendations and requirements. The requirements formulated in the Ethics Screening Report or the Ethics Review Report form the basis for specific obligations in the Grant Agreement. When national approvals of competent authorities and opinions of ethics committees are required, the European Commission ascertains that these authorizations and favourable opinions are in place before the start of the corresponding research.

The Optimal Composition of an Ethics Review Panel

Ethics Reviews at the European Commission are performed by a panel of experts from different disciplines such as law, sociology, philosophy, ethics, psychology, information technology, medicine, molecular biology, and veterinary science. Representatives of civil society may also be invited, such as representatives of patient organisations. The experts in the Ethics Review Panel have the same status as the experts performing the scientific evaluation and are bound by the European Commission obligations concerning conflict of interest and confidentiality. Ethics Review panel members are selected according their expertise, but also other criteria such as the gender balance of a panel group are taken into account. The overall objective is to include at least 45% of women in the panels. The Commission also makes constant efforts to recruit experts from all Member States.

All research proposals submitted to the European Commission are evaluated both on their scientific merit and on its ethical and social impact. When preparing a proposal, it can be appropriate or required to include an Ethics Annex with a completed Ethical Issues Table.[16] During the scientific evaluation of the proposals, *"the experts identify the proposals that may require further assessment due to the importance of the ethical issues raised by the proposal or the degree of adequacy of the way the ethical issues are addressed in the proposal."*[17]

The proposals retained by the experts with a view to funding, but identified as raising ethical issues, will be submitted to the Ethics Review.

Ethics Screening

The first phase of the Ethics Review, the Ethics Screening, is meant to identify all proposals that require (ethical) approval at the national level (e.g. with regards to data protection, the conduct of clinical trials and animal welfare) and identifies the proposals that require a full Ethics Review due to the ethical issues they raise (such as intervention on humans, use of non-human primates in research and research on human embryos and human embryonic stem cells).

Ethics Review

After the Ethics Screening process the European Commission may decide to submit proposals to a full Ethics Review. This is mandatory when the research involves intervention on humans, the use of non-human primates, human embryos or human embryonic stem cells.

After an individual assessment of the proposals, the experts meet as a panel and discuss and produce an Ethics Review Report. The Ethics Review Panel assesses the compliance with ethical rules and standards, relevant European legislation and relevant international conventions and declarations, national authorizations and ethics approvals, proportionality of the research methods and the applicants' awareness of the ethical aspects and social impact of their planned research.

Ethics Follow-up and Audit

During the Ethics Screening or the Ethics Review, the experts identify the projects that need a follow-up or audit. The follow-up and audit procedures are executed during the course of the research project and is meant *"to assist the beneficiaries to deal with the ethical issues that are raised by their work and if necessary take preventive and/or corrective measures."* [18]

This procedure is established by the *Commission Decision of 28 February 2011 amending Decision C(2008) 4617 related to the rules for proposals submission, evaluation, selection and award procedures for indirect actions such as the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011).*

Chapter III: Ethical Issues

Ethics might seem a very abstract concept, but, confronted with reality, ethics becomes the challenge to do what ought to be done. Although many of the rules and principles outlined above seem evident, several recent examples indicate we need to remain alert and cautious when it comes to research ethics. Often unintended, important ethics principles are violated.

Clinical Trials Case[19]

In 2008 Nature reported a case of misconduct at the University of Innsbruck. The Austrian government Agency for Health and Food Safety stated that the clinical trials conducted to test the therapeutic efficacy of a stem-cell procedure for urinary incontinence had serious shortcomings. The agency reported a poor study design, inconsistent handling of patients and failure to randomize patients properly. Moreover, they failed to properly inform the patients about the nature of the intervention and the clinical trial was not approved by the relevant government authorities, nor by an ethics committee. Also the insurance certificates for the patients appeared to be dubious.

Indian Trials Case[20]

In 2011, the British newspaper The Independent reported problems with the informed consent procedures applied by Western pharmaceutical companies for their clinical trials conducted in India. Because of its loose regulations for clinical trials, India has become a popular destination. These loose regulations and a lack of oversight led to situations where poor and illiterate people, who have little possibility of redress, are used in trials without giving proper informed consent. One example is the immunisation of hundreds of tribal girls without parental consent. This case was revealed because a young girl died after participating in the study. Although it is very unlikely that the girl died because of the vaccine, the parents only found out afterwards.

Any points raised in ethics reviews are not meant to be punishments or attempts to interfere with your research. Rather, they are requests for safeguards to ensure that human subjects, animals or the environment are protected and the public perception of research remains positive. If certain research methods may raise ethical concerns, you should take measures to ensure that widely shared societal values are not compromised. This is the human element that some researchers can easily overlook or downplay.

MMR Autism Case[21]

In 1998 the medical journal the Lancet published a study linking the Measles, Mumps and Rubella (MMR) vaccine with autism and bowel disorders in children. Since, the research and the publication, leading to a public health panic, have been discredited. The General medical Council in the UK ruled that the responsible scientist acted "dishonestly and irresponsibly during his research and with callous disregard for the children involved in his study." Invasive tests were carried out without due regard for how the children might be affected and blood samples were collected paying children 8 $ at a birthday party. Also, there seemed to be a conflict of interest, because the responsible scientist was being paid by lawyers acting on behalf of parents who believe their children have been harmed by the MMR vaccine. The public health consequences of this fraudulent case continue until today. Due to the public health scare, thousands of children in the UK did not receive the MMR vaccine and remain unprotected. Recognizing that the MMR case exposed failings in the regulatory framework, the University College London revised its research governance framework. More robust procedures, properly embedded into the

management structure of research organisations, must safeguard quality and ethical standards and ensure proper handling of allegations of research misconduct.

Derived from the international and European declarations and legislation, the Ethics Review by the European Commission is based on a list of ethical issues. Whilst this list is not exhaustive, it helps to define the ethical issues a proposal might raise. The most important ethical issues are *privacy and data protection, informed consent, research on human embryos and foetuses, dual use, animal research and research involving developing countries.* Other ethical issues that should be taken into consideration are *scientific misconduct* (such as fabrication, falsification and plagiarism) and the possible *environmental impact* of the proposed research.

PROPORTIONALITY

Are all the data collected really necessary to conduct the research? Often, more data are collected than necessary for the research purpose, raising the question of proportionality. For example, when conducting a survey the full identity of participants is registered when only some basic demographic information would suffice. Personal data collection must be adequate and relevant. The principle of proportionality is also important in other domains. The Ethics Review will verify the necessity to work with children or vulnerable adults or use animals in the experiments. One should always search for alternatives and the methods used must be proportional to the research objectives.

ANONYMISATION, CODIFICATION AND IDENTIFIABLE INFORMATION.

When dealing with privacy and data protection issues, it is important to correctly distinguish between the following categories of data: When personal data are collected, processed and stored, these data can remain **identifiable**, they can be **codified** or completely **anonymised**. Anonymised data are data that cannot be linked back to the individual. Codified data are data where the most obvious identifiers such as names and addresses are replaced with an indirect system of identification, usually through codes. It remains possible to link the indirect identifiers with names and addresses. For each category of data, different rules might apply.

1. Data Protection and Privacy

Laid down as principles in the *Charter of Fundamental Rights*[22] and the *Treaty on the Functioning of the European Union*[23], privacy and data protection are fundamental rights which need to be protected at all time. **Privacy** can mean many different things in different contexts. Not all people have the same notion of the right to privacy, but most people want to maintain control over personal information and personal communications. If personal information is disclosed, we expect this information to be treated confidentially.

Data protection is meant to guarantee our right to privacy. Data protection refers to the technical framework and security measures designed to guarantee that all personal data are safe from unforeseen, unintended or malevolent use. Data protection therefore includes both measure with regard to access to data and the conservation of data. Also measures to assure the accuracy of the data can be included in a data protection strategy.

In the context of research, privacy issues arise whenever data relating to persons are collected and stored, in digital form or otherwise. The main challenge for research is to use and share the data, and at the same time protect all identifiable information to guarantee personal privacy. The personal data needed in research can include health information, genetic information, information on behaviour such as criminal records, financial information, travel records, information on religious beliefs and sexual orientation or ethnic identification records.

The *Data Protection Directive*[24] contains a number of key principles for the handling of personal data. This directive provides the framework for the regulation of data protection and privacy issues in the Member States. When the collection and processing of data is part of the planned research, applicants need to identify the applicable local or national legal requirements and the competent authorities to provide the necessary authorizations. A good overview of the implementation of *Data Protection Directive* by the member states can be found on the website of DG Justice under 'Data Protection.'[25] Please note that recently, the European Commission made an official proposal[26] to amend the current

EXPECTATIONS

What is expected with regards to privacy and data protection? For the Ethics Review, it is important that all relevant regulations and guidelines are followed and that the application is fully documented and prepared to meet all the requirements.

The application should provide an overview of the research activities where collection, processing or transfers of data are involved, including a detailed description of the procedures (e.g. informed consent) to comply with the relevant legislation.

All copies of the necessary national and local authorizations and approvals for all relevant research activities need to be provided. If authorizations or approvals aren't in place yet, a timeframe can be included explaining when approvals and authorizations will be requested or are expected to be granted. If no approvals or authorizations are required, this should also be explained.

Data Protection Directive, so changes in the regulatory framework are to be expected in the near future.[27]

When preparing a proposal to receive funding from the 7th Framework Programme, one should pay very careful attention to privacy and data compliance. In the Ethics Review, it is expected that proposals adequately deal with these issues and clearly show how compliance with all regulations will be assured. Apart from the strict regulatory obligations, it is important to demonstrate the awareness that privacy and data protection are issues which need to be addressed and that a strategy and methodology are developed and implemented.

Further reading & Legal framework:

- Ethical Review in FP7: Data protection and privacy ethical guidelines[28]
- European Textbook on Ethics in Research: Chapter 4: Privacy and confidentiality[29]
- Treaty on the Functioning of the European Union, article 16[30]
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[31]
- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[32]
- UNESCO International Declaration on Human Genetic Data[33]

Although the specifics of an informed consent procedure can vary according to the nature of the research and the needs of the research subjects involved, certain information should be provided to the research subjects before they participate:

- The purposes of the research and information about what will happen with the results of the research.
- The experimental procedures and a detailed description of the involvement of the participants, including the expected duration, and all the relevant procedures.
- All foreseeable risks or discomforts expected to occur for the research subjects during and after their participation.
- All benefits to the participants or to others which may reasonably be expected to occur.
- The insurance guarantees for the participants during and after participation and information on the foreseen treatments and compensations. Alternative procedures or treatments that might be advantageous to the participant need to be disclosed.
- Procedures in case of incidental findings
- A description of the procedures adopted to guarantee the participant's privacy: the levels of confidentiality, the measures to protect the data, the duration of the storage of the data and what will happen with the data or samples at the end of the research.
- Contact details for researchers who can be contacted at any time to answer pertinent questions about the research and the participant's rights and that can be contacted in the event of a research-related injury.
- A clear statement that the participation is voluntary, that the refusal to participate will involve no penalty or loss of benefits to which the participant would otherwise be entitled and that the participant may decide, at any time, to discontinue participation without penalty.
- Information about the organisation and funding of the research project.

2. Informed Consent

Declared one of the most pivotal principles in research ethics in many international conventions and guidelines[34], informed consent is meant to guarantee the voluntary participation in research and is probably the most important procedure to address privacy issues in research. Informed consent consists of three components: adequate information, voluntariness and competence. This implies that, prior to consenting to participation, participants should be clearly informed of the research goals, possible adverse events, possibilities to refuse participation or withdraw from the research, at any time, and without consequences. Research participants must also be competent to understand the information and should be fully aware of the consequences of their consent. Although informed consent is often seen in the context of clinical research, this principle is important for all types of research, including the social sciences.

Informed consent is required in when the research involves the participation of human beings, when the research uses human genetic material or biological samples and when the research involves personal data collection. In some cases, the 'traditional' informed consent procedure might not be sufficient to ensure that the rights and interests of the research subjects are fully respected. It is very important to take into account people's autonomy and vulnerability when deciding on how to organise the consent procedure. Some categories of people require special attention:

- Children[35]
- Vulnerable adults (elderly, prisoners, mentally deficient persons, severely injured patients …)
- People with certain cultural or traditional background: In some communities, the notion of individuality is lacking, written agreements do not exist, or women are not permitted to act autonomously. Strategies must be developed to address these issues with respect for the specificities of the situation.

The way participants are informed is a critical part of the informed consent process. When participants are informed, it is crucial that they fully realize the impact of the research for themselves and for society. Numerous anthropological studies have pointed out that participants rarely recall what they agreed upon when signing an informed consent form. A more interactive approach can address this issue. Good examples are making a presentation of the research project or conducting interviews with the participants to ensure that they understand all the issues at stake. Researchers might forget to explain what will happen with the research data and/or samples at the end of the research. If the data or samples are retained for further research this needs to be included in the consent procedure.

Further reading & Legal framework:

- Ethics Review in FP7: Guidance for Applicants: Informed Consent[36]
- European Textbook on Ethics in Research: Chapter 2: Consent and Chapter 3: Vulnerable and non-competent subjects[37]
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[38]
- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products[39]
- Ethical Considerations for Clinical Trials on Medicinal Products Conducted with the Paediatric Population: Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use[40]

3. Research on human embryo's and foetuses

Since the development of the techniques, the use of human embryos and foetuses for stem cell research is high on the political and ethical agenda. Research with human embryonic stem cells (hESC) gives the prospect to address medical needs, but at the same time raises fundamental ethical questions because research implies the use and destruction of human embryos. These fundamental ethical questions touch upon basic beliefs about the intrinsic value of life and our place in the universe: When does human life start? If an embryo is a human being, can it be destructed for the purpose of research? If hESC research is allowed, which conditions and procedures should apply? Can we allow the production of embryos for the purpose of research or can only spare embryos from IVF treatments be used? For all these questions, the answers vary according to one's beliefs and world views.

Because of the inherent pluralism of Europe, the acceptability and the conditions for the conduct of hESC research are not everywhere the same. In the context of the 7th Framework Programme the diversity in national regulations is addressed as follows:

"Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved. Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved."[41]

Consequently, no research will be funded that is not allowed in all Member States, and no research will be funded in a Member State where such research is forbidden.[42]

Three field of research are explicitly excluded from the 7th Framework Programme[43]:

- Research activities aiming at human cloning for reproductive purposes.
- Research activities intended to modify the genetic heritage of human beings which could make such changes heritable.
- Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Because hESC research is such a sensitive issue, all research proposals involving hESC are closely monitored from beginning to end:

- All proposals are assessed in the Member State(s) where the research will take place. If the research is not authorized by the Member State(s) relevant bodies, the proposal cannot be funded.
- The scientific evaluation of the research proposal assesses the necessity of using human embryonic stem cells to achieve the research objectives.

- Proposals involving the use of human embryonic stem cells or foetal samples will always be automatically referred to an Ethics Review Panel, ensuring an independent ethical assessment on the European level.

For a more details on the specific provisions about hESC research please consult:

- *Statements of the Commission (Re Article 6)* added to *Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)*[44]

- *Annex A "Ethics Review Procedures"* of the *Commission Decision of 28 February 2011 amending Decision C (2008) 4617 related to the rules for proposals submission, evaluation, selection and award procedures for indirect actions such as the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011)*[45]

Further reading & Legal framework:

- UNESCO Universal Declaration on the Human Genome and the Human Rights[46]

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[47]

- European Textbook on Ethics in Research: Chapter 8: Ethical Issues in the New Biotechnologies[48]

4. Dual Use

Dual use is a term often used in politics and diplomacy to refer to technology which can be used for both peaceful and military aims. In the context of research, dual use is to be understood as potential misuse of research. This means that the research activities involve or generate materials, methods or knowledge that could be misused.

- Research that, based on current understanding, can be reasonably anticipated to provide knowledge which could be misused for criminal or terrorist purposes.
- Research involving human, animal and plant pathogens, toxic chemicals, and radioactive materials that, when misused, could cause severe harm to humans, animals, plants or the environment.
- Research which uses classified information, materials or techniques or uses other dangerous or restricted materials.

"A dual-use dilemma is an ethical dilemma (…) since it is about promoting the good in the context of the potential for also causing harm. (…) It is an ethical dilemma for the researcher not because he or she is aiming at anything other than a good outcome; (…) Rather, the dilemma arises for the researcher because of the potential actions of others."[49]

For example, following the definition of the National Science Advisory Board for Biosecurity in the USA, bio-medical dual-use research is research which may enhance the virulence of microorganisms causing diseases; diminish the immunity of the host; enhance the transmissibility of the pathogens (enhance the contagiousness); alter (enlarge) the host range of the pathogen; render a vaccine ineffective; confer resistance to life-saving antibiotics; prevent diagnosis of infection or detection of a pathogen; enable eventual weaponization, severity of disease/symptoms or mass casualty.[50]

The phenomenon is not new, but the existence of weapons of mass destruction, the increase in international terrorism and the introduction of the concepts of bio-warfare and bioterrorism increased the importance of the concept of dual-use. In the past, the concept of dual use focussed on the proliferation of nuclear weapons, in the 21th century, the focus shifted to pathogenic organisms and viruses.

The possible dual use of new technologies and new scientific results creates ethical problems for the scientist and the scientific community, especially with regard to how to define the responsibility to prevent such dual use. European research funding is only possible for research with an exclusive focus on civil applications. This does not mean that dual use research is excluded from the 7th Framework Programme, but special measures need to be taken to ensure that the potential for misuse is adequately addressed and managed.

Applicants are expected to develop a comprehensive approach: A detailed strategy addressing the specifics of the situation, putting the necessary safeguards in place.

1. **Awareness –** Project applicant should be sufficiently aware of the potential risks (the direct risks for the participants and the risks for the society as a whole). Possible measures can be an ex-ante biosecurity assessment, an early flagging system for biosecurity and biosafety problems and education and training.

2. **A strategy –** Project applicants should develop appropriate and detailed procedures to deal with dangerous or restricted materials or information. Biosecurity and biosafety risk management procedures should comply with relevant standards.[1] These procedures can include access controls, assignment of confidentiality levels, the effective control and monitoring of all procedures and the reporting of near misses.

3. **Independent expertise –** Expertise on biosecurity and dual use should be included in the project management structure or in an independent ethics advisory board. It is the role of experts to oversee and assist in the creation of a comprehensive risk management system.

4. **Dissemination, communication and exploitation of the results –** Can the research results be shared with a wider public? What are the risks and possible consequences? How would the public opinion react? Independent experts can assist in the development of a strategy.

Further reading & Legal framework:

- Guidance document: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research[51]
- WHO Biorisk management: Laboratory biosecurity guidance[52]
- Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items[53] and Annex I of Regulation (EU) No 388/2012 of the European Parliament and of the Council of 19 April 2012[54]
- European Textbook on Ethics in Research: Chapter 7: Science and Society: Dual use[55]
- Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences by S. Miller and M.J. Selgelid[56]

5. Animal Research

Animal testing or animal research refers to the use of animals in experiments. The latest Commission report estimates that over 12 million animals are used for experimental or other scientific purposes in Europe each year. The most common used animals for these purposes are rodents, rabbits, mice and rats.[58]

A first important document protecting the animals used in experiments is the *European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes,* adopted in 1986.[59] At the European level, the *Directive on the Protection of Animals*[60] is meant to ensure the protection of animals used in experiments or for other scientific purposes. The directive sets standards for control on the use of laboratory animals, housing and care of the animals and for the training of the personnel involved in the animal testing.[61] Special rules apply for endangered species and non-human primates.[62]

Apart from setting standards, the directive aims at reducing the numbers of animals used for experiments, following the concept of the "Three Rs."

To realize compliance with the three principles, animal research must be systematically and thoroughly evaluated, requiring the assessment of pain, distress and lasting harm. For the Ethics Review organised by the European Commission, the researcher should provide all the details of the species (and strains) used, justify why they are used, explain why the anticipated benefits of the research justify the use of animals and why methods avoiding the use of animals cannot be used. All the planned measures to comply with the 'three Rs' should be indicated, in particular the procedures to alleviate or minimize the suffering of animals.

Specific rules and conditions for the conduct of animal studies (authorization procedures, inspection, etc.) are established by national law. National authorities are responsible for the implementation of the *Directive on the Protection of Animals*.[63] Keep in mind that this directive allows for the member states to adopt stricter national measures.[64]

THREE RS[57]

The three Rs represent three fundamental principles for conducting research on animals.

1. **Reduction** = methods should be used that enable the researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.
2. **Replacement** = non-animal methods are preferred above animal methods whenever it is possible to achieve the same scientific aim.
3. **Refinement** = all methods used for the research should alleviate or minimize the potential pain, suffering and distress and enhance the animal welfare for the animals still used.

Further reading & Legal framework:

- European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes[65]
- Consolidated Version of the Treaty on the Functioning of the European Union, article 13[66]
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[67]

6. Research Involving Developing Countries

A particular situation arises when research is conducted in or in collaboration with non-EU countries. In the first place, all activities conducted beyond the borders of the European Union must comply with the general objectives of the Union's external action.[68] Secondly, it is not because research is conducted beyond these borders that European standards for research no longer apply.

Special attention is required with regards to developing countries and emerging economies. Collaboration with developing countries can raise ethical concerns. The overall level of development of a certain country and the conduct of research with potentially vulnerable people, demand attention for the specific characteristics of the situation. Developing countries are often disproportionally burdened by diseases, poverty, high levels of illiteracy and basic health care infrastructure and resources are often lacking. Special measures can ensure that the rights and interest of all participants are adequately protected and that the benefits of the research are equally shared.

- The research needs to comply with all the relevant European legislation, national legislation and with relevant accepted international standards.
- International research projects must be beneficial for all stakeholders, with emphasis on benefits for the research participants and their communities. Special initiatives to support local communities (e.g. provide access to basic health care and the benefits generated by the research), can help achieving this goal.
- If local resources are used, this should be adequately compensated.
- Potentially vulnerable populations need to be able to provide **genuine** informed consent. This requires taking into account potential cultural differences, economic and linguistic barriers and levels of education and illiteracy.
- Although adequate scientific and ethics infrastructure might not be available, the relevant local and independent ethics approvals need to be provided.

Further reading & Legal framework:

- UNESCO's Declaration on Science and the Use of Scientific Knowledge[69]
- Nuffield Council on Bioethics: The Ethics of Research Related to Healthcare in Developing Countries.[70]
- Ethics Review in FP7: Ethics in research and international cooperation[71]
- European Textbook on Ethics in Research: Chapter 6: Justice in Research: Research in developing countries[72]
- Ethical and Regulatory Challenges to Science and Research Policy at the Global Level: Chapter 3: Scientific-Technological Divides and Benefit Sharing[73]

Conclusions

The 7th Framework Programme is a research programme that promotes excellence and innovation. While respecting the freedom of research, the programme is designed to ensure that all research is conducted with respect for fundamental ethical principles and aims for the highest ethical standards.

The most important and common ethical issues in research are privacy and data protection, the involvement of children, patients or other vulnerable people, the use of human embryonic stem cells, adequate informed consent, the potential dual use of research, research on animals and non-human primates and research involving developing countries. Other issues, such as the potential environmental impact of research activities, can also be of importance and should not be ignored.

Although many ethical issues are codified using legal instruments, research ethics is much more than defining the difference between legal and illegal. Research ethics requires an independent evaluation of the research activities and its possible consequences. It is a matter of awareness and looking beyond the research objectives, to consequences for everyone involved and the possible impact on society as a whole. The Ethics Review procedure organised by the European Commission is designed to help scientists and researchers achieving this.

The further development of responsible research and innovation activities is of crucial importance for the future. Striving for responsible research and innovation is not only necessary to address specific ethical problems, but to avoid corrosive effects on research and innovation in general. Policy initiatives and legislation can help to ensure the integrity of research, but the attitudes and behaviour of scientists and researchers are as important as the institutional framework.

Three Tips to be more ethically prepared

Try to integrate ethical and societal expertise into your research projects

While everyone feels that they know right from wrong, sometimes researchers get too close to the work they are doing, and would benefit from someone who can look at their work from another angle. A research project that engages with an independent ethics expert, or an ethics panel that can provide insight and advice, generally tends to address ethical issues or societal obstacles. Multidisciplinary expertise will always add value to research both in opening up potential new research applications and in preventing negative societal reactions. For example, a synthetic biology research project on biofuel catalysts could benefit from a forest management expert to better understand the societal concerns about biodiversity loss from biofuels harvesting. Or, in cases where human samples are taken and stored, an ethicist will design and implement an informed consent process and a data protection system that can also reassure and keep human subjects involved.

Use existing codes of conduct for researchers

It is rarely the case that researchers act improperly. Unfortunately, a few well-publicised instances have created an elevated public fear and distrust of scientists. The public wants the benefits of research and wants to trust science so by articulating a code of conduct, how researchers should behave, the non-scientific community can be reassured that the research process is being managed responsibly. While codes have been expressed in many past activities and much of it is based on common sense, the mere presence of a code on your research project serves as a benchmark for the research community. This in itself can reassure the general public. As many projects have partners from different countries, expressing the code and comparing its elements could have a learning effect for researchers.

Do not hesitate to seek advice

Ethics panels are made up of individuals from different backgrounds in order to provide a multidisciplinary assessment and recommendations from a broad range of societal interests. Sometimes the conclusions of an ethical review may be difficult to understand. The European Commission operates on the principles of openness and engagement. If any conclusions are unclear or contain vocabulary that may seem ambivalent, researchers should not feel inhibited from asking for clarification or guidance. This document, in itself, is recognition that sometimes the advice from ethical panels is not altogether clear. Remember one of the first sentences of this booklet: points raised in ethical reviews are not meant to be punishments or attempts to interfere with your research. Rather, they are requests for safeguards to ensure that the public perception of research remains positive, within the remit of the law and in line with national, European and international ethics guidelines. The Commission is here to work with you so when in doubt, seek further advice.

Twelve Golden Rules to Ethical Research Conduct

You must ensure that your research:

1. Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits)
2. Follows the “Do no harm” principle. Any risks must be clearly communicated to subjects involved
3. Recognises the rights of individuals to privacy, personal data protection and freedom of movement
4. Honours the requirement of informed consent and continuous dialogue with research subjects
5. Treats animals with respect and works under humane conditions before, during and after the research
6. Designs animal research in accordance with the 3 Rs: Replacement, Reduction, Refinement
7. Respects the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives (mission creep)
8. Treats societal concerns seriously - a researcher’s first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity
9. Tries to prevent being openly available for misuse or malignant dual use by terrorists or military organisations
10. Recognises the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle
11. Respects biodiversity and does not impose irreversible change that threatens the environment or ecological balance
12. Builds on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned)

[1] Shuster, E., (1997) Fifty years later: The significance of the Nuremberg Code, the New England Journal of Medicine, Massachusetts Medical Society, pp. 1436 – 1440.

[2] WORLD MEDICAL ASSOCIATION, *Declaration of Helsinki: ethical principles for research involving human subjects (2008).* http://www.wma.net/en/30publications/10policies/b3/index.html

[3] All information on the subsequent reviews of the *Declaration of Helsinki* can be found on the website of the World Medical Association.
http://www.wma.net/en/60about/70history/01declarationHelsinki/index.html

[4] WORLD MEDICAL ASSOCIATION, *Declaration of Helsinki: ethical principles for research involving human subjects (2008),* articles 1, 6, 11 – 30 and 31 – 35.

[5] INTERNATIONAL SOCIOLOGICAL ASSOCIATION, *Code of Ethics.*
http://www.isa-sociology.org/about/isa_code_of_ethics.htm
BRITISH PSYCHOLOGICAL SOCIETY, *Code of Ethics and Conduct (August 2009).* http://www.bps.org.uk/what-we-do/ethics-standards/ethics-standards
BRITISH EDUCATIONAL RESEARCH ASSOCIATION, *Ethical Guidelines for Educational Research (2011).*
http://www.bera.ac.uk/publications/Ethical%20Guidelines.

[6] COUNCIL OF EUROPE, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine CETS No. 164,* Oviedo, 4.4.1997.
http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=8&DF=04/02/2013&CL=ENG

[7] COUNCIL OF EUROPE, *Biomedicine and human rights – The Oviedo Convention and its additional protocols (2010),* pp. 5 – 6.

[8] COUNCIL OF EUROPE, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine CETS No. 164,* Oviedo, 4.4.1997, articles 2, 5 – 9 and article 10.

[9] COUNCIL OF EUROPE, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine CETS No. 164,* Oviedo, 4.4.1997, articles 11 – 14 and article 18.

[10] COUNCIL OF EUROPE, *Signatories of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research CETS No. 195*.
http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=195&CM=8&DF=10/12/2012&CL=ENG

[11] COUNCIL OF EUROPE, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research CETS No. 195,* Strasbourg 25.1.2005, articles 9 – 12, 13 – 16 and articles 25 – 28.
http://conventions.coe.int/Treaty/EN/Treaties/Html/195.htm

[12] UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION, *Universal Declaration on Bioethics and Human Rights (2005).*
http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (in collaboration with the World Health Organization), *International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002).*
http://www.cioms.ch/publications/layout_guide2002.pdf

[13] *Consolidated Version of the Treaty on European Union,* Official Journal of the European Union (30.3.2010) No. C 83/17, article 2.

[14] *Charter of Fundamental Rights of the European Union,* Official Journal of the European Union (30.3.2010) No. C 83/389 – 403.

[15] *Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 – 2013),* Official Journal of the European Union (30.12.2006) No. L 412/1 – 40.

[16] EUROPEAN COMMISSION, *Ethical Issues Table.* ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethical-issues-table-annex4.pdf

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[22] *Charter of Fundamental Rights of the European Union,* Official Journal of the European Union (30.3.2010) No. C 83/393, articles 7 – 8.

[23] *Consolidated Version of the Treaty on the Functioning of the European Union*, Official Journal of the European Union (30.3.2010) No. 83/55, article 16.

[24] *Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data,* Official Journal of the European Communities (23.11.95) No. L 281/31 – 39.

[25] EUROPEAN COMMISSION (DG JUSTICE), *Status of implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data.* http://ec.europa.eu/justice/data-protection/law/status-implementation/index_en.htm#h2-10

[26] EUROPEAN COMMISSION, *Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)*, Brussels, 25.1.2012, COM(2012) 11 final, 2012/0011 (COD).

[27] Information on the data protection reform can be found on the website of the European Commission DG Justice: http://ec.europa.eu/justice/data-protection/document/index_en.htm

[28] EUROPEAN COMMISSION, *Ethical Review in FP7: Data protection and privacy ethical guidelines version 5 (2009),* http://cordis.europa.eu/fp7/ethics_en.html

[29] EUROPEAN COMMISSION, *European Textbook on Ethics in Research (2010),* pp. 75 – 93. http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1362

[30] *Consolidated Version of the Treaty on the Functioning of the European Union*, Official Journal of the European Union (30.3.2010) No. 83/55, article 16.

[31] Official Journal of the European Communities (23.11.95) No. L 281/31 – 39.

[32] Official Journal of the European Communities (7.4.2004) No. L 102/48 – 58.

[33] UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION, *International Declaration on Human Genetic Data (2003).* http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/

[34] Informed consent is explicitly mentioned as a principle in article 7 of the *International Covenant on Civil and Political Rights (1966)*, a United Nations Treaty. http://www2.ohchr.org/english/law/ccpr.htm

[35] When children are involved in research, care and consideration are pivotal. First of all the involvement of children in the research must be absolutely necessary and, if so, all particular ethical sensitivities that relate to research involving children must be identified and taken into account. A special section on the use of children in research can be found in the *European Textbook on Ethics in Research*, pp. 65 – 74.

[36] EUROPEAN COMMISSION, *Ethics Review in FP7: Guidance for Applicants: Informed Consent*. ftp://ftp.cordis.europa.eu/pub/fp7/docs/informed-consent_en.pdf

[37] EUROPEAN COMMISSION, *European Textbook on Ethics in Research (2010),* pp. 35 – 74. http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1362

[38] Official Journal of the European Communities (1.5.2001) No. L 121/34 – 44. The *Clinical Trials Directive* is currently under revision. In July 2012 the Commission proposed a new regulation which should simplify the procedural burden for the conduct of clinical trials in Europe and guarantees the rules for conduction clinical trials in Europe are identical. More information can be found on the website of the European Commission, DG Health & Consumers: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm#rlctd

[39] Official Journal of the European Union (9.4.2005) No. L 91/13 – 19.

[40] EUROPEAN COMMISSION, *Ethical Considerations for Clinical Trials on Medicinal Products Conducted with the Paediatric Population: Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use (2008).* ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethical-considerations-paediatrics_en.pdf

[41] *Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013),* Official Journal of the European Union (30.12.2006) No. L 412/5 – 6, article 6 (3).

[42] *Statements by the Commission: Re Article 6*, Official Journal of the European Union (30.12.2006) No. L 412/42.

[43] *Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013),* Official Journal of the European Union (30.12.2006) No. L 412/5 – 6, article 6 (2).

[44] Official Journal of the European Union (30.12.2006) No. L 412/42.

[45] Official Journal of the European Union (22.3.2011) No. L 75/20 – 23.

[46] UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION, *Universal Declaration on the Human Genome and Human Rights (1997).*
http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/

[47] Official Journal of the European Union (7.4.2004) No. L 102/48 – 58.

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Researchers have the opportunity to be part of the Seventh Framework Program, a research programme that promotes excellence and innovation, and which respects freedom of research whilst ensuring the respect of fundamental ethical principles. Ethics must be given the highest priority in EU funded research as an integral part of research, permeating every area of research and it is only by getting the ethics rights that research excellence can be achieved. This publication presents the Ethics Review procedure of the European Commission in details: the objectives, the relevant legislation, the composition of Ethics Review panels. As for methodology, it defines ethical issues – informed consent, data protection and privacy, research on human embryos, animals, dual use and developing countries -, gives practical advice to researchers and explains via case studies. The moral from this publication is: do not forget research ethics.

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Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

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The Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

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PREAMBLE

> "The dialogue between science and the rest of society has never been more important... After ten years of action at EU level to develop and promote the role of science in society, at least one thing is very clear: we can only find the right answers to the challenges we face by involving as many stakeholders as possible in the research and innovation process. Research and innovation must respond to the needs and ambitions of society, reflect its values, and be responsible."[i]

The European Research Area (ERA) was established in 2002 as part of the implementation of the Lisbon Agreement. It aims to make the EU the most competitive and dynamic knowledge economy in the world in order to: enhance quality of life; ensure the welfare of European citizens; and contribute to European competitiveness.[ii] The Commission has, in particular, proposed to restore European leadership in life sciences and biotechnology research through actions aimed at enhancing industrial competitiveness.[iii] However, these ERA goals are being pursued amidst concern that, although the public often relies upon, accepts, and even shows enthusiasm for many aspects of science, there is also a perceived uneasiness towards science. Indeed, one reason for the EC carrying out Ethics Reviews of all projects in response to what is perceived to be the demand for scrutiny of research by society. Although the products of science are important, a "growing suspicion" has been expressed about the direction chosen for scientific research, who is in control, and what their motivations are. The reasons for mistrust include the increased scope for global impacts on fundamental aspects of human biological and social life, the high level of commercial involvement in research, and the need to ensure that the fruits reach a broad population.[iv] The responses to this situation include a political and academic focus on the relationship between science and governance, ethics in research and, more practically, a focus on public participation, especially regarding the risks of scientific endeavours.[v]

Consequently, the role of Ethics Advisors (EAs) and Ethics Advisory Boards (EABs) should be seen as the EC fulfilling its obligations to help avoid public uneasiness towards science and to mitigate concerns where they exist. However, it must be made clear that EAs and EABs are acting as independent experts when they assist the Commission in meeting its duty of accountability towards EU citizens.

This document was produced by the above Working Group at the request of the Ethics Sector (DG Research and Innovation) to provide guidance on the roles and operation of EAs and EABs boards established to monitor, guide and counsel EC-funded projects. The target audience for this document includes Commission staff, advisors and members of advisory boards as well as project proposers and participating partners.

The guidance is intended to apply to all substantive fields in EC-funded projects; whether in the natural, social sciences and the humanities as well as fundamental and applied research – this includes: medicine and biomedicine, security, synthetic biology, nanotechnology, CBRNE etc. It should also apply where there are industrial and/or publicly funded bodies involved and/or commercial/market-sensitive issues apply.

Necessarily, given the nature of ethical debate, there are differences of opinion and interpretation that remain to be resolved. Nevertheless, whenever possible, consensus has been reached and action points proposed. The aim is to offer a focused and practical guidance for EAs and EABs both in FP7 and in Horizon 2020 projects.

The current document is based on wide experience of ethics review, assessment and guidance both within and beyond the European Commission. This made it possible to draw on this breadth of knowledge to address the concerns and to propose ways of progressing the advisory role in a constructive and facilitative manner. It must be stressed that ethics advice is not to be treated as a trivial matter and ethical 'errors' can have serious repercussions for projects and their impact.

(1) Definitions and Clarifications

(a) "Ethics Advisory Board" (EAB) or "Ethics Advisor" (EA) is defined in this Guidance Document as a group of ethics experts or an individual ethics expert giving advice to a researcher, research group or project consortium partners in the context of an EC-funded project. Such a provision might arise as a requirement by an EC Ethics Review Panel, might become a contractual obligation for the applicants/beneficiaries, and/or might have been proposed as a work package as part of the original research proposal and thereby become included in the Description of Work (DOW). The work of these experts should facilitate, build upon and complement existing oversight regimes by competent ethical and legal authorities.

(b) The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy. It is part of a process of 'governance'. In this vein, the EC document "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research" asserts that ethics is a "key oversight mechanism" to ensure that EU funded research is not misused.[vi]

(c) The consideration of ethical issues, starting at the conceptual stage of a proposal, enhances the quality of research, increases its likely social impact, promotes research integrity, promotes a better alignment of research with social needs and expectations and, finally, supports the societal uptake of the fruits of research because high ethical standards generally merit public trust.[vii] In this spirit, the Commission aims to build a relationship between the research process and ethics that is collaborative and constructive (rather than negative and inhibitive). The challenge addressed in this document is to position EAs and

EABs so as to be part of a positive research quality assurance strategy. However, EAs and EABs must retain the courage to be unpopular in cases where significant ethics problems arise and their intervention is necessary to maintain research ethics standards. Such challenges must be equally backed by effective powers.

(d) Ethics advice can be incorporated into a project either as part of a Work Package (WP) and so contained in the original proposal, or can depend on the nomination of an EA or EAB. In some cases consultation with ethics advisors can be on a voluntary basis, in other cases consultation becomes mandatory. The specific advisory 'form' can depend upon the following factors among others:

Anticipated seriousness of potential risks
The size of the project and, therefore, the multiple issues it raises
Already existing legal and ethical oversight structures
The maturity of the proposal

Variations in form and function of EAs/EABs can directly affect the ways in which the advisor/board relates to the consortium partners and to the character and effectiveness of the relationship.

(2) Appointment/Recruitment, Expertise and Membership Criteria

(a) The size and constituency of the EAB seems vital to good working relationships and effective delivery of advice. Membership should cover a range of ethics and topic-relevant expertise and EU states involved in the Project. This is even more vital for complex projects with a variety of ethical issues at stake. The size of the EAB should allow for all members to be fully engaged and committed. Too large a group might permit too much of a 'disconnect'. The appropriateness of the members' competencies and proven expertise is essential to the effectiveness of the performance of the role – perhaps even more so when only one EA is appointed. Membership should cover expertise in law, data protection/privacy and research ethics and substantive experience in the assessment of ethics issues in the specific topic area of the project. Occasionally, also having experts without such subject-relevant expertise can be helpful – a degree of 'naivety' might allow the asking of challenging questions that subject experts might not have considered themselves. Members are often recruited based on previous work relationships with partners of the consortium. This may create concerns when it comes to the independence of the EA/EAB. In many situations, independence will be essential in providing fair ethical judgements and expertise and recruitment practice should take this into consideration.

(b) The concept and application of EABs is well established in the medical and animal welfare area and adequate expertise is usually readily available. However, in other areas of ethics (e.g. dual use, biosecurity, privacy, societal implications of research), it is often difficult to recruit adequate expertise.

(c) For projects that clearly require security clearances, it should be made clear that the members of the EAB or the EA will also need adequate clearance in order to access relevant information. This should be clarified beforehand to

ensure adequate time is given to obtain such clearances and to have a functional EA/EAB at the start of the project. (Security clearances for all EAs or EAB members might be considered given the growing number of security-related projects being funded, the multidisciplinary nature of most projects and the potential dual-use issues associated with many projects - but this does raise considerable cost implications.)

(d) Ongoing liaison between the EA/EAB and project partners might be optimized by identifying an individual from each of the partners with responsibility for communicating with the EA/EAB. It might be of some help if this individual had some expertise in research ethics, data protection and/or privacy issues – but this is by no means the only way to ensure effective liaison.

(e) There is a possibility that representatives from the partners' national data protection agencies (NDPAs) and/or any other competent ethical/legal bodies/authorities, or those with previous NDPA experience and/or other competent ethical/legal body/authority experience could become members of the EAB. This could help ensure an appropriate discourse on the specific relationship or even contrast between EAB recommendations and/or requirements and what NDPAs/competent ethical/legal bodies/authorities in specific countries require. Sharing practices at EAB level could also help NDPAs etc. learn from each other. (This is only a suggestion since there could be charges of collusion and/or conflicts of interest; so it needs to be considered fully and carefully managed if implemented.)

(f) With membership constituted in this way the EAB becomes less 'external' to the project – rather it comprises partners and 'non-partner'/independent experts who 'work together' in the best interests of the overall project.

(g) Attendance by members at as many relevant meetings as possible (whether virtual or face-to-face) continues to be important for consistency and continuity. If a member's formal attendance is limited for any reason, they should employ other means to ensure they are fully acquainted with how the project is progressing.

(h) The points raised above demonstrate the need to maintain a fine balance between the 'independence' of the EAB, any 'critical friend' function they might adopt and the achievement of productive connections with the partners. Even if WPs include ethics review as part of the project structure, the means for sustaining this independence of operation is essential. The following proposed methods of operation are aimed at ensuring this 'balance' is maintained.

(3) Establishing Working Practices

(a) Working practices should be formally agreed and clarified from the outset. A 'division of labour' between the EAB members and applied to specific project deliverables according to members' expertise can increase the efficiency of operations. An EAB Chairperson should be elected from the membership and

may speak on their behalf. To avoid confusing flows of information it should be clearly outlined in a Memorandum of Understanding (MOU) how the interaction between the consortium and the Ethics Advisory Board takes place and the mandate of the EAB (e.g. advice on approval requirements, risk benefit assessments, guidance on specific ethical questions, reporting obligations, guidance concerning the relevant legal framework and regulatory requirements in the countries where the research takes place) should be clearly defined. The MOU should be negotiated between the Chair of the EAB and the Consortium Management if not already contained in the DOW.

(b) Ethical issues can become quite formidable or can be capable of being addressed in a straightforward way – largely dependent on the primary substantive focus of the project. In all cases 'proportionality' is of the utmost importance. EA/EAB practice should be proportionate to the topic in hand. The format and frequency of meetings should reflect this proportionality, as should the reporting function. Project partners should be invited to meetings in case specific questions need to be addressed.

(c) Securing the 'best interests' of the general public and civil society is one of the main goals. EAs/EABs exist to offer guidance, advice, monitoring and recommendations for future work. Boards and advisors should operate according to the mandate outlined in the MOU at the beginning of the project – neither dominating the work nor obstructing it unnecessarily. They should be facilitative. However, there are times when EAs/EABs will and must be able to apply mandatory or regulatory powers.

(d) Funding must be adequate to the task. Clarity over fees and expenses is vital. The workload in complicated projects can be very high and may require the commitment of several full days per year. The commitment can be substantially higher if the DOW links the advisory work to specific research and/or networking activities. Advisors may have to gain some level of familiarity with the technical aspects of a consortium's work and the research field in general, as well as gaining fuller understanding of how the consortium plans to operate. To have a real impact, they may have to be part of the management structure. To ensure that adequate expertise can be recruited and the task is treated in a professional manner, compensation for the work should be foreseen in the project application. To avoid conflicts of interests and compromising its independence as a result of financial interests, the compensation budget should not be linked to any specific outcome of the ethical assessments. Since members are acting in an advisory capacity, it is hard to fully anticipate the budget in advance since the need to address unanticipated issues might occur. This suggests that some room for manoeuvre within the budget is needed. There must also be clarity over who and what is to be paid for and what activities are "voluntary" in order to ensure members are treated equitably.

(e) Although face-to-face meetings are advantageous in solving complicated issues, it is often not feasible to convene all members together at a certain place and time due to time and financial constraints. Alternatives might be e-mail conversation or videoconferences or one-off site visits. Nevertheless, face-to-face

meetings should take place as often as possible to ensure active discussions between the members of the EAB and also with the researchers involved in the project.

(f) The individual members of the EAB should cooperate to work out consensus-based recommendations. In cases where no consensus can be reached, it is recommended that the EAB provide a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.

(g) All meetings of the EAB should be based on an agreed agenda to ensure efficient decision-making. Relevant documents should be circulated beforehand to allow for adequate preparation. Meetings should be co-ordinated by the Chairperson and a report should be prepared for each meeting and communicated to the project management.

(4) Nature of Advisory Role – Practice 'culture', Powers and Managing Relationships

(a) The EA/EAB must maintain an overview of operations throughout a project, helping with preparation in terms of thinking ahead about possible problems and how they can be addressed. Any sense of static, 'tick-box' approvals must be avoided. EAs/EABs are resources for advice and guidance when ethical dilemmas arise during a project. EABs with oversight functions will usually check compliance with ethical standards within the relevant research fields. Independence and freedom of any conflict of interests are requirements for the participation in these EABs.

(b) If there is an additional Advisory Board (AB) with oversight of the project – with an EC Project Officer attending – then the EA/EAB Chair should be *ex officio* a member of the AB. If there is no AB, the Chair of the EAB should be allowed to actively participate in Consortium meetings. Ideally, the EAB must be fully integrated into the management structure, should attend Kick-Off and Plenary Meetings, participate in all significant technical group meetings, review all Annual Reports and papers for publication and help in preparing authorizations and approvals and monitor all the authorizations, approvals and licences etc. This active engagement facilitates ongoing liaison between the various agents and groups and helps ensure thorough knowledge of overall project activities and better acceptance and integration of the EAB into the consortium activities.

(c) It is important that the EA/EAB keeps up regular contact with any partner bearing WP responsibilities for ethics-related actions and that both know what actions the other is taking and planning. This should ensure consistency and help avoid any unnecessary duplication of effort. It is highly recommended that principal link to the consortium be established between the Chairman of the EAB and Project Coordinator. This is also important for ensuring consistency of advice and avoiding confusion – as controversial issues might need discussion among all members of the EAB prior to the formulation of clear advice.

(d) Clarity in all communications coming from the EA/EAB is essential. Advice offered must be understandable by the partners so that appropriate actions can be taken – it must be pragmatic/workable. Direct communications between advisors and partners is vital.

(e) In EU member states EABs might need to have specific powers to put a hold on the project on ethical grounds and/or to call for an Ethics Audit by the European Commission. These powers should apply without any restriction with respect to non-EU countries. The funding contract can give power to the EA/EAB to come up with binding judgments (as a contractual obligation). Such requirements should be clearly outlined in the funding contract/DOW and incorporated in the MOU established at the beginning of the project. In such situations, it is of paramount importance to ensure the selection of fully independent experts that are free of any conflict of interest and that the EAB is given full access to all necessary information.

(f) Grant Agreements often indicate that beneficiaries shall comply with all applicable EU/national legislation, and any relevant future legislation and the requirements of FP7 specific programs. However, the local standards (on which the necessary approvals, e.g. from RECs, are based) can be less onerous or less appropriate than the best practice standards set by the EC for applications in FP7 funded projects. The role of EA/EAB would be in such instances to ensure that appropriate EU standards are met, with an additional role to play in research carried out outside Europe to ensure that it complies with EU standards. Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006, concerning the Seventh Framework Programme, does make mandatory statements for all research funded by the EC.

(g) In cases where the role of the EAB is closely linked to a technical deliverable (e.g. participation in the development of "Privacy by Design" concepts), it might be worthwhile considering the use of individual work packages and integration of ethics experts as project partners as part of the working structure that ensures easier integration of the expertise in the daily research. Similarly, where ethics is integrated and part of the research work packages including project partners familiar with the legal and ethical requirements might serve the project better than an independent EA or EAB. The work package construction usually allows a better integration into the daily research and management structure of the project and sometimes does not require independence. Ensuring independence and avoiding conflicts of interests in a situation where the ethics work is so closely linked to a successful project output requires special attention. Nonetheless, to ensure independent judgement in highly sensitive research, the establishment of an EAB should be considered in addition. All functions and responsibilities of the EAB must be properly addressed. This requires a clear description of the tasks in the DOW and an appropriate management structure.

(h) Provision for indemnity insurance has to be considered. Recent liability claims and even criminal charges for wrong advice have made public headlines

and it is unclear what the legal status of the EAB is. This should be clarified, and adequate safeguards, such as indemnity insurance, implemented.

(i) The work of EABs can produce judgements that may conflict with project goals. Therefore, much higher emphasis must be given to ensuring independence and limiting conflicts of interest in such circumstances.

(j) In addition 'conflicts of personalities' can impede effective ethical practice, so the operational mechanisms must be such that personality 'clashes' can be overridden. In all cases a culture of mutual respect and understanding of the other's position should be cultivated.

(k) Transparency and critical detachment are important components of ethical oversight. Being open and clear about decision, actions to take and the rationales behind them is good practice. All other project groups (partners and advisors) should be encouraged to raise issues with the EA/EAB knowing they are to be treated with discretion.

(l) In summary, the EA/EAB should do whatever is necessary to diligently monitor the aims, objectives, methodology and implications of the research to ensure that it conforms to the highest ethical standards and ensures that the researchers, the Commission and the general public are not exposed, by the work of the project, to activities that would be considered to be ethically unacceptable. As research activity is dynamic and evolves along unpredicted pathways advisors must be prepared to tackle new issues and concerns as they arise and the ethical perspective will need to be modified throughout the lifetime of the project.

(m) Ethics advisors should include independent summaries of discussions and issues arising in formal meetings in their regular reports. Suggestions for items to include in reports are in attached Appendix 2.

(5) Identifying Appropriate Ethical Principles and Criteria to Apply

(a) Ethics needs to permeate all parts of the project 'culture' to be effective. In the interests of raising and maintaining ethical awareness, all aspects of the project's activities require the maintenance of an ethical perspective. A sound ethics policy requires transparency and balance. Evidently some risks of harm for any project can be anticipated, but by no means all.

(b) One way of maintaining ethics awareness is to establish a set of 'core values' or 'principles' to be signed up to by all partners. Additionally an ethics checklist to act as an aide memoire and modified to apply specifically to the project in hand can be a focus for ethical practice. Application of the checklist can highlight misunderstandings of terminology and conceptual problems associated with the rationales that lie behind conventional ethical principles. A basis for core values and principles relevant to FP7 is outlined in N 1982/2006/EC, ("fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union"); this together with applicable legal

provisions, codes of conduct and guidance documents provided by the European Commission should form a base for the work of any EAB. The EAs/EABs should ensure, to the best of their ability, that the consortia adhere to the Fundamental Rights Declaration of the European Union.

(c) Clarification of remit in terms of appropriate ethical issues should be carried out at the start of the whole process. They should clearly justify making any recommendations and requirement for an EA/EAB. The EA/EAB should ensure that both ethics screening reports and ethics review reports (ERRs), when they exist, are fully available to partners, that they are acted upon and, as far as is possible, there is consistency of advice and practice across all ethics experts. The partners' actions are consistent with their responses to the Ethics Issues Table contained in the original proposal. Any subsequent amendments should be reported and explained to the EA/EAB. In some cases, the DOW might introduce specific criteria e.g. lawfulness in the context of Special Clause 15/1 or further requirements usually derived from the Ethics Review. It is an important function of the EAB to ensure compliance with the requirements outlined in the DOW, e.g. by providing reports as Ethics Deliverables. Where differences of opinion, judgment and/or interpretation exist within the EAB, these should be explained to partners to assist in their application to practice.

(6) Liaison with other relevant EC-projects/EC- information 'resources'

(a) EAs/EABs should be aware of, and able to liaise with, other relevant EC-funded projects. Many EC-funded projects have faced and continue to face very similar ethical issues. It should be possible for each new project to learn from them. A range of factors inhibits open cross-fertilisation and interaction between projects. These include intellectual property rights, security and confidentiality. But unless such 'obstacles' are overcome there is likely to be considerable duplication of effort, which is wasteful of resources and impedes the building of foundational work that could enable more rapid and widespread ethical awareness.

(b) EU projects that have established 'codes of conduct' could provide the basis for similar ethics progress elsewhere. One example is the code of conduct for responsible nanosciences and nanotechnologies research: http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf
Another is the RESPECT project code for socioeconomic research http://www.respectproject.org/code/
Another excellent model for large scale EC collaborative project that could inform practice is the ETICA Project (completed May 2011):
http://www.etica-project.eu/
The 'official' status of such codes can very greatly – the main point is to be aware of foundational advice they contain and perhaps view them as 'helpful tools'.

(c) Any liaison activities between EABs directly related to project actions should be discussed and agreed with the project management in advance, to ensure that no confidential, project-specific information is exchanged between competing research consortia. This could be contained in a confidentiality

agreement. An exception should be included in any such agreement for the option to report ethical misconducts directly to the European Commission, to ensure adequate and timely information of the funding institution.

(7) Principle of Ensuring Consistency in Practices and Policy

(a) This section is directly linked to sections 4 and 5 above and will affect section 7 below. It is not particularly helpful if different advisors and different groups are applying advice in different ways. The core of this 'principle' requires effective communication between advisors, a repository of knowledge on 'best practice' (what has been shown to work and what doesn't) and clarity over legal and regulatory compliancy, EC-required principles and norms, and wider ethics reflections and analysis. An online community for advisors and occasional face-to-face conferences might help in securing consistency in practice and enable contributions to policy development.

(b) The societal implications of any EC-funded projects might be considered to be relevant to ethics oversight. EAs/EABs might be tasked with including some assessment of societal implications and/or risks as part of their duties.

(c) Ethics advice should incorporate the assurance that EU/national laws are complied with, as well as international 'soft laws,' and widely accepted ethics codes and guidelines. This position is reflected in the statement that "…research activities supported by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union. The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account."[viii] One of the greatest challenges is to ensure that all advice given is underpinned and justified by an EU appropriate document. What is required is a list of all normative documents that EA/EABs should refer to in order that their work has legitimacy and is coherent across the board. *[Some suggested sources of legal and ethical guidance are indicated in Appendix III.)*

(d) Reflection on the experiences and outcomes of the project, in terms of meeting ethics requirements, should be compiled and subsequent reports summarizing the lessons learned delivered to the Commission. Some degree of flexibility is of benefit when thinking through both ethical and societal impact issues. The combination of partner ethics, independent expertise and the potential to draw upon a breadth of experience across an EAB allows for a balance of 'interests' and could help ensure that no 'vested interests' dominate.

(8) Sustainability – developing and sharing enduring principles and practices.

There is a need for clear archives both for EU projects and related work located in specific nations within and outside the EU. A resource centre and even an information centre with a degree of autonomy to allow it to offer independent advice and networking.

CONCLUSION

This document is intended to draw some initial observations and recommendations. The Working Group is seeking to establish some guidance for best practice and ground rules that outline what the Group believes should be the framework of operation of the ethics advisor and/or advisory board. There is still a great deal to be done and it is proposed that these suggestions are taken further and aired more fully with all stakeholder representatives.

In certain respects, the role of EA/EAB can be seen as the EC fulfilling obligations that arise from the funding of emerging, innovative (often weakly governed) research to ensure that the most appropriate standards are applied and met, whilst admitting that some standards that develop in a complex innovative environment can only be provisional best practices. Meeting the challenge of making the EU the most competitive and dynamic knowledge economy in the world requires that innovative research be funded, but it is precisely such research that may pose the most complex ethical challenges.

Nevertheless, it is hoped that proposers take into account the views expressed here so that proposals do not merely pay lip service to the advisory function, but recognize how seriously it is to be taken throughout the life of a project. Any attempt to simply use the EA/EAB to satisfy the Commission concerns while ensuring that Advisors do not inhibit or interfere with the main direction of the research is to be strongly resisted. An Ethics Advisor must not simply become a symbolic cipher without any effective power to influence the direction of the research activities or the methodology that will be used. The advisory role is a proactive one. The cultivation of mutual understanding between advisors and partners can see differences resolved through diplomacy and clear communications. Problems can be forestalled through cooperative endeavour and a culture of collaborative working.

There is no doubt that serving as an Ethics Advisor on a major project is a very challenging and demanding job and requires a great deal of dedication, experience, commitment and enthusiasm. It is essential to master the details of the research, keep up-to-date with the latest developments in the field whilst at the same time keeping pace with developments in the ethical opinions and legislation. It also requires the patience to win over what may initially be a critical group of researchers, enthuse them with the concept of ethical probity and demonstrate that the Advisor has something positive to contribute to the project. It should be clear from the foregoing that the Working Group sees it as imperative that the forms and functions of EAs/EABs are strengthened in recognition of the vital service performed by ethics assessment, the public protections it affords and the checks and balances on the massive investment of public funds. When seeking to formulate good practices in the area of ethics the uncertainty that often surrounds emerging, innovative science that may give rise to further aspects of ethics uncertainty. It is thus suggested that a strong focus should be on developing procedures for deciding what should be done, applying the principles of participation, procedural justice, responsible stewardship, accountability, transparency, effectiveness, and coherence.

APPENDIX I: QUICK REFERENCE LIST OF "DO'S" and "DON'TS" WHEN APPOINTING AND WORKING WITH AN ETHICS ADVISOR OR ETHICS ADVISORY BOARD.

Recruitment/Appointment/Establishing Tasks of EA/EABs (See section 2):

	Do's	***Don'ts***
Expertise	Select advisors on the basis of their known competence	Select on basis of prior knowledge alone and/or their known compliance.
Range	Cover the range of skills relevant to the project	Merely look for 'breadth' of coverage
Complementarity	Ensure the advisors' skills match project needs and fit with each other	Neglect to examine CVs to determine skills
Adequacy	Check for relevant experience	Assume all ethics advisors have same skills
Independency, Conflict of Interest	Recruit independent professional experts	Ask your best friend for a favour or recruit your EAB from the project partners or their home institutions
Security clearances	Define clearly for whom and from whom security clearances are needed and request such clearances in advance	Wait until project starts to think about security clearances
Confidentiality agreements	Clarify what can be 'shared' outside the project and allow for direct interactions with EC representatives	Assume advisors know what can be shared
Handling of confidential information	Provide clear guidance on what constitutes project confidential information or security sensitive information and provide adequate platforms for sharing such information	Assume advisors know how to handle project confidential agreements
Indemnity insurance	Check what insurance can be/has been provided	Assume liability cover is unnecessary

Relationship to Consortium (section 3):

	Do's	**Don'ts**
Memorandum of Understanding	Agree terms of working relationship	Believe that it works anyway
Points of contact	Work through project management/coordinator	Fail to formalize liaison arrangements
Participation in Consortium Meetings	Be involved from planning proposals through the project at all stages to completion	Sideline advisors
Independence v. integration	Invite partner representatives in EABs meetings if necessary	Compromise independence

Within EAB (section 4):

	Do's	**Don'ts**
Nominate a Chairperson	Elect the Chair from the EAB members	Accept an appointee from the consortium
Decision making procedure	Clarify decision making within EAB	Be vague about decisions to be taken
Meetings protocol	Set agenda and record decisions and actions	Allow meetings to be informal 'conversations'

EA/EAB Powers:

	Do's	**Don'ts**
Oversight	Maintain vigilance over the whole project	Assume all recommendations will be followed
Contractual approval obligations	Be clear about what is allowed and be willing to apply contractual powers if necessary	Approve if full information is not given. Hesitate to act due to 'personal' concerns
Guidance	Be clear and precise about actions to be implemented	Leave room for doubt
Whistleblowing clause	Encourage disclosure of problems	Accept complaints at face value
Budgetary control	Ensure adequate finances for whole project	Devalue the work of ethics advice

External relationships (obligation and responsibilities) (sections 6 & 7):

	Do's	***Don'ts***
European Commission	Ensure contractual ethics obligations are met	Fail to use Commission expertise
National Data Protection Agencies, Radiation safety authorities, Biosafety Authorities, RECs with legal authority (e.g. animal welfare, clinical trials)	Ensure compliance with local requirements	Forget to ascertain 'proper' authority
Institutional RECs with 'local' jurisdiction	Find out the limits to jurisdiction, obtain and implement their advice	Upset or ignore local institutional RECs

APPENDIX II: REPORTING TEMPLATE FOR EAs/EABs

Reporting Guidance

EAs/EABs should develop:
(a) a Program of Work lasting for the duration of the project that includes reporting deadlines;
(b) procedures for conducting its work that apply the principles of appropriate participation, procedural justice, responsible stewardship, accountability, transparency, effectiveness, and coherence.

The Program should define and shape reporting; the stated procedures should guide the decision making process and be reflected in all Reports.

EAs/EABs should recall that the reports and advice offered be pragmatic/workable, clearly explained and justified (with reference to the principles, criteria, approached being applied, and the sources of this guidance), and be understandable by the partners so that appropriate actions can be taken.

The EA /EAB should aim to give consensus-based recommendations. In cases where no consensus can be reached, it is recommended that the EAB provide a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.

REPORT ITEM HEADINGS

Number of Report **Date of Report**

Date(s) of actions referred to

Author of Report

Report Title:
Subtitle: with reference to Deliverables, Item in Work Programme, Task, Issue to Hand

Target Audience

Minutes of/notes from any previous meeting

In Attendance at Meetings and/or Contributors to Report

Actions Completed (by whom)

Decisions taken

Information given

Next Steps

Actions on whom

Next meeting (date and place)

APPENDIX III: POTENTIAL SOURCES OF LEGAL AND ETHICS GUIDANCE (Non-exhaustive list)

1. Council Decision 2006/973/EC) concerning the specific programme 'People' implementing the Seventh Framework Programme of the European Community

"Ethical aspects

During the implementation of this specific programme and in the research activities arising from it, fundamental ethical principles are to be respected. These include, inter alia, the principles reflected in the Charter of Fundamental Rights of the EU, including the following: protection of human dignity and human life, protection of personal data and privacy, as well as animals and the environment in accordance with Community law and the latest versions of relevant international conventions, guidelines and codes of conduct, e.g.

a. *the Helsinki Declaration,*
b. *the Convention of the Council of Europe on Human Rights and Bio-medicine signed in Oviedo on 4 April 1997 and its Additional Protocols, the UN Convention on the Rights of the Child,*
c. *the Universal Declaration on the human genome and human rights adopted by UNESCO,*
d. *UN Biological and Toxin Weapons Convention (BTWC),*
e. *International Treaty on Plant Genetic Resources for Food and Agriculture,*
f. *relevant World Health Organisation (WHO) resolutions."*

2. Decision 1982/2006/EC of the European Parliament and of the Council (Recital 30 and Article 6)

Research activities supported by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the

- *Charter of Fundamental Rights of the European Union.*
- *The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account. Research activities should also take into account the Protocol on the Protection and Welfare of Animals and reduce the use of animals in research and testing, with a view ultimately to replacing animal use.*

*The European Charter of Fundamental Rights_*

- *Art. 3: Right to the integrity of the person;*
- *Art. 8: Protection of personal data*

3. 2012, Directorate-General for Research and Innovation, Ethical and Regulatory Challenges to Science and Research Policy at the Global Level

Recommendation 11: Following the Millennium Development Goal approach, the European Commission should work to engage all relevant sectors of society in contributing to the aspiration of benefit sharing.
Recommendation 12: The European Commission should collaborate with the WHO to devise a comprehensive benefit sharing framework relevant to future access to human biological resources as well as global public health.

4. The European Charter for Researchers The Code of Conduct for the Recruitment

of Researchers, European Community 2005

Research freedom, ethical principles: researchers should adhere to the recognised ethical practices and fundamental ethical principles appropriate to their discipline(s) as well as to ethical standards as documented in the different national, sectoral or institutional codes of ethics; professional responsibility; professional attitude; contractual and legal obligations; accountability (researchers need to be aware that they are accountable towards their employers, funders or other related public or private bodies as well as, on more ethical grounds, towards society as a whole. in particular, researchers funded by public funds are also accountable for the efficient use of taxpayers' money); good practice in research (researchers should at all times adopt safe working practices); dissemination, exploitation of results, public engagement ("researchers should ensure that their research activities are made known to society at large in such a way that they can be understood by non-specialists, thereby improving the public's understanding of science. Direct engagement with the public will help researchers to better understand public interest in priorities for science and technology and also the public's concerns.")

5. Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research 2010.

"Underlying ethical principles
Avoidance of exploitation, just distribution of benefits and burden, beneficence, respect for persons, respect for human dignity, scientific validity, social value, the rights and interests of research participants are overarching ethical principles of any scientific research. From the stage of research design to the dissemination of research outcomes these principles should be taken into account when identifying and dealing with the ethical issues raised by a particular research."

6. Principles of European research ethics (Power point presentation, European Commission DGRI Ethics)

Ethics principles:
- *The principle of respect for human dignity*
- *The principle of utility*
- *The principle of precaution*
- *The principle of justice*

7. 2010 EC European Textbook on Ethics in Research

8. European Commission, "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research"

9. FP7 Guidance For Applicants, Informed Consent. European Commission

10. FP7 Guidance For Applicants, Ethics in research and international cooperation",. European Commission

11. Commission Decision (2001/497/EC) of 5 June 2001 on standard contractual clauses for the transfer of personal data to third countries

12. Introduction to IP rules in FP7 Projects (http://www.iprhelpdesk.eu/, 2011)

13. EU Data Protection Directive

14. Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

15. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. OJ L 121, 1.5.2001

16. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ 23 November 1995 No L. 281 pp. 0031-0050

17. Council for International Organizations of Medical Sciences (CIOMS) ISBN 92 9036 075 5
http://www.cioms.ch/frame_guidelines_nov_2002.htm

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[i] Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science Message delivered at the conference «Science in Dialogue - Towards a European Model for Responsible Research and Innovation» Odense, Denmark, 23-25 April 2012

[ii] Commission of the European Communities, Communication from the Commission: Competitive European Regions Through Research and Innovation, 2007. A contribution to more growth and more and better jobs {SEC(2007)1045}

[iii] 4.9.2001 COM(2001) 454 final Communication From The Commission Towards A Strategic Vision Of Life Sciences And Biotechnology: Consultation Document

[iv] European Textbook on Ethics in Research, Directorate-General for Research Science, Economy and Society, 2010

[v] Ibid.

[vi] European Commission, "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research". The report is addressed towards The EU Commission; EU Ethics Screeners, Reviewers and Auditors, and Research project applicants.

[vii] European Commission, „*Ethics for Researchers* – Facilitating Research Excellence in FP7," Luxembourg: Office for Official Publications of the European Community, 2007, Göran Hermerén, President of the European Group on Ethics (EGE).

[viii] Decision No 1982/2006/EC Of The European Parliament And Of The Council
of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)

Guidance Note – Ethics and Food-Related Research

This document provides:

- guidance for applicants, reviewers and European Commission staff on core issues of ethical concern in the field of food-related research within the EC's ethics review process
- an appendix, which outlines broader concerns in the field of food ethics.

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Introduction

> *Research activities supported by the Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union and take into account opinions of the European Group on Ethics in Science and New Technologies (EGE).*[1]

Adherence to ethical principles is essential in all branches of research. Only ethically sound research can achieve public acceptance and demonstrate the integrity required of European researchers and their international colleagues.

This Guidance note aims to make food researchers aware of potential ethical issues that may arise in their work. Research involving food and nutrition is very diverse, ranging from interviewing children about their food preferences, to animal studies on contaminants, research on sustainable agriculture or the impact of certain foods on gene expression, to name just a few. As a result, research methods within the field vary widely. Furthermore, individual food and dietary decisions are often very personal and culturally or spiritually based. Therefore a guidance note such as this one cannot be exhaustive. What it can do is assist researchers in proper ethical conduct through awareness raising on many of the key issues of concern.

The following principles of the Charter of Fundamental Rights of the European Union[2] are relevant to all scientific endeavours supported by the Framework Programme and should serve as the basis for reflective deliberation.

- *Dignity*
- *Freedoms*
- *Equality*
- *Solidarity*
- *Citizens' rights*
- *Justice*

These principles are based, in particular, on the fundamental rights and freedoms recognised by the European Convention on Human Rights, the constitutional traditions of the EU Member States, the Council of Europe's Social Charter, the Community Charter of Fundamental Social Rights of Workers, and other international conventions to which the European Union or its Member States are parties.

[1] FP7 Getting Through Ethics Review. http://cordis.europa.eu/fp7/ethics_en.html

[2] The Charter of Fundamental Rights of the European Union. http://www.europarl.europa.eu/charter/default_en.htm

Food Related Research Ethics Review – Generic Guidance

The European Commission provides information on the main ethical issues that may arise in research and indicates how each topic might be addressed to ensure compliance at: http://cordis.europa.eu/fp7/ethics_en.html. Here is a short overview, with the first two entries being likely to apply to all research covered in this document:

Informed Consent

Participation in research must be voluntary and it is the researcher's duty to ensure that research participants understand the scope and the details of the project. The minimum information given to potential participants must include: purpose and duration of the research, identity of the researchers, risks and benefits, information on data protection, privacy and data retention, the right not to take part, the right to withdraw, and contact details for questions. Evidence, usually in writing, of a completed informed consent process must be obtained. *It is important to emphasise that informed consent procedures must be followed by all researchers and are not restricted to medical research.*

Data Protection and Privacy

The right to privacy and data protection is part of the Fundamental Rights of the European Union.[3] In order to respect this right, researchers must comply with the legislation on data protection within their Member State and carefully plan data storage, handling and retention so as to minimise the risk of confidentiality breaches. For a detailed description of this issue see: FP7 "Data protection and privacy ethical guidelines".[4]

Research on Animals

Food-related research, in particular with regard to health claims or safety assessments, may include research on animals. It is expected of researchers to use the "three Rs" as guiding principles in such research[5].

- **Reduction** refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.
- **Replacement** refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim.
- **Refinement** refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals still used.

[3] The Charter of Fundamental Rights of the European Union. http://www.europarl.europa.eu/charter/default_en.htm.

[4] FP7 Data Protection and Privacy Ethical Guidelines, ftp://ftp.cordis.europa.eu/pub/fp7/docs/privacy.doc

[5] For ongoing information on the 3Rs see http://www.nc3rs.org.uk, http://www.ecopa.eu/ or http://www.forschung3r.ch/en/information.

Food Related Qualitative Social Science Research

Example Topics:

Public perceptions and attitudes towards personalised nutrition

Dietary behaviour of defined groups (e.g. children, obese, low income)

Example Methods:

Interviews and focus groups

Food diaries, life histories

Observation

Social scientists are interested in a wide range of topics in connection with food. Some of these are of interest to public health (e.g. research on obesity), others are of particular interest to industry (e.g. marketing, public acceptance of novel foods), and yet others to development or agricultural science (e.g. livelihoods within fisheries). Unlike medical science, social science has not been strictly regulated through research ethics review for several decades. And attempts at applying procedures from medical ethics review to social science have proved challenging. Within social science research, it has been argued that:

> [t]he quandary that the institutional discourse of ethical research confronts is that it is always/already vulnerable to being disconnected and dislocated from the relational ethics of the "real world" of research because the micropolitics of research practice are too messy and diffuse to be pinned down and regulated by systematized rituals and practices. Power is never innocent in the construction of research relationships.[6]

Social science researchers have found that it can be difficult to work with formalised codes of practice which inscribe rigid rules that do not take account of the breadth and complexity of empirical studies.[7] Importantly, it has been argued that within some research methods (e.g. observation):

> it is not possible for the [social science] researcher to specify in advance precisely what will be observed and the degree to which they will participate in the setting. Understandably, this lack of specificity raises challenges for research ethics boards.[8]

However, many professional associations have now drawn up codes of practice, such as the *Statement of Ethical Practice for the British Sociological Association*[9] or the *Statement of Principles of Ethical Research Practice*[10] by the UK's Socio-Legal Studies Association (SLSA). These and similar codes of practice usually distinguish between obligations towards

6 Christine Halse and Anne Honey (2007) Rethinking Ethics Review as Institutional Discourse, *Qualitative Inquiry* 13: 336-352.

7 Jacqui Gabb (2010) Home truths: ethical issues in family research, *Qualitative Research* 10: 461-478.

8 Carnevale et al (2008) Using participant observation in pediatric health care settings, *Journal of Child Health Care* 12: 18-32.

9 Statement of Ethical Practice for the British Sociological Association, http://www.britsoc.co.uk/NR/rdonlyres/801B9A62-5CD3-4BC2-93E1-FF470FF10256/0/StatementofEthicalPractice.pdf

10 SLSA Statement of Principles of Ethical Research Practice, http://www.slsa.ac.uk/content/view/247/270/

research participants, society as a whole, the discipline, as well as colleagues, sponsors & funders. In the following, the focus shall be on research participants.

In addition, some research councils have issued specific guidance for regulating social science research, such as the Canadian *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*, Chapter 10[11], launched in December 2010 or the *Australian National Statement on Ethical Conduct in Human Research*[12], Chapter 3.1 (2007).

In addition to the generic guidelines outlined at the start of this document, the following are relevant directly to social science food research employing qualitative methods.

Risks and Benefits

When assessing risks, the focus in medical research is mostly on physical *harms*, whilst the focus in protecting research participants in social science research is mostly on mental *distress*. It has been argued that the degree of risk in social science research is in no way equivalent to those in medical research and should therefore not be overestimated. "At most there is a potential for causing minor and reversible emotional distress or some measure of reputational damage".[13] However, it is essential that potential research participants are made aware of the possibility for distress and that the researcher takes responsibility for reducing it to an absolute minimum.

A risk that applies to both medical and social science research is negative impact from a breach of confidentiality. For instance, a person interviewed on sensitive topics may risk detrimental consequences for his or her social status/employment/financial situation through a breach of confidentiality. Hence, as noted under generic guidelines, it is important to fulfil all requirements for data protection and to inform participants of such potential risks in advance.

One advantage social science research has over medical research is that the benefits are unlikely to be overestimated by potential participants; hence the therapeutic misconception[14] poses less of a problem. The main benefit that research participants should expect is feedback on the outcome of the research.

Withholding the Truth – Covert Research

An important characteristic of social science research is that revealing detailed information about the scope and objectives of the study may heavily influence response behaviour (e.g. social desirability bias). Hence, one of the main differences between medical research and social science research is that covert research may be justifiable although it violates the principle of informed consent.

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[11] Canadian Panel on Research Ethics, Chapter 10, Qualitative Research, http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/

[12] Australian National Statement on Ethical Conduct in Human Research http://www.nhmrc.gov.au/publications/ethics/2007_humans/section3.1.htm

[13] Robert Dingwall (2008) The Ethical Case Against Ethical Regulation in Humanities and Social Science Research. *Academy of the Social Sciences* 3(1)1-12.

[14] A patient who takes part in non-therapeutic research may erroneously assume that the research will provide a cure.

Covert research should only be undertaken if it is impossible to obtain data with overt methods, if risks to research participants are minimal, if anonymity is guaranteed, if the project has societal importance and if the relevant research ethics committee has approved a detailed justification for the approach. In the context of covert, research ethics committees may impose a second postponed consent process, between the obtaining and the analysis/publication of data.[15]

Observation Research

One of the main ethical hurdles for social science research & data protection is observation research in public places. Within the area of food related research, this could for instance take place in restaurants or canteens. Observation research, which requires written consent from every individual present, even if there is only a minimal encounter, would render potentially important research impossible. However, the European Union's commitment to the protection of individual privacy must be upheld.

Research ethics committees should decide about the extent of informed consent requirements imposed prior to approving a study based on the risks and benefits of any individual study. For instance, it would be inappropriate to make the same demands on an observational study in a closed ward for anorexia and a busy fast food restaurant.

Inclusion of those Unable to Consent

By contrast to some medical research (which would then be termed 'therapeutic'), social science research is unlikely to benefit research participants directly, as noted before. This requires especially strong protections for persons unable to consent.

Social science research must only be carried out with those unable to consent if all of the following conditions obtain: the research cannot be carried out on those who are able to consent, consent by proxy/legal representative has been obtained, the person does not object, only minimal burdens are imposed, the research results are relevant to future persons in the same category, and the study has been approved by the relevant ethics committee.

New Technologies and Web-Based Research

Increasingly, social scientists collect data using new technologies (e.g. iPhones) and/or web based research (e.g. blogs, chat rooms). Many potentially vulnerable populations, who are the subjects of food research, for instance children and teenagers, make extensive use of such technologies and web-based forums. Data collection using new and web-based technologies is therefore becoming an important method in qualitative research and comparative international studies within food related research. For instance, people with eating disorders, ranging from anorexia to obesity, or their parents and family members may be reluctant to take part in face-to-face research but less so in web-based research.

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15 For postponed consent in the medical context see: Han Boter, Johannes JM van Delden, Rob J de Haan, Gabriël JE Rinkel (2004) Patients' evaluation of informed consent to postponed information: cohort study, *British Medical Journal*, 329: 86. Angus Dawson (2004) Commentary: Methodological reasons for not gaining prior informed consent are sometimes justified, *British Medical Journal*, 329: 87.

Such use of technologies raises new ethical issues around recruitment, consent, privacy as well as authenticity of data. For example, it may be problematic to procure and verify the authenticity of parental consent for children; or the identities of individuals engaging in web mediums because their internet identity may not reflect the 'authentic persona'[16].

It should be noted that web-based communications, where contributors can be identified, such as chat-rooms or self-help groups, require the obtaining of informed consent prior to taking part in research, even though they can be considered as public spaces.

Research Using Ethnography and Photographic Methods

Some research examining how families and groups engage with food and develop particular food behaviours involves ethnographic methods using observations, videos and photographs e.g. videoing of family meals, cooking. Such data can provide valuable social information and inform clinical diagnosis and family therapy programs in the treatment of eating disorders. Ethically, these methods raise issues of anonymity and confidentially. Hence, as in other research, they need to be carefully balanced against the risks and benefits of the research, particularly since videos cannot be anonymised in the way interview data can.

[16] Ward, G. (2002). *Crossing Cyber Boundaries: Where Is the Body Located in the Online Community? Reframing the Body*. London.: Palgrave MacMillan.

Interdisciplinary Food Related Research

Example Topics:	Example Methods:
Assessing economic impact of food-related chronic disease.	Analysis of economic *and* epidemiological data.
Food-related quality of life research.	As above plus interviews.

Food related research often employs interdisciplinary approaches, combining not only activities across the social sciences (for example qualitative social psychology research and quantitative economics research) but also across the natural and the social sciences (allergy studies, human nutrition, ethnography and public perceptions, for instance). Dealing with ethical issues may be complex when research fields with different ethical concerns and traditions collaborate.

In interdisciplinary research all interventions, which are medical in nature, need to comply with standard requirements as outlined on http://cordis.europa.eu/fp7/ethics_en.html. See also, Food Related Research Equivalent to Medical Research, below.

The main ethical issues in quantitative research fall under the generic issues raised at the outset (informed consent and data protection) plus the inclusion of those unable to consent (see section on qualitative research). The main ethical issue in this context that has not yet been discussed elsewhere in this document is secondary use of data or tissue.

Secondary Use of Data or Tissue

Most European countries allow the secondary use of data or tissue, if the data is fully anonymised, the research participant has not specifically objected to secondary use and approval for it has been obtained from the relevant research ethics committee. However, the value of research data can be compromised by anonymisation, for instance, when economic and epidemiological data are regularly updated and linked. In this situation, the expectation is that researchers obtain active consent for such data by contacting research participants again and discussing the new research project.

Nutrigenomics

Example Topics:

Interplay of genes and nutrition on the development of heart disease

Effect of polyunsaturated fat intake on "good cholesterol" (HDL) levels based on genetic make-up

Example Methods:

Bioinformatics

Genetics

Human clinical studies

Nutrigenomics studies how genetic and cellular processes relate to nutrition and health, including how people with different genetic variants respond to alternative dietary conditions and how diet can switch genes on or off. Food companies are interested in nutrigenomics because it can help them to develop and market new functional foods.

Guidelines by the European Nutrigenomics Organisation

The "European Nutrigenomics Organisation", a Network of Excellence funded by the European Commission, issued detailed guidelines on the ethical conduct of neutrogenomics research in 2007.[17] The guidelines cover the following 19 topics:

1. Information during consent process
2. Content of the consent form for a nutrigenomics study
3. Informed consent for research involving research volunteers not able to consent
4. Informed consent for biobanks
5. Extent of informed consent for biobanking
6. Disclosure of genotype test results
7. Disclosure of genotype test results on an individual level
8. Ownership and governance
9. Storage of samples and data
10. Independent review of research using materials stored in a biobank
11. Benefit sharing
12. Fate of the sample and associated data if consent is withdrawn
13. Samples from deceased persons
14. Quality control
15. Potential legal successor in case the hosting institution closes down or the responsible scientist is not working for the biobank anymore
16. Access to biobanks
17. Disclosure of personal data
18. Use of biological materials and data in further research projects
19. Transfer of a biobank

Due to space restrictions, please see detailed information on all the above topics at: http://nugo.dife.de/bot/index.php.

[17] See also: Manuela M. Bergmann, Marek Bodzioch, M. Luisa Bonet, Catherine Defoort, Georg Lietz and John C. Mathers (2006) Bioethics in human nutrigenomics research. *British Journal of Nutrition*, 95:1024-27.

In this context, it needs to be borne in mind that:

- Potential nutrigenomic benefit claims to public health must be justified (see also legitimacy of publicly funded research).
- Priorities for public research spending on nutrigenomics should be informed by public engagement in order to achieve acceptance.
- When public funds are used to develop personalised genetic diets, the outcomes of the research should be accessible to all parts of the population and not just benefit the more affluent.
- Information provided to individuals from nutrigenetic tests should be accompanied by genetic counselling, where necessary.

Novel Foods, GM Foods and Health Claims

Example Topics:

Development of nutritionally enhanced functional foods for the elderly

Development of cultured meat

Example Methods:

Animal experimentation

Human clinical studies

Food-related research is particularly ethically sensitive if (a) it enlists human participants who are exposed to risks and (b) if the research itself develops new materials and techniques whose risks are unknown. The development of health claims will be given as an example for (a) and nano- as well as GM technologies as an example for (b).

Labelling and Health Claim Certification

The food market for foods that claim to contribute positively to health and well-being has been growing steadily in developed countries. Since December 2006 nutrition and health claims made on foods are regulated under harmonised rules across the European Union. The main aim of Regulation No 1924/2006 is "to ensure a high level of protection for consumers and to facilitate their choice" and to achieve "free movement of foods and create … equal conditions of competition."[18]

The market trend and the regulatory move combined spur additional food research, (i) to develop novel products, the commercial viability of which depends on their supposed contribution to health and well-being, and (ii) to build the evidence base for health claims. As Regulation No 1924/2006 emphasises, the protection of the consumer is one of its main aims. Consumer rights in the area of food are usually associated with choice and thereby the possibility for "exit". Genuine "exit" is only feasible if the consumer receives all the information required to make an informed decision. Two main possibilities arise: First, consumers might *not* want to buy certain products. To make this choice possible, strict labelling regulations, which include process information, have to be in place. Second, consumers might *want* to buy the product with the most potent and reliable health effect. Again, strict health claim regulations, which ensure that claims are trustworthy, have to be in place.

For the development of health claims, interventions on human participants are likely to be necessary (e.g. blood sampling). These interventions have to be guided by the principles relevant to similar medical research. Details can be found on: http://cordis.europa.eu/fp7/ethics_en.html. Hence, this type of research also falls under the section below, Food Research When Equivalent to Medical Research.

Up-to-date information on European Food Safety Authority (EFSA) requirements for health claims, can be found at: http://www.efsa.europa.eu/en/nda/ndaclaims.htm.

[18] Regulation 1924/2006, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20080304:EN:PDF

Nanotechnology and Food

Nanotechnology aims to produce materials or devices at the nanometre scale (a nanometre is one millionth of a millimetre). When nanotechnology is used within food production, its safety must be assessed as some of the chemicals used may have different characteristics and properties at the nano level than could be observed at the larger level.[19]

The European Food Safety Authority (EFSA) advises member states and public health officials on the potential risks of nanotechnology in food. An EFSA opinion commissioned by the EC established that international approaches to risk assessment can also be applied to nanomaterials. However, this must be done on a case-by-case basis and may be "very difficult and subject to a high degree of uncertainty", with current data limitations and the lack of relevant test methodologies.[20]

In 2008, the European Commission committed to reporting again on the topic of nanotechnology regulation to the European Parliament and the European Council in 2011.[21] At this point, important recommendations were included in the "Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research".[22]

GM Foods

Foods whose DNA has been genetically modified (GM) to engineer certain characteristics (e.g. pesticide resistance) have been on the market since the 1990s. 20 years later, the controversies about GM foods are still ongoing. There have been many politically and economically motivated debates on this research field creating polarity both within and outside of the scientific community.

It is important to keep in mind that scientific uncertainty in itself does not raise ethical issues, but that commitment to safety must be evident. Any research using GM technologies or products must be accompanied by commitments to adhere to relevant EU and national legislation, namely: EU Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms (GMOs) and GMPs as well as Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs.

In this context, it would also be advisable for researchers to organise public consultations or engagement on the safety measures and public perception of their GM research.

Permissions obtained from relevant national authorities will need to be presented to the European Commission as part of the reporting requirements.

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19 EFSA, Frequently Asked Questions on Nanotechnology, http://www.efsa.europa.eu/en/faqs/faqnanotechnology.htm

20 Ibid.

21 Regulatory Aspects of Nanomaterials, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF

22 Code of conduct for responsible nanosciences and nanotechnologies research, http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

Developing Country Research incl. Indigenous Peoples Research

Example Topics:

Developing nutrition packages for severely undernourished children

Developing Aboriginal Australian "bush tucker" for other markets

Example Methods:

Human clinical studies

Access to Traditional Knowledge

EC guidance on developing countries research is currently being developed. A cross-reference to this research for more detail will be given once it is available.

Equitable Partnerships

Research involving developing countries must take account of local research needs and potential benefits to local communities. It is unethical to undertake research in developing countries (for instance, because it is cheaper) when the results of the research will be of no benefit to local communities. Wherever feasible, the developing country perspective should be integrated into any research proposal in a way that makes them equitable partners. In practice, this means that they should be involved in setting the initial objectives of research as relevant to local populations, as well as in the implementation (e.g. analysis) and dissemination (e.g. publications).

Risks to Researchers

When undertaking research in some developing countries or in certain parts of other developing countries, researchers may face risks, which they would not encounter in a European setting (e.g. war zone, high risk of violent crime, malaria). Health and safety assessments by employers (e.g. European universities) need to precede such research so that researchers are fully aware of the risks and adequately insured and equipped if they undertake it.

The Convention on Biological Diversity[23]

In 1992, The Convention on Biological Diversity (CBD) was opened for signature at the Earth Summit in Rio de Janeiro and has since been signed by 193 parties. Only Andorra, Holy See (the Vatican), and notably the United States of America (USA) are not party to it.[24] The convention has three objectives.

- the conservation of biological diversity
- the sustainable use of its components, and
- the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.[25]

[23] This text is generic to the CBD, even though the FAO has issued some benefit sharing requirements for seeds only.

[24] Convention on Biodiversity, List of Parties, http://www.cbd.int/convention/parties/list/

[25] Convention on Biodiversity, Article 1, http://www.cbd.int/convention/articles/?a=cbd-01

According to the preamble of the CBD[26], non-human biological resources fall under the national sovereignty of states. This means that plants, animals, micro-organisms and traditional knowledge associated with these resources fall under the decision-making powers of national governments. Based on the sovereignty principle, each CBD party agrees to develop and implement national laws to govern access and benefit sharing of non-human biological resources.

When non-human genetic resources and associated traditional knowledge is used in food research, the CBD has to be respected. This requires at least:

- the obtaining of authorizations from national governments and of prior informed consent from the holders of traditional knowledge before using relevant genetic resources.
- the setting up of mutually agreed terms for access and benefit sharing.

Food-related Research in Emergency Situations

Food aid is one of the components of most development programmes. Its importance was emphasised in the Millennium Development Goals.[27]

Target 1c: Reduce by half the proportion of people who suffer from hunger

1.8 Prevalence of underweight children under-five years of age
1.9 Proportion of population below minimum level of dietary energy consumption

However, giving food aid to mal- or undernourished and stunted children or adults to improve their health and prospects is not easy. Whilst some interventions have been tested sufficiently (e.g. micronutrient supplements such as iron or Vitamin A, fortified foods such as foods with iodised salts, or powered micronutrients to be sprinkled on staple foods), others require further research (including genetic modification of crops or nutrigenomic solutions). Such research will be undertaken on highly vulnerable populations and is therefore particularly ethically sensitive. Double ethical review both in the North and in the South is therefore important.

Target populations for research in this area vary from mild to acutely malnourished individuals and from socially deprived to refugee and internally displaced groups. Their apparent extreme vulnerability at the individual level is sometimes compounded by social and political oppression, a fact that creates an additional requirement for protection as research participants. The relief community has entered an, as yet, unofficial dialogue on ethics guidelines for research undertaken in such situations. Guiding documents in this debate are not only the Declaration of Helsinki[28] and the relevant CIOMS Guidelines[29], but also the 1951

[26] Convention on Biodiversity, Preamble, http://www.cbd.int/convention/articles/?a=cbd-00
[27] Millennium Development Goals, Goal 1, http://www.undp.org/mdg/goal1.shtml
[28] Declaration of Helsinki, http://www.wma.net/en/30publications/10policies/b3/index.html

UN Convention on Refugees and its Additional Protocols[30]. These provide basic guidance although they are not dealing with the apparent complexities that crisis settings are creating for research.

The ensuing discussion amongst humanitarian agencies has resulted in the first draft of guidelines for research in refugee and internally displaced populations. Recommendations include the following:[31]

- Undertake only those studies that are urgent and vital to the health and welfare of the study population.
- Restrict studies to those questions that cannot be addressed in any other context.
- Restrict studies to those that would provide important direct benefit to the individuals recruited to the study or to the population from which the individuals come.
- Ensure the study design imposes the absolute minimum of additional risk.
- Select study participants on the basis of scientific principles without bias introduced by issues of accessibility, cost, or malleability.
- Establish highest standards for obtaining informed consent from all individual study participants and where necessary and culturally appropriate from heads of households and community leaders (but this consent cannot substitute for individual consent).
- Institute procedures to assess for, minimise, and monitor the risks to safety and confidentiality for individual participants, their community, and for their future security.
- Promote the well-being, dignity, and autonomy of all study participants in all phases of the research study.

These guidelines represent the first step towards raising awareness in the research ethics communities of the need to consider crisis settings as deserving particular attention in the field.

29 CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm

30 UN 1951 Refugee Convention, http://www.unhcr.org/pages/49da0e466.html

31 Leaning, J. (2001) Ethics of research in refugee populations, *Lancet*, 357, 1432-3.

Food Related Research Equivalent to Medical Research

Example Topics:

Dietary-based cancer risks

Satiety mechanisms

Foodborne contaminants

Example Methods:

Animal experimentation

Human clinical studies

A range of food research can be regarded as equivalent to research in health care. The following gives some examples:

- As has already been noted above, medical interventions necessary to provide evidence for health claims (e.g. blood samples) fall under this category.
- In addition, human participants or animals may be involved in safety assessments or ingestion tests.
- Research on food allergies may include medical interventions.
- MRI use to understand the neuropsychological basis for satiety mechanisms or physiological responses such as gastric emptying.

Such research has to be guided by the principles of equivalent health research. We therefore refer to the main ethics pages of the European Commission's Ethical Review.

http://cordis.europa.eu/fp7/ethics_en.html

Appendix:

Broader Issues in Food Ethics

Food is fundamental to human existence. It is essential for survival, health, and well-being; it carries strong spiritual-symbolic significance (e.g. Buddhist vegetarianism) and it helps to form and maintain social relationships. Thus, it is unsurprising that food is intimately bound up with ethics, the study of norms, principles, or values that ought to guide human action. For instance, starvation and malnutrition pose some of the oldest questions about the duties of beneficence towards strangers. In addition to the issue of global hunger, food ethics faces a series of new questions that only emerged with the introduction of modern agricultural practices and biotechnologies. Is the exploitation of animals associated with intensive farming ethically acceptable? Do modern technologies produce safe, nutritious, and good quality food? Is food marketing ethically sound? What needs to be done about the detrimental effects of modern food production on the environment in terms of soil erosion, loss of biodiversity, and global warming? Or on a more general level: Where does state responsibility for citizen nutrition start and stop? Ought the health system to adopt punitive measures for those who put their health at risk through junk foods? The following section describes some of the most prominent issues that provide the context for research relating to food. In the context of this guidance document, this description is by necessity brief and of a general nature.

Food Security

> *Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life.*[32]

How we can feed a growing population that demands more resource-intensive diets, while tackling climate change and environmental degradation, is the key question of food security.

Over a billion people suffer from hunger[33] and climate change threatens to exacerbate this food insecurity further. However, sufficient food is available to feed the world population. *Access to food* is the primary problem. As Nobel Laureate Amartya Sen has shown in his seminal work "Poverty and Famines"[34], famines do not occur because of lack of food, but because no food entitlements for the poor are built into the mechanisms for distributing food. This means that increasing global agricultural productivity on its own cannot solve the problem. Likewise emergency responses to food shortages will always remain an unsatisfactory ad-hoc solution to more deep-seated problems. There is a need to look at distributional justice. At the individual and household level, the root cause of food insecurity - poverty - has to be tackled.

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32 Food and Agriculture Organization (FAO). 1996. Rome Declaration on World Food Security and World Food Summit Plan of Action. World Food Summit 13-17 November 1996. Rome, http://www.fao.org/docrep/003//w3613e/w3613e00.htm.

33 BBC, World Hunger hits 1 Billion, http://news.bbc.co.uk/1/hi/world/europe/8109698.stm

34 Amartya Sen (1983) Poverty and Famines, Oxford: Oxford University Press.

Sustainable Food Production and Distribution

> *The sustainability and security of European agricultural, forestry, aquaculture and fisheries production is under threat from intensive production practices, global competition and climate change factors.*
>
> *Agriculture, forestry and fisheries can no longer be viewed in a traditional sense and multidisciplinary, generic research from different disciplines must be applied.*
>
> *It must…: reassess the "public good" role of life science research and its interactions with society and the environment, along with redefining the role of public research funding.*[35]

Climate Change

Climate change threatens global agriculture, particularly in countries already facing water shortages and areas vulnerable to rising sea levels and flooding. At the same time, agriculture is a considerable contributing factor to greenhouse gas (GHG) levels and therefore climate change.

In the EU, agriculture accounts for around 2% of gross domestic product (GDP) but contributes about 9% of GHG emissions, much in the form of methane (from digestion in ruminants and waste decomposition) and nitrous oxide (from fertilisers), which have a strong warming effect.[36] When one broadens the perspective to food in general and takes into account its production, packaging, transport, retail and preparation, the contribution to climate change is even greater.

- Mitigating agriculture's contribution to climate change means embracing low-GHG farming practices, including less reliance on energy-intensive inputs.
- However, there is no benefit in reducing European agricultural emissions if Europeans offshore their contributions by substituting high GHG-emitting products with similar energy-intensive imports.

Meat Production[37]

Farming animals on a large scale raises many ethical concerns, their contribution to GHGs being only one of them. Most of the 60 billion animals farmed for food worldwide every year are intensively reared with implications for animal welfare and consumer safety (e.g. increased occurrence of zoonoses, diseases that are associated with farmed animals and are transferable to humans such as salmonella, BSE, avian flu, swine flu). One could formulate the following ethical obligations or opportunities for action:

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35 Agriculture, forestry and fisheries: meeting tomorrow's economic, social and environmental objectives An FP7 guide to sustainable production and management of biological resources from land, forest and aquatic environments, ftp://ftp.cordis.europa.eu/pub/fp7/kbbe/docs/fiche-agriculture-080305_en.pdf

36 How will Farming in the EU be Affected by Climate Change, http://ec.europa.eu/agriculture/climate_change/index_en.htm

37 Similar concerns apply to farmed fish.

- We have an ethical duty to treat farm animals in ways that respect their welfare and the environment.
- Meat-eating consumers in the developed world could signal their support for high animal welfare standards by choosing meat from farms where animals are extensively reared and their needs met.
- The EU could be a powerful force for good, by enforcing its animal welfare standards on all imports. FP7 already imposes EU ethical standards on all budget holders.

Food Miles or Long Supply Chains

Debates about sustainable agriculture and food production rarely stop on the field or at the processing plant. They reach into food distribution and supply chains. At the centre of public controversies over sustainable food supply has been the concept of "food miles", and the complicated logistics required to provide ever more choice to consumers in developed countries.

Taking the UK as an example, food is responsible for a quarter of lorry travel (by distance) and consumers drive around 19 billion kilometres a year to buy it. The UK Government puts the social and environmental costs of food transport at £9 billion a year.[38]

There are concerns that long supply chains:

- Contribute excessively to climate change, especially when food travels by air, though food transport makes a smaller contribution to total GHG-emissions than agricultural production.
- Depend on dwindling oil reserves and are geopolitically vulnerable.
- Widen the gap in understanding between consumers and producers.
- Compromise animal welfare by transporting livestock long distances.
- Harm local economies and the communities they support.
- Go hand in hand with a deeper industrialisation of our food and food culture.
- At the same time, local food initiatives and campaigning can be parochial, downplaying the development benefits of international trade and alienating ethnic communities in Europe.

Food Waste

Food waste is costly, environmentally irresponsible and deeply troubling in a world where one billion people suffer from hunger. "The Dutch Ministry of Agriculture, Nature and Food Quality has estimated that Dutch consumers throw away approximately 8–11% of food purchased, equating to 43–60 kg of food waste … per person per year."[39]

Research in the UK[40] has shown that

- Every household in the UK wastes between £250 and £400 of food per year.

[38] Food Ethics Council (2008) Food Distribution, an Ethical Agenda, http://www.foodethicscouncil.org/node/158

[39] No detailed information is available for other EU countries, for more information see: Parfitt, J, Barthel, M and Macnaughton, S (2010) Food waste within food supply chains: quantification andpotential for change to 2050, *Philosophical Transactions of the Royal Society B*, 365, 3065-3081

[40] Food Ethics Council (2009) Waste – Dishing the Dirt, http://www.foodethicscouncil.org/node/329.

- Avoidable waste of cereal-based food in the UK and USA could lift 224 million people out of hunger.
- Around 7 million tonnes of food ends up in landfill in the UK every year.
- Producing and distributing edible food that goes to waste accounts for around 5% of all UK GHG emissions.

Given the scale of the problem of food waste and its main concentration in individual households, considerable improvements to food efficiency could be achieved through behavioural change.

Fair Trade, Accreditation Systems

The slogan "We are what we eat", which is usually subscribed to Rousseau, is understood to have a health background. Healthy diets lead to healthy lives. However, increasingly it is also taken to express life-choices irrespective of health considerations. Food markets make it possible to express ethical values by consuming food correspondingly: the value of animal well-being is expressed by free-range and vegetarian products, the value of environmental protection by organic products and the value of social justice by fair trade products. We shall look at the latter as an example of this kind.

Millions of people around the world rely on agriculture for their livelihoods. In some poorer countries the majority of the population is fully or partly dependent on it.[41] The growing market share and power of retailers has contributed to a situation where workers' rights and environmental standards are put under pressure by efforts to secure large quantities of products at the cheapest possible price.

Labelling and accreditation systems like *Fairtrade* and *Max Havelaar* have been crucial in raising the profile of ethical issues in food and farming. The problems that arise from accrediting some products as fairer than others include:

- Why are unfair products - for instance those made in illegal working conditions - on the shelves at all?
- Do 'ethical labels' live up to their promises - are they rewarding fair trade or just fairer trade?
- When large corporations buy into ethical standards, does that erode their value either in practice or in principle?
- Is competition in the 'ethical' foods sector creating too many different levels and types of 'ethical' standard, damaging consumer trust in the movement?

[41] World Bank, Employment in Agriculture, http://data.worldbank.org/indicator/SL.AGR.EMPL.ZS/countries?page=1&display=default

Food Science, Financial Conflicts and Scientific Integrity

A conflict of interest is 'a conflict between the private interests and the official responsibilities of a person in a position of trust.' A conflict of interest thus arises when a person has to play one set of interests against another.[42]

FP7 encourages collaboration between academic researchers and private industry[43] to enhance European competitiveness. It is important to understand that collaboration with industry-partners does not represent an ethical issue *per se*. The potential for biases in research are numerous. But given public sensitivities and allegations of specific bias in the food industry[44], the following guidelines may be helpful.

In 2009, the International Life Sciences Institute in the United States issued "proposed conflict-of-interest guidelines, regarding industry funding to protect the integrity and credibility of the scientific record, particularly with respect to health, nutrition, and food-safety science".[45]

These are[46]:

1. conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2. require control of both study design and research itself to remain with scientific investigators;
3. not offer or accept remuneration geared to the outcome of a research project;
4. ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;
5. require, in publications and conference presentations, full signed disclosure of all financial interests;
6. not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7. guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers;

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42 Coughlin SS, Soskolne CL, Goodman KW. (1997) *Case Studies in Public Health Ethics*. Washington: American Public Health Association.

43 See for instance Marie Curie Industry-Academia Partnerships and Pathways (IAPP), http://cordis.europa.eu/fp7/people/industry-academia_en.html.

44 Centre for Science in the Public Interest (2007) New Aspartame Safety Review 'Perfectly Predictable', http://www.cspinet.org/new/200709122.html and Animals Australia (2008) Farming Critics Fault Industry's Influence, http://www.animalsaustralia.org/media/in_the_news.php?article=132

45 Sylvia Rowe, Nick Alexander, Fergus M Clydesdale, Rhona S Applebaum, Stephanie Atkinson, Richard M Black, Johanna T Dwyer, Eric Hentges, Nancy A Higley, Michael Lefevre, Joanne R Lupton, Sanford A Miller, Doris L Tancredi, Connie M Weaver, Catherine E Woteki, and Elaine Wedral (2009) Funding food science and nutrition research: financial conflicts and scientific integrity, *Nutrition Reviews*, 67(5)264-272.

46 Ibid.

8. require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

The drafting group of the above guidelines emphasised that financial conflicts of interest do not necessarily lead to bias, that a large number of well-known forms of scientific and personal bias exist and that *all* need to be kept in check. They also noted that whilst disclosure of conflicts of interest are an essential element of safeguarding research, it is not sufficient (hence the guidelines) and that the success of such guidelines rely on open communication between researchers and funding bodies in a spirit of collaboration.[47]

A broader issue which is difficult to address through such guidelines, yet nevertheless warrants attention, is the issue of 'cultural bias' within scientific institutions. The heated controversies over issues such as GM foods illustrate how scientists may see the world differently from non-scientists, or how perspectives on problems may vary greatly between research disciplines. In addition, the regional cultural differences may impact. For instance, in Europe the precautionary principle is used to guide research involving GM organisms. At the same time, they are generally recognized as safe (GRAS) by the American Food and Drug Administration. This suggests the benefit of engaging stakeholders and members of the public in the process of defining research problems and subjecting research projects to ongoing critical scrutiny.

Legitimacy of Publicly-Funded Research / Societal Benefits

Much publicly-funded research relating to food aspires to deliver benefits to the population or to specific groups of people. Thus, a project in nutrigenomics may aim to benefit public health, or agricultural research may be intended to improve food security in developing countries. Claims about the potential public benefits of research are relevant to specific decisions on public sector research funding and also affect the broader licence to operate of the scientific community.

High-profile controversies over research in food and agriculture, for example the Golden Rice project to combat vitamin A deficiency through biofortification, have seen the legitimacy of such claims subjected to intense scrutiny. In particular, critics are concerned about the practical relevance and the opportunity costs of scientific projects to develop technical solutions to problems that also have social, economic and political dimensions.

The appropriate response to this concern is to ensure that any promises by researchers of potential public benefit are well-founded and take all foreseeable consequences into account. The first priority is therefore to ensure that the public interest elements of research problems are defined robustly and legitimacy. This entails that they:

[47] Ibid.

- Are intellectually robust. If research claims to have potential to contribute to addressing a real-world problem, then a robust problem definition is likely to depend on reviewing evidence from multiple disciplines across the social and natural sciences.

- Are informed by the demands of constituencies experiencing the problem in question. For example, a social science or plant breeding project may respond directly to the food security priorities of a rural communities in a region of sub-Saharan Africa identified through prior participatory research; or researchers may identify priorities for nutrigenomic research by working with patient groups. At best, projects should include governance mechanisms to ensure they are accountable to any groups they claim to benefit.

- Invite ongoing scrutiny by independent third parties. Many problems relating to food disproportionately affect marginal groups – people in poverty, ill-health or food insecurity – who have few resources to ensure their voices are heard in research decision-making or public debate. Inviting scrutiny from third parties that have a remit to represent the interests of such groups, such as civil society organisations, can help to ensure their definition of the research problem remains prominent throughout the research process.

With regards to developing country research relating to food, agriculture and rural development, a key resource and reference point is the report of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD).[48] The IAASTD process involved 400 experts and civil society groups from around the world. Its report provides guidance on priorities relating to agricultural and food research, and methods for ensuring that aspirations to benefit food security, sustainability, rural livelihoods and poverty reduction are developed robustly and legitimately.

Food Habits and Public Health

Considerable research is being undertaken on eating disorders and food habits, which have a detrimental effect on public health. Here, obesity will be taken as an example.

According to the World Health Organisation (2005) approximately 1.6 billion adults worldwide are overweight and at least 400 million adults are obese, with predictions that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million obese. Obesity is a major risk factor for chronic diseases such as cardiovascular disease, diabetes, musculoskeletal disorders and some cancers. While obesity is sometimes characterised as a disease of affluence, many of the wide range of social, environmental, technological and other factors contributing to the rising incidence of overweight and obesity differentially affect individuals in lower socioeconomic groups. Globally, there are more obese people in developing and newly industrialised countries than there are in the industrialised world.

Unhealthy eating is one factor contributing to rising rates of obesity and overweight. However, changes in body shape are only one of the possible consequences of poor diet, and public health intervention seeks to improve dietary health for other reasons in addition to reducing

[48] IAASTD Reports, http://www.agassessment.org/

overweight and obesity. For example, consumption of fruit and vegetables is relevant to a wide range of health outcomes and varies considerably across EU member states, with per capita intakes in Greece more than five times higher than in the UK.[49] At the same time, considerable "junk food" consumption can outweigh the benefits of fruit and vegetable intake.[50]

Ethical issues relating to healthy eating focus on the appropriate responsibilities of government, businesses and individuals. A key factor in this discussion is the level of autonomy that individuals are understood to experience as consumers in the marketplace. A relevant consideration is the degree to which socioeconomic inequalities explain poor diet and related health conditions. The balance of evidence suggests that while such inequalities do not fully determine differences in diet, they do provide an important explanation.[51]

The Nuffield Council on Bioethics has explored in depth the ethical issues relating to public health, including diet, outlining a 'stewardship model': [52]

> The concept of 'stewardship' is intended to convey that liberal states have a duty to look after important needs of people individually and collectively. It emphasises the obligation of states to provide conditions that allow people to be healthy and, in particular, to take measures to reduce health inequalities. The stewardship-guided state recognises that a primary asset of a nation is its health: higher levels of health are associated with greater overall well-being and productivity.

In this context, it is also important to bear in mind that food research often involves working with individuals and groups whose relationship with food and patterns of food consumption are entwined with more complex social, cultural, physical and psychological issues that extend beyond mere food 'behaviours'. For example, Western medicine and culture often attach moral overtones to the behaviour of overweight and obese individuals: they eat 'bad' and 'unhealthy' food; lack self-discipline and control; are negligent in caring and respecting their bodies and health.[53] However, food behaviours and attitudes differ across cultures. Among Australian Aborigines and Pacific Islander, for example, an older person who consumes lots of food and is physically large is viewed as a person who is comfortable with their own identity and who has a zest for enjoying life. While there are deleterious medical consequences to being overweight or obese, public health interventions designed to improve diet, weight and health problems within these groups are viewed as a cultural assault and form of cultural imperialism that seeks to erode the cultural values, heritage and identity of already oppressed native peoples. Hence, ethical research needs to consider the particularity of the specific populations involved in any food research.

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Food, Social Life and Personal Identity

[T]he things we eat and drink play important roles in our social and personal (not just biological) life. To almost any citizen… food is connected with identity and social life. A good food research project should try to address these issues in advance, because neglecting them would almost certainly hamper the implementation.[54]

"Food lies at the centre of human sociability"[55] (Korthals 2002: 322). For instance, it plays an important role in family life and other forms of social bonding. "Drinks are for strangers, acquaintances, workmen… Meals are for family, close friends, honoured guests"[56]. This is, of course, a simplification but having a meal with somebody often makes the difference between intimacy and distance. Meals, particularly at home, express close friendships. Common meals are meeting places for family members and friends.

With individualist eating either in terms of functional foods or foods tailored to one's genetic make-up, the social bonding function of food might be breaking down. Such foods:

> can have detrimental effects on these social dimensions, because of their individualizing intake: what is healthy for me isn't for you, because of differences in genome, age, life style and ideals, and expectations. So in the end, the common meal, which, at least in European and Asian traditions of eating, is a cherished good in upholding relationships, could vanish.[57]

Researchers need to be aware of potential public resistance to certain foods and may want to consider public engagement exercises to accompany their research.

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55 Korthals M (2001) The Struggle over Functional Foods: Justice and the Social Meaning of Functional Foods. In: *Journal of Agricultural & Environmental Ethics*, 15: 315-324, p.322.

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European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

Multi-beneficiary Annotated General Grant Agreement

Articles 1 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58

Version 1.2
17 February 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added

Foreword

The **Horizon 2020 Annotated Model Grant Agreement** ('Annotated MGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are **annotated** are bold and in **blue**.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

2. As the Annotated GA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

The Annotated GA will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

ⓘ For more information, see the Horizon 2020 Online Manual on the Participant Portal.

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[1] **Horizon 2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
Horizon 2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ⓘ For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 General Model Grant Agreement annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[1],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 15 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'Beneficiaries' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The signature arrangements are the following:

- the **coordinator** directly signs the GA
- the **other beneficiaries** sign the GA by signing the Accession form.

  Amendments to the GA, if any, will be signed by the coordinator on their behalf.

⚠ An applicant who accepts the grant by signing the GA becomes a beneficiary of the grant and is bound by the entirety of its terms and conditions.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' (see Article 8).

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

[2] For the definition, see Article 2.1(15) of the Rules for Participation: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 [Horizon 2020] having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Commission, in the electronic exchange system ('My Area' section of the Participant Portal).

These data will be automatically used for all communications concerning this grant (see Article 52) and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant (see also Article 17).

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (see Articles 17 and 52).

ⓘ For more information on the procedures for beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. Action

The term '**action**' is used in the Financial Regulation[3] and **means** '**project**', which is the term traditionally used in EU Research Framework Programmes.

The actions covered by the General MGA are all types of:

- research and innovation actions (i.e. actions with activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- innovation actions (i.e. actions with activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[4]
- coordination and support actions (i.e. actions consisting in accompanying measures such as standardisation, dissemination, awareness-raising and communication,

[3] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[4] For the definition, see Article 2.1(6) of the Rules for Participation Regulation (EU) No 1290/2013: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

networking, coordination or support services, policy dialogues and mutual learning exercises and studies)[5].

2. Complementary grants

Complementary grants are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action (see Article 41.4). It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

Joint actions (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

⚠ The beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action (see Article 41.5).

[5] For the definition, see Article 2.1(7) of the Rules for Participation Regulation (EU) No 1290/2013: '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it (see Article 58).

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA (Annex 2).

These estimated eligible costs are used to determine the 'maximum grant amount' ('EU/Euratom financial contribution' in FP7 projects) of the action (see Article 5.2).

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant (see Article 9).

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

For the General MGA, these are:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs and
- specific categories of costs (if option applies).

⚠ The budget category 'specific categories of costs' only applies when a Commission decision has specifically foreseen to use:

- unit costs for one or several categories of costs for specific activities (they may include both direct and indirect costs)

For the General MGA, this is currently provided for:

- access costs for providing trans-national access to research infrastructures (Decision C(2013) 8199[6]; see Article 6.2.F)
- costs of energy efficiency measures in buildings (Decision C(2013) 8196[7]; see Article 6.2.F)

– lump sum costs for one or several categories of costs for specific activities (they may include both direct and indirect costs).

This option is currently not foreseen for the General MGA.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment (see Article 55) if the action is implemented as described in Annex 1.

⚠ The maximum grant amount mentioned in Article 5 cannot however be increased.

What can be transferred? If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)
Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

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[6] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme.
Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[7] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No adjustment of amounts set out as lump sums

If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category, or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No adding of costs relating to subcontracts not provided for in Annex 1

Subcontracting a task while the action is being implemented *(e.g. the beneficiary decided not to recruit additional personnel as initially foreseen but to call upon a subcontractor)* is considered as a significant change of Annex 1.

Therefore, the transfer of budget intended to increase the eligible costs under the budget category 'subcontracting' (due to an additional subcontract) is considered as reflecting a significant change in Annex 1and would normally require an amendment (see above).

If an additional subcontract (not foreseen in Annex 1 and Annex 2) needs to be awarded and no amendment has been signed, it can be approved by the Commission/Agency together with the periodic report (see conditions in Article 13), but the beneficiary will assume the risk of non-approval and consequent rejection of costs.

Example:

A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary fails to request the amendment (at its own risk) but justifies the change in the periodic technical report and the Commission approves the report. The cost of the additional subcontract may thus be eligible.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

*[**OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation Regulation (EU) No 1290/2013: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[5] For the definition, see Article 2.1(14) Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[6] To be used only if option in Point (f) is used.

[7] To be used only if option in Point (f) is used.

[8] To be used only if option in Point (f) is used.

[9] To be used only if option in Point (f) is used.

[10] To be used only if option in Point (f) is used.

[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.

[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a price due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for research actions ('research and innovation actions') is in principle 100% of the total eligible costs. For innovation actions it is in principle 70% of the total eligible costs.

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

3. Forms of costs

The different types of forms of costs are as follows:

– **actual costs** (i.e. costs which are real and not estimated budgeted or imputed)

[8] See Article 28(6) of the Rules for Participation.

Examples:

EUR 62 500 actual yearly salary for senior researcher A

EUR 2000 actual price for a computer

The actual price paid for the subcontracting of a trial

The financial support actually paid to third parties

- **unit costs** (i.e.
  - either a fixed amount per unit of measure, where the total amount depends on the number of units used for the action

    Example: *Direct personnel costs of SME owners not receiving a salary and of natural persons not receiving a salary may be declared using a fixed amount per unit of measure fixed by the Commission*

  - or an amount per unit of measure calculated by the beneficiary in accordance with its usual cost accounting practices for personnel costs)

    Example: *EUR 60,000 average salary for senior researchers*

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs)

  ⚠ In Horizon 2020, flat-rate costs will only be used to declare eligible indirect costs (i.e. as a flat rate of 25% of direct costs minus subcontracting and in-kind contributions by third parties not used on the beneficiaries' premises to declare the eligible indirect costs).

- **lump sum costs** (i.e. an fixed amount based on an estimate which is used by a beneficiary to declare as eligible):
  - either the overall implementation costs of an action

    Example: *EUR 150 000 to carry out a study*

  - or the costs of one or several specific categories of eligible costs.

    Example: *EUR 10 000 for travel expenses of each beneficiary within a project*

⚠ The conditions for eligibility, for each form of costs, are set out in Article 6.1.

⚠ Unit costs, flat-rates and lump sums must be authorised by Commission decision[9] (unless already set out in the Rules for Participation) and be set out in the work programme.

For the General MGA, a Commission decision currently exists for:

- direct personnel costs of SME owners not receiving a salary and of natural persons not receiving a salary (Decision C(2013) 8197[10]; see Article 6.2.A.4)

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[9] See Article 124 of the Financial Regulation.

[10] Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-

– access costs for providing trans-national access to research infrastructures (Decision C(2013) 8199[11]; see Article 6.2.F)

⚠ This specific category concerns only *access costs*. It does not concern other costs that may be incurred for providing trans-national access to research infrastructures (i.e. costs of travel and subsistence for the selected users; see Article 6.2.F and Article 16).

– costs of energy efficiency measures in buildings (Decision C(2013) 8196[12]; see Article 6.2.F)

The unit cost on the basis of the beneficiaries' usual accounting practices and the flat-rate of 25% for indirect costs are provided for in the Rules for Participation.[13]

Each category of costs can be covered by different forms of costs. Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO

2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[11] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[12] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[13] See Article 29(1) and 33(2) of the Rules for Participation.

Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared under any other budget category.

Thus, if for instance personnel costs are included in the costs under Article 5.2(f), these personnel costs cannot also be declared as direct personnel costs under Article 5.2(a).

Example:

A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.
Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

ⓘ For the types of costs included in the unit or lump sum costs under Article 5.2(f), see Article 6.2.F.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

When? The final grant amount is calculated by the Commission/Agency after the end of the action or in case of termination of the GA, in order to determine the balance to be paid.

How much? The final grant amount depends on all of the following:

- the **reimbursement rate** (Step 1)
- the amount of **eligible costs** approved by the Commission (Step 1)
- the limitation to the **maximum grant amount** (Step 2)
- compliance with the **no-profit rule** (Step 3)
- the extent to which the action was implemented properly (**work implementation**, i.e. if the work was carried out as described in Annex 1; Step 4) and
- **compliance** with all the **other rules** set out in the GA (Step 4).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria, see Article 6) will — if found at payment of the balance — be **rejected** and not approved.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation or **breach of another obligation under the GA** may lead to a **reduction of the grant** (i.e. reduction of the 'maximum grant amount').

Example: *One of the 3 test plants was not built, and several testing activities were not carried out*

Example: *Breach of the obligation to display the EU emblem (article 29.4) or to respect confidentiality of information identified as confidential.*

⚠ The Commission/Agency will decide on a case by case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; see Article 43).

⚠ In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Examples:

A deliverable is delayed by a couple of days because the researcher responsible is on sick leave.

A scientific test has to be redone at a later time due to meteorological conditions.

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

2. No-profit rule

The EU/Euratom grant amount may not have the purpose or effect of producing a profit for the beneficiaries.

For this reason, the total funding requested from EU/Euratom + receipts cannot exceed the total eligible costs.

At the time of payment of the balance, this means that the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts ≤ total eligible costs ➔ no reduction of EU/Euratom grant amount

⚠ Contrary to FP7, in Horizon 2020 profit must be assessed at the level of the action and not at the level of the individual beneficiaries.

The grant amount, receipts and eligible costs taken into account are the consolidated grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

3. Receipts

What? Three kinds of receipts must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples:

  Admission fee to a conference organised by the consortium.

  Sale of equipment bought for the action.

  ⚠ The receipt from the sale of assets is capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

  ⚠ It is considered a receipt if the value of the in-kind contribution given free of charge (corresponding to the costs incurred by the third party and not by the beneficiaries who receive it) has been declared by the beneficiary receiving it as an eligible cost for the action.

What not? The following are not receipts:

- **income generated by exploiting the results** of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

– **financial contributions** given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to **cover costs other** than the eligible costs

Example: currency exchange losses

– **financial contributions** given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

Example:

A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same project are not considered receipts either, since receipts are only contributions from *third parties*. Therefore, if a beneficiary funds another beneficiary in the same GA to help it carry out work, this will not be considered a receipt.

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Conversely, the financial contribution made by the beneficiary to another beneficiary is not considered as an eligible cost for the beneficiary giving the contribution.

In summary, this financial contribution is not a receipt for the beneficiary receiving it, and it is not either an eligible cost for the beneficiary giving it.

When? Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (for FP7 the 'final payment').

Beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

⚠ In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

⚠ Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the consortium agreement (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7).

⚠ You will have been requested to estimate the receipts of your action when submitting the proposal.

4. Calculation of the final grant amount

Calculation of final grant amount

Step 1 — Application of reimbursement rates to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA at the payment of the balance

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

⬇

final grant amount

Example:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Step 1 — Application of the reimbursement rates to the eligible costs

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000
Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Step 2 — Limit to the maximum grant amount

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Step 3 — Reduction due to the no-profit rule

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA at the payment of the balance:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*

- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

When? The final grant amount (see above) may be revised, if the Commission/Agency finds — after the payment of the balance — that a beneficiary declared costs that are ineligible, or that a beneficiary breached its obligations or improperly implemented its work under the GA (and therefore **rejects the costs** or **reduces the grant** for that beneficiary).

The 'revised final grant amount' is calculated at beneficiary's level:

2. Calculation of the revised final grant amount

If the **costs** unduly declared as eligible by the beneficiary concerned are **rejected** by the Commission/Agency as ineligible, the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement (see Article 42.3). The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount (calculated according to Article 44.1.3), it must repay the difference to the Commission/Agency.

If the **grant** is **reduced** due to improper implementation or breach of obligations by the beneficiary, the Commission/Agency will:

- reduce the maximum grant amount set out in Article 5.1, in proportion to the improper implementation or to the seriousness of the breach (see Article 43)
- calculate the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

Example 1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

Example 1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount (calculated according to Article 44.1.3), it must repay the difference to the Commission/Agency.

⚠ In case of rejection of costs *and* reduction of the grant, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

Only eligible costs can be reimbursed by the Commission/Agency ('reimbursement of eligible costs grant').

⚠ This must be taken into account already at proposal stage, when the beneficiaries prepare the estimated budget for the action (see Article 4).

⚠ Moreover, all the costs the beneficiaries declare in their financial statements (see Article 20) must comply with the general and specific conditions set out in this Article.

Article 6.1 refers to general eligibility conditions applicable per form of cost.

Article 6.2 refers to specific eligibility conditions applicable per budget category.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action (see Article 3).

  Example: *A conference for which costs are claimed must take place during the course of the action.*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

  This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

  Costs actually incurred should normally also be **paid** during the action duration.

  In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — if the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action, see Article 6.2.D.2).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — if the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category (see Annex 2).

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. they must be necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation).

  ⚠ Accounting documentation is necessary only for actual costs.

  ⚠ In addition, indirect costs do not need supporting evidence because they are declared using a flat-rate.

Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

Example: if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.

⚠ This principle cannot be used as justification for non-compliance with other GA provisions.

It is clear that a beneficiary is obliged to introduce any changes necessary to bring its usual cost accounting practices in line with all GA provisions.

Examples: conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)

⚠ For in-kind contributions provided by third parties free of charge and costs of linked third parties, eligible direct costs must be:

– recorded in the third party's accounting records;

– calculated in accordance with the accounting standards applicable in the country in which the third party is established;

– calculated according to the third party's usual cost accounting practices;

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive).

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality.

  It can be linked to 'efficiency', which is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.

⚠ The conditions described here are cumulative, i.e. all of them have to be met_for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit').

Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

For personnel costs declared on the basis of the beneficiary's usual cost accounting practices, the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices;
- must budget and declare a total amount; the amount per unit must not be included in Annex 2;

⚠ Beneficiaries cannot declare other types of unit costs according to their own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be calculated according to a Commission decision and agreed on by the Commission (see in Annex 2 of the GA, Article 5.2).

Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action.

⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

Example:

A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900
Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*: *costs of [insert cost category or activity*[13]*]*]**.

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Direct costs

Direct costs are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (this may comprise internal invoices, which must not include indirect costs elements or profit margin or mark-up, see Article 6.2.D).

2. Indirect costs

Indirect costs are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

In Horizon 2020, indirect costs are charged under the form of a 25% flat-rate of the eligible direct costs (minus certain direct eligible costs, see Article 6.2.E).

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[*A.6* ***[OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.]* ***[OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81) ('Rules for Participation Regulation No 1290/2013'): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs — Types of costs — Conditions for eligibility

Beneficiaries may declare the following **types of costs** as direct personnel costs:

- basic remuneration — **basic salary and complements**
- for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs of **personnel seconded by a third party**
- costs of '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs of '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

Direct personnel costs may be declared as actual costs or on the basis of unit costs (see Article 5.2(a)).

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as direct personnel costs.

Basic salary and complements ('basic remuneration')

The basic salary and complements (or parts of them, 'components') are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.. see Article 6.1(a) and (b))
- they are **mandatory** under national law, collective labour agreements or the employment contract
- they are paid to the employee (or benefit to him/her) **for** his/her ***usual*** **work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

⚠ It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract but he/she must be 'assigned to the action' (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

⚠ If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration (see below) will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

⚠ For secondments or linked third parties, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

What? The basic salary includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

'Parental leave' covers both maternity leave and parental leave.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

The complements may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

What not? The basic remuneration does not include components that must be considered to be 'additional remuneration'.

Example (variable remuneration component acceptable as basic remuneration):

The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.

⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs. ERC Grants are an exception to this rule: there, recruitment costs are eligible as direct costs because recruitment is one of the action's activities.

Remuneration of post graduate students employed by the university (beneficiary) — if a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible if they fulfil the conditions set out in Article 6.

ⓘ For more information on personnel (resources) made available to a beneficiary by a third party, see below and Articles 11 and 12.

Additional remuneration ('bonus' payments) for non-profit legal entities

Additional remuneration is **eligible**, if all of the following apply:

- it **fulfils** the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a) and (b))

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

  Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

  Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours

Remuneration components:
a = annual salary: EUR 50 000
b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
c = additional remuneration for being Head scientist in a project: EUR 2 000
d = additional remuneration for being First Assistant on an internal action: EUR 1 000

***a** and **b** would be used to calculate the researcher's hourly rate:*

hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34

***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*

***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- it is paid to the employee (or benefits him/her) for **additional work** or **expertise**

  The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

  Examples (acceptable additional remuneration):

  A normal salary is paid for teaching + additional remuneration is paid for doing research.

  A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

  A normal salary is paid for laboratory research + additional remuneration is paid for field research.

  Examples (not acceptable additional remuneration):

  Additional remuneration paid for using English.

  Additional remuneration is paid for participating in EU funded or multi-partner actions.

- it is part of the beneficiary's usual remuneration practices and is consistently paid whenever the same kind of work or expertise is required

- the **criteria** used to calculate the extra payments are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

  The objective criteria must be related to the additional work or expertise.

  The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

  ⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

  Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

  Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling', see below).

What? 'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

Costs for natural persons working under a direct contract

Costs for natural persons working under a direct contract are **eligible** as personnel costs, if all or the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.. see Article 6.1(a) and (b))
- there is a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.
- the person works under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.
- the **result** of the work carried out **belongs to** the **beneficiary**

The work carried out, including any resulting patents or copyrights, must belong to the beneficiary.

- the **costs** are **not significantly different** from those for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

What? This is typically the case of in-house consultants (i.e. self-employed natural persons working part-time or full-time for the action; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' (see Article 10) or as a 'subcontracting cost' (see Article 13).

Costs of personnel seconded by a third party

Costs of personnel seconded by a third party are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; see Article 6.1(a) and (b))

- the person is **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.

- the beneficiary **reimburses the costs** to the third party (not for free)

- the **additional specific eligibility conditions** set out in Article 11.1 are fulfilled.

⚠ The seconded personnel is considered an 'in-kind contribution provided by a third party against payment' (see Article 11).

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

Costs of beneficiaries that are SMEs for their owners not receiving a salary

Personnel costs of SME owners not receiving a salary are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; see Article 6.1(b))

- they correspond to the amount per unit (EUR/hour worked on the action; hourly rate) set out in Annex 2 multiplied by the number of **actual hours worked on the action**

- they are declared for an **owner** of an **SME** who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

⚠ The cost must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[14] and set out in Annex 2 of the GA.

Costs of beneficiaries that are natural persons not receiving a salary

Costs of beneficiaries that are natural persons not receiving a salary are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; see Article 6.1(b))
- they correspond to the amount per unit (EUR/hour worked on the action; hourly rate) set out in Annex 2 multiplied by the number of **actual hours worked on the action**
- they are declared for a beneficiary that is **natural person** who **works on the action** but **does not receive a salary**.

⚠ The cost must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[15] and set out in Annex 2 of the GA.

Personnel costs for providing trans-national or virtual access to research infrastructure

This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities (see Article 16).

Personnel costs (i.e. basic remuneration, additional remuneration, costs for natural persons working under a direct contract, costs of personnel seconded by a third party against payment; see above) incurred for providing trans-national or virtual access to research infrastructure must — in addition to the conditions above — comply with the **additional cost eligibility rules** set out in Article 16.1 or 16.2.

2. Direct personnel costs — Calculation

Basic remuneration costs, costs of personnel seconded by a third party against payment and personnel costs for providing trans-national access to research infrastructure

All types of personnel cost — except for costs for natural persons working under a direct contract, costs of SME owners not receiving a salary, and costs of beneficiaries that are natural persons not receiving a salary (see below) — must be calculated using the following formula set out in the GA:

{{**hourly rate**

multiplied by

[14] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[15] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate (see below).

On the basis of this formula, the beneficiary must — for each person for whom it declares costs — follow three steps:

Step 1 — Calculation of the hourly rate

Step 2 — Multiplying the hourly rate by the number of actual hours worked on the action

Step 3 — For non-profit legal entities: Addition of additional remuneration, if any

Example (for calculation of basic remuneration costs):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant

S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.

*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***

Addition of the additional remuneration: = ***2 000***

Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400* ***< 1 600****)*

Step 1 — Calculation of the hourly rate

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.

Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000

__a__ and __b__ would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.

*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

Example: When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs (see example below).

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception: **Employees hired** during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Example:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- the total number of hours worked by the person in the year for the beneficiary (**'individual annual productive hours**')

– the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices (**'standard annual productive hours'**).

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities.

Using only the so-called 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	**In all cases** Any beneficiary can use this option.	∅ **Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: o employment contract of the person concerned o applicable collective labour agreement o national law on working time *Example: contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group of personnel under similar conditions). ***Example (calculation of individual annual workable hours):***	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days. *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. ⚠ The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. ⚠ The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: o the employment contracts of the reference group o an applicable collective labour agreement or	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than

		○ the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* ⚠ If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. ⚠ If its number of standard annual productive hours is lower than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* ***Standard annual productive hours** for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:*	90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		*Annual working days = **228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = **212*** *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = **1 642*** ***1 696 hours** (usual cost accounting practice) **> 1 642 hours** (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

For personnel costs declared as a unit cost on the basis of the **beneficiary's usual cost accounting practices ('average personnel costs')**, the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

– the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

– the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

If necessary, it must be adjusted to fulfil all eligibility criteria.

Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

Costs that are already included in other budget categories must be taken out (double funding of the same costs).

Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

– are relevant, i.e. clearly related to personnel costs

– are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

– correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.

– the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the electronic exchange system) an audit certificate on their usual cost accounting practices (for information on this point see Article 18.1.2(b) and Annex 6). Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — Multiplying the hourly rate by the number of actual hours worked on the action

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — For non-profit legal entities: Addition of the additional remuneration, if any

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

***Example**:*

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (eligibility ceiling):

{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000

The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

Costs for natural persons working under a direct contract

The calculation of costs for natural persons working under a direct contract for a beneficiary (i.e. a contract which is not governed by labour law) depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount).

A calculation method is required, in particular if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same formula explained in point 1 above (i.e. hourly rate multiplied by the number of actual hours worked on the action).

⚠ Even if the formula is the same, the hourly rate is different, as it is not based on the annual personnel costs as registered on the payroll.

How? Beneficiaries must use one of the following options:

- if the contract specifies an hourly rate, then this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person, then this global amount must be divided by the number of hours worked for the beneficiary under that contract.

Costs of SME owners and beneficiaries that are natural persons not receiving a salary

Costs of an SME owner not receiving a salary and costs of a beneficiary that is a natural person not receiving a salary must be calculated by multiplying the amount per unit (EUR/hour worked on the action, the hourly rate) set out in Annex 2 by the number of actual hours worked on the action.

This amount per unit (hourly rate) is based on the calculation set out in Commission Decision C(2013) 8197[16]:

{Monthly living allowance for experienced researchers under the Individual Fellowship actions of the Marie Skłodowska-Curie actions / 143 hours}

multiplied by

{country-specific correction coefficient / 100}

The amount of the monthly living allowance for experienced researchers under the Individual Fellowship actions of the Marie Skłodowska-Curie to be used here is always the same: EUR 4,650.

This is a reference amount for all cases of SME owners and beneficiaries that are natural persons not receiving a salary.

It does not require that the SME owner or the natural person is an experienced researcher.

On the other hand, the country-specific correction coefficients will vary according to the country. They are published in the Marie Skłodowska-Curie Actions (MSCA) part of the Work Programme[17] (Table 4).

Example:

A German SME owner not receiving a salary will calculate the hourly rate as follows:
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

⚠ SME owners who receive a salary registered as such in the accounts of the SME cannot declare costs based on this unit cost.

[16] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[17] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

⚠ If the SME owner can show evidence that his/her salary corresponds exclusively to the management of the SME, s/he may declare his/her personnel costs for the action based on the unit cost set out in Annex 2. The salary for the management of the SME cannot be declared.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment (via the electronic exchange system), in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting — Types of costs — Conditions for eligibility — Calculation

Direct costs of subcontracting are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))
- they are incurred for the **subcontracting of action tasks** described in Annex 1 (see Article 13)
- the **additional cost eligibility rules** set out in Article 13.1.1 are fulfilled
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: the **additional cost eligibility rules** set out in Article 16.1 or 16.2 are fulfilled.

  This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities (see Article 16).

Direct costs of subcontracting must be declared as actual costs (i.e. on the basis of the prices actually paid) (see Article 5.2(b)).

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as direct costs of subcontracting.

> ***Example:*** *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

What? Subcontracting costs include (and are limited to) the price paid and the related taxes (for VAT see Article 6.5).

C. Direct costs of providing financial support to third parties *[(not included in Point F)] [OPTION to be used if Article 15 applies:* *are eligible if the conditions set out in Article 15 are met.]**[OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties — Types of costs — Conditions for eligibility — Calculation

Direct costs of providing financial support to third parties are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))
- the **additional cost eligibility rules** set out in Article 15.1.1 are fulfilled.

⚠ This budget category is optional and can be used only if the option applies.

Direct costs of providing financial support to third parties must be declared as actual costs (i.e. on the basis of the financial support actually paid) (see Article 5.2(c)).

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as direct costs of providing financial support to third parties.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.**]***

1. Travel costs and related subsistence allowances — Types of costs — Conditions for eligibility — Calculation

Travel cost and related subsistence allowances are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- they are in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.

  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

  If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

  If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

  ⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary).

  The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: the **additional cost eligibility rules** set out in Article 16.1 are fulfilled.

  This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities (see Article 16).

Travel and subsistence costs must be declared as actual costs (see Article 5.2(d)).

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

⚠ Travel and subsistence costs incurred for the selected users are not included in the unit cost for access costs for providing trans-national access to research infrastructure (see Article 6.2.D.1 and Article 16).

What? Travel costs and related subsistence allowances may also include all related duties, taxes and charges that the beneficiary has paid (such as non-deductible VAT see Article 6.5), if including them is part of the its usual practices for travel.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the

experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs — Types of costs — Conditions for eligibility — Calculation

Beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets

– or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

– costs of **renting or leasing** of equipment, infrastructure or other assets

– costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

Equipment costs must be declared as actual costs (see Article 5.2(d)).

⚠ No equipment costs may be declared for providing trans-national or virtual access to research infrastructure.

This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities (see Article 16).

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

Depreciation costs of equipment, infrastructure or other assets

Depreciation costs are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; see Article 6.1(a))
- they have been **purchased** in **accordance with Article 10.1.1**
- they are **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.

What? Equipment costs include the depreciation for the relevant periodic report. It is expected that the beneficiary allocates the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; see also 'cash-based accounting' below).

Depreciated equipment costs can never exceed the equipment's purchase price.

Depreciation cannot be spread over a period longer than the equipment's useful life

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs (see Article 6.2.E). Any depreciation charged as a direct cost under a

Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices (see concept of direct cost in Article 6.2.)

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

Specific cases:

Equipment not used exclusively for the action — if the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible (see cash-based accounting below).

Depreciation costs for **equipment** used for the action but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

{equipment's total useful life}.

'Useful life' means the time during which the equipment is useful to the beneficiary.

⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

Cost of purchasing equipment, infrastructure or other assets

Under this option, the full purchase costs of the assets are eligible (not only the depreciation costs).

This option will apply if it is specifically included in the work programme. Otherwise, the beneficiary cannot use this option and the general depreciation rule applies.

Costs of renting or leasing equipment

Costs of renting or leasing equipment are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))
- they do **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- they do **not** include any **financing fees**.

What? Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.

⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the

property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

Costs of equipment, infrastructure or other assets contributed in-kind against payment

Costs of equipment, infrastructure or other assets contributed in-kind against payment are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))
- they do **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- they do **not** include any **financing fees**
- the **additional cost eligibility rules** set out in Article 13.1.1 are fulfilled.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services — Types of costs — Conditions for eligibility — Calculation

Costs of other goods and services are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))

and

  - they are either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: the **additional cost eligibility rules** set out in Article 16.1 or 16.2 are fulfilled.

  This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities (see Article 16).

Costs of other goods and services must be declared as actual costs (see Article 5.2(d)).

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

What? The list of **types** of goods and services that may be declared under this article includes:

- consumables and supplies
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results *(e.g. fees paid to the patent office for patent registration)* and royalties on access rights
- certificates on financial statements (CFS) and certificates on methodology

  ⚠ If the grant agreement does not require a CFS (i.e. if the EU or Euratom contribution is less than EUR 325 000), CFS costs are not eligible, because they are not considered necessary.
- translation costs, if translation is necessary for the action's implementation, is justified, etc.

⚠ If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If considering all or some of these costs as indirect costs is part of the beneficiary's usual accounting practices, the costs cannot be charged to the action as direct costs, as they are covered by the 25 % flat rate.

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) **paid to a third party** (i.e. not a beneficiary) (see Article 24) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees **paid for access rights to background granted by other beneficiaries** (see Article 25) are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Examples:

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

⚠ Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[16] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December. 2013 establishing H2020 - The Framework Programme for Research and Innovation (2014-2020): **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure — Types of costs — Conditions for eligibility — Calculation[18]

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; see Article 6.1(a))
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)

[18] This part of the Annotated MGA was adopted by Commission Decision C(2013) 8699 of 10 December 2013 on guidelines on the application of Point D.4 of Article 6.2 of the General Model Grant Agreement for Horizon 2020 – the Framework Programme for Research and Innovation of the European Union (2014-2020) and the Research and Training Programme of the European Atomic Energy Community (2014-2018) (direct costing for large research infrastructure). Available at [hyperlink].

- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs (see Article 5.2(d)).

⚠ No capitalised and operating costs of large research infrastructure may be declared in certain calls under the Part 'Research Infrastructure'.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

What? Beneficiaries may declare **capitalised costs** and **operating costs** of research infrastructure used for the action.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) (see also below Section 2).

Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

[19] See also International Financial Reporting Standard No 16.
[20] See Article 126 of the Financial Regulation.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold (see below) and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)

- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)

- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);

- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs (see Point E of Article 6.2).

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary (see above).

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments)

- knowledge-based resources such as collections, archives or scientific data

- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

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[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] See Article 2(6) of the Horizon 2020 Framework Programme Regulation No 1291/2013.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways. The best practice recommended by the Commission is recording them using a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps:

Step 1 — Status validation (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field 'Declaration of costs under Point D.4: YES/NO' in Annex 2. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — Methodology compliance (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the Beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to amend previous financial statements already lodged by submitting a '**corrected financial statement**'.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. The auditors will:

(i) ensure that the methodology positively assessed is the one being used and

(ii) verify the accuracy of the calculations made applying the methodology.

ⓘ For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs (see Point E of Article 6.2).

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Point D.4 of Article 6.2.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

– internal management exchanges necessary for the approval of an underlying transaction

– purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

– for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

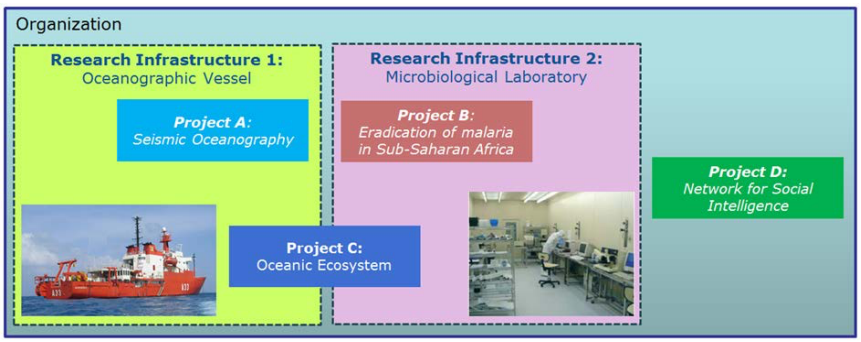

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice (see Article 6.5)[23].

Thus:

[23] See Article 129(1) of the Financial Regulation.

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again (e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)

  ⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

  ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

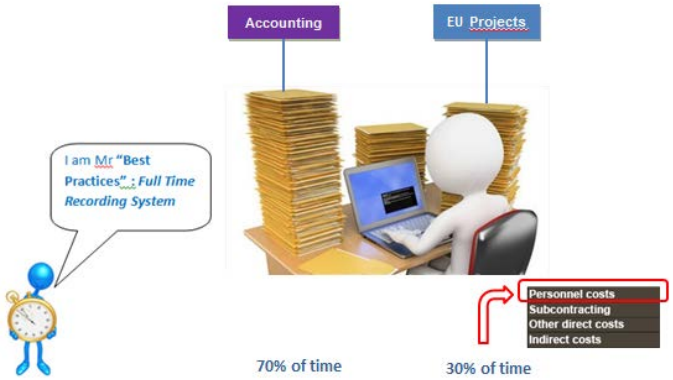

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (best practice: time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices for direct measurement:

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical

specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[25].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

[25] See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('Financial Regulation No 966/2012'): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs — Types of costs — Conditions for eligibility — Calculation

Indirect costs are **eligible**, if they are declared by applying a 25% flat rate to the beneficiary's eligible direct costs, minus:

- subcontracting costs (see Article 13)

  Example: *subcontracting of opinion surveys.*

  ⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 (see Article 10) is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties, if this option is included in the GA

- unit or lump-sum costs covering specific categories of costs which include indirect costs.

Indirect costs are covered and must be declared under the form of the flat-rate (see Article 5.2(e)).

What? Indirect costs are costs that are not directly linked to the action (see Article 6.2).

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),
- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]

1. Specific categories of costs — Types of costs — Conditions for eligibility — Calculation

Under this option, beneficiaries may currently declare the following **types of costs** as specific categories of costs:

- **costs of additional energy efficiency measures** (Decision C(2013) 8196[26])

  This option will be inserted in the GA only for actions involving additional energy efficiency measures.

- **access costs for providing trans-national access to research infrastructures** (Decision C(2013) 8199[27]).

  This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities (see Article 16).

⚠ If this option 5.2.(f) is used in a GA, the costs covered by this option may not be declared under any other budget category. They have to be excluded from the calculation of the other direct and indirect costs of the beneficiary (declared under the budget categories 5.2(a) to (e)).

Example:

A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

The situation of A is the following:

A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.

A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.

A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*67 500 = 25% (150 000 + 80 000)*	*300x800= 240 000*	*537 500*

Costs of additional energy efficiency measures

Costs of additional energy efficiency measures *must* be declared on the basis of unit costs.

These costs are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; see Article 6.1(b))
- they correspond to the amount per unit (EUR/m^2 of eligible conditioned gross floor area (excluding parts of the buildings which are not affected by the measures, *e.g. garages*)) set out in Annex 2 multiplied by the number of **actual m^2 of surface area built or refurbished**

  This amount per unit is based on the calculation set out in Commission Decision C(2013) 8196:

  {standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

  with:

  the 'standard cost to save 1 kWh' being EUR 0.1

  the 'standard payback period' to be used being 10 years

  Example (calculation):

  Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
  Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

⚠ Applicants for Horizon 2020 funding may submit a proposal requesting funding for a number of kWh saved per m² per year lower than the estimated one. But this will not be evaluated as an advantage against other proposals.

- they are incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*.

⚠ This category of unit costs will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

How? Beneficiaries submit **specifications per type of demonstration building in the project proposal** by completing the BEST table (Building Energy Specification Table)[28]. These specifications per type of demonstration building are set out in Annex 1.

In Smart Cities and Communities buildings, the grant is always composed of a combination of different forms of grants as defined in Articles 5 and 6 of the GA. The reimbursement on the basis of unit costs only applies for the building-related demonstration activities part of the building.

What? Two categories of eligible costs are covered:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and
- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs are not eligible.

Access costs for providing trans-national access to research infrastructure

Access costs for providing trans-national access to research infrastructure can be declared as one of the following:

- as actual costs
- on the basis of a unit cost or

[28] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

– on the basis of a combination of actual cost and unit cost, if a part of the eligible access costs (in particular, costs for the specific support to users) varies significantly between users.

Only one of the three forms may be used per installation (i.e. per part or service of a research infrastructure that could be used independently from the rest). A research infrastructure consists of one or more installations. No alternative use is allowed for one installation.

These costs are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; see Article 6.1(a) and (b))
- they are incurred for **providing trans-national access to research infrastructure** to scientific communities
- the **additional cost eligibility rules** set out in Article 16.1 are fulfilled
- for actual costs: they comply with the conditions set out above (see Article 6.2.A to 6.2.E)
- for unit costs: they correspond to the amount per unit (EUR/unit of access) set out in Annex 2 multiplied by the number of actual units of access provided

  This amount per unit is based on the calculation set out in Commission Decision C(2013) 8199:

  The unit cost is defined on the basis of the average over the last two years of the annual total access costs to the installation, for the categories covered by the unit cost, divided by the average over the last two years of the total quantity of access to the installation annually provided, as follows:

  $$\textbf{Unit cost} = \frac{\textbf{average annual total access costs to the installation}}{\textbf{average total quantity of access to the installation annually provided}}$$

  The average amounts must be based on certified or auditable historical data of the beneficiary over the last 2 years (years N-1 and N-2) for the concerned installation, according to the beneficiary's usual cost accounting practices. The average over the last two years of the access costs and quantity of access to the installation does not include periods where the installation was not usable because it was out of order or under repair or maintenance.

  The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

  The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

  – the direct costs incurred by the access provider for the provision of the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for the following categories of direct costs:

- personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users. By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices

- costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

- costs of consumables specifically used for the installation and the research work of the users

- costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

- costs of energy power and water supplied for the installation

- costs of general services when they are specifically included in the provided access services (library costs, shipping costs)

- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

- costs of specific scientific services included in the access provided or needed for the provision of access

– the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

and excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible (see also Article 6.2.D.2)

- travel and subsistence costs to support the visits of users.

  ⚠ Travel and subsistence costs incurred for the selected users can however be reimbursed separately, as 'other direct costs' (see Article 6.2.D.1 and Article 16).

⚠ A specific form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ In exceptional and duly justified cases, the Commission/Agency may agree to use a different reference period than the last 2 years.

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs= average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Applicants for Horizon 2020 funding must describe the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation;

- for a combination of actual and unit costs: the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs.

⚠ This category of costs will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015).*

What? The access costs for the provision of trans-national access to an installation are defined as the costs incurred by the access provider for the provision of access to an installation. Access costs cover the running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities that may be necessary to carry out user's work on the installation.

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs.

⚠ These costs can however be reimbursed separately, as 'other direct costs' (see Article 6.2.D.1 and Article 16).

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.**]***

[OPTION: *not applicable**]***

1. Costs of linked third parties — Types of costs — Conditions for eligibility — Calculation

The costs of linked third parties may be **eligible**, if:

- they **fulfil** the **general conditions** and **specific conditions** for costs to be eligible (see Article 6.1 and 6.2) and
- the **additional cost eligibility rules** set out in Article 14.1.1 are fulfilled.

2. Mutatis mutandis

'Mutatis mutandis' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge — Types of costs — Conditions for eligibility — Calculation

Contributions provided by third parties free of charge are **eligible** if:

- they **fulfil** the **general conditions** and **specific conditions** for costs to be eligible (see Article 6.1 and 6.2) and
- the **additional cost eligibility rules** set out in Article 12.1 are fulfilled.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

In general, ineligible costs are those costs that do not meet the general and specific eligibility criteria set out in Articles 6.1 to 6.4.

Examples:

Additional remuneration ('bonuses') paid by for-profit or non-profit entities that do not fulfil the conditions set out in Article 6.2,

Subcontracting costs that do not comply with the terms of Article 13.

What? Article 6.5 specifies certain types of ineligible costs, including:

Costs related to return on capital or return generated by an investment.

Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

Debt and debt service charges — debt service is the amount paid on a loan in principal and interest, over a period of time

Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

Provisions for future losses or debts — a provision is an amount set aside in an organisation's accounts to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

Interest owed — Interest on a loan to borrow capital

Excessive or reckless expenditure — excessive must be understood as paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary, resulting in an avoidable financial loss to the action. Reckless means failing to exercise care in the selection of products, services or personnel resulting in an avoidable financial loss to the action.

Currency exchange losses — for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)* is not eligible.

Bank costs charged by the beneficiary's bank for transfers from the Commission/Agency.

Deductible VAT — deductible VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is neither actually incurred by the beneficiary nor identifiable and verifiable.

Deductible VAT should be recorded in separate payable or receivable accounts, not affecting revenue or cost line items. VAT that is paid to suppliers and is deductible is a claim against the tax authority which will reimburse it, therefore it is recorded in the 'assets' part of the balance sheet. VAT collected on sales is a debt towards the tax authority and is recorded in the 'liabilities' part of the balance sheet. In other terms, where VAT is deductible, the accounts are presented exclusive of VAT.

This means that VAT paid on goods or services by a beneficiary that can recover it under national VAT legislation should not be recorded as expenditure in the profit and loss accounts (only the purchase price excluding VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

Conversely, if VAT is not deductible it is in principle an eligible cost. The full price of the goods or services bought by the beneficiary is recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought is then recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

⚠ In exceptional cases where the beneficiary cannot identify VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price should be recorded in the accounts, since non-identifiable VAT is not deductible. VAT would thus be eligible (in any case).

Costs incurred during the suspension of the implementation of the action

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

Costs declared under another EU or Euratom grant, to avoid double funding. This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

  Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The general obligation to properly implement the action is twofold, i.e. the obligation:

- to carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- to comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Example: Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the **beneficiaries retain** sole **responsibility** towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources

The beneficiaries must in principle have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services (see Article 10), use in-kind contributions provided by third parties (see Articles 11 and 12) or call upon subcontractors or linked third parties to carry out work under the action (see Articles 13 and 14) ('**third party resources**').

⚠ A third party is any legal entity that has not signed the GA (see Article 1).

The differences between subcontracts (Article 13) and other contracts for purchase of goods, works or services (Article 10) are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.

Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors (Article 13) and contractors (Article 10) on one side and linked third parties (Article 14) on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts (Article 10) and in-kind contributions against payment (Article 11) are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the

	profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

2. Beneficiaries retain responsibility

⚠ Beneficiaries using third parties or resources of third parties in an action remain responsible for the work attributed to them under the GA.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

*Chapter 3, **Articles** 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 **[OPTION:** with the exception of additional exploitation obligations], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 **do not apply** to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.**]***

[OPTION:** not applicable**]

9.2 Consequences of non-compliance

***[**If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION:** not applicable**]

1. Beneficiaries not receiving EU funding

This Article is an option that will be inserted in the GA only if one of the beneficiaries does not receive EU funding.

⚠ Even if they do not receive EU funding, these entities carry out work under the action, and therefore sign the GA and are recognised as beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

2. Articles that do not apply

The rights and obligations set out in the GA will normally apply to these beneficiaries, but the GA lists a number of provisions that don't. These exceptions must be interpreted restrictively.

Thus, these beneficiaries will, for instance, not be subject to **financial** checks, reviews and audits, but they may be subject to **technical** checks, reviews or audits of their work under the action (see Article 22).

In case of breach of any of their obligations, beneficiaries not receiving EU funding will generally be treated as all other beneficiaries, i.e. their participation may be terminated and any of the other measures of Chapter 6 may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

In addition, the American beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

⚠ The costs of the beneficiary not receiving EU funding itself cannot be rejected.

Given that no payment is due to the beneficiary, conversely it may not have either a debt towards the Commission or Agency.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Best value for money or lowest price

The purchase must be based on the best value for money, considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs of the contract concerned (see Article 6.2.D.3 and 6.6).

⚠ Beneficiaries have to demonstrate upon request that the selection of the contractor complied with these rules.

Specific cases:

May the beneficiary declare as eligible the costs of goods, works or services necessary for the action but purchased under framework contracts and contracts existing before the signature of the GA? Yes, if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Occasionally, and only for contracts with a value higher than EUR 60 000, the Commission may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the EU contribution).

⚠ These conditions must also be described in the call for proposals — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *Minimum number of offers received; publication in the OJ or in specific media such as internet, national newspapers, etc.*

3. Beneficiaries that are 'contracting authorities'

Beyond these minimal obligations, a beneficiary that is a 'contracting authority' within the meaning of the EU Directive 2004/18/EC or a 'contracting entity' as described in Directive 2004/17/EC must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law (see Article 1(9) of Directive 2004/18).

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies (see for the full definition Article 1(9) of that Directive).

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights (see for the full definition Article 2 of Directive 2004/17).

⚠ Non-compliance with this obligation is considered improper implementation of the GA (breach of an obligation other than compliance with cost eligiblity rules that are set out in Article 10.1.1). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive against payment.

⚠ A third party is any legal entity that has not signed the GA (see Article 1).

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

Example: *medical equipment provided by a hospital to a university in order to carry out research;*

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Beneficiaries may declare the costs related to the payment — Up to the third parties' costs

The payments made to the third party are costs of the beneficiary.

If the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, these costs may be declared by the beneficiary it in its financial statements.

The obligations in Article 11.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs concerned (see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6).

Beneficiaries may **not** declare as eligible **more than** the direct costs **actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The direct costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account if they are used in the premises of the beneficiary.

Example of in-kind contribution against payment used on the beneficiary's premises (the payments by the beneficiary correspond only to the direct costs of third party):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (the payments by the beneficiary correspond to the direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

3. Third parties and their contributions must be set out in Annex 1 — Approval without formal amendment

The third parties, their in-kind contributions (*i.e. non-financial resources*) and an estimation of the costs budgeted for the in-kind contributions must be mentioned in Annex 1 to the GA.

⚠ If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an amendment of the GA in order to introduce it in the Annex 1.

Exceptionally, the Commission/Agency may approve costs related to the payment of in-kind contributions not included in Annex 1 without formally amending the GA (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Audits of the third parties by the Commission/Agency, ECA and OLAF

The Commission/Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) must have the right to audit the underlying costs of the third parties.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party.

If the third party refuses access, the Commission/Agency cannot verify the eligibility of the costs related to the payment of in-kind contributions and will reject the costs concerned (no-compliance with the cost eligibility criterion set out in Article 6.2).

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (*i.e. without any payment, contrary to the case covered by Article 11*).

There is therefore no cost incurred by the beneficiary for the use of those resources.

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Beneficiaries may declare the costs incurred by the third parties

Since in this case the costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services are not paid by the beneficiary, there is no cost of the beneficiary, but only a cost of the third party.

If the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*, these costs may nevertheless be declared by the beneficiary receiving the in-kind contribution in its financial statements.

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs concerned (see Article 6.4 and 6.6).

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For in-kind contributions that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Third parties and their contributions must be set out in Annex 1 — Approval without formal amendment

The third parties, their in-kind contributions and an estimation of the costs budgeted for the in-kind contributions must be mentioned in Annex 1 to the GA.

⚠ If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an amendment of the GA in order to introduce it in the Annex 1.

ⓘ For more information on approvals without formal amendment, see Article 11.

4. Audits of the third parties by the Commission/Agency, ECA and OLAF

The Commission/Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) must have the right to audit the costs of third parties.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party.

If the third party refuses access, the Commission/Agency cannot verify the costs related to in-kind contributions free of charge and will reject the costs concerned (non-compliance with the cost eligibility criterion set out in Article 6.1 (v)).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

For the purposes of the GA, a 'subcontract' is a contract for the purchase of goods, works or services that are identified in Annex 1 as action tasks.

Subcontracting has the following characteristics:

- the subcontract signed with the beneficiary is based on 'business conditions'; this means that the subcontractor charges a price, which usually includes a profit

  This makes it different from the cases of linked third parties of Article 14 (see also Article 8).

- the subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants (see page 35).

- the subcontractor's motivation is pecuniary, it is not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- the responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  ⚠ The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA);

- a subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries, as it has no contractual relation with them.

  ⚠ However, the beneficiary must ensure that the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

⚠ Only **limited parts of the action** may be subcontracted.

Exception:

For **actions involving PCP or PPI,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI (see point 3 below).

⚠ Subcontracting between beneficiaries in the same GA is forbidden.

All beneficiaries by definition contribute to and are interested in the action, if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

⚠ Coordination tasks of the coordinator *(such as the distribution of funds, the review of reports and others tasks listed under Article 41.2 (b))* cannot be subcontracted (see Article 41.2(b))

Other activities of the coordinator may in principle be subcontracted.

⚠ In principle, beneficiaries cannot subcontract part of the work to its affiliates unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions.

Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Best value for money or lowest price

The subcontract must be based on the best value for money, considering the quality of the service proposed (also called '**best price-quality ratio'**) or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs of the subcontract concerned (see Article 6.2.B and 6.6).

Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Actions involving PCP or PPI

The additional conditions for actions involving PCP or PPI mirror the key obligations in the GA for PCP/PPI Cofund actions.

⚠ The latter GA contains more detailed obligations since these PCP/PPI Cofund actions consist mainly in subcontracting and undertake PCPs and PPIs as the main objective of an action.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 — Total estimated costs of subcontracting must be set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1.

In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

For **existing framework contracts or subcontracts**, the name of the subcontractor should however be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an amendment of the GA in order to introduce it in Annex 1 and 2.

Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (section 'unforeseen subcontractor'*)*.

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

5. Beneficiaries that are 'contracting authorities'

Beyond these minimal obligations, a beneficiary that is a 'contracting authority' within the meaning of the EU Directive 2004/18/EC or a 'contracting entity' as described in Directive 2004/17/EC must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law (see Article 1(9) of Directive 2004/18).
>
> ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies (see for the full definition Article 1(9) of that Directive).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights (see for the full definition Article 2 of Directive 2004/17).

⚠ Non-compliance with this obligation is considered improper implementation of the GA (breach of an obligation other than compliance with cost eligiblity rules that are set out in Article 13.1.1). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

The GA allows that linked third parties implement part of the action, even if they do not sign the GA. Those linked third parties are therefore not beneficiaries.

The characteristics of action implementation by linked third parties are as follows:

- the linked third party does not charge a price, but declares its own costs for implementing the action tasks
- the linked third party itself performs certain action tasks directly and is responsible for it vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability) (see Article 44.1).

- the work is attributed to the linked third party (in Annex 1) and it is usually carried out on its premises
- the work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and **not specifically created for the work in the GA**

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

- a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from "owner" entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[29]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, exceptions for legitimate reasons may be accepted.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

[29] See Articles 8 and 9 of the Rules for Participation.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Linked third parties must be identified in Article 14 — Tasks to be implemented must be set out in Annex 1 — Estimated costs must be set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment (see Article 55).

⚠ There is no procedure for approval without amendment.

3. Joint and several liability

This is an option, which the Commission/Agency can use if the financial capacity assessment for a beneficiary is 'weak' while the financial capacity of its linked third parties is strong or if the beneficiary mainly coordinates the work of its linked third parties.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (using Annex 3a) which will be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA) (see Article 56).

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

ⓘ For more information on the financial capacity check, see the Horizon 2020 Online Manual.

4. Linked third parties may declare the costs they incur

If the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*, these costs may be declared by the linked third party in its financial statements (see Article 20.3).

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

⚠ The obligations in Article 14.1.1 are considered to be cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs concerned (see Article 6.3 and 6.6).

Linked third parties have to demonstrate upon request that the costs comply with these rules.

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own financial statements, but these statements must be *submitted* by its beneficiary via the electronic exchange system (since linked third parties do not have access).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals (see Article 18.1.2 last option).

⚠ Each linked third party has to provide its own certificate on the financial statements (see Article 20.4).

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate (see Article 18.1.2 last option).

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 Obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep **information** stored **in the 'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events which are likely to affect significantly or delay the implementation of the action or the EU's financial interests**, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances affecting**:

(i) **the decision to award the grant** or

(ii) **compliance with requirements under the Agreement**.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data (see Article 39), in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information at any time, either during the action's implementation or **afterwards**.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

Beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

⚠ If the Commission/Agency, ECA or OLAF need further clarification or information, they may request it.

The beneficiary must provide accurate, precise and complete information, in the format and within the deadline requested (see Article 22).

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries (see Articles 20, 22, 23, 30, 41, 55).

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent via the electronic exchange system. Afterwards, it must be sent in writing by registered post with proof of delivery (see Article 52).

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the Beneficiary Register up-to-date, including after the end of the grant (see the preamble and Article 52).

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The electronic exchange system automatically informs the coordinator whenever the beneficiary updates its information.

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

⚠ Beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

Examples of situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests:

A beneficiary is under financial stress and chooses to liquidate.

A beneficiary is bought by another legal entity.

A beneficiary plans to move its laboratory from a Member State to a non-EU country.

⚠ For events linked to changes that also require an update of the Beneficiary Register (see above), the beneficiary must **update** the **Beneficiary Register** and **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with acknowledgement of receipt, etc.) and not* via the Commission's electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ Beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example of a situation that could have affected the decision to award the grant or compliance with requirements under the GA:

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p.1) ('Rules of Application Regulation No 1268/2012): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

Beneficiaries must keep appropriate and sufficient evidence to prove that properly implemented the action and declared costs.

Sufficiency relates to the quantity of evidence; appropriateness relates to its quality.

⚠ Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[30]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60.000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

⚠ If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ This requirement does not affect national laws on keeping documents.

[30] International Standard on Auditing ISA 500 'Audit Evidence'.

2. Original documents

Beneficiaries must **keep original documents**.

⚠ The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, beneficiaries must:

– keep detailed records and other supporting documents to prove the eligibility of the costs declared

– use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

⚠ The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as personnel costs must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

⚠ It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices (called **'average personnel costs'** under FP7), beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the beneficiary's actual personnel costs as recorded in its statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  ⚠ Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

⚠ It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

To get additional assurance, a beneficiary may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2 by approving a certificate on its methodology (CoMUC).

⚠ Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

Exception:

The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval.

The Commission/Agency will not approve the CoMUC if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary can show that they were declared according to the approved practices).

⚠ Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

⚠ Approval is for Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency. The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA (Article 6.2 Point A).

Where should the CoMUC be sent to? ⓘ For more information on the procedure, see the Horizon 2020 Online Manual.

7. Records for flat-rate costs

For flat-rate costs, beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

  Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

⚠ Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiary must:

- sign one **declaration** per reporting period to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  ⚠ This declaration must be dated and countersigned for acceptance by the person concerned. A template[hyperlink] is provided on the Participant Portal.

  ⚠ If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiary must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor. A template[hyperlink] is provided on the Participant Portal.

  Time records should include:

  – the title and number of the action, as specified in the GA

  – the beneficiary's full name, as specified in the GA

  – the full name, date and signature of the person working for the action

  – the number of hours per day declared for the action

  – the supervisor's full name and signature

  – a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned

  – a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditor will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

⚠ Alternative evidence will only be accepted if these three criteria are met.

Example of acceptable alternative evidence:

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned;

Criterion 2 is met – the project is identified as XYZ;

Criterion 3 is met – the time is quantified: two weeks.

Example of unacceptable alternative evidence:

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;

Criterion 2 is not met: the project name is not mentioned;

Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

⚠ Beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

It is the beneficiary that must keep the originals of the **financial statements** and the **certificates** on the financial statements of the linked third parties.

⚠ Beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

Beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

Beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

The deliverables are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For 'energy challenge' actions involving additional energy efficiency measures (see also Article 6.2.F and Decision C(2013) 8196), beneficiaries must deliver a 'handover certificate' with their periodic reports (see Article 20.3).This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

When? Deliverables must be submitted at the time specified in Annex 1.

How? The coordinator must submit them through the electronic exchange system (see Article 52), unless Annex 1 specifies another way.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[31] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a best effort obligation.

If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[31] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The access rights set out in Article 25 presuppose that the beneficiaries first identify and agree on what constitutes background for their action. They may do so in any manner *(e.g. positive list, negative list)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

The agreement on background may be a separate agreement (*e.g. if it concerns only certain beneficiaries*) or may be part of the consortium agreement (see Article 41).

Although not obligatory, it is advised to agree on background before the GA is signed, to ensure that beneficiaries have access rights to what is needed to implement the action or exploit its results.

⚠ Beneficiaries must inform the other beneficiaries — before signing the GA — if access to their background is subject to legal restrictions or limits (see Article 25).

2. Background

Beneficiaries may identify as background any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed.

'Intellectual property' should be understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[32].

Possible background extends to input held by other parts of the beneficiary's organisation.

[32] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*.

ⓘ For more information on the eligibility of the royalty fees paid for such licences, see Article 6.2.D.3.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the **right to sub-license**.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a **royalty-free** basis — to background **needed** to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background **needed** for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to **legal restrictions or limits**, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is **needed** to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013 [Horizon 2020]).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider* ***needed*** *to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access rights to background

The GA generally provides that the beneficiaries must provide access rights for background needed (see below).

Beneficiaries may grant additional or more favourable access rights to background, beyond the rights foreseen in the GA.

Examples

Additional or more favourable access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country) or to other input which is not results or background (e.g. information or rights generated or acquired in parallel to the action, informally defined as sideground).

Such additional provisions may be included in the consortium agreement or in a separate agreement, if, for example, they only concern certain beneficiaries.

⚠ Beneficiaries may foresee in the consortium agreement that access rights will be removed if a beneficiary defaults on its obligations (see Article 41.3).

The granting of access rights may be conditional on the acceptance of specific conditions *(e.g. appropriate confidentiality obligations)*.

In such cases, it is recommended, for legal certainty purposes, to specify these conditions in writing as well.

2. Requests for access

Access rights to background are not automatic. They must be requested in writing.

Beneficiaries may use their internal rules to specify how to make such written requests.

⚠ Access may be requested, under the same conditions, even from a beneficiary whose participation was terminated before the action's end.

Access to background for exploitation may be requested **up to one year** after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

Once requested, access rights may be exercised as long as they are needed for exploiting the results *(e.g. until the background patent expires)*.

3. When is the background 'needed'?

There is no definition of 'needed' in the GA. Beneficiaries must assess whether or not access rights are needed on a case-by-case basis, taking into account their action's specificities.

⚠ The background needed must already be taken into account when the beneficiaries identify and agree (in writing) on the background for the action.

To avoid conflicts, it is recommended that beneficiaries agree *(e.g. in the consortium agreement)* on a **common interpretation of what is needed** and

***Example (background needed for implementation)**: if without this background, tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without this background, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Beneficiaries may refuse access to background if they consider that such access is not needed.

In this case, the requesting beneficiary must better substantiate its request or withdraw it.

Disagreements must be solved through the agreed *(e.g. in the consortium agreement)* conflict resolution system.

⚠ The beneficiaries and the coordinator must inform (see Article 17.2.) if such conflicts are likely to affect compliance with requirements under the GA, in particular, the execution of the action.

4. Legal restrictions or limits

Beneficiaries must inform the other beneficiaries — before acceding to the GA — of any legal limitations for granting access to their background.

Restrictions or limits can be set out in law or contract.

***Example:** A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ If beneficiaries agree on additional background after they sign the GA, they must immediately inform the other beneficiaries of any related restrictions or limits.

⚠ When contracting on background with third parties after accession to the GA, the beneficiaries must ensure that that they comply with their obligations under the GA.

There is no general rule preventing beneficiaries to grant licenses, including quasi exclusive licenses, to their own background, as long as they can ensure compliance with their obligations under the GA(ie. Guarantee access). Bbeneficiaries are even free to grant exclusive licences, if they agree on a waiver of access rights.

5. Royalty-free — Fair and reasonable conditions

For **implementation,** beneficiaries must, in general, grant **royalty-free** access to their background.

Exception:

If agreed by the beneficiaries before the GA is signed, other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

For **exploitation,** beneficiaries must agree on what constitutes **fair and reasonable conditions**, preferably in writing.

⚠ New terminology in Horizon 2020: fair and reasonable conditions include also royalty-free conditions.

Access may be royalty-free or it may include financial (i.e. monetary compensation) or non-financial terms.

Examples:

Monetary compensation could take the form of a lump sum, a royalty percentage, or a combination of both.

Non-financial terms could include a requirement for the beneficiary requesting access:

(a) to grant access to other technology in its possession, or

(b) to agree on cooperation in a different field or in a future project.

ⓘ For more information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3.

6. Sublicensing of access rights to background

Access rights do not give the right to sub-licence; sub-licensing is only allowed with the consent of the beneficiary that gives access.

Example:

The beneficiary owning the background agrees that another beneficiary may sublicense its access rights to background to its affiliated entity.

⚠ If sublicensing was freely allowed, this would imply that access rights to the background could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors.

There may be cases where sublicensing of access rights is necessary. In this case, sub-licensing should not be unduly refused.

Example:

A university may need the right to sub-license access to background to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

The terms and conditions of such sub-licensing must be agreed, preferably in writing.

The terms and conditions of sub-licensing may be a separate agreement (*e.g. if it concerns only certain beneficiaries*) or may be part of the consortium agreement (see Article 41).

Sub-licensing does not have to be royalty-free (even if the access rights concerned are).

Specific conditions can be established regarding sub-licensing.

Examples: *Sub-licensing could apply to the background (or part of it), but not to the results; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

7. Waiver of access rights to background

Waivers of access rights to background should be made only on a case-by-case basis, once the background has been correctly identified.

Only written waivers are valid.

The waiver should not be broader than what is actually necessary.

Example:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the background concerned is not exploited by the licensee within a certain period.

8. Access rights for third parties

This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities (see Article 16).

It ensures that the selected users have royalty-free access to the background they need for using the research infrastructure.

The access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid **a conflict of interests**

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflict of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A conflict of interests exists if shared interests:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

⚠ If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, see Article 52), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, '**formal notifications**', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all **communication** must be made **through the electronic exchange system** and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a '**Legal Entity Appointed Representative (LEAR)'**. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the **electronic exchange system**).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Formal notifications

The beneficiaries must make a formal notification if this is required by the GA (i.e. if the GA refers to 'formal notifications' or 'formally notify').

Formal notification via the electronic exchange system must be made using the 'formal notifications box' in the 'My Area' section of the Participant Portal).

2. Communicating via the electronic exchange system

All communication between the consortium and the Commission/Agency must be in electronic form via the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

In principle, all communications from/to the Commission/Agency must go **through the coordinator**, unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations)*.

⚠ Only people who have access to the electronic exchange system (have a user account) and are authorised to use the system may directly communicate with the Commission/Agency.

Access requires a European Commission Authentication System (ECAS) account.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only people who have been assigned one of these roles may directly communicate with the Commission/Agency.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ For more information on access and roles in the electronic exchange system, see the Horizon 2020 Online Manual.

⚠ Only formal notifications made after the balance is paid may be sent on paper, by registered letter with acknowledgement of receipt.

All other communication made after the balance is paid must be done via the electronic exchange system.

3. Date and time of messages sent through the electronic exchange system

The electronic exchange system keeps logs of all communication.

The date, time and content of each message is visible to all parties in the 'Grant File' section (the 'My Area' section of the Participant Portal).

Formal notifications are also recorded, but are only visible in the 'formal notifications box' (see above). Information on when they are sent and received (i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp) is included.

⚠ Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent.

A delay in reacting (if set within the formal notification) is counted as of day eleven.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must **accede to the Agreement** by signing the **Accession Form** (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Acceding to the GA

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form (see Annex 3) in the electronic exchange system. They must do this within 30 days after the GA enters into force (see Article 58).

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

⚠ Unlike under FP7, the coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries.

All documents are available in the electronic exchange system (in the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** (see Article 14), the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two parties signs it:

- the coordinator;
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

In addition to this 2002 report, AOIR has also produced a 2012 report to assist researchers in making decisions about internet research. Available at: http://www.aoir.org/reports/ethics2.pdf

Approved by the AoIR membership - 11/27/02

Ethical decision-making and Internet research

Recommendations from the aoir ethics working committee[1]

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PLEASE NOTE: we intend for this document to be publicly accessible, precisely so that it may contribute to reflection, debate, and education regarding Internet research ethics. At the same time, it is copyrighted and thus entails the usual requirements for "fair use" of copyrighted materials.

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Authors: Charles Ess and the AoIR ethics working committee
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The ethics committee would also appreciate notification of the use of this document. Please write to: Steve Jones <sjones@uic.edu> and/or Charles Ess <cmess@drury.edu>.

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I. Audience, Purpose, Rationale and Approach

Audience

This document is addressed to

Researchers, ethicists, and *students* in the social sciences and humanities, within the academic world and/or private and/or public research institutes, who study human inter/actions[2] in the various venues made possible by the Internet;

Organizations that commission, fund, or have oversight responsibility for Internet research (e.g., Institutional Review Boards in the United States; external Learning and Teaching Support Networks' subject centres and internal Academic Standards and Policy committees in the United Kingdom; in Australia,[3] the National Health and Medical Research Council and the Australian Research Council [see <http://www.nhmrc.gov.au/issues/researchethics.htm>], etc.

Academic societies and/or groups within the social sciences and humanities that promote and/or incorporate research concerning the Internet (e.g., the Japan Society for Socio-Information Studies (JSIS), <http://wwwsoc.nii.ac.jp/jsis/>, affiliated with the National Institute of Informatics, <http://www.nii.ac.jp/index.html>; the Information Ethics Group, Oxford Computing Laboratory <http://web.comlab.ox.ac.uk/oucl/research/areas/ieg/>; and the International Center for Information Ethics (Center for Art and Media, Karlsruhe, Germany) <http://icie.zkm.de/>, etc.).

Purpose

This document represents a series of recommendations designed to support and inform those responsible for making decisions about the ethics of Internet research.

It provides a resource for *researchers, ethicists,* and *students* by bringing together current discussion of important ethical issues and pertinent literature in the field.

It can provide support for *organisations* and related groups that commission, fund or have overall responsibility for or an interest in Internet research practices in an international context and can be used to help inform any such bodies of the ethical issues that might be considered and possible ways of resolving ethical problems.

[The committee - whose members represent eleven national cultures - is acutely aware that English, while currently the *lingua franca* of the Web, is but one of many languages in which important research and reflection takes place. As noted below, a central goal of this document is to present Internet research ethics that are intentionally pluralistic, first of all in order to preserve and foster the often diverse ethical insights of the world's cultures. While the committee has attempted to develop a comprehensive overview of issues and resources in Internet research ethics - we would welcome suggestions for additions, especially from national cultures and in languages not well represented in the current document.]

Rationale

The Internet has opened up a wide range of new ways to examine human inter/actions in new contexts, and from a variety of disciplinary and interdisciplinary approaches. As in its offline counterpart, online research also raises critical issues of risk and safety to the human subject. Hence, online researchers may encounter conflicts between the requirements of research and its possible benefits, on the one hand, and human subjects' rights to and *expectations* of autonomy, privacy, informed consent, etc.

The many disciplines already long engaged in human subjects research (sociology, anthropology, psychology, medicine, communication studies, etc.[4]) have established ethics statements intended to guide researchers and those charged with ensuring that research on human subjects follows both legal requirements and ethical practices. *Researchers and those charged with research oversight are encouraged in the first instance to turn to the discipline-specific principles and practices of research* (many of which are listed below - see **IV. Resources**, pp. 11-17).

But as online research takes place in a range of new venues (email, chatrooms, webpages, various forms of "instant messaging," MUDs and MOOs, USENET newsgroups, audio/video exchanges, etc.) – researchers, research subjects, and those charged with research oversight will often encounter ethical questions and dilemmas that are not directly addressed in extant statements and guidelines. In addition, both the great variety of human inter/actions observable online and the clear need to study these inter/actions in *interdisciplinary* ways have thus engaged researchers and scholars in disciplines beyond those traditionally involved in human subjects research: for example, researching the multiple uses of texts and graphics images in diverse Internet venues often benefits from approaches drawn from art history, literary studies, etc. This interdisciplinary approach to research leads, however, to a central ethical difficulty: the primary assumptions and guiding metaphors and analogies - and thus the resulting ethical codes - can vary sharply from discipline to discipline, especially as we shift from the social sciences (which tend to rely on medical models and law for human subjects' protections) to the humanities (which stress the agency and publicity of persons as artists and authors).

This array of ethical issues and possible (and sometimes conflicting) approaches to ethical decision-making are daunting, if not overwhelming. Nonetheless, as we have worked through a wide range of issues, case studies, and pertinent literature, we are convinced that it is possible - up to a point, at least - to clarify and resolve at least many of the more common ethical difficulties.

This document - as it synthesizes the results of our nearly two years' of work together - is intended to aid both researchers from a variety of disciplines and those responsible for insuring that this research adhere to legal and ethical requirements in their work of clarifying and resolving ethical issues encounter in online research.

Approach

This document stresses:

Ethical pluralism

Ethical concerns arise not only when we encounter apparent conflicts in values and interests – but also when we recognize that there is more than one ethical decision-making framework used to analyze and resolve those conflicts. In philosophical ethics, these frameworks are commonly classified in terms of deontology, consequentialism, virtue ethics, feminist ethics, and several others.[5]

Researchers and their institutions, both within a given national tradition and across borders and cultures, take up these diverse frameworks in grappling with ethical conflicts. Our first goal in this document is to emphasize and represent this diversity of frameworks – <u>not</u> in order to pit one against another, but to help researchers and those charged with research oversight to understand how these frameworks operate in specific situations. On occasion, in fact, ethical conflicts can be resolved by recognizing that apparently opposing values represent different ethical frameworks. By shifting the debate from the conflict between specific values to a contrast between ethical frameworks, researchers and their colleagues may understand the conflict in new light, and discern additional issues and considerations that help resolve the specific conflict.[6]

Cross-cultural awareness

Different nations and cultures enjoy diverse legal protections and traditions of ethical decision-making. Especially as Internet research may entail a literally global scope, efforts to respond to ethical concerns and resolve ethical conflicts must take into account diverse national and cultural frameworks.[7]

Guidelines – not "recipes"

As noted in our Preliminary Report (October, 2001), given the range of possible ethical decision-making procedures (utilitarianism, deontology, feminist ethics, etc.), the multiple interpretations and applications of these procedures to specific cases, and their refraction through culturally-diverse emphases and values across the globe – the issues raised by

Internet research are *ethical* problems precisely because they evoke more than one ethically defensible response to a specific dilemma or problem. *Ambiguity, uncertainty, and disagreement are inevitable*.

In this light, it is a mistake to view our recommendations as providing general principles that can be applied without difficulty or ambiguity to a specific ethical problem so as to algorithmically deduce the correct answer.

At the same time, recognizing the possibility of a range of defensible ethical responses to a given dilemma does not commit us to ethical relativism ("anything goes").[8] On the contrary, the general values and guidelines endorsed here articulate parameters that entail significant restrictions on what may – and what may not – be defended as ethical behavior. In philosophical terms, then, like most philosophers and ethicists, we endorse here a middle-ground between ethical relativism and an ethical dogmatism (a single set of ostensibly absolute and unquestionable values, applied through a single procedure, issuing in "the" only right answer - with all differing responses condemned as immoral).

To make this point a last way: since Aristotle (in the West), ethicists have recognized that doing the right thing, for the right reason, in the right way, at the right time remains a matter of judgment or *phronesis*.[9] Again, such judgment cannot be reduced to a simple deduction from general rules to particular claims. Rather, it is part of the function of judgment to determine just what general rules indeed apply to a particular context. Developing and fostering such judgment, as Aristotle stressed, requires both guidance from those more experienced than ourselves and our own cumulative experience in seeking to reflect carefully on ethical matters and to discern what the right thing at the right time for the right reason and in the right way may be (cf. Dreyfus, 2001).

Our hope is that the materials collected here will serve Internet researchers and those who collaborate with them in attempting to resolve the ethical issues that emerge in their work - first of all, that these materials will foster precisely their own sense of *phronesis* or judgment.

II. Questions to ask when undertaking Internet research

(For additional examples of such question lists, see **V. Addendum 1**, pp. 18f.)

A. Venue/environment - expectations -authors/subjects - informed consent

Where does the inter/action, communication, etc. under study take place?

Current venues include:

- Homepages
  - Weblogs
  - Google searches
- Email (personal e-mail exchanges)
- Listservs (exchanges and archives)
- USENET newsgroups
- ICQ/IM (text-based)
- CUSeeMe (and other audio-video exchanges)
- Chatrooms, including IRC
- MUDs/MOOs
- gaming
- images and other forms of multi-media presentation (webcams, etc.)
  - (some forms of) Computer-Supported Cooperative Work systems

What ethical expectations are established by the venue?

For example:

Is there is a posted site policy that establishes specific expectations – e.g., a statement notifying users that the site is public, the possible technical limits to privacy in specific areas or domains, etc.

Example: Sally Hambridge (Intel Corporation, 1998) has developed an extensive set of "Netiquette Guidelines" that includes the following advice:

> Unless you are using an encryption device (hardware or software), you should assume that mail on the Internet is not secure. Never put in a mail message anything you would not put on a postcard.
> (see <http://www.pcplayer.dk/Netikette_reference.doc>)

Is there a statement affiliated with the venue (chatroom, listserv, MOO or MUD, etc.) indicating whether discussion, postings, etc., are ephemeral, logged for a specific time, and/or archived in a private and/or publicly-accessible location such as a website, etc.?

Are there mechanisms that users may choose to employ to indicate that their exchanges should be regarded as private – e.g., "moving" to a private chatroom, using specific encryption software, etc.? – to indicate their desire to have their exchanges kept private?

One broad consideration: *the greater the acknowledged publicity of the venue, the less obligation there may be to protect individual privacy, confidentiality, right to informed consent, etc.*

Who are the subjects posters / authors / creators of the material and/or inter/actions under study?

While all persons have rights and researchers the obligation to protect those rights, the obligation - and attendant difficulties - of researchers to protect their subjects is heightened if the subjects are (a) children and/or (b) minors (between the age of 12 and 18). In the United States, for example, children can<u>not</u> give informed consent, according to the Code of Federal Regulations (<http://ohsr.od.nih.gov/mpa/45cfr46.php3>: cf. Walther, 2002).

Minors also represent special difficulties, as they inhabit something of a middle ground - legally and ethically - between children and adults. For example, are web pages created by minors - but often without much understanding of the possible *harms* some kinds of posted information might bring either to the author and/or others - to be treated as the same sort of document as authored by adults, who (presumably) are better informed about and sensitive to the dangers of posting personal information on the Web? Or are researchers rather required to exercise <u>greater</u> care in protecting the identity of minors - perhaps even to inform them when their materials may pose risks to themselves and/or others (see Ridderström, 2002).

A broad consideration: *the greater the vulnerability of the author / subject - the greater the obligation of the researcher to protect the author / subject.*

[See the sample consent forms for parent(s), children (aged 13-17), and children (aged 9-12) from Leslie Regan Shade, **VII. Addendum 3**, pp. 21ff.]

Informed consent: specific considerations

Timing

Ideally, protecting human subjects' rights to privacy, confidentiality, autonomy, and informed consent means approaching subjects at the very beginning of research to ask for consent, etc.

In some contexts, however, the goals of a research project may shift over time as emerging patterns suggest new questions, etc. *Determining not only if, but when to ask for informed consent is thus somewhat context-dependent and requires particular attention to the "fine-grained" details of the research project not only in its inception but also as it may change over its course.*

Medium?

Researchers should determine what medium – e-mail? postal letter? –for both requesting and receiving informed consent best protects both the subject(s) and their project. (As is well known, compared with electronic records, paper records are less subject to erasure and corruption through power drops, operator error, etc.)

Addressees?

In studying groups with a high turnover rate, is obtaining permission from the moderator/facilitator/list owner, etc., sufficient?

How material is to be used?

Will the material be referred to by direct quotation or paraphrased?
Will the material be attributed to a specified person? Referred to by his/her real name? Pseudonym? "Double-pseudonym" (i.e, a pseudonym for a frequently used pseudonym)?
(Obviously, the more published research protects the confidentiality of persons involved as subjects, the less risk such publication entails for those persons.
Such protections do not necessarily lessen the need for informed consent. Rather, researchers seeking informed consent need to make clear to their subjects how material about them and/or from them will be used - i.e., the specific uses of material and how their identities will be protected are part of what subjects are informed about and asked to consent to.)

B. Initial ethical and legal considerations

How far do extant legal requirements and ethical guidelines in your discipline "cover" the research? (For the guidelines as published by a number of disciplines, see Resources, below. See as well the discussion of the ethical and legal contrasts between the United States and Europe, "**VI. Addendum 2**," pp. 20f.)

How far do extant legal requirements and ethical guidelines in the countries implicated in the research apply?

For example: all persons who are citizens of the European Union enjoy strong privacy rights by law as established in the European Union Data Protection Directive (1995), according to which data-subjects must:

* Unambiguously give consent for personal information to be gathered online;
* Be given notice as to why data is being collected about them;
* Be able to correct erroneous data;

* Be able to opt-out of data collection; and
* Be protected from having their data transferred to countries with less stringent privacy protections.
(see <http://www.privacy.org/pi>

U.S. citizens, by contrast, enjoy somewhat less stringent privacy protections (see "**VI. Addendum 2,"** pp. 20f.).

Obviously, research cannot violate the legal requirements for privacy protection enforced in the countries under whose jurisdiction the research and subjects find themselves.

What are the initial ethical expectations/assumptions of the authors/subjects being studied?

For example: *Do participants in this environment assume/believe that their communication is private?*[10] If so – and if this assumption is warranted – then there may be a greater obligation on the part of the researcher to protect individual privacy in the ways outlined in human subjects research (i.e., protection of confidentiality, exercise of informed consent, assurance of anonymity - or at least pseudonymity - in any publication of the research, etc.).

If not – e.g., if the research focuses on

publicly accessible archives;

inter/actions intended by their authors/agents as public, performative (e.g., intended as a public act or performance that invites recognition for accomplishment), etc.;

venues assigned the equivalent of a "public notice" that participants and their communications may be monitored for research purposes;

….

then there may be less obligation to protect individual privacy.[11]

Alternatively: *Are participants in this environment best understood as "subjects" (in the senses common in human subjects research in medicine and the social sciences) – or as authors whose texts/artifacts are intended as public?*

If participants are best understood as subjects in the first sense (e.g., as they participate in small chatrooms, MUDs or MOOs intended to provide reasonably secure domains for private exchanges), then greater obligations to protect autonomy, privacy, confidentiality, etc., are likely to follow.

If, by contrast, subjects may be understood as authors intending for their work to be public (e.g., e-mail postings to large listserves and USENET groups; public webpages such as homepages, Web logs, etc.; chat exchanges in publicly accessible chatrooms, etc.) – then fewer obligations to protect autonomy, privacy, confidentiality, etc., will likely follow.[12]

[The following three questions are interrelated: as will be seen, they reflect both prevailing approaches to ethical decision-making – e.g., in Deborah Johnson (2001) – as well as cultural/national differences in law and ethical traditions.]

What <u>ethically</u> significant risks does the research entail for the subject(s)?

Examples (*form/content* distinction):

If the *content* of a subject's communication were to become known beyond the confines of the venue being studied – would harm likely result?

For example: if a person is discussing intimate topics – psychological/medical/spiritual issues, sexual experience/fantasy/orientation, etc. – would the publication of this material result in shame, threats to material well-being (denial of insurance, job loss, physical harassment, etc.), etc.?

A primary ethical obligation is to *do no harm*. Good research design, of course, seeks to minimize risk of harm to the subjects involved.

By contrast, if the *form* of communication is under study - for instance the linguistic *form* of requests ("Open the door" vs. I'd appreciate it if you'd open the door," etc.), not *what* is being requested - this shift of focus away from *content* may reduce the risk to the subject.

In either case (i.e., whether it is the *form* or *content* that is most important for the researcher), if the content is relatively trivial, doesn't address sensitive topics, etc., then clearly the risk to the subject is low.

What benefits might be gained from the research?

This question is obviously crucial when research in fact may entail significant risk to the author(s)/agent(s) considered as *subjects*.

From a utilitarian standpoint, research can only be justified - especially if it risks harm to individuals - if the likely benefits arguably outweigh the real and possible costs (including potential harm).

From a deontological standpoint, even if significant benefits may be reasonably expected from the research - such research may remain ethically unjustified if it violates basic principles, rights, duties, etc., e.g., rights to autonomy, privacy, and so forth (cf. the "ethical protocols," **V. Addendum 1**, pp. 18f.; Elgesem, 2002).

What are the ethical traditions of researchers and subjects' culture and country?

This question is crucial precisely when facing the conflict between possible risks to subjects, including the violation of basic human rights to self-determination, privacy, informed consent, etc., and the benefits of research.

In the United States, for example, there may be a greater reliance on *utilitarian* approaches to deciding such conflicts – specifically in the form of "risk/benefit" analyses - as compared with other countries and cultures. Crudely, if the benefits promise to be large, and the risks/costs small, then the utilitarian calculus may find that the benefits outweigh the risks and costs.

By contrast (and as is illustrated in the differences in laws on privacy), at least on an ideal level, European approaches tend to emphasize more *deontological* approaches – i.e., approaches that take basic human rights (self-determination, privacy, informed consent, etc.) as so foundational that virtually no set of possible benefits that might be gained from violating these ethically justifies that violation.[13]

When considering conflicts between subjects' rights and benefits to be gained from research that compromises those rights – researchers and those charged with research oversight may well arrive at different decisions as to what is ethically acceptable and unacceptable, depending on which of these cultural/ethical approaches they utilize.

(See "**VI. Addendum 2,**" pp. 20f.)

We hope this list is useful as a first effort to suggest a characteristic range of questions that Internet researchers and those responsible for oversight of such research should consider - and that it is further useful as it suggests an initial range of ethically defensible ways to respond in to such questions.

But of course, this list is neither complete nor final. Invariably, as Internet researchers encounter new venues, contexts, inter/actions, etc., additional questions and responses will inevitably arise (either as variations of these and/or as distinctively new). Perhaps this list will remain useful in those new contexts as it at least suggests starting points and possible analogies for raising new questions and developing new responses.

In any case, we hope this document will prove helpful, at least for a while, to researchers, ethicists, and others concerned with the important ethical challenges of Internet research.

III. Case Studies

A. Are chatrooms public spaces? When should researchers obtain consent for recording conversations in a chatroom?

[*From:* Hudson, James M. and Amy Bruckman. "IRC Français: The Creation of an Internet-Based SLA Community." Computer Assisted Language Learning (CALL), forthcoming 2002. Quoted by permission from the authors and CALL.]

In our first version of IRC Français, an ethical dilemma immediately emerged. Our plan was for students to converse with native French speakers already on IRC. Clearly, the rules governing human subjects research dictate that we need freely given informed consent from our students before we can ethically use them as experimental subjects ("The Nuremberg Code," 1949). But what about their conversational partners? Were they research subjects or not? We were not studying them in particular, but were recording their conversations with our students and analyzing their words. Did we need their consent?

The status of real-time chatrooms is ambiguous. On the one hand, one can argue that they are like a public square. It is considered ethical to record activities in a public place without consent, provided that individuals are not identifiable (Eysenbach & Till, 2001). In this view, we would be justified to simply record conversations and not tell anyone that this was taking place. On the other hand, one can argue that chatroom conversations are normally ephemeral. Participants have a reasonable expectation that they are not being recorded without their freely given informed consent. Under this stricter interpretation, we would need consent from any person whom we wish to record. Additionally, if the process of requesting that consent proved too intrusive, we would need to abandon the research (Department of Health, 1979).

With the approval of the Institutional Review Board (IRB) for human subjects research, we settled on a compromise approach: we would get written consent from our students, but merely notify other people on the channel of our study. These individuals would also be given the option to opt out if they so chose. Because we wrote our own client software, we could automatically send a public message to this effect when one of our students joined the channel, and then privately inform others who join the channel subsequently.

To our surprise, this compromise failed. IRC participants were angered at the idea of being studied without their prior consent. Our students were greeted with hostility. They were routinely harassed by IRC channel members, and often had threats and obscenities directed at them. This seems to indicate that an opt in solution might be more acceptable than an opt out. However, there was a further problem: our messages notifying channel participants of the study and offering the opportunity to opt out were found in themselves to be unacceptably intrusive. Even though each person saw the message only once, it was still deemed unacceptable by many members. An opt in message would have that same problem.

Based on the reaction our study generated, we concluded that the "public square" model is untenable and, in fact, the second interpretation holds: you may not ethically record an otherwise ephemeral medium without consent from participants. How then could we continue our research? We came upon a solution: create our own IRC channel explicitly for this project. We could direct our students to that channel, and others would not normally join. Since it was our channel, we could create a channel logon message informing people about the study and its purpose. We could also limit access to the channel to our students only; however, to date we have not found this necessary. Few people come to the channel outside of students assigned to use it, and those few are warned by the channel logon message. Now, we do not intrude on a pre-existing space, but instead have our own.

In addition to solving our ethical dilemma, the new channel also provided pedagogical benefits. While people come to general IRC channels for a variety of social purposes, everyone on the IRC Français channel is there for the purpose of practicing French. This shared goal greatly improved the educational value of the conversation for all concerned.

B. Brenda Danet, "Studies of Cyberpl@y: Ethical and Methodological Aspects," available from <http://atar.mscc.huji.ac.il/~msdanet/papers/ethics2.pdf>.
Prof. Danet reviews five studies presented more fully in her recent book, and discusses the ethical issues these studies raise in the contexts of

(1) two-person email
(2) typed chat in performance situations; and
(3) communication via visual images on IRC.

Out of this experience and reflection, Prof. Danet develops a list of guidelines (included as Appendix III in the "aoir ethics working committee – a preliminary report" - <aoir.org/reports/ethics.html>.
Prof. Danet's paper is to be recommended as a primary example of a more utilitarian approach to Internet research ethics, in contrast with the more deontological approach represented by James Hudson and Amy Bruckman in case study A, above.

IV. References, Resources

References / annotated bibliography

Allen, Christina. 1996. What's Wrong with the "Golden Rule"? Conundrums of Conducting Ethical Research in Cyberspace. *The Information Society* 12 (2), 175-187.
Allen describes a method of "dialogical ethics" (my terms) that works from the bottom up (following the approach of Mikhail Bakhtin) rather than beginning with general principles and moving "top down." Her approach - illustrated with an example of her own research on LambdaMOO - further draws from anthropology and cultural studies as these "acknowledge and seek to understand the ramifications of the positionality of the researcher for the phenomena and individuals under study," and thereby challenges the more prevailing approaches in medicine and social science as these instead emphasize the researcher adopting the posture of dispassionate observer (186). In contrast with the usual emphasis on protecting subjects from potential harm - Allen finds that when the research process is undertaken "as a respectful dialogism between two equal interlocutors," participants enjoy "positive gains from the process of interviewing and reflecting on their cyberspace stories" (186).
In these ways, in fact, Allen's approach recalls Aristotle's emphasis on *praxis* as reshaping our ethical considerations - with the goal of achieving *phronesis* (practical wisdom or judgment): while skeptical of the possibility of abstractly codifying research ethics (because of the sorts of differences between research venues noted in this report), Allen concludes that "Researchers can, however, develop ethical wisdom that comes from experience with many configurations of research in cyberspace, and report on the conditions that grounded their ethical choices, and the results that emerged from their work in the site" (186).
On this view, ethical considerations are not separate from research considerations, but rather an integral component, one interwoven as an explicit and intentional dimension of the research project itself.

American Psychological Association. 1992. Ethical Principles of Psychologists and Codes of Conduct (currently under revision). <http://www.apa.org/ethics/code.html>

Association for Computing Machinery. 1992 (October 16). ACM Code of Ethics and Professional Conduct. <http://www.acm.org/constitution/code.html>

aoir ethics working committee website: <http://www.cddc.vt.edu/aoir/ethics/>.

aoir ethics working committee – a preliminary report. 2001. <aoir.org/reports/ethics.html>

Baird, Robert M., Reagan Ramsower, and Stuart E. Rosenbaum (eds.). 2000. *Cyberethics: Social and Moral Issues in the Computer Age*. Amherst, NY: Prometheus Books.
A superb anthology – the best I've seen for both philosophically rich and fine-grained, practically-oriented analyses of specific issues (anonymity, privacy, property, and community/citizenship/democracy).
Two articles are of seminal importance for those interested in Internet research ethics:

Kling, Rob, Ya-ching lee, Al Teich, and Mark S. Frankel, "Anonymous Communication Policies for the Internet: Results and Recommendations of the AAAS Conference," and "Assessing Anonymous Communication on the Internet: Policy Deliberations," both of which originally appeared in *Information Society* 15 (1999): 71-77, 79-90.

In the first, Kling et al describe their ethical foundations in the Universal Declaration of Human Rights (UDHR), adopted by the General Assembly of the United Nations in 1948 – specifically, articles 12 and 19. They interpret these articles to mean that

> recipients have the right to choose to accept or refuse anonymous messages and that individuals do not have the right to impose messages upon an unwilling recipient. At the same time, law enforcement agencies and commercial interests do not have the right to interfere with individual privacy in electronic communication, regardless of whether it is anonymous or not. (100)

They further argue that the First Amendment of the U.S. Constitution, guaranteeing the right of free speech to all Americans, "…applies equally to communications in which the initiator is identified and to those that are sent anonymously." (ibid) At the same time, they further recognize that while the right to send communications anonymously ought to be considered a "strong right," is not absolute. Any proposed limitations should be no more restrictive than those outlined in the UDHR, and "Those who propose to restrict this right in any way must assume the burden of proof and must fulfill that burden to the highest level." (ibid)

Bakardjieva, Maria and Andrew Feenberg. 2001. Involving the Virtual Subject. *Ethics and Information Technology* 2: 233-240.

Bassett, E. H. and Kathleen O'Riordan. 2002. Ethics of Internet Research: Contesting the Human Subjects Research Model. *Ethics and Information Technology*, 4 (3), 233-249. Available online: <http://www.nyu.edu/projects/nissenbaum/ethics_bassett.html>

Boehlefeld, Sharon Polancic. 1996. Doing the Right Thing: Ethical Cyberspace Research. The Information Society 12(2), 141-152.

Boehlefeld argues that "doing ethical cyberspace research is not much different from doing any ethical research involving human subjects" (142). She recognizes utilitarian considerations (see p. 142) in establishing the importance of treating subjects ethically, and carefully develops guidelines for research - again, utilizing her own work as a case study - based on the ethics statement of the Association of Computing Machinery. In particular, she stresses anonymity and seeking permission to use long quotes (149f.) Here she observes that "The act of seeking permission, while it may lead to 'loss' of data, could also lead to developing potentially valuable 'key informant' relationships with list participants" (150) - thus reinforcing Allen's more dialogical orientation (1996).

Bruckman, Amy. 2002a. Ethical Guidelines for Research Online. <http://www.cc.gatech.edu/~asb/ethics/>

_____. 2002b. Personal communication, 8 August 2002.

_____. 2002c. Studying the Amateur Artist:A Perspective on Disguising Data Collected in Human Subjects Research on the Internet. *Ethics and Information Technology*, 4 (3), 217-231. Available online: <http://www.nyu.edu/projects/nissenbaum/ethics_bruckman.html>

Buchanan, Elizabeth A. 2002. Internet Research Ethics and Institutional Review Boards: New Challenges, New Opportunities. In *Advances in Library Administration and Organization*, 19 (pp. 85-99). Edited by Edward D. Garten and Delmus Williams. Elsevier Science.

_____ (ed). 2003. *Readings in Virtual Research Ethics: Issues and Controversies*. Hershey, Pennsvlvania: Idea Group Publishing,

Bynum, Terrell Ward. 1998. Global Information Ethics and the Information Revolution. In *The Digital Phoenix: How Computers are Changing Philosophy*, Terrell Ward Bynum and James H. Moor, eds., 274-291.

Bynum and Moor have pioneered the philosophical analyses of computer-related ethical issues; they have also centrally contributed to the reshaping of the professional discipline of

philosophy such that the American Philosophical Association now recognizes computer ethics and other aspects of computing as indeed philosophically significant.
In this chapter, Bynum provides a classic historical timeline of how CE began with the work of Norbert Wiener in the 1940s and 1950s, and develops through the "second generation" of CE begun in the mid-1990s. He further provides a taxonomy of responses to the meta-ethical questions raised by Deborah Johnson (i.e., whether CE represents anything genuinely new, or simply requires the application of extant moral theories), as well as a listing of sample topics in CE and a discussion of the ethical implications of the global reach of IT.

Danet, Brenda. 2001. "Ethical Aspects in CyberPl@y," available from <http://atar.mscc.huji.ac.il/~msdanet/papers/ethics2.pdf>.

Dreyfus, Hubert. 2001. *On the Internet*. New York: Routledge.

Elgesem, Dag. 2002. What is Special about the Ethical Issues in Online Research? *Ethics and Information Technology*, 4 (3), 195-203. Available online: <http://www.nyu.edu/projects/nissenbaum/ethics_elgesem.html>

Ermann, M. David, Mary B. Williams, and Michele S. Shauf. 1997. *Computers, Ethics, and Society*. New York: Oxford University Press.
An extensive collection that seeks to provide representative discussions of diverse ethical frameworks and characteristic positions regarding hacking, social and political impacts (Bill Gates vs. Jeremy Rifkin and Neil Postman!), work, copyright, privacy, and the ethical responsibilities of professionals. This would be a useful anthology of readings to supplement a more basic text such as Deborah Johnson's.
For our purposes, the chapters on professional codes are perhaps most relevant – in particular, the discussion of the ACM Code of Ethics and Professional Conduct, which includes specific injunctions to respect privacy and honor confidentiality (pp. 317f.).
This general discussion is followed by a chapter presenting nine case studies – none of which, however, deal with specific issues of Internet research.

Ess, Charles. 2002. Introduction. Special Issue on Internet Research Ethics, *Ethics and Information Technology*, 4 (3), 177-188. Available online: <http://www.nyu.edu/projects/nissenbaum/ethics_ess.html>

Frankel, Mark S. and Sanyin Siang (for the American Association for the Advancement of Science). 1999. "Ethical and Legal Aspects of Human Subjects Research on the Internet." <http://www.aaas.org/spp/dspp/sfrl/projects/intres/main.htm>

European Commission. Privacy on the Internet - An integrated EU Approach to On-line Data Protection."
<http://europa.eu.int/comm/internal_market/en/dataprot/wpdocs/wpdocs_2k.htm>
[Posted by Christine M. Hine to aoir ethics list]

Eysenbach, Gunther and Jim Till. 2001. "Ethical issues in qualitative research on internet communities." British Medical Journal 2001(10 Nov); 323(7321): 1103-1105.
<http://www.bmj.com/cgi/content/full/323/7321/1103>
["an interesting utilitarian-oriented perspective for medical practitioners using social science methods" - Amanda Lenhart, posted to aoir list.]

Hamelink, Cees J. 2000. *The Ethics of Cyberspace*. London: Sage Publications.
Hamelink, a prominent voice in UN and EU discussions of ethical issues in IT, develops a book-length argument for specific positions regarding rights, entitlement, security, free speech, and democratization. I'm especially taken with this work because Hamelink draws in part on Habermas in his analyses and arguments for what "democratization" via IT would look like. As well, I applaud Hamelink's final call for a Socratic education as a necessary condition for cyber-democracy (182-185).

Jankowski, Nickolas and Martine van Selm. 2001 (?). "Research Ethics in a Virtual World: Some Guidelines and Illustrations" <http://www.brunel.ac.uk/depts/crict/vmpapers/nick.htm>

Johnson, Deborah G. 2001. *Computer Ethics*. 3rd ed. Upper Saddle River, NJ: Prentice-Hall.
The third edition of perhaps the classic text in computer ethics.

Johnson provides a bit more detail on specific ethical theories than, say, Spinello, and further makes the important distinction between philosophical ethics (ch. 2) and professional ethics (ch. 3). Her topics include hacking, privacy, (intellectual) property rights, individual vs. collective responsibility, and social questions (democratization, the digital divide, and freedom of expression).
Johnson's text has been enormously valuable as a pioneering text in the field, one that – unlike many philosophy texts – remains resolutely focussed on the practical, real-world problems of pressing interest to IT designers and users. Hence its popularity as a teaching text in technical and professional IT programs and departments. At the same time, Johnson's text is highly regarded by philosophers as she raises a central *meta-ethical* issue of whether, at one extreme, computer ethics (CE) represents "nothing new" (and thus can be simply subsumed under extant ethical decision-making procedures) and/or, at the other extreme, CE represents radically new ethical issues for which our traditional frameworks are largely useless). Equally important is her response: Johnson defends an important middle-ground – i.e., CE issues as a "new species" of existing generic moral problems.

King, Storm. 1996. Researching Internet Communities: Proposed Ethical Guidelines for the Reporting of Results. *The Information Society*, 12: 119–128.

Mann, Chris and Fiona Stewart. 2000. An Ethical Framework (ch. 3), in Mann and Stewart, *Internet Communication and Qualitative Research: A Handbook for Researching Online,* 39-64.
An excellent discussion - shaped within the framework of the E.U. Data Privacy Protection Act and informed by the authors' own extensive research experience - of what the authors call "Principles of Fair Information Processing Online."
Chris Mann used this chapter as part of her teaching of a recent graduate course on Internet research ethics (June 1-6, 2002, NTNU, Trondheim, Norway). It is very well suited to classroom use, especially as complemented with materials on philosophical ethics to help establish the larger framework.

Nancarrow, Clive, John Pallister and Ian Brace. 2001. A new research medium, new research populations and seven deadly sins for Internet researchers. *Qualitative Market Research: An International Journal*, 4 (3): 136-149
"This paper follows on from our previous work on ethical issues in marketing research and deontological influences, in particular, codes of conduct…." (136). In fact, the authors seek to balance both deontological codes with utilitarian considerations (most importantly: if people have had unpleasant experiences of privacy violation by researchers, if they are not assured of confidentiality, etc. - they will not cooperate with researchers).
[Recommended by Chris Mann.]

National Committee for Research Ethics in the Social Sciences and the Humanities (NESH – Norway). 2001. "Guidelines for research ethics in the social sciences, law and the humanities." <http://www.etikkom.no/NESH/guidelines.htm>

Natural Sciences and Engineering Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans <http://www.nserc.ca/programs/ethics/english/ policy.htm >

Office for Protection from Research Risks, National Institutes of Health, Department Of Health And Human Services. 1991. Code of Federal Regulations. 1991. Title 45, Part 46, "Protection of Human Subjects." <http://ohsr.od.nih.gov/mpa/45cfr46.php3>

O'Riordan, Kathleen. 2002. Personal communication, 13 August 2002.

Schrum, Lynne. 1997. "Ethical Research in the Information Age: Beginning the Dialog," *Computers in Human Behavior*, Vol. 13 (2), pp. 117-125.
Excellent for its discussion of the qualitative research tradition and its connecting extant guidelines with research on listservs. Schrum develops a list of ten guidelines that stress that the authors of listserv postings are the owners of that material; e-mail should be treated as private correspondence "that is not to be forwarded, shared, or used as research data unless express permission is given"; and she likewise stresses the importance of informed consent and protecting the confidentiality of listserv members.

Sharf, B. F. 1999. Beyond netiquette: the ethics of doing naturalistic discourse research on the internet. In S. Jones (Ed.), *Doing internet research* (pp. 243-256). Thousand Oaks, CA: Sage.
[Posted to aoir list by David Eddy-Spicer.]

Smith, Katherine Clegg. 2003. 'Electronic Eavesdropping': The ethical issues involved in conducting a virtual ethnography. In Sarina Chen and Jon Hall (eds.), *Online Social Research: Methods, Issues, and Ethics*. New York: Peter Lang.

Spinello, Richard. 2002. *CyberEthics: Morality and Law in Cyberspace*, 2nd edition. Sudbury, Mass.: Jones and Bartlett.
The first chapter provides a brief but accurate introduction to basic (Western) ethical frameworks – utilitarianism, contract rights (contractarianism / Locke, Rousseau, Rawls), natural rights, and moral duty (Kant). Following these, Spinello summarizes "principilism" (used in biomedical ethics and popularized by Beauchamp and Childress), a position that asserts four *prima facie* duties: autonomy, nonmaleficence, beneficence, and justice.
A second chapter then details a history of the Internet and a broad survey of the issues (technical, ethical, and legal) evoked by efforts to govern and regulate the Internet.
With ethical theory and technical *praxis* thus established, Spinello then provides extensive overview and detailed discussion of the technical and ethical aspects of four crux problems: free speech (including attention to pornography, hate speech, and spam), intellectual property rights, privacy, and security. Each of these chapters concludes with at least one case study for analysis (some hypothetical, some real-life).
Spinello's chapter on privacy comes closest to addressing issues relevant to Internet research. Of interest here is his discussion of James Moor's theory of "just consequentialism." (Within the discipline of philosophy, James Moor is one of the most significant founders and expositors of computer ethics.)
I appreciated here his (brief) discussion of the differences between U.S. and European approaches to privacy issues with regard to workers (see 171f.). Consistent with the larger contrast I have articulated here (including "**VI. Addendum 2**," pp. 20f.), U.S. law provides virtually no protection for workers' privacy, in contrast with European (specifically, French and Italian) law which forbid employers' surveillance and monitoring of their employees.

Suler, John (2000). Ethics in Cyberspace Research. In Psychology of Cyberspace. <http://www.rider.edu/users/suler/psycyber/ethics.html>
[John Suler provides an excellent list of questions for researchers to help them consider how far their work fulfills the requirements for informed consent, privacy, and consultation and evaluation of the study.
Submitted to the aoir list by Lois Ann Scheidt <lscheidt@indiana.edu>]

Sussex Technology Group. 2001. The Company of Strangers, in S. R. Munt (ed.), *Technospaces: Inside the New Media*. London: Continuum.

Sveningsson, Malin. 2001. *Creating a Sense of Community: Experiences from a SwedishWeb Chat* (dissertation). The Tema Institute – Department of Communication Studies. Linköping University. Linköping, Sweden, pp.26-44)

_____. 2002. Posting to aoir ethics working group e-mail list, 25 September.

Swedish Council for Research in the Humanities and Social Sciences (HSFR). 1990. "Ethical principles for scientific research in the Humanities and Social Sciences." <http://www.cddc.vt.edu/aoir/ethics/private/Swedish_HFSR_1990b.pdf>

The UK Data Protection Site. <http://www.dataprotection.gov.uk>
Posted to the aoir ethics list by Christine Hine, who comments that the site

> …contains some useful items in relatively plain English, including a FAQ on how data protection issues apply to the web (locates it via "Guidance and Other Publications", "Compliance Advice", then "FAQs - Web"). This has some good advice for web site owners on how to protect visitors' privacy. However, most of this applies to commercial data use. "Scientific research" may be exempt from many of the provisions, as long as fundamental rights to privacy are not infringed

and anonymity of subjects is ensured. The situation on exemptions is too complex to explain in brief...but European researchers who are doing relevant research will need to clarify with their own country's data protection framework and their own institutions what their obligations are. It may come down to such issues as whether you can ensure that the data subjects are fully anonymised well before research reaches publication.... which seems to me that it might cause problems if direct quotations from newsgroup postings are used in reports.

University of Bristol, "Self Assessment Questionnaire for Researchers Using Personal Data," available from < http://www.bris.ac.uk/Depts/Secretary/datapro.htm>
[Submitted by Christine Hine to aoir ethics list]

Waern, Yvonne. 2001. Ethics in Global Internet Research. Report from the Department of Communication Studies, Linköping University, 2001:3. (Available in PDF format from the author, <yvowa@tema.liu.se>)
Includes a good discussion of utilitarian vs. rights approaches, and a series of careful reflections of how to apply the guidelines from the Natural Sciences and Engineering Research Council of Canada, including

> Respecting human dignity implies protecting the multiple and interdependent interests of the person - from bodily to psychological to cultural integrity. (cited in Waern, p. 7)

While she recognizes the utilitarian benefits of research, Waern tends to lean much more towards observing rights in research (and in this way, is an example of a stronger tendency towards the deontological among European and Scandinavian researchers). So she says in her conclusion, for example:

> …research should provide more benefit than harm. However, the exposition here shows that it is problematic to propose that no harm is done, and even more so to claim what benefit research gives. (11)

Waern also describes a bit of Internet research on her own - one documenting the dominance of English- and German-language literature on research ethics. This leads to her observation that there is a cultural bias in Internet research and its ethics:

> …the ethical guidelines found (on the Internet) are based on Western culture in general and Anglo/Saxon culture in particular. It may well be the case that these guidelines place less value upon establishing trust and intimate relationship between the research and the subject than other cultures. On the other hand, it might place higher value on privacy than other cultures. A continued investigation of ethical issues in various cultures is therefore greatly needed for research with the aim of studying global Internet use. (12)

Walther, Joe. 2002. Research Ethics in Internet-Enabled Research: Human Subjects Issues and Methodological Myopia. *Ethics and Information Technology*, 4 (3). Available online: <http://www.nyu.edu/projects/nissenbaum/ethics_walther.html>

White, Michele. 2002. Representations or People? *Ethics and Information Technology*, 4 (3), 249-266. Available online: <http://www.nyu.edu/projects/nissenbaum/ethics_white.html>

Additional Web-based resources

Information Ethics Group, Oxford Computing Laboratory
< http://web.comlab.ox.ac.uk/oucl/research/areas/ieg/>

International Center for Information Ethics (Center for Art and Media, Karlsruhe, Germany)
<http://icie.zkm.de/>

For a discussion of legal and other aspects, see
<http://www.unet.brandeis.edu/~jacobson/Doing_Research.html>

Stuart Offenbach (Department of Psychological Sciences, Purdue University) offers the following:

> If you are interested in Codes of Professional Ethics/Standards, I recommend the site at Illinois Institute of Technology. Vivial Weil has put together a very nice collection at
>
> <http://csep.iit.edu/codes/>
>
> In addition, there are a number of research ethics sites including the following:
>
> Ethics in Science: <http://www.chem.vt.edu/ethics/ethics.html>
>
> Office of Human Research Protection: <http://ohrp.osophs.dhhs.gov/>
>
> The Association for Practical and Professional Ethics: <http://ezinfo.ucs.indiana.edu/~appe/home.html>
>
> The Online Resource for Instruction in Responsible Conduct of Research: <http://rcr.ucsd.edu/>

Resources on US / EU / European differences

Aguilar, John R. 1999/2000. Over the Rainbow: European and American Consumer Protection Policy and Remedy Conflicts on the Internet and a Possible Solution. *International Journal of Communications of Law and Policy* (Issue 4, Winter 1999/2000, 1-57):
Documents extensively the differences in consumer protection - see especially section III, "E-Commerce Concerns and the Cultural Battle Waging Between the EU and US" (11ff.)

Nihoul, Paul. 1998-1999. Convergence in European Telecommunications: A Case Study on the Relationship between Regulation and Competition (Law). *International Journal of Communications Law and Policy*, Issue 2 (Winter), 1-33.

Reidenberg, Joel R. 2000. Resolving Conflicting International Data Privacy Rules in Cyberspace, Stanford Law Review, Vol. 52:1315-1376.

[My thanks to Kirk St. Amant for making me aware of these resources.]

Resources in Philosophical Ethics

Birsch, Douglas. 1999. *Ethical Insights: A Brief Introduction*. Mountain View, California: Mayfield.

Boss, Judith. 2001. *Ethics for Life: An Interdisciplinary and Multicultural Introduction*, 2nd ed. Mountain View, CA: Mayfield Publishing.

Rachels, James. 1999. *The Elements of Moral Philosophy*, 3rd ed. Boston: McGraw-Hill.

Thomson, Anne. 1999. *Critical Reasoning in Ethics: A Practical Introduction*. London, New York: Routledge.

Weston, Anthony. 2001. *A 21st Century Ethical Toolbox*. New York, Oxford: Oxford University Press.

Zeuschner, Robert B. 2001. *Classical Ethics: East and West*. Boston: McGraw-Hill.

V. Addendum 1: "Ethical Protocols" - Questions and decision-making guides for Internet research ethics.

1. From Dag Elgesem, What is Special about the Ethical Issues in Online Research? *Ethics and Information Technology*, 4 (3), 195-203; available online: <http://www.nyu.edu/projects/nissenbaum/ethics_elgesem.html>. Used by permission.

Is there only minimal risk of harm? No Exit

Yes

Are the integrity and the autonomy for research subjects adequately secured? No Exit

Yes

Is the method adequate? No Exit

Yes

Is the knowledge produced relevant enough? No Exit

Yes

OK?

From Chris Mann, Generating data online: ethical concerns and challenges for the C21 researcher. Keynote lecture, Nordic Conference on Internet Research Ethics, Trondheim, Norway, June1-2, 2002. Used by permission.

Are we seeking to magnify the good?

What question is the research project addressing

Is the research aiming at a goal which is good and desirable

What research methods will be used to achieve that goal

How will these methods be designed to ensure the results are reliable

How will the results of the research be disseminated

Are we acting in ways that do not harm others?

What is the level of risk to a participant?

How are risks assessed?

Do we recognise the autonomy of others and acknowledge that they of equal worth to ourselves and should be treated so?

Will informed consent be sought from participants?

What procedures to obtain consent will be followed?

How will confidentiality be respected?

=====

For additional question lists and protocols, see:

Bruckman, Amy. 2002a. Ethical Guidelines for Research Online. <http://www.cc.gatech.edu/~asb/ethics/>

Danet, Brenda. 2001. Suggested Guidelines for Discussion, aoir ethics working committee preliminary report, **Addendum III** <aoir.or/reports/ethics.html>.

University of Bristol, "Self Assessment Questionnaire for Researchers Using Personal Data," available from < http://www.bris.ac.uk/Depts/Secretary/datapro.htm> [Posted by Christine M. Hine to aoir ethics working committee]

Suler, John (2000). Ethics in Cyberspace Research. In Psychology of Cyberspace. <http://www.rider.edu/users/suler/psycyber/ethics.html> [Posted by Lois Ann Scheidt to aoir list])

VI. Addendum 2: Discussion of contrast between utilitarian and deontological approaches - as these are reflected in contrasts between the U.S. and Europe (Scandinavia and the EU) in laws regarding privacy and consumer protection.

As noted in our Preliminary Report, a comparison between extant US (e.g., the Belmont Report, the Federal Codes, the 1999 AAAS report, and a spread of articles from US-based researchers and ethicists) and EU guidelines (first of all, the NESH guidelines [National Committee for Research Ethics in the Social Sciences and the Humanities [NESH], Norway) "Guidelines for research ethics in the social sciences, law and the humanities." [2001]: <http://www.etikkom.no/NESH/guidelines.htm>] and the EU Data Privacy Protection Act) - there appears to be a clear contrast between US and EU approaches. In ethical terms, it is the contrast between more utilitarian (US) approaches (e.g., as these are more likely to allow cost-benefit analyses to override concerns regarding primary rights and responsibilities) and more deontological (EU) approaches (as these lay greater stress on protecting individual rights - first of all, the right to privacy - even at the cost of thereby losing what might be research that promises to benefit the larger whole).[14]

This contrast can be seen, for example, in the differences between two "ethical protocols" available on the web, the first from the UK and the second from the US:

> University of Bristol, "Self Assessment Questionnaire for Researchers Using Personal Data," available from < http://www.bris.ac.uk/Depts/Secretary/datapro.htm>;
> Suler, John (2000). Ethics in Cyberspace Research. In Psychology of Cyberspace. <http://www.rider.edu/users/suler/psycyber/ethics.html>.[15]

More broadly, it appears that this contrast is further mirrored in the contrast between the EU and the US in terms of laws regarding privacy and consumer protection. According to the **1995 E.U. Data Privacy Protection Act**, data-subjects must:

* Unambiguously give consent for personal information to be gathered online;
* Be given notice as to why data is being collected about them;
* Be able to correct erroneous data;
* Be able to opt-out of data collection; and
* Be protected from having their data transferred to countries with less stringent privacy protections.
  (see <http://www.privacy.org/pi>

In this light, it is clear that ***E.U. citizens enjoy a priority on individual privacy*** vis-a-vis business interests
- i.e., a *deontological* emphasis on **respect for persons** in the form of privacy protections
vs.
U.S. favoring **business interests** over individual privacy. For example, Reidenberg argues that while there is *global convergence* on what he calls the First Principles of data protection - there are clear *differences* in how these First Principles are implemented, i.e., through "*either liberal, market-based governance or socially-protective, rights-based governance*." (Joel R. Reidenberg, Resolving Conflicting International Data Privacy Rules in Cyberspace, *STANFORD LAW REVIEW* [Vol. 52 (2000):1315-1376], 1315)

In particular, the European model is one in which

> omnibus legislation strives to create a complete set of rights and responsibilities for the processing of personal information, whether by the public or private sector. First Principles become statutory rights and these statutes create data protection supervisory agencies to assure oversight and enforcement of those rights. Within this framework, additional precision and flexibility may also be achieved through codes of conduct and other devices. Overall, this implementation approach treats data privacy as a political right anchored among the panoply of fundamental human rights and the rights are attributed to "data subjects" or citizens. (1331f.)

By contrast, the United States is distinctive in its approach, in which

> … the primary source for the terms and conditions of information privacy is self-regulation. Instead of relying on governmental regulation, this approach seeks to protect privacy through practices developed by industry norms, codes of conduct, and contracts rather than statutory legal rights. Data privacy becomes a market issue rather than a basic political question, and the rhetoric casts the debate in terms of "consumers" and users rather than "citizens." (1332)

- i.e., a *consequentialist* position, one that emphasizes economic benefit at large over possible risks to individual privacy.
However well the associations between U.S.+consequentialism and E.U.+deontology will hold up[16] - recent discussion among the aoir ethics committee, following informal research by Christine M. Hine, has made even clearer that the problems of contrasts between the US and the EU on data privacy protection are paralleled by more fine-grained contrasts between the EU member states themselves.

VII. Addendum 3: Sample consent forms (courtesy, Leslie Regan Shade) for parents and children involved in Internet research.

Consent form (Parent)

Leslie Regan Shade
Department of Communication
University of Ottawa
Tel: 562-5800 x3827
shade@aix1.uottawa,ca

I,_____, agree to allow my child to participate in the research, *Children, Young People, and New Media in the Home*, conducted by Leslie Shade, of the Department of Communication, Faculty of Arts at the University of Ottawa. The project is under the supervision of Leslie Shade. The purpose of the research is to develop new insights into the social meanings that Internet and related new media give for children and families by discussing with children in detail their experiences with these services, both in the context of their actual use, and in their home environment.

My participation will consist essentially of attending one session in my house for two times during one 12-month period of time, during which I will remain within the house while the interview session with my child is being conducted, which will last for approximately one hour in length. The sessions have been scheduled for _____. I understand that the contents of this research will be used by the Researcher only for the purposes of academic research, including sharing with colleagues at academic conferences and in academic publications, and that my and my child's anonymity will be respected (real names will not be used in the research dissemination nor will any personal details be revealed that could compromise our identity).

My child and I can choose the methods in which the interviews will take place, which can include digital videography, audio tape-recording, or note-taking. I can also choose whether to allow the digital videography to be used in conference presentations, and to be published (via Web video-streaming) on a website maintained for this project. I understand that the anonymity of my child will be maintained in the digital videography, as no real names will be revealed. If, during the course of the videography, real names are disclosed, they will be edited out. At the end of this form are the appropriate permissions for these activities.

I understand that since this activity deals with very personal information, if it becomes apparent to me, as a parent, or to the Researcher, Leslie Shade, that this is causing some discomfort for my child, the interview will cease. I have received assurance from the Researcher that every effort will be made to minimize these occurrences, through sensitive questioning of my child. If, at any time, my child is uncomfortable with the digital videography or tape-recording, my child is free to ask the Researcher to stop. My child is also free to withdraw from the project at any time, before or during an interview, refuse to participate and refuse to answer particular questions.

I have received assurance from the researchers that the information my child and I will share will remain strictly confidential. Anonymity will be assured through the use of pseudonyms in research analysis and in publications and academic presentations of this research.
Digital video recordings, tape recordings of interviews and other data collected will be kept in a secure manner. Contents will be kept in a locked filing cabinet at the researchers' office for a period of between 5-10 years after the date of research publications, and be only available to the researcher and her research assistants.

Benefits of the research: This research will examine the point of view of children and youth and their everyday experiences of using new media in their home. Similar research, to date, has been conducted from an adult-centred perspective. However, children and youth are the fastest growing segment of Internet users, using new media in both the educational and social realms. Children and young people will have an important role to play in the future development of new media, and this is recognized by the federal and provincial government because diverse programs have been established in Canada to make sure that children and youth have access to the Internet in schools and community centers.

It is therefore an opportune time to investigate how children and youth are using new media within their home, because many families have computers and Internet access. One of the research questions this study will investigate is how socio-economics determines media access and opportunities for social participation. In terms of lifestyle, how do children and young people relate to the variety of new media now available to them? What influences their media choices? What new media forms are being created and marketed to children and young people? Are there gender differences in the ways children and youth utilize new media?

Any information about my rights as a research participant may be addressed to Catherine Lesage, Protocol Officer for Ethics in Research, 30 Stewart Street, Room 301, (613) 562-5387 or clesage@uottawa.ca .

There are two copies of the consent form, one of which I may keep.

If I have any questions about the conduct of the research project, I may contact the Researcher at Department of Communication, University of Ottawa, 554 King Edward Ave., Ottawa ON K1N 6N5. Tel: 613-562-5800 x3827; fax: 613-562-5240; e-mail: shade@aix1.uottawa.ca

_____
Researcher's signature

_____
Date

_____
Research Subject's Parent's signature

_____
Date

I consent to allowing my child to be recorded via digital videography

_____
Parents initials

I do not consent to allowing my child to be recorded via digital videography

_____
Parents initials

I consent to allowing the digital videography of my child to be presented at academic conferences

_____
Parents initials

I do not consent to allowing the digital videography of my child to be presented at academic conferences

_____
Parents initials

I consent to allowing the digital videography of my child to be published on the Project Website

_____
Parents initials

I do not consent to allowing the digital videography of my child to be published on the Project Website

_____
Parents initials

Assent form (Child, aged 13-17)

Leslie Regan Shade
Department of Communication
University of Ottawa
Tel: 562-5800 x3827
shade@aix1.uottawa,ca

I,_____, agree to participate in the research, *Children, Young People, and New Media in the Home*, conducted by Leslie Shade, of the Department of Communication, Faculty of Arts at the University of Ottawa. The project is under the supervision of the researcher Leslie Shade. The purpose of the research is to understand how young people are using the Internet and other new media (such as videogames) in their daily lives. I understand that the research will consist of me agreeing to be interviewed for two interviews, for one-hour in length, twice in one 12-month period. During these interviews, I will be asked questions from the Researcher about how I use the Internet and other new media, while I am in my home. I can also show the Researcher what I do on the Internet and with videogames.

I understand that the contents of this research will be used by the Researcher only for the purposes of her academic research, including sharing with colleagues at academic conferences and in academic publications, and that my anonymity will be respected (my real name will not be used, and no personal details will be disclosed that could reveal my real identity).

I may choose whether I want to be recorded on the digital videorecorder, or tape-recorder, and I can also refuse to allow the digital videography to be used in conference presentations, and to be published on a website maintained for this project. I understand that my anonymity will be assured as my real name will not be revealed. If I have agreed to be filmed, but during the course of the filming, my real name is disclosed, I understand it will be edited out.

If, during the course of the interview, I feel uncomfortable about any questions that are asked of me, I can refuse to answer at any time during the interview, or ask for the interview to stop. I am under no pressure to answer all of the questions, and I have been told by the Researcher that I can stop at any time.

I understand that my interview and identity will remain confidential. My anonymity will be protected through the use of a pseudonym (a made-up name) when the Researcher is analyzing the material and in her publications and conference presentations of this research.

I understand that digital video recordings, tape recordings of interviews and other data collected will be kept in a secure manner. Contents will be kept in a locked filing cabinet at the Researchers' office for a period of between 5-10 years after the date of publications, and be only available to the researcher and her research assistants.

Benefits of the research: This research will examine the point of view of children and youth and their everyday experiences of using new media in their home. Similar research, to date, has been conducted from an adult-centred perspective. However, children and youth are the fastest growing segment of Internet users, using new media in both the educational and social realms. Children and young people will have an important role to play in the future development of new media, and this is recognized by the federal and provincial government because diverse programs have been established in Canada to make sure that children and youth have access to the Internet in schools and community centers.

It is therefore an opportune time to investigate how children and youth are using new media within their home, because many families have computers and Internet access. One of the research questions this study will investigate is how socio-economics determines media access and opportunities for social participation. In terms of lifestyle, how do children and young people relate to the variety of new media now available to them? What influences their media choices? What new media forms are being created and marketed to children and young people? Are there gender differences in the ways children and youth utilize new media?

If I am concerned about any of this research, I can talk to the Researcher or my parent(s). My parent(s) can also contact the University of Ottawa if they or I have questions about my rights as a research participant: Catherine Lesage, Protocol Officer for Ethics in Research, 30 Stewart Street, Room 301, (613) 562-5387 or clesage@uottawa.ca.

There are two copies of the consent form, one of which I may keep.

If I have any questions about the conduct of the research project, I may contact the Researcher at the Department of Communication, University of Ottawa, 554 King Edward Ave., Ottawa ON K1N 6N5. Tel: 613-562-5800 x3827; fax: 613-562-5240; e-mail: shade@aix1.uottawa.ca

_____
Researcher's signature

_____
Date

_____
Research Subject's signature

_____
Date

I consent to be recorded via digital videography

_____
Research subject's initials

I do not consent to be recorded via digital videography

_____
Research subject's initials

I consent to allowing the digital videography to be presented at academic conferences

_____
Research subject's initials

I do not consent to allowing the digital videography to be presented at academic conferences

_____
Research subject's initials

I consent to allowing the digital videography to be published on the Project Website

_____
Research subject's initials

I do not consent to allowing the digital videography to be published on the Project Website

_____
Research subject's initials

====
Assent form (Child, aged 9-12)

Leslie Regan Shade
Department of Communication
University of Ottawa
Tel: 562-5800 x3827
shade@aix1.uottawa,ca

I,_____, and my parents agree that I can participate in the research, *Children, Young People, and New Media in the Home*. This research is being done by Leslie Shade, of the Department of Communication, Faculty of Arts at the University of Ottawa.. This research is looking at how kids like me are using the Internet and videogames in their homes. The research will be beneficial to educators and society because it will look at how kids are actually using new media and whether it can be improved. The talk with the Researcher will last for about one hour, and will happen two times in a year.

The Researcher will be coming into my home and asking me questions about what I do on the Internet or with videogames. I can also show the Researcher what I do on the Internet and with videogames. My parents and I can choose whether I will be filmed or tape-recorded. We can also say if we allow the film of me to be shown at conferences, or to be put on a website for others to look at.

I understand that my talk with the Researcher will be used only used by her. I understand that my real name will never be used. The researcher will give me a made-up name to describe me.

If I ever feel uncomfortable about any questions the Researcher asks me, I can refuse to answer at any time. I can also ask for the interview to stop at any time. I am under no pressure to answer all of the questions.

I understand that the interviews with me will be safe in the Researchers office, and that no one except her will be able to look at them.

If I am concerned about any of this research, I can talk to the Researcher or my parent(s). My parent(s) can also contact the University of Ottawa if we have questions about my rights as a research participant: Catherine Lesage, Protocol Officer for Ethics in Research, 30 Stewart Street, Room 301, (613) 562-5387 or clesage@uottawa.ca .

There are two copies of the consent form, one of which I may keep.

If my parents and I have any questions about the conduct of the research project, I may contact the Researcher at the Department of Communication, University of Ottawa, 554 King Edward Ave., Ottawa ON K1N 6N5. Tel: 613-562-5800 x3827; fax: 613-562-5240; e-mail: shade@aix1.uottawa.ca

_____
Researcher's signature

_____
Date

_____
Research Subject's signature

_____
Date

====

Assent form (Child, aged 6-8)

Leslie Regan Shade
Department of Communication
University of Ottawa
Tel: 562-5800 x3827
shade@aix1.uottawa,ca

I,_____, and my parents agree that I can participate in the research, *Children, Young People, and New Media in the Home*. This research is being done by Leslie Shade, of the Department of Communication, Faculty of Arts at the University of Ottawa.

This research is looking at how kids like me are using the Internet and videogames in their homes. The Researcher will be coming into my home and asking me questions about what I do on the Internet or with videogames. My parents and I can choose whether I will be filmed or tape-recorded.

If I ever feel uncomfortable about any questions the Researcher asks me, I can refuse to answer at any time. I can also ask for the interview to stop at any time.

If I am concerned about any of this research, I can talk to the Researcher or my parent(s). My parent(s) can also contact the University of Ottawa if we have questions about my rights as a research participant: Catherine Lesage, Protocol Officer for Ethics in Research, 30 Stewart Street, Room 301, (613) 562-5387 or clesage@uottawa.ca .

There are two copies of the consent form, one of which I may keep.

If my parents and I have any questions about the conduct of the research project, I may contact the Researcher at the Department of Communication, University of Ottawa, 554 King Edward Ave., Ottawa ON K1N 6N5. Tel: 613-562-5800 x3827; fax: 613-562-5240; e-mail: shade@aix1.uottawa.ca

_____
Researcher's signature

_____
Date

_____
Research Subject's signature

_____
Date

====

Endnotes

[1] My profound thanks to the members of the committee who have generously shared their time, expertise, and care through discussion and critical evaluation of the issues raised in this document. The committee includes: Poline Bala – Malaysia; Amy Bruckman – USA; Sarina Chen - USA; Brenda Danet – Israel/USA; Dag Elgesem – Norway; Andrew Feenberg - USA; Stine Gotved – Denmark; Christine M. Hine – UK; Soraj Hongladarom - Thailand; Jeremy Hunsinger - USA; Klaus Jensen - Denmark; Storm King - USA; Chris Mann - UK; Helen Nissenbaum - USA; Kate O'Riordan - UK; Paula Roberts - Australia; Wendy Robinson - USA; Leslie Shade - Canada; Malin Sveningson - Sweden; Leslie Tkach - Japan; John Weckert - Australia.

[2] "Inter/action" is intended as a shorthand for "actions and/or interactions" - i.e., what humans do, whether or not our actions engage and/or are intended to engage with others. Part of the intention here is to avoid other terms, e.g., "behavior," that are too closely tied in the social sciences to specific approaches, schools of thought, etc. (By contrast, as the citations from Deborah Johnson make clear [note 5, below], "behavior" is used as a more neutral term in philosophical ethics.)

[3] Matthew Allen explains that in Australia,

> research ethics are covered by national processes, mainly formulated by the National Health and Medical Research Council but also adopted by the Australian Research Council (which covers all other types of research). Each university has instituted a scheme, based on the NHMRC requirements, for internal ethics management, since most of the available research funds come from those two councils.
> While each university Office of Research (or similar) will have its specific procedures and guidelines, the national position is best explained by the documents found at the NHMRC's ethical issues webpage, <http://www.nhmrc.gov.au/issues/researchethics.htm>.
> It should be noted that while most of the specific ethical considerations covered by the NHMRC will not apply to Internet researchers (most involve the use of medical procedures), there are still key aspects of the process that are highly relevant; moreover the overall framework of for ethical research is covered in detail by the NHMRC.
> (E-mail to Charles Ess, 3 November 2002)

[4] In their project to collect all (English) literature pertinent to online research, the Committee on Scientific Freedom and Responsibility of the AAAS (American Association for the Advancement of Science) includes the following disciplines: Anthropology, Business, Communications/Media, Computer Science, Economics, Education, Law, Linguistics, Medicine,

Nursing, Pharmacology, Philosophy, Political Science, Psychology, Public Health, Social Work, Sociology, and Statistics. (AAAS CSFR, "Categories.doc," quoted by permission.)

[5] Deborah Johnson (2001) provides excellent definitions of these (and other) basic terms in her classic introduction to computer ethics.

"*Utilitarianism* is an ethical theory claiming that what makes behavior right or wrong depends wholly on the consequences….utilitarianism affirms that what is important about human behavior is the outcome or results of the behavior and not the intention a person has when he or she acts" (36: emphasis added, CE). When faced with competing possible actions or choices, utilitarian approaches apply an ethical sort of cost/benefit approach, in the effort to determine which act will lead to the greater benefit, usually couched in terms of happiness (a notoriously difficult and ambiguous concept – thus making utilitarian approaches often difficult to apply in *praxis*). As Johnson goes on to point out here, there are several species of utilitarianism (what some ethicists also call *teleological* or goal-oriented theories). Briefly, one can be concerned solely with maximizing benefit or happiness for oneself (*ethical egoism*) and/or maximizing benefit or happiness for a larger group (hence the utilitarian motto of seeking "the greatest good for the greatest number").

"By contrast, *deontological theories* put the emphasis on the internal character of the act itself," and thus focuses instead on the motives, intentions, principles, values, duties, etc., that may guide our choices" (Johnson 2001, 42: emphasis added, CE). For *deontologists*, at least some values, principles, or duties require (near) absolute endorsement – no matter the consequences. As we will see in this document, *deontologists* are thus more likely to insist on protecting the fundamental rights and integrity of human subjects, *no matter the consequences* – e.g., including the possibility of curtailing research that might threaten such rights and integrity. Utilitarians, by contrast, might argue that the potential benefits of such research outweigh the possible harms to research subjects: in other words, the greatest good for the greatest number would justify overriding any such rights and integrity.

Virtue ethics derives in the Western tradition from Plato and Aristotle. The English word "virtue" in this context translates the Greek αρετε – better translated as "excellence." In this tradition, "…ethics was concerned with excellences of human character. A person possessing such qualities exhibited the excellences of human good. To have these qualities is to function well as a human being" (Johnson 2001, 51).

Contemporary feminist ethics traces much of its development to Carol Gilligan's work on how women make ethical decisions – in ways that both parallel and often sharply contrast with the ethical developmental schema established by Lawrence Kohlberg. Briefly, Gilligan found that women as a group are more likely to include attention to the details of relationships and caring, choosing those acts that best sustain the web of relationships constituting an ethical community – in contrast with men who as a group tend to rely more on general principles and rules. For Gilligan, this basic contrast between an ethics of care and an ethics of justice is by no means an either/or choice: on the contrary, she finds that the highest stages of ethical development are marked by the ability to make use of both approaches. See Rachels (1999, 162-74) for an overview and suggestions for further reading.

Rachels also provides a more complete account of utilitarianism, deontology, and still other ethical decision-making procedures. In addition, interested readers are encouraged to review Weston (2001), Thomson (1999), Birsch (1999), and Boss (2001) for both more extensive discussion and applications of ethical theory. (See note 7 below for additional resources in cross-cultural ethics.)

Finally, while ethicists find that these distinctions between diverse theories and approaches are useful for clarifying discussion and resolving conflicts – they (largely) agree that a complete ethical framework requires a careful *synthesis* of several of these theories.

[6] See Bruckman (2002c) and Walther (2002) for specific examples of an *ethical pluralism* that allows us to recognize a range of specific ethical positions as legitimate, rather than either insisting on a single ethical value (monolithic ethical dogmatism) or simply giving up on ethics altogether and embracing ethical relativism. The examples and models of such pluralism, as a middle ground between dogmatism and relativism, are consistent with the larger convergence that I suggest is taking place (Ess, 2002) - i.e., as these offer us specific instances and frameworks that encompass both agreement (e.g., on basic values or first principles) and irreducible differences (e.g., in the specific application of those basic values, principles, etc.): see also King (1996) and Smith (2003).

[7] *Cross-cultural* differences are addressed especially by an ethical pluralism that rests on a shared commitment to a fundamental norm, value, or guideline: the *interpretation* or *application* of that norm, however, differs in different contexts. For example, a central issue for Internet researchers is whether, and if so, under what circumstances *informed consent* is required - especially if *recording* activity is taking place. For U.S.-based researcher Joe Walther (2002), such recording is ethically unproblematic. For Norwegian ethicist Dag Elgesem (2002), by contrast, such recording (audio and/or video) requires informed consent. In both cases, however, the issue is one of *expectations*. For Elgesem and the

NESH guidelines, people in public places do not *expect* to be recorded without their knowledge and consent. By contrast, Walther follows Jacobsen's argument that such expectations are misplaced. Hence, while Elgesem and Walther reach different conclusions regarding the ethical propriety of recording inter/actions in public spaces on the Net - they do so through a *shared* argument: in both cases, the *expectations* of the actors/agents involved are paramount. Hence, while the U.S. and Norwegian positions differ on a first level - on a second (meta-ethical) level, they *agree* on the ethical importance of actors' expectations. This *ethical pluralism* thus conjoins both important *shared norms or values* (the importance of expectations in guiding our ethical responses) and *differences* (in the interpretation or application of those norms or values).

This same sort of pluralistic structure, finally, is at work with regard to the significant differences between U.S. and European Union approaches to computer ethics in general and Internet research ethics in particular. Broadly, the European Union Data Privacy Protection laws and ethical codes for research (primarily, the NESH guidelines) more fully endorse a *deontological* insistence on protecting the rights of individuals, *no matter the consequences*. By contrast, U.S. law regarding data privacy appears to favor the *utilitarian* interests of economic efficiency (see Aguilar 1999/2000 for an extensive comparison). This same contrast can be seen in research guidelines: for example, where U.S.-based research guidelines focus on the protection solely of the *individual* participating in a research project - the NESH guidelines require researchers to respect not only the individual, but also "….his or her private life and close relations…." (2001). But again, these large differences may again be seen as differences on a first level - i.e., with regard to *interpretation*, *implementation*, etc. - coupled with fundamental *agreements* on a second level, i.e., with regard to shared *values, norms, commitments*, etc. So Paul Reidenberg discerns a global convergence on what he calls the First Principles of Data Protection: the differences we have noted result from differences in *implementation*, i.e., through "either [current U.S.-style] liberal, market based governance or [current E.U.-style] socially-protective, rights-based governance" (2000, 1315). Similarly, Diane Michelfelder traces the ways in which both U.S. and European law are rooted in a *shared* conception of fundamental human rights - conceptions articulated both in the 1950 European Convention for the Protection of Human Rights and in the U.S. Constitution itself (2001, 132).

See also **VI**: **Addendum 2**, pp. 20f. For cross-cultural approaches to ethics in addition to Boss (2001), see, for example Zeuschner (2001).

[8] The term "ethical relativism" as used here is often - but unnecessarily - the occasion for considerable confusion, because philosophers usually use the term differently from their colleagues in the social sciences.

That is: ethicists distinguish between *ethical relativism*, on the one hand, and *cultural relativism*, on the other. The latter is a methodological starting point for anthropology and other human sciences, one that takes a morally neutral stance in the effort to simply *describe*, rather than judge, the morés, beliefs, habits, and values of a particular culture or time. In this way, cultural relativism consists of *descriptive* "is" statements: it simply <u>is</u> the case, descriptively considered, that values, beliefs, customs, habits, practices, etc., <u>differ</u> from culture to culture.

Ethical relativism, by contrast, is a *normative* position - i.e., one that *prescribes* a specific moral stance and in the language of "ought." Most briefly, ethical relativism begins with the claim that *there <u>are</u> no universally valid values*, and therefore, one *ought* not to feel any obligation to any claims to such universal values: and in the absence of such universal values, one *ought* to do whatever seems best to the individual (whether as inspired by desire, reason, self-interest, altruism, dis/conformity with prevailing norms, etc.). Finally, because no universal values exist, and one *ought* to do what seems best to the individual - one also *ought* to not impose one's own moral views on others, one *ought* not to judge others, etc. In sum, "anything goes."

Confusion between these two views often arises in part because *ethical relativism* usually supports its premise that there are no universally valid values with the *descriptions* developed from the perspective of *cultural relativism*. That is, given the simple *description* that values, etc., vary from culture to culture, ethical relativism draws the conclusion (erroneously, on both logical and empirical grounds) that this diversity must mean there are no universal values, valid for all times and places. From here, then, there is the move to the *ought* statements - e.g., one *ought* to do as it seems best to the individual, etc.

Most contemporary ethicists, to my knowledge, generally reject *ethical relativism* on a range of grounds (empirical and logical) as the last word in ethics: but it is recognized as an important position among a range of positions, one that is defensible at least up to a point (e.g., with regard to fashion, etc.) Hence, to identify someone as an ethical relativist does not automatically count as a statement of ethical condemnation. Rather, ethical relativism is to be examined seriously, along with its supporting and critical arguments and evidence, as part of a critical analysis of diverse ethical views.

Despite their overlap, *cultural relativism* - as a methodological principle and correlative descriptions within the social sciences - is not to be confused with *ethical relativism* as a particular *normative* theory. Specifically: when philosophers criticize ethical relativism - they thereby do not mean to attack cultural relativism as an important component of the social sciences, as if the philosophers were seeking to make ethical judgments that would restrict and undermine the

disciplines and findings of the social sciences. Rather to the contrary, philosophers distinguish between ethical and cultural relativism, precisely in order to distinguish the (legitimate, if arguable) ethical position from the methodological starting point and (more or less) universally accepted description of diverse cultures.

[9] Aristotle defines *phronesis* as "…a truth-attaining rational quality, concerned with action in relation to things that are good and bad for human beings." (*Nichomachean Ethics, VI.v.4*, Rackham trans.)

[10] Amy Bruckman points out that people's expectations regarding their online communication are often out of sync with the realities of online communication - e.g., BLOG authors' expectations as to who will read their material, etc. (Bruckman, 2002b).

[11] The NESH guidelines (National Committee for Research Ethics in the Social Sciences and the Humanities [NESH], Norway) "Guidelines for research ethics in the social sciences, law and the humanities." [2001]: <http://www.etikkom.no/NESH/guidelines.htm>) point out that "public persons" and people in public spaces have a reduced expectation of privacy, such that simple observation of such persons and people is not ethically problematic. By contrast, *recording* (e.g., using audio- or videotape) such persons and people does require their (informed) consent. In this direction, see also Bakardjjeva and Feenberg (2000), who argue for taking into account "participant interests" and expectations, leading to their principle of non-alienation – granting participants' the right to control what happens to their communications as part of a collaborative model of Internet research especially suited to the "dialogical affordances" of the Internet (238).

On the other hand, with reference, for example, to Benjamin's concept of the *flaneur* and the Sussex Technology Group (2001), O'Riordan observes that "some research/theory also points the other way, to the inversion of publics where the private-in-public space can be perceived to be <u>more</u> private than the spatially 'private.' (2002).

[12] For discussion of participants as subjects - and thus subject to U.S. Federal Codes - see Walther (2002). For discussion of participants as activists, authors, and/or amateur authors whose work - especially as treated from the disciplines and ethical perspectives of the humanities - see Bassett and O'Riordan (2002), Bruckman (2002c), and White (2002).

As a middle ground between more public and more private domains, and between greater and lesser obligation to protect privacy – there is the correlative set of expectations as to what counts as polite or courteous behavior, sometimes called "Netiquette." For example, it is arguable that any listserv or e-mail is public because the Internet is technologically biased in favor of publicity, listserv archives are often made available publicly on the Web, etc. Insofar as this is true, there is no strict ethical obligation, say, to ask permission before quoting an e-mail in another context. Nonetheless, it seems a matter of simple courtesy, if not ethical obligation, to ask authors for permission to quote their words in other electronic domains.

If the request is for quoting an electronic document *in print*, then prevailing practice – and perhaps the requirements of copyright law? – strongly suggest that all such quotes require explicit permission from the author. (For arguments that *everything* posted on the Web is *de facto* subject to copyright law, see Bruckman [2002c] and Walther [2002].)

See also Allen (1996), who argues for a "ground-up" dialogical ethics - i.e., one developed over the course of the research project through on-going communication with one's research *authors* (in contrast with the usual social science and medical approach that presumes these are *subjects*). The results of this approach are a concrete instance of the sort of middle ground described above.

[13] The point of the contrast sketched out here (and developed more fully below - see especially endnotes 14, 16) is simply to illustrate that ethical approaches and traditions vary among countries and cultures, and thus it is important to be aware of and take these larger contexts into account.

For its own part, of course, this particular example is open to criticism and further refinement. In particular, Malin Sveningsson has challenged this contrast as follows:

> If we look at Sweden, for example, there <u>is</u> a difference between what is stated in the ethical guidelines and what is actually done. I guess you could say that the ethical guidelines draw up lines for what would be the **ideal** research design. At the same time, the Swedish Research Council acknowledges that it might not always be possible to strictly follow the guidelines. They also stress the importance of doing important research that will benefit society and its members, and state that ethical guidelines sometimes have to be measured against this. So, my point is: It is possible that ethical GUIDELINES are more strict and deontological, but in practice, researchers might not be more strict than in, for example, the US. (2002)

Sveningsson points to her own work (2001) as an example of research more utilitarian in its ethics, in contrast with Amy Bruckman's guidelines (<http://www.cc.gatech.edu/~asb/ethics/>) as more deontological.

[14] Consider the following comments on the NESH guidelines (from aoir ethics working committee Preliminary Report):
More stringent ethical obligations – and requirements
The ethical requirements established here appear to be somewhat more stringent than in other statements we've examined. For example:
The obligation to respect human dignity

> Human dignity implies that every one of us has interests that can not be set aside, whether in the interests of greater insight or to benefit society in other ways.

That is, *contra* the utilitarian approach that allows individual interests, including life, to be overridden if necessary for the greater good – this statement seems to say that human dignity is an absolute, which cannot be overridden for the sake of benefit for others.

The obligation to inform research subjects

> Persons who are the subjects of research must be given the information they need for a reasonable understanding of the research field, of the consequences of participating in the research project, and of the object of the research. They must also be told who is paying for the research.

While we have discussed the advisability of subjects knowing about funding sources, I don't recall that we've been collectively insistent on this point.

The obligation to respect individuals' private lives and families

> Researchers must show due respect for the individual's private life. Each person is entitled to control over whether or not to make identifiable information on his or her private life and close relations available to others. Respect for privacy is intended to protect people against unwanted interference and against unwanted observation.

I find this striking as it <u>includes</u> one's family and/or other close relations as part of the circle of protection that researchers must draw. By contrast, I've always assumed in reading other guidelines and statements that the obligation to protect the identity of one's subjects mean <u>solely</u> the individual.

The confidentiality requirement

> Persons who are made the subjects of research are entitled to confidential treatment of all information they give. The researcher must prevent the use and transmission of information which may harm the individual on whom the research is being carried out. *The research material must normally be rendered anonymous, and the storage and destruction of lists of names or personal identity numbers must satisfy strict requirements.* (Emphasis added, CE)

[15] This contrast is also apparent, for example, between the guidelines suggested by Amy Bruckman and Susan Herring - both U.S.-based researchers. See Jankowski, Nickolas and Martine van Selm. 2001 (?). "Research Ethics in a Virtual World: Some Guidelines and Illustrations" <http://www.brunel.ac.uk/depts/crict/vmpapers/nick.htm> for a discussion of this contrast as presented as part of a panel discussion at aoir 2.0.

[16] Diane Michelfelder (The moral value of informational privacy in cyberspace. *Ethics and Information Technology* 3 [2001]: 129-135) has argued that <u>both</u> the U.S. and European law are able to root privacy as a fundamental human right. To begin with,

> legal protection for privacy in the US has grown up around two fundamental privacy interests. On the one hand, there is the constitutional right to privacy first established by the US Supreme Court decision in Griswold v. Connecticut.(4) On the other hand, there is the …constitutional right to informational privacy backed by the Fourth Amendment as well as by tort-related guarantees. The former finds its moral basis largely rooted in a single value, the value of personal autonomy. The latter finds its moral basis in a host of different values, including personal liberty and dignity, solitude, self-esteem, self-identity, and the development of one's individuality for the sake of achieving happiness.(5) (131, with references)

With regard to the European Union Data Protection Directive (1995), she writes,

> The DPD explicitly states that "data-processing systems are designed to serve man." With this in mind, the DPD finds its moral basis in the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms, specifically in this Convention's statement that "everyone has the right to respect for his private and family life, his home and his correspondence." These words, particularly the mention of 'correspondence,' ring of the language of the Fourth Amendment and privacy construed as the 'right to be left alone.' They are also though suggestive of the constitutional 'zone of privacy' that Justice Douglas argued for in the Griswold decision. *The moral values underlying the DPD can accordingly be tied in both to the European Convention for the Protection of Human Rights, and to the US Constitution.* (132: emphasis added, CE)

Nonetheless, beyond the initial comparison offered here between the NESH Guidelines and the U.S. AAAS report, additional support for my claim that the U.S. approach is more consequentialist in contrast with a more deontological European approach may be seen in the different approaches each takes to laws concerning e-commerce and e-consumers. Briefly, U.S. law places the burden of privacy protection first of all on the *consumer* - placing corporate "rights" to gather information on consumers ahead of individual rights. By contrast, the E.U. Data Protection Act, as noted above, places priority on protecting individual privacy rights over corporations' and governments' interests in collecting information on individuals. See John R. Aguilar ("Over the Rainbow: European and American Consumer Protection Policy and Remedy Conflicts on the Internet and a Possible Solution," *International Journal of Communications of Law and Policy* (Issue 4, Winter 1999/2000, 1-57) extensively documents this contrast: see especially section III, "E-Commerce Concerns and the Cultural Battle Waging Between the EU and US" (11ff.)

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Multi-beneficiary Annotated General Grant Agreement

Articles 1 to 14, 16 to 19, 23a to 25, 32 to 35, 41 to 44, 52 to 54, 56 and 58

Version 1.3
26 March 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added

Foreword

The **Horizon 2020 Annotated Model Grant Agreement** ('Annotated MGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are **annotated** are bold and in **blue**.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

2. As the Annotated GA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

The Annotated GA will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

ⓘ *For more information, see the Horizon 2020 Online Manual on the Participant Portal.*

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[1] **Horizon 2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
Horizon 2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 General Model Grant Agreement annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[1],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

> The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]
>
> *ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.*

The **division of roles and responsibilities within the consortium** is explained in Article 41.2. Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 [Horizon 2020] having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Commission, in the electronic exchange system ('My Area' section of the Participant Portal).

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on the procedures for beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. Action

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The actions covered by the General MGA are all types of:

- research and innovation actions (i.e. actions with activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- innovation actions (i.e. actions with activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- coordination and support actions (i.e. actions consisting in aaccompanying measures such as standardization, dissemination, awareness-raising and communication,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation Regulation (EU) No 1290/2013: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.*

networking, coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

Complementary grants are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*. .

[6] *For the definition, see Article 2.1(7) of the Rules for Participation Regulation (EU) No 1290/2013: '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' ('EU/Euratom financial contribution' in FP7 projects) of the action *(see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

For the General MGA, these are:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs and
- specific categories of costs (if option applies).

⚠ The budget category 'specific categories of costs' only applies when a Commission decision has specifically foreseen to use:

- unit costs for one or several categories of costs for specific activities (they may include both direct and indirect costs)

  For the General MGA, this is currently provided for:

  - access costs for providing trans-national access to research infrastructures (Decision C(2013) 8199[7]; *see Article 6.2.F*)
  - costs of energy efficiency measures in buildings (Decision C(2013) 8196[8]; *see Article 6.2.F*)

- lump sum costs for one or several categories of costs for specific activities (they may include both direct and indirect costs).

  This option is currently not foreseen for the General MGA.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount mentioned in Article 5 cannot however be increased.

What can be transferred? If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

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[7] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme.
Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[8] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No adjustment of amounts set out as lump sums

If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category, or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No adding of costs relating to subcontracts not provided for in Annex 1

Subcontracting a task while the action is being implemented *(e.g. the beneficiary decided not to recruit additional personnel as initially foreseen but to call upon a subcontractor)* is considered as a significant change of Annex 1.

Therefore, the transfer of budget intended to increase the eligible costs under the budget category 'subcontracting' (due to an additional subcontract) is considered as reflecting a significant change in Annex 1and would normally require an amendment *(see above)*.

If an additional subcontract (not foreseen in Annex 1 and Annex 2) needs to be awarded and no amendment has been signed, it can be approved by the Commission/Agency together with the periodic report *(for the conditions, see Article 13)*, but the beneficiary will assume the risk of non-approval and consequent rejection of costs.

Example:

A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new

subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary fails to request the amendment (at its own risk) but justifies the change in the periodic technical report and the Commission approves the report. The cost of the additional subcontract may thus be eligible.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

*[**OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation Regulation (EU) No 1290/2013: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[5] For the definition, see Article 2.1(14) Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[6] To be used only if option in Point (f) is used.

[7] To be used only if option in Point (f) is used.

[8] To be used only if option in Point (f) is used.

[9] To be used only if option in Point (f) is used.

[10] To be used only if option in Point (f) is used.

[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.

[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a price due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for research actions ('research and innovation actions') is in principle 100% of the total eligible costs. For innovation actions it is in principle 70% of the total eligible costs.

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[9] and all budget categories.

3. Forms of costs

The different types of forms of costs are as follows:

[9] *See Article 28(6) of the Rules for Participation.*

- **actual costs** (i.e. costs which are real and not estimated budgeted or imputed)

  Examples:

  EUR 62 500 actual yearly salary for senior researcher A

  EUR 2000 actual price for a computer

  The actual price paid for the subcontracting of a trial

  The financial support actually paid to third parties

- **unit costs** (i.e.

  - either a fixed amount per unit of measure, where the total amount depends on the number of units used for the action

    Example: *Direct personnel costs of SME owners not receiving a salary and of natural persons not receiving a salary may be declared using a fixed amount per unit of measure fixed by the Commission*

  - or an amount per unit of measure calculated by the beneficiary in accordance with its usual cost accounting practices for personnel costs)

    Example: *EUR 60,000 average salary for senior researchers*

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs)

  ⚠ In Horizon 2020, flat-rate costs will only be used to declare eligible indirect costs (i.e. as a flat rate of 25% of direct costs minus subcontracting and in-kind contributions by third parties not used on the beneficiaries' premises to declare the eligible indirect costs).

- **lump sum costs** (i.e. an fixed amount based on an estimate which is used by a beneficiary to declare as eligible):

  - either the overall implementation costs of an action

    Example: *EUR 150 000 to carry out a study*

  - or the costs of one or several specific categories of eligible costs.

    Example: *EUR 10 000 for travel expenses of each beneficiary within a project*

⚠ The conditions for eligibility, for each form of costs, are set out in Article 6.1.

⚠ Unit costs, flat-rates and lump sums must be authorised by Commission decision[10] (unless already set out in the Rules for Participation) and be set out in the work programme.

For the General MGA, a Commission decision currently exists for:

- direct personnel costs of SME owners not receiving a salary and of natural persons not receiving a salary (Decision C(2013) 8197[11]; *see Article 6.2.A.4*)

[10] *See Article 124 of the Financial Regulation.*

[11] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are

– access costs for providing trans-national access to research infrastructures (Decision C(2013) 8199[12]; *see Article 6.2.F*)

⚠ This specific category concerns only *access costs*. It does not concern other costs that may be incurred for providing trans-national access to research infrastructures (i.e. costs of travel and subsistence for the selected users; *see Article 6.2.F and Article 16*).

– costs of energy efficiency measures in buildings (Decision C(2013) 8196[13]; *see Article 6.2.F*)

The unit cost on the basis of the beneficiaries' usual accounting practices and the flat-rate of 25% for indirect costs are provided for in the Rules for Participation.[14]

Each category of costs can be covered by different forms of costs. Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

12 Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

13 Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

14 *See Article 29(1) and 33(2) of the Rules for Participation.*

	salary					
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared under any other budget category.

Thus, if for instance personnel costs are included in the costs under Article 5.2(f), these personnel costs cannot also be declared as direct personnel costs under Article 5.2(a).

Example:

A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.

Personnel Costs of beneficiary A:

100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis

Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)

Number of sample analysis in a laboratory for beneficiary A: 450

Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

ⓘ For the types of costs included in the unit or lump sum costs under Article 5.2(f), see Article 6.2.F.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

– the **reimbursement rate** (Step 1)

– the amount of **eligible costs** approved by the Commission (Step 1)

– the limitation to the **maximum grant amount** (Step 2)

- compliance with the **no-profit rule** (Step 3)
- the extent to which the action was implemented properly (**work implementation**, i.e. if the work was carried out as described in Annex 1; Step 4) and
- **compliance** with all the **other rules** set out in the GA (Step 4).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** and not approved.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation or **breach of another obligation under the GA** may lead to a **reduction of the grant** (i.e. reduction of the 'maximum grant amount').

Example: *One of the 3 test plants was not built, and several testing activities were not carried out*

Example: *Breach of the obligation to display the EU emblem (article 29.4) or to respect confidentiality of information identified as confidential.*

⚠ The Commission/Agency will decide on a case by case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*).

⚠ In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Examples:

A deliverable is delayed by a couple of days because the researcher responsible is on sick leave.

A scientific test has to be redone at a later time due to meteorological conditions.

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

2. No-profit rule

The EU/Euratom grant amount may not have the purpose or effect of producing a profit for the beneficiaries.

For this reason, the total funding requested from EU/Euratom + receipts cannot exceed the total eligible costs.

At the time of payment of the balance, this means that the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts ≤ total eligible costs ➔ no reduction of EU/Euratom grant amount

⚠ Contrary to FP7, in Horizon 2020 profit must be assessed at the level of the action and not at the level of the individual beneficiaries.

The grant amount, receipts and eligible costs taken into account are the consolidated grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

3. Receipts

What? Three kinds of receipts must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples:

  Admission fee to a conference organised by the consortium.

  Sale of equipment bought for the action.

  ⚠ The receipt from the sale of assets is capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

  ⚠ It is considered a receipt if the value of the in-kind contribution given free of charge (corresponding to the costs incurred by the third party and not by the beneficiaries who receive it) has been declared by the beneficiary receiving it as an eligible cost for the action.

What not? The following are not receipts:

- **income generated by exploiting the results** of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- **financial contributions** given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to **cover costs other** than the eligible costs

  Example: *currency exchange losses*

– **financial contributions** given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

Example:

A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same project are not considered receipts either, since receipts are only contributions from *third parties*. Therefore, if a beneficiary funds another beneficiary in the same GA to help it carry out work, this will not be considered a receipt.

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Conversely, the financial contribution made by the beneficiary to another beneficiary is not considered as an eligible cost for the beneficiary giving the contribution.

In summary, this financial contribution is not a receipt for the beneficiary receiving it, and it is not either an eligible cost for the beneficiary giving it.

When? Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (for FP7 the 'final payment').

Beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

⚠ In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

Eligible costs: 100 and grant amount: 70

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

Eligible costs: 100 and grant amount: 100

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

⚠ Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the consortium agreement (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7).

⚠ You will have been requested to estimate the receipts of your action when submitting the proposal.

4. Calculation of the final grant amount

Calculation of final grant amount

Step 1 — Application of reimbursement rates to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA at the payment of the balance

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

⬇

final grant amount

Example:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Step 1 — Application of the reimbursement rates to the eligible costs

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Step 2 — Limit to the maximum grant amount

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Step 3 — Reduction due to the no-profit rule

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA at the payment of the balance:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

When? The final grant amount *(see above)* may be revised, if the Commission/Agency finds — after the payment of the balance — that a beneficiary declared costs that are ineligible, or that a beneficiary breached its obligations or improperly implemented its work under the GA (and therefore **rejects the costs** or **reduces the grant** for that beneficiary).

The 'revised final grant amount' is calculated at beneficiary's level:

2. Calculation of the revised final grant amount

If the **costs** unduly declared as eligible by the beneficiary concerned are **rejected** by the Commission/Agency as ineligible, the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000

Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500

Costs rejected following audit: 30 000

Revised direct eligible costs: 120 000

Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000

Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount (calculated according to Article 44.1.3), it must repay the difference to the Commission/Agency.

If the **grant** is **reduced** due to improper implementation or breach of obligations by the beneficiary, the Commission/Agency will:

- reduce the maximum grant amount set out in Article 5.1, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.

Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

Example 1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

Example 1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A

Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount (calculated according to Article 44.1.3), it must repay the difference to the Commission/Agency.

⚠ In case of rejection of costs *and* reduction of the grant, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

Only eligible costs can be reimbursed by the Commission/Agency ('reimbursement of eligible costs grant').

⚠ This must be taken into account already at proposal stage, when the beneficiaries prepare the estimated budget for the action *(see Article 4)*.

⚠ Moreover, all the costs the beneficiaries declare in their financial statements *(see Article 20)* must comply with the general and specific conditions set out in this Article.

Article 6.1 refers to general eligibility conditions applicable per form of cost.

Article 6.2 refers to specific eligibility conditions applicable per budget category.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action.*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

  This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

  Costs actually incurred should normally also be **paid** during the action duration.

  In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — if the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — if the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*.

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. they must be necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation).

  ⚠ Accounting documentation is necessary only for actual costs.

  ⚠ In addition, indirect costs do not need supporting evidence because they are declared using a flat-rate.

Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

Example: if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.

⚠ This principle cannot be used as justification for non-compliance with other GA provisions.

It is clear that a beneficiary is obliged to introduce any changes necessary to bring its usual cost accounting practices in line with all GA provisions.

Examples: conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)

⚠ For in-kind contributions provided by third parties free of charge and costs of linked third parties, eligible direct costs must be:

- recorded in the third party's accounting records;
- calculated in accordance with the accounting standards applicable in the country in which the third party is established;
- calculated according to the third party's usual cost accounting practices;

- in **compliance with applicable national laws on taxes, labour and social security**
- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive).

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality.

  It can be linked to 'efficiency', which is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit').

Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

For personnel costs declared on the basis of the beneficiary's usual cost accounting practices, the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices;
- must budget and declare a total amount; the amount per unit must not be included in Annex 2;

⚠ Beneficiaries cannot declare other types of unit costs according to their own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be calculated according to a Commission decision and agreed on by the Commission *(see in Annex 2 of the GA, Article 5.2)*.

Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action.

⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

Example:

A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.

Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600

Total eligible costs: 11 900 + 2 600 = EUR 14 500.

Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*: *costs of [insert cost category or activity*[13]*]*]**.

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Direct costs

Direct costs are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (this may comprise internal invoices, which must not include indirect costs elements or profit margin or mark-up; *see Article 6.2.D*).

2. Indirect costs

Indirect costs are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

In Horizon 2020, indirect costs are charged under the form of a 25% flat-rate of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81) ('Rules for Participation Regulation No 1290/2013'): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs — Types of costs — Conditions for eligibility

Beneficiaries may declare the following **types of costs** as direct personnel costs:

- basic remuneration — **basic salary and complements**
- for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs of **personnel seconded by a third party**
- costs of '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs of '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

Direct personnel costs may be declared as actual costs or on the basis of unit costs *(see Article 5.2(a))*.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as direct personnel costs.

Basic salary and complements ('basic remuneration')

The basic salary and complements (or parts of them, 'components') are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- they are **mandatory** under national law, collective labour agreements or the employment contract
- they are paid to the employee (or benefit to him/her) **for** his/her ***usual*** **work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

⚠ It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract but he/she must be 'assigned to the action' (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

⚠ If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

⚠ For secondments or linked third parties, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

What? The basic salary includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

'Parental leave' covers both maternity leave and parental leave.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

The complements may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

What not? The basic remuneration does not include components that must be considered to be 'additional remuneration'.

Example (variable remuneration component acceptable as basic remuneration):

The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.

⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs. ERC Grants are an exception to this rule: there, recruitment costs are eligible as direct costs because recruitment is one of the action's activities.

Remuneration of post graduate students employed by the university (beneficiary) — if a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible if they fulfil the conditions set out in Article 6.

ⓘ For more information on personnel (resources) made available to a beneficiary by a third party, see below and Articles 11 and 12.

Additional remuneration ('bonus' payments) for non-profit legal entities

Additional remuneration is **eligible**, if all of the following apply:

- it **fulfils** the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

  Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours

Remuneration components:

a = annual salary: EUR 50 000

b = salary complement for holding a management post (e.g. Head of department): EUR 5 000

c = additional remuneration for being Head scientist in a project: EUR 2 000

d = additional remuneration for being First Assistant on an internal action: EUR 1 000

***a** and **b** would be used to calculate the researcher's hourly rate:*

hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34

***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*

***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- it is paid to the employee (or benefits him/her) for **additional work** or **expertise**

  The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

  Examples (acceptable additional remuneration):

  A normal salary is paid for teaching + additional remuneration is paid for doing research.

  A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

  A normal salary is paid for laboratory research + additional remuneration is paid for field research.

  Examples (not acceptable additional remuneration):

  Additional remuneration paid for using English.

  Additional remuneration is paid for participating in EU funded or multi-partner actions.

- it is part of the beneficiary's usual remuneration practices and is consistently paid whenever the same kind of work or expertise is required

- the **criteria** used to calculate the extra payments are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

  The objective criteria must be related to the additional work or expertise.

  The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

  ⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

What? 'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

Costs for natural persons working under a direct contract

Costs for natural persons working under a direct contract are **eligible** as personnel costs, if all or the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there is a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.
- the person works under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out **belongs to** the **beneficiary**

  The work carried out, including any resulting patents or copyrights, must belong to the beneficiary.

- the **costs** are **not significantly different** from those for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

What? This is typically the case of in-house consultants (i.e. self-employed natural persons working part-time or full-time for the action; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

Costs of personnel seconded by a third party

Costs of personnel seconded by a third party are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- the person is **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.

- the beneficiary **reimburses the costs** to the third party (not for free)

- the **additional specific eligibility conditions** set out in Article 11.1 are fulfilled.

⚠ The seconded personnel is considered an 'in-kind contribution provided by a third party against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

Costs of beneficiaries that are SMEs for their owners not receiving a salary

Personnel costs of SME owners not receiving a salary are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- they correspond to the amount per unit (EUR/hour worked on the action; hourly rate) set out in Annex 2 multiplied by the number of **actual hours worked on the action**
- they are declared for an **owner** of an **SME** who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

⚠ The cost must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[15] and set out in Annex 2 of the GA.

Costs of beneficiaries that are natural persons not receiving a salary

Costs of beneficiaries that are natural persons not receiving a salary are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- they correspond to the amount per unit (EUR/hour worked on the action; hourly rate) set out in Annex 2 multiplied by the number of **actual hours worked on the action**
- they are declared for a beneficiary that is **natural person** who **works on the action** but **does not receive a salary**.

⚠ The cost must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[16] and set out in Annex 2 of the GA.

Personnel costs for providing trans-national or virtual access to research infrastructure

This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities *(see Article 16)*.

Personnel costs (i.e. basic remuneration, additional remuneration, costs for natural persons working under a direct contract, costs of personnel seconded by a third party against payment; *see above*) incurred for providing trans-national or virtual access to research infrastructure must — in addition to the conditions above — comply with the **additional cost eligibility rules** set out in Article 16.1 or 16.2.

2. Direct personnel costs — Calculation

Basic remuneration costs, costs of personnel seconded by a third party against payment and personnel costs for providing trans-national access to research infrastructure

All types of personnel cost — except for costs for natural persons working under a direct contract, costs of SME owners not receiving a salary, and costs of beneficiaries that are natural

[15] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[16] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

persons not receiving a salary *(see below)* — must be calculated using the following formula set out in the GA:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

On the basis of this formula, the beneficiary must — for each person for whom it declares costs — follow three steps:

Step 1 — Calculation of the hourly rate

Step 2 — Multiplying the hourly rate by the number of actual hours worked on the action

Step 3 — For non-profit legal entities: Addition of additional remuneration, if any

Example (for calculation of basic remuneration costs):

A nuclear researcher working for a public research laboratory (non-profit) worked:

1 600 productive hours

800 hours declared for the action (at an hourly rate of EUR 40)

400 hours declared for another EU grant

S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.

*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***

Addition of the additional remuneration: = ***2 000***

Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Step 1 — Calculation of the hourly rate

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.

Remuneration components:

a = annual salary: EUR 50 000

b = extra payment for holding a post involving radioactive hazards: EUR 5 000

c = additional remuneration for being Head Scientist in a Project: EUR 2 000

***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*

*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception: **Employees hired** during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Example:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:

From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.

From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.

From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 → the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) (‘**1720 fixed hours**’)
- the total number of hours worked by the person in the year for the beneficiary (‘**individual annual productive hours**’)
- the ‘standard number of annual hours’ generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices (‘**standard annual productive hours**’).

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities.

Using only the so-called ‘billable hours’ is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary’s cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	**In all cases** Any beneficiary can use this option.	∅ **Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: ○ employment contract of the person concerned ○ applicable collective labour agreement ○ national law on working time ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group of personnel under similar conditions).	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		Example (calculation of individual annual workable hours): *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. ⚠ The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. ⚠ The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: o the employment contracts of the reference group o an applicable collective labour agreement or	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than

		○ the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* ⚠ If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. ⚠ If its number of standard annual productive hours is lower than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* ***Standard annual productive hours** for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:*	90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		*Annual working days = **228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = **212*** *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = **1 642*** ***1 696 hours** (usual cost accounting practice) **> 1 642 hours** (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

For personnel costs declared as a unit cost on the basis of the **beneficiary's usual cost accounting practices ('average personnel costs')**, the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

– the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

– the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

If necessary, it must be adjusted to fulfil all eligibility criteria.

Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

Costs that are already included in other budget categories must be taken out (double funding of the same costs).

Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

– are relevant, i.e. clearly related to personnel costs

– are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

– correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.

– the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the electronic exchange system) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — Multiplying the hourly rate by the number of actual hours worked on the action

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — For non-profit legal entities: Addition of the additional remuneration, if any

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

***Example**:*

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (eligibility ceiling):

{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000

The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

Costs for natural persons working under a direct contract

The calculation of costs for natural persons working under a direct contract for a beneficiary (i.e. a contract which is not governed by labour law) depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount).

A calculation method is required, in particular if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same formula explained in point 1 above (i.e. hourly rate multiplied by the number of actual hours worked on the action).

⚠ Even if the formula is the same, the hourly rate is different, as it is not based on the annual personnel costs as registered on the payroll.

How? Beneficiaries must use one of the following options:

- if the contract specifies an hourly rate, then this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person, then this global amount must be divided by the number of hours worked for the beneficiary under that contract.

Costs of SME owners and beneficiaries that are natural persons not receiving a salary

Costs of an SME owner not receiving a salary and costs of a beneficiary that is a natural person not receiving a salary must be calculated by multiplying the amount per unit (EUR/hour worked on the action, the hourly rate) set out in Annex 2 by the number of actual hours worked on the action.

This amount per unit (hourly rate) is based on the calculation set out in Commission Decision C(2013) 8197[17]:

{Monthly living allowance for experienced researchers under the Individual Fellowship actions of the Marie Skłodowska-Curie actions / 143 hours}

multiplied by

{country-specific correction coefficient / 100}

The amount of the monthly living allowance for experienced researchers under the Individual Fellowship actions of the Marie Skłodowska-Curie to be used here is always the same: EUR 4,650.

This is a reference amount for all cases of SME owners and beneficiaries that are natural persons not receiving a salary.

It does not require that the SME owner or the natural person is an experienced researcher.

On the other hand, the country-specific correction coefficients will vary according to the country. They are published in the Marie Skłodowska-Curie Actions (MSCA) part of the Work Programme[18] (Table 4).

Example:

A German SME owner not receiving a salary will calculate the hourly rate as follows:

EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

⚠ SME owners who receive a salary registered as such in the accounts of the SME cannot declare costs based on this unit cost.

[17] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[18] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

⚠ If the SME owner can show evidence that his/her salary corresponds exclusively to the management of the SME, s/he may declare his/her personnel costs for the action based on the unit cost set out in Annex 2. The salary for the management of the SME cannot be declared.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment (via the electronic exchange system), in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting — Types of costs — Conditions for eligibility — Calculation

Direct costs of subcontracting are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- they are incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- the **additional cost eligibility rules** set out in Article 13.1.1 are fulfilled
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: the **additional cost eligibility rules** set out in Article 16.1 or 16.2 are fulfilled.

  This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities *(see Article 16)*.

Direct costs of subcontracting must be declared as actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as direct costs of subcontracting.

> ***Example:*** *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

What? Subcontracting costs include (and are limited to) the price paid and the related taxes *(for VAT, see Article 6.5)*.

C. Direct costs of providing financial support to third parties *[(not included in Point F)] [OPTION to be used if Article 15 applies:* *are eligible if the conditions set out in Article 15 are met.]*[***OPTION***: *not applicable]*

1. Direct costs of providing financial support to third parties — Types of costs — Conditions for eligibility — Calculation

Direct costs of providing financial support to third parties are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **additional cost eligibility rules** set out in Article 15.1.1 are fulfilled.

⚠ This budget category is optional and can be used only if the option applies.

Direct costs of providing financial support to third parties must be declared as actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as direct costs of providing financial support to third parties.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances — Types of costs — Conditions for eligibility — Calculation

Travel cost and related subsistence allowances are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- they are in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.

  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

  If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

  If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

  ⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary).

  The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: the **additional cost eligibility rules** set out in Article 16.1 are fulfilled.

  This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities *(see Article 16)*.

Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

⚠ Travel and subsistence costs incurred for the selected users are not included in the unit cost for access costs for providing trans-national access to research infrastructure *(see Article 6.2.D.1 and Article 16)*.

What? Travel costs and related subsistence allowances may also include all related duties, taxes and charges that the beneficiary has paid *(such as non-deductible VAT; see Article 6.5)*, if including them is part of the its usual practices for travel.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the

experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs — Types of costs — Conditions for eligibility — Calculation

Beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs':

one of the following:

– either **depreciation costs** of equipment, infrastructure or other assets

– or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

– costs of **renting or leasing** of equipment, infrastructure or other assets

– costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

Equipment costs must be declared as actual costs *(see Article 5.2(d))*.

⚠ No equipment costs may be declared for providing trans-national or virtual access to research infrastructure.

This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities *(see Article 16)*.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

Depreciation costs of equipment, infrastructure or other assets

Depreciation costs are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- they have been **purchased** in **accordance with Article 10.1.1**
- they are **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

What? Equipment costs include the depreciation for the relevant periodic report. It is expected that the beneficiary allocates the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

Depreciated equipment costs can never exceed the equipment's purchase price.

Depreciation cannot be spread over a period longer than the equipment's useful life

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a

Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

Specific cases:

Equipment not used exclusively for the action — if the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

{equipment's total useful life}.

'Useful life' means the time during which the equipment is useful to the beneficiary.

⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

Cost of purchasing equipment, infrastructure or other assets

Under this option, the full purchase costs of the assets are eligible (not only the depreciation costs).

This option will apply if it is specifically included in the work programme. Otherwise, the beneficiary cannot use this option and the general depreciation rule applies.

Costs of renting or leasing equipment

Costs of renting or leasing equipment are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- they do **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- they do **not** include any **financing fees**.

What? Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.

⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the

property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

Costs of equipment, infrastructure or other assets contributed in-kind against payment

Costs of equipment, infrastructure or other assets contributed in-kind against payment are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- they do **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- they do **not** include any **financing fees**
- the **additional cost eligibility rules** set out in Article 13.1.1 are fulfilled.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services — Types of costs — Conditions for eligibility — Calculation

Costs of other goods and services are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - they are either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: the **additional cost eligibility rules** set out in Article 16.1 or 16.2 are fulfilled.

  This option will be inserted in the GA only for actions involving trans-national or virtual access to research infrastructure for scientific communities *(see Article 16)*.

Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

What? The list of **types** of goods and services that may be declared under this article includes:

- consumables and supplies
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results *(e.g. fees paid to the patent office for patent registration)* and royalties on access rights
- certificates on financial statements (CFS) and certificates on methodology

  ⚠ If the grant agreement does not require a CFS (i.e. if the EU or Euratom contribution is less than EUR 325 000), CFS costs are not eligible, because they are not considered necessary.
- translation costs, if translation is necessary for the action's implementation, is justified, etc.

⚠ If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If considering all or some of these costs as indirect costs is part of the beneficiary's usual accounting practices, the costs cannot be charged to the action as direct costs, as they are covered by the 25 % flat rate.

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) **paid to a third party** (i.e. not a beneficiary) (see Article 24) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees **paid for access rights to background granted by other beneficiaries** *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Examples:

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

⚠ Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[16] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December. 2013 establishing H2020 - The Framework Programme for Research and Innovation (2014-2020): **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure — Types of costs — Conditions for eligibility — Calculation[19]

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

⚠ No capitalised and operating costs of large research infrastructure may be declared in certain calls under the Part 'Research Infrastructure'.

⚠ Costs that are already covered by a unit cost or lump sum under Article 5.2(f) may not be declared as other direct costs.

What? Beneficiaries may declare **capitalised costs** and **operating costs** of research infrastructure used for the action.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Capitalised costs are:

– all costs incurred in setting up and/or renewing the research infrastructure and

[19] This part of the Annotated MGA was adopted by Commission Decision C(2013) 8699 of 10 December 2013 on guidelines on the application of Point D.4 of Article 6.2 of the General Model Grant Agreement for Horizon 2020 – the Framework Programme for Research and Innovation of the European Union (2014-2020) and the Research and Training Programme of the European Atomic Energy Community (2014-2018) (direct costing for large research infrastructure). Available at [hyperlink].

– some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

Operating costs are costs:

– which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and

– are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

– personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;

– rental/lease of the research infrastructure (for the period of its actual use for the action);

[20] *See also International Financial Reporting Standard No 16.*
[21] *See Article 126 of the Financial Regulation.*

- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments)
- knowledge-based resources such as collections, archives or scientific data
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways. The best practice recommended by the Commission is recording them using a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps:

Step 1 — Status validation (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field 'Declaration of costs under Point D.4: YES/NO' in Annex 2. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

[23] *See Article 2(6) of the Horizon 2020 Framework Programme Regulation No 1291/2013.*

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — Methodology compliance (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the Beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to amend previous financial statements already lodged by submitting a '**corrected financial statement**'.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. The auditors will:

(i) ensure that the methodology positively assessed is the one being used and

(ii) verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  ⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

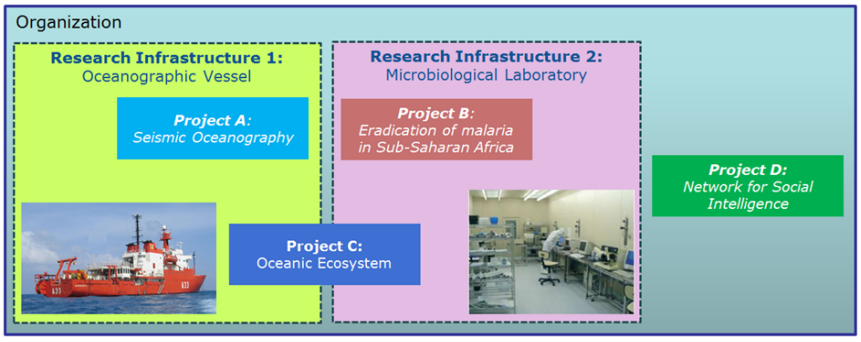

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again (e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; *see Article 16*); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)

  ⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

  ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

[24] *See Article 129(1) of the Financial Regulation.*

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the

number of productive hours/days/months corresponding to the full potential use of the infrastructure)

This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

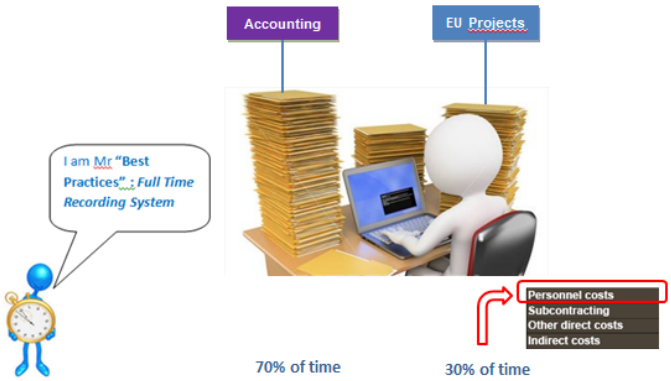

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (best practice: time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices for direct measurement:

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[26].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

[26] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('Financial Regulation No 966/2012'): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs — Types of costs — Conditions for eligibility — Calculation

Indirect costs are **eligible**, if they are declared by applying a 25% flat rate to the beneficiary's eligible direct costs, minus:

- subcontracting costs *(see Article 13)*

  Example: *subcontracting of opinion surveys.*

  ⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties, if this option is included in the GA

- unit or lump-sum costs covering specific categories of costs which include indirect costs.

Indirect costs are covered and must be declared under the form of the flat-rate *(see Article 5.2(e))*.

What? Indirect costs are costs that are not directly linked to the action *(see Article 6.2)*.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs

- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,

- EUR 10 000 in consumables costs.

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]

1. Specific categories of costs — Types of costs — Conditions for eligibility — Calculation

Under this option, beneficiaries may currently declare the following **types of costs** as specific categories of costs:

– **costs of additional energy efficiency measures** (Decision C(2013) 8196[27])

  This option will be inserted in the GA only for actions involving additional energy efficiency measures.

– **access costs for providing trans-national access to research infrastructures** (Decision C(2013) 8199[28]).

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[28] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities *(see Article 16)*.

⚠ If this option 5.2.(f) is used in a GA, the costs covered by this option may not be declared under any other budget category. They have to be excluded from the calculation of the other direct and indirect costs of the beneficiary (declared under the budget categories 5.2(a) to (e)).

Example:

A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.

The situation of A is the following:

A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.

A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.

A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Costs of additional energy efficiency measures

Costs of additional energy efficiency measures *must* be declared on the basis of unit costs.

These costs are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- they correspond to the amount per unit (EUR/m^2 of eligible conditioned gross floor area (excluding parts of the buildings which are not affected by the measures, *e.g. garages*)) set out in Annex 2 multiplied by the number of **actual m^2 of surface area built or refurbished**

This amount per unit is based on the calculation set out in Commission Decision C(2013) 8196:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

with:

the 'standard cost to save 1 kWh' being EUR 0.1

the 'standard payback period' to be used being 10 years

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

⚠ Applicants for Horizon 2020 funding may submit a proposal requesting funding for a number of kWh saved per m² per year lower than the estimated one. But this will not be evaluated as an advantage against other proposals.

- they are incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*.

⚠ This category of unit costs will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

How? Beneficiaries submit **specifications per type of demonstration building in the project proposal** by completing the BEST table (Building Energy Specification Table)[29]. These specifications per type of demonstration building are set out in Annex 1.

In Smart Cities and Communities buildings, the grant is always composed of a combination of different forms of grants as defined in Articles 5 and 6 of the GA. The reimbursement on the basis of unit costs only applies for the building-related demonstration activities part of the building.

What? Two categories of eligible costs are covered:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and
- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

[29] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs are not eligible.

Access costs for providing trans-national access to research infrastructure

Access costs for providing trans-national access to research infrastructure can be declared as one of the following:

- as actual costs
- on the basis of a unit cost or
- on the basis of a combination of actual cost and unit cost, if a part of the eligible access costs (in particular, costs for the specific support to users) varies significantly between users.

Only one of the three forms may be used per installation (i.e. per part or service of a research infrastructure that could be used independently from the rest). A research infrastructure consists of one or more installations. No alternative use is allowed for one installation.

These costs are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- they are incurred for **providing trans-national access to research infrastructure** to scientific communities
- the **additional cost eligibility rules** set out in Article 16.1 are fulfilled
- for actual costs: they comply with the conditions set out above *(see Article 6.2.A to 6.2.E)*
- for unit costs: they correspond to the amount per unit (EUR/unit of access) set out in Annex 2 multiplied by the number of actual units of access provided

  This amount per unit is based on the calculation set out in Commission Decision C(2013) 8199:

  The unit cost is defined on the basis of the average over the last two years of the annual total access costs to the installation, for the categories covered by the unit cost, divided by the average over the last two years of the total quantity of access to the installation annually provided, as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access costs to the installation}}{\textbf{average total quantity of access to the installation annually provided}}$$

  The average amounts must be based on certified or auditable historical data of the beneficiary over the last 2 years (years N-1 and N-2) for the concerned installation, according to the beneficiary's usual cost accounting practices. The average over the last two years of the access costs and quantity of access to the installation does not

include periods where the installation was not usable because it was out of order or under repair or maintenance.

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the provision of the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for the following categories of direct costs:
    - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users. By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices
    - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
    - costs of consumables specifically used for the installation and the research work of the users
    - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
    - costs of energy power and water supplied for the installation
    - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)
    - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
    - costs of specific scientific services included in the access provided or needed for the provision of access
- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

and excluding:

– all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

– travel and subsistence costs to support the visits of users.

⚠ Travel and subsistence costs incurred for the selected users can however be reimbursed separately, as 'other direct costs' *(see Article 6.2.D.1 and Article 16)*.

⚠ A specific form [hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ In exceptional and duly justified cases, the Commission/Agency may agree to use a different reference period than the last 2 years.

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs= average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Applicants for Horizon 2020 funding must describe the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation;

- for a combination of actual and unit costs: the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs.

⚠ This category of costs will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015)*.

What? The access costs for the provision of trans-national access to an installation are defined as the costs incurred by the access provider for the provision of access to an installation. Access costs cover the running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities that may be necessary to carry out user's work on the installation.

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs.

⚠ These costs can however be reimbursed separately, as 'other direct costs' *(see Article 6.2.D.1 and Article 16)*.

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.****]***

[OPTION: *not applicable****]***

1. Costs of linked third parties — Types of costs — Conditions for eligibility — Calculation

The costs of linked third parties may be **eligible**, if:

- they **fulfil** the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- the **additional cost eligibility rules** set out in Article 14.1.1 are fulfilled.

2. Mutatis mutandis

'Mutatis mutandis' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge — Types of costs — Conditions for eligibility — Calculation

Contributions provided by third parties free of charge are **eligible** if:

- they **fulfil** the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- the **additional cost eligibility rules** set out in Article 12.1 are fulfilled.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

In general, ineligible costs are those costs that do not meet the general and specific eligibility criteria set out in Articles 6.1 to 6.4.

Examples:

Additional remuneration ('bonuses') paid by for-profit or non-profit entities that do not fulfil the conditions set out in Article 6.2,

Subcontracting costs that do not comply with the terms of Article 13.

What? Article 6.5 specifies certain types of ineligible costs, including:

Costs related to return on capital or return generated by an investment.

Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

Debt and debt service charges — debt service is the amount paid on a loan in principal and interest, over a period of time

Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

Provisions for future losses or debts — a provision is an amount set aside in an organisation's accounts to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

Interest owed — Interest on a loan to borrow capital

Excessive or reckless expenditure — excessive must be understood as paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary, resulting in an avoidable financial loss to the action. Reckless means failing to exercise care in the selection of products, services or personnel resulting in an avoidable financial loss to the action.

Currency exchange losses — for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)* is not eligible.

Bank costs charged by the beneficiary's bank for transfers from the Commission/Agency.

Deductible VAT — deductible VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is neither actually incurred by the beneficiary nor identifiable and verifiable.

Deductible VAT should be recorded in separate payable or receivable accounts, not affecting revenue or cost line items. VAT that is paid to suppliers and is deductible is a claim against the tax authority which will reimburse it, therefore it is recorded in the 'assets' part of the balance sheet. VAT collected on sales is a debt towards the tax authority and is recorded in the 'liabilities' part of the balance sheet. In other terms, where VAT is deductible, the accounts are presented exclusive of VAT.

This means that VAT paid on goods or services by a beneficiary that can recover it under national VAT legislation should not be recorded as expenditure in the profit and loss accounts (only the purchase price excluding VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

Conversely, if VAT is not deductible it is in principle an eligible cost. The full price of the goods or services bought by the beneficiary is recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought is then recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

⚠ In exceptional cases where the beneficiary cannot identify VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price should be recorded in the accounts, since non-identifiable VAT is not deductible. VAT would thus be eligible (in any case).

Costs incurred during the suspension of the implementation of the action

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

Costs declared under another EU or Euratom grant, to avoid double funding. This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

  Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The general obligation to properly implement the action is twofold, i.e. the obligation:

- to carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- to comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the **beneficiaries retain** sole **responsibility** towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third party involvement

The beneficiaries must in principle have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third party involvement**').

⚠ A third party is any legal entity that has not signed the GA *(see Article 1)*.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.

Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors

beneficiary).	usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

2. Beneficiaries retain responsibility

⚠ Beneficiaries using third parties or resources of third parties in an action remain responsible for the work attributed to them under the GA.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

*Chapter 3, **Articles** 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 [**OPTION:** with the exception of additional exploitation obligations], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 **do not apply** to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.**]***

[OPTION: *not applicable**]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION: *not applicable**]***

1. Beneficiaries not receiving EU funding

This Article is an option that will be inserted in the GA only if one of the beneficiaries does not receive EU funding.

⚠ Even if they do not receive EU funding, these entities carry out work under the action, and therefore sign the GA and are recognised as beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

2. Articles that do not apply

The rights and obligations set out in the GA will normally apply to these beneficiaries, but the GA lists a number of provisions that don't. These exceptions must be interpreted restrictively.

Thus, these beneficiaries will, for instance, not be subject to **financial** checks, reviews and audits, but they may be subject to **technical** checks, reviews or audits of their work under the action *(see Article 22)*.

In case of breach of any of their obligations, beneficiaries not receiving EU funding will generally be treated as all other beneficiaries, i.e. their participation may be terminated and any of the other measures of Chapter 6 may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

⚠ The costs of the beneficiary not receiving EU funding itself cannot be rejected.

Given that no payment is due to the beneficiary, conversely it may not have either a debt towards the Commission or Agency.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Best value for money or lowest price

The purchase must be based on the best value for money, considering the quality of the service, good or works proposed (also called '**best price-quality ratio**') or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*.

⚠ Beneficiaries have to demonstrate upon request that the selection of the contractor complied with these rules.

Specific cases:

May the beneficiary declare as eligible the costs of goods, works or services necessary for the action but purchased under framework contracts and contracts existing before the signature of the GA? Yes, if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Occasionally, and only for contracts with a value higher than EUR 60 000, the Commission may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the EU contribution).

⚠ These conditions must also be described in the call for proposals — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *Minimum number of offers received; publication in the OJ or in specific media such as internet, national newspapers, etc.*

3. Beneficiaries that are 'contracting authorities'

Beyond these minimal obligations, a beneficiary that is a 'contracting authority' within the meaning of the EU Directive 2004/18/EC or a 'contracting entity' as described in Directive 2004/17/EC must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive No 2004/18)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive No 2004/17)*.

⚠ Non-compliance with this obligation is considered improper implementation of the GA (breach of an obligation other than compliance with cost eligiblity rules that are set out in Article 10.1.1). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive against payment.

⚠ A third party is any legal entity that has not signed the GA *(see Article 1)*.

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

Example: *medical equipment provided by a hospital to a university in order to carry out research;*

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Beneficiaries may declare the costs related to the payment — Up to the third parties' costs

The payments made to the third party are costs of the beneficiary.

If the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, these costs may be declared by the beneficiary it in its financial statements.

The obligations in Article 11.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

Beneficiaries may **not** declare as eligible **more than** the direct costs **actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The direct costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account if they are used in the premises of the beneficiary.

Example of in-kind contribution against payment used on the beneficiary's premises (the payments by the beneficiary correspond only to the direct costs of third party):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (the payments by the beneficiary correspond to the direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*

- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

3. Third parties and their contributions must be set out in Annex 1 — Approval without formal amendment

The third parties, their in-kind contributions (*i.e. non-financial resources*) and an estimation of the costs budgeted for the in-kind contributions must be mentioned in Annex 1 to the GA.

⚠ If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an amendment of the GA in order to introduce it in the Annex 1.

Exceptionally, the Commission/Agency may approve costs related to the payment of in-kind contributions not included in Annex 1 without formally amending the GA (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Audits of the third parties by the Commission/Agency, ECA and OLAF

The Commission/Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) must have the right to audit the underlying costs of the third parties.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party.

If the third party refuses access, the Commission/Agency cannot verify the eligibility of the costs related to the payment of in-kind contributions and will reject the costs concerned (no-compliance with the cost eligibility criterion set out in Article 6.2).

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (*i.e. without any payment, contrary to the case covered by Article 11*).

There is therefore no cost incurred by the beneficiary for the use of those resources.

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Beneficiaries may declare the costs incurred by the third parties

Since in this case the costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services are not paid by the beneficiary, there is no cost of the beneficiary, but only a cost of the third party.

If the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*, these costs may nevertheless be declared by the beneficiary receiving the in-kind contribution in its financial statements.

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For in-kind contributions that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Third parties and their contributions must be set out in Annex 1 — Approval without formal amendment

The third parties, their in-kind contributions and an estimation of the costs budgeted for the in-kind contributions must be mentioned in Annex 1 to the GA.

⚠ If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an amendment of the GA in order to introduce it in the Annex 1.

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Audits of the third parties by the Commission/Agency, ECA and OLAF

The Commission/Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) must have the right to audit the costs of third parties.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party.

If the third party refuses access, the Commission/Agency cannot verify the costs related to in-kind contributions free of charge and will reject the costs concerned (non-compliance with the cost eligibility criterion set out in Article 6.1 (v)).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

For the purposes of the GA, a 'subcontract' is a contract for the purchase of goods, works or services that are identified in Annex 1 as action tasks.

Subcontracting has the following characteristics:

- the subcontract signed with the beneficiary is based on 'business conditions'; this means that the subcontractor charges a price, which usually includes a profit

  This makes it different from the cases of 'linked third parties' of Article 14 *(see also Article 8)*.

- the subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- the subcontractor's motivation is pecuniary, it is not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- the responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  ⚠ The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA);

- a subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries, as it has no contractual relation with them.

  ⚠ However, the beneficiary must ensure that the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

⚠ Only **limited parts of the action** may be subcontracted.

Exception:

For **actions involving PCP or PPI,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI *(see point 3 below)*.

⚠ Subcontracting between beneficiaries in the same GA is forbidden.

All beneficiaries by definition contribute to and are interested in the action, if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

⚠ Coordination tasks of the coordinator *(such as the distribution of funds, the review of reports and others tasks listed under Article 41.2 (b))* cannot be subcontracted *(see Article 41.2(b))*.

Other activities of the coordinator may in principle be subcontracted.

⚠ In principle, beneficiaries cannot subcontract part of the work to its affiliates unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions.

Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Best value for money or lowest price

The subcontract must be based on the best value for money, considering the quality of the service proposed (also called '**best price-quality ratio'**) or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are considered to be additional cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*.

Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ *For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.*

3. Actions involving PCP or PPI

The additional conditions for actions involving PCP or PPI mirror the key obligations in the GA for PCP/PPI Cofund actions.

⚠ The latter GA contains more detailed obligations since these PCP/PPI Cofund actions consist mainly in subcontracting and undertake PCPs and PPIs as the main objective of an action.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 — Total estimated costs of subcontracting must be set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1.

In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

For **existing framework contracts or subcontracts**, the name of the subcontractor should however be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an amendment of the GA in order to introduce it in Annex 1 and 2.

Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

5. Beneficiaries that are 'contracting authorities'

Beyond these minimal obligations, a beneficiary that is a 'contracting authority' within the meaning of the EU Directive No 2004/18/EC or a 'contracting entity' as described in Directive No 2004/17/EC must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive No 2004/18)*.
>
> ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive No 2004/17)*.

⚠ Non-compliance with this obligation is considered improper implementation of the GA (breach of an obligation other than compliance with cost eligiblity rules that are set out in Article 13.1.1). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

The GA allows that linked third parties implement part of the action, even if they do not sign the GA. Those linked third parties are therefore not beneficiaries.

The characteristics of action implementation by linked third parties are as follows:

– the linked third party does not charge a price, but declares its own costs for implementing the action tasks

– the linked third party itself performs certain action tasks directly and is responsible for it vis-à-vis the beneficiary

⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

– the work is attributed to the linked third party (in Annex 1) and it is usually carried out on its premises

– the work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

– broad and **not specifically created for the work in the GA**

Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from "owner"*

entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[30]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

[30] *See Articles 8 and 9 of the Rules for Participation.*

2. Linked third parties must be identified in Article 14 — Tasks to be implemented must be set out in Annex 1 — Estimated costs must be set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment *(see Article 55)*.

⚠ There is no procedure for approval without amendment.

3. Joint and several liability

This is an option, which the Commission/Agency can use if the financial capacity assessment for a beneficiary is 'weak' while the financial capacity of its linked third parties is strong or if the beneficiary mainly coordinates the work of its linked third parties.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (using Annex 3a) which will be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*).

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

ⓘ *For more information on the financial capacity check, see the Horizon 2020 Online Manual.*

4. Linked third parties may declare the costs they incur

If the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*, these costs may be declared by the linked third party in its financial statements *(see Article 20.3)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

⚠ The obligations in Article 14.1.1 are considered to be cost eligibility rules. Non-compliance will therefore lead to the rejection in full of the costs concerned *(see Article 6.3 and 6.6)*.

Linked third parties have to demonstrate upon request that the costs comply with these rules.

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own financial statements, but these statements must be *submitted* by its beneficiary via the electronic exchange system (since linked third parties do not have access).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**][28].

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

16.2 Rules for providing virtual access to research infrastructure

***[OPTION virtual access to research infrastructure:** '**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION:** not applicable]*

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Providing trans-national or virtual access to research infrastructure

For actions under the Research Infrastructures Part of Horizon 2020, the GA may provide for this option.

These are actions with the following activity:

- providing trans-national or virtual access to research infrastructure[31] and installations[32] for scientific communities ('provision of access activity')

⚠ Research Infrastructure Part actions will always be combined with other activities that can be funded by a Horizon 2020 grant *(e.g. under the General MGA: RIA, IA, CSA activities)*.

They are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics.

'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

The access provided can be trans-national or virtual.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

[31] *For the definition, see Article 2(6) of the Horizon 2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA: '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.*

[32] *For the definition, see the footnote in Article 16 of the MGA.*

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

- for trans-national access:
  - 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
  - users' travel and subsistence costs
  - costs of advertising the trans-national access offered under the action
  - costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
  - costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*
- for virtual access:
  - operating costs of the installation during the course of the action
  - costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
  - costs of advertising virtual access offered under the action
  - costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
  - costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional cost eligibility rules. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

⚠ Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

For trans-national access, beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions;
- the nature of access; and
- the number of units of access provided.

In addition, they must include — both for trans-national and for virtual access — detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided. For virtual access, this must include statistics on all users in the reporting period, compiled through web analytical tools.

2. Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation; or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*, while virtual access applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access is given to selected user groups (free-of-charge).

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet.*

Access is open to all users; users are not selected or even identified.

3. Trans-national access: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Trans-national access: Selection procedure with a selection panel

For trans-national access, cccess providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: *different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. Virtual access: Other conditions — Access services assessed periodically by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 Obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep **information** stored **in the 'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events which are likely to affect significantly or delay the implementation of the action or the EU's financial interests**, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances affecting**:

(i) **the decision to award the grant** or

(ii) **compliance with requirements under the Agreement**.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information at any time, either during the action's implementation or **afterwards**.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

Beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

⚠ If the Commission/Agency, ECA or OLAF need further clarification or information, they may request it.

The beneficiary must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent via the electronic exchange system. Afterwards, it must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the Beneficiary Register up-to-date, including after the end of the grant *(see the preamble and Article 52)*.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The electronic exchange system automatically informs the coordinator whenever the beneficiary updates its information.

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

⚠ Beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

Examples of situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests:

A beneficiary is under financial stress and chooses to liquidate.

A beneficiary is bought by another legal entity.

A beneficiary plans to move its laboratory from a Member State to a non-EU country.

⚠ For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the **Beneficiary Register** and **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with acknowledgement of receipt, etc.) and not* via the Commission's electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ Beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example of a situation that could have affected the decision to award the grant or compliance with requirements under the GA:

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p.1) ('Rules of Application Regulation No 1268/2012): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

Beneficiaries must keep appropriate and sufficient evidence to prove that properly implemented the action and declared costs.

Sufficiency relates to the quantity of evidence; appropriateness relates to its quality.

⚠ Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[33]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60.000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

⚠ If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ This requirement does not affect national laws on keeping documents.

[33] International Standard on Auditing ISA 500 'Audit Evidence'.

2. Original documents

Beneficiaries must **keep original documents**.

⚠ The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, beneficiaries must:

– keep detailed records and other supporting documents to prove the eligibility of the costs declared

– use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

⚠ The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as personnel costs must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

⚠ It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices (called **'average personnel costs'** under FP7), beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the beneficiary's actual personnel costs as recorded in its statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  ⚠ Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

⚠ It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

To get additional assurance, a beneficiary may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2 by approving a certificate on its methodology (CoMUC).

⚠ Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

Exception:

The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval.

The Commission/Agency will not approve the CoMUC if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary can show that they were declared according to the approved practices).

⚠ Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

⚠ Approval is for Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency. The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ *For more information on the certification procedure, see the Horizon 2020 Online Manual.*

7. Records for flat-rate costs

For flat-rate costs, beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

  Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

⚠ Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiary must:

- sign one **declaration** per reporting period to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  ⚠ This declaration must be dated and countersigned for acceptance by the person concerned. A template [hyperlink] is provided on the Participant Portal.

  ⚠ If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiary must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor. A template [hyperlink] is provided on the Participant Portal.

  Time records should include:

  – the title and number of the action, as specified in the GA

  – the beneficiary's full name, as specified in the GA

  – the full name, date and signature of the person working for the action

  – the number of hours per day declared for the action

  – the supervisor's full name and signature

  – a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned

  – a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditor will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

⚠ Alternative evidence will only be accepted if these three criteria are met.

Example of acceptable alternative evidence:

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned;

Criterion 2 is met – the project is identified as XYZ;

Criterion 3 is met – the time is quantified: two weeks.

Example of unacceptable alternative evidence:

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;

Criterion 2 is not met: the project name is not mentioned;

Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

⚠ Beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

It is the beneficiary that must keep the originals of the **financial statements** and the **certificates** on the financial statements of the linked third parties.

⚠ Beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

Beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

Beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

The deliverables are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For 'energy challenge' actions involving additional energy efficiency measures (see also Article 6.2.F and Decision C(2013) 8196), beneficiaries must deliver a 'handover certificate' with their periodic reports (see Article 20.3).This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

When? Deliverables must be submitted at the time specified in Annex 1.

How? The coordinator must submit them through the electronic exchange system *(see Article 52)*, unless Annex 1 specifies another way.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[34] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a best effort obligation.

If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[34] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The access rights set out in Article 25 presuppose that the beneficiaries first identify and agree on what constitutes background for their action. They may do so in any manner *(e.g. positive list, negative list)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

The agreement on background may be a separate agreement (*e.g. if it concerns only certain beneficiaries*) or may be part of the consortium agreement *(see Article 41)*.

Although not obligatory, it is advised to agree on background before the GA is signed, to ensure that beneficiaries have access rights to what is needed to implement the action or exploit its results.

⚠ Beneficiaries must inform the other beneficiaries — before signing the GA — if access to their background is subject to legal restrictions or limits *(see Article 25)*.

2. Background

Beneficiaries may identify as background any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed.

'Intellectual property' should be understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[35].

Possible background extends to input held by other parts of the beneficiary's organisation.

[35] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*.

ⓘ For more information on the eligibility of the royalty fees paid for such licences, see Article 6.2.D.3.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the **right to sub-license**.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a **royalty-free** basis — to background **needed** to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background **needed** for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to **legal restrictions or limits**, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is **needed** to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013 [Horizon 2020]).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider* ***needed*** *to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access rights to background

The GA generally provides that the beneficiaries must provide access rights for background needed *(see below)*.

Beneficiaries may grant additional or more favourable access rights to background, beyond the rights foreseen in the GA.

Examples

Additional or more favourable access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country) or to other input which is not results or background (e.g. information or rights generated or acquired in parallel to the action, informally defined as sideground).

Such additional provisions may be included in the consortium agreement or in a separate agreement, if, for example, they only concern certain beneficiaries.

⚠ Beneficiaries may foresee in the consortium agreement that access rights will be removed if a beneficiary defaults on its obligations *(see Article 41.3)*.

The granting of access rights may be conditional on the acceptance of specific conditions *(e.g. appropriate confidentiality obligations)*.

In such cases, it is recommended, for legal certainty purposes, to specify these conditions in writing as well.

2. Requests for access

Access rights to background are not automatic. They must be requested in writing.

Beneficiaries may use their internal rules to specify how to make such written requests.

⚠ Access may be requested, under the same conditions, even from a beneficiary whose participation was terminated before the action's end.

Access to background for exploitation may be requested **up to one year** after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

Once requested, access rights may be exercised as long as they are needed for exploiting the results *(e.g. until the background patent expires)*.

3. When is the background 'needed'?

There is no definition of 'needed' in the GA. Beneficiaries must assess whether or not access rights are needed on a case-by-case basis, taking into account their action's specificities.

⚠ The background needed must already be taken into account when the beneficiaries identify and agree (in writing) on the background for the action.

To avoid conflicts, it is recommended that beneficiaries agree *(e.g. in the consortium agreement)* on a **common interpretation of what is needed** and

***Example (background needed for implementation)**: if without this background, tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without this background, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Beneficiaries may refuse access to background if they consider that such access is not needed.

In this case, the requesting beneficiary must better substantiate its request or withdraw it.

Disagreements must be solved through the agreed *(e.g. in the consortium agreement)* conflict resolution system.

⚠ The beneficiaries and the coordinator must inform if such conflicts are likely to affect compliance with requirements under the GA, in particular, the execution of the action *(see Article 17.2.)*.

4. Legal restrictions or limits

Beneficiaries must inform the other beneficiaries — before acceding to the GA — of any legal limitations for granting access to their background.

Restrictions or limits can be set out in law or contract.

***Example:** A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ If beneficiaries agree on additional background after they sign the GA, they must immediately inform the other beneficiaries of any related restrictions or limits.

⚠ When contracting on background with third parties after accession to the GA, the beneficiaries must ensure that that they comply with their obligations under the GA.

There is no general rule preventing beneficiaries to grant licenses, including quasi exclusive licenses, to their own background, as long as they can ensure compliance with their obligations under the GA(i.e. Guarantee access). Beneficiaries are even free to grant exclusive licences, if they agree on a waiver of access rights.

5. Royalty-free — Fair and reasonable conditions

For **implementation,** beneficiaries must, in general, grant **royalty-free** access to their background.

Exception:

If agreed by the beneficiaries before the GA is signed, other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

For **exploitation,** beneficiaries must agree on what constitutes **fair and reasonable conditions**, preferably in writing.

⚠ New terminology in Horizon 2020: fair and reasonable conditions include also royalty-free conditions.

Access may be royalty-free or it may include financial (i.e. monetary compensation) or non-financial terms.

Examples:

Monetary compensation could take the form of a lump sum, a royalty percentage, or a combination of both.

Non-financial terms could include a requirement for the beneficiary requesting access:

(a) to grant access to other technology in its possession, or

(b) to agree on cooperation in a different field or in a future project.

ⓘ *For more information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3.*

6. Sublicensing of access rights to background

Access rights do not give the right to sub-licence; sub-licensing is only allowed with the consent of the beneficiary that gives access.

Example:

The beneficiary owning the background agrees that another beneficiary may sublicense its access rights to background to its affiliated entity.

⚠ If sublicensing was freely allowed, this would imply that access rights to the background could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors.

There may be cases where sublicensing of access rights is necessary. In this case, sub-licensing should not be unduly refused.

Example:

A university may need the right to sub-license access to background to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

The terms and conditions of such sub-licensing must be agreed, preferably in writing.

The terms and conditions of sub-licensing may be a separate agreement (*e.g. if it concerns only certain beneficiaries*) or may be part of the consortium agreement *(see Article 41)*.

Sub-licensing does not have to be royalty-free (even if the access rights concerned are).

Specific conditions can be established regarding sub-licensing.

Examples: *Sub-licensing could apply to the background (or part of it), but not to the results; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

7. Waiver of access rights to background

Waivers of access rights to background should be made only on a case-by-case basis, once the background has been correctly identified.

Only written waivers are valid.

The waiver should not be broader than what is actually necessary.

Example:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the background concerned is not exploited by the licensee within a certain period.

8. Access rights for third parties

This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities *(see Article 16)*.

It ensures that the selected users have royalty-free access to the background they need for using the research infrastructure.

The access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

Beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[36] and the Code of Conduct for their Recruitment.[37]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: Beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ *For guidance in this process, see the 'Human Resources Strategy for Researchers' tool*[38] *developed by the Commission.*

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment

[36] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter

[37] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

[38] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must take all measures to implement the General Principles and Requirements of the Charter[39] and of the Code of Conduct[40] that relate to recruitment.

List of principles:

These are in particular the following:

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments.

Detailed obligations:

According to these principles, beneficiaries should have a **clear policy** for recruiting and selecting researchers, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[41])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

[39] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter

[40] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

[41] Available at http://ec.europa.eu/euraxess/jobs

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

3. Working conditions

The beneficiaries must take all measures to implement the General Principles and Requirements of the Charter[42] that relate to working conditions.

List of principles:

These are in particular the following:

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

4. Career development

The beneficiaries must take all measures to implement the General Principles and Requirements of the Charter[43] that relate to career development.

List of principles:

These are in particular the following:

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

[42] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter

[43] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim, to the extent possible for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: Beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

Beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

List of ethical principles:

Ethical principles include in particular:

- respecting human dignity and integrity
- ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- protecting vulnerable persons
- ensuring privacy and confidentiality
- promoting justice and inclusiveness
- minimising harm and maximising benefit
- sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- respecting and protecting the environment and future generations
- following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[44].

[44] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[45].

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink])

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

⚠ Beneficiaries are advised to obtain the approval of a European ethics committee (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 (in addition to requirements that must already be fulfilled before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

[45] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit copies of the following before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

For new opinions, authorisations or notifications, beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications, the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

⚠ When preparing the documents, beneficiaries are advised to request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[46] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including ethics requirements that will be set out in Annex 1; *see point 4*).

[46] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid **a conflict of interests**

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflict of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A conflict of interests exists if shared interests:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

⚠ If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

Beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and **complying with the GA**.

This means the following:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

Beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless for specific reasons, the Commission/Agency expressly renounces it. They will have to do it without any additional EU contribution unless, in the case of termination, the Guarantee Fund provides additional funds to compensate the debt of any withdrawing beneficiary not repaid to the remaining members of the consortium.

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

⚠ An amendment to the GA will be required, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary)

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for whichthe financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **beneficiaries** must send all documents/information via the coordinator, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

> ***Example:** in case of an audit, beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Detailed coordination tasks:

The coordinator must, in particular:

- **monitor** that the action is implemented properly
- act as the **intermediary for all communications**, unless the Agreement specifies otherwise
- **request** and **review** any **documents** or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary (e.g. the summary, the questionnaire etc)

- verifying that the beneficiary submits the documents in the requested format

- ing that the technical information submitted by a beneficiary concerns the action tasks of the related beneficiary as described in Annex 1 (and not something unrelated to the action).

- **submit** the **deliverables** and **reports**

- **distribute payment**s to the other beneficiaries, without unjustified delay

- **inform** the Commission/Agency of the **amounts paid** to each beneficiary, if requested to do so *(see Article 44.1.2)*.

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the Horizon 2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action)*.

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The consortium agreement (CA) is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

They are normally **mandatory** for Horizon 2020 actions, unless exceptionally stipulated otherwise in the Work Programmes, for a specific call for proposals.

In view of their importance for avoiding disputes and ensuring a smooth implementation of the action, the Commission/Agencies **strongly recommend** that every consortium sets up a consortium agreement, even if not mandatory.

The consortium agreement should in principle be negotiated and concluded **before the action starts**. If the consortium agreement is not agreed before that moment, there is usually a serious risk that prolonged disagreement jeopardises the action.

The CA must be in writing. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity , such as a European Economic Interest Grouping, association or joint venture)*.

⚠ The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the Horizon 2020 Online Manual.

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the GA will provide for this option.

The collaboration agreement is an agreement between the beneficiaries and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

They are mandatory for all complementary actions under Horizon 2020.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the GA will provide for this option.

The coordination agreement is an agreement between the beneficiaries and partners from a third country — including scientific and technological organisations and agencies — or an international organisation, with which the joint call was organised.

Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

A Coordination agreement is mandatory for all joint actions under Horizon 2020.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds ineligible costs *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the amount that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* 'contradictory procedure'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('review procedure')

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Detailed procedure (contradictory procedure):

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention to reject costs (and their amount and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** the rejection.

⚠ This procedure will normally be **combined** with the procedures on **reduction** of the grant and/or **recovery** *(see Articles 43 and 44)*. In this case, there will be one single pre-information letter for all procedures and one single reply and beneficiaries are expected to submit one **single set of observations** that address the different aspects.

Detailed procedure (review procedure):

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in the 'My Area' section of the Participant Portal).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — if the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has not been properly implemented or that other obligations have been breached, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant amount will be proportionate to the improper implementation of the action or the seriousness of the breach.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the detailed procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Detailed procedure:

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.
Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).

Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.
Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries):

During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000

For recovery (see Article 44.1.3):
The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries):

During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

41.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[1] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency paid too much, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the amount that is undue.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The **basic procedure** for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issue a **debit note** against the beneficiary concerned.

The beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the beneficiary does not pay by this date the Commission/Agency will **recover** the amount (with interest at the rate fixed according to Article 21.11) in one of the following ways:

- by offsetting it[47]

  Offsetting consists of subtracting the amount the debtor (i.e. beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[48]If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the debit note on behalf of the Guarantee Fund (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by holding the linked third party liable

  or

  - by either:

    - taking legal action in a national court or the Court of Justice of the EU *(see Article 57.2)* or

[47] *See Article 80(1) of the Financial Regulation.*
[48] *See Article 87 of the Rules for Application.*

– adopting a Commission decision that is enforceable within the meaning of Article 299 TFEU[49].[50]

The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and following this, the Guarantee Fund had to intervene.

ⓘ For the detailed procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Detailed procedure:

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

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[49] *See Article 299 TFEU: 'Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.'*

[50] *See Article 79(2) of the Financial Regulation.*

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000 .

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Detailed procedure (recovery due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see above point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Detailed procedure (recovery due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate
- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000;C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000
Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.
Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:
Beneficiary approved costs multiplied by the reimbursement rate (100%)
** final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)
Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, '**formal notifications**', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all **communication** must be made **through the electronic exchange system** and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a '**Legal Entity Appointed Representative (LEAR)'**. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the **electronic exchange system**).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Formal notifications

The beneficiaries must make a formal notification if this is required by the GA (i.e. if the GA refers to 'formal notifications' or 'formally notify').

Formal notification via the electronic exchange system must be made using the 'formal notifications box' in the 'My Area' section of the Participant Portal).

2. Communicating via the electronic exchange system

All communication between the consortium and the Commission/Agency must be in electronic form via the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

In principle, all communications from/to the Commission/Agency must go **through the coordinator**, unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations)*.

⚠ Only people who have access to the electronic exchange system (have a user account) and are authorised to use the system may directly communicate with the Commission/Agency.

Access requires a European Commission Authentication System (ECAS) account.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only people who have been assigned one of these roles may directly communicate with the Commission/Agency.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ For more information on access and roles in the electronic exchange system, see the Horizon 2020 Online Manual.

⚠ Only formal notifications made after the balance is paid may be sent on paper, by registered letter with acknowledgement of receipt.

All other communication made after the balance is paid must be done via the electronic exchange system.

3. Date and time of messages sent through the electronic exchange system

The electronic exchange system keeps logs of all communication.

The date, time and content of each message is visible to all parties in the 'Grant File' section (the 'My Area' section of the Participant Portal).

Formal notifications are also recorded, but are only visible in the 'formal notifications box' *(see above)*. Information on when they are sent and received (i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp) is included.

⚠ Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent.

A delay in reacting (if set within the formal notification) is counted as of day eleven.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must **accede to the Agreement** by signing the **Accession Form** (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Acceding to the GA

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

⚠ Unlike under FP7, the coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries.

All documents are available in the electronic exchange system (in the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two parties signs it:

- the coordinator;
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

Multi-beneficiary Annotated General Grant Agreement

Articles 1 to 58

Version 1.5
25 April 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added

Foreword

The **Horizon 2020 Annotated Model Grant Agreements** ('AGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

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[1] **H2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Over the next months, this text will be transformed into an on-line version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs.

It is complemented by the Horizon 2020 Online Manual, which gives an overview of Horizon 2020 and its implementation.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *Energy Challenge actions (see the Smart Cities and Communities calls); actions under the Research Infrastructures Part (see a Research Infrastructure call); Health Challenge actions, etc*
>
> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 Annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

[3] *See Article 15(9) of the Rules for Participation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- for **coordination and support actions (CSA)**: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

'Complementary grants' are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*, which links the two action and ensures the necessary synergies.

[6] *For the definition, see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies)

  ⚠ The budget category 'specific categories of costs' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings' and 'costs for clinical studies'.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

***[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
[5] For the definition, see Article 2.1(14) Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[7]; for IA actions it is normally 70% of the total eligible costs[8].

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[9]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[10] and all budget categories.

[7] *See Article 28(4) of the Rules for Participation.*
[8] *See Article 28(5) of the Rules for Participation.*
[9] *See Article 28(5) of the Rules for Participation.*
[10] *See Article 28(6) of the Rules for Participation.*

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[11]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[12]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [13]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific categories of costs for:
    - 'costs for **energy efficiency measures** in buildings'[14]
    - '**access costs** for providing trans-national access to research infrastructures'[15]
    - 'costs for **clinical studies**'[16]

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[11] *See Articles 123, 124 of the Financial Regulation.*

[12] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[13] *See Article 33(2) of the Rules for Participation.*

[14] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[15] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs ⚠ new in Horizon 2020)[17]

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme.

[17] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum EU contribution.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact
If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

2. Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:
Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000
Reimbursement rate= 100%
Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:
The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:
In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:
Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000
The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries (and linked third parties) must:

- at proposal stage: enter only eligible costs into the estimated budget for your action *(see Article 4)*
- at reporting stage: declare only eligible costs in your financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries** (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action.*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  ⚠ Accounting documentation is necessary only for actual costs.

  Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  ⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  Specific case:

  For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

  – recorded in the third party's accounting records

  – calculated in accordance with the accounting standards applicable in the country in which the third party is established

  – calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit')

  Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

  ⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

  Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

  For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

  – must calculate them (the average or standard personnel costs) according to its usual accounting practices

  – must budget and declare a total amount; the amount per unit must not be included in Annex 2.

  ⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

  Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

  Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

  ⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

  Example:

  A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*:** *costs of [insert cost category or activity*[13]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure:** **Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 This budget category **covers** the following **types of costs**:

- **basic remuneration** (basic salary and complements) and
- for non-profit legal entities: **additional remuneration** ('bonus payments').

What is 'basic remuneration'?

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

'Parental leave' covers both maternity leave and parental leave.

The 'complements' may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — If a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6.

> ⓘ *For more information on personnel made available to a beneficiary by a third party, see below and Articles 11 and 12.*

What not?

The basic remuneration does not include components that must be considered to be 'additional remuneration'.

> ***Example (variable remuneration component acceptable as basic remuneration):*** *The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.*

> ⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

What is 'additional remuneration'?

'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

1.1.2 Costs for employees (or equivalent) may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

For basic remuneration (basic salary and complements):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- be **mandatory** under national law, collective labour agreements or the employment contract
- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract, but he/she **must be 'assigned to the action'** (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

Specific case:

For **secondments** or **linked third parties**, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

For additional remuneration ('bonus' payments) **for non-profit legal entities:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours
Remuneration components:
a = annual salary: EUR 50 000
b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
c = additional remuneration for being Head scientist in a project: EUR 2 000
d = additional remuneration for being First Assistant on an internal action: EUR 1 000
***a** and **b** would be used to calculate the researcher's hourly rate:*
hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34
***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*
***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for **additional work** or **expertise**

The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

Examples (acceptable additional remuneration):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

Examples (not acceptable additional remuneration):

Additional remuneration paid for using English.

Additional remuneration is paid for participating in EU funded or multi-partner actions.

- be part of the beneficiary's usual remuneration practices and be consistently paid whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

The objective criteria must be related to the additional work or expertise.

The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***
Addition of the additional remuneration: = ***2 000***
Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Procedure for calculating personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception:

Employees hired during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Examples:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')

- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours')**

- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	Can be used **in all cases**; any beneficiary can use this option.	**Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: – employment contract of the person concerned – applicable collective labour agreement – national law on working time ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1;

		group – an applicable collective labour agreement or – the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours*	– if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		per day = 1 824 hours ***Standard annual productive hours*** *for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days =* ***228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* ➔ *productive days =* ***212*** *Multiplied by 8 working hours per day* ➔ *standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 =* ***1 642*** ***1 696 hours*** *(usual cost accounting practice)* ***> 1 642 hours*** *(90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case:

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs

- are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate
- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

  Example: *calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example*: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Example*:*

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.
S/he worked 1 600 annual productive hours, 800 of them for the EU action.
Maximum additional remuneration eligible for the EU action (eligibility ceiling):
{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000
The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 This budget category **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action, under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

1.2.4 The **calculation** of the costs depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount). A calculation method is required, especially if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same **formula** explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the hourly rate is different (since it is not based on the annual personnel costs as registered on the payroll).

For the **hourly rate**, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person: this global amount must be divided by the number of hours worked for the beneficiary under that contract.

1.3 Direct personnel costs: Costs for personnel seconded by a third party

1.3.1 This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 These budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and indicated in Annex 2 of the GA.

This unit cost (hourly rate) is calculated according to the following formula:

{EUR 4,650/ 143 hours}

multiplied by

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

{country-specific correction coefficient / 100}

ⓘ *For the country-specific correction coefficient, see the* MSC calls conditions of the Main Work Programme[19] *(Table 4).*

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **owner** of an **SME/ beneficiary that is natural person**, who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They must be **calculated** as follows:

amount per unit (hourly rate) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 This budget category **covers** the personnel costs in actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

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[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties *[(not included in Point F)] [OPTION to be used if Article 15 applies:* *are eligible if the conditions set out in Article 15 are met.][**OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2. Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs (equipment costs)':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment cost: Depreciation costs of equipment, infrastructure or other assets

1.1.1 This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following:

It is expected that the beneficiaries allocate the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

⚠ Depreciated equipment costs can never exceed the equipment's purchase price.

⚠ Depreciation cannot be spread over a period longer than the equipment's useful life

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  {equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

1.2 Equipment costs: Cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of the equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

> ⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.
>
> ⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a*))
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional eligibility conditions** set out in Article 11.1.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results and royalties on access rights

Specific cases:

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) paid to a third party (i.e. not a beneficiary) *(see Article 24)* are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees paid for access rights to background granted by other beneficiaries *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Best practice: Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled.

Costs for drafting the 'plan for the exploitation and dissemination of the results' are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when implementing this plan may be eligible.

– costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).

– translation costs, if translation is necessary for the action's implementation, is justified, etc.

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Internal invoices must not include indirect costs elements or profit margin or mark-up.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[6] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013: **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

What? Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ The beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.), together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

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[20] *See also International Financial Reporting Standard No 16.*

[21] *See Article 126 of the Financial Regulation.*

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments)
- knowledge-based resources such as collections, archives or scientific data
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

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[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the H2020 Framework Programme.*

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. During an audit, the auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

The beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  ⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

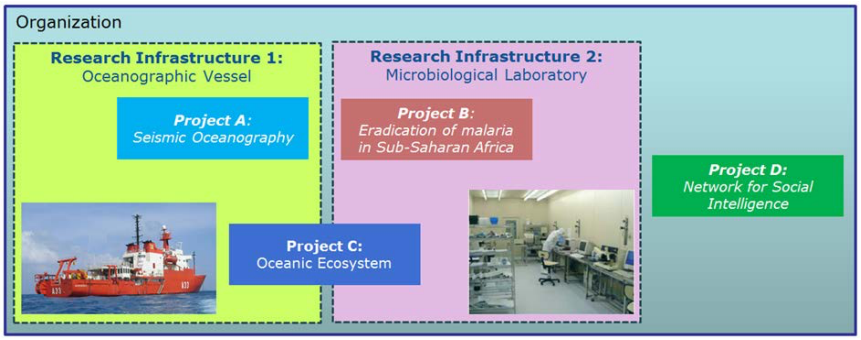

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

[24] *See Article 129(1) of the Financial Regulation.*

⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

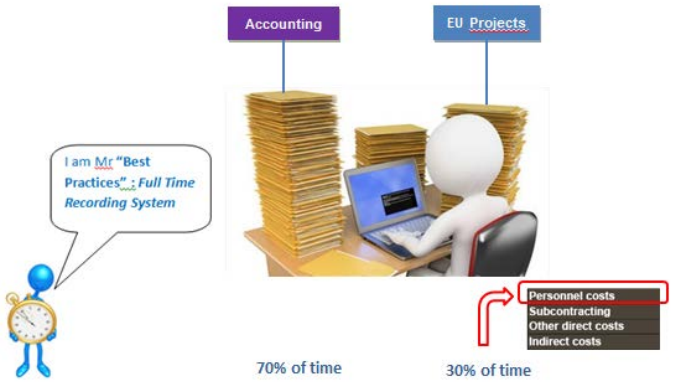

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to the best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[26].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

[26] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category covers costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be declared on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– unit or lump-sum costs covering specific categories of costs which include indirect costs.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

***[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]*

1. Specific categories of costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific categories of costs**, i.e.:

- for Energy Challenge actions involving additional energy efficiency measures: **costs for additional energy efficiency measures**

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

  These grants combine different activities. The reimbursement on the basis of the unit cost applies only for the building-related demonstration activities.

- for actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity': **access costs for providing trans-national access to research infrastructures**

  ⚠ This unit cost will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015)*.

- for actions under Health Challenge actions involving clinical studies: **costs for clinical studies**

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are already covered by the unit cost may not be declared (a second time) as direct costs *(for the costs that are covered, see below)*.

Examples:

Case 1: *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for*

subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

Case 2:*A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.*

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Case 3: *A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.*

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 Specific category 'costs for additional energy efficiency measures'

1.1.1 This budget category **covers** two categories of eligible costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and

- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost (EUR/m^2 of eligible conditioned gross floor area) set out in Commission Decision C(2013) 8196[27] and indicated in Annex 2 of the GA.

This unit cost (EUR/m^2 of eligible conditioned gross floor area) is calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

'standard cost to save 1 kWh' = EUR 0.1
'standard payback period' to be used = 10 years

The m^2 of eligible conditioned gross floor area do not include parts of the buildings which are not affected by the measures, *e.g. garages*.

⚠ The specifications per type of demonstration building must already be part of your project proposal (by completing the BEST table (Building Energy Specification Table))[28]. These specifications are then included in Annex 1.

⚠ You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit (EUR/m^2 of eligible conditioned gross floor area) x number of actual m^2 of surface area built or refurbished

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.
[28] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

1.2 Specific category 'access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category, these costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[29] and set out in Annex 2 of the GA.

⚠ The Decision does not *fix* the unit cost for access costs; the unit cost must be established for each installation — before signature of the GA — as follows (and then reflected in Annex 2 of the GA):

- identification of a *unit* of access to the installation; this is used to measure the total quantity of access that the installation provides to its users

- establishment of the *unit cost* of access, calculated as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access cost (over past two years}^{30}\textbf{)}}{\textbf{average annual total quantity of access (over past two years}^{31}\textbf{)}}$$

The averages are based on:

- the beneficiary's certified or auditable historical data

- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for less than two years) and

- a period excluding times when the installation was not usable (out of order, under repair or undergoing maintenance).

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

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[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[31] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for:

  - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    By way of exception, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

  - costs of consumables specifically used for the installation and the research work of the users

  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

  - costs of energy power and water supplied for the installation

  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)

  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

  - costs of specific scientific services included in the access provided or needed for the provision of access

- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

  and excluding:

  - all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

  - travel and subsistence costs to support the visits of users.

A form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ Do not forget to describe in your proposal the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs= average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Before signature of the GA, the beneficiaries can opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation) not as unit cost but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*. If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for **providing trans-national access to research infrastructure** to scientific communities
- fulfil the **additional eligibility conditions** set out in Article 16.1

1.1.4 They must be **calculated** as follows:

– for each installation:

amount per unit (EUR/unit of access) x number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil —* ***mutatis mutandis*** *— the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.****]***

[OPTION: *not applicable****]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties free of charge are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

    Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

  - **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national VAT system. Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible** it is an eligible cost.

The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

Specific cases:

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding).

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[32] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

[32] *For the definition, see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are	Subcontracts concern the implementation of action tasks; they imply the implementation of

necessary to implement action tasks by beneficiaries.	specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or*

	other goods and services).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 ***[OPTION:*** *with the exception of additional exploitation obligations****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.****]***

[OPTION: *not applicable****]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[33]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

ⓘ For more information on third country participants, see the Horizon 2020 Online Manual.

[33] *For the definition, see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

Obligations that do not apply to beneficiaries not receiving EU funding:

These beneficiaries must, in particular, **not**:

- comply with the conditions for declaring costs *(e.g. cost form, eligibility, calculation, etc) (Chapter 3 and Articles 10-15)*
- keep records and other supporting documentation for costs *(Article 18.1.2)*
- submit financial reports and convert their costs in euro *(Articles 20.3(b), 20.4(b) and 20.6)*
- comply with some of the rules on management of intellectual property, background and results *(Articles 26.4, 28.1, 28.2, 30.3 and 31.5)*
- fear rejection of costs, reduction of the grant or recoveries, suspension of the payment deadline or suspension of payments *(Articles 42, 43 and 44)* .

⚠ Apart from this, they are treated like the other beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs, reduction of the grant or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the best value for money considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the Work Programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[34] and 2004/17/EC[35] — or any EU legislation that replaces these Directives[36]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[34] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[35] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[36] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*,

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]*.**]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means a contract for the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is forbidden in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is forbidden, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the best value for money considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

⚠ The latter GA contains more detailed obligations since these PCP/PPI Cofund actions consist mainly in subcontracting and undertake PCPs and PPIs as the main objective of an action.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. Other obligation: Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks

- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises

- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an **established relationship** (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

– *scientific and economic unity*

– *last a certain length of time*
– *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

– the financial viability/capacity of a beneficiary is 'weak' while that of its linked third parties is strong

ⓘ For more information on the financial viability and the financial capacity check, see the Horizon 2020 Online Manual.

– the beneficiary mainly coordinates the work of its linked third party.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

[38] *See Articles 8 and 9 of the Rules for Participation.*

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is **no** procedure for **approval without amendment**.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

⚠ The obligations in Article 14.1.1 additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

Each linked third party has its own financial statements, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA ('**cascade funding**').

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is **not** considered financial support.

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties (recipients) that actually implement research and/or innovation projects.)

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ *For financial support given in the form of prizes, see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g. 3 grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

⚠ All these conditions must already be described in your proposal (see the Proposal Templates).

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- avoid conflicts of interest *(see Article 35)*

- maintain confidentiality *(see Article 36)*
- promote the action and give visibility to the EU funding *(see Article 38)*
- are liable for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *not applicable**]***

15.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[28]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

1. Trans-national access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[39] and installations[40] for scientific communities ('provision of access activity').

Such Research Infrastructures Part actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **cover** — for the provision of access activity — the following **types of costs**:

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[39] *For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] *For the definition, see the footnote in Article 16 of the MGA.*

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

The Beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Virtual access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

– operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

⚠ There are no 'access costs' for virtual access.

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected or even identified.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General oobligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Rules of Application: **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ The rules in the GA do not affect national laws on keeping documents.

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

– documents received or created in paper form should be kept in paper form

– documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units

declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary (or linked third party) may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

⚠ The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval. It will also challenge the costs, if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary/ can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ *For more information on the certification procedure, see the Horizon 2020 Online Manual.*

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiaries must:

- sign one **declaration** per reporting period, to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  This declaration must be dated and countersigned for acceptance by the person concerned.

  A template [hyperlink] is provided on the Participant Portal.

  Best practice: If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  A template [hyperlink] is provided on the Participant Portal.

  Time records should include:

  – the title and number of the action, as specified in the GA

  – the beneficiary's full name, as specified in the GA

  – the full name, date and signature of the person working for the action

  – the number of hours per day declared for the action

  – the supervisor's full name and signature

  – a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned

  – a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

The beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For Energy Challenge actions involving additional energy efficiency measures, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*), unless Annex 1 specifies another way.

Specific case:

'**Classified deliverables**' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

– a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions).****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

– a '**periodic financial report**' containing:

(ii) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(iii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iv) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(v) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[32] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the coordinator, which must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (they do not see their grants in the electronic exchange system and therefore have no access to them). Before submission, the beneficiary completes the data for the linked third party, prints it and sends it to the linked third party which must sign it *on paper* and then send it back to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system are identical to the signed paper version.

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

CFSs must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

ⓘ *For information on the eligibility of costs incurred for reporting, see Article 6.2.D.3.*

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified deliverables' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on

security of information in the Commission internal Rules of Procedure *(see also Guide for classification[hyperlink]).*

ⓘ For more information on information security, see the Horizon 2020 Online Manual.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on cross–cutting issues (described in Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined vis-à-vis societal challenges (Annex I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed, if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more), as reimbursement of actual costs and personnel costs

on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25 % flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, it must be an independent public officer, with formal competence to audit the beneficiary/linked third party.

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro:**
  - for costs incurred in the currency of their accounting records conversion of costs by one of the following:
    - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[44].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart corresponding to your currency.

Step 3 — Choose the start and end date of the period for which the average daily exchange rate is calculated (i.e. the reporting period) by using the sliding tool in the second table.

Step 4 — The average appears above the first table.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if no daily euro exchange rate is published : using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

– for **costs incurred in a currency other than EUR and the one used in their accounting records:** conversion in accordance with the applicable national law and their usual accounting practices.

– for costs incurred in EUR, beneficiaries **with accounting records in a currency other than the euro** must declare the amount in EUR; no conversion has to be made.

⚠ This means that a beneficiary with accounting in a currency other than EUR will act differently according to the currency in which it incurs the costs (the currency in which the contract/invoice is established).

Examples:

1. *If the UK beneficiary buys the equipment in the USA (costs incurred in US dollars), it will convert the price of this equipment into pounds (the currency in which its accounts are established) according to its usual accounting practices. When reporting the costs to the Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.*

2. *If the UK beneficiary buys the equipment in UK pounds (it will record those equipment costs incurred in pounds in its accounts kept in pounds). When reporting the costs to the*

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.

3. If the UK beneficiary buys the equipment in Germany in EUR (e.g. EUR 10 000) it will report these costs incurred in EUR (i.e. 10 000) to the Commission/Agency without converting them first from EUR to pounds and then back to EUR.

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline *(see Article 47)*
- terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

  ⚠ This may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90 % of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - the work has started.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed start date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed start date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)
- the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, see Articles 42, 43 and 44.

2. Amount of pre-financing payment

There is no standard amount or percentage for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods (it will be in any case less for actions with only one reporting period, as 100% would mean the totality of the EU grant for the action).

⚠ At the moment of the pre-financing payment, an amount equivalent to 5% of the maximum grant amount is deducted from the payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.
Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1 : application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:
- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)
Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
Payment of the balance amounts to EUR 100 000 and will be ***paid*** *to the coordinator as follows:*
- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*
- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

22.1.1 Right to carry out checks

The Commission *[or the Agency]* will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission *[or the Agency]* may be assisted by external persons or bodies.

The Commission *[or the Agency]* may also request additional information in accordance with Article 17. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.

2. The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).

3. After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.

4. After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check (see Article 17). All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

It may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the check shows ineligible costs or the violation of other obligations under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

The Commission/Agency may carry out checks remotely, based on documents it received beforehand. It can do so using its own staff or with the assistance of external expert(s) or bodies.

⚠ If the Commission/Agency is assisted by external expert(s) or bodies, it does not need to send their name(s) for approval to the beneficiaries before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report'** will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed

- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the review shows improper implementation of the action, ineligible costs or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42- 44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a letter sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the **names** of the **independent experts** that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, you will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days ('**contradictory review procedure**').

22.1.3 Right to carry out audits

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission *[or the Agency]* in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission *[or the Agency]* may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

Specific case:

The Commission may audit the accounting records of beneficiaries, to obtain general information about actual costs for cost items that are reimbursed as unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will however normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

They consist in an in-depth examination (by professional auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to **third parties** involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

*1. The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

*2. The Commission/Agency may audit **third parties providing in-kind contributions** (free-of-charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

*3. The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or if appropriate the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. .*

⚠ *For this category of third parties, audits will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

*4. The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary.*

⚠ *For recipients of financial support or prizes, audits normally will not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs), except if Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties. .*

⚠ If the audit shows, ineligible costs, improper implementation of the action or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

2. Procedure

The audit will be initiated by a letter sent to the beneficiary concerned.

⚠ The Commission/Agency will transmit this letter (and the other communications relating to an audit as formal notifications, through the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its **name**.

The beneficiary may **object** to an external auditor on grounds of commercial confidentiality (and explain the reasons for this). If justified the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit with its own auditors).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit (**i.e. on the beneficiary's premises or on the site on which the action is being implemented). (There may however also be audits that consist only in a desk review.)

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc)* and will indicate how and when it must be provided (and in which format).

ⓘ *For more information on records and supporting documentation for the different cost forms, see Article 18.*

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

> ***Example:*** *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

⚠ Objections based on data protection or confidentiality will not be accepted.

Once an audit has started, the beneficiary must keep all the records and supporting documents until the audit procedure and its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This avoids any unnecessary delays in retrieving original documents from the archives (and thus minimises the risk of the rejection of costs).

> ***Example:*** *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

This includes granting access to research facilities and interviewing the researchers that worked on the action.

⚠ Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc).

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Moreover, all confidential data will be processed in accordance with Article 36.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory review procedure**').

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [1]and No 2185/96[1] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42- 44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[1], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

⚠ If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission *[or the Agency]* may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission *[or the Agency]* will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the Commission *[or the Agency]* on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission *[or the Agency]* in justified cases.

The Commission *[or the Agency]* will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission *[or the Agency]* does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission *[or the Agency]* accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission *[or the Agency]* intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission *[or the Agency]* does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission [*or the Agency*] accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

⚠ These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Regulation (EU) No 1291/2013).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to background

The rules on access to background (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is **no** (or a more limited) obligation to give **access**, if there are **restrictions** or **limits** (legal or otherwise) regarding the background and the beneficiary owning or holding the background has informed the others — before acceding to the GA (or immediately when additional background is agreed on after signature of the GA).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ Don't forget that — when contracting on background with third parties — you must at all times ensure that you can still comply with your access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

  > ***Example:*** *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

– for the exploitation of results: under fair and reasonable conditions

  ⓘ *For more information on fair and reasonable conditions, see Article 31.*

Also, there are no **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties, except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure *(see Article 31)*.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the **beneficiary** that **produced** them.

> 'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries are advised to keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases:

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must — as much in advance as possible before the jointly-owned results are produced — conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  ⚠ Don't fix a *ceiling* for fair and reasonable compensation before the action starts, unless you can precisely determine the results you expect to produce.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries are advised to include general principles on joint ownership already in the consortium agreement.

⚠ The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection (*e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (⚠ without prior authorisation from the other joint owners), unless otherwise agreed in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

⚠ The joint ownership status may **change**:

– it may need to be reviewed later on, when protecting the results.

Example:

Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.

– joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that any agreements with third parties who could claim rights to the action's results *(e.g. employees, subcontractors, linked third parties etc.)* contain provisions that allow them to respect their obligations under the GA *(e.g. transferring ownership to the beneficiary, grant the beneficiary access rights with a right to sub-license, etc)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Specific cases:

Joint research units (JRUs) — Where the internal arrangements of a JRU, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ⓘ *For information on JRUs, see Article 14.*

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, protect them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

⚠ This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*

The beneficiaries are in principle free to choose any available **form** of protection.

Examples of classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

For an invention: e.g. patent, confidential information.

For the design of a technology: e.g. industrial design, copyright.

For a website: e.g. industrial design, copyright, trademark, confidential information.

⚠ In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

ⓘ *For information on the eligibility of costs related to protection, see Article 6.2.D.3.*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

⚠ Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include a reference to EU funding, as specified in the GA.

⚠ **No** information on EU funding is needed, if it is (technically or legally) impossible to include such a reference

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure exploitation of their results.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

Example: *Exploitation is justified from an economic point of view (commercially) or from a standardisation perspective (for use in standardisation activities).*

Where possible, the measures should be consistent with the impact expected from the action and the '**plan for the exploitation and dissemination of the results**'.

They may aim for exploitation by the beneficiary itself (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (⚠ Such additional exploitation obligations will already be mentioned in the Work Programme.)

⚠ This obligation only applies to beneficiaries receiving EU funding.

If the results can reasonably be expected to contribute to European or international standards, the beneficiaries must also communicate them to the Commission/Agency.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

⚠ This obligation applies only if it is foreseen in your GA.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — disseminate their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

No dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA (*e.g. personal data protection, security-related obligations, etc)*.

The beneficiaries may choose **how** they would like to disseminate their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

If the GA provides for additional dissemination obligations, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the Work Programme.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated, unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries are advised to foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

2. Visibility of EU funding

Any dissemination of results (in any form) must include a reference to EU funding, as specified in the GA.

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission]/ Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —**]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions* ***]***

[OPTION: *not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may transfer ownership of their results.

⚠ Security-related obligations *(see Article 37)* may prohibit a transfer or require certain conditions to be fulfilled before it takes place.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

The beneficiary must ensure that the new owners comply with the following obligations:

- joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- protection of results and visibility of EU funding *(see Article 27)*
- exploitation of results and visibility of EU funding *(see Article 28)*
- dissemination of results, open access and visibility of EU funding (see Article 29)
- transfer and licensing of results *(see Article 30)*
- access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

⚠ The mere fact that the results concerned are transferred to a competitor is not in itself a valid reason for an objection. The beneficiary concerned must *demonstrate* the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases:

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of before).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them)*. In this case, there is no need to inform the other beneficiaries of such transfers in advance (and the other beneficiaries do not have the right to object).

⚠ Before agreeing to such a 'global' authorisation, you should carefully consider the situation (and in particular the identity of the third party concerned), to determine if your access rights would be affected.

Example: For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country not associated with Horizon 2020 must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

Best practice: Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant licences to their results.

They must however ensure that **access rights** can be exercised and that any additional exploitation obligations are complied with.

⚠ **Exclusive licences** *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If this option is included in your GA, the Commission/Agency may **object** to transfers or exclusive licences to third parties established in a non-EU country not associated to Horizon 2020, on the following grounds:

- the planned transfer or licence is not in line with EU **competitiveness interests**

  Example: if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU

- the planned transfer or licence is not consistent with **ethical principles**

  Example: if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level

- the planned transfer or licence is not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

⚠ **No** right to object for transfers or exclusive licences by beneficiaries not receiving EU funding *(see Article 9)*.

⚠ For Euratom grants, the Commission has the right to object also to non–exclusive licences.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[40], for the purposes of the complementary grant agreement(s) (see Article 2).**]

[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.**]***

[OPTION for access to research infrastructures:** The access provider must give the users access to the results, if needed to implement the action.**]

[OPTION:** not applicable**]

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When ?

The beneficiaries must provide access to results, if it is **needed**:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity (established in a Member State or associated country), to exploit the results produced by the beneficiary to which it is affiliated (unless otherwise provided for in the consortium agreement).

There is **no definition** of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

Example (results needed for implementation): *if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

Example (background needed for exploitation): *if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries are advised to agree *(e.g. in the consortium agreement)* on a **common interpretation** of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they **must be requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a Member State or associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

The agreement by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

⚠ Don't forget to notify the Commission/Agency of any conflicts on results that are likely to affect the action implementation *(see Article 17.2.)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free
- for the exploitation of results: under fair and reasonable conditions

  'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

  'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

  Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

  Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

  Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

ⓘ For information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

⚠ Access rights do not automatically give the right to **sub-licence** to the requesting beneficiary (since this would imply that access rights to results could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries are advised to agree on the terms and conditions of the sub-licensing generally and in writing (at the level of the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

> ***Examples:*** *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country).*
>
> **Best practice:** Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

> ***Example:***
>
> *The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.*
>
> **Best practice:** Beneficiaries are advised — for legal certainty purposes — to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

The General MGA provides for several options for specific access rights for EU institutions, bodies, offices or agencies and/or EU Member States, for policy purposes.

> ⚠ These obligations apply only if they are foreseen in your GA.

5. Specific access rights for Euratom and its joint undertakings

The option gives Euratom and its joint undertakings (such as Fusion for Energy) royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to sub-license *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

> ***Example:***
>
> *Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.*

6. Specific access rights for third parties

The General MGA also provides for several options for specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  ⚠ In this case, the access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

⚠ These obligations apply only if they are foreseen in your GA.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ *For guidance in this process, see the 'Human Resources Strategy for Researchers' tool*[50] *developed by the Commission.*

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[51] and of the Code of Conduct[52] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[53])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[53] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[54].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[55].

[54] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[55] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink].

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

Best practice: Beneficiaries are advised to obtain the **approval of** a **European ethics committee** (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[56] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[56] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[43], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81)

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed — during the action and for four years afterwards.

> ⚠ This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves (for example, for access rights or third parties involved in the action).
>
> A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information concerned.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

Best practice: Beneficiaries are advised to inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

⚠ Stricter confidentiality obligations apply for information that is that is 'EU-classified' and subject to 'security requirements' in Annex 1 of the GA (see Article 37).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *not applicable****]***

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

1. Activities raising security issues — Classified deliverables

If the security scrutiny (carried out by the Commission/Agency during the selection procedure) finds that the action raises security issues because it deals with information that is 'EU-classified' (under the Commission internal Rules of Procedure), the Commission/Agency will make it subject to '**security requirements**' (set out in a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' in Annex 1 of the GA).

In this case, the beneficiaries must comply with the security requirements.

Moreover, they may not subcontract action tasks involving such information or disseminate results linked to such information, without prior approval by the Commission/Agency.

'Classified deliverables' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 19)*.

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[57].

Moreover, the coordinator must submit a **copy** of any export or transfer licence, before the action starts.

[57] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> 'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Promoting the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange.

⚠ *Ad hoc* efforts or mere dissemination of results are not sufficient. The communication activities[58] must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and address the **public policy perspective** of EU research and innovation funding, by considering aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)

[58] *For the definition of 'communication activities', see the Glossary.*

- scientific excellence
- contributing to competitiveness and to solving societal challenges

❖ impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*

❖ better use of results and spill-over to policy-makers, industry and the scientific community.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity).

⚠ The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them in another work package).

The beneficiaries are free to choose the type of communication activities.

> ***Examples:*** *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

⚠ Information given may **not** cover EU-classified information or information relating to 'classified deliverables' *(see Article 37)*.

⚠ Don't forget that any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa). Both obligations must be complied with.

ⓘ *For more information on how to promote your action, see the H2020 Online Manual*

2. Visibility of EU funding

The beneficiaries must ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure (including equipment or major supplies) funded by the grant, by:

– displaying the EU emblem and

– including the reference to EU funding, as specified in the GA.

For infrastructure (including equipment or major supplies) a sticker (or other equivalent means) should be used.

ⓘ For more information, see the Guide to using the EU emblem[59].

⚠ The beneficiaries must ensure the visibility of EU funding even after the action ends.

[59] Available at http://publications.europa.eu/code/en/en-5000100.htm.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[44], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[44] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities by the Commission/Agency

The Commission/Agency may use any (⚠ non-confidential and non- classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material); *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

⚠ The beneficiaries must make **arrangements** with any **third parties** that could claim rights to the material, in order to legally allow the use by the Commission/Agency.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

1. Processing of personal data by the Commission/Agency

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency 'Data Protection Officer (DPO)'.

This notification will be available in the Register of the DPO[60] (and will describe the processing operations, security safeguards, data transfer, retention period, etc.).

⚠For the processing of sensitive data *(e.g. health data)* and processing for the purpose of administrative penalties and termination, the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ For more information, see the data privacy statement ('SSPS')[61] on the Participant Portal.

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS) to:

- obtain information about what data is collected and how it is used, usually given via a privacy statement
- see which of their data are being held
- correct any errors in the data, block access to this data, or delete their data

[60] Available at http://ec.europa.eu/dpo-register/search.htm.
[61] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

– complain about data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ *For information on the complaints procedure, see the EDPS website.*

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data, by the beneficiaries

The beneficiaries must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[62] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [63]

[62] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing** of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[64]

Beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform staff** (whose personal data are collected and processed by the Commission/Agency) about this disclosure, by providing them with the SSPS.

Examples:

Before encoding its staff's personal data in the Beneficiary Register or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must tell the staff concerned and provide them with the SSPS.

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ *For more information on ethics, see the H2020 Online Manual.*

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63 *See Article 8 of Directive 95/46/EC.*

64 *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party, unless the Commission/Agency has explicitly agreed in writing.

'Assignment' normally means the transfer of rights held by one party to another party.

⚠ However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity

Assignment for the benefit of creditors in a bankruptcy procedure

⚠ Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

Example: *The obligation to allow audits by the Commission/Agency*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.**]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator**, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

> ***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications, unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the H2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action).*

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement (unless exceptionally stipulated otherwise in the Work Programme, for a specific call).

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded **before the action starts**. (Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action.)

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ *For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the H2020 Online Manual.*

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiaries must conclude a coordination agreement.

> 'Coordination agreements' are agreements between the consortium and partners from a third country (including scientific and technological organisations and agencies) or an international organisation, with which the joint call was organised.
>
> Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the basic contradictory procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100%.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

41.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[65]

  Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[66]

  If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

[65] *See Article 80(1) of the Financial Regulation.*
[66] *See Article 87 of the Rules for Application.*

– taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or

– adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[67].[68]

The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an

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[67] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[68] *See Article 79(2) of the Financial Regulation.*

amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000
Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

Beneficiary approved costs multiplied by the reimbursement rate (100%) * *final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between 2% and 10% of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

  Example:

  GA with an EU contribution of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

  During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in

the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the decision to apply the penalty may also be **published** on Commission or Agency websites —together with the name of the person responsible for the misconduct, information on the misconduct and the penalty(ies) (duration of the exclusion and/or amount of the financial penalty).

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

1. Liability for damages, of the Commission/Agency

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

– causes damage to a third party (including another beneficiary)

Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

– suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability for damages, of the beneficiaries

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples: *Costs of legal proceedings borne by the Commission.*

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

  ⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

- calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

❖ **Payment request does not comply with the provisions of the GA**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

> ***Examples:*** *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

❖ **Payment request is incomplete or requires clarification**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

> ***Examples:*** *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.*

❖ **Doubts on the eligibility of costs in the financial statements that require additional verifications**

The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

> ***Example:*** *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is no *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

- **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: statements made by the beneficiary in the declaration form are found to be false.

  ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **no individual financial statements** for the beneficiary (or beneficiaries) concerned may be submitted.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation, by the beneficiaries

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Grounds for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

  ⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the suspension is lifted and the action continues, the action's remaining budget can be used to implement the action.

⚠ However, it is possible that the action is resumed with a lower budget to adapt it to the new situation (agreed as part of the amendment).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) ***cannot* be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation, by the Commission/Agency

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

- **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

  ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

  The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

- **Suspicion of loss of scientific or technological relevance**

  The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

  Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA, by the beneficiaries

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery (see Article 21.4 and 44.1.2).
- is lower than the final grant amount, the Commission/Agency will pay the balance (see Article 21.4).

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

> ***Example:*** *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

> ***Example:*** *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries, by the beneficiaries

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ For more information on the roles and access rights in the electronic exchange system, see the H2020 Online Manual.

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action (unless it concerns the coordinator, since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action — including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so —, unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.][OPTION: not applicable];

(j) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries, by the Commission/Agency

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

❖ **Non-accession to the GA**

The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA).

⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [69]

Examples:

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this.

[69] *See also Article 8 of the Rules for Participation.*

The Commission terminates the GA because the conditions set out in the work programme are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

- **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

- **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

❖ **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

❖ **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

❖ **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

❖ **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country's or international organisation's action does not start by the date specified in Annex 1

  ⚠ In this case, **no costs** incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country's or international organisation's action is terminated

- the third country's or international organisation's action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

❖ **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA —

substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:

- systemic or recurrent and,
- have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ **Ineligible costs** may be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure
- labour disputes or strikes

– financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has **no specific effects** on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation (see Article 49) or termination of the GA (see Article 50).

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate* [*complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use a 'Messaging' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal Notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ *For more information on access and roles in the electronic exchange system, see the H2020 Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** (unless the GA or other rules provide for direct communication with the other beneficiaries, *e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations*).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

An amendment is necessary whenever there is a need to **change** the **terms and conditions** of the GA. In some cases, the GA explicitly provides for them.

⚠ Amendments may **not** result in changes that — if known before awarding the grant — would have had an impact on the decision to award it. Those are mostly changes that:

- may have had an impact on the assessment of the applicant with regard to the eligibility and selection criteria *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- breach the principle of equal treatment of applicants
- involve modifications in the action and/or the related budget which may have affected the assessment with regard to the award criteria announced in the call *(e.g. the tasks in*

Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)

– do not comply with the rules applicable to the GA (i.e. Financial Regulation, Rules for Participation, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified or to modify Annex 1 following a review of the action).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removing a beneficiary whose participation was terminated** by the beneficiaries or by the Commission/Agency *(see Article 50.2 and 50.3)*.

  For termination by the beneficiaries, the request for amendment must be part of the notification of termination. In this case, don't forget to also submit the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency, the request for amendment must be submitted together with the report on the distribution of payments and the termination report (if needed).

  ⚠ No need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)*, unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

- **Adding a new beneficiary** *(see Article 56.2)*

  The request for amendment must include the Accession Form (signed by the new beneficiary in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; see Article 52).

  The new beneficiary must provide a declaration on joint and several liability of its linked third party if required by the Commission/Agency.

  ⚠ Don't forget that the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

  Depending on the Horizon 2020 status(es) of the new beneficiary, the applicable options will be added.

  Example:

  If the new beneficiary is an international organisation, the options related to international organisations specified under Articles 22.4, 53.2, will be added to the GA and the options specified under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

  For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Change of beneficiary due to partial takeover (called 'partial transfer of rights and obligations' in FP7)**

  'Partial takeover' means that some assets of the beneficiary have been taken over by another entity *(e.g. partial acquisition)*.

If the GA is part of the assets taken over, the beneficiary must request an amendment: the entity to which the GA has been transferred may become the new party of the GA if the Commission/Agency agrees on that.

The contractual position of the old and the new party (vis-à-vis the Commission/Agency and the other beneficiaries) must be clearly spelled out in the request for amendment: in particular, it must clarify which is the financial liability of the new party for the old party's debts towards the Commission/Agency or the Guarantee Fund.

⚠ Don't forget that the new party must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

- **Change of coordinator**

The amendment request may be submitted after the period set out under Article 3 of the GA ends.

The initial coordinator may continue to participate in the action as a beneficiary (or may terminate its participation).

If the new coordinator is already a beneficiary of the GA, he will start his new functions from the date agreed by the parties, or — in the absence of such an agreement — the date on which the amendment enters into force. The date agreed cannot be before the initial coordinator has terminated its functions.

⚠ If the new coordinator is not a beneficiary of the GA, it must also accede to the GA as a new beneficiary *(see Article 56.2)*.

- **Change of the coordinator's bank account for payments**

Example: The coordinator changes bank.

The coordinator must submit the necessary supporting documents and update the banking information on the Participant Portal.

⚠ Do not forget to first update the bank account data in the Beneficiary Register (and get it validated).

- **Change of the action's title and/or acronym**

Example: the consortium finds out that the acronym of their action is a protected trademark.

- **Change of the starting date, duration of the action or reporting periods**

Example: The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.

An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

⚠ Even if the action is prolonged, the maximum grant amount cannot be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

⚠ Don't forget to communicate the date from which the action's implementation can restart ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:

- a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries

- changes concerning **in-kind contributions** provided by third parties (against payment or free-of-charge) or **subcontracts**

  Such changes could in principle also be made as 'approval without formal amendment' (*see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency's *agreement* (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency may consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).

- changes concerning the tasks to be carried out by **linked third parties** and related costs

  There is no 'approval without formal amendment' *(see Article 14)*.

- changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

❖ **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

Changes to the maximum grant amount and/or the action's estimated eligible costs will be accepted only in very exceptional cases *(e.g. due to a clerical mistake)*.

⚠ The maximum grant amount cannot be increased.

Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

❖ **Changes to Annex 2 (estimated budget)** which require an amendment *(see Article 4)*, in particular:

- a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

- a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*

  Examples:

  During the action's implementation, a beneficiary that declared its direct personnel costs as actual costs in Annex 2 decides to change this and instead to declare its direct personnel costs as unit costs in accordance with its usual accounting practices.

  An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to add the appropriate option under Article 5.2 and to modify the action's estimated budget in Annexes 1 and 2.

Indicative list of cases where no amendment is needed:

❖ **Budget transfers not listed above**

Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary or coordinator**

Changes concerning name, legal form *(e.g. Ltd., S.A.)*, registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA) do not require a formal amendment; an update of this data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

ⓘ For more information on data updates, see the Horizon 2020 Online Manual.

⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may request it.

Example: *Company RO moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates*

- **Change of beneficiary due to universal takeover (called 'universal transfer of rights and obligations' in FP7)**

'Universal takeover' means that all the rights and obligations of the beneficiary have been taken over by another entity *(e.g. in cases of merger or full acquisition)*. The beneficiary ceases to exist and all its rights and obligations (including those under the GA) are taken over by the new entity.

Example:

Beneficiary X may merge with another existing entity Y by:

(i) becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or

(ii) establishing a new separate legal entity (X and Y are together known as 'Z').

Since *all* the rights and obligations of the old entity (including the GA) are transferred to the new one, there is normally no issue of legal certainty and it is therefore not necessary to make a formal amendment under Article 55. An update of the data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may request it.

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement*

rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

⚠ Don't forget that — in addition to updating the data in the Beneficiary Register — you must also inform your coordinator (offline) under Article 17.2, if the universal takeover may:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinators must then inform the Commission/Agency (via the electronic exchange system) and may request an amendment.

The same is true if the universal takeover concerns one of your linked third parties.

How?

An amendment request must be **prepared** by the **coordinator**, normally by filling out the forms **directly in the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

Specific case:

A request to **change the coordinator** (against the coordinator's will) can be submitted by any beneficiary (acting on behalf of the others).

⚠ If none of the available forms are appropriate, beneficiaries are advised to contact the Commission/Agency for the drafting of the request.

⚠ **Requests** for amendment must be unambiguous and complete and submitted **sufficiently in advance** (to allow proper analysis and preparation before they are due to take effect) and, generally, **before the end of the action** (i.e. the date set out in Article 3).

Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance).*

Once completed, the amendment request (with all its supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator. (⚠ The coordinator submits and signs on behalf of the other beneficiaries; *see Annex 3*).

Coordinators must ensure internally that they have the agreement of the consortium, on the basis of their internal decision-making processes *(e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement)*.

⚠ Don't forget:

- for new beneficiaries (or linked third parties): to ensure that they have obtained all necessary validations in the 'Beneficiary Register'

Example:

Validation of the new bank account, to change the bank account

Legal entity validation, to add a new beneficiary that is not yet validated. This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

– to include the necessary information and supporting documents (as required for certain amendments)

Examples:

For a change of coordinator without his/her agreement, the coordinator's opinion (or written proof that this has been requested).

To add a new beneficiary, an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

To amend Annexes 1 and 2, amended versions of these annexes.

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

The coordinator may at any moment **withdraw** the amendment request (before it has been accepted or rejected). However, it cannot be *change*d (without withdrawing it and submitting a new one).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

ⓘ *For more information on the preparation and submission procedure, see above point 1.*

⚠ Beneficiaries are advised to contact the Commission/Agency beforehand (via the 'Messages' function of the electronic exchange system), in order to discuss the amendment.

The other party must — within 45 days — agree or disagree, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

If there is **no reaction** within this deadline, the request is considered to have been rejected (⚠ new in Horizon 2020: contrary to FP7, there is no tacit approval of amendments). A new amendment request may be submitted (even if it fully or partly repeats the initial request).

A request containing several changes to the GA will be considered as a **package** that cannot be divided into several requests. The request will be agreed or rejected by the other party as a whole.

If, the receiving party requests additional information/documents a new deadline will apply, i.e. 45 days from receipt of the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may be extended by the Commission/Agency — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

⚠ A signed and submitted amendment requests (including supporting documents) cannot be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

Unless the parties agree otherwise, the amendment will **take effect** (i.e. the modifications to the GA will start to apply) on the day of entry into force of the amendment.

If the parties agree on another date, it should normally be *after* the entry into force. In justified cases it may be before (retroactivity of the amendment). (⚠ In certain cases, the GA itself provides for retroactivity.)

Examples (retroactivity foreseen in the GA):

Where a new beneficiary or linked third party is added to the GA, it must assume the rights and obligations from the date of its accession specified in the Accession Form. This retroactivity implies that its costs will be considered eligible as from the date of its accession to the GA (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

⚠ Depending on the nature of the modification, the date of taking effect may have an impact on the eligibility of costs.

If an amendment request involves a number of changes, these could take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA, by the beneficiaries mentioned in the Preamble

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Specific case:

For mono-beneficiary actions, replacing the beneficiary during the action implementation is only possible under exceptional circumstances *(e.g. the beneficiary transfers all its rights and obligations, including those related to the action, to another legal entity).*

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated (unless it already has a validated Participant Identification Code (PIC))
- sign the Accession Form directly in electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an amendment for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned])*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for international organisations (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[70]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the *Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States*, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN system (⚠ new in Horizon 2020).

It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU-arbitration clause, referring disputes on the interpretation, application or validity of the GA to the Court of Justice of the European Union.

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This

[70] *See Article 180(1) of the Rules of Application.*

referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[71]).

If a dispute is of public law nature (i.e. concerns offsetting or an enforceable decision under Article 299 TFEU), actions must be brought before the Court of Justice of the European Union not under Article 272, but under Article 263 TFEU.

[71] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

Multi-beneficiary Annotated General Grant Agreement

Articles 1 to 21, 23 to 25, 32 to 35, 39 to 54, 56 to 58

Version 1.4
16 April 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised

Foreword

The **Horizon 2020 Annotated Model Grant Agreements** ('AGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

[1] **H2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Over the next months, this text will be transformed into an on-line version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs.

It is complemented by the Horizon 2020 Online Manual, which gives an overview of Horizon 2020 and its implementation.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *Energy Challenge actions (see the Smart Cities and Communities calls); actions under the Research Infrastructures Part (see a Research Infrastructure call); Health Challenge actions, etc.*
>
> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 Annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[1],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

– the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.
[3] *See Article 15(9) of the Rules for Participation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- for **coordination and support actions (CSA)**: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

'Complementary grants' are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7; ⚠ new in Horizon 2020) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*, which links the two action and ensures the necessary synergies.

[6] *For the definition, see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; ⚠ new in Horizon 2020; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies)

  ⚠ The budget category 'specific categories of costs' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings' and 'costs for clinical studies'.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

***[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
[5] For the definition, see Article 2.1(14) Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[7]; for IA actions it is normally 70% of the total eligible costs[8].

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[9]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[10] and all budget categories.

[7] *See Article 28(4) of the Rules for Participation.*
[8] *See Article 28(5) of the Rules for Participation.*
[9] *See Article 28(5) of the Rules for Participation.*
[10] *See Article 28(6) of the Rules for Participation.*

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[11]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[12]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [13]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific categories of costs for:
    - 'costs for **energy efficiency measures** in buildings'[14]
    - '**access costs** for providing trans-national access to research infrastructures'[15]
    - 'costs for **clinical studies**'[16]

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[11] *See Articles 123, 124 of the Financial Regulation.*

[12] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[13] *See Article 33(2) of the Rules for Participation.*

[14] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[15] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (⚠ new in Horizon 2020)[17]

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme.

[17] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum EU contribution.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7; ⚠ new in Horizon 2020).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact
If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

2. Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Step 1 — Rejection of ineligible costs and application of the reimbursement rates

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Step 2 — Limit to the maximum grant amount

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Step 3 — Reduction due to the no-profit rule and receipts

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*

- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*

- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that you must:

- at proposal stage: enter only eligible costs into the estimated budget for your action *(see Article 4)*
- at reporting stage: declare only eligible costs in your financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on you**. You must keep sufficient supporting documents *(see Article 18)* to show that the costs you declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action.*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

  This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

⚠ Accounting documentation is necessary only for actual costs.

Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

Specific case:

For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**
- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g.*

number of square meters for energy efficiency in buildings) **by the value per unit** ('amount per unit')

Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices
- must budget and declare a total amount; the amount per unit must not be included in Annex 2.

⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

Example:

A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900
Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.

Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*:** *costs of [insert cost category or activity*[13]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[*A.6 [****OPTION to be used for trans-national access to research infrastructure:*** ***Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

Beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 The budget category 'costs for employees (or equivalent)' **covers** the following **types of costs**:

- **basic remuneration** (basic salary and complements) and
- for non-profit legal entities: **additional remuneration** ('bonus payments').

What is 'basic remuneration'?

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

'Parental leave' covers both maternity leave and parental leave.

The 'complements' may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if

  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and

  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25 % flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — If a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6.

ⓘ For more information on personnel made available to a beneficiary by a third party, see below and Articles 11 and 12.

What not?

The basic remuneration does not include components that must be considered to be 'additional remuneration'.

Example (variable remuneration component acceptable as basic remuneration): *The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.*

⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the

relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

What is 'additional remuneration'?

'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

1.1.2 Costs for employees (or equivalent) may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

For basic remuneration (basic salary and complements):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- be **mandatory** under national law, collective labour agreements or the employment contract
- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract, but he/she **must be 'assigned to the action'** (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

Specific case:

For **secondments** or **linked third parties**, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

For additional remuneration ('bonus' payments) **for non-profit legal entities:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

  Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

  Example:

  A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours
  Remuneration components:
  a = annual salary: EUR 50 000
  b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
  c = additional remuneration for being Head scientist in a project: EUR 2 000
  d = additional remuneration for being First Assistant on an internal action: EUR 1 000
  ***a** and **b** would be used to calculate the researcher's hourly rate:*
  hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34
  ***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*
  ***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for **additional work** or **expertise**

  The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

  Examples (acceptable additional remuneration):

  A normal salary is paid for teaching + additional remuneration is paid for doing research.

  A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

  A normal salary is paid for laboratory research + additional remuneration is paid for field research.

  Examples (not acceptable additional remuneration):

  Additional remuneration paid for using English.

  Additional remuneration is paid for participating in EU funded or multi-partner actions.

- be part of the beneficiary's usual remuneration practices and be consistently paid whenever the same kind of work or expertise is required
- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

The objective criteria must be related to the additional work or expertise.

The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours = **32 000***
*Addition of the additional remuneration: = **2 000***
*Total costs charged to the action for the year: **32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 **< 1 600**)*

Procedure for calculating costs personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception:

Employees hired during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Examples:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 → the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- the total number of hours worked by the person in the year for the beneficiary (**'individual annual productive hours**')
- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices (**'standard annual productive hours'**).

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*

total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	**In all cases** Any beneficiary can use this option.	∅ **Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: o employment contract of the person concerned o applicable collective labour agreement o national law on working time *Example: contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		option cannot be used. – this calculation method is consistently applied (per group of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. ⚠ The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. ⚠ The beneficiary may include or	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90 % of 'standard annual workable hours'. The standard annual workable hours is the standard	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of

	exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: o the employment contracts of the reference group o an applicable collective labour agreement or o the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* ⚠ If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. ⚠ If its number of standard annual productive hours is lower than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment*	annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave. *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* ***Standard annual productive hours** for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = **228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = **212*** *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = **1 642*** ***1 696 hours** (usual cost accounting practice) **> 1 642 hours** (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable*	

		hours). ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case:

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs

- are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate
- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

  Example: *calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example*: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

***Example**:*

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.
S/he worked 1 600 annual productive hours, 800 of them for the EU action.
Maximum additional remuneration eligible for the EU action (eligibility ceiling):
{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000
The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 The budget category 'costs for natural persons working under a direct contract' **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action, under a contract which is not governed by labour law; not companies)

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

1.2.4 The **calculation** of the costs depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount). A calculation method is required, especially if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same **formula** explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the hourly rate is different (since it is not based on the annual personnel costs as registered on the payroll).

For the **hourly rate**, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person: this global amount must be divided by the number of hours worked for the beneficiary under that contract.

1.3 Direct personnel costs: Costs for personnel seconded by a third party

1.3.1 This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 These budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and indicated in Annex 2 of the GA.

This unit cost (hourly rate) is calculated according to the following formula:

{EUR 4,650/ 143 hours}

multiplied by

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

{country-specific correction coefficient / 100}

ⓘ *For the country-specific correction coefficient, see the* MSC calls conditions of the Main Work Programme[19] *(Table 4).*

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **owner** of an **SME/ beneficiary that is natural person**, who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They must be **calculated** as follows:

amount per unit (hourly rate) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 This budget category **covers** the personnel costs in actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties *[(not included in Point F)] [OPTION to be used if Article 15 applies:* *are eligible if the conditions set out in Article 15 are met.]**[OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2. Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.
  If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

  If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

  ⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.****]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[15]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.****]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).****]***

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

Beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment cost: Depreciation costs of equipment, infrastructure or other assets

1.1.1 This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

It is expected that the beneficiaries allocate the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

⚠ Depreciated equipment costs can never exceed the equipment's purchase price.

⚠ Depreciation cannot be spread over a period longer than the equipment's useful life

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  {equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

1.2 Equipment costs: Cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of the equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

> ⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.
>
> ⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets

- **not** include any **financing fees**
- fulfil the **additional eligibility conditions** set out in Article 13.1.1.

1.4.4 The costs must be **calculated** following the beneficiary's usual practices and may not exceed the costs of purchasing the equipment (i.e. must be comparable to the depreciation costs of similar equipment).

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results and royalties on access rights

Specific cases:

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) paid to a third party (i.e. not a beneficiary) *(see Article 24)* are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees paid for access rights to background granted by other beneficiaries *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Best practice: Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled.

Costs for drafting the 'plan for the exploitation and dissemination of the results' are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when implementing this plan may be eligible.

– costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).

– translation costs, if translation is necessary for the action's implementation, is justified, etc.

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Internal invoices must not include indirect costs elements or profit margin or mark-up.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

- be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
- **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[16] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013: **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary

- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

⚠ No capitalised and operating costs of large research infrastructure may be declared in certain calls under the Part 'Research Infrastructure'.

What? Beneficiaries may declare **capitalised costs** and **operating costs** of research infrastructure used for the action.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ The beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.), together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should

[20] *See also International Financial Reporting Standard No 16.*
[21] *See Article 126 of the Financial Regulation.*

be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)

- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)

- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);

- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).These costs

are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments)

- knowledge-based resources such as collections, archives or scientific data

- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

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[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the H2020 Framework Programme.*

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. During an audit, the auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

The beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

– internal management exchanges necessary for the approval of an underlying transaction

– purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

– for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

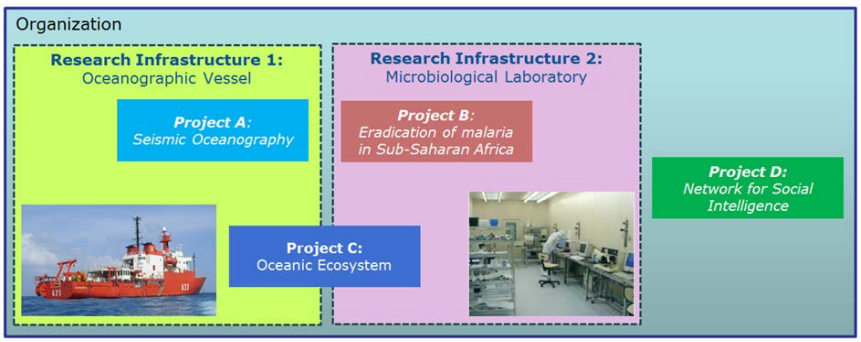

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

[24] *See Article 129(1) of the Financial Regulation.*

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  ⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

  ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

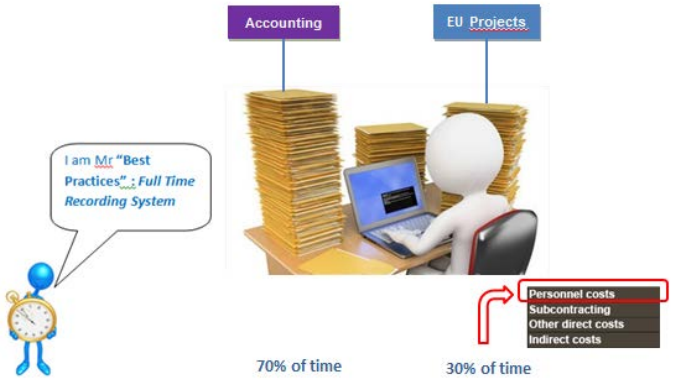

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to the best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[26].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

$$\{\text{actual eligible costs per unit of use}\} \ \mathbf{x} \ \{\text{actual number of units of use used on the action}\}.$$

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

[26] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category covers costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be declared on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– unit or lump-sum costs covering specific categories of costs which include indirect costs.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs

- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),
- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

***[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]*

1. Specific categories of costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific categories of costs**, i.e.:

- for Energy Challenge actions involving additional energy efficiency measures: **costs for additional energy efficiency measures**

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015).*

  These grants combine different activities. The reimbursement on the basis of the unit cost applies only for the building-related demonstration activities.

- for actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity': **access costs for providing trans-national access to research infrastructures**

  ⚠ This unit cost will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015).*

- for actions under Health Challenge actions involving clinical studies: **costs for clinical studies**

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are already covered by the unit cost may not be declared (a second time) as direct costs *(for the costs that are covered, see below)*.

Examples:

Case 1: *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

Case 2:*A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.*

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 = 25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Case 3: *A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.*

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 Specific category 'costs for additional energy efficiency measures'

1.1.1 This budget category **covers** two categories of eligible costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and
- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost (EUR/m^2 of eligible conditioned gross floor area) set out in Commission Decision C(2013) 8196[27] and indicated in Annex 2 of the GA.

This unit cost (EUR/m^2 of eligible conditioned gross floor area) is calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

'standard cost to save 1 kWh' = EUR 0.1
'standard payback period' to be used = 10 years

The m^2 of eligible conditioned gross floor area do not include parts of the buildings which are not affected by the measures, *e.g. garages*.

⚠ The specifications per type of demonstration building must already be part of your project proposal (by completing the BEST table (Building Energy Specification Table))[28]. These specifications are then included in Annex 1.

⚠ You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit (EUR/m^2 of eligible conditioned gross floor area) x number of actual m^2 of surface area built or refurbished

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[28] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

1.2 Specific category 'access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category, these costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[29] and set out in Annex 2 of the GA.

⚠ The Decision does not fix the unit cost for access costs; it must be established for each installation as follows (and then reflected in Annex 2 of the GA):

- the access provider identifies a *unit* of access to the installation; this is used to measure the total quantity of access that the installation provides to its users
- the Commission and the access provider agree the *unit cost* of access calculated as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access cost (over past two years}^{30}\textbf{)}}{\textbf{average annual total quantity of access (over past two years}^{31}\textbf{)}}$$

The averages are based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for under two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing maintenance).

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.
[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[31] In exceptional and duly justified cases, the Commission may agree to a different reference period.

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for:
  - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    By way of exception, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the research work of the users
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)
  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

  and excluding:
  - all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as

depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

– travel and subsistence costs to support the visits of users.

A form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ Do not forget to describe in your proposal the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs= average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Before signature of the GA, the beneficiaries can opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation) not as unit cost but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*. If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for **providing trans-national access to research infrastructure** to scientific communities
- fulfil the **additional eligibility conditions** set out in Article 16.1

1.1.4 They must be **calculated** as follows:

– for each installation:

amount per unit (EUR/unit of access) x number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.**]***

[OPTION: *not applicable**]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties free of charge are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

    Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

  - **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

- **interest owed** (i.e. interest on a loan to borrow capital)

- **excessive or reckless expenditure**

  'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

  'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

- **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

- **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency

- **deductible VAT ('recoverable VAT')**

  'Deductible (or recoverable) VAT' means VAT that is recoverable under the national VAT legislation. (Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is neither actually incurred by the beneficiary nor identifiable and verifiable.)

  The accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

  The VAT *paid* is a claim against the tax authority and will be reimbursed. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

  The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible** it is an eligible cost.

The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

Specific cases:

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

Under the Financial Regulation VAT will in all cases be considered as 'not recoverable' for:

- exempt activities without right of deduction
- activities which fall outside the scope of VAT
- activities for which VAT is not deductible, but refunded by means of specific refund schemes or compensation funds not foreseen by Directive 2006/112/EC (even if established by national VAT legislation).[32]

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding).

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[33] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

[32] *See Article 187 of the Rules of Application.*

[33] *For the definition, see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the	Subcontracts concern the implementation of

implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic

are necessary for the action.	activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 ***[OPTION:*** *with the exception of additional exploitation obligations****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.****]***

[OPTION: *not applicable****]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

- 'Beneficiaries not receiving EU funding' are third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[34]) that:are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure).

ⓘ For more information on third country participants, see the Horizon 2020 Online Manual.

[34] *For the definition, see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

Obligations that do not apply to beneficiaries not receiving EU funding:

These beneficiaries must, in particular, **not**:

- comply with the conditions for declaring costs *(e.g. cost form, eligibility, calculation, etc) (Chapter 3 and Articles 10-15)*
- keep records and other supporting documentation for costs *(Article 18.1.2)*
- submit financial reports and convert their costs in euro *(Articles 20.3(b), 20.4(b) and 20.6)*
- comply with some of the rules on management of intellectual property, background and results *(Articles 26.4, 28.1, 28.2, 30.3 and 31.5)*
- fear rejection of costs, reduction of the grant or recoveries, suspension of the payment deadline or suspension of payments *(Articles 42, 43 and 44)* .

⚠ Apart from this, they are treated like the other beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs, reduction of the grant or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the best value for money considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the Work Programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[35] and 2004/17/EC[36] — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[35] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[36] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[37] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*,

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]*.**]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means a contract for the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is forbidden in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is forbidden, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the best value for money considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

⚠ The latter GA contains more detailed obligations since these PCP/PPI Cofund actions consist mainly in subcontracting and undertake PCPs and PPIs as the main objective of an action.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. Other obligation: Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[38]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[38] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks

- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises

- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an **established relationship** (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

– *scientific and economic unity*

– *last a certain length of time*
– *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[39]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

– the financial viability/capacity of a beneficiary is 'weak' while that of its linked third parties is strong

  ⓘ For more information on the financial viability and the financial capacity check, see the Horizon 2020 Online Manual.

– the beneficiary mainly coordinates the work of its linked third party.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

[39] *See Articles 8 and 9 of the Rules for Participation.*

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is **no** procedure for **approval without amendment**.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

⚠ The obligations in Article 14.1.1 additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

Each linked third party has its own financial statements, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA ('**cascade funding**').

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is **not** considered financial support.

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties (recipients) that actually implement research and/or innovation projects.)

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ *For financial support given in the form of prizes, see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g. 3 grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

⚠ All these conditions must already be described in your proposal (see the Proposal Templates).

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- avoid conflicts of interest *(see Article 35)*
- maintain confidentiality *(see Article 36)*
- promote the action and give visibility to the EU funding *(see Article 38)*
- are liable for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *not applicable**]***

15.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

Example: *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.
- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[28]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

1. Trans-national access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[40] and installations[41] for scientific communities ('provision of access activity').

Such Research Infrastructures Part actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **cover** — for the provision of access activity — the following **types of costs**:

[40] *For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[41] *For the definition, see the footnote in Article 16 of the MGA.*

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

The Beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Virtual access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

– operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

⚠ There are no 'access costs' for virtual access.

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected or even identified.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 Obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[42] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[42] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Rules of Application: **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

Sufficiency relates to the quantity of evidence; appropriateness relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[43]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ This does not affect national laws on keeping documents.

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

[43] International Standard on Auditing ISA 500 'Audit Evidence'.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

– keep detailed records and other supporting documents to prove the eligibility of the costs declared

– use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as personnel costs must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units

declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the beneficiary's actual personnel costs as recorded in its statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

To get additional assurance, a beneficiary may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2 by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

Exception:

The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval.

The Commission/Agency will not approve the CoMUC if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary can show that they were declared according to the approved practices).

> **Best practice:** Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).
>
> Approval is for Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

> If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.
>
> If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (directly in the electronic exchange system, i.e. the 'My Area' section of the Participant Portal; see Article 52). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ *For more information on the certification procedure, see the Horizon 2020 Online Manual.*

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

  Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiaries must:

- sign one **declaration** per reporting period, to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  This declaration must be dated and countersigned for acceptance by the person concerned.

  A template [hyperlink] is provided on the Participant Portal.

  Best practice: If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiary must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  A template [hyperlink] is provided on the Participant Portal.

  Time records should include:

  - the title and number of the action, as specified in the GA
  - the beneficiary's full name, as specified in the GA
  - the full name, date and signature of the person working for the action
  - the number of hours per day declared for the action
  - the supervisor's full name and signature
  - a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned
  - a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

The beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For Energy Challenge actions involving additional energy efficiency measures, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*), unless Annex 1 specifies another way.

Specific case:

'**Classified deliverables**' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

– a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions).****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

– a '**periodic financial report**' containing:

(ii) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(iii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iv) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(v) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[32] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the coordinator, which must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (they do not see their grants in the electronic exchange system and therefore have no access to them). Before submission, the beneficiary completes the data for the linked third party, prints it and sends it to the linked third party which must sign it *on paper* and then send it back to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system are identical to the signed paper version.

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

CFSs must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

ⓘ *For information on the eligibility of costs incurred for reporting, see Article 6.2.D.3.*

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified deliverables' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on

security of information in the Commission internal Rules of Procedure *(see also Guide for classification[hyperlink]).*

ⓘ For more information on information security, see the Horizon 2020 Online Manual.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on cross–cutting issues (described in Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined vis-à-vis societal challenges (Annex I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.).*

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed, if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more), as reimbursement of actual costs and personnel costs

on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25 % flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, it must be an independent public officer, with formal competence to audit the beneficiary/linked third party.

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[44] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries and linked third parties must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro:**
  - for costs incurred in the currency of their accounting records conversion of costs by one of the following:
    - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[44] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[45].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart corresponding to your currency.

Step 3 — Choose the start and end date of the period for which the average daily exchange rate is calculated (i.e. the reporting period) by using the sliding tool in the second table.

Step 4 — The average appears above the first table.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if no daily euro exchange rate is published : using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[46].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

– for **costs incurred in a currency other than EUR and the one used in their accounting records:** conversion in accordance with the applicable national law and their usual accounting practices.

– for costs incurred in EUR, beneficiaries **with accounting records in a currency other than the euro** must declare the amount in EUR; no conversion has to be made.

⚠ This means that a beneficiary with accounting in a currency other than EUR will act differently according to the currency in which it incurs the costs (the currency in which the contract/invoice is established).

Examples:

1. *If the UK beneficiary buys the equipment in the USA (costs incurred in US dollars), it will convert the price of this equipment into pounds (the currency in which its accounts are established) according to its usual accounting practices. When reporting the costs to the Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.*

2. *If the UK beneficiary buys the equipment in UK pounds (it will record those equipment costs incurred in pounds in its accounts kept in pounds). When reporting the costs to the*

[45] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[46] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.

3. If the UK beneficiary buys the equipment in Germany in EUR (e.g. EUR 10 000) it will report these costs incurred in EUR (i.e. 10 000) to the Commission/Agency without converting them first from EUR to pounds and then back to EUR.

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline *(see Article 47)*
- terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

⚠ This may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90 % of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - the work has started.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed start date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed start date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)
- the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, see Articles 42, 43 and 44.

2. Amount of pre-financing payment

There is no standard amount or percentage for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods (it will be in any case less for actions with only one reporting period, as 100% would mean the totality of the EU grant for the action).

⚠ At the moment of the pre-financing payment, an amount equivalent to 5% of the maximum grant amount is deducted from the payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.
Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.
Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1 : application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:
- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)
Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
Payment of the balance amounts to EUR 100 000 and will be ***paid*** *to the coordinator as follows:*
- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*
- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

⚠ These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[47] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[47] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[48]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

[48] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the **right to sub-license**.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a **royalty-free** basis — to background **needed** to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background **needed** for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to **legal restrictions or limits**, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is **needed** to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013 [Horizon 2020]).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider* ***needed*** *to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access rights to background

The GA generally provides that the beneficiaries must provide access rights for background needed *(see below)*.

Beneficiaries may grant additional or more favourable access rights to background, beyond the rights foreseen in the GA.

Examples

Additional or more favourable access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country) or to other input which is not results or background (e.g. information or rights generated or acquired in parallel to the action, informally defined as sideground).

Such additional provisions may be included in the consortium agreement or in a separate agreement, if, for example, they only concern certain beneficiaries.

⚠ Beneficiaries may foresee in the consortium agreement that access rights will be removed if a beneficiary defaults on its obligations *(see Article 41.3)*.

The granting of access rights may be conditional on the acceptance of specific conditions *(e.g. appropriate confidentiality obligations)*.

In such cases, it is recommended, for legal certainty purposes, to specify these conditions in writing as well.

2. Requests for access

Access rights to background are not automatic. They must be requested in writing.

Beneficiaries may use their internal rules to specify how to make such written requests.

⚠ Access may be requested, under the same conditions, even from a beneficiary whose participation was terminated before the action's end.

Access to background for exploitation may be requested **up to one year** after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

Once requested, access rights may be exercised as long as they are needed for exploiting the results *(e.g. until the background patent expires)*.

3. When is the background 'needed'?

There is no definition of 'needed' in the GA. Beneficiaries must assess whether or not access rights are needed on a case-by-case basis, taking into account their action's specificities.

⚠ The background needed must already be taken into account when the beneficiaries identify and agree (in writing) on the background for the action.

To avoid conflicts, it is recommended that beneficiaries agree *(e.g. in the consortium agreement)* on a **common interpretation of what is needed** and

***Example (background needed for implementation)**: if without this background, tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without this background, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Beneficiaries may refuse access to background if they consider that such access is not needed.

In this case, the requesting beneficiary must better substantiate its request or withdraw it.

Disagreements must be solved through the agreed *(e.g. in the consortium agreement)* conflict resolution system.

⚠ The beneficiaries and the coordinator must inform if such conflicts are likely to affect compliance with requirements under the GA, in particular, the execution of the action *(see Article 17.2.)*.

4. Legal restrictions or limits

Beneficiaries must inform the other beneficiaries — before acceding to the GA — of any legal limitations for granting access to their background.

Restrictions or limits can be set out in law or contract.

***Example:** A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ If beneficiaries agree on additional background after they sign the GA, they must immediately inform the other beneficiaries of any related restrictions or limits.

⚠ When contracting on background with third parties after accession to the GA, the beneficiaries must ensure that that they comply with their obligations under the GA.

There is no general rule preventing beneficiaries to grant licenses, including quasi exclusive licenses, to their own background, as long as they can ensure compliance with their obligations under the GA(i.e. Guarantee access). Beneficiaries are even free to grant exclusive licences, if they agree on a waiver of access rights.

5. Royalty-free — Fair and reasonable conditions

For **implementation,** beneficiaries must, in general, grant **royalty-free** access to their background.

Exception:

If agreed by the beneficiaries before the GA is signed, other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

For **exploitation,** beneficiaries must agree on what constitutes **fair and reasonable conditions**, preferably in writing.

⚠ New terminology in Horizon 2020: fair and reasonable conditions include also royalty-free conditions.

Access may be royalty-free or it may include financial (i.e. monetary compensation) or non-financial terms.

Examples:

Monetary compensation could take the form of a lump sum, a royalty percentage, or a combination of both.

Non-financial terms could include a requirement for the beneficiary requesting access:

(a) to grant access to other technology in its possession, or

(b) to agree on cooperation in a different field or in a future project.

ⓘ *For more information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3.*

6. Sublicensing of access rights to background

Access rights do not give the right to sub-licence; sub-licensing is only allowed with the consent of the beneficiary that gives access.

Example:

The beneficiary owning the background agrees that another beneficiary may sublicense its access rights to background to its affiliated entity.

⚠ If sublicensing was freely allowed, this would imply that access rights to the background could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors.

There may be cases where sublicensing of access rights is necessary. In this case, sub-licensing should not be unduly refused.

Example:

A university may need the right to sub-license access to background to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

The terms and conditions of such sub-licensing must be agreed, preferably in writing.

The terms and conditions of sub-licensing may be a separate agreement (*e.g. if it concerns only certain beneficiaries*) or may be part of the consortium agreement *(see Article 41)*.

Sub-licensing does not have to be royalty-free (even if the access rights concerned are).

Specific conditions can be established regarding sub-licensing.

Examples: *Sub-licensing could apply to the background (or part of it), but not to the results; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

7. Waiver of access rights to background

Waivers of access rights to background should be made only on a case-by-case basis, once the background has been correctly identified.

Only written waivers are valid.

The waiver should not be broader than what is actually necessary.

Example:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the background concerned is not exploited by the licensee within a certain period.

8. Access rights for third parties

This option will be inserted in the GA only for actions involving trans-national access to research infrastructure for scientific communities *(see Article 16)*.

It ensures that the selected users have royalty-free access to the background they need for using the research infrastructure.

The access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[49] and the Code of Conduct for their Recruitment.[50]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ *For guidance in this process, see the 'Human Resources Strategy for Researchers' tool*[51] *developed by the Commission.*

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[52] and of the Code of Conduct[53] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[54])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[53] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[54] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[55].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[56].

[55] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[56] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink])

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

Best practice: Beneficiaries are advised to obtain the **approval of** a **European ethics committee** (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and

- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[57] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[57] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

1. Processing of personal data by the Commission/Agency

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency 'Data Protection Officer (DPO)'.

This notification will be available in the Register of the DPO[58] (and will describe the processing operations, security safeguards, data transfer, retention period, etc.).

⚠For the processing of sensitive data *(e.g. health data)* and processing for the purpose of administrative penalties and termination, the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ *For more information, see the data privacy statement ('SSPS')[59] on the Participant Portal.*

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS) to:

– obtain information about what data is collected and how it is used, usually given via a privacy statement

[58] Available at http://ec.europa.eu/dpo-register/search.htm.
[59] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

– see which of their data are being held

– correct any errors in the data, block access to this data, or delete their data

– complain about data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ *For information on the complaints procedure, see the EDPS website.*

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data, by the beneficiaries

The beneficiaries (and linked third parties) must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[60] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

[60] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [61]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing** of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[62]

Beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform staff** (whose personal data are collected and processed by the Commission/Agency) about this disclosure, by providing them with the SSPS.

Examples:

Before encoding its staff's personal data in the Beneficiary Register or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must tell the staff concerned and provide them with the SSPS.

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61 *See Article 8 of Directive 95/46/EC.*

62 *See Articles 6, 16, 17 of Directive 95/46/EC.*

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ *For more information on ethics, see the H2020 Online Manual.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party, unless the Commission/Agency has explicitly agreed in writing.

> 'Assignment' normally means the transfer of rights held by one party to another party. However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.
>
> Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

> The Commission/Agency will assess the reasons given and approve or reject the request in writing.
>
> ***Examples (reasonable requests for assignment):***
>
> *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity*
>
> *Assignment for the benefit of creditors in a bankruptcy procedure*

Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

> ***Example:*** *The obligation to allow audits by the Commission/Agency*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

[OPTION for joint actions (joint call with a third country or an international organisation)*: The beneficiaries must conclude a '****coordination agreement****' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.****]***

[OPTION: *not applicable****]***

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator**, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

Example: *in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- **Monitor** that the action is implemented properly
- Act as the **intermediary for all communications**, unless the Agreement specifies otherwise
- **Request** and **review** any **documents** or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- **Submit** the **deliverables** and **reports**

- **Distribute payment**s to the other beneficiaries, without unjustified delay

- **Inform** the Commission/Agency of the **amounts paid** to each beneficiary, if requested to do so *(see Article 44.1.2)*.

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the H2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action).*

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement (unless exceptionally stipulated otherwise in the Work Programme, for a specific call).

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded **before the action starts**. (Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action.)

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the H2020 Online Manual.

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiaries must conclude a coordination agreement.

'Coordination agreements' are agreements between the consortium and partners from a third country (including scientific and technological organisations and agencies) or an international organisation, with which the joint call was organised.

Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the basic contradictory procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100%.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries):

During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries):

During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[1] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[63]

  Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[64]

  If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

[63] *See Article 80(1) of the Financial Regulation.*
[64] *See Article 87 of the Rules for Application.*

- by either:
  - taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or
  - adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[65].[66]

    The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

    This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

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[65] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[66] *See Article 79(2) of the Financial Regulation.*

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary approved costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10% o**f the maximum EU contribution (as indicated in the estimated budget, for the beneficiary), depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

  Example:

  GA with an EU contribution of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

  During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in

the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 1 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the penalty may also be **published** on Commission or Agency websites — together with your name and information on the misconduct.

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note and — if the beneficiary does not pay by the due date — **recover** the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment within the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

1. Liability for damages, of the Commission/Agency

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

– causes damage to a third party (including another beneficiary)

Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

– suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability for damages, of the beneficiaries

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples:

Costs of additional audits that must be carried out because of doubts about the eligibility of costs.

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms the claim, it will issue a debit note and — if the beneficiary does not pay by the due date — recover the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment within the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

  ⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

- calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

❖ **Payment request does not comply with the provisions of the GA**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.

❖ **Payment request is incomplete or requires clarification**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

Examples: the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.

❖ **Doubts on the eligibility of costs in the financial statements that require additional verifications**

The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

Example: The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is no *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

- **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *statements made by the beneficiary in the declaration form are found to be false.*

  ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

– **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **no individual financial statements** for the beneficiary (or beneficiaries) concerned may be submitted.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation, by the beneficiaries

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Grounds for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

  ⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the suspension is lifted and the action continues, the action's remaining budget can be used to implement the action.

⚠ However, it is possible that the action is resumed with a lower budget to adapt it to the new situation (agreed as part of the amendment).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) ***cannot* be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation, by the Commission/Agency

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

❖ **Suspicion of loss of scientific or technological relevance**

The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

This may in particular be the case:

- if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
- if work has significantly deviated from the original work plan
- if a key beneficiary leaves the action and the consortium needs time to find a replacement
- after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA, by the beneficiaries

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery (see Article 21.4 and 44.1.2).
- is lower than the final grant amount, the Commission/Agency will pay the balance (see Article 21.4).

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

> ***Example:*** *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

> ***Example:*** *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries, by the beneficiaries

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ *For more information on the roles and access rights in the electronic exchange system, see the H2020 Online Manual.*

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action (unless it concerns the coordinator, since the new coordinator has many obligations also after the end of the action, *e.g submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action — including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so —, unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.][OPTION: not applicable];

(j) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries, by the Commission/Agency

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

❖ **Non-accession to the GA**

The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA).

⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*.[67]

Examples:

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this.

[67] *See also Article 8 of the Rules for Participation.*

The Commission terminates the GA because the conditions set out in the work programme are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

- **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

- **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

❖ **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

❖ **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

❖ **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

❖ **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country's or international organisation's action does not start by the date specified in Annex 1

  ⚠ In this case, **no costs** incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country's or international organisation's action is terminated

- the third country's or international organisation's action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

❖ **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA —

substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the participation of the beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:

– **systemic** or **recurrent**

'Recurrent' means systematic infringements of an obligation under the GA, found in several grants of the beneficiary and therefore likely to also have occurred in the other grants of that beneficiary.

'Systemic' means infringements that are related to the beneficiary's methodologies, accounting, management or internal control practices.

– have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ **Ineligible costs** may be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate a beneficiary *(see Article 50.2.2)***.**

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure
- labour disputes or strikes

– financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has **no specific effects** on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation (see Article 49) or termination of the GA (see Article 50).

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use a 'Messaging' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal Notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and

amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ For more information on access and roles in the electronic exchange system, see the H2020 Online Manual.

In principle, all communications from/to the Commission/Agency must go **via the coordinator** (unless the GA or other rules provide for direct communication with the other beneficiaries, *e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations*).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA, by the beneficiaries mentioned in the Preamble

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned])*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for international organisations (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[68]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the *Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States*, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN system (⚠ new in Horizon 2020).

It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU-arbitration clause, referring disputes on the interpretation, application or validity of the GA to the Court of Justice of the European Union.

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[69]).

[68] *See Article 180(1) of the Rules of Application.*

[69] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238).

If a dispute is of public law nature (i.e. concerns offsetting or an enforceable decision under Article 299 TFEU), actions must be brought before the Court of Justice of the European Union not under Article 272, but under Article 263 TFEU.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Horizon 2020
Annotated Model Grant Agreements

General Model Grant Agreement
and specific Model Grant Agreements (ERC, SME Instrument, ERA-NET Cofund, PCP-PPI Cofund, EJP Cofund, Framework Partnerships and Specific Agreements)

Version 1.6
2 May 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations regarding the following derived model grant agreements: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnerships and specific agreements

Foreword

The **Horizon 2020 Annotated Model Grant Agreements** ('AGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

---

[1] **H2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

Over the next months, this text will be transformed into an on-line version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Horizon 2020 Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

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I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *Energy Challenge actions (see the Smart Cities and Communities calls); actions under the Research Infrastructures Part (see a Research Infrastructure call); Health Challenge actions, etc*
>
> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 Annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

[3] *See Article 15(9) of the Rules for Participation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- for **coordination and support actions (CSA)**: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

'Complementary grants' are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*, which links the two action and ensures the necessary synergies.

[6] *For the definition, see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies)

The budget category 'specific categories of costs' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings' and 'costs for clinical studies'.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);][OPTION: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

*[**OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
[5] For the definition, see Article 2.1(14) Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[7]; for IA actions it is normally 70% of the total eligible costs[8].

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[9]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[10] and all budget categories.

[7] *See Article 28(4) of the Rules for Participation.*
[8] *See Article 28(5) of the Rules for Participation.*
[9] *See Article 28(5) of the Rules for Participation.*
[10] *See Article 28(6) of the Rules for Participation.*

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[11]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[12]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [13]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific categories of costs for:
    - 'costs for **energy efficiency measures** in buildings'[14]
    - '**access costs** for providing trans-national access to research infrastructures'[15]
    - 'costs for **clinical studies**'[16]

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[11] *See Articles 123, 124 of the Financial Regulation.*

[12] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[13] *See Article 33(2) of the Rules for Participation.*

[14] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[15] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs ⚠ new in Horizon 2020)[17]

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme.

[17] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum EU contribution.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact
If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

2. Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000
Reimbursement rate= 100%
Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:
The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:
In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:
Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000
The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries (and linked third parties) must:

– at proposal stage: enter only eligible costs into the estimated budget for your action *(see Article 4)*

– at reporting stage: declare only eligible costs in your financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries** (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  ⚠ Accounting documentation is necessary only for actual costs.

  Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  ⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  Specific case:

  For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

  – recorded in the third party's accounting records

  – calculated in accordance with the accounting standards applicable in the country in which the third party is established

  – calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit')

  Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

  ⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

  Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

  For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

  – must calculate them (the average or standard personnel costs) according to its usual accounting practices

  – must budget and declare a total amount; the amount per unit must not be included in Annex 2.

  ⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

  Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

  Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

  ⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

  Example:

  A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.

Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900
Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*:** *costs of [insert cost category or activity*[13]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure:** **Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 This budget category **covers** the following **types of costs**:

- **basic remuneration** (basic salary and complements) and
- for non-profit legal entities: **additional remuneration** ('bonus payments').

What is 'basic remuneration'?

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

'Parental leave' covers both maternity leave and parental leave.

The 'complements' may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — If a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6.

> ⓘ *For more information on personnel made available to a beneficiary by a third party, see below and Articles 11 and 12.*

What not?

The basic remuneration does not include components that must be considered to be 'additional remuneration'.

> ***Example (variable remuneration component acceptable as basic remuneration):*** *The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.*

> ⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

What is 'additional remuneration'?

'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

1.1.2 Costs for employees (or equivalent) may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

For basic remuneration (basic salary and complements):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- be **mandatory** under national law, collective labour agreements or the employment contract
- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract, but he/she **must be 'assigned to the action'** (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

Specific case:

For **secondments** or **linked third parties**, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

For additional remuneration ('bonus' payments) **for non-profit legal entities:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours
Remuneration components:
a = annual salary: EUR 50 000
b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
c = additional remuneration for being Head scientist in a project: EUR 2 000
d = additional remuneration for being First Assistant on an internal action: EUR 1 000
***a** and **b** would be used to calculate the researcher's hourly rate:*
hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34
***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*
***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for **additional work** or **expertise**

The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

Examples (acceptable additional remuneration):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

Examples (not acceptable additional remuneration):

Additional remuneration paid for using English.

Additional remuneration is paid for participating in EU funded or multi-partner actions.

- be part of the beneficiary's usual remuneration practices and be consistently paid whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

The objective criteria must be related to the additional work or expertise.

The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***
Addition of the additional remuneration: = ***2 000***
Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Procedure for calculating personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception:

Employees hired during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Examples:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')

- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours')**

- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	Can be used **in all cases**; any beneficiary can use this option.	**Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: – employment contract of the person concerned – applicable collective labour agreement – national law on working time ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1;

		group – an applicable collective labour agreement or – the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours*	– if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		per day = 1 824 hours ***Standard annual productive hours*** *for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days =* ***228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days =* ***212*** *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 =* ***1 642*** ***1 696 hours*** *(usual cost accounting practice)* ***> 1 642 hours*** *(90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case:

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs

– are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

– correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.

– the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Example:

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.
S/he worked 1 600 annual productive hours, 800 of them for the EU action.
Maximum additional remuneration eligible for the EU action (eligibility ceiling):
{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000
The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 This budget category **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action, under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

1.2.4 The **calculation** of the costs depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount). A calculation method is required, especially if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same **formula** explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the hourly rate is different (since it is not based on the annual personnel costs as registered on the payroll).

For the **hourly rate**, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person: this global amount must be divided by the number of hours worked for the beneficiary under that contract.

1.3 Direct personnel costs: Costs for personnel seconded by a third party

1.3.1 This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 These budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and indicated in Annex 2 of the GA.

This unit cost (hourly rate) is calculated according to the following formula:

{EUR 4,650/ 143 hours}

multiplied by

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

{country-specific correction coefficient / 100}

ⓘ *For the country-specific correction coefficient, see the* MSC calls conditions of the Main Work Programme[19] *(Table 4).*

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **owner** of an **SME/ beneficiary that is natural person**, who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They must be **calculated** as follows:

amount per unit (hourly rate) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 This budget category **covers** the personnel costs in actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not included in Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15 are met.][**OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2. Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs (equipment costs)':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment cost: Depreciation costs of equipment, infrastructure or other assets

1.1.1 This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following:

It is expected that the beneficiaries allocate the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

⚠ Depreciated equipment costs can never exceed the equipment's purchase price.

⚠ Depreciation cannot be spread over a period longer than the equipment's useful life

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  {equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

1.2 Equipment costs: Cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of the equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

> ⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.
>
> ⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a*))
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional eligibility conditions** set out in Article 11.1.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. costs of purchasing scientific publications (e.g. books, manuscripts, articles, digital copies, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results and royalties on access rights

Specific cases:

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) paid to a third party (i.e. not a beneficiary) *(see Article 24)* are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees paid for access rights to background granted by other beneficiaries *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Best practice: Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled.

Costs for drafting the 'plan for the exploitation and dissemination of the results' are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when implementing this plan may be eligible.

– costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).

– translation costs, if translation is necessary for the action's implementation, is justified, etc.

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Internal invoices must not include indirect costs elements or profit margin or mark-up.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

6 '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

17 For the definition see Article 2(6) of Regulation (EU) No 1291/2013: **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

What? Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ The beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.), together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

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[20] *See also International Financial Reporting Standard No 16.*
[21] *See Article 126 of the Financial Regulation.*

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments)
- knowledge-based resources such as collections, archives or scientific data
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

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[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the H2020 Framework Programme.*

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. During an audit, the auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

The beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  ⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

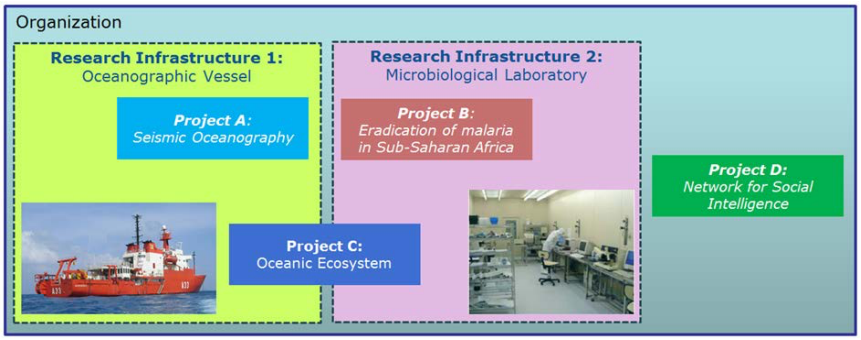

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure;*

[24] *See Article 129(1) of the Financial Regulation.*

see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)

⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

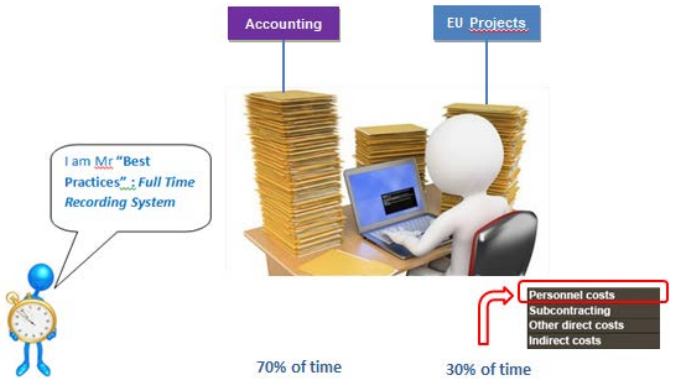

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to the best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[26].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

[26] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category covers costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be declared on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– unit or lump-sum costs covering specific categories of costs which include indirect costs.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]

1. Specific categories of costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific categories of costs**, i.e.:

- for Energy Challenge actions involving additional energy efficiency measures: **costs for additional energy efficiency measures**

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

  These grants combine different activities. The reimbursement on the basis of the unit cost applies only for the building-related demonstration activities.

- for actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity': **access costs for providing trans-national access to research infrastructures**

  ⚠ This unit cost will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015)*.

- for actions under Health Challenge actions involving clinical studies: **costs for clinical studies**

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are already covered by the unit cost may not be declared (a second time) as direct costs *(for the costs that are covered, see below)*.

Examples:

Case 1: The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

Case 2:A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Case 3: A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 Specific category 'costs for additional energy efficiency measures'

1.1.1 This budget category **covers** two categories of eligible costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and

– costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost (EUR/m^2 of eligible conditioned gross floor area) set out in Commission Decision C(2013) 8196[27] and indicated in Annex 2 of the GA.

This unit cost (EUR/m^2 of eligible conditioned gross floor area) is calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

'standard cost to save 1 kWh' = EUR 0.1
'standard payback period' to be used = 10 years

The m^2 of eligible conditioned gross floor area do not include parts of the buildings which are not affected by the measures, *e.g. garages*.

⚠ The specifications per type of demonstration building must already be part of your project proposal (by completing the BEST table (Building Energy Specification Table))[28]. These specifications are then included in Annex 1.

⚠ You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit (EUR/m^2 of eligible conditioned gross floor area) x number of actual m^2 of surface area built or refurbished

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.
[28] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

1.2 Specific category 'access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category, these costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[29] and set out in Annex 2 of the GA.

⚠ The Decision does not *fix* the unit cost for access costs; the unit cost must be established for each installation — before signature of the GA — as follows (and then reflected in Annex 2 of the GA):

- identification of a *unit* of access to the installation; this is used to measure the total quantity of access that the installation provides to its users

- establishment of the *unit cost* of access, calculated as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access cost (over past two years}^{30}\textbf{)}}{\textbf{average annual total quantity of access (over past two years}^{31}\textbf{)}}$$

The averages are based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing maintenance).

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[31] In exceptional and duly justified cases, the Commission may agree to a different reference period.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for:

  - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    By way of exception, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

  - costs of consumables specifically used for the installation and the research work of the users

  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

  - costs of energy power and water supplied for the installation

  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)

  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

  - costs of specific scientific services included in the access provided or needed for the provision of access

- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

  and excluding:

  - all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

  - travel and subsistence costs to support the visits of users.

A form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ Do not forget to describe in your proposal the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs= average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Before signature of the GA, the beneficiaries can opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation) not as unit cost but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*. If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for **providing trans-national access to research infrastructure** to scientific communities
- fulfil the **additional eligibility conditions** set out in Article 16.1

1.1.4 They must be **calculated** as follows:

– for each installation:

amount per unit (EUR/unit of access) x number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil —* ***mutatis mutandis*** *— the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.****]***

[OPTION: *not applicable****]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties free of charge are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

    Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

  - **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national VAT system. Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible** it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

Specific cases:

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding).

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[32] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

[32] *For the definition, see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the	Subcontracts concern the implementation of

implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic

are necessary for the action.	activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 ***[OPTION:*** *with the exception of additional exploitation obligations****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.****]***

[OPTION: *not applicable****]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[33]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

ⓘ For more information on third country participants, see the Horizon 2020 Online Manual.

[33] *For the definition, see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

Obligations that do not apply to beneficiaries not receiving EU funding:

These beneficiaries must, in particular, **not**:

- comply with the conditions for declaring costs *(e.g. cost form, eligibility, calculation, etc) (Chapter 3 and Articles 10-15)*
- keep records and other supporting documentation for costs *(Article 18.1.2)*
- submit financial reports and convert their costs in euro *(Articles 20.3(b), 20.4(b) and 20.6)*
- comply with some of the rules on management of intellectual property, background and results *(Articles 26.4, 28.1, 28.2, 30.3 and 31.5)*
- fear rejection of costs, reduction of the grant or recoveries, suspension of the payment deadline or suspension of payments *(Articles 42, 43 and 44)* .

⚠ Apart from this, they are treated like the other beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs, reduction of the grant or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the best value for money considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the Work Programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[34] and 2004/17/EC[35] — or any EU legislation that replaces these Directives[36]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[34] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[35] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[36] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*,

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]*.****]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means a contract for the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is forbidden in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is forbidden, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the best value for money considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. Other obligation: Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks

- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises

- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an **established relationship** (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak' while that of its linked third parties is strong

  ⓘ For more information on the financial viability and the financial capacity check, see the Horizon 2020 Online Manual.

- the beneficiary mainly coordinates the work of its linked third party.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery).

[38] *See Articles 8 and 9 of the Rules for Participation.*

The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is **no** procedure for **approval without amendment**.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

⚠ The obligations in Article 14.1.1 additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

Each linked third party has its own financial statements, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA ('**cascade funding**').

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is **not** considered financial support.

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties (recipients) that actually implement research and/or innovation projects.)

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ *For financial support given in the form of prizes, see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g. 3 grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

⚠ All these conditions must already be described in your proposal (see the Proposal Templates).

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- avoid conflicts of interest *(see Article 35)*
- maintain confidentiality *(see Article 36)*
- promote the action and give visibility to the EU funding *(see Article 38)*
- are liable for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *not applicable**]***

15.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

Example: *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.
- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[28]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

1. Trans-national access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[39] and installations[40] for scientific communities ('provision of access activity').

Such Research Infrastructures Part actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **cover** — for the provision of access activity — the following **types of costs**:

[39] *For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] *For the definition, see the footnote in Article 16 of the MGA.*

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

The Beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Virtual access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

– operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

⚠ There are no 'access costs' for virtual access.

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected or even identified.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General oobligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Rules of Application: **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ The rules in the GA do not affect national laws on keeping documents.

2. Original documents

The beneficiaries must **keep original documents**.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary (or linked third party) may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

⚠ The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval. It will also challenge the costs, if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary/ can show that they were declared according to the approved practices).

> **Best practice:** Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).
>
> Approval is for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

> If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.
>
> If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ For more information on the certification procedure, see the Horizon 2020 Online Manual.

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

> ***Example:*** *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*
>
> *a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;*
>
> *b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.*

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiaries must:

- sign one **declaration** per reporting period, to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  This declaration must be dated and countersigned for acceptance by the person concerned.

  A template [hyperlink] is provided on the Participant Portal.

  Best practice: If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  A template [hyperlink] is provided on the Participant Portal.

  Time records should include:

  - the title and number of the action, as specified in the GA
  - the beneficiary's full name, as specified in the GA
  - the full name, date and signature of the person working for the action
  - the number of hours per day declared for the action
  - the supervisor's full name and signature
  - a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned
  - a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books;*

professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

The beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For Energy Challenge actions involving additional energy efficiency measures, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*), unless Annex 1 specifies another way.

Specific case:

'**Classified deliverables**' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

– a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions).****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

– a '**periodic financial report**' containing:

(ii) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(iii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iv) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(v) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[32] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the coordinator, which must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (they do not see their grants in the electronic exchange system and therefore have no access to them). Before submission, the beneficiary completes the data for the linked third party, prints it and sends it to the linked third party which must sign it *on paper* and then send it back to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system are identical to the signed paper version.

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

CFSs must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

ⓘ *For information on the eligibility of costs incurred for reporting, see Article 6.2.D.3.*

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified deliverables' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on

security of information in the Commission internal Rules of Procedure *(see also Guide for classification[hyperlink]).*

ⓘ For more information on information security, see the Horizon 2020 Online Manual.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on cross–cutting issues (described in Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined vis-à-vis societal challenges (Annex I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed, if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more), as reimbursement of actual costs and personnel costs

on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25 % flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, it must be an independent public officer, with formal competence to audit the beneficiary/linked third party.

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro:**
  - for costs incurred in the currency of their accounting records conversion of costs by one of the following:
    - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[44].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart corresponding to your currency.

Step 3 — Choose the start and end date of the period for which the average daily exchange rate is calculated (i.e. the reporting period) by using the sliding tool in the second table.

Step 4 — The average appears above the first table.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if no daily euro exchange rate is published : using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

– for **costs incurred in a currency other than EUR and the one used in their accounting records:** conversion in accordance with the applicable national law and their usual accounting practices.

– for costs incurred in EUR, beneficiaries **with accounting records in a currency other than the euro** must declare the amount in EUR; no conversion has to be made.

⚠ This means that a beneficiary with accounting in a currency other than EUR will act differently according to the currency in which it incurs the costs (the currency in which the contract/invoice is established).

Examples:

1. *If the UK beneficiary buys the equipment in the USA (costs incurred in US dollars), it will convert the price of this equipment into pounds (the currency in which its accounts are established) according to its usual accounting practices. When reporting the costs to the Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.*

2. *If the UK beneficiary buys the equipment in UK pounds (it will record those equipment costs incurred in pounds in its accounts kept in pounds). When reporting the costs to the*

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.

3. If the UK beneficiary buys the equipment in Germany in EUR (e.g. EUR 10 000) it will report these costs incurred in EUR (i.e. 10 000) to the Commission/Agency without converting them first from EUR to pounds and then back to EUR.

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline *(see Article 47)*
- terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

⚠ This may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - the work has started.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed start date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed start date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)
- the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, see Articles 42, 43 and 44.

2. Amount of pre-financing payment

There is no standard amount or percentage for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods (it will be in any case less for actions with only one reporting period, as 100% would mean the totality of the EU grant for the action).

⚠ At the moment of the pre-financing payment, an amount equivalent to 5% of the maximum grant amount is deducted from the payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.
Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.
Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1 : application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:
- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)
Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
Payment of the balance amounts to EUR 100 000 and will be ***paid*** *to the coordinator as follows:*
- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*
- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

22.1.1 Right to carry out checks

The Commission *[or the Agency]* will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission *[or the Agency]* may be assisted by external persons or bodies.

The Commission *[or the Agency]* may also request additional information in accordance with Article 17. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.

2. The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).

3. After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.

4. After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check (see Article 17). All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

It may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the check shows ineligible costs or the violation of other obligations under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

The Commission/Agency may carry out checks remotely, based on documents it received beforehand. It can do so using its own staff or with the assistance of external expert(s) or bodies.

⚠ If the Commission/Agency is assisted by external expert(s) or bodies, it does not need to send their name(s) for approval to the beneficiaries before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report'** will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed

- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the review shows improper implementation of the action, ineligible costs or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42- 44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a letter sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the **names** of the **independent experts** that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, you will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days (‘**contradictory review procedure**’).

22.1.3 Right to carry out audits

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a ‘**draft audit report**’ will be drawn up.

The Commission *[or the Agency]* will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations (‘**contradictory audit procedure**’). This period may be extended by the Commission *[or the Agency]* in justified cases.

The ‘**final audit report**’ will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission *[or the Agency]* may also access the beneficiaries’ statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

Specific case:

The Commission may audit the accounting records of beneficiaries, to obtain general information about actual costs for cost items that are reimbursed as unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will however normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

They consist in an in-depth examination (by professional auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to **third parties** involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

*1. The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

*2. The Commission/Agency may audit **third parties providing in-kind contributions** (free-of-charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

*3. The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or if appropriate the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. .*

⚠ *For this category of third parties, audits will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

*4. The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary.*

⚠ *For recipients of financial support or prizes, audits normally will not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs), except if Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties. .*

⚠ If the audit shows, ineligible costs, improper implementation of the action or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

2. Procedure

The audit will be initiated by a letter sent to the beneficiary concerned.

⚠ The Commission/Agency will transmit this letter (and the other communications relating to an audit as formal notifications, through the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its **name**.

The beneficiary may **object** to an external auditor on grounds of commercial confidentiality (and explain the reasons for this). If justified the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit with its own auditors).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit (**i.e. on the beneficiary's premises or on the site on which the action is being implemented). (There may however also be audits that consist only in a desk review.)

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc)* and will indicate how and when it must be provided (and in which format).

ⓘ *For more information on records and supporting documentation for the different cost forms, see Article 18.*

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

> ***Example:*** *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

⚠ Objections based on data protection or confidentiality will not be accepted.

Once an audit has started, the beneficiary must keep all the records and supporting documents until the audit procedure and its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This avoids any unnecessary delays in retrieving original documents from the archives (and thus minimises the risk of the rejection of costs).

> ***Example:*** *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

This includes granting access to research facilities and interviewing the researchers that worked on the action.

⚠ Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc).

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Moreover, all confidential data will be processed in accordance with Article 36.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory review procedure**').

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [1]and No 2185/96[1] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42- 44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[1], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

⚠ If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission *[or the Agency]* may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission *[or the Agency]* will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the Commission *[or the Agency]* on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission *[or the Agency]* in justified cases.

The Commission *[or the Agency]* will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission *[or the Agency]* does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission *[or the Agency]* accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission *[or the Agency]* intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission *[or the Agency]* does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission [*or the Agency*] accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

⚠ These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Regulation (EU) No 1291/2013).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to background

The rules on access to background (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is **no** (or a more limited) obligation to give **access**, if there are **restrictions** or **limits** (legal or otherwise) regarding the background and the beneficiary owning or holding the background has informed the others — before acceding to the GA (or immediately when additional background is agreed on after signature of the GA).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ Don't forget that — when contracting on background with third parties — you must at all times ensure that you can still comply with your access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

  > ***Example:*** *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

– for the exploitation of results: under fair and reasonable conditions

  ⓘ *For more information on fair and reasonable conditions, see Article 31.*

Also, there are no **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties, except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure *(see Article 31)*.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the **beneficiary** that **produced** them.

> 'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries are advised to keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases:

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must — as much in advance as possible before the jointly-owned results are produced — conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  ⚠ Don't fix a *ceiling* for fair and reasonable compensation before the action starts, unless you can precisely determine the results you expect to produce.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries are advised to include general principles on joint ownership already in the consortium agreement.

⚠ The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection (*e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (⚠ without prior authorisation from the other joint owners), unless otherwise agreed in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

⚠ The joint ownership status may **change**:

– it may need to be reviewed later on, when protecting the results.

Example:

Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.

– joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that any agreements with third parties who could claim rights to the action's results *(e.g. employees, subcontractors, linked third parties etc.)* contain provisions that allow them to respect their obligations under the GA *(e.g. transferring ownership to the beneficiary, grant the beneficiary access rights with a right to sub-license, etc)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Specific cases:

Joint research units (JRUs) — Where the internal arrangements of a JRU, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ⓘ *For information on JRUs, see Article 14.*

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, protect them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

⚠ This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*

The beneficiaries are in principle free to choose any available **form** of protection.

Examples of classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

For an invention: e.g. patent, confidential information.

For the design of a technology: e.g. industrial design, copyright.

For a website: e.g. industrial design, copyright, trademark, confidential information.

⚠ In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

ⓘ *For information on the eligibility of costs related to protection, see Article 6.2.D.3.*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

⚠ Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include a reference to EU funding, as specified in the GA.

⚠ **No** information on EU funding is needed, if it is (technically or legally) impossible to include such a reference

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure exploitation of their results.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

Example: *Exploitation is justified from an economic point of view (commercially) or from a standardisation perspective (for use in standardisation activities).*

Where possible, the measures should be consistent with the impact expected from the action and the '**plan for the exploitation and dissemination of the results**'.

They may aim for exploitation by the beneficiary itself (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (⚠ Such additional exploitation obligations will already be mentioned in the Work Programme.)

⚠ This obligation only applies to beneficiaries receiving EU funding.

If the results can reasonably be expected to contribute to European or international standards, the beneficiaries must also communicate them to the Commission/Agency.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

⚠ This obligation applies only if it is foreseen in your GA.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — disseminate their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

No dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA (*e.g. personal data protection, security-related obligations, etc)*.

The beneficiaries may choose **how** they would like to disseminate their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

If the GA provides for additional dissemination obligations, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the Work Programme.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated, unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries are advised to foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

2. Visibility of EU funding

Any dissemination of results (in any form) must include a reference to EU funding, as specified in the GA.

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission]/ Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION:** not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may transfer ownership of their results.

⚠ Security-related obligations *(see Article 37)* may prohibit a transfer or require certain conditions to be fulfilled before it takes place.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

The beneficiary must ensure that the new owners comply with the following obligations:

- joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- protection of results and visibility of EU funding *(see Article 27)*
- exploitation of results and visibility of EU funding *(see Article 28)*
- dissemination of results, open access and visibility of EU funding (see Article 29)
- transfer and licensing of results *(see Article 30)*
- access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

⚠ The mere fact that the results concerned are transferred to a competitor is not in itself a valid reason for an objection. The beneficiary concerned must *demonstrate* the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases:

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of before).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them)*. In this case, there is no need to inform the other beneficiaries of such transfers in advance (and the other beneficiaries do not have the right to object).

⚠ Before agreeing to such a 'global' authorisation, you should carefully consider the situation (and in particular the identity of the third party concerned), to determine if your access rights would be affected.

Example: For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country not associated with Horizon 2020 must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

Best practice: Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant licences to their results.

They must however ensure that **access rights** can be exercised and that any additional exploitation obligations are complied with.

⚠ **Exclusive licences** *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If this option is included in your GA, the Commission/Agency may **object** to transfers or exclusive licences to third parties established in a non-EU country not associated to Horizon 2020, on the following grounds:

- the planned transfer or licence is not in line with EU **competitiveness interests**

  Example: if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU

- the planned transfer or licence is not consistent with **ethical principles**

  Example: if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level

- the planned transfer or licence is not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

⚠ **No** right to object for transfers or exclusive licences by beneficiaries not receiving EU funding *(see Article 9)*.

⚠ For Euratom grants, the Commission has the right to object also to non–exclusive licences.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[40], for the purposes of the complementary grant agreement(s) (see Article 2).**]

[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.**]***

[OPTION for access to research infrastructures:** The access provider must give the users access to the results, if needed to implement the action.**]

[OPTION:** not applicable**]

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When ?

The beneficiaries must provide access to results, if it is **needed**:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity (established in a Member State or associated country), to exploit the results produced by the beneficiary to which it is affiliated (unless otherwise provided for in the consortium agreement).

There is **no definition** of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

Example (results needed for implementation): *if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

Example (background needed for exploitation): *if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries are advised to agree *(e.g. in the consortium agreement)* on a **common interpretation** of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they **must be requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a Member State or associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

The agreement by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

⚠ Don't forget to notify the Commission/Agency of any conflicts on results that are likely to affect the action implementation *(see Article 17.2.)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free
- for the exploitation of results: under fair and reasonable conditions

  'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

  'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

  Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

  Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

  Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

ⓘ For information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

⚠ Access rights do not automatically give the right to **sub-licence** to the requesting beneficiary (since this would imply that access rights to results could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries are advised to agree on the terms and conditions of the sub-licensing generally and in writing (at the level of the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

> ***Examples:*** *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country).*
>
> **Best practice:** Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

> ***Example:***
>
> *The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.*
>
> **Best practice:** Beneficiaries are advised — for legal certainty purposes — to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

The General MGA provides for several options for specific access rights for EU institutions, bodies, offices or agencies and/or EU Member States, for policy purposes.

> ⚠ These obligations apply only if they are foreseen in your GA.

5. Specific access rights for Euratom and its joint undertakings

The option gives Euratom and its joint undertakings (such as Fusion for Energy) royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to sub-license *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

> ***Example:***
>
> *Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.*

6. Specific access rights for third parties

The General MGA also provides for several options for specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  ⚠ In this case, the access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

⚠ These obligations apply only if they are foreseen in your GA.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ For guidance in this process, see the 'Human Resources Strategy for Researchers' tool[50] developed by the Commission.

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[51] and of the Code of Conduct[52] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[53])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[53] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[54].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[55].

[54] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[55] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink].

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

Best practice: Beneficiaries are advised to obtain the **approval of** a **European ethics committee** (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[56] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[56] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[43], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81)

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed — during the action and for four years afterwards.

> ⚠ This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves (for example, for access rights or third parties involved in the action).
>
> A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information concerned.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

Best practice: Beneficiaries are advised to inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

⚠ Stricter confidentiality obligations apply for information that is that is 'EU-classified' and subject to 'security requirements' in Annex 1 of the GA *(see Article 37)*.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *not applicable****]***

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

1. Activities raising security issues — Classified deliverables

If the security scrutiny (carried out by the Commission/Agency during the selection procedure) finds that the action raises security issues because it deals with information that is 'EU-classified' (under the Commission internal Rules of Procedure), the Commission/Agency will make it subject to '**security requirements**' (set out in a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' in Annex 1 of the GA).

In this case, the beneficiaries must comply with the security requirements.

Moreover, they may not subcontract action tasks involving such information or disseminate results linked to such information, without prior approval by the Commission/Agency.

'Classified deliverables' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 19)*.

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[57].

Moreover, the coordinator must submit a **copy** of any export or transfer licence, before the action starts.

[57] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> 'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Promoting the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange.

⚠ *Ad hoc* efforts or mere dissemination of results are not sufficient. The communication activities[58] must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and address the **public policy perspective** of EU research and innovation funding, by considering aspects such as:

[58] *For the definition of 'communication activities', see the Glossary.*

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges

❖ impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*

❖ better use of results and spill-over to policy-makers, industry and the scientific community.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity).

⚠ The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them in another work package).

The beneficiaries are free to choose the type of communication activities.

> ***Examples:*** *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

⚠ Information given may **not** cover EU-classified information or information relating to 'classified deliverables' *(see Article 37)*.

⚠ Don't forget that any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa). Both obligations must be complied with.

ⓘ *For more information on how to promote your action, see the H2020 Online Manual*

2. Visibility of EU funding

The beneficiaries must ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure (including equipment or major supplies) funded by the grant, by:

- displaying the EU emblem and
- including the reference to EU funding, as specified in the GA.

For infrastructure (including equipment or major supplies) a sticker (or other equivalent means) should be used.

ⓘ For more information, see the Guide to using the EU emblem[59].

⚠ The beneficiaries must ensure the visibility of EU funding even after the action ends.

[59] Available at http://publications.europa.eu/code/en/en-5000100.htm.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[44], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[44] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities by the Commission/Agency

The Commission/Agency may use any (⚠ non-confidential and non- classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material); *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

⚠ The beneficiaries must make **arrangements** with any **third parties** that could claim rights to the material, in order to legally allow the use by the Commission/Agency.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

1. Processing of personal data by the Commission/Agency

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency 'Data Protection Officer (DPO)'.

This notification will be available in the Register of the DPO[60] (and will describe the processing operations, security safeguards, data transfer, retention period, etc.).

⚠For the processing of sensitive data *(e.g. health data)* and processing for the purpose of administrative penalties and termination, the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ *For more information, see the data privacy statement ('SSPS')[61] on the Participant Portal.*

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS) to:

- obtain information about what data is collected and how it is used, usually given via a privacy statement
- see which of their data are being held
- correct any errors in the data, block access to this data, or delete their data

[60] Available at http://ec.europa.eu/dpo-register/search.htm.
[61] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

– complain about data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ *For information on the complaints procedure, see the EDPS website.*

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data, by the beneficiaries

The beneficiaries must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[62] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [63]

[62] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing** of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[64]

Beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform staff** (whose personal data are collected and processed by the Commission/Agency) about this disclosure, by providing them with the SSPS.

Examples:

Before encoding its staff's personal data in the Beneficiary Register or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must tell the staff concerned and provide them with the SSPS.

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ *For more information on ethics, see the H2020 Online Manual.*

[63] *See Article 8 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party, unless the Commission/Agency has explicitly agreed in writing.

'Assignment' normally means the transfer of rights held by one party to another party.

⚠ However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity

Assignment for the benefit of creditors in a bankruptcy procedure

⚠ Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

Example: *The obligation to allow audits by the Commission/Agency*

[64] *See Articles 6, 16, 17 of Directive 95/46/EC.*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— *RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES]* [— *RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— *RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES]* [— *RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator**, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

> ***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications, unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the H2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action)*.

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement (unless exceptionally stipulated otherwise in the Work Programme, for a specific call).

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded **before the action starts**. (Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action.)

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture)*.

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ *For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the H2020 Online Manual.*

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiaries must conclude a coordination agreement.

'Coordination agreements' are agreements between the consortium and partners from a third country (including scientific and technological organisations and agencies) or an international organisation, with which the joint call was organised.

Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the basic contradictory procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.
Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

41.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

– by **offsetting** it[65]

  Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[66]

  If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

– by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  – if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

[65] *See Article 80(1) of the Financial Regulation.*
[66] *See Article 87 of the Rules for Application.*

- by either:
  - taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or
  - adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[67].[68]

    The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

    This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

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[67] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[68] *See Article 79(2) of the Financial Regulation.*

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary approved costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between 2% and 10% of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

  Example:

  GA with an EU contribution of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the decision to apply the penalty may also be **published** on Commission or Agency websites —together with the name of the person responsible for the misconduct, information on the misconduct and the penalty(ies) (duration of the exclusion and/or amount of the financial penalty).

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund

– joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

1. Liability for damages, of the Commission/Agency

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

– causes damage to a third party (including another beneficiary)

Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

– suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability for damages, of the beneficiaries

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples: *Costs of legal proceedings borne by the Commission.*

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

  ⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

- calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

❖ **Payment request does not comply with the provisions of the GA**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.

❖ **Payment request is incomplete or requires clarification**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

Examples: the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.

❖ **Doubts on the eligibility of costs in the financial statements that require additional verifications**

The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

Example: The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is no *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

Example: statements made by the beneficiary in the declaration form are found to be false.

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

– **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **no individual financial statements** for the beneficiary (or beneficiaries) concerned may be submitted.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation, by the beneficiaries

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Grounds for suspension of the action implementation (by the beneficiaries):

❖ **Action can no longer be implemented (or becomes excessively difficult)**.

The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the suspension is lifted and the action continues, the action's remaining budget can be used to implement the action.

⚠ However, it is possible that the action is resumed with a lower budget to adapt it to the new situation (agreed as part of the amendment).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) ***cannot*** **be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation, by the Commission/Agency

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

❖ **Suspicion of loss of scientific or technological relevance**

The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

This may in particular be the case:

- if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
- if work has significantly deviated from the original work plan
- if a key beneficiary leaves the action and the consortium needs time to find a replacement
- after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ For the basic contradictory procedure, see Article 42.

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA, by the beneficiaries

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

> ***Example:*** *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

> ***Example:*** *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries, by the beneficiaries

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ For more information on the roles and access rights in the electronic exchange system, see the H2020 Online Manual.

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action (unless it concerns the coordinator, since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action — including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so —, unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.][OPTION: not applicable];

(j) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries, by the Commission/Agency

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

❖ **Non-accession to the GA**

The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA).

⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [69]

Examples:

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this.

[69] *See also Article 8 of the Rules for Participation.*

The Commission terminates the GA because the conditions set out in the work programme are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

❖ **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

❖ **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

❖ **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

❖ **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

❖ **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

❖ **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

❖ **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

❖ **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country's or international organisation's action does not start by the date specified in Annex 1

  ⚠ In this case, **no costs** incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country's or international organisation's action is terminated

- the third country's or international organisation's action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

❖ **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA — substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and,
  - have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ For the basic contradictory procedure, see Article 42.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ **Ineligible costs** may be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure

– labour disputes or strikes

– financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has **no specific effects** on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate* [*complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use a 'Messaging' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal Notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and

amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ *For more information on access and roles in the electronic exchange system, see the H2020 Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** (unless the GA or other rules provide for direct communication with the other beneficiaries, *e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations*).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

When & What?

An amendment is necessary whenever there is a need to **change** the **terms and conditions** of the GA. In some cases, the GA explicitly provides for them.

⚠ Amendments may **not** result in changes that — if known before awarding the grant — would have had an impact on the decision to award it. Those are mostly changes that:

- may have had an impact on the assessment of the applicant with regard to the eligibility and selection criteria *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- breach the principle of equal treatment of applicants

- involve modifications in the action and/or the related budget which may have affected the assessment with regard to the award criteria announced in the call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*

- do not comply with the rules applicable to the GA (i.e. Financial Regulation, Rules for Participation, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified or to modify Annex 1 following a review of the action).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removing a beneficiary whose participation was terminated** by the beneficiaries or by the Commission/Agency *(see Article 50.2 and 50.3)*.

  For termination by the beneficiaries, the request for amendment must be part of the notification of termination. In this case, don't forget to also submit the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency, the request for amendment must be submitted together with the report on the distribution of payments and the termination report (if needed).

  ⚠ No need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)*, unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

- **Adding a new beneficiary** *(see Article 56.2)*

  The request for amendment must include the Accession Form (signed by the new beneficiary in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

  The new beneficiary must provide a declaration on joint and several liability of its linked third party if required by the Commission/Agency.

  ⚠ Don't forget that the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

  Depending on the Horizon 2020 status(es) of the new beneficiary, the applicable options will be added.

  Example:

  If the new beneficiary is an international organisation, the options related to international organisations specified under Articles 22.4, 53.2, will be added to the GA and the options specified under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

  For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Change of beneficiary due to partial takeover (called 'partial transfer of rights and obligations' in FP7)**

'Partial takeover' means that some assets of the beneficiary have been taken over by another entity *(e.g. partial acquisition)*.

If the GA is part of the assets taken over, the beneficiary must request an amendment: the entity to which the GA has been transferred may become the new party of the GA if the Commission/Agency agrees on that.

The contractual position of the old and the new party (vis-à-vis the Commission/Agency and the other beneficiaries) must be clearly spelled out in the request for amendment: in particular, it must clarify which is the financial liability of the new party for the old party's debts towards the Commission/Agency or the Guarantee Fund.

⚠ Don't forget that the new party must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

❖ **Change of coordinator**

The amendment request may be submitted after the period set out under Article 3 of the GA ends.

The initial coordinator may continue to participate in the action as a beneficiary (or may terminate its participation).

If the new coordinator is already a beneficiary of the GA, he will start his new functions from the date agreed by the parties, or — in the absence of such an agreement — the date on which the amendment enters into force. The date agreed cannot be before the initial coordinator has terminated its functions.

⚠ If the new coordinator is not a beneficiary of the GA, it must also accede to the GA as a new beneficiary *(see Article 56.2)*.

❖ **Change of the coordinator's bank account for payments**

Example: *The coordinator changes bank.*

The coordinator must submit the necessary supporting documents and update the banking information on the Participant Portal.

⚠ Do not forget to first update the bank account data in the Beneficiary Register (and get it validated).

❖ **Change of the action's title and/or acronym**

Example: *the consortium finds out that the acronym of their action is a protected trademark.*

❖ **Change of the starting date, duration of the action or reporting periods**

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

⚠ Even if the action is prolonged, the maximum grant amount cannot be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

  ⚠ Don't forget to communicate the date from which the action's implementation can restart ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:

  – a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries

  – changes concerning **in-kind contributions** provided by third parties (against payment or free-of-charge) or **subcontracts**

    Such changes could in principle also be made as 'approval without formal amendment' (*see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency's *agreement* (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency may consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).

  – changes concerning the tasks to be carried out by **linked third parties** and related costs

    There is no 'approval without formal amendment' *(see Article 14)*.

  – changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount and/or the action's estimated eligible costs will be accepted only in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount cannot be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2 (estimated budget)** which require an amendment *(see Article 4)*, in particular:

  – a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

  – a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*

    Examples:

    During the action's implementation, a beneficiary that declared its direct personnel costs as actual costs in Annex 2 decides to change this and instead to declare its direct personnel costs as unit costs in accordance with its usual accounting practices.

    An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it

is necessary to amend the GA to add the appropriate option under Article 5.2 and to modify the action's estimated budget in Annexes 1 and 2.

Indicative list of cases where no amendment is needed:

- **Budget transfers not listed above**

Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary or coordinator**

Changes concerning name, legal form *(e.g. Ltd., S.A.)*, registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA) do not require a formal amendment; an update of this data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

ⓘ For more information on data updates, see the Horizon 2020 Online Manual.

⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may request it.

Example: *Company RO moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates*

- **Change of beneficiary due to universal takeover (called 'universal transfer of rights and obligations' in FP7)**

'Universal takeover' means that all the rights and obligations of the beneficiary have been taken over by another entity *(e.g. in cases of merger or full acquisition)*. The beneficiary ceases to exist and all its rights and obligations (including those under the GA) are taken over by the new entity.

Example:

Beneficiary X may merge with another existing entity Y by:

(i) becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or

(ii) establishing a new separate legal entity (X and Y are together known as 'Z').

Since *all* the rights and obligations of the old entity (including the GA) are transferred to the new one, there is normally no issue of legal certainty and it is therefore not necessary to make a formal amendment under Article 55. An update of the data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may request it.

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.

Case 2: A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

⚠ Don't forget that — in addition to updating the data in the Beneficiary Register — you must also inform your coordinator (offline) under Article 17.2, if the universal takeover may:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinators must then inform the Commission/Agency (via the electronic exchange system) and may request an amendment.

The same is true if the universal takeover concerns one of your linked third parties.

How?

An amendment request must be **prepared** by the **coordinator**, normally by filling out the forms **directly in the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

Specific case:

A request to **change the coordinator** (against the coordinator's will) can be submitted by any beneficiary (acting on behalf of the others).

⚠ If none of the available forms are appropriate, beneficiaries are advised to contact the Commission/Agency for the drafting of the request.

⚠ **Requests** for amendment must be unambiguous and complete and submitted **sufficiently in advance** (to allow proper analysis and preparation before they are due to take effect) and, generally, **before the end of the action** (i.e. the date set out in Article 3).

Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance).*

Once completed, the amendment request (with all its supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator. (⚠ The coordinator submits and signs on behalf of the other beneficiaries; *see Annex 3*).

Coordinators must ensure internally that they have the agreement of the consortium, on the basis of their internal decision-making processes *(e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement).*

⚠ Don't forget:

- for new beneficiaries (or linked third parties): to ensure that they have obtained all necessary validations in the 'Beneficiary Register'

  Example:

  Validation of the new bank account, to change the bank account

  Legal entity validation, to add a new beneficiary that is not yet validated. This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

- to include the necessary information and supporting documents (as required for certain amendments)

  Examples:

  For a change of coordinator without his/her agreement, the coordinator's opinion (or written proof that this has been requested).

  To add a new beneficiary, an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

  To amend Annexes 1 and 2, amended versions of these annexes.

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

The coordinator may at any moment **withdraw** the amendment request (before it has been accepted or rejected). However, it cannot be *change*d (without withdrawing it and submitting a new one).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

ⓘ *For more information on the preparation and submission procedure, see above point 1.*

⚠ Beneficiaries are advised to contact the Commission/Agency beforehand (via the 'Messages' function of the electronic exchange system), in order to discuss the amendment.

The other party must — within 45 days — agree or disagree, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

If there is **no reaction** within this deadline, the request is considered to have been rejected (⚠ new in Horizon 2020: contrary to FP7, there is no tacit approval of amendments). A new amendment request may be submitted (even if it fully or partly repeats the initial request).

A request containing several changes to the GA will be considered as a **package** that cannot be divided into several requests. The request will be agreed or rejected by the other party as a whole.

If, the receiving party requests additional information/documents a new deadline will apply, i.e. 45 days from receipt of the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may be extended by the Commission/Agency — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

⚠ A signed and submitted amendment requests (including supporting documents) cannot be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

Unless the parties agree otherwise, the amendment will **take effect** (i.e. the modifications to the GA will start to apply) on the day of entry into force of the amendment.

If the parties agree on another date, it should normally be *after* the entry into force. In justified cases it may be before (retroactivity of the amendment). (⚠ In certain cases, the GA itself provides for retroactivity.)

Examples (retroactivity foreseen in the GA):

Where a new beneficiary or linked third party is added to the GA, it must assume the rights and obligations from the date of its accession specified in the Accession Form. This retroactivity implies that its costs will be considered eligible as from the date of its accession to the GA (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

⚠ Depending on the nature of the modification, the date of taking effect may have an impact on the eligibility of costs.

If an amendment request involves a number of changes, these could take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA, by the beneficiaries mentioned in the Preamble

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Specific case:

For mono-beneficiary actions, replacing the beneficiary during the action implementation is only possible under exceptional circumstances *(e.g. the beneficiary transfers all its rights and obligations, including those related to the action, to another legal entity).*

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated (unless it already has a validated Participant Identification Code (PIC))
- sign the Accession Form directly in electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an amendment for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned])*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for international organisations (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[70]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the *Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States*, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN system (⚠ new in Horizon 2020).

It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU-arbitration clause, referring disputes on the interpretation, application or validity of the GA to the Court of Justice of the European Union.

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This

[70] *See Article 180(1) of the Rules of Application.*

referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[71]).

If a dispute is of public law nature (i.e. concerns offsetting or an enforceable decision under Article 299 TFEU), actions must be brought before the Court of Justice of the European Union not under Article 272, but under Article 263 TFEU.

[71] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

II. ERC

II.1 Background information and approach

The ERC General Model Grant Agreement ('ERC General MGA') is used for the following ERC grants ('frontier research grants'):

- ERC Starting Grants (StG)
- ERC Consolidator Grants (CoG)
- ERC Advanced Grants (AdG)
- ERC Synergy Grants (SyG).

The ERC General MGA is not used for ERC PoC and ERC low value grants (which have specific MGAs; *see below*).

⚠ ERC grants are open to **principal investigators** (PIs) of any nationality who intend to conduct a **frontier research project** in a Member State or associated country and which are hosted by a host institution that is based in an EU Member State or associated country and can receive EU funds.

ⓘ *For more information on ERC actions, see Article 2.*

ⓘ *For information on ERC funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on ERC standard eligibility criteria, see the ERC calls conditions of the ERC Work Programme.*

The ERC General MGA follows the General MGA for numbering and content, except for the following:

Introductory remark all ERC MGAs

The ERC Model Grant Agreements deviate from the General Model Grant Agreement as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
-
- The table of contents is adapted
- Cross-references in the footnotes are adapted

Introductory remark ERC General MGA

The ERC General Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

Introductory remark ERC PoC MGA

The ERC PoC Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

ERC frontier research grants are however different from General MGA grants because:

- EU funding is granted to an individual action proposed by a Principal Investigator (PI) (or several, in the case of SyG), while

- the grant is signed between the Agency on one side and the beneficiaries on the other, one of which is the host institution of the PI and his/her research team.

⚠ By signing the GA, the beneficiaries take on a series of obligations towards the PI and the research team. In order to participate in the action, the PI must sign a supplementary agreement (SA) with its host institution where s/he also takes on a series of rights and obligations *(see Article 32)*.

ERC PoC grants are then follow-up grants to explore the innovation potential of results generated in a previous ERC frontier research grant.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC actions)
- Article 4.1 (ERC budget categories)
- Article 6 (ERC eligible and ineligible costs)
- Article 8 (ERC rules on third party involvement).

Since the ERC General MGA and the ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC PoC MGA will be limited to major differences from the ERC General MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 ERC General MGA: Annotations

ERC MULTI-BENEFICIARY MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][1],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname], hosting [and engaging] the following

***[OPTION by default:** 'principal investigator':*

*- [**Name**][Date and place of birth][2]*

***[OPTION for SyG:** 'corresponding principal investigator':*

*- [**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),****]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called 'principal beneficiary'.

Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that host (or employ) a principal investigator ('host institution').

The PI is usually employed by the host institution.

Exceptions:

A PI may be employed by a third party. In this case, the third party must also sign the supplementary agreement *(see Article 32)* and agree to the obligations included in it.

Retired researchers, in case the PI is no longer under an active labour contract.

ⓘ For more information on arrangements for signature and third parties, see the preamble of the General MGA.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

⚠ Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities.

PIs must be supported by their host institution during the entire duration of the action.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions, must sign a supplementary agreement (SA) *(see Article 32)*.

⚠ In the case of ERC Synergy grants (with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

⚠ ERC PoC grants do not require a supplementary agreement.

⚠ ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI').

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERC actions

ERC actions are mono- or multi-beneficiary actions with the following activities:

– any type of frontier research activity in any field of research (except nuclear energy; see the ERC calls conditions of the ERC Work Programme).

What? ERC grants fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

ⓘ For examples of successful ERC actions, see the ERC website[72].

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

[72] Available at http://erc.europa.eu/erc-stories.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC General MGA uses in principle the **same budget categories** as the **General MGA**.

Budget categories of the ERC General MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences (compared to the General MGA):

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs *for the action* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(f) for **direct personnel costs** *[(excluding personnel costs for activities in Point (f))]*[5]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(g) for **direct costs of subcontracting** *[(excluding subcontracting costs for activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(h) *not applicable;*

(i) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(j) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

[…]

[5] To be used only if option in Point (f) is used.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC calls conditions of the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are the **same** as in the **General MGA** *(see Article 5 General MGA)*.

Exception:

The ERC General MGA does not use the same **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, the ERC General MGA uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[73]

However, the unit costs for the 'specific categories of costs' of the General MGA do not apply.

[73] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 General MGA)* (with the exception of 'direct costs of providing financial support to third parties', 'specific categories of costs' and 'costs for providing access to trans-national research infrastructure').

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

Specific cases:

For **direct personnel costs**:

⚠ Costs for 'teaching buy-outs' are not eligible: if the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, they cannot declare the costs related to these substitutes.

If the **PI** is exceptionally **engaged by a third party** (which pays his/her salary) and seconded to work on the premises of the beneficiary (against reimbursement by the beneficiary), the **salary costs** may be declared as direct personnel costs (costs of personnel seconded by a third party).

⚠ In this case, the supplementary agreement must be signed by the PI, the host institution *and* the third party.

For **other direct costs**:

For ERC actions, **recruitment costs** are eligible as other direct costs because recruitment is one of the action's activities.

⚠ Recruitment costs are not considered as one of the action's activities for PoC.

⚠ As in actions under the General MGA, for ERC actions the **purchase of scientific publications** *(e.g. books, manuscripts, articles, digital copies, etc.)* needed for the implementation of the action may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Given the increasing emphasis on the protection of inventions, the PIs are encouraged to **protect** their **intellectual property rights properly** and the related costs are considered eligible.

Costs related to open access (to publications – including monographs – and research data) are eligible during the duration of the action. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (it cannot be with other beneficiaries or linked third parties).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies*: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.****]***

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 General MGA)*.

In addition, the beneficiaries must however prove that the conditions concerning the time-commitments of the PI for implementing the action (as described in Annex 1) have been complied with.

Thus, they must be able to provide evidence that the PI dedicated the minimum time commitment (i.e. percentage of the total working time, i.e. percentage of the annual productive hours calculated in compliance with Article 6) to the action, via time sheets or alternative time recording system.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

Moreover, they must be able to provide evidence that the PI spent the minimum time commitment *in a Member State or associated country* (i.e. a Member State or an associated country), via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

⚠ Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) scientific and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

ⓘ For more information on how to submit the reports, see Article 20 General MGA and the H2020 Online Manual.

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC General MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies - make the pre-financing payment to the principal beneficiary within 30 days ***[OPTION:*** *from the entry into force of the Agreement (see Article 58)****][OPTION:*** *from the starting date of the action (see Article 3)****][OPTION:*** *from the 45th day before the starting date of the action (see Article 3)****]***.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([****insert amount*** *(insert amount in words)] is not paid to the principal beneficiary, but kept by the [Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90 % of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90 % of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90 % of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the principal beneficiary
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

[…]

1. Payments

For ERC actions, the same rules on payments apply as in the General MGA *(see Article 21 General MGA)*.

There is however an additional option for pre-financing payments. These cannot only be foreseen within the 30 days from:

- the starting date of the action (see Article 3) or
- from the date of entry into force of Grant Agreement (see Article 58)

but also

- from the 45th day *before* the starting date of the action (see Article 3)), if the action starts late (well after the entry into force of the GA).

⚠ In any case, it is not possible to make a payment before the GA is signed.

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Rights of third parties

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 General MGA)*.

⚠ Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

[…]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

*[OPTION: **not applicable**]*

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

Examples: *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

For publications issued after the end of the action, beneficiaries are not obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

For bibliographic metadata, the ERC General MGA foresees lighter requirements, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[74] or other systems).

⚠ As far as the chosen repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

For ERC actions, there is no formal requirement for a '**data management plan**'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and

[74] *For more information, see http://www.doi.org/.*

afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

The exception allowing beneficiaries not to give access to specific parts of research data applies not only if this would jeopardise the main objective of the action, but any one of the action objectives.

⚠ For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[32] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a)

[…]

[32] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC General MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of intellectual property rights
- Allow for transfer of the GA to another host institution (**portability**).

⚠ PIs cannot be prevented from applying independently (i.e. in their own name) for further EU funding for other actions. They can also apply for further EU funding for the same action, as long as it is for costs that are not eligible (or not declared) under the ERC grant.

In this context, 'action' refers to the specific ERC action, for which the beneficiaries receive the ERC grant *(see Article 2)*.

⚠ The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ⓘ For more information on combining EU funding for different actions ('complementary EU funding'), see the H2020 Online Manual.

2. Supplementary agreement — Obligations on the PI

The ERC General MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also vis-à-vis the PI.

The supplementary agreement should cover all the practical issues that may arise in the context of the grant implementation, and in particular the ones listed in Article 32.1(b).

Model clauses for supplementary agreements are available on the Participant Portal and the ERC website. [hyperlinks]

Host institutions and their PIs may add or use other clauses, if they benefit the research action and do not contradict the GA. Provisions that contradict the GA are considered void and may not be opposed to the Agency.

⚠ The supplementary agreement must be concluded before the GA is signed (and a copy must be sent to the Agency).

It does not replace an employment or collaboration contract between the PI and its host institution (which remain necessary under national labour and social laws).

Specific cases:

In the case of **ERC Synergy grants** (with **several PIs**), each host institution must conclude a supplementary agreement with the PI(s) they engage.

ERC PoC grants do not require a supplementary agreement.

In case of transfer of the Agreement to another host institution (**portability**; *see Article 56a*), the PI must sign a new supplementary agreement with its new host institution and forward it to the Agency. The GA cannot be amended before the PI has sent this new supplementary agreement.

Via the supplementary agreement, the PI must take on a number of obligations, to ensure the smooth implementation of grant.

Main obligations (of the PI):

- Supervision of the scientific and technological implementation of the action
- Responsibility for the scientific reporting for the beneficiary and contribution to the financial reporting
- Meeting the time commitments for implementing the action
- Applying the beneficiary's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the visibility of EU funding
- Upholding the intellectual property rights of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.

- Maintaining confidentiality

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(c) display the EU emblem and the ERC logo and

(d) include the following text:

"This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem and the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

Guidance on the use of the ERC logo is available on the ERC homepage[75].

[75] Available at http://erc.europa.eu/logos-and-banners.

MULTI-BENEFICIARY: **ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the Agency has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: **ARTICLE 56 — ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: [...][...][...][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 General MGA)*.

However, unlike the General MGA, ERC ***mono*-beneficiary** grants can **become *multi*-beneficiary** grants, by addition of a new beneficiary.

The procedure to be followed is that of Article 56 of the General MGA.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

Upon request by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

Portability makes it possible to transfer ERC grants — at any time during the action implementation.

The PI may **request a transfer** of his/her grant to any other entity based in an EU Member State or associated country ('new host institution'), if doing so is beneficial for the PI and supports achieving the action's objectives.

Specific case:

For **ERC Synergy Grants**, each PI maintains the right to transfer their part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

If **certain team members** or **equipment remain** with the former host institution, that institution may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

Thus, both host institutions must agree on the transfer of intellectual property, in conformity with the GA and after consulting the PI. The transfer plan should cover:

- the results produced under the action and the access rights to them and
- the PI's and new host institution's access rights to background held by the former host institution but necessary for implementing the rest of the action.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs are advised to keep records of the consultation and decision-making process for each portability case.

The former host institution must then submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 General MGA)*.

A change of beneficiary usually takes effect on the first day of the month.

This date may be retroactive, but only in very exceptional circumstances. This should be discussed on a case by case basis with the Agency.

⚠ The request should be made well in advance, to allow sufficient time for the amendment procedure.

⚠ The GA cannot be transferred without the explicit agreement by the Agency *and* the amendment of the GA. Any partial or full transfers made without a formal amendment to the grant agreement are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** all **remaining pre-financing** (not covered by eligible costs) to the new host institution.

⚠ If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will not pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary).

⚠ Scientific reporting periods will usually remain unchanged as they are linked to the action's scientific development and must be submitted by the PI, who holds this position for the whole duration of the GA.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law.

It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

II.2 ERC PoC: Annotations

⚠ The ERC PoC MGA is very similar to the ERC General MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however no specific provisions on the working conditions of the PI and his/her team, no supplementary agreement and no grant portability

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC General MGA apply mutatis mutandis.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. ERC PoC actions

ERC PoC actions are actions with the following activities:

– verifing the innovation potential of ideas arising from ERC funded projects

What? Any activities (that were not scheduled to be funded by the initial ERC frontier research grant) but that develop research output towards new commercial or societal applications.

ERC PoC grants can cover very diverse activities *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

What not? ERC PoC grants cannot cover activities under the ERC frontier research grant (*e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential*) or activities which are the result of research not performed under the ERC actions (*e.g. results of research not found by the ERC action*).

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) report(s), including requests for payment.

The report(s) must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP):

20.2 Reporting period

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)**]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]

***[**- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].**]***

20.3 Periodic reports — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(f) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *Agency* may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Agency*, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What ?

For ERC PoC actions, the principal beneficiary must submit reports — only one 'report' if there is one reporting period, otherwise one 'periodic report' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  ⚠ The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

⚠ Only at the moment of the submission of the last reporting period, the 'certificate on the financial statements' will have to be added.

How?

All reports mut be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' section of the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period (and thus the duration of the action) lasts **18 months**.

If provided in the GA, an ERC PoC action may however also have more reporting periods.

IV. SME Instrument

IV.1 Background information and approach

The Model Grant Agreements for the SME Instrument ('SME Instrument MGAs') are used for grants for **SME Instrument actions only** *(see General Annex D to the Main Work Programme)*.

The SME Instrument funds actions in different phases.

The minimum requirement for participation is one for-profit SME (as defined in the SME Recommendation 2003/361/EC), established in an EU Member State or associated country

'For profit' means not a non-profit legal entity (i.e. not an entity that is by its legal form non-profit-making or has a legal or statutory obligation not to distribute profits to its share-holders or members).

⚠ If the Work Programme/call, exceptionally foresees SME Instrument Ph2 actions that predominantly concern research activities, they will be considered 'research and innovation action (RIA)' actions and will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ⓘ For more information on SME Instrument actions, see Article 2 SME Instrument MGAs.

ⓘ For information on SME Instrument funding opportunities, see the 'Search Topic' function on the Participant Portal.

ⓘ For information on SME Instrument standard eligibility criteria, see General Annex C to the Main Work Programme.

ⓘ For more information on the procedure for SME status validation, see the H2020 Online Manual.

The SME Instrument MGAs **follow the General MGA** for numbering and content, **except** for the following:

Introductory remark SME Instrument Ph1 MGA

The SME Instrument Phase 1 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 4.1 (SME Instrument Ph1 estimated budget of the action)
- Article 5.1-5.3 (SME Instrument Ph1 maximum grant amount, specific reimbursement rate and form of costs, no Step 2 'limit to maximum grant amount', no Step 3 'reduction due to the no-profit rule')
- Article 6 (SME Instrument Ph1 specific conditions for eligibility of costs)
- Article 7 SME Instrument Ph1 consequences of improper implementation)
- Articles 8, 11, 12, 14, 15, 16, 23a - 33, 37, 39 (not applicable)
- Article 10 (SME Instrument Ph1 specific provision for purchases)
- Article 13 (SME Instrument Ph1 specific provision for subcontracting)
- Article 18 (SME Instrument Ph1 specific provision for record-keeping)
- Article 20 (SME Instrument Ph1 specific reporting provisions)
- Article 21 (SME Instrument Ph1 specific payment provisions)
- Article 36 (SME Instrument Ph1 specific provision on confidentiality)

- Article 38 (SME Instrument Ph1 specific provision on promoting the action)
- Article 42.2 (SME Instrument Ph1 specific provision for lump-sum
- Article 50.1.2, 50.3.3 (SME Instrument Ph1 specific provision for lump-sum

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

Introductory remark SME Instrument Ph2 MGA

The SME Instrument Phase 2 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 5.2 (SME Instrument Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Instrument Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Instrument Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 SME Instrument Ph1 MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Instrument Ph1:
- Article 2 (SME Instrument Ph1 actions)
- Article 8 (SME Instrument Ph1 rules on third party involvement)

For SME Instrument Ph2:
- Article 2 (SME Instrument Ph2 actions)
- Article 4.1 (SME Instrument Ph2 budget categories)
- Article 6 (SME Instrument Ph2 eligible and ineligible costs)
- Article 8 (SME Instrument Ph2 rules on third party involvement)
- Article 20 (SME instrument Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since that is most common for SME Instrument actions. The differences between mono and multi-beneficiary versions are marginal.

IV.2 SME Instrument Phase 1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** (**'action'**), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]]***.]**

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.***]***

1. SME Instrument Ph1 actions

SME Instrument Ph1 actions are mono- or multi-beneficiary actions with the following activities:

– making a feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service)

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a 'technology readiness level' of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc)*.

⚠ The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph2 actions, see Article 2 SME Instrument Ph2 MGA.

ARTICLE 4 — ESTIMATED BUDGET

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the form of costs (see Articles 5 and 6).

1. Budget category

The SME Instrument does **not** use the **budget categories** of the **General MGA**.

Since SME Instrument Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Instrument Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

⚠ The budget category is relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The grant amount for SME Instrument Ph1 actions is fixed as a **lump sum** of **EUR 50 000**.

The lump sum is provided for by Commission Decision C(2013) 8198[76], for all SME Instrument Ph1 actions.

The amount of EUR 50 000 stays the same, both for multi-beneficiary and mono-beneficiary actions.

It is deemed to reimburse 70 % of the action's total eligible costs (that are in turn set by this Decision at EUR 71 429).

If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ No other costs will be reimbursed; the lump sum is deemed to cover all (direct or indirect) costs that may have been incurred for the feasibility study.

⚠ The SME Instrument Ph1 MGA does not use any of the **unit costs** and **flat-rates** of the General MGA.

The conditions for eligibility are set out in Article 6.

[76] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to improper implementation or breach of other obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

[…]

1. Calculation of the final grant amount

For SME Instrument Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is no:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

A. Costs for the feasibility study (direct and indirect costs) are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Instrument Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 The budget category 'costs for the feasibility study' **covers** the costs for the feasibility study for the innovation idea *(see Article 2)*.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[77] and set out in Annex 2 of the GA (currently **EUR 71 429** per action).

This lump sum is deemed to cover all (direct and indirect) eligible costs that may have been incurred for the feasibility study.

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 No **calculation** is necessary.

The beneficiaries must declare the amount of EUR 71 429 as the total eligible costs of the action; they cannot declare the costs actually incurred. The final financial report and individual financial statement are therefore automatically pre-filled by the system *(see Article 20)*.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

1. Consequences of improper implementation

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation does not always lead to the reduction of the grant, but leads to the ineligibility of the costs (namely, if the improper implementation consists in non-compliance with Annex 1; *see Article 6*).

If the action is not carried out as described in Annex 1, costs will be rejected proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

By contrast, if other provisions of the GA or provisions of EU, international and national law are not complied with, the grant may be reduced.

[77] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Instrument Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs for purchases and subcontracts are covered by the lump sum.

⚠ In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) are **not** allowed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Instrument Ph1 actions are almost identical to the General MGA *(see Article 13 General MGA)*.

Since SMEs are not contracting authorities, there is however no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph1 actions are similar to the General MGA *(see Article 13 General MGA)*.

Subcontracting is however not restricted to a limited part of the action.

Moreover, the estimated costs do **not** have to be included in Annex 1or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are **not** considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ⓘ For more information on the characteristics of subcontracting and best value for money, see Article 13 General MGA.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Instrument Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit the report

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) the **final report**, including a request for payment.

The report must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing an '**individual financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The individual financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME instrument Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial report and statement are automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

For multi-beneficiary actions, each beneficiary must fill in an individual financial statement (in order to certify conformity of the costs declared). This does not however change the EU contribution requested (which remains one single lump sum of EUR 50 000 for the whole consortium).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made — No interim payments

For SME Instrument Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are no interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Instrument Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(f) the disclosing party agrees to release the other party;

(g) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(h) the recipient proves that the information was developed without the use of confidential information;

(i) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(j) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Instrument Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(e) display the EU emblem and

(f) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

Not applicable

38.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Promoting the action — Visibility of EU funding

The SME Instrument Ph1 MGA foresees lighter requirements for promoting the action and acknowledgment of EU funding.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

[…]

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

[…]

1. Calculation of the ineligible costs to be rejected

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation leads to the ineligibility of the costs *(see Article 7)*.

If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

ARTICLE 50 — TERMINATION OF THE AGREEMENT

[…]

50.1 Termination of the Agreement, by the beneficiary

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

[…]

50.3 Termination of the Agreement, by the *[Commission][Agency]*

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

1. Termination of the Agreement

For SME Instrument Ph1 actions, the same rules on termination apply as in the General MGA *(see Article 50 General MGA)*.

⚠ Improper termination by the beneficiary will however lead to a 100% reduction of the grant.

IV.3 SME Instrument Phase 2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a ‘**complementary grant**’ to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a ‘**jointly funded action**’ which must be coordinated with the ‘joint action’ called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. SME Instrument Ph2 actions

SME Instrument Ph2 actions are actions with the following activity:

– implementing an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication).

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a ‘technology readiness level’ of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

⚠ An project may be funded in Phase 2 even if it was not funded in Phase 1.

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph1 actions, see Article 2 SME Instrument Ph1 MGA.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The SME Instrument Ph2 MGA uses the **same budget categories as** the **General MGA**.

Budget categories of the SME Instrument Ph2 MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences compared to the General MGA:

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(k) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(l) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(m) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(n) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*: as actually incurred costs (**actual costs**);

(o) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

***[**(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]*[1]*]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

1. Reimbursement rate

How much? For SME Instrument Ph2 actions, the reimbursement rate is normally set at 70% *(see General Annex D to the Main Work Programme)*.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs.
.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Eligible costs — Ineligible costs

The SME Instrument Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

Exception:

The SME Instrument Ph2 MGA does not reimburse:

- 'direct costs of providing financial support to third parties'
- 'specific categories of costs'.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Instrument Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [1].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph2 actions are similar to those of the General MGA *(see Article 13 General MGA)*.

However, subcontracting is not restricted to a limited part of the action.

Moreover, for the SME Instrument Ph2, the Commission/Agency will assess compliance with best value for money during the evaluation of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

⚠ If you know the subcontractor, include the key information on the award procedure for the subcontract in the proposal (name of subcontractor, price and object), together with the action task(s) that will be subcontracted and an explanation why the subcontractor and the price are appropriate.

⚠ If you do not know the subcontractor, your proposal should set out the task(s) to be subcontracted, the estimated budget and the procedure you will follow to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits (unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

ⓘ For more information on evaluation, see the H2020 Online Manual.

Finally, for SME Instrument Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Instrument Ph2 actions are normally the same as for the General MGA *(see Article 20.2 General MGA)*.

The reporting periods may however be adapted to reflect the duration of the action. Thus, if considered necessary, SME instrument Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

1. Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example****: if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

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V. ERA-NET Cofund

V.1 Background information and approach

The Model Grant Agreement for ERA-NET Cofund ('ERA-NET Cofund MGA) is used for grants for **ERA-NET Cofund actions only**.

⚠ ERA-NET Cofund grants are open only to **research funders** (i.e. legal entities owning or managing research and innovation programmes).

'Programme owners' are typically national/regional ministries or authorities responsible for defining, financing or managing national/regional research programmes.

'Programme managers' are typically research councils, funding agencies or other national/regional organisations that implement research programmes under the supervision of the programme owners.

The minimum requirements for participation are 3 independent research funders established in different Member States or associated countries.

ⓘ *For more information on ERA-NET Cofund actions, see Article 2.*

ⓘ *For information on ERA-NET Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on ERA-NET Cofund standard eligibility criteria, see General Annex C to the Main Work Programme.*

The ERA-NET Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for ERA-NET Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)

- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1.ERA-NET Cofund actions

ERA-NET Cofund actions are actions with the following activities:

- the preparation, implementation and follow-up of a single joint call for proposals for trans-national research and/or innovation projects

  ⚠ Only one co-funded call per GA.

  There are two ways of implementing the joint call:

  - by **providing financial support to third parties**

    This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties.

    Most ERA-NET Cofund actions are implemented in this way.

  - by **implementation of the trans-national projects by the beneficiaries**

    This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding. Beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  What? The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  ⚠ These activities must be *in addition* to implementing a joint call.

⚠ If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do not apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[the first day of the month following the date the Agreement enters into force (see Article 58)] [insert date]*[4] ('starting date of the action').

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Duration of the action

For ERA-NET Cofund actions, the duration is usually **60 months**.

⚠ This time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects, which typically takes 36 months.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*).

⚠ Normally, the action's duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its **own budget categories**.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries
  - direct subcontracting costs for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities
- indirect costs

Differences (compared to General MGA):

- No 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- No 'costs for providing trans-national or virtual access to research infrastructure'
- No 'specific categories of costs'

⚠ These budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[…%] of the action's eligible costs* (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (unless declared as unit cost)

- s**ubcontracting** costs for implementing the trans-national projects
- **other direct costs** for implementing the trans-national projects

❖ **unit costs** for:

- direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
- direct **coordination costs** for additional activities[78]

❖ **flat-rate costs** for:

- **indirect costs**

[78] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for of additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[5] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(d) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(e) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(f) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(d) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(e) the result of the work carried out belongs to the beneficiary, and

(f) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[6] *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

[5] For the definition, see Article 2.1(14) of Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[6] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[7] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form —Conditions for eligibility — Calculation

1.1 The budget category 'direct costs related to trans-national projects' **covers** the following **types of costs**:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration — basic salary and complements
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract and
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries

- other direct costs for the implementation of trans-national projects by the beneficiaries:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure.

What not? The ERA-NET Cofund MGA does not reimburse:

- 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- 'costs for providing trans-national or virtual access to research infrastructure'
- 'specific categories of costs'

⚠ No indirect costs for providing financial support to third parties.

1.2 All costs (except direct personnel costs) must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

In some Articles, the conditions in the General MGA must however be read as referring to 'trans-national projects' (instead of 'action').

For financial support to third parties, there are moreover additional eligibility conditions in Article 15 *(e.g. selection procedure, compliance with national funding rules)*.

⚠ For financial support to third parties, costs are usually eligible only after the trans-national projects have ended.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA*).

B. Direct coordination costs of additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see Article 2)*.

1.2 These costs must be declared on the basis of the **unit cost** fixed by Commission Decision C(2013) 8200[79] and set out in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

⚠ If the beneficiaries do not properly implement the additional activities set out in Annex 1, the grant may be reduced *(see Article 43)*.

Example: Beneficiaries make only two meetings on general strategy.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

⚠ Beneficiaries that implement trans-national projects cannot declare coordination costs for additional activities.

1.4 They must be **calculated** as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU contribution to coordination costs should not exceed 20% of the maximum grant amount.

[79] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[8] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[8] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, the same rules apply as in the General MGA *(see Article 6 General MGA)*.

The eligible direct costs (on which the flat-rate is calculated) include:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

⚠ They do not include direct costs of providing financial support to third parties implementing trans-national projects.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, in principle the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however **only** allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all action activities *(see Article 2)*.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(f) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(g) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**;

(h) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to third parties ('cascade grants')).

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties that actually implement research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

2. Additional eligibility condition: Two-step selection procedure

A two-step procedure is necessary to ensure that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating Member State and associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to the expert evaluators, the consortium must appoint an independent expert as an observer, to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The selection of trans-national projects ('**joint selection list**') must be based on the order of the ranking list (or the ranking lists, if there are different topics).

⚠ If proposals have identical scores, the proposals coming from participating Member States or associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

5. Additional eligibility condition: Compliance with national funding rules

Financial support to third parties must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the third parties) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

The beneficiaries must comply with the maximum amount and the criteria for determining the exact amount under national funding rules that are set out in Annex 1.

⚠ This information must already be part of your proposal *(see Table 4.1 of the Standard proposal template ERA-NET)*. If national funding rules do not specify a maximum amount, the beneficiaries should enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *The coordinator must submit: in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency]**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects, with the required information.

Example: *data on each participant and abstracts of the project proposals.*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects.

Example: *data on each participant and an overview of the results.*

⚠ The Commission/Agency will contact you to give you information on the format to be used (and where to find it) and how to submit the deliverables.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[16]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[17]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the *[Commission's][Agency's]* accounting purposes and will not be used to calculate the final grant amount.

[…]

[16] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[17] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? Normally, ERA-NET Cofund actions are divided into **2 reporting periods** (with two pre-financing payments; *see Article 21*).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][18], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] [19], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

[18] Should correspond to 10% of the maximum grant amount (see Article 5.1).
[19] Should be 80%, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, ERA-NET Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10% of the maximum grant amount
- the second pre-financing payment is 80% of the maximum grant amount.

Exception:

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10% for the first pre-financing payment
- 40% for the second pre-financing payment
- 40% for the third pre-financing payment.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full

– if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund

VI.1 Background information and approach

The Model Grant Agreement for PCP-PPI Cofund ('PCP-PPI Cofund MGA') is used for grants for **PCP-PPI Cofund actions only**.

⚠ PCP-PPI Cofund grants are only open to **actions** that have as main objective to implement a **pre-commercial procurement or a public procurement of innovative solution**. The minimum requirements for participation are 3 independent legal entities established in different Member States or associated countries and 2 independent legal entities that are public procurers from different Member States or associated countries (unless they are sole participants; *see General Annex D to the Work Programme*).

ⓘ *For more information on PCP-PPI Cofund actions, see Article 2.*

ⓘ *For information on PCP or PPI Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on PCP-PPI Cofund standard eligibility criteria and specific provisions, see General Annex C, D and E to the Main Work Programme.*

The PCP-PPI MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for PCP-PPI Cofund deviates from the General Model Grant Agreement as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation][Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of financial resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. PCP/PPI Cofund actions

PCP/PPI Cofund actions are actions with both of the following activities:

– a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI) and its implementation

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'.

The suppliers do not become beneficiaries of the GA.

'Implementation' means implementation of the subcontracts ('subcontract implementation stage')

⚠ Only one co-funded PCP or PPI per GA.

– related additional coordination and networking activities.

What? The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

Examples: *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

⚠ It is mandatory (both for PCP and PPI Cofund actions) to include not only a PCP/PPI itself, but also those coordination activities that are needed to coordinate the PCP/PPI procurement. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

ⓘ *For more information on which activities are required and which ones are optional, see General Annex D and E to the Main Work Programme.*

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the lead procurer he pays all subcontractors)

  ⚠ This implies that the consortium must have a common jointly-committed budget and that the lead procurer is mandated to sign the subcontracts *(see Article 13)*.

- or the members of the buyers group.

  ⚠ This implies that the individual members of the buyers group pay the subcontractors pro rata *(see Article 13)*.

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  ⚠ Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities:
  - direct personnel costs for related additional coordination and networking activities
  - direct subcontracting costs for related additional coordination and networking activities
  - other direct costs for related additional coordination and networking activities
  - indirect costs for related additional coordination and networking activities
  - specific categories of costs for related additional coordination and networking activities (if option applies).

Differences (compared to General MGA):

- No 'direct costs of providing financial support to third parties'.

⚠ These budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs for the activities in Point (f))]*[5]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs of subcontracting for related additional coordination and networking activities** *[(excluding subcontracting costs for the activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

[(f) [OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of [insert cost category or activity**[9]*]:

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[10] *[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of [insert cost category or activity]**: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.
10 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rates

How much? The Work Programme *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs of related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

⚠ Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are not eligible under PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1 *(see Article 13)*
- fulfil the additional eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs of related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[11]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Types of eligible personnel costs

B.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[12] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[*B.1.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not included in Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not included in Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[1]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure:** Costs of other goods and services **for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.**]

[OPTION to be used for virtual access to research infrastructure:** Costs of other goods and services **for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.**]

B.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[1] *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[1]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *not applicable.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises*[;]* ***[****and*

(c) ***OPTION if Point B.5 applies and that unit or lump sum cost includes indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][lump sum costs under Article 5.2(f) and Point B.5]****]****.*

Beneficiaries receiving an operating grant[1] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[*B.5* ***OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]***

Costs of [insert cost category or activity]:

(a) declared as ***unit costs****: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

(b) [declared as ***actual costs****: are eligible, if they comply with the conditions set out above (Points B.1 to [B.3][B.4]) [and if [insert eligibility conditions];]*

(c) [declared as a ***combination of the two****: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[*same for each specific category of costs****]***

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity] *are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the related additional coordination and networking activities have been properly implemented in accordance with Annex 1.]****]***

[…]

[11] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[12] For the definition, see Article 2.1(14) of the Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[13] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[14] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[15] For the definition see Article 2(6) of the Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[16] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

1.1 The budget category 'costs of related additional coordination and networking activities' **covers** the following **types of costs**:

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration — basic salary and complements
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party
  - costs of 'beneficiaries that are SMEs for their owners not receiving a salary'
  - costs of 'beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies).
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific categories of costs for related additional coordination and networking activities.

What not? The PCP-PPI Cofund MGA does not reimburse:

– 'costs for providing financial support to third parties'.

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

Personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[80] and set out in Annex 2 of the GA. (⚠ This concerns only beneficiaries that are SMEs, not PCP/PPI subcontractors that are SMEs.)

Examples: *Contracting authorities or contracting entities that are SMEs.*

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

⚠ Costs incurred by the beneficiaries for validation and testing of solutions provided by the subcontractors are part of the follow-up and monitoring of the results of the PCP/PPI and as such considered eligible direct personnel costs.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

The General Annex D to the Main Work Programme specifies that the costs of related additional coordination and networking activities are eligible up to a **maximum** amount of 30%/50% of the total requested grant amount (for PCP/PPI actions).

For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*.Thus, the amount of EU funding earmarked to finance related additional coordination and networking activities does not change, even if it the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*). The EU funding is not automatically proportionally reduced.

[80] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however **only** allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting *(Article 13)* is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties *(Article 14)* can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[20] and 2004/17/EC[21].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

The beneficiaries concerned must ***prepare****,* ***procure*** *and* ***implement*** *the subcontracts in accordance with the following* ***requirements****:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common procurement specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[22];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP ;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*
- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common procurement specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[22] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

For PCP Cofund actions, the beneficiaries will award subcontracts for the PCP research and development services ('PCP R&D services') that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PCP subcontract' is a contract for the purchase of R&D services that is identified in Annex 1 as action task.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('**buyers group**'), with a joint procurement in **3 phases**

  The 'buyers group' is the group that finances and undertakes together the joint PCP procurement.

  For PCP/PPI Cofund actions, it must normally be made up of:

  - a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[81])

  - that are established in two different Member States or associated countries *(see General Annex D to the Main Work Programme)*.

  ⚠ This is *in addition* to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different Member States or associated countries; *see General Annex C to the Main Work Programme*)

  Exceptionally, the Work Programme allows for the participation of sole participants *(see General Annex D to the Work Programme)*.

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  ⚠ The buyers group is not open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Other entities may be involved in the action as:

  - beneficiaries (or linked third parties) responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*

  - third parties providing in-kind contributions

  if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

  The PCP procurement is implemented in 3 phases.

  The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

[81] *See Directives 2014/24/EC and 2014/25/EC.*

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

❖ Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

⚠ The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

⚠ This does not extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' *(as used in the WTO GPA)*.

⚠ Supplies cannot constitute the majority of the contract value.

❖ All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

❖ **Joint procurement procedure** (i.e. joint call for tender, joint evaluation of offers and joint award) is **coordinated and led** by one beneficiary ('**lead procurer**')

The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[82]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  ⚠ The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')

- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

⚠ PCP subcontracting is not restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

⚠ There can only be one PCP, per PCP Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PCP subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States or associated countries**.

[82] *See Directives 2014/24/EC and 2014/25/EC.*

⚠ This includes R&D and operational activities (*e.g. research, development, testing, certifying solutions, etc.)*.

ⓘ *For more information on associated countries, see Article 25 General MGA*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves.

⚠ This obligation must be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

PCP subcontracts must be based on the **best value for money** criteria *(see Articles 10 and 13 General MGA)*.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

⚠ The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

- a **specific procurement procedure** must be followed

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:

    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

  - the procurement must be preceded by an '**open market consultation**'

This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[83]).

A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

– the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

– the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

– the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PCP subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The **framework agreement** (with each selected subcontractor) must set out the framework conditions for all 3 phases of the PCP implementation, including:

– the practical set-up of the implementation of the subcontracts, in particular:

  – the number, duration and budget of the PCP phases

  – the minimum number of expected subcontractors per PCP phase

  – the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)

  – the process for monitoring of on-going R&D work and reporting obligations of subcontractors

[83] *See Directives 2014/24/EC and 2014/25/EC.*

  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

⚠ The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

  - the details of the PCP R&D services purchased by each buyer

- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PCP.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

7. Other obligation: Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[84]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[85]) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ For more information on this obligation, see Article 13 General MGA.

[84] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*
[85] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[23], 2004/17/EC[24].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex** 1. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

***[OPTION:** not applicable]*

*(iii) prepare **common procurement specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common procurement specifications (see above), according to **best value for money** criteria and ensuring that the price corresponds to **market conditions**;*

*(iii) **Step 3**: **award the subcontract(s)** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);]*

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[1] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common procurement specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.]*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.']*

[23] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

[24] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries will award subcontracts for procuring the 'PPI innovative solution(s)' that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PPI subcontract' is a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

Exceptions:

There is no requirement to split the PPI procurement procedure in **phases**.

The buyers group may select one or more subcontractors.

The common challenge does not concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

⚠ PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure*[86]*)*.

Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

There is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

The subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.

If there is no mandate, the general rule is that:

- framework agreement(s) must be signed by all members of the buyers group together
- specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

⚠ PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

⚠ There can be only one PPI, per PPI Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

⚠ Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes

[86] *See Article 31 of Directive 2014/24/EC and Article 49 in Directive 2014/25/EC.*

are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

⚠ For PPI subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

Like PCP subcontracts, PPI subcontracts must:

- be based on the **best price-quality ratio**,
- have a price that corresponds to **market conditions**
- must follow the **specific procurement procedure** set out in the GA.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**'

    Exception:

    If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for an open market consultation procedure.

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

⚠ This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)*.

  Exception:

  If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for contract notice and a request for tender; a request for offers from at least 3 providers suffices.

  ⚠ The request must also be addressed to the providers that successfully completed the last PCP phase in the pre-ceding PCP Cofund action.

  ⚠ Do not forget to specify in the request for tenders the arrangements for intellectual property rights (for these arrangements*, see below point 4*) and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  ⚠ In case of framework contracts/agreements there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned**.**

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots need to be deployed at different times and/or by different procurers.*

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PPI subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The subcontract(s) must specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate, unless in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  ⚠ The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

⚠ If the buyers group choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PPI.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. Other obligation: Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[87]) normally apply to PPI procurements.

Therefore, the lead procurer and the members of the buyers group that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ *For more information on this obligation, see Article 13 General MGA.*

[87] *See Directives 2014/24/EC and 2014/25/EC.*

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[1]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(including after the intermediate evaluations before the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [Y] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each project financed by the procurement**, including data on each contractor that participated in the procurement, an overview of the results (for publication and evaluation purposes) and an assessment by the buyers group of the final results of each participating tenderer (in terms of achieving the performance and functionality requirements of the initial tender specifications).
- any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (including data on each contractor that participated in the procurement and overview of the results)

⚠ Templates[hyperlink] are provided on the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[41]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[42]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions)**]*** ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure**]**;*

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of funds**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(a) an overview of the results and their exploitation and dissemination;

(b) the conclusions on the action, and

(c) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(a) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(b) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(e) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into **two** reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage (preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of funds — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of funds needed to pay the subcontracts*(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a statement on use of the previous pre-financing instalment *(see Annex 12)*.

  ⚠ This document includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  ⚠ It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][44], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][451], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

[44] Should correspond to the percentage of the maximum grant amount that is foreseen for the related additional coordination and networking activities related to the preparation of the call for tender (see Article 5.1).

[45] Should correspond to a maximum of 90% minus the amount of the first pre-financing payment, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; see Article 21) minus the amount of the first pre-financing payment).

Exception:

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

[…]

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

[…]

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund

VII.1 Background information and approach

The Model Grant Agreement for EJP Cofund ('EJP Cofund MGA') is used for grants for EJP Cofund actions only.

⚠ EJP Cofund grants are open mainly to **entities owning** or **managing research and innovation programmes** (and exceptionally other entities — if justified by the nature of the action —, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from both national and private sources). The minimum number of participants is five independent legal entities from different Member States or associated countries (unless they are sole participants; *see General Annexes C and D to the Work Programme*).

ⓘ *For more information on EJP Cofund actions, see Article 2.*

ⓘ *For information on EJP Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on eligibility criteria, see the Work Programmes.*

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for EJP Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Model for the annual work plan
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.F (Fusion Cofund programme action specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

EJP Cofund actions are actions with the following activity:

– implementing a joint programme of activities of coordinated national research and innovation programmes.

What? The joint programme of activities may range from research and innovation activities to coordination activities, training activities, dissemination activities and financial support to third parties.

> ***Examples:*** *NFRP7–2015 Integrating radiation research in the European Union; Fusion programme Cofund action (FEJP) (see sections A and B.1 Euratom Work Programme 2014-2015)*

What not? The EJP only funds joint programmes, not individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the Work Programmes, and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[4] (‘**starting date of the action**’).

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Duration of the action

For EJP Cofund actions, the duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55 General MGA*).

⚠ The action’s duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same **budget categories** as the **General MGA**.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies).

Differences (compared to the General MGA):

- For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are replaced by the following specific categories:
  - 'costs for mobility of personnel'
  - 'costs for fellowships for researchers'
  - 'access costs for research infrastructure'.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

***[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[…]

[5] To be used only if option in Point (f) is used.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings', costs of 'mobility of personnel', costs of 'researcher fellowships', costs of 'access to research infrastructures (EURATOM)'.
[11] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed — for each call or action — in the Work Programmes. It cannot exceed 70%[88].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Specific case:

For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), there are **different unit costs** for three 'specific categories of costs':

- costs for **mobility** of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for **fellowships** for researchers: monthly living allowance, mobility allowance and family allowance
- **access costs** for research infrastructure [89]

⚠ These unit costs replace the unit costs for the 'specific categories of costs' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 General MGA)*.

[88] *See Article 28(5) of the Rules for Participation.*

[89] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

F. direct personnel costs;
G. direct costs of subcontracting;
H. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
I. other direct costs;
J. indirect costs;
[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision**: costs of [insert cost category or activity*[1]*]].

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

For one specific EJP Cofund action, i.e. the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are however replaced by the other categories.

For ease of reference, the annotations for Article 6.2 will be limited to these specific categories of costs and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (g) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (h) a **summary progress report** *on* the activities carried out during the on-going reporting period.

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1.

⚠ Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*.

⚠ However, since the annual work plan for the next period must be agreed with the Commission/Agency before the start of activities for the next reporting period, it must be submitted 3 months (i.e. 90 days) in advance.

⚠ The annual work plan for the first reporting period must already be included in your proposal.

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan**.

⚠ The coordinator has **30 days** from the date of receipt of the request to submit a revised annual work plan.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

⚠ It should **not** contain an **analysis of *all* activities** carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

⚠ Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

⚠ Payment of the **second pre-financing** payment is not automatic. It must be **requested** in the statement on the use of the first pre-financing payment using the template in Annex 8.

ⓘ For more information on the other provisions of this Article, see Article 20 General MGA.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]* ***[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.***]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Exception:

Large EJPs may benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The need for a second pre-financing payment will be assessed during the preparation of the GA.

⚠ If a second pre-financing payment is agreed, the Guarantee Fund retention (of 5% of the maximum amount of the grant) will be split between the two pre-financing payments.

The second pre-financing payment is not automatic but must be requested by the coordinator and supported by a statement on the use of the first pre-financing payment *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum amount of the grant

Exception:

Depending on the size and the needs of the EJP, the reimbursement rate in the Work Programme and the availability of Union funds, the pre-financing may be higher or lower.

In case of two pre-financing payments, the second pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the first pre-financing was insufficiently used:

– if 70% or more of the first pre-financing has been used: the second pre-financing is paid in full

– if less than 70% of the first pre-financing has been used: the second pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The Model Framework Partnership Agreement ('MFPA') and Model Specific Agreement ('MSGA') are used for framework partnerships (and specific grants under such framework partnerships) only.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement potential action (i.e. the FPA and SGAs).

They are established in a FPA and implemented by SGAs for specific actions. Both FPAs and SGAs are treated as grants for the purpose of the award procedure.

⚠ The minimum requirements for participation in FPAs will generally depend on the types of specific actions that are envisaged in the action plan.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals in the Work Programme and in the invitation to submit a proposal —) *(see Article 4 MFPA and Article 14 MSGA)*.

⚠ Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

ⓘ *For more information on framework partnerships and specific grants, see Article 2.*

ⓘ *For information on FPA funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on standard eligibility criteria for different types of specific actions, see General Annex C of the Main Work Programme.*

The MFPA and MSGA generally follow the General MGA for content, but with a different numbering:

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⚠ In addition, all references in the General MGA to 'beneficiary(ies)' are to be taken as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the MFPA or MSGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

VIII.2 Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission') ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname] [2],

and

on the other part,

1. 'the **coordinator**':

[full official name] [short name][legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. **[full official name] [short name]** [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[3]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model for the certificate on the methodology

[1] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.

[3] The action plan should include the common objectives of the parties in compliance with the objectives stipulated in the Preamble and the types of activities covered under this Framework partnership, contributing to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Partners that have also signed an SGA become beneficiaries (i.e. a 'participant'[90] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

If you do not want to actively participate, you may participate as 'partner not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble to the SGA).

This means that you will not have to comply with some of the obligations under that SGA *(see Preamble MSGA)*

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

– the other partners sign the Accession Form *(see Article 62 MFPA and Annex 3)*.

[90] For the definition, see Article 2.1(15) of the Rules for Participation: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ Any amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in the action plan (see Annex 1))] [open to all applicants meeting the announced criteria]] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The Commission will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the Commission decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[4] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[5] Please use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

Framework partnerships may in principle be awarded in all areas of the Horizon 2020 Framework Programme.

⚠ Currently, framework partnerships are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and

coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

The partnership is based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership

  ⚠ For the objectives, please refer to the FPA call.

- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in the Work Programme.

⚠ Signing an FPA does not oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

⚠ The partners may continue to participate in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

2. Award of specific grants

The Specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  ⚠ Such calls are restricted to the consortia that have signed a FPA and will be in competition.

  Example: *The Commission signs different FPAs for FET Flagships. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the Work Programme.

  The date must be set out in the action plan or in Article 2 of the FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

The Framework Partnership Agreement shall be concluded for a period of [...][6] years as of its entry into force (see Article 64). This period cannot be extended.

[6] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 MFPA)*.

> ***Example:*** *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

⚠ The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

⚠ SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** not applicable]*

1. Consortium agreement

As a general rule, FPA consortium agreements must ensure that the Framework Partnership and the specific actions are implemented properly.

⚠ If necessary, the consortium may decide to have — in addition to the consortium agreement under the FPA — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ⓘ *For more information on consortium agreements, see Article 41.3 General MGA.*

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 General MGA)*.

Exceptions:

Amendments made following suspension cannot have the effect of extending the duration of the FPA as set out in its Article 3.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the Agreement

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties**.**

⚠ Termination of the FPA has no effect on ongoing specific agreements (unless these are also terminated; *see Article 56 MFPA and Article 17 MSGA*)

ⓘ *For more information, see Article 50 General MGA.*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *subcontracting costs*
- *costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific categories of costs (if option applies) (see Article 4 General MGA).*

ARTICLE 10 — GRANT MAXIMUM, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 14 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 13 SGA) and approved by the *[Commission][Agency]* (see Article 14 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 SGA).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 MSGA and Article 5 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 General and specific conditions for costs to be eligible

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Specific conditions for costs to be eligible

The specific eligibility conditions applicable per budget category are set out in Article 5 MSGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS

The rules on resources to implement the specific actions and third party involvement are set out in the specific agreements (see Article XX SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 General MGA).*

⚠ The third parties are normally involved in the specific actions, not in the framework partnership.

Example: *Third parties making resources available against payment or free of charge (see Articles 16 and 17 FPA) must be identified in Annex I of the SGA.*

Partners must however — already at FPA proposal stage — indicate if they intend to use third parties or not.

Moreover, linked third parties must be identified already in the FPA *(see Article 19)*.

Example: *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64).

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

[OPTION if Article 19 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the partner to which it is linked must also submit — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the agreements with effect from the date of the entry into force (see Article 64 and Article 18 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGA

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ Accession to SGAs is effected only by means of the signature of the coordinator. The other partners do not need to sign accession forms for the SGA.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA cannot be amended before the FPA.

ⓘ *For more information on the conditions for accepting new partners, see Article 56 General MGA.*

ⓘ *For more information on the procedure for amendments, see the H2020 Online Manual*

VIII.3 Model Specific Agreement specific annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],

and

on the other part,

1. 'the coordinator':

[**full official name**] [**short name**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3a of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement**: X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreements:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 9),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
Annex 3	Model financial statements
Annex 4	Model for the certificate on the financial statements

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

⚠ However, not all partners of a framework partnership must actively participate in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

⚠ These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

As a consequence, these partners do not however need to comply with most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc)*.

⚠ Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* do remain applicable also for these partners.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

⚠ The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ The other partners do not need to sign accession forms.

⚠ Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

ARTICLE 14 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

14.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the Work Programme and in the invitation to submit a proposal).

⚠ If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Horizon 2020
Annotated Model Grant Agreements

General Model Grant Agreement
and specific Model Grant Agreements (ERC, SME Instrument, ERA-NET Cofund, PCP-PPI Cofund, EJP Cofund, Framework Partnerships and Specific Agreements)

Version 1.6.1
16 June 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations regarding the following derived model grant agreements: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnerships and specific agreements
1.6.1	16.06.2014	▪ Clickable table of contents added

Foreword

The **Horizon 2020 Annotated Model Grant Agreements** ('AGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

---

[1] **H2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

Over the next months, this text will be transformed into an on-line version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Horizon 2020 Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

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I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *Energy Challenge actions (see the Smart Cities and Communities calls); actions under the Research Infrastructures Part (see a Research Infrastructure call); Health Challenge actions, etc*
>
> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 Annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),**]

[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),**]

[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

[3] *See Article 15(9) of the Rules for Participation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- for **coordination and support actions (CSA)**: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

'Complementary grants' are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*, which links the two action and ensures the necessary synergies.

[6] *For the definition, see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies)

  ⚠ The budget category 'specific categories of costs' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings' and 'costs for clinical studies'.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

*[**OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
[5] For the definition, see Article 2.1(14) Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[7]; for IA actions it is normally 70% of the total eligible costs[8].

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[9]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[10] and all budget categories.

[7] *See Article 28(4) of the Rules for Participation.*
[8] *See Article 28(5) of the Rules for Participation.*
[9] *See Article 28(5) of the Rules for Participation.*
[10] *See Article 28(6) of the Rules for Participation.*

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[11]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[12]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [13]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific categories of costs for:
    - 'costs for **energy efficiency measures** in buildings'[14]
    - '**access costs** for providing trans-national access to research infrastructures'[15]
    - 'costs for **clinical studies**'[16]

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[11] *See Articles 123, 124 of the Financial Regulation.*

[12] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[13] *See Article 33(2) of the Rules for Participation.*

[14] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[15] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs ⚠ new in Horizon 2020)[17]

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme.

[17] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum EU contribution.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact
If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

2. Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:
Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000
Reimbursement rate= 100%
Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:
The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:
In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:
Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000
The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries (and linked third parties) must:

- at proposal stage: enter only eligible costs into the estimated budget for your action *(see Article 4)*
- at reporting stage: declare only eligible costs in your financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries** (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  ⚠ Accounting documentation is necessary only for actual costs.

  Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  ⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  Specific case:

  For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

  – recorded in the third party's accounting records

  – calculated in accordance with the accounting standards applicable in the country in which the third party is established

  – calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit')

  Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

  ⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

  Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

  For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

  – must calculate them (the average or standard personnel costs) according to its usual accounting practices

  – must budget and declare a total amount; the amount per unit must not be included in Annex 2.

  ⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

  Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

  Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

  ⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

  Example:

  A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*:** *costs of [insert cost category or activity*[13]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure:** **Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 This budget category **covers** the following **types of costs**:

- **basic remuneration** (basic salary and complements) and
- for non-profit legal entities: **additional remuneration** ('bonus payments').

What is 'basic remuneration'?

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

'Parental leave' covers both maternity leave and parental leave.

The 'complements' may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — If a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6.

> ⓘ *For more information on personnel made available to a beneficiary by a third party, see below and Articles 11 and 12.*

What not?

The basic remuneration does not include components that must be considered to be 'additional remuneration'.

> ***Example (variable remuneration component acceptable as basic remuneration):*** *The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.*

> ⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

What is 'additional remuneration'?

'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

1.1.2 Costs for employees (or equivalent) may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

For basic remuneration (basic salary and complements):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- be **mandatory** under national law, collective labour agreements or the employment contract
- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract, but he/she **must be 'assigned to the action'** (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

Specific case:

For **secondments** or **linked third parties**, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

For additional remuneration ('bonus' payments) **for non-profit legal entities:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours
Remuneration components:
a = annual salary: EUR 50 000
b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
c = additional remuneration for being Head scientist in a project: EUR 2 000
d = additional remuneration for being First Assistant on an internal action: EUR 1 000
***a** and **b** would be used to calculate the researcher's hourly rate:*
hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34
***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*
***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for **additional work** or **expertise**

The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

Examples (acceptable additional remuneration):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

Examples (not acceptable additional remuneration):

Additional remuneration paid for using English.

Additional remuneration is paid for participating in EU funded or multi-partner actions.

- be part of the beneficiary's usual remuneration practices and be consistently paid whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

The objective criteria must be related to the additional work or expertise.

The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***
Addition of the additional remuneration: = ***2 000***
Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Procedure for calculating personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception:

Employees hired during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Examples:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')

- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours')**

- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	Can be used **in all cases**; any beneficiary can use this option.	**Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: – employment contract of the person concerned – applicable collective labour agreement – national law on working time ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1;

		group – an applicable collective labour agreement or – the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours*	– if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		per day = 1 824 hours ***Standard annual productive hours*** *for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days =* ***228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days =* ***212*** *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 =* ***1 642*** ***1 696 hours*** *(usual cost accounting practice)* ***> 1 642 hours*** *(90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case:

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs

– are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

– correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.

– the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Example:

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.
S/he worked 1 600 annual productive hours, 800 of them for the EU action.
Maximum additional remuneration eligible for the EU action (eligibility ceiling):
{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000
The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 This budget category **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action, under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

1.2.4 The **calculation** of the costs depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount). A calculation method is required, especially if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same **formula** explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the hourly rate is different (since it is not based on the annual personnel costs as registered on the payroll).

For the **hourly rate**, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person: this global amount must be divided by the number of hours worked for the beneficiary under that contract.

1.3 Direct personnel costs: Costs for personnel seconded by a third party

1.3.1 This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 These budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and indicated in Annex 2 of the GA.

This unit cost (hourly rate) is calculated according to the following formula:

{EUR 4,650/ 143 hours}

multiplied by

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

{country-specific correction coefficient / 100}

ⓘ *For the country-specific correction coefficient, see the* MSC calls conditions of the Main Work Programme[19] *(Table 4).*

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **owner** of an **SME/ beneficiary that is natural person**, who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They must be **calculated** as follows:

amount per unit (hourly rate) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 This budget category **covers** the personnel costs in actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not included in Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15 are met.][**OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2. Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs (equipment costs)':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment cost: Depreciation costs of equipment, infrastructure or other assets

1.1.1 This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following:

It is expected that the beneficiaries allocate the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

⚠ Depreciated equipment costs can never exceed the equipment's purchase price.

⚠ Depreciation cannot be spread over a period longer than the equipment's useful life

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  {equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

1.2 Equipment costs: Cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of the equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

> ⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.
>
> ⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional eligibility conditions** set out in Article 11.1.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. costs of purchasing scientific publications (e.g. books, manuscripts, articles, digital copies, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results and royalties on access rights

Specific cases:

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) paid to a third party (i.e. not a beneficiary) *(see Article 24)* are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees paid for access rights to background granted by other beneficiaries *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Best practice: Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled.

Costs for drafting the 'plan for the exploitation and dissemination of the results' are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when implementing this plan may be eligible.

– costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).

– translation costs, if translation is necessary for the action's implementation, is justified, etc.

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Internal invoices must not include indirect costs elements or profit margin or mark-up.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[6] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013: **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

What? Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ The beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.), together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

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[20] *See also International Financial Reporting Standard No 16.*

[21] *See Article 126 of the Financial Regulation.*

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments)
- knowledge-based resources such as collections, archives or scientific data
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

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[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the H2020 Framework Programme.*

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. During an audit, the auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

The beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  ⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

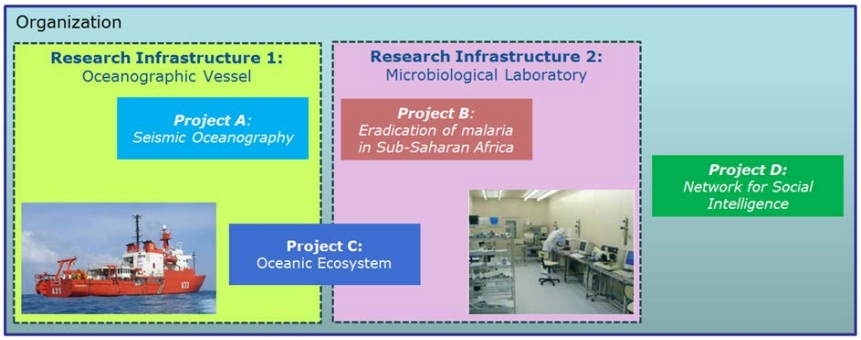

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

[24] *See Article 129(1) of the Financial Regulation.*

⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

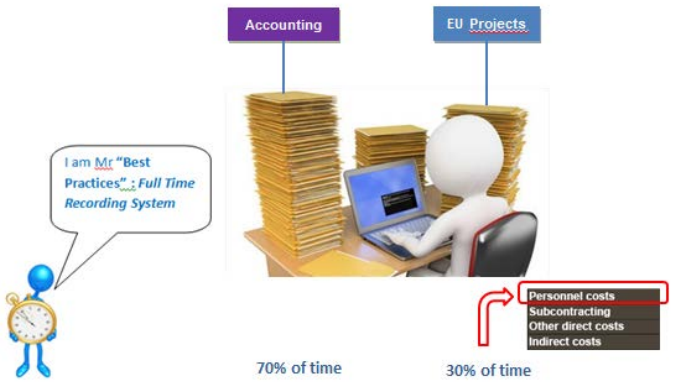

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to the best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[26].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

[26] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category covers costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be declared on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– unit or lump-sum costs covering specific categories of costs which include indirect costs.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]

1. Specific categories of costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific categories of costs**, i.e.:

- for Energy Challenge actions involving additional energy efficiency measures: **costs for additional energy efficiency measures**

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

  These grants combine different activities. The reimbursement on the basis of the unit cost applies only for the building-related demonstration activities.

- for actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity': **access costs for providing trans-national access to research infrastructures**

  ⚠ This unit cost will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015)*.

- for actions under Health Challenge actions involving clinical studies: **costs for clinical studies**

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are already covered by the unit cost may not be declared (a second time) as direct costs *(for the costs that are covered, see below)*.

Examples:

Case 1: *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for*

subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

Case 2:*A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.*

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Case 3: *A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.*

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 Specific category 'costs for additional energy efficiency measures'

1.1.1 This budget category **covers** two categories of eligible costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and

- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost (EUR/m^2 of eligible conditioned gross floor area) set out in Commission Decision C(2013) 8196[27] and indicated in Annex 2 of the GA.

This unit cost (EUR/m^2 of eligible conditioned gross floor area) is calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

'standard cost to save 1 kWh' = EUR 0.1
'standard payback period' to be used = 10 years

The m^2 of eligible conditioned gross floor area do not include parts of the buildings which are not affected by the measures, *e.g. garages*.

⚠ The specifications per type of demonstration building must already be part of your project proposal (by completing the BEST table (Building Energy Specification Table))[28]. These specifications are then included in Annex 1.

⚠ You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit (EUR/m^2 of eligible conditioned gross floor area) x number of actual m^2 of surface area built or refurbished

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.
[28] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

1.2 Specific category 'access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category, these costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[29] and set out in Annex 2 of the GA.

⚠ The Decision does not *fix* the unit cost for access costs; the unit cost must be established for each installation — before signature of the GA — as follows (and then reflected in Annex 2 of the GA):

- identification of a *unit* of access to the installation; this is used to measure the total quantity of access that the installation provides to its users

- establishment of the *unit cost* of access, calculated as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access cost (over past two years}^{30}\textbf{)}}{\textbf{average annual total quantity of access (over past two years}^{31}\textbf{)}}$$

The averages are based on:

- the beneficiary's certified or auditable historical data

- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for less than two years) and

- a period excluding times when the installation was not usable (out of order, under repair or undergoing maintenance).

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[31] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for:

  - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    By way of exception, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

  - costs of consumables specifically used for the installation and the research work of the users

  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

  - costs of energy power and water supplied for the installation

  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)

  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

  - costs of specific scientific services included in the access provided or needed for the provision of access

- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

  and excluding:

  - all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

  - travel and subsistence costs to support the visits of users.

A form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ Do not forget to describe in your proposal the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs= average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Before signature of the GA, the beneficiaries can opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation) not as unit cost but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*. If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for **providing trans-national access to research infrastructure** to scientific communities
- fulfil the **additional eligibility conditions** set out in Article 16.1

1.1.4 They must be **calculated** as follows:

– for each installation:

amount per unit (EUR/unit of access) x number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.**]***

[OPTION: *not applicable**]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties free of charge are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

    Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

  - **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national VAT system. Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible** it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.
>
> **Specific cases:**

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding).

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[32] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

[32] *For the definition, see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are	Subcontracts concern the implementation of action tasks; they imply the implementation of

necessary to implement action tasks by beneficiaries.	specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or*

	other goods and services).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 ***[OPTION:*** *with the exception of additional exploitation obligations****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.****]***

[OPTION: *not applicable****]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[33]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

ⓘ For more information on third country participants, see the Horizon 2020 Online Manual.

[33] *For the definition, see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

Obligations that do not apply to beneficiaries not receiving EU funding:

These beneficiaries must, in particular, **not**:

- comply with the conditions for declaring costs *(e.g. cost form, eligibility, calculation, etc) (Chapter 3 and Articles 10-15)*
- keep records and other supporting documentation for costs *(Article 18.1.2)*
- submit financial reports and convert their costs in euro *(Articles 20.3(b), 20.4(b) and 20.6)*
- comply with some of the rules on management of intellectual property, background and results *(Articles 26.4, 28.1, 28.2, 30.3 and 31.5)*
- fear rejection of costs, reduction of the grant or recoveries, suspension of the payment deadline or suspension of payments *(Articles 42, 43 and 44)* .

⚠ Apart from this, they are treated like the other beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs, reduction of the grant or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the best value for money considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the Work Programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[34] and 2004/17/EC[35] — or any EU legislation that replaces these Directives[36]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[34] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[35] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[36] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*,

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]*.****]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means a contract for the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is forbidden in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is forbidden, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the best value for money considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. Other obligation: Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks

- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises

- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an **established relationship** (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

– *scientific and economic unity*

– *last a certain length of time*
– *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

– the financial viability/capacity of a beneficiary is 'weak' while that of its linked third parties is strong

  ⓘ For more information on the financial viability and the financial capacity check, see the Horizon 2020 Online Manual.

– the beneficiary mainly coordinates the work of its linked third party.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

[38] *See Articles 8 and 9 of the Rules for Participation.*

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is **no** procedure for **approval without amendment**.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

⚠ The obligations in Article 14.1.1 additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

Each linked third party has its own financial statements, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA ('**cascade funding**').

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is **not** considered financial support.

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties (recipients) that actually implement research and/or innovation projects.)

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ *For financial support given in the form of prizes, see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g. 3 grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

⚠ All these conditions must already be described in your proposal (see the Proposal Templates).

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- avoid conflicts of interest *(see Article 35)*
- maintain confidentiality *(see Article 36)*
- promote the action and give visibility to the EU funding *(see Article 38)*
- are liable for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *not applicable**]***

15.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

Example: *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.
- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[28]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

1. Trans-national access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[39] and installations[40] for scientific communities ('provision of access activity').

Such Research Infrastructures Part actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **cover** — for the provision of access activity — the following **types of costs**:

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[39] *For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] *For the definition, see the footnote in Article 16 of the MGA.*

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

The Beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Virtual access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

– operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

⚠ There are no 'access costs' for virtual access.

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected or even identified.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General oobligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Rules of Application: **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ The rules in the GA do not affect national laws on keeping documents.

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

– documents received or created in paper form should be kept in paper form

– documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units

declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary (or linked third party) may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

⚠ The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval. It will also challenge the costs, if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary/ can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ *For more information on the certification procedure, see the Horizon 2020 Online Manual.*

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiaries must:

- sign one **declaration** per reporting period, to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  This declaration must be dated and countersigned for acceptance by the person concerned.

  A template [hyperlink] is provided on the Participant Portal.

  Best practice: If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  A template [hyperlink] is provided on the Participant Portal.

  Time records should include:

  – the title and number of the action, as specified in the GA

  – the beneficiary's full name, as specified in the GA

  – the full name, date and signature of the person working for the action

  – the number of hours per day declared for the action

  – the supervisor's full name and signature

  – a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned

  – a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

The beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For Energy Challenge actions involving additional energy efficiency measures, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*), unless Annex 1 specifies another way.

Specific case:

'**Classified deliverables**' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

– a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions).****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

– a '**periodic financial report**' containing:

(ii) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(iii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iv) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(v) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[32] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the coordinator, which must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (they do not see their grants in the electronic exchange system and therefore have no access to them). Before submission, the beneficiary completes the data for the linked third party, prints it and sends it to the linked third party which must sign it *on paper* and then send it back to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system are identical to the signed paper version.

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

CFSs must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

ⓘ *For information on the eligibility of costs incurred for reporting, see Article 6.2.D.3.*

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified deliverables' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on

security of information in the Commission internal Rules of Procedure *(see also Guide for classification[hyperlink]).*

ⓘ For more information on information security, see the Horizon 2020 Online Manual.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on cross–cutting issues (described in Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined vis-à-vis societal challenges (Annex I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed, if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more), as reimbursement of actual costs and personnel costs

on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25 % flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, it must be an independent public officer, with formal competence to audit the beneficiary/linked third party.

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro:**
  - for costs incurred in the currency of their accounting records conversion of costs by one of the following:
    - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[44].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart corresponding to your currency.

Step 3 — Choose the start and end date of the period for which the average daily exchange rate is calculated (i.e. the reporting period) by using the sliding tool in the second table.

Step 4 — The average appears above the first table.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if no daily euro exchange rate is published : using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

– for **costs incurred in a currency other than EUR and the one used in their accounting records:** conversion in accordance with the applicable national law and their usual accounting practices.

– for costs incurred in EUR, beneficiaries **with accounting records in a currency other than the euro** must declare the amount in EUR; no conversion has to be made.

⚠ This means that a beneficiary with accounting in a currency other than EUR will act differently according to the currency in which it incurs the costs (the currency in which the contract/invoice is established).

Examples:

1. *If the UK beneficiary buys the equipment in the USA (costs incurred in US dollars), it will convert the price of this equipment into pounds (the currency in which its accounts are established) according to its usual accounting practices. When reporting the costs to the Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.*

2. *If the UK beneficiary buys the equipment in UK pounds (it will record those equipment costs incurred in pounds in its accounts kept in pounds). When reporting the costs to the*

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.

3. If the UK beneficiary buys the equipment in Germany in EUR (e.g. EUR 10 000) it will report these costs incurred in EUR (i.e. 10 000) to the Commission/Agency without converting them first from EUR to pounds and then back to EUR.

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline *(see Article 47)*
- terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

  ⚠ This may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - the work has started.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed start date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed start date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)
- the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, see Articles 42, 43 and 44.

2. Amount of pre-financing payment

There is no standard amount or percentage for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods (it will be in any case less for actions with only one reporting period, as 100% would mean the totality of the EU grant for the action).

⚠ At the moment of the pre-financing payment, an amount equivalent to 5% of the maximum grant amount is deducted from the payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.
Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1 : application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:
- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)
Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
Payment of the balance amounts to EUR 100 000 and will be ***paid*** *to the coordinator as follows:*
- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*
- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

22.1.1 Right to carry out checks

The Commission *[or the Agency]* will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission *[or the Agency]* may be assisted by external persons or bodies.

The Commission *[or the Agency]* may also request additional information in accordance with Article 17. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.

2. The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).

3. After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.

4. After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check (see Article 17). All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

It may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the check shows ineligible costs or the violation of other obligations under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

The Commission/Agency may carry out checks remotely, based on documents it received beforehand. It can do so using its own staff or with the assistance of external expert(s) or bodies.

⚠ If the Commission/Agency is assisted by external expert(s) or bodies, it does not need to send their name(s) for approval to the beneficiaries before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report'** will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed

- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the review shows improper implementation of the action, ineligible costs or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42- 44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a letter sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the **names** of the **independent experts** that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, you will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days (‘**contradictory review procedure**’).

22.1.3 Right to carry out audits

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a ‘**draft audit report**’ will be drawn up.

The Commission *[or the Agency]* will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations (‘**contradictory audit procedure**’). This period may be extended by the Commission *[or the Agency]* in justified cases.

The ‘**final audit report**’ will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission *[or the Agency]* may also access the beneficiaries’ statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

Specific case:

The Commission may audit the accounting records of beneficiaries, to obtain general information about actual costs for cost items that are reimbursed as unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will however normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

They consist in an in-depth examination (by professional auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to **third parties** involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

*1. The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

*2. The Commission/Agency may audit **third parties providing in-kind contributions** (free-of-charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

*3. The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or if appropriate the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. .*

⚠ *For this category of third parties, audits will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

*4. The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary.*

⚠ *For recipients of financial support or prizes, audits normally will not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs), except if Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties. .*

⚠ If the audit shows, ineligible costs, improper implementation of the action or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

2. Procedure

The audit will be initiated by a letter sent to the beneficiary concerned.

⚠ The Commission/Agency will transmit this letter (and the other communications relating to an audit as formal notifications, through the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its **name**.

The beneficiary may **object** to an external auditor on grounds of commercial confidentiality (and explain the reasons for this). If justified the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit with its own auditors).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit (**i.e. on the beneficiary's premises or on the site on which the action is being implemented). (There may however also be audits that consist only in a desk review.)

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc)* and will indicate how and when it must be provided (and in which format).

ⓘ *For more information on records and supporting documentation for the different cost forms, see Article 18.*

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

> ***Example:*** *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

⚠ Objections based on data protection or confidentiality will not be accepted.

Once an audit has started, the beneficiary must keep all the records and supporting documents until the audit procedure and its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This avoids any unnecessary delays in retrieving original documents from the archives (and thus minimises the risk of the rejection of costs).

> ***Example:*** *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

This includes granting access to research facilities and interviewing the researchers that worked on the action.

⚠ Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc).

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Moreover, all confidential data will be processed in accordance with Article 36.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory review procedure**').

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [1]and No 2185/96[1] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42- 44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[1], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

⚠ If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission *[or the Agency]* may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission *[or the Agency]* will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the Commission *[or the Agency]* on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission *[or the Agency]* in justified cases.

The Commission *[or the Agency]* will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission *[or the Agency]* does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission *[or the Agency]* accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission *[or the Agency]* intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission *[or the Agency]* does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission [*or the Agency*] accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

⚠ These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or ‘**associated country**’[39], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: ‘**associated country**’ means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Regulation (EU) No 1291/2013).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to background

The rules on access to background (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is **no** (or a more limited) obligation to give **access**, if there are **restrictions** or **limits** (legal or otherwise) regarding the background and the beneficiary owning or holding the background has informed the others — before acceding to the GA (or immediately when additional background is agreed on after signature of the GA).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ Don't forget that — when contracting on background with third parties — you must at all times ensure that you can still comply with your access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

  > ***Example:*** *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

– for the exploitation of results: under fair and reasonable conditions

  ⓘ *For more information on fair and reasonable conditions, see Article 31.*

Also, there are no **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties, except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure *(see Article 31)*.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the **beneficiary** that **produced** them.

> 'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries are advised to keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases:

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must — as much in advance as possible before the jointly-owned results are produced — conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  ⚠ Don't fix a *ceiling* for fair and reasonable compensation before the action starts, unless you can precisely determine the results you expect to produce.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries are advised to include general principles on joint ownership already in the consortium agreement.

⚠ The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection (*e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (⚠ without prior authorisation from the other joint owners), unless otherwise agreed in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

⚠ The joint ownership status may **change**:

– it may need to be reviewed later on, when protecting the results.

Example:

Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.

– joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that any agreements with third parties who could claim rights to the action's results *(e.g. employees, subcontractors, linked third parties etc.)* contain provisions that allow them to respect their obligations under the GA *(e.g. transferring ownership to the beneficiary, grant the beneficiary access rights with a right to sub-license, etc)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Specific cases:

Joint research units (JRUs) — Where the internal arrangements of a JRU, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ⓘ *For information on JRUs, see Article 14.*

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, protect them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

⚠ This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*

The beneficiaries are in principle free to choose any available **form** of protection.

Examples of classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

For an invention: e.g. patent, confidential information.

For the design of a technology: e.g. industrial design, copyright.

For a website: e.g. industrial design, copyright, trademark, confidential information.

⚠ In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

ⓘ *For information on the eligibility of costs related to protection, see Article 6.2.D.3.*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

⚠ Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include a reference to EU funding, as specified in the GA.

⚠ **No** information on EU funding is needed, if it is (technically or legally) impossible to include such a reference

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure exploitation of their results.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

Example: *Exploitation is justified from an economic point of view (commercially) or from a standardisation perspective (for use in standardisation activities).*

Where possible, the measures should be consistent with the impact expected from the action and the '**plan for the exploitation and dissemination of the results**'.

They may aim for exploitation by the beneficiary itself (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (⚠ Such additional exploitation obligations will already be mentioned in the Work Programme.)

⚠ This obligation only applies to beneficiaries receiving EU funding.

If the results can reasonably be expected to contribute to European or international standards, the beneficiaries must also communicate them to the Commission/Agency.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

⚠ This obligation applies only if it is foreseen in your GA.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — disseminate their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).

No dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA (*e.g. personal data protection, security-related obligations, etc)*.

The beneficiaries may choose **how** they would like to disseminate their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

If the GA provides for additional dissemination obligations, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the Work Programme.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated, unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries are advised to foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

2. Visibility of EU funding

Any dissemination of results (in any form) must include a reference to EU funding, as specified in the GA.

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission]/ Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION:** not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may transfer ownership of their results.

⚠ Security-related obligations *(see Article 37)* may prohibit a transfer or require certain conditions to be fulfilled before it takes place.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

The beneficiary must ensure that the new owners comply with the following obligations:

- joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- protection of results and visibility of EU funding *(see Article 27)*
- exploitation of results and visibility of EU funding *(see Article 28)*
- dissemination of results, open access and visibility of EU funding (see Article 29)
- transfer and licensing of results *(see Article 30)*
- access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

⚠ The mere fact that the results concerned are transferred to a competitor is not in itself a valid reason for an objection. The beneficiary concerned must *demonstrate* the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases:

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of before).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them)*. In this case, there is no need to inform the other beneficiaries of such transfers in advance (and the other beneficiaries do not have the right to object).

⚠ Before agreeing to such a 'global' authorisation, you should carefully consider the situation (and in particular the identity of the third party concerned), to determine if your access rights would be affected.

Example: For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country not associated with Horizon 2020 must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

Best practice: Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant licences to their results.

They must however ensure that **access rights** can be exercised and that any additional exploitation obligations are complied with.

⚠ **Exclusive licences** *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If this option is included in your GA, the Commission/Agency may **object** to transfers or exclusive licences to third parties established in a non-EU country not associated to Horizon 2020, on the following grounds:

- the planned transfer or licence is not in line with EU **competitiveness interests**

  Example: if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU

- the planned transfer or licence is not consistent with **ethical principles**

  Example: if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level

- the planned transfer or licence is not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

⚠ **No** right to object for transfers or exclusive licences by beneficiaries not receiving EU funding *(see Article 9)*.

⚠ For Euratom grants, the Commission has the right to object also to non–exclusive licences.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[40], for the purposes of the complementary grant agreement(s) (see Article 2).**]

[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.**]***

[OPTION for access to research infrastructures:** The access provider must give the users access to the results, if needed to implement the action.**]

[OPTION:** not applicable**]

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When ?

The beneficiaries must provide access to results, if it is **needed**:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity (established in a Member State or associated country), to exploit the results produced by the beneficiary to which it is affiliated (unless otherwise provided for in the consortium agreement).

There is **no definition** of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

Example (results needed for implementation): *if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

Example (background needed for exploitation): *if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries are advised to agree *(e.g. in the consortium agreement)* on a **common interpretation** of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they **must be requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a Member State or associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

The agreement by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

⚠ Don't forget to notify the Commission/Agency of any conflicts on results that are likely to affect the action implementation *(see Article 17.2.)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

– for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

ⓘ *For information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3*

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

⚠ Access rights do not automatically give the right to **sub-licence** to the requesting beneficiary (since this would imply that access rights to results could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries are advised to agree on the terms and conditions of the sub-licensing generally and in writing (at the level of the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: Beneficiaries are advised — for legal certainty purposes — to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

The General MGA provides for several options for specific access rights for EU institutions, bodies, offices or agencies and/or EU Member States, for policy purposes.

⚠ These obligations apply only if they are foreseen in your GA.

5. Specific access rights for Euratom and its joint undertakings

The option gives Euratom and its joint undertakings (such as Fusion for Energy) royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to sub-license *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

The General MGA also provides for several options for specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)

- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  ⚠ In this case, the access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

⚠ These obligations apply only if they are foreseen in your GA.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ For guidance in this process, see the 'Human Resources Strategy for Researchers' tool[50] developed by the Commission.

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[51] and of the Code of Conduct[52] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[53])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[53] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[54].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[55].

[54] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[55] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink].

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

Best practice: Beneficiaries are advised to obtain the **approval of** a **European ethics committee** (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[56] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[56] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[43], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81)

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed — during the action and for four years afterwards.

> ⚠ This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves (for example, for access rights or third parties involved in the action).
>
> A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information concerned.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

Best practice: Beneficiaries are advised to inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

⚠ Stricter confidentiality obligations apply for information that is that is 'EU-classified' and subject to 'security requirements' in Annex 1 of the GA *(see Article 37)*.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *not applicable****]***

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

1. Activities raising security issues — Classified deliverables

If the security scrutiny (carried out by the Commission/Agency during the selection procedure) finds that the action raises security issues because it deals with information that is 'EU-classified' (under the Commission internal Rules of Procedure), the Commission/Agency will make it subject to '**security requirements**' (set out in a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' in Annex 1 of the GA).

In this case, the beneficiaries must comply with the security requirements.

Moreover, they may not subcontract action tasks involving such information or disseminate results linked to such information, without prior approval by the Commission/Agency.

'Classified deliverables' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 19)*.

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[57].

Moreover, the coordinator must submit a **copy** of any export or transfer licence, before the action starts.

[57] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> 'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Promoting the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange.

⚠ *Ad hoc* efforts or mere dissemination of results are not sufficient. The communication activities[58] must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and address the **public policy perspective** of EU research and innovation funding, by considering aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)

[58] *For the definition of 'communication activities', see the Glossary.*

- scientific excellence
- contributing to competitiveness and to solving societal challenges

❖ impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*

❖ better use of results and spill-over to policy-makers, industry and the scientific community.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity).

⚠ The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them in another work package).

The beneficiaries are free to choose the type of communication activities.

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

⚠ Information given may **not** cover EU-classified information or information relating to 'classified deliverables' *(see Article 37)*.

⚠ Don't forget that any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa). Both obligations must be complied with.

ⓘ *For more information on how to promote your action, see the H2020 Online Manual*

2. Visibility of EU funding

The beneficiaries must ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure (including equipment or major supplies) funded by the grant, by:

– displaying the EU emblem and

– including the reference to EU funding, as specified in the GA.

For infrastructure (including equipment or major supplies) a sticker (or other equivalent means) should be used.

ⓘ For more information, see the Guide to using the EU emblem[59].

⚠ The beneficiaries must ensure the visibility of EU funding even after the action ends.

[59] Available at http://publications.europa.eu/code/en/en-5000100.htm.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[44], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[44] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities by the Commission/Agency

The Commission/Agency may use any (⚠ non-confidential and non- classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material); *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

⚠ The beneficiaries must make **arrangements** with any **third parties** that could claim rights to the material, in order to legally allow the use by the Commission/Agency.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

1. Processing of personal data by the Commission/Agency

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency 'Data Protection Officer (DPO)'.

This notification will be available in the Register of the DPO[60] (and will describe the processing operations, security safeguards, data transfer, retention period, etc.).

⚠For the processing of sensitive data *(e.g. health data)* and processing for the purpose of administrative penalties and termination, the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ *For more information, see the data privacy statement ('SSPS')[61] on the Participant Portal.*

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS) to:

- obtain information about what data is collected and how it is used, usually given via a privacy statement
- see which of their data are being held
- correct any errors in the data, block access to this data, or delete their data

[60] Available at http://ec.europa.eu/dpo-register/search.htm.
[61] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

– complain about data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ *For information on the complaints procedure, see the EDPS website.*

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data, by the beneficiaries

The beneficiaries must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[62] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [63]

[62] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing** of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[64]

Beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform staff** (whose personal data are collected and processed by the Commission/Agency) about this disclosure, by providing them with the SSPS.

Examples:

Before encoding its staff's personal data in the Beneficiary Register or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must tell the staff concerned and provide them with the SSPS.

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ *For more information on ethics, see the H2020 Online Manual.*

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63 *See Article 8 of Directive 95/46/EC.*

64 *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party, unless the Commission/Agency has explicitly agreed in writing.

'Assignment' normally means the transfer of rights held by one party to another party.

⚠ However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity

Assignment for the benefit of creditors in a bankruptcy procedure

⚠ Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

Example: *The obligation to allow audits by the Commission/Agency*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator**, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications, unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the H2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action)*.

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement (unless exceptionally stipulated otherwise in the Work Programme, for a specific call).

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded **before the action starts**. (Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action.)

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture)*.

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ *For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the H2020 Online Manual.*

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiaries must conclude a coordination agreement.

> 'Coordination agreements' are agreements between the consortium and partners from a third country (including scientific and technological organisations and agencies) or an international organisation, with which the joint call was organised.
>
> Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the basic contradictory procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100%.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

41.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[65]

  Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[66]

  If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

[65] *See Article 80(1) of the Financial Regulation.*
[66] *See Article 87 of the Rules for Application.*

– taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or

– adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[67].[68]

The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an

[67] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[68] *See Article 79(2) of the Financial Regulation.*

amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000
Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

Beneficiary approved costs multiplied by the reimbursement rate (100%) * *final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between 2% and 10% of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

  Example:

  GA with an EU contribution of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

  During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in

the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the decision to apply the penalty may also be **published** on Commission or Agency websites —together with the name of the person responsible for the misconduct, information on the misconduct and the penalty(ies) (duration of the exclusion and/or amount of the financial penalty).

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

1. Liability for damages, of the Commission/Agency

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

– causes damage to a third party (including another beneficiary)

Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

– suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability for damages, of the beneficiaries

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples: *Costs of legal proceedings borne by the Commission.*

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

  ⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

- calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

❖ **Payment request does not comply with the provisions of the GA**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.

❖ **Payment request is incomplete or requires clarification**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

Examples: the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.

❖ **Doubts on the eligibility of costs in the financial statements that require additional verifications**

The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

Example: The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is no *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

Example: statements made by the beneficiary in the declaration form are found to be false.

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

– **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **no individual financial statements** for the beneficiary (or beneficiaries) concerned may be submitted.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation, by the beneficiaries

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Grounds for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

  ⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the suspension is lifted and the action continues, the action's remaining budget can be used to implement the action.

⚠ However, it is possible that the action is resumed with a lower budget to adapt it to the new situation (agreed as part of the amendment).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) ***cannot*** **be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation, by the Commission/Agency

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

❖ **Suspicion of loss of scientific or technological relevance**

The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

This may in particular be the case:

- if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
- if work has significantly deviated from the original work plan
- if a key beneficiary leaves the action and the consortium needs time to find a replacement
- after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ For the basic contradictory procedure, see Article 42.

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA, by the beneficiaries

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

> ***Example:*** *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

> ***Example:*** *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries, by the beneficiaries

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ For more information on the roles and access rights in the electronic exchange system, see the H2020 Online Manual.

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action (unless it concerns the coordinator, since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action — including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so —, unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.][OPTION: not applicable];

(j) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries, by the Commission/Agency

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

❖ **Non-accession to the GA**

The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA).

⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [69]

Examples:

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this.

[69] *See also Article 8 of the Rules for Participation.*

The Commission terminates the GA because the conditions set out in the work programme are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

- **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

- **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

❖ **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

❖ **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

❖ **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

❖ **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country's or international organisation's action does not start by the date specified in Annex 1

  ⚠ In this case, **no costs** incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country's or international organisation's action is terminated

- the third country's or international organisation's action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

❖ **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA —

substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:

- systemic or recurrent and,
- have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ **Ineligible costs** may be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure
- labour disputes or strikes

– financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has **no specific effects** on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate* [*complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use a 'Messaging' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal Notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ *For more information on access and roles in the electronic exchange system, see the H2020 Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** (unless the GA or other rules provide for direct communication with the other beneficiaries, *e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations*).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

When & What?

An amendment is necessary whenever there is a need to **change** the **terms and conditions** of the GA. In some cases, the GA explicitly provides for them.

⚠ Amendments may **not** result in changes that — if known before awarding the grant — would have had an impact on the decision to award it. Those are mostly changes that:

- may have had an impact on the assessment of the applicant with regard to the eligibility and selection criteria *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- breach the principle of equal treatment of applicants
- involve modifications in the action and/or the related budget which may have affected the assessment with regard to the award criteria announced in the call *(e.g. the tasks in*

Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)

– do not comply with the rules applicable to the GA (i.e. Financial Regulation, Rules for Participation, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified or to modify Annex 1 following a review of the action).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removing a beneficiary whose participation was terminated** by the beneficiaries or by the Commission/Agency *(see Article 50.2 and 50.3)*.

  For termination by the beneficiaries, the request for amendment must be part of the notification of termination. In this case, don't forget to also submit the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency, the request for amendment must be submitted together with the report on the distribution of payments and the termination report (if needed).

  ⚠ No need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)*, unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

- **Adding a new beneficiary** *(see Article 56.2)*

  The request for amendment must include the Accession Form (signed by the new beneficiary in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

  The new beneficiary must provide a declaration on joint and several liability of its linked third party if required by the Commission/Agency.

  ⚠ Don't forget that the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

  Depending on the Horizon 2020 status(es) of the new beneficiary, the applicable options will be added.

  Example:

  If the new beneficiary is an international organisation, the options related to international organisations specified under Articles 22.4, 53.2, will be added to the GA and the options specified under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

  For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Change of beneficiary due to partial takeover (called 'partial transfer of rights and obligations' in FP7)**

  'Partial takeover' means that some assets of the beneficiary have been taken over by another entity *(e.g. partial acquisition)*.

If the GA is part of the assets taken over, the beneficiary must request an amendment: the entity to which the GA has been transferred may become the new party of the GA if the Commission/Agency agrees on that.

The contractual position of the old and the new party (vis-à-vis the Commission/Agency and the other beneficiaries) must be clearly spelled out in the request for amendment: in particular, it must clarify which is the financial liability of the new party for the old party's debts towards the Commission/Agency or the Guarantee Fund.

⚠ Don't forget that the new party must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

❖ **Change of coordinator**

The amendment request may be submitted after the period set out under Article 3 of the GA ends.

The initial coordinator may continue to participate in the action as a beneficiary (or may terminate its participation).

If the new coordinator is already a beneficiary of the GA, he will start his new functions from the date agreed by the parties, or — in the absence of such an agreement — the date on which the amendment enters into force. The date agreed cannot be before the initial coordinator has terminated its functions.

⚠ If the new coordinator is not a beneficiary of the GA, it must also accede to the GA as a new beneficiary *(see Article 56.2)*.

❖ **Change of the coordinator's bank account for payments**

Example: *The coordinator changes bank.*

The coordinator must submit the necessary supporting documents and update the banking information on the Participant Portal.

⚠ Do not forget to first update the bank account data in the Beneficiary Register (and get it validated).

❖ **Change of the action's title and/or acronym**

Example: *the consortium finds out that the acronym of their action is a protected trademark.*

❖ **Change of the starting date, duration of the action or reporting periods**

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

⚠ Even if the action is prolonged, the maximum grant amount cannot be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

  ⚠ Don't forget to communicate the date from which the action's implementation can restart ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:

  - a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries

  - changes concerning **in-kind contributions** provided by third parties (against payment or free-of-charge) or **subcontracts**

    Such changes could in principle also be made as 'approval without formal amendment' (*see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency's *agreement* (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency may consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).

  - changes concerning the tasks to be carried out by **linked third parties** and related costs

    There is no 'approval without formal amendment' *(see Article 14)*.

  - changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount and/or the action's estimated eligible costs will be accepted only in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount cannot be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2 (estimated budget)** which require an amendment *(see Article 4)*, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

  - a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*

    Examples:

    During the action's implementation, a beneficiary that declared its direct personnel costs as actual costs in Annex 2 decides to change this and instead to declare its direct personnel costs as unit costs in accordance with its usual accounting practices.

    An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to add the appropriate option under Article 5.2 and to modify the action's estimated budget in Annexes 1 and 2.

Indicative list of cases where no amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary or coordinator**

  Changes concerning name, legal form *(e.g. Ltd., S.A.)*, registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA) do not require a formal amendment; an update of this data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

  ⓘ *For more information on data updates, see the Horizon 2020 Online Manual.*

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may request it.

  Example: *Company RO moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates*

- **Change of beneficiary due to universal takeover (called 'universal transfer of rights and obligations' in FP7)**

  'Universal takeover' means that all the rights and obligations of the beneficiary have been taken over by another entity *(e.g. in cases of merger or full acquisition)*. The beneficiary ceases to exist and all its rights and obligations (including those under the GA) are taken over by the new entity.

  Example:

  Beneficiary X may merge with another existing entity Y by:

  (i) becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or

  (ii) establishing a new separate legal entity (X and Y are together known as 'Z').

  Since *all* the rights and obligations of the old entity (including the GA) are transferred to the new one, there is normally no issue of legal certainty and it is therefore not necessary to make a formal amendment under Article 55. An update of the data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may request it.

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

  Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

Case 2: A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

⚠ Don't forget that — in addition to updating the data in the Beneficiary Register — you must also inform your coordinator (offline) under Article 17.2, if the universal takeover may:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinators must then inform the Commission/Agency (via the electronic exchange system) and may request an amendment.

The same is true if the universal takeover concerns one of your linked third parties.

How?

An amendment request must be **prepared** by the **coordinator**, normally by filling out the forms **directly in the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

Specific case:

A request to **change the coordinator** (against the coordinator's will) can be submitted by any beneficiary (acting on behalf of the others).

⚠ If none of the available forms are appropriate, beneficiaries are advised to contact the Commission/Agency for the drafting of the request.

⚠ **Requests** for amendment must be unambiguous and complete and submitted **sufficiently in advance** (to allow proper analysis and preparation before they are due to take effect) and, generally, **before the end of the action** (i.e. the date set out in Article 3).

Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance).*

Once completed, the amendment request (with all its supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator. (⚠ The coordinator submits and signs on behalf of the other beneficiaries; *see Annex 3*).

Coordinators must ensure internally that they have the agreement of the consortium, on the basis of their internal decision-making processes *(e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement)*.

⚠ Don't forget:

- for new beneficiaries (or linked third parties): to ensure that they have obtained all necessary validations in the 'Beneficiary Register'

Example:

Validation of the new bank account, to change the bank account

Legal entity validation, to add a new beneficiary that is not yet validated. This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

– to include the necessary information and supporting documents (as required for certain amendments)

Examples:

For a change of coordinator without his/her agreement, the coordinator's opinion (or written proof that this has been requested).

To add a new beneficiary, an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

To amend Annexes 1 and 2, amended versions of these annexes.

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

The coordinator may at any moment **withdraw** the amendment request (before it has been accepted or rejected). However, it cannot be *change*d (without withdrawing it and submitting a new one).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

ⓘ *For more information on the preparation and submission procedure, see above point 1.*

⚠ Beneficiaries are advised to contact the Commission/Agency beforehand (via the 'Messages' function of the electronic exchange system), in order to discuss the amendment.

The other party must — within 45 days — agree or disagree, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

If there is **no reaction** within this deadline, the request is considered to have been rejected (⚠ new in Horizon 2020: contrary to FP7, there is no tacit approval of amendments). A new amendment request may be submitted (even if it fully or partly repeats the initial request).

A request containing several changes to the GA will be considered as a **package** that cannot be divided into several requests. The request will be agreed or rejected by the other party as a whole.

If, the receiving party requests additional information/documents a new deadline will apply, i.e. 45 days from receipt of the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may be extended by the Commission/Agency — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

⚠ A signed and submitted amendment requests (including supporting documents) cannot be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

Unless the parties agree otherwise, the amendment will **take effect** (i.e. the modifications to the GA will start to apply) on the day of entry into force of the amendment.

If the parties agree on another date, it should normally be *after* the entry into force. In justified cases it may be before (retroactivity of the amendment). (⚠ In certain cases, the GA itself provides for retroactivity.)

Examples (retroactivity foreseen in the GA):

Where a new beneficiary or linked third party is added to the GA, it must assume the rights and obligations from the date of its accession specified in the Accession Form. This retroactivity implies that its costs will be considered eligible as from the date of its accession to the GA (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

⚠ Depending on the nature of the modification, the date of taking effect may have an impact on the eligibility of costs.

If an amendment request involves a number of changes, these could take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA, by the beneficiaries mentioned in the Preamble

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Specific case:

For mono-beneficiary actions, replacing the beneficiary during the action implementation is only possible under exceptional circumstances *(e.g. the beneficiary transfers all its rights and obligations, including those related to the action, to another legal entity).*

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated (unless it already has a validated Participant Identification Code (PIC))
- sign the Accession Form directly in electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an amendment for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned])*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for international organisations (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[70]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the *Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States*, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN system (⚠ new in Horizon 2020).

It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU-arbitration clause, referring disputes on the interpretation, application or validity of the GA to the Court of Justice of the European Union.

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This

[70] *See Article 180(1) of the Rules of Application.*

referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[71]).

If a dispute is of public law nature (i.e. concerns offsetting or an enforceable decision under Article 299 TFEU), actions must be brought before the Court of Justice of the European Union not under Article 272, but under Article 263 TFEU.

[71] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

II. ERC

II.1 Background information and approach

The ERC General Model Grant Agreement ('ERC General MGA') is used for the following ERC grants ('frontier research grants'):

- ERC Starting Grants (StG)
- ERC Consolidator Grants (CoG)
- ERC Advanced Grants (AdG)
- ERC Synergy Grants (SyG).

The ERC General MGA is not used for ERC PoC and ERC low value grants (which have specific MGAs; *see below*).

⚠ ERC grants are open to **principal investigators** (PIs) of any nationality who intend to conduct a **frontier research project** in a Member State or associated country and which are hosted by a host institution that is based in an EU Member State or associated country and can receive EU funds.

ⓘ *For more information on ERC actions, see Article 2.*

ⓘ *For information on ERC funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on ERC standard eligibility criteria, see the ERC calls conditions of the ERC Work Programme.*

The ERC General MGA follows the General MGA for numbering and content, except for the following:

Introductory remark all ERC MGAs

The ERC Model Grant Agreements deviate from the General Model Grant Agreement as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
-
- The table of contents is adapted
- Cross-references in the footnotes are adapted

Introductory remark ERC General MGA

The ERC General Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

Introductory remark ERC PoC MGA

The ERC PoC Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

ERC frontier research grants are however different from General MGA grants because:

- EU funding is granted to an individual action proposed by a Principal Investigator (PI) (or several, in the case of SyG), while

- the grant is signed between the Agency on one side and the beneficiaries on the other, one of which is the host institution of the PI and his/her research team.

⚠ By signing the GA, the beneficiaries take on a series of obligations towards the PI and the research team. In order to participate in the action, the PI must sign a supplementary agreement (SA) with its host institution where s/he also takes on a series of rights and obligations *(see Article 32)*.

ERC PoC grants are then follow-up grants to explore the innovation potential of results generated in a previous ERC frontier research grant.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC actions)
- Article 4.1 (ERC budget categories)
- Article 6 (ERC eligible and ineligible costs)
- Article 8 (ERC rules on third party involvement).

Since the ERC General MGA and the ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC PoC MGA will be limited to major differences from the ERC General MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 ERC General MGA: Annotations

ERC MULTI-BENEFICIARY MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][1],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname], hosting [and engaging] the following

***[OPTION by default:** 'principal investigator':*

*- [**Name**][Date and place of birth][2]*

***[OPTION for SyG:** 'corresponding principal investigator':*

*- [**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),****]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called 'principal beneficiary'.

Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that host (or employ) a principal investigator ('host institution').

The PI is usually employed by the host institution.

Exceptions:

A PI may be employed by a third party. In this case, the third party must also sign the supplementary agreement *(see Article 32)* and agree to the obligations included in it.

Retired researchers, in case the PI is no longer under an active labour contract.

ⓘ For more information on arrangements for signature and third parties, see the preamble of the General MGA.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

⚠ Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities.

PIs must be supported by their host institution during the entire duration of the action.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions, must sign a supplementary agreement (SA) *(see Article 32)*.

⚠ In the case of ERC Synergy grants (with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

⚠ ERC PoC grants do not require a supplementary agreement.

⚠ ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI').

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERC actions

ERC actions are mono- or multi-beneficiary actions with the following activities:

– any type of frontier research activity in any field of research (except nuclear energy; see the ERC calls conditions of the ERC Work Programme).

What? ERC grants fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

ⓘ For examples of successful ERC actions, see the ERC website[72].

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

[72] Available at http://erc.europa.eu/erc-stories.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC General MGA uses in principle the **same budget categories** as the **General MGA**.

Budget categories of the ERC General MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences (compared to the General MGA):

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs *for the action* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(f) for **direct personnel costs** *[(excluding personnel costs for activities in Point (f))]*[5]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(g) for **direct costs of subcontracting** *[(excluding subcontracting costs for activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(h) *not applicable;*

(i) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(j) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

[…]

[5] To be used only if option in Point (f) is used.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC calls conditions of the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are the **same** as in the **General MGA** *(see Article 5 General MGA)*.

Exception:

The ERC General MGA does not use the same **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, the ERC General MGA uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[73]

However, the unit costs for the 'specific categories of costs' of the General MGA do not apply.

[73] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 General MGA)* (with the exception of 'direct costs of providing financial support to third parties', 'specific categories of costs' and 'costs for providing access to trans-national research infrastructure').

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

Specific cases:

For **direct personnel costs**:

⚠ Costs for 'teaching buy-outs' are not eligible: if the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, they cannot declare the costs related to these substitutes.

If the **PI** is exceptionally **engaged by a third party** (which pays his/her salary) and seconded to work on the premises of the beneficiary (against reimbursement by the beneficiary), the **salary costs** may be declared as direct personnel costs (costs of personnel seconded by a third party).

⚠ In this case, the supplementary agreement must be signed by the PI, the host institution *and* the third party.

For **other direct costs**:

For ERC actions, **recruitment costs** are eligible as other direct costs because recruitment is one of the action's activities.

⚠ Recruitment costs are not considered as one of the action's activities for PoC.

⚠ As in actions under the General MGA, for ERC actions the **purchase of scientific publications** *(e.g. books, manuscripts, articles, digital copies, etc.)* needed for the implementation of the action may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Given the increasing emphasis on the protection of inventions, the PIs are encouraged to **protect** their **intellectual property rights properly** and the related costs are considered eligible.

Costs related to open access (to publications – including monographs – and research data) are eligible during the duration of the action. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (it cannot be with other beneficiaries or linked third parties).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies*: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.****]***

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 General MGA)*.

In addition, the beneficiaries must however prove that the conditions concerning the time-commitments of the PI for implementing the action (as described in Annex 1) have been complied with.

Thus, they must be able to provide evidence that the PI dedicated the minimum time commitment (i.e. percentage of the total working time, i.e. percentage of the annual productive hours calculated in compliance with Article 6) to the action, via time sheets or alternative time recording system.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

Moreover, they must be able to provide evidence that the PI spent the minimum time commitment *in a Member State or associated country* (i.e. a Member State or an associated country), via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

⚠ Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) scientific and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

ⓘ For more information on how to submit the reports, see Article 20 General MGA and the H2020 Online Manual.

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC General MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies - make the pre-financing payment to the principal beneficiary within 30 days ***[OPTION:*** *from the entry into force of the Agreement (see Article 58)****][OPTION:*** *from the starting date of the action (see Article 3)****][OPTION:*** *from the 45th day before the starting date of the action (see Article 3)****]***.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([****insert amount*** *(insert amount in words)] is not paid to the principal beneficiary, but kept by the [Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90 % of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90 % of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90 % of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the principal beneficiary
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

[…]

1. Payments

For ERC actions, the same rules on payments apply as in the General MGA *(see Article 21 General MGA)*.

There is however an additional option for pre-financing payments. These cannot only be foreseen within the 30 days from:

- the starting date of the action (see Article 3) or
- from the date of entry into force of Grant Agreement (see Article 58)

but also

- from the 45th day *before* the starting date of the action (see Article 3)), if the action starts late (well after the entry into force of the GA).

⚠ In any case, it is not possible to make a payment before the GA is signed.

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Rights of third parties

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 General MGA)*.

⚠ Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

[…]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

*[OPTION: **not applicable**]*

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

Examples: *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

For publications issued after the end of the action, beneficiaries are not obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

For bibliographic metadata, the ERC General MGA foresees lighter requirements, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[74] or other systems).

⚠ As far as the chosen repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

For ERC actions, there is no formal requirement for a '**data management plan**'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

[74] *For more information, see http://www.doi.org/.*

The exception allowing beneficiaries not to give access to specific parts of research data applies not only if this would jeopardise the main objective of the action, but any one of the action objectives.

⚠ For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[32] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a)

[…]

[32] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC General MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of intellectual property rights
- Allow for transfer of the GA to another host institution (**portability**).

⚠ PIs cannot be prevented from applying independently (i.e. in their own name) for further EU funding for other actions. They can also apply for further EU funding for the same action, as long as it is for costs that are not eligible (or not declared) under the ERC grant.

In this context, 'action' refers to the specific ERC action, for which the beneficiaries receive the ERC grant *(see Article 2)*.

⚠ The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ⓘ For more information on combining EU funding for different actions ('complementary EU funding'), see the H2020 Online Manual.

2. Supplementary agreement — Obligations on the PI

The ERC General MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also vis-à-vis the PI.

The supplementary agreement should cover all the practical issues that may arise in the context of the grant implementation, and in particular the ones listed in Article 32.1(b).

Model clauses for supplementary agreements are available on the Participant Portal and the ERC website. [hyperlinks]

Host institutions and their PIs may add or use other clauses, if they benefit the research action and do not contradict the GA. Provisions that contradict the GA are considered void and may not be opposed to the Agency.

⚠ The supplementary agreement must be concluded before the GA is signed (and a copy must be sent to the Agency).

It does not replace an employment or collaboration contract between the PI and its host institution (which remain necessary under national labour and social laws).

Specific cases:

In the case of **ERC Synergy grants** (with **several PIs**), each host institution must conclude a supplementary agreement with the PI(s) they engage.

ERC PoC grants do not require a supplementary agreement.

In case of transfer of the Agreement to another host institution (**portability**; *see Article 56a*), the PI must sign a new supplementary agreement with its new host institution and forward it to the Agency. The GA cannot be amended before the PI has sent this new supplementary agreement.

Via the supplementary agreement, the PI must take on a number of obligations, to ensure the smooth implementation of grant.

Main obligations (of the PI):

- Supervision of the scientific and technological implementation of the action
- Responsibility for the scientific reporting for the beneficiary and contribution to the financial reporting
- Meeting the time commitments for implementing the action
- Applying the beneficiary's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the visibility of EU funding
- Upholding the intellectual property rights of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.

- Maintaining confidentiality

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(c) display the EU emblem and the ERC logo and

(d) include the following text:

"This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem and the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

Guidance on the use of the ERC logo is available on the ERC homepage[75].

[75] Available at http://erc.europa.eu/logos-and-banners.

MULTI-BENEFICIARY: **ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the Agency has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: **ARTICLE 56 — ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: [...][...][...][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 General MGA)*.

However, unlike the General MGA, ERC ***mono*-beneficiary** grants can **become *multi*-beneficiary** grants, by addition of a new beneficiary.

The procedure to be followed is that of Article 56 of the General MGA.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

Upon request by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

Portability makes it possible to transfer ERC grants — at any time during the action implementation.

The PI may **request a transfer** of his/her grant to any other entity based in an EU Member State or associated country ('new host institution'), if doing so is beneficial for the PI and supports achieving the action's objectives.

Specific case:

For **ERC Synergy Grants**, each PI maintains the right to transfer their part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

If **certain team members** or **equipment remain** with the former host institution, that institution may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

Thus, both host institutions must agree on the transfer of intellectual property, in conformity with the GA and after consulting the PI. The transfer plan should cover:

- the results produced under the action and the access rights to them and
- the PI's and new host institution's access rights to background held by the former host institution but necessary for implementing the rest of the action.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs are advised to keep records of the consultation and decision-making process for each portability case.

The former host institution must then submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 General MGA)*.

A change of beneficiary usually takes effect on the first day of the month.

This date may be retroactive, but only in very exceptional circumstances. This should be discussed on a case by case basis with the Agency.

⚠ The request should be made well in advance, to allow sufficient time for the amendment procedure.

⚠ The GA cannot be transferred without the explicit agreement by the Agency *and* the amendment of the GA. Any partial or full transfers made without a formal amendment to the grant agreement are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** all **remaining pre-financing** (not covered by eligible costs) to the new host institution.

⚠ If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will not pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary).

⚠ Scientific reporting periods will usually remain unchanged as they are linked to the action's scientific development and must be submitted by the PI, who holds this position for the whole duration of the GA.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law.

It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

II.2 ERC PoC: Annotations

⚠ The ERC PoC MGA is very similar to the ERC General MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however no specific provisions on the working conditions of the PI and his/her team, no supplementary agreement and no grant portability

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC General MGA apply mutatis mutandis.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. ERC PoC actions

ERC PoC actions are actions with the following activities:

– verifing the innovation potential of ideas arising from ERC funded projects

What? Any activities (that were not scheduled to be funded by the initial ERC frontier research grant) but that develop research output towards new commercial or societal applications.

ERC PoC grants can cover very diverse activities *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

What not? ERC PoC grants cannot cover activities under the ERC frontier research grant (*e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential*) or activities which are the result of research not performed under the ERC actions (*e.g. results of research not found by the ERC action*).

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) report(s), including requests for payment.

The report(s) must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP):

20.2 Reporting period

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)**]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]

***[**- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].**]***

20.3 Periodic reports — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(f) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *Agency* may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Agency*, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What ?

For ERC PoC actions, the principal beneficiary must submit reports — only one 'report' if there is one reporting period, otherwise one 'periodic report' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  ⚠ The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

⚠ Only at the moment of the submission of the last reporting period, the 'certificate on the financial statements' will have to be added.

How?

All reports mut be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' section of the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period (and thus the duration of the action) lasts **18 months**.

If provided in the GA, an ERC PoC action may however also have more reporting periods.

IV. SME Instrument

IV.1 Background information and approach

The Model Grant Agreements for the SME Instrument ('SME Instrument MGAs') are used for grants for **SME Instrument actions only** *(see General Annex D to the Main Work Programme)*.

The SME Instrument funds actions in different phases.

The minimum requirement for participation is one for-profit SME (as defined in the SME Recommendation 2003/361/EC), established in an EU Member State or associated country

'For profit' means not a non-profit legal entity (i.e. not an entity that is by its legal form non-profit-making or has a legal or statutory obligation not to distribute profits to its share-holders or members).

⚠ If the Work Programme/call, exceptionally foresees SME Instrument Ph2 actions that predominantly concern research activities, they will be considered 'research and innovation action (RIA)' actions and will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ⓘ For more information on SME Instrument actions, see Article 2 SME Instrument MGAs.

ⓘ For information on SME Instrument funding opportunities, see the 'Search Topic' function on the Participant Portal.

ⓘ For information on SME Instrument standard eligibility criteria, see General Annex C to the Main Work Programme.

ⓘ For more information on the procedure for SME status validation, see the H2020 Online Manual.

The SME Instrument MGAs **follow the General MGA** for numbering and content, **except** for the following:

Introductory remark SME Instrument Ph1 MGA

The SME Instrument Phase 1 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 4.1 (SME Instrument Ph1 estimated budget of the action)
- Article 5.1-5.3 (SME Instrument Ph1 maximum grant amount, specific reimbursement rate and form of costs, no Step 2 'limit to maximum grant amount', no Step 3 'reduction due to the no-profit rule')
- Article 6 (SME Instrument Ph1 specific conditions for eligibility of costs)
- Article 7 SME Instrument Ph1 consequences of improper implementation)
- Articles 8, 11, 12, 14, 15, 16, 23a - 33, 37, 39 (not applicable)
- Article 10 (SME Instrument Ph1 specific provision for purchases)
- Article 13 (SME Instrument Ph1 specific provision for subcontracting)
- Article 18 (SME Instrument Ph1 specific provision for record-keeping)
- Article 20 (SME Instrument Ph1 specific reporting provisions)
- Article 21 (SME Instrument Ph1 specific payment provisions)
- Article 36 (SME Instrument Ph1 specific provision on confidentiality)

- Article 38 (SME Instrument Ph1 specific provision on promoting the action)
- Article 42.2 (SME Instrument Ph1 specific provision for lump-sum
- Article 50.1.2, 50.3.3 (SME Instrument Ph1 specific provision for lump-sum

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

Introductory remark SME Instrument Ph2 MGA

The SME Instrument Phase 2 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 5.2 (SME Instrument Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Instrument Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Instrument Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 SME Instrument Ph1 MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Instrument Ph1:
- Article 2 (SME Instrument Ph1 actions)
- Article 8 (SME Instrument Ph1 rules on third party involvement)

For SME Instrument Ph2:
- Article 2 (SME Instrument Ph2 actions)
- Article 4.1 (SME Instrument Ph2 budget categories)
- Article 6 (SME Instrument Ph2 eligible and ineligible costs)
- Article 8 (SME Instrument Ph2 rules on third party involvement)
- Article 20 (SME instrument Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since that is most common for SME Instrument actions. The differences between mono and multi-beneficiary versions are marginal.

IV.2 SME Instrument Phase 1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** (**'action'**), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]]***.]**

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.***]***

1. SME Instrument Ph1 actions

SME Instrument Ph1 actions are mono- or multi-beneficiary actions with the following activities:

– making a feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service)

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a 'technology readiness level' of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc)*.

⚠ The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph2 actions, see Article 2 SME Instrument Ph2 MGA.

ARTICLE 4 — ESTIMATED BUDGET

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the form of costs (see Articles 5 and 6).

1. Budget category

The SME Instrument does **not** use the **budget categories** of the **General MGA**.

Since SME Instrument Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Instrument Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

⚠ The budget category is relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The grant amount for SME Instrument Ph1 actions is fixed as a **lump sum** of **EUR 50 000**.

The lump sum is provided for by Commission Decision C(2013) 8198[76], for all SME Instrument Ph1 actions.

The amount of EUR 50 000 stays the same, both for multi-beneficiary and mono-beneficiary actions.

It is deemed to reimburse 70 % of the action's total eligible costs (that are in turn set by this Decision at EUR 71 429).

If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ No other costs will be reimbursed; the lump sum is deemed to cover all (direct or indirect) costs that may have been incurred for the feasibility study.

⚠ The SME Instrument Ph1 MGA does not use any of the **unit costs** and **flat-rates** of the General MGA.

The conditions for eligibility are set out in Article 6.

[76] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to improper implementation or breach of other obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

[…]

1. Calculation of the final grant amount

For SME Instrument Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is no:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

A. Costs for the feasibility study (direct and indirect costs) are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Instrument Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 The budget category 'costs for the feasibility study' **covers** the costs for the feasibility study for the innovation idea *(see Article 2)*.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[77] and set out in Annex 2 of the GA (currently **EUR 71 429** per action).

This lump sum is deemed to cover all (direct and indirect) eligible costs that may have been incurred for the feasibility study.

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 No **calculation** is necessary.

The beneficiaries must declare the amount of EUR 71 429 as the total eligible costs of the action; they cannot declare the costs actually incurred. The final financial report and individual financial statement are therefore automatically pre-filled by the system *(see Article 20)*.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

1. Consequences of improper implementation

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation does not always lead to the reduction of the grant, but leads to the ineligibility of the costs (namely, if the improper implementation consists in non-compliance with Annex 1; *see Article 6*).

If the action is not carried out as described in Annex 1, costs will be rejected proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

By contrast, if other provisions of the GA or provisions of EU, international and national law are not complied with, the grant may be reduced.

[77] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Instrument Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs for purchases and subcontracts are covered by the lump sum.

⚠ In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) are **not** allowed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Instrument Ph1 actions are almost identical to the General MGA *(see Article 13 General MGA)*.

Since SMEs are not contracting authorities, there is however no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph1 actions are similar to the General MGA *(see Article 13 General MGA)*.

Subcontracting is however not restricted to a limited part of the action.

Moreover, the estimated costs do **not** have to be included in Annex 1or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are **not** considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ⓘ For more information on the characteristics of subcontracting and best value for money, see Article 13 General MGA.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Instrument Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit the report

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) the **final report**, including a request for payment.

The report must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing an '**individual financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The individual financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME instrument Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial report and statement are automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

⚠ For multi-beneficiary actions, each beneficiary must fill in an individual financial statement (in order to certify conformity of the costs declared). This does not however change the EU contribution requested (which remains one single lump sum of EUR 50 000 for the whole consortium).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made — No interim payments

For SME Instrument Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are no interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Instrument Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(f) the disclosing party agrees to release the other party;

(g) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(h) the recipient proves that the information was developed without the use of confidential information;

(i) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(j) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Instrument Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(e) display the EU emblem and

(f) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

Not applicable

38.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Promoting the action — Visibility of EU funding

The SME Instrument Ph1 MGA foresees lighter requirements for promoting the action and acknowledgment of EU funding.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

[…]

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

[…]

1. Calculation of the ineligible costs to be rejected

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation leads to the ineligibility of the costs *(see Article 7)*.

If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

ARTICLE 50 — TERMINATION OF THE AGREEMENT

[…]

50.1 Termination of the Agreement, by the beneficiary

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

[…]

50.3 Termination of the Agreement, by the *[Commission][Agency]*

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

1. Termination of the Agreement

For SME Instrument Ph1 actions, the same rules on termination apply as in the General MGA *(see Article 50 General MGA)*.

⚠ Improper termination by the beneficiary will however lead to a 100% reduction of the grant.

IV.3 SME Instrument Phase 2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a ‘**complementary grant**’ to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a ‘**jointly funded action**’ which must be coordinated with the ‘joint action’ called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. SME Instrument Ph2 actions

SME Instrument Ph2 actions are actions with the following activity:

– implementing an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication).

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a ‘technology readiness level’ of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

⚠ An project may be funded in Phase 2 even if it was not funded in Phase 1.

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph1 actions, see Article 2 SME Instrument Ph1 MGA.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The SME Instrument Ph2 MGA uses the **same budget categories as** the **General MGA**.

Budget categories of the SME Instrument Ph2 MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences compared to the General MGA:

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(k) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(l) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(m) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(n) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*: as actually incurred costs (**actual costs**);

(o) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

***[**(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]*[1]*]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

1. Reimbursement rate

How much? For SME Instrument Ph2 actions, the reimbursement rate is normally set at 70% *(see General Annex D to the Main Work Programme)*.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs.
.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Eligible costs — Ineligible costs

The SME Instrument Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

Exception:

The SME Instrument Ph2 MGA does not reimburse:

- 'direct costs of providing financial support to third parties'
- 'specific categories of costs'.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Instrument Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [1].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph2 actions are similar to those of the General MGA *(see Article 13 General MGA)*.

However, subcontracting is not restricted to a limited part of the action.

Moreover, for the SME Instrument Ph2, the Commission/Agency will assess compliance with best value for money during the evaluation of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

⚠ If you know the subcontractor, include the key information on the award procedure for the subcontract in the proposal (name of subcontractor, price and object), together with the action task(s) that will be subcontracted and an explanation why the subcontractor and the price are appropriate.

⚠ If you do not know the subcontractor, your proposal should set out the task(s) to be subcontracted, the estimated budget and the procedure you will follow to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits (unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

ⓘ For more information on evaluation, see the H2020 Online Manual.

Finally, for SME Instrument Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Instrument Ph2 actions are normally the same as for the General MGA *(see Article 20.2 General MGA)*.

The reporting periods may however be adapted to reflect the duration of the action. Thus, if considered necessary, SME instrument Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

1. Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example****: if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

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V. ERA-NET Cofund

V.1 Background information and approach

The Model Grant Agreement for ERA-NET Cofund ('ERA-NET Cofund MGA) is used for grants for **ERA-NET Cofund actions only**.

⚠ ERA-NET Cofund grants are open only to **research funders** (i.e. legal entities owning or managing research and innovation programmes).

'Programme owners' are typically national/regional ministries or authorities responsible for defining, financing or managing national/regional research programmes.

'Programme managers' are typically research councils, funding agencies or other national/regional organisations that implement research programmes under the supervision of the programme owners.

The minimum requirements for participation are 3 independent research funders established in different Member States or associated countries.

ⓘ For more information on ERA-NET Cofund actions, see Article 2.

ⓘ For information on ERA-NET Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.

ⓘ For information on ERA-NET Cofund standard eligibility criteria, see General Annex C to the Main Work Programme.

The ERA-NET Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for ERA-NET Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 ERA-NET Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1.ERA-NET Cofund actions

ERA-NET Cofund actions are actions with the following activities:

- the preparation, implementation and follow-up of a single joint call for proposals for trans-national research and/or innovation projects

  ⚠ Only one co-funded call per GA.

  There are two ways of implementing the joint call:

  - by **providing financial support to third parties**

    This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties.

    Most ERA-NET Cofund actions are implemented in this way.

  - by **implementation of the trans-national projects by the beneficiaries**

    This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding. Beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  What? The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  ⚠ These activities must be *in addition* to implementing a joint call.

⚠ If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do not apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[the first day of the month following the date the Agreement enters into force (see Article 58)] [insert date]*[4] ('starting date of the action').

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Duration of the action

For ERA-NET Cofund actions, the duration is usually **60 months**.

⚠ This time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects, which typically takes 36 months.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*).

⚠ Normally, the action's duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its **own budget categories**.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries
  - direct subcontracting costs for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities
- indirect costs

Differences (compared to General MGA):

- No 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- No 'costs for providing trans-national or virtual access to research infrastructure'
- No 'specific categories of costs'

⚠ These budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[…%] of the action's eligible costs* (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (unless declared as unit cost)
  - **subcontracting** costs for implementing the trans-national projects

- **other direct costs** for implementing the trans-national projects

❖ **unit costs** for:

- direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
- direct **coordination costs** for additional activities[78]

❖ **flat-rate costs** for:

- **indirect costs**

[78] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for of additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[5] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(d) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(e) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(f) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(d) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(e) the result of the work carried out belongs to the beneficiary, and

(f) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[6] *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

[5] For the definition, see Article 2.1(14) of Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[6] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[7] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form —Conditions for eligibility — Calculation

1.1 The budget category 'direct costs related to trans-national projects' **covers** the following **types of costs**:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration — basic salary and complements
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract and
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries

- other direct costs for the implementation of trans-national projects by the beneficiaries:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure.

What not? The ERA-NET Cofund MGA does not reimburse:

- 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- 'costs for providing trans-national or virtual access to research infrastructure'
- 'specific categories of costs'

⚠ No indirect costs for providing financial support to third parties.

1.2 All costs (except direct personnel costs) must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

In some Articles, the conditions in the General MGA must however be read as referring to 'trans-national projects' (instead of 'action').

For financial support to third parties, there are moreover additional eligibility conditions in Article 15 *(e.g. selection procedure, compliance with national funding rules)*.

⚠ For financial support to third parties, costs are usually eligible only after the trans-national projects have ended.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA*).

B. Direct coordination costs of additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see Article 2)*.

1.2 These costs must be declared on the basis of the **unit cost** fixed by Commission Decision C(2013) 8200[79] and set out in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

⚠ If the beneficiaries do not properly implement the additional activities set out in Annex 1, the grant may be reduced *(see Article 43)*.

Example: Beneficiaries make only two meetings on general strategy.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

⚠ Beneficiaries that implement trans-national projects cannot declare coordination costs for additional activities.

1.4 They must be **calculated** as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU contribution to coordination costs should not exceed 20% of the maximum grant amount.

[79] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[8] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[8] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, the same rules apply as in the General MGA *(see Article 6 General MGA)*.

The eligible direct costs (on which the flat-rate is calculated) include:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

⚠ They do not include direct costs of providing financial support to third parties implementing trans-national projects.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, in principle the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however **only** allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all action activities *(see Article 2)*.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(f) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(g) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**;

(h) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to third parties ('cascade grants')).

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties that actually implement research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

2. Additional eligibility condition: Two-step selection procedure

A two-step procedure is necessary to ensure that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating Member State and associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to the expert evaluators, the consortium must appoint an independent expert as an observer, to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The selection of trans-national projects ('**joint selection list**') must be based on the order of the ranking list (or the ranking lists, if there are different topics).

⚠ If proposals have identical scores, the proposals coming from participating Member States or associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

5. Additional eligibility condition: Compliance with national funding rules

Financial support to third parties must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the third parties) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

The beneficiaries must comply with the maximum amount and the criteria for determining the exact amount under national funding rules that are set out in Annex 1.

⚠ This information must already be part of your proposal *(see Table 4.1 of the Standard proposal template ERA-NET)*. If national funding rules do not specify a maximum amount, the beneficiaries should enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *The coordinator must submit: in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency]**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects, with the required information.

Example: *data on each participant and abstracts of the project proposals.*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects.

Example: *data on each participant and an overview of the results.*

⚠ The Commission/Agency will contact you to give you information on the format to be used (and where to find it) and how to submit the deliverables.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[16]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[17]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the *[Commission's][Agency's]* accounting purposes and will not be used to calculate the final grant amount.

[…]

[16] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[17] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? Normally, ERA-NET Cofund actions are divided into **2 reporting periods** (with two pre-financing payments; *see Article 21*).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][18], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] [19], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

[18] Should correspond to 10% of the maximum grant amount (see Article 5.1).
[19] Should be 80%, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, ERA-NET Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10% of the maximum grant amount
- the second pre-financing payment is 80% of the maximum grant amount.

Exception:

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10% for the first pre-financing payment
- 40% for the second pre-financing payment
- 40% for the third pre-financing payment.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full

– if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund

VI.1 Background information and approach

The Model Grant Agreement for PCP-PPI Cofund ('PCP-PPI Cofund MGA') is used for grants for **PCP-PPI Cofund actions only**.

⚠ PCP-PPI Cofund grants are only open to **actions** that have as main objective to implement a **pre-commercial procurement or a public procurement of innovative solution**. The minimum requirements for participation are 3 independent legal entities established in different Member States or associated countries and 2 independent legal entities that are public procurers from different Member States or associated countries (unless they are sole participants; *see General Annex D to the Work Programme*).

ⓘ *For more information on PCP-PPI Cofund actions, see Article 2.*

ⓘ *For information on PCP or PPI Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on PCP-PPI Cofund standard eligibility criteria and specific provisions, see General Annex C, D and E to the Main Work Programme.*

The PCP-PPI MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for PCP-PPI Cofund deviates from the General Model Grant Agreement as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation] [Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of financial resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 PCP/PPI Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. PCP/PPI Cofund actions

PCP/PPI Cofund actions are actions with both of the following activities:

– a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI) and its implementation

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'.

The suppliers do not become beneficiaries of the GA.

'Implementation' means implementation of the subcontracts ('subcontract implementation stage')

⚠ Only one co-funded PCP or PPI per GA.

– related additional coordination and networking activities.

What? The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

Examples: *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

⚠ It is mandatory (both for PCP and PPI Cofund actions) to include not only a PCP/PPI itself, but also those coordination activities that are needed to coordinate the PCP/PPI procurement. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

ⓘ *For more information on which activities are required and which ones are optional, see General Annex D and E to the Main Work Programme.*

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the lead procurer he pays all subcontractors)

  ⚠ This implies that the consortium must have a common jointly-committed budget and that the lead procurer is mandated to sign the subcontracts *(see Article 13)*.

- or the members of the buyers group.

  ⚠ This implies that the individual members of the buyers group pay the subcontractors pro rata *(see Article 13)*.

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  ⚠ Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities:
  - direct personnel costs for related additional coordination and networking activities
  - direct subcontracting costs for related additional coordination and networking activities
  - other direct costs for related additional coordination and networking activities
  - indirect costs for related additional coordination and networking activities
  - specific categories of costs for related additional coordination and networking activities (if option applies).

Differences (compared to General MGA):

- No 'direct costs of providing financial support to third parties'.

⚠ These budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs for the activities in Point (f))]*[5]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs of subcontracting for related additional coordination and networking activities** *[(excluding subcontracting costs for the activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

[(f) [OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of [insert cost category or activity**[9]*]:

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[10] *[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of [insert cost category or activity]**: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.
10 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rates

How much? The Work Programme *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs of related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

⚠ Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are not eligible under PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1 *(see Article 13)*
- fulfil the additional eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs of related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[11]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Types of eligible personnel costs

B.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[12] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[*B.1.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not included in Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not included in Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[1]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure:** Costs of other goods and services **for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.**]

[OPTION to be used for virtual access to research infrastructure:** Costs of other goods and services **for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.**]

B.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[1] *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[1]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *not applicable.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises*[;]* ***[****and*

(c) ***OPTION if Point B.5 applies and that unit or lump sum cost includes indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][lump sum costs under Article 5.2(f) and Point B.5]****]****.*

Beneficiaries receiving an operating grant[1] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[*B.5* ***OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]***

Costs of [insert cost category or activity]:

(a) declared as ***unit costs****: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

(b) [declared as ***actual costs****: are eligible, if they comply with the conditions set out above (Points B.1 to [B.3][B.4]) [and if [insert eligibility conditions];]*

(c) [declared as a ***combination of the two****: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[*same for each specific category of costs****]***

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity] *are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the related additional coordination and networking activities have been properly implemented in accordance with Annex 1.]****]***

[…]

[11] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[12] For the definition, see Article 2.1(14) of the Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[13] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[14] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[15] For the definition see Article 2(6) of the Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[16] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

1.1 The budget category 'costs of related additional coordination and networking activities' **covers** the following **types of costs**:

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration — basic salary and complements
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party
  - costs of 'beneficiaries that are SMEs for their owners not receiving a salary'
  - costs of 'beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies).
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific categories of costs for related additional coordination and networking activities.

What not? The PCP-PPI Cofund MGA does not reimburse:

– 'costs for providing financial support to third parties'.

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

Personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[80] and set out in Annex 2 of the GA. (⚠ This concerns only beneficiaries that are SMEs, not PCP/PPI subcontractors that are SMEs.)

Examples: *Contracting authorities or contracting entities that are SMEs.*

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

⚠ Costs incurred by the beneficiaries for validation and testing of solutions provided by the subcontractors are part of the follow-up and monitoring of the results of the PCP/PPI and as such considered eligible direct personnel costs.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

The General Annex D to the Main Work Programme specifies that the costs of related additional coordination and networking activities are eligible up to a **maximum** amount of 30%/50% of the total requested grant amount (for PCP/PPI actions).

For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*.Thus, the amount of EU funding earmarked to finance related additional coordination and networking activities does not change, even if it the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*). The EU funding is not automatically proportionally reduced.

[80] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however **only** allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting *(Article 13)* is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties *(Article 14)* can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[20] and 2004/17/EC[21].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

The beneficiaries concerned must ***prepare****,* ***procure*** *and* ***implement*** *the subcontracts in accordance with the following* ***requirements****:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common procurement specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[22];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP ;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*
- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common procurement specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[22] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

For PCP Cofund actions, the beneficiaries will award subcontracts for the PCP research and development services ('PCP R&D services') that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PCP subcontract' is a contract for the purchase of R&D services that is identified in Annex 1 as action task.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('**buyers group**'), with a joint procurement in **3 phases**

The 'buyers group' is the group that finances and undertakes together the joint PCP procurement.

For PCP/PPI Cofund actions, it must normally be made up of:

- a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[81])

- that are established in two different Member States or associated countries *(see General Annex D to the Main Work Programme)*.

⚠ This is *in addition* to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different Member States or associated countries; *see General Annex C to the Main Work Programme*)

Exceptionally, the Work Programme allows for the participation of sole participants *(see General Annex D to the Work Programme)*.

Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

Example: *a group of a minimum of two public hospitals from two different EU Member States or associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

⚠ The buyers group is not open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

Other entities may be involved in the action as:

- beneficiaries (or linked third parties) responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*

- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in 3 phases.

The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

[81] *See Directives 2014/24/EC and 2014/25/EC.*

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

❖ Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

⚠ The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

⚠ This does not extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' *(as used in the WTO GPA)*.

⚠ Supplies cannot constitute the majority of the contract value.

❖ All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

❖ **Joint procurement procedure** (i.e. joint call for tender, joint evaluation of offers and joint award) is **coordinated and led** by one beneficiary ('**lead procurer**')

The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[82]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  ⚠ The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')

- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

⚠ PCP subcontracting is not restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

⚠ There can only be one PCP, per PCP Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PCP subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States or associated countries**.

⚠ This includes R&D and operational activities (*e.g. research, development, testing, certifying solutions, etc.)*.

[82] *See Directives 2014/24/EC and 2014/25/EC.*

ⓘ *For more information on associated countries, see Article 25 General MGA.*

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves.

⚠ This obligation must be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

PCP subcontracts must be based on the **best value for money** criteria *(see Articles 10 and 13 General MGA)*.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

⚠ The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

- a **specific procurement procedure** must be followed

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*
  - the procurement must be preceded by an '**open market consultation**'

This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[83]).

A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

– the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

– the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

– the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PCP subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The **framework agreement** (with each selected subcontractor) must set out the framework conditions for all 3 phases of the PCP implementation, including:

– the practical set-up of the implementation of the subcontracts, in particular:

  – the number, duration and budget of the PCP phases

  – the minimum number of expected subcontractors per PCP phase

  – the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)

  – the process for monitoring of on-going R&D work and reporting obligations of subcontractors

[83] *See Directives 2014/24/EC and 2014/25/EC.*

  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

⚠ The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

  - the details of the PCP R&D services purchased by each buyer

- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PCP.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

7. Other obligation: Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[84]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[85]) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ For more information on this obligation, see Article 13 General MGA.

[84] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*
[85] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[23], 2004/17/EC[24].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex** 1. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

***[OPTION:** not applicable]*

*(iii) prepare **common procurement specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common procurement specifications (see above), according to **best value for money** criteria and ensuring that the price corresponds to **market conditions**;*

*(iii) **Step 3**: **award the subcontract(s)** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);]*

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[1] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common procurement specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.]*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.']*

[23] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

[24] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries will award subcontracts for procuring the 'PPI innovative solution(s)' that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PPI subcontract' is a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

Exceptions:

There is no requirement to split the PPI procurement procedure in **phases**.

The buyers group may select one or more subcontractors.

The common challenge does not concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

⚠ PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure*[86]*)*.

Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

There is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

The subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.

If there is no mandate, the general rule is that:

- framework agreement(s) must be signed by all members of the buyers group together
- specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

⚠ PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

⚠ There can be only one PPI, per PPI Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

⚠ Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes

[86] *See Article 31 of Directive 2014/24/EC and Article 49 in Directive 2014/25/EC.*

are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

⚠ For PPI subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

Like PCP subcontracts, PPI subcontracts must:

- be based on the **best price-quality ratio**,
- have a price that corresponds to **market conditions**
- must follow the **specific procurement procedure** set out in the GA.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**'

    Exception:

    If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for an open market consultation procedure.

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

⚠ This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)*.

  Exception:

  If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for contract notice and a request for tender; a request for offers from at least 3 providers suffices.

  ⚠ The request must also be addressed to the providers that successfully completed the last PCP phase in the pre-ceding PCP Cofund action.

  ⚠ Do not forget to specify in the request for tenders the arrangements for intellectual property rights (for these arrangements*, see below point 4*) and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  ⚠ In case of framework contracts/agreements there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned**.**

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots need to be deployed at different times and/or by different procurers.*

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PPI subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The subcontract(s) must specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate, unless in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  ⚠ The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

⚠ If the buyers group choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PPI.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. Other obligation: Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[87]) normally apply to PPI procurements.

Therefore, the lead procurer and the members of the buyers group that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ *For more information on this obligation, see Article 13 General MGA.*

[87] *See Directives 2014/24/EC and 2014/25/EC.*

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[1]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(including after the intermediate evaluations before the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [Y] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each project financed by the procurement**, including data on each contractor that participated in the procurement, an overview of the results (for publication and evaluation purposes) and an assessment by the buyers group of the final results of each participating tenderer (in terms of achieving the performance and functionality requirements of the initial tender specifications).
- any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (including data on each contractor that participated in the procurement and overview of the results)

⚠ Templates[hyperlink] are provided on the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[41]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[42]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions)**]*** ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure**]**;*

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of funds**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(a) an overview of the results and their exploitation and dissemination;

(b) the conclusions on the action, and

(c) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(a) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(b) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(e) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into **two** reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage (preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of funds — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of funds needed to pay the subcontracts*(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a statement on use of the previous pre-financing instalment *(see Annex 12)*.

  ⚠ This document includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  ⚠ It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][44], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][451], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

[44] Should correspond to the percentage of the maximum grant amount that is foreseen for the related additional coordination and networking activities related to the preparation of the call for tender (see Article 5.1).

[45] Should correspond to a maximum of 90% minus the amount of the first pre-financing payment, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; see Article 21) minus the amount of the first pre-financing payment).

Exception:

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

[…]

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

[…]

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund

VII.1 Background information and approach

The Model Grant Agreement for EJP Cofund ('EJP Cofund MGA') is used for grants for EJP Cofund actions only.

⚠ EJP Cofund grants are open mainly to **entities owning** or **managing research and innovation programmes** (and exceptionally other entities — if justified by the nature of the action —, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from both national and private sources). The minimum number of participants is five independent legal entities from different Member States or associated countries (unless they are sole participants; *see General Annexes C and D to the Work Programme*).

ⓘ *For more information on EJP Cofund actions, see Article 2.*

ⓘ *For information on EJP Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on eligibility criteria, see the Work Programmes.*

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for EJP Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Model for the annual work plan
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.F (Fusion Cofund programme action specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 EJP Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

EJP Cofund actions are actions with the following activity:

– implementing a joint programme of activities of coordinated national research and innovation programmes.

What? The joint programme of activities may range from research and innovation activities to coordination activities, training activities, dissemination activities and financial support to third parties.

> ***Examples:*** *NFRP7–2015 Integrating radiation research in the European Union; Fusion programme Cofund action (FEJP) (see sections A and B.1 Euratom Work Programme 2014-2015)*

What not? The EJP only funds joint programmes, not individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the Work Programmes, and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[4] (‘**starting date of the action**’).

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Duration of the action

For EJP Cofund actions, the duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55 General MGA*).

⚠ The action’s duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same **budget categories** as the **General MGA**.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies).

Differences (compared to the General MGA):

- For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are replaced by the following specific categories:
  - 'costs for mobility of personnel'
  - 'costs for fellowships for researchers'
  - 'access costs for research infrastructure'.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

***[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings', costs of 'mobility of personnel', costs of 'researcher fellowships', costs of 'access to research infrastructures (EURATOM)'.
11 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed — for each call or action — in the Work Programmes. It cannot exceed 70%[88].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Specific case:

For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), there are **different unit costs** for three 'specific categories of costs':

- costs for **mobility** of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for **fellowships** for researchers: monthly living allowance, mobility allowance and family allowance
- **access costs** for research infrastructure [89]

⚠ These unit costs replace the unit costs for the 'specific categories of costs' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 General MGA)*.

[88] *See Article 28(5) of the Rules for Participation.*

[89] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

F. direct personnel costs;
G. direct costs of subcontracting;
H. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
I. other direct costs;
J. indirect costs;
[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision**: costs of [insert cost category or activity*[1]*]].

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

For one specific EJP Cofund action, i.e. the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are however replaced by the other categories.

For ease of reference, the annotations for Article 6.2 will be limited to these specific categories of costs and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (g) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (h) a **summary progress report** *on* the activities carried out during the on-going reporting period.

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1.

⚠ Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*.

⚠ However, since the annual work plan for the next period must be agreed with the Commission/Agency before the start of activities for the next reporting period, it must be submitted 3 months (i.e. 90 days) in advance.

⚠ The annual work plan for the first reporting period must already be included in your proposal.

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan**.

⚠ The coordinator has **30 days** from the date of receipt of the request to submit a revised annual work plan.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

⚠ It should **not** contain an **analysis of *all* activities** carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

⚠ Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

⚠ Payment of the **second pre-financing** payment is not automatic. It must be **requested** in the statement on the use of the first pre-financing payment using the template in Annex 8.

ⓘ *For more information on the other provisions of this Article, see Article 20 General MGA.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]* ***[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Exception:

Large EJPs may benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The need for a second pre-financing payment will be assessed during the preparation of the GA.

⚠ If a second pre-financing payment is agreed, the Guarantee Fund retention (of 5% of the maximum amount of the grant) will be split between the two pre-financing payments.

The second pre-financing payment is not automatic but must be requested by the coordinator and supported by a statement on the use of the first pre-financing payment *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum amount of the grant

Exception:

Depending on the size and the needs of the EJP, the reimbursement rate in the Work Programme and the availability of Union funds, the pre-financing may be higher or lower.

In case of two pre-financing payments, the second pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the first pre-financing was insufficiently used:

- if 70% or more of the first pre-financing has been used: the second pre-financing is paid in full
- if less than 70% of the first pre-financing has been used: the second pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The Model Framework Partnership Agreement ('MFPA') and Model Specific Agreement ('MSGA') are used for framework partnerships (and specific grants under such framework partnerships) only.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement potential action (i.e. the FPA and SGAs).

They are established in a FPA and implemented by SGAs for specific actions. Both FPAs and SGAs are treated as grants for the purpose of the award procedure.

⚠ The minimum requirements for participation in FPAs will generally depend on the types of specific actions that are envisaged in the action plan.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals in the Work Programme and in the invitation to submit a proposal —) *(see Article 4 MFPA and Article 14 MSGA)*.

⚠ Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

ⓘ *For more information on framework partnerships and specific grants, see Article 2.*

ⓘ *For information on FPA funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on standard eligibility criteria for different types of specific actions, see General Annex C of the Main Work Programme.*

The MFPA and MSGA generally follow the General MGA for content, but with a different numbering:

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⚠ In addition, all references in the General MGA to 'beneficiary(ies)' are to be taken as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the MFPA or MSGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

VIII.2 Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission') ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname] [2],

and

on the other part,

1. 'the **coordinator**':

[full official name] [short name][legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. **[full official name] [short name]** [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[3]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model for the certificate on the methodology

[1] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
[3] The action plan should include the common objectives of the parties in compliance with the objectives stipulated in the Preamble and the types of activities covered under this Framework partnership, contributing to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Partners that have also signed an SGA become beneficiaries (i.e. a 'participant'[90] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

If you do not want to actively participate, you may participate as 'partner not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble to the SGA).

This means that you will not have to comply with some of the obligations under that SGA *(see Preamble MSGA)*

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

– the other partners sign the Accession Form *(see Article 62 MFPA and Annex 3)*.

[90] For the definition, see Article 2.1(15) of the Rules for Participation: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ Any amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2— ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in the action plan (see Annex 1))] [open to all applicants meeting the announced criteria]] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The Commission will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the Commission decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[4] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[5] Please use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

Framework partnerships may in principle be awarded in all areas of the Horizon 2020 Framework Programme.

⚠ Currently, framework partnerships are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and

coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

The partnership is based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership

  ⚠ For the objectives, please refer to the FPA call.

- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in the Work Programme.

⚠ Signing an FPA does not oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

⚠ The partners may continue to participate in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

2. Award of specific grants

The Specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  ⚠ Such calls are restricted to the consortia that have signed a FPA and will be in competition.

  Example: *The Commission signs different FPAs for FET Flagships. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the Work Programme.

  The date must be set out in the action plan or in Article 2 of the FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

The Framework Partnership Agreement shall be concluded for a period of [...][6] years as of its entry into force (see Article 64). This period cannot be extended.

[6] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 MFPA)*.

> ***Example:*** *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

⚠ The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

⚠ SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** not applicable]*

1. Consortium agreement

As a general rule, FPA consortium agreements must ensure that the Framework Partnership and the specific actions are implemented properly.

⚠ If necessary, the consortium may decide to have — in addition to the consortium agreement under the FPA — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ⓘ *For more information on consortium agreements, see Article 41.3 General MGA.*

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 General MGA)*.

Exceptions:

Amendments made following suspension cannot have the effect of extending the duration of the FPA as set out in its Article 3.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the Agreement

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties**.**

⚠ Termination of the FPA has no effect on ongoing specific agreements (unless these are also terminated; *see Article 56 MFPA and Article 17 MSGA*)

ⓘ *For more information, see Article 50 General MGA.*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *subcontracting costs*
- *costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific categories of costs (if option applies) (see Article 4 General MGA).*

ARTICLE 10 — GRANT MAXIMUM, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 14 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 13 SGA) and approved by the *[Commission][Agency]* (see Article 14 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 SGA).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 MSGA and Article 5 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 General and specific conditions for costs to be eligible

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Specific conditions for costs to be eligible

The specific eligibility conditions applicable per budget category are set out in Article 5 MSGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS

The rules on resources to implement the specific actions and third party involvement are set out in the specific agreements (see Article XX SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 General MGA).*

⚠ The third parties are normally involved in the specific actions, not in the framework partnership.

Example: *Third parties making resources available against payment or free of charge (see Articles 16 and 17 FPA) must be identified in Annex I of the SGA.*

Partners must however — already at FPA proposal stage — indicate if they intend to use third parties or not.

Moreover, linked third parties must be identified already in the FPA *(see Article 19)*.

Example: *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64).

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

[OPTION if Article 19 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the partner to which it is linked must also submit — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the agreements with effect from the date of the entry into force (see Article 64 and Article 18 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGA

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ Accession to SGAs is effected only by means of the signature of the coordinator. The other partners do not need to sign accession forms for the SGA.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA cannot be amended before the FPA.

ⓘ *For more information on the conditions for accepting new partners, see Article 56 General MGA.*

ⓘ *For more information on the procedure for amendments, see the H2020 Online Manual*

VIII.3 Model Specific Agreement specific annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],

and

on the other part,

1. 'the coordinator':

[**full official name**] [**short name**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3a of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement:** X. **[full official name (short name)]** [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreements:** X. **[full official name (short name)]** [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 9),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
Annex 3	Model financial statements
Annex 4	Model for the certificate on the financial statements

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

⚠ However, not all partners of a framework partnership must actively participate in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

⚠ These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

As a consequence, these partners do not however need to comply with most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc)*.

⚠ Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* do remain applicable also for these partners.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

⚠ The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ The other partners do not need to sign accession forms.

⚠ Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

ARTICLE 14 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

14.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the Work Programme and in the invitation to submit a proposal).

⚠ If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Horizon 2020
Annotated Model Grant Agreements

General Model Grant Agreement
and specific Model Grant Agreements (ERC, SME Instrument, ERA-NET Cofund, PCP-PPI Cofund, EJP Cofund, Framework Partnerships and Specific Agreements)

Version 1.6.2
17 July 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations regarding the following derived model grant agreements: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnerships and specific agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to timesheet model and declaration model for personnel costs

Foreword

The **Horizon 2020 Annotated Model Grant Agreements** ('AGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

---

[1] **H2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

Over the next months, this text will be transformed into an on-line version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Horizon 2020 Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

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I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *Energy Challenge actions (see the Smart Cities and Communities calls); actions under the Research Infrastructures Part (see a Research Infrastructure call); Health Challenge actions, etc*
>
> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 Annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),**]

[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),**]

[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.
The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

[3] *See Article 15(9) of the Rules for Participation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- for **coordination and support actions (CSA)**: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

'Complementary grants' are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*, which links the two action and ensures the necessary synergies.

[6] *For the definition, see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies)

The budget category 'specific categories of costs' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings' and 'costs for clinical studies'.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

*[**OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
[5] For the definition, see Article 2.1(14) Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[7]; for IA actions it is normally 70% of the total eligible costs[8].

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[9]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[10] and all budget categories.

[7] *See Article 28(4) of the Rules for Participation.*
[8] *See Article 28(5) of the Rules for Participation.*
[9] *See Article 28(5) of the Rules for Participation.*
[10] *See Article 28(6) of the Rules for Participation.*

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[11]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[12]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [13]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific categories of costs for:
    - 'costs for **energy efficiency measures** in buildings'[14]
    - '**access costs** for providing trans-national access to research infrastructures'[15]
    - 'costs for **clinical studies**'[16]

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[11] *See Articles 123, 124 of the Financial Regulation.*

[12] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[13] *See Article 33(2) of the Rules for Participation.*

[14] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[15] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs ⚠ new in Horizon 2020)[17]

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme.

[17] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum EU contribution.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact
If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

2. Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:
Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000
Reimbursement rate= 100%
Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:
The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:
In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:
Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000
The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries (and linked third parties) must:

- at proposal stage: enter only eligible costs into the estimated budget for your action *(see Article 4)*
- at reporting stage: declare only eligible costs in your financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries** (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  ⚠ Accounting documentation is necessary only for actual costs.

  Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  ⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  Specific case:

  For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

  – recorded in the third party's accounting records

  – calculated in accordance with the accounting standards applicable in the country in which the third party is established

  – calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit')

  Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

  ⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

  Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

  For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

  – must calculate them (the average or standard personnel costs) according to its usual accounting practices

  – must budget and declare a total amount; the amount per unit must not be included in Annex 2.

  ⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

  Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

  Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

  ⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

  Example:

  A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*:** *costs of [insert cost category or activity*[13]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure:** **Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 This budget category **covers** the following **types of costs**:

- **basic remuneration** (basic salary and complements) and
- for non-profit legal entities: **additional remuneration** ('bonus payments').

What is 'basic remuneration'?

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

'Parental leave' covers both maternity leave and parental leave.

The 'complements' may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — If a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6.

> ⓘ *For more information on personnel made available to a beneficiary by a third party, see below and Articles 11 and 12.*

What not?

The basic remuneration does not include components that must be considered to be 'additional remuneration'.

> ***Example (variable remuneration component acceptable as basic remuneration):*** *The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.*

> ⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

What is 'additional remuneration'?

'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

1.1.2 Costs for employees (or equivalent) may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

For basic remuneration (basic salary and complements):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- be **mandatory** under national law, collective labour agreements or the employment contract
- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract, but he/she **must be 'assigned to the action'** (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

Specific case:

For **secondments** or **linked third parties**, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

For additional remuneration ('bonus' payments) **for non-profit legal entities:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours
Remuneration components:
a = annual salary: EUR 50 000
b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
c = additional remuneration for being Head scientist in a project: EUR 2 000
d = additional remuneration for being First Assistant on an internal action: EUR 1 000
***a** and **b** would be used to calculate the researcher's hourly rate:*
hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34
***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*
***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for **additional work** or **expertise**

The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

Examples (acceptable additional remuneration):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

Examples (not acceptable additional remuneration):

Additional remuneration paid for using English.

Additional remuneration is paid for participating in EU funded or multi-partner actions.

- be part of the beneficiary's usual remuneration practices and be consistently paid whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

The objective criteria must be related to the additional work or expertise.

The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***
Addition of the additional remuneration: = ***2 000***
Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Procedure for calculating personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception:

Employees hired during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Examples:

1. Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

2. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')

- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours')**

- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	Can be used **in all cases**; any beneficiary can use this option.	**Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: – employment contract of the person concerned – applicable collective labour agreement – national law on working time ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1;

		group – an applicable collective labour agreement or – the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours*	– if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		per day = 1 824 hours ***Standard annual productive hours*** *for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days =* ***228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* ➔ *productive days =* ***212*** *Multiplied by 8 working hours per day* ➔ *standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 =* ***1 642*** ***1 696 hours*** *(usual cost accounting practice)* ***> 1 642 hours*** *(90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case:

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs

– are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

– correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.

– the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Example:

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.
S/he worked 1 600 annual productive hours, 800 of them for the EU action.
Maximum additional remuneration eligible for the EU action (eligibility ceiling):
{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000
The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 This budget category **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action, under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

1.2.4 The **calculation** of the costs depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount). A calculation method is required, especially if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same **formula** explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the hourly rate is different (since it is not based on the annual personnel costs as registered on the payroll).

For the **hourly rate**, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person: this global amount must be divided by the number of hours worked for the beneficiary under that contract.

1.3 Direct personnel costs: Costs for personnel seconded by a third party

1.3.1 This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 These budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and indicated in Annex 2 of the GA.

This unit cost (hourly rate) is calculated according to the following formula:

{EUR 4,650/ 143 hours}

multiplied by

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

{country-specific correction coefficient / 100}

ⓘ *For the country-specific correction coefficient, see the* MSC calls conditions of the Main Work Programme[19] *(Table 4).*

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **owner** of an **SME/ beneficiary that is natural person**, who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They must be **calculated** as follows:

amount per unit (hourly rate) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 This budget category **covers** the personnel costs in actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2014-15.

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not included in Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15 are met.][**OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2. Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs (equipment costs)':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment cost: Depreciation costs of equipment, infrastructure or other assets

1.1.1 This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following:

It is expected that the beneficiaries allocate the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

⚠ Depreciated equipment costs can never exceed the equipment's purchase price.

⚠ Depreciation cannot be spread over a period longer than the equipment's useful life

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  {equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

1.2 Equipment costs: Cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of the equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

> ⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.
>
> ⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a*))
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional eligibility conditions** set out in Article 11.1.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. costs of purchasing scientific publications (e.g. books, manuscripts, articles, digital copies, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results and royalties on access rights

Specific cases:

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) paid to a third party (i.e. not a beneficiary) *(see Article 24)* are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees paid for access rights to background granted by other beneficiaries *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Best practice: Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled.

Costs for drafting the 'plan for the exploitation and dissemination of the results' are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when implementing this plan may be eligible.

– costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).

– translation costs, if translation is necessary for the action's implementation, is justified, etc.

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Internal invoices must not include indirect costs elements or profit margin or mark-up.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[6] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013: **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

What? Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ The beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.), together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

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[20] *See also International Financial Reporting Standard No 16.*

[21] *See Article 126 of the Financial Regulation.*

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments)
- knowledge-based resources such as collections, archives or scientific data
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

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[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the H2020 Framework Programme.*

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. During an audit, the auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

The beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  ⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

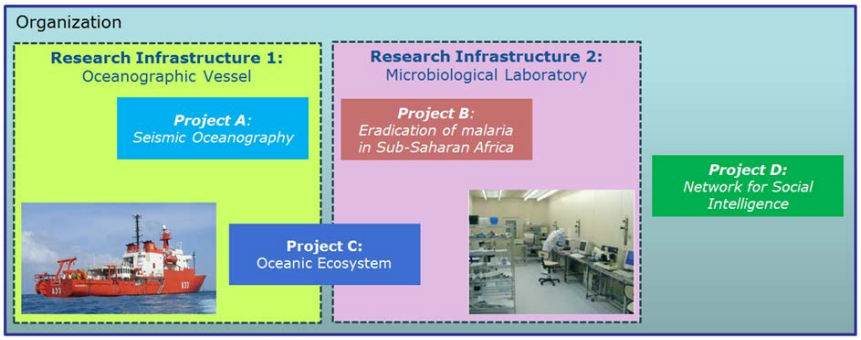

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

[24] *See Article 129(1) of the Financial Regulation.*

⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

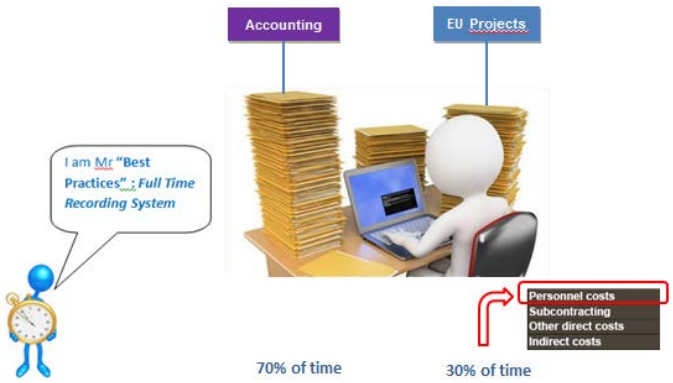

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to the best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[26].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

[26] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category covers costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be declared on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– unit or lump-sum costs covering specific categories of costs which include indirect costs.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

***[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]*

1. Specific categories of costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific categories of costs**, i.e.:

- for Energy Challenge actions involving additional energy efficiency measures: **costs for additional energy efficiency measures**

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

  These grants combine different activities. The reimbursement on the basis of the unit cost applies only for the building-related demonstration activities.

- for actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity': **access costs for providing trans-national access to research infrastructures**

  ⚠ This unit cost will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015)*.

- for actions under Health Challenge actions involving clinical studies: **costs for clinical studies**

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are already covered by the unit cost may not be declared (a second time) as direct costs *(for the costs that are covered, see below)*.

Examples:

Case 1: *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for*

subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

Case 2:*A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.*

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Case 3: *A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.*

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 Specific category 'costs for additional energy efficiency measures'

1.1.1 This budget category **covers** two categories of eligible costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and

- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost (EUR/m^2 of eligible conditioned gross floor area) set out in Commission Decision C(2013) 8196[27] and indicated in Annex 2 of the GA.

This unit cost (EUR/m^2 of eligible conditioned gross floor area) is calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

'standard cost to save 1 kWh' = EUR 0.1
'standard payback period' to be used = 10 years

The m^2 of eligible conditioned gross floor area do not include parts of the buildings which are not affected by the measures, *e.g. garages*.

⚠ The specifications per type of demonstration building must already be part of your project proposal (by completing the BEST table (Building Energy Specification Table))[28]. These specifications are then included in Annex 1.

⚠ You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit (EUR/m^2 of eligible conditioned gross floor area) x number of actual m^2 of surface area built or refurbished

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.
[28] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

1.2 Specific category 'access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category, these costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[29] and set out in Annex 2 of the GA.

⚠ The Decision does not *fix* the unit cost for access costs; the unit cost must be established for each installation — before signature of the GA — as follows (and then reflected in Annex 2 of the GA):

- identification of a *unit* of access to the installation; this is used to measure the total quantity of access that the installation provides to its users

- establishment of the *unit cost* of access, calculated as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access cost (over past two years}^{30}\textbf{)}}{\textbf{average annual total quantity of access (over past two years}^{31}\textbf{)}}$$

The averages are based on:

- the beneficiary's certified or auditable historical data

- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for less than two years) and

- a period excluding times when the installation was not usable (out of order, under repair or undergoing maintenance).

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[31] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for:

  - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    By way of exception, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

  - costs of consumables specifically used for the installation and the research work of the users

  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

  - costs of energy power and water supplied for the installation

  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)

  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

  - costs of specific scientific services included in the access provided or needed for the provision of access

- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

  and excluding:

  - all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

  - travel and subsistence costs to support the visits of users.

A form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ Do not forget to describe in your proposal the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs= average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Before signature of the GA, the beneficiaries can opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation) not as unit cost but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*. If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for **providing trans-national access to research infrastructure** to scientific communities
- fulfil the **additional eligibility conditions** set out in Article 16.1

1.1.4 They must be **calculated** as follows:

– for each installation:

amount per unit (EUR/unit of access) x number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil —* ***mutatis mutandis*** *— the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.****]***

[OPTION: *not applicable****]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties free of charge are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

    Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

  - **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national VAT system. Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible** it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.
>
> **Specific cases:**

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding).

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[32] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

[32] *For the definition, see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are	Subcontracts concern the implementation of action tasks; they imply the implementation of

necessary to implement action tasks by beneficiaries.	specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or*

	other goods and services).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 ***[OPTION:*** *with the exception of additional exploitation obligations****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.****]***

[OPTION: *not applicable****]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[33]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

ⓘ For more information on third country participants, see the Horizon 2020 Online Manual.

[33] *For the definition, see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

Obligations that do not apply to beneficiaries not receiving EU funding:

These beneficiaries must, in particular, **not**:

- comply with the conditions for declaring costs *(e.g. cost form, eligibility, calculation, etc) (Chapter 3 and Articles 10-15)*
- keep records and other supporting documentation for costs *(Article 18.1.2)*
- submit financial reports and convert their costs in euro *(Articles 20.3(b), 20.4(b) and 20.6)*
- comply with some of the rules on management of intellectual property, background and results *(Articles 26.4, 28.1, 28.2, 30.3 and 31.5)*
- fear rejection of costs, reduction of the grant or recoveries, suspension of the payment deadline or suspension of payments *(Articles 42, 43 and 44)* .

⚠ Apart from this, they are treated like the other beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs, reduction of the grant or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the best value for money considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the Work Programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[34] and 2004/17/EC[35] — or any EU legislation that replaces these Directives[36]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[34] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[35] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[36] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*,

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]*.****]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means a contract for the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is forbidden in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is forbidden, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the best value for money considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. Other obligation: Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks

- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises

- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an **established relationship** (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

– *scientific and economic unity*

– *last a certain length of time*
– *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

– the financial viability/capacity of a beneficiary is 'weak' while that of its linked third parties is strong

ⓘ For more information on the financial viability and the financial capacity check, see the Horizon 2020 Online Manual.

– the beneficiary mainly coordinates the work of its linked third party.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

[38] *See Articles 8 and 9 of the Rules for Participation.*

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is **no** procedure for **approval without amendment**.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

⚠ The obligations in Article 14.1.1 additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

Each linked third party has its own financial statements, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA ('**cascade funding**').

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is **not** considered financial support.

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties (recipients) that actually implement research and/or innovation projects.)

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ *For financial support given in the form of prizes, see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g. 3 grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

⚠ All these conditions must already be described in your proposal (see the Proposal Templates).

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- avoid conflicts of interest *(see Article 35)*
- maintain confidentiality *(see Article 36)*
- promote the action and give visibility to the EU funding *(see Article 38)*
- are liable for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *not applicable**]***

15.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

Example: *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.
- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[28]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

1. Trans-national access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[39] and installations[40] for scientific communities ('provision of access activity').

Such Research Infrastructures Part actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **cover** — for the provision of access activity — the following **types of costs**:

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[39] *For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] *For the definition, see the footnote in Article 16 of the MGA.*

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

The Beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Virtual access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

– operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

⚠ There are no 'access costs' for virtual access.

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected or even identified.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General oobligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Rules of Application: **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ The rules in the GA do not affect national laws on keeping documents.

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

– documents received or created in paper form should be kept in paper form

– documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units

declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary (or linked third party) may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

⚠ The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval. It will also challenge the costs, if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary/ can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ *For more information on the certification procedure, see the Horizon 2020 Online Manual.*

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiaries must:

- sign one **declaration** per reporting period, to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  This declaration must be dated and countersigned for acceptance by the person concerned.

  A template is provided on the Participant Portal.

  Best practice: If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  A template is provided on the Participant Portal.

  Please note that this template is only an example of an acceptable timesheet. It is not a mandatory model. Beneficiaries are entitled to use any other model of timesheet provided that it fulfils the minimum conditions and it contains at least the information detailed below.

  Time records should include:

  - the title and number of the action, as specified in the GA
  - the beneficiary's full name, as specified in the GA
  - the full name, date and signature of the person working for the action
  - the number of hours per day declared for the action
  - the supervisor's full name and signature
  - a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned
  - a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda*

and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

The beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For Energy Challenge actions involving additional energy efficiency measures, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*), unless Annex 1 specifies another way.

Specific case:

'**Classified deliverables**' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

– a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions).****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

– a '**periodic financial report**' containing:

(ii) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(iii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iv) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(v) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements'** (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[32] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the coordinator, which must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (they do not see their grants in the electronic exchange system and therefore have no access to them). Before submission, the beneficiary completes the data for the linked third party, prints it and sends it to the linked third party which must sign it *on paper* and then send it back to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system are identical to the signed paper version.

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

CFSs must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

ⓘ *For information on the eligibility of costs incurred for reporting, see Article 6.2.D.3.*

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified deliverables' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on

security of information in the Commission internal Rules of Procedure *(see also Guide for classification[hyperlink]).*

ⓘ For more information on information security, see the Horizon 2020 Online Manual.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on cross–cutting issues (described in Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined vis-à-vis societal challenges (Annex I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed, if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more), as reimbursement of actual costs and personnel costs

on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25 % flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, it must be an independent public officer, with formal competence to audit the beneficiary/linked third party.

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro:**
  - for costs incurred in the currency of their accounting records conversion of costs by one of the following:
    - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[44].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart corresponding to your currency.

Step 3 — Choose the start and end date of the period for which the average daily exchange rate is calculated (i.e. the reporting period) by using the sliding tool in the second table.

Step 4 — The average appears above the first table.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if no daily euro exchange rate is published : using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

– for **costs incurred in a currency other than EUR and the one used in their accounting records:** conversion in accordance with the applicable national law and their usual accounting practices.

– for costs incurred in EUR, beneficiaries **with accounting records in a currency other than the euro** must declare the amount in EUR; no conversion has to be made.

⚠ This means that a beneficiary with accounting in a currency other than EUR will act differently according to the currency in which it incurs the costs (the currency in which the contract/invoice is established).

Examples:

1. *If the UK beneficiary buys the equipment in the USA (costs incurred in US dollars), it will convert the price of this equipment into pounds (the currency in which its accounts are established) according to its usual accounting practices. When reporting the costs to the Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.*

2. *If the UK beneficiary buys the equipment in UK pounds (it will record those equipment costs incurred in pounds in its accounts kept in pounds). When reporting the costs to the*

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.

3. If the UK beneficiary buys the equipment in Germany in EUR (e.g. EUR 10 000) it will report these costs incurred in EUR (i.e. 10 000) to the Commission/Agency without converting them first from EUR to pounds and then back to EUR.

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline *(see Article 47)*
- terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

  ⚠ This may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - the work has started.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed start date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed start date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)
- the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, see Articles 42, 43 and 44.

2. Amount of pre-financing payment

There is no standard amount or percentage for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods (it will be in any case less for actions with only one reporting period, as 100% would mean the totality of the EU grant for the action).

⚠ At the moment of the pre-financing payment, an amount equivalent to 5% of the maximum grant amount is deducted from the payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.
Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1 : application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)
Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
Payment of the balance amounts to EUR 100 000 and will be ***paid*** *to the coordinator as follows:*

- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

22.1.1 Right to carry out checks

The Commission *[or the Agency]* will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission *[or the Agency]* may be assisted by external persons or bodies.

The Commission *[or the Agency]* may also request additional information in accordance with Article 17. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.

2. The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).

3. After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.

4. After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check (see Article 17). All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

It may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the check shows ineligible costs or the violation of other obligations under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

The Commission/Agency may carry out checks remotely, based on documents it received beforehand. It can do so using its own staff or with the assistance of external expert(s) or bodies.

⚠ If the Commission/Agency is assisted by external expert(s) or bodies, it does not need to send their name(s) for approval to the beneficiaries before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report'** will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed

- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the review shows improper implementation of the action, ineligible costs or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42- 44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a letter sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the **names** of the **independent experts** that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, you will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days (‘**contradictory review procedure**’).

22.1.3 Right to carry out audits

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a ‘**draft audit report**’ will be drawn up.

The Commission *[or the Agency]* will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations (‘**contradictory audit procedure**’). This period may be extended by the Commission *[or the Agency]* in justified cases.

The ‘**final audit report**’ will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission *[or the Agency]* may also access the beneficiaries’ statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

Specific case:

The Commission may audit the accounting records of beneficiaries, to obtain general information about actual costs for cost items that are reimbursed as unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will however normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

They consist in an in-depth examination (by professional auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to **third parties** involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

*1. The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

*2. The Commission/Agency may audit **third parties providing in-kind contributions** (free-of-charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

*3. The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or if appropriate the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. .*

⚠ *For this category of third parties, audits will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

*4. The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary.*

⚠ *For recipients of financial support or prizes, audits normally will not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs), except if Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties. .*

⚠ If the audit shows, ineligible costs, improper implementation of the action or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

2. Procedure

The audit will be initiated by a letter sent to the beneficiary concerned.

⚠ The Commission/Agency will transmit this letter (and the other communications relating to an audit as formal notifications, through the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its **name**.

The beneficiary may **object** to an external auditor on grounds of commercial confidentiality (and explain the reasons for this). If justified the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit with its own auditors).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit (**i.e. on the beneficiary's premises or on the site on which the action is being implemented). (There may however also be audits that consist only in a desk review.)

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc)* and will indicate how and when it must be provided (and in which format).

ⓘ *For more information on records and supporting documentation for the different cost forms, see Article 18.*

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

> ***Example:*** *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

⚠ Objections based on data protection or confidentiality will not be accepted.

Once an audit has started, the beneficiary must keep all the records and supporting documents until the audit procedure and its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This avoids any unnecessary delays in retrieving original documents from the archives (and thus minimises the risk of the rejection of costs).

> ***Example:*** *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

This includes granting access to research facilities and interviewing the researchers that worked on the action.

⚠ Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc).

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Moreover, all confidential data will be processed in accordance with Article 36.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory review procedure**').

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [1]and No 2185/96[1] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42- 44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[1], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

⚠ If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission *[or the Agency]* may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission *[or the Agency]* will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the Commission *[or the Agency]* on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission *[or the Agency]* in justified cases.

The Commission *[or the Agency]* will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission *[or the Agency]* does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission *[or the Agency]* accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission *[or the Agency]* intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission *[or the Agency]* does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission [*or the Agency*] accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

⚠ These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or ‘**associated country**’[39], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: ‘**associated country**’ means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Regulation (EU) No 1291/2013).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to background

The rules on access to background (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is **no** (or a more limited) obligation to give **access**, if there are **restrictions** or **limits** (legal or otherwise) regarding the background and the beneficiary owning or holding the background has informed the others — before acceding to the GA (or immediately when additional background is agreed on after signature of the GA).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ Don't forget that — when contracting on background with third parties — you must at all times ensure that you can still comply with your access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

  > ***Example:*** *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

– for the exploitation of results: under fair and reasonable conditions

  ⓘ *For more information on fair and reasonable conditions, see Article 31.*

Also, there are no **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties, except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure *(see Article 31)*.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the **beneficiary** that **produced** them.

> 'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries are advised to keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases:

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must — as much in advance as possible before the jointly-owned results are produced — conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  ⚠ Don't fix a *ceiling* for fair and reasonable compensation before the action starts, unless you can precisely determine the results you expect to produce.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries are advised to include general principles on joint ownership already in the consortium agreement.

⚠ The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection (*e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (⚠ without prior authorisation from the other joint owners), unless otherwise agreed in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

⚠ The joint ownership status may **change**:

– it may need to be reviewed later on, when protecting the results.

Example:

Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.

– joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that any agreements with third parties who could claim rights to the action's results *(e.g. employees, subcontractors, linked third parties etc.)* contain provisions that allow them to respect their obligations under the GA *(e.g. transferring ownership to the beneficiary, grant the beneficiary access rights with a right to sub-license, etc)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Specific cases:

Joint research units (JRUs) — Where the internal arrangements of a JRU, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ⓘ *For information on JRUs, see Article 14.*

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, protect them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

⚠ This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*

The beneficiaries are in principle free to choose any available **form** of protection.

Examples of classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

For an invention: e.g. patent, confidential information.

For the design of a technology: e.g. industrial design, copyright.

For a website: e.g. industrial design, copyright, trademark, confidential information.

⚠ In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

ⓘ *For information on the eligibility of costs related to protection, see Article 6.2.D.3.*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

⚠ Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include a reference to EU funding, as specified in the GA.

⚠ **No** information on EU funding is needed, if it is (technically or legally) impossible to include such a reference

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure exploitation of their results.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

Example: *Exploitation is justified from an economic point of view (commercially) or from a standardisation perspective (for use in standardisation activities).*

Where possible, the measures should be consistent with the impact expected from the action and the '**plan for the exploitation and dissemination of the results**'.

They may aim for exploitation by the beneficiary itself (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (⚠ Such additional exploitation obligations will already be mentioned in the Work Programme.)

⚠ This obligation only applies to beneficiaries receiving EU funding.

If the results can reasonably be expected to contribute to European or international standards, the beneficiaries must also communicate them to the Commission/Agency.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

⚠ This obligation applies only if it is foreseen in your GA.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — disseminate their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

No dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA (*e.g. personal data protection, security-related obligations, etc)*.

The beneficiaries may choose **how** they would like to disseminate their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

If the GA provides for additional dissemination obligations, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the Work Programme.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated, unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries are advised to foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

2. Visibility of EU funding

Any dissemination of results (in any form) must include a reference to EU funding, as specified in the GA.

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission]/ Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION:** not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may transfer ownership of their results.

⚠ Security-related obligations *(see Article 37)* may prohibit a transfer or require certain conditions to be fulfilled before it takes place.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

The beneficiary must ensure that the new owners comply with the following obligations:

- joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- protection of results and visibility of EU funding *(see Article 27)*
- exploitation of results and visibility of EU funding *(see Article 28)*
- dissemination of results, open access and visibility of EU funding (see Article 29)
- transfer and licensing of results *(see Article 30)*
- access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

⚠ The mere fact that the results concerned are transferred to a competitor is not in itself a valid reason for an objection. The beneficiary concerned must *demonstrate* the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases:

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of before).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them)*. In this case, there is no need to inform the other beneficiaries of such transfers in advance (and the other beneficiaries do not have the right to object).

⚠ Before agreeing to such a 'global' authorisation, you should carefully consider the situation (and in particular the identity of the third party concerned), to determine if your access rights would be affected.

Example: For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country not associated with Horizon 2020 must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

Best practice: Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant licences to their results.

They must however ensure that **access rights** can be exercised and that any additional exploitation obligations are complied with.

⚠ **Exclusive licences** *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If this option is included in your GA, the Commission/Agency may **object** to transfers or exclusive licences to third parties established in a non-EU country not associated to Horizon 2020, on the following grounds:

- the planned transfer or licence is not in line with EU **competitiveness interests**

  Example: if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU

- the planned transfer or licence is not consistent with **ethical principles**

  Example: if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level

- the planned transfer or licence is not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

⚠ **No** right to object for transfers or exclusive licences by beneficiaries not receiving EU funding *(see Article 9)*.

⚠ For Euratom grants, the Commission has the right to object also to non–exclusive licences.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[40], for the purposes of the complementary grant agreement(s) (see Article 2).**]

[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.**]***

[OPTION for access to research infrastructures:** The access provider must give the users access to the results, if needed to implement the action.**]

[OPTION:** not applicable**]

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When ?

The beneficiaries must provide access to results, if it is **needed**:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity (established in a Member State or associated country), to exploit the results produced by the beneficiary to which it is affiliated (unless otherwise provided for in the consortium agreement).

There is **no definition** of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

Example (results needed for implementation): *if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

Example (background needed for exploitation): *if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries are advised to agree *(e.g. in the consortium agreement)* on a **common interpretation** of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they **must be requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a Member State or associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

The agreement by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

⚠ Don't forget to notify the Commission/Agency of any conflicts on results that are likely to affect the action implementation *(see Article 17.2.)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

– for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

ⓘ *For information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3*

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

⚠ Access rights do not automatically give the right to **sub-licence** to the requesting beneficiary (since this would imply that access rights to results could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries are advised to agree on the terms and conditions of the sub-licensing generally and in writing (at the level of the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: Beneficiaries are advised — for legal certainty purposes — to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

The General MGA provides for several options for specific access rights for EU institutions, bodies, offices or agencies and/or EU Member States, for policy purposes.

⚠ These obligations apply only if they are foreseen in your GA.

5. Specific access rights for Euratom and its joint undertakings

The option gives Euratom and its joint undertakings (such as Fusion for Energy) royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to sub-license *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

The General MGA also provides for several options for specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)

- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  ⚠ In this case, the access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

⚠ These obligations apply only if they are foreseen in your GA.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ For guidance in this process, see the 'Human Resources Strategy for Researchers' tool[50] developed by the Commission.

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[51] and of the Code of Conduct[52] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[53])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[53] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[54].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[55].

[54] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[55] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink].

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

Best practice: Beneficiaries are advised to obtain the **approval of** a **European ethics committee** (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[56] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[56] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[43], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81)

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed — during the action and for four years afterwards.

> ⚠ This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves (for example, for access rights or third parties involved in the action).
>
> A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information concerned.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

Best practice: Beneficiaries are advised to inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

⚠ Stricter confidentiality obligations apply for information that is that is 'EU-classified' and subject to 'security requirements' in Annex 1 of the GA *(see Article 37)*.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *not applicable****]***

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

1. Activities raising security issues — Classified deliverables

If the security scrutiny (carried out by the Commission/Agency during the selection procedure) finds that the action raises security issues because it deals with information that is 'EU-classified' (under the Commission internal Rules of Procedure), the Commission/Agency will make it subject to '**security requirements**' (set out in a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' in Annex 1 of the GA).

In this case, the beneficiaries must comply with the security requirements.

Moreover, they may not subcontract action tasks involving such information or disseminate results linked to such information, without prior approval by the Commission/Agency.

'Classified deliverables' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 19)*.

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[57].

Moreover, the coordinator must submit a **copy** of any export or transfer licence, before the action starts.

[57] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> 'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Promoting the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange.

Ad hoc efforts or mere dissemination of results are not sufficient. The communication activities[58] must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and address the **public policy perspective** of EU research and innovation funding, by considering aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)

[58] *For the definition of 'communication activities', see the Glossary.*

- scientific excellence
- contributing to competitiveness and to solving societal challenges

❖ impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*

❖ better use of results and spill-over to policy-makers, industry and the scientific community.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity).

⚠ The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them in another work package).

The beneficiaries are free to choose the type of communication activities.

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

⚠ Information given may **not** cover EU-classified information or information relating to 'classified deliverables' *(see Article 37)*.

⚠ Don't forget that any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa). Both obligations must be complied with.

ⓘ *For more information on how to promote your action, see the H2020 Online Manual*

2. Visibility of EU funding

The beneficiaries must ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure (including equipment or major supplies) funded by the grant, by:

– displaying the EU emblem and

– including the reference to EU funding, as specified in the GA.

For infrastructure (including equipment or major supplies) a sticker (or other equivalent means) should be used.

ⓘ For more information, see the Guide to using the EU emblem[59].

⚠ The beneficiaries must ensure the visibility of EU funding even after the action ends.

[59] Available at http://publications.europa.eu/code/en/en-5000100.htm.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[44], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[44] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities by the Commission/Agency

The Commission/Agency may use any (⚠ non-confidential and non- classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material); *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

⚠ The beneficiaries must make **arrangements** with any **third parties** that could claim rights to the material, in order to legally allow the use by the Commission/Agency.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

1. Processing of personal data by the Commission/Agency

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency 'Data Protection Officer (DPO)'.

This notification will be available in the Register of the DPO[60] (and will describe the processing operations, security safeguards, data transfer, retention period, etc.).

⚠For the processing of sensitive data *(e.g. health data)* and processing for the purpose of administrative penalties and termination, the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ *For more information, see the data privacy statement ('SSPS')[61] on the Participant Portal.*

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS) to:

- obtain information about what data is collected and how it is used, usually given via a privacy statement
- see which of their data are being held
- correct any errors in the data, block access to this data, or delete their data

[60] Available at http://ec.europa.eu/dpo-register/search.htm.
[61] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

– complain about data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ *For information on the complaints procedure, see the EDPS website.*

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data, by the beneficiaries

The beneficiaries must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[62] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [63]

[62] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing** of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[64]

Beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform staff** (whose personal data are collected and processed by the Commission/Agency) about this disclosure, by providing them with the SSPS.

Examples:

Before encoding its staff's personal data in the Beneficiary Register or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must tell the staff concerned and provide them with the SSPS.

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ *For more information on ethics, see the H2020 Online Manual.*

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63 *See Article 8 of Directive 95/46/EC.*

64 *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party, unless the Commission/Agency has explicitly agreed in writing.

'Assignment' normally means the transfer of rights held by one party to another party.

⚠ However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity

Assignment for the benefit of creditors in a bankruptcy procedure

⚠ Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

Example: *The obligation to allow audits by the Commission/Agency*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator**, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications, unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the H2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action).*

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement (unless exceptionally stipulated otherwise in the Work Programme, for a specific call).

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded **before the action starts**. (Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action.)

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the H2020 Online Manual.

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiaries must conclude a coordination agreement.

> 'Coordination agreements' are agreements between the consortium and partners from a third country (including scientific and technological organisations and agencies) or an international organisation, with which the joint call was organised.
>
> Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the basic contradictory procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100%.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

41.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[65]

  Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[66]

  If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

[65] *See Article 80(1) of the Financial Regulation.*
[66] *See Article 87 of the Rules for Application.*

– taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or

– adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[67].[68]

The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an

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[67] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[68] *See Article 79(2) of the Financial Regulation.*

amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000
Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

Beneficiary approved costs multiplied by the reimbursement rate (100%) * *final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between 2% and 10% of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

  Example:

  GA with an EU contribution of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

  During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in

the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the decision to apply the penalty may also be **published** on Commission or Agency websites —together with the name of the person responsible for the misconduct, information on the misconduct and the penalty(ies) (duration of the exclusion and/or amount of the financial penalty).

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

1. Liability for damages, of the Commission/Agency

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

– causes damage to a third party (including another beneficiary)

Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

– suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability for damages, of the beneficiaries

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples: *Costs of legal proceedings borne by the Commission.*

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

  ⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

- calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

❖ **Payment request does not comply with the provisions of the GA**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.

❖ **Payment request is incomplete or requires clarification**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

Examples: the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.

❖ **Doubts on the eligibility of costs in the financial statements that require additional verifications**

The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

Example: The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is no *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

Example: statements made by the beneficiary in the declaration form are found to be false.

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

– **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **no individual financial statements** for the beneficiary (or beneficiaries) concerned may be submitted.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation, by the beneficiaries

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Grounds for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

  ⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the suspension is lifted and the action continues, the action's remaining budget can be used to implement the action.

⚠ However, it is possible that the action is resumed with a lower budget to adapt it to the new situation (agreed as part of the amendment).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) ***cannot*** **be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation, by the Commission/Agency

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

❖ **Suspicion of loss of scientific or technological relevance**

The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

This may in particular be the case:

- if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
- if work has significantly deviated from the original work plan
- if a key beneficiary leaves the action and the consortium needs time to find a replacement
- after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA, by the beneficiaries

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

> ***Example:*** *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

> ***Example:*** *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries, by the beneficiaries

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ For more information on the roles and access rights in the electronic exchange system, see the H2020 Online Manual.

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action (unless it concerns the coordinator, since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action — including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so —, unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.][OPTION: not applicable];

(j) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries, by the Commission/Agency

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

❖ **Non-accession to the GA**

The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA).

⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [69]

Examples:

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this.

[69] *See also Article 8 of the Rules for Participation.*

The Commission terminates the GA because the conditions set out in the work programme are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

❖ **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

❖ **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

❖ **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

❖ **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

❖ **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

❖ **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

❖ **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

❖ **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country's or international organisation's action does not start by the date specified in Annex 1

  ⚠ In this case, **no costs** incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country's or international organisation's action is terminated

- the third country's or international organisation's action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

❖ **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA —

substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:

- systemic or recurrent and,
- have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ **Ineligible costs** may be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure
- labour disputes or strikes

– financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has **no specific effects** on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission]*[*name of the Agency]*
[*Directorate-General]*[*Department]* [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use a 'Messaging' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal Notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ *For more information on access and roles in the electronic exchange system, see the H2020 Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** (unless the GA or other rules provide for direct communication with the other beneficiaries, *e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations*).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

When & What?

An amendment is necessary whenever there is a need to **change** the **terms and conditions** of the GA. In some cases, the GA explicitly provides for them.

⚠ Amendments may **not** result in changes that — if known before awarding the grant — would have had an impact on the decision to award it. Those are mostly changes that:

- may have had an impact on the assessment of the applicant with regard to the eligibility and selection criteria *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- breach the principle of equal treatment of applicants
- involve modifications in the action and/or the related budget which may have affected the assessment with regard to the award criteria announced in the call *(e.g. the tasks in*

Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)

– do not comply with the rules applicable to the GA (i.e. Financial Regulation, Rules for Participation, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified or to modify Annex 1 following a review of the action).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removing a beneficiary whose participation was terminated** by the beneficiaries or by the Commission/Agency *(see Article 50.2 and 50.3)*.

  For termination by the beneficiaries, the request for amendment must be part of the notification of termination. In this case, don't forget to also submit the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency, the request for amendment must be submitted together with the report on the distribution of payments and the termination report (if needed).

  ⚠ No need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)*, unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

- **Adding a new beneficiary** *(see Article 56.2)*

  The request for amendment must include the Accession Form (signed by the new beneficiary in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

  The new beneficiary must provide a declaration on joint and several liability of its linked third party if required by the Commission/Agency.

  ⚠ Don't forget that the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

  Depending on the Horizon 2020 status(es) of the new beneficiary, the applicable options will be added.

  Example:

  If the new beneficiary is an international organisation, the options related to international organisations specified under Articles 22.4, 53.2, will be added to the GA and the options specified under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

  For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Change of beneficiary due to partial takeover (called 'partial transfer of rights and obligations' in FP7)**

  'Partial takeover' means that some assets of the beneficiary have been taken over by another entity *(e.g. partial acquisition)*.

If the GA is part of the assets taken over, the beneficiary must request an amendment: the entity to which the GA has been transferred may become the new party of the GA if the Commission/Agency agrees on that.

The contractual position of the old and the new party (vis-à-vis the Commission/Agency and the other beneficiaries) must be clearly spelled out in the request for amendment: in particular, it must clarify which is the financial liability of the new party for the old party's debts towards the Commission/Agency or the Guarantee Fund.

⚠ Don't forget that the new party must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

❖ **Change of coordinator**

The amendment request may be submitted after the period set out under Article 3 of the GA ends.

The initial coordinator may continue to participate in the action as a beneficiary (or may terminate its participation).

If the new coordinator is already a beneficiary of the GA, he will start his new functions from the date agreed by the parties, or — in the absence of such an agreement — the date on which the amendment enters into force. The date agreed cannot be before the initial coordinator has terminated its functions.

⚠ If the new coordinator is not a beneficiary of the GA, it must also accede to the GA as a new beneficiary *(see Article 56.2)*.

❖ **Change of the coordinator's bank account for payments**

Example: *The coordinator changes bank.*

The coordinator must submit the necessary supporting documents and update the banking information on the Participant Portal.

⚠ Do not forget to first update the bank account data in the Beneficiary Register (and get it validated).

❖ **Change of the action's title and/or acronym**

Example: *the consortium finds out that the acronym of their action is a protected trademark.*

❖ **Change of the starting date, duration of the action or reporting periods**

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

⚠ Even if the action is prolonged, the maximum grant amount cannot be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

  ⚠ Don't forget to communicate the date from which the action's implementation can restart ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:

  – a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries

  – changes concerning **in-kind contributions** provided by third parties (against payment or free-of-charge) or **subcontracts**

    Such changes could in principle also be made as 'approval without formal amendment' (*see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency's *agreement* (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency may consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).

  – changes concerning the tasks to be carried out by **linked third parties** and related costs

    There is no 'approval without formal amendment' *(see Article 14)*.

  – changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount and/or the action's estimated eligible costs will be accepted only in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount cannot be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2 (estimated budget)** which require an amendment *(see Article 4)*, in particular:

  – a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

  – a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*

    Examples:

    During the action's implementation, a beneficiary that declared its direct personnel costs as actual costs in Annex 2 decides to change this and instead to declare its direct personnel costs as unit costs in accordance with its usual accounting practices.

    An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to add the appropriate option under Article 5.2 and to modify the action's estimated budget in Annexes 1 and 2.

Indicative list of cases where no amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary or coordinator**

  Changes concerning name, legal form *(e.g. Ltd., S.A.)*, registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA) do not require a formal amendment; an update of this data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

  ⓘ *For more information on data updates, see the Horizon 2020 Online Manual.*

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may request it.

  Example: *Company RO moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates*

- **Change of beneficiary due to universal takeover (called 'universal transfer of rights and obligations' in FP7)**

  'Universal takeover' means that all the rights and obligations of the beneficiary have been taken over by another entity *(e.g. in cases of merger or full acquisition)*. The beneficiary ceases to exist and all its rights and obligations (including those under the GA) are taken over by the new entity.

  Example:

  Beneficiary X may merge with another existing entity Y by:

  (i) becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or

  (ii) establishing a new separate legal entity (X and Y are together known as 'Z').

  Since *all* the rights and obligations of the old entity (including the GA) are transferred to the new one, there is normally no issue of legal certainty and it is therefore not necessary to make a formal amendment under Article 55. An update of the data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may request it.

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

  Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

Case 2: A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

⚠ Don't forget that — in addition to updating the data in the Beneficiary Register — you must also inform your coordinator (offline) under Article 17.2, if the universal takeover may:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinators must then inform the Commission/Agency (via the electronic exchange system) and may request an amendment.

The same is true if the universal takeover concerns one of your linked third parties.

How?

An amendment request must be **prepared** by the **coordinator**, normally by filling out the forms **directly in the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

Specific case:

A request to **change the coordinator** (against the coordinator's will) can be submitted by any beneficiary (acting on behalf of the others).

⚠ If none of the available forms are appropriate, beneficiaries are advised to contact the Commission/Agency for the drafting of the request.

⚠ **Requests** for amendment must be unambiguous and complete and submitted **sufficiently in advance** (to allow proper analysis and preparation before they are due to take effect) and, generally, **before the end of the action** (i.e. the date set out in Article 3).

Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance).*

Once completed, the amendment request (with all its supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator. (⚠ The coordinator submits and signs on behalf of the other beneficiaries; *see Annex 3*).

Coordinators must ensure internally that they have the agreement of the consortium, on the basis of their internal decision-making processes *(e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement)*.

⚠ Don't forget:

- for new beneficiaries (or linked third parties): to ensure that they have obtained all necessary validations in the 'Beneficiary Register'

Example:

Validation of the new bank account, to change the bank account

Legal entity validation, to add a new beneficiary that is not yet validated. This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

– to include the necessary information and supporting documents (as required for certain amendments)

Examples:

For a change of coordinator without his/her agreement, the coordinator's opinion (or written proof that this has been requested).

To add a new beneficiary, an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

To amend Annexes 1 and 2, amended versions of these annexes.

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

The coordinator may at any moment **withdraw** the amendment request (before it has been accepted or rejected). However, it cannot be *change*d (without withdrawing it and submitting a new one).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

ⓘ *For more information on the preparation and submission procedure, see above point 1.*

⚠ Beneficiaries are advised to contact the Commission/Agency beforehand (via the 'Messages' function of the electronic exchange system), in order to discuss the amendment.

The other party must — within 45 days — agree or disagree, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

If there is **no reaction** within this deadline, the request is considered to have been rejected (⚠ new in Horizon 2020: contrary to FP7, there is no tacit approval of amendments). A new amendment request may be submitted (even if it fully or partly repeats the initial request).

A request containing several changes to the GA will be considered as a **package** that cannot be divided into several requests. The request will be agreed or rejected by the other party as a whole.

If, the receiving party requests additional information/documents a new deadline will apply, i.e. 45 days from receipt of the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may be extended by the Commission/Agency — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

⚠ A signed and submitted amendment requests (including supporting documents) cannot be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

Unless the parties agree otherwise, the amendment will **take effect** (i.e. the modifications to the GA will start to apply) on the day of entry into force of the amendment.

If the parties agree on another date, it should normally be *after* the entry into force. In justified cases it may be before (retroactivity of the amendment). (⚠ In certain cases, the GA itself provides for retroactivity.)

Examples (retroactivity foreseen in the GA):

Where a new beneficiary or linked third party is added to the GA, it must assume the rights and obligations from the date of its accession specified in the Accession Form. This retroactivity implies that its costs will be considered eligible as from the date of its accession to the GA (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

⚠ Depending on the nature of the modification, the date of taking effect may have an impact on the eligibility of costs.

If an amendment request involves a number of changes, these could take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA, by the beneficiaries mentioned in the Preamble

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Specific case:

For mono-beneficiary actions, replacing the beneficiary during the action implementation is only possible under exceptional circumstances *(e.g. the beneficiary transfers all its rights and obligations, including those related to the action, to another legal entity).*

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated (unless it already has a validated Participant Identification Code (PIC))
- sign the Accession Form directly in electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an amendment for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned])*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for international organisations (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[70]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the *Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States*, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN system (⚠ new in Horizon 2020).

It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU-arbitration clause, referring disputes on the interpretation, application or validity of the GA to the Court of Justice of the European Union.

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This

[70] *See Article 180(1) of the Rules of Application.*

referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[71]).

If a dispute is of public law nature (i.e. concerns offsetting or an enforceable decision under Article 299 TFEU), actions must be brought before the Court of Justice of the European Union not under Article 272, but under Article 263 TFEU.

[71] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

II. ERC

II.1 Background information and approach

The ERC General Model Grant Agreement ('ERC General MGA') is used for the following ERC grants ('frontier research grants'):

- ERC Starting Grants (StG)
- ERC Consolidator Grants (CoG)
- ERC Advanced Grants (AdG)
- ERC Synergy Grants (SyG).

The ERC General MGA is not used for ERC PoC and ERC low value grants (which have specific MGAs; *see below*).

⚠ ERC grants are open to **principal investigators** (PIs) of any nationality who intend to conduct a **frontier research project** in a Member State or associated country and which are hosted by a host institution that is based in an EU Member State or associated country and can receive EU funds.

ⓘ *For more information on ERC actions, see Article 2.*

ⓘ *For information on ERC funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on ERC standard eligibility criteria, see the ERC calls conditions of the ERC Work Programme.*

The ERC General MGA follows the General MGA for numbering and content, except for the following:

Introductory remark all ERC MGAs

The ERC Model Grant Agreements deviate from the General Model Grant Agreement as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
-
- The table of contents is adapted
- Cross-references in the footnotes are adapted

Introductory remark ERC General MGA

The ERC General Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

Introductory remark ERC PoC MGA

The ERC PoC Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

ERC frontier research grants are however different from General MGA grants because:

- EU funding is granted to an individual action proposed by a Principal Investigator (PI) (or several, in the case of SyG), while

- the grant is signed between the Agency on one side and the beneficiaries on the other, one of which is the host institution of the PI and his/her research team.

⚠ By signing the GA, the beneficiaries take on a series of obligations towards the PI and the research team. In order to participate in the action, the PI must sign a supplementary agreement (SA) with its host institution where s/he also takes on a series of rights and obligations *(see Article 32)*.

ERC PoC grants are then follow-up grants to explore the innovation potential of results generated in a previous ERC frontier research grant.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC actions)
- Article 4.1 (ERC budget categories)
- Article 6 (ERC eligible and ineligible costs)
- Article 8 (ERC rules on third party involvement).

Since the ERC General MGA and the ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC PoC MGA will be limited to major differences from the ERC General MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 ERC General MGA: Annotations

ERC MULTI-BENEFICIARY MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][1],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname], hosting [and engaging] the following

***[OPTION by default:** 'principal investigator':*

*- [**Name**][Date and place of birth][2]*

***[OPTION for SyG:** 'corresponding principal investigator':*

*- [**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),****]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called 'principal beneficiary'.

Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that host (or employ) a principal investigator ('host institution').

The PI is usually employed by the host institution.

Exceptions:

A PI may be employed by a third party. In this case, the third party must also sign the supplementary agreement *(see Article 32)* and agree to the obligations included in it.

Retired researchers, in case the PI is no longer under an active labour contract.

ⓘ For more information on arrangements for signature and third parties, see the preamble of the General MGA.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

⚠ Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities.

PIs must be supported by their host institution during the entire duration of the action.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions, must sign a supplementary agreement (SA) *(see Article 32)*.

⚠ In the case of ERC Synergy grants (with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

⚠ ERC PoC grants do not require a supplementary agreement.

⚠ ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI').

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERC actions

ERC actions are mono- or multi-beneficiary actions with the following activities:

– any type of frontier research activity in any field of research (except nuclear energy; see the ERC calls conditions of the ERC Work Programme).

What? ERC grants fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

ⓘ For examples of successful ERC actions, see the ERC website[72].

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

[72] Available at http://erc.europa.eu/erc-stories.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC General MGA uses in principle the **same budget categories** as the **General MGA**.

Budget categories of the ERC General MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences (compared to the General MGA):

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs *for the action* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(f) for **direct personnel costs** *[(excluding personnel costs for activities in Point (f))]*[5]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(g) for **direct costs of subcontracting** *[(excluding subcontracting costs for activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(h) *not applicable;*

(i) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(j) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

[…]

[5] To be used only if option in Point (f) is used.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC calls conditions of the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are the **same** as in the **General MGA** *(see Article 5 General MGA)*.

Exception:

The ERC General MGA does not use the same **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, the ERC General MGA uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[73]

However, the unit costs for the 'specific categories of costs' of the General MGA do not apply.

[73] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 General MGA)* (with the exception of 'direct costs of providing financial support to third parties', 'specific categories of costs' and 'costs for providing access to trans-national research infrastructure').

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

Specific cases:

For **direct personnel costs**:

⚠ Costs for 'teaching buy-outs' are not eligible: if the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, they cannot declare the costs related to these substitutes.

If the **PI** is exceptionally **engaged by a third party** (which pays his/her salary) and seconded to work on the premises of the beneficiary (against reimbursement by the beneficiary), the **salary costs** may be declared as direct personnel costs (costs of personnel seconded by a third party).

⚠ In this case, the supplementary agreement must be signed by the PI, the host institution *and* the third party.

For **other direct costs**:

For ERC actions, **recruitment costs** are eligible as other direct costs because recruitment is one of the action's activities.

⚠ Recruitment costs are not considered as one of the action's activities for PoC.

⚠ As in actions under the General MGA, for ERC actions the **purchase of scientific publications** *(e.g. books, manuscripts, articles, digital copies, etc.)* needed for the implementation of the action may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Given the increasing emphasis on the protection of inventions, the PIs are encouraged to **protect** their **intellectual property rights properly** and the related costs are considered eligible.

Costs related to open access (to publications – including monographs – and research data) are eligible during the duration of the action. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (it cannot be with other beneficiaries or linked third parties).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies*: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.****]***

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 General MGA)*.

In addition, the beneficiaries must however prove that the conditions concerning the time-commitments of the PI for implementing the action (as described in Annex 1) have been complied with.

Thus, they must be able to provide evidence that the PI dedicated the minimum time commitment (i.e. percentage of the total working time, i.e. percentage of the annual productive hours calculated in compliance with Article 6) to the action, via time sheets or alternative time recording system.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

Moreover, they must be able to provide evidence that the PI spent the minimum time commitment *in a Member State or associated country* (i.e. a Member State or an associated country), via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

⚠ Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) scientific and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

ⓘ For more information on how to submit the reports, see Article 20 General MGA and the H2020 Online Manual.

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC General MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies - make the pre-financing payment to the principal beneficiary within 30 days ***[OPTION:*** *from the entry into force of the Agreement (see Article 58)****][OPTION:*** *from the starting date of the action (see Article 3)****][OPTION:*** *from the 45th day before the starting date of the action (see Article 3)****]***.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([****insert amount*** *(insert amount in words)] is not paid to the principal beneficiary, but kept by the [Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90 % of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90 % of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90 % of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the principal beneficiary
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

[…]

1. Payments

For ERC actions, the same rules on payments apply as in the General MGA *(see Article 21 General MGA)*.

There is however an additional option for pre-financing payments. These cannot only be foreseen within the 30 days from:

- the starting date of the action (see Article 3) or
- from the date of entry into force of Grant Agreement (see Article 58)

but also

- from the 45th day *before* the starting date of the action (see Article 3)), if the action starts late (well after the entry into force of the GA).

⚠ In any case, it is not possible to make a payment before the GA is signed.

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Rights of third parties

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 General MGA)*.

⚠ Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

[…]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

*[OPTION: **not applicable**]*

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

Examples: *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

For publications issued after the end of the action, beneficiaries are not obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

For bibliographic metadata, the ERC General MGA foresees lighter requirements, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[74] or other systems).

⚠ As far as the chosen repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

For ERC actions, there is no formal requirement for a '**data management plan**'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

[74] *For more information, see http://www.doi.org/.*

The exception allowing beneficiaries not to give access to specific parts of research data applies not only if this would jeopardise the main objective of the action, but any one of the action objectives.

⚠ For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[32] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a)

[…]

[32] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC General MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of intellectual property rights
- Allow for transfer of the GA to another host institution (**portability**).

⚠ PIs cannot be prevented from applying independently (i.e. in their own name) for further EU funding for other actions. They can also apply for further EU funding for the same action, as long as it is for costs that are not eligible (or not declared) under the ERC grant.

In this context, 'action' refers to the specific ERC action, for which the beneficiaries receive the ERC grant *(see Article 2)*.

⚠ The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ⓘ For more information on combining EU funding for different actions ('complementary EU funding'), see the H2020 Online Manual.

2. Supplementary agreement — Obligations on the PI

The ERC General MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also vis-à-vis the PI.

The supplementary agreement should cover all the practical issues that may arise in the context of the grant implementation, and in particular the ones listed in Article 32.1(b).

Model clauses for supplementary agreements are available on the Participant Portal and the ERC website. [hyperlinks]

Host institutions and their PIs may add or use other clauses, if they benefit the research action and do not contradict the GA. Provisions that contradict the GA are considered void and may not be opposed to the Agency.

⚠ The supplementary agreement must be concluded before the GA is signed (and a copy must be sent to the Agency).

It does not replace an employment or collaboration contract between the PI and its host institution (which remain necessary under national labour and social laws).

Specific cases:

In the case of **ERC Synergy grants** (with **several PIs**), each host institution must conclude a supplementary agreement with the PI(s) they engage.

ERC PoC grants do not require a supplementary agreement.

In case of transfer of the Agreement to another host institution (**portability**; *see Article 56a*), the PI must sign a new supplementary agreement with its new host institution and forward it to the Agency. The GA cannot be amended before the PI has sent this new supplementary agreement.

Via the supplementary agreement, the PI must take on a number of obligations, to ensure the smooth implementation of grant.

Main obligations (of the PI):

- Supervision of the scientific and technological implementation of the action
- Responsibility for the scientific reporting for the beneficiary and contribution to the financial reporting
- Meeting the time commitments for implementing the action
- Applying the beneficiary's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the visibility of EU funding
- Upholding the intellectual property rights of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.

- Maintaining confidentiality

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(c) display the EU emblem and the ERC logo and

(d) include the following text:

"This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem and the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

Guidance on the use of the ERC logo is available on the ERC homepage[75].

[75] Available at http://erc.europa.eu/logos-and-banners.

MULTI-BENEFICIARY: **ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the Agency has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: **ARTICLE 56 — ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: [...][...][...][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 General MGA)*.

However, unlike the General MGA, ERC ***mono*-beneficiary** grants can **become *multi*-beneficiary** grants, by addition of a new beneficiary.

The procedure to be followed is that of Article 56 of the General MGA.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

Upon request by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

Portability makes it possible to transfer ERC grants — at any time during the action implementation.

The PI may **request a transfer** of his/her grant to any other entity based in an EU Member State or associated country ('new host institution'), if doing so is beneficial for the PI and supports achieving the action's objectives.

Specific case:

For **ERC Synergy Grants**, each PI maintains the right to transfer their part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

If **certain team members** or **equipment remain** with the former host institution, that institution may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

Thus, both host institutions must agree on the transfer of intellectual property, in conformity with the GA and after consulting the PI. The transfer plan should cover:

- the results produced under the action and the access rights to them and
- the PI's and new host institution's access rights to background held by the former host institution but necessary for implementing the rest of the action.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs are advised to keep records of the consultation and decision-making process for each portability case.

The former host institution must then submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 General MGA)*.

A change of beneficiary usually takes effect on the first day of the month.

This date may be retroactive, but only in very exceptional circumstances. This should be discussed on a case by case basis with the Agency.

⚠ The request should be made well in advance, to allow sufficient time for the amendment procedure.

⚠ The GA cannot be transferred without the explicit agreement by the Agency *and* the amendment of the GA. Any partial or full transfers made without a formal amendment to the grant agreement are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** all **remaining pre-financing** (not covered by eligible costs) to the new host institution.

⚠ If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will not pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary).

⚠ Scientific reporting periods will usually remain unchanged as they are linked to the action's scientific development and must be submitted by the PI, who holds this position for the whole duration of the GA.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law.

It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

II.2 ERC PoC: Annotations

⚠ The ERC PoC MGA is very similar to the ERC General MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however no specific provisions on the working conditions of the PI and his/her team, no supplementary agreement and no grant portability

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC General MGA apply mutatis mutandis.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERC PoC actions

ERC PoC actions are actions with the following activities:

– verifing the innovation potential of ideas arising from ERC funded projects

What? Any activities (that were not scheduled to be funded by the initial ERC frontier research grant) but that develop research output towards new commercial or societal applications.

ERC PoC grants can cover very diverse activities *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

What not? ERC PoC grants cannot cover activities under the ERC frontier research grant (*e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential*) or activities which are the result of research not performed under the ERC actions (*e.g. results of research not found by the ERC action*).

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) report(s), including requests for payment.

The report(s) must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP):

20.2 Reporting period

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)**]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]

***[**- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].**]***

20.3 Periodic reports — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(f) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *Agency* may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Agency*, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What ?

For ERC PoC actions, the principal beneficiary must submit reports — only one 'report' if there is one reporting period, otherwise one 'periodic report' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  ⚠ The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

⚠ Only at the moment of the submission of the last reporting period, the 'certificate on the financial statements' will have to be added.

How?

All reports mut be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' section of the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period (and thus the duration of the action) lasts **18 months**.

If provided in the GA, an ERC PoC action may however also have more reporting periods.

IV. SME Instrument

IV.1 Background information and approach

The Model Grant Agreements for the SME Instrument ('SME Instrument MGAs') are used for grants for **SME Instrument actions only** *(see General Annex D to the Main Work Programme)*.

The SME Instrument funds actions in different phases.

The minimum requirement for participation is one for-profit SME (as defined in the SME Recommendation 2003/361/EC), established in an EU Member State or associated country

'For profit' means not a non-profit legal entity (i.e. not an entity that is by its legal form non-profit-making or has a legal or statutory obligation not to distribute profits to its share-holders or members).

⚠ If the Work Programme/call, exceptionally foresees SME Instrument Ph2 actions that predominantly concern research activities, they will be considered 'research and innovation action (RIA)' actions and will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ⓘ For more information on SME Instrument actions, see Article 2 SME Instrument MGAs.

ⓘ For information on SME Instrument funding opportunities, see the 'Search Topic' function on the Participant Portal.

ⓘ For information on SME Instrument standard eligibility criteria, see General Annex C to the Main Work Programme.

ⓘ For more information on the procedure for SME status validation, see the H2020 Online Manual.

The SME Instrument MGAs **follow the General MGA** for numbering and content, **except** for the following:

Introductory remark SME Instrument Ph1 MGA

The SME Instrument Phase 1 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 4.1 (SME Instrument Ph1 estimated budget of the action)
- Article 5.1-5.3 (SME Instrument Ph1 maximum grant amount, specific reimbursement rate and form of costs, no Step 2 'limit to maximum grant amount', no Step 3 'reduction due to the no-profit rule')
- Article 6 (SME Instrument Ph1 specific conditions for eligibility of costs)
- Article 7 SME Instrument Ph1 consequences of improper implementation)
- Articles 8, 11, 12, 14, 15, 16, 23a - 33, 37, 39 (not applicable)
- Article 10 (SME Instrument Ph1 specific provision for purchases)
- Article 13 (SME Instrument Ph1 specific provision for subcontracting)
- Article 18 (SME Instrument Ph1 specific provision for record-keeping)
- Article 20 (SME Instrument Ph1 specific reporting provisions)
- Article 21 (SME Instrument Ph1 specific payment provisions)
- Article 36 (SME Instrument Ph1 specific provision on confidentiality)

- Article 38 (SME Instrument Ph1 specific provision on promoting the action)
- Article 42.2 (SME Instrument Ph1 specific provision for lump-sum
- Article 50.1.2, 50.3.3 (SME Instrument Ph1 specific provision for lump-sum

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

Introductory remark SME Instrument Ph2 MGA

The SME Instrument Phase 2 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 5.2 (SME Instrument Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Instrument Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Instrument Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 SME Instrument Ph1 MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Instrument Ph1:
- Article 2 (SME Instrument Ph1 actions)
- Article 8 (SME Instrument Ph1 rules on third party involvement)

For SME Instrument Ph2:
- Article 2 (SME Instrument Ph2 actions)
- Article 4.1 (SME Instrument Ph2 budget categories)
- Article 6 (SME Instrument Ph2 eligible and ineligible costs)
- Article 8 (SME Instrument Ph2 rules on third party involvement)
- Article 20 (SME instrument Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since that is most common for SME Instrument actions. The differences between mono and multi-beneficiary versions are marginal.

IV.2 SME Instrument Phase 1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** (**'action'**), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]]***.]**

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.***]***

1. SME Instrument Ph1 actions

SME Instrument Ph1 actions are mono- or multi-beneficiary actions with the following activities:

– making a feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service)

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a 'technology readiness level' of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc)*.

⚠ The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph2 actions, see Article 2 SME Instrument Ph2 MGA.

ARTICLE 4 — ESTIMATED BUDGET

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the form of costs (see Articles 5 and 6).

1. Budget category

The SME Instrument does **not** use the **budget categories** of the **General MGA**.

Since SME Instrument Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Instrument Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

⚠ The budget category is relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The grant amount for SME Instrument Ph1 actions is fixed as a **lump sum** of **EUR 50 000**.

The lump sum is provided for by Commission Decision C(2013) 8198[76], for all SME Instrument Ph1 actions.

The amount of EUR 50 000 stays the same, both for multi-beneficiary and mono-beneficiary actions.

It is deemed to reimburse 70 % of the action's total eligible costs (that are in turn set by this Decision at EUR 71 429).

If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ No other costs will be reimbursed; the lump sum is deemed to cover all (direct or indirect) costs that may have been incurred for the feasibility study.

⚠ The SME Instrument Ph1 MGA does not use any of the **unit costs** and **flat-rates** of the General MGA.

The conditions for eligibility are set out in Article 6.

[76] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to improper implementation or breach of other obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

[…]

1. Calculation of the final grant amount

For SME Instrument Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is no:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

A. Costs for the feasibility study (direct and indirect costs) are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Instrument Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 The budget category 'costs for the feasibility study' **covers** the costs for the feasibility study for the innovation idea *(see Article 2)*.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[77] and set out in Annex 2 of the GA (currently **EUR 71 429** per action).

This lump sum is deemed to cover all (direct and indirect) eligible costs that may have been incurred for the feasibility study.

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 No **calculation** is necessary.

The beneficiaries must declare the amount of EUR 71 429 as the total eligible costs of the action; they cannot declare the costs actually incurred. The final financial report and individual financial statement are therefore automatically pre-filled by the system *(see Article 20)*.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

1. Consequences of improper implementation

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation does not always lead to the reduction of the grant, but leads to the ineligibility of the costs (namely, if the improper implementation consists in non-compliance with Annex 1; *see Article 6*).

If the action is not carried out as described in Annex 1, costs will be rejected proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

By contrast, if other provisions of the GA or provisions of EU, international and national law are not complied with, the grant may be reduced.

[77] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Instrument Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs for purchases and subcontracts are covered by the lump sum.

⚠ In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) are **not** allowed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Instrument Ph1 actions are almost identical to the General MGA *(see Article 13 General MGA)*.

Since SMEs are not contracting authorities, there is however no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph1 actions are similar to the General MGA *(see Article 13 General MGA)*.

Subcontracting is however not restricted to a limited part of the action.

Moreover, the estimated costs do **not** have to be included in Annex 1or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are **not** considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ⓘ For more information on the characteristics of subcontracting and best value for money, see Article 13 General MGA.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Instrument Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit the report

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) the **final report**, including a request for payment.

The report must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing an '**individual financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The individual financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME instrument Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial report and statement are automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

⚠ For multi-beneficiary actions, each beneficiary must fill in an individual financial statement (in order to certify conformity of the costs declared). This does not however change the EU contribution requested (which remains one single lump sum of EUR 50 000 for the whole consortium).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made — No interim payments

For SME Instrument Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are no interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Instrument Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(f) the disclosing party agrees to release the other party;

(g) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(h) the recipient proves that the information was developed without the use of confidential information;

(i) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(j) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Instrument Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(e) display the EU emblem and

(f) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

Not applicable

38.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Promoting the action — Visibility of EU funding

The SME Instrument Ph1 MGA foresees lighter requirements for promoting the action and acknowledgment of EU funding.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

[…]

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

[…]

1. Calculation of the ineligible costs to be rejected

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation leads to the ineligibility of the costs *(see Article 7)*.

If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

ARTICLE 50 — TERMINATION OF THE AGREEMENT

[…]

50.1 Termination of the Agreement, by the beneficiary

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

[…]

50.3 Termination of the Agreement, by the *[Commission][Agency]*

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

1. Termination of the Agreement

For SME Instrument Ph1 actions, the same rules on termination apply as in the General MGA *(see Article 50 General MGA)*.

⚠ Improper termination by the beneficiary will however lead to a 100% reduction of the grant.

IV.3 SME Instrument Phase 2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a ‘**complementary grant**’ to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a ‘**jointly funded action**’ which must be coordinated with the ‘joint action’ called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. SME Instrument Ph2 actions

SME Instrument Ph2 actions are actions with the following activity:

– implementing an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication).

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a ‘technology readiness level’ of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

⚠ An project may be funded in Phase 2 even if it was not funded in Phase 1.

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph1 actions, see Article 2 SME Instrument Ph1 MGA.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The SME Instrument Ph2 MGA uses the **same budget categories as** the **General MGA**.

Budget categories of the SME Instrument Ph2 MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences compared to the General MGA:

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(k) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(l) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(m) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(n) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*: as actually incurred costs (**actual costs**);

(o) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

***[**(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]*[1]*]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

1. Reimbursement rate

How much? For SME Instrument Ph2 actions, the reimbursement rate is normally set at 70% *(see General Annex D to the Main Work Programme)*.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs.
.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Eligible costs — Ineligible costs

The SME Instrument Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

Exception:

The SME Instrument Ph2 MGA does not reimburse:

- 'direct costs of providing financial support to third parties'
- 'specific categories of costs'.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Instrument Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [1].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph2 actions are similar to those of the General MGA *(see Article 13 General MGA)*.

However, subcontracting is not restricted to a limited part of the action.

Moreover, for the SME Instrument Ph2, the Commission/Agency will assess compliance with best value for money during the evaluation of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

⚠ If you know the subcontractor, include the key information on the award procedure for the subcontract in the proposal (name of subcontractor, price and object), together with the action task(s) that will be subcontracted and an explanation why the subcontractor and the price are appropriate.

⚠ If you do not know the subcontractor, your proposal should set out the task(s) to be subcontracted, the estimated budget and the procedure you will follow to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits (unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

ⓘ For more information on evaluation, see the H2020 Online Manual.

Finally, for SME Instrument Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Instrument Ph2 actions are normally the same as for the General MGA *(see Article 20.2 General MGA)*.

The reporting periods may however be adapted to reflect the duration of the action. Thus, if considered necessary, SME instrument Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

1. Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example****: if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

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V. ERA-NET Cofund

V.1 Background information and approach

The Model Grant Agreement for ERA-NET Cofund ('ERA-NET Cofund MGA) is used for grants for **ERA-NET Cofund actions only**.

⚠ ERA-NET Cofund grants are open only to **research funders** (i.e. legal entities owning or managing research and innovation programmes).

'Programme owners' are typically national/regional ministries or authorities responsible for defining, financing or managing national/regional research programmes.

'Programme managers' are typically research councils, funding agencies or other national/regional organisations that implement research programmes under the supervision of the programme owners.

The minimum requirements for participation are 3 independent research funders established in different Member States or associated countries.

ⓘ For more information on ERA-NET Cofund actions, see Article 2.

ⓘ For information on ERA-NET Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.

ⓘ For information on ERA-NET Cofund standard eligibility criteria, see General Annex C to the Main Work Programme.

The ERA-NET Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for ERA-NET Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 ERA-NET Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1.ERA-NET Cofund actions

ERA-NET Cofund actions are actions with the following activities:

- the preparation, implementation and follow-up of a single joint call for proposals for trans-national research and/or innovation projects

  ⚠ Only one co-funded call per GA.

  There are two ways of implementing the joint call:

  - by **providing financial support to third parties**

    This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties.

    Most ERA-NET Cofund actions are implemented in this way.

  - by **implementation of the trans-national projects by the beneficiaries**

    This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding. Beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  What? The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  ⚠ These activities must be *in addition* to implementing a joint call.

⚠ If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do not apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[the first day of the month following the date the Agreement enters into force (see Article 58)] [insert date]*[4] ('starting date of the action').

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Duration of the action

For ERA-NET Cofund actions, the duration is usually **60 months**.

⚠ This time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects, which typically takes 36 months.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*).

⚠ Normally, the action's duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its **own budget categories**.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries
  - direct subcontracting costs for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities
- indirect costs

Differences (compared to General MGA):

- No 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- No 'costs for providing trans-national or virtual access to research infrastructure'
- No 'specific categories of costs'

⚠ These budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[…%] of the action's eligible costs* (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (unless declared as unit cost)
  - **subcontracting** costs for implementing the trans-national projects

- **other direct costs** for implementing the trans-national projects

❖ **unit costs** for:

- direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
- direct **coordination costs** for additional activities[78]

❖ **flat-rate costs** for:

- **indirect costs**

[78] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for of additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[5] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(d) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(e) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(f) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(d) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(e) the result of the work carried out belongs to the beneficiary, and

(f) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[6] *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

5 For the definition, see Article 2.1(14) of Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

6 '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

7 For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form —Conditions for eligibility — Calculation

1.1 The budget category 'direct costs related to trans-national projects' **covers** the following **types of costs**:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration — basic salary and complements
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract and
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries

- other direct costs for the implementation of trans-national projects by the beneficiaries:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure.

What not? The ERA-NET Cofund MGA does not reimburse:

- 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- 'costs for providing trans-national or virtual access to research infrastructure'
- 'specific categories of costs'

⚠ No indirect costs for providing financial support to third parties.

1.2 All costs (except direct personnel costs) must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

In some Articles, the conditions in the General MGA must however be read as referring to 'trans-national projects' (instead of 'action').

For financial support to third parties, there are moreover additional eligibility conditions in Article 15 *(e.g. selection procedure, compliance with national funding rules)*.

⚠ For financial support to third parties, costs are usually eligible only after the trans-national projects have ended.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA*).

B. Direct coordination costs of additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see Article 2)*.

1.2 These costs must be declared on the basis of the **unit cost** fixed by Commission Decision C(2013) 8200[79] and set out in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

⚠ If the beneficiaries do not properly implement the additional activities set out in Annex 1, the grant may be reduced *(see Article 43)*.

Example: Beneficiaries make only two meetings on general strategy.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

⚠ Beneficiaries that implement trans-national projects cannot declare coordination costs for additional activities.

1.4 They must be **calculated** as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU contribution to coordination costs should not exceed 20% of the maximum grant amount.

[79] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[8] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[8] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, the same rules apply as in the General MGA *(see Article 6 General MGA)*.

The eligible direct costs (on which the flat-rate is calculated) include:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

⚠ They do not include direct costs of providing financial support to third parties implementing trans-national projects.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, in principle the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however **only** allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all action activities *(see Article 2)*.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(f) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(g) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**;

(h) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to third parties ('cascade grants')).

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties that actually implement research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

2. Additional eligibility condition: Two-step selection procedure

A two-step procedure is necessary to ensure that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating Member State and associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to the expert evaluators, the consortium must appoint an independent expert as an observer, to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The selection of trans-national projects ('**joint selection list**') must be based on the order of the ranking list (or the ranking lists, if there are different topics).

⚠ If proposals have identical scores, the proposals coming from participating Member States or associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

5. Additional eligibility condition: Compliance with national funding rules

Financial support to third parties must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the third parties) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

The beneficiaries must comply with the maximum amount and the criteria for determining the exact amount under national funding rules that are set out in Annex 1.

⚠ This information must already be part of your proposal *(see Table 4.1 of the Standard proposal template ERA-NET)*. If national funding rules do not specify a maximum amount, the beneficiaries should enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *The coordinator must submit: in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency]**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects, with the required information.

Example: *data on each participant and abstracts of the project proposals.*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects.

Example: *data on each participant and an overview of the results.*

⚠ The Commission/Agency will contact you to give you information on the format to be used (and where to find it) and how to submit the deliverables.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[16]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[17]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the *[Commission's][Agency's]* accounting purposes and will not be used to calculate the final grant amount.

[…]

[16] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[17] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? Normally, ERA-NET Cofund actions are divided into **2 reporting periods** (with two pre-financing payments; *see Article 21*).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][18], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] [19], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

[18] Should correspond to 10% of the maximum grant amount (see Article 5.1).
[19] Should be 80%, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, ERA-NET Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10% of the maximum grant amount
- the second pre-financing payment is 80% of the maximum grant amount.

Exception:

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10% for the first pre-financing payment
- 40% for the second pre-financing payment
- 40% for the third pre-financing payment.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full

– if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund

VI.1 Background information and approach

The Model Grant Agreement for PCP-PPI Cofund ('PCP-PPI Cofund MGA') is used for grants for **PCP-PPI Cofund actions only**.

⚠ PCP-PPI Cofund grants are only open to **actions** that have as main objective to implement a **pre-commercial procurement or a public procurement of innovative solution**. The minimum requirements for participation are 3 independent legal entities established in different Member States or associated countries and 2 independent legal entities that are public procurers from different Member States or associated countries (unless they are sole participants; *see General Annex D to the Work Programme*).

ⓘ *For more information on PCP-PPI Cofund actions, see Article 2.*

ⓘ *For information on PCP or PPI Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on PCP-PPI Cofund standard eligibility criteria and specific provisions, see General Annex C, D and E to the Main Work Programme.*

The PCP-PPI MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for PCP-PPI Cofund deviates from the General Model Grant Agreement as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation] [Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of financial resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 PCP/PPI Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. PCP/PPI Cofund actions

PCP/PPI Cofund actions are actions with both of the following activities:

– a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI) and its implementation

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'.

The suppliers do not become beneficiaries of the GA.

'Implementation' means implementation of the subcontracts ('subcontract implementation stage')

⚠ Only one co-funded PCP or PPI per GA.

– related additional coordination and networking activities.

What? The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

Examples: *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

⚠ It is mandatory (both for PCP and PPI Cofund actions) to include not only a PCP/PPI itself, but also those coordination activities that are needed to coordinate the PCP/PPI procurement. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

ⓘ *For more information on which activities are required and which ones are optional, see General Annex D and E to the Main Work Programme.*

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the lead procurer he pays all subcontractors)

  ⚠ This implies that the consortium must have a common jointly-committed budget and that the lead procurer is mandated to sign the subcontracts *(see Article 13)*.

- or the members of the buyers group.

  ⚠ This implies that the individual members of the buyers group pay the subcontractors pro rata *(see Article 13)*.

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  ⚠ Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities:
  - direct personnel costs for related additional coordination and networking activities
  - direct subcontracting costs for related additional coordination and networking activities
  - other direct costs for related additional coordination and networking activities
  - indirect costs for related additional coordination and networking activities
  - specific categories of costs for related additional coordination and networking activities (if option applies).

Differences (compared to General MGA):

- No 'direct costs of providing financial support to third parties'.

⚠ These budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs for the activities in Point (f))]*[5]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs of subcontracting for related additional coordination and networking activities** *[(excluding subcontracting costs for the activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

[(f) [OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of [insert cost category or activity**[9]*]:

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[10] *[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of [insert cost category or activity]**: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.
10 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rates

How much? The Work Programme *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs of related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

⚠ Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are not eligible under PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1 *(see Article 13)*
- fulfil the additional eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs of related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[11]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Types of eligible personnel costs

B.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[12] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[*B.1.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not included in Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not included in Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[1]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure:** Costs of other goods and services **for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.**]

[OPTION to be used for virtual access to research infrastructure:** Costs of other goods and services **for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.**]

B.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[1] *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[1]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *not applicable.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises*[;]* ***[****and*

(c) ***OPTION if Point B.5 applies and that unit or lump sum cost includes indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][lump sum costs under Article 5.2(f) and Point B.5]****]****.*

Beneficiaries receiving an operating grant[1] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[*B.5* ***OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]***

Costs of [insert cost category or activity]:

(a) declared as ***unit costs****: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

(b) [declared as ***actual costs****: are eligible, if they comply with the conditions set out above (Points B.1 to [B.3][B.4]) [and if [insert eligibility conditions];]*

(c) [declared as a ***combination of the two****: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[*same for each specific category of costs****]***

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity] *are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the related additional coordination and networking activities have been properly implemented in accordance with Annex 1.]****]***

[…]

[11] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[12] For the definition, see Article 2.1(14) of the Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[13] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[14] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[15] For the definition see Article 2(6) of the Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[16] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

1.1 The budget category 'costs of related additional coordination and networking activities' **covers** the following **types of costs**:

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration — basic salary and complements
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party
  - costs of 'beneficiaries that are SMEs for their owners not receiving a salary'
  - costs of 'beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies).
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific categories of costs for related additional coordination and networking activities.

What not? The PCP-PPI Cofund MGA does not reimburse:

– 'costs for providing financial support to third parties'.

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

Personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[80] and set out in Annex 2 of the GA. (⚠ This concerns only beneficiaries that are SMEs, not PCP/PPI subcontractors that are SMEs.)

Examples: *Contracting authorities or contracting entities that are SMEs.*

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

⚠ Costs incurred by the beneficiaries for validation and testing of solutions provided by the subcontractors are part of the follow-up and monitoring of the results of the PCP/PPI and as such considered eligible direct personnel costs.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

The General Annex D to the Main Work Programme specifies that the costs of related additional coordination and networking activities are eligible up to a **maximum** amount of 30%/50% of the total requested grant amount (for PCP/PPI actions).

For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*.Thus, the amount of EU funding earmarked to finance related additional coordination and networking activities does not change, even if it the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*). The EU funding is not automatically proportionally reduced.

[80] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however **only** allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting *(Article 13)* is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties *(Article 14)* can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[20] and 2004/17/EC[21].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

The beneficiaries concerned must ***prepare****,* ***procure*** *and* ***implement*** *the subcontracts in accordance with the following* ***requirements****:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common procurement specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[22];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP ;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*
- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common procurement specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[22] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

For PCP Cofund actions, the beneficiaries will award subcontracts for the PCP research and development services ('PCP R&D services') that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PCP subcontract' is a contract for the purchase of R&D services that is identified in Annex 1 as action task.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('**buyers group**'), with a joint procurement in **3 phases**

  The 'buyers group' is the group that finances and undertakes together the joint PCP procurement.

  For PCP/PPI Cofund actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[81])

  – that are established in two different Member States or associated countries *(see General Annex D to the Main Work Programme)*.

  ⚠ This is *in addition* to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different Member States or associated countries; *see General Annex C to the Main Work Programme*)

  Exceptionally, the Work Programme allows for the participation of sole participants *(see General Annex D to the Work Programme)*.

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  ⚠ The buyers group is not open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Other entities may be involved in the action as:

  – beneficiaries (or linked third parties) responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*

  – third parties providing in-kind contributions

  if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

  The PCP procurement is implemented in 3 phases.

  The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

[81] *See Directives 2014/24/EC and 2014/25/EC.*

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

❖ Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

⚠ The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

⚠ This does not extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' *(as used in the WTO GPA)*.

⚠ Supplies cannot constitute the majority of the contract value.

❖ All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

❖ **Joint procurement procedure** (i.e. joint call for tender, joint evaluation of offers and joint award) is **coordinated and led** by one beneficiary ('**lead procurer**')

The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[82]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  ⚠ The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')

- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

⚠ PCP subcontracting is not restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

⚠ There can only be one PCP, per PCP Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PCP subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States or associated countries**.

⚠ This includes R&D and operational activities (*e.g. research, development, testing, certifying solutions, etc.)*.

[82] *See Directives 2014/24/EC and 2014/25/EC.*

ⓘ *For more information on associated countries, see Article 25 General MGA.*

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves.

⚠ This obligation must be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

PCP subcontracts must be based on the **best value for money** criteria *(see Articles 10 and 13 General MGA)*.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

⚠ The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

- a **specific procurement procedure** must be followed

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*
  - the procurement must be preceded by an '**open market consultation**'

This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[83]).

A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

– the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

– the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

– the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PCP subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The **framework agreement** (with each selected subcontractor) must set out the framework conditions for all 3 phases of the PCP implementation, including:

– the practical set-up of the implementation of the subcontracts, in particular:

  – the number, duration and budget of the PCP phases

  – the minimum number of expected subcontractors per PCP phase

  – the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)

  – the process for monitoring of on-going R&D work and reporting obligations of subcontractors

[83] *See Directives 2014/24/EC and 2014/25/EC.*

  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

⚠ The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

  - the details of the PCP R&D services purchased by each buyer

– quantity and

– price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PCP.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

7. Other obligation: Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[84]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[85]) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ For more information on this obligation, see Article 13 General MGA.

[84] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*

[85] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[23], 2004/17/EC[24].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex** 1. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

***[OPTION:** not applicable]*

*(iii) prepare **common procurement specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common procurement specifications (see above), according to **best value for money** criteria and ensuring that the price corresponds to **market conditions**;*

*(iii) **Step 3**: **award the subcontract(s)** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);]*

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[1] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common procurement specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.]*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.']*

[23] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

[24] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries will award subcontracts for procuring the 'PPI innovative solution(s)' that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PPI subcontract' is a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

Exceptions:

There is no requirement to split the PPI procurement procedure in **phases**.

The buyers group may select one or more subcontractors.

The common challenge does not concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

⚠ PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure*[86]*)*.

Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

There is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

The subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.

If there is no mandate, the general rule is that:

- framework agreement(s) must be signed by all members of the buyers group together
- specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

⚠ PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

⚠ There can be only one PPI, per PPI Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

⚠ Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes

[86] *See Article 31 of Directive 2014/24/EC and Article 49 in Directive 2014/25/EC.*

are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

⚠ For PPI subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

Like PCP subcontracts, PPI subcontracts must:

- be based on the **best price-quality ratio**,
- have a price that corresponds to **market conditions**
- must follow the **specific procurement procedure** set out in the GA.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**'

    Exception:

    If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for an open market consultation procedure.

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

⚠ This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

– the buyers group and the lead procurer must prepare '**common procurement specifications**'

The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

– the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)*.

Exception:

If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for contract notice and a request for tender; a request for offers from at least 3 providers suffices.

⚠ The request must also be addressed to the providers that successfully completed the last PCP phase in the pre-ceding PCP Cofund action.

⚠ Do not forget to specify in the request for tenders the arrangements for intellectual property rights (for these arrangements*, see below point 4*) and the buyers' right to publish summaries of the results and the subcontractors' identities.

The request for tenders does not have to be published. It can be provided on request.

– the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

⚠ In case of framework contracts/agreements there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned**.**

Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots need to be deployed at different times and/or by different procurers.*

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PPI subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The subcontract(s) must specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate, unless in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  ⚠ The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

⚠ If the buyers group choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PPI.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. Other obligation: Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[87]) normally apply to PPI procurements.

Therefore, the lead procurer and the members of the buyers group that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ *For more information on this obligation, see Article 13 General MGA.*

[87] *See Directives 2014/24/EC and 2014/25/EC.*

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[1]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(including after the intermediate evaluations before the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [Y] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each project financed by the procurement**, including data on each contractor that participated in the procurement, an overview of the results (for publication and evaluation purposes) and an assessment by the buyers group of the final results of each participating tenderer (in terms of achieving the performance and functionality requirements of the initial tender specifications).
- any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (including data on each contractor that participated in the procurement and overview of the results)

⚠ Templates[hyperlink] are provided on the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[41]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[42]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions)**]*** ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure**]**;*

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of funds**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(a) an overview of the results and their exploitation and dissemination;

(b) the conclusions on the action, and

(c) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(a) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(b) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(e) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into **two** reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage (preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of funds — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of funds needed to pay the subcontracts*(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a statement on use of the previous pre-financing instalment *(see Annex 12)*.

  ⚠ This document includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  ⚠ It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][44], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][451], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

[44] Should correspond to the percentage of the maximum grant amount that is foreseen for the related additional coordination and networking activities related to the preparation of the call for tender (see Article 5.1).

[45] Should correspond to a maximum of 90% minus the amount of the first pre-financing payment, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; see Article 21) minus the amount of the first pre-financing payment).

Exception:

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

[…]

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

[…]

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund

VII.1 Background information and approach

The Model Grant Agreement for EJP Cofund ('EJP Cofund MGA') is used for grants for EJP Cofund actions only.

⚠ EJP Cofund grants are open mainly to **entities owning** or **managing research and innovation programmes** (and exceptionally other entities — if justified by the nature of the action —, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from both national and private sources). The minimum number of participants is five independent legal entities from different Member States or associated countries (unless they are sole participants; *see General Annexes C and D to the Work Programme*).

ⓘ *For more information on EJP Cofund actions, see Article 2.*

ⓘ *For information on EJP Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on eligibility criteria, see the Work Programmes.*

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for EJP Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Model for the annual work plan
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.F (Fusion Cofund programme action specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 EJP Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

EJP Cofund actions are actions with the following activity:

– implementing a joint programme of activities of coordinated national research and innovation programmes.

What? The joint programme of activities may range from research and innovation activities to coordination activities, training activities, dissemination activities and financial support to third parties.

> ***Examples:*** *NFRP7–2015 Integrating radiation research in the European Union; Fusion programme Cofund action (FEJP) (see sections A and B.1 Euratom Work Programme 2014-2015)*

What not? The EJP only funds joint programmes, not individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the Work Programmes, and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[4] (‘**starting date of the action**’).

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Duration of the action

For EJP Cofund actions, the duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55 General MGA*).

⚠ The action’s duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same **budget categories** as the **General MGA**.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies).

Differences (compared to the General MGA):

- For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are replaced by the following specific categories:
  - 'costs for mobility of personnel'
  - 'costs for fellowships for researchers'
  - 'access costs for research infrastructure'.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

***[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings', costs of 'mobility of personnel', costs of 'researcher fellowships', costs of 'access to research infrastructures (EURATOM)'.
11 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed — for each call or action — in the Work Programmes. It cannot exceed 70%[88].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Specific case:

For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), there are **different unit costs** for three 'specific categories of costs':

- costs for **mobility** of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for **fellowships** for researchers: monthly living allowance, mobility allowance and family allowance
- **access costs** for research infrastructure [89]

⚠ These unit costs replace the unit costs for the 'specific categories of costs' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 General MGA)*.

[88] *See Article 28(5) of the Rules for Participation.*

[89] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

F. direct personnel costs;
G. direct costs of subcontracting;
H. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
I. other direct costs;
J. indirect costs;
[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision**: costs of [insert cost category or activity*[1]*]].

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

For one specific EJP Cofund action, i.e. the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are however replaced by the other categories.

For ease of reference, the annotations for Article 6.2 will be limited to these specific categories of costs and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (g) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (h) a **summary progress report** *on* the activities carried out during the on-going reporting period.

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1.

⚠ Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*.

⚠ However, since the annual work plan for the next period must be agreed with the Commission/Agency before the start of activities for the next reporting period, it must be submitted 3 months (i.e. 90 days) in advance.

⚠ The annual work plan for the first reporting period must already be included in your proposal.

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan**.

⚠ The coordinator has **30 days** from the date of receipt of the request to submit a revised annual work plan.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

⚠ It should **not** contain an **analysis of *all* activities** carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

⚠ Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

⚠ Payment of the **second pre-financing** payment is not automatic. It must be **requested** in the statement on the use of the first pre-financing payment using the template in Annex 8.

ⓘ *For more information on the other provisions of this Article, see Article 20 General MGA.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]* ***[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Exception:

Large EJPs may benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The need for a second pre-financing payment will be assessed during the preparation of the GA.

⚠ If a second pre-financing payment is agreed, the Guarantee Fund retention (of 5% of the maximum amount of the grant) will be split between the two pre-financing payments.

The second pre-financing payment is not automatic but must be requested by the coordinator and supported by a statement on the use of the first pre-financing payment *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum amount of the grant

Exception:

Depending on the size and the needs of the EJP, the reimbursement rate in the Work Programme and the availability of Union funds, the pre-financing may be higher or lower.

In case of two pre-financing payments, the second pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the first pre-financing was insufficiently used:

- if 70% or more of the first pre-financing has been used: the second pre-financing is paid in full
- if less than 70% of the first pre-financing has been used: the second pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The Model Framework Partnership Agreement ('MFPA') and Model Specific Agreement ('MSGA') are used for framework partnerships (and specific grants under such framework partnerships) only.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement potential action (i.e. the FPA and SGAs).

They are established in a FPA and implemented by SGAs for specific actions. Both FPAs and SGAs are treated as grants for the purpose of the award procedure.

⚠ The minimum requirements for participation in FPAs will generally depend on the types of specific actions that are envisaged in the action plan.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals in the Work Programme and in the invitation to submit a proposal —) *(see Article 4 MFPA and Article 14 MSGA)*.

⚠ Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

ⓘ *For more information on framework partnerships and specific grants, see Article 2.*

ⓘ *For information on FPA funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on standard eligibility criteria for different types of specific actions, see General Annex C of the Main Work Programme.*

The MFPA and MSGA generally follow the General MGA for content, but with a different numbering:

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⚠ In addition, all references in the General MGA to 'beneficiary(ies)' are to be taken as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the MFPA or MSGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

VIII.2 Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission') ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname] [2],

and

on the other part,

1. 'the **coordinator**':

[full official name] [short name][legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. **[full official name] [short name]** [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[3]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model for the certificate on the methodology

[1] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
[3] The action plan should include the common objectives of the parties in compliance with the objectives stipulated in the Preamble and the types of activities covered under this Framework partnership, contributing to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Partners that have also signed an SGA become beneficiaries (i.e. a 'participant'[90] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

If you do not want to actively participate, you may participate as 'partner not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble to the SGA).

This means that you will not have to comply with some of the obligations under that SGA *(see Preamble MSGA)*

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

– the other partners sign the Accession Form *(see Article 62 MFPA and Annex 3)*.

[90] For the definition, see Article 2.1(15) of the Rules for Participation: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ Any amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2— ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in the action plan (see Annex 1))] [open to all applicants meeting the announced criteria]] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The Commission will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the Commission decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[4] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[5] Please use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

Framework partnerships may in principle be awarded in all areas of the Horizon 2020 Framework Programme.

⚠ Currently, framework partnerships are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and

coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

The partnership is based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership

  ⚠ For the objectives, please refer to the FPA call.

- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in the Work Programme.

⚠ Signing an FPA does not oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

⚠ The partners may continue to participate in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

2. Award of specific grants

The Specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  ⚠ Such calls are restricted to the consortia that have signed a FPA and will be in competition.

  Example: The Commission signs different FPAs for FET Flagships. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the Work Programme.

  The date must be set out in the action plan or in Article 2 of the FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

The Framework Partnership Agreement shall be concluded for a period of [...][6] years as of its entry into force (see Article 64). This period cannot be extended.

[6] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 MFPA)*.

> ***Example:*** *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

⚠ The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

⚠ SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** not applicable]*

1. Consortium agreement

As a general rule, FPA consortium agreements must ensure that the Framework Partnership and the specific actions are implemented properly.

⚠ If necessary, the consortium may decide to have — in addition to the consortium agreement under the FPA — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ⓘ *For more information on consortium agreements, see Article 41.3 General MGA.*

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 General MGA)*.

Exceptions:

Amendments made following suspension cannot have the effect of extending the duration of the FPA as set out in its Article 3.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the Agreement

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties**.**

⚠ Termination of the FPA has no effect on ongoing specific agreements (unless these are also terminated; *see Article 56 MFPA and Article 17 MSGA*)

ⓘ *For more information, see Article 50 General MGA.*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *subcontracting costs*
- *costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific categories of costs (if option applies) (see Article 4 General MGA).*

ARTICLE 10 — GRANT MAXIMUM, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 14 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 13 SGA) and approved by the *[Commission][Agency]* (see Article 14 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 SGA).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 MSGA and Article 5 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 General and specific conditions for costs to be eligible

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Specific conditions for costs to be eligible

The specific eligibility conditions applicable per budget category are set out in Article 5 MSGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

> ***Example:*** *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS

The rules on resources to implement the specific actions and third party involvement are set out in the specific agreements (see Article XX SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 General MGA).*

⚠ The third parties are normally involved in the specific actions, not in the framework partnership.

Example: *Third parties making resources available against payment or free of charge (see Articles 16 and 17 FPA) must be identified in Annex I of the SGA.*

Partners must however — already at FPA proposal stage — indicate if they intend to use third parties or not.

Moreover, linked third parties must be identified already in the FPA *(see Article 19)*.

Example: *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64).

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

[OPTION if Article 19 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the partner to which it is linked must also submit — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the agreements with effect from the date of the entry into force (see Article 64 and Article 18 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGA

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ Accession to SGAs is effected only by means of the signature of the coordinator. The other partners do not need to sign accession forms for the SGA.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA cannot be amended before the FPA.

ⓘ *For more information on the conditions for accepting new partners, see Article 56 General MGA.*

ⓘ *For more information on the procedure for amendments, see the H2020 Online Manual*

VIII.3 Model Specific Agreement specific annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],

and

on the other part,

1. 'the coordinator':

[**full official name**] [**short name**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3a of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreements:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 9),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
Annex 3	Model financial statements
Annex 4	Model for the certificate on the financial statements

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

⚠ However, not all partners of a framework partnership must actively participate in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

⚠ These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

As a consequence, these partners do not however need to comply with most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc)*.

⚠ Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* do remain applicable also for these partners.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

⚠ The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ The other partners do not need to sign accession forms.

⚠ Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

ARTICLE 14 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

14.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the Work Programme and in the invitation to submit a proposal).

⚠ If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Horizon 2020
Annotated Model Grant Agreements

General Model Grant Agreement
and specific Model Grant Agreements (ERC, SME Instrument, ERA-NET Cofund, PCP-PPI Cofund, EJP Cofund, Framework Partnerships and Specific Agreements)

Version 1.6.3
20 August 2014

Disclaimer:
The purpose of this document is to provide explanations on the main financial provisions of the MGA. Please note that the final version of this document is still under discussion and may still change. The final version will be available in the first half of 2014. For any questions about any aspects of European research in general and the EU Research Framework Programmes in particular, please send them to Horizon 2020 Helpdesk.

Research and Innovation

History of changes

Version	Date	Change
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations regarding the following derived model grant agreements: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnerships and specific agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to timesheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to "MSC calls conditions of the Main Work Programme" (page 55)

Foreword

The **Horizon 2020 Annotated Model Grant Agreements** ('AGA') is a user guide that aims to explain the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020[1].

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

---

[1] **H2020 Framework Programme** — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

Over the next months, this text will be transformed into an on-line version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Horizon 2020 Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

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I. General Model Grant Agreement

I.1 Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *Energy Challenge actions (see the Smart Cities and Communities calls); actions under the Research Infrastructures Part (see a Research Infrastructure call); Health Challenge actions, etc*
>
> ⓘ *For more information on research and innovation actions, innovation actions and coordination and support actions, see Article 2.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 Annotations

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),**]

[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),**]

[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission'),**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], established in [official **address** in full] [VAT number],

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

Text in italics shows the options of the Model Grant Agreement that are applicable to this Agreement.

[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 'Mise en place de la Charte des ordonnateurs'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[2] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[3]

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, see the Horizon 2020 Online Manual.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

[2] *For the definition, see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

[3] *See Article 15(9) of the Rules for Participation.*

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ *For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.*

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

The term '**action**' is used in the Financial Regulation[4] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[5]
- for **coordination and support actions (CSA)**: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking,

[4] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

[5] *For the definition, see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

coordination or support services, policy dialogues and mutual learning exercises and studies)[6].

2. Complementary grants

'Complementary grants' are other EU grants funded under the specified topics or calls supporting actions which are identified as complementary actions in the work programme.

They must share results and access rights to each other.

⚠ The beneficiaries must conclude a written 'collaboration agreement' with complementary beneficiaries regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. It covers the case included under Special Clause 41 in FP7.

3. Jointly funded actions

'Joint actions' (called 'coordinated calls' in FP7) are the results of joint calls for proposals with third countries or their scientific and technological organisations and agencies or with an international organisation, launched in priority areas of common interest and expected mutual benefit where there is a clear added value for the EU.

The joint calls for proposals are issued by the EU and by the third country/international organisation together, in order to jointly fund the actions. The proposals are evaluated and selected through joint procedures.

The participants of the EU action sign a GA with the EU and the participants of the third country or international organisation action sign one with their funding agency. The description of work *(Annex 1)* contains the research carried out under the European-funded action, including detailed explanations about the research to be carried out under the coordinated action.

To ensure coordination, the beneficiaries must conclude a 'coordination agreement' with the partners of the third country or international organisation action *(see Article 41.5)*, which links the two action and ensures the necessary synergies.

[6] *For the definition, see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts **before the entry into force** of the GA (i.e. before the grant agreement is signed by both parties), provided that the consortium requests it (usually in its proposal) and can show that there is a need to start the action earlier *(e.g. an action that is dependent on environmental conditions)*.

Example:

Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed start date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), as the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed start date is approved.

⚠ If the coordinator, for the whole consortium, requests a fixed starting date prior to the expected entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

A starting date fixed **later** in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2****: adjust amounts set out as lump sums in Annex 2;****]***
- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies)

  ⚠ The budget category 'specific categories of costs' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings' and 'costs for clinical studies'.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex I which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum cannot be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[11]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

*[**OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[4] For the definition, see Article 2.1(6) of the Rules for Participation: '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
[5] For the definition, see Article 2.1(14) Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[7]; for IA actions it is normally 70% of the total eligible costs[8].

Exceptions:

In exceptional cases fixed in the work programme, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[9]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[10] and all budget categories.

[7] *See Article 28(4) of the Rules for Participation.*
[8] *See Article 28(5) of the Rules for Participation.*
[9] *See Article 28(5) of the Rules for Participation.*
[10] *See Article 28(6) of the Rules for Participation.*

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[11]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[12]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [13]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific categories of costs for:
    - 'costs for **energy efficiency measures** in buildings'[14]
    - '**access costs** for providing trans-national access to research infrastructures'[15]
    - 'costs for **clinical studies**'[16]

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[11] *See Articles 123, 124 of the Financial Regulation.*

[12] Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

[13] *See Article 33(2) of the Rules for Participation.*

[14] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[15] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs ⚠ new in Horizon 2020)[17]

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of subcontracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific categories of costs (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	YES
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme.

[17] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum EU contribution.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (the IPR) is not considered a receipt since using the resulting IPR is one of the main objectives of research actions

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. Eligible costs: 100 and grant amount: 70
If receipts: 30 ➔ no impact
If receipts: 20 ➔ no impact
If receipts: 60 ➔ the grant amount will be reduced to 40.

2. Eligible costs: 100 and grant amount: 100
If receipts: 0 ➔ no impact;
If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:
Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000
Reimbursement rate= 100%
Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:
The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:
In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.
Total eligible costs: EUR 3 075 000.
Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000
Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:
Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000
The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries (and linked third parties) must:

- at proposal stage: enter only eligible costs into the estimated budget for your action *(see Article 4)*
- at reporting stage: declare only eligible costs in your financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries** (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** (including costs of certificates of financial statements required by the GA) are eligible — even if they are incurred after the action duration.

This exception refers exclusively to costs related to the drafting and sending of the reports, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  ⚠ Accounting documentation is necessary only for actual costs.

  Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  ⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  Specific case:

  For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

  – recorded in the third party's accounting records

  – calculated in accordance with the accounting standards applicable in the country in which the third party is established

  – calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit')

  Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

  ⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

  Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

  For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

  – must calculate them (the average or standard personnel costs) according to its usual accounting practices

  – must budget and declare a total amount; the amount per unit must not be included in Annex 2.

  ⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

  Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

  Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

  ⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

  Example:

  A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*:** *costs of [insert cost category or activity*[13]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: 'access costs for providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

> In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not included in Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure:** **Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

[14] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 This budget category **covers** the following **types of costs**:

- **basic remuneration** (basic salary and complements) and
- for non-profit legal entities: **additional remuneration** ('bonus payments').

What is 'basic remuneration'?

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll, including salaries paid during parental leave
- social security contributions, including social security contributions paid during parental leave
- taxes and other costs included in the remuneration.

Salaries and social security contributions paid during parental leave are eligible only if:

- they are mandatory under national law or collective labour agreements *(e.g. statutory maternity pay)*
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities, (in other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action) and
- the employee worked for the action before the parental leave.

'Parental leave' covers both maternity leave and parental leave.

The 'complements' may include:

- general contractual complements to the basic salary and

  Examples: *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements, if
  - they must be paid for the performance of the usual work, duties or tasks of the employee, on the basis of objective conditions and
  - the amounts and the conditions are established by national law or in the employment contract (or equivalent appointing act) and are in accordance with the internal regulations of the beneficiary.

Specific cases:

Teleworking may be accepted if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the productive hours worked for the action.

Costs of **benefits in-kind** to personnel (company car, vouchers, etc.) may be accepted if they are justified and in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25% flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — If a student works for a university, he/she may be exempt from paying (part of) the academic fees. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Like any personnel costs, **PhD costs** (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6.

> ⓘ *For more information on personnel made available to a beneficiary by a third party, see below and Articles 11 and 12.*

What not?

The basic remuneration does not include components that must be considered to be 'additional remuneration'.

> ***Example (variable remuneration component acceptable as basic remuneration):*** *The contract of a professor includes as part of his/her usual tasks both teaching and researching; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour, for each hour spent on research activities.*

> ⚠ The classification of a component of the remuneration as basic remuneration or as additional remuneration depends also on the classification of that component under the relevant national fiscal legislation, i.e. if the national tax authority considers something as part of the basic remuneration of the employee or as an additional remuneration ('bonus').

What is 'additional remuneration'?

'Additional remuneration' refers to payments higher than the employee's usual remuneration *(e.g. a 'bonus' resulting in an hourly rate higher than the normal one)*.

What not? It does not refer to additional salary paid to the employee due to an increase in the number of hours worked on the standard work or expertise defined in the employment contract *(e.g. via an additional contract)* when this additional hours are remunerated according to the standard salary conditions of the employee.

Specific case:

'Supplementary contracts' (whatever their form) for carrying out tasks for specific actions *(e.g. an EU action)* with remuneration that is different from the standard remuneration are acceptable, if it is the beneficiary's usual practice, the beneficiary is a non-profit legal entity and this is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package in the first non-action-related contract is considered 'additional remuneration' and is subject to the specific cost eligibility conditions mentioned above and, if eligible, to the eligibility ceiling.

1.1.2 Costs for employees (or equivalent) may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

For basic remuneration (basic salary and complements):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)
- be **mandatory** under national law, collective labour agreements or the employment contract
- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointment act).

  Payments linked to tasks *other* than those covered by the basic remuneration are not eligible.

  Example: *A payment linked to participation in a specific action (whether EU or non-EU) or project.*

It doesn't matter whether the employee works part time or full time or with a temporary or permanent employment contract, but he/she **must be 'assigned to the action'** (i.e. work for the action according to internal written instructions, organisation chart or other documented management decision).

If the employee does not work exclusively on the action, personnel costs can be charged only in proportion to the time dedicated to the action.

⚠ To avoid abuses, the eligibility ceiling for additional remuneration *(see below)* will exceptionally also be applied to the basic salary and complements, if they have been artificially increased for participation in the EU action.

Examples:

A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity to work on the EU action for a higher salary.

A researcher worked for a beneficiary of the grant, resigned, and subsequently signed a new contract with another beneficiary (or a third party) to work on the EU action for a higher salary.

Specific case:

For **secondments** or **linked third parties**, the employment contract or equivalent appointing act must be with the third party and the salaries must be on the third party's payroll.

For additional remuneration ('bonus' payments) **for non-profit legal entities:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration paid to a researcher that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the corporate performance)* is not eligible.

Additional remuneration is considered linked to the action if the researcher would not have received it if s/he had not participated in the action.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 600 productive hours
Remuneration components:
a = annual salary: EUR 50 000
b = salary complement for holding a management post (e.g. Head of department): EUR 5 000
c = additional remuneration for being Head scientist in a project: EUR 2 000
d = additional remuneration for being First Assistant on an internal action: EUR 1 000
***a** and **b** would be used to calculate the researcher's hourly rate:*
hourly rate for the EU action = {(50 000 + 5 000)/1 600} = EUR 34
***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*
***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for **additional work** or **expertise**

The work to be carried out (or expertise used) must be different from the standard work or expertise defined in the employment contract (or equivalent appointment act) and covered by the standard remuneration package. This difference must be relevant and verifiable.

Examples (acceptable additional remuneration):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking on the role of 'principal investigator' (in an ERC action).

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

Examples (not acceptable additional remuneration):

Additional remuneration paid for using English.

Additional remuneration is paid for participating in EU funded or multi-partner actions.

- be part of the beneficiary's usual remuneration practices and be consistently paid whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used.

The objective criteria must be related to the additional work or expertise.

The system for making additional payments should be established in the beneficiary's internal rules or at least be documented and known by the employees.

⚠ The additional remuneration cannot be paid to a specific employee at the discretion of the management.

Example (acceptable additional remuneration): *All teachers carrying out research on top of their usual teaching activities get an extra payment equal to 10% of their salary.*

Example (not acceptable additional remuneration): *The Director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

When a supplementary contract is used, the remuneration scheme must be described in it.

The rules for additional remuneration may not depend on the fund provider. In particular, they cannot be set up for actions funded by a specific donor, if these actions do not require a clearly identifiable different kind of work or expertise.

Examples (acceptable additional remuneration): *All professors carrying out research will be paid 10% more.*

Examples (not acceptable additional remuneration): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

⚠ Additional remuneration is only eligible for non-profit legal entities.

⚠ Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see below*).

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***
Addition of the additional remuneration: = ***2 000***
Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Procedure for calculating personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
*hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

⚠ For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the last closed financial year. In other words, if on a reporting period there are months for which the financial year is not closed the beneficiaries must use the last closed financial year available to declare those costs *(see example below)*.

⚠ The beneficiary cannot submit adjustments (neither positive nor negative) in the next reporting period resulting from a re-calculation of the hourly rate once the on-going financial year is closed.

Exception:

Employees hired during the **on-going financial year** (at the end of the reporting period). Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Examples:

***1.** Action with 1 reporting period of 18 months from 1.10.2014 to 31.3.2016. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:
From 1.10.2014 to 31.12.2014: on the basis of the closed financial year 2014.
From 1.01.2015 – 31.12.2015: on the basis of the closed financial year 2015.
From 1.01.2016 – 31.3.2016: hourly rate calculated for the last closed financial year available → 2015.

***2.** The beneficiary hires a new employee on 1.2.2016 → the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

⚠ *In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours (e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287).*

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')

- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours')**

- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*
for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

The table below explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time).	Can be used **in all cases**; any beneficiary can use this option.	**Not applicable**
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: – employment contract of the person concerned – applicable collective labour agreement – national law on working time ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The **individual annual workable hours** would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours** for Researcher X:* *Annual working hours = **1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* *➔ individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this researcher.*	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90 % of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1;

		group – an applicable collective labour agreement or – the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example (calculation of standard annual workable hours):*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The **standard annual workable hours** for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours*	– if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		per day = 1 824 hours ***Standard annual productive hours*** *for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days =* ***228*** *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days =* ***212*** *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 =* ***1 642*** ***1 696 hours*** *(usual cost accounting practice)* ***> 1 642 hours*** *(90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* ⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case:

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs

– are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

– correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.

– the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

Example: A researcher employed part time by the beneficiary to work four days a week would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000 0.8 = EUR 6 400 per year.*

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Example:

*A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.
S/he worked 1 600 annual productive hours, 800 of them for the EU action.
Maximum additional remuneration eligible for the EU action (eligibility ceiling):
{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000
The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 This budget category **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action, under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency.

⚠ The cost of using a temporary work agency that makes personnel available to a beneficiary may nevertheless be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*.

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products.

1.2.4 The **calculation** of the costs depends on how the contract is established (i.e. if it is based on an hourly rate, or on a monthly one, or even on a fixed amount). A calculation method is required, especially if the natural person works on different projects.

Cost of natural persons working under a direct contract for a beneficiary must be calculated according to the same **formula** explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the hourly rate is different (since it is not based on the annual personnel costs as registered on the payroll).

For the **hourly rate**, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person: this global amount must be divided by the number of hours worked for the beneficiary under that contract.

1.3 Direct personnel costs: Costs for personnel seconded by a third party

1.3.1 This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, see Articles 6.4 and 12.

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 These budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and indicated in Annex 2 of the GA.

This unit cost (hourly rate) is calculated according to the following formula:

{EUR 4,650/ 143 hours}

multiplied by

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

{country-specific correction coefficient / 100}

ⓘ *For the country-specific correction coefficient, see the* MSC calls conditions of the Main Work Programme *(Table 4).*

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
*EUR 4.650/143 * 98.8% = EUR 32,13/hour*

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)

- be declared for an **owner** of an **SME/ beneficiary that is natural person**, who **works on the action** but **does not receive a salary**.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They must be **calculated** as follows:

amount per unit (hourly rate) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost, and if it applied the formula correctly.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 This budget category **covers** the personnel costs in actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not included in Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15 are met.][**OPTION**: not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

1.2. Travel and subsistence costs must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's usual practices on travel

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[15]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs (equipment costs)':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment cost: Depreciation costs of equipment, infrastructure or other assets

1.1.1 This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following:

It is expected that the beneficiaries allocate the depreciable amount (purchase price) of an asset on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).

⚠ Depreciated equipment costs can never exceed the equipment's purchase price.

⚠ Depreciation cannot be spread over a period longer than the equipment's useful life

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable.

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — if recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period. This is however only accepted, if all of the following apply:

- the cost is economic and necessary;
- only the portion of the equipment used for the action is charged.

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable.
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  {equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

1.2 Equipment costs: Cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of the equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

Leasing (finance leasing) with the option to buy the durable equipment: the equipment leased by the beneficiary is recorded as an asset of the beneficiary and the corresponding depreciation costs may be charged in accordance with the beneficiary's usual accounting practices.

> ⚠ The cost claimed cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. The finance charges included in the finance lease payments are thus ineligible.
>
> ⚠ The costs declared under the action cannot include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary. There is no depreciation involved (as the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional eligibility conditions** set out in Article 11.1.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. costs of purchasing scientific publications (e.g. books, manuscripts, articles, digital copies, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs of intellectual property rights (IPR), including protecting results and royalties on access rights

Specific cases:

Royalty fees for background — Royalty fees (and by extension any down payments, etc.) paid to a third party (i.e. not a beneficiary) *(see Article 24)* are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the project, etc.)*. Eligibility may however be limited in specific cases.

Examples (limitations):

Eligibility of royalty fees with respect to an exclusive licence: it must be demonstrated that the exclusivity (and the higher royalty fees which are likely to be associated with it) is absolutely necessary for the implementation of the project.

Eligibility of royalty fees with respect to licensing agreements which were already in force before the start of the action: as a rule only a fraction of the corresponding licence fees should be considered eligible, as the licence was presumably taken for reasons other than participation in Horizon 2020.

Royalty fees paid for access rights to background granted by other beneficiaries *(see Article 25)* are exceptionally eligible on a case-by-case basis, if justified, if agreed by all beneficiaries before the GA is signed and if all the other eligibility conditions *(e.g. incurred during the action, etc)* are met.

Best practice: Eligibility of royalty fees for background should be discussed with the Commission/Agency on a case-by-case basis

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled.

Costs for drafting the 'plan for the exploitation and dissemination of the results' are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when implementing this plan may be eligible.

– costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).

– translation costs, if translation is necessary for the action's implementation, is justified, etc.

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used, only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases:

Supplies and consumables which were **already in** the **stock** of the beneficiary may be eligible as a direct cost if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Sometimes the use of certain resources is shared between different units of the same legal entity, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the beneficiary.

Internal invoices must not include indirect costs elements or profit margin or mark-up.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the Horizon 2020 Grant Manual.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable.****]***

[6] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(6) of Regulation (EU) No 1291/2013: **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below Section 2)*.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

What? Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ The beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.), together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility criteria. *Ad hoc* accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

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[19] *See also International Financial Reporting Standard No 16.*

[20] *See Article 126 of the Financial Regulation.*

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.);
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments)
- knowledge-based resources such as collections, archives or scientific data
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

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[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] *See Article 2(6) of the H2020 Framework Programme.*

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2)

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below)

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the Beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. During an audit, the auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology.

ⓘ *For more information on the procedure for the ex-ante assessment, see the Horizon 2020 Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

The beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  ⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  ⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

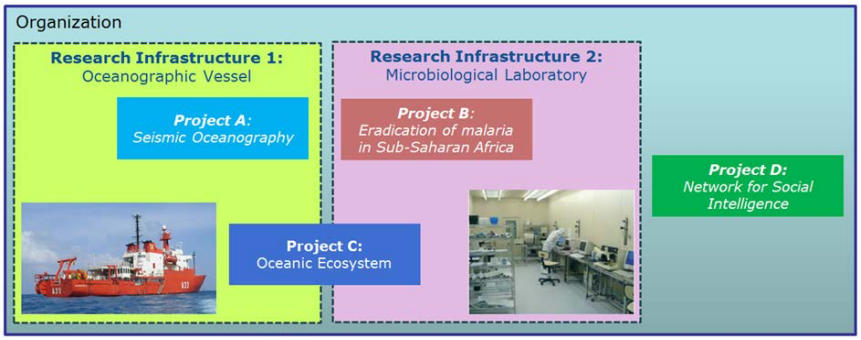

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[23].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under the Research Infrastructures Part of Horizon 2020 (i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

[23] *See Article 129(1) of the Financial Regulation.*

⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

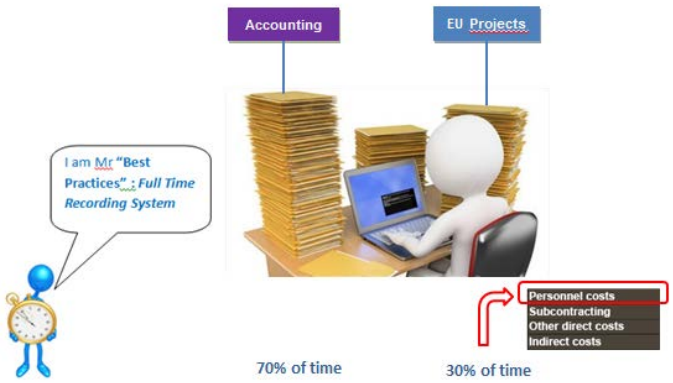

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 *Calculation of the rental costs that can be directly attributed to the research infrastructure*

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to the best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with using 'unit cost' as a simplified form of grant which is subject to a Commission decision[25].

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure}\} + \{\text{all operating costs of the research infrastructure}\}}{\{\text{total annual capacity}\}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

[25] *See Articles 29(2) and 33 of the Rules for Participation and Article 124 of the Financial Regulation.*

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

{actual eligible costs per unit of use} **x** {actual number of units of use used on the action}.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

*(d) **OPTION if Point F applies and the unit or lump sum cost includes indirect costs:** [unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]**]**.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[18] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category covers costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be declared on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– unit or lump-sum costs covering specific categories of costs which include indirect costs.

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

*(a) declared as **unit costs**: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

*(b) [declared as **actual costs**: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

*(c) [declared as a **combination of the two**: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

***[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]** are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]]*

1. Specific categories of costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific categories of costs**, i.e.:

- for Energy Challenge actions involving additional energy efficiency measures: **costs for additional energy efficiency measures**

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)*.

  These grants combine different activities. The reimbursement on the basis of the unit cost applies only for the building-related demonstration activities.

- for actions under the Research Infrastructures Part of Horizon 2020 with 'provision of access activity': **access costs for providing trans-national access to research infrastructures**

  ⚠ This unit cost will apply only to Research Infrastructure calls *(e.g. INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015 of the Work Programme 2014-2015)*.

- for actions under Health Challenge actions involving clinical studies: **costs for clinical studies**

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are already covered by the unit cost may not be declared (a second time) as direct costs *(for the costs that are covered, see below)*.

Examples:

Case 1: *The unit costs for efficiency energy measures covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. However, costs for*

subcontracts not included in the unit cost or lump sum (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

Case 2:*A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted in order to cover the costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.*

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Case 3: *A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. This is included in the GA under the option of article 5.2 (f). That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.*

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 Specific category 'costs for additional energy efficiency measures'

1.1.1 This budget category **covers** two categories of eligible costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings and

- costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids and indirect costs.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost (EUR/m^2 of eligible conditioned gross floor area) set out in Commission Decision C(2013) 8196[26] and indicated in Annex 2 of the GA.

This unit cost (EUR/m^2 of eligible conditioned gross floor area) is calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

'standard cost to save 1 kWh' = EUR 0.1
'standard payback period' to be used = 10 years

The m^2 of eligible conditioned gross floor area do not include parts of the buildings which are not affected by the measures, *e.g. garages*.

⚠ The specifications per type of demonstration building must already be part of your project proposal (by completing the BEST table (Building Energy Specification Table))[27]. These specifications are then included in Annex 1.

⚠ You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for **additional energy efficiency measures in buildings** that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit (EUR/m^2 of eligible conditioned gross floor area) x number of actual m^2 of surface area built or refurbished

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1€/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.
[27] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

*0.1€/kWh * 100kWh/m²/year * 10 years= 100€/m²*

After application of the 70% funding rate for innovation actions, it will give an indicative EU contribution of 70€/m².

1.2 Specific category 'access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs incurred for the selected users are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category, these costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[28] and set out in Annex 2 of the GA.

⚠ The Decision does not *fix* the unit cost for access costs; the unit cost must be established for each installation — before signature of the GA — as follows (and then reflected in Annex 2 of the GA):

- identification of a *unit* of access to the installation; this is used to measure the total quantity of access that the installation provides to its users

- establishment of the *unit cost* of access, calculated as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total access cost (over past two years}^{29}\textbf{)}}{\textbf{average annual total quantity of access (over past two years}^{30}\textbf{)}}$$

The averages are based on:

- the beneficiary's certified or auditable historical data

- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for less than two years) and

- a period excluding times when the installation was not usable (out of order, under repair or undergoing maintenance).

The 'total quantity of access to the installation' includes all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

[28] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[29] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2) for:

  - personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    By way of exception, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

  - costs of consumables specifically used for the installation and the research work of the users

  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

  - costs of energy power and water supplied for the installation

  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs)

  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

  - costs of specific scientific services included in the access provided or needed for the provision of access

- the eligible indirect costs for providing access to the installation, equal to 25% of the identified direct costs, minus any costs of subcontracting (i.e. costs in the categories 'costs of contracts for maintenance and repair', 'costs of contracts for installation management', 'costs of scientific services' and 'cost for other electronic services')

  and excluding:

  - all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). Those costs are not eligible *(see also Article 6.2.D.2)*

  - travel and subsistence costs to support the visits of users.

A form[hyperlink] for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

⚠ Do not forget to describe in your proposal the services provided to users as well as the support users need to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs= average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ Before signature of the GA, the beneficiaries can opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation) not as unit cost but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*. If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- **fulfil** the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for **providing trans-national access to research infrastructure** to scientific communities
- fulfil the **additional eligibility conditions** set out in Article 16.1

1.1.4 They must be **calculated** as follows:

– for each installation:

amount per unit (EUR/unit of access) x number of actual units of access provided

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.**]***

[OPTION: *not applicable**]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties free of charge are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

    Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

  - **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national VAT system. Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible** it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.
>
> **Specific cases:**

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding).

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[31] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

[31] *For the definition, see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are	Subcontracts concern the implementation of action tasks; they imply the implementation of

necessary to implement action tasks by beneficiaries.	specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (creating the website is not an action task); contract for organization of the rooms and catering for a meeting (if the organization of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures and building of a prototype plant).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or*

	other goods and services).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 ***[OPTION:*** *with the exception of additional exploitation obligations****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.****]***

[OPTION: *not applicable****]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[32]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

ⓘ For more information on third country participants, see the Horizon 2020 Online Manual.

[32] *For the definition, see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

Obligations that do not apply to beneficiaries not receiving EU funding:

These beneficiaries must, in particular, **not**:

- comply with the conditions for declaring costs *(e.g. cost form, eligibility, calculation, etc) (Chapter 3 and Articles 10-15)*
- keep records and other supporting documentation for costs *(Article 18.1.2)*
- submit financial reports and convert their costs in euro *(Articles 20.3(b), 20.4(b) and 20.6)*
- comply with some of the rules on management of intellectual property, background and results *(Articles 26.4, 28.1, 28.2, 30.3 and 31.5)*
- fear rejection of costs, reduction of the grant or recoveries, suspension of the payment deadline or suspension of payments *(Articles 42, 43 and 44)* .

⚠ Apart from this, they are treated like the other beneficiaries.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs, reduction of the grant or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].*[19]]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together; contract for logistic support (e.g. organization of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the best value for money considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility criterion set out in Article 6.1(a)(vii) — to be eligible, costs must be reasonable and comply with the principle of sound financial management — to the costs of the purchase of goods, works or services.

For the best price-quality ratio, price is an essential aspect — together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc. —, but it is not automatically necessary to select the offer with the lowest price.

Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value for money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the Work Programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[33] and 2004/17/EC[34] — or any EU legislation that replaces these Directives[35]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[33] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[34] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[35] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the **Agency**]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs : 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even though they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the **Commission** *[and the Agency]*, the European Court of Auditors (**ECA**) and the European Anti-fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.)*,

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ *For more information on approvals without formal amendment, see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]*.****]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means a contract for the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Building of a prototype or pilot plant, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is forbidden in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is forbidden, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the best value for money considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, see Article 10.

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

ⓘ For more information on the conditions for PCP or PPI subcontracting, see section VI PCP-PPI Cofund MGA.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value for money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'Unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. Other obligation: Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. Other obligation: Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[36]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[36] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *(‘****linked third parties****’) may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary]* ***[OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

[24] For the definition see Article 2.1(2) Rules for Participation: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] ‘Third party with a legal link to a beneficiary’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks

- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party.

  ⚠ Moreover, beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties (unless the GA foresees joint and several liability; *see Article 44.1*).

- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises

- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

⚠ Only affiliated entities and entities with a legal link to a beneficiary can be linked third parties.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves (e.g. entities controlled by the same entity).

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

'Entities with a legal link' refers to an **established relationship** (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore not covered by this case. In this case both legal entities should be beneficiaries.

– a legal relationship.

  This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

– *scientific and economic unity*

– *last a certain length of time*
– *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities composed of members *(where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[37]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not identified in the Work Programme) are not eligible for funding under Article 9 of the H2020 Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, see the Horizon 2020 Online Manual.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

– the financial viability/capacity of a beneficiary is 'weak' while that of its linked third parties is strong

  ⓘ For more information on the financial viability and the financial capacity check, see the Horizon 2020 Online Manual.

– the beneficiary mainly coordinates the work of its linked third party.

Examples:

The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary. The successful applicants will carry out the work as linked third parties.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

[37] *See Articles 8 and 9 of the Rules for Participation.*

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the **entity performing most of the work** should be the one appearing as **beneficiary**, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of **subcontractors and contractors** are **not** exchangeable with the role of **linked third party**.

ⓘ *For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, see Article 8.*

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is **no** procedure for **approval without amendment**.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the eligibility conditions set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be **recorded in the accounts of the linked third party**.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

⚠ The obligations in Article 14.1.1 additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

Each linked third party has its own financial statements, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

⚠ Each linked third party has to provide its own certificate on the financial statements *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA ('**cascade funding**').

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is **not** considered financial support.

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties (recipients) that actually implement research and/or innovation projects.)

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ *For financial support given in the form of prizes, see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g. 3 grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

⚠ All these conditions must already be described in your proposal (see the Proposal Templates).

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- avoid conflicts of interest *(see Article 35)*
- maintain confidentiality *(see Article 36)*
- promote the action and give visibility to the EU funding *(see Article 38)*
- are liable for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *not applicable**]***

15.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

Example: *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the Work Programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.
- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. Other obligation: Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country** is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[28]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** not applicable**]

1. Trans-national access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[38] and installations[39] for scientific communities ('provision of access activity').

Such Research Infrastructures Part actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **cover** — for the provision of access activity — the following **types of costs**:

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[38] *For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[39] *For the definition, see the footnote in Article 16 of the MGA.*

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)
- users' travel and subsistence costs
- costs of advertising the trans-national access offered under the action
- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility rules** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

'Access costs' for trans-national access may be **declared as** unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs listed above must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

⚠ If access costs are declared as unit cost, they must be declared under the budget category 'specific categories of costs' *(see Article 5.2(f) and 6.2.F)*. Otherwise they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

⚠ For trans-national access, the GA will always specify a unit of access, even when access costs are not reimbursed on the basis of a unit cost (i.e. not declared under the budget category 'specific categories of costs', but as actual costs under the other budget categories or as a combination of both).

The Beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ For trans-national access, this must include the exact amount of access provided.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[29] must provide access to research infrastructure or installations[30] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** not applicable**]

16.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[28] If the authorising officer considers necessary to give priority to certain categories of users.

1. Virtual access to research infrastructure

Actions under the Research Infrastructures Part of Horizon 2020, may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

– operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

⚠ There are no 'access costs' for virtual access.

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected or even identified.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General oobligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any **information requested** in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested, unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[40] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[40] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the Horizon 2020 Online Manual.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[31] For the definition, see Article 185 of Rules of Application: **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[41]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ The rules in the GA do not affect national laws on keeping documents.

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

[41] International Standard on Auditing ISA 500 'Audit Evidence'.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

– documents received or created in paper form should be kept in paper form

– documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units

declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25% flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary (or linked third party) may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

⚠ The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval. It will also challenge the costs, if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary/ can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ *For more information on the certification procedure, see the Horizon 2020 Online Manual.*

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **people working exclusively for the action** (100% of their working time), the beneficiaries must:

- sign one **declaration** per reporting period, to confirm that the people concerned worked exclusively for the action during the whole reporting period.

  This declaration must be dated and countersigned for acceptance by the person concerned.

  A template is provided on the Participant Portal.

  Best practice: If there is a doubt about exclusivity, beneficiaries should keep a record of actual hours worked *(e.g. timesheets)*.

For **people who do not work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. timesheets*), either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  A template is provided on the Participant Portal.

  Please note that this template is only an example of an acceptable timesheet. It is not a mandatory model. Beneficiaries are entitled to use any other model of timesheet provided that it fulfils the minimum conditions and it contains at least the information detailed below.

  Time records should include:

  – the title and number of the action, as specified in the GA

  – the beneficiary's full name, as specified in the GA

  – the full name, date and signature of the person working for the action

  – the number of hours per day declared for the action

  – the supervisor's full name and signature

  – a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned

  – a description of the activities carried out, to understand and show what work was carried out.

  ⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if this proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda*

and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot justify the number of hours or costs declared by using appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ If the beneficiary does not have reliable time records and uses alternative evidence to justify actual hours worked for the action, s/he risks not being able to adequately justify the full amount of costs declared. This may lead to only a partial acceptance of these costs (and a rejection for the rest).

10. Records of (linked) third parties

The beneficiaries must ensure that linked third parties comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to third parties that made in-kind contributions and to subcontractors.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For Energy Challenge actions involving additional energy efficiency measures, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*), unless Annex 1 specifies another way.

Specific case:

'**Classified deliverables**' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

– a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions).****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

– a '**periodic financial report**' containing:

(ii) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(iii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iv) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(v) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[32] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the coordinator, which must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (they do not see their grants in the electronic exchange system and therefore have no access to them). Before submission, the beneficiary completes the data for the linked third party, prints it and sends it to the linked third party which must sign it *on paper* and then send it back to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system are identical to the signed paper version.

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

CFSs must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

ⓘ *For information on the eligibility of costs incurred for reporting, see Article 6.2.D.3.*

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified deliverables' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on

security of information in the Commission internal Rules of Procedure *(see also Guide for classification[hyperlink]).*

ⓘ For more information on information security, see the Horizon 2020 Online Manual.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on cross–cutting issues (described in Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined vis-à-vis societal challenges (Annex I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed, if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more), as reimbursement of actual costs and personnel costs

on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25 % flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, it must be an independent public officer, with formal competence to audit the beneficiary/linked third party.

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[42] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro:**
  - for costs incurred in the currency of their accounting records conversion of costs by one of the following:
    - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[42] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[43].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart corresponding to your currency.

Step 3 — Choose the start and end date of the period for which the average daily exchange rate is calculated (i.e. the reporting period) by using the sliding tool in the second table.

Step 4 — The average appears above the first table.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if no daily euro exchange rate is published : using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[44].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

– for **costs incurred in a currency other than EUR and the one used in their accounting records:** conversion in accordance with the applicable national law and their usual accounting practices.

– for costs incurred in EUR, beneficiaries **with accounting records in a currency other than the euro** must declare the amount in EUR; no conversion has to be made.

⚠ This means that a beneficiary with accounting in a currency other than EUR will act differently according to the currency in which it incurs the costs (the currency in which the contract/invoice is established).

Examples:

1. *If the UK beneficiary buys the equipment in the USA (costs incurred in US dollars), it will convert the price of this equipment into pounds (the currency in which its accounts are established) according to its usual accounting practices. When reporting the costs to the Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.*

2. *If the UK beneficiary buys the equipment in UK pounds (it will record those equipment costs incurred in pounds in its accounts kept in pounds). When reporting the costs to the*

[43] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[44] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Commission/Agency, the UK beneficiary must convert the cost of the equipment from pounds into euros at the average of the daily exchange rate as explained above.

3. If the UK beneficiary buys the equipment in Germany in EUR (e.g. EUR 10 000) it will report these costs incurred in EUR (i.e. 10 000) to the Commission/Agency without converting them first from EUR to pounds and then back to EUR.

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline *(see Article 47)*
- terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

  ⚠ This may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - the work has started.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed start date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed start date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)
- the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, see Articles 42, 43 and 44.

2. Amount of pre-financing payment

There is no standard amount or percentage for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods (it will be in any case less for actions with only one reporting period, as 100% would mean the totality of the EU grant for the action).

⚠ At the moment of the pre-financing payment, an amount equivalent to 5% of the maximum grant amount is deducted from the payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility criteria; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.
Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1 : application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:
- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)
Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
Payment of the balance amounts to EUR 100 000 and will be ***paid*** *to the coordinator as follows:*
- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*
- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

22.1.1 Right to carry out checks

The Commission *[or the Agency]* will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission *[or the Agency]* may be assisted by external persons or bodies.

The Commission *[or the Agency]* may also request additional information in accordance with Article 17. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.

2. The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).

3. After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.

4. After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check (see Article 17). All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

It may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the check shows ineligible costs or the violation of other obligations under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

The Commission/Agency may carry out checks remotely, based on documents it received beforehand. It can do so using its own staff or with the assistance of external expert(s) or bodies.

⚠ If the Commission/Agency is assisted by external expert(s) or bodies, it does not need to send their name(s) for approval to the beneficiaries before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report'** will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed

- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the review shows improper implementation of the action, ineligible costs or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42- 44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a letter sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the **names** of the **independent experts** that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, you will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days (‘**contradictory review procedure**’).

22.1.3 Right to carry out audits

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a ‘**draft audit report**’ will be drawn up.

The Commission *[or the Agency]* will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations (‘**contradictory audit procedure**’). This period may be extended by the Commission *[or the Agency]* in justified cases.

The ‘**final audit report**’ will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission *[or the Agency]* may also access the beneficiaries’ statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

Specific case:

The Commission may audit the accounting records of beneficiaries, to obtain general information about actual costs for cost items that are reimbursed as unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will however normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

They consist in an in-depth examination (by professional auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to **third parties** involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

*1. The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

*2. The Commission/Agency may audit **third parties providing in-kind contributions** (free-of-charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

*3. The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or if appropriate the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. .*

⚠ *For this category of third parties, audits will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

*4. The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary.*

⚠ *For recipients of financial support or prizes, audits normally will not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs), except if Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties. .*

⚠ If the audit shows, ineligible costs, improper implementation of the action or the violation of other obligations under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

2. Procedure

The audit will be initiated by a letter sent to the beneficiary concerned.

⚠ The Commission/Agency will transmit this letter (and the other communications relating to an audit as formal notifications, through the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its **name**.

The beneficiary may **object** to an external auditor on grounds of commercial confidentiality (and explain the reasons for this). If justified the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit with its own auditors).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit (**i.e. on the beneficiary's premises or on the site on which the action is being implemented). (There may however also be audits that consist only in a desk review.)

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc)* and will indicate how and when it must be provided (and in which format).

ⓘ *For more information on records and supporting documentation for the different cost forms, see Article 18.*

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

> ***Example:*** *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

⚠ Objections based on data protection or confidentiality will not be accepted.

Once an audit has started, the beneficiary must keep all the records and supporting documents until the audit procedure and its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This avoids any unnecessary delays in retrieving original documents from the archives (and thus minimises the risk of the rejection of costs).

> ***Example:*** *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

This includes granting access to research facilities and interviewing the researchers that worked on the action.

⚠ Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc).

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Moreover, all confidential data will be processed in accordance with Article 36.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory review procedure**').

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [1]and No 2185/96[1] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42- 44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[1], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

⚠ If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission *[or the Agency]* may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission *[or the Agency]* will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the Commission *[or the Agency]* on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission *[or the Agency]* in justified cases.

The Commission *[or the Agency]* will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission *[or the Agency]* does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission *[or the Agency]* accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission *[or the Agency]* intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission *[or the Agency]* does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission [*or the Agency*] accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[37] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[45] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[45] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[46]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

[46] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Regulation (EU) No 1291/2013).

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to background

The rules on access to background (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is **no** (or a more limited) obligation to give **access**, if there are **restrictions** or **limits** (legal or otherwise) regarding the background and the beneficiary owning or holding the background has informed the others — before acceding to the GA (or immediately when additional background is agreed on after signature of the GA).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ Don't forget that — when contracting on background with third parties — you must at all times ensure that you can still comply with your access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

  > ***Example:*** *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such a case the other beneficiary might agree to grant access to other technologies in his possession.*

– for the exploitation of results: under fair and reasonable conditions

  ⓘ *For more information on fair and reasonable conditions, see Article 31.*

Also, there are no **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties, except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure *(see Article 31)*.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the **beneficiary** that **produced** them.

> 'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries are advised to keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases:

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must — as much in advance as possible before the jointly-owned results are produced — conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  ⚠ Don't fix a *ceiling* for fair and reasonable compensation before the action starts, unless you can precisely determine the results you expect to produce.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries are advised to include general principles on joint ownership already in the consortium agreement.

⚠ The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection (*e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (⚠ without prior authorisation from the other joint owners), unless otherwise agreed in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

⚠ The joint ownership status may **change**:

– it may need to be reviewed later on, when protecting the results.

Example:

Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.

– joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that any agreements with third parties who could claim rights to the action's results *(e.g. employees, subcontractors, linked third parties etc.)* contain provisions that allow them to respect their obligations under the GA *(e.g. transferring ownership to the beneficiary, grant the beneficiary access rights with a right to sub-license, etc)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Specific cases:

Joint research units (JRUs) — Where the internal arrangements of a JRU, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ⓘ *For information on JRUs, see Article 14.*

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, protect them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

⚠ This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*

The beneficiaries are in principle free to choose any available **form** of protection.

Examples of classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

For an invention: e.g. patent, confidential information.

For the design of a technology: e.g. industrial design, copyright.

For a website: e.g. industrial design, copyright, trademark, confidential information.

⚠ In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

ⓘ *For information on the eligibility of costs related to protection, see Article 6.2.D.3.*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

⚠ Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include a reference to EU funding, as specified in the GA.

⚠ **No** information on EU funding is needed, if it is (technically or legally) impossible to include such a reference

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure exploitation of their results.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

Example: *Exploitation is justified from an economic point of view (commercially) or from a standardisation perspective (for use in standardisation activities).*

Where possible, the measures should be consistent with the impact expected from the action and the '**plan for the exploitation and dissemination of the results**'.

They may aim for exploitation by the beneficiary itself (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (⚠ Such additional exploitation obligations will already be mentioned in the Work Programme.)

⚠ This obligation only applies to beneficiaries receiving EU funding.

If the results can reasonably be expected to contribute to European or international standards, the beneficiaries must also communicate them to the Commission/Agency.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

⚠ This obligation applies only if it is foreseen in your GA.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — disseminate their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

No dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA (*e.g. personal data protection, security-related obligations, etc)*.

The beneficiaries may choose **how** they would like to disseminate their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

If the GA provides for additional dissemination obligations, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the Work Programme.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated, unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries are advised to foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

2. Visibility of EU funding

Any dissemination of results (in any form) must include a reference to EU funding, as specified in the GA.

ⓘ *For more information on visibility of EU funding, see Article 38.*

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission]/ Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION:** not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may transfer ownership of their results.

⚠ Security-related obligations *(see Article 37)* may prohibit a transfer or require certain conditions to be fulfilled before it takes place.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

The beneficiary must ensure that the new owners comply with the following obligations:

- joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- protection of results and visibility of EU funding *(see Article 27)*
- exploitation of results and visibility of EU funding *(see Article 28)*
- dissemination of results, open access and visibility of EU funding (see Article 29)
- transfer and licensing of results *(see Article 30)*
- access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

⚠ The mere fact that the results concerned are transferred to a competitor is not in itself a valid reason for an objection. The beneficiary concerned must *demonstrate* the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases:

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of before).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them)*. In this case, there is no need to inform the other beneficiaries of such transfers in advance (and the other beneficiaries do not have the right to object).

⚠ Before agreeing to such a 'global' authorisation, you should carefully consider the situation (and in particular the identity of the third party concerned), to determine if your access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country not associated with Horizon 2020 must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant licences to their results.

They must however ensure that **access rights** can be exercised and that any additional exploitation obligations are complied with.

> ⚠ **Exclusive licences** *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If this option is included in your GA, the Commission/Agency may **object** to transfers or exclusive licences to third parties established in a non-EU country not associated to Horizon 2020, on the following grounds:

- the planned transfer or licence is not in line with EU **competitiveness interests**

  > ***Example:*** *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- the planned transfer or licence is not consistent with **ethical principles**

  > ***Example:*** *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- the planned transfer or licence is not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

⚠ **No** right to object for transfers or exclusive licences by beneficiaries not receiving EU funding *(see Article 9)*.

⚠ For Euratom grants, the Commission has the right to object also to non–exclusive licences.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[40], for the purposes of the complementary grant agreement(s) (see Article 2).**]

[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.**]***

[OPTION for access to research infrastructures:** The access provider must give the users access to the results, if needed to implement the action.**]

[OPTION:** not applicable**]

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When ?

The beneficiaries must provide access to results, if it is **needed**:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity (established in a Member State or associated country), to exploit the results produced by the beneficiary to which it is affiliated (unless otherwise provided for in the consortium agreement).

There is **no definition** of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

Example (results needed for implementation): *if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

Example (background needed for exploitation): *if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries are advised to agree *(e.g. in the consortium agreement)* on a **common interpretation** of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they **must be requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a Member State or associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3, unless the beneficiaries agreed on another time limit.

The agreement by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

⚠ Don't forget to notify the Commission/Agency of any conflicts on results that are likely to affect the action implementation *(see Article 17.2.)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

– for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

ⓘ *For information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3*

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

⚠ Access rights do not automatically give the right to **sub-licence** to the requesting beneficiary (since this would imply that access rights to results could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries are advised to agree on the terms and conditions of the sub-licensing generally and in writing (at the level of the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: Beneficiaries are advised — for legal certainty purposes — to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

The General MGA provides for several options for specific access rights for EU institutions, bodies, offices or agencies and/or EU Member States, for policy purposes.

⚠ These obligations apply only if they are foreseen in your GA.

5. Specific access rights for Euratom and its joint undertakings

The option gives Euratom and its joint undertakings (such as Fusion for Energy) royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to sub-license *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

The General MGA also provides for several options for specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)

- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  ⚠ In this case, the access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

⚠ These obligations apply only if they are foreseen in your GA.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [41], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[41] Commission Recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[47] and the Code of Conduct for their Recruitment.[48]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ For guidance in this process, see the 'Human Resources Strategy for Researchers' tool[49] developed by the Commission.

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

[47] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[50] and of the Code of Conduct[51] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[52])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[52] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ *For more information on gender equality, see the H2020 Online Manual.*

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: ***Activities involving research on human embryos or human embryonic stem cells*** *may be carried out only if:*

- *they are set out in Annex 1 or*
- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).****]***

[OPTION*: not applicable****]***

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, see the European Code of Conduct for Research Integrity[53].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, see the Science in Society e-library[54].

[53] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[54] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, see the Ethics self-assessment guide 'How to complete your ethics self-assessment' [hyperlink].

ⓘ For more information on the H2020 ethics appraisal scheme, see the H2020 Online Manual.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must also be allowed in at least one Member State.

Best practice: Beneficiaries are advised to obtain the **approval of** a **European ethics committee** (*e.g. the ethics committee of the institution hosting the researcher(s) conducting the concerned activity*).

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[55] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[55] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[43], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81)

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed — during the action and for four years afterwards.

> ⚠ This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves (for example, for access rights or third parties involved in the action).
>
> A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information concerned.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

Best practice: Beneficiaries are advised to inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

⚠ Stricter confidentiality obligations apply for information that is that is 'EU-classified' and subject to 'security requirements' in Annex 1 of the GA *(see Article 37)*.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *not applicable****]***

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *not applicable****]***

1. Activities raising security issues — Classified deliverables

If the security scrutiny (carried out by the Commission/Agency during the selection procedure) finds that the action raises security issues because it deals with information that is 'EU-classified' (under the Commission internal Rules of Procedure), the Commission/Agency will make it subject to '**security requirements**' (set out in a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' in Annex 1 of the GA).

In this case, the beneficiaries must comply with the security requirements.

Moreover, they may not subcontract action tasks involving such information or disseminate results linked to such information, without prior approval by the Commission/Agency.

'Classified deliverables' may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 19)*.

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[56].

Moreover, the coordinator must submit a **copy** of any export or transfer licence, before the action starts.

[56] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> 'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Promoting the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange.

⚠ *Ad hoc* efforts or mere dissemination of results are not sufficient. The communication activities[57] must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and address the **public policy perspective** of EU research and innovation funding, by considering aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)

[57] *For the definition of 'communication activities', see the Glossary.*

- scientific excellence
- contributing to competitiveness and to solving societal challenges

❖ impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*

❖ better use of results and spill-over to policy-makers, industry and the scientific community.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity).

⚠ The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them in another work package).

The beneficiaries are free to choose the type of communication activities.

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

⚠ Information given may **not** cover EU-classified information or information relating to 'classified deliverables' *(see Article 37)*.

⚠ Don't forget that any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa). Both obligations must be complied with.

ⓘ *For more information on how to promote your action, see the H2020 Online Manual*

2. Visibility of EU funding

The beneficiaries must ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure (including equipment or major supplies) funded by the grant, by:

– displaying the EU emblem and

– including the reference to EU funding, as specified in the GA.

For infrastructure (including equipment or major supplies) a sticker (or other equivalent means) should be used.

ⓘ For more information, see the Guide to using the EU emblem[58].

⚠ The beneficiaries must ensure the visibility of EU funding even after the action ends.

[58] Available at http://publications.europa.eu/code/en/en-5000100.htm.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[44], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[44] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities by the Commission/Agency

The Commission/Agency may use any (⚠ non-confidential and non- classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material); *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

⚠ The beneficiaries must make **arrangements** with any **third parties** that could claim rights to the material, in order to legally allow the use by the Commission/Agency.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

1. Processing of personal data by the Commission/Agency

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency 'Data Protection Officer (DPO)'.

This notification will be available in the Register of the DPO[59] (and will describe the processing operations, security safeguards, data transfer, retention period, etc.).

⚠For the processing of sensitive data *(e.g. health data)* and processing for the purpose of administrative penalties and termination, the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ For more information, see the data privacy statement ('SSPS')[60] on the Participant Portal.

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS) to:

- obtain information about what data is collected and how it is used, usually given via a privacy statement
- see which of their data are being held
- correct any errors in the data, block access to this data, or delete their data

[59] Available at http://ec.europa.eu/dpo-register/search.htm.
[60] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

– complain about data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ *For information on the complaints procedure, see the EDPS website.*

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data, by the beneficiaries

The beneficiaries must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[61] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [62]

[61] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing** of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[63]

Beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform staff** (whose personal data are collected and processed by the Commission/Agency) about this disclosure, by providing them with the SSPS.

Examples:

Before encoding its staff's personal data in the Beneficiary Register or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must tell the staff concerned and provide them with the SSPS.

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ *For more information on ethics, see the H2020 Online Manual.*

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62 *See Article 8 of Directive 95/46/EC.*

63 *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party, unless the Commission/Agency has explicitly agreed in writing.

'Assignment' normally means the transfer of rights held by one party to another party.

⚠ However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity

Assignment for the benefit of creditors in a bankruptcy procedure

⚠ Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

Example: *The obligation to allow audits by the Commission/Agency*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator**, unless in specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

> ***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications, unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, see the H2020 Online Manual.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action).*

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement (unless exceptionally stipulated otherwise in the Work Programme, for a specific call).

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded **before the action starts**. (Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action.)

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation Regulation No 1290/2013 and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ *For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, see the H2020 Online Manual and the guidance on establishing a consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with partners of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiaries must conclude a coordination agreement.

'Coordination agreements' are agreements between the consortium and partners from a third country (including scientific and technological organisations and agencies) or an international organisation, with which the joint call was organised.

Coordination agreements are also internal; the EU/Euratom is not party and has no responsibility for them (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be no *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ *For the basic contradictory procedure, see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100%.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial

responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[64]

  Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

  ⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

  In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[65]

  If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

[64] *See Article 80(1) of the Financial Regulation.*
[65] *See Article 87 of the Rules for Application.*

– taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or

– adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[66].[67]

The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an

[66] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[67] *See Article 79(2) of the Financial Regulation.*

amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, see point 2.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, see point 2.

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D
According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000 ; C = EUR 600 000 ; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000 ; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ *For the calculation of the share of the final grant amount, see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ *For the rest of the procedure, see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum EU contribution for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum EU contribution for the GA (maximum grant amount); in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000
Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

Beneficiary approved costs multiplied by the reimbursement rate (100%) * *final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between 2% and 10% of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

  Example:

  GA with an EU contribution of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

  During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in

the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5% (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the decision to apply the penalty may also be **published** on Commission or Agency websites —together with the name of the person responsible for the misconduct, information on the misconduct and the penalty(ies) (duration of the exclusion and/or amount of the financial penalty).

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

1. Liability for damages, of the Commission/Agency

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

– causes damage to a third party (including another beneficiary)

Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

– suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability for damages, of the beneficiaries

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples: *Costs of legal proceedings borne by the Commission.*

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ *For the basic contradictory procedure, see Article 42.*

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

ⓘ *For the basic recovery procedure, see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

  ⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

- calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

❖ **Payment request does not comply with the provisions of the GA**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.

❖ **Payment request is incomplete or requires clarification**

The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

Examples: the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.

❖ **Doubts on the eligibility of costs in the financial statements that require additional verifications**

The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

Example: The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is no *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

Example: statements made by the beneficiary in the declaration form are found to be false.

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

– **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **no individual financial statements** for the beneficiary (or beneficiaries) concerned may be submitted.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation, by the beneficiaries

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Grounds for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

  ⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the suspension is lifted and the action continues, the action's remaining budget can be used to implement the action.

⚠ However, it is possible that the action is resumed with a lower budget to adapt it to the new situation (agreed as part of the amendment).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) ***cannot*** **be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation, by the Commission/Agency

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

❖ **(Suspicion of) Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, see Article 50.3.

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

❖ **Suspicion of loss of scientific or technological relevance**

The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

This may in particular be the case:

- if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
- if work has significantly deviated from the original work plan
- if a key beneficiary leaves the action and the consortium needs time to find a replacement
- after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ For the basic contradictory procedure, see Article 42.

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, no further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA, by the beneficiaries

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

> ***Example:*** *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

> ***Example:*** *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries, by the beneficiaries

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ For more information on the roles and access rights in the electronic exchange system, see the H2020 Online Manual.

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action (unless it concerns the coordinator, since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action — including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so —, unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.][OPTION: not applicable];

(j) [OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries, by the Commission/Agency

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

❖ **Non-accession to the GA**

The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA).

⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [68]

Examples:

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this.

[68] *See also Article 8 of the Rules for Participation.*

The Commission terminates the GA because the conditions set out in the work programme are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

❖ **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

❖ **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

❖ **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

❖ **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

❖ **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

❖ **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

❖ **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

❖ **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

– the third country's or international organisation's action does not start by the date specified in Annex 1

⚠ In this case, **no costs** incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

– the third country's or international organisation's action is terminated

– the third country's or international organisation's action can no longer contribute to the subject of the GA.

Example: *if the coordination agreement is not signed.*

❖ **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

❖ **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA —

substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:

- systemic or recurrent and,
- have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ *For the basic contradictory procedure, see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ **Ineligible costs** may be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure
- labour disputes or strikes

– financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has **no specific effects** on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate* [*complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use a 'Messaging' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal Notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

Only Coordinator Contacts (CoCos) may submit information to the Commission.

Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ *For more information on access and roles in the electronic exchange system, see the H2020 Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** (unless the GA or other rules provide for direct communication with the other beneficiaries, *e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations*).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 28 February 2018.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

When & What?

An amendment is necessary whenever there is a need to **change** the **terms and conditions** of the GA. In some cases, the GA explicitly provides for them.

⚠ Amendments may **not** result in changes that — if known before awarding the grant — would have had an impact on the decision to award it. Those are mostly changes that:

- may have had an impact on the assessment of the applicant with regard to the eligibility and selection criteria *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- breach the principle of equal treatment of applicants
- involve modifications in the action and/or the related budget which may have affected the assessment with regard to the award criteria announced in the call *(e.g. the tasks in*

Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)

– do not comply with the rules applicable to the GA (i.e. Financial Regulation, Rules for Participation, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified or to modify Annex 1 following a review of the action).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removing a beneficiary whose participation was terminated** by the beneficiaries or by the Commission/Agency *(see Article 50.2 and 50.3)*.

  For termination by the beneficiaries, the request for amendment must be part of the notification of termination. In this case, don't forget to also submit the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency, the request for amendment must be submitted together with the report on the distribution of payments and the termination report (if needed).

  ⚠ No need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)*, unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

- **Adding a new beneficiary** *(see Article 56.2)*

  The request for amendment must include the Accession Form (signed by the new beneficiary in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

  The new beneficiary must provide a declaration on joint and several liability of its linked third party if required by the Commission/Agency.

  ⚠ Don't forget that the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

  Depending on the Horizon 2020 status(es) of the new beneficiary, the applicable options will be added.

  Example:

  If the new beneficiary is an international organisation, the options related to international organisations specified under Articles 22.4, 53.2, will be added to the GA and the options specified under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

  For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Change of beneficiary due to partial takeover (called 'partial transfer of rights and obligations' in FP7)**

  'Partial takeover' means that some assets of the beneficiary have been taken over by another entity *(e.g. partial acquisition)*.

If the GA is part of the assets taken over, the beneficiary must request an amendment: the entity to which the GA has been transferred may become the new party of the GA if the Commission/Agency agrees on that.

The contractual position of the old and the new party (vis-à-vis the Commission/Agency and the other beneficiaries) must be clearly spelled out in the request for amendment: in particular, it must clarify which is the financial liability of the new party for the old party's debts towards the Commission/Agency or the Guarantee Fund.

⚠ Don't forget that the new party must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal (unless it already has a validated Participant Identification Code (PIC)).

❖ **Change of coordinator**

The amendment request may be submitted after the period set out under Article 3 of the GA ends.

The initial coordinator may continue to participate in the action as a beneficiary (or may terminate its participation).

If the new coordinator is already a beneficiary of the GA, he will start his new functions from the date agreed by the parties, or — in the absence of such an agreement — the date on which the amendment enters into force. The date agreed cannot be before the initial coordinator has terminated its functions.

⚠ If the new coordinator is not a beneficiary of the GA, it must also accede to the GA as a new beneficiary *(see Article 56.2)*.

❖ **Change of the coordinator's bank account for payments**

Example: *The coordinator changes bank.*

The coordinator must submit the necessary supporting documents and update the banking information on the Participant Portal.

⚠ Do not forget to first update the bank account data in the Beneficiary Register (and get it validated).

❖ **Change of the action's title and/or acronym**

Example: *the consortium finds out that the acronym of their action is a protected trademark.*

❖ **Change of the starting date, duration of the action or reporting periods**

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

⚠ Even if the action is prolonged, the maximum grant amount cannot be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

  ⚠ Don't forget to communicate the date from which the action's implementation can restart ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:

  – a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries

  – changes concerning **in-kind contributions** provided by third parties (against payment or free-of-charge) or **subcontracts**

    Such changes could in principle also be made as 'approval without formal amendment' (*see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency's *agreement* (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency may consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).

  – changes concerning the tasks to be carried out by **linked third parties** and related costs

    There is no 'approval without formal amendment' *(see Article 14)*.

  – changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount and/or the action's estimated eligible costs will be accepted only in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount cannot be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2 (estimated budget)** which require an amendment *(see Article 4)*, in particular:

  – a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

  – a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*

    Examples:

    During the action's implementation, a beneficiary that declared its direct personnel costs as actual costs in Annex 2 decides to change this and instead to declare its direct personnel costs as unit costs in accordance with its usual accounting practices.

    An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to add the appropriate option under Article 5.2 and to modify the action's estimated budget in Annexes 1 and 2.

Indicative list of cases where no amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary or coordinator**

  Changes concerning name, legal form *(e.g. Ltd., S.A.)*, registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA) do not require a formal amendment; an update of this data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

  ⓘ *For more information on data updates, see the Horizon 2020 Online Manual.*

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may request it.

  Example: *Company RO moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates*

- **Change of beneficiary due to universal takeover (called 'universal transfer of rights and obligations' in FP7)**

  'Universal takeover' means that all the rights and obligations of the beneficiary have been taken over by another entity *(e.g. in cases of merger or full acquisition)*. The beneficiary ceases to exist and all its rights and obligations (including those under the GA) are taken over by the new entity.

  Example:

  Beneficiary X may merge with another existing entity Y by:

  (i) becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or

  (ii) establishing a new separate legal entity (X and Y are together known as 'Z').

  Since *all* the rights and obligations of the old entity (including the GA) are transferred to the new one, there is normally no issue of legal certainty and it is therefore not necessary to make a formal amendment under Article 55. An update of the data in the Beneficiary Register (by the LEAR, validated by the Commission validation service) is normally sufficient.

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may request it.

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

  Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

Case 2: A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

⚠ Don't forget that — in addition to updating the data in the Beneficiary Register — you must also inform your coordinator (offline) under Article 17.2, if the universal takeover may:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinators must then inform the Commission/Agency (via the electronic exchange system) and may request an amendment.

The same is true if the universal takeover concerns one of your linked third parties.

How?

An amendment request must be **prepared** by the **coordinator**, normally by filling out the forms **directly in the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

Specific case:

A request to **change the coordinator** (against the coordinator's will) can be submitted by any beneficiary (acting on behalf of the others).

⚠ If none of the available forms are appropriate, beneficiaries are advised to contact the Commission/Agency for the drafting of the request.

⚠ **Requests** for amendment must be unambiguous and complete and submitted **sufficiently in advance** (to allow proper analysis and preparation before they are due to take effect) and, generally, **before the end of the action** (i.e. the date set out in Article 3).

Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance).*

Once completed, the amendment request (with all its supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator. (⚠ The coordinator submits and signs on behalf of the other beneficiaries; *see Annex 3*).

Coordinators must ensure internally that they have the agreement of the consortium, on the basis of their internal decision-making processes *(e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement)*.

⚠ Don't forget:

- for new beneficiaries (or linked third parties): to ensure that they have obtained all necessary validations in the 'Beneficiary Register'

Example:

Validation of the new bank account, to change the bank account

Legal entity validation, to add a new beneficiary that is not yet validated. This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

– to include the necessary information and supporting documents (as required for certain amendments)

Examples:

For a change of coordinator without his/her agreement, the coordinator's opinion (or written proof that this has been requested).

To add a new beneficiary, an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

To amend Annexes 1 and 2, amended versions of these annexes.

ⓘ *For more information on the submission procedure, see the Horizon 2020 Online Manual.*

The coordinator may at any moment **withdraw** the amendment request (before it has been accepted or rejected). However, it cannot be *change*d (without withdrawing it and submitting a new one).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

ⓘ *For more information on the preparation and submission procedure, see above point 1.*

⚠ Beneficiaries are advised to contact the Commission/Agency beforehand (via the 'Messages' function of the electronic exchange system), in order to discuss the amendment.

The other party must — within 45 days — agree or disagree, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

If there is **no reaction** within this deadline, the request is considered to have been rejected (⚠ new in Horizon 2020: contrary to FP7, there is no tacit approval of amendments). A new amendment request may be submitted (even if it fully or partly repeats the initial request).

A request containing several changes to the GA will be considered as a **package** that cannot be divided into several requests. The request will be agreed or rejected by the other party as a whole.

If, the receiving party requests additional information/documents a new deadline will apply, i.e. 45 days from receipt of the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may be extended by the Commission/Agency — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

⚠ A signed and submitted amendment requests (including supporting documents) cannot be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

Unless the parties agree otherwise, the amendment will **take effect** (i.e. the modifications to the GA will start to apply) on the day of entry into force of the amendment.

If the parties agree on another date, it should normally be *after* the entry into force. In justified cases it may be before (retroactivity of the amendment). (⚠ In certain cases, the GA itself provides for retroactivity.)

Examples (retroactivity foreseen in the GA):

Where a new beneficiary or linked third party is added to the GA, it must assume the rights and obligations from the date of its accession specified in the Accession Form. This retroactivity implies that its costs will be considered eligible as from the date of its accession to the GA (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

⚠ Depending on the nature of the modification, the date of taking effect may have an impact on the eligibility of costs.

If an amendment request involves a number of changes, these could take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA, by the beneficiaries mentioned in the Preamble

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign a hard copy of this declaration and must send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will not be considered a party to the GA.

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Specific case:

For mono-beneficiary actions, replacing the beneficiary during the action implementation is only possible under exceptional circumstances *(e.g. the beneficiary transfers all its rights and obligations, including those related to the action, to another legal entity).*

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated (unless it already has a validated Participant Identification Code (PIC))
- sign the Accession Form directly in electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an amendment for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned])*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for international organisations (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[69]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the *Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States*, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN system (⚠ new in Horizon 2020).

It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU-arbitration clause, referring disputes on the interpretation, application or validity of the GA to the Court of Justice of the European Union.

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This

[69] *See Article 180(1) of the Rules of Application.*

referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[70]).

If a dispute is of public law nature (i.e. concerns offsetting or an enforceable decision under Article 299 TFEU), actions must be brought before the Court of Justice of the European Union not under Article 272, but under Article 263 TFEU.

[70] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

II. ERC

II.1 Background information and approach

The ERC General Model Grant Agreement ('ERC General MGA') is used for the following ERC grants ('frontier research grants'):

- ERC Starting Grants (StG)
- ERC Consolidator Grants (CoG)
- ERC Advanced Grants (AdG)
- ERC Synergy Grants (SyG).

The ERC General MGA is not used for ERC PoC and ERC low value grants (which have specific MGAs; *see below*).

⚠ ERC grants are open to **principal investigators** (PIs) of any nationality who intend to conduct a **frontier research project** in a Member State or associated country and which are hosted by a host institution that is based in an EU Member State or associated country and can receive EU funds.

ⓘ *For more information on ERC actions, see Article 2.*

ⓘ *For information on ERC funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on ERC standard eligibility criteria, see the ERC calls conditions of the ERC Work Programme.*

The ERC General MGA follows the General MGA for numbering and content, except for the following:

Introductory remark all ERC MGAs

The ERC Model Grant Agreements deviate from the General Model Grant Agreement as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
-
- The table of contents is adapted
- Cross-references in the footnotes are adapted

Introductory remark ERC General MGA

The ERC General Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

Introductory remark ERC PoC MGA

The ERC PoC Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

ERC frontier research grants are however different from General MGA grants because:

- EU funding is granted to an individual action proposed by a Principal Investigator (PI) (or several, in the case of SyG), while

- the grant is signed between the Agency on one side and the beneficiaries on the other, one of which is the host institution of the PI and his/her research team.

⚠ By signing the GA, the beneficiaries take on a series of obligations towards the PI and the research team. In order to participate in the action, the PI must sign a supplementary agreement (SA) with its host institution where s/he also takes on a series of rights and obligations *(see Article 32)*.

ERC PoC grants are then follow-up grants to explore the innovation potential of results generated in a previous ERC frontier research grant.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC actions)
- Article 4.1 (ERC budget categories)
- Article 6 (ERC eligible and ineligible costs)
- Article 8 (ERC rules on third party involvement).

Since the ERC General MGA and the ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC PoC MGA will be limited to major differences from the ERC General MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 ERC General MGA: Annotations

ERC MULTI-BENEFICIARY MODEL GRANT AGREEMENT

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][1],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname], hosting [and engaging] the following

***[OPTION by default:** 'principal investigator':*

*- [**Name**][Date and place of birth][2]*

***[OPTION for SyG:** 'corresponding principal investigator':*

*- [**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**][Date and place of birth]*

*- [**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),****]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called 'principal beneficiary'.

Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that host (or employ) a principal investigator ('host institution').

The PI is usually employed by the host institution.

Exceptions:

A PI may be employed by a third party. In this case, the third party must also sign the supplementary agreement *(see Article 32)* and agree to the obligations included in it.

Retired researchers, in case the PI is no longer under an active labour contract.

ⓘ For more information on arrangements for signature and third parties, see the preamble of the General MGA.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

⚠ Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities.

PIs must be supported by their host institution during the entire duration of the action.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions, must sign a supplementary agreement (SA) *(see Article 32)*.

⚠ In the case of ERC Synergy grants (with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

⚠ ERC PoC grants do not require a supplementary agreement.

⚠ ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI').

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERC actions

ERC actions are mono- or multi-beneficiary actions with the following activities:

– any type of frontier research activity in any field of research (except nuclear energy; see the ERC calls conditions of the ERC Work Programme).

What? ERC grants fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

ⓘ For examples of successful ERC actions, see the ERC website[71].

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

[71] Available at http://erc.europa.eu/erc-stories.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC General MGA uses in principle the **same budget categories** as the **General MGA**.

Budget categories of the ERC General MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences (compared to the General MGA):

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs *for the action* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(f) for **direct personnel costs** *[(excluding personnel costs for activities in Point (f))]*[5]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(g) for **direct costs of subcontracting** *[(excluding subcontracting costs for activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(h) *not applicable;*

(i) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(j) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

[…]

[5] To be used only if option in Point (f) is used.
[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC calls conditions of the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are the **same** as in the **General MGA** *(see Article 5 General MGA)*.

Exception:

The ERC General MGA does not use the same **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, the ERC General MGA uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[72]

However, the unit costs for the 'specific categories of costs' of the General MGA do not apply.

[72] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 General MGA)* (with the exception of 'direct costs of providing financial support to third parties', 'specific categories of costs' and 'costs for providing access to trans-national research infrastructure').

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

Specific cases:

For **direct personnel costs**:

⚠ Costs for 'teaching buy-outs' are not eligible: if the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, they cannot declare the costs related to these substitutes.

If the **PI** is exceptionally **engaged by a third party** (which pays his/her salary) and seconded to work on the premises of the beneficiary (against reimbursement by the beneficiary), the **salary costs** may be declared as direct personnel costs (costs of personnel seconded by a third party).

⚠ In this case, the supplementary agreement must be signed by the PI, the host institution *and* the third party.

For **other direct costs**:

For ERC actions, **recruitment costs** are eligible as other direct costs because recruitment is one of the action's activities.

⚠ Recruitment costs are not considered as one of the action's activities for PoC.

⚠ As in actions under the General MGA, for ERC actions the **purchase of scientific publications** *(e.g. books, manuscripts, articles, digital copies, etc.)* needed for the implementation of the action may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Given the increasing emphasis on the protection of inventions, the PIs are encouraged to **protect** their **intellectual property rights properly** and the related costs are considered eligible.

Costs related to open access (to publications – including monographs – and research data) are eligible during the duration of the action. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (it cannot be with other beneficiaries or linked third parties).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies*: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.****]***

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 General MGA)*.

In addition, the beneficiaries must however prove that the conditions concerning the time-commitments of the PI for implementing the action (as described in Annex 1) have been complied with.

Thus, they must be able to provide evidence that the PI dedicated the minimum time commitment (i.e. percentage of the total working time, i.e. percentage of the annual productive hours calculated in compliance with Article 6) to the action, via time sheets or alternative time recording system.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

Moreover, they must be able to provide evidence that the PI spent the minimum time commitment *in a Member State or associated country* (i.e. a Member State or an associated country), via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

ⓘ *For the percentage required, see the ERC calls conditions of the work programme.*

⚠ Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) scientific and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

ⓘ For more information on how to submit the reports, see Article 20 General MGA and the H2020 Online Manual.

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC General MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies - make the pre-financing payment to the principal beneficiary within 30 days ***[OPTION:*** *from the entry into force of the Agreement (see Article 58)****][OPTION:*** *from the starting date of the action (see Article 3)****][OPTION:*** *from the 45th day before the starting date of the action (see Article 3)****]***.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([****insert amount*** *(insert amount in words)] is not paid to the principal beneficiary, but kept by the [Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90 % of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90 % of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90 % of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the principal beneficiary
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

[…]

1. Payments

For ERC actions, the same rules on payments apply as in the General MGA *(see Article 21 General MGA)*.

There is however an additional option for pre-financing payments. These cannot only be foreseen within the 30 days from:

- the starting date of the action (see Article 3) or
- from the date of entry into force of Grant Agreement (see Article 58)

but also

- from the 45th day *before* the starting date of the action (see Article 3)), if the action starts late (well after the entry into force of the GA).

⚠ In any case, it is not possible to make a payment before the GA is signed.

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Rights of third parties

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 General MGA)*.

⚠ Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

[…]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

*[OPTION: **not applicable**]*

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

Examples: *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

For publications issued after the end of the action, beneficiaries are not obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

For bibliographic metadata, the ERC General MGA foresees lighter requirements, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[73] or other systems).

⚠ As far as the chosen repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

For ERC actions, there is no formal requirement for a '**data management plan**'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

[73] *For more information, see http://www.doi.org/.*

The exception allowing beneficiaries not to give access to specific parts of research data applies not only if this would jeopardise the main objective of the action, but any one of the action objectives.

⚠ For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[32] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a)

[…]

[32] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC General MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of intellectual property rights
- Allow for transfer of the GA to another host institution (**portability**).

⚠ PIs cannot be prevented from applying independently (i.e. in their own name) for further EU funding for other actions. They can also apply for further EU funding for the same action, as long as it is for costs that are not eligible (or not declared) under the ERC grant.

In this context, 'action' refers to the specific ERC action, for which the beneficiaries receive the ERC grant *(see Article 2)*.

⚠ The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ⓘ For more information on combining EU funding for different actions ('complementary EU funding'), see the H2020 Online Manual.

2. Supplementary agreement — Obligations on the PI

The ERC General MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also vis-à-vis the PI.

The supplementary agreement should cover all the practical issues that may arise in the context of the grant implementation, and in particular the ones listed in Article 32.1(b).

Model clauses for supplementary agreements are available on the Participant Portal and the ERC website. [hyperlinks]

Host institutions and their PIs may add or use other clauses, if they benefit the research action and do not contradict the GA. Provisions that contradict the GA are considered void and may not be opposed to the Agency.

⚠ The supplementary agreement must be concluded before the GA is signed (and a copy must be sent to the Agency).

It does not replace an employment or collaboration contract between the PI and its host institution (which remain necessary under national labour and social laws).

Specific cases:

In the case of **ERC Synergy grants** (with **several PIs**), each host institution must conclude a supplementary agreement with the PI(s) they engage.

ERC PoC grants do not require a supplementary agreement.

In case of transfer of the Agreement to another host institution (**portability**; *see Article 56a*), the PI must sign a new supplementary agreement with its new host institution and forward it to the Agency. The GA cannot be amended before the PI has sent this new supplementary agreement.

Via the supplementary agreement, the PI must take on a number of obligations, to ensure the smooth implementation of grant.

Main obligations (of the PI):

- Supervision of the scientific and technological implementation of the action
- Responsibility for the scientific reporting for the beneficiary and contribution to the financial reporting
- Meeting the time commitments for implementing the action
- Applying the beneficiary's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the visibility of EU funding
- Upholding the intellectual property rights of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.

- Maintaining confidentiality

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(c) display the EU emblem and the ERC logo and

(d) include the following text:

"This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem and the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

Guidance on the use of the ERC logo is available on the ERC homepage[74].

[74] Available at http://erc.europa.eu/logos-and-banners.

MULTI-BENEFICIARY: **ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the Agency has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: **ARTICLE 56 — ARTICLE 56 — ACCESSION TO THE AGREEMENT**

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: [...][...][...][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 General MGA)*.

However, unlike the General MGA, ERC ***mono*-beneficiary** grants can **become *multi*-beneficiary** grants, by addition of a new beneficiary.

The procedure to be followed is that of Article 56 of the General MGA.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

Upon request by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

Portability makes it possible to transfer ERC grants — at any time during the action implementation.

The PI may **request a transfer** of his/her grant to any other entity based in an EU Member State or associated country ('new host institution'), if doing so is beneficial for the PI and supports achieving the action's objectives.

Specific case:

For **ERC Synergy Grants**, each PI maintains the right to transfer their part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

If **certain team members** or **equipment remain** with the former host institution, that institution may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

Thus, both host institutions must agree on the transfer of intellectual property, in conformity with the GA and after consulting the PI. The transfer plan should cover:

- the results produced under the action and the access rights to them and
- the PI's and new host institution's access rights to background held by the former host institution but necessary for implementing the rest of the action.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs are advised to keep records of the consultation and decision-making process for each portability case.

The former host institution must then submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 General MGA)*.

A change of beneficiary usually takes effect on the first day of the month.

This date may be retroactive, but only in very exceptional circumstances. This should be discussed on a case by case basis with the Agency.

⚠ The request should be made well in advance, to allow sufficient time for the amendment procedure.

⚠ The GA cannot be transferred without the explicit agreement by the Agency *and* the amendment of the GA. Any partial or full transfers made without a formal amendment to the grant agreement are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** all **remaining pre-financing** (not covered by eligible costs) to the new host institution.

⚠ If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will not pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary).

⚠ Scientific reporting periods will usually remain unchanged as they are linked to the action's scientific development and must be submitted by the PI, who holds this position for the whole duration of the GA.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law.

It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

II.2 ERC PoC: Annotations

⚠ The ERC PoC MGA is very similar to the ERC General MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however no specific provisions on the working conditions of the PI and his/her team, no supplementary agreement and no grant portability

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC General MGA apply mutatis mutandis.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. ERC PoC actions

ERC PoC actions are actions with the following activities:

– verifing the innovation potential of ideas arising from ERC funded projects

What? Any activities (that were not scheduled to be funded by the initial ERC frontier research grant) but that develop research output towards new commercial or societal applications.

ERC PoC grants can cover very diverse activities *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

What not? ERC PoC grants cannot cover activities under the ERC frontier research grant (*e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential*) or activities which are the result of research not performed under the ERC actions (*e.g. results of research not found by the ERC action*).

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual, the ERC home page or the ERC calls conditions of the ERC Work Programme and the call and topics pages of your call.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) report(s), including requests for payment.

The report(s) must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP):

20.2 Reporting period

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)**]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]

***[**- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].**]***

20.3 Periodic reports — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs [and lump sum costs]; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(f) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *Agency* may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Agency*, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What ?

For ERC PoC actions, the principal beneficiary must submit reports — only one 'report' if there is one reporting period, otherwise one 'periodic report' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  ⚠ The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

⚠ Only at the moment of the submission of the last reporting period, the 'certificate on the financial statements' will have to be added.

How?

All reports mut be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' section of the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period (and thus the duration of the action) lasts **18 months**.

If provided in the GA, an ERC PoC action may however also have more reporting periods.

IV. SME Instrument

IV.1 Background information and approach

The Model Grant Agreements for the SME Instrument ('SME Instrument MGAs') are used for grants for **SME Instrument actions only** *(see General Annex D to the Main Work Programme)*.

The SME Instrument funds actions in different phases.

The minimum requirement for participation is one for-profit SME (as defined in the SME Recommendation 2003/361/EC), established in an EU Member State or associated country

'For profit' means not a non-profit legal entity (i.e. not an entity that is by its legal form non-profit-making or has a legal or statutory obligation not to distribute profits to its share-holders or members).

⚠ If the Work Programme/call, exceptionally foresees SME Instrument Ph2 actions that predominantly concern research activities, they will be considered 'research and innovation action (RIA)' actions and will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ⓘ For more information on SME Instrument actions, see Article 2 SME Instrument MGAs.

ⓘ For information on SME Instrument funding opportunities, see the 'Search Topic' function on the Participant Portal.

ⓘ For information on SME Instrument standard eligibility criteria, see General Annex C to the Main Work Programme.

ⓘ For more information on the procedure for SME status validation, see the H2020 Online Manual.

The SME Instrument MGAs **follow the General MGA** for numbering and content, **except** for the following:

Introductory remark SME Instrument Ph1 MGA

The SME Instrument Phase 1 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 4.1 (SME Instrument Ph1 estimated budget of the action)
- Article 5.1-5.3 (SME Instrument Ph1 maximum grant amount, specific reimbursement rate and form of costs, no Step 2 'limit to maximum grant amount', no Step 3 'reduction due to the no-profit rule')
- Article 6 (SME Instrument Ph1 specific conditions for eligibility of costs)
- Article 7 SME Instrument Ph1 consequences of improper implementation)
- Articles 8, 11, 12, 14, 15, 16, 23a - 33, 37, 39 (not applicable)
- Article 10 (SME Instrument Ph1 specific provision for purchases)
- Article 13 (SME Instrument Ph1 specific provision for subcontracting)
- Article 18 (SME Instrument Ph1 specific provision for record-keeping)
- Article 20 (SME Instrument Ph1 specific reporting provisions)
- Article 21 (SME Instrument Ph1 specific payment provisions)
- Article 36 (SME Instrument Ph1 specific provision on confidentiality)

- Article 38 (SME Instrument Ph1 specific provision on promoting the action)
- Article 42.2 (SME Instrument Ph1 specific provision for lump-sum
- Article 50.1.2, 50.3.3 (SME Instrument Ph1 specific provision for lump-sum

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

Introductory remark SME Instrument Ph2 MGA

The SME Instrument Phase 2 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 5.2 (SME Instrument Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Instrument Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Instrument Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 SME Instrument Ph1 MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Instrument Ph1:

- Article 2 (SME Instrument Ph1 actions)
- Article 8 (SME Instrument Ph1 rules on third party involvement)

For SME Instrument Ph2:

- Article 2 (SME Instrument Ph2 actions)
- Article 4.1 (SME Instrument Ph2 budget categories)
- Article 6 (SME Instrument Ph2 eligible and ineligible costs)
- Article 8 (SME Instrument Ph2 rules on third party involvement)
- Article 20 (SME instrument Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since that is most common for SME Instrument actions. The differences between mono and multi-beneficiary versions are marginal.

IV.2 SME Instrument Phase 1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** (**'action'**), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]]***.]**

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.***]***

1. SME Instrument Ph1 actions

SME Instrument Ph1 actions are mono- or multi-beneficiary actions with the following activities:

– making a feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service)

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a 'technology readiness level' of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc)*.

⚠ The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph2 actions, see Article 2 SME Instrument Ph2 MGA.

ARTICLE 4 — ESTIMATED BUDGET

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the form of costs (see Articles 5 and 6).

1. Budget category

The SME Instrument does **not** use the **budget categories** of the **General MGA**.

Since SME Instrument Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Instrument Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

⚠ The budget category is relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The grant amount for SME Instrument Ph1 actions is fixed as a **lump sum** of **EUR 50 000**.

The lump sum is provided for by Commission Decision C(2013) 8198[75], for all SME Instrument Ph1 actions.

The amount of EUR 50 000 stays the same, both for multi-beneficiary and mono-beneficiary actions.

It is deemed to reimburse 70 % of the action's total eligible costs (that are in turn set by this Decision at EUR 71 429).

If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ No other costs will be reimbursed; the lump sum is deemed to cover all (direct or indirect) costs that may have been incurred for the feasibility study.

⚠ The SME Instrument Ph1 MGA does not use any of the **unit costs** and **flat-rates** of the General MGA.

The conditions for eligibility are set out in Article 6.

[75] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to improper implementation or breach of other obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

[…]

1. Calculation of the final grant amount

For SME Instrument Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is no:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

A. Costs for the feasibility study (direct and indirect costs) are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Instrument Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 The budget category 'costs for the feasibility study' **covers** the costs for the feasibility study for the innovation idea *(see Article 2)*.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[76] and set out in Annex 2 of the GA (currently **EUR 71 429** per action).

This lump sum is deemed to cover all (direct and indirect) eligible costs that may have been incurred for the feasibility study.

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 No **calculation** is necessary.

The beneficiaries must declare the amount of EUR 71 429 as the total eligible costs of the action; they cannot declare the costs actually incurred. The final financial report and individual financial statement are therefore automatically pre-filled by the system *(see Article 20)*.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

1. Consequences of improper implementation

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation does not always lead to the reduction of the grant, but leads to the ineligibility of the costs (namely, if the improper implementation consists in non-compliance with Annex 1; *see Article 6*).

If the action is not carried out as described in Annex 1, costs will be rejected proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

By contrast, if other provisions of the GA or provisions of EU, international and national law are not complied with, the grant may be reduced.

[76] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Instrument Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs for purchases and subcontracts are covered by the lump sum.

⚠ In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) are **not** allowed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Instrument Ph1 actions are almost identical to the General MGA *(see Article 13 General MGA)*.

Since SMEs are not contracting authorities, there is however no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph1 actions are similar to the General MGA *(see Article 13 General MGA)*.

Subcontracting is however not restricted to a limited part of the action.

Moreover, the estimated costs do **not** have to be included in Annex 1or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are **not** considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ⓘ For more information on the characteristics of subcontracting and best value for money, see Article 13 General MGA.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Instrument Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit the report

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) the **final report**, including a request for payment.

The report must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing an '**individual financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The individual financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME instrument Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial report and statement are automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

⚠ For multi-beneficiary actions, each beneficiary must fill in an individual financial statement (in order to certify conformity of the costs declared). This does not however change the EU contribution requested (which remains one single lump sum of EUR 50 000 for the whole consortium).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made — No interim payments

For SME Instrument Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are no interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Instrument Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(f) the disclosing party agrees to release the other party;

(g) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(h) the recipient proves that the information was developed without the use of confidential information;

(i) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(j) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Instrument Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(e) display the EU emblem and

(f) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

Not applicable

38.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Promoting the action — Visibility of EU funding

The SME Instrument Ph1 MGA foresees lighter requirements for promoting the action and acknowledgment of EU funding.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

[…]

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

[…]

1. Calculation of the ineligible costs to be rejected

Since the SME Instrument Ph1 grant consists in a reimbursement of lump sum costs, improper implementation leads to the ineligibility of the costs *(see Article 7)*.

If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, *all* costs will be declared ineligible and there will be no financial contribution from the EU.

ARTICLE 50 — TERMINATION OF THE AGREEMENT

[…]

50.1 Termination of the Agreement, by the beneficiary

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

[…]

50.3 Termination of the Agreement, by the *[Commission][Agency]*

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

1. Termination of the Agreement

For SME Instrument Ph1 actions, the same rules on termination apply as in the General MGA *(see Article 50 General MGA)*.

⚠ Improper termination by the beneficiary will however lead to a 100% reduction of the grant.

IV.3 SME Instrument Phase 2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a ‘**complementary grant**’ to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a ‘**jointly funded action**’ which must be coordinated with the ‘joint action’ called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. SME Instrument Ph2 actions

SME Instrument Ph2 actions are actions with the following activity:

– implementing an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication).

What? The innovation idea must have considerable novelty to the sector in which it is presented (for technological innovation ideas, this means a ‘technology readiness level’ of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

⚠ An project may be funded in Phase 2 even if it was not funded in Phase 1.

What not? Ideas without commercial potential or ideas without considerable novelty to the sector will not be funded by the SME Instrument.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.

ⓘ For more information on SME Instrument Ph1 actions, see Article 2 SME Instrument Ph1 MGA.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The SME Instrument Ph2 MGA uses the **same budget categories as** the **General MGA**.

Budget categories of the SME Instrument Ph2 MGA:

- direct personnel costs
- subcontracting costs
- other direct costs
- indirect costs

Differences compared to the General MGA:

- No 'direct costs of providing financial support to third parties'
- No 'specific categories of costs'

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(k) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(l) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(m) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(n) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*: as actually incurred costs (**actual costs**);

(o) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

***[**(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]*[1]*]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

1. Reimbursement rate

How much? For SME Instrument Ph2 actions, the reimbursement rate is normally set at 70% *(see General Annex D to the Main Work Programme)*.

Exception:

If provided for in the Work Programme/call, an SME Instrument Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. *not applicable*;
D. other direct costs;
E. indirect costs.
.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Eligible costs — Ineligible costs

The SME Instrument Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

Exception:

The SME Instrument Ph2 MGA does not reimburse:

- 'direct costs of providing financial support to third parties'
- 'specific categories of costs'.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Instrument Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [1].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiary must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph2 actions are similar to those of the General MGA *(see Article 13 General MGA)*.

However, subcontracting is not restricted to a limited part of the action.

Moreover, for the SME Instrument Ph2, the Commission/Agency will assess compliance with best value for money during the evaluation of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

⚠ If you know the subcontractor, include the key information on the award procedure for the subcontract in the proposal (name of subcontractor, price and object), together with the action task(s) that will be subcontracted and an explanation why the subcontractor and the price are appropriate.

⚠ If you do not know the subcontractor, your proposal should set out the task(s) to be subcontracted, the estimated budget and the procedure you will follow to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits (unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

ⓘ For more information on evaluation, see the H2020 Online Manual.

Finally, for SME Instrument Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ⓘ For more information on the differences between contracts and subcontracts, see Article 8 General MGA.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Instrument Ph2 actions are normally the same as for the General MGA *(see Article 20.2 General MGA)*.

The reporting periods may however be adapted to reflect the duration of the action. Thus, if considered necessary, SME instrument Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

1. Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example****: if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

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V. ERA-NET Cofund

V.1 Background information and approach

The Model Grant Agreement for ERA-NET Cofund ('ERA-NET Cofund MGA) is used for grants for **ERA-NET Cofund actions only**.

⚠ ERA-NET Cofund grants are open only to **research funders** (i.e. legal entities owning or managing research and innovation programmes).

'Programme owners' are typically national/regional ministries or authorities responsible for defining, financing or managing national/regional research programmes.

'Programme managers' are typically research councils, funding agencies or other national/regional organisations that implement research programmes under the supervision of the programme owners.

The minimum requirements for participation are 3 independent research funders established in different Member States or associated countries.

ⓘ *For more information on ERA-NET Cofund actions, see Article 2.*

ⓘ *For information on ERA-NET Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on ERA-NET Cofund standard eligibility criteria, see General Annex C to the Main Work Programme.*

The ERA-NET Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for ERA-NET Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 ERA-NET Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1.ERA-NET Cofund actions

ERA-NET Cofund actions are actions with the following activities:

- the preparation, implementation and follow-up of a single joint call for proposals for trans-national research and/or innovation projects

  ⚠ Only one co-funded call per GA.

  There are two ways of implementing the joint call:

  - by **providing financial support to third parties**

    This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties.

    Most ERA-NET Cofund actions are implemented in this way.

  - by **implementation of the trans-national projects by the beneficiaries**

    This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding. Beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  What? The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  ⚠ These activities must be *in addition* to implementing a joint call.

⚠ If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do not apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[the first day of the month following the date the Agreement enters into force (see Article 58)] [insert date]*[4] ('starting date of the action').

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Duration of the action

For ERA-NET Cofund actions, the duration is usually **60 months**.

⚠ This time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects, which typically takes 36 months.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*).

⚠ Normally, the action's duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its **own budget categories**.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries
  - direct subcontracting costs for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities
- indirect costs

Differences (compared to General MGA):

- No 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- No 'costs for providing trans-national or virtual access to research infrastructure'
- No 'specific categories of costs'

⚠ These budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[…%] of the action's eligible costs* (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (unless declared as unit cost)
  - **subcontracting** costs for implementing the trans-national projects

- **other direct costs** for implementing the trans-national projects

❖ **unit costs** for:

- direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
- direct **coordination costs** for additional activities[77]

❖ **flat-rate costs** for:

- **indirect costs**

[77] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for of additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[5] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(d) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(e) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(f) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(d) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(e) the result of the work carried out belongs to the beneficiary, and

(f) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[6] *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

5 For the definition, see Article 2.1(14) of Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

6 '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

7 For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form —Conditions for eligibility — Calculation

1.1 The budget category 'direct costs related to trans-national projects' **covers** the following **types of costs**:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration — basic salary and complements
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract and
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries

- other direct costs for the implementation of trans-national projects by the beneficiaries:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure.

What not? The ERA-NET Cofund MGA does not reimburse:

- 'personnel costs for SME owners without salary or beneficiaries that are natural persons without salary'
- 'costs for providing trans-national or virtual access to research infrastructure'
- 'specific categories of costs'

⚠ No indirect costs for providing financial support to third parties.

1.2 All costs (except direct personnel costs) must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

In some Articles, the conditions in the General MGA must however be read as referring to 'trans-national projects' (instead of 'action').

For financial support to third parties, there are moreover additional eligibility conditions in Article 15 *(e.g. selection procedure, compliance with national funding rules)*.

⚠ For financial support to third parties, costs are usually eligible only after the trans-national projects have ended.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA*).

B. Direct coordination costs of additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see Article 2)*.

1.2 These costs must be declared on the basis of the **unit cost** fixed by Commission Decision C(2013) 8200[78] and set out in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

⚠ If the beneficiaries do not properly implement the additional activities set out in Annex 1, the grant may be reduced *(see Article 43)*.

Example: Beneficiaries make only two meetings on general strategy.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

⚠ Beneficiaries that implement trans-national projects cannot declare coordination costs for additional activities.

1.4 They must be **calculated** as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU contribution to coordination costs should not exceed 20% of the maximum grant amount.

[78] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[8] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[8] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, the same rules apply as in the General MGA *(see Article 6 General MGA)*.

The eligible direct costs (on which the flat-rate is calculated) include:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

⚠ They do not include direct costs of providing financial support to third parties implementing trans-national projects.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, in principle the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however **only** allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all action activities *(see Article 2)*.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(f) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(g) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**;

(h) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to third parties ('cascade grants')).

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties that actually implement research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

2. Additional eligibility condition: Two-step selection procedure

A two-step procedure is necessary to ensure that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating Member State and associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to the expert evaluators, the consortium must appoint an independent expert as an observer, to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The selection of trans-national projects ('**joint selection list**') must be based on the order of the ranking list (or the ranking lists, if there are different topics).

⚠ If proposals have identical scores, the proposals coming from participating Member States or associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

⚠ The obligations in Article 15.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

5. Additional eligibility condition: Compliance with national funding rules

Financial support to third parties must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the third parties) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

The beneficiaries must comply with the maximum amount and the criteria for determining the exact amount under national funding rules that are set out in Annex 1.

⚠ This information must already be part of your proposal *(see Table 4.1 of the Standard proposal template ERA-NET)*. If national funding rules do not specify a maximum amount, the beneficiaries should enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *The coordinator must submit: in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency]**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects, with the required information.

Example: *data on each participant and abstracts of the project proposals.*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects.

Example: *data on each participant and an overview of the results.*

⚠ The Commission/Agency will contact you to give you information on the format to be used (and where to find it) and how to submit the deliverables.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[16]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[17]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the *[Commission's][Agency's]* accounting purposes and will not be used to calculate the final grant amount.

[…]

[16] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[17] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? Normally, ERA-NET Cofund actions are divided into **2 reporting periods** (with two pre-financing payments; *see Article 21*).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][18], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] [19], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

[18] Should correspond to 10% of the maximum grant amount (see Article 5.1).
[19] Should be 80%, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, ERA-NET Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10% of the maximum grant amount
- the second pre-financing payment is 80% of the maximum grant amount.

Exception:

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10% for the first pre-financing payment
- 40% for the second pre-financing payment
- 40% for the third pre-financing payment.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full

– if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund

VI.1 Background information and approach

The Model Grant Agreement for PCP-PPI Cofund ('PCP-PPI Cofund MGA') is used for grants for **PCP-PPI Cofund actions only**.

⚠ PCP-PPI Cofund grants are only open to **actions** that have as main objective to implement a **pre-commercial procurement or a public procurement of innovative solution**. The minimum requirements for participation are 3 independent legal entities established in different Member States or associated countries and 2 independent legal entities that are public procurers from different Member States or associated countries (unless they are sole participants; *see General Annex D to the Work Programme*).

ⓘ *For more information on PCP-PPI Cofund actions, see Article 2.*

ⓘ *For information on PCP or PPI Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on PCP-PPI Cofund standard eligibility criteria and specific provisions, see General Annex C, D and E to the Main Work Programme.*

The PCP-PPI MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for PCP-PPI Cofund deviates from the General Model Grant Agreement as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation] [Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of financial resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 PCP/PPI Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. PCP/PPI Cofund actions

PCP/PPI Cofund actions are actions with both of the following activities:

– a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI) and its implementation

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'.

The suppliers do not become beneficiaries of the GA.

'Implementation' means implementation of the subcontracts ('subcontract implementation stage')

⚠ Only one co-funded PCP or PPI per GA.

– related additional coordination and networking activities.

What? The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

Examples: *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

⚠ It is mandatory (both for PCP and PPI Cofund actions) to include not only a PCP/PPI itself, but also those coordination activities that are needed to coordinate the PCP/PPI procurement. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

ⓘ *For more information on which activities are required and which ones are optional, see General Annex D and E to the Main Work Programme.*

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the lead procurer he pays all subcontractors)

  ⚠ This implies that the consortium must have a common jointly-committed budget and that the lead procurer is mandated to sign the subcontracts *(see Article 13)*.

- or the members of the buyers group.

  ⚠ This implies that the individual members of the buyers group pay the subcontractors pro rata *(see Article 13)*.

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  ⚠ Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities:
  - direct personnel costs for related additional coordination and networking activities
  - direct subcontracting costs for related additional coordination and networking activities
  - other direct costs for related additional coordination and networking activities
  - indirect costs for related additional coordination and networking activities
  - specific categories of costs for related additional coordination and networking activities (if option applies).

Differences (compared to General MGA):

- No 'direct costs of providing financial support to third parties'.

⚠ These budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs for the activities in Point (f))]*[5]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs of subcontracting for related additional coordination and networking activities** *[(excluding subcontracting costs for the activities in Point (f))]*[6]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs for the activities in Point (f))]*[8]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

[(f) [OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of [insert cost category or activity**[9]*]:

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[10] *[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of [insert cost category or activity]**: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.
10 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rates

How much? The Work Programme *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs of related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

⚠ Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are not eligible under PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1 *(see Article 13)*
- fulfil the additional eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs of related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[11]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Types of eligible personnel costs

B.1.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[12] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not included in Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not included in Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[1]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure:** Costs of other goods and services **for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.**]

[OPTION to be used for virtual access to research infrastructure:** Costs of other goods and services **for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.**]

B.3.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[1] *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[1]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *not applicable.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises*[;]* ***[****and*

(c) ***OPTION if Point B.5 applies and that unit or lump sum cost includes indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][lump sum costs under Article 5.2(f) and Point B.5]****]****.*

Beneficiaries receiving an operating grant[1] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[*B.5* ***OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]***

Costs of [insert cost category or activity]:

(a) declared as ***unit costs****: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

(b) [declared as ***actual costs****: are eligible, if they comply with the conditions set out above (Points B.1 to [B.3][B.4]) [and if [insert eligibility conditions];]*

(c) [declared as a ***combination of the two****: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[*same for each specific category of costs****]***

*[****OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity]*** *are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the related additional coordination and networking activities have been properly implemented in accordance with Annex 1.]****]***

[…]

[11] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[12] For the definition, see Article 2.1(14) of the Rules for Participation: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[13] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[14] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[15] For the definition see Article 2(6) of the Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[16] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

1.1 The budget category 'costs of related additional coordination and networking activities' **covers** the following **types of costs**:

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration — basic salary and complements
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party
  - costs of 'beneficiaries that are SMEs for their owners not receiving a salary'
  - costs of 'beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies).
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific categories of costs for related additional coordination and networking activities.

What not? The PCP-PPI Cofund MGA does not reimburse:

– 'costs for providing financial support to third parties'.

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

Personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[79] and set out in Annex 2 of the GA. (⚠ This concerns only beneficiaries that are SMEs, not PCP/PPI subcontractors that are SMEs.)

Examples: *Contracting authorities or contracting entities that are SMEs.*

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

⚠ Costs incurred by the beneficiaries for validation and testing of solutions provided by the subcontractors are part of the follow-up and monitoring of the results of the PCP/PPI and as such considered eligible direct personnel costs.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

The General Annex D to the Main Work Programme specifies that the costs of related additional coordination and networking activities are eligible up to a **maximum** amount of 30%/50% of the total requested grant amount (for PCP/PPI actions).

For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*.Thus, the amount of EU funding earmarked to finance related additional coordination and networking activities does not change, even if it the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*). The EU funding is not automatically proportionally reduced.

[79] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however **only** allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting *(Article 13)* is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties *(Article 14)* can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[20] and 2004/17/EC[21].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

The beneficiaries concerned must ***prepare****,* ***procure*** *and* ***implement*** *the subcontracts in accordance with the following* ***requirements****:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common procurement specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[22];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP ;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*
- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common procurement specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[22] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

For PCP Cofund actions, the beneficiaries will award subcontracts for the PCP research and development services ('PCP R&D services') that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PCP subcontract' is a contract for the purchase of R&D services that is identified in Annex 1 as action task.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('**buyers group**'), with a joint procurement in **3 phases**

The 'buyers group' is the group that finances and undertakes together the joint PCP procurement.

For PCP/PPI Cofund actions, it must normally be made up of:

- a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[80])

- that are established in two different Member States or associated countries *(see General Annex D to the Main Work Programme)*.

⚠ This is *in addition* to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different Member States or associated countries; *see General Annex C to the Main Work Programme*)

Exceptionally, the Work Programme allows for the participation of sole participants *(see General Annex D to the Work Programme)*.

Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

Example: *a group of a minimum of two public hospitals from two different EU Member States or associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

⚠ The buyers group is not open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

Other entities may be involved in the action as:

- beneficiaries (or linked third parties) responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*

- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in 3 phases.

The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

[80] *See Directives 2014/24/EC and 2014/25/EC.*

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

❖ Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

⚠ The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

⚠ This does not extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' *(as used in the WTO GPA)*.

⚠ Supplies cannot constitute the majority of the contract value.

❖ All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

❖ **Joint procurement procedure** (i.e. joint call for tender, joint evaluation of offers and joint award) is **coordinated and led** by one beneficiary ('**lead procurer**')

The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[81]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  ⚠ The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')

- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

⚠ PCP subcontracting is not restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

⚠ There can only be one PCP, per PCP Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PCP subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States or associated countries**.

⚠ This includes R&D and operational activities (*e.g. research, development, testing, certifying solutions, etc.)*.

[81] *See Directives 2014/24/EC and 2014/25/EC.*

ⓘ *For more information on associated countries, see Article 25 General MGA.*

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves.

⚠ This obligation must be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

PCP subcontracts must be based on the **best value for money** criteria *(see Articles 10 and 13 General MGA)*.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

⚠ The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

- a **specific procurement procedure** must be followed

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*
  - the procurement must be preceded by an '**open market consultation**'

This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[82]).

A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

– the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

– the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

– the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PCP subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The **framework agreement** (with each selected subcontractor) must set out the framework conditions for all 3 phases of the PCP implementation, including:

– the practical set-up of the implementation of the subcontracts, in particular:

  – the number, duration and budget of the PCP phases

  – the minimum number of expected subcontractors per PCP phase

  – the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)

  – the process for monitoring of on-going R&D work and reporting obligations of subcontractors

[82] *See Directives 2014/24/EC and 2014/25/EC.*

  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

⚠ The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

  - the details of the PCP R&D services purchased by each buyer

– quantity and

– price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PCP.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

7. Other obligation: Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[83]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[84]) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ For more information on this obligation, see Article 13 General MGA.

[83] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*

[84] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[23], 2004/17/EC[24].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex** 1. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

***[OPTION:** not applicable]*

*(iii) prepare **common procurement specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common procurement specifications (see above), according to **best value for money** criteria and ensuring that the price corresponds to **market conditions**;*

*(iii) **Step 3**: **award the subcontract(s)** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);]*

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[1] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common procurement specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.]*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.']*

[23] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

[24] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries will award subcontracts for procuring the 'PPI innovative solution(s)' that are necessary to address the 'common challenge' set out in Annex 1.

For the purposes of the GA, a 'PPI subcontract' is a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

Exceptions:

There is no requirement to split the PPI procurement procedure in **phases**.

The buyers group may select one or more subcontractors.

The common challenge does not concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

⚠ PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure*[85]*)*.

Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

There is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

The subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.

If there is no mandate, the general rule is that:

- framework agreement(s) must be signed by all members of the buyers group together
- specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

⚠ PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

⚠ There can be only one PPI, per PPI Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

⚠ Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes

[85] *See Article 31 of Directive 2014/24/EC and Article 49 in Directive 2014/25/EC.*

are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

⚠ For PPI subcontracting, there is no procedure for approval without amendment (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value for money— Price corresponding to market conditions

Like PCP subcontracts, PPI subcontracts must:

- be based on the **best price-quality ratio**,
- have a price that corresponds to **market conditions**
- must follow the **specific procurement procedure** set out in the GA.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**'

    Exception:

    If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for an open market consultation procedure.

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

⚠ This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)*.

  Exception:

  If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for contract notice and a request for tender; a request for offers from at least 3 providers suffices.

  ⚠ The request must also be addressed to the providers that successfully completed the last PCP phase in the pre-ceding PCP Cofund action.

  ⚠ Do not forget to specify in the request for tenders the arrangements for intellectual property rights (for these arrangements*, see below point 4*) and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  ⚠ In case of framework contracts/agreements there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned**.**

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots need to be deployed at different times and/or by different procurers.*

⚠ The obligations in Article 13.1.1 are additional eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PPI subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The subcontract(s) must specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate, unless in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  ⚠ The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

⚠ If the buyers group choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PPI.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. Other obligation: Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[86]) normally apply to PPI procurements.

Therefore, the lead procurer and the members of the buyers group that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of another obligation). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ *For more information on this obligation, see Article 13 General MGA.*

[86] *See Directives 2014/24/EC and 2014/25/EC.*

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[1]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC[1] or as contracting entities within the meaning of Directive 2004/17/EC[1] must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(including after the intermediate evaluations before the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [Y] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each project financed by the procurement**, including data on each contractor that participated in the procurement, an overview of the results (for publication and evaluation purposes) and an assessment by the buyers group of the final results of each participating tenderer (in terms of achieving the performance and functionality requirements of the initial tender specifications).
- any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (including data on each contractor that participated in the procurement and overview of the results)

⚠ Templates[hyperlink] are provided on the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[41]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[42]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions)**]*** ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure**]**;*

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of funds**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(a) an overview of the results and their exploitation and dissemination;

(b) the conclusions on the action, and

(c) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(a) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(b) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the Commission to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(e) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

⚠ No financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into **two** reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage (preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of funds — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of funds needed to pay the subcontracts*(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a statement on use of the previous pre-financing instalment *(see Annex 12)*.

  ⚠ This document includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  ⚠ It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][44], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)][451], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

[44] Should correspond to the percentage of the maximum grant amount that is foreseen for the related additional coordination and networking activities related to the preparation of the call for tender (see Article 5.1).

[45] Should correspond to a maximum of 90% minus the amount of the first pre-financing payment, unless option with three pre-financing payments is used.

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment

There are no interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; see Article 21) minus the amount of the first pre-financing payment).

Exception:

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

[…]

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

[…]

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund

VII.1 Background information and approach

The Model Grant Agreement for EJP Cofund ('EJP Cofund MGA') is used for grants for EJP Cofund actions only.

⚠ EJP Cofund grants are open mainly to **entities owning** or **managing research and innovation programmes** (and exceptionally other entities — if justified by the nature of the action —, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from both national and private sources). The minimum number of participants is five independent legal entities from different Member States or associated countries (unless they are sole participants; *see General Annexes C and D to the Work Programme*).

ⓘ *For more information on EJP Cofund actions, see Article 2.*

ⓘ *For information on EJP Cofund funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on eligibility criteria, see the Work Programmes.*

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for EJP Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Model for the annual work plan
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.F (Fusion Cofund programme action specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 EJP Cofund Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

EJP Cofund actions are actions with the following activity:

– implementing a joint programme of activities of coordinated national research and innovation programmes.

What? The joint programme of activities may range from research and innovation activities to coordination activities, training activities, dissemination activities and financial support to third parties.

> ***Examples:*** *NFRP7–2015 Integrating radiation research in the European Union; Fusion programme Cofund action (FEJP) (see sections A and B.1 Euratom Work Programme 2014-2015)*

What not? The EJP only funds joint programmes, not individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, see the H2020 Online Manual or the Work Programmes, and the call and topics pages of your call.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[4] (‘**starting date of the action**’).

[4] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Duration of the action

For EJP Cofund actions, the duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55 General MGA*).

⚠ The action’s duration cannot exceed **72 months**.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same **budget categories** as the **General MGA**.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
- subcontracting costs
- costs of providing financial support to third parties (if option applies)
- other direct costs
- indirect costs
- specific categories of costs (if option applies).

Differences (compared to the General MGA):

- For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are replaced by the following specific categories:
  - 'costs for mobility of personnel'
  - 'costs for fellowships for researchers'
  - 'access costs for research infrastructure'.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[1]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[1]*: as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[1]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[1]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) [**OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**[1]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[1]*[or*
- *as a combination of the two].]*

***[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of** [**insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]*

[…]

5 To be used only if option in Point (f) is used.
6 To be used only if option in Point (f) is used.
7 To be used only if option in Point (f) is used.
8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'access costs for providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings', costs of 'mobility of personnel', costs of 'researcher fellowships', costs of 'access to research infrastructures (EURATOM)'.
11 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed — for each call or action — in the Work Programmes. It cannot exceed 70%[87].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Specific case:

For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), there are **different unit costs** for three 'specific categories of costs':

- costs for **mobility** of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for **fellowships** for researchers: monthly living allowance, mobility allowance and family allowance
- **access costs** for research infrastructure [88]

⚠ These unit costs replace the unit costs for the 'specific categories of costs' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 General MGA)*.

[87] *See Article 28(5) of the Rules for Participation.*

[88] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

F. direct personnel costs;
G. direct costs of subcontracting;
H. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
I. other direct costs;
J. indirect costs;
[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision**: costs of [insert cost category or activity*[1]*]].

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

For one specific EJP Cofund action, i.e. the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the 'specific categories of costs' of the General MGA are however replaced by the other categories.

For ease of reference, the annotations for Article 6.2 will be limited to these specific categories of costs and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (g) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (h) a **summary progress report** *on* the activities carried out during the on-going reporting period.

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1.

⚠ Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*.

⚠ However, since the annual work plan for the next period must be agreed with the Commission/Agency before the start of activities for the next reporting period, it must be submitted 3 months (i.e. 90 days) in advance.

⚠ The annual work plan for the first reporting period must already be included in your proposal.

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan**.

⚠ The coordinator has **30 days** from the date of receipt of the request to submit a revised annual work plan.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

⚠ It should **not** contain an **analysis of *all* activities** carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) reports, including requests for payments.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

⚠ Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

⚠ Payment of the **second pre-financing** payment is not automatic. It must be **requested** in the statement on the use of the first pre-financing payment using the template in Annex 8.

ⓘ *For more information on the other provisions of this Article, see Article 20 General MGA.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]* ***[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Exception:

Large EJPs may benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The need for a second pre-financing payment will be assessed during the preparation of the GA.

⚠ If a second pre-financing payment is agreed, the Guarantee Fund retention (of 5% of the maximum amount of the grant) will be split between the two pre-financing payments.

The second pre-financing payment is not automatic but must be requested by the coordinator and supported by a statement on the use of the first pre-financing payment *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum amount of the grant

Exception:

Depending on the size and the needs of the EJP, the reimbursement rate in the Work Programme and the availability of Union funds, the pre-financing may be higher or lower.

In case of two pre-financing payments, the second pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the first pre-financing was insufficiently used:

- if 70% or more of the first pre-financing has been used: the second pre-financing is paid in full
- if less than 70% of the first pre-financing has been used: the second pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The Model Framework Partnership Agreement ('MFPA') and Model Specific Agreement ('MSGA') are used for framework partnerships (and specific grants under such framework partnerships) only.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement potential action (i.e. the FPA and SGAs).

They are established in a FPA and implemented by SGAs for specific actions. Both FPAs and SGAs are treated as grants for the purpose of the award procedure.

⚠ The minimum requirements for participation in FPAs will generally depend on the types of specific actions that are envisaged in the action plan.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals in the Work Programme and in the invitation to submit a proposal —) *(see Article 4 MFPA and Article 14 MSGA)*.

⚠ Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

ⓘ *For more information on framework partnerships and specific grants, see Article 2.*

ⓘ *For information on FPA funding opportunities, see the 'Search Topic' function on the Participant Portal.*

ⓘ *For information on standard eligibility criteria for different types of specific actions, see General Annex C of the Main Work Programme.*

The MFPA and MSGA generally follow the General MGA for content, but with a different numbering:

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⚠ In addition, all references in the General MGA to 'beneficiary(ies)' are to be taken as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the MFPA or MSGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

VIII.2 Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission') ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname] [2],

and

on the other part,

1. 'the **coordinator**':

[full official name] [short name][legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. **[full official name] [short name]** [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[3]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model for the certificate on the methodology

[1] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.

[3] The action plan should include the common objectives of the parties in compliance with the objectives stipulated in the Preamble and the types of activities covered under this Framework partnership, contributing to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Partners that have also signed an SGA become beneficiaries (i.e. a 'participant'[89] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

If you do not want to actively participate, you may participate as 'partner not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble to the SGA).

This means that you will not have to comply with some of the obligations under that SGA *(see Preamble MSGA)*

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

– the other partners sign the Accession Form *(see Article 62 MFPA and Annex 3)*.

[89] For the definition, see Article 2.1(15) of the Rules for Participation: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ Any amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2— ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in the action plan (see Annex 1))] [open to all applicants meeting the announced criteria]] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The Commission will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the Commission decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[4] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[5] Please use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

Framework partnerships may in principle be awarded in all areas of the Horizon 2020 Framework Programme.

⚠ Currently, framework partnerships are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and

coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

The partnership is based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership

  ⚠ For the objectives, please refer to the FPA call.

- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in the Work Programme.

⚠ Signing an FPA does not oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

⚠ The partners may continue to participate in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

2. Award of specific grants

The Specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  ⚠ Such calls are restricted to the consortia that have signed a FPA and will be in competition.

  Example: The Commission signs different FPAs for FET Flagships. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the Work Programme.

  The date must be set out in the action plan or in Article 2 of the FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

The Framework Partnership Agreement shall be concluded for a period of [...][6] years as of its entry into force (see Article 64). This period cannot be extended.

[6] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 MFPA)*.

> ***Example:*** *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

⚠ The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

⚠ SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** not applicable]*

1. Consortium agreement

As a general rule, FPA consortium agreements must ensure that the Framework Partnership and the specific actions are implemented properly.

⚠ If necessary, the consortium may decide to have — in addition to the consortium agreement under the FPA — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ⓘ *For more information on consortium agreements, see Article 41.3 General MGA.*

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 General MGA)*.

Exceptions:

Amendments made following suspension cannot have the effect of extending the duration of the FPA as set out in its Article 3.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the Agreement

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties**.**

⚠ Termination of the FPA has no effect on ongoing specific agreements (unless these are also terminated; *see Article 56 MFPA and Article 17 MSGA*)

ⓘ *For more information, see Article 50 General MGA.*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *subcontracting costs*
- *costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific categories of costs (if option applies) (see Article 4 General MGA).*

ARTICLE 10 — GRANT MAXIMUM, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 14 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 13 SGA) and approved by the *[Commission][Agency]* (see Article 14 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 SGA).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 MSGA and Article 5 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 General and specific conditions for costs to be eligible

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Specific conditions for costs to be eligible

The specific eligibility conditions applicable per budget category are set out in Article 5 MSGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS

The rules on resources to implement the specific actions and third party involvement are set out in the specific agreements (see Article XX SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 General MGA).*

⚠ The third parties are normally involved in the specific actions, not in the framework partnership.

Example: *Third parties making resources available against payment or free of charge (see Articles 16 and 17 FPA) must be identified in Annex I of the SGA.*

Partners must however — already at FPA proposal stage — indicate if they intend to use third parties or not.

Moreover, linked third parties must be identified already in the FPA *(see Article 19)*.

Example: *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64).

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

[OPTION if Article 19 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the partner to which it is linked must also submit — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the agreements with effect from the date of the entry into force (see Article 64 and Article 18 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGA

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ Accession to SGAs is effected only by means of the signature of the coordinator. The other partners do not need to sign accession forms for the SGA.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA cannot be amended before the FPA.

ⓘ *For more information on the conditions for accepting new partners, see Article 56 General MGA.*

ⓘ *For more information on the procedure for amendments, see the H2020 Online Manual*

VIII.3 Model Specific Agreement specific annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'),]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],

and

on the other part,

1. 'the coordinator':

[**full official name**] [**short name**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3a of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreements:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 9),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the administrative arrangement]*, the partners accept the grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
Annex 3	Model financial statements
Annex 4	Model for the certificate on the financial statements

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

⚠ However, not all partners of a framework partnership must actively participate in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

⚠ These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

As a consequence, these partners do not however need to comply with most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc)*.

⚠ Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* do remain applicable also for these partners.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

⚠ The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ The other partners do not need to sign accession forms.

⚠ Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

ARTICLE 14 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

14.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the Work Programme and in the invitation to submit a proposal).

⚠ If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

AGA – Annotated Model Grant Agreement

Version 1.7
19 December 2014

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.1	20.12.2013	▪ Article 6 added
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to timesheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSC ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles

⚠ With version 1.7 the AGA covers all model grant agreements, including MSC. It will be reformatted into a version 2.0 allowing easier online reading (font, inter-linked, clickable cross-references, etc.) to be published in 2015.

IMPORTANT NOTICE

The '**AGA — Annotated Model Grant Agreement**' is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020.

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the relevant **article** appears shaded in grey, to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and blue.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices**, **lists** and **procedures** are in bold and turquoise.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

Over the next months, this text will be transformed into an online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).
Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).
H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).
Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

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I. General Model Grant Agreement (MGA)

I.1 General MGA: Background information

The General MGA is used for grants for all types of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA).

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1'Health, Demographic Change and Wellbeing' , etc.*

ⓘ For more information on research and innovation actions, innovation actions and coordination and support actions, *see Article 2.*

ⓘ For an overview of the areas funded under Horizon 2020, *see Article 3 of the Specific Programme.*

⚠ The General MGA is not used for actions that fall under one of the Specific MGAs (i.e. ERC, MSC, SME Instrument, ERA-NET Cofund, Pre-commercial procurement or Public procurement of innovative solutions (PCP-PPI) Cofund, European Joint Programme (EJP) Cofund, Framework Partnerships).

I.2 General MGA: Annotations

GENERAL MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1] (H2020 GENERAL MGA – MULTI)

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [**official registration No**], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties]*

[OPTION if the JRC participates: *3b Administrative Arrangement]*

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[1] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a **sufficient financial capacity** to be able to implement the action (i.e. achieve its expected objectives and results).

> The Commission/Agency will systematically verify the financial capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial capacity (of the coordinator or other beneficiaries), if there are grounds to doubt their financial capacity.[2]

[1] For the definition, *see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

[2] *See Article 15(9) of the Rules for Participation.*

ⓘ For more information on the rules regarding the financial viability and financial capacity checks, *see the Online Manual*.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

2. Name, legal form, official registration No, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

'Official registration No' refers not to the 'participant identification code (PIC)' attributed by the Beneficiary Register, but to the official registration number in the national registry, if any.

These data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must therefore keep this data up-to-date at all times, including after the end of this grant *(see also Article 17)*.

In case of changes to these data, the **Legal Entity Appointed Representative** (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

ⓘ For more information on beneficiary registration, validation and data updates*, see the Online Manual*.

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

What? The RIA, IA and CSA actions of the General MGA are mono- or multi-beneficiary actions with the following activities:

- for **research and innovation actions (RIA)**: activities aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[3]
- for **coordination and support actions (CSA)**: accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)[4].

RIA, IA and CSA actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3)*.

[3] For the definition, *see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[4] For the definition, *see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

⚠ The term '**action**' is used in the Financial Regulation[5] and **means** '**project**', which is the term traditionally, used in EU Research Framework Programmes.

2. Complementary grants

'Complementary grants' are different EU grants which are 'linked' by the work programme/calls by identifying them as 'complementary actions'.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

⚠ They must conclude a written '**collaboration agreement**' regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions

'Joint actions' are the result of **joint or coordinated calls** for proposals, launched in parallel by the EU and a third country *(e.g. a scientific and technological organisation or agency)* or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).

For *joint* calls: the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the Commission/Agency will only evaluate the proposals for the EU action. (However, the evaluation may also often be coordinated, i.e. include experts from the third country/IOuse the same expert panels; apply the same evaluation criteria, etc.).

The participants in the EU action sign a GA with the EU (while the participants of the third country/IO action sign one with their funding agency/IO). The description of the action (Annex 1 to the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants in the EU action must conclude a '**coordination agreement**' with the participants in the third country/IO action *(see Article 41.5)*. This coordination agreement links the actions (although legally separate and ensures the necessary synergies.

ⓘ For more guidance on coordination agreements, *see the Online Manual*.

[5] **Financial Regulation (FR)** — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).
Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Starting date of the action

The starting date of the action is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example:

  Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The starting date of the action would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.

  ⚠ If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the project before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  ⚠ In any case, the starting date cannot be earlier than the date of the submission of the proposal.

- **after the entry into for of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  ⚠ A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated Budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.2)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
  - 'personnel costs for providing trans-national access to research infrastructure'
- 'direct costs of subcontracting'

- ‘direct costs of providing financial support to third parties’ (if option applies)
- ‘other direct costs’
  - ‘travel costs and related subsistence allowances’
  - ‘equipment costs’
  - ‘costs of other goods and services’
  - ‘capitalised and operating costs of large research infrastructure’
- ‘indirect costs’
- ‘specific cost categories’ (if option applies).

⚠ The budget category ‘specific cost categories’ only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for ‘access costs for providing trans-national access to research infrastructure’, ‘costs for energy efficiency measures in buildings’ and ‘costs for clinical studies’.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

In particular, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories without the need of a notification to the Commission/Agency or an amendment *(see Article 55)* if the action is implemented as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however never be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example:

The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount (at the level of the action).

If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example:

A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

⚠ The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

No transfers of lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

No new costs for new subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example: *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor.*

⚠ If the beneficiary uses the simplified approval procedure it bears the risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

Example: *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request the amendment, but justifies the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION for innovation actions (IA)**[7] **if all beneficiaries and all linked third parties are non-profit legal entities**[8]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions (IA) if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities][**OPTION for exceptional cases if foreseen in the work programme:** [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][11]: ***[OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);][**OPTION**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**][14]: on the basis of the amount(s) per unit set out in Annex 2*[15] ***(unit costs).]***

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]

[OPTION: specific cost category(ies):** not applicable.]

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 To be used only if option in point (f) is used.

10 To be used only if option point (f) is used.

11 To be used only if option in point (f) is used.

12 To be used only if option in point (f) is used.

13 To be used only if option in point (f) is used.

14 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount specified in this Article cannot be exceeded or raised by the Commission/Agency.

⚠ No additional funding is possible even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally 100% of the total *eligible* costs[6]; for IA actions it is normally 70% of the total eligible costs[7].

Exceptions:

In exceptional cases fixed in the work programme/call, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[8]

ⓘ *For information on eligibility of costs, see Article 6.*

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

Exception:

If non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

6 *See Article 28(4) of the Rules for Participation.*

7 *See Article 28(5) of the Rules for Participation.*

8 *See Article 28(5) of the Rules for Participation.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[9] and all budget categories.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[10]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (— unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[11]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [12]

    Example: *EUR 60,000 average salary for senior researchers*
  - specific unit costs for:
    - 'costs for **energy efficiency measures** in buildings'[13]
    - '**access costs** for providing trans-national access to research infrastructure'[14]

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9 *See Article 28(6) of the Rules for Participation.*

10 *See Articles 123, 124 of the Financial Regulation.*

11 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

12 *See Article 33(2) of the Rules for Participation.*

13 Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

14 Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020

– 'costs for **clinical studies**'[15]

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:

  – indirect costs (25% flat-rate for indirect costs ⚠ new in Horizon 2020)[16]

- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

  Example: *EUR 150,000 to carry out a study within an action*

  ⚠ For the General MGA, there are currently NO lump sum costs foreseen.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

15 Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

16 *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount

Step 3 — Reduction due to the no-profit rule and receipts

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

Profit must be assessed at the level of the action and not at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the consolidated receipts and the consolidated approved costs.

Three kinds of **receipts** must be taken into consideration:

- **income generated by the action** (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the duration of the action)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  ⚠ Receipt from the sale of assets are capped to the amount declared as eligible under the GA.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the duration of the action) for EUR 16 000.
  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)
  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 X 3 500) =EUR 8 000.

- **financial contributions given by third parties specifically to be used for the action** (i.e. money given as a donation by a third party (a donor) to a beneficiary (or linked third party) specifically for the action covered by the GA

- **in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs** (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

⚠ In-kind contributions are considered receipts only if their value (i.e. the costs incurred by the third party for it) has been declared by the beneficiary as an eligible cost for the action.

The following are **not** receipts:

- income generated by exploiting the results of the project (*e.g. the IPR*) is not considered a receipt since successfully exploiting the results is one of the main objectives of the action

- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action if the donor did not set the obligation to repay any unused amount at the end of the action

  ⚠ The full amount of the financial contribution is not considered as a receipt, not only the unused amount.

  Example:

  A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This contribution in kind from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.

Financial contributions made **by one beneficiary to another** within the same action are not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

Example:

Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.

Receipts will be taken into account by the Commission/Agency **only** at the moment of the **payment of the balance** (called the 'final payment' in FP7).

The beneficiaries must declare all receipts that are **established** (i.e. revenue that has been collected and entered in the accounts), **generated** or **confirmed** (i.e. revenue that has not yet been collected, but which has been generated or for which the beneficiary has a commitment or written confirmation) during the duration of the action.

Beneficiaries are obliged to declare them when submitting the final report. However, they may also declare them in the periodic reports.

In many cases receipts do not affect the grant amount since they do not lead to a profit. However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*
   If receipts: 30 ➔ no impact
   If receipts: 20 ➔ no impact
   If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*
   If receipts: 0 ➔ no impact;
   If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: Beneficiaries are advised to foresee the potential implications of receipts — before the signature of the GA — in the **consortium agreement** (given that the receipts will be appreciated at the level of the action, and not anymore on the level of each beneficiary as was the case in FP7) and the proposal.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a reduction of the grant (i.e. reduction of the 'maximum grant amount') — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is not a sanction, but the consequence of a breach of an obligation under the GA.

Example (calculation of the final grant amount):

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of article 36 GA, namely EUR 60 000 → 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level)

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.
Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*
Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*
2% of the maximum grant amount = 10 000
The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

If for the beneficiary the revised final grant amount is lower than its share of the final grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs *and* reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**:*

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries (and linked third parties) must:

- at proposal stage: enter only eligible costs into the estimated budget for the action *(see Article 4)*
- at reporting stage: declare only eligible costs in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries** (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

If the Commission/Agency finds ineligible costs, they will be rejected *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))

  The beneficiary must have an obligation to pay the amount of the cost (for depreciation costs, the amount of the costs must be recorded in the beneficiary's profit and loss accounts).

  Specific case:

  For **in-kind contributions provided by third parties free of charge** and **costs of linked third parties**, eligible direct costs must be actually incurred by the third party.

- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the duration of the action)

  The duration of the action is the period running from the starting date of the action to the end date of the action *(see Article 3)*.

  Example: *A conference for which costs are claimed must take place during the course of the action*

  Exception:

  Costs related to drafting and submitting the **periodic report for the last reporting period** and the **final report** are eligible even if they are incurred after the action duration. Those costs include the cost of certificates on the financial statements required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports.

⚠ This exception refers exclusively to costs related to the drafting and sending of the reports, as well as participation in a final review, and not to RTD/innovation activities (which as indicated above, must be carried out during the action duration).

Costs actually incurred should normally also be **paid** during the action duration.

In general, costs declared but not paid during the action duration *(for instance because the beneficiary is waiting for the payment of the balance)* are eligible only if the debt (and invoice) exists, and the final cost is known.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration.

⚠ If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs).

⚠ Costs of services or equipment **supplied after the end** of the action or the GA termination are not eligible.

Specific cases:

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Depreciation costs for equipment used for the action but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Travel costs for the kick-off meeting — If the first leg of the journey takes place before the starting date of the action *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  ⚠ Accounting documentation is necessary only for actual costs.

  Indirect costs do not need supporting evidence because they are declared using a flat-rate (⚠ new in Horizon 2020).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  ⚠ This principle cannot be used as justification for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  Specific case:

  For **in-kind contributions** provided by third parties **free of charge** and costs of **linked third parties**, eligible direct costs must be:

  – recorded in the third party's accounting records

  – calculated in accordance with the accounting standards applicable in the country in which the third party is established

  – calculated according to the third party's usual cost accounting practices.

- in **compliance with applicable national laws on taxes, labour and social security**

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  ⚠ Costs must reflect the budget allocation and cost breakdown.

  Examples: *The beneficiary may not increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

⚠ The conditions described here are cumulative, i.e. all of them have to be met for a cost to be eligible.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by the value per unit** ('amount per unit')

  Example: *A Commission decision that sets the unit costs related to laboratory analysis at EUR 300 per test. This amount per unit is included in Annex 2.*

  ⚠ The number of actual units used or produced may change based on actual implementation and it may be subject to controls by the Commission.

  Example: *Audit carried out after the action ends to verify that the number of hours declared for the action corresponds to reality.*

  For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

  – must calculate them (the average or standard personnel costs) according to its usual accounting practices

  – must budget and declare a total amount; the amount per unit must not be included in Annex 2.

  ⚠ You may not declare other types of unit costs according to your own usual cost accounting practices. For the other types of unit costs, the amounts per unit will be pre-defined *(in Annex 2 of the GA; see Article 5.2)*.

  Example (eligible unit cost): *Average personnel costs declared in Annex 2 by a beneficiary. Annex 2 includes the total value of eligible personnel costs estimated by the beneficiary for the action.*

  Example (ineligible unit cost): *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

- the **number of units** must be **necessary** for the action, the units must be used or produced during the course of the action and the beneficiaries must be able to show the link between the number of units charged and the work on the action

  ⚠ It is the number of units used for work on the action which must be recorded, documented and justified in case of an audit, not the actual costs of the work.

  Example:

  A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be calculated by **applying** a **flat rate** to the relevant **eligible costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.
Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900
Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600
Total eligible costs: 11 900 + 2 600 = EUR 14 500.
Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must correspond to the amount of lump sum costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

⚠ Therefore, the beneficiaries do not need to justify that the actual eligible costs correspond to the amount of the lump sum; they only need to prove that the action tasks described in Annex 1 have been carried out.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the project
- or costs that have been caused in full by the activities of several projects, the attribution of which to a single project can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

⚠ Any cost declared by a beneficiary as a direct cost of the action must be justified by supporting evidence (showing the link to the action).

3. Indirect costs

'Indirect costs' are costs not identifiable as specific costs directly linked to the performance of the action.

> In practice, they are costs whose attribution to the specific action cannot be or has not been measured directly, but only by means of cost drivers or a proxy, which apportion the total indirect costs (overheads) among the different activities.

⚠ In Horizon 2020, indirect costs are charged under the form of a 25% **flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*) .

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure:** **Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as direct personnel costs:

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- **personnel costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 What? **'**Personnel costs for employees or equivalent' (i.e. persons working for the beneficiary on the basis of employment contracts or equivalent appointing acts) **cover**:

- **basic remuneration** (i.e. basic salary and complements) and
- ⚠ only for non-profit legal entities: **additional remuneration**.

What is 'basic remuneration' and 'additional remuneration' and how to distinguish them? The 'basic remuneration' will be used to calculate the hourly rate of the employee for the purposes of the grant *(see calculation in point 1.1.4)*.

'Basic remuneration' refers to the 'basic salary' of the employee plus 'complements' that fulfil the eligibility conditions explained in point 1.1.3.

The 'basic salary' includes (and is limited to):

- the salary stated on the beneficiary's payroll (except for any part of that salary which must be considered as 'additional remuneration', ⚠ even if it that part is also registered in the payroll)
- social security contributions (mandatory parts to be paid by the employee and the beneficiary that employs him/her) — except any part included in additional remuneration.
- taxes included in the remuneration *(e.g. income tax to be paid by the employee retained by the beneficiary who employs him/her)* — except any part included in additional remuneration.
- other costs included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee)* — except any part included in additional remuneration.

The 'complements' may include:

- mandatory complements to the basic salary resulting from national law, collective labour agreement or the employment contract

  Example (mandatory complement): *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements if they fulfil the eligibility conditions set out in point 1.1.2.

  Example (variable complement acceptable as basic remuneration): *The contract of a professor includes as part of his/her usual tasks both teaching and research; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour for each hour spent on research activities.*

By contrast, 'additional remuneration' refers to payments made *on top* of the employee's usual remuneration, which result in a higher hourly rate.

⚠ Additional remuneration includes not only the extra salary, but also the social security contributions, taxes included in the remuneration and other costs included in the remuneration that result from that extra salary.

Example (additional remuneration): *a 'bonus' for participating in a project; an additional contract for specific tasks with a salary higher than the one under the main contract*

Example (not additional remuneration, but basic remuneration): *additional salary paid to the employee for additional hours worked on its standard work or expertise as defined in the employment contract (e.g. overtime or additional contract for those additional hours), if the additional hours are remunerated according to the standard salary conditions of the employee (i.e. do not result in a higher hourly rate). Note that the standard salary conditions may provide for a mandatory complement for those additional hours (e.g. overtime during night shifts).*

Thus, the two main features that help characterising a remuneration component as basic or additional are:

- hourly rate (no change to hourly rate would indicate basic remuneration, while a higher hourly rate would indicate generally additional remuneration) and
- kind of work or expertise (usual kind of work or expertise according to the contract or different/additional work or expertise).

Work or expertise	**Hourly rate**	
	Usual	**Higher**
Usual	Indicates basic remuneration	○ Indicates additional remuneration: if triggered by the participation in a project ○ May however qualify as basic remuneration if not dependent on a project or type of projects (and therefore spread over all activities, e.g. *based on merit of the employee at stake*)
Additional/different	Indicates basic remuneration	Indicates additional remuneration

⚠ In case of doubt, the classification will be made also taking into account the classification of the component under national tax law (i.e. if the tax authorities explicitly consider it as part of the basic remuneration of the employee or as an additional remuneration within the meaning of this guidance).

1.1.2 Costs for employees (or equivalent) must be **declared** on the basis of:

- either **the individual actual personnel costs** of each employee participating in the action (the most common case) or
- on the basis of **unit costs:**
  - either calculated by the beneficiary in accordance with its usual cost accounting practices (i.e. 'average personnel costs') if in line with the specific eligibility criteria (see further down in this article 'Specific case: for personnel costs declared as a unit cost') or
  - where applicable, unit costs fixed by the Commission; e.g. the mandatory unit cost for SME owners and natural persons without a salary.

1.1.3 The costs for employees (or equivalent) must comply with the following **conditions for eligibility**:

⚠ Only costs for personnel '**assigned to the action**' (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Certain employment contracts indicate that the person is hired to work on a specific project. If the person is supposed to work in the H2020 action but in accordance to the employment contract s/he was hired to work on another project then an amendment to the employment contract may be necessary to reflect its assignment to the H2020 action.

⚠ Moreover, personnel costs can be charged only for the **hours dedicated to the action**. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

For basic salary and mandatory complements:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  ⚠ Any part of the remuneration which is calculated with reference to commercial targets (*e.g. x € for reaching a sales target, x % on sales*) or fund raising targets *(e.g. x € premium per externally funded project gained, x % of the external funding gained)* is ineligible. The reason is that they are neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation.

  ***Example (not eligible because linked to fund raising target)**: a premium paid as a reward for having obtained a specific grant is not eligble.*

  Payments of dividends to employees (profit distribution) are ineligible under Article 6.5(a)(i). (However, complements based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted as variable complements, if they fulfil the conditions set out below.)

- be **fixed** (conditions and amount or percentage) and **mandatory** according to national law, collective labour agreements or the employment contract

  ***Example**: the employment contract between the entity and the person fixes a gross salary of EUR 3000 per month plus a transportation allowance of EUR 5 per working day.*

  ⚠ This condition for eligibility does not apply to 'variable complements'.

- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract or equivalent appointing act). Therefore, they cannot depend on the participation in a specific action/project

  ⚠ Any part of the remuneration linked to tasks *other* than those covered by the basic remuneration, in particular amounts triggered by the participation in a specific action/project, are not eligible as part of the basic remuneration. (They may however still be eligible as additional remuneration, *see below*.)

  A payment is linked to a specific action/project, if the employee would not have received it if s/he had not participated in work of the action/project; i.e. the triggering event is in fact the participation in the action/project *(e.g. an EU action)*, not the

performance of the tasks defined in the employment contract or equivalent appointing act.

For variable complements (in addition to the first and third conditions above):

- the variable complement is authorised by national law, collective labour agreement or the employment contract (or equivalent appointing act)

  Examples:

  1. *the collective labour agreement establishes that all researchers may receive a complement between EUR 100 and EUR 200 per month based on their seniority.*

  2. *the national law authorises public universities to pay a complement based on merit of the employees.*

  3. *the contract fixes a premium of EUR 1000 for each research paper published in peer reviewed international research journals.*

- the amount to be actually paid as variable complement is determined on the basis of objective conditions which are, at least, established and documented in the internal regulations of the beneficiary.

  Example: *based on the provisions of the collective labour agreement (see first example above) the internal regulations of the employer provide that: all researchers with seniority between 3 and 5 years will receive a complement of EUR 150 and all researchers with seniority above 5 years will receive a complement of EUR 180.*

  ⚠ The variable complement cannot be paid to the employee at the sole discretion of the manager (arbitrary complement). The decision to grant the complement must be based on objective conditions, which should be documented in a procedure and be verifiable.

  Example: *national law authorises public universities to pay a complement based on merit or performance of the employees and the internal regulations of the public university provide for an annual assessment exercise to determine the 'merit points' of each employee. The internal regulations also set up the objective criteria based on which the 'merit points' are decided. The internal regulations provide that all researchers with more than 10 'merit points' will receive a complement of EUR 1000.*

For additional remuneration (⚠only for non-profit legal entities)**:**

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the participation in another project)* is not eligible.

  Example:

  A nuclear researcher in a public research centre (non-profit) worked for 1 720 productive hours
  Remuneration components:

  a = annual salary: EUR 50 000

  b = a complement for holding a management post (e.g. Head of department): EUR 1 600

  c = additional remuneration for being Head scientist in the EU project: EUR 2 000

  d = additional remuneration for being First Assistant on an internal action: EUR 1 000

a *and* ***b*** *would be used to calculate the researcher's hourly rate:*

hourly rate for the EU action = {(50 000 + 1 600)/1 720} = EUR 30

c *would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*

d *would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for the performance of **additional work** or **different expertise** than his/her usual tasks

The work to be carried out (or expertise used) must be different from the standard work or expertise (defined in the employment contract or equivalent appointing act and covered by the standard remuneration package). This difference must be verifiable.

- be part of the beneficiary's usual remuneration practices and be consistently applied whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used

The objective criteria must be related to the additional work or expertise.

Examples (acceptable criteria):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking up the management of the research team and infrastructure.

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

A normal salary is paid for research on internal projects + additional remuneration is paid for participating in a special type of projects as for example international cooperative projects, projects awarded under competitive calls, etc.

Examples (not acceptable criteria):

Additional remuneration paid for using English.

Additional remuneration is paid only when participating in EU funded actions.

The system for making additional payments should be established in the beneficiary's internal rules (or at least be documented and known by the employees). (⚠ As for variable complements, the additional remuneration cannot be paid to a specific employee at the sole discretion of the management (arbitrary complement).)

Example (acceptable): *All teachers carrying out research on top of their usual teaching activities get an extra payment of 10% of their salary.*

Example (not acceptable): *The director decides at its sole initiative to pay an extra 10% to one professor carrying out research.*

However, the additional remuneration does not have to be the *same* for all persons working in the same project. The objective criteria used to determine the additional remuneration may result in different amounts for persons working in the same project *(e.g. the rule is that all teachers that carry out research on top of their*

usual teaching activities get an extra payment between 10% and 20 % of their salary, the precise percentage per teacher and project is determined according to the level of responsibility in the specific project).

The rules for additional remuneration may not differ according to *where* the funds come from. In particular, they cannot be set up for actions funded by a specific donor. (Additional remuneration schemes that are applicable only to EU actions are not acceptable.)

Example (acceptable): *All professors carrying out research will be paid 10% more.*

Example (not acceptable): *All professors carrying out research will be paid 10% more when they work on EU funded actions.*

Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see point 1.1.4*).

⚠ To avoid abuses, the rules for additional remuneration will be exceptionally also applied to the basic remuneration, if it has been artificially increased for participation in the EU action.

Examples:

1. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the same entity (beneficiary) to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

2. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with a linked third party (or a third party providing in-kind contribution) to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

3. *Employees of a specific department/service of the company which is in charge of carrying out only EU actions are paid a higher salary than their homologues in other departments carrying out the same tasks requiring a similar level of expertise (i.e. the salary differential is attributable to the source of funding). The rules for additional remuneration will apply to the difference between the salaries of employees working for the specific department and those of employees of other departments carrying out the same tasks with the same level of expertise (see point 1.1.4).*

Decision tree to determine eligibility of complements:

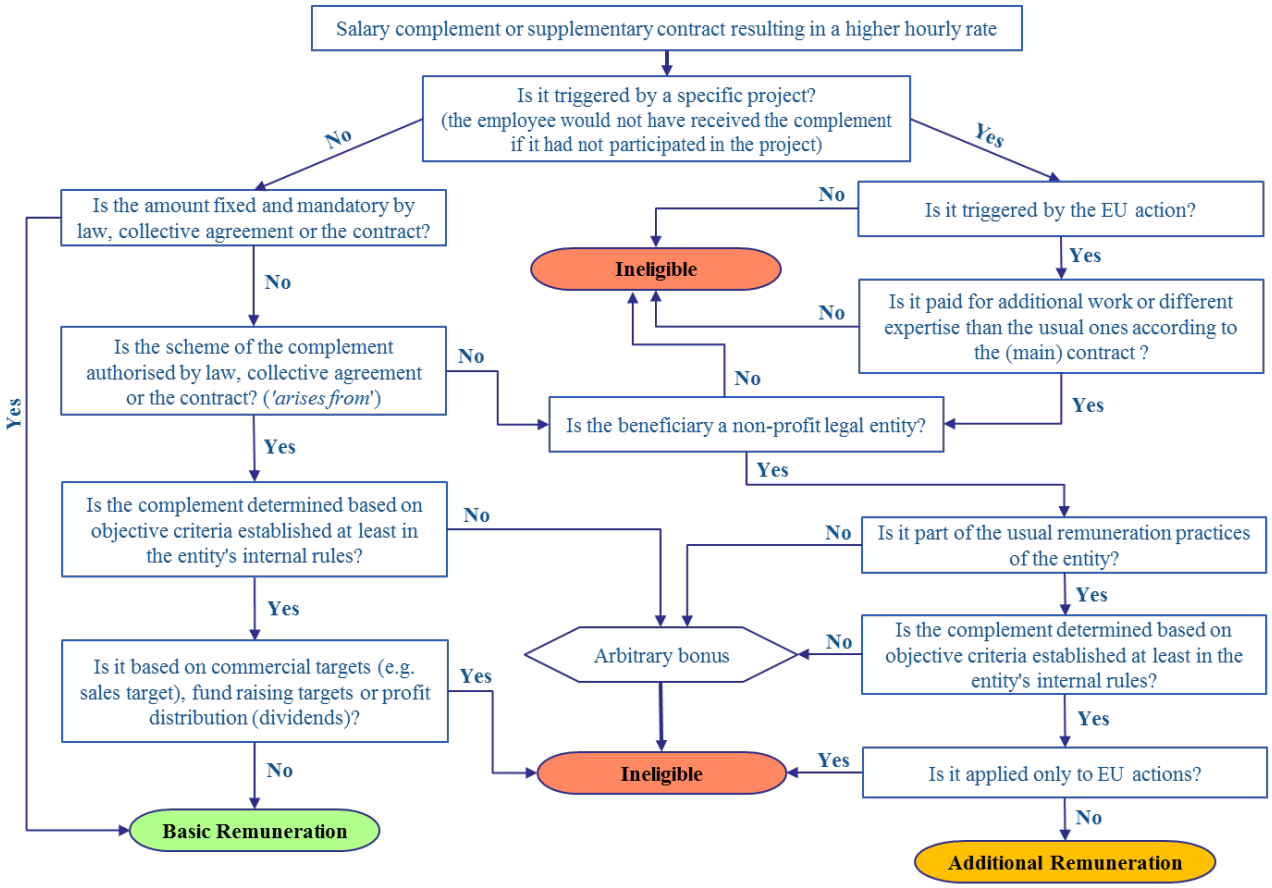

Specific cases:

Remuneration costs of employees (or equivalent) not working on the premises of the beneficiary, i.e. **teleworking** may be accepted as eligible if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Costs of **benefits in-kind** provided by the beneficiary to its personnel (e.g. costs of a company car made available to certain categories of employees for their own use) or of benefits equivalent to financial ones (e.g. costs of lunch vouchers) may be accepted as eligible if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

In general, **recruitment costs** are not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25 % flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — Like any personnel costs, PhD costs (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6. In this context, fellowships/scholarship/stipends are assimilated to salaries provided that this remuneration complies with the application national law on taxes, labour and social security. Furthermore,

the assignment of tasks must respect the laws in force in the place of establishment of the beneficiary and the persons must have the necessary qualifications for the performance of the tasks attributed to them in the context of the H2020 action.

If a student works for a university, he/she may be exempt from paying (part of) the **academic fees**. Those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Salaries and social security contributions paid during **parental leave** (either maternity leave or parental leave) are eligible as part of the basic salary only if:

- they are mandatory under national law or collective labour agreement *(e.g. statutory maternity pay)*; and
- the beneficiary has actually incurred them; and
- they are not reimbursed by national (central, regional or local) authorities. In other words, only the net amount paid by the beneficiary can be used to calculate the proportion to be charged to the action; and
- the employee worked for the action before the parental leave.

For public bodies, the **costs related to public officials** paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge.

ⓘ For more information on personnel made available to a beneficiary by a third party, *see below and Articles 11 and 12.*

'**Supplementary contracts**' (whatever their form, i.e. a contract additional to the main contract between a beneficiary and its employee) for carrying out tasks for specific actions *(e.g. international projects)* are acceptable if it is the beneficiary's usual practice and it is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package (basic remuneration) in the first non-action-related contract is considered 'additional remuneration'. As such it is subject to the specific cost eligibility conditions explained above for additional remuneration and, if eligible, to the eligibility ceiling.

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**

multiplied by

number of actual **hours worked on the action**},

plus

for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)}.

⚠ The total number of hours declared in EU and Euratom grants, for a person for a year, cannot be higher than the number of annual productive hours used for the calculation of the hourly rate *(see below)*.

⚠ This calculation method also applies for persons working exclusively for the action.

Example (for calculation of costs for employees):

A nuclear researcher working for a public research laboratory (non-profit) worked:
1 600 productive hours
800 hours declared for the action (at an hourly rate of EUR 40)
400 hours declared for another EU grant
S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.
*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***
Addition of the additional remuneration: = ***2 000***
Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

⚠ *Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 <* ***1 600****)*

Procedure for calculating personnel costs:

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.
Remuneration components:
a = annual salary: EUR 50 000
b = extra payment for holding a post involving radioactive hazards: EUR 5 000
c = additional remuneration for being Head Scientist in a Project: EUR 2 000
a *and* ***b*** *would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*
hourly rate for the action = {(50 000 + 5 000)/1 600} = ***EUR 34***

For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated **by financial year** and has to be made always on the basis of full financial years.

Example: *When the financial year matches the calendar year (most common case), i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs from January to December 2014.*

If at the end of the reporting period the on-going financial year is not yet completed, the beneficiary must use the same hourly rate it calculated for the **last closed** financial year. In other words: if on a reporting period there are months for which the financial year is not closed, the beneficiaries must use the last closed financial year available to declare those costs. (⚠ It is not necessary to wait until the annual accounts have been audited — 'last closed financial year available' refers here to the most recent full financial year for which all information necessary to calculate the hourly rates in accordance to the model grant agreement is available.)

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in that period.

⚠ The beneficiary cannot adjust the declared amounts (neither via positive nor negative adjustments in the next reporting period) resulting from a re-calculation of the hourly rate once the on-going financial year is closed. However, if the hourly rates for the last closed financial year were incorrectly calculated (e.g. resulting from incorrect accounting information) the beneficiary must correct them.

Example: *an audit on the annual accounts of the beneficiary finds later errors in the acconting information used to calculate the hourly rates.*

Specific cases:

Persons working exclusively in the action — There is no different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does not make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A applies in all cases.

Example:

Researcher Y worked exclusively in the project during the reporting period running from 01/10/2014 to 31/03/2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours.

The personnel cost to be reported would be calculated as follows:

	Hourly rate		*Hours worked for the project*	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

Employees hired during the **on-going financial year** (at the end of the reporting period) — Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Example:*The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

⚠ In order to avoid calculation errors, particular attention must be given in order to correctly determine the pro-rata of the annual productive hours *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the corresponding part of the indemnity in the reporting period in which the employee's contract ends. However, the indemnity may be accepted only if:

- arise from the applicable national labour law
- is recorded in the accounts of the beneficiary and
- is incurred during the duration of the action (although the actual payment may take place latter).

⚠ Only the part of the indemnity that corresponds to the time worked by the person on the action can be charged (i.e. pro-rata of the total time during which the entitlement was generated).

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours')**
- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ The option must be applied not only to the person for whom it declares costs, but per group of personnel employed under similar conditions.

⚠ Productive hours must be calculated on the basis of *all* working activities. Using only 'billable hours' is not acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a Horizon 2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	***Annual productive hours/activity***	***Billable hours***
for Horizon 2020 action	***400***	***400***
for other projects	*200*	*200*

for the preparation of proposals for new projects	*600*	*0*
member of the management board of the RO	*400*	*0*
total number of hours	***1 600***	***600***

⚠ In case the person concerned has been on parental leave during the year, the annual productive hours may be reduced by subtracting from them the actual time spent on parental leave.

This table explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** *1. Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* *2. The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types*	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors

	of special leave).	plus overtime worked minus absences (such as sick leave and special leave)} – the 'annual workable hours' are established according to one of the following: – employment contract of the person concerned – applicable collective labour agreement – national law on working time. ***Example:*** *contract stipulating 35 hours of work per week* ⚠ If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. – this calculation method is consistently applied (per group of personnel under similar conditions). ***Example (calculation of individual annual workable hours):*** *X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.* *The* ***individual annual workable hours*** *would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours* ***Individual annual productive hours*** *for Researcher X:* *Annual working hours =* ***1 848*** *+ overtime (hours) = 29* *- annual sick leave (5 days x 8 hours) = 40* ➔ *individual annual productive hours for Researcher X = 1 837* *Research Centre Z may use 1 837 as individual annual productive hours for this*	will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible. – if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1. – if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		researcher. **Specific case:** Employment contract remunerated 'per hour' — Some employment contracts do not establish a fixed salary and a number of hours to be worked, but an amount to be paid for each hour worked by the employee. In those cases, option 2 can be applied if all of the following conditions are fulfilled: – the employment contract explicitly fixes the hourly rate to be paid – the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked – the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)* – the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract). If those conditions are fulfilled, the 'individual annual productive hours' may be calculated as follows: {total salary paid to the employee in the financial year divided by hourly rate fixed in the employment contract}.	
Option 3 **Standard annual**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows:

productive hours	beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours'. The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time legislation. ⚠ If the contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours, this option cannot be used. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).* If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard	– if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

annual productive hours.

If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options.

Example (calculation of standard annual workable hours):

Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.

*The **standard annual workable hours** for Research Centre Z would therefore be: 365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours*

***Standard annual productive hours** for Research Centre Z:*
Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:

*Annual working days = **228***

- average annual sick leave (days) = 3

- days of general training = 4

- other unproductive activities (days) = 9

*➔ productive days = **212***

Multiplied by 8 working hours per day

➔ standard annual productive hours = 1 696

This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).

*90% of 1824 = **1 642***

***1 696 hours** (usual cost accounting practice) **> 1 642 hours** (90% annual workable hours)*

Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.

⚠ *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours),*

		Research Centre Z must apply 1 642 hours (90% of the annual workable hours). ⚠ *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	

Specific case (calculation of the hourly rate):

For **personnel costs declared as a unit cost** (on the basis of the beneficiary's usual cost accounting practices, i.e. 'average personnel costs'), the **hourly rate** must be calculated by the beneficiary in accordance with its usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  ⚠ This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual **personnel costs** recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2.These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate
- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

  Example: *calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

⚠ The beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(for information on this point, see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

⚠ The ceiling covers not only the additional salary but also all additional taxes, costs and social security contributions triggered by the additional salary.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples

1. *A researcher employed part time by the beneficiary to work four days a week during the entiry year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%), ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (eligibility ceiling):

{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000

The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 What? This budget category **covers** typically in-house consultants (i.e. self-employed *natural* persons working part-time or full-time for the action under a contract which is not governed by labour law; not companies) which comply with the eligibility conditions set out below.

What not? Persons provided by a temporary work agency. (Such costs may however be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs'; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products. (⚠ This implies that the beneficiary must keep records of the hours worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*).

1.2.4 Cost of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **formula** as the one explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the **hourly rate** is different (since it is not based on the annual personnel costs as registered on the payroll).

For the hourly rate, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used

- if the contract states a fixed amount for the services of the natural person and the number of hours to be worked: this global amount must be divided by the number of hours to be worked for the beneficiary under that contract.

  ⚠ If the contract fixes a global amount, but does not specify the time to be worked, the costs must be declared either as a purchase of service *(see Article 10)* or a subcontract *(see Article 13)*, but not as personnel costs.

1.3 Direct personnel costs: Costs for personnel seconded by a third party against payment

1.3.1 What? This budget category **covers** personnel seconded by a third party as an in-kind contribution against payment' *(see Article 11)*.

ⓘ For information on in-kind contributions provided by third parties free of charge, *see Articles 6.4 and 12.*

1.3.2 Costs for personnel seconded by a third party may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  Secondment refers to the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  ⚠ Secondment does not necessarily require the seconded person to work at the beneficiary's premises, though this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 What? These two budget categories **cover** the costs of SME owners and the costs of beneficiaries that are natural persons not receiving a salary.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

⚠ If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

Example:

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[17] and indicated in Annex 2 and 2a of the GA.

⚠ The Commission Decision does not *fix* the unit cost; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}

multiplied by

{country-specific correction coefficient of the country where the beneficiary is established}}

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*

EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

ⓘ For the country-specific correction coefficient, *see the Main Work Programme — MSCA*[18] in force at the time of the call.

⚠ In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and **almost completely automatised**

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an owner of an SME/beneficiary that is natural person, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

1.4.4 They are **calculated** as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ The total number of hours declared in EU and Euratom grants for an SME owner for a year cannot be higher than the standard number of annual productive hours used for the calculation of the hourly rate. For SME owners without salary, this is 1 720 hours.

[17] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[18] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes .

The Commission may verify that the beneficiary fulfils the conditions for charging this unit cost.

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 What? This budget category **covers** the personnel costs in actions under Part I, 'Research infrastructures' involving 'provision of access activity' *(see Article 16)*, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

⚠ You may use this option only if it is foreseen in your GA.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs (in accordance with the usual cost accounting practices, i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4., 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and the related taxes *(for VAT, see Article 6.5)*.

⚠ The options for access to research infrastructure may be used only if it is foreseen in your GA.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional cost eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]*

*[**OPTION**: Not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** costs for financial support to third parties under Article 15.

⚠ You may use this option only if it is foreseen in your GA.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel *(e.g. non-deductible VAT; see Article 6.5)*).

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

⚠ The option for access to research infrastructure may be used only if it is foreseen in your GA.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. ⚠ Travel costs related to an event at which the beneficiary carried out work not specifically related to the action are not eligible.

  All travel costs must be limited to the needs of the action; ⚠ costs related to extensions (for other professional or private reasons) are not eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  ***Example*:**

  Beneficiary A declares the cost of a business class airplane ticket for one of its employees.
  If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.
  If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*.

⚠ Such lump sums or per diem payments are not 'unit costs' or 'lump sum costs' under Article 5.2, but actual costs (because they are the actual cost incurred by the beneficiary). The amount of the per diem or lump sum paid by the beneficiary must be recorded in the beneficiary's accounting system and will be checked if there is an audit.

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation of equipment, infrastructure or other assets, for the relevant periodic report.

In some cases *(e.g. infrastructure)*, equipment costs may include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these cannot be charged as direct costs, but are covered by the 25% flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation charged as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see concept of 'direct cost' in Article 6.2.)*

Example: *Log book used to record the time and use of a wind tunnel for a specific action/activity.*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (international accounting standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- The depreciable amount (purchase price) of an asset must be allocated on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*).
- Depreciated equipment costs canNOT exceed the equipment's purchase price.
- Depreciation canNOT be spread over a period longer than the equipment's useful life.

Specific cases:

Equipment not used exclusively for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the part of the equipment's or asset's 'working time' for the action may be charged (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable (i.e. the hours that the equipment has been used for the project must be recorded).

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50% of the time and for other activities for the other 50% of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs charged to the project: EUR 50 000 (6 months of use) multiplied by 50% of use for the action during those 6 months = EUR 25 000.

Charging the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Depreciation costs for **equipment** used for the action, but **bought before the action start** are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — If recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may charge the *part* of the cost that corresponds to the use of the item for the action to the relevant reporting period.

This is however only accepted, if all of the following apply:

- the cost is economic and necessary
- only the portion of the equipment used for the action is charged

  ⚠ If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.

- the amount of use (percentage used and time) must be auditable
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary.

  ⚠ Useful life may be defined according to the beneficiary's practices or be established per type of equipment by national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50% of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50% (used for the action) = amount charged for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50% (used for the action) = amount charged for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only charge the depreciation costs for equipment, infrastructure or other assets that are *used for* the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the cost eligibility conditions of Articles 6.1 and 6.2 are met.

⚠ In particular the costs must be recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices (see *Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

⚠ If the full construction cost of the construction is eligible (rather than the depreciation) and if the construction was externalized to a third party (other than a linked third party), the costs will not be eligible as 'equipment costs', but may be eligible as 'direct costs of subcontracting' (Articles 6.2.B and 13).

1.2 Equipment costs: Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

⚠ You may use this option only if it is foreseen in your GA.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment (finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- For leasing (finance leasing) with the option to buy the durable equipment:
  - The equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices.
  - The costs declared canNOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices.

    ⚠ The finance charges included in the finance lease payments are thus ineligible.
  - The costs declared canNOT include any interest on loans taken to finance the purchase, or any other type of financing fee.
- For renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets contributed in-kind against payment.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** any goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials, scientific publications needed for the action, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).
- translation costs (if translation is necessary for the action's implementation, is justified, etc.).

Best practice: If there is any doubt about whether a cost is eligible, you should contact the Commission/Agency.

⚠ The option for access to research infrastructure may be used only if it is foreseen in your GA.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25% flat rate).

Specific cases/Exceptions:

Royalties paid for IPR access rights (and by extension any lump sum payments) — are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

⚠ Eligibility is however limited/excluded in the following cases:

- royalties for an **exclusive licence**: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action

- royalties for **licensing agreements** which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)

- royalties for **access rights to background granted by other beneficiaries under Article 25.2**: The default rule is that access rights needed to implement the action are granted on a royalty-free basis. Beneficiaries may deviate from the default rule only if agreed by them before signing the GA. Therefore, royalties paid may be eligible only if agreed by all beneficiaries before the GA is signed and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*.

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

- royalties for **access rights to background granted by other beneficiaries under Article 25.3** (and by extension royalties paid to third parties for exploitation of the results): are not eligible.

Costs related to protection of the action's results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* — are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Costs for drafting the 'plan for the exploitation and dissemination of the results' — Are normally not eligible since it is expected that they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising implementing this plan may be eligible.

Supplies and consumables which were **already in** the **stock** of the beneficiary — May be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs (i.e. where the use of certain resources is shared between different units of the same organisation and the costs of their use are charged through internal invoices) — May be eligible if their use and the usage (number of hours) for the action is specifically recorded and it is mentioned in the invoice. The internal invoice must refer to the use/dedication for the project of specific resources (*e.g. per researcher, piece of equipment, etc.)*.

> ***Example (acceptable internal invoice):*** *Internal invoice with 16 hours of the technician doing the analysis and 10 hours depreciation of the testing equipment used.*
>
> ***Example (not acceptable internal invoice):*** *Internal invoice with a global price for the use of a research infrastructure (e.g. laboratory) or for a service (e.g. an analysis).*

The costs must be declared under the budget category that corresponds to the invoiced resource (e.g. personnel, equipment, consumable, etc.) and must fulfil the eligibility criteria set out in Article 6.1 and 6.2.

⚠ They **may NOT include indirect costs elements** or **profit margin** or **mark-up**.

Internal invoices for the work of personnel: must be supported by time-records *(see Article 18.1)*. The hourly rate must be calculated as described in Article 6.2.A.

Internal invoices for the use of equipment must be limited to the depreciation for the relevant reporting period (only the part of the depreciation cost corresponding to the time the equipment was used for the action can be declared.) The use of the equipment must be properly recorded in

order to allow direct measurement of the use for the action and to ensure auditability *(see Article 6.2.D.2)*.

⚠ It is not possible to calculate an **all-in average cost** of internally invoiced equipment including, for instance, allocated indirect costs *(e.g. maintenance)*.

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

and

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1** or
  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

The General MGA provides for an optional budget category for capitalised and operating costs of large infrastructure.

⚠ This option is inserted into the grant agreement, except:

- if it is excluded by the work programme or
- for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics).

This budget category covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

Capitalised and operating costs of large research infrastructures are **eligible**, if all of the following apply:

- they **fulfil** the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the

research infrastructure, represents a total value of at least EUR 20 million for that beneficiary

- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **duration** of the action and the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the value of the specific research infrastructure used for the action (and for which the costs are charged to the action) is irrelevant (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

Costs of capitalised and operating costs of large research infrastructure must be declared as actual costs *(see Article 5.2(d))*.

What? Capitalised costs are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

⚠ Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. *Ad hoc* accounting and/or management schemes will not be accepted.

[19] *See also International Financial Reporting Standard No 16.*
[20] *See Article 126 of the Financial Regulation.*

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for such an infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

Operating costs are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not?

The following costs cannot be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature,

transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)

- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)

- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see* Point E of *Article 6.2)*.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '***large* research infrastructure**', if they comply with the definition and conditions listed in Point D.4 of Article 6.2 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

⚠ The values of contracts of renting or leasing of research infrastructure may be considered for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments);

- knowledge-based resources such as collections, archives or scientific data;

- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] *See Article 2(6) of the Horizon 2020 Framework Programme.*

⚠ In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure.

Only the costs actually incurred from the date of the positive ex-ante assessment can be declared in accordance with these guidelines.

When? Applications for ex-ante assessment can be submitted at any time during the preparation of any grant agreement.

⚠ Costs incurred for operating large research infrastructure can be declared according to these guidelines only after having obtained the positive ex-ante assessment from the Commission.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Point D.4 of Article 6.2).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

⚠ If the status is refused, the guidelines cannot be applied and the beneficiary cannot declare its costs of research infrastructure according to these guidelines.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

⚠ The guidelines cannot be applied before a positive final ex-ante assessment report. Therefore, any cost declared under Point D.4 of Article 6.2 without such a report (or declared before such a report is issued) will be rejected. However, a positive final ex-ante assessment report allows the beneficiary to adjust, if needed, the costs already declared in previous financial statements.

⚠ Costs declared in accordance with the methodology positively assessed by the Commission will **not** be **challenged during audits**, except in case of irregularity and fraud. The auditors will:

- ensure that the methodology positively assessed is the one being used and
- verify the accuracy of the calculations made applying the methodology

ⓘ For more information on the procedure, *see the Online Manual.*

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be identifiable and verifiable, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

⚠ The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, e.g. through time registration
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented (e.g. a research organisation, technical university, research enterprise). These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

⚠ Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

– internal management exchanges necessary for the approval of an underlying transaction

– purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

⚠ The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

– for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (Link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for the action.*

The costs of the two research infrastructures cannot be charged to the action on setting up the network for social intelligence.

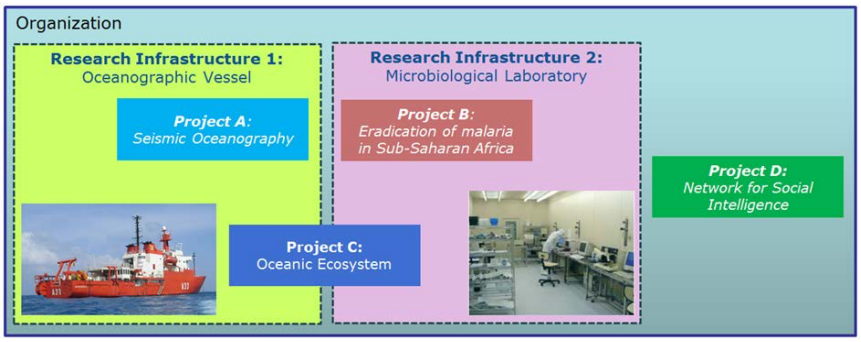

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[23].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  ⚠ This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

  ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds —may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Point D.4 of Article 6.2 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

⚠ Direct measurement of costs does not mean fair apportionment of costs through proxies or cost drivers (which was standard for declaring real indirect costs under FP7). Fair apportionment is not a *measurement* but an attempt to *estimate* the costs that were incurred for an action.

Example 2 (Comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

[23] *See Article 129(1) of the Financial Regulation.*

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

⚠ *Direct* measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action ('project time') and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  ⚠ If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. These data must be regularly updated.

Example 3 (Costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between

users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

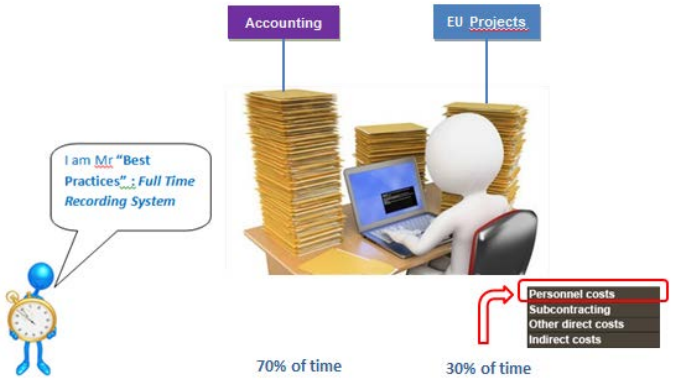

Example 4 (Part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be charged to the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

and not:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (Rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50% by a research infrastructure;*
** 50% by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

⚠ *On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).*

⚠ *The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50% of m²).*

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action;

- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action;

- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action);

- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action);

- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action);

- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action);

- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  ⚠ The energy consumption of a specific research infrastructure can be obtained from the measured consumption (e.g. number of kilowatts per hour of use) as stated in its technical specifications, or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

⚠ **Alternative to best practices:** The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

This option corresponds to the declaration of eligible costs actually incurred; it should not be confused with the 'unit costs' as a simplified form of grant which is subject to a Commission decision (see Articles 29(2) and 33 of the Rules for Participation Regulation No 1290/2013 and Article 124 of the Financial Regulation).

With this method, it is possible to determine a 'cost per unit of use' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

The **cost per unit of use** must be calculated as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure} + \text{all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence; or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The direct costs that can be claimed are calculated as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties[and][;]][**OPTION**: not applicable;]*

*(d) [**OPTION if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:** [unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]**]** [**OPTION:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

1.1 This budget category **covers** costs that are *not directly* linked to the action *(see Article 6.2)*.

1.2 Indirect costs must be **declared** on the basis of a flat-rate (*see Article 5.2(e)* ⚠ new in Horizon 2020).

⚠ In practice, the indirect costs are automatically calculated by the IT system.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25% flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: subcontracting of opinion surveys.

⚠ The purchase of goods, work or services that do not represent action tasks described in Annex 1 *(see Article 10)* is not considered subcontracting under a Horizon 2020 action, and must not be subtracted when calculating the 25% flat rate

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

– costs of providing financial support to third parties (if option applies)

– costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies').*

Example (indirect costs):

A public university is a beneficiary under a grant agreement and has incurred the following costs
- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),
- EUR 20 000 in subcontracting costs,
- EUR 10 000 in consumables costs.
Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000
Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750
Total eligible costs: EUR 155 750

⚠ Beneficiaries receiving an operating grant financed by the EU or Euratom budget canNOT declare indirect costs in any H2020 action for the period covered by the operating grant.

'Operating grants' are (normally annual) grants given by a separate grant agreement to finance the operation and running costs of an entity e.g. call COMM-C2/01-2013 under the 'Europe for Citizens' programme.

Since the calculation of the indirect costs is automatic, the beneficiaries must specifically alert the Commission/Agency, if they received an operating grant.

Best practice: The beneficiaries are advised to contact the project officer (via the via the 'My Area' section of the Participant Portal) when submitting their financial statements.

F. [OPTION: [Insert name of specific cost category(ies)[22]]][OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant): *[**insert name of specific cost category**] are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].***]***

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category] *are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.***]***

[same for each specific cost category]

[OPTION: *Not applicable****]***

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories: Types of costs — Cost forms — Conditions for eligibility — Calculation

For some actions under the General MGA, the beneficiaries may declare unit costs for **specific cost categories**, i.e.:

- for actions under Part III of the Horizon 2020 Framework Programme, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: '**costs for energy efficiency measures in buildings**'

  ⚠ This unit cost will only apply for Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and only for the building-related demonstration activities.

- for actions under Part I, 'Research infrastructures' involving 'provision of access activity': '**access costs for providing trans-national access to research infrastructure**'

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- for actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing' involving clinical studies: '**costs for clinical studies**'

⚠ You may use these options only if they are foreseen in your GA.

⚠ Costs that are covered by the unit cost of a specific cost category may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Examples:

Case 1: *The unit cost for 'efficiency energy measures in buildings' covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

Hypothetical case 2: *A is a beneficiary in an action with a specific activity on 'intelligent buildings', where a Commission decision setting unit costs has been adopted for costs of purchasing and operating (personnel + related indirect costs (overheads)) the equipment needed for the action.*

The situation of A is the following:
A has 3 employees operating the equipment in that specific activity on 'intelligent buildings', and another 2 working on other activities of the action. The personnel costs for the 3 employees operating the equipment are EUR 150 000, and the personnel costs of the other 2 employees are EUR 80 000.
A incurs other direct costs for the action worth EUR 250 000, out of which EUR 100 000 are the costs of purchasing the equipment needed for carrying out the activity on 'intelligent buildings'.
A declares as actual costs the personnel costs for the employees working on the activities other than the specific activity on 'intelligent buildings', as well as the other direct costs of those activities (not included in the unit costs).

The unit cost adopted by Commission decision is EUR 800. The number of units used for the project is 300.

Both the personnel costs and the purchasing costs included in the unit costs (150 000 +100 000) and the indirect costs associated to them must be excluded from the calculation of the actual costs of the beneficiary declared under the budget categories 'direct personnel costs' and 'other direct costs' and 'indirect costs'.

A will declare its costs in the financial statement (Annex 4):

Direct personnel costs	*Direct costs of subcontracting*	*Direct costs of support to third parties*	*Other direct costs (EUR)*	*Indirect costs*	*Costs of 'intelligent buildings' (special unit costs)*	*Total costs*
80 000	*0*	*0*	*150 000*	*57 500 =* *25% (150 000 + 80 000)*	*300x800= 240 000*	*527 500*

Hypothetical case 3: *A Commission decision allows for the use of a unit cost of 30 Euro for each laboratory analysis of the samples collected in an action. That unit cost covers the costs of the laboratory technicians involved in the analysis and of the equipment used. The beneficiary will declare the actual costs of the direct personnel working in the action under 'direct personnel costs', but excluding the costs of the laboratory technicians analysing the samples, because they are already covered by the unit cost under 'specific category of costs'.*

Personnel Costs of beneficiary A:
100 000 for 2 researchers working in the action + 10 000 for 2 laboratory technicians working on laboratory analysis
Eligible personnel costs under the budget category 'direct personnel costs': 100 000 as direct personnel costs (and not the 10 000 of the technicians)
Number of sample analysis in a laboratory for beneficiary A: 450
Eligible costs under 'specific category of costs': 450 X 30 = EUR 13 500

1.1 'Specific cost category – costs for energy efficiency measures in buildings'

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements as new isolation, new ventilation system, window, door, heating elements, system controlling the system will be reimbursed.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost set out in Commission Decision C(2013) 8196[25] and indicated in Annexes 2 and 2a [hyperlink] of the GA.

⚠ The Decision does not *fix* the unit cost; the 'amount per unit' (EUR/m^2 of eligible conditioned gross floor area) must be calculated for each BEST table (Building Energy Specification Table)[26]— before signature of the GA — according to the following formula:

Amount per unit = {EUR 0.1 x estimated total kWh saved per m² per year x 10}

⚠ The energy efficiency measures and the amount per unit must already be part of your project proposal (via the BEST table). They are then included in Annexes 1 and 2.

You may submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m^2 of surface area built or refurbished ('conditioned')

Example (calculation):

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year
Payback period (standard figure to be used in the calculation) = 10 years
Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m²).

⚠ The 'm^2 of eligible conditioned gross floor area' may not include parts of the buildings which are not affected by the measures, *e.g. garages*.

[25] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[26] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-grants-manual-amga.

1.2 'Specific cost category – access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** direct andindirect 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; Article 6.2.D.1 and Article 16).

1.2.2 If they are declared under this budget category (i.e. specific cost category – access costs for providing trans-national access to research infrastructure), the costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[27] and indicated in Annex 2 and 2a[hyperlink] of the GA.

⚠ The Decision does not *fix* the unit cost; it must be established for each access provider and installation — before signature of the GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{28})}{\text{average annual total quantity of access (over past two years}^{29})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost-accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    Exceptionally, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[29] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
- costs of consumables specifically used for the installation and the user's research work
- costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
- costs of energy power and water supplied for the installation
- costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)
- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
- costs of specific scientific services included in the access provided or needed for the provision of access

- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)
- travel and subsistence costs for users.

Example (calculation):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is
Average costs = average (3 200 000, 2 800 000) = 3 000 000
Average hours = average (6100, 5900) = 6000
Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €
Access providers are allowed to submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

⚠ The access activities and the parameters for calculating the unit cost must already be part of your project proposal. They are then included in Annexes 1 and 2.

A form for the calculation of unit cost will be provided on the Research Infrastructures call pages on the Participant Portal.

Do not forget to describe in your proposal the services provided to users as well as the support users need in order to make use of the installation: logistical, technological and scientific, including ad-hoc training needed by users and preparatory and closing activities that may be necessary to use the installation

⚠ As mentioned above, before signature of the GA, the beneficiaries can still opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation and access provider) not as unit cost, but as actual costs. Such costs must then be declared under the other budget categories (Article 6.2.A-E).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional cost eligibility conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 'Specific cost category – costs for clinical studies'

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study;
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
  - costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
  - indirect costs for the study.

1.3.2 If they are declared under this budget category (i.e. specific cost category – costs for clinical studies'), the costs must be **declared** on the basis of the unit cost set out in Commission Decision C(2014) 1393 and indicated in Annex 2 and 2a of the GA.

⚠ The Decision does not *fix* the unit cost; 'amount per unit' (EUR/patients or subjects included in the clinical study) must be calculated for each study and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA —according to the following formula:

Amount per unit ={Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks] }

The unit cost components must be calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':
{'average hourly cost for doctors', i.e.:
certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full-time equivalent for the personnel category doctors for year N-1}
multiplied by
estimated number of hours worked by doctors for the task (per patient/subject)}

For unit cost component 'personnel costs of other medical personnel':
{'average hourly cost for other medical personnel', i.e.:
certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full-time equivalent for the personnel category other medical personnel for year N-1}
multiplied by
estimated number of hours worked by other medical personnel for the task (per patient/subject)}

For unit cost component 'personnel costs of technical personnel':
{average hourly cost for technical personnel, i.e.:
certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full-time equivalent for the personnel category technical personnel for year N-1}
multiplied by
estimated number of hours worked by technical personnel for the task (per patient/subject)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc.)

For each category of consumables:
{'average price per item', i.e.:
{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned
total number of items purchased in year N-1 for the category of consumables concerned}
multiplied by
estimated number of items used for the task (per patient/subject)}

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:

{'average cost of depreciation and directly related services per unit of use', i.e.:

{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

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total capacity in year N-1

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)}

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value-for-money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:

'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

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total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%

multiplied by

{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}}

The following must be excluded:

- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

⚠ The estimation of the resources must be done on the basis of the protocol for the clinical study (and must be the same for all beneficiaries/linked third parties/third parties involved).

⚠ Each beneficiary/linked third party/third party providing in-kind contributions must calculate the direct costs by using its historical costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application).

⚠ Personnel costs must be defined in the 3 categories (doctors, other medical personnel, technical personnel) defined in the Commission Decision. No other categories (e.g. 'nurses') can be used.

⚠ The descriptions of the resources and the parameters for calculating the unit cost must already be part of your project proposal (via template provided on the call website). These specifications are then included in Annex 2 of the GA.

⚠ As indicated above, before signature of the GA, the beneficiaries can still opt for declaring costs for a study (⚠ one cost form per study and beneficiary/third party) not as unit cost, but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*.

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or of costs actually incurred for a given clinical study.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** the number of patients or subjects that participated in the study

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.**]***

[OPTION: *Not applicable**]***

1. Costs of linked third parties

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional cost eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply, but with the changes needed to render them applicable to the linked third parties.

Examples:

'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.

'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.

Depending on the type of cost, they must be declared by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. Remuneration of employees must be declared as 'personnel costs' (Article 6.2.A.1).

2. Depreciation costs of equipment must be declared as 'other direct costs – equipment' (Article 6.2.D.2).

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

Depending on the type of cost, they must be declared (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example:

1. Depreciation costs of equipment contributed free-of-charge must be declared as 'other direct costs – equipment' (Article 6.2.D.2).

⚠ In-kind contributions ***against payment*** are costs *of* the beneficiary/linked third party (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. They must be declared under those budget categories.

Example:

1. The cost of personnel seconded against payment must be declared as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3).

2. Costs of equipment contributed against payment must be declared as 'other direct costs – equipment – cost of equipment, infrastructure or other assets contributed in-kind against payment' (Article 6.2.D.2).

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

1. Ineligible costs

Cost are ineligible, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

– **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

⚠ Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the cost eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

⚠ Conversely, if VAT is **not deductible**, it is an eligible cost.

The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

Specific cases:

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

– **costs incurred during the suspension of the implementation of the action**

Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

– **costs declared under another EU or Euratom grant** (i.e. double funding)

This includes:

- costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*
- costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
- costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
- if a beneficiary is receiving an operating grant[30] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

  Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European Standards bodies (CEN, CENELEC, ETSI).*

– **cost categories explicitly excluded in the work programme/call** (if option applies).

[30] For the definition, *see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the project (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

⚠ Normally, the beneficiaries must comply with the national law of the country in which they are established and that of the country where the action is implemented.

Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

⚠ However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* ('**third parties involved in the action**').

Third parties involved in the action do not sign the GA *(see Article 1)*.

⚠ Beneficiaries using third parties in an action remain responsible for the work attributed to them under the GA.

The differences between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value-for-money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION 2, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *Not applicable****]***

1. Beneficiaries not receiving EU funding

Beneficiaries that do not receive EU funding are considered beneficiaries (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from an associated country[31]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

ⓘ For more information on third country participants, *see the Online Manual*.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate in the action, not all of the obligations under the GA apply to beneficiaries not receiving EU funding. (Which obligations apply or do not apply depends on the role of the beneficiary in the grant and if it has or not linked third parties that receive EU funding).

This table summarises the obligations of the General MGA that do not apply to beneficiaries not receiving EU funding (under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

⚠ Apart from this, they are treated like the other beneficiaries.

[31] For the definition, *see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and allow technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs or recovery) may be applied.

Example: *A non-EU beneficiary that does not receive EU funding does not carry out the tasks attributed to it in Annex 1.*

At the end of the action, only part of the action is implemented ⇨ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the non-EU beneficiary has breached fundamental ethical principles ⇨ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45.2).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […]*[23]]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[24] or 'contracting entities' within the meaning of Directive 2004/17/EC[25] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

'Contracts' for the purchase of goods, works or services are ordinary contracts for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

***Example (subcontracts):** Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

⚠ Contracts to purchase goods, works or services are usually limited in cost and scope.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, *see Article 8.*

2. Additional eligibility condition: Best value-for-money or lowest price

The beneficiaries must base their purchases on the 'best value-for-money' considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i..e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value-for-money principle does not require **competitive selection procedures** in all cases. (However, where a beneficiary did not request several offers, it must demonstrate how best value-for-money was nevertheless ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.)

Example: *electronic tendering for consumables*

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

⚠ The obligations in Article 10.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the contract concerned *(see Article 6.2.D.3 and 6.6)*. Beneficiaries must demonstrate (upon request) that the selection of the contractor complied with these rules.

Specific cases:

Goods, works or services purchased under framework contracts and contracts existing before the signature of the GA — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with these two conditions (best value-for-money and absence of conflict of interests).

Additional conditions — Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out additional conditions (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must also be described in the work programme/call — as special eligibility conditions for the subcontracting costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[32] and 2004/17/EC[33] — or any EU legislation that replaces these Directives[34]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > ⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

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[32] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[33] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[34] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

'Third party' means any legal entity that has not signed the GA *(see Article 1)*.

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. (⚠ In this case, the beneficiary makes a payment and therefore incurs a cost.)

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions, and do not concern the case of linked third parties carrying out part of the work of the action (which is covered by Article 14).

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, *see Article 8.*

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the*

action, recorded in the accounts of the beneficiary, etc.), up to the direct costs actually incurred by the third party for the in-kind contribution.

The *direct* costs incurred by the third party may not be based on unit costs[35] or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Specific case:

For **in-kind contributions** against payment that are **not used on the beneficiary's premises but on the third party's premises**, the amount charged by the third party and paid by the beneficiary may be eligible up to the direct costs actually incurred by the third party increased by a flat-rate of 25% on these costs (in order to take into account the indirect costs of the third party).

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may charge it to the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*

[35] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

⚠ If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

The obligations in Article 11.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

Example (approval without formal amendment): *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

⚠ The approval is at the discretion of the Commission/Agency, and there is no automatic entitlement to it.

Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the Commission/Agency and rejection of costs.

⚠ Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.*e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action*).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews,

audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, **for free** (*i.e. without any payment, contrary to the case covered by Article 11*). (⚠ In this case, the beneficiary makes no payment and there is therefore no cost incurred *by the beneficiary*).

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the duration of the action, etc.).*

⚠ These costs **must be recorded in the accounts of the third party**.

The obligations in Article 12.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.4 and 6.6)*.

⚠ Normally, **only** the **direct costs actually incurred by the third party** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services may be declared.

The direct costs incurred by the third party may not be based on unit costs[36] or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*).

Following this, the beneficiary cannot declare as a cost the unit costs for SME owners or natural persons who do not receive a salary from the third party.

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises.

The indirect costs of the beneficiary related to the use of in-kind contributions free of charge on its own premises will be covered by the 25% flat-rate for indirect costs applied to the value of the in-kind contributions used on its premises.

Specific case:

For **in-kind contributions** that are **not used on the beneficiary's premises but on the third party's premises**, the beneficiary may declare as eligible the direct costs actually incurred by the third party increased by a 25% flat-rate on these costs, calculated according to the formula specified in Article 6. 2. E of the GA.

The beneficiary must exclude the costs of the in-kind contributions free of charge not used on its own premises from its eligible direct costs when it calculates the 25% flat-rate for indirect costs.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the costs in excess will be rejected as ineligible.

⚠ If these in-kind contributions free of charge fulfil the conditions set out in Article 5.3.3(c) they also have to be declared as receipts of the action (for an amount corresponding to the amount declared as eligible costs).

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Approval without formal amendment

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in **Annex 1** to the GA.

[36] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may **approve** costs related to the payment of in-kind contributions not included in Annex 1 **without formally amending the GA** (under the conditions set out in this Article).

ⓘ For more information on approvals without formal amendment, *see Article 11.*

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[26]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC*[27]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[26] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[27] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a 'subcontract' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Characteristics of subcontracting:

- Based on 'business conditions'

  ⚠ This means that the subcontractor **charges a price**, which usually includes a profit (which distinguishes it from 'linked third parties' of Article 14; *see also Article 8*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary

  This distinguishes a subcontract from action tasks implemented by in-house consultants *(see Article 6.2.A.2)*.

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility vis-à-vis the EU/Euratom for the work subcontracted lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations vis-à-vis the Commission or the other beneficiaries (it has no contractual relation with them).

  ⚠ However, the subcontractor can be audited by the Commission/Agency, the European Anti-Fraud Office (OLAF) and the Court of Auditors.

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted.

Exception:

For actions involving PCP or PPI**,** action tasks (research and innovation tasks) may be fully subcontracted by means of PCP or PPI.

Specific cases:

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to its **affiliates** — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2 (b))* — cannot be subcontracted *(see Article 41.2(b))*. Other activities of the coordinator may in principle be subcontracted.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, *see Article 8.*

2. Additional eligibility condition: Best value-for-money or lowest price

The beneficiaries must base their subcontracts on the 'best value-for-money' considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i..e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value-for-money principle does not require **competitive selection procedures** in all cases. (However, if a beneficiary did not request several offers, it must demonstrate how best value-for-money was ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.)

⚠ In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

⚠ The obligations in Article 13.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of the subcontract concerned *(see Article 6.2.B and 6.6)*. Beneficiaries have to demonstrate upon request that the selection of the subcontractor complied with these rules.

ⓘ For more information on additional conditions, framework contracts and subcontracts existing before the signature of the GA, *see Article 10.*

3. Additional eligibility conditions for actions involving PCP or PPI

For actions involving PCP or PPI, the beneficiaries must follow additional rules. These additional rules mirror the key obligations in the GA for PCP/PPI Cofund actions.

ⓘ For more information on the conditions for PCP or PPI subcontracting, *see PCP-PPI Cofund MGA.*

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Approval without formal amendment

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1.

It is the **work** (the **action tasks**) to be performed by a subcontractor which has to be identified in Annex 1. In principle, the identity of the subcontractors does not need to be indicated.

Specific case:

Existing framework contracts or subcontracts — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with the two conditions (best value-for-money and absence of conflict of interests) at the time of their award.

The description should also **include an estimation of costs for each subcontract**.

Moreover, it should explain the **need** for a subcontract, taking into account the specific characteristics of the action.

Additionally, the total estimated costs for subcontracting per beneficiary must appear in the table of estimated costs of Annex 2.

⚠ Costs for **subcontracts not set out in Annex 1 and 2** are in principle **not eligible.**

If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may **approve** costs related to subcontracts not included in Annex 1 and 2 **without formally amending** the GA (under the conditions set out in this Article).

Example (approval without formal amendment): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are justified in the report and it is approved by the Commission.*

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Therefore, a beneficiary that does not amend the GA to include a subcontract in Annex 1 and 2 assumes the risk of non-approval by the Commission/Agency and rejection of costs.

Approval will not be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *Action where an essential beneficiary leaves and the coordinator subcontracts all the tasks of this beneficiary*

4. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose **contractual arrangements** on the third parties.

6. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

⚠ 'Bodies governed by public law' also include entities **financed** mostly by the State, regional or local authorities, or other bodies governed by public law and entities **controlled** by those bodies *(for the full definition, see Article 1(9) of that Directive)*.

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following ***affiliated entities***[28] *and* ***third parties with a legal link to a beneficiary***[29] *('****linked third parties****') may implement the action tasks* ***attributed to them in Annex 1****:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [****OPTION if joint and several liability has been requested:****, if it has accepted* ***joint and several liability*** *with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [****OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked parties]

The linked third parties ***may declare*** *as eligible the* ***costs they incur*** *for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *Not applicable****]***

[28] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[29] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

Linked third parties may **implement part of the action**, although they do not sign the GA (and are therefore not beneficiaries).

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them vis-à-vis the beneficiary

  ⚠ However the beneficiary remains responsible vis-à-vis the Commission for the work carried out by the linked third party. Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties — unless the GA foresees joint and several liability *(see Article 44.1)*.
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only 'affiliated entities or entities with a legal link to a beneficiary can be linked third parties.

'**Affiliated entities**' cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples:

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

⚠ If the only relation between two entities is a ***capital* link** (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity', i.e.:

- under the direct or indirect control of the beneficiary or
- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

'Entities with a **legal link**' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the duration of the action and it usually pre-dates and outlasts the GA.

  ⚠ 'Ad hoc' collaboration agreements or contracts between legal entities to carry out work in the action are therefore NOT covered by this case. In this case, both legal entities should be beneficiaries.
- a legal relationship.

This may be in the framework of a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

Examples:

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. The beneficiary concerned shall provide to the Commission/Agency during the evaluation, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any alternative document proving that research facilities are put in a common structure, and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities *composed of members (where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may charge costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not listed in the work programme/call) are not eligible for funding under Article 10 of the Rules for Participation.*

ⓘ For more information on the general conditions for participation and funding, *see the Online Manual.*

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak'

  ⓘ For more information on the financial viability and the financial capacity check, *see the Online Manual.*

- the beneficiary mainly coordinates the work of its linked third party.

Examples:

1. *The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

[38] *See Articles 8 and 9 of the Rules for Participation.*

3. The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.

⚠ If the Commission/Agency requests it, the third party **must accept** joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

⚠ In principle, the entity performing most of the work should be the one appearing as beneficiary, and the others should appear in the GA as the linked third parties.

However, in some specific cases, the linked third parties may perform the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) have a common research agenda. They have an structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

The roles of subcontractors and contractors are not exchangeable with the role of linked third party.

ⓘ For more information on the differences between contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties, *see Article 8.*

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No approval without formal amendment

The third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the signature of the GA (or added later, through an amendment; *see Article 55*).

⚠ There is no procedure for approval without formal amendment.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **cost eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the duration of the action, etc.)*.

⚠ These costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

Each linked third party has to provide its own ***certificate* on the financial statements** *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each linked third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

⚠ The obligations in Article 14.1.1 additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.3 and 6.6)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the linked third party *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties

Horizon 2020 actions under the General MGA may involve financial support to third parties as part of the action activities. In this case, the beneficiaries must pass on the EU funding to one (or more) recipients that are not party to the GA (also called '**cascade funding**').

⚠ These third parties are not party to the GA; therefore, they do not need a PIC, nor the GA needs to be amended to include each of them when they are selected.

This may be done via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (⚠ Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.)

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

⚠ In this case, the beneficiaries' activity consists in providing financial support to the target population of the activity implemented by the beneficiaries, with the aim to achieve the objectives of the call for proposals (set up already in the Work Programme).

Linked third parties may award financial support to third parties under the same conditions as the beneficiaries.

ⓘ For financial support given in the form of prizes, *see Article 15.2.*

⚠ You may use this option only if it is foreseen in your GA (and in the work programme/call).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party (as a general rule must not exceed EUR 60 000 per third party)

  This is a limit *per* third party; several third parties could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

  ⚠ In exceptional cases, a higher amount can be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries to third parties may take the form, for instance, of a lump sum, or of the reimbursement of actual costs incurred by these third parties when performing the activities that qualify for such support.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  ⚠ The activities that qualify for financial support benefit, primarily, the third parties and must not be performed exclusively for the benefit of the beneficiaries awarding such financial support.

  The financial support is not the same that the award of the implementation of certain action tasks (see *subcontracting under Article 13*), nor the purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the third parties that may receive the financial support.

- the criteria for giving financial support*(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives of the call for proposals (set up already in the Work Programme) for which the financial support to third parties is allowed.

⚠ All these conditions must already be described in your proposal *(see the Proposal Templates)*.

⚠ The obligations in Article 15.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them)*.

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: The beneficiaries are advised to impose contractual arrangements on the third parties (which include control measures and/or reducing the financial support). The beneficiaries remain fully responsible towards the Commission regarding the implementation of the action.

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties (via prizes)

The actions under the General MGA may also involve financial support via prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

⚠ You may use this option only if it is foreseen in your GA (and in the work programme/call).

⚠ Notwithstanding the obligation for the winner of the prize to promote the action and give visibility of the EU funding (*see Article 38*), it is not an EU prize.

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for the support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*
- the award criteria for assessing the quality of entries in light of the objectives and expected results

  ⚠ The criteria must be objective.
- the amount of the prize *(e.g. EUR 70 000)*
- the payment arrangements (usually one instalment).

⚠ The obligations in Article 15.2.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that this obligation is accepted by the recipients.

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[30] must provide access to research infrastructure or installations[31] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free-of-charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country**[32] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**]***[33]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

[OPTION:** Not applicable**]

[30] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[31] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[32] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.**][OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.**]***

[33] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

Actions under Part I, 'Research infrastructures' may (in addition, to their normal RIA, IA or CSA activities) provide for trans-national (or virtual; *see below*) access to research infrastructure[39] and installations[40] for scientific communities ('provision of access activity').

Such actions are funded under the following topics:

- 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
- 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
- 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

[39] For the definition, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructures**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] For the definition, *see the footnote in Article 16 of the MGA.*

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

⚠ You may use this option only if it is foreseen in your GA.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  ⚠ If access costs are declared as *unit cost*, they must be declared under the budget category 'specific cost category – access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

⚠ Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

The basic **cost eligibility conditions** are set out in Article 6.

⚠ In addition, Article 16.1.1 and 16.2 specify additional cost eligibility conditions. If the beneficiary does not comply with these rules, the Commission may reject the costs concerned *(see Article 6.2.A-F and 6.6)*.

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

> ***Examples (units of access):*** *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

The beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

Examples of remote access: *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

⚠ Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free-of-charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU or associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20% of the total number of units of access provided under the grant.

The consortium should itself define if this 20% limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

⚠ If justified, an access provider may use several different selection sub-panels.

Example: *different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. Additional eligibility condition: Controls on the users by the Commission/Agency, ECA and OLAF — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

⚠ It is the beneficiaries' responsibility to ensure that this obligation is accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual **access services assessed periodically by a board** composed **of international experts** in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[35] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

Actions under Part I, 'Research infrastructures' may also provide for virtual access to research infrastructure.

⚠ The EU will only support virtual services that are widely used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action
- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

Virtual access can in principle not be measured; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

⚠ The assessment reports must be included in the list of **deliverables** in the proposal (and will then be included in Annex 1; *see the Proposal templates*).

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for any purpose *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request any type of information it needs. The level of detail will depend on the purpose of the request.

⚠ The Commission/Agency may need to request personal data *(see Article 39)*, in particular in order to verify that costs declared for specific people are eligible.

The Commission may request information **at any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

⚠ It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator does not legally exist after the action ends (i.e. if it went bankrupt), beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary is obliged to keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

This includes its:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The system automatically informs the coordinator whenever a beneficiary updates its information.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

⚠ Since information may be sent or requested after the action and GA end (*e.g. formal notifications, requests for information, etc.*), it is in the beneficiary's interest to regularly update its data, even after the balance is paid.

ⓘ For more information on beneficiary registration, validation and data updates, see the *Online Manual*.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests): *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

⚠ The beneficiaries must prevent delays in implementing the action, or reduce them to the extent possible.

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):

A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *[**OPTION by default:** five]**[OPTION for low value grants[36]:** three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents.** Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[36] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** the proper implementation of the action and other obligation and eligibility of all the costs declared.

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

⚠ The rules in the GA do not affect national laws on keeping documents.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept the destruction of hard copies of documents and their digitalisation, if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

⚠ Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs set by the Commission, the beneficiaries must keep detailed records and other supporting documents to prove the number of units declared.

It is not necessary to keep records on the actual costs incurred.

The Commission has the right to access the accounting records, but it will not reject any costs recorded as lower than the costs declared based on unit costs (except if the number of units declared is incorrect). If the Commission detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For unit costs calculated in accordance with the beneficiary's usual cost accounting practices ('**average personnel costs**'), the beneficiaries must show that the cost accounting practices used comply with the conditions set out in Article 6.2.

To do this, they must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is not necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary (or linked third party) may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology. This means that if the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared by the beneficiary in subsequent audits.

⚠ The Commission/Agency will challenge these costs if it suspects that information was concealed or fraud or corruption was used to obtain approval. It will also challenge the costs, if the beneficiary calculated its personnel costs using cost accounting practices different from the ones described in the certificate.

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission's/Agency's approval (if the beneficiary/ can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant.

⚠ Certificates of the methodology issued for FP7 beneficiaries are not valid for Horizon 2020 actions.

When? Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How? The beneficiary must submit its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor. If the beneficiary is a public body, the certificate should be drawn up by an independent public officer using the template in Annex 6.

The Commission will assess if the methodology described and certified is in compliance with the GA *(see Article 6.2.A)*.

ⓘ For more information on the certification procedure, *see the Online Manual*.

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate applies are eligible.

Example: *For the flat rate of 25% of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

Beneficiaries do not need to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

– sign a '**declaration on exclusive work for the action**' (one per reporting period), to confirm that the person worked exclusively for the action, either:

  – during the whole reporting period or

  – during a an uninterrupted time-period, covering at least a full natural month within the reporting period.

  ⚠ Only one declaration per reporting period. Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be covered by a declaration. If the person worked for the action also *after* the uninterrupted time-period covered by the declaration, then it must keep time records for that period.

  Example: *the person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

  The declaration must be dated and countersigned for acceptance by the person concerned.

  Best practice: Beneficiaries are advised to take a prudent approach and use this possibility only if it can be reasonably expected that the person will really work only on the action and during a long and continuous period of time. If there is any doubt about exclusivity, keep a record of actual hours worked *(e.g. timesheets)*.

– keep **time records.**

⚠ The question of exclusive work matters only for the *record-keeping*; it has no impact on the *calculation* of the costs to be declared. The personnel costs must therefore be calculated in the same way as for persons who do not work exclusively for the action (i.e. through an hourly rate, per full financial year, etc.; *see Article 6.2.A*).

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

– show the actual hours worked, with reliable **time records** (*i.e. timesheets*) either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

Time records should include:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record; for reasons of assurance and legal certainly it is highly recommended that the number of hours is detailed per day (hours worked for the action in each day)
- the supervisor's full name and signature
- a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned and the person-months reported to the action
- a brief description of the activities carried out, to understand and show what work was carried out.

⚠ Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

A template for time-sheets is provided on the Participant Portal. (⚠ This template is not mandatory. You may use your own model provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'
Criterion 1 is met – the sender of the email is the person concerned;
Criterion 2 is met – the project is identified as XYZ;
Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'
Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;
Criterion 2 is not met: the project name is not mentioned;
Criterion 3 is not met – the time is not quantified.

⚠ If the beneficiary cannot support the number of hours or costs declared by appropriate and sufficient evidence, the costs concerned may be rejected (and other measures described in Chapter 6 may be applied as well).

⚠ Relying on alternative evidence bears a high risk of costs being rejected.

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Examples:

Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.

Specific case:

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free-of-charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the project)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the project that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them through the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*) — unless Annex 1 specifies another way.

Specific case:

'**Classified results**' that are deliverables may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements'** (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[37]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[37] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement).

  The final financial report basically consists of the final summary financial statement that is automatically created by the system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration

The reports (and their documents) must be distinguished from 'deliverables' (that are part of Annex 1 and covered by Article 19) and 'milestones' (that may be part of Annex 1 but are normally neither covered by Article 19 nor by Article 20).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication

- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary)*. Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary)*.

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the **coordinator**, who must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary. The linked third parties cannot see their grants in the electronic exchange system and therefore have no access to them.

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system is correct (i.e. identical to the signed paper version).

⚠ If a beneficiary **cannot submit** its individual **financial statement on time**, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked explicit confirmation of the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) to the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

⚠ If the Commission/Agency considers the report **incomplete** or **not in compliance** with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

ⓘ For more information on the submission procedure, *see the Online Manual*.

ⓘ For information on the eligibility of costs incurred for reporting, *see Article 6.2.D.3*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, you must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

⚠ Do not report using information that is in 'classified results' *(see Article 37)*. Technical reports should not contain any information that is 'EU classified' under the rules on security of information in the Commission internal Rules of Procedure *(see also Guide for classification)*.

ⓘ For more information on information security, *see the Online Manual*.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on 'cross–cutting issues' *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

⚠ Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ For information on the submission procedure, see point 1.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period and
- fulfil the eligibility conditions set out in Article 6.

You can also declare costs you incurred during a previous reporting period, if you haven't yet declared them.

⚠ Each beneficiary/linked third party should declare all their costs, even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs as ineligible.

The costs of *linked third parties* must not be included in the beneficiary's financial statements. Linked third parties must fill out their *own* financial statements.

For the last reporting period, beneficiaries have to declare their receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

Forms for the different parts of the reports are available in the electronic exchange system.

ⓘ *For information on the submission procedure, see point 1.*

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the *whole* action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

⚠ The coordinator must ensure that material submitted for publication does not include any confidential or 'EU classified' information.

You should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

You may also include a list of all beneficiaries, with contact names (if you want this to be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

For some beneficiaries/linked third parties, a **certificate on the financial statement (CFS)** must be provided.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement of actual costs and personnel costs on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs'). If a CFS is required, all costs declared as actual costs and all costs declared as average personnel costs must be covered by the certificate. If the CFS does not cover all those costs, the CFS is incomplete and it must be completed / complemented.

⚠ This means that costs based on lump sums, flat-rates *(e.g. indirect costs)* or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs* = *EUR 250 000*
- *subcontracting costs* = *EUR 40 000*
- *depreciation costs of equipment used to carry out the action* = *EUR 60 000*
- *indirect costs (25% flat rate)* = *EUR 77 500*
- *total eligible costs claimed by A* = *EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

A linked third party must only submit a CFS if it individually (without its beneficiary) reaches the EUR 325 000 threshold.

CFS below the EUR 325 000 threshold will be rejected.

Beneficiaries/linked third parties may submit either **one CFS per reporting period or** a **single CFS for the whole action**.

⚠ In both cases, the CFS may only be submitted with the *final* financial report. The Commission/Agency will not accept any CFS submitted at any other moment (and corresponding costs for the CFS will not be considered eligible, because not necessary).

The CFS must be issued by an **external auditor**, using the template in Annex 5.

Specific cases:

For **public bodies**, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

For **international organisations**, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Only qualified auditors may issue a CFS.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

Specific cases:

Beneficiaries/linked third parties **established in third countries** must comply with national regulations in the field.

Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

To calculate this rate, you may use the editable charts on the ECB website[44].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart icon [ ] corresponding to your currency.

Step 3 — Choose the 'HTML5 version' which appears under the name of your currency in the top-left corner.

Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

– suspend the payment deadline *(see Article 47)*

– terminate the GA if the coordinator continues to breach its obligations after a written reminder *(see Article 50)*.

⚠ This may also lead to a recovery of payments already made.

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][38]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a pre-financing payment at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  ⚠ Pre-financing will not be paid before:

  - the GA is signed (even if the action starts **prior** to that)
  - 10 days before the starting date of the action.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the action would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- interim payment(s) to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

– the payment of the balance after the end of the action.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

⚠ The consortium agreement may set up, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

If the coordinator doesn't distribute the amounts received, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The amount distributed by the coordinator to each beneficiary may differ from the EU contribution justified by each of them; the consortium may have agreements that provide for a distribution of the funding which is not in line with the costs claimed.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

– if it specifically requests this

– in the event of recovery at the payment of the balance *(see Article 44)*

– if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable).

ⓘ For more information on the procedures for rejection of costs, reduction of the grant and recoveries, *see Articles 42, 43 and 44.*

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the amount is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100% of the average EU funding per period (i.e. maximum grant amount / number of periods) for actions with at least two reporting periods. (It will be howevr less for actions with only one reporting period, since 100% would mean the totality of the grant amount.)

At the moment of the pre-financing, an amount equivalent to 5% of the maximum grant amount is deducted from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.
Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000
Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.
JRC share of grant: 15% (150000/1 000 000)
JRC share of pre-financing (kept by the Commission/Agency): 15% of 350 000 = EUR 52 500
Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

⚠ The amount to be paid may be offset against any debt of the beneficiaries towards the Commission/Agency (without the consent of the beneficiary concerned) — up to the 'maximum EU contribution' foreseen for that beneficiary in Annex 2.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

↓

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90% of the maximum grant amount minus the pre-financing

Example:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.
Pre-financing of EUR 333 334.
Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1; application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

⚠ The amount to be paid may be offset against any debt of the beneficiaries towards the Commission/Agency (without the consent of the beneficiary concerned) — up to the 'maximum EU contribution' foreseen for that beneficiary in Annex 2.

4. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.
Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).
Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.
Total eligible costs accepted for 1st interim period: EUR 537 500;
1st interim payment: EUR 500 000 (the 90% limit is reached).
Total eligible costs accepted for 2nd interim period: EUR 162 500.
2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*
Final grant amount: EUR 750 000.
Payment of the balance takes the form of a ***recovery*** *as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*
The amount of EUR 150 000 will be recovered as follows:
- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.
Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.
*Payment of the balance amounts to EUR 100 000 and will be **paid** to the coordinator as follows:*

- *EUR 50 000 directly by the Commission; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*
Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.
*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

⚠ The amount to be paid may be offset against any debt of the beneficiaries towards the Commission/Agency (without the consent of the beneficiary concerned) — up to the 'maximum EU contribution' foreseen for that beneficiary in Annex 2.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]*Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.

2. The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).

3. After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.

4. After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check (see Article 17). All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the check shows ineligible costs or the violation of 'other obligations' under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles*

42, 43 and 44). If a more in-depth examination is required, the Commission may start a review or audit.

The Commission/Agency may carry out checks remotely, based on documents it received beforehand.

It can do so using its own staff or with the assistance of external expert(s) or bodies.

Example: *Ethics checks are normally carried out with the help of external experts.*

⚠ If the Commission/Agency is assisted by external expert(s) or bodies, it does not need to send their name(s) for approval to the beneficiaries before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report'** will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

⚠ If the review shows improper implementation of the action, ineligible costs or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42- 44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a letter sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the **names** of the **independent experts** that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, you will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due

– for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days ('**contradictory review procedure**').

⚠ This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant etc.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

Specific case:

The Commission may also audit the accounting records of beneficiaries, to obtain general information about actual costs for cost items that are reimbursed as unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will however normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to **third parties** involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

*1. The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

*2. The Commission/Agency may audit **third parties providing in-kind contributions** (free-of-charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

*3. The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value-for-money or, if appropriate, the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. .*

⚠ *For this category of third parties, audits will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

*4. The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary.*

⚠ *For recipients of financial support or prizes, audits normally will not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs), except if Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties. .*

⚠ If the audit shows, ineligible costs, improper implementation of the action or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

2. Procedure

The audit will be initiated by a letter sent to the beneficiary concerned.

⚠ The Commission/Agency will transmit this letter (and the other communications relating to an audit as formal notifications, through the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its **name**.

The beneficiary may **object** to an external auditor on grounds of commercial confidentiality (and explain the reasons for this). If justified, the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit themselves).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit (**i.e. on the beneficiary's premises or on the site on which the action is being implemented). (There may however also be audits that consist only in a desk review.)

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

ⓘ For more information on records and supporting documentation for the different cost forms, *see Article 18.*

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

> ***Example:*** *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

⚠ Objections based on data protection or confidentiality will not be accepted.

Once an audit has started, the beneficiary must keep all the records and supporting documents until the audit procedure and its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This avoids any unnecessary delays in retrieving original documents from the archives (and thus minimises the risk of the rejection of costs).

> ***Example:*** *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

This includes granting access to research facilities and interviewing the researchers that worked on the action.

⚠ Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Moreover, all confidential data will be processed in accordance with Article 36.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory audit procedure**').

⚠ This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant etc.

The audit procedure will be closed (by the Commission/Agency auditors) with the '**letter of audit conclusions**' (and the file will then be passed on to the operational services (authorising officer) for audit implementation, if necessary).

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[39] and No 2185/96[40] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

39 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

40 Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42- 44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[41], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[41] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

⚠ If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION:** Not applicable]*

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are international organisations (IOs).

⚠ If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** Those agreements may include, for example, a Financial and Administrative Framework Agreement (FAFA) signed between the European Union an the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the *[Agency or the]* Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the *[Agency or the]* Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the *[Agency or the]* Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the *[Agency or the]* Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings

If the Commission/Agency finds substantial errors, irregularities, fraud, improper implementation or serious breach of other obligations that are **systemic** or **recurrent**, it may make a correction (rejection of costs or reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed ('extension of the findings')
- other H2020 grants of the beneficiary ('extension of the findings').

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

⚠ Extension of findings is possible for all grants awarded under Horizon 2020, regardless of the entity that awarded the grant (i.e. Commission, executive agency or funding body in charge of implementing Horizon 2020).

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld after this contradictory audit/review procedure, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an 'audit extension procedure' (which is then followed by 'audit/review implementation').

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure ('**letter of audit conclusions**'), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for ineligibility of costs:
  - a request to submit revised financial statements for the grants/reporting periods on the list
  - the proposed correction rate for extrapolation (to be used if the beneficiary does not submit revised financial statements)
  - the conditions for the external counter audit needed to propose an alternative correction method *(see below)*

- for improper implementation or breach of other obligations: the proposed flat-rate for the correction.

The extrapolation rate will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The flat-rate will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit the revised financial statements or refuses to cooperate (in time)

- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)

- the Commission/Agency cannot accept an alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:

  - for ineligibility of costs: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    ⚠ The purpose of the independent audit canNOT be to contest the audit/review findings of the Commission/Agency, but to determine a more precise calculation of the error rate (linked to those findings).

  - for improper implementation or breach of other obligations: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has full discretion to accept or refuse the alternative correction method.

Step 3 — Audit implementation. If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the costs to be rejected/reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the costs to be rejected/reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]*[***OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out interim and final evaluations of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

⚠ These evaluations will thus have **no effect** on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[42].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[42] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out the Code of Practice[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations (by promoting exploitation and dissemination of research results).

⚠ This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Point 1 (Principles for an internal intellectual property policy) and Point 2 (Principles for a knowledge transfer policy) of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists before the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

Best practice: Although not obligatory, beneficiaries are highly advised to agree on background **before the GA is signed**, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

⚠ Don't forget to inform the other beneficiaries — before signing the GA — if access to your background is subject to legal restrictions or limits *(see Article 25)*.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[43] established in an EU Member State or ‘**associated country**’[44], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[44] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on access to background (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is **no** (or a more limited) obligation to give **access**, if there are **restrictions** or **limits** (legal or otherwise) regarding the background and the beneficiary owning or holding the background has informed the others — before acceding to the GA (or immediately when additional background is agreed on after signature of the GA).

Example: *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

⚠ Don't forget that — when contracting on background with third parties — you must at all times ensure that you can still comply with your access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions

ⓘ For more information on fair and reasonable conditions, *see Article 31*.

Also, there are no **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties, except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the **beneficiary** that **produced** them.

> 'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries are advised to keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases:

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must — as much in advance as possible before the jointly-owned results are produced — conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  ⚠ Don't fix a *ceiling* for fair and reasonable compensation before the action starts — unless you can precisely determine the results you expect to produce.

- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries are advised to include general principles on joint ownership already in the consortium agreement.

⚠ The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection (*e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (⚠ without prior authorisation from the other joint owners) — unless otherwise agreed in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

⚠ The joint ownership status may **change**:

- it may need to be reviewed later on, when protecting the results.

  Example:

  Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.

– joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that any agreements with third parties who could claim rights to the action's results *(e.g. employees, subcontractors, linked third parties etc.)* contain provisions that allow them to respect their obligations under the GA *(e.g. transferring ownership to the beneficiary, grant the beneficiary access rights with a right to sub-license, etc.)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Specific cases:

Joint research units (JRUs) — Where the internal arrangements of a JRU, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ⓘ For information on JRUs, *see Article 14.*

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, protect them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

⚠ This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*

The beneficiaries are in principle free to choose any available **form** of protection.

Examples of classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

For an invention: e.g. patent, confidential information.

For the design of a technology: e.g. industrial design, copyright.

For a website: e.g. industrial design, copyright, trademark.

⚠ In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

ⓘ For information on the eligibility of costs related to protection, *see Article 6.2.D.3.*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

⚠ Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include a reference to EU funding, as specified in the GA.

> ⚠ NO information on EU funding is needed, if it is (technically or legally) impossible to include such a reference

ⓘ For more information on visibility of EU funding, *see Article 38*.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure exploitation of their results.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

> ***Example:*** *Exploitation is justified from an economic point of view (commercially) or from a standardisation perspective (for use in standardisation activities).*

Where possible, the measures should be consistent with the impact expected from the action and the '**plan for the exploitation and dissemination of the results**'.

They may aim for exploitation by the beneficiary itself (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (⚠ Such additional exploitation obligations will already be mentioned in the work programme/call.)

⚠ This obligation only applies to beneficiaries receiving EU funding.

If the results can reasonably be expected to contribute to European or international standards, the beneficiaries must also communicate them to the Commission/Agency.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

⚠ This obligation applies only if it is foreseen in your GA.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — disseminate their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

⚠ NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA (*e.g. personal data protection, security-related obligations, etc.)*.

The beneficiaries may choose how they would like to disseminate their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries are advised to foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

2. Open access

ⓘ For detailed information on open access, see *Guidelines on Open Access to Scientific Publications and Research Data* and the *Guidelines on Data Management*.

3. Visibility of EU funding

Any dissemination of results (in any form) must include a reference to EU funding, as specified in the GA.

ⓘ For more information on visibility of EU funding, *see Article 38*.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —****]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions* ***]***

[OPTION: *Not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may transfer ownership of their results.

⚠ Security-related obligations *(see Article 37)* may prohibit a transfer or require certain conditions to be fulfilled before it takes place.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

⚠ The mere fact that the results concerned are transferred to a competitor is not in itself a valid reason for an objection. The beneficiary concerned must *demonstrate* the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases:

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of before).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or*

an affiliate of one of them). In this case, there is no need to inform the other beneficiaries of such transfers in advance (and the other beneficiaries do not have the right to object).

⚠ Before agreeing to such a 'global' authorisation, you should carefully consider the situation (and in particular the identity of the third party concerned), to determine if your access rights would be affected.

Example: *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country not associated with Horizon 2020 must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

Best practice: Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant licences to their results.

They must however ensure that **access rights** can be exercised and that any additional exploitation obligations are complied with.

⚠ **Exclusive licences** *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If this option is included in your GA, the Commission/Agency may **object** to transfers or exclusive licences to third parties established in a non-EU country not associated to Horizon 2020.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

⚠ NO right to object for transfers or exclusive licences by beneficiaries not receiving EU funding *(see Article 9)*.

⚠ For Euratom grants, the Commission has the right to object also to non–exclusive licences.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

[OPTION by default for EU grants: *The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens': *The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

[OPTION for Euratom grants: *The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme*: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries*[45]*, for the purposes of the complementary grant agreement(s) (see Article 2).]*

[OPTION for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.]*

[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

[OPTION for trans-national access to research infrastructure: *The access provider must give the users royalty-free access to the results needed to implement the action.]*

[OPTION: *Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

45 **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide access to results, if it is **needed**:

- by another beneficiary, for implementing action tasks or exploiting results

– by an affiliated entity (established in a Member State or associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO **definition** of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

Example (results needed for implementation): *if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

Example (background needed for exploitation): *if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries are advised to agree *(e.g. in the consortium agreement)* on a **common interpretation** of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they **must be requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a Member State or associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The agreement by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

⚠ Don't forget to notify the Commission/Agency of any conflicts on results that are likely to affect the action implementation *(see Article 17.2.)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free
- for the exploitation of results: under fair and reasonable conditions

  'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

  'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

  Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

  Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

  Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

ⓘ *For information on the eligibility of the royalty fees paid for access, see Article 6.2.D.3*

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

⚠ Access rights do not automatically give the right to **sub-licence** to the requesting beneficiary (since this would imply that access rights to results could be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries are advised to agree on the terms and conditions of the sub-licensing generally and in writing (at the level of the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: Beneficiaries are advised — for legal certainty purposes — to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

The General MGA provides for several options for specific access rights for EU institutions, bodies, offices or agencies and/or EU Member States, for policy purposes.

⚠ These obligations apply only if they are foreseen in your GA.

5. Specific access rights for Euratom and its joint undertakings

The option gives Euratom and its joint undertakings (such as Fusion for Energy) royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to sub-license *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

The General MGA also provides for several options for specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  ⚠ In this case, the access rights are limited to the research work of the user that is supported under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

⚠ These obligations apply only if they are foreseen in your GA.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [46], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[46] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

ⓘ For guidance, *see the 'Human Resources Strategy for Researchers' tool*[50] *developed by the Commission.*

⚠ Keep appropriate documentation about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/strategy4Researcher

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[51] and of the Code of Conduct[52] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[53])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[53] Available at http://ec.europa.eu/euraxess/jobs

⚠ These principles also apply to selection procedures that do not lead to formal employment relationship (*e.g. award of research fellowships)*.

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

⚠ This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

⚠ If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, it must explain the reasons for this in the first periodic technical report and in the final report *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

ⓘ For more information on gender equality, *see the Online Manual*.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[47] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct).

  ⓘ For more information on the standards of research integrity, *see the European Code of Conduct for Research Integrity*[54].

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols.

ⓘ For an overview of the main EU and international legal texts, *see the Science in Society e-library*[55].

[54] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[55] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the global approach on ethics issues), which includes all of the following:

- ethics self-assessment (by the applicants, in their proposal; *see the Proposal templates*)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

ⓘ For help with the ethics self-assessment, *see the Guidance — How to complete your ethics self-assessment*[56].

ⓘ For more information on the H2020 ethics appraisal scheme, *see the Online Manual*.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must ALSO be allowed in at least one Member State.

The beneficiaries must confirm in the 'ethics self-assessment' section of their proposal that this condition is met.

ⓘ For more information, *see the Guidance — How to complete your ethics self-assessment*.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.*

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.*

[56] Available at http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf.

Moreover, the coordinator must submit **copies** of the following, before the activity starts:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries are advised to request the **assistance of ethics experts**, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries concerned must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation costs, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

⚠ Do not submit copies of *requests* for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[57] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[57] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value-for-money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

– **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

– **other shared interests**.

Examples:

If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[48], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[48] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed — during the action and for four years afterwards.

> ⚠ This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves (for example, for access rights or third parties involved in the action).
>
> A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information concerned.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

Best practice: Beneficiaries are advised to inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

⚠ Stricter confidentiality obligations apply for information that is that is 'EU-classified' and subject to 'security requirements' in Annex 1 of the GA *(see Article 37)*.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *Not applicable****]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *Not applicable****]***

1. Results with a security recommendation — Classified results

If the security scrutiny (carried out by the Commission/Agency during the selection procedure) finds that the action raises security issues because it deals with information that is 'EU-classified' (under the Commission internal Rules of Procedure), the Commission/Agency will make it subject to '**security requirements**' (set out in a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' in Annex 1 of the GA).

In this case, the beneficiaries must comply with the security requirements.

Moreover, they may not subcontract action tasks involving such information or disseminate results linked to such information, without prior approval by the Commission/Agency.

⚠ 'Classified results' that are **deliverables** may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 19)*.

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[58].

Moreover, the coordinator must submit a **copy** of any export or transfer licence, before the action starts.

[58] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Communication activities (by the beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange.

⚠ *Ad hoc* efforts or mere dissemination of results are not sufficient. The communication activities[59] must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and address the **public policy perspective** of EU research and innovation funding, by considering aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity).

⚠ The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them in another work package).

The beneficiaries are free to choose the type of communication activities.

> ***Examples:*** *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

⚠ Information given may NOT cover EU-classified information or information relating to 'classified results' *(see Article 37)*.

⚠ Don't forget that any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

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[59] For the definition of 'communication activities', *see the Glossary*.

⚠ Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa). Both obligations must be complied with.

ⓘ For more information on how to promote your action, *see the Online Manual*

2. Visibility of EU funding

The beneficiaries must ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the EU emblem and
- including the reference to EU funding, as specified in the GA.

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object).

Examples: *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

ⓘ For more information, *see the Guide to using the EU emblem*[60].

⚠ The beneficiaries must ensure the visibility of EU funding even *after* the action ends.

[60] Available at http://publications.europa.eu/code/en/en-5000100.htm.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[49], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][insert the name of the Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[49] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities (by the Commission/Agency)

The Commission/Agency may use (free-of-charge) any (⚠ non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material);*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

⚠ The beneficiaries must make **arrangements** with any **third parties** that could claim rights to the material, in order to legally allow the use by the Commission/Agency.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[50] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statements (SSPS)' that are published on the *[Agency and]* Commission websites.

They also have the **right to** have recourse at any time **to the European Data Protection Supervisor (EDPS)**.

[50] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (by the Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the financial interests).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission's/Agency's Data Protection Officer (DPO).

This notification will be available in the Public Register of the DPO[61] (and will describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

⚠ For the processing of operations implying specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will also be consulted.

ⓘ For more information, *see the 'service specific privacy statements (SSPS)'*[62] *on the Participant Portal.*

[61] Available at http://ec.europa.eu/dpo-register/search.htm.
[62] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data are being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries are advised to first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

ⓘ For information on the complaints procedure, *see the EDPS website*.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the service specific privacy statements (SSPS) (see above), before transmitting their data to the *[Agency or the]Commission.*

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (by the beneficiaries)

The beneficiaries must process personnel data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[63] —or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

[63] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [64]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[65]

The beneficiaries may give their staff access to the personal data only on a **need to know** basis, for carrying out their functions within the GA.

⚠ This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must also **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the SSPS).

Examples:

Before encoding its staff's personal data in the 'Beneficiary Register' or for a project proposal, the beneficiary must provide the staff concerned with the SSPS.

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64 *See Article 8 of Directive 95/46/EC.*

65 *See Articles 6, 16, 17 of Directive 95/46/EC.*

If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the relevant SSPS.

⚠ Do not forget that processing of personal data is also an aspect related to ethics and that you may have to provide notifications or authorisations from the national data protection authorities *(see Article 34)*.

ⓘ For more information on ethics, *see the Online Manual*.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

> The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).
>
> If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.
>
> In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

The beneficiaries may not assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to any third party — unless the Commission/Agency has explicitly agreed in writing.

> 'Assignment' normally means the transfer of rights held by one party to another party.
>
> ⚠ However, this Article only concerns assignment of claims for *payment*, (i.e. the claims for payment under Article 21). Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.
>
> Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is not possible for future claims.

The **request for approval** must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

> The Commission/Agency will assess the reasons given and approve or reject the request in writing.
>
> ***Examples (reasonable requests for assignment):***
>
> *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity*
>
> *Assignment for the benefit of creditors in a bankruptcy procedure*

⚠ Regardless of any assignment of its rights to payment, the beneficiary **remains bound by** its ***obligations*** under the GA. The Commission/Agency approval to the assignment does not affect the fulfilment of the beneficiary's obligations under the GA; any present and future obligation of the beneficiary remains with the beneficiary.

> ***Example:*** *The obligation to allow audits by the Commission/Agency*

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (vis-à-vis the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

Example: *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is limited to its own debt, including undue amounts paid for costs declared by its linked third parties, except for the amount retained for the Guarantee Fund (for which the financial responsibility c is shared; *see Article 21.4)*.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION: *Not applicable****]***

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** Not applicable**]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (vis-à-vis the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

The coordinator must check the quality of the documents submitted by the beneficiaries, including:

- reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*.

  The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).

- verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*

- verifying that the beneficiary submits the documents in the requested format

- verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).

- Submit the deliverables and reports

- Distribute payments to the other beneficiaries, without unjustified delay

- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

⚠ These coordination tasks **cannot be subcontracted or outsourced** to a third party. They cannot be carried out by other beneficiaries.

Specific cases:

Authorisation to administer — Secondary or higher education establishments and public bodies may delegate some of their coordination tasks *(e.g. the obligation to pay the other beneficiaries and to inform the Commission/Agency of the amounts paid to each beneficiary)* to another legal entity (third party), in most cases a foundation.

This third party must fulfil the following cumulative conditions:

- it must have been granted the 'authorisation to administer' by the coordinator and

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

This entity must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

ⓘ For more information on beneficiary registration and validation, *see the Online Manual*.

⚠ The coordinator will retain sole responsibility for the EU's financial contribution and for complying with its obligations under the GA. Thus, if the third party does not comply with its obligations *(e.g. does not properly administer the monies)*, the coordinator will be held responsible.

Scientific coordinator other than the coordinator — coordination tasks not listed in this Article can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action)*.

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

The tasks of scientific coordination performed by this beneficiary can be reimbursed, if they comply with the eligibility criteria set out in Article 6.

The coordinator remains free to subcontract other (non-coordination) action tasks, according to the conditions set out in Article 13.

Example: *performance of some research activities.*

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement — unless exceptionally stipulated otherwise in the work programme/call.

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement (CA)' is an internal agreement between members of the consortium, to set out their internal arrangements for implementing the grant.

Consortium agreements are purely internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

The consortium agreement should in principle be negotiated and concluded before the signature of the GA (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The CA must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries are advised to carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

⚠ Consortium agreements **must comply with all obligations** under the Rules for Participation and the GA. If necessary, they can contain contractual provisions *complementing* these obligations, but they may not *contradict* or *ignore* them.

ⓘ For more guidance on consortium agreements and links to stakeholder organisations that have developed models for consortium agreements, *see the Online Manual and the Guidance — Establishing a consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

For complementary actions *(see Article 2)*, the beneficiaries must conclude a collaboration agreement.

'Collaboration agreement' are agreements between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs.

Collaboration agreements are also internal; the EU/Euratom is not party and has no responsibility for them (nor for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

5. Relationship with participants of a joint action — Coordination agreement

For joint actions *(see Article 2)*, the beneficiariesmust conclude a coordination agreement with the participants of the joint action.

'Coordination agreements' are agreements between the consortium and the participants of the third country/IO action *(see Article 2)*.

The EU/Euratom is not party to the coordination agreement and has no responsibility for it (or for any adverse consequences).

⚠ This obligation applies only if it is foreseen in your GA.

ⓘ For the preparation of a coordination agreement, *see the Online Manual*.

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, these costs will be rejected.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

Ineligible costs will always be rejected in **full** (i.e. for the **amount** that is ineligible).

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request by the coordinator/beneficiary concerned — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

⚠ If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-information letter** for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000.
Pre-financing: EUR 200 000.
Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25%) = EUR 118 750.
Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25%) = EUR 143 750.
Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25%) = EUR 112 500.
Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.
Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.
Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:
Application of the reimbursement rate: 100%: EUR 362 500
Limit to 90% of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.
Amount due as interim payment: EUR 250 000

Specific case:

Ineligible costs in-between payments — If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) in-between payments, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example:

Total costs declared for the action in the 1st periodic report: = EUR 375 000
Interim payment for the 1st periodic report = EUR 375 000
Cost rejected after interim payment or 1st periodic report: EUR 12 500
Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000
Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.

Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750
An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:
EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.
The share of beneficiary A in the final grant amount = EUR 187 500.
The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.
The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount.

⚠ A reduction is possible for any breach of obligation (under the GA or applicable EU, international and national law; *see Article 7)* and it will be proportion to the seriousness of the breach *(e.g. in case of fraud, systemic irregularities or submission of false information — in the award procedure or during action implementation the reduction may be up to a 100%)*.

⚠ A reduction can also concern a beneficiary not receiving EU funding (due to improper implementation or breach of obligations by that beneficiary).

Reduction of the grant can take place at or after the payment of the balance, not before.

⚠ If the improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

The reduction of the grant **amount** will be **proportionate to** the improper implementation of the action or the seriousness of the **breach**.

2. Procedure

The Commission/Agency will follow a contradictory procedure.

ⓘ For the basic contradictory procedure, *see Article 42.*

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant at the payment of the balance, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)
Pre-financing: EUR 750 000
Interim payments: EUR 1 500 000
Eligible costs accepted at the time of payment of the balance: EUR 2 900 000
The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20% (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.
Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.
Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000
Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000
Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the grant is reduced after the payment of the balance, a **revised grant amount** has to be calculated at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

⚠ If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Example:

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.
Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).
Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:
The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3% (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Examples (calculation of revised final grant amount for each beneficiary concerned):

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *During a review, the Commission found out that the improper implementation is due to the fact that beneficiary A carried out only 50% of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:
Lower between costs accepted (EUR 700 000) and 50% of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50% x 800 000 = EUR 400 000) = EUR 400 000
For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *During the review, the Commission found out that the breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:
beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333
beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667
beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):
The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:
beneficiary A: 700 000-693 333 = EUR 6 667
beneficiary B: 1600 000-1 386 667 = EUR 213 333
beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[51] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[51] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****]*** ***[OPTION:*** *not applicable****]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency **paid too much**, it will recover the undue amounts. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

Recovery can normally take place only at payment of the balance or afterwards. It can take place before only in the case of terminating a beneficiary's participation.

The recovery will be for the **amount** that is **undue**.

The Commission/Agency will recover the undue amounts from the beneficiary owing money to it (i.e. with a debt towards the Commission/Agency).

⚠ In case of recovery, each beneficiary's financial responsibility is normally limited to its own debt (including undue amounts paid for costs declared by its linked third parties, if any). Only the responsibility for the amount retained for the Guarantee Fund is shared.

Specific case:

If the Commission/Agency has requested **joint and several liability of** a **linked third party** *(see Article 14.1)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

– by **offsetting** it[66]

Offsetting consists of subtracting the amount the debtor (i.e. coordinator/beneficiary) owes to the Commission/Agency from another amount that the Commission/Agency owes to it.

⚠ For the coordinator/beneficiary, offsetting is the same as paying the debit note normally (i.e. by bank transfer).

In principle, offsetting is carried out after the payment deadline stated in the debit note has expired. However, in exceptional circumstances, the Commission/Agency may offset the amount to be recovered before this date, in order to safeguard the EU's financial interests.[67]

[66] *See Article 80(1) of the Financial Regulation.*
[67] *See Article 87 of the Rules for Application.*

If the offsetting takes place after the deadline for payment has expired, both the principal amount and the interest must be offset against a payment due to the debtor (starting with the interest).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or
    - adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[68].[69]

      The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency may recover after termination of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene.

ⓘ For the procedure, see Article 50.

4. Recovery at the payment of the balance

The payment of the balance may take the form of a recovery if the sum of the pre-financing and the interim payments exceeds the final grant amount calculated by the Commission/Agency *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

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[68] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[69] *See Article 79(2) of the Financial Regulation.*

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

ⓘ For the rest of the procedure, *see point 2.*

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

ⓘ For the rest of the procedure, *see point 2.*

Example (recovery at the payment of the balance):

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100%
Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)
Total eligible costs approved by the Commission: EUR 2 430 000
Final grant amount: EUR 2 430 000
EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000
Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90% of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5% of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:
A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

First step: *identification of the beneficiaries that received funds in excess:*
Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);
beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)
beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);
beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).
Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Second step: *distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:*
The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.
Total payments made in excess = 320 000.
Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25%.
Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5%.
Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25%.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25% x 120 000 = 37 500; beneficiary C for the amount of 62.5% x 120 000 = 75 000; beneficiary D for the amount of 6.25% x 120 000 = 7 500.*

⚠ *Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium*

5. Recovery after payment of the balance

The Commission/Agency may recover after payment of the balance, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — the Commission/Agency paid too much.

⚠ The Commission/Agency will recover from the coordinator, if it finds out that the coordinator has not distributed amounts received (as pre-financing, interim payments or payment of the balance).

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

ⓘ For the calculation of the share of the final grant amount, *see point 4.*

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

ⓘ For the rest of the procedure, *see point 2.*

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** An underspent GA means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum grant amount for the GA. In other words, a GA where the consortium declared less costs than could have been reimbursed: it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

- **for an overspent GA:** An overspent GA means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount for the GA; in other words, a GA where the consortium declared more costs than could be reimbursed: Each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example (recovery in an underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.
Maximum grant amount: EUR 500 000
Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500
Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250
Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000
Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:
(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example (recovery in an overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C
Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000
Reimbursement rate for all the beneficiaries: 100%
Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000
Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000
Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000
Total eligible costs of the consortium approved by the Commission = EUR 600 000
Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000
Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1 Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary approved costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*
EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667
Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000
Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2 Calculation of the revised grant amount after the audits:
The revised final grant amount is calculated as follows:
For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500
For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3 Calculation of the amount to be recovered:
The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.
Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount
For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered
For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. As, for Beneficiary C, the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Agency or the]* Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation no 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose an administrative and/or financial penalty.

> ***Examples:*** *plagiarism; absence of time-recording systems (that were required); false declaration concerning SME status.*

⚠ The Commission/Agency will apply penalties only on a case-by-case basis and where this is justified, in view of the misconduct.

Administrative and financial penalties may be cumulative, depending on the nature and seriousness of the misconduct. This means that the misconduct may lead both to the exclusion of the beneficiary from EU procurement and grant procedures *and* to the obligation to pay a certain amount to the Commission.

The **amount/duration** is as follows:

- for administrative penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  ⚠ If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for financial penalties: between 2% and 10% of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  ⚠ If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and 20%.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

Example:

GA with a maximum grant amount of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

During an audit of the first reporting period, the Commission finds that beneficiary A has overcharged for its personnel costs by 20% and has falsely certified that the information on the time spent on the action set out in the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5% of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5% of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overcharged for its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15%.*

New financial penalty: 15% of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overcharged for its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15%, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15% of 450 000 = EUR 67 500.
Financial penalty in first GA: 5% (no change).

Additional amount to recover after the second audit: EUR 67 500

⚠ If appropriate, the decision to apply the penalty may also be **published** on Commission or Agency websites —together with the name of the person responsible for the misconduct, information on the misconduct and the penalty(ies) (duration of the exclusion and/or amount of the financial penalty).

The decision to publish will take into account, in particular:

- seriousness of the misconduct (including impact on the EU's financial interest and image)
- time that has elapsed since it took place
- duration and recurrence of the misconduct
- intention or degree of negligence and
- measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ For the basic contradictory procedure, *see Article 42.*

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount.

ⓘ For the basic recovery procedure, *see Article 44.*

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability (of the Commission/Agency) for damages

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

- causes damage to a third party (including another beneficiary)

  Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

- suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by any third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability (of the beneficiaries) for damages

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency.

Examples: *Costs of legal proceedings borne by the Commission.*

At a meeting on Commission premises, a beneficiary smokes and causes a fire.

The **amount** claimed will correspond to the damage caused.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned.

ⓘ For the basic contradictory procedure, *see Article 42*.

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

ⓘ For the basic recovery procedure, *see Article 44*.

⚠ However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

In the absence of payment by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (by the Commission/Agency)

The Commission/Agency may 'stop the clock' **(suspend the deadline)** if a payment request cannot be immediately approved, on the grounds listed in this Article.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- verify the eligibility of the claimed costs

⚠ This is not an in-depth verification and can therefore not vouch for their compliance or correctness. The costs may therefore still be rejected later on, if the

Commission/Agency finds — in a more in-depth verification — that they are ineligible.

– calculate the amount to be paid

– approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

  Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

⚠ There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* the Commission/Agency will lift the suspension and formally notify the coordinator.

⚠ With the lifting of the suspension the remaining payment period starts to run again.

⚠ If a deadline has been suspended for a number of reasons, it will be lifted only when the consortium has satisfactorily addressed all the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (by the Commission/Agency)

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

Grounds for suspension of payments:

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *statements made by the beneficiary in the declaration form are found to be false.*

  ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations, *see Article 50.3.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example:

During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

For the ongoing GAs of the beneficiary, the Commission may suspend:

- *outstanding pre-financing and/or interim payments to the beneficiary in question*
- *(if necessary) outstanding payment of the balance for all beneficiaries.*

until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

⚠ Suspension of payment does not mean suspension of the *action implementation* — the consortium should continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

If necessary, the consortium may however decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator.

ⓘ For the basic contradictory procedure, *see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned.

Costs incurred (for continuing to implement the action during suspension) are **eligible** and may be included in the next financial report, after suspension has been lifted.

⚠ Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August: *the Commission pays for all beneficiaries except B.*
25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation (by the beneficiaries)

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Ground for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.

  ⚠ This means that you stop the implementation of the action, in order to fix specific problems. Suspension should therefore only be used in exceptional situations that can be resolved through a temporary interruption. Otherwise, it may be better to terminate *(see Article 50)*.

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

⚠ Do not forget that — depending on the reasons for suspension — you may also have to take other measures under the GA *(e.g. inform the Commission/Agency under Article 17.2; notify a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  ⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the '**resumption date**' set out in the amendment), if the Commission/Agency approves the amendment.

Example: The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation.(⚠ However, it is possible that the Commission/Agency fixes a lower budget to adapt it to the new situation (agreed as part of the amendment)).

Example: After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.

If the **action** (or part of it) ***cannot* be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, NO further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

Example: The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation (by the Commission/Agency)

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

  ⓘ For more information on substantial errors, irregularities, fraud or serious breach of obligations*, see Article 50.3.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  – the other grants were awarded under similar conditions and

  – the substantial errors, irregularities, fraud or serious breach of obligations are:

    – systemic or recurrent and

    – have a material impact on this grant.

  Example:

  During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

  The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  – if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment

  – if work has significantly deviated from the original work plan

  – if a key beneficiary leaves the action and the consortium needs time to find a replacement

  – after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure**.

ⓘ For the basic contradictory procedure, *see Article 42.*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are **not eligible** *(see Article 6.5)*. Costs may again be charged to the action, once the action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

⚠ The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the Commission/Agency may decide to terminate the GA (or the participation of a beneficiary).

If the suspension leads to the termination, NO further costs (incurred after the date of suspension) can be declared, except for costs related to submitting the periodic report for the last reporting period and the final report *(see Article 6.1)*.

⚠ **Ineligible costs** will be rejected. The **grant** may be **reduced,** if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative and/or financial penalties** *(see Article 45)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.
The Commission suspends its implementation.
The coordinator confirms having received notification of the suspension on 18.3.2017.
The suspension takes effect on 23.3.2017.
On 23.6.2017, the consortium formally notifies the termination of the GA.
Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.
The Commission will reject the ineligible personnel costs.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly'**

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The beneficiaries have the right to terminate the GA.

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

⚠ If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example:

A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored.

If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

⚠ Improper termination of the GA may lead to a reduction of the grant.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries are advised to contact the Commission/Agency beforehand, in order to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **periodic report for the last reporting period** and the **final report** are eligible, even though incurred after the end of the action *(see Article 6.1)*.

Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

Costs related to contracts or subcontracts are eligible for the part of the contract/subcontract delivered before the termination.

Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

⚠ If the coordinator **fails to submit the reports** (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will not be taken into account when the final grant amount is calculated. The Commission/Agency will not send a reminder and will not extend the deadline.

⚠ If the Commission/Agency considers that the **termination** was **improper**, it may reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Specific case:

The decision to terminate the **coordinator**'s **participation without its agreement**, must be made by the rest of the consortium, according to its internal decision-making procedures.

Termination may in principle be based on **any ground**.

⚠ If a beneficiary goes bankrupt or is wound up**,** it or the coordinator must inform the Commission/Agency and notify the termination of its participation without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

⚠ Termination extends to linked third parties. Terminating a beneficiary's participation implies that its linked third parties' may not implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Specific case:

In case the **coordinator's participation** is terminated **without its agreement**, the notification must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

⚠ Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system).

ⓘ For more information on the roles and access rights in the electronic exchange system, *see the Online Manual*.

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Exception:

No amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example:

A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so) — unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

⚠ The information contained in the beneficiary's termination report must also be included in the periodic report for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only costs incurred before termination (i.e. before the notified date on which termination takes effect) are **eligible**.

Exception/Specific case:

Costs related to submission of the **termination report** are eligible, even though incurred after the end of the action for that beneficiary *(see Article 6.1)*.

Costs related to **contracts** or **subcontracts** are eligible for the part of the contract/subcontract delivered before the termination.

⚠ If the coordinator **fails to submit the termination report** (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will not be taken into account when the contribution is calculated. The Commission/Agency will not send a written reminder and will not extend the deadline. In this case:

⚠ If the coordinator **fails to submit the report on the distribution of payments**, the beneficiary whose participation was terminated will not have to repay any amounts.

If the Commission/Agency considers that the **termination** was **improper**, it may terminate the GA *(see Article 50.3.1(c)) and/*or — at the payment of the balance — reduce the grant *(see Articles 5.3 and 43)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION:*** *not applicable];*

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(iii) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:
  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
    - termination takes effect after an interim payment and
    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA or of the participation for one or more beneficiaries (by the Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the grounds listed in this Article.

Grounds for termination (by the Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  ⚠ Non-accession of a beneficiary does not automatically lead to the termination of the GA.

  The coordinator can request an amendment, to adapt the action to the new situation and ensure its proper implementation (even without the beneficiary) *(see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if the consortium does not find an appropriate solution or no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [70]

  Examples:

  1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).

  2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

[70] *See also Article 8 of the Rules for Participation.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

- **GA cannot be amended after termination** of a beneficiary's participation

  The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

  Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Action can no longer be implemented**

  The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

  Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

  The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

  Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

  ⚠ The beneficiaries must inform the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

- **Professional misconduct**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

- **Non-compliance with tax or social security obligations**

  The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

  Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

  Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

  For joint actions (i.e. actions funded following a joint or coordinated call with a third country or an international organisation; *see Article 2*), the Commission/Agency may terminate the GA, if:

  – the third country's or international organisation's action does not start by the date specified in Annex 1

    ⚠ In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

  – the third country's or international organisation's action is terminated

  – the third country's or international organisation's action can no longer contribute to the subject of the GA.

    Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

  Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA — substantial errors, irregularities, fraud or a serious breach of obligations (including improper

implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary charged costs in its individual financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 or of the ethics requirements set out in Annex 1.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

⚠ The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:

- systemic or recurrent and,
- have a material impact on this grant.

⚠ Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure**.

ⓘ For the basic contradictory procedure, *see Article 42.*

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc.), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

⚠ Only costs incurred before termination (i.e. before the date on which termination takes effect) are **eligible**. Costs relating to contracts due for execution only after termination are not eligible. **Ineligible costs** may be **rejected**.

⚠ The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43)*.

⚠ In certain cases, the Commission/Agency may moreover impose **administrative and/or financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

In case of force majeure, a party will be excused from not fulfilling its obligations. (Therefore, if the Commission agrees that an event should be considered force majeure, it is understood that there is no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied.)

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure cannot be used as justification in situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

The following cases are explicitly **not** considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

In a case of force majeure, the party concerned must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

Force majeure normally has no specific effects on the **eligibility of costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible (⚠ new in Horizon 2020).

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[the Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate* [*complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal).

The electronic exchange system offers different **functions**:

- you can view and change your legal entity data in the 'Beneficiary Register'
- for reporting, deliverables and amendments, you can directly access the necessary forms and applications and make submissions
- to contact the Commission/Agency, you can use the 'Messages' function
- to make formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), you can use the 'Formal notifications' function
- where necessary, the electronic exchange system allows for secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the 'Grant File' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

⚠ Even if the recipient beneficiary never accesses the notification in the electronic exchange system *(e.g. refusal of reception or omission)*, the formal notification is **considered to have been accepted** ten days after it is sent. Any delay for reacting is counted as of day eleven.

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and

amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system.

Examples:

1. Only Legal Signatories (PLSIGNs) may sign the GA and amendments.

2. Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.

3. Only Coordinator Contacts (CoCos) may submit information to the Commission.

4. Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.

5. Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).

6. Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.

7. Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.

ⓘ For more information on access and roles in the electronic exchange system, *see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations)*.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[52], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[52] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 18.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example:

Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue.

The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example:

Under Article 22.1.2, reviews may be started up to two years after the balance is paid.

A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

An amendment is necessary whenever there is a need to **change** the **terms and conditions** of the GA.

⚠ The general terms and conditions cannot be modified via an amendment. Only the data specific to a GA *(e.g. duration of the reporting periods, start date etc.)* and the options in the GA can be added or removed via an amendment.

⚠ Amendments may **not** result in changes that — if known before awarding the grant — would have had an impact on the decision to award it. Those are mostly changes that:

– may have had an impact on the assessment of the applicant with regard to the eligibility and selection criteria *(e.g. consortium of three entities established in three*

different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)

- breach the principle of equal treatment of applicants
- involve modifications in the action and/or the related budget which may have affected the assessment with regard to the award criteria announced in the call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- do not comply with the rules applicable to the GA (i.e. Financial Regulation, Rules for Participation, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified or to modify Annex 1 following a review of the action).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation is terminated** *(see Article 50.2 and 50.3)*.

  There are two main cases for removing a beneficiary:

  - if it never became beneficiary (because of non-accession to the GA or non-provision of the requested declaration on joint and several liability).

    In this case, the amendment will be triggered by the Commission/Agency and the beneficiary is removed *ex tunc* (i.e. from the beginning since it has never been a beneficiary)

  - for other reasons set out in Article 50.

    The amendment may be triggered by the beneficiaries or by the Commission/Agency. The termination date will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs until that day.

  For termination by the beneficiaries:

  - the request for amendment must be part of the notification of termination
  - it has to include the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing)
  - the 'termination date' must be after notification *(see Article 50.2.1)*.

  For termination by the Commission/Agency:

  - there has to be a contradictory procedure *(see Article 50.3.2)*

- the 'termination date' will be either:
  - the date specified in notification confirming termination or
  - the day after the coordinator receives the notification confirming termination
- after termination, the coordinator must submit (within 60 days from the termination date) the amendment request with all the supporting documents *(see Article 50.3.3)*.

⚠ NO need to request an amendment if termination takes effect ***after* the end of the action** *(see Article 3)* — unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

If the coordinator is removed, the amendment has to propose a new coordinator.

If the beneficiary was participating with linked third parties, they will also have to be removed (with the same date as their beneficiary).

The termination will imply a change of Annexes 1 and 2 and — depending on the type of beneficiary and its H2020 status(es) — GA options will be deleted or become not applicable.

- **Adding a new beneficiary** *(see Article 56.2)*

⚠ Don't forget that:

- the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC),'
- the request for amendment must include;
  - Annex 3 (Accession Form) signed by the new beneficiary in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*) before submitting the amendment request,
  - a PDF copy of the signed Annex 3a (declaration of joint and several liability of its linked third parties if requested by the Commission/Agency),
  - Annex 3b (Administrative Arrangement signed by the Joint Research Center (JRC), if applicable).

The new beneficiary will join the action on the 'accession date' stated in the Accession Form.

The addition will imply a change of Annexes 1 and 2 and — depending on the type of beneficiary and its H2020 status(es) — GA options will be added.

Examples:

If the new beneficiary is an international organisation, the options related to international organisations specified under Articles 22.4, 53.2, will be added to the GA and the options specified under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Adding or removing a linked third party** *(see Article 14)*

Although they are not beneficiaries, the change of a linked third party (i.e. if it ends its participation or joins the action) also requires an amendment to update Article 14 (to state/remove their name and to fix their starting/end date).

⚠ Don't forget that the new linked third party must first be registered (and validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC)'.

⚠ NO amendment is necessary for a **change of name**; a change of the linked third party data (and validation) in the 'Beneficiary Register' is sufficient.

- **Change of beneficiary due to partial takeover** (called 'partial transfer of rights and obligations' in FP7)

'**Partial takeover**' means that a part of the business of the beneficiary (including the GA) is taken over by another entity ('transfer of a business unit as a going concern', *e.g. partial acquisition, distribution of a business unit on dissolution/liquidation, division/demerger, etc.).*

'**Partial acquisition**' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, some of the rights and obligations (and contracts) of the original entity are transferred to the new entity(ies) (i.e. a partial transfer of the rights and obligations of the original entity). Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells it mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'**Distribution of a business unit on dissolution/liquidation**' means that the original entity disappears (due to dissolution or liquidation), but that a new entity purchases a department, business unit or similar (and absorbs or takes over part of the rights and obligations of the original entity). Since only some of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'**Division/demerger**' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples: Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.

⚠ **Simple acquisition** of (one or more) individual **assets** of the beneficiary is NOT covered. (If the sale of an asset makes it impossible for the beneficiary to fulfil its obligations, it may request an amendment to change beneficiary (i.e. termination and addition of a new beneficiary)).

If the GA is part of the assets taken over, the beneficiary must request an amendment; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as 'new beneficiary').

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and the other beneficiaries). You must, in particular, explain the financial liability of the old beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts if possible). (⚠ Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.)

⚠ Don't forget that the new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC)'.

⚠ NO amendment is necessary for '**universal takeovers**' (i.e. where the original entity is replaced by one new entity and all the rights and obligations are transferred to this new entity); a change of the beneficiary data (and validation) in the 'Beneficiary Register' is sufficient (*see below*).

- **Changes to the status of a beneficiary/linked third party as 'receiving EU funding' or 'not receiving EU funding'**

If the status of a beneficiary/linked third party — exceptionally — changes during action implementation *(e.g. due to a change of establishment)*, this change of status will require an amendment.

Example: Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.

⚠ New association agreements (between the EU and third countries) do NOT have an impact on ongoing grants. The beneficiaries keep the status they had at the moment of the signature of the GA.

- **Change of coordinator**

If the new coordinator is not a beneficiary of the GA, it must first accede to the GA as a new beneficiary *(see Article 56.2)*.

The former coordinator may continue to participate in the action as a beneficiary (or may terminate its participation).

If you would like to set a specific date for the change, the amendment request must indicate a 'handover date'. (If the former coordinator leaves consortium, this date must

be after the 'termination date'; if the new coordinator joins the consortium, this date must be after the 'accession date'). Otherwise, the change will take effect on the date of the last signature of the amendment.

⚠ An amendment to change the coordinator remains possible (and necessary) *after* the end of the action *(see Article 3)*.

- **Change of the coordinator's bank account for payments**

  An amendment is necessary for all changes that imply a change to the account number/IBAN code.

  Example: *The coordinator changes bank account.*

  ⚠ Do not forget to first update the bank account data in the Beneficiary Register (and get it validated).

  ⚠ NO amendment is necessary for a change of the name of the bank, address of branch or name of the account holder; a change of the bank account data (and validation) in the 'Beneficiary Register' is sufficient.

- **Change of the option for 'authorisation to administer'**

  The option in Article 41.2 can be added/deleted or modified *(e.g. change of name of the entity with 'authorisation to administer'')*.

- **Change of the action's title and/or acronym**

  Example: *the consortium finds out that the acronym of their action is a protected trademark.*

- **Change of the starting date, duration of the action or reporting periods**

  Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

  An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases. (⚠ Even if the action is prolonged, the maximum grant amount cannot be increased).

- **Amendment for resuming the action after a suspension of the action implementation**

  The amendment request must specify the date when the suspension ended. The action implementation is then automatically resumed as from the following day ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:

  – a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries

  – changes concerning **in-kind contributions** provided by third parties (against payment or free-of-charge) or **subcontracts**

Such changes could in principle also be made as 'approval without formal amendment' (*see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency's *agreement* (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency may consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).

– changes concerning the tasks to be carried out by **linked third parties** and related costs

There is NO 'approval without formal amendment' *(see Article 14)*.

– changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

Changes to the maximum grant amount and/or the action's estimated eligible costs will be accepted only in very exceptional cases *(e.g. due to a clerical mistake)*.

⚠ The maximum grant amount canNOT be increased.

Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2** and Annex 2a **(estimated budget)** which require an amendment *(see Article 4)*, in particular:

– a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

– a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*.

Examples:

1. During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices.

2. An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to add the appropriate option under Article 5.2 and to modify the action's estimated budget in Annexes 1,2 and 2a.

A change to unit costs may also require a change of Annex 2a (done automatically by the IT system, according to changes introduced by the project officer).

- **Change concerning specific cost categories ('specific unit costs')**

If the options in Articles 5.2 and 6.2 must be added/deleted, an amendment to the GA is necessary.

Indicative list of cases where NO amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary, linked third party or coordinator**

  Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA do not require an amendment; an update of the beneficiary/data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

  ⚠ Linked third parties must communicate such changes via their beneficiary who must communicate them to the Commission/Agency (since they do not have a LEAR) (via the electronic exchange system) *(see Article 17.2)*. The data will be updated in the Beneficiary Register by the Commission/Agency and validated.

  ⓘ For more information on data updates, *see the Online Manual*.

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may request it.

  Example: *Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.*

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

  Universal takeovers (i.e. where the original entity is replaced by one new entity and all the rights and obligations (including the GA) are transferred to this new entity, *e.g. merger or full acquisition*) do not require an amendment; an update of the beneficiary data by the LEAR (and validation) in the 'Beneficiary Register' is normally sufficient.

  Example:

  Beneficiary X merges with another existing entity Y by:

  - *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
  - *establishing a new separate legal entity (X and Y are together known as 'Z').*

  ⚠ If — exceptionally — the Commission/Agency considers that the change you registered affects the implementation of the action, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may request it.

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.

Case 2: A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

⚠ Don't forget that — in addition to updating the data in the Beneficiary Register — you must also inform your coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinators must then inform the Commission/Agency (via the electronic exchange system) and may request an amendment.

The same applies if the universal takeover concerns one of your linked third parties.

How?

Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) **directly in the electronic exchange system** (i.e. the 'My Area' section of the Participant Portal; *see Article 52*).

Specific case:

Requests to **change the coordinator** (against the coordinator's will) can be submitted by any beneficiary (acting on behalf of the others).

Best practice: If none of the amendment clauses available in the IT tool are appropriate, beneficiaries are advised to contact the Commission/Agency (via the 'Messages' function of the electronic exchange system) to discuss the amendment.

⚠ The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action, i.e. the date set out in Article 3). (Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases, *e.g. change of bank account, change of coordinator to make the payment of the balance*.)

The coordinators must ensure internally that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

⚠ Don't forget:

- for new beneficiaries (or linked third parties): to ensure that they have obtained all necessary validations in the 'Beneficiary Register'.

  Example:

  Validation of the new bank account, to change the bank account

  Legal entity validation, to add a new beneficiary that is not yet validated. This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal

- to include the necessary information and supporting documents (as required for certain amendments).

  Examples:

  For a change of coordinator without his/her agreement, the coordinator's opinion (or written proof that this has been requested).

  To add a new beneficiary, an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

  To amend Annexes 1 and 2, amended versions of these annexes.

  ⓘ For the supporting documents, *see the List of supporting documents.*

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator. (⚠ The coordinator submits and signs on behalf of the other beneficiaries; *see Annex 3*).

Before it has been accepted or rejected, it may at any moment be **withdrawn**. However, it canNOT be *changed* (without withdrawing it and submitting a new one).

If accepted it will be **counter-signed** by the receiving party (again, directly in the electronic exchange system by the PLSGIN).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

ⓘ For more information on the preparation and submission procedure, *see above point 1.*

The other party must — within **45 days** — **agree or disagree**, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

A request containing several changes to the GA will be considered as a **package** that cannot be divided into several requests. The request will be agreed or rejected by the other party as a whole.

If, the receiving party requests **additional information/documents** a new deadline will apply, i.e. **45 days** from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked*

third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.

The **deadline** may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

⚠ A signed and submitted amendment request (including supporting documents) canNOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

⚠ If there is **no reaction** within the deadline, the request is considered to have been **rejected** (new in Horizon 2020: contrary to FP7, there is no tacit approval of amendments). A new amendment request may be submitted (even if it fully or partly repeats the initial request).

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

Unless the parties agree otherwise, the amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) for the different changes.

If the parties agree on another date, it should normally be *after* the entry into force. In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (⚠ In certain cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

Where a new beneficiary is added to the GA, it must assume the rights and obligations from the 'accession date' specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the 'resumption date' set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

⚠ Depending on the nature of the change, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (by the beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by signing the Accession Form *(see Annex 3)* in the electronic exchange system. They must do this within 30 days after the GA enters into force *(see Article 58)*.

⚠ Only the beneficiary's Legal Signatories (PLSIGNs) may sign the Accession Forms.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020).

All documents are available in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

Specific case:

If the Commission/Agency requested **joint and several liability** of a **linked third party** *(see Article 14)*, the beneficiary to which the third party is linked must also submit a declaration on joint and several liability (using the template in Annex 3a).

The third party must sign the declaration on paper and send it to its beneficiary. The beneficiary must scan it and submit it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

⚠ If the beneficiary does not submit this declaration, it will NOT be able to access to the GA (and thus not be considered a party to the GA).

Third parties are not required to sign an Accession Form (since they are not parties to the grant).

Specific case:

⚠ If the **JRC** is a beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

⚠ For **mono-beneficiary actions**: replacing the beneficiary during the action implementation is only possible under exceptional circumstances *(e.g. the beneficiary transfers all its rights and obligations, including those related to the action, to another legal entity).*

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated — unless it already has a validated 'participant identification code (PIC)'
- sign the Accession Form directly in electronic exchange system (i.e. the 'My Area' section of the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an amendment for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned]].*

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].**]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.**]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.**]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).**]***

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Exception:

The GA may provide for derogations for 'international organisations (IOs)' (if requested by the international organisation):

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[71]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA. In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

2. Dispute settlement

As a general rule, Horizon 2020 GAs contain an Article 272 TFEU - arbitration clause, referring **disputes on the interpretation, application or validity of the GA** to the Court of Justice of the European Union.

[71] *See Article 180(1) of the Rules of Application.*

Exceptions/Specific cases:

For non-EU beneficiaries, disputes are normally referred to the competent Belgian courts. So far (i.e. until end of 2014) none of the agreements associating third countries to Horizon 2020 provides for the sole jurisdiction of the Court of Justice.

For beneficiaries that cannot be subject to the jurisdiction of the Court of Justice (i.e. beneficiaries that do not receive EU funding and are established in a non-EU or associated country and international organisations (IOs)), disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[72]).

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against 'confirmation letters', 'debit notes', etc.; NOT against 'audit reports', 'letters of audit conclusions' 'pre-information letters', etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative or financial penalties, offsetting** or **enforceable decisions** under Article 299 TFEU; see Articles 44, 45 and 46), actions (by all beneficiaries — including non-EU beneficiaries, 'beneficiaries not receiving EU funding' and international organisations (IOs)) must be brought before the Court of Justice of the European Union under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ All procedures are organised in a way that the beneficiaries will be informed of the available means of redress (via a 'redress clause' in the letters).

ⓘ For more information on complaints, *see the Online Manual*.

[72] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

⚠ It is usually the Commission/Agency who signs last.

II. ERC MGAs

II.1 ERC MGAs: Background information and approach

The ERC General Model Grant Agreement ('ERC General MGA') is used for the following ERC grants ('frontier research grants'):

- ERC Starting Grants (StG)
- ERC Consolidator Grants (CoG)
- ERC Advanced Grants (AdG)
- ERC Synergy Grants (SyG).

The ERC General MGA is not used for ERC PoC and ERC low value grants (which have specific MGAs; *see below*).

⚠ ERC grants are open to **principal investigators** (PIs) of any nationality who intend to conduct a **frontier research project** in a Member State or associated country and which are hosted by a host institution that is based in an EU Member State or associated country and can receive EU funds. They are mainly individual projects (using the mono-beneficiary MGA).

ⓘ For more information on ERC actions, *see Article 2.*

ⓘ For information on ERC funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ⓘ For information on ERC standard eligibility criteria, *see the ERC Work Programme.*

The ERC General MGA follows the General MGA for numbering and content, except for the following:

Introductory remark all ERC MGAs

The ERC Model Grant Agreements deviate from the General Model Grant Agreement as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
-
- The table of contents is adapted
- Cross-references in the footnotes are adapted

Introductory remark ERC General MGA

The ERC General Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

Introductory remark ERC PoC MGA

The ERC PoC Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

ERC frontier research grants are however different from General MGA grants because:

- EU funding is granted to an individual action proposed and supervised by a Principal Investigator (PI) (or several, in the case of SyG), while

- the grant is signed between the Agency on one side and the beneficiaries on the other, one of which is the host institution of the PI and his/her research team.

⚠ By signing the GA, the beneficiaries take on a series of obligations towards the PI and the research team. In order to participate in the action, the PI must sign a supplementary agreement (SA) with its host institution where s/he also takes on a series of rights and obligations *(see Article 32)*.

ERC PoC grants are then follow-up grants to explore the innovation potential of results generated in a previous ERC frontier research grant.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC actions)
- Article 4.1 (ERC budget categories)
- Article 6 (ERC eligible and ineligible costs)
- Article 8 (ERC rules on third party involvement).

Since the ERC General MGA and the ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC PoC MGA will be limited to major differences from the ERC General MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 ERC General MGA: Annotations

H2020[1] MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR ERC GRANTS[2] (H2020 ERC MGA – MULTI)

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for principal beneficiary not receiving EU funding:*** *as 'beneficiary not receiving EU funding' (see Article 9),**]*** represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

[OPTION by default: *'**principal investigator**':*[4]

- *[**Name**][Date and place of birth]**]***[5]

[OPTION for SyG: *'**corresponding principal investigator**':*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]].**]***

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG****: hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

*[same for each beneficiary**]***

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).**]***.

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties**]***

[OPTION if the JRC participates: *3b Administrative Arrangement**]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called 'principal beneficiary'.

Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that host (or employ) a principal investigator ('host institution').

The PI is usually employed (or engaged) by the host institution for the entire duration of the action.

Exceptions/Specific cases:

PI may (exceptionally) be employed by a third party *(see Article 8)*, i.e.:

– a third party from an EU Member State or associated country providing the PI as in-kind contribution or

– a linked third party.

This must be specifically justified in the proposal and included in Annex 1. Moreover, the third party must also sign the supplementary agreement and agree to the obligations included in it *(see Article 32)*.

Retired researchers — The PI is no longer under an active labour contract.

The PI and the host institution must also sign a 'supplementary agreement (SA)' *(see Article 32)*. (⚠ The supplementary agreement canNOT replace the employment/engagement contract.)

If the PI is entitled to sign the supplementary agreement on behalf of the institution (because of his/her position in the host institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties)

ⓘ For more information on arrangements for signature and third parties, *see the Preamble of the General MGA*.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities. The engagement of the team follows the rules of the beneficiary and its country.

PIs must be supported by their host institution during the entire duration of the action.

⚠ The Agency must be contacted before any change in employment or location of the PI.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions must sign a '**supplementary agreement (SA)**' *(see Article 32)*.

Specific cases:

ERC Synergy grants — Have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

ERC PoC grants — NO supplementary agreement is needed.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC actions

What? ERC actions are mono- or multi-beneficiary actions with the following activities:

– any type of frontier research activity in any field of research (except nuclear energy; *see the ERC Work Programme*).

ERC grants fund ground-breaking, high-gain/high-risk research at the frontiers of knowledge by excellent investigators and their research teams.

ⓘ For examples of successful ERC actions, *see the ERC website*[73].

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-STG)*.

ⓘ For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of your call.*

[73] Available at http://erc.europa.eu/erc-stories.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC General MGA uses in principle the **same budget categories** as the **General MGA**.

Budget categories of the ERC General MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'.

⚠ Thus, the ERC General MGA does NOT have:

– 'personnel costs for providing trans-national access to research infrastructure'

– 'direct costs of providing financial support to third parties'

– 'specific cost categories'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 General MGA)*.

However, the ERC General MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and

beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[74]

It does NOT use the unit costs of the 'specific cost categories' of the General MGA.

[74] *See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 General MGA)* — with the exception of 'direct costs of providing financial support to third parties', 'specific cost categories' and 'costs for providing access to trans-national research infrastructure'.

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

Specific cases:

For '**direct personnel costs'**:

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI (exceptionally) engaged by a third party (which pays his/her salary secondeds him/her to work on the premises of the beneficiary, for free or against reimbursement by the beneficiary; *see Article 8*) — The salary costs may be declared as direct personnel costs (if for free: as 'personnel costs – costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3)).

⚠ In this case, the supplementary agreement must be signed by the PI, the host institution *and* the third party.

For '**other direct costs'**:

Recruitment costs — Recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs' (because recruitment is part of the activities of ERC actions — unlike General MGA actions).

⚠ Recruitment costs are NOT considered as one action activities for ERC PoC grants.

Purchase of scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* — May be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access (to publications, including monographs, and research data) — Are eligible during the duration of the action. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (it canNOT be with other beneficiaries or linked third parties).

Exception/Specific case:

The **PI may (exceptionally) be engaged by a third party from an EU Member State or associated country**:

- a third party providing the PI as in-kind contribution or
- a linked third party.

This must be specifically justified in the proposal and included in Annex 1. Moreover, the third party must also sign the supplementary agreement *(see Article 32)* and agree to the obligations included in it.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 General MGA)*.

In addition, the beneficiaries must however prove that the **time-commitment of the PI** (as described in Annex 1) wascomplied with.

Thus, they must be able to provide evidence that the PI dedicated the minimum time commitment (i.e. percentage of the total working time, i.e. percentage of the annual productive hours calculated in compliance with Article 6) to the action — via time-sheets or alternative time recording systems.

ⓘ For the percentage required, *see the ERC Work Programme*.

Moreover, they must be able to provide evidence that the PI spent the minimum time commitment *in a Member State or associated country* (i.e. a Member State or an associated country), via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

ⓘ For the percentage required, *see the ERC Work Programme*.

⚠ Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
    - information about the scientific progress of the work
    - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
    - information on whether and how open access has been provided to these results *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
    - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted **directly in the electronic exchange system**, i.e. 'My Area' section of the Participant Portal*; see Article 52*).

ⓘ For more information on how to submit the reports, *see Article 20 General MGA and the Online Manual*.

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC General MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

[…]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.****]***

[OPTION: *Not applicable****]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

Examples: *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

For publications issued after the end of the action, beneficiaries are not obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

For bibliographic metadata, the ERC General MGA foresees lighter requirements, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[75] or other systems).

⚠ As far as the chosen repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 General MGA)*.

Exceptions/Specific cases:

For ERC actions, there is NO formal requirement for a '**data management plan**'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and

[75] For more information, *see http://www.doi.org/*.

afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

The exception allowing beneficiaries not to give access to specific parts of research data applies not only if this would jeopardise the main objective of the action, but any one of the action objectives.

⚠ For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[36] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary *[**OPTION for SyG:** and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement *[**OPTION for SyG:** and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[36] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005.p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC General MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow for transfer of the GA to another host institution (**portability**).

⚠ PIs cannot be prevented from applying independently (i.e. in their own name) for further EU funding for other actions. They can also apply for further EU funding for the same action, as long as it is for costs that are not eligible (or not declared) under the ERC grant.

In this context, 'action' refers to the specific ERC action, for which the beneficiaries receive the ERC grant *(see Article 2)*.

⚠ The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ⓘ For more information on combining EU funding for different actions ('complementary EU funding'), *see the Online Manual*.

2. Supplementary agreement — Obligations on the PI

The ERC General MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

The supplementary agreement should cover all the practical issues that may arise in the context of the grant implementation, and in particular the ones listed in Article 32.1(b).

A model supplementary agreement is available on the Participant Portal and the ERC website. (⚠ The model is not mandatory. Host institutions and their PIs may add or use other clauses, if they benefit the research action and do not contradict the GA. Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

⚠ The supplementary agreement must be concluded *before* the GA is signed (and a copy must be sent to the Agency).

It must cover at least the duration of the action (see Article 3) — without any interruptions, even if the PI should work only part-time on the ERC project.

⚠ It cannot replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

Specific cases:

ERC Synergy grants (with **several PIs**) — Each host institution must conclude a supplementary agreement with the PI(s) they engage.

ERC PoC grants — NO supplementary agreement is needed.

PI (exceptionally) engaged by a third party from the EU or Associated Country (and seconded to work on the premises of the beneficiary for the duration of the grant) — The supplementary agreement must be signed by the PI, the host institution AND the third party.

PI entitled to sign the supplementary agreement (because ofhis/her position in the host institution) — The supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties).

Transfer of the GA to another host institution (**portability**; *see Article 56a*) — A new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

Via the supplementary agreement, the PI must take on a number of obligations, to ensure the smooth implementation of grant.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** for the beneficiary and contribution to the **financial reporting**
- Meeting the time commitments for **implementing the action**
- Applying the beneficiary's usual management practices

- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA

- Ensure the **visibility of EU funding**

- Upholding the **intellectual property rights** of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.

- Maintaining **confidentiality**.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(c) display the EU emblem and the ERC logo and

(d) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

ⓘ For more information on the use of the ERC logo, *see the ERC homepage*[76].

[76] Available at http://erc.europa.eu/logos-and-banners.

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 General MGA)*.

However, unlike the General MGA, ERC ***mono*-beneficiary** grants can **become *multi*-beneficiary** grants, by addition of a new beneficiary.

The procedure to be followed is that of Article 56 of the mono-beneficiary General MGA.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

Portability makes it possible to transfer ERC grants — at any time during the action implementation.

The PI may **request a transfer** of his/her grant to any other entity based in an EU Member State or associated country ('new host institution'), if this is beneficial for him/her and supports achieving the action's objectives.

Specific cases:

ERC Synergy grants — Each PI maintains the right to transfer their part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Certain team members or **equipment remain with the former host institution** — The former institution may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

Thus, both host institutions must agree on the transfer of intellectual property, in conformity with the GA and after consulting the PI. The transfer plan should cover:

- the results produced under the action and the access rights to them and
- the PI's and new host institution's access rights to background held by the former host institution but necessary for implementing the rest of the action.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs are advised to keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency (together with the necessary supporting documents).

There is a specific transfer clause for portability (i.e. NO combination of 'termination' and 'addition of a new beneficiary' needed).

The beneficiaries may choose to let the transfer take effect from the entry into force of the amendment or a specific 'transfer date' (before or after the amendment). (⚠ Retroactive dates are allowed only in exceptional cases and with a specific justification. Contact the Agency in advance, to see if it can agree).

⚠ Otherwise, the rules for amendments of the General MGA apply *(see Article 55 General MGA)*.

The amendment request should be made well in advance, to allow sufficient time for the amendment procedure.

⚠ The GA canNOT be transferred before the amendment is signed by the Agency. Any partial or full transfers made without a formal amendment to the grant agreement are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

⚠ The beneficiaries and the PI are advised to contact the Agency prior to any change in employment or location of the PI.

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** all **remaining pre-financing** (not covered by eligible costs) to the new host institution.

⚠ If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will not pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary).

⚠ Scientific reporting periods will usually remain unchanged as they are linked to the action's scientific development and must be submitted by the PI, who holds this position for the whole duration of the GA.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law.

It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

II.3 ERC PoC MGA: Annotations

⚠ The ERC PoC MGA is very similar to the ERC General MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 ERC General MGA)*, no supplementary agreement and no grant portability *(Article 56a ERC General MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC General MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC actions are actions with the following activities:

- verifing the innovation potential of ideas arising from ERC funded projects

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

⚠ ERC PoC grants canNOT cover activities under the ERC frontier research grant (*e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential*) or activities which are the result of research not performed under the ERC actions (*e.g. results of research not found by the ERC action*).

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-PoC)*.

ⓘ For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of your call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)**]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
***[**- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].**]***

20.3 Periodic reports — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What ?

For ERC PoC actions, the principal beneficiary must submit reports — only one '**report**' if there is one reporting period, otherwise one '**periodic report**' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  ⚠ The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

⚠ Only at the moment of the submission of the last reporting period, the 'certificate on the financial statements (CFS)' will have to be added.

How?

All reports mut be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' section of the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the duration of the action).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie (MSC) Model Grant Agreements

III.1 Background information and approach

The MSC Model Grant Agreements ('MSC MGAs') are used for grants for MSC actions only.

⚠ MSC grants are open to different types of beneficiaries.

MSC-ITN grants are open to networks of universities (and industry) that hire early-stage researchers to conduct research training activities.

MSC-IF grants are open to experienced researchers for a fellowship.

MSC-RISE grants are open to universities and industry for staff exchanges involving research training activities.

MSC-COFUND grants are open to research funders (i.e. organisations implementing or managing a research training programme).

ℹ For more information on the different MSC actions, *see Articles 2 of the different agreements.*

ℹ For information on MSC funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ℹ For information on MSC standard eligibility criteria, *see the Main Work Programme — MSCA.*

The MSC MGAs follow the General MGA for numbering and content, except for the following:

Introductory remark

MSC-ITN — Multi deviates from the General MGA — Multi as follows:

- Article 4.2 (MSC-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

MSC-IF — Mono deviates from the General MGA— Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 8-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSC-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSC-IF specific conditions for termination)
- Article 55 (MSC-IF specific conditions for amendments)
- Article 56a (MSC-IF portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

MSC-RISE — Multi deviates from the General MGA — Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSC-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (MSC specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

MSC-COFUND — Mono deviates from the General MGA — Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of programmes)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 8-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSC actions are added:

- Article 2 (MSC actions)
- Article 4.1 (MSC budget categories)
- Article 8 (MSC rules on third party involvement)

III.2 MSC Innovative Training Networks (MSC-ITN): Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-ITN actions

What? MSC-ITN actions are multi-beneficiary actions with the following activities:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs and other socio-economic actors from different countries across Europe and beyond).

MSC-ITN actions take the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of your call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[OPTION for all actions except EID: *However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.****]***

1. Budget categories

The MSC-ITN MGA does **not** use the **budget categories** of the **General MGA**.

Budget categories of the MSC-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Budget transfers between *beneficiaries* are the consequence of the redistribution of person-months between them (as compared with the original planning set out in Annex 2). (⚠ Transfers between *budget categories* are, by contrast, NOT possible because MSC unit costs are all linked to the person-months declared for the recruited researchers.)

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. (⚠ Changes that only concern the consortium-internal arrangements on the distribution of the institutional unit cost for management tasks do NOT need to be notified to the Agency.)

Example:

Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.

⚠ Budget transfers will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Transfers are subject to the following:

- no impact on the action as described in Annex 1 (⚠ If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment will be required.)
- correct application of the country correction coefficient
- the minimum and maximum recruitment durations per researcher
- for all actions except for MSC-ITN EID: the 40 % limit of budget allocated to beneficiaries established in the same country or to the same international European interest organisation or international organisation.

  The 40% is counted on the basis of the number of person-months allocated to each beneficiary in Annex 1.

⚠ The 'maximum grant amount' mentioned in Article 5 canNOT be increased.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-ITN actions, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs use only one **cost form**, i.e. the **unit costs** set out in Commission Decision C(2013) 8194[77].

For MSC-ITN these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

⚠ The MSC MGAs do not use any of the **unit costs** and **flat-rates** of the General MGA.

[77] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since MSC uses only unit costs, there is **no reduction due to the no-profit rule** in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries must:

– at proposal stage: enter only eligible person-months into the estimated budget for the action *(see Article 4)*

– at reporting stage: declare only eligible person-months in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries**. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible. (If the Agency finds ineligible person-months, they will be rejected; *see Article 42*).

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for recruited researchers (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country where the research training activities take place for more than 12 months in the 3 years immediately prior to the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country).

For beneficiaries that are the international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately prior to the recruitment date;

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree[;][.]**]***

(viii) ***[OPTION for EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

1. Costs for recruited researchers: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance for researchers with family, to reduce family-related obstacles to researcher mobility.)

What not? Costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

Example:

Costs for student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[78] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** per researcher per month ('person-month')

  ⚠ To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient**'.

- for the mobility allowance: **EUR 600** per person-month

[78] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the family allowance: **EUR 500** per person-month.)

For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of your call.*

In practice, the declaration of costs for MSC grants is very simple and **almost completely automatised**: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years of their research career.)

    '**Date of recruitment**' normally means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract or equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    Example:
    The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as 'date of recruitment'.

    Years of '**research career**' are counted as 'full-time equivalent research experience', from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract** (or '**other direct contract**' with equivalent benefits and social security coverage), including:

    – sickness, parental, unemployment and invalidity benefits

    – pension rights and

    – benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract (or other direct contract), beneficiaries may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

⚠ In this case, the living allowance will be reduced by 50%.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:

  - subject to prior approval by the Agency
  - on personal or family grounds only and
  - not for professional reasons.

- **work exclusively** on the research training activities

  Any complementary skills training *(e.g. a minor teaching activity)* is not incompatible, but must not jeopardise execution of the research training activities and must be set out in Annex 1 to the GA.

- are supported for **at least three months**

  ⚠ Person-months linked to shorter contracts will not be eligible. However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. Thus, if the contract is set out for a longer duration, but the training is interrupted within the first three months *(e.g. the researcher resigns)*, the costs may still be claimed.

- comply — at the time of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the recruitment date

  Specific case:

  Beneficiaries that are '**international European interest organisations**'[79] or **international organisations** — The researcher may not have spent more than 12 months with the beneficiary in the three years immediately prior to the recruitment date.

- for the doctoral programmes (MSC-ITN EJD and EID): are enrolled in a **doctoral programme**

  In the case of MSC-ITN EJD, the programme must lead to the award of:

[79] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

- a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
- a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals)

The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

⚠ MSC-ITN researchers may NOT be charged tuition fees for their research training and/or PhD degree programme. (Costs usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation)* can be covered by the institutional unit costs.)

⚠ Family and mobility allowances can be paid to the researcher in various ways (*e.g. as part of his/her salary, in the form of a flight ticket directly purchased or reimbursed by the beneficiary, etc.)*, provided that:

- the researcher can freely decide on the form of payment
- it is not in contradiction to national (tax) legislation and
- there is no underpayment.

For beneficiaries with accounting in a **currency other than** the **euro**:

- if a daily rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[80]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[81].

⚠ For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

[80] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[81] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

Example:

Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.

⚠ The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers that have — at the date of the recruitment — a family, i.e.
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example:

If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.

⚠ Do NOT declare more than 36 person-months per researcher. (Person-months exceeding this number will be rejected by the Agency.)

⚠ For MSC-ITN EID: make sure that each researcher spent at least 50% of the number of person-months declared in the non-academic sector. This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences and training)*
  - costs for research expenses
- management and indirect[82] costs (i.e. the beneficiary's additional costs in connection with the action).

  The management and indirect costs received can be distributed within the consortium (via an internal agreement). The distribution should however roughly correspond to the actual division of (management) tasks within the consortium.

  They should also be shared with partner organisations which incurred management or indirect costs for secondments.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[83] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 1200** per person-month (⚠ For beneficiaries that already receive an EU/Euratom operating grant[84], this amount is halved, i.e. EUR 600).)

⚠ In practice the declaration of institutional costs for MSC grants is **completely automatised** because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to the **eligibility** of the costs for the recruited researchers.

⚠ Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researchers are met. Person-

[82] For the definition, *see Article 6.2 of the General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[83] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[84] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

months which are not eligible for the budget category 'costs for recruited researchers' are also not eligible for the budget category 'institutional costs'.

Institutional costs cannot be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for recruited researchers:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

MSC-ITN actions do however allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that provide trainings and host researchers during a secondment).

Partner organisations canNOT employ the researcher under the action.

⚠ The beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA. (**Best practice:** It is therefore strongly recommended that beneficiaries establish internal arrangements *(e.g. partnership agreements)* with partner organisations, to ensure that they fulfil their obligations (especially under Article 32) during secondment periods.)

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSC-ITN actions, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these procedures end.)

⚠ If you throw supporting documents away during this period, you risk that costs are rejected or the grant is reduced (and undue amounts paid may be recovered).

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of the researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after the first year** of the action — send to the Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal) a progress report, to inform the project officer about progress on the action.

A template is provided on 'Reference documents' page of the Participant Portal.

2. Deliverable: Mid-term review meeting

What & When? The coordinator must:

- **before** the deadline for the **periodic report for RP 1**: organise a mid-term review meeting and
- **no later than 30 days** before this meeting: send to the Agency (via the electronic exchange system) a draft version of the periodic report, as a basis for the mid-term review meeting.

3. Deliverable: Researcher declaration

What & When? The beneficiary must send to the Agency (via the electronic exchange system) a document with information about each recruited researcher ('researcher declaration') — within **20 days** after the recruitment (of the researcher).

A template will be provided on the Participant Portal.

⚠ It is important to give correct and complete information since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. (If the researcher declaration is not provided, you will NOT be able to declare person-months for that researcher).

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSC-ITN actions, the MSC-ITN MGA foresees special access rights for them.

For more information on access rights, *see Articles 25 and 31 General MGA.*

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[14] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or any other entity referred to in Annex 1);

(j) host the researchers at their premises and provide training as well as the necessary means for implementing the action;

(k) ensure that the researchers are adequately supervised;

(l) ensure that a career development plan is established and support its implementation;

(m) ensure an appropriate exposure to the non-academic sector;

(n) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[14] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSC-ITN actions, the MSC-ITN MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for them.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[85]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:

  – family

  – emotional life

  – political or national affinity

  – economic interest or

  – any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

[85] Available at http://ec.europa.eu/euraxess/.

- **Host** the researchers at their premises and **provide training** as well as the necessary means for implementing the action

  ⚠ If the Agency has evidence that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**

- Ensure that a **career development plan** is established and support its implementation

- Ensure an appropriate **exposure to** the **non-academic sector**

- Comply with the arrangements on **intellectual property rights**

  ℹ For assistance with intellectual property rights, consult the IPR Helpdesk[86].

- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  ℹ For assistance with relocating researchers, *see EURAXESS Services*[87].

- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:

  - basic facts about the Marie Skłodowska-Curie programme, to make the researcher aware that s/he is a **MSC fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSC website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities, including during secondments/placements with other beneficiaries and/or partner organisations.

  Moreover, the employment contract (or 'other direct contract' or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6)*

- Ensure that the researchers do **no**t receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)

- Ensure that **secondments** are **limited** to a maximum of 30% of the months spent implementing the research training activities under the action.

[86] Available at https://www.iprhelpdesk.eu/.
[87] Available at http://ec.europa.eu/euraxess/.

⚠ For MSC-ITN EID and EJD, the 30% rule applies only to short secondments, summer schools and other activities that complement the main doctoral training.

Example:

In the context of an MSC-ITN EID action, University X hires a researcher for three years. Under 'inter-sectoral mobility', the researcher works in a laboratory in the non-academic sector for the obligatory one and a half years (50%). In addition, the researcher may be seconded to partner organisations, but for no more than 30% of the recruitment period.

2. Employment contract — Obligations on the researchers

The MSC-ITN GA foresees that there must be an employment contract (or other direct contract or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also vis-à-vis the researchers.

Via the employment contract, the researchers must take on a number of obligations, to ensure the smooth implementation of the grant.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities
- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*
- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 General MGA)*.

Exception:

Beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 MSC Individual Fellowships (MSC-IF): Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-IF actions

What? MSC-IF actions are mono-beneficiary actions with the following activities:

- recruitment of an experienced researcher for research training activities ('fellowship').

MSC-IF actions take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include two additional funding strands: the 'career restart panel' and the 'reintegration panel'.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of your call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION if needed for the action:** insert date]*[5] ('**starting date of the action**').

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Starting date of the action

For MSC-IF actions, the rules on the starting date of the action are in principle the same as in the General MGA *(see Article 3 General MGA)*.

However, the MSC-IF MGA provides for an additional option, where the starting date is *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, the notified starting date must be:

- after the entry into force of the GA and within the period of months set out in Article 3
- notified by the beneficiary in *advance* (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal).

⚠ If the action does not start or the starting date is not notified (in time), the Agency may terminate the GA *(see Article 50)*. If the notification is sent *after* the start of the action, this will have an impact on the timing of the pre-financing payment and will delay it *(see Article 21.2)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSC-IF MGA does **not** use the **budget categories** of the **General MGA**.

Budget categories of the MSC-IF MGA:

- costs for the recruited researcher
- institutional costs.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

2. Budget transfers

Given that MSC-IF is a mono-beneficiary action, there are NO budget transfers between *beneficiaries*.

Transfers between *budget categories* are not possible because MSC unit costs are all linked to the person-months declared for the recruited researcher.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-IF actions, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs use only one **cost form**, i.e. the **unit costs** set out in Commission Decision C(2013) 8194[88].

For MSC-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

⚠ The MSC MGAs do not use any of the **unit costs** and **flat-rates** of the General MGA.

[88] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since MSC uses only unit costs, there is **no reduction due to the no-profit rule** in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

This means that the beneficiary must:

– at proposal stage: enter only eligible person-months into the estimated budget for the action *(see Article 4)*

– at reporting stage: declare only eligible person-months in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiary**. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months declared are eligible. (If the Agency finds ineligible person-months, they will be rejected; *see Article 42*).

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[24][**OPTION for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including for a period of secondment to a **partner organisation**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action;

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Costs for the recruited researcher: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))

- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance if the researcher has family, to reduce family-related obstacles to researcher mobility.)

What not? Other costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[89] and indicated in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 4650** for the researcher per month ('person-month')

  ⚠ To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  ⚠ For MSC-IF GF: there are two different country-specific correction coefficients:

  - for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month
- for the family allowance: **EUR 500** per person-month.)

ℹ For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of your call.*

⚠ In practice, the declaration of costs for MSC grants is very simple and **almost completely automatised**: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  ⚠ Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

[89] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

- is — at the time of the deadline for submission of proposals — an **experienced researcher** ('ER'; i.e. have a doctoral degree or have at least four years of research career)

  Years of '**research career**' are counted as 'full-time equivalent research experience', from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- is recruited under an **employment contract** (or '**other direct contract**' with equivalent benefits and social security coverage), including

  – sickness, parental, unemployment and invalidity benefits

  – pension rights and

  – benefits for accidents at work and occupational diseases.

  If national law prevents the beneficiary from recruiting the researcher under an employment contract (or other direct contract), the beneficiary may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:

  – sickness, parental and invalidity benefits and

  – benefits for accidents at work and occupational diseases.

  ⚠ In this case, the living allowance will be reduced by 50%.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:

  – subject to prior approval by the Agency

  – on personal or family grounds only and

  – not for professional reasons.

- **work exclusively** on the research training activities

  Any complementary skills training *(e.g. a minor teaching activity)* is not incompatible, but must not jeopardise execution of the research activities and must be set out in Annex 1 to the GA.

- have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  For beneficiaries with accounting in a **currency other than** the **euro**:

– if a daily rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[90]

– if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[91].

⚠ For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example:

Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.

⚠ Family and mobility allowances can be paid to the researcher in various ways (*e.g. as part of his/her salary, in the form of a flight ticket directly purchased or reimbursed by the beneficiary, etc.)*, provided that:

– the researcher can freely decide on the form of payment

– it is not in contradiction to national (tax) legislation and

– there is no underpayment.

⚠ The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs (for the researcher).

⚠ Although not formal cost eligibility conditions for MSC-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the time of the deadline for submission of proposals —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the deadline for submission

Specific cases:

Beneficiaries that are 'international European interest organisations'[92] or international organisations — The researcher may not have spent more than 12 months with the beneficiary in the three years immediately prior to the deadline for submission

[90] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html

[91] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

[92] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

MSC-IF EF 'career restart' and 'reintegration' panels — the researcher may not have resided or carried out his/her main activity in the country of the beneficiary for more than three years in the five years immediately prior to the deadline for submission of proposals.

MSC-IF GF — the researcher must comply with the mobility rule with regard to the country of the partner organisation (i.e. where the outgoing phase takes place), not for the country of the beneficiary (i.e. where the return phase takes place).

– for MSC-IF GF and MSC-IF EF Reintegration: be nationals or long-term residents of a Member State or an associated country.

'Long-term resident' means full-time research activity in a Member State (or associated country) for five or more consecutive years.

- for the family allowance: have a family, i.e.:
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example:

If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.

⚠ Do NOT declare more than 24 person-months for the researcher (or 36 months for MSC-IF GF). (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences and training)*
  - costs for research expenses
- management and indirect[93] costs (i.e. the beneficiary's additional costs in connection with the action).

  They should be shared with a partner organisation which incurred management or indirect costs for a secondment.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[94] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 800** for the researcher per month ('person-month')
- for management and indirect costs: **EUR 650** per person-month (⚠ For beneficiaries that already receive an EU/Euratom operating grant[95], this amount is halved, i.e. EUR 325).)

⚠ In practice, the declaration of institutional costs for MSC grants is **completely automatised** because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to the **eligibility** of the costs for the recruited researcher.

⚠ Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for the budget category 'costs for the recruited researcher' are also not eligible for the budget category 'institutional costs'.

Institutional costs cannot be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

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93 For the definition, *see Article 6.2 of the General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

94 Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

95 For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for recruited researchers:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

MSC-IF actions do however allow for the involvement of **partner organisation(s)** (i.e. organisations that are not beneficiaries, but that provide trainings and host researchers during a secondment).

Partner organisations canNOT employ the researcher under the action.

For MSC-IF GF: the partner organisation must be located in a third country and must be described in Annex 1.

⚠ The beneficiary remains solely and fully responsible for the implementation of the action in accordance with the GA. (**Best practice:** It is therefore strongly recommended (especially for MSC-IF GF) that beneficiaries establish internal arrangements *(e.g. partnership agreements)* with partner organisations, to ensure that they fulfil their obligations (especially under Article 32) during secondment periods.)

ℹ For more information on secondments, *see Article 32*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSC-IF actions, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ If you throw supporting documents away during this period, you risk that costs are rejected or the grant is reduced (and undue amounts paid may be recovered).

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSC-IF actions, the MSC-IF MGA foresees special access rights for him/her.

For more information on access rights, *see Articles 25 and 31 General MGA.*

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[1] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(g) host the researcher at its premises and provide training as well as the necessary means for implementing the action;

(h) ensure that the researcher is adequately supervised;

(i) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(j) support the secondment of the researcher in Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(k) ***[OPTION for GF:*** *support the return of the researcher to its premises to carry out a mandatory return period of 12 months.****]***

[…]

[11] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSC-IF actions, the MSC-IF MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for him/her.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises and **provide training** as well as the necessary means for implementing the action

  ⚠ If the Agency has evidence that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- Support **secondments** of the researcher, if any (and, for MSC-IF GF, support his/her return during a mandatory 'return-period' of 12 months)

  Researchers may be seconded to a partner organisation established in a Member State or associated country:

  - if this is provided for in Annex 1 to the GA
  - for a maximum of three months in an action with a duration of up to 18 months, or up to six months in an action of up to 24 months

  ⚠ The beneficiary remains **solely and fully responsible** for the implementation of the action in accordance with the GA.

- Comply with the arrangements on **intellectual property rights**.

  ℹ For assistance with intellectual property rights, consult the IPR Helpdesk[96].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  ℹ For assistance with relocating researchers, *see EURAXESS Services*[97].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie programme, to make the researcher aware that s/he is a **MSC fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSC website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during secondments to partner organisations.

  Moreover, the employment contract (or 'other direct contract' or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    ⚠ The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6)*

- Ensure that the researcher does NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

2. Employment contract — Obligations on the researcher

The MSC-IF GA foresees that there must be an employment contract (or other direct contract or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also vis-à-vis the researcher.

[96] Available at https://www.iprhelpdesk.eu/.
[97] Available at http://ec.europa.eu/euraxess/.

Via the employment contract, the researcher must take on a number of obligations, to ensure the smooth implementation of the grant.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities
- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*
- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 General MGA)*.

Exception:

The beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiary must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Articles 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. Suspension of the action implementation — Additional ground for suspension: Professional, personal or family reasons

In addition to the normal grounds for suspension of the action implementation *(see Article 49 General MGA)*, beneficiaries of MSC-IF actions may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

– the starting and end date of the suspension and

– the 'resumption date' when the action is resumed (i.e. automatically one day after the end date).

⚠ In principle, suspensions (other than for parental leave) **may not exceed 30%** of the duration of the action.

For the amendment, the rules of the General MGA apply *(see Article 55 General MGA)*.

3. Effects

Costs incurred during the suspension are not eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional ground for amendment: Change to part-time employment

For MSC-IF actions, there is an explicit possibility to request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time), on personal or family grounds (including parental leave).

⚠ Such amendments are not possible for other reasons *(e.g. other professional opportunities, etc.)*. In those cases, suspension or termination of the action may be requested.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and a statement from the new beneficiary to take over all rights and obligations under the Agreement.

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a **'transfer report'**, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The maximum grant amount set out in Article 5.1 will be decreased if a lower country correction coefficient is applicable to the new beneficiary.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSC-IF grants can be transferred.

'Transfer' means automatic transfer of rights and obligations from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

The beneficiary may request that the researcher training activities are transferred to a new beneficiary, if there are **circumstances with** the **beneficiary** itself which would affect the researcher's ability to perform the activities.

> ***Examples:*** *Internal reorganisation affecting implementation of the project; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

> ⚠ Personal **circumstances of the researcher** are **not** considered valid grounds for transferring the GA to a new beneficiary. (This must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55),* so that the researcher can benefit from other professional opportunities or better reconcile work and family commitments without having to forego the grant).

Like any amendment, a transfer may not entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

> ***Example:*** *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility criteria or financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

> For the amendment, the rules of the General MGA apply *(see Article 55 General MGA)*.
>
> The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed in the electronic exchange system).

⚠ The GA canNOT be transferred without the **explicit agreement** by the Agency *and* the amendment of the GA. (Any interruption of implementation due to an unauthorised transfer is a breach of contractual obligations and the former beneficiary is entirely responsible for any activity/commitment undertaken before the Agency has approved the amendment.)

3. Effects

The transfer may result in a reduction of the **maximum grant amount**, if the correction coefficient for the country of the new beneficiary is lower than the one of the former beneficiary.

> ⚠ The maximum grant amount can never be increased.

After approval of the amendment, the former beneficiary must**:**

- **transfer** the **remaining contribution** to the new beneficiary and
- **submit a report** to the Agency, including:
  - an overview of progress on results and
  - a financial statement up to the date of the transfer.

⚠ In view of the complexity of this amendment procedure, good collaboration between both beneficiaries (old and new) is essential for a successful transfer.

III.4 MSC Research and Innovation Staff Exchange (MSC-RISE): Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-RISE actions

What? MSC-RISE actions are multi-beneficiary actions with the following activities:

- exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of your call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSC-RISE MGA does **not** use the **budget categories** of the **General MGA**.

Budget categories of the MSC-RISE MGA:

- costs for seconded staff members
- institutional costs.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, forms of costs *(Article 5)*, cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

2. Budget transfers

Budget transfers between *beneficiaries* are the consequence of the redistribution of person-months between them (as compared to the original planning set out in Annex 2). (⚠ Transfers between *budget categories* are, by contrast, NOT possible because MSC unit costs are all linked to the person-months declared for the seconded staff.)

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. (⚠ Changes that only concern the consortium-internal arrangements on the distribution of the institutional unit cost for management tasks do NOT need to be notified to the Agency.)

Example:

Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.

⚠ Budget transfers will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Transfers are subject to the following:

- no impact on the action as described in Annex 1 (⚠ If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment will be required.)
- the minimum and maximum secondment duration.

⚠ The 'maximum grant amount' mentioned in Article 5 canNOT be increased.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs**).

1. Reimbursement rate

How much? For MSC-RISE actions, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs use only one **cost form**, i.e. the **unit costs** set out in Commission Decision C(2013) 8194[98].

For MSC-RISE these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

⚠ The MSC MGAs do not use any of the **unit costs** and **flat-rates** of the General MGA.

[98] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since MSC uses only unit costs, there is **no reduction due to the no-profit rule** in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiaries must:

– at proposal stage: enter only eligible person-months into the estimated budget for the action *(see Article 4)*

– at reporting stage: declare only eligible person-months in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiaries**. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible. (If the Agency finds ineligible person-months, they will be rejected; *see Article 42*).

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for seconded staff members are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the beneficiary or a partner organisation;

(c) the secondment complies with the following conditions:

(i) last at least 1 month and no longer than 12 months;

(ii) be between:

- a beneficiary established in a EU Member State (or associated country[6]) and a beneficiary established in another EU Member State (or associated country) from different sectors (academic and non-academic) or
- a beneficiary established in a EU Member State (or associated country) and a partner organisation established in a non-EU Member State (or non-associated country), and

(iii) the beneficiary or partner organisation sending the person is established in a country listed in General Annex A of the Main Work Programme.

[6] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

1. Costs for seconded staff members: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members (by providing for:

– a monthly top-up allowance for travel, accommodation and subsistence costs relating to the secondment.)

What not? Costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

1.2 These costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[99] and set out in Annex 2 and 2a of the GA (currently

- for the top-up allowance: **EUR 2 000** per seconded staff member per month ('person-month').)

For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of your call.*

In practice, the declaration of costs for MSC grants is very simple and **almost completely automatised**: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - an **early stage researcher** (i.e. not have a doctoral degree and be in the first four years of his/her research career)
    - an **experienced researcher** (i.e. have a doctoral degree or at least four years of research career) or
    - **administrative, managerial** or **technical staff supporting research and innovation activities** under the action (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

      Examples (not eligible administrative, managerial or technical staff):

      1. Ms A, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.

      2. Mr X, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.

    Years of '**research career**' are counted as 'full-time equivalent research experience', from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (in the country in which it was obtained or in which s/he is recruited).

[99] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- have already worked for at least six months on research and innovation activities at the premises of the beneficiary or partner organisation

  Example: *Mr X is employed by beneficiary Y as from 1 January 2014; Mr X will not be eligible for a secondment from 1 March but would be eligible for secondment as from 1 July 2014.*

- be incurred for secondments:

  - that last at least 1 month and no longer than 12 months

    ⚠ Splitting into several periods is allowed. (**Best practice:** If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.)

    Example: *If a secondment is split into two 2-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first 2-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

  - that are one of the following three:

    - secondments between beneficiaries in different EU Member States (or associated countries) and between different sectors, i.e. academic and non-academic

      ⚠ Both elements must be fulfilled (i.e. location in different Member States or associated countries AND different sectors (academic and non-academic sector).

      'Academic sector' means:

      - public or private higher education establishments awarding academic degrees
      - public or private non-profit research organisations whose primary mission is to pursue research or
      - international European interest organisations.

      'Non-academic sector' means any socio-economic actor not included in the academic sector.

    - secondments from a beneficiary in an EU Member State (or associated country) to a partner organisation in a third country.

    or

    - secondments from a partner organisation in a third country listed in General Annex A to the Main Work Programme to a beneficiary in an EU Member State (or associated country)

    Examples:

    A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

    Case 1: A is a beneficiary established in an EU Member State or associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work

Programme.
A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

Case 2: A is a beneficiary established in an EU Member State or associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.
A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: A and B are both beneficiaries established in an EU Member State or associated country. They may each claim 120 person-months (for their own staff).

⚠ Partner organisations are NOT beneficiaries and therefore do not declare costs (they are included in the costs declared by the beneficiaries). During a secondment to a partner organisation, the beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA *(see Article 8)*. (**Best practice:** The internal relationship between beneficiaries and partner organisations should be governed by an internal arrangement, *e.g. partnership agreement*).

⚠ ONLY one secondment per person. (If a person is a staff member of two or more organisations which participate in a RISE project, s/he cannot be seconded from both organisations.)

Example:

A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.

⚠ Full use of the top-up allowance to the staff member is for MSC-RISE not a cost eligibility condition, but an 'other obligation' under Article 32 (meaning that non-compliance may lead to a reduction of the grant).

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('number of implemented person-months')

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example:

A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert '5.47' as number of person-months.

⚠ Don't declare more than 12 person-months per seconded staff member. (⚠ Person-months exceeding this number will be rejected.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[100] costs (i.e. the beneficiary's additional costs in connection with the action).

  The management and indirect costs received can be distributed within the consortium (via an internal agreement). The distribution should however roughly correspond to the actual division of (management) tasks within the consortium.

  They should be shared with partner organisations which incurred management or indirect costs for secondments.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[101] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 700** per person-month (⚠ For beneficiaries that already receive an EU/Euratom operating grant[102], this amount will be halved, i.e. EUR 350).)

⚠ In practice the declaration of institutional costs for MSC grants is **completely automatised** because the IT system automatically calculates them on the basis of the number of person-months declared for the costs for seconded staff.

1.3 The eligibility of the institutional costs is directly linked to the **eligibility** of the costs for seconded staff.

⚠ Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for seconded staff are met. Person-months

[100] For the definition, *see Article 6.2 of the General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[101] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[102] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

which are not eligible for the budget category 'costs for seconded staff' are also not eligible for the budget category 'institutional costs'.

Institutional costs cannot be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for seconded staff members:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

MSC-RISE actions do however allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that participate in the exchanges by seconding and hosting staff).

⚠ The beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA. (**Best practice:** It is therefore strongly recommended that beneficiaries establish internal arrangements *(e.g. partnership agreements)* with partner organisations, to ensure that they fulfil their obligations (especially under Article 32) during secondments.)

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.

[…]

1. Records and other supporting documentation

For MSC-RISE actions, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and access rights to show duration; lab books, scientific articles, library records to show research and innovation activities*)

    ⚠ The nature of the records and supporting documents to be kept by the beneficiary depends must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with (including that the top-up allowance was fully paid to the seconded staff members)

⚠ For secondments from partner organisations, the beneficiary must keep the documents also for the staff of the partner organisation.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ If you throw supporting documents away during this period, you risk that costs are rejected or the grant is reduced (and undue amounts paid may be recovered).

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1) and
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after each year except if a periodic report is due** (i.e. normally after the first and third year of the action) — submit to the Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal) a progress report, to inform the project officer about progress on the action.

A template will be provided on the Participant Portal.

2. Deliverable: Mid-term review meeting

What & when? The coordinator must:

- **before** the deadline for the **periodic report for RP 1**: organise a mid-term review meeting and
- **no later than 30 days** before this meeting: send to the Agency (via the electronic exchange system) a draft version of the periodic report (if requested).

3. Deliverable: Researcher declaration

What? The beneficiary must send to the Agency (via the electronic exchange system) a document with information about each seconded staff member ('researcher declaration').

A template will be provided on the Participant Portal.

⚠ The researcher declaration must also be submitted by the beneficiary for seconded staff members from a partner organisation.

When? The researcher declaration must be submitted within **20 days from the start of the secondment**.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — (and indicate each split).

Example:

Beneficiary A is sending Mr X to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment. No additional declaration is necessary for the second half.

If a staff member is seconded to **more than one beneficiary/partner organisation** within the duration of the action, several researcher declarations must be submitted (an updated one within 20 days from the start date of each secondment).

Example:

Beneficiary A is sending Mr X to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.

⚠ It is important to give correct and complete information. (This information will be used to determine the eligibility of the person-months you declare.)

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSC-RISE actions, the MSC-RISE MGA foresees special access rights for them.

Beneficiaries must moreover ensure that the partner organisations give similar access.

For more information on access rights, *see Articles 25 and 31 General MGA.*

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[1] and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSC-RISE actions, the MSC-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is a top-up allowance), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are obviously accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary or partner organisation) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time**

- Comply with the arrangements on **intellectual property rights**.

  For assistance with intellectual property rights, consult the IPR Helpdesk[103].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*

- **Inform** the researcher about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the EU contribution is **fully used for** the benefit of the **seconded staff** members

  It can be:

[103] Available at https://www.iprhelpdesk.eu/.

- paid directly to the seconded staff member or
- managed centrally by the beneficiary according to the specific needs of the secondment.

Detailed arrangements for the use of the contribution may also be agreed internally between beneficiaries and partner organisations, to address the specific financial needs of each secondment.

⚠ Since the beneficiaries remain solely responsible for the implementation of the action, it is strongly recommended that they establish internal arrangements *(e.g. partnership agreements)* with partner organisations to ensure that they fulfil their obligations *(see Article 8)*.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract, some of the basic obligations under the MSC-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 General MGA)*.

Exception:

Beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiaries must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 MSC-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-COFUND actions

What? MSC-COFUND actions are mono-beneficiary actions with the following activities:

- implementing or co-funding of regional, national or international doctoral or fellowship programmes for researcher training, mobility and career development.

MSC-COFUND actions cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of your call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSC-COFUND MGA does **not** use the **budget categories** of the **General MGA**.

Budget categories of the MSC-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget *(Article 4 and Annex 2)*, the forms of costs *(Article 5)*, the cost eligibility rules *(Article 6.2)* and the cost declarations (i.e. financial statements; *Article 20 and Annex 4*).

2. Budget transfers

Given that MSC-COFUND is a mono-beneficiary action, there are NO budget transfers between beneficiaries.

Transfers between *budget categories* are NOT possible because MSC unit costs are all linked to the person-months declared for the recruited researchers.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in programmes implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**);

(b) for **costs of providing financial support to costs for researchers in programmes implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-COFUND actions, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Form of costs

The MSC MGAs use only one **cost form**, i.e. the **unit costs** set out in Commission Decision C(2013) 8194[104].

For MSC-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

⚠ The MSC MGAs do not use any of the **unit costs** and **flat-rates** of the General MGA.

[104] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since MSC applies only unit costs, there is **no reduction due to the no-profit rule** in the MSC MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ This means that the beneficiary must:

– at proposal stage: enter only eligible person-months into the estimated budget for the action *(see Article 4)*

– at reporting stage: declare only eligible person-months in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is **on the beneficiary**. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months declared are eligible. (If the Agency finds ineligible person-months, they will be rejected; *see Article 42*).

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in programmes implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in programmes implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Costs for researchers: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme) (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount)).)

What not? Other costs are not covered. Thus, management costs can be declared under the other budget category ('management costs', Article 6.2.B). Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are not eligible under the grant; they may be funded through other EU funding programmes.

For more information on combining EU funding ('complementary EU funding' or 'synergies'), *see the Online Manual.*

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[105] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance:
  - for early-stage researchers ('ESRs') in doctoral programmes: **EUR 3 710** per researcher per month ('person-month')
  - for experienced researchers ('ERs') in fellowship programmes: **EUR 5 250** per person-month.)

For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of your call.*

In practice, the declaration of costs for MSC grants is very simple and **almost completely automatised**: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (including its duration), identifiable and verifiable etc.; *see Article 6.1*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example:

If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.

[105] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** only the:

- management costs (i.e. direct costs of managing the action).

The management costs should be shared with partner organisations which incurred management costs for secondments or for the implementation of programmes.

What not? Other costs (such as research, training and networking costs and indirect costs) are not eligible under the grant; they may be funded through other EU funding programmes.

For more information on combining EU funding ('complementary EU funding' or 'synergies'), *see the Online Manual.*

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[106] and set out in Annex 2 and 2a of the GA (currently:

- for management costs: **EUR 650** per researcher per month ('person-month').)

In practice, the declaration of management costs for MSC-COFUND grants is **completely automatised** because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the management costs is directly linked to the **eligibility** of the costs for researchers.

Management costs are eligible only if all the eligibility conditions for the researchers are met. Person-months which are not eligible for the budget category 'costs for researchers' are also not eligible for the budget category 'management costs'.

Management costs cannot be claimed separately *(i.e. management costs cannot be claimed without living allowance)*.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for researchers:

- for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

[106] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

MSC-COFUND actions do however allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that participate in the action either:

- by implementing a doctoral or fellowship programme (i.e. recruiting the researchers)
- by providing trainings and hosting researchers during a secondment.)

Partner organisations that *implement* a doctoral or fellowship programme must be established in a Member State, associated country, or third country listed in General Annex A to the Main Work Programme. *Other* partner organisations can be established anywhere.

Partner organisations that implement a doctoral or fellowship programme and are established in a third country must recruit researchers that are nationals or long-term residents of a Member State (or associated country) *(see Article 15.1.1(b))*.

⚠ The beneficiary remains solely and fully responsible for the implementation of the action in accordance with the GA. (**Best practice:** It is therefore strongly recommended that beneficiaries establish internal arrangements *(e.g. partnership agreements)* with partner organisations, to ensure that they fulfil their obligations (especially under Article 15).)

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

15.1 Rules for providing financial support to or implementation of *[doctoral][fellowship]* programmes

15.1.1 The beneficiary must **implement** ***[doctoral][fellowship]*** **programmes** or **provide financial support** to such programmes implemented by partner organisations, in accordance with the following conditions:

(f) **types of programmes**:

[OPTION for DPs: *The programmes must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programmes**');**]***

[OPTION for FPs: *The programmes must concern fellowships for research training activities for recruited researchers ('**fellowship programmes**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country, the return phase to an EU Member State or associated country[1] may not be more than 50% of the total duration of the research training activity;**]***

(g) **categories of persons** that may be supported by the programmes:

[OPTION for DPs: *The doctoral programmes must support researchers, who — at the time of recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION for FPs: *The fellowship programmes must support researchers, who — at the time of recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1. **]***

Researchers that are already permanently employed by the entity where the research training activities take place and that is recruiting them may not be supported.

(h) **procedure and criteria for selecting researchers** in the programmes:

[OPTION for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

Selection committees must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(i) **conditions for the recruitment** of researchers under the programmes:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[7] and ensure that the researchers are aware of them;

- ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;

- ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);

- ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;

- ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;

- ensure that researchers work exclusively on the research training activities;
- ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
- ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
- ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of foreground, promoting the action) — during the research training activities and afterwards;
- inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;
- in case of third parties implementing the programmes: ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards those third parties;

[OPTIONS for DPs:

- *ensure gender balance in the recruited researchers;*
- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[7] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing doctoral/fellowship programmes

MSC-COFUND provides support both for programmes implemented by the beneficiary and programmes where the beneficiary only provides financial support.

'Providing financial support' means that the beneficiary passes on the EU support it receives via grants to partner organisations and that it is the partner organisations which actually implement the doctoral/fellowship programmes ('financial support to third parties' or 'cascading grants').

2. Additional eligibility condition: Types of programmes — Categories of persons

MSC-COFUND actions can fund the following **types of** research training **programmes** supporting transnational mobility:

- doctoral programmes (DP), i.e. programmes with research training activities for recruited early-stage researchers that lead to the award of a doctoral degree and
- fellowship programmes (FP), i.e. programmes with fellowships for recruited experienced researchers.

The **researchers** must — at the date of recruitment —:

- be one of the following two:
  - **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years of their research career) or
  - **experienced researchers** ('ERs'; i.e. have a doctoral degree or have at least four years of research career).

  Years of '**research career**' are counted as 'full-time equivalent research experience', from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited — even if the doctorate was never started or envisaged.
- comply with the mobility rule, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary (or partner organisation) for more than 12 months in the three years immediately prior to the recruitment date (unless Annex 1 to the GA specifies otherwise for already existing programmes).

  Specific case:
  Beneficiary/partner organisation that is an '**international European interest organisation**'[107] — the researchers may not have spent more than 12 months with the beneficiary/partner organisation in the three years immediately prior to the recruitment date.

  ⚠ Researchers are not eligible if they are already permanently employed by the entity where the research training activities take place.
- if the programme is implemented by a partner organisation established in a third country or if a secondment to such an organisation constitutes the main part of the research training activities: be nationals or long-term residents of a Member State (or associated country). (⚠ Short secondments are possible also for researchers that are not nationals or long-term residents.)

  'Long-term resident' normally means full-time research activity in a Member State (or associated country) for five or more consecutive years. (The Agency may however,

[107] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

exceptionally accept a different definition, if it is linked long-term residence and justified in the proposal).

⚠ The obligations in Article 15.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned (see Article 6.2 and Chapter 6).

3. Additional eligibility condition: Selection procedure

The procedure for selecting researchers must follow criteria that are:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary (or partner organisation) must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[108]*)*.

For fellowship programmes: the beneficiary (or partner organisation) must publish calls for proposals (with a maximum of 4 fixed deadlines or regular cut-off dates per year) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

⚠ The obligations in Article 15.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned (see Article 6.2 and Chapter 6).

4. Additional eligibility condition: Recruitment and working conditions

The beneficiary (or partner organisation) must recruit the researchers under an:

- **employment contract** or
- '**other direct contract**' with equivalent benefits and social security coverage, including
  - sickness, parental, unemployment and invalidity benefits
  - pension rights and

[108] Available at http://ec.europa.eu/euraxess/.

- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract (or other direct contract), beneficiaries/partner organisations may offer a **'fixed-amount fellowship agreement**' with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

⚠ In this case, the researcher unit costs will be reduced by 50%.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract must receive a minimum monthly remuneration (including salary, social security contributions, taxes and other costs included in the remuneration) of:

- for **early-stage researchers** (doctoral programmes); EUR 2 597
- for **experienced researchers** (fellowship programmes): EUR 3 675

⚠ These amounts are halved for fixed-amount fellowship agreements (i.e. for **early stage researchers** EUR 1298,50; for **experienced researchers** EUR 1837,50).

⚠ The obligations in Article 15.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned (see Article 6.2 and Chapter 6).

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, Article 15.1.2 of the MSC-COFUND MGA sets out 'other obligations', such as that:

- the researchers must:
  - be **employed full-time**
  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)
  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency
- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  ℹ For assistance with intellectual property rights, consult the IPR Helpdesk[109].
- for doctoral programmes: that the beneficiary/partner organisation must
  - ensure **gender balance** regarding the recruited researchers
  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career plan.

[109] Available at https://www.iprhelpdesk.eu/.

⚠ Non-compliance with these obligations does not lead to a rejection of costs, but is considered improper implementation of the GA (i.e. breach of 'another obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSC-COFUND actions, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the researcher unit cost was fully paid to the researchers.

⚠ For programmes implemented by partner organisations, the beneficiary must keep these documents also for the partner organisations.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ If you throw supporting documents away during this period, you risk that costs are rejected or the grant is reduced (and undue amounts paid may be recovered).

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit:

- a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What and When? The beneficiary must send to the Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal) a document with information about each recruited researcher ('researcher declaration') — within **20 days** of the start of the research training activities (of the researcher).

A template will be provided on the Participant Portal.

⚠ It is important to give correct and complete information since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units.

2. No deliverable: Mid-term review meeting

⚠ For MSC-COFUND actions, it is the Agency that will organise a mid-term review meeting (to monitor implementation of the action in the light of the schedule in Annex 1). The mid-term review is therefore not a deliverable, as in the other MSC actions.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 General MGA)*.

Exception:

The beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 General MGA)*.

In addition, the beneficiary must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument

IV.1 SME Instrument MGAs: Background information and approach

The Model Grant Agreements for the SME Instrument ('SME Instrument MGAs') are used for grants for **SME Instrument actions only** *(see General Annex D to the Main Work Programme)*.

The SME Instrument funds actions in different phases.

The minimum requirement for participation is one for-profit SME (as defined in the SME Recommendation 2003/361/EC), established in an EU Member State or associated country.

'For profit' means not a non-profit legal entity (i.e. not an entity that is by its legal form non-profit-making or has a legal or statutory obligation not to distribute profits to its share-holders or members).

⚠ If the work programme/call, exceptionally foresees SME Instrument Ph2 actions that predominantly concern research activities, they will be considered 'research and innovation action (RIA)' actions and will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ⓘ For more information on SME Instrument actions, *see Article 2 SME Instrument MGAs.*

ⓘ For information on SME Instrument funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ⓘ For information on SME Instrument standard eligibility criteria, *see General Annex C to the Main Work Programme.*

ⓘ For more information on the procedure for SME status validation, *see the Online Manual.*

The SME Instrument MGAs **follow the General MGA** for numbering and content, **except** for the following:

Introductory remark SME Instrument Ph1 MGA

The SME Instrument Phase 1 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 4.1 (SME Instrument Ph1 estimated budget of the action)
- Article 5.1-5.3 (SME Instrument Ph1 maximum grant amount, specific reimbursement rate and form of costs, no Step 2 'limit to maximum grant amount', no Step 3 'reduction due to the no-profit rule')
- Article 6 (SME Instrument Ph1 specific conditions for eligibility of costs)
- Article 7 SME Instrument Ph1 consequences of improper implementation)
- Article 8 (SME instrument Ph1 third parties)
- Articles 11, 12, 14, 15, 16, 23a - 33, 37, (not applicable)
- Article 10 (SME Instrument Ph1 specific provision for purchases)
- Article 13 (SME Instrument Ph1 specific provision for subcontracting)
- Article 18 (SME Instrument Ph1 specific provision for record-keeping)
- Article 20 (SME Instrument Ph1 specific reporting provisions)
- Article 21 (SME Instrument Ph1 specific payment provisions)
- Article 36 (SME Instrument Ph1 specific provision on confidentiality)

- Article 38 (SME Instrument Ph1 specific provision on promoting the action)
- Article 42.2 (SME Instrument Ph1 specific provision for lump-sum
- Article 43 (SME instrument Ph1 reduction of the grant)
- Article 44 (SME instrument Ph1 MULTI recovery undue amounts)
- Article 45 (SME instrument Ph1 MULTI penalties)
- Article 48 (SME instrument Ph1 MULTI suspension of payments) Article 50.1.2, 50.3.3 (SME Instrument Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

Introductory remark SME Instrument Ph2 MGA

The SME Instrument Phase 2 Model Grant Agreement deviates from the General Model Grant Agreement as follows:

- Article 5.2 (SME Instrument Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Instrument Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Instrument Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 SME Instrument Ph1 MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Instrument Ph1:

- Article 2 (SME Instrument Ph1 actions)
- Article 8 (SME Instrument Ph1 rules on third party involvement)

For SME Instrument Ph2:

- Article 2 (SME Instrument Ph2 actions)
- Article 4.1 (SME Instrument Ph2 budget categories)
- Article 6 (SME Instrument Ph2 eligible and ineligible costs)
- Article 8 (SME Instrument Ph2 rules on third party involvement)
- Article 20 (SME instrument Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 SME Instrument Phase 1 MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 actions are mono- or multi-beneficiary actions with the following activities:

– making a feasibility study for an innovation idea (i.e. a ‘proof of concept’ or ‘business plan’ for new, altered or improved product, process or service)

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

⚠ The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

Exception:

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ⓘ For more information on SME Instrument Ph2 actions, *see Article 2 SME Instrument Ph2 MGA.*

SME actions are funded under Part II of the Horizon 2020 Framework Programme: ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-1-2014*).

ⓘ For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Instrument Ph 1 does **not** use the **budget categories** of the **General MGA**.

Since SME Instrument Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Instrument Ph1 MGA:

- 'costs for the feasibility study (direct and indirect costs)'

⚠ The budget category is relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The grant amount for SME Instrument Ph1 actions is fixed by Commission Decision C(2013) 8198[110] as a **lump sum** of **EUR 50 000** (⚠ for mono and multi-beneficiary actions).

It is deemed to reimburse 70 % of the action's total eligible costs (which are in turn fixed by the Decision at EUR 71 429).

⚠ NO other costs will be reimbursed; the lump sum is deemed to cover all (direct and indirect) costs that may have been incurred for the feasibility study.

The conditions for eligibility are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The SME Instrument Ph1 MGA does not use any of the **unit costs** and **flat-rates** of the General MGA.

[110] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to breach of obligations other than improper implementation — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Instrument Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is no:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Instrument Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to ineligibility of the costs (NOT to the reduction of the grant). The calculation for the reduction therefore does not relate to this form or improper implementation of the action.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Instrument Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 What? The budget category 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ NO other costs will be reimbursed; the lump sum is deemed to cover all direct and indirect costs that may have been incurred for the feasibility study.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[111] and indicated in Annex 2 of the GA (currently **EUR 71 429** per action).

⚠ In practice the declaration of costs for SME instrument Ph1 grants is **completely automatised**. The beneficiaries only need to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

[111] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Instrument Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6*).

If the action is not carried out as described in Annex 1, costs will be *rejected* proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

⚠ If the feasibility study is **incomplete** and thus does not meet the intended objective or is of **insufficient quality** *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO financial contribution from the EU.

By contrast, if 'other obligations' have been breached (e.g. other provisions of the GA or provisions of EU, international and national law are not complied with), the grant may be *reduced*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Instrument Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs for purchases and subcontracts are covered by the lump sum.

In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Instrument Ph1 actions are almost identical to the General MGA *(see Article 13 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph1 actions are similar to the General MGA *(see Article 13 General MGA)*.

Subcontracting is however not restricted to a limited part of the action.

Moreover, the estimated costs do **not** have to be included in Annex 1or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also no obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are **not** considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ⓘ For more information on the differences between contracts and subcontracts, *see Article 8 General MGA*.

ⓘ For more information on the characteristics of subcontracting and best value-for-money, *see Article 13 General MGA*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Instrument Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME instrument Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial statement is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

⚠ For **multi-beneficiary** actions: there is only one (common) financial statement for the consortium.

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency*, the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Instrument Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Instrument Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

⚠ For **multi-beneficiary actions**: the coordinator alone is financially responsible (for the entire grant; *see also Article 44*).

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Instrument Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency responsibility — Agency right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(e) display the EU emblem and

(f) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Promoting the action — Visibility of EU funding

The SME Instrument Ph1 MGA foresees lighter requirements for promoting the action and acknowledgment of EU funding.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submit to the Agency in good time any documents or information required by it

and may not subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 General MGA)*.

Since for SME instrument Ph1 **multi-beneficiary actions** there is however only one (common) financial statement *(see Article 20)*, there is no obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 General MGA)*.

However, since SME Instrument Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*).

If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ If the feasibility study is **incomplete** and thus does not meet the intended objective or is of **insufficient quality** *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO financial contribution from the EU.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if an obligation under the Agreement (other than improper implementation of the action as described in Annex 1) has been breached

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify confirmation of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 General MGA)*.

However, since SME Instrument Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an eligibility rule and does NOT lead to the reduction of the grant *(see also Articles 6 and 7)*. The grant may thus be reduced if another obligation has been breached *(e.g. another obligation under the GA or applicable EU, international and national law; see Article 43 General MGA)*..

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 General MGA)*.

Since for SME instrument Ph1 **multi-beneficiary actions** the coordinator alone is financially responsible (for the entire grant), the Agency will recover only from him.

Best practice: Beneficiaries are advised to foresee internal arrangements to redistribute the financial responsibility internally in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) the beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

i. substantial errors, irregularities, fraud or

ii. serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 General MGA)*.

However, for SME Instrument Ph1 actions, improper termination by the beneficiaries will lead to a 100% reduction of the grant.

2. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 General MGA)*.

However, for SME instrument Ph1 **multi-beneficiary** actions, the notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. Termination of the Agreement or of the participation of one or more beneficiaries (by the Agency)

The rules on termination are in principle the same as in the General MGA *(see Article 50 General MGA)*.

However, for SME instrument Ph1 **multi-beneficiary actions**, the request for amendment must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

IV.3 SME Instrument Phase 2 MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph2 actions

What? SME Instrument Ph2 actions are actions with the following activity:

- implementing an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

⚠ A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-2-2014*).

ⓘ For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme, and the call and topics pages of your call.*

ⓘ For more information on SME Instrument Ph1 actions, *see Article 2 SME Instrument Ph1 MGA.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Instrument Ph2 MGA uses the **same budget categories as** the **General MGA**.

Budget categories of the SME Instrument Ph2 MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific cost categories' (if option applies).

⚠ Thus, the SME Instrument Ph2 does NOT have:

– 'personnel costs for providing trans-national access to research infrastructure'

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) *for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost under Point (f))]*[8]: ***[OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[10]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

(f) ***[OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): for [insert name of specific cost category(ies)***[11]*]:on the basis of the amount(s) per unit set out in Annex 2*[12] ***(unit costs).]***

[OPTION: specific cost category(ies):** not applicable.**]

[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used
[11] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures';, 'costs for clinical studies'; 'costs for energy efficiency measures in buildings'.
[12] Annex 2 must clearly show, for the beneficiary (and each linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For SME Instrument Ph2 actions, the reimbursement rate is normally set at 70% *(see General Annex D to the Main Work Programme)*.

Exception:

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs****: [insert name(s) of specific cost category(ies)*[1]*]][OPTION:*** *not applicable]*.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Instrument Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

However, since SMEs are not, by definition, 'non-profit legal entities', they can NOT declare additional remuneration (as part of the 'personnel costs – costs for employees (or equivalent)'; *see Article 6.2.A.1 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Instrument Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[24] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [25].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results:** Classified results may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).**]

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[24] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[25] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. Subcontracting

The rules on subcontracting for SME Instrument Ph2 actions are similar to those of the General MGA *(see Article 13 General MGA)*.

However, subcontracting is not restricted to a limited part of the action.

Moreover, for the SME Instrument Ph2, the Commission/Agency will assess compliance with best value-for-money during the evaluation of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

⚠ If you know the subcontractor, include the key information on the award procedure for the subcontract in the proposal (name of subcontractor, price and object), together with the action task(s) that will be subcontracted and an explanation why the subcontractor and the price are appropriate.

⚠ If you do not know the subcontractor, your proposal should set out the task(s) to be subcontracted, the estimated budget and the procedure you will follow to ensure best value-for-money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value-for-money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

ⓘ For more information on evaluation, *see the Online Manual*.

Finally, for SME Instrument Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ⓘ For more information on the differences between contracts and subcontracts, *see Article 8 General MGA*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Instrument Ph2 actions are normally the same as for the General MGA *(see Article 20.2 General MGA)*.

The reporting periods may however be adapted to reflect the duration of the action. Thus, if considered necessary, SME instrument Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example****: if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 ERA-NET Cofund MGA: Background information and approach

The Model Grant Agreement for ERA-NET Cofund ('ERA-NET Cofund MGA') is used for grants for ERA-NET Cofund actions ONLY.

⚠ ERA-NET Cofund grants are open only to **research *funders*** (i.e. legal entities owning or managing research and innovation programmes).

'Programme owners' are typically national/regional ministries or authorities responsible for defining, financing or managing national/regional research programmes.

'Programme managers' are typically research councils, funding agencies or other national/regional organisations that implement research programmes under the supervision of the programme owners.

The minimum requirements for participation are 3 independent research funders established in different Member States or associated countries.

ⓘ For more information on ERA-NET Cofund actions, *see Article 2.*

ⓘ For information on ERA-NET Cofund funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ⓘ For information on ERA-NET Cofund standard eligibility criteria, *see General Annex C to the Main Work Programme*.

The ERA-NET Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for ERA-NET Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 ERA-NET Cofund MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERA-NET Cofund actions

What? ERA-NET Cofund actions are actions with the following activities:

- the preparation, implementation and follow-up of a single joint call for proposals for trans-national research and/or innovation projects

  There are two ways of implementing the joint call:

  - by **providing financial support to third parties**

    This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties.

    Most ERA-NET Cofund actions are implemented in this way.

  - by **implementation of the trans-national projects by the beneficiaries**

    This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding. Beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  ⚠ Only one co-funded call per GA.

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

⚠ These activities must be *in addition* to implementing a joint call.

⚠ If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do not apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-NMP-ERA-NET-2015)*.

ⓘ For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action**: [insert date]]*[7] ('starting date of the action').

[4] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Duration of the action

For ERA-NET Cofund actions, the duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). (⚠ Normally, the action's duration cannot exceed **72 months**.)

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its **own budget categories**.

Budget categories of the ERA-NET Cofund MGA:

- 'direct costs related to trans-national projects'
- 'direct costs of providing financial support to third parties implementing trans-national projects'
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - 'direct personnel costs for the implementation of trans-national projects by the beneficiaries'
    - 'costs for employees (or equivalent)'
    - 'costs for natural persons working under a direct contract'
    - 'costs of personnel seconded by a third party against payment'
  - 'direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries'
  - 'other direct costs for the implementation of trans-national projects by the beneficiaries'
    - 'travel costs and related subsistence allowances'
    - 'equipment costs'
    - 'costs of other goods and services'
    - 'capitalised and operating costs of large research infrastructure'
- 'direct coordination costs for additional activities'
- 'indirect costs'

⚠ Thus, the ERA-NET Cofund MGA does NOT have:

– 'personnel costs for SME owners without salary'

- ‘personnel costs for beneficiaries that are natural persons without salary’
- ‘personnel costs for providing trans-national or virtual access to research infrastructure’
- ‘specific cost categories’

⚠ These budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - direct costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (— unless declared as unit cost)

  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects
- **unit costs** for:
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
  - direct **coordination costs** for additional activities[112]
- **flat-rate costs** for:
  - **indirect costs**

[112] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects (‘**costs for employees (or equivalent)**’). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary’s usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary’s instructions and, unless otherwise agreed with the beneficiary, on the beneficiary’s premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.**]***

[OPTION to be used if foreseen in the work programme: *Not applicable.**]***

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as 'direct costs related to trans-national projects':

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)

    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment
    - other goods and services
    - costs of large research infrastructure.

All costs — except direct personnel costs — must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

In some Articles, the conditions in the General MGA must however be read as referring to 'trans-national projects' (instead of 'action').

For financial support to third parties, there are moreover additional cost eligibility conditions in Article 15 *(e.g. selection procedure, compliance with national funding rules)*.

⚠ For financial support to third parties, costs are usually eligible only after the trans-national projects have ended.

The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA*).

B. Direct coordination costs for additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8200[113] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

⚠ In practice, the declaration of costs for additional activities is very simple and **almost completely automatised**: The beneficiary must only indicate the number of years (during which such activites were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

⚠ Beneficiaries that implement trans-national projects cannot declare coordination costs for additional activities.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU contribution to coordination costs should not exceed 20 % of the maximum grant amount.

⚠ If the beneficiaries do not properly implement the additional activities set out in Annex 1, the grant may be reduced *(see Article 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[113] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, the same rules apply as in the General MGA *(see Article 6 General MGA)*.

The flat-rate is calculated on the following eligible direct costs:

- 'direct costs for the implementation of trans-national projects by the beneficiaries'
- 'direct coordination costs for additional activities'.

⚠ 'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however ONLY allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all action activities *(see Article 2)*.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.3);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to third parties ('cascade grants')).

⚠ In this case, the beneficiaries' activity consists in providing financial support, while it is the third parties that actually implement research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

2. Additional eligibility condition: Two-step selection procedure

A two-step procedure is necessary to ensure that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating Member State and associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to the expert evaluators, the consortium must appoint an independent expert as an observer, to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The selection of trans-national projects ('**joint selection list**') must be based on the order of the ranking list (or the ranking lists, if there are different topics).

⚠ If proposals have identical scores, the proposals coming from participating Member States or associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

⚠ The obligations in Article 15.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs concerned *(see Article 6.2.D.3 and 6.6)*.

5. Additional eligibility condition: Compliance with national funding rules

Financial support to third parties must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the third parties) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

The beneficiaries must comply with the maximum amount and the criteria for determining the exact amount under national funding rules that are set out in Annex 1.

⚠ This information must already be part of your proposal *(see Table 4.1 of the Proposal template ERA-NET)*. If national funding rules do not specify a maximum amount, the beneficiaries should enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects, with the required information.

Example: *data on each participant and abstracts of the project proposals.*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects.

Example: *data on each participant and an overview of the results.*

⚠ The Commission/Agency will contact you to give you information on the format to be used (and where to find it) and how to submit the deliverables.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following* ***'reporting periods'****:*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]****]***

[OPTION in case of three pre-financing payments: *The action is divided into the following* ***'reporting periods'****:*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]****]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

⚠ NO financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? Normally, ERA-NET Cofund actions are divided into **2 reporting periods** (with two pre-financing payments; *see Article 21*).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

Normally, ERA-NET Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10% of the maximum grant amount
- the second pre-financing payment is 80% of the maximum grant amount.

Exception:

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10% for the first pre-financing payment
- 40% for the second pre-financing payment
- 40% for the third pre-financing payment.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund MGA

VI.1 PCP-PPI Cofund MGA: Background information and approach

The Model Grant Agreement for PCP-PPI Cofund ('PCP-PPI Cofund MGA') is used for grants for PCP-PPI Cofund actions ONLY.

⚠ PCP-PPI Cofund grants are open to **actions** that have as main objective to implement a **pre-commercial procurement** or **a public procurement of innovative solution**.

The minimum requirements for participation are 3 independent legal entities established in different Member States or associated countries and 2 independent legal entities that are public procurers from different Member States or associated countries (— unless they are sole participants; *see General Annex D to the Work Programme*).

ⓘ For more information on PCP-PPI Cofund actions, *see Article 2.*

ⓘ For information on PCP or PPI Cofund funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ⓘ For information on PCP-PPI Cofund standard eligibility criteria and specific provisions, *see General Annex C, D and E to the Main Work Programme.*

The PCP-PPI MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for PCP-PPI Cofund deviates from the General Model Grant Agreement as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 — Model for the estimated budget for the action
- Annex 4 — Model for the financial statement
- Annex 7 — *[Model for the PCP prior information notice (PIN) for the open market consultation] [Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 — Model for the PCP contract notice
- Annex 9 — *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 — Model for the PCP contract award notice
- Annex 11 — Model for the commitment on availability of resources
- Annex 12 — Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 PCP-PPI Cofund MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. PCP/PPI Cofund actions

What? PCP/PPI Cofund actions are actions with both of the following activities:

– a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI) and its implementation

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'.

The suppliers do not become beneficiaries of the GA.

'Implementation' means implementation of the subcontracts ('subcontract implementation stage')

⚠ Only one PCP or PPI per GA.

– related additional coordination and networking activities.

The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

⚠ It is mandatory (both for PCP and PPI Cofund actions) to include not only a PCP/PPI itself, but also those coordination activities that are needed to coordinate the PCP/PPI

procurement. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

ⓘ For more information on which activities are required and which ones are optional, *see General Annex D and E to the Main Work Programme*.

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

ⓘ For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of your call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

– either the lead procurer (centralised payment; the lead procurer he pays all subcontractors)

⚠ This implies that the consortium must have a common jointly-committed budget and that the lead procurer is mandated to sign the subcontracts *(see Article 13)*.

– or the members of the buyers group.

⚠ This implies that the individual members of the buyers group pay the subcontractors pro rata *(see Article 13)*.

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- 'direct costs of PCP/PPI subcontracting'

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  ⚠ Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- 'costs of related additional coordination and networking activities'
  - 'direct personnel costs for related additional coordination and networking activities'
    - 'costs for employees (or equivalent)'
    - 'costs for natural persons working under a direct contract'
    - 'costs of personnel seconded by a third party against payment'

        - ‘costs for SME owners without salary’
        - ‘costs for beneficiaries that are natural persons without salary’
        - ‘personnel costs for providing trans-national access to research infrastructure’
    - ‘direct costs of subcontracting for related additional coordination and networking activities’
    - ‘other direct costs for related additional coordination and networking activities’
        - ‘travel costs and related subsistence allowances’
        - ‘equipment costs’
        - ‘costs of other goods and services’
        - ‘capitalised and operating costs of large research infrastructure’
    - ‘indirect costs for related additional coordination and networking activities’
    - ‘specific cost categories’’ (if option applies).

Thus, the PCP-PPI Cofund MGA does NOT have:

- ‘direct costs of providing financial support to third parties’.

⚠ These budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2*[13] ***(unit costs).]***

[OPTION: specific cost category(ies): *not applicable.**]***

[…]

[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[13] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The work programme/call *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

⚠ Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are not eligible under PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1 *(see Article 13)*
- fulfil the additional cost eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[15]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[16] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[*B.1.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or
- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:
  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

  and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** ***[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[17]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[18] ***[OPTION by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.****]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][****OPTION****: not applicable****]****.*

Beneficiaries receiving an operating grant[20] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

B.5 ***[OPTION: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION for specific unit costs, if foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category[21] *] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, [and if [insert additional eligibility conditions if any]].*

[*same for each specific cost category****]***

[OPTION: *Not applicable****]***

[…]

[15] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[16] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[17] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[18] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[19] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[20] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[21] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

The beneficiaries may declare the following **types of costs** as 'costs of related additional coordination and networking activities':

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure

- indirect costs for related additional coordination and networking activities
- specific cost categories (if option applies).

All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost (in accordance with the usual cost accounting practices).

Personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[114] and indicated in Annex 2 and 2a of the GA. (⚠ This concerns only beneficiaries that are SMEs, not PCP/PPI subcontractors that are SMEs.)

Examples: *Contracting authorities or contracting entities that are SMEs.*

The same **conditions for eligibility** apply as in the General MGA *(see Article 6 General MGA)*.

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

⚠ Costs incurred by the beneficiaries for validation and testing of solutions provided by the subcontractors are part of the follow-up and monitoring of the results of the PCP/PPI and as such eligible as direct personnel costs.

The same rules for **calculation** apply as in the General MGA *(see Article 6 General MGA)*.

The General Annex D to the Main Work Programme specifies that the costs of related additional coordination and networking activities are eligible up to a **maximum** amount of 30%/50% of the total requested grant amount (for PCP/PPI actions). (⚠ For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding earmarked to finance related additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*). The EU funding is not automatically proportionally reduced.)

[114] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however ONLY allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties (Article 14) can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

*13.1.1 The beneficiaries will award **subcontracts** for the **PCP** research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[25] and 2004/17/EC[26].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

*The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' **must be set out in Annex 1**. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[28];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*
- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[25] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[28] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

For PCP Cofund actions, the beneficiaries will award PCP subcontracts for the research and development services ('PCP R&D services') that are necessary to address the 'common challenge'

set out in Annex 1. ('PCP subcontract' thus means a contract for the purchase of R&D services that is identified in Annex 1 as action task.)

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('**buyers group**'), with a joint procurement in **3 phases**

  The 'buyers group' is the group that finances and undertakes together the joint PCP procurement.

  For PCP/PPI Cofund actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[115])

    ⚠ Any entity that fits the definition of a 'contracting authority' or 'contracting entity' as defined in those directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the Public Procurement Directives definition of contracting authorities, but to which those Directives are not applicable, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI Cofund actions.*

  – that are established in two different Member States or associated countries *(see General Annex D to the Main Work Programme)*.

  ⚠ This is *in addition* to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different Member States or associated countries; *see General Annex C to the Main Work Programme*)

  Exceptionally, the work programme/call allows for the participation of sole participants *(see General Annex D to the Main Work Programme)*.

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  ⚠ The buyers group is not open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Other entities may be involved in the action as:

[115] *See Directives 2014/24/EC and 2014/25/EC.*

– beneficiaries (or linked third parties) responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*

– third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in 3 phases.

The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value-for-money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

⚠ The tenders for the PCP call for tender must therefore contain:

– a detailed offer for phase 1

– the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

⚠ The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

⚠ This does not extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' *(as used in the WTO GPA)*.

⚠ Supplies canNOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

  This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

- **Joint procurement procedure** (i.e. joint call for tender, joint evaluation of offers and joint award) is **coordinated and led** by one beneficiary ('**lead procurer**')

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

  > ***Example:*** *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[116]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  ⚠ The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')

- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

⚠ PCP subcontracting is not restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

⚠ There can only be one PCP per PCP Cofund action.

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

> ⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers

[116] *See Directives 2014/24/EC and 2014/25/EC.*

group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PCP subcontracting, there is NO 'approval without formal amendment' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States or associated countries**.

⚠ This includes R&D and operational activities (*e.g. research, development, testing, certifying solutions, etc.)*.

ⓘ For more information on associated countries, *see Article 25 General MGA*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves.

⚠ This obligation must be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value-for-money— Price corresponding to market conditions

PCP subcontracts must be based on the **best value-for-money** criteria *(see Articles 10 and 13 General MGA)*.

⚠ The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

⚠ The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

- a **specific procurement procedure** must be followed

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:

    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*

  - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
  - specifies in-kind contributions provided by third parties
  - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

- the procurement must be preceded by an '**open market consultation**'

  This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[117]).

  A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

- the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

⚠ The obligations in Article 13.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PCP subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

[117] *See Directives 2014/24/EC and 2014/25/EC.*

The **framework agreement** (with each selected subcontractor) must set out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:

- at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
- after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

⚠ The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PCP.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

7. 'Other obligation': Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[118]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[119]) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (breach of an 'other obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

[118] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*
[119] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

ⓘ For more information on this obligation, *see Article 13 General MGA*.

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[29], 2004/17/EC[30].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex** 1. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **best value for money** criteria and ensuring that the price corresponds to **market conditions**;*

*(iii) **Step 3**: **award the subcontract(s)** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[32] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[29] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

[30] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[32] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries will award PPI subcontracts for procuring the innovative solutions ('PPI innovative solution(s)') that are necessary to address the 'common challenge' set out in Annex 1. ('PPI subcontract' thus means a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.)

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

Exceptions:

There is no requirement to split the PPI procurement procedure in **phases**.

The buyers group may select one or more subcontractors.

The common challenge does not concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

⚠ PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure*[120]*)*.

Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

There is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

The subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.

If there is no mandate, the general rule is that:

- framework agreement(s) must be signed by all members of the buyers group together
- specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

⚠ PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

⚠ There can be only one PPI, per PPI Cofund action.

[120] *See Article 31 of Directive 2014/24/EC and Article 49 of Directive 2014/25/EC.*

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No approval without formal amendment

⚠ Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55 General MGA*).

⚠ At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

⚠ For PPI subcontracting, there is NO 'approval without formal amendment' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value-for-money— Price corresponding to market conditions

Like PCP subcontracts, PPI subcontracts must:

- be based on the **best price-quality ratio**,
- have a price that corresponds to **market conditions**
- must follow the **specific procurement procedure** set out in the GA.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**'

Exception:

If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for an open market consultation procedure.

The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

The PIN must contain information on:

- the expected launch date for the call for tender

  ⚠ This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)*.

  Exception:

  If the PPI is limited to procuring a limited set of prototypes or test products *resulting from a prior PCP Cofund action* carried out by the same procurers, there is no need for contract notice and a request for tender; a request for offers from at least 3 providers suffices.

  ⚠ The request must also be addressed to the providers that successfully completed the last PCP phase in the pre-ceding PCP Cofund action.

  ⚠ Do not forget to specify in the request for tenders the arrangements for intellectual property rights (for these arrangements, *see below point 4*) and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  ⚠ In case of framework contracts/agreements there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned**.**

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots need to be deployed at different times and/or by different procurers.*

⚠ The obligations in Article 13.1.1 are additional cost eligibility conditions. Non-compliance will therefore lead to the rejection (in full) of the costs of all the PPI subcontracts *(see Article 6.2.A and 6.6)*.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The subcontract(s) must specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  ⚠ The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

  - do not conflict with their obligations under other Articles and
  - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

⚠ If the buyers group choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the buyers group must ensure the timely allocation of resources in order to implement the PPI.

⚠ This includes allocating sufficient time and resources for testing solutions in real-life operational end-user environments.

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[121]) normally apply to PPI procurements.

Therefore, the lead procurer and the members of the buyers group that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

⚠ Non-compliance with this obligation does not lead to the rejection of costs, but is considered improper implementation of the GA (i.e. breach of an 'other obligation'). The Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach.

ⓘ For more information on this obligation, *see Article 13 General MGA.*

[121] *See Directives 2014/24/EC and 2014/25/EC.*

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR […], the beneficiaries must comply with the following rules: […].[35]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[35] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [****Y****] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each subcontract financed by the procurement**, including data on each contractor that participated in the procurement, an overview of the results for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the initial tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. the 'My Area' section of the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (including data on each contractor that participated in the procurement and overview of the results)

⚠ Templates will be provided on the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[47]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[48]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC)*;***][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

[47] Month X should be the end of the preparation phase and submission of second pre-financing request.
[48] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

⚠ NO financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into **two** reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage

(preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Exception:

Actions will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

⚠ The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of resources — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of resources needed to pay the subcontracts*(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a statement on use of the previous pre-financing instalment *(see Annex 12)*.

  ⚠ This document includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  ⚠ It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into two reporting periods *(see Article 20.2)*, with two pre-financing payments.

Exception:

The action will be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; see Article 21) minus the amount of the first pre-financing payment).

Exception:

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was insufficiently used:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

[…]

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 EJP Cofund MGA: Background information and approach

The Model Grant Agreement for EJP Cofund ('EJP Cofund MGA') is used for grants for EJP Cofund actions ONLY.

⚠ EJP Cofund grants are open mainly to **entities owning** or **managing research and innovation programmes** (and exceptionally other entities — if justified by the nature of the action —, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from both national and private sources).

The minimum number of participants is five independent legal entities from different Member States or associated countries (— unless they are sole participants; *see General Annexes C and D to the Work Programme*).

ⓘ For more information on EJP Cofund actions, *see Article 2.*

ⓘ For information on EJP Cofund funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ⓘ For information on eligibility criteria, *see the Main Work Programme.*

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

Introductory remark

The Model Grant Agreement for EJP Cofund deviates from the General Model Grant Agreement as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 EJP Cofund MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

What? EJP Cofund actions are actions with the following activity:

– implementing a joint programme of activities of coordinated national research and innovation programmes.

The joint programme of activities may range from research and innovation activities to coordination activities, training activities, dissemination activities and financial support to third parties.

⚠ EJP does NOT fund *individual* projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of the H2020 Framework Programme and the Euratom Research and Training Programme. *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*

ⓘ For more information on the conditions for participation and funding, *see the Online Manual or the Work Programmes, and the call and topics pages of your call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[7] (‘**starting date of the action**’).

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Duration of the action

For EJP Cofund actions, the duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55 General MGA*). (⚠ The action’s duration cannot exceed **72 months**.)

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same **budget categories** as the **General MGA**.

Budget categories of the EJP Cofund MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific categories of costs' (if option applies).

⚠ Thus, the EJP Cofund MGA does NOT have:

– 'personnel costs for providing trans-national access to research infrastructure'.

⚠ By contrast, for the Fusion programme EJP Cofund action (FEJP; *see Article 2*), there are three 'specific cost categories':

– 'costs for mobility of personnel'

- ‘costs for fellowships for researchers’
- ‘access costs for research infrastructure’.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2*[15] *(**unit costs**).]***

[OPTION: specific cost category(ies)**: not applicable**]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.
14 Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[122].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 General MGA*).

Specific case:

Fusion programme EJP Cofund action (FEJP; *see also Article 2*) — There three specific **unit costs** as 'specific cost categories':

- costs for **mobility** of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for **fellowships** for researchers: monthly living allowance, mobility allowance and family allowance
- **access costs** for research infrastructure. [123]

⚠ These unit costs replace the 'specific cost categories' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 General MGA)*.

[122] *See Article 28(5) of the Rules for Participation.*

[123] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;*] **[*OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[17]***]][OPTION: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[17] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 General MGA)*.

For one specific EJP Cofund action, i.e. the Fusion programme EJP Cofund action (FEJP; *see also Article 2*), there is however also:

- a specific equipment cost option for 'JET facilities'
- three 'specific cost categories'.

For ease of reference, the annotations for Article 6.2 will be limited to this additional equipment cost option (Article 6.2.D.2) and the specific cost categories (Article 6.2.F) and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1);

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

*(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.**]***

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

As in the General MGA, the beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs - equipment costs' *(see Article 6.2.D General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets

- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

and:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

In addition, for the Fusion programme EJP Cofund action (FEJP; *see also Article 2*), there is however a special option for equipment costs for JET facilities.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with **international accounting standards** and the beneficiary's **usual accounting practice**
- be **purchased** in **accordance with Article 10.1.1**.

⚠ Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. *[OPTION: [Insert name of specific cost category(ies)]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]*

[OPTION for specific unit costs (unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[23]] *are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units,[and if [insert additional eligibility conditions if any]].]***

[same for each specific cost category]

[OPTION: *not applicable]*

[…]

[23] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories: Types of costs — Cost form — Conditions for eligibility — Calculation

For the Fusion programme EJP Cofund action (FEJP; *see Article 2*), the EJP Cofund MGA provides for the three specific cost categories (foreseen by Decision C(2013) 8201[124]):

- 'costs for mobility of personnel'
- 'costs for fellowships for researchers'
- 'access costs for research infrastructure'.

⚠ The FEJP specific cost categories replace those of the General MGA *(e.g. 'access costs for providing trans-national access to research infrastructure', 'costs of energy efficiency measures in buildings', 'costs for clinical studies'; see Articles 5, 6 General MGA)*.

⚠ Costs that are already covered by the unit cost of a specific cost category may NOT be declared (a second time) under another budget category.

1.1 'Specific cost category – costs for mobility of personnel'

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment (by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and

[124] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

– a monthly family allowance).

It may be used for secondments of personnel NOT *employed* by the beneficiary (or linked third party) but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free-of-charge*.

⚠ It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8201[125] and indicated in Annexes 2 and 2a of the GA (currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

⚠ This amount is subject to a '**country-specific correction coefficient**' for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[126]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8

[125] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[126] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto.

Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.4	Sweden	131.9
Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) will be applied as from 1 January 2016. The FEJP GA will be amended and the Annotated MGA will be updated accordingly.

– for the monthly subsistence allowance: between **EUR 0 and 720.27** per individual per month — depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1 300	**601.73**
> 2 000	**720.27**

⚠ This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 258.81**, per dependent child per month).

The Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10% or more. In this event, the FEJP GA will be amended and the Annotated MGA will be revised accordingly.

⚠ As mentioned above, mobility costs for personnel contributed in-kind *against payment* must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties are advised to use the rates fixed by Commission Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
    - a location other than the seconded person's place of employment and
    - one of the following:
        - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
        - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
        - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between five and 18 years of age), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

– the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment

– to this amount, add the following for each leg of the journey (outward and return):

– for train travel: a maximum of 30 minutes for each leg

– for air travel: a maximum of 2 hours for each leg.

⚠ NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

– for the monthly subsistence allowance:

amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

– for the family allowance:

amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

The family allowance is paid for each full month of secondment in which the dependent child is between five and 18 years of age.

'**Month of secondment**' means each *full month* of secondment (⚠ NO *pro-rata* payments for partial months of secondment).

A 'full month' can be one of the following two:

– a **calendar month** *(e.g. 1 to 31 July inclusive)* or

– a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

Specific case:

February (since there is never a 30 February and a 29 February only in leap years) — If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February.

Examples (calculation of unit costs for mobility of personnel):

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*
*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*
*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*
Subtotal = EUR 85 697.25
** correction coefficient of 106.4% (Germany Munich) = EUR 91 181.87*
*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*
Total declared unit costs: EUR 96 238.07

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*
*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*
** correction coefficient of 112.5% (Culham, UK) = EUR 430.82*
Total declared unit costs: EUR 430.82

1.2 'Specific cost category – costs for fellowships for researchers'

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships (by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility).

What not? This budget category does not cover the salary costs of the fellows, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.2.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8201[127] and indicated in Annexes 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  ⚠ This amount is subject to a '**country-specific correction coefficient**' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [128]:

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%

[127] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[128] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Finland	116.6%	Slovenia	86.1%
France	111.0%	Slovakia	82.6%
Croatia	97.5%	United Kingdom	120.3%
Hungary	76.2%		
Ireland	113.5%	Switzerland	113.1%

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[129]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

[129] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

⚠ These are calculated per individual per complete month (NO *pro-rata* payments).

Example of calculation of unit costs for researchers fellowships

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.
*Living allowance: 18 months * EUR 3 110 = EUR 55 980*
** correction coefficient of 116.6% (Finland) = EUR 65 272.68*
*Mobility allowance: 18 months * EUR 600 = EUR 10 800*
No family allowance
Total declared unit costs: EUR 76 072.68

1.3 'Specific category – access costs for research infrastructure'

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

It may also be used for access to infrastructure provided by a third party *free-of-charge*.

⚠ It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; Article 6.2.D.1).

1.3.2 If they are declared under this budget category, these costs must be declared on the basis of the **unit cost** calculated in accordance with Commission Decision C(2013) 8201[130] and indicated in Annexes 2 and 2a of the GA.

⚠ The Commission Decision does not *fix* the unit cost; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{131})}{\text{average annual total quantity of access (over past two years}^{132})}$$

The averages must be based on:

– the beneficiary's certified or auditable historical data

[130] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf
[131] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[132] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- costs allocated to the installation according to the beneficiary's usual cost-accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 to the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users

    Exceptionally, these costs may be those calculated in accordance with the beneficiary's usual cost-accounting practices ('average personnel costs').
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installatioann
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation
- indirect costs for providing access to the installation equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can only be changed via an amendment to the agreement *(see Article 55 General MGA)*.

⚠ As already mentioned above, access costs for installations contributed in-kind *against payment* must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.3*).

⚠ Indirect costs for providing access are already covered by the unit cost and may therefore NOT be declared (a second time) as 'indirect costs' (Article 6.2.E).

⚠ Before signature of the FEJP GA, the beneficiaries can still opt for declaring all access costs (or a part relating to a given installation — ⚠ one cost form per installation and access provider)) not as unit cost, but as actual costs. Such costs must then be declared under the other budget categories *(see Article 6.2.A-E)*.

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55 General MGA)*.

1.3.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example (calculation of unit cost of access to research infrastructure):

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

$$\text{Unit cost} = \frac{\text{EUR 35 000 000 (average annual total cost)}}{\text{175 days (average annual total access)}} = \text{EUR 200 000 per day}$$

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (g) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (h) a **summary progress report** *on* the activities carried out during the on-going reporting period.

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1.

⚠ Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*.

⚠ However, since the annual work plan for the next period must be agreed with the Commission/Agency before the start of activities for the next reporting period, it must be submitted 3 months (i.e. 90 days) in advance.

⚠ The annual work plan for the first reporting period must already be included in your proposal.

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan**.

⚠ The coordinator has **30 days** from the date of receipt of the request to submit a revised annual work plan.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

⚠ It should **not** contain an **analysis of *all* activities** carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

⚠ Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

⚠ Payment of the **second pre-financing** payment is not automatic. It must be **requested** in the statement on the use of the first pre-financing payment using the template in Annex 8.

ⓘ For more information on the other provisions of this Article, *see Article 20 General MGA.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]****[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Exception:

Large EJPs may benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The need for a second pre-financing payment will be assessed during the preparation of the GA.

⚠ If a second pre-financing payment is agreed, the Guarantee Fund retention (of 5% of the maximum amount of the grant) will be split between the two pre-financing payments.

The second pre-financing payment is not automatic but must be requested by the coordinator and supported by a statement on the use of the first pre-financing payment *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum amount of the grant

Exception:

Depending on the size and the needs of the EJP, the reimbursement rate in the work programme/call and the availability of EU funds, the pre-financing may be higher or lower.

In case of two pre-financing payments, the second pre-financing payment will be reduced, if — according to the statement on use of the previous pre-financing instalment — the first pre-financing was insufficiently used:

- if 70% or more of the first pre-financing has been used: the second pre-financing is paid in full
- if less than 70% of the first pre-financing has been used: the second pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Framework Partnerships and Specific Agreements: Background information and approach

The Model Framework Partnership Agreement ('Model FPA') and Model Specific Agreement ('Model SGA') are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

They are established in a FPA and implemented by SGAs for specific actions. Both FPAs and SGAs are treated as grants for the purpose of the award procedure.

⚠ The minimum requirements for participation in FPAs will generally depend on the types of specific actions that are envisaged in the action plan.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals in the work programme and in the invitation to submit a proposal —) *(see Article 4 MFPA and Article 14 MSGA)*.

⚠ Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

ⓘ For more information on framework partnerships and specific grants, *see Article 2.*

ⓘ For information on FPA funding opportunities, *see the 'Search Topic' function on the Participant Portal.*

ⓘ For information on standard eligibility criteria for different types of specific actions, *see General Annex C of the Main Work Programme.*

The MFPA and MSGA generally follow the General MGA for content, but with a different numbering:

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⚠ In addition, all references in the General MGA to 'beneficiary(ies)' are to be taken as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the MFPA or MSGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

VIII.2 Framework Partnership Agreement (FPA): Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name**] (**short name**)legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
[6] The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Partners that have also signed an SGA become beneficiaries (i.e. a 'participant'[133] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

If you do not want to actively participate, you may participate as 'partner not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble to the SGA).

This means that you will not have to comply with some of the obligations under that SGA *(see Preamble MSGA)*

[133] For the definition, *see Article 2.1(15) of the Rules for Participation*: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 MFPA and Annex 3)*.

The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ Any amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation vis-à-vis third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan (see Annex 1))] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership

  ⚠ For the objectives, please refer to the FPA call.

- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

⚠ Signing an FPA does not oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

⚠ The partners may continue to participate in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships are in principle funded in all areas of the Horizon 2020 Framework Programme.

⚠ Currently, framework partnerships are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA), *e.g.* *H2020-FETFLAG-2014*; *H2020-EINFRA-2014-2*).

Framework partnerships are currently not open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  ⚠ Such calls are restricted to the consortia that have signed a FPA and will be in competition.

Example: *The Commission signs different FPAs for FET Flagships. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

– **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

– **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  – in monopoly situations or where partners are designated in the basic act

  – in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts

  – for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

– **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 of the FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 MFPA)*.

> ***Example:*** *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

⚠ The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

⚠ SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

*The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.**]***

[OPTION:** Not applicable**]

1. Consortium agreement

As a general rule, FPA consortium agreements must ensure that the Framework Partnership and the specific actions are implemented properly.

⚠ If necessary, the consortium may decide to have — in addition to the consortium agreement under the FPA — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ⓘ For more information on consortium agreements, *see Article 41.3 General MGA.*

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 General MGA)*.

Exceptions:

Amendments made following suspension cannot have the effect of extending the duration of the FPA as set out in its Article 3.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the Agreement

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties**.**

⚠ Termination of the FPA has no effect on ongoing specific agreements (— unless these are also terminated; *see Article 56 MFPA and Article 20 MSGA*)

ⓘ For more information, *see Article 50 General MGA.*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *'direct personnel costs'*
- *'direct costs of subcontracting'*
- *'direct costs of providing financial support to third parties' (if option applies)*
- *'other direct costs'*
- *'indirect costs'*
- *'specific cost categories' (if option applies) (see Article 4 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 MSGA and Article 5 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions applicable per budget category are set out in Article 5 MSGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS – THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 General MGA).*

⚠ The third parties are normally involved in the specific actions, not in the framework partnership.

Example: *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

Partners must however — already at FPA proposal stage — indicate if they intend to use third parties or not.

Moreover, linked third parties must be identified already in the FPA *(see Article 19)*.

Example: *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGA

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ Accession to SGAs is effected only by means of the signature of the coordinator. The other partners do not need to sign accession forms for the SGA.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA cannot be amended before the FPA.

ⓘ For more information on the conditions for accepting new partners, *see Article 56 General MGA.*

ⓘ For more information on the procedure for amendments, *see the Online Manual*

VIII.3 Specific Agreement (SGA): Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'[3]),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement**: X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
Annex 3	Model for the financial statements
Annex 4	Model for the certificate on the financial statements

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

⚠ However, not all partners of a framework partnership must actively participate in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

As a consequence, these partners do not however need to comply with most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc.)*.

⚠ Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* do remain applicable also for these partners.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed electronically in the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

⚠ The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligations towards them.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and in the invitation to submit a proposal).

⚠ If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

AGA – Annotated Model Grant Agreement

Version 2.0
30 March 2015

Disclaimer

This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

Research and Innovation

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	– Initial version. Article 6.
1.2	17.02.2014	– Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	– Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	– Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	– Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	– New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	– Clickable table of contents added
1.6.2	17.07.2014	– Links to timesheet model and declaration model for personnel costs
1.6.3	20.08.2014	– Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	– Updates due to the amendment of the model grant agreement, in particular Articles 3, 9, 20.6 and 38.1.2 – New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 – New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; – Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 – New Annotations for the MSC – Other minor corrections and clarifications – Improved clickable table of contents including Articles
2.0	30.03.2015	– Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. – Clickable cross-references (Articles) – New table explaining the treatment of the different types of work contracts (under Article 6.2.A). – New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. – Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSC: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 – Other minor corrections and clarifications For easy identification, the paragraphs, indents or sections with relevant updates are marked with the symbol " ■ " in the left-hand margin of the document.

IMPORTANT NOTICE

The '**AGA — Annotated Model Grant Agreement**' is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020.

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA is reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found on the Reference documents page of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

If you need help, you can also contact the Horizon 2020 Helpdesk.

H2020 legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (GENERAL MGA)

I.1 General MGA: Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1'Health, Demographic Change and Wellbeing' , etc.*

⚠ The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSC MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [**official registration No**], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form [OPTION if the JRC is a beneficiary: or the Administrative Arrangement], the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[1] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

⚠ Both beneficiaries and coordinators must have a sufficient financial viability/capacity to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial viability/capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial viability/capacity (of the coordinator or other beneficiaries), if there are grounds to doubt them *(see Article 15(9) of the Rules for Participation)*.

For more information on financial viability/capacity, see the *Online Manual.*

[1] For the definition, *see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation towards third parties.

2. Name, legal form, official registration No, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

'Official registration No' refers NOT to the 'participant identification code (PIC)' attributed by the Beneficiary Register, but to the official registration number in the national registry, if any.

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must keep their beneficiary data up-to-date at all times, including after the end of the grant *(see also Article 17)*. In case of changes, the Legal Entity Appointed Representative (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52)*.

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[2]:

- for **research and innovation actions** (**RIA**): R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions** (**IA**): innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[3]
- for **coordination and support actions** (**CSA**): accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[4].

[2] More information on the types of action can be found on the General Annexes to the Work Programmes.

[3] For the definition, *see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[4] For the definition, *see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

⚠ The term '**action**' comes from the Financial Regulation No 966/2012 and the Rules of Application Regulation No 1268/2012 and **means** '**project**'. (Previous EU Research Framework Programmes used 'project'.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

ℹ For more information on RIA, IA and CSA actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

2. Complementary grants

'Complementary grants' are different EU grants which are 'linked' by the work programme/calls by identifying them as 'complementary actions'.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written '**collaboration agreement**' regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a third country *(e.g. a scientific and technological organisation or funding agency)* or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[5]

- For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

- For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

- For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 to the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

  To ensure coordination, the participants of the two actions must conclude a '**coordination agreement**' *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

  ℹ For guidance on coordination agreements*, see the Guidance — How to draw up your coordination agreement.*

[5] *See Article 12 of the Rules for Participation.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The starting date of the action ('action starting date') is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example: *Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the action before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  ⚠ The action starting date can NEVER be before the submission of the proposal.

- **after the entry into for of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The duration of the action ('action duration') is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the *action tasks* (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as 'project closure' or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
  - 'personnel costs for providing trans-national access to research infrastructure'
- 'direct costs of subcontracting'

- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific cost categories' (if option applies).

  The budget category 'specific cost categories' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

Moreover, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories — without requesting an amendment *(see Article 55)* (unless Annex 1 must be changed).

⚠ The maximum grant amount *(see Article 5.1)* can however NEVER be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

> ***Example:*** *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

> ***Example:***
>
> *Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)*
>
> *Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)*
>
> *Total possible transfer to another budget category: EUR 2 000*

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example: *A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the 'simplified approval procedure' without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the 'simplified approval procedure' bear the full risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION for innovation actions (IA)**[7] **if all beneficiaries and all linked third parties are non-profit legal entities**[8]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions (IA) if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][11]: *[**OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);][**OPTION**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant):** for **[insert name of specific cost category(ies)**[14]*]: on the basis of the amount(s) per unit set out in Annex 2*[15] ***(unit costs).]***

***[OPTION: specific cost category(ies):** not applicable.]*

***[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 To be used only if option in point (f) is used.

10 To be used only if option point (f) is used.

11 To be used only if option in point (f) is used.

12 To be used only if option in point (f) is used.

13 To be used only if option in point (f) is used.

14 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount can NEVER be increased — even if the eligible costs of the action are higher than planned

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally **100%** of the total *eligible* costs[6]; for IA actions it is normally **70%** of the total eligible costs[7].

In exceptional cases fixed in the work programme/call, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[8]

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

6 *See Article 28(4) of the Rules for Participation.*

7 *See Article 28(5) of the Rules for Participation.*

8 *See Article 28(5) of the Rules for Participation.*

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[9] and all budget categories.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[10]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (— unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[11]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [12]
  - specific unit costs for:
    - 'costs for **energy efficiency measures** in buildings'[13]
    - '**access costs** for providing trans-national access to research infrastructure'[14]
    - 'costs for **clinical studies**'[15]

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9 *See Article 28(6) of the Rules for Participation.*

10 *See Articles 123, 124 of the Financial Regulation.*

11 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

12 *See Article 33(2) of the Rules for Participation.*

13 Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

14 Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

15 Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; new in Horizon 2020)[16]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

  Example: *EUR 150 000 to carry out a study within an action*

  The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s).

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions (IA), there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount *(see Article 5.1)*.

Step 3 — Reduction due to the no-profit rule and receipts.

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the *consolidated* receipts and the *consolidated* approved costs.

The **receipts** that must be taken into account are receipts that are:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation)

during the action duration (see Article 3).

The following **are** considered '**receipts**':

- income generated by the action (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped to the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 00,0 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action (i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for the action covered by the GA

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

Examples: *the free use of equipment; the secondment of an expert without reimbursement*

Free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered '**receipts**':

- income generated by exploiting the results of the project (*e.g. the IPR*) is not considered a receipt since successfully exploiting the results is one of the main objectives of the action
- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

  Example: *A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This in-kind contribution from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions made **by one beneficiary to another** within the same action are also not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (i.e. the final payment at the end of the action).

They must be declared in the final report (although beneficiaries are free to do so also in the periodic reports).

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a **reduction** of the **grant** (i.e. reduction of the 'maximum grant amount'; *see Article 5.1*) — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is NOT a sanction, but the consequence of a breach of an obligation under the GA.

Example for calculating the final grant amount:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of Article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level).

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000

Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500

Costs rejected following audit: 30 000

Revised direct eligible costs: 120 000

Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000

Revised final grant amount: 100% of 150 000 = 150 000

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount set out in Article 5.1, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.

Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs AND reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

> ⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.
>
> Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.
>
> Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are (invoiced or) paid later, they are eligible only if the debt (and invoice) exists and the final cost is known.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action or the GA termination are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  > ***Example:*** *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  > ***Examples:*** *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  > ***Examples:*** *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting

practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They do NOT extend to research or innovation activities undertaken after the end date of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

  Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2.*

- the **number of units** must be **necessary** for the action

- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

Example: *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Personnel costs declared on the basis of the usual accounting practices — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices

- must budget and declare a total amount; the amount per unit must not be included in Annex 2.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency *(in Annex 2 of the GA; see Article 5.2)*.

> ***Example:*** *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump-sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]***]**.

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the action
- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action cannot be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a 25% fixed flat-rate of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[A.6 [OPTION to be used for trans-national access to research infrastructure: Personnel costs for

providing trans-national access to research infrastructure *are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 What? 'Personnel costs for employees or equivalent' (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) **cover**:

- the **basic remuneration** (i.e. basic salary and complements) and
- only for non-profit legal entities: the **additional remuneration**

for personnel that worked on the action.

What is 'basic remuneration' and 'additional remuneration' and how to distinguish them?

Basic remuneration refers to the 'basic salary' of the employee plus 'complements' that fulfil the eligibility conditions explained in point 1.1.3.

The basic salary includes (and is limited to):

- the salary stated on the beneficiary's payroll (except for any part of that salary which must be considered as 'additional remuneration', even if it that part is also registered in the payroll)
- social security contributions (mandatory parts to be paid by the employee and the beneficiary that employs him/her) — except any part included in additional remuneration.
- taxes included in the remuneration *(e.g. income tax to be paid by the employee retained by the beneficiary who employs him/her)* — except any part included in additional remuneration.
- other costs included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee)* — except any part included in additional remuneration.

The complements may include:

- mandatory complements to the basic salary resulting from national law, collective labour agreement or the employment contract

  Example (mandatory complement): *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements if they fulfil the eligibility conditions set out in point 1.1.2.

  Example (variable complement acceptable as basic remuneration): *The contract of a professor includes as part of his/her usual tasks both teaching and research; it foresees a basic fixed*

remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour for each hour spent on research activities.

By contrast, **additional remuneration** refers to payments made *on top* of the employee's usual remuneration, which result in a higher hourly rate.

Additional remuneration includes not only the extra salary, but also the social security contributions, taxes and other costs included in the remuneration that result from that extra salary.

Example (additional remuneration): *a 'bonus' for participating in a project; an additional contract for specific tasks with a salary higher than the one under the main contract*

Example (not additional remuneration, but basic remuneration): *additional salary paid to the employee for additional hours worked on its standard work or expertise as defined in the employment contract (e.g. overtime or additional contract for those additional hours), if the additional hours are remunerated according to the standard salary conditions of the employee (i.e. do not result in a higher hourly rate). Note that the standard salary conditions may provide for a mandatory complement for those additional hours (e.g. overtime during night shifts).*

Thus, the two main features that help characterising a remuneration component as basic or additional are:

- hourly rate (no change to hourly rate would indicate basic remuneration, while a higher hourly rate would indicate generally additional remuneration) and

- kind of work or expertise (usual kind of work or expertise according to the contract or different/additional work or expertise).

Work or expertise	**Hourly rate**	
	Usual	**Higher**
Usual	Indicates basic remuneration	○ Indicates additional remuneration: if triggered by the participation in a project ○ May however qualify as basic remuneration if not dependent on a project or type of projects (and therefore spread over all activities, e.g. *based on merit of the employee at stake*)
Additional/different	Indicates basic remuneration	Indicates additional remuneration

In case of doubt, the classification will be made also taking into account the classification of the component under national tax law (i.e. if the tax authorities explicitly consider it as part of the basic remuneration of the employee or as additional remuneration).

⚠ It is the basic remuneration that must be used to calculate the hourly rate *(see below)*.

1.1.2 Costs for employees (or equivalent) must be **declared** on the basis of:

- either **the individual actual personnel costs** of each employee participating in the action (the most common case) or

- on the basis of **unit costs:**

- either calculated by the beneficiary in accordance with its usual cost accounting practices (i.e. 'average personnel costs') if in line with the specific eligibility criteria *(see below)* or

- where applicable, unit costs fixed by the Commission; *e.g. the mandatory unit cost for SME owners and natural persons without a salary*.

1.1.3 The costs for employees (or equivalent) must comply with the following **conditions for eligibility**:

> ⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. (If the employment contract indicates that the person was hired to work on *another* project, it must be changed.)

For basic salary and mandatory complements:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are ineligible under *Article 6.5(a)(i)*. (However, complements based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted as variable complements, if they fulfil the conditions set out below.)

  > ***Examples (acceptable):***
  > *If the profit of the company at the end of the year is more that X € (or more than X %), each employee will receive a complement of z % of his/her basic remuneration (or a fixed complement of x € more as part of the gross salary).*

  > ***Examples (not acceptable):***
  > *If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.*

  Any part of the remuneration which is calculated with reference to commercial targets *(e.g. x € for reaching a sales target, x % on sales)* or fund raising targets *(e.g. x € premium per externally funded project gained, x % of the external funding gained)* is ineligible. The reason is that they are neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation.

  > ***Example (not eligible because linked to fund raising target)****: A premium paid as a reward for having obtained a specific grant is not eligible.*

- be **fixed** (conditions and amount or percentage) and **mandatory** according to national law, collective labour agreements or the employment contract

  > ***Example:*** *The employment contract between the entity and the person fixes a gross salary of EUR 3000 per month plus a transportation allowance of EUR 5 per working day.*

- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract/equivalent appointing act). Therefore, they can NOT depend on the participation in a specific action/project

  A 'payment linked to a specific action/project' is a payment the employee would not have received if s/he had not participated in the work of the action/project (i.e. the triggering event is the participation in the action/project *(e.g. an EU action)*, not the performance of the tasks defined in the employment contract/equivalent appointing act).

  Any part of the remuneration linked to tasks other than those covered by the basic remuneration, in particular amounts triggered by the participation in a specific action/project, are NOT eligible as part of the basic remuneration. (They may however still be eligible as additional remuneration; *see below*.)

For variable complements (in addition to the first and third conditions above):

- the variable complement is authorised by national law, collective labour agreement or the employment contract/equivalent appointing act

  Examples:

  1. *The collective labour agreement establishes that all researchers may receive a complement between EUR 100 and EUR 200 per month based on their seniority.*

  2. *The national law authorises public universities to pay a complement based on merit of the employees.*

  3. *The contract fixes a premium of EUR 1000 for each research paper published in peer reviewed international research journals.*

- the amount to be actually paid as variable complement is determined on the basis of objective conditions which are, at least, established and documented in the internal regulations of the beneficiary.

  Example: *Based on the provisions of the collective labour agreement (see first example above), the internal regulations of the employer provide that: all researchers with seniority between 3 and 5 years will receive a complement of EUR 150 and all researchers with seniority above 5 years will receive a complement of EUR 180.*

  The variable complement must NOT be paid to the employee at the sole discretion of the manager (**arbitrary** complement). The decision to grant the complement must be based on objective conditions, which should be documented in a procedure and be verifiable.

  Example: *National law authorises public universities to pay a complement based on merit or performance of the employees and the internal regulations of the public university provide for an annual assessment exercise to determine the 'merit points' of each employee. The internal regulations also set up the objective criteria based on which the 'merit points' are decided. The internal regulations provide that all researchers with more than 10 'merit points' will receive a complement of EUR 1000.*

For additional remuneration (only for non-profit legal entities):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the participation in another project)* is not eligible.

  Example:

  A nuclear researcher in a public research centre (non-profit) worked for 1 720 productive hours

  Remuneration components:

  a = annual salary: EUR 50 000

  b = a complement for holding a management post (e.g. Head of department): EUR 1 600

  c = additional remuneration for being Head scientist in the EU project: EUR 2 000

  d = additional remuneration for being First Assistant on an internal action: EUR 1 000

  a *and* ***b*** *would be used to calculate the researcher's hourly rate:*

  hourly rate for the EU action = {(50 000 + 1 600)/1 720} = EUR 30

  c *would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*

  d *would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for the performance of **additional work** or **different expertise** than his/her usual tasks

  The work to be carried out (or expertise used) must be different from the standard work or expertise (defined in the employment contract/equivalent appointing act and covered by the standard remuneration package). This difference must be verifiable.

- be part of the beneficiary's usual remuneration practices and be consistently applied whenever the same kind of work or expertise is required
- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used

The objective criteria must be related to the additional work or expertise.

Examples (acceptable criteria):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking up the management of the research team and infrastructure.

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

A normal salary is paid for research on internal projects + additional remuneration is paid for participating in a special type of projects as for example international cooperative projects, projects awarded under competitive calls, etc.

Examples (not acceptable criteria):

Additional remuneration paid for using English.

Additional remuneration is paid only when participating in EU funded actions.

The system for making additional payments should be established in the beneficiary's internal rules (or at least be documented and known by the employees). (Like for variable complements, the additional remuneration must NOT be paid to the employee at the sole discretion of the management (arbitrary complement).)

Example (acceptable): *All teachers carrying out research on top of their usual teaching activities get an extra payment of 10 % of their salary.*

Example (not acceptable): *The director decides at its sole initiative to pay an extra 10 % to one professor carrying out research.*

However, the additional remuneration does not have to be the *same* for all persons working in the same project. The objective criteria used to determine the additional remuneration may result in different amounts for persons working in the same project *(e.g. the rule is that all teachers that carry out research on top of their usual teaching activities get an extra payment between 10 % and 20 % of their salary, the precise percentage per teacher and project is determined according to the level of responsibility in the specific project)*.

The rules for additional remuneration may not differ according to *where* the funds come from. In particular, they cannot be set up for actions funded by a specific donor. (Additional remuneration schemes that are applicable only to EU actions are not acceptable.)

Example (acceptable): *All professors carrying out research will be paid 10 % more.*

Example (not acceptable): *All professors carrying out research will be paid 10 % more when they work on EU funded actions.*

Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see point 1.1.4*).

⚠ To avoid abuses, the rules for additional remuneration will be exceptionally also applied to the basic remuneration, if it has been **artificially increased** for participation in the EU action.

Examples:

1. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the beneficiary to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

2. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with a linked third party (or a third party providing in-kind contribution) to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

3. *Employees of a specific department/service of the company which is in charge of carrying out only EU actions are paid a higher salary than their homologues in other departments carrying out the same tasks requiring a similar level of expertise (i.e. the salary differential is attributable to the source of funding). The rules for additional remuneration will apply to the difference between the salaries of employees working for the specific department and those of employees of other departments carrying out the same tasks with the same level of expertise (see point 1.1.4).*

Decision tree to determine eligibility of complements:

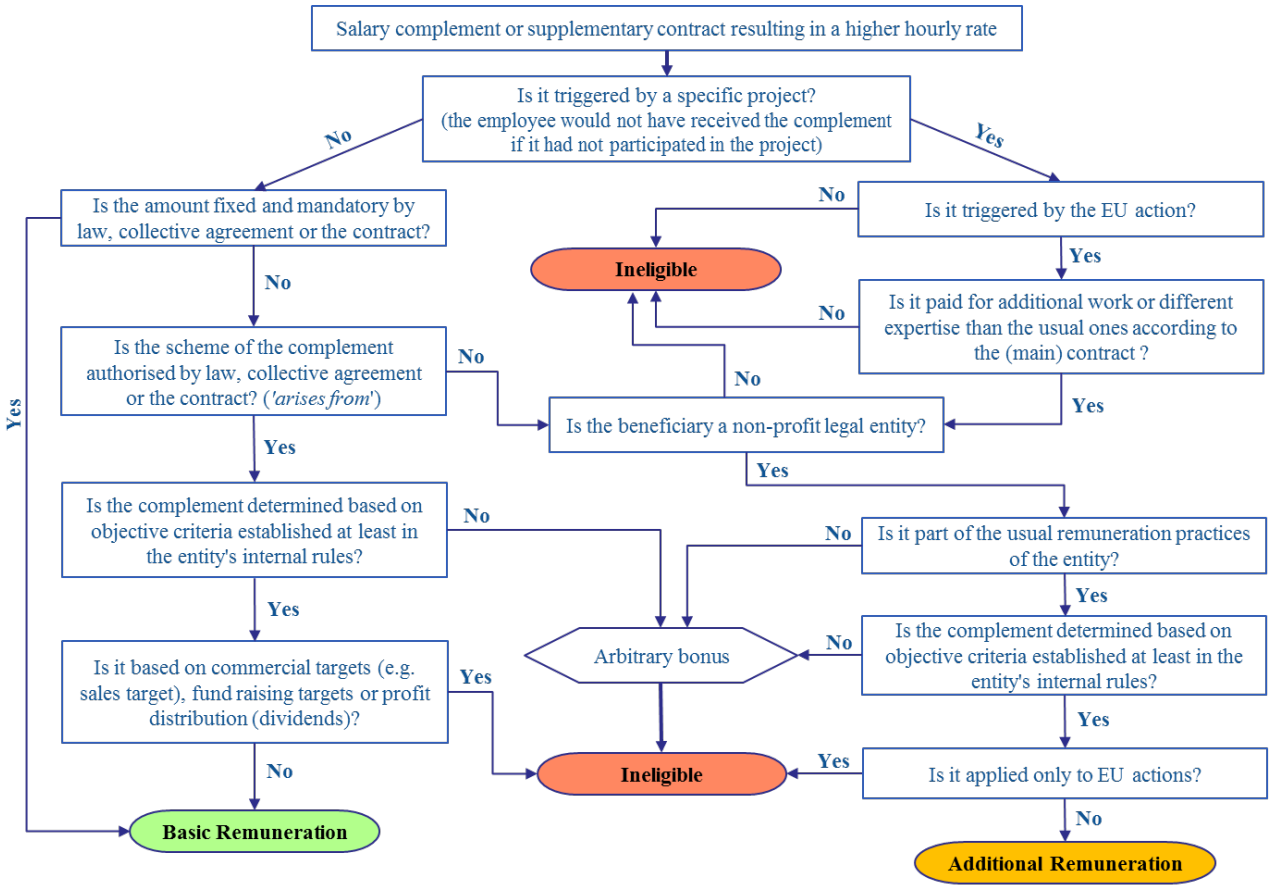

Specific cases (direct personnel costs for employees (or equivalent)):

Teleworking — Remuneration costs of employees (or equivalent) not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of benefits equivalent to financial ones *(e.g. costs of lunch vouchers)* may be accepted as eligible if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25 % flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — Like any personnel costs, PhD costs (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6. In this context, fellowships/scholarship/stipends are assimilated to salaries provided that this remuneration complies with the application national law on taxes, labour and social security. Furthermore, the assignment of tasks must respect the laws in force in the place of establishment of the beneficiary and the persons must have the necessary qualifications for the performance of the tasks attributed to them in the context of the H2020 action.

Academic fees — If a student works for a university and is exempt from paying (part of) the academic fees, those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic salary only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible)

AND

- the employee worked for the action during the financial year used for calculating the personnel costs.

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts (whatever their form, i.e. a contract additional to the main contract between a beneficiary and its employee) for carrying out tasks for specific actions *(e.g. international projects)* are acceptable, if it is the beneficiary's usual practice and it is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package (basic remuneration) in the first non-action-related contract is considered 'additional remuneration'. As such it is subject to the specific cost eligibility conditions explained above for additional remuneration and, if eligible, to the eligibility ceiling.

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**
multiplied by
number of actual **hours worked on the action**},
plus
for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

This calculation method also applies for persons working exclusively for the action.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ The **total number of hours** declared in EU and Euratom grants **for a person for a year** may NOT be higher than the number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Procedure for calculating direct personnel costs for employees (or equivalent):

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.

Remuneration components:

a = annual salary: EUR 50 000

b = extra payment for holding a post involving radioactive hazards: EUR 5 000

c = additional remuneration for being Head Scientist in a Project: EUR 2 000

***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*

Hourly rate for the action = {(50 000 + 5 000)/1 600} = ***EUR 34***

For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated by ***financial* year** (i.e. the 12-month period covered by the annual accounts of the entity) and has to be made always on the basis of full financial years.

Example: *When the financial year matches the* ***calendar year****, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance to the GA is available. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Once declared, the personnel costs can normally NOT be adjusted/changed due to a recalculation of the hourly rate (even if a re-calculation after the closure of the financial year on-going at the end of the period would give another result). A correction is only possible (and must be made) if there was a mistake in the

calculation of the hourly rate that was used to declare those costs *(e.g. incorrect accounting information).*

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Specific case (financial year):

If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes) the entity may use the **fiscal yea**r instead of the financial year for the purposes of calculating the hourly rate for personnel costs. The method must however be consistently applied and can NOT be changed within the same grant.

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours**')
- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

The option must be applied not only to the person for whom the beneficiary declares costs, but per group of personnel employed under similar conditions.

Productive hours must be calculated on the basis of all working activities; using only 'billable hours' is NOT acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a H2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	Annual productive hours/activity	Billable hours
for Horizon 2020 action	**400**	**400**
for other projects	200	200
for the preparation of proposals for new projects	600	0
member of the management board of the RO	400	0
total number of hours	**1 600**	**600**

If the person concerned was on parental leave during the year, the annual productive hours may be reduced by the actual time spent on parental leave.

This table explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types*	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive

	of special leave).	plus
		overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual working hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
			hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		⚠ This option can NOT be used If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time legislation. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options.	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of

		Example for calculation of standard annual workable hours: *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual*	annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours). *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).* ⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow determining the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow determining the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).*	

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional salary but also all additional taxes, costs and social security contributions triggered by the additional salary.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80%) ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (eligibility ceiling):

{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000

The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

Example for calculating direct personnel costs for employees (or equivalent):

A nuclear researcher working for a public research laboratory (non-profit) worked:

1 600 productive hours

800 hours declared for the action (at an hourly rate of EUR 40)

400 hours declared for another EU grant

S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.

*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***

Addition of the additional remuneration: = ***2 000***

Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

Condition: Actual hours declared for action + actual hours declared for another EU grant ***≤*** *total productive hours (800 + 400* ***< 1 600****)*

Specific cases (direct personnel costs for employees (or equivalent)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A applies.

- For persons who sign the 'declaration on exclusive work for the action' the number of hours worked in the action during the period covered by the declaration will be the pro-rata (corresponding to the period of exclusive dedication) of the annual productive hours used to calculate the hourly rate.

Example:

Researcher Y worked exclusively in the H2020 action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours.

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*Hours worked for the project*	
2014 ➔	*(32 000 / 1720) x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60 x	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720) x*	*1720*	
	20 x	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*		
	20 x	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
		TOTAL	*= 51 000*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Example: *The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the corresponding part of the indemnity in the reporting period in which the employee's contract ends. However, the indemnity may be accepted only if:

- arise from the applicable national labour law
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Only the part of the indemnity that corresponds to the time worked by the person on the action can be charged (i.e. pro-rata of the total time during which the entitlement was generated).

Employment contract remunerated 'per hour' — Some employment contracts do not establish a fixed salary and a number of hours to be worked, but an amount to be paid for each hour worked by the employee.

In those cases, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the 'individual annual productive hours' may be calculated as follows:

{total salary paid to the employee in the financial year
divided by
hourly rate fixed in the employment contract}.

Personnel costs on the basis of the usual cost accounting practices — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices (i.e. 'average personnel costs'), the hourly rate must be calculated in accordance with the beneficiary's usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

Costs that are already included in other budget categories must be taken out (double funding of the same costs).

Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25%, so personnel costs cannot include any indirect costs.*

Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate
- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

Beneficiaries may request the **approval** of the methodology used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 What? This budget category **covers** typically the costs for in-house consultants and similar persons that worked on the action (i.e. self-employed *natural* persons working part-time or full-time for the action under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency. (Such costs may however be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs'; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.
- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.
- the **result** of the work carried out must **belong to** the **beneficiary**

The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products. This implies that the beneficiary must keep records of the hours worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.2.4 Cost of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **formula** as the one explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the **hourly rate** is different (since it is not based on the annual personnel costs as registered on the payroll).

For the hourly rate, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person and the number of hours to be worked: this global amount must be divided by the number of hours to be worked for the beneficiary under that contract.

If the contract fixes only a global amount and does not specify the time to be worked, the costs can NOT be declared as personnel costs, but may be eligible as purchase of a service *(see Article 10)* or a subcontract *(see Article 13)*.

This table explains how to treat **different types of work contracts** for declaring costs under H2020[17]:

General case: Single contract between the entity and the person		
Characteristics of the contract	**Contract remunerating time** (*e.g. the contract establishes that the person must work for the hiring entity 40 hours per week*)	**Contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes that the person must carry out a specific task but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ However only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. *Example: Contract from 01/01/2015 to 31/03/2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430* ➔ The personnel cost will be the result of multiplying the hourly rate by the number of hours worked by the person for the action (as recorded in its timesheets).

[17] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5).*

Other contract (i.e. not covered above)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared as 'personnel costs – costs for natural persons working under a direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.	**CASE D** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.

Special case: the contract covering the work for the H2020 action is additional to the main contract of the person		
Characteristics of the additional contract	**Additional contract remunerating time** (*e.g. the additional contract establishes that the person must work for the hiring entity 10 hours per week in addition to the basic contract*)	**Additional contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes that the person must carry out a specific task but the working time needed is not defined; e.g. the contract specifies that the work has to be carried out within the working time of the main contract)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE E1:** the additional contract is NOT triggered by the participation of the person in the H2020 action (e.g. the contract pre-dates and outlasts the grant agreement). The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ In this case a single hourly rate must be calculated taking the figures of the main and the additional contract/s together (i.e. total basic remuneration and total annual productive hours). **CASE E2:** the additional contract is triggered by the participation of the person in the H2020 action. The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ However, the hourly rate must be calculated only on the additional contract (remuneration and productive	**CASE F** The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated for the additional contract as described in CASE B above: ➔ However, if the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1).* Therefore: **CASE F1** (the hiring entity is a non-profit legal entity): the costs of the additional contract may be eligible up to the following ceiling: *{Hours worked for the action (as recorded in the time records)* *multiplied by* *{Hourly rate of the main contract + EUR 4,65}}* Note: EUR 4,65 is the result of dividing 8000 (annual ceiling for additional remuneration) by 1720 (option 1 annual productive hours); thus, 4,65 is the hourly pro-rata of the annual ceiling

	hours of the additional contract). If the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1)*.	**CASE F2** (the hiring entity is NOT a non-profit legal entity, i.e. for profit entity): the costs of the additional contract may be eligible up to the following ceiling: {*Hours worked for the action (as recorded in the time records)* *multiplied by* *Hourly rate of the main contract*}
Other contract (i.e. not covered above)	**CASE G1:** the costs fulfil the conditions of Article 6.2.A.2. Depending on the main contract, the costs may be declared either as: – 'costs of employees (or equivalent)' (Article 6.2.A.1) or as – 'costs for natural persons working under a direct contract' (Article 6.2.A.2). If the main contract is under CASE A, CASE B or CASE C1, the cost must be calculated as indicated above for CASE E1 or E2 (depending if the additional contract is or not triggered by the participation in the H2020 action). If the main contract is under CASE C2 or D, the costs must be calculated as described in point 1.2.4. **CASE G2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10).	**CASE H** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.

	⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.	

1.3 Direct personnel costs: Costs for persons seconded by a third party against payment

1.3.1 What? This budget category **covers** the costs of persons that worked on the action and that were seconded by a third party as an 'in-kind contribution *against payment*' *(see Article 11)*.

> For information on in-kind contributions provided by third parties *free of charge*, *see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  > ***Example:*** *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  A secondment does not necessarily require the seconded person to work at the beneficiary's premises, although this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons not receiving a salary that worked on the action.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

> ***Example:***
>
> *A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.*
>
> *In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.*

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *Main Work Programme — MSCA*[19] in force at the time of the call.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatised: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an owner of an SME/beneficiary that is natural person, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than the standard number of annual productive hours used for the calculation of the hourly rate (i.e. 1 720 hours).

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 What? This budget category **covers** the personnel costs for access to infrastructure activities, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes .

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional cost eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]*

*[**OPTION**: Not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

This optional budget category (together with the corresponding Article 15 and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  > ***Example*:**
  > *Beneficiary A declares the cost of a business class airplane ticket for one of its employees.*
  > *If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.*
  > *If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.*

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of an asset must be allocated on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life.

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs):

Equipment used only partly for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the *part* of the equipment's or asset's 'working time' for the action may be declared (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable (i.e. the hours that the equipment has been used for the project must be recorded).

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

Full price of an asset in one single year — Declaring the *full* price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — If recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may declare the *part* of the cost that corresponds to the use of the item for the action in each relevant reporting period or in a single reporting period.

The amount declared can be only accepted if all of the following apply:

- the cost is economic and necessary
- only the portion of the equipment used for the action is declared

  If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.
- the amount of use (percentage used and time) must be auditable
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary. It may be defined according to the beneficiary's practices or be established per type of equipment in line with national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50 % of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the cost eligibility conditions of Articles 6.1 and 6.2 are met (in particular, recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices; *see Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

If the full construction cost of the construction are eligible, but the construction was externalized to a third party (other than a linked third party), the costs can NOT be declared as 'equipment costs', but may be eligible as 'direct costs of subcontracting' *(see Articles 6.2.B and 13)*.

1.2 Equipment costs: Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:
  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the

item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials, scientific publications needed for the action, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).
- translation costs (if translation is necessary for the action's implementation, is justified, etc.).

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the 'plan for the exploitation and dissemination of the results' are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Internally invoiced costs (i.e. where the use of certain resources is shared between different units of the same organisation and the costs of their use are declared through internal invoices) may be eligible if their use and the usage (number of hours) for the action is

specifically recorded and it is mentioned in the invoice. The internal invoice must refer to the use/dedication for the action of specific resources (*e.g. per researcher, piece of equipment, etc.)*.

Example (acceptable internal invoice): *Internal invoice with 16 hours of the technician doing the analysis and 10 hours depreciation of the testing equipment used.*

Example (not acceptable internal invoice): *Internal invoice with a global price for the use of a research infrastructure (e.g. laboratory) or for a service (e.g. an analysis).*

The costs must be declared under the budget category that corresponds to the invoiced resource *(e.g. personnel, equipment, other direct costs, etc.)* and must fulfil the eligibility criteria set out in Article 6.1 and 6.2.

Internal invoices may NOT include indirect costs elements or profit margin or mark-up.

Internal invoices for the work of personnel must be supported by time-records *(see Article 18.1)*. The hourly rate must be calculated as described in Article 6.2.A.

Internal invoices for the use of equipment must be limited to the depreciation for the relevant reporting period (only the part of the depreciation cost corresponding to the time the equipment was used for the action during that reporting period can be declared.) The use of the equipment must be properly recorded in order to allow direct measurement of the use for the action and to ensure auditability *(see Article 6.2.D.2)*. It is NOT possible to calculate an all-in average cost of internally invoiced equipment including, for instance, allocated indirect costs *(e.g. maintenance)*.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of the Horizon 2020 Framework Programme 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's

[20] *See also International Financial Reporting Standard No 16.*

usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[21] *See Article 126 of the Financial Regulation.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared** as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '**large research infrastructure**', if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once, a positive ex-ante assessment is obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any grant agreement.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (Link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

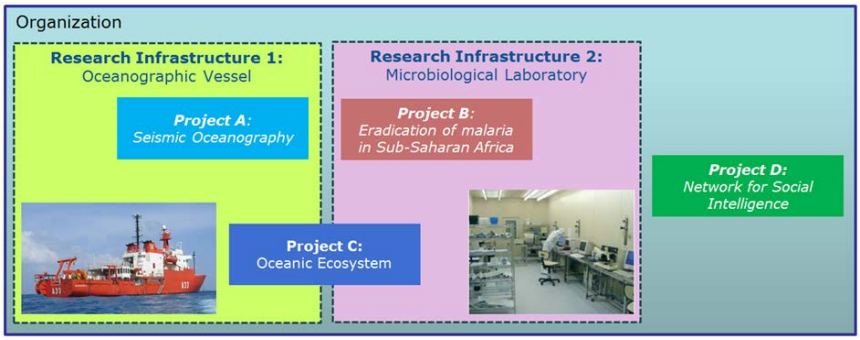

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

> ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds — may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Article 6.2.D.4 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[24] *See Article 129(1) of the Financial Regulation.*

Example 2 (Comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (‘**project time’**) and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of ‘**units of actual usage**’ for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary’s analytical cost accounting system. This data must be regularly updated.

  Example 3 (Costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

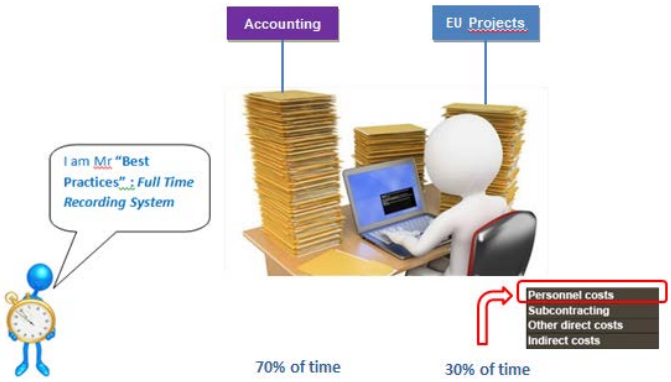

Example 4 (Part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (Rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]][**OPTION**: not applicable;]*

(d) ***[OPTION if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

However, beneficiaries that receive an **operating grant** financed by the EU or Euratom budget can NOT declare any indirect costs for the reporting period(s) covered by the operating grant.

Best practice: The beneficiary must **inform** both the coordinator and the Commission/Agency during grant preparation and before submitting financial statements (via 'My Area' in the Participant Portal).

'Operating grants' are (normally annual) grants given by a separate grant agreement to finance the operation and running costs of an entity e.g. call COMM-C2/01-2013 under the 'Europe for Citizens' programme.

1.1 This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared** on the basis of a flat-rate (*see Article 5.2(e)*; new in Horizon 2020).

In practice, the declaration is completely automatised: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25 % flat-rate to the beneficiary's eligible direct costs, minus:

- subcontracting costs *(see Article 13)*

  Example: *subcontracting of opinion surveys.*

  The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties (if option applies)

- costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a grant agreement and has incurred the following costs

- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,

- EUR 10 000 in consumables costs.

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

F. [OPTION: [Insert name of specific cost category(ies)[22]]][OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant): *[**insert name of specific cost category**] are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]***

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category] *are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]***

[same for each specific cost category]

[OPTION: *Not applicable**]***

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories: Types of costs — Cost forms — Conditions for eligibility — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of the Horizon 2020 Framework Programme, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: '**costs for energy efficiency measures in buildings**'

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': '**access costs for providing trans-national access to research infrastructure**'

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': '**costs for clinical studies**'

  The unit cost applies ONLY to actions with clinical studies.

⚠ Costs that are declared as a specific unit or lump sum cost may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

Example:

Case 1: *The unit cost for 'efficiency energy measures in buildings' covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

1.1 'Specific cost category – costs for energy efficiency measures in buildings'

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new isolation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost set out in Commission *Decision C(2013) 8196*[26] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) must be calculated — before signature of the GA — according to the following formula:

Amount per unit = {EUR 0.1 x estimated total kWh saved per m² per year x 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m² of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 'Specific cost category – access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** direct and indirect 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; see Article 6.2.D.1 and Article 16).

1.2.2 If they are declared under this budget category (i.e. specific cost category – access costs for providing trans-national access to research infrastructure), the costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[27] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{28})}{\text{average annual total quantity of access (over past two years}^{29})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[29] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

  Exceptionally, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

- costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

- costs of consumables specifically used for the installation and the user's research work

- costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

- costs of energy power and water supplied for the installation

- costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)

- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

- costs of specific scientific services included in the access provided or needed for the provision of access

- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)

- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

The access activities and the parameters for calculating the unit cost must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annexes 1 and 2a.

The proposal should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per installation and access provider).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

During the GA, the beneficiaries may change their choice, but only via an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional cost eligibility conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 'Specific cost category – costs for clinical studies'

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study;
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
  - costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
  - indirect costs for the study.

1.3.2 If they are declared under this budget category (i.e. specific cost category – costs for clinical studies'), the costs must be **declared** on the basis of the unit cost set out in Commission Decision C(2014) 1393 and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/patients or subjects included in the clinical study) must be calculated for each study and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — according to the following formula:

Amount per unit ={Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks] }

The unit cost components must be calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':

{'average hourly cost for doctors', i.e.:

certified or auditable total personnel costs for doctors for year N-1

{1720 * number of full-time-equivalent for the personnel category doctors for year N-1}

multiplied by

estimated number of hours worked by doctors for the task (per patient/subject)**}**

For unit cost component 'personnel costs of other medical personnel':

{'average hourly cost for other medical personnel', i.e.:

certified or auditable total personnel costs for other medical personnel for year N-1

{1720 * number of full-time-equivalent for the personnel category other medical personnel for year N-1}

multiplied by

estimated number of hours worked by other medical personnel for the task (per patient/subject)**}**

For unit cost component 'personnel costs of technical personnel':

{average hourly cost for technical personnel, i.e.:

certified or auditable total personnel costs for technical personnel for year N-1

{1720 * number of full-time-equivalent for the personnel category technical personnel for year N-1}

multiplied by

estimated number of hours worked by technical personnel for the task (per patient/subject)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc.)

For each category of consumables:

{'average price per item', i.e.:

{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned

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total number of items purchased in year N-1 for the category of consumables concerned}

multiplied by

estimated number of items used for the task (per patient/subject)**}**

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:

{'average cost of depreciation and directly related services per unit of use', i.e.:

{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

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total capacity in year N-1

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value-for-money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:
'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

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total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%
multiplied by
{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}**}**

The following must be excluded:
- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

The estimation of the resources must be done on the basis of the protocol for the clinical study (and must be the same for all beneficiaries/linked third parties/third parties involved).

Each beneficiary/linked third party/third party providing in-kind contributions must calculate the direct costs by using its historical costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application).

Personnel costs must be defined in the 3 categories (doctors, other medical personnel, technical personnel) defined in the Commission Decision. No other categories *(e.g. 'nurses')* can be used.

The descriptions of the resources and the parameters for calculating the unit cost must already be part of the proposal *(see the proposal templates and the* template for essential information to be provided for proposals including clinical trials / studies/ investigations *provided on the call pages)* and be included in Annex 1 and 2a of the GA.

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per study and beneficiary/third party.)

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or of costs actually incurred for a given clinical study.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** the number of patients or subjects that participated in the study

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION: *Not applicable****]***

1. Costs of linked third parties

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional cost eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply, but with the changes needed to render them applicable to the linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared as 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared as 'other direct costs – equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared as 'other direct costs – equipment' (Article 6.2.D.2).*

'In-kind contributions free of charge' must be **distinguished** from 'in-kind contributions against payment' *(see Article 11)*.

In-kind contributions against payment are costs *of* the beneficiary/linked third party (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. They must be declared under those budget categories.

Example:

1. *The cost of personnel seconded against payment must be declared as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared as 'other direct costs – equipment – cost of equipment, infrastructure or other assets contributed in-kind against payment' (Article 6.2.D.2).*

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

1. Ineligible costs

Cost are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

- **provisions for future losses or debts**

  'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

- **interest owed** (i.e. interest on a loan to borrow capital)

- **excessive or reckless expenditure**

  'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

  'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

- **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

- **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

  Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the cost eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

- **deductible VAT**

  'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

  The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

  The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

  The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

  Conversely, if VAT is NOT deductible, it is an eligible cost.

  The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*

  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*

  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*

  - if a beneficiary is receiving an operating grant[30] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

Specific cases (ineligible costs):

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

[30] For the definition, *see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

⚠ Normally, the beneficiaries must comply BOTH with the national law of the country in which they are established and that of the country where the action is implemented.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Third parties involved in the action do not sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value-for-money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION 2, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *Not applicable****]***

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

These beneficiaries are considered 'beneficiaries' (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from a H2020 associated country[31]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

For more information on third country participants, *see the Online Manual*.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on the role of the beneficiary in the grant and if it has or not linked third parties that receive EU funding).

[31] For the definition, *see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

This table summarises the obligations of the General MGA that do not apply to beneficiaries not receiving EU funding (under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs or recovery) may be applied.

Example:

A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […]*[23]]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[24] or 'contracting entities' within the meaning of Directive 2004/17/EC[25] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

⚠ For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

> ***Example (contracts):*** *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional eligibility condition: Best value-for-money or lowest price

The beneficiaries must base their purchases on the 'best value-for-money' considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value-for-money principle does not require **competitive selection procedures** in all cases. (However, where a beneficiary did not request several offers, it must demonstrate how best value-for-money was nevertheless ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.)

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[32] and 2004/17/EC[33] — or any EU legislation that replaces these Directives[34]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 1(9) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

Specific cases (purchases):

Existing framework contracts or **purchase contracts** — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with best value-for-money and absence of conflict of interests.

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[32] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[33] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[34] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the costs actually incurred by the third party.

Normally, only the *direct* costs of the third party are taken into account

These *direct* costs may not be based on unit costs[35] or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot, for instance, use the unit costs for SME owners or natural persons who do not receive a salary.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary, except if the in-kind contributions are used on the third party's premises. In this latter case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on these costs *(see Article 6.2.E)*.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those actually incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

[35] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** to the GA.

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ((‘**simplified approval procedure**’).

> ***Example:*** *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

> ***Example (no approval):*** *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the ‘simplified approval procedure’ bear the full risk of non-approval and rejection of costs by the Commission/Agency.

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary makes no payment and there is therefore NO cost incurred by the beneficiary.

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

⚠ Article 12 contains additional cost eligibility conditions.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts of the third party.

Normally, only the *direct* costs of the third party may be declared.

These direct costs may not be based on unit costs[36] or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*). Thus, the beneficiary cannot, for instance, use the unit costs for SME owners or natural persons who do not receive a salary.

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises. In this latter case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on these costs *(see Article 6.2.E)*.

If the indirect costs are claimed in this way, the beneficiary may not include them a second time in its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 to the GA.

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**'; *see Article 11*).

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

[36] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[26]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [27]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[26] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[27] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on 'business conditions'

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from 'linked third parties'; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2)*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

Stricter rules apply to information that is 'EU-classified' or subject to a 'security recommendation' in Annex 1 of the GA *(see Article 37).*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Best value-for-money or lowest price

The beneficiaries must base their subcontracts on the 'best value-for-money' considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i..e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value-for-money principle does not require **competitive selection procedures** in all cases. (However, if a beneficiary did not request several offers, it must demonstrate how best value-for-money was ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.)

In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI). It is important not to confuse a Research and Innovation action, or an Innovation action, involving PCP or PPI with a PCP/PPI Cofund action. For the latter, the main objective of the action is the implementation of a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI).

The additional rules mirror the key obligations from the H2020 MGA PCP/PPI Cofund.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA ('**simplified approval procedure**').

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the **full discretion** of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the full risk of non-approval and rejection of costs by the Commission/Agency.

5. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 1(9) of that Directive*).

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* — cannot be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Existing framework contracts or **subcontracts** — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with best value-for-money and absence of conflict of interests at the time of their award.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[28] and **third parties with a legal link to a beneficiary**[29] ('**linked third parties**') may implement the action tasks **attributed to them in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked parties]

*The linked third parties **may declare** as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

[28] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[29] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).

  The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only '**affiliated entities**' or '**entities with a legal link to a beneficiary**' can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; 'ad hoc' collaboration agreements or contracts to carry out work in the action are NOT covered. (In this latter case, both legal entities should be beneficiaries.)

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or
- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*

- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities *composed of members (where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Examples (affiliated entities):

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not listed in the work programme/call) are not eligible for funding under Article 10 of the Rules for Participation.*

For more information on conditions for participation and funding, *see the Online Manual*.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak'
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

1. *The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

3. *The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.*

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

For more information on the financial viability/capacity check, *see the Online Manual*.

[38] *See Articles 8 and 9 of the Rules for Participation.*

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO 'simplified approval procedure'.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **cost eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

Each linked third party has to provide its own ***certificate* on the financial statements** *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each linked third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties only where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*)

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[30] must provide access to research infrastructure or installations[31] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country**[32] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]]*[33]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

***[OPTION:** Not applicable]*

30 **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

31 **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

32 For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

33 If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures' under the following topics:
  - 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[39] or installation[40] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category 'specific cost category – access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

The beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions

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[39] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU Member State or H2020 associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. Additional eligibility condition: Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[35] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for **any purpose** *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission may request information at **any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. 'My Area' in the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary must keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, validation and data updates, *see the Online Manual*.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

> ***Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[36]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[36] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For personnel costs declared in accordance with their usual cost accounting practices (i.e. '**average personnel costs**'), the beneficiaries must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is NOT necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What?

To get additional assurance, a beneficiary/linked third parties may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificates is NOT valid for Horizon 2020.)

When?

Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How?

The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 to the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

> ⚠ Exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a 'declaration on exclusive work for the action' (one per reporting period), to confirm that the person worked exclusively for the action, either:
  - during the whole reporting period or
  - during a an uninterrupted time-period, covering at least a full natural month within the reporting period.

    Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration.

    If a person worked randomly for the action after an uninterrupted time-period covered by a declaration, time records for the period of random work.

    > ***Example:*** *the person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

  The declaration must be dated and countersigned for acceptance by the person concerned.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. timesheets)*.

- keep **time records**.

  Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (even if it the person keeps time records). This way the declaration can serve as evidence that that the person worked for the action all its annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  If the time-recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

  Time records should include:

  - the title and number of the action, as specified in the GA
  - the beneficiary's full name, as specified in the GA

- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record; for reasons of assurance and legal certainly it is highly recommended that the number of hours is detailed per day (hours worked for the action in each day)
- the supervisor's full name and signature
- a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned and the person-months reported to the action
- a brief description of the activities carried out, to understand and show what work was carried out.

Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

A template for time-sheets is available on the Participant Portal. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the full risk of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned;

Criterion 2 is met – the project is identified as XYZ;

Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;

Criterion 2 is not met: the project name is not mentioned;

Criterion 3 is not met – the time is not quantified.

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

> ***Example:*** *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

> ***Examples:***
>
> *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*
>
> *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must **submit** them through the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*) — unless Annex 1 specifies another way.

Specific cases (deliverables):

Classified results — If the deliverables are classified results, they may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1]to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[37]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[37] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of action ('reporting').

> These 'reports' must be **distinguished** from 'deliverables' (that are part of Annex 1; see Article 19) and 'milestones' (that may be part of Annex 1, but are normally neither covered by Article 19 nor by Article 20).

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically created by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration.

Forms and templates for the different parts of the reports are available in the electronic exchange system.

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly** in the **electronic exchange system**, i.e. 'My Area' in the Participant Portal).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress

- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication
- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary).* Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the **coordinator**, who must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary. The linked third parties can NOT view their grants in the electronic exchange system and therefore have no access to them.

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system is correct (i.e. identical to the signed paper version).

If a beneficiary **cannot submit** its individual financial statement on time, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

Technical reports should not contain any information that is 'EU classified' under the Commission internal Rules of Procedure *(see also Article 37, the Online Manual and the Guidance — Guidelines for the classification of research results)*.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on 'cross–cutting issues' (see Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' (*see Article 3 and Annex* I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the whole action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

The coordinator must ensure that none of the material submitted for publication includes confidential or 'EU classified' information.

The summary should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

It may also include a list of all beneficiaries, with contact names (if this information should be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

Some beneficiaries/linked third parties must submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and personnel costs declared on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

This means that costs based on lump sums, flat-rates (e.g. indirect costs) or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

– *average personnel costs*	=	*EUR 250 000*
– *subcontracting costs*	=	*EUR 40 000*
– *depreciation costs of equipment used to carry out the action*	=	*EUR 60 000*
– *indirect costs (25 % flat rate)*	=	*EUR 77 500*
– *total eligible costs claimed by A*	=	*EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or average personnel costs must be covered by the certificate. Incomplete certificates will be returned for correction.

Linked third parties must submit a certificate if it (on its own, without its beneficiary) reaches the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

In both cases, the certificate may only be submitted with the final financial report. The Commission/Agency will not accept certificates submitted at any other moment (and costs incurred for those certificates will not be considered eligible, because not necessary).

The certificate must be issued by an **external auditor**, using the template in Annex 5.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a third country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[44].

    Procedure for calculating the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

    Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline (see *Article 47*)
- terminate the GA if the coordinator continues to breach its obligations after a written reminder (see *Article 50*).

It may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][38]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts prior to that)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or another executive agency — without the consent of the beneficiary concerned and up to the 'maximum EU contribution' foreseen for that beneficiary in Annex 2.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the **amount** is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100 % of the average EU funding per period (i.e. maximum grant amount set out in Article 5.1 / number of periods) for actions with at least two reporting periods. (It will be however less for actions with only one reporting period, since 100 % would mean the totality of the grant amount.)

At the moment of the pre-financing, an amount that corresponds to **5 %** of the maximum grant amount *(see Article 5.1)* is **deducted** from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:
Maximum grant amount: EUR 1 000 000 with 100 % reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90 % of the maximum grant amount minus the pre-financing

Example for calculating interim payments:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1; application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The **amount** of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples for calculating the payment of the balance:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.

Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).

Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.

Total eligible costs accepted for 1st interim period: EUR 537 500;

1st interim payment: EUR 500 000 (the 90% limit is reached).

Total eligible costs accepted for 2nd interim period: EUR 162 500.

2nd interim payment: EUR 0 (the 90 % limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*

Final grant amount: EUR 750 000.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*

The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*

Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.

Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.

*EUR 150 000 will be **paid** to the coordinator as follows:*

- *EUR 100 000 directly by the Commission as payment of the balance; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*

Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check *(see Article 17)*. All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks remotely, based on documents it received beforehand.

It can do so using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

Example: *Ethics checks are normally carried out with the help of external experts.*

If the check shows ineligible costs or the violation of 'other obligations' under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows improper implementation of the action, ineligible costs or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the beneficiaries will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days ('**contradictory review procedure**'). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant, etc. under Articles 41 to 46.)

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit* ***linked third parties****, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit* ***third parties providing in-kind contributions*** *(free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit* ***contractors*** *or* ***subcontractors****, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value-for-money or, if appropriate, the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

4. *The Commission/Agency may audit* ***recipients of financial support*** *or* ***prizes****, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, ineligible costs, improper implementation of the action or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission may also audit the accounting records of beneficiaries to obtain general information about actual costs for cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct

consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory audit procedure**'). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the '**letter of audit conclusions**' (and the file will then be passed on to the operational services (authorising officer) for audit implementation, if necessary).

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[39] and No 2185/96[40] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

39 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

40 Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42-44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[41], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[41] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable**]

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

> ***Example:*** *A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the *[Agency or the]* Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the *[Agency or the]* Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the *[Agency or the]* Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the *[Agency or the]* Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings

Findings in checks, reviews, audits or investigations may be **extended** to other grants.

Extension of findings is possible for ALL H2020 grants — regardless of the entity that awarded the grant (i.e. Commission, executive agency or H2020 funding body).

If the Commission/Agency finds substantial errors, irregularities, fraud, improper implementation or serious breach of other obligations that are **systemic** or **recurrent**, it may make a correction (rejection of costs or reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and

  - reporting periods that were not audited/reviewed ('extension of the findings')
- other H2020 grants of the beneficiary ('extension of the findings').

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

> ***Examples (recurrent):*** *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

> ***Examples (systemic):*** *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld after this contradictory audit/review procedure, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an 'audit extension procedure' (which is then followed by 'audit/review implementation').

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure ('**letter of audit conclusions**'), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for ineligibility of costs:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (to be used if the beneficiary does not submit revised financial statements)
  - the conditions for the external counter audit needed to propose an alternative correction method *(see below)*
- for improper implementation or breach of other obligations: the proposed flat-rate for the correction.

The 'extrapolation rate' will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The 'flat-rate' will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit the revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept an alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for ineligibility of costs: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for improper implementation or breach of other obligations: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative correction method and there is no entitlement to it.

Step 3 — Audit implementation. If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the costs to be rejected/reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the costs to be rejected/reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:** five]**[OPTION for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[42].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[42] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

> **Best practice:** Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

> ***Examples:*** *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

> ***Example:*** *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

> ***Example:*** *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[43] established in an EU Member State or '**associated country**'[44], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[44] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED RO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 <u>Rights of third parties</u> (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

The joint ownership status may **change**:

- it may need to be reviewed later on, when protecting the results.

  Example:

  Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

  A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

  However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.
- joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. employees, subcontractors, linked third parties etc.)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Examples (arrangements): *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14)*, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):
For an invention: e.g. patent, confidential information.
For the design of a technology: e.g. industrial design, copyright.
For a website: e.g. industrial design, copyright, trademark.

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (i.e. use where relevant the wording from the corresponding translation of the MGA that is available on the 'Reference documents' page of the Participant Portal).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the 'plan for the exploitation and dissemination of the results'.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security-related obligations, etc.)*.

The beneficiaries may choose the **form** for disseminating their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination— unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

2. Open access

For detailed information on open access, see *Guidelines on Open Access to Scientific Publications and Research Data* and the *Guidelines on Data Management*.

3. Visibility of EU funding

Any dissemination of results (in any form) must include the reference to EU funding set out in the GA *(see Article 38*).

Best practice: Where possible, beneficiaries should make this reference in the language of the dissemination activity (i.e. use where relevant the wording from the corresponding translation of the MGA that is available on the 'Reference documents' page of the Participant Portal).

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —****]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions* ***]***

[OPTION: *Not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results — unless prohibited (or restricted) by security-related obligations *(see Article 37)*.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

- The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

- Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

  The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

  Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a 'global' authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

Example: *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country (i.e. not EU Member State or H2020 associated country) must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

Best practice: Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

Exclusive licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a third country (i.e. not EU Member State or H2020 associated country).

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to beneficiaries not receiving EU funding *(see Article 9)*.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[45], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results

- by an affiliated entity (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [46], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[46] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[50] and of the Code of Conduct[51] that relate to recruitment, working conditions and career development.

For guidance, *see the 'Human Resources Strategy for Researchers' tool developed by the Commission.*

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[52])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[52] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more information on gender in research, *see the Online Manual.*

ARTICLE 34 — ETHICS

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[47] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct; *see also the European Code of Conduct for Research Integrity*[53]).

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols (for other texts, *see the Science in Society e-library*[54]).

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

- 'ethics self-assessment' (by the applicants, in their proposal; *see the proposal templates and the Guidance — How to complete your ethics self-assessment*)

[53] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[54] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

- two-stage 'ethics review', with an ethics screening and, if necessary, an 'ethics assessment' (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more information on ethics in research, see *the Online Manual.*

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must ALSO be allowed in at least one Member State.

The beneficiaries must confirm in the 'ethics self-assessment' section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board*.

Moreover, the coordinator must — before the activity starts — submit **copies** of the following,:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation **costs**, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

There is NO need to submit copies of requests for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[55] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[55] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value-for-money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

  If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

  If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[48], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[48] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Stricter confidentiality obligations apply for information that is 'EU-classified' or subject to a 'security recommendation' in Annex 1 of the GA *(see Article 37)*.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *Not applicable****]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

1. Results with a security recommendation — Classified results

If the GA provides for (one of these) options, the beneficiaries must comply with the **specific security-related obligations** ('security requirements') set out in Annex 1 (via a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)') and in this Article and other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises 'security issues', the Commission/Agency will make them subject to a security recommendation and/or classify the results (under the Commission internal Rules of Procedure).

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[56].

Moreover, the coordinator must — before the action starts — submit a **copy** of:

- any export or transfer licence.

[56] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Communication activities (by the beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[57].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

Information given may NOT include classified (or otherwise restricted) results *(see Article 37)*.

[57] For the definition of 'communication activities', *see the Glossary*.

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the proposal templates*) and be included in Annex 1 and 2.

For more information on promoting the action, *see the Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the EU emblem

AND

- including the reference to EU funding set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity (or, for infrastructure, equipment or major results, the official language(s) of the country where they are located). Where relevant, beneficiaries should use the wording from the corresponding translation of the MGA that is available on the 'Reference documents' page of the Participant Portal).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object). ***Examples:*** *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[49], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][insert the name of the Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[49] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities (by the Commission/Agency)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material): *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[50] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statements (SSPS)' that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[50] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (by the Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its privacy statements on the Participant Portal ('service-specific privacy statements (SSPS)'[58]).

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the financial interests).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[59] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

[58] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.
[59] Available at http://ec.europa.eu/dpo-register/search.htm.

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the service specific privacy statements (SSPS) (see above), before transmitting their data to the *[Agency or the]Commission.*

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (by the beneficiaries)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[60] — or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [61]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use

[60] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[61] *See Article 8 of Directive 95/46/EC*.

- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[62]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the SSPS).

Examples:

Before encoding its staff's personal data in the 'Beneficiary Register' or into a proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the relevant SSPS.

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[62] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]**

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What?

The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is NOT possible for future claims.

How?

Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.

Assignment for the benefit of creditors in a bankruptcy procedure.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not subcontract these tasks to any third party.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% retained from the pre-financing for the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION:** Not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

The coordination agreement must not contain any provision contrary to the Agreement.]

***[OPTION:** Not applicable]*

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can NOT be subcontracted or outsourced to a third party. They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use in-kind contributions for *other* tasks; *see Articles 11, 12, 13*).

Specific cases (coordinator):

Authorisation to administer — Secondary or higher education establishments and public bodies may exceptionally delegate the coordination tasks listed in Article 41.2 (and other administration tasks, if needed) to another legal entity (third party), in most cases a foundation.

> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

The third party must fulfil the following conditions:

- it must have been granted the 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

It must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article) can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action).*

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

Costs for scientific coordination can be eligible, if they comply with the eligibility criteria set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see the Online Manual and the Guidance — How to draw up your consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted for 'complementary actions' *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted for 'jointly funded actions' *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

- The coordination agreement should **complement** the grant agreements and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

- Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

- The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see the Online Manual and the Guidance — How to draw up your coordination agreement.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

⚠ A '**rejection of costs**' will be made for any **violation of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request by the coordinator/beneficiary concerned — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-**

information letter for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) **in-between payments**, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example for calculating a rejection at an interim payment/payment of the balance:

Case 1: *Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.*

Maximum grant amount: EUR 500 000.

Pre-financing: EUR 200 000.

Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25 %) = EUR 118 750.

Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25 %) = EUR 143 750.

Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25 %) = EUR 112 500.

Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:

Application of the reimbursement rate: 100%: EUR 362 500

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.

Amount due as interim payment: EUR 250 000

Case 2 (in between payments): *Total costs declared for the action in the 1st periodic report: = EUR 375 000*

Interim payment for the 1st periodic report = EUR 375 000

Cost rejected after interim payment or 1st periodic report: EUR 12 500

Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000

Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example for calculating a rejection after the payment of the balance:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount set out in Article 5.1 (— in proportion to the improper implementation of the action or the seriousness of the breach).

A '**reduction of the grant**' is possible for **any breach of obligation** (under the GA or applicable EU, international and national law; *see Article 7)* and it will be made in proportion to the seriousness of that breach *(e.g. in case of fraud, systemic irregularities or submission of false information — in the award procedure or during action implementation the reduction may be up to a 100%).*

Reduction of the grant can take place at or after the payment of the balance, NOT before.

If improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

A reduction can also be due to a beneficiary not receiving EU funding (i.e. improper implementation or breach of obligations by that beneficiary; *see Article 9*).

2. Procedure

The Commission/Agency will follow a contradictory procedure (for the basic contradictory procedure, *see Article 42*).

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant *at the payment of the balance*, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example for calculating a reduction at the payment of the balance:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)

Pre-financing: EUR 750 000

Interim payments: EUR 1 500 000

Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20 % (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.

Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000

Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000

Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the Commission/Agency reduces the grant *after the payment of the balance*, it will calculate a **revised grant amount** at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Example for calculating a reduction after the payment of the balance:

Step 1 reduction of the maximum grant amount

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).

Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:

The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3 % (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 allocation to each beneficiary

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *The improper implementation is due to the fact that beneficiary A carried out only 50 % of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:

Lower between costs accepted (EUR 700 000) and 50 % of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50 % x 800 000 = EUR 400 000) = EUR 400 000

For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *The breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:

beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333

beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667

beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):

The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:

beneficiary A: 700 000-693 333 = EUR 6 667

beneficiary B: 1600 000-1 386 667 = EUR 213 333

beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[51] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[51] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable****]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

The Commission/Agency will '**recover**' the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

Recovery normally takes place only at payment of the balance or afterwards. Exceptionally, it can take place before, if a beneficiary's participation is terminated.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[63]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered 'paid'.

[63] *See Article 80(1) of the Financial Regulation.*

Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission/Agency may offset before this date, in order to safeguard the EU's financial interests.[64]

If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. (The interest is normally offset first, before the principal amount).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or
    - adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[65].[66]

      The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency will recover *after termination* of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

4. Recovery at the payment of the balance

The Commission/Agency will recover *at the payment of the balance*, if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

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[64] *See Article 87 of the Rules for Application.*

[65] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[66] *See Article 79(2) of the Financial Regulation.*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

For the rest of the procedure, *see point 2*.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery at the payment of the balance:

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100 %
Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)

Total eligible costs approved by the Commission: EUR 2 430 000

Final grant amount: EUR 2 430 000

EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000

Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5 % of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:

A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

Step 1: identification of the beneficiaries that received funds in excess:

Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);

beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)

beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);

beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Step 2: distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:

The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.

Total payments made in excess = 320 000.

Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.

Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.

Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium.

5. Recovery after payment of the balance

The Commission/Agency will recover *after payment of the balance*, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid too much (or that the coordinator has not distributed the payments received).

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount *(see point 4)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

For the rest of the procedure, *see point 2*.

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

'Underspent GA' means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

– **for an overspent GA:** Each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example for calculating a recovery in an underspent GA:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:

(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example for calculating a recovery in an overspent GA:

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C

Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000

Reimbursement rate for all the beneficiaries: 100%

Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000

Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000

Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000

Total eligible costs of the consortium approved by the Commission = EUR 600 000

Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1: Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary approved costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*

EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667

Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000

Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2: Calculation of the revised grant amount after the audits:

The revised final grant amount is calculated as follows:

For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500

For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3: Calculation of the amount to be recovered:

The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount

For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered

For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. Since for Beneficiary C the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Agency or the]* Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation no 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose administrative and/or financial penalties (— in proportion to the seriousness of the misconduct).

'**Financial and/or administrative penalties**' are possible (in addition to other measures) for **serious misconduct** (i.e. substantial errors, irregularities or fraud, serious breach of obligations or false declarations) and will be imposed in proportion to the seriousness of the misconduct.

Examples: *plagiarism; absence of time-recording systems (although required); false declaration concerning SME status.*

The **maximum penalties** are as follows:

- for *administrative* penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for *financial* penalties: between 2% and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and **20%**.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

The Commission/Agency may **publish** the decision to apply penalties on their websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU's financial interest and image)
- the time that has elapsed since it took place
- the duration and recurrence of the misconduct
- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned (for the basic contradictory procedure, *see Article 42*).

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount

The basic recovery procedure *(see Article 44)* applies.

However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

Example for calculating a financial penalty:

GA with a maximum grant amount of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

During an audit of the first reporting period, the Commission finds that beneficiary A has overdeclared its personnel costs by 20 % and has falsely certified that the information on the time spent on the action set out in the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5 % of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5 % of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overdeclared its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15 %.*

New financial penalty: 15 % of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overdeclared its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15 %, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15 % of 450 000 = EUR 67 500.

Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability (of the Commission/Agency) for damages

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

- causes damage to a third party (including another beneficiary)

  Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

- suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability (of the beneficiaries) for damages

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency (— for the amount of damage caused).

Examples: *Costs of legal proceedings borne by the Commission.*
At a meeting on Commission premises, a beneficiary smokes and causes a fire.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned (for the basic contradictory procedure, *see Article 42*).

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

The basic recovery procedure *(see Article 44)* applies.

However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

If the damages are not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (by the Commission/Agency)

The Commission/Agency may 'stop the clock' (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

'Suspension of the payment deadline' must be distinguished from 'suspension of payments' (see Article 48). Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary that is, for example, suspected of serious misconducts.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs

  This is not an in-depth verification and can therefore not guarantee their eligibility or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.
- calculate the amount to be paid
- approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

  Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*
- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.*
- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (by the Commission/Agency)

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

⚠ 'Suspension of payments' has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments:

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations *(see also Article 50.3)* — either during the award procedure or under the GA.

  Example: *statements made by the beneficiary in the declaration form are found to be false.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

  For the ongoing GAs of the beneficiary, the Commission may suspend:

  - *outstanding pre-financing and/or interim payments to the beneficiary in question*
  - *(if necessary) outstanding payment of the balance for all beneficiaries.*

  until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator (for the basic contradictory procedure, see *Article 42)*.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned.

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted.

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*

15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*

1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*

1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*

10 August: *the Commission pays for all beneficiaries except B.*

25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation (by the beneficiaries)

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

⚠ 'Suspension of the action implementation' may be used exceptionally if it is necessary to stop the implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g.* ***inform*** *the Commission/Agency under Article 17.2;* ***notify*** *a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the '**resumption date**' set out in the amendment), if the Commission/Agency approves the amendment.

> ***Example:*** *The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the Commission/Agency has set a lower budget in the amendment, to adapt the action to the new situation).

> ***Example:*** *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **cannot be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:*** *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*
>
> - *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
> - *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation (by the Commission/Agency)

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations *(see also Article 50.3)* — either during the award procedure or under the GA

  Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

  The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42).*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the GA (or the participation of a beneficiary) may be terminated.

If the suspension leads to the termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the termination of the GA.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative** and/or **financial penalties** *(see Article 45)*.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The beneficiaries have the right to terminate the GA.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

Improper termination of the GA may lead to a reduction of the grant (see *(see Articles 5.3 and 43)*.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. before the notified date on which termination takes effect) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. (The Commission/Agency will not send a reminder and will not extend the deadline.)

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Termination may in principle be based on **any ground**.

If a beneficiary goes **bankrupt** or is wound up, it or the coordinator must **inform** the Commission/Agency and notify the termination of its participation — without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

Improper termination of the participation of a beneficiary may lead to the termination of the GA *(see Article 50.3.1(c))* and/or to a reduction of the grant at the payment of the balance *(see Articles 5.3 and 43)*.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52* of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system; *see the Online Manual*).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

NO amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example: *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so) — unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only **costs** incurred before termination (i.e. before the notified date on which termination takes effect) are eligible— except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. (The Commission/Agency will not send a written reminder and will not extend the deadline.)

If the coordinator fails to submit the *report on the distribution of payments*, the beneficiary whose participation was terminated will NOT have to repay any amounts.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION:*** *not applicable];*

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:
  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
    - termination takes effect after an interim payment and
    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. Termination of the GA or of the participation for one or more beneficiaries (by the Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

Grounds for termination (by the Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the termination of the GA; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55*).

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or the consortium no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [67]

  Examples:

[67] *See also Article 8 of the Rules for Participation.*

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

- **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.

- **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.

The beneficiaries must **inform** the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e.

the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country/IO action does not start by the date specified in Annex 1

  In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country/IO action is terminated

- the third country/IO action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA — substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The*

Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary cdeclared costs in its financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 and 34.3 or of the ethics requirements set out in Annex 1 *(see Article 34.2)*.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and,
  - have a material impact on this grant.

Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*).

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc.), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take

effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. before the date on which termination takes effect) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative** and/or **financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

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ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What?

In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Force majeure normally has no specific effects on the eligibility of **costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

New in Horizon 2020: This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

How?

The party concerned by force majeure must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

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ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[the Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[European Commission][name of the Agency]
[Directorate-General][Department] [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. 'My Area' in the Participant Portal).

The electronic exchange system offers different **functions**:

- viewing and changing the legal entity data in the 'Beneficiary Register'
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the My Area 'messages' function
- formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), via the My Area 'formal notifications' function
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

A formal notification is **considered to have been accepted** ten days after it is sent (— even if it has not been opened by recipient, *e.g. refusal of reception or omission*).

Deadlines that are counted from the date of receipt are counted as of day eleven.

All messages are recorded in the 'grant file' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system (*see the Online Manual*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Coordinator Contacts (CoCos) may submit information to the Commission.*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.*

5. *Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.*

For more information on access and roles in the electronic exchange system*, see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations)*.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[52], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[52] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid.A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

- An amendment is necessary whenever there is a need to **change** the GA (i.e. its 'Terms and Conditions' and/or the Annexes).

⚠ The *general* terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.

If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.

If a linked third party ends its participation, the option in Article 14.1 will be updated to fix its 'end date'.

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and with an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified; to modify Annex 1 following a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation is terminated** *(see Article 50.2 and 50.3)*.

  There are two main cases for removing a beneficiary:

  - if it never became beneficiary (because of non-accession to the GA or non-provision of the requested declaration on joint and several liability).

    In this case, the amendment will be triggered by the Commission/Agency and the beneficiary is removed from the beginning (since it has never been a beneficiary).
  - for other reasons set out in Article 50.

  The amendment may be triggered by the beneficiaries or by the Commission/Agency.

  For termination by the beneficiaries:

  - the request for amendment must be part of the notification of termination
  - it has to include the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency:

  - there has to be a contradictory procedure *(see Article 50.3.2)*
  - after termination, the coordinator must submit (within 60 days from the termination date) the amendment request with all the supporting documents *(see Article 50.3.3).*

There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

If the coordinator is removed, the amendment has to propose a new coordinator.

The 'termination date' will be added to the Preamble and the beneficiary will be entitled to submit costs until that day.

For termination by the beneficiaries: the 'termination date' must be specified in the notification and must be a future date (i.e. after notification; *see Article 50.2.1*).

For termination by the Commission/Agency: the 'termination date' will be either:

- the date specified in notification confirming termination or
- the day after the coordinator receives the notification confirming termination.

Combination with other changes: If the beneficiary was participating with linked third parties, they will also have to be removed (with effect from the same date) and the 'end date of participation' will be added to Article 14.

The termination will normally also imply a change of Annexes 1 and 2.

By contrast, the GA options for the beneficiary (and its linked third parties) will NOT be deleted or become not applicable (since they were part of the GA and (many) obligations continue to apply after termination).

- **Adding a new beneficiary** *(see Article 56.2)*

The new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC),'

The request for amendment must include;

- Annex 3 (Accession Form) signed by the new beneficiary in the electronic exchange system (i.e. via 'My Area' in the Participant Portal; *see Article 52*) before submitting the amendment request,
- a PDF copy of the signed Annex 3a (declaration of joint and several liability of its linked third parties if requested by the Commission/Agency),
- Annex 3b (Administrative Arrangement signed by the Joint Research Center (JRC), if applicable).

The 'accession date' will be added to the Preamble of the GA.

The new beneficiary has to indicate the accession date in its Accession Form.

Combination with other changes: The addition will also imply a change of Annexes 1 and 2 and — depending on the type of beneficiary and its H2020 status(es) — GA options will be added.

Examples:

If the new beneficiary is an international organisation, the options for international organisations under Articles 22.4 and 53.2 will be added to the GA and the options under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Adding or removing a linked third party** *(see Article 14)*

Although they are not beneficiaries, the change of a linked third party (i.e. if it ends its participation or joins the action) also requires an amendment to update Article 14 (to state/remove their name and to fix their starting/end date).

The new linked third party must first be registered (and validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC)'.

NO amendment is necessary for a change of name; a change of the linked third party data (and validation) in the 'Beneficiary Register' is sufficient.

- **Change of beneficiary due to partial takeover** (called 'partial transfer of rights and obligations' in FP7)

> ⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

What? '**Partial takeover**' means that a PART of the business of the beneficiary (including the GA) is taken over by (one or more) other entity(ies) ('transfer of a business unit as a going concern', *e.g. partial acquisition, distribution of a business unit on dissolution/liquidation, division/demerger, etc.).*

'**Partial acquisition**' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorb or take over part of the rights and obligations of the original entity). Thus, some of the rights and obligations (and contracts) of the original entity are transferred to the new entity (i.e. a partial transfer of the rights and obligations of the original entity). Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'**Distribution of a business unit on dissolution/liquidation**' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entity(ies) purchase(s) a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only some of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'**Division/demerger**' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has one ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two 'partial takeovers': one to company E and one to company O.*

> ⚠ The new beneficiary(ies) will (each) be **fully** jointly and severally **liabl**e with the former beneficiary for recoveries under Article 44. (By contrast: No joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

What not? Simple **sale** of (one or more) **assets** of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. (In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary).

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

⚠ NO amendment is necessary for '**universal takeovers**' (i.e. where the original entity is replaced by one new entity and all the rights and obligations are transferred to this new entity); a change of the beneficiary data (and validation) in the 'Beneficiary Register' is sufficient (*see below*).

How? The coordinator must request an amendment; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as 'new beneficiary').

'New beneficiary' is used only for the purpose of the amendment; it may means either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular, explain the financial liability of the former beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts, if possible). (Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.)

If the new beneficiary joins the GA, it must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code' (PIC).

- **Changes to the status of a beneficiary/linked third party as 'receiving EU funding' or 'not receiving EU funding'**

If the status of a beneficiary/linked third party — exceptionally — changes during action implementation *(e.g. due to a change of establishment)*, this change of status will require an amendment.

Example: *Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.*

New association agreements (between the EU and third countries) do NOT have an impact on ongoing grants. The beneficiaries keep the status they had at the moment of the signature of the GA.

- **Change of coordinator**

If the new coordinator is not a beneficiary of the GA, it must first accede to the GA as a new beneficiary *(see Article 56.2)*. The former coordinator may continue to participate in the action as a beneficiary or may terminate its participation.

An amendment to change the coordinator remains possible (and necessary) *after* the end of the action *(see Article 3)*.

The 'handover' date will be added to the Preamble of the GA.

The beneficiaries may choose a 'handover date' in their amendment request. (If the former coordinator leaves the consortium, this date must be after the 'termination date'; if the new coordinator joins the consortium, the date must be after the 'accession date'). Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the coordinator's bank account for payments**

An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

The bank account data must first be updated in the Beneficiary Register (and be validated).

NO amendment is necessary for a change of the name of the bank, address of branch or name of the account holder; a change of the bank account data (and validation) in the 'Beneficiary Register' is sufficient.

- **Change of the option for 'authorisation to administer'**

  The option in Article 41.2 can be added/deleted or changed *(e.g. change of name of the entity with 'authorisation to administer")*.

- **Change of the action's title and/or acronym**

  Example: *the consortium finds out that the acronym of their action is a protected trademark.*

- **Change of the starting date, action duration or reporting periods**

  Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

  An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

  ⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

  The amendment request must specify the dates when the suspension started and ended. The action implementation is then automatically resumed as from the following day ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:
  - a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning **in-kind contributions** provided by third parties (against payment or free of charge) or **subcontracts**

    Such changes could in principle also be made via the 'simplified approval procedure' *(see Articles 11, 12 and 13)*; however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency agreement (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency could consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).
  - changes concerning the tasks to be carried out by **linked third parties** and related costs
  - changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount *(see Article 5.1)* and/or the action's estimated eligible costs *(see Article 5.2)* will be accepted ONLY in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount *(see Article 5.1)* can NEVER be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2** and Annex 2a **(estimated budget)** which require an amendment *(see Article 4)*, in particular:
  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

– a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*.

Examples:

1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices ('average personnel costs').*

2. *An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to modify the action's estimated budget in Annexes 1,2 and 2a.*

Best practice: If Annex 2a needs to be changed, the beneficiaries should contact the Commission/Agency (via the My Area 'messages' function).

- **Change concerning specific cost categories ('specific unit costs')**

If the options in Articles 5.2 and 6.2 must be added/deleted, an amendment to the GA is necessary.

Best practice: If the change concerns specific unit costs, the beneficiaries should contact the Commission/Agency (via the My Area 'messages' function).

Indicative list of cases where NO amendment is needed:

- **Budget transfers not listed above**

Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary, linked third party or coordinator**

Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA do NOT require an amendment; an update of the beneficiary/data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

Linked third parties must **inform** their beneficiary who must inform the Commission/Agency (since they do not have a LEAR) (via the electronic exchange system) *(see Article 17.2)*. The data will be updated in the Beneficiary Register by the Commission/Agency and validated.

If — exceptionally — the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may then request it.

Example: *Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.*

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

Transfers of the GA linked to a **universal takeover** (i.e. where the original entity is replaced by one new entity and all the rights and obligations (including the GA) are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the 'Beneficiary Register' is normally sufficient.

Example: *Beneficiary X merges with another existing entity Y by:*

– *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*

– *establishing a new separate legal entity (X and Y are together known as 'Z').*

If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may then request it.

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.*

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

In addition to updating the data in the Beneficiary Register, the beneficiary must **inform** the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the electronic exchange system) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

How?

Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) **directly in the electronic exchange system** (i.e. 'My Area' in the Participant Portal; *see Article 52*).

Best practice: If none of the amendment clauses available in the IT tool are appropriate, beneficiaries should contact the Commission/Agency (via the My Area 'messages' function), to discuss the amendment.

⚠ Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the 'Beneficiary Register'.

Examples:

A new beneficiary must be validated ('legal entity validation'). This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

Validation of the new bank account, to change the bank account.

⚠ The amendment request must include the necessary information and supporting documents.

Examples:

For a change of coordinator without his/her agreement: the coordinator's opinion (or written proof that this has been requested).

To add a new beneficiary: an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

To amend Annexes 1 and 2: amended versions of these annexes.

⚠ A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action, i.e. the date set out in Article 3). Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance*)).

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Before it has been accepted or rejected, it may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

If accepted it will be **counter-signed** by the receiving party (again, directly in the electronic exchange system by the PLSIGN).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

The other party must — within **45 days** — **agree or disagree**, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

If the parties agree on a specific date, it should normally be *after* the entry into force. In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

Where a new beneficiary is added to the GA, it must assume the rights and obligations from the 'accession date' specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the 'resumption date' set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (by the beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* in the electronic exchange system (together with the declaration(s) of joint and several liability, if any). They must do this within 30 days after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on joint and several liability *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

If the beneficiary does not submit this declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Linked third parties do not become parties to the GA and therefore do NOT sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020). All documents are available in the electronic exchange system (i.e. 'My Area' in the Participant Portal).

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated — unless it already has a validated 'participant identification code (PIC)'
- sign the Accession Form directly in electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium *[**OPTION for international organisations that do not accept application of Union law:** except for [insert name(s) of the international organisations concerned]].*

[OPTION for international organisations that accept application of Union law but not Belgian law:** For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].**]

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations for international organisations:

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[68]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA.

[68] *See Article 180(1) of the Rules of Application.*

	In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).****]***

1. Dispute settlement

As a general rule, Horizon 2020 GAs contain an 'Article 272 TFEU arbitration clause', referring **disputes on the interpretation, application or validity of the GA** to the Court of Justice of the European Union.

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against 'confirmation letters', 'debit notes', etc.; NOT against 'audit reports', 'letters of audit conclusions' 'pre-information letters', etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative or financial penalties, offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions (by any beneficiary — including non-EU beneficiaries, 'beneficiaries not receiving EU funding' and IOs) must be brought before the Court of Justice of the European Union under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ All procedures are organised in a way that the beneficiaries will be **informed** of the available **means of redress** (via a 'redress clause' in the letters).

For more information on complaints*, see the Online Manual.*

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, disputes on the interpretation, application or validity of the GA are normally referred to the competent Belgian courts. (So far (i.e. until end of 2014) none of the agreements associating third countries to Horizon 2020 provides for the sole jurisdiction of the Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Non-EU beneficiaries not receiving EU funding and **international organisations (IOs) —** For beneficiaries not receiving EU funding and international organisations disputes on the interpretation, application or validity of the GA, disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[69]).

Disputes of public law nature remain before the European Court of Justice.

[69] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)
- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for principal beneficiary not receiving EU funding:*** *as 'beneficiary not receiving EU funding' (see Article 9),**]*** represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

[OPTION by default: 'principal investigator':[4]

- *[**Name**][Date and place of birth]**]***[5]

[OPTION for SyG: 'corresponding principal investigator':

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]].**]***

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

*[same for each beneficiary**]***

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

- Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that hosts (and or employs/engages) a **principal investigator** ('**host institution**').
- The PI is usually employed (or engaged) by the host institution for the entire action duration.

The PI and the host institution must also sign a 'supplementary agreement (SA)' *(see Article 32)*.

The supplementary agreement can NOT replace the employment/engagement contract.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

PIs can be of any nationality, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted by a host institution that is based in an EU Member State or H2020 associated country and can receive EU funding.

Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

The Agency must be **informed** before any change in employment or location of the PI.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities. The engagement of the team follows the rules of the beneficiary and its country.

PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions must sign a '**supplementary agreement (SA)**' *(see Article 32)*.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party *(see Article 8)*, i.e.:

- a third party from an EU Member State or H2020 associated country that provides the PI as in-kind contribution or
- a linked third party.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution *and* the third party.

Retired PI — The PI may be retired (i.e. normally no longer under an active labour contract).

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties)

Portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'.

Thus, the ERC MGA does NOT have:

- 'personnel costs for providing trans-national access to research infrastructure'
- 'direct costs of providing financial support to third parties'
- 'specific cost categories'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[70]

It does NOT use the unit costs of the 'specific cost categories' of the General MGA.

[70] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* **—** with the exception of 'direct costs of providing financial support to third parties', 'specific cost categories' and 'costs for providing access to trans-national research infrastructure'.

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the **following specificities**:

– for 'direct personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: as 'personnel costs – costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3)).

– for 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs' (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs, and research data) are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

2. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

⚠ ERC grants do NOT prevent PIs from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ℹ For more information on how to combine EU funding from different programmes ('complementary EU funding' or 'synergies'), *see the Online Manual.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (NOT with other beneficiaries or linked third parties — unless s/he is exceptionally employed/engaged by a third party.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

In addition, the beneficiaries must however prove that the **time-commitment of the PI** (as described in Annex 1) was complied with.

Thus, they must be able to provide evidence that the PI complied with the minimum time-commitment set out in the ERC work programme for *time spent on the action* (percentage of the total working time, i.e. annual productive hours calculated in compliance with Article 6) — via time-sheets or alternative time recording systems.

Moreover, they must be able to provide evidence that the PI complied with the minimum time-commitment set out in the ERC work programme for *research work in a EU Member State or H2020 associated country* — via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
    - information about the scientific progress of the work
    - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
    - information on whether and how open access has been provided to these results *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
    - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How?

All reports must be prepared and submitted **directly in the electronic exchange system**, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

Example: *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

[OPTION:** Not applicable**]

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

ERC grants have however the **following specificiti**es:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

> ***Examples:*** *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

Moreover, the ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

Also, for publications issued after the end of the action, beneficiaries are NOT obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

Moreover, with explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[71] or other systems).

> **Best practice:** If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the **following specificities**:

For ERC actions, there is NO formal requirement for a 'data management plan'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

[71] For more information, *see http://www.doi.org/.*

Moreover, the exception allowing beneficiaries NOT to give access to specific parts of research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives. (For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.)

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[36] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary *[**OPTION for SyG:** and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement *[**OPTION for SyG:** and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[36] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005.p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow for transfer of the GA to another host institution (**portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** for the beneficiary and contribution to the **financial reporting**
- Meeting the time commitments for **implementing the action**
- Applying the beneficiary's usual management practices

- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**
- Upholding the **intellectual property rights** of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: *The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.*
- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the beneficiary and the PI, to set out their internal arrangements for implementing the grant. It is **purely internal**; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must last at least for the action duration *(see Article 3)* (**—** without any interruptions, even if the PI works only part-time on the ERC project).

The supplementary agreement must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and can not be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

The supplementary agreement must be concluded **before GA signature** (and a copy must be sent to the Agency).

A model supplementary agreement is available on the Participant Portal and the ERC website. (The model is not mandatory; beneficiaries may may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research or PoC grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties).

Portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC homepage*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new beneficiary — at any time during the action implementation.

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

⚠ NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 of the H2020 General MGA)*.

The beneficiaries may choose to let the transfer **take effect** from the entry into force of the amendment or a specific 'transfer date' (before or after the amendment). (Retroactive dates are allowed only in exceptional cases and with a specific justification.)

Best practice: For a retroactive transfer date, the beneficiaries should contact the Agency in advance (via the My Area 'messages' function).

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** the remaining **pre-financing** (not covered by eligible costs) to the new host institution.

If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will NOT pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount set out in Article 5.1.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary). **Scientific reporting periods** will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

A certificate on the financial statement (CFS) must be submitted by the former host institution prior to the last reporting period if it reached the threshold set up in Article 20.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research or PoC grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, it may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

II.3 H2020 ERC MGA PoC: Annotations

The H2020 ERC MGA PoC is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability (*Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not found by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(f) *a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

(g) *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)****]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Periodic reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) *a summary for publication by the Agency;*

(b) *an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

(c) *detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

(d) *an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What?

For ERC PoC actions, the principal beneficiary must submit reports — only one '**report**' if there is one reporting period, otherwise one '**periodic report**' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a 'certificate on the financial statements (CFS)' will have to be added (if necessary).

How?

All reports mut be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie (MSC) MGAs

III.1 Background information and approach

The Marie Skłodowka-Curie (MSC) Model Grant Agreements are used for grants for MSC actions only, i.e.:

- MSC-ITN
- MSC-IF
- MSC-RISE and
- MSC-COFUND.

The MSC MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA MSC-ITN deviates from the General MGA as follows:

- Article 4.2 (MSC-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to ‘mainstream media coverage’)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

The H2020 MGA MSC-IF deviates from the General MGA as follows:

- Article 3 (notified starting date)
- Articles 4.2, 8-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSC-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSC-IF specific conditions for termination)
- Article 55 (MSC-IF specific conditions for amendments)
- Article 56a (MSC-IF portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The H2020 MGA MSC-RISE deviates from the General MGA as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSC-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (MSC specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

The H2020 MSC-COFUND deviates from the General MGA as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of programmes)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 8-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSC actions are added:

- Article 2 (MSC-ITN actions; MSC-IF actions; MSC-RISE actions; MSC-COFUND actions)
- Article 4.1 (MSC-ITN budget categories; MSC-IF budget categories ; MSC-RISE budget categories; MSC-COFUND budget categories)
- Article 8 (MSC-ITN rules on third party involvement; MSC-IF rules on third party involvement; MSC-RISE rules on third party involvement; MSC-COFUND rules on third party involvement)

III.2 H2020 MGA MSC-ITN: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-ITN actions

What? MSC-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by 'networks' of universities, research institutions, research infrastructures, businesses, SMEs and other socio-economic actors from different countries).

MSC-ITN actions take the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSC-ITN actions are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSC-ITN actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

***[OPTION for all actions except EID:** However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.]*

1. Budget categories

The MSC-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSC-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may re-distribute *person-months* between them (as compared with the original planning set out in Annex 2) — without requesting an amendment *(see Article 55)*.

⚠ The maximum grant amount *(see Article 5)* can however NEVER be increased.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the distribution of the institutional unit cost for management tasks do NOT need to be notified to the Agency.

***Example:** Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

Budget transfers will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Transfers are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment *(see Article 55)* will be required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID: the 40 % limit of budget allocated to beneficiaries established in the same country or to the same international European interest organisation or international organisation.

  The 40% is counted on the basis of the number of person-months allocated to each beneficiary in Annex 1.

Transfers between *budget categories* are, by contrast, NOT possible because MSC unit costs are all linked to the person-months declared for the recruited researchers.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-ITN actions, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[72].

For MSC-ITN these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[72] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC uses only unit costs, there is NO reduction due to the no-profit rule in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiary (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country where the research training activities take place for more than 12 months in the 3 years immediately prior to the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country).

For beneficiaries that are the international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately prior to the recruitment date;

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree[;][.]**]***

(viii) ***[OPTION for EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

1. Costs for recruited researchers: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover costs related to their mobility, *e.g. relating to travel and accommodation*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by the budget category 'research, training and networking costs"

AND

- a monthly family allowance for researchers with family, to reduce family-related obstacles to researcher mobility.)

The mobility and family allowances are due to the researcher for each month worked.

What not? Costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

Example:

Costs for student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[73] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** per researcher per month ('person-month')

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient**'.

- for the mobility allowance: **EUR 600** per person-month

[73] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the family allowance: **EUR 500** per person-month.)

> For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities (e.g. during maternity/parental leave) are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years of their research career.)

    '**Date of recruitment**' normally means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    > ***Example:***
    > *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as 'date of recruitment'.*

    Years of '**research career**' are counted as 'full-time-equivalent research experience', from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:

    – sickness, parental, unemployment and invalidity benefits

    – pension rights and

    – benefits for accidents at work and occupational diseases.

    If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:

    – sickness, parental and invalidity benefits and

    – benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

  - as a rule, be employed **full-time**

Part-time employment can be accepted:

- subject to prior approval by the Agency
- on personal or family grounds only and
- not for professional reasons.

- **work exclusively** on the research training activities

  Any complementary skills training *(e.g. a minor teaching activity)* is not incompatible, but must not jeopardise execution of the research training activities and must be set out in Annex 1 to the GA.

- are supported for **at least three months**

  Person-months linked to shorter contracts will not be eligible. However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. Thus, if the contract is set out for a longer duration, but the training is interrupted within the first three months (e.g. the researcher resigns), the costs may still be claimed.

- comply — at the time of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the recruitment date (unless the beneficiary is an 'international European interest organisations'[74] or international organisation, for whom the mobility rule is limited to time spent *with* them)

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  In the case of EJD, the programme must lead to the award of:

  - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
  - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  MSC-ITN researchers may NOT be requested to pay tuition fees for their research training and/or PhD degree programme (from their own funds or from the researcher unit cost). (The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation)* may be covered by the budget category 'institutional costs'.)

  Family and mobility allowances can be paid to the researcher in various ways *(e.g. with his/her salary, in the form of a flight ticket directly purchased or reimbursed by the beneficiary, etc.)*, provided that:

  - the researcher can freely decide on the form of payment

[74] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

- it is not in contradiction to national (tax) legislation and
- there is no underpayment.

For beneficiaries with accounting in a **currency other than** the **euro**:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[75]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[76].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers that have — at the date of the recruitment — a family, i.e.
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country or region in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

[75] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[76] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

⚠ Beneficiaries may NOT declare more than 36 person-months per researcher. (Person-months exceeding this number will be rejected by the Agency.)

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector. This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations.

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, and training)*
  - costs for research expenses
- management and indirect[77] costs (i.e. the beneficiary's additional costs in connection with the action).

  The management and indirect costs received can be distributed within the consortium (via an internal agreement). The distribution should however roughly correspond to the actual division of (management) tasks within the consortium. They should also be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[78] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 1200** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[79], this amount is halved, i.e. EUR 600).)

In practice the declaration of institutional costs for MSC grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for the budget category 'costs for recruited researchers' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

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[77] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[78] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[79] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for recruited researchers:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-ITN actions do allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that provide training and host researchers during a secondment).

Partner organisations can NOT employ the researcher under the action.

The beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSC-ITN actions, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these procedures end.)

Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of the researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after the first year** of the action — send to the Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal) a progress report, to inform the project officer about progress on the action.

How? The report must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. Deliverable: Mid-term review meeting

What & When? The coordinator must:

- **before** the deadline for the **periodic report for RP 1**: organise a mid-term review meeting and
- **no later than 30 days** before this meeting: send to the Agency (via the electronic exchange system) a draft version of the periodic report, as a basis for the mid-term review meeting.

3. Deliverable: Researcher declaration

What & When? The beneficiary must send to the Agency (via the electronic exchange system) a document with information about each recruited researcher ('researcher declaration') — within **20 days** after the recruitment (of the researcher).

It is important to give correct and complete information since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. (If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher).

- **How?** The researcher declaration must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSC-ITN actions, the MSC-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA).*

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[14] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or any other entity referred to in Annex 1);

(j) host the researchers at their premises and provide training as well as the necessary means for implementing the action;

(k) ensure that the researchers are adequately supervised;

(l) ensure that a career development plan is established and support its implementation;

(m) ensure an appropriate exposure to the non-academic sector;

(n) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[14] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSC-ITN actions, the MSC-ITN MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for them.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[80]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises and **provide training** as well as the necessary means for implementing the action

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**

[80] Available at http://ec.europa.eu/euraxess/

- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[81].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[82].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie programme, to make the researcher aware that s/he is a **MSC fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSC website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities, including during secondments/placements with other beneficiaries and/or partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2)*
- Ensure that the researchers do NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Ensure that **secondments** are **limited** to a maximum of 30 % of the months spent implementing the research training activities under the action.

  Secondments may be either to another beneficiary within the consortium or to a partner organisation and must involve research training activities.

  For EID and EJD, the 30% rule applies only to secondments, summer schools and other activities that complement the main doctoral training.

  Example: *In the context of an EID action, University X hires a researcher for three years. Under 'inter-sectoral mobility', the researcher works in a laboratory in the non-academic sector for the obligatory one and a half years (50 %). In addition, the researcher may be seconded to partner organisations, but for no more than 30 % of the recruitment period.*

2. Employment contract — Obligations on the researchers

The MSC-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSC grants at the same time.

[81] Available at https://www.iprhelpdesk.eu/.
[82] Available at http://ec.europa.eu/euraxess/.

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MGA MSC-IF: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-IF actions

What? MSC-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSC-IF actions take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include two additional funding strands: the 'Career Restart Panel' and the 'Reintegration Panel'.

MSC-IF actions are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSC-IF actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION if needed for the action:** insert date]*[5] ('**starting date of the action**').

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSC-IF actions, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSC-IF MGA provides for an additional option, where the starting date is *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, the notified starting date must be:

- after the entry into force of the GA and within the period of months set out in Article 3
- notified by the beneficiary in *advance* (via the electronic exchange system, i.e. 'My Area' in the Participant Portal).

If the action does not start or the starting date is not notified (in time), the Agency may terminate the GA *(see Article 50)*. If the notification is sent after the start of the action, this will have an impact on the timing of the pre-financing payment and will delay it *(see Article 21.2)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSC-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSC-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSC-IF is a mono-beneficiary action, there is NO re-distribution of person-months between *beneficiaries*.

Transfers between *budget categories* are not possible because MSC unit costs are all linked to the person-months declared for the recruited researcher.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-IF actions, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs do not use the **cost forms** of the General MGA, but the the **unit costs** set out in Commission Decision C(2013) 8194[83].

For MSC-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[83] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC uses only unit costs, there is NO reduction due to the no-profit rule in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42).*

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[24]*[***OPTION for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including for a period of secondment to a **partner organisation**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action;

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Costs for the recruited researcher: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover costs related to his/her mobility, *e.g. relating to travel and accommodation*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by the budget category the 'research, training and networking costs").

AND

- a monthly family allowance if the researcher has family, to reduce family-related obstacles to researcher mobility.)

The mobility and family allowances are due to the researcher for each month worked.

What not? Other costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[84] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 4650** for the researcher per month ('person-month')

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient**'.

  For GF: there are two different country-specific correction coefficients:

  - for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month
- for the family allowance: **EUR 500** per person-month.)

> For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

[84] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

- be incurred for a researcher who:
  - is — at the time of the call deadline — an **experienced researcher** ('ER'; i.e. have a doctoral degree or have at least four years of research career)

    Years of '**research career**' are counted as 'full-time-equivalent research experience', from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.
  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including
    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases.

    If national law prevents the beneficiary from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:
    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.
  - as a rule, be employed **full-time**

    Part-time employment can be accepted:
    - subject to prior approval by the Agency
    - on personal or family grounds only and
    - not for professional reasons.
  - **work exclusively** on the research training activities

    Any complementary skills training *(e.g. a minor teaching activity)* is not incompatible, but must not jeopardise execution of the research activities and must be set out in Annex 1 to the GA.
- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  Family and mobility allowances can be paid to the researcher in various ways (e.g. with his/her salary, in the form of a flight ticket directly purchased or reimbursed by the beneficiary, etc.), provided that:
  - the researcher can freely decide on the form of payment
  - it is not in contradiction to national (tax) legislation and
  - there is no underpayment.

For beneficiaries with accounting in a **currency other than** the **euro**:

- if a daily rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[85]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[86].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs (for the researcher).

[85] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[86] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

⚠ Although NOT formal cost eligibility conditions for MSC-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the time of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the call deadline

  Specific cases:

  Beneficiaries that are 'international European interest organisations' or international organisations — The researcher may not have spent more than 12 months with the beneficiary in the three years immediately before the call deadline

  EF Career Restart Panel and **Reintegration Panel** — the researcher may not have resided or carried out his/her main activity in the country of the beneficiary for more than three years in the five years immediately before the call deadline.

  GF — the researcher must comply with the mobility rule with regard to the country of the partner organisation (i.e. where the outgoing phase takes place), not for the country of the beneficiary (i.e. where the return phase takes place).

- for GF and EF Reintegration Panel: be nationals or long-term residents of a Member State or an associated country.

  'Long-term resident' means full-time research activity in a Member State (or associated country) for five or more consecutive years.

- for EF Reintegration Panel: not have been active in research for at least 12 months immediately before the call deadline

- for the family allowance: have a family, i.e.:
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country or region in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

⚠ The beneficiary may NOT declare more than 24 person-months for the researcher (or 36 months for GF). (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action and training)*
  - costs for research expenses
- management and indirect[87] costs (i.e. the beneficiary's additional costs in connection with the action).

  They should be shared with a partner organisation which incurred management or indirect costs for a secondment *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[88] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 800** for the researcher per month ('person-month')
- for management and indirect costs: **EUR 650** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[89], this amount is halved, i.e. EUR 325).)

In practice, the declaration of institutional costs for MSC grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for the budget category 'costs for the recruited researcher' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for recruited researchers:

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87 For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

88 Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

89 For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-IF actions do allow for the involvement of **partner organisation(s)** (i.e. organisations that are not beneficiaries, but that provide training and host researchers during a secondment; *see Article 32*).

Partner organisations can NOT employ the researcher under the action. (For GF: this does not however prevent a partner organisation in a third country from contributing to the income of the researcher, in line with Article 32.1(c)(v).)

For GF: the partner organisation must be located in a third country and must be described in Annex 1.

The beneficiary remains solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should (especially for GF) establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSC-IF actions, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSC-IF actions, the MSC-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(g) host the researcher at its premises and provide training as well as the necessary means for implementing the action;

(h) ensure that the researcher is adequately supervised;

(i) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(j) support the secondment of the researcher in Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(k) ***[OPTION for GF:*** *support the return of the researcher to its premises to carry out a mandatory return period of 12 months.****]***

[…]

[11] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSC-IF actions, the MSC-IF MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for him/her.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises and **provide training** as well as the necessary means for implementing the action

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- Support **secondments** of the researcher, if any (and, for GF, support his/her return during a mandatory 'return-period' of 12 months)

  Researchers may be seconded to a partner organisation established in a EU Member State or H2020 associated country *(see Article 8)*:

  – if this is provided for in Annex 1 to the GA

  - for a maximum of three months in an action with a duration of up to 18 months, or up to six months in an action of up to 24 months

> ⚠ The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[90].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[91].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie programme, to make the researcher aware that s/he is a **MSC fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSC website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during secondments to partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6)*

- Ensure that the researcher does NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

2. Employment contract — Obligations on the researcher

The MSC-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

  This also means that a researcher can NOT hold two MSC grants at the same time.

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

[90] Available at https://www.iprhelpdesk.eu/.
[91] Available at http://ec.europa.eu/euraxess/.

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*
- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.
- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. Suspension of the action implementation — Additional grounds for suspension: Professional, personal or family reasons

In addition to the normal grounds for suspension of the action implementation *(see Article 49 H2020 General MGA)*, beneficiaries of MSC-IF actions may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and end date of the suspension and
- the 'resumption date' when the action is resumed (i.e. automatically one day after the end date).

In principle, suspensions (other than for parental leave) **may not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are not eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional grounds for amendments: Change to part-time employment

For MSC-IF actions, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time), on personal or family grounds (including parental leave).

Such amendments are NOT possible for any other reasons *(e.g. other professional opportunities, etc.)*. In those cases, the beneficiary must request suspension of the action implementation or termination of the action.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and a statement from the new beneficiary to take over all rights and obligations under the Agreement.

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a **'transfer report'**, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The maximum grant amount set out in Article 5.1 will be decreased if a lower country correction coefficient is applicable to the new beneficiary.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSC-IF grants can be **transferred** to a new beneficiary.

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

⚠ NO transfer before the amendment has been accepted by the Agency. Any interruption of the action implementation due to an unauthorised transfer is a breach of contractual obligations and the former beneficiary bears the full responsibility for any activity/commitment undertaken before the Agency has approved the amendment.)

The transfer may be based on any **ground** that is linked to the beneficiary and affects the researcher's ability to perform the activities.

Examples: *Internal reorganisation affecting implementation of the project; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher are NOT considered valid grounds for transferring the GA to a new beneficiary. (These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55),* so that the researcher can benefit from other professional opportunities or better reconcile work and family commitments without having to forego the grant).

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility criteria or financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed in the electronic exchange system).

3. Effects

The transfer may result in a reduction of the **maximum grant amount** *(see Article 5.1)*, if the correction coefficient for the country of the new beneficiary is lower than the one of the former beneficiary.

⚠ By contrast, the maximum grant amount will NOT be increased if the country correction coefficient for the country of the new beneficiary is higher.

After approval of the amendment, the former beneficiary must**:**

- **transfer** the **remaining contribution** to the new beneficiary and
- **submit a report** to the Agency, including:
  - an overview of progress on results and
  - a financial statement up to the date of the transfer.

III.4 H2020 MGA MSC-RISE: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-RISE actions

What? MSC-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

MSC-RISE actions are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

For more information on MSC-RISE actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSC-RISE MGA does **not use the budget categories of the General MGA**.

Budget categories of the MSC-RISE MGA:

- costs for seconded staff members
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may re-distribute *person-months* between them (as compared with the original planning set out in Annex 2) — without requesting an amendment *(see Article 55)*.

⚠ The maximum grant amount *(see Article 5)* can however NEVER be increased.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the distribution of the 'institutional costs' do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

Budget transfers will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Transfers are subject to the following:

- no impact on the action as described in Annex 1

If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment will be required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are, by contrast, NOT possible because MSC unit costs are all linked to the person-months declared for the seconded staff.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs)**.

1. Reimbursement rate

How much? For MSC-RISE actions, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA).*

2. Cost forms

The MSC MGAs do not use the **cost forms** of the General MGA, but the the **unit costs** set out in Commission Decision C(2013) 8194[92].

For MSC-RISE these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[92] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC uses only unit costs, there is NO reduction due to the no-profit rule in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42).*

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for seconded staff members are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the beneficiary or a partner organisation;

(c) the secondment complies with the following conditions:

(i) last at least 1 month and no longer than 12 months;

(ii) be between:

- a beneficiary established in a EU Member State (or associated country[6]) and a beneficiary established in another EU Member State (or associated country) from different sectors (academic and non-academic) or
- a beneficiary established in a EU Member State (or associated country) and a partner organisation established in a non-EU Member State (or non-associated country), and

(iii) the beneficiary or partner organisation sending the person is established in a country listed in General Annex A of the Main Work Programme.

[6] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

1. Costs for seconded staff members: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members (by providing for:

- a monthly top-up allowance for travel, accommodation and subsistence costs relating to the secondment.)

What not? Costs of the beneficiaries for research, training, networking and management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

1.2 These costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[93] and set out in Annex 2 and 2a of the GA (currently

- for the top-up allowance: **EUR 2 000** per seconded staff member per month ('person-month').)

> For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - an **early stage researcher** (i.e. not have a doctoral degree and be in the first four years of his/her research career)
    - an **experienced researcher** (i.e. have a doctoral degree or at least four years of research career) or
    - **administrative, managerial** or **technical staff supporting research and innovation activities** under the action (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

      Examples (not eligible administrative, managerial or technical staff):

      1. *Ms A, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

      2. *Mr X, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

    Years of 'research career' are counted as 'full-time-equivalent research experience', from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (in the country in which it was obtained or in which s/he is recruited).

  - have **already worked** continuously for at least **six months** (full-time equivalent) on research and innovation activities at the premises of the beneficiary/partner organisation

    Example: *Mr X is employed by beneficiary Y as from 1 January 2014; Mr X will not be eligible for a secondment from 1 March but would be eligible for secondment as from 1 July 2014.*

- be incurred for secondments:

[93] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- that last at **least 1 month** and no longer than 12 months

  Splitting into several periods is allowed.

  Example: *If a secondment is split into two 2-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first 2-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

  Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

  However, only splits within the *same secondment* (same staff, same sending organisation, same hosting organisation) can be added to reach the minimum duration of 1 month.

  Example: *Two secondments of 2 weeks of the same staff member to different organisations are not eligible since the minimum duration of 1 month is not reached.*

- that are one of the following three:

  - secondments **between beneficiaries** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in different EU Member States or H2020 associated countries AND different sectors (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary** in an EU Member State (or H2020 associated country) **to** a **partner organisation** in a third country *(see Article 8)*

  OR

  - secondments **from** a **partner organisation** in a third country listed in General Annex A to the Main Work Programme *(see Article 8)* **to** a **beneficiary** in an EU Member State (or H2020 associated country).

  Examples:

  A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

  Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work Programme.*
  A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

  Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.*
  A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
They may each claim 120 person-months (for their own staff).

Partner organisations are not beneficiaries and therefore can NOT declare costs; their costs must be included in the costs declared by the beneficiary that hosted the seconded staff member from the partner organisation.

During a secondment to a partner organisation, the beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA *(see Article 8)*.

If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded from both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

⚠ Although NOT a cost eligibility condition for MSC-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must also be fully used for the staff member.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('number of implemented person-months')

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert '5.47' as number of person-months.*

⚠ Beneficiaries may NOT declare more than 12 person-months per seconded staff member. (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[94] costs (i.e. the beneficiary's additional costs in connection with the action).

The institutional costs received can be distributed within the consortium (via an internal agreement) according to the needs of the action and of each secondment *(e.g. to further cover the travel and subsistence costs of the staff members, provided this does not have a negative impact on the implementation of the research and innovation activities set out in Annex 1)*. They should also be shared with partner organisations which incurred institutional costs for secondments *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[95] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 700** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[96], this amount will be halved, i.e. EUR 350).)

In practice the declaration of institutional costs for MSC grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the costs for seconded staff.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for seconded staff.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for seconded staff are met. Person-months which are not eligible for the budget category 'costs for seconded staff' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

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[94] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[95] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[96] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for seconded staff members:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-RISE actions do allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that participate in the exchanges by seconding and hosting staff).

The beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.

[…]

1. Records and other supporting documentation

For MSC-RISE actions, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and access rights to show duration; lab books, scientific articles, library records to show research and innovation activities*)

    The nature of the records and supporting documents to be kept by the beneficiary depends must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations — For secondments from partner organisations, it is the beneficiary that must keep the documents for the staff of the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1) and
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after each year except if a periodic report is due** (i.e. normally after the first and third year of the action) — submit to the Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal) a progress report, to inform the project officer about progress on the action.

How? The report must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. Deliverable: Mid-term review meeting

What & When? The coordinator must — **before** the deadline for the **periodic report for RP 1** — organise a mid-term review meeting.

3. Deliverable: Researcher declaration

What? The beneficiary must send to the Agency (via the electronic exchange system) a document with information about each seconded staff member ('researcher declaration').

It is important to give correct and complete information. (This information will be used to determine the eligibility of the person-months that are declared.)

When? The researcher declaration must be submitted within **20 days from the start of the secondment**.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — (and indicate each split).

> ***Example:*** *Beneficiary A is sending Mr X to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (an updated one within 20 days from the start date of each secondment).

> ***Example:*** *Beneficiary A is sending Mr X to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

- **How?** The researcher declaration must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

Specific case (deliverables):

Researcher declaration for staff of the partner organisations — For secondments from partner organisations, it is the the beneficiary that must submit the researcher declaration.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSC-RISE actions, the MSC-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA).*

Beneficiaries must moreover ensure that the partner organisations give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSC-RISE actions, the MSC-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is a top-up allowance), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are obviously accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary or partner organisation) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)
- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there
- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme
- Ensure that the staff members are seconded **full-time**
- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[97].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*
- **Inform** the researcher about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the EU contribution is **fully used for** the benefit of the **seconded staff** members

  It can be:

  - paid directly to the seconded staff member or
  - managed centrally by the beneficiary according to the specific needs of the secondment.

⚠ The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Best practice: It is strongly recommended that the beneficiaries establish internal arrangements *(e.g. partnership agreements)* with the partner organisations, to ensure that they fulfil their obligations *(see Article 8)*.

[97] Available at https://www.iprhelpdesk.eu/.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract, some of the basic obligations under the MSC-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This

allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MGA MSC-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-COFUND actions

What? MSC-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSC-COFUND actions cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSC-COFUND actions are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSC-COFUND actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSC-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSC-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSC-COFUND is a mono-beneficiary action, there is NO re-distribution of person-months between *beneficiaries*.

Transfers between *budget categories* are NOT possible because MSC unit costs are all linked to the person-months declared for the recruited researchers.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in programmes implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**);

(b) for **costs of providing financial support to costs for researchers in programmes implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-COFUND actions, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Form of costs

The MSC MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[98].

For MSC-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[98] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC applies only unit costs, there is NO reduction due to the no-profit rule in the MSC MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in programmes implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in programmes implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Costs for researchers: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme) (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount)).)

What not? Other costs are not covered. Thus, management costs can be declared under the other budget category ('management costs'; *see Article 6.2.B*). Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are not eligible under the grant; they may be funded through other EU funding programmes.

For more information on how to combine EU funding from different programmes ('complementary EU funding' or 'synergies'), *see the Online Manual.*

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[99] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance:
  - for early-stage researchers ('ESRs') in doctoral programmes: **EUR 3 710** per researcher per month ('person-month')
  - for experienced researchers ('ERs') in fellowship programmes: **EUR 5 250** per person-month.)

For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

[99] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (including its duration), identifiable and verifiable etc.; *see Article 6.1*)

- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** only the:

- management costs (i.e. direct costs of managing the action).

The management costs should be shared with partner organisations which incurred management costs for secondments or for the implementation of programmes *(see Article 8)*.

What not? Other costs (such as research, training and networking costs and indirect costs) are not eligible under the grant; they may be funded through other EU funding programmes.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[100] and set out in Annex 2 and 2a of the GA (currently:

- for management costs: **EUR 650** per researcher per month ('person-month').)

In practice, the declaration of management costs for MSC-COFUND grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the management costs is directly linked to and conditional on the **eligibility** of the costs for researchers.

Management costs are eligible only if all the eligibility conditions for the researchers are met. Person-months which are not eligible for the budget category 'costs for researchers' are also not eligible for the budget category 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The costs are **calculated** (automatically by the IT system) like the costs for researchers:

- for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

[100] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-COFUND actions do allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that participate in the action either:

- by implementing a doctoral or fellowship programme (i.e. recruiting the researchers)
- by providing training and hosting researchers during a secondment.)

Partner organisations that *implement* a doctoral or fellowship programme must be established in a EU Member State, H2020 associated country, or third country listed in General Annex A to the Main Work Programme. *Other* partner organisations can be established anywhere.

Partner organisations that implement a doctoral or fellowship programme and are established in a third country must recruit researchers that are nationals or long-term residents of a EU Member State (or H2020 associated country) *(see Article 15.1.1(b))*.

The beneficiary remains solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

15.1 Rules for providing financial support to or implementation of *[doctoral][fellowship]* programmes

15.1.1 The beneficiary must **implement *[doctoral][fellowship]* programmes** or **provide financial support** to such programmes implemented by partner organisations, in accordance with the following conditions:

(a) **types of programmes**:

[OPTION for DPs: *The programmes must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programmes**');**]***

[OPTION for FPs: *The programmes must concern fellowships for research training activities for recruited researchers ('**fellowship programmes**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country, the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programmes:

[OPTION for DPs: *The doctoral programmes must support researchers, who — at the time of recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION for FPs: *The fellowship programmes must support researchers, who — at the time of recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1. **]***

Researchers that are already permanently employed by the entity where the research training activities take place and that is recruiting them may not be supported.

(c) **procedure and criteria for selecting researchers** in the programmes:

[OPTION for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

Selection committees must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(d) **conditions for the recruitment** of researchers under the programmes:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[7] and ensure that the researchers are aware of them;

- ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;

- ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);

- ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;

- ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
- ensure that researchers work exclusively on the research training activities;
- ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
- ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
- ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of foreground, promoting the action) — during the research training activities and afterwards;
- inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;
- in case of third parties implementing the programmes: ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards those third parties;

[OPTIONS for DPs:

- *ensure gender balance in the recruited researchers;*
- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[7] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing doctoral/fellowship programmes

MSC-COFUND provides support both for programmes implemented by the beneficiary itself or programmes of partner organisations which the beneficiary funds by providing financial support.

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSC-COFUND grant to the partner organisations that implement doctoral/fellowship programmes (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Types of programmes — Categories of persons

The beneficiary/partner organisation must implement the following **types of** research training **programmes** supporting transnational mobility:

- doctoral programmes (DP), i.e. programmes with research training activities for recruited early-stage researchers that lead to the award of a doctoral degree or
- fellowship programmes (FP), i.e. programmes with fellowships for recruited experienced researchers.

The **researchers** must — at the date of recruitment —:

- be one of the following two:
  - **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years of their research career) or
  - **experienced researchers** ('ERs'; i.e. have a doctoral degree or have at least four years of research career).

  Years of '**research career**' are counted as 'full-time-equivalent research experience', from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited — even if the doctorate was never started or envisaged.
- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than 12 months in the three years immediately prior to the recruitment date (unless Annex 1 to the GA specifies otherwise for already existing programmes or the beneficiary/partner organisation is an 'international European interest organisation'[101] for whom the mobility rule is limited to time spent *with* them).

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.
- if the programme is implemented by a partner organisation established in a third country or if a secondment to such an organisation constitutes the *main* part of the research training activities: be nationals or long-term residents of a EU Member State (or H2020 associated country).

  'Long-term resident' normally means full-time research activity in a EU Member State (or associated country) for five or more consecutive years. (The Agency may however, exceptionally accept a different definition, if it is linked long-term residence and justified in the proposal).

  Short secondments are possible also for researchers that are not nationals or long-term residents.

[101] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

3. Additional eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[102]*)*.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a maximum of 4 fixed deadlines or regular cut-off dates per year) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

4. Additional eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits
- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries/partner organisations may offer a **'fixed-amount fellowship agreement**' with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the researcher unit costs will be reduced by 50%.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum monthly remuneration** (including salary, social security contributions, taxes and other costs included in the remuneration) of:

[102] Available at http://ec.europa.eu/euraxess/.

- for early-stage researchers (doctoral programmes); EUR 2 597
- for experienced researchers (fellowship programmes): EUR 3 675

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1298,50; for experienced researchers EUR 1837,50).

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**

    This also means that a researcher can NOT hold two MSC grants at the same time.
  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)
  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency
- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[103].
- for doctoral programmes: the beneficiary/partner organisation must
  - ensure **gender balance** regarding the recruited researchers
  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career plan.

[103] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSC-COFUND actions, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the researcher unit cost was fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

Specific case (record-keeping):

Documents for programmes implemented by partner organisations —For programmes implemented by partner organisations, it is the beneficiary that must keep the documents also for the partner organisations.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit:

- a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What and When? The beneficiary must send to the Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal) a document with information about each recruited researcher ('researcher declaration') — within **20 days** of the start of the research training activities (of the researcher).

It is important to give correct and complete information since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units.

How? The researcher declaration must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. No deliverable: Mid-term review meeting

For MSC-COFUND actions, the Agency will organise a mid-term review meeting (to monitor implementation of the action in the light of the schedule in Annex 1). The mid-term review is therefore not a deliverable, as in other types of MSC actions.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)*

addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA SME Ph1 deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 MGA SME Ph 2 deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 MGA SME Ph1, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 MGA SME Ph1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 funds:

- the feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: 'Innovation in SMEs' (*e.g. H2020-SMEINST-1-2014*).

For more information on SME Instrument Ph1 actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph 1 MGA does not use the budget categories of the General MGA.

Since SME Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 MGA:

- 'costs for the feasibility study (direct and indirect costs)'

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The SME Ph 1 MGA does not use the **cost forms** of the General MGA, but the **lump sum** fixed by Commission Decision C(2013) 8198[104] (**EUR 50 000** for mono and multi-beneficiary actions).

It is deemed to reimburse 70 % of the action's total eligible costs (which are in turn fixed by the Decision at EUR 71 429).

NO other costs will be reimbursed; the lump sum is deemed to cover all (direct and indirect) costs that may have been incurred for the feasibility study.

The conditions for eligibility are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

[104] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to breach of obligations other than improper implementation — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). The calculation for the reduction therefore does not relate to this form or improper implementation of the action.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 What? The budget category 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

NO other costs will be reimbursed; the lump sum is deemed to cover all direct and indirect costs that may have been incurred for the feasibility study.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[105] and indicated in Annex 2 of the GA (currently **EUR 71 429** per action).

In practice the declaration of costs for SME Ph1 grants is completely automatised. The beneficiaries only need to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

[105] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be *rejected* proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO financial contribution from the EU.

By contrast, if 'other obligations' have been breached *(e.g. other provisions of the GA or provisions of EU, international and national law are not complied with)*, the grant may be *reduced*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

The costs for purchases and subcontracts are covered by the lump sum.

In-kind contributions (see Articles 11 and 12 H2020 General MGA) and linked third parties (Article 14 H2020 General MGA) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are NOT considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency responsibility — Agency right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (by the beneficiaries) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submit to the Agency in good time any documents or information required by it

and may not subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

A 'rejection of costs' will be made for **improper implementation** of the action (*see Article 6*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO financial contribution from the EU.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if an obligation under the Agreement (other than improper implementation of the action as described in Annex 1) has been breached

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify confirmation of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced if 'other obligations' have been breached *(e.g. another obligation under the GA or applicable EU, international and national law; see Article 43 H2020 General MGA)*.

⚠ A 'reduction of the grant' is possible for **any breach of obligation other than proper implementation** (under the GA or applicable EU, international and national law; *see Article 7)*.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from him.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) the beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. Termination of the Agreement or of the participation of one or more beneficiaries (by the Agency)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The request for amendment must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

IV.3 H2020 MGA SME Ph2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: 'Innovation in SMEs' (*e.g. H2020-SMEINST-2-2014*).

For more information on SME Instrument Ph2 actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific cost categories' (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– 'personnel costs for providing trans-national access to research infrastructure'

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) *for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost under Point (f))]*[8]: ***[OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[10]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

(f) ***[OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): for [insert name of specific cost category(ies)***[11]*]:on the basis of the amount(s) per unit set out in Annex 2*[12] ***(unit costs).]***

[OPTION: specific cost category(ies):** not applicable.**]

[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used
[11] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures';, 'costs for clinical studies'; 'costs for energy efficiency measures in buildings'.
[12] Annex 2 must clearly show, for the beneficiary (and each linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the Main Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs****: [insert name(s) of specific cost category(ies)]]****[OPTION:*** *not applicable]*.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are not, by definition, 'non-profit legal entities', they can NOT declare additional remuneration (as part of the 'personnel costs – costs for employees (or equivalent)'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[24] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [25].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').***]**

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).***]**

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[24] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[25] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Commission/Agency will assess compliance with best value-for-money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value-for-money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value-for-money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Finally, for SME Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1] to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as for the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be adapted to reflect the action duration. Thus, if considered necessary, SME Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 MGA ERA-NET Cofund deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 MGA ERA-NET Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are 'research funders' and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implementated by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-NMP-ERA-NET-2015)*.

For more information on ERA-NET Cofund actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of ***[OPTION by default:*** *the first day of the month following the date the Agreement enters into force (see Article 58)]* ***[OPTION if needed for the action****: [insert date]]*[7] ('starting date of the action').

[4] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). Normally, the action's duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- 'direct costs related to trans-national projects'
- 'direct costs of providing financial support to third parties implementing trans-national projects'
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - 'direct personnel costs for the implementation of trans-national projects by the beneficiaries'
    - 'costs for employees (or equivalent)'
    - 'costs for natural persons working under a direct contract'
    - 'costs of personnel seconded by a third party against payment'
  - 'direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries'
  - 'other direct costs for the implementation of trans-national projects by the beneficiaries'
    - 'travel costs and related subsistence allowances'
    - 'equipment costs'
    - 'costs of other goods and services'
    - 'capitalised and operating costs of large research infrastructure'
- 'direct coordination costs for additional activities'
- 'indirect costs'

Thus, the ERA-NET Cofund MGA does NOT have:

- 'personnel costs for SME owners without salary'
- 'personnel costs for beneficiaries that are natural persons without salary'
- 'personnel costs for providing trans-national or virtual access to research infrastructure'

– ‘specific cost categories’.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - direct costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (— unless declared as unit cost)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects
- **unit costs** for:
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
  - direct **coordination costs** for additional activities[106]
- **flat-rate costs** for:
  - **indirect costs**.

[106] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.**]***

[OPTION to be used if foreseen in the work programme: *Not applicable.**]***

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 The beneficiaries may declare the following **types of costs** as 'direct costs related to trans-national projects':

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)

    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment
    - other goods and services
    - costs of large research infrastructure.

1.2 All costs — except direct personnel costs — must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost in accordance with the usual cost accounting practices (i.e. 'average personnel costs').

1.3 In principle, the same **conditions for eligibility** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the **following specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also* Article 2*)*.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8200[107] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatised: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare coordination costs for additional activities.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[107] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- 'direct costs for the implementation of trans-national projects by the beneficiaries'
- 'direct coordination costs for additional activities'.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however ONLY allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.3);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection ('**joint selection list**') on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report (see Article 20.3).

5. Additional eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

> ***Example:*** *data on each participant and abstracts of the proposals.*

The beneficiaries will be contacted about the format to be used and details on how to submit the deliverables.

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

Example: *data on each participant and an overview of the results*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 <u>Information on cumulative expenditure incurred</u>

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? ERA-NET Cofund actions are normally divided into 2 reporting periods with two pre-financing payments (or exceptionally 3 reporting periods with three pre-financing payments, if the

Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

ERA-NET Cofund actions normally are divided into two reporting periods *(see Article 20.2)* with two pre-financing payments (— unless the action is exceptionally divided into three reporting periods with three pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

> The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first (or second) pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10 % of the maximum grant amount *(see Article 5.1)*
- the second pre-financing payment is 80 % of the maximum grant amount.

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10 % for the first pre-financing payment
- 40 % for the second pre-financing payment
- 40 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was i**nsufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund MGA

VI.1 Background information and approach

The PCP-PPI Cofund Model Grant Agreement is used for PCP-PPI Cofund actions only.

The PCP-PPI MGA follows the General MGA for numbering and content, except for:

The H2020 MGA PCP-PPI Cofund deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation][Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 H2020 MGA PCP-PPI Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI Cofund actions

What? PCP/PPI Cofund funds:

- a joint public procurement of research and development (R&D) services (PCP) or innovative solutions (PPI)

AND

- related additional coordination and networking activities.

Only one PCP or PPI per GA.

The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects*.

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

For more information on PCP/PPI Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- 'direct costs of PCP/PPI subcontracting'

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- 'costs of related additional coordination and networking activities'
  - 'direct personnel costs for related additional coordination and networking activities'
    - 'costs for employees (or equivalent)'
    - 'costs for natural persons working under a direct contract'
    - 'costs of personnel seconded by a third party against payment'
    - 'costs for SME owners without salary'
    - 'costs for beneficiaries that are natural persons without salary'

        - 'personnel costs for providing trans-national access to research infrastructure'
    - 'direct costs of subcontracting for related additional coordination and networking activities'
    - 'other direct costs for related additional coordination and networking activities'
        - 'travel costs and related subsistence allowances'
        - 'equipment costs'
        - 'costs of other goods and services'
        - 'capitalised and operating costs of large research infrastructure'
    - 'indirect costs for related additional coordination and networking activities'
    - 'specific cost categories'' (if option applies).

Thus, the PCP-PPI Cofund MGA does NOT have:

– 'direct costs of providing financial support to third parties'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2*[13] ***(unit costs).]***

[OPTION: specific cost category(ies): *not applicable.**]***

[…]

[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[13] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The work programme/call *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1
- fulfil the additional cost eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[15]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[16] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

  and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[17]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[18] ***[OPTION by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.****]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]* ***[OPTION****: not applicable****]****.*

Beneficiaries receiving an operating grant[20] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

B.5 ***[OPTION: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION for specific unit costs, if foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category[21] *] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, [and if [insert additional eligibility conditions if any]].*

[*same for each specific cost category****]***

[OPTION: *Not applicable****]***

[…]

[15] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[16] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[17] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[18] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[19] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[20] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[21] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

1.1 The beneficiaries may declare the following **types of costs** as 'costs of related additional coordination and networking activities':

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and

  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost in accordance with the usual cost accounting practices (i.e. 'average personnel costs').

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[108] and set out in Annex 2 and 2a of the GA.

This concerns only beneficiaries that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI Cofund MGA has however the **following specificities**:

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

Costs for validation and testing of solutions provided by the subcontractors.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the Main Work Programme, the costs of related additional coordination and networking activities are eligible up to a maximum amount of 30/50% of the total requested grant amount (for PCP/PPI actions). (For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for related additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).)

[108] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

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The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however ONLY allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties (Article 14) can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

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13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[25] and 2004/17/EC[26].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('****place of performance obligation****').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[28];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[25] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[28] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

In PCP Cofund actions, the beneficiaries award PCP subcontracts for research and development services ('PCP R&D services') that are necessary to address a 'common challenge' set out in Annex 1. ('PCP subcontract' thus means a contract for the purchase of R&D services that is identified in Annex 1 as action task.)

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('buyers group'), with a joint procurement in 3 phases

  The '**buyers group**' is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI Cofund actions, it must normally be made up of:

  - a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[109])

    Any entity that fits the definition of a 'contracting authority' or 'contracting entity' as defined in those directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives are not applicable, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI Cofund actions.*

  - that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the Main Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the Main Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

  - beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
  - third parties providing in-kind contributions

[109] *See Directives 2014/24/EC and 2014/25/EC.*

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in **3 phases**.

The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value-for-money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done*.

This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (as used in the WTO GPA).

Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary ('**lead procurer**')

The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[110]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

[110] *See Directives 2014/24/EC and 2014/25/EC.*

The lead procurer must be mandated by the buyers group in the joint procurement agreement.

The subcontracts to be signed are:

- a framework contract with each selected subcontractor, covering the whole PCP and
- specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')
- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

There can only be one PCP per PCP Cofund action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*).

For PCP subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value-for-money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value-for-money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*
  - the procurement must be preceded by an '**open market consultation**'

    This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[111]).

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.
  - the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

    These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

[111] *See Directives 2014/24/EC and 2014/25/EC.*

They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*

  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments.)

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[112]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[113]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[112] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*
[113] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[29], 2004/17/EC[30].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[32] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

29 Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

30 Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

32 See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries award PPI subcontracts for procuring the innovative solutions ('PPI innovative solution(s)') necessary to address the 'common challenge' set out in Annex 1. ('PPI subcontract' thus means a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.)

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the **following specificities**:

There is no requirement to split the PPI procurement procedure in phases.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

> PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.
>
> Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

> The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).
>
> The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.
>
> If there is no mandate, the general rule is that:
>
> - framework agreement(s) must be signed by all members of the buyers group together
> - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

There can be only one PPI, per PPI Cofund action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PPI subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value-for-money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**' (— unless the PPI is limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

      This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

        - whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)* (— unless the PPI is limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP Cofund action) suffices.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
    - the process for monitoring of on-going work and reporting obligations of subcontractors
    - the role and the rights and obligations of third parties involved in the PPI
    - the procedures for accounting and payments
    - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:

  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[114]) normally apply to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[35]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[35] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

[114] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [****Y****] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **<u>information on each subcontract financed by the procurement</u>**, including data on each contractor that participated in the procurement, an overview of the results for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the initial tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

The beneficiaries will be contacted about the format to be used and details on how to submit the deliverables.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (together with data on each contractor that participated in the procurement and overview of the results)

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[47]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[48]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

[47] Month X should be the end of the preparation phase and submission of second pre-financing request.

[48] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into 2 reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage

(preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Actions will exceptionally be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of resources — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of resources needed to pay the subcontracts *(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a 'statement on use of the previous pre-financing instalment *(see Annex 12)*.

  This statement includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into 2 reporting periods *(see Article 20.2)* with two pre-financing payments (— unless the action is exceptionally divided into three reporting periods with three pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first (or second) pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount *(see Article 5.1)* that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; *see Article 21.2 H2020 General MGA*) minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 MGA EJP Cofund deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 MGA EJP Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of the H2020 Framework Programme and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General work programmes and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[7] ('**starting date of the action**').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). The action's duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific categories of costs' (if option applies).

Thus, the EJP Cofund MGA does NOT have:

- 'personnel costs for providing trans-national access to research infrastructure'.

For the FEJP action, there are however three 'specific cost categories':

- 'costs for mobility of personnel'
- 'costs for fellowships for researchers'
- 'access costs for research infrastructure'.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2*[15] *(**unit costs**).]***

[OPTION: specific cost category(ies)**: not applicable]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.
14 Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[115].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however three specific unit costs as 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [116]

For this action, these unit costs replace the 'specific cost categories' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 H2020 General MGA)*.

[115] *See Article 28(5) of the Rules for Participation.*
[116] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[17]***][OPTION: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[17] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will be limited to this additional equipment cost option (Article 6.2.D.2) and the specific cost categories (Article 6.2.F) and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** as 'other direct costs - equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional cost eligibility conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. ***[OPTION: [Insert name of specific cost category(ies)]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION for specific unit costs (unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[23]] *are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION: *not applicable****]***

[…]

[23] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the the Fusion programme EJP Cofund action (FEJP), the specific cost categories will be replaced by the three categories set out in Commission Decision C(2013) 8201[117]:

- 'costs for mobility of personnel'
- 'costs for fellowships for researchers'
- 'access costs for research infrastructure'.

⚠ Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 'Specific cost category – costs for mobility of personnel'

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment (by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance).

[117] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8201[118] and set out in Annexes 2 and 2a of the GA (currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

  This amount is subject to a '**country-specific correction coefficient**' for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[119]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.4	Sweden	131.9

[118] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[119] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto.

Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) will be applied as from 1 January 2016. The FEJP GA will be amended and the Annotated MGA will be updated accordingly.

– for the monthly subsistence allowance: between **EUR 0 and 720.27** per individual per month **—** depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1 300	**601.73**
> 2 000	**720.27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 258.81**, per dependent child per month).

The Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this event, the FEJP GA will be amended and the Annotated MGA will be revised accordingly.

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Commission Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and

- one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
    - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between five and 18 years of age), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

– the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment

– to this amount, add the following for each leg of the journey (outward and return):

– for train travel: a maximum of 30 minutes for each leg

– for air travel: a maximum of 2 hours for each leg.

NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

– for the monthly subsistence allowance:

amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

– for the family allowance:

amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

The family allowance is paid for each full month of secondment in which the dependent child is between five and 18 years of age.

'**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

A 'full month' can be one of the following two:

– a **calendar month** *(e.g. 1 to 31 July inclusive)* or

- a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*

*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*

Subtotal = EUR 85 697.25

** correction coefficient of 106.4 % (Germany Munich) = EUR 91 181.87*

*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*

Total declared unit costs: EUR 96 238.07

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*

** correction coefficient of 112.5 % (Culham, UK) = EUR 430.82*

Total declared unit costs: EUR 430.82

1.2 'Specific cost category – costs for fellowships for researchers'

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships (by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility).

What not? This budget category does not cover the salary costs of the fellows, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.2.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8201[120] and set out in Annexes 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions)[121]:

[120] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[121] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%
Finland	116.6%	Slovenia	86.1%
France	111.0%	Slovakia	82.6%
Croatia	97.5%	United Kingdom	120.3%
Hungary	76.2%		
Ireland	113.5%	Switzerland	113.1%

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[122]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

[122] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

- for the living allowance:

  amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

- for the mobility allowance:

  amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

- for the family allowance:

  amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 'Specific category – access costs for research infrastructure'

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below*).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be declared on the basis of the **unit cost** calculated in accordance with Decision C(2013) 8201[123] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

[123] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{124})}{\text{average annual total quantity of access (over past two years}^{125})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 to the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users

    Exceptionally, these costs may be those calculated in accordance with the beneficiary's usual cost accounting practices (i.e. 'average personnel costs').
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

[124] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[125] In exceptional and duly justified cases, the Commission may agree to a different reference period.

As already mentioned above, access costs for installations contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a 'statement on the use of the first pre-financing payment' *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]**[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU funds)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not (yet) open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

For more information on framework partnerships, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name**] (**short name**)legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
[6] The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Once an SGA is signed, the partners also become 'beneficiaries' (i.e. a 'participant'[126] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

Partners that do not want to actively participate, may participate as 'partners not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble of the SGA). Those partners will not have to comply with some of the obligations under that SGA *(see Preamble SGA)*

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

[126] For the definition, *see Article 2.1(15) of the Rules for Participation*: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

– the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed electronically in the electronic exchange system (i.e. 'My Area' in the Participant Portal).

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan (see Annex 1))] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all areas of the Horizon 2020 Framework Programme.

Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2);* Framework partnerships are currently NOT (yet) open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

  Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** Not applicable]*

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 H2020 General MGA)*.

Amendments after a suspension can NOT however have the effect of extending the FPA duration set out in Article 3 FPA.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the FPA

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ Termination of the FPA has NO effect on ongoing SGAs (— unless these are also terminated; *see Article 56 FPA and Article 20 SGA*).

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *'direct personnel costs'*
- *'direct costs of subcontracting'*
- *'direct costs of providing financial support to third parties' (if option applies)*
- *'other direct costs'*
- *'indirect costs'*
- *'specific cost categories' (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions applicable per budget category are set out in Article 5 SGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

The third parties are normally involved in the specific actions, not in the framework partnership.

> ***Example:*** *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

However, partners must — already at FPA proposal stage — indicate if they intend to use third parties or not. Moreover, linked third parties must be identified already in the FPA *(see Article 19 FPA)*.

> ***Example:*** *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ Only linked third parties of partners implementing the action covered by the SGA can carry out tasks and be identified in the Annex 1 of that SGA. If a linked third party of an FPA partner which does not implement the SGA action needs to carry out tasks in that SGA, then that entity (i.e. the linked third party) will have first to become partner of the FPA and of the SGA.

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA can NOT be amended before the FPA.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'[3]),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must **actively participate** in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* are applicable also for these partners. However, most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc.)* are NOT.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed electronically in the electronic exchange system (i.e. 'My Area' in the Participant Portal).

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligations towards them.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and in the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

AGA – Annotated Model Grant Agreement

Version 2.0.1
12 May 2015

Disclaimer

This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

Research and Innovation

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	– Initial version. Article 6.
1.2	17.02.2014	– Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	– Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	– Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	– Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	– New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	– Clickable table of contents added
1.6.2	17.07.2014	– Links to timesheet model and declaration model for personnel costs
1.6.3	20.08.2014	– Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	– Updates due to the amendment of the model grant agreement, in particular Articles 3, 9, 20.6 and 38.1.2 – New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 – New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; – Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 – New Annotations for the MSC – Other minor corrections and clarifications – Improved clickable table of contents including Articles
2.0	30.03.2015	– Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. – Clickable cross-references (Articles) – New table explaining the treatment of the different types of work contracts (under Article 6.2.A). – New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. – Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSC: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 – Other minor corrections and clarifications For easy identification, the paragraphs, indents or sections with relevant updates are marked with the symbol " ■ " in the left-hand margin of the document.
2.0.1	12.05.2015	– Corrigendum of annotations on Article 4 of the MSC-ITN and the MSC-RISE grants

IMPORTANT NOTICE

The '**AGA — Annotated Model Grant Agreement**' is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020.

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA is reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found on the Reference documents page of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

If you need help, you can also contact the Horizon 2020 Helpdesk.

H2020 legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (GENERAL MGA)

I.1 General MGA: Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1'Health, Demographic Change and Wellbeing' , etc.*

⚠ The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSC MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [**official registration No**], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form [OPTION if the JRC is a beneficiary: or the Administrative Arrangement], the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[1] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

Both beneficiaries and coordinators must have a sufficient financial viability/capacity to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial viability/capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial viability/capacity (of the coordinator or other beneficiaries), if there are grounds to doubt them *(see Article 15(9) of the Rules for Participation)*.

For more information on financial viability/capacity, see the *Online Manual*.

[1] For the definition, *see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) becomes a beneficiary of the grant and is **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation towards third parties.

2. Name, legal form, official registration No, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the 'Beneficiary Register' of the Participant Portal.

'Official registration No' refers NOT to the 'participant identification code (PIC)' attributed by the Beneficiary Register, but to the official registration number in the national registry, if any.

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other Horizon 2020 grants.

⚠ The beneficiaries must keep their beneficiary data up-to-date at all times, including after the end of the grant *(see also Article 17)*. In case of changes, the Legal Entity Appointed Representative (LEAR) of the concerned beneficiary must introduce a change request via the electronic exchange system (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[2]:

- for **research and innovation actions** (**RIA**): R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions** (**IA**): innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[3]
- for **coordination and support actions** (**CSA**): accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[4].

[2] More information on the types of action can be found on the General Annexes to the Work Programmes.

[3] For the definition, *see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[4] For the definition, *see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

⚠ The term '**action**' comes from the Financial Regulation No 966/2012 and the Rules of Application Regulation No 1268/2012 and **means** '**project**'. (Previous EU Research Framework Programmes used 'project'.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

ℹ For more information on RIA, IA and CSA actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

2. Complementary grants

'Complementary grants' are different EU grants which are 'linked' by the work programme/calls by identifying them as 'complementary actions'.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written '**collaboration agreement**' regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a third country *(e.g. a scientific and technological organisation or funding agency)* or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[5]

- For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

- For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

- For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 to the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

  To ensure coordination, the participants of the two actions must conclude a '**coordination agreement**' *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

ℹ For guidance on coordination agreements*, see the Guidance — How to draw up your coordination agreement.*

[5] *See Article 12 of the Rules for Participation.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The starting date of the action ('action starting date') is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example: *Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the action before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  The action starting date can NEVER be before the submission of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The duration of the action ('action duration') is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the *action tasks* (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as 'project closure' or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
  - 'personnel costs for providing trans-national access to research infrastructure'
- 'direct costs of subcontracting'

- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific cost categories' (if option applies).

  The budget category 'specific cost categories' only applies where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

Moreover, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories — without requesting an amendment *(see Article 55)* (unless Annex 1 must be changed).

⚠ The maximum grant amount *(see Article 5.1)* can however NEVER be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

> ***Example:*** *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

> ***Example:***
>
> *Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)*
>
> *Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)*
>
> *Total possible transfer to another budget category: EUR 2 000*

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2**.

Example: *A beneficiary declares all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of direct personnel costs.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the 'simplified approval procedure' without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the 'simplified approval procedure' bear the full risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION for innovation actions (IA)**[7] **if all beneficiaries and all linked third parties are non-profit legal entities**[8]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions (IA) if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][11]: *[**OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);][**OPTION**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant):** for **[insert name of specific cost category(ies)**[14]*]: on the basis of the amount(s) per unit set out in Annex 2*[15] ***(unit costs).]***

***[OPTION: specific cost category(ies):** not applicable.]*

***[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 To be used only if option in point (f) is used.

10 To be used only if option point (f) is used.

11 To be used only if option in point (f) is used.

12 To be used only if option in point (f) is used.

13 To be used only if option in point (f) is used.

14 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount can NEVER be increased — even if the eligible costs of the action are higher than planned

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally **100%** of the total *eligible* costs[6]; for IA actions it is normally **70%** of the total eligible costs[7].

In exceptional cases fixed in the work programme/call, a **lower reimbursement rate** than the two mentioned above may apply.

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**.[8]

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

6 *See Article 28(4) of the Rules for Participation.*

7 *See Article 28(5) of the Rules for Participation.*

8 *See Article 28(5) of the Rules for Participation.*

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to the different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[9] and all budget categories.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[10]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (— unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[11]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [12]
  - specific unit costs for:
    - 'costs for **energy efficiency measures** in buildings'[13]
    - '**access costs** for providing trans-national access to research infrastructure'[14]
    - 'costs for **clinical studies**'[15]

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9 *See Article 28(6) of the Rules for Participation.*

10 *See Articles 123, 124 of the Financial Regulation.*

11 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

12 *See Article 33(2) of the Rules for Participation.*

13 Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

14 Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

15 Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[16]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

  Example: *EUR 150 000 to carry out a study within an action*

  The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in Horizon 2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (if option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[16] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s).

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions (IA), there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount *(see Article 5.1)*.

Step 3 — Reduction due to the no-profit rule and receipts.

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the *consolidated* receipts and the *consolidated* approved costs.

The **receipts** that must be taken into account are receipts that are:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation)

during the action duration (see Article 3).

The following **are** considered '**receipts**':

- income generated by the action (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped to the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action (i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for the action covered by the GA

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

Examples: *the free use of equipment; the secondment of an expert without reimbursement*

Free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered '**receipts**':

- income generated by exploiting the results of the project (*e.g. the IPR*) is not considered a receipt since successfully exploiting the results is one of the main objectives of the action
- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

  Example: *A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This in-kind contribution from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions made **by one beneficiary to another** within the same action are also not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (i.e. the final payment at the end of the action).

They must be declared in the final report (although beneficiaries are free to do so also in the periodic reports).

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a **reduction** of the **grant** (i.e. reduction of the 'maximum grant amount'; *see Article 5.1*) — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is NOT a sanction, but the consequence of a breach of an obligation under the GA.

Example for calculating the final grant amount:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of Article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level).

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000

Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500

Costs rejected following audit: 30 000

Revised direct eligible costs: 120 000

Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000

Revised final grant amount: 100% of 150 000 = 150 000

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount set out in Article 5.1, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

According to the estimated budget, Beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.

Total eligible costs accepted for Beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that Beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of Beneficiary A: 80% of the share of Beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that Beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to Beneficiary A: 100% of the reduction is allocated to Beneficiary A
Revised final grant amount of Beneficiary A: 187 500 – 10 000= 177 500

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs AND reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

> ⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.
>
> Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.
>
> Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are (invoiced or) paid later, they are eligible only if the debt (and invoice) exists and the final cost is known.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action, if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action or the GA termination are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  > ***Example:*** *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for Horizon 2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  > ***Examples:*** *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  > ***Examples:*** *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting

practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They do NOT extend to research or innovation activities undertaken after the end date of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

  Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2.*

- the **number of units** must be **necessary** for the action

- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

Example: *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Personnel costs declared on the basis of the usual accounting practices — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices

- must budget and declare a total amount; the amount per unit must not be included in Annex 2.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency *(in Annex 2 of the GA; see Article 5.2)*.

> ***Example:*** *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump-sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]***]**.

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the action
- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action cannot be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a 25% fixed flat-rate of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[A.6 [OPTION to be used for trans-national access to research infrastructure: Personnel costs for

providing trans-national access to research infrastructure *are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for '**beneficiaries that are SMEs for their owners not receiving a salary**'
- costs for '**beneficiaries that are natural persons not receiving a salary**'
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 What? 'Personnel costs for employees or equivalent' (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) **cover**:

- the **basic remuneration** (i.e. basic salary and complements) and
- only for non-profit legal entities: the **additional remuneration**

for personnel that worked on the action.

What is 'basic remuneration' and 'additional remuneration' and how to distinguish them?

Basic remuneration refers to the 'basic salary' of the employee plus 'complements' that fulfil the eligibility conditions explained in point 1.1.3.

The basic salary includes (and is limited to):

- the salary stated on the beneficiary's payroll (except for any part of that salary which must be considered as 'additional remuneration', even if it that part is also registered in the payroll)
- social security contributions (mandatory parts to be paid by the employee and the beneficiary that employs him/her) — except any part included in additional remuneration.
- taxes included in the remuneration *(e.g. income tax to be paid by the employee retained by the beneficiary who employs him/her)* — except any part included in additional remuneration.
- other costs included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee)* — except any part included in additional remuneration.

The complements may include:

- mandatory complements to the basic salary resulting from national law, collective labour agreement or the employment contract

  Example (mandatory complement): *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements if they fulfil the eligibility conditions set out in point 1.1.2.

  Example (variable complement acceptable as basic remuneration): *The contract of a professor includes as part of his/her usual tasks both teaching and research; it foresees a basic fixed*

remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour for each hour spent on research activities.

By contrast, **additional remuneration** refers to payments made *on top* of the employee's usual remuneration, which result in a higher hourly rate.

Additional remuneration includes not only the extra salary, but also the social security contributions, taxes and other costs included in the remuneration that result from that extra salary.

Example (additional remuneration): *a 'bonus' for participating in a project; an additional contract for specific tasks with a salary higher than the one under the main contract*

Example (not additional remuneration, but basic remuneration): *additional salary paid to the employee for additional hours worked on its standard work or expertise as defined in the employment contract (e.g. overtime or additional contract for those additional hours), if the additional hours are remunerated according to the standard salary conditions of the employee (i.e. do not result in a higher hourly rate). Note that the standard salary conditions may provide for a mandatory complement for those additional hours (e.g. overtime during night shifts).*

Thus, the two main features that help characterising a remuneration component as basic or additional are:

- hourly rate (no change to hourly rate would indicate basic remuneration, while a higher hourly rate would indicate generally additional remuneration) and
- kind of work or expertise (usual kind of work or expertise according to the contract or different/additional work or expertise).

Work or expertise	**Hourly rate**	
	Usual	**Higher**
Usual	Indicates basic remuneration	○ Indicates additional remuneration: if triggered by the participation in a project ○ May however qualify as basic remuneration if not dependent on a project or type of projects (and therefore spread over all activities, e.g. *based on merit of the employee at stake*)
Additional/different	Indicates basic remuneration	Indicates additional remuneration

In case of doubt, the classification will be made also taking into account the classification of the component under national tax law (i.e. if the tax authorities explicitly consider it as part of the basic remuneration of the employee or as additional remuneration).

⚠ It is the basic remuneration that must be used to calculate the hourly rate *(see below)*.

1.1.2 Costs for employees (or equivalent) must be **declared** on the basis of:

- either **the individual actual personnel costs** of each employee participating in the action (the most common case) or
- on the basis of **unit costs:**

- either calculated by the beneficiary in accordance with its usual cost accounting practices (i.e. 'average personnel costs') if in line with the specific eligibility criteria *(see below)* or

- where applicable, unit costs fixed by the Commission; *e.g. the mandatory unit cost for SME owners and natural persons without a salary*.

1.1.3 The costs for employees (or equivalent) must comply with the following **conditions for eligibility**:

> ⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. (If the employment contract indicates that the person was hired to work on *another* project, it must be changed.)

For basic salary and mandatory complements:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are ineligible under *Article 6.5(a)(i)*. (However, complements based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted as variable complements, if they fulfil the conditions set out below.)

  > ***Examples (acceptable):***
  > *If the profit of the company at the end of the year is more that X € (or more than X %), each employee will receive a complement of z % of his/her basic remuneration (or a fixed complement of x € more as part of the gross salary).*

  > ***Examples (not acceptable):***
  > *If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.*

  Any part of the remuneration which is calculated with reference to commercial targets *(e.g. x € for reaching a sales target, x % on sales)* or fund raising targets *(e.g. x € premium per externally funded project gained, x % of the external funding gained)* is ineligible. The reason is that they are neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation.

  > ***Example (not eligible because linked to fund raising target)****: A premium paid as a reward for having obtained a specific grant is not eligible.*

- be **fixed** (conditions and amount or percentage) and **mandatory** according to national law, collective labour agreements or the employment contract

  > ***Example:*** *The employment contract between the entity and the person fixes a gross salary of EUR 3000 per month plus a transportation allowance of EUR 5 per working day.*

- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract/equivalent appointing act). Therefore, they can NOT depend on the participation in a specific action/project

  A 'payment linked to a specific action/project' is a payment the employee would not have received if s/he had not participated in the work of the action/project (i.e. the triggering event is the participation in the action/project *(e.g. an EU action)*, not the performance of the tasks defined in the employment contract/equivalent appointing act).

  Any part of the remuneration linked to tasks other than those covered by the basic remuneration, in particular amounts triggered by the participation in a specific action/project, are NOT eligible as part of the basic remuneration. (They may however still be eligible as additional remuneration; *see below*.)

For variable complements (in addition to the first and third conditions above):

- the variable complement is authorised by national law, collective labour agreement or the employment contract/equivalent appointing act

  Examples:

  1. *The collective labour agreement establishes that all researchers may receive a complement between EUR 100 and EUR 200 per month based on their seniority.*

  2. *The national law authorises public universities to pay a complement based on merit of the employees.*

  3. *The contract fixes a premium of EUR 1000 for each research paper published in peer reviewed international research journals.*

- the amount to be actually paid as variable complement is determined on the basis of objective conditions which are, at least, established and documented in the internal regulations of the beneficiary.

  Example: *Based on the provisions of the collective labour agreement (see first example above), the internal regulations of the employer provide that: all researchers with seniority between 3 and 5 years will receive a complement of EUR 150 and all researchers with seniority above 5 years will receive a complement of EUR 180.*

  The variable complement must NOT be paid to the employee at the sole discretion of the manager (**arbitrary** complement). The decision to grant the complement must be based on objective conditions, which should be documented in a procedure and be verifiable.

  Example: *National law authorises public universities to pay a complement based on merit or performance of the employees and the internal regulations of the public university provide for an annual assessment exercise to determine the 'merit points' of each employee. The internal regulations also set up the objective criteria based on which the 'merit points' are decided. The internal regulations provide that all researchers with more than 10 'merit points' will receive a complement of EUR 1000.*

For additional remuneration (only for non-profit legal entities):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the participation in another project)* is not eligible.

  Example:

  A nuclear researcher in a public research centre (non-profit) worked for 1 720 productive hours

  Remuneration components:

  a = annual salary: EUR 50 000

  b = a complement for holding a management post (e.g. Head of department): EUR 1 600

  c = additional remuneration for being Head scientist in the EU project: EUR 2 000

  d = additional remuneration for being First Assistant on an internal action: EUR 1 000

  a *and* ***b*** *would be used to calculate the researcher's hourly rate:*

  hourly rate for the EU action = {(50 000 + 1 600)/1 720} = EUR 30

  c *would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*

  d *would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for the performance of **additional work** or **different expertise** than his/her usual tasks

  The work to be carried out (or expertise used) must be different from the standard work or expertise (defined in the employment contract/equivalent appointing act and covered by the standard remuneration package). This difference must be verifiable.

- be part of the beneficiary's usual remuneration practices and be consistently applied whenever the same kind of work or expertise is required
- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used

The objective criteria must be related to the additional work or expertise.

Examples (acceptable criteria):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking up the management of the research team and infrastructure.

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

A normal salary is paid for research on internal projects + additional remuneration is paid for participating in a special type of projects as for example international cooperative projects, projects awarded under competitive calls, etc.

Examples (not acceptable criteria):

Additional remuneration paid for using English.

Additional remuneration is paid only when participating in EU funded actions.

The system for making additional payments should be established in the beneficiary's internal rules (or at least be documented and known by the employees). (Like for variable complements, the additional remuneration must NOT be paid to the employee at the sole discretion of the management (arbitrary complement).)

Example (acceptable): *All teachers carrying out research on top of their usual teaching activities get an extra payment of 10 % of their salary.*

Example (not acceptable): *The director decides at its sole initiative to pay an extra 10 % to one professor carrying out research.*

However, the additional remuneration does not have to be the *same* for all persons working in the same project. The objective criteria used to determine the additional remuneration may result in different amounts for persons working in the same project *(e.g. the rule is that all teachers that carry out research on top of their usual teaching activities get an extra payment between 10 % and 20 % of their salary, the precise percentage per teacher and project is determined according to the level of responsibility in the specific project)*.

The rules for additional remuneration may not differ according to *where* the funds come from. In particular, they cannot be set up for actions funded by a specific donor. (Additional remuneration schemes that are applicable only to EU actions are not acceptable.)

Example (acceptable): *All professors carrying out research will be paid 10 % more.*

Example (not acceptable): *All professors carrying out research will be paid 10 % more when they work on EU funded actions.*

Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see point 1.1.4*).

⚠ To avoid abuses, the rules for additional remuneration will be exceptionally also applied to the basic remuneration, if it has been **artificially increased** for participation in the EU action.

Examples:

1. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the beneficiary to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

2. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with a linked third party (or a third party providing in-kind contribution) to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

3. *Employees of a specific department/service of the company which is in charge of carrying out only EU actions are paid a higher salary than their homologues in other departments carrying out the same tasks requiring a similar level of expertise (i.e. the salary differential is attributable to the source of funding). The rules for additional remuneration will apply to the difference between the salaries of employees working for the specific department and those of employees of other departments carrying out the same tasks with the same level of expertise (see point 1.1.4).*

Decision tree to determine eligibility of complements:

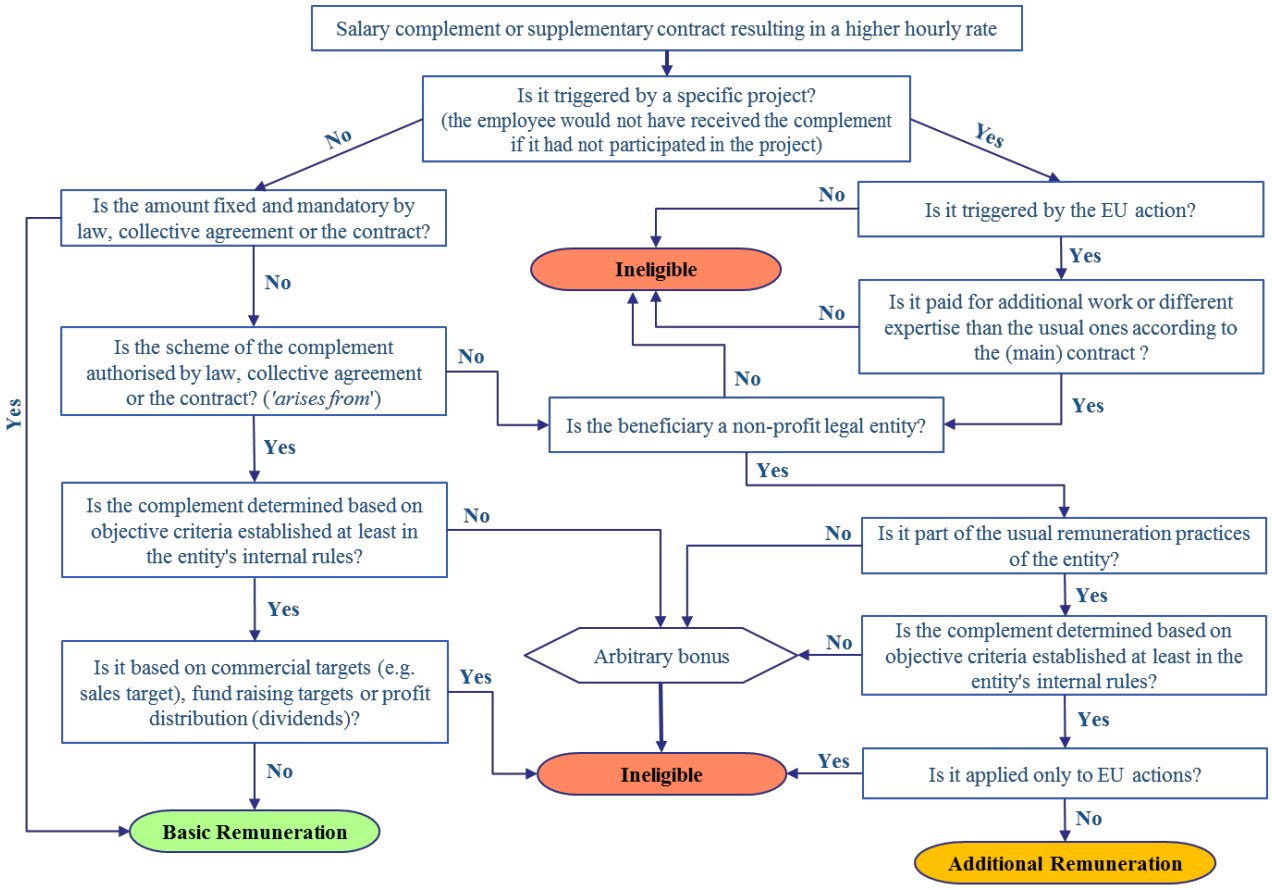

Specific cases (direct personnel costs for employees (or equivalent)):

Teleworking — Remuneration costs of employees (or equivalent) not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of benefits equivalent to financial ones *(e.g. costs of lunch vouchers)* may be accepted as eligible if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which under Horizon 2020 are covered by a 25 % flat-rate of the eligible direct costs.

Remuneration of post graduate students employed by the university (beneficiary) — Like any personnel costs, PhD costs (i.e. personnel costs of students) are eligible, if they fulfil the conditions set out in Article 6. In this context, fellowships/scholarship/stipends are assimilated to salaries provided that this remuneration complies with the application national law on taxes, labour and social security. Furthermore, the assignment of tasks must respect the laws in force in the place of establishment of the beneficiary and the persons must have the necessary qualifications for the performance of the tasks attributed to them in the context of the H2020 action.

Academic fees — If a student works for a university and is exempt from paying (part of) the academic fees, those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic salary only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible)

AND

- the employee worked for the action during the financial year used for calculating the personnel costs.

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts (whatever their form, i.e. a contract additional to the main contract between a beneficiary and its employee) for carrying out tasks for specific actions *(e.g. international projects)* are acceptable, if it is the beneficiary's usual practice and it is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package (basic remuneration) in the first non-action-related contract is considered 'additional remuneration'. As such it is subject to the specific cost eligibility conditions explained above for additional remuneration and, if eligible, to the eligibility ceiling.

1.1.4 The costs must be **calculated** as follows:

{{**hourly rate**
multiplied by
number of actual **hours worked on the action**},
plus
for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

This calculation method also applies for persons working exclusively for the action.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ The **total number of hours** declared in EU and Euratom grants **for a person for a year** may NOT be higher than the number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Procedure for calculating direct personnel costs for employees (or equivalent):

Step 1 — **Calculation of the hourly rate**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.

Remuneration components:

a = annual salary: EUR 50 000

b = extra payment for holding a post involving radioactive hazards: EUR 5 000

c = additional remuneration for being Head Scientist in a Project: EUR 2 000

***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*

Hourly rate for the action = {(50 000 + 5 000)/1 600} = ***EUR 34***

For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated by ***financial* year** (i.e. the 12-month period covered by the annual accounts of the entity) and has to be made always on the basis of full financial years.

Example: *When the financial year matches the* ***calendar year****, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance to the GA is available. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Once declared, the personnel costs can normally NOT be adjusted/changed due to a recalculation of the hourly rate (even if a re-calculation after the closure of the financial year on-going at the end of the period would give another result). A correction is only possible (and must be made) if there was a mistake in the

calculation of the hourly rate that was used to declare those costs *(e.g. incorrect accounting information).*

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Specific case (financial year):

If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes) the entity may use the **fiscal year** instead of the financial year for the purposes of calculating the hourly rate for personnel costs. The method must however be consistently applied and can NOT be changed within the same grant.

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (since that will be added at the end).

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours'**)
- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

The option must be applied not only to the person for whom the beneficiary declares costs, but per group of personnel employed under similar conditions.

Productive hours must be calculated on the basis of all working activities; using only 'billable hours' is NOT acceptable.

Example productive hours vs. billable hours:

X is a researcher employed full time in a research organisation participating in a H2020 action. According to the beneficiary's cost accounting practices, the standard number of annual hours (productive hours) is 1 600 hours.

At the end of the year, the distribution of time of X is as follows:

Type of activity	Annual productive hours/activity	Billable hours
for Horizon 2020 action	**400**	**400**
for other projects	200	200
for the preparation of proposals for new projects	600	0
member of the management board of the RO	400	0
total number of hours	**1 600**	**600**

If the person concerned was on parental leave during the year, the annual productive hours may be reduced by the actual time spent on parental leave.

This table explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types*	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive

	of special leave).	plus
		overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual working hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
			hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		⚠ This option can NOT be used If the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time legislation. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options.	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if conditions a) and b) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of

		Example for calculation of standard annual workable hours: *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual*	annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours). *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).* ⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow determining the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow determining the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).*	

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional salary but also all additional taxes, costs and social security contributions triggered by the additional salary.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (eligibility ceiling):

{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000

The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

Example for calculating direct personnel costs for employees (or equivalent):

A nuclear researcher working for a public research laboratory (non-profit) worked:

1 600 productive hours

800 hours declared for the action (at an hourly rate of EUR 40)

400 hours declared for another EU grant

S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.

*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***

Addition of the additional remuneration: = ***2 000***

Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

Condition: Actual hours declared for action + actual hours declared for another EU grant ***≤*** *total productive hours (800 + 400* ***< 1 600****)*

Specific cases (direct personnel costs for employees (or equivalent)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A applies.

- For persons who sign the 'declaration on exclusive work for the action' the number of hours worked in the action during the period covered by the declaration will be the pro-rata (corresponding to the period of exclusive dedication) of the annual productive hours used to calculate the hourly rate.

Example:

Researcher Y worked exclusively in the H2020 action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours.

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*Hours worked for the project*	
2014 ➔	*(32 000 / 1720) x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60 x	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720) x*	*1720*	
	20 x	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*		
	20 x	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
		TOTAL	*= 51 000*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Example: *The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the corresponding part of the indemnity in the reporting period in which the employee's contract ends. However, the indemnity may be accepted only if:

- arise from the applicable national labour law
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Only the part of the indemnity that corresponds to the time worked by the person on the action can be charged (i.e. pro-rata of the total time during which the entitlement was generated).

Employment contract remunerated 'per hour' — Some employment contracts do not establish a fixed salary and a number of hours to be worked, but an amount to be paid for each hour worked by the employee.

In those cases, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the 'individual annual productive hours' may be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

Personnel costs on the basis of the usual cost accounting practices — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices (i.e. 'average personnel costs'), the hourly rate must be calculated in accordance with the beneficiary's usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility criteria.

Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

Costs that are already included in other budget categories must be taken out (double funding of the same costs).

Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to Horizon 2020 actions. In Horizon 2020 actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.*

Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate
- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using the number of annual productive hours (i.e. either option 1 or 3).

Beneficiaries may request the **approval** of the methodology used by them, by submitting (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 What? This budget category **covers** typically the costs for in-house consultants and similar persons that worked on the action (i.e. self-employed *natural* persons working part-time or full-time for the action under a contract which is not governed by labour law; not companies).

What not? Persons provided by a temporary work agency. (Such costs may however be eligible as 'purchase of a service' *(see Article 10)* or as a 'subcontracting cost' *(see Article 13)*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs'; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.
- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.
- the **result** of the work carried out must **belong to** the **beneficiary**

The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products. This implies that the beneficiary must keep records of the hours worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.2.4 Cost of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **formula** as the one explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the **hourly rate** is different (since it is not based on the annual personnel costs as registered on the payroll).

For the hourly rate, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person and the number of hours to be worked: this global amount must be divided by the number of hours to be worked for the beneficiary under that contract.

If the contract fixes only a global amount and does not specify the time to be worked, the costs can NOT be declared as personnel costs, but may be eligible as purchase of a service *(see Article 10)* or a subcontract *(see Article 13)*.

This table explains how to treat **different types of work contracts** for declaring costs under H2020[17]:

General case: Single contract between the entity and the person		
Characteristics of the contract	**Contract remunerating time** (*e.g. the contract establishes that the person must work for the hiring entity 40 hours per week*)	**Contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes that the person must carry out a specific task but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ However only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. *Example: Contract from 01/01/2015 to 31/03/2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430* ➔ The personnel cost will be the result of multiplying the hourly rate by the number of hours worked by the person for the action (as recorded in its timesheets).

[17] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

Other contract (i.e. not covered above)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared as 'personnel costs – costs for natural persons working under a direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.	**CASE D** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.

Special case: the contract covering the work for the H2020 action is additional to the main contract of the person		
Characteristics of the additional contract	**Additional contract remunerating time** (*e.g. the additional contract establishes that the person must work for the hiring entity 10 hours per week in addition to the basic contract*)	**Additional contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes that the person must carry out a specific task but the working time needed is not defined; e.g. the contract specifies that the work has to be carried out within the working time of the main contract)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE E1:** the additional contract is NOT triggered by the participation of the person in the H2020 action (e.g. the contract pre-dates and outlasts the grant agreement). The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ In this case a single hourly rate must be calculated taking the figures of the main and the additional contract/s together (i.e. total basic remuneration and total annual productive hours). **CASE E2:** the additional contract is triggered by the participation of the person in the H2020 action. The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A.Calculation (point 1.1.4 above): ➔ However, the hourly rate must be calculated only on the additional contract (remuneration and productive	**CASE F** The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated for the additional contract as described in CASE B above: ➔ However, if the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1).* Therefore: **CASE F1** (the hiring entity is a non-profit legal entity): the costs of the additional contract may be eligible up to the following ceiling: *{Hours worked for the action (as recorded in the time records)* *multiplied by* *{Hourly rate of the main contract + EUR 4,65}}* Note: EUR 4,65 is the result of dividing 8000 (annual ceiling for additional remuneration) by 1720 (option 1 annual productive hours); thus, 4,65 is the hourly pro-rata of the annual ceiling

	hours of the additional contract). If the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1)*.	**CASE F2** (the hiring entity is NOT a non-profit legal entity, i.e. for profit entity): the costs of the additional contract may be eligible up to the following ceiling: {*Hours worked for the action (as recorded in the time records)* *multiplied by* *Hourly rate of the main contract*}
Other contract (i.e. not covered above)	**CASE G1:** the costs fulfil the conditions of Article 6.2.A.2. Depending on the main contract, the costs may be declared either as: – 'costs of employees (or equivalent)' (Article 6.2.A.1) or as – 'costs for natural persons working under a direct contract' (Article 6.2.A.2). If the main contract is under CASE A, CASE B or CASE C1, the cost must be calculated as indicated above for CASE E1 or E2 (depending if the additional contract is or not triggered by the participation in the H2020 action). If the main contract is under CASE C2 or D, the costs must be calculated as described in point 1.2.4. **CASE G2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10).	**CASE H** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.

	⚠ The beneficiary must award the contracts ensuring best value-for-money and avoiding any conflict of interests *(see Articles 10 and 13)*.	

1.3 Direct personnel costs: Costs for persons seconded by a third party against payment

1.3.1 What? This budget category **covers** the costs of persons that worked on the action and that were seconded by a third party as an 'in-kind contribution *against payment*' *(see Article 11)*.

> For information on in-kind contributions provided by third parties *free of charge*, *see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  > ***Example:*** *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  A secondment does not necessarily require the seconded person to work at the beneficiary's premises, although this is what usually happens.
- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.3.4 The same rules for **calculation** apply as in point 1.1.4.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons not receiving a salary that worked on the action.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

> ***Example:***
>
> *A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.*
>
> *In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the Horizon 2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.*

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[18] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *Main Work Programme — MSCA*[19] in force at the time of the call.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatised: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an owner of an SME/beneficiary that is natural person, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than the standard number of annual productive hours used for the calculation of the hourly rate (i.e. 1 720 hours).

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 What? This budget category **covers** the personnel costs for access to infrastructure activities, i.e.:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

[18] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[19] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes .

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **calculation** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting ***[(not covered by Point F)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional cost eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]*

*[**OPTION**: Not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Calculation

This optional budget category (together with the corresponding Article 15 and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  > ***Example*:**
  > *Beneficiary A declares the cost of a business class airplane ticket for one of its employees.*
  > *If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.*
  > *If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.*

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a Horizon 2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of an asset must be allocated on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; *see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life.

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs):

Equipment used only partly for the action — If the beneficiary does not use the equipment, assets, etc. exclusively for the action, only the *part* of the equipment's or asset's 'working time' for the action may be declared (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable (i.e. the hours that the equipment has been used for the project must be recorded).

Example:

A microscope was bought but had not been fully depreciated before the action started. For 6 months in reporting period 1, it was used for action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).

Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

Full price of an asset in one single year — Declaring the *full* price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible *(see 'cash-based accounting' below)*.

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.

If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — If recording the equipment's *total* purchase cost as an expense follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may declare the *part* of the cost that corresponds to the use of the item for the action in each relevant reporting period or in a single reporting period.

The amount declared can be only accepted if all of the following apply:

- the cost is economic and necessary
- only the portion of the equipment used for the action is declared

  If the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities.
- the amount of use (percentage used and time) must be auditable
- the percentage of the purchase cost charged to the action is calculated as follows:

  {amount of time during which the equipment was used for the action (from the purchase date to the end of use for the action)

  divided by

  equipment's total useful life}.

  'Useful life' means the time during which the equipment is useful to the beneficiary. It may be defined according to the beneficiary's practices or be established per type of equipment in line with national tax regulations.

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. The machine is used for the action 50 % of the time from 1 July 2015. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare part of the purchase cost, taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the cost eligibility conditions of Articles 6.1 and 6.2 are met (in particular, recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices; *see Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

If the full construction cost of the construction are eligible, but the construction was externalized to a third party (other than a linked third party), the costs can NOT be declared as 'equipment costs', but may be eligible as 'direct costs of subcontracting' *(see Articles 6.2.B and 13)*.

1.2 Equipment costs: Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:
  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the

item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials, scientific publications needed for the action, etc.)*
- dissemination costs (including open access during the action) and conference fees for presenting project-related research
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is less than EUR 325 000) or the certificate was submitted not for the final report but before*).
- translation costs (if translation is necessary for the action's implementation, is justified, etc.).

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the 'plan for the exploitation and dissemination of the results' are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Internally invoiced costs (i.e. where the use of certain resources is shared between different units of the same organisation and the costs of their use are declared through internal invoices) may be eligible if their use and the usage (number of hours) for the action is

specifically recorded and it is mentioned in the invoice. The internal invoice must refer to the use/dedication for the action of specific resources (*e.g. per researcher, piece of equipment, etc.)*.

Example (acceptable internal invoice): *Internal invoice with 16 hours of the technician doing the analysis and 10 hours depreciation of the testing equipment used.*

Example (not acceptable internal invoice): *Internal invoice with a global price for the use of a research infrastructure (e.g. laboratory) or for a service (e.g. an analysis).*

The costs must be declared under the budget category that corresponds to the invoiced resource *(e.g. personnel, equipment, other direct costs, etc.)* and must fulfil the eligibility criteria set out in Article 6.1 and 6.2.

Internal invoices may NOT include indirect costs elements or profit margin or mark-up.

Internal invoices for the work of personnel must be supported by time-records *(see Article 18.1)*. The hourly rate must be calculated as described in Article 6.2.A.

Internal invoices for the use of equipment must be limited to the depreciation for the relevant reporting period (only the part of the depreciation cost corresponding to the time the equipment was used for the action during that reporting period can be declared.) The use of the equipment must be properly recorded in order to allow direct measurement of the use for the action and to ensure auditability *(see Article 6.2.D.2)*. It is NOT possible to calculate an all-in average cost of internally invoiced equipment including, for instance, allocated indirect costs *(e.g. maintenance)*.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of the Horizon 2020 Framework Programme 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[20]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's

[20] *See also International Financial Reporting Standard No 16.*

usual accounting practices.[21] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under Horizon 2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other Horizon 2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[21] *See Article 126 of the Financial Regulation.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared** as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '**large research infrastructure**', if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[22] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[23].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once, a positive ex-ante assessment is obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[22] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[23] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any grant agreement.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and criteria for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the 'Beneficiary Register' of the Participant Portal. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (Link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

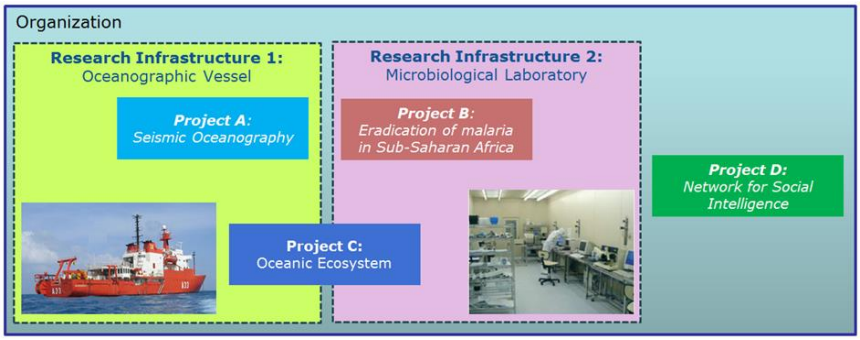

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[24].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

> ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds — may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Article 6.2.D.4 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[24] *See Article 129(1) of the Financial Regulation.*

Example 2 (Comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (‘**project time’**) and therefore require reliable time-recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of ‘**units of actual usage**’ for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary’s analytical cost accounting system. This data must be regularly updated.

  Example 3 (Costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

Example 4 (Part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[25]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (Rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[25] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]][**OPTION**: not applicable;]*

(d) ***[OPTION if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

However, beneficiaries that receive an **operating grant** financed by the EU or Euratom budget can NOT declare any indirect costs for the reporting period(s) covered by the operating grant.

Best practice: The beneficiary must **inform** both the coordinator and the Commission/Agency during grant preparation and before submitting financial statements (via 'My Area' in the Participant Portal).

'Operating grants' are (normally annual) grants given by a separate grant agreement to finance the operation and running costs of an entity e.g. call COMM-C2/01-2013 under the 'Europe for Citizens' programme.

1.1 This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared** on the basis of a flat-rate (*see Article 5.2(e)*; new in Horizon 2020).

In practice, the declaration is completely automatised: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25 % flat-rate to the beneficiary's eligible direct costs, minus:

- subcontracting costs *(see Article 13)*

  Example: *subcontracting of opinion surveys.*

  The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties (if option applies)

- costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a grant agreement and has incurred the following costs

- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,

- EUR 10 000 in consumables costs.

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

F. [OPTION: [Insert name of specific cost category(ies)[22]]][OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant): *[**insert name of specific cost category**] are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].***]***

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category] *are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.***]***

[same for each specific cost category]

[OPTION: *Not applicable****]***

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories: Types of costs — Cost forms — Conditions for eligibility — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of the Horizon 2020 Framework Programme, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: '**costs for energy efficiency measures in buildings**'

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': '**access costs for providing trans-national access to research infrastructure**'

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': '**costs for clinical studies**'

  The unit cost applies ONLY to actions with clinical studies.

⚠ Costs that are declared as a specific unit or lump sum cost may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

Example:

Case 1: *The unit cost for 'efficiency energy measures in buildings' covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.*

1.1 'Specific cost category – costs for energy efficiency measures in buildings'

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new isolation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost set out in Commission *Decision C(2013) 8196*[26] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) must be calculated — before signature of the GA — according to the following formula:

Amount per unit = {EUR 0.1 x estimated total kWh saved per m² per year x 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m^2 of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 'Specific cost category – access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** direct and indirect 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; see Article 6.2.D.1 and Article 16).

1.2.2 If they are declared under this budget category (i.e. specific cost category – access costs for providing trans-national access to research infrastructure), the costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[27] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{28}\text{)}}{\text{average annual total quantity of access (over past two years}^{29}\text{)}}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[29] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

  Exceptionally, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

- costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

- costs of consumables specifically used for the installation and the user's research work

- costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

- costs of energy power and water supplied for the installation

- costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)

- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

- costs of specific scientific services included in the access provided or needed for the provision of access

- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)

- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

The access activities and the parameters for calculating the unit cost must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annexes 1 and 2a.

The proposal should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per installation and access provider).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

During the GA, the beneficiaries may change their choice, but only via an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional cost eligibility conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 'Specific cost category – costs for clinical studies'

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study;
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
  - costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
  - indirect costs for the study.

1.3.2 If they are declared under this budget category (i.e. specific cost category – costs for clinical studies'), the costs must be **declared** on the basis of the unit cost set out in Commission Decision C(2014) 1393 and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/patients or subjects included in the clinical study) must be calculated for each study and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — according to the following formula:

Amount per unit ={Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks] **}**

The unit cost components must be calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':
{'average hourly cost for doctors', i.e.:
certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full-time-equivalent for the personnel category doctors for year N-1}
multiplied by
estimated number of hours worked by doctors for the task (per patient/subject)**}**

For unit cost component 'personnel costs of other medical personnel':
{'average hourly cost for other medical personnel', i.e.:
certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full-time-equivalent for the personnel category other medical personnel for year N-1}
multiplied by
estimated number of hours worked by other medical personnel for the task (per patient/subject)**}**

For unit cost component 'personnel costs of technical personnel':
{average hourly cost for technical personnel, i.e.:
certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full-time-equivalent for the personnel category technical personnel for year N-1}
multiplied by
estimated number of hours worked by technical personnel for the task (per patient/subject)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc.)

For each category of consumables:
{'average price per item', i.e.:
{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned
total number of items purchased in year N-1 for the category of consumables concerned}
multiplied by
estimated number of items used for the task (per patient/subject)**}**

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:
{'average cost of depreciation and directly related services per unit of use', i.e.:
{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}
total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per patient/subject)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value-for-money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:
'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

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total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%
multiplied by
{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}**}**

The following must be excluded:
- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

The estimation of the resources must be done on the basis of the protocol for the clinical study (and must be the same for all beneficiaries/linked third parties/third parties involved).

Each beneficiary/linked third party/third party providing in-kind contributions must calculate the direct costs by using its historical costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application).

Personnel costs must be defined in the 3 categories (doctors, other medical personnel, technical personnel) defined in the Commission Decision. No other categories *(e.g. 'nurses')* can be used.

The descriptions of the resources and the parameters for calculating the unit cost must already be part of the proposal *(see the proposal templates and the* template for essential information to be provided for proposals including clinical trials / studies/ investigations *provided on the call pages)* and be included in Annex 1 and 2a of the GA.

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per study and beneficiary/third party.)

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or of costs actually incurred for a given clinical study.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** the number of patients or subjects that participated in the study

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION: *Not applicable****]***

1. Costs of linked third parties

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional cost eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply, but with the changes needed to render them applicable to the linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared as 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared as 'other direct costs – equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared as 'other direct costs – equipment' (Article 6.2.D.2).*

'In-kind contributions free of charge' must be **distinguished** from 'in-kind contributions against payment' *(see Article 11)*.

In-kind contributions against payment are costs *of* the beneficiary/linked third party (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. They must be declared under those budget categories.

Example:

1. *The cost of personnel seconded against payment must be declared as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared as 'other direct costs – equipment – cost of equipment, infrastructure or other assets contributed in-kind against payment' (Article 6.2.D.2).*

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

1. Ineligible costs

Cost are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility criteria** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

- **provisions for future losses or debts**

  'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

- **interest owed** (i.e. interest on a loan to borrow capital)

- **excessive or reckless expenditure**

  'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

  'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

- **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

- **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

  Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the cost eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

- **deductible VAT**

  'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

  The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

  The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

  The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

  Conversely, if VAT is NOT deductible, it is an eligible cost.

  The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other Horizon 2020 grants)*

  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*

  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*

  - if a beneficiary is receiving an operating grant[30] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

Specific cases (ineligible costs):

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

[30] For the definition, *see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

⚠ Normally, the beneficiaries must comply BOTH with the national law of the country in which they are established and that of the country where the action is implemented.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Third parties involved in the action do not sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action tasks mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value-for-money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION 2, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *Not applicable****]***

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

These beneficiaries are considered 'beneficiaries' (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from a H2020 associated country[31]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

For more information on third country participants, *see the Online Manual*.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on the role of the beneficiary in the grant and if it has or not linked third parties that receive EU funding).

[31] For the definition, *see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

This table summarises the obligations of the General MGA that do not apply to beneficiaries not receiving EU funding (under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs or recovery) may be applied.

Example:

A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[23]]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[24] or 'contracting entities' within the meaning of Directive 2004/17/EC[25] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional eligibility condition: Best value-for-money or lowest price

The beneficiaries must base their purchases on the 'best value-for-money' considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value-for-money principle does not require **competitive selection procedures** in all cases. (However, where a beneficiary did not request several offers, it must demonstrate how best value-for-money was nevertheless ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.)

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[32] and 2004/17/EC[33] — or any EU legislation that replaces these Directives[34]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 1(9) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

Specific cases (purchases):

Existing framework contracts or **purchase contracts** — Costs may be declared if they are necessary for the action and if the award of the contracts by the beneficiary complied with best value-for-money and absence of conflict of interests.

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[32] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[33] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[34] *See Directive 2014/24/EC of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EC of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

Article 11 contains additional cost eligibility conditions.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare *their* costs for paying the in-kind contribution, if the eligibility conditions set out in Article 11.1 and in Article 6.1 and 6.2 are fulfilled *(e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.)*, up to the costs actually incurred by the third party.

Normally, only the *direct* costs of the third party are taken into account

These *direct* costs may not be based on unit costs[35] or lump sums (i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot, for instance, use the unit costs for SME owners or natural persons who do not receive a salary.

Indirect costs of the third party are not taken into account (when calculating the limit), if they are used in the premises of the beneficiary, except if the in-kind contributions are used on the third party's premises. In this latter case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on these costs *(see Article 6.2.E)*.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those actually incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

[35] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** to the GA.

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ((‘**simplified approval procedure**’).

> ***Example:*** *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

> ***Example (no approval):*** *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the ‘simplified approval procedure’ bear the full risk of non-approval and rejection of costs by the Commission/Agency.

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary makes no payment and there is therefore NO cost incurred by the beneficiary.

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

⚠ Article 12 contains additional cost eligibility conditions.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs *of the third party* for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in Article 6.4 are fulfilled *(e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts of the third party.

Normally, only the *direct* costs of the third party may be declared.

These direct costs may not be based on unit costs[36] or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*). Thus, the beneficiary cannot, for instance, use the unit costs for SME owners or natural persons who do not receive a salary.

Indirect costs of the third party are normally not taken into account, except if the in-kind contributions are used by the beneficiary in the third party's premises. In this latter case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on these costs *(see Article 6.2.E)*.

If the indirect costs are claimed in this way, the beneficiary may not include them a second time in its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 to the GA.

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**'; *see Article 11*).

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

[36] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[26]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [27]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[26] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[27] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on 'business conditions'

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from 'linked third parties'; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2)*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

Stricter rules apply to information that is 'EU-classified' or subject to a 'security recommendation' in Annex 1 of the GA *(see Article 37).*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Best value-for-money or lowest price

The beneficiaries must base their subcontracts on the 'best value-for-money' considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i..e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value-for-money principle does not require **competitive selection procedures** in all cases. (However, if a beneficiary did not request several offers, it must demonstrate how best value-for-money was ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.)

In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI). It is important not to confuse a Research and Innovation action, or an Innovation action, involving PCP or PPI with a PCP/PPI Cofund action. For the latter, the main objective of the action is the implementation of a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI).

The additional rules mirror the key obligations from the H2020 MGA PCP/PPI Cofund.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA ('**simplified approval procedure**').

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the **full discretion** of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the full risk of non-approval and rejection of costs by the Commission/Agency.

5. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

[37] *See Directives 2014/24/EC and 2014/25/EC.*

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.

'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 1(9) of that Directive*).

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* — cannot be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Existing framework contracts or **subcontracts** — The name of the subcontractor should be indicated (because it is known). Moreover, these (sub)contracts must have complied with best value-for-money and absence of conflict of interests at the time of their award.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[28] and **third parties with a legal link to a beneficiary**[29] ('**linked third parties**') may implement the action tasks **attributed to them in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked parties]

*The linked third parties **may declare** as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

[28] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[29] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).

  The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only '**affiliated entities**' or '**entities with a legal link to a beneficiary**' can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; 'ad hoc' collaboration agreements or contracts to carry out work in the action are NOT covered. (In this latter case, both legal entities should be beneficiaries.)

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract (not limited to the action).

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or
- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*

- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities *composed of members (where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Examples (affiliated entities):

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a Horizon 2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not listed in the work programme/call) are not eligible for funding under Article 10 of the Rules for Participation*.

For more information on conditions for participation and funding, *see the Online Manual*.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak'
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

1. *The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

3. *The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.*

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

For more information on the financial viability/capacity check, *see the Online Manual*.

[38] *See Articles 8 and 9 of the Rules for Participation.*

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

National research associations established according to the national law in order to carry out research not limited to the action.

A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the Horizon 2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO 'simplified approval procedure'.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **cost eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

Each linked third party has to provide its own ***certificate* on the financial statements** *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each linked third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

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15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties only where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*)

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[30] must provide access to research infrastructure or installations[31] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country**[32] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]]*[33]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

***[OPTION:** Not applicable]*

30 **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

31 **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

32 For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

33 If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures' under the following topics:
  - 'integrating activities' (INFRAIA-1-2014-2015: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(INFRADEV-3-2015: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (INFRADEV-4-2014-2015: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[39] or installation[40] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category 'specific cost category – access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

The beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions

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[39] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU Member State or H2020 associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. Additional eligibility condition: Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[35] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for **any purpose** *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission may request information at **any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the electronic exchange system** (i.e. 'My Area' in the Participant Portal). Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary must keep its information in the 'Beneficiary Register'[41] up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, validation and data updates, *see the Online Manual*.

[41] Available at http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

> ***Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the 'Beneficiary Register' *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[36]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[36] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[42]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

[42] International Standard on Auditing ISA 500 'Audit Evidence'.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For personnel costs declared in accordance with their usual cost accounting practices (i.e. '**average personnel costs**'), the beneficiaries must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is NOT necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What?

To get additional assurance, a beneficiary/linked third parties may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all Horizon 2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificates is NOT valid for Horizon 2020.)

When?

Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How?

The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following functional mailbox: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 to the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

> ⚠ Exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a 'declaration on exclusive work for the action' (one per reporting period), to confirm that the person worked exclusively for the action, either:
  - during the whole reporting period or
  - during a an uninterrupted time-period, covering at least a full natural month within the reporting period.

    Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration.

    If a person worked randomly for the action after an uninterrupted time-period covered by a declaration, time records for the period of random work.

    > ***Example:*** *the person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

  The declaration must be dated and countersigned for acceptance by the person concerned.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. timesheets)*.

- keep **time records**.

  Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (even if it the person keeps time records). This way the declaration can serve as evidence that that the person worked for the action all its annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  If the time-recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

  Time records should include:

  - the title and number of the action, as specified in the GA
  - the beneficiary's full name, as specified in the GA

- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record; for reasons of assurance and legal certainly it is highly recommended that the number of hours is detailed per day (hours worked for the action in each day)
- the supervisor's full name and signature
- a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned and the person-months reported to the action
- a brief description of the activities carried out, to understand and show what work was carried out.

Information included in timesheets must match records of annual and sick leave taken, and work-related travel.

A template for time-sheets is available on the Participant Portal. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the full risk of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned;

Criterion 2 is met – the project is identified as XYZ;

Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;

Criterion 2 is not met: the project name is not mentioned;

Criterion 3 is not met – the time is not quantified.

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

> ***Example:*** *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

> ***Examples:***
>
> *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*
>
> *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must **submit** them through the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*) — unless Annex 1 specifies another way.

Specific cases (deliverables):

Classified results — If the deliverables are classified results, they may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1]to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[37]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[37] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of action ('reporting').

> These 'reports' must be **distinguished** from 'deliverables' (that are part of Annex 1; see Article 19) and 'milestones' (that may be part of Annex 1, but are normally neither covered by Article 19 nor by Article 20).

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically created by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration.

Forms and templates for the different parts of the reports are available in the electronic exchange system.

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms **directly** in the **electronic exchange system**, i.e. 'My Area' in the Participant Portal).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress

- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication
- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary).* Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the **coordinator**, who must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary. The linked third parties can NOT view their grants in the electronic exchange system and therefore have no access to them.

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system is correct (i.e. identical to the signed paper version).

If a beneficiary **cannot submit** its individual financial statement on time, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

Technical reports should not contain any information that is 'EU classified' under the Commission internal Rules of Procedure *(see also Article 37, the Online Manual and the Guidance — Guidelines for the classification of research results)*.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on 'cross–cutting issues' (see Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' (*see Article 3 and Annex* I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the whole action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

The coordinator must ensure that none of the material submitted for publication includes confidential or 'EU classified' information.

The summary should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

It may also include a list of all beneficiaries, with contact names (if this information should be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

Some beneficiaries/linked third parties must submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and personnel costs declared on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

This means that costs based on lump sums, flat-rates (e.g. indirect costs) or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

– *average personnel costs*	=	*EUR 250 000*
– *subcontracting costs*	=	*EUR 40 000*
– *depreciation costs of equipment used to carry out the action*	=	*EUR 60 000*
– *indirect costs (25 % flat rate)*	=	*EUR 77 500*
– *total eligible costs claimed by A*	=	*EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or average personnel costs must be covered by the certificate. Incomplete certificates will be returned for correction.

Linked third parties must submit a certificate if it (on its own, without its beneficiary) reaches the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

In both cases, the certificate may only be submitted with the final financial report. The Commission/Agency will not accept certificates submitted at any other moment (and costs incurred for those certificates will not be considered eligible, because not necessary).

The certificate must be issued by an **external auditor**, using the template in Annex 5.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[43] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a third country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

[43] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[44].

    Procedure for calculating the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[45].

    Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

[44] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[45] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline (see *Article 47*)
- terminate the GA if the coordinator continues to breach its obligations after a written reminder (see *Article 50*).

It may also lead to a recovery of payments already made.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][38]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts prior to that)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or another executive agency — without the consent of the beneficiary concerned and up to the 'maximum EU contribution' foreseen for that beneficiary in Annex 2.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the **amount** is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100 % of the average EU funding per period (i.e. maximum grant amount set out in Article 5.1 / number of periods) for actions with at least two reporting periods. (It will be however less for actions with only one reporting period, since 100 % would mean the totality of the grant amount.)

At the moment of the pre-financing, an amount that corresponds to **5 %** of the maximum grant amount *(see Article 5.1)* is **deducted** from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100 % reimbursement rate

Pre-financing: EUR 333 334 of which:

EUR 283 334 transferred to the consortium (coordinator)

EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90 % of the maximum grant amount minus the pre-financing

Example for calculating interim payments:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1; application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The **amount** of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples for calculating the payment of the balance:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.

Pre-financing of EUR 400 000 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).

Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.

Total eligible costs accepted for 1st interim period: EUR 537 500;

1st interim payment: EUR 500 000 (the 90% limit is reached).

Total eligible costs accepted for 2nd interim period: EUR 162 500.

2nd interim payment: EUR 0 (the 90 % limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*

Final grant amount: EUR 750 000.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*

The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*

Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 312 500 = EUR 1 012 500.

Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.

*EUR 150 000 will be **paid** to the coordinator as follows:*

- *EUR 100 000 directly by the Commission as payment of the balance; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 187 500*

Total eligible costs accepted for the action: EUR 537 500 + EUR 162 500 + EUR 187 500 = EUR 887 500.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check *(see Article 17)*. All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks remotely, based on documents it received beforehand.

It can do so using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

Example: *Ethics checks are normally carried out with the help of external experts.*

If the check shows ineligible costs or the violation of 'other obligations' under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows improper implementation of the action, ineligible costs or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the beneficiaries will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days ('**contradictory review procedure**'). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant, etc. under Articles 41 to 46.)

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit* ***linked third parties****, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit* ***third parties providing in-kind contributions*** *(free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit* ***contractors*** *or* ***subcontractors****, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value-for-money or, if appropriate, the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

4. *The Commission/Agency may audit* ***recipients of financial support*** *or* ***prizes****, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, ineligible costs, improper implementation of the action or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission may also audit the accounting records of beneficiaries to obtain general information about actual costs for cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct

consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory audit procedure**'). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the '**letter of audit conclusions**' (and the file will then be passed on to the operational services (authorising officer) for audit implementation, if necessary).

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[39] and No 2185/96[40] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

39 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

40 Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42-44, 47-50)* but also to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[41], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[41] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable**]

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

> ***Example:*** *A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the *[Agency or the]* Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the *[Agency or the]* Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the *[Agency or the]* Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the *[Agency or the]* Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings

Findings in checks, reviews, audits or investigations may be **extended** to other grants.

Extension of findings is possible for ALL H2020 grants — regardless of the entity that awarded the grant (i.e. Commission, executive agency or H2020 funding body).

If the Commission/Agency finds substantial errors, irregularities, fraud, improper implementation or serious breach of other obligations that are **systemic** or **recurrent**, it may make a correction (rejection of costs or reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and

  - reporting periods that were not audited/reviewed ('extension of the findings')
- other H2020 grants of the beneficiary ('extension of the findings').

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

> ***Examples (recurrent):*** *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

> ***Examples (systemic):*** *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld after this contradictory audit/review procedure, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an 'audit extension procedure' (which is then followed by 'audit/review implementation').

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure ('**letter of audit conclusions**'), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for ineligibility of costs:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (to be used if the beneficiary does not submit revised financial statements)
  - the conditions for the external counter audit needed to propose an alternative correction method *(see below)*
- for improper implementation or breach of other obligations: the proposed flat-rate for the correction.

The 'extrapolation rate' will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The 'flat-rate' will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit the revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept an alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for ineligibility of costs: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for improper implementation or breach of other obligations: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative correction method and there is no entitlement to it.

Step 3 — Audit implementation. If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the costs to be rejected/reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the costs to be rejected/reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:** five]**[OPTION for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[42].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[42] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[46] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[46] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

Best practice: Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[47]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[47] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

> ***Example:*** *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

> ***Example:*** *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such an exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[43] established in an EU Member State or '**associated country**'[44], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[44] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

– for the implementation of action tasks: the default rule is royalty-free

However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

- for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED RO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 <u>Rights of third parties</u> (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

The joint ownership status may **change**:

- it may need to be reviewed later on, when protecting the results.

  Example:

  Whether or not a patent is jointly owned depends on the exact scope of work carried out by each of the joint owners, as well as on the claims and the inventive step condition that must be fulfilled.

  A patent application might include both a new process called A (developed jointly by organisations X and Y) and an improvement called B (developed by Y only). This patent application would clearly be jointly owned by organisations X and Y.

  However, if it turns out that process A is not patentable, the patent will only be granted for improvement B (developed by Y only) and will belong exclusively to Y.
- joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. employees, subcontractors, linked third parties etc.)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Examples (arrangements): *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14)*, state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):
For an invention: e.g. patent, confidential information.
For the design of a technology: e.g. industrial design, copyright.
For a website: e.g. industrial design, copyright, trademark.

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (i.e. use where relevant the wording from the corresponding translation of the MGA that is available on the 'Reference documents' page of the Participant Portal).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the 'plan for the exploitation and dissemination of the results'.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

The beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security-related obligations, etc.)*.

The beneficiaries may choose the **form** for disseminating their results.

Classic forms of dissemination:

- Website
- Presentation at a scientific conference
- Peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination— unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

2. Open access

For detailed information on open access, see *Guidelines on Open Access to Scientific Publications and Research Data* and the *Guidelines on Data Management*.

3. Visibility of EU funding

Any dissemination of results (in any form) must include the reference to EU funding set out in the GA *(see Article 38*).

Best practice: Where possible, beneficiaries should make this reference in the language of the dissemination activity (i.e. use where relevant the wording from the corresponding translation of the MGA that is available on the 'Reference documents' page of the Participant Portal).

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —****]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions* ***]***

[OPTION: *Not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results — unless prohibited (or restricted) by security-related obligations *(see Article 37)*.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a 'global' authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country (i.e. not EU Member State or H2020 associated country) must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a third country (i.e. not EU Member State or H2020 associated country).

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  > ***Example:*** *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  > ***Example:*** *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  > ***Example:*** *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to beneficiaries not receiving EU funding *(see Article 9)*.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 <u>Access rights for the EU institutions, bodies, offices or agencies and EU Member States</u>

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[45], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results

- by an affiliated entity (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **refusal**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [46], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[46] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[48] and the Code of Conduct for their Recruitment.[49]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[50] and of the Code of Conduct[51] that relate to recruitment, working conditions and career development.

For guidance, *see the 'Human Resources Strategy for Researchers' tool developed by the Commission.*

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[52])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[51] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[52] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more information on gender in research, *see the Online Manual.*

ARTICLE 34 — ETHICS

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[47] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct; *see also the European Code of Conduct for Research Integrity*[53]).

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols (for other texts, *see the Science in Society e-library*[54]).

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

- 'ethics self-assessment' (by the applicants, in their proposal; *see the proposal templates and the Guidance — How to complete your ethics self-assessment*)

[53] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[54] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

- two-stage 'ethics review', with an ethics screening and, if necessary, an 'ethics assessment' (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more information on ethics in research, see *the Online Manual.*

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must ALSO be allowed in at least one Member State.

The beneficiaries must confirm in the 'ethics self-assessment' section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board*.

Moreover, the coordinator must — before the activity starts — submit **copies** of the following,:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation **costs**, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

There is NO need to submit copies of requests for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[55] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[55] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value-for-money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best-value-for-money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

  If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

  If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[48], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[48] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Stricter confidentiality obligations apply for information that is 'EU-classified' or subject to a 'security recommendation' in Annex 1 of the GA *(see Article 37)*.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and Horizon 2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '**security requirements**' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *Not applicable****]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

1. Results with a security recommendation — Classified results

If the GA provides for (one of these) options, the beneficiaries must comply with the **specific security-related obligations** ('security requirements') set out in Annex 1 (via a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)') and in this Article and other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises 'security issues', the Commission/Agency will make them subject to a security recommendation and/or classify the results (under the Commission internal Rules of Procedure).

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation (EC) No 428/2009[56].

Moreover, the coordinator must — before the action starts — submit a **copy** of:

- any export or transfer licence.

[56] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Communication activities (by the beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[57].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

Information given may NOT include classified (or otherwise restricted) results *(see Article 37)*.

[57] For the definition of 'communication activities', *see the Glossary.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the proposal templates*) and be included in Annex 1 and 2.

For more information on promoting the action, *see the Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the EU emblem

AND

- including the reference to EU funding set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity (or, for infrastructure, equipment or major results, the official language(s) of the country where they are located). Where relevant, beneficiaries should use the wording from the corresponding translation of the MGA that is available on the 'Reference documents' page of the Participant Portal).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object). ***Examples:*** *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[49], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][insert the name of the Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[49] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities (by the Commission/Agency)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material): *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[50] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statements (SSPS)' that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[50] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (by the Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its privacy statements on the Participant Portal ('service-specific privacy statements (SSPS)'[58]).

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the financial interests).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[59] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

[58] Available at http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html.
[59] Available at http://ec.europa.eu/dpo-register/search.htm.

2. Right to access and correct personal data

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the SSPS), since s/he might be able to solve the problem quickly.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the service specific privacy statements (SSPS) (see above), before transmitting their data to the *[Agency or the]Commission.*

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (by the beneficiaries)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[60] — or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [61]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use

[60] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[61] *See Article 8 of Directive 95/46/EC*.

- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[62]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the SSPS).

Examples:

Before encoding its staff's personal data in the 'Beneficiary Register' or into a proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the relevant SSPS.

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[62] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]**

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What?

The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned. Assignment is NOT possible for future claims.

How?

Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.

Assignment for the benefit of creditors in a bankruptcy procedure.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not subcontract these tasks to any third party.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% retained from the pre-financing for the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION:** Not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

The coordination agreement must not contain any provision contrary to the Agreement.]

***[OPTION:** Not applicable]*

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can NOT be subcontracted or outsourced to a third party. They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use in-kind contributions for *other* tasks; *see Articles 11, 12, 13*).

Specific cases (coordinator):

Authorisation to administer — Secondary or higher education establishments and public bodies may exceptionally delegate the coordination tasks listed in Article 41.2 (and other administration tasks, if needed) to another legal entity (third party), in most cases a foundation.

> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

The third party must fulfil the following conditions:

- it must have been granted the 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds (administration is considered an action task).

It must be registered in the 'Beneficiary Register' and validated by the Commission/Agency. It will get its own PIC, although it is not a beneficiary.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article) can in principle be carried out by another beneficiary *(e.g. scientific coordination of the action).*

Such a beneficiary may — internally (i.e. within the consortium) — be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

Costs for scientific coordination can be eligible, if they comply with the eligibility criteria set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see the Online Manual and the Guidance — How to draw up your consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted for 'complementary actions' *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary Horizon 2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted for 'jointly funded actions' *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

- The coordination agreement should **complement** the grant agreements and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

- Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

- The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see the Online Manual and the Guidance — How to draw up your coordination agreement.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

A '**rejection of costs**' will be made for any **violation of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request by the coordinator/beneficiary concerned — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-**

information letter for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) **in-between payments**, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example for calculating a rejection at an interim payment/payment of the balance:

Case 1: *Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.*

Maximum grant amount: EUR 500 000.

Pre-financing: EUR 200 000.

Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25 %) = EUR 118 750.

Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25 %) = EUR 143 750.

Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25 %) = EUR 112 500.

Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:

Application of the reimbursement rate: 100%: EUR 362 500

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.

Amount due as interim payment: EUR 250 000

Case 2 (in between payments): *Total costs declared for the action in the 1st periodic report: = EUR 375 000*

Interim payment for the 1st periodic report = EUR 375 000

Cost rejected after interim payment or 1st periodic report: EUR 12 500

Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000

Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example for calculating a rejection after the payment of the balance:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount set out in Article 5.1 (— in proportion to the improper implementation of the action or the seriousness of the breach).

A '**reduction of the grant**' is possible for **any breach of obligation** (under the GA or applicable EU, international and national law; *see Article 7)* and it will be made in proportion to the seriousness of that breach *(e.g. in case of fraud, systemic irregularities or submission of false information — in the award procedure or during action implementation the reduction may be up to a 100%)*.

Reduction of the grant can take place at or after the payment of the balance, NOT before.

If improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

A reduction can also be due to a beneficiary not receiving EU funding (i.e. improper implementation or breach of obligations by that beneficiary; *see Article 9*).

2. Procedure

The Commission/Agency will follow a contradictory procedure (for the basic contradictory procedure, *see Article 42*).

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant *at the payment of the balance*, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example for calculating a reduction at the payment of the balance:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)

Pre-financing: EUR 750 000

Interim payments: EUR 1 500 000

Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20 % (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.

Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000

Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000

Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

If the Commission/Agency reduces the grant *after the payment of the balance*, it will calculate a **revised grant amount** at **beneficiary level**, by first reducing the grant and then calculating the revised final grant amount for each beneficiary concerned.

If the improper implementation or breach of obligations cannot be linked to one (or more) specific beneficiaries (and therefore concerns the whole consortium), a revised final grant amount will be calculated for all of them (i.e. they will all have to bear their pro-rata share of the reduction).

Procedure for reduction of the grant (after payment of the balance):

Step 1 — The Commission/Agency reduces the maximum grant amount set out in Article 5.1 in proportion to the improper implementation or to the seriousness of the breach.

Step 2 — The Commission/Agency calculates the revised final grant amount for each beneficiary concerned, by allocating the amount of the reduction to each of them, in proportion to their improper implementation or breach of obligation.

Example for calculating a reduction after the payment of the balance:

Step 1 reduction of the maximum grant amount

Maximum grant amount: EUR 3 000 000 for an action with a 100% reimbursement rate. Three beneficiaries: A, B and C.

Estimated budget per beneficiary (Annex 2): EUR 800 000 (A); EUR 1 600 000 (B) and EUR 600 000 (C).

Total eligible costs and EU contribution accepted for each beneficiary at payment of the balance: Beneficiary A: EUR 700 000; beneficiary B: EUR 1600 000; beneficiary C: EUR 700 000.

Reduction of grant amount:

The Commission carries out a review after the payment of the balance. Following the review, the Commission reduces the maximum grant amount by 13,3 % (EUR 400 000) because of improper implementation/breach of obligations and notifies the consortium via a pre-information letter.

Reduced maximum grant amount: EUR 3 000 000 — EUR 400 000 = EUR 2 600 000.

Step 2 allocation to each beneficiary

1. (improper implementation/breach of obligation can be linked to specific beneficiaries): *The improper implementation is due to the fact that beneficiary A carried out only 50 % of its tasks as set out in Annex 1.*

Revised final grant amount for beneficiary A will be the lower amount between the costs accepted at the payment of the balance and the figure resulting from the reduction:

Lower between costs accepted (EUR 700 000) and 50 % of beneficiary A's share of the maximum grant amount set out in the estimated budget in Annex 2 (50 % x 800 000 = EUR 400 000) = EUR 400 000

For recovery (see Article 44.1.3):

The revised final grant amount for beneficiary A needs to be compared with beneficiary A's share of the final grant amount and the difference must be recovered: EUR 700 000-400 000 = EUR 300 000.

The other beneficiaries' share of the final grant amount is not affected

2. (improper implementation/breach of obligation cannot be linked to specific beneficiaries): *The breach of obligations is due to the fact that the consortium did not use the EU emblem in the communication activities of the action. Therefore, the reduction by 13,3% will affect all beneficiaries, because the breach is not specifically linked to one (or more) of them.*

Each beneficiary's revised final grant amount after reduction of the grant:

beneficiary A: lower between (EUR 700 000 and (800 000/3 000 000) x 2600 000 = EUR 693 333) = EUR 693 333

beneficiary B: lower between (EUR 1 600 000 and (1600 000/3 000 000) x 2 600 000 = EUR 1 386 667) = EUR 1 386 667

beneficiary C: lower between (EUR 700 000 and (600 000/3 000 000) x 2 600 000 = EUR 520 000) = EUR 520 000

For recovery (see Article 44.1.3):

The revised final grant amount for each beneficiary (as calculated above) needs to be compared with its share of the final grant amount and the difference must be recovered:

beneficiary A: 700 000-693 333 = EUR 6 667

beneficiary B: 1600 000-1 386 667 = EUR 213 333

beneficiary C: 700 000-520 000 = EUR 180 000

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[51] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[51] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable****]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

The Commission/Agency will '**recover**' the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

Recovery normally takes place only at payment of the balance or afterwards. Exceptionally, it can take place before, if a beneficiary's participation is terminated.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[63]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered 'paid'.

[63] *See Article 80(1) of the Financial Regulation.*

Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission/Agency may offset before this date, in order to safeguard the EU's financial interests.[64]

If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. (The interest is normally offset first, before the principal amount).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or
    - adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[65].[66]

      The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

The Commission/Agency will recover *after termination* of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

4. Recovery at the payment of the balance

The Commission/Agency will recover *at the payment of the balance*, if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

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[64] *See Article 87 of the Rules for Application.*

[65] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[66] *See Article 79(2) of the Financial Regulation.*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

For the rest of the procedure, *see point 2*.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The '**share of the final grant amount**' is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery at the payment of the balance:

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100 %
Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)

Total eligible costs approved by the Commission: EUR 2 430 000

Final grant amount: EUR 2 430 000

EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000

Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5 % of the maximum grant amount; see Article 21.2) = EUR 150 000.
Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:

A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

Step 1: identification of the beneficiaries that received funds in excess:

Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);

beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)

beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);

beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Step 2: distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:

The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.

Total payments made in excess = 320 000.

Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.

Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.

Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium.

5. Recovery after payment of the balance

The Commission/Agency will recover *after payment of the balance*, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid too much (or that the coordinator has not distributed the payments received).

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount *(see point 4)*.

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

For the rest of the procedure, *see point 2*.

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised grant amount for the beneficiary concerned with its share of the final grant amount.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

'Underspent GA' means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

– **for an overspent GA:** Each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

If the revised grant amount is lower than its share of the final grant amount, the beneficiary must repay the difference.

Example for calculating a recovery in an underspent GA:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:

(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example for calculating a recovery in an overspent GA:

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C

Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000

Reimbursement rate for all the beneficiaries: 100%

Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000

Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000

Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000

Total eligible costs of the consortium approved by the Commission = EUR 600 000

Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Step 1: Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary approved costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*

EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667

Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000

Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Step 2: Calculation of the revised grant amount after the audits:

The revised final grant amount is calculated as follows:

For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500

For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Step 3: Calculation of the amount to be recovered:

The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount

For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered

For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. Since for Beneficiary C the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Agency or the]* Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation no 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose administrative and/or financial penalties (— in proportion to the seriousness of the misconduct).

'**Financial and/or administrative penalties**' are possible (in addition to other measures) for **serious misconduct** (i.e. substantial errors, irregularities or fraud, serious breach of obligations or false declarations) and will be imposed in proportion to the seriousness of the misconduct.

Examples: *plagiarism; absence of time-recording systems (although required); false declaration concerning SME status.*

The **maximum penalties** are as follows:

- for *administrative* penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for *financial* penalties: between 2% and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and **20%**.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

The Commission/Agency may **publish** the decision to apply penalties on their websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU's financial interest and image)
- the time that has elapsed since it took place
- the duration and recurrence of the misconduct
- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned (for the basic contradictory procedure, *see Article 42*).

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount

The basic recovery procedure *(see Article 44)* applies.

However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

Example for calculating a financial penalty:

GA with a maximum grant amount of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

During an audit of the first reporting period, the Commission finds that beneficiary A has overdeclared its personnel costs by 20 % and has falsely certified that the information on the time spent on the action set out in the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5 % of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5 % of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and overdeclared its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15 %.*

New financial penalty: 15 % of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also overdeclared its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15 %, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15 % of 450 000 = EUR 67 500.

Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability (of the Commission/Agency) for damages

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

- causes damage to a third party (including another beneficiary)

  Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

- suffers damage

even if the beneficiary was grossly negligent.

Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability (of the beneficiaries) for damages

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency (— for the amount of damage caused).

Examples: *Costs of legal proceedings borne by the Commission.*
At a meeting on Commission premises, a beneficiary smokes and causes a fire.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned (for the basic contradictory procedure, *see Article 42*).

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

The basic recovery procedure *(see Article 44)* applies.

However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

If the damages are not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (by the Commission/Agency)

The Commission/Agency may 'stop the clock' (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

'Suspension of the payment deadline' must be distinguished from 'suspension of payments' (see Article 48). Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary that is, for example, suspected of serious misconducts.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**
- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs

  This is not an in-depth verification and can therefore not guarantee their eligibility or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.
- calculate the amount to be paid
- approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

  Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*
- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete.*
- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (by the Commission/Agency)

The Commission/Agency may suspend (pre-financing or interim payments for one or more beneficiaries or the final payment for all of them), on the grounds listed in this Article.

'Suspension of payments' has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments:

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations *(see also Article 50.3)* — either during the award procedure or under the GA.

  Example: *statements made by the beneficiary in the declaration form are found to be false.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

  For the ongoing GAs of the beneficiary, the Commission may suspend:

  - *outstanding pre-financing and/or interim payments to the beneficiary in question*
  - *(if necessary) outstanding payment of the balance for all beneficiaries.*

  until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator (for the basic contradictory procedure, see *Article 42)*.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned.

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted.

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*

15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*

1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*

1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*

10 August: *the Commission pays for all beneficiaries except B.*

25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation (by the beneficiaries)

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

'Suspension of the action implementation' may be used exceptionally if it is necessary to stop the implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g.* ***inform*** *the Commission/Agency under Article 17.2;* ***notify*** *a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the '**resumption date**' set out in the amendment), if the Commission/Agency approves the amendment.

> ***Example:*** *The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the Commission/Agency has set a lower budget in the amendment, to adapt the action to the new situation).

> ***Example:*** *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **cannot be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:*** *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*
>
> - *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
> - *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation (by the Commission/Agency)

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations *(see also Article 50.3)* — either during the award procedure or under the GA

  Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

  The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42).*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the GA (or the participation of a beneficiary) may be terminated.

If the suspension leads to the termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the termination of the GA.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative** and/or **financial penalties** *(see Article 45)*.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The beneficiaries have the right to terminate the GA.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

Improper termination of the GA may lead to a reduction of the grant (see *(see Articles 5.3 and 43)*.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*) of the termination on behalf of the beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. before the notified date on which termination takes effect) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. (The Commission/Agency will not send a reminder and will not extend the deadline.)

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion and provide it to the Commission/Agency if obtained.

Termination may in principle be based on **any ground**.

If a beneficiary goes **bankrupt** or is wound up, it or the coordinator must **inform** the Commission/Agency and notify the termination of its participation — without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

Improper termination of the participation of a beneficiary may lead to the termination of the GA *(see Article 50.3.1(c))* and/or to a reduction of the grant at the payment of the balance *(see Articles 5.3 and 43)*.

2. Procedure

The coordinator must formally notify the Commission/Agency (through the electronic exchange system; *see Article 52* of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the electronic exchange system).

Notification can only be made by a person authorised to do so in the electronic exchange system (authorisation is linked certain roles (i.e. functions) in the electronic exchange system; *see the Online Manual*).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

NO amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example: *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so) — unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only **costs** incurred before termination (i.e. before the notified date on which termination takes effect) are eligible— except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. (The Commission/Agency will not send a written reminder and will not extend the deadline.)

If the coordinator fails to submit the *report on the distribution of payments*, the beneficiary whose participation was terminated will NOT have to repay any amounts.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION:** not applicable];*

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION:** not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:
  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
    - termination takes effect after an interim payment and
    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. Termination of the GA or of the participation for one or more beneficiaries (by the Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

Grounds for termination (by the Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the termination of the GA; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or the consortium no longer complies with the eligibility criteria set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*. [67]

  Examples:

[67] *See also Article 8 of the Rules for Participation.*

1. Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).

2. A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.

- **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.

- **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.

- **Bankruptcy, winding-up, administration**, **arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.

The beneficiaries must **inform** the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e.

the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country/IO action does not start by the date specified in Annex 1

  In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

- the third country/IO action is terminated

- the third country/IO action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA — substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

A '**serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity**.**

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The*

Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary cdeclared costs in its financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 and 34.3 or of the ethics requirements set out in Annex 1 *(see Article 34.2)*.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and,
  - have a material impact on this grant.

Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*).

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy, winding-up, administration, etc.), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**.

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases, the termination will take

effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. before the date on which termination takes effect) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative** and/or **financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What?

In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Force majeure normally has no specific effects on the eligibility of **costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

New in Horizon 2020: This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

How?

The party concerned by force majeure must immediately **formally notify** the other party (via the coordinator, via the electronic exchange system, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[the Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[European Commission][name of the Agency]
[Directorate-General][Department] [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

1. Communication between the parties — Electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via the electronic exchange system** (i.e. 'My Area' in the Participant Portal).

The electronic exchange system offers different **functions**:

- viewing and changing the legal entity data in the 'Beneficiary Register'
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the My Area 'messages' function
- formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), via the My Area 'formal notifications' function
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

The electronic exchange system keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

⚠ A formal notification is **considered to have been accepted** ten days after it is sent (— even if it has not been opened by recipient, *e.g. refusal of reception or omission*).

Deadlines that are counted from the date of receipt are counted as of day eleven.

All messages are recorded in the 'grant file' (with date and time).

Formal notifications are also recorded via the 'formal notifications' function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access to the electronic exchange system is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' (i.e. function) that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system (*see the Online Manual*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Coordinator Contacts (CoCos) may submit information to the Commission.*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the electronic exchange system). They cannot submit information directly to the Commission.*

5. *Only the Participant Contact (PaCo, or CoCo in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.*

For more information on access and roles in the electronic exchange system*, see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations)*.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[52], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[52] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid.A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

- An amendment is necessary whenever there is a need to **change** the GA (i.e. its 'Terms and Conditions' and/or the Annexes).

⚠ The *general* terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.

If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.

If a linked third party ends its participation, the option in Article 14.1 will be updated to fix its 'end date'.

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and with an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be rectified; to modify Annex 1 following a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Indicative list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation is terminated** *(see Article 50.2 and 50.3)*.

  There are two main cases for removing a beneficiary:

  - if it never became beneficiary (because of non-accession to the GA or non-provision of the requested declaration on joint and several liability).

    In this case, the amendment will be triggered by the Commission/Agency and the beneficiary is removed from the beginning (since it has never been a beneficiary).
  - for other reasons set out in Article 50.

  The amendment may be triggered by the beneficiaries or by the Commission/Agency.

  For termination by the beneficiaries:

  - the request for amendment must be part of the notification of termination
  - it has to include the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency:

  - there has to be a contradictory procedure *(see Article 50.3.2)*
  - after termination, the coordinator must submit (within 60 days from the termination date) the amendment request with all the supporting documents *(see Article 50.3.3).*

There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

If the coordinator is removed, the amendment has to propose a new coordinator.

The 'termination date' will be added to the Preamble and the beneficiary will be entitled to submit costs until that day.

For termination by the beneficiaries: the 'termination date' must be specified in the notification and must be a future date (i.e. after notification; *see Article 50.2.1*).

For termination by the Commission/Agency: the 'termination date' will be either:

- the date specified in notification confirming termination or
- the day after the coordinator receives the notification confirming termination.

Combination with other changes: If the beneficiary was participating with linked third parties, they will also have to be removed (with effect from the same date) and the 'end date of participation' will be added to Article 14.

The termination will normally also imply a change of Annexes 1 and 2.

By contrast, the GA options for the beneficiary (and its linked third parties) will NOT be deleted or become not applicable (since they were part of the GA and (many) obligations continue to apply after termination).

- **Adding a new beneficiary** *(see Article 56.2)*

The new beneficiary must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC),'

The request for amendment must include;

- Annex 3 (Accession Form) signed by the new beneficiary in the electronic exchange system (i.e. via 'My Area' in the Participant Portal; *see Article 52*) before submitting the amendment request,
- a PDF copy of the signed Annex 3a (declaration of joint and several liability of its linked third parties if requested by the Commission/Agency),
- Annex 3b (Administrative Arrangement signed by the Joint Research Center (JRC), if applicable).

The 'accession date' will be added to the Preamble of the GA.

The new beneficiary has to indicate the accession date in its Accession Form.

Combination with other changes: The addition will also imply a change of Annexes 1 and 2 and — depending on the type of beneficiary and its H2020 status(es) — GA options will be added.

Examples:

If the new beneficiary is an international organisation, the options for international organisations under Articles 22.4 and 53.2 will be added to the GA and the options under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Adding or removing a linked third party** *(see Article 14)*

Although they are not beneficiaries, the change of a linked third party (i.e. if it ends its participation or joins the action) also requires an amendment to update Article 14 (to state/remove their name and to fix their starting/end date).

The new linked third party must first be registered (and validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code (PIC)'.

NO amendment is necessary for a change of name; a change of the linked third party data (and validation) in the 'Beneficiary Register' is sufficient.

- **Change of beneficiary due to partial takeover** (called 'partial transfer of rights and obligations' in FP7)

> ⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

What? '**Partial takeover**' means that a PART of the business of the beneficiary (including the GA) is taken over by (one or more) other entity(ies) ('transfer of a business unit as a going concern', *e.g. partial acquisition, distribution of a business unit on dissolution/liquidation, division/demerger, etc.).*

'**Partial acquisition**' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorb or take over part of the rights and obligations of the original entity). Thus, some of the rights and obligations (and contracts) of the original entity are transferred to the new entity (i.e. a partial transfer of the rights and obligations of the original entity). Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'**Distribution of a business unit on dissolution/liquidation**' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entity(ies) purchase(s) a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only some of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'**Division/demerger**' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has one ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two 'partial takeovers': one to company E and one to company O.*

> ⚠ The new beneficiary(ies) will (each) be **fully** jointly and severally **liabl**e with the former beneficiary for recoveries under Article 44. (By contrast: No joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

What not? Simple **sale** of (one or more) **assets** of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. (In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary).

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

⚠ NO amendment is necessary for '**universal takeovers**' (i.e. where the original entity is replaced by one new entity and all the rights and obligations are transferred to this new entity); a change of the beneficiary data (and validation) in the 'Beneficiary Register' is sufficient (*see below*).

How? The coordinator must request an amendment; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as 'new beneficiary').

'New beneficiary' is used only for the purpose of the amendment; it may means either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular, explain the financial liability of the former beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts, if possible). (Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.)

If the new beneficiary joins the GA, it must first register (and get validated) in the 'Beneficiary Register' of the Participant Portal — unless it already has a validated 'participant identification code' (PIC).

- **Changes to the status of a beneficiary/linked third party as 'receiving EU funding' or 'not receiving EU funding'**

If the status of a beneficiary/linked third party — exceptionally — changes during action implementation *(e.g. due to a change of establishment)*, this change of status will require an amendment.

Example: *Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.*

New association agreements (between the EU and third countries) do NOT have an impact on ongoing grants. The beneficiaries keep the status they had at the moment of the signature of the GA.

- **Change of coordinator**

If the new coordinator is not a beneficiary of the GA, it must first accede to the GA as a new beneficiary *(see Article 56.2)*. The former coordinator may continue to participate in the action as a beneficiary or may terminate its participation.

An amendment to change the coordinator remains possible (and necessary) *after* the end of the action *(see Article 3)*.

The 'handover' date will be added to the Preamble of the GA.

The beneficiaries may choose a 'handover date' in their amendment request. (If the former coordinator leaves the consortium, this date must be after the 'termination date'; if the new coordinator joins the consortium, the date must be after the 'accession date'). Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the coordinator's bank account for payments**

An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

The bank account data must first be updated in the Beneficiary Register (and be validated).

NO amendment is necessary for a change of the name of the bank, address of branch or name of the account holder; a change of the bank account data (and validation) in the 'Beneficiary Register' is sufficient.

- **Change of the option for 'authorisation to administer'**

  The option in Article 41.2 can be added/deleted or changed *(e.g. change of name of the entity with 'authorisation to administer")*.

- **Change of the action's title and/or acronym**

  Example: *the consortium finds out that the acronym of their action is a protected trademark.*

- **Change of the starting date, action duration or reporting periods**

  Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

  An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

  ⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

  The amendment request must specify the dates when the suspension started and ended. The action implementation is then automatically resumed as from the following day ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:
  - a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning **in-kind contributions** provided by third parties (against payment or free of charge) or **subcontracts**

    Such changes could in principle also be made via the 'simplified approval procedure' *(see Articles 11, 12 and 13)*; however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency agreement (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency could consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).
  - changes concerning the tasks to be carried out by **linked third parties** and related costs
  - changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount *(see Article 5.1)* and/or the action's estimated eligible costs *(see Article 5.2)* will be accepted ONLY in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount *(see Article 5.1)* can NEVER be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2** and Annex 2a **(estimated budget)** which require an amendment *(see Article 4)*, in particular:
  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

– a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*.

Examples:

1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices ('average personnel costs').*

2. *An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to modify the action's estimated budget in Annexes 1,2 and 2a.*

Best practice: If Annex 2a needs to be changed, the beneficiaries should contact the Commission/Agency (via the My Area 'messages' function).

- **Change concerning specific cost categories ('specific unit costs')**

If the options in Articles 5.2 and 6.2 must be added/deleted, an amendment to the GA is necessary.

Best practice: If the change concerns specific unit costs, the beneficiaries should contact the Commission/Agency (via the My Area 'messages' function).

Indicative list of cases where NO amendment is needed:

- **Budget transfers not listed above**

Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name or address of a beneficiary, linked third party or coordinator**

Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA do NOT require an amendment; an update of the beneficiary/data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

Linked third parties must **inform** their beneficiary who must inform the Commission/Agency (since they do not have a LEAR) (via the electronic exchange system) *(see Article 17.2)*. The data will be updated in the Beneficiary Register by the Commission/Agency and validated.

If — exceptionally — the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may then request it.

Example: *Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.*

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

Transfers of the GA linked to a **universal takeover** (i.e. where the original entity is replaced by one new entity and all the rights and obligations (including the GA) are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the 'Beneficiary Register' is normally sufficient.

Example: *Beneficiary X merges with another existing entity Y by:*

– *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*

– *establishing a new separate legal entity (X and Y are together known as 'Z').*

If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may then request it.

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.*

For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

In addition to updating the data in the Beneficiary Register, the beneficiary must **inform** the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the electronic exchange system) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

How?

Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) **directly in the electronic exchange system** (i.e. 'My Area' in the Participant Portal; *see Article 52*).

Best practice: If none of the amendment clauses available in the IT tool are appropriate, beneficiaries should contact the Commission/Agency (via the My Area 'messages' function), to discuss the amendment.

⚠ Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the 'Beneficiary Register'.

Examples:

A new beneficiary must be validated ('legal entity validation'). This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

Validation of the new bank account, to change the bank account.

⚠ The amendment request must include the necessary information and supporting documents.

Examples:

For a change of coordinator without his/her agreement: the coordinator's opinion (or written proof that this has been requested).

To add a new beneficiary: an Accession Form (Annex 3) duly signed in the electronic exchange system (see Article 56.2).

To amend Annexes 1 and 2: amended versions of these annexes.

⚠ A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action, i.e. the date set out in Article 3). Requests introduced after the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance*)).

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Before it has been accepted or rejected, it may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

If accepted it will be **counter-signed** by the receiving party (again, directly in the electronic exchange system by the PLSIGN).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the electronic exchange system).

The other party must — within **45 days** — **agree or disagree**, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the electronic exchange system.

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the electronic exchange system).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

If the parties agree on a specific date, it should normally be *after* the entry into force. In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

Where a new beneficiary is added to the GA, it must assume the rights and obligations from the 'accession date' specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the 'resumption date' set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (by the beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* in the electronic exchange system (together with the declaration(s) of joint and several liability, if any). They must do this within 30 days after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on joint and several liability *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

If the beneficiary does not submit this declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Linked third parties do not become parties to the GA and therefore do NOT sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020). All documents are available in the electronic exchange system (i.e. 'My Area' in the Participant Portal).

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How?

The new beneficiary must:

- register in the 'Beneficiary Register' of the Participant Portal and be validated — unless it already has a validated 'participant identification code (PIC)'
- sign the Accession Form directly in electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium *[**OPTION for international organisations that do not accept application of Union law:** except for [insert name(s) of the international organisations concerned]].*

[OPTION for international organisations that accept application of Union law but not Belgian law:** For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].**]

1. Applicable law

As a general rule, Horizon 2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations for international organisations:

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[68]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA.

[68] *See Article 180(1) of the Rules of Application.*

	In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).****]***

1. Dispute settlement

As a general rule, Horizon 2020 GAs contain an 'Article 272 TFEU arbitration clause', referring **disputes on the interpretation, application or validity of the GA** to the Court of Justice of the European Union.

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against 'confirmation letters', 'debit notes', etc.; NOT against 'audit reports', 'letters of audit conclusions' 'pre-information letters', etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative or financial penalties, offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions (by any beneficiary — including non-EU beneficiaries, 'beneficiaries not receiving EU funding' and IOs) must be brought before the Court of Justice of the European Union under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ All procedures are organised in a way that the beneficiaries will be **informed** of the available **means of redress** (via a 'redress clause' in the letters).

For more information on complaints*, see the Online Manual.*

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, disputes on the interpretation, application or validity of the GA are normally referred to the competent Belgian courts. (So far (i.e. until end of 2014) none of the agreements associating third countries to Horizon 2020 provides for the sole jurisdiction of the Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Non-EU beneficiaries not receiving EU funding and **international organisations (IOs) —** For beneficiaries not receiving EU funding and international organisations disputes on the interpretation, application or validity of the GA, disputes are referred to the Permanent Court of Arbitration *(see also point 1)*. (⚠ This referral is in line with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[69]).

Disputes of public law nature remain before the European Court of Justice.

[69] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)
- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for principal beneficiary not receiving EU funding:*** *as 'beneficiary not receiving EU funding' (see Article 9),**]*** represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

[OPTION by default: 'principal investigator':[4]

- *[**Name**][Date and place of birth]**]***[5]

[OPTION for SyG: 'corresponding principal investigator':

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]].**]***

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

*[same for each beneficiary**]***

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

- Depending on the type of ERC grant, (at least) one of the beneficiaries is the institution that hosts (and or employs/engages) a **principal investigator** ('**host institution**').
- The PI is usually employed (or engaged) by the host institution for the entire action duration.

The PI and the host institution must also sign a 'supplementary agreement (SA)' *(see Article 32)*.

The supplementary agreement can NOT replace the employment/engagement contract.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

PIs can be of any nationality, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted by a host institution that is based in an EU Member State or H2020 associated country and can receive EU funding.

Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

The Agency must be **informed** before any change in employment or location of the PI.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities. The engagement of the team follows the rules of the beneficiary and its country.

PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions must sign a '**supplementary agreement (SA)**' *(see Article 32)*.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party *(see Article 8)*, i.e.:

- a third party from an EU Member State or H2020 associated country that provides the PI as in-kind contribution or
- a linked third party.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution *and* the third party.

Retired PI — The PI may be retired (i.e. normally no longer under an active labour contract).

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties)

Portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'.

Thus, the ERC MGA does NOT have:

- 'personnel costs for providing trans-national access to research infrastructure'
- 'direct costs of providing financial support to third parties'
- 'specific cost categories'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[70]

It does NOT use the unit costs of the 'specific cost categories' of the General MGA.

[70] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* **—** with the exception of 'direct costs of providing financial support to third parties', 'specific cost categories' and 'costs for providing access to trans-national research infrastructure'.

The same **conditions for eligibility** and rules for **calculation** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the **following specificities**:

– for 'direct personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: as 'personnel costs – costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3)).

– for 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs' (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs, and research data) are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

2. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

⚠ ERC grants do NOT prevent PIs from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ℹ For more information on how to combine EU funding from different programmes ('complementary EU funding' or 'synergies'), *see the Online Manual.*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must however be hosted (or engaged) by the principal beneficiary (NOT with other beneficiaries or linked third parties — unless s/he is exceptionally employed/engaged by a third party.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

In addition, the beneficiaries must however prove that the **time-commitment of the PI** (as described in Annex 1) was complied with.

Thus, they must be able to provide evidence that the PI complied with the minimum time-commitment set out in the ERC work programme for *time spent on the action* (percentage of the total working time, i.e. annual productive hours calculated in compliance with Article 6) — via time-sheets or alternative time recording systems.

Moreover, they must be able to provide evidence that the PI complied with the minimum time-commitment set out in the ERC work programme for *research work in a EU Member State or H2020 associated country* — via time records or alternative evidence *(e.g. a self-declaration by the beneficiary)*.

Both must be proved, even if the salary of the PI is not covered by the grant (i.e. if the salary is not part of the estimated budget).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How?

All reports must be prepared and submitted **directly in the electronic exchange system**, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

Example: *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.****]***

[OPTION: *Not applicable****]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

ERC grants have however the **following specificiti**es:

Open access to scientific publications for monographs or books (or parts of them) is only a best effort obligation. It is sufficient that the beneficiary makes its best efforts to comply as far as possible and can provide evidence for these efforts.

> ***Examples:*** *Fulfilling all aspects of Article 29.2 may not be possible if there is no open access option, if the publisher does not allow depositing of the electronic version in a repository, or if a book is only published as print edition with no electronic version available.*

Moreover, the ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

Also, for publications issued after the end of the action, beneficiaries are NOT obliged to provide for immediate open access within the given deadlines if this would incur additional costs for 'gold' open access. Instead, they may choose 'green' open access even if the embargo period imposed by the publisher goes beyond the given time limit of six/twelve months.

Moreover, with explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[71] or other systems).

> **Best practice:** If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if provided in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the **following specificities**:

For ERC actions, there is NO formal requirement for a 'data management plan'. Nonetheless it is Annex 1 that sets out how research data will be handled during the action implementation and afterwards *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*.

[71] For more information, *see http://www.doi.org/.*

Moreover, the exception allowing beneficiaries NOT to give access to specific parts of research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives. (For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does not need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.)

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[36] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary *[**OPTION for SyG:** and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement *[**OPTION for SyG:** and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[36] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005.p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g. access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow for transfer of the GA to another host institution (**portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** for the beneficiary and contribution to the **financial reporting**
- Meeting the time commitments for **implementing the action**
- Applying the beneficiary's usual management practices

- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**
- Upholding the **intellectual property rights** of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: *The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.*
- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the beneficiary and the PI, to set out their internal arrangements for implementing the grant. It is **purely internal**; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must last at least for the action duration *(see Article 3)* (**—** without any interruptions, even if the PI works only part-time on the ERC project).

The supplementary agreement must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

The supplementary agreement must be concluded **before GA signature** (and a copy must be sent to the Agency).

A model supplementary agreement is available on the Participant Portal and the ERC website. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research or PoC grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties).

Portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC homepage*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new beneficiary — at any time during the action implementation.

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

⚠ NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 of the H2020 General MGA)*.

The beneficiaries may choose to let the transfer **take effect** from the entry into force of the amendment or a specific 'transfer date' (before or after the amendment). (Retroactive dates are allowed only in exceptional cases and with a specific justification.)

Best practice: For a retroactive transfer date, the beneficiaries should contact the Agency in advance (via the My Area 'messages' function).

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** the remaining **pre-financing** (not covered by eligible costs) to the new host institution.

If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will NOT pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount set out in Article 5.1.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary). **Scientific reporting periods** will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

A certificate on the financial statement (CFS) must be submitted by the former host institution prior to the last reporting period if it reached the threshold set up in Article 20.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research or PoC grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, it may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and employs the PI will become the new host institution.

II.3 H2020 ERC MGA PoC: Annotations

The H2020 ERC MGA PoC is very similar to the H2020 ERC MGA.

> Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.
>
> There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability (*Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not found by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(f) *a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

(g) *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)****]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Periodic reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) *a summary for publication by the Agency;*

(b) *an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

(c) *detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

(d) *an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What?

For ERC PoC actions, the principal beneficiary must submit reports — only one '**report**' if there is one reporting period, otherwise one '**periodic report**' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a 'certificate on the financial statements (CFS)' will have to be added (if necessary).

How?

All reports must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie (MSC) MGAs

III.1 Background information and approach

The Marie Skłodowka-Curie (MSC) Model Grant Agreements are used for grants for MSC actions only, i.e.:

- MSC-ITN
- MSC-IF
- MSC-RISE and
- MSC-COFUND.

The MSC MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA MSC-ITN deviates from the General MGA as follows:

- Article 4.2 (MSC-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to ‘mainstream media coverage’)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

The H2020 MGA MSC-IF deviates from the General MGA as follows:

- Article 3 (notified starting date)
- Articles 4.2, 8-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSC-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSC-IF specific conditions for termination)
- Article 55 (MSC-IF specific conditions for amendments)
- Article 56a (MSC-IF portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The H2020 MGA MSC-RISE deviates from the General MGA as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSC-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (MSC specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

The H2020 MSC-COFUND deviates from the General MGA as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of programmes)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 8-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSC actions are added:

- Article 2 (MSC-ITN actions; MSC-IF actions; MSC-RISE actions; MSC-COFUND actions)
- Article 4.1 (MSC-ITN budget categories; MSC-IF budget categories ; MSC-RISE budget categories; MSC-COFUND budget categories)
- Article 8 (MSC-ITN rules on third party involvement; MSC-IF rules on third party involvement; MSC-RISE rules on third party involvement; MSC-COFUND rules on third party involvement)

III.2 H2020 MGA MSC-ITN: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-ITN actions

What? MSC-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by 'networks' of universities, research institutions, research infrastructures, businesses, SMEs and other socio-economic actors from different countries).

MSC-ITN actions take the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSC-ITN actions are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSC-ITN actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

***[OPTION for all actions except EID:** However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.]*

1. Budget categories

The MSC-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSC-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may re-distribute person-months between them (as compared with the original planning set out in Annex 2). This re-distribution can be done without requesting an amendment (see *Article 55*) provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however NEVER be increased.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the distribution of the institutional unit cost for management tasks do NOT need to be notified to the Agency.

***Example:** Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

Budget transfers will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Transfers are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment *(see Article 55)* will be required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID: the 40 % limit of budget allocated to beneficiaries established in the same country or to the same international European interest organisation or international organisation.

  The 40% is counted on the basis of the number of person-months allocated to each beneficiary in Annex 1.

Transfers between *budget categories* are, by contrast, NOT possible because MSC unit costs are all linked to the person-months declared for the recruited researchers.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-ITN actions, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[72].

For MSC-ITN these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[72] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC uses only unit costs, there is NO reduction due to the no-profit rule in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiary (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country where the research training activities take place for more than 12 months in the 3 years immediately prior to the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country).

For beneficiaries that are the international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately prior to the recruitment date;

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree[;][.]**]***

(viii) ***[OPTION for EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

1. Costs for recruited researchers: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover costs related to their mobility, *e.g. relating to travel and accommodation*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by the budget category 'research, training and networking costs"

AND

- a monthly family allowance for researchers with family, to reduce family-related obstacles to researcher mobility.)

The mobility and family allowances are due to the researcher for each month worked.

What not? Costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

Example:

Costs for student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[73] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** per researcher per month ('person-month')

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient**'.

- for the mobility allowance: **EUR 600** per person-month

[73] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the family allowance: **EUR 500** per person-month.)

> For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities (e.g. during maternity/parental leave) are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years of their research career.)

    '**Date of recruitment**' normally means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    > ***Example:***
    > *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as 'date of recruitment'.*

    Years of '**research career**' are counted as 'full-time-equivalent research experience', from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:

    – sickness, parental, unemployment and invalidity benefits

    – pension rights and

    – benefits for accidents at work and occupational diseases.

    If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:

    – sickness, parental and invalidity benefits and

    – benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

  - as a rule, be employed **full-time**

Part-time employment can be accepted:

- subject to prior approval by the Agency
- on personal or family grounds only and
- not for professional reasons.

- **work exclusively** on the research training activities

  Any complementary skills training *(e.g. a minor teaching activity)* is not incompatible, but must not jeopardise execution of the research training activities and must be set out in Annex 1 to the GA.

- are supported for **at least three months**

  Person-months linked to shorter contracts will not be eligible. However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. Thus, if the contract is set out for a longer duration, but the training is interrupted within the first three months (e.g. the researcher resigns), the costs may still be claimed.

- comply — at the time of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the recruitment date (unless the beneficiary is an 'international European interest organisations'[74] or international organisation, for whom the mobility rule is limited to time spent *with* them)

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  In the case of EJD, the programme must lead to the award of:

  - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
  - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  MSC-ITN researchers may NOT be requested to pay tuition fees for their research training and/or PhD degree programme (from their own funds or from the researcher unit cost). (The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation)* may be covered by the budget category 'institutional costs'.)

  Family and mobility allowances can be paid to the researcher in various ways *(e.g. with his/her salary, in the form of a flight ticket directly purchased or reimbursed by the beneficiary, etc.)*, provided that:

  - the researcher can freely decide on the form of payment

[74] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

- it is not in contradiction to national (tax) legislation and
- there is no underpayment.

For beneficiaries with accounting in a **currency other than** the **euro**:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[75]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[76].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers that have — at the date of the recruitment — a family, i.e.
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country or region in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

[75] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[76] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

⚠ Beneficiaries may NOT declare more than 36 person-months per researcher. (Person-months exceeding this number will be rejected by the Agency.)

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector. This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations.

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, and training)*
  - costs for research expenses
- management and indirect[77] costs (i.e. the beneficiary's additional costs in connection with the action).

  The management and indirect costs received can be distributed within the consortium (via an internal agreement). The distribution should however roughly correspond to the actual division of (management) tasks within the consortium. They should also be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[78] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 1200** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[79], this amount is halved, i.e. EUR 600).)

In practice the declaration of institutional costs for MSC grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for the budget category 'costs for recruited researchers' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

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[77] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[78] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[79] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for recruited researchers:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-ITN actions do allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that provide training and host researchers during a secondment).

Partner organisations can NOT employ the researcher under the action.

The beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSC-ITN actions, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these procedures end.)

Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of the researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after the first year** of the action — send to the Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal) a progress report, to inform the project officer about progress on the action.

How? The report must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. Deliverable: Mid-term review meeting

What & When? The coordinator must:

- **before** the deadline for the **periodic report for RP 1**: organise a mid-term review meeting and
- **no later than 30 days** before this meeting: send to the Agency (via the electronic exchange system) a draft version of the periodic report, as a basis for the mid-term review meeting.

3. Deliverable: Researcher declaration

What & When? The beneficiary must send to the Agency (via the electronic exchange system) a document with information about each recruited researcher ('researcher declaration') — within **20 days** after the recruitment (of the researcher).

It is important to give correct and complete information since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. (If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher).

- **How?** The researcher declaration must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSC-ITN actions, the MSC-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA).*

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[14] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or any other entity referred to in Annex 1);

(j) host the researchers at their premises and provide training as well as the necessary means for implementing the action;

(k) ensure that the researchers are adequately supervised;

(l) ensure that a career development plan is established and support its implementation;

(m) ensure an appropriate exposure to the non-academic sector;

(n) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[14] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSC-ITN actions, the MSC-ITN MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for them.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[80]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises and **provide training** as well as the necessary means for implementing the action

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**

[80] Available at http://ec.europa.eu/euraxess/

- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[81].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[82].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie programme, to make the researcher aware that s/he is a **MSC fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSC website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities, including during secondments/placements with other beneficiaries and/or partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2)*
- Ensure that the researchers do NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Ensure that **secondments** are **limited** to a maximum of 30 % of the months spent implementing the research training activities under the action.

  Secondments may be either to another beneficiary within the consortium or to a partner organisation and must involve research training activities.

  For EID and EJD, the 30% rule applies only to secondments, summer schools and other activities that complement the main doctoral training.

  Example: *In the context of an EID action, University X hires a researcher for three years. Under 'inter-sectoral mobility', the researcher works in a laboratory in the non-academic sector for the obligatory one and a half years (50 %). In addition, the researcher may be seconded to partner organisations, but for no more than 30 % of the recruitment period.*

2. Employment contract — Obligations on the researchers

The MSC-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSC grants at the same time.

[81] Available at https://www.iprhelpdesk.eu/.
[82] Available at http://ec.europa.eu/euraxess/.

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MGA MSC-IF: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-IF actions

What? MSC-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSC-IF actions take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include two additional funding strands: the 'Career Restart Panel' and the 'Reintegration Panel'.

MSC-IF actions are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSC-IF actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION if needed for the action:** insert date]*[5] ('**starting date of the action**').

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSC-IF actions, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSC-IF MGA provides for an additional option, where the starting date is *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, the notified starting date must be:

- after the entry into force of the GA and within the period of months set out in Article 3
- notified by the beneficiary in *advance* (via the electronic exchange system, i.e. 'My Area' in the Participant Portal).

If the action does not start or the starting date is not notified (in time), the Agency may terminate the GA *(see Article 50)*. If the notification is sent after the start of the action, this will have an impact on the timing of the pre-financing payment and will delay it *(see Article 21.2)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSC-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSC-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSC-IF is a mono-beneficiary action, there is NO re-distribution of person-months between *beneficiaries*.

Transfers between *budget categories* are not possible because MSC unit costs are all linked to the person-months declared for the recruited researcher.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-IF actions, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSC MGAs do not use the **cost forms** of the General MGA, but the the **unit costs** set out in Commission Decision C(2013) 8194[83].

For MSC-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[83] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC uses only unit costs, there is NO reduction due to the no-profit rule in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42).*

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[24]*[***OPTION for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including for a period of secondment to a **partner organisation**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action;

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Costs for the recruited researcher: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover costs related to his/her mobility, *e.g. relating to travel and accommodation*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by the budget category the 'research, training and networking costs").

AND

- a monthly family allowance if the researcher has family, to reduce family-related obstacles to researcher mobility.)

The mobility and family allowances are due to the researcher for each month worked.

What not? Other costs of the beneficiaries for management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[84] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 4650** for the researcher per month ('person-month')

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient**'.

  For GF: there are two different country-specific correction coefficients:

  - for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month
- for the family allowance: **EUR 500** per person-month.)

> For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

[84] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

- be incurred for a researcher who:
  - is — at the time of the call deadline — an **experienced researcher** ('ER'; i.e. have a doctoral degree or have at least four years of research career)

    Years of '**research career**' are counted as 'full-time-equivalent research experience', from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.
  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including
    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases.

    If national law prevents the beneficiary from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:
    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.
  - as a rule, be employed **full-time**

    Part-time employment can be accepted:
    - subject to prior approval by the Agency
    - on personal or family grounds only and
    - not for professional reasons.
  - **work exclusively** on the research training activities

    Any complementary skills training *(e.g. a minor teaching activity)* is not incompatible, but must not jeopardise execution of the research activities and must be set out in Annex 1 to the GA.
- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  Family and mobility allowances can be paid to the researcher in various ways (e.g. with his/her salary, in the form of a flight ticket directly purchased or reimbursed by the beneficiary, etc.), provided that:
  - the researcher can freely decide on the form of payment
  - it is not in contradiction to national (tax) legislation and
  - there is no underpayment.

For beneficiaries with accounting in a **currency other than** the **euro**:

- if a daily rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[85]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[86].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs (for the researcher).

[85] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[86] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

⚠ Although NOT formal cost eligibility conditions for MSC-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the time of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the call deadline

  Specific cases:

  Beneficiaries that are 'international European interest organisations' or international organisations — The researcher may not have spent more than 12 months with the beneficiary in the three years immediately before the call deadline

  EF Career Restart Panel and **Reintegration Panel** — the researcher may not have resided or carried out his/her main activity in the country of the beneficiary for more than three years in the five years immediately before the call deadline.

  GF — the researcher must comply with the mobility rule with regard to the country of the partner organisation (i.e. where the outgoing phase takes place), not for the country of the beneficiary (i.e. where the return phase takes place).

- for GF and EF Reintegration Panel: be nationals or long-term residents of a Member State or an associated country.

  'Long-term resident' means full-time research activity in a Member State (or associated country) for five or more consecutive years.

- for EF Reintegration Panel: not have been active in research for at least 12 months immediately before the call deadline

- for the family allowance: have a family, i.e.:
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country or region in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

⚠ The beneficiary may NOT declare more than 24 person-months for the researcher (or 36 months for GF). (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action and training)*
  - costs for research expenses
- management and indirect[87] costs (i.e. the beneficiary's additional costs in connection with the action).

  They should be shared with a partner organisation which incurred management or indirect costs for a secondment *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[88] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 800** for the researcher per month ('person-month')
- for management and indirect costs: **EUR 650** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[89], this amount is halved, i.e. EUR 325).)

In practice, the declaration of institutional costs for MSC grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for the budget category 'costs for the recruited researcher' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for recruited researchers:

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87 For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

88 Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

89 For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-IF actions do allow for the involvement of **partner organisation(s)** (i.e. organisations that are not beneficiaries, but that provide training and host researchers during a secondment; *see Article 32*).

Partner organisations can NOT employ the researcher under the action. (For GF: this does not however prevent a partner organisation in a third country from contributing to the income of the researcher, in line with Article 32.1(c)(v).)

For GF: the partner organisation must be located in a third country and must be described in Annex 1.

The beneficiary remains solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should (especially for GF) establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSC-IF actions, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSC-IF actions, the MSC-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(g) host the researcher at its premises and provide training as well as the necessary means for implementing the action;

(h) ensure that the researcher is adequately supervised;

(i) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(j) support the secondment of the researcher in Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(k) ***[OPTION for GF:*** *support the return of the researcher to its premises to carry out a mandatory return period of 12 months.****]***

[…]

[11] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSC-IF actions, the MSC-IF MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for him/her.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises and **provide training** as well as the necessary means for implementing the action

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- Support **secondments** of the researcher, if any (and, for GF, support his/her return during a mandatory 'return-period' of 12 months)

  Researchers may be seconded to a partner organisation established in a EU Member State or H2020 associated country *(see Article 8)*:

  – if this is provided for in Annex 1 to the GA

  - for a maximum of three months in an action with a duration of up to 18 months, or up to six months in an action of up to 24 months

> ⚠ The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[90].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[91].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie programme, to make the researcher aware that s/he is a **MSC fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSC website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during secondments to partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6)*

- Ensure that the researcher does NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

2. Employment contract — Obligations on the researcher

The MSC-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

  This also means that a researcher can NOT hold two MSC grants at the same time.

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

[90] Available at https://www.iprhelpdesk.eu/.
[91] Available at http://ec.europa.eu/euraxess/.

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*
- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.
- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. Suspension of the action implementation — Additional grounds for suspension: Professional, personal or family reasons

In addition to the normal grounds for suspension of the action implementation *(see Article 49 H2020 General MGA)*, beneficiaries of MSC-IF actions may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and end date of the suspension and
- the 'resumption date' when the action is resumed (i.e. automatically one day after the end date).

In principle, suspensions (other than for parental leave) **may not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are not eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional grounds for amendments: Change to part-time employment

For MSC-IF actions, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time), on personal or family grounds (including parental leave).

Such amendments are NOT possible for any other reasons *(e.g. other professional opportunities, etc.)*. In those cases, the beneficiary must request suspension of the action implementation or termination of the action.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and a statement from the new beneficiary to take over all rights and obligations under the Agreement.

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a **'transfer report'**, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The maximum grant amount set out in Article 5.1 will be decreased if a lower country correction coefficient is applicable to the new beneficiary.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSC-IF grants can be **transferred** to a new beneficiary.

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

⚠ NO transfer before the amendment has been accepted by the Agency. Any interruption of the action implementation due to an unauthorised transfer is a breach of contractual obligations and the former beneficiary bears the full responsibility for any activity/commitment undertaken before the Agency has approved the amendment.)

The transfer may be based on any **ground** that is linked to the beneficiary and affects the researcher's ability to perform the activities.

Examples: *Internal reorganisation affecting implementation of the project; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher are NOT considered valid grounds for transferring the GA to a new beneficiary. (These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*, so that the researcher can benefit from other professional opportunities or better reconcile work and family commitments without having to forego the grant).

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility criteria or financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed in the electronic exchange system).

3. Effects

The transfer may result in a reduction of the **maximum grant amount** *(see Article 5.1)*, if the correction coefficient for the country of the new beneficiary is lower than the one of the former beneficiary.

⚠ By contrast, the maximum grant amount will NOT be increased if the country correction coefficient for the country of the new beneficiary is higher.

After approval of the amendment, the former beneficiary must**:**

- **transfer** the **remaining contribution** to the new beneficiary and
- **submit a report** to the Agency, including:
  - an overview of progress on results and
  - a financial statement up to the date of the transfer.

III.4 H2020 MGA MSC-RISE: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-RISE actions

What? MSC-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

MSC-RISE actions are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

For more information on MSC-RISE actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSC-RISE MGA does **not use the budget categories of the General MGA**.

Budget categories of the MSC-RISE MGA:

- costs for seconded staff members
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may re-distribute person-months between them (as compared with the original planning set out in Annex 2). This re-distribution can be done without requesting an amendment (see *Article 55*) provided that it does not imply a substantial change to the action as described in Annex 1.

The maximum grant amount *(see Article 5)* can however NEVER be increased.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the distribution of the 'institutional costs' do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

Budget transfers will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Transfers are subject to the following:

- no impact on the action as described in Annex 1

If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment will be required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are, by contrast, NOT possible because MSC unit costs are all linked to the person-months declared for the seconded staff.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs)**.

1. Reimbursement rate

How much? For MSC-RISE actions, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA).*

2. Cost forms

The MSC MGAs do not use the **cost forms** of the General MGA, but the the **unit costs** set out in Commission Decision C(2013) 8194[92].

For MSC-RISE these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[92] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC uses only unit costs, there is NO reduction due to the no-profit rule in MSC MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42).*

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for seconded staff members are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the beneficiary or a partner organisation;

(c) the secondment complies with the following conditions:

(i) last at least 1 month and no longer than 12 months;

(ii) be between:

- a beneficiary established in a EU Member State (or associated country[6]) and a beneficiary established in another EU Member State (or associated country) from different sectors (academic and non-academic) or
- a beneficiary established in a EU Member State (or associated country) and a partner organisation established in a non-EU Member State (or non-associated country), and

(iii) the beneficiary or partner organisation sending the person is established in a country listed in General Annex A of the Main Work Programme.

[6] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

1. Costs for seconded staff members: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members (by providing for:

- a monthly top-up allowance for travel, accommodation and subsistence costs relating to the secondment.)

What not? Costs of the beneficiaries for research, training, networking and management and indirect costs are not covered; they can be declared under the budget category 'institutional costs' (Article 6.2.B).

1.2 These costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[93] and set out in Annex 2 and 2a of the GA (currently

- for the top-up allowance: **EUR 2 000** per seconded staff member per month ('person-month').)

> For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - an **early stage researcher** (i.e. not have a doctoral degree and be in the first four years of his/her research career)
    - an **experienced researcher** (i.e. have a doctoral degree or at least four years of research career) or
    - **administrative, managerial** or **technical staff supporting research and innovation activities** under the action (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

      Examples (not eligible administrative, managerial or technical staff):

      1. *Ms A, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

      2. *Mr X, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

    Years of 'research career' are counted as 'full-time-equivalent research experience', from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (in the country in which it was obtained or in which s/he is recruited).

    - have **already worked** continuously for at least **six months** (full-time equivalent) on research and innovation activities at the premises of the beneficiary/partner organisation

      Example: *Mr X is employed by beneficiary Y as from 1 January 2014; Mr X will not be eligible for a secondment from 1 March but would be eligible for secondment as from 1 July 2014.*

  - be incurred for secondments:

[93] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- that last at **least 1 month** and no longer than 12 months

  Splitting into several periods is allowed.

  Example: *If a secondment is split into two 2-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first 2-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

  Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

  However, only splits within the *same secondment* (same staff, same sending organisation, same hosting organisation) can be added to reach the minimum duration of 1 month.

  Example: *Two secondments of 2 weeks of the same staff member to different organisations are not eligible since the minimum duration of 1 month is not reached.*

- that are one of the following three:

  - secondments **between beneficiaries** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in different EU Member States or H2020 associated countries AND different sectors (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary** in an EU Member State (or H2020 associated country) **to** a **partner organisation** in a third country *(see Article 8)*

  OR

  - secondments **from** a **partner organisation** in a third country listed in General Annex A to the Main Work Programme *(see Article 8)* **to** a **beneficiary** in an EU Member State (or H2020 associated country).

  Examples:

  A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

  Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work Programme.*
  A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

  Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.*
  A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
They may each claim 120 person-months (for their own staff).

Partner organisations are not beneficiaries and therefore can NOT declare costs; their costs must be included in the costs declared by the beneficiary that hosted the seconded staff member from the partner organisation.

During a secondment to a partner organisation, the beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA *(see Article 8)*.

If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded from both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

⚠ Although NOT a cost eligibility condition for MSC-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must also be fully used for the staff member.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('number of implemented person-months')

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert '5.47' as number of person-months.*

⚠ Beneficiaries may NOT declare more than 12 person-months per seconded staff member. (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[94] costs (i.e. the beneficiary's additional costs in connection with the action).

The institutional costs received can be distributed within the consortium (via an internal agreement) according to the needs of the action and of each secondment *(e.g. to further cover the travel and subsistence costs of the staff members, provided this does not have a negative impact on the implementation of the research and innovation activities set out in Annex 1)*. They should also be shared with partner organisations which incurred institutional costs for secondments *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[95] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 700** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[96], this amount will be halved, i.e. EUR 350).)

In practice the declaration of institutional costs for MSC grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the costs for seconded staff.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for seconded staff.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for seconded staff are met. Person-months which are not eligible for the budget category 'costs for seconded staff' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

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[94] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[95] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[96] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.4 The costs are **calculated** (automatically by the IT system) like the costs for seconded staff members:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-RISE actions do allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that participate in the exchanges by seconding and hosting staff).

The beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.

[…]

1. Records and other supporting documentation

For MSC-RISE actions, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and access rights to show duration; lab books, scientific articles, library records to show research and innovation activities*)

    The nature of the records and supporting documents to be kept by the beneficiary depends must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations — For secondments from partner organisations, it is the beneficiary that must keep the documents for the staff of the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1) and
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after each year except if a periodic report is due** (i.e. normally after the first and third year of the action) — submit to the Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal) a progress report, to inform the project officer about progress on the action.

How? The report must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. Deliverable: Mid-term review meeting

What & When? The coordinator must — **before** the deadline for the **periodic report for RP 1** — organise a mid-term review meeting.

3. Deliverable: Researcher declaration

What? The beneficiary must send to the Agency (via the electronic exchange system) a document with information about each seconded staff member ('researcher declaration').

It is important to give correct and complete information. (This information will be used to determine the eligibility of the person-months that are declared.)

When? The researcher declaration must be submitted within **20 days from the start of the secondment**.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — (and indicate each split).

> ***Example:*** *Beneficiary A is sending Mr X to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (an updated one within 20 days from the start date of each secondment).

> ***Example:*** *Beneficiary A is sending Mr X to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

- **How?** The researcher declaration must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

Specific case (deliverables):

Researcher declaration for staff of the partner organisations — For secondments from partner organisations, it is the beneficiary that must submit the researcher declaration.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSC-RISE actions, the MSC-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA).*

Beneficiaries must moreover ensure that the partner organisations give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSC-RISE actions, the MSC-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is a top-up allowance), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are obviously accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary or partner organisation) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)
- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there
- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme
- Ensure that the staff members are seconded **full-time**
- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[97].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*
- **Inform** the researcher about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the EU contribution is **fully used for** the benefit of the **seconded staff** members

  It can be:

  - paid directly to the seconded staff member or
  - managed centrally by the beneficiary according to the specific needs of the secondment.

⚠ The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Best practice: It is strongly recommended that the beneficiaries establish internal arrangements *(e.g. partnership agreements)* with the partner organisations, to ensure that they fulfil their obligations *(see Article 8)*.

[97] Available at https://www.iprhelpdesk.eu/.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract, some of the basic obligations under the MSC-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the Marie Skłodowska-Curie action in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This

allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MGA MSC-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSC-COFUND actions

What? MSC-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSC-COFUND actions cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSC-COFUND actions are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSC-COFUND actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSC-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSC-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSC-COFUND is a mono-beneficiary action, there is NO re-distribution of person-months between *beneficiaries*.

Transfers between *budget categories* are NOT possible because MSC unit costs are all linked to the person-months declared for the recruited researchers.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in programmes implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**);

(b) for **costs of providing financial support to costs for researchers in programmes implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSC-COFUND actions, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Form of costs

The MSC MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[98].

For MSC-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in Article 6.

[98] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

1. Final grant amount

For MSC actions, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSC applies only unit costs, there is NO reduction due to the no-profit rule in the MSC MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSC actions: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSC MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSC actions: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in programmes implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in programmes implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Costs for researchers: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme) (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount)).)

What not? Other costs are not covered. Thus, management costs can be declared under the other budget category ('management costs'; *see Article 6.2.B*). Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are not eligible under the grant; they may be funded through other EU funding programmes.

For more information on how to combine EU funding from different programmes ('complementary EU funding' or 'synergies'), *see the Online Manual.*

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[99] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance:
  - for early-stage researchers ('ESRs') in doctoral programmes: **EUR 3 710** per researcher per month ('person-month')
  - for experienced researchers ('ERs') in fellowship programmes: **EUR 5 250** per person-month.)

For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSC grants is very simple and almost completely automatised: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSC actions: the person-months) must fulfil the following **conditions for eligibility**:

[99] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (including its duration), identifiable and verifiable etc.; *see Article 6.1*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 The costs are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a 'pro-rata unit cost' of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** only the:

- management costs (i.e. direct costs of managing the action).

The management costs should be shared with partner organisations which incurred management costs for secondments or for the implementation of programmes *(see Article 8)*.

What not? Other costs (such as research, training and networking costs and indirect costs) are not eligible under the grant; they may be funded through other EU funding programmes.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[100] and set out in Annex 2 and 2a of the GA (currently:

- for management costs: **EUR 650** per researcher per month ('person-month').)

In practice, the declaration of management costs for MSC-COFUND grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the management costs is directly linked to and conditional on the **eligibility** of the costs for researchers.

Management costs are eligible only if all the eligibility conditions for the researchers are met. Person-months which are not eligible for the budget category 'costs for researchers' are also not eligible for the budget category 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The costs are **calculated** (automatically by the IT system) like the costs for researchers:

- for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

[100] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are not applicable.

Nevertheless, MSC-COFUND actions do allow for the involvement of **partner organisations** (i.e. organisations that are not beneficiaries, but that participate in the action either:

- by implementing a doctoral or fellowship programme (i.e. recruiting the researchers)
- by providing training and hosting researchers during a secondment.)

Partner organisations that *implement* a doctoral or fellowship programme must be established in a EU Member State, H2020 associated country, or third country listed in General Annex A to the Main Work Programme. *Other* partner organisations can be established anywhere.

Partner organisations that implement a doctoral or fellowship programme and are established in a third country must recruit researchers that are nationals or long-term residents of a EU Member State (or H2020 associated country) *(see Article 15.1.1(b))*.

The beneficiary remains solely and fully responsible for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

15.1 Rules for providing financial support to or implementation of *[doctoral][fellowship]* programmes

15.1.1 The beneficiary must **implement *[doctoral][fellowship]* programmes** or **provide financial support** to such programmes implemented by partner organisations, in accordance with the following conditions:

(a) **types of programmes**:

[OPTION for DPs: *The programmes must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programmes**');**]***

[OPTION for FPs: *The programmes must concern fellowships for research training activities for recruited researchers ('**fellowship programmes**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country, the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programmes:

[OPTION for DPs: *The doctoral programmes must support researchers, who — at the time of recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION for FPs: *The fellowship programmes must support researchers, who — at the time of recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1. **]***

Researchers that are already permanently employed by the entity where the research training activities take place and that is recruiting them may not be supported.

(c) **procedure and criteria for selecting researchers** in the programmes:

[OPTION for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

Selection committees must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(d) **conditions for the recruitment** of researchers under the programmes:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[7] and ensure that the researchers are aware of them;

- ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;

- ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);

- ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;

- ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
- ensure that researchers work exclusively on the research training activities;
- ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
- ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
- ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of foreground, promoting the action) — during the research training activities and afterwards;
- inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;
- in case of third parties implementing the programmes: ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards those third parties;

[OPTIONS for DPs:

- *ensure gender balance in the recruited researchers;*
- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[7] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing doctoral/fellowship programmes

MSC-COFUND provides support both for programmes implemented by the beneficiary itself or programmes of partner organisations which the beneficiary funds by providing financial support.

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSC-COFUND grant to the partner organisations that implement doctoral/fellowship programmes (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Types of programmes — Categories of persons

The beneficiary/partner organisation must implement the following **types of** research training **programmes** supporting transnational mobility:

- doctoral programmes (DP), i.e. programmes with research training activities for recruited early-stage researchers that lead to the award of a doctoral degree or
- fellowship programmes (FP), i.e. programmes with fellowships for recruited experienced researchers.

The **researchers** must — at the date of recruitment —:

- be one of the following two:
  - **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years of their research career) or
  - **experienced researchers** ('ERs'; i.e. have a doctoral degree or have at least four years of research career).

  Years of '**research career**' are counted as 'full-time-equivalent research experience', from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited — even if the doctorate was never started or envisaged.
- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than 12 months in the three years immediately prior to the recruitment date (unless Annex 1 to the GA specifies otherwise for already existing programmes or the beneficiary/partner organisation is an 'international European interest organisation'[101] for whom the mobility rule is limited to time spent *with* them).

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.
- if the programme is implemented by a partner organisation established in a third country or if a secondment to such an organisation constitutes the *main* part of the research training activities: be nationals or long-term residents of a EU Member State (or H2020 associated country).

  'Long-term resident' normally means full-time research activity in a EU Member State (or associated country) for five or more consecutive years. (The Agency may however, exceptionally accept a different definition, if it is linked long-term residence and justified in the proposal).

  Short secondments are possible also for researchers that are not nationals or long-term residents.

[101] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

3. Additional eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[102]*)*.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a maximum of 4 fixed deadlines or regular cut-off dates per year) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

4. Additional eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits
- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries/partner organisations may offer a **'fixed-amount fellowship agreement**' with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the researcher unit costs will be reduced by 50%.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum monthly remuneration** (including salary, social security contributions, taxes and other costs included in the remuneration) of:

[102] Available at http://ec.europa.eu/euraxess/.

- for early-stage researchers (doctoral programmes); EUR 2 597
- for experienced researchers (fellowship programmes): EUR 3 675

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1298,50; for experienced researchers EUR 1837,50).

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**

    This also means that a researcher can NOT hold two MSC grants at the same time.
  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)
  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency
- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[103].
- for doctoral programmes: the beneficiary/partner organisation must
  - ensure **gender balance** regarding the recruited researchers
  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career plan.

[103] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSC-COFUND actions, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the researcher unit cost was fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

Specific case (record-keeping):

Documents for programmes implemented by partner organisations —For programmes implemented by partner organisations, it is the beneficiary that must keep the documents also for the partner organisations.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit:

- a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What and When? The beneficiary must send to the Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal) a document with information about each recruited researcher ('researcher declaration') — within **20 days** of the start of the research training activities (of the researcher).

It is important to give correct and complete information since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units.

How? The researcher declaration must be prepared and submitted directly in the electronic exchange system (i.e. 'My Area' in the Participant Portal; *see Article 52*).

2. No deliverable: Mid-term review meeting

For MSC-COFUND actions, the Agency will organise a mid-term review meeting (to monitor implementation of the action in the light of the schedule in Annex 1). The mid-term review is therefore not a deliverable, as in other types of MSC actions.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSC actions, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)*

addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must however make specific reference to the Marie Skłodowska-Curie grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA SME Ph1 deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 MGA SME Ph 2 deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 MGA SME Ph1, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 MGA SME Ph1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 funds:

- the feasibility study for an innovation idea (i.e. a ‘proof of concept’ or ‘business plan’ for new, altered or improved product, process or service).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-1-2014*).

For more information on SME Instrument Ph1 actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph 1 MGA does not use the budget categories of the General MGA.

Since SME Ph1 grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 MGA:

- 'costs for the feasibility study (direct and indirect costs)'

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is EUR 50 000 (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & Which form? The SME Ph 1 MGA does not use the **cost forms** of the General MGA, but the **lump sum** fixed by Commission Decision C(2013) 8198[104] (**EUR 50 000** for mono and multi-beneficiary actions).

It is deemed to reimburse 70 % of the action's total eligible costs (which are in turn fixed by the Decision at EUR 71 429).

NO other costs will be reimbursed; the lump sum is deemed to cover all (direct and indirect) costs that may have been incurred for the feasibility study.

The conditions for eligibility are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

[104] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to breach of obligations other than improper implementation — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). The calculation for the reduction therefore does not relate to this form or improper implementation of the action.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Calculation

2.1 What? The budget category 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

NO other costs will be reimbursed; the lump sum is deemed to cover all direct and indirect costs that may have been incurred for the feasibility study.

2.2 These costs must be **declared as** the lump sum fixed by Commission Decision C(2013) 8198[105] and indicated in Annex 2 of the GA (currently **EUR 71 429** per action).

In practice the declaration of costs for SME Ph1 grants is completely automatised. The beneficiaries only need to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

[105] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be *rejected* proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO financial contribution from the EU.

By contrast, if 'other obligations' have been breached *(e.g. other provisions of the GA or provisions of EU, international and national law are not complied with)*, the grant may be *reduced*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESSOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

The costs for purchases and subcontracts are covered by the lump sum.

In-kind contributions (see Articles 11 and 12 H2020 General MGA) and linked third parties (Article 14 H2020 General MGA) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2004/17/EC and 2004/18/EC (or national legislation implementing them).

Finally, the obligations in Article 13.1 are NOT considered to be additional eligibility conditions, but *other obligations*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

Examples: *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency responsibility — Agency right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (by the beneficiaries) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submit to the Agency in good time any documents or information required by it

and may not subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

A 'rejection of costs' will be made for **improper implementation** of the action (*see Article 6*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO financial contribution from the EU.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if an obligation under the Agreement (other than improper implementation of the action as described in Annex 1) has been breached

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify confirmation of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced if 'other obligations' have been breached *(e.g. another obligation under the GA or applicable EU, international and national law; see Article 43 H2020 General MGA)*.

⚠ A 'reduction of the grant' is possible for **any breach of obligation other than proper implementation** (under the GA or applicable EU, international and national law; *see Article 7)*.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from him.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) the beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. Termination of the Agreement or of the participation of one or more beneficiaries (by the Agency)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The request for amendment must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

IV.3 H2020 MGA SME Ph2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: 'Innovation in SMEs' (*e.g. H2020-SMEINST-2-2014*).

For more information on SME Instrument Ph2 actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific cost categories' (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– 'personnel costs for providing trans-national access to research infrastructure'

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) *for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost under Point (f))]*[8]: ***[OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[10]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

(f) ***[OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): for [insert name of specific cost category(ies)***[11]*]:on the basis of the amount(s) per unit set out in Annex 2*[12] ***(unit costs).]***

[OPTION: specific cost category(ies):** not applicable.**]

[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used
[11] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures';, 'costs for clinical studies'; 'costs for energy efficiency measures in buildings'.
[12] Annex 2 must clearly show, for the beneficiary (and each linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the Main Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs****: [insert name(s) of specific cost category(ies)]]****[OPTION:*** *not applicable]*.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are not, by definition, 'non-profit legal entities', they can NOT declare additional remuneration (as part of the 'personnel costs – costs for employees (or equivalent)'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[24] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [25].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').***]**

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).***]**

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[24] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[25] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Commission/Agency will assess compliance with best value-for-money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value-for-money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Commission/Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value-for-money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Finally, for SME Ph2 actions, subcontracts should provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as for the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be adapted to reflect the action duration. Thus, if considered necessary, SME Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 MGA ERA-NET Cofund deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 MGA ERA-NET Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are 'research funders' and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-NMP-ERA-NET-2015)*.

For more information on ERA-NET Cofund actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action**: [insert date]]*[7] ('starting date of the action').

[4] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). Normally, the action's duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- 'direct costs related to trans-national projects'
- 'direct costs of providing financial support to third parties implementing trans-national projects'
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - 'direct personnel costs for the implementation of trans-national projects by the beneficiaries'
    - 'costs for employees (or equivalent)'
    - 'costs for natural persons working under a direct contract'
    - 'costs of personnel seconded by a third party against payment'
  - 'direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries'
  - 'other direct costs for the implementation of trans-national projects by the beneficiaries'
    - 'travel costs and related subsistence allowances'
    - 'equipment costs'
    - 'costs of other goods and services'
    - 'capitalised and operating costs of large research infrastructure'
- 'direct coordination costs for additional activities'
- 'indirect costs'

Thus, the ERA-NET Cofund MGA does NOT have:

- 'personnel costs for SME owners without salary'
- 'personnel costs for beneficiaries that are natural persons without salary'
- 'personnel costs for providing trans-national or virtual access to research infrastructure'

– ‘specific cost categories’.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

2. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - direct costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (— unless declared as unit cost)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects
- **unit costs** for:
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
  - direct **coordination costs** for additional activities[106]
- **flat-rate costs** for:
  - **indirect costs**.

[106] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.**]***

[OPTION to be used if foreseen in the work programme: *Not applicable.**]***

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 The beneficiaries may declare the following **types of costs** as 'direct costs related to trans-national projects':

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)

        - for non-profit legal entities: additional remuneration ('bonus payments')
        - costs for natural persons working under a direct contract
        - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries:
        - travel and related subsistence allowances
        - equipment
        - other goods and services
        - costs of large research infrastructure.

1.2 All costs — except direct personnel costs — must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost in accordance with the usual cost accounting practices (i.e. 'average personnel costs').

1.3 In principle, the same **conditions for eligibility** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the **following specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also* Article 2*)*.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8200[107] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatised: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare coordination costs for additional activities.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[107] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- 'direct costs for the implementation of trans-national projects by the beneficiaries'
- 'direct coordination costs for additional activities'.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however ONLY allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.3);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection ('**joint selection list**') on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report (see Article 20.3).

5. Additional eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

Example: *data on each participant and abstracts of the proposals.*

The beneficiaries will be contacted about the format to be used and details on how to submit the deliverables.

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

Example: *data on each participant and an overview of the results*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 <u>Information on cumulative expenditure incurred</u>

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report, with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

When? ERA-NET Cofund actions are normally divided into 2 reporting periods with two pre-financing payments (or exceptionally 3 reporting periods with three pre-financing payments, if the

Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

ERA-NET Cofund actions normally are divided into two reporting periods *(see Article 20.2)* with two pre-financing payments (— unless the action is exceptionally divided into three reporting periods with three pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first (or second) pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10 % of the maximum grant amount *(see Article 5.1)*
- the second pre-financing payment is 80 % of the maximum grant amount.

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10 % for the first pre-financing payment
- 40 % for the second pre-financing payment
- 40 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund MGA

VI.1 Background information and approach

The PCP-PPI Cofund Model Grant Agreement is used for PCP-PPI Cofund actions only.

The PCP-PPI MGA follows the General MGA for numbering and content, except for:

The H2020 MGA PCP-PPI Cofund deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation][Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that are not applicable or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 H2020 MGA PCP-PPI Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI Cofund actions

What? PCP/PPI Cofund funds:

- a joint public procurement of research and development (R&D) services (PCP) or innovative solutions (PPI)

AND

- related additional coordination and networking activities.

Only one PCP or PPI per GA.

The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

For more information on PCP/PPI Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- 'direct costs of PCP/PPI subcontracting'

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- 'costs of related additional coordination and networking activities'
  - 'direct personnel costs for related additional coordination and networking activities'
    - 'costs for employees (or equivalent)'
    - 'costs for natural persons working under a direct contract'
    - 'costs of personnel seconded by a third party against payment'
    - 'costs for SME owners without salary'
    - 'costs for beneficiaries that are natural persons without salary'

        - 'personnel costs for providing trans-national access to research infrastructure'
    - 'direct costs of subcontracting for related additional coordination and networking activities'
    - 'other direct costs for related additional coordination and networking activities'
        - 'travel costs and related subsistence allowances'
        - 'equipment costs'
        - 'costs of other goods and services'
        - 'capitalised and operating costs of large research infrastructure'
    - 'indirect costs for related additional coordination and networking activities'
    - 'specific cost categories'' (if option applies).

Thus, the PCP-PPI Cofund MGA does NOT have:

- 'direct costs of providing financial support to third parties'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2*[13] ***(unit costs).]***

[OPTION: specific cost category(ies): *not applicable.**]***

[…]

[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[13] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The work programme/call *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **calculation** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1
- fulfil the additional cost eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[15]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[16] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or
- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:
  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

  and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** ***[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[17]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[18] ***[OPTION by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.****]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][****OPTION****: not applicable****]****.*

Beneficiaries receiving an operating grant[20] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

B.5 ***[OPTION: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION for specific unit costs, if foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category[21] *] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, [and if [insert additional eligibility conditions if any]].*

[*same for each specific cost category****]***

[OPTION: *Not applicable****]***

[…]

[15] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[16] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[17] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[18] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[19] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[20] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[21] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Calculation

1.1 The beneficiaries may declare the following **types of costs** as 'costs of related additional coordination and networking activities':

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and

  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost in accordance with the usual cost accounting practices (i.e. 'average personnel costs').

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[108] and set out in Annex 2 and 2a of the GA.

This concerns only beneficiaries that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI Cofund MGA has however the **following specificities**:

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

Costs for validation and testing of solutions provided by the subcontractors.

1.4 The same rules for **calculation** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the Main Work Programme, the costs of related additional coordination and networking activities are eligible up to a maximum amount of 30/50% of the total requested grant amount (for PCP/PPI actions). (For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for related additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).)

[108] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however ONLY allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties (Article 14) can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[25] and 2004/17/EC[26].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('****place of performance obligation****').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[28];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[25] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[28] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

In PCP Cofund actions, the beneficiaries award PCP subcontracts for research and development services ('PCP R&D services') that are necessary to address a 'common challenge' set out in Annex 1. ('PCP subcontract' thus means a contract for the purchase of R&D services that is identified in Annex 1 as action task.)

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('buyers group'), with a joint procurement in 3 phases

  The '**buyers group**' is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI Cofund actions, it must normally be made up of:

  - a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[109])

    Any entity that fits the definition of a 'contracting authority' or 'contracting entity' as defined in those directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives are not applicable, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI Cofund actions.*

  - that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the Main Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the Main Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

  - beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
  - third parties providing in-kind contributions

[109] *See Directives 2014/24/EC and 2014/25/EC.*

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in **3 phases**.

The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value-for-money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

  The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

  If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

  The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

  If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

  Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done*.

  This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (as used in the WTO GPA).

  Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

  This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary ('**lead procurer**')

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

  Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[110]).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

[110] *See Directives 2014/24/EC and 2014/25/EC.*

The lead procurer must be mandated by the buyers group in the joint procurement agreement.

The subcontracts to be signed are:

- a framework contract with each selected subcontractor, covering the whole PCP and
- specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')
- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

There can only be one PCP per PCP Cofund action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*).

For PCP subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional eligibility condition: Procurement procedure — Best value-for-money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value-for-money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:

    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*

    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*

    - specifies in-kind contributions provided by third parties

    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

  - the procurement must be preceded by an '**open market consultation**'

    This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[111]).

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

  - the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

    These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

[111] *See Directives 2014/24/EC and 2014/25/EC.*

They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** *(see Annex 10)* to launch the **request for tenders** (see *Annex 9)*.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries ('place of performance obligation')
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*

  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments.)

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The EU public procurement Directives 2004/17/EC and 2004/18/EC do not apply to the pre-commercial procurement of R&D services (because such services are exempted[112]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC — or any EU legislation that replaces these Directives[113]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[112] *See Article 16(f) of Directive 2004/18/EC and Article 24(e) of Directive 2004/17/EC.*
[113] *See Article 14 of Directive 2014/24/EC and Article 25 of Directive 2014/25/EC.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[29], 2004/17/EC[30].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[32] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[29] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

[30] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[32] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries award PPI subcontracts for procuring the innovative solutions ('PPI innovative solution(s)') necessary to address the 'common challenge' set out in Annex 1. ('PPI subcontract' thus means a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.)

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the **following specificities**:

There is no requirement to split the PPI procurement procedure in phases.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

> PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.
>
> Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

> The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).
>
> The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.
>
> If there is no mandate, the general rule is that:
>
> - framework agreement(s) must be signed by all members of the buyers group together
> - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

There can be only one PPI, per PPI Cofund action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PPI subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value-for-money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**' (— unless the PPI is limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN; *see Annex 7*) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

      This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** *(see Annex 9)* (— unless the PPI is limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP Cofund action) suffices.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:

  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the EU public procurement Directives 2004/17/EC and 2004/18/EC (— or any EU legislation that replaces these Directives[114]) normally apply to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[35]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[35] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

[114] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [****Y****] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **<u>information on each subcontract financed by the procurement</u>**, including data on each contractor that participated in the procurement, an overview of the results for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the initial tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency (via the electronic exchange system, i.e. 'My Area' in the Participant Portal):

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

The beneficiaries will be contacted about the format to be used and details on how to submit the deliverables.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (together with data on each contractor that participated in the procurement and overview of the results)

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[47]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[48]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

[47] Month X should be the end of the preparation phase and submission of second pre-financing request.

[48] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a periodic report with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report).

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into 2 reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage

(preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Actions will exceptionally be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of resources — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of resources needed to pay the subcontracts *(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a 'statement on use of the previous pre-financing instalment *(see Annex 12)*.

  This statement includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into 2 reporting periods *(see Article 20.2)* with two pre-financing payments (— unless the action is exceptionally divided into three reporting periods with three pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first (or second) pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount *(see Article 5.1)* that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; *see Article 21.2 H2020 General MGA*) minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 MGA EJP Cofund deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 MGA EJP Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of the H2020 Framework Programme and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General work programmes and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[7] ('**starting date of the action**').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). The action's duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- 'direct personnel costs'
  - 'costs for employees (or equivalent)'
  - 'costs for natural persons working under a direct contract'
  - 'costs of personnel seconded by a third party against payment'
  - 'costs for SME owners without salary'
  - 'costs for beneficiaries that are natural persons without salary'
- 'direct costs of subcontracting'
- 'direct costs of providing financial support to third parties' (if option applies)
- 'other direct costs'
  - 'travel costs and related subsistence allowances'
  - 'equipment costs'
  - 'costs of other goods and services'
  - 'capitalised and operating costs of large research infrastructure'
- 'indirect costs'
- 'specific categories of costs' (if option applies).

Thus, the EJP Cofund MGA does NOT have:

- 'personnel costs for providing trans-national access to research infrastructure'.

For the FEJP action, there are however three 'specific cost categories':

- 'costs for mobility of personnel'
- 'costs for fellowships for researchers'
- 'access costs for research infrastructure'.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2*[15] *(**unit costs**).]***

[OPTION: specific cost category(ies)**: not applicable]

[…]

[8] This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] To be used only if option in Point (f) is used.
[13] To be used only if option in Point (f) is used.
[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[115].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however three specific unit costs as 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [116]

For this action, these unit costs replace the 'specific cost categories' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 H2020 General MGA)*.

[115] *See Article 28(5) of the Rules for Participation.*
[116] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable;*]**
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[17]***][OPTION: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[17] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **calculation** apply *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will be limited to this additional equipment cost option (Article 6.2.D.2) and the specific cost categories (Article 6.2.F) and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Calculation

This budget category applies to all to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** as 'other direct costs - equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional cost eligibility conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. ***[OPTION: [Insert name of specific cost category(ies)]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION for specific unit costs (unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[23]] *are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION: *not applicable****]***

[…]

[23] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories: Types of costs — Cost form — Conditions for eligibility — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the the Fusion programme EJP Cofund action (FEJP), the specific cost categories will be replaced by the three categories set out in Commission Decision C(2013) 8201[117]:

- 'costs for mobility of personnel'
- 'costs for fellowships for researchers'
- 'access costs for research infrastructure'.

⚠ Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 'Specific cost category – costs for mobility of personnel'

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment (by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance).

[117] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8201[118] and set out in Annexes 2 and 2a of the GA (currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

  This amount is subject to a '**country-specific correction coefficient**' for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[119]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.4	Sweden	131.9

[118] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[119] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto.

Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) will be applied as from 1 January 2016. The FEJP GA will be amended and the Annotated MGA will be updated accordingly.

– for the monthly subsistence allowance: between **EUR 0 and 720.27** per individual per month — depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1 300	**601.73**
> 2 000	**720.27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 258.81**, per dependent child per month).

The Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this event, the FEJP GA will be amended and the Annotated MGA will be revised accordingly.

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Commission Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and

- one of the following:
  - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
  - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
  - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between five and 18 years of age), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

– the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment

– to this amount, add the following for each leg of the journey (outward and return):

– for train travel: a maximum of 30 minutes for each leg

– for air travel: a maximum of 2 hours for each leg.

NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

– for the monthly subsistence allowance:

amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

– for the family allowance:

amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

The family allowance is paid for each full month of secondment in which the dependent child is between five and 18 years of age.

'**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

A 'full month' can be one of the following two:

– a **calendar month** *(e.g. 1 to 31 July inclusive)* or

- a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*

*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*

Subtotal = EUR 85 697.25

** correction coefficient of 106.4 % (Germany Munich) = EUR 91 181.87*

*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*

Total declared unit costs: EUR 96 238.07

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*

** correction coefficient of 112.5 % (Culham, UK) = EUR 430.82*

Total declared unit costs: EUR 430.82

1.2 'Specific cost category – costs for fellowships for researchers'

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships (by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility).

What not? This budget category does not cover the salary costs of the fellows, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.2.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8201[120] and set out in Annexes 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions)[121]:

[120] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[121] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%
Finland	116.6%	Slovenia	86.1%
France	111.0%	Slovakia	82.6%
Croatia	97.5%	United Kingdom	120.3%
Hungary	76.2%		
Ireland	113.5%	Switzerland	113.1%

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[122]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

[122] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

- for the living allowance:

  amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

- for the mobility allowance:

  amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

- for the family allowance:

  amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 'Specific category – access costs for research infrastructure'

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below*).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be declared on the basis of the **unit cost** calculated in accordance with Decision C(2013) 8201[123] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

[123] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{124})}{\text{average annual total quantity of access (over past two years}^{125})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 to the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users

    Exceptionally, these costs may be those calculated in accordance with the beneficiary's usual cost accounting practices (i.e. 'average personnel costs').
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

[124] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[125] In exceptional and duly justified cases, the Commission may agree to a different reference period.

As already mentioned above, access costs for installations contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What? For EJP Cofund actions, the coordinator must submit to the Commission/Agency (via the electronic exchange system) — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a 'statement on the use of the first pre-financing payment' *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]**[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU funds)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not (yet) open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

For more information on framework partnerships, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name**] (**short name**)legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
[6] The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Once an SGA is signed, the partners also become 'beneficiaries' (i.e. a 'participant'[126] in an action supported by a grant).

Not all partners of a framework partnership must actively participate in all specific actions.

Partners that do not want to actively participate, may participate as 'partners not carrying out action tasks under that Specific Agreement' (and will be identified as such in the preamble of the SGA). Those partners will not have to comply with some of the obligations under that SGA *(see Preamble SGA)*

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

[126] For the definition, *see Article 2.1(15) of the Rules for Participation*: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed electronically in the electronic exchange system (i.e. 'My Area' in the Participant Portal).

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan (see Annex 1))] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all areas of the Horizon 2020 Framework Programme.

Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2);* Framework partnerships are currently NOT (yet) open to ERANET, PCP-PPI, EJP, ERC, MSC or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

  Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals.

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** Not applicable]*

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the General MGA *(see Article 49 H2020 General MGA)*.

Amendments after a suspension can NOT however have the effect of extending the FPA duration set out in Article 3 FPA.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the FPA

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ Termination of the FPA has NO effect on ongoing SGAs (— unless these are also terminated; *see Article 56 FPA and Article 20 SGA*).

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *'direct personnel costs'*
- *'direct costs of subcontracting'*
- *'direct costs of providing financial support to third parties' (if option applies)*
- *'other direct costs'*
- *'indirect costs'*
- *'specific cost categories' (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions applicable per budget category are set out in Article 5 SGA.

The SGA will use the budget categories that belong to the type of specific action, with the same types of costs, conditions for eligibility and rules for calculation.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for calculation of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

The third parties are normally involved in the specific actions, not in the framework partnership.

Example: *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

However, partners must — already at FPA proposal stage — indicate if they intend to use third parties or not. Moreover, linked third parties must be identified already in the FPA *(see Article 19 FPA)*.

Example: *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ Only linked third parties of partners implementing the action covered by the SGA can carry out tasks and be identified in the Annex 1 of that SGA. If a linked third party of an FPA partner which does not implement the SGA action needs to carry out tasks in that SGA, then that entity (i.e. the linked third party) will have first to become partner of the FPA and of the SGA.

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA can NOT be amended before the FPA.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'[3]),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement**: X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

An entity that is not party to the FPA cannot become party to the SGA.

Conversely, all parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must **actively participate** in all specific actions.

Partners who do not actively participate in a specific action are 'partners not carrying out action tasks under that Specific Agreement' (and must be identified as such in the preamble to the SGA).

These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* are applicable also for these partners. However, most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc.)* are NOT.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed electronically in the electronic exchange system (i.e. 'My Area' in the Participant Portal).

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligations towards them.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and in the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

European Commission

The EU Framework Programme for Research and Innovation

HORIZON 2020

AGA – Annotated Model Grant Agreement

Version 2. 1
30 October 2015

Disclaimer

This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

Research and Innovation

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	– Initial version. Article 6.
1.2	17.02.2014	– Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	– Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	– Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	– Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	– New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	– Clickable table of contents added
1.6.2	17.07.2014	– Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	– Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	– Updates due to the amendment of the model grant agreement, in particular Articles 3, 9, 20.6 and 38.1.2 – New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 – New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; – Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 – New Annotations for the MSCA – Other minor corrections and clarifications – Improved clickable table of contents including Articles
2.0	30.03.2015	– Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. – Clickable cross-references (Articles) – New table explaining the treatment of the different types of work contracts (under Article 6.2.A). – New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. – Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 – Other minor corrections and clarifications
2.0.1	18.05.2015	– Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants
2.1	30.10.2015	– New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47,

		50, 55 and 56. – New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses – New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Phase 1: Article 5; – SME Instrument Phase 2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. – Other minor corrections and clarifications. For easy identification, paragraphs, indents or sections with new interpretations are marked with the symbol ■ on the left.

IMPORTANT NOTICE

The '**AGA — Annotated Model Grant Agreement**' is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement ('General MGA') and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020.

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and conditions for eligibility of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the Horizon 2020 MGAs. For a more general overview of how Horizon 2020 grants work, see the Online Manual.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found on the Participant Portal Reference documents page.

Horizon 2020 terms are explained in the Participant Portal Glossary.

If necessary, you can also contact the Horizon 2020 Helpdesk.

H2020 legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1'Health, Demographic Change and Wellbeing' , etc.*

⚠ The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [**official registration No**], established in [official **address** in full] [VAT number],

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form [OPTION if the JRC is a beneficiary: or the Administrative Arrangement], the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Coordinator — Beneficiaries

'**Beneficiaries**' means the legal entities who have signed the Grant Agreement (GA) with the Commission/Agency (i.e. a '**participant**'[1] in an action supported by a grant).

The '**coordinator'** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

Both beneficiaries and coordinators must have a sufficient financial viability/capacity to be able to implement the action (i.e. achieve its expected objectives and results).

The Commission/Agency will systematically verify the financial viability/capacity of the coordinator, if the requested EU contribution for the action is equal or superior to EUR 500 000. Exceptionally, it will also verify the financial viability/capacity (of the coordinator or other beneficiaries), if there are grounds to doubt them *(see Article 15(9) of the Rules for Participation)*.

For more information on financial viability/capacity, see the *Online Manual.*

[1] For the definition, *see Article 2.1(15) of the Rules for Participation:* '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation') and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including entities linked to the beneficiaries) are considered as '**third parties involved in the action**' *(see Article 8)*.

They are not bound by the terms and conditions of the GA; conversely, the Commission/Agency has no obligation towards third parties.

2. Name, legal form, official registration No, address — Legal entity data

The legal entity data (legal name, address, legal form, legal representatives, etc.) of the beneficiaries comes from the Participant Portal Beneficiary Register.

'Official registration No' refers NOT to the 'participant identification code (PIC)' attributed by the Beneficiary Register, but to the official registration number in the national registry, if any.

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries must keep their beneficiary data up-to-date at all times, including after the end of the grant *(see also Article 17)*. In case of changes, the 'legal entity appointed representative (LEAR)' of the concerned beneficiary must introduce a change request directly in the Participant Portal (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[2]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[3]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[4].

[2] More information on the types of action can be found on the General Annexes to the *Work Programmes*.

[3] For the definition, *see Article 2.1(6) of the Rules for Participation:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[4] For the definition, *see Article 2.1(7) of the Rules for Participation:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

⚠ The term '**action**' comes from the Financial Regulation No 966/2012 and the Rules of Application Regulation No 1268/2012 and **means** '**project**'. (Previous EU Research Framework Programmes used 'project'.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

ℹ For more information on RIA, IA and CSA actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

2. Complementary grants

'Complementary grants' are different EU grants which are 'linked' by the work programme/calls by identifying them as 'complementary actions'.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written '**collaboration agreement**' regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a third country *(e.g. a scientific and technological organisation or funding agency)* or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[5]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 to the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a '**coordination agreement**' *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

ℹ For guidance on coordination agreements*, see the Guidance — How to draw up your coordination agreement.*

[5] *See Article 12 of the Rules for Participation.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The starting date of the action ('action starting date') is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example: *Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the action before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  ⚠ The action starting date can NEVER be before the submission of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The duration of the action ('action duration') is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the *action tasks* (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as 'project closure' or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs'
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

Moreover, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories — without requesting an amendment *(see Article 55)* (unless Annex 1 must be changed).

⚠ The maximum grant amount *(see Article 5.1)* can however NEVER be increased.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

> ***Example:*** *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

> ***Example:***
>
> *Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)*
>
> *Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)*
>
> *Total possible transfer to another budget category: EUR 2 000*

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that has **not** been **foreseen in Annex 2** (for that beneficiary).

Example: *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is not acceptable without an amendment of the GA to modify the form of costs for direct personnel costs.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work (the 'tasks' of the action) of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the 'simplified approval procedure' without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the 'simplified approval procedure' bear the full risk of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION for innovation actions (IA)**[7] **if all beneficiaries and all linked third parties are non-profit legal entities**[8]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions (IA) if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][11]: *[**OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);][**OPTION**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant):** for **[insert name of specific cost category(ies)**[14]*]: on the basis of the amount(s) per unit set out in Annex 2*[15] ***(unit costs).]***

***[OPTION: specific cost category(ies):** not applicable.]*

***[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 To be used only if option in point (f) is used.

10 To be used only if option point (f) is used.

11 To be used only if option in point (f) is used.

12 To be used only if option in point (f) is used.

13 To be used only if option in point (f) is used.

14 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount can NEVER be increased — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally **100%** of the total *eligible* costs[6]; for IA actions it is normally **70%** of the total eligible costs[7].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[8].

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

6 *See Article 28(4) of the Rules for Participation.*

7 *See Article 28(5) of the Rules for Participation.*

8 *See Article 28(5) of the Rules for Participation.*

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[9] and all budget categories.

⚠ The grant can NEVER reimburse more than the maximum grant amount fixed in Article 5.1.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[10]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (— unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[11]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**') [12]
  - specific unit costs for:
    - costs for **energy efficiency measures** in buildings[13]
    - **access costs** for providing trans-national access to research infrastructure[14]
    - costs for **clinical studies**[15]

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9 *See Article 28(6) of the Rules for Participation.*

10 *See Articles 123, 124 of the Financial Regulation.*

11 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

12 *See Article 33(2) of the Rules for Participation.*

13 Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

14 Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

15 Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme available at

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[16]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

  Example: *EUR 150 000 to carry out a study within an action*

  The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	**Budget categories**					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[16] *See Article 29(1) of the Rules for Participation.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of termination of the GA) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex I?

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 to the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s).

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions (IA), there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount *(see Article 5.1)*.

Step 3 — Reduction due to the no-profit rule and receipts.

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the *consolidated* receipts and the *consolidated* approved costs.

The **receipts** that must be taken into account are receipts that are:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation)

during the action duration (see Article 3).

The following **are** considered '**receipts**':

- income generated by the action (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped to the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action (i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for the action covered by the GA

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs (i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

Examples: *the free use of equipment; the secondment of an expert without reimbursement*

Free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered '**receipts**':

- income generated by exploiting the results of the project (*e.g. the IPR*) is not considered a receipt since successfully exploiting the results is one of the main objectives of the action
- financial contributions given by a third party (a donor) specifically to be used for the action if they may be used according to the donor's rules to cover costs other than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (a donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

  Example: *A university professor whose costs are charged by the university in the GA, but whose salary is paid by the Ministry and not reimbursed by the university: This in-kind contribution from a third party (the Ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the Ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions made **by one beneficiary to another** within the same action are also not considered receipts either, since receipts are only contributions from *third parties*. (Conversely, such a financial contribution cannot either be declared as cost for the action.)

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (i.e. the final payment at the end of the action).

They must be declared in the final report (although beneficiaries are free to do so also in the periodic reports).

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

Step 4 — Reduction due to improper implementation or breach of other obligations under the GA.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1.

Improper implementation may lead to a **reduction** of the **grant** (i.e. reduction of the 'maximum grant amount'; *see Article 5.1*) — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*). In principle, the Commission/Agency will not reduce the final grant amount for minor delays/deviations in the technical work foreseen in Annex 1.

Example (reduction): *of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A reduction of the maximum grant amount is NOT a sanction, but the consequence of a breach of an obligation under the GA.

Example for calculating the final grant amount:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the "action"). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs = EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate= 100%

Amount obtained = EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to improper implementation or breach of other obligations under the GA:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of Article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1, 2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000*

Final grant amount = *EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, improper implementation of the action or breach of other obligations (and therefore **rejects the costs** or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level).

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000

Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500

Costs rejected following audit: 30 000

Revised direct eligible costs: 120 000

Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000

Revised final grant amount: 100% of 150 000 = 150 000

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a recovery *(see Article 44.1.3)*.

For **reduction of the grant**: the Commission/Agency will:

- reduce the maximum grant amount set out in Article 5.1, in proportion to the improper implementation or to the seriousness of the breach *(see Article 43)*
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000

There are three beneficiaries A, B and C

Reimbursement rate: 100%

According to the estimated budget, beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.

Total eligible costs accepted for beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of beneficiary A: 80% of the share of beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to beneficiary A: 100% of the reduction is allocated to beneficiary A.

Revised final grant amount of beneficiary A: 187 500 – 10 000= 177 500

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a recovery *(see Article 44.1.3)*.

For **rejection of costs AND reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form (see Article 5)*.

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries*, see the List of issues applicable to particular countries on the Participant Portal.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action or the GA termination are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the

initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  Examples:

  1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

  2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

  3. *Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

  Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2.*

- the **number of units** must be **necessary** for the action
- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

Example: *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Personnel costs declared on the basis of the usual accounting practices — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices ('average personnel costs'), the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices
- must budget and declare a total amount; the amount per unit must not be included in Annex 2.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency *(in Annex 2 of the GA; see Article 5.2)*.

Example: *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under Horizon 2020 rules.*

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump-sum costs).

Example (25 % flat rate for indirect costs):

A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.

Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600

Total eligible costs: 11 900 + 2 600 = EUR 14 500.

Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]***]**.

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries on the Participant Portal.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

- either costs that have been caused in full by the activities of the action
- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action cannot be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a 25% fixed flat-rate of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs for personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[A.6 [OPTION to be used for trans-national access to research infrastructure: Personnel costs for

providing trans-national access to research infrastructure *are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]***

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

1. Direct personnel costs: Types of costs — Cost forms — Conditions for eligibility — Cost calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Costs for employees (or equivalent)

1.1.1 What? 'Personnel costs for employees or equivalent' (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) **cover**:

- the **basic remuneration** (i.e. basic salary and complements) and
- only for non-profit legal entities: the **additional remuneration**

for personnel that worked on the action.

What is 'basic remuneration' and 'additional remuneration' and how to distinguish them?

Basic remuneration refers to the 'basic salary' of the employee plus 'complements' that fulfil the eligibility conditions explained in point 1.1.3.

The basic salary includes (and is limited to):

- the salary stated on the beneficiary's payroll (except for any part of that salary which must be considered as 'additional remuneration', even if it that part is also registered in the payroll)
- social security contributions (mandatory parts to be paid by the employee and the beneficiary that employs him/her) — except any part included in additional remuneration.
- taxes included in the remuneration *(e.g. income tax to be paid by the employee retained by the beneficiary who employs him/her)* — except any part included in additional remuneration.
- other costs included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee)* — except any part included in additional remuneration.

The complements may include:

- mandatory fixed complements to the basic salary, resulting from national law, collective labour agreement or the employment contract

  Example (mandatory fixed complement): *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements not triggered by the work in specific projects[17] if they fulfil the eligibility conditions set out in point 1.1.3. (for instance complements that are

[17] 'Project' in this context refers to a set of activities carried out with a specific aim.

authorised under national law and foreseen in the employment contract with a variable amount for usual work)

Example (variable complement acceptable as basic remuneration): *The contract of a professor includes as part of his/her usual tasks both teaching and research; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour for each hour spent on research activities.*

By contrast, **additional remuneration** refers to payments made *on top* of the employee's usual remuneration (for instance for additional work or specific expertise), which result in a higher hourly rate in specific projects[18].

Additional remuneration includes not only the extra salary, but also the social security contributions, taxes and other costs included in the remuneration that result from that extra salary.

Example (additional remuneration): *a 'bonus' for participating in a project; an additional contract for specific tasks with a salary higher than the one under the main contract*

Example (not additional remuneration, but basic remuneration): *additional salary paid to the employee for additional hours worked on its standard work or expertise as defined in the employment contract (e.g. overtime or additional contract for those additional hours), if the additional hours are remunerated according to the standard salary conditions of the employee (i.e. do not result in a higher hourly rate). Note that the standard salary conditions may provide for a mandatory complement for those additional hours (e.g. overtime during night shifts).*

Thus, the two main features that help characterising a remuneration component as basic or additional are:

- hourly rate (no change to hourly rate would indicate basic remuneration, while a higher hourly rate would indicate generally additional remuneration) and
- kind of work or expertise (usual kind of work or expertise according to the contract or different/additional work or expertise).

Work or expertise	**Hourly rate**	
	Usual	**Higher**
Usual	Indicates basic remuneration	○ Indicates additional remuneration: if triggered by the participation in a project ○ May however qualify as basic remuneration if not dependent on a project or type of projects (and therefore spread over all activities, e.g. *based on merit of the employee at stake*)
Additional/different	Indicates basic remuneration	Indicates additional remuneration

In case of doubt, the classification will be made also taking into account the classification of the component under national tax law (i.e. if the tax authorities explicitly consider it as part of the basic remuneration of the employee or as additional remuneration).

⚠ It is the basic remuneration that must be used to calculate the hourly rate *(see below)*.

[18] 'Project' in this context refers to a set of activities carried out with a specific aim.

1.1.2 Costs for employees (or equivalent) must be **declared** on the basis of:

- either **the individual actual personnel costs** of each employee participating in the action (the most common case) or
- on the basis of **unit costs:**
  - either calculated by the beneficiary in accordance with its usual cost accounting practices (i.e. 'average personnel costs') if in line with the specific eligibility criteria *(see below)* or
  - where applicable, unit costs fixed by the Commission; *e.g. the mandatory unit cost for SME owners and natural persons without a salary*.

1.1.3 The costs for employees (or equivalent) must comply with the following **conditions for eligibility**:

> ⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. (If the employment contract indicates that the person was hired to work on *another* project, it must be changed.)

For basic salary and mandatory complements:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are ineligible under *Article 6.5(a)(i)*. (However, complements based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted as variable complements, if they fulfil the conditions set out below.)

  > ***Examples (acceptable):***
  > *If the profit of the company at the end of the year is more that X € (or more than X %), each employee will receive a complement of z % of his/her basic remuneration (or a fixed complement of x € more as part of the gross salary).*
  >
  > ***Examples (not acceptable):***
  > *If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.*

  Any part of the remuneration which is calculated with reference to commercial targets *(e.g. x € for reaching a sales target, x % on sales)* or fund raising targets *(e.g. x € premium per externally funded project gained, x % of the external funding gained)* is ineligible. The reason is that they are neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation.

  > ***Example (not eligible because linked to fund raising target):*** *A premium paid as a reward for having obtained a specific grant is not eligible.*

- be **fixed** (conditions and amount or percentage) and **mandatory** according to national law, collective labour agreements or the employment contract

  > ***Example:*** *The employment contract between the entity and the person fixes a gross salary of EUR 3000 per month plus a transportation allowance of EUR 5 per working day.*

- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract/equivalent appointing act). Therefore, they can NOT depend on the participation in a specific action/project

  A 'payment linked to a specific action/project' is a payment the employee would not have received if s/he had not participated in the work of the action/project (i.e. the triggering

event is the participation in the action/project *(e.g. an EU action)*, not the performance of the tasks defined in the employment contract/equivalent appointing act).

Any part of the remuneration linked to tasks other than those covered by the basic remuneration, in particular amounts triggered by the participation in a specific action/project, are NOT eligible as part of the basic remuneration. (They may however still be eligible as additional remuneration; *see below*.)

For variable complements (in addition to the first and third conditions above):

- the variable complement is authorised under national law, collective labour agreement or set up in the employment contract/equivalent appointing act.

  Examples:

  1. *The collective labour agreement establishes that all researchers may receive a complement between EUR 100 and EUR 200 per month based on their seniority.*

  2. *The national law authorises public universities to pay a complement based on merit of the employees.*

  3. *The contract fixes a premium of EUR 1000 for each research paper published in peer reviewed international research journals.*

- the **amount** to be actually paid as variable complement is determined on the basis of **objective conditions** (which should be established and documented, for instance in the internal regulations of the beneficiary).

  Example: *Based on the provisions of the collective labour agreement (see first example above), the internal regulations of the employer provide that: all researchers with seniority between 3 and 5 years will receive a complement of EUR 150 and all researchers with seniority above 5 years will receive a complement of EUR 180.*

  The variable complement must NOT be paid to the employee at the sole discretion of the manager (**arbitrary** complement). The decision to grant the complement should be be based on objective conditions, which should be documented and be verifiable.

  Example: *National law authorises public universities to pay a complement based on merit or performance of the employees and the internal regulations of the public university provide for an annual assessment exercise to determine the 'merit points' of each employee. The internal regulations also set up the objective criteria based on which the 'merit points' are decided. The internal regulations provide that all researchers with more than 10 'merit points' will receive a complement of EUR 1000.*

  If the Commission/Agency has doubts whether the decision to pay the variable complement is actually based on objective conditions it may still accept (a part of) the complement if:

  - the employee has already been receiving the same complement before the award of the H2020 grant (and independently from it)
  - the complement was not increased after the award of the H2020 grant

  AND

  - the other cost eligibility conditions are fulfilled.

  Increases of the complement after the award of the H2020 grant will be considered ineligible in these cases; the Commission/Agency would accept only the amount up to the level that was paid before the award of the H2020 grant.

For additional remuneration (only for non-profit legal entities):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the participation in another project)* is not eligible.

Example:

A nuclear researcher in a public research centre (non-profit) worked for 1 720 productive hours

Remuneration components:

a = annual salary: EUR 50 000

b = a complement for holding a management post (e.g. Head of department): EUR 1 600

c = additional remuneration for being Head scientist in the EU project: EUR 2 000

d = additional remuneration for being First Assistant on an internal action: EUR 1 000

***a** and **b** would be used to calculate the researcher's hourly rate:*

hourly rate for the EU action = {(50 000 + 1 600)/1 720} = EUR 30

***c** would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the eligibility ceiling.*

***d** would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for the performance of **additional work** or **different expertise** than his/her usual tasks

The work to be carried out (or expertise used) must be different from the standard work or expertise (defined in the employment contract/equivalent appointing act and covered by the standard remuneration package). This difference must be verifiable.

- be part of the beneficiary's usual remuneration practices and be consistently applied whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used

The objective criteria must be related to the additional work or expertise.

Examples (acceptable criteria):

A normal salary is paid for teaching + additional remuneration is paid for doing research.

A normal salary is paid for research + additional remuneration is paid for taking up the management of the research team and infrastructure.

A normal salary is paid for laboratory research + additional remuneration is paid for field research.

A normal salary is paid for research on internal projects + additional remuneration is paid for participating in a special type of projects as for example international cooperative projects, projects awarded under competitive calls, etc.

Examples (not acceptable criteria):

Additional remuneration paid for using English.

Additional remuneration is paid only when participating in EU-funded actions.

The system for making additional payments should be established in the beneficiary's internal rules (or at least be documented and known by the employees). (Like for variable complements, the additional remuneration must NOT be paid to the employee at the sole discretion of the management (arbitrary complement).)

***Example (acceptable):** All teachers carrying out research on top of their usual teaching activities get an extra payment of 10 % of their salary.*

***Example (not acceptable):** The director decides at its sole initiative to pay an extra 10 % to one professor carrying out research.*

However, the additional remuneration does not have to be the *same* for all persons working in the same project. The objective criteria used to determine the additional remuneration may result in different amounts for persons working in the same project *(e.g. the rule is that all teachers that carry out research on top of their usual teaching activities get an extra payment between 10 % and 20 % of their salary, the precise percentage per teacher and project is determined according to the level of responsibility in the specific project)*.

The rules for additional remuneration may not differ according to *where* the funds come from. In particular, they cannot be set up for actions funded by a specific donor.

(Additional remuneration schemes that are applicable only to EU actions are not acceptable.)

Example (acceptable): *All professors carrying out research will be paid 10 % more.*

Example (not acceptable): *All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

Additional remuneration is eligible only **up to a certain ceiling** ('eligibility ceiling'; *see point 1.1.4*).

⚠ To avoid abuses, the rules for additional remuneration will be exceptionally also applied to the basic remuneration, if it has been **artificially increased** for participation in the EU action.

Examples:

1. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the beneficiary to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

2. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with a linked third party (or a third party providing in-kind contribution) to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

3. *Employees of a specific department/service of the company which is in charge of carrying out only EU actions are paid a higher salary than their homologues in other departments carrying out the same tasks requiring a similar level of expertise (i.e. the salary differential is attributable to the source of funding). The rules for additional remuneration will apply to the difference between the salaries of employees working for the specific department and those of employees of other departments carrying out the same tasks with the same level of expertise (see point 1.1.4).*

Decision tree to determine eligibility of complements:

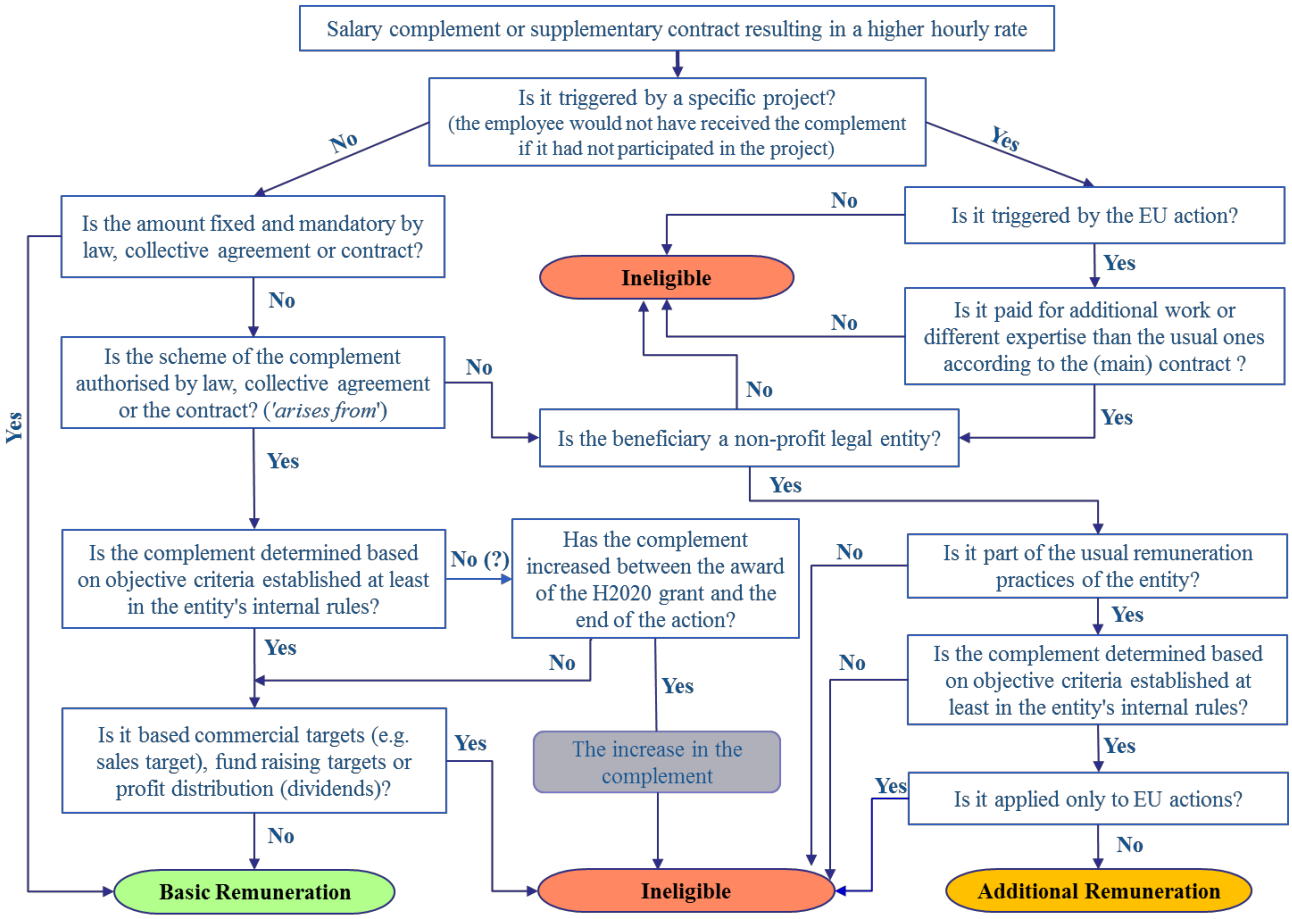

Specific cases (direct personnel costs for employees (or equivalent)):

Teleworking — Remuneration costs of employees (or equivalent) not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of benefits equivalent to financial ones *(e.g. costs of lunch vouchers)* may be accepted as eligible if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally not eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action duration, the related costs would be considered part of the entity's normal indirect costs, which are covered in Horizon 2020 by a 25 % flat-rate of the eligible direct costs.

Remuneration of students working for the beneficiary under a scholarship, internship or other similar agreement (not employees) — Like any personnel costs, personnel costs of students (including PhDs) are eligible if they fulfil the conditions set out in . In this context, fellowships/scholarship/stipends are assimilated to salaries provided that:

- this remuneration complies with the application national law on taxes, labour and social security

- the assignment of tasks respects the laws in force in the place of establishment of the beneficiary
- the students have the necessary qualifications for the performance of the tasks attributed to them in the context of the H2020 action.

Thus, if the agreement is training-oriented (i.e. aimed at helping the student to acquire professional skills) its cost can NOT be charged to the grant.

Academic fees — If a student works for a university and is exempt from paying (part of) the academic fees, those fees (or part of them) are eligible as a personnel cost if the student's contract included the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic salary only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible)

AND

- the employee worked for the action during the financial year used for calculating the personnel costs.

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts (whatever their form, i.e. a contract additional to the main contract between a beneficiary and its employee) for carrying out tasks for specific actions *(e.g. international projects)* are acceptable, if it is the beneficiary's usual practice and it is authorised under national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package (basic remuneration) in the first non-action-related contract is considered 'additional remuneration'. As such it is subject to the specific cost eligibility conditions explained above for additional remuneration and, if eligible, to the eligibility ceiling.

1.1.4 The **costs** must be **calculated** as follows:

{{**hourly rate**
multiplied by
number of actual **hours worked on the action**},
plus
for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

This calculation method also applies for persons working exclusively for the action.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ The **total number of hours** declared in EU and Euratom grants **for a person for a year** may NOT be higher than the number of annual productive hours used for the calculation of the hourly rate *(see below)*.

Procedure for calculating direct personnel costs for employees (or equivalent):

Step 1 — **Calculation of the hourly rate (per person)**

According to the GA, the **hourly rate** — for personnel costs declared as **actual costs** — must be calculated as follows:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.

Remuneration components:

a = annual salary: EUR 50 000

b = extra payment for holding a post involving radioactive hazards: EUR 5 000

c = additional remuneration for being Head Scientist in a Project: EUR 2 000

***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*

*Hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

For the sake of simplicity and in order to avoid calculation errors, the hourly rate must be calculated by ***financial* year** (i.e. the 12-month period covered by the annual accounts of the entity) and has to be made always on the basis of full financial years.

***Example:** When the financial year matches the **calendar year**, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

***Example:** Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance to the GA is available. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Once declared, the personnel costs can normally NOT be adjusted/changed due to a re-calculation of the hourly rate (even if a re-calculation after the closure of the financial year on-going at the end of the period would give another result). A correction is only possible (and must be made) if there was a mistake in the calculation of the hourly rate that was used to declare those costs *(e.g. incorrect accounting information).*

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate for personnel costs. The method must however be consistently applied and can NOT be changed within the same grant.

The **annual personnel costs** may include only eligible personnel costs and must exclude eligible additional remuneration (because that will be added separately at the end of the calculation).

Any part of the basic remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours**')
- the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option must be applied to all personnel working for the beneficiary in H2020 actions. However, the beneficiary may use different options for different types of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must use the same option(s) for calculating the annual productive hours during one full financial year. It can only change its option(s) for the next financial year.

If the person concerned was on parental leave during the year, the annual productive hours may be reduced by the actual time spent on parental leave.

This table explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types*	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive

	of special leave).	plus
		overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus eight days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for five days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual working hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
			hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow determining the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time legislation. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options.	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation method

		Example for calculation of standard annual workable hours: *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual*	consistently applied) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours). *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).* This option can NOT be used if the employment contract, collective labour agreement or national law does not allow determining the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow determining the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 annual productive hours).*	

Step 2 — **Multiplying the hourly rate by the number of actual hours worked on the action**

By multiplying the hourly rate by the number of hours actually worked by the person, the beneficiary determines the amount it can declare as personnel cost.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action in the way described below.

If the resulting amount is above the following **eligibility ceilings**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The eligibility ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional salary but also all additional taxes, costs and social security contributions triggered by the additional salary.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the standard hourly rate is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (eligibility ceiling):

{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000

The additional remuneration paid for the EU action is eligible in full because it is lower than the eligibility ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the eligibility ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the eligibility ceiling would have been:

{(EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

Example for calculating direct personnel costs for employees (or equivalent):

A nuclear researcher working for a public research laboratory (non-profit) worked:

1 600 productive hours

800 hours declared for the action (at an hourly rate of EUR 40)

400 hours declared for another EU grant

S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.

*Calculation of the personnel costs: EUR 40/hour * 800 hours =* ***32 000***

Addition of the additional remuneration: = ***2 000***

Total costs charged to the action for the year: ***32 000 + 2 000 = EUR 34 000***

Condition: Actual hours declared for action + actual hours declared for another EU grant ***≤*** *total productive hours (800 + 400* ***< 1 600****)*

Specific cases (direct personnel costs for employees (or equivalent)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A applies.

For persons who sign the 'declaration on exclusive work for the action' the number of hours worked in the action during the period covered by the declaration will be the pro-rata (corresponding to the period of exclusive dedication) of the annual productive hours used to calculate the hourly rate.

Example:

Researcher Y worked exclusively in the H2020 action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours.

The personnel cost to be reported would be calculated as follows:

	Hourly rate		*Hours worked for the project*	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of his/her personnel costs incurred during the reporting period.

Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the corresponding part of the indemnity in the reporting period in which the employee's contract ends.

However, the indemnity may be accepted ONLY if:

- arise from the applicable national labour law
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Only the part of the indemnity that corresponds to the time worked by the person on the action can be charged (i.e. pro-rata of the total time during which the entitlement was generated).

Employment contract remunerated 'per hour' — Some employment contracts do not establish a fixed salary and a number of hours to be worked, but an amount to be paid for each hour worked by the employee.

In those cases, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the 'individual annual productive hours' may be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

Personnel costs on the basis of the usual cost accounting practices — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices (i.e. 'average personnel costs'), the hourly rate must be calculated in accordance with the beneficiary's usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility conditions.

Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

Costs that are already included in other budget categories must be taken out (double funding of the same costs).

Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020 actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.*

Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate
- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using one of the three options provided in the MGA for the number of annual productive hours (e.g. *option 3 'standard annual productive hours')*.

Beneficiaries may request the **approval** of the methodology used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

1.2 Direct personnel costs: Costs for natural persons working under a direct contract

1.2.1 What? This budget category **covers** typically the costs of in-house consultants and similar persons that worked on the action (i.e. self-employed *natural* persons – not companies – working part-time or full-time for the action under a contract which is not governed by labour law for employees).

What not? Persons provided by a temporary work agency or, more generally, by any other entity against a price (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

Those costs may however be eligible as:

- 'purchase of services' *(see Article 10)* if the work done by the person is not part of the action tasks identified in Annex 1, or
- 'subcontracting cost' *(see Article 13)* if the work done by the person is part of the action tasks identified in Annex 1.

In both cases, the beneficiary must comply with the conditions of best value for money and no conflict of interest when concluding the contract/subcontract (as well as with the other eligibility conditions).

1.2.2 Costs for natural persons working under a direct contract may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs'; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working hours, rather than on delivering specific outputs/products. This implies that the beneficiary must keep records of the hours worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **formula** as the one explained in point *1.1.4* (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the **hourly rate** is different (since it is not based on the annual personnel costs as registered on the payroll).

For the hourly rate, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person and the number of hours to be worked: this global amount must be divided by the number of hours to be worked for the beneficiary under that contract.

If the contract fixes only a global amount and does not specify the time to be worked, the costs can NOT be declared as personnel costs, but may be eligible as purchase of a service *(see Article 10)* or a subcontract *(see Article 13)*.

This table explains how to treat **different types of work contracts** for declaring costs under H2020[19]:

General case: Single contract between the entity and the person		
Characteristics of the contract	**Contract remunerating time** (*e.g. the contract establishes that the person must work for the hiring entity 40 hours per week*)	**Contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes that the person must carry out a specific task but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4 above): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4 above): ➔ However only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. *Example: Contract from 01/01/2015 to 31/03/2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430* ➔ The personnel cost will be the result of multiplying the hourly rate by the number of hours worked by the person for the action (as recorded in its time-sheets).

[19] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

Other contract (i.e. not covered above)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared as 'personnel costs – costs for natural persons working under a direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.	**CASE D** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

Special case: the contract covering the work for the H2020 action is additional to other contract(s) of the person with the entity		
Characteristics of the additional contract	**Additional contract remunerating time** (*e.g. the additional contract establishes that the person must work for the hiring entity 10 hours per week in addition to the basic contract*)	**Additional contract remunerating duties (without specifying the working time conditions)** *(e.g. the additional contract establishes that the person must carry out a specific task but the working time needed is not defined; e.g. the contract specifies that the work has to be carried out within the working time of the main contract)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE E1:** the additional contract is NOT triggered by the participation of the person in the H2020 action (e.g. the contract pre-dates and outlasts the grant agreement). The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4 above): ➔ In this case a single hourly rate must be calculated taking the figures of the main and the additional contract/s together (i.e. total basic remuneration and total annual productive hours). **CASE E2:** the additional contract is triggered by the participation of the person in the H2020 action. The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4 above): ➔ However, the hourly rate must be calculated only on the additional contract (remuneration and productive	**CASE F** The costs may be declared as 'personnel costs – costs of employees (or equivalent)' (Article 6.2.A.1). They must be calculated for the additional contract as described in CASE B above: ➔ However, if the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1).* Therefore: **CASE F1** (the hiring entity is a non-profit legal entity): the costs of the additional contract may be eligible up to the following ceiling: *{Hours worked for the action (as recorded in the time records)* *multiplied by* *{Hourly rate of the main contract + EUR 4,65}}* Note: EUR 4,65 is the result of dividing 8000 (annual ceiling for additional remuneration) by 1720 (option 1 annual productive hours); thus, 4,65 is the hourly pro-rata of the annual ceiling

	hours of the additional contract). If the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1)*.	**CASE F2** (the hiring entity is NOT a non-profit legal entity, i.e. for profit entity): the costs of the additional contract may be eligible up to the following ceiling: {*Hours worked for the action (as recorded in the time records)* *multiplied by* *Hourly rate of the main contract*}
Other contract (i.e. not covered above)	**CASE G1:** the costs fulfil the conditions of Article 6.2.A.2. Depending on the main contract, the costs may be declared either as: – 'costs of employees (or equivalent)' (Article 6.2.A.1) or as – 'costs for natural persons working under a direct contract' (Article 6.2.A.2). If the main contract is under CASE A, CASE B or CASE C1, the cost must be calculated as indicated above for CASE E1 or E2 (depending if the additional contract is or not triggered by the participation in the H2020 action). If the main contract is under CASE C2 or D, the costs must be calculated as described in point 1.2.4. **CASE G2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10).	**CASE H** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: as 'direct costs of subcontracting' (Articles 6.2.B and 13) or – as 'costs of other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

	⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.	

1.3 Direct personnel costs: Costs for persons seconded by a third party against payment

1.3.1 What? This budget category **covers** the costs of persons that worked on the action and that were seconded by a third party as an 'in-kind contribution *against payment*' *(see Article 11)*.

> For information on in-kind contributions provided by third parties *free of charge*, *see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may only be **declared as** actual costs.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  > ***Example:*** *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.3.4 There is no specific **cost calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1*).

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

Those rules imply, among others, that the beneficiary must keep reliable time records of the time worked by the seconded person for the action.

1.4 Direct personnel costs: Costs of beneficiaries that are SMEs for their owners not receiving a salary — Costs of beneficiaries that are natural persons not receiving a salary

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons not receiving a salary that worked on the action.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs*).

***Example**:*

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the H2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[20] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *Main Work Programme — MSCA*[21] in force at the time of the call.

***Example:** A German SME owner not receiving a salary will calculate the hourly rate as follows:*

EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an owner of an SME/beneficiary that is natural person, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than the standard number of annual productive hours used for the calculation of the hourly rate (i.e. 1 720 hours).

1.5 Direct personnel costs: Personnel costs for providing trans-national or virtual access to research infrastructure

1.5.1 What? This budget category **covers** the personnel costs for access to infrastructure activities, i.e.:

[20] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[21] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons working under a direct contract and
- costs of personnel seconded by a third party against payment.

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as** actual costs or on the basis of unit costs in accordance with the usual cost accounting practices (i.e. 'average personnel costs') *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.5.4 The same rules for **cost calculation** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting ***[(not covered by Point F)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting: Types of costs — Cost form — Conditions for eligibility — Cost calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional cost eligibility conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional eligibility conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **cost calculation** method; the costs must correspond to the eligible costs actually incurred.

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)] [OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]*

*[**OPTION**: Not applicable]*

1. Direct costs of providing financial support to third parties: Types of costs — Cost form — Conditions for eligibility — Cost calculation

This optional budget category (together with the corresponding Article 15 and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 There is no specific **cost calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances: Types of costs — Cost form — Conditions for eligibility — Cost calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is envisaged in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in or outside of Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  > ***Example*:**
  > *Beneficiary A declares the cost of a business class airplane ticket for one of its employees.*
  > *If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.*
  > *If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.*

If the beneficiary reimburses travel and/or related subsistence allowances as a lump sum and/or *per diem* payment, it is the lump sum or *per diem* amount that is considered an eligible cost, not the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1.

1.4 There is no specific **cost calculation** method; the costs must correspond to the eligible costs actually incurred.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

  only the part of the equipment's 'full capacity'[22] actually used for the action may be declared (i.e. time used for the action and, in case of shared use, the percentage of actual use for the action). If the beneficiary does not use the equipment exclusively for

[22] Full capacity means the number of productive hours/days/months corresponding to the full potential use of the equipment by the beneficiary. This includes any time during which the equipment is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time, etc.

the action (or if it does not use it for its full capacity), the time that the equipment has been used for the project must be recorded

> ***Example:*** *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*
>
> *Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.*

– the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

> ***Example:*** *A microscope was bought in 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs):

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. If the equipment is expected to be used over more than one year, declaring its *full* price in one single year may be considered either as not compliant with the international accounting standards or as an 'excessive' cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

> ***Example:***
>
> *According to the beneficiary's accounting practices, an equipment bought in January 2013 has a depreciation period of 48 months.*
>
> *If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.*

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. In the general case beneficiaries may therefore only charge the annual depreciation costs that correspond to the part of the equipment's 'full capacity' that was used for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

> 'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year the beneficiary can NOT charge the total costs of the item in a single year. This applies even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year.

> ***Example:***
>
> *A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.*
>
> *In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:*
>
> > *EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period*
>
> *In the reporting period ending in December 2017, the beneficiary must declare:*

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the cost eligibility conditions of Articles 6.1 and 6.2 are met (in particular, recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices; *see Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

If the full construction cost of the construction are eligible, but the construction was externalized to a third party (other than a linked third party), the costs can NOT be declared as 'equipment costs', but may be eligible as 'direct costs of subcontracting' *(see Articles 6.2.B and 13)*.

1.2 Equipment costs: Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs: Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:
  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.

  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee

- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are comparable to the depreciation costs of similar equipment).

1.4 Equipment costs: Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional cost eligibility conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services: Types of costs — Cost forms — Conditions for eligibility — Cost calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access during the action*, e.g. article processing or equivalent charges*), costs related to data maintenance or storage and conference fees for presenting project-related research
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4) or the certificate was submitted not for the final report but before*).
- translation costs (if translation is necessary for the action's implementation, is justified, etc.).

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional cost eligibility conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **cost calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the 'plan for the exploitation and dissemination of the results' are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Internally invoiced costs (i.e. where the use of certain resources is shared between different units of the same organisation and the costs of their use are declared through internal invoices) may be eligible if their use and the usage (number of hours) for the action is specifically recorded and it is mentioned in the invoice. The internal invoice must refer to the use/dedication for the action of specific resources (*e.g. per researcher, piece of equipment, etc.)*.

> ***Example (acceptable internal invoice):*** *Internal invoice with 16 hours of the technician doing the analysis and 10 hours depreciation of the testing equipment used.*
>
> ***Example (not acceptable internal invoice):*** *Internal invoice with a global price for the use of a research infrastructure (e.g. laboratory) or for a service (e.g. an analysis).*

The costs must be declared under the budget category that corresponds to the invoiced resource *(e.g. personnel, equipment, other direct costs, etc.)* and must fulfil the eligibility conditions set out in Article 6.1 and 6.2.

Internal invoices may NOT include indirect costs elements or profit margin or mark-up.

Internal invoices for the work of personnel must be supported by time records *(see Article 18.1)*. The hourly rate must be calculated as described in Article 6.2.A.

Internal invoices for the use of equipment must be limited to the depreciation for the relevant reporting period (only the part of the depreciation cost corresponding to the time the equipment was used for the action during that reporting period can be declared.) The use of the equipment must be properly recorded in order to allow direct measurement of the use for the action and to ensure auditability *(see Article 6.2.D.2)*. It is NOT possible to calculate an all-in average cost of internally invoiced equipment including, for instance, allocated indirect costs *(e.g. maintenance)*.

Self-produced consumables — the eligible cost of a consumable is generally determined by its purchase price. The purchase price is the actual direct cost of the consumable for the beneficiary. However, consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price. The consumable is normally recorded in the accounts of the beneficiary (as part of the *inventory)* for its cost of production. In consequence, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.

The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

⚠ Beneficiaries can NOT charge the commercial price for self-produced consumables.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure: Types of costs — Cost forms — Conditions for eligibility — Cost calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of the Horizon 2020 Framework Programme 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[23]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's

[23] *See also International Financial Reporting Standard No 16.*

usual accounting practices.[24] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure for the calculation of the EUR 20 million threshold *(see below)* and consequently declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[24] *See Article 126 of the Financial Regulation.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared** as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **conditions for eligibility**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **cost calculation** is explained in point 4.4.

2. Large research infrastructure

Beneficiaries can declare capitalised and operating costs for '**large research infrastructure**', if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[25] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a '**research infrastructure**' in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[26].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a '**grouping of costs**' (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once, a positive ex-ante assessment is obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[25] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[26] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any grant agreement.

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Beneficiary Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) 'ex-ante assessment report' will be issued.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs under Article 6.2.D.4.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (Link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

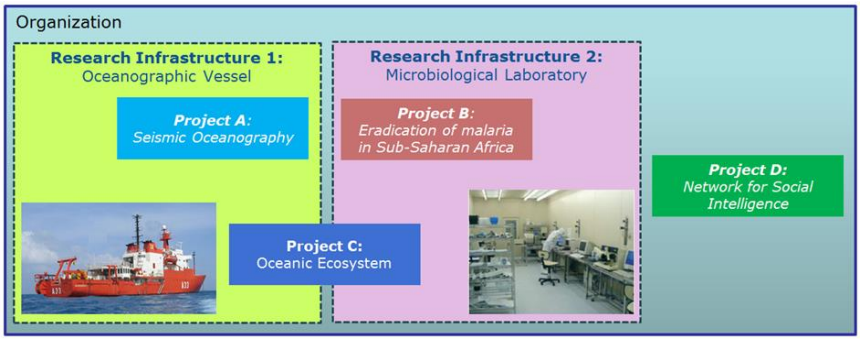

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[27].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the Horizon 2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the Horizon 2020 grant, even if they belong to the same action ('synergies between Horizon 2020 and the Structural Funds and ESIF Funds').

> ⚠ The terminology under the different regimes — Horizon 2020, the Structural Funds and the ESIF Funds — may differ (e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).

4.4 Costs must be directly measured

Costs can be claimed as direct costs under Article 6.2.D.4 only if they are '**directly measured**' (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[27] *See Article 129(1) of the Financial Regulation.*

Example 2 (Comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (‘**project time**’) and therefore require reliable time recording (through timesheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of ‘**units of actual usage**’ for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary’s analytical cost accounting system. This data must be regularly updated.

  Example 3 (Costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

Example 4 (Part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[28]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (Rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[28] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints (e.g. opening hours), but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]][**OPTION**: not applicable;]*

(d) ***[OPTION if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost forms — Conditions for eligibility — Cost calculation

This budget category applies to all to all RIA, IA and CSA grants under the General MGA.

However, beneficiaries that receive an **operating grant** financed by the EU or Euratom budget can NOT declare any indirect costs for the reporting period(s) covered by the operating grant.

Best practice: The beneficiary must **inform** both the coordinator and the Commission/Agency during grant preparation and before submitting financial statements (via the Participant Portal).

'Operating grants' are (normally annual) grants given by a separate grant agreement to finance the operation and running costs of an entity e.g. call COMM-C2/01-2013 under the 'Europe for Citizens' programme.

1.1 This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared** on the basis of a flat-rate (*see Article 5.2(e)*; new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25 % flat-rate to the beneficiary's eligible direct costs, minus:

- subcontracting costs *(see Article 13)*

  Example: *subcontracting of opinion surveys.*

  The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties (if option applies)

- costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a grant agreement and has incurred the following costs

- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,

- EUR 10 000 in consumables costs.

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

F. [OPTION: [Insert name of specific cost category(ies)[22]]][OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant): *[**insert name of specific cost category**] are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].***]***

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category] *are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.***]***

[same for each specific cost category]

[OPTION: *Not applicable****]***

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories: Types of costs — Cost forms — Conditions for eligibility — Cost calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of the Horizon 2020 Framework Programme, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: '**costs for energy efficiency measures in buildings**'

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': '**access costs for providing trans-national access to research infrastructure**'

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': '**costs for clinical studies**'

  The unit cost applies ONLY to actions with clinical studies.

⚠ Costs that are declared as a specific unit or lump sum cost may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

Example:

The unit cost for 'efficiency energy measures in buildings' covers subcontracting costs related to the energy efficiency measures. These cannot be declared as direct costs of subcontracting. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

1.1 'Specific cost category – costs for energy efficiency measures in buildings'

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost set out in Commission *Decision C(2013) 8196*[29] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) must be calculated — before signature of the GA — according to the following formula:

Amount per unit = {EUR 0.1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m^2 of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 'Specific cost category – access costs for providing trans-national access to research infrastructure'

1.2.1 This budget category **covers** direct and indirect 'access costs for providing trans-national access to research infrastructure' (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; see Article 6.2.D.1 and Article 16).

1.2.2 If they are declared under this budget category (i.e. specific cost category – access costs for providing trans-national access to research infrastructure), the costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[30] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{31}\text{)}}{\text{average annual total quantity of access (over past two years}^{32}\text{)}}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:

[30] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[31] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[32] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

  Exceptionally, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices ('average personnel costs').

- costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)

- costs of consumables specifically used for the installation and the user's research work

- costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation

- costs of energy power and water supplied for the installation

- costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)

- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services

- costs of specific scientific services included in the access provided or needed for the provision of access

- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)

- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

The access activities and the parameters for calculating the unit cost must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annexes 1 and 2a.

The proposal should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per installation and access provider).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

During the GA, the beneficiaries may change their choice, but only via an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional cost eligibility conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 'Specific cost category – costs for clinical studies'

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study;
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
  - costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
  - indirect costs for the study.

1.3.2 If they are declared under this budget category (i.e. specific cost category – costs for clinical studies'), the costs must be **declared** on the basis of the unit cost set out in Commission Decision C(2014) 1393 and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/patients or subjects included in the clinical study) must be calculated for each study and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — according to the following formula:

Amount per unit ={Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks] **}**

The unit cost components must be calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':

{'average hourly cost for doctors', i.e.:

certified or auditable total personnel costs for doctors for year N-1

{1720 * number of full-time-equivalent for the personnel category doctors for year N-1}

multiplied by

estimated number of hours worked by doctors for the task (per patient/subject)**}**

For unit cost component 'personnel costs of other medical personnel':

{'average hourly cost for other medical personnel', i.e.:

certified or auditable total personnel costs for other medical personnel for year N-1

{1720 * number of full-time-equivalent for the personnel category other medical personnel for year N-1}

multiplied by

estimated number of hours worked by other medical personnel for the task (per patient/subject)**}**

For unit cost component 'personnel costs of technical personnel':

{average hourly cost for technical personnel, i.e.:

certified or auditable total personnel costs for technical personnel for year N-1

{1720 * number of full-time-equivalent for the personnel category technical personnel for year N-1}

multiplied by

estimated number of hours worked by technical personnel for the task (per patient/subject)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc.)

For each category of consumables:

{'average price per item', i.e.:

{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned

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total number of items purchased in year N-1 for the category of consumables concerned}

multiplied by

estimated number of items used for the task (per patient/subject)**}**

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:

{'average cost of depreciation and directly related services per unit of use', i.e.:

{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

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total capacity in year N-1

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:
'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

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total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%
multiplied by
{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}**}**

The following must be excluded:
- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

The estimation of the resources must be done on the basis of the protocol for the clinical study (and must be the same for all beneficiaries/linked third parties/third parties involved).

Each beneficiary/linked third party/third party providing in-kind contributions must calculate the direct costs by using its historical costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application).

Personnel costs must be defined in the 3 categories (doctors, other medical personnel, technical personnel) defined in the Commission Decision. No other categories *(e.g. 'nurses')* can be used.

The descriptions of the resources and the parameters for calculating the unit cost must already be part of the proposal *(see the proposal templates and the* template for essential information to be provided for proposals including clinical trials / studies/ investigations *provided on the call pages)* and be included in Annex 1 and 2a of the GA.

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per study and beneficiary/third party.)

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or of costs actually incurred for a given clinical study.

1.3.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** the number of patients or subjects that participated in the study

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION: *Not applicable****]***

1. Costs of linked third parties

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional cost eligibility conditions** set out in Article 14.1.1.

'*Mutatis mutandis*' means with the necessary modifications; the same rules apply, but with the changes needed to render them applicable to the linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared as 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared as 'other direct costs – equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions provided by third parties free of charge

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional eligibility conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared as 'other direct costs – equipment' (Article 6.2.D.2).*

'In-kind contributions free of charge' must be **distinguished** from 'in-kind contributions against payment' *(see Article 11)*.

In-kind contributions against payment are costs *of* the beneficiary/linked third party (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. They must be declared under those budget categories.

Example:

1. *The cost of personnel seconded against payment must be declared as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared as 'other direct costs – equipment – cost of equipment, infrastructure or other assets contributed in-kind against payment' (Article 6.2.D.2).*

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

  - **debt and debt service charges**

    'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

Example: *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

- **provisions for future losses or debts**

  'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

- **interest owed** (i.e. interest on a loan to borrow capital)

- **excessive or reckless expenditure**

  'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

  'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

- **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

- **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

  Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the cost eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

- **deductible VAT**

  'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

  The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

  The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.

  The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

  Conversely, if VAT is NOT deductible, it is an eligible cost.

  The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*

  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*

  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*

  - if a beneficiary is receiving an operating grant[33] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

Specific cases (ineligible costs):

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

[33] For the definition, *see Article 121(1)(b) of the Financial Regulation:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of declaration of ineligible costs

The other measures specified in Chapter 6 *(e.g. reduction of the grant)* may be applied in addition to the ineligible costs being rejected.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

⚠ Normally, the beneficiaries must comply BOTH with the national law of the country in which they are established and that of the country where the action is implemented.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Third parties involved in the action do not sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks.
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the Government (the Ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the Government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the Government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). According to the secondment agreement, the Government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the Ministry/Government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ Coordination and administration tasks are considered **action tasks**.

Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

Summary table of third parties:

Types of third parties	CHARACTERISTICS						
	Does work of the action	Provides resources or services	What is eligible?	Must be indicated in Annex 1	Indirect costs	Selecting the third party	Articles
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link	**Article 14**
Subcontractors	**YES**	**NO**	**Price**	**YES**	**NO**	Best value for money, avoid conflict of interest	**Article 13**
Third party providing in-kind contributions	**NO**	**YES**	**Costs**	**YES**	**YES**	Cannot be used to circumvent the rules	**Articles 11 and 12**
Contractors	**NO**	**YES**	**Price**	**NO**	**YES**	Best value for money, avoid conflict of interest	**Article 10**
Financial support to third parties	**Only if allowed in the call** The beneficiaries' activity consists in providing financial support to the target population			**YES**	**NO**	According to the conditions in Annex 1	**Article 15**

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION 2, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION by default****: these beneficiaries][****OPTION if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION: *Not applicable****]***

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

These beneficiaries are considered 'beneficiaries' (although they do not receive EU funding) and therefore must carry out the work under the action and comply with most of the obligations under the GA. However, some obligations will not apply.

'Beneficiaries not receiving EU funding' are usually third country participants (i.e. participants that are neither from an EU Member State nor from a H2020 associated country[34]) that:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

For more information on third country participants, *see the Online Manual*.

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on the role of the beneficiary in the grant and if it has or not linked third parties that receive EU funding).

[34] For the definition, *see Article 2.1(3) Rules for Participation:* '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013.

This table summarises the obligations of the General MGA that do not apply to beneficiaries not receiving EU funding (under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of breach of any of their obligations, their participation may be terminated and any of the other measures of Chapter 6 (except for rejection of costs or recovery) may be applied.

Example:

A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[23]]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 **Beneficiaries that are 'contracting authorities'** within the meaning of Directive 2004/18/EC[24] or 'contracting entities' within the meaning of Directive 2004/17/EC[25] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases on the 'best value for money' considering the quality of the service, good or works proposed (also called '**best price-quality ratio'**) or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value for money principle does not require **competitive selection procedures** in all cases. (However, where a beneficiary did not request several offers, it must demonstrate how best value for money was nevertheless ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, running costs, delivery times, after-sales service and technical assistance, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.)

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purpose of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the EU contribution). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs **—** and be based on the rules applied by the Commission for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC[35] and 2004/17/EC[36,37] — or any EU legislation that replaces these Directives[38]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 1(9) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 2 of Directive 2004/17/EC)*.

Specific cases (purchases):

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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35 Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

36 Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

37 Directive 2009/81/EC uses the definitions of Directives 2004/17/EC and 2004/18/EC *(see Article 1(17) of Directive 2009/81/EC)*.

38 *See Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 94, 28.3.2014, p. 243).*

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

1. In-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to 'in-kind contributions' (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example: *medical equipment provided by a hospital to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs actually incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2*; *e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

For the upper limit (third party's actual costs), normally only the *direct* costs are taken into account.

These *direct* costs may not be based on unit costs[39] or lump sums *(i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot, for instance, use the unit costs for SME owners or natural persons who do not receive a salary*.

When calculating the actual costs incurred by the third party, *indirect* costs of the third party are:

- either not taken into account if the resources (in-kind contribution) are used in the premises of the beneficiary; or
- taken into account by using the 25% flat-rate if the in-kind contributions are used in the third party's premises. In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those actually incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

[39] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

3. Additional eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** to the GA.

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ((‘**simplified approval procedure**’).

> ***Example:*** *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

> ***Example (no approval):*** *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the ‘simplified approval procedure’ bear the full risk of non-approval and rejection of costs by the Commission/Agency.

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The **beneficiaries may declare costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the **Commission**, the European Court of Auditors (**ECA**) and the European Anti-Fraud Office (**OLAF**) can exercise their rights under Articles 22 and 23 also towards the **third parties**.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary makes no payment and there is therefore NO cost incurred by the beneficiary.

Examples (in-kind contributions provided by third parties free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the Government (the Ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the Ministry/Government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like Universities/Ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

⚠ Article 12 contains additional cost eligibility conditions.

2. Additional eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and *in Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs of the third party may be declared.

These direct costs may not be based on unit costs[40] or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*). Thus, the beneficiary cannot, for instance, use *the unit costs for SME owners or natural persons who do not receive a salary*.

When calculating the actual costs incurred by the third party, *indirect* costs of the third party are:

- either not taken into account if the resources (in-kind contribution) are used in the premises of the beneficiary; or
- taken into account by using the 25% flat-rate if the in-kind contributions are used in the third party's premises. In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

If the indirect costs are claimed in this way, the beneficiary may not include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 to the GA.

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**'; *see Article 11*).

4. Additional eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

[40] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[26]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(i) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(ii) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(iii) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(iv) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(v) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [27]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').***]**

The **tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1** and the **total estimated costs** of subcontracting per beneficiary **must be set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).***]**

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[26] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[27] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on 'business conditions'

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from 'linked third parties'; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2)*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

Stricter rules apply to information that is 'EU-classified' or subject to a 'security recommendation' in Annex 1 of the GA *(see Article 37).*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts on the 'best value for money' considering the quality of the service proposed (also called '**best price-quality ratio**') or on the lowest price.

This requirement is the mere application of the general cost eligibility condition set out in Article 6.1(a)(vii) (i..e. that costs must be reasonable and comply with the principle of sound financial management) to the costs of the purchase of goods, works or services.

The best value for money principle does not require **competitive selection procedures** in all cases. (However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.)

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is not automatically necessary to select the offer with the **lowest price**. (Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.)

In order to provide a good analysis of the price-quality ratio, the criteria defining 'quality' must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI). It is important not to confuse a Research and Innovation action, or an Innovation action, involving PCP or PPI with a PCP/PPI Cofund action. For the latter, the main objective of the action is the implementation of a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI).

The additional rules mirror the key obligations from the H2020 MGA PCP/PPI Cofund.

4. Additional eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the name of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the specific subcontractor. For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA ('**simplified approval procedure**').

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the **full discretion** of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the full risk of non-approval and rejection of costs by the Commission/Agency.

5. Additional eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC[41] — or any EU legislation that replaces these Directives[42]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 1(9) of Directive 2004/18/EC)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 1(9) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 2 of Directive 2004/17/EC)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* — Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

[41] Directive 2009/81/EC uses the definitions of Directives 2004/17/EC and 2004/18/EC *(see Article 1(17) of Directive 2009/81/EC)*.

[42] *See Directives 2014/24/EU and 2014/25/EU.*

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[28] and **third parties with a legal link to a beneficiary**[29] ('**linked third parties**') may implement the action tasks **attributed to them in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked parties]

*The linked third parties **may declare** as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

[28] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[29] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).

  The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission as reimbursement of costs of their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only '**affiliated entities**' or '**entities with a legal link to a beneficiary**' can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; 'ad hoc' collaboration agreements or contracts to carry out work in the action are NOT covered. (In this latter case, both legal entities should be beneficiaries.)

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or
- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities *composed of members (where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Examples (affiliated entities):

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a H2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

Linked third parties must fulfil the general conditions for participation and funding under Horizon 2020.[43]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country, and the costs of participants established in third countries (not listed in the work programme/call) are not eligible for funding under Article 10 of the Rules for Participation.*

For more information on conditions for participation and funding, *see the Online Manual*.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak'
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

1. *The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

3. *The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.*

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery). The beneficiary must keep the original in its files and upload it (as a scanned PDF copy) in the system.

The liability is for any amount owned by the beneficiary under the GA, and up to the maximum EU contribution indicated for the third party in the Annex 2 to the GA.

For more information on the financial viability/capacity check, *see the Online Manual*.

[43] *See Articles 8 and 9 of the Rules for Participation.*

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. *Entities specifically established for the purpose of implementing the action (e.g. EEIGs).*

2. *National research associations established according to the national law in order to carry out research not limited to the action.*

3. *A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.*

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO 'simplified approval procedure'.

3. Additional eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **cost eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* via the electronic exchange system (since linked third parties do not have access; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary. The beneficiary must keep the originals *(see Article 18.1.2 last option)*.

Each linked third party has to provide its own ***certificate* on the financial statements** *(see Article 20.4)*.

The threshold of EUR 325 000 applies to each linked third party (independently of the EU contribution of its beneficiary).

For the same reasons as above, the beneficiary must keep the original of the certificate *(see Article 18.1.2 last option)*.

4. Additional eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties only where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*)

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[30] must provide access to research infrastructure or installations[31] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

*Access for **user groups with a majority of users not working in a EU or associated country**[32] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) **procedure** and criteria **for selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]]*[33]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.*

***[OPTION:** Not applicable]*

30 **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

31 **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

32 For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

33 If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[44] or installation[45] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category 'specific cost category – access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 to the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

The beneficiaries must **keep** appropriate **records** and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions

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[44] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[45] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional condition for eligibility: Access which must be provided

Trans-national access can be either:

- **in person** ('hands-on'), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional condition for eligibility: Categories of users that may have access — User groups with a majority of users not working in an EU Member State or H2020 associated country

For trans-national access, user groups in which all or most users work in **third countries** may only have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional condition for eligibility: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. Additional eligibility condition: Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[35] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action

- costs related to technological and scientific support for users' access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will not be reimbursed (for the provision of access activity; *see Article 6.2.D.2*).

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional condition for eligibility: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*.

Access must be open to all users; users are not selected.

3. Additional condition for eligibility: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the **'Beneficiary Register'** (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may at any point request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request information for **any purpose** *(e.g. monitoring the action, assessing reports and requests for payment, checks, reviews, audits or investigations or evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission may request information at **any time**, either during the action's implementation or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information must be sent **via the Participant Portal**. Afterwards, formal notifications must be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary must keep its information in the Participant Portal Beneficiary Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form (*e.g. private limited liability company, public law body, S.A., S.L.*)
- organisation type (*e.g. SME, secondary or higher education establishment, etc.*).

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, validation and data updates, *see the Online Manual*.

3. Information about events likely to affect or delay the action or affect the EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

> ***Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the Beneficiary Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and not via the electronic exchange system.

In any case, it is advisable that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the electronic exchange system
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[36]:*** *three]* years after the payment of the balance — keep **records and other supporting documentation** in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[36] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (and linked third parties; *see point 10*) must keep appropriate and sufficient evidence to **prove** eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[46]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least five years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

[46] International Standard on Auditing ISA 500 'Audit Evidence'.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared as 'personnel costs' must be detailed per employee carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For 'other direct costs', the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For personnel costs declared in accordance with their usual cost accounting practices (i.e. '**average personnel costs**'), the beneficiaries must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is NOT necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What?

To get additional assurance, a beneficiary/linked third parties may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificates is NOT valid for Horizon 2020.)

When?

Beneficiaries may submit their requests for approval at **any time** — before or during the course of the grant.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

If the beneficiary declares personnel costs according to the changed cost accounting practices before the new certificate is approved, it accepts to bear the risk that the changed practices are not compliant anymore and that the costs may be declared ineligible.

How?

The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 to the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

> ⚠ Exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a 'declaration on exclusive work for the action' (one per reporting period), to confirm that the person worked exclusively for the action, either:
  - during the whole reporting period or
  - during a an uninterrupted time-period, covering at least a full natural month within the reporting period.

    Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration.

    If a person worked randomly for the action after an uninterrupted time-period covered by a declaration, time records are needed for the period of random work.

    > ***Example:*** *the person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

  The declaration must be dated and signed by the person concerned and her/his supervisor.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

- keep **time records**.

  Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

  Time records should include:

  - the title and number of the action, as specified in the GA
  - the beneficiary's full name, as specified in the GA

- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record; for reasons of assurance and legal certainty it is highly recommended that the number of hours is detailed per day (hours worked for the action in each day)
- the supervisor's full name and signature
- a reference to the action tasks or work package described in Annex 1, to easily verify that the work carried out matches the work assigned and the person-months reported to the action
- a brief description of the activities carried out, to understand and show what work was carried out.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template for time-sheets is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept '**alternative evidence**' if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the full risk of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned;

Criterion 2 is met – the project is identified as XYZ;

Criterion 3 is met – the time is quantified: two weeks.

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown;

Criterion 2 is not met: the project name is not mentioned;

Criterion 3 is not met – the time is not quantified.

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

> ***Example:*** *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

> ***Examples:***
>
> *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*
>
> *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in a specific section of Annex 1 to the GA ('list of deliverables').

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

How?

The coordinator must submit them via the **Participant Portal** *(see Article 52)* — unless Annex 1 specifies another way.

Specific cases (deliverables):

Classified results — If the deliverables are classified results, they may only be submitted to the Commission/Agency via means (electronic or not) that have been approved *(see Article 37)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1] to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary for publication** containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[37]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.**]***

[OPTION: *Not applicable**]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

[37] To be added in the case of grants of mare than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

When & What?

In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of action ('reporting').

> These 'reports' must be **distinguished** from 'deliverables' (that are part of Annex 1; see Article 19) and 'milestones' (that may be part of Annex 1, but are normally neither covered by Article 19 nor by Article 20).

The coordinator must submit both:

- a '**periodic report**' after the end of each reporting period (including the last one) and
- a '**final report**' at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically created by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration.

Forms and templates for the different parts of the reports are available in the electronic exchange system.

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, by filling out the forms directly in the **Participant Portal**).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress

- updated plan for the exploitation and dissemination of results (if necessary)
- summary for publication
- questionnaire (i.e. the structured information requested)
- individual financial statements for each beneficiary and linked party
- explanation on the use of resources
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication
- certificates on the financial statements (CFS) (if necessary).

Generally, the documents can be **drafted together** (i.e. by several users from different beneficiaries). Some forms are continuously open and can be updated at any moment *(e.g. questionnaire, publishable summary).* Some are linked, so that they must be filled out together *(e.g. the financial statement and the explanation on the use of resources: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense if necessary).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (via the electronic exchange system).

This includes the **coordinator**, who must also submit its individual financial statement.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary. The linked third parties can NOT view their grants in the electronic exchange system and therefore have no access to them.

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must keep the original in its files and must ensure that the data encoded in the electronic exchange system is correct (i.e. identical to the signed paper version).

If a beneficiary **cannot submit** its individual financial statement on time, the report can be submitted without this financial statement. The costs will be considered 'zero' for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned. The beneficiary must keep the signed original in its files.

Once completed, the (periodic or final) report must be **submitted** by the coordinator (CoCo) (with all its parts, as a single package; '**single submission**').

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator (through the electronic exchange system), as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) ('**single suspension**'). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified ('**single re-submission**').

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated '**plan for the exploitation and dissemination of the results**' (if such a plan is foreseen in Annex 1).

Technical reports should not contain any information that is 'EU classified' under the Commission internal Rules of Procedure *(see also Article 37, the Online Manual and the Guidance — Guidelines for the classification of research results)*.

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an 'easy to read' way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential or 'EU classified' information.

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the Horizon 2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the Horizon 2020 Specific Programme)
- information to monitor the implementation of Horizon 2020 on 'cross–cutting issues' (see Annex III to the Specific Programme) and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' (*see Article 3 and Annex* I to the Specific Programme).

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Periodic financial report: Individual financial statements — Explanation of the use of resource — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 ('cost overruns'). The EU contribution will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is created automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact.

The final summary must cover the whole action

Like the summaries for the periodic reports, the final summary must be written in an 'easy to read' way and be understandable for a non-specialist audience.

The coordinator must ensure that none of the material submitted for publication includes confidential or 'EU classified' information.

The summary should include:

- an up-to-date link to the action's website
- project logos, diagrams, photographs and videos illustrating the work of the action (if available)
- the final version of the 'plan for the exploitation and dissemination of the results' (if such a plan is foreseen in Annex 1).

It may also include a list of all beneficiaries, with contact names (if this information should be published).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically created by the system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

Some beneficiaries/linked third parties must submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and personnel costs declared on the basis of unit costs calculated according to its usual accounting practices (i.e. 'average personnel costs').

This means that costs based on lump sums, flat-rates (e.g. indirect costs) or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

– *average personnel costs*	=	*EUR 250 000*
– *subcontracting costs*	=	*EUR 40 000*
– *depreciation costs of equipment used to carry out the action*	=	*EUR 60 000*
– *indirect costs (25 % flat rate)*	=	*EUR 77 500*
– *total eligible costs claimed by A*	=	*EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the corresponding EU contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or average personnel costs must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency do not have to be covered again by the certificate.

Example:

A beneficiary participates in a H2020 action with three reporting periods. During the second reporting period the Commission's auditors carry out an audit of the costs incurred by the beneficiary in the first reporting period. At the end of the action, the beneficiary requests a total contribution of EUR 425 000 and has to submit a CFS with the final reports. In this case, the CFS may exclude the costs of the first reporting period (which were already covered by the Commission audit).

Linked third parties must submit a certificate if it (on its own, without its beneficiary) reaches the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

- In both cases, the certificate may only be submitted with the final financial report. The Commission/Agency will not accept certificates submitted at any other moment (and costs incurred for those certificates will not be considered eligible, because not necessary).

The certificate must be issued by an **external auditor**, using the template in Annex 5.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[47] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

[47] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a third country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants of more than EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[48].

    Procedure for calculating the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[49].

[48] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

10. Suspension of the payment deadline — Termination

If the coordinator breaches its obligation to submit the reports, the Commission/Agency may decide to:

- suspend the payment deadline (see *Article 47*)
- terminate the GA if the coordinator continues to breach its obligations after a written reminder (see *Article 50*).

It may also lead to a recovery of payments already made.

[49] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][38]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts prior to that)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or another executive agency — without the consent of the beneficiary concerned and up to the 'maximum EU contribution' foreseen for that beneficiary in Annex 2 *(see also Article 44)*.

The payments are made **to the coordinator**; the beneficiaries are not paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only at termination of the participation of the coordinator that the Guarantee Fund may exceptionally intervene *(see Article 50)*.

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the **amount** is fixed in each GA.

Normally it will be (depending on the availability of budget credits) up to 100 % of the average EU funding per period (i.e. maximum grant amount set out in Article 5.1 / number of periods) for actions with at least two reporting periods. (It will be however less for actions with only one reporting period, since 100 % would mean the totality of the grant amount.)

At the moment of the pre-financing, an amount that corresponds to **5 %** of the maximum grant amount *(see Article 5.1)* is **deducted** from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:
Maximum grant amount: EUR 1 000 000 with 100 % reimbursement rate
Pre-financing: EUR 333 334 of which:
EUR 283 334 transferred to the consortium (coordinator)
EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 — EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until they are 'cleared' against eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90 % of the maximum grant amount minus the pre-financing

Example for calculating interim payments:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1; application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The **amount** of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples for calculating the payment of the balance:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.

Pre-financing of EUR 333 334 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).

Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.

Total eligible costs accepted for 1st interim period: EUR 570 000;

1st interim payment: EUR 566 666 (the 90% limit is reached).

Total eligible costs accepted for 2nd interim period: EUR 162 500.

2nd interim payment: EUR 0 (the 90 % limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*

Final grant amount: EUR 750 000.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*

The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 312 500 = EUR 1 045 000.

Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.

*EUR 150 000 will be **paid** to the coordinator as follows:*

- *EUR 100 000 directly by the Commission as payment of the balance; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 155 000*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 155 000 = EUR 887 500.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

1. Checks by the Commission/Agency

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Commission/Agency regularly performs plagiarism checks on documents submitted by consortia. It uses an IT tool to do this. If it finds plagiarism, the Commission must inform the consortium/coordinator/beneficiary concerned (see also Article 34).*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The Commission/Agency may ask the coordinator or directly the beneficiaries for any additional information it needs to carry out a check *(see Article 17)*. All requested information must be provided within the given deadline.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date (and suspends the payment deadline).*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks remotely, based on documents it received beforehand.

It can do so using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. The Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

Example: *Ethics checks are normally carried out with the help of external experts.*

If the check shows ineligible costs or the violation of 'other obligations' under the GA, it may lead to the rejection of costs or a reduction of the grant and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Reviews by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows improper implementation of the action, ineligible costs or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (via the electronic exchange system, *see Article 52*).

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or '**review meeting**' (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the beneficiaries will be invited (via the coordinator, via the electronic exchange system) and the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a '**review report**'.

The draft review report will be sent to the coordinator for comments within 30 days ('**contradictory review procedure**'). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant, etc. under Articles 41 to 46.)

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits by the Commission/Agency

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including procedure of extension of findings, rejection of costs, reduction of the grant, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit* ***linked third parties****, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit* ***third parties providing in-kind contributions*** *(free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit* ***contractors*** *or* ***subcontractors****, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

4. *The Commission/Agency may audit* ***recipients of financial support*** *or* ***prizes****, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, ineligible costs, improper implementation of the action or the violation of 'other obligations' under the GA, it may lead to suspension, termination, rejection of costs, reduction of the grant and, if necessary, recovery *(see Articles 42-44, 47-50)*.

In some cases, findings may result in the acceptance of previously rejected costs (if the beneficiary declared them).

In very serious cases, audit results may also lead administrative or financial penalties *(see Article 45)*.

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission may also audit the accounting records of beneficiaries to obtain general information about actual costs for cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the electronic exchange system or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an '**audit report**'.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days ('**contradictory audit procedure**'). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for rejection of costs, reduction of the grant, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the '**letter of audit conclusions**' (and the file will then be passed on to the operational services (authorising officer) for audit implementation, if necessary).

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[39] and No 2185/96[40] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

39 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

40 Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. Investigations by OLAF

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the conclusions of the investigation to the Commission/Agency, who will then decide how to proceed.

An OLAF investigation may lead to suspension, termination, rejection of costs, reduction of the grant and recovery *(see Articles 42-44, 47-50)*, to administrative and financial penalties *(see Article 45)* as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[41], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[41] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. Checks and audits by the European Court of Auditors (ECA)

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable**]

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

> ***Example:*** *A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the *[Agency or the]* Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the *[Agency or the]* Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the **findings concern improper implementation or a breach of another obligation:** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the *[Agency or the]* Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the *[Agency or the]* Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings

Findings in checks, reviews, audits or investigations may be **extended** to other EU or Euratom grants awarded under similar conditions.

Extension of findings is possible for ALL H2020 grants — regardless of the entity that awarded the grant (i.e. Commission, executive agency or H2020 funding body).

If the Commission/Agency finds substantial errors, irregularities, fraud, improper implementation or serious breach of other obligations that are **systemic** or **recurrent**, it may make a correction (rejection of costs or reduction; *see Articles 42 and 43*) in:

– the grant, both for

  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed ('extension of the findings')
- other H2020 grants of the beneficiary ('extension of the findings').

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

> ***Examples (recurrent):*** *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

> ***Examples (systemic):*** *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld after this contradictory audit/review procedure, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an 'audit extension procedure' (which is then followed by 'audit/review implementation').

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure ('**letter of audit conclusions**'), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for ineligibility of costs:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (to be used if the beneficiary does not submit revised financial statements)
  - the conditions for the external counter audit needed to propose an alternative correction method *(see below)*
- for improper implementation or breach of other obligations: the proposed flat-rate for the correction.

The 'extrapolation rate' will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The 'flat-rate' will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit the revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept an alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for ineligibility of costs: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for improper implementation or breach of other obligations: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative correction method and there is no entitlement to it.

Step 3 — Audit implementation. If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the costs to be rejected/reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the costs to be rejected/reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:** five]**[OPTION for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the Horizon 2020 Framework Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the Horizon 2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of Horizon 2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[42].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[42] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[50] annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[50] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

> **Best practice:** Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

> ***Examples:*** *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[51]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[51] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[43] established in an EU Member State or '**associated country**'[44], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[43] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[44] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED RO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 <u>Rights of third parties</u> (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (⚠ new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. employees, subcontractors, linked third parties etc.)*.

> ***Examples (third parties that may claim rights):*** *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*
>
> ***Examples (arrangements):*** *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

> **Best practice:** Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> 'The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]'.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is 'impossible under Union or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Classic forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):
For an invention: e.g. patent, confidential information.
For the design of a technology: e.g. industrial design, copyright.
For a website: e.g. industrial design, copyright, trademark.

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (i.e. use where relevant the wording from the corresponding translation of the MGA that is available on the Participant Portal Reference documents page).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

'Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the 'plan for the exploitation and dissemination of the results'.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

⚠ Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *['European Union (EU)' and 'Horizon 2020'][‘Euratom' and Euratom research and training programme 2014-2018']*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[**OPTION: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

'This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]'.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Disclosing of results of activities raising security issues requires prior approval from the Commission/Agency *(see Article 37)*.

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security-related obligations, etc.)*.

The beneficiaries may choose the **form** for disseminating their results.

Classic forms of dissemination:

- website
- presentation at a scientific conference
- peer reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination— unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

2. Open access to scientific publications

What?

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals)*.

⚠ Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature' (i.e. informally published material not having gone through a classic publishing process, e.g. reports),* are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications.

Best practice: Open access has no impact on the other terms and conditions that apply to scientific publications (e.g. as regards use, etc). However, in order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights such as the right to copy, distribute, search, link, crawl and mine).

A 'repository for scientific publications' is an online archive. Beneficiaries are free to choose the repository; it can be institutional, subject-based or centralised.

Best practice: The Open Access Infrastructure for Research in Europe (OpenAIRE) links existing repositories. It is not obligatory for projects to deposit in OpenAIRE itself, but it is the recommended entry point for researchers deciding on a repository. OpenAIRE also offers support services for researchers, such as the National Open Access Desks. Other useful listings are the Registry of Open Access Repositories (ROAR), the Directory of Open Access Repositories (OpenDOAR) and OAPEN (for monographs). Beneficiaries should not choose a repository with rules which could conflict with open access.

Open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets certain requirements that must be fulfilled if they do decide to publish them.

Open access can be provided through:

a) '**gold open access**' (also called '**open-access publishing**')

'Gold open access' means that open access is provided immediately via the publisher when an article is published, i.e. where it is published in open access journals or in 'hybrid' journals combining subscription access and open access to individual articles.

In gold open access, the payment of publication costs ('article processing charges') is shifted from readers' subscriptions to (generally one-off) payments by the author. Such author processing costs may be eligible *(see Article 6.2.D.3)* — if incurred before the end of the action. Currently, an action for dealing with such costs incurred after the end of the action in FP7 is being piloted and further action in Horizon 2020 will be considered based on the outcome.

⚠ Although gold open access already ensures access via the publisher, the beneficiaries must nevertheless also provide open access via a repository (see below) in order to ensure the long-term preservation and availability of the publication.

b) '**green open access**' (also called 'self-archiving').

'Green open access' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in an online repository. Access to the article is often — but not necessarily — delayed (H2020 'embargo period' between 6 and 12 months; *see below*) as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download view fees during an exclusivity period.

Best practice: Authors are encouraged to retain their copyright and grant appropriate licences to publishers.

How?

Open access to scientific publications involves four steps — which may or may not be taken at the same time:

Procedure for open access (scientific publications):

Step 1 — **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication).

This must be done as soon as possible (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*) and at the latest on publication.

'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

Step 2 — Provide **open access** to the scientific **publication** — either as 'gold open access' (i.e. via the publisher AND via the repository) or as 'green open access' (i.e. via the repository only).

Open access must be given:

- in case of 'gold open access': at the latest on publication
- in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

Step 3 — Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

This is needed for visibility, traceability and monitoring.

It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and
- a 'persistent identifier' *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

The metadata compliance of the repository can be checked using OpenAIRE.

Step 4 — Aim to **deposit** at the same time, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

For more information on why open access to scientific publications and digital research data is an important aspect of Horizon 2020, *see the Online Manual.*

3. Open access to research data ('Pilot on Open Research Data')

What?

Beneficiaries of actions that participate in the Pilot on Open Research Data must give **open, free-of-charge access** to the end-user to **specified digital research data** generated during the action (⚠ new in Horizon 2020).

⚠ For certain areas ('core areas'), the work programme foresees automatic participation in the pilot, but actions may opt out if they have good reason to do so. In other areas, actions may participate in the pilot on a voluntary basis ('opt in').

After signing the GA, actions may always opt out or opt in (via an amendment; *see Article 55*).

'Digital research data' is information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

The pilot applies to two types of digital research data:

- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data *(e.g. curated data not directly attributable to a publication or raw data)* and associated metadata, as specified by the beneficiaries in their 'data management plan' *(see below)*.

⚠ Beneficiaries may decide not to provide open access to specific datasets, if justified in Annex 1, if this would put into question the respect of other GA obligations or if the action's main objective would be jeopardised by making specific parts of the research data openly accessible (This must be explained in the data management plan, *see below*).

Open access means taking measures to make it possible for third parties to **access, mine, exploit, reproduce** and **disseminate** data — via a research data repository.

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories (Re3data) and Databib. One key entry point for accessing and depositing related data and tools is Zenodo.

Actions participating in the pilot must draw up a '**data management plan (DMP)**' within the first six months of the project implementation. The DMP must support the management life-cycle for all data that will be collected, processed or generated by the action.

It must include:

- what data the action will generate
- whether and how it will be made accessible and
- how it will be maintained and preserved.

The DMP must be updated and completed (i.e. become more precise) as the project evolves. New versions of the DMP should be created whenever important changes to the project occur (due to inclusion of new data sets, changes in consortium policies or external factors).

ℹ For more information on data management plans (and a template), *see the proposal forms and the Online Manual* on the Participant Portal.

Costs relating to the implementation of the pilot *(e.g. costs related to research data management, data curation and data storage)* may be eligible *(see Article 6.2.D.3)*.

How?

Open access to digital research data involves 3 steps:

Procedure for open access (research data):

Step 1 — **Deposit** the digital research data, preferably in a research data repository.

Step 2 — Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. by attaching a 'creative commons licence' (CC-BY or CC0 tool) to the data)*.

Open access must not be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

Step 3 — Provide **information**, via the repository, about **tools and instruments** for validating the results.

Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.)*.

ℹ For more information on the research data pilot (and especially how actions may opt out or opt in), see *the Online Manual.*

4. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38*).

> **Best practice:** Where possible, beneficiaries should make this reference in the language of the dissemination activity (i.e. use where relevant the wording from the corresponding translation of the MGA that is available on the Participant Portal Reference documents page).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

> ⚠ If those outputs were developed in another EU-funded action (funded not by H2020, but another EU funding programme — including grants awarded by a Member State or by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget, such as for instance the Structural Funds or ESIF Funds), do NOT however forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results — unless prohibited (or restricted) by security-related obligations *(see Article 37)*.

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a 'global' authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, a transfer to a specifically-identified third party established in a third country (i.e. not EU Member State or H2020 associated country) must be formally **notified to** the Commission/Agency (via the electronic exchange system; *see Article 52*) — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — 'Common legal structures (CLS)' (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a third country (i.e. not EU Member State or H2020 associated country).

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  > ***Example:*** *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  > ***Example:*** *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  > ***Example:*** *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The Commission/Agency must be formally **notified in advance** (via the electronic exchange system; see Article 52) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 <u>Access rights for the EU institutions, bodies, offices or agencies and EU Member States</u>

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[45], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results

- by an affiliated entity (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

'Fair and reasonable conditions' includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicencing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations, obligations related to existing license agreements)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [46], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[46] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[52] and the Code of Conduct for their Recruitment.[53]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

[52] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[53] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[54] and of the Code of Conduct[55] that relate to recruitment, working conditions and career development.

For guidance, *see the 'Human Resources Strategy for Researchers' tool developed by the Commission.*

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[56])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria;
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

[54] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[55] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[56] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more information on gender in research, *see the Online Manual.*

ARTICLE 34 — ETHICS

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[47] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct; *see also the European Code of Conduct for Research Integrity*[57]).

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols (for other texts, *see the Science in Society e-library*[58]). Other important sources include the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

[57] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[58] Available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407

- 'ethics self-assessment' (by the applicants, in their proposal; *see the proposal templates and the Guidance — How to complete your ethics self-assessment*)
- two-stage 'ethics review', with an ethics screening and, if necessary, an 'ethics assessment' (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more information on ethics in research, see *the Online Manual.*

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must ALSO be allowed in at least one Member State.

The beneficiaries must confirm in the 'ethics self-assessment' section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): *the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board*.

Moreover, the coordinator must — before the activity starts — submit **copies** of the following,:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.)*.

Best practice: When preparing the documents, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation **costs**, they will be considered eligible *(see Article 6.2.D.3)* — at the rate of non-official translations.

There is NO need to submit copies of requests for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements *(see Article 22)*.

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells[59] and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; *see point 4*).

[59] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

1. Conflicts of interests

The beneficiaries (and linked third parties) must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

  If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

  If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the beneficiary must **inform** the Commission/Agency (via the electronic exchange system, *see Article 52*), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[48], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[48] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Stricter confidentiality obligations apply for information that is 'EU-classified' or subject to a 'security recommendation' in Annex 1 of the GA *(see Article 37)*.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].**]***

[OPTION: *Not applicable**]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '**security requirements**' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).**]***

[OPTION: *Not applicable**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

1. Results with a security recommendation — Classified results

If the GA provides for (one of these) options, the beneficiaries must comply with the **specific security-related obligations** set out in this Article, in Annex 1 (via a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)') and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure ('security scrutiny') that the action raises security issues and must be subject to a security recommendation and/or security classification of information under Commission Decision No 2015/544[60].

For more information, *see the Guidance — How to complete your ethics self-assessment, the Guidance note — Research focusing exclusively on civil applications and the Guidance note — Potential misuse of research results.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[61].

Moreover, the coordinator must — before the action starts — submit a **copy** of:

any export or transfer licence

For more information on dual use goods, *see the Guidance — How to complete your ethics self-assessment* and the *Guidance note — Research involving dual use items.*

[60] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[61] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

1. Communication activities (by the beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[62].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a sole participant of a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to multiple audiences (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a '**major media impact**' (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

Information given may NOT include classified (or otherwise restricted) results *(see Article 37)*.

[62] For the definition of 'communication activities', *see the Glossary.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the proposal templates*) and be included in Annex 1 and 2.

For more information on promoting the action, *see the Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the EU emblem

AND

- including the reference to EU funding set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity (or, for infrastructure, equipment or major results, the official language(s) of the country where they are located). Where relevant, beneficiaries should use the wording from the corresponding translation of the MGA that is available on the Participant Portal Reference documents page).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object). ***Examples:*** *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[49], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> '© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][insert the name of the Agency]* under conditions.'

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[49] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

1. Communication activities (by the Commission/Agency)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

Examples (material): *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*

Examples (communication activities): *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*

Examples (publicising activities): *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[50] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the **right to access and correct their own personal data**. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statements (SSPS)' that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[50] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (by the Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its privacy statements on the Participant Portal.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligible costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the financial interests).

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[63] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

[63] Available at http://ec.europa.eu/dpo-register/search.htm.

Persons whose data is being processed ('data subjects') can contact the data controller or the DPO (via the contact information in the SSPS), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the service specific privacy statements (SSPS) (see above), before transmitting their data to the *[Agency or the]Commission.*

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (by the beneficiaries)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[64] — or any EU legislation that replaces this Directive — and the corresponding national law).

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [65]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration
- retrieval and consultation
- use

[64] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[65] *See Article 8 of Directive 95/46/EC*.

- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[66]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the SSPS).

Examples:

Before encoding its staff's personal data in the Beneficiary Register or into a proposal, the beneficiary must provide the staff concerned with the SSPS.

If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the relevant SSPS.

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[66] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What?

The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How?

Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.

Assignment for the benefit of creditors in a bankruptcy procedure.

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not subcontract these tasks to any third party.

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is not responsible for the implementation of the action and has no responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them withdraws, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless, for specific reasons, the Commission/Agency expressly renounces it. They will have to do this without any additional EU contribution (even if — in case of termination — the Guarantee Fund may provide additional funds to compensate the debt of a withdrawing beneficiary not paid back to the remaining members of the consortium).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% retained from the pre-financing for the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION:** Not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

The coordination agreement must not contain any provision contrary to the Agreement.]

***[OPTION:** Not applicable]*

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly to it *(see Article 22)*.

***Example:** in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can NOT be subcontracted or outsourced to a third party. They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use in-kind contributions for *other* tasks; *see Articles 11, 12, 13*).

Specific cases (coordinator):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

.The third party must fulfil the following conditions:

- they have must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ Coordination and administration tasks are considered **action tasks**.

Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article) can in principle be carried out by another beneficiary (*e.g. scientific coordination of the action*).

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it remains however one of the 'other beneficiaries' of the GA; it will not be considered the action's coordinator.

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

> **Best practice:** In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

> **Best practice:** The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see the Online Manual and the Guidance — How to draw up your consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted for 'complementary actions' *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted for 'jointly funded actions' *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the grant agreements and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see the Online Manual and the Guidance — How to draw up your coordination agreement.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* **rejects costs at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* **rejects costs after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

A **rejection of costs** will be made for any **violation of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Rejection of costs can take place at any moment — at the time of an interim payment, of the payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if rejection of costs is combined with a reduction of the grant or a recovery: there will be an *ex ante* '**contradictory procedure**'
- if there is only rejection of costs: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection ('**review procedure**').

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post review procedure allows the Commission/Agency however to pay promptly within the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter** (sent via the electronic exchange system, *see Article 52*).

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request by the coordinator/beneficiary concerned — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

If necessary, this procedure will be combined with a procedure on the reduction of the grant and/or recovery *(see Articles 43 and 44)*. In this case, there will be one **single pre-**

information letter for all procedures and one single reply (i.e. beneficiaries are expected to submit one **single set of observations** that address the different aspects).

Review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out ('**notification of amounts due**'; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections (using the 'formal notifications box' in electronic exchange system).

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for rejections the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

3. Rejection of costs at the time of an interim payment or the payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) **at the moment of an interim payment or the payment of the balance**, it will deduct them and calculate the amount to be paid accordingly.

If the Commission/Agency finds ineligible costs (declared in a previous report and already paid for) **in-between payments**, it will reject the costs at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example for calculating a rejection at an interim payment/payment of the balance:

Case 1: *Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.*

Maximum grant amount: EUR 500 000.

Pre-financing: EUR 200 000.

Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25 %) = EUR 118 750.

Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25 %) = EUR 143 750.

Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25 %) = EUR 112 500.

Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:

Application of the reimbursement rate: 100%: EUR 362 500

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.

Amount due as interim payment: EUR 250 000

Case 2 (in between payments): *Total costs declared for the action in the 1st periodic report: = EUR 375 000*

Interim payment for the 1st periodic report = EUR 375 000

Cost rejected after interim payment or 1st periodic report: EUR 12 500

Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000

Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Rejection of costs after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*. If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will recover the difference *(see Article 44)*.

Example for calculating a rejection after the payment of the balance:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — at the payment of the balance or afterwards — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* **reduces the grant at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **reduces the grant after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* that the action has **not** been **properly implemented** or that **other obligations** have been **breached**, it may reduce the maximum grant amount set out in Article 5.1 (— in proportion to the improper implementation of the action or the seriousness of the breach).

⚠ A **reduction of the grant** is possible for **any breach of obligation** (under the GA or applicable EU, international and national law; *see Article 7)* and it will be made in proportion to the seriousness of that breach *(e.g. in case of fraud, systemic irregularities or submission of false information — in the award procedure or during action implementation the reduction may be up to a 100%)*.

Reduction of the grant can take place at or after the payment of the balance, NOT before.

If improper implementation *(e.g. delays)* or a breach of obligations is found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

A reduction can also be due to a beneficiary not receiving EU funding (i.e. improper implementation or breach of obligations by that beneficiary; *see Article 9*).

2. Procedure

The Commission/Agency will follow a contradictory procedure (for the basic contradictory procedure, *see Article 42*).

Depending on the moment the reduction takes place, this procedure will be directed either at the coordinator or the beneficiary concerned:

- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

3. Reduction of the grant at the payment of the balance

If the Commission/Agency reduces the grant *at the payment of the balance*, it will make the reduction **at the level of the action** and calculate the balance to be paid (i.e. final grant amount) accordingly.

Example for calculating a reduction at the payment of the balance:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)

Pre-financing: EUR 750 000

Interim payments: EUR 1 500 000

Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20 % (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.

Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000

Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000

Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

4. Reduction of the grant after payment of the balance

The financial consequences of a reduction of the grant *after the payment of the balance* will be calculated at **beneficiary level** for each beneficiary concerned.

The 'beneficiaries concerned' are those who have breached their obligations or improperly implemented the action resulting in the reduction.

Procedure for reduction of the grant after payment of the balance:

The Commission/Agency:

Step 1 — Determines the amount to be reduced (in proportion to the improper implementation or seriousness of the breach).

Step 2 — Identifies the beneficiaries in fault and allocates that amount among them according to their responsibility in the improper implementation or breach of obligation.

If the improper implementation or breach of obligation cannot be linked to one or more specific beneficiaries (and therefore concerns the whole consortium) each beneficiary will have to bear a pro-rata share of the reduction.

For each of those beneficiaries (the 'beneficiaries concerned'):

Step 3 — Determines the beneficiary's **share in the final grant amount'**, as follows:

{{total accepted eligible costs for the beneficiary x reimbursement rate}[67]

divided by

{sum of total accepted eligible costs x reimbursement rate, for each beneficiary}[68]

multiplied by

the final grant amount before the reduction (see Article 5.3)}

Step 4 — Calculates the beneficiary's **revised final grant amount** as follows:

{total accepted eligible costs for the beneficiary x reimbursement rate}[69] – amount of reduction allocated to the beneficiary under step 2

Step 5 — If **revised final grant amount < share in the final grant amount**, the Commission / Agency will recover the difference from the beneficiary.

Example for calculating a reduction linked to (one or more) specific beneficiaries:

Innovation action with beneficiaries: X, Y and Z. Beneficiaries X and Z are non-profit legal entities with a 100% reimbursement rate. Maximum grant amount = EUR 2 900 000.

Situation at payment of the balance:

	Data source		*Beneficiary X*	*Beneficiary Y*	*Beneficiary Z*	*Total*
	Annex 2 (estimated budget)	*Estimated costs budgeted*	*700 000*	*2 000 000*	*800 000*	*3 500 000*
A		*Reimbursement rate (%)*	***100***	***70***	***100***	

[67] Plus the same formula applied to third parties linked to the beneficiary (if any).
[68] Including linked third parties.
[69] Plus the same formula applied to third parties linked to the beneficiary (if any).

B		*Maximum grant amount according to costs budgeted*				*2 900 000*
C	*Final financial statements*	*Beneficiary's total accepted eligible costs*	*825 000*	*1 850 000*	*800 000*	*3 475 000*
D	*First step for the calculation of the "Final Grant Amount (Article 5.3.1)*	*Beneficiary's total accepted costs x reimbursement rate* *(C x A)*	*825 000*	*1 295 000*	*800 000*	*2 920 000**

** The final grant amount is capped at EUR 2 900 000 (maximum grant amount). Even if D results in a higher amount, the Commission/Agency can never pay more than the maximum grant amount set in the grant agreement.*

Following a review after the payment of the balance, the Commission decides to reduce the grant due to improper implementation because some of the action tasks were not carried out.

Step 1 Reduction of the maximum grant amount:

The Commission decides on the amount to be reduced in proportion to the improper implementation identified

Example: the Commission decides to reduce the maximum grant amount by EUR 300 000.

Step 2 Identification of the beneficiaries concerned and allocation of the amount to be reduced:

The review concluded that the improper implementation was due to the fact that beneficiary X carried out only part of its tasks as set out in Annex 1. Therefore, the reduction is allocated in full to beneficiary X (see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*300 000*	*0*	*0*	*300.000*
G	*Beneficiary's revised final grant amount (D - F)*	*525 000*	*1 295 000*	*800 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*294 349*	*0*	*0*	*294 349*

The amount to be recovered is less than the amount reduced because of the overspending (eligible costs that were declared but not taken into account at payment of the balance because of the capping at maximum grant amount).

For recovery (see Article 44.1.3)

Example for calculating a reduction NOT linked to (one or more) specific beneficiaries:

Same example as above except that the reduction is not linked to specific beneficiaries.

The review concluded that the improper implementation was due to the consortium as a whole and cannot be attributed to (one or more) specific beneficiaries. The amount to be reduced is therefore allocated evenly among the beneficiaries (300 000 / 3 = 100 000; see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*100 000*	*100 000*	*100 000*	*300 000*
G	*Beneficiary's revised final grant amount (D - F)*	*725 000*	*1 195 000*	*700 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*94 349,32*	*91 130,14*	*94 520,55*	*280 000*

For recovery (see Article 44.1.3)

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[51] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[51] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable****]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue. In addition, recovery may also take place in the context of the termination of the participation of a beneficiary.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to the maximum EU contribution specified for the third party in the estimated budget *(Annex 2)*.

Recovery normally takes place only at payment of the balance or afterwards. Exceptionally, it can take place before, if a beneficiary's participation is terminated.

2. Procedure

The basic procedure for recovery is almost always the same: After a contradictory procedure, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency analyses the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[70]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered 'paid'.

[70] *See Article 80(1) of the Financial Regulation.*

⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 action, arbitration, etc; *see Article 57.2*).

Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission/Agency may offset before this date, in order to safeguard the EU's financial interests.[71]

If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. (The interest is normally offset first, before the principal amount).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the Court of Justice of the EU *(see Article 57.2)* or
    - adopting a **Commission decision** that is **enforceable** within the meaning of Article 299 TFEU[72].[73]

      The decision taken by the Commission describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      ⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

      This decision — duly endorsed with the 'order for enforcement' issued by the competent authority in the Member State concerned — enables the Commission to have the debtor's assets seized.

3. Recovery after termination of a beneficiary's participation

[71] *See Article 87 of the Rules for Application.*

[72] *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

[73] *See Article 79(2) of the Financial Regulation.*

The Commission/Agency will recover *after termination* of a beneficiary's participation, if that beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

4. Recovery at the payment of the balance

The Commission/Agency will recover *at the payment of the balance*, if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the 'report on the distribution of payments'.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified and if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** exclusively.

For the rest of the procedure, *see point 2*.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, but has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds** in excess, the amount each beneficiary *actually* received (as established on the basis of in the 'report on the distribution of payments') is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The share in the final grant amount is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage so obtained to the final grant amount.

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt towards the Commission/Agency among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess, for its proportional share in the debt to the Commission/Agency.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery at the payment of the balance:

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100 % Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)

Total eligible costs approved by the Commission: EUR 2 430 000

Final grant amount: EUR 2 430 000

EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000

Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5 % of the maximum grant amount; see Article 21.2) = EUR 150 000. Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:

A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

Identification of the beneficiaries that received funds in excess:

Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);

Beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)

Beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);

Beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:

The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.

Total payments made in excess = 320 000.

Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.

Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.

Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

The Commission will notify three debit notes for a cumulative amount of EUR 120,000 *(270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium.

5. Recovery after payment of the balance

The Commission/Agency will recover *after payment of the balance*, if — due to a rejection of costs or a reduction of the grant *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid too much (or that the coordinator has not distributed the payments received).

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised final grant amount for the beneficiary concerned with its **share of the final grant amount** *(see point 4)*.

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

For the rest of the procedure, *see point 2*.

Procedure for recovery after payment of the balance (due to a rejection of costs):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised final grant amount for the beneficiary concerned with its **share of the final grant amount** *(see point 4)*.

The '**share of the final grant amount**' is calculated as follows:

- **for an underspent GA:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with Article 5.3.1) is lower than the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for an overspent GA:** Each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see the calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

Example for calculating a recovery in an underspent GA:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:

(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example for calculating a recovery in an overspent GA:

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C

Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000

Reimbursement rate for all the beneficiaries: 100%

Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000

Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000

Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000

Total eligible costs of the consortium approved by the Commission = EUR 600 000

Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Calculation of each beneficiary's share in the final grant amount:

*Beneficiary approved costs multiplied by the reimbursement rate (100%) * final grant amount (500 000)*

EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667

Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000

Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Calculation of the revised grant amount after the audits:

The revised final grant amount is calculated as follows:

For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500

For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Calculation of the amount to be recovered:

The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount

For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered

For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. Since for beneficiary C the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Agency or the]* Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation no 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

1. Administrative and financial penalties

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary has committed substantial errors, irregularities or fraud, is in serious breach of its obligations under the GA or has made false declarations, it may impose administrative and/or financial penalties (— in proportion to the seriousness of the misconduct).

Financial and/or administrative penalties are **public law measures** (i.e. taken directly on the basis of Articles 109 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(*substantial errors, irregularities or fraud, serious breach of obligations or false declarations*)*.

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum penalties** are as follows:

- for *administrative* penalties: up to **five years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the penalty and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the exclusion period may be extended to **10 years**.

- for *financial* penalties: between 2% and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again (under the same GA or another EU or Euratom grant or contract), the rate may be increased to between 4% and **20%**.

  If the new infringement concerns the same GA, the rate will be increased in that GA *(e.g. from 5% to 15%)*.

  If the infringement concerns a different GA, the new rate *(e.g. 15%)* will apply in that GA and the original rate *(e.g. 5%)* will be maintained in the GA concerned by the first infringement.

The Commission/Agency may **publish** the decision to apply penalties on their websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU's financial interest and image)
- the time that has elapsed since it took place
- the duration and recurrence of the misconduct
- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

Before applying a penalty, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned (for the basic contradictory procedure, *see Article 42*).

If the Commission/Agency confirms a financial penalty, it will issue a debit note to **recover** the amount

The basic recovery procedure *(see Article 44)* applies.

However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

Example for calculating a financial penalty:

GA with a maximum grant amount of EUR 2 500 000. The estimated EU contribution for beneficiary A in Annex 2 is EUR 600 000.

During an audit of the first reporting period, the Commission finds that beneficiary A has over-declared its personnel costs by 20 % and has falsely certified that the information on the time spent on the action set out in the report was true. Following the contradictory procedure, the Commission imposes a financial penalty of 5 % of beneficiary A's estimated budget and asks the beneficiary to amend its practice.

Financial penalty/amount to recover: 5 % of EUR 600 000 = EUR 30 000.

Case 1: *A year after the action ends and the balance is paid, the Commission decides to verify the situation and carries out another audit (of the same GA). It finds that beneficiary A has maintained its practice and over-declared its personnel costs also in the second and final reporting periods of that grant. Following the contradictory procedure, the Commission imposes an increased rate of 15 %.*

New financial penalty: 15 % of EUR 600 000 = EUR 90 000; additional amount to recover: EUR 60 000

Case 2: *Six months after the first infringement was established, the Commission audits another GA of the same beneficiary, with an estimated EU contribution in Annex 2 of EUR 450 000. It finds that the beneficiary also over-declared its personnel costs in this other GA. Following the contradictory procedure, the Commission imposes an increased rate of 15 %, given that it is the beneficiary's second infringement of the same rule under an EU contract/grant.*

Financial penalty in second GA: 15 % of 450 000 = EUR 67 500.

Financial penalty in first GA: 5 % (no change).

Additional amount to recover after the second audit: EUR 67 500

Specific case (administrative and financial penalties):

International organisations — Decisions on administrative or financial penalties (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability (of the Commission/Agency) for damages

The Commission/Agency cannot be held liable for any damages where — in implementing the GA — a beneficiary:

- causes damage to a third party (including another beneficiary)

  Example: *An experiment carried out by a beneficiary in a GA which leads to an accidental escape of pollutants into the local river.*

- suffers damage.

  Example: *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the GA.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third party involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Liability (of the beneficiaries) for damages

If a beneficiary causes damage to the Commission/Agency (in implementing the action), it must compensate the Commission/Agency (— for the amount of damage caused).

Examples: *Costs of legal proceedings borne by the Commission.*
At a meeting on Commission premises, a beneficiary smokes and causes a fire.

2. Procedure

Before claiming damages, the Commission/Agency will follow a **contradictory procedure** with the beneficiary concerned (for the basic contradictory procedure, *see Article 42*).

If the Commission/Agency confirms the claim, it will issue a debit note to recover the amount.

The basic recovery procedure *(see Article 44)* applies.

However, there is no:

- separate contradictory procedure on recovery
- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

If the damages are not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (by the Commission/Agency)

The Commission/Agency may 'stop the clock' (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

Suspension of the payment deadline must be distinguished from 'suspension of payments' (see Article 48). Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary that is, for example, suspected of serious misconducts.

The **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request) depends on the type of payment *(see Article 21)*:

- for pre-financing: **30 days**

- for interim payments and payment of the balance: **90 days**.

Before paying, the Commission/Agency will:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs

  This is not an in-depth verification and can therefore not guarantee their eligibility or correctness. The costs may therefore still be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.
- calculate the amount to be paid
- approve the payment request and authorise the payment.

Late payment by the Commission/Agency gives rise to **late-payment interest** *(see Article 21.11)*.

Grounds for suspension of the payment deadline:

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

  Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*
- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*
- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why (via the electronic exchange system; *see Article 52*).

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (by the Commission/Agency)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more beneficiaries), on the grounds listed in this Article.

Suspension of payments has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments:

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations *(see also Article 50.3)* — either during the award procedure or under the GA.

  Example: *statements made by the beneficiary in the declaration form are found to be false.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of other grants, the Commission detects systemic substantial errors in the calculation of personnel costs of a beneficiary participating in several H2020 actions. Since these errors stem from the beneficiary's methodology for declaring personnel costs, they also affect this GA.

  For the ongoing GAs of the beneficiary, the Commission may suspend:

  - *outstanding pre-financing and/or interim payments to the beneficiary in question*
  - *(if necessary) outstanding payment of the balance for all beneficiaries.*

  until the beneficiary submits revised cost statements or the Commission implements the correction for extrapolation (see Article 22.5.3).

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may decide to:

- suspend action implementation *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** with the coordinator (for the basic contradictory procedure, see *Article 42)*.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must immediately inform the beneficiary concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously suspends payments for a beneficiary in several actions *(e.g. for errors or irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned.

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted.

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*

15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*

1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*

1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*

10 August: *the Commission pays for all beneficiaries except B.*

25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. Suspension of the action implementation (by the beneficiaries)

The beneficiaries may suspend the action implementation (in full or in part), on the ground set out in this Article.

Suspension of the action implementation may be used exceptionally if it is necessary to stop the implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for suspension of the action implementation (by the beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**.

  The beneficiaries may suspend the action implementation (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g.* ***inform*** *the Commission/Agency under Article 17.2;* ***notify*** *a situation of 'force majeure' under Article 51)*.

2. Procedure

The coordinator must immediately formally notify the Commission/Agency (through the electronic exchange system; *see Article 52*)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the '**resumption date**' set out in the amendment), if the Commission/Agency approves the amendment.

> ***Example:*** *The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the Commission/Agency has set a lower budget in the amendment, to adapt the action to the new situation).

> ***Example:*** *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **cannot be continued** (or the Commission does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:*** *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the termination of the GA. The eligible costs are:*
>
> - *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
> - *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. Suspension of the action implementation (by the Commission/Agency)

The Commission/Agency may suspend the action implementation (in full or in part), on the grounds listed in this Article.

Grounds for suspension of the action implementation (by the Commission/Agency):

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action implementation, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations *(see also Article 50.3)* — either during the award procedure or under the GA

  Example: *A beneficiary is suspected to have provided false documents in order to participate in the EU action.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action implementation if such substantial errors, irregularities, fraud or serious breach of obligations were found in *other* award procedures or GAs ('extension of findings from other grants to this grant'), if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities, fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example:

  During an audit of a beneficiary participating in several H2020 actions, the Commission detected systematic substantial errors in the calculation of personnel costs (which mainly include costs of personnel employed by another company). These errors are not limited to the GA audited, but also affect all other GAs signed by the audited beneficiary.

  The Commission may suspend the part of the implementation of the action concerned by the audit findings (i.e. the part of the action to be implemented by the beneficiary audited) until the error is corrected for the on-going action.

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action implementation, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** five days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the action implementation, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42).*

If possible, the Commission/Agency will give an estimation of the length of the suspension period.

The contradictory procedure will be made using the electronic exchange system *(see Article 52)*. The coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)*.

If the Commission/Agency simultaneously suspends a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once action implementation is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator (or the Commission/Agency) must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **cannot be continued**, the GA (or the participation of a beneficiary) may be terminated.

If the suspension leads to the termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the termination of the GA.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative** and/or **financial penalties** *(see Article 45)*.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The beneficiaries have the right to terminate the GA.

Termination of the GA should be a last resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Termination may in principle be based on **any ground** *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Example: *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

The Commission/Agency **cannot oppose**, but termination will be considered '**improper**' if there are no legitimate reasons for discontinuing the action.

Improper termination of the GA may lead to a reduction of the grant (see *(see Articles 5.3 and 43)*.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a reduction of the grant.*

2. Procedure

The coordinator must formally notify the Commission/Agency (directly through the **Participant Portal**; *see Article 52*) of the termination — on behalf of the beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect ('**termination date**'). This date must be a date after the notification: Terminations **cannot be retroactive** (notably to ensure the fulfilment of obligations and deadlines arising from termination — see Point 3 Effects).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. before the termination date) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 calendar days of the date on which termination takes effect), the costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. (The Commission/Agency will not send a reminder and will not extend the deadline.)

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the obligations concerning security-related issues (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf draw upon the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion (and provide it if obtained or — if the beneficiary didn't reply — the request to the Commission/Agency).

Termination may in principle be based on **any ground**.

If a beneficiary has good reasons, it may **withdraw** from the GA.

For a beneficiary involved in several EU GAs, withdrawal from one GA does not necessarily imply that it has to also withdraw from the others.

If a beneficiary goes **bankrupt** or is wound up, it or the coordinator must **inform** the Commission/Agency and notify the termination of its participation — without delay. Late notification will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT implement part of the action either.

The Commission/Agency **cannot oppose** the termination of a beneficiary's participation, but termination will be considered '**improper**' if there are no legitimate reasons.

Improper termination of the participation of a beneficiary may lead to the termination of the GA *(see Article 50.3.1(c))* and/or to a reduction of the grant at the payment of the balance *(see Articles 5.3 and 43)*.

2. Procedure

The coordinator must formally notify the Commission/Agency (directly through the **Participant Portal**; *see Article 52* of the termination. At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline, i.e. **not** via the Participant Portal).

Notification can only be made by a person authorised to do so in the Participant Portal electronic exchange system (authorisation is linked certain roles (i.e. functions); *see the Online Manual*).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

NO amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example: *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect ('**termination date**'). This date must be a date after the notification: Terminations **cannot be retroactive** (notably to ensure the fulfilment of obligations and deadlines arising from termination — see Point 3 Effects).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional EU contribution to do so) — unless the Commission/Agency expressly renounces it.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes amounts to the Commission/Agency, those amounts must be repaid by it.

Only **costs** incurred before termination (i.e. before the notified date on which termination takes effect) are eligible— except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. (The Commission/Agency will not send a written reminder and will not extend the deadline.)

If the coordinator fails to submit the *report on the distribution of payments*, the beneficiary whose participation was terminated will NOT have to repay any amounts.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries).

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION:*** *not applicable];*

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:
  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
    - termination takes effect after an interim payment and
    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. Termination of the GA or of the participation for one or more beneficiaries (by the Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

Termination of the participation of a beneficiary may lead to **termination of the GA**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

Grounds for termination (by the Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the termination of the GA; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or the consortium no longer complies with the eligibility criteria

set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the number of participants, their legal situation, or their place of establishment)*.[74]

Examples:

1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

- **GA cannot be amended after termination** of a beneficiary's participation

The Commission/Agency may terminate the GA, if it cannot be amended after the termination of a beneficiary's participation (because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify termination of the participation of the beneficiary because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

The beneficiaries must **inform** the Commission/Agency immediately of any such proceedings *(see Article 17.2)*.

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

[74] *See also Article 8 of the Rules for Participation.*

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is to be implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

  - the third country/IO action does not start by the date specified in Annex 1

    In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission in full.

  - the third country/IO action is terminated
  - the third country/IO action can no longer contribute to the subject of the GA.

    Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have falsified documents to illicitly obtain European funds.*

- **Substantial errors, irregularities, fraud or serious breach of obligations (in this grant or other grants)**

The Commission/Agency may terminate the GA or the participation of a beneficiary, if it (or one of its representatives) has committed — either during the award procedure or under the GA — substantial errors, irregularities, fraud or a serious breach of obligations (including improper implementation of the action, submission of false information, failure to provide required information or breach of ethical principles).

An '**irregularity**' means a violation of the applicable rules (i.e. GA or applicable international, EU or national law) that may result from an act or omission and has (or would have) a negative effect on the EU budget (through unjustified expenditure).

'**Serious breach of obligations**' may refer to any of the consortium's or beneficiaries' obligations under the GA. It is normally also considered an irregularity.

Examples:

The coordinator of the GA failed to transfer EUR 200.000 to the other beneficiaries and used these funds to pursue its own aims. The Commission therefore decides to terminate the participation of the coordinator in the GA.

The beneficiaries failed to submit the reports required for the action and the request for payment within the given deadlines, despite the reminders sent by the project officer. The Agency therefore decides to terminate the GA.

'**Improper implementation of the action**' is specifically linked to the implementation of the action tasks (as described in Annex 1).

Example: *The Commission reviews an action and concludes that it failed to achieve its critical objectives and is absolutely not on schedule. It then requires the consortium to provide a short-term implementation plan to be carried out in the second half of the year to solve the situation. The consortium submits the short-term implementation plan. The Commission/Agency concludes that the plan provided is not acceptable and decides to terminate the GA.*

Submission of false information

Example: *The Commission may decide to terminate a beneficiary's participation if an audit reveals that the beneficiary declared costs in its financial statement that did not correspond to the services rendered and they were based on fake invoices.*

'Failure to provide required information' normally happens if a beneficiary refuses — in the context of a check, review, audit or investigation *(see Article 22)* — to provide the requested information or allow access to its premises.

Example: *The Commission decides to carry an on-the-spot audit of a beneficiary that is participating in a GA. It requests the beneficiary to provide certain information, including its accounts. The beneficiary refuses to provide this information. After this refusal, the Commission may in writing request this information within a given deadline. If it does this and the beneficiary again fails to provide the information required, the Commission may terminate the beneficiary's participation in the GA.*

'Breach of ethical principles' means breach of the obligations under Article 34.1 and 34.3 or of the ethics requirements set out in Annex 1 *(see Article 34.2)*.

Example: *The Agency decides to terminate a GA after discovering that the scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism).*

The Commission/Agency may also terminate the GA or the participation of the concerned beneficiary, if such substantial errors, irregularities, fraud or serious breach of obligations were found in other award procedures or GAs ('**extension of findings** from other grants to this grant'), if:

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities, fraud or serious breach of obligations are:
  - systemic or recurrent and,
  - have a material impact on this grant.

Before terminating (the GA or the participation of a beneficiary), the Commission/Agency may first *suspend* the action implementation *(see Article 49.2)* to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before terminating a GA or the participation of one or more beneficiaries, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*).

The contradictory procedure will be made using the Participant Portal *(see Article 52)*. The coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If the Commission/Agency simultaneously terminates a beneficiary's participation in several actions *(e.g. for irregularities having a material impact on several grants)*, it will make a separate contradictory procedure with each coordinator individually.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) *(i.e. bankruptcy, winding-up, administration, etc.)*, the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will **take effect**. This date will be a date after the notification: Terminations **can NOT be retroactive** (notably to ensure the fulfilment of obligations and deadlines arising from termination — see Point 3 Effects).

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of terminating the GA are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. before the date on which termination takes effect) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative** and/or **financial penalties** *(see Article 45)*.

The effects of terminating the participation of one (or more) of the beneficiaries are the same as when the beneficiaries terminate the participation of another beneficiary *(see Article 50.2.2)***.**

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

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ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What?

In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Force majeure normally has no specific effects on the eligibility of **costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

New in Horizon 2020: This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Force majeure may lead to suspension of the action implementation *(see Article 49)* or termination of the GA *(see Article 50)*.

How?

The party concerned by force majeure must immediately **formally notify** the other party (via the coordinator, via the Participant Portal, *see Article 52*). The coordinator must inform the other beneficiaries offline.

The party concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

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ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[the Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[European Commission][name of the Agency]
[Directorate-General][Department] [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

1. Communication between the parties — Participant Portal electronic exchange system

All communication between the consortium and the Commission/Agency (except for *formal* notifications after payment of the balance) must be in electronic form **via** the **Participant Portal electronic exchange system**.

This system offers different **functions**:

- viewing and changing the legal entity data in the Beneficiary Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications (i.e. when the GA refers to 'formal notifications' or 'formally notify'), via the formal notifications function
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

A formal notification is **considered to have been accepted** ten days after it is sent (— even if it has not been opened by recipient, *e.g. refusal of reception or omission*).

Deadlines that are counted from the date of receipt are counted as of day eleven.

All messages are recorded in the project file (with date and time).

Formal notifications are also recorded via the formal notifications function (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation is linked to the 'role' that is attributed to the person (each beneficiary's LEAR does this for the people authorised to sign grant agreements and amendments (LSIGNs) or financial statements (FSIGNs)). Only persons who have been assigned one of these roles can use the electronic exchange system (*see the Online Manual*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator (information that must be submitted via the Participant Portal). They cannot submit information directly to the Commission.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission.*

For more information on access and roles in the Participant Portal electronic exchange system*, see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations)*.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means an intergovernmental organisation (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the relevant legal texts provide otherwise), public law decisions cannot be applied; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative or financial penalties *(see Article 45).*

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration (*see Article 57.2*). The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[52], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[52] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods expressed in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*

The action is divided into the following reporting periods:

RP1: from 1 March 2015 to 31 August 2016

RP2: from 1 September 2016 to 28 February 2017

Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.

The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods expressed in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the appropriate supporting documents; and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature by the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

An amendment is necessary whenever there is a need to **change** the GA (i.e. its 'Terms and Conditions' and/or the Annexes).

⚠ The *general* terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to fix its 'end date'.*

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and with an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

⚠ Changes in the name, address, legal form and organisation type AND changes in the legal, financial, technical, organisational or ownership situation may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary to amend the GA to terminate its participation*

2. *Beneficiary B moves from Europe to Australia during grant implementation. If the change of address implies that the beneficiary becomes not eligible for EU funding, then it will be necessary to amend the GA to make it a 'beneficiary not receiving EU funding'*

3. *Beneficiary C participates in an innovation action and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Beneficiary Register is sufficient; no amendment is needed.*

2. *Beneficiary E moves from Australia to Europe during grant implementation. This change of address has no effect on eligibility, because beneficiary/linked third party that was ineligible for receiving EU funding at the moment of grant signature, can NOT become eligible later on.*

3. *Beneficiary F participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation is terminated** (*see Article 50.2 and 50.3*).

  There are two main cases for removing a beneficiary:

  - if it never became beneficiary (because of non-accession to the GA or non-provision of the requested declaration on joint and several liability).

    In this case, the amendment will be triggered by the Commission/Agency and the beneficiary is removed from the beginning (since it has never been a beneficiary).

  - for other reasons set out in Article 50.

  The amendment may be triggered by the beneficiaries or by the Commission/Agency.

  For termination by the beneficiaries:

  - the request for amendment must be part of the notification of termination
  - it has to include the opinion of the beneficiary whose participation is terminated (or proof that its opinion has been requested in writing).

  For termination by the Commission/Agency:

  - there has to be a contradictory procedure *(see Article 50.3.2)*
  - after termination, the coordinator must submit (within 60 days from the termination date) the amendment request with all the supporting documents *(see Article 50.3.3).*

  There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  If the coordinator is removed, the amendment has to propose a new coordinator.

  The 'termination date' will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

  For termination by the beneficiaries: the 'termination date' must be specified in the notification.

  The beneficiaries must select the date in the notification template. It must be either a fixed date or 'the day after notification of termination'. The fixed date must be in the future (i.e. after notification: terminations can NOT be retroactive notably to ensure the fulfilment of obligations and deadlines arising from termination; *see Article 50.2.1*)

  For termination by the Commission/Agency: the 'termination date' will be either:

  - the date specified in notification confirming termination or
  - the day after the coordinator receives the notification confirming termination.

Combination with other changes: If the beneficiary was participating with linked third parties, they will also have to be removed (with effect from the same date) and the 'end date of participation' will be added to Article 14.

The termination will normally also imply a change of Annexes 1 and 2.

By contrast, the GA options for the beneficiary (and its linked third parties) will NOT be deleted or become not applicable (since they were part of the GA and (many) obligations continue to apply after termination).

- **Adding a new beneficiary** (*see Article 56.2*)

  The new beneficiary must first register (and get validated) in the Beneficiary Register — unless it already has a validated 'participant identification code (PIC),'

  The request for amendment must include;

  - Annex 3 (Accession Form) — signed by the new beneficiary in the Participant Portal *(see Article 52*) before submitting the amendment request

- a PDF copy of the signed Annex 3a (declaration of joint and several liability of its linked third parties if requested by the Commission/Agency)
- Annex 3b (Administrative Arrangement signed by the Joint Research Center (JRC), if applicable).

The 'accession date' will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

The new beneficiary must select the date in the Accession Form (attached to the amendment request). It must be either:

- 'the date of signature of the Accession Form'
- 'the date of entry into force of the amendment'

OR

- a fixed date:
  - either a retroactive date (i.e. before signature of the Accession Form)

  OR
  - a future date (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

If new beneficiaries join the action to replace a beneficiary that leaves, they may set the accession date before the termination date (of the beneficiary that is replaced) — and thus *both* incur costs for a certain period.

Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

Combination with other changes: The addition will also imply a change of Annexes 1 and 2 and — depending on the type of beneficiary and its H2020 status(es) — GA options will be added.

Examples:

If the new beneficiary is an international organisation, the options for international organisations under Articles 22.4 and 53.2 will be added to the GA and the options under Articles 57.1 and 57.2 will be added if applicable to that international organisation.

For the JRC, the options in the Preamble, Article 20.3(b)(iii) and Article 21.2 will be added.

- **Change of beneficiary due to partial takeover** (called 'partial transfer of rights and obligations' in FP7)

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment type for 'addition of a beneficiary'.

What? '**Partial takeover**' means that a PART of the business of the beneficiary (including the GA) is taken over by (one or more) other entity(ies) ('transfer of a business unit as a going concern', *e.g. partial acquisition, distribution of a business unit on dissolution/liquidation, division/demerger, etc.).*

'**Partial acquisition**' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorb or take over part of the rights and obligations of the original entity). Thus, some of the rights and obligations (and contracts) of the original entity are transferred to the new entity (i.e. a partial transfer of the rights and obligations of the original entity). Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'**Distribution of a business unit on dissolution/liquidation**' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entity(ies) purchase(s) a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only some of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'**Division/demerger**' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has one ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two 'partial takeovers': one to company E and one to company O.*

⚠The new beneficiary(ies) will (each) be **fully** jointly and severally **liabl**e with the former beneficiary for recoveries under Article 44. (By contrast: No joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

What not? Simple **sale** of (one or more) **assets** of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. (In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary).

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Participant Portal messages function).

NO amendment is necessary for '**universal takeovers**' (*see below*).

How? The coordinator must request an amendment; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as 'new beneficiary').

'New beneficiary' is used here only for the purpose of the amendment; it may mean either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular, explain the financial liability of the former beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts, if possible). (Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.)

The 'transfer date' will be added to the Preamble of the GA.

The beneficiaries must select the date in their amendment request. (If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Beneficiary Register — unless it already has a validated 'participant identification code' (PIC).

- **Adding or removing a linked third party** (*see Article 14*)

Although they are not beneficiaries, the change of a linked third party (i.e. if it ends its participation or joins the action) also requires an amendment — to update Article 14 (to state/remove their name and to fix their starting/end date).

For adding linked third parties:

The new linked third party must first be registered (and validated) in the Beneficiary Register — unless it already has a validated 'participant identification code (PIC)'.

The 'starting date of participation' will be added to Article 14.

The beneficiaries must select the date in the amendment request. It must be either a fixed date or 'the date of entry into force of the amendment'.

If the linked third party joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

For removal of linked third parties:

Beneficiaries can remove a linked third party via the amendment request to the Commission/Agency (because termination of participation does not apply to linked third parties; it applies only to beneficiaries; *see Article 50.2*)

If the Commission/Agency considers that the participation of a linked third party must be ended *(e.g. because of audit results or an OLAF investigation),* it will ask the consortium to remove the linked third party (via an amendment request).

⚠ If the consortium does not follow-up this request, the Commission/Agency may terminate the participation of the *beneficiary* (and thus automatically also remove the linked third party).

The 'end date of participation' will be added to Article 14.

The beneficiaries must select the date in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'**

If a beneficiary/linked third party — exceptionally — becomes not eligible for receiving EU funding during action implementation *(e.g. due to a change of establishment)*, this change will require an amendment (to change Annex 2 and the options in Article 9).

Example: *Beneficiary R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it may be necessary to amend the GAs in which it participates.*

By contrast, beneficiaries/linked third parties cannot become eligible during action implementation. If a beneficiary/linked third party was ineligible for receiving EU funding at the moment of grant signature, this will not change during the action implementation.

New association agreements (between the EU and third countries) do NOT have an impact on ongoing grants.

- **Change of coordinator**

If the new coordinator is not a beneficiary of the GA, it must first accede to the GA as a new beneficiary *(see Article 56.2)*. The former coordinator may continue to participate in the action as a beneficiary or may terminate its participation.

An amendment to change the coordinator remains possible (and necessary) *after* the end of the action *(see Article 3)*.

The 'handover date' will be added to the Preamble of the GA.

The beneficiaries must select the date in the amendment request. (If the former coordinator leaves the consortium, this date must be after the 'termination date'; if the new coordinator joins the consortium, the date must be after the 'accession date'). Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the option for 'authorisation to administer'**

The option in Article 41.2 can be added/deleted or changed *(e.g. change of name of the entity with 'authorisation to administer")*.

- **Change of the coordinator's bank account for payments**

An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

The bank account data must first be updated in the Beneficiary Register (and be validated).

NO amendment is necessary for a change of the **name of the bank**, **address of branch** or **name of the account holder**; a change of the bank account data (and validation) in the Beneficiary Register is sufficient.

- **Change of the action's title and/or acronym**

Example: *the consortium finds out that the acronym of their action is a protected trademark.*

- **Change of the starting date, action duration or reporting periods**

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

- **Amendment for resuming the action after a suspension of the action implementation**

The amendment request must specify the dates when the suspension started and ended. The action implementation is then automatically resumed as from the following day ('resumption date').

- **Changes to Annex 1 (description of the action)**, in particular:
  - a significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning **in-kind contributions** provided by third parties (against payment or free of charge) or **subcontracts**

    Such changes could in principle also be made via the 'simplified approval procedure' *(see Articles 11, 12 and 13)*; however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency agreement (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency could consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).
  - changes concerning the tasks to be carried out by **linked third parties** and related costs
  - changes concerning optional clauses in the GA (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to the maximum grant amount, the action's estimated eligible costs, amount of pre-financing or contribution to the Guarantee Fund**

  Changes to the maximum grant amount *(see Article 5.1)* and/or the action's estimated eligible costs *(see Article 5.2)* will be accepted ONLY in very exceptional cases *(e.g. due to a clerical mistake)*.

  ⚠ The maximum grant amount *(see Article 5.1)* can NEVER be increased.

  Changes to the maximum grant amount may have an effect on the pre-financing (and the contribution to the Guarantee Fund).

- **Changes to Annex 2 and Annex 2a (estimated budget)** which require an amendment *(see Article 4)*, in particular:

  – a budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1)

  – a budget transfer to a form of costs that is not provided for in Annex 2 *(e.g. from actual costs to unit costs)*.

  Examples:

  1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices ('average personnel costs').*

  2. *An SME joins an on-going GA. The SME owner does not have a salary and requests to be reimbursed for his/her personnel costs based on the unit costs for SME owners. In this case, it is necessary to amend the GA to modify the action's estimated budget in Annexes 1,2 and 2a.*

  Best practice: If Annex 2a needs to be changed, the beneficiaries should contact the Commission/Agency (via the Participant Portal messages function).

- **Change concerning specific cost categories ('specific unit costs')**

  If the options in Articles 5.2 and 6.2 must be added/deleted, an amendment to the GA is necessary.

  Best practice: If the change concerns specific unit costs, the beneficiaries should contact the Commission/Agency (via the Participant Portal messages function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

  Simple changes of **name**, **legal form** *(e.g. Ltd., S.A.)*, **official registration number**, **address**, **VAT number** require an amendment; an update of the beneficiary/data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

  Linked third parties must inform their beneficiary who must inform the Commission/Agency (since they do not have a LEAR) (via the Participant Portal) *(see Article 17.2)*. The data will be updated in the Beneficiary Register by the Commission/Agency and validated.

  If — exceptionally — the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator. If an amendment of the GA is needed, the coordinator may then request it.

  Example: *Company R moves from Europe to Australia. If the change of address implies that the beneficiary is not going to be anymore eligible for EU funding, then it will be necessary to amend the GAs in which it participates ('change concerning a beneficiary/linked third party not receiving EU funding').*

- **Short names** have no legal value and only serve as easy identifiers within the GA. Therefore, short names cannot be changes through a dedicated amendment type. They may eventually be modified during the course of an amendment initiated on other grounds.

  A change of the **person authorised to represent it** for the purposes of signing the GA requires, by contrast, no follow-up at all (not even a change in the Beneficiary Register since this name is only relevant for the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

  Transfers of the GA linked to a **universal takeover** (i.e. where the original entity is replaced by one new entity and all the rights and obligations (including the GA) are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

  Example: *Beneficiary X merges with another existing entity Y by:*

  - *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
  - *establishing a new separate legal entity (X and Y are together known as 'Z').*

  If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator. If an amendment to the GA is needed, the coordinator may then request it.

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

  Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information.*

  Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going Innovation GAs. The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% but to a reimbursement rate of 70%. It may be necessary to modify the GA via an amendment, notably to update the table of costs.*

  For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

  In addition to updating the data in the Beneficiary Register, the beneficiary must **inform** the coordinator (offline) under Article 17.2, if the universal takeover could:

  - significantly affect or delay the implementation of the action or the EU's financial interests or
  - affect the decision to award the grant or the compliance with requirements under the GA.

  The coordinator must then inform the Commission/Agency (via the Participant Portal) and, if necessary, request an amendment.

  The same applies if the universal takeover concerns a linked third party.

How?

Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) **directly in the Participant Portal** *(see Article 52)*.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Participant Portal messages function), to discuss the amendment.

⚠ Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Beneficiary Register.

Examples:

A new beneficiary must be validated ('legal entity validation'). This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.

Validation of the new bank account, to change the bank account.

⚠ The amendment request must include the necessary information and supporting documents

A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications (through the electronic exchange system) or additional information/documents.

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action, i.e. the date set out in Article 3). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases (*e.g. change of bank account, change of coordinator to make the payment of the balance*)).

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Before it has been accepted or rejected, it may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

If accepted it will be **counter-signed** by the receiving party (again, directly in the Participant Portal by the PLSIGN).

2. Procedure

The requesting party must formally notify the request for amendment to the other party (through the Participant Portal).

The other party must — within **45 days** — **agree or disagree**, by sending a formal notification (for the consortium: signed by the PLSIGN of the coordinator) through the Participant Portal.

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked*

third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Participant Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

Where a new beneficiary is added to the GA, it must assume the rights and obligations from the 'accession date' specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).

Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the 'resumption date' set out in the amendment. This date may be before the date on which the amendment enters into force (see Article 49.2.2).

If the amendment intends to correct an error, the change will be made with effect from entry into force of the GA (i.e. from the beginning).

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (by the beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* in the Participant Portal (together with the declaration(s) of joint and several liability, if any). They must do this within 30 days after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on joint and several liability *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, together with the Accession Form.

The beneficiary must keep the original version.

If the beneficiary does not submit this declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Linked third parties do not become parties to the GA and therefore do NOT sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (⚠ new in Horizon 2020). All documents are available in the 'My Area' in the Participant Portal.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How?

The new beneficiary must:

- register in the Beneficiary Register and be validated — unless it already has a validated 'participant identification code (PIC)'
- sign the Accession Form directly in Participant Portal *(see Article 52*)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the 'accession date' in the Accession Form. It must be either:

- 'the date of signature of the Accession Form'
- 'the date of entry into force of the Amendment'

OR

- a fixed date:
  - either a retroactive date (i.e. before signature of the Accession Form)

  OR

- a future date (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

If new beneficiaries join the action to replace a beneficiary that leaves, they may set the accession date before the termination date (of the beneficiary that is replaced) — and thus *both* incur costs for a certain period. .

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium *[**OPTION for international organisations that do not accept application of Union law:** except for [insert name(s) of the international organisations concerned]].*

[OPTION for international organisations that accept application of Union law but not Belgian law:** For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].**]

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations for international organisations:

	Applicable law
For international organisations that do not accept EU law	No reference to any applicable law[75]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that accept EU law, but not Belgian law	EU law applies, supplemented by the law of the Member state or EFTA country that is mentioned in the GA.

[75] *See Article 180(1) of the Rules of Application.*

	In addition, a reference to the general principles governing the law of the international organisations and the rules of general international law may be included in the GA.

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).****]***

1. Dispute settlement

As a general rule, H2020 GAs contain an 'Article 272 TFEU arbitration clause', referring **disputes on the interpretation, application or validity of the GA** to the Court of Justice of the European Union.

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against 'confirmation letters', 'debit notes', etc.; NOT against 'audit reports', 'letters of audit conclusions' 'pre-information letters', etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative or financial penalties, offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions (by any beneficiary — including non-EU beneficiaries, 'beneficiaries not receiving EU funding') must be brought before the Court of Justice of the European Union under Article 263 TFEU (NOT before any other court and NOT under Article 272).

All procedures are organised in a way that the beneficiaries will be **informed** of the available **means of redress** (via a 'redress clause' in the letters).

For more information on complaints*, see the Online Manual.*

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, disputes on the interpretation, application or validity of the GA are normally referred to the competent Belgian courts. (So far (i.e. until end of 2014) NONE of the agreements associating third countries to the Horizon 2020 programme provides for the sole jurisdiction of the European Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Non-EU beneficiaries not receiving EU funding — For beneficiaries not receiving EU funding which according to their national law cannot be subject to the jurisdiction of the European Court of Justice, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration *(see also point 1)*.

Other non-EU beneficiaries not receiving EU funding will be treated as normal non-EU beneficiaries (i.e. Belgian courts).

Disputes of public law nature remain before the European Court of Justice.

International organisations — For international organisations, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration *(see also point 1)*. (in line, for instance, with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[76]).

Disputes of public law will not in most cases arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

For this reason, the Commission/Agency will normally not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative or financial penalties *(see Article 45).*

Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[76] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

The Commission will keep a record of its official position on issues raised by specific situations or by the legal framework applicable in particular countries — see the List of issues applicable to particular countries on the Participant Portal.

> Only countries for which the Commission has carried out a formal assessment of specific issues will appear in this section.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)
- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for principal beneficiary not receiving EU funding:*** *as 'beneficiary not receiving EU funding' (see Article 9),**]*** represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

[OPTION by default: 'principal investigator':[4]

- *[**Name**][Date and place of birth]**]***[5]

[OPTION for SyG: 'corresponding principal investigator':

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]].**]***

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][**legal form**], [official registration No], [official address in full] [VAT number], ***[OPTION for SyG**: hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

*[same for each beneficiary**]***

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The **'host institution (HI)'** is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**'.

2. Principal investigator(s)

For ERC grants, the main researcher (i.e. the 'principal investigator (PI)') is named in the GA.

PIs can be of any nationality, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted by a host institution that is based in an EU Member State or H2020 associated country and can receive EU funding.

Due to the key role of the PI, s/he cannot be replaced by any other researcher during the implementation of the action. Requests for amendments to change the PI will be rejected.

The Agency must be **informed** before any change in employment or location of the PI.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of innovative research, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium of undertakings, universities, research centres or other legal entities. The engagement of the team follows the rules of the beneficiary and its country.

PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the implementation of the ERC action), PIs and their host institutions must sign a '**supplementary agreement (SA)**' *(see Article 32)*.

The supplementary agreement can NOT replace the employment/engagement contract.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party *(see Article 8)*, i.e.:

- a third party from an EU Member State or H2020 associated country that provides the PI as in-kind contribution or
- a linked third party.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution *and* the third party.

Retired PI — The PI may be retired (i.e. normally no longer under an active labour contract).

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties)

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs.

Thus, the ERC MGA does NOT have:

- 'personnel costs for providing trans-national access to research infrastructure'
- 'direct costs of providing financial support to third parties'
- 'specific cost categories'.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices, the unit costs for SME owners without salary and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[77]

It does NOT use the unit costs of the 'specific cost categories' of the General MGA.

[77] See Article 29(1) and 33(2) of the Rules for Participation and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* **—** with the exception of 'direct costs of providing financial support to third parties', 'specific cost categories' and 'costs for providing access to trans-national research infrastructure'.

The same **conditions for eligibility** and rules for **cost calculation** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the **following specificities**:

– for 'direct personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: as 'personnel costs – costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: as 'personnel costs – costs of personnel seconded by a third party against payment' (Article 6.2.A.3)).

– for 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs' (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs, and research data) are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[78]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

2. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

ERC grants do NOT prevent PIs from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

For more information on how to combine EU funding from different programmes ('complementary EU funding' or 'synergies'), *see the Online Manual.*

[78] See http://erc.europa.eu/implementing-arrangements.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

In addition, the beneficiaries must prove that the **PI time commitments** (set out in Annex 1 and 2) were respected, i.e.:

- for the percentage of total working time on the action:
  - if the PI works 100% of his/her total working time for the host institution, but only partially on the ERC action: by using time sheets
  - if the PI works 100% of his/her total working time for the host institution and exclusively on the ERC action (during its entire duration): via a declaration signed by the beneficiary and the PI
  - if the PI works partly for other institutions (i.e. has working time outside the contract between PI and HI): via a declaration signed by the beneficiary and the PI
- for the minimum percentage of total working time in a EU Member State or H2020 associated country: via a declaration signed by the beneficiary and the PI.

In the absence of this documentation, the ERC may accept alternative evidence, if it considers that it offers adequate level of assurance.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- the costs declared are eligible (see Article 6);

(c) a '**summary financial statement**' (see Annex 4), created automatically by thesystem, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(d) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or a linked third party]* has accounting established in euro, it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Reports

When & What?

For ERC actions, the principal beneficiary must submit both:

- a '**periodic scientific report**' after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a '**final scientific report**' at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a '**financial report**' at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a 'breakdown of direct costs table' and a 'budget follow-up table'
- an 'individual financial statement'
- a 'summary financial statement', created automatically by the system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a 'certificate on the financial statements (CFS)'.

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How?

All reports must be prepared and submitted directly in the Participant Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

Example: *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(d) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(e) ensure open access to the deposited publication — via the repository — at the latest:

(iii) on publication, if an electronic version is available for free via the publisher, or

(iv) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(f) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(c) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(iii) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(iv) other data, including associated metadata, as specified in Annex 1;

(d) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.****]***

[OPTION: *Not applicable****]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars

Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature' (i.e. informally published material not having gone through a classic publishing process, e.g. reports),* are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

See also the Open Access Guidelines for research results funded by the ERC.

ERC grants have however the **following specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org).

For publications issued after the end of the action, if beneficiaries cannot provide open access without incurring additional costs for 'gold' open access, they may choose 'green' open access with an extended embargo period which goes beyond six/twelve months.

Moreover, with explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a 'Digital Object Identifier (DOI)'[79] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable).

For more information, *see Open Access Guidelines for research results funded by the ERC.*

[79] For more information, *see http://www.doi.org/.*

2. Open access to research data

This option will be inserted in the GA only for ERC frontier research actions that opt-in to the open research data pilot on a voluntary basis (if foreseen in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the **following specificities**:

For ERC actions, there is NO formal requirement for a 'data management plan'. Annex 1 can make reference to a separate document in which the specification of the research data is provided *(e.g. what data will be collected or generated; methodology and standards; whether and how this data will be shared and/or made open; how it will be curated and preserved)*. This separate document can be updated by the beneficiaries if necessary during the implementation of the action. Justification to open access exceptions to specific parts of the research data can also be provided through the separate document.

Moreover, the exception allowing beneficiaries NOT to give access to specific parts of research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives. (For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does not need to be the scientific objective of the action but can refer to other objectives, *such as the intended later commercialisation of the scientific findings*.)

The beneficiaries may opt out at any stage freeing themselves retroactively from the obligations associated with opting-in.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[36] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary *[**OPTION for SyG:** and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement *[**OPTION for SyG:** and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[36] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005.p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow for transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** for the beneficiary and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action

The percentages for time commitments should be established with reference to the total productive hours worked by the PI for *all* his/her employers.

The total productive hours should be calculated in accordance with Article 6.

The percentages must be reached for the action duration (not annually or per reporting period).

- Applying the beneficiary's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**
- Upholding the **intellectual property rights** of the beneficiary

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it, if s/he becomes aware of any violation of the latter's IPRs related to the project.

  Example: *The PI reads a research article and discovers a violation of the host institution's IPRs related to the project. S/he is obliged to inform the host institution.*
- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the beneficiary and the PI, to set out their internal arrangements for implementing the grant. It is **purely internal**; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must last at least for the action duration *(see Article 3)* (**—** without any interruptions, even if the PI works only part-time on the ERC project).

The supplementary agreement must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

The supplementary agreement must be concluded **before GA signature** (and a copy must be sent to the Agency).

A model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research or PoC grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution (i.e. the principal investigator cannot sign his/her own supplementary agreement for both parties).

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the European Research Council (ERC). Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC homepage*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new beneficiary — at any time during the action implementation.

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

⚠ NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are considered in breach of contractual obligations and may result in costs being declared ineligible and/or the Agency terminating the action early.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** the transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

2. Procedure

The PI should first contact the beneficiary that signed the GA (i.e. the former host institution).

Best practice: Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The 'transfer date' will be added to the Preamble of the GA.

The beneficiaries must select the date in their amendment request. (If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed only in exceptional cases and with a specific justification.)

Best practice: For a retroactive transfer date, the beneficiaries should contact the Agency in advance (via the Participant Portal messages function).

3. Effects

After the amendment, the Agency will **calculate** the **eligible costs** of the former host institution and instruct it to **transfer** the remaining **pre-financing** (not covered by eligible costs) to the new host institution.

If the former host institution spent all the pre-financing payment *(see Article 21.2)*, the Agency will NOT pay out any additional pre-financing to the new host institution. The new host institution will have to advance the funds and its eligible costs will only be reimbursed up to the maximum grant amount set out in Article 5.1.

Financial reporting periods will be **adapted** to take into account the exact date of the transfer (if necessary). **Scientific reporting periods** will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

A certificate on the financial statement (CFS) must be submitted by the former host institution prior to the last reporting period if it reached the threshold set up in Article 20.

If the PI's requests it, the Agency may require the former host institution to **transfer** the **equipment** purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate the transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may in principle declare the costs of this reimbursement and any other related costs (i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research or PoC grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, it may remain party to the GA (as an additional beneficiary); the new beneficiary that hosts and engages the PI will become the new host institution.

II.3 H2020 ERC MGA PoC: Annotations

The H2020 ERC MGA PoC is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability *(Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not found by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(f) *a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

(g) *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A)****]***

[OPTION for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Periodic reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a periodic report to the Agency.

*The **periodic report** must include the following:*

(a) *a summary for publication by the Agency;*

(b) *an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

(c) *detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

(d) *an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION:** not applicable;**]***

*(f) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

1. Report(s)

When & What?

For ERC PoC actions, the principal beneficiary must submit reports — only one '**report**' if there is one reporting period, otherwise one '**periodic report**' at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a '(periodic) summary financial statement', which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a 'certificate on the financial statements (CFS)' will have to be added (if necessary).

How?

All reports must be prepared and submitted directly in the Participant Portal *(see Article 52*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowka-Curie (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE and
- MSCA-COFUND.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA MSC-ITN deviates from the General MGA as follows:

- Article 4.2 (MSC-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to ‘mainstream media coverage’)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

The H2020 MGA MSC-IF deviates from the General MGA as follows:

- Article 3 (notified starting date)
- Articles 4.2, 8-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSC-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSC-IF specific conditions for termination)
- Article 55 (MSC-IF specific conditions for amendments)
- Article 56a (MSC-IF portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The H2020 MGA MSC-RISE deviates from the General MGA as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSC-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 32 (MSC specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 5 and 6 (not applicable)

The H2020 MSC-COFUND deviates from the General MGA as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Articles 8-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of programmes)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSC-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSC funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annexes 3, 5 and 6 (not applicable)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 8-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement)

III.2 H2020 MGA MSCA-ITN: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-ITN

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by 'networks' of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN take the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

***[OPTION for all actions except EID:** However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.]*

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may re-distribute person-months between *them* (as compared with the original planning set out in Annex 2). This re-distribution can be done without requesting an amendment (see *Article 55*) provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however NEVER be increased.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the distribution of the institutional unit cost for management tasks do NOT need to be notified to the Agency.

***Example:** Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A re-distribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Re-distributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment *(see Article 55)* will be required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID: the 40 % limit of budget allocated to beneficiaries established in the same country or to the same international European interest organisation or international organisation.

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In a project with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (=40%). However, if the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are all linked to the *same* person-months declared for the recruited researchers. (It is therefore technically not possible to move budgeted amounts from one budget category to another.)

⚠ **Budget flexibility** — Since MSCA-ITN uses unit costs, there is however some flexibility as regards the *use* of the amounts received:

- The unit costs for recruited researchers (i.e. living, mobility and family allowances) must be fully used for each researcher. They can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c)).*
- The unit cost for research, training and networking should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes, *for instance to increase the salary of a researcher or to organise additional training activities*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to increase the salary of a researcher*.

  Re-distributions of management and indirect costs within the consortium are allowed, but should be done via an internal agreement and should roughly correspond to the actual division of (management) tasks within the consortium.

  Management and indirect costs should also be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[80].

For MSCA-ITN these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if any)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they can NOT be changed.

The conditions for eligibility are set out in *Article 6*.

[80] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiary (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **cost calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country where the research training activities take place for more than 12 months in the 3 years immediately prior to the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country).

For beneficiaries that are the international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately prior to the recruitment date;

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree[;][.]**]***

(viii) ***[OPTION for EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

1. Costs for recruited researchers: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** the costs for the recruited researchers (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover costs related to their mobility, *e.g. relating to travel and accommodation*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by the budget category 'research, training and networking costs'

AND

- a monthly family allowance for researchers with family, to reduce family-related obstacles to researcher mobility.)

The mobility and family allowances are due to the researcher for each month worked.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the unit costs for recruited researchers (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Costs of the beneficiaries for management and indirect costs are not covered under this budget category; they are covered under the budget category 'institutional costs' (*Article 6.2.B*).

Example:

Costs for student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[81] and set out in Annex 2 and 2a of the GA (currently:

[81] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the living allowance: **EUR 3 110** per researcher per month ('person-month')

To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient** (**CCC**)'.

The list of coefficients is published in the Main Work Programme — MSCA in force at the time of the call.

On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does not change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action duration).

– for the mobility allowance: **EUR 600** per person-month

– for the family allowance: **EUR 500** per person-month).

For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities (e.g. during maternity/parental leave) are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first 4 years (full-time equivalent research experience) of their research career),

    '**Date of recruitment**' normally means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    Example:
    The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as 'date of recruitment'.

    Years of '**research career**' are counted as full-time-equivalent research experience, from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:

  - sickness, parental, unemployment and invalidity benefits
  - pension rights and
  - benefits for accidents at work and occupational diseases.

  If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:

  - sickness, parental and invalidity benefits and
  - benefits for accidents at work and occupational diseases.

  In this case, the living allowance will be reduced by 50%.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:

  - subject to prior approval by the Agency
  - on personal or family grounds only and
  - not for professional reasons

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  While it is not possible to request *part-time* employment for professional reasons, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or suspension of the action; it is sufficient not to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Any complementary skills training *(e.g. a minor teaching activity as part of the research training)* is not incompatible, but must not jeopardise execution of the research training activities and must be set out in Annex 1 to the GA.

- are supported for **at least three months**

  Person-months linked to shorter contracts will not be eligible. However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training.

  Example: *If the contract is set out for a longer duration, but the training is interrupted within the first three months for reasons which are beyond the control of the beneficiary (e.g. because the researcher resigns), the costs may still be claimed.*

- comply — at the time of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the recruitment date (unless the beneficiary is an 'international European interest organisation'[82] or international organisation, for whom the mobility rule is limited to time spent *with* them)

[82] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or

The mobility rule applies only to the first recruitment under the action. It does not apply to beneficiaries to which the researcher is sent or seconded afterwards.

For refugees under the Geneva Convention[83], the refugee procedure (i.e. before refugee status is conferred) will not be counted as 'period of residence/activity in the country of the beneficiary'.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  In the case of EJD, the PhD-programme must lead to the award of:

  - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
  - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

  The degree must not necessarily be awarded within the action duration.

  However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs (gross amount).

  MSCA-ITN researchers may NOT be requested to pay tuition fees for their research training and/or PhD degree programme (from their own funds or from the researcher unit cost). (The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing etc.), teaching, supervision, examination and graduation)* may be covered by the budget category 'institutional costs'.)

  Family and mobility allowances can be paid to the researcher in various ways, *for example as*:

  - *part of his/her salary*
  - *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under the budget category of 'research, training and networking costs')*
  - *rental costs, directly paid or reimbursed by the beneficiary .*

  Any form is acceptable, provided that:

  - both sides agree
  - it is allowed under national law

  AND

  - there is no underpayment.

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associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[83] 1951 Refugee Convention and the 1967 Protocol.

Example: *Researcher X chooses to take up residence in an apartment with a rent of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the simplest way to pay these allowances.

For beneficiaries with accounting in a **currency other than** the **euro**:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[84]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[85].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers that have — at the date of the recruitment — a family, i.e.
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country or region in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

[84] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[85] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

⚠ Beneficiaries may NOT declare more than 36 person-months per researcher. (Person-months exceeding this number will be rejected by the Agency.)

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector. This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
- management and indirect[86] costs (i.e. the beneficiary's additional costs in connection with the action).

Budget flexibility — Since MSCA-ITN uses unit costs, there is some flexibility as regards the *use* of the amounts received:

- The unit cost for research, training and networking should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes, *for instance to increase the salary of a researcher or to organise additional training activities*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to increase the salary of a researcher*.

  Re-distributions of management and indirect costs within the consortium are allowed, but should be done via an internal agreement and should roughly correspond to the actual division of (management) tasks within the consortium.

  Management and indirect costs should also be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[87] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 1200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[88]: this amount is halved, i.e. EUR 600)).

[86] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[87] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[88] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for the budget category 'costs for recruited researchers' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

⚠ **Budget flexibility** — Even if the consortium re-distributes parts of the institutional unit costs, the reporting is always based on the person-months implemented by the beneficiary.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement do not apply.

Specific cases (third parties involved in the action):

Partner organisations — MSCA-ITN allow nevertheless for the involvement of partner organisations (i.e. organisations that are not beneficiaries, but that provide training and host researchers during a secondment).

The beneficiaries remain **fully responsible** for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

Partner organisations are not explicitly mentioned as third parties in the GA, since no additional costs arise for the action. Their costs are covered by the unit costs paid to the beneficiaries.

Partner organisations can NOT employ the researcher under the action.

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

Coordination and administration tasks are considered **action tasks**.

Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these procedures end.)

Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of the researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after the first year** of the action — send to the Agency a progress report, to inform the project officer about progress on the action.

How? The report must be prepared and submitted directly in the Participant Portal *(see Article 52*).

2. Deliverable: Mid-term review meeting

What & When? The coordinator must:

- **before** the deadline for the **periodic report for RP 1**: organise a mid-term review meeting and
- **no later than 30 days** before this meeting: send to the Agency (via the Participant Portal) a draft version of the periodic report, as a basis for the mid-term review meeting.

3. Deliverable: Researcher declaration

What & When? The beneficiary must send to the Agency (via the Participant Portal) a document with information about each recruited researcher ('researcher declaration') — within **20 days** after the recruitment (of the researcher).

It is important to give correct and complete information since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family

allowance units. (If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher).

How? The researcher declaration must be prepared and submitted directly in the Participant Portal *(see Article 52*).

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA):*

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[14] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or any other entity referred to in Annex 1);

(j) host the researchers at their premises and provide training as well as the necessary means for implementing the action;

(k) ensure that the researchers are adequately supervised;

(l) ensure that a career development plan is established and support its implementation;

(m) ensure an appropriate exposure to the non-academic sector;

(n) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[14] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for them.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[89]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises and **provide training** as well as the necessary means for implementing the action

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**

[89] Available at http://ec.europa.eu/euraxess/

- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[90].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[91].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities, including during secondments/placements with other beneficiaries and/or partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2)*.

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.
- Ensure that the researchers do NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Ensure that **secondments** are **limited** to a maximum of 30 % of the months spent implementing the research training activities under the action.

  'Secondments' may be either to another beneficiary within the consortium or to a partner organisation and must involve research training activities.

  For EID or EJD: The 30% rule does not apply to time spent with other beneficiaries or partner organisations, if the secondment is foreseen in Annex 1.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment.

[90] Available at https://www.iprhelpdesk.eu/.
[91] Available at http://ec.europa.eu/euraxess/.

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MGA MSCA-IF: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-IF

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include two additional funding strands: the 'Career Restart Panel' and the 'Reintegration Panel'.

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION if needed for the action:** insert date]*[5] ('**starting date of the action**').

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the starting date is *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, the notified starting date must be:

- after the entry into force of the GA and within the number of months set out in Article 3 (i.e. normally 12 months from the entry into force).
- notified by the beneficiary in *advance* (via the Participant Portal).

If the action does not start or the starting date is not notified (in time), the Agency may terminate the GA *(see Article 50)*. If the notification of the starting date is sent after the start of the action, this will have an impact on the timing of the pre-financing payment and will delay it *(see Article 21.2)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO re-distribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are all linked to the *same* person-months declared for the recruited researcher. (It is therefore technically not possible to move budgeted amounts from one budget category to another.)

Budget flexibility — Since MSCA-IF uses unit costs, there is however some flexibility as regards the *use* of the amounts received:

- The unit costs for the recruited researcher (i.e. living, mobility and family allowances) must be fully used for the researcher. They can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.
- The unit cost for research, training and networking should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes, *for instance to increase the salary of the researcher or to organise additional training activities*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to increase the salary of the researcher*.

  Management and indirect costs should be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[92].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and, if applicable, family allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in *Article 6*.

[92] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA uses only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **cost calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[24]*[***OPTION for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including for a period of secondment to a **partner organisation**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action;

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Costs for the recruited researcher: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** the costs for the recruited researcher (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law (i.e. gross amount))
- a monthly mobility allowance to cover costs related to his/her mobility, *e.g. relating to travel and accommodation*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by the budget category the 'research, training and networking costs').

AND

- a monthly family allowance if the researcher has family, to reduce family-related obstacles to researcher mobility.)

The mobility and family allowances are due to the researcher for each month worked.

Budget flexibility — There is NO flexibility as regards the *use* of the unit costs for the recruited researcher (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Costs of the beneficiaries for management and indirect costs are not covered under this budget category; they are covered under the budget category 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[93] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance: **EUR 4650** for the researcher per month ('person-month')

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a '**country-specific correction coefficient (CCC)**'.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the Main Work Programme — MSCA in force at the time of the call and according to the country of recruitment.

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month
- for the family allowance: **EUR 500** per person-month).

For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[93] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the time of the call deadline — an **experienced researcher** ('ER'; i.e. have a doctoral degree or have at least four years (full-time equivalent research experience) of research career)

    Years of '**research career**' are counted as full-time-equivalent research experience, from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases.

    If national law prevents the beneficiary from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may (exceptionally and subject to the Agency's prior agreement) offer a '**fixed-amount fellowship**' with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency
    - on personal or family grounds only and
    - not for professional reasons.

    In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

    Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ While it is not possible to request *part-time* employment for professional reasons, beneficiaries may — in exceptional cases — request a suspension of the action to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Any complementary skills' training *(e.g. teaching activity as part of the research training)* is not incompatible, but must not jeopardise execution of the research activities and must be set out in Annex 1 to the GA.

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as 'underpayment'.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs (gross amount).

  Family and mobility allowances can be paid to the researcher in various ways, *for example as:*

  – *- part of his/her salary*

  – *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under the budget category of 'research, training and networking costs')*

  – *rental costs paid or reimbursed by the beneficiary etc.*

  Any form is acceptable, provided that:

  - both sides agree

  – it is allowed under national law

  AND

  – there is no underpayment.

  Example: *Researcher X chooses to take up residence in an apartment with a rent of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

  Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

  ⚠ Usually, payment as part of the salary is the simplest way to pay these allowances.

For a beneficiary with accounting in a **currency other than** the **euro**:

– if a daily rate is published in the in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[94]

– if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[95].

[94] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[95] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs (for the researcher).

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the time of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the three years immediately prior to the call deadline

  Beneficiaries that are 'international European interest organisations' or international organisations — The researcher may not have spent more than 12 months with the beneficiary in the three years immediately before the call deadline.

  EF Career Restart Panel and **Reintegration Panel** — The researcher may not have resided or carried out his/her main activity in the country of the beneficiary for more than three years in the five years immediately before the call deadline.

  GF — The researcher must comply with the mobility rule with regard to the country of the partner organisation (i.e. where the outgoing phase takes place), not for the country of the beneficiary (i.e. where the return phase takes place).

  Researchers that are refugees — For refugees under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol), the refugee procedure (i.e. before refugee status is conferred) will not be counted as 'period of residence/activity in the country of the beneficiary'.

- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a Member State or an associated country.

  'Long-term resident' means full-time research activity in a Member State (or associated country) for five or more consecutive years.

- for EF Reintegration Panel: not have been **active** in research for at least 12 months immediately before the call deadline

- for the family allowance: have a **family**, i.e.:
  - be married
  - be in a partnership with equivalent status to marriage as recognised by the legislation of the country or region in which it was formalised or
  - have dependent children for whose maintenance s/he is actually responsible under national law.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

⚠ The beneficiary may NOT declare more than 24 person-months for the researcher (or 36 months for GF). (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
- management and indirect[96] costs (i.e. the beneficiary's additional costs in connection with the action).

Budget flexibility — Since MSCA-IF uses unit costs, there is some flexibility as regards the *use* of the amounts received:

- The unit cost for research, training and networking should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes, *for instance to increase the salary of the researcher or to organise additional training activities*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to increase the salary of the researcher*.

  Management and indirect costs should be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[97] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 800** for the researcher per month ('person-month')
- for management and indirect costs: **EUR 650** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[98]: this amount is halved, i.e. EUR 325)).

In practice, the declaration of institutional costs for MSCA grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

[96] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[97] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[98] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for the budget category 'costs for the recruited researcher' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement do not apply.

Specific cases (third parties involved in the action):

Partner organisations — MSCA-IF allow nevertheless for the involvement of partner organisations (i.e. organisations that are not beneficiaries, but that provide training and host researchers during a secondment; *see Article 32*).

The beneficiary remains **fully responsible** for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

Partner organisations are not explicitly mentioned as third parties in the GA, since no additional costs arise for the action. Their costs are covered by the unit costs paid to the beneficiary.

Partner organisations can NOT employ the researcher under the action. (For GF: this does not however prevent a partner organisation in a third country from contributing to the income of the researcher, in line with *Article 32.1(c)(v)*)

For GF: the partner organisation must be located in a third country and must be described in Annex 1.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before they accede to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or any other entity referred to in Annex 1);

(g) host the researcher at its premises and provide training as well as the necessary means for implementing the action;

(h) ensure that the researcher is adequately supervised;

(i) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(j) support the secondment of the researcher in Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(k) ***[OPTION for GF:*** *support the return of the researcher to its premises to carry out a mandatory return period of 12 months.****]***

[…]

[11] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee objective selection procedures and best possible working conditions for him/her.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises and **provide training** as well as the necessary means for implementing the action

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 to the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- Support **secondments** of the researcher, if any (and, for GF, support his/her return during a mandatory 'return-period' of 12 months)

  Researchers may be seconded to a partner organisation established in a EU Member State or H2020 associated country *(see Article 8)*:
  - if this is provided for in Annex 1 to the GA
  - for a maximum of three months in an action with a duration of up to 18 months, or up to six months in an action of up to 24 months

⚠ The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[99].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[100].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during secondments to partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

- Ensure that the researcher does NOT receive, for activities carried out in the frame of the action, **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

  This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment.

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

[99] Available at https://www.iprhelpdesk.eu/.
[100] Available at http://ec.europa.eu/euraxess/.

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*
- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA in publications, communications or patent applications.
- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must however make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. Suspension of the action implementation — Additional grounds for suspension: Professional, personal or family reasons

In addition to the normal grounds for suspension of the action implementation *(see Article 49 H2020 General MGA)*, beneficiaries of MSCA-IF may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and end date of the suspension and
- the 'resumption date' when the action is resumed (i.e. automatically one day after the end date).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are not eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional grounds for amendments: Change to part-time employment

For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time), on personal or family grounds (including parental leave).

Such amendments are NOT possible for any other reasons *(e.g. other professional opportunities, etc.)*. In those cases, the beneficiary must request suspension of the action implementation or termination of the action.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and a statement from the new beneficiary to take over all rights and obligations under the Agreement.

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a **'transfer report'**, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The maximum grant amount set out in Article 5.1 will be decreased if a lower country correction coefficient is applicable to the new beneficiary.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via 'termination' (Article 50) or 'addition of a new beneficiary' (Article 56).

⚠ NO transfer before the amendment has been accepted by the Agency. Any interruption of the action implementation due to an unauthorised transfer is a breach of contractual obligations and the former beneficiary bears the full responsibility for any activity/commitment undertaken before the Agency has approved the amendment.)

The transfer may be based on any **ground** that is linked to the beneficiary and affects the researcher's ability to perform the activities.

Examples: *Internal reorganisation affecting implementation of the project; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher are NOT considered valid grounds for transferring the GA to a new beneficiary. (These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*, so that the researcher can benefit from other professional opportunities or better reconcile work and family commitments without having to forego the grant).

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility criteria or financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed in the Participant Portal).

3. Effects

The transfer may result in a reduction of the **maximum grant amount** *(see Article 5.1)*, if the correction coefficient for the country of the new beneficiary is lower than the one of the former beneficiary.

⚠ By contrast, the maximum grant amount will NOT be increased if the country correction coefficient (CCC) for the country of the new beneficiary is higher.

In order to allow the new beneficiary to pay the higher CCC , the action duration can be reduced accordingly. (If, by contrast, the initial action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new CCC *(using e.g. the management and indirect costs)*.

After approval of the amendment, the former beneficiary must**:**

- **transfer** the **remaining contribution** to the new beneficiary and
- **submit a report** to the Agency, including:
  - an overview of progress on results and
  - a financial statement up to the date of the transfer.

III.4 H2020 MGA MSCA-RISE: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-RISE

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

For more information on MSCA-RISE, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does **not use the budget categories of the General MGA**.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may re-distribute person-months between *them* (as compared with the original planning set out in Annex 2). This re-distribution can be done without requesting an amendment (see *Article 55*) provided that it does not imply a substantial change to the action as described in Annex 1.

The maximum grant amount *(see Article 5)* can however NEVER be increased.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the distribution of the 'institutional costs' do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A re-distribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Re-distributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change to the action as described in Annex 1, a formal amendment will be required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are all linked to the *same* person-months declared for the seconded staff. (It is therefore technically not possible to move budgeted amounts from one budget category to another.)

⚠ **Budget flexibility** — Since MSCA-RISE uses unit costs, there is however some flexibility as regards the *use* of the amounts received:

- The unit cost for the seconded staff members (i.e. top-up allowance) must be fully used for each staff member. They can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
- The unit cost for research, training and networking should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes, *for instance to cover travel and subsistence costs of a staff member or to organise additional training activities*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to cover travel and subsistence costs a staff member*.

  Re-distributions of management and indirect costs within the consortium are allowed, but should be done via an internal agreement and should roughly correspond to the actual division of (management) tasks within the consortium.

  Management and indirect costs should also be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs)**.

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[101].

For MSCA-RISE these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in *Article 6*.

[101] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA uses only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42).*

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **cost calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for seconded staff members are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the beneficiary or a partner organisation;

(c) the secondment complies with the following conditions:

(i) last at least 1 month and no longer than 12 months;

(ii) be between:

- a beneficiary established in a EU Member State (or associated country[6]) and a beneficiary established in another EU Member State (or associated country) from different sectors (academic and non-academic) or
- a beneficiary established in a EU Member State (or associated country) and a partner organisation established in a non-EU Member State (or non-associated country), and

(iii) the beneficiary or partner organisation sending the person is established in a country listed in General Annex A of the Main Work Programme.

[6] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

1. Costs for seconded staff members: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** the costs for the seconded staff members (by providing for:

- a monthly top-up allowance for travel, accommodation and subsistence costs relating to the secondment.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the unit cost for the seconded staff members (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.

What not? Costs of the beneficiaries for research, training, networking and management and indirect costs are not covered under this budget category; they are covered under the budget category 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[102] and set out in Annex 2 and 2a of the GA (currently

- for the top-up allowance: **EUR 2 000** per seconded staff member per month ('person-month')).

ℹ For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatised: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (and its duration), identifiable and verifiable etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - an **early stage researcher** (i.e. not have a doctoral degree and be in the first four years (full-time equivalent research experience) of his/her research career);
    - an **experienced researcher** (i.e. have a doctoral degree or at least four years (full-time equivalent research experience) of research career), or
    - **administrative, managerial** or **technical staff supporting research and innovation activities** under the action (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

      Examples (not eligible administrative, managerial or technical staff):

      1. *Ms A, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

      2. *Mr X, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

    Years of '**research career**' are counted as full-time-equivalent research experience, from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited).

[102] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- have **already worked** continuously for at least **six months** (full-time equivalent) on research and innovation activities at the premises of the sending beneficiary/partner organisation

  Examples:

  1. *Mr X is employed by beneficiary Y as from 1 January 2014; Mr X will not be eligible for a secondment from 1 March but would be eligible for secondment as from 1 July 2014.*

  2. *Ms Y is employed 50% part-time by beneficiary X as from 1 January 2014. Ms Y will not be eligible for a secondment from 1 July, but would be eligible for secondment as from 1 January 2015.*

  The type is NOT relevant — as long as it:

  - complies with national law
  - complies with internal practices and
  - confers to the sending beneficiary/partner organisation the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

  Example: *A PhD-candidate can be seconded if s/he:*
  - *is at least an early stage researcher (ESR)*
  - *has been linked/actively engaged in the R&I activities of the sending beneficiary/partner organisation for at least six months (full-time equivalent) and*
  - *will be covered by an appropriate contract allowing him/her to work full-time on the R&I activities of the project during the secondment under the instructions of the sending beneficiary/partner organisation.*

- be incurred for secondments:

  - that last at **least 1 month** and no longer than 12 months

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

    However, only splits within the *same secondment* (same staff, same sending beneficiary/partner organisation, same hosting beneficiary/partner organisation) can be added to reach the minimum duration of one month.

    Example: *Two secondments of two weeks of the same staff member to different organisations are not eligible since the minimum duration of 1 month is not reached.*

  - that are one of the following three:

    - secondments **between beneficiaries** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

      Both elements must be fulfilled (i.e. location in different EU Member States or H2020 associated countries AND different sectors (academic and non-academic sector).

      'Academic sector' means:

      - public or private higher education establishments awarding academic degrees
      - public or private non-profit research organisations whose primary mission is to pursue research or

– international European interest organisations.

'Non-academic sector' means any socio-economic actor not included in the academic sector.

- secondments from a **beneficiary** in an EU Member State (or H2020 associated country) **to** a **partner organisation** in a third country *(see Article 8)*

OR

- secondments **from** a **partner organisation** in a third country listed in General Annex A to the Main Work Programme *(see Article 8)* **to** a **beneficiary** in an EU Member State (or H2020 associated country).

Examples:

A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work Programme.*
A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.*
A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
They may each claim 120 person-months (for their own staff).

Partner organisations are not beneficiaries and therefore can NOT declare costs; their costs are covered by the unit costs paid to the beneficiary that hosted the seconded staff member from the partner organisation.

During a secondment to a partner organisation, the beneficiaries remain solely and fully responsible for the implementation of the action in accordance with the GA *(see Article 8)*.

If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded from both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation to two or more participating organisations in a RISE project (— as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must also be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert '5.47' as number of person-months.*

⚠ Beneficiaries may NOT declare more than 12 person-months per seconded staff member. (Person-months exceeding this number will be rejected by the Agency.)

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers**:

- research, training and networking costs, i.e.:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[103] costs (i.e. the beneficiary's additional costs in connection with the action).

Budget flexibility — Since MSCA-RISE uses unit costs, there is some flexibility as regards the *use* of the amounts received:

- The unit cost for research, training and networking should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes, *for instance to cover travel and subsistence costs of a staff member or to organise additional training activities*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to cover travel and subsistence costs of a staff member*.

  Re-distributions of management and indirect costs within the consortium are allowed, but should be done via an internal agreement and should roughly correspond to the actual division of (management) tasks within the consortium.

  Management and indirect costs should also be shared with partner organisations which incurred management or indirect costs for secondments (see Article 8).

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[104] and set out in Annex 2 and 2a of the GA (currently:

- for research, training and networking costs: **EUR 1800** per researcher per month ('person-month')
- for management and indirect costs: **EUR 700** per person-month (For beneficiaries that already receive an EU/Euratom operating grant[105], this amount will be halved, i.e. EUR 350)).

In practice the declaration of institutional costs for MSCA grants is completely automatised because the IT system automatically calculates them on the basis of the number of person-months declared for the costs for seconded staff.

[103] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[104] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[105] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

1.3 The eligibility of the institutional costs is directly linked to and conditional on the **eligibility** of the costs for seconded staff.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if all the eligibility conditions for seconded staff are met. Person-months which are not eligible for the budget category 'costs for seconded staff' are also not eligible for the budget category 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the costs for seconded staff)

⚠ **Budget flexibility** — Even if the consortium re-distributes parts of the institutional unit costs, the reporting is always based on the person-months implemented by the beneficiary.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, management and indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement do not apply.

Specific cases (third parties involved in the action):

Partner organisations — MSCA-COFUND allow nevertheless for the involvement of partner organisations (i.e. organisations that are not beneficiaries, but that participate in the exchanges by seconding and hosting staff).

The beneficiaries remain **fully responsible** for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

Partner organisations are not explicitly mentioned as third parties in the GA, since no additional costs arise for the action. Their costs are covered by the unit costs paid to the beneficiaries.

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

Coordination and administration tasks are considered **action tasks**.

Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities*)

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these procedures end).

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations — For secondments from partner organisations, it is the beneficiary that must keep the documents for the staff of the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term review meeting**' between the beneficiaries, the partner organisation(s) and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1) and
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — **after each year except if a periodic report is due** (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform the project officer about progress on the action.

How? The report must be prepared and submitted directly in the Participant Portal *(see Article 52*).

2. Deliverable: Mid-term review meeting

What & When? The coordinator must — **before** the deadline for the **periodic report for RP 1** — organise a mid-term review meeting.

3. Deliverable: Researcher declaration

What? The beneficiary must send to the Agency a document with information about each seconded staff member ('researcher declaration').

It is important to give correct and complete information. (This information will be used to determine the eligibility of the person-months that are declared.)

When? The researcher declaration must be submitted within **20 days from the start of the secondment**.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — (and indicate each split).

> ***Example:*** *Beneficiary A is sending Mr X to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (an updated one within 20 days from the start date of each secondment).

> ***Example:*** *Beneficiary A is sending Mr X to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declaration must be prepared and submitted directly in the Participant Portal *(see Article 52*).

Specific case (deliverables):

Researcher declaration for staff of the partner organisations — For secondments from partner organisations, it is the beneficiary that must submit the researcher declaration.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA):*

The beneficiaries must give the seconded staff members access to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that the **partner organisations** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are obviously accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary or partner organisation) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)
- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there
- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme
- Ensure that the staff members are seconded **full-time**
- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[106].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*
- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

  They can be:

  - paid directly to the seconded staff member in advance or via different instalments or
  - managed centrally by the beneficiary according to the specific needs of the secondment.

[106] Available at https://www.iprhelpdesk.eu/.

⚠ The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Best practice: It is strongly recommended that the beneficiaries establish internal arrangements *(e.g. partnership agreements)* with the partner organisations, to ensure that they fulfil their obligations *(see Article 8)*.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract, some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)* addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This

allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MGA MSCA-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-COFUND

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO re-distribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are all linked to the *same* person-months declared for the recruited researchers. (It is therefore technically not possible to move budgeted amounts from one budget category to another.)

⚠ **Budget flexibility** — Since MSCA-COFUND uses unit costs; there is however some flexibility as regards the *use* of the amounts received:

- The unit cost for the recruited researchers (i.e. living allowance) must be fully used for the researchers (the unit cost covers only a part of the minimum remuneration that must be paid to them; *see Articles 6 and 15*).
- The unit costs for management should be used for the management of the action, but unused amounts may also be used for other action-related purposes, *for example, to increase the salary of the researchers*.

  Management costs should be shared with partner organisations which incurred management or indirect costs for secondments *(see Article 8)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in programmes implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**);

(b) for **costs of providing financial support to costs for researchers in programmes implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Commission Decision C(2013) 8194[107].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities ('person-months'); they cannot be changed.

The conditions for eligibility are set out in *Article 6*.

[107] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA applies only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Moreover, the **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions applicable *per cost form* (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions applicable *per budget category (see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **conditions for eligibility** and rules for **cost calculation**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- conditions for eligibility
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in programmes implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in programmes implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Costs for researchers: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme) (by providing for:

- a monthly living allowance to cover the employment or fixed-amount fellowship (with social security coverage, including compulsory deductions under national law, i.e. gross amount)).

Budget flexibility — There is NO flexibility as regards the *use* of the unit cost for the recruited researchers (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs are not covered. Thus, management costs are covered under the other budget category ('management costs'; *see Article 6.2.B*). Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are not eligible under the grant; they may be funded through other EU funding programmes.

For more information on how to combine EU funding from different programmes ('complementary EU funding' or 'synergies'), *see the Online Manual.*

1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8194[108] and set out in Annex 2 and 2a of the GA (currently:

- for the living allowance:
  - for early-stage researchers ('ESRs') in doctoral programmes: EUR 3 710 per researcher per month ('person-month')
  - for experienced researchers ('ERs') in fellowship programmes: EUR 5 250 per person-month).

Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is **EUR 1 855/2 625**.

For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of the call.*

[108] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be demonstrably linked to the implementation of the action (including its duration), identifiable and verifiable etc.; *see Article 6.1*)
- fulfil the **additional cost eligibility conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert '20.5' as number of person-months.*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** only the:

- management costs (i.e. direct costs of managing the action).

Budget flexibility — Since MSCA-COFUND uses unit costs, there is some flexibility as regards the *use* of the amounts received:

- The unit cost for management should be used for the management of the action, but unused amounts may be used for other action-related purposes, *for example, to increase the salary of the researchers*.

  Management costs should be shared with partner organisations which incurred management or indirect costs for secondments or for the implementation of programmes *(see Article 8)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER EU funding programmes.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8194[109] and set out in Annex 2 and 2a of the GA (currently:

- for management costs: EUR 650 per researcher per month ('person-month')).

Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is **EUR 325**.

For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher cost.

1.3 The eligibility of the management costs is directly linked to and conditional on the **eligibility** of the costs for researchers.

Management costs are eligible only if all the eligibility conditions for the researchers are met. Person-months which are not eligible for the budget category 'costs for researchers' are also not eligible for the budget category 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

- for the management costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

[109] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

Not applicable

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement do not apply.

Specific cases (third parties involved in the action):

Partner organisations —MSCA-COFUND allows nevertheless for the involvement of partner organisations (i.e. organisations that are not beneficiaries, but that participate in the action either:

- by implementing a doctoral or fellowship programme (i.e. recruiting the researchers)
- by providing training and hosting researchers during a secondment) *(see Article 15)*.

The beneficiary remains **fully responsible** for the implementation of the action in accordance with the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should establish internal arrangements *(e.g. partnership agreements)* with partner organisations.

Partner organisations are not explicitly mentioned as third parties in the GA, since no additional costs arise for the action. Their costs are covered by the unit costs paid to the beneficiary.

Partner organisations that *implement* a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *Main Work Programme*. *Other* partner organisations can be established anywhere.

Partner organisations that implement a doctoral or fellowship programme and are established in a third country must recruit researchers that are nationals or long-term residents of a EU Member State (or H2020 associated country) *(see Article 15.1.1(b))*.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF *[DOCTORAL] [FELLOWSHIP]* PROGRAMMES

15.1 Rules for providing financial support to or implementation of *[doctoral][fellowship]* programmes

15.1.1 The beneficiary must **implement *[doctoral][fellowship]* programmes** or **provide financial support** to such programmes implemented by partner organisations, in accordance with the following conditions:

(a) **types of programmes**:

[OPTION for DPs: *The programmes must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programmes**');**]***

[OPTION for FPs: *The programmes must concern fellowships for research training activities for recruited researchers ('**fellowship programmes**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country, the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programmes:

[OPTION for DPs: *The doctoral programmes must support researchers, who — at the time of recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION for FPs: *The fellowship programmes must support researchers, who — at the time of recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — in this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately prior to the recruitment, unless otherwise specified in Annex 1 for existing programmes;*
- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1. **]***

Researchers that are already permanently employed by the entity where the research training activities take place and that is recruiting them may not be supported.

(c) **procedure and criteria for selecting researchers** in the programmes:

[OPTION for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

Selection committees must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(d) **conditions for the recruitment** of researchers under the programmes:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[7] and ensure that the researchers are aware of them;

- ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;

- ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);

- ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;

- ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
- ensure that researchers work exclusively on the research training activities;
- ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
- ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
- ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
- ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of foreground, promoting the action) — during the research training activities and afterwards;
- inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;
- in case of third parties implementing the programmes: ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards those third parties;

[OPTIONS for DPs:

- *ensure gender balance in the recruited researchers;*
- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[7] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing doctoral/fellowship programmes

MSCA-COFUND provides support both for programmes implemented by the beneficiary itself or programmes of partner organisations which the beneficiary funds by providing financial support.

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisations that implement doctoral/fellowship programmes (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Types of programmes — Categories of persons

The beneficiary/partner organisation must implement the following **types of** research training **programmes** supporting transnational mobility:

- doctoral programmes (DP), i.e. programmes with research training activities for recruited early-stage researchers that lead to the award of a doctoral degree

  The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programmes (FP), i.e. programmes with fellowships for recruited experienced researchers.

The **researchers** must — at the date of recruitment —:

- be one of the following two:
  - **early-stage researchers** ('ESRs'; i.e. not have a doctoral degree and be in the first four years (full-time-equivalent research experience) of their research career) or
  - **experienced researchers** ('ERs'; i.e. have a doctoral degree or have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted as full-time-equivalent research experience, from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than 12 months in the three years immediately prior to the recruitment date (unless Annex 1 to the GA specifies otherwise for already existing programmes or the beneficiary/partner organisation is an 'international European interest organisation'[110] for whom the mobility rule is limited to time spent *with* them).

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

  For refugees under the Geneva Convention[111], the refugee procedure (i.e. before refugee status is conferred) will not be counted as 'period of residence/activity in the country of the beneficiary'.

[110] For the definition, *see Article 2.1(12) of the Rules for Participation:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[111] 1951 Refugee Convention and the 1967 Protocol.

- if the programme is implemented by a partner organisation established in a third country or if a secondment to such an organisation constitutes the *main* part of the research training activities: be nationals or **long-term residents** of a EU Member State (or H2020 associated country).

  'Long-term resident' normally means full-time research activity in a EU Member State (or associated country) for five or more consecutive years. (The Agency may however, exceptionally accept a different definition, if it is linked to long-term residence and justified in the proposal).

  'Full-time research activity' is measured from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  Short secondments are possible also for researchers that are not nationals or long-term residents.

3. Additional eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[112]*)*.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a maximum of 4 fixed deadlines or regular cut-off dates per year) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

4. Additional eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits

[112] Available at http://ec.europa.eu/euraxess/.

- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries/partner organisations may offer a **'fixed-amount fellowship agreement**' with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the researcher unit costs will be reduced by 50%.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum monthly remuneration** (including salary, social security contributions, taxes and other costs included in the remuneration) of:

- for early-stage researchers (doctoral programmes); EUR 2 597
- for experienced researchers (fellowship programmes): EUR 3 675.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 298,50; for experienced researchers EUR 1 837,50).

⚠ Since the MSCA-COFUND grant reimburses 50% of the unit cost for the researchers (i.e. EUR 1 855/EUR 2 625), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 742/1050** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral programme/fellowship — the average monthly remuneration (over the duration of the doctoral programme/fellowship) respects the minimum remuneration.

Amounts must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: costs must be converted into euro at the average of the daily exchange rates published over the doctoral programme/fellowship duration, as reported on the ECB website[113]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the fellowship period, using the currency converter on the Commission's website[114].

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

5. 'Other obligations'

In addition to the additional cost eligibility conditions in *Article 15.1.1,* the beneficiary/partner organisation must comply with the following 'other obligations':

[113] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[114] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

- the researchers must:
  - be **employed full-time**

    This also means that a researcher can NOT hold two MSCA grants at the same time.
  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* are not incompatible, but must not jeopardise the implementation of the research training activities.
  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency
- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[115].
- for doctoral programmes: the beneficiary/partner organisation must
  - ensure **gender balance** regarding the recruited researchers
  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career plan.

[115] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 15* were complied with
  - the minimum remuneration was paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least five years after the balance is paid (three years for grants up to EUR 60 000) or longer if:

- national laws foresee longer document retention periods *(e.g. for tax or social security purposes)*
- there are ongoing procedures *(such as audits, investigations or litigation)*. (In this case the evidence must be kept until these procedures end.)

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the full risk of rejection by the Agency.

Specific case (record-keeping):

Documents for programmes implemented by partner organisations —For programmes implemented by partner organisations, it is the beneficiary that must keep the documents also for the partner organisations.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit:

- a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What and When? The beneficiary must send to the Agency a document with information about each recruited researcher ('researcher declaration') — within **20 days** of the start of the research training activities (of the researcher).

It is important to give correct and complete information since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units.

How? The researcher declaration must be prepared and submitted directly in the Participant Portal *(see Article 52)*.

2. No deliverable: Mid-term review meeting

For MSCA-COFUND, the Agency will organise a mid-term review meeting (to monitor implementation of the action in the light of the schedule in Annex 1). The mid-term review is therefore not a deliverable, as in other types of MSCA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (by the beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major media impact*, but before any activity expected to have *mainstream media coverage* (i.e. coverage in any forms of media *(e.g. print, TV, radio and electronic)*

addressing a non-specialist, non-scientific audience (*e.g. local, regional or national news)*. (This allows the Agency to ensure maximum publicity and to disseminate the coverage further through social media, news updates, etc.).

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must however make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA SME Ph1 deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 MGA SME Ph 2 deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 MGA SME Ph1, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 MGA SME Ph1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 funds:

- the feasibility study for an innovation idea (i.e. a ‘proof of concept’ or ‘business plan’ for new, altered or improved product, process or service).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-1-2014)*.

For more information on SME Instrument Ph1 actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph 1 MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph 1 MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Commission Decision C(2013) 8198[116].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The conditions for eligibility are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the feasibility study. NO other costs will be reimbursed.

[116] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to breach of obligations other than improper implementation — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to breaches of 'other obligations'; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **cost calculation**.

2. Costs for the feasibility study: Types of costs — Cost form — Conditions for eligibility — Cost calculation

2.1 What? The budget category 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Commission Decision C(2013) 8198[117] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **cost calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[117] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be *rejected* proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, if 'other obligations' have been breached *(e.g. other provisions of the GA or provisions of EU, international and national law are not complied with)*, the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

> ⚠ The costs of purchases and subcontracts are ALL covered by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12 H2020 General MGA) and linked third parties (Article 14 H2020 General MGA) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2004/18/EC, 2004/17/EC or Directive 2009/81/EC and the national legislation implementing them (— or any EU legislation that replaces these Directives[118]).

Moreover, the obligations in Article 10.1 are NOT considered to be additional eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[118] *See Directives 2014/24/EU and 2014/25/EU.*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2004/18/EC, 2004/17/EC or Directive 2009/81/EC and the national legislation implementing them (— or any EU legislation that replaces these Directives[119]).

Finally, the obligations in Article 13.1 are NOT considered to be additional eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[119] *See Directives 2014/24/EC and 2014/25/EC.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency responsibility — Agency right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (by the beneficiaries) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submit to the Agency in good time any documents or information required by it

and may not subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ A 'rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality (e.g. does not permit to assess the quality and potential of the innovation idea), ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if an obligation under the Agreement (other than improper implementation of the action as described in Annex 1) has been breached

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify confirmation of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced if 'other obligations' have been breached *(e.g. another obligation under the GA or applicable EU, international and national law; see Article 43 H2020 General MGA)*.

⚠ A 'reduction of the grant' is possible for **any breach of obligation other than proper implementation** (under the GA or applicable EU, international and national law; *see Article 7)*.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) the beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. Termination of the Agreement or of the participation of one or more beneficiaries (by the Agency)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 MGA SME Ph2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: 'Innovation in SMEs' (*e.g. H2020-SMEINST-2-2014*).

For more information on SME Instrument Ph2 actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) *for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost under Point (f))]*[8]: ***[OPTION to be used if Article 15 applies:** as actually incurred costs (**actual costs**);**][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[10]: on the basis of a flat-rate of 25% of the eligible direct costs, from which are excluded the costs set out in Article 6, Point E ('**flat-rate costs**')*[;][.]*

(f) ***[OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): for [insert name of specific cost category(ies)***[11]*]:on the basis of the amount(s) per unit set out in Annex 2*[12] ***(unit costs).]***

[OPTION: specific cost category(ies):** not applicable.**]

[6] To be used only if option in Point (f) is used.
[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used
[11] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures';, 'costs for clinical studies'; 'costs for energy efficiency measures in buildings'.
[12] Annex 2 must clearly show, for the beneficiary (and each linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the Main Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs****: [insert name(s) of specific cost category(ies)]]****[OPTION:*** *not applicable]*.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **conditions for eligibility** and rules for **cost calculation** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are not, by definition, 'non-profit legal entities', they can NOT declare additional remuneration (as part of the 'personnel costs – costs for employees (or equivalent)'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.' **]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[24] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [25].**]***

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').***]**

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).***]**

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[24] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[25] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Participant Portal messages function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage), OR
- OR refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the 'simplified approval procedure: there is' NO assessment (and therefore full risk).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as for the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be adapted to reflect the action duration. Thus, if considered necessary, SME Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 MGA ERA-NET Cofund deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 MGA ERA-NET Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are 'research funders' and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-NMP-ERA-NET-2015)*.

For more information on ERA-NET Cofund actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action**: [insert date]]*[7] ('starting date of the action').

[4] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). Normally, the action's duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment, to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

2. Reimbursement rate

How much? For ERA-NET Cofund actions, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - direct costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (— unless declared as unit cost)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects
- **unit costs** for:
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices ('**average personnel costs**')
  - direct **coordination costs** for additional activities[120]
- **flat-rate costs** for:
  - **indirect costs**.

[120] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **cost calculation** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[7]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.**]***

[OPTION to be used if foreseen in the work programme: *Not applicable.**]***

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Direct costs related to trans-national projects: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 The beneficiaries may declare the following **types of costs** as 'direct costs related to trans-national projects':

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)

    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment
    - other goods and services
    - costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc). Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs — except direct personnel costs — must be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may be declared as unit cost in accordance with the usual cost accounting practices (i.e. 'average personnel costs').

1.3 In principle, the same **conditions for eligibility** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the **following specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same rules for **cost calculation** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Direct coordination costs of additional activities: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** the costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also* Article 2*)*.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Commission Decision C(2013) 8200[121] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the general conditions for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the additional activities described in Annex 1.

Coordination costs for additional activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare coordination costs for additional activities.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[121] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is however ONLY allowed for **beneficiaries that implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be trans-national projects, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.3);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and
- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

3. Additional eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

4. Additional eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection ('**joint selection list**') on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report (see Article 20.3).

5. Additional eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

6. Additional eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

Example: *data on each participant and abstracts of the proposals.*

The beneficiaries will be contacted about the format to be used and details on how to submit the deliverables.

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

Example: *data on each participant and an overview of the results*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.3 Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a **periodic technical report**, with information on the technical implementation.

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a 'statement on the use of the previous pre-financing instalment' (which includes also the request for further pre-financing payments; *see Annex 7*).

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)

- ranking list of the projects
- observers' report on the evaluation
- joint selection list
- 'commitment on availability of funds' (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8)

At the end of the action, the coordinator has to submit a **final report**, with both the technical and financial report.

2. Reporting periods

When? ERA-NET Cofund actions are normally divided into two reporting periods with two pre-financing payments (or exceptionally three reporting periods with three pre-financing payments, if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions will normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5 % of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

ERA-NET Cofund actions normally are divided into two reporting periods *(see Article 20.2)* with two pre-financing payments (— unless the action is exceptionally divided into three reporting periods with three pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

> The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first (or second) pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- the first pre-financing payment is 10 % of the maximum grant amount *(see Article 5.1)*
- the second pre-financing payment is 80 % of the maximum grant amount.

If the GA provides for a third pre-financing payment, then the amount is divided as follows:

- 10 % for the first pre-financing payment
- 40 % for the second pre-financing payment
- 40 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI Cofund MGA

VI.1 Background information and approach

The PCP-PPI Cofund Model Grant Agreement is used for PCP-PPI Cofund actions only.

The PCP-PPI MGA follows the General MGA for numbering and content, except for:

The H2020 MGA PCP-PPI Cofund deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI Cofund specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI Cofund specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI Cofund specific payment provisions)
- Article 23 (PCP-PPI Cofund specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation][Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI Cofund actions are added:

- Article 2 (PCP-PPI Cofund actions)
- Article 4.1 (PCP-PPI Cofund budget categories)
- Article 8 (PCP-PPI Cofund rules on third party involvement).

VI.2 H2020 MGA PCP-PPI Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI Cofund actions

What? PCP/PPI Cofund funds:

- a joint public procurement of research and development (R&D) services (PCP) or innovative solutions (PPI)

AND

- related additional coordination and networking activities.

Only one PCP or PPI per GA.

The additional activities must relate to the call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects*.

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP-PPI Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

For more information on PCP/PPI Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP-PPI Cofund MGA uses its **own budget categories**.

Budget categories of the PCP-PPI Cofund MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare 'PCP/PPI subcontracting costs'. Who pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP-PPI Cofund MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses *[**OPTION (reimbursement rate foreseen in the work programme)**: [**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**'), (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2*[13] ***(unit costs).]***

[OPTION: specific cost category(ies): *not applicable.**]***

[…]

[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[13] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The work programme/call *(see General Annex D to the Main Work Programme)* sets the reimbursement rate currently at:

- **70%** for PCP Cofund actions
- **20 %** for PPI Cofund actions.

2. Cost forms

The PCP-PPI Cofund MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The PCP-PPI Cofund MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **conditions for eligibility** and rules for **cost calculation** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. Direct costs of PCP/PPI subcontracting: Types of costs — Cost form — Conditions for eligibility — Cost calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP-PPI Cofund actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the general conditions for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the PCP/PPI subcontracting described in Annex 1
- fulfil the additional cost eligibility conditions set out in Article 13.1.1.

1.4 There is no specific **cost calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[15]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[16] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

    The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

  and

  - the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** ***[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[17]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[18] ***[OPTION by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the Horizon 2020 Grant Agreements.****]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable.****]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5][****OPTION****: not applicable****]****.*

Beneficiaries receiving an operating grant[20] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

B.5 ***[OPTION: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION for specific unit costs, if foreseen by Commission decision and applicable to the grant: [Insert name of specific cost category[21] *] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, [and if [insert additional eligibility conditions if any]].*

[*same for each specific cost category****]***

[OPTION: *Not applicable****]***

[…]

[15] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[16] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[17] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[18] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[19] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[20] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[21] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Costs of related additional coordination and networking activities: Types of costs —Cost form — Conditions for eligibility — Cost calculation

1.1 The beneficiaries may declare the following **types of costs** as 'costs of related additional coordination and networking activities':

- direct personnel costs for related additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for related additional coordination and networking activities
- other direct costs for related additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and

  - costs of large research infrastructure
- indirect costs for related additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs — except direct personnel costs and personnel costs of SME owners or of beneficiaries that are natural persons not receiving a salary — must be **declared as** actual costs.

Direct personnel costs may be declared as unit cost in accordance with the usual cost accounting practices (i.e. 'average personnel costs').

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary must be declared on the basis of the unit cost fixed by Commission Decision C(2013) 8197[122] and set out in Annex 2 and 2a of the GA.

This concerns only beneficiaries that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **conditions for eligibility** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI Cofund MGA has however the **following specificities**:

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.

Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

Costs for validation and testing of solutions provided by the subcontractors.

1.4 The same rules for **cost calculation** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the Main Work Programme, the costs of related additional coordination and networking activities are eligible up to a maximum amount of 30/50% of the total requested grant amount (for PCP/PPI actions). (For each GA, this maximum amount is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for related additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).)

[122] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

Certain **third party resources** (i.e. purchasing of goods, works or services *(Article 10)*, in-kind contributions *(Articles 11 and 12)*) are however ONLY allowed for **related additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, subcontracting (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities. Linked third parties (Article 14) can be part of the buyers group for subcontracting.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[25] and 2004/17/EC[26].

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('****place of performance obligation****').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**' (drawn up in accordance with Annex 8), which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17[28];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** (drawn up in accordance with Annex 9) inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' (drawn up in accordance with Annex 10) which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'* ***]***

[25] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[28] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

1. PCP subcontracting

In PCP Cofund actions, the beneficiaries award PCP subcontracts for research and development services ('PCP R&D services') that are necessary to address a 'common challenge' set out in Annex 1. ('PCP subcontract' thus means a contract for the purchase of R&D services that is identified in Annex 1 as action task.)

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries (and linked third parties) ('buyers group'), with a joint procurement in 3 phases

  The '**buyers group**' is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI Cofund actions, it must normally be made up of:

  - a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2004/18/EC and 2004/17/EC[123] — or any EU legislation that replaces these Directives[124])

    Any entity that fits the definition of a 'contracting authority' or 'contracting entity' as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI Cofund actions.*

  - that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the Main Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the Main Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

  - beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
  - third parties providing in-kind contributions

[123] Directive 2009/81/EC uses the definitions of Directives 2004/17/EC and 2004/18/EC *(see Article 1(17) of Directive 2009/81/EC)*.

[124] *See Directives 2014/24/EU and 2014/25/EU.*

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in **3 phases**.

The buyers group must select multiple competing subcontractors (with a minimum of three subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum two subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a '**common challenge**' (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

  The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

  If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

  The procurement must be for an 'R&D services contract' (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

  If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

  Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done*.

  This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[125]).

  Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement ('**common jointly-committed budget**')

  This budget is based on the financial commitments of the beneficiaries in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary ('**lead procurer**')

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is not part of the buyers group).

  Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[126]).

[125] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.
- **Subcontracts implemented** by the selected subcontractors ('PCP implementation')
- **Subcontractors paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP Cofund actions).

There can only be one PCP per PCP Cofund action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*).

For PCP subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

[126] *See Directives 2014/24/EU and 2014/25/EU.*

4. Additional eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 respectively phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*
  - the procurement must be preceded by an '**open market consultation**'

    This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2004/17/EC and 2004/18/EC (or any EU legislation that replaces these Directives[127]).

    A prior information notice (PIN) must be published in the *Official Journal of European Union (OJEU)* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.
  - the procurement must be based on '**common procurement specifications**' prepared by the buyers group and the lead procurer

[127] *See Directives 2014/24/EC and 2014/25/EC.*

These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more information on the tender documents*, see the Guidance — How to complete your simap forms for PCPs and the template for PCP request for tenders.*

The template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions laid down in the grant agreement and it contains at least the information detailed in the template.

5. Additional eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontactors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries ('place of performance obligation')

  - additional national requirements, ethical and/or security requirements (if applicable)

- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions - and without the right to sub-licence
  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments.)

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2004/17/EC, 2004/18/EC and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[128]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2004/18/EC and 2004/17/EC[129] — or any EU legislation that replaces these Directives[130]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[128] *See Article 16(f) of Directive 2004/18/EC (Article 14 of Directive 2014/24/EU), Article 24(e) of Directive 2004/17/EC (Article 32 of Directive 2014/25/EU) and Article 13(f)(j) of Directive 2009/81/EC.*

[129] Directive 2009/81/EC uses the definitions of Directives 2004/17/EC and 2004/18/EC *(see Article 1(17) of Directive 2009/81/EC)*.

[130] *See Directive 2014/24/EU and Directive 2014/25/EU.*

[OPTION for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' within the meaning of Directives 2004/18/EC[29], 2004/17/EC[30].

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION for PPI Cofund actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP Cofund action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in accordance with Annex 7 in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION for PPI Cofund actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP cofund action:

*(i) **Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group),*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders** (drawn up in accordance with Annex 9).*

*(ii) **Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION for PPI Cofund actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC and 2004/17/EC[32] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

29 Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114)..

30 Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

32 See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

1. PPI subcontracting

For PPI Cofund actions, the beneficiaries award PPI subcontracts for procuring the innovative solutions ('PPI innovative solution(s)') necessary to address the 'common challenge' set out in Annex 1. ('PPI subcontract' thus means a contract for the purchase of innovative solutions that is identified in Annex 1 as an action task.)

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the **following specificities**:

There is no requirement to split the PPI procurement procedure in phases.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer ('early adopter') of innovative solutions that are not yet available on a large-scale commercial basis.

> PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.
>
> Each PPI Cofund action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional 'local' functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement ('**common jointly-committed budget**') only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

> The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).
>
> The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.
>
> If there is no mandate, the general rule is that:
>
> - framework agreement(s) must be signed by all members of the buyers group together
> - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI Cofund actions).

There can be only one PPI, per PPI Cofund action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid (or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation))*.

For PPI subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an '**open market consultation**' (— unless the PPI is limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement 2004/17/EC and 2004/18/EC.

    A prior information notice (PIN) must be published in the *Official Journal of the European Union* and must be promoted widely, in particular via the websites specified by the Commission/Agency and the National Contact Points (NCPs) for Horizon 2020.

    The PIN must contain information on:

    - the expected launch date for the call for tender

      This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

  - whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**'

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products *resulting from a previous PCP Cofund action* carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP Cofund action) suffices.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

For more information on the tender documents, *see the Guidance — How to complete your simap forms for PPIs*.

The template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions laid down in the grant agreement and it contains at least the information detailed in the template.

4. Additional eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI

  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions (e.g. regarding access to background, licensing etc.) if these:

    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2004/17/EC, 2004/18/EC and 2009/81/EC (— or any EU legislation that replaces these Directives[131]) normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2004/18/EC and 2004/17/EC[132]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[131] *See Directives 2014/24/EU and 2014/25/EU.*

[132] Directive 2009/81/EC uses the definitions of Directives 2004/17/EC and 2004/18/EC *(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[35]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified deliverables:** Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[35] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
  - (i) **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
  - (ii) **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
  - *(iii)* ***[OPTION for PCP: assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (not applicable to the initial evaluation of tenders at the start of the PCP);****]***
- ***[OPTION by default (two pre-financing payments):*** *the coordinator must submit in month [****Y****] a progress report containing:*
  - *a '****periodic summary technical report****' for publication by the [Commission][Agency];*
  - *an* ***overview of the progress*** *towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **<u>information on each subcontract financed by the procurement</u>**, including data on each contractor that participated in the procurement, an overview of the results for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the initial tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[****OPTION for PCP:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[****OPTION for PPI:*** *at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What?

For PCP-PPI Cofund actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency:

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

The beneficiaries will be contacted about the format to be used and details on how to submit the deliverables.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (together with data on each contractor that participated in the procurement and overview of the results).

How?

The information must be submitted via in the Participant Portal *(see Article 52*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[47]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[48]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.3 <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 11), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 12), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing instalment** (see Annex 8), including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

[47] Month X should be the end of the preparation phase and submission of second pre-financing request.

[48] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP-PPI Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are three pre-financing payments, also after the second reporting period) — a **periodic technical report** with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a 'statement on the use of the previous pre-financing instalment' (which includes also the request for further pre-financing payments; *see Annex 12*)

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

2. Reporting periods

Normally, PCP-PPI Cofund actions are divided into two reporting periods (with two pre-financing payments; *see Article 21*). The first reporting period corresponds to the action's preparation stage (preparation of the joint procurement); the second reporting period corresponds to the action's execution stage (execution and follow-up of the joint procurement).

Actions will exceptionally be divided into three reporting periods (with three pre-financing payments), if the Commission/Agency has insufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are two pre-financing payments, also the second) reporting period triggers a periodic report.

3. Periodic reports: Call for tender documents — Report on the outcome of the preparation phase — Commitment on availability of resources — Statement on the use of the previous pre-financing instalment — Request for a further pre-financing payment

The coordinator must submit — as part of the periodic report —:

- the call for tender documents and
- a report on the outcome of the preparation phase.

In addition, the periodic report must include:

- for each member of the buyers group: a formal and signed commitment on availability of resources needed to pay the subcontracts *(see Annex 11)*

  This ensures that the PCP/PPI subcontracting costs are covered.

- a 'statement on use of the previous pre-financing instalment *(see Annex 12)*.

  This statement includes the request for a further pre-financing payment (only the first pre-financing payment is automatic).

  It is moreover used to calculate the amount of the next pre-financing payment *(see Article 21)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP-PPI Cofund actions are divided into two reporting periods *(see Article 20.2)* with two pre-financing payments (— unless the action is exceptionally divided into three reporting periods with three pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first (or second) pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? Typically, the amounts of the pre-financing payments for PCP-PPI Cofund actions are as follows:

- the first pre-financing payment amounts to the percentage of the maximum grant amount *(see Article 5.1)* that is foreseen for the related additional networking and coordination activities related to the preparation of the call for tender
- the second pre-financing payment is a maximum of 90% (general limit for pre-financing payments; *see Article 21.2 H2020 General MGA*) minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP-PPI Cofund actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP Cofund actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 MGA EJP Cofund deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 MGA EJP Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of the H2020 Framework Programme and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General work programmes and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[7] ('**starting date of the action**').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the duration; *see Article 55*). The action's duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

Thus, the EJP Cofund MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure.

By contrast, for the FEJP action, there are three specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2*[15] *(**unit costs**).]***

[OPTION: specific cost category(ies)**: not applicable]

[…]

[8] This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] To be used only if option in Point (f) is used.
[13] To be used only if option in Point (f) is used.
[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund actions, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[133].

2. Cost forms

For EJP Cofund actions, the **cost forms** are the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however three specific unit costs as 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [134]

For this action, these unit costs replace the 'specific cost categories' of the General MGA *(e.g. access costs for providing trans-national access to research infrastructures, costs of energy efficiency measures in buildings; see Article 5 H2020 General MGA)*.

[133] *See Article 28(5) of the Rules for Participation.*
[134] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable;*]**
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[17]***][OPTION: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[17] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **conditions for eligibility** and rules for **cost calculation** apply *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will be limited to this additional equipment cost option (Article 6.2.D.2) and the specific cost categories (Article 6.2.F) and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. conditions for eligibility
4. how the costs must be calculated.

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

1. Equipment costs: Types of costs — Cost form — Conditions for eligibility — Cost calculation

This budget category applies to all to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** as 'other direct costs - equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional cost eligibility conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **cost calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. *[OPTION: [Insert name of specific cost category(ies)]][OPTION if no specific cost categories applicable to grant: Specific cost category(ies)]*

[OPTION for specific unit costs (unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[23]] *are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION: *not applicable****]***

[…]

[23] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories: Types of costs — Cost form — Conditions for eligibility — Cost calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the the Fusion programme EJP Cofund action (FEJP), the specific cost categories will be replaced by the three categories set out in Commission Decision C(2013) 8201[135]:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

⚠ Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 'Specific cost category – costs for mobility of personnel'

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment (by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance).

[135] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared** on the basis of the unit costs fixed by Commission Decision C(2013) 8201[136] and set out in Annexes 2 and 2a of the GA (currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

  This amount is subject to a '**country-specific correction coefficient**' for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[137]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.4	Sweden	131.9

[136] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[137] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto.

Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) will be applied as from 1 January 2016. The FEJP GA will be amended and the Annotated MGA will be updated accordingly.

– for the monthly subsistence allowance: between **EUR 0 and 720.27** per individual per month — depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1 300	**601.73**
> 2 000	**720.27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 258.81**, per dependent child per month).

The Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this event, the FEJP GA will be amended and the Annotated MGA will be revised accordingly.

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Commission Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and

- one of the following:
  - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
  - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
  - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

– the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment

– to this amount, add the following for each leg of the journey (outward and return):

– for train travel: a maximum of 30 minutes for each leg

– for air travel: a maximum of 2 hours for each leg.

NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

– for the monthly subsistence allowance:

amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

– for the family allowance:

amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

'**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

A 'full month' can be one of the following two:

– a **calendar month** *(e.g. 1 to 31 July inclusive)* or

- a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*

*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*

Subtotal = EUR 85 697.25

** correction coefficient of 106.4 % (Germany Munich) = EUR 91 181.87*

*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*

Total declared unit costs: EUR 96 238.07

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*

** correction coefficient of 112.5 % (Culham, UK) = EUR 430.82*

Total declared unit costs: EUR 430.82

1.2 'Specific cost category – costs for fellowships for researchers'

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships (by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility).

What not? This budget category does not cover the salary costs of the fellows, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'direct personnel costs' or 'other direct costs'; Article 6.2.A, 6.2.D).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.2.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8201[138] and set out in Annexes 2 and 2a of the GA (currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions)[139]:

[138] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[139] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%
Finland	116.6%	Slovenia	86.1%
France	111.0%	Slovakia	82.6%
Croatia	97.5%	United Kingdom	120.3%
Hungary	76.2%		
Ireland	113.5%	Switzerland	113.1%

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[140]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

[140] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

- for the living allowance:

  amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

- for the mobility allowance:

  amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

- for the family allowance:

  amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 'Specific category – access costs for research infrastructure'

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below*).

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, as 'other direct costs'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be declared on the basis of the **unit cost** calculated in accordance with Decision C(2013) 8201[141] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

[141] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{142})}{\text{average annual total quantity of access (over past two years}^{143})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 to the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users

    Exceptionally, these costs may be those calculated in accordance with the beneficiary's usual cost accounting practices (i.e. 'average personnel costs').
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

[142] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[143] In exceptional and duly justified cases, the Commission may agree to a different reference period.

As already mentioned above, access costs for installations contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. 'other direct costs'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **conditions for eligibility**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What?

For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How?

The annual work plan must be submitted through the Participant Portal.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the 'explanation of the work carried out' and the 'overview of the progress'; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing instalment****' (see Annex 8).****]***

[OPTION: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **five** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing instalment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a 'statement on the use of the first pre-financing payment' *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION in case of a single pre-financing payment:*** *5%]**[OPTION in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

Example 1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

Example1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU funds)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not (yet) open to ERANET, PCP-PPI, EJP, ERC, MSCA or SME Instrument specific actions.

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

For more information on framework partnerships, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission'[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name**] (**short name**)legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties have agreed to enter into the Framework Partnership Agreement under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Coordinator — Partners

The '**partners**' are the legal entities that have signed a framework partnership with the Commission/Agency.

Once an SGA is signed, the partners also become 'beneficiaries' (i.e. a 'participant'[144] in an action supported by a grant).

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. However, partners that do not want to actively participate in a specific action, may participate as '**partners not carrying out action tasks**' (for that Specific Agreement and will not have to comply with most of the obligations under that SGA *(see Preamble SGA)*.

Arrangements for signing the FPA are as follows:

– the coordinator signs the FPA directly

144 For the definition, *see Article 2.1(15) of the Rules for Participation*: '**participant**' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under the terms of this Regulation.

- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed electronically in Participant Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan (see Annex 1))] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across consortia of partners]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all areas of the Horizon 2020 Framework Programme.

Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2);* Framework partnerships are currently NOT (yet) open to ERANET, PCP-PPI, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

  Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 RAP).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Duration of the framework partnership

The duration of framework partnerships may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

The duration of a framework partnership cannot be extended (i.e. it is not possible to request an amendment extending the duration).

SGAs must be signed before the end of the FPA.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION:** Not applicable]*

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — specific consortium agreements for each SGA. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the *[Commission][Agency]* suspends the framework partnership implementation, all specific actions are also deemed suspended (see Article 55), from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to the suspension of action implementation *(see Article 49 H2020 General MGA)*.

Amendments after a suspension can NOT however have the effect of extending the FPA duration set out in Article 3 FPA.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. Termination of the FPA

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties**.**

⚠ Termination of the FPA has NO effect on ongoing SGAs (— unless these are also terminated; *see Article 56 FPA and Article 20 SGA*).

2. Termination of the participation of one or more partners

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ Termination of participation in the framework partnership has NO effect on ongoing SGAs (— unless these are also terminated; *see Article 56 FPA*).

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

⚠ **Same partners at FPA and SGA level** — Partners must generally be the same at FPA and SGA level. Termination of participation will however exceptionally lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners can participate as 'partners not carrying out action tasks' for certain specific actions.

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also contains the estimated costs of the partners not receiving EU funding, if applicable (see Article 6 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the specific action or to the seriousness of the breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to its improper implementation of the specific action or to the seriousness of its breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and forms of costs of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions applicable per budget category are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **conditions for eligibility** and **rules for cost calculation**.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, conditions for eligibility and rules for cost calculation of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

The third parties are normally involved in the specific actions, not in the framework partnership.

> ***Example:*** *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

However, partners must — already at FPA proposal stage — indicate if they intend to use third parties or not.

Moreover, linked third parties must be identified already in the FPA *(see Article 19 FPA)*.

> ***Example:*** *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ If a linked third party wants to participate in a specific action, its partner must also fully participate in that action (i.e. NOT be 'partner not carrying out action tasks').

If the partner does not want to, the linked third party can however itself become a partner of the FPA and SGA.

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

⚠ **Same partners at FPA and SGA level** — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must submit the request(s) for amendments.

The request for amendment must include a proposal to amend Annex 1 to the FPA and the SGAs (if necessary).

⚠ Requests for amendment of the FPA and the SGA must be made in parallel. The SGA can NOT be amended before the FPA.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'[3]),]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Specific Agreement by [function, forename and surname]

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 of the Framework Partnership Agreement and Article 62 of the Framework Partnership Agreement):

2. [**full official name**] [**short name**] [legal form] [official registration No] [official address in full] [VAT number].

***[OPTION for partners not carrying out action tasks under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number]]*

***[OPTION for partners not receiving EU funding under this Specific Agreement:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'partners not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Partners — Partners not carrying out action tasks under this SGA

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. An entity that is not party to the FPA cannot become party to the SGA. Conversely, all parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners who do not actively participate in a specific action are '**partners not carrying out action tasks**' under that Specific Agreement (and must be identified as such in the preamble to the SGA).

These partners nevertheless remain part of the consortium implementing the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will also be identified in Annex 1, but it will be specified that they do not carry out any tasks covered by the SGA.

Moreover, they will also be mentioned in Annex 2, without being associated with any costs or request for an EU contribution.

Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* are applicable also for these partners. However, most of the other obligations concerning that SGA *(e.g.*

implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc.) are NOT.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed electronically in the Participant Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including entities linked to the partners) are considered as '**third parties involved in the specific action**'.

They are not bound by the terms and conditions of the FPA or SGA; conversely, the Commission/Agency has no obligations towards them.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and in the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump sum MGA

IX.1 Background information and approach

The Lump sum Model Grant Agreement (H2020 MGA Lump sum) is used mainly for 'coordination and support actions (CSA) and (exceptionally) for 'research and innovation actions (RIA)' and 'innovation actions (IA)') — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5 Peer learning of innovation agencies*

The MGA Lump sum follows the General MGA for numbering and content, except for:

The H2020 MGA Lump sum deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)
- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5, Annexes)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 MGA lump sum: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. CSA, RIA and IA lump sum actions

What? Lump sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for a lump sum grant.

For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

CSA, RIA and IA lump sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The MGA Lump sum does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the MGA Lump sum:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION for innovation actions (IA): 70%** of the action's eligible costs]*[8] *[**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The MGA Lump sum does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The conditions for eligibility are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to breach of obligations other than improper implementation — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For lump sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For lump sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to breaches of 'other obligations'; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The MGA Lump sum has its **own budget category**, with its own **types of costs**, **conditions for eligibility** and rules for **cost calculation**.

2. Costs for the action: Types of costs — Cost form — Conditions for eligibility — Cost calculation

2.1 What? The budget category 'costs' **covers** the (direct and indirect) costs for the action.

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice the declaration of costs for lump sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **cost calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

Since the lump sum grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

⚠ If the action is not carried out as described in Annex 1, costs will be *rejected* proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, if 'other obligations' have been breached *(e.g. other provisions of the GA or provisions of EU, international and national law are not complied with)*, the grant may be *reduced (see article43_LS)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

The rules on third party involvement in lump sum actions are limited to purchases (Article 10), subcontracting (Article 13) and linked third parties (Article 14).

The provisions on in-kind contributions (Articles 11 and 12 H2020 General MGA) do NOT apply — since, for lump sum grants, in-kind contributions are not linked to any specific conditions. (Specific rules are only needed where a grant reimburses *actual* costs).

⚠ For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the costs are ALL covered by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC24[9] or 'contracting entities' within the meaning of Directive 2004/17/EC25[10] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[10] Directive 2014/17/EC of the European Parliament and of the Council of 31 March 2014 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for Lump sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for lump sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The MGA Lump sum has however the **following specificities**:

The estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[13]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[13] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For lump sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

Such records and supporting documentation must:

- refer to the scientific and technical implementation of the action in line with the accepted standards in the respective field (see article18) and

- prove that the corresponding tasks or part of the action allocated to the beneficiary as described in Annex 1 were implemented properly (see article18_2).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a **'statement on the use of the previous pre-financing instalment',** including **the request for a further pre-financing payment** (Annex 7).

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

1. Reports

When & What? For lump sum actions, the coordinator has to submit — after each reporting period — a **periodic technical report**, with information on the technical implementation.

NO financial report is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a 'statement on the use of the previous pre-financing instalment' (which includes also the request for further pre-financing payments; *see article07_LS*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

At the end of the action, the coordinator has to submit a **final report** with both the technical and financial report.

2. Reporting periods

When? The lump sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*

  [same for more pre-financing payments]
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2 if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the beneficiary

    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments— No interim payments

Lump sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a 'statement on the use of the previous pre-financing payment' (see *Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment(s)

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

> The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.
>
> The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:
>
> – if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
>
> – if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.
>
> ***Example:***
>
> *Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.*
> *90% limit of the maximum grant amount: EUR 360 000.*
> *3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.*
> *Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.*
> *2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;*
> *3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;*
> *Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
> *70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
> *Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000*
> *3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.*

3. Amount of the payment of the balance

The amount of the payment of the balance depends on:

– the amount of pre-financing(s) already paid *(see article21_2)*

– the proper implementation of the action *(see article42)* and

- any breach of 'other obligations' (i.e. other than improper implementation of the action) *(see article43_LS)*.

ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submit to the *[Commission][Agency]* in good time any documents or information required by it

and may not subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or]* the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or]* the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for lump Sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since lump sum grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ 'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if an obligation under the Agreement (other than improper implementation of the action as described in Annex 1) has been breached.

43.1.2 The *[Commission] [Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since lump sum grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced if 'other obligations' have been breached *(e.g. another obligation under the GA or applicable EU, international and national law; see Article 43 H2020 General MGA)*.

⚠ A 'reduction of the grant' is possible for **any breach of obligation other than proper implementation** (under the GA or applicable EU, international and national law; *see Article 7)*.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(c) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(d) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The lump sum multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant) the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a 'report on the distribution of payments' between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see) — unless the Agreement or the participation of a beneficiary has been terminated (see).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(d) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(e) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see), or

(f) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see) — unless the Agreement has already been terminated (see).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see), reduce the grant or recover amounts unduly paid (see and).

1. Suspension of the action implementation (by the beneficiaries or the Commission/Agency)

The rules on suspension of the action implementation are in principle the same as for the General MGA (see *Article 49 H2020 General MGA)*.

The lump sum MGA has, however, the **following specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36 and 37) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *[**OPTION for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION:** not applicable]*;

(j) *[**OPTION for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION:** not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) the beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36 and 37) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Commission/Agency

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION:*** *not applicable****]***;

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

1. Termination of the GA (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for actions under lump sum actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Termination of the participation of one or more beneficiaries (by the beneficiaries)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the lump sum multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. Termination of the Agreement or of the participation of one or more beneficiaries (by the Commission/Agency)

The rules on termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the multi-beneficiary MGA Lump sum has the **following specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

H2020 Programme

AGA – Annotated Model Grant Agreement

Version 2.2
25 November 2016

Disclaimer
This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor its executive Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	▪ Initial version. Article 6.
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSCA ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles
2.0	30.03.2015	▪ Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. ▪ Clickable cross-references (Articles) ▪ New table explaining the treatment of the different types of work contracts (under Article 6.2.A). ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. ▪ Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 ▪ Other minor corrections and clarifications
2.0.1	18.05.2015	▪ Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants
2.1	30.10.2015	▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47, 50, 55

		and 56. ▪ New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses ▪ New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Phase 1: Article 5; – SME Instrument Phase 2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. ▪ Other minor corrections and clarifications.
2.1.1	01.07.2016	▪ Update of the explanations on Article 18 regarding time records; including a model of time-sheet with the minimum requirements. ▪ For easy identification, paragraphs, indents or sections with new interpretations are marked with the symbol ■ on the left.
2.2	25.11.2016	▪ Updates due to the amendment of the model grant agreement, in particular Articles 4.2, 5, 6.2.A, 10, 13, 16, 20, 34, 37, 41, 42, 43, 45, 46, 48, 49, 50 and 55 ▪ New annotations on Articles 29.2 and 29.3. ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6, 6.1, 6.2, 6.5 and 18. ▪ Updates in the annotations to specific model grant agreements: – ERC: Preamble, Articles 6, 29 and 56a – MSCA: Preamble ITN, Articles 4, 5, 6, 8, 18, 19 and 32; IF Articles 2, 4, 6, 8, 18, 32 and 56a; RISE Articles 4, 6, 8, 18, 19, 31 and 32; COFUND Articles 4, 6, 8, 15 and 18. – ERA-NET Co-fund: Articles 2, 19 and 21 – PCP-PPI: Articles 5 and 13 – EJP Co-fund: Articles 5, 6.F and 20 ▪ Synchronised presentation for grounds for Chapter 6 measures, security obligations and information obligations. ▪ Other minor corrections and clarifications ▪ Update in Section I.3 'List of issues applicable to particular countries' For easy identification, paragraphs, indents or sections with new explanations are marked with the symbol ■ on the left. New rules that apply in principle only for grant agreements signed with version 3.0 are marked with 3.0

IMPORTANT NOTICE

The **AGA — Annotated Model Grant Agreement** is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement (General MGA) and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020 (H2020).

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and eligibility conditions of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

   New rules that apply do not apply to all signed grant agreements (but instead only to those signed after a certain version, e.g. version 3.0), will be marked with: 3.0 ▸▸ and 3.0 ▸▸

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the H2020 MGAs. For a more general overview of how H2020 grants work, see the Online Manual.

A comprehensive list of all H2020 reference documents (including legislation, work programme and templates) can be found on the Participant Portal Reference documents page.

H2020 terms are explained in the Participant Portal Glossary.

If necessary, you can also contact the Research Enquiry Service.

Legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1 'Health, Demographic Change and Wellbeing' , etc.*

⚠ **Specific MGAs —** The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**] established in [official **address** in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full]* ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]* *as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form [OPTION if the JRC is a beneficiary: or the Administrative Arrangement], the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

'**Beneficiaries**' means the legal entities who have signed the grant agreement (GA) with the Commission/Agency (i.e. participate in a project supported by an EU grant).

⚠ The term **participant** is used in this document in a wider meaning than in the definition of Article 1.1(15) of the Rules for Participation Regulation No 1290/2013. It covers normally beneficiaries and linked third parties (and sometimes also other third parties involved in the action).

The '**coordinator**' is the beneficiary which is the central contact point for the

Commission/Agency and represents the consortium (towards the Commission/Agency).

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency

- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 (technical implementation) and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including **linked third parties**, subcontractors, third parties giving in-kind contributions, etc.) are considered as **third parties involved in the action** *(see Articles 8 and 9-14)*.

They are formally speaking not bound by the terms and conditions of the GA, although it implies certain obligations for them; conversely, the Commission/Agency has no formal contractual link with them.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries.

2. Name and address — Legal entity data

The legal entity data (legal name, address, legal representatives, etc.) of the beneficiaries comes from the Participant Portal Beneficiary Register.

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries (via their **legal entity appointed representative (LEAR)**) must keep their **data** in the Participant Portal up-to-date at all times including after the end of the grant (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

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ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[1]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[2]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[3].

[1] More information on the types of action can be found on the General Annexes to the Work Programmes.

[2] For the definition, *see Article 2.1(6) of the Rules for Participation Regulation No 1290/2013:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[3] For the definition, *see Article 2.1(7) of the Rules for Participation Regulation No 1290/2013:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

The term **action** comes from the Financial Regulation No 966/2012 and **means project**. (Previous EU Research Framework Programmes used project.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

For more information on RIA, IA and CSA actions, *see the Online Manual and the H2020 grants fact sheets.*

2. Complementary grants

'Complementary grants' are different EU grants which are linked by the work programme/calls by identifying them as complementary actions.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written **collaboration agreement** regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a third country *(e.g. a scientific and technological organisation or funding agency)* or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[4]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 of the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a **coordination agreement** *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

For guidance on coordination agreements, *see the Guidance — How to draw up your coordination agreement.*

[4] *See Article 12 of the Rules for Participation Regulation No 1290/2013.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

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The duration of the action will be **[insert number] months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)]* *[**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The action starting date is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example: *Grant agreement signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the action before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  ⚠ The action starting date can **NEVER** be **before** the **submission** of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The action duration is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the ***action tasks*** (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as project closure or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

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4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*:* Moreover, *lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

⚠ Costs for personnel, equipment, goods or services that are in-kind contributions by a third party (for free or against payment) can in practice simply be added to the budget category they correspond to (i.e. personnel costs or other direct costs) — if they comply with the eligibility rules set out in Articles 6 and 11 and 12.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

Moreover, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories — without requesting an amendment *(see Article 55)* (unless Annex 1 must be changed).

⚠ The maximum grant amount *(see Article 5.1)* can however **NEVER** be **increased**.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example: *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

- A beneficiary cannot transfer budget to a **form of costs** that it did not set out **in its estimated budget** — except within the personnel costs category.

  Example (allowed transfer): *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is acceptable without an amendment of the GA.*

  Example (not allowed transfer): *A beneficiary budgets all its costs as 'actual costs' in the estimated budget. However, at the end of the first reporting period, the beneficiary wants to declare part of the costs by using a specific unit cost allowed in the call (e.g. unit cost for clinical studies). This is NOT possible without an amendment of the GA.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work ('action tasks') of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the 'simplified approval procedure' without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

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ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA)**[7]**, if all beneficiaries and all linked third parties are non-profit legal entities**[8]**: 100%** of the action's eligible costs][**OPTION 3 for innovation actions (IA) if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION 4 for innovation actions (IA), if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities][**OPTION 5 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][11]: *[**OPTION 1 to be used if Article 15 applies:** as actually incurred costs (**actual costs**);][**OPTION 2**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for **[insert name of specific cost category(ies)**[14]**]**: on the basis of the amount(s) per unit set out in Annex 2a*[15] *(**unit costs**).]*

***[OPTION** 1b **for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION 2: specific cost category(ies):** not applicable.]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 To be used only if option in point (f) is used.

10 To be used only if option point (f) is used.

11 To be used only if option in point (f) is used.

12 To be used only if option in point (f) is used.

13 To be used only if option in point (f) is used.

14 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

15 Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount can **NEVER** be **increased** — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA actions is normally **100%** of the total *eligible* costs[5]; for IA actions it is normally **70%** of the total eligible costs[6].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[7].

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

5 *See Article 28(4) of the Rules for Participation Regulation No 1290/2013.*
6 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*
7 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rate of a beneficiary does NOT condition the reimbursement rate of its linked third parties.

> ***Example:*** *The beneficiary is entitled to 70 % but it has a linked third party entitled to 100 %. The linked third party will have a reimbursement rate of 100 % — despite the lower reimbursement rate of the beneficiary to which it is linked.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

⚠ The grant can **NEVER** reimburse **more** than the maximum grant amount fixed in Article 5.1.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[9]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - direct **personnel** costs (— unless declared as unit cost)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs**

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - direct personnel costs of **SME owners/natural persons** not receiving a salary[10]
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)[11]
  - specific unit costs for:
    - costs for **energy efficiency measures** in buildings[12]
    - **access costs** for providing trans-national access to research infrastructure[13]

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8 *See Article 28(6) of the Rules for Participation Regulation No 1290/2013.*

9 *See Articles 123, 124 of the Financial Regulation No 966/2012.*

10 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

11 *See Article 33(2) of the Rules for Participation Regulation No 1290/2013.*

12 Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme.
Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

- costs for **clinical studies**[14]

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[15]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

Example: *EUR 150 000 to carry out a study within an action*

The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	Budget categories					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not receiving a salary	NO	NO	NO	NO	YES, only if foreseen by Commission Decision
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

[13] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

[14] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[15] *See Article 29(1) of the Rules for Participation Regulation No 1290/2013.*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the **errors, irregularities or fraud** or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of GA termination) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex 1

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 of the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s).

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions (IA), there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount *(see Article 5.1)*.

Step 3 — Reduction due to the no-profit rule and receipts.

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the *consolidated* receipts and the *consolidated* approved costs.

The **receipts** that must be taken into account are receipts that are:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation)

during the action duration (see Article 3).

The following **are** considered '**receipts**':

- income generated by the action (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped to the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action (i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for the action covered by the GA)

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs (i.e. not

money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

Examples: *the free use of equipment; the secondment of an expert without reimbursement*

Free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered '**receipts**':

- in-kind contributions given by a **third party (donor)** free of charge — if they were not given specifically to be used for the action

  Example: *A university professor whose costs are charged by the beneficiary university in the GA, but whose salary is paid by the ministry and not reimbursed by the university: This in-kind contribution from a third party (the ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions given by a third party (donor) specifically to be used for the action — if they may be used according to the donor's rules to cover costs *other* than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

- financial contributions made **by one beneficiary to another** within the same action — since receipts are only contributions from *third parties*

  Conversely, such a financial contribution cannot either be declared as cost for the action.

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

- income generated by exploiting the results of the project (*e.g. the IPR*) — since successfully exploiting the results is one of the main objectives of the action

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (i.e. the final payment at the end of the action).

They must be declared in the final report (although beneficiaries are free to do so also in the periodic reports).

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations.

What? Serious breach of obligations refers to (non-exhaustive list):

- improper implementation of the action
- submission of false information
- failure to provide required information
- breach of ethical principles.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1. Improper implementation may lead to a grant reduction (i.e. reduction of the maximum grant amount'; see Article 5.1) — on a case-by-case basis (and only after a contradictory procedure with the coordinator/beneficiary concerned; *see Article 43*).

Minor delays/deviations in the technical work foreseen in Annex 1 will not give rise to a grant reduction.

Example (reduction): *one of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A grant reduction is NOT a sanction, but the consequence of substantial errors, irregularities or fraud or serious breach of obligations under the GA.

Example for calculating the final grant amount:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project (the 'action'). The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs: EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate: 100%

Amount obtained: EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts (60 000 + 80 000), over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to substantial errors, irregularities or fraud or serious breach of obligations:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of Article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Steps 1,2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000.*

Final grant amount *= EUR 2 2935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, substantial errors, irregularities or fraud or serious breach of obligations (and therefore **rejects the costs** and/or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level).

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:

Maximum grant amount: 500 000

There are three Beneficiaries A, B and C

Reimbursement rate: 100%

Direct eligible costs accepted for Beneficiary A at the payment of balance: 150 000

Total eligible costs accepted for Beneficiary A at the payment of balance = 150 000 + 25% (indirect costs) = 187 500

Costs rejected following audit: 30 000

Revised direct eligible costs: 120 000

Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000

Revised final grant amount: 100% of 150 000 = 150 000

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a **recovery** *(see Article 44.1.3)*.

For **reduction of the grant**:

- the Commission/Agency will reduce the grant amount set out in Article 5.1, in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations *(see Article 43)*.
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to the seriousness of the errors,

irregularities or fraud or breach of obligations to its improper implementation or breach of obligation

Example 1:

Maximum grant amount and final grant amount: 500 000

There are three beneficiaries A, B and C

Reimbursement rate: 100%

According to the estimated budget, beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex I.

Total eligible costs accepted for beneficiary A at the payment of balance = 187 500

1a: *The Commission/Agency finds that beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of beneficiary A: 80% of the share of beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000

1b: *The Commission/Agency finds that beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to beneficiary A: 100% of the reduction is allocated to beneficiary A.

Revised final grant amount of beneficiary A: 187 500 – 10 000= 177 500

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a **recovery** *(see Article 44.1.3)*.

For **rejection of costs AND reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above (i.e. after cost rejection or after grant reduction).

Example:

The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amounts following the reduction of the grant in the 2 examples above).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only** reimburse **eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Article 6.1 refers to general eligibility conditions, applicable per cost form *(see Article 5)*.

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action (or after GA termination) are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

  ⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  Examples:

  1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

  2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

3. *Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible, if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements (CFS) required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

Personnel costs for ERA chairs — Are eligible even if the salary is above national salaries, provided that it does not go beyond normal EU/international salaries for similar positions (since the ERA chairs aim to incentivise international mobility for internationally outstanding researchers and research managers. When the level of remuneration of the ERA Chair is indicated in Annex 1, this will be duly taken into account in case of check, audits or reviews.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

  Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2a.*

- the **number of units** must be **necessary** for the action
- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

> ***Example:*** *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Personnel costs declared on the basis of the usual accounting practices (average personnel costs) — For personnel costs declared on the basis of the beneficiary's usual cost accounting practices, the beneficiary:

- must calculate them (the average or standard personnel costs) according to its usual accounting practices
- must budget and declare a total amount; the amount per unit must not be included in Annex 2.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency *(in Annex 2a of the GA; see Article 5.2)*.

> ***Example:*** *Costs of minor consumables (e.g. a department's total minor consumable costs per hour worked), declared according to the beneficiary's usual accounting practices. This is not possible under H2020 rules.*

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump-sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION 1 for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]*][***OPTION 2:*** *not applicable*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

– either costs that have been caused in full by the activities of the action

- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action can NOT be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a **25% fixed flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is calculated per full financial year, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

1. Direct personnel costs (A.): Types of costs — Forms — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
  - **basic remuneration** (basic salary and complements) and
  - for non-profit legal entities: **additional remuneration** ('bonus payments')
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Employees (or equivalent) (A.1)

1.1.1 What? Personnel costs for employees or equivalent (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) **cover**:

- the **basic remuneration** (i.e. basic salary and complements) and
- only for non-profit legal entities: the **additional remuneration**

for personnel that worked on the action.

⚠ '**Equivalent appointing act**' means the appointing acts of civil servants (who do not sign employment contracts but receive official nominations for their posts).

What not? Persons that work for the beneficiary but NOT with an employment contract or equivalent appointing act *(e.g. staff provided by a temporary work agency, seconded staff, self-employed persons with a direct contract with the beneficiary)*.

Staff provided by a temporary work agency — A contract with a temporary work agency for the provision of staff qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (e.g. best value for money and no conflict of interest; see *Articles 10 and 13*).

Seconded staff and self-employed persons with a direct contract can be declared under other budget categories *(see below, points 1.2 and 1.3)*.

What is basic remuneration and additional remuneration & how to distinguish them?

Basic remuneration refers to the **basic salary** of the employee plus **complements** that fulfil the eligibility conditions explained in point 1.1.3.

The basic salary includes (and is limited to):

- the salary stated on the beneficiary's payroll (except for any part of that salary which must be considered as 'additional remuneration', even if that part is also registered in the payroll)
- social security contributions (mandatory parts to be paid by the employee and the beneficiary that employs him/her) — except any part included in additional remuneration.
- taxes included in the remuneration *(e.g. income tax to be paid by the employee retained by the beneficiary who employs him/her)* — except any part included in additional remuneration.
- other costs included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee)* — except any part included in additional remuneration.

The complements may include:

- mandatory fixed complements to the basic salary, resulting from national law, collective labour agreement or the employment contract

  Example (mandatory fixed complement): *a 13th month payment; complement for hazardous work or night shifts; transportation allowance, etc.*

- variable complements not triggered by the work in specific projects[16] if they fulfil the eligibility conditions set out in point 1.1.3.

  Example (variable complement acceptable as basic remuneration): *The contract of a professor includes as part of his/her usual tasks both teaching and research; it foresees a basic fixed remuneration of 1 000 EUR/month plus a variable part of 10 EUR/hour for each hour spent on research activities*.

By contrast, **additional remuneration** refers to payments made *on top* of the employee's usual remuneration (for instance for additional work or specific expertise), which result in a higher hourly rate in specific projects[17].

[16] 'Project' in this context refers to a set of activities carried out with a specific aim.
[17] 'Project' in this context refers to a set of activities carried out with a specific aim.

Additional remuneration includes not only the extra salary, but also the social security contributions, taxes and other costs included in the remuneration that result from that extra salary.

Example (additional remuneration): *a 'bonus' for participating in a project; an additional contract for specific tasks with a salary higher than the one under the main contract*

Example (not additional remuneration, but basic remuneration): *additional salary paid to the employee for additional hours worked on its standard work or expertise as defined in the employment contract (e.g. overtime or additional contract for those additional hours), if the additional hours are remunerated according to the standard salary conditions of the employee (i.e. do not result in a higher hourly rate). Note that the standard salary conditions may provide for a mandatory complement for those additional hours (e.g. overtime during night shifts).*

Thus, the two main features that help characterising a remuneration component as basic or additional are:

- hourly rate (no change to hourly rate would indicate basic remuneration, while a higher hourly rate would indicate generally additional remuneration) and

- kind of work or expertise (usual kind of work or expertise according to the contract or different/additional work or expertise).

Work or expertise	**Hourly rate**	
	Usual	**Higher**
Usual	Indicates basic remuneration	○ Indicates additional remuneration: if triggered by the participation in a project ○ May however qualify as basic remuneration if not dependent on a project or type of projects (and therefore spread over all activities, e.g. *based on merit of the employee at stake*)
Additional/different	Indicates basic remuneration	Indicates additional remuneration

In case of doubt, the classification will be made also taking into account the classification of the component under national tax law (i.e. if the tax authorities explicitly consider it as part of the basic remuneration of the employee or as additional remuneration).

⚠ It is the **basic remuneration** that must be used to calculate the **hourly rate** *(see below)*.

1.1.2 Costs for employees (or equivalent) must be **declared** as:

- **actual personnel costs** (most common case)

OR

- on the basis of **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*.

1.1.3 The costs for employees (or equivalent) must comply with the following **eligibility conditions**:

⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Reliable time records will normally be sufficient proof for this requirement — unless there is other contradicting evidence *(e.g. the employment contract indicates that the person was hired to work on another project)*

For basic salary and mandatory complements:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are NOT eligible under *Article 6.5(a)(i)*. (However, complements based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted as variable complements, if they fulfil the conditions set out below.)

  Examples (acceptable):

  If the profit of the company at the end of the year is more that X € (or more than X %), each employee will receive a complement of z % of his/her basic remuneration (or a fixed complement of x € more as part of the gross salary).

  Examples (not acceptable):

  If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.

  Any part of the remuneration which is calculated with reference to commercial targets or fund raising targets is NOT eligible (because neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation).

  ***Examples**: x € for reaching a sales target; x % on sales; x € premium per externally funded project gained; x % of the external funding gained*

- be **fixed** (conditions and amount or percentage) and **mandatory** according to national law, collective labour agreements or the employment contract

  ***Example:** The employment contract between the entity and the person fixes a gross salary of EUR 3000 per month plus a transportation allowance of EUR 5 per working day.*

- be paid to the employee (or benefit to him/her) **for** his/her ***usual* work**, duties or tasks (as defined in the employment contract/equivalent appointing act)

  ***Example:** a mandatory complement for working with radioactive materials that has to be paid when the researcher works in projects using such materials — even if this happens only in the framework of an H2020 action (because the triggering event is not the participation in the H2020 action, but the fact that the person has to work with radioactive materials*)

  Payments that depend on the participation in a specific project (that the employee would not have received if s/he had not participated in the project, i.e. the triggering event is the participation in the project, not the performance of the tasks defined in the employment contract) are NOT eligible.

  Any part of the remuneration linked to tasks other than those covered by the basic remuneration, are NOT eligible as part of the basic remuneration. (They may however still be eligible as additional remuneration; *see below*.)

For variable complements (in addition to the first and third conditions above):

- the variable complement is authorised under national law, collective labour agreement or set up in the employment contract/equivalent appointing act.

  Examples:

  ***1.** The collective labour agreement establishes that all researchers may receive a complement between EUR 100 and EUR 200 per month based on their seniority.*

2. The national law authorises public universities to pay a complement based on merit of the employees.

3. The contract fixes a premium of EUR 1000 for each research paper published in peer-reviewed international research journals.

- the **amount** to be actually paid as variable complement is determined on the basis of **objective conditions** (which should be established and documented, for instance in the internal regulations of the beneficiary).

  Example: *Based on the provisions of the collective labour agreement (see first example above), the internal regulations of the employer provide that: all researchers with seniority between 3 and 5 years will receive a complement of EUR 150 and all researchers with seniority above 5 years will receive a complement of EUR 180.*

  The variable complement must NOT be paid to the employee at the sole discretion of the manager (**arbitrary** complement). The decision to grant the complement should be be based on objective conditions, which should be documented and be verifiable.

  Example: *National law authorises public universities to pay a complement based on merit or performance of the employees and the internal regulations of the public university provide for an annual assessment exercise to determine the merit points of each employee. The internal regulations also set up the objective criteria based on which the merit points are decided. The internal regulations provide that all researchers with more than 10 merit points will receive a complement of EUR 1 000.*

  If the Commission/Agency has doubts whether the decision to pay the variable complement is actually based on objective conditions it may still accept (a part of) the complement if:

  - the employee has already been receiving the same complement before the award of the H2020 grant (and independently from it)
  - the complement was not increased after the award of the H2020 grant

  AND

  - the other eligibility conditions are fulfilled.

  Increases of the complement after the award of the H2020 grant will be considered ineligible in these cases; the Commission/Agency would accept only the amount up to the level that was paid before the award of the H2020 grant.

For additional remuneration (only for non-profit legal entities):

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

  Additional remuneration that is not directly linked to the participation in the EU action *(e.g. additional remuneration based on the participation in another project)* is not eligible.

  Example:

  A nuclear researcher in a public research centre (non-profit) worked for 1 720 productive hours

  Remuneration components:

  a = annual salary: EUR 50 000

  b = a complement for holding a management post (e.g. Head of department): EUR 1 600

  c = additional remuneration for being Head scientist in the EU project: EUR 2 000

  d = additional remuneration for being First Assistant on an internal action: EUR 1 000

  a *and* ***b*** *would be used to calculate the researcher's hourly rate:*

  hourly rate for the EU action = {(50 000 + 1 600)/1 720} = EUR 30

  c *would be subject to the specific eligibility conditions for additional remuneration. If eligible, it would be subject to the 8000 EUR ceiling.*

  d *would not be eligible and would not be taken into account when calculating the hourly rate for the EU action, as it is not linked to the participation in the EU action.*

- be paid to the employee (or benefits him/her) for the performance of **additional work** or **different expertise** than his/her usual tasks

  The work to be carried out (or expertise used) must be different from the standard work or expertise (defined in the employment contract/equivalent appointing act and covered by the standard remuneration package). This difference must be verifiable.

- be part of the beneficiary's usual remuneration practices and be consistently applied whenever the same kind of work or expertise is required

- be calculated on the basis of **criteria** that are **objective** and **generally applied** by the beneficiary, regardless of the source of funding used

  The objective criteria must be related to the additional work or expertise.

  Examples (acceptable criteria):

  A normal salary is paid for teaching + additional remuneration is paid for doing research.

  A normal salary is paid for research + additional remuneration is paid for taking up the management of the research team and infrastructure.

  A normal salary is paid for laboratory research + additional remuneration is paid for field research.

  A normal salary is paid for research on internal projects + additional remuneration is paid for participating in a special type of projects as for example international cooperative projects, projects awarded under competitive calls, etc.

  Examples (not acceptable criteria):

  Additional remuneration paid for using English.

  Additional remuneration is paid only when participating in EU-funded actions.

  The system for making additional payments should be established in the beneficiary's internal rules (or at least be documented and known by the employees). (Like for variable complements, the additional remuneration must NOT be paid to the employee at the sole discretion of the management (arbitrary complement).)

  Example (acceptable): *All teachers carrying out research on top of their usual teaching activities get an extra payment of 10 % of their salary.*

  Example (not acceptable): *The director decides at its sole initiative to pay an extra 10 % to one professor carrying out research.*

  However, the additional remuneration does not have to be the *same* for all persons working in the same project. The objective criteria used to determine the additional remuneration may result in different amounts for persons working in the same project *(e.g. the rule is that all teachers that carry out research on top of their usual teaching activities get an extra payment between 10 % and 20 % of their salary, the precise percentage per teacher and project is determined according to the level of responsibility in the specific project)*.

  The rules for additional remuneration may not differ according to *where* the funds come from. In particular, they cannot be set up for actions funded by a specific donor. (Additional remuneration schemes that are applicable only to EU actions are not acceptable.)

  Example (acceptable): *All professors carrying out research will be paid 10 % more.*

  Example (not acceptable): *All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

  Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

⚠ **8000 EUR ceiling —** Additional remuneration is eligible **ONLY up to** a ceiling of **8000 EUR** annual costs; *see point 1.1.4*).

To avoid abuses, the rules for additional remuneration will be exceptionally also applied to the **basic remuneration**, if it has been **artificially increased** for participation in the EU action.

Examples:

1. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with the beneficiary to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

2. *A researcher worked for the beneficiary, resigned, and subsequently signed a new contract with a linked third party (or a third party providing in-kind contribution) to work on the EU action for a higher salary. The rules for additional remuneration will apply to the difference between the salary it used to receive (before resigning) and the new higher salary (see point 1.1.4).*

3. *Employees of a specific department/service of the company which is in charge of carrying out only EU actions are paid a higher salary than their homologues in other departments carrying out the same tasks requiring a similar level of expertise (i.e. the salary differential is attributable to the source of funding). The rules for additional remuneration will apply to the difference between the salaries of employees working for the specific department and those of employees of other departments carrying out the same tasks with the same level of expertise (see point 1.1.4).*

Decision tree to determine eligibility of complements:

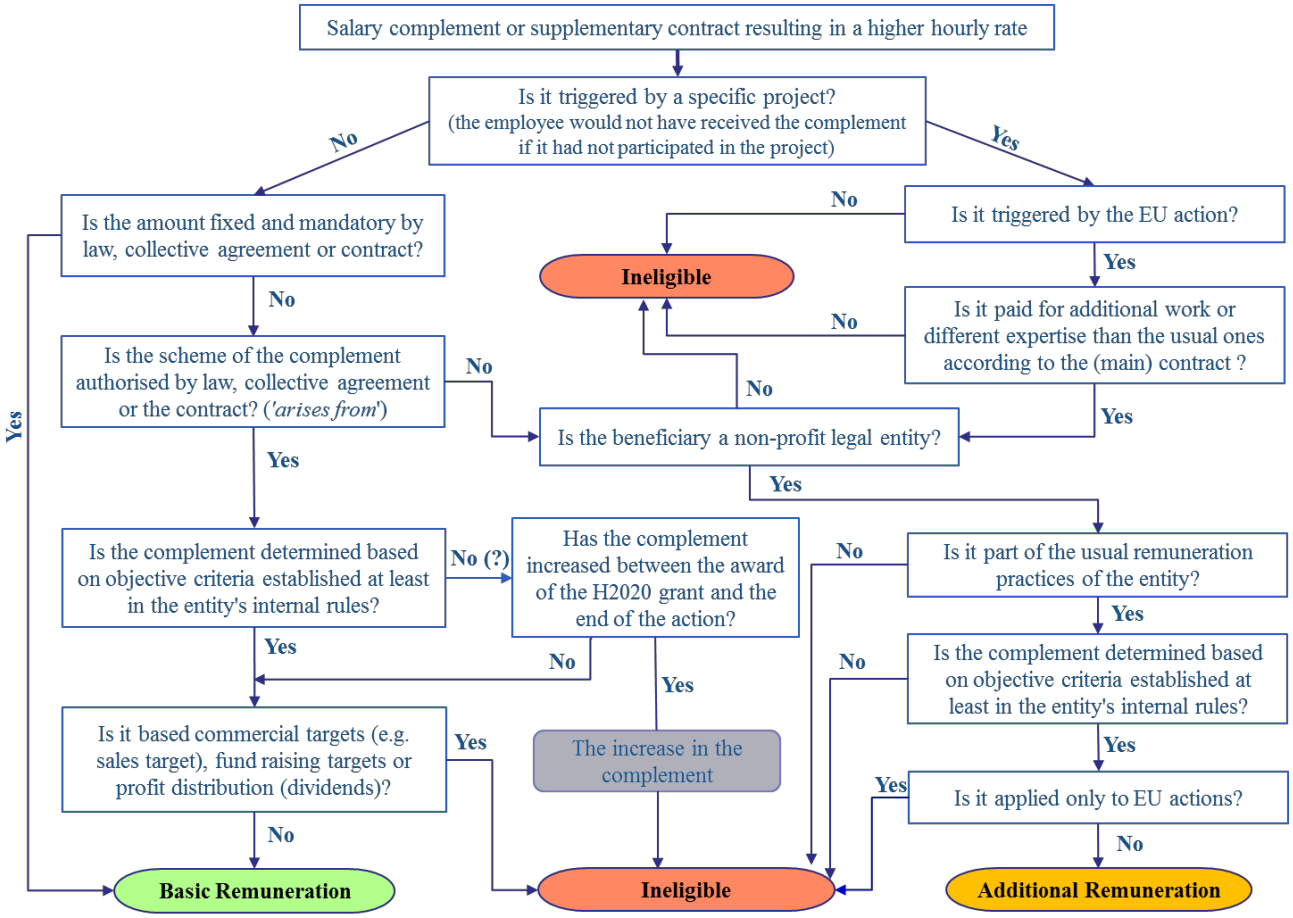

Specific cases (direct personnel costs for employees (or equivalent)):

Teleworking — Remuneration costs of personnel not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible, if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of quasi-financial benefits *(e.g. costs of lunch vouchers)* may be accepted as eligible, if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally NOT eligible as direct personnel costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action, the related costs would be considered part of the entity's normal indirect costs, which are covered by the 25 % flat-rate.

Costs for students, PhDs and other researchers under scholarship, internship or similar agreements (not employees) — Costs of students that work for the beneficiary can be accepted, if the agreement is work-oriented (not training-oriented: i.e. not aimed at helping the student to acquire professional skills).

PhD agreements will be considered work-oriented. However, time for training, if any, may NOT be charged to the H2020 action.

Fellowships/scholarships/stipends — Can be charged to the action (as personnel costs), if they fulfil the conditions set out Article 6.1 and 6.2.A.2, and in particular:

- the remuneration complies with the application national law on taxes, labour and social security
- the assignment of tasks respects the laws in force in the country of the beneficiary
- the students have the necessary qualifications to carry out the tasks allocated to them under the H2020 action.

Cost for exemptions from academic fees — The fees (or part of them) are eligible as personnel cost, if the student's contract includes the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic salary only, if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible).

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts (whatever their form, i.e. a contract additional to the main contract between a beneficiary and its employee) for carrying out tasks for specific actions *(e.g. international projects)* are acceptable, if it is the beneficiary's usual practice and compatible with national law. However, the difference between the remuneration paid in the additional contract and the standard remuneration package (basic remuneration) in the first non-action-related contract is considered additional remuneration. As such it is subject to the specific cost eligibility conditions explained above for additional remuneration and, if eligible, to the 8000 EUR ceiling.

1.1.4 The **costs** must be **calculated** as follows:

For each person (assigned to the action):

{{**hourly rate**
multiplied by
number of actual **hours worked on the action**},
plus
for non-profit legal entities: **additional remuneration** to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

This calculation method also applies to persons working exclusively for the action.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ **Double ceiling —** Beneficiaries must ensure that:

- the **total number of hours** worked **declared** in EU and Euratom grants for a person for a year is NOT higher than the number of **annual productive hours** used for the calculation of the hourly rate *(see below)*
- the **total** amount of **personnel costs declared** (for reimbursement as actual costs) in EU and Euratom grants for a person for a year is NOT higher than the total personnel costs recorded in the **beneficiary's accounts** (for that person for that year).

Procedure for calculating direct personnel costs for employees (or equivalent):

Step 1 — **Calculation of the hourly rate (per person)**

The hourly rates must be calculated by using one of the following methods:

- **per full financial year** (main method): single hourly rate for each person for each full financial year
- **per month** (alternative method): one hourly rate for each person for each month (i.e. 12 hourly rates per person for each financial year).

Each beneficiary may choose any of the two options. However, the option chosen must be applied during the full financial year to all its personnel in all H2020 grants. If the beneficiary wants to change option, it can do so for the next financial year (— again for all its personnel in all its H2020 grants).

⚠ **Recalculations & adjustments of financial statements (exceptional) —** To benefit from this new option beneficiaries may apply it retroactively for all grants on-going (i.e. for which the final report has not been submitted) on 20 July 2016 (i.e. date of adoption of the H2020 MGA version 3.0). The beneficiary may re-calculate costs already declared on the basis the full financial year by using the monthly calculation method. However, in that case it must do the recalculation for all personnel costs declared for that/those financial year(s) in all on-going H2020 grants agreement. The beneficiary shall declare the differences, either positive or negative, as adjustments in the next reporting period.

⚠ The grant agreement **formulas for the hourly rates are mandatory**. Those formulas may lead to minor/temporary differences with the personnel cost recorded in the accounts. Those temporary differences have no impact on the eligibility of the costs provided that the formula has been correctly applied and that the *double ceiling* explained above has been respected.

Calculation of the hourly rates *per full financial year*

Annual hourly rates must be calculated as follows:

for each person:

{actual **annual personnel costs** (excluding additional remuneration) for the person

divided by

number of **annual productive hours**}.

Example (for calculation of hourly rate):

A nuclear researcher working for a public research laboratory (non-profit) worked 1 600 productive hours.

Remuneration components:

a = annual salary: EUR 50 000

b = extra payment for holding a post involving radioactive hazards: EUR 5 000

c = additional remuneration for being Head Scientist in a Project: EUR 2 000

***a** and **b** would be used to calculate the hourly rate. The calculation must exclude any additional remuneration which, if eligible, will have to be calculated separately.*

*Hourly rate for the action = {(50 000 + 5 000)/1 600} = **EUR 34***

The rates must be calculated by ***full financial* year** (i.e. the 12-month period covered by the annual accounts of the entity).

***Example:** When the financial year matches the **calendar year**, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

***Example:** Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance with the GA is available. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate. The method must however be consistently applied and can NOT be changed within the same grant.

⚠ **No adjustments of financial statements —** Adjustments are normally allowed ONLY for mistakes *(e.g. incorrect accounting information; error in the calculation; etc).*

***Example:** An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed (even if a recalculation of the hourly rate after the closure of the financial year would give another result).

The **annual personnel costs** may include only eligible personnel costs and must exclude additional remuneration (because that will be added separately at the end of the calculation).

Any part of the basic remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 2:** the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours'**)
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed ad-hoc for specific employees)*.

The beneficiary must keep the same option(s) for *the full financial year*. It can only change its option(s) for the next financial year.

Absences & overtime —

Absences: the three options treat absences (leave) in different ways:

- under option 1 (1720 fixed): ONLY actual time spent on parental leave (maternity and parental leave) may be deducted from the 1720 fixed hours. NO other leave *(e.g. sick leave, special leave, annual leave, etc.)* can be deducted.
- under option 2 (individual): the beneficiary must deduct all leaves (i.e. *actual time* on sick leave, parental leave or special leave, etc.) to calculate the annual productive hours.

  In order to calculate the annual workable hours, the beneficiary has to deduct the annual leave entitlement (see example in the table below). However, if the employment contract allows end-of-year transfers for leave entitlements (i.e. the days not taken one year can be taken the next one; days not taken are not paid out), the beneficiary may opt for deducting instead *actual time* of annual leave (if this is done consistently throughout the years).
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard time of absence in the organisation. However, the beneficiary may deduct on top the actual time spent on parental leave (maternity and parental leave) by the individual employee.

Overtime: all three options include potential overtime in the annual productive hours, either implicitly (options 1 and 3) or explicitly (option 2):

- under option 1 (1720 fixed): NO overtime may be added to the 1720 fixed hours
- under option 2 (individual): all overtime worked (paid or unpaid) must be added to the annual workable hours to calculate the annual productive hours
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard overtime hours in the organisation (if any).

No impact on the hours worked — The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate. However, beneficiaries must make sure that they don't reach the *double ceiling*: i.e. number of annual productive hours used and costs recorded in accounts *(see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding hours worked can NOT be charged to the action (they must be capped at the ceilings).

This table explains the three **different options** for **annual productive hours**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types*	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the grant agreement {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive

	of special leave).	plus
		overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus 8 days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for 5 days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual workable hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
			hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow to determine the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example for calculation of standard annual workable hours:***	If our auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation method consistently applied) are fulfilled but the

		Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave. *The standard annual workable hours for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).*	beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours). ⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 fixed hours).*	

Calculation of the hourly rates *per month*

Monthly hourly rates must be calculated as follows:

for each person:

{actual **monthly personnel costs** (excluding additional remuneration)
divided by
{number of **annual productive hours/12**}**}**.

The rates must be calculated **for each month**.

The **monthly personnel costs** may include only eligible personnel costs and must exclude additional remuneration (because — if eligible — it will be added at the end of the calculation separately and on top of the personnel costs declared based on the hourly rate).

If a part of the basic remuneration is generated over a period longer than a month *(e.g. the thirteenth salary)*, only the entitlement generated in the month can be included in the monthly personnel costs (— irrespectively of how much is actually paid in that month).

Example:

In accordance with the collective labour agreement, Ms T is entitled to a thirteenth salary (another full month salary in addition to her 12 monthly salaries) to be paid in July each year. The monthly salary of MS T is EUR 3 000.

The monthly personnel costs in July will be:

EUR 3 000 + {EUR 3 000 / 12} = 3 000 + 250 = EUR 3 250

The beneficiary can therefore NOT include the total of the thirteenth salary in the personnel costs for July, but must distribute it over the months in which it was generated (in this example 1/12 per month). Otherwise, the hours of July would be incorrectly priced at the double of the hours worked in normal months.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** If a later event *(e.g. the unexpected leave of the employee)* means that the payments made for the employee are actually lower (i.e. that the monthly hourly rates were overstated) the beneficiary must recalculate the hourly rates with the correct amount. If some of the related personnel costs were already declared, the beneficiary must declare the difference as adjustment in the next reporting period.

If the monthly entitlement of an extra salary is not known in advance *(for example for an annual merit pay whose amount is decided in December — if eligible as basic remuneration —)* the beneficiary cannot take into account the extra salary until the amount is known. It may therefore recalculate the hourly rates at that moment and, if needed, declare the difference as adjustment in the next reporting period.

For calculating the **annual productive hours**, the beneficiary must use one of the following two options *(see the table of options above for the details on each option)*:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ Option 2 can NOT be used for monthly hourly rates because the individual annual productive hours — and thus also the monthly hours, i.e. 1/12 of the annual — are known only at the end of the financial year. It would be therefore impossible to calculate the hourly rates at the end of each month

In principle, the same option must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must keep the same option(s) *during the entire financial year*. It can only change its option(s) for the next financial year.

Absences & overtime —

The same rules on the treatment of absences and overtime apply as for annual hourly rates, except that time spent on parental leave can NOT be deducted from the annual productive hours.

However, these beneficiaries may charge to the action the *costs* incurred for parental leave (as personnel costs) in proportion to the time the person worked for the action during the financial year. This must be done separately and on top of the personnel costs declared by multiplying the hours worked for the action by the monthly hourly rates.

Example:

In 2015 Ms T has been five months in parental leave. During that time the social security reimbursed to the beneficiary 50 % of her salary. Her monthly salary was EUR 3 000 (reimbursement EUR 1 500). The beneficiary used option 1 (fixed 1720 hours) for the annual productive hours and Ms T worked in 2015 320 hours on the H2020 action.

Personnel costs incurred during parental leave= {EUR 3 000 x 5} - {EUR 1 500 x 5} = 15 000 – 7 500 = EUR 7 500

(Note: amounts reimbursed to the beneficiary by the social security are not actual costs for it and, therefore, must be deducted)

Proportion of time worked for the action in 2015 = Time worked for the action / Total productive time excluding the parental leave = 320 / {1720 - {1 720 x 5/12}} = 320 / {1 720 – 716,7} = 320 / 1 003,3 = 31,89 %

Cost of parental leave for the H2020 action = EUR 7 500 x 31,89 % = EUR 2 391,75

No impact on the hours worked — The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate. However, beneficiaries must make sure that they don't reach the *double ceiling*: i.e. number of annual productive hours used and costs recorded in accounts *(see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding hours worked can NOT be charged to the action (they must be capped at the ceilings). The ceilings apply per full financial year, not per month.

However, do not forget that your personnel costs must comply with national labour law.

Example:

If the national law provides for a prohibition for employees to work more than 48 hours per week, it is not possible to charge to the H2020 action 250 hours in a month for an employee.

Step 2 — **Multiplying the hourly rates by the hours worked on the action**

The amount that can be declared for each person must be calculated by multiplying the hourly rate by the number of hours actually worked on the action.

Step 3 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the person received eligible additional remuneration (and if the beneficiary is a non-profit legal entity), it may also declare the share of the additional remuneration that can be attributed to the action *(see below)*.

If the resulting amount is above the **8000 EUR ceiling**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional salary but also all additional taxes, costs and social security contributions triggered by the additional salary.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration paid on top of the usual remuneration is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example:

An employee received a EUR 2 000 bonus for being Head of Project for the EU action.

S/he worked 1 600 annual productive hours, 800 of them for the EU action.

Maximum additional remuneration eligible for the EU action (ceiling):

*{EUR 8 000 / 1 600} * 800 ➔ 5 * 800 = EUR 4 000*

The additional remuneration paid for the EU action is eligible in full because it is lower than the ceiling (2 000 < 4 000).

If the additional remuneration paid for being Head Scientist in the action had been EUR 7 000 instead of EUR 2 000, the ceiling would apply and only EUR 4 000 could be charged to the action (even if the actual payment was EUR 7 000).

If the researcher had worked 200 hours instead of 800 hours for the EU action, the ceiling would have been:

*{EUR 8 000 / 1 600} * 200 ➔ 5 * 200 = EUR 1 000*

In this case, the ceiling would also apply, since EUR 2 000 (additional remuneration paid) > EUR 1 000 (ceiling). Only EUR 1 000 could be charged to the action even if the actual payment was EUR 2 000.

Example for calculating direct personnel costs for employees (or equivalent):

A nuclear researcher working for a public research laboratory (non-profit) worked:

1 600 productive hours

800 hours declared for the action (at an hourly rate of EUR 40)

400 hours declared for another EU grant

S/he received eligible additional remuneration of EUR 2 000 for being Head of Project.

*Calculation of the personnel costs: EUR 40/hour * 800 hours = 32 000*

Addition of the additional remuneration: = 2 000

Total costs charged to the action for the year: 32 000 + 2 000 = EUR 34 000

Condition: Actual hours declared for action + actual hours declared for another EU grant ≤ total productive hours (800 + 400 < 1 600)

Specific cases (direct personnel costs for employees (or equivalent)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A (as chosen by the beneficiary) applies.

For persons who sign the 'declaration on exclusive work for the action' the number of hours worked in the action during the period covered by the declaration will be the pro-rata (corresponding to the period of exclusive dedication) of the annual productive hours used to calculate the hourly rate.

Example:

1a *Researcher Y worked exclusively in the H2020 action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*Hours worked for the project*	
2014 ➔	*(32 000 / 1720) x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60 x	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720) x*	*1720*	
	20 x	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*		
	20 x	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
		TOTAL	*= 51 000*

- **Employees hired during on-going financial year** (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the hourly rate can only be calculated on the basis of the personnel costs incurred during the ongoing financial year.

  Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

  In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

- **End-of-contract indemnities —** Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the indemnity in the reporting period in which the employee's contract ends — but outside the hourly rate (i.e. separately and on top of the personnel costs declared on the basis of the hourly rate) AND only for the part that corresponds to the time worked by the person on the action (i.e. pro-rata of the total time during which the entitlement was generated).

Moreover, the indemnity can be accepted ONLY if it:

- arises from the applicable national labour law and
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Employment contract remunerated per hour — For employment contracts that do not establish a fixed salary and a number of hours to be worked but only an amount to be paid for each hour worked by the employee, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the individual annual productive hours can be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

Personnel costs on the basis of the usual cost accounting practices (average personnel costs) — The hourly rate must be calculated in accordance with the beneficiary's usual cost accounting practices for determining the hourly rates of its personnel.

The GA sets the following conditions:

- the cost accounting practices used must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  This does not mean that cost accounting practices must be the same for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

  Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

  Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

- the hourly rate must be calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs already included in other budget categories

  Any cost considered ineligible by the Commission but included in the beneficiary's usual accounting practices must be excluded when calculating the personnel costs for the action.

  If necessary, it must be adjusted to fulfil all eligibility conditions.

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

  Costs that are already included in other budget categories must be taken out (double funding of the same costs).

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020 actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.*

  Budgeted or estimated figures are not costs actually incurred and may only be accepted as eligible components of the hourly rate if they:

  - are relevant, i.e. clearly related to personnel costs
  - are used in a reasonable way, i.e. they do not play a major role in calculating the hourly rate

- correspond to objective and verifiable information, i.e. their basis is clearly defined and the beneficiary can show how they were calculated

  Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

- the hourly rate must be calculated using one of the three options provided in the MGA for the number of annual productive hours (e.g. *option 3 'standard annual productive hours')*.

Beneficiaries may request the **approval** of the methodology used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

1.2 Direct personnel costs: Natural persons with direct contract (A.2)

1.2.1 What? This budget category **covers** typically the costs of **in-house consultants** and similar persons that worked on the action (i.e. **self-employed *natural* persons** — not companies — working part-time or full-time for the action under a contract which is NOT governed by the labour law for employees).

What not? Staff provided by a temporary work agency or, more generally, by any other entity against a price (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

Staff provided by a temporary work agency — A contract with a temporary work agency for the provision of staff qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as:**

- **actual costs** (most common case)

OR

- on the basis of **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)

- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency)*.

- the person must work under the **beneficiary's instructions** and, unless otherwise agreed with the beneficiary through a teleworking agreement, on the **beneficiary's premises**

  It must be the beneficiary who decides on, designs and supervises all work. The consultant must report to the beneficiary.

- the **result** of the work carried out must **belong to** the **beneficiary**

  The work carried out, including any resulting patents or copyright, must belong to the beneficiary.

- **not** be **significantly different** from costs for personnel performing similar tasks under an employment contract with the beneficiary.

  The remuneration must be based on working time, rather than on delivering specific outputs/products.

  ⚠ **Record-keeping —** The beneficiary must keep records of the hours which the person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **formula** as the one explained in point *1.1.4* (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, the **hourly rate** is different (since it is not based on the annual personnel costs as registered on the payroll).

For the hourly rate, the beneficiaries must use one of the following options:

- if the contract specifies an hourly rate: this hourly rate must be used
- if the contract states a fixed amount for the services of the natural person and the number of hours to be worked: this global amount must be divided by the number of hours to be worked for the beneficiary under that contract.

If the contract fixes only a global amount and does not specify the time to be worked, the costs can NOT be declared as personnel costs, but may be eligible as purchase of a service *(see Article 10)* or a subcontract *(see Article 13)*.

This table explains how to treat **different types of work contracts** for declaring costs under H2020[18]:

General case: Single contract between the entity and the person		
Characteristics of the contract	**Contract remunerating time** (*e.g. the contract establishes that the person must work for the hiring entity 40 hours per week*)	**Contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes that the person must carry out a specific task but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ However only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. *Example: Contract from 01/01/2015 to 31/03/2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430* ➔ The personnel cost will be the result of multiplying the hourly rate by the number of hours worked by the person for the action (as recorded in its time-sheets).

[18] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

Other contract (i.e. not covered above)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared in category A.2 'natural persons with direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A. 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B. 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.	**CASE D** The costs can NOT be declared in category A. 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B. 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

Special case: the contract covering the work for the H2020 action is additional to other contract(s) of the person with the entity		
Characteristics of the additional contract	**Additional contract remunerating time** (*e.g. the additional contract establishes that the person must work for the hiring entity 10 hours per week in addition to the basic contract*)	**Additional contract remunerating duties (without specifying the working time conditions)** *(e.g. the additional contract establishes that the person must carry out a specific task but the working time needed is not defined; e.g. the contract specifies that the work has to be carried out within the working time of the main contract)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE E1:** the additional contract is NOT triggered by the participation of the person in the H2020 action (e.g. the contract pre-dates and outlasts the grant agreement). The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ In this case a single hourly rate must be calculated taking the figures of the main and the additional contract/s together (i.e. total basic remuneration and total annual productive hours). **CASE E2:** the additional contract is triggered by the participation of the person in the H2020 action. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ However, the hourly rate must be calculated only on the additional contract (remuneration and productive	**CASE F** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated for the additional contract as described in CASE B above: ➔ However, if the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1).* Therefore: **CASE F1** (the hiring entity is a non-profit legal entity): the costs of the additional contract may be eligible up to the following ceiling: *{Hours worked for the action (as recorded in the time records)* *multiplied by* *{Hourly rate of the main contract + EUR 4,65}}* Note: EUR 4,65 is the result of dividing 8000 (annual ceiling for additional remuneration) by 1720 (option 1 annual productive hours); thus, 4,65 is the hourly pro-rata of the annual ceiling

	hours of the additional contract). If the hourly rate of the additional contract is higher than the hourly rate of the main contract, the difference must be treated as *additional remuneration (see Article 6.2.A.1)*.	**CASE F2** (the hiring entity is NOT a non-profit legal entity, i.e. for profit entity): the costs of the additional contract may be eligible up to the following ceiling: {*Hours worked for the action (as recorded in the time records)* *multiplied by* *Hourly rate of the main contract*}
Other contract (i.e. not covered above)	**CASE G1:** the costs fulfil the conditions of Article 6.2.A.2. Depending on the main contract, the costs may be declared either in: – category A.1 'employees (or equivalent)' (Article 6.2.A.1) or – category A.2 'natural persons with direct contract' (Article 6.2.A.2). If the main contract is under CASE A, CASE B or CASE C1, the cost must be calculated as indicated above for CASE E1 or E2 (depending if the additional contract is or not triggered by the participation in the H2020 action). If the main contract is under CASE C2 or D, the costs must be calculated as described in point 1.2.4. **CASE G2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B. 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10).	**CASE H** The costs can NOT be declared as 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B. 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

	⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.	

1.3 Direct personnel costs: Seconded personnel (against payment) (A.3)

1.3.1 What? This budget category **covers** the costs of persons that worked on the action and that were **seconded** by a third party as an in-kind contribution ***against payment*** *(see Article 11)*.

What not? Persons provided by a temporary work agency, secondment of staff between beneficiaries (or linked third parties) in the same grant or secondment by a third party free of charge.

Staff provided by a temporary work agency — A contract with a temporary work agency for the provision of staff qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

Secondment of staff between beneficiaries (or linked third parties) — Is allowed, but it is the beneficiary/third party who employs the person who has to declare its costs (NOT the beneficiary/third party to whom the person has been seconded). The costs declared must be supported by reliable time records of the number of hours the person worked for the action. Those time records must be produced under the responsibility of the beneficiary/third party to whom the person is seconded

Persons seconded free of charge — Costs for persons seconded free of charge (i.e. the third party's costs) can be declared as personnel costs by the beneficiary, if they fulfil the conditions of Articles 6.4 and 12.

> For information on in-kind contributions provided by third parties *free of charge, see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared** ONLY as **actual costs**.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.3.4 There is no specific **calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1)*.

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the seconded person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.4 Direct personnel costs: SMEs owners & natural persons not receiving a salary (A.4 & A.5)

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons which work on the action, but **don't receive a salary**.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts/other non-employment contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

If the remuneration status of the SME owner changes during the course of the action, the beneficiary has to request an amendment *(see Article 55)*, in order to change the form of costs used *(e.g. from unit cost to actual costs)*.

***Example**:*

A GA was signed in 2014 with an SME whose owner does not receive a salary. The action's personnel costs are calculated based on the unit cost set out in Annex 2.

In 2016, the SME starts paying the owner a salary for his/her work. From that moment on, any costs charged to the H2020 action require an amendment to the GA to remove the unit cost and to allow the SME owner to charge personnel costs based on his/her salary. The SME may no longer use unit costs to declare the costs of its owner.

1.4.2 These costs must be **declared** on the basis of the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[19] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *Main Work Programme — MSCA*[20] in force at the time of the call.

***Example:** A German SME owner not receiving a salary will calculate the hourly rate as follows:*

EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **eligibility conditions**:

[19] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

[20] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an SME owner/beneficiary that is natural person, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ **Ceiling** — The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than 1 720.

1.5 Direct personnel costs: Access to research infrastructure personnel costs (A.6)

1.5.1 What? This budget category **covers** the personnel costs for access to infrastructure activities, i.e. normally:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons with direct contract and
- costs of seconded personnel (against payment).

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as:**

- **actual costs** (most common case)

OR

- on the basis of **unit costs** in accordance with the usual cost accounting practices (iaverage personnel costs) *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.5.4 The same **calculation rules** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting (B.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing trans-national or virtual access to research infrastructure: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (subcontracting costs):

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency may exceptionally have to be declared under category B. 'subcontracting' (instead of category D.3 'other goods and services') if the temporary work agency carries out directly some task of the action (provided they comply with the eligibility conditions).

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)]***

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

1. Direct costs of providing financial support to third parties (C.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category (together with the corresponding Article 15 and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances (D.1): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is foreseen in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in- or outside of Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  > ***Example*:**
  > *Beneficiary A declares the cost of a business class airplane ticket for one of its employees.*
  > *If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.*
  > *If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.*

If the beneficiary reimburses travel and/or subsistence allowances as a lump sum/*per diem* payment, it is the lump sum/*per diem* amount that is considered an eligible cost, NOT the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these lump sum/per diem costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (travel costs):

Combination with personal travels or travels for other purposes —The costs of a combined travel can be charged to the action — but ONLY up to the cost that would have been incurred if the travel would have been made exclusively for the action AND if:

- it is the usual practice of the beneficiary to pay for such travels *(e.g. travels combining professional and personal reasons)*
- it has been an actual cost for the beneficiary.

***Example*:**

The researcher flies from Madrid, where the beneficiary is established, to Prague for a project meeting. After the meeting, instead of flying back to Madrid, the researcher flies directly to New York to participate in an event not related to the H2020 action.
The beneficiary may charge to the action:

- *the cost of the flight from Madrid to Prague, and*
- *the part of the flight back from New York to Madrid up to the cost that it would have incurred for a flight back from Prague to Madrid after the end of the project meeting.*

⚠ **Record-keeping —** The beneficiary must keep evidence not only of the actual cost of the flight back, but also of the cost of the flight that the person would have taken if it would have returned directly after the end of the work for the action.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).]*

***[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.2): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs (D.2): Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

- if the beneficiary does not use the equipment exclusively for the action, only the portion used on the action may be charged. The amount of use must be auditable

  Example: *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*

  Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

- the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

  Example: *A microscope was bought on 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs):

Low-value assets — The full cost of a low value asset may be eligible in the year when it is purchased if:

- the full cost is recorded in the accounts of the entity as expenditure of that year (i.e. NOT recorded as an asset subject to depreciation)

and

- the cost of the asset is below the low-value ceiling as defined under national law (e.g. *national tax legislation)* or other objective reference compatible with the materiality principle

and

- the item is used exclusively for the H2020 action in the year of purchase.

  If the item is not used exclusively for the action in the year of purchase, only the portion used on the action may be charged.

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that correspond to the part of the equipment's use for the action. Declaring its *full* price in one single year would be considered either as not compliant with the international accounting standards or as an excessive cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, a piece of equipment bought in January 2013 has a depreciation period of 48 months.
If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that corresponds to the part of the equipment's use for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year, the beneficiary can NOT charge the full price in one single year (— even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year).

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the eligibility conditions of Articles 6.1 and 6.2 are met (in particular, recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices; *see Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

If the full construction costs of the prototype are eligible according to the conditions above, but the construction was outsourced to a third party (other than a linked third party), the costs can NOT be declared in category D.2 'equipment', but may be eligible in category B. 'subcontracting' *(see Articles 6.2.B and 13)*.

1.2 Equipment costs (D.2): Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs (D.2): Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:

- the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
- the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

  The finance charges included in the finance lease payments are therefore NOT eligible.
- the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee

- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are not higher than the depreciation costs of similar equipment).

1.4 Equipment costs (D.2): Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services (D.3): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access to peer-reviewed scientific publications*, e.g. article processing or equivalent charges*, costs related to open access to research data and related costs, *such as data maintenance or storage and conference fees for presenting project-related research*)
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4) or the certificate was submitted not for the final report but before*).
- translation costs (if translation is necessary for the action's implementation, is justified, etc.).

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be declared as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the plan for the exploitation and dissemination of the results are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access to peer-reviewed scientific publications and research data are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Internally invoiced costs — Internally invoiced costs (i.e. where the use of certain resources is shared between different units of the same organisation and the costs of their use are declared through internal invoices) may be eligible if their use and the usage (number of hours) for the action is specifically recorded and it is mentioned in the invoice. The internal invoice must refer to the use/dedication for the action of specific resources (*e.g. per researcher, piece of equipment, etc.)*.

> ***Example (acceptable internal invoice):*** *Internal invoice with 16 hours of the technician doing the analysis and 10 hours depreciation of the testing equipment used.*
>
> ***Example (not acceptable internal invoice):*** *Internal invoice with a global price for the use of a research infrastructure (e.g. laboratory) or for a service (e.g. an analysis).*

The costs must be declared under the budget category that corresponds to the invoiced resource *(e.g. personnel, equipment, other direct costs, etc.)* and must fulfil the eligibility conditions set out in Article 6.1 and 6.2.

Internal invoices may NOT include indirect costs elements or profit margin or mark-up.

Internal invoices for the work of personnel must be supported by time records *(see Article 18.1)*. The hourly rate must be calculated as described in Article 6.2.A.

Internal invoices for the use of equipment must be limited to the depreciation for the relevant reporting period (only the part of the depreciation cost corresponding to the time the equipment was used for the action during that reporting period can be declared.) The use of the equipment must be properly recorded in order to allow direct measurement of the use for the action and to ensure auditability *(see Article 6.2.D.2)*. It is NOT possible to calculate an all-in average cost of internally invoiced equipment including, for instance, allocated indirect costs *(e.g. maintenance)*.

Self-produced consumables — the eligible cost of a consumable is generally determined by its purchase price. The purchase price is the actual direct cost of the consumable for the beneficiary. However, consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price. The consumable is normally recorded in the accounts of the beneficiary (as part of the *inventory)* for its cost of production. In consequence, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

> ⚠ Beneficiaries can **NOT** charge the **commercial price** for self-produced consumables.

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.
The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency are eligible normally under category D.3 'other goods and services' if they comply with the eligibility conditions (and unless the temporary work agency carries out directly some task of the action, in which case it can be considered as subcontracting and should be declared under category B. 'subcontracting').

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure (D.4): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of the Horizon 2020 Framework Programme 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[21]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in particular, based on the useful economic life of the infrastructure) and with the beneficiary's

[21] *See also International Financial Reporting Standard No 16.*

usual accounting practices.[22] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure to calculate the EUR 20 million threshold *(see below)* and therefore declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[22] *See Article 126 of the Financial Regulation No 966/2012.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared** as actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure (LRI)

Beneficiaries can declare capitalised and operating costs for **large research infrastructure**, if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[23] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a **research infrastructure** in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[24].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a **grouping of costs** (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[23] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[24] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any grant agreement (by ticking the LRI box either in the Beneficiary Register or during grant agreement preparation).

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Beneficiary Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) ex-ante assessment report will be issued.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs in category D.4 'large research infrastructure'.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (Link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

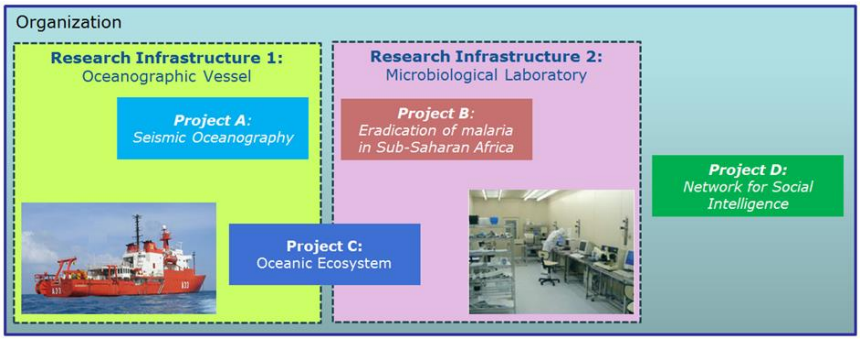

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[25].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the H2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the H2020 grant, even if they belong to the same action.

> ⚠ **Combining H2020 & other EU grants —** The terminologies under the different EU funds/funding programmes may differ *(e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).*

4.4 Costs must be directly measured

Costs can be claimed as direct costs in category D.4 'Large research infrastructure' only if they are **directly measured** (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[25] *See Article 129(1) of the Financial Regulation No 966/2012.*

Example 2 (Comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (**project time**) and therefore require reliable time recording (through time-sheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No 1290/2013

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. This data must be regularly updated.

  Example 3 (Costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

Example 4 (Part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[26]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (Rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[26] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints *(e.g. opening hours)*, but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Article 6.2. Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]]**[OPTION 2**: not applicable;]*

(d) ***[OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]]* ***[OPTION 2:*** *not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (E.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

⚠ **Combining H2020 & other EU grants —** Beneficiaries that also receive an EU **operating grant** can NOT declare any indirect costs for the reporting period(s) covered by the operating grant.

Best practice: The beneficiary must **inform** both the coordinator and the Commission/Agency during grant preparation and before submitting financial statements (via the Participant Portal).

'Operating grants' are (normally annual) grants given by a separate grant agreement to finance the operation and running costs of an entity *(e.g. call COMM-C2/01-2013 under the Europe for Citizens programme)*.

1.1 This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared** on the basis of a flat-rate (*see Article 5.2(e)*; ⚠ new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying a 25 % flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: *subcontracting of opinion surveys.*

The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises
- costs of providing financial support to third parties (if option applies)
- costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a grant agreement and has incurred the following costs

- EUR 100 000 in personnel costs (EUR 7 000 of which are an in-kind contribution made by a laboratory technician carrying out work for the action from his/her laboratory in a public research centre),

- EUR 20 000 in subcontracting costs,

- EUR 10 000 in consumables costs.

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

F. [OPTION 1: [Insert name of specific cost category(ies)[22]]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION** 1a **for** specific unit costs **(if unit cost foreseen by Commission decision and applicable to the grant): [insert name of specific cost category]** are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]]**.]

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category]** are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]

[same for each specific cost category]

[OPTION 2:** Not applicable**]

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of the Horizon 2020 Framework Programme, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: **costs for energy efficiency measures in buildings**

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': **access costs for providing trans-national access to research infrastructure**

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': **costs for clinical studies**

  The unit cost applies ONLY to actions with clinical studies.

⚠ **Double funding risk —** Costs that are declared as a specific unit or lump sum cost may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Example:

The unit cost for efficiency energy measures in buildings covers subcontracting costs related to the energy efficiency measures. These cannot be declared as subcontracting costs. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

1.1 Specific cost category – costs for energy efficiency measures in buildings (F.2)

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared** on the basis of the unit cost set out in Commission *Decision C(2013) 8196*[27] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) must be calculated — before signature of the GA — according to the following formula:

Amount per unit = {EUR 0.1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m^2 of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

[27] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 Specific cost category – access costs for providing trans-national access to research infrastructure (F.2)

1.2.1 This budget category **covers** direct and indirect access costs for providing trans-national access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

> ⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.
>
> Beneficiaries that use budget category F.2 'access costs for providing trans-national access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, in category D.1 'travel'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing trans-national access to research infrastructure'), the costs must be **declared** on the basis of the unit cost calculated in accordance with Commission Decision C(2013) 8199[28] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{29}\text{)}}{\text{average annual total quantity of access (over past two years}^{30}\text{)}}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

[28] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[29] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[30] In exceptional and duly justified cases, the Commission may agree to a different reference period.

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users

    Exceptionally, these costs may be calculated in accordance with the beneficiary's usual cost accounting practices (average personnel costs).
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the user's research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)
  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)
- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

The access activities and the parameters for calculating the unit cost must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annexes 1 and 2a.

The proposal should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per installation and access provider).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

During the GA, the beneficiaries may change their choice, but only via an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 Specific cost category – costs for clinical studies (F.2)

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study;
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
  - costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
  - indirect costs for the study.

1.3.2 If they are declared under this budget category (i.e. F.2 'costs for clinical studies'), the costs must be **declared** on the basis of the unit cost set out in Commission Decision C(2014) 1393[31] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/patients or subjects included in the clinical study) must be calculated for each study and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — according to the following formula:

[31] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

Amount per unit ={Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks] }

The unit cost components must be calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':
{'average hourly cost for doctors', i.e.:
certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full-time-equivalent for the personnel category doctors for year N-1}
multiplied by
estimated number of hours worked by doctors for the task (per patient/subject)}

For unit cost component 'personnel costs of other medical personnel':
{'average hourly cost for other medical personnel', i.e.:
certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full-time-equivalent for the personnel category other medical personnel for year N-1}
multiplied by
estimated number of hours worked by other medical personnel for the task (per patient/subject)}

For unit cost component 'personnel costs of technical personnel':
{average hourly cost for technical personnel, i.e.:
certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full-time-equivalent for the personnel category technical personnel for year N-1}
multiplied by
estimated number of hours worked by technical personnel for the task (per patient/subject)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc.)

For each category of consumables:
{'average price per item', i.e.:
{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned
total number of items purchased in year N-1 for the category of consumables concerned}
multiplied by
estimated number of items used for the task (per patient/subject)}

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:
{'average cost of depreciation and directly related services per unit of use', i.e.:

{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

total capacity in year N-1

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:

'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%

multiplied by

{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}**}**

The following must be excluded:

- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

The estimation of the resources must be done on the basis of the protocol for the clinical study (and must be the same for all beneficiaries/linked third parties/third parties involved).

Each beneficiary/linked third party/third party providing in-kind contributions must calculate the direct costs by using its historical costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application).

Personnel costs must be defined in the 3 categories (doctors, other medical personnel, technical personnel) defined in the Commission Decision. No other categories *(e.g. 'nurses')* can be used.

The descriptions of the resources and the parameters for calculating the unit cost must already be part of the proposal *(see the proposal templates and the* template for essential information to be provided for proposals including clinical trials / studies/ investigations *provided on the call pages)* and be included in Annex 1 and 2a of the GA.

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per study and beneficiary/third party.)

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or of costs actually incurred for a given clinical study.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** the number of patients or subjects that participated in the study

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

1. Costs of linked third parties (A.-F.)

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility) like beneficiaries.

The same rules apply, but with the changes needed to render them applicable to linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 14.1.1.

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared in category A.1 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions by third parties free of charge (A.-F.)

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared in category D.2 'equipment' (Article 6.2.D.2).*

In-kind contributions *free of charge* must be **distinguished** from **in-kind contributions *against payment*** *(see Article 11)*.

In-kind contributions *against payment* are costs *of* the beneficiary (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. Their costs (i.e. the payment) must be declared under those specific budget categories.

Examples:

1. *The cost of personnel seconded against payment must be declared in category A.3 'seconded personnel (against payment)' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

The costs of in-kind contributions free of charge (i.e. the costs of the third party offering them) can be assimilated to beneficiary costs and must be declared in the budget category that the beneficiary would have used.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

– **debt and debt service charges**

'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

> ***Example:*** *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

– **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

Conversely, if VAT is NOT deductible, it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction

between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*
  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 bodies)*
  - if a beneficiary is receiving an operating grant[32] from the EU/Euratom (i.e. a grant to finance its functioning), then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Specific cases (ineligible costs):

Non-identifiable VAT — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts, since non-identifiable VAT is not deductible. VAT is thus eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

Duties — The eligibility of duties depends on the eligibility of the cost item to which they are linked (i.e. in whose price they are included). If the item is eligible, the duty is also eligible.

[32] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the relevant national law.*

⚠ Normally, the beneficiaries must comply **BOTH** with the national law of the **country** in which they are **established** AND that of the country where the **action** is **implemented**.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Example (acceptable): *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

Example (acceptable): *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action (**'third parties involved in the action'**).

⚠ Beneficiaries using third parties remain **fully responsible** for them under the GA.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues like beneficiaries.

Third parties involved in the action do NOT sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks. They must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme). For more information on conditions for participation and funding, *see the Online Manual.*
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the

subcontractors but not for the beneficiary).	beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the government (the ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the ministry/government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

This table gives an **overview** of the different kinds of **third parties**:

TYPE	CHARACTERISTICS						
	Works on action tasks?	**Provides resources or services for action?**	**What is eligible?**	**Must be indicated in Annex 1?**	**Indirect costs?**	**Selecting the third party**	**GA articles**
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link	Article 14
Subcontractor	**YES**	**NO**	**Price**	**YES**	**NO**	Must be best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contribution	**NO**	**YES**	**Costs**	**YES**	**YES**	May not be used to circumvent the rules	Articles 11 and 12
Contractor (selling, equipment, good or service)	**NO**	**YES**	**Price**	**NO**	**YES**	Must be best value for money, avoid conflict of interest	Article 10
Third parties receiving financial support[33]	The third parties participate in the action as recipients.		**Amount of support given**	**YES**	**NO**	According to the conditions in Annex 1	Article 15

[33] Only if allowed in the work programme/call.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION 2: *Not applicable****]***

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

These beneficiaries are beneficiaries (although they do not receive any funding) and therefore must carry out the work under the action and comply with the GA (although not with *all* its obligations).

'Beneficiaries not receiving EU funding' are usually third country participants which:

- are not from a country listed in General Annex A to the Main Work Programme and
- were not granted exceptional EU funding by the Commission/Agency (during the selection procedure

For more information on third country participants, *see the Online Manual (international cooperation).*

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on their role in the grant and if it has linked third parties that receive EU funding or not).

This table summarises the **GA obligations** that do **NOT apply** to beneficiaries not receiving EU funding (marked by X under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of **breach** of any **of** their **obligations**, their participation may be terminated and any of the other Chapter 6 measures (except for rejection of costs or recovery) may be taken.

Example:

A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.

In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […][23]**]

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EU)[25] or 'contracting entities' within the meaning of Directive 2004/17/EC[26] (or 2014/25/EU)[27] must **comply** with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the purchasing context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, *such as technical quality, etc.*), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the grant amount). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules which the European Commission applies for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional cost eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[34] must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 4 of Directive 2014/25/EU)*.

Specific cases (purchases):

- **Purchases between beneficiaries** — Are in principle not accepted. If a beneficiary needs supplies from another beneficiary, it is the latter beneficiary that should charge them to the action. (Otherwise there is the risk that the grant is used to charge commercial profit margins.) Purchases between beneficiaries will only be accepted in exceptional and properly justified cases *(e.g. beneficiary A is the usual supplier of beneficiary B for a generic consumable that beneficiary B needs for the action)*.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

[34] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the measures described in Chapter 6.

1. In-kind contributions by third parties against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example (in-kind contributions against payment): *medical equipment provided by a hospital (against a fee) to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs actually incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2*; *e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

For the upper limit (third party's actual costs), normally only the *direct* costs are taken into account.

These *direct* costs may not be based on unit costs[35] or lump sums *(i.e. they must be identifiable and verifiable in the accounts of the third party). Thus, the beneficiary cannot, for instance, use the unit costs for SME owners or natural persons who do not receive a salary*.

When calculating the actual costs incurred by the third party, *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used on the beneficiary's premises

or

- taken into account: if the in-kind contributions are NOT used on the beneficiary's premises (*but, for instance, on the third party's premises*).

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

[35] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

If an audit shows that the costs declared by the beneficiary are higher than those actually incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

3. Additional cost eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**').

> ***Example:*** *A new researcher brought into a team working for a H2020 action during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

> ***Example (no approval):*** *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The beneficiaries may declare **costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions by third parties free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary itself makes no payment and there is therefore NO cost incurred by the beneficiary. However, the GA provides that it may charge the costs incurred by the third party for its in-kind contribution *(see also Article 6.4)*.

Examples (in-kind contributions free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the ministry/government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like universities/ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

⚠ Article 12 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and *in Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs of the third party may be declared.

These direct costs may not be based on unit costs[36] or lump sums (*e.g. they must be identifiable and verifiable in the accounts of the third party*). Thus, the beneficiary cannot, for instance, use *the unit costs for SME owners or natural persons who do not receive a salary*.

When calculating the actual costs incurred by the third party, *indirect* costs of the third party are:

- either not taken into account if the resources (in-kind contribution) are used in the premises of the beneficiary; or
- taken into account by using the 25% flat-rate if the in-kind contributions are used in the third party's premises. In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

  If the indirect costs are claimed in this way, the beneficiary may not include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional cost eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**'; *see Article 11*).

[36] With the exception of unit costs for conducting clinical studies, for which specific provisions apply (see 'Specific cost category – costs for clinical studies' under Article 6.2.F)

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[28]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION 1 only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]***.]***

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be **set out in Annex 1** and the total estimated costs of subcontracting per beneficiary must be **set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) **must comply** with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on business conditions

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from linked third parties; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2).*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work.

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary.

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

  Subcontracts should in particular foresee that intellectual property generated by a subcontractor reverts to the beneficiary (so that it can meet its obligations towards the other beneficiaries in the GA and respect the other obligations of the GA).

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

Security obligations — Stricter rules apply for action tasks that involve information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37*).

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts either on the best value for money (considering the quality of the service proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the subcontracting context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional cost eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI). It is important not to confuse a Research and Innovation action, or an Innovation action, involving PCP or PPI with a PCP/PPI action. For the latter, the main objective of the action is the implementation of a single joint public procurement of research and development (R&D) services (in the case of PCP) or innovative solutions (in the case of PPI).

The additional rules mirror the key obligations from the H2020 MGA PCP/PPI.

4. Additional cost eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the **name** of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the subcontract (or the subcontracting costs). For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA ('**simplified approval procedure**').

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the full discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

5. Additional cost eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[37]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.

'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 4 of Directive 2014/25/EU)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* — Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

[37] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

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[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[30] and **third parties with a legal link to a beneficiary**[31] ('**linked third parties**') may implement the action tasks attributed to them **in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

*The linked third parties may declare as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

*The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their linked third parties.*

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries.

⚠ **Combining H2020 & other EU grants —** The terminologies under different EU funds/funding programmes may differ *(e.g. 'linked third parties' under H2020 are the SAME as 'affiliated entities' under the Financial Regulation, while 'affiliated entities' under H2020 is NARROWER than 'affiliated entities' under the Financial Regulation (see Articles 2.1(2) and 23(5) of the Rules for Participation Regulation No 1290/2013 and Article 122 of the Financial Regulation No 966/2012).*

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).

  The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission/Agency as reimbursement of costs for their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only **affiliated entities** or **entities with a legal link to a beneficiary** can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; 'ad hoc' collaboration agreements or contracts to carry out work in the action are NOT covered. (In this latter case, both legal entities should be beneficiaries.)

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or
- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research). They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

Associations, foundations or other legal entities *composed of members (where the association/foundation etc. is the beneficiary and the members are the linked third parties).*

Examples (affiliated entities):

Company A established in France holding 20% of the shares in Company B established in Italy. However, that 20% of shares has 60% of the voting rights in company B. Therefore company A controls company B and both companies may be linked third parties in a H2020 GA.

Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.

Linked third parties must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme).[38]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an American company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country that is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.*

For more information on conditions for participation and funding, *see the Online Manual*.

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak'
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

1. *The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

3. *The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.*

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the

[38] *See Articles 8 and 9 of the Rules for Participation Regulation No 1290/2013.*

amendment introducing the linked third party in the GA; *see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery), who must upload it (as a scanned PDF copy) in the system.

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files.

The liability is for any amount owned by the beneficiary under the GA, and up to the linked third party's maximum EU contribution in Annex 2.

ℹ For more information on the financial viability/capacity check, *see the Online Manual*.

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. *Entities specifically established for the purpose of implementing the action (e.g. EEIGs).*

2. *National research associations established according to the national law in order to carry out research not limited to the action.*

3. *A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.*

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional cost eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO 'simplified approval procedure'.

3. Additional cost eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* (since linked third parties cannot sign them in the IT system; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary.

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Each linked third party has to provide its own ***certificate* on the financial statements** (**CFS**; *see Article 20.4*).

The threshold of EUR 325 000 applies to each linked third party (independently of its beneficiary).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

4. Additional cost eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

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15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving financial support.*

15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving financial support.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties ONLY where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*)

Examples:

An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.

One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving a prize.*

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving a prize.****]***

[OPTION 2: *Not applicable****]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

***Access** for user groups with a majority of users not working in a EU or associated country[34] is **limited** to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) procedure and criteria for **selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]]*[35]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

1. *advertise widely, including on a dedicated website, the access offered under the Agreement;*
2. *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
3. *ensure that users **comply** with the terms and conditions of the Agreement;*
4. *ensure that its obligations under Articles 35, 36, 38 and 46 **also apply** to the users.*

***[OPTION 2:** Not applicable]*

[32] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[34] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[35] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Main Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[39] or installation[40] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 of the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

[39] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[40] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

⚠ **Record-keeping —** The beneficiaries must keep appropriate records and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional cost eligibility condition: Access which must be provided

Trans-national access can be either:

- **in person** (hands-on), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional cost eligibility condition: Categories of users that may have access — Limited access for special user groups

For trans-national access, user groups in which all or most users work in **third countries** may ONLY have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional cost eligibility condition: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. 'Other obligation': Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action — Extension of obligations under the GA to users

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

The beneficiaries must also ensure that the users comply with certain obligations under the GA.

Obligations that must be extended to users:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

16.2 Rules for providing virtual access to research infrastructure

***[OPTION 1 for virtual access to research infrastructure:** 'Access providers'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2:** Not applicable**]

16.3 Consequences of non-compliance

***[OPTION 1 to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of the Horizon 2020 Framework Programme, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **cover** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action
- costs related to technological and scientific support for users access *(e.g. a helpdesk)*

- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed — unless provided for in the work programme/call.

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*

Access must be open to all users; users are not selected.

3. Additional cost eligibility condition: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request the information for **any purpose** *(e.g. checks for monitoring the action or assessing reports and requests for payment; reviews; audits; investigations; evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission/Agency may request the information at **any time**, either during the action or afterwards.

Examples:

In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid.

The Commission may request information from the beneficiaries in order to evaluate the action's impact (Article 23) up to five years after the balance is paid.

The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information is sent via the Participant Portal. Afterwards, information requests may have to be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary must keep its information in the Beneficiary Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form *(e.g. private limited liability company, public law body, S.A., S.L.)*
- organisation type *(e.g. SME, secondary or higher education establishment, etc.)*.

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, validation and data updates, *see the Online Manual*.

3. Information likely to delay or affect the action or EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

> ***Examples (situations likely to significantly affect or delay the action's implementation or affect the EU's financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the Beneficiary Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.).*

Best practice: It is recommended that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the Participant Portal
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (for linked third parties, *see point 10*) must keep appropriate and sufficient evidence to **prove** the eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[41]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least 5 years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

[41] International Standard on Auditing ISA 500 'Audit Evidence'.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission/Agency will accept any document considered an original under national law.

Examples:

The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.

The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

Costs declared in category A.1 (employees or equivalent) must be detailed for each person carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).

For costs declared in category D.1, D.2, D.3 and D.4 (other direct costs), the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.) It should provide details of individual transactions for each type of cost. For depreciation, it must provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For personnel costs declared in accordance with their usual cost accounting practices (**average personnel costs**), the beneficiaries must keep detailed records and other supporting documents to:

- show that the personnel costs used to calculate the unit cost (hourly rate) match the actual personnel costs as recorded in the statutory accounts

  Examples: *accounting records, financial statement extracts, labour contracts, collective labour agreements, applicable national tax law, labour and social security contributions, pay slips, bank statements showing salary payments, classification of employees based on experience, qualifications, salary, department, etc.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost (hourly rate) is free of ineligible cost components

  Examples: *records that show that the hourly rate does not include an indirect cost component (that should be covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (that should be claimed under 'other direct costs').*

- assess the acceptability of budgeted and estimated elements

  Example: *records that show adjustments corresponding to the consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases.*

- verify the number of productive hours used to calculate the unit cost (hourly rate).

It is NOT necessary to keep records on the actual personnel costs incurred per person.

6. Certificate on the methodology (CoMUC)

What?

To get additional assurance, a beneficiary/linked third parties may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared before the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificate is NOT valid for H2020.)

When?

Beneficiaries may in principle submit their requests for approval at **any time** — before or during the grant.

Best practice: In order to ensure that the auditor has enough information to get assurance on the methodology, it is recommended to request it only after the first reporting period has passed.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

⚠ If the beneficiary declares personnel costs according to the changed cost accounting practices *before* the new certificate is approved, it bears the **full risk** of non-approval and cost rejection by the Commission/Agency.

How?

The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 of the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

> ⚠ For H2020, exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, monthly or per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a declaration on exclusive work for the action (one per reporting period), to confirm that the person worked exclusively for the action, either:

  - during the whole reporting period

  or

  - during an uninterrupted time-period, covering at least a full natural month within the reporting period.

  Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration.

  If a person worked randomly for the action after an uninterrupted time-period covered by a declaration, time records are needed for the period of random work.

  > ***Example:*** *the person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

  The declaration must be **dated** and **signed** by the person concerned AND her/his supervisor.

- keep **time records**.

  Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

- show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

  Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

  If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic

validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

Time records should include, as a minimum:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record;
- the supervisor's full name and signature
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template for time-sheets with these minimum requirements is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept **alternative evidence** if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has full discretion to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the **full risk** of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned

Criterion 2 is met – the project is identified as XYZ

Criterion 3 is met – the time is quantified: two weeks

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown

Criterion 2 is not met: the project name is not mentioned

Criterion 3 is not met – the time is not quantified

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Example: *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.

The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

('Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points)

The deliverables that must be produced are listed in Annex 1 of the GA.

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

Security obligations — If the deliverables contain **EU classified information**, the coordinator must first contact the Commission/Agency to discuss how to submit them (approval needed; *see Article 37*).

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

How?

The coordinator must upload them directly in the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1]to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2 : *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

What & When?

In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of the action (reporting).

> These reports must be **distinguished** from **deliverables** (that are part of Annex 1; see Article 19) and milestones (that may be part of Annex 1, but are normally neither covered by Article 19 nor by Article 20).

The coordinator must submit both:

- a **periodic report** after the end of each reporting period (including the last one) and
- a **final report** at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically generated by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (CFS; one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration.

Forms and templates for the different parts of the reports are available in the Participant Portal.

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

If the coordinator **breaches** its **obligation** to submit the reports, the Commission/Agency may suspend the payment deadline and — if not remedied after a written reminder — terminate the GA or take any of the other Chapter 6 measures *(e.g. cost rejection, grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50).*

The GA will not be terminated if the breach concerns the last reporting period/final report (because the action duration is already over).

How?

The report(s) must be **prepared** by the **coordinator** and the **beneficiaries together** (directly in the Participant Portal).

List of documents for the periodic reports:

- explanation of the work carried out (periodic reporting - part B technical report)
- overview of the progress (periodic reporting - part B technical report)
- updated plan for the exploitation and dissemination of results (if necessary) (periodic reporting - part B technical report)
- summary for publication (continuous reporting)
- answers to the questionnaire (continuous reporting)
- individual financial statements for each beneficiary and linked party (periodic reporting - financial report)
- explanation of the use of resources (periodic reporting - financial report)
- summary financial statement (generated automatically by the IT system)
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication (generated automatically by the IT system)
- final summary financial statement (generated automatically by the IT system)
- certificates on the financial statements (CFS) (if necessary).

Generally, they can be **prepared together** (i.e. by several users from different beneficiaries), via the Participant Portal Continuous and Periodic Reporting Modules. The parts in the **continuous reporting** can be filled out at any moment in time (continuously open) and are then automatically added into the periodic or final report by the IT system *(part A of the technical report with the questionnaire and the summary for publication; consolidated financial statement*). Other parts are opened only at **periodic reporting** *(part B of the technical report, individual financial statements, explanation of the use of resources)*. Data is cross-linked to avoid duplication of data input *(e.g. the financial statement and the explanation on the use of resources are linked: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense, if necessary; the final report is completely automatized: assembled on the basis of elements from the periodic report).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (directly in the Participant Portal).

This includes the **coordinator**, who must also submit the individual financial statement for itself.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (since the linked third parties cannot sign them in the IT system).

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must ensure that the data encoded is correct (i.e. identical to the signed paper version).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

If a beneficiary cannot submit its individual financial statement on time, the report can be **submitted without this financial statement**. The costs will be considered zero for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned.

⚠ **Record-keeping —** The beneficiary must keep the originals for itself and its linked third parties in its files *(see Article 18.1.2)*.

When all parts are ready, the report(s) are assembled automatically by the IT system and must be **submitted** by the coordinator (as a single package; **single submission**).

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator, as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) (**suspension of the payment deadline**). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified (**single re-submission**).

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

⚠ **Adjustments of financial statements (exceptional) —** If the beneficiaries notice a mistake *(e.g. incorrect accounting information; error in the calculation; etc)*, they can make an adjustment (positive or negative) in the following reporting period to the financial statements for any previous reporting period.

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed *(e.g. to take into account of a different hourly rate after the closure of the financial year)*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods

1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated **plan for the exploitation and dissemination of the results** (if such a plan is foreseen in Annex 1).

3.0 For grants signed after GA version 3.0, the overview of the progress must also indicate the communication activities carried out by the consortium *(see also Article 38.1).*

Security obligations — Technical reports may NOT contain any information that has been **EU-classified** in Annex 1 of the GA *(see Article 37).*

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an easy-to-read way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential (or EU-classified) information.

For the last reporting period: The summary should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact (because it will be directly re-used for the final report).

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the H2020 Framework Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the H2020 Specific Programme)
- information to monitor the implementation of H2020 on cross–cutting issues *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020

against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Periodic financial report: Individual financial statements — Explanation of the use of resources — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 (**cost overruns**). The grant will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is generated automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact. It will be generated automatically by the IT system (on the basis of the summary for publication of the last reporting period).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically generated by the IT system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

Some beneficiaries/linked third parties must submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and personnel costs declared on the basis of unit costs calculated according to its usual accounting practices (average personnel costs).

This means that costs based on lump sums, flat-rates (*e.g. indirect costs*) or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in a H2020 action which declared the following total eligible costs for the action:

- *average personnel costs = EUR 250 000*
- *subcontracting costs = EUR 40 000*
- *depreciation costs of equipment used to carry out the action = EUR 60 000*
- *indirect costs (25 % flat rate) = EUR 77 500*
- *total eligible costs claimed by A = EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and average personnel costs incurred by A (and hence the requested financial contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or average personnel costs must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency do not have to be covered again by the certificate.

Example:

A beneficiary participates in a H2020 action with three reporting periods. During the second reporting period the Commission's auditors carry out an audit of the costs incurred by the beneficiary in the first reporting period. At the end of the action, the beneficiary requests a total contribution of EUR 425 000 and has to submit a CFS with the final reports. In this case, the CFS may exclude the costs of the first reporting period (which were already covered by the Commission audit).

Linked third parties must submit a certificate if it (on its own, without its beneficiary) reaches the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

The certificate(s) may be submitted ONLY **with** the **final financial report**. Certificates submitted at any other moment will NOT be accepted (and costs incurred for them will be considered ineligible, because not necessary).

Costs for partial certificates (i.e. one certificate per reporting period) will be accepted ONLY if:

- a CFS is mandatory (i.e. the threshold is reached at the end of the action) and
- the total costs of the partial certificates is similar to the cost that would have been incurred for a single certificate.

The certificate must be issued by an **external auditor**, using the template in Annex 5 of the GA.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[42] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a non-EU country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in non-EU countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants above EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

A template is available in the Participant Portal.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices

[42] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:

  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[43].

    Procedure for calculating the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[44].

    Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

[43] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[44] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts prior to that)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or an(other) executive agency — without the consent of the beneficiary concerned and up to the beneficiary's maximum EU contribution in Annex 2 *(see also Article 44)*.

All payments are subject to a **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request). The deadline depends on the type of payment:

- for pre-financing: 30 days
- for interim payments and payment of the balance: 90 days *(see Article 21)*.

If there are issues with the payment request or with the costs declared which make it impossible to comply with the payment deadline, the Commission/Agency will **suspend the deadline** *(see Article 47)*.

The pre-financing payment is automatic, while for interim and final payments the Commission/Agency must first:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs
- calculate the amount to be paid
- approve the payment request and authorise the payment.

This is not an in-depth verification and therefore no guarantee for eligibility or correctness. The costs may still have to be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

The payments are made **to the coordinator**; the beneficiaries are NOT paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only if the coordinator is terminated that the Commission/Agency (and especially the Guarantee Fund) will intervene; *see Article 50*).

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the **amount** is fixed in each GA.

Normally it will be (depending on the availability of EU budget credits) **100 %** of the **average EU funding per period** (i.e. maximum grant amount set out in Article 5.1 / number of periods) for actions with at least two reporting periods. It will be however less for actions with only one reporting period, since 100 % would mean the totality of the grant amount.

At the moment of the pre-financing, an amount that corresponds to **5 %** of the maximum grant amount *(see Article 5.1)* is **deducted** from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100 % reimbursement rate

Pre-financing: EUR 333 334 of which:

EUR 283 334 transferred to the consortium (coordinator)

EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 - EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until the payment of the balance — when they are cleared against the eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90 % of the maximum grant amount minus the pre-financing

Example for calculating interim payments:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1; application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The **amount** of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples for calculating the payment of the balance:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.

Pre-financing of EUR 333 334 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).

Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.

Total eligible costs accepted for 1st interim period: EUR 570 000;

1st interim payment: EUR 566 666 (the 90% limit is reached).

Total eligible costs accepted for 2nd interim period: EUR 162 500.

2nd interim payment: EUR 0 (the 90 % limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*

Final grant amount: EUR 750 000.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*

The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 312 500 = EUR 1 045 000.

Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.

*EUR 150 000 will be **paid** to the coordinator as follows:*

- *EUR 100 000 directly by the Commission as payment of the balance; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 155 000*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 155 000 = EUR 887 500.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Commission/Agency checks

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Agency performs a plagiarism check on documents submitted by the consortium.*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in H2020 actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The checks itself are **internal**. They may however have external effects, since the Commission/Agency may have to **ask** the coordinator (or directly the beneficiaries) for **additional information** needed for the check *(see Article 17.1)* or it may take Chapter 6 measures in view of the results.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date.*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. In this case, the Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

Example: *Ethics checks are normally carried out with the help of external experts.*

If the check shows **ineligible costs** or serious **breach of obligations**, it may lead to cost rejection or grant reduction and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission/Agency may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Commission/Agency reviews

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA and may exceptionally also concern issues related to only one specific beneficiary.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows **ineligible costs** or **substantial errors, irregularities or fraud** or serious **breach of obligations** (including non- or improper implementation of the action as described in Annex 1), it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (or, exceptionally, the beneficiary concerned) via the Participant Portal.

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or a **review meeting** (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a **review report**.

- The review report together with the Commission/Agency comments will be notified to the coordinator (or, exceptionally, the beneficiary concerned) for comments within 30 days (**contradictory review procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The Commission/Agency operational services (authorising officers) will analyse the comments received and decide on the follow-up, if any.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Commission/Agency audits

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ **Record-keeping** — Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including cost rejection, grant reduction, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit **third parties providing in-kind contributions** (free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest) and that the payments made under the contract/subcontract were in line with the GA (e.g. amounts paid to the contractor/subcontractor match those declared by the beneficiary). The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to assess the contractors'/subcontractors' costs, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).*

4. *The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will therefore be with the beneficiary. The beneficiary is responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and, in very serious cases, to exclusion and/or financial penalties *(see Article 45)*.

In some cases, findings may result in the **acceptance** of additional costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about actual costs for cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data

to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the Participant Portal or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an **audit report**.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days (**contradictory audit procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the **final audit report** and the **letter of audit conclusions** (LoC) — and the file will then be passed on to the Commission/Agency operational services (authorising officers) for the follow-up, if any.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[41] and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. OLAF investigations

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the outcome of the investigation to the Commission/Agency, who will then decide how to proceed.

If an OLAF investigation shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)*, to exclusion and/or financial penalties *(see Article 45)*, as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. ECA checks and audits

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

If an ECA audit shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, this may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION 2:** Not applicable.**]

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the **findings concern substantial errors, irregularities or fraud or serious breach of obligations,** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings (rejection and grant reduction)

If the Commission/Agency finds (in a check, review, audit or investigation) **substantial errors, irregularities or fraud** or serious **breach of obligations** which are **systemic** or **recurrent**, it may make a correction (cost rejection or grant reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed (extension of the findings)
- other H2020 grants of the beneficiary (extension of the findings).

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

Findings may be extended to all other EU or Euratom grants awarded under similar conditions.

⚠ Findings will normally be extended only within one programme *(e.g. findings in an H2020 audit to all H2020 grants)* but they may exceptionally also be extended to similar programmes *(e.g. if justified by the nature of the findings and the similarity of the applicable grant agreements or in case of serious irregularities or fraud).*

2. Procedure

If findings are systemic or recurrent**,** this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an audit extension procedure (which is then followed by an audit/review implementation procedure).

Procedure for extension of findings and audit implementation:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure (**letter of audit conclusions**), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for cost rejection:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (if the beneficiary does not submit revised financial statements)
  - the conditions for external counter-audits to propose an alternative correction method *(see below)*
- for grant reduction: the proposed flat-rate for the correction.

The 'extrapolation rate' will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The 'flat-rate' will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept the alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for cost rejection: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for grant reduction: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has **full discretion** to accept or refuse an alternative correction method proposed by the beneficiary and there is NO entitlement to it.

Step 3 — Audit implementation. If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the cost rejection/grant reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the cost rejection/grant reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:** five]**[OPTION 2 for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the H2020 Framework Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the H2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of H2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[45] annexed to the EU Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[45] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

Best practice: Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[46]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[46] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or '**associated country**'[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 <u>Rights of third parties</u> (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Record-keeping

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. subcontractors, linked third parties, employees, etc.)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action; beneficiaries for which linked third parties carry out a significant part of the work.*

Examples (arrangements): *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is impossible under EU or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.)*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Standard forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):
For an invention: e.g. patent, confidential information.
For the design of a technology: e.g. industrial design, copyright.
For a website: e.g. industrial design, copyright, trademark.

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example: *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (using the text of the GA language version available on the Participant Portal Reference documents page).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the plan for the exploitation and dissemination of the results.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

⚠ Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018'];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1 for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2**: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security obligations, etc.)*.

Security obligations — Dissemination may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

Results that contain **EU-classified information**, can be disclosed only after approval by the Commission/Agency *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The beneficiaries may choose the **form** for disseminating their results.

Standard forms of dissemination:

- website
- presentation at a scientific conference
- peer-reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination — unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

2. Open access to scientific publications

What?

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals)*.

⚠ Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications.

Best practice: Open access has no impact on the other terms and conditions that apply to scientific publications *(e.g. as regards use, etc)*. However, in order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights such as the right to copy, distribute, search, link, crawl and mine).

A 'repository for scientific publications' is an online archive. Beneficiaries are free to choose the repository; it can be institutional, subject-based or centralised.

Best practice: The Open Access Infrastructure for Research in Europe (OpenAIRE) links existing repositories. It is not obligatory for projects to deposit in OpenAIRE itself, but it is the recommended entry point for researchers deciding on a repository. OpenAIRE also offers support services for researchers, such as the National Open Access Desks. Other useful listings are the Registry of Open Access Repositories (ROAR), the Directory of Open Access Repositories (OpenDOAR) and OAPEN (for monographs). Beneficiaries should not choose a repository with rules which could conflict with open access.

Open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets certain requirements that must be fulfilled if they do decide to publish them.

Open access can be provided through:

a) **gold open access** (**open-access publishing**)

'Gold open access means that open access is provided immediately via the publisher when an article is published, i.e. where it is published in open access journals or in 'hybrid' journals combining subscription access and open access to individual articles.

In gold open access, the payment of publication costs (article processing charges) is shifted from readers' subscriptions to (generally one-off) payments by the author. Such author processing costs may be eligible *(see Article 6.2.D.3)* — if incurred before the end of the action. Currently, an action for dealing with such costs incurred after the end of the action in FP7 is being piloted and further action in H2020 will be considered based on the outcome.

⚠ Although gold open access already ensures access via the publisher, the beneficiaries must nevertheless also provide open access via a repository *(see below)* in order to ensure the long-term preservation and availability of the publication.

b) **green open access** (self-archiving).

'Green open access' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in an online repository. Access to the article is often — but not necessarily — delayed (H2020 embargo period between 6 and 12 months; *see below*) as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download view fees during an exclusivity period.

Best practice: Authors are encouraged to retain their copyright and grant appropriate licences to publishers.

How?

Open access to scientific publications involves four steps — which may or may not be taken at the same time:

Procedure for open access (scientific publications):

Step 1 — **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication).

This must be done as soon as possible (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*) and at the latest on publication.

'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

Step 2 — Provide **open access** to the scientific **publication** — either as 'gold open access (i.e. via the publisher AND via the repository) or as 'green open access (i.e. via the repository only).

Open access must be given:

- in case of 'gold open access': at the latest on publication

- in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

Step 3 — Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

This is needed for visibility, traceability and monitoring.

It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and
- a persistent identifier *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

Best practice: For ease of tracking, beneficiaries should also include the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601) in the funding acknowledgement field in their metadata.

The metadata compliance of the repository can be checked using OpenAIRE.

Step 4 — Aim to **deposit** at the same time, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

ℹ For more information on why open access to scientific publications and digital research data is an important aspect of Horizon 2020, *see the Online Manual.*

3. Open access to research data (Extended Open Research Data Pilot)

What?

Beneficiaries of actions that participate in the Open Research Data Pilot must give **open, free-of-charge access** to the end-user to **digital research data** generated during the action (⚠ new in Horizon 2020).

⚠ As of the Work Programme 2017, the Open Research Data pilot has been extended to all thematic areas of Horizon 2020 (except ERC PoC actions, SME instrument Ph1 actions, ERA-NET Cofund actions that do not produce data, EJP Cofund actions, and prizes).

Participation is therefore now in principle **the default**. However, actions may **opt out** at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55)* —, if:

- participation is incompatible with the obligation to protect results *(see Article 27)*

- participation is incompatible with the security obligations *(see Article 37)*
- participation is incompatible with rules on protection of personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate/collect any research data or
- there are other legitimate reasons not to take part.

'Digital research data' is information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Only data that is generated digitally *in the action* is concerned. Actions are encouraged to digitise any other data and provide open access to it, but they are not obliged to do so.

The pilot applies to **2 types** of digital research **data**:

- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data and associated metadata, as specified by the beneficiaries themselves in their data management plan.

Examples: *curated data not directly attributable to a publication or raw data*

⚠ Beneficiaries may decide not to provide open access to specific datasets if this would go against other GA obligations *(e.g. to protect results or personal data)* or if the action's main objective, as described in Annex 1, would be jeopardised by giving open access to those specific datasets. In this case, the reasons must be explained in the data management plan, *see below*).

Open access to research data means taking measures to make it possible for third parties to **access, mine, exploit, reproduce** and **disseminate** data — via a research data repository.

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories (Re3data) and Databib. One key entry point for accessing and depositing related data and tools is Zenodo.

Actions participating in the pilot must draw up a **data management plan (DMP)** within the first 6 months of the project implementation.

The data management plan must support the management life-cycle for all data that will be collected, processed or generated by the action. It must cover how to make data findable, accessible, interoperable and re-usable (FAIR), including:

- the handling of data during and after the project
- what data will be collected, processed or generated
- what methodology and standards will be applied
- whether data will be shared / made open access (and how) and, if any, what data will not be shared / made open access (and why)
- how data will be curated and preserved.

The data management plan should be updated (and become more precise) as the project evolves. New versions should be created whenever important changes to the project occur *(e.g. new data sets, changes in consortium policies, etc),* at least as part of the mid-term review (if any) and at the end of the project.

For more information on data management plans (and a template), *see the proposal forms and the Online Manual.*

Costs related to the implementation of the Open Research Data pilot *(e.g. costs for providing open access, related research data management costs, data curation and data storage costs)* may be eligible *(see Article 6.2.D.3)*.

How?

Open access to digital research data involves 3 steps:

Procedure for open access (research data):

Step 1 — **Deposit** the digital research data, preferably in a research data repository.

Step 2 — Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. for databases: by attaching an appropriate creative commons licence (CC-BY or CC0 tool) to the data; if the access/use is not subject to any rights: by indicating that no licence is needed)*.

Open access must not be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

Step 3 — Provide **information**, via the repository, about **tools and instruments** for validating the results.

Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.).*

For more information on the research data pilot (and especially how actions may opt out or opt in), see *the Online Manual.*

4. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of the dissemination activity (using the text of the GA language version available on the Participant Portal Reference documents page).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

Combining H2020 & other EU grants — If the outputs were developed in another EU-funded action (funded not by H2020, but another EU funding programme, including Structural Funds/ESIF Funds), do NOT forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION 2 for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results.

> ⚠ **Security obligations —** Transfer may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a global authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, the beneficiary must **formally notify in advance** (via the Participant Portal) any transfer to a specifically-identified third party established in a third country — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — Common legal structures (CLS) (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a third country.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  > ***Example:*** *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  > ***Example:*** *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiary must **formally notify** the Commission/Agency **in advance** (via the Participant Portal) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION 2 for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION 3 for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[47], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION 1b for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION 1d for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION 2:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results

- by an affiliated entity of another beneficiary (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).

If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.

How?

Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

Fair and reasonable conditions includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicensing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.

In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [48], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[47] and the Code of Conduct for their Recruitment.[48]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

[47] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[49] and of the Code of Conduct[50] that relate to recruitment, working conditions and career development.

For guidance, *see the 'Human Resources Strategy for Researchers' tool developed by the Commission.*

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[51])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[50] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[51] Available at http://ec.europa.eu/euraxess/jobs

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more information on gender in research, *see the Online Manual.*

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

– present their research goals and intentions in an honest and transparent manner;

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3]* as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced ;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the Commission's **H2020 ethics appraisal scheme** (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

- ethics *self*-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more information on ethics, *see the Guidance — How to complete your ethics self-assessment, the Guidance note — Research involving dual use items, the Guidance note — Research focusing exclusively on civil applications, the Guidance note — Potential misuse of research results and more generally, the Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State.

The beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that the research results cannot peripherally be useful in a military context. Research related to *dual-use* products or technologies (usually used for civilian purposes but with possible military applications) is not prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

Beneficiaries must commit to the highest standards of research integrity (as set out, for instance, in the European Code of Conduct for Research Integrity[52]) and comply with the essential research integrity principles listed in Article 34.1.

Essential research integrity principles:

- honesty
- reliability
- objectivity
- impartiality
- open communication
- duty of care
- fairness and
- responsibility for future science generations

According to these principles, beneficiaries must ensure that their researchers:

- present their research goals and intentions in an honest and transparent manner
- design their research carefully and conduct it in a reliable fashion (taking its societal impact into account)
- use appropriate techniques and methodologies (including for data collection and management)
- exercise due care for research subjects (human beings, animals, environment or cultural objects)
- ensure objectivity, accuracy and impartiality when disseminating the results
- allow access to research data (as much as possible and taking into account the legitimate interest of the beneficiaries and open access obligations, if any)
- make the necessary references to their work and that of other researchers
- refrain from practicing any form of plagiarism, data falsification or fabrication
- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

[52] Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define **ethics requirements** and include them as **deliverables** in Annex 1 of the GA.

> ***Examples (ethics issues):*** *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.
>
> ***Examples (ethics deliverables):*** *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

> ***Examples (other ethics requirements):*** *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

> **Best practice:** When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

> ⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18).*
>
> The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.
>
> If the documents are not in English, the beneficiary may be asked to provide an English summary.
>
> This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.
>
> Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

The Commission/Agency may carry out **ethics checks, reviews or audits**, to ensure that the beneficiaries have properly implemented the ethics requirements and obtained the opinions/notifications/authorisations *(see Article 22)*.

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

Activities that involve human embryos (hE) or human embryonic stem cells (hESC) can only be funded, if:

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[53] (in particular, do NOT result in the destruction of human embryos)

[53] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.

  A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.

  A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits*.

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.

  If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.

  If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.

If there is a **(risk of) a conflict of interests**, the coordinator must **inform** the Commission/Agency (via the Participant Portal), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Security obligations — Stricter confidentiality obligations apply for information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2: *Not applicable**]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[51] — until it is declassified.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].**[OPTION 2:*** *Not applicable.**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable.**]***

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

1. Results with a security recommendation — EU-classified information

If the GA provides for (one of) these options, the beneficiaries must comply with the **security obligations** set out in this Article, in Annex 1 and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises security issues and must be subject to a security recommendation and/or EU-classification under Decision No 2015/444[54].

For more information on security obligations, *see the Guidance — Guidelines for the classification of information in research projects, the Guidance — Guidelines for the handling of classified information in EU research projects, the Guidance note — Potential misuse of research results and, more generally, the Online Manual.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[55].

Moreover, the coordinator must — before the start of the activity for which it is needed — submit a **copy** of any **export** or **transfer licence**.

For more information on dual use goods, *see the Guidance — How to complete your ethics self-assessment* and the *Guidance note — Research involving dual use items.*

[54] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[55] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and] Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is] [are]* not responsible for any use that may be made of the information it contains.

1. Communication activities (beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[56].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a beneficiary in a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to **multiple audiences** (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a **major media impact** (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

[56] For the definition of 'communication activities', *see the Glossary.*

Security obligations — Information given may NOT include **EU-classified information** or information on results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the classification of information in research projects, Guidance — Guidelines for the handling of classified information in EU research projects and, more generally, the Online Manual.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the proposal templates*) and be included in Annex 1 and 2.

For more information on promoting the action, *see the Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the **EU emblem**

AND

- including the **reference to EU funding** set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity or, for infrastructure, equipment or major results, the official language(s) of the country where they are located (using the text of the GA language version available on the Participant Portal Reference documents page).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object). ***Examples:*** *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency; the]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of *[the Agency or]* the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency and the]* Commission will insert the following information:

> "© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the measures described in Chapter 6.

1. Communication activities (Commission/Agency)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material):*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its Participant Portal privacy statements.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligibility of costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the EU financial interests).

When the Commission/Agency collects and processes personal data under the GA, national data protection law is NOT applicable and will NOT be accepted as a pretext for not complying with obligations under the GA.

Disclosure of staff data under the GA *(e.g. data requested by the Commission/Agency project officer or auditors)* is automatically justified under Article 5(c) of Regulation 45/2001.

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[57] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

[57] Available at http://ec.europa.eu/dpo-register/search.htm.

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

Persons whose data is being processed (data subjects) can contact the data controller or the DPO (via the contact information in the privacy statement), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (beneficiaries)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[58] and the corresponding national law).

The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [59]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc.*

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage
- adaptation or alteration

[58] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[59] *See Article 8 of Directive 95/46/EC*.

- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[60]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the relevant Participant Portal privacy statement).

Examples:

1. *Before encoding staff data in the Beneficiary Register or into a proposal, the beneficiary must provide the staff concerned with the privacy statement.*

2. *If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the privacy statement.*

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[60] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What?

The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How?

Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.

Assignment for the benefit of creditors in a bankruptcy procedure.

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

[OPTION to be used when the beneficiary is an European Research Infrastructure Consortium (ERIC)*[54] *without own resources: *As an exception, the beneficiary delegates the tasks set out above to [insert name of member of the ERIC]. The beneficiary retains sole responsibility for compliance with the obligations under the Agreement.]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is NOT responsible for the implementation of the action and has NO responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them **withdraws**, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless the Commission/Agency expressly agrees otherwise (exceptional; only for specific reasons). They will have to do this without any additional funding (although — in case of beneficiary termination — the Guarantee Fund may intervene for the defaulting beneficiary; *see Article 50*).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% contribution to the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

Specific cases:

ERIC (European Research Infrastructure Consortium)[61]: If the beneficiary is an ERIC which does not have its own resources, it may exceptionally delegate the following responsibilities to one of its members:

- monitor that the action is implemented properly *(see Article 7)*
- inform about events or circumstances likely to affect significantly or delay the action implementation *(see Article 17.2)*

[61] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1).

- submit deliverables and reports *(see Articles 19 and 20)*
- submit documents or information required

⚠ An ERIC using one of its members remains **fully responsible** for it under the GA.

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION 1 for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION 2: *Not applicable****]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly *(see Article 22)*.

> ***Example:*** *in case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.*

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can normally NOT be subcontracted or outsourced to a third party (including linked third parties). They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use linked third parties for *other* tasks; *see Articles 13, 14*).

Specific cases (coordinator):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- they must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs (and those must include receiving and administering EU funds).

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It also will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

ERICs (European Research Infrastructure Consortia)[62]***:*** Beneficiaries that are ERICs and do not have their own resources may exceptionally delegate the following coordination tasks to one of its members:

- monitor that the action is implemented properly *(see Article 7)*;
- act as intermediary for communications *(see Article 17)*;
- request and review documents or information required and verify completeness and correctness;
- submit deliverables and reports *(see Articles 19 and 20)*;

⚠ ERICs using one of their members remain **fully responsible** for it under the GA.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article, *e.g. scientific coordination of the action*) can be carried out by any beneficiary.

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it will however NOT be considered the action's coordinator (but one of the other beneficiaries).

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

Best practice: In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement

[62] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1)

jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see the Online Manual and the Guidance — How to draw up your consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted ONLY for complementary actions *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted ONLY for jointly funded actions *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the grant agreements and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see the Online Manual and the Guidance — How to draw up your coordination agreement.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Cost rejection

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

Cost rejections will be made for **violations of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Grounds for cost rejection (Commission/Agency):

- **Costs** do **not comply with** the GA **eligibility rules (in this grant)**

  The Commission/Agency will reject costs, if they do not comply with the eligibility rules set out in Articles 6 and 8-16.

- **Costs** do **not comply with** the GA **eligibility rules (in other grants)**

  The Commission/Agency may also reject costs, if such ineligibility was found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the ineligibility is:
    - systemic or recurrent and
    - has a material impact on this grant.

Rejection of costs can take place at any moment — at the time of beneficiary termination, interim payment, payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if cost rejection leads to a recovery: there will be an *ex ante* **contradictory procedure**
- if cost rejection does NOT lead to a recovery: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection (**payment review procedure**).

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post payment review procedure allows the

Commission/Agency however to pay quickly without having to suspend the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Payment review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out (**notification of amounts due**; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections.

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for rejections at the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after beneficiary termination and after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

Information obligation — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Cost rejection at the time of an interim payment or payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) at the moment **of** an **interim payment** or the **payment of the balance**, it will deduct them and calculate the **amount to be paid** accordingly.

If ineligible costs (declared in a previous report and already paid for) are found **in-between payments**, the Commission/Agency will reject them at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example for calculating a rejection at an interim payment/payment of the balance:

Case 1: *Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.*

Maximum grant amount: EUR 500 000.

Pre-financing: EUR 200 000.

Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25 %) = EUR 118 750.

Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25 %) = EUR 143 750.

Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25 %) = EUR 112 500.

Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Interim payment:

Application of the reimbursement rate: 100%: EUR 362 500

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.

Amount due as interim payment: EUR 250 000

Case 2 (in between payments): *Total costs declared for the action in the 1st periodic report: = EUR 375 000*

Interim payment for the 1st periodic report = EUR 375 000

Cost rejected after interim payment or 1st periodic report: EUR 12 500

Total costs declared and accepted for the action in 2nd periodic report: = EUR 100 000

Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 — EUR 12 500 = EUR 87 500

4. Cost rejection after beneficiary termination

If the Commission/Agency rejects costs **after beneficiary termination**, it will deduct the rejected amount from the costs the beneficiary declared in the **termination report** and calculate **the amount due** to the beneficiary *(see Articles 50.2 and 50.3)*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible. Costs relating to contracts due for execution only after termination are NOT eligible.

If the amount which is due to the beneficiary is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will **recover** the difference *(see Article 44)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

Example for calculating a rejection after beneficiary termination:

Grant with 5 beneficiaries (A, B, C, D and E).

Maximum grant amount: EUR 500 000 (beneficiary maximum EU contribution: each beneficiary 100 000 EUR).

Reimbursement rate: 100 %.

Pre-financing: EUR 200 000.

Beneficiary termination:

Beneficiary A goes bankrupt in the middle of the action and its participation is terminated.

Eligible costs declared by beneficiary A in termination report: EUR 50 000 (direct costs) + EUR 25 000 (25 % flat rate for indirect costs) = EUR 62 500.

Costs rejected for beneficiary A following audit: EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

No grant reduction.

The amount which is due for beneficiary A: EUR 62 500 – EUR 12 500 = EUR 50 000

Recovery:

Payments received by beneficiary A (according to the report on the distribution of payments): EUR 40 000.

Amount to be recovered from beneficiary A: EUR 40 000 – EUR 50 000 = EUR - 10 000 (no recovery; the positive balance of EUR 10 000 will be paid out at the next interim payment).

5. Cost rejection after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*.

If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will **recover** the difference *(see Article 44)*.

Example for calculating a rejection after the payment of the balance:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 — EUR 30 000 = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **redu**ces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Grant reduction

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* **substantial errors, irregularities or fraud** or **breach of obligations** (under the GA or during the award procedure; *e.g. the action has not been properly implemented)*, it may reduce the grant amount — in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations.

⚠ **Grant reductions** will be made (at the end of the action) for substantial errors, irregularities or fraud or serious breach of obligations, in proportion to the seriousness of the error, irregularity, fraud or breach *(e.g. in case of fraud the reduction may be up to a 100%)*.

⚠ If the issues are found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

Grounds for grant reduction (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may make a grant reduction, if a beneficiary has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: : *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also make a grant reduction, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if:

  – the other grants were awarded under similar conditions and

  – the substantial errors, irregularities or fraud or serious breach of obligations are:

    – systemic or recurrent and

    – have a material impact on this grant.

3.0 Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol[63]).

Grant reduction can take place:

– after beneficiary termination

– at the payment of the balance or

– after the payment of the balance.

3.0 Reduction at beneficiary termination was introduced explicitly with GA version 3.0. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination is possible

[63] See judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128.

for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 *(see above)*.

A grant reduction can also be imposed on beneficiaries not receiving EU funding *(e.g. for improper implementation by the beneficiary; see Article 9)*.

2. Procedure

The Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42*).

Depending on the moment the reduction takes place, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for reductions after beneficiary termination: normally with the beneficiary concerned
- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Grant reduction after beneficiary termination

If the Commission/Agency reduces the grant **after beneficiary termination**, it will calculate the reduction at beneficiary-level and calculate the **amount due** to the beneficiary *(see Articles 50.2 and 50.3)*.

If the amount which is due to the beneficiary is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will **recover** the difference *(see Article 44)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

4. Grant reduction at the payment of the balance

If the Commission/Agency reduces the grant at the **payment of the balance**, it will make the reduction at action-level and calculate the balance to be paid to the consortium (i.e. final grant amount) accordingly.

Example for calculating a reduction at the payment of the balance:

Consortium with a maximum grant amount of EUR 3 000 000 (100 %.reimbursement rate)

Pre-financing: EUR 750 000

Interim payments: EUR 1 500 000

Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carries out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20 % (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000- EUR 600 000 = EUR 2 400 000.

Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = 2 400 000

Payments already made (pre-financing + interim) EUR 2 250 000= EUR 750 000 + EUR 1 500 000

Amount due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000).

5. Grant reduction after payment of the balance

The financial consequences of a reduction of the grant *after the payment of the balance* will be calculated at **beneficiary level** for each beneficiary concerned.

The 'beneficiaries concerned' are those who have committed irregularities, errors or fraud or have breached their obligations *(for example, improperly implemented the action, submitted false information, failed to submit required information or breached the ethical principles)* resulting in the reduction.

Procedure for reduction of the grant after payment of the balance:

The Commission/Agency:

Step 1 — Determines the amount to be reduced (in proportion to the seriousness of the errors, irregularities or fraud or the breach of obligations).

Step 2 — Identifies the beneficiaries in fault and allocates that amount among them according to their responsibility in the errors, irregularities or fraud or breach of obligation.

If the breach of obligation cannot be linked to one or more specific beneficiaries (and therefore concerns the whole consortium) each beneficiary will have to bear a pro-rata share of the reduction.

For each of those beneficiaries (the 'beneficiaries concerned'):

Step 3 — Determines the beneficiary's **share in the final grant amount'**, as follows:

{{total accepted eligible costs for the beneficiary x reimbursement rate}[64]

divided by

{sum of total accepted eligible costs x reimbursement rate, for each beneficiary}[65]

multiplied by

the final grant amount before the reduction (see Article 5.3)}

Step 4 — Calculates the beneficiary's **revised final grant amount** as follows:

{total accepted eligible costs for the beneficiary x reimbursement rate}[66] – amount of reduction allocated to the beneficiary under step 2

[64] Plus the same formula applied to third parties linked to the beneficiary (if any).
[65] Including linked third parties.
[66] Plus the same formula applied to third parties linked to the beneficiary (if any).

Step 5 — If **revised final grant amount < share in the final grant amount**, the Commission / Agency will recover the difference from the beneficiary.

Example for calculating a reduction linked to (one or more) specific beneficiaries:

Innovation action with beneficiaries: X, Y and Z. Beneficiaries X and Z are non-profit legal entities with a 100% reimbursement rate. Maximum grant amount = EUR 2 900 000.

Situation at payment of the balance:

	Data source		*Beneficiary X*	*Beneficiary Y*	*Beneficiary Z*	*Total*
	Annex 2 (estimated budget)	*Estimated costs budgeted*	*700 000*	*2 000 000*	*800 000*	*3 500 000*
A		*Reimbursement rate (%)*	***100***	***70***	***100***	
B		*Maximum grant amount according to costs budgeted*				*2 900 000*
C	*Final financial statements*	*Beneficiary's total accepted eligible costs*	*825 000*	*1 850 000*	*800 000*	*3 475 000*
D	*First step for the calculation of the "Final Grant Amount (Article 5.3.1)*	*Beneficiary's total accepted costs x reimbursement rate (C x A)*	*825 000*	*1 295 000*	*800 000*	*2 920 000**

** The final grant amount is capped at EUR 2 900 000 (maximum grant amount). Even if D results in a higher amount, the Commission/Agency can never pay more than the maximum grant amount set in the grant agreement.*

Following a review after the payment of the balance, the Commission decides to reduce the grant due to improper implementation because some of the action tasks were not carried out.

Step 1 Reduction of the maximum grant amount:

The Commission decides on the amount to be reduced in proportion to the improper implementation identified

Example: the Commission decides to reduce the maximum grant amount by EUR 300 000.

Step 2 Identification of the beneficiaries concerned and allocation of the amount to be reduced:

The review concluded that the improper implementation was due to the fact that beneficiary X carried out only part of its tasks as set out in Annex 1. Therefore, the reduction is allocated in full to beneficiary X (see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*

F	*Part of the reduction allocated to the beneficiary*	*300 000*	*0*	*0*	*300.000*
G	*Beneficiary's revised final grant amount (D - F)*	*525 000*	*1 295 000*	*800 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*294 349*	*0*	*0*	*294 349*

The amount to be recovered is less than the amount reduced because of the overspending (eligible costs that were declared but not taken into account at payment of the balance because of the capping at maximum grant amount).

For recovery (see Article 44.1.3)

Example for calculating a reduction NOT linked to (one or more) specific beneficiaries:

Same example as above except that the reduction is not linked to specific beneficiaries.

The review concluded that the improper implementation was due to the consortium as a whole and cannot be attributed to (one or more) specific beneficiaries. The amount to be reduced is therefore allocated evenly among the beneficiaries (300 000 / 3 = 100 000; see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*100 000*	*100 000*	*100 000*	*300 000*
G	*Beneficiary's revised final grant amount (D - F)*	*725 000*	*1 195 000*	*700 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*94 349,32*	*91 130,14*	*94 520,55*	*280 000*

For recovery (see Article 44.1.3)

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION 2:** not applicable**];***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**] [OPTION 2:** not applicable**]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to early termination, cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to its maximum EU contribution in Annex 2.

Grounds for recovery (Commission/Agency):

- Commission/Agency **paid too much**

  The Commission/Agency will make a recovery, if the amounts paid out exceed the amounts that are due for the grant.

Recovery normally takes place only at payment of the balance or afterwards. Exceptionally, it can take place before, if a beneficiary's participation is terminated.

2. Procedure

The basic procedure for recovery is almost always the same: After a **contradictory procedure**, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency examines the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission/Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[67]

[67] *See Article 80(1) of the Financial Regulation No 966/2012.*

'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 TFEU action, arbitration, etc; *see Article 57.2*).

Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission/Agency may offset before this date, in order to safeguard the EU financial interests.[68]

If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. (The interest is normally offset first, before the principal amount).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU[69].[70]

      The decision describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      ⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

      This decision — duly endorsed with the order for enforcement issued by the competent authority in the Member State concerned — allows to have the debtor's **assets seized**.

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68 *See Article 87 of the Rules of Application Regulation No 1268/2012.*

69 *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

70 *See Article 79(2) of the Financial Regulation No 966/2012.*

- The contradictory procedure will normally be **combined** with the **contradictory procedure** for cost rejection and/or grant reduction (if any).

3. Recovery after beneficiary termination

The Commission/Agency will recover **after beneficiary termination**, if the beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

4. Recovery at the payment of the balance

The Commission/Agency will recover at the **payment of the balance**, if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the report on the distribution of payments.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified AND if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** alone.

For the rest of the procedure, *see point 2*.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, BUT has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds in excess**, the amount each beneficiary *actually* received (as established on the basis of the report on the distribution of payments) is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The **share in the final grant amount** is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage obtained to the final grant amount.

In practice:

- **for underspent GAs:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with *Article 5.3.1)* is lower than the maximum grant amount set out in Article 5.1 (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for overspent GAs:** each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess — for its proportional share in the debt to the Commission/Agency.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery at the payment of the balance:

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100 %
Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)

Total eligible costs approved by the Commission: EUR 2 430 000

Final grant amount: EUR 2 430 000

EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000

Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

The Commission needs to recover EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5 % of the maximum grant amount; see Article 21.2) = EUR 150 000. Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:

A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

Identification of the beneficiaries that received funds in excess:

Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);

Beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)

Beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);

Beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:

The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.

Total payments made in excess = 320 000.

Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.

Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.

Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

***The Commission will notify three debit notes for a cumulative amount of EUR 120,000** (270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium.

5. Recovery after payment of the balance

The Commission/Agency will recover **after payment of the balance**, if — due to cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid too much (or that the coordinator has not distributed the payments received).

Procedure for recovery after payment of the balance (due to a reduction of the grant):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised final grant amount for the beneficiary concerned with its share of the final grant amount.

The **share of the final grant amount** is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage obtained to the final grant amount.

In practice:

- **for underspent GAs:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with *Article 5.3.1)* is lower than the maximum grant amount set out in Article 5.1 (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for overspent GAs:** each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

For the rest of the procedure, *see point 2*.

Procedure for recovery after payment of the balance (due to a rejection of the costs):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised final grant amount for the beneficiary concerned with its **share of the final grant amount** *(see point 4)*.

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

Example for calculating a recovery after payment of the balance (underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:

(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example for calculating a recovery after payment of the balance (overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C

Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000

Reimbursement rate for all the beneficiaries: 100%

Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000

Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000

Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000

Total eligible costs of the consortium approved by the Commission = EUR 600 000

Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary approved costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*

EU contribution for the action according to 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667

Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000

Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Calculation of the revised grant amount after the audits:

The revised final grant amount is calculated as follows:

For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500

For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Calculation of the amount to be recovered:

The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount

For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered

For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. Since for beneficiary C the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants and expert contracts and/or financial penalties).

1. Administrative sanctions

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary is in an exclusion situation under Article 106(1) of the Financial Regulation No 966/2012, it may impose administrative sanctions (— in proportion to the seriousness of the misconduct).

Administrative sanctions (financial penalties and/or exclusion from future procurement contracts, grants and expert contracts) are **public law measures** (i.e. taken directly on the basis of Articles 106 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(substantial errors, irregularities or fraud, serious breach of obligations, bankruptcy, non-compliance with tax or social security obligations, grave professional misconduct, fraud, corruption, or criminal/illegal activity).*

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum sanctions** are as follows:

- for exclusion: up to **5 years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the sanction and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again, the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget (Annex 2) — depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again, the rate may be increased to between **4%** and **20%**.

The decision to apply an administrative sanction may be **published** on the Commission/Agency websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU's financial interest and image)

- the time that has elapsed since it took place

- the duration and recurrence of the misconduct
- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

The Commission/Agency will follow the procedures set out in 106 of the Financial Regulation No 966/2012 (i.e. **contradictory procedure, panel, decision)**.

If the Commission/Agency imposes a financial penalty, it will also issue a debit note to **recover** the amount.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

However, there is NO:

- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

Specific case (administrative sanctions):

International organisations — Decisions on administrative sanctions (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability for damages (Commission/Agency)

The Commission/Agency can NOT be held liable if — in implementing the GA — its own services cause damage (to a beneficiary or third party).

Moreover, the Commission/Agency can NOT be held liable if — in implementing the GA — a beneficiary or third party involved in the action causes damage (to another beneficiary or third party).

Examples:

1. *An experiment carried out by a beneficiary leads to an accidental escape of pollutants into the local river.*

2. *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the action.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third parties involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

1. Liability for damages (beneficiaries)

If a beneficiary causes damage to the Commission/Agency (in implementing the action), the Commission/Agency may claim compensation).

Examples:

1. *Costs of legal proceedings borne by the Commission.*

2. *At a meeting on Commission premises, a beneficiary smokes and causes a fire.*

2. Procedure

The Commission/Agency will follow the normal procedure for damages claims (i.e. bringing an action for contractual damages before the European Court of Justice; not direct claim via a debit note).

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (Commission/Agency)

The Commission/Agency may stop the clock (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

Suspension of the payment deadline must be **distinguished** from **suspension of payments** *(see Article 48)*. Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary which is, for example, suspected of serious misconducts.

Grounds for suspension of the payment deadline (Commission/Agency):

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

In practice, suspension is needed if there are issues with the payment request or with the costs declared which make it impossible for the Commission/Agency to comply with the **payment deadline** (i.e. for interim payments and payment of the balance: 90 days after payment request; *see Article 21*).

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

Late payment without suspension of the payment deadline gives rise to late-payment interest for the beneficiaries *(see Article 21.11)*.

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why.

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

Suspension will normally last until it is possible to make all the necessary checks and verifications that are needed for the payment (*e.g. analysis of technical reports and financial statements, eligibility of claimed costs, calculation of amount to be paid, approval and authorisation of payment*).

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (Commission/Agency)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more or for all beneficiaries), on the grounds listed in this Article.

⚠ **Suspension of payments** has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systemic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend all outstanding payments for the audited beneficiary until the issue is resolved.*

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may also decide to:

- suspend the GA *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*) with the:

- coordinator or
- beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension in several grants).*

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator separately (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2).*

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned with the periodic reports (except with the report for the last reporting period).

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted. They must be included in the periodic report for the last reporting period (— even if suspension is still ongoing).

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*

15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*

1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*

1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*

10 August: *the Commission pays for all beneficiaries except B.*

25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

If payments for one (or some) of the beneficiaries are still suspended at the end of the action, the Commission/Agency will make a partial payment of the balance for the amount that is not suspended (— but ONLY after having received all the necessary information for the final calculations for ALL consortium members, i.e. including the suspended beneficiaries).

The partial final payment is NOT the payment that closes the action. That payment will be made only after the payment suspensions are lifted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. GA suspension (beneficiaries)

The beneficiaries may suspend the action (in full or in part), on the ground set out in this Article.

GA suspension may be used exceptionally if it is necessary to stop the action implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for GA suspension (beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**

  The beneficiaries may suspend the action (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment after resumption).

⚠ **Information obligation** — Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g. **inform** the Commission/Agency under Article 17.2; **notify** a situation of force majeure under Article 51)*.

2. Procedure

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the **resumption date** set out in the amendment), if the Commission/Agency approves the amendment.

> ***Example:*** *The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the budget must be lowered in the amendment, to adapt the action to the new situation).

> ***Example:*** *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **can NOT be continued** (or the Commission/Agency does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:*** *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the GA termination. The eligible costs are:*
>
> - *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
> - *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities, or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false declaration, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 <u>Procedure</u>

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (Commission/Agency)

The Commission/Agency may suspend the action (in full or in part), on the grounds listed in this Article.

Grounds for GA suspension (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend the audited beneficiary's part of the action until the issue is resolved.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** 5 days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the GA, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42)* with the:

- coordinator or

– beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension of several grants).*

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator separately (in a way that preserves confidentiality).

> ⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2).*

If possible, the Commission/Agency will give an estimation of how long the suspension will be needed.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once the action is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **can NOT be continued**, the GA (or the beneficiary concerned) may be terminated.

If the suspension leads to the GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:***
>
> *A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.*
>
> *The GA starts on 1.5.2015 and lasts 42 months.*
>
> *The Commission suspends its implementation.*
>
> *The coordinator confirms having received notification of the suspension on 18.3.2017.*
>
> *The suspension takes effect on 23.3.2017.*
>
> *On 23.6.2017, the consortium formally notifies the GA termination.*
>
> *Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.*
>
> *The Commission will reject the ineligible personnel costs.*

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases,

the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The beneficiaries have the right to terminate the GA.

GA termination should be a last-resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Grounds for GA termination (beneficiaries):

- **Any ground** that **justifies** early termination of the action

The beneficiaries may terminate the GA in principle on any ground — as long as there is a good reason *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

Examples:

1. *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

2*. The consortium requests termination because the action was finished ahead of schedule.*

If there are no legitimate reasons for discontinuing the action, the Commission/Agency **can NOT oppose**, but termination will be considered **improper**.

⚠ **Improper termination** of the GA may lead to a grant reduction (see *(see Articles 5.3 and 43)*.

This will be the case, for instance, if:

- the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
- the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
- implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a grant reduction.*

2. Procedure

The coordinator must **formally notify** the Commission/Agency (via the Participant Portal) of the termination — on behalf of the other beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. before the termination date) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. (The Commission/Agency will NOT send a reminder and will NOT extend the deadline.)

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the security obligations (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*
- Chapter 6 measures (i.e. rejection of costs *(see Article 42)* grant reduction *(see Article 43)* recovery *(see Article 44)*.

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Partner termination (beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion (and provide it if obtained or — if the beneficiary didn't reply — the request to the Commission/Agency).

Grounds for partner termination (beneficiaries):

- **Any ground** that **justifies** termination of the participation of the beneficiary

  The beneficiaries may terminate the participation of one of their consortium members in principle on any ground — as long as there is a good reason *(e.g. withdrawal by a beneficiary because due to a change in ownership; the beneficiary cannot implement its tasks in the same way; bankruptcy)*.

  For beneficiaries that are involved in **several EU GAs,** withdrawal from one GA does NOT necessarily imply that it has to also withdraw from the others.

  Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2).*

  If there are no legitimate reasons, the Commission/Agency **can NOT oppose** partner termination, but it will be considered **improper**.

  Improper termination of the participation of a beneficiary may lead to GA termination *(see Article 50.3.1(c))* and/or to a grant reduction at the payment of the balance *(see Articles 5.3 and 43).*

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT continue participating in the action.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like beneficiaries.

Linked third parties can NOT however do more than the beneficiary they are linked to: If their beneficiary is terminated, they must also leave the action.

2. Procedure

The coordinator must **formally notify** the Commission/Agency of the termination (via the Participant Portal). At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Since for partner termination the notification is combined with an amendment request, they must be submitted and signed by the PLSIGN of the coordinator (on behalf of the other beneficiaries *(see Annex 3)*.

NO amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example: *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional funding to do so) — unless the Commission/Agency expressly agrees otherwise.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)

- if the beneficiary owes, those amounts must be repaid by it (normally to the consortium).

Only **costs** incurred before termination (i.e. before the notified date on which termination takes effect) are eligible— except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. (The Commission/Agency will not send a written reminder and will not extend the deadline.)

If the coordinator fails to submit the *report on the distribution of payments*, the beneficiary whose participation was terminated will NOT have to repay any amounts.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (partner termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*).

Coordinator in bankruptcy/liquidation/administration (or similar) — In principle the coordinator must be changed. If the coordinator can no longer submit the request, the same procedure as for coordinator termination without its agreement should be used *(see above and Article 55)*.

Exceptionally, at the end of the action it may not be necessary to change the coordinator, but only its bank account if the administrator/liquidator accepts to do the final transfers of amounts.

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable];*

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**); see Article 22.5.2;

(n) despite a specific request by the *[Commission][Agency]*, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. GA or beneficiary termination (Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

⚠ Beneficiary termination may lead to **GA termination**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

⚠ The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

Grounds for termination (Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the GA termination; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or if the consortium no longer complies with the eligibility conditions set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the minimum number of beneficiaries, their legal situation, or their place of establishment)*. [71]

  Examples:

  1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

  2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there was a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Example: *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA, or the GA if the other beneficiaries fail to find a solution to this.*

- **GA cannot be amended after termination** of a beneficiary's participation

  The Commission/Agency may terminate the GA, if it cannot be amended after termination of a beneficiary's participation because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

  Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

  The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

- **Action can no longer be implemented**

[71] *See also Article 8 of the Rules for Participation Regulation No 1290/2013.*

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

> ***Example:*** *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

> ***Example:*** *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify partner termination because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

> ⚠ **Information obligation** — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2).*

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

> ***Example:*** *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is implemented; *see Article 7*).

> ***Example:*** *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

> ***Example:*** *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

  - the third country/IO action does not start by the date specified in Annex 1

    In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission/Agency in full.

  - the third country/IO action is terminated

  - the third country/IO action can no longer contribute to the subject of the GA.

Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have participated in large-scale drug trafficking.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

The Commission/Agency may terminate the GA or the participation of a beneficiary, if a beneficiary (or one of its representatives) has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

Example: *false declarations in the proposal form, in order to obtain EU funding; coordinator does not transfer payments to the other beneficiaries, but uses them for itself; coordinator does not submit the reports (despite a reminder); consortium does not inform the Commission/Agency about the receipt of a second grant for the same/similar proposal; review shows that action does not achieve its critical objectives and is way behind schedule and consortium submits a short-term implementation plan that is not acceptable; audit shows that beneficiary declared costs based on fake invoices; consortium does not provide requested information (despite a reminder); a check shows that scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism); consortium does not submit an amendment request after beneficiary termination.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

The Commission/Agency may also terminate the GA or the participation of a beneficiary, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that appear intentional and also affect all other GAs signed by the audited beneficiary. The Commission may terminate the participation of the audited beneficiary in the GA.*

- **Non-removal of a linked third party**

The Commission/Agency may terminate the participation of a beneficiary if it refuses to remove one of its linked third parties which is in one of the following situations:

- bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings;
- professional misconduct
- non-compliance with tax or social security obligations
- fraud, corruption or other criminal activities
- substantial errors, irregularities or fraud or serious breach of obligations (in this grant or other grants).

3.0

This termination ground was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, beneficiary termination/linked third party removal was however already implicitly included in the different grounds of Article 50.3.3 (given that linked third parties have to fulfil the same conditions as the beneficiaries for participating in the action).

Before terminating (GA or beneficiary), the Commission/Agency may first suspend the GA *(see Article 49.2)*, to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before GA or beneficiary termination, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*), with the:

- coordinator or
- beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension in several grants)*.

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator separately (in a way that preserves confidentiality).

> ⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy or similar), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will take effect **(termination date)**.

This date will be a date after the notification: Terminations can**not** be **retroactive** (notably to ensure the fulfilment of obligations and deadlines after termination; *see point 3*).

For some cases, the Commission/Agency may choose a **future** date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of GA termination are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. before the date on which termination takes effect) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

The effects of beneficiary termination are the same as when the beneficiaries terminate one of their partners *(see Article 50.2.2)*.

- Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What?

In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Force majeure normally has no specific effects on the eligibility of **costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

New in Horizon 2020: This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Force majeure may lead to GA suspension *(see Article 49)* or GA termination *(see Article 50)*.

How?

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal).

The beneficiary concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

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ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[European Commission][Name of the Agency]
[Directorate-General] [complete]
[Street name and number]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

1. Communication between the parties — Participant Portal electronic exchange system

All communication between the consortium and the Commission/Agency must normally be in electronic form **via** the **Participant Portal**.

The Participant Portal offers different **functions**:

- viewing and changing the legal entity data in the Beneficiary Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

⚠ A formal notification is considered to have been **accepted 10 days after** it is **sent** (— even if it has not been opened by recipient, *e.g. refusal of reception or omission*).

Deadlines that are counted from the date of receipt are counted as of day eleven.

All messages are recorded in the Participant Portal project file (with date and time).

Formal notifications are also recorded (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation and access are linked to the user role *(e.g. LEAR, PLSIGN or PFSIGN*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer*

in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)

4. *Only Participant Contacts (PaCos) may submit information to the coordinator. They cannot submit information directly to the Commission/Agency.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission/Agency.*

For more information on access and roles in the Participant Portal*, see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations No 883/2013 and No 2185/2996)*.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means intergovernmental organisations (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the applicable legal texts provide otherwise), public law decisions cannot be applied to international organisations; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions (i.e. exclusion or financial penalties; *see Article 45*).

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration *(see Article 57.2)*. The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*
The action is divided into the following reporting periods:
RP1: from 1 March 2015 to 31 August 2016
RP2: from 1 September 2016 to 28 February 2017
Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.
The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

An amendment is necessary whenever there is a need to **change** the GA (i.e. the core agreement and/or the Annexes).

⚠ The cases where an amendment is necessary are called 'amendment types' (AT); the amendment clauses are called 'AT clauses'.

⚠ The general terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to set its 'end date of participation'.*

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and have an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

⚠ **Information obligation — Changes** in the **name, address, legal form** and **organisation type** AND changes in the **legal, financial, technical, organisational** or **ownership situation** may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary terminate its participation and to amend the GA.*

2. *Beneficiary B moves from Europe to Australia during the action. The change of address implies that the beneficiary becomes not eligible for EU funding, so the GA will have to be amended to make it a 'beneficiary not receiving EU funding'.*

3. *Beneficiary C participates in an innovation action (IA) and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Beneficiary Register is sufficient; no amendment is needed.*

2. *Beneficiary E participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

ℹ For more information on AT clauses (including required supporting documents and how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation was terminated due to non-accession to the GA OR non-provision of the requested declaration on joint and several liability** (**AT1**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary that never became part of the GA.

  How? The amendment is normally triggered by the beneficiaries.

  In case of partner termination (by the beneficiaries), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  The changes will be made **ex tunc** (i.e. since the beginning) since the beneficiary never participated in the grant.

  If the beneficiary was participating with **linked third parties**, they will automatically be removed.

  GA options for the beneficiary (and its linked third parties) are automatically removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Removal of a beneficiary whose participation was terminated for other reasons** (**AT2**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary during the action.

  What not? There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator and the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  How? The amendment is normally triggered by the beneficiaries.

  In case of partner termination (by the beneficiaries), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the request for amendment, the same procedure as for coordinator change without its agreement should be used.

  Changes will be made **ex nunc** (because the beneficiary participated in the grant up until termination and many obligations are moreover applicable after termination).

  The **termination date** will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

  If the beneficiary was participating with **linked third parties**, they will also have to be removed (with effect from the same date) and the end date of participation will be added to Article 14 (AT5).

  By contrast, the **GA options** for the beneficiary (and its linked third parties) will NOT be removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will normally have to be changed (AT21 and AT 31).

- **Adding a new beneficiary** (**AT 3**; *see Article 56.2*)

  What? Addition of a new beneficiary during the action.

  How? The amendment is normally triggered by the beneficiaries.

The new beneficiary must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

The **accession date** will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

The date must be selected in the Accession Form (attached to the amendment request). It is possible to choose between:

- the date of signature of the Accession Form
- the date of entry into force of the amendment

OR

- a fixed date:
  - retroactive (before signature of the Accession Form)

  OR

  - future (after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

If the new beneficiary is participating with **linked third parties**, they will also have to be added (with effect from the same date) and the starting date of participation will be added to Article 14 (AT6).

The **GA options** for the beneficiary (and its linked third parties) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change of beneficiary due to partial takeover** (**AT4**; called 'partial transfer of rights and obligations' in FP7)

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination *(see Article 50)* or addition of a new beneficiary *(see Article 56)*.

This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment clause for addition of a new beneficiary (AT3).

What? Transfer due to partial takeover.

'**Partial takeover**' means that a part of the business of the beneficiary **—** including the GA **—** is taken over by (one or more) other entity(ies) (transfer of a business unit as a going concern, *e.g. partial acquisition, distribution of a business unit on dissolution/liquidation, division/demerger, etc.*).

'Partial acquisition' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, *some* of the rights and obligations (and contracts) of the original entity are transferred to the new entity. Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'Distribution of a business unit on dissolution/liquidation' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entities purchase a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only *some* of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'Division/demerger' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has an ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two partial takeovers: one to company E and one to company O.*

What not? Simple sale of (one or more) **assets** of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary.

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

NO amendment is necessary for **universal takeovers** *(see below)*.

How? The amendment is normally triggered by the beneficiaries; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as new beneficiary).

'New beneficiary' is used here only for the purpose of the amendment; it may mean either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

⚠The new beneficiary(ies) will (each) be fully **jointly and severally liable** with the former beneficiary for recoveries under Article 44. (By contrast: NO joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular, explain the financial liability of the former beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts, if possible). Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.

If the former beneficiary was participating with linked third parties, the new beneficiary will have to determine which of the former beneficiary's **linked third parties** stay on as linked third parties of the new beneficiary (AT6) — all other linked third parties will be automatically removed.

The **GA options** for the beneficiary (and its linked third parties) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

The former beneficiary does NOT need to submit any reports to the Commission/Agency. The financial statement for the open reporting period until transfer must be uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

- **Removing a linked third party** (**AT5**; *see Article 14*)

What? Removal of a linked third party during the action.

How? The amendment is normally triggered by the beneficiaries.

If requested by the Commission/Agency *(e.g. because of audit results or an OLAF investigation)*, the consortium MUST submit an amendment to remove a linked third party.

> ⚠ If the consortium does not follow-up this request, the Commission/Agency may **terminate** the participation of the *beneficiary* (and thus automatically also remove the linked third party).

NO termination notification — Linked third parties can be removed by the consortium by simple amendment; no formal termination notification is required (termination notification applies only to beneficiaries; *see Article 50.2*)

Changes will be made **ex nunc** (because the linked third party participated in the grant up until removal and many obligations are moreover applicable after termination).

The **end date of participation** will be added to Article 14.

The date must be selected in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

The **GA options** for the linked third party will normally NOT be removed/changed/become not applicable *(e.g. linked third party options)*.

Annexes 1 and 2 will have to be changed (AT21 and AT 31).

- **Adding a linked third party** (**AT6**; *see Article 14*)

What? Addition of a new linked third party during the action.

How? The amendment is normally triggered by the beneficiaries.

The new linked third party must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

The **name of the linked third party and the starting date of participation** will be added to Article 14.

The date must be selected in the amendment request. It is possible to choose between a fixed date or the 'date of entry into force of the amendment'. If the linked third party joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

The **GA options** for the linked third party will be added/changed/become applicable *(e.g. linked third party options)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'** (**AT7a**; *see Article 9*)

  What? If a beneficiary/linked third party — exceptionally — becomes not eligible for receiving EU funding during the action *(e.g. due to a change of establishment)*, this change will require an amendment (to change Annex 1, Annex 2 and the options in Article 9).

  > ***Example:*** *Beneficiary R moves from Europe to Australia and thus is no longer eligible for receiving EU funding. The GA must be amended. If R is participating with a linked third party M established in France, M will continue being eligible for funding.*

  How? This amendment can normally be triggered only by the Commission/Agency.

  The **change date** will be added to the Preamble of the GA.

  The **GA options** for the beneficiary/linked third party will be added/removed/changed/become applicable/become not applicable *(e.g. beneficiary receiving/not receiving EU funding; dispute settlement)*.

- **Change of coordinator (AT8)**

  What? Replacement of the coordinator during the action *(e.g. because of financial difficulties)*.

  Exceptionally, an amendment remains possible and necessary *after* the end of the action *(see Article 3)* —until the payment of the balance is paid out and distributed.

  Coordinator in bankruptcy/liquidation/administration (or similar) — After the end of the action, if the coordinator can continue its participation with the bank account of the administrator/liquidator (i.e. termination and coordinator change not really needed), it is exceptionally sufficient to change the bank account (AT40) without changing the coordinator.

  What not? There is NO need to request an amendment for a change of the *person* in charge of the coordination of the project (since the person's name is not mentioned in the GA).

  > ⚠ **Information obligation** — In case of a **change of person in charge of coordination**, the coordinator must — in addition to updating the data in the Participant Portal inform the Commission/Agency under Article 17.2).

  How? The amendment is normally triggered by the beneficiaries.

  If the new coordinator is not a beneficiary of the GA, it must first accede to the GA as a new beneficiary (AT3).

  The former coordinator may continue to participate in the action as a normal beneficiary or may terminate its participation (AT2).

  > **Termination of the coordinator without its agreement —** If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*
  >
  > **Coordinator in bankruptcy/liquidation/administration (or similar) —** If the coordinator must be changed but can no longer submit the amendment request, the same procedure as for coordinator change without its agreement should be used.

  The **handover date** will be added to the Preamble of the GA.

  > The date must be selected in the amendment request. If the former coordinator leaves the consortium, this date must be after the termination date; if the new coordinator joins the consortium, the date must be after the accession date. Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the option for authorisation to administer** (**AT9a**; *see Article 41.2*)

  What? Change concerning the authorisation to administer (i.e. delegation of administration tasks to a third party).

  > ***Example:*** *change of name of the entity with authorisation to administer*

- **Change of the coordinator's bank account for payments (AT40)**

  What? An amendment is necessary for all changes that imply a change to the account number/IBAN code.

  Example: *The coordinator changes bank account.*

  What not? NO amendment is necessary for a change of the name of the bank or name of the account holder; a change of the bank account data (and validation) in the Participant Portal Beneficiary Register is sufficient.

  How? The bank account data must first be updated in the Beneficiary Register (and be validated).

- **Change of the action's title and/or acronym (AT22)**

  What? Change of the action title or acronym.

  Example: *the consortium finds out that the acronym of their action is a protected trademark*

- **Change of the starting date, action duration or reporting periods (AT23, AT24, AT25)**

  What? Change of the action's schedule (starting date, action duration or reporting periods).

  Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

  ⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

  How? An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

- **Amendment for resuming the action after GA suspension (AT26)**

  What? Amendment to resume the action after GA suspension.

  How? The amendment request must specify the dates when the suspension started and ended. The action implementation is then automatically resumed as from the following day (**resumption date**).

- **Changes to Annex 1 (description of the action) (AT21)**

  What? Changes to the description of the action, in particular:

  - significant change of the **action tasks** *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning **in-kind contributions** provided by third parties (against payment or free of charge) or **subcontracts**

    Such changes could in principle also be made via the 'simplified approval procedure' *(see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it has prior assurance of the Commission/Agency agreement (on the in-kind contribution or subcontracting). If no amendment is requested, the Commission/Agency could consider them as not compliant with the GA, and declare their costs ineligible (when approving the reports).
  - changes concerning the tasks to be carried out by **linked third parties** and related costs (including if a linked third party is removed).
  - changes concerning **GA options** (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to Annex 2 and Annex 2a (estimated budget) or specific unit costs (AT31 and AT36)**

  What? Changes to the estimated budget, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which are linked to a significant change in the action's work (i.e. Annex 1)

– a budget transfer to a form of costs that is not used by the beneficiary (i.e. with 0 EUR costs in Annex 2) — except for transfer of amounts within the budget category A. ' personnel costs'.

Example:

During the action implementation, the beneficiary decides to use the access costs for transnational access to research infrastructure unit cost. This requires an amendment to fix the unit cost and to move budget to budget category F.2.

What not? There is NO need to request an amendment for changes covered by the budget transfers rule in Article 4.2 *(e.g. budget transfers within the personnel cost; see also below)*.

How? The amendment is normally triggered by the beneficiaries.

Best practice: If Annex 2a or specific unit costs need to be changed, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

Budget transfers within the personnel cost category are possible without having to amend the GA.

Examples:

1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices (average personnel costs).*

2. *An SME joins an on-going GA. The SME owner does not have a salary but incorrectly budgets its costs as actual personnel costs (category A.1). He realises the mistake and then switches to the unit costs for SME owners (category A.4).*

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

Simple changes of **name**, **legal form** *(e.g. Ltd., S.A.)*, **official registration number**, **address**, **VAT number** do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

Linked third parties — Since they normally do not have direct access to the Beneficiary Register, linked third parties must inform their beneficiary who must inform the Commission/Agency. The data will then be updated by the Commission/Agency (and validated).

If — exceptionally — the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator (and instruct it to request an amendment or trigger itself an amendment, if needed).

Example: *Company R moves from Europe to Australia and this implies that the beneficiary is no longer eligible for EU funding. In such a case, the Commission will make an amendment to the GA to change the beneficiary status into 'beneficiary not receiving EU funding'.*

Short names have no legal value and only serve as easy identifiers in the GA. If needed, they can be changed in the context of an amendment initiated on other grounds.

A change of the **person that represent the coordinator** for the purposes of signing the GA requires, by contrast, NO follow-up at all (not even a change in the Beneficiary Register — since this name is only relevant at the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

Transfers of the GA linked to a **universal takeover** (i.e. where the original entity is replaced by one new entity and all the rights and obligations — including the GA — are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

Example: *Beneficiary X merges with another existing entity Y by:*

- *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
- *establishing a new separate legal entity (X and Y are together known as 'Z').*

If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator (and instruct it to request an amendment, if needed).

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information (AT40).*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going innovation actions (IAs). The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% (but only to a reimbursement rate of 70%). The GA must be amended to change the reimbursement rate (AT33) and the estimated budget (AT31).*
For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

Information obligation — In case of a **universal takeover**, the beneficiary must — in addition to updating the data in the Beneficiary Register— inform the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the Participant Portal) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

2. Procedure

How? Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) directly in the Participant Portal.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function), to discuss the amendment.

Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Beneficiary Register.

Examples:

1. *A new beneficiary must be validated (legal entity validation). This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.*

2. *Validation of the new bank account, to change the bank account.*

The amendment request must include the necessary information and supporting documents. A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications or additional information/documents.

For more information on combination of amendment clauses and supporting documents, *see the Guidance – Amendment types & supporting documents.*

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action; *see Article 3*). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases *(e.g. change of bank account, change of coordinator to make the payment of the balance)*.

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Termination of the coordinator without its agreement — For change of coordinator without its agreement a special procedure applies: The other beneficiaries must nominate one of them to act on their behalf to notify termination and request the amendment. The nominated beneficiary must name a contact person (NoCo) responsible for the amendment.

Before it has been accepted or rejected, an amendment request may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The other party must — within **45 days** — **agree or disagree**.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If **accepted** it will be **counter-signed** by the receiving party directly in the Participant Portal (for the consortium: by the PLSIGN of the coordinator).

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Participant Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

  The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

1. *Where a new beneficiary is added to the GA (AT3), it must assume the rights and obligations from the accession date specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).*

2. *Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment (AT26). This date may be before the date on which the amendment enters into force (see Article 49.2.2).*

3. *If the amendment intends to correct an error (AT60), the change will be made with effect from entry into force of the GA (i.e. from the beginning).*

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* directly in the Participant Portal. They must do this **within 30 days** after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on **joint and several liability** *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, before signing the Accession Form.

Without the declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Linked third parties do not become parties to the GA and therefore do NOT need to sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (new in Horizon 2020). All documents are available in the Participant Portal project file.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries (amendment)

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How?

The new beneficiary must:

- register in the Beneficiary Register and be validated — unless it already has a validated participant identification code (PIC)
- sign the Accession Form (directly in Participant Portal)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the **accession date**. It must be either:

- the date of signature of the Accession Form
- the date of entry into force of the Amendment

OR

- a fixed date:
  - either retroactive (i.e. before signature of the Accession Form)

  OR

- future (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned].****]***

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations:

Situation	Applicable law
For international organisations that do NOT accept any applicable law clause	No reference to any applicable law[72]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned

[72] *See Article 180(1) of the Rules of Application Regulation No 1268/2012.*

	– the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law)	The international organisation can choose any of the following combinations of applicable laws: – only EU law – only Belgian law – only other MS or EFTA country law – only general principles governing law of IOs + rules of general international law – EU law + MS or EFTA country law (except Belgium) – EU law + general principles governing law of IOs + rules of general international law – EU law + Belgian law + general principles governing law of IOs + rules of general international law – EU law + other MS or EFTA country law + general principles governing law of IOs + rules of general international law – Belgian law + general principles governing law of IOs + rules of general international law – other MS or EFTA country law + general principles governing law of IOs + rules of general international law

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for non-EU beneficiaries not receiving EU funding, which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or non-EU beneficiary not receiving EU funding]*
- *[insert name of international organisation or non-EU beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiary not receiving EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

1. Dispute settlement

As a general rule, H2020 GAs contain an Article 272 TFEU arbitration clause — referring **disputes on the interpretation, application or validity of the GA** to the European Court of Justice.

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against confirmation letters, debit notes, etc.; NOT against audit reports, audit letters, pre-information letters, etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative sanctions**, **offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions must be brought before the European Court of Justice under Article 263 TFEU (NOT before any other court and NOT under Article 272).

Public law measures must ALWAYS be brought to the European Court of Justice under Article 263 TFEU (including actions brought by non-EU beneficiaries or beneficiaries not receiving EU funding).

All procedures are organised in a way that the beneficiaries will always be **informed** about what they can do if they disagree (**means of redress** information in the letters).

For more information on complaints, see the *Online Manual*

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, disputes on the interpretation, application or validity of the GA are normally referred to the competent Belgian courts. (So far (i.e. until end of 2016) NONE of the H2020 association agreements provides for the sole jurisdiction of the European Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Non-EU beneficiaries not receiving EU funding — For beneficiaries not receiving EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration *(see also point 1)*.

Other non-EU beneficiaries not receiving EU funding will be treated as normal non-EU beneficiaries (i.e. Belgian courts).

Disputes of public law nature remain before the European Court of Justice.

International organisations — For international organisations, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration (in line, for instance, with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[73]; *see also point 1*).

Disputes of public law will normally not arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

For this reason, the Commission/Agency will normally NOT adopt enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions *(see Article 45).*

Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (NOT as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[73] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

For countries for which it has carried out a formal assessment of specific situations or their legal framework, the Commission will keep record of its official position.

See the List of issues applicable to particular countries.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- Low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants. Other ERC actions (coordination and support actions (CSA)) use the H2020 General MGA.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)
- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

***[OPTION by default:** 'principal investigator':*[4]

- *[**Name**][Date and place of birth]]*[5]

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**] [official address in full] *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

[same for each beneficiary]

***[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*:* ***and other ERC grants with more than one principal investigator****: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Participants: Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The '**host institution (HI)**' is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**'.

2. Participants: Principal investigator(s)

For ERC grants, the main researcher (i.e. the principal investigator (PI)) is named in the GA.

PIs can be of any nationality, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted by a host institution that is based in an EU Member State or H2020 associated country.

Due to the key role of the PI, s/he can NOT be replaced by any other researcher during the action. Requests for amendments to change the PI will be rejected.

The Agency must be **informed** before any change in employment or location of the PI.

Should the PI move to another host institution (in an EU Member State or H2020 associated country), the GA can be transferred to the new host institution (**portability**; *see Article 56a*). If the PI moves to an institution established in a third country, the GA can be terminated *(see Article 50.1)*.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of the research activities, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

1. A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium. The engagement of the team follows the rules of the beneficiary and its country.

2. PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the action), PIs and their host institutions must sign a **supplementary agreement (SA)** *(see Article 32)*.

The supplementary agreement can NOT replace the employment/engagement contract.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party (from an EU Member State or H2020 associated country), i.e.:

- a third party that provides the PI as in-kind contribution or
- a linked third party *(see Article 8)*.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution AND the third party.

Retired PI — The PI may be retired (i.e. normally no longer under an active labour contract).

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs.

Thus, the ERC MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure
- direct costs of providing financial support to third parties
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices (average personnel costs), the unit costs for SME owners and beneficiaries that are natural persons without salary and the flat-rate of 25% for indirect costs.[74]

It does NOT use the unit costs of category F. 'specific cost categories' of the General MGA.

[74] See *Article 29(1) and 33(2) of the Rules for Participation Regulation No 1290/2013 and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period *[.][;]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* — with the exception of categories C. 'financial support to third parties' and F. 'specific cost categories'.

The same **eligibility conditions** and **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the **following specificities**:

– for category A. 'personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: under budget category A.1 'costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: under budget category A.3 'seconded persons' (Article 6.2.A.3)).

– for category D. 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs', even for the unsuccessful candidates (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs, and research data) are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[75]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

2. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

⚠ **Combining H2020 & other EU grants —** ERC grants do NOT prevent **PIs** from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

ℹ For more information on how to combine EU funding from different programmes, *see the Online Manual (links to Regional funding).*

[75] See http://erc.europa.eu/implementing-arrangements.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record-keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

In addition, the beneficiaries must prove that the **PI time commitments** (set out in Annex 1 and 2) were respected, i.e.:

- for the percentage of total working time on the action:
  - if the PI works 100% of his/her total working time for the host institution, but only partially on the ERC action: by using time sheets
  - if the PI works 100% of his/her total working time for the host institution and exclusively on the ERC action (during its entire duration): via a declaration signed by the beneficiary and the PI
  - if the PI works partly for other institutions (i.e. has working time outside the contract between PI and host institution): via a declaration signed by the beneficiary and the PI
- for the minimum percentage of total working time in a EU Member State or H2020 associated country: via a declaration signed by the beneficiary and the PI.

In the absence of this documentation, the ERC may accept alternative evidence, if it considers that it offers adequate level of assurance.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary**: information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC)*;*]**[OPTION 2**: not applicable;**]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When?

For ERC actions, the principal beneficiary must submit both:

- a **periodic scientific report** after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a **final scientific report** at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a **financial report** at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a breakdown of direct costs table and a budget follow-up table
- an individual financial statement
- a summary financial statement, created automatically by the IT system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a certificate on the financial statements (CFS).

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How?

All reports must be prepared and submitted directly in the Participant Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

Example: *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in **the data management plan**;*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2: *Not applicable**]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars

Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

See also the Open Access Guidelines for research results funded by the ERC.

ERC grants have however the **following specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org). For monographs, book chapters and other long-text publications, the recommended repository is the OAPEN Library (http://oapen.org).

For publications issued after the end of the action, if beneficiaries cannot provide open access without incurring additional costs for gold open access, they may choose green open access with an extended embargo period which goes beyond six/twelve months.

Moreover, with explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a digital object identifier (DOI)[76] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable). For ease of tracking, beneficiaries should include the digital object identifier for the 'European Research Council' (http://dx.doi.org/10.13039/501100000781) in the funding acknowledgement field in their

[76] For more information, *see http://www.doi.org/.*

metadata, in addition to the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601).

For more information, *see Open Access Guidelines for research results funded by the ERC.*

2. Open access to research data

This option will be inserted in the GA for ERC frontier research actions that participate in the Open Research Data Pilot (in line with provisions in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the **following specificities**:

For ERC actions, the data management plan (DMP) is not a deliverable of the action but a separate document required for participating actions.

It should describe the data management life cycle for the data to be collected, processed or generated by the research project.

Moreover it can provide justification for NOT ensuring open access to specific parts of the research data. (For ERC actions, the exception allowing beneficiaries not to give access to specific parts of their research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives.)

For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does NOT need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

A first version of the data management plan must be submitted within the first 6 months of the project implementation and should then be updated during the lifetime of the project, as needed.

The beneficiaries may **opt out** of the pilot at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55 H2020 General MGA)*. No reasons have to be provided for opting out. By opting out, they free themselves retroactively from the obligations associated with taking part in the pilot.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow for transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action

The percentages for time commitments should be established by reference to the total productive hours worked by the PI for *all* his/her employers.

The total productive hours should be calculated in accordance with Article 6.

The percentages must be reached for the action duration (NOT annually or per reporting period).

- Applying the host institution's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**
- Upholding the **intellectual property rights** of the host institution

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it if s/he becomes aware of any violations.

  Example: *The PI reads a research article and discovers a violation of the host institution's project IPRs. S/he is obliged to inform the host institution.*
- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the host institution and the PI, to set out their internal arrangements for implementing the grant.

It is **purely internal**; the EU/Euratom is NOT party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must last at least for the action duration *(see Article 3)* (— without any interruptions, even if the PI works only part-time on the ERC project).

It must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

It must be concluded **before GA signature** (and a copy must be sent to the Agency).

A model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*), a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make **specific reference to the European Research Council (ERC)**. Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC homepage*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION 1:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION 2:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG and other ERC grants with more than one principal investigator: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new host institution ('new beneficiary') — at any time during the action.

Transfer — The rights and obligations under the GA are transferred from the former host institution to a new host institution — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former host institution remains fully responsible until the Agency has approved the amendment.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution ('former beneficiary') may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the view of the PI.

2. Procedure

The PI should first contact the host institution that signed the GA (i.e. the former host institution).

> ⚠ **Record-keeping**
> **Best practice:** Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new host institution joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The **financial reporting periods** will be automatically adapted to match the transfer date (unless the transfer date coincides with the end of a financial reporting period).

Scientific reporting periods will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

> ℹ For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents*

3. Effects

The principal beneficiary must — within 60 days from either the transfer date or the date of signature of the amendment whichever is the latest — submit:

- a financial report to the Agency (for the open period until transfer)
- a report on the distribution of payments (only in case of multi-beneficiary GA)
- if the costs reach the threshold set out in Article 20:, a certificate on the financial statement (CFS) (— even if this is not the last reporting period).

These documents will be used for calculating the interim payment due to the former beneficiary. The Agency will moreover instruct the former host institution to transfer the remaining pre-financing to the new host institution.

If the PI requests it, the Agency may require the former host institution to **transfer equipment** that was purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate transfer conditions with the new host institution, taking into account the view of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may declare the costs of this reimbursement (and any other

related costs, i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, while the PI moves to a new host institution, the GA is transferred and changed into a multi-beneficiary grant agreement (allowing both the former host institution and the new host institution to participate in the grant). The former host institution stays on as beneficiary, the organisation that hosts and engages the PI is the new host institution. If the former host institution remains only for a limited time *(e.g. to ensure a smooth handover)*, it can then be terminated at a later stage, via a partner termination *(see Article 50.2 H2020 General MGA)*.

II.3 H2020 ERC MGA PoC: Annotations

The H2020 ERC MGA PoC is very similar to the H2020 ERC MGA.

> Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.
>
> There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability (*Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not found by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of the Horizon 2020 Framework Programme, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION 1 by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION A if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION B:*** *not applicable;****]***

(f) *a '****summary financial statement****', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the* ***request for payment of the balance****;*

(g) *a '****certificate on the financial statements****' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).****]***

[OPTION 2 for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a report to the Agency.

The ***report*** *must include the following:*

(a) *a summary for publication by the Agency;*

(b) *an* ***overview of the progress of work*** *towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

(c) *detailed information on the costs declared, including a '****breakdown of direct costs table****' and a '****budget follow-up table****';*

(d) *an* ***'individual financial statement'*** *(see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the report for the next reporting period.

The individual financial statements of the last reporting period must also detail the ***receipts of the action*** *(see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION A if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION B:** not applicable;**]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Report(s)

What & When?

For ERC PoC actions, the principal beneficiary must submit reports — only one **report** if there is one reporting period, otherwise one **periodic report** at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a (periodic) summary financial statement, which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a certificate on the financial statements (CFS) will have to be added (if necessary).

How?

All reports must be prepared and submitted directly in the Participant Portal *(see Article 20 H2020 General MGA*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowska-Curie (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE and
- MSCA-COFUND.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA MSCA - ITN deviates from the General MGA - Multi as follows:

- Article 4.2 (MSCA-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to ‘mainstream media coverage’)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MGA MSCA-IF deviates from the General MGA - Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 9-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSCA-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSCA-IF specific conditions for termination)
- Article 55 (MSCA-IF specific conditions for amendments)
- Article 56a (MSCA-IF portability)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MGA MSCA-RISE deviates from the General MGA - Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9 - 16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSCA-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (MSCA specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-COFUND deviates from the General MGA - Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of a programme)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 3, 5 and 6 Not applicable

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 9-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement)

III.2 H2020 MGA MSCA-ITN: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-ITN

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by networks of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN takes the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[OPTION for all actions except EID with only two beneficiaries: *However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.****]***

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NEVER** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment *(see Article 55)* is required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID with only two beneficiaries: a maximum of 40 % of the budget may be allocated to beneficiaries established in the same country (or to the same international European interest organisation or international organisation).

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In an action with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (= 40%). If the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes (*e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes (*e.g. to increase the salary of a researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

For MSCA-ITN, the maximum grant amount is limited to a maximum unit cost equivalent of 540 person-months (and for EID with only two beneficiaries: 180 person-months).

2. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

3. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[77].

For MSCA-ITN, these are unit costs for:

[77] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they can NOT be changed.

The eligibility conditions are set out in *Article 6*.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country) – unless as part of a procedure for obtaining refugee status under the Geneva Convention[6].

For beneficiaries that are international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately before the recruitment date.

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for 1 EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree [;][.]**]***

(viii) ***[OPTION for 2 EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

[6] 1951 Refugee Convention and the 1967 Protocol.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)
- a monthly mobility allowance (A.2) — to cover costs related to their mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by budget category B.1 'research, training and networking costs')

AND

- a monthly family allowance (A.3) — for researchers with family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B. 'institutional costs' (*Article 6.2.B*).

Example: *Costs for student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.*

1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8194[78] and set out in Annex 2 and 2a of the GA.

This is currently:

[78] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the living allowance: **EUR 3 110** per researcher per month (person-month)

To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

The list of coefficients is published in the Main Work Programme — MSCA in force at the time of the call.

On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does NOT change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action).

– for the mobility allowance: **EUR 600** per person-month

– for the family allowance: **EUR 500** per person-month.

For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first 4 years (full-time equivalent research experience) of their research career)

    '**Date of recruitment**' means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    Example: *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as recruitment date.*

    Years of '**research career**' are counted from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:

    – sickness, parental, unemployment and invalidity benefits

- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — Beneficiaries must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:

  - subject to prior approval by the Agency
  - on personal or family grounds only (i.e. not for professional reasons).

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  While it is not possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities (and must be set out in Annex 1 of the GA).

- are supported for **at least 3 months**

  Person-months linked to shorter contracts will not be eligible.

  However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. If the contract is set out for a longer duration, but the training is interrupted within the first three months for reasons not linked to the beneficiary *(e.g. because the researcher resigns)*, the costs may still be claimed.

- comply — at the date of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (— unless the beneficiary is an 'international European interest

organisation'[79] or international organisation, for whom the mobility rule is limited to time spent *with* them)

The mobility rule applies only to the **first recruitment** under the action. For instance, it does not apply to beneficiaries or partner organisations to which the researcher is sent or seconded afterwards.

Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[80] are NOT counted.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  In the case of EJD, the PhD-programme must lead to the award of:

  - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
  - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

  The degree must not necessarily be awarded within the action duration.

  However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researchers (gross amount).

MSCA-ITN researchers may NOT be requested to pay tuition fees for their research training and/or PhD degree programme (neither from their own funds, nor from the researcher unit cost). The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* can be reimbursed under category B. 'institutional costs'.

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as*:

- *part of his/her salary*
- *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
- *rental costs, directly paid or reimbursed by the beneficiary .*

[79] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[80] 1951 Refugee Convention and the 1967 Protocol.

Any form is acceptable, provided that:

- both sides agree
- it is allowed under national law

AND

- there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[81]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[82].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers who have — at the date of the recruitment — a family, i.e.:
  - persons linked to them by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

[81] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[82] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ Beneficiaries may declare a **maximum** of **36 person-months** per researcher. Person-months exceeding this number will be rejected by the Agency.

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector.

This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations/entities with a capital or legal link. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary, *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 50% rule.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - additional costs arising from secondments *(e.g. travel and accommodation costs)*
- management and indirect[83] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of a researcher)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8194[84] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1800** per researcher per month (person-month)

[83] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[84] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

– for management and indirect costs: **EUR 1200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[85] in the same period, only management costs, i.e. EUR 600).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A. 'costs for recruited researchers'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for budget category A. 'costs for recruited researchers' are also not eligible for budget category B. 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[85] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon **entities with a capital or legal link** to the beneficiaries[7], to implement certain action tasks described in Annex 1 (i.e. hosting and training of researchers);
- call upon **partner organisations** to implement certain action tasks described in Annex 1 (i.e. hosting and training researchers during secondments).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[7] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-ITN allows the beneficiaries to use:

– entities with a capital or legal link to them

and

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them).

'**Entities with a capital or legal link**' are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. A university is beneficiary of an MSCA-ITN grant (i.e. recruits the researchers), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-ITN action as entity with a capital or legal link implementing the research training activities, while the foundation or subsidiary participates as beneficiary (because it can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-ITN action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and training of researchers — and can even implement ALL those activities under the action. But they can NOT recruit the researchers (only beneficiaries can recruit the researchers) and can NOT host secondments (only partner organisations can host secondments).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary, tasks to be carried out and time spent with them).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme).

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers during **secondments**.

Secondments — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country) in order to further enrich the training experience of the researchers.

They are limited to a **maximum of 30%** of the time that is declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out and time spent with them).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations can be established anywhere.

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

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[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the **full risk** of rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

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19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term review meeting**' between the beneficiaries, entities with a capital or legal link, partner organisations and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of each researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — within 30 days after the first year of the action — send to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term review meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term review meeting.

> **Best practice:** It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** after the recruitment date.

> It is important to give correct and complete information in the researcher declaration since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA):*

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[16] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or other entity mentioned in Annex 1);

(j) host the researchers at their premises (or at the premises of an entity with a capital or legal link);

(k) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(l) ensure that the researchers are adequately supervised;

(m) ensure that a career development plan is established and support its implementation;

(n) ensure an appropriate exposure to the non-academic sector;

(o) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[16] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective recruitment procedures and best possible working conditions.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[86]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises (or those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or ensure that this is provided by the entity with a capital or legal link).

[86] Available at http://ec.europa.eu/euraxess/

If the Agency finds that a beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**
- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Ensure that **secondments** are **limited** to a **maximum** of **30 %** of the months declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD).

> ⚠ **Secondments** — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country), in order to further enrich the training experience of the researchers *(see Article 8)*.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

- Ensure that the researchers do NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[87].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[88].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities (including during secondments with other beneficiaries and/or partner organisations).

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2)*.

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

[87] Available at https://www.iprhelpdesk.eu/.
[88] Available at http://ec.europa.eu/euraxess/.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MGA MSCA-IF: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-IF

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include three additional funding strands: the 'Career Restart Panel', the 'Reintegration Panel' and the 'Society & Enterprise Panel'.

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION 3 if needed for the action:** [insert date]]*[4] ('**starting date of the action**').

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the actual starting date must be *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, there will be a **maximum deadline for notification** set out in Article 3 for both starting the action and notifying this to the Agency (normally 12 months from the entry into force of the GA).

The notification must be done directly in the Participant Portal.

Late notification will delay the pre-financing payment *(see Article 21.2 of the H2020 General MGA)*.

If the action does not start or the starting date is not notified in time, the Agency may terminate the GA *(see Article 50 of the H2020 General MGA)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researcher (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The institutional unit cost should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (*including for GF outgoing phase; see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[89].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[89] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed ***[OPTION 1 by default:** 24]**[OPTION 2 for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including periods of secondment to '**partner organisations**';

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action.

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory

deductions under national law, *such as employer/employee social security contributions and direct taxes*)

- a monthly mobility allowance (A.2) — to cover costs related to his/her mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by category B.1 'research, training and networking costs').

AND

- a monthly family allowance (A.3) — if the researcher has family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiary are not covered under this budget category; they are covered under category B. 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8194[90] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 4 650** for the researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the Main Work Programme — MSCA in force at the time of the call and according to the country of recruitment (i.e. the country of the beneficiary).

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

ℹ For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[90] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the date of the call deadline — an **experienced researcher** (i.e. have a doctoral degree OR have at least four years (full-time equivalent research experience) of research career).

    Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases

    If national law prevents it from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

    The social security coverage must be guaranteed for the entire action (i.e. also during optional secondments, if any, and for the GF outgoing phase).

    For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent coverage during the stay in the third country.

    Example: *A German university recruits the fellow for the total duration of the action (i.e. provides the main employment contract under the action) and sends him/her to a US university. Continuing the German social security during the stay in the US would be so expensive, that the beneficiary asks the US partner organisation to conclude an additional employment contract, in order to insure the researcher in the US.*

    Staff provided by a temporary work agency — The beneficiary must always recruit the researcher directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency

– on personal or family grounds only (i.e. not for professional reasons).

In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ While it is NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researcher (gross amount).

  The mobility and family allowances are due to the researchers for each month worked.

  Mobility and family allowances can be paid to the researcher in various ways, *for example as:*

  – *part of his/her salary*

  – *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*

  – *rental costs paid or reimbursed by the beneficiary, etc.*

  Any form is acceptable, provided that:

  - both sides agree

  – it is allowed under national law

  AND

  – there is no underpayment.

  Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

  Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

  ⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[91]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[92].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the date of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the 3 years immediately before to the call deadline (— unless the beneficiary is an 'international European interest organisations' or international organisations, for whom the mobility rule is limited to time spent *with* them)

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) are NOT counted.

  For EF Career Restart Panel, Reintegration Panel and Society & Enterprise Panel: specific mobility rule — not more than 3 years in the 5 years immediately before the call deadline

  For GF: the mobility rule is checked for the country of the partner organisation, not for the country of the beneficiary (i.e. where the outgoing phase takes place, not where the return phase takes place).

- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a EU Member State or an H2020 associated country.

  'Long-term resident' means full-time research activity in a EU Member State or H2020 associated country for 5 or more consecutive years.

  Time spent in procedures for obtaining refugee status in a EU Member State or H2020 associated country will be counted.

- for EF Career Restart Panel: not have been **active** in research for at least 12 months immediately before the call deadline

  'Active in research' means being employed or holding a scholarship. Publication activities or mere association to a university are not taken into account.

- for the family allowance: have a **family**, i.e.
  - persons linked to the researcher by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or
  - dependent children who are actually being maintained by the researcher.

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs for the researcher.

[91] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[92] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ The beneficiary may declare a **maximum** of **24 person-months** for the researcher (or **36 months** for GF). Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.1): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - additional costs arising from secondments *(e.g. travel and accommodation costs)*
- management and indirect[93] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (including for GF outgoing phase; *see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8194[94] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 800** for the researcher per month (person-month)
- for management and indirect costs: **EUR 650** per person-month (Beneficiaries that already receive an EU/Euratom operating grant[95] in the same period, only management costs, i.e. EUR 325).

[93] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[94] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A. 'costs for the recruited researcher'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for budget category A. 'costs for the recruited researcher' are also not eligible for budget category B. 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for the recruited researcher:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[95] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon entities with a capital or legal link to the beneficiary[5], to implement certain action tasks described in Annex 1 (i.e. hosting and training of the researcher);
- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. hosting and training the researcher during secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

[5] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-IF allows the beneficiary to use:

– entities with a capital or legal link to it

and

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

'**Entities with a capital or legal link**' are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to the beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-IF grant (i.e. recruits the researcher), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. *A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation or subsidiary participates as beneficiary (because it is can recruit the researchers).*

3. *A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).*

Entities with a capital or legal link may be used for hosting and research training of researchers — — and can even implement ALL those activities under the action. But they can NOT recruit the researcher (only the beneficiary can recruit the researcher) and can NOT host secondments (only partner organisations can host secondments).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of link with the beneficiary and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary (for instance, be established in an EU Member State or H2020 associated country).

Example: *For the EF Society & Enterprise Panel, the entities with a capital or legal link must also be from the non-academic sector.*

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers during **a secondment**.

Secondments — For MSCA-IF, secondments are either:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country).

Optional secondments are limited to a **maximum of 3 months** (for actions with duration of up to 18 months) and **6 months** (for actions with duration of more than 18 months).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researcher (only the beneficiary can recruit the researcher).

For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent social security coverage during the stay in the third country *(see Article 6)*.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations for optional secondments must be established in an EU Member State or H2020 associated country; partner organisations for GF outgoing phase must be established in a third country.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

A beneficiary that throws supporting documents away during the retention period bears the **full risk** of rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** and **entities with a capital or legal link** (if any) give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[12] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(g) host the researcher at its premises (or at the premises of an entity with a capital or legal link);

(h) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(i) ensure that the researcher is adequately supervised;

(j) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(k) support the secondment of the researcher to a partner organisation in a Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(l) ***[OPTION for GF:*** *support the return of the researcher to its premises (or those of the entity with a capital or legal link) to carry out a mandatory return period of 12 months.****]***

[…]

[12] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises (or at those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or to ensure that this is provided by the entity with a capital or legal link).

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- **Support secondments** of the researcher (if any) and ensure that they are **limited** to a **maximum** of **3 months** (for actions of up to 18 months) or **6 months** (for actions of more than 18 months)

Secondments — For MSCA-IF, secondments can be:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

and/or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country) *(see Article 8)*

For GF: Also support the researcher's return (during the mandatory 12 months return-period)

- Ensure that the researcher does NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[96].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[97].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during optional secondments/GF outgoing phase with partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

[96] Available at https://www.iprhelpdesk.eu/.
[97] Available at http://ec.europa.eu/euraxess/.

This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. GA suspension — Additional grounds for suspension: Professional, personal or family reasons

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, beneficiaries of MSCA-IF may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and (planned) end date of the suspension and
- the (planned) resumption date when the action will be resumed (i.e. automatically end date +1 day).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are NOT eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional grounds for amendments: Change to part-time employment

What? For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time) — on personal or family grounds (including parental leave).

What not? Such amendments are NOT possible for any other reasons *(e.g. other professional opportunities, etc.)*. In those cases, the beneficiary must request a GA suspension or GA termination.

How? The amendment should be requested immediately (retroactive change is possible, if justified; *see Article 55 H2020 General MGA*).

The action duration will be automatically adapted (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months, so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working time; AT23 clause) and the reporting periods will be changed (to adapt them to the new action duration; AT25 clause).

For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ **Transfer** — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains **fully responsible** until the Agency has approved the amendment.

The transfer may be based on any **ground** that is linked to the beneficiary and affects objectives of the action (i.e. implementing the research training activities).

Examples: *Internal reorganisation affecting implementation of the action; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher (e.g. other professional opportunities, personal or family commitments) are NOT considered valid grounds for transferring the GA to a new beneficiary. These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*.

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility conditions or does not have sufficient financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed directly in the Participant Portal).

The **maximum grant amount/action duration** will be adapted to take into account the country correction coefficient of the new beneficiary.

⚠ The maximum grant amount *(see Article 5)* will **NEVER** be **increased**.

If the new beneficiary is in a country with a lower country correction coefficient, the maximum grant amount *(see Article 5.1) will be lowered*.

If the new beneficiary is in a country with a higher country correction coefficient, the action duration will normally be adapted, so that the maximum grant amount can stay the same. If (exceptionally) the action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new correction coefficient *(using e.g. the management and indirect costs or own funding)*.

ℹ For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to check the eligible costs and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary. The real financial statement for the open reporting period until transfer must be also uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

III.4 H2020 MGA MSCA-RISE: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-RISE

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

> **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

> For more information on MSCA-RISE, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*
>
> For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55)* — provided that it does not imply a substantial change to the action as described in Annex 1.

The maximum grant amount *(see Article 5)* can however **NEVER** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

If the transfer of person-months implies a substantial change of Annex 1, a formal amendment is required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the seconded staff (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs a staff member, to organise additional training activities or horizontal networking events)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs)**.

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[98].

For MSCA-RISE, these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[98] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42).*

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for seconded staff members</u> are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the sending:

- beneficiary (or entity with a capital or legal link[6] to it and located in the same country), or
- partner organisation (or entity with a capital or legal link to it and located in the same country).

(c) the secondments comply with the following conditions:

(i) last at least 1 month and no longer than 12 months (per secondment);

(ii) be between different countries;

(iii) for secondments within the EU (or associated countries)[7]: be between different sectors (academic and non-academic)[8];

(iv) for secondments from EU (or associated countries): be from a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country) to a partner organisation (or entity with a capital or legal link) established in a non-EU Member State (or non-associated country), and

(v) for secondments to EU (or associated countries): be from a partner organisation (or entity with a capital or legal link) established in a country listed in General Annex A of the Main Work Programme to a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country).

[6] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] For secondments for entities with a capital link or legal link to the beneficiaries or partner organisations: only the sector (academic or non-academic) of the beneficiary counts; the entity will be considered to belong to the same sector as their beneficiary.

1. Seconded staff costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members, by providing for:

- a monthly top-up allowance (A.) — for travel, accommodation and subsistence costs relating to the secondment.

> ⚠ **Budget flexibility —** There is NO flexibility as regards the *use* of the seconded staff unit costs (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
>
> ⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

What not? Research, training and networking costs and management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B. 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared** on the basis of the unit cost fixed by Decision C(2013) 8194[99] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the top-up allowance: **EUR 2 000** per seconded staff member per month (person-month).

> ℹ For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - **early stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time equivalent research experience) of their research career)
    - **experienced researchers** (i.e. have a doctoral degree OR at least four years (full-time equivalent research experience) of research career), or

[99] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- **administrative, managerial** or **technical staff supporting research and innovation activities** (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

  Examples (not eligible administrative, managerial or technical staff):

  1. *Ms B, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

  2. *Mr Y, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

Years of '**research career**' are counted from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited or from where s/he is seconded) — even if a doctorate was never started or envisaged.

- have already been actively **engaged** in or **linked** to research and innovation activities at the premises of the sending beneficiary/partner organisation/entity with a capital or legal link, continuously for at least **6 months** (full-time equivalent)

  Examples:

  1. *Mr Y is employed by/has a fellowship with/is a registered PhD candidate of beneficiary Y as from 1 January 2014; Mr Y will not be eligible for a secondment from 1 March 2014 but would be eligible for secondment as from 1 July 2014.*

  2. *Ms X is employed 50% part-time by beneficiary X as from 1 January 2014. Ms X will not be eligible for a secondment from 1 July 2014, but would be eligible for secondment as from 1 January 2015.*

  The type of relationship (employment contract, fellowship or other) is NOT relevant — as long as it:

  - complies with national law
  - complies with internal practices and
  - during the secondment: confers to the sending beneficiary/partner organisation/entity with a capital or legal link the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

    If this is not the case, the beneficiary/partner organisation/entity with a capital or legal link must conclude a contract which allows this (or a supplementary agreement) — before the secondment.

    Example: *A PhD-candidate can be seconded if s/he: has a contract allowing him/her to work full-time on the R&I activities of the action during the secondment under the instructions of the sending beneficiary/partner organisation/entity with a capital or legal link.*

- be incurred for secondments:

  - that last at **least 1 month** and **no longer than 12 months**

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

    For the minimum duration, only splits within *secondments of* same staff, from same sending beneficiary/partner organisation to same hosting beneficiary/partner organisation can be added. Secondments from/to entities with a capital or legal link

will be counted as secondments from/to the beneficiaries/partner organisations they are linked to.

Example: *Two secondments of two weeks of the same staff member to different beneficiaries are not eligible since the minimum duration of 1 month is not reached.*

For the maximum duration, all secondments (and all splits) for the *same staff member* must be added.

- that are one of the following three:
  - secondments **between beneficiaries/entities with a capital or legal link** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in **different** EU Member States or H2020 associated **countries** AND **different sectors** (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country) **to** a **partner organisation/entity with a capital or legal link** in a third country

  OR

  - secondments **from** a **partner organisation/entity with a capital or legal link** in a third country listed in General Annex A to the Main Work Programme **to** a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country).

Examples:

A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work Programme.*
A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.*
A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
They may each claim 120 person-months (for their own staff).

If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded *from* both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation *to* two or more participating organisations in a RISE project — as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('implemented person-months')

⚠ Beneficiaries may declare a **maximum** of **12 person-months** per seconded staff member. Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert 5.47 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[100] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility —There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.

1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8194[101] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1800** per researcher per month (person-month)
- for management and indirect costs: **EUR 700** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[102] in the same period, only management costs, i.e. EUR 350).

[100] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[101] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[102] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A. 'costs for seconded staff members'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for seconded staff members.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the seconded staff members are met. Person-months which are not eligible for budget category A. 'costs for seconded staff members' are also not eligible for budget category B. 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) *[**OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]]*.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff);
- call upon entities with a capital or legal link to the beneficiaries or to partner organisations[9], to implement certain action tasks described in Annex 1 (i.e. seconding staff).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[9] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-RISE allows the beneficiaries to use:

- partner organisations

and

- entities with a capital or legal link to a beneficiary or a partner organisation

to carry out work under the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them.)

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to a beneficiary.

They may participate in the exchanges by seconding and hosting staff.

⚠ **Secondments** — For MSCA-RISE, secondments are the core activity of the action. They can be between beneficiaries/entities with a capital or legal link OR between beneficiaries/entities with a capital or legal link and partner organisations (from a third country).

They must have a **minimum** duration of **1 month** and a **maximum** duration of **12 months** (per seconded staff member).

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations must be established in a third country.

- **Entities with a capital or legal link** are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary or a partner organisation — which is neither limited to the action nor established for the sole purpose of its implementation).

They may participate in the exchanges by seconding and hosting staff.

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary/partner organisation and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary/partner organisation they are linked to (for instance, if linked to a beneficiary: be established in an EU Member State or H2020 associated country; if linked to a partner organisation: be established in a third country) AND be established in the same country as their beneficiary/partner organisation.

Examples (eligible entities with capital or legal link):

1. *University X (established in France) is part of a Joint Research Unit (JRU) with beneficiary Y (also established in France). Mr. X is employed by university X and is to be sent on a secondment to beneficiary Z. University X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

2. *SME X (established in Portugal) is a subsidiary of beneficiary Y (also established in Portugal). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. SME X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Ms. X.*

3. *Mr. X is formally employed by foundation X (established in Spain) which does the HR management for beneficiary Y (also established in Spain). Mr. X actually works with beneficiary Y and should be sent on a secondment to beneficiary Z. Foundation X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

Examples (ineligible entities with capital or legal link):

1. *SME X (established in Germany) is a subsidiary of applicant Y (established in Greece). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. Since SME X is not established in the same country as applicant Y, it cannot act as entity with a capital or legal link for the purposes of a MSCA-RISE grant. Therefore, Ms X cannot be seconded.*

2. *University X (validated as academic; established in Sweden) is member of an association of universities (applicant Y; validated as non-academic). Mr. X is employed by university X and is to be sent on a secondment to applicant Z (validated as academic). University X cannot act as entity with a capital or legal link of applicant Y for the purposes of the MSCA-RISE grant because this would circumvent the inter-sector mobility rules (mix of academic and non-academic).*

ℹ For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities)*

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until these procedures end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the **full risk** of rejection by the Agency.

Specific cases (record-keeping):

- **Documents for staff of the partner organisations and entities with a capital or legal link** — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must keep the documents for the staff of the partner organisation/entity with a capital or legal link.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term review meeting**' between the beneficiaries, partner organisations, entities with a capital or legal link and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1) and
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — after each year except if a periodic report is due (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term review meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term review meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a 'researcher declaration' for each seconded staff member — within **20 days** from the start of the secondment.

It is important to give correct and complete information in the researcher declaration, since this information will be used to determine the eligibility of the person-months that are declared.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — and indicate each split.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment, indicating the split. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (within 20 days from the start date of each secondment). Secondments to entities with a capital or legal link will be counted as secondments to the beneficiary/partner organisation they are linked to and must therefore be covered by the same researcher declaration.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

Specific case (deliverables):

Researcher declaration for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must submit the researcher declarations.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the seconded staff members **access** to both **background** AND **results** necessary for their research and innovation activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

- Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time.**

  For part-time staff members this may require a change of their relationship (i.e. conclude a contract or a supplementary agreement), to allow the secondment to be implemented on a full-time basis.

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is only a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are of course accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary/partner organisation/entity with a capital or legal link) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[103].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*

- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

  They can be:

[103] Available at https://www.iprhelpdesk.eu/.

- paid directly to the seconded staff member in advance or via different instalments or
- managed centrally by the beneficiary according to the specific needs of the secondment.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract (or fellowship or other relationship), some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA grant in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MGA MSCA-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-COFUND

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of the Horizon 2020 Framework Programme, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in a programme implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**');

(b) for **costs of providing financial support to costs for researchers in a programme implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[104].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[104] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced maximum grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in a programme implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in a programme implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme), by providing for:

- a monthly living allowance (A.1 or A.2) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*).

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit cost (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs of the beneficiary are not covered. Management costs are covered under budget category B. 'management costs' *(see Article 6.2.B)*. Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are NOT eligible under the grant; they may be funded through other sources (including other EU funding programmes).

Combining H2020 & other EU grants — A MSCA-COFUND grant does NOT prevent the beneficiary or partner organisations from applying for further (non-H2020) EU funding for their programme — for costs that are not eligible (or not declared) under the MSCA-COFUND grant.

For more information on how to combine EU funding from different programmes, *see the Online Manual (links to Regional funding).*

1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8194[105] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance:
  - for early-stage researchers in doctoral programmes: EUR 3 710 per researcher per month (person-month)

[105] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for experienced researchers in fellowship programmes: EUR 5 250 per person-month.

⚠ Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is ONLY **EUR 1 855** and **EUR 2 625** respectively.

ℹ For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** only the:

- management costs (B.) — for direct costs of managing the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER sources (including other EU funding programmes).

1.2 The costs must be **declared** on the basis of the unit cost fixed by Decision C(2013) 8194[106] and set out in Annex 2 and 2a of the GA.

This is currently:

- for management costs: EUR 650 per researcher per month (person-month).

Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is **EUR 325**.

For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher costs.

1.3 The **eligibility** of the management costs is directly linked to (and conditional on) the eligibility of the costs for researchers.

Management costs are eligible only if ALL the eligibility conditions for the researchers are met. Person-months which are not eligible for budget category A. 'costs for researchers' are also not eligible for budget category B. 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

[106] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. implementing a doctoral or fellowship programme including recruiting researchers or hosting and training researchers during a secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-COFUND allows the beneficiary to use:

- partner organisations

to carry out work under the action ('**third parties involved in the action**').

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to:

- implement a doctoral or fellowship programme (i.e. recruit the researchers)
- provide training and hosting of researchers during a secondment *(see Article 15)*.

⚠ **Secondments —** For MSCA-COFUND, secondments can be:

- (optional) additional periods of research training with a partner organisation, in order to further enrich the training experience of the researchers

and/or

- for fellowship programmes similar to MSCA-IF GF: (mandatory) outgoing phase with a partner organisation (from a third country).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during secondments.

Partner organisations can recruit the researchers (and MUST do so if it is the partner organisation that implements the doctoral or fellowship programme; *see Article 15.1.1(b)*).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations that implement a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *Main Work Programme*. Partner organisations hosting secondments can be established anywhere.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

15.1 Rules for providing financial support to or implementation of a *[doctoral][fellowship]* programme

15.1.1 The beneficiary must ensure that the ***[doctoral][fellowship]* programme** (implemented by itself or a partner organisation) complies with the following conditions:

(a) **types of programme**:

[OPTION 1 for DPs: *The programme must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programme**');**]***

[OPTION 2 for FPs: *The programme must concern fellowships for research training activities for recruited researchers ('**fellowship programme**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country[5], the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programme:

[OPTION 1 for DPs: *The doctoral programme must support researchers, who — at the time of the call deadline or recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately before the recruitment — unless:*
  - *otherwise specified in Annex 1 for existing programme or*
  - *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[6];*
- *are nationals or long-term residents of an EU Member State or associated country[7], in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION 2 for FPs: *The fellowship programme must support researchers, who — at the time of the call deadline or recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than [**OPTION A by default:** 12 months in the 3][**OPTION B for actions with activities similar to the MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel:** 3 years in the 5] years immediately prior to the call deadline or recruitment — unless:*

- *otherwise specified in Annex 1 for existing programmes or;*
- *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[8];*

- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.]*

Researchers that are already permanently employed by the entity where the research training activities take place may not be supported.

(c) **procedure and criteria for selecting researchers** in the programme:

[OPTION 1 for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION 2 for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

The selection committee(s) must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(d) **conditions for the recruitment** of researchers under the programme:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;
- researchers must be recruited for at least 3 months;
- ***[OPTION 1 for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION 2 for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- for programmes implemented by itself:
  - take measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[9] and ensure that the researchers are aware or them;
  - ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;
  - ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);
  - ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;
  - ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
  - ensure that researchers work exclusively on the research training activities;
  - ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
  - ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
  - ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of results, promoting the action) — during the research training activities and afterwards;
  - inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — a follow-up questionnaire provided by the Agency;
  - ***[OPTIONS for DPs:****ensure a fair gender representation in the recruited researchers (by promoting genuine equal access opportunities between men and women throughout the recruitment process);*
  - *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.****]***
- for programmes implemented by a partner organisation:
  - ensure that the partner organisation complies with the obligations set out in this Article and

- ensure that the partner organisation allows that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[5] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[6] 1951 Refugee Convention and the 1967 Protocol.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] 1951 Refugee Convention and the 1967 Protocol.

[9] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing a doctoral/fellowship programme

MSCA-COFUND can provide support both for a programme implemented by the beneficiary itself or for a programme of a partner organisation (which the beneficiary funds by providing financial support).

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisation that implements the doctoral/fellowship programme (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Types of programme — Categories of persons

The beneficiary/partner organisation must implement one of the following **types of** research training **programme** supporting transnational mobility:

– doctoral programme (DP), i.e. a programme with research training activities for recruited early-stage researchers that leads to the award of a doctoral degree

The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programme (FP), i.e. a programme with fellowships for recruited experienced researchers.

The **researchers** must — at the date of the call deadline or recruitment —:

- be one of the following two:
  - **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time-equivalent research experience) of their research career) or
  - **experienced researchers** (i.e. have a doctoral degree OR have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than:
  - for fellowship programmes similar to MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel: 3 years in the 5 years immediately before the recruitment date or call deadline
  - for all other programmes (doctoral programmes and other fellowship programmes): 12 months in the 3 years immediately before the recruitment date or call deadline

  — unless Annex 1 of the GA specifies otherwise for an already existing programme or the beneficiary/partner organisation is an 'international European interest organisation'[107], for whom the mobility rule is limited to time spent *with* them.

  Exceptions in Annex 1 are only possible for existing programmes (NO exceptions for new programmes).

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[108] are NOT counted.

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

- if the programme is implemented by a partner organisation established in a **third country** (only third countries listed in General Annex A to the Main Work Programme) or if a secondment to a partner organisation in a third country (any third country) constitutes the ***main* part** of the research training activities: be nationals or **long-term residents** of a EU Member State or H2020 associated country.

  'Long-term resident' normally means full-time research activity in a EU Member State or H2020 associated country — for 5 or more consecutive years.

  NO other restrictions on researcher nationality or researcher origin or destination allowed.

3. Additional cost eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

[107] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[108] 1951 Refugee Convention and the 1967 Protocol.

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[109]*)*.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a **maximum** of **4** fixed deadlines or regular cut-off dates **per year**) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

4. Additional cost eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits
- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, the beneficiary/partner organisation may — exceptionally and subject to the Agency's prior agreement— offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — The beneficiary/partner organisation must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

The researchers must be recruited for **at least 3 months**.

[109] Available at http://ec.europa.eu/euraxess/.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum remuneration —** monthly **living allowance** (i.e. gross amount including salary, social security contributions, taxes and other costs included in the remuneration) and, if applicable, a single mobility allowance for the researcher to take up the doctoral or fellowship programme (to be funded through other sources) **—** of:

- for early-stage researchers (doctoral programmes): EUR 2 597
- for experienced researchers (fellowship programmes): EUR 3 675.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 298,50; for experienced researchers EUR 1 837,50).

Lower payments are considered as underpayment.

⚠ Since the MSCA-COFUND grant reimburses 50% of the researcher unit cost (i.e. EUR 1 855 and EUR 2 625 respectively), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 742** or **EUR 1050** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

The total cost of the doctoral/fellowship programme, in particular the amounts to be provided for the benefit of the researchers and for the hosting organisation, must be specified in Annex 1.

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral/fellowship programme — the average monthly allowance (over the duration of the programme) respects the above-mentioned minimum.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[110]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[111].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:

[110] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[111] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

  - be **employed full-time**

    This also means that a researcher can NOT benefit from two MSCA grants at the same time.

  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities.

  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency

- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[112].

- for doctoral programmes: the beneficiary/partner organisation must:

  - ensure **gender balance** regarding the recruited researchers

  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career development plan.

[112] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas, documents relating to selection procedure)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the minimum remuneration was paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

A beneficiary that throws supporting documents away during the retention period bears the full risk of rejection by the Agency.

Specific case (record-keeping):

Documents for a programme implemented by a partner organisation — For a programme implemented by a partner organisation, it is the beneficiary that must keep the documents also for the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit:

- a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** of the start of the research training activities of the researcher.

> It is important to give correct and complete information in the researcher declaration since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

2. No deliverable: Mid-term review meeting

For MSCA-COFUND, the Agency will organise a mid-term review meeting to monitor implementation of the action in the light of the schedule in Annex 1. The mid-term review is therefore not a deliverable, as in other types of MSCA grants.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,*

addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA SME Ph1 deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 MGA SME Ph 2 deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 MGA SME Ph1, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 MGA SME Ph1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 funds:

- the feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: 'Innovation in SMEs' (*e.g. H2020-SMEINST-01-2016-2017*).

For more information on SME Instrument Ph1 actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph 1 MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70% of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph 1 MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Decision C(2013) 8198[113].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

[113] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to grant *reduction*). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the feasibility study (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A. 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Decision C(2013) 8198[114] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[114] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to grant *reduction*, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs of purchases and subcontracts are **ALL covered** by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12 H2020 General MGA) and **linked third parties** (Article 14 H2020 General MGA) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[115] or 2009/81/EC and the national legislation implementing them.

Moreover, the obligations in Article 10.1 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[115] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[116] or 2009/81/EC and the national legislation implementing them.

[116] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Finally, the obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The Agency may disclose confidential information also to its staff, other EU institutions and bodies.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency and Commission responsibility — Agency and the Commission right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (beneficiaries) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submiting the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submiting to the Agency in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the Agency will formally notify the beneficiary of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a **recovery**, the Agency will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT grant *reduction*; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

Cost rejections will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide required information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Partner termination (beneficiaries)

The rules on partner termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. GA or beneficiary termination (Agency)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The request for amendment (which the coordinator must send 60 days after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 MGA SME Ph2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of the Horizon 2020 Framework Programme: 'Innovation in SMEs' (*e.g. H2020-SMEINST-05-2016-2017)*.

For more information on SME Instrument Ph2 actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **if the beneficiary is a natural person** not receiving a salary (see Article 6.2, points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific costs category(ies)**: not applicable.

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the Main Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are by definition NO non-profit legal entities, they can NOT declare additional remuneration (under budget category A. 'personnel costs'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

***[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules [...]*[11]*.]*

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement." **]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries*[12] *and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[24]*.**]***

***[OPTION 2 only for actions involving PCP:** Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*

- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).]*

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[11] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[12] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[13] See Articles 28 and 31(2)(a) of Directive 2004/18 replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Participant Portal messaging function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage)

OR

- refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the 'simplified approval procedure: there is' NO assessment (and the beneficiary therefore bears the **full risk**).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as for the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be adapted to reflect the action duration. Thus, if considered necessary, SME Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 MGA ERA-NET Cofund deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 MGA ERA-NET Cofund: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],* ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

Annex 7 Model for the commitment on availability of funds

Annex 8 Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

ERA-NET Cofund uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities participating financially to the joint call for proposals MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8*).

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. FETPROACT-02-2017; SC5-33-2017)*.

For more information on ERA-NET Cofund actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action**: [insert date]]*[7] ('starting date of the action').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). Normally, the duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs.

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment, to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

2. Reimbursement rate

How much? For ERA-NET Cofund, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - direct costs of providing **financial support**
  - direct **personnel** costs for implementing the trans-national projects (— unless declared as unit cost, *see below*)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects
- **unit costs** for:
  - direct personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)
  - direct **coordination costs** for additional activities[117]
- **flat-rate costs** for:
  - **indirect costs**.

[117] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.2.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION 1 by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Costs for trans-national projects (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as direct costs related to trans-national projects:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment
    - other goods and services
    - costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc.) or for additional coordination and networking activities of beneficiaries implementing trans-national project themselves. Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs must normally be **declared as** actual costs *(see Article 5.2(b))*.

Direct personnel costs may also be declared as unit cost in accordance with the usual cost accounting practices (average personnel costs).

1.3 In principle, the same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the **following specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities

Direct coordination costs for additional activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Additional coordination costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the direct costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared** on the basis of the unit cost fixed by Decision C(2013) 8200[118] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the **additional coordination activities** described in Annex 1.

Costs for additional coordination activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare any additional coordination costs.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[118] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (C.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing to the joint call for proposals can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action).

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is ONLY allowed for beneficiaries/linked third parties that **implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be **trans-national projects**, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.2a);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients (third parties) that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Trans-national projects

The projects must be trans-national (i.e. they must involve at least two independent entities from two different EU Member States or H2020 associated countries), both in case of:

- financial support to third parties and
- implementation of the projects by the beneficiaries themselves.

3. Additional cost eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and

- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

4. Additional cost eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

5. Additional cost eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection (**joint selection list**) on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

6. Additional cost eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

7. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION 1 by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

> ***Example:*** *data on each participant and abstracts of the proposals*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

> ***Example:*** *data on each participant and an overview of the results*

How? The information must be uploaded directly in the Participant Portal

2. Deliverable: Information on cumulative expenditure incurred

What & When? The coordinator must submit to the Commission/Agency — on a yearly basis — information on the cumulative expenditure incurred by the consortium

How? In practice, this mandatory declaration for ERA-NET Cofund *(see Article 20.5)* is handled as deliverable and must be uploaded directly in the Participant Portal.

It does NOT need to be set out in Annex 1 (since legally speaking the obligation is not based on Article 19 but on Article 20.5).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.2a Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.3 Request for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4), from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are 3 pre-financing payments, also after the second reporting period) — a **periodic technical report**, with information on the technical implementation.

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 8*).

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)

- ranking list of the projects
- observer report on the evaluation
- joint selection list
- commitment on availability of funds (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8).

At the end of the action, the coordinator has to submit a **final report**, with both the technical and financial report.

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

ERA-NET Cofund actions are normally divided into 2 reporting periods with 2 pre-financing payments (or exceptionally 3 reporting periods with 3 pre-financing payments, if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

The declaration is normally handled as deliverable *(see Article 19)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

ERA-NET Cofund actions normally are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because the Commission/Agency does not have sufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since ERA-NET Cofund pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Amount of pre-financing payments

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- for the first pre-financing payment: between 10% and 30 % of the maximum grant amount
- for the second pre-financing payment: between 60 % and 80% of the maximum grant amount.

If the GA provides for a 3 pre-financing payments, then the amount is divided as follows:

- 30 % for the first pre-financing payment
- 30 % for the second pre-financing payment
- 30 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP-PPI MGA

VI.1 Background information and approach

The PCP-PPI Model Grant Agreement is used for PCP-PPI actions only.

The PCP-PPI MGA follows the General MGA for numbering and content, except for:

The H2020 MGA PCP-PPI deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI specific payment provisions)
- Article 23 (PCP-PPI specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 *[Model for the PCP prior information notice (PIN) for the open market consultation][Model for the PPI prior information notice (PIN) for an open market consultation]*
- Annex 8 Model for the PCP contract notice
- Annex 9 *[Model for the PCP request for tenders] [Model for the PPI request for tenders]*
- Annex 10 Model for the PCP contract award notice
- Annex 11 Model for the commitment on availability of resources
- Annex 12 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP-PPI actions are added:

- Article 2 (PCP-PPI actions)
- Article 4.1 (PCP-PPI budget categories)
- Article 8 (PCP-PPI rules on third party involvement).

VI.2 H2020 MGA PCP-PPI: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],* ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

Annex 7 Model for the commitment on availability of funds

Annex 8 Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

PCP-PPI uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities contributing financially to the joint procurement budget MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8)*. They form the buyers group.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. PCP/PPI actions

What? PCP/PPI funds:

- a joint public procurement of research and development (R&D) services (PCP) or innovative solutions (PPI)

AND

- related additional coordination and networking activities.

Only one PCP or PPI per GA.

The additional activities must relate to the joint call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP-PPI grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

PCP-PPI actions are funded in all Parts of the Horizon 2020 Framework Programme *(e.g. SEC-09-FCT-2017)*.

For more information on PCP/PPI actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP-PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP-PPI MGA uses its **own budget categories**.

Budget categories of the PCP-PPI MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare PCP/PPI subcontracting costs. Who actually pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP-PPI MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **[…%]** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION 1 for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2a*[13] ***(unit costs).]***

[OPTION 2: specific cost category(ies): *not applicable.**]***

[…]

8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
13 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The PCP-PPI, normally uses the same reimbursement rates as the General MGA (**100%** for research and innovation actions (RIA) and **70% or 100%** for innovation actions (IA) actions; *see Article 5 H2020 General MGA*), unless the call provides exceptionally for another rate.

2. Cost forms

The PCP-PPI MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The PCP-PPI MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. PCP/PPI subcontracting costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP-PPI actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **PCP/PPI subcontracting** described in Annex 1
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[14]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[15] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of annual productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or option (iii) above, i.e.:

-fixed number of hours;

-standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for during each full financial year;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[16]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[17] ***[OPTION 1 by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[18]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]* ***[OPTION 2****: not applicable****]****.*

Beneficiaries receiving an operating grant[19] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

B.5 ***[OPTION 1: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION *1a* ***for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *[****Insert name of specific cost category***[20] *] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units, [and if [insert additional eligibility conditions, if any]].****]***

[*same for each specific cost category****]***

[OPTION 2: *Not applicable****]***

[…]

14 This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

15 For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

16 To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

17 '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

18 For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

19 For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

20 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Additional coordination and networking costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as costs for additional coordination and networking activities related to the joint call for tender:

- direct personnel costs for additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for additional coordination and networking activities
- other direct costs for additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs must normally be **declared as** actual costs.

Direct personnel costs may also be declared as unit cost in accordance with the usual cost accounting practices (average personnel costs).

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary MUST be declared on the basis of the unit cost fixed by Decision C(2013) 8197[119] and set out in Annex 2 and 2a of the GA.

This concerns only *beneficiaries* that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI MGA has however the **following specificities**:

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the joint call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

1. *The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.*

[119] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

2. Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).

3. Costs for validation and testing of solutions provided by the subcontractors.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the Main Work Programme, the costs of additional coordination and networking activities are eligible up to a maximum amount of 30% (for PCP)/50% (for PPI) of the total requested grant amount. For each GA, this ceiling is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP-PPI actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing financially to the joint procurement budget can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action). They form the buyers group.

Certain **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12)) are however ONLY allowed for **additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, **subcontracting** (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities.

Linked third parties (Article 14) may participate in all activities under the action.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION 1 for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('****place of performance obligation****').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[26];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[26] See Article 16(f) of Directive 2004/18/EC replaced by Article 14 of Directive 2014/24/EU, and Article 24(e) of Directive 2004/17/EC replaced by Article 32 of Directive 2014/25/EU..

1. PCP subcontracting

In PCP actions, the beneficiaries award PCP subcontracts for research and development services that are necessary to address a common challenge set out in Annex 1 (PCP R&D services). 'PCP

subcontract' thus means a contract for the purchase of R&D services (identified in Annex 1 as action task).

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries and linked third parties (buyers group), with a joint procurement in 3 phases

  The **buyers group** is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[120])

    Any entity that fits the definition of a contracting authority or contracting entity as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI actions.*

  – that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the Main Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the Main Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

[120] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in **3 phases**.

The buyers group must select multiple competing subcontractors (with a minimum of 3 subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum 2 subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a **common challenge** (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

  The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

  If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

  The procurement must be for an R&D services contract (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

  If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

  Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

  This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[121]).

  Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement (**common jointly-committed budget**)

  This budget is based on the financial commitments of the beneficiaries and linked third parties in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary (**lead procurer**)

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is NOT part of the buyers group).

[121] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[122].

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors (PCP implementation)
- **Subcontractors** are **paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP actions).

There can only be one PCP per PCP action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PCP subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

[122] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

3. Additional cost eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 and phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*
  - the procurement must be preceded by an **open market consultation**

This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[123].

A prior information notice (PIN) must be published in the Official Journal of European Union (OJEU) and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

- the procurement must be based on **common procurement specifications** prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more information on the tender documents, *see the Guidance — How to complete your simap forms for PCPs and the template for PCP request for tenders.*

The template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions laid down in the grant agreement and it contains at least the information detailed in the template.

5. Additional cost eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase

[123] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
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Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontractors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries (place of performance obligation)
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions and without the right to sub-licence

    This right serves as a safeguard to ensure a competitive supply chain (during or after the PCP action) in case of problems. It does NOT mean that every subcontractor will always and automatically be obliged to grant non-exclusive licenses to third parties to exploit its results.

    Examples (licences needed): *other providers working for the buyers group need access to the IPR to work for the buyers group; a PCP subcontractor abuses its monopoly situation*

  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*

    This right serves as a safeguard to ensure commercial exploitation in the public interest, in case the subcontractors fail to do so themselves. It will be for exceptional cases.
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2014/24/EU, 2014/25/EU[124] and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[125]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[126]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[124] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[125] *See Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.*

[126] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

[OPTION 2 for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint procurement procedure by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and, 2004/17/EC (or 2014/25/EU).

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint PPI procurement ('**joint procurement agreement**');*

*(ii) **[OPTION 1 for PPI actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION 2:** not applicable**]

PPI

(iii) *prepare **common tender specifications**, based on the needs analysis of the buyers group;*

(b) *For the '**procurement/tendering stage**':*

[OPTION 1 for PPI actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP action:

(i) ***Step 1**: make a '**contract notice**', which:*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the tender documentation and the 'PPI request for tenders';*

*and the **tender documentation** and **PPI request for tenders**.*

(ii) ***Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

(iii) ***Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

(iv) ***Step 4**: make a '**contract award notice**', which is published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION 2 for PPI actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

(i) ***Step 1**: make a **request for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25//EU)[271] —:*

- *uses technical specifications that are functional or performance based;*
- *avoids selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specifies award criteria based on best value for money*

- *describes the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describes the arrangements for intellectual property rights*
- *describes the arrangements for liability for damages;*

(iv) ***Step 2:*** *make an* ***evaluation of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2.*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24/EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

1. PPI subcontracting

For PPI actions, beneficiaries award PPI subcontracts for procuring the innovative solutions that are necessary to address the common challenge set out in Annex 1 (PPI innovative solution(s)). 'PPI subcontract' thus means a contract for the purchase of innovative solutions (identified in Annex 1 as an action task).

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the **following specificities**:

There is no requirement to split the PPI procurement procedure in phases.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer (early adopter) of innovative solutions that are not yet available on a large-scale commercial basis.

> PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.
>
> Each PPI action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them jointly (i.e. the core functionality and performance characteristics must be the same; there may be additional local functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement (**common jointly-committed budget**) only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

> The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).
>
> The buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts.
>
> If there is no mandate, the general rule is that:
>
> - framework agreement(s) must be signed by all members of the buyers group together
> - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI actions).

There can be only one PPI, per PPI action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PPI subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an **open market consultation** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[127].

    A prior information notice (PIN) must be published in the Official Journal of the European Union and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

    The PIN must contain information on:

    - the expected launch date for the call for tender

[127] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

  - whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP action) is sufficient.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional cost eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments

  - an exclusion of contract renegotiations

- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:

  - implementation of the innovative solutions in accordance with the objectives of the action

  - additional national requirements, ethical and/or security requirements (if applicable)

- the arrangements for intellectual property rights (IPRs), in particular:

  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions *(e.g. regarding access to background, licensing etc.)* if these:

    - do not conflict with their obligations under other Articles and

    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results

- the right of the buyers to publish:

  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)

  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)

- the specific conditions for each buyer, in particular:

  - details of the innovative solutions purchased by each buyer

  - quantity and

  - price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties).*

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2014/24/EU, 2014/25/EU[128] and 2009/81/EC normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2014/24/EU and 2014/25/EU[129]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[128] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[129] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU*(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[28]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24//EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
    - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
    - **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
    - ***[OPTION for PCP: an assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP)****]****;*
- ***[OPTION 1 by default (two pre-financing payments):*** *the coordinator must submit in month [**Y**] a progress report containing:*
    - *a '**periodic summary technical report**' for publication by the [Commission][Agency];*
    - *an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **<u>information on each subcontract financed by the procurement</u>**, including data on each contractor that participated in the procurement, and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[**OPTION 1 for PCP:** at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[**OPTION 2 for PPI:** at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What? For PCP-PPI actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency:

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (together with data on each contractor that participated in the procurement and overview of the results).

How? The information must be uploaded directly in the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[38]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[39]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.2a <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities[.][;]

[OPTION 1 for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION 2 for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment**, including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.3 Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2).

[…]

[38] Month X should be the end of the preparation phase and submission of second pre-financing request.
[39] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP-PPI actions, the coordinator has to submit — after the first reporting period (and, if there are 3 pre-financing payments, also after the second reporting period) — a **periodic technical report** with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 7*)

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- call for tender documents (including contract notice, invitation to tender and procurement contracts)
- report on outcome of the preparation phase *(e.g. open market consultation)*
- commitment on availability of funds (Annex 7)

  This ensures that the PCP/PPI subcontracting costs are covered.
- statement on the use of the previous pre-financing instalment (Annex 8)

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

How?

Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

Normally, PCP-PPI actions are divided into 2 reporting periods (with 2 pre-financing payments; *see Article 21*). The first reporting period corresponds to the preparation of the joint procurement; the second reporting period corresponds to the implementation and follow-up of the joint procurement.

Actions will exceptionally be divided into 3 reporting periods (with 3 pre-financing payments), if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP-PPI actions are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since PCP-PPI pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Amount of pre-financing payments

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for PCP-PPI actions are as follows:

- for the first pre-financing payment: the percentage of the maximum grant amount foreseen for the additional networking and coordination activities related to the preparation of the call for tender
- for the second pre-financing payment: a maximum of 90% (general limit for pre-financing payments; *see Article 21.2 H2020 General MGA*) minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP-PPI actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 MGA EJP Cofund deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing payment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 MGA EJP Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of the H2020 Framework Programme and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General work programmes and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[7] ('**starting date of the action**').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). The duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

For the FEJP action, there are moreover 3 additional specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Thus, the EJP Cofund MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);**][OPTION 2**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1 **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] ***(unit costs).]***

[OPTION 2: specific cost category(ies)**: not applicable.**]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.
14 Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[130].

2. Cost forms

For EJP Cofund actions, the **cost forms** are in principle the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however 3 specific unit costs for category F. 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [131]

[130] *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*
[131] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION 1 to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION 2:* *not applicable*;]**
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[16]***]][OPTION 2: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[16] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, EJP grants have the **following specificities**:

- for category A. 'personnel costs'

  Costs of students, PhDs and other researchers (under scholarship, internship or similar agreement or under employment contract) — Are eligible even if the agreement is training-oriented (or work-oriented but with a non-negligeable training component), the costs fulfil the eligibility conditions set out in Article 6 and Annex 1 explicitly includes the training activities.

- for category D.2 'equipment costs'

  There is a special cost category for the FEJP action: full purchase cost for JET equipment *(see below)*.

- for category F. 'specific cost categories'

  There are special cost categories for the FEJP action: specific cost categories *(see below)*.

The annotations below will be limited to these special cost categories for the FEJP action (and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated).

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme**[18]**:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** under category D.2 'equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional** cost eligibility **conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. *[OPTION 1: [Insert name of specific cost category(ies)]][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]*

[OPTION 1a for specific unit costs (if unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[22]] *are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION 2: *not applicable****]***

[…]

[22] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the Fusion programme EJP Cofund action (FEJP), there are however 3 additional specific cost categories set out in Decision C(2013) 8201[132] available:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

⚠ **Double funding risk —** Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 Specific cost category – costs for mobility of personnel (F.2)

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment, by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance.

[132] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party, but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. category A. 'personnel costs' or D.3 'other goods and services'; *see Article 6.2.A, 6.2.D.3*).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8201[133] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[134]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1

[133] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[134] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

Germany Munich	106.4	Sweden	131.9
Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) are applied as from 1 January 2016:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	105.9	Italy	99.4
Bulgaria	52.1	*Italy Varese*	92.2
Croatia	74.6	Latvia	74.2
Cyprus	77.3	Lithuania	69.0
Czech Rep.	73.4	Malta	84.5
Denmark	131.8	Netherlands	107.8
Estonia	78.0	Poland	71.8
Finland	119.7	Portugal	79.2
France	114.6	Romania	64.8
Germany	96.6	Slovakia	76.4
Germany Bonn	93.4	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.0	Sweden	131.9
Greece	79.9	*Switzerland*	142.4
Hungary	69.0		
Ireland	116.6	United Kingdom	166.9
		UK Culham	127.7

– for the monthly subsistence allowance: between **EUR 0 and 720.27**, per individual per month — depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)

0 – 150	**0**
> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1 300	**601.73**
> 2 000	**720.27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 252.81**, per dependent child per month).

The European Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this event, the FEJP GA will be amended and the Annotated MGA will be revised accordingly.

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. category D.1 'travel'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and
  - one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
    - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

- the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment
- to this amount, add the following for each leg of the journey (outward and return):
  - for train travel: a maximum of 30 minutes for each leg
  - for air travel: a maximum of 2 hours for each leg.

  NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

- for the monthly subsistence allowance:

  amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

- for the family allowance:

  amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

  The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

  '**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

  A full month can be one of the following two:

  - a **calendar month** *(e.g. 1 to 31 July inclusive)* or
  - a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

  If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*

*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*

Subtotal = EUR 85 697.25

** correction coefficient (2016) of 106.0 % (Germany Munich) = EUR 90 839.09*

*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*

Total declared unit costs: EUR 95 895.29

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*

** correction coefficient (2016) of 127.7% (Culham, UK) = EUR 489.03*
Total declared unit costs: EUR 489.03

1.2 Specific cost category – costs for fellowships for researchers (F.2)

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships, by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility.

What not? This budget category does not cover direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category E. 'indirect costs'; *see Article 6.2.E*).

1.2.2 The costs must be **declared** on the basis of the unit costs fixed by Decision C(2013) 8201[135] and set out in Annexes 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [136]:

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%

[135] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf
[136] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Finland	116.6 %	Slovenia	86.1 %
France	111.0 %	Slovakia	82.6 %
Croatia	97.5 %	United Kingdom	120.3 %
Hungary	76.2 %		
Ireland	113.5 %	Switzerland	113.1 %

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[137]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.
- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)
- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

[137] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 Specific cost category – access costs for research infrastructure (F.2)

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

> ⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4 H2020 General MGA)*. FEJP beneficiaries that that have obtained a positive ex-ante assessment may opt between declaring costs under:
>
> – category D.4 'capitalised and operating costs of large research infrastructure'
>
> or
>
> – category F.2 'access cost for research infrastructure'.

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, under category 'travel'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be declared on the basis of the **unit cost** calculated in accordance with Decision C(2013) 8201[138] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{139})}{\text{average annual total quantity of access (over past two years}^{140})}$$

The averages must be based on:

– the beneficiary's certified or auditable historical data

[138] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[139] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[140] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 of the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users

    Exceptionally, these costs may be those calculated in accordance with the beneficiary's usual cost accounting practices (average personnel costs).
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

As already mentioned above, access costs for installations contributed in-kind must be declared as actual costs under another budget category (i.e. category 'other goods and services'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What?

For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission/Agency (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How?

The annual work plan must be uploaded directly in the Participant Portal.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the explanation of the work carried out and the overview of the progress; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION 1 in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing payment****' (see Annex 8).****]***

[OPTION 2: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **5** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing payment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a statement on the use of the first pre-financing payment *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a *[first]* **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a *[first]* pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION 1 in case of a single pre-financing payment:*** *5%]****[OPTION 2 in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU budget credits)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)). Framework partnerships are currently not (yet) open to ERANET, PCP-PPI, EJP, ERC, MSCA or SME Instrument specific actions.

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement).

For more information on framework partnerships, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name** (**short name**)], established in [official address in full] ***[OPTION for partners with VAT**: VAT number [insert number],] [**OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding (see Article 14),]* represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] (**short name**)], established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number],]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not receiving EU funding (see Article 14),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the framework partnership under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Participants: Coordinator — Partners — Linked third parties — Third parties involved in the action

In FPAs and SGAs the beneficiaries are called '**partners**' (because technically speaking they become beneficiaries only once an SGA is signed).

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. However, partners/linked third parties that do not want to actively participate in a specific action, may participate as **partners not carrying out action tasks** and will not have to comply with most of the obligations under that SGA *(see Preamble SGA).*

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed directly in Participant Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION 1 by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION 2 if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across partners of different framework partnerships]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and the Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all areas of the Horizon 2020 Framework Programme.

Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2);* Framework partnerships are currently NOT (yet) open to ERANET, PCP-PPI, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

  Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

  Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 Rules of Application Regulation No 1268/2012).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA.

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Framework partnership duration

The framework partnership duration may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Framework Programme)*.

The FPA duration can NOT be extended (i.e. it is not possible to request an amendment extending the duration). The duration of an FPA only determines the moment up to which SGAs can be signed. The SGAs can still be implemented after the end of the framework partnership.

All SGAs must be signed before the end of the FPA.

⚠ Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA has ended.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

[OPTION 2:** Not applicable**]

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — **specific consortium agreements for each SGA**. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the framework partnership implementation is suspended, all specific actions are also suspended (see Article 55) — from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to GA suspension *(see Article 49 H2020 General MGA)*.

FPA suspension automatically supends all on-going specific actions.

Amendments (to resume the action) after a suspension can NOT have the effect of extending the FPA duration set out in Article 3 FPA.). The duration of an FPA only determines the moment up to which SGAs can be signed An SGA can be implemented *after* the end of the framework partnership.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. FPA termination

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ FPA termination has NO effect on ongoing SGAs (— unless they are also terminated; *see Article 56 FPA and Article 20 SGA*). Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA is terminated.

2. Partner termination

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ **Different partners at FPA and SGA level (exceptional)** — Partner termination will exceptionally lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners/linked third parties can participate as partners not carrying out action tasks for certain specific actions.

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also shows the estimated costs of the partners not receiving EU funding, if applicable (see Article 7 SGA)

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and* ***forms of costs*** *of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions, applicable per budget category, are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **eligibility conditions** and **calculation rules**.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, eligibility conditions and calculation rules of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

Linked third parties must already be identified in the FPA *(see Article 19 FPA)*. Their specific activities must then be set out in the specific actions.

Examples:

1. *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

2. *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

Linked third parties — Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like the partner they are linked to.

Linked third parties can NOT however do more than their partners: If a linked third party wants to participate in a specific action, its partner must also be active in that action (i.e. NOT be partner not carrying out action tasks). If the partner does not want to, the linked third party could itself become a partner of the FPA and SGA (— after the consortium composition is changed).

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the Agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the Agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must first submit a request for the FPA amendment (which will automatically include the change in the consortium composition for the SGAs — the new beneficiary is added (automatically) as 'inactive' to all signed SGAs under that FPA).

The coordinator must then request for each SGA a separate amendment to activate the new beneficiary *(e.g. to change Annex 1, Annex 2)*.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name** (**short name**)],established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number]], [**OPTION for coordinators not receiving EU funding:** as 'partner not receiving EU funding' (see Article 7),]* represented for the purposes of signing the Specific Agreement by [function, forename and surname],

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 FPA and Article 62 FPA):

2. [**full official name**] (**short name**)], established in[official address in full], ***[OPTION FOR partners with VAT:** VAT number [insert number]],*

***[OPTION for partners not carrying out action tasks under this SGA:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not carrying out action tasks',]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT :** VAT number [insert number]], as 'partner not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 5)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Additional information on the estimated budget

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[OPTION if the JRC participates: *Annex 5: Administrative Arrangement]*

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Partners — Partners not carrying out action tasks under the SGA — Linked third parties

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

⚠ **Same partners at FPA and SGA level** — Partners must generally be the same at FPA and SGA level. An entity that is not partner/linked third party in the FPA cannot become party in the SGA. Conversely, all partners/linked third parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners (and linked third parties) who do NOT actively participate in a specific action are **partners not carrying out action tasks** under that Specific Agreement (and must be identified as such in the preamble to the SGA).

⚠ **Linked third parties —** If a partner participates as not carrying out action tasks, its **linked third parties** get the same status. They can NOT actively participate in the specific action (— unless they themselves become partners of the FPA and SGA).

These partners are formally part of the consortium for the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will be identified in Annex 1 as 'partners not carrying action tasks' (as they do not carry out any action tasks). Moreover, they will also be mentioned in Annex 2 with zero costs.

Some obligations *(e.g. IPR, checks reviews and audits and confidentiality)* may apply also for these partners. However, most of the other obligations concerning that SGA *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, etc.)* are NOT.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed directly in the Participant Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including **linked third parties**) are considered as '**third parties involved in the specific action**'.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

Same partners at FPA and SGA level — If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump sum MGA

IX.1 Background information and approach

The Lump sum Model Grant Agreement (H2020 MGA Lump sum) is used mainly for coordination and support actions (CSA) and, exceptionally, for research and innovation actions (RIA) and innovation actions (IA) — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5*

The MGA Lump sum follows the General MGA for numbering and content, except for:

The H2020 MGA Lump sum deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5, Annexes)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 MGA lump sum: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. CSA, RIA and IA lump sum actions

What? Lump sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for a lump sum grant.

For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

CSA, RIA and IA lump sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of the Horizon 2020 Framework Programme *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The MGA Lump sum does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the MGA Lump sum:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA): 70%** of the action's eligible costs]*[8] *[**OPTION 3 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The MGA Lump sum does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For Lump sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For Lump sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The MGA Lump sum has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the action (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A. 'costs' **covers** the (direct and indirect) costs for the action.

The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice the declaration of costs for Lump sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

Since the Lump sum grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

⚠ If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

The rules on third party involvement in lump sum actions are limited to purchases (Article 10), subcontracting (Article 13) and **linked third parties** (Article 14 H2020 General MGA).

The provisions on in-kind contributions (Articles 11 and 12 H2020 General MGA) do NOT apply — since, for Lump sum grants, in-kind contributions are not linked to any specific conditions. (Specific rules are only needed where a grant reimburses *actual* costs).

⚠ For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[9] (or 2014/24/EU)[10] or 'contracting entities' within the meaning of Directive 2004/17/EC[11] (or 2014/25/EU)[12] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).
[10] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).
[11] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).
[12] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for Lump sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for lump sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The MGA Lump sum has however the **following specificities**:

The estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[18]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For lump sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

Such records and supporting documentation must:

- refer to the scientific and technical implementation of the action in line with the accepted standards in the respective field *(see Article 18 General MGA)* and
- prove that the corresponding tasks or part of the action allocated to the beneficiary as described in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.2a Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a **'statement on the use of the previous pre-financing instalment',** including **the request for a further pre-financing payment** (Annex 7).

20.3. Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2 :*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

When & What? For lump sum actions, the coordinator has to submit — after each reporting period — a **periodic technical report**, with information on the technical implementation.

NO financial report is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; *see Article 7*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

At the end of the action, the coordinator has to submit a **final report** with both the technical and financial report.

2. Reporting periods

When? The lump sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- a *[first]* **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- *[same for more pre-financing payments]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2 if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments — No interim payments

Lump sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment(s)

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

> ⚠ The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.
>
> The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:
>
> – if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
>
> – if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.
>
> ***Example:***
>
> *Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.*
> *90% limit of the maximum grant amount: EUR 360 000.*
> *3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.*
> *Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.*
> *2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;*
> *3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;*
> *Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
> *70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
> *Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000*
> *3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.*

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation at the end of the action, and in particular:

– the amount of pre-financing(s) already paid *(see Article 21 H2020 General MGA)*

– cost rejections (improper implementation of the action; *see Article 42)*

– grant reduction (other serious breaches or substantial errors, irregularities or fraud *see Article 43)*.

ARTICLE 41 — BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Agency][Commission]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for lump sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs does not lead to a **recovery,** *[Commission][Agency]* will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since Lump sum grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1).* Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide requested information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since Lump sum grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION 2 :*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(c) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(d) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or]* ***[OPTION 2:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The lump sum multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant) the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide requested information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Article 43 and Article 44).

1. GA suspension (beneficiaries or Commission/Agency)

The rules on GA suspension are in principle the same as for the General MGA (see *Article 49 H2020 General MGA)*.

The lump sum MGA has, however, the **following specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable]*;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2).

(n) despite a specific request by the *[Commission][Agency],* the beneficiary does not request an amendment to the Agreement to end the participation of one of its linked third parties that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks.

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n)above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the [Commission][Agency]

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) despite a specific request by the *[Commission][Agency],* a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or to beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for actions under lump sum actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Partner termination (beneficiaries)

The rules on partner termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the lump sum multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. GA or beneficiary termination (Commission/Agency)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the multi-beneficiary MGA Lump sum has the **following specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

H2020 Programme

AGA – Annotated Model Grant Agreement

Version 4.1
26 October 2017

Disclaimer
This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the its executive Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	▪ Initial version following adoption of the grant agreement v.1.0. Article 6.
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement v.2.0, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSCA ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles
2.0	30.03.2015	▪ Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. ▪ Clickable cross-references (Articles) ▪ New table explaining the treatment of the different types of work contracts (under Article 6.2.A). ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. ▪ Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 ▪ Other minor corrections and clarifications
2.0.1	18.05.2015	▪ Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants

2.1	30.10.2015	▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47, 50, 55 and 56. ▪ New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses ▪ New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Phase 1: Article 5; – SME Instrument Phase 2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. ▪ Other minor corrections and clarifications.
2.1.1	01.07.2016	▪ Update of the explanations on Article 18 regarding time records; including a model of time-sheet with the minimum requirements.
2.2	25.11.2016	▪ Updates due to the amendment of the model grant agreement v.3.0, in particular Articles 4.2, 5, 6.2.A, 10, 13, 16, 20, 34, 37, 41, 42, 43, 45, 46, 48, 49, 50 and 55 ▪ New annotations on Articles 29.2 and 29.3. ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6, 6.1, 6.2, 6.5 and 18. ▪ Updates in the annotations to specific model grant agreements: - ERC: Preamble, Articles 6, 29 and 56a - MSCA: Preamble ITN, Articles 4, 5, 6, 8, 18, 19 and 32; IF Articles 2, 4, 6, 8, 18, 32 and 56a; RISE Articles 4, 6, 8, 18, 19, 31 and 32; COFUND Articles 4, 6, 8, 15 and 18. - ERA-NET Co-fund: Articles 2, 19 and 21 - PCP-PPI: Articles 5 and 13 - EJP Co-fund: Articles 5, 6.F and 20 ▪ Synchronised presentation for grounds for Chapter 6 measures, security obligations and information obligations. ▪ Other minor corrections and clarifications ▪ Update in Section I.3 'List of issues applicable to particular countries' New rules that apply in principle only for grant agreements signed with version 3.0 are marked with 3.0 » (This version refers to MGA v3.0 to align it no AGA v3.0 was created)
4.0	21.04.2017	▪ Updates due to the amendment of the model grant agreement v.4.0, in particular Articles 5, 6 and 52 ▪ New annotations on Article 14a following the introduction of this Article in the revised model grant agreements v.4.0 ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6 and 18. ▪ Updates in the annotations to specific model grant agreements: ERC, MSCA, PCP-PPI and FPA/SGA ▪ Other minor corrections and clarifications For easy identification, paragraphs, indents or sections with new explanations are marked with the symbol ■ on the left. New rules that apply in principle only for grant agreements signed with version 4.0 are marked with 4.0 »

4.0.1	20.06.2017	▪ Addition of index at the bottom of the pages
4.1	26.10.2017	▪ New explanations and examples, in particular in Articles, 6.2.F, 18, 50 and 55 of the general MGA ▪ Corrigendum of annotations on Article 6 of the MSCA-ITN, IF, Cofund and the MSCA-RISE grants ▪ Corrigendum of annotation on Article 6.2.F of the EJP Cofund grant ▪ Update in Section I.3 'List of issues applicable to particular countries' ▪ Other minor corrections and clarifications For easy identification, paragraphs, indents or sections with new explanations are marked with the symbol ■ on the left.

IMPORTANT NOTICE

The **AGA — Annotated Model Grant Agreement** is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement (General MGA) and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020 (H2020).

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and eligibility conditions of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

   New rules that do not apply to all signed grant agreements (but instead only to those signed after a certain version, e.g. version 3.0), will be marked with: 3.0 and 3.0

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the H2020 MGAs. For a more general overview of how H2020 grants work, see the Online Manual.

A comprehensive list of all H2020 reference documents (including legislation, work programme and templates) can be found on the Participant Portal Reference documents page.

H2020 terms are explained in the Participant Portal Glossary.

If necessary, you can also contact the Research Enquiry Service.

Legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1 'Health, Demographic Change and Wellbeing', etc.*

⚠ **Specific MGAs —** The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**] established in [official **address** in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full]* ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]* *as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

'**Beneficiaries**' means the legal entities who have signed the grant agreement (GA) with the Commission/Agency (i.e. participate in a project supported by an EU grant).

⚠ The term **participant** is used in this document in a wider meaning than in the definition of Article 1.1(15) of the Rules for Participation Regulation No 1290/2013. It covers normally beneficiaries and linked third parties (and sometimes also other third parties involved in the action).

The '**coordinator**' is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the

action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 (technical implementation) and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including **linked third parties**, subcontractors, third parties giving in-kind contributions, etc.) are considered as **third parties involved in the action** *(see Articles 8 and 9-14)*.

They are formally speaking not bound by the terms and conditions of the GA, although it implies certain obligations for them; conversely, the Commission/Agency has no formal contractual link with them.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries.

2. Name and address — Legal entity data

The legal entity data (legal name, address, legal representatives, etc.) of the beneficiaries comes from the Participant Portal Beneficiary Register.

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries (via their **legal entity appointed representative (LEAR)**) must keep their **data** in the Participant Portal up-to-date at all times including after the end of the grant (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[1]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[2]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[3].

[1] More information on the types of action can be found on the General Annexes to the Work Programme.

[2] For the definition, *see Article 2.1(6) of the Rules for Participation Regulation No 1290/2013:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[3] For the definition, *see Article 2.1(7) of the Rules for Participation Regulation No 1290/2013:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may

The term **action** comes from the Financial Regulation No 966/2012 and **means project**. (Previous EU Research Framework Programmes used project.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of Horizon 2020 *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

For more information on RIA, IA and CSA actions, *see the Online Manual and the H2020 grants fact sheets.*

2. Complementary grants

'Complementary grants' are different EU grants which are linked by the work programme/calls by identifying them as complementary actions.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written **collaboration agreement** regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a non-associated third country (i.e. a third country not associated to Horizon 2020) or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[4]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 of the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a **coordination agreement** *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

For guidance on coordination agreements, *see the Guidance — How to draw up your coordination agreement.*

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also include complementary activities of networking and coordination between programmes in different countries.

[4] *See Article 12 of the Rules for Participation Regulation No 1290/2013.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The action starting date is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example: *GA signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the action before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  The action starting date can **NEVER** be **before** the **submission** of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The action duration is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the ***action tasks*** (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as project closure or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*:* Moreover, *lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding and costs of international partners will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9 and Article 14a)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

⚠ Costs for personnel, equipment, goods or services that are in-kind contributions by a third party (for free or against payment) can in practice simply be added to the budget category they correspond to (i.e. personnel costs or other direct costs) — if they comply with the eligibility rules set out in Articles 6 and 11 and 12.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

Moreover, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories — without requesting an amendment *(see Article 55)* (unless Annex 1 must be changed).

⚠ The maximum grant amount *(see Article 5.1)* can however **NEVER** be **increased**.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example: *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that it did not set out **in its estimated budget** — except within the personnel costs category and to costs of internally invoiced goods and services (*Article 6.2.D.5*).

Example (allowed transfer): *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is acceptable without an amendment of the GA.*

Example (not allowed transfer): *A beneficiary budgets all its costs as 'actual costs' in the estimated budget. However, at the end of the first reporting period, the beneficiary wants to declare part of the costs by using a specific unit cost allowed in the call (e.g. unit cost for clinical studies). This is NOT possible without an amendment of the GA.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work ('action tasks') of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the 'simplified approval procedure' without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %*** *of the action's eligible costs]* ***[OPTION 2 for innovation actions (IA)***[7]***: 100%*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[8] *and* ***70%*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]* ***[OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA:*** *[…%] of the action's eligible costs]* ***[OPTION B for IA:*** *[…%] of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[9] *and […%] of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]]*** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[10]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[12]: ***[OPTION 1 to be used if Article 15 applies:*** *as actually incurred costs (**actual costs**);]* ***[OPTION 2****: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[13]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[14]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a[16] ('**unit costs**').]*

***[OPTION** 1b **for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION 2: specific cost category(ies):** not applicable.]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

10 To be used only if option in Point (f) is used.

11 To be used only if option in Point (f) is used.

12 To be used only if option in Point (f) is used.

13 To be used only if option in Point (f) is used.

14 To be used only if option in Point (f) is used.

15 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

16 Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount can **NEVER** be **increased** — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA and CSA actions is normally **100%** of the total *eligible* costs[5]; for IA actions it is normally **70%** of the total eligible costs[6].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[7].

5 *See Article 28(4) of the Rules for Participation Regulation No 1290/2013.*

6 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rate of a beneficiary does NOT condition the reimbursement rate of its linked third parties.

Example: *The beneficiary is entitled to 70 % but it has a linked third party entitled to 100 %. The linked third party will have a reimbursement rate of 100 % — despite the lower reimbursement rate of the beneficiary to which it is linked.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

⚠ The grant can **NEVER** reimburse **more** than the maximum grant amount fixed in Article 5.1.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[9]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - **personnel** costs (— unless declared as unit cost; *see below*)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs** (— unless declared as unit cost; *see below*)

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - personnel costs of **SME owners/natural persons** not receiving a salary[10]
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)[11]
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices

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7 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

8 *See Article 28(6) of the Rules for Participation Regulation No 1290/2013.*

9 *See Articles 123, 124 of the Financial Regulation No 966/2012.*

10 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

11 *See Article 33(2) of the Rules for Participation Regulation No 1290/2013.*

- specific unit costs for:
  - costs for **energy efficiency measures** in buildings[12]
  - **access costs** for providing trans-national access to research infrastructure[13]
  - costs for **clinical studies**[14]
- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[15]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

Example: *EUR 150 000 to carry out a study within an action*

The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	Budget categories					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not	NO	NO	YES, only for: costs of internally invoice goods and services	NO	YES, only if foreseen by Commission Decision

[12] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[13] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

[14] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[15] *See Article 29(1) of the Rules for Participation Regulation No 1290/2013.*

	receiving a salary					
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the **errors, irregularities or fraud** or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of GA termination) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex 1

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 of the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

How to calculate the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — **Rejection of ineligible costs & application of the reimbursement rate(s)**

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions (IA), there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — **Limit to the maximum grant amount**

The contribution is limited to the maximum grant amount *(see Article 5.1)*.

Step 3 — **Reduction due to the no-profit rule & receipts**

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the *consolidated* receipts and the *consolidated* approved costs.

The **receipts** that must be taken into account are receipts that are:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation)

during the action duration (see Article 3).

The following **are** considered '**receipts**':

- income generated by the action (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped to the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action (i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for the action covered by the GA)

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs (i.e. not

money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

Examples: *the free use of equipment; the secondment of an expert without reimbursement*

Free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered '**receipts**':

- in-kind contributions given by a **third party (donor)** free of charge — if they were not given specifically to be used for the action

  Example: *A university professor whose costs are charged by the beneficiary university in the GA, but whose salary is paid by the ministry and not reimbursed by the university: This in-kind contribution from a third party (the ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions given by a third party (donor) specifically to be used for the action — if they may be used according to the donor's rules to cover costs *other* than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

- financial contributions made **by one beneficiary to another** within the same action — since receipts are only contributions from *third parties*

  Conversely, such a financial contribution cannot either be declared as cost for the action.

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

- income generated by exploiting the results of the project (*e.g. the IPR*) — since successfully exploiting the results is one of the main objectives of the action

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (i.e. the final payment at the end of the action). They must be declared in the final report.

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

Step 4 — **Reduction due to substantial errors, irregularities or fraud or serious breach of obligations**

What? Serious breach of obligations refers to (non-exhaustive list):

- improper implementation of the action
- submission of false information
- failure to provide required information
- breach of ethical principles.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1. Improper implementation may lead to a grant reduction (i.e. reduction of the 'maximum grant amount'; see Article 5.1) — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*).

Minor delays/deviations in the technical work foreseen in Annex 1 will not give rise to a grant reduction.

Example (reduction): *one of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A grant reduction is NOT a sanction, but the consequence of substantial errors, irregularities or fraud or serious breach of obligations under the GA.

Example for calculating the final grant amount:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project. The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).EUR EUR

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs: EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate: 100%

Amount obtained: EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts, over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to substantial errors, irregularities or fraud or serious breach of obligations:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of Article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Step 1,2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000.*

***Final grant amount**: EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, substantial errors, irregularities or fraud or serious breach of obligations (and therefore **rejects the costs** and/or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level).

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:
Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of the balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of the balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a **recovery** *(see Article 44.1.3)*.

For **reduction of the grant**:

– the Commission/Agency will reduce the maximum grant amount set out in Article 5.1, in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations *(see Article 43)*.

– calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations to its improper implementation or breach of obligation

Example:

Maximum grant amount and final grant amount: 500 000.

There are three Beneficiaries A, B and C.

Reimbursement rate: 100%.

According to the estimated budget, beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex 1.

Total eligible costs accepted for Beneficiary A at the payment of balance: 187 500

1a: *The Commission finds that beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of beneficiary A: 80% of the share of beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000.

1b: *The Commission/Agency finds that beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to beneficiary A: 100% of the reduction is allocated to beneficiary A.

Revised final grant amount of beneficiary A: 187 500 – 10 000= 177 500.

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a **recovery** *(see Article 44.1.3)*.

For **rejection of costs AND reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above (i.e. after cost rejection or after grant reduction).

Example: *The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amount following the reduction of the grant in the 2 examples above).*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only** reimburse **eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Article 6.1 refers to general eligibility conditions, applicable per cost form *(see Article 5)*.

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action (or after GA termination) are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

  ⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  Examples:

  1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

  2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

3. *Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible, if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements (CFS) required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

Personnel costs for ERA chairs — Are eligible even if the salary is above national salaries, provided that it does not go beyond normal EU/international salaries for similar positions (since the ERA chairs aim to incentivise international mobility for internationally outstanding researchers and research managers. When the level of remuneration of the ERA Chair is indicated in Annex 1, this will be duly taken into account in case of checks, audits or reviews.

Costs to allow for the participation of disabled people *(e.g. costs for sign language interpreters required for dissemination events organised under the action)* — May be eligible if they fulfil the general and specific eligibility conditions listed under Articles 6.1 and 6.2. The beneficiaries must keep records *(see Article 18)* to prove in case of an audit, check or review the actual costs incurred and that they were necessary for the implementation of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2a.*

- the **number of units** must be **necessary** for the action
- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

> ***Example:*** *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Costs declared on the basis of the usual accounting practices— For two budget categories (A. personnel costs and D.5 costs of internally invoiced goods and services), costs may be declared not as a fixed unit cost, but on the basis of the beneficiary's usual cost accounting practices. In this case,:

- the beneficiary:
  - must calculate the costs according to its usual accounting practices
  - must budget and declare a total amount (not the units used)
- the amount per unit is not fixed in Annex 2a.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency and set out in Annex 2a of the GA *(see Article 5.2)*.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump-sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and

- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION 1 for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]*][***OPTION 2:*** *not applicable*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to **specific eligibility** conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

– either costs that have been caused in full by the activities of the action

- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action can NOT be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a **25% fixed flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual** costs (i.e. budget categories A.1, A.2, A.3 [*and A.6*]): the hourly rate is calculated per full financial year, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories A.1, A.2, A.4, A.5 [*and A.6*]): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(iii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

1. Direct personnel costs (A.): Types of costs — Forms — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Employees (or equivalent) (A.1)

1.1.1 What? Personnel costs for employees or equivalent (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) that worked in the action.

⚠ '**Equivalent appointing act**' means the appointing acts of civil servants (who do not sign employment contracts but receive official nominations for their posts).

⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Reliable time records will normally be sufficient proof of the assignment to the action — unless there is other contradicting evidence *(e.g. the employment contract indicates that the person was hired to work on another project)*

It covers (and is limited to):

- **basic remuneration** (i.e. the payments for the employee's normal work and participation in projects — up to what is the beneficiary's usual remuneration practice for national projects)

and, in addition:

- for non-profit legal entities: **additional remuneration** (i.e. extra payments made for the participation in projects — above the beneficiary's usual remuneration practice for national projects).

⚠ **National projects** are to be understood in the large sense, meaning all types of projects funded under any type of national (public or private) funding scheme (including projects co-financed by EU funds that are managed by the Member States, *e.g. regional funds, agricultural and fisheries funds*).

Projects from EU programmes directly managed by the Commission/Agencies or their funding bodies *(e.g. LIFE, ERASMUS, Health, etc.)* do not, however, qualify as national projects (but as EU/international projects).

Both basic remuneration and additional remuneration do not only cover the payment itself (salary or bonus), but also the social security contributions *(mandatory employer and employee contributions)*, taxes included in the remuneration *(e.g. income tax)* and other costs and payments included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee).*

What not? Cost of persons who work for the beneficiary, but NOT with an employment contract or equivalent appointing act *(e.g. staff provided by a temporary work agency, seconded staff, self-employed persons with a direct contract with the beneficiary)*.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions *(e.g. best value for money and no conflict of interest; see Articles 10 and 13)*.

Seconded staff and **self-employed persons with a direct contract —** Can also be declared under other categories within the personnel costs *(see below, points 1.2 and 1.3)*.

1.1.2 Costs for employees (or equivalent) must be **declared** as:

- **actual personnel costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.1.3 The costs for employees (or equivalent) must comply with the following **eligibility conditions**:

- **For basic remuneration**:

  - fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

    Payments of dividends to employees (profit distribution) are NOT eligible under *Article 6.5(a)(i)*. However, bonuses based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted, if they fulfil the conditions set out below, i.e. as part of the usual remuneration practices for national projects and thus eligible as basic remuneration.

    Examples (positive):

    If the profit of the company at the end of the year is more that x € (or more than x %), each employee will receive a bonus of z % of his/her basic remuneration (or a fixed bonus of x € more as part of the gross salary).

    Examples (negative):

    If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.

    Any part of the remuneration which is based on commercial targets or fund raising targets is NOT eligible (because neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation).

    ***Examples**: x € for reaching a sales target; x % on sales; x € premium per externally funded project gained; x % of the external funding gained*

  - be paid in accordance with national law, the collective labour agreement and the employment contract/equivalent appointing act

    Examples:

    ***1.** The collective labour agreement establishes that all researchers may receive a bonus between EUR 100 and EUR 200 per month based on their seniority.*

    ***2.** The national law authorises public universities to pay a bonus based on merit of the employees.*

    ***3.** The contract fixes a premium of EUR 1000 for each research paper published in peer-reviewed international research journals.*

  - **exclude arbitrary bonuses** (i.e. bonuses which are not part of the beneficiary's usual remuneration practices and/or which are not based on objective conditions).

- **For additional remuneration** (in addition to the conditions above):

  - be a **non-profit legal entity**

  - be paid for the performance of **additional work** or **different expertise** than his/her usual tasks

    This is usually the case, since additional remuneration aims precisely to reimburse the additional work/expertise that is required for EU and international projects.

  - be **consistently applied** whenever the same kind of work or expertise is required and **regardless of the source of funding** used

    The additional remuneration may not differ according to *where* the funds come from. In particular, it cannot be set up for actions funded by a specific donor; additional remuneration schemes that are applicable only to EU projects are not acceptable.

    ***Example (not acceptable):** All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

    Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

However, the additional remuneration does not have to be the *same* for all persons working in the same project (provided that objective criteria are used to determine the differences).

⚠ **8000 EUR ceiling —** Additional remuneration is eligible **ONLY up to** a ceiling of **8000 EUR** annual costs; *see point 1.1.4*).

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Teleworking — Remuneration costs of personnel not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible, if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of quasi-financial benefits *(e.g. costs of lunch vouchers)* may be accepted as eligible, if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally NOT eligible as direct costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action, the related costs would be considered part of the entity's normal indirect costs, which are covered by the 25 % flat-rate.

Costs for students, PhDs and other researchers under scholarship, internship or similar agreements (not employees) — Costs of students that work for the beneficiary can be accepted, if the agreement is work-oriented (not training-oriented: i.e. not aimed at helping the student to acquire professional skills).

PhD agreements will be considered work-oriented. However, time for training, if any, may NOT be charged to the action.

Fellowships/scholarships/stipends — Can be charged to the action (as personnel costs), if they fulfil the conditions set out Article 6.1 and 6.2.A.2, and in particular:

- the remuneration complies with the application national law on taxes, labour and social security
- the assignment of tasks respects the laws in force in the country of the beneficiary
- the students have the necessary qualifications to carry out the tasks allocated to them under the action.

Cost for exemptions from academic fees — The fees (or part of them) are eligible as personnel cost, if the student's contract includes the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic remuneration only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible).

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts for participation in projects (whatever their form) are acceptable if it is the beneficiary's usual practice and compatible with national law. The remuneration will be qualified as basic or additional remuneration, depending on the scope (national OR

EU/international) and amount (above, equal or below usual remuneration practices for national projects).

1.1.4 The **costs** must be **calculated** as follows:

In general, personnel costs for H2020 actions are calculated (for each person assigned to the action, including persons working exclusively on the action) as follows:

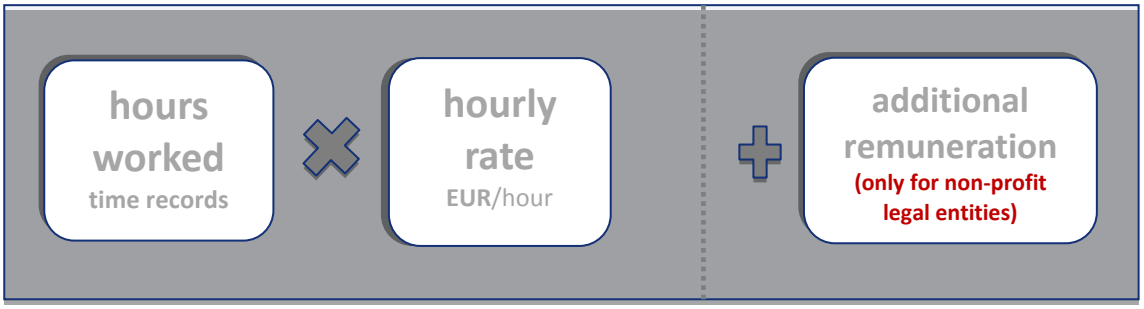

In practice, the calculation will differ (per type of beneficiary/employee) depending on the remuneration practices of the beneficiary:

Case 1: beneficiaries declaring personnel costs as actual costs

Case 1A: employee whose remuneration is not project-based (i.e. same remuneration, regardless if they are involved or not in specific projects)

Case 1B: employee whose remuneration is project-based (i.e. different remuneration levels, depending on whether they work in specific projects or not)

Examples:

1. *The beneficiary and the researcher sign a separate employment contract for the work of the person in the Horizon 2020 action. The hourly rate resulting from that additional employment contract is different from the hourly rate of the other employment contract of the person with the beneficiary.*

2.*The beneficiary has a remuneration scheme which includes the payment of a bonus for work in specific projects. The bonus is paid as part of the total salary of the person in addition to the basic salary and other general bonuses.*

3. *The employment contract of the person fixes a specific hourly rate to be paid for work in specific projects. This hourly rate replaces the standard salary of the person while it works in those projects.*

Case 2: beneficiaries declaring personnel costs as unit costs in accordance with the usual cost accounting practices (average personnel costs).

Additional remuneration is in practice an issue ONLY for case 1B beneficiaries. All other beneficiaries will automatically fall under 'basic remuneration only' and therefore are not concerned by the provisions on additional remuneration.

Case 1B beneficiaries need to differentiate between payments that are basic remuneration and payments that are additional remuneration. For them, the hourly rate charged to the action must be calculated using only basic remuneration (i.e. excluding any part that qualifies as additional remuneration). Additional remuneration may be charged (separately and on top), if the beneficiary is a non-profit entity, if that remuneration is eligible and only up to a ceiling of 8000 EUR per year.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ **Double ceiling —** Beneficiaries must ensure that:

- the **total number of hours** worked **declared** in EU and Euratom grants for a person for a year is NOT higher than the number of **annual productive hours** used for the calculation of the hourly rate *(see below)*
- the **total** amount of **personnel costs declared** (for reimbursement as actual costs) in EU and Euratom grants for a person for a year is NOT higher than the total personnel costs recorded in the **beneficiary's accounts** (for that person for that year).

How to calculate direct personnel costs for employees (or equivalent):

For case 1A beneficiaries (actual costs, not project-based remuneration): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary must calculate, for each employee, the hourly rate to be charged to the action by using one of the following methods:

- **per full financial year** (main method): single hourly rate for each person for each full financial year
- **per month** (alternative method): one hourly rate for each person for each month (i.e. 12 hourly rates per person for each financial year).

Each beneficiary may choose any of the two options. However, the option chosen must be applied during the full financial year to all its personnel in all H2020 grants. If the beneficiary wants to change option, it can do so for the next financial year (— again for all its personnel in all its H2020 grants).

⚠ **Recalculations & adjustments of financial statements (exceptional) —** To benefit from this new option (i.e. hourly rate per month) beneficiaries may apply it retroactively for all grants on-going (i.e. for which the final report has not been submitted) on 20 July 2016 (i.e. date of adoption of the H2020 MGA version 3.0). The beneficiary may re-calculate costs already declared on the basis the full financial year by using the monthly calculation method. However, in that case it must do the recalculation for ALL personnel costs declared for that/those financial year(s) in ALL on-going H2020 grants. The beneficiary must declare the differences, either positive or negative, as adjustments in the next reporting period.

⚠ The grant agreement **formulas for the hourly rates are mandatory**. Those formulas may lead to minor/temporary differences with the personnel cost recorded in the accounts. Those differences have no impact on the eligibility of the costs, provided that the formula has been correctly applied and that the *double ceiling* explained above has been respected.

Calculation of the hourly rate *per full financial year*

Annual hourly rates must be calculated as follows:

for each person:

{actual **annual personnel costs** for the person
divided by
number of **annual productive hours**}.

The rate must be calculated by ***full financial* year** (i.e. the 12-month period covered by the annual accounts of the entity).

Example: *When the financial year matches the **calendar year**, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

> ***Example:*** *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*
>
> *Calculation of the hourly rate:*
>
> *For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.*
>
> *For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.*
>
> *For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.*

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance with the GA is available. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate. The method must however be consistently applied and can NOT be changed within the same grant.

> ⚠ **No adjustments of financial statements —** Adjustments to the hourly rate are normally allowed ONLY for mistakes *(e.g. incorrect accounting information; error in the calculation; etc).*
>
> > ***Example:*** *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*
>
> Otherwise, costs that have already been declared can normally NOT be adjusted/changed (even if a recalculation of the hourly rate after the closure of the financial year would give another result).

The **annual personnel costs** may include only eligible personnel costs.

Any part of the remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 2:** the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option (1, 2 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed ad-hoc for specific employees)*.

The beneficiary must keep the same option(s) for *the full financial year*. It can only change its option(s) for the next financial year.

⚠ **Absences & overtime —**

Absences: the three options treat absences (leave) in different ways:

- under option 1 (1720 fixed): ONLY actual time spent on parental leave (maternity and parental leave) may be deducted from the 1720 fixed hours. NO other leave *(e.g. sick leave, special leave, annual leave, etc.)* can be deducted.
- under option 2 (individual): the beneficiary must deduct all leaves (i.e. *actual time* on sick leave, parental leave or special leave, etc.) to calculate the annual productive hours.

  ⚠ In order to calculate the annual workable hours, the beneficiary has to deduct the annual leave entitlement (see example in the *table of options*). However, if the employment contract allows end-of-year transfers for leave entitlements (i.e. the days not taken one year can be taken the next one; days not taken are not paid out), the beneficiary may opt for deducting instead *actual time* of annual leave (if this is done consistently throughout the years).
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard time of absence in the organisation. However, the beneficiary may deduct on top the actual time spent on parental leave (maternity and parental leave) by the individual employee.

Overtime: all three options include potential overtime in the annual productive hours, either implicitly (options 1 and 3) or explicitly (option 2):

- under option 1 (1720 fixed): NO overtime may be added to the 1720 fixed hours
- under option 2 (individual): all overtime worked (paid or unpaid) must be added to the annual workable hours to calculate the annual productive hours
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard overtime hours in the organisation (if any).

⚠ **No impact on the hours worked —** The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding hours worked can NOT be charged to the action (they must be capped at the ceilings).

Calculation of the hourly rate *per month*

Monthly hourly rates must be calculated as follows:

for each person:

{actual **monthly personnel costs**
divided by
{number of **annual productive hours/12**}**}**.

The rate must be calculated **for each month**.

The **monthly personnel costs** may include only eligible personnel costs.

If a part of the remuneration is generated over a period longer than a month *(e.g. the thirteenth salary)*, only the entitlement generated in the month can be included in the monthly personnel costs (— irrespectively of how much is actually paid in that month).

Example:

In accordance with the collective labour agreement, Ms T is entitled to a thirteenth salary (another full month salary in addition to her 12 monthly salaries) to be paid in July each year. The monthly salary of MS T is EUR 3 000.

The monthly personnel costs in July will be:

EUR 3 000 + {EUR 3 000 / 12} = 3 000 + 250 = EUR 3 250

The beneficiary can therefore NOT include the total of the thirteenth salary in the personnel costs for July, but must distribute it over the months in which it was generated (in this example 1/12 per month). Otherwise, the hours of July would be incorrectly priced at the double of the hours worked in normal months.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** If a later event *(e.g. the unexpected leave of the employee)* means that the payments made for the employee are actually lower (i.e. that the monthly hourly rates were overstated) the beneficiary must recalculate the hourly rates with the correct amount. If some of the related personnel costs were already declared, the beneficiary must declare the difference as adjustment in the next reporting period.

If the monthly entitlement of an extra salary is not known in advance *(for example for an annual merit pay whose amount is decided in December — if eligible as basic remuneration —)* the beneficiary cannot take into account the extra salary until the amount is known. It may therefore recalculate the hourly rates at that moment and, if needed, declare the difference as adjustment in the next reporting period.

For calculating the **annual productive hours**, the beneficiary must use one of the following two options *(see the table of options above for the details on each option)*:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ Option 2 can NOT be used for monthly hourly rates because the individual annual productive hours — and thus also the monthly hours, i.e. 1/12 of the annual — are known only at the end of the financial year. It would be therefore impossible to calculate the hourly rates at the end of each month.

In principle, the same option (1 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must keep the same option(s) *during the entire financial year*. It can only change its option(s) for the next financial year.

Absences & overtime —

The same rules on the treatment of absences and overtime apply as for annual hourly rates, except that time spent on parental leave can NOT be deducted from the annual productive hours.

However, beneficiaries may charge to the action the *costs* incurred for parental leave (as personnel costs) in proportion to the time the person worked for the action during the financial year (time worked on the action over total productive hours for the year). This must be done separately and on top of the personnel costs declared by multiplying the hours worked for the action by the monthly hourly rates.

Example:

In 2015 Ms T has been five months in parental leave. During that time the social security reimbursed to the beneficiary 50 % of her salary. Her monthly salary was EUR 3 000 (reimbursement EUR 1 500). The beneficiary used option 1 (fixed 1720 hours) for the annual productive hours and Ms T worked in 2015 320 hours on the H2020 action.

Personnel costs incurred during parental leave= {EUR 3 000 x 5} - {EUR 1 500 x 5} = 15 000 – 7 500 = EUR 7 500

(Note: amounts reimbursed to the beneficiary by the social security are not actual costs for it and, therefore, must be deducted)

Proportion of time worked for the action in 2015 = Time worked for the action / Total productive hours excluding the parental leave = 320 / {1720 - {1 720 x 5/12}} = 320 / {1 720 – 716,7} = 320 / 1 003,3 = 31,89 %

Cost of parental leave for the H2020 action = EUR 7 500 x 31,89 % = EUR 2 391,75

No impact on the hours worked — The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding hours worked can NOT be charged to the action (they must be capped at the ceilings). The ceilings apply per full financial year, not per month.

However, do not forget that your personnel costs must comply with national labour law.

Example:

If the national law provides for a prohibition for employees to work more than 48 hours per week, it is not possible to charge to the H2020 action 250 hours in a month for an employee.

Step 2 — **Multiplying the hourly rates by the hours worked on the action**

The hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

For case 1B beneficiaries (actual costs, project-based remuneration): 4 steps

Step 1 — **Checking the nature of the remuneration (basic or additional) for each employee)**

The beneficiary must first find out, for each employee, if the remuneration it is paying is all basic remuneration or contains also additional remuneration.

To do this, the beneficiary must calculate **two reference hourly rates**:

- reference rate for the work on the H2020 action ('**action reference**')

and

- reference rate for the usual remuneration practice for national projects ('**national projects reference**').

If the action reference is *equal or below* the national projects reference, the remuneration is all basic remuneration. If it is *higher*, the exceeding part is additional remuneration and must be taken out for the calculation of the hourly rate to be charged to the action.

Step 1a — **Calculation of the reference hourly rates**

For the **action reference**: the beneficiary must calculate an hourly rate (either *annual* or *monthly*) based on the remuneration paid to the employee for his/her work in the H2020 action.

For *annual* reference rates:

{annual personnel costs for the person for his/her work in the action

divided by

number of hours worked for the action in the financial year}.

If the reporting period ends before the end of the financial year, the beneficiary must use the personnel costs and the hours from the beginning of the year until the end of the reporting period.

For *monthly* reference rates:

{monthly personnel costs for the person for his/her work on the action

divided by

number of hours worked for the action in the month}.

For the **national projects reference**: the beneficiary must calculate an hourly rate based on either:

- regulatory requirements *(e.g. national law or collective labour agreements)* setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The national law establishes that the maximum monthly salary of engineers acceptable for national grants is EUR 4 000. Beneficiary A has paid that salary to its engineers while working in national grants. Beneficiary B has signed a collective labour agreement whereby the monthly salary to be paid for work under national grants is fixed at EUR 3 500. Beneficiary B has paid that salary to its engineers working in national grants.*

  Maximum amount acceptable as basic remuneration for beneficiary A = EUR 4 000/month for a person working full-time. If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

  Maximum amount acceptable as basic remuneration for beneficiary B = EUR 3 500/month for a person working full-time. If the remuneration of the person for the work in the H2020 action was more than this ceiling, the excess will qualify as additional remuneration.

- internal rules setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The internal rules of University Z provide that a professor working in externally-funded projects may get an extra salary of up to 50 % for the time its works for those projects. The maximum extra salary University Z has actually paid for work in national projects was 30 %.*

  Maximum amount acceptable as basic remuneration = salary of the person + 30 % (for the time worked in the H2020 action). If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

or

- if none of these are available or if the beneficiary never had any national projects before the submission of the H2020 proposal: the average remuneration of the employee in the previous financial year.

The hourly rate of the national project reference must be calculated using 1720 fixed annual productive hours (unless there is an hourly rate directly set in the law, collective labour agreement or internal rules).

For the average remuneration of the employee, the beneficiary must moreover exclude remuneration that came from H2020 actions; i.e.:

{total annual personnel costs* for the person for year n-1 excluding remuneration paid for work in H2020 actions

divided by

1720** minus hours worked in H2020 actions in year n-1}

* The total annual personnel costs include all remuneration paid by the beneficiary to the person for work, irrespectively of the tasks of the person and the projects for which the person was working; but excludes all remuneration paid for work in H2020 actions. If the remuneration included ineligible items *(e.g. profit distribution, arbitrary bonuses)* those must also be removed.

** 1720 is the fixed number of annual productive hours. The beneficiary must remove from those annual productive hours the hours worked in H2020 actions. If in year n-1 the person worked exclusively in H2020 actions, the beneficiary must use the average salary of the last year in which the person did not work exclusively in H2020 actions *(e.g. year n-2 or year n-3)*.

If the national law or the internal rules set up different levels of remuneration for different categories of staff, the reference will be the one of the category to which the person belongs.

If the national law or the internal rules set up different remuneration levels for different types of national projects (or for different work within the projects), the reference will be the one applicable to the type of project/work that is closest to the H2020 action.

Example: *The internal rules of University Z provide that a professor working in basic research projects will receive 10 % extra salary; while a professor working in applied research projects will receive 15 % extra salary. Both extra salaries are systematically paid also for projects funded by national schemes. The H2020 action is an innovation action. The reference that would apply in this case is the extra salary for applied research projects (15 %) as the type of project is closer to the H2020 innovation action than basic research projects.*

The beneficiary must keep appropriate and sufficient evidence to support the action and national project references used *(see Article 18)*.

Example: *If the beneficiary uses the internal rules it must keep documental evidence of the internal rules applied, the category of the person (if applicable), and the payslip and payment documents proving that such remuneration was paid at least once prior to the submission of the proposal.*

Step 1b — **Comparing the action reference with the national project reference**

If the action reference is *higher* than the national project reference, the exceeding part is additional remuneration:

{total additional remuneration = difference between the two reference rates * number of hours worked on the action}

{total basic remuneration = national project reference rate * number of hours worked on the action}

If the action reference is *equal or lower* than the national project reference, there is no additional remuneration; the remuneration paid to the employee is all basic remuneration.

Example personnel costs with additional remuneration (Part 1 of 3):

1. *Ms R is employed full-time as professor at University X. She has a basic annual gross salary of EUR 24 000. The internal rules of the university provide that professors involved in research projects financed by external funders can get up to EUR 6 000 per month of full dedication to the*

project. However, due to budgetary restrictions the maximum that has been paid to any professor in a national project was EUR 4 800. Ms R worked in 2017 for the H2020 action 200 hours. For those hours she received an extra salary of EUR 6 500. She also participated in other projects generating other extras for her. So, her total gross annual salary was EUR 36 000. The hourly rate for the H2020 action is as follows:

The salary of Ms R varies depending on her participation in certain projects. Therefore, the beneficiary must assess if any part of that salary qualifies as additional remuneration. For that, it must compare the action reference with the national project reference:

Action reference rate = basic salary corresponding to the 200 hours worked for the action ((24 000 / 1720) x 200 = 2 790,70 €) + bonus paid for the action (6 500 €) = 9 290,70 € / 200 (hours worked in the action) = 46,45 €/hour (hourly rate)

National project reference rate (in this example based on the internal rules of the university applicable to national projects) = maximum salary paid for any professor working in a national project in accordance with the internal rules = 4 800 € / (1720 annual productive hour / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

The Action reference (i.e. 46,45) is higher than the national project reference (i.e. 33,49). The excess (46,45 – 33,49 = 12,96 €/hour) qualifies as additional remuneration. Therefore:

The total basic remuneration = 33,49 €/hour x 200 (hours worked in the action) = 6 698 €

The total additional remuneration = 12,96 €/hour x 200 (hours worked in the action) = 2 592 €

(This example continues here for the calculation of the hourly rate)

***2.** Same situation as above, but in this case the work in the action has been done under a supplementary employment contract covering additional working hours (on top of the full-time contract of the professor).*

Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour

National project reference rate = 4 800 € / (1720 annual productive hour / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary is NOT paying additional remuneration.

The total basic remuneration = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 2 — **Calculation of the hourly rate (for each employee; on the basis of basic remuneration)**

The beneficiary must then calculate the hourly rate to be charged to the action for the employee:

- **If** there is **additional remuneration**, the beneficiary must calculate the hourly rate using only the basic remuneration. In practice, this will be the action reference, capped at the national project reference (i.e. the hourly rate will normally be equal to the national project reference rate).

  Example personnel costs with additional remuneration (Part 2 of 3):

  ***1.** Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of 9 290,70 €. In the calculations made in part 1 of the example we identified that 2 592 € qualify as additional remuneration.*

  The hourly rate applicable to the action will be, therefore:

  (Actual annual personnel costs for the action - additional remuneration) / hours worked in the action over the year = (9 290,70 € - 2 592 €) / 200 = 33,49 €/hour.

  Personnel costs resulting from the hourly rate = 33,49 €/hour x 200 = 6 698 €.

  (This example continues here for the eligibility of additional remuneration)

- **If** there is **NO additional remuneration** (i.e. all is basic remuneration), the beneficiary can simply use the action reference as hourly rate to charge to the H2020 action.

  Example personnel costs without additional remuneration (Part 2 of 3):
  Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of EUR 6 500 through an additional contract.
  Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour
  National project reference rate = 4 800 € / (1720 annual productive hour / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour
  In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary must use the action reference as hourly rate to charge to the H2020 action:
  Total personnel costs to be declared = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 3 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount of basic remuneration that can be charged to the action *(see examples in Step 2 above)*.

Step 4 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the beneficiary is a non-profit entity and the payments that are additional remuneration are eligible, it may also declare them to the action.

If the resulting amount (for the year) is above the **8000 EUR ceiling**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional payment (bonus) but also the additional taxes, costs and social security contributions triggered by the additional payment.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example personnel costs with additional remuneration (Part 3 of 3):

1. *Ms R worked 200 hours over the financial year. For that work she received 6 698 € of basic remuneration and 2 592 € of additional remuneration.*

If the beneficiary is a for-profit legal entity, the 2 592 € of additional remuneration would be automatically ineligible. The personnel costs which the beneficiary can charge to the action would be therefore 6 698 €.

If the beneficiary is a non-profit legal entity, additional remuneration may be eligible up to the ceiling. To calculate the eligibly part, you need to determine the pro-rata of the cap which corresponds to the 200 hours worked for the action:

(8 000 / 1 720) x 200 = 930,23 €

Although the beneficiary paid 2 592 € of additional remuneration, only 930,23 € are eligible. The difference (2 592 – 930, 23 = 1 661,77 €) is ineligible, since it exceeds the ceiling.

Therefore, the personnel costs which the beneficiary could charge to the action would be: 6 698 € of basic remuneration + 930,23 € of additional remuneration = 7 628,23 €.

For case 2 beneficiaries (unit costs in accordance with the usual cost accounting practices): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary can use the hourly rate(s) that it uses normally (usual cost accounting practices) as average personnel costs, provided that:

- the cost accounting practices are applied in a **consistent** manner, based on objective criteria, regardless of the source of funding
- the hourly rate is calculated using the **actual personnel costs recorded** in the beneficiary's **accounts**, excluding any ineligible cost or costs already included in other budget categories and
- the hourly rate is calculated using one of the **three options** provided in the MGA for the number of **annual productive hours** *(e.g. option 3 'standard annual productive hours')*.

The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

This does not mean that cost accounting practices must be the *same* for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

If necessary, the hourly rate must be adjusted to remove:

- cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the hourly rate).

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

- costs that are already included in other budget categories (double funding of the same costs;

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020 actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.*

Budgeted or estimated elements used to calculate the hourly rate can only be accepted if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way (i.e. do not play a major role in calculating the hourly rate)
- correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

Beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A (as chosen by the beneficiary) applies.

Since there is no obligation to keep time-sheets for periods covered by a declaration on exclusive work, beneficiaries should report:

- for annual hourly rates: a pro-rata of the annual productive hours corresponding to the period covered by the declaration (at the annual hourly rate)
- for monthly hourly rates: 1/12 of the annual productive hours for each month actually worked for the action in the period covered by the declaration (at the monthly hourly rate).

Example:

1a *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours and calculates annual hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate		Hours worked for the project	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

1b *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its monthly personnel cost were 2 666,66 EUR in 2014, 2 860 EUR from January 2015 until October 2015 and 2 900 EUR from then on. The beneficiary applies 1720 as annual productive hours and calculates monthly hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate	x	Hours worked for the project =	Total	
2014 ➔					
October	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 666*	
November	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 666*	
December	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 666*	
			Total	*=*	*8 000**
2015 ➔					
January	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*	
February	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*	
March	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*	

April	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
Mai	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
June	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
July	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
August	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
September	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
October	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
November	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
December	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
		Total	*=*	*34 400*
2016➔				
January	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
February	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
March	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
		Total	*=*	*8 700*
		TOTAL	*=*	*51 100*

* *Decimals have been rounded*

If the declaration covers months in which the person was **absent** for more than half of the working days those months can NOT be taken into account to calculate the hours worked in the action (— unless the absence is linked to annual leave AND the duration does not exceed the pro-rata of annual leave entitlements corresponding to the period covered by the declaration).

Example:

1. *Researcher Y worked exclusively in the action from1 July 2014 to 31 October 2014. In August it took three weeks of holidays and in September it was 10 days on sick leave. The beneficiary applies 1720 as annual productive hours*

Number of hours that can be charged to the action based on the declaration = 3 months (July, September and October) x (1720 / 12) = 3 x 143,33 = 430 hours

August is not taken into account because the person was absent more than half of the working days, since s/he took three weeks of holidays.

2. *The person has the right to two working days of annual leave per month worked. The period covered by the declaration is from January to September (i.e. 9 months). Therefore, the leave entitlement of the person for that period is 9 x 2 = 18 working days. The person takes 3 weeks of annual leave in August. August could also be counted because the leave taken (i.e. 15 working days) is less that the leave entitlement for that period (i.e. 18 working days).*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the annual hourly rate can only be calculated on the basis of the personnel costs incurred during the ongoing financial year.

Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the indemnity in the reporting period in which the employee's contract ends — but outside the hourly rate (i.e. separately and on top of the personnel costs declared on the basis of the hourly rate) AND only for the part that corresponds to the time worked by the person on the action (i.e. pro-rata of the total time during which the entitlement was generated).

Moreover, the indemnity can be accepted ONLY if it:

- arises from the applicable national labour law and
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Employment contract remunerated per hour — For employment contracts that do not establish a fixed salary and a number of hours to be worked but only an amount to be paid for each hour worked by the employee, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*

- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the individual annual productive hours can be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

This summary table explains the three **different options** for **annual productive hours (for case 1A and case 2 beneficiaries)**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave*	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the GA {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*:

	or other types of special leave).	overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus 8 days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for 5 days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual workable hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.
			the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow to determine the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example for calculation of standard annual workable hours:***	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation method consistently applied) are fulfilled but the beneficiary uses 90% of standard annual

		Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave. *The standard annual workable hours for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).*	workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours). ⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 fixed hours).*	

1.2 Direct personnel costs: Natural persons with direct contract (A.2)

1.2.1 What? This budget category **covers** typically the costs of **in-house consultants** and similar persons (i.e. **self-employed *natural* persons**) that worked on the action for the beneficiary under conditions similar to those of an employee, but under a contract which is NOT legally the same as for employees. It regards, in particular, contracts qualified as quasi-subordinate work contracts under national law when the conditions under which the work is carried out are similar to those of an employee.

What not? Staff provided by another entity against a price, including staff provided by a temporary work agency (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

> **Staff provided by a temporary work agency —** A contract with a temporary work agency qualifies typically as purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency),* even if that third party is a one-person company.
- the person must work **under conditions similar to those of an employee,** in particular:

> ⚠ **Similar does not mean equal —** The working conditions of the person do NOT have to be exactly the same that those of an employee, but overall similar.

  - the beneficiary must organise and supervise the work of the person in a way similar to that of its employees

    Example (acceptable):

    The beneficiary's project leader and the person discuss regularly the work to be carried out for the action. The project leader decides the tasks and timing of the work and instructs the person accordingly.

    Example (not acceptable):

    The beneficiary's project leader and the person meet only once a month or irregularly, for updates on the state of play of the entrusted work. If changes are needed, they have to be agreed by the person and may lead to a change of the amount charged to the beneficiary.

  - the beneficiary must be able to ensure reliable time recording (for the hours that the person works for the action)

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

– the person is subject to similar presence requirements as the employees.

Examples (acceptable):

The person works physically at the beneficiary's premises, following a time schedule similar to that of the employees (e.g. the beneficiary authorises up to two days of teleworking per week to its personnel and the person has chosen to benefit from this regime, i.e. works 2 days in teleworking and 3 days physically at the beneficiary's premises).

Example (not acceptable):

The entity authorises up to two days of teleworking per week. However, the person works four days in teleworking and only one day at the beneficiary's premises.

- the **result** of the work carried out (including patents or copyright) must in principle **belong to** the **beneficiary**

  If (exceptionally) they belong to the person, the beneficiary must (just like for employees) obtain the necessary rights from the person (transfer, licences or other), in order to be able to respect its obligations under the GA *(see Article 26.3)*.

- **not** be **significantly different** from costs for employees performing similar tasks

  The remuneration must be based on working time, rather than on delivering specific outputs/products.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **rules** as explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, for the **actual costs hourly rate**, the beneficiaries must use one of the following options:

– if the contract specifies an hourly rate: this hourly rate must be used

– if the contract states a fixed amount for the work and the number of hours to be worked: the global amount for the work must be divided by the number of hours to be worked

– if the contract states a fixed amount for the work but does not specify the number of hours to be worked: the global amount for the work must be divided by the pro-rata of 1 720 annual productive hours which corresponds to the duration of the contract over the financial year.

Example: *The contract provides that the person will work at the beneficiary's premises for assisting in research tasks. The contract is for 6 months starting on 1 January 2017 and ending on 30 June 2017. According to its time records, the person worked 500 hours in the H2020 action over that period. The contract sets a monthly payment of EUR 3 000 but does not explicitly establish the number of hours to be worked.*

Personnel costs for the action = hourly rate x 500 (hours worked in the action)

Hourly rate = annual personnel costs / annual productive hours = (3 000 € x 6 months) / (1 720 hours x (6 months/12 months)) = 18 000 € / (1 720 x 0,5) = 18 000 € / 860 hours = 20,93 €/hour

Personnel costs for the action = 20,93 x 500 = 10 465 €.

For the **unit costs** hourly rate (average personnel costs), the rules in point 1.1.4 apply without any changes.

This summary table explains how to treat **different types of work contracts** for declaring costs under H2020[16]:

Characteristics of the contract	**Contract remunerating time** *(e.g. the contract establishes that the person must work for the beneficiary 40 hours per week)*	**Contract not specifying the working time conditions)** *(e.g. the contract establishes the tasks, but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4); however: ➔ Only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. *Example: Contract from 01.01.2015 to 31.03.2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430*
Other contract (i.e. not an employment contract)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared in category A.2 'natural persons with direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A. 'personnel costs'. They must be treated like CASE D1.	**CASE D1:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

[16] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

		CASE D2: the costs fulfil the conditions of Article 6.2.A.2. The costs can be declared in category A 'personnel costs'. They must be calculated as described in Article 6.2.A. Calculation (point 1.2.4); however: ➔ Only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720.

1.3 Direct personnel costs: Seconded personnel (against payment) (A.3)

1.3.1 What? This budget category **covers** the costs of persons that worked on the action and that were **seconded** by a third party as an in-kind contribution ***against payment*** *(see Article 11)*.

What not? Persons provided by a temporary work agency, secondment of staff between beneficiaries (or linked third parties) in the same grant or secondment by a third party free of charge.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

Secondment of staff between beneficiaries (or linked third parties) — Is allowed, but it is the beneficiary/third party who employs the person who has to declare its costs (NOT the beneficiary/third party to whom the person has been seconded). The costs declared must be supported by reliable time records of the number of hours the person worked for the action. Those time records must be produced under the responsibility of the beneficiary/third party to whom the person is seconded

Persons seconded free of charge — Costs for persons seconded free of charge (i.e. the third party's costs) can be declared as personnel costs by the beneficiary, if they fulfil the conditions of Articles 6.4 and 12.

> For information on in-kind contributions provided by third parties *free of charge, see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared** ONLY as **actual costs**.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.3.4 There is no specific **calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1*).

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the seconded person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.4 Direct personnel costs: SMEs owners & natural persons not receiving a salary (A.4 & A.5)

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons which work on the action, but **don't receive a salary**.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts/other non-employment contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

1.4.2 These costs must be **declared as** the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[17] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *Main Work Programme — MSCA*[18] in force at the time of the call.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **SME owner/beneficiary that is natural person**, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

[17] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf
[18] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ **Ceiling** — The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than 1 720.

1.5 Direct personnel costs: Access to research infrastructure personnel costs (A.6)

1.5.1 What? This budget category **covers** the personnel costs for access to infrastructure activities, i.e. normally:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons with direct contract and
- costs of seconded personnel (against payment).

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs) *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.5.4 The same **calculation rules** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting (B.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing trans-national or virtual access to research infrastructure: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (subcontracting costs (B.)):

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency may exceptionally have to be declared under category B 'subcontracting' (instead of category D.3 'other goods and services') if the temporary work agency carries out directly some task of the action (provided they comply with the eligibility conditions).

C. Direct costs of providing financial support to third parties *[(not covered by Point F)]*

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

1. Direct costs of providing financial support to third parties (C.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category (together with the corresponding Article 15 and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances (D.1): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is foreseen in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in- or outside of Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  > ***Example*:**
  > *Beneficiary A declares the cost of a business class airplane ticket for one of its employees.*
  > *If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.*

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or subsistence allowances as a lump sum/*per diem* payment, it is the lump sum/*per diem* amount that is considered an eligible cost, NOT the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these lump sum/per diem costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (travel costs (D.1)):

Combination with personal travels or travels for other purposes — The costs of a combined travel can be charged to the action — but ONLY up to the cost that would have been incurred if the travel would have been made exclusively for the action AND if:

- it is the usual practice of the beneficiary to pay for such travels *(e.g. travels combining professional and personal reasons)*
- it has been an actual cost for the beneficiary.

***Example*:**

The researcher flies from Madrid, where the beneficiary is established, to Prague for a project meeting. After the meeting, instead of flying back to Madrid, the researcher flies directly to New York to participate in an event not related to the action.
The beneficiary may charge to the action:

- *the cost of the flight from Madrid to Prague, and*
- *the part of the flight back from New York to Madrid up to the cost that it would have incurred for a flight back from Prague to Madrid after the end of the project meeting.*

⚠ **Record-keeping —** The beneficiary must keep evidence not only of the actual cost of the flight back, but also of the cost of the flight that the person would have taken if it would have returned directly after the end of the work for the action.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).]*

***[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.2): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs (D.2): Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

- if the beneficiary does not use the equipment exclusively for the action, only the portion used on the action may be charged. The amount of use must be auditable

  Example: *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*

  Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

- the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

  Example: *A microscope was bought on 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs (D.2)):

Low-value assets — The full cost of a low value asset may be eligible in the year when it is purchased if:

- the full cost is recorded in the accounts of the entity as expenditure of that year (i.e. NOT recorded as an asset subject to depreciation)

and

- the cost of the asset is below the low-value ceiling as defined under national law (e.g. *national tax legislation)* or other objective reference compatible with the materiality principle

and

- the item is used exclusively for the action in the year of purchase.

  If the item is not used exclusively for the action in the year of purchase, only the portion used on the action may be charged.

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that correspond to the part of the equipment's use for the action. Declaring its *full* price in one single year would be considered either as not compliant with the international accounting standards or as an excessive cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, a piece of equipment bought in January 2013 has a depreciation period of 48 months.
If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that corresponds to the part of the equipment's use for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year, the beneficiary can NOT charge the full price in one single year (— even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year).

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the eligibility conditions of Articles 6.1 and 6.2 are met (in particular, recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices; *see Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

If the full construction costs of the prototype are eligible according to the conditions above, but the construction was outsourced to a third party (other than a linked third party), the costs can NOT be declared in category D.2 'equipment', but may be eligible in category B 'subcontracting' *(see Articles 6.2.B and 13)*.

1.2 Equipment costs (D.2): Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs (D.2): Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:

  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are not higher than the depreciation costs of similar equipment).

1.4 Equipment costs (D.2): Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services (D.3): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access to peer-reviewed scientific publications*, e.g. article processing or equivalent charges*, costs related to open access to research data and related costs, *such as data maintenance or storage and conference fees for presenting project-related research*)
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4 or the certificate was submitted not for the final report but before*).
- translation costs *(if translation is necessary for the action's implementation, is justified, etc.)*.

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services (D.3)):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the plan for the exploitation and dissemination of the results are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access to peer-reviewed scientific publications and research data are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Self-produced consumables with an accounting value in the inventory of the beneficiary (i.e. not internally invoiced costs for goods and services) — Consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price; the cost of production for the beneficiary is however are normally recorded in the accounts of the beneficiary (as part of the *inventory)*. Therefore, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

> ⚠ Beneficiaries can **NOT** charge the **commercial price** for self-produced consumables.

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.
The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency are eligible normally under category D.3 'other goods and services' if they comply with the eligibility conditions (and unless the temporary work agency carries out directly some task of the action, in which case it can be considered as subcontracting and should be declared under category B 'subcontracting').

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure (D.4): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of Horizon 2020 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in

[19] *See also International Financial Reporting Standard No 16.*

particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure to calculate the EUR 20 million threshold *(see below)* and therefore declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[20] *See Article 126 of the Financial Regulation No 966/2012.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure (LRI)

Beneficiaries can declare capitalised and operating costs for **large research infrastructure**, if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a **research infrastructure** in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a **grouping of costs** (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any grant agreement (by ticking the LRI box either in the Beneficiary Register or during grant preparation).

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Beneficiary Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) ex-ante assessment report will be issued.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs in category D.4 'large research infrastructure'.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

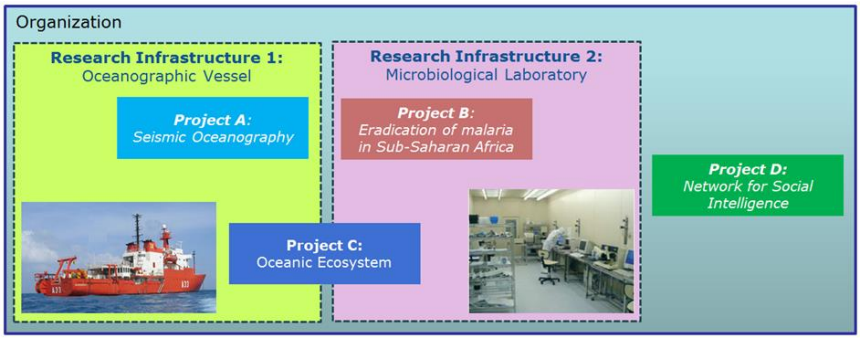

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[23].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the H2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the H2020 grant, even if they belong to the same action.

> ⚠ **Combining H2020 & other EU grants —** The terminologies under the different EU funds/funding programmes may differ *(e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).*

4.4 Costs must be directly measured

Costs can be claimed as direct costs in category D.4 'Large research infrastructure' only if they are **directly measured** (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

[23] *See Article 129(1) of the Financial Regulation No 966/2012.*

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (**project time**) and therefore require reliable time recording (through time-sheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No *1290/2013*

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. This data must be regularly updated.

  Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

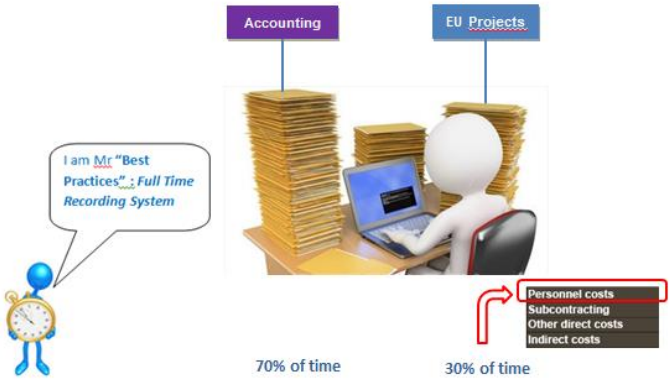

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints *(e.g. opening hours)*, but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

D.5 Costs of internally invoiced goods and services directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

1. Costs of internally invoiced goods and services (D.5): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category covers the costs for goods and services which the beneficiary itself produced or provided for the action. They include (non-exhaustive list):

- self-produced consumables *(e.g. electronic wafers, chemicals)*
- use of specific research devices or research facilities *(e.g. clean room, wind tunnel, supercomputer facilities, electronic microscope)*
- specialised premises for hosting the research specimens used for the action *(e.g. animal house, greenhouse, aquarium)*
- standardised testing or research processes *(e.g. genomic test, mass spectrometry analysis)*
- hosting services for visiting researchers participating in the action *(e.g. housing, canteen*).

What not? Costs of goods of services purchased and costs of goods or services internally invoiced which are not directly used for the action *(e.g. supporting services like cleaning, general accountancy, administrative support, etc.)*.

1.2 Costs of internally invoiced goods and services must be **declared as** unit costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following cumulative **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. used during the action duration, necessary for the action, etc.; *see Article 6.1(b)*)

- be in line with the beneficiary's **usual cost accounting practices**

  It must be the usual practice of the beneficiary to calculate a unit cost for that good or service (i.e. an internal cost per unit invoiced to other departments of the same entity – not prices charged in the context of commercial sales or grants from other fund providers).

- the cost accounting practices must have been applied in a **consistent** manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  Example: *if the beneficiary sets up a new unit cost which applies only to EU actions, the internally invoiced costs based on that new unit cost would be ineligible.*

- the amount per unit must have been **calculated** using the actual costs recorded in the beneficiary's accounts, excluding any ineligible costs or costs already included in other budget categories

  If necessary, the unit cost must be adjusted to remove:

  - cost elements that are ineligible under the Grant Agreement (even if they are part of the beneficiary's usual methodology for determining the unit cost for its internal invoices)

    Example: *The beneficiary uses internal invoices for the use of an electronic microscope based on a unit cost per hour of use. The methodology to calculate the unit cost includes costs of capital (e.g. interest charged by the bank for a loan used to buy the microscope). Those costs are ineligible under the Grant Agreement (see Article 6.5) and must therefore be removed. The unit cost must be recalculated without them.*

    A beneficiary cannot simply apply an estimated percentage of deduction on the amount of its internal invoices to remove ineligible costs. It has to ensure that the internal invoice does not include any ineligible costs under the GA.

  - costs of resources that do not belong to the beneficiary and which it uses free of charge *(e.g. personnel or equipment of a third party provided free of charge)*, because they are not in its accounts *(see Article 6.1(a)(v))*

  - costs that are already included in other budget categories (double funding of the same costs, *see Article 6.1(a)(i)*).

    Example: *The beneficiary uses internal invoices for water chemistry analyses, based on a unit cost per water sample analysed. The methodology to calculate the unit cost includes the cost of the staff carrying out the analysis. However, the costs for those persons are already charged to the action under direct personnel costs (category A.1). The cost of the staff must therefore be removed and the unit cost must be recalculated without them.*

- if budgeted or estimated elements were used to calculate the amount per unit, those elements must:

  - be relevant (i.e. clearly related to invoiced item)

  - be used in a reasonable way (i.e. do not play major role in calculating the unit cost)

  - correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

- the amount per unit must have been calculated using only costs of items which were **directly linked** to the production of the internally invoiced goods or services *(e.g. staff, equipment, raw materials, etc.)*

If a cost item is not used exclusively for the internally invoiced good or service, only the share used for the good or service may be counted (the percentage taken must be substantiated by persuasive evidence).

Example: ***Shared staff —*** *Among the persons operating the beneficiary's wind tunnel, there is one person that is assigned only part-time to that wind tunnel; the rest of the time it works in another department. If the beneficiary includes the costs of this person at the rate of 50 %, it must be able to justify the reality of that percentage, for example, by any of the following:*

- *reliable time recording system*
- *a statistic survey performed in the past based on actual data*
- *detailed calculations based on technical specifications or other scientific and technical requirements of the equipment or infrastructure allowing to reconcile the time spent by the person for the functioning of the wind tunnel*

or

- *a combination of these methods.*

Ceiling — The (share of the) working time of a person which is included in the calculation of the unit cost reduces the number of hours that the person can charge over the year to EU/Euratom grants (see Article 6.2.A. Calculation). The same hours of the person cannot be charged twice to the grant, once embedded in the unit cost and again as direct personnel costs.

If necessary, the unit cost must be adjusted to remove costs elements allocated to the unit cost indirectly; i.e. through cost drivers/allocation keys based on other cost items included in the unit cost *(e.g. for a clean room: the costs of the of the human resources department charged to the unit cost as a fixed amount per employee assigned to the clean room; or power supply costs allocated to the clean room on the basis of the square meters it occupies)*.

Example: *Costs for an animal housing facility*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. keepers, veterinarians and other persons directly assigned to run the animal house)* – *consumables used for the animal housing (e.g. animal food, bedding)* – *depreciation of cages and other equipment directly linked to the housing of the animals* – *generic supplies like electricity or water — BUT only if the consumption of the facility has been directly measured (so that the cost can be accurately determined)* – *maintenance and cleaning of the animal house facility — BUT only if the cost is directly identifiable (e.g. a separate invoice for the cleaning of the cages)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the animal house facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the animal housing is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

Example: *Wind tunnel*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. technicians, engineers and other persons directly assigned to the functioning of the wind tunnel)* – *depreciation of the equipment, including specific software and hardware necessary*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the facility (e.g. cleaning*

for the functioning of the wind tunnel – *generic supplies like electricity — BUT only if the consumption of the facility has been directly measured (so the cost can be accurately determined)* – *insurance — BUT only if the cost is directly identifiable (e.g. a separate invoice for the insurance of the facility)* – *maintenance and cleaning of the wind tunnel equipment (e.g. air cooling system) — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)* – *calibration/metrology tests — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)*	*services)* – *depreciation of shared buildings (e.g. the building where the installation is located is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

1.1.4 They must be **calculated** according to the rules set out above (point 1.1.3).

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Article 6.2. Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]][**OPTION 2**: not applicable;]*

(d) ***[OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION 2:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (E.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared as** a fixed flat-rate (*see Article 5.2(e)*; ⚠ new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation, etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying the 25 % flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: *subcontracting of opinion surveys*

The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties (if option applies)
- costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a GA and has incurred the following costs:

- *EUR 100 000 personnel costs (EUR 7 000 of which are an in-kind contribution in the form of a laboratory technician who carries out work for the action from his/her laboratory in a public research centre)*
- *EUR 20 000 subcontracting costs,*
- *EUR 10 000 other direct costs (consumables).*

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

⚠ **Combining H2020 & other EU grants —** Beneficiaries that also receive an EU **operating grant** can NOT declare any indirect costs for the reporting period(s) covered by the operating grant, unless they are able to demonstrate cost separation (i.e. that the operating grant does not cover any costs that may be claimed under the action).

Operating grants are annual grants to finance the operation and running costs of an entity *(e.g. call COMM-C2/01-2013 under the Europe for Citizens programme)*.

Example: *Entity A receives an operating grant under the Europe for Citizens programme for the financial year 2016 (i.e. from 01.01.2016 until 31.12.2016) The operating grant is not renewed in 2017. On 01.04.2016, entity A signs an H2020 action grant with one reporting period of 18 months (01.04.2016 – 31.12.2017). Beneficiary A may declare the indirect costs in the H2020 action grant as follows:*

- *from 01.04.2016 to 31.12.2016 ONLY IF it can demonstrate that the operating grant does not cover any costs of the action (see beow);*
- *from 01.01.2017 – 31.12.2017 under the normal H2020 rules (i.e 25% of the direct eligible costs since there is no operating grant covering the 2017 financial year).*

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grant may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be a full operating grant)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant or the operating grant)
- the beneficiary must record:
  - all costs incurred for the operating grant (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all costs incurred for the action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that cannot fulfil these conditions must EITHER:

- terminate the operating grant, in order to sign the action grant with indirect costs
- keep the operating grant, but sign the action grant without indirect costs.

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of an overlapping EU operating grant, the beneficiary should immediately contact the Commission/Agency (via the Participant Portal). Be aware that operating grants are not always easy to identify. They exist under various labels (operating grants; financial contributions/support to the functioning/operation of entities; etc.). Check your call text.

F. [OPTION 1: [Insert name of specific cost category(ies)[22]]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION** 1a **for** **specific unit costs** **(if unit cost foreseen by Commission decision and applicable to the grant): [insert name of specific cost category]** are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category]** are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]

[same for each specific cost category]

[OPTION 2:** Not applicable**]

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of Horizon 2020, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: **costs for energy efficiency measures in buildings**

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': **access costs for providing trans-national access to research infrastructure**

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': **costs for clinical studies**

  The unit cost applies ONLY to actions with clinical studies.

⚠ **Double funding risk —** Costs that are declared as a specific unit or lump sum cost may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Example:

The unit cost for efficiency energy measures in buildings covers subcontracting costs related to the energy efficiency measures. These cannot be declared as subcontracting costs. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

1.1 Specific cost category – costs for energy efficiency measures in buildings (F.2)

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared as** the unit cost set out in Commission *Decision C(2013) 8196*[25] and set out in Annexes 2 and 2a of the GA.

The precise unit cost ('amount per unit', i.e. EUR/m2 of eligible conditioned gross floor area) is not pre-fixed by the Decision; it must be calculated for each beneficiary/linked third party — before signature of the GA — using the following table:

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

The formula for calculating the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) is:

Amount per unit = {EUR 0.1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

[25] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

The use of the unit cost is mandatory. The beneficiaries/linked third parties cannot choose between unit and actual costs.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m^2 of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 Specific cost category – access costs for providing trans-national access to research infrastructure (F.2)

1.2.1 This budget category **covers** direct and indirect access costs for providing trans-national access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.

Beneficiaries that use budget category F.2 'access costs for providing trans-national access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, in category D.1 'travel'; *see Article 6.2.D.1 and Article 16*.)

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing trans-national access to research infrastructure'), the costs must be **declared as** the unit cost calculated in accordance with Commission Decision C(2013) 8199[26] and set out in Annex 2 and 2a of the GA.

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

The precise unit cost (amount per unit, i.e. EUR/unit of access) is not pre-fixed by the Decision; it must be calculated for each access provider and installation, using the calculation table provided on the call page and then summarised in the following table:

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The formula for calculating the 'amount per unit of access' (EUR/unit of access) is:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{27})}{\text{average annual total quantity of access (over past two years}^{28})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the user's research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)

[27] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
- costs of specific scientific services included in the access provided or needed for the provision of access

Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.

- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)
- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

The detailed calculation table s (one for each installation) must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annex 1; the summary table must be included in Annex 2a.

The proposal and Annex 1 should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per installation).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

Afterwards (once the GA is signed), the choice can be changed only via an amendment *(see Article 55)*.

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 Specific cost category – costs for clinical studies (F.2)

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
- costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
- indirect costs for the study.

What not? Travel and subsistence costs of study participants and horizontal tasks *(e.g. study monitoring, study coordination)* are not covered by the clinical studies unit cost. (These costs can be reimbursed separately, *e.g. in categories A. 'personnel', D.1 'travel' and D.3 'other goods and services'; see Articles 6.2.A, 6.2.D.1, 6.2.D.3*.)

1.3.2 If they are declared under this budget category (i.e. F.2 'costs for clinical studies'), the costs must be **declared as** the unit cost set out in Commission Decision C(2016) 7553[29] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/study participant) is not pre-fixed by the Decision; it must be calculated for each study/study sequence *(see below)* and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — using the following table:

Task, Direct cost categories	Resource per patient	Costs year N-1 Beneficiary 1 [short name]	Costs year N-1 Linked third party 1a [short name]	Costs year N-1 Beneficiary 2 [short name]	Costs year N-1 Linked third party 2a [short name]	Costs year N-1 Third party giving in-kind contributions 1 [short name]
Sequence No. 1						
Task No. 1 Blood sample						

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1 XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR

Task No. 2						
…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

⚠ Where the nature of the clinical study allows it, it can be split into sequences, *e.g. treatment cycles*. The number of sequences should be limited to the necessary minimum *(e.g. 3 sequences)*.

Separating the unit cost table into sequences will allow you to declare unit costs for study participants that dropped out during the study, but finalised the tasks of a sequence. Thus, the sequence unit cost can be charged for the participant, for the completed sequence(s).

Each beneficiary/linked third party/third party must calculate its unit cost on the basis of its historical data (estimated costs of the components per task and study participant). Historical cost reference data should be taken from the last closed financial year at the time of submission of the grant proposal (certified or auditable profit and loss account for 'year N-1').

Beneficiaries can choose whether to include *all* the cost components in their unit cost or only *some*, but they may NOT add any other cost categories.

They may choose whether to include personnel costs or not, but if they do, *all* the study-related personnel costs must be included (they cannot choose for individual persons/types of personnel). Moreover, this choice must be applied to all the tasks and sequences of the study. If personnel costs are included, they must moreover use one of the three available categories: doctors, other medical personnel or technical personnel (no other categories, *e.g. nurses must be included in 'other medical personnel').*

For consumables, medical equipment and services, there is more flexibility. They can choose for each individual cost items, if they would like to include it in their unit cost (or declare them as actual costs).

The choice (whether to include a cost component in the unit cost or not) is made by adding the costs into the table (or leaving it blank). All blank cost components are outside the unit cost (and can normally be declared as actual costs, if all the eligibility conditions are met).

The beneficiaries/linked third parties/third parties may therefore (for the same study/sequence) not only obtain completely different amounts per unit, but also include different components into their calculation.

Example:

Beneficiary No 1 decided to claim:

- *personnel costs as unit costs*
- *all consumables for sequence 1 as actual costs, all consumables in sequence 2 as unit cost and consumables in sequence 3 partially as actual, partially as unit costs*
- *medical equipment partially as actual, partially as unit cost (e.g. cost of a standard MRI scan — part of the study protocol sequence 2 task 3 — as unit costs and the costs for the use of an novel imaging tool — also sequence 2 task 3 — as actual costs, for instance because the historical data is not fully available)*
- *all services as unit costs.*

Beneficiary No 2 decided to claim all study costs as unit costs.

Linked third party 2a decided not to use the unit cost for any of the study costs (all costs as actual costs).

The formulas for calculating the individual cost components are:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

{certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full-time-equivalent for doctors for year N-1}
multiplied by
estimated number of hours to be worked by doctors for the task (per participant)**}**

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full-time-equivalent for other medical personnel for year N-1}
multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)**}**

For personnel costs of technical personnel: 'average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full-time-equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1
total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)**}**

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}
total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1
total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1**}**

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the

contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}**}**

multiplied by

25%**}**

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

This table must already be part of the proposal *(see the proposal templates and the template for essential information to be provided for proposals including clinical studies provided on the call pages)* and be included in Annex 1 and 2a of the GA.

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs components not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*.

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently (and for the different cost components/cost items) whether to be reimbursed on the basis of unit costs or of costs actually incurred.

Once the GA is signed, the choice can be changed only via an amendment *(see Article 55)*.

⚠ Amendment requests to change the unit cost calculation will be accepted ONLY if there was a change in the study protocol *(e.g. due to requests from competent authorities, regulatory agencies or ethics committees)* or if there was an error in the calculation.

⚠ The maximum grant amount *(see Article 5.1)* will NOT be increased.

⚠ In case of an amendment, it is still the historical costs of the last closed financial year at the time of submission of the grant proposal that must be used to re-calculate the unit cost.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**
- **1.3.4** They must be **calculated** as follows:
- amount per unit *(see Annex 2a GA)* **x** the number of study participants

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

1. Costs of linked third parties (A-F)

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility) like beneficiaries.

The same rules apply, but with the changes needed to render them applicable to linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 14.1.1.

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared in category A.1 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions by third parties free of charge (A-F)

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared in category D.2 'equipment' (Article 6.2.D.2).*

In-kind contributions *free of charge* must be **distinguished** from **in-kind contributions *against payment*** *(see Article 11).*

In-kind contributions *against payment* are costs *of* the beneficiary (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. Their costs (i.e. the payment) must be declared under those specific budget categories.

Examples:

1. *The cost of personnel seconded against payment must be declared in category A.3 'seconded personnel (against payment)' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

The costs of in-kind contributions free of charge (i.e. the costs of the third party offering them) can be assimilated to beneficiary costs and must be declared in the budget category that the beneficiary would have used.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action [;][.]

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

– **debt and debt service charges**

'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

> ***Example:*** *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

– **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

Conversely, if VAT is NOT deductible, it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction

between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*
  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
  - if a beneficiary is receiving an operating grant[30] from the EU/Euratom, then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied — unless it can demonstrate that the operating grant does not cover any costs of the action *(see Article 6.2.E)*.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Specific cases (ineligible costs):

Non-identifiable VAT (in foreign invoices) — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts if it is not possible to deduct the VAT. That VAT would therefore be eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

Duties — The eligibility of duties depends on the eligibility of the cost item to which they are linked (i.e. in whose price they are included). If the item is eligible, the duty is also eligible.

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[30] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the applicable national law.*

⚠ Normally, the beneficiaries must comply **BOTH** with the national law of the **country** in which they are **established** AND that of the country where the **action** is **implemented**.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Examples (acceptable):

1. *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

2. *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action. They may also call on international partners to carry out work under the action without receiving EU funding (see Article 14a) (‘**third parties involved in the action**’).

⚠ Beneficiaries using third parties remain **fully responsible** for them under the GA.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues like beneficiaries.

Third parties involved in the action do NOT sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks. They must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme). For more information on conditions for participation and funding, *see the Online Manual.*
The eligible costs are the prices charged to	The eligible costs are only the costs of the

the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the government (the ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the ministry/government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

This table gives an **overview** of the different kinds of **third parties**:

TYPE	CHARACTERISTICS						
	Works on action tasks?	**Provides resources or services for action?**	**What is eligible?**	**Must be indicated in Annex 1?**	**Indirect costs?**	**Selecting the third party**	**GA articles**
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link	Article 14
International partners	**YES**	**NO**	**N/A**	**YES**	**N/A**	Must not be eligible for funding	Article 14a
Subcontractor	**YES**	**NO**	**Price**	**YES**	**NO**	Must be best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contribution	**NO**	**YES**	**Costs**	**YES**	**YES**	May not be used to circumvent the rules	Articles 11 and 12
Contractor (selling, equipment, good or service)	**NO**	**YES**	**Price**	**NO**	**YES**	Must be best value for money, avoid conflict of interest	Article 10
Third parties receiving financial support[31]	The third parties participate in the action as recipients.		**Amount of support given**	**YES**	**NO**	According to the conditions in Annex 1	Article 15

[31] Only if allowed in the work programme/call.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

*[****additional OPTION for beneficiaries requesting zero funding****: If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION 2:** Not applicable]*

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

Beneficiaries not receiving EU funding — They participate in the action as beneficiaries, but NOT with EU funding. They must carry out the work under the action and comply with the GA (although not with *all* its obligations; the financial obligations and some IPR obligations do not apply for them).

'**Beneficiaries not receiving EU funding**' are either:

- 'beneficiaries **not eligible** for funding', i.e. beneficiaries which:
  - are NOT from an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme AND
  - were NOT granted exceptional EU funding by the Commission/Agency (during the selection procedure)

For more information on third country participants, *see the Online Manual (international cooperation).*

Beneficiaries that (exceptionally) become eligible for funding during the action, may in principle request funding (as from their eligibility), if the grant agreement is amended to change Articles 9, 57 and Annex 2 (*see Article 55*).

Since the maximum grant amount cannot be increased *(see Article 5.1)*, this would only be possible if the consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY as from the date of eligibility for funding and if they comply with all the obligations under the GA *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

- 'beneficiaries **requesting zero funding**', i.e. beneficiaries that are eligible for funding, but decided not to request any funding.

Beneficiaries requesting zero funding may in principle request funding later on, if the GA is amended (to change Article 9 and Annex 2; *see Article 55*).

Since the maximum grant amount cannot be increased *(see Article 5.1), this would only be possible if the* consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY if they comply with all the obligations under the GA retroactively *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate as beneficiaries in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on their role in the grant and if the beneficiary has linked third parties that receive EU funding or not).

This table shows the **GA obligations** that do **NOT apply** to beneficiaries not receiving EU funding (marked by X under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of **breach** of any **of** their **obligations**, their participation may be terminated and any of the other Chapter 6 measures (except for rejection of costs or recovery) may be taken.

Examples:

1. *A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

2. *In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).*

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […][23]**]

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EU)[25] or 'contracting entities' within the meaning of Directive 2004/17/EC[26] (or 2014/25/EU)[27] must **comply** with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

Purchases — For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the purchasing context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, *such as technical quality, etc.*), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the grant amount). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules which the European Commission applies for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional cost eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[32] must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 4 of Directive 2014/25/EU)*.

Specific cases (purchases):

Purchases between beneficiaries — Are in principle not accepted. If a beneficiary needs supplies from another beneficiary, it is the latter beneficiary that should charge them to the action. (Otherwise there is the risk that the grant is used to charge commercial profit margins.) Purchases between beneficiaries will only be accepted in exceptional and properly justified cases *(e.g. beneficiary A is the usual supplier of beneficiary B for a generic consumable that beneficiary B needs for the action)*.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[32] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the measures described in Chapter 6.

1. In-kind contributions by third parties against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example (in-kind contributions against payment): *medical equipment provided by a hospital (against a fee) to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2; e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

If the amount paid by the beneficiary is lower than the cost incurred by the third party, the beneficiary may in addition declare the difference as in-kind contributions free of charge (see Article 12). If it decides to do so, it may have to declare that difference also as receipt (*see Article 5.3.3*).

For the upper limit (third party's costs), normally only the *direct* costs *actually* incurred by the third party will be taken into account.

The following costs may however be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[33] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the grant agreement (alternative to actual costs; *see Article 6.2.F*).

The actual costs must be identifiable and verifiable in the third party's accounts.

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used on the beneficiary's premises

or

- taken into account: if the in-kind contributions are NOT used on the beneficiary's premises (*but, for instance, on the third party's premises*).

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

[33] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

3. Additional cost eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**').

Example (approval): *A new researcher is brought into a team working during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The beneficiaries may declare **costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions by third parties free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary itself makes no payment and there is therefore NO cost incurred by the beneficiary. However, the GA provides that it may charge the costs incurred by the third party for its in-kind contribution *(see also Article 6.4)*.

Examples (in-kind contributions free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the ministry/government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like universities/ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

⚠ Article 12 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in *Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs *actually* incurred by the third party may be declared.

The following costs may however (alternatively) be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[34] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the grant agreement (alternative to actual costs; *see Article 6.2.F*).

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used in the beneficiary's premises

or

- taken into account: if the in-kind contributions are used on the third party's premises.

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs; but the beneficiary may NOT include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional cost eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

[34] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**'; *see Article 11*).

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[28]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION 1 only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]***.]***

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be **set out in Annex 1** and the total estimated costs of subcontracting per beneficiary must be **set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) **must comply** with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ **Subcontractors —** Subcontractors participate in the action by carrying out action tasks *for* the beneficiary. They are NOT beneficiaries and therefore have no direct obligations under the grant agreement (but their beneficiaries must ensure that they comply with certain key obligations).

Subcontract — For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on business conditions

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from linked third parties; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2).*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work.

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary.

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

The beneficiaries must make special arrangements regarding **results** produced by the subcontractors (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

⚠ **Security obligations —** Stricter rules apply for action tasks that involve information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37).*

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts either on the best value for money (considering the quality of the service proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the subcontracting context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional cost eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI).

⚠ This concerns research and innovation actions or innovation actions *with* a PCP or PPI.

This should NOT be confused with PCP/PPI action (separate type of action, which use a different model grant agreement and whose *main* action task is the implementation of the PCP or PPI).

The additional rules mirror the key obligations for PCP/PPI actions from the H2020 MGA PCP/PPI.

4. Additional cost eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the **name** of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the subcontract (or the subcontracting costs). For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA ('**simplified approval procedure**').

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the full discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

5. Additional cost eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*

- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[35]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.

'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 4 of Directive 2014/25/EU)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* — Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of

[35] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[30] and **third parties with a legal link to a beneficiary**[31] ('**linked third parties**') may implement the action tasks attributed to them **in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

*The linked third parties may declare as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

*The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their linked third parties.*

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

⚠ **Linked third parties —** Linked third parties are allowed to participate in the action, like the beneficiary they are linked to. They are NOT beneficiaries, but they are allowed to participate fully in the action and receive EU funding; they will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries and their beneficiaries must ensure that they comply with certain key obligations.

⚠ **Combining H2020 & other EU grants —** The terminologies under different EU funds/funding programmes may differ *(e.g. 'linked third parties' under H2020 are the SAME as 'affiliated entities' under the Financial Regulation, while 'affiliated entities' under H2020 is NARROWER than 'affiliated entities' under the Financial Regulation (see Articles 2.1(2) and 23(5) of the Rules for Participation Regulation No 1290/2013 and Article 122 of the Financial Regulation No 966/2012).*

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission/Agency as reimbursement of costs for their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only **affiliated entities** or **entities with a legal link to a beneficiary** can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; 'ad hoc' collaboration agreements or contracts to carry out work in the action are NOT covered. (In this latter case, both legal entities should be beneficiaries.)

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or

- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

1. Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research)* ***—*** *They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

2. Associations, foundations *or* ***other legal entities composed of members —*** *The association/foundation etc. is the beneficiary and the members are the linked third parties.*

Examples (affiliated entities):

1. *Company A established in France holding 20% of the shares in Company B established in Italy. However, with 20% of the shares it has 60% of the voting rights in company B. Therefore, company A controls company B and both companies may be linked third parties in a H2020 GA.*

2. *Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.*

Linked third parties must fulfil the same **conditions for participation** and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme).[36]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an US company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country that is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.*

For more information on conditions for participation and funding, *see the Online Manual*.

They must be **named** in Article 14 and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the linked third party is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the linked third parties (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak' and
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

[36] *See Articles 9 and 10 of the Rules for Participation Regulation No 1290/2013.*

1. The financially weak beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

2. The financially weak beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

3. The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery), who must upload it (as a scanned PDF copy) in the system.

Record-keeping — The beneficiary must keep the original of the linked third party in its files.

The liability is for any amount owned by the beneficiary under the GA, and up to the linked third party's maximum EU contribution in Annex 2.

For more information on the financial viability/capacity check, *see the Online Manual*.

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

2. National research associations established according to the national law in order to carry out research not limited to the action.

3. A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional cost eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO 'simplified approval procedure'.

3. Additional cost eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* (since linked third parties cannot sign them in the IT system; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary.

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Each linked third party has to provide its own ***certificate* on the financial statements** (**CFS**; *see Article 20.4*).

The threshold of EUR 325 000 applies to each linked third party (independently of its beneficiary).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

4. Additional cost eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. 'Other obligation': Extension of obligations under the GA to linked third parties

The beneficiaries must ensure that the linked third parties comply with certain obligations under the GA.

Obligations that must be extended to linked third parties:

- Record-keeping obligations *(see Article 18)*
- Reporting *(see Article 20)*
- Avoiding conflicts of interest *(see Article 35)*

- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties.

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following **international partners**[37] may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

– *will not be reimbursed and*

– *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36 and 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary braches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[37] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

1. International partners

4.0 This optional Article (together with the corresponding options in Article 4) will be inserted into the GA if the action is implemented with international partners. It was introduced with GA version 4.0 and does NOT automatically apply to older grant agreements.

International partners — International partners are allowed to participate in the action without EU funding. They are NOT beneficiaries and do NOT receive EU funding; they therefore have no direct obligations under the grant agreement (but their beneficiaries must to ensure that they comply with certain key obligations).

Characteristics of implementation by international partners:

- International partners perform their action tasks directly. They do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the action tasks performed by its international partner.
- International partners perform their action tasks without receiving EU funding, i.e. their costs are NOT eligible for reimbursement under the grant. Therefore, they will not be subject to financial checks, reviews or audits.

  The costs of the international partners are estimated in Annex 2 (to get an overview of the overall project budget). But this is for information purposes only, the international partners are not required to report on their costs.

International partners do NOT need to have a (capital or legal) link to the beneficiary (but they may have one).

They must NOT be eligible for funding, i.e. be established in a third country not listed in General Annex A to the Main Work Programme.

Example: *A consortium of legal entities from EU Member States, H2020 associated countries and third countries listed in General Annex A to the Main Work Programme wants to work with a legal entity established in New Zealand. Since the New Zealand entity would like to be involved in the action without requesting EU funding and without becoming a beneficiary, one of the beneficiaries may decide to list the New Zealand entity as its international partner and attribute certain action tasks to it (provided that the international partner agrees to the action tasks and the related obligations under the GA).*

They may be used to implement any of the action tasks.

They must be **named** in Article 14a and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the international partner is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the international partners (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

Although they are not beneficiaries and do not receive EU funding, their beneficiaries must ensure that they comply with certain key (non-financial) obligations:

Thus, they must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 to verify the proper implementation of the action tasks and that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

Moreover, they must extend the following obligations under the GA to the international partners:

Obligations that must be extended to international partners:

- Record-keeping obligations (on the scientific and technical implementation; *see Article 18.1.1*)
- Technical reporting (in the required language; *see Article 20.3(a), 20.4(a) and 20.7)*
- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38).*

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the international partners.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving financial support.*

15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving financial support.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties ONLY where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*)

Examples:

1. *An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.*

2. *One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.*

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving a prize.*

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving a prize.****]***

[OPTION 2: *Not applicable****]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

***Access** for user groups with a majority of users not working in a EU or associated country[34] is **limited** to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) procedure and criteria for **selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: […]*[35]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

1. *advertise widely, including on a dedicated website, the access offered under the Agreement;*
2. *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
3. *ensure that users **comply** with the terms and conditions of the Agreement;*
4. *ensure that its obligations under Articles 35, 36, 38 and 46 **also apply** to the users.*

[OPTION 2:** Not applicable**]

[32] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[34] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[35] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[37] or installation[38] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 of the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

[37] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[38] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

⚠ **Record-keeping —** The beneficiaries must keep appropriate records and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional cost eligibility condition: Access which must be provided

Trans-national access can be either:

- **in person** (hands-on), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional cost eligibility condition: Categories of users that may have access — Limited access for special user groups

For trans-national access, user groups in which all or most users work in non-associated **third countries** may ONLY have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional cost eligibility condition: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. 'Other obligation': Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to users

The beneficiaries must also ensure that the users comply with certain obligations under the GA.

Obligations that must be extended to users:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users.

16.2 Rules for providing virtual access to research infrastructure

[OPTION 1 for virtual access to research infrastructure: *'**Access providers**'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2:** Not applicable**]

16.3 Consequences of non-compliance

***[OPTION 1 to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **reimburse** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action
- costs related to technological and scientific support for users access *(e.g. a helpdesk)*

- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

The specific unit cost for access to research infrastructure (F.2) does NOT cover virtual access (only trans-national access).

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed — unless provided for in the work programme/call.

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*

Access must be open to all users; users are not selected.

3. Additional cost eligibility condition: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request the information for **any purpose** *(e.g. checks for monitoring the action or assessing reports and requests for payment; reviews; audits; investigations; evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission/Agency may request the information at **any time**, either during the action or afterwards.

Examples:

1. *In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid (see Article 22).*

2. *The Commission may request information from the beneficiaries in order to evaluate the action's impact up to five years after the balance is paid (see Article 23).*

3. *The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.*

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information is sent via the Participant Portal. Afterwards, information requests may have to be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary must keep its information in the Beneficiary Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form *(e.g. private limited liability company, public law body, S.A., S.L.)*
- organisation type *(e.g. SME, secondary or higher education establishment, etc.)*.

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, validation and data updates, *see the Online Manual*.

3. Information likely to delay or affect the action or EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

> ***Examples (situation likely to significantly affect or delay the action's implementation or affect the EU's financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the Beneficiary Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.).*

Best practice: It is recommended that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the Participant Portal
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (for linked third parties, *see point 10*) must keep appropriate and sufficient evidence to **prove** the eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[39]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least 5 years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

[39] International Standard on Auditing ISA 500 'Audit Evidence'.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission/Agency will accept any document considered an original under national law.

Examples:

1. *The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.*

2. *The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.*

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

1. *For costs declared in category A.1 (employees or equivalent): the costs must be detailed for each person carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).*

2. *For costs declared in category D.1, D.2, D.3 and D.4 (other direct costs): the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.). It should be able to provide details of individual transactions for each type of cost. For depreciation, it must be able to provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).*

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For costs declared in accordance with their usual cost accounting practices (**average personnel** costs and costs of **internally invoiced goods and services**), the beneficiaries must keep detailed records and other supporting documents to:

- show that the costs used to calculate the unit cost match the actual costs as recorded in the statutory accounts

  Examples:

  1. *For personnel costs: accounting records; financial statement extracts; labour contracts; collective labour agreements; applicable tax, labour and social security laws; pay slips; bank statements showing salary payments; classification of employees (based on experience, qualifications, salary, department, etc.).*

  2. *For internally invoiced goods and services: accounting records; financial statement extracts; time records (or other records) for the share of personnel costs included in the unit costs; invoices or contracts for maintenance costs, cleaning costs, other services, showing that the cost are directly identifiable.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost is free of ineligible cost components

  Examples:

  1. *For personnel costs: records that show that the hourly rate does not include an indirect cost component (already covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (they should be claimed under category D.1 'travel').*

  2. *For internally invoiced goods and services: evidence that shows that there is no profit/margin/mark-up included in the internally invoiced goods and services (e.g. different rates: one for billing the activity, with mark-up, and another one for internal costing, free of any mark-up); lists of accounts/cost centres that were excluded from the calculation of internally invoiced goods and services — because already included in the costs claimed under another budget categories (e.g. LRI costs, indirect costs, in-kind contributions, etc.).*

- assess the acceptability of budgeted and estimated elements

  Examples:

  1. *For personnel costs: records that show the method for calculating the annual salary increases (e.g. consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases).*

  2. *For internally invoiced goods and services: traceable data used to determine the budgeted/ estimated elements; records on the nature and frequency of the updates of the budgeted and estimated elements; etc.*

- for personnel costs: verify the number of productive hours used to calculate the unit cost (hourly rate)

- for internally invoiced goods and services: verify that the cost items used for the calculation of the unit cost were directly linked to the production of the invoiced good or service.

Examples (not acceptable):

1. *Maintenance which goes beyond than the maintenance of the infrastructure/facilities used to produce the good/service (e.g. maintenance costs for all the beneficiary's cleanrooms; maintenance costs for an entire building, while the cleanroom used for the good/service occupies only a part of the building).*

2. *Generic supplies for which there is no evidence that they were directly linked to the infrastructure/facilities used to produce the good/service (e.g. electricity costs when there is no electricity counter or technical specifications to measure the consumption).*

By contrast, it is NOT necessary to keep records on the actual costs incurred (per person/good or service) — unless they are needed to document the usual cost accounting practices (as just described).

6. Certificate on the methodology (CoMUC)

What?

To get additional assurance, a beneficiary/linked third party may request that the Commission/Agency confirms that its cost accounting practices for personnel costs comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared *before* the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificate is NOT valid for H2020.)

When?

Beneficiaries may in principle submit their requests for approval at **any time** — before or during the grant.

Best practice: In order to ensure that the auditor has enough information to get assurance on the methodology, it is recommended to request it only *after* the first reporting period has passed.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

⚠ If the beneficiary declares personnel costs according to the changed cost accounting practices *before* the new certificate is approved, it bears the **full risk** of non-approval and cost rejection by the Commission/Agency.

How?

The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 of the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

⚠ For H2020, exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, monthly or per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a declaration on exclusive work for the action [ODT format] (one per reporting period), to confirm that the person worked exclusively for the action, either:

  - during the whole reporting period

  or

  - during an uninterrupted time-period, covering at least a full calendar month within the reporting period.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

  'Exclusive work' means that the person carried out NO OTHER activities for the beneficiary than those of the action.

  Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration. If a person worked randomly for the action after an

uninterrupted time-period covered by a declaration, time-sheets are needed for the period of random work.

> ***Example:*** *The person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

If a person worked under different regimes during the reporting period (exclusive and non-exclusive), the declaration may be used ONLY for a period of exclusive work. The other months must be recorded with time-sheets.

If there were several periods of exclusive work during one reporting period, the beneficiary may choose to use the declaration for the longest one (and use the monthly time-sheets for the others).

The declaration must be **dated** and **signed** by the person concerned AND her/his supervisor.

– keep **time records**.

Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

– show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

Time records should include, as a minimum:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record
- the supervisor's full name and signature
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template [ODT format] for time-sheets with these minimum requirements is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept **alternative evidence** if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has full discretion to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the **full risk** of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned

Criterion 2 is met – the project is identified as XYZ

Criterion 3 is met – the time is quantified: two weeks

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown

Criterion 2 is not met: the project name is not mentioned

Criterion 3 is not met – the time is not quantified

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Example: *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

1. *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*

2. *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

For **international partners,** beneficiaries must keep appropriate and sufficient evidence ONLY on scientific and technical implementation of the action. Beneficiaries are not required to prove the costs of the international partners, since the latter do not receive EU funding (*see Article 14a*).

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

'Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points.

The deliverables that must be produced are listed in Annex 1 of the GA.

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

Security obligations — If the deliverables contain **EU classified information**, the coordinator must first contact the Commission/Agency to discuss how to submit them (approval needed; *see Article 37*).

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

For deliverables that are not in writing *(e.g. cell line or prototype)*, the beneficiaries must submit a short written description.

How?

The coordinator must upload them directly in the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2 : *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

What & When?

In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of the action (reporting).

> These reports must be **distinguished** from **deliverables** (that are part of Annex 1; see Article 19) and milestones (that may be part of Annex 1, but are normally neither covered by Article 19 nor by Article 20).

The coordinator must submit both:

- a **periodic report** after the end of each reporting period (including the last one) and
- a **final report** at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically generated by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (CFS; one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration.

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

If the coordinator **breaches** its **obligation** to submit the reports, the Commission/Agency may suspend the payment deadline and — if not remedied after a written reminder — terminate the GA or take any of the other Chapter 6 measures *(e.g. cost rejection, grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50).*

> The GA will not be terminated if the breach concerns the last reporting period/final report (because the action duration is already over).

How?

The report(s) must be **prepared** by the **coordinator** and the **beneficiaries together** (directly in the Participant Portal Continuous and Periodic Reporting Modules).

List of documents for the periodic reports:

- explanation of the work carried out (periodic reporting - part B technical report)
- overview of the progress (periodic reporting - part B technical report)
- updated plan for the exploitation and dissemination of results (if necessary) (periodic reporting - part B technical report)
- summary for publication (continuous reporting)
- answers to the questionnaire (continuous reporting)
- individual financial statements for each beneficiary and linked party (periodic reporting - financial report)
- explanation of the use of resources (periodic reporting - financial report)
- summary financial statement (generated automatically by the IT system)
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication (generated automatically by the IT system)
- final summary financial statement (generated automatically by the IT system)
- certificates on the financial statements (CFS) (if necessary).

Generally, they can be **prepared together** (i.e. by several users from different beneficiaries), via the Participant Portal Continuous and Periodic Reporting Modules. The parts in the **continuous reporting** can be filled out at any moment in time (continuously open) and are then automatically added into the periodic or final report by the IT system *(part A of the technical report with the questionnaire and the summary for publication; consolidated financial statement*). Other parts are opened only at **periodic reporting** *(part B of the technical report, individual financial statements, explanation of the use of resources)*. Data is cross-linked to avoid duplication of data input *(e.g. the financial statement and the explanation on the use of resources are linked: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense, if necessary; the final report is completely automatized: assembled on the basis of elements from the periodic report).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (directly in the Participant Portal).

This includes the **coordinator**, who must also submit the individual financial statement for itself.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (since the linked third parties cannot sign them in the IT system).

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must ensure that the data encoded is correct (i.e. identical to the signed paper version).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

If a beneficiary cannot submit its individual financial statement on time, the report can be **submitted without this financial statement**. The costs will be considered zero

for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned.

⚠ **Record-keeping —** The beneficiary must keep the originals for itself and its linked third parties in its files *(see Article 18.1.2)*.

When all parts are ready, the report(s) are assembled automatically by the IT system and must be **submitted** by the coordinator (as a single package; **single submission**).

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator, as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) (**suspension of the payment deadline**). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified (**single re-submission**).

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

⚠ **Adjustments of financial statements (exceptional) —** If the beneficiaries notice a mistake *(e.g. incorrect accounting information; error in the calculation; etc)*, they can make an adjustment (positive or negative) in the following reporting period to the financial statements for any previous reporting period.

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed *(e.g. to take into account of a different hourly rate after the closure of the financial year)*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1

19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated **plan for the exploitation and dissemination of the results** (if such a plan is foreseen in Annex 1).

3.0 For grants signed after GA version 3.0, the overview of the progress must also indicate the communication activities carried out by the consortium *(see also Article 38.1).*

Security obligations — Technical reports may NOT contain any information that has been **EU-classified** in Annex 1 of the GA *(see Article 37).*

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an easy-to-read way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential (or EU-classified) information.

For the last reporting period: The summary should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact (because it will be directly re-used for the final report).

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the H2020 Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the H2020 Specific Programme)
- information to monitor the implementation of H2020 on cross–cutting issues *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Periodic financial report: Individual financial statements — Explanation of the use of resources — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 (**cost overruns**). The grant will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is generated automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact. It will be generated automatically by the IT system (on the basis of the summary for publication of the last reporting period).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically generated by the IT system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

Some beneficiaries/linked third parties must submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and unit costs calculated according to its usual accounting practices (average personnel costs and costs for internally invoiced goods and services).

This means that costs based on lump sums, flat-rates (*e.g. indirect costs*) or unit costs (other than those for personnel costs and costs for internally invoiced goods and services calculated according to the beneficiary's usual cost accounting practices) are NOT counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in an action which declared the following total eligible costs for the action:

- *personnel costs according to usual accounting practices = EUR 250 000*
- *subcontracting costs = EUR 40 000*
- *depreciation costs of equipment used to carry out the action = EUR 60 000*
- *indirect costs (25 % flat rate) = EUR 77 500*
- *total eligible costs claimed by A = EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and personnel costs according to usual accounting practices incurred by A (and hence the requested financial contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or unit costs calculated according to usual accounting practices must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency do not have to be covered again by the certificate.

Example:

A beneficiary participates in an action with three reporting periods. During the second reporting period the Commission's auditors carry out an audit of the costs incurred by the beneficiary in the first reporting period. At the end of the action, the beneficiary requests a total contribution of EUR 425 000 and has to submit a CFS with the final reports. In this case, the CFS may exclude the costs of the first reporting period (which were already covered by the Commission audit).

Linked third parties must submit a certificate if it reaches (on its own, without its beneficiary) the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

The certificate(s) may be submitted ONLY **with** the ***final*** **financial report**. Certificates submitted at any other moment will NOT be accepted (and costs incurred for them will be considered ineligible, because not necessary).

Costs for partial certificates (i.e. one certificate per reporting period) will be accepted ONLY in the last reporting period and ONLY if:

- a CFS is mandatory (i.e. the threshold is reached at the end of the action) and

- the total costs of the partial certificates is similar to the cost that would have been incurred for a single certificate.

The certificate must be issued by an **external auditor**, using the template in Annex 5 of the GA.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[40] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a non-EU country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in non-EU countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants above EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

A template is available and must be submitted via the Participant Portal Continuous Reporting Module.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:

[40] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

– daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

To calculate this rate, the beneficiaries may use the editable charts on the ECB website[41].

How to calculate the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart icon [ ] for the currency.

Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[42].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

[41] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[42] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts prior to that)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or an(other) executive agency — without the consent of the beneficiary concerned and up to the beneficiary's maximum EU contribution in Annex 2 *(see also Article 44)*.

All payments are subject to a **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request). The deadline depends on the type of payment:

- for pre-financing: 30 days
- for interim payments and payment of the balance: 90 days *(see Article 21)*.

If there are issues with the payment request or with the costs declared which make it impossible to comply with the payment deadline, the Commission/Agency will **suspend the deadline** *(see Article 47)*.

The pre-financing payment is automatic, while for interim and final payments the Commission/Agency must first:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs
- calculate the amount to be paid
- approve the payment request and authorise the payment.

This is not an in-depth verification and therefore no guarantee for eligibility or correctness. The costs may still have to be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

The payments are made **to the coordinator**; the beneficiaries are NOT paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only if the coordinator is terminated that the Commission/Agency (and especially the Guarantee Fund) will intervene; *see Article 50*).

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the **amount** is fixed in each GA.

Normally it will be (depending on the availability of EU budget credits) **100 %** of the **average EU funding per period** (i.e. maximum grant amount set out in Article 5.1 / number of periods) for actions with at least two reporting periods. It will be however less for actions with only one reporting period, since 100 % would mean the totality of the grant amount.

At the moment of the pre-financing, an amount that corresponds to **5 %** of the maximum grant amount *(see Article 5.1)* is **deducted** from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100 % reimbursement rate

Pre-financing: EUR 333 334 of which:

EUR 283 334 transferred to the consortium (coordinator)

EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 - EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until the payment of the balance — when they are cleared against the eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

How to calculate interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — **Rejection of ineligible costs & application of the reimbursement rate(s)**

Ineligible costs (i.e. costs that do not comply with one or more eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — **Limit to 90% of the maximum grant amount**

The interim payment is limited to 90 % of the maximum grant amount minus the pre-financing

Example for calculating interim payments:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1: application of reimbursement rate: 100% = EUR 585 000

Step 2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The **amount** of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples for calculating the payment of the balance:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.

Pre-financing of EUR 333 334 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).

Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.

Total eligible costs accepted for 1st interim period: EUR 570 000;

1st interim payment: EUR 566 666 (the 90% limit is reached).

Total eligible costs accepted for 2nd interim period: EUR 162 500.

2nd interim payment: EUR 0 (the 90 % limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*

Final grant amount: EUR 750 000.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*

The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 312 500 = EUR 1 045 000.

Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.

*EUR 150 000 will be **paid** to the coordinator as follows:*

- *EUR 100 000 directly by the Commission as payment of the balance; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 155 000*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 155 000 = EUR 887 500.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Commission/Agency checks

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Agency performs a plagiarism check on documents submitted by the consortium.*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in EU actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The checks itself are **internal**. They may however have external effects, since the Commission/Agency may have to **ask** the coordinator (or directly the beneficiaries) for **additional information** needed for the check *(see Article 17.1)* or it may take Chapter 6 measures in view of the results.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date.*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. In this case, the Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

If the check shows **ineligible costs** or serious **breach of obligations**, it may lead to cost rejection or grant reduction and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission/Agency may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Commission/Agency reviews

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA and may exceptionally also concern issues related to only one specific beneficiary.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows **ineligible costs** or **substantial errors, irregularities or fraud** or serious **breach of obligations** (including non- or improper implementation of the action as described in Annex 1), it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (or, exceptionally, the beneficiary concerned) via the Participant Portal.

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or a **review meeting** (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a **review report**.

> The review report together with the Commission/Agency comments will be notified to the coordinator (or, exceptionally, the beneficiary concerned) for comments within 30 days (**contradictory review procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The Commission/Agency operational services (authorising officers) will analyse the comments received and decide on the follow-up, if any.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Commission/Agency audits

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ **Record-keeping** — Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including cost rejection, grant reduction, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit **third parties providing in-kind contributions** (free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to:*

- *see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest)*
- *see if payments made under the contract/subcontract match the costs declared by the beneficiary*
- *assess the technical work carried out by the subcontractor.*

The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to check the contractors'/subcontractors' costs or accounts, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).

4. *The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and, in very serious cases, to exclusion and/or financial penalties *(see Article 45)*.

In some cases, findings may result in the **acceptance** of additional costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about actual costs for cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the Participant Portal or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an **audit report**.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days (**contradictory audit procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the **final audit report** and the **letter of audit conclusions** (LoC) — and the file will then be passed on to the Commission/Agency operational services (authorising officers) for the follow-up, if any.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[41] and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. OLAF investigations

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the outcome of the investigation to the Commission/Agency, who will then decide how to proceed.

If an OLAF investigation shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50),* to exclusion and/or financial penalties *(see Article 45),* as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. ECA checks and audits

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

If an ECA check or audit shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, this may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION 2:** Not applicable.]*

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

⚠ Checks, reviews, audits and investigations must however respect the privileges and immunities accorded to an international organisation by its constituent documents or international law.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the **findings concern substantial errors, irregularities or fraud or serious breach of obligations,** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings (rejection and grant reduction)

If the Commission/Agency finds (in a check, review, audit or investigation) **substantial errors, irregularities or fraud** or serious **breach of obligations** which are **systemic** or **recurrent**, it may make a correction (cost rejection or grant reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed (extension of the findings)
- other H2020 grants of the beneficiary (extension of the findings).

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

Findings may be extended to all other EU or Euratom grants awarded under similar conditions.

⚠ Findings will normally be extended only within one programme *(e.g. findings in an H2020 audit to all H2020 grants)* but they may exceptionally also be extended to similar programmes *(e.g. if justified by the nature of the findings and the similarity of the applicable grant agreements or in case of serious irregularities or fraud).*

2. Procedure

If findings are systemic or recurrent**,** this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an audit extension procedure (which is then followed by an audit/review implementation procedure).

Procedure for extension of findings and audit implementation:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure (**letter of audit conclusions**), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for cost rejection:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (if the beneficiary does not submit revised financial statements)
  - the conditions for external counter-audits to propose an alternative correction method *(see below)*
- for grant reduction: the proposed flat-rate for the correction.

The 'extrapolation rate' will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The 'flat-rate' will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept the alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for cost rejection: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for grant reduction: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has **full discretion** to accept or refuse an alternative correction method proposed by the beneficiary and there is NO entitlement to it.

Step 3 — **Audit implementation**

If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the cost rejection/grant reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the cost rejection/grant reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:** five]**[OPTION 2 for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the H2020 Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the H2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of H2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[43] annexed to the EU Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[43] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

> **Best practice:** Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

> ***Examples:*** *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[44]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[44] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or '**associated country**'[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

Access rights are therefore normally limited to other beneficiaries and certain affiliated entities of other beneficiaries, unless otherwise agreed.

Example: *Beneficiary A used background from beneficiary B to generate its results. Beneficiary A would like to use its affiliated entity A established in a MS to exploit the results. For this, affiliated entity A needs access rights to beneficiary B's background.*

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 <u>Rights of third parties</u> (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Record-keeping

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. subcontractors, linked third parties, international partners, employees, etc.)*.

> ***Examples (third parties that may claim rights):*** *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action (if they have rights under national law or their contract); beneficiaries for which linked third parties carry out a significant part of the work.*
>
> ***Examples (arrangements):*** *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

> **Best practice:** Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

> ***Example (no protection necessary):*** *if protection is impossible under EU or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.)*

> **Best practice:** Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Standard forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

1. *For an invention: e.g. patent, confidential information.*

2. *For the design of a technology: e.g. industrial design, copyright.*

3. *For a website: e.g. industrial design, copyright, trademark.*

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example (better not to protect for the moment): *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3)*.

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (using the text of the GA language version available on the Participant Portal Reference documents page).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the plan for the exploitation and dissemination of the results.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

⚠ Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018'];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1 for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2**: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security obligations, etc.)*.

Security obligations — Dissemination may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

Results that contain **EU-classified information**, can be disclosed only after approval by the Commission/Agency *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The beneficiaries may choose the **form** for disseminating their results.

Standard forms of dissemination:

- website
- presentation at a scientific conference
- peer-reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination — unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

2. Open access to scientific publications

What?

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals)*.

⚠ Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications.

Best practice: Open access has no impact on the other terms and conditions that apply to scientific publications *(e.g. as regards use, etc)*. However, in order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights such as the right to copy, distribute, search, link, crawl and mine).

A 'repository for scientific publications' is an online archive. Beneficiaries are free to choose the repository; it can be institutional, subject-based or centralised.

Best practice: The Open Access Infrastructure for Research in Europe (OpenAIRE) links existing repositories. It is not obligatory for projects to deposit in OpenAIRE itself, but it is the recommended entry point for researchers deciding on a repository. OpenAIRE also offers support services for researchers, such as the National Open Access Desks. Other useful listings are the Registry of Open Access Repositories (ROAR), the Directory of Open Access Repositories (OpenDOAR) and OAPEN (for monographs). Beneficiaries should not choose a repository with rules which could conflict with open access.

Open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets certain requirements that must be fulfilled if they do decide to publish them.

Open access can be provided through:

a) **gold open access** (**open-access publishing**)

'Gold open access means that open access is provided immediately via the publisher when an article is published, i.e. where it is published in open access journals or in 'hybrid' journals combining subscription access and open access to individual articles.

In gold open access, the payment of publication costs (article processing charges) is shifted from readers' subscriptions to (generally one-off) payments by the author. Such author processing costs may be eligible *(see Article 6.2.D.3)* — if incurred before the end of the action. Currently, an action for dealing with such costs incurred after the end of the action in FP7 is being piloted and further action in H2020 will be considered based on the outcome.

⚠ Although gold open access already ensures access via the publisher, the beneficiaries must nevertheless also provide open access via a repository *(see below)* in order to ensure the long-term preservation and availability of the publication.

b) **green open access** (self-archiving).

'Green open access' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in an online repository. Access to the article is often — but not necessarily — delayed (H2020 embargo period between 6 and 12 months; *see below*) as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download view fees during an exclusivity period.

Best practice: Authors are encouraged to retain their copyright and grant appropriate licences to publishers.

A template for an **open access clause** addendum which can be added to **publishing agreements** is available on the Participant Portal.

How?

Open access to scientific publications involves four steps — which may or may not be taken at the same time.

Procedure for open access (scientific publications):

Step 1 — **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication).

This must be done as soon as possible (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*) and at the latest on publication.

'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

Step 2 — Provide **open access** to the scientific **publication** — either as 'gold open access (i.e. via the publisher AND via the repository) or as 'green open access (i.e. via the repository only).

Open access must be given:

- in case of 'gold open access': at the latest on publication
- in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

Step 3 — Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

This is needed for visibility, traceability and monitoring.

It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and
- a persistent identifier *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

Best practice: For ease of tracking, beneficiaries should also include the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601) in the funding acknowledgement field in their metadata.

The metadata compliance of the repository can be checked using OpenAIRE.

Step 4 — Aim to **deposit** at the same time, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

ℹ For more information on why open access to scientific publications and digital research data is an important aspect of Horizon 2020, *see the Online Manual.*

3. Open access to research data (Extended Open Research Data Pilot)

What?

Beneficiaries of actions that participate in the Open Research Data Pilot must give **open, free-of-charge access** to the end-user to **digital research data** generated during the action (⚠ new in Horizon 2020).

⚠ As of the Work Programme 2017, the Open Research Data pilot has been extended to all thematic areas of Horizon 2020 (except ERC PoC actions, SME instrument Ph1 actions, ERA-NET Cofund actions that do not produce data, EJP Cofund actions, and prizes).

Participation is therefore now in principle **the default**. However, actions may **opt out** at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55)* —, if:

- participation is incompatible with the obligation to protect results *(see Article 27)*

- participation is incompatible with the security obligations *(see Article 37)*
- participation is incompatible with rules on protection of personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate/collect any research data or
- there are other legitimate reasons not to take part.

'Digital research data' is information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Only data that is generated digitally *in the action* is concerned. Actions are encouraged to digitise any other data and provide open access to it, but they are not obliged to do so.

The pilot applies to **2 types** of digital research **data**:

- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data and associated metadata, as specified by the beneficiaries themselves in their data management plan.

Examples: *curated data not directly attributable to a publication or raw data*

⚠ Beneficiaries may decide not to provide open access to specific datasets if this would go against other GA obligations *(e.g. to protect results or personal data)* or if the action's main objective, as described in Annex 1, would be jeopardised by giving open access to those specific datasets. In this case, the reasons must be explained in the data management plan, *see below*).

Open access to research data means taking measures to make it possible for third parties to **access, mine, exploit, reproduce** and **disseminate** data — via a research data repository.

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories (Re3data) and Databib. One key entry point for accessing and depositing related data and tools is Zenodo.

Actions participating in the pilot must draw up a **data management plan (DMP)** within the first 6 months of the project implementation.

The data management plan must support the management life-cycle for all data that will be collected, processed or generated by the action. It must cover how to make data findable, accessible, interoperable and re-usable (FAIR), including:

- the handling of data during and after the project
- what data will be collected, processed or generated
- what methodology and standards will be applied
- whether data will be shared / made open access (and how) and, if any, what data will not be shared / made open access (and why)
- how data will be curated and preserved.

The data management plan should be updated (and become more precise) as the project evolves. New versions should be created whenever important changes to the project occur *(e.g. new data sets, changes in consortium policies, etc.),* at least as part of the mid-term review (if any) and at the end of the project.

For more information on data management plans (and a template), *see the proposal forms and the Online Manual.*

Costs related to the implementation of the Open Research Data pilot *(e.g. costs for providing open access, related research data management costs, data curation and data storage costs)* may be eligible *(see Article 6.2.D.3)*.

How?

Open access to digital research data involves 3 steps:

Procedure for open access (research data):

Step 1 — **Deposit** the digital research data, preferably in a research data repository.

Step 2 — Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. for databases: by attaching an appropriate creative commons licence (CC-BY or CC0 tool) to the data; if the access/use is not subject to any rights: by indicating that no licence is needed)*.

Open access must not be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

Step 3 — Provide **information**, via the repository, about **tools and instruments** for validating the results.

Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.).*

For more information on the research data pilot (and especially how actions may opt out or opt in), see *the Online Manual.*

4. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of the dissemination activity (using the text of the GA language version available on the Participant Portal Reference documents page).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

Combining H2020 & other EU grants — If the outputs were developed in another EU-funded action (funded not by H2020, but another EU funding programme, including Structural Funds/ESIF Funds), do NOT forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION 2 for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results.

> ⚠ **Security obligations —** Transfer may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a global authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, the beneficiary must **formally notify in advance** (via the Participant Portal) any transfer to a specifically-identified third party established in a non-associated third country — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — Common legal structures (CLS) (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights and other access rights are preserved, *(e.g. the access rights of the EU, Member States and third parties; see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a non-associated third country.

> ⚠ As of the Work Programme 2018, the calls will normally already indicate if this option will be activated in the GAs. The option may however still be activated (without such indication):
>
> – for calls which do not fix the type of research and innovation activities ("bottom-up" calls, such as FET Open or MSCA) or
>
> – in other calls, exceptionally, if justified by the nature of the research and innovation activities or other action-related reasons.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiary must **formally notify** the Commission/Agency **in advance** (via the Participant Portal) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

A notification before the results are generated is allowed, if the specific results concerned (and the details of the transfer/licence) can already be identified.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 <u>Access rights for the EU institutions, bodies, offices or agencies and EU Member States</u>

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION 2 for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION 3 for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[47], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION 1b for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION 1d for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION 2:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results

– by an affiliated entity of another beneficiary (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

***1.** If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).*

***2.** If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.*

How?

Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

– for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

Fair and reasonable conditions includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicensing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

1. *A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.*

2. *In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.*

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [48], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[45] and the Code of Conduct for their Recruitment.[46]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

⚠ **Record-keeping —** Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

[45] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[46] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[47] and of the Code of Conduct[48] that relate to recruitment, working conditions and career development.

For guidance, *see the 'Human Resources Strategy for Researchers' tool developed by the Commission.*

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[49])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism

[47] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[49] Available at http://ec.europa.eu/euraxess/jobs

– the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more information on gender in research, *see the Online Manual.*

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

– present their research goals and intentions in an honest and transparent manner;

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3]* as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced ;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the Commission's **H2020 ethics appraisal scheme** (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

- ethics *self*-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more information on ethics, *see the Guidance — How to complete your ethics self-assessment, the Guidance note — Research involving dual use items, the Guidance note — Research focusing exclusively on civil applications, the Guidance note — Potential misuse of research results and more generally, the Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State.

The beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that the research results cannot peripherally be useful in a military context. Research related to *dual-use* products or technologies (usually used for civilian purposes but with possible military applications) is not prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

Beneficiaries must commit to the highest standards of research integrity (as set out, for instance, in the European Code of Conduct for Research Integrity[50]) and comply with the essential research integrity principles listed in Article 34.1.

Essential research integrity principles:

- honesty
- reliability
- objectivity
- impartiality
- open communication
- duty of care
- fairness and
- responsibility for future science generations

According to these principles, beneficiaries must ensure that their researchers:

- present their research goals and intentions in an honest and transparent manner
- design their research carefully and conduct it in a reliable fashion (taking its societal impact into account)
- use appropriate techniques and methodologies (including for data collection and management)
- exercise due care for research subjects (human beings, animals, environment or cultural objects)
- ensure objectivity, accuracy and impartiality when disseminating the results
- allow access to research data (as much as possible and taking into account the legitimate interest of the beneficiaries and open access obligations, if any)
- make the necessary references to their work and that of other researchers
- refrain from practicing any form of plagiarism, data falsification or fabrication

[50] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

– avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define **ethics requirements** and include them as **deliverables** in Annex 1 of the GA.

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

Examples (ethics deliverables): *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

Examples (other ethics requirements): *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

Best practice: When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18)*.

The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

If the documents are not in English, the beneficiary may be asked to provide an English summary.

This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.

Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

The Commission/Agency may carry out **ethics checks, reviews or audits**, to ensure that the beneficiaries have properly implemented the ethics requirements and obtained the opinions/notifications/authorisations *(see Article 22)*.

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

Activities that involve human embryos (hE) or human embryonic stem cells (hESC) can only be funded, if:

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[51] (in particular, do NOT result in the destruction of human embryos)

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

[51] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  1. *A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.*

  2. *A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.*

  3. *A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).*

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits*.

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  1. *If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.*

  2. *If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.*

  3. *If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.*

If there is a **(risk of) a conflict of interests**, the coordinator must **inform** the Commission/Agency (via the Participant Portal), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Security obligations — Stricter confidentiality obligations apply for information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[51] *— until it is declassified.*

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].****[OPTION 2:*** *Not applicable.****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION 2: *Not applicable****]***

37.4 Consequences of non-compliance

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable.****]***

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

1. Results with a security recommendation — EU-classified information

If the GA provides for (one of) these options, the beneficiaries must comply with the **security obligations** set out in this Article, in Annex 1 and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises security issues and must be subject to a security recommendation and/or EU-classification under Decision No 2015/444[52].

For more information on security obligations, *see the Guidance — Guidelines for the classification of information in research projects, the Guidance — Guidelines for the handling of classified information in EU research projects, the Guidance note — Potential misuse of research results and, more generally, the Online Manual.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[53].

Moreover, the coordinator must — before the start of the activity for which it is needed — submit a **copy** of any **export** or **transfer licence**.

For more information on dual use goods, *see the Guidance — How to complete your ethics self-assessment* and the *Guidance note — Research involving dual use items.*

[52] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[53] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and] Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is] [are]* not responsible for any use that may be made of the information it contains.

1. Communication activities (beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[54].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a beneficiary in a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to **multiple audiences** (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a **major media impact** (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

[54] For the definition of 'communication activities', *see the Glossary.*

Security obligations — Information given may NOT include **EU-classified information** or information on results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the classification of information in research projects, Guidance — Guidelines for the handling of classified information in EU research projects and, more generally, the Online Manual.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the proposal templates*) and be included in Annex 1 and 2.

For more information on promoting the action, *see the Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the **EU emblem**

AND

- including the **reference to EU funding** set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity or, for infrastructure, equipment or major results, the official language(s) of the country where they are located (using the text of the GA language version available on the Participant Portal Reference documents page).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object).

Examples: *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency; the]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of *[the Agency or]* the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency and the]* Commission will insert the following information:

> "© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the measures described in Chapter 6.

1. Communication activities (Commission/Agency)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material):*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its Participant Portal privacy statements.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligibility of costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the EU financial interests).

When the Commission/Agency collects and processes personal data under the GA, national data protection law is NOT applicable and will NOT be accepted as a pretext for not complying with obligations under the GA.

Disclosure of staff data under the GA *(e.g. data requested by the Commission/Agency project officer or auditors)* is automatically justified under Article 5(c) of Regulation 45/2001.

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[55] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

Persons whose data is being processed (data subjects) can contact the data controller or the DPO (via the contact information in the privacy statement), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

[55] Available at http://ec.europa.eu/dpo-register/search.htm.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (beneficiaries)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[56] and the corresponding national law).

The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [57]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc*.

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage

[56] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[57] *See Article 8 of Directive 95/46/EC*.

- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[58]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the relevant Participant Portal privacy statement).

Examples:

1. *Before encoding staff data in the Beneficiary Register or into a proposal, the beneficiary must provide the staff concerned with the privacy statement.*

2. *If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the privacy statement.*

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[58] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What?

The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How?

Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

1. *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.*

2. *Assignment for the benefit of creditors in a bankruptcy procedure.*

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

[OPTION to be used when the beneficiary is an European Research Infrastructure Consortium (ERIC)*[54] *without own resources:** As an exception, the beneficiary delegates the tasks set out above to [insert name of member of the ERIC]. The beneficiary retains sole responsibility for compliance with the obligations under the Agreement.]

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is NOT responsible for the implementation of the action and has NO responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them **withdraws**, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless the Commission/Agency expressly agrees otherwise (exceptional; only for specific reasons). They will have to do this without any additional funding (although — in case of beneficiary termination — the Guarantee Fund may intervene for the defaulting beneficiary; *see Article 50*).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% contribution to the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

Specific cases (beneficiaries' responsibilities):

ERIC (European Research Infrastructure Consortium)[59]: If the beneficiary is an ERIC which does not have its own resources, it may exceptionally delegate the following responsibilities to one of its members:

- monitor that the action is implemented properly *(see Article 7)*
- inform about events or circumstances likely to affect significantly or delay the action

[59] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1).

implementation *(see Article 17.2)*
- submit deliverables and reports *(see Articles 19 and 20)*
- submit documents or information required

⚠ An ERIC using one of its members remains **fully responsible** for it under the GA.

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION 1 for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION 2: *Not applicable****]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly *(see Article 22)*.

Example:

In case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can normally NOT be subcontracted or outsourced to a third party (including linked third parties). They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use linked third parties for *other* tasks; *see Articles 13, 14*).

Specific cases (coordinator's responsibilities):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- they must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs (and those must include receiving and administering EU funds).

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It also will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

ERICs (European Research Infrastructure Consortia)[60]***:*** Beneficiaries that are ERICs and do not have their own resources may exceptionally delegate the following coordination tasks to one of its members:

- monitor that the action is implemented properly *(see Article 7)*;
- act as intermediary for communications *(see Article 17)*;
- request and review documents or information required and verify completeness and correctness;
- submit deliverables and reports *(see Articles 19 and 20)*;

⚠ ERICs using one of their members remain **fully responsible** for it under the GA.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article, *e.g. scientific coordination of the action*) can be carried out by any beneficiary.

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it will however NOT be considered the action's coordinator (but one of the other beneficiaries).

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

> **Best practice:** In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before

[60] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1)

acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see the Online Manual and the Guidance — How to draw up your consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted ONLY for complementary actions *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted ONLY for jointly funded actions *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the grant agreements and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see the Online Manual and the Guidance — How to draw up your coordination agreement.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Cost rejection

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

Cost rejections will be made for **violations of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Grounds for cost rejection (Commission/Agency):

- **Costs** do **not comply with** the GA **eligibility rules (in this grant)**

  The Commission/Agency will reject costs, if they do not comply with the eligibility rules set out in Articles 6 and 8-16.

- **Costs** do **not comply with** the GA **eligibility rules (in other grants)**

  The Commission/Agency may also reject costs, if such ineligibility was found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the ineligibility is:
    - systemic or recurrent and
    - has a material impact on this grant.

Rejection of costs can take place at any moment — at the time of beneficiary termination, interim payment, payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if cost rejection leads to a recovery: there will be an *ex ante* **contradictory procedure**
- if cost rejection does NOT lead to a recovery: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection (**payment review procedure**).

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post payment review procedure allows the

Commission/Agency however to pay quickly without having to suspend the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Payment review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out (**notification of amounts due**; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections.

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for rejections at the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after beneficiary termination and after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

Information obligation — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Cost rejection at the time of an interim payment or payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) at the moment **of** an **interim payment** or the **payment of the balance**, it will deduct them and calculate the **amount to be paid** accordingly.

If ineligible costs (declared in a previous report and already paid for) are found **in-between payments**, the Commission/Agency will reject them at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example for calculating a rejection at an interim payment:

Case 1: *Action with three beneficiaries (A, B andC) and a reimbursement rate 100 %.*

Maximum grant amount: EUR 500 000.

Pre-financing: EUR 200 000.

Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25 %) = EUR 118 750 .

Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25 %) = EUR 143 750.

Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25 %) = EUR 112 500.

Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Application of the reimbursement rate 100%: EUR 362 500

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.

Amount due as interim payment: EUR 250 000

Case 2 (in between payments): *Total costs declared for the action in the 1st periodic report: EUR 375 000.*

Interim payment for the 1st periodic report = EUR 375 000

Costs rejected after interim payment or 1st periodic report: EUR 12 500

Total costs declared and accepted for the action in 2nd periodic report = EUR 100 000

Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 – EUR 12 500 = EUR 87 500.

4. Cost rejection after beneficiary termination

If the Commission/Agency rejects costs **after beneficiary termination**, it will deduct the rejected amount from the costs the beneficiary declared in the **termination report** and calculate **the amount due** to the beneficiary *(see Articles 50.2 and 50.3)*.

> Only costs incurred by the beneficiary concerned until termination takes effect are eligible. Costs relating to contracts due for execution only after termination are NOT eligible.

If the amount which is due to the beneficiary is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will **recover** the difference *(see Article 44)*.

> Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

Example for calculating a rejection after beneficiary termination:

Grant with 5 beneficiaries (A, B, C, D and E).

Maximum grant amount: EUR 500 000 (beneficiary maximum EU contribution: each beneficiary 100 000 EUR).

Reimbursement rate: 100 %.

Pre-financing: EUR 200 000.

Beneficiary termination:

Beneficiary A goes bankrupt in the middle of the action and its participation is terminated.

Eligible costs declared by beneficiary A in termination report: EUR 50 000 (direct costs) + EUR 25 000 (25 % flat rate for indirect costs) = EUR 62 500.

Costs rejected for beneficiary A following audit: EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

No grant reduction.

The amount which is due for beneficiary A: EUR 62 500 – EUR 12 500 = EUR 50 000

Recovery:

Payments received by beneficiary A (according to the report on the distribution of payments): EUR 40 000.

Amount to be recovered from beneficiary A: EUR 40 000 – EUR 50 000 = EUR - 10 000 (no recovery; the positive balance of EUR 10 000 will be paid out at the next interim payment).

5. Cost rejection after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*.

If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will **recover** the difference *(see Article 44)*.

Example for calculating a rejection after the payment of the balance:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 – EUR 30 000 = EUR 120 000 + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

The share of Beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **redu**ces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Grant reduction

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* **substantial errors, irregularities or fraud** or **breach of obligations** (under the GA or during the award procedure; *e.g. the action has not been properly implemented)*, it may reduce the grant amount— in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations.

⚠ **Grant reductions** will be made (at the end of the action) for substantial errors, irregularities or fraud or serious breach of obligations, in proportion to the seriousness of the error, irregularity, fraud or breach *(e.g. in case of fraud the reduction may be up to a 100%)*.

⚠ If the issues are found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

Grounds for grant reduction (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may make a grant reduction, if a beneficiary has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also make a grant reduction, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

3.0 Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol[61]).

Grant reduction can take place:

- after beneficiary termination
- at the payment of the balance or
- after the payment of the balance.

3.0 Reduction at beneficiary termination was introduced explicitly with GA version 3.0. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of

[61] See judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128.

contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination is possible for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 *(see above)*.

A grant reduction can also be imposed on beneficiaries not receiving EU funding *(e.g. for improper implementation by the beneficiary; see Article 9)*.

2. Procedure

The Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42*).

Depending on the moment the reduction takes place, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for reductions after beneficiary termination: normally with the beneficiary concerned
- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Grant reduction after beneficiary termination

If the Commission/Agency reduces the grant **after beneficiary termination**, it will calculate the reduction at beneficiary-level and calculate the **amount due** to the beneficiary *(see Articles 50.2 and 50.3)*.

If the amount which is due to the beneficiary is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will **recover** the difference *(see Article 44)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

4. Grant reduction at the payment of the balance

If the Commission/Agency reduces the grant at the **payment of the balance**, it will make the reduction at action-level and calculate the balance to be paid to the consortium (i.e. final grant amount) accordingly.

Example for calculating a reduction at the payment of the balance:

Consortium with a maximum grant amount of EUR 3 000 000 (100% reimbursement rate)

Pre-financing: EUR 750 000

Interim payments: EUR 1 500 000

Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carried out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20 % (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000 – EUR 600 000 = EUR 2 400 000

Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = EUR 2 400 000

Payments already made (pre-financing + interim) EUR 2 250 000 = EUR 750 000 + EUR 1 500 000

Amounts due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000)

5. Grant reduction after payment of the balance

The financial consequences of a grant reduction **after the payment of the balance** will be calculated at beneficiary level for each beneficiary concerned.

The 'beneficiaries concerned' are those who have committed irregularities, errors or fraud or have breached their obligations *(for example, improperly implemented the action, submitted false information, failed to submit required information or breached the ethical principles)* resulting in the reduction.

Procedure for reduction of the grant after payment of the balance:

The Commission/Agency:

Step 1 — Determines the amount to be reduced (in proportion to the seriousness of the errors, irregularities or fraud or the breach of obligations).

Step 2 — Identifies the beneficiaries in fault and allocates that amount among them according to their responsibility in the errors, irregularities or fraud or breach of obligation.

If the breach of obligation cannot be linked to one or more specific beneficiaries (and therefore concerns the whole consortium) each beneficiary will have to bear a pro-rata share of the reduction.

For each of those beneficiaries (the 'beneficiaries concerned'):

Step 3 — Determines the beneficiary's **share in the final grant amount'**, as follows:

{{total accepted eligible costs for the beneficiary x reimbursement rate}[62]

divided by

{sum of total accepted eligible costs x reimbursement rate, for each beneficiary}[63]

multiplied by

the final grant amount before the reduction (see Article 5.3)}

Step 4 — Calculates the beneficiary's **revised final grant amount** as follows:

{total accepted eligible costs for the beneficiary x reimbursement rate}[64] – amount of reduction allocated to the beneficiary under step 2

[62] Plus the same formula applied to third parties linked to the beneficiary (if any).
[63] Including linked third parties.

Step 5 — If **revised final grant amount < share in the final grant amount**, the Commission / Agency will recover the difference from the beneficiary.

Example for calculating a reduction linked to (one or more) specific beneficiaries:

Innovation action with beneficiaries: X, Y and Z. Beneficiaries X and Z are non-profit legal entities with a 100% reimbursement rate. Maximum grant amount = EUR 2 900 000.

Situation at payment of the balance:

	Data source		*Beneficiary X*	*Beneficiary Y*	*Beneficiary Z*	*Total*
	Annex 2 (estimated budget)	*Estimated costs budgeted*	*700 000*	*2 000 000*	*800 000*	*3 500 000*
A		*Reimbursement rate (%)*	***100***	***70***	***100***	
B		*Maximum grant amount according to costs budgeted*				*2 900 000*
C	*Final financial statements*	*Beneficiary's total accepted eligible costs*	*825 000*	*1 850 000*	*800 000*	*3 475 000*
D	*First step for the calculation of the "Final Grant Amount (Article 5.3.1)*	*Beneficiary's total accepted costs x reimbursement rate (C x A)*	*825 000*	*1 295 000*	*800 000*	*2 920 000**

** The final grant amount is capped at EUR 2 900 000 (maximum grant amount). Even if D results in a higher amount, the Commission/Agency can never pay more than the maximum grant amount set in the GA.*

Following a review after the payment of the balance, the Commission decides to reduce the grant due to improper implementation because some of the action tasks were not carried out.

Step 1 Reduction of the maximum grant amount:

The Commission decides on the amount to be reduced in proportion to the improper implementation identified

Example: *the Commission decides to reduce the maximum grant amount by EUR 300 000.*

Step 2 Identification of the beneficiaries concerned and allocation of the amount to be reduced:

The review concluded that the improper implementation was due to the fact that beneficiary X carried out only part of its tasks as set out in Annex 1. Therefore, the reduction is allocated in full to beneficiary X (see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

[64] Plus the same formula applied to third parties linked to the beneficiary (if any).

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*300 000*	*0*	*0*	*300.000*
G	*Beneficiary's revised final grant amount (D - F)*	*525 000*	*1 295 000*	*800 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*294 349*	*0*	*0*	*294 349*

The amount to be recovered is less than the amount reduced because of the overspending (eligible costs that were declared but not taken into account at payment of the balance because of the capping at maximum grant amount).

For recovery (see Article 44.1.3)

Example for calculating a reduction NOT linked to (one or more) specific beneficiaries:

Same example as above except that the reduction is not linked to specific beneficiaries.

The review concluded that the improper implementation was due to the consortium as a whole and cannot be attributed to (one or more) specific beneficiaries. The amount to be reduced is therefore allocated evenly among the beneficiaries (300 000 / 3 = 100 000; see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*100 000*	*100 000*	*100 000*	*300 000*
G	*Beneficiary's revised final grant amount (D - F)*	*725 000*	*1 195 000*	*700 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*94 349,32*	*91 130,14*	*94 520,55*	*280 000*

For recovery (see Article 44.1.3)

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION 2:** not applicable**];***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**] [OPTION 2:** not applicable**]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to early termination, cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to its maximum EU contribution in Annex 2.

Grounds for recovery (Commission/Agency):

- Commission/Agency **paid too much**

  The Commission/Agency will make a recovery, if the amounts paid out exceed the amounts that are due for the grant.

Recovery normally takes place only at payment of the balance or afterwards. Exceptionally, it can take place before, if a beneficiary's participation is terminated.

2. Procedure

The basic procedure for recovery is almost always the same: After a **contradictory procedure**, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — **Contradictory procedure**

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — **Confirmation of recovery**

The Commission/Agency examines the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — **Recovery**

If the coordinator/beneficiary concerned does not pay by this date, the Commission or the Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

– by **offsetting** it[65]

'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 TFEU action, arbitration, etc.; *see Article 57.2*).

Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission or the Agency may offset before this date, in order to safeguard the EU financial interests.[66]

If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. (The interest is normally offset first, before the principal amount).

– by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  – if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  – by either:

    – taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or

    – adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU[67].[68]

      The decision describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

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65 *See Article 80(1) of the Financial Regulation No 966/2012.*

66 *See Article 87 of the Rules of Application Regulation No 1268/2012.*

67 *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

68 *See Article 79(2) of the Financial Regulation No 966/2012.*

This decision — duly endorsed with the order for enforcement issued by the competent authority in the Member State concerned — allows to have the debtor's **assets seized**.

The contradictory procedure will normally be **combined** with the **contradictory procedure** for cost rejection and/or grant reduction (if any).

3. Recovery after beneficiary termination

The Commission/Agency will recover **after beneficiary termination**, if the beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

4. Recovery at the payment of the balance

The Commission/Agency will recover at the **payment of the balance**, if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the report on the distribution of payments.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the Guarantee Fund. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified AND if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** alone.

For the rest of the procedure, *see point 2*.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, BUT has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds in excess**, the amount each beneficiary *actually* received (as established on the basis of the report on the distribution of payments) is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The **share in the final grant amount** is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the

final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage obtained to the final grant amount.

In practice:

- **for underspent GAs:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with *Article 5.3.1)* is lower than the maximum grant amount set out in Article 5.1 (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for overspent GAs:** each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess — for its proportional share in the debt to the Commission/Agency.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery at the payment of the balance:

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100 %
Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)

Total eligible costs approved by the Commission: EUR 2 430 000

Final grant amount: EUR 2 430 000

EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000

Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Amount to be recovered: EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5 % of the maximum grant amount; see Article 21.2) = EUR 150 000. Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:

A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

Identification of the beneficiaries that received funds in excess:

Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);

Beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)

Beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);

Beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:

The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.

Total payments made in excess = 320 000.

Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.

Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.

Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

***The Commission will notify three debit notes for a cumulative amount of EUR 120,000** (270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium.

5. Recovery after payment of the balance

The Commission/Agency will recover **after payment of the balance**, if — due to cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid too much (or that the coordinator has not distributed the payments received).

Procedure for recovery after payment of the balance (due to cost rejection):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised final grant amount for the beneficiary concerned with its share of the final grant amount.

The **share of the final grant amount** is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage obtained to the final grant amount.

In practice:

- **for underspent GAs:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with *Article 5.3.1)* is lower than the maximum grant amount set out in Article 5.1 (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for overspent GAs:** each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

Procedure for recovery after payment of the balance (due to grant reduction):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised final grant amount for the beneficiary concerned with its **share of the final grant amount** *(see point 4)*.

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery after payment of the balance (underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:

(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The amount to be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example for calculating a recovery after payment of the balance (overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C

Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000

Reimbursement rate for all the beneficiaries: 100%

Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000

Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000

Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000

Total eligible costs of the consortium approved by the Commission = EUR 600 000

Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary's accepted costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*

Total accepted costs for the action according to Article 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667

Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000

Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Calculation of the revised grant amount after the audits:

The revised final grant amount is calculated as follows:

For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500

For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Calculation of the amount to be recovered:

The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount

For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered

For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. Since for beneficiary C the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

1. Administrative sanctions

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary is in an exclusion situation under Article 106(1) of the Financial Regulation No 966/2012, it may impose administrative sanctions (— in proportion to the seriousness of the misconduct).

Administrative sanctions (financial penalties and/or exclusion from future procurement contracts, grants and expert contracts) are **public law measures** (i.e. taken directly on the basis of Articles 106 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(substantial errors, irregularities or fraud, serious breach of obligations, bankruptcy, non-compliance with tax or social security obligations, grave professional misconduct, fraud, corruption, or criminal/illegal activity).*

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum sanctions** are as follows:

- for exclusion: up to **5 years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the sanction and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again, the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget (Annex 2) — depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again, the rate may be increased to between **4%** and **20%**.

The decision to apply an administrative sanction may be **published** on the Commission/Agency websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU's financial interest and image)

- the time that has elapsed since it took place

- the duration and recurrence of the misconduct
- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

The Commission/Agency will follow the procedures set out in 106 of the Financial Regulation No 966/2012 (i.e. **contradictory procedure, panel, decision)**.

If the Commission/Agency imposes a financial penalty, it will also issue a debit note to **recover** the amount.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

However, there is NO:

- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

Specific case (administrative sanctions):

International organisations — Decisions on administrative sanctions (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability for damages (Commission/Agency)

The Commission/Agency can NOT be held liable if — in implementing the GA — its own services cause damage (to a beneficiary or third party).

Moreover, the Commission/Agency can NOT be held liable if — in implementing the GA — a beneficiary or third party involved in the action causes damage (to another beneficiary or third party).

Examples:

1. *An experiment carried out by a beneficiary leads to an accidental escape of pollutants into the local river.*

2. *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the action.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third parties involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

1. Liability for damages (beneficiaries)

If a beneficiary causes damage to the Commission/Agency (in implementing the action), the Commission/Agency may claim compensation).

Examples:

1. *Costs of legal proceedings borne by the Commission.*

2. *At a meeting on Commission premises, a beneficiary smokes and causes a fire.*

2. Procedure

The Commission/Agency will follow the normal procedure for damages claims (i.e. bringing an action for contractual damages before the European Court of Justice; not direct claim via a debit note).

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (Commission/Agency)

The Commission/Agency may stop the clock (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

Suspension of the payment deadline must be **distinguished** from **suspension of payments** *(see Article 48)*. Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary which is, for example, suspected of serious misconducts.

Grounds for suspension of the payment deadline (Commission/Agency):

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

In practice, suspension is needed if there are issues with the payment request or with the costs declared which make it impossible for the Commission/Agency to comply with the **payment deadline** (i.e. for interim payments and payment of the balance: 90 days after payment request; *see Article 21*).

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

Late payment without suspension of the payment deadline gives rise to late-payment interest for the beneficiaries *(see Article 21.11)*.

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why.

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

Suspension will normally last until it is possible to make all the necessary checks and verifications that are needed for the payment (*e.g. analysis of technical reports and financial statements, eligibility of claimed costs, calculation of amount to be paid, approval and authorisation of payment*).

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (Commission/Agency)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more or for all beneficiaries), on the grounds listed in this Article.

⚠ **Suspension of payments** has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systemic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend all outstanding payments for the audited beneficiary until the issue is resolved.*

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may also decide to:

- suspend the GA *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*) with the:

- coordinator or
- beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension in several grants).*

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator separately (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2).*

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned with the periodic reports (except with the report for the last reporting period).

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted. They must be included in the periodic report for the last reporting period (— even if suspension is still ongoing).

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*

15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*

1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*

1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*

10 August: *the Commission pays for all beneficiaries except B.*

25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

If payments for one (or some) of the beneficiaries are still suspended at the end of the action, the Commission/Agency will make a partial payment of the balance for the amount that is not suspended (— but ONLY after having received all the necessary information for the final calculations for ALL consortium members, i.e. including the suspended beneficiaries).

⚠ The partial final payment is NOT the payment that closes the action. That payment will be made only after the payment suspensions are lifted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. GA suspension (beneficiaries)

The beneficiaries may suspend the action (in full or in part), on the ground set out in this Article.

GA suspension may be used exceptionally if it is necessary to stop the action implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for GA suspension (beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**

  The beneficiaries may suspend the action (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment after resumption).

⚠ **Information obligation** — Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g. **inform** the Commission/Agency under Article 17.2; **notify** a situation of force majeure under Article 51)*.

2. Procedure

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the **resumption date** set out in the amendment), if the Commission/Agency approves the amendment.

> ***Example:*** *The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the budget must be lowered in the amendment, to adapt the action to the new situation).

> ***Example:*** *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **can NOT be continued** (or the Commission/Agency does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:*** *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the GA termination. The eligible costs are:*
>
> - *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
> - *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities, or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 <u>Procedure</u>

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (Commission/Agency)

The Commission/Agency may suspend the action (in full or in part), on the grounds listed in this Article.

Grounds for GA suspension (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend the audited beneficiary's part of the action until the issue is resolved.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** 5 days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the GA, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42)* with the:

- coordinator or

– beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension of several grants).*

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator separately (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2).*

If possible, the Commission/Agency will give an estimation of how long the suspension will be needed.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once the action is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **can NOT be continued**, the GA (or the beneficiary concerned) may be terminated.

If the suspension leads to the GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the GA termination.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases,

the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The beneficiaries have the right to terminate the GA.

GA termination should be a last-resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Grounds for GA termination (beneficiaries):

- **Any ground** that **justifies** early termination of the action

  The beneficiaries may terminate the GA in principle on any ground — as long as there is a good reason *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

  Examples:

  1. *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

  2*. The consortium requests termination because the action was finished ahead of schedule.*

  If there are no legitimate reasons for discontinuing the action, the Commission/Agency **can NOT oppose**, but termination will be considered **improper**.

  ⚠ **Improper termination** of the GA may lead to a grant reduction (see *(see Articles 5.3 and 43)*.

  This will be the case, for instance, if:

  - the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
  - the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
  - implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

  Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a grant reduction.*

2. Procedure

The coordinator must **formally notify** the Commission/Agency (via the Participant Portal) of the termination — on behalf of the other beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. before the termination date) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. (The Commission/Agency will NOT send a reminder and will NOT extend the deadline.)

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the security obligations (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*
- Chapter 6 measures (i.e. rejection of costs *(see Article 42)* grant reduction *(see Article 43)* recovery *(see Article 44)*.

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Partner termination (beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion (and provide it if obtained or — if the beneficiary didn't reply — the request to the Commission/Agency).

Grounds for partner termination (beneficiaries):

- **Any ground** that **justifies** termination of the participation of the beneficiary

  The beneficiaries may terminate the participation of one of their consortium members in principle on any ground — as long as there is a good reason *(e.g. withdrawal by a beneficiary because due to a change in ownership; the beneficiary cannot implement its tasks in the same way; bankruptcy)*.

  For beneficiaries that are involved in **several EU GAs,** withdrawal from one GA does NOT necessarily imply that it has to also withdraw from the others.

  Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

  If there are no legitimate reasons, the Commission/Agency **can NOT oppose** partner termination, but it will be considered **improper**.

  Improper termination of the participation of a beneficiary may lead to GA termination *(see Article 50.3.1(c))* and/or to a grant reduction at the payment of the balance *(see Articles 5.3 and 43)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT continue participating in the action.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like beneficiaries.

Linked third parties can NOT however do more than the beneficiary they are linked to: If their beneficiary is terminated, they must also leave the action.

2. Procedure

The coordinator must **formally notify** the Commission/Agency of the termination (via the Participant Portal). At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Since for partner termination the notification is combined with an amendment request, they must be submitted and signed by the PLSIGN of the coordinator (on behalf of the other beneficiaries *(see Annex 3)*.

NO amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example: *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional funding to do so) — unless the Commission/Agency expressly agrees otherwise.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)

- if the beneficiary owes, those amounts must be repaid by it (normally to the consortium).

Only **costs** incurred before termination (i.e. before the notified date on which termination takes effect) are eligible— except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated.

If the coordinator fails to submit the *report on the distribution of payments*, the beneficiary whose participation was terminated will NOT have to repay any amounts.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (partner termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*).

Coordinator in bankruptcy/liquidation/administration (or similar) — In principle the coordinator must be changed. If the coordinator can no longer submit the request, the same procedure as for coordinator termination without its agreement should be used *(see above and Article 55)*.

Exceptionally, at the end of the action it may not be necessary to change the coordinator, but only its bank account if the administrator/liquidator accepts to do the final transfers of amounts.

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable];*

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**); see Article 22.5.2;

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks****][OPTION 2:*** *not applicable]*.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. GA or beneficiary termination (Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

⚠ Beneficiary termination may lead to **GA termination**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

⚠ The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

Grounds for termination (Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the GA termination; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or if the consortium no longer complies with the eligibility conditions set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the minimum number of beneficiaries, their legal situation, or their place of establishment)*. [69]

  Examples:

  1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

  2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there has been a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Such changes can be of any kind and can be triggered by the beneficiary itself or outside circumstances.

  Examples:

  1. *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

  2. *The country in which one of the beneficiaries is established ceases to be an EU Member State. This means that the beneficiary is no longer eligible for funding and that the decision to award the grant is called into question. The Commission may decide to terminate the beneficiary's participation in the GA (or the GA).*

- **GA cannot be amended after termination** of a beneficiary's participation

  The Commission/Agency may terminate the GA, if it cannot be amended after termination of a beneficiary's participation because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

  Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation.*

[69] *See also Article 8 of the Rules for Participation Regulation No 1290/2013.*

The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.

The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify partner termination because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

  – the third country/IO action does not start by the date specified in Annex 1

In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission/Agency in full.

- the third country/IO action is terminated
- the third country/IO action can no longer contribute to the subject of the GA.

Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity.

Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have participated in large-scale drug trafficking.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

The Commission/Agency may terminate the GA or the participation of a beneficiary, if a beneficiary (or one of its representatives) has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

Example: *false declarations in the proposal form, in order to obtain EU funding; coordinator does not transfer payments to the other beneficiaries, but uses them for itself; coordinator does not submit the reports (despite a reminder); consortium does not inform the Commission/Agency about the receipt of a second grant for the same/similar proposal; review shows that action does not achieve its critical objectives and is way behind schedule and consortium submits a short-term implementation plan that is not acceptable; audit shows that beneficiary declared costs based on fake invoices; consortium does not provide requested information (despite a reminder); a check shows that scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism); consortium does not submit an amendment request after beneficiary termination.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

The Commission/Agency may also terminate the GA or the participation of a beneficiary, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

- the other grants were awarded under similar conditions and
- the substantial errors, irregularities or fraud or serious breach of obligations are:
  - systemic or recurrent and
  - have a material impact on this grant.

Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that appear intentional and also affect all other GAs signed by the audited beneficiary. The Commission may terminate the participation of the audited beneficiary in the GA.*

- **Non-removal of a linked third party/international partner**

The Commission/Agency may terminate the participation of a beneficiary if it refuses to remove one of its linked third parties or an international partner which is in one of the following situations:

- bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings;
- professional misconduct
- non-compliance with tax or social security obligations
- fraud, corruption or other criminal activities
- substantial errors, irregularities or fraud or serious breach of obligations (in this grant or other grants).

3.0 This termination ground was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, beneficiary termination/linked third party removal was however already implicitly included in the different grounds of Article 50.3.3 (given that linked third parties have to fulfil the same conditions as the beneficiaries for participating in the action).

Before terminating (GA or beneficiary), the Commission/Agency may first suspend the GA *(see Article 49.2)*, to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before GA or beneficiary termination, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*), with the:

- coordinator or
- beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension in several grants)*.

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator separately (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy or similar), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will take effect **(termination date)**.

This date will be a date after the notification: Terminations can**not** be **retroactive** (notably to ensure the fulfilment of obligations and deadlines after termination; *see point 3*).

For some cases, the Commission/Agency may choose a **future** date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of GA termination are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. before the date on which termination takes effect) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases,

the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

The effects of beneficiary termination are the same as when the beneficiaries terminate one of their partners *(see Article 50.2.2)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What?

In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Force majeure normally has no specific effects on the eligibility of **costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

New in Horizon 2020: This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Force majeure may lead to GA suspension *(see Article 49)* or GA termination *(see Article 50)*.

How?

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal).

The beneficiary concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal electronic exchange system and using the forms and templates provided there.

If — after the payment of the balance — the [Commission][Agency] finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

1. Communication between the parties — Participant Portal electronic exchange system

All communication between the consortium and the Commission/Agency – before and after the payment of the balance – must be in electronic form **via** the **Participant Portal**.

Beneficiaries will receive Participant Portal notifications even after the end of the action (and the LEARs are obliged to keep beneficiary contact data up to date, in order to ensure that the communication channels remain active).

The responsibility for opening notifications in time is with the beneficiaries.

Formal notifications are normally considered to have been **accessed 10 days after** they have been **sent** (— even not actually opened by recipient, *e.g. refusal of reception or omission*). Deadlines that are counted from the date of receipt are counted as of day eleven.

The same is in principle valid for formal notifications **after the payment of the balance** — except that the Commission/Agency will check that the notification has *actually* been accessed by the beneficiary (at any time, before or after the 10 days deadline). If it was not accessed, the Commission/Agency will send a second notification, this time on paper by registered post with proof of delivery. In that case, the deadlines will start to run from the date of receipt of the second notification and the communication will continue outside the Participant Portal.

4.0 The communication via the Participant Portal after the payment of the balance was introduced with GA version 4.0. For older grant agreements, it is in principle on paper, unless the beneficiary explicitly agrees to accept communication via the Participant Portal.

The Participant Portal offers different **functions**:

- viewing and changing the legal entity data in the Beneficiary Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the Participant Portal project file (with date and time).

Formal notifications are also recorded (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation and access are linked to the user role *(e.g. LEAR, PLSIGN or PFSIGN*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator. They cannot submit information directly to the Commission/Agency.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission/Agency.*

For more information on access and roles in the Participant Portal*, see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations No 883/2013 and No 2185/2996)*.

Specific cases (PP access rights):

Beneficiaries in bankruptcy — If during a beneficiary goes bankrupt during the action, the liquidator may be granted the necessary access rights in the Participant Portal, in order to complete the beneficiaries' obligations. If exceptionally necessary, the Commission/Agency can also agree to communication outside the Participant Portal electronic exchange system (i.e. via registered post or e-mails).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means intergovernmental organisations (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the applicable legal texts provide otherwise), public law decisions cannot be applied to international organisations; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions (i.e. exclusion or financial penalties; *see Article 45*).

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration *(see Article 57.2)*. The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*
The action is divided into the following reporting periods:
RP1: from 1 March 2015 to 31 August 2016
RP2: from 1 September 2016 to 28 February 2017
Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.
The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

An amendment is necessary whenever there is a need to **change** the GA (i.e. the core agreement and/or the Annexes).

⚠ The cases where an amendment is necessary are called 'amendment types' (AT); the amendment clauses are called 'AT clauses'.

⚠ The general terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to set its 'end date of participation'.*

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and have an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

⚠ **Information obligation — Changes** in the **name, address, legal form** and **organisation type** AND changes in the **legal, financial, technical, organisational** or **ownership situation** may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary terminate its participation and to amend the GA.*

2. *Beneficiary B moves from Europe to Australia during the action. The change of address implies that the beneficiary becomes not eligible for EU funding, so the GA will have to be amended to make it a 'beneficiary not receiving EU funding'.*

3. *Beneficiary C participates in an innovation action (IA) and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Beneficiary Register is sufficient; no amendment is needed.*

2. *Beneficiary E participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

ℹ For more information on AT clauses (including required supporting documents and how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation was terminated** due to **non-accession** to the GA or non-provision of the requested declaration on **joint and several liability** (**AT1**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary that never became part of the GA.

  How? The amendment is normally triggered by the beneficiaries.

  In case of partner termination (by the beneficiaries), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  The changes will be made ex tunc (i.e. since the beginning) since the beneficiary never participated in the grant.

  If the beneficiary was participating with linked third parties/international partners, they will automatically be removed.

  GA options for the beneficiary (and its linked third parties/international partners) are automatically removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Removal of a beneficiary whose participation was terminated** for **other reasons** (**AT2**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary during the action.

  What not? There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator AND the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  How? The amendment is normally triggered by the beneficiaries.

  In case of partner termination (by the beneficiaries), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the request for amendment, the same procedure as for coordinator change without its agreement should be used.

  Changes will be made ex nunc (because the beneficiary participated in the grant up until termination and, moreover, many obligations are applicable after termination).

  The termination date will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

  If the beneficiary was participating with linked third parties/international partners, they will also have to be removed (with effect from the same date) and the end date of participation will be added to Article 14/Article 14a (AT5a/5b).

  By contrast, the GA options for the beneficiary (and its linked third parties/international partners) will NOT be removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will normally have to be changed (AT21 and AT 31).

- **Adding a new beneficiary** (**AT 3**; *see Article 56.2*)

  What? Addition of a new beneficiary during the action.

  How? The amendment is normally triggered by the beneficiaries.

The new beneficiary must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

The accession date will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

The date must be selected in the Accession Form (attached to the amendment request). It is possible to choose between:

- the date of signature of the Accession Form
- the date of entry into force of the amendment

OR

- a fixed date:
  - retroactive (before signature of the Accession Form)

  OR

  - future (after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

If the new beneficiary is participating with linked third parties/international partners, they will also have to be added (with effect from the same date) and the starting date of participation will be added to Article 14/Article 14a (AT6a/6b).

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change of beneficiary due to partial takeover** (**AT4**; called 'partial transfer of rights and obligations' in FP7)

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination *(see Article 50)* or addition of a new beneficiary *(see Article 56)*.

This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment clause for addition of a new beneficiary (AT3).

What? Transfer due to partial takeover.

'Partial takeover' means that a part of the business of the beneficiary — including the GA — is taken over by (one or more) other entity(ies) (transfer of a business unit as a going concern, *e.g. partial acquisition, distribution of a business unit after dissolution/liquidation, division/demerger, etc.*).

'Partial acquisition' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, *some* of the rights and obligations (and contracts) of the original entity are transferred to the new entity. Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'Distribution of a business unit on dissolution/liquidation' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entities purchase a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only *some* of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'Division/demerger' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has an ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two partial takeovers: one to company E and one to company O.*

What not? Simple sale of (one or more) assets of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary.

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

NO amendment is necessary for universal takeovers *(see below)*.

How? The amendment is normally triggered by the beneficiaries; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as new beneficiary).

'New beneficiary' is used here only for the purpose of the amendment; it can be either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

⚠The new beneficiary(ies) will (each) be fully **jointly and severally liable** with the former beneficiary for recoveries under Article 44. (By contrast: NO joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular, explain the financial liability of the former beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts, if possible). Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.

The transfer date will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.

If the former beneficiary was participating with linked third parties/international partners, the new beneficiary will have to determine which of the former beneficiary's linked third parties/international partners stay on as linked third parties/international partners of the new beneficiary (AT6a/6b) — all other linked third parties/international partners will be automatically removed.

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

The former beneficiary does NOT need to submit any reports to the Commission/Agency. The financial statement for the open reporting period until transfer must be uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

- **Removing a linked third party/international partner** (**AT5a/5b**; *see Articles 14 and 14a*)

  What? Removal of a linked third party/international partner during the action.

  How? The amendment is normally triggered by the beneficiaries.

  If requested by the Commission/Agency *(e.g. because of audit results or an OLAF investigation)*, the consortium MUST submit an amendment to remove a linked third party/international partner.

  > ⚠ If the consortium does not follow-up this request, the Commission/Agency may **terminate** the participation of the *beneficiary* (and thereby also remove the linked third party/international partner).

  NO termination notification — Linked third parties/international partners can be removed by the consortium by simple amendment; no formal termination notification is required (termination notification applies only to beneficiaries; *see Article 50.2*)

  Changes will be made ex nunc (because the linked third party/international partner participated in the grant up until removal and, moreover, many obligations are applicable after termination).

  The end date of participation will be added to Article 14/ 14a.

  The date must be selected in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

  The GA options for the linked third party/international partner will normally NOT be removed/changed/become not applicable.

  Annexes 1 and 2 will have to be changed (AT21 and AT 31).

- **Adding a linked third party/international partner** (**AT6a/6b**; *see Articles 14 and 14a*)

  What? Addition of a new linked third party/international partner during the action.

  How? The amendment is normally triggered by the beneficiaries.

  The new linked third party/international partner must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

  The name of the linked third party/international partner and the starting date of participation will be added to Article 14/14a.

  The date must be selected in the amendment request. It is possible to choose between a fixed date or the 'date of entry into force of the amendment'. If the linked third party/international partner joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

  The GA options for the linked third party/international partner will be added/changed/become applicable.

  Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'** (**AT7a**; *see Article 9*)

  What? If a beneficiary/linked third party — exceptionally — becomes eligible/not eligible for receiving EU funding during the action *(e.g. due to a change of establishment or a country changing eligibility status)* OR if it suddenly requests funding/zero funding, this change will require an amendment (to change Annex 1, Annex 2 and the options in Articles 9 and 57).

  Examples:

  1. *Beneficiary R moves from Europe to Australia and thus is no longer eligible for receiving EU funding. The GA must be amended. If R is participating with a linked third party M established in France, M will continue being eligible for funding.*

  2. *The country in which beneficiary X is established leaves the EU (without an agreement ensuring continued eligibility). The beneficiary is therefore no longer eligible for funding and the GA may have to be amended (or terminated; see Article 50).*

  3. *Beneficiary Y is eligible but signed the grant with zero funding. During the action the responsibilities within the consortium are shifted and beneficiary Y takes on a bigger role involving more costs. The other consortium members agree to adapt the budget and renounce to some funding in order to allow beneficiary Y to claim funding.*

  How? This amendment can normally be triggered only by the Commission/Agency.

- **Change of coordinator (AT8)**

  What? Replacement of the coordinator during the action *(e.g. because of financial difficulties)*.

  Exceptionally, an amendment remains possible and necessary *after* the end of the action *(see Article 3)* — until the payment of the balance is paid out and distributed.

  Coordinator in bankruptcy/liquidation/administration (or similar) — After the end of the action, if the coordinator can continue its participation with the bank account of the administrator/liquidator (i.e. termination and coordinator change not really needed), it is therefore exceptionally sufficient to change the bank account (AT40) without changing the coordinator.

  What not? There is NO need to request an amendment for a change of the *person* in charge of the coordination of the project (since the person's name is not mentioned in the GA).

  > ⚠ **Information obligation** — In case of a **change of person in charge of coordination**, the coordinator must — in addition to updating the data in the Participant Portal inform the Commission/Agency under Article 17.2).

  How? The amendment is normally triggered by the beneficiaries.

  If the new coordinator is not already a beneficiary of the GA, it must first accede to the GA as a new beneficiary (AT3).

  The former coordinator may continue to participate in the action as a normal beneficiary or may terminate its participation (AT2).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the amendment request, the same procedure as for coordinator change without its agreement should be used.

  The handover date will be added to the Preamble of the GA.

  The date must be selected in the amendment request. If the former coordinator leaves the consortium, this date must be after the termination date; if the new coordinator joins the consortium, the date must be after the accession date. Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the option for authorisation to administer** (**AT9a**; *see Article 41.2*)

What? Change concerning the authorisation to administer (i.e. delegation of administration tasks to a third party).

Example: *change of name of the entity with authorisation to administer*

- **Change of the coordinator's bank account for payments (AT40)**

What? An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

What not? NO amendment is necessary for a change of the name of the bank or name of the account holder; a change of the bank account data (and validation) in the Participant Portal Beneficiary Register is sufficient.

How? The bank account data must first be updated in the Beneficiary Register (and be validated).

- **Change of the action's title and/or acronym (AT22)**

What? Change of the action title or acronym.

Example: *the consortium finds out that the acronym of their action is a protected trademark*

- **Change of the starting date, action duration or reporting periods (AT23, AT24, AT25)**

What? Change of the action's schedule (starting date, action duration or reporting periods).

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

How? An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

- **Amendment for resuming the action after GA suspension (AT26)**

What? Amendment to resume the action after GA suspension.

How? The amendment request must specify the dates when the suspension started and ended. The action implementation is then automatically resumed as from the following day (resumption date).

- **Changes to Annex 1 (description of the action) (AT21)**

What? Changes to the description of the action, in particular:

  - significant change of the action tasks *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning in-kind contributions provided by third parties (against payment or free of charge) or subcontracts

    Such changes could in principle also be made via the 'simplified approval procedure' *(see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it will immediately know if the Commission/Agency agrees (or not). Without amendment, this decision is left for later and the Commission/Agency may reject the costs as ineligible later on (at the moment of the payment).
  - changes concerning the tasks to be carried out by linked third parties and related costs (including if a linked third party is removed)
  - significant changes to the plan for exploitation and dissemination (unless Annex 1 already foresees an update to be submitted with the periodic report)
  - changes concerning GA options (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to Annex 2 and Annex 2a (estimated budget) or specific unit costs (AT31 and AT36)**

  What? Changes to the estimated budget, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which are linked to a significant change in the action's work (i.e. Annex 1)
  - a budget transfer to a form of costs that is not used by the beneficiary (i.e. with 0 EUR costs in Annex 2) — except for transfer of amounts within the budget category A 'personnel costs' and for transfers to the budget category 'costs of internally invoiced goods and services'.

    Example:

    During the action implementation, the beneficiary decides to use the access costs for transnational access to research infrastructure unit cost. This requires an amendment to fix the unit cost and to move budget to budget category F.2.

  What not? There is NO need to request an amendment for changes covered by the budget transfers rule in Article 4.2 *(e.g. budget transfers within the personnel cost; see also below)*.

  How? The amendment is normally triggered by the beneficiaries.

  Best practice: If Annex 2a or specific unit costs need to be changed, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment, provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

  Budget transfers within the personnel cost category and budget transfers to costs of internally invoiced goods and services are possible without having to amend the GA.

  Examples:

  1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices (average personnel costs).*

  2. *An SME joins an on-going GA. The SME owner does not have a salary but incorrectly budgets its costs as actual personnel costs (category A.1). He realises the mistake and then switches to the unit costs for SME owners (category A.4).*

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

  Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

  Linked third parties/international partners — Since they normally do not have direct access to the Beneficiary Register, linked third parties/international partners must inform their beneficiary who must inform the Commission/Agency. The data will then be updated by the Commission/Agency (and validated).

  If — exceptionally — the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator (and instruct it to request an amendment or trigger itself an amendment, if needed).

  Example: Company R moves from Europe to Australia and this implies that the beneficiary is no longer eligible for EU funding. In such a case, the Commission will make an amendment to the GA to change the beneficiary status into 'beneficiary not receiving EU funding'.

  Short names have no legal value and only serve as easy identifiers in the GA. If needed, they can be changed in the context of an amendment initiated on other grounds.

  A change of the person that represent the coordinator for the purposes of signing the GA requires NO follow-up at all (not even a change in the Beneficiary Register — since this name is only relevant at the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

  Transfers of the GA linked to a universal takeover (i.e. where the original entity is replaced by one new entity and all the rights and obligations — including the GA — are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

  Example: *Beneficiary X merges with another existing entity Y by:*

  - *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
  - *establishing a new separate legal entity (X and Y are together known as 'Z').*

  If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator (and instruct it to request an amendment, if needed).

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

  Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information (AT40).*

  Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going innovation actions (IAs). The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% (but only to a reimbursement rate of 70%). The GA must be amended to change the reimbursement rate (AT33) and the estimated budget (AT31).*
  For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

Information obligation — In case of a **universal takeover**, the beneficiary must — in addition to updating the data in the Beneficiary Register— inform the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the Participant Portal) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

2. Procedure

How? Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) directly in the Participant Portal.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function), to discuss the amendment.

Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Beneficiary Register.

Examples:

1. *A new beneficiary must be validated (legal entity validation). This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.*

2. *Validation of the new bank account, to change the bank account.*

⚠ The amendment request must include the necessary information and supporting documents. A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications or additional information/documents.

ℹ For more information on combination of amendment clauses and supporting documents, *see the Guidance – Amendment types & supporting documents.*

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action; *see Article 3*). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases *(e.g. change of bank account, change of coordinator to make the payment of the balance)*.

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Termination of the coordinator without its agreement — For change of coordinator without its agreement a special procedure applies: The other beneficiaries must nominate one of them to act on their behalf to notify termination and request the amendment. The nominated beneficiary must name a contact person (NoCo) responsible for the amendment.

Before it has been accepted or rejected, an amendment request may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The other party must — within **45 days** — **agree or disagree**.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If **accepted** it will be **counter-signed** by the receiving party directly in the Participant Portal (for the consortium: by the PLSIGN of the coordinator).

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Participant Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

1. *Where a new beneficiary is added to the GA (AT3), it must assume the rights and obligations from the accession date specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).*

2. *Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment (AT26). This date may be before the date on which the amendment enters into force (see Article 49.2.2).*

3. *If the amendment intends to correct an error (AT60), the change will be made with effect from entry into force of the GA (i.e. from the beginning).*

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* directly in the Participant Portal. They must do this **within 30 days** after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on **joint and several liability** *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, before signing the Accession Form.

Without the declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Linked third parties do not become parties to the GA and therefore do NOT need to sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (new in Horizon 2020). All documents are available in the Participant Portal project file.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries (amendment)

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How?

The new beneficiary must:

- register in the Beneficiary Register and be validated — unless it already has a validated participant identification code (PIC)
- sign the Accession Form (directly in Participant Portal)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the **accession date**. It must be either:

- the date of signature of the Accession Form
- the date of entry into force of the Amendment

OR

- a fixed date:
  - either retroactive (i.e. before signature of the Accession Form)

  OR

- future (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned].****]***

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations:

Situation	Applicable law
For international organisations that do NOT accept any applicable law clause	No reference to any applicable law[70]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are:

[70] *See Article 180(1) of the Rules of Application Regulation No 1268/2012.*

	– the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law)	The international organisation can choose any of the following combinations of applicable laws: – only EU law – only Belgian law – only other MS or EFTA country law – only general principles governing law of IOs + rules of general international law – EU law + MS or EFTA country law (except Belgium) – EU law + general principles governing law of IOs + rules of general international law – EU law + Belgian law + general principles governing law of IOs + rules of general international law – EU law + other MS or EFTA country law + general principles governing law of IOs + rules of general international law – Belgian law + general principles governing law of IOs + rules of general international law – other MS or EFTA country law + general principles governing law of IOs + rules of general international law

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not eligible for EU funding, which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. [OPTION for Agency grants: Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).]

1. Dispute settlement

As a general rule, H2020 GAs contain an Article 272 TFEU arbitration clause — referring **disputes on the interpretation, application or validity of the GA** to the European Court of Justice.

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against confirmation letters, debit notes, etc.; NOT against audit reports, audit letters, pre-information letters, etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative sanctions**, **offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions must be brought before the European Court of Justice under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ **Public law measures** must ALWAYS be brought to the European Court of Justice under Article 263 TFEU (including actions brought by non-EU beneficiaries or beneficiaries not receiving EU funding).

⚠ All procedures are organised in a way that the beneficiaries will always be **informed** about what they can do if they disagree (**means of redress** information in the letters).

ℹ For more information on complaints, see the *Online Manual*

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, disputes on the interpretation, application or validity of the GA are normally referred to the competent Belgian courts. (So far (i.e. until end of 2016) NONE of the H2020 association agreements provides for the sole jurisdiction of the European Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Beneficiaries not receiving EU funding — For beneficiaries that are not eligible for funding *(see Article 9)*, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration *(see also point 1)* if their national law provides that they cannot be subject to the jurisdiction of the Belgian courts.

Otherwise they will be treated as normal non-EU beneficiaries (i.e. Belgian courts).

Disputes of public law nature remain before the European Court of Justice.

International organisations — For international organisations, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration (in line, for instance, with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[71]; *see also point 1*).

Disputes of public law will normally not arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

For this reason, the Commission/Agency will normally NOT adopt enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions *(see Article 45).*

Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (NOT as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[71] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

For countries for which it has carried out a formal assessment of specific situations or their legal framework, the Commission will keep record of its official position.

See the List of issues applicable to particular countries.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- Low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants. Other ERC actions (coordination and support actions (CSA)) use the H2020 General MGA.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)
- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

***[OPTION by default:** 'principal investigator':*[4]

- *[**Name**][Date and place of birth]]*[5]

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**] established in [official address in full] *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]*

[same for each beneficiary]

***[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*:* ***and other ERC grants with more than one principal investigator****: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Participants: Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The '**host institution (HI)**' is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**' for at least the duration of the action.

2. Participants: Principal investigator(s)

For ERC grants, the main researcher (i.e. the principal investigator (PI)) is named in the GA.

PIs can be of any **nationality**, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted (and usually engaged) by a host institution that is based in an EU Member State or H2020 associated country.

Due to the key role of the PI, s/he can NOT be replaced by any other researcher during the action. Requests for amendments to change the PI will be rejected.

The PI must comply with certain minimum requirements regarding working time on the action (fixed in Annex 1 and 2) and working time in an EU Member State or H2020 associated country (set out in the work programme/call; **PI time commitments**).

The Agency must be **informed** before any change in employment or location of the PI.

In case of breach, the Agency may terminate the GA or take any of the other Chapter 6 measures *(e.g. grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50 H2020 General MGA).*

Should the PI move to another host institution (in an EU Member State or H2020 associated country), the GA can be transferred to the new host institution (**portability**; *see Article 56a*). If the PI moves to an institution established in a non-associated third country, the GA may be terminated *(see Article 50.1 H2020 General MGA)*.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of the research activities, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

1. A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium. The engagement of the team follows the rules of the beneficiary and its country.

2. PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the action), PIs and their host institutions must sign a **supplementary agreement (SA)** *(see Article 32)*.

The supplementary agreement can NOT replace the employment/engagement contract and is not sufficient by itself.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party (from an EU Member State or H2020 associated country), i.e.:

- a third party that provides the PI as in-kind contribution or
- a linked third party *(see Article 8)*.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution AND the third party.

Retired PI — The PI may be retired.

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the

supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)] [and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
  - costs of internally invoiced goods and services
- indirect costs.

Thus, the ERC MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure
- direct costs of providing financial support to third parties
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices (average personnel costs), the unit costs for SME owners and beneficiaries that are natural persons without salary, the unit costs for internally invoiced goods and services and the flat-rate of 25% for indirect costs.[72]

It does NOT use the unit costs of category F 'specific cost categories' of the General MGA.

[72] See *Article 29(1) and 33(2) of the Rules for Participation Regulation No 1290/2013 and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* — with the exception of categories C. 'financial support to third parties' and F 'specific cost categories'.

The same **eligibility conditions** and **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the **following specificities**:

– for category A 'personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: under budget category A.1 'costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: under budget category A.3 'seconded persons' (Article 6.2.A.3)).

– for category D 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs', even for the unsuccessful candidates (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs) and to research data are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[73]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

2. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

Combining H2020 & other EU grants — ERC grants do NOT prevent **PIs** from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

For more information on how to combine EU funding from different programmes, *see the Online Manual (links to Regional funding).*

[73] See http://erc.europa.eu/implementing-arrangements

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record-keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

In addition, the beneficiaries must prove that the **PI time commitments** *(see Preamble)* were respected, i.e.:

- for the percentage of total working time on the action:
  - if the PI works 100% of his/her total working time for the host institution, but only partially on the ERC action: by using time-sheets
  - if the PI works 100% of his/her total working time for the host institution and exclusively on the ERC action (during its entire duration): via a declaration signed by the beneficiary and the PI
  - if the PI works partly for other institutions (i.e. has working time outside the contract between PI and host institution): via a declaration signed by the beneficiary and the PI
- for the minimum percentage of total working time in an EU Member State or H2020 associated country: via a declaration signed by the beneficiary and the PI.

In the absence of this documentation, the ERC may accept alternative evidence, if it considers that it offers adequate level of assurance.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary**: information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC)*;*]**[OPTION 2**: not applicable;**]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2.

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When?

For ERC actions, the principal beneficiary must submit both:

- a **periodic scientific report** after the end of each scientific reporting period (except the last one), with:
    - information about the scientific progress of the work
    - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
    - information on whether and how open access has been provided to these results *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.
- a **final scientific report** at the end of the action, with:
    - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a **financial report** at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a breakdown of direct costs table and a budget follow-up table
- an individual financial statement
- a summary financial statement, created automatically by the IT system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a certificate on the financial statements (CFS).

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How?

All reports must be prepared and submitted directly in the Participant Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

Example: *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in **the data management plan**;*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2:** Not applicable**]

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars

⚠ Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

ERC grants have however the **following specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org). For monographs, book chapters and other long-text publications, the recommended repository is the OAPEN Library (http://oapen.org).

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Moreover, for publications after the end of the action, if beneficiaries cannot provide open access within the time limits set by Article 29.2 without incurring additional costs for gold open access, they may choose green open access with an extended embargo period which goes beyond six/twelve months.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a digital object identifier (DOI)[74] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable). For ease of tracking, beneficiaries should include the digital object identifier for the 'European Research Council' (http://dx.doi.org/10.13039/501100000781) in the funding acknowledgement field in their

[74] For more information, *see http://www.doi.org/*.

metadata, in addition to the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601).

For more information, *see Open Access on the ERC website, the ERCEA Implementation Guidelines and the ERC Scientific Council's Open Access Guidelines for research results funded by the ERC.*

2. Open access to research data

This option will be inserted in the GA for ERC frontier research actions that participate in the Open Research Data Pilot (in line with provisions in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the **following specificities**:

The data management plan (DMP) must be submitted using the ERC template and address the following issues:

1. Making data Findable
2. Making data openly Accessible
3. Making data Interoperable
4. Increase data Re-use
5. Allocations of resources and data security

Moreover the DMP can provide justification for NOT ensuring open access to specific parts of the research data. For ERC actions, the exception allowing beneficiaries not to give access to specific parts of their research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives.)

For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does NOT need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

A first version of the data management plan must be submitted within the first 6 months of the project implementation and should then be updated during the lifetime of the project, as needed.

The beneficiaries may **opt out** of the pilot at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55 H2020 General MGA)*. No reasons have to be provided for opting out. By opting out, they free themselves retroactively from the obligations associated with taking part in the pilot.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow and facilitate the transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action.

The PI must ensure a sufficient time commitment and presence throughout the course of the project to guarantee its proper execution.

The percentages for time commitments should be established by reference to the total productive hours worked by the PI for *all* his/her employers.

The total productive hours should be calculated in accordance with Article 6.

The percentages must be reached for the action duration (NOT annually or per reporting period).

- Applying the host institution's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**
- Upholding the **intellectual property rights** of the host institution

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it if s/he becomes aware of any violations.

  Example: *The PI reads a research article and discovers a violation of the host institution's project IPRs. S/he is obliged to inform the host institution.*
- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the host institution and the PI, to set out their internal arrangements for implementing the grant.

It is **purely internal**; the EU/Euratom is NOT party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must remain in place at least for the action duration *(see Article 3)* (— without any interruptions, even if the PI works only part-time on the ERC project).

It must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

It must be concluded **before GA signature** (or in case of portability before submission of the amendment request) and a copy must be sent to the Agency.

A template [ODT format] for a model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution *(see Article 56a)*, a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The new agreement must take effect from the grant transfer date (or before). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make **specific reference to the European Research Council (ERC)**. Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC homepage*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION 1:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION 2:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG and other ERC grants with more than one principal investigator: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new host institution ('new beneficiary') — at any time during the action.

Transfer — The rights and obligations under the GA are transferred from the former host institution to a new host institution — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former host institution remains fully responsible until the Agency has approved the amendment.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution ('former beneficiary') may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the views of the PI.

2. Procedure

The PI should first contact the host institution that signed the GA (i.e. the former host institution).

> ⚠ **Record-keeping**
> **Best practice:** Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new host institution joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The **financial reporting periods** will be automatically adapted to match the transfer date (unless the transfer date coincides with the end of a financial reporting period).

Scientific reporting periods will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

> ℹ For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

3. Effects

The principal beneficiary must — within 60 days from either the transfer date or the date of signature of the amendment whichever is the latest — submit:

- a financial report to the Agency (for the open period until transfer)
- a report on the distribution of payments (only in case of multi-beneficiary GA)
- if the costs reach the threshold set out in Article 20:, a certificate on the financial statement (CFS) (— even if this is not the last reporting period).

These documents will be used for calculating the interim payment due to the former beneficiary. The Agency will moreover instruct the former host institution to transfer the remaining pre-financing to the new host institution.

If the PI requests it, the Agency may require the former host institution to **transfer equipment** that was purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate transfer conditions with the new host institution, taking into account the views of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may declare the costs of this reimbursement (and any other

related costs, i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, while the PI moves to a new host institution, the GA is transferred and changed into a multi-beneficiary grant agreement (allowing both the former host institution and the new host institution to participate in the grant). The former host institution stays on as beneficiary, the organisation that hosts and engages the PI is the new host institution. If the former host institution remains only for a limited time *(e.g. to ensure a smooth handover)*, it can then be terminated at a later stage, via a partner termination *(see Article 50.2 H2020 General MGA)*.

II.3 H2020 ERC MGA PoC: Annotations

The H2020 ERC MGA PoC is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability *(Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION 1 by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION A if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION B:*** *not applicable;****]***

*(f) a '****summary financial statement****', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the* ***request for payment of the balance****;*

*(g) a '****certificate on the financial statements****' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).****]***

[OPTION 2 for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1] to [the last month of the project].]

20.3 Reports — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a report to the Agency.

The ***report*** *must include the following:*

(a) a summary for publication by the Agency;

(b) an ***overview of the progress of work*** *towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '****breakdown of direct costs table****' and a '****budget follow-up table****';*

(d) an ***'individual financial statement'*** *(see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the report for the next reporting period.

The individual financial statements of the last reporting period must also detail the ***receipts of the action*** *(see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION A if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION B:** not applicable;**]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Report(s)

What & When?

For ERC PoC actions, the principal beneficiary must submit reports — only one **report** if there is one reporting period, otherwise one **periodic report** at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a (periodic) summary financial statement, which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a certificate on the financial statements (CFS) will have to be added (if necessary).

How?

All reports must be prepared and submitted directly in the Participant Portal *(see Article 20 H2020 General MGA*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowska-Curie Actions (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE and
- MSCA-COFUND.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA MSCA - ITN deviates from the General MGA - Multi as follows:

- Article 4.2 (MSCA-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MGA MSCA-IF deviates from the General MGA - Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 9-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSCA-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSCA-IF specific conditions for termination)
- Article 55 (MSCA-IF specific conditions for amendments)
- Article 56a (MSCA-IF portability)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MGA MSCA-RISE deviates from the General MGA - Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9 - 16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSCA-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (MSCA specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-COFUND deviates from the General MGA - Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of a programme)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 3, 5 and 6 Not applicable

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 9-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement)

III.2 H2020 MGA MSCA-ITN: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-ITN

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by networks of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN takes the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[OPTION for all actions except EID with only two beneficiaries: *However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.****]***

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

The maximum grant amount *(see Article 5)* can however **NEVER** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment *(see Article 55)* is required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID with only two beneficiaries: a maximum of 40 % of the budget may be allocated to beneficiaries established in the same country (or to the same international European interest organisation or international organisation).

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In an action with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (= 40%). If the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes (*e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes (*e.g. to increase the salary of a researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

For MSCA-ITN, the maximum grant amount is limited to a maximum unit cost equivalent of 540 person-months (and for EID with only two beneficiaries: 180 person-months).

2. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

3. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[75].

For MSCA-ITN, these are unit costs for:

[75] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they can NOT be changed.

The eligibility conditions are set out in *Article 6*.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5 H2020 General MGA*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country) – unless as part of a procedure for obtaining refugee status under the Geneva Convention[6].

For beneficiaries that are international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately before the recruitment date.

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for 1 EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree [;][.]**]***

(viii) ***[OPTION for 2 EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

[6] 1951 Refugee Convention and the 1967 Protocol.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)
- a monthly mobility allowance (A.2) — to cover costs related to their mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by budget category B.1 'research, training and networking costs')

AND

- a monthly family allowance (A.3) — for researchers with family, to reduce family-related obstacles to researcher mobility.

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

Example: *Costs for student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.*

1.2 The costs must be **declared** as the unit costs fixed by Decision C(2013) 8194[76] and set out in Annex 2 and 2a of the GA.

This is currently:

[76] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the living allowance: **EUR 3 110** per researcher per month (person-month)

To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

The list of coefficients is published in the Main Work Programme — MSCA in force at the time of the call.

On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does NOT change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action).

– for the mobility allowance: **EUR 600** per person-month

– for the family allowance: **EUR 500** per person-month.

For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first 4 years (full-time equivalent research experience) of their research career)

    '**Date of recruitment**' means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    Example: *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as recruitment date.*

    Years of '**research career**' are counted from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:

    – sickness, parental, unemployment and invalidity benefits

- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — Beneficiaries must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:

  - subject to prior approval by the Agency
  - on personal or family grounds only (i.e. not for professional reasons).

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  ⚠ While it is not possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities (and must be set out in Annex 1 of the GA).

- are supported for **at least 3 months**

  Person-months linked to shorter contracts will not be eligible.

  However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. If the contract is set out for a longer duration, but the training is interrupted within the first three months for reasons not linked to the beneficiary *(e.g. because the researcher resigns)*, the costs may still be claimed.

- comply — at the date of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (— unless the beneficiary is an 'international European interest

organisation'[77] or international organisation, for whom the mobility rule is limited to time spent *with* them)

The mobility rule applies only to the **first recruitment** under the action. For instance, it does not apply to beneficiaries or partner organisations to which the researcher is sent or seconded afterwards.

Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[78] are NOT counted.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  In the case of EJD, the PhD-programme must lead to the award of:

  - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
  - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

  The degree must not necessarily be awarded within the action duration.

  However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researchers (gross amount).

MSCA-ITN researchers may NOT be requested to pay tuition fees for their research training and/or PhD degree programme (neither from their own funds, nor from the researcher unit cost). The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* can be reimbursed under category B 'institutional costs'.

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as*:

- *part of his/her salary*
- *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
- *rental costs, directly paid or reimbursed by the beneficiary.*

[77] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[78] 1951 Refugee Convention and the 1967 Protocol.

Any form is acceptable, provided that:

- both sides agree
- it is allowed under national law

AND

- there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[79]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[80].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers who have — at the date of the recruitment — a family, i.e.:
  - persons linked to them by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

[79] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[80] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ Beneficiaries may declare a **maximum** of **36 person-months** per researcher. Person-months exceeding this number will be rejected by the Agency.

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector.

This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations/entities with a capital or legal link. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary, *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 50% rule.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - additional costs arising from secondments *(e.g. travel and accommodation costs)*
- management and indirect[81] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of a researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[82] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1800** per researcher per month (person-month)

[81] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[82] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

– for management and indirect costs: **EUR 1200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[83] in the same period: only management costs, i.e. EUR 600 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for recruited researchers'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for budget category A 'costs for recruited researchers' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[83] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon **entities with a capital or legal link** to the beneficiaries[7], to implement certain action tasks described in Annex 1 (i.e. hosting and training of researchers);
- call upon **partner organisations** to implement certain action tasks described in Annex 1 (i.e. hosting and training researchers during secondments).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[7] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-ITN allows the beneficiaries to use:

– entities with a capital or legal link to them

and

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them).

'**Entities with a capital or legal link**' are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-ITN grant (i.e. recruits the researchers), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-ITN action as entity with a capital or legal link implementing the research training activities, while the foundation or subsidiary participates as beneficiary (because it can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-ITN action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and training of researchers — and can even implement ALL those activities under the action. But they can NOT recruit the researchers (only beneficiaries can recruit the researchers) and can NOT host secondments (only partner organisations can host secondments).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary, tasks to be carried out and time spent with them).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme).

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers during **secondments**.

Secondments — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country) in order to further enrich the training experience of the researchers.

They are limited to a **maximum of 30%** of the time that is declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out and time spent with them).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations can be established anywhere (EU Member State, H2020 associated country or non-associated third country).

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the **full risk** of rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term meeting**' between the beneficiaries, entities with a capital or legal link, partner organisations and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of each researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — within 30 days after the first year of the action — send to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** after the recruitment date.

It is important to give correct and complete information in the researcher declaration since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[16] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or other entity mentioned in Annex 1);

(j) host the researchers at their premises (or at the premises of an entity with a capital or legal link);

(k) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(l) ensure that the researchers are adequately supervised;

(m) ensure that a career development plan is established and support its implementation;

(n) ensure an appropriate exposure to the non-academic sector;

(o) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[16] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective recruitment procedures and best possible working conditions.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[84]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises (or those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or ensure that this is provided by the entity with a capital or legal link).

[84] Available at http://ec.europa.eu/euraxess/

If the Agency finds that a beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**
- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Ensure that **secondments** are **limited** to a **maximum** of **30 %** of the months declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD).

> ⚠ **Secondments** — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country), in order to further enrich the training experience of the researchers *(see Article 8)*.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

- Ensure that the researchers do NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[85].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[86].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities (including during secondments with other beneficiaries and/or partner organisations).

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2 H2020 General MGA)*.

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

[85] Available at https://www.iprhelpdesk.eu/.
[86] Available at http://ec.europa.eu/euraxess/.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MGA MSCA-IF: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-IF

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include three additional funding strands: the 'Career Restart Panel', the 'Reintegration Panel' and the 'Society & Enterprise Panel'.

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION 3 if needed for the action:** [insert date]]*[4] ('**starting date of the action**').

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the actual starting date must be *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, there will be a **maximum deadline for notification** set out in Article 3 for both starting the action and notifying this to the Agency (normally 12 months from the entry into force of the GA).

The notification must be done directly in the Participant Portal.

Late notification will delay the pre-financing payment *(see Article 21.2 H2020 General MGA)*.

If the action does not start or the starting date is not notified in time, the Agency may terminate the GA *(see Article 50 H2020 General MGA)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researcher (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The institutional unit cost should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (*including for GF outgoing phase; see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[87].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[87] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[**OPTION 1 by default:** 24][**OPTION 2 for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including periods of secondment to '**partner organisations**';

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action.

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory

deductions under national law, *such as employer/employee social security contributions and direct taxes*)

- a monthly mobility allowance (A.2) — to cover costs related to his/her mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by category B.1 'research, training and networking costs').

AND

- a monthly family allowance (A.3) — if the researcher has family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiary are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[88] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 4 650** for the researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the Main Work Programme — MSCA in force at the time of the call and according to the country of recruitment (i.e. the country of the beneficiary).

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

ℹ For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[88] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the date of the call deadline — an **experienced researcher** (i.e. have a doctoral degree OR have at least four years (full-time equivalent research experience) of research career).

    Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases

    If national law prevents it from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

    The social security coverage must be guaranteed for the entire action (i.e. also during optional secondments, if any, and for the GF outgoing phase).

    For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent coverage during the stay in the third country.

    Example: *A German university recruits the fellow for the total duration of the action (i.e. provides the main employment contract under the action) and sends him/her to a US university. Continuing the German social security during the stay in the US would be so expensive, that the beneficiary asks the US partner organisation to conclude an additional employment contract, in order to insure the researcher in the US.*

    Staff provided by a temporary work agency — The beneficiary must always recruit the researcher directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency
    - on personal or family grounds only (i.e. not for professional reasons).

In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ While it is NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researcher (gross amount).

  The mobility and family allowances are due to the researchers for each month worked.

  Mobility and family allowances can be paid to the researcher in various ways, *for example as:*

  - *part of his/her salary*
  - *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
  - *rental costs paid or reimbursed by the beneficiary, etc.*

  Any form is acceptable, provided that:

  - both sides agree
  - it is allowed under national law

  AND

  - there is no underpayment.

  Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

  Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

  ⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the

average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[89]

– if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[90].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the date of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the 3 years immediately before to the call deadline (— unless the beneficiary is an 'international European interest organisations' or international organisations, for whom the mobility rule is limited to time spent *with* them)

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) are NOT counted.

  For EF Career Restart Panel, Reintegration Panel and Society & Enterprise Panel: specific mobility rule — not more than 3 years in the 5 years immediately before the call deadline

  For GF: the mobility rule is checked for the country of the partner organisation, not for the country of the beneficiary (i.e. where the outgoing phase takes place, not where the return phase takes place).
- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a EU Member State or an H2020 associated country.

  'Long-term resident' means full-time research activity in a EU Member State or H2020 associated country for 5 or more consecutive years.

  Time spent in procedures for obtaining refugee status in a EU Member State or H2020 associated country will be counted.
- for EF Career Restart Panel: not have been **active** in research for at least 12 months immediately before the call deadline

  'Active in research' means being employed or holding a scholarship. Parental leaves and unpaid leaves of absence will not be counted as periods of active engagement in research, even if a formal employment relationship exists during these periods. Publication activities or mere association to a university are not taken into account either.
- for the family allowance: have a **family**, i.e.
  - persons linked to the researcher by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or
  - dependent children who are actually being maintained by the researcher.

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs for the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

[89] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[90] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ The beneficiary may declare a **maximum** of **24 person-months** for the researcher (or **36 months** for GF). Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by requesting an amendment to suspend the action; *see Article 49.1.1.2*).

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.1): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - additional costs arising from secondments *(e.g. travel and accommodation costs, visa-related fees and travel expenses)*
- management and indirect[91] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (including for GF outgoing phase; *see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[92] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 800** for the researcher per month (person-month)
- for management and indirect costs: **EUR 650** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[93] in the same period: only

[91] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[92] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

management costs, i.e. EUR 325 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for the recruited researcher'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for budget category A 'costs for the recruited researcher' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for the recruited researcher:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[93] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon entities with a capital or legal link to the beneficiary[5], to implement certain action tasks described in Annex 1 (i.e. hosting and training of the researcher);
- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. hosting and training the researcher during secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

[5] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-IF allows the beneficiary to use:

– entities with a capital or legal link to it

and

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

'**Entities with a capital or legal link**' are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to the beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-IF grant (i.e. recruits the researcher), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation or subsidiary participates as beneficiary (because it is can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and research training of researchers — — and can even implement ALL those activities under the action. But they can NOT recruit the researcher (only the beneficiary can recruit the researcher) and can NOT host secondments (only partner organisations can host secondments).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of link with the beneficiary and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary (for instance, be established in an EU Member State or H2020 associated country).

Example: *For the EF Society & Enterprise Panel, the entities with a capital or legal link must also be from the non-academic sector.*

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers during **a secondment**.

Secondments — For MSCA-IF, secondments are either:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country).

Optional secondments are limited to a **maximum of 3 months** (for actions with duration of up to 18 months) and **6 months** (for actions with duration of more than 18 months).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researcher (only the beneficiary can recruit the researcher).

For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent social security coverage during the stay in the third country *(see Article 6)*.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations for optional secondments must be established in an EU Member State or H2020 associated country; partner organisations for GF outgoing phase must be established in a non-associated third country.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

A beneficiary that throws supporting documents away during the retention period bears the **full risk** of rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** and **entities with a capital or legal link** (if any) give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[12] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(g) host the researcher at its premises (or at the premises of an entity with a capital or legal link);

(h) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(i) ensure that the researcher is adequately supervised;

(j) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(k) support the secondment of the researcher to a partner organisation in a Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(l) ***[OPTION for GF:*** *support the return of the researcher to its premises (or those of the entity with a capital or legal link) to carry out a mandatory return period of 12 months.****]***

[…]

[12] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises (or at those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or to ensure that this is provided by the entity with a capital or legal link).

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- **Support secondments** of the researcher (if any) and ensure that they are **limited** to a **maximum** of **3 months** (for actions of up to 18 months) or **6 months** (for actions of more than 18 months)

Secondments — For MSCA-IF, secondments can be:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

and/or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country) *(see Article 8)*

For GF: Also support the researcher's return (during the mandatory 12 months return-period)

- Ensure that the researcher does NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[94].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[95].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during optional secondments/GF outgoing phase with partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

[94] Available at https://www.iprhelpdesk.eu/.
[95] Available at http://ec.europa.eu/euraxess/.

This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. GA suspension — Additional grounds for suspension: Professional, personal or family reasons

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, beneficiaries of MSCA-IF may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and (planned) end date of the suspension and
- the (planned) resumption date when the action will be resumed (i.e. automatically end date +1 day).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are NOT eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional grounds for amendments: Change to part-time employment

What? For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time) — on personal or family grounds (including parental leave).

What not? Such amendments are NOT possible for any other reasons *(e.g. other professional opportunities, etc.)*. In those cases, the beneficiary must request a GA suspension or GA termination.

How? The amendment should be requested immediately (retroactive change is possible, if justified; *see Article 55 H2020 General MGA*).

The action duration will be automatically adapted (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months, so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working time; AT23 clause) and the reporting periods will be changed (to adapt them to the new action duration; AT25 clause).

For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ **Transfer** — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains **fully responsible** until the Agency has approved the amendment.

The transfer may be based on any **ground** that is linked to the beneficiary and affects objectives of the action (i.e. implementing the research training activities).

Examples: *Internal reorganisation affecting implementation of the action; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher (e.g. other professional opportunities, personal or family commitments) are NOT considered valid grounds for transferring the GA to a new beneficiary. These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*.

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility conditions or does not have sufficient financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed directly in the Participant Portal).

The **maximum grant amount/action duration** will be adapted to take into account the country correction coefficient of the new beneficiary.

⚠ The maximum grant amount *(see Article 5)* will **NEVER** be **increased**.

If the new beneficiary is in a country with a lower country correction coefficient, the maximum grant amount *(see Article 5.1) will be lowered*.

If the new beneficiary is in a country with a higher country correction coefficient, the action duration will normally be adapted, so that the maximum grant amount can stay the same. If (exceptionally) the action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new correction coefficient *(using e.g. the management and indirect costs or own funding)*.

ℹ For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to check the eligible costs and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary. The real financial statement for the open reporting period until transfer must be also uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

III.4 H2020 MGA MSCA-RISE: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-RISE

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

> **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

> For more information on MSCA-RISE, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*
>
> For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NEVER** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

If the transfer of person-months implies a substantial change of Annex 1, a formal amendment is required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the seconded staff (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs a staff member, to organise additional training activities or horizontal networking events)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs)**.

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[96].

For MSCA-RISE, these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[96] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for seconded staff members</u> are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the sending:

- beneficiary (or entity with a capital or legal link[6] to it and located in the same country), or
- partner organisation (or entity with a capital or legal link to it and located in the same country).

(c) the secondments comply with the following conditions:

(i) last at least 1 month and no longer than 12 months (per secondment);

(ii) be between different countries;

(iii) for secondments within the EU (or associated countries)[7]: be between different sectors (academic and non-academic)[8];

(iv) for secondments from EU (or associated countries): be from a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country) to a partner organisation (or entity with a capital or legal link) established in a non-EU Member State (or non-associated country), and

(v) for secondments to EU (or associated countries): be from a partner organisation (or entity with a capital or legal link) established in a country listed in General Annex A of the Main Work Programme to a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country).

[6] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] For secondments for entities with a capital link or legal link to the beneficiaries or partner organisations: only the sector (academic or non-academic) of the beneficiary counts; the entity will be considered to belong to the same sector as their beneficiary.

1. Seconded staff costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members, by providing for:

- a monthly top-up allowance (A) — for travel, accommodation and subsistence costs relating to the secondment.

> ⚠ **Budget flexibility —** There is NO flexibility as regards the *use* of the seconded staff unit costs (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
>
> ⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

What not? Research, training and networking costs and management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared as** the unit cost fixed by Decision C(2013) 8194[97] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the top-up allowance: **EUR 2 000** per seconded staff member per month (person-month).

> ℹ For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - **early stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time equivalent research experience) of their research career)
    - **experienced researchers** (i.e. have a doctoral degree OR at least four years (full-time equivalent research experience) of research career), or
    - **administrative, managerial** or **technical staff supporting research and innovation activities** (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

[97] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

Examples (not eligible administrative, managerial or technical staff):

1. *Ms B, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

2. *Mr Y, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

Years of '**research career**' are counted from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited or from where s/he is seconded) — even if a doctorate was never started or envisaged.

- have already been actively **engaged** in or **linked** to research and innovation activities at the premises of the sending beneficiary/partner organisation/entity with a capital or legal link, continuously for at least **6 months** (full-time equivalent)

Examples:

1. *Mr Y is employed by/has a fellowship with/is a registered PhD candidate of beneficiary Y as from 1 January 2014; Mr Y will not be eligible for a secondment from 1 March 2014 but would be eligible for secondment as from 1 July 2014.*

2. *Ms X is employed 50% part-time by beneficiary X as from 1 January 2014. Ms X will not be eligible for a secondment from 1 July 2014, but would be eligible for secondment as from 1 January 2015.*

The type of relationship (employment contract, fellowship or other) is NOT relevant — as long as it:

- complies with national law
- complies with internal practices and
- during the secondment: confers to the sending beneficiary/partner organisation/entity with a capital or legal link the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

  If this is not the case, the beneficiary/partner organisation/entity with a capital or legal link must conclude a contract which allows this (or a supplementary agreement) — before the secondment.

  Example: *A PhD-candidate can be seconded if s/he: has a contract allowing him/her to work full-time on the R&I activities of the action during the secondment under the instructions of the sending beneficiary/partner organisation/entity with a capital or legal link.*

- be incurred for secondments:
  - that last at **least 1 month** and **no longer than 12 months**

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

    For the minimum duration, only splits within *secondments of* same staff, from same sending beneficiary/partner organisation to same hosting beneficiary/partner organisation can be added. Secondments from/to entities with a capital or legal link will be counted as secondments from/to the beneficiaries/partner organisations they are linked to.

    Example: *Two secondments of two weeks of the same staff member to different beneficiaries are not eligible since the minimum duration of 1 month is not reached.*

For the maximum duration, all secondments (and all splits) for the *same staff member* must be added.

- that are one of the following three:

  - secondments **between beneficiaries/entities with a capital or legal link** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in **different** EU Member States or H2020 associated **countries** AND **different sectors** (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country) **to** a **partner organisation/entity with a capital or legal link** in a third country

  OR

  - secondments **from** a **partner organisation/entity with a capital or legal link** in a third country listed in General Annex A to the Main Work Programme **to** a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country).

  Secondments from/to branches/departments of beneficiaries/partner organisations which are not separate legal entities are NOT eligible, if they are located in countries other than the country of their beneficiary/partner organisation.

  Examples:

  A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

  Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work Programme.*
  A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

  Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.*
  A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

  Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
  They may each claim 120 person-months (for their own staff).

  If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded *from* both organisations.

  Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation *to* two or more participating organisations in a RISE project — as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('implemented person-months')

⚠ Beneficiaries may declare a **maximum** of **12 person-months** per seconded staff member. Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert 5.47 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[98] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility —There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[99] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1800** per researcher per month (person-month)
- for management and indirect costs: **EUR 700** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[100] in the same period: only management costs, i.e. EUR 350 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

98 For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

99 Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

100 For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for seconded staff members'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for seconded staff members.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the seconded staff members are met. Person-months which are not eligible for budget category A 'costs for seconded staff members' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff);
- call upon entities with a capital or legal link to the beneficiaries or to partner organisations[9], to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[9] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-RISE allows the beneficiaries to use:

– partner organisations

and

– entities with a capital or legal link to a beneficiary or a partner organisation

to carry out work under the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them.)

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to a beneficiary.

They may participate in the exchanges by seconding and hosting staff.

⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action. They can be between beneficiaries/entities with a capital or legal link OR between beneficiaries/entities with a capital or legal link and partner organisations (from a third country).

They must have a **minimum** duration of **1 month** and a **maximum** duration of **12 months** (per seconded staff member).

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations must be established in a non-associated third country (i.e. not EU Member State or H2020 associated country).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary or a partner organisation — which is neither limited to the action nor established for the sole purpose of its implementation).

They may participate in the exchanges by seconding and hosting staff.

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary/partner organisation and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary/partner organisation they are linked to (for instance, if linked to a beneficiary: be established in an EU Member State or H2020 associated country; if linked to a partner organisation: be established in a non-associated third country AND be established in the same country as their beneficiary/partner organisation.

Examples (eligible entities with capital or legal link):

1. *University X (established in France) is part of a Joint Research Unit (JRU) with beneficiary Y (also established in France). Mr. X is employed by university X and is to be sent on a secondment to beneficiary Z. University X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

2. *SME X (established in Portugal) is a subsidiary of beneficiary Y (also established in Portugal). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. SME X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Ms. X.*

3. *Mr. X is formally employed by foundation X (established in Spain) which does the HR management for beneficiary Y (also established in Spain). Mr. X actually works with beneficiary Y and should be sent on a secondment to beneficiary Z. Foundation X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

Examples (ineligible entities with capital or legal link):

1. *SME X (established in Germany) is a subsidiary of applicant Y (established in Greece). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. Since SME X is not established in the same country as applicant Y, it cannot act as entity with a capital or legal link for the purposes of a MSCA-RISE grant. Therefore, Ms X cannot be seconded.*

2. *University X (validated as academic; established in Sweden) is member of an association of universities (applicant Y; validated as non-academic). Mr. X is employed by university X and is to be sent on a secondment to applicant Z (validated as academic). University X cannot act as entity with a capital or legal link of applicant Y for the purposes of the MSCA-RISE grant because this would circumvent the inter-sector mobility rules (mix of academic and non-academic).*

ℹ For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities)*

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until these procedures end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the **full risk** of rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must keep the documents for the staff of the partner organisation/entity with a capital or legal link.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term meeting**' between the beneficiaries, partner organisations, entities with a capital or legal link and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — after each year except if a periodic report is due (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a 'researcher declaration' for each seconded staff member — within **20 days** from the start of the secondment.

It is important to give correct and complete information in the researcher declaration, since this information will be used to determine the eligibility of the person-months that are declared.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — and indicate each split.

Example: *Beneficiary A is sending Mr A to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment, indicating the split. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (within 20 days from the start date of each secondment). Secondments to entities with a capital or legal link will be counted as secondments to the beneficiary/partner organisation they are linked to and must therefore be covered by the same researcher declaration.

Example: *Beneficiary A is sending Mr A to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

Specific case (deliverables):

Researcher declaration for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must submit the researcher declarations.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the seconded staff members **access** to both **background** AND **results** necessary for their research and innovation activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time.**

  For part-time staff members this may require a change of their relationship (i.e. conclude a contract or a supplementary agreement), to allow the secondment to be implemented on a full-time basis.

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is only a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are of course accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary/partner organisation/entity with a capital or legal link) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[101].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*

- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

  They can be:

[101] Available at https://www.iprhelpdesk.eu/.

- paid directly to the seconded staff member in advance or via different instalments or
- managed centrally by the beneficiary according to the specific needs of the secondment.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract (or fellowship or other relationship), some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA grant in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MGA MSCA-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-COFUND

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

⚠ **Budget flexibility** — There is however some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in a programme implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**');

(b) for **costs of providing financial support to costs for researchers in a programme implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[102].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[102] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced maximum grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in a programme implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in a programme implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme), by providing for:

- a monthly living allowance (A.1 or A.2) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*).

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit cost (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs of the beneficiary are not covered. Management costs are covered under budget category B 'management costs' *(see Article 6.2.B)*. Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are NOT eligible under the grant; they may be funded through other sources (including other EU funding programmes).

Combining H2020 & other EU grants — A MSCA-COFUND grant does NOT prevent the beneficiary or partner organisations from applying for further (non-H2020) EU funding for their programme — for costs that are not eligible (or not declared) under the MSCA-COFUND grant.

For more information on how to combine EU funding from different programmes, *see the Online Manual (links to Regional funding).*

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[103] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance:
  - for early-stage researchers in doctoral programmes: EUR 3 710 per researcher per month (person-month)

[103] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for experienced researchers in fellowship programmes: EUR 5 250 per person-month.

⚠ Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is ONLY **EUR 1 855** and **EUR 2 625** respectively.

ℹ For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is:*

Periods in which a researcher was **absent** for more than 30 days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** only the:

- management costs (B) — for direct costs of managing the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER sources (including other EU funding programmes).

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8194[104] and set out in Annex 2 and 2a of the GA.

This is currently:

- for management costs: EUR 650 per researcher per month (person-month).

Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is **EUR 325**.

For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher costs.

1.3 The **eligibility** of the management costs is directly linked to (and conditional on) the eligibility of the costs for researchers.

Management costs are eligible only if ALL the eligibility conditions for the researchers are met. Person-months which are not eligible for budget category A 'costs for researchers' are also not eligible for budget category B 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

[104] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. implementing a doctoral or fellowship programme including recruiting researchers or hosting and training researchers during a secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-COFUND allows the beneficiary to use:

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to:

– implement a doctoral or fellowship programme (i.e. recruit the researchers)

– provide training and hosting of researchers during a secondment *(see Article 15)*.

⚠ **Secondments —** For MSCA-COFUND, secondments can be:

- (optional) additional periods of research training with a partner organisation, in order to further enrich the training experience of the researchers

and/or

- for fellowship programmes similar to MSCA-IF GF: (mandatory) outgoing phase with a partner organisation (from a third country).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during secondments.

Partner organisations can recruit the researchers (and MUST do so if it is the partner organisation that implements the doctoral or fellowship programme; *see Article 15.1.1(b)*).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations that implement a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *Main Work Programme*. Partner organisations hosting secondments can be established anywhere.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

15.1 Rules for providing financial support to or implementation of a *[doctoral][fellowship]* programme

15.1.1 The beneficiary must ensure that the ***[doctoral][fellowship]* programme** (implemented by itself or a partner organisation) complies with the following conditions:

(a) **types of programme**:

[OPTION 1 for DPs: *The programme must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programme**');**]***

[OPTION 2 for FPs: *The programme must concern fellowships for research training activities for recruited researchers ('**fellowship programme**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country[5], the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programme:

[OPTION 1 for DPs: *The doctoral programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately before the call deadline or recruitment — unless:*
  - *otherwise specified in Annex 1 for existing programme or*
  - *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[6];*
- *are nationals or long-term residents of an EU Member State or associated country[7], in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION 2 for FPs: *The fellowship programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than [**OPTION A by default:** 12 months in the 3][**OPTION B for actions with activities similar to the MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel:** 3 years in the 5] years immediately before to the call deadline or recruitment — unless:*

- *otherwise specified in Annex 1 for existing programmes or;*
- *this time was part of a procedure for obtaining refugee status under the Geneva Convention[8];*

- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.]*

Researchers that are already permanently employed by the entity where the research training activities take place may not be supported.

(c) **procedure and criteria for selecting researchers** in the programme:

[OPTION 1 for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION 2 for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

The selection committee(s) must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(d) **conditions for the recruitment** of researchers under the programme:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;
- researchers must be recruited for at least 3 months;
- ***[OPTION 1 for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION 2 for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- for programmes implemented by itself:
  - take measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[9] and ensure that the researchers are aware or them;
  - ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;
  - ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);
  - ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;
  - ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
  - ensure that researchers work exclusively on the research training activities;
  - ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
  - ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
  - ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of results, promoting the action) — during the research training activities and afterwards;
  - inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — a follow-up questionnaire provided by the Agency;
  - ***[OPTIONS for DPs:****ensure a fair gender representation in the recruited researchers (by promoting genuine equal access opportunities between men and women throughout the recruitment process);*
  - *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.****]***
- for programmes implemented by a partner organisation:
  - ensure that the partner organisation complies with the obligations set out in this Article and

- ensure that the partner organisation allows that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[5] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[6] 1951 Refugee Convention and the 1967 Protocol.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] 1951 Refugee Convention and the 1967 Protocol.

[9] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing a doctoral/fellowship programme

MSCA-COFUND can provide support both for a programme implemented by the beneficiary itself or for a programme of a partner organisation (which the beneficiary funds by providing financial support).

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisation that implements the doctoral/fellowship programme (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Types of programme — Categories of persons

The beneficiary/partner organisation must implement one of the following **types of** research training **programme** supporting transnational mobility:

– doctoral programme (DP), i.e. a programme with research training activities for recruited early-stage researchers that leads to the award of a doctoral degree

The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programme (FP), i.e. a programme with fellowships for recruited experienced researchers.

The **researchers** must — at the date of the call deadline or recruitment —:

- be one of the following two:
  - **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time-equivalent research experience) of their research career) or
  - **experienced researchers** (i.e. have a doctoral degree OR have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than:
  - for fellowship programmes similar to MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel: 3 years in the 5 years immediately before the recruitment date or call deadline
  - for all other programmes (doctoral programmes and other fellowship programmes): 12 months in the 3 years immediately before the recruitment date or call deadline

  — unless Annex 1 of the GA specifies otherwise for an already existing programme or the beneficiary/partner organisation is an 'international European interest organisation'[105], for whom the mobility rule is limited to time spent *with* them.

  Exceptions in Annex 1 are only possible for existing programmes (NO exceptions for new programmes).

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[106] are NOT counted.

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

- if the programme is implemented by a partner organisation established in a **third country** (only third countries listed in General Annex A to the Main Work Programme) or if a secondment to a partner organisation in a non-associated third country constitutes the ***main* part** of the research training activities: be nationals or **long-term residents** of a EU Member State or H2020 associated country.

  'Long-term resident' normally means full-time research activity in a EU Member State or H2020 associated country — for 5 or more consecutive years.

  NO other restrictions on researcher nationality or researcher origin or destination allowed.

3. Additional cost eligibility condition: Selection procedure

[105] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[106] 1951 Refugee Convention and the 1967 Protocol.

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[107]*)*.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a **maximum** of **4** fixed deadlines or regular cut-off dates **per year**) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

4. Additional cost eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits
- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, the beneficiary/partner organisation may — exceptionally and subject to the Agency's prior agreement— offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — The beneficiary/partner organisation must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

[107] Available at http://ec.europa.eu/euraxess/.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum remuneration —** monthly **living allowance** (i.e. gross amount including salary, social security contributions, taxes and other costs included in the remuneration) and, if applicable, a single mobility allowance for the researcher to take up the doctoral or fellowship programme (to be funded through other sources) **—** of:

- for early-stage researchers (doctoral programmes): EUR 2 597
- for experienced researchers (fellowship programmes): EUR 3 675.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 298,50; for experienced researchers EUR 1 837,50).

Lower payments are considered as underpayment.

⚠ Since the MSCA-COFUND grant reimburses 50% of the researcher unit cost (i.e. EUR 1 855 and EUR 2 625 respectively), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 742** or **EUR 1050** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

The total cost of the doctoral/fellowship programme, in particular the amounts to be provided for the benefit of the researchers and for the hosting organisation, must be specified in Annex 1.

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral/fellowship programme — the average monthly allowance (over the duration of the programme) respects the above-mentioned minimum.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[108]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[109].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

5. 'Other obligations'

[108] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[109] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**

    This also means that a researcher can NOT benefit from two MSCA grants at the same time.
  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities.
  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency
- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[110].
- for doctoral programmes: the beneficiary/partner organisation must:
  - ensure **gender balance** regarding the recruited researchers
  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career development plan.

[110] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas, documents relating to selection procedure)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the minimum remuneration was paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

A beneficiary that throws supporting documents away during the retention period bears the full risk of rejection by the Agency.

Specific case (record-keeping):

Documents for a programme implemented by a partner organisation — For a programme implemented by a partner organisation, it is the beneficiary that must keep the documents also for the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must

- submit a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- organise a **'mid-term meeting'** with the Agency;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** of the start of the research training activities of the researcher.

It is important to give correct and complete information in the researcher declaration since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The beneficiary must organise a mid-term meeting with the Agency to present the implementation of the action in the light of the schedule in Annex 1 .

Best practice: Please contact the Agency for the timing.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researchers in MSCA-COFUND, the MSCA-COFUND MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** (if any) give similar access.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,*

addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA SME Ph1 deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 MGA SME Ph 2 deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 MGA SME Ph1, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 MGA SME Ph1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 funds:

- the feasibility study for an innovation idea (i.e. a ‘proof of concept’ or ‘business plan’ for new, altered or improved product, process or service).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-01-2016-2017)*.

For more information on SME Instrument Ph1 actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding*, see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph 1 MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph 1 MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Decision C(2013) 8198[111].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

[111] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to grant *reduction*). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the feasibility study (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Decision C(2013) 8198[112] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the

[112] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to grant *reduction*, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

> ⚠ The costs of purchases and subcontracts are **ALL covered** by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12 H2020 General MGA) and **linked third parties** (Article 14 H2020 General MGA) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[113] or 2009/81/EC and the national legislation implementing them.

Moreover, the obligations in Article 10.1 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[113] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[114] or 2009/81/EC and the national legislation implementing them.

[114] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Finally, the obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

Examples: *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The Agency may disclose confidential information also to its staff, other EU institutions and bodies.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency and Commission responsibility — Agency and the Commission right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (beneficiaries) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submiting the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submiting to the Agency in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the Agency will formally notify the beneficiary of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a **recovery**, the Agency will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT grant *reduction*; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

Cost rejections will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide required information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Partner termination (beneficiaries)

The rules on partner termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. GA or beneficiary termination (Agency)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The request for amendment (which the coordinator must send 60 days after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 MGA SME Ph2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-05-2016-2017)*.

For more information on SME Instrument Ph2 actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **if the beneficiary is a natural person** not receiving a salary (see Article 6.2, points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific costs category(ies)**: not applicable.

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the Main Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are by definition NO non-profit legal entities, they can NOT declare additional remuneration (under budget category A 'personnel costs'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules [...]*[11]*.]*

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement." ***]***

[OPTION 1 only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries*[12] *and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[24]***.]***

[OPTION 2 only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*

- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).]*

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[11] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[12] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[13] See Articles 28 and 31(2)(a) of Directive 2004/18 replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Participant Portal messaging function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage)

OR

- refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the 'simplified approval procedure: there is' NO assessment (and the beneficiary therefore bears the **full risk**).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as for the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be adapted to reflect the action duration. Thus, if considered necessary, SME Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 MGA ERA-NET Cofund deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 MGA ERA-NET Cofund: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],* ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

Annex 7 Model for the commitment on availability of funds

Annex 8 Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

ERA-NET Cofund uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities participating financially to the joint call for proposals MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8*).

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of Horizon 2020 *(e.g. FETPROACT-02-2017; SC5-33-2017)*.

For more information on ERA-NET Cofund actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action**: [insert date]]*[7] ('starting date of the action').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). Normally, the duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs.

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**:

- for costs of internally invoiced goods and services: on the basis of an mount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment, to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

2. Reimbursement rate

How much? For ERA-NET Cofund, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - **personnel** costs for implementing the trans-national projects (— unless declared as unit cost, *see below*)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects (— unless declared as unit cost, *see below*)
- **unit costs** for:
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices
  - **coordination costs** for additional activities[115]
- **flat-rate costs** for:
  - **indirect costs**.

[115] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.2.1.1,A.2.1.2 and A.2.1.3) : the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or

- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.2.1.1 and A.2.1.2) **calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION 1 by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

A.2.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:***:***

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Costs for trans-national projects (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as direct costs related to trans-national projects:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment

- other goods and services
- costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc.) or for additional coordination and networking activities of beneficiaries implementing trans-national project themselves. Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs must normally be **declared as** actual costs *(see Article 5.2(b))*.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

1.3 In principle, the same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the **following specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities

Direct coordination costs for additional activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Additional coordination costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the direct costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8200[116] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the **additional coordination activities** described in Annex 1.

Costs for additional coordination activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare any additional coordination costs.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[116] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (C.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing to the joint call for proposals can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action).

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is ONLY allowed for beneficiaries/linked third parties that **implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be **trans-national projects**, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.2a);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients (third parties) that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Trans-national projects

The projects must be trans-national (i.e. they must involve at least two independent entities from two different EU Member States or H2020 associated countries), both in case of:

- financial support to third parties and
- implementation of the projects by the beneficiaries themselves.

3. Additional cost eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and

- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

4. Additional cost eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

5. Additional cost eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection (**joint selection list**) on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

6. Additional cost eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

7. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION 1 by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

Example: *data on each participant and abstracts of the proposals*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

Example: *data on each participant and an overview of the results*

How? The information must be uploaded directly in the Participant Portal

2. Deliverable: Information on cumulative expenditure incurred

What & When? The coordinator must submit to the Commission/Agency — on a yearly basis — information on the cumulative expenditure incurred by the consortium

How? In practice, this mandatory declaration for ERA-NET Cofund *(see Article 20.5)* is handled as deliverable and must be uploaded directly in the Participant Portal.

It does NOT need to be set out in Annex 1 (since legally speaking the obligation is not based on Article 19 but on Article 20.5).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.2a Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.3 Request for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4), from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are 3 pre-financing payments, also after the second reporting period) — a **periodic technical report**, with information on the technical implementation.

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 8*).

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)

- ranking list of the projects
- observer report on the evaluation
- joint selection list
- commitment on availability of funds (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8).

At the end of the action, the coordinator has to submit a **final report**, with both the technical and financial report.

How? Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

ERA-NET Cofund actions are normally divided into 2 reporting periods with 2 pre-financing payments (or exceptionally 3 reporting periods with 3 pre-financing payments, if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

The declaration is normally handled as deliverable *(see Article 19)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

ERA-NET Cofund actions normally are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because the Commission/Agency does not have sufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since ERA-NET Cofund pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Amount of pre-financing payments

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- for the first pre-financing payment: between 10% and 30 % of the maximum grant amount
- for the second pre-financing payment: between 60 % and 80% of the maximum grant amount.

If the GA provides for a 3 pre-financing payments, then the amount is divided as follows:

- 30 % for the first pre-financing payment
- 30 % for the second pre-financing payment
- 30 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP/PPI MGA

VI.1 Background information and approach

The PCP/PPI Model Grant Agreement is used for PCP/PPI actions only.

The PCP/PPI MGA follows the General MGA for numbering and content, except for:

The H2020 MGA PCP-PPI deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI specific payment provisions)
- Article 23 (PCP-PPI specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of resources
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP/PPI actions are added:

- Article 2 (PCP/PPI actions)
- Article 4.1 (PCP/PPI budget categories)
- Article 8 (PCP/PPI rules on third party involvement).

VI.2 H2020 MGA PCP/PPI: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],* ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***
	[OPTION if the JRC participates: *3b Administrative Arrangement****]***
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

PCP/PPI uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities contributing financially to the PCP or PPI procurement budget MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8)*. They form the buyers group.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI actions

What? PCP/PPI funds:

- one single joint public procurement of research and development (R&D) services (PCP) or one joint or several coordinated public procurements for innovative solutions (PPI)

AND

- related additional coordination and networking activities.

For PCP actions, it must be only one PCP per GA; for PPI actions, it can be one joint or several coordinated PPIs per GA.

The additional activities must relate to the joint call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP/PPI grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

PCP/PPI actions are funded in all Parts of Horizon 2020 *(e.g. SEC-09-FCT-2017)*.

The possibility to have several coordinated PPIs was introduced with GA version 4.0 but is also open to older grant agreements.

For more information on PCP/PPI actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14 a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP/PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP/PPI MGA uses its **own budget categories**.

Budget categories of the PCP/PPI MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare PCP/PPI subcontracting costs. Who actually pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP/PPI MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **[…%]** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION 1 for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2a*[13] ***(unit costs).]***

[OPTION 2: specific cost category(ies): *not applicable.**]***

[…]

8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
13 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The PCP/PPI, normally uses the same reimbursement rates as the General MGA (**100%** for research and innovation actions (RIA) and **70% or 100%** for innovation actions (IA) actions; *see Article 5 H2020 General MGA*), unless the call provides exceptionally for another rate.

2. Cost forms

The PCP/PPI MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The PCP/PPI MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs of *[PCP]/[PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. PCP/PPI subcontracting costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP/PPI actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **PCP/PPI subcontracting** described in Annex 1
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[14]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[15] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed;

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agree otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)**}**.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories B.1.1, B.1.2, B.1.3 [and B.1.6]): the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of annual productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90 % of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or option (iii) above, i.e.:

-fixed number of hours;

-standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for during each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories B.1.1, B.1.2, B.1.4, B.1.5 [*and B.1.6*]): the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** ***[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[16]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[17] ***[OPTION 1 by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[18]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable****.]***

B.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]*[***OPTION 2***: *not applicable*]***]***.

Beneficiaries receiving an operating grant[19] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

B.5 ***[OPTION 1: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION *1a* ***for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *[**Insert name of specific cost category**[20]] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units, [and if [insert additional eligibility conditions, if any]].***]***

[*same for each specific cost category****]***

[OPTION 2: *Not applicable****]***

[…]

[14] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[15] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[16] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[17] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[18] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[19] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[20] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Additional coordination and networking costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as costs for additional coordination and networking activities related to the joint call for tender:

- direct personnel costs for additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for additional coordination and networking activities
- other direct costs for additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs must normally be **declared as** actual costs.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary MUST be declared as the unit cost fixed by Decision C(2013) 8197[117] and set out in Annex 2 and 2a of the GA.

This concerns only *beneficiaries* that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI MGA has however the **following specificities**:

[117] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the joint call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

1. *The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.*

2. *Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).*

3. *Costs for validation and testing of solutions provided by the subcontractors*.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the Main Work Programme, the costs of additional coordination and networking activities are eligible up to a maximum amount of 30% (for PCP)/50% (for PPI) of the total requested grant amount. For each GA, this ceiling is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP/PPI actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing financially to the joint procurement budget can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action). They form the buyers group.

Certain **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12)) are however ONLY allowed for **additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, **subcontracting** (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities.

Linked third parties (Article 14) may participate in all activities under the action.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION 1 for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('****place of performance obligation****').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[26];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[26] See Article 16(f) of Directive 2004/18/EC replaced by Article 14 of Directive 2014/24/EU, and Article 24(e) of Directive 2004/17/EC replaced by Article 32 of Directive 2014/25/EU..

1. PCP subcontracting

In PCP actions, the beneficiaries award PCP subcontracts for research and development services that are necessary to address a common challenge set out in Annex 1 (PCP R&D services). 'PCP

subcontract' thus means a contract for the purchase of R&D services (identified in Annex 1 as action task).

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries and linked third parties (buyers group), with a joint procurement in 3 phases

  The **buyers group** is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[118])

    Any entity that fits the definition of a contracting authority or contracting entity as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI actions.*

  – that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the Main Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the Main Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

[118] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is split in **3 phases** (solution design, prototyping, original development and testing of a limited set of 'first' products or services) which are implemented via 3 different specific contracts (under the overall PCP framework agreement).

The buyers group must select multiple competing subcontractors (with a minimum of 3 subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum 2 subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a **common challenge** (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an R&D services contract (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[119]).

Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement (**common jointly-committed budget**)

This budget is based on the financial commitments of the beneficiaries and linked third parties in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

[119] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary (**lead procurer**)

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is NOT part of the buyers group).

  Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[120].

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors (PCP implementation)

- **Subcontractors** are **paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP actions).

There can only be one PCP per PCP action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid — or whether

[120] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PCP subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 and phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must normally be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties

  - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

- the procurement must be preceded by an **open market consultation**

  This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[121].

  A prior information notice (PIN) must be published in the Official Journal of European Union (OJEU) and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

- the procurement must be based on **common procurement specifications** prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more information on the tender documents, *see the Guidance — PCP procurement documents [ODT format].*

5. Additional cost eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

[121] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontractors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries (place of performance obligation)
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions and without the right to sub-licence

    This right serves as a safeguard to ensure a competitive supply chain (during or after the PCP action) in case of problems. It does NOT mean that every subcontractor will always and automatically be obliged to grant non-exclusive licenses to third parties to exploit its results.

    Examples (licences needed): *other providers working for the buyers group need access to the IPR to work for the buyers group; a PCP subcontractor abuses its monopoly situation*

  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*

    This right serves as a safeguard to ensure commercial exploitation in the public interest, in case the subcontractors fail to do so themselves. It will be for exceptional cases.
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2014/24/EU, 2014/25/EU[122] and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[123]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[124]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[122] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[123] *See Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.*

[124] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

[OPTION 2 for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint (or several coordinated) procurement procedure(s) by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and, 2004/17/EC (or 2014/25/EU).

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint (or coordinated) PPI procurement(s) ('**joint procurement agreement**');*

*(ii) **[OPTION 1 for PPI actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION 2:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION 1 for PPI actions that are not limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) '**contract notice**'(s), which:*

- *are published by the lead procurer (or beneficiary) in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specify a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call(s) for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allow for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *are promoted and advertised widely;*
- *indicate how potential tenderers can obtain the tender documentation and the 'PPI request(s) for tenders';*

*and the **tender documentation** and **PPI request for tenders**.*

*(ii) **Step 2**: make one (or several) **evaluation(s) of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **best value for money** criteria and ensuring that the price corresponds to **market conditions**;*

*(iii) **Step 3**: **award the subcontract(s)** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make one (or several) '**contract award notice**'(s), which are published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION 2 for PPI actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) **request(s) for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25//EU)[271] —:*

- *use technical specifications that are functional or performance based;*
- *avoid selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specify award criteria based on best value for money*

- *describe the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describe the arrangements for intellectual property rights*
- *describe the arrangements for liability for damages;*

(iv) ***Step 2:*** *make one (or several)* ***evaluation(s) of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24/EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[27] See Articles 28 and 31(2)(a) of Directive 2004/18/EU replaced by Article 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. PPI subcontracting

For PPI actions, beneficiaries award PPI subcontracts for procuring the innovative solutions that are necessary to address the common challenge set out in Annex 1 (PPI innovative solution(s)). 'PPI subcontract' thus means a contract for the purchase of innovative solutions (identified in Annex 1 as an action task).

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the **following specificities**:

The PPI procurement covers 2 phases (deployment and operational validation) — but there is no requirement to split the PPI procurement for those 2 phases in different contracts.

The beneficiaries may choose between implementing *one single* or *several coordinated* PPI procurements.

For joint procurements, there is one joint PPI call for tender launched by the lead procurer and one joint evaluation of offers.

For coordinated procurements, there are several separate PPI procurements carried out individually by the different procurers in the buyers group.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer (early adopter) of innovative solutions that are not yet available on a large-scale commercial basis.

PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.

Each PPI action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them together (i.e. the core functionality and performance characteristics must be the same; there may be additional local functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement (**common jointly-committed budget**) only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

For joint procurements:

- the buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts
- if there is no mandate, the general rule is that:
  - framework agreement(s) must be signed by all members of the buyers group together
  - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI actions).

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PPI subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an **open market consultation** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[125].

[125] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:

A prior information notice (PIN) must be published in the Official Journal of the European Union and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

The PIN must contain information on:

- the expected launch date for the call for tender

  This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP action) is sufficient.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

For more information on the tender documents, *see the Guidance — PPI procurement documents [ODT format].*

4. Additional cost eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions *(e.g. regarding access to background, licensing etc.)* if these:
    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2014/24/EU, 2014/25/EU[126] and 2009/81/EC normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2014/24/EU and 2014/25/EU[127]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[126] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[127] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU*(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[28]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24//EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
    - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
    - **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
    - ***[OPTION for PCP: an assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP)****]****;*
- ***[OPTION 1 by default (two pre-financing payments):*** *the coordinator must submit in month [**Y**] a progress report containing:*
    - *a '**periodic summary technical report**' for publication by the [Commission][Agency];*
    - *an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each subcontract financed by the procurement**, including data on each contractor that participated in the procurement, and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[**OPTION 1 for PCP:** at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[**OPTION 2 for PPI:** at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed — Assessment of the results

When & What? For PCP/PPI actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after the evaluation for each PCP phase) — submit to the Commission/Agency information on:

- the total number of bids received
- the evaluation of tenders and
- the winning tenderer(s) and abstracts of the winning tenders (using the following template [ODT])

The information must be complemented by the coordinator at the end of the action (and, for PCP actions, also at the end of each PCP phase) by submitting an assessment of the results and conclusions (using the following template [ODT]).

How? The information must be submitted via the Participant Portal Continuous Reporting Module.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[38]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[39]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.2a <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities[.][;]

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment**, including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.3 Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

[…]

[38] Month X should be the end of the preparation phase and submission of second pre-financing request.
[39] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP/PPI actions, the coordinator has to submit — after the first reporting period (and, if there are 3 pre-financing payments, also after the second reporting period) — a **periodic technical report** with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 7*)

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- call for tender documents (including contract notice, invitation to tender and procurement contracts)
- report on outcome of the preparation phase *(e.g. open market consultation)*
- commitment on availability of funds (Annex 7)

  This ensures that the PCP/PPI subcontracting costs are covered.
- statement on the use of the previous pre-financing instalment (Annex 8)

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

How? Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

Normally, PCP/PPI actions are divided into 2 reporting periods (with 2 pre-financing payments; *see Article 21*). The first reporting period corresponds to the preparation of the joint procurement; the second reporting period corresponds to the implementation and follow-up of the joint procurement.

Actions will exceptionally be divided into 3 reporting periods (with 3 pre-financing payments), if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP/PPI actions are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since PCP/PPI pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Amount of pre-financing payments

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for PCP/PPI actions are as follows:

- for the first pre-financing payment: the percentage of the maximum grant amount foreseen for the additional networking and coordination activities related to the preparation of the call for tender
- for the second pre-financing payment: a maximum of 90% (general limit for pre-financing payments; *see Article 21.2 H2020 General MGA*) minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP/PPI actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 MGA EJP Cofund deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing payment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 MGA EJP Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of Horizon 2020 and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General work programmes and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[7] ('**starting date of the action**').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). The duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a].]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

For the FEJP action, there are moreover 3 additional specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Thus, the EJP Cofund MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION 2**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1 **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] *(**unit costs**).]***

[OPTION 2: specific cost category(ies)**: not applicable.]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.
14 Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[128].

2. Cost forms

For EJP Cofund actions, the **cost forms** are in principle the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however 3 specific unit costs for category F 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [129]

[128] *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*
[129] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[16]***]][OPTION 2: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[16] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, EJP grants have the **following specificities**:

- for category A 'personnel costs'

  Costs of students, PhDs and other researchers (under scholarship, internship or similar agreement or under employment contract) — Are eligible even if the agreement is training-oriented (or work-oriented but with a non-negligeable training component), the costs fulfil the eligibility conditions set out in Article 6 and Annex 1 explicitly includes the training activities.

- for category D.2 'equipment costs'

  There is a special cost category for the FEJP action: full purchase cost for JET equipment *(see below)*.

- for category F 'specific cost categories'

  There are special cost categories for the FEJP action: specific cost categories *(see below)*.

The annotations below will be limited to these special cost categories for the FEJP action (and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated).

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** under category D.2 'equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional** cost eligibility **conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. ***[OPTION 1: [Insert name of specific cost category(ies)]][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION 1a for specific unit costs (if unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[22]] *are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION 2: *not applicable****]***

[…]

[22] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the Fusion programme EJP Cofund action (FEJP), there are however 3 additional specific cost categories set out in Decision C(2013) 8201[130] available:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

⚠ **Double funding risk —** Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 Specific cost category – costs for mobility of personnel (F.2)

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment, by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance.

[130] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party, but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. category A 'personnel costs' or D.3 'other goods and services'; *see Article 6.2.A, 6.2.D.3*).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[131] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[132]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.4	Sweden	131.9

[131] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[132] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) are applied as from 1 January 2016:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	105.9	Italy	99.4
Bulgaria	52.1	*Italy Varese*	92.2
Croatia	74.6	Latvia	74.2
Cyprus	77.3	Lithuania	69.0
Czech Rep.	73.4	Malta	84.5
Denmark	131.8	Netherlands	107.8
Estonia	78.0	Poland	71.8
Finland	119.7	Portugal	79.2
France	114.6	Romania	64.8
Germany	96.6	Slovakia	76.4
Germany Bonn	93.4	Slovenia	81.2
Germany Karlsruhe	93.8	Spain	90.2
Germany Munich	106.0	Sweden	127.9
Greece	79.9	*Switzerland*	142.4
Hungary	69.0		
Ireland	116.6	United Kingdom	166.9
		UK Culham	127.7

– for the monthly subsistence allowance: between **EUR 0 and 720.27**, per individual per month **—** depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**

> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1300	**601.73**
> 2000	**720.27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 252.81**, per dependent child per month).

The European Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this case, the FEJP GA will be **amended** (and the Annotated MGA will be revised accordingly).

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. category D.1 'travel'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and
  - one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
    - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

- the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment
- to this amount, add the following for each leg of the journey (outward and return):
  - for train travel: a maximum of 30 minutes for each leg
  - for air travel: a maximum of 2 hours for each leg.

  NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

- for the monthly subsistence allowance:

  amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

- for the family allowance:

  amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

  The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

  '**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

  A full month can be one of the following two:

  - a **calendar month** *(e.g. 1 to 31 July inclusive)* or
  - a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

  If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*

*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*

Subtotal = EUR 85 697.25

** correction coefficient (2016) of 106.0 % (Germany Munich) = EUR 90 839.09*

*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*

Total declared unit costs: EUR 95 895.29

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*

** correction coefficient (2016) of 127.7 % (Culham, UK) = EUR 489.03*

Total declared unit costs: EUR 489.03

1.2 Specific cost category – costs for fellowships for researchers (F.2)

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships, by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility.

What not? This budget category does not cover direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; *see Article 6.2.E*).

1.2.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[133] and set out in Annexes 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [134]:

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%

[133] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[134] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Finland	116.6%	Slovenia	86.1%
France	111.0%	Slovakia	82.6%
Croatia	97.5%	United Kingdom	120.3%
Hungary	76.2%		
Ireland	113.5%	Switzerland	113.1%

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[135]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

[135] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 Specific cost category – access costs for research infrastructure (F.2)

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4 H2020 General MGA)*. FEJP beneficiaries that that have obtained a positive ex-ante assessment may opt between declaring costs under:

- category D.4 'capitalised and operating costs of large research infrastructure'

or

- category F.2 'access cost for research infrastructure'.

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, under category D.1 'travel'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be **declared as** the unit cost calculated in accordance with Decision C(2013) 8201[136] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{137}\text{)}}{\text{average annual total quantity of access (over past two years}^{138}\text{)}}$$

The averages must be based on:

[136] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[137] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[138] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 of the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

As already mentioned above, access costs for installations contributed in-kind must be declared as actual costs under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What?

For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission/Agency (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How?

The annual work plan must be uploaded directly in the Participant Portal.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the explanation of the work carried out and the overview of the progress; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION 1 in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing payment****' (see Annex 8).****]***

[OPTION 2: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **5** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing payment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a statement on the use of the first pre-financing payment *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a *[first]* **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a *[first]* pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION 1 in case of a single pre-financing payment:*** *5%]****[OPTION 2 in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU budget credits)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)) and for PCP/PPI actions. Framework partnerships are currently not (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

4.0 As from GA 4.0 FPA/SGAs are also possible for PCP/PPI actions. This does NOT apply to older grant agreements.

> ⚠ The FPA/SGA therefore now covers both research and innovation actions or innovation actions *with* a PCP or PPI and PCP/PPI actions (separate type of action with PCP/PPI as *main* action task).

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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Title of Article	FPA Article	SGA Article	MGA Article
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SECTION 2 SPECIFIC GRANTS			
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ELIGIBLE AND INELIGIBLE COSTS	11	5	6
SECTION 3 RIGHTS AND OBLIGATIONS OF THE PARTIES UNDER THE SPECIFIC GRANTS			
SUBSECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE SPECIFIC ACTIONS			
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RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS	13	6	8
IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING	14	7	9
PURCHASE OF GOODS, WORKS OR SERVICES	15	8	10
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USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE	17	10	12
IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS	18	11	13
IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES	19	12	14
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PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURES	22	14	16
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EVALUATION OF THE IMPACT OF THE SPECIFIC ACTIONS	29		23
SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS OF THE SPECIFIC ACTIONS			
MANAGEMENT OF INTELLECTUAL PROPERTY	29a		23a
AGREEMENT ON BACKGROUND	30		24
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PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING	33		27
EXPLOITATION OF RESULTS	34	18	28
DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING	35	18	29
TRANSFER AND LICENSING OF RESULTS	36	18	30
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SUBSECTION 4 OTHER RIGHTS AND OBLIGATIONS			
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PROCESSING OF PERSONAL DATA	45		39
ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*	46		40
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APPLICABLE LAW AND SETTLEMENT OF DISPUTES	63		57
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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement)
- Article 63.2 (FPA/SGA rules on dispute settlement).

For more information on framework partnerships*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name** (**short name**)], established in [official address in full] ***[OPTION for partners with VAT**: VAT number [insert number],] [**OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding (see Article 14),]* represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] (**short name**)], established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number],]*

*[**OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not receiving EU funding (see Article 14),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)]*.

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties have agreed to enter into the framework partnership under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Participants: Coordinator — Partners — Linked third parties — Third parties involved in the action

In FPAs and SGAs the beneficiaries are called '**partners**' (because technically speaking they become beneficiaries only once an SGA is signed).

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. However, partners/linked third parties that do not want to actively participate in a specific action, may participate as **partners not carrying out action tasks** and will not have to comply with most of the obligations under that SGA *(see Preamble SGA).*

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed directly in Participant Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION 1 by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION 2 if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across partners of different framework partnerships]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and the Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all Parts of Horizon 2020.

4.0 Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2)* and PCP- PPI actions; Framework partnerships are currently NOT (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

  Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 Rules of Application Regulation No 1268/2012).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA.

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Framework partnership duration

The framework partnership duration may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Programme)*.

The FPA duration can NOT be extended (i.e. it is not possible to request an amendment extending the duration). The duration of an FPA only determines the moment up to which SGAs can be signed. The SGAs can still be implemented after the end of the framework partnership.

All SGAs must be signed before the end of the FPA.

⚠ Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA has ended.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

[OPTION 2:** Not applicable**]

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

⚠ If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — **specific consortium agreements for each SGA**. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the framework partnership implementation is suspended, all specific actions are also suspended (see Article 55) — from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to GA suspension *(see Article 49 H2020 General MGA)*.

FPA suspension automatically supends all on-going specific actions.

Amendments (to resume the action) after a suspension can NOT have the effect of extending the FPA duration set out in Article 3 FPA.). The duration of an FPA only determines the moment up to which SGAs can be signed An SGA can be implemented *after* the end of the framework partnership.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. FPA termination

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ FPA termination has NO effect on ongoing SGAs (— unless they are also terminated; *see Article 56 FPA and Article 20 SGA*). Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA is terminated.

2. Partner termination

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ **Different partners at FPA and SGA level (exceptional)** — Partner termination will exceptionally lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners/linked third parties can participate as partners not carrying out action tasks for certain specific actions.

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also shows, if applicable, the estimated costs of the partners not receiving EU funding, if applicable (see Article 7 SGA) and of the international partners (see Article 12a SGA).

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and* ***forms of costs*** *of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions, applicable per budget category, are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **eligibility conditions** and **calculation rules**.

> ***Example:*** *For RIA, IA or CSA specific actions, the budget categories, types of costs, eligibility conditions and calculation rules of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

Linked third parties must already be identified in the FPA *(see Article 19 FPA)*. Their specific activities must then be set out in the specific actions.

Examples:

1. *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

2. *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like the partner they are linked to.

Linked third parties can NOT however do more than their partners: If a linked third party wants to participate in a specific action, its partner must also be active in that action (i.e. NOT be partner not carrying out action tasks). If the partner does not want to, the linked third party could itself become a partner of the FPA and SGA (— after the consortium composition is changed).

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the Agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the Agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must first submit a request for the FPA amendment (which will automatically include the change in the consortium composition for the SGAs — the new beneficiary is added (automatically) as 'inactive' to all signed SGAs under that FPA).

The coordinator must then request for each SGA a separate amendment to activate the new beneficiary *(e.g. to change Annex 1, Annex 2)*.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

63.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Framework Partnership Agreement or a Specific Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU partners (except partners established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU partner(s) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for partners not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: As an exception, *for the following partners:*

- *[insert name of international organisation or partner not eligible for EU funding]*
- *[insert name of international organisation or partner not eligible for EU funding]*

[same for other partners that are international organisations or partner not eligible for EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Framework Partnership Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 50, 51 and 52), the partners must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must always be brought against the Commission (not against the Agency — even in Agency specific grants).

1. Dispute settlement

The rules on dispute settlement are similar to those of the General MGA *(see Article 57.2 H2020 General MGA)*.

However for FPAs, the Commission/Agency will determine already at FPA-level which partners must participate as 'beneficiaries not receiving EU funding' — because of a general issue with the jurisdiction clause (i.e. Belgian courts). Those beneficiaries can NEVER receive EU funding.

All other partners' status will be determined at SGA-level. Thus, partners from eligible countries (EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme) may participate as normal partners or as 'partners not receiving EU

funding'. Partners from non-eligible countries may participate as 'partners not receiving EU funding' or — exceptionally — be granted funding.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name** (**short name**)],established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number]], [**OPTION for coordinators not receiving EU funding:** as 'partner not receiving EU funding' (see Article 7),]* represented for the purposes of signing the Specific Agreement by [function, forename and surname],

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 FPA and Article 62 FPA):

2. [**full official name**] (**short name**)], established in[official address in full], ***[OPTION FOR partners with VAT:** VAT number [insert number]],*

***[OPTION for partners not carrying out action tasks under this SGA:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not carrying out action tasks',]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT :** VAT number [insert number]], as 'partner not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 5)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Additional information on the estimated budget

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[OPTION if the JRC participates: *Annex 5: Administrative Arrangement]*

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Partners — Partners not carrying out action tasks under the SGA — Linked third parties

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. An entity that is not partner/linked third party in the FPA cannot become party in the SGA. Conversely, all partners/linked third parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners (and linked third parties) who do NOT actively participate in a specific action are **partners not carrying out action tasks** under that Specific Agreement (and must be identified as such in the preamble to the SGA).

Partners not carrying out action tasks — They formally participate in the action as partners, but NOT with any action tasks or EU funding. In practice, most of the obligations therefore do not apply to them for that specific action.

Linked third parties — If a partner participates as not carrying out action tasks, its **linked third parties** get the same status. They can NOT actively participate in the specific action (— unless they themselves become partners of the FPA and SGA).

These partners are formally part of the consortium for the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will be identified in Annex 1 as 'partners not carrying action tasks' (as they do not carry out any action tasks). Moreover, they will also be mentioned in Annex 2 with zero costs.

Formally, the rights and obligations under the FPA and SGA fully apply to them. In practice however, many of them *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, financial or technical audits or reviews, IPR results, access to background and results of others, etc.)* are NOT applicable because these partners do not carry out action tasks and do not receive any EU funding. Other obligations remain relevant *(e.g. checks, information obligations, confidentiality)*.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed directly in the Participant Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including **linked third parties**) are considered as '**third parties involved in the specific action**'.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

Same partners at FPA and SGA level — If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump sum MGA

IX.1 Background information and approach

The Lump sum Model Grant Agreement (H2020 MGA Lump sum) is used mainly for coordination and support actions (CSA) and, exceptionally, for research and innovation actions (RIA) and innovation actions (IA) — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5*

The MGA Lump sum follows the General MGA for numbering and content, except for:

The H2020 MGA Lump sum deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5, Annexes)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 MGA lump sum: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. CSA, RIA and IA lump sum actions

What? Lump sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for a lump sum grant.

For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

CSA, RIA and IA lump sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of Horizon 2020 *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The MGA Lump sum does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the MGA Lump sum:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA): 70%** of the action's eligible costs]*[8]*[**OPTION 3 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The MGA Lump sum does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For Lump sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For Lump sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The MGA Lump sum has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the action (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs' **covers** the (direct and indirect) costs for the action.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice the declaration of costs for Lump sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

Since the Lump sum grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

⚠ If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

The rules on third party involvement in lump sum actions are limited to purchases (Article 10), subcontracting (Article 13) and **linked third parties** (Article 14 H2020 General MGA).

The provisions on in-kind contributions (Articles 11 and 12 H2020 General MGA) do NOT apply — since, for Lump sum grants, in-kind contributions are not linked to any specific conditions. (Specific rules are only needed where a grant reimburses *actual* costs).

For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[9] (or 2014/24/EU)[10] or 'contracting entities' within the meaning of Directive 2004/17/EC[11] (or 2014/25/EU)[12] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).
[10] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).
[11] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).
[12] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for Lump sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for lump sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The MGA Lump sum has however the **following specificities**:

The estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[18]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For lump sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

Such records and supporting documentation must:

- refer to the scientific and technical implementation of the action in line with the accepted standards in the respective field *(see Article 18 General MGA)* and
- prove that the corresponding tasks or part of the action allocated to the beneficiary as described in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.2a Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a **'statement on the use of the previous pre-financing instalment',** including **the request for a further pre-financing payment** (Annex 7).

20.3. Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2 :*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

When & What? For lump sum actions, the coordinator has to submit — after each reporting period — a **periodic technical report**, with information on the technical implementation.

NO financial report is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; *see Article 7*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

At the end of the action, the coordinator has to submit a **final report** with both the technical and financial report.

2. Reporting periods

When? The lump sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- a *[first]* **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- *[same for more pre-financing payments]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2a if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments — No interim payments

Lump sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment(s)

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

> The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.
>
> The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:
>
> – if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
>
> – if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.
>
> ***Example:***
>
> *Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.*
> *90% limit of the maximum grant amount: EUR 360 000.*
> *3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.*
> *Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.*
> *2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;*
> *3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;*
> *Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
> *70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
> *Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000*
> *3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.*

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation at the end of the action, and in particular:

– the amount of pre-financing(s) already paid *(see Article 21 H2020 General MGA)*

– cost rejections (improper implementation of the action; *see Article 42)*

– grant reduction (other serious breaches or substantial errors, irregularities or fraud *see Article 43)*.

ARTICLE 41 — BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Agency][Commission]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for lump sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs does not lead to a **recovery,** *[Commission][Agency]* will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since Lump sum grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1).* Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ 'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide requested information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since Lump sum grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Agency or the]* Commission*]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION 2 :*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or]* ***[OPTION 2:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The lump sum multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant) the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide requested information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Article 43 and Article 44).

1. GA suspension (beneficiaries or Commission/Agency)

The rules on GA suspension are in principle the same as for the General MGA (see *Article 49 H2020 General MGA)*.

The lump sum MGA has, however, the **following specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION 2:** not applicable]*;

(j) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION 2:** not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2).

*(n) [**OPTION 1**: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][**OPTION 2**: not applicable].*

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n)above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the [Commission][Agency]

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) ***[OPTION 1****: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][****OPTION 2****: not applicable].*

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or to beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for actions under lump sum actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Partner termination (beneficiaries)

The rules on partner termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the lump sum multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. GA or beneficiary termination (Commission/Agency)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the multi-beneficiary MGA Lump sum has the **following specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

H2020 Programme

AGA – Annotated Model Grant Agreement

Version 4.0
21 April 2017

Disclaimer
This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the its executive Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	▪ Initial version following adoption of the grant agreement v.1.0. Article 6.
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to Main Work Programme – MSCA (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement v.2.0, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSCA ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles
2.0	30.03.2015	▪ Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. ▪ Clickable cross-references (Articles) ▪ New table explaining the treatment of the different types of work contracts (under Article 6.2.A). ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. ▪ Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 ▪ Other minor corrections and clarifications
2.0.1	18.05.2015	▪ Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants

2.1	30.10.2015	▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47, 50, 55 and 56. ▪ New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses ▪ New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Phase 1: Article 5; – SME Instrument Phase 2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. ▪ Other minor corrections and clarifications.
2.1.1	01.07.2016	▪ Update of the explanations on Article 18 regarding time records; including a model of time-sheet with the minimum requirements.
2.2	25.11.2016	▪ Updates due to the amendment of the model grant agreement v.3.0, in particular Articles 4.2, 5, 6.2.A, 10, 13, 16, 20, 34, 37, 41, 42, 43, 45, 46, 48, 49, 50 and 55 ▪ New annotations on Articles 29.2 and 29.3. ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6, 6.1, 6.2, 6.5 and 18. ▪ Updates in the annotations to specific model grant agreements: - ERC: Preamble, Articles 6, 29 and 56a - MSCA: Preamble ITN, Articles 4, 5, 6, 8, 18, 19 and 32; IF Articles 2, 4, 6, 8, 18, 32 and 56a; RISE Articles 4, 6, 8, 18, 19, 31 and 32; COFUND Articles 4, 6, 8, 15 and 18. - ERA-NET Co-fund: Articles 2, 19 and 21 - PCP-PPI: Articles 5 and 13 - EJP Co-fund: Articles 5, 6.F and 20 ▪ Synchronised presentation for grounds for Chapter 6 measures, security obligations and information obligations. ▪ Other minor corrections and clarifications ▪ Update in Section I.3 'List of issues applicable to particular countries' New rules that apply in principle only for grant agreements signed with version 3.0 are marked with 3.0 » (This version refers to MGA v3.0 to align it no AGA v3.0 was created)
4.0	21.04.2017	▪ Updates due to the amendment of the model grant agreement v.4.0, in particular Articles 5, 6 and 52 ▪ New annotations on Article 14a following the introduction of this Article in the revised model grant agreements v.4.0 ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6 and 18. ▪ Updates in the annotations to specific model grant agreements: ERC, MSCA, PCP-PPI and FPA/SGA ▪ Other minor corrections and clarifications For easy identification, paragraphs, indents or sections with new explanations are marked with the symbol ■ on the left. New rules that apply in principle only for grant agreements signed with version 4.0 are marked with 4.0 »

IMPORTANT NOTICE

The **AGA — Annotated Model Grant Agreement** is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement (General MGA) and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020 (H2020).

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and eligibility conditions of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

   New rules that do not apply to all signed grant agreements (but instead only to those signed after a certain version, e.g. version 3.0), will be marked with: 3.0 and 3.0

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the H2020 MGAs. For a more general overview of how H2020 grants work, see the Online Manual.

A comprehensive list of all H2020 reference documents (including legislation, work programme and templates) can be found on the Participant Portal Reference documents page.

H2020 terms are explained in the Participant Portal Glossary.

If necessary, you can also contact the Research Enquiry Service.

Legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1 'Health, Demographic Change and Wellbeing', etc.*

⚠ **Specific MGAs —** The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**] established in [official **address** in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full]* ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]* *as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form [OPTION if the JRC is a beneficiary: or the Administrative Arrangement], the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

'**Beneficiaries**' means the legal entities who have signed the grant agreement (GA) with the Commission/Agency (i.e. participate in a project supported by an EU grant).

⚠ The term **participant** is used in this document in a wider meaning than in the definition of Article 1.1(15) of the Rules for Participation Regulation No 1290/2013. It covers normally beneficiaries and linked third parties (and sometimes also other third parties involved in the action).

The '**coordinator**' is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the

action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 (technical implementation) and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including **linked third parties**, subcontractors, third parties giving in-kind contributions, etc) are considered as **third parties involved in the action** *(see Articles 8 and 9-14)*.

They are formally speaking not bound by the terms and conditions of the GA, although it implies certain obligations for them; conversely, the Commission/Agency has no formal contractual link with them.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries.

2. Name and address — Legal entity data

The legal entity data (legal name, address, legal representatives, etc.) of the beneficiaries comes from the Participant Portal Beneficiary Register.

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries (via their **legal entity appointed representative (LEAR)**) must keep their **data** in the Participant Portal up-to-date at all times including after the end of the grant (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[1]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[2]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[3].

[1] More information on the types of action can be found on the General Annexes to the Work Programme.

[2] For the definition, *see Article 2.1(6) of the Rules for Participation Regulation No 1290/2013:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[3] For the definition, *see Article 2.1(7) of the Rules for Participation Regulation No 1290/2013:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may

The term **action** comes from the Financial Regulation No 966/2012 and **means project**. (Previous EU Research Framework Programmes used project.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of Horizon 2020 *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

For more information on RIA, IA and CSA actions, *see the Online Manual and the H2020 grants fact sheets.*

2. Complementary grants

'Complementary grants' are different EU grants which are linked by the work programme/calls by identifying them as complementary actions.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written **collaboration agreement** regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a non-associated third country (i.e. a third country not associated to Horizon 2020) or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[4]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 of the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a **coordination agreement** *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

For guidance on coordination agreements, *see the Guidance — How to draw up your coordination agreement.*

also include complementary activities of networking and coordination between programmes in different countries.

[4] *See Article 12 of the Rules for Participation Regulation No 1290/2013.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)]* *[**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The action starting date is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties

  Example: *GA signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium (via the coordinator) requests a *fixed* starting date before the entry into force of the GA, it (the consortium) assumes the risks implied by starting the action before the GA is signed, in particular not being reimbursed for the costs incurred (*e.g. the eventuality that the proposal is not successful or that the GA is not signed)*

  ⚠ The action starting date can **NEVER** be **before** the **submission** of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The action duration is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the ***action tasks*** (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as project closure or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*:* Moreover, *lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding and costs of international partners will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9 and Article 14a)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

⚠ Costs for personnel, equipment, goods or services that are in-kind contributions by a third party (for free or against payment) can in practice simply be added to the budget category they correspond to (i.e. personnel costs or other direct costs) — if they comply with the eligibility rules set out in Articles 6 and 11 and 12.

3. Budget transfers

The budget in Annex 2 is an estimation.

Therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget.

Moreover, beneficiaries may transfer budget among themselves, between linked third parties or between budget categories — without requesting an amendment *(see Article 55)* (unless Annex 1 must be changed).

⚠ The maximum grant amount *(see Article 5.1)* can however **NEVER** be **increased**.

What can be transferred?

If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example: *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not?

The GA allows transfers of budget, not of **tasks**.

A beneficiary cannot transfer budget to a **form of costs** that it did not set out **in its estimated budget** — except within the personnel costs category.

Example (allowed transfer): *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is acceptable without an amendment of the GA.*

Example (not allowed transfer): *A beneficiary budgets all its costs as 'actual costs' in the estimated budget. However, at the end of the first reporting period, the beneficiary wants to declare part of the costs by using a specific unit cost allowed in the call (e.g. unit cost for clinical studies). This is NOT possible without an amendment of the GA.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work ('action tasks') of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the 'simplified approval procedure' without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %*** *of the action's eligible costs]* ***[OPTION 2 for innovation actions (IA)***[7]***: 100%*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[8] *and* ***70%*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]* ***[OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA:*** *[…%] of the action's eligible costs]* ***[OPTION B for IA:*** *[…%] of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[9] *and […%] of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]]*** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[10]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[12]: ***[OPTION 1 to be used if Article 15 applies:*** *as actually incurred costs (**actual costs**);]* ***[OPTION 2****: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[13]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[14]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a[16] ('**unit costs**').]*

***[OPTION** 1b **for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION 2: specific cost category(ies):** not applicable.]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

10 To be used only if option in Point (f) is used.

11 To be used only if option in Point (f) is used.

12 To be used only if option in Point (f) is used.

13 To be used only if option in Point (f) is used.

14 To be used only if option in Point (f) is used.

15 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

16 Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount can **NEVER** be **increased** — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA and CSA actions is normally **100%** of the total *eligible* costs[5]; for IA actions it is normally **70%** of the total eligible costs[6].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[7].

5 *See Article 28(4) of the Rules for Participation Regulation No 1290/2013.*

6 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rate of a beneficiary does NOT condition the reimbursement rate of its linked third parties.

Example: *The beneficiary is entitled to 70 % but it has a linked third party entitled to 100 %. The linked third party will have a reimbursement rate of 100 % — despite the lower reimbursement rate of the beneficiary to which it is linked.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

⚠ The grant can **NEVER** reimburse **more** than the maximum grant amount fixed in Article 5.1.

3. Costs forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump-sum costs)[9]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - **personnel** costs (— unless declared as unit cost; *see below*)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs** (— unless declared as unit cost; *see below*)

    Example: *EUR 2000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - personnel costs of **SME owners/natural persons** not receiving a salary[10]
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)[11]
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices

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7 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

8 *See Article 28(6) of the Rules for Participation Regulation No 1290/2013.*

9 *See Articles 123, 124 of the Financial Regulation No 966/2012.*

10 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

11 *See Article 33(2) of the Rules for Participation Regulation No 1290/2013.*

- specific unit costs for:
  - costs for **energy efficiency measures** in buildings[12]
  - **access costs** for providing trans-national access to research infrastructure[13]
  - costs for **clinical studies**[14]
- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[15]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

Example: *EUR 150 000 to carry out a study within an action*

The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	Budget categories					
	Direct personnel costs	**Direct costs of sub-contracting**	**Direct costs of financial support to third parties (option used if Article 15 applies)**	**Other direct costs**	**Indirect costs**	**Specific cost categories (option used if Article 6.2 (F) applies)**
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: -costs established according to the usual cost accounting practices of the beneficiary -costs of SME owners and natural persons not	NO	NO	YES, only for: costs of internally invoice goods and services	NO	YES, only if foreseen by Commission Decision

[12] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[13] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

[14] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[15] *See Article 29(1) of the Rules for Participation Regulation No 1290/2013.*

	receiving a salary					
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the **errors, irregularities or fraud** or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action (or in case of GA termination) —, in order to determine the balance to be paid.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex 1

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 of the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

Procedure for calculating the final grant amount:

Calculation of final grant amount

Step 1 — Application of reimbursement rate(s) to eligible costs

Step 2 — Limit to the maximum grant amount

The grant amount following Steps 1 and 2 is the lower of the two amounts.

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

The final grant amount is the lower of the following two amounts obtained following Steps 1 to 3 or following Step 4.

final grant amount

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s).

Ineligible costs (i.e. costs that do not comply with one or more cost eligibility conditions; *see Article 6*) will — if found at payment of the balance — be **rejected** (i.e. not approved).

If, for innovation actions (IA), there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The contribution is limited to the maximum grant amount *(see Article 5.1)*.

Step 3 — Reduction due to the no-profit rule and receipts.

Since the grant amount may not have the purpose or effect of producing a profit for the beneficiaries, the total funding requested + receipts is capped at the total eligible costs; the grant amount following Steps 1 and 2 plus receipts cannot exceed the approved costs.

If grant amount + receipts > total eligible costs ➔ reduction of grant amount

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The grant amount, receipts and eligible costs taken into account are the *consolidated* grant amount (following Steps 1 and 2), the *consolidated* receipts and the *consolidated* approved costs.

The **receipts** that must be taken into account are receipts that are:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or
- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation)

during the action duration (see Article 3).

The following **are** considered '**receipts**':

- income generated by the action (i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped to the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action (i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for the action covered by the GA)

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs (i.e. not

money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action covered by the GA)

Examples: *the free use of equipment; the secondment of an expert without reimbursement*

Free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered '**receipts**':

- in-kind contributions given by a **third party (donor)** free of charge — if they were not given specifically to be used for the action

  Example: *A university professor whose costs are charged by the beneficiary university in the GA, but whose salary is paid by the ministry and not reimbursed by the university: This in-kind contribution from a third party (the ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions given by a third party (donor) specifically to be used for the action — if they may be used according to the donor's rules to cover costs *other* than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

- financial contributions made **by one beneficiary to another** within the same action — since receipts are only contributions from *third parties*

  Conversely, such a financial contribution cannot either be declared as cost for the action.

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

- income generated by exploiting the results of the project (*e.g. the IPR*) — since successfully exploiting the results is one of the main objectives of the action

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance (i.e. the final payment at the end of the action). They must be declared in the final report.

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations.

What? Serious breach of obligations refers to (non-exhaustive list):

- improper implementation of the action
- submission of false information
- failure to provide required information
- breach of ethical principles.

Proper implementation will be analysed by the Commission/Agency, comparing the work performed (according to the periodic and final technical reports) to the activities described in Annex 1. Improper implementation may lead to a grant reduction (i.e. reduction of the 'maximum grant amount'; see Article 5.1) — on a case-by-case basis (and only after a contradictory procedure with the coordinator or the beneficiary concerned; *see Article 43*).

Minor delays/deviations in the technical work foreseen in Annex 1 will not give rise to a grant reduction.

Example (reduction): *one of the 3 test plants was not built, and several testing activities were not carried out; breach of the obligation to display the EU emblem or to respect confidentiality of information identified as confidential.*

Examples (no reduction): *a deliverable is delayed by a couple of days because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions*

⚠ A grant reduction is NOT a sanction, but the consequence of substantial errors, irregularities or fraud or serious breach of obligations under the GA.

Example for calculating the final grant amount:

Grant for a consortium with a maximum grant amount of EUR 3 000 000, where the eligible costs are reimbursed at 100%, and the indirect costs are calculated on the basis of a flat rate of 25% on the direct costs (minus subcontracting, costs incurred by third parties not used in the beneficiaries' premises and costs of providing financial support to third parties).

The total direct eligible costs of the consortium approved by the Commission/Agency are EUR 2 500 000.

One of the beneficiaries is sponsored for this project by a private company, with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher, and another beneficiary (a university) receives as in-kind contribution from its government the secondment of a scientist specifically assigned to the project. The salary of this seconded scientist (EUR 80 000) is declared as eligible by this beneficiary, even if paid by the Government.

Both these contributions fit the definition of receipts (see above).EUR EUR

Rejection of ineligible costs and application of the reimbursement rates:

Eligible costs: EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000

Reimbursement rate: 100%

Amount obtained: EUR 3 075 000

Limit to the maximum grant amount:

The total eligible costs of EUR 3 075 000 are higher than the maximum grant amount of EUR 3 000 000. However, the maximum amount cannot be increased and therefore, it is limited to EUR 3 000 000.

Reduction due to the no-profit rule and receipts:

In the example above, the profit at the level of the action would be calculated by taking the surplus of EUR 3 000 000 (amount obtained after steps 1 and 2), plus the action's total receipts, over the action's total approved eligible costs (EUR 3 075 000):

3 000 000 + 60 000 + 80 000 = EUR 3 140 000.

Total eligible costs: EUR 3 075 000.

Profit: EUR 3 140 000 – EUR 3 075 000=EUR 65 000

Grant amount after reduction due to no-profit rule: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Reduction due to substantial errors, irregularities or fraud or serious breach of obligations:

Reduction of 2% of the maximum grant amount as the Coordinator of the consortium breached a confidentiality obligation of Article 36 GA, namely EUR 60 000→ 3 000 000 - 60 000 = EUR 2 940 000

The final amount of the grant will be the lower between the following two:

- *the amount obtained after applying the reimbursement rates to the total eligible costs, within the ceiling of the maximum grant amount and after applying the no-profit rule (Step 1,2 and 3): 2 935 000*
- *the reduced maximum grant amount obtained in Step 4: 2 940 000.*

***Final grant amount**: EUR 2 935 000.*

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, substantial errors, irregularities or fraud or serious breach of obligations (and therefore **rejects the costs** and/or **reduces the grant**), it will revise the final grant amount, for each beneficiary concerned (i.e. at beneficiary level).

For **rejection of costs**: the Commission/Agency will deduct the amount rejected from the total eligible costs declared by the beneficiary in the final summary financial statement *(see Article 42.3)*. The revised final grant amount will be calculated by applying the reimbursement rate to the revised eligible costs of the beneficiary concerned.

Example:
Maximum grant amount: 500 000
There are three Beneficiaries A, B and C
Reimbursement rate: 100%
Direct eligible costs accepted for Beneficiary A at the payment of the balance: 150 000
Total eligible costs accepted for Beneficiary A at the payment of the balance = 150 000 + 25% (indirect costs) = 187 500
Costs rejected following audit: 30 000
Revised direct eligible costs: 120 000
Revised total eligible costs= 120 000 + 25% (indirect costs) = 150 000
Revised final grant amount: 100% of 150 000 = 150 000

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a **recovery** *(see Article 44.1.3)*.

For **reduction of the grant**:

- the Commission/Agency will reduce the maximum grant amount set out in Article 5.1, in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations *(see Article 43)*.
- calculate the revised final grant amount (for each beneficiary concerned), by allocating the amount of the reduction to each of them in proportion to the seriousness of the errors,

irregularities or fraud or breach of obligations to its improper implementation or breach of obligation

Example:

Maximum grant amount and final grant amount: 500 000.

There are three Beneficiaries A, B and C.

Reimbursement rate: 100%.

According to the estimated budget, beneficiary A was entitled to a maximum contribution of 200 000 for carrying out its work set out in Annex 1.

Total eligible costs accepted for Beneficiary A at the payment of balance: 187 500

1a: *The Commission finds that beneficiary A has implemented only 80% of its work provided for in Annex 1.*

Revised final grant amount of beneficiary A: 80% of the share of beneficiary A in the maximum grant amount: 80% of 200 000 = 160 000.

1b: *The Commission/Agency finds that beneficiary A breached its confidentiality obligations, which had an impact of the full action and for which the reduction rate is set at 2%.*

2% of the maximum grant amount = 10 000

The breach is entirely attributable to beneficiary A: 100% of the reduction is allocated to beneficiary A.

Revised final grant amount of beneficiary A: 187 500 – 10 000= 177 500.

⚠ If for the beneficiary the *revised* final grant amount is lower than its share of the *final* grant amount, there will be a **recovery** *(see Article 44.1.3)*.

For **rejection of costs AND reduction of the grant**: the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above (i.e. after cost rejection or after grant reduction).

Example: *The revised final grant amount for beneficiary A will be 150 000 (the lowest between 150 000 (amount obtained following the rejection of ineligible costs) and 160 000/ 177 500 (amount following the reduction of the grant in the 2 examples above).*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only** reimburse **eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Article 6.1 refers to general eligibility conditions, applicable per cost form *(see Article 5)*.

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action (or after GA termination) are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

  ⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  Examples:

  1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

  2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

3. Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible, if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements (CFS) required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

Personnel costs for ERA chairs — Are eligible even if the salary is above national salaries, provided that it does not go beyond normal EU/international salaries for similar positions (since the ERA chairs aim to incentivise international mobility for internationally outstanding researchers and research managers. When the level of remuneration of the ERA Chair is indicated in Annex 1, this will be duly taken into account in case of checks, audits or reviews.

Costs to allow for the participation of disabled people *(e.g. costs for sign language interpreters required for dissemination events organised under the action)* — May be eligible if they fulfil the general and specific eligibility conditions listed under Articles 6.1 and 6.2. The beneficiaries must keep records *(see Article 18)* to prove in case of an audit, check or review the actual costs incurred and that they were necessary for the implementation of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

Example: A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2a.

- the **number of units** must be **necessary** for the action
- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

> ***Example:*** *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Costs declared on the basis of the usual accounting practices— For two budget categories (A. personnel costs and D.5 costs of internally invoiced goods and services), costs may be declared not as a fixed unit cost, but on the basis of the beneficiary's usual cost accounting practices. In this case,:

- the beneficiary:
  - must calculate the costs according to its usual accounting practices
  - must budget and declare a total amount (not the units used)
- the amount per unit is not fixed in Annex 2a.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency and set out in Annex 2a of the GA *(see Article 5.2)*.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump-sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and

- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION 1 for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)*[16]*]*][***OPTION 2:*** *not applicable*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to **specific eligibility** conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

– either costs that have been caused in full by the activities of the action

- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action can NOT be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a **25% fixed flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual** costs (i.e. budget categories A.1, A.2, A.3 [*and A.6*]): the hourly rate is calculated per full financial year, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories A.1, A.2, A.4, A.5 [*and A.6*]): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(iii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

1. Direct personnel costs (A.): Types of costs — Forms — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Employees (or equivalent) (A.1)

1.1.1 What? Personnel costs for employees or equivalent (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) that worked in the action.

⚠ '**Equivalent appointing act**' means the appointing acts of civil servants (who do not sign employment contracts but receive official nominations for their posts).

⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Reliable time records will normally be sufficient proof of the assignment to the action — unless there is other contradicting evidence *(e.g. the employment contract indicates that the person was hired to work on another project)*

It covers (and is limited to):

- **basic remuneration** (i.e. the payments for the employee's normal work and participation in projects — up to what is the beneficiary's usual remuneration practice for national projects)

and, in addition:

- for non-profit legal entities: **additional remuneration** (i.e. extra payments made for the participation in projects — above the beneficiary's usual remuneration practice for national projects).

⚠ **National projects** are to be understood in the large sense, meaning all types of projects funded under any type of national (public or private) funding scheme (including projects co-financed by EU funds that are managed by the Member States, *e.g. regional funds, agricultural and fisheries funds*).

Projects from EU programmes directly managed by the Commission/Agencies or their funding bodies *(e.g. LIFE, ERASMUS, Health, etc.)* do not, however, qualify as national projects (but as EU/international projects).

Both basic remuneration and additional remuneration do not only cover the payment itself (salary or bonus), but also the social security contributions *(mandatory employer and employee contributions)*, taxes included in the remuneration *(e.g. income tax)* and other costs and payments included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee).*

What not? Cost of persons who work for the beneficiary, but NOT with an employment contract or equivalent appointing act *(e.g. staff provided by a temporary work agency, seconded staff, self-employed persons with a direct contract with the beneficiary)*.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions *(e.g. best value for money and no conflict of interest; see Articles 10 and 13)*.

Seconded staff and **self-employed persons with a direct contract —** Can also be declared under other categories within the personnel costs *(see below, points 1.2 and 1.3)*.

1.1.2 Costs for employees (or equivalent) must be **declared** as:

- **actual personnel costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.1.3 The costs for employees (or equivalent) must comply with the following **eligibility conditions**:

- **For basic remuneration**:

  - fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

    Payments of dividends to employees (profit distribution) are NOT eligible under *Article 6.5(a)(i)*. However, bonuses based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted, if they fulfil the conditions set out below, i.e. as part of the usual remuneration practices for national projects and thus eligible as basic remuneration.

    Examples (positive):

    If the profit of the company at the end of the year is more that x € (or more than x %), each employee will receive a bonus of z % of his/her basic remuneration (or a fixed bonus of x € more as part of the gross salary).

    Examples (negative):

    If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.

    Any part of the remuneration which is based on commercial targets or fund raising targets is NOT eligible (because neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation).

    ***Examples**: x € for reaching a sales target; x % on sales; x € premium per externally funded project gained; x % of the external funding gained*

  - be paid in accordance with national law, the collective labour agreement and the employment contract/equivalent appointing act

    Examples:

    ***1.** The collective labour agreement establishes that all researchers may receive a bonus between EUR 100 and EUR 200 per month based on their seniority.*

    ***2.** The national law authorises public universities to pay a bonus based on merit of the employees.*

    ***3.** The contract fixes a premium of EUR 1000 for each research paper published in peer-reviewed international research journals.*

  - **exclude arbitrary bonuses** (i.e. bonuses which are not part of the beneficiary's usual remuneration practices and/or which are not based on objective conditions).

- **For additional remuneration** (in addition to the conditions above):

  - be a **non-profit legal entity**

  - be paid for the performance of **additional work** or **different expertise** than his/her usual tasks

    This is usually the case, since additional remuneration aims precisely to reimburse the additional work/expertise that is required for EU and international projects.

  - be **consistently applied** whenever the same kind of work or expertise is required and **regardless of the source of funding** used

    The additional remuneration may not differ according to *where* the funds come from. In particular, it cannot be set up for actions funded by a specific donor; additional remuneration schemes that are applicable only to EU projects are not acceptable.

    ***Example (not acceptable):** All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

    Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

However, the additional remuneration does not have to be the *same* for all persons working in the same project (provided that objective criteria are used to determine the differences).

⚠ **8000 EUR ceiling —** Additional remuneration is eligible **ONLY up to** a ceiling of **8000 EUR** annual costs; *see point 1.1.4*).

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Teleworking — Remuneration costs of personnel not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible, if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of quasi-financial benefits *(e.g. costs of lunch vouchers)* may be accepted as eligible, if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally NOT eligible as direct costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action, the related costs would be considered part of the entity's normal indirect costs, which are covered by the 25 % flat-rate.

Costs for students, PhDs and other researchers under scholarship, internship or similar agreements (not employees) — Costs of students that work for the beneficiary can be accepted, if the agreement is work-oriented (not training-oriented: i.e. not aimed at helping the student to acquire professional skills).

PhD agreements will be considered work-oriented. However, time for training, if any, may NOT be charged to the action.

Fellowships/scholarships/stipends — Can be charged to the action (as personnel costs), if they fulfil the conditions set out Article 6.1 and 6.2.A.2, and in particular:

- the remuneration complies with the application national law on taxes, labour and social security
- the assignment of tasks respects the laws in force in the country of the beneficiary
- the students have the necessary qualifications to carry out the tasks allocated to them under the action.

Cost for exemptions from academic fees — The fees (or part of them) are eligible as personnel cost, if the student's contract includes the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic remuneration only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible).

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts for participation in projects (whatever their form) are acceptable if it is the beneficiary's usual practice and compatible with national law. The remuneration will be qualified as basic or additional remuneration, depending on the scope (national OR

EU/international) and amount (above, equal or below usual remuneration practices for national projects).

1.1.4 The **costs** must be **calculated** as follows:

In general, personnel costs for H2020 actions are calculated (for each person assigned to the action, including persons working exclusively on the action) as follows:

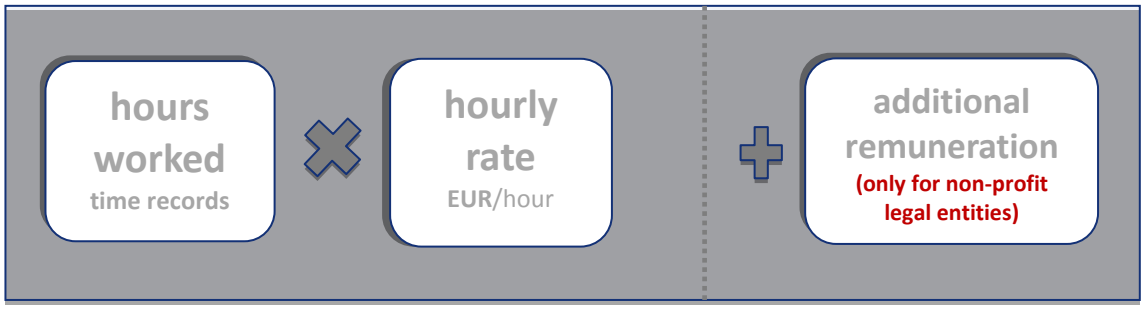

In practice, the calculation will differ (per type of beneficiary/employee) depending on the remuneration practices of the beneficiary:

Case 1: beneficiaries declaring personnel costs as actual costs

Case 1A: employee whose remuneration is not project-based (i.e. same remuneration, regardless if they are involved or not in specific projects)

Case 1B: employee whose remuneration is project-based (i.e. different remuneration levels, depending on whether they work in specific projects or not)

Examples:

1. *The beneficiary and the researcher sign a separate employment contract for the work of the person in the Horizon 2020 action. The hourly rate resulting from that additional employment contract is different from the hourly rate of the other employment contract of the person with the beneficiary.*

2.*The beneficiary has a remuneration scheme which includes the payment of a bonus for work in specific projects. The bonus is paid as part of the total salary of the person in addition to the basic salary and other general bonuses.*

3. *The employment contract of the person fixes a specific hourly rate to be paid for work in specific projects. This hourly rate replaces the standard salary of the person while it works in those projects.*

Case 2: beneficiaries declaring personnel costs as unit costs in accordance with the usual cost accounting practices (average personnel costs).

Additional remuneration is in practice an issue ONLY for case 1B beneficiaries. All other beneficiaries will automatically fall under 'basic remuneration only' and therefore are not concerned by the provisions on additional remuneration.

Case 1B beneficiaries need to differentiate between payments that are basic remuneration and payments that are additional remuneration. For them, the hourly rate charged to the action must be calculated using only basic remuneration (i.e. excluding any part that qualifies as additional remuneration). Additional remuneration may be charged (separately and on top), if the beneficiary is a non-profit entity, if that remuneration is eligible and only up to a ceiling of 8000 EUR per year.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ **Double ceiling —** Beneficiaries must ensure that:

- the **total number of hours** worked **declared** in EU and Euratom grants for a person for a year is NOT higher than the number of **annual productive hours** used for the calculation of the hourly rate *(see below)*
- the **total** amount of **personnel costs declared** (for reimbursement as actual costs) in EU and Euratom grants for a person for a year is NOT higher than the total personnel costs recorded in the **beneficiary's accounts** (for that person for that year).

How to calculate direct personnel costs for employees (or equivalent):

For case 1A beneficiaries (actual costs, not project-based remuneration): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary must calculate, for each employee, the hourly rate to be charged to the action by using one of the following methods:

- **per full financial year** (main method): single hourly rate for each person for each full financial year
- **per month** (alternative method): one hourly rate for each person for each month (i.e. 12 hourly rates per person for each financial year).

Each beneficiary may choose any of the two options. However, the option chosen must be applied during the full financial year to all its personnel in all H2020 grants. If the beneficiary wants to change option, it can do so for the next financial year (— again for all its personnel in all its H2020 grants).

⚠ **Recalculations & adjustments of financial statements (exceptional) —** To benefit from this new option (i.e. hourly rate per month) beneficiaries may apply it retroactively for all grants on-going (i.e. for which the final report has not been submitted) on 20 July 2016 (i.e. date of adoption of the H2020 MGA version 3.0). The beneficiary may re-calculate costs already declared on the basis the full financial year by using the monthly calculation method. However, in that case it must do the recalculation for ALL personnel costs declared for that/those financial year(s) in ALL on-going H2020 grants. The beneficiary must declare the differences, either positive or negative, as adjustments in the next reporting period.

⚠ The grant agreement **formulas for the hourly rates are mandatory**. Those formulas may lead to minor/temporary differences with the personnel cost recorded in the accounts. Those differences have no impact on the eligibility of the costs, provided that the formula has been correctly applied and that the *double ceiling* explained above has been respected.

Calculation of the hourly rate *per full financial year*

Annual hourly rates must be calculated as follows:

for each person:

{actual **annual personnel costs** (excluding additional remuneration) for the person
divided by
number of **annual productive hours**}.

The rate must be calculated by ***full financial* year** (i.e. the 12-month period covered by the annual accounts of the entity).

Example: *When the financial year matches the* ***calendar year****, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance with the GA is available. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate. The method must however be consistently applied and can NOT be changed within the same grant.

⚠ **No adjustments of financial statements —** Adjustments to the hourly rate are normally allowed ONLY for mistakes *(e.g. incorrect accounting information; error in the calculation; etc).*

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed (even if a recalculation of the hourly rate after the closure of the financial year would give another result).

The **annual personnel costs** may include only eligible personnel costs.

Any part of the remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 2:** the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours'**)
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option (1, 2 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed ad-hoc for specific employees)*.

The beneficiary must keep the same option(s) for *the full financial year*. It can only change its option(s) for the next financial year.

⚠ **Absences & overtime —**

Absences: the three options treat absences (leave) in different ways:

- under option 1 (1720 fixed): ONLY actual time spent on parental leave (maternity and parental leave) may be deducted from the 1720 fixed hours. NO other leave *(e.g. sick leave, special leave, annual leave, etc.)* can be deducted.
- under option 2 (individual): the beneficiary must deduct all leaves (i.e. *actual time* on sick leave, parental leave or special leave, etc.) to calculate the annual productive hours.

  ⚠ In order to calculate the annual workable hours, the beneficiary has to deduct the annual leave entitlement (see example in the *table of options*). However, if the employment contract allows end-of-year transfers for leave entitlements (i.e. the days not taken one year can be taken the next one; days not taken are not paid out), the beneficiary may opt for deducting instead *actual time* of annual leave (if this is done consistently throughout the years).
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard time of absence in the organisation. However, the beneficiary may deduct on top the actual time spent on parental leave (maternity and parental leave) by the individual employee.

Overtime: all three options include potential overtime in the annual productive hours, either implicitly (options 1 and 3) or explicitly (option 2):

- under option 1 (1720 fixed): NO overtime may be added to the 1720 fixed hours
- under option 2 (individual): all overtime worked (paid or unpaid) must be added to the annual workable hours to calculate the annual productive hours
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard overtime hours in the organisation (if any).

⚠ **No impact on the hours worked —** The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding hours worked can NOT be charged to the action (they must be capped at the ceilings).

Calculation of the hourly rate *per month*

Monthly hourly rates must be calculated as follows:

for each person:

{actual **monthly personnel costs** (excluding additional remuneration)
divided by
{number of **annual productive hours/12**}**}**.

The rate must be calculated **for each month**.

The **monthly personnel costs** may include only eligible personnel costs.

If a part of the remuneration is generated over a period longer than a month *(e.g. the thirteenth salary)*, only the entitlement generated in the month can be included in the monthly personnel costs (— irrespectively of how much is actually paid in that month).

Example:

In accordance with the collective labour agreement, Ms T is entitled to a thirteenth salary (another full month salary in addition to her 12 monthly salaries) to be paid in July each year. The monthly salary of MS T is EUR 3 000.

The monthly personnel costs in July will be:

EUR 3 000 + {EUR 3 000 / 12} = 3 000 + 250 = EUR 3 250

The beneficiary can therefore NOT include the total of the thirteenth salary in the personnel costs for July, but must distribute it over the months in which it was generated (in this example 1/12 per month). Otherwise, the hours of July would be incorrectly priced at the double of the hours worked in normal months.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** If a later event *(e.g. the unexpected leave of the employee)* means that the payments made for the employee are actually lower (i.e. that the monthly hourly rates were overstated) the beneficiary must recalculate the hourly rates with the correct amount. If some of the related personnel costs were already declared, the beneficiary must declare the difference as adjustment in the next reporting period.

If the monthly entitlement of an extra salary is not known in advance *(for example for an annual merit pay whose amount is decided in December — if eligible as basic remuneration —)* the beneficiary cannot take into account the extra salary until the amount is known. It may therefore recalculate the hourly rates at that moment and, if needed, declare the difference as adjustment in the next reporting period.

For calculating the **annual productive hours**, the beneficiary must use one of the following two options *(see the table of options above for the details on each option)*:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ Option 2 can NOT be used for monthly hourly rates because the individual annual productive hours — and thus also the monthly hours, i.e. 1/12 of the annual — are known only at the end of the financial year. It would be therefore impossible to calculate the hourly rates at the end of each month.

In principle, the same option (1 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must keep the same option(s) *during the entire financial year*. It can only change its option(s) for the next financial year.

Absences & overtime —

The same rules on the treatment of absences and overtime apply as for annual hourly rates, except that time spent on parental leave can NOT be deducted from the annual productive hours.

However, beneficiaries may charge to the action the *costs* incurred for parental leave (as personnel costs) in proportion to the time the person worked for the action during the financial year (time worked on the action over total productive hours for the year). This must be done separately and on top of the personnel costs declared by multiplying the hours worked for the action by the monthly hourly rates.

Example:

In 2015 Ms T has been five months in parental leave. During that time the social security reimbursed to the beneficiary 50 % of her salary. Her monthly salary was EUR 3 000 (reimbursement EUR 1 500). The beneficiary used option 1 (fixed 1720 hours) for the annual productive hours and Ms T worked in 2015 320 hours on the H2020 action.

Personnel costs incurred during parental leave= {EUR 3 000 x 5} - {EUR 1 500 x 5} = 15 000 – 7 500 = EUR 7 500

(Note: amounts reimbursed to the beneficiary by the social security are not actual costs for it and, therefore, must be deducted)

Proportion of time worked for the action in 2015 = Time worked for the action / Total productive hours excluding the parental leave = 320 / {1720 - {1 720 x 5/12}} = 320 / {1 720 – 716,7} = 320 / 1 003,3 = 31,89 %

Cost of parental leave for the H2020 action = EUR 7 500 x 31,89 % = EUR 2 391,75

No impact on the hours worked — The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding hours worked can NOT be charged to the action (they must be capped at the ceilings). The ceilings apply per full financial year, not per month.

However, do not forget that your personnel costs must comply with national labour law.

Example:

If the national law provides for a prohibition for employees to work more than 48 hours per week, it is not possible to charge to the H2020 action 250 hours in a month for an employee.

Step 2 — **Multiplying the hourly rates by the hours worked on the action**

The hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

For case 1B beneficiaries (actual costs, project-based remuneration): 4 steps

Step 1 — **Checking the nature of the remuneration (basic or additional) for each employee)**

The beneficiary must first find out, for each employee, if the remuneration it is paying is all basic remuneration or contains also additional remuneration.

To do this, the beneficiary must calculate **two reference hourly rates**:

- reference rate for the work on the H2020 action ('**action reference**')

and

- reference rate for the usual remuneration practice for national projects ('**national projects reference**').

If the action reference is *equal or below* the national projects reference, the remuneration is all basic remuneration. If it is *higher*, the exceeding part is additional remuneration and must be taken out for the calculation of the hourly rate to be charged to the action.

Step 1a — **Calculation of the reference hourly rates**

For the **action reference**: the beneficiary must calculate an hourly rate (either *annual* or *monthly*) based on the remuneration paid to the employee for his/her work in the H2020 action.

For *annual* reference rates:

{annual personnel costs for the person for his/her work in the action

divided by

number of hours worked for the action in the financial year}.

If the reporting period ends before the end of the financial year, the beneficiary must use the personnel costs and the hours from the beginning of the year until the end of the reporting period.

For *monthly* reference rates:

{monthly personnel costs for the person for his/her work on the action

divided by

number of hours worked for the action in the month}.

For the **national projects reference**: the beneficiary must calculate an hourly rate based on either:

- regulatory requirements *(e.g. national law or collective labour agreements)* setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The national law establishes that the maximum monthly salary of engineers acceptable for national grants is EUR 4 000. Beneficiary A has paid that salary to its engineers while working in national grants. Beneficiary B has signed a collective labour agreement whereby the monthly salary to be paid for work under national grants is fixed at EUR 3 500. Beneficiary B has paid that salary to its engineers working in national grants.*

  Maximum amount acceptable as basic remuneration for beneficiary A = EUR 4 000/month for a person working full-time. If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

  Maximum amount acceptable as basic remuneration for beneficiary B = EUR 3 500/month for a person working full-time. If the remuneration of the person for the work in the H2020 action was more than this ceiling, the excess will qualify as additional remuneration.

- internal rules setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The internal rules of University Z provide that a professor working in externally-funded projects may get an extra salary of up to 50 % for the time its works for those projects. The maximum extra salary University Z has actually paid for work in national projects was 30 %.*

  Maximum amount acceptable as basic remuneration = salary of the person + 30 % (for the time worked in the H2020 action). If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

or

- if none of these are available or if the beneficiary never had any national projects before the submission of the H2020 proposal: the average remuneration of the employee in the previous financial year.

The hourly rate of the national project reference must be calculated using 1720 fixed annual productive hours (unless there is an hourly rate directly set in the law, collective labour agreement or internal rules).

For the average remuneration of the employee, the beneficiary must moreover exclude remuneration that came from H2020 actions; i.e.:

{total annual personnel costs* for the person for year n-1 excluding remuneration paid for work in H2020 actions

divided by

1720** minus hours worked in H2020 actions in year n-1}

* The total annual personnel costs include all remuneration paid by the beneficiary to the person for work, irrespectively of the tasks of the person and the projects for which the person was working; but excludes all remuneration paid for work in H2020 actions. If the remuneration included ineligible items *(e.g. profit distribution, arbitrary bonuses)* those must also be removed.

** 1720 is the fixed number of annual productive hours. The beneficiary must remove from those annual productive hours the hours worked in H2020 actions. If in year n-1 the person worked exclusively in H2020 actions, the beneficiary must use the average salary of the last year in which the person did not work exclusively in H2020 actions *(e.g. year n-2 or year n-3)*.

If the national law or the internal rules set up different levels of remuneration for different categories of staff, the reference will be the one of the category to which the person belongs.

If the national law or the internal rules set up different remuneration levels for different types of national projects (or for different work within the projects), the reference will be the one applicable to the type of project/work that is closest to the H2020 action.

Example: *The internal rules of University Z provide that a professor working in basic research projects will receive 10 % extra salary; while a professor working in applied research projects will receive 15 % extra salary. Both extra salaries are systematically paid also for projects funded by national schemes. The H2020 action is an innovation action. The reference that would apply in this case is the extra salary for applied research projects (15 %) as the type of project is closer to the H2020 innovation action than basic research projects.*

The beneficiary must keep appropriate and sufficient evidence to support the action and national project references used *(see Article 18)*.

Example: *If the beneficiary uses the internal rules it must keep documental evidence of the internal rules applied, the category of the person (if applicable), and the payslip and payment documents proving that such remuneration was paid at least once prior to the submission of the proposal.*

Step 1b — **Comparing the action reference with the national project reference**

If the action reference is *higher* than the national project reference, the exceeding part is additional remuneration:

{total additional remuneration = difference between the two reference rates * number of hours worked on the action}

{total basic remuneration = national project reference rate * number of hours worked on the action}

If the action reference is *equal or lower* than the national project reference, there is no additional remuneration; the remuneration paid to the employee is all basic remuneration.

Example personnel costs with additional remuneration (Part 1 of 3):

1. *Ms R is employed full-time as professor at University X. She has a basic annual gross salary of EUR 24 000. The internal rules of the university provide that professors involved in research projects financed by external funders can get up to EUR 6 000 per month of full dedication to the*

project. However, due to budgetary restrictions the maximum that has been paid to any professor in a national project was EUR 4 800. Ms R worked in 2017 for the H2020 action 200 hours. For those hours she received an extra salary of EUR 6 500. She also participated in other projects generating other extras for her. So, her total gross annual salary was EUR 36 000. The hourly rate for the H2020 action is as follows:

The salary of Ms R varies depending on her participation in certain projects. Therefore, the beneficiary must assess if any part of that salary qualifies as additional remuneration. For that, it must compare the action reference with the national project reference:

Action reference rate = basic salary corresponding to the 200 hours worked for the action ((24 000 / 1720) x 200 = 2 790,70 €) + bonus paid for the action (6 500 €) = 9 290,70 € / 200 (hours worked in the action) = 46,45 €/hour (hourly rate)

National project reference rate (in this example based on the internal rules of the university applicable to national projects) = maximum salary paid for any professor working in a national project in accordance with the internal rules = 4 800 € / (1720 annual productive hour / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

The Action reference (i.e. 46,45) is higher than the national project reference (i.e. 33,49). The excess (46,45 – 33,49 = 12,96 €/hour) qualifies as additional remuneration. Therefore:

The total basic remuneration = 33,49 €/hour x 200 (hours worked in the action) = 6 698 €

The total additional remuneration = 12,96 €/hour x 200 (hours worked in the action) = 2 592 €

(This example continues here for the calculation of the hourly rate)

***2.** Same situation as above, but in this case the work in the action has been done under a supplementary employment contract covering additional working hours (on top of the full-time contract of the professor).*

Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour

National project reference rate = 4 800 € / (1720 annual productive hour / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary is NOT paying additional remuneration.

The total basic remuneration = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 2 — **Calculation of the hourly rate (for each employee; on the basis of basic remuneration)**

The beneficiary must then calculate the hourly rate to be charged to the action for the employee:

- **If** there is **additional remuneration**, the beneficiary must calculate the hourly rate using only the basic remuneration. In practice, this will be the action reference, capped at the national project reference (i.e. the hourly rate will normally be equal to the national project reference rate).

  Example personnel costs with additional remuneration (Part 2 of 3):

  ***1.** Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of 9 290,70 €. In the calculations made in part 1 of the example we identified that 2 592 € qualify as additional remuneration.*

  The hourly rate applicable to the action will be, therefore:

  (Actual annual personnel costs for the action - additional remuneration) / hours worked in the action over the year = (9 290,70 € - 2 592 €) / 200 = 33,49 €/hour.

  Personnel costs resulting from the hourly rate = 33,49 €/hour x 200 = 6 698 €.

  (This example continues here for the eligibility of additional remuneration)

- **If** there is **NO additional remuneration** (i.e. all is basic remuneration), the beneficiary can simply use the action reference as hourly rate to charge to the H2020 action.

  Example personnel costs without additional remuneration (Part 2 of 3):
  Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of EUR 6 500 through an additional contract.
  Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour
  National project reference rate = 4 800 € / (1720 annual productive hour / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour
  In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary must use the action reference as hourly rate to charge to the H2020 action:
  Total personnel costs to be declared = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 3 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount of basic remuneration that can be charged to the action *(see examples in Step 2 above)*.

Step 4 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the beneficiary is a non-profit entity and the payments that are additional remuneration are eligible, it may also declare them to the action.

If the resulting amount (for the year) is above the **8000 EUR ceiling**, it must be capped:

Occupation	**Contract**	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The ceiling is *fixed* at EUR 8 000 per year for each full-time-equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional payment (bonus) but also the additional taxes, costs and social security contributions triggered by the additional payment.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0.8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0.25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0.25 * 0.80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} * \text{hours worked by the employee for the action over the year}$$

Example personnel costs with additional remuneration (Part 3 of 3):

1. *Ms R worked 200 hours over the financial year. For that work she received 6 698 € of basic remuneration and 2 592 € of additional remuneration.*

If the beneficiary is a for-profit legal entity, the 2 592 € of additional remuneration would be automatically ineligible. The personnel costs which the beneficiary can charge to the action would be therefore 6 698 €.

If the beneficiary is a non-profit legal entity, additional remuneration may be eligible up to the ceiling. To calculate the eligibly part, you need to determine the pro-rata of the cap which corresponds to the 200 hours worked for the action:

(8 000 / 1 720) x 200 = 930,23 €

Although the beneficiary paid 2 592 € of additional remuneration, only 930,23 € are eligible. The difference (2 592 – 930, 23 = 1 661,77 €) is ineligible, since it exceeds the ceiling.

Therefore, the personnel costs which the beneficiary could charge to the action would be: 6 698 € of basic remuneration + 930,23 € of additional remuneration = 7 628,23 €.

For case 2 beneficiaries (unit costs in accordance with the usual cost accounting practices): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary can use the hourly rate(s) that it uses normally (usual cost accounting practices) as average personnel costs, provided that:

- the cost accounting practices are applied in a **consistent** manner, based on objective criteria, regardless of the source of funding
- the hourly rate is calculated using the **actual personnel costs recorded** in the beneficiary's **accounts**, excluding any ineligible cost or costs already included in other budget categories and
- the hourly rate is calculated using one of the **three options** provided in the MGA for the number of **annual productive hours** *(e.g. option 3 'standard annual productive hours')*.

The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

This does not mean that cost accounting practices must be the *same* for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

If necessary, the hourly rate must be adjusted to remove:

- cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the hourly rate).

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

- costs that are already included in other budget categories (double funding of the same costs;

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020 actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.*

Budgeted or estimated elements used to calculate the hourly rate can only be accepted if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way (i.e. do not play a major role in calculating the hourly rate)
- correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

  Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

Beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A (as chosen by the beneficiary) applies.

Since there is no obligation to keep time-sheets for periods covered by a declaration on exclusive work, beneficiaries should report:

- for annual hourly rates: a pro-rata of the annual productive hours corresponding to the period covered by the declaration (at the annual hourly rate)
- for monthly hourly rates: 1/12 of the annual productive hours for each month actually worked for the action in the period covered by the declaration (at the monthly hourly rate).

Example:

1a *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours and calculates annual hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate		*Hours worked for the project*	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

1b *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its monthly personnel cost were 2 666,66 EUR in 2014, 2 860 EUR from January 2015 until October 2015 and 2 900 EUR from then on. The beneficiary applies 1720 as annual productive hours and calculates monthly hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*x*	*Hours worked for the project*	*=*	*Total*	
2014➔						
October	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)}*	*=*	*2 666*	
November	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)}*	*=*	*2 666*	
December	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)}*	*=*	*2 666*	
				Total	*= 8 000**	
2015 ➔						
January	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)}*	*=*	*2 860*	
February	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)}*	*=*	*2 860*	
March	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)}*	*=*	*2 860*	

April	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
Mai	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
June	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
July	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
August	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
September	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
October	*{[2860 EUR /(1720/12)] x (1720/12)} =*		*2 860*	
November	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
December	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
		Total	*=*	*34 400*
2016➔				
January	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
February	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
March	*{[2900 EUR /(1720/12)] x (1720/12)} =*		*2 900*	
		Total	*=*	*8 700*
		TOTAL	*=*	*51 100*

* *Decimals have been rounded*

If the declaration covers months in which the person was **absent** for more than half of the working days those months can NOT be taken into account to calculate the hours worked in the action (— unless the absence is linked to annual leave AND the duration does not exceed the pro-rata of annual leave entitlements corresponding to the period covered by the declaration).

Example:

1. *Researcher Y worked exclusively in the action from1 July 2014 to 31 October 2014. In August it took three weeks of holidays and in September it was 10 days on sick leave. The beneficiary applies 1720 as annual productive hours*

Number of hours that can be charged to the action based on the declaration = 3 months (July, September and October) x (1720 / 12) = 3 x 143,33 = 430 hours

August is not taken into account because the person was absent more than half of the working days, since s/he took three weeks of holidays.

2. *The person has the right to two working days of annual leave per month worked. The period covered by the declaration is from January to September (i.e. 9 months). Therefore, the leave entitlement of the person for that period is 9 x 2 = 18 working days. The person takes 3 weeks of annual leave in August. August could also be counted because the leave taken (i.e. 15 working days) is less that the leave entitlement for that period (i.e. 18 working days).*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the annual hourly rate can only be calculated on the basis of the personnel costs incurred during the ongoing financial year.

Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if 1 720 hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 287)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the indemnity in the reporting period in which the employee's contract ends — but outside the hourly rate (i.e. separately and on top of the personnel costs declared on the basis of the hourly rate) AND only for the part that corresponds to the time worked by the person on the action (i.e. pro-rata of the total time during which the entitlement was generated).

Moreover, the indemnity can be accepted ONLY if it:

- arises from the applicable national labour law and
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Employment contract remunerated per hour — For employment contracts that do not establish a fixed salary and a number of hours to be worked but only an amount to be paid for each hour worked by the employee, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*

- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the individual annual productive hours can be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

This summary table explains the three **different options** for **annual productive hours (for case 1A and case 2 beneficiaries)**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full-time-equivalent covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary,	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the GA {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another*

	including the overtime worked and absences *(such as sick leave or other types of special leave)*.	plus
		overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus 8 days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for 5 days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual workable hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
			employee employed under similar conditions): the auditors will adjust the number of annual productive hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow to determine the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.	
Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options.	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation

		Example for calculation of standard annual workable hours: *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would therefore be:* *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20*	method consistently applied) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive hours to the higher number.

		days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours). *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).* ⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 fixed hours).*	

1.2 Direct personnel costs: Natural persons with direct contract (A.2)

1.2.1 What? This budget category **covers** typically the costs of **in-house consultants** and similar persons (i.e. **self-employed *natural* persons**) that worked on the action for the beneficiary under conditions similar to those of an employee, but under a contract which is NOT legally the same as for employees. It regards, in particular, contracts qualified as quasi-subordinate work contracts under national law when the conditions under which the work is carried out are similar to those of an employee.

What not? Staff provided by another entity against a price, including staff provided by a temporary work agency (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

> **Staff provided by a temporary work agency —** A contract with a temporary work agency qualifies typically as purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency),* even if that third party is a one-person company.
- the person must work **under conditions similar to those of an employee,** in particular:

> ⚠ **Similar does not mean equal —** The working conditions of the person do NOT have to be exactly the same that those of an employee, but overall similar.

  - the beneficiary must organise and supervise the work of the person in a way similar to that of its employees

    Example (acceptable):

    The beneficiary's project leader and the person discuss regularly the work to be carried out for the action. The project leader decides the tasks and timing of the work and instructs the person accordingly.

    Example (not acceptable):

    The beneficiary's project leader and the person meet only once a month or irregularly, for updates on the state of play of the entrusted work. If changes are needed, they have to be agreed by the person and may lead to a change of the amount charged to the beneficiary.

  - the beneficiary must be able to ensure reliable time recording (for the hours that the person works for the action)

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

– the person is subject to similar presence requirements as the employees.

Examples (acceptable):

The person works physically at the beneficiary's premises, following a time schedule similar to that of the employees (e.g. the beneficiary authorises up to two days of teleworking per week to its personnel and the person has chosen to benefit from this regime, i.e. works 2 days in teleworking and 3 days physically at the beneficiary's premises).

Example (not acceptable):

The entity authorises up to two days of teleworking per week. However, the person works four days in teleworking and only one day at the beneficiary's premises.

- the **result** of the work carried out (including patents or copyright) must in principle **belong to** the **beneficiary**

  If (exceptionally) they belong to the person, the beneficiary must (just like for employees) obtain the necessary rights from the person (transfer, licences or other), in order to be able to respect its obligations under the GA *(see Article 26.3)*.

- **not** be **significantly different** from costs for employees performing similar tasks

  The remuneration must be based on working time, rather than on delivering specific outputs/products.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **rules** as explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, for the **actual costs hourly rate**, the beneficiaries must use one of the following options:

– if the contract specifies an hourly rate: this hourly rate must be used

– if the contract states a fixed amount for the work and the number of hours to be worked: the global amount for the work must be divided by the number of hours to be worked

– if the contract states a fixed amount for the work but does not specify the number of hours to be worked: the global amount for the work must be divided by the pro-rata of 1 720 annual productive hours which corresponds to the duration of the contract over the financial year.

Example: *The contract provides that the person will work at the beneficiary's premises for assisting in research tasks. The contract is for 6 months starting on 1 January 2017 and ending on 30 June 2017. According to its time records, the person worked 500 hours in the H2020 action over that period. The contract sets a monthly payment of EUR 3 000 but does not explicitly establish the number of hours to be worked.*

Personnel costs for the action = hourly rate x 500 (hours worked in the action)

Hourly rate = annual personnel costs / annual productive hours = (3 000 € x 6 months) / (1 720 hours x (6 months/12 months)) = 18 000 € / (1 720 x 0,5) = 18 000 € / 860 hours = 20,93 €/hour

Personnel costs for the action = 20,93 x 500 = 10 465 €.

For the **unit costs** hourly rate (average personnel costs), the rules in point 1.1.4 apply without any changes.

This summary table explains how to treat **different types of work contracts** for declaring costs under H2020[16]:

Characteristics of the contract	**Contract remunerating time** *(e.g. the contract establishes that the person must work for the beneficiary 40 hours per week)*	**Contract remunerating duties (without specifying the working time conditions)** *(e.g. the contract establishes the tasks, but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4); however: ➔ Only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. *Example: Contract from 01.01.2015 to 31.03.2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430*
Other contract (i.e. not an employment contract)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared in category A.2 'natural persons with direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A. 'personnel costs'. They must be treated like CASE D1.	**CASE D1:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

[16] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

		CASE D2: the costs fulfil the conditions of Article 6.2.A.2. The costs can be declared in category A 'personnel costs'. They must be calculated as described in Article 6.2.A. Calculation (point 1.2.4); however: ➔ Only option 1 (i.e. 1720 annual productive hours) can be used to calculate the hourly rate. ➔ If the contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720.

1.3 Direct personnel costs: Seconded personnel (against payment) (A.3)

1.3.1 What? This budget category **covers** the costs of persons that worked on the action and that were **seconded** by a third party as an in-kind contribution ***against payment*** *(see Article 11)*.

What not? Persons provided by a temporary work agency, secondment of staff between beneficiaries (or linked third parties) in the same grant or secondment by a third party free of charge.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

Secondment of staff between beneficiaries (or linked third parties) — Is allowed, but it is the beneficiary/third party who employs the person who has to declare its costs (NOT the beneficiary/third party to whom the person has been seconded). The costs declared must be supported by reliable time records of the number of hours the person worked for the action. Those time records must be produced under the responsibility of the beneficiary/third party to whom the person is seconded

Persons seconded free of charge — Costs for persons seconded free of charge (i.e. the third party's costs) can be declared as personnel costs by the beneficiary, if they fulfil the conditions of Articles 6.4 and 12.

> For information on in-kind contributions provided by third parties *free of charge, see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared** ONLY as **actual costs**.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.3.4 There is no specific **calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1*).

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the seconded person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.4 Direct personnel costs: SMEs owners & natural persons not receiving a salary (A.4 & A.5)

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons which work on the action, but **don't receive a salary**.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts/other non-employment contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

1.4.2 These costs must be **declared as** the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[17] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4,650/143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *Main Work Programme — MSCA*[18] in force at the time of the call.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*
EUR 4.650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **SME owner/beneficiary that is natural person**, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

[17] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf
[18] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ **Ceiling** — The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than 1 720.

1.5 Direct personnel costs: Access to research infrastructure personnel costs (A.6)

1.5.1 What? This budget category **covers** the personnel costs for access to infrastructure activities, i.e. normally:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons with direct contract and
- costs of seconded personnel (against payment).

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs) *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.5.4 The same **calculation rules** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting (B.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing trans-national or virtual access to research infrastructure: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (subcontracting costs (B.)):

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency may exceptionally have to be declared under category B 'subcontracting' (instead of category D.3 'other goods and services') if the temporary work agency carries out directly some task of the action (provided they comply with the eligibility conditions).

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)]***

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

1. Direct costs of providing financial support to third parties (C.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category (together with the corresponding Article 15 and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances (D.1): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if the experts' participation is foreseen in Annex 1. In this case, the beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly).

There is no distinction between travelling in- or outside of Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

  > ***Example*:**
  > *Beneficiary A declares the cost of a business class airplane ticket for one of its employees.*
  > *If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.*
  > *If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.*

If the beneficiary reimburses travel and/or subsistence allowances as a lump sum/*per diem* payment, it is the lump sum/*per diem* amount that is considered an eligible cost, NOT the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these lump sum/per diem costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (travel costs (D.1)):

Combination with personal travels or travels for other purposes — The costs of a combined travel can be charged to the action — but ONLY up to the cost that would have been incurred if the travel would have been made exclusively for the action AND if:

- it is the usual practice of the beneficiary to pay for such travels *(e.g. travels combining professional and personal reasons)*
- it has been an actual cost for the beneficiary.

***Example*:**

The researcher flies from Madrid, where the beneficiary is established, to Prague for a project meeting. After the meeting, instead of flying back to Madrid, the researcher flies directly to New York to participate in an event not related to the action.
The beneficiary may charge to the action:

- *the cost of the flight from Madrid to Prague, and*
- *the part of the flight back from New York to Madrid up to the cost that it would have incurred for a flight back from Prague to Madrid after the end of the project meeting.*

⚠ **Record-keeping —** The beneficiary must keep evidence not only of the actual cost of the flight back, but also of the cost of the flight that the person would have taken if it would have returned directly after the end of the work for the action.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).**]

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).**]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.2): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs (D.2): Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

- if the beneficiary does not use the equipment exclusively for the action, only the portion used on the action may be charged. The amount of use must be auditable

  Example: *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*

  Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

- the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

  Example: *A microscope was bought on 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs (D.2)):

Low-value assets — The full cost of a low value asset may be eligible in the year when it is purchased if:

- the full cost is recorded in the accounts of the entity as expenditure of that year (i.e. NOT recorded as an asset subject to depreciation)

and

- the cost of the asset is below the low-value ceiling as defined under national law (e.g. *national tax legislation)* or other objective reference compatible with the materiality principle

and

- the item is used exclusively for the action in the year of purchase.

  If the item is not used exclusively for the action in the year of purchase, only the portion used on the action may be charged.

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that correspond to the part of the equipment's use for the action. Declaring its *full* price in one single year would be considered either as not compliant with the international accounting standards or as an excessive cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, a piece of equipment bought in January 2013 has a depreciation period of 48 months.
If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that corresponds to the part of the equipment's use for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year, the beneficiary can NOT charge the full price in one single year (— even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year).

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plant (constructed as part of the action tasks) — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

(Full) Construction costs (of a prototype or pilot plant) may however exceptionally be eligible as 'equipment costs', if all of the following apply:

- building the prototype or pilot plant is part of the action tasks (i.e. described in Annex 1 of the GA)
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the eligibility conditions of Articles 6.1 and 6.2 are met (in particular, recorded in the beneficiary's accounts in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices; *see Article 6.1(a)(v)*).

Example:

If according to national accounting standards the prototype must be depreciated, the beneficiary may only declare the depreciation costs (as recorded in its accounts), not the full construction cost.

If the full construction costs of the prototype are eligible according to the conditions above, but the construction was outsourced to a third party (other than a linked third party), the costs can NOT be declared in category D.2 'equipment', but may be eligible in category B 'subcontracting' *(see Articles 6.2.B and 13)*.

1.2 Equipment costs (D.2): Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs (D.2): Costs of renting or leasing equipment

1.3.1 What? This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:

  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are not higher than the depreciation costs of similar equipment).

1.4 Equipment costs (D.2): Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services (D.3): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access to peer-reviewed scientific publications*, e.g. article processing or equivalent charges*, costs related to open access to research data and related costs, *such as data maintenance or storage and conference fees for presenting project-related research*)
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4) or the certificate was submitted not for the final report but before*).
- translation costs (if translation is necessary for the action's implementation, is justified, etc.).

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services (D.3)):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are met *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are met *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the plan for the exploitation and dissemination of the results are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access to peer-reviewed scientific publications and research data are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Self-produced consumables with an accounting value in the inventory of the beneficiary (i.e. not internally invoiced costs for goods and services) — Consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price; the cost of production for the beneficiary is however are normally recorded in the accounts of the beneficiary (as part of the *inventory)*. Therefore, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

> ⚠ Beneficiaries can **NOT** charge the **commercial price** for self-produced consumables.

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.
The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency are eligible normally under category D.3 'other goods and services' if they comply with the eligibility conditions (and unless the temporary work agency carries out directly some task of the action, in which case it can be considered as subcontracting and should be declared under category B 'subcontracting').

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure (D.4): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of Horizon 2020 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in

[19] *See also International Financial Reporting Standard No 16.*

particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure to calculate the EUR 20 million threshold *(see below)* and therefore declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[20] *See Article 126 of the Financial Regulation No 966/2012.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure (LRI)

Beneficiaries can declare capitalised and operating costs for **large research infrastructure**, if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a **research infrastructure** in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a **grouping of costs** (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any grant agreement (by ticking the LRI box either in the Beneficiary Register or during grant preparation).

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Beneficiary Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) ex-ante assessment report will be issued.

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs in category D.4 'large research infrastructure'.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) prior to signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

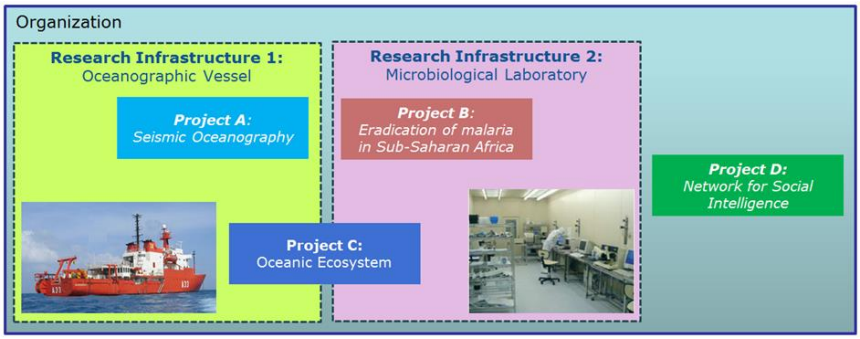

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[23].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU or Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU or Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the H2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the H2020 grant, even if they belong to the same action.

> ⚠ **Combining H2020 & other EU grants —** The terminologies under the different EU funds/funding programmes may differ *(e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).*

4.4 Costs must be directly measured

Costs can be claimed as direct costs in category D.4 'Large research infrastructure' only if they are **directly measured** (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

[23] *See Article 129(1) of the Financial Regulation No 966/2012.*

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (**project time**) and therefore require reliable time recording (through time-sheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No *1290/2013*

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. This data must be regularly updated.

  Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to the time the employee actually spent on the action and provided that this is recorded reliably.

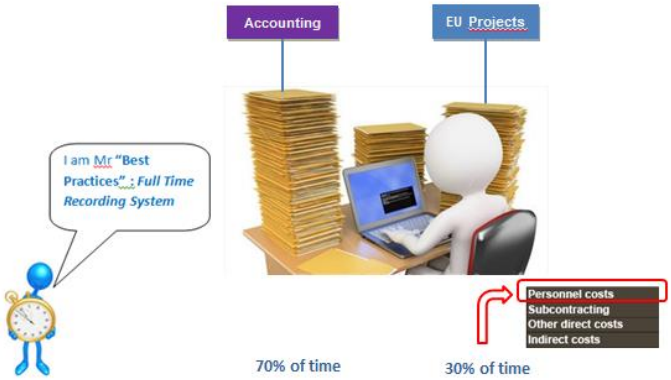

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

Step 2 *The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints *(e.g. opening hours)*, but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

D.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

1. Costs of internally invoiced goods and services (D.5): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category covers the costs for goods and services which the beneficiary itself produced or provided for the action. They include (non-exhaustive list):

- self-produced consumables *(e.g. electronic wafers, chemicals)*
- use of specific research devices or research facilities *(e.g. clean room, wind tunnel, supercomputer facilities, electronic microscope)*
- specialised premises for hosting the research specimens used for the action *(e.g. animal house, greenhouse, aquarium)*
- standardised testing or research processes *(e.g. genomic test, mass spectrometry analysis)*
- hosting services for visiting researchers participating in the action *(e.g. housing, canteen*).

What not? Costs of goods of services purchased and costs of goods or services internally invoiced which are not directly used for the action *(e.g. supporting services like cleaning, general accountancy, administrative support, etc.)*.

1.2 Costs of internally invoiced goods and services must be **declared as** unit costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following cumulative **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. used during the action duration, necessary for the action, etc.; *see Article 6.1(b)*)

- be in line with the beneficiary's **usual cost accounting practices**

  It must be the usual practice of the beneficiary to calculate a unit cost for that good or service (i.e. an internal cost per unit invoiced to other departments of the same entity – not prices charged in the context of commercial sales or grants from other fund providers).

- the cost accounting practices must have been applied in a **consistent** manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  Example: *if the beneficiary sets up a new unit cost which applies only to EU actions, the internally invoiced costs based on that new unit cost would be ineligible.*

- the amount per unit must have been **calculated** using the actual costs recorded in the beneficiary's accounts, excluding any ineligible costs or costs already included in other budget categories

  If necessary, the unit cost must be adjusted to remove:

  - cost elements that are ineligible under the Grant Agreement (even if they are part of the beneficiary's usual methodology for determining the unit cost for its internal invoices)

    Example: *The beneficiary uses internal invoices for the use of an electronic microscope based on a unit cost per hour of use. The methodology to calculate the unit cost includes costs of capital (e.g. interest charged by the bank for a loan used to buy the microscope). Those costs are ineligible under the Grant Agreement (see Article 6.5) and must therefore be removed. The unit cost must be recalculated without them.*

    ⚠ A beneficiary cannot simply apply an estimated percentage of deduction on the amount of its internal invoices to remove ineligible costs. It has to ensure that the internal invoice does not include any ineligible costs under the GA.

  - costs of resources that do not belong to the beneficiary and which it uses free of charge *(e.g. personnel or equipment of a third party provided free of charge)*, because they are not in its accounts *(see Article 6.1(a)(v))*

  - costs that are already included in other budget categories (double funding of the same costs, *see Article 6.1(a)(i)*).

    Example: *The beneficiary uses internal invoices for water chemistry analyses, based on a unit cost per water sample analysed. The methodology to calculate the unit cost includes the cost of the staff carrying out the analysis. However, the costs for those persons are already charged to the action under direct personnel costs (category A.1). The cost of the staff must therefore be removed and the unit cost must be recalculated without them.*

- if budgeted or estimated elements were used to calculate the amount per unit, those elements must:

  - be relevant (i.e. clearly related to invoiced item)

  - be used in a reasonable way (i.e. do not play major role in calculating the unit cost)

  - correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

- the amount per unit must have been calculated using only costs of items which were **directly linked** to the production of the internally invoiced goods or services *(e.g. staff, equipment, raw materials, etc.)*

If a cost item is not used exclusively for the internally invoiced good or service, only the share used for the good or service may be counted (the percentage taken must be substantiated by persuasive evidence).

Example: ***Shared staff —*** *Among the persons operating the beneficiary's wind tunnel, there is one person that is assigned only part-time to that wind tunnel; the rest of the time it works in another department. If the beneficiary includes the costs of this person at the rate of 50 %, it must be able to justify the reality of that percentage, for example, by any of the following:*

- *reliable time recording system*
- *a statistic survey performed in the past based on actual data*
- *detailed calculations based on technical specifications or other scientific and technical requirements of the equipment or infrastructure allowing to reconcile the time spent by the person for the functioning of the wind tunnel*

or

- *a combination of these methods.*

Ceiling — The (share of the) working time of a person which is included in the calculation of the unit cost reduces the number of hours that the person can charge over the year to EU/Euratom grants (see Article 6.2.A. Calculation). The same hours of the person cannot be charged twice to the grant, once embedded in the unit cost and again as direct personnel costs.

If necessary, the unit cost must be adjusted to remove costs elements allocated to the unit cost indirectly; i.e. through cost drivers/allocation keys based on other cost items included in the unit cost *(e.g. for a clean room: the costs of the of the human resources department charged to the unit cost as a fixed amount per employee assigned to the clean room; or power supply costs allocated to the clean room on the basis of the square meters it occupies)*.

Example: *Costs for an animal housing facility*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. keepers, veterinarians and other persons directly assigned to run the animal house)* – *consumables used for the animal housing (e.g. animal food, bedding)* – *depreciation of cages and other equipment directly linked to the housing of the animals* – *generic supplies like electricity or water — BUT only if the consumption of the facility has been directly measured (so that the cost can be accurately determined)* – *maintenance and cleaning of the animal house facility — BUT only if the cost is directly identifiable (e.g. a separate invoice for the cleaning of the cages)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the animal house facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the animal housing is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

Example: *Wind tunnel*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. technicians, engineers and other persons directly assigned to the functioning of the wind tunnel)* – *depreciation of the equipment, including specific software and hardware necessary*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the facility (e.g. cleaning*

for the functioning of the wind tunnel – *generic supplies like electricity — BUT only if the consumption of the facility has been directly measured (so the cost can be accurately determined)* – *insurance — BUT only if the cost is directly identifiable (e.g. a separate invoice for the insurance of the facility)* – *maintenance and cleaning of the wind tunnel equipment (e.g. air cooling system) — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)* – *calibration/metrology tests — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)*	*services)* – *depreciation of shared buildings (e.g. the building where the installation is located is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

1.1.4 They must be **calculated** according to the rules set out above (point 1.1.3).

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Article 6.2. Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]][**OPTION 2**: not applicable;]*

(d) ***[OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION 2:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (E.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared as** a fixed flat-rate (*see Article 5.2(e);* new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation, etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying the 25 % flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: *subcontracting of opinion surveys*

The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

– costs of in-kind contributions incurred by third parties outside of the beneficiary's premises

- costs of providing financial support to third parties (if option applies)
- costs from specific cost categories (unit or lump-sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a GA and has incurred the following costs:

- *EUR 100 000 personnel costs (EUR 7 000 of which are an in-kind contribution in the form of a laboratory technician who carries out work for the action from his/her laboratory in a public research centre)*
- *EUR 20 000 subcontracting costs,*
- *EUR 10 000 other direct costs (consumables).*

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

Combining H2020 & other EU grants — Beneficiaries that also receive an EU **operating grant** can NOT declare any indirect costs for the reporting period(s) covered by the operating grant, unless they are able to demonstrate cost separation (i.e. that the operating grant does not cover any costs that may be claimed under the action).

Operating grants are annual grants to finance the operation and running costs of an entity *(e.g. call COMM-C2/01-2013 under the Europe for Citizens programme)*.

Example: *Entity A receives an operating grant under the Europe for Citizens programme for the financial year 2016 (i.e. from 01.01.2016 until 31.12.2016) The operating grant is not renewed in 2017. On 01.04.2016, entity A signs an H2020 action grant with one reporting period of 18 months (01.04.2016 – 31.12.2017). Beneficiary A may declare the indirect costs in the H2020 action grant as follows:*

- *from 01.04.2016 to 31.12.2016 ONLY IF it can demonstrate that the operating grant does not cover any costs of the action (see beow);*
- *from 01.01.2017 – 31.12.2017 under the normal H2020 rules (i.e 25% of the direct eligible costs since there is no operating grant covering the 2017 financial year).*

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grant may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be a full operating grant)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant or the operating grant)
- the beneficiary must record:
  - all costs incurred for the operating grant (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all costs incurred for the action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

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Beneficiaries that cannot fulfil these conditions must EITHER:

- terminate the operating grant, in order to sign the action grant with indirect costs
- keep the operating grant, but sign the action grant without indirect costs.

The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of an overlapping EU operating grant, the beneficiary should immediately contact the Commission/Agency (via the Participant Portal). Be aware that operating grants are not always easy to identify. They label under various names (operating grants; financial contributions/support to the functioning/operation of entities; etc.). Check your call text.

F. [OPTION 1: [Insert name of specific cost category(ies)[22]]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): [insert name of specific cost category]** are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]]**.]

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category]** are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]

[same for each specific cost category]

[OPTION 2:** Not applicable**]

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of Horizon 2020, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: **costs for energy efficiency measures in buildings**

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': **access costs for providing trans-national access to research infrastructure**

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': **costs for clinical studies**

  The unit cost applies ONLY to actions with clinical studies.

⚠ **Double funding risk —** Costs that are declared as a specific unit or lump sum cost may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Example:

The unit cost for efficiency energy measures in buildings covers subcontracting costs related to the energy efficiency measures. These cannot be declared as subcontracting costs. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

1.1 Specific cost category – costs for energy efficiency measures in buildings (F.2)

1.1.1 This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared as** the unit cost set out in Commission *Decision C(2013) 8196*[25] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) must be calculated — before signature of the GA — according to the following formula:

Amount per unit = {EUR 0.1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m^2 of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

[25] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0.1EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 Specific cost category – access costs for providing trans-national access to research infrastructure (F.2)

1.2.1 This budget category **covers** direct and indirect access costs for providing trans-national access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

> ⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.
>
> Beneficiaries that use budget category F.2 'access costs for providing trans-national access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, in category D.1 'travel'; *see Article 6.2.D.1 and Article 16*).

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing trans-national access to research infrastructure'), the costs must be **declared as** the unit cost calculated in accordance with Commission Decision C(2013) 8199[26] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{27}\text{)}}{\text{average annual total quantity of access (over past two years}^{28}\text{)}}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

[27] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed by the EU under previous grant agreements, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the user's research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)
  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)
- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800.000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6100, 5900) = 6000

Unit cost = average (3 200 000, 2 800 000) / average (6100, 5900) = 3 000 000 /6000 = 500 €

The access activities and the parameters for calculating the unit cost must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annexes 1 and 2a.

The proposal should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per installation and access provider).

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

During the GA, the beneficiaries may change their choice, but only via an amendment to the agreement *(see Article 55)*.

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 Specific cost category – costs for clinical studies (F.2)

1.3.1 This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study;
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
  - costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
  - indirect costs for the study.

1.3.2 If they are declared under this budget category (i.e. F.2 'costs for clinical studies'), the costs must be **declared as** the unit cost set out in Commission Decision C(2014) 1393[29] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (EUR/patients or subjects included in the clinical study) must be calculated for each study and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — according to the following formula:

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

Amount per unit ={Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks] }

The unit cost components must be calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':
{'average hourly cost for doctors', i.e.:
certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full-time-equivalent for the personnel category doctors for year N-1}
multiplied by
estimated number of hours worked by doctors for the task (per patient/subject)}

For unit cost component 'personnel costs of other medical personnel':
{'average hourly cost for other medical personnel', i.e.:
certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full-time-equivalent for the personnel category other medical personnel for year N-1}
multiplied by
estimated number of hours worked by other medical personnel for the task (per patient/subject)}

For unit cost component 'personnel costs of technical personnel':
{average hourly cost for technical personnel, i.e.:
certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full-time-equivalent for the personnel category technical personnel for year N-1}
multiplied by
estimated number of hours worked by technical personnel for the task (per patient/subject)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc.)

For each category of consumables:
{'average price per item', i.e.:
{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned
total number of items purchased in year N-1 for the category of consumables concerned}
multiplied by
estimated number of items used for the task (per patient/subject)}

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:
{'average cost of depreciation and directly related services per unit of use', i.e.:

{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

total capacity in year N-1

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:

'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%

multiplied by

{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}**}**

The following must be excluded:

- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

The estimation of the resources must be done on the basis of the protocol for the clinical study (and must be the same for all beneficiaries/linked third parties/third parties involved).

Each beneficiary/linked third party/third party providing in-kind contributions must calculate the direct costs by using its historical costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application).

Personnel costs must be defined in the 3 categories (doctors, other medical personnel, technical personnel) defined in the Commission Decision. No other categories *(e.g. 'nurses')* can be used.

The descriptions of the resources and the parameters for calculating the unit cost must already be part of the proposal *(see the proposal templates and the* template for essential information to be provided for proposals including clinical trials / studies/ investigations *provided on the call pages)* and be included in Annex 1 and 2a of the GA.

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. (One cost form per study and beneficiary/third party.)

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or of costs actually incurred for a given clinical study.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** the number of patients or subjects that participated in the study

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

1. Costs of linked third parties (A-F)

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility) like beneficiaries.

The same rules apply, but with the changes needed to render them applicable to linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 14.1.1.

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared in category A.1 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions by third parties free of charge (A-F)

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared in category D.2 'equipment' (Article 6.2.D.2).*

In-kind contributions *free of charge* must be **distinguished** from **in-kind contributions *against payment*** *(see Article 11)*.

In-kind contributions *against payment* are costs *of* the beneficiary (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. Their costs (i.e. the payment) must be declared under those specific budget categories.

Examples:

1. *The cost of personnel seconded against payment must be declared in category A.3 'seconded personnel (against payment)' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

The costs of in-kind contributions free of charge (i.e. the costs of the third party offering them) can be assimilated to beneficiary costs and must be declared in the budget category that the beneficiary would have used.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action [;][.]

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

- **debt and debt service charges**

  'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

  > ***Example:*** *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

- **provisions for future losses or debts**

  'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

- **interest owed** (i.e. interest on a loan to borrow capital)

- **excessive or reckless expenditure**

  'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

  'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

- **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

- **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

  Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

- **deductible VAT**

  'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

  The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

  > The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
  >
  > The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

  Conversely, if VAT is NOT deductible, it is an eligible cost.

  > The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction

between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*
  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
  - if a beneficiary is receiving an operating grant[30] from the EU/Euratom, then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied — unless it can demonstrate that the operating grant does not cover any costs of the action *(see Article 6.2.E)*.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Specific cases (ineligible costs):

Non-identifiable VAT (in foreign invoices) — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts if it is not possible to deduct the VAT. That VAT would therefore be eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

Duties — The eligibility of duties depends on the eligibility of the cost item to which they are linked (i.e. in whose price they are included). If the item is eligible, the duty is also eligible.

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[30] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the applicable national law.*

⚠ Normally, the beneficiaries must comply **BOTH** with the national law of the **country** in which they are **established** AND that of the country where the **action** is **implemented**.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA).

However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Examples (acceptable):

1. *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

2. *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action. They may also call on international partners to carry out work under the action without receiving EU funding (see Article 14a) (**'third parties involved in the action'**).

⚠ Beneficiaries using third parties remain **fully responsible** for them under the GA.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues like beneficiaries.

Third parties involved in the action do NOT sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 **Contracts to purchase goods, works or services**	**Article 13** **Subcontracts**
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 **Contracts and subcontracts**	**Article 14** **Implementation by linked third parties**
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks. They must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme). For more information on conditions for participation and funding, *see the Online Manual.*
The eligible costs are the prices charged to	The eligible costs are only the costs of the

the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 **Contracts**	**Article 11** **In-kind contributions against payment**
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the government (the ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the ministry/government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

This table gives an **overview** of the different kinds of **third parties**:

TYPE	CHARACTERISTICS						
	Works on action tasks?	**Provides resources or services for action?**	**What is eligible?**	**Must be indicated in Annex 1?**	**Indirect costs?**	**Selecting the third party**	**GA articles**
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link	Article 14
International partners	**YES**	**NO**	**N/A**	**YES**	**N/A**	Must not be eligible for funding	Article 14a
Subcontractor	**YES**	**NO**	**Price**	**YES**	**NO**	Must be best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contribution	**NO**	**YES**	**Costs**	**YES**	**YES**	May not be used to circumvent the rules	Articles 11 and 12
Contractor (selling, equipment, good or service)	**NO**	**YES**	**Price**	**NO**	**YES**	Must be best value for money, avoid conflict of interest	Article 10
Third parties receiving financial support[31]	The third parties participate in the action as recipients.		**Amount of support given**	**YES**	**NO**	According to the conditions in Annex 1	Article 15

[31] Only if allowed in the work programme/call.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

[additional OPTION for beneficiaries requesting zero funding*: If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION 2:** Not applicable]*

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

Beneficiaries not receiving EU funding — They participate in the action as beneficiaries, but NOT with EU funding. They must carry out the work under the action and comply with the GA (although not with *all* its obligations; the financial obligations and some IPR obligations do not apply for them).

'**Beneficiaries not receiving EU funding**' are either:

- 'beneficiaries **not eligible** for funding', i.e. beneficiaries which:
  - are NOT from an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme AND
  - were NOT granted exceptional EU funding by the Commission/Agency (during the selection procedure)

For more information on third country participants, *see the Online Manual (international cooperation).*

- 'beneficiaries **requesting zero funding**', i.e. beneficiaries that are eligible for funding, but decided not to request any funding.

Beneficiaries requesting zero funding may receive funding later only if they amend the grant agreement (to change Annex 2; *see Article 55*).

In that case, the maximum grant amount cannot be increased *(see Article 5.1)*. Therefore, the consortium would need to reshuffle the estimated budget in order to free funding for the beneficiary concerned.

Costs incurred before the amendment would however be eligible ONLY if they comply with all the obligations under the GA retroactively *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate as beneficiaries in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on their role in the grant and if the beneficiary has linked third parties that receive EU funding or not).

This table shows the **GA obligations** that do **NOT apply** to beneficiaries not receiving EU funding (marked by X under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Article 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of **breach** of any **of** their **obligations**, their participation may be terminated and any of the other Chapter 6 measures (except for rejection of costs or recovery) may be taken.

Examples:

1. *A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

2. *In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).*

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […][23]**]

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EU)[25] or 'contracting entities' within the meaning of Directive 2004/17/EC[26] (or 2014/25/EU)[27] must **comply** with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

Purchases — For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the purchasing context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, *such as technical quality, etc.*), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the grant amount). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules which the European Commission applies for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional cost eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[32] must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 4 of Directive 2014/25/EU)*.

Specific cases (purchases):

Purchases between beneficiaries — Are in principle not accepted. If a beneficiary needs supplies from another beneficiary, it is the latter beneficiary that should charge them to the action. (Otherwise there is the risk that the grant is used to charge commercial profit margins.) Purchases between beneficiaries will only be accepted in exceptional and properly justified cases *(e.g. beneficiary A is the usual supplier of beneficiary B for a generic consumable that beneficiary B needs for the action)*.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[32] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the measures described in Chapter 6.

1. In-kind contributions by third parties against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example (in-kind contributions against payment): *medical equipment provided by a hospital (against a fee) to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2; e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

If the amount paid by the beneficiary is lower than the cost incurred by the third party, the beneficiary may in addition declare the difference as in-kind contributions free of charge (see Article 12). If it decides to do so, it may have to declare that difference also as receipt (*see Article 5.3.3*).

For the upper limit (third party's costs), normally only the *direct* costs *actually* incurred by the third party will be taken into account.

The following costs may however be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[33] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the grant agreement (alternative to actual costs; *see Article 6.2.F*).

The actual costs must be identifiable and verifiable in the third party's accounts.

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used on the beneficiary's premises

or

- taken into account: if the in-kind contributions are NOT used on the beneficiary's premises (*but, for instance, on the third party's premises*).

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

[33] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

3. Additional cost eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**').

Example (approval): *A new researcher is brought into a team working during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The beneficiaries may declare **costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions by third parties free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary itself makes no payment and there is therefore NO cost incurred by the beneficiary. However, the GA provides that it may charge the costs incurred by the third party for its in-kind contribution *(see also Article 6.4)*.

Examples (in-kind contributions free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the ministry/government).

Foundations, spin-off companies, etc., created in order to handle the administrative/financial tasks of the beneficiary. This is typically the case of a legal entity created or controlled by a beneficiary (usually public bodies like universities/ministries) which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the action. This third party handles the financial and administrative aspects of the beneficiaries' involvement in RTD actions — including issues related to employment and payment of personnel, purchase of equipment, consumables, etc. — with the aim in most cases to improve and rationalise the administrative and financial management of these public bodies.

⚠ Article 12 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in *Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs *actually* incurred by the third party may be declared.

The following costs may however (alternatively) be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[34] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the grant agreement (alternative to actual costs; *see Article 6.2.F*).

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used in the beneficiary's premises

or

- taken into account: if the in-kind contributions are used on the third party's premises.

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs; but the beneficiary may NOT include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional cost eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

[34] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA ('**simplified approval procedure**'; *see Article 11*).

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[28]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[OPTION 1 only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]***.]***

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be **set out in Annex 1** and the total estimated costs of subcontracting per beneficiary must be **set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) **must comply** with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

Subcontractors — Subcontractors participate in the action by carrying out action tasks *for* the beneficiary. They are NOT beneficiaries and therefore have no direct obligations under the grant agreement (but their beneficiaries must ensure that they comply with certain key obligations).

Subcontract — For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on business conditions

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from linked third parties; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2).*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work.

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary.

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

The beneficiaries must make special arrangements regarding **results** produced by the subcontractors (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

Security obligations — Stricter rules apply for action tasks that involve information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37).*

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts either on the best value for money (considering the quality of the service proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the subcontracting context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional cost eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI).

⚠ This concerns research and innovation actions or innovation actions *with* a PCP or PPI.

This should NOT be confused with PCP/PPI action (separate type of action, which use a different model grant agreement and whose *main* action task is the implementation of the PCP or PPI).

The additional rules mirror the key obligations for PCP/PPI actions from the H2020 MGA PCP/PPI.

4. Additional cost eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the **name** of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the subcontract (or the subcontracting costs). For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2. Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA ('**simplified approval procedure**').

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the full discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the 'simplified approval procedure' bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

5. Additional cost eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*

- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[35]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.

'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).

'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 4 of Directive 2014/25/EU)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* — Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of

[35] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[30] and **third parties with a legal link to a beneficiary**[31] ('**linked third parties**') may implement the action tasks attributed to them **in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

*The linked third parties may declare as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

*The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their linked third parties.*

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

⚠ **Linked third parties —** Linked third parties are allowed to participate in the action, like the beneficiary they are linked to. They are NOT beneficiaries, but they are allowed to participate fully in the action and receive EU funding; they will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries and their beneficiaries must ensure that they comply with certain key obligations.

⚠ **Combining H2020 & other EU grants —** The terminologies under different EU funds/funding programmes may differ *(e.g. 'linked third parties' under H2020 are the SAME as 'affiliated entities' under the Financial Regulation, while 'affiliated entities' under H2020 is NARROWER than 'affiliated entities' under the Financial Regulation (see Articles 2.1(2) and 23(5) of the Rules for Participation Regulation No 1290/2013 and Article 122 of the Financial Regulation No 966/2012).*

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission/Agency as reimbursement of costs for their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only **affiliated entities** or **entities with a legal link to a beneficiary** can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; 'ad hoc' collaboration agreements or contracts to carry out work in the action are NOT covered. (In this latter case, both legal entities should be beneficiaries.)

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or
- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

1. Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research) — They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

2. Associations, foundations *or* ***other legal entities composed of members —*** *The association/foundation etc. is the beneficiary and the members are the linked third parties.*

Examples (affiliated entities):

1. *Company A established in France holding 20% of the shares in Company B established in Italy. However, with 20% of the shares it has 60% of the voting rights in company B. Therefore, company A controls company B and both companies may be linked third parties in a H2020 GA.*

2. *Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.*

Linked third parties must fulfil the same **conditions for participation** and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme).[36]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an US company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country that is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.*

For more information on conditions for participation and funding, *see the Online Manual*.

They must be **named** in Article 14 and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the linked third party is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the linked third parties (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial viability/capacity of a beneficiary is 'weak'
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

1. *The beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

[36] *See Articles 9 and 10 of the Rules for Participation Regulation No 1290/2013.*

3. The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery), who must upload it (as a scanned PDF copy) in the system.

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files.

The liability is for any amount owned by the beneficiary under the GA, and up to the linked third party's maximum EU contribution in Annex 2.

ℹ For more information on the financial viability/capacity check, *see the Online Manual*.

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. *Entities specifically established for the purpose of implementing the action (e.g. EEIGs).*

2. *National research associations established according to the national law in order to carry out research not limited to the action.*

3. *A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.*

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional cost eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO 'simplified approval procedure'.

3. Additional cost eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* (since linked third parties cannot sign them in the IT system; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary.

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Each linked third party has to provide its own ***certificate* on the financial statements** (**CFS**; *see Article 20.4*).

The threshold of EUR 325 000 applies to each linked third party (independently of its beneficiary).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

4. Additional cost eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. 'Other obligation': Extension of obligations under the GA to linked third parties

The beneficiaries must ensure that the linked third parties comply with certain obligations under the GA.

Obligations that must be extended to linked third parties:

- Record-keeping obligations *(see Article 18)*
- Reporting *(see Article 20)*
- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties.

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARNERS

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

The following ***international partners***[37] *may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

– *will not be reimbursed and*

– *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36 and 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary braches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION 2: *Not applicable****]***

[37] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

1. International partners

4.0 This optional Article (together with the corresponding options in Article 4) will be inserted into the GA if the action is implemented with international partners. It was introduced with GA version 4.0 and does NOT apply to older grant agreements.

International partners — International partners are allowed to participate in the action without EU funding. They are NOT beneficiaries and do NOT receive EU funding; they therefore have no direct obligations under the grant agreement (but their beneficiaries must to ensure that they comply with certain key obligations).

Characteristics of implementation by international partners:

- International partners perform their action tasks directly. They do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the action tasks performed by its international partner.
- International partners perform their action tasks without receiving EU funding, i.e. their costs are NOT eligible for reimbursement under the grant.

  The costs of the international partners are estimated in Annex 2 (to get an overview of the overall project budget). But this is for information purposes only, the international partners are not required to report on their costs.

International partners do NOT need to have a (capital or legal) link to the beneficiary (but they may have one).

They must NOT be eligible for funding, i.e. be established in a third country not listed in General Annex A to the Main Work Programme.

Example: *A consortium of legal entities from EU Member States, H2020 associated countries and third countries listed in General Annex A to the Main Work Programme wants to work with a legal entity established in New Zealand. Since the New Zealand entity would like to be involved in the action without requesting EU funding and without becoming a beneficiary, one of the beneficiaries may decide to list the New Zealand entity as its international partner and attribute certain action tasks to it (provided that the international partner agrees to the action tasks and the related obligations under the GA).*

They may be used to implement any of the action tasks.

They must be **named** in Article 14a and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the international partner is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the linked third parties (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

Although they are not beneficiaries and do not receive EU funding, their beneficiaries must ensure that they comply with certain key (non-financial) obligations:

Thus, they must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 to verify the proper implementation of the action tasks and that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

Moreover, they must extend the following obligations under the GA to the international partners:

Obligations that must be extended to international partners:

- Record-keeping obligations (on the scientific and technical implementation; *see Article 18.1.1*)
- Technical reporting (in the required language; *see Article 20.3(a), 20.4(a) and 20.7)*
- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38).*

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the international partners.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving financial support.*

15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving financial support.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties ONLY where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*)

Examples:

1. *An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.*

2. *One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.*

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving a prize.*

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving a prize.****]***

[OPTION 2: *Not applicable****]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

***Access** for user groups with a majority of users not working in a EU or associated country[34] is **limited** to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) procedure and criteria for **selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: […]*[35]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

1. *advertise widely, including on a dedicated website, the access offered under the Agreement;*
2. *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
3. *ensure that users **comply** with the terms and conditions of the Agreement;*
4. *ensure that its obligations under Articles 35, 36, 38 and 46 **also apply** to the users.*

[OPTION 2:** Not applicable**]

[32] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[34] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.**][OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.**]***

[35] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[37] or installation[38] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 of the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

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[37] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[38] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

⚠ **Record-keeping —** The beneficiaries must keep appropriate records and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and
- the number of units of access provided.

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional cost eligibility condition: Access which must be provided

Trans-national access can be either:

- **in person** (hands-on), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional cost eligibility condition: Categories of users that may have access — Limited access for special user groups

For trans-national access, user groups in which all or most users work in non-associated **third countries** may ONLY have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional cost eligibility condition: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. 'Other obligation': Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to users

The beneficiaries must also ensure that the users comply with certain obligations under the GA.

Obligations that must be extended to users:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users.

16.2 Rules for providing virtual access to research infrastructure

***[OPTION 1 for virtual access to research infrastructure:** 'Access providers'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2:** Not applicable**]

16.3 Consequences of non-compliance

***[OPTION 1 to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **reimburse** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action
- costs related to technological and scientific support for users access *(e.g. a helpdesk)*
- costs of advertising virtual access offered under the action

- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 6)*.

The specific unit cost for access to research infrastructure (F.2) does NOT cover virtual access (only trans-national access).

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed — unless provided for in the work programme/call.

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*

Access must be open to all users; users are not selected.

3. Additional cost eligibility condition: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request the information for **any purpose** *(e.g. checks for monitoring the action or assessing reports and requests for payment; reviews; audits; investigations; evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission/Agency may request the information at **any time**, either during the action or afterwards.

Examples:

1. *In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid (see Article 22).*

2. *The Commission may request information from the beneficiaries in order to evaluate the action's impact up to five years after the balance is paid (see Article 23).*

3. *The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.*

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information is sent via the Participant Portal. Afterwards, information requests may have to be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Beneficiary Register

Each beneficiary must keep its information in the Beneficiary Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form *(e.g. private limited liability company, public law body, S.A., S.L.)*
- organisation type *(e.g. SME, secondary or higher education establishment, etc.)*.

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, validation and data updates, *see the Online Manual*.

3. Information likely to delay or affect the action or EU's financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU's financial interests.

> ***Examples (situation likely to significantly affect or delay the action's implementation or affect the EU's financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Beneficiary Register *(see above)*, the beneficiary must **update** the Beneficiary Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.).*

Best practice: It is recommended that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the Participant Portal
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (for linked third parties, *see point 10*) must keep appropriate and sufficient evidence to **prove** the eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[39]

All evidence must be verifiable, auditable and available.

It must therefore be correctly archived for at least 5 years after the balance is paid (three years for grants up to EUR 60 000). If the beneficiaries throw supporting documents away during this period, they risk that the grant is reduced, costs are declared ineligible or rejected, or recoveries are more difficult.

[39] International Standard on Auditing ISA 500 'Audit Evidence'.

If there are ongoing procedures such as audits, investigations or litigations, the evidence must be kept until these end, even if this is longer than five (or three) years.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission/Agency will accept any document considered an original under national law.

Examples:

1. *The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.*

2. *The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.*

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

1. *For costs declared in category A.1 (employees or equivalent): the costs must be detailed for each person carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).*

2. *For costs declared in category D.1, D.2, D.3 and D.4 (other direct costs): the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.). It should be able to provide details of individual transactions for each type of cost. For depreciation, it must be able to provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).*

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For costs declared in accordance with their usual cost accounting practices (**average personnel** costs and costs of **internally invoiced goods and services**), the beneficiaries must keep detailed records and other supporting documents to:

- show that the costs used to calculate the unit cost match the actual costs as recorded in the statutory accounts

  Examples:

  1. *For personnel costs: accounting records; financial statement extracts; labour contracts; collective labour agreements; applicable tax, labour and social security laws; pay slips; bank statements showing salary payments; classification of employees (based on experience, qualifications, salary, department, etc).*

  2. *For internally invoiced goods and services: accounting records; financial statement extracts; time records (or other records) for the share of personnel costs included in the unit costs; invoices or contracts for maintenance costs, cleaning costs, other services, showing that the cost are directly identifiable.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost is free of ineligible cost components

  Examples:

  1. *For personnel costs: records that show that the hourly rate does not include an indirect cost component (already covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (they should be claimed under category D.1 'travel').*

  2. *For internally invoiced goods and services: evidence that shows that there is no profit/margin/mark-up included in the internally invoiced goods and services (e.g. different rates: one for billing the activity, with mark-up, and another one for internal costing, free of any mark-up); lists of accounts/cost centres that were excluded from the calculation of internally invoiced goods and services — because already included in the costs claimed under another budget categories (e.g. LRI costs, indirect costs, in-kind contributions, etc.).*

- assess the acceptability of budgeted and estimated elements

  Examples:

  1. *For personnel costs: records that show the method for calculating the annual salary increases (e.g. consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases).*

  2. *For internally invoiced goods and services: traceable data used to determine the budgeted/ estimated elements; records on the nature and frequency of the updates of the budgeted and estimated elements; etc.*

- for personnel costs: verify the number of productive hours used to calculate the unit cost (hourly rate)

- for internally invoiced goods and services: verify that the cost items used for the calculation of the unit cost were directly linked to the production of the invoiced good or service.

Examples (not acceptable):

1. *Maintenance which goes beyond than the maintenance of the infrastructure/facilities used to produce the good/service (e.g. maintenance costs for all the beneficiary's cleanrooms; maintenance costs for an entire building, while the cleanroom used for the good/service occupies only a part of the building).*

2. *Generic supplies for which there is no evidence that they were directly linked to the infrastructure/facilities used to produce the good/service (e.g. electricity costs when there is no electricity counter or technical specifications to measure the consumption).*

By contrast, it is NOT necessary to keep records on the actual costs incurred (per person/good or service) — unless they are needed to document the usual cost accounting practices (as just described).

6. Certificate on the methodology (CoMUC)

What?

To get additional assurance, a beneficiary/linked third party may request that the Commission/Agency confirms that its cost accounting practices comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared *before* the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificate is NOT valid for H2020.)

When?

Beneficiaries may in principle submit their requests for approval at **any time** — before or during the grant.

Best practice: In order to ensure that the auditor has enough information to get assurance on the methodology, it is recommended to request it only *after* the first reporting period has passed.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

⚠ If the beneficiary declares personnel costs according to the changed cost accounting practices *before* the new certificate is approved, it bears the **full risk** of non-approval and cost rejection by the Commission/Agency.

How?

The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 of the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump-sum costs

For lump-sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

⚠ For H2020, exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, monthly or per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a declaration on exclusive work for the action [ODT format] (one per reporting period), to confirm that the person worked exclusively for the action, either:

  - during the whole reporting period

  or

  - during an uninterrupted time-period, covering at least a full calendar month within the reporting period.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

'Exclusive work' means that the person carried out NO OTHER activities for the beneficiary than those of the action.

Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration. If a person worked randomly for the action after an

uninterrupted time-period covered by a declaration, time-sheets are needed for the period of random work.

> ***Example:*** *The person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

If a person worked under different regimes during the reporting period (exclusive and non-exclusive), the declaration may be used ONLY for a period of exclusive work. The other months must be recorded with time-sheets.

If there were several periods of exclusive work during one reporting period, the beneficiary may choose to use the declaration for the longest one (and use the monthly time-sheets for the others).

The declaration must be **dated** and **signed** by the person concerned AND her/his supervisor.

– keep **time records**.

Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

– show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

Time records should include, as a minimum:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record;
- the supervisor's full name and signature
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template [ODT format] for time-sheets with these minimum requirements is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept **alternative evidence** if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has full discretion to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the **full risk** of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned

Criterion 2 is met – the project is identified as XYZ

Criterion 3 is met – the time is quantified: two weeks

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown

Criterion 2 is not met: the project name is not mentioned

Criterion 3 is not met – the time is not quantified

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Example: *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

1. *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*

2. *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When?

The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).

'Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points.

The deliverables that must be produced are listed in Annex 1 of the GA.

Example: *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

Security obligations — If the deliverables contain **EU classified information**, the coordinator must first contact the Commission/Agency to discuss how to submit them (approval needed; *see Article 37*).

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

For deliverables that are not in writing *(e.g. cell line or prototype)*, the beneficiaries must submit a short written description.

How?

The coordinator must upload them directly in the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1]to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2 : *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

What & When?

In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of the action (reporting).

> These reports must be **distinguished** from **deliverables** (that are part of Annex 1; see Article 19) and milestones (that may be part of Annex 1, but are normally neither covered by Article 19 nor by Article 20).

The coordinator must submit both:

- a **periodic report** after the end of each reporting period (including the last one) and
- a **final report** at the end of the action.

Each report should be seen as a single package, composed of several parts, i.e.:

- a (periodic or final) **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a (periodic or final) **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically generated by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (CFS; one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

The periodic report for the *last* reporting period covers only the last period, while the final report must give an overview of the action's results over its entire duration.

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

If the coordinator **breaches** its **obligation** to submit the reports, the Commission/Agency may suspend the payment deadline and — if not remedied after a written reminder — terminate the GA or take any of the other Chapter 6 measures *(e.g. cost rejection, grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50).*

> The GA will not be terminated if the breach concerns the last reporting period/final report (because the action duration is already over).

How?

The report(s) must be **prepared** by the **coordinator** and the **beneficiaries together** (directly in the Participant Portal Continuous and Periodic Reporting Modules).

List of documents for the periodic reports:

- explanation of the work carried out (periodic reporting - part B technical report)
- overview of the progress (periodic reporting - part B technical report)
- updated plan for the exploitation and dissemination of results (if necessary) (periodic reporting - part B technical report)
- summary for publication (continuous reporting)
- answers to the questionnaire (continuous reporting)
- individual financial statements for each beneficiary and linked party (periodic reporting - financial report)
- explanation of the use of resources (periodic reporting - financial report)
- summary financial statement (generated automatically by the IT system)
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication (generated automatically by the IT system)
- final summary financial statement (generated automatically by the IT system)
- certificates on the financial statements (CFS) (if necessary).

Generally, they can be **prepared together** (i.e. by several users from different beneficiaries), via the Participant Portal Continuous and Periodic Reporting Modules. The parts in the **continuous reporting** can be filled out at any moment in time (continuously open) and are then automatically added into the periodic or final report by the IT system *(part A of the technical report with the questionnaire and the summary for publication; consolidated financial statement*). Other parts are opened only at **periodic reporting** *(part B of the technical report, individual financial statements, explanation of the use of resources)*. Data is cross-linked to avoid duplication of data input *(e.g. the financial statement and the explanation on the use of resources are linked: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense, if necessary; the final report is completely automatized: assembled on the basis of elements from the periodic report).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (directly in the Participant Portal).

This includes the **coordinator**, who must also submit the individual financial statement for itself.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (since the linked third parties cannot sign them in the IT system).

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must ensure that the data encoded is correct (i.e. identical to the signed paper version).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

If a beneficiary cannot submit its individual financial statement on time, the report can be **submitted without this financial statement**. The costs will be considered zero

for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned.

⚠ **Record-keeping —** The beneficiary must keep the originals for itself and its linked third parties in its files *(see Article 18.1.2)*.

When all parts are ready, the report(s) are assembled automatically by the IT system and must be **submitted** by the coordinator (as a single package; **single submission**).

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator, as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) (**suspension of the payment deadline**). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified (**single re-submission**).

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

⚠ **Adjustments of financial statements (exceptional) —** If the beneficiaries notice a mistake *(e.g. incorrect accounting information; error in the calculation; etc)*, they can make an adjustment (positive or negative) in the following reporting period to the financial statements for any previous reporting period.

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed *(e.g. to take into account of a different hourly rate after the closure of the financial year)*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1

19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Periodic technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated **plan for the exploitation and dissemination of the results** (if such a plan is foreseen in Annex 1).

3.0 For grants signed after GA version 3.0, the overview of the progress must also indicate the communication activities carried out by the consortium *(see also Article 38.1).*

Security obligations — Technical reports may NOT contain any information that has been **EU-classified** in Annex 1 of the GA *(see Article 37).*

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an easy-to-read way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential (or EU-classified) information.

For the last reporting period: The summary should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact (because it will be directly re-used for the final report).

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the H2020 Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the H2020 Specific Programme)
- information to monitor the implementation of H2020 on cross–cutting issues *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Periodic financial report: Individual financial statements — Explanation of the use of resources — Summary financial statement

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 (**cost overruns**). The grant will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

The **summary financial statement** is generated automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

5. Final technical report: Summary for publication

The final technical report is a **summary for publication** that should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact. It will be generated automatically by the IT system (on the basis of the summary for publication of the last reporting period).

6. Final financial report: Final summary financial statement — Certificates on the financial statements (CFS)

The **final summary financial statement** is automatically generated by the IT system (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

The final summary financial statement will be the basis for calculating the payment of the balance *(see Article 21.4)*.

Some beneficiaries/linked third parties must submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and unit costs calculated according to its usual accounting practices (average personnel costs and costs for internally invoiced goods and services).

This means that costs based on lump sums, flat-rates (*e.g. indirect costs*) or unit costs (other than those for personnel costs and costs for internally invoiced goods and services calculated according to the beneficiary's usual cost accounting practices) are NOT counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in an action which declared the following total eligible costs for the action:

- *personnel costs according to usual accounting practices = EUR 250 000*
- *subcontracting costs = EUR 40 000*
- *depreciation costs of equipment used to carry out the action = EUR 60 000*
- *indirect costs (25 % flat rate) = EUR 77 500*
- *total eligible costs claimed by A = EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and personnel costs according to usual accounting practices incurred by A (and hence the requested financial contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or unit costs calculated according to usual accounting practices must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency do not have to be covered again by the certificate.

Example:

A beneficiary participates in an action with three reporting periods. During the second reporting period the Commission's auditors carry out an audit of the costs incurred by the beneficiary in the first reporting period. At the end of the action, the beneficiary requests a total contribution of EUR 425 000 and has to submit a CFS with the final reports. In this case, the CFS may exclude the costs of the first reporting period (which were already covered by the Commission audit).

Linked third parties must submit a certificate if it reaches (on its own, without its beneficiary) the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

The certificate(s) may be submitted ONLY **with** the ***final*** **financial report**. Certificates submitted at any other moment will NOT be accepted (and costs incurred for them will be considered ineligible, because not necessary).

Costs for partial certificates (i.e. one certificate per reporting period) will be accepted ONLY in the last reporting period and ONLY if:

- a CFS is mandatory (i.e. the threshold is reached at the end of the action) and

- the total costs of the partial certificates is similar to the cost that would have been incurred for a single certificate.

The certificate must be issued by an **external auditor**, using the template in Annex 5 of the GA.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[40] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a non-EU country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in non-EU countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

7. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants above EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

A template is available in the Participant Portal and must be submitted via the Participant Portal Continuous Reporting Module.

8. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:

[40] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

– daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

To calculate this rate, the beneficiaries may use the editable charts on the ECB website[41].

Procedure for calculating the rate on the ECB website:

Step 1 — Go to the ECB website.

Step 2 — Click on the chart icon [ ] for the currency.

Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

– if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[42].

Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16.7531 for EUR 1. The university will report costs of EUR 29 845, 22 (MDL 500 000 / MDL 16.7531 * EUR 1).*

9. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

[41] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[42] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts prior to that)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or an(other) executive agency — without the consent of the beneficiary concerned and up to the beneficiary's maximum EU contribution in Annex 2 *(see also Article 44)*.

All payments are subject to a **payment deadline** (i.e. the number of days within which the Commission/Agency has to pay the consortium — after having received the payment request). The deadline depends on the type of payment:

- for pre-financing: 30 days
- for interim payments and payment of the balance: 90 days *(see Article 21)*.

If there are issues with the payment request or with the costs declared which make it impossible to comply with the payment deadline, the Commission/Agency will **suspend the deadline** *(see Article 47)*.

The pre-financing payment is automatic, while for interim and final payments the Commission/Agency must first:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs
- calculate the amount to be paid
- approve the payment request and authorise the payment.

This is not an in-depth verification and therefore no guarantee for eligibility or correctness. The costs may still have to be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

The payments are made **to the coordinator**; the beneficiaries are NOT paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only if the coordinator is terminated that the Commission/Agency (and especially the Guarantee Fund) will intervene; *see Article 50*).

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

2. Amount of the pre-financing payment

There is no standard amount (or percentage) for the pre-financing payment; the **amount** is fixed in each GA.

Normally it will be (depending on the availability of EU budget credits) **100 %** of the **average EU funding per period** (i.e. maximum grant amount set out in Article 5.1 / number of periods) for actions with at least two reporting periods. It will be however less for actions with only one reporting period, since 100 % would mean the totality of the grant amount.

At the moment of the pre-financing, an amount that corresponds to **5 %** of the maximum grant amount *(see Article 5.1)* is **deducted** from the pre-financing payment and transferred to the **Guarantee Fund**.

Example:

Maximum grant amount: EUR 1 000 000 with 100 % reimbursement rate

Pre-financing: EUR 333 334 of which:

EUR 283 334 transferred to the consortium (coordinator)

EUR 50 000 kept by the Commission for the Guarantee Fund.

For the Commission's Joint Research Centre (JRC), the Commission/Agency keeps the share of the pre-financing (based on the estimated budget of the Annex 2 in proportion of JRC weight in the total grant) and does not pay it out to the coordinator.

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 - EUR 52 500 = EUR 297 500

Pre-financing funds remain **EU property** until the payment of the balance — when they are cleared against the eligible costs accepted by the Commission/Agency.

3. Amount of interim payments

The amount of the interim payments will be calculated by the Commission/Agency (on the basis of the costs declared in the financial statement).

Procedure for calculating interim payments:

Calculation of interim payments

Step 1 — Application of reimbursement rates to eligible costs approved by the Commission/Agency

Step 2 — Limit to the 90% of the maximum grant amount

amount of the interim payment

Step 1 — Rejection of ineligible costs and application of the reimbursement rate(s)

Ineligible costs (i.e. costs that do not comply with one or more eligibility conditions; *see Article 6*) will be **rejected** (i.e. not approved).

If, for innovation actions, there are different **reimbursement rates** for different beneficiaries, the Commission/Agency will apply the reimbursement rate for each beneficiary to the costs it has approved for that beneficiary.

Step 2 — The interim payment is limited to 90 % of the maximum grant amount minus the pre-financing

Example for calculating interim payments:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Costs declared by the consortium at end of the first reporting period: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = € 625 000.

After checking the reports, the Commission finds that EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are not eligible and therefore rejects them. (The Commission rejects EUR 32 000 direct costs + EUR 8 000 flat rate for indirect costs = EUR 40 000).

Total costs accepted by the Commission at the end of the first period: EUR 585 000

Step 1; application of reimbursement rate: 100% = EUR 585 000

Step2: 90% limit of the maximum grant amount for pre-financing and interim payments = EUR 900 000

1st interim payment to the coordinator is EUR (900 000 – 333 334) = 566 666.

Total accepted eligible costs for 2nd interim period: EUR 162 500

2nd interim payment: EUR 0 (the 90% limit has already been reached in the first period).

4. Amount of the payment of the balance

The **amount** of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*:

- if the final grant amount is *higher* than the payments already made, the balance will take the form of a **payment**
- if the final grant amount is *lower* than the payments made, the balance will take the form of a **recovery**.

Examples for calculating the payment of the balance:

Maximum grant amount: EUR 1 000 000 with 100% reimbursement rate and three reporting periods.

Pre-financing of EUR 333 334 (of which EUR 50 000 kept from the pre-financing for the Guarantee Fund).

Limit for pre-financing and interim payments: 90% of the maximum grant amount: EUR 900 000.

Total eligible costs accepted for 1st interim period: EUR 570 000;

1st interim payment: EUR 566 666 (the 90% limit is reached).

Total eligible costs accepted for 2nd interim period: EUR 162 500.

2nd interim payment: EUR 0 (the 90 % limit has already been reached in the first period).

Case 1: *Total eligible costs claimed and accepted for the last reporting period: EUR 50 000.*

Final grant amount: EUR 750 000.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 750 000) = EUR 150 000 higher than the final grant amount.*

The amount of EUR 150 000 will be recovered as follows:

- *EUR 50 000 from the Guarantee Fund and*
- *EUR 100 000 from the coordinator (see procedure in Article 44.1.2).*

Case 2: *Total eligible costs accepted for the last reporting period: EUR 312 500.*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 312 500 = EUR 1 045 000.

Final grant amount: EUR 1 000 000 (maximum grant amount)

Balance to be paid: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments already made, of which EUR 50 000 transferred from the first pre-financing to the Guarantee Fund) = EUR 100 000.

*EUR 150 000 will be **paid** to the coordinator as follows:*

- *EUR 100 000 directly by the Commission as payment of the balance; and*
- *EUR 50 000 corresponding to the amount retained for the Guarantee Fund and returned to the consortium.*

Case 3: *Total eligible costs accepted for the last reporting period: EUR 155 000*

Total eligible costs accepted for the action: EUR 570 000 + EUR 162 500 + EUR 155 000 = EUR 887 500.

*Payment of the balance takes the form of a **recovery** as the payments made by the Commission are (EUR 900 000 – EUR 887 500) = EUR 12 500 higher than the final grant amount.*

- *The Commission/Agency will recover (deduct) this amount of EUR 12 500 from the amount retained for the Guarantee Fund.*
- *The remaining EUR 37 500 retained for the Guarantee Fund will be returned to the consortium and paid to the coordinator.*

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Commission/Agency checks

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Agency performs a plagiarism check on documents submitted by the consortium.*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in EU actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The checks itself are **internal**. They may however have external effects, since the Commission/Agency may have to **ask** the coordinator (or directly the beneficiaries) for **additional information** needed for the check *(see Article 17.1)* or it may take Chapter 6 measures in view of the results.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date.*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. In this case, the Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

If the check shows **ineligible costs** or serious **breach of obligations**, it may lead to cost rejection or grant reduction and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission/Agency may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Commission/Agency reviews

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA and may exceptionally also concern issues related to only one specific beneficiary.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows **ineligible costs** or **substantial errors, irregularities or fraud** or serious **breach of obligations** (including non- or improper implementation of the action as described in Annex 1), it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (or, exceptionally, the beneficiary concerned) via the Participant Portal.

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or a **review meeting** (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a **review report**.

> The review report together with the Commission/Agency comments will be notified to the coordinator (or, exceptionally, the beneficiary concerned) for comments within 30 days (**contradictory review procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The Commission/Agency operational services (authorising officers) will analyse the comments received and decide on the follow-up, if any.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Commission/Agency audits

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

Record-keeping — Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including cost rejection, grant reduction, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit **third parties providing in-kind contributions** (free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to:*

- *see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest)*
- *see if payments made under the contract/subcontract match the costs declared by the beneficiary*
- *assess the technical work carried out by the subcontractor.*

The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to check the contractors'/subcontractors' costs or accounts, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).

4. *The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 to the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and, in very serious cases, to exclusion and/or financial penalties *(see Article 45)*.

In some cases, findings may result in the **acceptance** of additional costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about actual costs for cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the Participant Portal or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an **audit report**.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days (**contradictory audit procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the **final audit report** and the **letter of audit conclusions** (LoC) — and the file will then be passed on to the Commission/Agency operational services (authorising officers) for the follow-up, if any.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[41] and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. OLAF investigations

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the outcome of the investigation to the Commission/Agency, who will then decide how to proceed.

If an OLAF investigation shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)*, to exclusion and/or financial penalties *(see Article 45)*, as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. ECA checks and audits

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

If an ECA check or audit shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, this may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION 2:** Not applicable.**]

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

⚠ Checks, reviews, audits and investigations must however respect the privileges and immunities accorded to an international organisation by its constituent documents or international law.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the **findings concern substantial errors, irregularities or fraud or serious breach of obligations,** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings (rejection and grant reduction)

If the Commission/Agency finds (in a check, review, audit or investigation) **substantial errors, irregularities or fraud** or serious **breach of obligations** which are **systemic** or **recurrent**, it may make a correction (cost rejection or grant reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed (extension of the findings)
- other H2020 grants of the beneficiary (extension of the findings).

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; confidential information is insufficiently protected.*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

Findings may be extended to all other EU or Euratom grants awarded under similar conditions.

⚠ Findings will normally be extended only within one programme *(e.g. findings in an H2020 audit to all H2020 grants)* but they may exceptionally also be extended to similar programmes *(e.g. if justified by the nature of the findings and the similarity of the applicable grant agreements or in case of serious irregularities or fraud).*

2. Procedure

If findings are systemic or recurrent**,** this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings are upheld, the audit/review will be closed (by the Commission/Agency auditors/reviewers) and continue with an audit extension procedure (which is then followed by an audit/review implementation procedure).

Procedure for extension of findings and audit implementation:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure (**letter of audit conclusions**), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for cost rejection:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (if the beneficiary does not submit revised financial statements)
  - the conditions for external counter-audits to propose an alternative correction method *(see below)*
- for grant reduction: the proposed flat-rate for the correction.

The 'extrapolation rate' will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The 'flat-rate' will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept the alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for cost rejection: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for grant reduction: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The Commission/Agency has **full discretion** to accept or refuse an alternative correction method proposed by the beneficiary and there is NO entitlement to it.

Step 3 — Audit implementation. If the Commission/Agency maintains its findings, it then may start rejection, reduction and, if necessary, recovery procedures *(see Articles 42 to 44)* — either on the basis of the revised financial statements, the correction rate announced or an alternative correction rate.

If the Commission/Agency **received and approved the revised financial statements**, the costs to be rejected will be calculated, for each grant, according to the revised financial statements.

If the Commission/Agency **could not approve the revised financial statements**, the costs to be rejected will be calculated, for each grant, by applying the correction rate for extrapolation.

If the Commission/Agency **received and accepted an alternative correction method**, the cost rejection/grant reduction will be calculated, for each grant, by applying the accepted alternative correction rate.

If the beneficiary did **not send any comments** or if the Commission/Agency does **not accept its comments or alternative method** proposed, the cost rejection/grant reduction will be calculated, for each grant, by applying the correction rate initially notified.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:** five]**[OPTION 2 for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the H2020 Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the H2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of H2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[43] annexed to the EU Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[43] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

Best practice: Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[44]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[44] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background prior to providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or '**associated country**'[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

Access rights are therefore normally limited to other beneficiaries and certain affiliated entities of other beneficiaries, unless otherwise agreed.

Example: *Beneficiary A used background from beneficiary B to generate its results. Beneficiary A would like to use its affiliated entity A established in a MS to exploit the results. For this, affiliated entity A needs access rights to beneficiary B's background.*

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 <u>Rights of third parties</u> (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Record-keeping

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. subcontractors, linked third parties, international partners, employees, etc.)*.

> ***Examples (third parties that may claim rights):*** *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action (if they have rights under national law or their contract); beneficiaries for which linked third parties carry out a significant part of the work.*
>
> ***Examples (arrangements):*** *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

> **Best practice:** Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is impossible under EU or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.)*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Standard forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

1. *For an invention: e.g. patent, confidential information.*

2. *For the design of a technology: e.g. industrial design, copyright.*

3. *For a website: e.g. industrial design, copyright, trademark.*

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example (better not to protect for the moment): *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

> **Best practice:** Where possible, beneficiaries should make this reference in the language of their application (using the text of the GA language version available on the Participant Portal Reference documents page).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the plan for the exploitation and dissemination of the results.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

⚠ Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018'];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1 for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2**: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) prior to filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security obligations, etc.)*.

Security obligations — Dissemination may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

Results that contain **EU-classified information**, can be disclosed only after approval by the Commission/Agency *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The beneficiaries may choose the **form** for disseminating their results.

Standard forms of dissemination:

- website
- presentation at a scientific conference
- peer-reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination — unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

2. Open access to scientific publications

What?

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals)*.

⚠ Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications.

Best practice: Open access has no impact on the other terms and conditions that apply to scientific publications *(e.g. as regards use, etc)*. However, in order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights such as the right to copy, distribute, search, link, crawl and mine).

A 'repository for scientific publications' is an online archive. Beneficiaries are free to choose the repository; it can be institutional, subject-based or centralised.

Best practice: The Open Access Infrastructure for Research in Europe (OpenAIRE) links existing repositories. It is not obligatory for projects to deposit in OpenAIRE itself, but it is the recommended entry point for researchers deciding on a repository. OpenAIRE also offers support services for researchers, such as the National Open Access Desks. Other useful listings are the Registry of Open Access Repositories (ROAR), the Directory of Open Access Repositories (OpenDOAR) and OAPEN (for monographs). Beneficiaries should not choose a repository with rules which could conflict with open access.

Open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets certain requirements that must be fulfilled if they do decide to publish them.

Open access can be provided through:

a) **gold open access** (**open-access publishing**)

'Gold open access means that open access is provided immediately via the publisher when an article is published, i.e. where it is published in open access journals or in 'hybrid' journals combining subscription access and open access to individual articles.

In gold open access, the payment of publication costs (article processing charges) is shifted from readers' subscriptions to (generally one-off) payments by the author. Such author processing costs may be eligible *(see Article 6.2.D.3)* — if incurred before the end of the action. Currently, an action for dealing with such costs incurred after the end of the action in FP7 is being piloted and further action in H2020 will be considered based on the outcome.

⚠ Although gold open access already ensures access via the publisher, the beneficiaries must nevertheless also provide open access via a repository *(see below)* in order to ensure the long-term preservation and availability of the publication.

b) **green open access** (self-archiving).

'Green open access' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in an online repository. Access to the article is often — but not necessarily — delayed (H2020 embargo period between 6 and 12 months; *see below*) as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download view fees during an exclusivity period.

Best practice: Authors are encouraged to retain their copyright and grant appropriate licences to publishers.

A template for an **open access clause** addendum which can be added to **publishing agreements** is available on the Participant Portal.

How?

Open access to scientific publications involves four steps — which may or may not be taken at the same time.

Procedure for open access (scientific publications):

Step 1 — **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication).

This must be done as soon as possible (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*) and at the latest on publication.

'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

Step 2 — Provide **open access** to the scientific **publication** — either as 'gold open access (i.e. via the publisher AND via the repository) or as 'green open access (i.e. via the repository only).

Open access must be given:

- in case of 'gold open access': at the latest on publication
- in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

Step 3 — Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

This is needed for visibility, traceability and monitoring.

It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and
- a persistent identifier *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

Best practice: For ease of tracking, beneficiaries should also include the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601) in the funding acknowledgement field in their metadata.

The metadata compliance of the repository can be checked using OpenAIRE.

Step 4 — Aim to **deposit** at the same time, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

ℹ For more information on why open access to scientific publications and digital research data is an important aspect of Horizon 2020, *see the Online Manual.*

3. Open access to research data (Extended Open Research Data Pilot)

What?

Beneficiaries of actions that participate in the Open Research Data Pilot must give **open, free-of-charge access** to the end-user to **digital research data** generated during the action (⚠ new in Horizon 2020).

⚠ As of the Work Programme 2017, the Open Research Data pilot has been extended to all thematic areas of Horizon 2020 (except ERC PoC actions, SME instrument Ph1 actions, ERA-NET Cofund actions that do not produce data, EJP Cofund actions, and prizes).

Participation is therefore now in principle **the default**. However, actions may **opt out** at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55)* —, if:

- participation is incompatible with the obligation to protect results *(see Article 27)*

- participation is incompatible with the security obligations *(see Article 37)*
- participation is incompatible with rules on protection of personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate/collect any research data or
- there are other legitimate reasons not to take part.

'Digital research data' is information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Only data that is generated digitally *in the action* is concerned. Actions are encouraged to digitise any other data and provide open access to it, but they are not obliged to do so.

The pilot applies to **2 types** of digital research **data**:

- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data and associated metadata, as specified by the beneficiaries themselves in their data management plan.

Examples: *curated data not directly attributable to a publication or raw data*

⚠ Beneficiaries may decide not to provide open access to specific datasets if this would go against other GA obligations *(e.g. to protect results or personal data)* or if the action's main objective, as described in Annex 1, would be jeopardised by giving open access to those specific datasets. In this case, the reasons must be explained in the data management plan, *see below*).

Open access to research data means taking measures to make it possible for third parties to **access, mine, exploit, reproduce** and **disseminate** data — via a research data repository.

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories (Re3data) and Databib. One key entry point for accessing and depositing related data and tools is Zenodo.

Actions participating in the pilot must draw up a **data management plan (DMP)** within the first 6 months of the project implementation.

The data management plan must support the management life-cycle for all data that will be collected, processed or generated by the action. It must cover how to make data findable, accessible, interoperable and re-usable (FAIR), including:

- the handling of data during and after the project
- what data will be collected, processed or generated
- what methodology and standards will be applied
- whether data will be shared / made open access (and how) and, if any, what data will not be shared / made open access (and why)
- how data will be curated and preserved.

The data management plan should be updated (and become more precise) as the project evolves. New versions should be created whenever important changes to the project occur *(e.g. new data sets, changes in consortium policies, etc),* at least as part of the mid-term review (if any) and at the end of the project.

For more information on data management plans (and a template), *see the proposal forms and the Online Manual.*

Costs related to the implementation of the Open Research Data pilot *(e.g. costs for providing open access, related research data management costs, data curation and data storage costs)* may be eligible *(see Article 6.2.D.3)*.

How?

Open access to digital research data involves 3 steps:

Procedure for open access (research data):

Step 1 — **Deposit** the digital research data, preferably in a research data repository.

Step 2 — Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. for databases: by attaching an appropriate creative commons licence (CC-BY or CC0 tool) to the data; if the access/use is not subject to any rights: by indicating that no licence is needed)*.

Open access must not be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

Step 3 — Provide **information**, via the repository, about **tools and instruments** for validating the results.

Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.).*

For more information on the research data pilot (and especially how actions may opt out or opt in), see *the Online Manual.*

4. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of the dissemination activity (using the text of the GA language version available on the Participant Portal Reference documents page).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

Combining H2020 & other EU grants — If the outputs were developed in another EU-funded action (funded not by H2020, but another EU funding programme, including Structural Funds/ESIF Funds), do NOT forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION 2 for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results.

> ⚠ **Security obligations —** Transfer may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a global authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, the beneficiary must **formally notify in advance** (via the Participant Portal) any transfer to a specifically-identified third party established in a non-associated third country — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — Common legal structures (CLS) (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights *(see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a non-associated third country.

> ⚠ As of the Work Programme 2018, the calls will normally already indicate if this option will be activated in the GAs. The option may however still be activated (without such indication):
>
> – for calls which do not fix the type of research and innovation activities ("bottom-up" calls, such as FET Open or MSCA) or
>
> – in other calls, exceptionally, if justified by the nature of the research and innovation activities or other action-related reasons.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiary must **formally notify** the Commission/Agency **in advance** (via the Participant Portal) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

A notification before the results are generated is allowed, if the specific results concerned (and the details of the transfer/licence) can already be identified.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 <u>Access rights for the EU institutions, bodies, offices or agencies and EU Member States</u>

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION 2 for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

[OPTION 3 for Euratom grants: *The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme*: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries*[47]*, for the purposes of the complementary grant agreement(s) (see Article 2).]*

[OPTION 1b for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

[OPTION 1d for trans-national access to research infrastructure: *The access provider must give the users royalty-free access to the results needed to implement the action.]*

[OPTION 2: *Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[47] **'Complementary beneficiary'** means a beneficiary of a complementary grant agreement

1. Access to results

What & When ?

The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results

- by an affiliated entity of another beneficiary (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

***1.** If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).*

***2.** If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.*

How?

Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries whose participation was terminated before the end of the action, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free

– for the exploitation of results: under fair and reasonable conditions

'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

Fair and reasonable conditions includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicensing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

1. *A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.*

2. *In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.*

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [48], in particular regarding:

- **working conditions**;
- **transparent recruitment processes based on merit**, and
- **career development**.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[45] and the Code of Conduct for their Recruitment.[46]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

[45] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[46] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[47] and of the Code of Conduct[48] that relate to recruitment, working conditions and career development.

For guidance, *see the 'Human Resources Strategy for Researchers' tool developed by the Commission.*

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[49])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

[47] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[49] Available at http://ec.europa.eu/euraxess/jobs

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more information on gender in research, *see the Online Manual.*

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

– present their research goals and intentions in an honest and transparent manner;

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3]* as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced ;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the Commission's **H2020 ethics appraisal scheme** (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

- ethics *self*-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more information on ethics, *see the Guidance — How to complete your ethics self-assessment, the Guidance note — Research involving dual use items, the Guidance note — Research focusing exclusively on civil applications, the Guidance note — Potential misuse of research results and more generally, the Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State.

The beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that the research results cannot peripherally be useful in a military context. Research related to *dual-use* products or technologies (usually used for civilian purposes but with possible military applications) is not prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

Beneficiaries must commit to the highest standards of research integrity (as set out, for instance, in the European Code of Conduct for Research Integrity[50]) and comply with the essential research integrity principles listed in Article 34.1.

Essential research integrity principles:

- honesty
- reliability
- objectivity
- impartiality
- open communication
- duty of care
- fairness and
- responsibility for future science generations

According to these principles, beneficiaries must ensure that their researchers:

- present their research goals and intentions in an honest and transparent manner
- design their research carefully and conduct it in a reliable fashion (taking its societal impact into account)
- use appropriate techniques and methodologies (including for data collection and management)
- exercise due care for research subjects (human beings, animals, environment or cultural objects)
- ensure objectivity, accuracy and impartiality when disseminating the results
- allow access to research data (as much as possible and taking into account the legitimate interest of the beneficiaries and open access obligations, if any)
- make the necessary references to their work and that of other researchers
- refrain from practicing any form of plagiarism, data falsification or fabrication

[50] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

– avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define **ethics requirements** and include them as **deliverables** in Annex 1 of the GA.

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

Examples (ethics deliverables): *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

Examples (other ethics requirements): *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

Best practice: When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18).*

The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

If the documents are not in English, the beneficiary may be asked to provide an English summary.

This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.

Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

The Commission/Agency may carry out **ethics checks, reviews or audits**, to ensure that the beneficiaries have properly implemented the ethics requirements and obtained the opinions/notifications/authorisations *(see Article 22)*.

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

Activities that involve human embryos (hE) or human embryonic stem cells (hESC) can only be funded, if:

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[51] (in particular, do NOT result in the destruction of human embryos)

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

[51] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A 'conflict of interests' exists if **shared interests**:

- influenced the contract's/subcontract's selection/award procedure
- influenced the contract's/subcontract's price and this does not correspond to the market price or
- affected the action's performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  1. *A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.*

  2. *A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.*

  3. *A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).*

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

  Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits.*

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  1. *If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.*

  2. *If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.*

  3. *If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.*

If there is a **(risk of) a conflict of interests**, the coordinator must **inform** the Commission/Agency (via the Participant Portal), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Security obligations — Stricter confidentiality obligations apply for information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the handling of classified information in EU research projects, Guidance — Guidelines for the classification of information in research projects and, more generally, the Online Manual.*

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU's financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2: *Not applicable**]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[51] — until it is declassified.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].**[OPTION 2:*** *Not applicable.**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable.**]***

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

1. Results with a security recommendation — EU-classified information

If the GA provides for (one of) these options, the beneficiaries must comply with the **security obligations** set out in this Article, in Annex 1 and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises security issues and must be subject to a security recommendation and/or EU-classification under Decision No 2015/444[52].

For more information on security obligations, *see the Guidance — Guidelines for the classification of information in research projects, the Guidance — Guidelines for the handling of classified information in EU research projects, the Guidance note — Potential misuse of research results and, more generally, the Online Manual.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[53].

Moreover, the coordinator must — before the start of the activity for which it is needed — submit a **copy** of any **export** or **transfer licence**.

For more information on dual use goods, *see the Guidance — How to complete your ethics self-assessment* and the *Guidance note — Research involving dual use items.*

[52] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[53] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and] Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is] [are]* not responsible for any use that may be made of the information it contains.

1. Communication activities (beneficiaries) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[54].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a beneficiary in a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to **multiple audiences** (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a **major media impact** (i.e. media coverage (online and printed press, broadcast media, social media, etc.) that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

[54] For the definition of 'communication activities', *see the Glossary.*

Security obligations — Information given may NOT include **EU-classified information** or information on results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more information on security obligations, *see the Guidance — Guidelines for the classification of information in research projects, Guidance — Guidelines for the handling of classified information in EU research projects and, more generally, the Online Manual.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the proposal templates*) and be included in Annex 1 and 2.

For more information on promoting the action, *see the Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the **EU emblem**

AND

- including the **reference to EU funding** set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity or, for infrastructure, equipment or major results, the official language(s) of the country where they are located (using the text of the GA language version available on the Participant Portal Reference documents page).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object).

Examples: *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency; the]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of *[the Agency or]* the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency and the]* Commission will insert the following information:

> "© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the measures described in Chapter 6.

1. Communication activities (Commission/Agency)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material):*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (Commission/Agency)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its Participant Portal privacy statements.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligibility of costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the EU financial interests).

When the Commission/Agency collects and processes personal data under the GA, national data protection law is NOT applicable and will NOT be accepted as a pretext for not complying with obligations under the GA.

Disclosure of staff data under the GA *(e.g. data requested by the Commission/Agency project officer or auditors)* is automatically justified under Article 5(c) of Regulation 45/2001.

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[55] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

Persons whose data is being processed (data subjects) can contact the data controller or the DPO (via the contact information in the privacy statement), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

[55] Available at http://ec.europa.eu/dpo-register/search.htm.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (beneficiaries)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[56] and the corresponding national law).

⚠ The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [57]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc*.

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage

[56] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[57] *See Article 8 of Directive 95/46/EC*.

- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[58]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the relevant Participant Portal privacy statement).

Examples:

1. *Before encoding staff data in the Beneficiary Register or into a proposal, the beneficiary must provide the staff concerned with the privacy statement.*

2. *If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the privacy statement.*

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[58] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What?

The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How?

Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

1. *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.*

2. *Assignment for the benefit of creditors in a bankruptcy procedure.*

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

[OPTION to be used when the beneficiary is an European Research Infrastructure Consortium (ERIC)*[54] *without own resources: *As an exception, the beneficiary delegates the tasks set out above to [insert name of member of the ERIC]. The beneficiary retains sole responsibility for compliance with the obligations under the Agreement.]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is NOT responsible for the implementation of the action and has NO responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them **withdraws**, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless the Commission/Agency expressly agrees otherwise (exceptional; only for specific reasons). They will have to do this without any additional funding (although — in case of beneficiary termination — the Guarantee Fund may intervene for the defaulting beneficiary; *see Article 50*).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% contribution to the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

Specific cases (beneficiaries' responsibilities):

ERIC (European Research Infrastructure Consortium)[59]: If the beneficiary is an ERIC which does not have its own resources, it may exceptionally delegate the following responsibilities to one of its members:

- monitor that the action is implemented properly *(see Article 7)*
- inform about events or circumstances likely to affect significantly or delay the action

[59] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1).

implementation *(see Article 17.2)*
- submit deliverables and reports *(see Articles 19 and 20)*
- submit documents or information required

⚠ An ERIC using one of its members remains **fully responsible** for it under the GA.

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION 1 for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION 2: *Not applicable****]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly *(see Article 22)*.

Example:

In case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can normally NOT be subcontracted or outsourced to a third party (including linked third parties). They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use linked third parties for *other* tasks; *see Articles 13, 14*).

Specific cases (coordinator's responsibilities):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- they must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs (and those must include receiving and administering EU funds).

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It also will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

ERICs (European Research Infrastructure Consortia)[60]***:*** Beneficiaries that are ERICs and do not have their own resources may exceptionally delegate the following coordination tasks to one of its members:

- monitor that the action is implemented properly *(see Article 7)*;
- act as intermediary for communications *(see Article 17)*;
- request and review documents or information required and verify completeness and correctness;
- submit deliverables and reports *(see Articles 19 and 20)*;

⚠ ERICs using one of their members remain **fully responsible** for it under the GA.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article, *e.g. scientific coordination of the action*) can be carried out by any beneficiary.

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it will however NOT be considered the action's coordinator (but one of the other beneficiaries).

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

> **Best practice:** In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before

[60] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1)

acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

Best practice: The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see the Online Manual and the Guidance — How to draw up your consortium agreement.*

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted ONLY for complementary actions *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted ONLY for jointly funded actions *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the grant agreements and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see the Online Manual and the Guidance — How to draw up your coordination agreement.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Cost rejection

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

Cost rejections will be made for **violations of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Grounds for cost rejection (Commission/Agency):

- **Costs** do **not comply with** the GA **eligibility rules (in this grant)**

  The Commission/Agency will reject costs, if they do not comply with the eligibility rules set out in Articles 6 and 8-16.

- **Costs** do **not comply with** the GA **eligibility rules (in other grants)**

  The Commission/Agency may also reject costs, if such ineligibility was found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the ineligibility is:
    - systemic or recurrent and
    - has a material impact on this grant.

Rejection of costs can take place at any moment — at the time of beneficiary termination, interim payment, payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if cost rejection leads to a recovery: there will be an *ex ante* **contradictory procedure**
- if cost rejection does NOT lead to a recovery: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection (**payment review procedure**).

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post payment review procedure allows the

Commission/Agency however to pay quickly without having to suspend the payment deadlines (by postponing the discussion on the disputed costs).

Basic contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. (An extension may be granted on justified request — if submitted within the 30 days.)

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Payment review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out (**notification of amounts due**; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections.

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for rejections at the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after beneficiary termination and after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Cost rejection at the time of an interim payment or payment of the balance

If the Commission/Agency rejects costs (declared in the periodic or final report) at the moment **of** an **interim payment** or the **payment of the balance**, it will deduct them and calculate the **amount to be paid** accordingly.

If ineligible costs (declared in a previous report and already paid for) are found **in-between payments**, the Commission/Agency will reject them at the next payment (i.e. deduct the amount rejected from the costs declared in the next summary financial statement and calculate the amount to be paid accordingly).

Example for calculating a rejection at an interim payment:

Case 1: *Action with three beneficiaries (A, B andC) and a reimbursement rate 100 %.*

Maximum grant amount: EUR 500 000.

Pre-financing: EUR 200 000.

Costs declared by beneficiary A at the end of the first reporting period: EUR 95 000 (direct costs) + EUR 23 750 (indirect costs 25 %) = EUR 118 750 .

Costs declared by beneficiary B at the end of the first reporting period: EUR 115 000 (direct costs) +EUR 28 750 (indirect costs 25 %) = EUR 143 750.

Costs declared by beneficiary C at the end of the first reporting period: EUR 90 000 (direct costs) +EUR 22 500 (indirect costs 25 %) = EUR 112 500.

Total costs declared for the action at the end of the first reporting period: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total declared eligible costs approved by the Commission at the end of the first reporting period: EUR 375 000 — EUR 12 500 = EUR 362 500.

Application of the reimbursement rate 100%: EUR 362 500

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000— EUR 200 000 = EUR 250 000.

Amount due as interim payment: EUR 250 000

Case 2 (in between payments): *Total costs declared for the action in the 1st periodic report: EUR 375 000.*

Interim payment for the 1st periodic report = EUR 375 000

Costs rejected after interim payment or 1st periodic report: EUR 12 500

Total costs declared and accepted for the action in 2nd periodic report = EUR 100 000

Total eligible costs to be considered for the 2nd interim payment: EUR 100 000 – EUR 12 500 = EUR 87 500.

4. Cost rejection after beneficiary termination

If the Commission/Agency rejects costs **after beneficiary termination**, it will deduct the rejected amount from the costs the beneficiary declared in the **termination report** and calculate **the amount due** to the beneficiary *(see Articles 50.2 and 50.3)*.

> Only costs incurred by the beneficiary concerned until termination takes effect are eligible. Costs relating to contracts due for execution only after termination are NOT eligible.

If the amount which is due to the beneficiary is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will **recover** the difference *(see Article 44)*.

> Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

Example for calculating a rejection after beneficiary termination:

Grant with 5 beneficiaries (A, B, C, D and E).

Maximum grant amount: EUR 500 000 (beneficiary maximum EU contribution: each beneficiary 100 000 EUR).

Reimbursement rate: 100 %.

Pre-financing: EUR 200 000.

Beneficiary termination:

Beneficiary A goes bankrupt in the middle of the action and its participation is terminated.

Eligible costs declared by beneficiary A in termination report: EUR 50 000 (direct costs) + EUR 25 000 (25 % flat rate for indirect costs) = EUR 62 500.

Costs rejected for beneficiary A following audit: EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

No grant reduction.

The amount which is due for beneficiary A: EUR 62 500 – EUR 12 500 = EUR 50 000

Recovery:

Payments received by beneficiary A (according to the report on the distribution of payments): EUR 40 000.

Amount to be recovered from beneficiary A: EUR 40 000 – EUR 50 000 = EUR - 10 000 (no recovery; the positive balance of EUR 10 000 will be paid out at the next interim payment).

5. Cost rejection after payment of the balance

If the Commission/Agency rejects costs (declared in a periodic or final report) **after the payment of the balance**, it will deduct the amount rejected from the costs declared by the beneficiary in the final summary financial statement and calculate a **revised grant amount** for this beneficiary *(see Article 5.4)*.

If the revised grant amount for the beneficiary is lower than its share in the final grant amount, the Commission/Agency will **recover** the difference *(see Article 44)*.

Example for calculating a rejection after the payment of the balance:

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100%.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25% flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25% flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance (action properly implemented, no receipt): EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000

Revised grant amount for beneficiary A:

EUR 150 000 – EUR 30 000 = EUR 120 000 + EUR 30 000 (25% flat rate for indirect costs) = EUR 150 000

The share of Beneficiary A in the final grant amount = EUR 187 500.

The EU contribution that will be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries are unchanged.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **redu**ces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Grant reduction

If the Commission/Agency finds *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* **substantial errors, irregularities or fraud** or **breach of obligations** (under the GA or during the award procedure; *e.g. the action has not been properly implemented)*, it may reduce the grant amount— in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations.

⚠ **Grant reductions** will be made (at the end of the action) for substantial errors, irregularities or fraud or serious breach of obligations, in proportion to the seriousness of the error, irregularity, fraud or breach *(e.g. in case of fraud the reduction may be up to a 100%)*.

⚠ If the issues are found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

Grounds for grant reduction (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may make a grant reduction, if a beneficiary has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also make a grant reduction, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

3.0 Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol[61]).

Grant reduction can take place:

- after beneficiary termination
- at the payment of the balance or
- after the payment of the balance.

3.0 Reduction at beneficiary termination was introduced explicitly with GA version 3.0. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of

[61] See judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128.

contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination is possible for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 *(see above)*.

A grant reduction can also be imposed on beneficiaries not receiving EU funding *(e.g. for improper implementation by the beneficiary; see Article 9)*.

2. Procedure

The Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42*).

Depending on the moment the reduction takes place, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for reductions after beneficiary termination: normally with the beneficiary concerned
- for reductions at payment of the balance: normally the coordinator
- for reductions after payment of the balance:
  - normally the beneficiary concerned, if the finding of improper implementation or breach concerns a beneficiary
  - normally the coordinator, if the finding cannot be linked to one (or more) specific beneficiaries (and therefore concerns the consortium).

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Grant reduction after beneficiary termination

If the Commission/Agency reduces the grant **after beneficiary termination**, it will calculate the reduction at beneficiary-level and calculate the **amount due** to the beneficiary *(see Articles 50.2 and 50.3)*.

If the amount which is due to the beneficiary is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will **recover** the difference *(see Article 44)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

4. Grant reduction at the payment of the balance

If the Commission/Agency reduces the grant at the **payment of the balance**, it will make the reduction at action-level and calculate the balance to be paid to the consortium (i.e. final grant amount) accordingly.

Example for calculating a reduction at the payment of the balance:

Consortium with a maximum grant amount of EUR 3 000 000 (100% reimbursement rate)

Pre-financing: EUR 750 000

Interim payments: EUR 1 500 000

Eligible costs accepted at the time of payment of the balance: EUR 2 900 000

The Commission carried out a review which demonstrates that some work packages were not carried out and only 80% of the action was carried out. Following the review, the Commission reduces the maximum grant amount by 20 % (EUR 600 000) because of improper implementation and notifies the consortium via a pre-information letter notified to the coordinator.

Reduced maximum grant amount at the payment of the balance: EUR 3 000 000 – EUR 600 000 = EUR 2 400 000

Final grant amount: Lower between EUR 2 900 000 and EUR 2 400 000 = EUR 2 400 000

Payments already made (pre-financing + interim) EUR 2 250 000 = EUR 750 000 + EUR 1 500 000

Amounts due as payment of the balance: EUR 150 000 (EUR 2 400 000 – EUR 2 250 000)

5. Grant reduction after payment of the balance

The financial consequences of a grant reduction **after the payment of the balance** will be calculated at beneficiary level for each beneficiary concerned.

The 'beneficiaries concerned' are those who have committed irregularities, errors or fraud or have breached their obligations *(for example, improperly implemented the action, submitted false information, failed to submit required information or breached the ethical principles)* resulting in the reduction.

Procedure for reduction of the grant after payment of the balance:

The Commission/Agency:

Step 1 — Determines the amount to be reduced (in proportion to the seriousness of the errors, irregularities or fraud or the breach of obligations).

Step 2 — Identifies the beneficiaries in fault and allocates that amount among them according to their responsibility in the errors, irregularities or fraud or breach of obligation.

If the breach of obligation cannot be linked to one or more specific beneficiaries (and therefore concerns the whole consortium) each beneficiary will have to bear a pro-rata share of the reduction.

For each of those beneficiaries (the 'beneficiaries concerned'):

Step 3 — Determines the beneficiary's **share in the final grant amount'**, as follows:

{{total accepted eligible costs for the beneficiary x reimbursement rate}[62]

divided by

{sum of total accepted eligible costs x reimbursement rate, for each beneficiary}[63]

multiplied by

the final grant amount before the reduction (see Article 5.3)}

Step 4 — Calculates the beneficiary's **revised final grant amount** as follows:

{total accepted eligible costs for the beneficiary x reimbursement rate}[64] – amount of reduction allocated to the beneficiary under step 2

[62] Plus the same formula applied to third parties linked to the beneficiary (if any).
[63] Including linked third parties.

Step 5 — If **revised final grant amount < share in the final grant amount**, the Commission / Agency will recover the difference from the beneficiary.

Example for calculating a reduction linked to (one or more) specific beneficiaries:

Innovation action with beneficiaries: X, Y and Z. Beneficiaries X and Z are non-profit legal entities with a 100% reimbursement rate. Maximum grant amount = EUR 2 900 000.

Situation at payment of the balance:

	Data source		*Beneficiary X*	*Beneficiary Y*	*Beneficiary Z*	*Total*
	Annex 2 (estimated budget)	*Estimated costs budgeted*	*700 000*	*2 000 000*	*800 000*	*3 500 000*
A		*Reimbursement rate (%)*	***100***	***70***	***100***	
B		*Maximum grant amount according to costs budgeted*				*2 900 000*
C	*Final financial statements*	*Beneficiary's total accepted eligible costs*	*825 000*	*1 850 000*	*800 000*	*3 475 000*
D	*First step for the calculation of the "Final Grant Amount (Article 5.3.1)*	*Beneficiary's total accepted costs x reimbursement rate (C x A)*	*825 000*	*1 295 000*	*800 000*	*2 920 000**

** The final grant amount is capped at EUR 2 900 000 (maximum grant amount). Even if D results in a higher amount, the Commission/Agency can never pay more than the maximum grant amount set in the GA.*

Following a review after the payment of the balance, the Commission decides to reduce the grant due to improper implementation because some of the action tasks were not carried out.

Step 1 Reduction of the maximum grant amount:

The Commission decides on the amount to be reduced in proportion to the improper implementation identified

Example: *the Commission decides to reduce the maximum grant amount by EUR 300 000.*

Step 2 Identification of the beneficiaries concerned and allocation of the amount to be reduced:

The review concluded that the improper implementation was due to the fact that beneficiary X carried out only part of its tasks as set out in Annex 1. Therefore, the reduction is allocated in full to beneficiary X (see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

[64] Plus the same formula applied to third parties linked to the beneficiary (if any).

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*300 000*	*0*	*0*	*300.000*
G	*Beneficiary's revised final grant amount (D - F)*	*525 000*	*1 295 000*	*800 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*294 349*	*0*	*0*	*294 349*

The amount to be recovered is less than the amount reduced because of the overspending (eligible costs that were declared but not taken into account at payment of the balance because of the capping at maximum grant amount).

For recovery (see Article 44.1.3)

Example for calculating a reduction NOT linked to (one or more) specific beneficiaries:

Same example as above except that the reduction is not linked to specific beneficiaries.

The review concluded that the improper implementation was due to the consortium as a whole and cannot be attributed to (one or more) specific beneficiaries. The amount to be reduced is therefore allocated evenly among the beneficiaries (300 000 / 3 = 100 000; see F below).

Step 3 Beneficiary's share in the final grant amount:

E	*Beneficiary's share in final grant amount*	*819 349***	*1 286 130*	*794 521*	*2 900 000*

*** Calculation: [(825 000 x 100 %) / 2 920 000] X 2 900 000*

Step 4 Calculation of the revised final grant amount:

		Beneficiary X	*Beneficiary Y*	*Beneficiary Z*	*Total*
F	*Part of the reduction allocated to the beneficiary*	*100 000*	*100 000*	*100 000*	*300 000*
G	*Beneficiary's revised final grant amount (D - F)*	*725 000*	*1 195 000*	*700 000*	*2 620 000*

Step 5 Calculation of the recovery:

	Amount to be recovered (E – G)	*94 349,32*	*91 130,14*	*94 520,55*	*280 000*

For recovery (see Article 44.1.3)

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION 2:** not applicable**];***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**] [OPTION 2:** not applicable**]***

(ii) by **taking legal action (**see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to early termination, cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to its maximum EU contribution in Annex 2.

Grounds for recovery (Commission/Agency):

- Commission/Agency **paid too much**

  The Commission/Agency will make a recovery, if the amounts paid out exceed the amounts that are due for the grant.

Recovery normally takes place only at payment of the balance or afterwards. Exceptionally, it can take place before, if a beneficiary's participation is terminated.

2. Procedure

The basic procedure for recovery is almost always the same: After a **contradictory procedure**, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Basic recovery procedure:

Step 1 — Contradictory procedure

The Commission/Agency informs the coordinator/beneficiary concerned of its intention to recover undue amounts (and their amount and the reasons why), in a **pre-information letter**.

The coordinator/beneficiary concerned has **30 days** to submit observations.

Step 2 — Confirmation of recovery

The Commission/Agency examines the observations and either stops the procedure or **confirms** the recovery and issues a **debit note** against the coordinator/beneficiary concerned.

The coordinator/beneficiary concerned must pay by the date specified in the debit note.

Step 3 — Recovery

If the coordinator/beneficiary concerned does not pay by this date, the Commission or the Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[65]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

  ⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

  For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 TFEU action, arbitration, etc; *see Article 57.2*).

  Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission or the Agency may offset before this date, in order to safeguard the EU financial interests.[66]

  If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. (The interest is normally offset first, before the principal amount).

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or

    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU[67].[68]

      The decision describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      ⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

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65 *See Article 80(1) of the Financial Regulation No 966/2012.*

66 *See Article 87 of the Rules of Application Regulation No 1268/2012.*

67 *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

68 *See Article 79(2) of the Financial Regulation No 966/2012.*

This decision — duly endorsed with the order for enforcement issued by the competent authority in the Member State concerned — allows to have the debtor's **assets seized**.

The contradictory procedure will normally be **combined** with the **contradictory procedure** for cost rejection and/or grant reduction (if any).

3. Recovery after beneficiary termination

The Commission/Agency will recover **after beneficiary termination**, if the beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

4. Recovery at the payment of the balance

The Commission/Agency will recover at the **payment of the balance**, if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Article 21.4)*.

Procedure for recovery (at payment of the balance):

Step 1 — Contradictory procedure with coordinator *(see above point 2)* and request to submit the report on the distribution of payments.

Step 2 — Confirmation of recovery *(see above point 2)*, together with notification of the amounts due *(see Article 21.5)*

Step 3 — Release of the amounts retained for the PGF. The Commission/Agency will **deduct** the amount the consortium owes from the **contribution to the Guarantee Fund** that needs to be reimbursed to the consortium.

If, after the debt is deducted, the difference is positive (i.e. part of the amount retained for the Guarantee Fund must be reimbursed) or if the result equals zero, the recovery process ends.

Step 4 — If the difference is negative (i.e. if the amount retained for the Guarantee Fund was not sufficient to cover the consortium's debt to the Commission/Agency and there is still an amount to be recovered), the Commission/Agency will send the coordinator a **debit note** for the amount still to be recovered.

If the coordinator pays the debt by the date specified in the debit note the recovery process ends.

Step 5a — If the coordinator does not repay the Commission/Agency by the date specified AND if it has not submitted the report on the distribution of payments: the Commission/Agency will **recover** the amount **from the coordinator** alone.

For the rest of the procedure, *see point 2*.

Step 5b — If the coordinator does not repay the Commission/Agency by the date specified, BUT has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

In order to **identify the beneficiaries that received funds in excess**, the amount each beneficiary *actually* received (as established on the basis of the report on the distribution of payments) is compared to its share of the final grant amount (as established on the basis of the accepted eligible costs in the final summary financial statement).

The **share in the final grant amount** is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the

final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage obtained to the final grant amount.

In practice:

- **for underspent GAs:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with *Article 5.3.1)* is lower than the maximum grant amount set out in Article 5.1 (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for overspent GAs:** each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

In order to **calculate the amount each beneficiary owes** (i.e. to distribute the debt among the beneficiaries that received funds in excess) the amount to be recovered will be split between the beneficiaries that have received payments in excess, in proportion to their relative share of the total payments in excess.

Step 6 — The Commission/Agency will cancel the debit note sent to the coordinator and send a debit note to each beneficiary that received funds in excess — for its proportional share in the debt to the Commission/Agency.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery at the payment of the balance:

GA with a maximum grant amount of EUR 3 000 000 and with a reimbursement rate: 100 %
Four beneficiaries: A (coordinator), B, C, D

According to the estimated budget in Annex 2, the four beneficiaries were entitled to a maximum contribution for carrying out their part of the action set out in Annex 1 of EUR 800 000 (A); EUR 1200 000 (B); EUR 600 000 (C); EUR 400 000 (D)

Total eligible costs approved by the Commission: EUR 2 430 000

Final grant amount: EUR 2 430 000

EU contribution per beneficiary based on the accepted eligible costs: A: EUR 600 000; B: EUR 1 100 000; C: EUR 400 000; D: EUR 330 000

Payments made by the Commission (pre-financing and interim payments): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Amount to be recovered: EUR 2 700 000 minus EUR 2 430 000 = EUR 270 000.

Amount retained for the Guarantee Fund (5 % of the maximum grant amount; see Article 21.2) = EUR 150 000. Payment effectively transferred to the coordinator: EUR 2 550 000 = EUR 2 700 000 - EUR 150 000

A pre-information letter is sent to the coordinator (beneficiary A) informing it that the Commission intends to recover EUR 270 000. No observations are made by the consortium, and the Commission confirms the amount.

The Commission deducts the amount it needs to recover from the consortium from the amount retained for the Guarantee Fund that needs to be reimbursed to the consortium (EUR 150 000).

The difference of EUR 120 000 needs to be recovered and the ***Commission sends a debit note for that amount****.*

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries:

A= EUR 400 000; B= EUR 1 200 000; C = EUR 600 000; D= EUR 350 000.

Identification of the beneficiaries that received funds in excess:

Coordinator A: share in the final grant: EUR 600 000; received EUR 400 000 (no payment in excess);

Beneficiary B: share in the final grant: EUR 1 100 000; received EUR 1 200 000 (payment in excess of 100 000)

Beneficiary C: share in the final grant: EUR 400 000; received EUR 600 000 (payment in excess of 200 000);

Beneficiary D: share in the final grant: EUR 330 000; received EUR 350 000 (payment in excess of 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Distribution of the debt to be reimbursed among the beneficiaries that have received payments in excess:

The distribution of the final debt towards the Commission will be made in proportion to the payments in excess received by each beneficiary compared to the total payments made in excess.

Total payments made in excess = 320 000.

Beneficiary B's share of the payments in excess: 100 000/320 000 = 31.25 %.

Beneficiary C's share of the payments in excess: 200 000/320 000 = 62.5 %.

Beneficiary D's share of the payments in excess: 20 000/320 000 = 6.25 %.

***The Commission will notify three debit notes for a cumulative amount of EUR 120,000** (270,000 – 150,000): beneficiary B with a debit note for the amount of 31.25 % x 120 000 = 37 500; beneficiary C for the amount of 62.5 % x 120 000 = 75 000; beneficiary D for the amount of 6.25 % x 120 000 = 7 500.*

Beneficiary A will have to recover the money owed to it from the other beneficiaries in the consortium.

5. Recovery after payment of the balance

The Commission/Agency will recover **after payment of the balance**, if — due to cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid too much (or that the coordinator has not distributed the payments received).

Procedure for recovery after payment of the balance (due to cost rejection):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 42)*

Step 2 — The Commission/Agency calculates the **amount to be recovered,** by comparing the revised final grant amount for the beneficiary concerned with its share of the final grant amount.

The **share of the final grant amount** is calculated by dividing the maximum EU contribution for the beneficiary (on the basis of the accepted eligible costs of the final summary financial statement) by the total maximum EU contribution for the consortium and by applying the percentage obtained to the final grant amount.

In practice:

- **for underspent GAs:** it equals the eligible costs declared by the beneficiary (and approved by the Commission) multiplied by its reimbursement rate

  'Underspent GA' means a GA for which the EU contribution (calculated in accordance with *Article 5.3.1)* is lower than the maximum grant amount set out in Article 5.1 (In other words: a GA where the consortium declared less costs than could have been reimbursed.)

- **for overspent GAs:** each beneficiary's maximum EU contribution must therefore be adjusted to bring it into line with the maximum grant amount. This adjustment is done in proportion to the eligible declared costs approved by the Commission/Agency *(see calculation in the example below)*.

  'Overspent GA' means a GA for which the EU contribution calculated in accordance with Article 5.3.1 exceeds the maximum grant amount set out in Article 5.1. (In other words: a GA where the consortium declared more costs than could be reimbursed.)

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

Procedure for recovery after payment of the balance (due to grant reduction):

Step 1 — The Commission/Agency calculates a **revised final grant amount** for the beneficiary concerned *(see Article 43)*

Step 2 — The Commission/Agency will calculate the **amount to be recovered** by comparing the revised final grant amount for the beneficiary concerned with its **share of the final grant amount** *(see point 4)*.

Step 3 — If **revised final grant amount < share of the final grant amount**, the Commission/Agency will recover the difference from the beneficiary.

For the rest of the procedure, *see point 2*.

Example for calculating a recovery after payment of the balance (underspent GA):

Action with three beneficiaries (A, B and C) and a reimbursement rate of 100 %.

Maximum grant amount: EUR 500 000

Eligible costs accepted for beneficiary A at payment of the balance: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

Eligible costs accepted for beneficiary B at payment of the balance: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

Eligible costs accepted for beneficiary C at payment of the balance: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Final grant amount at payment of the balance: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Revised grant amount for beneficiary A:

(Revised direct costs: EUR 150 000 — EUR 30 000 = EUR 120 000) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

The share of beneficiary A in the final grant amount = EUR 187 500.

The amount to be recovered from beneficiary A: EUR 187 500 — EUR 150 000 = EUR 37 500.

The EU contributions of the other beneficiaries remain unchanged.

Example for calculating a recovery after payment of the balance (overspent GA):

Maximum grant amount: EUR 500 000; Three beneficiaries A, B and C

Estimated budget indicated in Annex 2: A: EUR 200 000; B: EUR 100 000; C: EUR 200 000

Reimbursement rate for all the beneficiaries: 100%

Direct eligible costs approved for Beneficiary A at the payment of balance: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) =EUR 200 000

Direct eligible costs approved for Beneficiary B at the payment of balance: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) =EUR 150 000

Direct eligible costs approved for Beneficiary C at the payment of balance: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) =EUR 250 000

Total eligible costs of the consortium approved by the Commission = EUR 600 000

Difference between the maximum grant amount and the approved eligible costs= EUR 600 000 - 500 000 = EUR 100 000

Limit to the maximum grant amount: Final grant amount = EUR 500 000

An audit after payment of the balance concluded that direct costs claimed by beneficiary A are not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs claimed by beneficiary C are not eligible for an amount of EUR 20 000.

Calculation of each beneficiary's share in the final grant amount:

*<u>Beneficiary's accepted costs multiplied by the reimbursement rate (100%)</u> * final grant amount (500 000)*

Total accepted costs for the action according to Article 5.3.1 (EUR 600 000)

Beneficiary A's share in the final grant amount = (200 000/600 000) x 500 000 = EUR 166 667

Beneficiary B's share in the final grant amount = (150 000/600 000) x 500 000 = EUR 125 000

Beneficiary C's share in the final grant amount = (250 000/600 000) x 500 000 = EUR 208 333

Calculation of the revised grant amount after the audits:

The revised final grant amount is calculated as follows:

For beneficiary A: (Revised direct costs: 160 000 – 30 000 = 130 000) + 32 500 (indirect costs) = EUR 162 500

For beneficiary C: (Revised direct costs: 200 000 – 20 000 = 180 000) + 45 000 (indirect costs) = EUR 225 000

Calculation of the amount to be recovered:

The amount to be recovered is calculated on the basis of the beneficiary's share in the final grant amount and neither on the basis of the reported eligible costs nor on the basis of the amounts actually received from the coordinator.

Amount to be recovered per beneficiary = share in the final grant amount - revised final grant amount

For beneficiary A: EUR 166 667-162 500 = EUR 4 167 will be recovered

For beneficiary C: EUR 208 333- EUR 225 000 = - EUR 16 667. Since for beneficiary C the revised final grant amount is greater than the share in the final grant amount (in other terms, the revised eligible costs still justify the share in the final grant amount), nothing will be recovered.

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

1. Administrative sanctions

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary is in an exclusion situation under Article 106(1) of the Financial Regulation No 966/2012, it may impose administrative sanctions (— in proportion to the seriousness of the misconduct).

Administrative sanctions (financial penalties and/or exclusion from future procurement contracts, grants and expert contracts) are **public law measures** (i.e. taken directly on the basis of Articles 106 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(substantial errors, irregularities or fraud, serious breach of obligations, bankruptcy, non-compliance with tax or social security obligations, grave professional misconduct, fraud, corruption, or criminal/illegal activity).*

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum sanctions** are as follows:

- for exclusion: up to **5 years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the sanction and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again, the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget (Annex 2) — depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again, the rate may be increased to between **4%** and **20%**.

The decision to apply an administrative sanction may be **published** on the Commission/Agency websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU's financial interest and image)

- the time that has elapsed since it took place

- the duration and recurrence of the misconduct
- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

The Commission/Agency will follow the procedures set out in 106 of the Financial Regulation No 966/2012 (i.e. **contradictory procedure, panel, decision)**.

If the Commission/Agency imposes a financial penalty, it will also issue a debit note to **recover** the amount.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

However, there is NO:

- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

Specific case (administrative sanctions):

International organisations — Decisions on administrative sanctions (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability for damages (Commission/Agency)

The Commission/Agency can NOT be held liable if — in implementing the GA — its own services cause damage (to a beneficiary or third party).

Moreover, the Commission/Agency can NOT be held liable if — in implementing the GA — a beneficiary or third party involved in the action causes damage (to another beneficiary or third party).

Examples:

1. *An experiment carried out by a beneficiary leads to an accidental escape of pollutants into the local river.*

2. *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the action.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third parties involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

1. Liability for damages (beneficiaries)

If a beneficiary causes damage to the Commission/Agency (in implementing the action), the Commission/Agency may claim compensation).

Examples:

1. *Costs of legal proceedings borne by the Commission.*

2. *At a meeting on Commission premises, a beneficiary smokes and causes a fire.*

2. Procedure

The Commission/Agency will follow the normal procedure for damages claims (i.e. bringing an action for contractual damages before the European Court of Justice; not direct claim via a debit note).

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (Commission/Agency)

The Commission/Agency may stop the clock (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

Suspension of the payment deadline must be **distinguished** from **suspension of payments** *(see Article 48)*. Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary which is, for example, suspected of serious misconducts.

Grounds for suspension of the payment deadline (Commission/Agency):

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

In practice, suspension is needed if there are issues with the payment request or with the costs declared which make it impossible for the Commission/Agency to comply with the **payment deadline** (i.e. for interim payments and payment of the balance: 90 days after payment request; *see Article 21*).

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

Late payment without suspension of the payment deadline gives rise to late-payment interest for the beneficiaries *(see Article 21.11)*.

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why.

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

Suspension will normally last until it is possible to make all the necessary checks and verifications that are needed for the payment (*e.g. analysis of technical reports and financial statements, eligibility of claimed costs, calculation of amount to be paid, approval and authorisation of payment*).

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (Commission/Agency)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more or for all beneficiaries), on the grounds listed in this Article.

⚠ **Suspension of payments** has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systemic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend all outstanding payments for the audited beneficiary until the issue is resolved.*

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may also decide to:

- suspend the GA *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*) with the:

- coordinator or
- beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension in several grants).*

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator separately (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2).*

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned with the periodic reports (except with the report for the last reporting period).

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted. They must be included in the periodic report for the last reporting period (— even if suspension is still ongoing).

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May: *the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*

15 May: *the coordinator comments that beneficiary B was not aware of its obligations in this respect.*

1 June: *the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*

1 July: *the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*

10 August: *the Commission pays for all beneficiaries except B.*

25 October: *the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

If payments for one (or some) of the beneficiaries are still suspended at the end of the action, the Commission/Agency will make a partial payment of the balance for the amount that is not suspended (— but ONLY after having received all the necessary information for the final calculations for ALL consortium members, i.e. including the suspended beneficiaries).

⚠ The partial final payment is NOT the payment that closes the action. That payment will be made only after the payment suspensions are lifted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. GA suspension (beneficiaries)

The beneficiaries may suspend the action (in full or in part), on the ground set out in this Article.

GA suspension may be used exceptionally if it is necessary to stop the action implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for GA suspension (beneficiaries):

- **Action can no longer be implemented (or becomes excessively difficult)**

  The beneficiaries may suspend the action (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment after resumption).

⚠ **Information obligation** — Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g. **inform** the Commission/Agency under Article 17.2; **notify** a situation of force majeure under Article 51)*.

2. Procedure

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must:

- immediately formally notify the Commission/Agency of the date from which the action will start again
- request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration, modifying Annexes 1 and 2, updating the reporting periods)*.

  The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the **resumption date** set out in the amendment), if the Commission/Agency approves the amendment.

> ***Example:*** *The action was suspended on 24.03.2016. The consortium notifies the Commission that they wish to lift the suspension after 60 days, on 22.05.2016. Therefore, in accordance with Article 54 of the GA, the suspension will be lifted as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the budget must be lowered in the amendment, to adapt the action to the new situation).

> ***Example:*** *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **can NOT be continued** (or the Commission/Agency does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

> ***Example:*** *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the GA termination. The eligible costs are:*
>
> - *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
> - *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities, or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 <u>Procedure</u>

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (Commission/Agency)

The Commission/Agency may suspend the action (in full or in part), on the grounds listed in this Article.

Grounds for GA suspension (Commission/Agency):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend the audited beneficiary's part of the action until the issue is resolved.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** 5 days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the GA, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, *see Article 42)* with the:

- coordinator or

– beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension of several grants).*

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator separately (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2).*

If possible, the Commission/Agency will give an estimation of how long the suspension will be needed.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once the action is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator.

The coordinator must then request an amendment to the GA, to adapt it to the new situation *(e.g. by extending the action's duration modifying Annexes 1 and 2, updating the reporting periods)*.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

The suspension is lifted (as from the resumption date set out in the amendment), if the Commission/Agency approves the amendment.

If the **action** (or part of it) **can NOT be continued**, the GA (or the beneficiary concerned) may be terminated.

If the suspension leads to the GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the GA termination.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases,

the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The beneficiaries have the right to terminate the GA.

GA termination should be a last-resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Grounds for GA termination (beneficiaries):

- **Any ground** that **justifies** early termination of the action

  The beneficiaries may terminate the GA in principle on any ground — as long as there is a good reason *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

  Examples:

  1. *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

  2*. The consortium requests termination because the action was finished ahead of schedule.*

  If there are no legitimate reasons for discontinuing the action, the Commission/Agency **can NOT oppose**, but termination will be considered **improper**.

  ⚠ **Improper termination** of the GA may lead to a grant reduction (see *(see Articles 5.3 and 43)*.

  This will be the case, for instance, if:

  – the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence

  – the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties

  – implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

  Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a grant reduction.*

2. Procedure

The coordinator must **formally notify** the Commission/Agency (via the Participant Portal) of the termination — on behalf of the other beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. before the termination date) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. (The Commission/Agency will NOT send a reminder and will NOT extend the deadline.)

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the security obligations (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*
- Chapter 6 measures (i.e. rejection of costs *(see Article 42)* grant reduction *(see Article 43)* recovery *(see Article 44)*.

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Partner termination (beneficiaries)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must ask for the beneficiary's opinion (and provide it if obtained or — if the beneficiary didn't reply — the request to the Commission/Agency).

Grounds for partner termination (beneficiaries):

- **Any ground** that **justifies** termination of the participation of the beneficiary

  The beneficiaries may terminate the participation of one of their consortium members in principle on any ground — as long as there is a good reason *(e.g. withdrawal by a beneficiary because due to a change in ownership; the beneficiary cannot implement its tasks in the same way; bankruptcy)*.

  For beneficiaries that are involved in **several EU GAs,** withdrawal from one GA does NOT necessarily imply that it has to also withdraw from the others.

  Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

  If there are no legitimate reasons, the Commission/Agency **can NOT oppose** partner termination, but it will be considered **improper**.

  Improper termination of the participation of a beneficiary may lead to GA termination *(see Article 50.3.1(c))* and/or to a grant reduction at the payment of the balance *(see Articles 5.3 and 43)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT continue participating in the action.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like beneficiaries.

Linked third parties can NOT however do more than the beneficiary they are linked to: If their beneficiary is terminated, they must also leave the action.

2. Procedure

The coordinator must **formally notify** the Commission/Agency of the termination (via the Participant Portal). At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Since for partner termination the notification is combined with an amendment request, they must be submitted and signed by the PLSIGN of the coordinator (on behalf of the other beneficiaries *(see Annex 3)*.

NO amendment is needed, if the termination takes effect after the end of the action — unless it concerns the coordinator (since the new coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (*i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants)*, the GA may be terminated.

Example: *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional funding to do so) — unless the Commission/Agency expressly agrees otherwise.

The (new) coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the beneficiary whose participation is terminated:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)

- if the beneficiary owes, those amounts must be repaid by it (normally to the consortium).

Only **costs** incurred before termination (i.e. before the notified date on which termination takes effect) are eligible— except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 calendar days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. (The Commission/Agency will not send a written reminder and will not extend the deadline.)

If the coordinator fails to submit the *report on the distribution of payments*, the beneficiary whose participation was terminated will NOT have to repay any amounts.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (partner termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*).

Coordinator in bankruptcy/liquidation/administration (or similar) — In principle the coordinator must be changed. If the coordinator can no longer submit the request, the same procedure as for coordinator termination without its agreement should be used *(see above and Article 55)*.

Exceptionally, at the end of the action it may not be necessary to change the coordinator, but only its bank account if the administrator/liquidator accepts to do the final transfers of amounts.

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable];*

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**); see Article 22.5.2;

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks****][OPTION 2:*** *not applicable]*.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. GA or beneficiary termination (Commission/Agency)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

⚠ Beneficiary termination may lead to **GA termination**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

⚠ The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

Grounds for termination (Commission/Agency):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the GA termination; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or if the consortium no longer complies with the eligibility conditions set out General Annexes A and C to the Main Work Programme *(e.g. the rules regarding the minimum number of beneficiaries, their legal situation, or their place of establishment)*. [69]

  Examples:

  1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

  2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there has been a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Such changes can be of any kind and can be triggered by the beneficiary itself or outside circumstances.

  Example:

  An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).

- **GA cannot be amended after termination** of a beneficiary's participation

  The Commission/Agency may terminate the GA, if it cannot be amended after termination of a beneficiary's participation because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

  Example: *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

  The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

[69] *See also Article 8 of the Rules for Participation Regulation No 1290/2013.*

- **Action can no longer be implemented**

  The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

  Example: *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

  The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

  Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify partner termination because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

  ⚠ **Information obligation** — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2).*

- **Professional misconduct**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

  Example: *A legal entity's participation in a GA is terminated when an investigation uncovers that it has falsified the results of clinical studies.*

- **Non-compliance with tax or social security obligations**

  The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is implemented; *see Article 7*).

  Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

  Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

  For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

  - the third country/IO action does not start by the date specified in Annex 1

    In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission/Agency in full.

  - the third country/IO action is terminated

- the third country/IO action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity.

  Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have participated in large-scale drug trafficking.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may terminate the GA or the participation of a beneficiary, if a beneficiary (or one of its representatives) has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding; coordinator does not transfer payments to the other beneficiaries, but uses them for itself; coordinator does not submit the reports (despite a reminder); consortium does not inform the Commission/Agency about the receipt of a second grant for the same/similar proposal; review shows that action does not achieve its critical objectives and is way behind schedule and consortium submits a short-term implementation plan that is not acceptable; audit shows that beneficiary declared costs based on fake invoices; consortium does not provide requested information (despite a reminder); a check shows that scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism); consortium does not submit an amendment request after beneficiary termination.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also terminate the GA or the participation of a beneficiary, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that appear intentional and also affect all other GAs signed by the audited beneficiary. The Commission may terminate the participation of the audited beneficiary in the GA.*

- **Non-removal of a linked third party/international partner**

  The Commission/Agency may terminate the participation of a beneficiary if it refuses to remove one of its linked third parties or an international partner which is in one of the following situations:

  - bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings;
  - professional misconduct
  - non-compliance with tax or social security obligations
  - fraud, corruption or other criminal activities
  - substantial errors, irregularities or fraud or serious breach of obligations (in this grant or other grants).

3.0 This termination ground was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, beneficiary termination/linked third party removal was however already implicitly included in the different grounds of Article 50.3.3 (given that linked third parties have to fulfil the same conditions as the beneficiaries for participating in the action).

Before terminating (GA or beneficiary), the Commission/Agency may first suspend the GA *(see Article 49.2)*, to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before GA or beneficiary termination, the Commission/Agency will follow a **contradictory procedure** (for the basic contradictory procedure, see *Article 42*), with the:

- coordinator or
- beneficiary concerned *(e.g. for confidentiality reasons or simultaneous suspension in several grants)*.

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator separately (in a way that preserves confidentiality).

> ⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If a beneficiary's participation is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy or similar), the Commission/Agency will also contact the liquidator/administrator.

If it confirms termination, the Commission/Agency will specify the date on which termination will take effect **(termination date)**.

This date will be a date after the notification: Terminations can**not** be **retroactive** (notably to ensure the fulfilment of obligations and deadlines after termination; *see point 3*).

For some cases, the Commission/Agency may choose a **future** date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of GA termination are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. before the date on which termination takes effect) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

The effects of beneficiary termination are the same as when the beneficiaries terminate one of their partners *(see Article 50.2.2)*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What?

In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Force majeure normally has no specific effects on the eligibility of **costs**.

Costs are eligible, if they fulfil the conditions set out in Article 6 — like any other costs incurred under the action. However, if force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

New in Horizon 2020: This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Force majeure may lead to GA suspension *(see Article 49)* or GA termination *(see Article 50)*.

How?

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal).

The beneficiary concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal electronic exchange system and using the forms and templates provided there.

If — after the payment of the balance — the [Commission][Agency] finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

1. Communication between the parties — Participant Portal electronic exchange system

All communication between the consortium and the Commission/Agency – before and after the payment of the balance – must be in electronic form **via** the **Participant Portal**.

Beneficiaries will receive Participant Portal notifications even after the end of the action (and the LEARs are obliged to keep beneficiary contact data up to date, in order to ensure that the communication channels remain active).

The responsibility for opening notifications in time is with the beneficiaries.

Formal notifications are normally considered to have been **accessed 10 days after** they have been **sent** (— even not actually opened by recipient, *e.g. refusal of reception or omission*). Deadlines that are counted from the date of receipt are counted as of day eleven.

The same is in principle valid for formal notifications **after the payment of the balance** — except that the Commission/Agency will check that the notification has *actually* been accessed by the beneficiary (at any time, before or after the 10 days deadline). If it was not accessed, the Commission/Agency will send a second notification, this time on paper by registered post with proof of delivery. In that case, the deadlines will start to run from the date of receipt of the second notification and the communication will continue outside the Participant Portal.

4.0 The communication via the Participant Portal after the payment of the balance was introduced with GA version 4.0. For older grant agreements, it is in principle on paper, unless the beneficiary explicitly agrees to accept communication via the Participant Portal.

The Participant Portal offers different **functions**:

- viewing and changing the legal entity data in the Beneficiary Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the Participant Portal project file (with date and time).

Formal notifications are also recorded (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation and access are linked to the user role *(e.g. LEAR, PLSIGN or PFSIGN*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator. They cannot submit information directly to the Commission/Agency.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission/Agency.*

For more information on access and roles in the Participant Portal*, see the Online Manual.*

In principle, all communications from/to the Commission/Agency must go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations No 883/2013 and No 2185/2996)*.

Specific cases (PP access rights):

Beneficiaries in bankruptcy — If during a beneficiary goes bankrupt during the action, the liquidator may be granted the necessary access rights in the Participant Portal, in order to complete the beneficiaries' obligations. If exceptionally necessary, the Commission/Agency can also agree to communication outside the Participant Portal electronic exchange system (i.e. via registered post or e-mails).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means intergovernmental organisations (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the applicable legal texts provide otherwise), public law decisions cannot be applied to international organisations; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions (i.e. exclusion or financial penalties; *see Article 45*).

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration *(see Article 57.2)*. The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are calendar days.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*
The action is divided into the following reporting periods:
RP1: from 1 March 2015 to 31 August 2016
RP2: from 1 September 2016 to 28 February 2017
Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.
The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What?

An amendment is necessary whenever there is a need to **change** the GA (i.e. the core agreement and/or the Annexes).

The cases where an amendment is necessary are called 'amendment types' (AT); the amendment clauses are called 'AT clauses'.

The general terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to set its 'end date of participation'.*

Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and have an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Information obligation — Changes in the **name, address, legal form** and **organisation type** AND changes in the **legal, financial, technical, organisational** or **ownership situation** may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary terminate its participation and to amend the GA.*

2. *Beneficiary B moves from Europe to Australia during the action. The change of address implies that the beneficiary becomes not eligible for EU funding, so the GA will have to be amended to make it a 'beneficiary not receiving EU funding'.*

3. *Beneficiary C participates in an innovation action (IA) and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Beneficiary Register is sufficient; no amendment is needed.*

2. *Beneficiary E participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

For more information on AT clauses (including required supporting documents and how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation was terminated** due to **non-accession** to the GA or non-provision of the requested declaration on **joint and several liability** (**AT1**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary that never became part of the GA.

  How? The amendment is normally triggered by the beneficiaries.

  In case of partner termination (by the beneficiaries), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  The changes will be made ex tunc (i.e. since the beginning) since the beneficiary never participated in the grant.

  If the beneficiary was participating with linked third parties/international partners, they will automatically be removed.

  GA options for the beneficiary (and its linked third parties/international partners) are automatically removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Removal of a beneficiary whose participation was terminated** for **other reasons** (**AT2**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary during the action.

  What not? There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator AND the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  How? The amendment is normally triggered by the beneficiaries.

  In case of partner termination (by the beneficiaries), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the request for amendment, the same procedure as for coordinator change without its agreement should be used.

  Changes will be made ex nunc (because the beneficiary participated in the grant up until termination and, moreover, many obligations are applicable after termination).

  The termination date will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

  If the beneficiary was participating with linked third parties/international partners, they will also have to be removed (with effect from the same date) and the end date of participation will be added to Article 14/Article 14a (AT5/5a).

  By contrast, the GA options for the beneficiary (and its linked third parties/international partners) will NOT be removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will normally have to be changed (AT21 and AT 31).

- **Adding a new beneficiary** (**AT 3**; *see Article 56.2*)

  What? Addition of a new beneficiary during the action.

  How? The amendment is normally triggered by the beneficiaries.

The new beneficiary must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

The accession date will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

The date must be selected in the Accession Form (attached to the amendment request). It is possible to choose between:

- the date of signature of the Accession Form
- the date of entry into force of the amendment

OR

- a fixed date:
  - retroactive (before signature of the Accession Form)

  OR

  - future (after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

If the new beneficiary is participating with linked third parties/international partners, they will also have to be added (with effect from the same date) and the starting date of participation will be added to Article 14/Article 14a (AT6/6a).

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change of beneficiary due to partial takeover** (**AT4**; called 'partial transfer of rights and obligations' in FP7)

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination *(see Article 50)* or addition of a new beneficiary *(see Article 56)*.

This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment clause for addition of a new beneficiary (AT3).

What? Transfer due to partial takeover.

'Partial takeover' means that a part of the business of the beneficiary — including the GA — is taken over by (one or more) other entity(ies) (transfer of a business unit as a going concern, *e.g. partial acquisition, distribution of a business unit after dissolution/liquidation, division/demerger, etc.*).

'Partial acquisition' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, *some* of the rights and obligations (and contracts) of the original entity are transferred to the new entity. Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'Distribution of a business unit on dissolution/liquidation' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entities purchase a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only *some* of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'Division/demerger' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has an ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two partial takeovers: one to company E and one to company O.*

What not? Simple sale of (one or more) assets of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary.

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

NO amendment is necessary for universal takeovers *(see below)*.

How? The amendment is normally triggered by the beneficiaries; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as new beneficiary).

'New beneficiary' is used here only for the purpose of the amendment; it can be either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

⚠The new beneficiary(ies) will (each) be fully **jointly and severally liable** with the former beneficiary for recoveries under Article 44. (By contrast: NO joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular, explain the financial liability of the former beneficiary, attach a copy of the takeover contract and cite the applicable rules (with hyperlinks to the texts, if possible). Any elements that are not explained in the amendment request may not afterwards be held against the Commission/Agency.

The transfer date will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.

If the former beneficiary was participating with linked third parties/international partners, the new beneficiary will have to determine which of the former beneficiary's linked third parties/international partners stay on as linked third parties/international partners of the new beneficiary (AT6/6a) — all other linked third parties/international partners will be automatically removed.

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

The former beneficiary does NOT need to submit any reports to the Commission/Agency. The financial statement for the open reporting period until transfer must be uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

- **Removing a linked third party/international partner** (**AT5/5a**; *see Articles 14 and 14a*)

What? Removal of a linked third party/international partner during the action.

How? The amendment is normally triggered by the beneficiaries.

If requested by the Commission/Agency *(e.g. because of audit results or an OLAF investigation)*, the consortium MUST submit an amendment to remove a linked third party/international partner.

> ⚠ If the consortium does not follow-up this request, the Commission/Agency may **terminate** the participation of the *beneficiary* (and thereby also remove the linked third party/international partner).

NO termination notification — Linked third parties/international partners can be removed by the consortium by simple amendment; no formal termination notification is required (termination notification applies only to beneficiaries; *see Article 50.2*)

Changes will be made ex nunc (because the linked third party/international partner participated in the grant up until removal and, moreover, many obligations are applicable after termination).

The end date of participation will be added to Article 14/ 14a.

The date must be selected in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

The GA options for the linked third party/international partner will normally NOT be removed/changed/become not applicable.

Annexes 1 and 2 will have to be changed (AT21 and AT 31).

- **Adding a linked third party/international partner** (**AT6/6a**; *see Articles 14 and 14a*)

What? Addition of a new linked third party/international partner during the action.

How? The amendment is normally triggered by the beneficiaries.

The new linked third party/international partner must first register (and get validated) in the Beneficiary Register — unless it already has a validated participant identification code (PIC).

The name of the linked third party/international partner and the starting date of participation will be added to Article 14/14a.

The date must be selected in the amendment request. It is possible to choose between a fixed date or the 'date of entry into force of the amendment'. If the linked third party/international partner joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

The GA options for the linked third party/international partner will be added/changed/become applicable.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'** (**AT7a**; *see Article 9*)

  What? If a beneficiary/linked third party — exceptionally — becomes not eligible for receiving EU funding during the action *(e.g. due to a change of establishment or a country changing eligibility status)*, this change will require an amendment (to change Annex 1, Annex 2 and the options in Article 9).

  Example:

  Beneficiary R moves from Europe to Australia and thus is no longer eligible for receiving EU funding. The GA must be amended. If R is participating with a linked third party M established in France, M will continue being eligible for funding.

  How? This amendment can normally be triggered only by the Commission/Agency.

  The change date will be added to the Preamble of the GA.

  The GA options for the beneficiary/linked third party will be added/removed/changed/become applicable/become not applicable *(e.g. beneficiary receiving/not receiving EU funding; dispute settlement)*.

- **Change of coordinator (AT8)**

  What? Replacement of the coordinator during the action *(e.g. because of financial difficulties)*.

  Exceptionally, an amendment remains possible and necessary *after* the end of the action *(see Article 3)* — until the payment of the balance is paid out and distributed.

  Coordinator in bankruptcy/liquidation/administration (or similar) — After the end of the action, if the coordinator can continue its participation with the bank account of the administrator/liquidator (i.e. termination and coordinator change not really needed), it is therefore exceptionally sufficient to change the bank account (AT40) without changing the coordinator.

  What not? There is NO need to request an amendment for a change of the *person* in charge of the coordination of the project (since the person's name is not mentioned in the GA).

  > ⚠ **Information obligation** — In case of a **change of person in charge of coordination**, the coordinator must — in addition to updating the data in the Participant Portal inform the Commission/Agency under Article 17.2).

  How? The amendment is normally triggered by the beneficiaries.

  If the new coordinator is not already a beneficiary of the GA, it must first accede to the GA as a new beneficiary (AT3).

  The former coordinator may continue to participate in the action as a normal beneficiary or may terminate its participation (AT2).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the amendment request, the same procedure as for coordinator change without its agreement should be used.

  The handover date will be added to the Preamble of the GA.

  The date must be selected in the amendment request. If the former coordinator leaves the consortium, this date must be after the termination date; if the new coordinator joins the consortium, the date must be after the accession date. Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the option for authorisation to administer** (**AT9a**; *see Article 41.2*)

  What? Change concerning the authorisation to administer (i.e. delegation of administration tasks to a third party).

Example: *change of name of the entity with authorisation to administer*

- **Change of the coordinator's bank account for payments (AT40)**

  What? An amendment is necessary for all changes that imply a change to the account number/IBAN code.

  Example: *The coordinator changes bank account.*

  What not? NO amendment is necessary for a change of the name of the bank or name of the account holder; a change of the bank account data (and validation) in the Participant Portal Beneficiary Register is sufficient.

  How? The bank account data must first be updated in the Beneficiary Register (and be validated).

- **Change of the action's title and/or acronym (AT22)**

  What? Change of the action title or acronym.

  Example: *the consortium finds out that the acronym of their action is a protected trademark*

- **Change of the starting date, action duration or reporting periods (AT23, AT24, AT25)**

  What? Change of the action's schedule (starting date, action duration or reporting periods).

  Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

  ⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

  How? An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

- **Amendment for resuming the action after GA suspension (AT26)**

  What? Amendment to resume the action after GA suspension.

  How? The amendment request must specify the dates when the suspension started and ended. The action implementation is then automatically resumed as from the following day (resumption date).

- **Changes to Annex 1 (description of the action) (AT21)**

  What? Changes to the description of the action, in particular:

  - significant change of the action tasks *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning in-kind contributions provided by third parties (against payment or free of charge) or subcontracts

    Such changes could in principle also be made via the 'simplified approval procedure' *(see Articles 11, 12 and 13)*; however, if the beneficiary requests an amendment, it will immediately know if the Commission/Agency agrees (or not). Without amendment, this decision is left for later and the Commission/Agency may reject the costs as ineligible later on (at the moment of the payment).
  - changes concerning the tasks to be carried out by linked third parties and related costs (including if a linked third party is removed).
  - changes concerning GA options (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2).*

- **Changes to Annex 2 and Annex 2a (estimated budget) or specific unit costs (AT31 and AT36)**

  What? Changes to the estimated budget, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which are linked to a significant change in the action's work (i.e. Annex 1)

– a budget transfer to a form of costs that is not used by the beneficiary (i.e. with 0 EUR costs in Annex 2) — except for transfer of amounts within the budget category A ' personnel costs'.

Example:

During the action implementation, the beneficiary decides to use the access costs for transnational access to research infrastructure unit cost. This requires an amendment to fix the unit cost and to move budget to budget category F.2.

What not? There is NO need to request an amendment for changes covered by the budget transfers rule in Article 4.2 *(e.g. budget transfers within the personnel cost; see also below)*.

How? The amendment is normally triggered by the beneficiaries.

Best practice: If Annex 2a or specific unit costs need to be changed, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment, provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

Budget transfers within the personnel cost category are possible without having to amend the GA.

Examples:

1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices (average personnel costs).*

2. *An SME joins an on-going GA. The SME owner does not have a salary but incorrectly budgets its costs as actual personnel costs (category A.1). He realises the mistake and then switches to the unit costs for SME owners (category A.4).*

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

Linked third parties/international partners — Since they normally do not have direct access to the Beneficiary Register, linked third parties/international partners must inform their beneficiary who must inform the Commission/Agency. The data will then be updated by the Commission/Agency (and validated).

If — exceptionally — the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator (and instruct it to request an amendment or trigger itself an amendment, if needed).

Example: Company R moves from Europe to Australia and this implies that the beneficiary is no longer eligible for EU funding. In such a case, the Commission will make an amendment to the GA to change the beneficiary status into 'beneficiary not receiving EU funding'.

Short names have no legal value and only serve as easy identifiers in the GA. If needed, they can be changed in the context of an amendment initiated on other grounds.

A change of the person that represent the coordinator for the purposes of signing the GA requires NO follow-up at all (not even a change in the Beneficiary Register — since this name is only relevant at the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

Transfers of the GA linked to a universal takeover (i.e. where the original entity is replaced by one new entity and all the rights and obligations — including the GA — are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Beneficiary Register is normally sufficient.

Example: *Beneficiary X merges with another existing entity Y by:*

- *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
- *establishing a new separate legal entity (X and Y are together known as 'Z').*

If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator (and instruct it to request an amendment, if needed).

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information (AT40).*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going innovation actions (IAs). The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% (but only to a reimbursement rate of 70%). The GA must be amended to change the reimbursement rate (AT33) and the estimated budget (AT31).*
For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

Information obligation — In case of a **universal takeover**, the beneficiary must — in addition to updating the data in the Beneficiary Register— inform the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU's financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the Participant Portal) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

2. Procedure

How? Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) directly in the Participant Portal.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function), to discuss the amendment.

Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Beneficiary Register.

Examples:

1. *A new beneficiary must be validated (legal entity validation). This means that the new beneficiary will first have to register in the Beneficiary Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.*

2. *Validation of the new bank account, to change the bank account.*

The amendment request must include the necessary information and supporting documents. A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications or additional information/documents.

For more information on combination of amendment clauses and supporting documents, *see the Guidance – Amendment types & supporting documents*.

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action; *see Article 3*). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases *(e.g. change of bank account, change of coordinator to make the payment of the balance)*.

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Termination of the coordinator without its agreement — For change of coordinator without its agreement a special procedure applies: The other beneficiaries must nominate one of them to act on their behalf to notify termination and request the amendment. The nominated beneficiary must name a contact person (NoCo) responsible for the amendment.

Before it has been accepted or rejected, an amendment request may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The other party must — within **45 days** — **agree or disagree**.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If **accepted** it will be **counter-signed** by the receiving party directly in the Participant Portal (for the consortium: by the PLSIGN of the coordinator).

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Participant Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

  The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

1. *Where a new beneficiary is added to the GA (AT3), it must assume the rights and obligations from the accession date specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).*

2. *Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment (AT26). This date may be before the date on which the amendment enters into force (see Article 49.2.2).*

3. *If the amendment intends to correct an error (AT60), the change will be made with effect from entry into force of the GA (i.e. from the beginning).*

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* directly in the Participant Portal. They must do this **within 30 days** after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on **joint and several liability** *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, before signing the Accession Form.

Without the declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Linked third parties do not become parties to the GA and therefore do NOT need to sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (new in Horizon 2020). All documents are available in the Participant Portal project file.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries (amendment)

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How?

The new beneficiary must:

- register in the Beneficiary Register and be validated — unless it already has a validated participant identification code (PIC)
- sign the Accession Form (directly in Participant Portal)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the **accession date**. It must be either:

- the date of signature of the Accession Form
- the date of entry into force of the Amendment

OR

- a fixed date:
  - either retroactive (i.e. before signature of the Accession Form)

  OR

- future (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned].****]***

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations:

Situation	Applicable law
For international organisations that do NOT accept any applicable law clause	No reference to any applicable law[70]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are:

[70] *See Article 180(1) of the Rules of Application Regulation No 1268/2012.*

	– the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of international organisations and the rules of general international law.
For international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law)	The international organisation can choose any of the following combinations of applicable laws: – only EU law – only Belgian law – only other MS or EFTA country law – only general principles governing law of IOs + rules of general international law – EU law + MS or EFTA country law (except Belgium) – EU law + general principles governing law of IOs + rules of general international law – EU law + Belgian law + general principles governing law of IOs + rules of general international law – EU law + other MS or EFTA country law + general principles governing law of IOs + rules of general international law – Belgian law + general principles governing law of IOs + rules of general international law – other MS or EFTA country law + general principles governing law of IOs + rules of general international law

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not eligible for EU funding, which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. [OPTION for Agency grants: Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).]

1. Dispute settlement

As a general rule, H2020 GAs contain an Article 272 TFEU arbitration clause — referring **disputes on the interpretation, application or validity of the GA** to the European Court of Justice.

> An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against confirmation letters, debit notes, etc.; NOT against audit reports, audit letters, pre-information letters, etc.).
>
> For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency.

For disputes of public law nature (i.e. which concern **administrative sanctions**, **offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions must be brought before the European Court of Justice under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ **Public law measures** must ALWAYS be brought to the European Court of Justice under Article 263 TFEU (including actions brought by non-EU beneficiaries or beneficiaries not receiving EU funding).

⚠ All procedures are organised in a way that the beneficiaries will always be **informed** about what they can do if they disagree (**means of redress** information in the letters).

ℹ For more information on complaints, see the *Online Manual*

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, disputes on the interpretation, application or validity of the GA are normally referred to the competent Belgian courts. (So far (i.e. until end of 2016) NONE of the H2020 association agreements provides for the sole jurisdiction of the European Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Beneficiaries not receiving EU funding — For beneficiaries that are not eligible for funding *(see Article 9)*, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration *(see also point 1)* if their national law provides that they cannot be subject to the jurisdiction of the Belgian courts.

Otherwise they will be treated as normal non-EU beneficiaries (i.e. Belgian courts).

Disputes of public law nature remain before the European Court of Justice.

International organisations — For international organisations, disputes on the interpretation, application or validity of the GA are referred to the Permanent Court of Arbitration (in line, for instance, with the Financial and Administrative Framework Agreement (FAFA) with the United Nations[71]; *see also point 1*).

Disputes of public law will normally not arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

For this reason, the Commission/Agency will normally NOT adopt enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions *(see Article 45).*

Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (NOT as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[71] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

For countries for which it has carried out a formal assessment of specific situations or their legal framework, the Commission will keep record of its official position.

See the List of issues applicable to particular countries.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- Low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants. Other ERC actions (coordination and support actions (CSA)) use the H2020 General MGA.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)
- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

***[OPTION by default:** 'principal investigator':*[4]

- *[**Name**][Date and place of birth]]*[5]

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**] established in [official address in full] *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]*

[same for each beneficiary]

***[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*:* ***and other ERC grants with more than one principal investigator****: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Participants: Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The '**host institution (HI)**' is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**' for at least the duration of the action.

2. Participants: Principal investigator(s)

For ERC grants, the main researcher (i.e. the principal investigator (PI)) is named in the GA.

PIs can be of any **nationality**, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted (and usually engaged) by a host institution that is based in an EU Member State or H2020 associated country.

Due to the key role of the PI, s/he can NOT be replaced by any other researcher during the action. Requests for amendments to change the PI will be rejected.

The PI must comply with certain minimum requirements regarding working time on the action (fixed in Annex 1 and 2) and working time in an EU Member State or H2020 associated country (set out in the work programme/call; **PI time commitments**).

The Agency must be **informed** before any change in employment or location of the PI.

In case of breach, the Agency may terminate the GA or take any of the other Chapter 6 measures *(e.g. grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50 H2020 General MGA).*

Should the PI move to another host institution (in an EU Member State or H2020 associated country), the GA can be transferred to the new host institution (**portability**; *see Article 56a*). If the PI moves to an institution established in a non-associated third country, the GA may be terminated *(see Article 50.1 H2020 General MGA)*.

PIs do not become party to the GA, but are key actors of ERC actions.

This leads to an asymmetrical relationship (in which the PI is the key actor in charge of the research activities, but it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary).

Examples:

1. A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium. The engagement of the team follows the rules of the beneficiary and its country.

2. PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the action), PIs and their host institutions must sign a **supplementary agreement (SA)** *(see Article 32)*.

The supplementary agreement can NOT replace the employment/engagement contract and is not sufficient by itself.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party (from an EU Member State or H2020 associated country), i.e.:

- a third party that provides the PI as in-kind contribution or
- a linked third party *(see Article 8)*.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution AND the third party.

Retired PI — The PI may be retired.

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the

supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)] [and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
  - costs of internally invoiced goods and services
- indirect costs.

Thus, the ERC MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure
- direct costs of providing financial support to third parties
- specific cost categories.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

- Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices (average personnel costs), the unit costs for SME owners and beneficiaries that are natural persons without salary, the unit costs for internally invoiced goods and services and the flat-rate of 25% for indirect costs.[72]

- It does NOT use the unit costs of category F 'specific cost categories' of the General MGA.

[72] See *Article 29(1) and 33(2) of the Rules for Participation Regulation No 1290/2013 and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* — with the exception of categories C. 'financial support to third parties' and F 'specific cost categories'.

The same **eligibility conditions** and **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the **following specificities**:

– for category A 'personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: under budget category A.1 'costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: under budget category A.3 'seconded persons' (Article 6.2.A.3)).

– for category D 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs', even for the unsuccessful candidates (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs) and to research data are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[73]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

2. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

Combining H2020 & other EU grants — ERC grants do NOT prevent **PIs** from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

For more information on how to combine EU funding from different programmes, *see the Online Manual (links to Regional funding).*

[73] See http://erc.europa.eu/implementing-arrangements.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record-keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

In addition, the beneficiaries must prove that the **PI time commitments** *(see Preamble)* were respected, i.e.:

- for the percentage of total working time on the action:
  - if the PI works 100% of his/her total working time for the host institution, but only partially on the ERC action: by using time-sheets
  - if the PI works 100% of his/her total working time for the host institution and exclusively on the ERC action (during its entire duration): via a declaration signed by the beneficiary and the PI
  - if the PI works partly for other institutions (i.e. has working time outside the contract between PI and host institution): via a declaration signed by the beneficiary and the PI
- for the minimum percentage of total working time in an EU Member State or H2020 associated country: via a declaration signed by the beneficiary and the PI.

In the absence of this documentation, the ERC may accept alternative evidence, if it considers that it offers adequate level of assurance.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary**: information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);]**[OPTION 2**: not applicable;**]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2.

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When?

For ERC actions, the principal beneficiary must submit both:

- a **periodic scientific report** after the end of each scientific reporting period (except the last one), with:
  - information about the scientific progress of the work
  - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
  - information on whether and how open access has been provided to these results *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.
- a **final scientific report** at the end of the action, with:
  - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
  - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a **financial report** at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a breakdown of direct costs table and a budget follow-up table
- an individual financial statement
- a summary financial statement, created automatically by the IT system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a certificate on the financial statements (CFS).

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How?

All reports must be prepared and submitted directly in the Participant Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA.

Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

Example: *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in **the data management plan**;*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2: *Not applicable**]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars

⚠ Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

ERC grants have however the **following specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org). For monographs, book chapters and other long-text publications, the recommended repository is the OAPEN Library (http://oapen.org).

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Moreover, for publications after the end of the action, if beneficiaries cannot provide open access within the time limits set by Article 29.2 without incurring additional costs for gold open access, they may choose green open access with an extended embargo period which goes beyond six/twelve months.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a digital object identifier (DOI)[74] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable). For ease of tracking, beneficiaries should include the digital object identifier for the 'European Research Council' (http://dx.doi.org/10.13039/501100000781) in the funding acknowledgement field in their

[74] For more information, *see http://www.doi.org/*.

metadata, in addition to the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601).

For more information, *see Open Access on the ERC website, the ERCEA Implementation Guidelines and the ERC Scientific Council's Open Access Guidelines for research results funded by the ERC.*

2. Open access to research data

This option will be inserted in the GA for ERC frontier research actions that participate in the Open Research Data Pilot (in line with provisions in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the **following specificities**:

The data management plan (DMP) must be submitted using the ERC template and address the following issues:

1. Making data Findable
2. Making data openly Accessible
3. Making data Interoperable
4. Increase data Re-use
5. Allocations of resources and data security

Moreover the DMP can provide justification for NOT ensuring open access to specific parts of the research data. For ERC actions, the exception allowing beneficiaries not to give access to specific parts of their research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives.)

For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does NOT need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

A first version of the data management plan must be submitted within the first 6 months of the project implementation and should then be updated during the lifetime of the project, as needed.

The beneficiaries may **opt out** of the pilot at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55 H2020 General MGA)*. No reasons have to be provided for opting out. By opting out, they free themselves retroactively from the obligations associated with taking part in the pilot.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow and facilitate the transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action.

The PI must ensure a sufficient time commitment and presence throughout the course of the project to guarantee its proper execution.

The percentages for time commitments should be established by reference to the total productive hours worked by the PI for *all* his/her employers.

The total productive hours should be calculated in accordance with Article 6.

The percentages must be reached for the action duration (NOT annually or per reporting period).

- Applying the host institution's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**
- Upholding the **intellectual property rights** of the host institution

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it if s/he becomes aware of any violations.

  Example: *The PI reads a research article and discovers a violation of the host institution's project IPRs. S/he is obliged to inform the host institution.*
- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the host institution and the PI, to set out their internal arrangements for implementing the grant.

It is **purely internal**; the EU/Euratom is NOT party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must remain in place at least for the action duration *(see Article 3)* (— without any interruptions, even if the PI works only part-time on the ERC project).

It must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

It must be concluded **before GA signature** (or in case of portability before submission of the amendment request) and a copy must be sent to the Agency.

A template [ODT format] for a model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution *(see Article 56a)*, a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The new agreement must take effect from the grant transfer date (or before). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make **specific reference to the European Research Council (ERC)**. Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC homepage*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION 1:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION 2:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****].***

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG and other ERC grants with more than one principal investigator: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new host institution ('new beneficiary') — at any time during the action.

Transfer — The rights and obligations under the GA are transferred from the former host institution to a new host institution — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former host institution remains fully responsible until the Agency has approved the amendment.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution ('former beneficiary') may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the views of the PI.

2. Procedure

The PI should first contact the host institution that signed the GA (i.e. the former host institution).

> ⚠ **Record-keeping**
> **Best practice:** Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new host institution joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The **financial reporting periods** will be automatically adapted to match the transfer date (unless the transfer date coincides with the end of a financial reporting period).

Scientific reporting periods will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

> ℹ For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

3. Effects

The principal beneficiary must — within 60 days from either the transfer date or the date of signature of the amendment whichever is the latest — submit:

- a financial report to the Agency (for the open period until transfer)
- a report on the distribution of payments (only in case of multi-beneficiary GA)
- if the costs reach the threshold set out in Article 20:, a certificate on the financial statement (CFS) (— even if this is not the last reporting period).

These documents will be used for calculating the interim payment due to the former beneficiary. The Agency will moreover instruct the former host institution to transfer the remaining pre-financing to the new host institution.

If the PI requests it, the Agency may require the former host institution to **transfer equipment** that was purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate transfer conditions with the new host institution, taking into account the views of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may declare the costs of this reimbursement (and any other

related costs, i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, while the PI moves to a new host institution, the GA is transferred and changed into a multi-beneficiary grant agreement (allowing both the former host institution and the new host institution to participate in the grant). The former host institution stays on as beneficiary, the organisation that hosts and engages the PI is the new host institution. If the former host institution remains only for a limited time *(e.g. to ensure a smooth handover)*, it can then be terminated at a later stage, via a partner termination *(see Article 50.2 H2020 General MGA)*.

II.3 H2020 ERC MGA PoC: Annotations

The H2020 ERC MGA PoC is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability *(Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION 1 by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION A if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION B:*** *not applicable;****]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).****]***

[OPTION 2 for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION A if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION B:** not applicable;**]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Report(s)

What & When?

For ERC PoC actions, the principal beneficiary must submit reports — only one **report** if there is one reporting period, otherwise one **periodic report** at the end of each reporting period.

The report (or periodic reports) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a (periodic) summary financial statement, which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a certificate on the financial statements (CFS) will have to be added (if necessary).

How?

All reports must be prepared and submitted directly in the Participant Portal *(see Article 20 H2020 General MGA*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowska-Curie Actions (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE and
- MSCA-COFUND.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA MSCA - ITN deviates from the General MGA - Multi as follows:

- Article 4.2 (MSCA-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to ‘mainstream media coverage’)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MGA MSCA-IF deviates from the General MGA - Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 9-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSCA-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSCA-IF specific conditions for termination)
- Article 55 (MSCA-IF specific conditions for amendments)
- Article 56a (MSCA-IF portability)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MGA MSCA-RISE deviates from the General MGA - Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9 - 16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSCA-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (MSCA specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-COFUND deviates from the General MGA - Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of a programme)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 3, 5 and 6 Not applicable

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 9-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement)

III.2 H2020 MGA MSCA-ITN: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-ITN

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by networks of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN takes the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[OPTION for all actions except EID with only two beneficiaries: *However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.****]***

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NEVER** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment *(see Article 55)* is required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID with only two beneficiaries: a maximum of 40 % of the budget may be allocated to beneficiaries established in the same country (or to the same international European interest organisation or international organisation).

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In an action with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (= 40%). If the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes (*e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes (*e.g. to increase the salary of a researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

For MSCA-ITN, the maximum grant amount is limited to a maximum unit cost equivalent of 540 person-months (and for EID with only two beneficiaries: 180 person-months).

2. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

3. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[75].

For MSCA-ITN, these are unit costs for:

[75] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they can NOT be changed.

The eligibility conditions are set out in *Article 6*.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5 H2020 General MGA*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country) – unless as part of a procedure for obtaining refugee status under the Geneva Convention[6].

For beneficiaries that are international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately before the recruitment date.

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for 1 EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree [;][.]**]***

(viii) ***[OPTION for 2 EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

[6] 1951 Refugee Convention and the 1967 Protocol.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)
- a monthly mobility allowance (A.2) — to cover costs related to their mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by budget category B.1 'research, training and networking costs')

AND

- a monthly family allowance (A.3) — for researchers with family, to reduce family-related obstacles to researcher mobility.

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

Example: *Costs for student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.*

1.2 The costs must be **declared** as the unit costs fixed by Decision C(2013) 8194[76] and set out in Annex 2 and 2a of the GA.

This is currently:

[76] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the living allowance: **EUR 3 110** per researcher per month (person-month)

To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

The list of coefficients is published in the Main Work Programme — MSCA in force at the time of the call.

On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does NOT change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action).

– for the mobility allowance: **EUR 600** per person-month

– for the family allowance: **EUR 500** per person-month.

For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first 4 years (full-time equivalent research experience) of their research career)

    '**Date of recruitment**' means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

    Example: *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as recruitment date.*

    Years of '**research career**' are counted from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:

    – sickness, parental, unemployment and invalidity benefits

  - pension rights and
  - benefits for accidents at work and occupational diseases.

  If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

  - sickness, parental and invalidity benefits and
  - benefits for accidents at work and occupational diseases.

  In this case, the living allowance will be reduced by 50%.

  The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

  Staff provided by a temporary work agency — Beneficiaries must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:

  - subject to prior approval by the Agency
  - on personal or family grounds only (i.e. not for professional reasons).

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  ⚠ While it is not possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities (and must be set out in Annex 1 of the GA).

- are supported for **at least 3 months**

  Person-months linked to shorter contracts will not be eligible.

  However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. If the contract is set out for a longer duration, but the training is interrupted within the first three months for reasons not linked to the beneficiary *(e.g. because the researcher resigns)*, the costs may still be claimed.

- comply — at the date of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (— unless the beneficiary is an 'international European interest

organisation'[77] or international organisation, for whom the mobility rule is limited to time spent *with* them)

The mobility rule applies only to the **first recruitment** under the action. For instance, it does not apply to beneficiaries or partner organisations to which the researcher is sent or seconded afterwards.

Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[78] are NOT counted.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  In the case of EJD, the PhD-programme must lead to the award of:

  - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or
  - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

  The degree must not necessarily be awarded within the action duration.

  However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researchers (gross amount).

MSCA-ITN researchers may NOT be requested to pay tuition fees for their research training and/or PhD degree programme (neither from their own funds, nor from the researcher unit cost). The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* can be reimbursed under category B 'institutional costs'.

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as*:

- *part of his/her salary*
- *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
- *rental costs, directly paid or reimbursed by the beneficiary.*

[77] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[78] 1951 Refugee Convention and the 1967 Protocol.

Any form is acceptable, provided that:

- both sides agree
- it is allowed under national law

AND

- there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[79]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[80].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.*

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers who have — at the date of the recruitment — a family, i.e.:
  - persons linked to them by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

[79] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[80] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ Beneficiaries may declare a **maximum** of **36 person-months** per researcher. Person-months exceeding this number will be rejected by the Agency.

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector.

This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations/entities with a capital or legal link. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary, *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 50% rule.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - additional costs arising from secondments *(e.g. travel and accommodation costs)*
- management and indirect[81] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of a researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[82] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1800** per researcher per month (person-month)

[81] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[82] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

– for management and indirect costs: **EUR 1200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[83] in the same period: only management costs, i.e. EUR 600 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for recruited researchers'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for budget category A 'costs for recruited researchers' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[83] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon **entities with a capital or legal link** to the beneficiaries[7], to implement certain action tasks described in Annex 1 (i.e. hosting and training of researchers);
- call upon **partner organisations** to implement certain action tasks described in Annex 1 (i.e. hosting and training researchers during secondments).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[7] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-ITN allows the beneficiaries to use:

– entities with a capital or legal link to them

and

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them).

'**Entities with a capital or legal link**' are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-ITN grant (i.e. recruits the researchers), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-ITN action as entity with a capital or legal link implementing the research training activities, while the foundation or subsidiary participates as beneficiary (because it can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-ITN action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and training of researchers — and can even implement ALL those activities under the action. But they can NOT recruit the researchers (only beneficiaries can recruit the researchers) and can NOT host secondments (only partner organisations can host secondments).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary, tasks to be carried out and time spent with them).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme).

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers during **secondments**.

Secondments — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country) in order to further enrich the training experience of the researchers.

They are limited to a **maximum of 30%** of the time that is declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out and time spent with them).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations can be established anywhere (EU Member State, H2020 associated country or non-associated third country).

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the **full risk** of rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term meeting**' between the beneficiaries, entities with a capital or legal link, partner organisations and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of each researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — within 30 days after the first year of the action — send to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** after the recruitment date.

It is important to give correct and complete information in the researcher declaration since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[16] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or other entity mentioned in Annex 1);

(j) host the researchers at their premises (or at the premises of an entity with a capital or legal link);

(k) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(l) ensure that the researchers are adequately supervised;

(m) ensure that a career development plan is established and support its implementation;

(n) ensure an appropriate exposure to the non-academic sector;

(o) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

[16] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective recruitment procedures and best possible working conditions.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[84]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises (or those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or ensure that this is provided by the entity with a capital or legal link).

[84] Available at http://ec.europa.eu/euraxess/

If the Agency finds that a beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**
- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Ensure that **secondments** are **limited** to a **maximum** of **30 %** of the months declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD).

> ⚠ **Secondments** — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country), in order to further enrich the training experience of the researchers *(see Article 8)*.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

- Ensure that the researchers do NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[85].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[86].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities (including during secondments with other beneficiaries and/or partner organisations).

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2 H2020 General MGA*).

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

[85] Available at https://www.iprhelpdesk.eu/.
[86] Available at http://ec.europa.eu/euraxess/.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MGA MSCA-IF: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-IF

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include three additional funding strands: the 'Career Restart Panel', the 'Reintegration Panel' and the 'Society & Enterprise Panel'.

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION 3 if needed for the action:** [insert date]]*[4] ('**starting date of the action**').

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the actual starting date must be *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, there will be a **maximum deadline for notification** set out in Article 3 for both starting the action and notifying this to the Agency (normally 12 months from the entry into force of the GA).

The notification must be done directly in the Participant Portal.

Late notification will delay the pre-financing payment *(see Article 21.2 H2020 General MGA)*.

If the action does not start or the starting date is not notified in time, the Agency may terminate the GA *(see Article 50 H2020 General MGA)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researcher (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The institutional unit cost should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (*including for GF outgoing phase; see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs'**) and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[87].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[87] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[**OPTION 1 by default:** 24][**OPTION 2 for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including periods of secondment to '**partner organisations**';

(ii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons (see Article 55), and

(iii) be working exclusively for the action.

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory

deductions under national law, *such as employer/employee social security contributions and direct taxes*)

- a monthly mobility allowance (A.2) — to cover costs related to his/her mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by category B.1 'research, training and networking costs').

AND

- a monthly family allowance (A.3) — if the researcher has family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiary are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[88] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 4 650** for the researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the Main Work Programme — MSCA in force at the time of the call and according to the country of recruitment (i.e. the country of the beneficiary).

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

ℹ For the latest information on the amounts and the country correction coefficients, *see the Main Work Programme — MSCA in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[88] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the date of the call deadline — an **experienced researcher** (i.e. have a doctoral degree OR have at least four years (full-time equivalent research experience) of research career).

    Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases

    If national law prevents it from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

    The social security coverage must be guaranteed for the entire action (i.e. also during optional secondments, if any, and for the GF outgoing phase).

    For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent coverage during the stay in the third country.

    Example: *A German university recruits the fellow for the total duration of the action (i.e. provides the main employment contract under the action) and sends him/her to a US university. Continuing the German social security during the stay in the US would be so expensive, that the beneficiary asks the US partner organisation to conclude an additional employment contract, in order to insure the researcher in the US.*

    Staff provided by a temporary work agency — The beneficiary must always recruit the researcher directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency

– on personal or family grounds only (i.e. not for professional reasons).

In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ While it is NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researcher (gross amount).

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as:*

– *part of his/her salary*

– *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*

– *rental costs paid or reimbursed by the beneficiary, etc.*

Any form is acceptable, provided that:

- both sides agree

– it is allowed under national law

AND

– there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[89]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[90].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the date of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the 3 years immediately before to the call deadline (— unless the beneficiary is an 'international European interest organisations' or international organisations, for whom the mobility rule is limited to time spent *with* them)

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) are NOT counted.

  For EF Career Restart Panel, Reintegration Panel and Society & Enterprise Panel: specific mobility rule — not more than 3 years in the 5 years immediately before the call deadline

  For GF: the mobility rule is checked for the country of the partner organisation, not for the country of the beneficiary (i.e. where the outgoing phase takes place, not where the return phase takes place).

- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a EU Member State or an H2020 associated country.

  'Long-term resident' means full-time research activity in a EU Member State or H2020 associated country for 5 or more consecutive years.

  Time spent in procedures for obtaining refugee status in a EU Member State or H2020 associated country will be counted.

- for EF Career Restart Panel: not have been **active** in research for at least 12 months immediately before the call deadline

  'Active in research' means being employed or holding a scholarship. Parental leaves and unpaid leaves of absence will not be counted as periods of active engagement in research, even if a formal employment relationship exists during these periods. Publication activities or mere association to a university are not taken into account either.

- for the family allowance: have a **family**, i.e.
  - persons linked to the researcher by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or
  - dependent children who are actually being maintained by the researcher.

[89] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[90] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs for the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ The beneficiary may declare a **maximum** of **24 person-months** for the researcher (or **36 months** for GF). Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.1): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - additional costs arising from secondments *(e.g. travel and accommodation costs, visa-related fees and travel expenses)*
- management and indirect[91] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (including for GF outgoing phase; *see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[92] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 800** for the researcher per month (person-month)
- for management and indirect costs: **EUR 650** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[93] in the same period: only

[91] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[92] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

management costs, i.e. EUR 325 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for the recruited researcher'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for budget category A 'costs for the recruited researcher' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for the recruited researcher:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[93] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon entities with a capital or legal link to the beneficiary[5], to implement certain action tasks described in Annex 1 (i.e. hosting and training of the researcher);
- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. hosting and training the researcher during secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

[5] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-IF allows the beneficiary to use:

– entities with a capital or legal link to it

and

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

'**Entities with a capital or legal link**' are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to the beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-IF grant (i.e. recruits the researcher), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. *A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation or subsidiary participates as beneficiary (because it is can recruit the researchers).*

3. *A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).*

Entities with a capital or legal link may be used for hosting and research training of researchers — — and can even implement ALL those activities under the action. But they can NOT recruit the researcher (only the beneficiary can recruit the researcher) and can NOT host secondments (only partner organisations can host secondments).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of link with the beneficiary and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary (for instance, be established in an EU Member State or H2020 associated country).

Example: *For the EF Society & Enterprise Panel, the entities with a capital or legal link must also be from the non-academic sector.*

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers during **a secondment**.

Secondments — For MSCA-IF, secondments are either:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country).

Optional secondments are limited to a **maximum of 3 months** (for actions with duration of up to 18 months) and **6 months** (for actions with duration of more than 18 months).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researcher (only the beneficiary can recruit the researcher).

For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent social security coverage during the stay in the third country *(see Article 6)*.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations for optional secondments must be established in an EU Member State or H2020 associated country; partner organisations for GF outgoing phase must be established in a non-associated third country.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

A beneficiary that throws supporting documents away during the retention period bears the **full risk** of rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** and **entities with a capital or legal link** (if any) give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[12] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(g) host the researcher at its premises (or at the premises of an entity with a capital or legal link);

(h) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(i) ensure that the researcher is adequately supervised;

(j) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(k) support the secondment of the researcher to a partner organisation in a Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(l) ***[OPTION for GF:*** *support the return of the researcher to its premises (or those of the entity with a capital or legal link) to carry out a mandatory return period of 12 months.****]***

[…]

[12] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises (or at those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or to ensure that this is provided by the entity with a capital or legal link).

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- **Support secondments** of the researcher (if any) and ensure that they are **limited** to a **maximum** of **3 months** (for actions of up to 18 months) or **6 months** (for actions of more than 18 months)

⚠ **Secondments —** For MSCA-IF, secondments can be:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

and/or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country) *(see Article 8)*

For GF: Also support the researcher's return (during the mandatory 12 months return-period)

- Ensure that the researcher does NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[94].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[95].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during optional secondments/GF outgoing phase with partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

[94] Available at https://www.iprhelpdesk.eu/.
[95] Available at http://ec.europa.eu/euraxess/.

This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave) of the recruited researcher.

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. GA suspension — Additional grounds for suspension: Professional, personal or family reasons

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, beneficiaries of MSCA-IF may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and (planned) end date of the suspension and
- the (planned) resumption date when the action will be resumed (i.e. automatically end date +1 day).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are NOT eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for personal or family reasons (including parental leave).

[…]

1. Amendments — Additional grounds for amendments: Change to part-time employment

What? For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time) — on personal or family grounds (including parental leave).

What not? Such amendments are NOT possible for any other reasons *(e.g. other professional opportunities, etc.)*. In those cases, the beneficiary must request a GA suspension or GA termination.

How? The amendment should be requested immediately (retroactive change is possible, if justified; *see Article 55 H2020 General MGA*).

The action duration will be automatically adapted (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months, so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working time; AT23 clause) and the reporting periods will be changed (to adapt them to the new action duration; AT25 clause).

For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ **Transfer** — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains **fully responsible** until the Agency has approved the amendment.

The transfer may be based on any **ground** that is linked to the beneficiary and affects objectives of the action (i.e. implementing the research training activities).

Examples: *Internal reorganisation affecting implementation of the action; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher (e.g. other professional opportunities, personal or family commitments) are NOT considered valid grounds for transferring the GA to a new beneficiary. These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*.

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility conditions or does not have sufficient financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed directly in the Participant Portal).

The **maximum grant amount/action duration** will be adapted to take into account the country correction coefficient of the new beneficiary.

⚠ The maximum grant amount *(see Article 5)* will **NEVER** be **increased**.

If the new beneficiary is in a country with a lower country correction coefficient, the maximum grant amount *(see Article 5.1) will be lowered*.

If the new beneficiary is in a country with a higher country correction coefficient, the action duration will normally be adapted, so that the maximum grant amount can stay the same. If (exceptionally) the action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new correction coefficient *(using e.g. the management and indirect costs or own funding)*.

ℹ For more information on the amendment (list of AT clauses, supporting documents and information on how amendment types can be combined) *see the Guidance – Amendment types & supporting documents.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to check the eligible costs and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary. The real financial statement for the open reporting period until transfer must be also uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

III.4 H2020 MGA MSCA-RISE: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-RISE

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

> **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

> For more information on MSCA-RISE, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*
>
> For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

The maximum grant amount *(see Article 5)* can however **NEVER** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

If the transfer of person-months implies a substantial change of Annex 1, a formal amendment is required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the seconded staff (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs a staff member, to organise additional training activities or horizontal networking events)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs)**.

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the Main Work Programme — MSCA).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[96].

For MSCA-RISE, these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[96] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for seconded staff members</u> are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 6 months at the sending:

- beneficiary (or entity with a capital or legal link[6] to it and located in the same country), or
- partner organisation (or entity with a capital or legal link to it and located in the same country).

(c) the secondments comply with the following conditions:

(i) last at least 1 month and no longer than 12 months (per secondment);

(ii) be between different countries;

(iii) for secondments within the EU (or associated countries)[7]: be between different sectors (academic and non-academic)[8];

(iv) for secondments from EU (or associated countries): be from a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country) to a partner organisation (or entity with a capital or legal link) established in a non-EU Member State (or non-associated country), and

(v) for secondments to EU (or associated countries): be from a partner organisation (or entity with a capital or legal link) established in a country listed in General Annex A of the Main Work Programme to a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country).

[6] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] For secondments for entities with a capital link or legal link to the beneficiaries or partner organisations: only the sector (academic or non-academic) of the beneficiary counts; the entity will be considered to belong to the same sector as their beneficiary.

1. Seconded staff costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members, by providing for:

- a monthly top-up allowance (A) — for travel, accommodation and subsistence costs relating to the secondment.

> ⚠ **Budget flexibility —** There is NO flexibility as regards the *use* of the seconded staff unit costs (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
>
> ⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

What not? Research, training and networking costs and management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared as** the unit cost fixed by Decision C(2013) 8194[97] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the top-up allowance: **EUR 2 000** per seconded staff member per month (person-month).

> ℹ For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - **early stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time equivalent research experience) of their research career)

[97] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- **experienced researchers** (i.e. have a doctoral degree OR at least four years (full-time equivalent research experience) of research career), or
- **administrative, managerial** or **technical staff supporting research and innovation activities** (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

Examples (not eligible administrative, managerial or technical staff):

1. *Ms B, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

2. *Mr Y, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

Years of '**research career**' are counted from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited or from where s/he is seconded) — even if a doctorate was never started or envisaged.

- have already been actively **engaged** in or **linked** to research and innovation activities at the premises of the sending beneficiary/partner organisation/entity with a capital or legal link, continuously for at least **6 months** (full-time equivalent)

Examples:

1. *Mr Y is employed by/has a fellowship with/is a registered PhD candidate of beneficiary Y as from 1 January 2014; Mr Y will not be eligible for a secondment from 1 March 2014 but would be eligible for secondment as from 1 July 2014.*

2. *Ms X is employed 50% part-time by beneficiary X as from 1 January 2014. Ms X will not be eligible for a secondment from 1 July 2014, but would be eligible for secondment as from 1 January 2015.*

The type of relationship (employment contract, fellowship or other) is NOT relevant — as long as it:

- complies with national law
- complies with internal practices and
- during the secondment: confers to the sending beneficiary/partner organisation/entity with a capital or legal link the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

  If this is not the case, the beneficiary/partner organisation/entity with a capital or legal link must conclude a contract which allows this (or a supplementary agreement) — before the secondment.

  Example: *A PhD-candidate can be seconded if s/he: has a contract allowing him/her to work full-time on the R&I activities of the action during the secondment under the instructions of the sending beneficiary/partner organisation/entity with a capital or legal link.*

- be incurred for secondments:
  - that last at **least 1 month** and **no longer than 12 months**

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

For the minimum duration, only splits within *secondments of* same staff, from same sending beneficiary/partner organisation to same hosting beneficiary/partner organisation can be added. Secondments from/to entities with a capital or legal link will be counted as secondments from/to the beneficiaries/partner organisations they are linked to.

Example: *Two secondments of two weeks of the same staff member to different beneficiaries are not eligible since the minimum duration of 1 month is not reached.*

For the maximum duration, all secondments (and all splits) for the *same staff member* must be added.

- that are one of the following three:
  - secondments **between beneficiaries/entities with a capital or legal link** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in **different** EU Member States or H2020 associated **countries** AND **different sectors** (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country) **to** a **partner organisation/entity with a capital or legal link** in a third country

  OR

  - secondments **from** a **partner organisation/entity with a capital or legal link** in a third country listed in General Annex A to the Main Work Programme **to** a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country).

  Secondments from/to branches/departments of beneficiaries/partner organisations which are not separate legal entities are NOT eligible, if they are located in countries other than the country of their beneficiary/partner organisation.

Examples:

A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the Main Work Programme.*
A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the Main Work Programme.*
A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
They may each claim 120 person-months (for their own staff).

If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded *from* both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation *to* two or more participating organisations in a RISE project — as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('implemented person-months')

⚠ Beneficiaries may declare a **maximum** of **12 person-months** per seconded staff member. Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert 5.47 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[98] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility —There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[99] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1800** per researcher per month (person-month)
- for management and indirect costs: **EUR 700** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[100] in the same period: only management costs, i.e. EUR 350 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

[98] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[99] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[100] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for seconded staff members'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for seconded staff members.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the seconded staff members are met. Person-months which are not eligible for budget category A 'costs for seconded staff members' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff);
- call upon entities with a capital or legal link to the beneficiaries or to partner organisations[9], to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[9] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-RISE allows the beneficiaries to use:

– partner organisations

and

– entities with a capital or legal link to a beneficiary or a partner organisation

to carry out work under the action ('**third parties involved in the action**').

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them.)

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to a beneficiary.

They may participate in the exchanges by seconding and hosting staff.

Secondments — For MSCA-RISE, secondments are the core activity of the action. They can be between beneficiaries/entities with a capital or legal link OR between beneficiaries/entities with a capital or legal link and partner organisations (from a third country).

They must have a **minimum** duration of **1 month** and a **maximum** duration of **12 months** (per seconded staff member).

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations must be established in a non-associated third country (i.e. not EU Member State or H2020 associated country).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary or a partner organisation — which is neither limited to the action nor established for the sole purpose of its implementation).

They may participate in the exchanges by seconding and hosting staff.

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary/partner organisation and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary/partner organisation they are linked to (for instance, if linked to a beneficiary: be established in an EU Member State or H2020 associated country; if linked to a partner organisation: be established in a non-associated third country AND be established in the same country as their beneficiary/partner organisation.

Examples (eligible entities with capital or legal link):

1. *University X (established in France) is part of a Joint Research Unit (JRU) with beneficiary Y (also established in France). Mr. X is employed by university X and is to be sent on a secondment to beneficiary Z. University X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

2. *SME X (established in Portugal) is a subsidiary of beneficiary Y (also established in Portugal). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. SME X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Ms. X.*

3. *Mr. X is formally employed by foundation X (established in Spain) which does the HR management for beneficiary Y (also established in Spain). Mr. X actually works with beneficiary Y and should be sent on a secondment to beneficiary Z. Foundation X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

Examples (ineligible entities with capital or legal link):

1. *SME X (established in Germany) is a subsidiary of applicant Y (established in Greece). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. Since SME X is not established in the same country as applicant Y, it cannot act as entity with a capital or legal link for the purposes of a MSCA-RISE grant. Therefore, Ms X cannot be seconded.*

2. *University X (validated as academic; established in Sweden) is member of an association of universities (applicant Y; validated as non-academic). Mr. X is employed by university X and is to be sent on a secondment to applicant Z (validated as academic). University X cannot act as entity with a capital or legal link of applicant Y for the purposes of the MSCA-RISE grant because this would circumvent the inter-sector mobility rules (mix of academic and non-academic).*

For more information on conditions for participation and funding, *see the Main Work Programme — MSCA.*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Beneficiary Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities)*

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until these procedures end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

Beneficiaries that throw supporting documents away during the retention period bear the **full risk** of rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must keep the documents for the staff of the partner organisation/entity with a capital or legal link.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term meeting**' between the beneficiaries, partner organisations, entities with a capital or legal link and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — after each year except if a periodic report is due (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a 'researcher declaration' for each seconded staff member — within **20 days** from the start of the secondment.

It is important to give correct and complete information in the researcher declaration, since this information will be used to determine the eligibility of the person-months that are declared.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — and indicate each split.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment, indicating the split. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (within 20 days from the start date of each secondment). Secondments to entities with a capital or legal link will be counted as secondments to the beneficiary/partner organisation they are linked to and must therefore be covered by the same researcher declaration.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

Specific case (deliverables):

Researcher declaration for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must submit the researcher declarations.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the seconded staff members **access** to both **background** AND **results** necessary for their research and innovation activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time.**

  For part-time staff members this may require a change of their relationship (i.e. conclude a contract or a supplementary agreement), to allow the secondment to be implemented on a full-time basis.

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is only a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are of course accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary/partner organisation/entity with a capital or legal link) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[101].

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*

- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.

- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

[101] Available at https://www.iprhelpdesk.eu/.

They can be:

- paid directly to the seconded staff member in advance or via different instalments or
- managed centrally by the beneficiary according to the specific needs of the secondment.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract (or fellowship or other relationship), some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA grant in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiaries) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MGA MSCA-COFUND: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. Action: MSCA-COFUND

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the Main Work Programme — MSCA and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in a programme implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**');

(b) for **costs of providing financial support to costs for researchers in a programme implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the Main Work Programme — MSCA)*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2013) 8194[102].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[102] Commission Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced maximum grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in a programme implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in a programme implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme), by providing for:

- a monthly living allowance (A.1 or A.2) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*).

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit cost (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs of the beneficiary are not covered. Management costs are covered under budget category B 'management costs' *(see Article 6.2.B)*. Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are NOT eligible under the grant; they may be funded through other sources (including other EU funding programmes).

Combining H2020 & other EU grants — A MSCA-COFUND grant does NOT prevent the beneficiary or partner organisations from applying for further (non-H2020) EU funding for their programme — for costs that are not eligible (or not declared) under the MSCA-COFUND grant.

For more information on how to combine EU funding from different programmes, *see the Online Manual (links to Regional funding).*

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8194[103] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance:
  - for early-stage researchers in doctoral programmes: EUR 3 710 per researcher per month (person-month)

[103] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for experienced researchers in fellowship programmes: EUR 5 250 per person-month.

⚠ Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is ONLY **EUR 1 855** and **EUR 2 625** respectively.

ℹ For the latest information on the amounts, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is:*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** only the:

- management costs (B) — for direct costs of managing the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER sources (including other EU funding programmes).

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8194[104] and set out in Annex 2 and 2a of the GA.

This is currently:

- for management costs: EUR 650 per researcher per month (person-month).

Since MSCA-COFUND grants have a **reimbursement rate** of **50%**, the unit cost that the beneficiary receives is **EUR 325**.

For the latest information on the amount, *see the Main Work Programme — MSCA in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher costs.

1.3 The **eligibility** of the management costs is directly linked to (and conditional on) the eligibility of the costs for researchers.

Management costs are eligible only if ALL the eligibility conditions for the researchers are met. Person-months which are not eligible for budget category A 'costs for researchers' are also not eligible for budget category B 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

[104] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. implementing a doctoral or fellowship programme including recruiting researchers or hosting and training researchers during a secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules of the General MGA on third party involvement do not apply.

Instead, MSCA-COFUND allows the beneficiary to use:

– partner organisations

to carry out work under the action ('**third parties involved in the action**').

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

'**Partner organisations**' are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to:

– implement a doctoral or fellowship programme (i.e. recruit the researchers)

– provide training and hosting of researchers during a secondment *(see Article 15)*.

⚠ **Secondments —** For MSCA-COFUND, secondments can be:

- (optional) additional periods of research training with a partner organisation, in order to further enrich the training experience of the researchers

and/or

- for fellowship programmes similar to MSCA-IF GF: (mandatory) outgoing phase with a partner organisation (from a third country).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during secondments.

Partner organisations can recruit the researchers (and MUST do so if it is the partner organisation that implements the doctoral or fellowship programme; *see Article 15.1.1(b)*).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations that implement a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *Main Work Programme*. Partner organisations hosting secondments can be established anywhere.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

15.1 Rules for providing financial support to or implementation of a *[doctoral][fellowship]* programme

15.1.1 The beneficiary must ensure that the ***[doctoral][fellowship]* programme** (implemented by itself or a partner organisation) complies with the following conditions:

(a) **types of programme**:

[OPTION 1 for DPs: *The programme must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programme**');**]***

[OPTION 2 for FPs: *The programme must concern fellowships for research training activities for recruited researchers ('**fellowship programme**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country[5], the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programme:

[OPTION 1 for DPs: *The doctoral programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately before the call deadline or recruitment — unless:*
  - *otherwise specified in Annex 1 for existing programme or*
  - *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[6];*
- *are nationals or long-term residents of an EU Member State or associated country[7], in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION 2 for FPs: *The fellowship programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than [**OPTION A by default:** 12 months in the 3][**OPTION B for actions with activities similar to the MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel:** 3 years in the 5] years immediately before to the call deadline or recruitment — unless:*

- *otherwise specified in Annex 1 for existing programmes or;*
- *this time was part of a procedure for obtaining refugee status under the Geneva Convention[8];*

- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.]*

Researchers that are already permanently employed by the entity where the research training activities take place may not be supported.

(c) **procedure and criteria for selecting researchers** in the programme:

[OPTION 1 for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency).****]***

[OPTION 2 for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

The selection committee(s) must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

*There must be no more than 4 deadlines or cut-off dates per year.****]***

(d) **conditions for the recruitment** of researchers under the programme:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;
- researchers must be recruited for at least 3 months;
- ***[OPTION 1 for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 597.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 298.50;****]***

- ***[OPTION 2 for FPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 675.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 837.50.****]***

15.1.2 In addition, the beneficiary must:

- for programmes implemented by itself:
  - take measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[9] and ensure that the researchers are aware or them;
  - ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;
  - ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);
  - ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;
  - ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
  - ensure that researchers work exclusively on the research training activities;
  - ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
  - ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
  - ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of results, promoting the action) — during the research training activities and afterwards;
  - inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — a follow-up questionnaire provided by the Agency;
  - ***[OPTIONS for DPs:****ensure a fair gender representation in the recruited researchers (by promoting genuine equal access opportunities between men and women throughout the recruitment process);*
  - *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.****]***
- for programmes implemented by a partner organisation:
  - ensure that the partner organisation complies with the obligations set out in this Article and

- ensure that the partner organisation allows that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[5] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[6] 1951 Refugee Convention and the 1967 Protocol.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] 1951 Refugee Convention and the 1967 Protocol.

[9] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing a doctoral/fellowship programme

MSCA-COFUND can provide support both for a programme implemented by the beneficiary itself or for a programme of a partner organisation (which the beneficiary funds by providing financial support).

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisation that implements the doctoral/fellowship programme (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Types of programme — Categories of persons

The beneficiary/partner organisation must implement one of the following **types of** research training **programme** supporting transnational mobility:

– doctoral programme (DP), i.e. a programme with research training activities for recruited early-stage researchers that leads to the award of a doctoral degree

The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programme (FP), i.e. a programme with fellowships for recruited experienced researchers.

The **researchers** must — at the date of the call deadline or recruitment —:

- be one of the following two:
  - **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time-equivalent research experience) of their research career) or
  - **experienced researchers** (i.e. have a doctoral degree OR have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than:
  - for fellowship programmes similar to MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel: 3 years in the 5 years immediately before the recruitment date or call deadline
  - for all other programmes (doctoral programmes and other fellowship programmes): 12 months in the 3 years immediately before the recruitment date or call deadline

  — unless Annex 1 of the GA specifies otherwise for an already existing programme or the beneficiary/partner organisation is an 'international European interest organisation'[105], for whom the mobility rule is limited to time spent *with* them.

  Exceptions in Annex 1 are only possible for existing programmes (NO exceptions for new programmes).

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[106] are NOT counted.

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

- if the programme is implemented by a partner organisation established in a **third country** (only third countries listed in General Annex A to the Main Work Programme) or if a secondment to a partner organisation in a non-associated third country constitutes the ***main* part** of the research training activities: be nationals or **long-term residents** of a EU Member State or H2020 associated country.

  'Long-term resident' normally means full-time research activity in a EU Member State or H2020 associated country — for 5 or more consecutive years.

  NO other restrictions on researcher nationality or researcher origin or destination allowed.

3. Additional cost eligibility condition: Selection procedure

[105] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[106] 1951 Refugee Convention and the 1967 Protocol.

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs*[107]*)*.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a **maximum** of **4** fixed deadlines or regular cut-off dates **per year**) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

4. Additional cost eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits
- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, the beneficiary/partner organisation may — exceptionally and subject to the Agency's prior agreement— offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — The beneficiary/partner organisation must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

[107] Available at http://ec.europa.eu/euraxess/.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum remuneration —** monthly **living allowance** (i.e. gross amount including salary, social security contributions, taxes and other costs included in the remuneration) and, if applicable, a single mobility allowance for the researcher to take up the doctoral or fellowship programme (to be funded through other sources) **—** of:

- for early-stage researchers (doctoral programmes): EUR 2 597
- for experienced researchers (fellowship programmes): EUR 3 675.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 298,50; for experienced researchers EUR 1 837,50).

Lower payments are considered as underpayment.

⚠ Since the MSCA-COFUND grant reimburses 50% of the researcher unit cost (i.e. EUR 1 855 and EUR 2 625 respectively), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 742** or **EUR 1050** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

The total cost of the doctoral/fellowship programme, in particular the amounts to be provided for the benefit of the researchers and for the hosting organisation, must be specified in Annex 1.

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral/fellowship programme — the average monthly allowance (over the duration of the programme) respects the above-mentioned minimum.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[108]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[109].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

5. 'Other obligations'

[108] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[109] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**

    This also means that a researcher can NOT benefit from two MSCA grants at the same time.
  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities.
  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency
- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[110].
- for doctoral programmes: the beneficiary/partner organisation must:
  - ensure **gender balance** regarding the recruited researchers
  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career development plan.

[110] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas, documents relating to selection procedure)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the minimum remuneration was paid to the researchers.

This evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

A beneficiary that throws supporting documents away during the retention period bears the full risk of rejection by the Agency.

Specific case (record-keeping):

Documents for a programme implemented by a partner organisation — For a programme implemented by a partner organisation, it is the beneficiary that must keep the documents also for the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must

- submit a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- organise a **'mid-term meeting'** with the Agency;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** of the start of the research training activities of the researcher.

It is important to give correct and complete information in the researcher declaration since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The beneficiary must organise a mid-term meeting with the Agency to present the implementation of the action in the light of the schedule in Annex 1 .

Best practice: Please contact the Agency for the timing.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researchers in MSCA-COFUND, the MSCA-COFUND MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** (if any) give similar access.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,*

addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 MGA SME Ph1 deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 MGA SME Ph 2 deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 MGA SME Ph1, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 MGA SME Ph1: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph1 actions

What? SME Instrument Ph1 funds:

- the feasibility study for an innovation idea (i.e. a ‘proof of concept’ or ‘business plan’ for new, altered or improved product, process or service).

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above*; see General Annex G to the Main Work Programme*).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-01-2016-2017)*.

For more information on SME Instrument Ph1 actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph 1 MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70% of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph 1 MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Decision C(2013) 8198[111].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

[111] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to grant *reduction*). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the feasibility study (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Decision C(2013) 8198[112] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the

[112] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf

amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

Since the SME Ph1 grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to grant *reduction*, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

Third party involvement in SME Ph1 actions is limited to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs of purchases and subcontracts are **ALL covered** by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12 H2020 General MGA) and **linked third parties** (Article 14 H2020 General MGA) are NOT allowed (Since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[113] or 2009/81/EC and the national legislation implementing them.

Moreover, the obligations in Article 10.1 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[113] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[114] or 2009/81/EC and the national legislation implementing them.

[114] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Finally, the obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

> ***Examples:*** *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Report

When & What? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a final report, containing a:

- final technical report
- final financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The Agency may disclose confidential information also to its staff, other EU institutions and bodies.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency and Commission responsibility — Agency and the Commission right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (beneficiaries) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submiting the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submiting to the Agency in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the Agency will formally notify the beneficiary of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a **recovery**, the Agency will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*. Improper implementation therefore leads to the *ineligibility* of the costs (NOT grant *reduction*; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

Cost rejections will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide required information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since SME Ph1 grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a 'report on the distribution of payments'.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Partner termination (beneficiaries)

The rules on partner termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. GA or beneficiary termination (Agency)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the **following specificities**:

The request for amendment (which the coordinator must send 60 days after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 MGA SME Ph2: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the Main Work Programme*).

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, 'Innovation in SMEs' (*e.g. H2020-SMEINST-05-2016-2017)*.

For more information on SME Instrument Ph2 actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **if the beneficiary is a natural person** not receiving a salary (see Article 6.2, points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific costs category(ies)**: not applicable.

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the Main Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are by definition NO non-profit legal entities, they can NOT declare additional remuneration (under budget category A 'personnel costs'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

***[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules [...]*[11]*.]*

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement." **]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries*[12] *and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[24]*.**]***

***[OPTION 2 only for actions involving PCP:** Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*

- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).]*

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[11] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[12] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[13] See Articles 28 and 31(2)(a) of Directive 2004/18 replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the **following specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Participant Portal messaging function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage)

OR

- refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the 'simplified approval procedure: there is' NO assessment (and the beneficiary therefore bears the **full risk**).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as for the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be adapted to reflect the action duration. Thus, if considered necessary, SME Ph2 actions may include shorter and more frequent reporting periods.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 MGA ERA-NET Cofund deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 MGA ERA-NET Cofund: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],* ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

Annex 7 Model for the commitment on availability of funds

Annex 8 Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

ERA-NET Cofund uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities participating financially to the joint call for proposals MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8*).

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the Main Work Programme*).

  These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the Main Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of Horizon 2020 *(e.g. FETPROACT-02-2017; SC5-33-2017)*.

For more information on ERA-NET Cofund actions*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action**: [insert date]]*[7] ('starting date of the action').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). Normally, the duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs.

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**:

- for costs of internally invoiced goods and services: on the basis of an mount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment, to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

2. Reimbursement rate

How much? For ERA-NET Cofund, the reimbursement rate is currently set at **33 %** *(see General Annex D to the Main Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - **personnel** costs for implementing the trans-national projects (— unless declared as unit cost, *see below*)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects (— unless declared as unit cost, *see below*)
- **unit costs** for:
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices
  - **coordination costs** for additional activities[115]
- **flat-rate costs** for:
  - **indirect costs**.

[115] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.2.1.1,A.2.1.2 and A.2.1.3) : the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.2.1.1 and A.2.1.2) **calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION 1 by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

A.2.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:***:***

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Costs for trans-national projects (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as direct costs related to trans-national projects:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment

- other goods and services
- costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc.) or for additional coordination and networking activities of beneficiaries implementing trans-national project themselves. Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs must normally be **declared as** actual costs *(see Article 5.2(b))*.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

1.3 In principle, the same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the **following specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities

Direct coordination costs for additional activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Additional coordination costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the direct costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8200[116] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the **additional coordination activities** described in Annex 1.

Costs for additional coordination activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare any additional coordination costs.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the Main Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[116] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (C.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing to the joint call for proposals can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action).

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is ONLY allowed for beneficiaries/linked third parties that **implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be **trans-national projects**, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.2a);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients (third parties) that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Trans-national projects

The projects must be trans-national (i.e. they must involve at least two independent entities from two different EU Member States or H2020 associated countries), both in case of:

- financial support to third parties and
- implementation of the projects by the beneficiaries themselves.

3. Additional cost eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and

- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

4. Additional cost eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

5. Additional cost eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection (**joint selection list**) on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

6. Additional cost eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

7. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION 1 by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Information on each selected project — Information on each implemented project

When & What? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

> ***Example:*** *data on each participant and abstracts of the proposals*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

> ***Example:*** *data on each participant and an overview of the results*

How? The information must be uploaded directly in the Participant Portal

2. Deliverable: Information on cumulative expenditure incurred

What & When? The coordinator must submit to the Commission/Agency — on a yearly basis — information on the cumulative expenditure incurred by the consortium

How? In practice, this mandatory declaration for ERA-NET Cofund *(see Article 20.5)* is handled as deliverable and must be uploaded directly in the Participant Portal.

It does NOT need to be set out in Annex 1 (since legally speaking the obligation is not based on Article 19 but on Article 20.5).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.2a Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment** (see Annex 8), including the **request for a third pre-financing payment**.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.3 Request for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4), from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

When & What? For ERA-NET Cofund actions, the coordinator has to submit — after the first reporting period (and, if there are 3 pre-financing payments, also after the second reporting period) — a **periodic technical report**, with information on the technical implementation.

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 8*).

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)

- ranking list of the projects
- observer report on the evaluation
- joint selection list
- commitment on availability of funds (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8).

At the end of the action, the coordinator has to submit a **final report**, with both the technical and financial report.

How? Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

ERA-NET Cofund actions are normally divided into 2 reporting periods with 2 pre-financing payments (or exceptionally 3 reporting periods with 3 pre-financing payments, if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

The declaration is normally handled as deliverable *(see Article 19)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments — No interim payments

ERA-NET Cofund actions normally are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because the Commission/Agency does not have sufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since ERA-NET Cofund pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Amount of pre-financing payments

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- for the first pre-financing payment: between 10% and 30 % of the maximum grant amount
- for the second pre-financing payment: between 60 % and 80% of the maximum grant amount.

If the GA provides for a 3 pre-financing payments, then the amount is divided as follows:

- 30 % for the first pre-financing payment
- 30 % for the second pre-financing payment
- 30 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP/PPI MGA

VI.1 Background information and approach

The PCP/PPI Model Grant Agreement is used for PCP/PPI actions only.

The PCP/PPI MGA follows the General MGA for numbering and content, except for:

The H2020 MGA PCP-PPI deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI specific payment provisions)
- Article 23 (PCP-PPI specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of resources
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP/PPI actions are added:

- Article 2 (PCP/PPI actions)
- Article 4.1 (PCP/PPI budget categories)
- Article 8 (PCP/PPI rules on third party involvement).

VI.2 H2020 MGA PCP/PPI: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],* ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***
	[OPTION if the JRC participates: *3b Administrative Arrangement****]***
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

PCP/PPI uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities contributing financially to the PCP or PPI procurement budget MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8)*. They form the buyers group.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. PCP/PPI actions

What? PCP/PPI funds:

- one single joint public procurement of research and development (R&D) services (PCP) or one joint or several coordinated public procurements for innovative solutions (PPI)

AND

- related additional coordination and networking activities.

For PCP actions, it must be only one PCP per GA; for PPI actions, it can be one joint or several coordinated PPIs per GA.

The additional activities must relate to the joint call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the Main Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP/PPI grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the Main Work Programme)*.

PCP/PPI actions are funded in all Parts of Horizon 2020 *(e.g. SEC-09-FCT-2017)*.

The possibility to have several coordinated PPIs was introduced with GA version 4.0 but is also open to older grant agreements.

For more information on PCP/PPI actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General Annexes to the Main Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14 a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP/PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP/PPI MGA uses its **own budget categories**.

Budget categories of the PCP/PPI MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare PCP/PPI subcontracting costs. Who actually pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP/PPI MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **[…%]** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION 1 for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2a*[13] ***(unit costs).]***

[OPTION 2: specific cost category(ies): *not applicable.**]***

[…]

[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
[13] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The PCP/PPI, normally uses the same reimbursement rates as the General MGA (**100%** for research and innovation actions (RIA) and **70% or 100%** for innovation actions (IA) actions; *see Article 5 H2020 General MGA*), unless the call provides exceptionally for another rate.

2. Cost forms

The PCP/PPI MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The PCP/PPI MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. PCP/PPI subcontracting costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP/PPI actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **PCP/PPI subcontracting** described in Annex 1
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[14]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[15] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed;

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agree otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories B.1.1, B.1.2, B.1.3 [and B.1.6]): the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of annual productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90 % of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or option (iii) above, i.e.:

-fixed number of hours;

-standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for during each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories B.1.1, B.1.2, B.1.4, B.1.5 [*and B.1.6*]): the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** ***[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[16]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[17] ***[OPTION 1 by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[18]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable****.]***

B.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]*[***OPTION 2***: *not applicable*]***]***.

Beneficiaries receiving an operating grant[19] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

B.5 ***[OPTION 1: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION *1a* ***for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *[***Insert name of specific cost category***[20]*** *] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units, [and if [insert additional eligibility conditions, if any]].***]***

[*same for each specific cost category****]***

[OPTION 2: *Not applicable****]***

[…]

14 This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

15 For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

16 To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

17 '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

18 For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

19 For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

20 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Additional coordination and networking costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as costs for additional coordination and networking activities related to the joint call for tender:

- direct personnel costs for additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for additional coordination and networking activities
- other direct costs for additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs must normally be **declared as** actual costs.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary MUST be declared as the unit cost fixed by Decision C(2013) 8197[117] and set out in Annex 2 and 2a of the GA.

This concerns only *beneficiaries* that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI MGA has however the **following specificities**:

[117] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the joint call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

1. *The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.*

2. *Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).*

3. *Costs for validation and testing of solutions provided by the subcontractors*.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the Main Work Programme, the costs of additional coordination and networking activities are eligible up to a maximum amount of 30% (for PCP)/50% (for PPI) of the total requested grant amount. For each GA, this ceiling is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP/PPI actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing financially to the joint procurement budget can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action). They form the buyers group.

Certain **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12)) are however ONLY allowed for **additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, **subcontracting** (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities.

Linked third parties (Article 14) may participate in all activities under the action.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION 1 for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('****place of performance obligation****').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[26];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[26] See Article 16(f) of Directive 2004/18/EC replaced by Article 14 of Directive 2014/24/EU, and Article 24(e) of Directive 2004/17/EC replaced by Article 32 of Directive 2014/25/EU..

1. PCP subcontracting

In PCP actions, the beneficiaries award PCP subcontracts for research and development services that are necessary to address a common challenge set out in Annex 1 (PCP R&D services). 'PCP

subcontract' thus means a contract for the purchase of R&D services (identified in Annex 1 as action task).

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries and linked third parties (buyers group), with a joint procurement in 3 phases

  The **buyers group** is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[118])

    Any entity that fits the definition of a contracting authority or contracting entity as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI actions.*

  – that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the Main Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the Main Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

[118] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is implemented in **3 phases**.

The buyers group must select multiple competing subcontractors (with a minimum of 3 subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum 2 subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a **common challenge** (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

  The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

  If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

  The procurement must be for an R&D services contract (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the Main Work Programme*).

  If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

  Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

  This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[119]).

  Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement (**common jointly-committed budget**)

  This budget is based on the financial commitments of the beneficiaries and linked third parties in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary (**lead procurer**)

[119] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is NOT part of the buyers group).

Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[120].

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors (PCP implementation)
- **Subcontractors** are **paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP actions).

There can only be one PCP per PCP action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

[120] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

For PCP subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 and phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

- the procurement must be preceded by an **open market consultation**

  This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[121].

  A prior information notice (PIN) must be published in the Official Journal of European Union (OJEU) and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

- the procurement must be based on **common procurement specifications** prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more information on the tender documents, *see the Guidance — How to complete your simap forms for PCPs and the template [ODT format] for PCP request for tenders.*

The template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions laid down in the grant agreement and it contains at least the information detailed in the template.

5. Additional cost eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases

[121] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the Main Work Programme)*
  - the obligation of the subcontractors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries (place of performance obligation)
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the Main Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions and without the right to sub-licence

    This right serves as a safeguard to ensure a competitive supply chain (during or after the PCP action) in case of problems. It does NOT mean that every subcontractor will always and automatically be obliged to grant non-exclusive licenses to third parties to exploit its results.

    Examples (licences needed): *other providers working for the buyers group need access to the IPR to work for the buyers group; a PCP subcontractor abuses its monopoly situation*

  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the Main Work Programme)*

    This right serves as a safeguard to ensure commercial exploitation in the public interest, in case the subcontractors fail to do so themselves. It will be for exceptional cases.
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2014/24/EU, 2014/25/EU[122] and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[123]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[124]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[122] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[123] *See Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.*

[124] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

[OPTION 2 for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint (or several coordinated) procurement procedure(s) by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and, 2004/17/EC (or 2014/25/EU).

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint (or coordinated) PPI procurement(s) ('**joint procurement agreement**');*

*(ii) **[OPTION 1 for PPI actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION 2:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION 1 for PPI actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) '**contract notice**'(s), which:*

- *are published by the lead procurer (or beneficiary) in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specify a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call(s) for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allow for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *are promoted and advertised widely;*
- *indicate how potential tenderers can obtain the tender documentation and the 'PPI request(s) for tenders';*

*and the **tender documentation** and **PPI request for tenders**.*

*(ii) **Step 2**: make one (or several) **evaluation(s) of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make one (or several) '**contract award notice**'(s), which are published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION 2 for PPI actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) **request(s) for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25//EU)[271] —:*

- *use technical specifications that are functional or performance based;*
- *avoid selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specify award criteria based on best value for money*

- *describe the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describe the arrangements for intellectual property rights*
- *describe the arrangements for liability for damages;*

(iv) ***Step 2:*** *make one (or several)* ***evaluation(s) of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24/EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[27] See Articles 28 and 31(2)(a) of Directive 2004/18/EU replaced by Article 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. PPI subcontracting

For PPI actions, beneficiaries award PPI subcontracts for procuring the innovative solutions that are necessary to address the common challenge set out in Annex 1 (PPI innovative solution(s)). 'PPI subcontract' thus means a contract for the purchase of innovative solutions (identified in Annex 1 as an action task).

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the **following specificities**:

There is no requirement to split the PPI procurement procedure in phases.

The beneficiaries may choose between implementing one single or several coordinated PPI procurements.

For joint procurements, there is one joint PPI call for tender launched by the lead procurer and one joint evaluation of offers.

For coordinated procurements, there are several separate PPI procurements carried out individually by the different procurers in the buyers group.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer (early adopter) of innovative solutions that are not yet available on a large-scale commercial basis.

PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.

Each PPI action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them together (i.e. the core functionality and performance characteristics must be the same; there may be additional local functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement (**common jointly-committed budget**) only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

For joint procurements:

- the buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts
- if there is no mandate, the general rule is that:
  - framework agreement(s) must be signed by all members of the buyers group together
  - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI actions).

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PPI subcontracting, there is NO 'simplified approval procedure' (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an **open market consultation** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[125].

[125] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

A prior information notice (PIN) must be published in the Official Journal of the European Union and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

The PIN must contain information on:

- the expected launch date for the call for tender

  This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP action) is sufficient.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

  Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

4. Additional cost eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions *(e.g. regarding access to background, licensing etc.)* if these:
    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and
  - price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2014/24/EU, 2014/25/EU[126] and 2009/81/EC normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2014/24/EU and 2014/25/EU[127]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[126] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[127] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU*(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[28]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24//EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
    - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
    - **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
    - ***[OPTION for PCP: an assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP)****]****;*
- ***[OPTION 1 by default (two pre-financing payments):*** *the coordinator must submit in month [**Y**] a progress report containing:*
    - *a '**periodic summary technical report**' for publication by the [Commission][Agency];*
    - *an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **<u>information on each subcontract financed by the procurement</u>**, including data on each contractor that participated in the procurement, and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[**OPTION 1 for PCP:** at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[**OPTION 2 for PPI:** at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed

When & What? For PCP/PPI actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after each intermediate evaluation of each PCP phase) — submit to the Commission/Agency:

- data on the total number of bids received
- the evaluation of tenders and its outcome (including the winning tenderer(s) and abstracts of the winning tenders)
- an assessment of the buyers group of the results achieved by each participating tenderer in the previous PCP phase.

This information must be updated by the coordinator at the end of the action, by submitting a list of all subcontracts financed (together with data on each contractor that participated in the procurement and overview of the results).

How? The information must be uploaded directly in the Participant Portal.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[38]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[39]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.2a <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities[.][;]

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment**, including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.3 Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

[…]

[38] Month X should be the end of the preparation phase and submission of second pre-financing request.
[39] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

When & What? For PCP/PPI actions, the coordinator has to submit — after the first reporting period (and, if there are 3 pre-financing payments, also after the second reporting period) — a **periodic technical report** with information on the technical implementation.

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 7*)

List of documents for the periodic report(s):

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- call for tender documents (including contract notice, invitation to tender and procurement contracts)
- report on outcome of the preparation phase *(e.g. open market consultation)*
- commitment on availability of funds (Annex 7)

  This ensures that the PCP/PPI subcontracting costs are covered.
- statement on the use of the previous pre-financing instalment (Annex 8)

At the end of the action, the coordinator has to submit a final report, with both a technical and a financial part.

How? Each (periodic or final) report must be **prepared** by the **coordinator** and the **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

Normally, PCP/PPI actions are divided into 2 reporting periods (with 2 pre-financing payments; *see Article 21*). The first reporting period corresponds to the preparation of the joint procurement; the second reporting period corresponds to the implementation and follow-up of the joint procurement.

Actions will exceptionally be divided into 3 reporting periods (with 3 pre-financing payments), if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments — No interim payments

Normally, PCP/PPI actions are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since PCP/PPI pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Amount of pre-financing payments

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for PCP/PPI actions are as follows:

- for the first pre-financing payment: the percentage of the maximum grant amount foreseen for the additional networking and coordination activities related to the preparation of the call for tender
- for the second pre-financing payment: a maximum of 90% (general limit for pre-financing payments; *see Article 21.2 H2020 General MGA*) minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP/PPI actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 MGA EJP Cofund deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing payment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 MGA EJP Cofund: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the Main Work Programme)*.

EJP Cofund actions are funded in all Parts of Horizon 2020 and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

For more information on the conditions for participation and funding, *see the Online Manual or the General work programmes and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[7] ('**starting date of the action**').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). The duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a].]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

For the FEJP action, there are moreover 3 additional specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Thus, the EJP Cofund MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);**][OPTION 2**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1 **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] *(**unit costs**).]***

[OPTION 2: specific cost category(ies)**: not applicable.]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.
14 Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.
15 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[128].

2. Cost forms

For EJP Cofund actions, the **cost forms** are in principle the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however 3 specific unit costs for category F 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [129]

[128] *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*
[129] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION 1 to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION 2:* *not applicable*;]**
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[16]***]][OPTION 2: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[16] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, EJP grants have the **following specificities**:

- for category A 'personnel costs'

  Costs of students, PhDs and other researchers (under scholarship, internship or similar agreement or under employment contract) — Are eligible even if the agreement is training-oriented (or work-oriented but with a non-negligeable training component), the costs fulfil the eligibility conditions set out in Article 6 and Annex 1 explicitly includes the training activities.

- for category D.2 'equipment costs'

  There is a special cost category for the FEJP action: full purchase cost for JET equipment *(see below)*.

- for category F 'specific cost categories'

  There are special cost categories for the FEJP action: specific cost categories *(see below)*.

The annotations below will be limited to these special cost categories for the FEJP action (and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated).

D. Other direct costs *[(not covered by Point F)]*

[…]

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme**[18]**:** The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

***[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018**: The **costs of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) **to be included in the JET facilities** are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** under category D.2 'equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional** cost eligibility **conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. *[OPTION 1: [Insert name of specific cost category(ies)]][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]*

[OPTION 1a for specific unit costs (if unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[22]] *are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION 2: *not applicable****]***

[…]

[22] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the Fusion programme EJP Cofund action (FEJP), there are however 3 additional specific cost categories set out in Decision C(2013) 8201[130] available:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

⚠ **Double funding risk —** Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 Specific cost category – costs for mobility of personnel (F.2)

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (⚠ irrespective of their duration) to another research institution, in a location other than their normal place of employment, by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance.

[130] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party, but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. category A 'personnel costs' or D.3 'other goods and services'; *see Article 6.2.A, 6.2.D.3*).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[131] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the daily subsistence allowance: **EUR 127.65**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[132]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
Germany	95.8	Slovakia	79.7
Germany Bonn	94.1	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.4	Sweden	131.9

[131] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[132] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6	United Kingdom	147.8
		UK Culham	112.5

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) are applied as from 1 January 2016:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	105.9	Italy	99.4
Bulgaria	52.1	*Italy Varese*	92.2
Croatia	74.6	Latvia	74.2
Cyprus	77.3	Lithuania	69.0
Czech Rep.	73.4	Malta	84.5
Denmark	131.8	Netherlands	107.8
Estonia	78.0	Poland	71.8
Finland	119.7	Portugal	79.2
France	114.6	Romania	64.8
Germany	96.6	Slovakia	76.4
Germany Bonn	93.4	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.0	Sweden	131.9
Greece	79.9	*Switzerland*	142.4
Hungary	69.0		
Ireland	116.6	United Kingdom	166.9
		UK Culham	127.7

– for the monthly subsistence allowance: between **EUR 0 and 720.27**, per individual per month **—** depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**

> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1300	**601.73**
> 2000	**720.27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 252.81**, per dependent child per month).

The European Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this case, the FEJP GA will be **amended** (and the Annotated MGA will be revised accordingly).

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. category D.1 'travel'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and
  - one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
    - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127.65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

- the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment
- to this amount, add the following for each leg of the journey (outward and return):
  - for train travel: a maximum of 30 minutes for each leg
  - for air travel: a maximum of 2 hours for each leg.

  NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

- for the monthly subsistence allowance:

  amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

- for the family allowance:

  amount per unit (EUR 252.81) **x** number of actual months of secondment **x** number of dependent children

  The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

  '**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

  A full month can be one of the following two:

  - a **calendar month** *(e.g. 1 to 31 July inclusive)* or
  - a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

  If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127.65 = EUR 77 738.85*

*Monthly subsistence allowance: 20 months * EUR 382.92 (800< distance >1 300) = EUR 7 658.40*

Subtotal = EUR 85 697.25

** correction coefficient (2016) of 106.0 % (Germany Munich) = EUR 90 839.09*

*Family allowance: 20 months * EUR 252.81 = EUR 5 056.20*

Total declared unit costs: EUR 95 895.29

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127.65 = EUR 382.95*

** correction coefficient (2016) of 127.7 % (Culham, UK) = EUR 489.03*

Total declared unit costs: EUR 489.03

1.2 Specific cost category – costs for fellowships for researchers (F.2)

1.2.1 What? This budget category **covers** direct costs for FEJP researcher fellowships, by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility.

What not? This budget category does not cover direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; *see Article 6.2.E*).

1.2.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[133] and set out in Annexes 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

  This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [134]:

Country	Coefficient	Country	Coefficient
Austria	104.8%	Italy	106.7%
Belgium	100.0%	Lithuania	73.1%
Bulgaria	71.5%	Luxembourg	100.0%
Cyprus	91.8%	Latvia	75.9%
Czech Republic	83.8%	Malta	89.6%
Germany	98.8%	Netherlands	104.3%
Denmark	135.3%	Poland	76.4%
Estonia	78.3%	Portugal	89.1%
Greece	92.7%	Romania	68.3%
Spain	97.6%	Sweden	111.7%

[133] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[134] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

Finland	116.6%	Slovenia	86.1%
France	111.0%	Slovakia	82.6%
Croatia	97.5%	United Kingdom	120.3%
Hungary	76.2%		
Ireland	113.5%	Switzerland	113.1%

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[135]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

[135] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 Specific cost category – access costs for research infrastructure (F.2)

1.3.1 What? This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4 H2020 General MGA)*. FEJP beneficiaries that that have obtained a positive ex-ante assessment may opt between declaring costs under:

- category D.4 'capitalised and operating costs of large research infrastructure'

or

- category F.2 'access cost for research infrastructure'.

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, under category D.1 'travel'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be **declared as** the unit cost calculated in accordance with Decision C(2013) 8201[136] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{137}\text{)}}{\text{average annual total quantity of access (over past two years}^{138}\text{)}}$$

The averages must be based on:

[136] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf

[137] In exceptional and duly justified cases, the Commission may agree to a different reference period.

[138] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 of the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing*)* specifically awarded to keep the installation functioning normally
  - costs of consumables specifically used for the installation and the users' research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*
  - costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access
  - depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds
  - renting or leasing the equipment, buildings and other assets that are part of the installation

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

- depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)
- travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

As already mentioned above, access costs for installations contributed in-kind must be declared as actual costs under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

When & What?

For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission/Agency (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How?

The annual work plan must be uploaded directly in the Participant Portal.

2. Deliverable: Summary progress report

When & What? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the explanation of the work carried out and the overview of the progress; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION 1 in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing payment****' (see Annex 8).****]***

[OPTION 2: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports and a final report, with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **5** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing payment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a statement on the use of the first pre-financing payment *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a *[first]* **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a *[first]* pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to ***[OPTION 1 in case of a single pre-financing payment:*** *5%]****[OPTION 2 in case of two pre-financing payments:*** 2,5%*]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

[OPTION in case of a second pre-financing payment: *The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary: *The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 = net payment of EUR 3 250 000*

1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2.5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Amount of pre-financing payments

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU budget credits)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

Framework partnerships are **long-term co-operations** that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)) and for PCP/PPI actions. Framework partnerships are currently not (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

4.0 As from GA 4.0 FPA/SGAs are also possible for PCP/PPI actions. This does NOT apply to older grant agreements.

> ⚠ The FPA/SGA therefore now covers both research and innovation actions or innovation actions *with* a PCP or PPI and PCP/PPI actions (separate type of action with PCP/PPI as *main* action task).

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

Table of correspondence

Title of Article	FPA Article	SGA Article	MGA Article
CHAPTER 1 GENERAL			
SUBJECT OF THE AGREEMENT	1	1	1
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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement)
- Article 63.2 (FPA/SGA rules on dispute settlement).

For more information on framework partnerships*, see the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name** (**short name**)**]**, established in [official address in full] ***[OPTION for partners with VAT**: VAT number [insert number],] [**OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding (see Article 14),]* represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] (**short name)**], established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number],]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not receiving EU funding (see Article 14),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties have agreed to enter into the framework partnership under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Participants: Coordinator — Partners — Linked third parties — Third parties involved in the action

In FPAs and SGAs the beneficiaries are called '**partners**' (because technically speaking they become beneficiaries only once an SGA is signed).

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. However, partners/linked third parties that do not want to actively participate in a specific action, may participate as **partners not carrying out action tasks** and will not have to comply with most of the obligations under that SGA *(see Preamble SGA).*

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed directly in Participant Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as '**third parties involved in the partnership**'.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions ('**third parties involved in the specific actions**').

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION 1 by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION 2 if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across partners of different framework partnerships]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and the Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions ('**action plan**').

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all Parts of Horizon 2020.

4.0 Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2)* and PCP- PPI actions; Framework partnerships are currently NOT (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options are inserted in the FPA):

- **calls for proposals open to all partners** for which this type of activity is included in the action plan

  Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

  Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

- **calls for proposals open to all applicants** meeting the criteria

Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **invitations to submit a proposal**

  Such invitations can only be issued in one of the following cases:

  - in monopoly situations or where partners are designated in the basic act
  - in if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
  - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals

- **submission** of a proposal **by a certain date**

  This option can be included in the FPA only if it is provided for in the work programme/call.

  The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 Rules of Application Regulation No 1268/2012).

1. Starting date of the framework partnership

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA.

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Framework partnership duration

The framework partnership duration may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Programme)*.

The FPA duration can NOT be extended (i.e. it is not possible to request an amendment extending the duration). The duration of an FPA only determines the moment up to which SGAs can be signed. The SGAs can still be implemented after the end of the framework partnership.

All SGAs must be signed before the end of the FPA.

⚠ Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA has ended.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

[OPTION 2:** Not applicable**]

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — **specific consortium agreements for each SGA**. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the framework partnership implementation is suspended, all specific actions are also suspended (see Article 55) — from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to GA suspension *(see Article 49 H2020 General MGA)*.

FPA suspension automatically supends all on-going specific actions.

Amendments (to resume the action) after a suspension can NOT have the effect of extending the FPA duration set out in Article 3 FPA.). The duration of an FPA only determines the moment up to which SGAs can be signed An SGA can be implemented *after* the end of the framework partnership.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. FPA termination

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ FPA termination has NO effect on ongoing SGAs (— unless they are also terminated; *see Article 56 FPA and Article 20 SGA*). Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA is terminated.

2. Partner termination

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ **Different partners at FPA and SGA level (exceptional)** — Partner termination will exceptionally lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners/linked third parties can participate as partners not carrying out action tasks for certain specific actions.

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also shows, if applicable, the estimated costs of the partners not receiving EU funding, if applicable (see Article 7 SGA) and of the international partners (see Article 12a SGA).

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and* ***forms of costs*** *of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions, applicable per budget category, are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **eligibility conditions** and **calculation rules**.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, eligibility conditions and calculation rules of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

Linked third parties must already be identified in the FPA *(see Article 19 FPA)*. Their specific activities must then be set out in the specific actions.

Examples:

1. *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

2. *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like the partner they are linked to.

Linked third parties can NOT however do more than their partners: If a linked third party wants to participate in a specific action, its partner must also be active in that action (i.e. NOT be partner not carrying out action tasks). If the partner does not want to, the linked third party could itself become a partner of the FPA and SGA (— after the consortium composition is changed).

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the Agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the Agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must first submit a request for the FPA amendment (which will automatically include the change in the consortium composition for the SGAs — the new beneficiary is added (automatically) as 'inactive' to all signed SGAs under that FPA).

The coordinator must then request for each SGA a separate amendment to activate the new beneficiary *(e.g. to change Annex 1, Annex 2)*.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

63.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Framework Partnership Agreement or a Specific Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU partners (except partners established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU partner(s) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for partners not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: As an exception, *for the following partners:*

- *[insert name of international organisation or partner not eligible for EU funding]*
- *[insert name of international organisation or partner not eligible for EU funding]*

[same for other partners that are international organisations or partner not eligible for EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Framework Partnership Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 50, 51 and 52), the partners must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must always be brought against the Commission (not against the Agency — even in Agency specific grants).

1. Dispute settlement

The rules on dispute settlement are similar to those of the General MGA *(see Article 57.2 H2020 General MGA)*.

However for FPAs, the Commission/Agency will determine already at FPA-level which partners must participate as 'beneficiaries not receiving EU funding' — because of a general issue with the jurisdiction clause (i.e. Belgian courts). Those beneficiaries can NEVER receive EU funding.

All other partners' status will be determined at SGA-level. Thus, partners from eligible countries (EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme) may participate as normal partners or as 'partners not receiving EU

funding'. Partners from non-eligible countries may participate as 'partners not receiving EU funding' or — exceptionally — be granted funding.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name** (**short name**)],established in [official address in full], *[**OPTION for partners with VAT:** VAT number [insert number]], [**OPTION for coordinators not receiving EU funding:** as 'partner not receiving EU funding' (see Article 7),]* represented for the purposes of signing the Specific Agreement by [function, forename and surname],

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 FPA and Article 62 FPA):

2. [**full official name**] (**short name**)], established in[official address in full], *[**OPTION FOR partners with VAT:** VAT number [insert number]],*

***[OPTION for partners not carrying out action tasks under this SGA:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not carrying out action tasks',]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT :** VAT number [insert number]], as 'partner not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 5)].*

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Additional information on the estimated budget

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[OPTION if the JRC participates: *Annex 5: Administrative Arrangement]*

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Partners — Partners not carrying out action tasks under the SGA — Linked third parties

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

⚠ **Same partners at FPA and SGA level** — Partners must generally be the same at FPA and SGA level. An entity that is not partner/linked third party in the FPA cannot become party in the SGA. Conversely, all partners/linked third parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners (and linked third parties) who do NOT actively participate in a specific action are **partners not carrying out action tasks** under that Specific Agreement (and must be identified as such in the preamble to the SGA).

⚠ **Partners not carrying out action tasks —** They formally participate in the action as partners, but NOT with any action tasks or EU funding. In practice, most of the obligations therefore do not apply to them for that specific action.

Linked third parties — If a partner participates as not carrying out action tasks, its **linked third parties** get the same status. They can NOT actively participate in the specific action (— unless they themselves become partners of the FPA and SGA).

These partners are formally part of the consortium for the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will be identified in Annex 1 as 'partners not carrying action tasks' (as they do not carry out any action tasks). Moreover, they will also be mentioned in Annex 2 with zero costs.

Formally, the rights and obligations under the FPA and SGA fully apply to them. In practice however, many of them *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, financial or technical audits or reviews, IPR results, access to background and results of others, etc.)* are NOT applicable because these partners do not carry out action tasks and do not receive any EU funding. Other obligations remain relevant *(e.g. checks, information obligations, confidentiality)*.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed directly in the Participant Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including **linked third parties**) are considered as '**third parties involved in the specific action**'.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

Same partners at FPA and SGA level — If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump sum MGA

IX.1 Background information and approach

The Lump sum Model Grant Agreement (H2020 MGA Lump sum) is used mainly for coordination and support actions (CSA) and, exceptionally, for research and innovation actions (RIA) and innovation actions (IA) — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5*

The MGA Lump sum follows the General MGA for numbering and content, except for:

The H2020 MGA Lump sum deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5, Annexes)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 MGA lump sum: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

1. CSA, RIA and IA lump sum actions

What? Lump sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for a lump sum grant.

> For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Online Manual and the H2020 grants fact sheets on the Participant Portal.*

CSA, RIA and IA lump sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of Horizon 2020 *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The MGA Lump sum does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the MGA Lump sum:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA): 70%** of the action's eligible costs]*[8]*[**OPTION 3 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The MGA Lump sum does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For Lump sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For Lump sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The MGA Lump sum has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the action (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs' **covers** the (direct and indirect) costs for the action.

> ⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice the declaration of costs for Lump sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

Since the Lump sum grant consists in a lump sum, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

⚠ If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION—THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable.

The rules on third party involvement in lump sum actions are limited to purchases (Article 10), subcontracting (Article 13) and **linked third parties** (Article 14 H2020 General MGA).

The provisions on in-kind contributions (Articles 11 and 12 H2020 General MGA) do NOT apply — since, for Lump sum grants, in-kind contributions are not linked to any specific conditions. (Specific rules are only needed where a grant reimburses *actual* costs).

For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[9] (or 2014/24/EU)[10] or 'contracting entities' within the meaning of Directive 2004/17/EC[11] (or 2014/25/EU)[12] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).
[10] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).
[11] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).
[12] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for Lump sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for lump sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The MGA Lump sum has however the **following specificities**:

The estimated costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]* ***[OPTION 2 for low value grants[18]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For lump sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action's tasks (as described in Annex 1) were properly carried out.

Such records and supporting documentation must:

- refer to the scientific and technical implementation of the action in line with the accepted standards in the respective field *(see Article 18 General MGA)* and
- prove that the corresponding tasks or part of the action allocated to the beneficiary as described in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.2a Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a **'statement on the use of the previous pre-financing instalment',** including **the request for a further pre-financing payment** (Annex 7).

20.3. Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2 :*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

When & What? For lump sum actions, the coordinator has to submit — after each reporting period — a **periodic technical report**, with information on the technical implementation.

NO financial report is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; *see Article 7*).

List of documents for the periodic reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

At the end of the action, the coordinator has to submit a **final report** with both the technical and financial report.

2. Reporting periods

When? The lump sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- a *[first]* **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- *[same for more pre-financing payments]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2a if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments — No interim payments

Lump sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Amount of pre-financing payment(s)

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.

The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:

- if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
- if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

Example:

Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.
90% limit of the maximum grant amount: EUR 360 000.
3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.
Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.
2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;
3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;
*Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
*70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000
3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.

3. Amount of the payment of the balance

The amount of the payment of the balance depends on the overall financial situation at the end of the action, and in particular:

- the amount of pre-financing(s) already paid *(see Article 21 H2020 General MGA)*
- cost rejections (improper implementation of the action; *see Article 42)*
- grant reduction (other serious breaches or substantial errors, irregularities or fraud *see Article 43)*.

ARTICLE 41 — BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Agency][Commission]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for lump sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs does not lead to a **recovery,** *[Commission][Agency]* will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since Lump sum grants consist in a lump sum, the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1).* Improper implementation therefore leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide requested information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since Lump sum grants consist in a lump sum, 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*. The grant may thus be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Agency or the]* Commission*]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION 2 :*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or]* ***[OPTION 2:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The lump sum multi-beneficiary MGA has, however, the **following specificities**:

Since the coordinator alone is financially responsible (for the entire grant) the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide requested information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Article 43 and Article 44).

1. GA suspension (beneficiaries or Commission/Agency)

The rules on GA suspension are in principle the same as for the General MGA (see *Article 49 H2020 General MGA)*.

The lump sum MGA has, however, the **following specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION 2:** not applicable]*;

(j) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION 2:** not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2).

*(n) [**OPTION 1**: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][**OPTION 2**: not applicable].*

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n)above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the [Commission][Agency]

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) ***[OPTION 1****: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][****OPTION 2****: not applicable].*

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or to beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (beneficiaries)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for actions under lump sum actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Partner termination (beneficiaries)

The rules on partner termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the lump sum multi-beneficiary MGA has the **following specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. GA or beneficiary termination (Commission/Agency)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the multi-beneficiary MGA Lump sum has the **following specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

H2020 Programme

AGA – Annotated Model Grant Agreement

Version 5.0
3 July 2018

Disclaimer
This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the its executive Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	▪ Initial version following adoption of the grant agreement v.1.0. Article 6.
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to H2020 Work Programme (section 3 MSCA) (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement v.2.0, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSCA ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles
2.0	30.03.2015	▪ Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. ▪ Clickable cross-references (Articles) ▪ New table explaining the treatment of the different types of work contracts (under Article 6.2.A). ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. ▪ Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 ▪ Other minor corrections and clarifications
2.0.1	18.05.2015	▪ Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants

2.1	30.10.2015	▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47, 50, 55 and 56. ▪ New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses ▪ New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Ph1 Lump Sum: Article 5; – SME Instrument Ph2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. ▪ Other minor corrections and clarifications.
2.1.1	01.07.2016	▪ Update of the explanations on Article 18 regarding time records; including a model of time-sheet with the minimum requirements.
2.2	25.11.2016	▪ Updates due to the amendment of the model grant agreement v.3.0, in particular Articles 4.2, 5, 6.2.A, 10, 13, 16, 20, 34, 37, 41, 42, 43, 45, 46, 48, 49, 50 and 55 ▪ New annotations on Articles 29.2 and 29.3. ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6, 6.1, 6.2, 6.5 and 18. ▪ Updates in the annotations to specific model grant agreements: - ERC: Preamble, Articles 6, 29 and 56a - MSCA: Preamble ITN, Articles 4, 5, 6, 8, 18, 19 and 32; IF Articles 2, 4, 6, 8, 18, 32 and 56a; RISE Articles 4, 6, 8, 18, 19, 31 and 32; COFUND Articles 4, 6, 8, 15 and 18. - ERA-NET Co-fund: Articles 2, 19 and 21 - PCP-PPI: Articles 5 and 13 - EJP Co-fund: Articles 5, 6.F and 20 ▪ Synchronised presentation for grounds for Chapter 6 measures, security obligations and information obligations. ▪ Other minor corrections and clarifications ▪ Update in Section I.3 'List of issues applicable to particular countries' New rules that apply in principle only for grant agreements signed with version 3.0 are marked with 3.0 » (This version refers to MGA v3.0 to align it no AGA v3.0 was created)
4.0	21.04.2017	▪ Updates due to the amendment of the model grant agreement v.4.0, in particular Articles 5, 6 and 52 ▪ New annotations on Article 14a following the introduction of this Article in the revised model grant agreements v.4.0 ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6 and 18. ▪ Updates in the annotations to specific model grant agreements: ERC, MSCA, PCP-PPI and FPA/SGA ▪ Other minor corrections and clarifications New rules that apply in principle only for grant agreements signed with version 4.0 are marked with 4.0 »
4.0.1	20.06.2017	▪ Addition of index at the bottom of the pages
4.1	26.10.2017	▪ New explanations and examples, in particular in Articles, 6.2.F, 18,

		50 and 55 of the general MGA ▪ Corrigendum of annotations on Article 6 of the MSCA-ITN, IF, Cofund and the MSCA-RISE grants ▪ Corrigendum of annotation on Article 6.2.F of the EJP Cofund grant ▪ Update in Section I.3 'List of issues applicable to particular countries' ▪ Other minor corrections and clarifications
5.0	03.07.2018	▪ Updates due to the amendment of the model grant agreement v.5.0, in particular Articles 29.3 and 34 ▪ New presentation of calculations for payments and recoveries, now compiled under Article 21 ▪ Updates due to the adoption of the Guide on grant reductions ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 6.2.A, 6.2.D, 11, 14a, 43, 44, 48, 49, 50.3, 51, 55 and 57.2. ▪ Annotations on the new Lump Sum Pilot model grant agreement ▪ Annotations on the new MSCA Special Needs model grant agreement ▪ New annotations and updates in the specific model grant agreements: – ERC: Articles 18, 29 and 32 – MSCA: ITN Articles 6.2.a, 6.2.B, 32; IF Articles 6.2.A, 6.2.B, 18, 32, 55.1, 56a; RISE Articles 6.2.A, 32 and Co-fund Articles 6.2.A and 15 – SME Phase 1: Article 8 – PCP/PPI: Article 8 – SGA: Article 3 – General lump sum: preamble, Articles 8 and 18 ▪ Other minor corrections and clarifications For easy identification, paragraphs, indents or sections with new explanations are marked with the symbol ■ on the left.

IMPORTANT NOTICE

The **AGA — Annotated Model Grant Agreement** is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement (General MGA) and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020 (H2020).

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and eligibility conditions of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

   New rules that do not apply to all signed grant agreements (but instead only to those signed after a certain version, e.g. version 3.0), will be marked with: 3.0 and 3.0

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the H2020 MGAs. For a more general overview of how H2020 grants work, *see the Participant Portal Online Manual*.

A comprehensive list of all H2020 reference documents (including legislation, work programme and templates) can be found on Participant Portal Reference Documents.

H2020 terms are explained in the Glossary.

If necessary, you can also contact the Research Enquiry Service.

Legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

Examples: *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1 'Health, Demographic Change and Wellbeing', etc.*

⚠ **Specific MGAs —** The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**] established in [official **address** in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full]* ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]* *as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties**]***
	[OPTION if the JRC participates: *3b Administrative Arrangement**]***
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

Beneficiaries means the legal entities who have signed the grant agreement (GA) with the Commission/Agency (i.e. participate in a project supported by an EU grant).

⚠ The term **participant** is used in this document in a wider meaning than in the definition of Article 1.1(15) of the Rules for Participation Regulation No 1290/2013. It covers normally beneficiaries and linked third parties (and sometimes also other third parties involved in the action).

The **coordinator** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 (technical implementation) and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including **linked third parties**, international partners, subcontractors, third parties giving in-kind contributions, etc.) are considered as **third parties involved in the action** (for the definitions and conditions, *see Articles 8 and 9-14a*).

Their involvement in the action varies depending on the role.

Since there is no formal contractual link with them, they are formally speaking not bound by the terms and conditions of the GA. However, by participating in the action and via the obligations on their beneficiary, they are indirectly bound to many of the GA obligations.

⚠ The consortium set-up must follow the roles of the GA. Participants should be attributed their roles according to their real contribution to the project. The main actors should be the beneficiaries. All other roles (third parties) should perform secondary tasks.

This means for instance that:

- linked third parties — are allowed to *fully* participate in the action, like the beneficiary they are linked to; they will therefore be treated for many issues (including cost eligibility; *see Article 6.3*) like beneficiaries
- subcontracting — beneficiaries/linked third parties may NOT subcontract tasks to other beneficiaries/linked third parties
- coordinator tasks — the key coordinator tasks listed in the GA may NOT be subcontracted or delegated to any other beneficiary or linked third party (except, under certain circumstances, to an entity with 'authorisation to administer')
- in-kind contributions between beneficiaries/linked third parties — if beneficiaries/linked third parties give in-kind contributions to other beneficiaries/linked third parties, their cost should normally simply be declared by the contributing beneficiary/linked third party (if the contributions are particularly important for the project, it may however be advisable to specifically mention them in the description of the action).

For an overview on the different types of third parties and their GA roles, rights and obligations, *see the table in Article 8*.

2. Name and address — Legal entity data

The legal entity data (legal name, address, legal representatives, etc.) of the beneficiaries comes from the Participant Portal Participant Register (former Beneficiary Register).

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries (via their **legal entity appointed representative (LEAR)**) must keep their **data** in the Participant Portal up-to-date at all times including after the end of the grant (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[1]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[2]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[3].

[1] More information on the types of action can be found on the General Annexes to the Work Programme.

[2] For the definition, *see Article 2.1(6) of the Rules for Participation Regulation No 1290/2013:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[3] For the definition, *see Article 2.1(7) of the Rules for Participation Regulation No 1290/2013:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may

⚠ The term **action** comes from the Financial Regulation No 966/2012 and **means project**. (Previous EU Research Framework Programmes used project.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of Horizon 2020 *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

ℹ For more information on RIA, IA and CSA actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

2. Complementary grants

'Complementary grants' are different EU grants which are linked by the work programme/calls by identifying them as complementary actions.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written **collaboration agreement** regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a non-associated third country (i.e. a third country not associated to Horizon 2020) or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[4]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 of the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a **coordination agreement** *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

ℹ For guidance on coordination agreements, *see How to draw up your coordination agreement.*

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also include complementary activities of networking and coordination between programmes in different countries.

[4] *See Article 12 of the Rules for Participation Regulation No 1290/2013.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The action starting date is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties (retroactive)

  Example: *GA signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium requests a fixed starting date before the entry into force of the GA, it assumes the risks implied by starting the action before the GA is signed (in particular not being reimbursed for the costs incurred, *e.g. if the proposal is not successful or that the GA is not signed*).

  The action starting date can **NEVER** be **before** the **submission** of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The action duration is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the ***action tasks*** (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as project closure or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2: Moreover, *lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding and costs of international partners will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9 and Article 14a)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

⚠ Costs for personnel, equipment, goods or services that are in-kind contributions by a third party (for free or against payment) can in practice simply be added to the budget category they correspond to (i.e. personnel costs or other direct costs) — if they comply with the eligibility rules set out in Articles 6 and 11 and 12.

3. Budget transfers (budget flexibility)

The budget in Annex 2 is an estimation.

⚠ **Budget flexibility** — The budget is in principle flexible (with the exceptions set out below).

Be however aware that the budget table will be used for the calculation of grant reductions *(see Article 43)*.

Beneficiaries may transfer budget among themselves, between linked third parties or between budget categories (without requesting an amendment; *see Article 55*) and — at the time of reporting — declare costs that are different from the estimated budget.

⚠ The maximum grant amount *(see Article 5.1)* can however **NOT** be **increased**.

What? If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example: *The estimated budget includes personnel costs of EUR 60 000 for Beneficiary A and EUR 75 000 for Beneficiary B. However, at the end of the action, the actual personnel costs of Beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of Beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of Beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)

Total possible transfer to another budget category: EUR 2 000

What not? The GA allows transfers of budget, NOT of **tasks**.

Moreover, a beneficiary can NOT transfer budget to a **form of costs** that it did not set out **in its estimated budget** — except within the personnel costs category and to costs of internally invoiced goods and services (*Article 6.2.D.5*).

Example (allowed transfer): *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is acceptable without an amendment of the GA.*

Example (not allowed transfer): *A beneficiary budgets all its costs as 'actual costs' in the estimated budget. However, at the end of the first reporting period, the beneficiary wants to declare part of the costs by using a specific unit cost allowed in the call (e.g. unit cost for clinical studies). This is NOT possible without an amendment of the GA.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work ('action tasks') of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %*** *of the action's eligible costs]* ***[OPTION 2 for innovation actions (IA)[7]: 100%*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities[8] and* ***70%*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]* ***[OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA:*** *[…%] of the action's eligible costs]****[OPTION B for IA:*** *[…%] of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities[9] and […%] of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]]*** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6**)** must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))][10]*:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))][10]*: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][12]: ***[OPTION 1 to be used if Article 15 applies:*** *as actually incurred costs (****actual costs****);]****[OPTION 2****: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))][13]*:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))][14]*: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a[16] ('**unit costs**').]*

***[OPTION** 1b **for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION 2: specific cost category(ies):** not applicable.]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

10 To be used only if option in Point (f) is used.

11 To be used only if option in Point (f) is used.

12 To be used only if option in Point (f) is used.

13 To be used only if option in Point (f) is used.

14 To be used only if option in Point (f) is used.

15 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

16 Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount will **NOT** be **increased** — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA and CSA actions is normally **100%** of the total *eligible* costs[5]; for IA actions it is normally **70%** of the total eligible costs[6].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[7].

5 *See Article 28(4) of the Rules for Participation Regulation No 1290/2013.*

6 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rate of a beneficiary does NOT condition the reimbursement rate of its linked third parties.

Example: *The beneficiary is entitled to 70 % but it has a linked third party entitled to 100 %. The linked third party will have a reimbursement rate of 100 % — despite the lower reimbursement rate of the beneficiary to which it is linked.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

⚠ The grant can **NEVER** reimburse **more** than the maximum grant amount fixed in Article 5.1.

3. Cost forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump sum costs)[9]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - **personnel** costs (— unless declared as unit cost; *see below*)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs** (— unless declared as unit cost; *see below*)

    Example: *EUR 2 000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - personnel costs of **SME owners/natural persons** not receiving a salary[10]
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)[11]
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices

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7 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*
8 *See Article 28(6) of the Rules for Participation Regulation No 1290/2013.*
9 *See Articles 123, 124 of the Financial Regulation No 966/2012.*
10 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.
11 *See Article 33(2) of the Rules for Participation Regulation No 1290/2013.*

- specific unit costs for:
  - costs for **energy efficiency measures** in buildings[12]
  - **access costs** for providing trans-national access to research infrastructure[13]
  - costs for **clinical studies**[14]
- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; ⚠ new in Horizon 2020)[15]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

Example: *EUR 150 000 to carry out a study within an action*

The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	Budget categories					
	Direct personnel costs	Direct costs of sub-contracting	Direct costs of financial support to third parties (option used if Article 15 applies)	Other direct costs	Indirect costs	Specific cost categories (option used if Article 6.2 (F) applies)
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: - costs established according to the usual cost accounting practices of the beneficiary - costs of SME owners and natural	NO	NO	YES, only for: costs of internally invoice goods and services	NO	YES, only if foreseen by Commission Decision

[12] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[13] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

[14] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[15] *See Article 29(1) of the Rules for Participation Regulation No 1290/2013.*

	persons not receiving a salary					
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the **errors, irregularities or fraud** or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action— as part of the calculation of the payment of the balance.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex 1

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 of the GA.
- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

The procedure for the final payment and detailed calculations are described in Article 21.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, substantial errors, irregularities or fraud or serious breach of obligations (and therefore **rejects costs** and/or **reduces the grant**), it will revise the final grant amount, for the beneficiary concerned and, if needed, make a recovery.

The detailed calculations are described in Article 21.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only** reimburse **eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Article 6.1 refers to general eligibility conditions, applicable per cost form *(see Article 5)*.

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity)).
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

  Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action (or after GA termination) are not eligible.

  Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

  ⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e. be in line with good housekeeping practice when spending public money and not be excessive)

  'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

  Examples:

  1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

  2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

3. *Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible, if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements (CFS) required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

Personnel costs for ERA chairs — Are eligible even if the salary is above national salaries, provided that it does not go beyond normal EU/international salaries for similar positions (since the ERA chairs aim to incentivise international mobility for internationally outstanding researchers and research managers. When the level of remuneration of the ERA Chair is indicated in Annex 1, this will be duly taken into account in case of checks, audits or reviews.

Costs to allow for the participation of disabled people *(e.g. costs for sign language interpreters required for dissemination events organised under the action)* — May be eligible if they fulfil the general and specific eligibility conditions listed under Articles 6.1 and 6.2. The beneficiaries must keep records *(see Article 18)* to prove in case of an audit, check or review the actual costs incurred and that they were necessary for the implementation of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2a.*

- the **number of units** must be **necessary** for the action
- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

> ***Example:*** *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Costs declared on the basis of the usual accounting practices— For two budget categories (A. personnel costs and D.5 costs of internally invoiced goods and services), costs may be declared not as a fixed unit cost, but on the basis of the beneficiary's usual cost accounting practices. In this case,:

- the beneficiary:
  - must calculate the costs according to its usual accounting practices
  - must budget and declare a total amount (not the units used)
- the amount per unit is not fixed in Annex 2a.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency and set out in Annex 2a of the GA *(see Article 5.2)*.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump sum costs).

> ***Example (25 % flat rate for indirect costs):***
>
> *A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR 30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.*
>
> *Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900*
>
> *Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600*
>
> *Total eligible costs: 11 900 + 2 600 = EUR 14 500.*
>
> *Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.*

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and

- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION 1 for specific unit[/lump sum] costs*:** *[insert name(s) of specific cost category(ies)[16]]*][***OPTION 2:*** *not applicable*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to **specific eligibility** conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

– either costs that have been caused in full by the activities of the action

- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action can NOT be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a **25% fixed flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

*[A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]]*

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual** costs (i.e. budget categories A.1, A.2, A.3 [*and A.6*]): the hourly rate is calculated per full financial year, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories A.1, A.2, A.4, A.5 [*and A.6*]): the hourly rate is one of the following:

(ii) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

1. Direct personnel costs (A.): Types of costs — Forms — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Employees (or equivalent) (A.1)

1.1.1 What? Personnel costs for employees or equivalent (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) that worked in the action.

⚠ '**Equivalent appointing act**' means the appointing acts of civil servants (who do not sign employment contracts but receive official nominations for their posts).

⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Reliable time records will normally be sufficient proof of the assignment to the action — unless there is other contradicting evidence *(e.g. the employment contract indicates that the person was hired to work on another project)*

It covers (and is limited to):

- **basic remuneration** (i.e. the payments for the employee's normal work and participation in projects — up to what is the beneficiary's usual remuneration practice for national projects)

and, in addition:

- for non-profit legal entities: **additional remuneration** (i.e. extra payments made for the participation in projects — above the beneficiary's usual remuneration practice for national projects).

⚠ **National projects** are to be understood in the large sense, meaning all types of projects funded under any type of national (public or private) funding scheme (including projects co-financed by EU funds that are managed by the Member States, *e.g. regional funds, agricultural and fisheries funds*).

Projects from EU programmes directly managed by the Commission/Agencies or their funding bodies *(e.g. LIFE, ERASMUS, Health, etc.)* do not, however, qualify as national projects (but as EU/international projects).

Both basic remuneration and additional remuneration do not only cover the payment itself (salary or bonus), but also the social security contributions *(mandatory employer and employee contributions)*, taxes included in the remuneration *(e.g. income tax)* and other costs and payments included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee).*

What not? Cost of persons who work for the beneficiary, but NOT with an employment contract or equivalent appointing act *(e.g. staff provided by a temporary work agency, seconded staff, self-employed persons with a direct contract with the beneficiary)*.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions *(e.g. best value for money and no conflict of interest; see Articles 10 and 13)*.

Seconded staff and **self-employed persons with a direct contract —** Can also be declared under other categories within the personnel costs *(see below, points 1.2 and 1.3)*.

1.1.2 Costs for employees (or equivalent) must be **declared** as:

- **actual personnel costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.1.3 The costs for employees (or equivalent) must comply with the following **eligibility conditions**:

For basic remuneration:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are NOT eligible under *Article 6.5(a)(i)*. However, bonuses based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted, if they fulfil the conditions set out below, i.e. as part of the usual remuneration practices for national projects and thus eligible as basic remuneration.

  Examples (positive):

  If the profit of the company at the end of the year is more that x € (or more than x %), each employee will receive a bonus of z % of his/her basic remuneration (or a fixed bonus of x € more as part of the gross salary).

  Examples (negative):

  If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.

  Any part of the remuneration which is based on commercial targets or fund raising targets is NOT eligible (because neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation).

  ***Examples**: x € for reaching a sales target; x % on sales; x € premium per externally funded project gained; x % of the external funding gained*

- be paid in accordance with national law, the collective labour agreement and the employment contract/equivalent appointing act

  Examples:

  ***1.** The collective labour agreement establishes that all researchers may receive a bonus between EUR 100 and EUR 200 per month based on their seniority.*

  ***2.** The national law authorises public universities to pay a bonus based on merit of the employees.*

  ***3.** The contract fixes a premium of EUR 1 000 for each research paper published in peer-reviewed international research journals.*

- **exclude arbitrary bonuses** (i.e. bonuses which are not part of the beneficiary's usual remuneration practices and/or which are not based on objective conditions).

For additional remuneration (in addition to the conditions above):

- be a **non-profit legal entity**

- be paid for the performance of **additional work** or **different expertise** than his/her usual tasks

  This is usually the case, since additional remuneration aims precisely to reimburse the additional work/expertise that is required for EU and international projects.

- be **consistently applied** whenever the same kind of work or expertise is required and **regardless of the source of funding** used

  The additional remuneration may not differ according to *where* the funds come from. In particular, it cannot be set up for actions funded by a specific donor; additional remuneration schemes that are applicable only to EU projects are not acceptable.

  ***Example (not acceptable):** All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

  Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

However, the additional remuneration does not have to be the *same* for all persons working in the same project (provided that objective criteria are used to determine the differences).

⚠ **8000 EUR ceiling —** Additional remuneration is eligible **ONLY up to** a ceiling of **8000 EUR** annual costs; *see point 1.1.4*).

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Teleworking — Remuneration costs of personnel not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible, if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of quasi-financial benefits *(e.g. costs of lunch vouchers)* may be accepted as eligible, if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally NOT eligible as direct costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action, the related costs would be considered part of the entity's normal indirect costs, which are covered by the 25 % flat-rate.

Costs for students, PhDs and other researchers under scholarship, internship or similar agreements (not employees) — Costs of students that work for the beneficiary can be accepted, if the agreement is work-oriented (not training-oriented: i.e. not aimed at helping the student to acquire professional skills).

PhD agreements will be considered work-oriented. However, time for training, if any, may NOT be charged to the action.

Fellowships/scholarships/stipends — Can be charged to the action (as personnel costs), if they fulfil the conditions set out Article 6.1 and 6.2.A.2, and in particular:

- the remuneration complies with the application national law on taxes, labour and social security
- the assignment of tasks respects the laws in force in the country of the beneficiary
- the students have the necessary qualifications to carry out the tasks allocated to them under the action.

Cost for exemptions from academic fees — The fees (or part of them) are eligible as personnel cost, if the student's contract includes the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic remuneration only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible).

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts for participation in projects (whatever their form) are acceptable if it is the beneficiary's usual practice and compatible with national law. The remuneration will be qualified as basic or additional remuneration, depending on the scope (national OR

EU/international) and amount (above, equal or below usual remuneration practices for national projects).

1.1.4 The **costs** must be **calculated** as follows:

In general, personnel costs for H2020 actions are calculated (for each person assigned to the action, including persons working exclusively on the action) as follows:

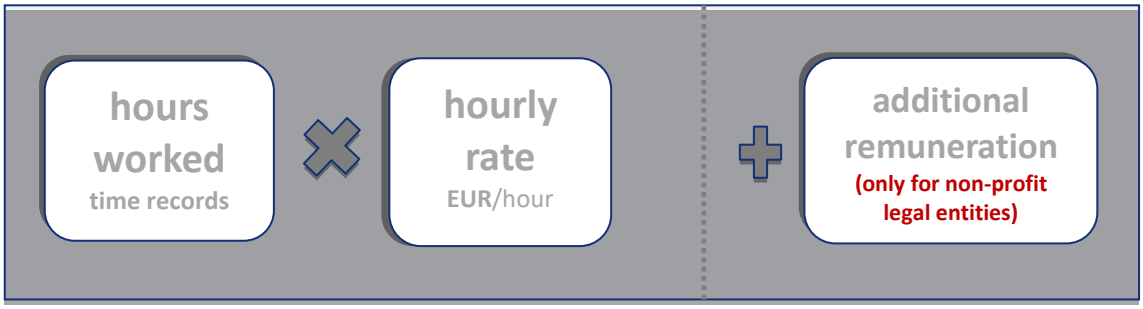

In practice, the calculation will differ (per type of beneficiary/employee) depending on the remuneration practices of the beneficiary:

Case 1: beneficiaries declaring personnel costs as actual costs

Case 1A: employee whose remuneration is not project-based (i.e. same remuneration, regardless if they are involved or not in specific projects)

Case 1B: employee whose remuneration is project-based (i.e. different remuneration levels, depending on whether they work in specific projects or not)

Examples:

1. *The beneficiary and the researcher sign a separate employment contract for the work of the person in the Horizon 2020 action. The hourly rate resulting from that additional employment contract is different from the hourly rate of the other employment contract of the person with the beneficiary.*

2.*The beneficiary has a remuneration scheme which includes the payment of a bonus for work in specific projects. The bonus is paid as part of the total salary of the person in addition to the basic salary and other general bonuses.*

3. *The employment contract of the person fixes a specific hourly rate to be paid for work in specific projects. This hourly rate replaces the standard salary of the person while it works in those projects.*

Case 2: beneficiaries declaring personnel costs as unit costs in accordance with the usual cost accounting practices (average personnel costs).

Additional remuneration is in practice an issue ONLY for case 1B beneficiaries. All other beneficiaries will automatically fall under 'basic remuneration only' and therefore are not concerned by the provisions on additional remuneration.

Case 1B beneficiaries need to differentiate between payments that are basic remuneration and payments that are additional remuneration. For them, the hourly rate charged to the action must be calculated using only basic remuneration (i.e. excluding any part that qualifies as additional remuneration). Additional remuneration may be charged (separately and on top), if the beneficiary is a non-profit entity, if that remuneration is eligible and only up to a ceiling of 8000 EUR per year.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ **Double ceiling —** Beneficiaries must ensure that:

- the **total number of hours** worked **declared** in EU and Euratom grants for a person for a year is NOT higher than the number of **annual productive hours** used for the calculation of the hourly rate *(see below)*

  Example: *Beneficiary using 1 720 as annual productive hours. According to the time-records, during the financial year 2017 employee Z worked 900 hours in a H2020 action and 900 hours in another EU project. The total hours worked for EU projects by employee Z would therefore be 1 800 (900 + 900). However, the beneficiary cannot declare more than 1 720 hours, since this is the number of annual productive hours it used for the calculation of the hourly rate. Therefore, for 2017, the beneficiary can only charge 820 hours to the H2020 action (i.e. 1 720 – 900 hours declared to other EU grant), even if the person worked 900 hours in the action.*

- the **total** amount of **personnel costs declared** (for reimbursement as actual costs) in EU and Euratom grants for a person for a year is NOT higher than the total personnel costs recorded in the **beneficiary's accounts** (for that person for that year).

  Example: *The total personnel costs recorded in the 2017 accounts of the beneficiary for employee Z is EUR 18 000. The beneficiary already declared EUR 9 000 to the other EU grant. The hourly rate for employee Z according to the formula in the H2020 Grant Agreement is 11 EUR/hour and employee Z worked 900 hours for the action in 2017. The eligible personnel costs for the H2020 action would therefore be: 11 EUR/hour x 900 hours = EUR 9 900. However, since the beneficiary already declared EUR 9 000 to the other EU grant, the maximum that it can declare to the H2020 action is: EUR 18 000 (total personnel costs for employee Z) – EUR 9 000 (already declared to other EU grant) = EUR 9 000. The beneficiary can therefore declare only EUR 9 000, even if the result of the formula for personnel costs would be EUR 9 900.*

How to calculate direct personnel costs for employees (or equivalent):

For case 1A beneficiaries (actual costs, not project-based remuneration): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary must calculate, for each employee, the hourly rate to be charged to the action by using one of the following methods:

- **per full financial year** (main method): single hourly rate for each person for each full financial year
- **per month** (alternative method): one hourly rate for each person for each month (i.e. 12 hourly rates per person for each financial year).

Each beneficiary may choose any of the two options. However, the option chosen must be applied during the full financial year to all its personnel in all H2020 grants. If the beneficiary wants to change option, it can do so for the next financial year (— again for all its personnel in all its H2020 grants).

⚠ **Recalculations & adjustments of financial statements (exceptional) —** To benefit from this new option (i.e. hourly rate per month) beneficiaries may apply it retroactively for all grants on-going (i.e. for which the final report has not been submitted) on 20 July 2016 (i.e. date of adoption of the H2020 MGA version 3.0). The beneficiary may re-calculate costs already declared on the basis the full financial year by using the monthly calculation method. However, in that case it must do the recalculation for ALL personnel costs declared for that/those financial year(s) in ALL on-going H2020 grants. The beneficiary must declare the differences, either positive or negative, as adjustments in the next reporting period.

⚠ The grant agreement **formulas for the hourly rates are mandatory**. Those formulas may lead to minor/temporary differences with the personnel cost recorded in the accounts. Those differences have no impact on the eligibility of the costs, provided that the formula has been correctly applied and that the *double ceiling* explained above has been respected.

Calculation of the hourly rate *per full financial year*

Annual hourly rates must be calculated as follows:

for each person:

{actual **annual personnel costs** for the person
divided by
number of **annual productive hours**}.

The rate must be calculated by ***full financial* year** (i.e. the 12-month period covered by the annual accounts of the entity).

Example: *When the financial year matches the **calendar year**, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance with the GA is available at the end of the reporting period. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate. The method must however be consistently applied and can NOT be changed within the same grant.

⚠ **Recalculations & adjustments of financial statements (exceptional)** — Adjustments to the hourly rate are normally allowed ONLY for mistakes *(e.g. incorrect accounting information; error in the calculation; etc.)* and must be done using the hourly rate which would have had to be used at the end of the reporting period concerned.

Examples:

1. *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

2. *Reporting period 1 runs from 1 January 2016 to 30 June 2017. The beneficiary used the hourly rate 2016 for the entire period (i.e. also for the part from 01/01/2017 – 30/06/2017) because the financial year 2017 was still on-going at the end of the reporting period. In 2018, the beneficiary realises that the 2016 hourly rate was incorrectly calculated and that it has to declare an adjustment for reporting period 1. To calculate the adjustment, the beneficiary must use the correct hourly rate for 2016 for the whole reporting period 1, including the period from January to June 2017.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed (even if a recalculation of the hourly rate after the closure of the financial year would give another result).

The **annual personnel costs** may include only eligible personnel costs.

Any part of the remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 2:** the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours'**)
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option (1, 2 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, same cost-centre, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed ad-hoc for specific employees)*.

The beneficiary must keep the same option(s) for *the full financial year*. It can only change its option(s) for the next financial year.

Absences & overtime —

Absences: the three options treat absences (leave) in different ways:

- under option 1 (1720 fixed): ONLY actual time spent on parental leave (maternity and parental leave) may be deducted from the 1720 fixed hours. NO other leave *(e.g. sick leave, special leave, annual leave, etc.)* can be deducted.
- under option 2 (individual): the beneficiary must deduct all leaves (i.e. *actual time* on sick leave, parental leave or special leave, etc.) to calculate the annual productive hours.

  In order to calculate the annual workable hours, the beneficiary has to deduct the annual leave entitlement (see example in the *table of options*). However, if the employment contract allows end-of-year transfers for leave entitlements (i.e. the days not taken one year can be taken the next one; days not taken are not paid out), the beneficiary may opt for deducting instead *actual time* of annual leave (if this is done consistently throughout the years).
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard time of absence in the organisation. However, the beneficiary may deduct on top the actual time spent on parental leave (maternity and parental leave) by the individual employee.

Overtime: all three options include potential overtime in the annual productive hours, either implicitly (options 1 and 3) or explicitly (option 2):

- under option 1 (1720 fixed): NO overtime may be added to the 1720 fixed hours
- under option 2 (individual): all overtime worked (paid or unpaid) must be added to the annual workable hours to calculate the annual productive hours
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard overtime hours in the organisation (if any).

No impact on the hours worked — The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding can NOT be charged to the action (they must be capped at the ceilings).

Calculation of the hourly rate *per month*

Monthly hourly rates must be calculated as follows:

for each person:

{actual **monthly personnel costs**
divided by
{number of **annual productive hours/12**}**}**.

The rate must be calculated **for each month**.

The **monthly personnel costs** may include only eligible personnel costs.

If a part of the remuneration is generated over a period longer than a month *(e.g. the thirteenth salary)*, only the entitlement generated in the month can be included in the monthly personnel costs (— irrespectively of how much is actually paid in that month).

Example:

In accordance with the collective labour agreement, Ms T is entitled to a thirteenth salary (another full month salary in addition to her 12 monthly salaries) to be paid in July each year. The monthly salary of MS T is EUR 3 000.

The monthly personnel costs in July will be:

EUR 3 000 + {EUR 3 000 / 12} = 3 000 + 250 = EUR 3 250

The beneficiary can therefore NOT include the total of the thirteenth salary in the personnel costs for July, but must distribute it over the months in which it was generated (in this example 1/12 per month). Otherwise, the hours of July would be incorrectly priced at the double of the hours worked in normal months.

Recalculations & adjustments of financial statements (exceptional) — If a later event *(e.g. the unexpected leave of the employee)* means that the payments made for the employee are actually lower (i.e. that the monthly hourly rates were overstated) the beneficiary must recalculate the hourly rates with the correct amount. If some of the related personnel costs were already declared, the beneficiary must declare the difference as adjustment in the next reporting period.

If the monthly entitlement of an extra salary is not known in advance *(for example for an annual merit pay whose amount is decided in December — if eligible as basic remuneration —)* the beneficiary cannot take into account the extra salary until the amount is known. It may therefore recalculate the hourly rates at that moment and, if needed, declare the difference as adjustment in the next reporting period.

For calculating the **annual productive hours**, the beneficiary must use one of the following two options *(see the table of options above for the details on each option)*:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

Option 2 can NOT be used for monthly hourly rates because the individual annual productive hours — and thus also the monthly hours, i.e. 1/12 of the annual — are known only at the end of the financial year. It would be therefore impossible to calculate the hourly rates at the end of each month.

In principle, the same option (1 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must keep the same option(s) *during the entire financial year*. It can only change its option(s) for the next financial year.

Absences & overtime —

The same rules on the treatment of absences and overtime apply as for annual hourly rates, except that time spent on parental leave can NOT be deducted from the annual productive hours.

However, beneficiaries may charge to the action the *costs* incurred for parental leave (as personnel costs) in proportion to the time the person worked for the action during the financial year (time worked on the action over total productive hours for the year). This must be done separately and on top of the personnel costs declared by multiplying the hours worked for the action by the monthly hourly rates.

Example:

In 2015 Ms T has been five months in parental leave. During that time the social security reimbursed to the beneficiary 50 % of her salary. Her monthly salary was EUR 3 000 (reimbursement EUR 1 500). The beneficiary used option 1 (1720 fixed hours) for the annual productive hours and Ms T worked in 2015 320 hours on the H2020 action.

Personnel costs incurred during parental leave= {EUR 3 000 x 5} - {EUR 1 500 x 5} = 15 000 – 7 500 = EUR 7 500

(Note: amounts reimbursed to the beneficiary by the social security are not actual costs for it and, therefore, must be deducted)

Proportion of time worked for the action in 2015 = Time worked for the action / Total productive hours excluding the parental leave = 320 / {1720 - {1 720 x 5/12}} = 320 / {1 720 – 716,7} = 320 / 1 003,3 = 31,89 %

Cost of parental leave for the H2020 action = EUR 7 500 x 31,89 % = EUR 2 391,75

No impact on the hours worked — The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding can NOT be charged to the action (they must be capped at the ceilings). The ceilings apply per full financial year, not per month.

However, do not forget that your personnel costs must comply with national labour law.

Example:

If the national law provides for a prohibition for employees to work more than 48 hours per week, it is not possible to charge to the H2020 action 250 hours in a month for an employee.

Step 2 — **Multiplying the hourly rates by the hours worked on the action**

The hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

For case 1B beneficiaries (actual costs, project-based remuneration): 4 steps

Step 1 — **Checking the nature of the remuneration (basic or additional) for each employee)**

The beneficiary must first find out, for each employee, if the remuneration it is paying is all basic remuneration or contains also additional remuneration.

To do this, the beneficiary must calculate **two reference hourly rates**:

– reference rate for the work on the H2020 action ('**action reference**')

and

– reference rate for the usual remuneration practice for national projects ('**national projects reference**').

If the action reference is *equal or below* the national projects reference, the remuneration is all basic remuneration. If it is *higher*, the exceeding part is additional remuneration and must be taken out for the calculation of the hourly rate to be charged to the action.

Step 1a — **Calculation of the reference hourly rates**

For the **action reference**: the beneficiary must calculate an hourly rate (either *annual* or *monthly*) based on the remuneration paid to the employee for his/her work in the H2020 action.

For *annual* reference rates:

{annual personnel costs for the person for his/her work in the action

divided by

number of hours worked for the action in the financial year}.

If the reporting period ends before the end of the financial year, the beneficiary must use the personnel costs and the hours from the beginning of the year until the end of the reporting period.

For *monthly* reference rates:

{monthly personnel costs for the person for his/her work on the action

divided by

number of hours worked for the action in the month}.

For the **national projects reference**: the beneficiary must calculate an hourly rate based on either:

– regulatory requirements *(e.g. national law or collective labour agreements)* setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

Example: *The national law establishes that the maximum monthly salary of engineers acceptable for national grants is EUR 4 000. Beneficiary A has paid that salary to its engineers while working in national grants. Beneficiary B has signed a collective labour agreement whereby the monthly salary to be paid for work under national grants is fixed at EUR 3 500. Beneficiary B has paid that salary to its engineers working in national grants.*

Maximum amount acceptable as basic remuneration for beneficiary A = EUR 4 000/month for a person working full-time. If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

Maximum amount acceptable as basic remuneration for beneficiary B = EUR 3 500/month for a person working full-time. If the remuneration of the person for the work in the H2020 action was more than this ceiling, the excess will qualify as additional remuneration.

– internal rules setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

Example: *The internal rules of University Z provide that a professor working in externally-funded projects may get an extra salary of up to 50 % for the time its works for those projects. The maximum extra salary University Z has actually paid for work in national projects was 30 %.*

Maximum amount acceptable as basic remuneration = salary of the person + 30 % (for the time worked in the H2020 action). If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

or

– if none of these are available or if the beneficiary never had any national projects before the submission of the H2020 proposal: the average remuneration of the employee in the previous financial year.

The hourly rate of the national project reference must be calculated using 1720 fixed annual productive hours (unless there is an hourly rate directly set in the law, collective labour agreement or internal rules).

For the average remuneration of the employee, the beneficiary must moreover exclude remuneration that came from H2020 actions; i.e.:

{total annual personnel costs* for the person for year n-1 excluding remuneration paid for work in H2020 actions

divided by

1720** minus hours worked in H2020 actions in year n-1}

* The total annual personnel costs include all remuneration paid by the beneficiary to the person for work, irrespectively of the tasks of the person and the projects for which the person was working; but excludes all remuneration paid for work in H2020 actions. If the remuneration included ineligible items *(e.g. profit distribution)* those must also be removed.

** 1720 is the fixed number of annual productive hours. The beneficiary must remove from those annual productive hours the hours worked in H2020 actions. If in year n-1 the person worked exclusively in H2020 actions, the beneficiary must use the average salary of the last year in which the person did not work exclusively in H2020 actions *(e.g. year n-2 or year n-3)*. If in year n-1 the person was on long-term sick leave, the beneficiary may use the average of year n-2 (instead of n-1).

If the national law or the internal rules set up different levels of remuneration for different categories of staff, the reference will be the one of the category to which the person belongs.

If the national law or the internal rules set up different remuneration levels for different types of national projects (or for different work within the projects), the reference will be the one applicable to the type of project/work that is closest to the H2020 action.

Example: *The internal rules of University Z provide that a professor working in basic research projects will receive 10 % extra salary; while a professor working in applied research projects will receive 15 % extra salary. Both extra salaries are systematically paid also for projects funded by national schemes. The H2020 action is an innovation action. The reference that would apply in this case is the extra salary for applied research projects (15 %) as the type of project is closer to the H2020 innovation action than basic research projects.*

The beneficiary must keep appropriate and sufficient evidence to support the action and national project references used *(see Article 18)*.

Example: *If the beneficiary uses the internal rules it must keep documental evidence of the internal rules applied, the category of the person (if applicable), and the payslip and payment documents proving that such remuneration was paid at least once prior to the submission of the proposal.*

Step 1b — **Comparing the action reference with the national project reference**

If the action reference is *higher* than the national project reference, the exceeding part is additional remuneration:

{total additional remuneration = difference between the two reference rates * number of hours worked on the action}

{total basic remuneration = national project reference rate * number of hours worked on the action}

If the action reference is *equal or lower* than the national project reference, there is no additional remuneration; the remuneration paid to the employee is all basic remuneration.

Example personnel costs with additional remuneration (Part 1 of 3):

1. *Ms R is employed full-time as professor at University X. She has a basic annual gross salary of EUR 24 000. The internal rules of the university provide that professors involved in research projects financed by external funders can get up to EUR 6 000 per month of full dedication to the project. However, due to budgetary restrictions the maximum that has been paid to any professor in a national project was EUR 4 800. Ms R worked in 2017 for the H2020 action 200 hours. For those hours she received an extra salary of EUR 6 500. She also participated in other projects generating other extras for her. So, her total gross annual salary was EUR 36 000. The hourly rate for the H2020 action is as follows:*

The salary of Ms R varies depending on her participation in certain projects. Therefore, the beneficiary must assess if any part of that salary qualifies as additional remuneration. For that, it must compare the action reference with the national project reference:

Action reference rate = basic salary corresponding to the 200 hours worked for the action ((24 000 / 1720) x 200 = 2 790,70 €) + bonus paid for the action (6 500 €) = 9 290,70 € / 200 (hours worked in the action) = 46,45 €/hour (hourly rate)

National project reference rate (in this example based on the internal rules of the university applicable to national projects) = maximum salary paid for any professor working in a national project in accordance with the internal rules = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

The Action reference (i.e. 46,45) is higher than the national project reference (i.e. 33,49). The excess (46,45 – 33,49 = 12,96 €/hour) qualifies as additional remuneration. Therefore:

The total basic remuneration = 33,49 €/hour x 200 (hours worked in the action) = 6 698 €

The total additional remuneration = 12,96 €/hour x 200 (hours worked in the action) = 2 592 €

(This example continues here for the calculation of the hourly rate)

2. *Same situation as above, but in this case the work in the action has been done under a supplementary employment contract covering additional working hours (on top of the full-time contract of the professor).*

Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour

National project reference rate = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary is NOT paying additional remuneration.

The total basic remuneration = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 2 — **Calculation of the hourly rate (for each employee; on the basis of basic remuneration)**

The beneficiary must then calculate the hourly rate to be charged to the action for the employee:

- **If** there is **additional remuneration**, the beneficiary must calculate the hourly rate using only the basic remuneration. In practice, this will be the action reference, capped at the national project reference (i.e. the hourly rate will normally be equal to the national project reference rate).

  Example personnel costs with additional remuneration (Part 2 of 3):

  1. *Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of 9 290,70 €. In the calculations made in part 1 of the example we identified that 2 592 € qualify as additional remuneration.*

  The hourly rate applicable to the action will be, therefore:

  (Actual annual personnel costs for the action - additional remuneration) / hours worked in the action over the year = (9 290,70 € - 2 592 €) / 200 = 33,49 €/hour.

  Personnel costs resulting from the hourly rate = 33,49 €/hour x 200 = 6 698 €.

  (This example continues here for the eligibility of additional remuneration)

- **If** there is **NO additional remuneration** (i.e. all is basic remuneration), the beneficiary can simply use the action reference as hourly rate to charge to the H2020 action.

  Example personnel costs without additional remuneration (Part 2 of 3):
  Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of EUR 6 500 through an additional contract.
  Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour
  National project reference rate = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary must use the action reference as hourly rate to charge to the H2020 action:
Total personnel costs to be declared = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 3 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount of basic remuneration that can be charged to the action *(see examples in Step 2 above)*.

Step 4 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the beneficiary is a non-profit entity and the payments that are additional remuneration are eligible, it may also declare them to the action.

If the resulting amount (for the year) is above the **8000 EUR ceiling**, it must be capped:

Occupation	Contract	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional payment (bonus) but also the additional taxes, costs and social security contributions triggered by the additional payment.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0,8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0,25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0,25 * 0,80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} \times \text{hours worked by the employee for the action over the year}$$

Example personnel costs with additional remuneration (Part 3 of 3):

1. *Ms R worked 200 hours over the financial year. For that work she received 6 698 € of basic remuneration and 2 592 € of additional remuneration.*

If the beneficiary is a for-profit legal entity, the 2 592 € of additional remuneration would be automatically ineligible. The personnel costs which the beneficiary can charge to the action would be therefore 6 698 €.

If the beneficiary is a non-profit legal entity, additional remuneration may be eligible up to the ceiling. To calculate the eligibly part, you need to determine the pro-rata of the cap which corresponds to the 200 hours worked for the action:

(8 000 / 1 720) x 200 = 930,23 €

Although the beneficiary paid 2 592 € of additional remuneration, only 930,23 € are eligible. The difference (2 592 – 930, 23 = 1 661,77 €) is ineligible, since it exceeds the ceiling.

Therefore, the personnel costs which the beneficiary could charge to the action would be: 6 698 € of basic remuneration + 930,23 € of additional remuneration = 7 628,23 €.

For case 2 beneficiaries (unit costs in accordance with the usual cost accounting practices): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary can use the hourly rate(s) that it uses normally (usual cost accounting practices) as average personnel costs, provided that:

- the cost accounting practices are applied in a **consistent** manner, based on objective criteria, regardless of the source of funding
- the hourly rate is calculated using the **actual personnel costs recorded** in the beneficiary's **accounts**, excluding any ineligible cost or costs already included in other budget categories and
- the hourly rate is calculated using one of the **three options** provided in the MGA for the number of **annual productive hours** *(e.g. option 3 'standard annual productive hours')*.

The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

This does not mean that cost accounting practices must be the *same* for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

If necessary, the hourly rate must be adjusted to remove:

- cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the hourly rate).

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

- costs that are already included in other budget categories (double funding of the same costs;

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020*

actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.

Budgeted or estimated elements used to calculate the hourly rate can only be accepted if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way (i.e. do not play a major role in calculating the hourly rate)
- correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

Beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A (as chosen by the beneficiary) applies.

Since there is no obligation to keep time-sheets for periods covered by a declaration on exclusive work, beneficiaries should report:

- for annual hourly rates: a pro-rata of the annual productive hours corresponding to the period covered by the declaration (at the annual hourly rate)
- for monthly hourly rates: 1/12 of the annual productive hours for each month actually worked for the action in the period covered by the declaration (at the monthly hourly rate).

Example:

1a *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours and calculates annual hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate		Hours worked for the project	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

1b *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its monthly personnel cost were 2 666,66 EUR in 2014, 2 860 EUR from January 2015 until October 2015 and 2 900 EUR from then on. The beneficiary applies 1720 as annual productive hours and calculates monthly hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*x*	*Hours worked for the project =*		*Total*
2014➔					
October	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 666*
November	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 666*
December	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 666*
				Total	*= 8 000**
2015 ➔					
January	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
February	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
March	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
April	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
Mai	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
June	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
July	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
August	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
September	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
October	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 860*
November	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
December	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
				Total	*= 34 400*
2016➔					
January	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
February	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
March	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*		*2 900*
				Total	*= 8 700*
				TOTAL	*= 51 100*

* *Decimals have been rounded*

If the declaration covers months in which the person was **absent** for more than half of the working days those months can NOT be taken into account to calculate the hours worked in the action (— unless the absence is linked to annual leave AND the duration does not exceed the pro-rata of annual leave entitlements corresponding to the period covered by the declaration).

Example:

1. *Researcher Y worked exclusively in the action from1 July 2014 to 31 October 2014. In August it took three weeks of holidays and in September it was 10 days on sick leave. The beneficiary applies 1720 as annual productive hours*

Number of hours that can be charged to the action based on the declaration = 3 months (July, September and October) x (1720 / 12) = 3 x 143,33 = 430 hours

August is not taken into account because the person was absent more than half of the working days, since s/he took three weeks of holidays.

2. *The person has the right to two working days of annual leave per month worked. The period covered by the declaration is from January to September (i.e. 9 months). Therefore, the leave entitlement of the person for that period is 9 x 2 = 18 working days. The person takes 3 weeks of annual leave in August. August could also be counted because the leave taken (i.e. 15 working days) is less that the leave entitlement for that period (i.e. 18 working days).*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the annual hourly rate can only be calculated on the basis of the personnel costs incurred during the ongoing financial year.

Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if option 1 - 1 720 fixed hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 286,66; if option 2 -individual annual productive hours- is used, the productive hours for the period February-March would be the actual productive hours for the period February-March; if option 3 – standard annual productive hours - is used, the productive hours for the period February-March would be the standard annual productive hours/12*2)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the indemnity in the reporting period in which the employee's contract ends — but outside the hourly rate (i.e. separately and on top of the personnel costs declared on the basis of the hourly rate) AND only for the part that corresponds to the time worked by the person on the action (i.e. pro-rata of the total time during which the entitlement was generated).

Moreover, the indemnity can be accepted ONLY if it:

- arises from the applicable national labour law and
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Employment contract remunerated per hour — For employment contracts that do not establish a fixed salary and a number of hours to be worked but only an amount to be paid for each hour worked by the employee, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the individual annual productive hours can be calculated as follows:

{total salary paid to the employee in the financial year
divided by
hourly rate fixed in the employment contract}.

This summary table explains the three **different options** for **annual productive hours (for case 1A and case 2 beneficiaries)**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full time equivalent (FTE) covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the GA {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust

		overtime worked
		minus
		absences (such as sick leave and special leave)}
		– the 'annual workable hours' are established according to one of the following:
		  – employment contract of the person concerned
		  – applicable collective labour agreement
		  – national law on working time.
		  Example: *contract stipulating 35 hours of work per week*
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		Example for calculation of individual annual workable hours:
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus 8 days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for 5 days.
		The individual annual workable hours would therefore be:
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		Individual annual productive hours for Researcher X:
		Annual workable hours = 1 848
		+ overtime (hours) = 29
		- annual sick leave (5 days x 8 hours) = 40
		➔ individual annual productive hours for Researcher X = 1 837
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.
			the number of annual productive hours by applying option 2 to all persons concerned, where possible.
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow to determine the number of individual annual workable hours: the auditors will apply option 1.
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example for calculation of standard annual workable hours:*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would*	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation method consistently applied) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive

		therefore be: *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	hours to the higher number. – If the standard annual productive hours is 90 % of the standard annual workable hours the auditor will not challenge that amount if the amount is in accordance with the usual cost accounting practices of the beneficiary and the calculation method is consistently applied.

		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 fixed hours).*	

1.2 Direct personnel costs: Natural persons with direct contract (A.2)

1.2.1 **What?** This budget category **covers** typically the costs of **in-house consultants** and similar persons (i.e. **self-employed *natural* persons**) that worked on the action for the beneficiary under conditions similar to those of an employee, but under a contract which is NOT legally the same as for employees. It regards, in particular, contracts qualified as quasi-subordinate work contracts under national law when the conditions under which the work is carried out are similar to those of an employee.

What not? Staff provided by another entity against a price, including staff provided by a temporary work agency (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

> **Staff provided by a temporary work agency —** A contract with a temporary work agency qualifies typically as purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency),* even if that third party is a one-person company.
- the person must work **under conditions similar to those of an employee,** in particular:

> ⚠ **Similar does not mean equal —** The working conditions of the person do NOT have to be exactly the same that those of an employee, but overall similar.

  - the beneficiary must organise and supervise the work of the person in a way similar to that of its employees

    Example (acceptable):

    The beneficiary's project leader and the person discuss regularly the work to be carried out for the action. The project leader decides the tasks and timing of the work and instructs the person accordingly.

    Example (not acceptable):

    The beneficiary's project leader and the person meet only once a month or irregularly, for updates on the state of play of the entrusted work. If changes are needed, they have to be agreed by the person and may lead to a change of the amount charged to the beneficiary.

  - the beneficiary must be able to ensure reliable time recording (for the hours that the person works for the action)

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

– the person is subject to similar presence requirements as the employees.

Examples (acceptable):

The person works physically at the beneficiary's premises, following a time schedule similar to that of the employees (e.g. the beneficiary authorises up to two days of teleworking per week to its personnel and the person has chosen to benefit from this regime, i.e. works 2 days in teleworking and 3 days physically at the beneficiary's premises).

Example (not acceptable):

The entity authorises up to two days of teleworking per week. However, the person works four days in teleworking and only one day at the beneficiary's premises.

- the **result** of the work carried out (including patents or copyright) must in principle **belong to** the **beneficiary**

  If (exceptionally) they belong to the person, the beneficiary must (just like for employees) obtain the necessary rights from the person (transfer, licences or other), in order to be able to respect its obligations under the GA *(see Article 26.3)*.

- **not** be **significantly different** from costs for employees performing similar tasks

  The remuneration must be based on working time, rather than on delivering specific outputs/products.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **rules** as explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, for the **actual costs hourly rate**, the beneficiaries must use one of the following options:

– if the contract specifies an hourly rate: this hourly rate must be used

– if the contract states a fixed amount for the work and the number of hours to be worked: the global amount for the work must be divided by the number of hours to be worked

– if the contract states a fixed amount for the work but does not specify the number of hours to be worked: the global amount for the work must be divided by the pro-rata of 1 720 annual productive hours which corresponds to the duration of the contract over the financial year.

Example: *The contract provides that the person will work at the beneficiary's premises for assisting in research tasks. The contract is for 6 months starting on 1 January 2017 and ending on 30 June 2017. According to its time records, the person worked 500 hours in the H2020 action over that period. The contract sets a monthly payment of EUR 3 000 but does not explicitly establish the number of hours to be worked.*

Personnel costs for the action = hourly rate x 500 (hours worked in the action)

Hourly rate = annual personnel costs / annual productive hours = (3 000 € x 6 months) / (1 720 hours x (6 months/12 months)) = 18 000 € / (1 720 x 0,5) = 18 000 € / 860 hours = 20,93 €/hour

Personnel costs for the action = 20,93 x 500 = 10 465 €.

Social security contributions which are mandatory under national law may be included in the calculation of the hourly rate.

For the **unit costs** hourly rate (average personnel costs), the rules in point 1.1.4 apply without any changes.

This summary table explains how to treat **different types of work contracts** for declaring costs under H2020[16]:

Characteristics of the contract	**Contract remunerating time** *(e.g. the contract establishes that the person must work for the beneficiary 40 hours per week)*	**Contract not specifying the working time conditions** *(e.g. the contract establishes the tasks, but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4); however: ➔ Only option 1 (i.e. 1720 fixed annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. ***Example:*** *Contract from 01.01.2015 to 31.03.2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430*
Other contract (i.e. not an employment contract)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared in category A.2 'natural persons with direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A. 'personnel costs'. They must be treated like CASE D1.	**CASE D1:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

[16] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

		CASE D2: the costs fulfil the conditions of Article 6.2.A.2. The costs can be declared in category A 'personnel costs'. They must be calculated as described in Article 6.2.A. Calculation (point 1.2.4); however: ➔ Only option 1 (i.e. 1720 fixed annual productive hours) can be used to calculate the hourly rate. ➔ If the contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720.

1.3 Direct personnel costs: Seconded personnel (against payment) (A.3)

1.3.1 **What?** This budget category **covers** the costs of persons that worked on the action and that were **seconded** by a third party as an in-kind contribution ***against payment*** *(see Article 11)*.

What not? Persons provided by a temporary work agency, secondment of staff between beneficiaries (or linked third parties) in the same grant or secondment by a third party free of charge.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

Secondment of staff between beneficiaries (or linked third parties) — Is allowed, but it is the beneficiary/third party who employs the person who has to declare its costs (NOT the beneficiary/third party to whom the person has been seconded). The costs declared must be supported by reliable time records of the number of hours the person worked for the action. Those time records must be produced under the responsibility of the beneficiary/third party to whom the person is seconded

Persons seconded free of charge — Costs for persons seconded free of charge (i.e. the third party's costs) can be declared as personnel costs by the beneficiary, if they fulfil the conditions of Articles 6.4 and 12.

> For information on in-kind contributions provided by third parties *free of charge, see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared** ONLY as **actual costs**.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.3.4 There is no specific **calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1*).

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the seconded person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.4 Direct personnel costs: SMEs owners & natural persons not receiving a salary (A.4 & A.5)

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons which work on the action, but **don't receive a salary**.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts/other non-employment contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

1.4.2 These costs must be **declared as** the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[17] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4 650 or 4 880* /143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *H2020 Work Programme (section 3 MSCA)*[18] in force at the time of the call.

*EUR 4 650 for calls under Work Programmes 2014-2015 and 2016-2017 and EUR 4 880 for calls under Work Programme 2018-2020.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*

EUR 4 650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **SME owner/beneficiary that is natural person**, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

[17] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf
[18] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ **Ceiling** — The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than 1 720.

1.5 Direct personnel costs: Access to research infrastructure personnel costs (A.6)

1.5.1 **What?** This budget category **covers** the personnel costs for access to infrastructure activities, i.e. normally:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons with direct contract and
- costs of seconded personnel (against payment).

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs) *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.5.4 The same **calculation rules** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting ***[(not covered by Point F)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting (B.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing trans-national or virtual access to research infrastructure: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (subcontracting costs (B.)):

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency may exceptionally have to be declared under category B 'subcontracting' (instead of category D.3 'other goods and services') if the temporary work agency carries out directly some task of the action (provided they comply with the eligibility conditions).

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)]***

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

1. Direct costs of providing financial support to third parties (C.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category (together with the corresponding *Article 15* and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances (D.1): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

Best practice: Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs relate to the personnel of the beneficiaries. They may also relate to experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if:

- the experts' participation is foreseen in Annex 1 or
- their participation is specifically justified in the periodic technical report and the Commission/Agency approved it without formally amending the GA (simplified approval procedure).

The beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly). There is no distinction between travelling in- or outside Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

***Example*:**

Beneficiary A declares the cost of a business class airplane ticket for one of its employees.

If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or subsistence allowances as a lump sum/*per diem* payment, it is the lump sum/*per diem* amount that is considered an eligible cost, NOT the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these lump sum/per diem costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (travel costs (D.1)):

Combination with personal travels or travels for other purposes — The costs of a combined travel can be charged to the action — but ONLY up to the cost that would have been incurred if the travel would have been made exclusively for the action AND if:

- it is the usual practice of the beneficiary to pay for such travels *(e.g. travels combining professional and personal reasons)*
- it has been an actual cost for the beneficiary.

***Example*:**

The researcher flies from Madrid, where the beneficiary is established, to Prague for a project meeting. After the meeting, instead of flying back to Madrid, the researcher flies directly to New York to participate in an event not related to the action.
The beneficiary may charge to the action:

- *the cost of the flight from Madrid to Prague, and*
- *the part of the flight back from New York to Madrid up to the cost that it would have incurred for a flight back from Prague to Madrid after the end of the project meeting.*

⚠ **Record-keeping —** The beneficiary must keep evidence not only of the actual cost of the flight back, but also of the cost of the flight that the person would have taken if it would have returned directly after the end of the work for the action.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).]*

***[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.2): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs (D.2): Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

- if the beneficiary does not use the equipment exclusively for the action, only the portion used on the action may be charged. The amount of use must be auditable

  Example: *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*

  Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

- the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

  Example: *A microscope was bought on 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs (D.2)):

Low-value assets — The full cost of a low value asset may be eligible in the year when it is purchased if:

- the full cost is recorded in the accounts of the entity as expenditure of that year (i.e. NOT recorded as an asset subject to depreciation)

and

- the cost of the asset is below the low-value ceiling as defined under national law (e.g. *national tax legislation)* or other objective reference compatible with the materiality principle

and

- the item is used exclusively for the action in the year of purchase.

  If the item is not used exclusively for the action in the year of purchase, only the portion used on the action may be charged.

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that correspond to the part of the equipment's use for the action. Declaring its *full* price in one single year would be considered either as not compliant with the international accounting standards or as an excessive cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, a piece of equipment bought in January 2013 has a depreciation period of 48 months.
If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that corresponds to the part of the equipment's use for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year, the beneficiary can NOT charge the full price in one single year (— even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year).

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

- **Prototype or pilot plants constructed by the beneficiary as part of the action tasks** — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

However, (full) direct costs for construction of a prototype or pilot plant may exceptionally be eligible, if all of the following apply:

- building the prototype or pilot plant is (one of) the main action task(s) as described in Annex 1 of the GA.
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the eligibility conditions of Articles 6.1 and 6.2 are met.

  If the beneficiary records the construction costs directly under a fixed assets account in the balance sheet rather than as expenses of the year, those costs will normally be considered as compliant with Article 6.1(a)(v) provided that:

  - it is in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices,
  - there is no double charging of costs (in particular, no charging of depreciation costs for the prototype or pilot plant to another EU or Euratom grant).

1.2 Equipment costs (D.2): Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs (D.2): Costs of renting or leasing equipment

1.3.1 **What?** This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:

  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are not higher than the depreciation costs of similar equipment).

1.4 Equipment costs (D.2): Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services (D.3): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access to peer-reviewed scientific publications*, e.g. article processing or equivalent charges*, costs related to open access to research data and related costs, *such as data maintenance or storage and conference fees for presenting project-related research*)
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4 or the certificate was submitted not for the final report but before*).
- translation costs *(if translation is necessary for the action's implementation, is justified, etc.)*.

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services (D.3)):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are fulfilled *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are fulfilled *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the plan for the exploitation and dissemination of the results are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access to peer-reviewed scientific publications and research data are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Self-produced consumables with an accounting value in the inventory of the beneficiary (i.e. not internally invoiced costs for goods and services) — Consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price; the cost of production for the beneficiary is however normally recorded in the accounts of the beneficiary (as part of the *inventory)*. Therefore, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

> ⚠ Beneficiaries can **NOT** charge the **commercial price** for self-produced consumables.

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.
The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency are eligible normally under category D.3 'other goods and services' if they comply with the eligibility conditions (and unless the temporary work agency carries out directly some task of the action, in which case it can be considered as subcontracting and should be declared under category B 'subcontracting').

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure (D.4): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of Horizon 2020 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in

[19] *See also International Financial Reporting Standard No 16.*

particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure to calculate the EUR 20 million threshold *(see below)* and therefore declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

[20] *See Article 126 of the Financial Regulation No 966/2012.*

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure (LRI)

Beneficiaries can declare capitalised and operating costs for **large research infrastructure**, if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a **research infrastructure** in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a **grouping of costs** (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any GA (by ticking the LRI box either in the Participant Register or during grant preparation).

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Participant Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) ex-ante assessment report will be issued.

⚠ Although the ex-ante assessment is granted at entity level, it does not necessarily mean that it covers the entire legal entity from the beginning of H2020. It may cover only some departments, cost centres or even individual infrastructures of the beneficiary, possibly with different starting dates.

In that case, the beneficiary may use budget category D.4 only for cost items that are covered by the positive assessment (i.e. that use the methodology and comply with the conditions of the approval).

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs in category D.4 'large research infrastructure'.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) before signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

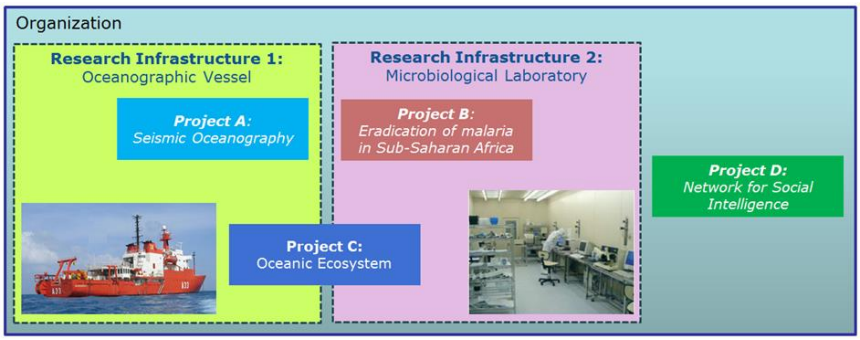

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[23].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU/Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU/Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the H2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the H2020 grant, even if they belong to the same action.

> ⚠ **Combining H2020 & other EU grants —** The terminologies under the different EU funds/funding programmes may differ *(e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).*

4.4 Costs must be directly measured

Costs can be claimed as direct costs in category D.4 'Large research infrastructure' only if they are **directly measured** (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[23] *See Article 129(1) of the Financial Regulation No 966/2012.*

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (**project time**) and therefore require reliable time recording (through time-sheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No *1290/2013*

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. This data must be regularly updated.

  Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints *(e.g. opening hours)*, but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

D.5 Costs of internally invoiced goods and services directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

1. Costs of internally invoiced goods and services (D.5): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category covers the costs for goods and services which the beneficiary itself produced or provided for the action. They include (non-exhaustive list):

- self-produced consumables *(e.g. electronic wafers, chemicals)*
- use of specific research devices or research facilities *(e.g. clean room, wind tunnel, supercomputer facilities, electronic microscope)*
- specialised premises for hosting the research specimens used for the action *(e.g. animal house, greenhouse, aquarium)*
- standardised testing or research processes *(e.g. genomic test, mass spectrometry analysis)*
- hosting services for visiting researchers participating in the action *(e.g. housing, canteen*).

What not? Costs of goods of services purchased and costs of goods or services internally invoiced which are not directly used for the action *(e.g. supporting services like cleaning, general accountancy, administrative support, etc.)*.

1.2 Costs of internally invoiced goods and services must be **declared as** unit costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following cumulative **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. used during the action duration, necessary for the action, etc.; *see Article 6.1(b)*)

- be in line with the beneficiary's **usual cost accounting practices**

  It must be the usual practice of the beneficiary to calculate a unit cost for that good or service (i.e. an internal cost per unit invoiced to other departments of the same entity – not prices charged in the context of commercial sales or grants from other fund providers).

- the cost accounting practices must have been applied in a **consistent** manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  Example: *if the beneficiary sets up a new unit cost which applies only to EU actions, the internally invoiced costs based on that new unit cost would be ineligible.*

- the amount per unit must have been **calculated** using the actual costs recorded in the beneficiary's accounts, excluding any ineligible costs or costs already included in other budget categories

  If necessary, the unit cost must be adjusted to remove:

  - cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the unit cost for its internal invoices)

    Example: *The beneficiary uses internal invoices for the use of an electronic microscope based on a unit cost per hour of use. The methodology to calculate the unit cost includes costs of capital (e.g. interest charged by the bank for a loan used to buy the microscope). Those costs are ineligible under the GA (see Article 6.5) and must therefore be removed. The unit cost must be recalculated without them.*

    ⚠ A beneficiary cannot simply apply an estimated percentage of deduction on the amount of its internal invoices to remove ineligible costs. It has to ensure that the internal invoice does not include any ineligible costs under the GA.

  - costs of resources that do not belong to the beneficiary and which it uses free of charge *(e.g. personnel or equipment of a third party provided free of charge)*, because they are not in its accounts *(see Article 6.1(a)(v))*

    As an exception, if the resource for which the unit cost is calculated is co-owned by the beneficiary and a third party, the costs registered in the accounts of the third party for the co-owned resource do not need to be removed if:

    - the third party is mentioned in the grant *(e.g. as third party providing in-kind contributions in Annex 1)* and

    - the costs fulfil the other eligibility conditions of this Article *(e.g. directly linked to the resource, exclude ineligible costs, etc.)*.

  - costs that are already included in other budget categories (double funding of the same costs, *see Article 6.1(a)(i)*).

    Example: *The beneficiary uses internal invoices for water chemistry analyses, based on a unit cost per water sample analysed. The methodology to calculate the unit cost includes the cost of the staff carrying out the analysis. However, the costs for those persons are already charged to the action under direct personnel costs (category A.1). The cost of the staff must therefore be removed and the unit cost must be recalculated without them.*

- if budgeted or estimated elements were used to calculate the amount per unit, those elements must:

  - be relevant (i.e. clearly related to invoiced item)

- be used in a reasonable way (i.e. do not play major role in calculating the unit cost)
- correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

- the amount per unit must have been calculated using only costs of items which were **directly linked** to the production of the internally invoiced goods or services *(e.g. staff, equipment, raw materials, etc.)*

  If a cost item is not used exclusively for the internally invoiced good or service, only the share used for the good or service may be counted (the percentage taken must be substantiated by persuasive evidence).

  Example: ***Shared staff —*** *Among the persons operating the beneficiary's wind tunnel, there is one person that is assigned only part-time to that wind tunnel; the rest of the time it works in another department. If the beneficiary includes the costs of this person at the rate of 50 %, it must be able to justify the reality of that percentage, for example, by any of the following:*
  - *reliable time recording system*
  - *a statistic survey performed in the past based on actual data*
  - *detailed calculations based on technical specifications or other scientific and technical requirements of the equipment or infrastructure allowing to reconcile the time spent by the person for the functioning of the wind tunnel*

  or
  - *a combination of these methods.*

  ⚠ **Ceiling** — The (share of the) working time of a person which is included in the calculation of the unit cost reduces the number of hours that the person can charge over the year to EU/Euratom grants *(see Article 6.2.A. Calculation)*. The same hours of the person cannot be charged twice to the grant, once embedded in the unit cost and again as direct personnel costs.

  If necessary, the unit cost must be adjusted to remove costs elements allocated to the unit cost indirectly; i.e. through cost drivers/allocation keys based on other cost items included in the unit cost *(e.g. for a clean room: the costs of the of the human resources department charged to the unit cost as a fixed amount per employee assigned to the clean room; or power supply costs allocated to the clean room on the basis of the square meters it occupies)*.

  Example: *Costs for an animal housing facility*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. keepers, veterinarians and other persons directly assigned to run the animal house)* – *consumables used for the animal housing (e.g. animal food, bedding)* – *depreciation of cages and other equipment directly linked to the housing of the animals* – *generic supplies like electricity or water — BUT only if the consumption of the facility has been directly measured (so that the cost can be accurately determined)* – *maintenance and cleaning of the animal house facility — BUT only if the cost is directly identifiable (e.g. a separate invoice for the cleaning of the cages)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the animal house facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the animal housing is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

Example: *Wind tunnel*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. technicians, engineers and other persons directly assigned to the functioning of the wind tunnel)* – *depreciation of the equipment, including specific software and hardware necessary for the functioning of the wind tunnel* – *generic supplies like electricity — BUT only if the consumption of the facility has been directly measured (so the cost can be accurately determined)* – *insurance — BUT only if the cost is directly identifiable (e.g. a separate invoice for the insurance of the facility)* – *maintenance and cleaning of the wind tunnel equipment (e.g. air cooling system) — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)* – *calibration/metrology tests — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the building where the installation is located is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

1.1.4 They must be **calculated** according to the rules set out above (point 1.1.3).

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Article 6.2. Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) *[**OPTION 1 to be used if Article 15 applies:** costs of providing financial support to third parties[and][;]][**OPTION 2**: not applicable;]*

(d) *[**OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:** [unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION 2:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (E.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared as** a fixed flat-rate (*see Article 5.2(e)*; ⚠ new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

⚠ The pre-filled amount may NOT be changed (except in case of a parallel operating grant, *see below*).

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation, etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying the 25 % flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

***Example:** subcontracting of opinion surveys*

The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises
- costs of providing financial support to third parties (if option applies)
- costs from specific cost categories (unit or lump sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a GA and has incurred the following costs:

- *EUR 100 000 personnel costs (EUR 7 000 of which are an in-kind contribution in the form of a laboratory technician who carries out work for the action from his/her laboratory in a public research centre)*
- *EUR 20 000 subcontracting costs,*
- *EUR 10 000 other direct costs (consumables).*

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

⚠ **Combining different EU grants —** Beneficiaries that have **action grants** and **operating grants** may claim indirect costs in their action grants ONLY if they are able to demonstrate cost separation (i.e. that their operating grants do not cover any costs which are covered by their action grants).

Operating grants are annual grants to finance the operation and running costs of an entity *(e.g. call COMM-C2/01-2013 under the Europe for Citizens programme)*.

Example: *Entity A receives an operating grant under the Europe for Citizens programme for the financial year 2016 (i.e. from 01.01.2016 until 31.12.2016) The operating grant is not renewed in 2017. On 01.04.2016, entity A signs an H2020 action grant with one reporting period of 18 months (01.04.2016 – 31.12.2017). Beneficiary A may declare the indirect costs in the H2020 action grant as follows:*

- *from 01.04.2016 to 31.12.2016 ONLY IF it can demonstrate that the operating grant does not cover any costs of the action (see beow);*
- *from 01.01.2017 – 31.12.2017 under the normal H2020 rules (i.e 25% of the direct eligible costs since there is no operating grant covering the 2017 financial year).*

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grants may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be full operating grants)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant activities or the operating grant activities)
- the beneficiary must record:
  - all real costs incurred for the activities that are covered by their operating grants (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all real costs incurred for the activities that are covered by their action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that **cannot fulfil these conditions** must EITHER:

- not sign/terminate the operating grants, in order to be able to claim indirect costs in the action grants
- keep the operating grants, but sign the action grants *without* indirect costs or request no indirect costs at reporting stage (i.e. lower the pre-filled amount in the indirect cost column of the financial statement).

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of overlapping EU action and operating grants, the beneficiary should immediately contact the Commission/Agency (via the Participant Portal). Be aware that operating grants are not always easy to identify.

F. [OPTION 1: [Insert name of specific cost category(ies)[22]]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION** 1a **for** specific unit costs **(if unit cost foreseen by Commission decision and applicable to the grant): [insert name of specific cost category]** are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category]** are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]

[same for each specific cost category]

[OPTION 2:** Not applicable**]

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of Horizon 2020, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: **costs for energy efficiency measures in buildings**

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': **access costs for providing trans-national access to research infrastructure**

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': **costs for clinical studies**

  The unit cost applies ONLY to actions with clinical studies.

⚠ **Double funding risk —** Costs that are declared as a specific unit or lump sum cost may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Example:

The unit cost for efficiency energy measures in buildings covers subcontracting costs related to the energy efficiency measures. These cannot be declared as subcontracting costs. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

1.1 Specific cost category – costs for energy efficiency measures in buildings (F.2)

1.1.1 What? This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared as** the unit cost set out in Commission *Decision C(2013) 8196*[25] and set out in Annexes 2 and 2a of the GA.

The precise unit cost ('amount per unit', i.e. EUR/m2 of eligible conditioned gross floor area) is not pre-fixed by the Decision; it must be calculated for each beneficiary/linked third party — before signature of the GA — using the following table:

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

The formula for calculating the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) is:

Amount per unit = {EUR 0,1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

[25] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

The use of the unit cost is mandatory. The beneficiaries/linked third parties cannot choose between unit and actual costs.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m² of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1 EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0,1 EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 Specific cost category – access costs for providing trans-national access to research infrastructure (F.2)

1.2.1 **What?** This budget category **covers** direct and indirect access costs for providing trans-national access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.

Beneficiaries that use budget category F.2 'access costs for providing trans-national access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, in category D.1 'travel'; *see Article 6.2.D.1 and Article 16*.)

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing trans-national access to research infrastructure'), the costs must be **declared as** the unit cost calculated in accordance with Commission Decision C(2013) 8199[26] and set out in Annex 2 and 2a of the GA.

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

The precise unit cost (amount per unit, i.e. EUR/unit of access) is not pre-fixed by the Decision; it must be calculated for each access provider and installation, using the calculation table provided on the call page and then summarised in the following table:

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The formula for calculating the 'amount per unit of access' (EUR/unit of access) is:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{27})}{\text{average annual total quantity of access (over past two years}^{28})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed under previous EU grants, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the user's research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)

[27] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
- costs of specific scientific services included in the access provided or needed for the provision of access

Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.

- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)
- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5 900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800 000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6 100, 5 900) = 6 000

Unit cost = average (3 200 000, 2 800 000) / average (6 100, 5 900) = 3 000 000 /6 000 = 500 €

The detailed calculation tables (one for each installation) must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annex 1; the summary table must be included in Annex 2a.

The proposal and Annex 1 should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. One cost form per installation.

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 Specific cost category – costs for clinical studies (F.2)

1.3.1 **What?** This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
- costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
- indirect costs for the study.

What not? Travel and subsistence costs of study participants and horizontal tasks *(e.g. study monitoring, study coordination)* are not covered by the clinical studies unit cost. (These costs can be reimbursed separately, *e.g. in categories A. 'personnel', D.1 'travel' and D.3 'other goods and services'; see Articles 6.2.A, 6.2.D.1, 6.2.D.3*.)

1.3.2 If they are declared under this budget category (i.e. F.2 'costs for clinical studies'), the costs must be **declared as** the unit cost set out in Commission Decision C(2016) 7553[29] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/study participant) is not pre-fixed by the Decision; it must be calculated for each study/study sequence *(see below)* and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — using the following table:

Task, Direct cost categories	Resource per patient	Costs year N-1 Beneficiary 1 [short name]	Costs year N-1 Linked third party 1a [short name]	Costs year N-1 Beneficiary 2 [short name]	Costs year N-1 Linked third party 2a [short name]	Costs year N-1 Third party giving in-kind contributions 1 [short name]
Sequence No. 1						
Task No. 1						

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1 XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR

	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

⚠ Where the nature of the clinical study allows it, it can be split into sequences, *e.g. treatment cycles*. The number of sequences should be limited to the necessary minimum *(e.g. 3 sequences)*.

Separating the unit cost table into sequences will allow you to declare unit costs for study participants that dropped out during the study, but finalised the tasks of a sequence. Thus, the sequence unit cost can be charged for the participant, for the completed sequence(s).

Each beneficiary/linked third party/third party must calculate its unit cost on the basis of its historical data (estimated costs of the components per task and study participant). Historical cost reference data should be taken from the last closed financial year at the time of submission of the grant proposal (certified or auditable profit and loss account for 'year N-1').

Beneficiaries can choose whether to include *all* the cost components in their unit cost or only *some*, but they may NOT add any other cost categories.

They may choose whether to include personnel costs or not, but if they do, *all* the study-related personnel costs must be included (they cannot choose for individual persons/types of personnel). Moreover, this choice must be applied to all the tasks and sequences of the study. If personnel costs are included, they must moreover use one of the three available categories: doctors, other medical personnel or technical personnel (no other categories, *e.g. nurses must be included in 'other medical personnel').*

For consumables, medical equipment and services, there is more flexibility. They can choose for each individual cost items, if they would like to include it in their unit cost (or declare them as actual costs).

The choice (whether to include a cost component in the unit cost or not) is made by adding the costs into the table (or leaving it blank). All blank cost components are outside the unit cost (and can normally be declared as actual costs, if all the eligibility conditions are met).

The beneficiaries/linked third parties/third parties may therefore (for the same study/sequence) not only obtain completely different amounts per unit, but also include different components into their calculation.

Example:

Beneficiary No 1 decided to claim:

- *personnel costs as unit costs*
- *all consumables for sequence 1 as actual costs, all consumables in sequence 2 as unit cost and consumables in sequence 3 partially as actual, partially as unit costs*
- *medical equipment partially as actual, partially as unit cost (e.g. cost of a standard MRI scan — part of the study protocol sequence 2 task 3 — as unit costs and the costs for the use of an novel imaging tool — also sequence 2 task 3 — as actual costs, for instance because the historical data is not fully available)*
- *all services as unit costs.*

Beneficiary No 2 decided to claim all study costs as unit costs.

Linked third party 2a decided not to use the unit cost for any of the study costs (all costs as actual costs).

The formulas for calculating the individual cost components are:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

{certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full time equivalent for doctors for year N-1}
multiplied by
estimated number of hours to be worked by doctors for the task (per participant)**}**

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full time equivalent for other medical personnel for year N-1}
multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)**}**

For personnel costs of technical personnel: 'average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full time equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1
total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)**}**

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}
total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned,

provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1 / total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1**}**

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}**}**

multiplied by

25%**}**

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

This table must already be part of the proposal *(see the proposal templates and the template for essential information to be provided for proposals including clinical studies provided on the call pages)* and be included in Annex 1 and 2a of the GA.

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs components not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*.

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently (and for the different cost components/cost items) whether to be reimbursed on the basis of unit costs or of costs actually incurred.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

⚠ Amendment requests to change the unit cost calculation will be accepted ONLY if there was a change in the study protocol *(e.g. due to requests from competent authorities, regulatory agencies or ethics committees)* or if there was an error in the calculation.

⚠ The maximum grant amount *(see Article 5.1)* will NOT be increased.

⚠ In case of an amendment, it is still the historical costs of the last closed financial year at the time of submission of the grant proposal that must be used to re-calculate the unit cost.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

- amount per unit *(see Annex 2a GA)* **x** the number of study participants

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

1. Costs of linked third parties (A-F)

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility) like beneficiaries.

The same rules apply, but with the changes needed to render them applicable to linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 14.1.1.

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared in category A.1 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions by third parties free of charge (A-F)

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared in category D.2 'equipment' (Article 6.2.D.2).*

In-kind contributions *free of charge* must be **distinguished** from **in-kind contributions *against payment*** *(see Article 11).*

In-kind contributions *against payment* are costs *of* the beneficiary (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. Their costs (i.e. the payment) must be declared under those specific budget categories.

Examples:

1. *The cost of personnel seconded against payment must be declared in category A.3 'seconded personnel (against payment)' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

The costs of in-kind contributions free of charge (i.e. the costs of the third party offering them) can be assimilated to beneficiary costs and must be declared in the budget category that the beneficiary would have used.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action [;][.]

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

– **debt and debt service charges**

'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

> ***Example:*** *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

– **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

Conversely, if VAT is NOT deductible, it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction

between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*
  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
  - if a beneficiary is receiving an operating grant[30] from the EU/Euratom, then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied — unless it can demonstrate that the operating grant does not cover any costs of the action *(see Article 6.2.E)*.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

If a beneficiary **declares ineligible costs**, they will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Specific cases (ineligible costs):

Non-identifiable VAT (in foreign invoices) — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts if it is not possible to deduct the VAT. That VAT would therefore be eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

Duties — The eligibility of duties depends on the eligibility of the cost item to which they are linked (i.e. in whose price they are included). If the item is eligible, the duty is also eligible.

[30] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the applicable national law.*

⚠ Normally, the beneficiaries must comply **BOTH** with the national law of the **country** in which they are **established** AND that of the country where the **action** is **implemented**.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA). However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Examples (acceptable):

1. *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

2. *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action. They may also call on international partners to carry out work under the action without receiving EU funding (see Article 14a) (**third parties involved in the action**).

Suppliers of goods, works or services and third parties providing in-kind contributions (against payment or free of charge) do not implement action tasks themselves but only make resources available to the beneficiary, whereas subcontractors, linked third parties and international partners implement action tasks.

⚠ Beneficiaries using third parties remain **fully responsible** for them under the GA.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues like beneficiaries.

Third parties involved in the action do NOT sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 Contracts to purchase goods, works or services	Article 13 Subcontracts
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 Contracts and subcontracts	Article 14 Implementation by linked third parties
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks. They must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme). ℹ For more information on conditions for participation and funding, *see the Participant Portal Online Manual.*

The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 Contracts	Article 11 In-kind contributions against payment
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the government (the ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the ministry/government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

This table gives an **overview** of the different kinds of **third parties**:

TYPE	CHARACTERISTICS						
	Works on action tasks?	Provides resources or services for action?	What is eligible?	Must be indicated in Annex 1?	Indirect costs?	Selecting the third party	GA articles
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link	Article 14
International partners	**YES**	**NO**	**N/A**	**YES**	**N/A**	Must not be eligible for funding	Article 14a
Subcontractor	**YES**	**NO**	**Price**	**YES**	**NO**	Must be best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contribution	**NO**	**YES**	**Costs**	**YES**	**YES**	May not be used to circumvent the rules	Articles 11 and 12
Contractor (selling, equipment, good or service)	**NO**	**YES**	**Price**	**NO**	**YES**	Must be best value for money, avoid conflict of interest	Article 10
Third parties receiving financial support[31]	The third parties participate in the action as recipients.		**Amount of support given**	**YES**	**NO**	According to the conditions in Annex 1	Article 15

[31] Only if allowed in the work programme/call.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

*[****additional OPTION for beneficiaries requesting zero funding****: If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION 2:** Not applicable]*

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

Beneficiaries not receiving EU funding — They participate in the action as beneficiaries, but NOT with EU funding. They must carry out the work under the action and comply with the GA (although not with *all* its obligations; the financial obligations and some IPR obligations do not apply for them).

'**Beneficiaries not receiving EU funding**' are either:

- 'beneficiaries **not eligible** for funding', i.e. beneficiaries which:
  - are NOT from an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme AND
  - were NOT granted exceptional EU funding by the Commission/Agency (during the selection procedure)

For more information on third country participants, *see the Participant Portal Online Manual (international cooperation).*

Beneficiaries that (exceptionally) become eligible for funding during the action, may in principle request funding (as from their eligibility), if the grant agreement is amended to change Articles 9, 57 and Annex 2 (*see Article 55*).

Since the maximum grant amount will NOT be increased *(see Article 5.1)*, this would only be possible if the consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY as from the date of eligibility for funding and if they comply with all the obligations under the GA *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

- 'beneficiaries **requesting zero funding**', i.e. beneficiaries that are eligible for funding, but decided not to request any funding.

Beneficiaries requesting zero funding may in principle request funding later on, if the GA is amended (to change Article 9 and Annex 2; *see Article 55*).

Since the maximum grant amount will NOT be increased *(see Article 5.1), this would only be possible if the* consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY if they comply with all the obligations under the GA retroactively *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate as beneficiaries in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on their role in the grant and if the beneficiary has linked third parties that receive EU funding or not).

This table shows the **GA obligations** that do **NOT apply** to beneficiaries not receiving EU funding (marked by X under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Articles 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of **breach** of any **of** their **obligations**, their participation may be terminated and any of the other Chapter 6 measures (except for rejection of costs or recovery) may be taken.

Examples:

1. *A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

2. *In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).*

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...][23]**]

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EU)[25] or 'contracting entities' within the meaning of Directive 2004/17/EC[26] (or 2014/25/EU)[27] must **comply** with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

Purchases — For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the purchasing context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, *such as technical quality, etc.*), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the grant amount). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules which the European Commission applies for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional cost eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[32] must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 4 of Directive 2014/25/EU)*.

Specific cases (purchases):

Purchases between beneficiaries — Are in principle not accepted. If a beneficiary needs supplies from another beneficiary, it is the latter beneficiary that should charge them to the action. (Otherwise there is the risk that the grant is used to charge commercial profit margins.) Purchases between beneficiaries will only be accepted in exceptional and properly justified cases *(e.g. beneficiary A is the usual supplier of beneficiary B for a generic consumable that beneficiary B needs for the action)*.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[32] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the measures described in Chapter 6.

1. In-kind contributions by third parties against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example (in-kind contributions against payment): *medical equipment provided by a hospital (against a fee) to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2; e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

If the amount paid by the beneficiary is lower than the cost incurred by the third party, the beneficiary may in addition declare the difference as in-kind contributions free of charge (see Article 12). If it decides to do so, it may have to declare that difference also as receipt (*see Article 5.3.3*).

For the upper limit (third party's costs), normally only the *direct* costs *actually* incurred by the third party will be taken into account.

The following costs may however be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[33] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the GA (alternative to actual costs; *see Article 6.2.F*).

The actual costs must be identifiable and verifiable in the third party's accounts.

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used on the beneficiary's premises

or

- taken into account: if the in-kind contributions are NOT used on the beneficiary's premises (*but, for instance, on the third party's premises*).

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

[33] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

3. Additional cost eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1 (*see Article 55*). Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA (**simplified approval procedure**).

Example (approval): *A new researcher is brought into a team working during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

Specific cases (in-kind contributions):

Foundations, spin-off companies, etc., created in order to manage the administrative tasks of the beneficiary and which are paid directly by the coordinator — These are typically legal entities (third parties) created or controlled by the beneficiary (usually a public body like a university/ministry) which handle the financial and administrative aspects of the beneficiaries' involvement in research projects.

Their tasks may include, among others, the employment of personnel, purchase of equipment or consumables that the third party puts at disposal of the beneficiary to carry out the work of the project.

Sometimes they also include the handling of the EU contribution (which means that the beneficiary will use the bank account of the third party and that all payments made to that account count for the beneficiary).

The contributions made by these entities are usually qualified as in-kind contributions against payment. If the costs for the services are not recorded in the accounts of the beneficiary *(e.g. there is no invoice from the entity)*:

- the beneficiary has to prove that such practice in line with national law and applicable accounting standards
- the costs must be recorded in the accounts of the third party.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The beneficiaries may declare **costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions by third parties free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary itself makes no payment and there is therefore NO cost incurred by the beneficiary. However, the GA provides that it may charge the costs incurred by the third party for its in-kind contribution *(see also Article 6.4)*.

Examples (in-kind contributions free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the ministry/government).

Article 12 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in *Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs *actually* incurred by the third party may be declared.

The following costs may however (alternatively) be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[34] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the GA (alternative to actual costs; *see Article 6.2.F*).

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used in the beneficiary's premises

or

- taken into account: if the in-kind contributions are used on the third party's premises.

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs; but the beneficiary may NOT include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional cost eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1 (*see Article 55)*. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA (**simplified approval procedure**; for details, *see Article 11*).

[34] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[28]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]*.**]***

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be **set out in Annex 1** and the total estimated costs of subcontracting per beneficiary must be **set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) **must comply** with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ **Subcontractors —** Subcontractors participate in the action by carrying out action tasks *for* the beneficiary. They are NOT beneficiaries and therefore have no direct obligations under the grant agreement (but their beneficiaries must ensure that they comply with certain key obligations).

Subcontract — For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on business conditions

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from linked third parties; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2).*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work.

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary.

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

The beneficiaries must make special arrangements regarding **results** produced by the subcontractors (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

⚠ **Security obligations —** Stricter rules apply for action tasks that involve information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

ⓘ For more information on security obligations, *see the Guidelines for the handling of classified*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts either on the best value for money (considering the quality of the service proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the subcontracting context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional cost eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI).

⚠ This concerns research and innovation actions or innovation actions *with* a PCP or PPI.

This should NOT be confused with PCP/PPI action (separate type of action, which use a different model grant agreement and whose *main* action task is the implementation of the PCP or PPI).

The additional rules mirror the key obligations for PCP/PPI actions from the H2020 MGA PCP/PPI.

4. Additional cost eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the **name** of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the subcontract (or the subcontracting costs). For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2 (*see Article 55*). Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA (**simplified approval procedure**).

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the full discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

5. Additional cost eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[35]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 4 of Directive 2014/25/EU)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* **—** Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts —** Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[35] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[30] and **third parties with a legal link to a beneficiary**[31] (**'linked third parties'**) may implement the action tasks attributed to them **in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

*The linked third parties may declare as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

*The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their linked third parties.*

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

⚠ **Linked third parties —** Linked third parties are allowed to participate in the action, like the beneficiary they are linked to. They are NOT beneficiaries, but they are allowed to participate fully in the action and receive EU funding; they will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries and their beneficiaries must ensure that they comply with certain key obligations.

⚠ **Combining H2020 & other EU grants —** The terminologies under different EU funds/funding programmes may differ *(e.g. 'linked third parties' under H2020 are the SAME as 'affiliated entities' under the Financial Regulation, while 'affiliated entities' under H2020 is NARROWER than 'affiliated entities' under the Financial Regulation (see Articles 2.1(2) and 23(5) of the Rules for Participation Regulation No 1290/2013 and Article 122 of the Financial Regulation No 966/2012).*

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission/Agency as reimbursement of costs for their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only **affiliated entities** or **entities with a legal link to a beneficiary** can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

- broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; ad hoc collaboration agreements or contracts to carry out work in the action are NOT covered. In this latter case, both legal entities should be beneficiaries.

AND

- a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

- under the direct or indirect control of the beneficiary or

- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

1. Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research)* ***—*** *They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

2. Associations, foundations *or* ***other legal entities composed of members —*** *That entity is generally the beneficiary and the members are the linked third parties.*

Examples (affiliated entities):

1. *Company A established in France holding 20% of the shares in Company B established in Italy. However, with 20% of the shares it has 60% of the voting rights in company B. Therefore, company A controls company B and both companies may be linked third parties in a H2020 GA.*

2. *Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.*

Linked third parties must fulfil the same **conditions for participation** and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme).[36]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an US company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country that is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.*

For more information on conditions for participation and funding, *see the Participant Portal Online Manual*.

They must be **named** in Article 14 and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the linked third party is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the linked third parties (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial capacity of a beneficiary is 'weak' and
- the beneficiary mainly coordinates the work of its linked third party.

Examples:

[36] *See Articles 9 and 10 of the Rules for Participation Regulation No 1290/2013.*

1. The financially weak beneficiary is an association and most of the work is carried out by several of its members as linked third parties.

2. The financially weak beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.

3. The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery), who must upload it (as a scanned PDF copy) in the system.

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files.

The liability is for any amount owned by the beneficiary under the GA, and up to the linked third party's maximum EU contribution in Annex 2.

For more information on the financial capacity check, *see the Participant Portal Online Manual*.

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. Entities specifically established for the purpose of implementing the action (e.g. EEIGs).

2. National research associations established according to the national law in order to carry out research not limited to the action.

3. A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional cost eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO simplified approval procedure.

3. Additional cost eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* (since linked third parties cannot sign them in the IT system; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary.

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Each linked third party has to provide its own ***certificate* on the financial statements** (**CFS**; *see Article 20.4*).

The threshold of EUR 325 000 applies to each linked third party (independently of its beneficiary).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

4. Additional cost eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. 'Other obligation': Extension of obligations under the GA to linked third parties

The beneficiaries must ensure that the linked third parties comply with certain obligations under the GA.

Obligations that must be extended to linked third parties:

- Record-keeping obligations *(see Article 18)*
- Reporting *(see Article 20)*

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties.

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following **international partners**[37] may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

– *will not be reimbursed and*

– *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36 and 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary braches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION 2:** Not applicable**]

[37] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

1. International partners

4.0 This optional Article (together with the corresponding options in Article 4) will be inserted into the GA if the action is implemented with international partners. It was introduced with GA version 4.0 and does NOT automatically apply to older grant agreements (however beneficiaries with older GAs may ask for an amendment to introduce international partners *see Article 55*).

International partners — International partners are allowed to participate in the action without EU funding. They are NOT beneficiaries and do NOT receive EU funding; they therefore have no direct obligations under the grant agreement (but their beneficiaries must to ensure that they comply with certain key obligations).

Characteristics of implementation by international partners:

- International partners perform their action tasks directly. They do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the action tasks performed by its international partner.
- International partners perform their action tasks without receiving EU funding, i.e. their costs are NOT eligible for reimbursement under the grant. Therefore, they will not be subject to financial checks, reviews or audits.

  The costs of the international partners are estimated in Annex 2 (to get an overview of the overall project budget). But this is for information purposes only, the international partners are not required to report on their costs.

International partners do NOT need to have a (capital or legal) link to the beneficiary (but they may have one).

They must NOT be eligible for funding, i.e. be:

- a legal entity established in a third country not listed in General Annex A to the H2020 Work Programme or

  Example: *A consortium of legal entities from EU Member States, H2020 associated countries and third countries listed in General Annex A to the H2020 Work Programme wants to work with a legal entity established in New Zealand. Since the New Zealand entity would like to be involved in the action without requesting EU funding and without becoming a beneficiary, one of the beneficiaries may decide to list the New Zealand entity as its international partner and attribute certain action tasks to it (provided that the international partner agrees to the action tasks and the related obligations under the GA).*

- an international organisation other than international European interest organisations[37].

They may be used to implement any of the action tasks.

They must be **named** in Article 14a and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the international partner is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the international partners (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

Although they are not beneficiaries and do not receive EU funding, their beneficiaries must ensure that they comply with certain key (non-financial) obligations:

Thus, they must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 to verify the proper implementation of the action tasks and that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

Moreover, they must extend the following obligations under the GA to the international partners:

Obligations that must be extended to international partners:

- Record-keeping obligations (on the scientific and technical implementation; *see Article 18.1.1*)
- Technical reporting (in the required language; *see Article 20.3(a), 20.4(a) and 20.7)*
- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*

[37] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013*: **'international European interest organisation'** means an international organisation, the majority of whose members are Member States or associated countries, and whose principle objective is to promote scientific and technological cooperation in Europe.

- Promoting the action and give visibility to the EU funding *(see Article 38).*

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the international partners.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

*At a minimum, these **conditions** must include:*

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

*The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties receiving financial support.*

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the third parties receiving financial support.**]***

[OPTION 2: *Not applicable**]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties ONLY where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*.)

Examples:

1. *An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.*

2. *One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.*

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving a prize.*

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving a prize.****]***

[OPTION 2: *Not applicable****]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

***Access** for user groups with a majority of users not working in a EU or associated country[34] is **limited** to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) procedure and criteria for **selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: […]*[35]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

(a) advertise widely, including on a dedicated website, the access offered under the Agreement;

(b) promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;

*(c) ensure that users **comply** with the terms and conditions of the Agreement;*

*(d) ensure that its obligations under Articles 35, 36, 38 and 46 **also apply** to the users.*

[OPTION 2:** Not applicable**]

[32] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[34] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]***

[35] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the H2020 Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[38] or installation[39] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 of the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

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[38] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[39] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

⚠ **Record-keeping —** The beneficiaries must keep appropriate records and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional cost eligibility condition: Access which must be provided

Trans-national access can be either:

- **in person** (hands-on), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional cost eligibility condition: Categories of users that may have access — Limited access for special user groups

For trans-national access, user groups in which all or most users work in non-associated **third countries** may ONLY have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional cost eligibility condition: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. 'Other obligation': Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to users

The beneficiaries must also ensure that the users comply with certain obligations under the GA.

Obligations that must be extended to users:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users.

16.2 Rules for providing virtual access to research infrastructure

[OPTION 1 for virtual access to research infrastructure: *'**Access providers**'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION 1 to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable**]***

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **reimburse** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action
- costs related to technological and scientific support for users access *(e.g. a helpdesk)*

- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 3)*.

The specific unit cost for access to research infrastructure (F.2) does NOT cover virtual access (only trans-national access).

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed — unless provided for in the work programme/call.

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*

Access must be open to all users; users are not selected.

3. Additional cost eligibility condition: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request the information for **any purpose** *(e.g. checks for monitoring the action or assessing reports and requests for payment; reviews; audits; investigations; evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission/Agency may request the information at **any time**, either during the action or afterwards.

Examples:

1. *In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid (see Article 22).*

2. *The Commission may request information from the beneficiaries in order to evaluate the action's impact up to five years after the balance is paid (see Article 23).*

3. *The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.*

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information is sent via the Participant Portal. Afterwards, information requests may have to be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Participant Register

Each beneficiary must keep its information in the Participant Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form *(e.g. private limited liability company, public law body, S.A., S.L.)*
- organisation type *(e.g. SME, secondary or higher education establishment, etc.)*.

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, *see the Participant Portal Online Manual*.

3. Information likely to delay or affect the action or EU financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU financial interests.

> ***Examples (situation likely to significantly affect or delay the action's implementation or affect the EU financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Participant Register *(see above)*, the beneficiary must **update** the Participant Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.).*

Best practice: It is recommended that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the Participant Portal
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (for linked third parties, *see point 10*) must keep appropriate and sufficient evidence to **prove** the eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[40]

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

[40] International Standard on Auditing ISA 500 'Audit Evidence'.

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Commission/Agency.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission/Agency will accept any document considered an original under national law.

Examples:

1. *The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.*

2. *The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.*

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

1. *For costs declared in category A.1 (employees or equivalent): the costs must be detailed for each person carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).*

2. *For costs declared in category D.1, D.2, D.3 and D.4 (other direct costs): the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.). It should be able to provide details of individual transactions for each type of cost. For depreciation, it must be able to provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).*

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For costs declared in accordance with their usual cost accounting practices (**average personnel** costs and costs of **internally invoiced goods and services**), the beneficiaries must keep detailed records and other supporting documents to:

- show that the costs used to calculate the unit cost match the actual costs as recorded in the statutory accounts

  Examples:

  1. *For personnel costs: accounting records; financial statement extracts; labour contracts; collective labour agreements; applicable tax, labour and social security laws; pay slips; bank statements showing salary payments; classification of employees (based on experience, qualifications, salary, department, etc.).*

  2. *For internally invoiced goods and services: accounting records; financial statement extracts; time records (or other records) for the share of personnel costs included in the unit costs; invoices or contracts for maintenance costs, cleaning costs, other services, showing that the cost are directly identifiable.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost is free of ineligible cost components

  Examples:

  1. *For personnel costs: records that show that the hourly rate does not include an indirect cost component (already covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (they should be claimed under category D.1 'travel').*

  2. *For internally invoiced goods and services: evidence that shows that there is no profit/margin/mark-up included in the internally invoiced goods and services (e.g. different rates: one for billing the activity, with mark-up, and another one for internal costing, free of any mark-up); lists of accounts/cost centres that were excluded from the calculation of internally invoiced goods and services — because already included in the costs claimed under another budget categories (e.g. LRI costs, indirect costs, in-kind contributions, etc.).*

- assess the acceptability of budgeted and estimated elements

  Examples:

  1. *For personnel costs: records that show the method for calculating the annual salary increases (e.g. consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases).*

  2. *For internally invoiced goods and services: traceable data used to determine the budgeted/ estimated elements; records on the nature and frequency of the updates of the budgeted and estimated elements; etc.*

- for personnel costs: verify the number of productive hours used to calculate the unit cost (hourly rate)

- for internally invoiced goods and services: verify that the cost items used for the calculation of the unit cost were directly linked to the production of the invoiced good or service.

Examples (not acceptable):

1. *Maintenance which goes beyond than the maintenance of the infrastructure/facilities used to produce the good/service (e.g. maintenance costs for all the beneficiary's cleanrooms; maintenance costs for an entire building, while the cleanroom used for the good/service occupies only a part of the building).*

2. *Generic supplies for which there is no evidence that they were directly linked to the infrastructure/facilities used to produce the good/service (e.g. electricity costs when there is no electricity counter or technical specifications to measure the consumption).*

By contrast, it is NOT necessary to keep records on the actual costs incurred (per person/good or service) — unless they are needed to document the usual cost accounting practices (as just described).

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary/linked third party may request that the Commission/Agency confirms that its cost accounting practices for personnel costs comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared *before* the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificate is NOT valid for H2020.)

When? Beneficiaries may in principle submit their requests for approval at **any time** — before or during the grant.

Best practice: In order to ensure that the auditor has enough information to get assurance on the methodology, it is recommended to request it only *after* the first reporting period has passed.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

⚠ If the beneficiary declares personnel costs according to the changed cost accounting practices *before* the new certificate is approved, it bears the **full risk** of non-approval and cost rejection by the Commission/Agency.

How? The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 of the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump sum costs

For lump sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

⚠ For H2020, exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, monthly or per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a declaration on exclusive work for the action [ODT format] (one per reporting period), to confirm that the person worked exclusively for the action, either:
  - during the whole reporting period

  or

  - during an uninterrupted time-period, covering at least a full calendar month within the reporting period.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

'Exclusive work' means that the person carried out NO OTHER activities for the beneficiary than those of the action.

Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration. If a person worked randomly for the action after an

uninterrupted time-period covered by a declaration, time-sheets are needed for the period of random work.

> ***Example:*** *The person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

If a person worked under different regimes during the reporting period (exclusive and non-exclusive), the declaration may be used ONLY for a period of exclusive work. The other months must be recorded with time-sheets.

If there were several periods of exclusive work during one reporting period, the beneficiary may choose to use the declaration for the longest one (and use the monthly time-sheets for the others).

The declaration must be **dated** and **signed** by the person concerned AND her/his supervisor.

– keep **time records**.

Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

– show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

Time records should include, as a minimum:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record
- the supervisor's full name and signature
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template [ODT format] for time-sheets with these minimum requirements is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept **alternative evidence** if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has full discretion to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the **full risk** of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned

Criterion 2 is met – the project is identified as XYZ

Criterion 3 is met – the time is quantified: two weeks

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown

Criterion 2 is not met: the project name is not mentioned

Criterion 3 is not met – the time is not quantified

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Example: *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

1. *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*

2. *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

For **international partners,** beneficiaries must keep appropriate and sufficient evidence ONLY on scientific and technical implementation of the action. Beneficiaries are not required to prove the costs of the international partners, since the latter do not receive EU funding (*see Article 14a*).

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When? The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

> 'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).
>
> 'Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points.

The deliverables that must be produced are listed in Annex 1 of the GA.

> ***Example:*** *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

For deliverables that are not in writing *(e.g. cell line or prototype)*, the beneficiaries must submit a short written description.

How? The coordinator must upload them directly in the Participant Portal.

Security obligations — If the deliverables contain **EU classified information**, the coordinator must first contact the Commission/Agency to discuss how to submit them (approval needed; *see Article 37*).

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1] to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2 : *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

What & When? In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of the action (reporting).

> These reports must be **distinguished** from **deliverables** (that are part of Annex 1; see Article 19) and milestones (part of Annex 1, but not covered by Article 19 or 20).

The coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Each report should be seen as a single package, composed of several parts, i.e.:

- a **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically generated by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (CFS; one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

If the coordinator **breaches** its **obligation** to submit the reports, the Commission/Agency may suspend the payment deadline and — if not remedied after a written reminder — terminate the GA or take any of the other Chapter 6 measures *(e.g. cost rejection, grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50).*

The GA will not be terminated if the breach concerns the last reporting period (because the action duration is already over).

How? The report(s) must be **prepared** by the **coordinator** and the other **beneficiaries together** (directly in the Participant Portal Continuous and Periodic Reporting Modules).

List of documents for the periodic reports:

- explanation of the work carried out (periodic reporting - part B technical report)
- overview of the progress (periodic reporting - part B technical report)
- updated plan for the exploitation and dissemination of results (if necessary) (periodic reporting - part B technical report)
- summary for publication (continuous reporting)
- answers to the questionnaire (continuous reporting)

- individual financial statements for each beneficiary and linked party (periodic reporting - financial report)
- explanation of the use of resources (periodic reporting - financial report)
- summary financial statement (generated automatically by the IT system)
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication (generated automatically by the IT system)
- final summary financial statement (generated automatically by the IT system)
- certificates on the financial statements (CFS) (if necessary).

Generally, they can be **prepared together** (i.e. by several users from different beneficiaries), via the Participant Portal Continuous and Periodic Reporting Modules. The parts in the **continuous reporting** can be filled out at any moment in time (continuously open) and are then automatically added into the periodic report by the IT system *(part A of the technical report with the questionnaire and the summary for publication; consolidated financial statement*). Other parts are opened only at **periodic reporting** *(part B of the technical report, individual financial statements, explanation of the use of resources)*. Data is cross-linked to avoid duplication of data input *(e.g. the financial statement and the explanation on the use of resources are linked: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense, if necessary; the final report is completely automatized: assembled on the basis of elements from the periodic report).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (directly in the Participant Portal).

This includes the **coordinator**, who must also submit the individual financial statement for itself.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (since the linked third parties cannot sign them in the IT system).

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must ensure that the data encoded is correct (i.e. identical to the signed paper version).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

If a beneficiary cannot submit its individual financial statement on time, the report can be **submitted without this financial statement**. The costs will be considered zero for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned.

⚠ **Record-keeping —** The beneficiary must keep the originals for itself and its linked third parties in its files *(see Article 18.1.2)*.

When all parts are ready, the report(s) are assembled automatically by the IT system and must be **submitted** by the coordinator (as a single package; **single submission**).

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator, as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) (**suspension of the payment deadline**). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified (**single re-submission**).

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

⚠ **Adjustments of financial statements (exceptional) —** If the beneficiaries notice a mistake *(e.g. incorrect accounting information; error in the calculation; etc)*, they can make an adjustment (positive or negative) in the following reporting period to the financial statements for any previous reporting period.

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed *(e.g. to take into account of a different hourly rate after the closure of the financial year)*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated **plan for the exploitation and dissemination of the results** (if such a plan is foreseen in Annex 1).

3.0 For grants signed after GA version 3.0, the overview of the progress must also indicate the communication activities carried out by the consortium *(see also Article 38.1).*

> ⚠ **Security obligations** — Technical reports may NOT contain any information that has been **EU-classified** in Annex 1 of the GA *(see Article 37).*
>
> ℹ For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an easy-to-read way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential (or EU-classified) information.

For the last reporting period: The summary should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact (because it will be directly re-used for the final report).

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the H2020 Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the H2020 Specific Programme)
- information to monitor the implementation of H2020 on cross–cutting issues *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Financial report: Individual financial statements — Explanation of the use of resources — Summary financial statement — Certificates on the financial statements (CFS)

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 (**cost overruns**). The grant will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

⚠ **Combining different EU grants —** Beneficiaries that have **action grants** and **operating grants** may claim indirect costs in their action grants ONLY if they are able to demonstrate cost separation (i.e. that their operating grants do not cover any costs which are covered by their action grants).

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grants may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be full operating grants)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant activities or the operating grant activities)
- the beneficiary must record:
  - all real costs incurred for the activities that are covered by their operating grants (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all real costs incurred for the activities that are covered by their action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that **cannot fulfil these conditions** must EITHER:

- not sign/terminate the operating grants, in order to be able to claim indirect costs in the action grants
- keep the operating grants, but sign the action grants *without* indirect costs or request no indirect costs at reporting stage (i.e. lower the pre-filled amount in the indirect cost column of the financial statement).

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of overlapping EU action and operating grants, the beneficiary should immediately contact the Commission/Agency (via the Participant Portal). Be aware that operating grants are not always easy to identify. They exist under various labels (operating grants; financial contributions/support to the functioning/operation of entities; etc.). Check your call text.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

For the final reporting period, some beneficiaries/linked third parties will also have to submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and unit costs calculated according to its usual accounting practices (average personnel costs and costs for internally invoiced goods and services).

This means that costs based on lump sums, flat-rates (*e.g. indirect costs*) or unit costs (other than those for personnel costs and costs for internally invoiced goods and services calculated according to the beneficiary's usual cost accounting practices) are NOT counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in an action which declared the following total eligible costs for the action:

- *personnel costs according to usual accounting practices = EUR 250 000*
- *subcontracting costs = EUR 40 000*
- *depreciation costs of equipment used to carry out the action = EUR 60 000*
- *indirect costs (25 % flat rate) = EUR 77 500*
- *total eligible costs claimed by A = EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and personnel costs according to usual accounting practices incurred by A (and hence the requested financial contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or unit costs calculated according to usual accounting practices must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency do not have to be covered again by the certificate.

Example:

A beneficiary participates in an action with three reporting periods. During the second reporting period the Commission's auditors carry out an audit of the costs incurred by the beneficiary in the first reporting period. At the end of the action, the beneficiary requests a total contribution of EUR 425 000 and has to submit a CFS with the final reports. In this case, the CFS may exclude the costs of the first reporting period (which were already covered by the Commission audit).

Linked third parties must submit a certificate if it reaches (on its own, without its beneficiary) the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

The certificate(s) may be submitted ONLY **with** the ***final*** **financial report**. Certificates submitted at any other moment will NOT be accepted (and costs incurred for them will be considered ineligible, because not necessary).

Costs for partial certificates (i.e. one certificate per reporting period) will be accepted ONLY in the last reporting period and ONLY if:

- a CFS is mandatory (i.e. the threshold is reached at the end of the action) and
- the total costs of the partial certificates is similar to the cost that would have been incurred for a single certificate.

The certificate must be issued by an **external auditor**, using the template in Annex 5 of the GA.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[41] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

The **summary financial statement** is generated automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

For the final reporting period, the IT system will also generate a **final summary financial statement** (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a non-EU country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in non-EU countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

5. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants above EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

A template is available and must be submitted via the Participant Portal Continuous Reporting Module.

[41] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

6. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[42].

    How to calculate the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[43].

    Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16,.7531 for EUR 1. The university will report costs of EUR 29 845,22 (MDL 500 000 / MDL 16,.7531 * EUR 1).*

7. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

[42] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[43] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments to be made

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts before)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or an(other) executive agency — without the consent of the beneficiary concerned and up to the beneficiary's maximum grant amount in Annex 2 *(see also Article 44)*.

All payments are subject to a **payment deadline** (i.e. number of days within which the Commission/Agency has to pay the consortium — after having received the payment request). The deadline depends on the type of payment:

- for pre-financing: 30 days
- for interim payments and payment of the balance: 90 days *(see Article 21)*.

If there are issues with the payment request or with the costs declared which make it impossible to comply with the payment deadline, the Commission/Agency will **suspend the deadline** *(see Article 47)*.

The pre-financing payment is automatic, while for interim and final payments the Commission/Agency must first:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs
- calculate the amount to be paid
- approve the payment request and authorise the payment.

This is not an in-depth verification and therefore no guarantee for eligibility or correctness. The costs may still have to be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

The payments are made **to the coordinator**; the beneficiaries are NOT paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only if the coordinator is terminated that the Commission/Agency (and especially the Guarantee Fund) will intervene; *see Article 50*).

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

The shares for the Commission's **Joint Research Centre (JRC)** will always be kept back and not be paid out to the coordinator (the JRC is a Commission DG and the amounts are therefore cleared internally).

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) is kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 - EUR 52 500 = EUR 297 500

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing amount does not depend on any financial statement. It is a float that is fixed in each GA and automatically paid at the beginning of the action.

How to calculate the pre-financing payment:

Step 1 — **Pre-financing amount**

The amount of pre-financing is fixed in the GA.

There is no standard amount (or percentage) for the pre-financing payment. For H2020 grants, it will normally be (depending on the availability of EU budget credits) 100 % of the average EU funding per reporting period (i.e. maximum grant amount set out in Article 5.1 / number of periods). For actions with only one reporting period, it will however be less, since 100 % would mean the totality of the grant amount.

Step 2 — **Deduction of the Guarantee Fund contribution**

At the moment of the pre-financing, an amount that corresponds to 5 % of the maximum grant amount *(see Article 5.1)* is deducted from the pre-financing payment and transferred to the Guarantee Fund. (The Guarantee Fund is a Fund that covers defaulting beneficiaries).

Step 3 — **Pre-financing payment letter**

The Commission/Agency will inform the coordinator about the amount due (pre-financing payment letter).

Pre-financing funds remain **EU property** until the payment of the balance — when they are cleared against the eligible costs accepted by the Commission/Agency.

Example for calculating the pre-financing payment:

Action with 3 reporting periods of 18 months.

Maximum grant amount: EUR 1 000 000.

Reimbursement rate: 100 %.

Guarantee Fund contribution: 5% of EUR 1 000 000 = EUR 50 000.

Pre-financing amount & deduction of Guarantee Fund contribution:

Pre-financing amount: EUR 333 334.

Amount to be paid out to the consortium as pre-financing: EUR 333 334 - EUR 50 000 = EUR 283 334.

Payment at beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Commission/Agency on the basis of the termination report, the payments already made and the report on the distribution of payments *(see also Articles 44.1.1, 50.2.2 and 50.3.3)*.

⚠ The **amount due** is used to determine whether the terminated beneficiary received too much from the consortium (and should pay it back to them) and will then flow into the calculation of the next interim and final payments in order to cap that beneficiary's accepted EU contribution.

⚠ The terminated beneficiary's share of the final grant amount (beneficiary's final grant share) will be calculated only at the end of the project (payment of the balance), together with the rest of the consortium.

⚠ If the terminated beneficiary is audited during the ongoing project, its amount due will be re-calculated. If the terminated beneficiary is audited after the end of the project, the recovery will follow the standard rules (revised final grant amount calculated on the basis of the final grant share).

How to calculate the amount due at beneficiary termination:

Amount due

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rate to the eligible costs)**

In order to calculate the amount of accepted EU contribution for the beneficiary concerned, the Commission/Agency will calculate the accepted costs for the beneficiary and each of its linked third parties (i.e. eligible/not rejected costs declared in the interim and termination reports; *see Articles 6 and 42*), apply the reimbursement rate(s) and sum them up to a total amount for the beneficiary.

Only costs incurred *(see Article 6.1(a))* by the beneficiary concerned until termination takes effect are eligible (except for costs for the termination report). Costs relating to contracts due for execution (i.e. delivery) only after termination are NOT eligible.

If the coordinator fails to submit the termination report (within the 30 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. The Commission/Agency will NOT send a written reminder and will not extend the deadline.

If the beneficiary requested less than the maximum EU contribution, the accepted EU contribution will be this lower requested amount.

➔ Amount resulting from Step 1.

Step 2 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions, the Commission/Agency will calculate the grant reductions for the beneficiary concerned and its linked third parties (if any; see *Article 43*) and then sum them up to a total amount for the beneficiary.

This total amount of grant reductions is then deducted from the pro rata temporis part of the beneficiary's and linked third parties' maximum grant amounts (Annex 2) — pro rata temporis corresponding to their period of participation (i.e. until termination).

Pro rata temporis formula:

{beneficiary's maximum grant amount *(see Annex 2)*

multiplied by

{months of participation

divided by

total action duration (months)}}

ℹ For more guidance on grant reductions, *see the Guide on grant reductions*.

➔ Amount resulting from Step 2.

The **amount due** is the lower of the two (amount resulting from Step 1 and amount resulting from Step 2).

Beneficiary balance

Step 3 — **Calculation of the beneficiary balance**

In order to establish if the beneficiary received excess funding, the Commission/Agency will deduct the total amount of pre-financing and interim payments made (according to the report on the distribution of payments) from the amount due.

If the amount due is *higher* than the payments already made, the difference will be paid by the Commission/Agency to the coordinator at the next interim/final payment.

If the amount due is *lower* than the payments made, the beneficiary must repay the difference (to the consortium; NOT to the Commission/Agency). If the beneficiary doesn't, the Commission/Agency will intervene, by activating the Guarantee Fund to pay the money to the consortium and then recovering it from the beneficiary in the name of the Guarantee Fund *(see below*).

If the coordinator does not submit the report on the distribution of payments, the terminated beneficiary will NOT have to repay any amounts to the consortium. If there are issues, the consortium will have to deal with them internally.

Step 4 — **Beneficiary calculation letter**

The Commission/Agency will inform the beneficiary about the balance, i.e. the amounts that are owed to the consortium or to the beneficiary concerned (beneficiary termination calculation letter).

If the closure involves grant reduction or recovery (refund to the consortium), there will be two letters: a pre-information letter (opening a contradictory procedure) and confirmation letter *(see Articles 43 and 44)*.

Recovery (if any)

Step 5 — **Beneficiary recovery letter & debit note**

If the beneficiary does not repay the consortium by the date specified in the confirmation letter, the Commission/Agency will activate the Guarantee Fund (to pay the consortium) and claim back the money paid by the Guarantee Fund from the beneficiary, (beneficiary recovery letter; *see Articles 44 and 50*).

Step 6 — **Enforced recovery**

If the beneficiary does not honour the debit note within the deadline, the Commission/Agency will enforce its claim, by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**
- taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
- adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Example for calculating the amount due at beneficiary termination:

Grant with three beneficiaries (A, B and C) and two reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100 %.

Pre-financing: EUR 200 000.

Amount due:

Beneficiary A goes bankrupt in the middle of the action and is terminated at month 18 (of 36), just before the end of RP1.

Costs declared by beneficiary A in termination report: EUR 50 000 (direct costs) + EUR 12 500 (25 % flat rate for indirect costs) = EUR 62 500.

Costs rejected for beneficiary A following audit: EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Accepted costs beneficiary A: EUR 62 500 – EUR 12 500 = EUR 50 000.

Application of reimbursement rate: EUR 50 000 (total accepted EU contribution).

Amount resulting from Step 1: EUR 50 000.

10% grant reduction beneficiary A due to breach of obligations: 10% of {{18/36} x EUR 200 000} = 10% of EUR 100 000 = EUR 10 000.

Amount resulting from Step 2: 100 000 – 10 000 = EUR 90 000.

Lower amount of the two: EUR 50 000.

Beneficiary A amount due: EUR 50 000.

Beneficiary balance:

Payments received by beneficiary A (according to the report on the distribution of payments): EUR 60 000.

Beneficiary A balance: EUR 50 000 (amount due) - EUR 60 000 (payments received) = EUR -10 000 (excess payments of EUR 10 000).

Recovery:

Amount to be recovered from beneficiary A: EUR 10 000 (negative balance of EUR 10 000 must be returned to the consortium; otherwise Commission/Agency will start a recovery procedure).

Interim payments

How much? The amount of the interim payments will be calculated by the Commission/Agency on the basis of the financial statements and the payments already made.

How to calculate interim payments:

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rates to the eligible costs)**

In order to calculate the amount of accepted EU contribution, the Commission/Agency will, for each beneficiary and linked third party, calculate the accepted costs (i.e. eligible/not rejected costs declared in the financial statement; *see Articles 6 and 42*), apply the reimbursement rate(s) and then sum them up to a total amount for the consortium.

If a beneficiary/linked third party requested in the financial statements less than the EU contribution, the accepted EU contribution will be this lower requested amount.

Step 2 — **Limit to 90% of the maximum grant amount**

If the total for the consortium is more than 90 % of the maximum grant amount minus pre-financing and previous interim payments, it will be capped.

Step 3 — **Interim payment letter**

The Commission/Agency will inform the coordinator about the amount due (interim payment letter).

Examples for calculating interim payments:

Case 1:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Interim payment RP1:

Costs declared by the consortium for RP1: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = EUR 625 000.

After checking the reports EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are considered not eligible and rejected. The Commission/Agency therefore rejects EUR 32 000 direct costs + EUR 8 000 (25% flat rate for indirect costs) = EUR 40 000.

Total accepted costs RP1: EUR 585 000.

Application of reimbursement rate: 100% = EUR 585 000 (total accepted EU contribution).

Limit to 90% of the maximum grant amount minus pre-financing = EUR 900 000 – EUR 333 334 = EUR 566 666.

Amount to be paid out to the consortium as interim payment for RP1: EUR 566 666.

Interim payment RP 2:

Total accepted costs RP2: EUR 162 500.

Amount to be paid out to the consortium as interim payment for RP2: EUR 0 (the 90% limit has already been reached in RP1: 333 334 + 566 666 = 900 000).

Case 2 (grant with terminated beneficiary):

Grant with three beneficiaries (A, B and C) and two reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Pre-financing: EUR 200 000.

Beneficiary A was terminated before the end of RP1 and the amount due was its accepted costs :EUR 62 500 EUR (no grant reductions applied).

Interim payment RP1:

Costs declared by beneficiary A for RP1: EUR 50 000 (direct costs) + EUR 12 500 (25% flat rate for indirect costs) = EUR 62 500.

Costs declared by beneficiary B for RP1: EUR 115 000 (direct costs) + EUR 28 750 (25% flat rate for indirect costs) = EUR 143 750.

Costs declared by beneficiary C for RP1: EUR 90 000 (direct costs) + EUR 22 500 (25% flat rate for indirect costs) = EUR 112 500.

Total costs declared RP1: EUR 62 500 + EUR 143 750 + EUR 112 500 = EUR 318 750.

Costs of beneficiary A are not capped since there were no grant reductions at beneficiary termination.

Some direct costs declared by beneficiary B are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total accepted costs RP 1: EUR 318 750– EUR 12 500 = EUR 306 250.

Application of the reimbursement rate 100%: EUR 306 250 (total accepted EU contribution).

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000 – EUR 200 000 = EUR 250 000.

Amount to be paid out to the consortium as interim payment for RP1: EUR 250 000.

Case 3:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Pre-financing: EUR 200 000.

Interim payment RP1:

Costs declared by beneficiary A for RP1: EUR 95 000 (direct costs) + EUR 23 750 (25% flat rate for indirect costs) = EUR 118 750.

Costs declared by beneficiary B for RP1: EUR 115 000 (direct costs) + EUR 28 750 (25% flat rate for indirect costs) = EUR 143 750.

Costs declared by beneficiary C for RP1: EUR 90 000 (direct costs) + EUR 22 500 (25% flat rate for indirect costs) = EUR 112 500.

Total costs declared RP1: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total accepted costs RP 1: EUR 375 000 – EUR 12 500 = EUR 362 500.

Application of the reimbursement rate 100%: EUR 362 500 (total accepted EU contribution).

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000 – EUR 200 000 = EUR 250 000.

Amount to be paid out to the consortium as interim payment for RP1: EUR 250 000.

Interim payment RP2:

Costs declared by beneficiary A for RP2: EUR 20 000 (direct costs) + EUR 5 000 (25% flat rate for indirect costs) = EUR 25 000.

Costs declared by beneficiary B for RP2: EUR 30 000 (direct costs) + EUR 7 500 (25% flat rate for indirect costs) = EUR 37 500.

Costs declared by beneficiary C for RP2: EUR 30 000 (direct costs) +EUR 7 500 (25% flat rate for indirect costs) = EUR 37 500.

Total costs declared RP2: EUR 25 000 + EUR 37 500 + EUR 37 500 = EUR 100 000.

Costs rejected for beneficiary B at RP2: EUR 10 000 (direct costs) + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.

Costs rejected for beneficiary C at RP2: 5 000 (direct costs) + 1 250 (25% flat rate for indirect costs) = EUR 6 250.

Total accepted costs RP2 = EUR 81 250.

Application of the reimbursement rate 100%: EUR 81 250 (total accepted EU contribution).

Amount to be paid out to the consortium as interim payment for RP2: EUR 0 (the 90% limit has already been reached in RP1: EUR 200 000 + EUR 250 000 = EUR 450 000).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Commission/Agency on the basis of the financial statements, the final grant amount, the payments already made and the report on the distribution of payments *(see also Articles 5.3 and 44.1.2)*.

If the final grant amount is *higher* than the payments already made, the balance will take the form of a *payment*; if the final grant amount is *lower* than the payments made, the balance will take the form of a *recovery*.

How to calculate the payment of the balance:

Final grant amount

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rates to the eligible costs)**

In order to calculate the amount of accepted EU contribution, the Commission/Agency will, for each beneficiary/linked third party, calculate the accepted costs (i.e. eligible/not rejected costs declared in the financial statements; *see Articles 6 and 42*), apply the reimbursement rate(s) and then sum them up to a total amount for the consortium.

If a beneficiary/linked third party requested less than the maximum EU contribution, the accepted EU contribution will be this lower requested amount.

Step 2 — **Limit to the maximum grant amount**

If the total for the consortium is more than the maximum grant amount for the action *(see Article 5.1)*, it will be capped at that amount

Step 3 — **Calculation of receipts & deduction of profit (no-profit rule)**

From this amount, the Commission/Agency will deduct any profit made due to receipts.

Thus, the total accepted EU contribution + receipts are capped at the total accepted costs; the amount resulting from Steps 1 and 2 plus receipts cannot exceed the accepted costs.

If grant amount + receipts > total accepted costs ➔ deduction of profit

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The amounts taken into account are the total accepted EU contribution (following Steps 1 and 2), the total receipts and the total accepted costs.

The **receipts** that must be taken into account are receipts which have been, during the action duration *(see Article 3)*:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or

- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation).

The following **are** considered **receipts**:

- income generated by the action *(i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)*

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped at the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action *(i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for being used for the action)*

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs *(i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action)*

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

  Receipts due to free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered **receipts**:

- in-kind contributions given by a **third party (donor)** free of charge — if they were not given specifically to be used for the action

  Example: *A university professor whose costs are charged by the beneficiary university in the GA, but whose salary is paid by the ministry and not reimbursed by the university: This in-kind contribution from a third party (the ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions given by a third party (donor) specifically to be used for the action — if they may be used according to the donor's rules to cover also costs *other* than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

- financial contributions made **by one beneficiary to another** within the same action — since receipts are only contributions from *third parties*

  Conversely, such a financial contribution cannot either be declared as cost for the action.

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

– income generated by exploiting the results of the project *(e.g. the IPR)* — since successfully exploiting the results is one of the main objectives of the action

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance *(i.e. the final payment at the end of the action)*. They must be declared in the final report.

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

➔ Amount resulting from Steps 1-3.

Step 4 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions (if any), the Commission/Agency will, for each beneficiary/linked third party, calculate the grant reductions at their level, add any reductions that must be made at action-level and then sum them up to a total amount for the consortium *(see Article 43)*.

This total amount of grant reductions for the consortium is then deducted from the maximum grant amount for the action set out in *Article 5.1*.

ℹ For more guidance on grant reductions, *see the Guide on grant reductions*.

➔ Amount resulting from Step 4.

The **final grant amount** is the lower of the 2 (amount resulting from Steps 1-3 and amount resulting from Step 4).

Balance

Step 5 — **Calculation of the balance & Guarantee Fund release**

In order to calculate the balance, the Commission/Agency will deduct the total amount of pre-financing and interim payments made from the final grant amount.

If the final grant amount is *higher* than the payments already made, the balance will take the form of a payment. In addition, the Guarantee Fund contribution (5% that were kept from the pre-financing) will be released with a separate payment.

If the final grant amount is *lower* than the payments made, the balance will take the form of a recovery (amount overpaid needs to be paid back to the Commission/Agency; *see Article 44*). In this case, the amount to be paid back will be directly compensated against the Guarantee Fund release and if this amount is sufficient to cover the debt, the recovery process ends (instead the consortium will be paid the remainder of the Guarantee Fund contribution, if any is left). If the Guarantee Fund amount is not sufficient, further steps will be taken to recover the rest *(see below)*.

Step 6 — **Payment of the balance letter & debit note**

The Commission/Agency will inform the coordinator about the amount due to the consortium or the amount that needs to be paid back (payment of the balance letter).

If the final payment involves a grant reduction or recovery, there will be two letters: a pre-information letter (opening a contradictory procedure) and a confirmation letter *(see Articles 43 and 44)*.

If there is still an amount to be recovered after compensation with the Guarantee Fund release, the confirmation letter will include a debit note to the coordinator for the amount and the division of final grant amount table *(see below)*.

Recovery (if any)

Step 7a — **Recovery from the coordinator**

If the coordinator pays the debt by the date specified in the debit note, the recovery process ends.

If the coordinator does NOT repay the Commission/Agency by the date specified AND if it has NOT submitted the report on the distribution of payments, the Commission/Agency will pursue recovery against the coordinator alone (enforced recovery, *see below*).

Step 7b — **Recovery from the beneficiaries**

If the coordinator does NOT repay the Commission/Agency by the date specified, BUT has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

Step 7ba — **Identifying the beneficiaries with excess funding**

In order to identify the beneficiaries that received excess funding, the Commission/Agency will compare the amount each beneficiary *actually* received (report on the distribution of payments) with its *share of the final grant amount* (beneficiary's accepted EU contribution divided by total accepted EU contribution and obtained percentage then applied to final grant amount).

Beneficiary's final grant share formula:

{{{beneficiary's accepted costs

multiplied by

reimbursement rate}

divided by

accepted EU contribution calculated under Step 1}

multiplied by

final grant amount for the action}

This means that the final grant amount is redistributed between the beneficiaries in proportion to their accepted costs (especially important for overspent grants, i.e. where the consortium declared costs *above* the maximum grant amount limit and each beneficiary's accepted EU contribution must therefore be adjusted to bring it into line with the maximum grant amount) and then compared to the amounts they received from the coordinator.

Recovery will be pursued only against the beneficiaries with a negative result (i.e. excess of payments received over final grant amount share).

Step 7bb — **Division of the debt**

In order to calculate the amount each of those beneficiaries has to pay back, the Commission/Agency will split the amount to be recovered between them (in proportion to their relative share of the total payments in excess; division of final grant amount table).

Step 7bc — **Beneficiary recovery letter & debit note**

The Commission/Agency will cancel the debit note sent to the coordinator and inform the beneficiaries concerned about the amounts to be paid back, together with a debit note for each beneficiary (beneficiary recovery letter).

Step 8 — **Enforced recovery**

If the coordinator/beneficiaries do not honour the debit note within the deadline, the Commission/Agency will enforce its claim(s) by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- by drawing on the Guarantee Fund and then follow it up with a **debit note on behalf of** the **Guarantee Fund**, to continue the recovery procedure by:
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Examples for calculating the payment of the balance:

Case 1 (payment):

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000.

Reimbursement rate: 100%.

Payments made (pre-financing and interim): EUR 900 000 (limit of 90% of the maximum grant amount).

Guarantee Fund contribution: 5% of EUR 1 000 000 = EUR 50 000.

Payments received: EUR 900 000 – EUR 50 000 = EUR 850 000.

Final grant amount:

Total accepted costs: EUR 1 045 000.

Application of the reimbursement rate: 100 % = EUR 1 045 000 (total accepted EU contribution).

Limit to the maximum grant amount: EUR 1 000 000.

No receipts/profit.

No grant reductions.

Final grant amount: EUR 1 000 000.

Balance & Guarantee Fund release:

Payments made: EUR 900 000.

Balance: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments made) = EUR +100 000 (positive balance to be paid to the consortium).

Release of Guarantee Fund: EUR 50 000 (to be paid to consortium).

Amounts to be paid out to the consortium: EUR 100 000 (positive balance) + EUR 50 000 (Guarantee Fund release)

Case 2 (grant with terminated beneficiary):

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Beneficiary A was terminated before the end of RP1 and the amount due calculated was EUR 62 500 EUR.

Payments made (pre-financing and interim): EUR 450 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 500 000 = EUR 25 000.

Payments received: EUR 450 000 - EUR 25 000 = EUR 425 000.

Final grant amount:

Total accepted costs: EUR 362 500.

Application of the reimbursement rate: 100% = EUR 362 500 (total accepted EU contribution).

Limit to maximum grant amount: EUR 362 500 (no limitation; costs below maximum grant amount).

No receipts/profit.

Amount resulting from Steps 1 to 3: EUR 362 500.

10% grant reduction beneficiary B: 10% of EUR 200 000 = EUR 20 000.

No other grant reductions.

Amount resulting from Step 4: 500 000 – 20 000 = EUR 480 000.

Lower amount of the two: EUR 362 500.

Final grant amount: EUR 362 500.

Balance & Guarantee Fund release:

Payments made: EUR 450 000.

Balance: EUR 362 500 (final grant amount) - EUR 450 000 (payments made) = EUR -87 500 (excess payments of EUR 87 500).

Offsetting against Guarantee Fund release: EUR 87 500 – EUR 25 000 = EUR -62 500.

Payment:

Amount to recovered from the consortium: EUR 62 500.

Case 3 (recovery – underspent grant):

Grant with four beneficiaries: A, B, C, D.

Maximum grant amount: EUR 3 000 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 800 000; B= EUR 1 200 000; C= EUR 600 000; D= EUR 400 000).

Reimbursement rate: 100 %.

Payments made (pre-financing and interim): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 3 000 000 = EUR 150 000.

Payments received: EUR 2 700 000 - EUR 150 000 = EUR 2 550 000.

Final grant amount:

Total accepted costs: EUR 2 430 000.

Application of the reimbursement rate: 100% = EUR 2 430 000 (total accepted EU contribution).

Limit to maximum grant amount: EUR 2 430 000 (no limitation; costs below maximum grant amount).

No receipts/profit.

Amount resulting from Steps 1 to 3: EUR 2 430 000.

10% grant reduction beneficiary B: 10% of EUR 1 200 000 = EUR 120 000.

No other grant reductions.

Amount resulting from Step 4: 3 000 000 - 120 000 = EUR 2 880 000.

Lower amount of the two: EUR 2 430 000.

Final grant amount: EUR 2 430 000 (underspent grant ➔ beneficiary shares: A= EUR 600 000; B= EUR 1 100 000; C= EUR 400 000; D= EUR 330 000).

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 430 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR -270 000 (excess payments of EUR 270 000).

Offsetting against Guarantee Fund release: EUR 270 000 – EUR 150 000 = EUR 120 000.

Recovery:

Amount to be recovered from the consortium: EUR 120 000 (negative balance of EUR 120 000 must be paid back by coordinator, otherwise Commission/Agency will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from coordinator:

The coordinator does not reimburse the Commission/Agency and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 400 000; B= EUR 1 200 000; C= EUR 600 000; D= EUR 350 000).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

A: EUR 600 000 (final grant share) - EUR 400 000 (payments received) = EUR 200 000 (no payment in excess)

B: EUR 1 100 000 (final grant share) - EUR 1 200 000 (payments received) = EUR -100 000 (excess payment of EUR 100 000)

C: EUR 400 000 (final grant share) - EUR 600 000 (payments received) = EUR -200 000 (excess payment of EUR 200 000)

D: EUR 330 000 (final grant share) - EUR 350 000 (payments received) = EUR -20 000 (excess payment of EUR 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission/Agency.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 320 000.

B: 100 000/320 000 = 31.25 %.

C: 200 000/320 000 = 62.5 %.

D: 20 000/320 000 = 6.25 %.

Total to be recovered: EUR 120 000.

B: 31.25 % x 120 000 = EUR 37 500

C: 62.5 % x 120 000 = EUR 75 000

D: 6.25 % x 120 000 = EUR 7 500.

Case 4 (recovery – overspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 3 000 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 1 000 000; B= EUR 1 500 000; C= EUR 500 000)

Reimbursement rate: 100%.

Payments made (pre-financing and interim): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 3 000 000 = EUR 150 000.

Payments received: EUR 2 700 000 - EUR 150 000 = EUR 2 550 000.

Receipts:

Beneficiary A was sponsored for this project by a private company with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher.

Beneficiary B (a university) received as in-kind contribution from its government the secondment of a scientist specifically assigned to the project. The salary of this seconded scientist (EUR 80 000) was declared as cost by this beneficiary, even if paid by the government.

Final grant amount:

Total accepted costs: EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000.

Application of the reimbursement rate: 100% = EUR 3 075 000 (total accepted EU contribution).

Limit to maximum grant amount: EUR 3 000 000.

Calculation of receipts and deduction of profit: Profit: EUR 3 140 000 (total accepted EU contribution + receipts : EUR 3 000 000 + EUR 60 000 + EUR 80 000) – EUR 3 075 000 (total accepted costs) = EUR 65 000

Amount after deducting profit: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Amount resulting from Steps 1 to 3: EUR 2 935 000.

10% grant reduction beneficiary A: 10% of EUR 1 000 000 = EUR 100 000.

No other grant reductions.

Amount resulting from Step 4: 3 000 000 - 100 000 = EUR 2 900 000.

Lower amount of the two: EUR 2 900 000.

Final grant amount: EUR 2 900 000.

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 900 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR +200 000 (positive balance to be paid to the consortium).

Release of Guarantee Fund: EUR 150 000 (to be paid to consortium).

Amounts to be paid out to the consortium: EUR 200 000 (positive balance) + EUR 150 000 (Guarantee Fund release)

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Commission/Agency on the basis of the final grant amount and the revised final grant amount *(see also Articles 5.4 and 44.1.3)*.

If the revised final grant amount is *lower* than the beneficiary's share of the final grant amount (beneficiary final grant share), the difference will be recovered.

How to calculate recoveries after payment of the balance:

Revised final grant amount

Step 1 — **Re-calculation of the accepted EU contribution**

In order to calculate the revised amount of accepted EU contribution for the beneficiary concerned, the Commission/Agency will calculate the revised amount of accepted costs for the beneficiary (i.e. eligible/not rejected costs declared in the financial statements; *see Articles 6 and 42*) and apply the reimbursement rate.

If the audit concerns a linked third party, the revised final grant amount will be calculated for its beneficiary.

➔ Amount resulting from Step 1.

Step 2 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions, the Commission/Agency will calculate the grant reduction for the beneficiary concerned (if any; see *Article 43*).

This amount of grant reduction is then deducted from the beneficiary's maximum grant amount set out in Annex 2.

If the audit concerns a linked third party, the grant reduction will be calculated for the linked third party (i.e. deducted from its maximum grant amount), but the revised final grant amount will be calculated at beneficiary-level.

For beneficiaries that overspent (i.e. declared more costs at payment of the balance than their maximum grant amount), the reduction rate (percentage) will be applied directly to their share of the final grant amount and the resulting amount will be recovered (—short cut to ensure a proportionate result for beneficiaries that contributed more to the action than initially planned in the estimated budget; avoids disproportionate grant reductions compared to the real project participation; *see also Article 4.2*).

For more guidance on grant reductions, *see the Guide on grant reductions*.

➔ Amount resulting from Step 2.

The revised final grant amount is the lower of the two (amount resulting from Step 1 and amount resulting from Step 2).

Balance & recovery (if any)

Step 3 — **Calculation of the beneficiary balance**

In order to calculate if the beneficiary has to pay back any amounts, the Commission/Agency will compare the beneficiary's revised final grant amount with its final grant share *(see above)*.

Beneficiary's final grant share formula:

{{{beneficiary's accepted costs

multiplied by

reimbursement rate}

divided by

accepted EU contribution calculated under Step 1}

multiplied by

final grant amount for the action}

If the revised final grant amount is *lower* than its final grant share, the difference will be recovered.

If exceptionally the audit (or check, review or investigation) showed that the beneficiary made errors resulting in less cost declared than its eligible costs, there will be no

recovery. Instead, the beneficiary will be allowed to submit corrected financial statements to claim the difference.

Step 4 — **Audit implementation letters & debit note**

The Commission/Agency will inform the beneficiary about the amounts put in question (audit implementation letter).

If the audit implementation involves a grant reduction or recovery (generally the case), there will be two letters: a pre-information letter (opening a contradictory procedure) and a confirmation letter *(see Articles 43 and 44)*.

If there is an amount to be recovered, the confirmation letter will include a debit note for the amount.

⚠ In case of European Court of Auditor audits, OLAF investigations and Member State judgments with a financial impact on the grant, similar procedures and letters will be used.

Step 5 — **Enforced recovery**

If the beneficiary does not honour the debit note within the deadline, the Commission/Agency will enforce its claim by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- by drawing on the Guarantee Fund and then follow it up with a **debit note on behalf of** the **Guarantee Fund**, to continue the recovery procedure by:
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Examples for calculating recoveries after payment of the balance:

Case 1 (recovery – underspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100 %.

Final grant amount:

Total accepted costs: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

A: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

B: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

C: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Application of the reimbursement rate: 100% = EUR 493 750 (total accepted EU contribution).

Limit to maximum grant amount: EUR 493 750 (no limitation; costs below maximum grant amount).

No receipts/profit.

No grant reductions

Final grant amount: EUR 493 750 (underspent grant ➔ beneficiary shares: A= 187 500 EUR; B= EUR 156 250; C= EUR 150 000).

Beneficiary revised final grant amount:

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000 and that there were issues with the visibility of EU funding and IPR.

Re-calculation of accepted EU contribution for beneficiary A: EUR 150 000 (direct costs) — EUR 30 000 (rejected direct costs) = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

Application of the reimbursement rate: 100% = EUR 150 000.

Amount resulting from Step 1: EUR 150 000.

10% grant reduction for beneficiary A: 10% of 200 000 = EUR 20 000.

Amount resulting from Step 2: 200 000 – 20 000 = EUR 180 000.

Lower amount of the two: EUR 150 000.

Beneficiary A revised final grant amount: EUR 150 000.

The other beneficiaries final grant amounts (i.e. their final grant shares) remain unchanged.

Beneficiary balance:

Balance: EUR 150 000 (revised final grant amount) - EUR 187 500 (final grant share) = EUR –37 500 (excess of EUR 37 500).

Recovery:

Amount to be recovered from beneficiary A: EUR 37 500 (negative balance of EUR 37 500 must be paid back by the beneficiary).

Case 2 (recovery – overspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 100 000; C= EUR 200 000).

Reimbursement rate: 100%.

Final grant amount:

Total accepted costs: EUR 200 000 + EUR 150 000 + EUR 250 000 = EUR 600 000

A: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) = EUR 200 000

B: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) = EUR 150 000

C: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) = EUR 250 000.

Application of the reimbursement rate: 100% = EUR 600 000 (total accepted EU contribution).

Limit to the maximum grant amount: EUR 500 000.

Final grant amount = EUR 500 000.

Beneficiary revised final grant amounts:

An audit concluded that direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs of beneficiary C were not eligible for an amount of EUR 20 000 and that there were issues with the confidentiality obligations.

Calculation of the beneficiaries final grant shares:

A: (200 000/600 000) x 500 000 = EUR 166 667

B: (150 000/600 000) x 500 000 = EUR 125 000

C: (250 000/600 000) x 500 000 = EUR 208 333.

Beneficiary A:

Re-calculation of accepted EU contribution for beneficiary A: EUR 160 000 (direct costs) – EUR 30 000 (rejected costs) = EUR 130 000 + EUR 32 500 (25% flat rate for indirect costs) = EUR 162 500.

Application of the reimbursement rate: 100% = EUR 162 500.

No grant reductions

Beneficiary A revised final grant amount: EUR 162 500.

Beneficiary C:

Re-calculation of accepted EU contribution for beneficiary C: EUR 200 000 (direct costs) – 20 000 (rejected costs) = EUR 180 000 + EUR 45 000 ((25% flat rate for indirect costs) = EUR 225 000.

Application of the reimbursement rate: 100% = EUR 225 000.

Amount resulting from Step 1: EUR 225 000.

10% grant reduction beneficiary C: 10% of 200 000 = EUR 20 000.

Amount resulting from Step 2: 200 000 – 20 000 = EUR 180 000.

Lower amount of the two: EUR 180 000.

Beneficiary C revised final grant amount: EUR 180 000.

Beneficiary B's final grant amounts (i.e. its final grant amount share) remains unchanged.

Beneficiary balance:

Beneficiary A:

Balance: EUR 162 500 (revised final grant amount) - EUR 166 667 (final grant share) = EUR –4 167 (excess of EUR 4 167).

Beneficiary C:

Balance: EUR 180 000 (revised final grant amount) - EUR 208 333 (final grant share) = EUR -28 333 (excess of EUR 4 167).

Recovery:

Amount to be recovered from beneficiary A: EUR 4 167 (negative balance of EUR 4 167 must be paid back by the beneficiary).

Amount to be recovered from beneficiary C:

In principle: EUR 28 333 (negative balance according to normal calculation).

However, since normal calculation leads to disproportionate grant reductions for beneficiaries that overspent at payment of the balance: shortcut calculation (see above): 10% of EUR 208 333 = EUR 20 833.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Agency performs a plagiarism check on documents submitted by the consortium.*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in EU actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The checks itself are **internal**. They may however have external effects, since the Commission/Agency may lead to a **request for information** *(see Article 17.1)* or it may take Chapter 6 measures in view of the results.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date.*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. In this case, the Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

If the check shows **ineligible costs** or serious **breach of obligations**, it may lead to cost rejection or grant reduction and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission/Agency may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Project reviews

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA and may exceptionally also concern issues related to only one specific beneficiary.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows **ineligible costs** or **substantial errors, irregularities or fraud** or serious **breach of obligations** (including non- or improper implementation of the action as described in Annex 1), it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (or, exceptionally, the beneficiary concerned) via the Participant Portal.

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or a **review meeting** (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a **review report**.

> The review report together with the Commission/Agency comments will be notified to the coordinator (or, exceptionally, the beneficiary concerned) for comments within 30 days (**contradictory review procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The Commission/Agency operational services (authorising officers) will analyse the comments received and decide on the follow-up, if any.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ **Record-keeping —** Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including cost rejection, grant reduction, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit **third parties providing in-kind contributions** (free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to:*

- *see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest)*
- *see if payments made under the contract/subcontract match the costs declared by the beneficiary*
- *assess the technical work carried out by the subcontractor.*

The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to check the contractors'/subcontractors' costs or accounts, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).

4. *The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 of the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and, in very serious cases, to exclusion and/or financial penalties *(see Article 45)*.

In some cases, findings may result in the **acceptance** of additional costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the Participant Portal or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an **audit report**.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days (**contradictory audit procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the **final audit report** and the **letter of audit conclusions** (LoC) — and the file will then be passed on to the Commission/Agency operational services (authorising officers) for the follow-up, if any.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[41] and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. OLAF investigations

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the outcome of the investigation to the Commission/Agency, who will then decide how to proceed.

If an OLAF investigation shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50),* to exclusion and/or financial penalties *(see Article 45),* as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. ECA checks and audits

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

If an ECA check or audit shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, this may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION 2:** Not applicable.]*

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

⚠ Checks, reviews, audits and investigations must however respect the privileges and immunities accorded to an international organisation by its constituent documents or international law.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the **findings concern substantial errors, irregularities or fraud or serious breach of obligations,** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings (rejection and grant reduction)

If the Commission/Agency finds (typically in a review, audit or OLAF investigation) **substantial errors, irregularities or fraud** or serious **breach of obligations** which are **systemic** or **recurrent**, it may make a correction (cost rejection or grant reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed (extension of the findings)
- other grants of the beneficiary (extension of the findings).

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; the beneficiary set up a fraudulent network to overcharge personnel costs .*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

Findings may be extended to all other EU or Euratom grants awarded under similar conditions.

⚠ Findings will normally be extended only within one programme *(e.g. findings in an H2020 audit to all H2020 grants)* but they may exceptionally also be extended to similar programmes *(e.g. if justified by the nature of the findings and the similarity of the applicable grant agreements or in case of serious irregularities or fraud).*

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings also impact other EU/Euratom grants, the audit/review procedure will be followed by an extension procedure, to fix the list of impacted grants and ask the beneficiary's views on the method for correction. In order to minimise the administrative burden, this procedure is usually centralised.

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure (**letter of audit conclusions**), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for cost rejection:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (if the beneficiary does not submit revised financial statements)
  - the conditions for external counter-audits to propose an alternative correction method *(see below)*
- for grant reduction: the proposed flat-rate for the correction.

The correction rate for cost rejection will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The flat-rate for grant reductions will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept the alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for cost rejection: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for grant reduction: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The beneficiary must choose one method for the entire extension procedure, i.e. submit for all grants either revised financial statements or an alternative correction method.

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative correction method proposed by the beneficiary; there is NO entitlement to it.

After the extension procedure is completed, the list of grants and beneficiary position is handed to the operational services which are in charge of managing the concerned grants. They will decide on the actions to be taken in their grants.

The implementation will be done on the basis of the:

- revised financial statements — if the beneficiary sent revised statements and they were approved
- initially notified correction rate for extrapolation — if the beneficiary did not send any revised statements or they could not be approved
- alternative correction method — if the beneficiary sent an alternative method and it was accepted.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:** five]**[OPTION 2 for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the H2020 Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the H2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of H2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[44] annexed to the EU Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[44] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

Best practice: Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[45]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[45] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

Example: *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

Example: *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background before providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or ‘**associated country**’[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

Access rights are therefore normally limited to other beneficiaries and certain affiliated entities of other beneficiaries, unless otherwise agreed.

Example: *Beneficiary A used background from beneficiary B to generate its results. Beneficiary A would like to use its affiliated entity A established in a MS to exploit the results. For this, affiliated entity A needs access rights to beneficiary B's background.*

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Record-keeping

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. subcontractors, linked third parties, international partners, employees, etc.)*.

> ***Examples (third parties that may claim rights):*** *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action (if they have rights under national law or their contract); beneficiaries for which linked third parties carry out a significant part of the work.*
>
> ***Examples (arrangements):*** *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

> **Best practice:** Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is impossible under EU or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.)*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Standard forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

1. *For an invention: e.g. patent, confidential information.*

2. *For the design of a technology: e.g. industrial design, copyright.*

3. *For a website: e.g. industrial design, copyright, trademark.*

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example (better not to protect for the moment): *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3)*.

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*.

Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

> **Best practice:** Where possible, beneficiaries should make this reference in the language of their application (using the text of the GA language version available on Participant Portal Reference Documents).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the plan for the exploitation and dissemination of the results.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

For more guidance on dissemination and exploitation, *see the Participant Portal Online Manual.*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018'];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1a for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) **[OPTION A for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme: data** which is **relevant for addressing a public health emergency**, if specifically requested by the [Commission][Agency] and within the deadline specified in the request]**[OPTION B**: not applicable];*

*(iii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

[additional OPTION for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme:** As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.]**]

***[OPTION 1b for health actions that do NOT participate in the Open Research Data Pilot, if foreseen in the work programme:** The [Commission][Agency] may require beneficiaries to:*

(a) deposit digital research data, which is generated in the action and relevant for addressing a public health emergency, in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user

(b) give specific access rights to third parties that need the digital research data to address the public health emergency (including the right to access, mine, exploit ad reproduce the data free of charge)

within the deadline specified in the [Commission][Agency]'s request.

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

[OPTION 1c for health actions targeting public health emergencies, if foreseen in the work programme: *The beneficiaries must deposit the digital research data generated in the action in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user, at the latest within 30 days after it has been generated.*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access, if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.**]***

[OPTION 2**: Not applicable**]

29.4 <u>Information on EU funding</u> — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) before filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security obligations, etc.)*.

Security obligations — Dissemination may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

Results that contain **EU-classified information**, can be disclosed only after approval by the Commission/Agency *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

The beneficiaries may choose the **form** for disseminating their results.

Standard forms of dissemination:

- website
- presentation at a scientific conference
- peer-reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination — unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the

interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

For more guidance on dissemination and exploitation, *see the Participant Portal Online Manual.*

2. Open access to scientific publications

What? Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals)*.

Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications.

Best practice: Open access has no impact on the other terms and conditions that apply to scientific publications *(e.g. as regards use, etc)*. However, in order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights such as the right to copy, distribute, search, link, crawl and mine).

A 'repository for scientific publications' is an online archive. Beneficiaries are free to choose the repository; it can be institutional, subject-based or centralised.

Best practice: The Open Access Infrastructure for Research in Europe (OpenAIRE) links existing repositories. It is not obligatory for projects to deposit in OpenAIRE itself, but it is the recommended entry point for researchers deciding on a repository. OpenAIRE also offers support services for researchers, such as the National Open Access Desks. Other useful listings are the Registry of Open Access Repositories (ROAR), the Directory of Open Access Repositories (OpenDOAR) and OAPEN (for monographs). Beneficiaries should not choose a repository with rules which could conflict with open access.

Open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets certain requirements that must be fulfilled if they do decide to publish them.

Open access can be provided through:

a) **gold open access** (**open-access publishing**)

'Gold open access means that open access is provided immediately via the publisher when an article is published, i.e. where it is published in open access journals or in 'hybrid' journals combining subscription access and open access to individual articles.

In gold open access, the payment of publication costs (article processing charges) is shifted from readers' subscriptions to (generally one-off) payments by the author. Such author processing costs may be eligible *(see Article 6.2.D.3)* — if incurred before the end of the action. Currently, an action for dealing with such costs incurred after the end of the action in FP7 is being piloted and further action in H2020 will be considered based on the outcome.

⚠ Although gold open access already ensures access via the publisher, the beneficiaries must nevertheless also provide open access via a repository *(see below)* in order to ensure the long-term preservation and availability of the publication.

b) **green open access** (self-archiving).

'Green open access' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in an online repository. Access to the article is often — but not necessarily — delayed (H2020 embargo period between 6 and 12 months; *see below*) as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download view fees during an exclusivity period.

Best practice: Authors are encouraged to retain their copyright and grant appropriate licences to publishers.

A template for an **open access clause** addendum which can be added to **publishing agreements** is available on the Participant Portal.

How? Open access to scientific publications involves four steps — which may or may not be taken at the same time.

Procedure for open access (scientific publications):

Step 1 — **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication).

This must be done as soon as possible (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*) and at the latest on publication.

'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

Step 2 — Provide **open access** to the scientific **publication** — either as 'gold open access (i.e. via the publisher AND via the repository) or as 'green open access (i.e. via the repository only).

Open access must be given:

- in case of 'gold open access': at the latest on publication
- in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

Step 3 — Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

This is needed for visibility, traceability and monitoring.

It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and

– a persistent identifier *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

Best practice: For ease of tracking, beneficiaries should also include the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601) in the funding acknowledgement field in their metadata.

The metadata compliance of the repository can be checked using OpenAIRE.

Step 4 — Aim to **deposit** at the same time, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

ℹ For more guidance on open access, *see the Participant Portal Online Manual.*

3. Open access to research data (Extended Open Research Data Pilot)

What? Beneficiaries of actions that participate in the Open Research Data Pilot must give **open, free-of-charge access** to the end-user to **digital research data** generated during the action (⚠ new in Horizon 2020).

⚠ As of the Work Programme 2017, the Open Research Data pilot has been extended to all thematic areas of Horizon 2020 (except ERC PoC actions, SME instrument Ph1 actions, ERA-NET Cofund actions that do not produce data, EJP Cofund actions, and prizes).

Participation is therefore now in principle **the default**. However, actions may **opt out** at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55)* —, if:

- participation is incompatible with the obligation to protect results *(see Article 27)*
- participation is incompatible with the security obligations *(see Article 37)*
- participation is incompatible with rules on protection of personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate/collect any research data or
- there are other legitimate reasons not to take part.

'Digital research data' is information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Only data that is generated digitally *in the action* is concerned. Actions are encouraged to digitise any other data and provide open access to it, but they are not obliged to do so.

The pilot applies to **2 types** of digital research **data**:

– the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and

– other data and associated metadata, as specified by the beneficiaries themselves in their data management plan.

Examples: *curated data not directly attributable to a publication or raw data*

⚠ Beneficiaries may decide not to provide open access to specific datasets if this would go against other GA obligations *(e.g. to protect results or personal data)* or if the action's main objective, as described in Annex 1, would be jeopardised by giving open access to those specific datasets. In this case, the reasons must be explained in the data management plan, *see below*).

Open access to research data means taking measures to make it possible for third parties to **access, mine, exploit, reproduce** and **disseminate** data — via a research data repository.

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories (Re3data) and Databib. One key entry point for accessing and depositing related data and tools is Zenodo.

Actions participating in the pilot must draw up a **data management plan (DMP)** within the first 6 months of the project implementation.

The data management plan must support the management life-cycle for all data that will be collected, processed or generated by the action. It must cover how to make data findable, accessible, interoperable and re-usable (FAIR), including:

- the handling of data during and after the project
- what data will be collected, processed or generated
- what methodology and standards will be applied
- whether data will be shared / made open access (and how) and, if any, what data will not be shared / made open access (and why) and
- how data will be curated and preserved.

The data management plan should be updated (and become more precise) as the project evolves. New versions should be created whenever important changes to the project occur *(e.g. new data sets, changes in consortium policies, etc.),* at least as part of the mid-term review (if any) and at the end of the project.

ℹ For more guidance on data management plans (and a template), *see the H2020 proposal forms and the Participant Portal Online Manual.*

Costs related to the implementation of the Open Research Data pilot *(e.g. costs for providing open access, related research data management costs, data curation and data storage costs)* may be eligible *(see Article 6.2.D.3)*.

How? Open access to digital research data involves 3 steps:

Procedure for open access (research data):

Step 1 — **Deposit** the digital research data, preferably in a research data repository.

Step 2 — Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. for databases: by attaching an appropriate creative commons licence (CC-BY or CC0 tool) to the data; if the access/use is not subject to any rights: by indicating that no licence is needed)*.

Open access must not be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

Step 3 — Provide **information**, via the repository, about **tools and instruments** for validating the results.

Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.).*

For more guidance on the research data pilot, see *the Participant Portal Online Manual.*

4. Data sharing for public health emergencies

If foreseen in the work programme/call, grant agreements for health actions will include specific contractual provisions concerning the sharing of research data for public health emergencies.

Public health emergencies are for instance:

- public health emergencies of international concern ('PHEIC') according to the World Health Organisation, or
- public health emergencies under Decision 1082/2013/EU, or
- public health emergencies under applicable national frameworks and regulations.

What? The data-sharing obligations for public health emergencies refer to any type of quality-controlled digital research data *(see point 3)* and associated metadata which is generated in the action and is relevant for the response to the public health emergency.

Personal data must be processed in accordance with applicable EU and national law (including international practices and standards; *see Article 39.2*).

For H2020 actions *targeting* public health emergencies, the beneficiaries must moreover:

- provide a data management plan (DMP) preferably with the proposal or at the latest before grant signature

  The data management plan should address the relevant aspects of making the data findable, accessible, interoperable and re-usable (FAIR), including:

  - what data the project will generate
  - whether and how the data will be made accessible for verification and re-use and
  - how it will be circulated and preserved.

  For more guidance on data management plans (and a template), *see the H2020 proposal forms and the Participant Portal Online Manual.*

- for relevant data (as agreed with the Commission/Agency): give free-of-charge access within 30 days after it has been generated
- for other data: give open access as soon as possible.

If agreed with the Commission/Agency, the open access obligation can exceptionally be replaced by special access rights to specific third parties that need the data to address the public health emergency.

In this case, the access rights must include the right to access, mine, exploit and reproduce the data free of charge (as further specified by the Commission/Agency, if needed) — but they may be used only for the access needed and only for addressing the public health emergency (i.e. limited both in scope and in time). Sub-licensing is only allowed if the beneficiary agrees.

For *other* H2020 actions, the special open access obligation [or the special access rights to specific third parties] in case public health emergency is linked to a specific request by the Commission/Agency and limited to datasets agreed with the Commission/Agency.

5. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38*).

> **Best practice:** Where possible, beneficiaries should make this reference in the language of the dissemination activity (using the text of the GA language version available on Participant Portal Reference Documents).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

> ⚠ **Combining H2020 & other EU grants —** If the outputs were developed in another EU-funded action (funded not by H2020, but another EU funding programme, including Structural Funds/ESIF Funds), do NOT forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION 2 for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results.

> ⚠ **Security obligations —** Transfer may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a global authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, the beneficiary must **formally notify in advance** (via the Participant Portal) any transfer to a specifically-identified third party established in a non-associated third country — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — Common legal structures (CLS) (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights and other access rights are preserved, *(e.g. the access rights of the EU, Member States and third parties; see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a non-associated third country.

> ⚠ As of the Work Programme 2018, the calls will normally already indicate if this option will be activated in the GAs. The option may however still be activated (without such indication):
>
> – for calls which do not fix the type of research and innovation activities ("bottom-up" calls, such as FET Open or MSCA) or
>
> – in other calls, exceptionally, if justified by the nature of the research and innovation activities or other action-related reasons.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiary must **formally notify** the Commission/Agency **in advance** (via the Participant Portal) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

A notification before the results are generated is allowed, if the specific results concerned (and the details of the transfer/licence) can already be identified.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION 2 for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION 3 for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[47], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION 1b for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION 1d for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION 2:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When? The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity of another beneficiary (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

***1.** If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).*

***2.** If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.*

How? Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries who left the action before the end, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free
- for the exploitation of results: under fair and reasonable conditions

  'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

Fair and reasonable conditions includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicensing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

1. *A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.*

2. *In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.*

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [48], in particular regarding:

- **working conditions**;
- transparent **recruitment** processes based on merit, and
- **career development**.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[46] and the Code of Conduct for their Recruitment.[47]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

[46] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[47] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[48] and of the Code of Conduct[49] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[50])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

For more guidance on researcher rights, *see the Human Resources Strategy for Researchers tool.*

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more guidance on gender in research, *see the Participant Portal Online Manual.*

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following fundamental principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries

- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the **H2020 ethics appraisal scheme** (i.e. the H2020 policy on ethics issues in research), which includes all of the following:

- ethics *self*-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more guidance on ethics, *see How to complete your ethics self-assessment, Research involving dual use items, Research focusing exclusively on civil applications, Potential misuse of research results and more generally, the Participant Portal Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State.

The beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that the research results cannot peripherally be useful in a military context. Research related to *dual-use* products or technologies (usually used for civilian purposes but with possible military applications) is not prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

In order to ensure the necessary level of research integrity, the beneficiaries must follow principles listed in this Article and ensure that the persons carrying out research tasks comply with the European Code of Conduct for Research Integrity[51] (i.e. follow the good research practices listed in this Code and refrain from any research integrity violations it describes).

Fundamental research integrity principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources

[51] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment
- **accountability** for the research from the idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

The Code constitutes a general reference framework and takes into account the legitimate interests of the beneficiaries (i.e. regarding IPRs and data sharing).

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply. In addition, beneficiaries should rely on local, national or discipline-specific guidelines, if such documents exist and are not contrary to the Code.

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define **ethics requirements** and include them as **deliverables** in Annex 1 of the GA.

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

Examples (ethics deliverables): *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

Examples (other ethics requirements): *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

Best practice: When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18).*

The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

If the documents are not in English, the beneficiary may be asked to provide an English summary.

This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.

Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

The Commission/Agency may carry out **ethics checks, reviews or audits**, to ensure that the beneficiaries have properly implemented the ethics requirements and obtained the opinions/notifications/authorisations *(see Article 22)*.

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

Activities that involve human embryos (hE) or human embryonic stem cells (hESC) can only be funded, if:

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[52] (in particular, do NOT result in the destruction of human embryos)

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

[52] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A ‘conflict of interests’ exists if **shared interests**:

- influenced the contract’s/subcontract’s selection/award procedure
- influenced the contract’s/subcontract’s price and this does not correspond to the market price or
- affected the action’s performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  1. *A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.*

  2. *A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.*

  3. *A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).*

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits*.

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  1. *If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.*

  2. *If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.*

  3. *If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.*

If there is a **(risk of) a conflict of interests**, the coordinator must **inform** the Commission/Agency (via the Participant Portal), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Security obligations — Stricter confidentiality obligations apply for information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual*.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2: *Not applicable**]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[51] — until it is declassified.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].**[OPTION 2:*** *Not applicable.**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable.**]***

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

1. Results with a security recommendation — EU-classified information

If the GA provides for (one of) these options, the beneficiaries must comply with the **security obligations** set out in this Article, in Annex 1 and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises security issues and must be subject to a security recommendation and/or EU-classification under Decision No 2015/444[53].

For more guidance on security obligations, *see the Guidelines for the classification of information in research projects, Potential misuse of research results and, more generally, the Participant Portal Online Manual.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[54].

Moreover, the coordinator must — before the start of the activity for which it is needed — submit a **copy** of any **export** or **transfer licence**.

For more guidance on dual use goods, *see How to complete your ethics self-assessment* and *Research involving dual use items.*

[53] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[54] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and] Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is] [are]* not responsible for any use that may be made of the information it contains.

1. Communication activities (consortium) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[55].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a beneficiary in a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to **multiple audiences** (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a **major media impact** (i.e. media coverage *(online and printed press, broadcast media, social media, etc.)* that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ **Security obligations —** Information given may NOT include **EU-classified information** or information on results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the classification of information in research projects and, more generally, the Participant Portal Online Manual.*

[55] For the definition of 'communication activities', *see the Glossary.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the H2020 proposal templates*) and be included in Annex 1 and 2.

For guidance on promoting the action, *see the Social media guide for EU funded R&I actions and the Participant Portal Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the **EU emblem**

AND

- including the **reference to EU funding** set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity or, for infrastructure, equipment or major results, the official language(s) of the country where they are located (using the text of the GA language version available on Participant Portal Reference Documents).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object).

Examples: *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency; the]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of *[the Agency or]* the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency and the]* Commission will insert the following information:

> "© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the measures described in Chapter 6.

1. Communication activities (EU)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material):*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (EU)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its Participant Portal privacy statements.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligibility of costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the EU financial interests).

When the Commission/Agency collects and processes personal data under the GA, national data protection law is NOT applicable and will NOT be accepted as a pretext for not complying with obligations under the GA.

Disclosure of staff data under the GA *(e.g. data requested by the Commission/Agency project officer or auditors)* is automatically justified under Article 5(c) of Regulation 45/2001.

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[56] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

Persons whose data is being processed (data subjects) can contact the data controller or the DPO (via the contact information in the privacy statement), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

[56] Available at http://ec.europa.eu/dpo-register/search.htm.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (consortium)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[57] and the corresponding national law).

⚠ The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [58]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc*.

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage

[57] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[58] *See Article 8 of Directive 95/46/EC*.

- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[59]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the relevant Participant Portal privacy statement).

Examples:

1. *Before encoding staff data in the Participant Register or into a proposal, the beneficiary must provide the staff concerned with the privacy statement.*

2. *If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the privacy statement.*

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[59] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What? The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How? Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

1. *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.*

2. *Assignment for the benefit of creditors in a bankruptcy procedure.*

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— *RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES*] [— *RELATIONSHIP WITH PARTNERS OF A JOINT ACTION*]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

[OPTION to be used when the beneficiary is an European Research Infrastructure Consortium (ERIC)*[54] *without own resources: *As an exception, the beneficiary delegates the tasks set out above to [insert name of member of the ERIC]. The beneficiary retains sole responsibility for compliance with the obligations under the Agreement.]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is NOT responsible for the implementation of the action and has NO responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them **withdraws**, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless the Commission/Agency expressly agrees otherwise (exceptional; only for specific reasons). They will have to do this without any additional funding (although — in case of beneficiary termination — the Guarantee Fund may intervene for the defaulting beneficiary; *see Article 50*).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% contribution to the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

Specific cases (beneficiaries' responsibilities):

ERIC (European Research Infrastructure Consortium)[60]: If the beneficiary is an ERIC which does not have its own resources, it may exceptionally delegate the following responsibilities to one of its members:

- monitor that the action is implemented properly *(see Article 7)*
- inform about events or circumstances likely to affect significantly or delay the action

[60] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1).

implementation *(see Article 17.2)*
- submit deliverables and reports *(see Articles 19 and 20)*
- submit documents or information required

⚠ An ERIC using one of its members remains **fully responsible** for it under the GA.

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION 1 for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION 2: *Not applicable****]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly *(see Article 22)*.

Example:

In case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can normally NOT be subcontracted or outsourced to a third party (including linked third parties). They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use linked third parties for *other* tasks; *see Articles 13, 14*).

Specific cases (coordinator's responsibilities):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- they must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs (and those must include receiving and administering EU funds).

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the *Participant Register* and validated by the Commission/Agency. It also will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

ERICs (European Research Infrastructure Consortia)[61] — Beneficiaries that are ERICs and do not have their own resources may exceptionally delegate the following coordination tasks to one of its members:

- monitor that the action is implemented properly *(see Article 7)*;
- act as intermediary for communications *(see Article 17)*;
- request and review documents or information required and verify completeness and correctness;
- submit deliverables and reports *(see Articles 19 and 20)*;

⚠ ERICs using one of their members remain **fully responsible** for it under the GA.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article, *e.g. scientific coordination of the action*) can be carried out by any beneficiary.

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it will however NOT be considered the action's coordinator (but one of the other beneficiaries).

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

> **Best practice:** In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the

[61] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1)

GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

> **Best practice:** The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see How to draw up your consortium agreement and the Participant Portal Online Manual*.

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted ONLY for complementary actions *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted ONLY for jointly funded actions *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the GA and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see How to draw up your coordination agreement and the Participant Portal Online Manual.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Cost rejection

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

Cost rejections will be made for **violations of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Grounds for cost rejection (EU):

- **Costs** do **not comply with** the GA **eligibility rules (in this grant)**

  The Commission/Agency will reject costs, if they do not comply with the eligibility rules set out in Articles 6 and 8-16.

- **Costs** do **not comply with** the GA **eligibility rules (in other grants)**

  The Commission/Agency may also reject costs, if such ineligibility was found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the ineligibility is:
    - systemic or recurrent and
    - has a material impact on this grant.

Rejection of costs can take place at any moment — at the time of beneficiary termination, interim payment, payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if cost rejection leads to a recovery: there will be an *ex ante* **contradictory procedure**
- if cost rejection does NOT lead to a recovery: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection (**payment review procedure**).

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post payment review procedure allows the

Commission/Agency however to pay quickly without having to suspend the payment deadline (by postponing the discussion on the disputed costs).

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Payment review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out (**notification of amounts due**; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections.

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for rejections at the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after beneficiary termination and after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

If the Commission/Agency rejects costs at **beneficiary termination**, it will deduct the rejected amount from the costs the beneficiary declared in the termination report and calculate the amount due to the beneficiary. If the amount is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will recover the difference *(see Articles 44 and 50)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

If the Commission/Agency rejects costs at the moment of an **interim payment** or the **payment of the balance**, it will deduct them and calculate the amount to be paid accordingly *(see Articles 5.3 and 21)*.

If ineligible costs are found **in-between payments**, the Commission/Agency will reject them at the next payment (i.e. deduct the amount rejected from the costs declared in the next financial statement and calculate the amount to be paid accordingly; *see Article 21*).

If the Commission/Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the costs accepted for the beneficiary at the payment of the balance and calculate a **revised grant amount**. If the revised grant amount is lower than its share of the final grant amount, the Commission/Agency will **recover** the difference *(see Articles 5.4 and Article 44)*.

The detailed calculations for all cases are described in Article 21.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **redu**ces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Grant reduction

If the Commission/Agency finds *(in particular following a check, audit, extension of audit findings, review or OLAF investigation)* **substantial errors, irregularities or fraud** or **breach of obligations** under the GA or during the award procedure *(e.g. the action has not been properly implemented)*, it may reduce the grant in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations.

⚠ **Grant reductions** will be made (at beneficiary termination, at the end of the action or after the payment of the balance) for substantial errors, irregularities or fraud or serious breach of obligations, in proportion to the seriousness of the error, irregularity, fraud or breach *(e.g. in case of fraud the reduction may be up to a 100%)*.

⚠ If the issues are found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

Grounds for grant reduction (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may make a grant reduction if a beneficiary has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Serious breach of obligations covers all kinds of non-compliance with GA obligations (including obligations during the award procedure).

  Example: *false declarations in the proposal form, in order to obtain EU funding*

  In practice, the most frequent breach is improper implementation of the action/non-compliance with Annex 1 GA (i.e. if the work performed does not correspond to the activities described in Annex 1). This will normally be examined on the basis of the periodic and final technical reports and, if needed, a project review.

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also make a grant reduction, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

3.0 Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol[62]).

Grant reduction can take place:

- at beneficiary termination
- at the payment of the balance or

[62] See judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128.

– after the payment of the balance.

3.0 Reduction at beneficiary termination was introduced explicitly with GA version 3.0. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination is possible for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 *(see above)*.

2. Procedure

The Commission/Agency will follow a **contradictory procedure.**

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Depending on the moment the reduction takes place, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

– for reductions at beneficiary termination: normally with the beneficiary concerned

– for reductions at payment of the balance: normally the coordinator

– for reductions after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

If the Commission/Agency reduces the grant at **beneficiary termination**, it will calculate the reduction at beneficiary-level and calculate the amount due to the beneficiary. If the amount is lower than the (pre-financing and interim) payments received by the beneficiary, the beneficiary will have to pay back the difference *(see Articles 44 and 50)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

If the Commission/Agency reduces the grant at the **payment of the balance**, it will calculate the reductions for each beneficiary and for the action (if any) and calculate the balance to be paid to the consortium (i.e. final grant amount) accordingly *(see Articles 5.3 and 21)*.

If the Commission/Agency reduces the grant **after the payment of the balance**, it will calculate the reduction for the beneficiary and compare the revised grant amount with its share of the final

grant amount. If the revised grant amount is lower, the Commission/Agency will recover the difference *(see Articles 5.4 and 44)*.

The detailed calculations for all cases are described in Article 21.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION 2:** not applicable**];***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency]* will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**]** **[OPTION 2:** not applicable**]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to early termination, cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to its maximum grant amount in Annex 2.

Grounds for recovery (EU):

- Commission/Agency **paid too much**

  The Commission/Agency will make a recovery, if the amounts paid out exceed the amounts that are due for the grant.

Recovery normally takes place only at **payment of the balance** or **afterwards**. Exceptionally, it can take place before, if a **beneficiary's participation is terminated**.

The Commission/Agency will recover after beneficiary termination if the beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

The Commission/Agency will recover at the payment of the balance if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Articles 5.3 and 21)*.

The Commission/Agency will recover after payment of the balance if — due to cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid in excess (or that the coordinator did not distribute the payments received; *see Article 5.4*).

The detailed calculations for all cases are described in *Article 21*.

2. Procedure

The basic procedure for recovery is almost always the same: After a **contradictory procedure**, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)* and issues a debit note.

Enforced recovery:

If the coordinator/beneficiary concerned does not pay by the date set out in the debit note, the Commission or the Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[63]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

  ⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

  For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 TFEU action, arbitration, etc.; *see Article 57.2*).

  Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission or the Agency may offset before this date, in order to safeguard the EU financial interests.[64]

  If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. The interest is normally offset first, before the principal amount.

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or

    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU[65].[66]

      The decision describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      ⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

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63 *See Article 80(1) of the Financial Regulation No 966/2012.*

64 *See Article 87 of the Rules of Application Regulation No 1268/2012.*

65 *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

66 *See Article 79(2) of the Financial Regulation No 966/2012.*

This decision — duly endorsed with the order for enforcement issued by the competent authority in the Member State concerned — allows to have the debtor's **assets seized**.

The contradictory procedure will normally be **combined** with the **contradictory procedure** for cost rejection and/or grant reduction (if any).

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

1. Administrative sanctions

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary is in an exclusion situation under Article 106(1) of the Financial Regulation No 966/2012, it may impose administrative sanctions (— in proportion to the seriousness of the misconduct).

Administrative sanctions (financial penalties and/or exclusion from future procurement contracts, grants and expert contracts) are **public law measures** (i.e. taken directly on the basis of Articles 106 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(substantial errors, irregularities or fraud, serious breach of obligations, bankruptcy, non-compliance with tax or social security obligations, grave professional misconduct, fraud, corruption, or criminal/illegal activity).*

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum sanctions** are as follows:

- for exclusion: up to **5 years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the sanction and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again, the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget (Annex 2) — depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again, the rate may be increased to between **4%** and **20%**.

The decision to apply an administrative sanction may be **published** on the Commission/Agency websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU financial interest and image)
- the time that has elapsed since it took place
- the duration and recurrence of the misconduct

- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

The Commission/Agency will follow the procedures set out in 106 of the Financial Regulation No 966/2012 (i.e. **contradictory procedure, panel, decision)**.

If the Commission/Agency imposes a financial penalty, it will also issue a debit note to **recover** the amount.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

However, there is NO:

- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

Specific case (administrative sanctions):

International organisations — Decisions on administrative sanctions (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability for damages (EU)

The Commission/Agency can NOT be held liable if — in implementing the GA — its own services cause damage (to a beneficiary or third party).

Moreover, the Commission/Agency can NOT be held liable if — in implementing the GA — a beneficiary or third party involved in the action causes damage (to another beneficiary or third party).

Examples:

1. *An experiment carried out by a beneficiary leads to an accidental escape of pollutants into the local river.*

2. *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the action.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third parties involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

1. Liability for damages (consortium)

If a beneficiary causes damage to the Commission/Agency (in implementing the action), the Commission/Agency may claim compensation).

Examples:

1. *Costs of legal proceedings borne by the Commission.*

2. *At a meeting on Commission premises, a beneficiary smokes and causes a fire.*

2. Procedure

The Commission/Agency will follow the normal procedure for damages claims (i.e. bringing an action for contractual damages before the European Court of Justice; not direct claim via a debit note).

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The Commission/Agency may stop the clock (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

⚠ Suspension of the payment deadline must be **distinguished** from **suspension of payments** *(see Article 48)*. Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary which is, for example, suspected of serious misconducts.

Grounds for suspension of the payment deadline (EU):

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

In practice, suspension is needed if there are issues with the payment request or with the costs declared which make it impossible for the Commission/Agency to comply with the **payment deadline** (i.e. for interim payments and payment of the balance: 90 days after payment request; *see Article 21*).

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

Late payment without suspension of the payment deadline gives rise to late-payment interest for the beneficiaries *(see Article 21.11)*.

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why.

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

Suspension will normally last until it is possible to make all the necessary checks and verifications that are needed for the payment (*e.g. analysis of technical reports and financial statements, eligibility of claimed costs, calculation of amount to be paid, approval and authorisation of payment*).

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (EU)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more or for all beneficiaries), on the grounds listed in this Article.

⚠ **Suspension of payments** has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systemic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend all outstanding payments for the audited beneficiary until the issue is resolved.*

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may also decide to:

- suspend the GA *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure**.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of suspension, this procedure will be directed either at the coordinator or the beneficiary concerned:

- suspension linked to the consortium: normally the coordinator
- suspension linked to a beneficiary *(e.g. simultaneous suspension of payments in several grants after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must make sure that the other members of the consortium are informed and ask for their comments.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator later on (in a way that preserves confidentiality).

> ⚠ **Information obligation** — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned with the periodic reports (except with the report for the last reporting period).

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted. They must be included in the periodic report for the last reporting period (— even if suspension is still ongoing).

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May:	*the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May:	*the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June:	*the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July:	*the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August:	*the Commission pays for all beneficiaries except B.*
25 October:	*the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

If payments for one (or some) of the beneficiaries are still suspended at the end of the action, the Commission/Agency will make a partial payment of the balance for the amount that is not suspended (— but ONLY after having received all the necessary information for the final calculations for ALL consortium members, i.e. including the suspended beneficiaries).

> ⚠ The partial final payment is NOT the payment that closes the action. That payment will be made only after the payment suspensions are lifted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. GA suspension (consortium)

The beneficiaries may suspend the action (in full or in part), on the ground set out in this Article.

GA suspension may be used exceptionally if it is necessary to stop the action implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for GA suspension (consortium):

- **Action can no longer be implemented (or becomes excessively difficult)**

  The beneficiaries may suspend the action (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment after resumption).

⚠ **Information obligation** — Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g. **inform** the Commission/Agency under Article 17.2; **notify** a situation of force majeure under Article 51)*.

2. Procedure

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must notify it to the Commission/Agency by requesting an amendment to the GA.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

It sets the resumption date and adapts the grant to the new situation *(e.g. by extending the action duration, modifying Annexes 1 and 2, updating the reporting periods)*.

If the Commission/Agency approves the amendment, the suspension is lifted and will be resumed as from the **resumption date** set out in the amendment. The resumption date can be retroactive (i.e. back to the date when the problem stopped/issue was clarified).

Example: *The action was suspended on 24.03.2016 due to weather conditions. Once the conditions improve, the coordinator requests and amendment to lift the suspension (e.g. after 60 days, on 22.05.2016). Therefore, in accordance with Article 54 of the GA, the action will be resumed as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the budget must be lowered in the amendment, to adapt the action to the new situation).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **can NOT be continued** (or the Commission/Agency does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the GA termination. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities, or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 <u>Procedure</u>

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (EU)

The Commission/Agency may suspend the action (in full or in part), on the grounds listed in this Article.

Grounds for GA suspension (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend the audited beneficiary's part of the action until the issue is resolved.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** 5 days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the GA, the Commission/Agency will follow a **contradictory procedure**.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of suspension, this procedure will be directed either at the coordinator or the beneficiary concerned:

- suspension linked to the consortium: normally the coordinator
- suspension linked to a beneficiary *(e.g. simultaneous suspension of several grants after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must make sure that the other members of the consortium are informed and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform the coordinator later on (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If possible, the Commission/Agency will give an estimation of how long the suspension will be needed.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once the action is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator (together with the suspension **end date**).

The suspension can be lifted retroactively (i.e. back to the date when the problem stopped/issue was clarified).

The coordinator must then request an amendment to the GA *(see Article 55)*, to set the **resumption date** in the tools and adapt the grant to the new situation *(e.g. by extending the action duration modifying Annexes 1 and 2, updating the reporting periods)*.

If the **action** (or part of it) **can NOT be continued**, the GA (or the beneficiary concerned) may be terminated.

If the suspension leads to the GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the GA termination.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The beneficiaries have the right to terminate the GA.

GA termination should be a last-resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA, but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Grounds for GA termination (consortium):

- **Any ground** that **justifies** early termination of the action

  The beneficiaries may terminate the GA in principle on any ground — as long as there is a good reason *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

  Examples:

  1. *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

  2*. The consortium requests termination because the action was finished ahead of schedule.*

  If there are no legitimate reasons for discontinuing the action, the Commission/Agency **can NOT oppose**, but termination will be considered **improper**.

  ⚠ **Improper termination** of the GA may lead to a grant reduction (see *(see Articles 5.3 and 43)*.

  This will be the case, for instance, if:

  - the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
  - the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
  - implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

  Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a grant reduction.*

2. Procedure

The coordinator must **formally notify** the Commission/Agency (via the Participant Portal) of the termination — on behalf of the other beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. generating event before the termination date; *see Article 6.1(a)*) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. The Commission/Agency will NOT send a reminder and will NOT extend the deadline.

The detailed calculations are described in Article 21.

Termination has NO effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the security obligations (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*
- Chapter 6 measures (i.e. rejection of costs *(see Article 42)*, grant reduction *(see Article 43)*, recovery *(see Article 44)*.

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Beneficiary termination (consortium)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must inform the beneficiary concerned, request the beneficiary's opinion in writing and provide it to the Commission/Agency (or — if the beneficiary didn't reply — provide proof that the beneficiary's opinion has been requested in writing).

Grounds for beneficiary termination (consortium):

- **Any ground** that **justifies** termination of the participation of the beneficiary

  The beneficiaries may terminate the participation of one of their consortium members in principle on any ground — as long as there is a good reason *(e.g. withdrawal by a beneficiary because due to a change in ownership; the beneficiary cannot implement its tasks in the same way; bankruptcy)*.

  For beneficiaries that are involved in **several EU GAs,** withdrawal from one GA does NOT necessarily imply that it has to also withdraw from the others.

  Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

  If there are no legitimate reasons, the Commission/Agency **can NOT oppose** beneficiary termination, but it will be considered **improper**.

  Improper termination of the participation of a beneficiary may lead to GA termination *(see Article 50.3.1(c))* and/or to a grant reduction at the payment of the balance *(see Articles 5.3 and 43)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT continue participating in the action.

> ⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in actions, like beneficiaries. Linked third parties can NOT however do more than the beneficiary they are linked to: If their beneficiary is terminated, they must also leave the action.

2. Procedure

The coordinator must **formally notify** the Commission/Agency of the termination (via the Participant Portal). At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Since for beneficiary termination the notification is combined with an amendment request, they must be submitted and signed by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3)*.

NO amendment is needed if the termination takes effect after the end of the action — unless it concerns the coordinator (since the coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants), the GA may be terminated.

> ***Example:*** *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional funding to do so) — unless the Commission/Agency expressly agrees otherwise.

The coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

In case of coordinator termination, the reports must be submitted by the new coordinator (to avoid problems with the payment). If the nomination of the new coordinator takes more time, the 30 days deadline may be extended.

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the terminated beneficiary:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes, those amounts must be paid back to the consortium.

Only **costs** incurred before termination (i.e. generating event before the termination date *see Article 6.1(a)*) are eligible — except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. The Commission/Agency will NOT send a written reminder and will not extend the deadline.

If the coordinator fails to submit the *report on the distribution of payments*, the terminated beneficiary whose participation was terminated will NOT have to repay any amounts.

The detailed calculations are described in *Article 21*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (beneficiary termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*) and the reports must be submitted by the new coordinator (to avoid problems with the payment). If needed, the 30 days deadline for submission of the reports can be extended *(see above)*.

Coordinator in bankruptcy/liquidation/administration (or similar) — In principle the coordinator must be changed. If the coordinator can no longer submit the request, the same procedure as for coordinator termination without its agreement should be used *(see above and Article 55)*.

Exceptionally, at the end of the action it may not be necessary to change the coordinator, but only its bank account if the administrator/liquidator accepts to do the final transfers of amounts.

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable];*

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**); see Article 22.5.2;

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks****][OPTION 2:*** *not applicable]*.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. GA or beneficiary termination (EU)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

⚠ Beneficiary termination may lead to **GA termination**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

⚠ The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

Grounds for termination (EU):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the GA termination; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or if the consortium no longer complies with the eligibility conditions set out General Annexes A and C to the H2020 Work Programme *(e.g. the rules regarding the minimum number of beneficiaries, their legal situation, or their place of establishment)*. [67]

  Examples:

  1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

  2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there has been a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Such changes can be of any kind and can be triggered by the beneficiary itself or outside circumstances.

  Examples:

  1. *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

  2. *The country in which one of the beneficiaries is established ceases to be an EU Member State. This means that the beneficiary is no longer eligible for funding and that the decision to award the grant is called into question. The Commission may decide to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

- **GA cannot be amended after termination** of a beneficiary's participation

  The Commission/Agency may terminate the GA, if it cannot be amended after termination of a beneficiary's participation because the necessary changes to the GA would call into question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

  The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

[67] *See also Article 8 of the Rules for Participation Regulation No 1290/2013.*

- **Action can no longer be implemented**

  The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

  Example:

  1. *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

  2. *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

  The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

  Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify beneficiary termination because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

  ⚠ **Information obligation** — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

- **Professional misconduct**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

  Example: *A legal entity's participation in a GA is terminated when a national investigation uncovers that it falsified the results of its clinical studies.*

- **Non-compliance with tax or social security obligations**

  The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is implemented; *see Article 7*).

  Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

  Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

  For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

- the third country/IO action does not start by the date specified in Annex 1

  In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission/Agency in full.

- the third country/IO action is terminated

- the third country/IO action can no longer contribute to the subject of the GA.

  Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity.

  Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have participated in large-scale drug trafficking.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may terminate the GA or the participation of a beneficiary, if a beneficiary (or one of its representatives) has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding; coordinator does not transfer payments to the other beneficiaries, but uses them for itself; coordinator does not submit the reports (despite a reminder); consortium does not inform the Commission/Agency about the receipt of a second grant for the same/similar proposal; review shows that action does not achieve its critical objectives and is way behind schedule and consortium submits a short-term implementation plan that is not acceptable; audit shows that beneficiary declared costs based on fake invoices; consortium does not provide requested information (despite a reminder); a check shows that scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism); consortium does not submit an amendment request after beneficiary termination.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also terminate the GA or the participation of a beneficiary, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that appear intentional and also affect all other GAs signed by the audited beneficiary. The Commission may terminate the participation of the audited beneficiary in the GA.*

- **Non-removal of a linked third party/international partner**

  The Commission/Agency may terminate the participation of a beneficiary if it refuses to remove one of its linked third parties or an international partner which is in one of the following situations:

  - bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings;
  - professional misconduct
  - non-compliance with tax or social security obligations
  - fraud, corruption or other criminal activities
  - substantial errors, irregularities or fraud or serious breach of obligations (in this grant or other grants).

3.0 This termination ground was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, beneficiary termination/linked third party removal was however already implicitly included in the different grounds of Article 50.3.3 (given that linked third parties have to fulfil the same conditions as the beneficiaries for participating in the action).

Before terminating (GA or beneficiary), the Commission/Agency may first suspend the GA *(see Article 49.2)*, to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before GA or beneficiary termination, the Commission/Agency will follow a **contradictory procedure**

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of termination, this procedure will be directed either at the coordinator or the beneficiary concerned:

- terminations linked to the consortium *(e.g. GA termination after a negative project review)*: normally the coordinator
- terminations linked to a beneficiary *(e.g. beneficiary termination or simultaneous termination of GAs after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator later on (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If a beneficiary is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy or similar), the Commission/Agency will also contact the liquidator/administrator (— as soon as possible after the termination is confirmed).

If it confirms termination, the Commission/Agency will specify the date on which termination will take effect **(termination date)**.

This date will be a date after the notification: Terminations can**not** be **retroactive** (notably to ensure the fulfilment of obligations and deadlines after termination; *see point 3*).

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of **GA termination** are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. generating event before the termination date; *see Article 6.1(a)*) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

The effects of **beneficiary termination** are the same as when the beneficiaries terminate one of their partners *(see Article 50.2.2)*.

The detailed calculations are described in Article 21.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific case:

Termination of the coordinator — The amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*) and the reports must be submitted by the new coordinator. If needed, the 60 days deadline for submission of the reports can be extended.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What? In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Personal reasons *(e.g. sickness)* or internal instructions are in general NOT considered as cases of force majeure.

If force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

New in Horizon 2020: If a task could not be executed due to a situation of force majeure but certain costs were incurred for that task and could not have been avoided, those costs may still be eligible. This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

Force majeure may lead to GA suspension *(see Article 49)* or GA termination *(see Article 50)*.

How? The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal).

The beneficiary concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal electronic exchange system and using the forms and templates provided there.

If — after the payment of the balance — the [Commission][Agency] finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

1. Communication between the parties — Participant Portal electronic exchange system

All communication between the consortium and the Commission/Agency – before and after the payment of the balance – must be in electronic form **via** the **Participant Portal**.

Beneficiaries will receive Participant Portal notifications even after the end of the action (and the LEARs are obliged to keep beneficiary contact data up to date, in order to ensure that the communication channels remain active).

The responsibility for opening notifications in time is with the beneficiaries.

Formal notifications are normally considered to have been **accessed 10 days after** they have been **sent** (— even not actually opened by recipient, *e.g. refusal of reception or omission*). Deadlines that are counted from the date of receipt are counted as of day eleven.

The same is in principle valid for formal notifications **after the payment of the balance** — except that the Commission/Agency will check that the notification has *actually* been accessed by the beneficiary (at any time, before or after the 10 days deadline). If it was not accessed, the Commission/Agency will send a second notification, this time on paper by registered post with proof of delivery. In that case, the deadlines will start to run from the date of receipt of the second notification and the communication will continue outside the Participant Portal.

4.0 The communication via the Participant Portal was extended to after the payment of the balance with GA version 4.0. For older grant agreements, it is in principle on paper, unless the beneficiary explicitly agrees to accept communication via the Participant Portal.

The Participant Portal offers different **functions**:

- viewing and changing the legal entity data in the Participant Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the Participant Portal project file (with date and time).

Formal notifications are also recorded (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation and access are linked to the user role *(e.g. LEAR, PLSIGN or PFSIGN*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator. They cannot submit information directly to the Commission/Agency.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission/Agency.*

For more guidance on access and roles in the Participant Portal, *see the Participant Portal Online Manual.*

In principle, all communications from/to the Commission/Agency must normally go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations No 883/2013 and No 2185/2996)*.

Specific cases (PP access rights):

Beneficiaries in bankruptcy — If during a beneficiary goes bankrupt during the action, the liquidator may be granted the necessary access rights in the Participant Portal, in order to complete the beneficiaries' obligations. If exceptionally necessary, the Commission/Agency can also agree to communication outside the Participant Portal electronic exchange system (i.e. via registered post or e-mails).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means intergovernmental organisations (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the applicable legal texts provide otherwise), public law decisions cannot be applied to international organisations; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions (i.e. exclusion or financial penalties; *see Article 45*).

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration *(see Article 57.2)*. The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are **calendar days**.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*
The action is divided into the following reporting periods:
RP1: from 1 March 2015 to 31 August 2016
RP2: from 1 September 2016 to 28 February 2017
Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.
The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What? An amendment is necessary whenever there is a need to **change** the GA (i.e. the core agreement and/or the Annexes).

The cases where an amendment is necessary are called 'amendment types' (AT); the amendment clauses are called 'AT clauses'.

The general terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to set its 'end date of participation'.*

Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and have an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

Information obligation — Changes in the **name, address, legal form** and **organisation type** AND changes in the **legal, financial, technical, organisational** or **ownership situation** may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary terminate its participation and to amend the GA.*

2. *Beneficiary B moves from Europe to Australia during the action. The change of address implies that the beneficiary becomes not eligible for EU funding, so the GA will have to be amended to make it a 'beneficiary not receiving EU funding'.*

3. *Beneficiary C participates in an innovation action (IA) and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Participant Register is sufficient; no amendment is needed.*

2. *Beneficiary E participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation was terminated** due to **non-accession** to the GA or non-provision of the requested declaration on **joint and several liability** (**AT1**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary that never became part of the GA.

  How? The amendment is normally triggered by the beneficiaries.

In case of beneficiary termination (by the consortium), the notification of termination and amendment must be combined.

If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

The changes will be made ex tunc (i.e. since the beginning) since the beneficiary never participated in the grant.

If the beneficiary was participating with linked third parties/international partners, they will automatically be removed.

GA options for the beneficiary (and its linked third parties/international partners) are automatically removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Removal of a beneficiary whose participation was terminated** for **other reasons** (**AT2**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary during the action.

  What not? There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator AND the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  How? The amendment is normally triggered by the beneficiaries.

  In case of beneficiary termination (by the consortium), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the request for amendment, the same procedure as for coordinator change without its agreement should be used.

  Changes will be made ex nunc (because the beneficiary participated in the grant up until termination and, moreover, many obligations are applicable after termination).

  The termination date will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

  If the beneficiary was participating with linked third parties/international partners, they will also have to be removed (with effect from the same date) and the end date of participation will be added to Article 14/Article 14a (AT5a/5b).

  By contrast, the GA options for the beneficiary (and its linked third parties/international partners) will NOT be removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will normally have to be changed (AT21 and AT31).

- **Adding a new beneficiary** (**AT3**; *see Article 56.2*)

  What? Addition of a new beneficiary during the action.

  How? The amendment is normally triggered by the beneficiaries.

  The new beneficiary must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

  The accession date will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

  The date must be selected in the Accession Form (attached to the amendment request). It is possible to choose between:

  - the date of signature of the Accession Form

- the date of entry into force of the amendment

OR

- a fixed date:
  - retroactive (before signature of the Accession Form)

  OR

  - future (after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

If the new beneficiary is participating with linked third parties/international partners, they will also have to be added (with effect from the same date) and the starting date of participation will be added to Article 14/Article 14a (AT6a/6b).

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change of beneficiary due to partial takeover** (**AT4**; called 'partial transfer of rights and obligations' in FP7)

Transfer — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination *(see Article 50)* or addition of a new beneficiary *(see Article 56)*.

This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment clause for addition of a new beneficiary (AT3).

What? Transfer due to partial takeover.

'Partial takeover' means that a part of the business of the beneficiary — including the GA — is taken over by (one or more) other entity(ies) (transfer of a business unit as a going concern, *e.g. partial acquisition, distribution of a business unit after dissolution/liquidation, division/demerger, etc.*).

'Partial acquisition' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, *some* of the rights and obligations (and contracts) of the original entity are transferred to the new entity. Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'Distribution of a business unit on dissolution/liquidation' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entities purchase a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only *some* of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'Division/demerger' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has an ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two partial takeovers: one to company E and one to company O.*

What not? Simple sale of (one or more) assets of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary.

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

NO amendment is necessary for universal takeovers *(see below)*.

How? The amendment is normally triggered by the beneficiaries; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as new beneficiary).

'New beneficiary' is used here only for the purpose of the amendment; it can be either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

⚠The new beneficiary(ies) will (each) be fully **jointly and severally liable** with the former beneficiary for recoveries under Article 44. (By contrast: NO joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular:

- explain the financial liability of the former beneficiary
- cite the applicable rules (with hyperlinks to the texts, if possible), and
- provide a copy of the takeover contract.

Best practice: In order to avoid multiple submission of documents, beneficiaries are recommended to upload the takeover contract in the Participant Portal Participant Register (via My Organisation page) and specify in the amendment request that the legal documents are available in the Participant Portal. This is particularly useful if several EU grant agreements or contracts are affected by a partial takeover.

The transfer date will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.

If the former beneficiary was participating with linked third parties/international partners, the new beneficiary will have to determine which of the former beneficiary's linked third parties/international partners stay on as linked third parties/international partners of the

new beneficiary (AT6a/6b) — all other linked third parties/international partners will be automatically removed.

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

The former beneficiary does NOT need to submit any reports to the Commission/Agency. The financial statement for the open reporting period until transfer must be uploaded with the next periodic report either by the former beneficiary (for the time it was a beneficiary) or by the new one together with its own financial statement.

- **Removing a linked third party/international partner** (**AT5a/5b**; *see Articles 14 and 14a*)

What? Removal of a linked third party/international partner during the action.

How? The amendment is normally triggered by the beneficiaries.

If requested by the Commission/Agency *(e.g. because of audit results or an OLAF investigation)*, the consortium MUST submit an amendment to remove a linked third party/international partner.

> ⚠ If the consortium does not follow-up this request, the Commission/Agency may **terminate** the participation of the *beneficiary* (and thereby also remove the linked third party/international partner).

NO termination notification — Linked third parties/international partners can be removed by the consortium by simple amendment; no formal termination notification is required (termination notification applies only to beneficiaries; *see Article 50.2*)

Changes will be made ex nunc (because the linked third party/international partner participated in the grant up until removal and, moreover, many obligations are applicable after termination).

The end date of participation will be added to Article 14/14a.

The date must be selected in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

The GA options for the linked third party/international partner will normally NOT be removed/changed/become not applicable.

Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Adding a linked third party/international partner** (**AT6a/6b**; *see Articles 14 and 14a*)

What? Addition of a new linked third party/international partner during the action.

How? The amendment is normally triggered by the beneficiaries.

The new linked third party/international partner must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

The name of the linked third party/international partner and the starting date of participation will be added to Article 14/14a.

The date must be selected in the amendment request. It is possible to choose between a fixed date or the 'date of entry into force of the amendment'. If the linked third party/international partner joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

The GA options for the linked third party/international partner will be added/changed/become applicable.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'** (**AT7a**; *see Article 9*)

  What? If a beneficiary/linked third party — exceptionally — becomes eligible/not eligible for receiving EU funding during the action *(e.g. due to a change of establishment or a country changing eligibility status)* OR if it suddenly requests funding/zero funding, this change will require an amendment (to change Annex 1, Annex 2 and the options in Articles 9 and 57).

  Examples:

  1. *Beneficiary R moves from Europe to Australia and thus is no longer eligible for receiving EU funding. The GA must be amended. If R is participating with a linked third party M established in France, M will continue being eligible for funding.*

  2. *The country in which beneficiary X is established leaves the EU (without an agreement ensuring continued eligibility). The beneficiary is therefore no longer eligible for funding and the GA may have to be amended (or terminated; see Article 50).*

  3. *Beneficiary Y is eligible but signed the grant with zero funding. During the action the responsibilities within the consortium are shifted and beneficiary Y takes on a bigger role involving more costs. The other consortium members agree to adapt the budget and renounce to some funding in order to allow beneficiary Y to claim funding.*

  How? This amendment can normally be triggered only by the Commission/Agency.

- **Change of coordinator (AT8)**

  What? Replacement of the coordinator during the action *(e.g. because of financial difficulties)*.

  Exceptionally, an amendment remains possible and necessary *after* the end of the action *(see Article 3)* — until the payment of the balance is paid out and distributed.

  Coordinator in bankruptcy/liquidation/administration (or similar) — After the end of the action, if the coordinator can continue its participation with the bank account of the administrator/liquidator (i.e. termination and coordinator change not really needed), it is therefore exceptionally sufficient to change the bank account (AT40) without changing the coordinator.

  What not? There is NO need to request an amendment for a change of the *person* in charge of the coordination of the project (since the person's name is not mentioned in the GA).

  > ⚠ **Information obligation** — In case of a **change of person in charge of coordination**, the coordinator must — in addition to updating the data in the Participant Portal inform the Commission/Agency under Article 17.2).

  How? The amendment is normally triggered by the beneficiaries.

  If the new coordinator is not already a beneficiary of the GA, it must first accede to the GA as a new beneficiary (AT3).

  The former coordinator may continue to participate in the action as a normal beneficiary or may terminate its participation (AT2).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the amendment request, the same procedure as for coordinator change without its agreement should be used.

  The handover date will be added to the Preamble of the GA.

  The date must be selected in the amendment request. If the former coordinator leaves the consortium, this date must be after the termination date; if the new coordinator joins the consortium, the date must be after the accession date. Otherwise, it will be the date the amendment enters into force (i.e. date of the last signature of the amendment).

- **Change of the coordinator's bank account for payments (AT40)**

What? An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

What not? NO amendment is necessary for a change of the name of the bank or name of the account holder; a change of the bank account data (and validation) in the Participant Portal Participant Register is sufficient.

How? The bank account data must first be updated in the Participant Register (and be validated).

- **Change of the starting date, action duration or reporting periods (AT23, AT24, AT25)**

What? Change of the action's schedule (starting date, action duration or reporting periods).

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

How? An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

- **Changes to Annex 1 (description of the action) (AT21)**

What? Changes to the description of the action, in particular:

  - significant change of the action tasks *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning in-kind contributions provided by third parties (against payment or free of charge) or subcontracts

    Such changes could in principle also be made via simplified approval procedure *(see Articles 11, 12 and 13)*; however, if the beneficiary requests an amendment, it will immediately know if the Commission/Agency agrees (or not). Without amendment, this decision is left for later and the Commission/Agency may reject the costs as ineligible later on (at the moment of the payment).
  - changes concerning the tasks to be carried out by linked third parties and related costs (including if a linked third party is removed)
  - significant changes to the plan for exploitation and dissemination (unless Annex 1 already foresees an update to be submitted with the periodic report)
  - changes concerning GA options (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2)*
  - significant changes concerning deliverables *(e.g. changes of ethics requirements to align to ethical principles and legislation; adding/removing deliverables; changes in substance of a project output which is reflected in a deliverable, etc.)*.

What not? Changes to the due date of a deliverable normally do not require an amendment (except for certain deliverables, where timeliness is key)

- **Changes to Annex 2 and Annex 2a (estimated budget) or specific unit costs (AT31 and AT36)**

What? Changes to the estimated budget, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which are linked to a significant change in the action's work (i.e. Annex 1)
  - a budget transfer to a form of costs that is not used by the beneficiary (i.e. with 0 EUR costs in Annex 2) — except for transfer of amounts within the budget category A 'personnel costs' and for transfers to the budget category 'costs of internally invoiced goods and services'.

Example:

During the action implementation, the beneficiary decides to use the access costs for transnational access to research infrastructure unit cost. This requires an amendment to fix the unit cost and to move budget to budget category F.2.

What not? There is NO need to request an amendment for changes covered by the budget transfers rule in Article 4.2 *(e.g. budget transfers within the personnel cost; see also below)*.

How? The amendment is normally triggered by the beneficiaries.

Best practice: If Annex 2a or specific unit costs need to be changed, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment, provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

  Budget transfers within the personnel cost category and budget transfers to costs of internally invoiced goods and services are possible without having to amend the GA.

  Examples:

  1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices (average personnel costs).*

  2. *An SME joins an on-going GA. The SME owner does not have a salary but incorrectly budgets its costs as actual personnel costs (category A.1). He realises the mistake and then switches to the unit costs for SME owners (category A.4).*

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

  Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is normally sufficient.

  Linked third parties/international partners — Since they normally do not have direct access to the Participant Register, linked third parties/international partners must inform their beneficiary who must inform the Commission/Agency. The data will then be updated by the Commission/Agency (and validated).

  If (exceptionally) the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator (and instruct it to request an amendment or trigger itself an amendment, if needed).

  Example: Company R moves from Europe to Australia and this implies that the beneficiary is no longer eligible for EU funding. In such a case, the Commission will make an amendment to the GA to change the beneficiary status into 'beneficiary not receiving EU funding'.

  Short names have no legal value and only serve as easy identifiers in the GA. If needed, they can be changed in the context of an amendment initiated on other grounds.

  A change of the person that represent the coordinator for the purposes of signing the GA requires NO follow-up at all (not even a change in the Participant Register — since this name is only relevant at the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

  Transfers of the GA linked to a universal takeover (i.e. where the original entity is replaced by one new entity and all the rights and obligations — including the GA — are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is normally sufficient.

  Example: *Beneficiary X merges with another existing entity Y by:*

  - *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
  - *establishing a new separate legal entity (X and Y are together known as 'Z').*

If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator (and instruct it to request an amendment, if needed).

Example:

The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information (AT40).*

Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going innovation actions (IAs). The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% (but only to a reimbursement rate of 70%). The GA must be amended to change the reimbursement rate (AT33) and the estimated budget (AT31).*
For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

Information obligation — In case of a **universal takeover**, the beneficiary must — in addition to updating the data in the Participant Register— inform the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the Participant Portal) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

2. Procedure

How? Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) directly in the Participant Portal.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function), to discuss the amendment.

Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Participant Register.

Examples:

1. *A new beneficiary must be validated (legal entity validation). This means that the new beneficiary will first have to register in the Participant Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.*

2. *Validation of the new bank account, to change the bank account.*

⚠ The amendment request must include the necessary information and supporting documents. A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications or additional information/documents.

ℹ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action; *see Article 3*). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases *(e.g. change of bank account, change of coordinator to make the payment of the balance)*.

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Termination of the coordinator without its agreement — For change of coordinator without its agreement a special procedure applies: The other beneficiaries must nominate one of them to act on their behalf to notify termination and request the amendment. The nominated beneficiary must name a contact person (NoCo) responsible for the amendment.

Before it has been accepted or rejected, an amendment request may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The other party must — within **45 days** — **agree or disagree**.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If **accepted** it will be **counter-signed** by the receiving party directly in the Participant Portal (for the consortium: by the PLSIGN of the coordinator).

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Participant Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

1. *Where a new beneficiary is added to the GA (AT3), it must assume the rights and obligations from the accession date specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).*

2. *Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment (AT26). This date may be before the date on which the amendment enters into force (see Article 49.2.2).*

3. *If the amendment intends to correct an error (AT60), the change will be made with effect from entry into force of the GA (i.e. from the beginning).*

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* directly in the Participant Portal. They must do this **within 30 days** after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on **joint and several liability** *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, before signing the Accession Form.

Without the declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Linked third parties do not become parties to the GA and therefore do NOT need to sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (new in Horizon 2020). All documents are available in the Participant Portal project file.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries (amendment)

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How? The new beneficiary must:

- register in the Participant Register and be validated — unless it already has a validated participant identification code (PIC)
- sign the Accession Form (directly in Participant Portal)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the **accession date**. It must be either:

- the date of signature of the Accession Form
- the date of entry into force of the Amendment

OR

- a fixed date:
  - either retroactive (i.e. before signature of the Accession Form)

  OR
  - future (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that both can incur costs for a certain period.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned].****]***

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations:

Situation	Applicable law
For international organisations that do NOT accept any applicable law clause	No reference to any applicable law[68]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of

[68] *See Article 180(1) of the Rules of Application Regulation No 1268/2012.*

	international organisations and the rules of general international law.
For international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law)	The international organisation can choose any of the following combinations of applicable laws: – only EU law – only Belgian law – only other MS or EFTA country law – only general principles governing law of IOs + rules of general international law – EU law + MS or EFTA country law (except Belgium) – EU law + general principles governing law of IOs + rules of general international law – EU law + Belgian law + general principles governing law of IOs + rules of general international law – EU law + other MS or EFTA country law + general principles governing law of IOs + rules of general international law – Belgian law + general principles governing law of IOs + rules of general international law – other MS or EFTA country law + general principles governing law of IOs + rules of general international law

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)**: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.]

***[additional OPTION for international organisations and for beneficiaries not eligible for EU funding, which according to their national law cannot be subject to the jurisdiction of the Belgian courts:** As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. [OPTION for Agency grants: Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).]

1. Dispute settlement

As a general rule, H2020 GAs contain an Article 272 TFEU arbitration clause — referring **contractual disputes** (i.e. disputes on the interpretation, application or validity of the GA) to the European Court of Justice.

An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against confirmation letters, debit notes, etc.; NOT against audit reports, audit letters, pre-information letters, etc.).

For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency (information is available both in the Preamble of your GA and in SyGMa).

For disputes of public law nature (i.e. which concern **administrative sanctions**, **offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions must be brought before the European Court of Justice under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ **Public law measures** must ALWAYS be brought to the European Court of Justice under Article 263 TFEU (including actions brought by non-EU beneficiaries or beneficiaries not receiving EU funding).

⚠ All procedures are organised in a way that the beneficiaries will always be **informed** about what they can do if they disagree (**means of redress** information in the letters).

Specific cases (dispute settlement):

- **Non-EU beneficiaries —** For non-EU beneficiaries, contractual disputes are normally referred to the courts of Brussels, Belgium. They can NOT choose another forum. (So far NONE of the H2020 association agreements provides for the sole jurisdiction of the European Court of Justice.)

  Disputes of public law nature remain before the European Court of Justice.

- **Beneficiaries not receiving EU funding —** Beneficiaries not receiving EU funding which are not eligible (meaning from a third country not eligible for funding; *see Article 9*) are treated like non-EU beneficiaries (i.e. courts of Brussels), unless their national law explicitly provides that they cannot be subject to the jurisdiction of the Belgian courts. In this latter case (very exceptional), contractual disputes are referred to the Permanent Court of Arbitration.

  Disputes of public law nature remain before the European Court of Justice.

- **International organisations —** For international organisations, contractual disputes are referred to the Permanent Court of Arbitration (in line, for instance, with their PAGODA agreement, e.g. for the United Nations, the Financial and Administrative Framework Agreement (FAFA) with the United Nations[69]).

  Disputes of public law will normally not arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

  For this reason, the Commission/Agency will normally NOT adopt enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions *(see Article 45).*

  Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (NOT as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[69] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

For countries for which it has carried out a formal assessment of specific situations or their legal framework, the Commission will keep record of its official position.

See the List of issues applicable to particular countries.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC) and
- Low value grants.

Frontier research actions use the H2020 ERC MGA; while two specific MGAs exist for ERC PoC and ERC Low value grants. Other ERC actions (coordination and support actions (CSA)) use the H2020 General MGA.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)
- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the ERC MGA PoC have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the ERC MGA PoC will be limited to major differences from the ERC MGA.

The annotations (for both MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

***[OPTION by default:** 'principal investigator':[4]*

*- [**Name**] [Date and place of birth]]*[5]

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

*- [**Name**] [Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**] [Date and place of birth]*

*- [**Name**] [Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**] established in [official address in full] *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**] [Date and place of birth]*

*- [**Name**] [Date and place of birth]*

[same for each beneficiary]

***[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*:* ***and other ERC grants with more than one principal investigator****: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Participants: Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The '**host institution (HI)**' is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**' for at least the duration of the action.

2. Participants: Principal investigator(s)

For ERC grants, the main researcher (i.e. the **principal investigator (PI)**) is named in the GA.

PIs can be of any **nationality**, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted (and usually engaged) by a host institution that is based in an EU Member State or H2020 associated country.

Due to the key role of the PI, s/he can NOT be replaced by any other researcher during the action. Requests for amendments to change the PI will be rejected.

PI time commitments — The PI must comply with certain minimum requirements regarding working time on the action (fixed in Annex 1 and 2) and working time in an EU Member State or H2020 associated country (set out in the work programme/call).

The Agency must be informed before any change in employment or location of the PI.

Should the PI move to another host institution (in an EU Member State or H2020 associated country), the GA can be transferred to the new host institution (**portability**; *see Article 56a*). If the PI moves to an institution established in a non-associated third country, the GA may be terminated *(see Article 50.1 H2020 General MGA)*.

In case of breach, the Agency may terminate the GA or take any of the other Chapter 6 measures *(e.g. grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50 H2020 General MGA).*

PIs do not become party to the GA, but they are the key actors in charge of the research activities. However, it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary.

Examples:

1. A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium. The engagement of the team follows the rules of the beneficiary and its country.

2. PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the action), PIs and their host institutions must sign a **supplementary agreement (SA)** *(see Article 32)*. The supplementary agreement can NOT replace the employment/engagement contract and is not sufficient by itself.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party (from an EU Member State or H2020 associated country), i.e.:

- a third party that provides the PI as in-kind contribution or
- a linked third party *(see Article 8)*.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution AND the third party.

Retired PI — The PI may be retired.

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)] [and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
  - costs of internally invoiced goods and services
- indirect costs.

Thus, the ERC MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure
- direct costs of providing financial support to third parties
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices (average personnel costs), the unit costs for SME owners and beneficiaries that are natural persons without salary, the unit costs for internally invoiced goods and services and the flat-rate of 25% for indirect costs.[70]

It does NOT use the unit costs of category F 'specific cost categories' of the General MGA.

[70] See *Article 29(1) and 33(2) of the Rules for Participation Regulation No 1290/2013 and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* — with the exception of categories C. 'financial support to third parties' and F 'specific cost categories'.

The same **eligibility conditions** and **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the following **specificities**:

– for category A 'personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: under budget category A.1 'costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: under budget category A.3 'seconded persons' (Article 6.2.A.3)).

– for category D 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs', even for the unsuccessful candidates (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs) and to research data are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[71]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

[71] See http://erc.europa.eu/implementing-arrangements

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

Combining H2020 & other EU grants — ERC grants do NOT prevent **PIs** from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

For more information on how to combine EU funding from different programmes, *see the Participant Portal Online Manual (links to Regional funding).*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record-keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary**: information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC)*;*]**[OPTION 2**: not applicable;**]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2.

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC actions, the principal beneficiary must submit both:

- a **periodic scientific report** after the end of each scientific reporting period (except the last one), with:
    - information about the scientific progress of the work
    - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
    - information on whether and how open access has been provided to these results *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.
- a **final scientific report** at the end of the action, with:
    - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a **financial report** at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a breakdown of direct costs table and a budget follow-up table
- an individual financial statement
- a summary financial statement, created automatically by the IT system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a certificate on the financial statements (CFS).

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted directly in the Participant Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA. Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in **the data management plan**;*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2:** Not applicable**]

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars.

Monographs, book chapters and other long-text publications are considered to be peer-reviewed, if the following conditions are fulfilled:

- at least one independent expert (i.e. external to the publishing house) has reviewed the manuscript before acceptance for publication. For monographs in the strict sense (i.e. not edited collections), external review of a substantial part of the work is sufficient to be considered peer-reviewed
- the external reviewer must not be a scientific series editor or a commercial editor related to the publication in question. For edited collections, it must not be the editor of the collection
- PhD theses and habilitations for professorial degrees are considered peer-reviewed if they are formally published (because the review by external experts is generally part of the assessment of the candidate's research work for the PhD degree or the 'venia legendi').

Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

ERC grants have however the following **specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

- for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)
- for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org). For monographs, book chapters and other long-text publications, the recommended repository is the OAPEN Library (http://oapen.org).

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Moreover, for publications after the end of the action, if beneficiaries cannot provide open access within the time limits set by Article 29.2 without incurring additional costs for gold open access, they may choose green open access with an extended embargo period which goes beyond six/twelve months.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a digital object identifier (DOI)[72] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable). For ease of tracking, beneficiaries should include the digital object identifier for the 'European Research Council' (http://dx.doi.org/10.13039/501100000781) in the funding acknowledgement field in their metadata, in addition to the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601).

For more guidance, *see Open Access on the ERC website, the ERCEA Implementation Guidelines and the ERC Scientific Council's Open Access Guidelines for research results funded by the ERC.*

2. Open access to research data

This option will be inserted in the GA for ERC frontier research actions that participate in the Open Research Data Pilot (in line with provisions in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the following **specificities**:

- The data management plan (DMP) must address the following issues (the use of the ERC template is strongly recommended but not mandatory):

  1. Making data Findable
  2. Making data openly Accessible
  3. Making data Interoperable
  4. Increase data Re-use
  5. Allocations of resources and data security

  Moreover the DMP can provide justification for NOT ensuring open access to specific parts of the research data. For ERC actions, the exception allowing beneficiaries not to give access to specific parts of their research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives.)

  For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does NOT need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

  A first version of the data management plan must be submitted within the first 6 months of the project implementation and should then be updated during the lifetime of the project, as needed.

[72] For more information, *see http://www.doi.org/.*

The beneficiaries may **opt out** of the pilot at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55 H2020 General MGA)*. No reasons have to be provided for opting out. By opting out, they free themselves retroactively from the obligations associated with taking part in the pilot.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow and facilitate the transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action

The PI must ensure a sufficient time commitment and presence throughout the course of the project to guarantee its proper execution.

The two time commitment obligations are as follows:

- % of working time that the PI must work on the action
- % of working time that the PI must work in an EU Member State or H2020 associated country.

To be operational, these two percentages must be translated into working hours, i.e.:

- minimum number of hours that the PI must work in the action over its duration
- minimum number of hours that the PI must work in an EU Member State or H2020 associated country over the duration of the action.

The calculation should be done as follows:

Step 1 — For each year of the action, the percentages of PI commitment are applied to:

a) either the annual hours of a standard full time equivalent at the host institution, or

b) 1720 annual hours (this option must be used in all cases when it is not possible to determine the number of hours of a full time equivalent at the host institution).

The standard full time equivalent (or 1720 annual hours) works as a ceiling: they apply even if the PI works in total *more* hours (i.e. has other parallel affiliations, freelance activities or work-related obligations or works more hours on the action). In this case, the time commitment is capped at 100% and the hours are calculated on the standard full time equivalent (or 1720 annual hours).

By contrast, if the PI works in total *less* hours than the standard full time equivalent (or 1720 annual hours), the time commitment obligation will be reduced proportionally.

To do so, the percentage of PI commitment will be applied to the total work of the PI (instead of to options a) or b) above).

The total work of the PI will be determined by adding up all her/his hours of remunerated work, including under contracts with entities other than the host institution.

Example: *The % of PI commitment to the ERC action is 50%. The PI works 60 % part time at the host institution and has another contract with a different entity to work 350 hours over the year. A full time equivalent at the host institution works 1750 hours per year. The hours that the PI works in total are = 60 % of 1750 + 350 = 1 050 + 350 = 1 400. Since this amount is lower than the full time equivalent, the time commitment obligation will be: 1 400 x 50 % = 700*

Step 2 — Sum up the results for each year of Step 1 to get the total number of hours over the action duration.

The percentages must be reached for the overall action duration (NOT annually or per reporting period).

The PI's time commitments obligations must be fulfilled even if no personnel costs are charged for him/her to the project.

- Applying the host institution's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**

- Upholding the **intellectual property rights** of the host institution

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it if s/he becomes aware of any violations.

  Example: *The PI reads a research article and discovers a violation of the host institution's project IPRs. S/he is obliged to inform the host institution.*

- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the host institution and the PI, to set out their internal arrangements for implementing the grant.

It is **purely internal**; the EU/Euratom is NOT party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must remain in place at least for the action duration *(see Article 3)* (— without any interruptions, even if the PI works only part-time on the ERC project).

It must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

It must be concluded **before GA signature** (or in case of portability before submission of the amendment request) and a copy must be sent to the Agency.

A template [ODT format] for a model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution *(see Article 56a)*, a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The new agreement must take effect from the grant transfer date (or before). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make **specific reference to the European Research Council (ERC)**. Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC home page*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION 1:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION 2:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****]***.

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG and other ERC grants with more than one principal investigator: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new host institution ('new beneficiary') — at any time during the action.

Transfer — The rights and obligations under the GA are transferred from the former host institution to a new host institution — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former host institution remains fully responsible until the Agency has approved the amendment.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution ('former beneficiary') may **oppose** a transfer only if it is not allowed under national law.

It may however **negotiate** transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the views of the PI.

2. Procedure

The PI should first contact the host institution that signed the GA (i.e. the former host institution).

> ⚠ **Record-keeping**
> **Best practice:** Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new host institution joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The **financial reporting periods** will be automatically adapted to match the transfer date (unless the transfer date coincides with the end of a financial reporting period).

Scientific reporting periods will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

> ℹ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The principal beneficiary must — within 60 days from either the transfer date or the date of signature of the amendment whichever is the latest — submit:

- a financial report to the Agency (for the open period until transfer)
- a report on the distribution of payments (only in case of multi-beneficiary GA)
- if the costs reach the threshold set out in Article 20:, a certificate on the financial statement (CFS) (— even if this is not the last reporting period).

These documents will be used for calculating the interim payment due to the former beneficiary. The Agency will moreover instruct the former host institution to transfer the remaining pre-financing to the new host institution.

If the PI requests it, the Agency may require the former host institution to **transfer equipment** that was purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate transfer conditions with the new host institution, taking into account the views of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may declare the costs of this reimbursement (and any other

related costs, i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, while the PI moves to a new host institution, the GA is transferred and changed into a multi-beneficiary grant agreement (allowing both the former host institution and the new host institution to participate in the grant). The former host institution stays on as beneficiary, the organisation that hosts and engages the PI is the new host institution. If the former host institution remains only for a limited time *(e.g. to ensure a smooth handover)*, it can then be terminated at a later stage, via a beneficiary termination *(see Article 50.2 H2020 General MGA)*.

II.3 H2020 ERC PoC MGA: Annotations

The H2020 ERC PoC MGA is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability *(Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION 1 by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION A if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION B:*** *not applicable;****]***

*(f) a '****summary financial statement****', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the* ***request for payment of the balance****;*

*(g) a '****certificate on the financial statements****' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).****]***

[OPTION 2 for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a report to the Agency.

The ***report*** *must include the following:*

(a) a summary for publication by the Agency;

(b) an ***overview of the progress of work*** *towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '****breakdown of direct costs table****' and a '****budget follow-up table****';*

(d) an ***'individual financial statement'*** *(see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the report for the next reporting period.

The individual financial statements of the last reporting period must also detail the ***receipts of the action*** *(see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION A if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION B:** not applicable;**]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC PoC actions, the principal beneficiary must submit **periodic reports** — only one if there is one reporting period, otherwise one at the end of each reporting period.

The report(s) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a summary financial statement, which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a certificate on the financial statements (CFS) will have to be added (if necessary).

How? All reports must be prepared and submitted directly in the Participant Portal *(see Article 20 H2020 General MGA*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowska-Curie Actions (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE
- MSCA-COFUND and
- MSCA-SNLS.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MSCA-ITN MGA deviates from the General MGA — Multi as follows:

- Article 4.2 (MSCA-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-IF MGA deviates from the General MGA — Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 9-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSCA-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSCA-IF specific conditions for termination)
- Article 55 (MSCA-IF specific conditions for amendments)
- Article 56a (MSCA-IF portability)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-RISE MGA deviates from the General MGA — Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9 - 16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSCA-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (MSCA specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-COFUND MGA deviates from the General MGA — Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of a programme)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)

The H2020 MSCA-SNLS MGA deviates from the General MGA — Mono as follows:

- Article 1 (linked grant)
- Article 4 (estimated lump sum breakdown, lump sum share transfers)
- Article 5 (maximum grant amount and form of grant)
- Article 6 (not applicable)
- Articles 9-16 (not applicable)
- Article 18 (special provisions for record-keeping)
- Articles 20, 21 (specific provisions for reporting and payments)
- Articles 23a-34 (not applicable)
- Article 37 (not applicable)
- Article 42 (not applicable)
- Article 44 (specific provisions for calculation of recoveries)
- Article 56 (not applicable)
- Article 56a (portability)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement
- Annexes 5 and 6 Not applicable

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 9-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND; MSCA-SNLS)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories; MSCA-SNLS estimated lump sum breakdown and lump sum share transfers)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement; MSCA-SNLS rules on third party involvement)

III.2 H2020 MSCA-ITN MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-ITN actions

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by networks of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN takes the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries.

This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

***[OPTION for all actions except EID with only two beneficiaries:** However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.]*

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

The maximum grant amount *(see Article 5)* can however **NOT** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

***Example:** Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment *(see Article 55)* is required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID with only two beneficiaries: a maximum of 40 % of the budget may be allocated to beneficiaries established in the same country (or to the same international European interest organisation or international organisation).

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In an action with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (= 40%). If the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes (*e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes (*e.g. to increase the salary of a researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

For MSCA-ITN, the maximum grant amount is limited to a maximum unit cost equivalent of 540 person-months (and for EID with only two beneficiaries: 180 person-months).

2. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the H2020 Work Programme (section 3 MSCA))*.

3. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[73].

For MSCA-ITN, these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if applicable)

[73] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they can NOT be changed.

The eligibility conditions are set out in *Article 6*.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5 H2020 General MGA*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(iv) ***[OPTION for EID:** if spent on inter-sectorial mobility between academic and non-academic beneficiaries (i.e. not partner organisations): are international (i.e. spent between beneficiaries established in different countries).]*

(v) ***[OPTION for EID:** are, for at least two-thirds of the recruited researchers, spent in a joint, multiple or double degree programme with two or more beneficiaries or partner organisations stablished in EU Member States or associated countries.]*

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country) – unless as part of a procedure for obtaining refugee status under the Geneva Convention[6].

For beneficiaries that are international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately before the recruitment date.

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for 1 EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree in at least one EU Member State or associated country [;][.]**]***

(viii) ***[OPTION for 2 EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

[6] 1951 Refugee Convention and the 1967 Protocol.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)
- a monthly mobility allowance (A.2) — to cover costs related to their mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by budget category B.1 'research, training and networking costs')

AND

- a monthly family allowance (A.3) — for researchers with family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

Example: *Costs for student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.*

1.2 The costs must be **declared** as the unit costs fixed by Decision C(2017) 6855[74] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 3 270** per researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The list of coefficients is published in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

  On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does NOT change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

For the latest information on the amounts and the country correction coefficients, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first 4 years (full time equivalent research experience) of their research career)

    '**Date of recruitment**' means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

[74] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

Example: *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as recruitment date.*

Years of '**research career**' are counted from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:
  - sickness, parental, unemployment and invalidity benefits
  - pension rights and
  - benefits for accidents at work and occupational diseases.

  If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:
  - sickness, parental and invalidity benefits and
  - benefits for accidents at work and occupational diseases.

  In this case, the living allowance will be reduced by 50%.

  The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

  Staff provided by a temporary work agency — Beneficiaries must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:
  - subject to prior approval by the Agency
  - on personal or family grounds only (i.e. not for professional reasons) and
  - if limited to a maximum of 50% of the time spent under the action.

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  ⚠ While it is not possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities (and must be set out in Annex 1 of the GA).

- are supported for **at least 3 months**

  Person-months linked to shorter contracts will not be eligible.

However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. If the contract is set out for a longer duration, but the training is interrupted within the first three months for reasons not linked to the beneficiary *(e.g. because the researcher resigns)*, the costs may still be claimed.

- comply — at the date of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (— unless the beneficiary is an 'international European interest organisation'[75] or international organisation, for whom the mobility rule is limited to time spent *with* them)

  The mobility rule applies only to the **first recruitment** under the action. For instance, it does not apply to beneficiaries or partner organisations to which the researcher is sent or seconded afterwards.

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[76] are NOT counted.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  For EJD:

  - the PhD-programme must lead to the award of:

    - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or

    - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

    in at least one EU Member State or H2020 associated country

  and

  - at least two-thirds of the recruited researchers must be enrolled in a joint, double or multiple degree programme within Europe, i.e. between two or more beneficiaries or partner organisations established in EU Member States or Horizon 2020 associated countries.

  The degree must not necessarily be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

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[75] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[76] 1951 Refugee Convention and the 1967 Protocol.

Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researchers (gross amount).

MSCA-ITN researchers must NOT be requested to pay tuition fees for their research training and/or PhD degree programme (neither from their own funds, nor from the researcher unit cost). The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* can be reimbursed under category B 'institutional costs'.

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as*:

- *part of his/her salary*
- *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
- *rental costs, directly paid or reimbursed by the beneficiary.*

Any form is acceptable, provided that:

- both sides agree
- it is allowed under national law

AND

- there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1 100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[77]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[78].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure*

[77] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html.
[78] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm.

that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers who have — at the date of the recruitment — a family, i.e.:
  - persons linked to them by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ Beneficiaries may declare a **maximum** of **36 person-months** per researcher. Person-months exceeding this number will be rejected by the Agency.

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector.

This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations/entities with a capital or legal link. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary, *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 50% rule.

Inter-sectoral mobility between beneficiaries must be international (i.e. spent between beneficiaries established in different countries).

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence).*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - costs for visa-related fees and travel expenses
  - additional costs arising from each secondment of 6 months or less which require mobility from the place of residence *(e.g. travel and accommodation costs)*

    Example: *A researcher does doctoral research at a beneficiary in Italy for 36 months. During this time, she goes on a 4-month secondment to Poland. The beneficiary must cover her travel and accommodation costs in Poland for this 4-month period with the research, training and networking costs category.*
- management and indirect[79] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:
- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of a researcher or to organise additional training activities, to cover travel and accommodation costs for secondments of more than 6 months in line with the consortium internal arrangements)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of a researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[80] and set out in Annex 2 and 2a of the GA.

[79] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

This is currently:

- for research, training and networking costs: **EUR 1 800** per researcher per month (person-month)

- for management and indirect costs: **EUR 1 200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[81] in the same period: only management costs, i.e. EUR 600 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for recruited researchers'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for budget category A 'costs for recruited researchers' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

[80] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[81] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon **entities with a capital or legal link** to the beneficiaries[7], to implement certain action tasks described in Annex 1 (i.e. hosting and training of researchers);
- call upon **partner organisations** to implement certain action tasks described in Annex 1 (i.e. hosting and training researchers during secondments).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[7] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-ITN allows the beneficiaries to use:

– entities with a capital or legal link to them

and

– partner organisations

to carry out work under the action (**third parties involved in the action**).

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-ITN grant (i.e. recruits the researchers), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-ITN action as entity with a capital or legal link implementing the research training activities, while the foundation or subsidiary participates as beneficiary (because it can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-ITN action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and training of researchers (including during secondments) — and can even implement ALL those activities under the action. But they can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary, tasks to be carried out and time spent with them).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme).

For more information on conditions for participation and funding, *see the H2020 Work Programme (section 3 MSCA).*

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers, but only during **secondments**.

Secondments — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country) in order to further enrich the training experience of the researchers.

They are limited to a **maximum of 30%** of the time that is declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out and time spent with them).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations can be established anywhere (EU Member State, H2020 associated country or non-associated third country).

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term meeting**' between the beneficiaries, entities with a capital or legal link, partner organisations and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of each researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — within 30 days after the first year of the action — send to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

> **Best practice:** It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** after the recruitment date.

> It is important to give correct and complete information in the researcher declaration since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA):*

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[16] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or other entity mentioned in Annex 1);

(j) ensure that the researchers do not have to bear any costs for the implementation of the action as described in Annex 1;

(k) host the researchers at their premises (or at the premises of an entity with a capital or legal link);

(l) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(m) ensure that the researchers are adequately supervised;

(n) ensure that a career development plan is established and support its implementation;

(o) ensure an appropriate exposure to the non-academic sector;

(p) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective recruitment procedures and best possible working conditions.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[82]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises (or those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or ensure that this is provided by the entity with a capital or legal link).

[82] Available at http://ec.europa.eu/euraxess/

If the Agency finds that a beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**
- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Ensure that **secondments** are **limited** to a **maximum** of **30 %** of the months declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD).

> ⚠ **Secondments** — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country), in order to further enrich the training experience of the researchers *(see Article 8)*.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

- Ensure that the researchers do NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Ensure that the researchers do NOT have to bear **any costs** for the implementation of the action as described in Annex 1

  Recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training and/or PhD degree programme (*e.g. student registration,, access to student services (e.g. library, computing, etc.), teaching, supervision, examination and graduation)* neither from their own funds, nor from the researcher unit cost.
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[83].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[84].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities (including during secondments with other beneficiaries and/or partner organisations).

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2 H2020 General MGA)*.

[83] Available at https://www.iprhelpdesk.eu/.
[84] Available at http://ec.europa.eu/euraxess/.

The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (consortium) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the

Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MSCA-IF MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-IF actions

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include three additional funding strands: the 'Career Restart Panel', the 'Reintegration Panel' and the 'Society & Enterprise Panel'.

The MSCA-IF annotations are equally applicable to the Widening Fellowships *see H2020 Work Programme (section 15 Spreading Excellence and Widening Participation)*).

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION 3 if needed for the action:** [insert date]]*[4] ('**starting date of the action**').

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the actual starting date must be *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, there will be a **maximum deadline for notification** set out in Article 3 for both starting the action and notifying this to the Agency (normally 12 months from the entry into force of the GA).

The notification must be done directly in the Participant Portal.

Late notification will delay the pre-financing payment *(see Article 21.2 H2020 General MGA)*.

If the action does not start or the starting date is not notified in time, the Agency may terminate the GA *(see Article 50 H2020 General MGA)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researcher (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The institutional unit cost should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (*including for GF outgoing phase; see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the H2020 Work Programme (section 3 MSCA))*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[85].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[85] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[**OPTION 1 by default:** 24] [**OPTION 2 for EF-CAR**: 36] [**OPTION 3 for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including periods of secondment to **'partner organisations'**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for professional, personal or family reasons (see Article 55), and

(iii) be working exclusively for the action.

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)

- a monthly mobility allowance (A.2) — to cover costs related to his/her mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by category B.1 'research, training and networking costs').

AND

- a monthly family allowance (A.3) — if the researcher has family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiary are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017)6855 [86] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 4 880** for the researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the H2020 Work Programme (section 3 MSCA) in force at the time of the call and according to the country of recruitment (i.e. the country of the beneficiary).

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

ℹ For the latest information on the amounts and the country correction coefficients, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[86] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the date of the call deadline — an **experienced researcher** (i.e. have a doctoral degree OR have at least four years (full time equivalent research experience) of research career).

    Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases

    If national law prevents it from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

    The social security coverage must be guaranteed for the entire action (i.e. also during optional secondments, if any, and for the GF outgoing phase).

    For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent coverage during the stay in the third country.

    Example: *A German university recruits the fellow for the total duration of the action (i.e. provides the main employment contract under the action) and sends him/her to a US university. Continuing the German social security during the stay in the US would be so expensive, that the beneficiary asks the US partner organisation to conclude an additional employment contract, in order to insure the researcher in the US.*

    Staff provided by a temporary work agency — The beneficiary must always recruit the researcher directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency
    - on personal and family grounds

– on professional grounds (except during the outgoing phase for GF) in agreement with the beneficiary

– if limited to a maximum of 50% of the time spent under the action

Part-time employment for professional reasons can be requested in order to pursue supplementary activities, *such as creating a company, pursuing another research project, engaging in advanced studies not related to the MSCA grant, etc.* It cannot be requested in order to participate in another MSCA grant at the same time.

When part-time employment for professional reasons is accepted, the beneficiary must ensure reliable **time records** *(e.g. timesheets)* either on paper or in a computer-based time recording system.

In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ If NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is NOT allowed (**—** unless part-time for professional reasons was approved). Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must not jeopardise the research activities (and must be set out in Annex 1 of the GA).

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researcher (gross amount).

  The mobility and family allowances are due to the researchers for each month worked.

  Mobility and family allowances can be paid to the researcher in various ways, *for example as:*

  – *part of his/her salary*

  – *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*

  – *rental costs paid or reimbursed by the beneficiary, etc.*

  Any form is acceptable, provided that:

  - both sides agree

  – it is allowed under national law

  AND

  – there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1 100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[87]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[88].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0,9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0,87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the date of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the 3 years immediately before to the call deadline (— unless the beneficiary is an 'international European interest organisations' or international organisations, for whom the mobility rule is limited to time spent *with* them)

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) are NOT counted.

  For EF Career Restart Panel, Reintegration Panel and Society & Enterprise Panel: specific mobility rule — not more than 3 years in the 5 years immediately before the call deadline

  For GF: the mobility rule is checked for the country of the partner organisation, not for the country of the beneficiary (i.e. where the outgoing phase takes place, not where the return phase takes place).
- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a EU Member State or an H2020 associated country.

  'Long-term resident' means a period of legal and continuous residence in a EU Member States or H2020 associated countries for 5 or more consecutive years. Periods outside these countries will be taken into account if shorter than 6 consecutive months and all in all not more than 10 months.

[87] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[88] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

For EF Reintegration Panel: The long-term residence requirement will not apply to researchers who have obtained refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) in a EU Member State or H2020 associated country.

- for EF Career Restart Panel: not have been **active** in research for at least 12 months immediately before the call deadline

  'Active in research' means being employed or holding a scholarship. Parental leaves and unpaid leaves of absence will not be counted as periods of active engagement in research, even if a formal employment relationship exists during these periods. Publication activities or mere association to a university are not taken into account either.

- for the family allowance: have a **family**, i.e.
  - persons linked to the researcher by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs for the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

– for the mobility allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

– for the family allowance:

amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ The beneficiary may declare a **maximum** of **24 person-months** for the researcher (or **36 months** for GF and EF Career Restart Panel). Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by requesting an amendment to suspend the action; *see Article 49.1.1.2*).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence) and the action must be suspended.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.1): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - costs for visa-related fees and travel expenses
  - additional costs arising from secondments *(e.g. travel costs and accommodation costs for optional secondments)*
- management and indirect[89] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (including for GF outgoing phase; *see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[90] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 800** for the researcher per month (person-month)

[89] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[90] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for management and indirect costs: **EUR 650** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[91] in the same period: only management costs, i.e. EUR 325 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for the recruited researcher'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for budget category A 'costs for the recruited researcher' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for the recruited researcher:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[91] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon entities with a capital or legal link to the beneficiary[5], to implement certain action tasks described in Annex 1 (i.e. hosting and training of the researcher);
- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. hosting and training the researcher during secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

[5] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-IF allows the beneficiary to use:

– entities with a capital or legal link to it

and

– partner organisations

to carry out work under the action (**third parties involved in the action**).

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations).*

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to the beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-IF grant (i.e. recruits the researcher), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation or subsidiary participates as beneficiary (because it is can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and research training of researchers (including during a secondment) — and can even implement ALL those activities under the action. But they can NOT recruit the researcher (only the beneficiary can recruit the researcher).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of link with the beneficiary and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary (for instance, be established in an EU Member State or H2020 associated country).

***Example:** For the EF Society & Enterprise Panel, the entities with a capital or legal link must also be from the non-academic sector.*

For more information on conditions for participation and funding, *see the H2020 Work Programme (section 3 MSCA).*

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers, but only during **a secondment**.

Secondments — For MSCA-IF, secondments are either:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country).

Optional secondments are limited to a **maximum of 3 months** (for actions with duration of up to 18 months) and **6 months** (for actions with duration of more than 18 months).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researcher (only the beneficiary can recruit the researcher).

For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent social security coverage during the stay in the third country *(see Article 6)*.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations for optional secondments must be established in an EU Member State or H2020 associated country; partner organisations for GF outgoing phase must be established in a non-associated third country.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher
  - in case of part-time for professional reasons, the work for the action has been reliably recorded *(through time-sheets, logbooks, counters etc.)*.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** and **entities with a capital or legal link** (if any) give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[12] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(g) ensure that the researcher does not have to bear any costs for the implementation of the action as described in Annex 1;

(h) host the researcher at its premises (or at the premises of an entity with a capital or legal link);

(i) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(j) ensure that the researcher is adequately supervised;

(k) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(l) support the secondment of the researcher to a partner organisation in a Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(m) ***[OPTION for GF:*** *support a maximum of 3 months spent by the researcher with the beneficiary (or an entity with a capital or legal link and/or a partner organisation) before the outgoing phase and the return of the researcher to the beneficiary (or an entity with a capital or legal link) to carry out a mandatory return period of 12 months.****]***

[…]

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises (or at those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or to ensure that this is provided by the entity with a capital or legal link).

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- **Support secondments** of the researcher (if any) and ensure that they are **limited** to a **maximum** of **3 months** (for actions of up to 18 months) or **6 months** (for actions of more than 18 months)

Secondments — For MSCA-IF, secondments can be:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

and/or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country) *(see Article 8)*

For GF: Also support time spent by the researcher with the beneficiary (or an entity with a capital or legal link and/or a partner organisation) before the outgoing phase (limited to a maximum of 3 months) and the researcher's return (mandatory return-period must always be 12 months)

- Ensure that the researcher does NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

- Ensure that the researcher does NOT have to bear **any costs** for the implementation of the action as described in Annex 1

  The recruited researcher must NOT be requested to pay visa-related fees or tuition fees for the research training neither from his/her own funds, nor from the researcher unit cost.

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[92].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[93].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during optional secondments/GF outgoing phase with partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

[92] Available at https://www.iprhelpdesk.eu/.
[93] Available at http://ec.europa.eu/euraxess/.

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

  This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment — unless part-time employment for professional reasons has been approved (see Article 55). Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave).

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. GA suspension — Additional grounds for suspension: Professional, personal or family reasons (beneficiary)

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, beneficiaries of MSCA-IF may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave or another professional opportunity)*.

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and (planned) end date of the suspension and
- the (planned) resumption date when the action will be resumed (i.e. automatically end date +1 day).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are NOT eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for professional, personal or family reasons (including parental leave).

[…]

1. Amendments — Additional ground for amendments: Change to part-time employment (beneficiary)

What? For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time) — on professional, personal or family grounds (including parental leave).

If NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

How? The amendment should be requested immediately (retroactive change is possible, if justified; *see Article 55 H2020 General MGA*).

The action duration will be automatically adapted (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months, so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working time; AT23 clause) and the reporting periods will be changed (to adapt them to the new action duration; AT25 clause).

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains **fully responsible** until the Agency has approved the amendment.

The transfer may be based on any **ground** that is linked to the beneficiary and affects objectives of the action (i.e. implementing the research training activities).

Examples: *Internal reorganisation affecting implementation of the action; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher *(e.g. other professional opportunities, personal or family commitments)* are NOT considered valid grounds for transferring the GA to a new beneficiary. These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*.

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility conditions or does not have sufficient financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed directly in the Participant Portal).

The **maximum grant amount/action duration** will be adapted to take into account the country correction coefficient of the new beneficiary.

⚠ The maximum grant amount *(see Article 5)* will **NOT** be **increased**.

If the new beneficiary is in a country with a lower country correction coefficient, the maximum grant amount *(see Article 5.1) will be lowered*.

If the new beneficiary is in a country with a higher country correction coefficient, the action duration will normally be adapted, so that the maximum grant amount can stay the same. If (exceptionally) the action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new correction coefficient *(using e.g. the management and indirect costs or own funding)*.

ℹ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to check the eligible costs and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must be also uploaded with the next periodic report (by the new beneficiary, together with its own financial statement).

The maximum grant amount will be split between the former beneficiary and the new beneficiary — on the basis of the researcher months already spent with the former beneficiary.

The former and the new beneficiary must agree on arrangements, where necessary, concerning intellectual property and other issues.

III.4 H2020 MSCA-RISE MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-RISE actions

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

> **Secondments** — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

> For more information on MSCA-RISE, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*
>
> For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries.

This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NOT** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment is required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the seconded staff (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs a staff member, to organise additional training activities or horizontal networking events)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs**).

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the H2020 Work Programme (section 3 MSCA)).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[94].

For MSCA-RISE, these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[94] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for seconded staff members</u> are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 1 month at the sending:

- beneficiary (or entity with a capital or legal link[6] to it and located in the same country), or
- partner organisation (or entity with a capital or legal link to it and located in the same country).

(c) the secondments comply with the following conditions:

(i) last at least 1 month and no longer than 12 months (per secondment);

(ii) be between different countries;

(iii) for secondments within the EU (or associated countries)[7]: be between different sectors (academic and non-academic)[8];

(iv) for secondments from EU (or associated countries): be from a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country) to a partner organisation (or entity with a capital or legal link) established in a non-EU Member State (or non-associated country), and

(v) for secondments to EU (or associated countries): be from a partner organisation (or entity with a capital or legal link) established in a country listed in General Annex A of the Main Work Programme to a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country).

[6] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] For secondments for entities with a capital link or legal link to the beneficiaries or partner organisations: only the sector (academic or non-academic) of the beneficiary counts; the entity will be considered to belong to the same sector as their beneficiary.

1. Seconded staff costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members, by providing for:

- a monthly top-up allowance (A) — for travel, accommodation and subsistence costs relating to the secondment.

> ⚠ **Budget flexibility —** There is NO flexibility as regards the *use* of the seconded staff unit costs (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
>
> ⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

What not? Research, training and networking costs and management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared as** the unit cost fixed by Decision C(2017) 6855[95] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the top-up allowance: **EUR 2 100** per seconded staff member per month (person-month).

> ℹ For the latest information on the amount, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - **early stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full time equivalent research experience) of their research career)
    - **experienced researchers** (i.e. have a doctoral degree OR at least four years (full time equivalent research experience) of research career), or

[95] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

- **administrative, managerial** or **technical staff supporting research and innovation activities** (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

  Examples (not eligible administrative, managerial or technical staff):

  1. *Ms B, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

  2. *Mr Y, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

Years of '**research career**' are counted from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited or from where s/he is seconded) — even if a doctorate was never started or envisaged.

- have already been actively **engaged** in or **linked** to research and innovation activities at the premises of the sending beneficiary/partner organisation/entity with a capital or legal link, continuously for at least **1 month** (full time equivalent)

  Examples:

  1. *Mr Y is employed by/has a fellowship with/is a registered PhD candidate of beneficiary Y as from 1 January 2014; Mr Y will not be eligible for a secondment from 1 January 2014 but would be eligible for secondment as from 1 February 2014.*

  2. *Ms X is employed 50% part-time by beneficiary X as from 1 January 2014. Ms X will not be eligible for a secondment from 1 February 2014, but would be eligible for secondment as from 1 March 2014.*

  The type of relationship (employment contract, fellowship or other) is NOT relevant — as long as it:

  - complies with national law
  - complies with internal practices and
  - during the secondment: confers to the sending beneficiary/partner organisation/entity with a capital or legal link the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

    If this is not the case, the beneficiary/partner organisation/entity with a capital or legal link must conclude a contract which allows this (or a supplementary agreement) — before the secondment.

    Example: *A PhD-candidate can be seconded if s/he: has a contract allowing him/her to work full-time on the R&I activities of the action during the secondment under the instructions of the sending beneficiary/partner organisation/entity with a capital or legal link.*

- be incurred for secondments:

  - that last at **least 1 month** and **no longer than 12 months**

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

    For the minimum duration, only splits within *secondments of* same staff, from same sending beneficiary/partner organisation to same hosting beneficiary/partner organisation can be added. Secondments from/to entities with a capital or legal link

will be counted as secondments from/to the beneficiaries/partner organisations they are linked to.

Example: *Two secondments of two weeks of the same staff member to different beneficiaries are not eligible since the minimum duration of 1 month is not reached.*

For the maximum duration, all secondments (and all splits) for the *same staff member* must be added.

- that are one of the following three:
  - secondments **between beneficiaries/entities with a capital or legal link** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in **different** EU Member States or H2020 associated **countries** AND **different sectors** (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country) **to** a **partner organisation/entity with a capital or legal link** in a third country

  OR

  - secondments **from** a **partner organisation/entity with a capital or legal link** in a third country listed in General Annex A to the H2020 Work Programme **to** a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country).

  Secondments from/to branches/departments of beneficiaries/partner organisations which are not separate legal entities are NOT eligible, if they are located in countries other than the country of their beneficiary/partner organisation.

  Examples:

  A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

  Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the H2020 Work Programme.*
  A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

  Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the H2020 Work Programme.*
  A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

  Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
  They may each claim 120 person-months (for their own staff).

  If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded *from* both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation *to* two or more participating organisations in a RISE project — as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('implemented person-months')

⚠ Beneficiaries may declare a **maximum** of **12 person-months** per seconded staff member. Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert 5.47 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[96] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility —There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[97] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1 800** per researcher per month (person-month)
- for management and indirect costs: **EUR 700** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[98] in the same period: only management costs, i.e. EUR 350 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

[96] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[97] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[98] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for seconded staff members'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for seconded staff members.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the seconded staff members are met. Person-months which are not eligible for budget category A 'costs for seconded staff members' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff);
- call upon entities with a capital or legal link to the beneficiaries or to partner organisations[9], to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[9] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-RISE allows the beneficiaries to use:

– partner organisations

and

– entities with a capital or legal link to a beneficiary or a partner organisation

to carry out work under the action (**third parties involved in the action**).

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them.)

Partner organisations are third parties involved in the action without a (capital or legal) link to a beneficiary.

They may participate in the exchanges by seconding and hosting staff.

⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action. They can be between beneficiaries/entities with a capital or legal link OR between beneficiaries/entities with a capital or legal link and partner organisations (from a third country).

They must have a **minimum** duration of **1 month** and a **maximum** duration of **12 months** (per seconded staff member).

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations must be established in a non-associated third country (i.e. not EU Member State or H2020 associated country).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary or a partner organisation — which is neither limited to the action nor established for the sole purpose of its implementation).

They may participate in the exchanges by seconding and hosting staff.

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary/partner organisation and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary/partner organisation they are linked to (for instance, if linked to a beneficiary: be established in an EU Member State or H2020 associated country; if linked to a partner organisation: be established in a non-associated third country AND be established in the same country as their beneficiary/partner organisation.

Examples (eligible entities with capital or legal link):

1. *University X (established in France) is part of a Joint Research Unit (JRU) with beneficiary Y (also established in France). Mr. X is employed by university X and is to be sent on a secondment to beneficiary Z. University X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

2. *SME X (established in Portugal) is a subsidiary of beneficiary Y (also established in Portugal). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. SME X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Ms. X.*

3. *Mr. X is formally employed by foundation X (established in Spain) which does the HR management for beneficiary Y (also established in Spain). Mr. X actually works with beneficiary Y and should be sent on a secondment to beneficiary Z. Foundation X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

Examples (ineligible entities with capital or legal link):

1. *SME X (established in Germany) is a subsidiary of applicant Y (established in Greece). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. Since SME X is not established in the same country as applicant Y, it cannot act as entity with a capital or legal link for the purposes of a MSCA-RISE grant. Therefore, Ms X cannot be seconded.*

2. *University X (validated as academic; established in Sweden) is member of an association of universities (applicant Y; validated as non-academic). Mr. X is employed by university X and is to be sent on a secondment to applicant Z (validated as academic). University X cannot act as entity with a capital or legal link of applicant Y for the purposes of the MSCA-RISE grant because this would circumvent the inter-sector mobility rules (mix of academic and non-academic).*

ℹ For more information on conditions for participation and funding, *see the Main H2020 Work Programme (section 3 MSCA).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities)*

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until these procedures end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents bear the **full risk** of cost rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must keep the documents for the staff of the partner organisation/entity with a capital or legal link.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term meeting**' between the beneficiaries, partner organisations, entities with a capital or legal link and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — after each year except if a periodic report is due (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a 'researcher declaration' for each seconded staff member — within **20 days** from the start of the secondment.

It is important to give correct and complete information in the researcher declaration, since this information will be used to determine the eligibility of the person-months that are declared.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — and indicate each split.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment, indicating the split. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (within 20 days from the start date of each secondment). Secondments to entities with a capital or legal link will be counted as secondments to the beneficiary/partner organisation they are linked to and must therefore be covered by the same researcher declaration.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

Specific case (deliverables):

Researcher declaration for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must submit the researcher declarations.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the seconded staff members **access** to both **background** AND **results** necessary for their research and innovation activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[17] and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

(k) ensure that the seconded staff members do not have to bear any costs for the implementation of the action as described in Annex 1.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[17] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time.**

  For part-time staff members this may require a change of their relationship (i.e. conclude a contract or a supplementary agreement), to allow the secondment to be implemented on a full-time basis.

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is only a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are of course accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary/partner organisation/entity with a capital or legal link) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[99].

[99] Available at https://www.iprhelpdesk.eu/.

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*
- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.
- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

  They can be:
  - paid directly to the seconded staff member in advance or via different instalments or
  - managed centrally by the beneficiary according to the specific needs of the secondment.
- Ensure that the seconded staff members do not have to bear **any costs** for the implementation of the action as described in Annex 1.

  The seconded staff members must NOT be requested to pay tuition fees for their research and innovation training neither from their own funds, nor from the staff member unit cost.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract (or fellowship or other relationship), some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA grant in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (consortium) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MSCA-COFUND MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-COFUND actions

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

⚠ **Budget flexibility** — There is however some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in a programme implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**');

(b) for **costs of providing financial support to costs for researchers in a programme implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the H2020 Work Programme (section 3 MSCA))*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[100].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[100] Commission Decision C(2017) 6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced maximum grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in a programme implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in a programme implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme), by providing for:

- a monthly living allowance (A.1 or A.2) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*).

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit cost (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs of the beneficiary are not covered. Management costs are covered under budget category B 'management costs' *(see Article 6.2.B)*. Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are NOT eligible under the grant; they may be funded through other sources (including other EU funding programmes).

Combining H2020 & other EU grants — A MSCA-COFUND grant does NOT prevent the beneficiary or partner organisations from applying for further (non-H2020) EU funding for their programme — for costs that are not eligible (or not declared) under the MSCA-COFUND grant.

For more information on how to combine EU funding from different programmes, *see the Participant Portal Online Manual (links to Regional funding).*

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[101] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance:
  - for early-stage researchers in doctoral programmes: EUR 3 870 per researcher per month (person-month)

[101] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for experienced researchers in fellowship programmes: EUR 5 480 per person-month.

⚠ The unit cost that the beneficiary receives is however **EUR 1 935** and **EUR 2 740** respectively (because of the MSCA COFUND reimbursement rate).

ℹ For the latest information on the amounts, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence)*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** only the:

- management costs (B) — for direct costs of managing the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER sources (including other EU funding programmes).

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2017) 6855[102] and set out in Annex 2 and 2a of the GA.

This is currently:

- for management costs: EUR 650 per researcher per month (person-month).

The unit cost that the beneficiary receives is however **EUR 325** (because of the MSCA COFUND reimbursement rate).

For the latest information on the amount, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher costs.

1.3 The **eligibility** of the management costs is directly linked to (and conditional on) the eligibility of the costs for researchers.

Management costs are eligible only if ALL the eligibility conditions for the researchers are met. Person-months which are not eligible for budget category A 'costs for researchers' are also not eligible for budget category B 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

[102] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

– for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. implementing a doctoral or fellowship programme including recruiting researchers or hosting and training researchers during a secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do not apply.

Instead, MSCA-COFUND allows the beneficiary to use:

– partner organisations

to carry out work under the action (**third parties involved in the action**).

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to:

– implement a doctoral or fellowship programme (i.e. recruit the researchers)

– provide training and hosting of researchers during a secondment *(see Article 15)*.

⚠ **Secondments —** For MSCA-COFUND, secondments can be:

- (optional) additional periods of research training with a partner organisation, in order to further enrich the training experience of the researchers

and/or

- for fellowship programmes similar to MSCA-IF GF: (mandatory) outgoing phase with a partner organisation (from a third country).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during secondments.

Partner organisations can recruit the researchers (and MUST do so if it is the partner organisation that implements the doctoral or fellowship programme; *see Article 15.1.1(b)*).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations that implement a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *H2020 Work Programme*. Partner organisations hosting secondments can be established anywhere.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

15.1 Rules for providing financial support to or implementation of a *[doctoral][fellowship]* programme

15.1.1 The beneficiary must ensure that the ***[doctoral][fellowship]* programme** (implemented by itself or a partner organisation) complies with the following conditions:

(a) **types of programme**:

[OPTION 1 for DPs: *The programme must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programme**');**]***

[OPTION 2 for FPs: *The programme must concern fellowships for research training activities for recruited researchers ('**fellowship programme**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country[5], the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programme:

[OPTION 1 for DPs: *The doctoral programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately before the call deadline or recruitment — unless:*
  - *otherwise specified in Annex 1 for existing programme or*
  - *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[6];*
- *are nationals or long-term residents of an EU Member State or associated country[7], in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION 2 for FPs: *The fellowship programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*

- *show* **transnational mobility** *by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than [**OPTION A by default:** 12 months in the 3][**OPTION B for actions with activities similar to the MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel:** 3 years in the 5] years immediately before to the call deadline or recruitment — unless:*

  - *otherwise specified in Annex 1 for existing programmes or;*

  - *this time was part of a procedure for obtaining refugee status under the Geneva Convention[8];*

- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*

- *fulfil any additional conditions set out in Annex 1.]*

Researchers that are already permanently employed by the entity where the research training activities take place may not be supported.

(c) **procedure and criteria for selecting researchers** in the programme:

[OPTION 1 for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency and must indicate the minimum gross salary to be offered to the researches, as set out in Annex 1).**]***

[OPTION 2 for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

The selection committee(s) must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

There must be no more than 4 deadlines or cut-off dates per year.

*The calls must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.**]***

(d) **conditions for the recruitment** of researchers under the programme:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION 1 for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 709.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 354.50;**]***

- ***[OPTION 2** for **FPs:** for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 836;**]**.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 918.**]***

- researchers should not have to bear any costs for the implementation of the action as described in Annex 1.

15.1.2 In addition, the beneficiary must:

- for programmes implemented by itself:
  - take measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[9] and ensure that the researchers are aware or them;
  - ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;
  - ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);
  - ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;
  - ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
  - ensure that researchers work exclusively on the research training activities;
  - ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
  - ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
  - ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of results, promoting the action) — during the research training activities and afterwards;
  - inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — a follow-up questionnaire provided by the Agency;
  - ***[OPTIONS for DPs:** ensure a fair gender representation in the recruited researchers (by promoting genuine equal access opportunities between men and women throughout the recruitment process);*

- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

- for programmes implemented by a partner organisation:

  - ensure that the partner organisation complies with the obligations set out in this Article and

  - ensure that the partner organisation allows that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[5] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[6] 1951 Refugee Convention and the 1967 Protocol.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] 1951 Refugee Convention and the 1967 Protocol.

[9] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing a doctoral/fellowship programme

MSCA-COFUND can provide support both for a programme implemented by the beneficiary itself or for a programme of a partner organisation (which the beneficiary funds by providing financial support).

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisation that implements the doctoral/fellowship programme (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Types of programme — Categories of persons

The beneficiary/partner organisation must implement one of the following **types of** research training **programme** supporting transnational mobility:

- doctoral programme (DP), i.e. a programme with research training activities for recruited early-stage researchers that leads to the award of a doctoral degree

  The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programme (FP), i.e. a programme with fellowships for recruited experienced researchers.

The **researchers** must — at the date of the call deadline or recruitment —:

- be one of the following two:

  - **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time-equivalent research experience) of their research career) or

  - **experienced researchers** (i.e. have a doctoral degree OR have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than:

  - for fellowship programmes similar to MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel: 3 years in the 5 years immediately before the recruitment date or call deadline

  - for all other programmes (doctoral programmes and other fellowship programmes): 12 months in the 3 years immediately before the recruitment date or call deadline

  — unless Annex 1 of the GA specifies otherwise for an already existing programme or the beneficiary/partner organisation is an 'international European interest organisation'[103], for whom the mobility rule is limited to time spent *with* them.

  Exceptions in Annex 1 are only possible for existing programmes (NO exceptions for new programmes).

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[104] are NOT counted.

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

- if the programme is implemented by a partner organisation established in a **third country** (only third countries listed in General Annex A to the H2020 Work Programme) or if a secondment to a partner organisation in a non-associated third country constitutes the ***main* part** of the research training activities: be nationals or **long-term residents** of a EU Member State or H2020 associated country.

[103] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[104] 1951 Refugee Convention and the 1967 Protocol.

'Long-term resident' normally means a period of legal and continuous residence in EU Member States or H2020 associated countries for 5 or more consecutive years. Periods outside these countries will be taken into account if shorter than 6 consecutive months and all in all not more than 10 months.

For fellowship programmes similar to MSCA-IF EF Reintegration Panel: The long-term residence requirement will not apply to researchers who have obtained refugee status under the Geneva Convention[105] in a EU Member State or H2020 associated country.

NO other restrictions on researcher nationality or researcher origin or destination allowed.

3. Additional cost eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs[106])*.

Vacancies must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a **maximum** of **4** fixed deadlines or regular cut-off dates **per year**) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

The calls must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.

4. Additional cost eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits

[105] 1951 Refugee Convention and the 1967 Protocol.
[106] Available at http://ec.europa.eu/euraxess/.

- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, the beneficiary/partner organisation may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — The beneficiary/partner organisation must always recruit researchers directly. Recruitments via other means *(e.g. temporary* work *agency)* are NOT allowed.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum remuneration —** monthly **living allowance** (i.e. gross amount including salary, social security contributions, taxes and other costs included in the remuneration) and, if applicable, a single mobility allowance for the researcher to take up the doctoral or fellowship programme (to be funded through other sources) **—** of:

- for early-stage researchers (doctoral programmes): EUR 2 709
- for experienced researchers (fellowship programmes): EUR 3 836.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 354,50; for experienced researchers EUR 1 918).

Lower payments are considered as underpayment.

⚠ Since the MSCA-COFUND grant reimburses 50% of the researcher unit cost (i.e. EUR 1 935 and EUR 2 740 respectively), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 774** or **EUR 1096** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

The total cost of the doctoral/fellowship programme, in particular the amounts to be provided for the benefit of the researchers and for the hosting organisation, must be specified in Annex 1.

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral/fellowship programme — the average monthly allowance (over the duration of the programme) respects the above-mentioned minimum.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the

average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[107]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[108].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

Recruited researchers should not have to bear **any costs** for the implementation of the action as described in Annex 1.

For doctoral programmes: recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training and/or PhD programme *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* neither from their own funds, nor from the researcher unit cost.

For fellowship programmes: the recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training neither from their own funds, nor from the researcher unit cost.

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**, unless duly justified for reasons associated with personal or family reasons.

    This also means that a researcher can NOT benefit from two MSCA grants at the same time.

    Part-time employment can be accepted:
    - subject to prior approval by the Agency
    - on personal and family grounds only (i.e. NOT for professional reasons) and
    - if limited to a maximum of 50% of the time spent under the action.

    In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

    Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

    ⚠ While it is not possible to request part-time employment for **professional reasons**, the beneficiary may — in exceptional cases — request an interruption of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

[107] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html.
[108] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm.

  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities.

  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency

- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[109].

- for doctoral programmes: the beneficiary/partner organisation must:

  - ensure **gender balance** regarding the recruited researchers

  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career development plan.

[109] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas, documents relating to selection procedure)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the minimum remuneration was paid to the researchers.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents bear the full risk of cost rejection by the Agency.

Specific case (record-keeping):

Documents for a programme implemented by a partner organisation — For a programme implemented by a partner organisation, it is the beneficiary that must keep the documents also for the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must

- submit a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- organise a **'mid-term meeting'** with the Agency;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** of the start of the research training activities of the researcher.

It is important to give correct and complete information in the researcher declaration since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The beneficiary must organise a mid-term meeting with the Agency to present the implementation of the action in the light of the schedule in Annex 1.

Best practice: Please contact the Agency for the timing.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researchers in MSCA-COFUND, the MSCA-COFUND MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** (if any) give similar access.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,*

addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.6 H2020 MSCA-SNLS MGA: Annotations

ARTICLE 1 — SUBJECT OF THE GRANT AGREEMENT

ARTICLE 1 – SUBJECT OF THE AGREEMENT

[…] This grant is **linked** to another MSCA **grant** (number [insert number] — [insert acronym]).

1. Linked grant

MSCA-SNLS grants are always linked to another MSCA grant of the beneficiary (main grant – IF, ITN, RISE or Cofund).

The MSCA-SNLS provides support only to researchers or staff members with disabilities who are eligible under the linked MSCA GA.

Moreover, the MSCA-SNLS grant shares the fate of the main grant *(e.g. if the main grant is suspended or terminated, the MSCA-SNLS grant may also be suspended or terminated; see Articles 49.2 and 50.3)*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the acquisition of the special needs items or services described in Annex 1, which are needed to allow the concerned researcher or staff member to participate in the linked grant ('**action**').

2. Action: MSCA-SNLS

What? MSCA-SNLS grants fund additional costs that MSCA researchers and staff members with disabilities face due to the increased costs of their mobility during another MSCA action (main grant).

MSCA-SNLS is awarded for the acquisition of special needs items or services *(e.g. assistance by third persons, adaptation of work environment, additional travel/transportation costs)* to allow the recruited or seconded researcher/staff member to participate in the main MSCA action.

What not? Additional costs entailed by the recruited or seconded researcher/staff member but already covered by another source *(e.g. social security or health insurance)* cannot be funded under the MSCA-SNLS.

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The '**estimated lump sum breakdown**' for the action is set out in Annex 2.

It contains the lump sum shares, per work package (i.e. special needs items or services).

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiary. It shows the amounts that the Agency commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 cannot be adjusted by transfers of amounts between work packages (not even via an amendment; see Article 55).

1. Estimated lump sum breakdown

Since MSCA-SNLS grants do not use eligible costs, the MSCA-SNLS MGA does not have any budget categories. Instead, it has either a single lump sum or, if several special needs items or services are needed, a lump sum breakdown.

For technical reasons, each item or service must be considered a separate work package.

The breakdown is used to determine:

- the share of the lump sum to which the beneficiary is entitled for each work package.
- the maximum amount of grant reduction that can be applied for improper implementation of a work package.

Example: *Annex 2 sets out EUR 10 000 for work package 1 (WP1) – Special assistance services for the entire action duration (12 months). The Agency carries out a review on the grant and concludes that WP1 was not properly implemented because only part of the activities of that work package were actually carried out (i.e. assistance was provided for 11 months instead of 12 months). The Agency will reduce the grant in proportion to the improper implementation of WP1 up to a maximum of EUR 10 000 (the share of the lump sum allocated to that work package).*

2. Lump sum share transfers

Given that MSCA-SNLS is a mono-beneficiary action, there is NO redistribution between *beneficiaries*.

Transfers between *work packages* are NOT possible, because the lump sum shares have been fixed for each special needs item or service.

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)].

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The MSCA-SNLS MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum is set out in the H2020 Work Programme (section 3 MSCA).

The lump sum will be fixed taking into account the H2020 MSCA funding rates. This means that the lump sum fixed in Article 5 does not have to be multiplied again by the funding rate; it is already the net maximum EU funding.

The lump sum is one amount for the entire action. It will be limited to a maximum of EUR 60 000 per researcher/staff member and will be available as of 2019.

There are no cost eligibility conditions. If the action is correctly implemented, the beneficiary is entitled to receive the lump sum fixed in the GA.

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs and cannot be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary are added together.

The grant is reduced (see Article 43) for all other work packages (i.e. all work packages that have not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For MSCA-SNLS grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation); see Article 43), it will calculate the '**revised final grant amount**'.

This amount is calculated by the Agency by reducing the grant in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For MSCA-SNLS grants, the rules on the revised final grant amount are also in principle the same as for the General MGA (see *Article 5.4 H2020 General MGA*).

However, since there is no reporting of costs, the calculations are different (see *Article 21*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services ;
- call upon subcontractors to implement action tasks described in Annex 1;

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Third parties involved in the action

For MSCA-SNLS actions, NEITHER the rules from the General MGA NOR from the MSCA main grant for third party involvement apply.

There are NO special rules for purchases or subcontracting. The beneficiary may make purchases or subcontract tasks if this is needed for the special needs items or services.

For all types of third party involvement (purchases and/or subcontracts), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiary must — for a period of three years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

Records and other supporting documentation on the implementation of the action must be in line with the accepted standards in the respective filed.

The beneficiary does not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For MSCA-SNLS actions, the beneficiary does not need to keep full records on its actual costs; it only needs to keep appropriate and sufficient evidence (documentation, records) that the special needs items or services were provided to the researcher/staff member as described in Annex 1.

The records and supporting documentation must also prove that:

- the eligibility conditions for the researcher/staff member as per MSCA main grant were complied with
- the special need(s) of the researcher/staff member was certified by a competent national authority.

By contrast, timesheets or invoices are NOT needed. The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 3 years (because not above 60 000 EUR) after the balance is paid or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit — within 60 days following the end of the reporting period — a final report.

The **final report** must include the following:

(a) a '**final technical report**' containing:

(i) an **overview of the results**.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

(ii) a summary for publication by the Agency: not applicable;

(iii) the answers to the '**questionnaire**': not applicable;

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4) which includes the **request for payment of the balance**.

The financial statement must declare the lump sum shares indicated in Annex 2, for the **work packages** that were completed.

If agreed by the Agency, the beneficiary may exceptionally also declare work packages that were not completed.

Lump sum shares which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the work packages have been completed and that the action in general has been properly implemented (see Article 7);

- the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Reports

What & When? For MSCA-SNLS actions, the beneficiary must submit a **final periodic report** at the end of the action.

Each report is composed of a technical and a financial report, however, the financial report is not to declare costs but completed work packages and corresponding lump sum shares (one or more, depending on the number of special needs items or services which are covered by the grant).

In principle, lump sum shares should be claimed only for special needs items and services that were fully provided to the researcher/staff member concerned. However, if agreed by the Agency, the beneficiary may exceptionally declare partial lump sum shares for work packages that were not completed, for example, due to technical reasons or reasons related to the researcher/staff member.

Best practice: In case of doubt, the beneficiary should contact the Agency about partial work packages.

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that it did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the beneficiary to have enough time.*

- non-implementation linked to financial reasons

  Example: *The special needs service turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].*

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3) whichever is the latest.

*An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.**]***

[OPTION 2 if the JRC is the beneficiary: *The Agency will make a pre-financing payment of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)], within 30 days from the submission of a debit note from the JRC after the signature of the 'Arrangement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the Agency to the Guarantee Fund.**]***

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining lump sum shares for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Incomplete work packages, and work packages that have not been delivered or cannot be approved will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for the beneficiary, in the estimated lump sum breakdown (see Annex 2).

[…]

1. Payments to be made

MSCA-SNLS actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Agency on the basis of the financial statement, the final grant amount and the payments already made.

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares for the accepted work packages. Partial work packages can exceptionally be accepted (i.e. shares for work packages that were not

completed, for example due to technical reasons or reasons related to the researcher/staff member).

Examples:

1. *The beneficiary of an ongoing MSCA-SNLS GA cannot complete the pending work packages because the person providing assistance to the MSCA-RISE staff member with special mobility needs is no longer able to provide the service and the staff member in question does not want to replace his/her assistant. Therefore, the beneficiary requests termination of the MSCA-SNLS GA. The Agency decides to accept part of the lump sum shares for the uncompleted work packages that is proportionate to the tasks already carried out under the MSCA-SNLS action.*

2. *The participation of an early-stage researcher (ESR) with physical impairment has been terminated in the linked MSCA-ITN GA due to personal circumstances of the researcher (e.g. another professional opportunity). Given that the grounds for termination of the MSCA-SNLS are not linked to the beneficiary, the Agency decides to exceptionally accept partial work packages that were initiated but could not be fully completed. The Agency will however verify if the reported lump sum shares for the uncompleted work packages are proportionate to the tasks carried out.*

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that it did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the beneficiary to have enough time.*

- non-implementation linked to financial reasons

  Example: *The special needs service turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

Steps 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to MSCA-SNLS grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 4 (Grant reductions) applies.

All other steps follow the General MGA.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued relevance of the action.

[…]

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

[…]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since MSCA-SNLS grants do not use eligible costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since the beneficiary has no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the *technical* implementation of the action (in particular whether the special needs items and services have been provided to the researcher/staff member as described in Annex 1 of the GA).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiaries that were audited.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[12] applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for MSCA-SNLS grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial report has not been submitted or is not complete or additional information is needed, or

(c) there is doubt about the amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA (see *Article 47 H2020 General MGA*).

The MSCA-SNLS MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for MSCA-SNLS grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work package implementation).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiary

49.1.1 Conditions

The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) the beneficiary or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2);

(c) not applicable;

(d) the action implementation of the linked grant (see Article 2) is suspended.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiary may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA (see *Article 49 H2020 General MGA*).

For *full* GA suspension (action is entirely suspended), all on-going work packages (i.e. special needs items or services) must be interrupted and no new work packages may be started.

For *partial* GA suspensions (suspension of specific work package(s)),, other work packages may be continued and new work packages may be started.

2. GA suspension — Additional ground for suspension: Suspension of main grant (EU)

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, the Agency may suspend the MSCA-SNLS action if the main grant (to which the MSCA-SNLS grant is linked) is suspended.

> ***Example:*** *The beneficiary of an ongoing MSCA-IF grant has requested GA suspension for family grounds of the recruited researcher with visual impairment. The beneficiary has already fully adapted the main work environment but the adaptation of a small laboratory is still missing. The Agency will suspend the MSCA-SNLS GA until the MSCA-IF action will be resumed.*

ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

[…]

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no lump sum shares will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21) on the basis of the report submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiary's obligations (in particular Article 20, 22, 23, 36, 38, 40, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary’s legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

If the Agency does not receive the report within the deadline (see above), no lump sum shares will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21) on the basis of the report submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 43 and 44) continue to apply.

1. GA termination

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for MSCA-SNLS grants there is no reporting of costs, the calculations are different *(see Article 21)*.

2. GA termination — Additional ground for termination: Termination of main grant or researcher/staff member's participation in main grant (EU)

In addition to the normal grounds for GA termination *(see Article 50.3 H2020 General MGA)*, the Agency may terminate the MSCA-SNLS action if the main grant or the researcher/staff member's participation in the main grant (to which the MSCA-SNLS grant is linked) is terminated.

Example: *The beneficiary of MSCA-COFUND grant has committed substantial errors and irregularities and the Agency has decided to terminate the GA. The MSCA-COFUND GA is linked to MSCA-SNLS GA which foresees the construction of multiple ramps at the premises of the beneficiary to create an accessible work environment. The termination of the MSCA-COFUND GA serves as a ground for termination of the MSCA-SNLS GA by the Agency.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

The rules for amendments are the same as in the General MGA *(see Article 55 H2020 General MGA)*.

Given the parallelism of the MSCA-SNLS grants and the main grant, there may be a need to amend both in a synchronised manner.

> ***Example:*** *If the time spent by the researcher or staff member on the linked MSCA action is changed (e.g. for MSCA-IF from full-time to part-time), the duration of the MSCA-SNLS action may also have to be adapted accordingly.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

If the linked grant (see Article 1) is transferred to a new beneficiary, the beneficiary may also request the transfer of this action.

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher or staff member;
- a proposal for the necessary changes, including the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The lump sum will be split between the former beneficiary and the new beneficiary, on the basis of the part performed by the former beneficiary and the remaining part to be given by the new beneficiary. If the pre-financing received by the former beneficiary (see Article 21) exceeds the amount of the lump sum recalculated for the former beneficiary, the Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing received in excess.

Where necessary, the former and the new beneficiary must agree on arrangements concerning the transfer of any equipment, materials and/or services purchased and used for the researcher or staff member concerned. The former beneficiary may object only on the basis that the transfer is technically not possible or not possible under national law.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-SNLS grant can be **transferred** to a new beneficiary if the main grant (MSCA-IF, MSCA-ITN, MSCA-RISE or MSCA-COFUND) is transferred to it.

Transfer of the main grant agreement may cover:

- 'transfer' in the sense of Article 56a MSCA-IF MGA
- change of beneficiary due to 'partial takeover'
- addition of a new beneficiary to the main grant, which will host the researcher/staff member with special needs.

Transfer — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (*Article 50*) or addition of a new beneficiary (*Article 56*).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains fully responsible until the Agency has approved the amendment.

The transfer may NOT entail changes to the GA which would call into question the decision to award the MSCA-SNLS grant.

Example: *The transfer will not be accepted if the special needs item or service is eligible for funding by another source in the country of the new beneficiary (e.g. social security or health insurance system).*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new beneficiary (signed directly in the Participant Portal).

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress of the work and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to decide on how to split the lump sum and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must be also uploaded with the final report (by the new beneficiary, together with its own financial statement).

The lump sum will be split between the former beneficiary and the new beneficiary — on the basis of the part performed by the former beneficiary and the remaining part to be given to the new beneficiary. If the pre-financing received by the former beneficiary (see *Article 21*) exceeds the amount of the lump sum recalculated for the former beneficiary, the Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing received in excess.

The former and the new beneficiary must agree on arrangements, where necessary, concerning the transfer of the equipment, materials and/or services purchased for the researcher/staff member.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1 Lump Sum
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 SME Ph1 Lump Sum MGA deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 SME Ph2 MGA deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 SME Ph1 Lump Sum MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1 Lump Sum:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 SME Ph1 Lump Sum MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (‘**action**’), as described in Annex 1.

1. SME Instrument Ph1 Lump Sum actions

What? SME Instrument Ph1 Lump Sum funds:

- the feasibility study for an innovation idea (i.e. a ‘proof of concept’ or ‘business plan’ for new, altered or improved product, process or service).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: ‘technology readiness level’ of 6 or above*; see General Annex G to the H2020 Work Programme*).

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, ‘Innovation in SMEs’ (*e.g. H2020-SMEINST-01-2016-2017)*.

For more information on SME Instrument Ph1 actions*, see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph1 Lump Sum MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 Lump Sum MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph1 Lump Sum MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Decision C(2013) 8198[110].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

[110] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME Instrument Phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, for SME Ph1 Lump Sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to grant *reduction*). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the feasibility study (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Decision C(2013) 8198[111] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

[111] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

For SME Ph1 Lump Sum grants, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to grant *reduction*, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the SME Ph1 Lump Sum MGA.

The special rules from the General MGA on third party involvement are limited in SME Ph1 actions to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs of purchases and subcontracts are **ALL covered** by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) or international partners (Article 14a) are NOT allowed (since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are in principle the same as in the General MGA *(see Article 10 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[112] or 2009/81/EC and the national legislation implementing them.

Moreover, the obligations in Article 10.1 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[112] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the following **specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated subcontracting costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[113] or 2009/81/EC and the national legislation implementing them.

[113] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Finally, the obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations'*. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

Examples: *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Reports

What & When? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a **final periodic report**, containing a technical and a financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

Payment of the balance

How much? The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The Agency may disclose confidential information also to its staff, other EU institutions and bodies.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency and Commission responsibility — Agency and the Commission right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (consortium) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submiting the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submiting to the Agency in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(iii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iv) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the Agency will formally notify the beneficiary of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a **recovery**, the Agency will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for SME Ph1 Lump Sum grants the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*, improper implementation leads to the *ineligibility* of the costs (NOT grant *reduction*; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

Cost rejections will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide required information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for SME Ph1 Lump Sum grants 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*, the grant can be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the following **specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (‘**extension of findings from other grants to this grant**’; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (‘**extension of findings from other grants to this grant**’; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Beneficiary termination (consortium)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the following **specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. GA or beneficiary termination (EU)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the following **specificities**:

The request for amendment (which the coordinator must send 60 days after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 SME Ph2 MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (**'action'**), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through Phase 1 or another means.

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the H2020 Work Programme*).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, 'Innovation in SMEs' (*e.g. H2020-SMEINST-05-2016-2017)*.

For more information on SME Instrument Ph2 actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **if the beneficiary is a natural person** not receiving a salary (see Article 6.2, points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific costs category(ies)**: not applicable.

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the H2020 Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are by definition NO non-profit legal entities, they can NOT declare additional remuneration (under budget category A 'personnel costs'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

***[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules [...][11].]*

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

*"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement." **]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[12] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[24].**]***

***[OPTION 2 only for actions involving PCP:** Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*

- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).]*

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[11] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[12] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[13] See Articles 28 and 31(2)(a) of Directive 2004/18 replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the following **specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Participant Portal messaging function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage)

OR

- refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the simplified approval procedure: there is NO assessment (and the beneficiary therefore bears the **full risk**).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as in the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be shorter and more frequent than in other H2020 actions.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 ERA-NET Cofund MGA deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 ERA-NET Cofund MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***
	[OPTION if the JRC participates: *3b Administrative Arrangement****]***
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

ERA-NET Cofund uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities participating financially to the joint call for proposals MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8*).

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the H2020 Work Programme*).

  These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the H2020 Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of Horizon 2020 *(e.g. FETPROACT-02-2017; SC5-33-2017)*.

For more information on ERA-NET Cofund actions*, see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action**: [insert date]]*[7] ('starting date of the action').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). Normally, the duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs.

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**:

- for costs of internally invoiced goods and services: on the basis of an mount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment, to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

2. Reimbursement rate

How much? For ERA-NET Cofund, the reimbursement rate is currently set at **33 %** *(see General Annex D to the H2020 Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - **personnel** costs for implementing the trans-national projects (— unless declared as unit cost, *see below*)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects (— unless declared as unit cost, *see below*)
- **unit costs** for:
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices
  - **coordination costs** for additional activities[114]
- **flat-rate costs** for:
  - **indirect costs**.

[114] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects (‘**costs for employees (or equivalent)**’). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary’s usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.2.1.1,A.2.1.2 and A.2.1.3) : the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or

- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.2.1.1 and A.2.1.2) **calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION 1 by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

A.2.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:***:***

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Costs for trans-national projects (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as direct costs related to trans-national projects:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment

- other goods and services
- costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc.) or for additional coordination and networking activities of beneficiaries implementing trans-national project themselves. Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs must normally be **declared as** actual costs *(see Article 5.2(b))*.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

1.3 In principle, the same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the following **specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities

Direct coordination costs for additional activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Additional coordination costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the direct costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8200[115] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the **additional coordination activities** described in Annex 1.

Costs for additional coordination activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare any additional coordination costs.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the H2020 Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[115] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (C.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing to the joint call for proposals can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action).

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is ONLY allowed for beneficiaries/linked third parties that **implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be **trans-national projects**, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.2a);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients (third parties) that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Trans-national projects

The projects must be trans-national (i.e. they must involve at least two independent entities from two different EU Member States or H2020 associated countries), both in case of:

- financial support to third parties and
- implementation of the projects by the beneficiaries themselves.

3. Additional cost eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and

- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

4. Additional cost eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

5. Additional cost eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection (**joint selection list**) on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

6. Additional cost eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

7. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION 1 by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Information on each selected project — Information on each implemented project

What & When? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

> ***Example:*** *data on each participant and abstracts of the proposals*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

> ***Example:*** *data on each participant and an overview of the results*

How? The information must be uploaded directly in the Participant Portal

2. Deliverable: Information on cumulative expenditure incurred

What & When? The coordinator must submit to the Commission/Agency — on a yearly basis — information on the cumulative expenditure incurred by the consortium

How? In practice, this mandatory declaration for ERA-NET Cofund *(see Article 20.5)* is handled as deliverable and must be uploaded directly in the Participant Portal.

It does NOT need to be set out in Annex 1 (since legally speaking the obligation is not based on Article 19 but on Article 20.5).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.2a Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

(a) a ***periodic technical report*** *(see point (a) above) and*

(b) a ***statement on the use of the second pre-financing payment*** *(see Annex 8), including the* ***request for a third pre-financing payment****.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.3 Request for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4), from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

What & When? For ERA-NET Cofund actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- ranking list of the projects
- observer report on the evaluation

- joint selection list
- commitment on availability of funds (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8).

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 8*).

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

ERA-NET Cofund actions are normally divided into 2 reporting periods with 2 pre-financing payments (or exceptionally 3 reporting periods with 3 pre-financing payments, if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

The declaration is normally handled as deliverable *(see Article 19)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments to be made — No interim payments

ERA-NET Cofund actions normally are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because the Commission/Agency does not have sufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since ERA-NET Cofund pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- for the first pre-financing payment: between 10% and 30 % of the maximum grant amount
- for the second pre-financing payment: between 60 % and 80% of the maximum grant amount.

If the GA provides for a 3 pre-financing payments, then the amount is divided as follows:

- 30 % for the first pre-financing payment
- 30 % for the second pre-financing payment
- 30 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP/PPI MGA

VI.1 Background information and approach

The PCP/PPI Model Grant Agreement is used for PCP/PPI actions only.

The PCP/PPI MGA follows the General MGA for numbering and content, except for:

The H2020 PCP-PPI MGA deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI specific payment provisions)
- Article 23 (PCP-PPI specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of resources
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP/PPI actions are added:

- Article 2 (PCP/PPI actions)
- Article 4.1 (PCP/PPI budget categories)
- Article 8 (PCP/PPI rules on third party involvement).

VI.2 H2020 PCP/PPI MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties]*
	[OPTION if the JRC participates: *3b Administrative Arrangement]*
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

PCP/PPI uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities contributing financially to the PCP or PPI procurement budget MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8)*. They form the buyers group.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI actions

What? PCP/PPI funds:

- one single joint public procurement of research and development (R&D) services (PCP) or one joint or several coordinated public procurements for innovative solutions (PPI)

AND

- related additional coordination and networking activities.

For PCP actions, it must be only one PCP per GA; for PPI actions, it can be one joint or several coordinated PPIs per GA.

The additional activities must relate to the joint call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the H2020 Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP/PPI grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the H2020 Work Programme)*.

PCP/PPI actions are funded in all Parts of Horizon 2020 *(e.g. SEC-09-FCT-2017)*.

The possibility to have several coordinated PPIs was introduced with GA version 4.0 but is also open to older grant agreements.

For more information on PCP/PPI actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14 a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP/PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP/PPI MGA uses its **own budget categories**.

Budget categories of the PCP/PPI MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare PCP/PPI subcontracting costs. Who actually pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP/PPI MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **[…%]** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION 1 for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2a*[13] ***(unit costs).]***

[OPTION 2: specific cost category(ies): *not applicable.**]***

[…]

8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
13 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The PCP/PPI, normally uses the same reimbursement rates as the General MGA (**100%** for research and innovation actions (RIA) and **70% or 100%** for innovation actions (IA) actions; *see Article 5 H2020 General MGA*), unless the call provides exceptionally for another rate.

2. Cost forms

The PCP/PPI MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The PCP/PPI MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. PCP/PPI subcontracting costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP/PPI actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **PCP/PPI subcontracting** described in Annex 1
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[14]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[15] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed;

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agree otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories B.1.1, B.1.2, B.1.3 [and B.1.6]): the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of annual productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or option (iii) above, i.e.:

-fixed number of hours;

-standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for during each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories B.1.1, B.1.2, B.1.4, B.1.5 [*and B.1.6*]): the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities *[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities *[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[16]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[17] ***[OPTION 1 by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[18]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable****.]***

B.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]*[***OPTION 2***: *not applicable*]***]***.

Beneficiaries receiving an operating grant[19] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

B.5 ***[OPTION 1: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION *1a* ***for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *[**Insert name of specific cost category**[20]] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units, [and if [insert additional eligibility conditions, if any]].***]***

[*same for each specific cost category****]***

[OPTION 2: *Not applicable****]***

[…]

[14] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[15] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[16] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[17] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[18] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[19] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[20] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Additional coordination and networking costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as costs for additional coordination and networking activities related to the joint call for tender:

- direct personnel costs for additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for additional coordination and networking activities
- other direct costs for additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs must normally be **declared as** actual costs.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary MUST be declared as the unit cost fixed by Decision C(2013) 8197[116] and set out in Annex 2 and 2a of the GA.

This concerns only *beneficiaries* that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI MGA has however the following **specificities**:

[116] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the joint call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

1. *The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.*

2. *Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).*

3. *Costs for validation and testing of solutions provided by the subcontractors*.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the H2020 Work Programme, the costs of additional coordination and networking activities are eligible up to a maximum amount of 30% (for PCP)/50% (for PPI) of the total requested grant amount. For each GA, this ceiling is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP/PPI actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing financially to the joint procurement budget can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action). They form the buyers group.

Moreover, certain **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12)) are ONLY allowed for **additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, **subcontracting** (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities.

Linked third parties (Article 14) may participate in all activities under the action.

In addition, PCP/PPI actions often have **other interested third parties** (preferred partners), which are neither lead procurer nor part of the buyers group nor linked third parties nor third parties providing in-kind contributions, but which have a special interest in closely following the PCP and may therefore be mentioned in Annex 1 (e.g. entities involved in the related additional networking activities; other potential buyers for the solutions that have expressed a special interest in the PCP/PPI).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 ***[OPTION 1 for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[26];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[26] See Article 16(f) of Directive 2004/18/EC replaced by Article 14 of Directive 2014/24/EU, and Article 24(e) of Directive 2004/17/EC replaced by Article 32 of Directive 2014/25/EU..

1. PCP subcontracting

In PCP actions, the beneficiaries award PCP subcontracts for research and development services that are necessary to address a common challenge set out in Annex 1 (PCP R&D services). 'PCP

subcontract' thus means a contract for the purchase of R&D services (identified in Annex 1 as action task).

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries and linked third parties (buyers group), with a joint procurement in 3 phases

  The **buyers group** is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[117])

    Any entity that fits the definition of a contracting authority or contracting entity as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI actions.*

  – that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the H2020 Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the H2020 Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

[117] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is split in **3 phases** (solution design, prototyping, original development and testing of a limited set of 'first' products or services) which are implemented via 3 different specific contracts (under the overall PCP framework agreement).

The buyers group must select multiple competing subcontractors (with a minimum of 3 subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum 2 subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a **common challenge** (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an R&D services contract (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the H2020 Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done.*

This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[118]).

Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement (**common jointly-committed budget**)

This budget is based on the financial commitments of the beneficiaries and linked third parties in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

[118] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary (**lead procurer**)

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is NOT part of the buyers group).

  Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget).*

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[119].

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors (PCP implementation)

- **Subcontractors** are **paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP actions).

There can only be one PCP per PCP action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid — or whether

[119] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PCP subcontracting, there is NO simplified approval procedure (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 and phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must normally be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties

  - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

- the procurement must be preceded by an **open market consultation**

  This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[120].

  A prior information notice (PIN) must be published in the Official Journal of European Union (OJEU) and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

- the procurement must be based on **common procurement specifications** prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more guidance and templates for the tender documents, *see the PCP procurement documents [ODT format].*

5. Additional cost eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

[120] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the H2020 Work Programme)*
  - the obligation of the subcontractors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries (place of performance obligation)
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the H2020 Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions and without the right to sub-licence

    This right serves as a safeguard to ensure a competitive supply chain (during or after the PCP action) in case of problems. It does NOT mean that every subcontractor will always and automatically be obliged to grant non-exclusive licenses to third parties to exploit its results.

    Examples (licences needed): *other providers working for the buyers group need access to the IPR to work for the buyers group; a PCP subcontractor abuses its monopoly situation*

  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the H2020 Work Programme)*

    This right serves as a safeguard to ensure commercial exploitation in the public interest, in case the subcontractors fail to do so themselves. It will be for exceptional cases.
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2014/24/EU, 2014/25/EU[121] and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[122]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[123]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[121] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[122] *See Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.*

[123] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

[OPTION 2 for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint (or several coordinated) procurement procedure(s) by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and, 2004/17/EC (or 2014/25/EU).

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint (or coordinated) PPI procurement(s) ('**joint procurement agreement**');*

*(ii) **[OPTION 1 for PPI actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION 2:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION 1 for PPI actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) '**contract notice**'(s), which:*

- *are published by the lead procurer (or beneficiary) in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specify a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call(s) for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allow for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *are promoted and advertised widely;*
- *indicate how potential tenderers can obtain the tender documentation and the 'PPI request(s) for tenders';*

*and the **tender documentation** and **PPI request for tenders**.*

*(ii) **Step 2**: make one (or several) **evaluation(s) of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make one (or several) '**contract award notice**'(s), which are published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION 2 for PPI actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) **request(s) for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25//EU)[271] —:*

- *use technical specifications that are functional or performance based;*
- *avoid selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specify award criteria based on best value for money*

- *describe the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describe the arrangements for intellectual property rights*
- *describe the arrangements for liability for damages;*

(iv) ***Step 2:*** *make one (or several)* ***evaluation(s) of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24/EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[27] See Articles 28 and 31(2)(a) of Directive 2004/18/EU replaced by Article 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. PPI subcontracting

For PPI actions, beneficiaries award PPI subcontracts for procuring the innovative solutions that are necessary to address the common challenge set out in Annex 1 (PPI innovative solution(s)). 'PPI subcontract' thus means a contract for the purchase of innovative solutions (identified in Annex 1 as an action task).

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the following **specificities**:

The PPI procurement covers 2 phases (deployment and operational validation) — but there is no requirement to split the PPI procurement for those 2 phases in different contracts.

The beneficiaries may choose between implementing *one single* or *several coordinated* PPI procurements.

For joint procurements, there is one joint PPI call for tender launched by the lead procurer and one joint evaluation of offers.

For coordinated procurements, there are several separate PPI procurements carried out individually by the different procurers in the buyers group.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer (early adopter) of innovative solutions that are not yet available on a large-scale commercial basis.

PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.

Each PPI action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them together (i.e. the core functionality and performance characteristics must be the same; there may be additional local functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement (**common jointly-committed budget**) only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).

For joint procurements:

- the buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts
- if there is no mandate, the general rule is that:
  - framework agreement(s) must be signed by all members of the buyers group together
  - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI actions).

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PPI subcontracting, there is NO simplified approval procedure (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an **open market consultation** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[124].

[124] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).

A prior information notice (PIN) must be published in the Official Journal of the European Union and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

The PIN must contain information on:

- the expected launch date for the call for tender

  This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP action) is sufficient.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

For more guidance and templates for the tender documents, *see the PPI procurement documents [ODT format].*

4. Additional cost eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions *(e.g. regarding access to background, licensing etc.)* if these:
    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and

– price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2014/24/EU, 2014/25/EU[125] and 2009/81/EC normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2014/24/EU and 2014/25/EU[126]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[125] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[126] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[28]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24//EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
    - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
    - **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
    - ***[OPTION for PCP: an assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP)****]****;*
- ***[OPTION 1 by default (two pre-financing payments):*** *the coordinator must submit in month [**Y**] a progress report containing:*
    - *a '**periodic summary technical report**' for publication by the [Commission][Agency];*
    - *an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each subcontract financed by the procurement**, including data on each contractor that participated in the procurement, and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[**OPTION 1 for PCP:** at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[**OPTION 2 for PPI:** at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed — Assessment of the results

What & When? For PCP/PPI actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after the evaluation for each PCP phase) — submit to the Commission/Agency information on:

- the total number of bids received
- the evaluation of tenders and
- the winning tenderer(s) and abstracts of the winning tenders (using the following template [ODT])

The information must be complemented by the coordinator at the end of the action (and, for PCP actions, also at the end of each PCP phase) by submitting an assessment of the results and conclusions (using the following template [ODT]).

How? The information must be submitted via the Participant Portal Continuous Reporting Module.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[38]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[39]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.2a <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities[.][;]

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

(a) a ***periodic technical report*** *(see point (a) above) and*

(b) a ***statement on the use of the second pre-financing payment****, including the* ***request for a third pre-financing payment****.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).****]***

20.3 Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

[…]

[38] Month X should be the end of the preparation phase and submission of second pre-financing request.
[39] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

What & When? For PCP/PPI actions, the coordinator must submit a periodic report after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress

- summary for publication
- questionnaire (i.e. the structured information requested)
- call for tender documents (including contract notice, invitation to tender and procurement contracts)
- report on outcome of the preparation phase *(e.g. open market consultation)*
- commitment on availability of funds (Annex 7)

  This ensures that the PCP/PPI subcontracting costs are covered.
- statement on the use of the previous pre-financing instalment (Annex 8)

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 7*)

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

Normally, PCP/PPI actions are divided into 2 reporting periods (with 2 pre-financing payments; *see Article 21*). The first reporting period corresponds to the preparation of the joint procurement; the second reporting period corresponds to the implementation and follow-up of the joint procurement.

Actions will exceptionally be divided into 3 reporting periods (with 3 pre-financing payments), if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments to be made — No interim payments

Normally, PCP/PPI actions are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since PCP/PPI pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for PCP/PPI actions are as follows:

- for the first pre-financing payment: the percentage of the maximum grant amount foreseen for the additional networking and coordination activities related to the preparation of the call for tender
- for the second pre-financing payment: if needed, up to 100% of the remaining part of the grant (minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP/PPI actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 EJP Cofund MGA deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing payment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 EJP Cofund MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the H2020 Work Programme)*.

EJP Cofund actions are funded in all Parts of Horizon 2020 and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[7] (‘**starting date of the action**’).

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). The duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a].]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

For the FEJP action, there are moreover 3 additional specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Thus, the EJP Cofund MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION 2**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1 **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] *(**unit costs**).]***

[OPTION 2: specific cost category(ies)**: not applicable.]

[…]

[8] This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] To be used only if option in Point (f) is used.
[13] To be used only if option in Point (f) is used.

[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[127].

2. Cost forms

For EJP Cofund actions, the **cost forms** are in principle the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however 3 specific unit costs for category F 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [128]

[127] *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

[128] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[16]***]][OPTION 2: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[16] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, EJP grants have the following **specificities**:

- for category A 'personnel costs'

  Costs of students, PhDs and other researchers (under scholarship, internship or similar agreement) — Are eligible even if the agreement is training-oriented (or work-oriented but with a non-negligeable training component), the costs fulfil the eligibility conditions set out in Article 6 and Annex 1 explicitly includes the training activities.

- for category D.2 'equipment costs'

  There is a special cost category for the FEJP action: full purchase cost for JET equipment *(see below)*.

- for category F 'specific cost categories'

There are special cost categories for the FEJP action: specific cost categories *(see below)*.

The annotations below will be limited to these special cost categories for the FEJP action (and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated).

D. Other direct costs ***[(not covered by Point F)]***

[…]

D.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]: *The* ***costs of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018*: The* ***costs of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand)* ***to be included in the JET facilities*** *are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** under category D.2 'equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional** cost eligibility **conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. ***[OPTION 1: [Insert name of specific cost category(ies)]][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION 1a for specific unit costs (if unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[22]] *are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION 2: *not applicable]*

[…]

[22] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the Fusion programme EJP Cofund action (FEJP), there are however 3 additional specific cost categories set out in Decision C(2013) 8201[129] available:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Double funding risk — Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 Specific cost category – costs for mobility of personnel (F.2)

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (irrespective of their duration) to another research institution, in a location other than their normal place of employment, by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance.

[129] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party, but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. category A 'personnel costs' or D.3 'other goods and services'; *see Article 6.2.A, 6.2.D.3*).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[130] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the daily subsistence allowance: **EUR 127,65**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[131]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106,4	Italy	104,2
Bulgaria	58,4	*Italy Varese*	93,4
Croatia	80,0	Latvia	77,6
Cyprus	84,1	Lithuania	71,5
Czech Rep.	80,6	Malta	83,3
Denmark	135,3	Netherlands	105,3
Estonia	77,6	Poland	74,2
Finland	122,1	Portugal	83,5
France	117,7	Romania	68,8
Germany	95,8	Slovakia	79,7
Germany Bonn	94,1	Slovenia	85,3
Germany Karlsruhe	93,8	Spain	97,1
Germany Munich	106,4	Sweden	131,9
Greece	90,5	*Switzerland Geneva*	124,6
Hungary	78,3	*Switzerland Berne*	123,3
Ireland	110,6	United Kingdom	147,8
		UK Culham	112.5

[130] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

[131] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) are applied as from 1 January 2016:

Country/place	Coefficient	Country/place	Coefficient
Austria	105,9 %	Italy	99,4 %
Bulgaria	52,1 %	*Italy Varese*	92,2 %
Croatia	74,6 %	Latvia	74,2 %
Cyprus	77,3 %	Lithuania	69,0 %
Czech Rep.	73,4 %	Malta	84,5 %
Denmark	131,8 %	Netherlands	107,8 %
Estonia	78,0 %	Poland	71,8 %
Finland	119,7 %	Portugal	79,2 %
France	114,6 %	Romania	64,8 %
Germany	96,6 %	Slovakia	76,4 %
Germany Bonn	93,4 %	Slovenia	81,2 %
Germany Karlsruhe	93,8 %	Spain	90,2 %
Germany Munich	106,0 %	Sweden	127,9 %
Greece	79,9 %	*Switzerland*	142,4 %
Hungary	69,0 %		
Ireland	116,6 %	United Kingdom	166,9 %
		UK Culham	127,7 %

– for the monthly subsistence allowance: between **EUR 0 and 720,27**, per individual per month **—** depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82,05**
> 300	**145,86**
> 500	**237,05**
> 800	**382,92**
> 1 300	**601,73**
> 2 000	**720,27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 252,81**, per dependent child per month).

The European Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this case, the FEJP GA will be **amended** (and the Annotated MGA will be revised accordingly).

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. category D.1 'travel'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and
  - one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
    - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127,65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

– the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment

– to this amount, add the following for each leg of the journey (outward and return):

  – for train travel: a maximum of 30 minutes for each leg

  – for air travel: a maximum of 2 hours for each leg.

NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

- for the monthly subsistence allowance:

  amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

- for the family allowance:

  amount per unit (EUR 252,81) **x** number of actual months of secondment **x** number of dependent children

  The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

  '**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

  A full month can be one of the following two:

  - a **calendar month** *(e.g. 1 to 31 July inclusive)* or
  - a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

  If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127,65 = EUR 77 738,85*

*Monthly subsistence allowance: 20 months * EUR 382,92 (800< distance >1 300) = EUR 7 658,40*

Subtotal = EUR 85 697,25

** correction coefficient (2016) of 106.0 % (Germany Munich) = EUR 90 839,09*

*Family allowance: 20 months * EUR 252,81 = EUR 5 056,20*

Total declared unit costs: EUR 95 895,29

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127,65 = EUR 382,95*

** correction coefficient (2016) of 127,7 % (Culham, UK) = EUR 489,03*

Total declared unit costs: EUR 489,03

1.2 Specific cost category – costs for fellowships for researchers (F.2)

1.2.1 <u>What?</u> This budget category **covers** direct costs for FEJP researcher fellowships, by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility.

What not? This budget category does not cover direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; *see Article 6.2.E*).

1.2.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[132] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [133]:

Country	Coefficient	Country	Coefficient
Austria	104,8%	Italy	106,7%
Belgium	100,0%	Lithuania	73,1%
Bulgaria	71,5%	Luxembourg	100,0%
Cyprus	91,8%	Latvia	75,9%
Czech Republic	83,8%	Malta	89,6%
Germany	98,8%	Netherlands	104,3%
Denmark	135,3%	Poland	76,4%
Estonia	78,3%	Portugal	89,1%
Greece	92,7%	Romania	68,3%
Spain	97,6%	Sweden	111,7%
Finland	116,6%	Slovenia	86,1%
France	111,0%	Slovakia	82,6%
Croatia	97,5%	United Kingdom	120,3%
Hungary	76,2%	Switzerland	113,1%
Ireland	113,5%		

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

[132] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.
[133] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[134]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 Specific cost category – access costs for research infrastructure (F.2)

1.3.1 **<u>What?</u>** This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc

[134] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4 H2020 General MGA)*. FEJP beneficiaries that that have obtained a positive ex-ante assessment may opt between declaring costs under:

- category D.4 'capitalised and operating costs of large research infrastructure'

or

- category F.2 'access cost for research infrastructure'.

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, under category D.1 'travel'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be **declared as** the unit cost calculated in accordance with Decision C(2013) 8201[135] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{136})}{\text{average annual total quantity of access (over past two years}^{137})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 of the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded to keep the installation functioning normally

[135] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.
[136] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[137] In exceptional and duly justified cases, the Commission may agree to a different reference period.

— costs of consumables specifically used for the installation and the users' research work

— costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation

— costs of energy power and water supplied for the installation

— costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*

— costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services

— costs of specific scientific services included in the access provided or needed for the provision of access

— depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds

— renting or leasing the equipment, buildings and other assets that are part of the installation

Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.

– indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

– depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)

– travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

As already mentioned above, access costs for installations contributed in-kind must be declared as actual costs under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

What & When? For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission/Agency (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How? The annual work plan must be uploaded directly in the Participant Portal.

2. Deliverable: Summary progress report

What & When? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the explanation of the work carried out and the overview of the progress; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION 1 in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing payment****' (see Annex 8).****]***

[OPTION 2: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports for each reporting period (including the final one), with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **5** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing payment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a statement on the use of the first pre-financing payment *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a *[first]* **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a *[first]* pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to *[**OPTION 1 in case of a single pre-financing payment:** 5%][**OPTION 2 in case of two pre-financing payments:** 2,5%]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

***[OPTION in case of a second pre-financing payment:** The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 = net payment of EUR 3 250 000*

1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU budget credits)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

'**Framework partnerships**' are long-term co-operations that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)) and for PCP/PPI actions. Framework partnerships are currently not (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

4.0 As from GA 4.0 FPA/SGAs are also possible for PCP/PPI actions. This does NOT apply to older grant agreements.

⚠ The FPA/SGA therefore now covers both research and innovation actions or innovation actions *with* a PCP or PPI and PCP/PPI actions (separate type of action with PCP/PPI as *main* action task).

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

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Title of Article	FPA Article	SGA Article	MGA Article
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SUBJECT OF THE AGREEMENT	1	1	1
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DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP	3		
RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP	4		
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RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS	13	6	8
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PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING	33		27
EXPLOITATION OF RESULTS	34	18	28
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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement)
- Article 63.2 (FPA/SGA rules on dispute settlement).

For more guidance on framework partnerships, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name** (**short name**)**]**, established in [official address in full] ***[OPTION for partners with VAT**: VAT number [insert number],] [**OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding (see Article 14),]* represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] (**short name)**], established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number],]*

*[**OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not receiving EU funding (see Article 14),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties have agreed to enter into the framework partnership under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Participants: Coordinator — Partners — Linked third parties — Third parties involved in the action

In FPAs and SGAs the beneficiaries are called '**partners**' (because technically speaking they become beneficiaries only once an SGA is signed).

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. However, partners/linked third parties that do not want to actively participate in a specific action, may participate as **partners not carrying out action tasks** and will not have to comply with most of the obligations under that SGA *(see Preamble SGA).*

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed directly in Participant Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as **third parties involved in the partnership**.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions (**third parties involved in the specific actions**).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION 1 by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION 2 if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across partners of different framework partnerships]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and the Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions (**action plan**).

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all Parts of Horizon 2020.

4.0 Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2)* and PCP- PPI actions; Framework partnerships are currently NOT (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options were inserted in the FPA):

- **with competition (calls for proposals):**
  - **open to all partners** for which this type of activity is included in the FPA action plan

    Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

    Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

  - **open to all applicants** meeting the criteria

    Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **without competition**:
  - **invitations to submit a proposal**

    Such invitations can only be issued in one of the following cases:

    - in monopoly situations or where partners are designated in the basic act
    - if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
    - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals
  - **submission** of a proposal **by a certain date**

    This option can be included in the FPA only if it is provided for in the work programme/call.

    The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 Rules of Application Regulation No 1268/2012).

1. Framework partnership starting date

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA.

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Framework partnership duration

The framework partnership duration may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Programme)*.

The FPA duration can NOT be extended (i.e. it is not possible to request an amendment extending the duration). The duration of an FPA only determines the moment up to which SGAs can be signed. The SGAs can still be implemented after the end of the framework partnership.

All SGAs must be signed before the end of the FPA.

⚠ Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA has ended.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

***[OPTION 2:** Not applicable]*

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

⚠ If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — **specific consortium agreements for each SGA**. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the framework partnership implementation is suspended, all specific actions are also suspended (see Article 55) — from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to GA suspension *(see Article 49 H2020 General MGA)*.

FPA suspension automatically supends all on-going specific actions.

Amendments (to resume the action) after a suspension can NOT have the effect of extending the FPA duration set out in Article 3 FPA.). The duration of an FPA only determines the moment up to which SGAs can be signed An SGA can be implemented *after* the end of the framework partnership.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. FPA termination

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ FPA termination has NO effect on ongoing SGAs (— unless they are also terminated; *see Article 56 FPA and Article 20 SGA*). Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA is terminated.

2. Beneficiary termination

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ **Different partners at FPA and SGA level (exceptional)** — Beneficiary termination may lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners/linked third parties can participate as partners not carrying out action tasks for certain specific actions.

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also shows, if applicable, the estimated costs of the partners not receiving EU funding, if applicable (see Article 7 SGA) and of the international partners (see Article 12a SGA).

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and* ***forms of costs*** *of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions, applicable per budget category, are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **eligibility conditions** and **calculation rules**.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, eligibility conditions and calculation rules of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

Linked third parties must already be identified in the FPA *(see Article 19 FPA)*. Their specific activities must then be set out in the specific actions.

Examples:

1. *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

2. *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like the partner they are linked to.

Linked third parties can NOT however do more than their partners: If a linked third party wants to participate in a specific action, its partner must also be active in that action (i.e. NOT be partner not carrying out action tasks). If the partner does not want to, the linked third party could itself become a partner of the FPA and SGA (— after the consortium composition is changed).

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the Agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the Agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must first submit a request for the FPA amendment (which will automatically include the change in the consortium composition for the SGAs — the new beneficiary is added (automatically) as 'inactive' to all signed SGAs under that FPA).

The coordinator must then request for each SGA a separate amendment to activate the new beneficiary *(e.g. to change Annex 1, Annex 2)*.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

63.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Framework Partnership Agreement or a Specific Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU partners (except partners established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU partner(s) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for partners not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: As an exception, *for the following partners:*

- *[insert name of international organisation or partner not eligible for EU funding]*
- *[insert name of international organisation or partner not eligible for EU funding]*

[same for other partners that are international organisations or partner not eligible for EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Framework Partnership Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 50, 51 and 52), the partners must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must always be brought against the Commission (not against the Agency — even in Agency specific grants).

1. Dispute settlement

The rules on dispute settlement are similar to those of the General MGA *(see Article 57.2 H2020 General MGA)*.

However for FPAs, the Commission/Agency will determine already at FPA-level which partners must participate as 'beneficiaries not receiving EU funding' — because of a general issue with the jurisdiction clause (i.e. Belgian courts). Those beneficiaries can NEVER receive EU funding.

All other partners' status will be determined at SGA-level. Thus, partners from eligible countries (EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme) may participate as normal partners or as 'partners not receiving EU funding'. Partners from non-eligible countries may participate as 'partners not receiving EU funding' or — exceptionally — be granted funding.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name** (**short name**)],established in [official address in full], *[**OPTION for partners with VAT:** VAT number [insert number]], [**OPTION for coordinators not receiving EU funding:** as 'partner not receiving EU funding' (see Article 7),]* represented for the purposes of signing the Specific Agreement by [function, forename and surname],

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 FPA and Article 62 FPA):

2. [**full official name**] (**short name**)], established in[official address in full], *[**OPTION FOR partners with VAT:** VAT number [insert number]],*

***[OPTION for partners not carrying out action tasks under this SGA**: X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not carrying out action tasks',]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT :** VAT number [insert number]], as 'partner not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 5)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Additional information on the estimated budget

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[OPTION if the JRC participates: *Annex 5: Administrative Arrangement]*

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Partners — Partners not carrying out action tasks under the SGA — Linked third parties

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. An entity that is not partner/linked third party in the FPA cannot become party in the SGA. Conversely, all partners/linked third parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners (and linked third parties) who do NOT actively participate in a specific action are **partners not carrying out action tasks** under that Specific Agreement (and must be identified as such in the preamble to the SGA).

Partners not carrying out action tasks — They formally participate in the action as partners, but NOT with any action tasks or EU funding. In practice, most of the obligations therefore do not apply to them for that specific action.

Linked third parties — If a partner participates as not carrying out action tasks, its **linked third parties** get the same status. They can NOT actively participate in the specific action (— unless they themselves become partners of the FPA and SGA).

These partners are formally part of the consortium for the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will be identified in Annex 1 as 'partners not carrying action tasks' (as they do not carry out any action tasks). Moreover, they will also be mentioned in Annex 2 with zero costs.

Formally, the rights and obligations under the FPA and SGA fully apply to them. In practice however, many of them *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, financial or technical audits or reviews, IPR results, access to background and results of others, etc.)* are NOT applicable because these partners do not carry out action tasks and do not receive any EU funding. Other obligations remain relevant *(e.g. checks, information obligations, confidentiality)*.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed directly in the Participant Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including **linked third parties**) are considered as **third parties involved in the specific action**.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the specific action will be [insert number] months as of *[OPTION 1 by default: the first day of the month following the date the Specific Agreement enters into force (see Article 21)] [OPTION 2 if needed for the action: insert date]* ('starting date of the action').

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.Normally, the SGA starting date should also be after the entry into force of the FPA (because one presumes the other). However, in justified cases, it is possible to exceptionally fix an SGA starting date before the entry into force of the FPA (i.e. retroactive).

If the consortium requests a starting date before the entry into force of the FPA, it assumes the risks implied by starting the action before the FPA and SGA are signed (in particular not being reimbursed for the costs incurred, *e.g. if the proposal is not successful or that the FPA/SGA are not signed*).

⚠ The SGA action starting date can in any case **NEVER** be **before** the **submission** of the SGA proposal.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

Same partners at FPA and SGA level — If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump Sum MGAs

IX.1 Background information and approach

The General Lump Sum Model Grant Agreement (H2020 General Lump Sum MGA) is used mainly for coordination and support actions (CSA) and, exceptionally, for research and innovation actions (RIA) and innovation actions (IA) — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5*

The Lump Sum Pilot Model Grant Agreement (H2020 Lump Sum Pilot MGA) is used in a limited number of cases provided for in the work programme/call.

Example: *Specific call within the Nanotechnologies, Advance Materials, Biotechnology and Advance Manufacturing and Processing topic DT-NMBP-20-2018*

The General Lump Sum MGA follows the General MGA for numbering and content, except for:

The H2020 General Lump Sum MGA deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The MGA Lump Sum Pilot follows the General MGA for numbering and content, except for:

The H2020 Lump Sum Pilot MGA deviates from the General MGA as follows:

- Article 4 (estimated lump sum breakdown and transfers)
- Article 5 (grant amount and form of grant)
- Article 6 (not applicable)
- Article 8 (resources to implement the action)
- Articles 10, 11, 12 (not applicable)
- Article 13 (subcontracting)
- Article 15 (financial support to third parties)
- Article 18 (keeping records)

- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 22 (specific procedure for extension of audit findings)
- Article 42 (not applicable)
- Article 47 (specific provision for suspension of payment deadline)
- Article 49 (specific provision for suspension of the action)
- Article 50 (specific provisions for termination)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement

The main difference between the General Lump Sum MGA and the Lump Sum Pilot MGA lies in the grant implementation mechanisms: the General Lump Sum MGA works with eligible costs and pre-financing payments (instead of interim payments); the Lump Sum Pilot MGA works with lump sum shares per work package and beneficiary (instead of eligible costs) and interim payments based on accomplished work packages.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply *(Articles 6, 10, 11, 12, 42 Lump Sum Pilot MGA)* or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5 General Lump Sum MGA, Article 43.3 Lump Sum Pilot MGA, Annexes)* will not be shown.

For the Lump Sum Pilot MGA, the Articles where the only difference is the removal of references to eligibility of costs *(e.g. Article 14, 14a, 17.1, 22.5, 41.2 – removal of CFS —)* or rejection of costs *(e.g. Articles 14.2, 15.3, 16.3, 18.2, 22.6)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 Lump Sum MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. General Lump Sum actions

What? General Lump Sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for it.

> For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Participant Portal Online Manual and the H2020 grants fact sheets.*

CSA, RIA and IA Lump Sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of Horizon 2020 *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The General Lump Sum MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the General Lump Sum MGA:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA): 70%** of the action's eligible costs]*[8]*[**OPTION 3 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The General Lump Sum MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the EU reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The eligibility conditions are set out in *Article 6*. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For General Lump Sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For General Lump Sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, for General Lump Sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The General Lump Sum MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the action (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs' **covers** the (direct and indirect) costs for the action.

> ⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice, the declaration of costs for General Lump Sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

For General Lump Sum grants, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

⚠ If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the General Lump Sum MGA.

The special rules from the General MGA on third party involvement are limited in General Lump Sum actions to purchases (*Article 10*), subcontracting (*Article 13*), linked third parties (*Article 14*) and international partners (*Article 14a*).

By contrast, there are NO special rules for in-kind contributions (Articles 11 and 12). Beneficiaries may use any in-kind contributions from third parties if they are needed to carry out the work of the action.

⚠ For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[9] (or 2014/24/EU)[10] or 'contracting entities' within the meaning of Directive 2004/17/EC[11] (or 2014/25/EU)[12] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).
[10] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).
[11] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).
[12] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for General Lump Sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for General Lump Sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The General Lump Sum MGA has however the following **specificities**:

The estimated subcontracting costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[18]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For General Lump Sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the actions tasks (as described in Annex 1) were properly carried out.

The records and supporting documentation must:

- refer to the technical implementation of the action in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and

- prove that the tasks or parts of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs incurred are NOT needed.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.2a Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**statement on the use of the previous pre-financing instalment**', including the **request for a further pre-financing payment** (Annex 7).

20.3. Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2 :*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For General Lump Sum actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes the request for further pre-financing payments; *see Article 7*).

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

General Lump Sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- a *[first]* **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- *[same for more pre-financing payments]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2a if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

General Lump Sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing instead of an interim payment).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

> The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.
>
> The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:
>
> – if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
>
> – if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.
>
> ***Example:***
>
> *Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.*
> *90% limit of the maximum grant amount: EUR 360 000.*
> *3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.*
> *Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.*
> *2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;*
> *3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;*
> *Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
> *70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
> *Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000*
> *3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.*

Payment of the balance

How much? The amount of the payment of the balance depends on the overall financial situation at the end of the action, and in particular:

– the amount of pre-financing(s) already paid *(see Article 21 H2020 General MGA)*

– cost rejections (improper implementation of the action; *see Article 42)*

– grant reduction (other serious breaches or substantial errors, irregularities or fraud *see Article 43)*.

ARTICLE 41 — BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Agency][Commission]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for General Lump Sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs does not lead to a **recovery,** *[Commission][Agency]* will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for General Lump Sum grants the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*, improper implementation leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ 'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide requested information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for General Lump Sum grants 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*, the grant can be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

> ⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Agency or the]* Commission*]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION 2 :*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or*** **[OPTION 2:** *not applicable;*** **]**

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The General Lump Sum multi-beneficiary MGA has, however, the following **specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide requested information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Article 43 and Article 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA (see *Article 49 H2020 General MGA)*.

The General Lump Sum MGA has, however, the following **specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION 2:** not applicable]*;

(j) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION 2:** not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2).

*(n) **[OPTION 1**: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][**OPTION 2**: not applicable].*

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n)above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the [Commission][Agency]

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) ***[OPTION 1****: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks]****[OPTION 2****: not applicable].*

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or to beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The rules on GA termination are the same as in the General MGA *(see Article 50 H2020 General MGA)*.

2. Beneficiary termination (consortium)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the General Lump Sum multi-beneficiary MGA has the following **specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. GA or beneficiary termination (EU)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the General Lump Sum multi-beneficiary MGA has the following **specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IX.3 H2020 Lump Sum Pilot MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED ***[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]***

The grant is awarded for the **action** entitled [**insert title of the action**] — [**insert acronym**] ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation): *The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. Lump Sum Pilot actions

What? Lump Sum Pilot grants are used in a limited number of cases provided for in the work programme/call. They can be research and **innovation actions (RIA)**, **innovation actions (IA)** or **coordination and support actions (CSA)**.

Examples: *Specific call within the Nanotechnologies, Advance Materials, Biotechnology and Advance Manufacturing and Processing topic DT-NMBP-20-2018, some R&I activities in the rail sector (topics S2R-CFM-IPX-XX-2018 and CCA-01-2018).*

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The '**estimated lump sum breakdown**' for the action is set out in Annex 2.

It contains the lump sum shares, per work package and beneficiary *[and linked third party]*.

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiaries. It shows the amounts that the *[Commission][Agency]* commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 can be adjusted by transfers of amounts between beneficiaries and/or work packages, via an amendment (see Article 55).

Transfers between work packages are however possible only if:

- the work packages are not already completed (and declared in a financial statement);
- the transfers are justified by the technical and scientific implementation of the action and
- a review in accordance with Article 22.1.2 confirms that the amendment does not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

1. Estimated lump sum breakdown

Since Lump Sum Pilot grants do not use eligible costs, the Lump Sum Pilot MGA does not have any budget categories. Instead, it has a breakdown of the lump sum, per work package and beneficiary.

The breakdown is used to determine:

- the share of the lump sum to which each beneficiary is entitled for each work package

  Example: *Annex 2 sets out EUR 200 000 for work package 1 (WP1). The consortium completed WP1 in the first reporting period as described in Annex 1. Therefore, the consortium declares EUR 200 000 for WP1 in the periodic reports of period 1. If the Commission confirms that the WP1 was completed as described in Annex 1, it will include EUR 200 000 in the periodic payment.*

- the maximum amount of grant reduction that can be applied for improper implementation of a work package

  Example: *In the example above, the Commission carries out a review on the grant in the last reporting period. The review concludes that WP1 was not properly implemented because only part of the activities of that work package were actually carried out. The Commission will reduce the grant in proportion to the improper implementation of WP1 up to a maximum of EUR 200 000 (the share of the lump sum allocated to that work package).*

- the maximum amount for which each beneficiary is liable in case of improper implementation of a work package.

Example: *In the example above, the Commission carries out a technical audit on the grant after the payment of the balance. The audit concludes that WP2 (value also EUR 200 000) was not implemented as indicated in Annex 1. On those grounds, the Commission decides to reduce the grant. Beneficiaries A and B were together responsible for carrying out WP2 (according to Annex 2 beneficiary A for EUR 150 000 and beneficiary B for EUR 50 000). Therefore, each beneficiary will be liable for their proportion of the work package (e.g. in case of a 50% reduction, Beneficiary A for EUR 75 000 and Beneficiary B for EUR 25 000).*

2. Lump sum share transfers

Unlike in the General MGA, transfers of Lump Sum Pilot shares are only possible via a formal amendment.

The transfer may be:

- within the same work package (i.e. increasing the share of a beneficiary and decreasing the share of another)
- between work packages (i.e. increasing the share allocated to a work package and decreasing the share of another).

Transfers between work packages can only be accepted in exceptional circumstances, if duly justified and after a project review .

Transfers from or to a work package which the consortium has already declared as completed in a reporting period are NOT allowed.

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR** [**insert amount** (insert amount in words)].

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The Lump Sum Pilot MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant** (see *Decisions* C(2017)7149 and C(2017)7151).

The use of the lump sum will be set out in the work programme/call.

The lump sum will be fixed taking into account the H2020 funding rates. This means that the lump sum fixed in Article 5 does not have to be multiplied again by the funding rate; it is already the net maximum EU funding.

The lump sum is one amount for the entire consortium.

There are no cost eligibility conditions. If the action is correctly implemented, the beneficiaries are entitled to receive the lump sum fixed in the GA.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** for the action and it can NOT be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiaries *[and linked third parties]* are added together.

The grant is reduced (see Article 43) for all other work packages (i.e. all work packages that have not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For Lump Sum Pilot grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation; see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For Lump Sum Pilot grants, the rules on the revised final grant amount are in principle the same as for the General MGA *(see Article 5.4 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services;
- use in-kind contributions provided by third parties against payment;
- use in-kind contributions provided by third parties free of charge;
- call upon subcontractors to implement action tasks described in Annex 1;
- call upon linked third parties to implement action tasks described in Annex 1;
- call upon international partners to implement action tasks described in Annex 1

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources —Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the Lump Sum Pilot MGA.

The special rules from the General MGA on third party involvement are limited in Lump Sum Pilot actions to subcontracting (*Article 13*), linked third parties (*Article 14*) and international partners (*Article 14a*).

By contrast, there are NO special rules for purchases (*Article 10*) and in-kind contributions (*Articles 11* and *12*)— since they are not necessary for Lump Sum Pilot grants. Beneficiaries may make purchases and use any in-kind contributions from third parties, if they are needed to carry out the work of the action.

⚠ For all types of third party involvement (purchases, in-kind contributions, subcontracts, linked third parties and international partners), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Specific rules for subcontracting action tasks

Subcontracting may cover only a limited part of the action.

The tasks to be implemented for each subcontract must be set out in Annex 1. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

***[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for Lump Sum Pilot actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The Lump Sum Pilot MGA has however the following **specificities**:

The estimated subcontracting costs do NOT need to be included in Annex 1 or shown in the table of estimated costs in Annex 2 (there is no such table for the Lump Sum Pilot; Annex 2 is not the budget, but the estimated lump sum breakdown). By contrast, the tasks to be subcontracted must still be indicated in Annex 1 as it happens in the General MGA

The principles of best value for money and no conflict of interest are not explicitly mentioned in Article 13. Nonetheless, they must still be complied with and confirmed by the beneficiaries at proposal stage.

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.*

*The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION 2: *Not applicable**]***

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.*

*The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION 2: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable**]***

1. Financial support to third parties

The rules for financial support to third parties in Lump Sum Pilot actions are in principle the same as in the General MGA *(see Article 15 H2020 General MGA)*.

Thus, although the minimum conditions for granting financial support are not explicitly listed in Article 15 of the Lump Sum Pilot MGA, they must still be complied with (and confirmed by the beneficiaries at proposal stage).

Moreover, like under General MGA, the proposal must fix the criteria that the beneficiaries intend to apply for their cascading grants (i.e. no more than EUR 60 000 maximum amount per recipient, the criteria for determining the exact amount of support, the types of activities, the categories of recipients and the conditions for giving support) and this description will also become part of Annex 1 of the GA.

The obligations in Article 15.1 and 15.2 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *[**OPTION 1 by default:** five][**OPTION 2 for low value grants:** three]* years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

Records and other supporting documentation on the scientific and technical implementation of the action must be in line with the accepted standards in the respective field.

The beneficiaries do not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For Lump Sum Pilot actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep appropriate and sufficient evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

The records and supporting documentation must:

- refer to the technical implementation of the action, in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and

- prove that the tasks or part of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs actually incurred are NOT needed. The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

[…]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including work packages, milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must declare the lump sum shares indicated in Annex 2, for the **work packages** that were completed in the reporting period.

For the last reporting period, the beneficiaries may exceptionally also declare partial lump sum shares for work packages that were not completed (e.g. due to scientific or technical reasons), if agreed by the *[Commission][Agency]*.

Lump sum shares which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the work packages have been completed and that the action in general has been properly implemented (see Article 7);
- the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) an **explanation of the use of resources**: not applicable;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action.

(b) a '**final financial report**' containing a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the financial statements for all reporting periods and including the **request for payment of the balance**.

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

Financial statements must be drafted in euro.

[…]

1. Reports

What & When? For Lump Sum Pilot actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Each report is composed of a technical and a financial report (like in the General MGA). However, unlike in the General MGA, beneficiaries do not declare costs but their lump sum shares (as set out in Annex 2), for the work packages completed during that reporting period.

Work packages can be declared only once fully completed (as described in Annex 1). If a work package is carried out by several beneficiaries, they cannot declare it until all of them have completed it.

Example:

Grant for a consortium with a maximum grant amount of EUR 3 000 000 and the following breakdown per work package and beneficiary:

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Annex 1 of the grant agreement indicates that at the end of the first reporting period WP1, WP2 and WP3 should have been completed. WP4 and WP5 should have been initiated.

At the end of the first reporting period (RP1) the actual situation is as follows:

	WP1	WP2	WP3	WP4	WP5
Beneficiary A	Completed			Initiated	Initiated
Beneficiary B		Completed	Completed	Not initiated	
Beneficiary C	Completed	Initiated		Initiated	
Beneficiary D		Completed		Completed	

Since the beneficiaries can only declare completed work packages, they can only declare the amounts for WP1 and WP3. They cannot declare any amount for the WP2, WP4 or WP5, even if they are initiated, because they are not completed.

Partial work packages are allowed only in the following two situations:

- beneficiary termination — terminated beneficiaries may declare (in the termination report) shares for on-going work packages, provided that their part was completed in accordance with Annex 1 *(see Article 50)*.

- last reporting period — at the end of the action, beneficiaries may exceptionally also declare partial shares for work packages that were not completed, for example due to technical reasons.

Best practice: In case of doubt, the coordinator should contact the Commission/Agency about partial work packages.

⚠ The Commission/Agency will **NOT** accept partial lump sum shares in the last reporting period if:

- the situation could have been solved via an amendment

  Example: *The consortium argues that they did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the consortium to have enough time.*

- non-implementation is linked to financial reasons

  Example: *The project resulted to be more expensive than initially expected and the consortium decided to stop the work in some WPs.*

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

In practice, the following steps will apply for the financial part:

Step 1 — The coordinator will indicate in the Participant Portal which work packages have been fully accomplished during the reporting period.

Step 2 — The beneficiaries will have to sign individual financial statements to confirm proper implementation of those work package(s) and submit them to the coordinator. All of them will be part of the financial report for the reporting period concerned.

Step 3 — The coordinator will submit both the technical and the financial report to the Commission/Agency.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.3 Interim payments — Amount — Calculation

Interim payments pay the lump sum shares for work packages completed during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Work packages that have not been completed in time or cannot be approved at the time of an interim payment may be submitted (again) for the next reporting period (or any other future reporting period, after they have been completed).

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiaries *[and linked third parties]* for the concerned reporting period are added together.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining lump sum shares for the implementation of the action.

If the total amount of earlier payments is greater than the **final grant amount** (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Incomplete work packages and work packages that have not been delivered or cannot be approved at the payment of the balance will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for that beneficiary, in the estimated lump sum breakdown (see Annex 2).

[…]

1. Payments to be made

The rules on payments are in principle the same as in the General MGA (one pre-financing payment, interim payments at the end of each reporting period, and a final payment of the balance).

2. Payment calculations — Amounts due — Recoveries?

Interim payments

How much? The amount of the interim payments will be calculated by the Commission/Agency on the basis of the financial statements and the payments already made.

The rules follow those of the General MGA *(see Article 21.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up the lump sum shares for the accepted work packages for this reporting period (the lump sum shares in Annex 2 already take into account the reimbursement rate; no need to apply it again). Partial work packages will NOT be accepted; the entire work package (i.e. work of all beneficiaries) needs to be done.

Beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Commission/Agency on the basis of the termination report, the payments already made and the report on the distribution of payments.

The rules follow those of the General MGA *(see Articles 21.3, 44.1.1, 50.2.2 and 50.3.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs but simply sums up all the lump sum shares for the beneficiary's accepted work packages. Partial work packages can be accepted (i.e. shares for work packages where the beneficiary's part is completed).

Exceptionally, the Commission/Agency may accept also *part* of a lump sum share for a work package in which the beneficiary has not carried out all its tasks.

> ***Example:*** *The beneficiary requests terminating its participation in the action because a fire devastated its laboratory where most of the technical equipment and computers used for the action were located. Therefore, the beneficiary cannot complete its tasks in the on-going work packages due to force majeure (see Article 51). On those grounds, the Commission decides to accept for that beneficiary a part of the lump sum shares for the on-going work packages proportionate to the tasks carried out by the beneficiary in those work packages.*

Not completed work packages (or not completed parts of them) can be finished and declared later on.

Example for calculating the amount due at beneficiary termination:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

The participation of beneficiary B is terminated before the end of the first reporting period. At the time when the termination takes effect beneficiary B had fully completed its tasks for WP2 and WP3 and initiated its tasks for WP4. The coordinator had transferred EUR 650 000 as pre-financing to beneficiary B.

Amount due:

Lump sum shares for accepted work packages: WP2 + WP3 = EUR 600 000.

Beneficiary B amount due: EUR 600 000.

Beneficiary balance:

Payments received by beneficiary B (according to the report on the distribution of payments): EUR 650 000.

Beneficiary B balance: EUR 600 000 (amount due) - EUR 650 000 (payments received) = EUR -50 000 (excess payments of EUR 50 000).

Recovery:

Amount to be recovered from beneficiary B: EUR 50 000 (negative balance of EUR 50 000 must be returned to the consortium; otherwise Commission/Agency will start a recovery procedure).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Commission/Agency on the basis of the financial statements, the final grant amount, the payments already made and the report on the distribution of payments

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs but simply sums up all the lump sum shares for the accepted work packages. Partial work packages can exceptionally be accepted (i.e. shares for work packages that were not completed, for example due to technical reasons).

The Commission/Agency will **NOT** accept partial lump sum shares in the last reporting period if:

- the situation could have been solved via an amendment

  Example: *The consortium argues that they did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the consortium to have enough time.*

- non-implementation is linked to financial reasons

  Example: *The project resulted to be more expensive than initially expected and the consortium decided to stop the work in some WPs.*

Steps 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to Lump Sum Pilot grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Example for calculating the payment of the balance:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Case 1:

At the end of the action, WP7 was not completed as described in Annex 1. The Commission decides to reduce 50 % of WP7, corresponding to the proportion of the undelivered part of that work package. All other work packages were completed as described in Annex 1. In addition, the consortium breached an important confidentiality obligation under Article 36. The Commission decides to reduce the maximum grant amount by 10 % for that reason.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP2 + WP3 + WP4 + WP5 + WP6 + 50 % WP7 + WP8 = EUR 2 900 000.

Amount resulting from Step 1: EUR 2 900 000.

Grant reduction for other breaches: 10% grant reduction for the action = maximum grant amount – 10 % (reduction) = 3 000 000 – 300 000 = EUR 2 700 000.

Amount resulting from Step 2: EUR 2 700 000.

Lower amount of the two: EUR 2 700 000.

Final grant amount: = EUR 2 700 000.

Case 2:

The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable. The termination takes effect before the end of the first reporting period. At the moment of termination the state of play of each work package is as follows:

	WP1	WP2	WP3	WP4	WP5	WP6, WP7, WP8
Beneficiary A	**Completed**			Initiated	Initiated	Not initiated
Beneficiary B		**Completed**	**Completed**	Not initiated		Not initiated
Beneficiary C	**Completed**	Not initiated		Not initiated		Not initiated
Beneficiary D		**Completed**		**Completed**		Not initiated

In the reports, the consortium justifies that for WP2 the work of beneficiary B and beneficiary D were fully accomplished in accordance with Annex 1, that the work of beneficiary C in this work package was ancillary and that beneficiary C stopped in fact collaborating in the action. On those grounds, the Commission accepts exceptionally 370 000 EUR for WP2.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP2 (part) + WP3 = 350 000 + 370 000 + 350 000 = EUR 1 070 000

No grant reductions for other breaches.

Final grant amount: EUR 1 070 000.

Case 3:

Work package 2 was not carried out (i.e. representing a total lump sum share of EUR 470 000) and therefore the Commission reduced the grant accordingly.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP3 + WP4 + WP5 + WP6 + WP7 + WP8 = EUR 2 530 000.

No grant reductions for other breaches.

Final grant amount: EUR 2 530 000 (➔ beneficiary shares: A = EUR 1 150 000; B = EUR 650 000; C = EUR 430 000; D = EUR 300 000).

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 530 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR -170 000 (excess payments of EUR 170 000).

Offsetting against Guarantee Fund release: EUR 170 000 - EUR 150 000 = EUR 20 000

Recovery:

Amount to be recovered from the consortium: EUR 20 000 (negative balance of EUR 20 000 must be paid back by coordinator, otherwise Commission will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from coordinator:

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 977 500; B= EUR 765 000; C = EUR 450 500; D= EUR 357 000).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

> *A: {(EUR 1 150 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 1 150 000 (share in the final grant)} - EUR 977 500 (payments received) = EUR 172 500 (no payment in excess)*
>
> *B: {(EUR 650 000 / (1 150 000 + 650 000 + 430 000 +300 000)) * 2 530 000 = EUR 650 000 (share in the final grant)} - EUR 765 000 (payments received) = EUR -115 000 (excess payment of EUR 115 000)*

*C: {(430 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 430 000 (share in the final grant)} - EUR 450 500 (payments received) = EUR -20 500 (excess payment of 20 500)*

*D: {(300 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 300 000 (share in the final grant)} - EUR 357 000 (payments received) = EUR -57 000 (excess payment of EUR 57 000).*

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 192 500.

B: 115 000/192 500 = 59.74 %.

C: 20 500 /192 500 = 10.65 %.

D: 57 000/192 500 = 29.61 %.

Total to be recovered: EUR 20 000.

B: 59.74 % x 20 000 = EUR 11 948

C: 10.65 % x 20 000 = EUR 2 130

D: 29.61 % x 20 000 = EUR 5 922

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Commission/Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 2 (Grant reductions) applies.

All other steps follow the General MGA.

Example for calculating recoveries after payment of the balance:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Case 1:

Final grant amount:

Final grant amount: EUR 1 150 000 + EUR 900 000 + EUR 530 000 + EUR 420 000 = EUR 3 000 000.
The Commission carries out a technical audit on the action and finds out that beneficiary B did not carry out its activities under the work package 4 (lump sum share EUR 50 000). The Commission therefore reduces the grant by EUR 50 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 900 000 (accepted lump sum shares) — EUR 50 000 (rejected lump sum shares) = EUR 850 000
Beneficiary B revised final grant amount: EUR 850 000.
The other beneficiaries final grant amounts (i.e. their final grant amount shares) remain unchanged.

Beneficiary balance:
The share of beneficiary B in the final grant amount = EUR 900 000 / 3 000 000 x 3 000 000 = EUR 900 000.
Balance: EUR 850 000 (revised final grant amount) – EUR 900 000 (final grant share) = EUR -50 000 (excess of EUR 50 000).
Recovery:
Amount to be recovered from beneficiary B: EUR 50 000 (negative balance of EUR 50 000 must be paid back by the beneficiary).

Case 2:

Same example as above, but in this case a reduction of the maximum grant amount had been performed at the time of the payment of the balance as follows: the consortium breached a confidentiality obligation under Article 36 and the Commission reduced the maximum grant amount by 10 % for that reason (i.e. EUR 3 000 000 – 10 % = EUR 2 700 000).

Final grant amount:

Final grant amount: = EUR 2 700 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 900 000 (accepted lump sum shares) — EUR 50 000 (rejected lump sum shares) = EUR 850 000.

Beneficiary B revised final grant amount: EUR 850 000.

Beneficiary balance:

The share of beneficiary B in the final grant amount = EUR 900 000 / EUR 3 000 000 x EUR 2 700 000 = EUR 810 000.

Balance: EUR 850 000 (revised final grant amount) – EUR 810 000 (final grant share) = EUR 40 000 (no excess).

Recovery:
No recovery.

Case 3:

Final grant amount:

Final grant amount: EUR 1 150 000 + EUR 900 000 + EUR 530 000 + EUR 420 000 = EUR 3 000 000.

The Commission carries out a technical audit on the action and finds out that work package 8 (EUR 600 000) has not been implemented as described in Annex 1 and decides to reject it.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for the consortium & revised final grant amount:

Beneficiary A: 1 150 000 – 300 000 = EUR 850 000.

Beneficiary B: 900 000 – 150 000= EUR 750 000.

Beneficiary D: 420 000 - 150 000= EUR 270 000.

The EU contributions of beneficiary C remain unchanged.

Beneficiary balance:

The share of beneficiary A in the final grant amount = EUR 1 150 000.

The share of beneficiary B in the final grant amount = EUR 900 000.

The share of beneficiary D in the final grant amount = EUR 420 000.

Balance:

A: EUR 850 000 (revised final grant amount) - EUR 1 150 000 (final grant share) = EUR -300 000.

B: EUR 750 000 (revised final grant amount) - EUR 900 000 (final grant share) = EUR -150 000.

D: EUR 270 000 (revised final grant amount) - EUR 420 000 (final grant share) = EUR -150 000.

Recovery:

Amount to be recovered from beneficiary A: EUR 300 000 (negative balance of EUR 300 000 must be paid back by the beneficiary).

Amount to be recovered from beneficiary B: EUR 150 000 (negative balance of EUR 150 000 must be paid back by the beneficiary).

Amount to be recovered from beneficiary D: EUR 150 000 (negative balance of EUR 150 000 must be paid back by the beneficiary).

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

[…]

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

[…]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since Lump Sum Pilot grants do not use eligible costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since beneficiaries have no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the *technical* implementation of the action (in particular full accomplishment of the work packages as described in Annex 1 of the GA), or on other aspects of the grant agreement, *such as ethics and research integrity, dissemination and exploitation of results, management of intellectual property, etc*.

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiaries that were audited.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — **after termination of a beneficiary's participation, at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for lump sum shares declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum grant amount indicated, for the linked third party, in the estimated lump sum breakdown (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[34] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments, the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's approved lump sum shares

[plus

its linked third parties' approved lump sum shares]},

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for approved work packages calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

[…]

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{beneficiary's approved lump sum shares

[plus

its linked third parties' approved lump sum shares]}

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for approved work packages calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

[...]

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial report has not been submitted or is not complete or additional information is needed, or

(c) there is doubt about amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will take effect the day notification is sent by the [Commission][Agency] (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be lifted — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the [Commission][Agency] if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the [Commission][Agency] may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA *(see Article 47 H2020 General MGA)*.

The Lump Sum Pilot MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for Lump Sum Pilot grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work package implementation).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the [*Commission*][*Agency*] the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiaries may not claim damages due to suspension by the *[Commission] [Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission][Agency]*'s right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA *(see Article 49 H2020 General MGA)*.

For *full* GA suspension (action is entirely suspended), all on-going work packages must be interrupted and NO new work packages may be started.

For *partial* GA suspensions other work packages may be continued and new work packages may be started(except for those covered by the suspension).

However, partial suspensions may have an indirect effect on other work packages, in the sense that it might not be possible to fully complete them (and thus not be possible to declare them for the reporting period — unless it is already the end of the action; *see Articles 20 and 21*).

Example: *A fire caused some damage to an equipment of a beneficiary which is used for a set of chemical 3D-analyses (large part of WP2) which are then needed for further experiments in WP4 and WP5. The consortium*

therefore requests that the part of the action that is affected (WP3) is suspended until the equipment is restored. The other beneficiaries may continue to work on the other work packages (WP4 and WP5). However, if these work packages cannot be fully completed at the end of the reporting period because the WP3 continues to be suspended, the lump sum shares for WP4 and WP5 cannot be declared by the beneficiaries.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

[…]

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), only lump sum shares included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21.4), on the basis of the reports submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

[…]

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages

The grant amount for the beneficiary is calculated by adding the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary *[and its linked third parties]* in the termination report.

Only lump sum shares for work packages fully completed by the beneficiary before termination will be approved — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the *[Commission][Agency]*

[…]

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), only lump sum shares included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4), on the basis of the reports submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated lump sum breakdown (see Annexes 1and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work

The grant amount for the beneficiary is calculated by adding the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary *[and its linked third parties]* in the termination report.

Only lump sum shares for work packages fully completed by the beneficiary before termination will be approved — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

1. GA termination (consortium or EU)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21*).

2. Beneficiary termination (consortium or EU)

The rules on beneficiary termination are in principle the same as in the General MGA (see *Article 50* H2020 General MGA).

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

H2020 Programme

AGA – Annotated Model Grant Agreement

Version 5.1
6 December 2018

Disclaimer
This guide is aimed at assisting beneficiaries. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the Commission nor the its executive Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	20.12.2013	▪ Initial version following adoption of the grant agreement v.1.0. Article 6.
1.2	17.02.2014	▪ Articles 7 to 14, 17 to 19, 23a to 25, 35, 52 to 54, 56 and 58 added
1.3	26.03.2014	▪ Articles 16, 32 to 34 and 41 to 44 added
1.4	16.04.2014	▪ Articles 4 to 6, 9 to 16, 20, 21, 23, 24, 39, 40, 45 to 52 and 57 added or revised
1.5	25.04.2014	▪ Articles 22, 26 to 31, 36 to 38, and 55 added
1.6	02.05.2014	▪ New annotations for: ERC, SME Instrument, ERA-NET COFUND, PCP-PPI COFUND, EJP COFUND, Framework Partnership and Specific Agreements
1.6.1	16.06.2014	▪ Clickable table of contents added
1.6.2	17.07.2014	▪ Links to time-sheet model and declaration model for personnel costs
1.6.3	20.08.2014	▪ Changed link to H2020 Work Programme (section 3 MSCA) (page 55)
1.7	19.12.2014	▪ Updates due to the amendment of the model grant agreement v.2.0, in particular Articles 3, 9, 20.6 and 38.1.2 ▪ New annotations on Articles 6.2.A, 6.2.E, 6.2.F, 22.4, 22.5 ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 6.1, 6.2.D.2, 6.2.D.3, 6.3, 6.4, 6.5, 10, 13, 14, 18, 20.4, 34, 39, 41.5, 43, 49.1, 50.3, 55 and 57; ▪ Updates in the derived model grant agreements: - ERC: Articles 2, 4, 6.2, 8, 32, 56.1 and 56.a - SME: Articles 2, 5.4, 8, 21, 41, 42, 43, 44, 50 Ph1 and Article 2, 4 and 6 Ph2 - ERA-NET Co-fund: Article 4, 6.2.B and 13 (option for PCP) - EJP Co-fund: Article 4, 6.2 ▪ New Annotations for the MSCA ▪ Other minor corrections and clarifications ▪ Improved clickable table of contents including Articles
2.0	30.03.2015	▪ Reformatting into the style of the Online AGA. Streamlined approach to information with exclamation mark, and info sign; presentation in yellow and blue text boxes. ▪ Clickable cross-references (Articles) ▪ New table explaining the treatment of the different types of work contracts (under Article 6.2.A). ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 2, 3, 6.2.A, 6.2.D, 6.2.E, 6.2.F, 13, 18.2, 21, 27, 28.3, 29, 30, 38, 41, 47 and substantial updates in Article 55. ▪ Updates in the derived model grant agreements: – ERC: ERC GA preamble, Article 56a – MSCA: ITN Articles 6.2, 19.2, 32; IF Articles 6.2, 8, 32; RISE Articles 6.2, 19; Co-fund Articles 6.2, 15, 19 – FPA: Article 13; SGA: Article 17 ▪ Other minor corrections and clarifications
2.0.1	18.05.2015	▪ Corrigendum of annotations on Article 4 of the MSCA-ITN and the MSCA-RISE grants

2.1	30.10.2015	▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 5.2, 6.1, 6.2.A, 6.2.D, 6.5, 9, 11, 12, 13, 14, 20, 21, 22.2, 24, 26, 29, 30, 31, 34, 40, 43, 47, 50, 55 and 56. ▪ New Section I.3 'List of issues applicable to particular countries' added — explanations on eligibility of national taxes, bonuses ▪ New annotations and updates in the derived model grant agreements: – ERC MGA: Preamble, Articles 6, 8, 18, 29 and 56a – MSCA: ITN Articles 4, 6.2, 8, 31; 32, IF Articles 4, 6.1, 6.2, 8, 31, 32; 56a RISE Articles 4, 6.2, 8, 18; 31 Co-fund Articles 4, 6.2, 8, 15 – SME Instrument Ph1 Lump Sum: Article 5; – SME Instrument Ph2: Article 13; – ERA-NET Co-fund: Articles 5.2, 6.2.A and 20; – FPA: Article 5; – MGA Lump sum: new annotations. ▪ Other minor corrections and clarifications.
2.1.1	01.07.2016	▪ Update of the explanations on Article 18 regarding time records; including a model of time-sheet with the minimum requirements.
2.2	25.11.2016	▪ Updates due to the amendment of the model grant agreement v.3.0, in particular Articles 4.2, 5, 6.2.A, 10, 13, 16, 20, 34, 37, 41, 42, 43, 45, 46, 48, 49, 50 and 55 ▪ New annotations on Articles 29.2 and 29.3. ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6, 6.1, 6.2, 6.5 and 18. ▪ Updates in the annotations to specific model grant agreements: - ERC: Preamble, Articles 6, 29 and 56a - MSCA: Preamble ITN, Articles 4, 5, 6, 8, 18, 19 and 32; IF Articles 2, 4, 6, 8, 18, 32 and 56a; RISE Articles 4, 6, 8, 18, 19, 31 and 32; COFUND Articles 4, 6, 8, 15 and 18. - ERA-NET Co-fund: Articles 2, 19 and 21 - PCP-PPI: Articles 5 and 13 - EJP Co-fund: Articles 5, 6.F and 20 ▪ Synchronised presentation for grounds for Chapter 6 measures, security obligations and information obligations. ▪ Other minor corrections and clarifications ▪ Update in Section I.3 'List of issues applicable to particular countries' New rules that apply in principle only for grant agreements signed with version 3.0 are marked with 3.0 » (This version refers to MGA v3.0 to align it no AGA v3.0 was created)
4.0	21.04.2017	▪ Updates due to the amendment of the model grant agreement v.4.0, in particular Articles 5, 6 and 52 ▪ New annotations on Article 14a following the introduction of this Article in the revised model grant agreements v.4.0 ▪ New explanations and examples resulting from frequently asked questions, in particular in Article 6 and 18. ▪ Updates in the annotations to specific model grant agreements: ERC, MSCA, PCP-PPI and FPA/SGA ▪ Other minor corrections and clarifications New rules that apply in principle only for grant agreements signed with version 4.0 are marked with 4.0 »
4.0.1	20.06.2017	▪ Addition of index at the bottom of the pages
4.1	26.10.2017	▪ New explanations and examples, in particular in Articles, 6.2.F, 18,

		50 and 55 of the general MGA ▪ Corrigendum of annotations on Article 6 of the MSCA-ITN, IF, Cofund and the MSCA-RISE grants ▪ Corrigendum of annotation on Article 6.2.F of the EJP Cofund grant ▪ Update in Section I.3 'List of issues applicable to particular countries' ▪ Other minor corrections and clarifications
5.0	03.07.2018	▪ Updates due to the amendment of the model grant agreement v.5.0, in particular Articles 29.3 and 34 ▪ New presentation of calculations for payments and recoveries, now compiled under Article 21 ▪ Updates due to the adoption of the Guide on grant reductions ▪ New explanations and examples resulting from frequently asked questions, in particular in Articles 6.2.A, 6.2.D, 11, 14a, 43, 44, 48, 49, 50.3, 51, 55 and 57.2. ▪ Annotations on the new Lump Sum Pilot model grant agreement ▪ Annotations on the new MSCA Special Needs model grant agreement ▪ New annotations and updates in the specific model grant agreements: – ERC: Articles 18, 29 and 32 – MSCA: ITN Articles 6.2.a, 6.2.B, 32; IF Articles 6.2.A, 6.2.B, 18, 32, 55.1, 56a; RISE Articles 6.2.A, 32 and Co-fund Articles 6.2.A and 15 – SME Phase 1: Article 8 – PCP/PPI: Article 8 – SGA: Article 3 – General lump sum: preamble, Articles 8 and 18 ▪ Other minor corrections and clarifications
5.1	06.12.2018	▪ Updates in the annotations of Articles 6.1, 8, 20, 22.1.3, 41.4 and 55 ▪ Annotations on the new ERC Lump Sum Pilot PoC model grant agreement ▪ New annotations and updates in the specific model grant agreements: - ERC: Article 56a - MSCA: IF Articles 38, 49.1.1 and 56a, ITN Article 8, RISE Article 8 - Lump sum pilot: Article 4 For easy identification, paragraphs, indents or sections with new explanations are marked with the symbol ■ on the left

IMPORTANT NOTICE

The **AGA — Annotated Model Grant Agreement** is a **user guide** that aims to explain to **applicants** and **beneficiaries** the General Model Grant Agreement (General MGA) and the different specific Model Grant Agreements ('Specific MGAs') for the Horizon 2020 Framework Programme for 2014-2020 (H2020).

The purpose of this document is to help users understand and interpret the GAs, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the GAs.

In the same spirit, the document's structure mirrors that of the GAs. It explains each GA Article and includes examples where appropriate.

Since the Specific MGAs have a similar set-up and provisions as the General MGA (i.e. they are all derived from the General MGA), the annotations will focus mainly on the General MGA (and the annotations of the other MGAs will be limited to major differences from that MGA). The key provisions on the amount, cost forms and eligibility conditions of your grant are however explained for all MGAs *(see Articles 4-6 of each MGA)*.

The annotations are — with some exceptions — done on the multi-beneficiary versions. The multi- and mono-beneficiary versions are largely identical.

Our approach

1. The **text** of the **article** appears in a grey text box — to differentiate it from the annotations.

   The **concepts** that are annotated are in bold and underlined.

   The annotations to the article are immediately underneath.

   Long articles are split into different parts, so the annotations can be placed below the relevant parts.

   Examples, **best practices** are in bold and green.

   Lists and **procedures** are in bold and red.

   Specific cases and **exceptions** are in bold and orange.

   New explanations (compared to the last update) will be marked with: ■

   New rules that do not apply to all signed grant agreements (but instead only to those signed after a certain version, e.g. version 3.0), will be marked with: 3.0 and 3.0

2. As the AGA intends to be comprehensive, it will cover all possible **options** envisaged in the different GA articles.

   Many of these options may not be relevant to your grant (and will not appear in the grant agreement you sign, or will be marked 'not applicable').

   The chosen options will appear in italics (without brackets and without the option title), to allow you to easily spot that a specific rule applies.

Updates

With version 2.0, the AGA was reformatted into a clickable online version.

It will be periodically updated with new examples and explanations, based on practical experience and on-going developments.

Other information

The AGA is limited to annotations to the provisions of the H2020 MGAs. For a more general overview of how H2020 grants work, *see the Participant Portal Online Manual*.

A comprehensive list of all H2020 reference documents (including legislation, work programme and templates) can be found on Participant Portal Reference Documents.

H2020 terms are explained in the Glossary.

If necessary, you can also contact the Research Enquiry Service.

Legislation

H2020 Framework Programme — Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) — Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme — Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) — Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) — Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

⚠ Please note that Regulation (EC, Euratom) No 966/2012 has been replaced by Regulation (EU, Euratom) 2018/1046 (with effect from 2 August 2018).

Rules of Application (RAP) — Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of l Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

⚠ Please note that Delegated Regulation (EC,Euratom) No 1268/2012 has been replaced by Regulation (EU, Euratom) 2018/1046 (with effect from 2 August 2018). The rules of the RAP are now included in the new Financial Regulation.

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I. GENERAL MODEL GRANT AGREEMENT (H2020 GENERAL MGA)

I.1 Background information

The General Model Grant Agreement (H2020 General MGA) is used for grants for 'research and innovation actions (RIA)', 'innovation actions (IA)' and 'coordination and support actions (CSA)'.

> ***Examples:*** *actions under Part III, Societal challenge 3 'Secure, clean and efficient energy' (see a Smart Cities and Communities call); actions under Part I, 'Research infrastructures' (see a Research Infrastructure call); actions under Part III, Societal challenge 1 'Health, Demographic Change and Wellbeing', etc.*

⚠ **Specific MGAs —** The General MGA is NOT used for actions that fall under one of the Specific MGAs (i.e. Lump sum MGA, ERC MGAs, MSCA MGAs, SME Instrument MGAs, ERA-NET Cofund MGA, PCP/PPI Cofund MGA, EJP Cofund MGA or Framework Partnerships).

I.2 H2020 General MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**] established in [official **address** in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number] ,]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full]* ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]* *as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

Beneficiaries means the legal entities who have signed the grant agreement (GA) with the Commission/Agency (i.e. participate in a project supported by an EU grant).

The term **participant** is used in this document in a wider meaning than in the definition of Article 1.1(15) of the Rules for Participation Regulation No 1290/2013. It covers normally beneficiaries and linked third parties (and sometimes also other third parties involved in the action).

The **coordinator** is the beneficiary which is the central contact point for the Commission/Agency and represents the consortium (towards the Commission/Agency).

The **division of roles and responsibilities within the consortium** is explained in Article 41.2.

Generally speaking:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation

of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The **signature arrangements** are the following:

- the coordinator directly signs the GA
- the other beneficiaries sign the GA by signing the Accession Form *(see Article 56)*.

Amendments to the GA, if any, will be signed by the coordinator on their behalf.

Applicants who accept the grant (by signing the GA) become beneficiaries of the grant and are **bound by the entirety of** its **terms and conditions**.

This means that the beneficiaries must:

- carry out the action (and especially the research work) as detailed in Annex 1 (technical implementation) and
- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

Other entities which participate in the action but do not sign the GA (including **linked third parties**, international partners, subcontractors, third parties giving in-kind contributions, etc.) are considered as **third parties involved in the action** (for the definitions and conditions, *see Articles 8 and 9-14a*).

Their involvement in the action varies depending on the role.

Since there is no formal contractual link with them, they are formally speaking not bound by the terms and conditions of the GA. However, by participating in the action and via the obligations on their beneficiary, they are indirectly bound to many of the GA obligations.

⚠ The consortium set-up must follow the roles of the GA. Participants should be attributed their roles according to their real contribution to the project. The main actors should be the beneficiaries. All other roles (third parties) should perform secondary tasks.

This means for instance that:

- linked third parties — are allowed to *fully* participate in the action, like the beneficiary they are linked to; they will therefore be treated for many issues (including cost eligibility; *see Article 6.3*) like beneficiaries
- subcontracting — beneficiaries/linked third parties may NOT subcontract tasks to other beneficiaries/linked third parties *(see Article 13)*
- coordinator tasks — the key coordinator tasks listed in the GA may NOT be subcontracted or delegated to any other beneficiary or linked third party (except, under certain circumstances, to an entity with 'authorisation to administer'; *see Article 41.2*)
- in-kind contributions between beneficiaries/linked third parties — if beneficiaries/linked third parties give in-kind contributions to other beneficiaries/linked third parties, their cost should normally simply be declared by the contributing beneficiary/linked third party (if the contributions are particularly important for the project, it may however be advisable to specifically mention them in the description of the action).

For an overview on the different types of third parties and their GA roles, rights and obligations, *see the table in Article 8*.

2. Name and address — Legal entity data

The legal entity data (legal name, address, legal representatives, etc.) of the beneficiaries comes from the Participant Portal Participant Register (former Beneficiary Register).

This data will be automatically used for all communications concerning this grant *(see Article 52)* and other H2020 grants.

⚠ The beneficiaries (via their **legal entity appointed representative (LEAR)**) must keep their **data** in the Participant Portal up-to-date at all times including after the end of the grant (*see Articles 17 and 52*).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. RIA, IA and CSA actions

What? The RIA, IA and CSA grants of the General MGA fund[1]:

- for **research and innovation actions (RIA)**: R&D aiming to establish new knowledge or explore the feasibility of a new technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)
- for **innovation actions (IA)**: innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)[2]
- for **coordination and support actions (CSA)**: accompanying measures *(such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies)*[3].

[1] More information on the types of action can be found on the General Annexes to the Work Programme.

[2] For the definition, *see Article 2.1(6) of the Rules for Participation Regulation No 1290/2013:* '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[3] For the definition, *see Article 2.1(7) of the Rules for Participation Regulation No 1290/2013:* '**coordination and support action**' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising, and communication, networking,

The term **action** comes from the Financial Regulation No 966/2012 and **means project**. (Previous EU Research Framework Programmes used project.)

RIA, IA and CSA actions are mono- or multi-beneficiary actions.

They are funded in all Parts of Horizon 2020 *(e.g. H2020-FETOPEN-2014-2015-RIA; H2020-WIDESPREAD-2014-3).*

For more information on RIA, IA and CSA actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

2. Complementary grants

'Complementary grants' are different EU grants which are linked by the work programme/calls by identifying them as complementary actions.

The beneficiaries and those of the complementary grants must cooperate and provide access to their results.

They must conclude a written **collaboration agreement** regarding the coordination of the complementary grants and the work of the action *(see Article 41.4)*. (It covers the case included under Special Clause 41 in FP7.)

3. Jointly funded actions ('joint actions')

'Joint actions' are the result of **joint** or **coordinated calls** for proposals, launched in parallel by the EU and a non-associated third country (i.e. a third country not associated to Horizon 2020) or international organisation (in policy areas of common interest and expected mutual benefit where there is a clear added value for the EU).[4]

For *joint* calls: the applicants prepare a joint proposal which is submitted to *both* the EU and the third country/IO; the proposals are evaluated and selected through joint evaluation and selection procedures, involving a balanced group of independent experts appointed by each party.

For *coordinated* calls: the applicants submit separate proposals (to the EU and the third country/IO), together with a summary of the work to be done under the coordinated proposal. The Commission/Agency will only evaluate the proposals for the EU action; however, the evaluation may be coordinated (i.e. include experts from the third country/IO use the same expert panels; apply the same evaluation criteria, etc.).

For both types of calls, the EU participants sign a GA with the EU, while the third country participants sign one with their funding agency/IO. The description of the action (Annex 1 of the GA) contains the research carried out under the EU action (but will also include detailed explanations about the research to be carried out under the third country/IO action).

To ensure coordination, the participants of the two actions must conclude a **coordination agreement** *(see Article 41.5)* to link the actions (although legally separate) and ensure a smooth and successful project implementation.

For guidance on coordination agreements, *see How to draw up your coordination agreement.*

coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries.

[4] *See Article 12 of the Rules for Participation Regulation No 1290/2013.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **[insert number] months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action starting date

The action starting date is fixed by the Commission/Agency in the GA.

It is usually the first day of the month following the date when the GA enters into force. The GA enters into force when the last party signs it *(see Article 58)*.

A fixed starting date may also be agreed between the Commission/Agency and the consortium.

Exceptionally, the Commission/Agency may agree that the action starts on another day than the first day of the month, if the consortium requests it (usually in its proposal) and can show that there is a need to start the action at that moment *(e.g. an action that is dependent on environmental conditions)*.

That starting date can be either:

- **before the entry into force** of the GA, i.e. before the grant agreement is signed by both parties (retroactive)

  Example: *GA signed by the coordinator on 30.12.2014. Commission signs on 5.1.2015. The action starting date would normally be the 1.2.2015, but the consortium has requested a fixed starting date of 1.9.2014 in its proposal (submitted by the consortium on 15.5.2014), since the action funded is the continuation of a previous FP7 project. Upon consideration of the reasons, this fixed starting date is approved.*

  If the consortium requests a fixed starting date before the entry into force of the GA, it assumes the risks implied by starting the action before the GA is signed (in particular not being reimbursed for the costs incurred, *e.g. if the proposal is not successful or that the GA is not signed*).

  ⚠ The action starting date can **NEVER** be **before** the **submission** of the proposal.

- **after the entry into force of the GA,** i.e. after the grant agreement is signed by both parties, but on another day than the first day of the following month

  A starting date fixed much later in time *(e.g. 2-3 months after the signature of the GA)* will have an impact on the timing of the pre-financing payment and will delay it.

2. Action duration

The action duration is fixed by the Commission/Agency in the GA.

It is expressed as a number of months, running from the action starting date until the end date of the action.

⚠ The action duration relates only to the period during which the ***action tasks*** (set out in Annex 1) are implemented.

The end date of the action is therefore NOT the same as project closure or the end of the GA.

After the end date of the action, the beneficiaries still have to submit their final report and the Commission/Agency has to make the payment of the balance. Moreover, certain obligations under the GA continue even afterwards.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2: Moreover, *lump sums set out in Annex 2 can never be adjusted.]*

1. Estimated budget

The estimated budget of the action is calculated on the basis of the estimated eligible costs submitted by the consortium and is annexed to the GA *(Annex 2)*.

These estimated eligible costs are used to determine the 'maximum grant amount' of the action (called 'EU/Euratom financial contribution' in FP7 projects; *see Article 5.1)*.

Costs of beneficiaries not receiving EU funding and costs of international partners will be indicated in Annex 2, but will not be included in the total eligible costs and will not count for the maximum amount of the grant *(see Article 9 and Article 14a)*.

2. Budget categories

The budget categories are listed in Article 6.2 and reflected in the table in Annex 2.

Budget categories of the General MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
  - personnel costs for providing trans-national access to research infrastructure
- direct costs of subcontracting

- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

  This budget category (specific cost categories) applies ONLY where specific activities are reimbursed by unit costs or lump sum costs. For the General MGA, this is currently the case for 'access costs for providing trans-national access to research infrastructure', 'costs for energy efficiency measures in buildings' and 'costs for clinical studies'.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and cost declarations (i.e. financial statements; Article 20 and Annex 4).

⚠ Costs for personnel, equipment, goods or services that are in-kind contributions by a third party (for free or against payment) can in practice simply be added to the budget category they correspond to (i.e. personnel costs or other direct costs) — if they comply with the eligibility rules set out in Articles 6 and 11 and 12.

3. Budget transfers (budget flexibility)

The budget in Annex 2 is an estimation.

⚠ **Budget flexibility** — The budget is in principle flexible (with the exceptions set out below).

Be however aware that the budget table will be used for the calculation of grant reductions *(see Article 43)*.

Beneficiaries may transfer budget among themselves, between linked third parties or between budget categories (without requesting an amendment; *see Article 55*) and — at the time of reporting — declare costs that are different from the estimated budget.

⚠ The maximum grant amount *(see Article 5.1)* can however **NOT** be **increased**.

What? If the incurred eligible costs are lower than the estimated eligible costs, the difference can be allocated to another beneficiary or another budget category. The amount reimbursed for the other beneficiary (by application of its reimbursement rate) or for the other budget category (to which the budget transfer is intended) may thus be higher than planned.

Example: *The estimated budget includes personnel costs of EUR 60 000 for beneficiary A and EUR 75 000 for beneficiary B. However, at the end of the action, the actual personnel costs of beneficiary A are EUR 75 000 due to an increase in salaries or to the need to employ additional personnel to carry out the tasks mentioned in Annex 1 while the actual personnel costs of beneficiary B are EUR 60 000. This may be acceptable provided the additional costs of beneficiary A fulfil the eligibility requirements of Article 6 and up to the maximum grant amount set out in Article 5.1 (at the level of the action).*

Unit costs — If the GA foresees unit costs, transferring amounts declared as unit costs to other categories or other beneficiaries is possible if the actual number of units used (or produced) by the beneficiary is less than the number estimated in Annex 2. The cost per unit cannot be changed.

Example:

Total estimated unit costs for beneficiary A: EUR 10 000 (100 units x 100 EUR/unit)

Total actual unit costs used (or produced) by beneficiary A: EUR 8 000 (80 units x 100 EUR/unit)
Total possible transfer to another budget category: EUR 2 000

What not? The GA allows transfers of budget, NOT of **tasks**.

Moreover, a beneficiary can NOT transfer budget to a **form of costs** that it did not set out **in its estimated budget** — except within the personnel costs category and to costs of internally invoiced goods and services (*Article 6.2.D.5*).

Example (allowed transfer): *A beneficiary budgets all its direct personnel costs as 'actual costs' in the estimated budget (column A (a) of Annex 2). However, at the end of the first reporting period, the beneficiary declares its direct personnel costs as 'unit costs determined according to its usual cost accounting practices' (average personnel costs, in column A (b) of Annex 2). This is acceptable without an amendment of the GA.*

Example (not allowed transfer): *A beneficiary budgets all its costs as 'actual costs' in the estimated budget. However, at the end of the first reporting period, the beneficiary wants to declare part of the costs by using a specific unit cost allowed in the call (e.g. unit cost for clinical studies). This is NOT possible without an amendment of the GA.*

If the budget transfer is due to a **significant change in Annex 1**, an amendment to the GA is needed. A significant change is a change that affects the technical work ('action tasks') of Annex 1.

Best practice: The coordinator can contact the Commission/Agency to ask whether the transfer of budget reflects a significant change in Annex 1 which requires an amendment.

Lump sums — If the GA provides for a lump sum, the lump sum set out in Annex 2 cannot be transferred to another category or to another beneficiary.

Furthermore, the amount of the lump sum can never be increased, decreased or split.

Example: *EUR 30 000 lump sum foreseen for travel in Annex 2 (under 'other direct costs') cannot be turned into a EUR 15 000 lump sum for travel and EUR 15 000 for personnel costs*

New subcontracts — The transfer of budget intended to increase the eligible costs for 'subcontracting' is considered to reflect a significant change of Annex 1 normally requires an amendment (unless the beneficiary uses the simplified approval procedure without formal amendment provided for in Article 13).

Example (amendment): *Beneficiary A subcontracts an action task during the action implementation, because it decided not to recruit additional personnel as initially foreseen, but to use a subcontractor. It requests an ex-ante approval via an amendment (see Article 55)*

Example (simplified approval procedure): *A beneficiary wants to subcontract a task that originally it was going to carry out by itself. It wants to transfer EUR 100 000 from personnel costs to subcontracting. In order to make sure that this new subcontracting is possible and its cost is eligible, this will require an amendment to the GA before the subcontracting takes place. However, the beneficiary doesn't request an amendment, but declares the change only with the next periodic technical report (at its own risk). Since the Commission approves the report, the costs of the additional subcontract are eligible.*

⚠ Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection by the Commission/Agency *(see Article 13)*.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %** of the action's eligible costs**] [OPTION 2 for innovation actions (IA)**[7]**: 100%** of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities[8] and **70%** of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities**] [OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA:** [**…%**] of the action's eligible costs**][OPTION B for IA:** [**…%**] of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities[9] and [**…%**] of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities**]*** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[10]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))][12]: ***[OPTION 1 to be used if Article 15 applies:** as actually incurred costs (**actual costs**);][**OPTION 2**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[13]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[14]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1a **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a[16] ('**unit costs**').]*

***[OPTION** 1b **for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION 2: specific cost category(ies):** not applicable.]*

7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

10 To be used only if option in Point (f) is used.

11 To be used only if option in Point (f) is used.

12 To be used only if option in Point (f) is used.

13 To be used only if option in Point (f) is used.

14 To be used only if option in Point (f) is used.

15 Insert precise name of the costs category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.

16 Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

⚠ The maximum grant amount will **NOT** be **increased** — even if the eligible costs of the action are higher than planned.

The maximum grant amount is not the 'final grant amount' and is not a 'price' due to the beneficiaries.

2. Reimbursement rates

How much? The 'reimbursement rate' for RIA and CSA actions is normally **100%** of the total *eligible* costs[5]; for IA actions it is normally **70%** of the total eligible costs[6].

The eligible costs of **non-profit** beneficiaries/linked third parties participating in innovation actions may be reimbursed at **100%**[7].

5 *See Article 28(4) of the Rules for Participation Regulation No 1290/2013.*

6 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

In exceptional cases fixed in the work programme/call, **lower reimbursement rates** may apply.

As a general principle there is only one funding (reimbursement) rate per action, the same for all activities and all beneficiaries of the action (**one project — one funding rate**).

However, if non-profit beneficiaries/linked third parties are in the same innovation action together with profit beneficiaries/linked third parties, their eligible costs will be reimbursed according to their different reimbursement rates.

The reimbursement rate of a beneficiary does NOT condition the reimbursement rate of its linked third parties.

Example: *The beneficiary is entitled to 70 % but it has a linked third party entitled to 100 %. The linked third party will have a reimbursement rate of 100 % — despite the lower reimbursement rate of the beneficiary to which it is linked.*

The reimbursement rates apply to all forms of costs (actual, unit, lump sums and flat-rates costs)[8] and all budget categories.

⚠ The grant can **NEVER** reimburse **more** than the maximum grant amount fixed in Article 5.1.

3. Cost forms

The General MGA foresees options for all four cost forms (i.e. actual, unit, flat-rate and lump sum costs)[9]. In practice, they are currently all used, except for lump sums (which are only used for SME Instrument actions).

Cost forms of the General MGA:

- **actual costs** (i.e. costs which are real and not estimated or budgeted) for:
  - **personnel** costs (— unless declared as unit cost; *see below*)

    Example: *EUR 62 500 actual yearly salary for senior researcher A*
  - **subcontracting** costs

    Example: *The actual price paid for the subcontracting of a clinical study*
  - costs of providing **financial support** to third parties (if option applies)

    Example: *The financial support actually paid to third parties*
  - **other direct costs** (— unless declared as unit cost; *see below*)

    Example: *EUR 2 000 actual price for a computer*
- **unit costs** (i.e. an amount per unit) for:
  - personnel costs of **SME owners/natural persons** not receiving a salary[10]
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)[11]

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7 *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

8 *See Article 28(6) of the Rules for Participation Regulation No 1290/2013.*

9 *See Articles 123, 124 of the Financial Regulation No 966/2012.*

10 Commission Decision C(2013) 8197 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.

11 *See Article 33(2) of the Rules for Participation Regulation No 1290/2013.*

- costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices
- specific unit costs for:
  - costs for **energy efficiency measures** in buildings[12]
  - **access costs** for providing trans-national access to research infrastructure[13]
  - costs for **clinical studies**[14]

- **flat-rate costs** (i.e. costs calculated by applying a percentage fixed in advance to other types of eligible costs) for:
  - indirect costs (25% flat-rate for indirect costs; new in Horizon 2020)[15]
- **lump sum costs** (i.e. a global amount deemed to cover all costs of the action or a specific category of costs).

Example: *EUR 150 000 to carry out a study within an action*

The General MGA currently does NOT use any lump sum costs.

Within a grant, different forms of costs can be used.

Example: *a budget category (e.g. personnel) covered by unit costs and another (e.g. equipment) by actual costs.*

The table below summarises the different budget categories and forms of costs that may be used in H2020 actions under the General MGA:

Forms of costs	Budget categories					
	Direct personnel costs	Direct costs of sub-contracting	Direct costs of financial support to third parties (option used if Article 15 applies)	Other direct costs	Indirect costs	Specific cost categories (option used if Article 6.2 (F) applies)
Actual costs	YES	YES	YES	YES	NO	NO
Unit costs	YES, only for: - costs established according to the usual cost accounting practices of the	NO	NO	YES, only for: costs of internally invoice goods	NO	YES, only if foreseen by Commission Decision

[12] Commission Decision C(2013) 8196 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

[13] Commission Decision C(2013) 8199 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme. Available at https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf

[14] Commission Decision C(2014) 1393 of 7 March 2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

[15] *See Article 29(1) of the Rules for Participation Regulation No 1290/2013.*

	beneficiary - costs of SME owners and natural persons not receiving a salary			and services		
Flat-rate costs	NO	NO	NO	NO	YES	NO
Lump sum costs	NO	NO	NO	NO	NO	YES, only if foreseen by Commission Decision

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the **errors, irregularities or fraud** or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

1. Final grant amount

The final grant amount will be calculated by the Commission/Agency — at the end of the action— as part of the calculation of the payment of the balance.

The final grant amount will depend on two types of criteria:

- **work implementation criteria**, i.e. was the work carried out as described in Annex 1

  This is a technical analysis by the Commission/Agency of the work performed during the action, as compared with the activities set out in Annex 1 of the GA.

- **financial criteria**, including:
  - the amount of eligible costs
  - the reimbursement rates
  - the maximum grant amount *(see Article 5.1)*.

The procedure for the final payment and detailed calculations are described in Article 21.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

1. Revised final grant amount

If the Commission/Agency finds — after the payment of the balance — ineligible costs, substantial errors, irregularities or fraud or serious breach of obligations (and therefore **rejects costs** and/or **reduces the grant**), it will revise the final grant amount, for the beneficiary concerned and, if needed, make a recovery.

The detailed calculations are described in Article 21.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) **for actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) **for unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) **for flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article *[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2: for lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

1. Eligible costs

The grant can **only** reimburse **eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4) and* declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden on proof** for eligibility is on the beneficiaries (and linked third parties). They must keep sufficient supporting documents *(see Article 18)* to show that the costs they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Cost eligibility is NOT the same as beneficiary/action eligibility. The latter are normally checked upstream (before Grant Agreement/Amendment signature) in order to make sure that only eligible beneficiaries/actions are selected for a grant. Loss of eligibility during an ongoing grant normally leads to termination or change of status *(see Articles 50 and 55)*; costs become automatically ineligible as from the date of loss of eligibility.

If a beneficiary **declares ineligible costs**, the ineligible costs will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Article 6.1 refers to general eligibility conditions, applicable per cost form *(see Article 5)*.

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. General eligibility conditions for actual costs

In order to be **eligible**, actual costs must be:

- **actually incurred by the beneficiary** (i.e.:
  - real and not estimated, budgeted or imputed and
  - definitively and genuinely borne by the beneficiary (not by any other entity))
- **incurred during the action duration** (i.e. the generating event that triggers the costs must take place during the action duration)

  The 'action duration' is the period running from the action starting date to the end date of the action *(see Article 3)*.

  If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the action duration (supported by documentary evidence) and the final cost was known at the moment of the financial report.

Costs of services or equipment supplied to a beneficiary (or to its linked third party) may be invoiced and paid after the end date of the action if the services or equipment were used by the beneficiary (or to its linked third party) during the action duration. By contrast, costs of services or equipment supplied after the end of the action (or after GA termination) are not eligible.

Example: *A conference for which costs are claimed must take place during the action duration.*

- **entered as eligible costs in the estimated budget of the action**, under the relevant budget category *(see Annex 2)*

  When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13.

  Costs included in the estimated budget may be transferred between beneficiaries and budget categories without amending the GA under the conditions set out in Article 4.2.

- **connected to the action as described in Annex 1** (i.e. necessary to achieve the action's objectives)

  The EU/Euratom grant cannot be used to finance activities other than those approved by the Commission.

  ⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

- **identifiable and verifiable** (i.e. come directly from the beneficiary's accounts (be directly reconcilable with them) and supported by documentation)

  The beneficiaries must be able to show (with records and supporting documents; *see Article 18*) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

  Costs must be calculated according to the applicable accounting rules of the country in which the beneficiary is established and according to the beneficiary's usual cost accounting practices.

  Example: *if a beneficiary always charges a particular cost as an indirect cost, it must do so also for H2020 actions, and should not charge it as a direct cost.*

  This may NOT be used as an excuse for non-compliance with other GA provisions. A beneficiary must make any changes needed to bring its usual cost accounting practices in line with all GA provisions.

  Examples: *conditions for calculation of productive hours (see below); conditions for the eligibility of depreciation costs (in line with the international accounting standards, which may deviate from the accounting rules of the country)*

  ⚠ new in Horizon 2020: Accounting documentation is necessary only for direct costs. Indirect costs do not need supporting evidence because they are declared using a flat-rate.

- in **compliance with applicable national laws on taxes, labour and social security**

AND

- **reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency** (i.e.

be in line with good housekeeping practice when spending public money and not be excessive)

'Economy' means minimising the costs of resources used for an activity (input), while maximising quality; 'efficiency' is the relationship between outputs and the resources used to produce them.

Examples:

1. *The beneficiary may NOT increase the remuneration of its personnel, upgrade its travel policy or its purchasing rules because of the Commission/Agency support.*

2. *Entertainment or hospitality expenses (including gifts, special meals and dinners) are generally not eligible.*

3. *Tips which are not obligatory are not eligible. By contrast, in some countries the invoice of the restaurant includes a certain mandatory amount as payment for the 'service'. In this case, the amount may be considered eligible — if the other eligibility conditions are fulfilled.*

Specific cases (actual costs):

In-kind contributions free of charge and **costs of linked third parties** — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis (see Article 6.3 and 6.4)*.

Thus, the costs must be:

- actually incurred by the third party
- recorded in the third party's accounting records
- calculated in accordance with the accounting standards applicable in the country in which the third party is established
- calculated according to the third party's usual cost accounting practices.

Depreciation costs for equipment used for the action, but bought before the action's start — If the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the action duration and for the rate of actual use for the action; *see Article 6.2.D.2*).

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the action starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date *(e.g. the day before the kick-off meeting)*, the costs may be eligible, if the meeting is held during the action duration.

Costs for reporting at end of the action — Costs related to drafting and submitting the periodic report for the last reporting period and the final report are eligible even if they are incurred after the action duration.

Those costs include the cost of certificates on the financial statements (CFS) required by the GA and the cost of participating in a final review carried out by the Commission/Agency before the submission of the final reports. They may also include the cost of personnel necessary to prepare the periodic report for the last reporting period and the final report. However, they do NOT include research or innovation activities undertaken after the end date of the action.

Personnel costs for ERA chairs — Are eligible even if the salary is above national salaries, provided that it does not go beyond normal EU/international salaries for similar positions (since the ERA chairs aim to incentivise international mobility for internationally outstanding researchers and research managers. When the level of remuneration of the ERA Chair is indicated in Annex 1, this will be duly taken into account in case of checks, audits or reviews.

Costs to allow for the participation of disabled people *(e.g. costs for sign language interpreters required for dissemination events organised under the action)* — May be eligible if they fulfil the general and specific eligibility conditions listed under Articles 6.1 and 6.2. The beneficiaries must keep records *(see Article 18)* to prove in case of an audit, check or review the actual costs incurred and that they were necessary for the implementation of the action.

3. General eligibility conditions for unit costs

In order to be **eligible**, unit costs must be:

- calculated by **multiplying** the **number of actual units** used to carry out the work *(e.g. number of hours worked on the action, number of tests performed, etc.)* or produced *(e.g. number of square meters for energy efficiency in buildings)* **by** the **amount per unit**

  Example: *A Commission decision that sets the amount per unit for laboratory analyses at EUR 300 per test. This amount per unit is also set out in Annex 2a.*

- the **number of units** must be **necessary** for the action

- the units must be **used or produced during the action duration**

AND

- the beneficiaries must be able to **show the link** between the number of units declared and the work on the action.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the number of units declared was actually used for the action. (The actual costs of the work are not relevant.)

Example: *A beneficiary which is a SME declares for its owner who does not receive a salary 300 hours worked for an action in 2014. If there is an audit, the SME beneficiary must be able to show a record of the number of hours worked by the owner for the action.*

Specific cases (unit costs):

Costs declared on the basis of the usual accounting practices— For two budget categories (A. personnel costs and D.5 costs of internally invoiced goods and services), costs may be declared not as a fixed unit cost, but on the basis of the beneficiary's usual cost accounting practices. In this case,:

- the beneficiary:
  - must calculate the costs according to its usual accounting practices
  - must budget and declare a total amount (not the units used)
- the amount per unit is not fixed in Annex 2a.

Other costs may NOT be declared according to the usual cost accounting practices. For them, the amounts per unit will be fixed by the Commission/Agency and set out in Annex 2a of the GA *(see Article 5.2)*.

4. General eligibility conditions for flat-rate costs

In order to be **eligible**, flat-rate costs must be:

- calculated by **applying** a **flat rate** to certain **costs** (whether actual, unit or lump sum costs).

  Example (25 % flat rate for indirect costs):

  A SME beneficiary that charges costs of its owner without a salary is working on an innovation action and uses the EUR 30 per hour unit cost fixed in Annex 2 for personnel costs. The SME beneficiary declares as eligible 300 hours of direct personnel costs for its owner + EUR 1 400 for other direct costs + EUR 1 500 for subcontracting for work in an innovation action during the first reporting period.

  Eligible direct costs: (30 X 300 = 9 000) + 1 400 + 1 500 = 11 900

  Eligible indirect cost: 25 % flat-rate of 9 000 + 1 400 (not the 1 500 for subcontracting) = EUR 2 600

  Total eligible costs: 11 900 + 2 600 = EUR 14 500.

Reimbursement rate of 70 % (innovation action, 'for profit' beneficiary) = EUR 10 150.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the costs to which the flat-rate is applied are eligible. (The actual indirect costs are not relevant.)

5. General eligibility conditions for lump sum costs

In order to be **eligible**:

- the lump sum costs must **correspond** to the amount of **lump sum** costs set out in Annex 2 and
- the **work** must have been **carried out** in accordance to Annex 1 of the GA.

The beneficiaries must be able to show (with records and supporting evidence; *see Article 18*) that the action tasks have been carried out as described in Annex 1. (The actual costs of the work are not relevant).

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable*;]
D. other direct costs;
E. indirect costs;
F. [***OPTION 1 for specific unit[/lump sum] costs***: *[insert name(s) of specific cost category(ies)*[16]*]*][***OPTION 2:*** *not applicable*].

'**Direct costs**' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'**Indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum. For example: 'access costs for providing trans-national access to research infrastructure', costs for 'clinical studies', costs for 'energy efficiency measures in buildings'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to **specific eligibility** conditions, applicable per budget category.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

For a consolidated list of eligibility issues relating to specific situations/legal framework in individual countries, *see the List of issues applicable to particular countries.*

2. Direct costs

'Direct costs' are specific costs directly linked to the performance of the action and which can therefore be directly booked to it.

They are:

– either costs that have been caused in full by the activities of the action

- or costs that have been caused in full by the activities of several actions (projects), the attribution of which to a single action can, and has been, directly measured (i.e. not attributed indirectly via an allocation key, a cost driver or a proxy).

The beneficiaries must be able to show (with records and supporting evidence) the link to the action.

3. Indirect costs

'Indirect costs' are costs that cannot be identified as specific costs directly linked to the performance of the action.

In practice, they are costs whose link to the action can NOT be (or has not been) measured directly, but only by means of cost drivers or a proxy (i.e. parameters that apportion the total indirect costs (overheads) among the different activities of the beneficiary).

⚠ In Horizon 2020, indirect costs are declared as a **25% fixed flat-rate** of the eligible direct costs (minus certain direct eligible costs; *see Article 6.2.E*).

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual** costs (i.e. budget categories A.1, A.2, A.3 [*and A.6*]): the hourly rate is calculated per full financial year, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories A.1, A.2, A.4, A.5 [*and A.6*]): the hourly rate is one of the following:

(ii) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

1. Direct personnel costs (A.): Types of costs — Forms — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An additional option for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

The beneficiaries may declare the following **types of costs** as 'direct personnel costs':

- costs for **employees** (or equivalent):
- costs for **natural persons working** under a direct contract
- costs for **personnel seconded by a third party**
- costs for **beneficiaries that are SMEs for their owners not receiving a salary**
- costs for **beneficiaries that are natural persons not receiving a salary**
- personnel **costs for** providing **trans-national or virtual access to research infrastructure** (if option applies).

1.1 Direct personnel costs: Employees (or equivalent) (A.1)

1.1.1 What? Personnel costs for employees or equivalent (i.e. persons working for the beneficiary on the basis of an employment contract or equivalent appointing act) that worked in the action.

⚠ '**Equivalent appointing act**' means the appointing acts of civil servants (who do not sign employment contracts but receive official nominations for their posts).

⚠ ONLY costs for **personnel assigned to the action** (i.e. working for the action according to internal written instructions, organisation chart or other documented management decision) can be eligible. Reliable time records will normally be sufficient proof of the assignment to the action — unless there is other contradicting evidence *(e.g. the employment contract indicates that the person was hired to work on another project)*

It covers (and is limited to):

- **basic remuneration** (i.e. the payments for the employee's normal work and participation in projects — up to what is the beneficiary's usual remuneration practice for national projects)

and, in addition:

- for non-profit legal entities: **additional remuneration** (i.e. extra payments made for the participation in projects — above the beneficiary's usual remuneration practice for national projects).

⚠ **National projects** are to be understood in the large sense, meaning all types of projects funded under any type of national (public or private) funding scheme (including projects co-financed by EU funds that are managed by the Member States, *e.g. regional funds, agricultural and fisheries funds*).

Projects from EU programmes directly managed by the Commission/Agencies or their funding bodies *(e.g. LIFE, ERASMUS, Health, etc.)* do not, however, qualify as national projects (but as EU/international projects).

Both basic remuneration and additional remuneration do not only cover the payment itself (salary or bonus), but also the social security contributions *(mandatory employer and employee contributions)*, taxes included in the remuneration *(e.g. income tax)* and other costs and payments included in the remuneration *(e.g. a fee paid by the beneficiary for a complementary health insurance scheme for the employee).*

What not? Cost of persons who work for the beneficiary, but NOT with an employment contract or equivalent appointing act *(e.g. staff provided by a temporary work agency, seconded staff, self-employed persons with a direct contract with the beneficiary)*.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions *(e.g. best value for money and no conflict of interest; see Articles 10 and 13)*.

Seconded staff and **self-employed persons with a direct contract —** Can also be declared under other categories within the personnel costs *(see below, points 1.2 and 1.3)*.

1.1.2 Costs for employees (or equivalent) must be **declared** as:

- **actual personnel costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.1.3 The costs for employees (or equivalent) must comply with the following **eligibility conditions**:

For basic remuneration:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, etc.; *see Article 6.1(a) and (b)*)

  Payments of dividends to employees (profit distribution) are NOT eligible under *Article 6.5(a)(i)*. However, bonuses based on the overall financial performance of the organisation *(e.g. profitability or surplus)* may be accepted, if they fulfil the conditions set out below, i.e. as part of the usual remuneration practices for national projects and thus eligible as basic remuneration.

  Examples (positive):

  If the profit of the company at the end of the year is more that x € (or more than x %), each employee will receive a bonus of z % of his/her basic remuneration (or a fixed bonus of x € more as part of the gross salary).

  Examples (negative):

  If the profit of the company at the end of the year is more that X € (or more than X %), z % of that profit will be distributed to employees trough extra remuneration.

  Any part of the remuneration which is based on commercial targets or fund raising targets is NOT eligible (because neither incurred in connection with the work described in Annex 1 of the action nor necessary for its implementation).

  ***Examples**: x € for reaching a sales target; x % on sales; x € premium per externally funded project gained; x % of the external funding gained*

- be paid in accordance with national law, the collective labour agreement and the employment contract/equivalent appointing act

  Examples:

  ***1.** The collective labour agreement establishes that all researchers may receive a bonus between EUR 100 and EUR 200 per month based on their seniority.*

  ***2.** The national law authorises public universities to pay a bonus based on merit of the employees.*

  ***3.** The contract fixes a premium of EUR 1 000 for each research paper published in peer-reviewed international research journals.*

- **exclude arbitrary bonuses** (i.e. bonuses which are not part of the beneficiary's usual remuneration practices and/or which are not based on objective conditions).

For additional remuneration (in addition to the conditions above):

- be a **non-profit legal entity**

- be paid for the performance of **additional work** or **different expertise** than his/her usual tasks

  This is usually the case, since additional remuneration aims precisely to reimburse the additional work/expertise that is required for EU and international projects.

- be **consistently applied** whenever the same kind of work or expertise is required and **regardless of the source of funding** used

  The additional remuneration may not differ according to *where* the funds come from. In particular, it cannot be set up for actions funded by a specific donor; additional remuneration schemes that are applicable only to EU projects are not acceptable.

  ***Example (not acceptable):** All professors carrying out research will be paid 10 % more when they work on EU-funded actions.*

  Also, they may not be subject to budget availability (i.e. only to be paid if there is remaining funds in the project budget).

However, the additional remuneration does not have to be the *same* for all persons working in the same project (provided that objective criteria are used to determine the differences).

⚠ **8000 EUR ceiling —** Additional remuneration is eligible **ONLY up to** a ceiling of **8000 EUR** annual costs; *see point 1.1.4*).

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Teleworking — Remuneration costs of personnel not working on the premises of the beneficiary (i.e. teleworking) may be accepted as eligible, if it is the beneficiary's usual practice (i.e. if clear rules are available). The system in place must make it possible to both identify and record the hours worked for the action.

Benefits in kind — Costs of benefits in-kind provided by the beneficiary to its personnel *(e.g. costs of a company car made available to certain categories of employees for their own use)* or of quasi-financial benefits *(e.g. costs of lunch vouchers)* may be accepted as eligible, if they are justified and registered as personnel costs in conformity with the beneficiary's usual remuneration practices. Like all costs, they must fulfil the eligibility conditions set out in Article 6.

Recruitment costs — Recruitment costs are generally NOT eligible as direct costs, because the beneficiary is required to have the necessary human resources to implement the action. If a beneficiary needs to recruit additional personnel during the action, the related costs would be considered part of the entity's normal indirect costs, which are covered by the 25 % flat-rate.

Costs for students, PhDs and other researchers under scholarship, internship or similar agreements (not employees) — Costs of students that work for the beneficiary can be accepted, if the agreement is work-oriented (not training-oriented: i.e. not aimed at helping the student to acquire professional skills).

PhD agreements will be considered work-oriented. However, time for training, if any, may NOT be charged to the action.

Fellowships/scholarships/stipends — Can be charged to the action (as personnel costs), if they fulfil the conditions set out Article 6.1 and 6.2.A.2, and in particular:

- the remuneration complies with the application national law on taxes, labour and social security
- the assignment of tasks respects the laws in force in the country of the beneficiary
- the students have the necessary qualifications to carry out the tasks allocated to them under the action.

Cost for exemptions from academic fees — The fees (or part of them) are eligible as personnel cost, if the student's contract includes the amount of waived fees as part of his/her remuneration. The other conditions set out in Article 6 have to be fulfilled as well *(e.g. the full remuneration, included the value of the waived fees, must be recorded in the university's accounts)*.

Parental leave — Salaries and social security contributions paid during parental leave (either maternity leave or parental leave) are eligible as part of the basic remuneration only if:

- they are mandatory under national law, under the relevant collective labour agreement (e.g. statutory maternity pay) or under the employment contract
- the beneficiary has actually incurred them
- they are not reimbursed by national (central, regional or local) authorities (i.e. only the net amounts paid by the beneficiary are eligible).

Costs related to public officials — For public bodies, the costs related to public officials paid directly from central, regional or local government budgets may be considered eligible, if they fulfil the conditions set out in Article 6 (applied to the central, regional or local government employing the public officials). In this case, the public officials will be considered as in-kind contributions (resources made available) provided by a third party (the government) free of charge (see Article 12).

Supplementary contracts — Supplementary contracts for participation in projects (whatever their form) are acceptable if it is the beneficiary's usual practice and compatible with national law. The remuneration will be qualified as basic or additional remuneration, depending on the scope (national OR EU/international) and amount (above, equal or below usual remuneration practices for national projects).

1.1.4 The **costs** must be **calculated** as follows:

In general, personnel costs for H2020 actions are calculated (for each person assigned to the action, including persons working exclusively on the action) as follows:

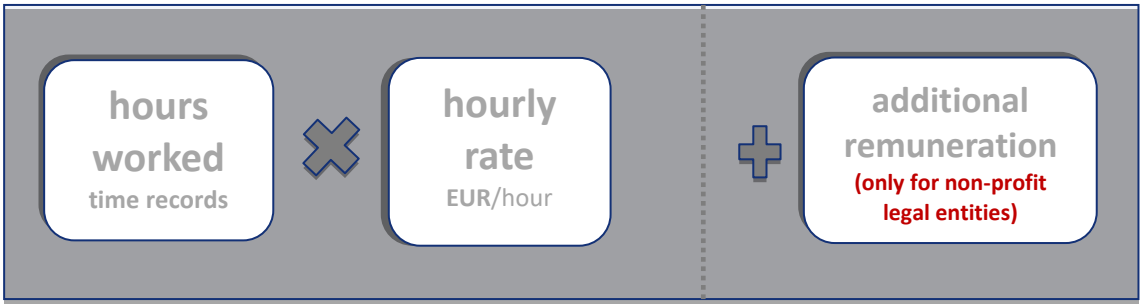

In practice, the calculation will differ (per type of beneficiary/employee) depending on the remuneration practices of the beneficiary:

Case 1: beneficiaries declaring personnel costs as actual costs

Case 1A: employee whose remuneration is not project-based (i.e. same remuneration, regardless if they are involved or not in specific projects)

Case 1B: employee whose remuneration is project-based (i.e. different remuneration levels, depending on whether they work in specific projects or not)

Examples:

1. *The beneficiary and the researcher sign a separate employment contract for the work of the person in the Horizon 2020 action. The hourly rate resulting from that additional employment contract is different from the hourly rate of the other employment contract of the person with the beneficiary.*

2.*The beneficiary has a remuneration scheme which includes the payment of a bonus for work in specific projects. The bonus is paid as part of the total salary of the person in addition to the basic salary and other general bonuses.*

3. *The employment contract of the person fixes a specific hourly rate to be paid for work in specific projects. This hourly rate replaces the standard salary of the person while it works in those projects.*

Case 2: beneficiaries declaring personnel costs as unit costs in accordance with the usual cost accounting practices (average personnel costs).

Additional remuneration is in practice an issue ONLY for case 1B beneficiaries. All other beneficiaries will automatically fall under 'basic remuneration only' and therefore are not concerned by the provisions on additional remuneration.

Case 1B beneficiaries need to differentiate between payments that are basic remuneration and payments that are additional remuneration. For them, the hourly rate charged to the action must be calculated using only basic remuneration (i.e. excluding any part that qualifies as additional remuneration). Additional remuneration may be charged (separately and on top), if the beneficiary is a non-profit entity, if that remuneration is eligible and only up to a ceiling of 8000 EUR per year.

⚠ ONLY **hours actually worked on the action** can be counted. Such hours must be registered via time records or, if the person works exclusively in the action, via a declaration (*see Article 18.1.2*).

⚠ **Double ceiling —** Beneficiaries must ensure that:

- the **total number of hours** worked **declared** in EU and Euratom grants for a person for a year is NOT higher than the number of **annual productive hours** used for the calculation of the hourly rate *(see below)*

  Example: *Beneficiary using 1 720 as annual productive hours. According to the time-records, during the financial year 2017 employee Z worked 900 hours in a H2020 action and 900 hours in another EU project. The total hours worked for EU projects by employee Z would therefore be 1 800 (900 + 900). However, the beneficiary cannot declare more than 1 720 hours, since this is the number of annual productive hours it used for the calculation of the hourly rate. Therefore, for 2017, the beneficiary can only charge 820 hours to the H2020 action (i.e. 1 720 – 900 hours declared to other EU grant), even if the person worked 900 hours in the action.*

- the **total** amount of **personnel costs declared** (for reimbursement as actual costs) in EU and Euratom grants for a person for a year is NOT higher than the total personnel costs recorded in the **beneficiary's accounts** (for that person for that year).

  Example: *The total personnel costs recorded in the 2017 accounts of the beneficiary for employee Z is EUR 18 000. The beneficiary already declared EUR 9 000 to the other EU grant. The hourly rate for employee Z according to the formula in the H2020 Grant Agreement is 11 EUR/hour and employee Z worked 900 hours for the action in 2017. The eligible personnel costs for the H2020 action would therefore be: 11 EUR/hour x 900 hours = EUR 9 900. However, since the beneficiary already declared EUR 9 000 to the other EU grant, the maximum that it can declare to the H2020 action is: EUR 18 000 (total personnel costs for employee Z) – EUR 9 000 (already declared to other EU grant) = EUR 9 000. The beneficiary can therefore declare only EUR 9 000, even if the result of the formula for personnel costs would be EUR 9 900.*

How to calculate direct personnel costs for employees (or equivalent):

For case 1A beneficiaries (actual costs, not project-based remuneration): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary must calculate, for each employee, the hourly rate to be charged to the action by using one of the following methods:

- **per full financial year** (main method): single hourly rate for each person for each full financial year
- **per month** (alternative method): one hourly rate for each person for each month (i.e. 12 hourly rates per person for each financial year).

Each beneficiary may choose any of the two options. However, the option chosen must be applied during the full financial year to all its personnel in all H2020 grants. If the beneficiary wants to change option, it can do so for the next financial year (— again for all its personnel in all its H2020 grants).

⚠ **Recalculations & adjustments of financial statements (exceptional) —** To benefit from this new option (i.e. hourly rate per month) beneficiaries may apply it retroactively for all grants on-going (i.e. for which the final report has not been submitted) on 20 July 2016 (i.e. date of adoption of the H2020 MGA version 3.0). The beneficiary may re-calculate costs already declared on the basis the full financial year by using the monthly calculation method. However, in that case it must do the recalculation for ALL personnel costs declared for that/those financial year(s) in ALL on-going H2020 grants. The beneficiary must declare the differences, either positive or negative, as adjustments in the next reporting period.

⚠ The grant agreement **formulas for the hourly rates are mandatory**. Those formulas may lead to minor/temporary differences with the personnel cost recorded in the accounts. Those differences have no impact on the eligibility of the costs, provided that the formula has been correctly applied and that the *double ceiling* explained above has been respected.

Calculation of the hourly rate *per full financial year*

Annual hourly rates must be calculated as follows:

for each person:

{actual **annual personnel costs** for the person
divided by
number of **annual productive hours**}.

The rate must be calculated by ***full financial* year** (i.e. the 12-month period covered by the annual accounts of the entity).

Example: *When the financial year matches the **calendar year**, i.e. 1st January – 31st December, the hourly rate for the hours worked in 2014 will be calculated using the personnel costs and the productive hours from January to December 2014.*

When at the end of the reporting period there are months for which the financial year is not closed yet *(e.g. the financial year is still on-going; necessary information for that year is not yet available, etc.)*, the beneficiary must use the figures of the last closed financial year available to declare the costs for those months (i.e. use the hourly rate of the last closed financial year available also to calculate the personnel costs for the hours worked on those months).

Example: *Action with 1 reporting period of 18 months from 1.10.2015 to 31.3.2017. The beneficiary's financial year closes on 31 December of every year.*

Calculation of the hourly rate:

For hours worked on the action from 1.10.2015 - 31.12.2015: the hourly rate of 2015 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2015.

For hours worked on the action from 1.1.2016 – 31.12.2016: the hourly rate of 2016 must be used; i.e. hourly rate calculated on the basis of the annual personnel costs and annual productive hours of the closed financial year 2016.

For hours worked on the action from 1.1.2017 – 31.3.2017: the hourly rate calculated for the last closed financial year available must be used, e.g. the one of the year 2016. Therefore, the beneficiary will not calculate another hourly rate for the period from 1.1.2017 - 31.3.2017. Instead, it will simply continue applying the hourly rate calculated for 2016 for the hours worked in 2017 until 31.03.

Last closed financial year available refers to the most recent *full* financial year for which all information necessary to calculate the hourly rates in accordance with the GA is available at the end of the reporting period. Therefore, it is NOT necessary to wait until the annual accounts have been audited.

Financial year different from fiscal year — If the financial year is different from the fiscal year (i.e. the 12-month period used to calculate the income taxes), the entity may use the **fiscal yea**r instead of the financial year for calculating the hourly rate. The method must however be consistently applied and can NOT be changed within the same grant.

⚠ **Recalculations & adjustments of financial statements (exceptional)** — Adjustments to the hourly rate are normally allowed ONLY for mistakes *(e.g. incorrect accounting information; error in the calculation; etc.)* and must be done using the hourly rate which would have had to be used at the end of the reporting period concerned.

Examples:

1. *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

2. *Reporting period 1 runs from 1 January 2016 to 30 June 2017. The beneficiary used the hourly rate 2016 for the entire period (i.e. also for the part from 01/01/2017 – 30/06/2017) because the financial year 2017 was still on-going at the end of the reporting period. In 2018, the beneficiary realises that the 2016 hourly rate was incorrectly calculated and that it has to declare an adjustment for reporting period 1. To calculate the adjustment, the beneficiary must use the correct hourly rate for 2016 for the whole reporting period 1, including the period from January to June 2017.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed (even if a recalculation of the hourly rate after the closure of the financial year would give another result).

The **annual personnel costs** may include only eligible personnel costs.

Any part of the remuneration which is paid once a year *(e.g. holiday pay)* will be taken into consideration for the hourly rate of the year in which it was accrued in the accounts.

For calculating the **annual productive hours**, the beneficiary must use one of the following three options:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 2:** the total number of hours worked by the person in the year for the beneficiary **('individual annual productive hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

In principle, the same option (1, 2 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, same cost-centre, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed ad-hoc for specific employees)*.

The beneficiary must keep the same option(s) for *the full financial year*. It can only change its option(s) for the next financial year.

⚠ **Absences & overtime —**

Absences: the three options treat absences (leave) in different ways:

- under option 1 (1720 fixed): ONLY actual time spent on parental leave (maternity and parental leave) may be deducted from the 1720 fixed hours. NO other leave *(e.g. sick leave, special leave, annual leave, etc.)* can be deducted.
- under option 2 (individual): the beneficiary must deduct all leaves (i.e. *actual time* on sick leave, parental leave or special leave, etc.) to calculate the annual productive hours.

  ⚠ In order to calculate the annual workable hours, the beneficiary has to deduct the annual leave entitlement (see example in the *table of options*). However, if the employment contract allows end-of-year transfers for leave entitlements (i.e. the days not taken one year can be taken the next one; days not taken are not paid out), the beneficiary may opt for deducting instead *actual time* of annual leave (if this is done consistently throughout the years).
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard time of absence in the organisation. However, the beneficiary may deduct on top the actual time spent on parental leave (maternity and parental leave) by the individual employee.

Overtime: all three options include potential overtime in the annual productive hours, either implicitly (options 1 and 3) or explicitly (option 2):

- under option 1 (1720 fixed): NO overtime may be added to the 1720 fixed hours
- under option 2 (individual): all overtime worked (paid or unpaid) must be added to the annual workable hours to calculate the annual productive hours
- under option 3 (standard): the standard annual productive hours defined by the beneficiary normally take into account the standard overtime hours in the organisation (if any).

⚠ **No impact on the hours worked —** The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding can NOT be charged to the action (they must be capped at the ceilings).

Calculation of the hourly rate *per month*

Monthly hourly rates must be calculated as follows:

for each person:

{actual **monthly personnel costs**
divided by
{number of **annual productive hours/12**}**}**.

The rate must be calculated **for each month**.

The **monthly personnel costs** may include only eligible personnel costs.

If a part of the remuneration is generated over a period longer than a month *(e.g. the thirteenth salary)*, only the entitlement generated in the month can be included in the monthly personnel costs (— irrespectively of how much is actually paid in that month).

Example:

In accordance with the collective labour agreement, Ms T is entitled to a thirteenth salary (another full month salary in addition to her 12 monthly salaries) to be paid in July each year. The monthly salary of MS T is EUR 3 000.

The monthly personnel costs in July will be:

EUR 3 000 + {EUR 3 000 / 12} = 3 000 + 250 = EUR 3 250

The beneficiary can therefore NOT include the total of the thirteenth salary in the personnel costs for July, but must distribute it over the months in which it was generated (in this example 1/12 per month). Otherwise, the hours of July would be incorrectly priced at the double of the hours worked in normal months.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** If a later event *(e.g. the unexpected leave of the employee)* means that the payments made for the employee are actually lower (i.e. that the monthly hourly rates were overstated) the beneficiary must recalculate the hourly rates with the correct amount. If some of the related personnel costs were already declared, the beneficiary must declare the difference as adjustment in the next reporting period.

If the monthly entitlement of an extra salary is not known in advance *(for example for an annual merit pay whose amount is decided in December — if eligible as basic remuneration —)* the beneficiary cannot take into account the extra salary until the amount is known. It may therefore recalculate the hourly rates at that moment and, if needed, declare the difference as adjustment in the next reporting period.

For calculating the **annual productive hours**, the beneficiary must use one of the following two options *(see the table of options above for the details on each option)*:

- **option 1:** 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time) ('**1720 fixed hours**')
- **option 3:** the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices **('standard annual productive hours')**.

⚠ Option 2 can NOT be used for monthly hourly rates because the individual annual productive hours — and thus also the monthly hours, i.e. 1/12 of the annual — are known only at the end of the financial year. It would be therefore impossible to calculate the hourly rates at the end of each month.

In principle, the same option (1 or 3) must be applied to *all personnel* working in H2020 actions. However, the beneficiary may use different options for different *types* of personnel, if:

- the same option is applied at least per group of personnel employed under similar conditions *(e.g. same staff category, same type of contract, etc.)* and
- the options are applied consistently *(e.g. the choice of the option is not changed at-hoc for specific employees)*.

The beneficiary must keep the same option(s) *during the entire financial year*. It can only change its option(s) for the next financial year.

⚠ **Absences & overtime —**

The same rules on the treatment of absences and overtime apply as for annual hourly rates, except that time spent on parental leave can NOT be deducted from the annual productive hours.

However, beneficiaries may charge to the action the *costs* incurred for parental leave (as personnel costs) in proportion to the time the person worked for the action during the financial year (time worked on the action over total productive hours for the year). This must be done separately and on top of the personnel costs declared by multiplying the hours worked for the action by the monthly hourly rates.

Example:

In 2015 Ms T has been five months in parental leave. During that time the social security reimbursed to the beneficiary 50 % of her salary. Her monthly salary was EUR 3 000 (reimbursement EUR 1 500). The beneficiary used option 1 (1720 fixed hours) for the annual productive hours and Ms T worked in 2015 320 hours on the H2020 action.

Personnel costs incurred during parental leave= {EUR 3 000 x 5} - {EUR 1 500 x 5} = 15 000 – 7 500 = EUR 7 500

(Note: amounts reimbursed to the beneficiary by the social security are not actual costs for it and, therefore, must be deducted)

Proportion of time worked for the action in 2015 = Time worked for the action / Total productive hours excluding the parental leave = 320 / {1720 - {1 720 x 5/12}} = 320 / {1 720 – 716,7} = 320 / 1 003,3 = 31,89 %

Cost of parental leave for the H2020 action = EUR 7 500 x 31,89 % = EUR 2 391,75

⚠ **No impact on the hours worked —** The rules on the calculation of the *hourly rate* have no impact on the hours that can be declared *as hours worked on the action.* ALL hours worked on the action can be declared (normal hours and overtime) and all at the same hourly rate.

However, beneficiaries must make sure that they don't reach the double ceiling (i.e. number of annual productive hours used and costs recorded in accounts; *see above)*. If the overtime results in more hours worked/more costs declared over the ceiling, the exceeding can NOT be charged to the action (they must be capped at the ceilings). The ceilings apply per full financial year, not per month.

However, do not forget that your personnel costs must comply with national labour law.

Example:

If the national law provides for a prohibition for employees to work more than 48 hours per week, it is not possible to charge to the H2020 action 250 hours in a month for an employee.

Step 2 — **Multiplying the hourly rates by the hours worked on the action**

The hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

For case 1B beneficiaries (actual costs, project-based remuneration): 4 steps

Step 1 — **Checking the nature of the remuneration (basic or additional) for each employee)**

The beneficiary must first find out, for each employee, if the remuneration it is paying is all basic remuneration or contains also additional remuneration.

To do this, the beneficiary must calculate **two reference hourly rates**:

- reference rate for the work on the H2020 action ('**action reference**')

and

- reference rate for the usual remuneration practice for national projects ('**national projects reference**').

If the action reference is *equal or below* the national projects reference, the remuneration is all basic remuneration. If it is *higher*, the exceeding part is additional

remuneration and must be taken out for the calculation of the hourly rate to be charged to the action.

Step 1a — **Calculation of the reference hourly rates**

For the **action reference**: the beneficiary must calculate an hourly rate (either *annual* or *monthly*) based on the remuneration paid to the employee for his/her work in the H2020 action.

For *annual* reference rates:

{annual personnel costs for the person for his/her work in the action

divided by

number of hours worked for the action in the financial year}.

If the reporting period ends before the end of the financial year, the beneficiary must use the personnel costs and the hours from the beginning of the year until the end of the reporting period.

For *monthly* reference rates:

{monthly personnel costs for the person for his/her work on the action

divided by

number of hours worked for the action in the month}.

For the **national projects reference**: the beneficiary must calculate an hourly rate based on either:

- regulatory requirements *(e.g. national law or collective labour agreements)* setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The national law establishes that the maximum monthly salary of engineers acceptable for national grants is EUR 4 000. Beneficiary A has paid that salary to its engineers while working in national grants. Beneficiary B has signed a collective labour agreement whereby the monthly salary to be paid for work under national grants is fixed at EUR 3 500. Beneficiary B has paid that salary to its engineers working in national grants.*

  Maximum amount acceptable as basic remuneration for beneficiary A = EUR 4 000/month for a person working full-time. If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

  Maximum amount acceptable as basic remuneration for beneficiary B = EUR 3 500/month for a person working full-time. If the remuneration of the person for the work in the H2020 action was more than this ceiling, the excess will qualify as additional remuneration.

- internal rules setting up the level of remuneration to be paid for work in projects funded under national schemes — if those amounts were actually paid at least once before the submission of the H2020 proposal for work in a national project

  Example: *The internal rules of University Z provide that a professor working in externally-funded projects may get an extra salary of up to 50 % for the time its works for those projects. The maximum extra salary University Z has actually paid for work in national projects was 30 %.*

  Maximum amount acceptable as basic remuneration = salary of the person + 30 % (for the time worked in the H2020 action). If the remuneration of the person for the work in the H2020 action is more than this ceiling, the excess will qualify as additional remuneration.

or

- if none of these are available or if the beneficiary never had any national projects before the submission of the H2020 proposal: the average remuneration of the employee in the previous financial year.

The hourly rate of the national project reference must be calculated using 1720 fixed annual productive hours (unless there is an hourly rate directly set in the law, collective labour agreement or internal rules).

For the average remuneration of the employee, the beneficiary must moreover exclude remuneration that came from H2020 actions; i.e.:

{total annual personnel costs* for the person for year n-1 excluding remuneration paid for work in H2020 actions

divided by

1720** minus hours worked in H2020 actions in year n-1}

* The total annual personnel costs include all remuneration paid by the beneficiary to the person for work, irrespectively of the tasks of the person and the projects for which the person was working; but excludes all remuneration paid for work in H2020 actions. If the remuneration included ineligible items *(e.g. profit distribution)* those must also be removed.

** 1720 is the fixed number of annual productive hours. The beneficiary must remove from those annual productive hours the hours worked in H2020 actions. If in year n-1 the person worked exclusively in H2020 actions, the beneficiary must use the average salary of the last year in which the person did not work exclusively in H2020 actions *(e.g. year n-2 or year n-3)*. If in year n-1 the person was on long-term sick leave, the beneficiary may use the average of year n-2 (instead of n-1).

If the national law or the internal rules set up different levels of remuneration for different categories of staff, the reference will be the one of the category to which the person belongs.

If the national law or the internal rules set up different remuneration levels for different types of national projects (or for different work within the projects), the reference will be the one applicable to the type of project/work that is closest to the H2020 action.

Example: *The internal rules of University Z provide that a professor working in basic research projects will receive 10 % extra salary; while a professor working in applied research projects will receive 15 % extra salary. Both extra salaries are systematically paid also for projects funded by national schemes. The H2020 action is an innovation action. The reference that would apply in this case is the extra salary for applied research projects (15 %) as the type of project is closer to the H2020 innovation action than basic research projects.*

The beneficiary must keep appropriate and sufficient evidence to support the action and national project references used *(see Article 18)*.

Example: *If the beneficiary uses the internal rules it must keep documental evidence of the internal rules applied, the category of the person (if applicable), and the payslip and payment documents proving that such remuneration was paid at least once prior to the submission of the proposal.*

Step 1b — **Comparing the action reference with the national project reference**

If the action reference is *higher* than the national project reference, the exceeding part is additional remuneration:

{total additional remuneration = difference between the two reference rates * number of hours worked on the action}

{total basic remuneration = national project reference rate * number of hours worked on the action}

If the action reference is *equal or lower* than the national project reference, there is no additional remuneration; the remuneration paid to the employee is all basic remuneration.

Example personnel costs with additional remuneration (Part 1 of 3):

1. *Ms R is employed full-time as professor at University X. She has a basic annual gross salary of EUR 24 000. The internal rules of the university provide that professors involved in research projects financed by external funders can get up to EUR 6 000 per month of full dedication to the project. However, due to budgetary restrictions the maximum that has been paid to any professor in a national project was EUR 4 800. Ms R worked in 2017 for the H2020 action 200 hours. For those hours she received an extra salary of EUR 6 500. She also participated in other projects*

generating other extras for her. So, her total gross annual salary was EUR 36 000. The hourly rate for the H2020 action is as follows:

The salary of Ms R varies depending on her participation in certain projects. Therefore, the beneficiary must assess if any part of that salary qualifies as additional remuneration. For that, it must compare the action reference with the national project reference:

Action reference rate = basic salary corresponding to the 200 hours worked for the action ((24 000 / 1720) x 200 = 2 790,70 €) + bonus paid for the action (6 500 €) = 9 290,70 € / 200 (hours worked in the action) = 46,45 €/hour (hourly rate)

National project reference rate (in this example based on the internal rules of the university applicable to national projects) = maximum salary paid for any professor working in a national project in accordance with the internal rules = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

The Action reference (i.e. 46,45) is higher than the national project reference (i.e. 33,49). The excess (46,45 – 33,49 = 12,96 €/hour) qualifies as additional remuneration. Therefore:

The total basic remuneration = 33,49 €/hour x 200 (hours worked in the action) = 6 698 €

The total additional remuneration = 12,96 €/hour x 200 (hours worked in the action) = 2 592 €

(This example continues here for the calculation of the hourly rate)

***2.** Same situation as above, but in this case the work in the action has been done under a supplementary employment contract covering additional working hours (on top of the full-time contract of the professor).*

Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour

National project reference rate = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour

In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary is NOT paying additional remuneration.

The total basic remuneration = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 2 — **Calculation of the hourly rate (for each employee; on the basis of basic remuneration)**

The beneficiary must then calculate the hourly rate to be charged to the action for the employee:

- **If** there is **additional remuneration**, the beneficiary must calculate the hourly rate using only the basic remuneration. In practice, this will be the action reference, capped at the national project reference (i.e. the hourly rate will normally be equal to the national project reference rate).

  Example personnel costs with additional remuneration (Part 2 of 3):

  ***1.** Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of 9 290,70 €. In the calculations made in part 1 of the example we identified that 2 592 € qualify as additional remuneration.*

  The hourly rate applicable to the action will be, therefore:

  (Actual annual personnel costs for the action - additional remuneration) / hours worked in the action over the year = (9 290,70 € - 2 592 €) / 200 = 33,49 €/hour.

  Personnel costs resulting from the hourly rate = 33,49 €/hour x 200 = 6 698 €.

  (This example continues here for the eligibility of additional remuneration)

- **If** there is **NO additional remuneration** (i.e. all is basic remuneration), the beneficiary can simply use the action reference as hourly rate to charge to the H2020 action.

  Example personnel costs without additional remuneration (Part 2 of 3):
  Ms R worked 200 hours over the financial year in the action. For that time she received a remuneration of EUR 6 500 through an additional contract.
  Action reference rate = 6 500 € (remuneration of the supplementary employment contract) / 200 hours (covered by that supplementary contract) = 32,50 €/hour
  National project reference rate = 4 800 € / (1720 annual productive hours / 12 months) = 4 800 € / 143,33 hours = 33,49 €/hour
  In this case, the action reference (i.e. 32,50) is lower than the national project reference (i.e. 33,49). Therefore, the beneficiary must use the action reference as hourly rate to charge to the H2020 action:
  Total personnel costs to be declared = 32,50 €/hour x 200 (hours worked in the action) = 6 500 €.

Step 3 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount of basic remuneration that can be charged to the action *(see examples in Step 2 above)*.

Step 4 — **For non-profit legal entities: addition of the additional remuneration (if any)**

If the beneficiary is a non-profit entity and the payments that are additional remuneration are eligible, it may also declare them to the action.

If the resulting amount (for the year) is above the **8000 EUR ceiling**, it must be capped:

Occupation	Contract	
	hired full time during the entire year	NOT hired full time during the entire year
working exclusively for the EU action during the full financial year	**EUR 8 000**	pro-rata amount of EUR 8 000
NOT working exclusively for the EU action during the full financial year	{8 000 / annual productive hours FTE} * hours worked for the action over the year	

The ceiling is *fixed* at EUR 8 000 per year for each full time equivalent (FTE), i.e. EUR 8 000 for a **full-time employee working exclusively for the action during the entire year**.

This ceiling covers not only the additional payment (bonus) but also the additional taxes, costs and social security contributions triggered by the additional payment.

For an **employee working exclusively for the action but not hired full time during the entire year**, the ceiling is reduced pro-rata.

Examples:

1. *A researcher employed part time by the beneficiary to work four days a week during the entire year would correspond to 0.8 FTE ➔ the ceiling would be fixed at EUR 8 000* 0,8 = EUR 6 400 per year.*

2. *A researcher employed full time to work for the action from January to March (i.e. for three months) would correspond to 0.25 FTE (3 out of 12 months) ➔ the ceiling would be fixed at EUR 8 000 * 0,25 = EUR 2 000.*

*If the researcher was employed part time (e.g. 80 %) ➔ the ceiling would be adjusted as follows: 8 000 * 0,25 * 0,80 = EUR 1 600.*

For **an employee not working exclusively for the action**, the ceiling is *calculated pro-rata*, based on the hours worked for the action. Therefore, additional remuneration is eligible up to a maximum of:

$$\frac{\text{EUR 8 000}}{\text{annual productive hours of an FTE}} \times \text{hours worked by the employee for the action over the year}$$

Example personnel costs with additional remuneration (Part 3 of 3):

1. *Ms R worked 200 hours over the financial year. For that work she received 6 698 € of basic remuneration and 2 592 € of additional remuneration.*

If the beneficiary is a for-profit legal entity, the 2 592 € of additional remuneration would be automatically ineligible. The personnel costs which the beneficiary can charge to the action would be therefore 6 698 €.

If the beneficiary is a non-profit legal entity, additional remuneration may be eligible up to the ceiling. To calculate the eligibly part, you need to determine the pro-rata of the cap which corresponds to the 200 hours worked for the action:

(8 000 / 1 720) x 200 = 930,23 €

Although the beneficiary paid 2 592 € of additional remuneration, only 930,23 € are eligible. The difference (2 592 – 930, 23 = 1 661,77 €) is ineligible, since it exceeds the ceiling.

Therefore, the personnel costs which the beneficiary could charge to the action would be: 6 698 € of basic remuneration + 930,23 € of additional remuneration = 7 628,23 €.

For case 2 beneficiaries (unit costs in accordance with the usual cost accounting practices): 2 steps

Step 1 — **Calculation of the hourly rate (for each employee)**

The beneficiary can use the hourly rate(s) that it uses normally (usual cost accounting practices) as average personnel costs, provided that:

- the cost accounting practices are applied in a **consistent** manner, based on objective criteria, regardless of the source of funding
- the hourly rate is calculated using the **actual personnel costs recorded** in the beneficiary's **accounts**, excluding any ineligible cost or costs already included in other budget categories and
- the hourly rate is calculated using one of the **three options** provided in the MGA for the number of **annual productive hours** *(e.g. option 3 'standard annual productive hours')*.

The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

This does not mean that cost accounting practices must be the *same* for all types of employees, departments or cost centres of the beneficiary. If, for instance, the beneficiary's usual cost accounting practices include different calculation methods for permanent personnel and temporary personnel, this is acceptable. However, the beneficiary cannot use different methods for specific research actions or projects on an ad-hoc basis.

Example (acceptable usual cost accounting practices): *Individual (actual) personnel costs are used for researchers, average personnel costs (unit costs calculated in accordance with the beneficiary's usual cost accounting practices) are used for technical support staff.*

Example (unacceptable usual cost accounting practices): *Average personnel costs are used to calculate costs in externally-funded projects only.*

If necessary, the hourly rate must be adjusted to remove:

- cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the hourly rate).

  Example: *A beneficiary calculates the hourly rate in accordance with its usual cost accounting practices and includes taxes not included in remuneration. These are ineligible and must therefore be removed from the hourly rate declared for personnel working on the action.*

- costs that are already included in other budget categories (double funding of the same costs;

  Example: *Beneficiaries whose cost accounting practices include for the calculation of the hourly rate indirect costs under Article 6.2. These indirect costs must be removed from the pool of costs used to calculate the hourly rate charged to H2020 actions. In H2020*

actions, indirect costs must be declared using a flat rate of 25 %, so personnel costs cannot include any indirect costs.

Budgeted or estimated elements used to calculate the hourly rate can only be accepted if they:

- are relevant, i.e. clearly related to personnel costs
- are used in a reasonable way (i.e. do not play a major role in calculating the hourly rate)
- correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

Example: *Calculating average 2014 hourly rates by using 2013 payroll data and increasing them by adding the CPI (consumer price index) on which the basic salaries are indexed.*

Beneficiaries may request the **approval of the methodology** used by them, by submitting (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu) an audit certificate on their usual cost accounting practices *(see Article 18.1.2(b) and Annex 6)*. Costs declared in line with an approved methodology will not be challenged subsequently (unless the beneficiaries concealed information for the purpose of the approval).

Step 2 — **Multiplying the hourly rate by the hours worked on the action**

After that, the hourly rate for the employee must be multiplied by the number of hours s/he actually worked on the action and this gives the amount that can be charged to the action.

Specific cases (direct personnel costs for employees (or equivalent) (A.1)):

Persons working exclusively on the action — There is NO different calculation method for staff working 100 % on the action. (The percentage of time dedicated to the action does NOT make a difference for the way how personnel costs must be calculated; it matters only for the types of records that must be kept *(see Article 18.1.2)*). Therefore, the calculation method for personnel costs of Article 6.2.A (as chosen by the beneficiary) applies.

Since there is no obligation to keep time-sheets for periods covered by a declaration on exclusive work, beneficiaries should report:

- for annual hourly rates: a pro-rata of the annual productive hours corresponding to the period covered by the declaration (at the annual hourly rate)
- for monthly hourly rates: 1/12 of the annual productive hours for each month actually worked for the action in the period covered by the declaration (at the monthly hourly rate).

Example:

1a *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its actual annual personnel costs were EUR 32 000 for 2014 and EUR 34 400 for 2015. The beneficiary applies 1720 as annual productive hours and calculates annual hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate		*Hours worked for the project*	
2014 ➔	*(32 000 / 1720)*	*x*	*[(1720 / 12 months) x 3 (Oct, Nov, Dec)]*	
	18,60	*x*	*430*	*= 8 000*
2015 ➔	*(34 400 / 1720)*	*x*	*1720*	
	20	*x*	*1720*	*= 34 400*
2016 ➔	*The financial year is not completed so we use the 2015 hourly rate*			
	20	*x*	*[(1720 / 12 months) x 3 (Jan, Feb, Mar)]*	*= 8 600*
			TOTAL	*= 51 000*

1b *Researcher Y worked exclusively in the action during the reporting period running from 1.10.2014 to 31.03.2016. Its monthly personnel cost were 2 666,66 EUR in 2014, 2 860 EUR from January 2015 until October 2015 and 2 900 EUR from then on. The beneficiary applies 1720 as annual productive hours and calculates monthly hourly rates.*

The personnel cost to be reported would be calculated as follows:

	Hourly rate	*x*	*Hours worked for the project =*	*Total*
2014➔				
October	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 666*
November	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 666*
December	*{[2666 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 666*
			Total	*= 8 000**
2015 ➔				
January	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
February	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
March	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
April	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
Mai	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
June	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
July	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
August	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
September	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
October	*{[2860 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 860*
November	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 900*
December	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 900*
			Total	*= 34 400*
2016➔				
January	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 900*
February	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 900*
March	*{[2900 EUR /(1720/12)]*	*x*	*(1720/12)} =*	*2 900*
			Total	*= 8 700*
			TOTAL	*= 51 100*

* *Decimals have been rounded*

If the declaration covers months in which the person was **absent** for more than half of the working days those months can NOT be taken into account to calculate the hours worked in the action (— unless the absence is linked to annual leave AND the duration does not exceed the pro-rata of annual leave entitlements corresponding to the period covered by the declaration).

Example:

1. *Researcher Y worked exclusively in the action from1 July 2014 to 31 October 2014. In August it took three weeks of holidays and in September it was 10 days on sick leave. The beneficiary applies 1720 as annual productive hours*

Number of hours that can be charged to the action based on the declaration = 3 months (July, September and October) x (1720 / 12) = 3 x 143,33 = 430 hours

August is not taken into account because the person was absent more than half of the working days, since s/he took three weeks of holidays.

2. *The person has the right to two working days of annual leave per month worked. The period covered by the declaration is from January to September (i.e. 9 months). Therefore, the leave entitlement of the person for that period is 9 x 2 = 18 working days. The person takes 3 weeks of annual leave in August. August could also be counted because the leave taken (i.e. 15 working days) is less that the leave entitlement for that period (i.e. 18 working days).*

Employees hired during on-going financial year (at the end of the reporting period) **—** Since these employees did not work for the beneficiary during the last financial year, the annual hourly rate can only be calculated on the basis of the personnel costs incurred during the ongoing financial year.

Example: *The reporting period runs from 1.10.2014 to 31.03.2016. The beneficiary hires a new employee on 1.2.2016 ➔ the hourly rate would be calculated taking into account his/her personnel costs for February and March 2016.*

In order to avoid calculation errors, it is particularly important to determine the pro-rata of the annual productive hours correctly *(e.g. if option 1 - 1 720 fixed hours are used, the productive hours for the period February-March would be 1 720 /12 * 2 = 286,66; if option 2 -individual annual productive hours- is used, the productive hours for the period February-March would be the actual productive hours for the period February-March; if option 3 – standard annual productive hours - is used, the productive hours for the period February-March would be the standard annual productive hours/12*2)*.

End-of-contract indemnities — Since the entitlement to end-of-contract indemnities is most often generated over a period of time longer than a financial year, the beneficiary may charge the indemnity in the reporting period in which the employee's contract ends — but outside the hourly rate (i.e. separately and on top of the personnel costs declared on the basis of the hourly rate) AND only for the part that corresponds to the time worked by the person on the action (i.e. pro-rata of the total time during which the entitlement was generated).

Moreover, the indemnity can be accepted ONLY if it:

- arises from the applicable national labour law and
- is recorded in the accounts of the beneficiary and
- is incurred during the action duration (although the actual payment may take place latter).

Employment contract remunerated per hour — For employment contracts that do not establish a fixed salary and a number of hours to be worked but only an amount to be paid for each hour worked by the employee, individual annual productive hours (i.e. option 2) can only be applied if all of the following conditions are fulfilled:

- the employment contract explicitly fixes the hourly rate to be paid
- the employment contract established that the salary is the result of multiplying the hourly rate by the number of hours worked
- the total salary paid under the employment contract is identifiable and supported by auditable documents *(e.g. payslips and declarations to the tax authorities)*
- the employment contract is the only contract between the person and the entity (i.e. there is no other parallel contract).

If those conditions are fulfilled, the individual annual productive hours can be calculated as follows:

{total salary paid to the employee in the financial year

divided by

hourly rate fixed in the employment contract}.

This summary table explains the three **different options** for **annual productive hours (for case 1A and case 2 beneficiaries)**:

Options	What does it mean?	When can it be used? How should it be used?	What happens if you make a mistake?
Option 1 **1 720 fixed hours**	The number of hours is fixed for full-time employees (and it is pro-rata for employees working part-time or working only part of the year for the beneficiary).	Can be used **in all cases**; any beneficiary can use this option. A pro-rata of 1720 hours can be used if: – the employee has not worked the full year for the beneficiary or – the employee's contract explicitly states (or allows to determine) a precise percentage of a full time equivalent (FTE) covered by such contract. ***Examples (pro-rata calculations):*** ***1.*** *Researcher X worked for Beneficiary Z from 1 October to 31 December; i.e. 3 full months. The pro-rata of the annual productive hors would be calculated as follows:* *1720 / 12 (months) * 3 (October, November, December) = 430 productive hours* ***2.*** *The contract of Researcher Y with Beneficiary Z establishes that it must work 20 hours per week, while a full-time employee at Beneficiary Z works 40 hours per week. Working days and leave entitlements are the same. The annual productive hours would be calculated as follows:* *1720 * [20 hours (Researcher Y) / 40 hours (full-time employee)] = 1720 * 50 % (part-time percentage) = 860 productive hours*	
Option 2 **Individual annual productive hours**	The number of hours is calculated on the basis of the 'annual workable hours' of the employee (i.e. the total number of hours for which a employee is working for the beneficiary, including the overtime worked and absences *(such as sick leave or other types of special leave)*.	This option can be used, if: – the number of 'individual annual productive hours' is calculated according to the formula specified in the GA {annual workable hours of the person (according to the employment contract, applicable labour agreement or national law) plus overtime worked	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the calculation method was not consistently applied *(e.g. the beneficiary used option 2 for one employee and option 3 for another employee employed under similar conditions)*: the auditors will adjust the number of annual productive hours by

		minus
		
		absences (such as sick leave and special leave)}
		
		– the 'annual workable hours' are established according to one of the following:
		
		  – employment contract of the person concerned
		
		  – applicable collective labour agreement
		
		  – national law on working time.
		
		  Example: *contract stipulating 35 hours of work per week*
		
		– this calculation method is consistently applied (per group of personnel under similar conditions).
		
		Example for calculation of individual annual workable hours:
		
		X is a full-time researcher (working eight hours per day, from Monday to Friday) at Research Centre Z. X's contract includes 22 working days of annual leave, plus 8 days of public holidays. In the financial year covered by the reporting period in question, X worked 29 hours of overtime and was on sick leave for 5 days.
		
		The individual annual workable hours would therefore be:
		
		365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) = 231 days x 8 hours per day = 1 848 hours
		
		Individual annual productive hours for Researcher X:
		
		Annual workable hours = 1 848
		
		+ overtime (hours) = 29
		
		- annual sick leave (5 days x 8 hours) = 40
		
		➔ individual annual productive hours for Researcher X = 1 837
		
		Research Centre Z may use 1 837 as individual annual productive hours for this researcher.
		
		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of individual annual workable hours.
			applying option 2 to all persons concerned, where possible.
			
			– if the employment contract, applicable collective labour agreement or national working time legislation does not allow to determine the number of individual annual workable hours: the auditors will apply option 1.
			
			– if not *all* annual workable hours were included, the auditors will recalculate the productive hours to include all workable hours.

Option 3 **Standard annual productive hours**	The number of hours is calculated on the basis of the 'standard annual productive hours' generally applied by the beneficiary for its personnel, in accordance with its usual cost accounting practices. The standard annual productive hours may be calculated for the entity as a whole, per category of personnel, per cost centre, etc. The beneficiary may include or exclude certain activities *(e.g. general training, general meetings etc.)* when calculating the standard annual productive hours, if this is in line with its usual cost accounting practices.	This option can be used if: – the number of standard annual productive hours is calculated in accordance with the beneficiary's usual cost accounting practices – this calculation method is consistently applied (per group of personnel under similar conditions) – the number of standard annual productive hours is at least 90% of 'standard annual workable hours' The standard annual workable hours is the standard number of hours that a full time employee of the group having the same standard productive hours ('reference group', *e.g. a category of employees, employees of a cost centre, etc.*) must be present at work under normal circumstances, as defined in: – the employment contracts of the reference group – an applicable collective labour agreement or – the national law on working time. If its number of standard annual productive hours is **higher** than 90%, the beneficiary must use the number of standard annual productive hours. If its number of standard annual productive hours is **lower** than 90%, the beneficiary must use the 90% or choose one of the other options. ***Example for calculation of standard annual workable hours:*** *Full-time researchers hired by Research Centre Z have an employment contract that states that they must work eight hours per day, from Monday to Friday. National legislation provides for 22 working days of annual leave, plus eight days of public holidays. The applicable collective labour agreement adds three extra days of annual leave.* *The standard annual workable hours for Research Centre Z would*	If our the auditors find that a beneficiary made a mistake, the Commission/Agency will recalculate the eligible costs as follows: – if the standard annual productive hours were calculated not in accordance with the beneficiary's usual cost accounting practices, the auditors will adjust the number of annual productive hours by applying option 2, if possible; – if the calculation method was not applied consistently, the auditor will adjust the number of annual productive hours by applying option 2, if possible; – if there is no applicable reference for the standard annual workable hours, the auditors will apply option 1; – if the number of standard annual productive hours used by the beneficiary was lower than 90% of standard annual workable hours, the auditor will use either the 90% of workable hours or option 1, whichever is more favourable for the beneficiary. – if the two first indents in the middle column (number calculated in accordance with usual accounting practices AND calculation method consistently applied) are fulfilled but the beneficiary uses 90% of standard annual workable hours instead of the number of annual productive hours arrived at by using its usual accounting practices (higher than 90%), the auditor will adjust the number of productive

		therefore be: *365 days — 104 days (Saturdays and Sundays) — 22 days (annual leave) — 8 days (public holidays) — 3 days (collective agreement) = 228 days * 8 hours per day = 1 824 hours* *Standard annual productive hours for Research Centre Z:* *Research Centre Z would like to use its usual cost accounting practices to calculate the hourly rates for EU actions. It calculates the number of standard annual productive hours as follows:* *Annual working days = 228* *- average annual sick leave (days) = 3* *- days of general training = 4* *- other unproductive activities (days) = 9* *➔ productive days = 212* *Multiplied by 8 working hours per day* *➔ standard annual productive hours = 1 696* *This number of standard annual productive hours must then be compared with 90% of standard annual workable hours (in this example 1 824).* *90% of 1824 = 1 642* *1 696 hours (usual cost accounting practice) > 1 642 hours (90% annual workable hours)* *Research Centre Z may apply its number of standard annual productive hours (i.e. 1 696) to EU actions since the number is higher than 90% of annual workable hours.* *If its number of standard annual hours is lower than 1 642 (e.g. 20 days of other unproductive tasks instead of 9 ➔ 1 608 annual productive hours), Research Centre Z must apply 1 642 hours (90% of the annual workable hours).* *If its number of standard annual productive hours is higher than 90% (in our example it is 93%: 1 696/1 824), Research Centre Z must use this number (and not 90% of annual workable hours).*	hours to the higher number. – If the standard annual productive hours is 90 % of the standard annual workable hours the auditor will not challenge that amount if the amount is in accordance with the usual cost accounting practices of the beneficiary and the calculation method is consistently applied.

		⚠ This option can NOT be used if the employment contract, collective labour agreement or national law does not allow to determine the number of annual workable hours for the group of personnel. ***Example (no applicable reference for standard annual workable hours):*** *A researcher carries out research for the beneficiary for a fixed salary per month. However, the employment contract does not allow to determine the number of hours to be worked. There is no applicable collective agreement and national legislation does not regulate the number of workable hours per year for this type of labour agreement.* *In this case, there is no applicable reference for standard annual workable hours. Therefore, the beneficiary must use option 1 (1 720 fixed hours).*	

1.2 Direct personnel costs: Natural persons with direct contract (A.2)

1.2.1 **What?** This budget category **covers** typically the costs of **in-house consultants** and similar persons (i.e. **self-employed *natural* persons**) that worked on the action for the beneficiary under conditions similar to those of an employee, but under a contract which is NOT legally the same as for employees. It regards, in particular, contracts qualified as quasi-subordinate work contracts under national law when the conditions under which the work is carried out are similar to those of an employee.

What not? Staff provided by another entity against a price, including staff provided by a temporary work agency (because in this case there is no direct contract between the person and the beneficiary; the contract is not with the beneficiary but with the entity hiring the person).

> **Staff provided by a temporary work agency —** A contract with a temporary work agency qualifies typically as purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it would be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

1.2.2 Costs for natural persons working under a direct contract may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs; *see Article 5.2(a)*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- there must be a **direct contract** between the natural person (individual) and the beneficiary

  The contract cannot be with a third party legal entity *(e.g. a temporary work agency),* even if that third party is a one-person company.
- the person must work **under conditions similar to those of an employee,** in particular:

> ⚠ **Similar does not mean equal —** The working conditions of the person do NOT have to be exactly the same that those of an employee, but overall similar.

  - the beneficiary must organise and supervise the work of the person in a way similar to that of its employees

    Example (acceptable):

    The beneficiary's project leader and the person discuss regularly the work to be carried out for the action. The project leader decides the tasks and timing of the work and instructs the person accordingly.

    Example (not acceptable):

    The beneficiary's project leader and the person meet only once a month or irregularly, for updates on the state of play of the entrusted work. If changes are needed, they have to be agreed by the person and may lead to a change of the amount charged to the beneficiary.

  - the beneficiary must be able to ensure reliable time recording (for the hours that the person works for the action)

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

– the person is subject to similar presence requirements as the employees.

Examples (acceptable):

The person works physically at the beneficiary's premises, following a time schedule similar to that of the employees (e.g. the beneficiary authorises up to two days of teleworking per week to its personnel and the person has chosen to benefit from this regime, i.e. works 2 days in teleworking and 3 days physically at the beneficiary's premises).

Example (not acceptable):

The entity authorises up to two days of teleworking per week. However, the person works four days in teleworking and only one day at the beneficiary's premises.

- the **result** of the work carried out (including patents or copyright) must in principle **belong to** the **beneficiary**

  If (exceptionally) they belong to the person, the beneficiary must (just like for employees) obtain the necessary rights from the person (transfer, licences or other), in order to be able to respect its obligations under the GA *(see Article 26.3)*.

- **not** be **significantly different** from costs for employees performing similar tasks

  The remuneration must be based on working time, rather than on delivering specific outputs/products.

1.2.4 Costs of natural persons working under a direct contract for a beneficiary must be **calculated** according to the same **rules** as explained in point 1.1.4 (i.e. hourly rate multiplied by the number of actual hours worked on the action).

However, for the **actual costs hourly rate**, the beneficiaries must use one of the following options:

– if the contract specifies an hourly rate: this hourly rate must be used

– if the contract states a fixed amount for the work and the number of hours to be worked: the global amount for the work must be divided by the number of hours to be worked

– if the contract states a fixed amount for the work but does not specify the number of hours to be worked: the global amount for the work must be divided by the pro-rata of 1 720 annual productive hours which corresponds to the duration of the contract over the financial year.

Example: *The contract provides that the person will work at the beneficiary's premises for assisting in research tasks. The contract is for 6 months starting on 1 January 2017 and ending on 30 June 2017. According to its time records, the person worked 500 hours in the H2020 action over that period. The contract sets a monthly payment of EUR 3 000 but does not explicitly establish the number of hours to be worked.*

Personnel costs for the action = hourly rate x 500 (hours worked in the action)

Hourly rate = annual personnel costs / annual productive hours = (3 000 € x 6 months) / (1 720 hours x (6 months/12 months)) = 18 000 € / (1 720 x 0,5) = 18 000 € / 860 hours = 20,93 €/hour

Personnel costs for the action = 20,93 x 500 = 10 465 €.

Social security contributions which are mandatory under national law may be included in the calculation of the hourly rate.

For the **unit costs** hourly rate (average personnel costs), the rules in point 1.1.4 apply without any changes.

This summary table explains how to treat **different types of work contracts** for declaring costs under H2020[16]:

Characteristics of the contract	**Contract remunerating time** *(e.g. the contract establishes that the person must work for the beneficiary 40 hours per week)*	**Contract not specifying the working time conditions** *(e.g. the contract establishes the tasks, but the time to be worked (hours) is not defined in the contract, collective labour agreement or national law)*
The contract is an employment contract, i.e.: – recognized as such by the national labour law AND – the hiring entity pays social security contributions for the hired person	**CASE A** **This is the standard situation**. The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4): ➔ The beneficiary may choose among the three options for annual productive hours to calculate the hourly rate.	**CASE B** The costs may be declared in category A.1 'employees (or equivalent)' (Article 6.2.A.1). They must be calculated as described in Article 6.2.A. Calculation (point 1.1.4); however: ➔ Only option 1 (i.e. 1720 fixed annual productive hours) can be used to calculate the hourly rate. ➔ If the employment contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720. ***Example:*** *Contract from 01.01.2015 to 31.03.2015. Annual productive hours = (1720/12) x 3 (Jan, Feb, Mar) = 430*
Other contract (i.e. not an employment contract)	**CASE C1:** the costs fulfil the conditions of Article 6.2.A.2. The costs may be declared in category A.2 'natural persons with direct contract' (Article 6.2.A.2). The costs must be calculated as described in point 1.2.4. **CASE C2:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A. 'personnel costs'. They must be treated like CASE D1.	**CASE D1:** the costs do NOT fulfil the conditions of Article 6.2.A.2. The costs can NOT be declared in category A 'personnel costs'. However, they may be eligible under another budget category: – if the contract covers tasks described in Annex 1: in category B 'subcontracting' (Articles 6.2.B and 13) or – in category D.3 'other goods and services' (Articles 6.2.D.3 and 10). ⚠ The beneficiary must award the contracts ensuring best value for money and avoiding any conflict of interests *(see Articles 10 and 13)*.

[16] These explanations do NOT apply to **SME owners** or **beneficiaries that are natural persons** not receiving a salary *(see Article 6.2.A.4 and 6.2.A.5)*.

		CASE D2: the costs fulfil the conditions of Article 6.2.A.2. The costs can be declared in category A 'personnel costs'. They must be calculated as described in Article 6.2.A. Calculation (point 1.2.4); however: ➔ Only option 1 (i.e. 1720 fixed annual productive hours) can be used to calculate the hourly rate. ➔ If the contract does not cover the full financial year, the annual productive hours must be calculated as a pro-rata of 1720.

1.3 Direct personnel costs: Seconded personnel (against payment) (A.3)

1.3.1 **What?** This budget category **covers** the costs of persons that worked on the action and that were **seconded** by a third party as an in-kind contribution ***against payment*** *(see Article 11)*.

What not? Persons provided by a temporary work agency, secondment of staff between beneficiaries (or linked third parties) in the same grant or secondment by a third party free of charge.

Staff provided by a temporary work agency — A contract with a temporary work agency qualifies typically as a purchase of services (unless the temporary work agency carries out directly some task of the action — in which case it can be considered as subcontracting). Thus, although NOT eligible as personnel costs, the costs can be charged under other budget categories (i.e. D.3 other goods and services or B. subcontracting), if they comply with the eligibility conditions (especially best value for money and no conflict of interest; see *Articles 10 and 13*).

Secondment of staff between beneficiaries (or linked third parties) — Is allowed, but it is the beneficiary/third party who employs the person who has to declare its costs (NOT the beneficiary/third party to whom the person has been seconded). The costs declared must be supported by reliable time records of the number of hours the person worked for the action. Those time records must be produced under the responsibility of the beneficiary/third party to whom the person is seconded

Persons seconded free of charge — Costs for persons seconded free of charge (i.e. the third party's costs) can be declared as personnel costs by the beneficiary, if they fulfil the conditions of Articles 6.4 and 12.

> For information on in-kind contributions provided by third parties *free of charge, see Articles 6.4 and 12.*

1.3.2 Costs for persons seconded by a third party may be **declared** ONLY as **actual costs**.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- the person must be **seconded**

  'Seconded' means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.

  Example: *A researcher in a public research centre is seconded to work in a university that is a beneficiary in a GA.*

  Best practice: Secondments should be formalized via a secondment agreement. The secondment agreement has to detail the conditions of secondment *(tasks, payment (or not) from one entity to the other, duration of the secondment, location, etc.)*.

  A secondment normally requires the seconded person to work at the beneficiary's premises, although in specific cases it may be agreed otherwise in the secondment agreement.

- the beneficiary must **reimburse the costs** to the third party (i.e. not for free)
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.3.4 There is no specific **calculation** method; the costs must correspond to the price paid by the beneficiary — up to the costs actually incurred by the third party *(see Article 11.1*).

For the calculation of the upper limit (i.e. the third party's actual costs), the same calculation rules apply as in point 1.1.4.

⚠ **Record-keeping —** The beneficiary must keep records of the hours which the seconded person worked for the action *(e.g. time-sheets etc.; see Article 18.1.2)*.

1.4 Direct personnel costs: SMEs owners & natural persons not receiving a salary (A.4 & A.5)

1.4.1 What? These budget categories **cover** the costs of SME owners and beneficiaries that are natural persons which work on the action, but **don't receive a salary**.

This includes SME owners who are remunerated/compensated for their work for the SME by any other means than a salary *(for example, dividends, service contracts/other non-employment contracts between the company and the owner, etc.)*.

What not? SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless s/he can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action). (In this case, the salary for the management of the SME cannot be declared.)

1.4.2 These costs must be **declared as** the unit cost (hourly rate) fixed by Commission Decision C(2013) 8197[17] and set out in Annex 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; the 'amount per unit' (hourly rate) must be calculated for each individual — before signature of the GA — according to the following formula:

Amount per unit = {{EUR 4 650 or 4 880* /143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}}

The country-specific correction coefficient is the one set out in the *H2020 Work Programme (section 3 MSCA)*[18] in force at the time of the call.

*EUR 4 650 for calls under Work Programmes 2014-2015 and 2016-2017 and EUR 4 880 for calls under Work Programme 2018-2020.

Example: *A German SME owner not receiving a salary will calculate the hourly rate as follows:*

EUR 4 650/143 * 98.8% = *EUR 32,13/hour*

In practice, the declaration of costs for SME owners and beneficiaries that are natural persons is very simple and almost completely automatized: The beneficiaries must only indicate the number of hours worked on the action and the costs are then automatically calculated by the IT system.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation etc.; *see Article 6.1(b)*)
- be declared for an **SME owner/beneficiary that is natural person**, who works on the action but does not receive a salary.

  The owner may be compensated by means such as dividends, service contracts between the company and the owner, etc.

[17] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf
[18] Available at http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html

The Commission/Agency may verify that the beneficiary fulfils the conditions for using this unit cost.

1.4.4 The **cost** are **calculated** (automatically by the IT system) as follows:

amount per unit (hourly rate; *see Annex 2a GA*) **x** number of actual hours worked on the action

⚠ **Ceiling** — The **total number of hours** declared in EU and Euratom grants **for an SME owner for a year** (i.e. a financial year) can NOT be higher than 1 720.

1.5 Direct personnel costs: Access to research infrastructure personnel costs (A.6)

1.5.1 **What?** This budget category **covers** the personnel costs for access to infrastructure activities, i.e. normally:

- costs for employees (or equivalent)
  - basic remuneration and
  - for non-profit legal entities: additional remuneration
- costs for natural persons with direct contract and
- costs of seconded personnel (against payment).

1.5.2 Personnel costs for providing trans-national or virtual access to research infrastructure may be **declared as:**

- **actual costs** (most common case)

OR

- **unit costs** in accordance with the usual cost accounting practices (average personnel costs) *(see Article 5.2(a))*.

1.5.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a) and (b)*)
- fulfil the specific conditions for costs for employees (or equivalent), costs for natural persons working under a direct contract or costs of personnel seconded by a third party against payment
- be incurred for providing **trans-national** or **virtual access** to research infrastructure
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.5.4 The same **calculation rules** apply as in points 1.1.4, 1.2.4 and 1.3.4.

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Direct costs of subcontracting (B.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** (and is limited to) the price paid for subcontracts and related taxes *(for VAT, see Article 6.5)*.

1.2 Direct costs of subcontracting must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(b))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **subcontracting of action tasks** described in Annex 1 *(see Article 13)*
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1
- for subcontracting costs incurred for providing trans-national or virtual access to research infrastructure: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (subcontracting costs (B.)):

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency may exceptionally have to be declared under category B 'subcontracting' (instead of category D.3 'other goods and services') if the temporary work agency carries out directly some task of the action (provided they comply with the eligibility conditions).

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)]***

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

1. Direct costs of providing financial support to third parties (C.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category (together with the corresponding *Article 15* and other provisions) will be inserted into the GA if the action also involves financial support to third parties.

1.1 What? This budget category **covers** the costs for the financial support given to third parties.

1.2 Direct costs of providing financial support to third parties must be **declared as** actual costs (i.e. on the basis of the financial support actually paid) *(see Article 5.2(c))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

1. Travel costs and related subsistence allowances (D.1): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional option for access to trans-national research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the travel costs and related subsistence allowances (including all related duties, taxes and charges that the beneficiary has paid, if including them is part of the usual practices for travel, *e.g. non-deductible VAT; see Article 6.5*) spent for the action.

> **Best practice:** Beneficiaries may contact the Commission/Agency to ask whether a particularly expensive travel plan would be accepted or not.

Travel and subsistence costs relate to the personnel of the beneficiaries. They may also relate to experts that participate in the action on an ad hoc basis *(e.g. attending specific meetings),* if:

- the experts' participation is foreseen in Annex 1 or
- their participation is specifically justified in the periodic technical report and the Commission/Agency approved it without formally amending the GA (simplified approval procedure).

The beneficiary may reimburse the experts or handle the travel arrangements itself (and be invoiced directly). There is no distinction between travelling in- or outside Europe.

1.2 Travel and subsistence costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

  The travel for which costs are claimed must be necessary for the action *(e.g. to present a paper explaining the results of a conference)*. Travel costs related to an event at which the beneficiary carried out work that was not specifically related to the action are NOT eligible.

  All travel costs must be limited to the needs of the action; costs related to extensions (for other professional or private reasons) are NOT eligible.

  Moreover, they must be adequately recorded.

- be in line with the beneficiary's **usual practices on travel**

***Example*:**

Beneficiary A declares the cost of a business class airplane ticket for one of its employees.

If the beneficiary usually pays for staff in this category to travel in business class, then the cost of the business class ticket is eligible.

If the beneficiary's usual practice is to only pay for economy class tickets for staff in this category, then the cost of the business class ticket is not eligible.

If the beneficiary reimburses travel and/or subsistence allowances as a lump sum/*per diem* payment, it is the lump sum/*per diem* amount that is considered an eligible cost, NOT the actual prices paid by the person receiving the lump sum or *per diem*. (For the purposes of the grant, these lump sum/per diem costs remain actual costs, NOT unit or lump sum costs under Article 5.2. They must be recorded in the beneficiary's accounts and will be checked if there is an audit.)

- for travel and subsistence costs incurred for providing **trans-national access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1.

1.4 There is no specific **calculation** method; the costs must correspond to the eligible costs actually incurred.

Specific cases (travel costs (D.1)):

Combination with personal travels or travels for other purposes — The costs of a combined travel can be charged to the action — but ONLY up to the cost that would have been incurred if the travel would have been made exclusively for the action AND if:

- it is the usual practice of the beneficiary to pay for such travels *(e.g. travels combining professional and personal reasons)*
- it has been an actual cost for the beneficiary.

***Example*:**

The researcher flies from Madrid, where the beneficiary is established, to Prague for a project meeting. After the meeting, instead of flying back to Madrid, the researcher flies directly to New York to participate in an event not related to the action.
The beneficiary may charge to the action:

- *the cost of the flight from Madrid to Prague, and*
- *the part of the flight back from New York to Madrid up to the cost that it would have incurred for a flight back from Prague to Madrid after the end of the project meeting.*

⚠ **Record-keeping —** The beneficiary must keep evidence not only of the actual cost of the flight back, but also of the cost of the flight that the person would have taken if it would have returned directly after the end of the work for the action.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The **costs of equipment, infrastructure or other assets contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

***[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).]*

***[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).]*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.2): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

An option for full purchase costs will be inserted into the GA, if explicitly provided in the work programme/call.

The beneficiaries may declare the following **types of** equipment **costs** as 'other direct costs – equipment costs':

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **full purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs (D.2): Depreciation costs of equipment, infrastructure or other assets

1.1.1 What? This budget category **covers** the depreciation costs of equipment, infrastructure or other assets used for the action.

In some cases *(e.g. infrastructure)*, equipment costs may also include the costs necessary to ensure that the asset is in good condition for its intended use *(e.g. site preparation, delivery and handling, installation, etc.)*.

What not? If the beneficiary's usual practice is to consider durable equipment costs (or some of them) as indirect costs, these can NOT be declared as direct costs, but are covered by the 25 % flat rate for indirect costs *(see Article 6.2.E)*. Any depreciation declared as a direct cost under a H2020 action must be a direct cost under the beneficiary's cost accounting practices *(see Article 6.2.)*

1.1.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- have been **purchased** in **accordance with Article 10.1.1**
- be **written off** in accordance with the beneficiary's **usual accounting practices** and with **international accounting standards**.

  'International accounting standards' are an internationally recognised set of rules for maintaining books and reporting company accounts, designed to be compared and understood across countries.

  Example: *The IAS 16 (International Accounting Standards) or the International Financial Reporting Standards (IFRS), originally created by the EU and now in common international use.*

1.1.4 They must be **calculated** according to the following principles:

- the depreciable amount (purchase price) of the equipment must be allocated on a systematic basis over its useful life (i.e. the period during which the equipment is expected to be usable). If the equipment's useful life is more than a year, the beneficiary can NOT charge the total cost of the item in a single year (*see also 'cash-based accounting' below*)
- depreciated equipment costs can NOT exceed the equipment's purchase price
- depreciation can NOT be spread over a period longer than the equipment's useful life

- if the beneficiary does not use the equipment exclusively for the action, only the portion used on the action may be charged. The amount of use must be auditable

  Example: *A microscope was bought before the action started and was not fully depreciated. For 6 months in reporting period 1 it was used for the action for 50 % of the time and for other activities for the other 50 % of the time. Linear depreciation is applied according to the beneficiary's usual practices (depreciation over the expected period of use of the microscope): EUR 100 000 per year (EUR 50 000 for 6 months).*

  Costs declared for the project: EUR 50 000 (6 months of use) multiplied by 50 % of use for the action during those 6 months = EUR 25 000.

- the beneficiary can NOT charge depreciation for periods before the purchase of the equipment

  Example: *A microscope was bought on 1 December. The reporting period ends on 31 December and the financial year also ends on 31 December. The maximum depreciation that the beneficiary may charge is 1 month (from 1 to 31 December); i.e. 1/12 of the annual depreciation. This applies even if the beneficiary recorded in its accounts at 31 December a full year of depreciation for the item.*

The depreciation costs must be calculated for each reporting period.

Specific cases (equipment costs (D.2)):

Low-value assets — The full cost of a low value asset may be eligible in the year when it is purchased if:

- the full cost is recorded in the accounts of the entity as expenditure of that year (i.e. NOT recorded as an asset subject to depreciation)

and

- the cost of the asset is below the low-value ceiling as defined under national law (e.g. *national tax legislation)* or other objective reference compatible with the materiality principle

and

- the item is used exclusively for the action in the year of purchase.

  If the item is not used exclusively for the action in the year of purchase, only the portion used on the action may be charged.

Full price of an asset in one single year — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that correspond to the part of the equipment's use for the action. Declaring its *full* price in one single year would be considered either as not compliant with the international accounting standards or as an excessive cost — and therefore in both cases ineligible; *see 'cash-based accounting' below*).

Equipment bought before the action start — Depreciation costs for equipment used for the action, but bought before the action start are eligible if they fulfil the general eligibility conditions of Article 6.1(a). These remaining depreciation costs (the equipment has not been fully depreciated before the action's start) may be eligible only for the portion corresponding to the action duration and to the rate of actual use for the purposes of the action.

Example:

According to the beneficiary's accounting practices, a piece of equipment bought in January 2013 has a depreciation period of 48 months.
If the GA is signed in January 2015 (when 24 months of depreciation have already passed) and the equipment is used for this action, the beneficiary can declare the depreciation costs incurred for the remaining 24 months, in proportion to the equipment's use for the action.

Cash-based accounting — As a general rule, beneficiaries cannot charge the total purchase price of equipment to the action, unless the GA explicitly foresees that option. The beneficiaries may therefore normally only charge the annual depreciation costs that corresponds to the part of the equipment's use for the action. This depreciation must be calculated in accordance with *international accounting standards* (i.e. notably spread over the equipment's useful life).

'Useful life' means the time during which the equipment is useful for the beneficiary. If the beneficiary does not normally calculate depreciation it may refer to its national tax regulations to define the useful life of the equipment.

Therefore, if the equipment's useful life is more than a year, the beneficiary can NOT charge the full price in one single year (— even if the beneficiary's usual accounting practice is to record the equipment's *total* purchase cost as an expense in one year).

Example:

A beneficiary that uses cash-based accounting buys a machine for EUR 100 000 in March 2015. According to the logbook of the machine, it is used for the action 50 % of the time from 1 July 2015 until the end of the action. The action started in January 2015 and runs for three years with two reporting periods. The machine's useful life is six years.

In the reporting period ending in June 2016, the beneficiary must declare depreciation costs taking into account the percentage of use, the time used for the action and the machine's useful life:

EUR 100 000 x (12/72 months) x 50 % (used for the action) = amount declared for the machine in the first reporting period

In the reporting period ending in December 2017, the beneficiary must declare:

EUR 100 000 x (18/72 months) x 50 % (used for the action) = amount declared for the machine in the second reporting period

Prototype or pilot plants constructed by the beneficiary as part of the action tasks — Normally beneficiaries may only declare the depreciation costs for equipment, infrastructure or other assets that are used for the project.

However, (full) direct costs for construction of a prototype or pilot plant may exceptionally be eligible, if all of the following apply:

- building the prototype or pilot plant is (one of) the main action task(s) as described in Annex 1 of the GA.
- the costs are foreseen in the estimated budget (Annex 2 of the GA)
- the eligibility conditions of Articles 6.1 and 6.2 are met.

  If the beneficiary records the construction costs directly under a fixed assets account in the balance sheet rather than as expenses of the year, those costs will normally be considered as compliant with Article 6.1(a)(v) provided that:

  - it is in accordance with the national accounting standards and with the beneficiary's usual cost accounting practices,
  - there is no double charging of costs (in particular, no charging of depreciation costs for the prototype or pilot plant to another EU or Euratom grant).

1.2 Equipment costs (D.2): Full cost of purchasing equipment, infrastructure or other assets

This budget category **covers** the *full* purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report).

'Capitalised' means recorded as assets in the beneficiary's balance sheet.

1.3 Equipment costs (D.2): Costs of renting or leasing equipment

1.3.1 **What?** This budget category **covers** the costs of renting or leasing equipment used for the action (i.e. finance leasing, renting and operational leasing).

1.3.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**.

1.3.4 They must be **calculated** according to the following principles:

- for leasing (finance leasing) with the option to buy the durable equipment:

  - the equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices
  - the costs declared can NOT exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices

    The finance charges included in the finance lease payments are therefore NOT eligible.
  - the costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee
- for renting and operational leasing: the equipment rented or leased by the beneficiary is not recorded as an asset of the beneficiary: There is no depreciation involved (since the item is still the property of the renting or leasing firm), but the rental or lease costs of the beneficiary (i.e. its periodic payments to the renting or leasing firm) are eligible, if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment (i.e. are not higher than the depreciation costs of similar equipment).

1.4 Equipment costs (D.2): Costs of equipment, infrastructure or other assets contributed in-kind against payment

1.4.1 What? This budget category **covers** the costs of equipment, infrastructure or other assets that were used for the action and 'contributed in-kind against payment'.

1.4.2 Equipment costs must be **declared as** actual costs *(see Article 5.2(d))*.

1.4.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- **not exceed** the depreciation **costs of similar equipment**, infrastructure or assets
- **not** include any **financing fees**
- fulfil the **additional** cost eligibility **conditions** set out in Article 11.1.

1.4.4 The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

1. Costs of other goods and services (D.3): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

The additional options for access to research infrastructure (together with the corresponding Article 16 and other provisions) will be inserted into the GA if the action also involves access to research infrastructure.

1.1 What? This budget category **covers** the costs for goods and services that were purchased for the action (or contributed in-kind against payment), including:

- costs for consumables and supplies *(e.g. raw materials etc.)*
- dissemination costs (including regarding open access to peer-reviewed scientific publications*, e.g. article processing or equivalent charges*, costs related to open access to research data and related costs, *such as data maintenance or storage and conference fees for presenting project-related research*)
- costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)
- costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, *for instance because the EU or Euratom contribution is below the threshold of Article 20.4 or the certificate was submitted not for the final report but before*).
- translation costs *(if translation is necessary for the action's implementation, is justified, etc.)*.

Best practice: If there is any doubt about whether a cost is eligible, the beneficiaries should contact the Commission/Agency.

What not? If it is the beneficiary's usual accounting practice to consider some of these costs (or all of them) as *indirect* costs, they cannot be declared as direct costs (since they will already be covered by the 25 % flat rate).

1.2 Costs of other goods and services must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)

AND

  - be either **purchased specifically** for the action and in **accordance with Article 10.1.1**

  OR

  - **contributed in kind against payment** and in **accordance with Article 11.1**

- for costs of other goods and services incurred for providing **trans-national or virtual access to research infrastructure**: fulfil the **additional** cost eligibility **conditions** set out in Article 16.1 or 16.2.

1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the goods or services).

Specific cases (costs for other goods and services (D.3)):

IPR access rights — Royalties paid for IPR access rights (and by extension any lump sum payments) are normally eligible, if all the eligibility conditions are fulfilled *(e.g. necessary for the implementation of the action, incurred during the action, reasonable, etc.)*.

The following are however NOT eligible (or eligible only within certain limits):

- royalties for an exclusive licence: are eligible only if it can be shown that the exclusivity (and thus the higher royalties) is absolutely necessary for the implementation of the action
- royalties for licensing agreements which were already in force before the start of the action: only the part of the licence fee that can be linked to the action is eligible (since the licence presumably goes beyond the action implementation)
- royalties for access rights to background granted by other beneficiaries under Article 25.2: Since the default rule is that access rights are granted on a royalty-free basis and beneficiaries may deviate only if agreed before GA signature, royalties are eligible only if explicitly agreed by all beneficiaries before GA signature and all the other eligibility conditions are fulfilled *(e.g. necessary for the implementation of the action, reasonable, etc.)*

  Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.
- royalties for access rights to background granted by other beneficiaries under Article 25.3 (and by extension royalties paid to third parties for exploitation of the results): are NOT eligible.

Protection of results — Costs related to the protection of the actions results *(e.g. consulting fees, fees paid to the patent office for patent registration; see Article 27)* are eligible if the eligibility conditions are fulfilled. Costs related to protection of other intellectual property (*e.g. background patents*) are NOT eligible.

Plan for the exploitation and dissemination of results — Costs for drawing up the plan for the exploitation and dissemination of the results are normally NOT eligible since they will have been incurred before the start of the action, to prepare the proposal. Costs that occur when revising or implementing this plan may be eligible.

Open access — Costs related to open access to peer-reviewed scientific publications and research data are eligible, if the eligibility conditions are fulfilled. With explicit agreement by the Commission/Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing in open access or if membership is a pre-condition for significantly lower article processing charges).

Supplies in stock — Supplies and consumables which were already in the stock of the beneficiary may be eligible as a direct cost, if they are used for the action and fit the definition of direct costs under Article 6.2.

Self-produced consumables with an accounting value in the inventory of the beneficiary (i.e. not internally invoiced costs for goods and services) — Consumables that are manufactured (produced) by the beneficiary itself do not have a purchase price; the cost of production for the beneficiary is however normally recorded in the accounts of the beneficiary (as part of the *inventory)*. Therefore, the eligible costs of self-produced consumables must be determined on the basis of its accounting value under the following conditions:

- only the *direct* costs within the accounting value of the consumable (cost of production) may be charged. If it is not possible to accurately determine the part of the accounting value corresponding to the direct costs then the beneficiary may charge the accounting value divided by 1,25 (in order to remove the H2020 flat-rate for indirect costs)

> ⚠ Beneficiaries can **NOT** charge the **commercial price** for self-produced consumables.

AND

- the amount resulting from the indent above may not be significantly higher than the market price of the consumable.

Example:

In an action in the field of agro-forestry research the beneficiary needs 100 plants to carry out tests. The beneficiary has a greenhouse where it keeps a stock of those plants. The market price of those plants (e.g. checked with offers or prices published in internet) is around EUR 10 per plant. The beneficiary has 150 plants in stock with a global accounting value of EUR 1 200 (= EUR 8 per plant). It is not possible to identify what part of that accounting value corresponds to direct costs of production of those plants.
The beneficiary may use the self-produced plants for the action and charge EUR 6,4 per plant (8/1,25).

Staff provided by a temporary work agency — Costs for staff provided by a temporary work agency are eligible normally under category D.3 'other goods and services' if they comply with the eligibility conditions (and unless the temporary work agency carries out directly some task of the action, in which case it can be considered as subcontracting and should be declared under category B 'subcontracting').

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the ***large research infrastructure*** *represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure*[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the ***conditions*** *as further detailed in the annotations to the H2020 grant agreements.****]***

OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable.****]***

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition see Article 2(6) of the 'H2020 Framework Programme Regulation No 1291/2013': **'Research infrastructure'** are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

1. Capitalised and operating costs of large research infrastructure (D.4): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, unless:

- it is excluded by the work programme or
- for calls under Part I of Horizon 2020 'Research Infrastructures' (except for e-Infrastructure topics).

1.1. What? It covers **capitalised costs** and **operating costs** of research infrastructure used for the action.

'Capitalised costs' are:

- all costs incurred in setting up and/or renewing the research infrastructure and
- some costs of specific repair and maintenance of the research infrastructure and parts or essential integral components.[19]

These costs are recorded as an asset in the balance sheet and expensed over the years. They can be claimed as direct costs through depreciation costs. The capitalised costs of the research infrastructure must be depreciated in line with international accounting standards (in

[19] *See also International Financial Reporting Standard No 16.*

particular, based on the useful economic life of the infrastructure) and with the beneficiary's usual accounting practices.[20] Only the depreciation costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

Methods and national reporting practices may differ, but, for the declaration of costs under H2020 grants, it is these guidelines that must be followed for the financial reporting.

Beneficiaries must use their 'usual accounting principles', i.e. the general and cost accounting principles, standards and procedures that they use to compile their legal/statutory financial accounts (i.e. balance sheet, profit and loss accounts, etc.) together with their analytical management information. These standards and principles must not be set up specifically for declaring costs under EU-funded actions. They should be changed/adapted only where strictly necessary to comply with the EU cost eligibility conditions. Ad hoc accounting and/or management schemes will not be accepted.

The costs of renting and/or leasing (excluding any finance fee/interest) of a research infrastructure may also be declared as eligible direct costs. As regards depreciation, only leasing costs of the research infrastructure corresponding to actual use may be declared as eligible direct costs.

⚠ If a (tenant) beneficiary uses the values of contracts of renting or leasing of a research infrastructure to calculate the EUR 20 million threshold *(see below)* and therefore declares costs for this infrastructure, these costs cannot be considered nor declared by any other beneficiary under any other H2020 grant (in particular not by the owner of the research infrastructure).

'Operating costs' are costs:

- which the beneficiary incurs specifically (i.e. directly for the research infrastructure that is used for the action) for running the research infrastructure (including scientific, technical and administrative personnel) and
- are directly linked to the research infrastructure.

In the statutory accounting, these are recorded in the beneficiary's statement of comprehensive income (profit and loss account).

Only the following operating costs can be claimed as direct costs:

- personnel cost of administrative and support staff directly assigned to the functioning of the research infrastructure;
- rental/lease of the research infrastructure (for the period of its actual use for the action);
- maintenance and repair contracts (including calibrating and testing) specifically awarded for the functioning of the research infrastructure;
- consumables, materials and spare parts specifically used for the research infrastructure;
- facility management contracts including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised), specifically awarded for the functioning of the research infrastructure;
- energy and water specifically supplied for the research infrastructure.

[20] *See Article 126 of the Financial Regulation No 966/2012.*

What not? The following costs can NOT be declared as direct costs (non-exhaustive list):

- rental, lease or depreciation of buildings or plants not directly used for the action (e.g. administrative buildings, headquarters)
- statutory audit and legal fees (not including costs of certificates required under the GA)
- office supplies and petty office equipment (purchased in bulk)
- other general services (cleaning, medical, library, services for publication, communication and connection, postage, dues and subscriptions, clothing, literature, transport, catering and similar items (i.e. items recorded by the beneficiary under the same account in the general ledger)
- management tasks and horizontal services (accounting and controlling, head office, corporate communications, HR and training, internal audit, management, quality management, strategic development, etc.)
- non-specific, non-activity-related or non-project-related costs (general): consumables, maintenance, general facilities management, conferences, hosted activities, security fees, insurance costs, general utilities, energy and water, and similar (i.e. items recorded by the beneficiary under the same account in the general ledger).

These costs are reimbursed through the flat-rate for indirect costs *(see Article 6.2.E)*.

1.2 Costs of capitalised and operating costs of large research infrastructure must be **declared as** actual costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following **eligibility conditions**:

- they fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- the **sum of historical asset values of each individual research infrastructure** of the beneficiary, as they appear in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure, represents a total value of at least EUR 20 million for that beneficiary
- the **value of large research infrastructures** of the beneficiary represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the GA or as determined on the basis of the rental and leasing costs of the research infrastructure)
- the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');
- the beneficiary declares as direct eligible costs only the **portion** which corresponds to the **action duration** and to the rate of **actual use** for the purposes of the action, and
- they comply with the **conditions** set out below.

⚠ The beneficiary must operate research infrastructure that falls under the definition of large research infrastructure (i.e. a total value of at least EUR 20 million and representing at least 75% of the total fixed assets). If this is the case, the **value of the specific research infrastructure used for the action** (and for which costs are declared) is **irrelevant** (i.e. it can be lower or higher than EUR 20 million) *(see also below point 2)*.

1.4 The **calculation** is explained in point 4.4.

2. Large research infrastructure (LRI)

Beneficiaries can declare capitalised and operating costs for **large research infrastructure**, if they comply with the definition and conditions listed in Article 6.2.D.4 (in particular if the large research infrastructure has a total value of at least EUR 20 million[21] and if the value of the large research infrastructure represents at least 75% of the beneficiary's total fixed assets, at historical value).

The values of contracts of renting or leasing of research infrastructure may be taken into account for the calculation of the EUR 20 million threshold of the (tenant) beneficiary *(see above)*.

The infrastructure used for the action must be a **research infrastructure** in technical terms, i.e. a facility, resource or service that is used by the research communities to conduct research and foster innovation in their fields; it may be used beyond research, e.g. for education or public services[22].

This covers for instance:

- major scientific equipment (or sets of instruments);
- knowledge-based resources such as collections, archives or scientific data;
- e-infrastructures, such as data, and computing systems, and communication networks.

The infrastructure may be 'single-sited', 'virtual' or 'distributed'.

Moreover, it must be a research infrastructure in accounting terms, i.e. recorded in the accounts of the beneficiary on the basis of a **grouping of costs** (comprising a wide range of items: buildings, machinery, equipment, IT, staff, repair and maintenance, specific security fees, etc.), specifically dedicated to the research infrastructure and necessary for it/them to function, and excluding costs that are incidental to the research infrastructure or necessary for accessing it, such as a car parks, conference and teaching rooms.

In analytical (cost) accounting, this grouping of costs can be recorded in many different ways.

Best practice: Recording them with a specific code for the research infrastructure or under a cost centre.

3. Ex-ante assessment

Only beneficiaries that have obtained a positive ex-ante assessment of their costing methodology may declare capitalised and operating costs for large research infrastructure under this budget category.

⚠ **Recalculations & adjustments of financial statements (exceptional) —** Costs can be declared under this budget category ONLY after having obtained the positive ex-ante assessment from the Commission. Once obtained, the beneficiaries may, however, exceptionally adjust previous financial statements.

⚠ Costs declared in accordance with a positive ex-ante assessment will not be challenged during audits, except in case of irregularity or fraud. The auditors will only:

- ensure that the methodology used is the one that was submitted for ex-ante assessment and
- verify that the calculations (applying the methodology) are correct.

[21] Calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the beneficiary's last closed balance sheet before the date on which the grant agreement is signed, or determined on the basis of the rental and leasing costs of the infrastructures.

[22] *See Article 2(6) of the Horizon 2020 Framework Programme.*

When? Applications for ex-ante assessment can be submitted at any time during grant preparation for any GA (by ticking the LRI box either in the Participant Register or during grant preparation).

How? The **ex-ante assessment** is composed of two steps: Status validation and methodology compliance.

Procedure for ex-ante assessment:

Step 1 — **Status validation** (i.e. if the beneficiary qualifies with definition and conditions for declaring costs under Article 6.2.D.4).

The beneficiary must self-declare whether it complies with the conditions set out above (in particular the EUR 20 million and the 75% thresholds), by filling the appropriate field in the Participant Register. The beneficiary must then provide the relevant supporting documents to the Commission within one month.

The Commission will confirm or — after a contradictory procedure — refuse the status and inform the beneficiary accordingly.

Step 2 — **Methodology compliance** (i.e. if the beneficiary's methodology complies with the conditions set out below).

Following an in-depth (in principle on-the-spot) assessment, the Commission will issue a draft report and submit it to a contradictory procedure with the beneficiary. During this phase the beneficiary has the possibility to amend its methodology by removing any non-compliant component of it. Thereafter, a final (negative or positive) ex-ante assessment report will be issued.

⚠ Although the ex-ante assessment is granted at entity level, it does not necessarily mean that it covers the entire legal entity from the beginning of H2020. It may cover only some departments, cost centres or even individual infrastructures of the beneficiary, possibly with different starting dates.

In that case, the beneficiary may use budget category D.4 only for cost items that are covered by the positive assessment (i.e. that use the methodology and comply with the conditions of the approval).

4. Other conditions

4.1 Costs must be identifiable and verifiable

All declared costs must be **identifiable and verifiable**, i.e. supported by persuasive evidence allowing for a sufficient audit trail.

The sufficiency and the persuasiveness of the evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Capitalised costs claimed as depreciation costs must be supported by:

- proper registration in the assets' register
- evidence of actual use for the action, *e.g. through time registration*
- adequate calculation of potential use (total productive time)
- adequate calculation of the useful economic life of the asset
- evidence that depreciation is calculated in line with the beneficiary's usual accounting principles and the applicable accounting standards.

4.2 Costs must be incurred in direct relationship with the research infrastructure *and* with the action

Beneficiaries cannot declare their full organisational or general operating costs, even if they are fully research-oriented *(e.g. a research organisation, technical university, research enterprise)*. These costs are covered by the flat-rate for indirect costs *(see Article 6.2.E)*.

Only costs that have been incurred in **direct relationship** with the research infrastructure and that are necessary for the implementation of the action can be claimed as direct costs in category D.4 'large research infrastructure'.

This applies if:

- for capitalised costs: the implementation of the action specifically requires the use of the research infrastructure
- for operating costs: the functioning of the research infrastructure specifically requires the assignment of administrative and support staff, or the award of service or supply contracts.

Beneficiaries must be able to demonstrate eligibility by means of an audit trail and sufficient evidence, such as:

- their usual management practices and procedures

  Only written and consigned practices and procedures which are part of the beneficiary's internal control framework will be accepted. Oral statements will not be accepted.

- internal management exchanges necessary for the approval of an underlying transaction
- purchase orders, delivery notes, invoices, proof of payment or any other evidence of exchanges between the client and the provider(s) before signature of the contract or agreement

  The beneficiary must prove the reality of the underlying transaction (including the absence of a credit note or back-payment offsetting the transaction). Gathering such evidence may require a comprehensive analysis of the beneficiary's general ledger.

- for works contracts, any statement of work in progress, delivery status or assembling overview.

The evidence mentioned in the last three points must be explicitly linked to the specific research infrastructure and/or action, and to the specific cost item.

Beneficiaries may prove the direct link through alternative persuasive evidence. The sufficiency and the persuasiveness of the alternative evidence provided, as well as the audit trail, will be assessed against the International Standards on Auditing.

Example 1 (link between research infrastructure and action(s)):

A beneficiary involved in different research areas owns several research infrastructures: an oceanographic vessel and a laboratory for microbiological analysis.

Costs relating to the oceanographic vessel cannot be claimed as direct costs for an action for which it is not used (e.g. an action on eradicating malaria in Africa or on setting up a network for social intelligence).

*Part of the **costs of the vessel** can however be claimed where the vessel is used for an action (e.g. an action on seismic oceanography or on the oceanic ecosystem), provided the beneficiary demonstrates the extent of use (e.g. through a board-book).*

*Similarly, part of the **laboratory costs** can be claimed for an action on eradicating malaria in Africa or on the oceanic ecosystem, provided the beneficiary demonstrates the extent to which the laboratory is used for **the** action.*

*The costs of the two research infrastructures cannot be declared for the action on setting up the network for **social** intelligence.*

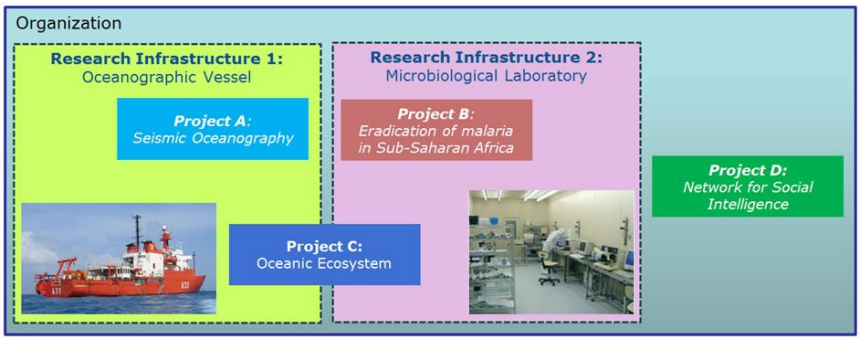

4.3 Costs must not be included as direct costs in any other category

Costs may not be declared twice *(see Article 6.5)*[23].

Thus:

- any (part of a) cost item that has been capitalised and recorded as an asset is *de facto* included in the depreciation costs of the infrastructure and cannot be declared in another cost category (e.g. if the capitalised costs of installing a large telescope are depreciated, they cannot be declared as operating costs)

- (part of) the costs of an infrastructure that have already been declared in respect of another EU/Euratom grant (including grants awarded by a Member State, or by bodies other than the Commission for the purpose of implementing the EU/Euratom budget) cannot be declared again *(e.g. costs already declared in an FP7 action to set up or renew an infrastructure; costs already declared in an action under* the 'Research Infrastructures' Part of Horizon 2020 with *(i.e. providing of trans-national access to research infrastructure; see Article 16); costs already declared in a grant co-financed by the Structural Funds or the ESIF Funds)*

  This means that a *cost item already declared* under a Structural Funds or ESIF grant cannot be declared again under the H2020 grant. However, *cost items that have not already been declared* under a Structural Funds or ESIF grant, may be declared under the H2020 grant, even if they belong to the same action.

> ⚠ **Combining H2020 & other EU grants —** The terminologies under the different EU funds/funding programmes may differ *(e.g. 'capitalised costs' under Horizon 2020 versus 'investment costs' under the Structural Funds, etc.).*

4.4 Costs must be directly measured

Costs can be claimed as direct costs in category D.4 'Large research infrastructure' only if they are **directly measured** (i.e. directly quantified by a monetary value assigned to a given cost item, or a share of it). The measurement system used by the beneficiary must accurately quantify the cost (i.e. reflect its actual true value), be supported by sufficient persuasive evidence and be auditable.

This is considered to be the case if the unit of measurement (generally obtained from the supplier's invoice) is that used to measure the direct consumption of the item.

This measurement must be accurate (i.e. show the *real* consumption and/or use of a cost item on the action), therefore only actual elements of cost and consumption or use are accepted.

Direct measurement of costs does NOT mean 'fair apportionment' through proxies or cost drivers — which was standard for declaring real indirect costs under FP7. (Fair apportionment is not a measurement but an attempt to estimate the costs that were incurred for an action. Direct measurement implies that a cost cannot be attributed to projects via an allocation key, a cost driver or a proxy.)

[23] *See Article 129(1) of the Financial Regulation No 966/2012.*

Example 2 (comparison between fair apportionment and direct measurement):

Under the fair apportionment method, the general electricity costs of a beneficiary operating a laboratory used for an action are allocated to the pool of indirect cost and then apportioned fairly via an absorption method (e.g. m^2).

Under the direct measurement method, the cost is claimed as direct cost; however the beneficiary must ensure that the electricity invoice specifies the electricity costs for the research infrastructure (explicitly labelled invoice or separate invoice). Moreover, the cost must then be measured with respect to the actual time of use of the research infrastructure for the action.

While accurate measurement systems may differ depending on the nature of the cost, they will normally involve time actually used for the action (**project time**) and therefore require reliable time recording (through time-sheets, logbooks, counters, etc.). The measurement system must be justifiable through sufficient persuasive evidence and auditable.

Project time must correspond:

- for the costs of administrative and support staff directly assigned to the functioning of the research infrastructure: to the number of hours actually worked for the action, measured and documented in accordance with Article 31 of the Rules for Participation Regulation No *1290/2013*

- for the other costs of the research infrastructure: to the number of hours/days/months of actual use of the research infrastructure for the action as a part of full capacity (i.e. the number of productive hours/days/months corresponding to the full potential use of the infrastructure)

  This includes any time during which the research infrastructure is usable but not used, but take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing) due to research activities.

  If a cost can be directly measured to the research infrastructure but — because of technical constraints — cannot be measured directly to the action, beneficiaries may measure costs by means of '**units of actual usage**' for the action, supported by accurate technical specifications and actual data and determined on the basis of the beneficiary's analytical cost accounting system. This data must be regularly updated.

  Example 3 (costs of administrative and support staff directly assigned to the functioning of the research infrastructure):

  If an employee of the administration and finance department is employed to carry out specific tasks necessary for the operation of a research infrastructure specifically used for an action (e.g. assigning time-slots between users, monitoring actual use, managing security contracts), the personnel costs can be declared as direct costs of the action, in proportion to

the time the employee actually spent on the action and provided that this is recorded reliably.

Example 4 (part-time use of the research infrastructure for the action):

An oceanographic vessel is used full-time for a period of two months for an EU- funded action and three months for a non-EU research project (or for a non-research activity (commercial, industrial, etc.) of the beneficiary) and stays idle for seven months.

If the annual costs of the vessel (i.e. capitalised and operating costs) amount to EUR 120 000, the part that can be declared for the EU funded action is:

(EUR 120 000 / 12 months) x 2 months = EUR 20 000

AND NOT:

(EUR 120 000 / 5 months[24]) x 2 months = EUR 48 000

Renting or leasing costs can be directly measured to an action as follows:

Example 5 (rental/leasing costs):

The surface area of the premises rented/leased by a beneficiary is occupied as follows:

** 50 % by a research infrastructure;*
** 50 % by conference rooms and offices.*

The overall rental/leasing costs are EUR 100 000 per year, split (according to the rental/leasing agreement) as follows:

** EUR 80 000 for the research infrastructure;*
** EUR 20 000 for the conference rooms and offices.*

The rental costs that can be claimed as direct costs for an action using this research infrastructure are determined as follows:

Step 1 Calculation of the rental costs that can be directly attributed to the research infrastructure

On the basis of the rental/leasing agreement, the invoice must refer to separate amounts for the research infrastructure and the conference rooms/offices (the rental/leasing costs cannot be directly allocated on the basis of the respective surface areas).

[24] 5 months = 2 months for an EU funded action + 3 months for non-EU research or other activities.

The basis for the calculation must be EUR 80 000 and not EUR 50 000 (EUR 100 000 x 50 % of m²).

*Step 2 The rental/leasing amount invoiced for the research infrastructure (i.e. EUR 80 000) is precisely distributed between the activity(ies) and project(s) that make use of it (**best practice:** time of actual use). Installed usage capacity is taken (so as not to exclude idle time) and the resulting cost per unit of usage is multiplied by actual usage on the action (which thus absorbs its share of the overall renting/leasing cost).*

Best practices (for direct measurement):

- Depreciation (for capitalised costs): accounting statements accompanied by the beneficiary's depreciation policy (under its usual accounting principles), to show adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Rental or lease of the research infrastructure: specific explicitly labelled rental or lease invoice/contract; adequate calculation of the potential use of the asset (total productive time based on full capacity) + calculation of the useful economic life of the asset, evidence of project time (or units of actual usage for the action) and evidence of the actual use of the asset for the action
- Personnel (administrative and support staff): time recording (without prejudice to the need for persuasive evidence of actual involvement in the action)
- Maintenance and repair (including calibrating and testing): specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Consumables, materials and spare parts: specific explicitly labelled invoice relating to the research infrastructure, if available, or stocktaking; actual consumption for the action (based on analytical cost accounting) or project time (or units of actual usage for the action)
- Facilities management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action)
- Energy and water: specific explicitly labelled invoice relating to the research infrastructure + project time (or units of actual usage for the action).

  The energy consumption of a specific research infrastructure can be obtained from the measured consumption *(e.g. number of kilowatts per hour of use)*, as stated in its technical specifications or provided by the supplier or an independent body. These specifications must be identifiable and verifiable.

Alternative to best practices: The beneficiaries may determine eligible direct costs on the basis of an aggregate of the capitalised and operating direct costs of each research infrastructure.

Direct measurement allows to determine a '**cost per unit of use**' covering all the actual direct costs relating to the operation of the research infrastructure being used for the action, i.e. depreciation costs plus necessary operating costs of the research infrastructure.

This cost remains however an actual cost, NOT a unit cost under Article 5.2.

The cost per unit of use must be **calculated** as follows:

$$\frac{\{\text{all capitalised costs of the research infrastructure + all operating costs of the research infrastructure}\}}{\text{total annual capacity}}$$

The unit of use must correspond to:

(i) the time of use expressed in hours, days or months and supported by evidence or

(ii) the number of accesses, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The calculation must take due account of real constraints *(e.g. opening hours)*, but must reflect the research infrastructure's full capacity and include any time during which the research infrastructure is usable but not used or any unit of access available but not used.

The **direct costs** that can be claimed are **calculated** as follows:

actual eligible costs per unit of use **x** actual number of units of use used on the action.

The calculation must be verifiable, i.e. allow for a sufficient audit trail reconciling it to the beneficiary's statutory accounts.

D.5 Costs of internally invoiced goods and services directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

1. Costs of internally invoiced goods and services (D.5): Types of costs — Form — Eligibility conditions — Calculation

The budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category covers the costs for goods and services which the beneficiary itself produced or provided for the action. They include (non-exhaustive list):

- self-produced consumables *(e.g. electronic wafers, chemicals)*
- use of specific research devices or research facilities *(e.g. clean room, wind tunnel, supercomputer facilities, electronic microscope)*
- specialised premises for hosting the research specimens used for the action *(e.g. animal house, greenhouse, aquarium)*
- standardised testing or research processes *(e.g. genomic test, mass spectrometry analysis)*
- hosting services for visiting researchers participating in the action *(e.g. housing, canteen*).

What not? Costs of goods of services purchased and costs of goods or services internally invoiced which are not directly used for the action *(e.g. supporting services like cleaning, general accountancy, administrative support, etc.)*.

1.2 Costs of internally invoiced goods and services must be **declared as** unit costs *(see Article 5.2(d))*.

1.3 The costs must comply with the following cumulative **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. used during the action duration, necessary for the action, etc.; *see Article 6.1(b)*)

- be in line with the beneficiary's **usual cost accounting practices**

  It must be the usual practice of the beneficiary to calculate a unit cost for that good or service (i.e. an internal cost per unit invoiced to other departments of the same entity – not prices charged in the context of commercial sales or grants from other fund providers).

- the cost accounting practices must have been applied in a **consistent** manner, based on objective criteria, regardless of the source of funding

  The beneficiary must consistently apply its usual cost accounting practices, based on objective criteria that must be verifiable if there is an audit. It must do this no matter who is funding the action.

  Example: *if the beneficiary sets up a new unit cost which applies only to EU actions, the internally invoiced costs based on that new unit cost would be ineligible.*

- the amount per unit must have been **calculated** using the actual costs recorded in the beneficiary's accounts, excluding any ineligible costs or costs already included in other budget categories

  If necessary, the unit cost must be adjusted to remove:

  - cost elements that are ineligible under the GA (even if they are part of the beneficiary's usual methodology for determining the unit cost for its internal invoices)

    Example: *The beneficiary uses internal invoices for the use of an electronic microscope based on a unit cost per hour of use. The methodology to calculate the unit cost includes costs of capital (e.g. interest charged by the bank for a loan used to buy the microscope). Those costs are ineligible under the GA (see Article 6.5) and must therefore be removed. The unit cost must be recalculated without them.*

    ⚠ A beneficiary cannot simply apply an estimated percentage of deduction on the amount of its internal invoices to remove ineligible costs. It has to ensure that the internal invoice does not include any ineligible costs under the GA.

  - costs of resources that do not belong to the beneficiary and which it uses free of charge *(e.g. personnel or equipment of a third party provided free of charge)*, because they are not in its accounts *(see Article 6.1(a)(v))*

    As an exception, if the resource for which the unit cost is calculated is co-owned by the beneficiary and a third party, the costs registered in the accounts of the third party for the co-owned resource do not need to be removed if:

    - the third party is mentioned in the grant *(e.g. as third party providing in-kind contributions in Annex 1)* and

    - the costs fulfil the other eligibility conditions of this Article *(e.g. directly linked to the resource, exclude ineligible costs, etc.)*.

  - costs that are already included in other budget categories (double funding of the same costs, *see Article 6.1(a)(i)*).

    Example: *The beneficiary uses internal invoices for water chemistry analyses, based on a unit cost per water sample analysed. The methodology to calculate the unit cost includes the cost of the staff carrying out the analysis. However, the costs for those persons are already charged to the action under direct personnel costs (category A.1). The cost of the staff must therefore be removed and the unit cost must be recalculated without them.*

- if budgeted or estimated elements were used to calculate the amount per unit, those elements must:

  - be relevant (i.e. clearly related to invoiced item)

  - be used in a reasonable way (i.e. do not play major role in calculating the unit cost)
  - correspond to objective and verifiable information (i.e. their basis is clearly defined and the beneficiary can show how they were calculated)

- the amount per unit must have been calculated using only costs of items which were **directly linked** to the production of the internally invoiced goods or services *(e.g. staff, equipment, raw materials, etc.)*

  If a cost item is not used exclusively for the internally invoiced good or service, only the share used for the good or service may be counted (the percentage taken must be substantiated by persuasive evidence).

  Example: ***Shared staff —*** *Among the persons operating the beneficiary's wind tunnel, there is one person that is assigned only part-time to that wind tunnel; the rest of the time it works in another department. If the beneficiary includes the costs of this person at the rate of 50 %, it must be able to justify the reality of that percentage, for example, by any of the following:*
  - *reliable time recording system*
  - *a statistic survey performed in the past based on actual data*
  - *detailed calculations based on technical specifications or other scientific and technical requirements of the equipment or infrastructure allowing to reconcile the time spent by the person for the functioning of the wind tunnel*

  or
  - *a combination of these methods.*

  ⚠ **Ceiling** — The (share of the) working time of a person which is included in the calculation of the unit cost reduces the number of hours that the person can charge over the year to EU/Euratom grants *(see Article 6.2.A. Calculation)*. The same hours of the person cannot be charged twice to the grant, once embedded in the unit cost and again as direct personnel costs.

  If necessary, the unit cost must be adjusted to remove costs elements allocated to the unit cost indirectly; i.e. through cost drivers/allocation keys based on other cost items included in the unit cost *(e.g. for a clean room: the costs of the of the human resources department charged to the unit cost as a fixed amount per employee assigned to the clean room; or power supply costs allocated to the clean room on the basis of the square meters it occupies)*.

  Example: *Costs for an animal housing facility*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. keepers, veterinarians and other persons directly assigned to run the animal house)* – *consumables used for the animal housing (e.g. animal food, bedding)* – *depreciation of cages and other equipment directly linked to the housing of the animals* – *generic supplies like electricity or water — BUT only if the consumption of the facility has been directly measured (so that the cost can be accurately determined)* – *maintenance and cleaning of the animal house facility — BUT only if the cost is directly identifiable (e.g. a separate invoice for the cleaning of the cages)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the animal house facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the animal housing is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

Example: *Wind tunnel*

*Examples of costs **generally eligible** as part of the unit cost*	*Examples of costs **ineligible** as part of the unit cost*
– *staff working for the facility (e.g. technicians, engineers and other persons directly assigned to the functioning of the wind tunnel)* – *depreciation of the equipment, including specific software and hardware necessary for the functioning of the wind tunnel* – *generic supplies like electricity — BUT only if the consumption of the facility has been directly measured (so the cost can be accurately determined)* – *insurance — BUT only if the cost is directly identifiable (e.g. a separate invoice for the insurance of the facility)* – *maintenance and cleaning of the wind tunnel equipment (e.g. air cooling system) — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)* – *calibration/metrology tests — BUT only if the cost is directly identifiable (e.g. a separate invoice for the services)*	– *cost of central services (e.g. accounting department, human resources department)* – *shared infrastructures (e.g. central heating, air-conditioning) and their maintenance* – *shared services with no differentiation of the costs incurred for the facility (e.g. cleaning services)* – *depreciation of shared buildings (e.g. the building where the installation is located is part of a main building of the beneficiary)* – *bank interests, provisions for future expenses and any other ineligible costs listed in Article 6.5*

1.1.4 They must be **calculated** according to the rules set out above (point 1.1.3).

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Article 6.2. Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 to be used if Article 15 applies:*** *costs of providing financial support to third parties[and][;]][**OPTION 2**: not applicable;]*

(d) ***[OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION 2:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

[21] For the definition, see Article 121(1)(b) of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (E.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all RIA, IA and CSA grants under the General MGA.

1.1 What? This budget category **covers** all costs for the action that are not *directly* linked to it *(see Article 6.2)*.

1.2 Indirect costs must be **declared as** a fixed flat-rate (*see Article 5.2(e)*; ⚠ new in Horizon 2020).

In practice, the declaration is completely automatized: The indirect costs are automatically calculated by the IT system (on the basis of the direct costs).

⚠ The pre-filled amount may NOT be changed (except in case of a parallel operating grant, *see below*).

1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for flat-rate costs to be eligible (i.e. costs to which the flat-rate is applied must be eligible, correct calculation, etc.; *see Article 6.1(c)*)

1.4 They must be **calculated** by applying the 25 % flat-rate to the beneficiary's eligible direct costs, minus:

– subcontracting costs *(see Article 13)*

Example: *subcontracting of opinion surveys*

The purchase of goods, work or services that are not action tasks described in Annex 1 *(see Article 10)* is NOT considered subcontracting, and are therefore not subtracted when calculating the 25 % flat rate.

- costs of in-kind contributions incurred by third parties outside of the beneficiary's premises
- costs of providing financial support to third parties (if option applies)
- costs from specific cost categories (unit or lump sum costs) that include indirect costs *(e.g. 'costs for energy efficiency measures in buildings', 'access costs for providing trans-national access to research infrastructure' and 'costs for clinical studies')*.

Example for calculating indirect costs:

A public university is a beneficiary under a GA and has incurred the following costs:

- *EUR 100 000 personnel costs (EUR 7 000 of which are an in-kind contribution in the form of a laboratory technician who carries out work for the action from his/her laboratory in a public research centre)*
- *EUR 20 000 subcontracting costs,*
- *EUR 10 000 other direct costs (consumables).*

Eligible direct costs: 100 000 + 20 000 + 10 000 = EUR 130 000

Eligible indirect costs: 25 % of (100 000 – 7 000 + 10 000) = EUR 25 750

Total eligible costs: EUR 155 750

⚠ **Combining different EU grants —** Beneficiaries that have **action grants** and **operating grants** may claim indirect costs in their action grants ONLY if they are able to demonstrate cost separation (i.e. that their operating grants do not cover any costs which are covered by their action grants).

Operating grants are annual grants to finance the operation and running costs of an entity *(e.g. call COMM-C2/01-2013 under the Europe for Citizens programme)*.

Example: *Entity A receives an operating grant under the Europe for Citizens programme for the financial year 2016 (i.e. from 01.01.2016 until 31.12.2016) The operating grant is not renewed in 2017. On 01.04.2016, entity A signs an H2020 action grant with one reporting period of 18 months (01.04.2016 – 31.12.2017). Beneficiary A may declare the indirect costs in the H2020 action grant as follows:*

- *from 01.04.2016 to 31.12.2016 ONLY IF it can demonstrate that the operating grant does not cover any costs of the action (see beow);*
- *from 01.01.2017 – 31.12.2017 under the normal H2020 rules (i.e 25% of the direct eligible costs since there is no operating grant covering the 2017 financial year).*

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grants may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be full operating grants)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant activities or the operating grant activities)
- the beneficiary must record:
  - all real costs incurred for the activities that are covered by their operating grants (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all real costs incurred for the activities that are covered by their action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that **cannot fulfil these conditions** must EITHER:

- not sign/terminate the operating grants, in order to be able to claim indirect costs in the action grants
- keep the operating grants, but sign the action grants *without* indirect costs or request no indirect costs at reporting stage (i.e. lower the pre-filled amount in the indirect cost column of the financial statement).

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of overlapping EU action and operating grants, the beneficiary should immediately contact the Commission/Agency (via the Participant Portal). Be aware that operating grants are not always easy to identify.

F. [OPTION 1: [Insert name of specific cost category(ies)[22]]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]

[OPTION** 1a **for** specific unit costs **(if unit cost foreseen by Commission decision and applicable to the grant): [insert name of specific cost category]** are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category]** are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]

[same for each specific cost category]

[OPTION 2:** Not applicable**]

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

This optional budget category will be inserted into RIA, IA and CSA GAs, if the action involves activities for which the beneficiaries may declare specific unit or lump sum costs, i.e. currently:

- actions under Part III of Horizon 2020, Societal Challenge 3 'Secure, clean and efficient energy' involving energy efficiency measures in buildings: **costs for energy efficiency measures in buildings**

  This unit cost applies ONLY to Smart Cities and Communities calls *(e.g. SCC-01-2014 for the Work Programme 2014-2015)* and ONLY to the building-related demonstration activities.

- actions under Part I, 'Research infrastructures': **access costs for providing trans-national access to research infrastructure**

  The unit cost applies ONLY to actions with 'provision of access activities'.

  Examples: *INFRAIA-1-2014-2015, INFRADEV-3-2015 and INFRADEV-4-2014-2015*

- actions under Part III, Societal Challenge 1 'Health, demographic change and wellbeing': **costs for clinical studies**

  The unit cost applies ONLY to actions with clinical studies.

Double funding risk — Costs that are declared as a specific unit or lump sum cost may NOT be declared (a second time) under another budget category *(for the costs that are covered, see below)*.

Example:

The unit cost for efficiency energy measures in buildings covers subcontracting costs related to the energy efficiency measures. These cannot be declared as subcontracting costs. By contrast, costs for subcontracts not included in the unit cost (e.g. subcontracts required by the implementation of the action but not related to the efficiency energy measures) can be declared.

1.1 Specific cost category – costs for energy efficiency measures in buildings (F.2)

1.1.1 **What?** This budget category **covers** three categories of direct and indirect costs:

- costs of purchasing equipment, infrastructures and other assets directly necessary for additional energy efficiency measures in buildings
- costs of subcontracting the works necessary for those measures
- indirect costs for those measures.

Examples: *the costs of building elements (such as new insulation, new ventilation system, window, door, heating elements, control system) and the man-days for installing the building elements will be covered.*

What not? Fluids.

1.1.2 Costs of additional energy efficiency measures must be **declared as** the unit cost set out in Commission *Decision C(2013) 8196*[25] and set out in Annexes 2 and 2a of the GA.

The precise unit cost ('amount per unit', i.e. EUR/m2 of eligible conditioned gross floor area) is not pre-fixed by the Decision; it must be calculated for each beneficiary/linked third party — before signature of the GA — using the following table:

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

The formula for calculating the 'amount per unit' (EUR/m2 of eligible conditioned gross floor area) is:

Amount per unit = {EUR 0,1 **x** estimated total kWh saved per m² per year **x** 10}

Beneficiaries may however submit a proposal requesting funding for a number of kWh saved per m² per year *lower* than the estimated one. But this will not be evaluated as an advantage against other proposals.

The energy efficiency measures and the amount per unit must already be part of the proposal *(see the proposal templates and the BEST table provided on the call pages)* and be included in Annexes 1 and 2a.

The use of the unit cost is mandatory. The beneficiaries/linked third parties cannot choose between unit and actual costs.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for energy efficiency measures in buildings that go beyond the national regulation or, if there is no national regulation applicable, beyond the market practice *(e.g. for refurbishment of buildings)*

[25] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_energy_en.pdf.

1.1.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual m² of surface area built or refurbished ('conditioned')

The 'm2 of eligible conditioned gross floor area' may NOT include parts of the buildings which are not affected by the measures, *e.g. garages*.

Example for calculating unit costs for energy efficiency measures:

Assuming that the refurbishment of a building results in energy savings of 100 kWh/m²/year

Payback period (standard figure to be used in the calculation) = 10 years

Standard cost in euro to save 1 kWh (standard figure to be used in the calculation)= 0,1 EUR/kWh

The formula gives:

*{standard cost in euro to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years} =*

*0,1 EUR/kWh * 100kWh/m²/year * 10 years= 100 EUR/m²*

After application of the 70% funding rate for innovation actions (or for non-profit beneficiaries/linked third parties: 100%), it will give an indicative EU contribution of 70 EUR/m² (or 100 EUR/m² if the funding rate is 100%).

1.2 Specific cost category – access costs for providing trans-national access to research infrastructure (F.2)

1.2.1 **What?** This budget category **covers** direct and indirect access costs for providing trans-national access to research infrastructure (i.e. the installation's operating costs and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4)*.

Beneficiaries that use budget category F.2 'access costs for providing trans-national access to research infrastructure' can NOT — under the same grant — declare costs under budget category D.4 'capitalised and operating costs of large research infrastructure'.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, in category D.1 'travel'; *see Article 6.2.D.1 and Article 16*.)

1.2.2 If they are declared under this budget category (i.e. F.2 'access costs for providing trans-national access to research infrastructure'), the costs must be **declared as** the unit cost calculated in accordance with Commission Decision C(2013) 8199[26] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/unit of access) is not pre-fixed by the Decision; it must be calculated for each access provider and installation, using the calculation table provided on the call page and then summarised in the following table:

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

[26] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_tna-infra_en.pdf.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The formula for calculating the 'amount per unit of access' (EUR/unit of access) is:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{27}\text{)}}{\text{average annual total quantity of access (over past two years}^{28}\text{)}}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices (including where the installation has been in operation for less than two years) and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

Access providers may however submit a proposal with a unit cost calculated on the basis of average costs lower than their historical costs.

The 'total quantity of access' means all the units of access annually provided by the installation, included access financed under previous EU grants, if any.

The 'annual total access costs to the installation' is calculated on the basis of the following categories of eligible costs:

- the direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised)
  - costs of consumables specifically used for the installation and the user's research work
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation
  - costs of energy power and water supplied for the installation
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs, transport costs)
  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services
  - costs of specific scientific services included in the access provided or needed for the provision of access

  Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.
- the indirect costs for providing access to the installation, equal to 25% of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

AND excluding:

[27] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[28] In exceptional and duly justified cases, the Commission may agree to a different reference period.

- all contributions to the capital investments of the installation (including costs of renting or leasing or depreciation costs of buildings as well as depreciation and leasing of instrumentation). (Those costs are not eligible; *see also Article 6.2.D.2*)
- travel and subsistence costs for users.

Example (amount per unit):

Assuming that a telescope provided 6 100 hours of access in year N-1 and 5 900 hours of access in year N-2 and that the total access costs (for the provision of these total quantities of access) in the two years calculated on the basis of the categories of costs indicated above (with the exclusion of any contribution to capital investment and of travel and subsistence costs of users) is respectively EUR 3 200 000 and EUR 2 800 000, then the unit cost is

Average costs = average (3 200 000, 2 800 000) = 3 000 000

Average hours = average (6 100, 5 900) = 6 000

Unit cost = average (3 200 000, 2 800 000) / average (6 100, 5 900) = 3 000 000 /6 000 = 500 €

The detailed calculation tables (one for each installation) must already be part of the proposal *(see proposal templates and the calculation table provided on the call pages)* and be included in Annex 1; the summary table must be included in Annex 2a.

The proposal and Annex 1 should describe both the access services provided and the logistical, technological and scientific support users need in order to make use of the installation (including ad-hoc training and preparatory and closing activities necessary to use the installation).

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*. One cost form per installation.

The use of unit costs for trans-national access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs, actual costs or a combination of the two.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred/used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(a) and (b)*)
- be incurred for providing trans-national access to research infrastructure to scientific communities
- fulfil the **additional** cost eligibility **conditions** set out in Article 16.1

1.2.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of actual units of access provided

1.3 Specific cost category – costs for clinical studies (F.2)

1.3.1 **What?** This budget category **covers** the following direct and indirect costs for 'clinical studies' (i.e. any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients):

- direct personnel costs of the doctors and other medical personnel and technical personnel (including data managers) that conducted the study
- direct costs of consumables used for the study
- direct costs of the medical equipment used for the study, including:
  - depreciation costs
  - costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair)
- costs of other specific service contracts necessary for the study (including data analysis, if subcontracted)
- indirect costs for the study.

What not? Travel and subsistence costs of study participants and horizontal tasks *(e.g. study monitoring, study coordination)* are not covered by the clinical studies unit cost. (These costs can be reimbursed separately, *e.g. in categories A. 'personnel', D.1 'travel' and D.3 'other goods and services'; see Articles 6.2.A, 6.2.D.1, 6.2.D.3*.)

1.3.2 If they are declared under this budget category (i.e. F.2 'costs for clinical studies'), the costs must be **declared as** the unit cost set out in Commission Decision C(2016) 7553[29] and set out in Annex 2 and 2a of the GA.

The precise unit cost (amount per unit, i.e. EUR/study participant) is not pre-fixed by the Decision; it must be calculated for each study/study sequence *(see below)* and beneficiary/linked third party/third party providing in-kind contributions — before signature of the GA — using the following table:

Task, Direct cost categories	Resource per patient	Costs year N-1 Beneficiary 1 [short name]	Costs year N-1 Linked third party 1a [short name]	Costs year N-1 Beneficiary 2 [short name]	Costs year N-1 Linked third party 2a [short name]	Costs year N-1 Third party giving in-kind contributions 1 [short name]
Sequence No. 1						
Task No. 1 Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR

[29] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf

	technician), 15 minutes					
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1 XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						

…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

⚠ Where the nature of the clinical study allows it, it can be split into sequences, *e.g. treatment cycles*. The number of sequences should be limited to the necessary minimum *(e.g. 3 sequences)*.

Separating the unit cost table into sequences will allow you to declare unit costs for study participants that dropped out during the study, but finalised the tasks of a sequence. Thus, the sequence unit cost can be charged for the participant, for the completed sequence(s).

Each beneficiary/linked third party/third party must calculate its unit cost on the basis of its historical data (estimated costs of the components per task and study participant). Historical cost reference data should be taken from the last closed financial year at the time of submission of the grant proposal (certified or auditable profit and loss account for 'year N-1').

Beneficiaries can choose whether to include *all* the cost components in their unit cost or only *some*, but they may NOT add any other cost categories.

They may choose whether to include personnel costs or not, but if they do, *all* the study-related personnel costs must be included (they cannot choose for individual persons/types of personnel). Moreover, this choice must be applied to all the tasks and sequences of the study. If personnel costs are included, they must moreover use one of the three available categories: doctors, other medical personnel or technical personnel (no other categories, *e.g. nurses must be included in 'other medical personnel').*

For consumables, medical equipment and services, there is more flexibility. They can choose for each individual cost items, if they would like to include it in their unit cost (or declare them as actual costs).

The choice (whether to include a cost component in the unit cost or not) is made by adding the costs into the table (or leaving it blank). All blank cost components are outside the unit cost (and can normally be declared as actual costs, if all the eligibility conditions are met).

The beneficiaries/linked third parties/third parties may therefore (for the same study/sequence) not only obtain completely different amounts per unit, but also include different components into their calculation.

Example:

Beneficiary No 1 decided to claim:

- *personnel costs as unit costs*
- *all consumables for sequence 1 as actual costs, all consumables in sequence 2 as unit cost and consumables in sequence 3 partially as actual, partially as unit costs*
- *medical equipment partially as actual, partially as unit cost (e.g. cost of a standard MRI scan — part of the study protocol sequence 2 task 3 — as unit costs and the costs for the use of an novel imaging tool — also sequence 2 task 3 — as actual costs, for instance because the historical data is not fully available)*
- *all services as unit costs.*

Beneficiary No 2 decided to claim all study costs as unit costs.

Linked third party 2a decided not to use the unit cost for any of the study costs (all costs as actual costs).

The formulas for calculating the individual cost components are:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

{certified or auditable total personnel costs for doctors for year N-1
{1720 * number of full time equivalent for doctors for year N-1}
multiplied by
estimated number of hours to be worked by doctors for the task (per participant)**}**

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1
{1720 * number of full time equivalent for other medical personnel for year N-1}
multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)**}**

For personnel costs of technical personnel: 'average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1
{1720 * number of full time equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1
total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)**}**

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}
total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1
total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1**}**

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}**}**

multiplied by

25%**}**

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

This table must already be part of the proposal *(see the proposal templates and the template for essential information to be provided for proposals including clinical studies provided on the call pages)* and be included in Annex 1 and 2a of the GA.

⚠ The Commission/Agency may verify that the proposed unit costs comply with the prescribed calculation method (and correct them, if needed).

As mentioned above, *before* GA signature, the beneficiaries can still opt for declaring the costs components not as unit cost, but as actual costs under other budget categories *(see Article 6.2.A-E)*.

The use of unit costs for clinical studies is optional, i.e. each beneficiary/linked third party can decide independently (and for the different cost components/cost items) whether to be reimbursed on the basis of unit costs or of costs actually incurred.

Afterwards (once the GA is signed), the choice can be changed only via an amendment (because it is necessary to determine the unit cost; *see Articles 4.2 and 55*).

⚠ Amendment requests to change the unit cost calculation will be accepted ONLY if there was a change in the study protocol *(e.g. due to requests from competent authorities, regulatory agencies or ethics committees)* or if there was an error in the calculation.

⚠ The maximum grant amount *(see Article 5.1)* will NOT be increased.

⚠ In case of an amendment, it is still the historical costs of the last closed financial year at the time of submission of the grant proposal that must be used to re-calculate the unit cost.

1.3.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for carrying out clinical studies**.**

1.3.4 They must be **calculated** as follows:

- amount per unit *(see Annex 2a GA)* **x** the number of study participants

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — **mutatis mutandis** — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

1. Costs of linked third parties (A-F)

This option (together with the corresponding Article 14 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues (including cost eligibility) like beneficiaries.

The same rules apply, but with the changes needed to render them applicable to linked third parties.

Examples:

1. *'Incurred by the beneficiary' should be read as 'incurred by the linked third party'.*

2. *'On the beneficiary's payroll' should be read as 'on the linked third party's payroll'.*

The costs of linked third parties are **eligible**, if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 14.1.1.

Depending on the type of cost, they must be **declared** by the linked third party under the corresponding budget category (as the beneficiary would use for its own costs).

Examples:

1. *Remuneration of employees must be declared in category A.1 'personnel costs' (Article 6.2.A.1).*

2. *Depreciation costs of equipment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

1. In-kind contributions by third parties free of charge (A-F)

Contributions provided by third parties *free of charge* are **eligible** if:

- they fulfil — *mutatis mutandis* — the **general conditions** and **specific conditions** for costs to be eligible *(see Article 6.1 and 6.2)* and
- they fulfil the **additional** cost eligibility **conditions** set out in Article 12.1.

Depending on the type of cost, they must be **declared** (by the beneficiary/linked third party) under the budget category they would use for their own costs.

Example: *Depreciation costs of equipment contributed free of charge must be declared in category D.2 'equipment' (Article 6.2.D.2).*

In-kind contributions *free of charge* must be **distinguished** from **in-kind contributions *against payment*** *(see Article 11).*

In-kind contributions *against payment* are costs *of* the beneficiary (because they have to pay) and are therefore already explicitly mentioned in the different budget categories *(see Article 6.2.A.3, 6.2.D.2, 6.2.D.3)*. Their costs (i.e. the payment) must be declared under those specific budget categories.

Examples:

1. *The cost of personnel seconded against payment must be declared in category A.3 'seconded personnel (against payment)' (Article 6.2.A.3).*

2. *Costs of equipment contributed against payment must be declared in category D.2 'equipment' (Article 6.2.D.2).*

The costs of in-kind contributions free of charge (i.e. the costs of the third party offering them) can be assimilated to beneficiary costs and must be declared in the budget category that the beneficiary would have used.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action [;][.]

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Ineligible costs

Costs are **ineligible**, if one of the following applies:

- they **do not meet the general and specific eligibility conditions** set out in Articles 6.1 to 6.4

  Examples: *additional remuneration ('bonuses') paid by for-profit or non-profit entities do not fulfil the conditions set out in Article 6.2; subcontracting costs do not comply with Article 13*

- they are **listed in Article 6.5**, in particular:

  - costs related to **return on capital** or **return generated by an investment**

    Examples: *dividends paid as remuneration for investing in the action; remuneration paid as a share in the company's equity.*

– **debt and debt service charges**

'Debt service' is the amount paid on a loan in principal and interest, over a period of time.

> ***Example:*** *If a beneficiary takes a loan used to acquire equipment or consumables for the project of EUR 100 000 at 9 percent interest for 10 years, the debt service for the first year (principal and interest) is EUR 15 582*

– **provisions for future losses or debts**

'Provision' means an amount set aside in an organisation's accounts, to cover for a known liability of uncertain timing or amount. This includes allowances for doubtful or bad debts.

– **interest owed** (i.e. interest on a loan to borrow capital)

– **excessive or reckless expenditure**

'Excessive' means paying significantly more for products, services or personnel than the prevailing market rates or the usual practices of the beneficiary (and thus resulting in an avoidable financial loss to the action).

'Reckless' means failing to exercise care in the selection of products, services or personnel (and thus resulting in an avoidable financial loss to the action).

– **currency exchange losses** (i.e. for beneficiaries using currencies other than euros or being invoiced in a currency other than the currency they use: any loss due to exchange rate fluctuations *(e.g. between the date of invoicing and the date of payment)*)

– **bank costs** charged by the beneficiary's bank for transfers from the Commission/Agency.

Conversely, bank charges for the distribution of the EU funding may constitute an eligible cost for the coordinator (if the eligibility conditions of Article 6.1 and Article 6.2.D.3 are met).

– **deductible VAT**

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary.

The cost and revenue accounts should exclude deductible VAT; such VAT should be recorded in *separate* payable or receivable accounts, without effect on revenue or cost line items.

> The VAT *paid* is a claim against the tax authority. It should be recorded in the 'assets' part of the balance sheet. It should not be recorded as expenditure in the profit and loss accounts (only the purchase price of goods and services *excluding* VAT should be recorded). Similarly, for the value of purchased equipment or assets, only the net purchase cost should be recorded in the balance sheet's fixed asset line, and the depreciation cost should be calculated based on this value, excluding VAT.
>
> The VAT *collected* is a debt towards the tax authority and should therefore be recorded in the 'liabilities' part of the balance sheet.

Conversely, if VAT is NOT deductible, it is an eligible cost.

> The full price of the goods or services bought by the beneficiary can be recorded as expenditure in its profit and loss accounts, without any distinction

between the net price and the amount of VAT charged on it. The full price of equipment and assets bought can be recorded in the balance sheet's fixed asset line and is the basis for the depreciation allowances recorded in the profit and loss accounts.

- **costs incurred during the suspension of the implementation of the action**

  Example: *Action is suspended and one of the beneficiaries continues working on it after the date of the suspension*

- **costs declared under another EU or Euratom grant** (i.e. double funding)

  This includes:

  - costs funded directly by EU programmes managed by the Commission or Executive Agencies *(e.g. other H2020 grants)*
  - costs managed/funded/awarded by Member States but co-funded with EU/Euratom funds *(e.g. European Structural and Investment Funds (ESIF))*
  - costs for grants awarded/funded/managed by other EU, international or national bodies and co-funded with EU/Euratom funds *(e.g. Joint Undertakings, Article 185 TFEU bodies)*
  - if a beneficiary is receiving an operating grant[30] from the EU/Euratom, then the indirect costs of that beneficiary are not eligible and the 25% flat-rate should not be applied — unless it can demonstrate that the operating grant does not cover any costs of the action *(see Article 6.2.E)*.

    Examples (operating grants): *Grants awarded to support the running costs of certain institutions pursuing an aim of European interest, such as: College of Europe, European standards bodies (CEN, CENELEC, ETSI).*

- **cost categories explicitly excluded in the work programme/call** (if option applies).

If a beneficiary **declares ineligible costs**, they will be rejected and, if needed, other measures specified in Chapter 6 *(e.g. suspension, termination, grant reduction, etc.)* may be taken.

Specific cases (ineligible costs):

Non-identifiable VAT (in foreign invoices) — In exceptional cases where the beneficiary cannot identify the VAT charged by the supplier *(e.g. small non-EU invoices)*, the full purchase price can be recorded in the accounts if it is not possible to deduct the VAT. That VAT would therefore be eligible.

Partially deductible VAT — Some entities have a mixed VAT regime, meaning that they carry out VAT exempt or out-of-the-scope activities AND VAT taxed activities. When VAT paid on goods or services by these entities cannot be directly allocated to one or the other category of activities it will be *partially* deductible. Therefore it will also be *partially* eligible. The eligible part corresponds to the pro-rata of the VAT which is not deductible for that entity.

In these cases, the beneficiary uses a provisional (estimated) deduction ratio during the year. The final ratio is only determined at the end of the fiscal year. The beneficiary must regularise VAT when closing its accounts. Therefore, the beneficiary must also regularize the VAT costs declared for the grant (by declaring, in the next reporting period, an adjustment for the difference between the provisional deduction ratio and the final ratio).

Duties — The eligibility of duties depends on the eligibility of the cost item to which they are linked (i.e. in whose price they are included). If the item is eligible, the duty is also eligible.

[30] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012:* '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

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SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Proper implementation of the action

The beneficiaries must properly implement the action. This general obligation is twofold, i.e. they must:

- carry out the action (and especially the research work) as detailed in Annex 1 ('technical implementation')

  The beneficiaries must prevent delays in implementing the action, or reduce them as much as possible. In addition, they must immediately inform the Commission/Agency *(see Article 17)*.

AND

- comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law.

  Example: *Each beneficiary must comply in particular with the labour law applicable to the personnel working on the action and must fulfil the tax and social obligations related to the activities it carries out under the applicable national law.*

⚠ Normally, the beneficiaries must comply **BOTH** with the national law of the **country** in which they are **established** AND that of the country where the **action** is **implemented**.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The beneficiaries must normally have the **technical and financial resources** needed to carry out the action **themselves**.

The resources must be available **at the moment of the implementation of the work** (but not necessarily at the moment of submitting the proposal or signing the GA). However, in these last two cases, the beneficiaries must show in the proposal how the resources will be made available when they are needed.

Examples (acceptable):

1. *Start-up company with no resources at the time of proposal submission, but with a credible business plan described in the application.*

2. *SME which, if successful, intends to double its capacity/staff.*

Example (not acceptable): *Consultancy company which submits a proposal where the majority of the work is subcontracted.*

As an exception, beneficiaries may purchase goods, works or services *(see Article 10)*, use in-kind contributions provided by third parties *(see Articles 11 and 12)* or call upon subcontractors or linked third parties to carry out work under the action *(see Articles 13 and 14)* and declare these costs for the action. They may also call on international partners to carry out work under the action without receiving EU funding (see Article 14a) (**third parties involved in the action**).

Suppliers of goods, works or services and third parties providing in-kind contributions (against payment or free of charge) do not implement action tasks themselves, but only make resources available to the beneficiary, whereas subcontractors, linked third parties and international partners implement action tasks.

⚠ Beneficiaries using third parties remain **fully responsible** for them under the GA.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the action, like the beneficiary they are linked to. They will therefore be treated for many issues like beneficiaries.

Third parties involved in the action do NOT sign the GA *(see Article 1)*.

The **differences** between subcontracts *(Article 13)* and other contracts for purchase of goods, works or services *(Article 10)* are:

Article 10 Contracts to purchase goods, works or services	Article 13 Subcontracts
These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.	Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action and are described in Annex 1.
Do not have to be indicated in Annex 1.	Must be indicated in Annex 1.
The price for these contracts will be declared as 'other direct costs' — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat-rate for indirect costs.	The price for the subcontracts will be declared as 'direct costs of subcontracting' — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat-rate for indirect costs.

Example (contracts): *Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables action's beneficiaries to work together (if creating the website is not an action task); contract for organisation of the rooms and catering for a meeting (if the organisation of the meeting is not an action task mentioned as such in Annex 1); contract for hiring IPR consultants/agents.*

Example (subcontracts): *Contract for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between subcontractors *(Article 13)* and contractors *(Article 10)* on one side and linked third parties *(Article 14)* on the other are:

Articles 10 & 13 Contracts and subcontracts	Article 14 Implementation by linked third parties
The beneficiaries have a contractual link with contractors or subcontractors having as their object the purchase goods, works or services or the implementation of specific action tasks.	The beneficiaries have a legal link with the linked third parties not limited to the action and not based on a contract for the purchase goods, works or services or the implementation of specific action tasks. They must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme). ℹ For more information on conditions for participation and funding, *see the Participant Portal Online Manual.*

The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are only the costs of the linked third party, no profit is allowed (neither for the linked third party nor for the beneficiary).
The beneficiary must award the contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests.	The linked third parties have to be affiliates to a beneficiary or must have a legal link (as explained in Article 14) with the beneficiary.

Example (implementation by linked third party): *Company X and company Y do not control each other, but they are both fully owned by company Z. Company X is beneficiary in the grant and company Y implements some of the action tasks described in Annex 1(Testing and analysis of the resistance of a new component under high temperatures).*

The differences between contracts *(Article 10)* and in-kind contributions against payment *(Article 11)* are:

Article 10 Contracts	Article 11 In-kind contributions against payment
Contractors act as economic operators selling to the beneficiary goods, works or services that are necessary for the action.	Third parties contributing in-kind make available some of their resources to a beneficiary without this being their economic activity (*i.e. seconding personnel, contributing equipment, infrastructure or other assets, or other goods and services*).
The eligible costs are the prices charged to the beneficiary by the contractors or subcontractors (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary).	The eligible costs are the amounts that the beneficiary pays to the contributors according to their agreements, within the limit of the third party's costs (the amounts to be paid to the contributors usually exclude a profit margin but if they do, the profit margin is not eligible).

Example (in-kind contribution against payment): *Civil servant working as a professor in a public university. His salary is paid by the government (the ministry) which employs him. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the paid salary. The reimbursed amount is a cost for the beneficiary and is recorded as such in its accounts. The beneficiary will declare the amount reimbursed to the government in its financial statements.*

Example (in-kind contribution free of charge): *Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in its financial statements, even if they are paid by a third party (the ministry/government).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

- In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

  The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

This table gives an **overview** of the different kinds of **third parties**:

TYPE	CHARACTERISTICS						
	Works on action tasks?	Provides resources or services for action?	What is eligible?	Must be indicated in Annex 1?	Indirect costs?	Selecting the third party	GA articles
Linked third party	**YES**	**NO**	**Costs**	**YES**	**YES**	Must be affiliated or have a legal link and be eligible for funding	Article 14
International partners	**YES**	**NO**	**N/A**	**YES**	**N/A**	Must not be eligible for funding	Article 14a
Subcontractor	**YES**	**NO**	**Price**	**YES**	**NO**	Must be best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contribution	**NO**	**YES**	**Costs**	**YES**	**YES**	May not be used to circumvent the rules	Articles 11 and 12
Contractor (selling, equipment, good or service)	**NO**	**YES**	**Price**	**NO**	**YES**	Must be best value for money, avoid conflict of interest	Article 10
Third parties receiving financial support[31]	The third parties participate in the action as recipients.		**Amount of support given**	**YES**	**NO**	According to the conditions in Annex 1	Article 15

[31] Only if allowed in the work programme/call.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1* ***[OPTION:*** *(with the exception of additional exploitation obligations)****]****, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.****]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [****OPTION:*** *(with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [****OPTION 1 by default****: these beneficiaries][****OPTION 2 if more than one of the three options apply to the grant****: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

*[****additional OPTION for beneficiaries requesting zero funding****: If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION 2:** Not applicable]*

1. Beneficiaries not receiving EU funding

This optional Article will be inserted into the GA if the action is implemented with beneficiaries that do not receive EU funding.

Beneficiaries not receiving EU funding — They participate in the action as beneficiaries, but NOT with EU funding. They must carry out the work under the action and comply with the GA (although not with *all* its obligations; the financial obligations and some IPR obligations do not apply for them).

'**Beneficiaries not receiving EU funding**' are either:

- 'beneficiaries **not eligible** for funding', i.e. beneficiaries which:
  - are NOT from an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme AND
  - were NOT granted exceptional EU funding by the Commission/Agency (during the selection procedure)

For more information on third country participants, *see the Participant Portal Online Manual (international cooperation).*

Beneficiaries that (exceptionally) become eligible for funding during the action, may in principle request funding (as from their eligibility), if the grant agreement is amended to change Articles 9, 57 and Annex 2 (*see Article 55*).

Since the maximum grant amount will NOT be increased *(see Article 5.1)*, this would only be possible if the consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY as from the date of eligibility for funding and if they comply with all the obligations under the GA *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

- 'beneficiaries **requesting zero funding**', i.e. beneficiaries that are eligible for funding, but decided not to request any funding.

Beneficiaries requesting zero funding may in principle request funding later on, if the GA is amended (to change Article 9 and Annex 2; *see Article 55*).

Since the maximum grant amount will NOT be increased *(see Article 5.1), this would only be possible if the* consortium reshuffles the estimated budget in order to free funding for the beneficiary concerned.

Moreover, costs incurred *before* the amendment would be eligible ONLY if they comply with all the obligations under the GA retroactively *(e.g. for actual personnel costs must be supported by time records in accordance with Article 18).*

Their tasks will appear in Annex 1 and their estimated costs (although not eligible) in Annex 2.

Although they participate as beneficiaries in the action, NOT all of the obligations under the GA apply to them. (Which obligations apply or do not apply depends on their role in the grant and if the beneficiary has linked third parties that receive EU funding or not).

This table shows the **GA obligations** that do **NOT apply** to beneficiaries not receiving EU funding (marked by X under each option).

Beneficiary	Articles 5, 6 — Grant amount, form of grant, reimbursement rates and forms of costs	Articles 10 to 15 — Purchases, subcontracting, in-kind contributions, etc	Article 18.1.2 — Keeping records for costs	Article 20.3.(b) and Article 20.4.(b) — Financial reports	Article 20.6 — Currency for financial statements	Article 21 — Payments	Article 22 — Financial checks, reviews and audits	Article 23a — Management of IP	Article 26.4 and Article 27.2 — EU ownership to protect results	Article 28.1 — Obligation to exploit results *	Article 28.2 — Results contributing to standards	Article 30.3 — EU/Agency right to object to transfers or licensing	Article 31.5 — Access rights for EU and MS	Article 40 — Assignment of claims	Articles 42 to 44 — Rejection of costs, reduction, recovery	Articles 47 and 48 — Suspension of payments
Option 1 — IS NOT coordinator and does not have third parties receiving EU funding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Option 2 — HAS linked third parties receiving EU funding	X	X			X		Do not apply for the own costs of the beneficiary	X	Do not apply only for results generated without EU funds					X		
Option 3 — IS coordinator and does NOT have linked third parties receiving EU funding	X	X	X		X		Do not apply for the own costs of the beneficiary	X	X	X	X	X	X	X		

* with the possible exception of additional exploitation obligations, which is a suboption to be activated where applicable

Apart from this, they are treated like the other beneficiaries.

The other obligations apply, just like for normal beneficiaries *(e.g. provide requested information and* allow *technical checks, reviews, audits, investigations or evaluations of the action's impact; maintain confidentiality; comply with security-related obligations; promote the action and give visibility to the EU funding).*

In case of **breach** of any **of** their **obligations**, their participation may be terminated and any of the other Chapter 6 measures (except for rejection of costs or recovery) may be taken.

Examples:

1. *A beneficiary not receiving EU funding does not carry out the tasks attributed to it in Annex 1. At the end of the action, only part of the action is implemented ➔ the Commission may, at the payment of the balance, if the action tasks were not properly implemented, reduce the grant awarded in accordance with Article 43.*

2. *In addition, the beneficiary has breached fundamental ethical principles ➔ it may be excluded from all contracts or grants financed by the EU or Euratom for a maximum period of five years (see Article 45).*

Best practice: The Commission/Agency will assess the consequences of breach of obligations or improper implementation by beneficiaries not receiving EU funding at action level (not at beneficiary level). Therefore, beneficiaries are advised to foresee this situation — before signature of the GA — in the **consortium agreement**.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may **purchase goods, works or services**.

The beneficiaries must make such purchases ensuring the **best value for money or**, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […][23]**]

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EU)[25] or 'contracting entities' within the meaning of Directive 2004/17/EC[26] (or 2014/25/EU)[27] must **comply** with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

Purchases — For the purposes of the GA, '**purchase contract**' means ordinary contract for services, works *(i.e. buildings)* or goods *(e.g. equipment)*, needed to carry out the action, including the purchase of consumables and supplies.

***Example (contracts):** Contract for a computer; contract for an audit certificate on the financial statements; contract for the translation of documents; contract for the publication of brochures; contract for the creation of a website that enables an action's beneficiaries to work together (if creating the website is not an action task); contract for logistic support (e.g. organisation of the rooms, catering) for organising a meeting (if this is not an action tasks described as such in Annex 1); contract for hiring IPR consultants/agents.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of purchase contracts:

- They are usually limited in cost and scope.

⚠ Article 10 contains both additional cost eligibility conditions (in Article 10.1.1) and 'other obligations' (in Article 10.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the purchasing context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, *such as technical quality, etc.*), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Example: *electronic tendering for consumables*

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the purchase.

Occasionally (and only for contracts with a value higher than EUR 60 000) the Commission/Agency may set out **additional conditions** (in view of the possible financial risks, taking into account the size of the contract and the grant amount). These conditions must be described in the work programme/call — as special eligibility conditions for the purchase costs — and be based on the rules which the European Commission applies for its own procurement contracts.

Examples (additional conditions): *minimum number of offers received; publication in the Official Journal or in specific media such as internet, national newspapers, etc.*

3. Additional cost eligibility condition: Controls on the contractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the contractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the contractor *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[32] must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for special procurement procedures, for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition, see Article 4 of Directive 2014/25/EU)*.

Specific cases (purchases):

Purchases between beneficiaries — Are in principle not accepted. If a beneficiary needs supplies from another beneficiary, it is the latter beneficiary that should charge them to the action. (Otherwise there is the risk that the grant is used to charge commercial profit margins.) Purchases between beneficiaries will only be accepted in exceptional and properly justified cases *(e.g. beneficiary A is the usual supplier of beneficiary B for a generic consumable that beneficiary B needs for the action)*.

Framework contracts or **subcontracts** — Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of goods). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[32] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **against payment**.

The **beneficiaries may declare costs related to the payment** of in-kind contributions as eligible (see Article 6.1 and 6.2), **up to the third parties' costs** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The **third parties and their contributions must be set out in Annex 1**. The *[Commission][Agency]* may however **approve** in-kind contributions not set out in Annex 1 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the measures described in Chapter 6.

1. In-kind contributions by third parties against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

A 'third party' can be any legal entity that has not signed the GA (see Article 1).

This Article refers to in-kind contributions (*i.e. non-financial resources of third parties put at the beneficiaries' disposal*) that beneficiaries receive **against payment**. In this case, the beneficiary makes a payment and therefore incurs a cost.

Example (in-kind contributions against payment): *medical equipment provided by a hospital (against a fee) to a university in order to carry out research*

Both this Article and Article 12 only refer to in-kind contributions; they do NOT concern the case of linked third parties carrying out part of the *action tasks* described in Annex 1 *(see Article 14)*.

⚠ Article 11 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the payment to the third party, up to the third parties' costs

The beneficiaries may declare their costs for paying the in-kind contribution *(e.g. the invoice from the third party),* but only up to the costs incurred by the third party — if the other eligibility conditions are fulfilled *(see in particular Article 6.1 and 6.2; e.g. necessary for the action, recorded in the accounts of the beneficiary, etc.).*

If the amount paid by the beneficiary is lower than the cost incurred by the third party, the beneficiary may in addition declare the difference as in-kind contributions free of charge (see Article 12). If it decides to do so, it may have to declare that difference also as receipt (*see Article 5.3.3*).

For the upper limit (third party's costs), normally only the *direct* costs *actually* incurred by the third party will be taken into account.

The following costs may however be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[33] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the GA (alternative to actual costs; *see Article 6.2.F*).

The actual costs must be identifiable and verifiable in the third party's accounts.

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used on the beneficiary's premises

or

- taken into account: if the in-kind contributions are NOT used on the beneficiary's premises (*but, for instance, on the third party's premises*).

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs.

Example (no indirect costs of the third party accepted):

A researcher is seconded to a beneficiary by a legal entity. This researcher works for the beneficiary on its premises. The third party charges the researcher's direct costs (salary and related social security charges of EUR 50 000) and is reimbursed by the beneficiary.

Additionally, the beneficiary has eligible direct costs of EUR 200 000.

The third party's direct costs equal EUR 50 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of beneficiary) + EUR 50 000 (up to the amount of third party's direct costs) = EUR 250 000*
- *eligible indirect costs; 25%* EUR 250 000 = EUR 62 500. No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 250 000 + EUR 62 500 = EUR 312 500

Example (direct costs of third party plus a 25% flat-rate for indirect costs):

[33] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

A legal entity makes available to a beneficiary the use of an installation or specialised piece of infrastructure that the beneficiary needs for the action. The third party charges the full direct and indirect costs of this and is reimbursed by the beneficiary.

The costs of the third party equal EUR 20 000 of actual direct costs plus EUR 8 000 of actual indirect costs. This is a cost for the beneficiary, which may declare it for the action. However, since in H2020 actions indirect costs are reimbursed on the basis of a flat-rate of 25% of the direct eligible costs (calculated as indicated in Article 6.2.E of the GA), the beneficiary will declare as eligible costs for in-kind contributions against payment only EUR 20 000 (payment of third party's direct costs) + EUR 5 000 for (cap for payment of third party's indirect costs) (flat-rate of 25% of 20 000) = EUR 25 000.

Additionally, the beneficiary has got eligible direct costs of EUR 200 000.

Total eligible costs declared by the beneficiary are:

- *total eligible direct costs: EUR 200 000 (direct costs of the beneficiary)+ EUR 25 000 (eligible costs of in-kind contributions against payment) = EUR 225 000*
- *eligible indirect costs: EUR 50 000= 25%* EUR 200 000 (direct costs of the beneficiary, excluding costs of in-kind contributions not used in its premises). No work was subcontracted, and no financial support by third parties was given.*

TOTAL eligible costs declared by the beneficiary: EUR 225 000 + EUR 50 000 = EUR 275 000.

If an audit shows that the costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible (even if they correspond to the amount actually paid by the beneficiary).

3. Additional cost eligibility condition: Third parties and their contributions be set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** (*i.e. non-financial resources*) and an estimation of the **costs budgeted** for the in-kind contributions must be set out in **Annex 1** of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1 (*see Article 55*). Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA (**simplified approval procedure**).

Example (approval): *A new researcher is brought into a team working during the action's second year of implementation. The beneficiary fails to inform the coordinator of the fact that this researcher is seconded from a public research centre to the beneficiary (a university), and therefore the GA is not amended (to include this in Annex 1). These circumstances are explained and justified in the technical report which includes the work carried out by this researcher.*

Approval will NOT be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (no approval): *A proposal includes a beneficiary owning a prestigious laboratory and employing a specialised team of technicians in the field of the call. The proposal is selected after evaluation, taking into account the value provided by the involvement of this laboratory in the action. The GA is signed, but then the beneficiary decides to carry out the tests in another laboratory of a third party, without informing the Commission and amending the GA.*

⚠ The approval is at the discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits, and investigations on the third parties (see Article 22), and in particular audit their underlying costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

Specific cases (in-kind contributions):

Foundations, spin-off companies, etc., created in order to manage the administrative tasks of the beneficiary and which are paid directly by the coordinator — These are typically legal entities (third parties) created or controlled by the beneficiary (usually a public body like a university/ministry) which handle the financial and administrative aspects of the beneficiaries' involvement in research projects.

Their tasks may include, among others, the employment of personnel, purchase of equipment or consumables that the third party puts at disposal of the beneficiary to carry out the work of the project.

Sometimes they also include the handling of the EU contribution (which means that the beneficiary will use the bank account of the third party and that all payments made to that account count for the beneficiary).

The contributions made by these entities are usually qualified as in-kind contributions against payment. If the costs for the services are not recorded in the accounts of the beneficiary *(e.g. there is no invoice from the entity)*:

- the beneficiary has to prove that such practice in line with national law and applicable accounting standards
- the costs must be recorded in the accounts of the third party.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties **free of charge**.

The beneficiaries may declare **costs incurred by the third parties** for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. In-kind contributions by third parties free of charge

If necessary to implement the action, the beneficiaries may use **in-kind contributions** provided by third parties free of charge.

This Article refers to the case where a third party makes available some of its resources to a beneficiary, for free (i.e. without any payment, contrary to the case covered by Article 11). In this case, the beneficiary itself makes no payment and there is therefore NO cost incurred by the beneficiary. However, the GA provides that it may charge the costs incurred by the third party for its in-kind contribution *(see also Article 6.4)*.

Examples (in-kind contributions free of charge):

Civil servant working as a professor in a public university. His salary is paid not by the beneficiary (the university) but by the government (the ministry). The beneficiary will declare these salary costs in its individual financial statements, even if they are paid by a third party (the ministry/government).

Article 12 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Costs of the third party

The beneficiaries may declare the costs of the third party for the in-kind contribution, if the eligibility conditions set out in Article 12.1 and in *Article 6.4* are fulfilled (*e.g. actually incurred by the third party, necessary for the action, incurred during the action duration, etc.).*

The costs must be recorded in the accounts *of the third party*.

Normally, only the *direct* costs *actually* incurred by the third party may be declared.

The following costs may however (alternatively) be quantified using unit costs (to ensure similar costing as for charging costs under the GA):

- for personnel costs: hourly rate on the basis of usual costs accounting practices (alternative to actual costs; *see Article 6.2.A.1*)
- for SME owner costs: hourly rate fixed by Commission Decision C(2013) 8197[34] *(see Article 6.2.A.4)*
- for internally invoiced goods and services: unit cost on the basis of usual accounting practices *(see Article 6.2.D.5)*
- for unit costs for clinical studies: unit cost fixed in the GA (alternative to actual costs; *see Article 6.2.F*).

The *indirect* costs of the third party are either:

- NOT taken into account: if the resources (in-kind contribution) are used in the beneficiary's premises

or

- taken into account: if the in-kind contributions are used on the third party's premises.

  In this case, the direct costs actually incurred by the third party may be increased by a flat-rate of 25% on those costs; but the beneficiary may NOT include them a second time to calculate its own indirect costs.

Free of charge in-kind contributions may also have to be declared as receipts *(see Article 5.3.3(c))* — capped by the amount declared as third party costs for the contribution.

If an audit shows that the direct costs declared by the beneficiary are higher than those incurred by the third party, the difference will be rejected as ineligible.

3. Additional cost eligibility condition: Third parties and their contributions set out in Annex 1 — Simplified approval procedure

The **third parties**, their **in-kind contributions** and an estimation of the **costs budgeted** for the in-kind contributions must be mentioned in Annex 1 of the GA.

If the in-kind contributions are NOT used on the beneficiary's premises, their estimated costs must be also set out in **Annex 2** (additional information column).

New in-kind contributions — If the need for third parties' in-kind contributions was not known at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in the Annex 1 (*see Article 55)*. Exceptionally, the Commission/Agency may approve costs related to in-kind contributions not included in Annex 1 without formally amending the GA (**simplified approval procedure**; for details, *see Article 11*).

[34] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

4. Additional cost eligibility condition: Controls on the third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the third parties *(see Article 22)*, and in particular to audit their costs.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the **best value for money** or, if appropriate, the **lowest price**. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...]*[28]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]*.**]***

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').**]***

The tasks to be implemented and the estimated cost for each subcontract must be **set out in Annex 1** and the total estimated costs of subcontracting per beneficiary must be **set out in Annex 2**. The *[Commission][Agency]* may however **approve** subcontracts not set out in Annex 1 and 2 **without amendment** (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 **also apply** to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) **must comply** with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

If necessary to implement the action, the beneficiaries may award subcontracts covering the **implementation** of certain **action tasks** described in Annex 1.

⚠ **Subcontractors —** Subcontractors participate in the action by carrying out action tasks *for* the beneficiary. They are NOT beneficiaries and therefore have no direct obligations under the grant agreement (but their beneficiaries must ensure that they comply with certain key obligations).

Subcontract — For the purposes of the GA, a '**subcontract**' means the purchase of goods, works or services *that are identified in Annex 1 as action tasks*.

Example (subcontracts): *Contracts for (parts of) the research or innovation tasks mentioned in Annex 1.*

The differences between purchase contracts, subcontracts, in-kind contributions against payment and implementation by linked third parties are explained in Article 8.

Characteristics of subcontracting:

- Based on business conditions

  This means that the subcontractor charges a price, which usually includes a profit (— this distinguishes it from linked third parties; *see Article 14*).

- Subcontractor works without the direct supervision of the beneficiary and is not hierarchically subordinate to the beneficiary (— this distinguishes it from action tasks implemented by in-house consultants; *see Article 6.2.A.2).*

- Subcontractor's motivation is pecuniary, not the research work itself. The subcontractor is paid by the beneficiary in exchange for its work.

- Responsibility towards the EU/Euratom for the subcontracted work lies fully with the beneficiary.

  The beneficiary remains responsible for all its rights and obligations under the GA, including the tasks carried out by a subcontractor.

- Subcontractor has no rights or obligations towards the Commission/Agency or the other beneficiaries (it has no contractual relation with them).

Examples (subcontracts):

Testing and analysis of the resistance of a new component under high temperatures, if described in Annex 1 as action task.

Only **limited parts of the action** may be subcontracted — except for actions involving PCP/PPI (because the PCP/PPI action tasks are by definition fully subcontracted).

The beneficiaries must make special arrangements regarding **results** produced by the subcontractors (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

⚠ **Security obligations —** Stricter rules apply for action tasks that involve information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

ⓘ For more information on security obligations, *see the Guidelines for the handling of classified*

⚠ Article 13 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Best value for money or lowest price

The beneficiaries must base their subcontracts either on the best value for money (considering the quality of the service proposed, i.e. the **best price-quality ratio**) or on the lowest price.

This requirement reflects the **general cost eligibility condition** set out in Article 6.1(a)(vii) (i.e. that costs must be reasonable and comply with the principle of sound financial management) and applies it specifically to the subcontracting context.

The best value for money principle does NOT in all cases require **competitive selection procedures**. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the **lowest price**. Selecting the lowest price may however be appropriate for automatic award procedures where the subcontract is awarded to the company that meets the conditions and quotes the lowest price.

In order to provide a good analysis of the price-quality ratio, the criteria defining quality must be clear and coherent with the purposes of the action task that is subcontracted.

3. Additional cost eligibility conditions for actions involving PCP or PPI

This additional option will be inserted into the GA if the action involves pre-commercial procurement (PCP) or procurement of innovative solutions (PPI).

⚠ This concerns research and innovation actions or innovation actions *with* a PCP or PPI.
This should NOT be confused with PCP/PPI action (separate type of action, which use a different model grant agreement and whose *main* action task is the implementation of the PCP or PPI).

The additional rules mirror the key obligations for PCP/PPI actions from the H2020 MGA PCP/PPI.

4. Additional cost eligibility condition: Tasks set out in Annex 1 — Total estimated costs of subcontracting set out in Annex 2 — Simplified approval procedure

The **tasks to be implemented** and the **estimated cost** for each subcontract must be set out in Annex 1.

It is the work (i.e. the action tasks) to be performed by a subcontractor that must be identified in Annex 1. The name of the subcontractors is in principle not necessary.

The description should also include an estimation of costs for each subcontract.

Moreover, it should explain the need for a subcontract, taking into account the specific characteristics of the action.

⚠ If the **name** of the subcontractor is known at the time of the grant signature the beneficiary may indicate it in Annex 1. However, the fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the Commission of the subcontract (or the subcontracting costs). For example, if the subcontractor was not selected based on best value-for-money the Commission may reject the costs even if its name was indicated in Annex 1.

Additionally, the **total estimated costs for subcontracting** per beneficiary must appear in the table of estimated costs of Annex 2.

New subcontracts — If the need for a subcontract is not foreseen at the moment of the signature of the GA, the coordinator must request an **amendment** of the GA in order to introduce it in Annex 1 and 2 (*see Article 55*). Exceptionally, the Commission/Agency may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the GA (**simplified approval procedure**).

The new subcontract must be included and explained in the technical periodic report (in the section 'unforeseen subcontractor').

Approval will NOT be granted if the subcontract risks to substantially change the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Example (approval): *A beneficiary loses some personnel specialised in a particular field, and as a result decides to subcontract some tasks it had originally foreseen to carry out itself. The beneficiary fails to inform the coordinator of this fact and therefore the GA is not amended. These circumstances are declared in the periodic report and it is approved by the Commission.*

Example (no approval): *A key beneficiary leaves the consortium and the coordinator subcontracts all the tasks of this beneficiary.*

⚠ The approval is at the full discretion of the Commission/Agency and there is no automatic entitlement to it. Beneficiaries that rely on the simplified approval procedure bear the **full risk** of non-approval and rejection of costs by the Commission/Agency.

5. Additional cost eligibility condition: Controls on the subcontractor (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the subcontractor *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to subcontractors

The beneficiaries must ensure that the subcontractors comply with certain obligations under the GA.

Obligations that must be extended to subcontractors:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the subcontractors.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

7. 'Other obligation': Compliance with national procurement rules

Beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[35]) must **moreover** comply with the applicable **national law on public procurement**. These rules normally provide for a special procurement procedure for the types of contracts they cover.

> 'Contracting authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law *(see Article 2.1(1) of Directive 2014/24/EU)*.
>
> > 'Bodies governed by public law' also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2.1(4) of that Directive*).
>
> 'Contracting entities' means entities operating in a utilities sector (water, energy, transport, postal services). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights *(for the full definition see Article 4 of Directive 2014/25/EU)*.

Specific cases (subcontracting):

Subcontracting between beneficiaries — Is NOT allowed in the same GA. All beneficiaries contribute to and are interested in the action; if one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.

Subcontracting to affiliates — Is NOT allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions. Otherwise, these affiliates may work in the action, but they must be identified as linked third parties under Article 14 and declare their own costs.

Coordination tasks of the coordinator *(e.g. distribution of funds, review of reports and others tasks listed under Article 41.2(b))* **—** Can NOT be subcontracted. Other activities of the coordinator may in principle be subcontracted.

Framework contracts or **subcontracts —** Framework contracts can be used for selecting a provider if this is the usual practice of the beneficiary (e.g. for a type of service). In order to be eligible, the framework contract must (have) be(en) awarded on the basis of best-value-for-money and absence of conflict of interest. The framework contract does not necessarily have to be concluded before the start of the action.

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[35] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[30] and **third parties with a legal link to a beneficiary**[31] (**'linked third parties'**) may implement the action tasks attributed to them **in Annex 1**:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted **joint and several liability** with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

*The linked third parties may declare as eligible the **costs they incur** for implementing the action tasks in accordance with Article 6.3.*

*The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can **exercise their rights** under Articles 22 and 23 also towards their linked third parties.*

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] **'Third party with a legal link to a beneficiary'** is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

1. Linked third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action is implemented with linked third parties.

⚠ **Linked third parties —** Linked third parties are allowed to participate in the action, like the beneficiary they are linked to. They are NOT beneficiaries, but they are allowed to participate fully in the action and receive EU funding; they will therefore be treated for many issues (including cost eligibility; see *Article 6.3*) like beneficiaries and their beneficiaries must ensure that they comply with certain key obligations.

⚠ **Combining H2020 & other EU grants —** The terminologies under different EU funds/funding programmes may differ *(e.g. 'linked third parties' under H2020 are the SAME as 'affiliated entities' under the Financial Regulation, while 'affiliated entities' under H2020 is NARROWER than 'affiliated entities' under the Financial Regulation (see Articles 2.1(2) and 23(5) of the Rules for Participation Regulation No 1290/2013 and Article 122 of the Financial Regulation No 966/2012)*.

Characteristics of implementation by linked third parties:

- Linked third party does not charge a price, but declares its *own costs* for implementing the action tasks
- Linked third party itself performs certain action tasks directly and is responsible for them towards the beneficiary. Linked third parties do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the work carried out by the linked third party.

  Moreover, the beneficiaries are financially responsible for any undue amount paid by the Commission/Agency as reimbursement of costs for their linked third parties — unless the GA foresees joint and several liability (see Article 44.1).
- Work is attributed to the linked third party (in Annex 1) and is usually carried out on its premises
- Work is under the full and direct control, instructions and management of the linked third party, who carries out this part of the action (with its employees).

Only **affiliated entities** or **entities with a legal link to a beneficiary** can be linked third parties.

'Entities with a legal link' refers to an established relationship (between the third party and the beneficiary), which is:

– broad and not specifically created for the work in the GA

  Accordingly, its duration must go beyond the action duration and it usually pre-dates and outlasts the GA; ad hoc collaboration agreements or contracts to carry out work in the action are NOT covered. In this latter case, both legal entities should be beneficiaries.

AND

– a legal relationship.

  This may be either a legal structure (*e.g. the relationship between an association and its members)* or through an agreement or contract not limited to the action *(e.g. a collaboration agreement for research in a particular field)*.

  If the only relation between two entities is a *capital link* (i.e. ownership of part of the issued share capital), the entity may only participate as a linked third party if it is an 'affiliated entity' *(see below)*.

'Affiliated entity' means:

– under the direct or indirect control of the beneficiary or

- under the same direct or indirect control as the beneficiary or
- directly or indirectly controlling the beneficiary.

Affiliated entities cover not only the case of parent companies or holdings and their daughter companies or subsidiaries and vice-versa, but also the case of affiliates between themselves *(e.g. entities controlled by the same entity)*.

Examples (entities with a legal link):

1. Joint Research Units (JRU) *(i.e. research laboratories/infrastructures created and owned by two or more different legal entities in order to carry out research)* ***—*** *They do not have a separate legal personality, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from 'owner' entities. A member of the JRU is the beneficiary and any other member of the JRU contributing to the action and who is not a beneficiary of the GA has to be identified in Article 14. The JRU has to meet all the following conditions:*

- *scientific and economic unity*
- *last a certain length of time*
- *recognised by a public authority.*

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the applicable national law. The beneficiary must provide to the Commission/Agency, a copy of the resolution, law, decree, decision, attesting the relationship between the beneficiary and the linked third party(ies), or a copy of the document establishing the 'joint research unit', or any other document that proves that research facilities are put in a common structure and correspond to the concept of scientific and economic unit.

2. Associations, foundations *or* ***other legal entities composed of members —*** *That entity is generally the beneficiary and the members are the linked third parties.*

Examples (affiliated entities):

1. *Company A established in France holding 20% of the shares in Company B established in Italy. However, with 20% of the shares it has 60% of the voting rights in company B. Therefore, company A controls company B and both companies may be linked third parties in a H2020 GA.*

2. *Company X and company Y do not control each other, but they are both owned by company Z. They are both considered affiliated entities.*

Linked third parties must fulfil the same **conditions for participation** and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme).[36]

Example: *Company A established in the UK is a beneficiary in a grant. A owns B, a French company and also owns C, an US company. B & C may be considered affiliates to A, however only B may declare costs as a third party linked to A, because company C is established in a third country that is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.*

For more information on conditions for participation and funding, *see the Participant Portal Online Manual*.

They must be **named** in Article 14 and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the linked third party is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the linked third parties (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

The Commission/Agency may (during the selection procedure) **require joint and several liability of a linked third party**, if:

- the financial capacity of a beneficiary is 'weak' and
- the beneficiary mainly coordinates the work of its linked third party.

[36] *See Articles 9 and 10 of the Rules for Participation Regulation No 1290/2013.*

Examples:

1. *The financially weak beneficiary is an association and most of the work is carried out by several of its members as linked third parties.*

2. *The financially weak beneficiary is a small company with a substantial part of its work implemented by a bigger affiliated company.*

3. *The proposal submitted by four independent entities established in four Member States is positively evaluated. The four successful applicants decide to form a legal entity to simplify the management of the project. The newly established entity will be the beneficiary, i.e. a new legal entity. The successful applicants will carry out the work as linked third parties of the new legal entity.*

If requested, the third party must accept joint and several liability with the beneficiary.

In this case it must sign a declaration (on paper and in blue-ink, using Annex 3a) to be submitted by the beneficiary at the moment of its accession to the GA (or of the amendment introducing the linked third party in the GA*; see Article 56*). The linked third party must send the original to the beneficiary (by registered post with proof of delivery), who must upload it (as a scanned PDF copy) in the system.

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files.

The liability is for any amount owned by the beneficiary under the GA, and up to the linked third party's maximum EU contribution in Annex 2.

ℹ For more information on the financial capacity check, *see the Participant Portal Online Manual*.

Entities performing a **substantial part of the work** (i.e. action tasks) should in principle be **beneficiaries**, NOT linked third parties. Linked third parties should only exceptionally perform a major part of the R&I work.

Examples:

1. *Entities specifically established for the purpose of implementing the action (e.g. EEIGs).*

2. *National research associations established according to the national law in order to carry out research not limited to the action.*

3. *A group of legal entities (companies/research organisations) that have a common research agenda and that have a structure consisting of an association coordinating the research. This structure/consortium is not limited to the H2020 action and the members have strong contractual commitments among each other and the coordinating association. The association represents its members and coordinates administratively their work in the action, even if it is not performing any R&I work in the action. In this case, the association may be the beneficiary and the members of the association are its linked third parties carrying out the R&I work.*

⚠ Article 14 contains both additional cost eligibility conditions (in Article 14.1.1) and 'other obligations' (in Article 14.1.2).

2. Additional cost eligibility condition: Linked third parties identified in Article 14 — Tasks set out in Annex 1 — Estimated costs set out in Annex 2 — No simplified approval procedure

The linked third parties must be named in Article 14 and their tasks and estimated costs must be identified in Annexes 1 and 2 already at the moment of the GA signature (or added later, through an amendment; *see Article 55*).

There is NO simplified approval procedure.

3. Additional cost eligibility condition: Costs of the linked third party

The linked third parties may declare *their costs* (in their financial statements; *see Article 20.3*), if the **eligibility conditions** set out in Article 6.3 are fulfilled *(e.g. actually incurred by the linked third party, necessary for the action, incurred during the action duration, etc.)*.

The costs must be recorded in the accounts of the linked third party.

Linked third parties may declare costs for all cost categories (as provided for in Article 5), including indirect costs (at the 25% flat rate).

Each linked third party declares its own costs. The costs of the linked third party must not be included in the beneficiary's financial statements.

Each linked third party has its own **financial statements**, but these statements must be *submitted by its beneficiary* (since linked third parties cannot sign them in the IT system; *see Article 20*).

For this purpose, linked third parties must send their signed financial statements on paper to their beneficiary.

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Each linked third party has to provide its own ***certificate* on the financial statements** (**CFS**; *see Article 20.4*).

The threshold of EUR 325 000 applies to each linked third party (independently of its beneficiary).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

4. Additional cost eligibility condition: Controls on the linked third parties (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the linked third parties *(see Article 22)*, and in particular to audit their costs and proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

5. 'Other obligation': Extension of obligations under the GA to linked third parties

The beneficiaries must ensure that the linked third parties comply with certain obligations under the GA.

Obligations that must be extended to linked third parties:

- Record-keeping obligations *(see Article 18)*
- Reporting *(see Article 20)*

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*

Best practice: In order to be able to fulfil this obligation, the beneficiaries should impose contractual arrangements on the third parties.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the linked third parties.

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following **international partners**[37] may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

– *will not be reimbursed and*

– *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission , the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36 and 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary braches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION 2:** Not applicable**]

[37] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

1. International partners

4.0 This optional Article (together with the corresponding options in Article 4) will be inserted into the GA if the action is implemented with international partners. It was introduced with GA version 4.0 and does NOT automatically apply to older grant agreements (however beneficiaries with older GAs may ask for an amendment to introduce international partners *see Article 55*).

International partners — International partners are allowed to participate in the action without EU funding. They are NOT beneficiaries and do NOT receive EU funding; they therefore have no direct obligations under the grant agreement (but their beneficiaries must to ensure that they comply with certain key obligations).

Characteristics of implementation by international partners:

- International partners perform their action tasks directly. They do NOT sign the GA (and are therefore not beneficiaries).
- The beneficiary remains responsible towards the Commission/Agency for the action tasks performed by its international partner.

- International partners perform their action tasks without receiving EU funding, i.e. their costs are NOT eligible for reimbursement under the grant. Therefore, they will not be subject to financial checks, reviews or audits.

  The costs of the international partners are estimated in Annex 2 (to get an overview of the overall project budget). But this is for information purposes only, the international partners are not required to report on their costs.

International partners do NOT need to have a (capital or legal) link to the beneficiary (but they may have one).

They must NOT be eligible for funding, i.e. be:

- a legal entity established in a third country not listed in General Annex A to the H2020 Work Programme or

  Example: *A consortium of legal entities from EU Member States, H2020 associated countries and third countries listed in General Annex A to the H2020 Work Programme wants to work with a legal entity established in New Zealand. Since the New Zealand entity would like to be involved in the action without requesting EU funding and without becoming a beneficiary, one of the beneficiaries may decide to list the New Zealand entity as its international partner and attribute certain action tasks to it (provided that the international partner agrees to the action tasks and the related obligations under the GA).*

- an international organisation other than international European interest organisations[37].

They may be used to implement any of the action tasks.

They must be **named** in Article 14a and their action tasks and estimated costs must be set out in Annexes 1 and 2 already at the moment of the GA signature (or if the international partner is added later, through an amendment; *see Article 55*).

The beneficiaries must make special arrangements regarding **results** produced by the international partners (in order to be able to fully comply with their obligations under the GA; *see Article 26.3*).

Although they are not beneficiaries and do not receive EU funding, their beneficiaries must ensure that they comply with certain key (non-financial) obligations:

Thus, they must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 to verify the proper implementation of the action tasks and that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

Moreover, they must extend the following obligations under the GA to the international partners:

Obligations that must be extended to international partners:

- Record-keeping obligations (on the scientific and technical implementation; *see Article 18.1.1*)
- Technical reporting (in the required language; *see Article 20.3(a), 20.4(a) and 20.7)*
- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38).*

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the international partners.

[37] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013*: **'international European interest organisation'** means an international organisation, the majority of whose members are

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving financial support.*

15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving financial support.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties (i.e. funding by the beneficiary of (one or more) recipients that are not party to the GA, also called '**cascade funding**').

⚠ Actions may involve financial support to third parties ONLY where this is explicitly allowed in the work programme/call.

'Financial support' may be given via a financial donation to natural persons *(e.g. allowance, scholarship, fellowship)* or legal persons *(e.g. non-repayable financial assistance to local NGOs)*, seed money to start-ups or microcredit, or other forms. (For prizes, *see Article 15.2*.)

Examples:

1. *An innovation project in the area of sustainable agriculture and forestry includes financial support for end-users (farmers) testing the technology developed within the action.*

2. *One of the work packages in Annex 1 includes funding for awarding three research scholarships in the field of the action.*

Member States or associated countries, and whose principle objective is to promote scientific and technological cooperation in Europe.

Support in kind *(e.g. transfer of material for free)* by the beneficiary to a third party is NOT considered financial support.

Linked third parties may provide financial support to third parties under the same conditions as the beneficiaries.

The recipients are not party to the GA and therefore do NOT need to be identified in the GA or have a PIC.

⚠ Article 15.1 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of the financial support — Types of activities — Categories of persons — Criteria for financial support

The beneficiaries must comply with the conditions for the support that are set out in Annex 1, and in particular:

- the maximum amount per third party

  The maximum amount may normally NOT be more than EUR 60 000 per recipient. A higher amount can exceptionally be set out in Annex 1, if the work programme/call explicitly allows it and the proposal (and Annex 1) explain why this is necessary for the objectives of the action.

  This is a limit *per* recipient; several recipients could receive up to EUR 60 000 each *(e.g.* 3 *grants of EUR 50 000 each)*.

- the criteria for determining the exact amount of financial support *(e.g. EUR 2 000 per hectare; EUR 30 000 per student for a two-year scholarship)*

  The financial support provided by the beneficiaries may take any form *(e.g. a lump sum or the reimbursement of the costs incurred by the recipients when implementing the supported activities)*.

- a clear and exhaustive list of the types of activities that qualify for financial support for third parties *(e.g. financial support for third parties allowed for technology-testing activities)*

  These activities should benefit, primarily, the recipients (NOT the beneficiaries).

  The financial support is NOT the same as subcontracting (see *Article 13*) or purchase of goods, works or services (*see Article 10*).

- the persons or category(ies) of persons that may receive it *(e.g. farmers; PhD students)*

  Beneficiaries should describe in Annex 1 the procedures for selecting the recipients.

- the criteria for giving financial support *(e.g. physical characteristics of the agricultural plots which make them suitable for the purpose of the action)*.

  These criteria should respond to the objectives set out in the work programme/call.

The conditions must also already be part of the proposal *(see the proposal templates)*.

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the proper use of the funding by the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

Best practice: In order to be able to fulfil this obligation, the beneficiaries should to impose contractual arrangements on the recipients (including control measures and/or reducing the financial support).

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these ***conditions*** *must include:*

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can ***exercise their rights*** *under Articles 22 and 23 also towards the third parties receiving a prize.*

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 ***also apply*** *to the third parties receiving a prize.****]***

[OPTION 2: *Not applicable****]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

1. Financial support to third parties (via prizes)

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves financial support to third parties in the form of prizes.

> ***Example:*** *Inducement prize announced at the beginning of the action for identifying a (new) approach to dealing with a technical implementation problem to be tackled at the end of the action.*

Such prizes are NOT EU prizes (although the beneficiaries must promote the action and give visibility to the EU funding received; *see Article 38*).

⚠ Article 15.2 contains both additional cost eligibility conditions (in Article 15.2.1) and 'other obligations' (in Article 15.2.2).

2. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Conditions for participation — Award criteria — Amount of the prize — Payment arrangements

Just like for financial support via grants, the beneficiaries must comply with the conditions for support that are set out in Annex 1 and in particular:

- the conditions for participation and the conditions for early termination of the contest, if any *(e.g. eligibility and exclusion criteria; deadline for submission of entries; possibility of hearings)*

- the award criteria for assessing the quality of entries in light of the objectives and expected results

  The criteria must be objective.

- the amount of the prize *(e.g. EUR 70 000)*

- the payment arrangements (usually one instalment).

3. Additional cost eligibility condition: Controls on the recipients (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the recipients of a prize, to verify that the conditions for the award of the prize have been respected *(see Article 22)*.

They must also ensure that the Commission/Agency has the right to make evaluations of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

4. 'Other obligation': Extension of obligations under the GA to recipients

The beneficiaries are responsible for the award of the prize to the recipients and must ensure that they comply with certain obligations under the GA.

Obligations that must be extended to recipients:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the recipients.

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

*(b) **categories of users that may have access**:*

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

***Access** for user groups with a majority of users not working in a EU or associated country[34] is **limited** to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

*(c) procedure and criteria for **selecting** user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a selection panel set up by the access providers.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

***[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: […]*[35]

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

(a) advertise widely, including on a dedicated website, the access offered under the Agreement;

(b) promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;

*(c) ensure that users **comply** with the terms and conditions of the Agreement;*

*(d) ensure that its obligations under Articles 35, 36, 38 and 46 **also apply** to the users.*

[OPTION 2:** Not applicable**]

[32] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[34] For the definition see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[35] If the authorising officer considers necessary to give priority to certain categories of users.

1. Trans-national access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves trans-national access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures' under the following topics:
  - 'integrating activities' (*INFRAIA-1-2014-2015*: Integrating and opening existing national and regional research infrastructures of European interest)
  - 'individual support'(*INFRADEV-3-2015*: Individual implementation and operation of ESFRI projects)
  - 'cluster support' (*INFRADEV-4-2014-2015*: Implementation and operation of cross-cutting services and solutions for clusters of ESFRI and other relevant research infrastructure initiatives).

For 'integrating activities', access to research infrastructure is a mandatory component, while it is optional for the other two topics. 'Cluster support' actions currently only include pilot provision of trans-national access, no virtual access *(see the H2020 Work Programme 2014-2015)*.

Grants for this type of action usually **reimburse** — for the provision of access activity — the following **types of costs**:

- 'access costs' (i.e. the operating costs of the research infrastructure[38] or installation[39] and costs related to logistical, technological and scientific support for users, including ad-hoc user training and the preparatory and closing activities needed to use the installation)

  'Access costs' for *trans-national* access may be declared as unit costs, actual costs or — under certain conditions — as a combination of the two *(see Articles 5.2(f) and 6.2.F)*, while the other costs in this list must be declared as actual costs *(see Articles 5.2(d) and 6.2.D)*.

  If access costs are declared as *unit cost*, they must be declared under the budget category F.2 'access costs for providing trans-national access to research infrastructure' *(see Article 5.2(f) and 6.2.F)*.

  If they are declared as *actual costs*, they must be declared under the other budget categories *(see Articles 5.2(a-e) and 6.2.A-E)*.

- users' travel and subsistence costs

- costs of advertising the trans-national access offered under the action

- costs related to the selection procedure *(e.g. the selection panel members' travel and subsistence costs, logistical costs of meetings, fees, etc.)*

- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)*.

Capital investments (i.e. equipment costs for renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed (for the provision of access activities; *see Article 6.2.D.2*).

Trans-national access must be **measured** (in 'units of access').

The units of access for the various installations that provide trans-national access under the grant must be specified in Annex 1 of the GA.

Examples (units of access): *per beam-hour for a synchrotron; per night for a telescope; per number of frozen embryos for a mouse repository; per week of access for a historical archive; per campaign-day for a research vessel.*

For trans-national access, the GA will always specify a unit of access (independently of whether the costs are declared as unit cost or actual costs).

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[38] For the definition of research infrastructure, *see Article 2(6) of the H2020 Framework Programme Regulation No (EU) No 1291/2013 and the footnote in Article 6.2.D.4 of the MGA:* '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructure such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructure may be 'single-sited', 'virtual' or 'distributed'.

[39] **'Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

⚠ **Record-keeping —** The beneficiaries must keep appropriate records and supporting documentation to justify the number of units of trans-national access for which they declare costs *(see Article 18)*, including:

- users' names, nationalities and home institutions
- the nature of access and

In addition, they must include (just like for virtual access) detailed information on the provision of access activity in the **periodic technical reports** *(see Article 20.3)*.

⚠ Article 16.1 contains both additional cost eligibility conditions (in Article 16.1.1) and 'other obligations' (in Article 16.1.2).

2. Additional cost eligibility condition: Access which must be provided

Trans-national access can be either:

- **in person** (hands-on), provided to selected users that visit the installation or
- **remote**, through the provision to selected users of remote scientific services.

  Examples (remote access): *provision of reference materials or samples (e.g. shipping of a virus strain); performing a remote sample analysis or sample deposition; remote access to a high-performance computing facility.*

  Remote trans-national access requires competitive selection of the users to be served under the GA as usually it applies to resources that are not unlimited *(e.g. computing hours on a supercomputer or remote analysis of a sample)*. It is thus different from virtual access, which applies to resources that can be simultaneously used by an unlimited number of users *(e.g. a dataset available on the internet)*.

Trans-national access must be given to selected user groups (free of charge).

3. Additional cost eligibility condition: Categories of users that may have access — Limited access for special user groups

For trans-national access, user groups in which all or most users work in non-associated **third countries** may ONLY have access for up to 20 % of the total number of units of access provided under the grant.

The consortium should itself define if this 20 % limit is uniformly applied to the different installations or if the above mentioned user groups may use some installations more than others. It should do this in the consortium agreement.

4. Additional cost eligibility condition: Selection procedure with a selection panel

For trans-national access, access providers must set up a common **selection panel** that regularly evaluates the applications for access and recommends a shortlist of the user groups that would benefit from access.

If justified, an access provider may use several different selection sub-panels.

Example: *Different thematic selection sub-panels could be set up for a set of analytical facilities serving multidisciplinary communities.*

5. 'Other obligation': Controls on the users (by the Commission/Agency, ECA and OLAF) — Evaluation of the impact of the action

The beneficiaries must ensure that the Commission/Agency, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to carry out checks, reviews, audits and investigations on the users *(see Article 22)*, and in particular to audit proper implementation of action tasks.

They must also ensure that the Commission/Agency has the right to make an evaluation of the impact of the action under Article 23.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users *(for example, if they refuse access and the Commission/Agency cannot verify the eligibility of the costs, it will reject them).*

6. 'Other obligation': Extension of obligations under the GA to users

The beneficiaries must also ensure that the users comply with certain obligations under the GA.

Obligations that must be extended to users:

- Avoiding conflicts of interest *(see Article 35)*
- Maintaining confidentiality *(see Article 36)*
- Promoting the action and give visibility to the EU funding *(see Article 38)*
- Liability for damages *(see Article 46)*.

It is the beneficiaries' responsibility to ensure that these obligations are accepted by the users.

16.2 Rules for providing virtual access to research infrastructure

[OPTION 1 for virtual access to research infrastructure: *'**Access providers**'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

*(a) **access which must be provided**:*

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services **assessed periodically** by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2: *Not applicable**]***

16.3 Consequences of non-compliance

[OPTION 1 to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable**]***

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

1. Virtual access to research infrastructure

This optional Article (together with the corresponding options in Article 6 and other provisions) will be inserted into the GA if the action involves virtual access to research infrastructure for scientific communities ('provision of access activities'), i.e.:

- actions under Part I of Horizon 2020, 'Research infrastructures'.

H2020 grants will only support virtual services that are *widely* used by the community of European researchers.

Grants for this type of actions usually **reimburse** — for the provision of access activity — the following **types of costs**:

- operating costs of the installation during the course of the action
- costs related to technological and scientific support for users access *(e.g. a helpdesk)*

- costs of advertising virtual access offered under the action
- costs related to the assessment carried out by the board of international experts *(e.g. costs of organising a board meeting)*
- costs of preparing the detailed access activity information that must be included in the periodic technical reports *(see Article 20.3)* and the assessment report *(see below point 3)*.

The specific unit cost for access to research infrastructure (F.2) does NOT cover virtual access (only trans-national access).

Capital investments (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure or other assets) will NOT be reimbursed — unless provided for in the work programme/call.

Virtual access can in principle NOT be **measured**; therefore the GA does not specify a unit of access for virtual access provision.

The beneficiaries must include detailed information on the provision of access activity in the **periodic technical reports**, in the form of statistics on all users in the reporting period compiled through web analytical tools *(see Article 20.3)*.

⚠ Article 16.2 contains additional cost eligibility conditions.

2. Additional cost eligibility condition: Access which must be provided

Virtual access applies to widely-used research resources that are openly and freely available **through communication networks**.

Example: *access to an open database available on the internet*

Access must be open to all users; users are not selected.

3. Additional cost eligibility condition: Periodic assessment by a board of international experts

For virtual access, the access services must be regularly assessed by an **external board** of international experts.

At least two assessments are usually carried out during the course of an action.

The assessment reports must already be part of the proposal (as deliverables; see the proposal templates) and be included in Annex 1 of the GA.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any **information requested** in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Requests for information

In addition to the specific information obligations set out in other parts of the GA *(e.g. Articles 22.1.2, 22.1.3 and 23)*, the Commission/Agency may request a beneficiary to provide any information it needs to verify that the beneficiary:

- properly implemented the tasks described in Annex 1
- complied with its obligations under the GA.

The Commission/Agency may request the information for **any purpose** *(e.g. checks for monitoring the action or assessing reports and requests for payment; reviews; audits; investigations; evaluation of the action's impact)*.

It may request **any type** of information it needs (including personal data, to order to verify that costs declared for specific people are eligible; *see Article 39*). The level of detail will depend on the purpose of the request.

The Commission/Agency may request the information at **any time**, either during the action or afterwards.

Examples:

1. *In an ex-post financial audit that starts 18 months after the balance is paid, the Commission/Agency may request any information it needs during the procedure. The audit may continue beyond the two years after the balance is paid (see Article 22).*

2. *The Commission may request information from the beneficiaries in order to evaluate the action's impact up to five years after the balance is paid (see Article 23).*

3. *The beneficiaries must comply with any additional exploitation obligations set out in Annex 1, for up to four years after the action ends (see Article 3). They are therefore obliged to provide any information the Commission/Agency requests to verify that the action was correctly implemented and that the beneficiaries complied with their obligations under the GA.*

The beneficiary concerned must provide accurate, precise and complete information, in the format and within the deadline requested *(see Article 22)*.

It is the coordinator who usually provides the information requested — unless the GA specifies direct communication with the other beneficiaries *(see Articles 20, 22, 23, 30, 41, 55)*.

If the coordinator no longer exists after the action ends *(e.g. if it went bankrupt)*, beneficiaries may provide the information requested directly to the Commission/Agency.

Until the balance is paid, all information is sent via the Participant Portal. Afterwards, information requests may have to be sent in writing by registered post with proof of delivery *(see Article 52)*.

2. Information in the Participant Register

Each beneficiary must keep its information in the Participant Register up-to-date, including after the end of the grant.

⚠ Updated information remains necessary both to contact the beneficiaries after the end of the action and if they want to participate in other EU grants.

The information includes:

- name
- address
- legal representatives
- legal form *(e.g. private limited liability company, public law body, S.A., S.L.)*
- organisation type *(e.g. SME, secondary or higher education establishment, etc.)*.

The IT system automatically informs the coordinator whenever a beneficiary updates its information.

ℹ For more information on beneficiary registration, *see the Participant Portal Online Manual*.

3. Information likely to delay or affect the action or EU financial interests

Each beneficiary must immediately inform the coordinator if an event is likely to significantly affect or delay the action's implementation or affect the EU financial interests.

> ***Examples (situation likely to significantly affect or delay the action's implementation or affect the EU financial interests):*** *a beneficiary is under financial stress and chooses to liquidate; a beneficiary is bought by another legal entity; a beneficiary plans to move its laboratory from a Member State to a non-EU country*

The beneficiaries must also inform the coordinator about any changes concerning their linked third parties.

For events linked to changes that also require an update of the Participant Register *(see above)*, the beneficiary must **update** the Participant Register *and* **inform the coordinator**.

The beneficiary must inform the coordinator offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.).*

Best practice: It is recommended that the beneficiary informs the coordinator in writing (not only orally).

After receiving the information from the beneficiary, the coordinator must immediately inform:

- the Commission/Agency, via the Participant Portal
- the other beneficiaries, through the usual communication channels (in writing and offline).

4. Information about circumstances affecting the decision to award the grant or compliance with requirements under the GA

Each beneficiary must immediately inform the coordinator about any situation that:

- could have affected the decision to award the grant if it had been known by the evaluators at the time of evaluation or
- could affect the fulfilment of obligations under the GA.

> ***Example (situation that could have affected the decision to award the grant or compliance with requirements under the GA):*** *A consortium has three beneficiaries. One of them has a laboratory with specialised equipment and personnel, including a team of internationally-renowned experts in the same field as the project. The quality of the work to be carried out by this laboratory was taken into account by the evaluators when the grant was awarded. During the action's implementation, the beneficiary sells the laboratory to an external company, losing a good part of the relevant expertise, and as a result has to outsource part of the work.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the **original documents**. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) **for actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) **for unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) **for flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: **for lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): **'low value grants'** are lower or equal to EUR 60 000.

1. Records and other supporting documentation

The beneficiaries (for linked third parties, *see point 10*) must keep appropriate and sufficient evidence to **prove** the eligibility of all the costs declared, proper implementation of the action and compliance with all the other obligations under the GA.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

'Sufficiency' relates to the quantity of evidence; 'appropriateness' relates to its quality. Evidence is considered sufficient and appropriate if it is persuasive enough for the auditors, who assess it according to generally accepted audit standards.[40]

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

[40] International Standard on Auditing ISA 500 'Audit Evidence'.

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Commission/Agency.

The rules in the GA do not affect national laws on keeping documents (which may require additional measures).

2. Original documents

The beneficiaries must **keep original documents**.

The Commission/Agency will accept any document considered an original under national law.

Examples:

1. *The Commission will accept authenticated copies or digitally-signed documents, if national law accepts these as originals.*

2. *The Commission will accept digitalised copies of documents (instead of hard copies), if this is acceptable under national law.*

In principle, documents should be kept in the format in which they were received or created.

This means that:

- documents received or created in paper form should be kept in paper form
- documents received or created electronically should be kept in their electronic format.

  Hard copies of original electronic documents are not required.

3. Records for actual costs

For actual costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove the eligibility of the costs declared
- use cost accounting practices and internal control procedures that make it possible to verify that the amounts declared, amounts recorded in the accounts and amounts recorded in supporting documentation match up.

Best practice: The information included in the financial statements for each budget category (i.e. personnel costs, other direct costs, indirect costs) must be broken down into details and must match the amounts recorded in the accounts and in supporting documentation.

Examples:

1. *For costs declared in category A.1 (employees or equivalent): the costs must be detailed for each person carrying out work for the action (individual hourly rate multiplied by the actual hours worked for the action). They must match the accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. labour contracts, collective labour agreements, applicable national law on taxes, labour and social security contributions, payslips, time records, bank statements showing salary payments, etc.).*

2. *For costs declared in category D.1, D.2, D.3 and D.4 (other direct costs): the beneficiary must keep a breakdown of costs declared by type (i.e. travel costs and related subsistence allowances, depreciation, costs of other goods and services etc.). It should be able to provide details of individual transactions for each type of cost. For depreciation, it must be able to provide details per individual equipment used for the action. Declared costs must match accounting records (i.e. general ledger transactions, annual financial statements) and supporting documentation (i.e. purchase orders, delivery notes, invoices, contracts, bank statements, asset usage logbook, depreciation policy, etc.).*

4. Records for unit costs set by the Commission

For unit costs, the beneficiaries must keep:

- detailed records and other supporting documents to prove the number of units declared.

It is NOT necessary to keep records on the actual costs incurred.

The Commission/Agency may access the accounting records, but will reject costs only if the number of units declared is incorrect. (The actual costs of the work are not relevant).

If the Commission/Agency detects an irregularity or fraud in the action's implementation, it may reduce the grant.

5. Records for unit costs calculated in accordance with the beneficiary's usual cost accounting practices

For costs declared in accordance with their usual cost accounting practices (**average personnel** costs and costs of **internally invoiced goods and services**), the beneficiaries must keep detailed records and other supporting documents to:

- show that the costs used to calculate the unit cost match the actual costs as recorded in the statutory accounts

  Examples:

  1. *For personnel costs: accounting records; financial statement extracts; labour contracts; collective labour agreements; applicable tax, labour and social security laws; pay slips; bank statements showing salary payments; classification of employees (based on experience, qualifications, salary, department, etc.).*

  2. *For internally invoiced goods and services: accounting records; financial statement extracts; time records (or other records) for the share of personnel costs included in the unit costs; invoices or contracts for maintenance costs, cleaning costs, other services, showing that the cost are directly identifiable.*

  Manual interventions into the accounting data must be traceable and documented.

- verify that the unit cost is free of ineligible cost components

  Examples:

  1. *For personnel costs: records that show that the hourly rate does not include an indirect cost component (already covered by the 25 % flat rate); records that show that the hourly rate does not include travel costs (they should be claimed under category D.1 'travel').*

  2. *For internally invoiced goods and services: evidence that shows that there is no profit/margin/mark-up included in the internally invoiced goods and services (e.g. different rates: one for billing the activity, with mark-up, and another one for internal costing, free of any mark-up); lists of accounts/cost centres that were excluded from the calculation of internally invoiced goods and services — because already included in the costs claimed under another budget categories (e.g. LRI costs, indirect costs, in-kind contributions, etc.).*

- assess the acceptability of budgeted and estimated elements

  Examples:

  1. *For personnel costs: records that show the method for calculating the annual salary increases (e.g. consumer price index which, according to the beneficiary's usual remuneration policy, serves as the basis for annual salary increases).*

  2. *For internally invoiced goods and services: traceable data used to determine the budgeted/ estimated elements; records on the nature and frequency of the updates of the budgeted and estimated elements; etc.*

- for personnel costs: verify the number of productive hours used to calculate the unit cost (hourly rate)

- for internally invoiced goods and services: verify that the cost items used for the calculation of the unit cost were directly linked to the production of the invoiced good or service.

Examples (not acceptable):

1. *Maintenance which goes beyond than the maintenance of the infrastructure/facilities used to produce the good/service (e.g. maintenance costs for all the beneficiary's cleanrooms; maintenance costs for an entire building, while the cleanroom used for the good/service occupies only a part of the building).*

2. *Generic supplies for which there is no evidence that they were directly linked to the infrastructure/facilities used to produce the good/service (e.g. electricity costs when there is no electricity counter or technical specifications to measure the consumption).*

By contrast, it is NOT necessary to keep records on the actual costs incurred (per person/good or service) — unless they are needed to document the usual cost accounting practices (as just described).

6. Certificate on the methodology (CoMUC)

What? To get additional assurance, a beneficiary/linked third party may request that the Commission/Agency confirms that its cost accounting practices for personnel costs comply with the conditions set out in Article 6.2.A, by approving a certificate on its methodology (CoMUC).

Approval concerns the cost accounting practices described and certified in the certificate on the methodology.

If the Commission/Agency approves the CoMUC, it will not challenge the personnel unit costs (hourly rates) declared — unless information was concealed or fraud or corruption was used to obtain approval (or another methodology was applied).

Approval is valid for all personnel costs declared according to these cost accounting practices, including costs declared *before* the Commission/Agency approval (if the beneficiary can show that they were declared according to the approved practices).

Best practice: Beneficiaries should nevertheless keep detailed records and other supporting documents (to prove that their methodology complied with the rules, if necessary).

Approval is valid for all H2020 grants (i.e. for the beneficiary's usual cost accounting practices) and is not linked or limited to a specific grant. (It is NOT valid for FP7 grants and, conversely an FP7 certificate is NOT valid for H2020.)

When? Beneficiaries may in principle submit their requests for approval at **any time** — before or during the grant.

Best practice: In order to ensure that the auditor has enough information to get assurance on the methodology, it is recommended to request it only *after* the first reporting period has passed.

If the beneficiary **changes its cost accounting practices**, it must obtain a new certificate and submit a new request for approval to the Commission/Agency.

⚠ If the beneficiary declares personnel costs according to the changed cost accounting practices *before* the new certificate is approved, it bears the **full risk** of non-approval and cost rejection by the Commission/Agency.

How? The beneficiary must **submit** its certificate on the methodology to the Commission/Agency (via the following address: EC-H2020-UNIT-COST-METHODOLOGY-CERTIFICATION@ec.europa.eu). The certificate should be drawn up by an independent auditor using the template in Annex 6 of the GA (or an independent public officer, if the beneficiary is a public body).

7. Records for flat-rate costs

For flat-rate costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the costs to which the flat rate is applied are eligible.

  Example: *For the flat rate of 25 % of indirect costs, the auditors will verify (and the beneficiaries must be able to show) that:*

  a) the actual direct costs are eligible, using the detailed records and supporting documents explained above;

  b) the following costs were excluded: subcontracting costs, the costs of resources made available by third parties not used on the beneficiary's premises and financial support to third parties from the pool of actual direct eligible costs to which the flat rate applies.

It is NOT necessary to keep records on the actual costs incurred.

8. Records for lump sum costs

For lump sum costs, the beneficiaries must:

- keep detailed records and other supporting documents to prove that the action tasks described in Annex 1 have been carried out in accordance with the GA.

It is NOT necessary to keep records on the actual costs incurred.

9. Records for personnel costs — Hours worked for the action

The records for personnel costs depend on whether the person worked exclusively for the action or not.

⚠ For H2020, exclusive work or not matters only for the record-keeping. It has NO impact on the calculation of the costs to be declared (— in both cases they must be calculated through an hourly rate, monthly or per full financial year, etc.; *see Article 6.2.A*).

For **persons who work exclusively for the action** (regardless if they are full-time or part-time employees), the beneficiary may either:

- sign a declaration on exclusive work for the action [ODT format] (one per reporting period), to confirm that the person worked exclusively for the action, either:
  - during the whole reporting period

  or

  - during an uninterrupted time-period, covering at least a full calendar month within the reporting period.

  Best practice: Beneficiaries should take a prudent approach and use this possibility only if it is planned that the person works exclusively on the action during a long and continuous period of time. If there are any doubts, a record of actual hours worked should be kept *(e.g. time-sheets)*.

'Exclusive work' means that the person carried out NO OTHER activities for the beneficiary than those of the action.

Intermittent (i.e. sporadic or random) periods of 'exclusive' dedication can NOT be subject of a declaration. If a person worked randomly for the action after an

uninterrupted time-period covered by a declaration, time-sheets are needed for the period of random work.

> ***Example:*** *The person worked for the action exclusively from 15/02 to 31/05 and then worked again in the action some days in July and October and the full month of November. The declaration will cover the period from 15/02 to 31/05 and time records must be kept for the time the person worked for the action in July, October and November.*

If a person worked under different regimes during the reporting period (exclusive and non-exclusive), the declaration may be used ONLY for a period of exclusive work. The other months must be recorded with time-sheets.

If there were several periods of exclusive work during one reporting period, the beneficiary may choose to use the declaration for the longest one (and use the monthly time-sheets for the others).

The declaration must be **dated** and **signed** by the person concerned AND her/his supervisor.

– keep **time records**.

Best practice: If the person works exclusively for the action during a *full financial year*, it is strongly recommended that the beneficiary signs the 'declaration on exclusive work for the action' (— even if the person keeps time records). In this way, the declaration can serve as evidence that the person worked for the action all her/his annual productive hours.

For **persons who do NOT work exclusively for the action**, the beneficiaries must:

– show the actual hours worked, with reliable **time records** (*i.e. time-sheets*) either on paper or in a computer-based time recording system.

Time records must be dated and signed at least monthly by the person working for the action and his/her supervisor.

If the time recording system is computer-based, the signatures may be electronic (i.e. linking the electronic identity data *(e.g. a password and user name)* to the electronic validation data, with a documented and secure process for managing user rights and an auditable log of all electronic transactions).

Time records should include, as a minimum:

- the title and number of the action, as specified in the GA
- the beneficiary's full name, as specified in the GA
- the full name, date and signature of the person working for the action
- the number of hours worked for the action in the period covered by the time record
- the supervisor's full name and signature
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in time-sheets must match records of annual leave, sick leave, other leaves and work-related travel.

A template [ODT format] for time-sheets with these minimum requirements is available. (This template is not mandatory; beneficiaries may use their own model, provided that it fulfils the minimum conditions and it contains at least the information detailed above.)

If time records are not reliable, the Commission/Agency may exceptionally accept **alternative evidence** if it proves the number of hours worked on the action with a similar (or at least satisfactory) level of assurance (assessed against generally-accepted audit standards).

⚠ The Commission/Agency has full discretion to accept or refuse the alternative evidence and there is no entitlement to it. Beneficiaries that rely on alternative evidence bear the **full risk** of refusal and rejection of costs by the Commission/Agency.

Examples of possible alternative evidence (non-exhaustive list): *travel documents proving participation in a project meeting (boarding pass, obliterated travel ticket, hotel invoice, etc.); agenda and minutes of the meeting; attendance lists; working papers; laboratory log books; professional/personal diaries; documents related to presentations; scientific publications; correspondence such as letters, notes, memos, emails; etc.*

The auditors will use the following three criteria to assess how credible the alternative evidence is:

1. Clear identification of the person concerned
2. Clear link to the project under scrutiny
3. Possibility to quantify time spent on project-related tasks.

Alternative evidence will only be accepted if these three criteria are met.

Example (acceptable alternative evidence):

A researcher submits the following email as alternative evidence: 'I hereby send you the results of the analysis of project XYZ that I have been working on for the last two weeks.'

Criterion 1 is met – the sender of the email is the person concerned

Criterion 2 is met – the project is identified as XYZ

Criterion 3 is met – the time is quantified: two weeks

Example (not acceptable alternative evidence):

A beneficiary submits the following email as alternative evidence: 'I hereby send you the results of the analysis recently carried out by my team.'

Criterion 1 is not met – it is unclear who the person concerned is; the team members and their contributions are unknown

Criterion 2 is not met: the project name is not mentioned

Criterion 3 is not met – the time is not quantified

10. Records of (linked) third parties

The beneficiaries must ensure that **linked third parties** comply with the same obligations in terms of keeping appropriate and sufficient evidence.

Example: *Linked third parties that carry out work themselves must document all their costs in the same way the beneficiaries do. However, it is the beneficiary who must keep the original financial statements and the certificates on financial statements of the linked third parties.*

The beneficiaries must also ensure that they keep appropriate and sufficient evidence related to **third parties that made in-kind contributions** and to **subcontractors**.

Examples:

1. *The beneficiaries must keep evidence of third parties' actual direct costs if there are in-kind contributions, either free of charge or against payment. Alternatively, they may ensure that the third parties keep the evidence.*

2. *The beneficiaries must keep evidence showing that subcontractors fulfilled their obligations in terms of the visibility of EU funding. Alternatively, they may ensure that the subcontractors keep this evidence.*

For **international partners,** beneficiaries must keep appropriate and sufficient evidence ONLY on scientific and technical implementation of the action. Beneficiaries are not required to prove the costs of the international partners, since the latter do not receive EU funding (*see Article 14a*).

Specific case (records of linked third parties):

Financial statements and certificates on the financial statements (CFS) — It is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables

What & When? The coordinator must submit the deliverables identified in Annex 1, in accordance with the timing and conditions set out in that Annex.

> 'Deliverables' are additional outputs *(e.g. information, special report, a technical diagram brochure, list, a software milestone or other building block of the action)* that must be produced at a given moment during the action (normally not at the same time as the periodic/final reports).
>
> 'Milestones' are, by contrast, control points in the action that help to chart progress. They may correspond to the completion of a key deliverable, allowing the next phase of the work to begin or be needed at intermediary points.

The deliverables that must be produced are listed in Annex 1 of the GA.

> ***Example:*** *For actions under Part III, 'Secure, clean and efficient energy' involving energy efficiency measures in buildings, the beneficiaries must deliver a 'handover certificate' at the same time as their periodic reports. This certificate must prove the actual specifications of the buildings constructed or refurbished, their surface area and address. It must be signed by a member of the consortium.*

For deliverables that are not in writing *(e.g. cell line or prototype)*, the beneficiaries must submit a short written description.

How? The coordinator must upload them directly in the Participant Portal.

Security obligations — If the deliverables contain **EU classified information**, the coordinator must first contact the Commission/Agency to discuss how to submit them (approval needed; *see Article 37*).

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1] to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2 : *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

1. Reports

What & When? In order to receive payments, the beneficiaries (and their linked third parties) must report on the (technical and financial) implementation of the action (reporting).

> These reports must be **distinguished** from **deliverables** (that are part of Annex 1; see Article 19) and milestones (part of Annex 1, but not covered by Article 19 or 20).

The coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Each report should be seen as a single package, composed of several parts, i.e.:

- a **technical report**

  The periodic technical report includes an explanation of work carried out, an overview of progress, a publishable summary and a questionnaire.

  The final technical report is a publishable summary of the entire action (describing the overview of the results and their exploitation and dissemination, the conclusions on the action and its socio-economic impact).

- a **financial report**.

  The periodic financial report includes the individual financial statements, an explanation of the use of resources and the periodic summary financial statement.

  The final financial report consists of the final summary financial statement that is automatically generated by the IT system. In some cases (and for some beneficiaries/linked third parties) it must be accompanied by a certificate on the financial statements (CFS; one certificate per beneficiary/linked third party).

  The financial reports also contain the requests for payment (necessary for any payment other than the pre-financing payment).

Costs related to reporting may be eligible (*see Article 6.2.D.3*).

If the coordinator **breaches** its **obligation** to submit the reports, the Commission/Agency may suspend the payment deadline and — if not remedied after a written reminder — terminate the GA or take any of the other Chapter 6 measures *(e.g. cost rejection, grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50).*

The GA will not be terminated if the breach concerns the last reporting period (because the action duration is already over).

How? The report(s) must be **prepared** by the **coordinator** and the other **beneficiaries together** (directly in the Participant Portal Continuous and Periodic Reporting Modules).

List of documents for the periodic reports:

- explanation of the work carried out (periodic reporting - part B technical report)
- overview of the progress (periodic reporting - part B technical report)
- updated plan for the exploitation and dissemination of results (if necessary) (periodic reporting - part B technical report)
- summary for publication (continuous reporting)
- answers to the questionnaire (continuous reporting)

- individual financial statements for each beneficiary and linked party (periodic reporting - financial report)
- explanation of the use of resources (periodic reporting - financial report)
- summary financial statement (generated automatically by the IT system)
- information on amounts to be paid to the Joint Research Centre (JRC) (if necessary).

List of documents for the final report:

- final summary for publication (generated automatically by the IT system)
- final summary financial statement (generated automatically by the IT system)
- certificates on the financial statements (CFS) (if necessary).

Generally, they can be **prepared together** (i.e. by several users from different beneficiaries), via the Participant Portal Continuous and Periodic Reporting Modules. The parts in the **continuous reporting** can be filled out at any moment in time (continuously open) and are then automatically added into the periodic report by the IT system *(part A of the technical report with the questionnaire and the summary for publication; consolidated financial statement*). Other parts are opened only at **periodic reporting** *(part B of the technical report, individual financial statements, explanation of the use of resources)*. Data is cross-linked to avoid duplication of data input *(e.g. the financial statement and the explanation on the use of resources are linked: for each cost declared in the financial statement, a box will pop up asking the beneficiary to give an explanation of the cost, link it to the relevant work package(s) and justify the expense, if necessary; the final report is completely automatized: assembled on the basis of elements from the periodic report).*

Individual financial statements must be filled out by each beneficiary (individually), and then signed and formally submitted to the coordinator (directly in the Participant Portal).

This includes the **coordinator**, who must also submit the individual financial statement for itself.

For **linked third parties**, the financial statements must be filled out and submitted by their beneficiary (since the linked third parties cannot sign them in the IT system).

Before submission, the beneficiary must complete the data for the linked third party (based on the information it received from the linked third party). The beneficiary then prints the financial statement and sends it to the linked third party, for signature (*on paper*) and return (by registered post with proof of delivery). The beneficiary must ensure that the data encoded is correct (i.e. identical to the signed paper version).

⚠ **Record-keeping —** The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

If a beneficiary cannot submit its individual financial statement on time, the report can be **submitted without this financial statement**. The costs will be considered zero for this reporting period, but the beneficiary can declare its costs with the next financial report (for the next reporting period).

The coordinator will be asked to confirm the non-submission, when submitting the report.

If a beneficiary fails to submit its financial statement for the *last* reporting period, the Commission/Agency may suspend the payment deadline *(see Article 47)*.

The **certificates on the financial statements (CFS)** must be submitted (by the coordinator) as scanned copy (PDF) together with the financial statement for the last reporting period of the beneficiary concerned.

⚠ **Record-keeping —** The beneficiary must keep the originals for itself and its linked third parties in its files *(see Article 18.1.2)*.

When all parts are ready, the report(s) are assembled automatically by the IT system and must be **submitted** by the coordinator (as a single package; **single submission**).

When a report is submitted, the other beneficiaries are automatically informed by the system.

If the Commission/Agency considers the report **incomplete** or not in compliance with the conditions of this Article, it will suspend the payment deadline *(see Article 47)*.

In this case, the Commission/Agency will send back the report to the coordinator, as a single package, together with a notification letter that explains the reasons and requests modifications and/or clarification(s) (**suspension of the payment deadline**). The coordinator (CoCo) must then re-submit the corrected report, as a single package, within the deadline specified (**single re-submission**).

The re-submission re-starts the payment deadline (remaining time, taking account of the time used before suspension).

⚠ **Adjustments of financial statements (exceptional) —** If the beneficiaries notice a mistake *(e.g. incorrect accounting information; error in the calculation; etc)*, they can make an adjustment (positive or negative) in the following reporting period to the financial statements for any previous reporting period.

Example: *An internal audit on the annual accounts of the beneficiary finds later errors in the accounting information used to calculate the hourly rates.*

Otherwise, costs that have already been declared can normally NOT be adjusted/changed *(e.g. to take into account of a different hourly rate after the closure of the financial year)*.

2. Reporting periods

Each action is divided into reporting periods.

The length of the reporting periods is set out in the GA. As a general rule, reporting periods last 18 months.

The number of reporting periods is also set out in the GA, and depends on the action duration. Normally it is determined as follows:

Duration in months	Max. number of periods
1 to 18	1
19 to 36	2
37 to 54	3
55 to 72	4
73 to 90	5

3. Technical report: Explanation of the work carried out — Overview of the progress — Summary for publication — Questionnaire

The **explanation of the work carried out** and the **overview of the progress** should show how the action is being implemented and what has already been achieved (as compared to the objectives, milestones and deliverables described in Annex 1).

The coordinator must check if all deliverables due for the period have been submitted. If work planned was not carried out, the beneficiaries must explain why.

The overview of the progress must also describe how achieved results are exploited and disseminated and include an updated **plan for the exploitation and dissemination of the results** (if such a plan is foreseen in Annex 1).

3.0 For grants signed after GA version 3.0, the overview of the progress must also indicate the communication activities carried out by the consortium *(see also Article 38.1).*

> ⚠ **Security obligations —** Technical reports may NOT contain any information that has been **EU-classified** in Annex 1 of the GA *(see Article 37).*
>
> ℹ For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

The **summary** must give a brief description of the action, presenting its objectives and the results achieved (in an easy-to-read way, understandable for a non-specialist audience).

The summary must be **fit for publication**, so that the Commission/Agency can publish it on its website right away.

If needed, the Commission/Agency may make changes to the summary and publish it (after having given the coordinator the opportunity to comment).

The coordinator must ensure that none of the material submitted for publication includes confidential (or EU-classified) information.

For the last reporting period: The summary should present an overview of the results, their exploitation and dissemination, the action's conclusions and its socio-economic impact (because it will be directly re-used for the final report).

The **questionnaire** must be filled out to provide the Commission/Agency with regular up-to-date information for monitoring the action (and ultimately the H2020 Programme).

The questionnaire consists in structured information on:

- performance indicators (defined in Annex II to the H2020 Specific Programme)
- information to monitor the implementation of H2020 on cross–cutting issues *(see Annex III to the Specific Programme)* and to assess the progress of Horizon 2020 against the objectives defined for the 'societal challenges' *(see Article 3 and Annex I to the Specific Programme)*.

It is designed in a modular way, consisting as much as possible of structured questions, by topic *(e.g. publications, patents, innovation, etc.)*.

4. Financial report: Individual financial statements — Explanation of the use of resources — Summary financial statement — Certificates on the financial statements (CFS)

The **individual financial statements** (see Annex 4) must contain all costs that:

- were incurred by the beneficiary/linked third parties during the reporting period

AND

- fulfil the eligibility conditions set out in Article 6.

⚠ Beneficiaries/linked third parties should declare ALL their eligible costs — even if they are above the estimated budget in Annex 2 (**cost overruns**). The grant will be capped at the maximum grant amount, but cost overruns may turn out useful, if the Commission/Agency should reject some of the costs (at payment or later on).

Beneficiaries may declare costs incurred during a previous reporting period, if they were not declared before.

The costs of linked third parties must NOT be included in the beneficiary's financial statements; linked third parties must fill out their own financial statements.

For the last reporting period, beneficiaries also have to declare the receipts for the action *(see Article 5.3.3)*.

⚠ **Combining different EU grants —** Beneficiaries that have **action grants** and **operating grants** may claim indirect costs in their action grants ONLY if they are able to demonstrate cost separation (i.e. that their operating grants do not cover any costs which are covered by their action grants).

To **demonstrate cost separation**, the following conditions must be fulfilled:

- the operating grants may NOT cover 100% of the beneficiary's annual budget (i.e. it may not be full operating grants)
- the beneficiary must use analytical accounting which allows for a cost accounting management with cost allocation keys and cost accounting codes AND must apply these keys and codes to identify and separate the costs (i.e. to allocate them to either the action grant activities or the operating grant activities)
- the beneficiary must record:
  - all real costs incurred for the activities that are covered by their operating grants (i.e. personnel, general running costs and other operating costs linked to the WP) and
  - all real costs incurred for the activities that are covered by their action grants (including the indirect costs linked to the action)
- the allocation of the costs must be done in a way that leads to a fair, objective and realistic result.

Beneficiaries that **cannot fulfil these conditions** must EITHER:

- not sign/terminate the operating grants, in order to be able to claim indirect costs in the action grants
- keep the operating grants, but sign the action grants *without* indirect costs or request no indirect costs at reporting stage (i.e. lower the pre-filled amount in the indirect cost column of the financial statement).

4.0 The possibility to combine operating grants with action grants if costs are separated was introduced with GA version 4.0. It applies also to older grant agreements, if the beneficiaries can demonstrate that there is no double funding, in accordance with the above-listed principles (analytical accounting tools, full cost recording, fair allocation).

Best practice: In case of overlapping EU action and operating grants, the beneficiary should immediately contact the Commission/Agency (via the Participant Portal). Be aware that operating grants are not always easy to identify. They exist under various labels (operating grants; financial contributions/support to the functioning/operation of entities; etc.). Check your call text.

The **explanation of the use of resources** must be consistent with the costs declared in the financial statement per beneficiary.

For the final reporting period, some beneficiaries/linked third parties will also have to submit a **certificate on the financial statement (CFS)**.

Such a certificate is needed if the beneficiary/linked third party requests a total financial contribution of EUR 325 000 (or more) as reimbursement for actual costs and unit costs calculated according to its usual accounting practices (average personnel costs and costs for internally invoiced goods and services).

This means that costs based on lump sums, flat-rates (*e.g. indirect costs*) or unit costs (other than those for personnel costs and costs for internally invoiced goods and services calculated according to the beneficiary's usual cost accounting practices) are NOT counted for the EUR 325 000 threshold (and do not need to be covered by the certificate).

Example:

A is a beneficiary in an action which declared the following total eligible costs for the action:

- *personnel costs according to usual accounting practices = EUR 250 000*
- *subcontracting costs = EUR 40 000*
- *depreciation costs of equipment used to carry out the action = EUR 60 000*
- *indirect costs (25 % flat rate) = EUR 77 500*
- *total eligible costs claimed by A = EUR 427 500*

The reimbursement rate is 100%.

As the amount of eligible actual costs and personnel costs according to usual accounting practices incurred by A (and hence the requested financial contribution) is higher than EUR 325 000, A must submit a CFS for the following costs:

Type of cost	*Direct personnel costs*	*Subcontracting costs*	*Other direct costs*	*Indirect costs*	*Total costs covered by the CFS*
Costs covered by the CFS	*250 000*	*40 000*	*60 000*	*0*	*350 000*

If a certificate is required, all costs declared as actual costs or unit costs calculated according to usual accounting practices must be covered by the certificate. Incomplete certificates will be returned for correction.

However, costs previously audited by the Commission/Agency are NOT counted for the EUR 325 000 threshold and they do not need to be covered (again) by the certificate).

Linked third parties must submit a certificate if it reaches (on its own, without its beneficiary) the EUR 325 000 threshold.

Certificates submitted before the EUR 325 000 threshold is reached will be rejected by the Commission/Agency.

Beneficiaries/linked third parties may submit either **one certificate per reporting period** or a **single CFS for** the **whole action**.

The certificate(s) may be submitted ONLY **with** the ***final*** **financial report**. Certificates submitted at any other moment will NOT be accepted (and costs incurred for them will be considered ineligible, because not necessary).

Costs for partial certificates (i.e. one certificate per reporting period) will be accepted ONLY in the last reporting period and ONLY if:

- a CFS is mandatory (i.e. the threshold is reached at the end of the action) and
- the total costs of the partial certificates is similar to the cost that would have been incurred for a single certificate.

The certificate must be issued by an **external auditor**, using the template in Annex 5 of the GA.

Only qualified auditors may issue a certificate.

'Qualified' means qualified in accordance with national legislation implementing Directive 2006/43/EC[41] (or any EU legislation that replaces this Directive).

The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared.

If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The Commission/Agency will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.

The **summary financial statement** is generated automatically by the IT system (with consolidated data from all individual financial statements for all beneficiaries and linked third parties, for the reporting period).

For the final reporting period, the IT system will also generate a **final summary financial statement** (consolidating the data from all individual financial statements for all beneficiaries and linked third parties, for all reporting periods).

Specific cases (certificates on the financial statements):

Public bodies — For public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary/linked third party (instead of by an external auditor).

International organisations — For international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.

Beneficiaries/linked third parties from a third country — Beneficiaries/linked third parties established in a non-EU country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in non-EU countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

5. Information on cumulative expenditure incurred

This option will be inserted in the GA for grants above EUR 5 million, for which pre-financing is paid and where the reporting period for interim payments or payment of the balance exceeds 18 months.

A template is available and must be submitted via the Participant Portal Continuous Reporting Module.

6. Currency for financial statements and conversion into euro

Beneficiaries (and linked third parties) must always use euros, to report costs in their financial statements.

The rules on conversion (of costs incurred in other currencies into euros) are as follows:

[41] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

- for beneficiaries/linked third parties **with accounting records in euros**: conversion of costs according to their usual accounting practices
- for beneficiaries/linked third parties **with accounting records in a currency other than the euro**: conversion of costs recorded in their accounts by one of the following:
  - daily euro exchange rate is published in the C series of the *Official Journal of the European Union* for the currency in question: using the average of the daily exchange rates published over the corresponding reporting period.

    To calculate this rate, the beneficiaries may use the editable charts on the ECB website[42].

    How to calculate the rate on the ECB website:

    Step 1 — Go to the ECB website.

    Step 2 — Click on the chart icon [ ] for the currency.

    Step 3 — Choose the 'HTML5 version' which appears under the name of the currency in the top-left corner.

    Step 4 — Insert the starting date of the reporting period in the field 'from' and the end date of the reporting period in the field 'to'. The average for the period will appear above the chart.

    Example: *A Romanian university with accounting in New Romanian Leu (RON) is the beneficiary of a GA with one reporting period, from 24.1.2013 to 23.1.2014. The costs incurred in RON during this period are RON 500 000. The university will convert its costs into euros at the average rate of RON 4.4274 for EUR 1 (established following the steps mentioned above). The university will report costs of EUR 112 933, 10 (RON 500 000 / RON 4.4274 * EUR 1).*

  - if NO daily euro exchange rate is published: using the average of the monthly accounting rates over the corresponding reporting period, using the currency converter on the Commission's website[43].

    Example: *A Moldovan university with accounting in Moldovan Lei (MDL) is the beneficiary of a GA with one reporting period, from 24.01.2013 to 23.01.2014. The costs incurred in MDL during this period are MDL 500 000. The university will calculate the average of the 13 monthly exchange rates (January 2013 until January 2014) published on the Commission's website. This average rate is MDL 16,.7531 for EUR 1. The university will report costs of EUR 29 845,22 (MDL 500 000 / MDL 16,.7531 * EUR 1).*

7. Language of reports

The reports must be drafted in the language of the GA (indicated at the end of the GA, next to the signatures of the parties).

[42] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[43] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

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21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

1. Payments to be made

The Commission/Agency will make the following payments to the coordinator:

- a **pre-financing payment** at the beginning of the action (to provide beneficiaries with cash to start working on the project and continue until the first interim payment)

  Pre-financing will NOT be paid before:

  - the GA is signed (even if the action starts before)
  - 10 days before the action starting date.

  Example:

  A GA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The action starting date would normally be 1 February 2015, but the consortium has requested a fixed starting date of 1 September 2014 in its proposal, as the action is a continuation of a previous FP7 project.

  After due consideration, the fixed starting date is approved. The pre-financing must be paid by 5 February 2015 (i.e. 30 days from the entry into force of the GA).

- **interim payment(s)** to cover eligible costs incurred in the reporting periods (as many interim payments as number of reporting periods)

- the **payment of the balance** after the end of the action.

⚠ Any payment (i.e. pre-financing, interim payments and payment of the balance) may be **offset** against debts of the beneficiaries towards the Commission/Agency or an(other) executive agency — without the consent of the beneficiary concerned and up to the beneficiary's maximum grant amount in Annex 2 *(see also Article 44)*.

All payments are subject to a **payment deadline** (i.e. number of days within which the Commission/Agency has to pay the consortium — after having received the payment request). The deadline depends on the type of payment:

- for pre-financing: 30 days
- for interim payments and payment of the balance: 90 days *(see Article 21)*.

If there are issues with the payment request or with the costs declared which make it impossible to comply with the payment deadline, the Commission/Agency will **suspend the deadline** *(see Article 47)*.

The pre-financing payment is automatic, while for interim and final payments the Commission/Agency must first:

- analyse the technical reports and financial statements
- check the eligibility of the claimed costs
- calculate the amount to be paid
- approve the payment request and authorise the payment.

This is not an in-depth verification and therefore no guarantee for eligibility or correctness. The costs may still have to be rejected later on, if the Commission/Agency finds — in a more in-depth verification — that they are ineligible.

The payments are made **to the coordinator**; the beneficiaries are NOT paid individually.

The coordinator must distribute the amounts received to the beneficiaries — without delay *(see Article 21.7*).

How and when the payments are distributed is in principle an internal matter for the consortium.

The consortium agreement may set out, for instance, specific periods for the distribution of payments or that the distribution will be carried out in instalments (and these will not be considered 'unjustified delays', if the arrangements set out in the consortium agreement are complied with).

Similarly, the consortium agreement may provide for a distribution of the funding which is different from the costs claimed.

Also, if the coordinator does NOT comply with its obligations, this is in principle an issue to be resolved within the consortium. It is only if the coordinator is terminated that the Commission/Agency (and especially the Guarantee Fund) will intervene; *see Article 50*).

The Commission/Agency will be informed of the distribution of the payments by the coordinator:

- if it specifically requests this
- in the event of recovery at the payment of the balance *(see Article 44)*
- if the participation of one or more beneficiary is terminated *(see Article 50)*.

The Commission/Agency will **notify** the coordinator of the amount due, explaining which costs have been accepted and which have been rejected (if applicable; see *Articles 42, 43 and 44*).

The shares for the Commission's **Joint Research Centre (JRC)** will always be kept back and not be paid out to the coordinator (the JRC is a Commission DG and the amounts are therefore cleared internally).

Example:

Four beneficiaries: A, B, C and JRC, with a maximum grant amount of EUR 1 000 000.

Estimated budget by beneficiary (Annex 2): A: EUR 300 000; B: EUR 250 000; C: EUR 300 000; JRC: EUR 150 000

Pre-financing: EUR 400 000, of which EUR 50 000 (5% of maximum grant amount) is kept for the Guarantee Fund and EUR 350 000 transferred to the consortium.

JRC share of grant: 15 % (150000/1 000 000)

JRC share of pre-financing (kept by the Commission/Agency): 15 % of 350 000 = EUR 52 500

Pre-financing payment to coordinator for beneficiaries A, B, C: EUR 350 000 - EUR 52 500 = EUR 297 500

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing amount does not depend on any financial statement. It is a float that is fixed in each GA and automatically paid at the beginning of the action.

How to calculate the pre-financing payment:

Step 1 — **Pre-financing amount**

The amount of pre-financing is fixed in the GA.

There is no standard amount (or percentage) for the pre-financing payment. For H2020 grants, it will normally be (depending on the availability of EU budget credits) 100 % of the average EU funding per reporting period (i.e. maximum grant amount set out in Article 5.1 / number of periods). For actions with only one reporting period, it will however be less, since 100 % would mean the totality of the grant amount.

Step 2 — **Deduction of the Guarantee Fund contribution**

At the moment of the pre-financing, an amount that corresponds to 5 % of the maximum grant amount *(see Article 5.1)* is deducted from the pre-financing payment and transferred to the Guarantee Fund. (The Guarantee Fund is a Fund that covers defaulting beneficiaries).

Step 3 — **Pre-financing payment letter**

The Commission/Agency will inform the coordinator about the amount due (pre-financing payment letter).

Pre-financing funds remain **EU property** until the payment of the balance — when they are cleared against the eligible costs accepted by the Commission/Agency.

Example for calculating the pre-financing payment:

Action with 3 reporting periods of 18 months.

Maximum grant amount: EUR 1 000 000.

Reimbursement rate: 100 %.

Guarantee Fund contribution: 5% of EUR 1 000 000 = EUR 50 000.

Pre-financing amount & deduction of Guarantee Fund contribution:

Pre-financing amount: EUR 333 334.

Amount to be paid out to the consortium as pre-financing: EUR 333 334 - EUR 50 000 = EUR 283 334.

Payment at beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Commission/Agency on the basis of the termination report, the payments already made and the report on the distribution of payments *(see also Articles 44.1.1, 50.2.2 and 50.3.3)*.

⚠ The **amount due** is used to determine whether the terminated beneficiary received too much from the consortium (and should pay it back to them) and will then flow into the calculation of the next interim and final payments in order to cap that beneficiary's accepted EU contribution.

⚠ The terminated beneficiary's share of the final grant amount (beneficiary's final grant share) will be calculated only at the end of the project (payment of the balance), together with the rest of the consortium.

⚠ If the terminated beneficiary is audited during the ongoing project, its amount due will be re-calculated. If the terminated beneficiary is audited after the end of the project, the recovery will follow the standard rules (revised final grant amount calculated on the basis of the final grant share).

How to calculate the amount due at beneficiary termination:

Amount due

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rate to the eligible costs)**

In order to calculate the amount of accepted EU contribution for the beneficiary concerned, the Commission/Agency will calculate the accepted costs for the beneficiary and each of its linked third parties (i.e. eligible/not rejected costs declared in the interim and termination reports; *see Articles 6 and 42*), apply the reimbursement rate(s) and sum them up to a total amount for the beneficiary.

Only costs incurred *(see Article 6.1(a))* by the beneficiary concerned until termination takes effect are eligible (except for costs for the termination report). Costs relating to contracts due for execution (i.e. delivery) only after termination are NOT eligible.

If the coordinator fails to submit the termination report (within the 30 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. The Commission/Agency will NOT send a written reminder and will not extend the deadline.

If the beneficiary requested less than the maximum EU contribution, the accepted EU contribution will be this lower requested amount.

➔ Amount resulting from Step 1.

Step 2 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions, the Commission/Agency will calculate the grant reductions for the beneficiary concerned and its linked third parties (if any; see *Article 43*) and then sum them up to a total amount for the beneficiary.

This total amount of grant reductions is then deducted from the pro rata temporis part of the beneficiary's and linked third parties' maximum grant amounts (Annex 2) — pro rata temporis corresponding to their period of participation (i.e. until termination).

ℹ For more guidance on grant reductions, *see the Guidanc on grant reductions*.

➔ Amount resulting from Step 2.

The **amount due** is the lower of the two (amount resulting from Step 1 and amount resulting from Step 2).

Beneficiary balance

Step 3 — **Calculation of the beneficiary balance**

In order to establish if the beneficiary received excess funding, the Commission/Agency will deduct the total amount of pre-financing and interim payments made (according to the report on the distribution of payments) from the amount due.

If the amount due is *higher* than the payments already made, the difference will be paid by the Commission/Agency to the coordinator at the next interim/final payment.

If the amount due is *lower* than the payments made, the beneficiary must repay the difference (to the consortium; NOT to the Commission/Agency). If the beneficiary doesn't, the Commission/Agency will intervene, by activating the Guarantee Fund to pay the money to the consortium and then recovering it from the beneficiary in the name of the Guarantee Fund *(see below*).

If the coordinator does not submit the report on the distribution of payments, the terminated beneficiary will NOT have to repay any amounts to the consortium. If there are issues, the consortium will have to deal with them internally.

Step 4 — **Beneficiary calculation letter**

The Commission/Agency will inform the beneficiary about the balance, i.e. the amounts that are owed to the consortium or to the beneficiary concerned (beneficiary termination calculation letter).

If the closure involves grant reduction or recovery (refund to the consortium), there will be two letters: a pre-information letter (opening a contradictory procedure) and confirmation letter *(see Articles 43 and 44)*.

Recovery (if any)

Step 5 — **Beneficiary recovery letter & debit note**

If the beneficiary does not repay the consortium by the date specified in the confirmation letter, the Commission/Agency will activate the Guarantee Fund (to pay the consortium) and claim back the money paid by the Guarantee Fund from the beneficiary, (beneficiary recovery letter; *see Articles 44 and 50*).

Step 6 — **Enforced recovery**

If the beneficiary does not honour the debit note within the deadline, the Commission/Agency will enforce its claim, by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**
- taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
- adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Example for calculating the amount due at beneficiary termination:

Grant with three beneficiaries (A, B and C) and two reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100 %.

Pre-financing: EUR 200 000.

Amount due:

Beneficiary A goes bankrupt in the middle of the action and is terminated at month 18 (of 36), just before the end of RP1.

Costs declared by beneficiary A in termination report: EUR 50 000 (direct costs) + EUR 12 500 (25 % flat rate for indirect costs) = EUR 62 500.

Costs rejected for beneficiary A following audit: EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Accepted costs beneficiary A: EUR 62 500 – EUR 12 500 = EUR 50 000.

Application of reimbursement rate: EUR 50 000 (total accepted EU contribution).

Amount resulting from Step 1: EUR 50 000.

10% grant reduction beneficiary A due to breach of obligations: 10% of {{18/36} x EUR 200 000} = 10% of EUR 100 000 = EUR 10 000.

Amount resulting from Step 2: 100 000 – 10 000 = EUR 90 000.

Lower amount of the two: EUR 50 000.

Beneficiary A amount due: EUR 50 000.

Beneficiary balance:

Payments received by beneficiary A (according to the report on the distribution of payments): EUR 60 000.

Beneficiary A balance: EUR 50 000 (amount due) - EUR 60 000 (payments received) = EUR -10 000 (excess payments of EUR 10 000).

Recovery:

Amount to be recovered from beneficiary A: EUR 10 000 (negative balance of EUR 10 000 must be returned to the consortium; otherwise Commission/Agency will start a recovery procedure).

Interim payments

How much? The amount of the interim payments will be calculated by the Commission/Agency on the basis of the financial statements and the payments already made.

How to calculate interim payments:

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rates to the eligible costs)**

In order to calculate the amount of accepted EU contribution, the Commission/Agency will, for each beneficiary and linked third party, calculate the accepted costs (i.e. eligible/not rejected costs declared in the financial statement; *see Articles 6 and 42*), apply the reimbursement rate(s) and then sum them up to a total amount for the consortium.

If a beneficiary/linked third party requested in the financial statements less than the EU contribution, the accepted EU contribution will be this lower requested amount.

Step 2 — **Limit to 90% of the maximum grant amount**

If the total for the consortium is more than 90 % of the maximum grant amount minus pre-financing and previous interim payments, it will be capped.

Step 3 — **Interim payment letter**

The Commission/Agency will inform the coordinator about the amount due (interim payment letter).

Examples for calculating interim payments:

Case 1:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000 and 100% reimbursement rate.

Pre-financing of EUR 333 334.

Interim payment RP1:

Costs declared by the consortium for RP1: EUR 500 000 (direct costs) + EUR 125 000 (25% flat rate for indirect costs) = EUR 625 000.

After checking the reports EUR 20 000 of the direct costs claimed by beneficiary A and EUR 12 000 of those claimed by beneficiary B are considered not eligible and rejected. The Commission/Agency therefore rejects EUR 32 000 direct costs + EUR 8 000 (25% flat rate for indirect costs) = EUR 40 000.

Total accepted costs RP1: EUR 585 000.

Application of reimbursement rate: 100% = EUR 585 000 (total accepted EU contribution).

Limit to 90% of the maximum grant amount minus pre-financing = EUR 900 000 – EUR 333 334 = EUR 566 666.

Amount to be paid out to the consortium as interim payment for RP1: EUR 566 666.

Interim payment RP 2:

Total accepted costs RP2: EUR 162 500.

Amount to be paid out to the consortium as interim payment for RP2: EUR 0 (the 90% limit has already been reached in RP1: 333 334 + 566 666 = 900 000).

Case 2 (grant with terminated beneficiary):

Grant with three beneficiaries (A, B and C) and two reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Pre-financing: EUR 200 000.

Beneficiary A was terminated before the end of RP1 and the amount due was its accepted costs :EUR 62 500 EUR (no grant reductions applied).

Interim payment RP1:

Costs declared by beneficiary A for RP1: EUR 50 000 (direct costs) + EUR 12 500 (25% flat rate for indirect costs) = EUR 62 500.

Costs declared by beneficiary B for RP1: EUR 115 000 (direct costs) + EUR 28 750 (25% flat rate for indirect costs) = EUR 143 750.

Costs declared by beneficiary C for RP1: EUR 90 000 (direct costs) + EUR 22 500 (25% flat rate for indirect costs) = EUR 112 500.

Total costs declared RP1: EUR 62 500 + EUR 143 750 + EUR 112 500 = EUR 318 750.

Costs of beneficiary A are not capped since there were no grant reductions at beneficiary termination.

Some direct costs declared by beneficiary B are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total accepted costs RP 1: EUR 318 750– EUR 12 500 = EUR 306 250.

Application of the reimbursement rate 100%: EUR 306 250 (total accepted EU contribution).

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000 – EUR 200 000 = EUR 250 000.

Amount to be paid out to the consortium as interim payment for RP1: EUR 250 000.

Case 3:

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Pre-financing: EUR 200 000.

Interim payment RP1:

Costs declared by beneficiary A for RP1: EUR 95 000 (direct costs) + EUR 23 750 (25% flat rate for indirect costs) = EUR 118 750.

Costs declared by beneficiary B for RP1: EUR 115 000 (direct costs) + EUR 28 750 (25% flat rate for indirect costs) = EUR 143 750.

Costs declared by beneficiary C for RP1: EUR 90 000 (direct costs) + EUR 22 500 (25% flat rate for indirect costs) = EUR 112 500.

Total costs declared RP1: EUR 118 750 + EUR 143 750 + EUR 112 500 = EUR 375 000.

Some direct costs declared by beneficiary A are rejected for an amount of EUR 10 000 + EUR 2 500 (25 % flat rate for indirect costs) = EUR 12 500.

Total accepted costs RP 1: EUR 375 000 – EUR 12 500 = EUR 362 500.

Application of the reimbursement rate 100%: EUR 362 500 (total accepted EU contribution).

Limit to 90 % of the maximum grant amount minus pre-financing: EUR 450 000 – EUR 200 000 = EUR 250 000.

Amount to be paid out to the consortium as interim payment for RP1: EUR 250 000.

Interim payment RP2:

Costs declared by beneficiary A for RP2: EUR 20 000 (direct costs) + EUR 5 000 (25% flat rate for indirect costs) = EUR 25 000.

Costs declared by beneficiary B for RP2: EUR 30 000 (direct costs) + EUR 7 500 (25% flat rate for indirect costs) = EUR 37 500.

Costs declared by beneficiary C for RP2: EUR 30 000 (direct costs) +EUR 7 500 (25% flat rate for indirect costs) = EUR 37 500.

Total costs declared RP2: EUR 25 000 + EUR 37 500 + EUR 37 500 = EUR 100 000.

Costs rejected for beneficiary B at RP2: EUR 10 000 (direct costs) + EUR 2 500 (25% flat rate for indirect costs) = EUR 12 500.

Costs rejected for beneficiary C at RP2: 5 000 (direct costs) + 1 250 (25% flat rate for indirect costs) = EUR 6 250.

Total accepted costs RP2 = EUR 81 250.

Application of the reimbursement rate 100%: EUR 81 250 (total accepted EU contribution).

Amount to be paid out to the consortium as interim payment for RP2: EUR 0 (the 90% limit has already been reached in RP1: EUR 200 000 + EUR 250 000 = EUR 450 000).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Commission/Agency on the basis of the financial statements, the final grant amount, the payments already made and the report on the distribution of payments *(see also Articles 5.3 and 44.1.2)*.

If the final grant amount is *higher* than the payments already made, the balance will take the form of a *payment*; if the final grant amount is *lower* than the payments made, the balance will take the form of a *recovery*.

How to calculate the payment of the balance:

Final grant amount

Step 1 — **Calculation of the accepted EU contribution (application of the reimbursement rates to the eligible costs)**

In order to calculate the amount of accepted EU contribution, the Commission/Agency will, for each beneficiary/linked third party, calculate the accepted costs (i.e. eligible/not rejected costs declared in the financial statements; *see Articles 6 and 42*), apply the reimbursement rate(s) and then sum them up to a total amount for the consortium.

If a beneficiary/linked third party requested less than the maximum EU contribution, the accepted EU contribution will be this lower requested amount.

Step 2 — **Limit to the maximum grant amount**

If the total for the consortium is more than the maximum grant amount for the action *(see Article 5.1)*, it will be capped at that amount

Step 3 — **Calculation of receipts & deduction of profit (no-profit rule)**

From this amount, the Commission/Agency will deduct any profit made due to receipts.

Thus, the total accepted EU contribution + receipts are capped at the total accepted costs; the amount resulting from Steps 1 and 2 plus receipts cannot exceed the accepted costs.

If grant amount + receipts > total accepted costs ➔ deduction of profit

⚠ Profit is assessed at the level of the action, NOT at the level of the individual beneficiaries (⚠ new in Horizon 2020).

The amounts taken into account are the total accepted EU contribution (following Steps 1 and 2), the total receipts and the total accepted costs.

The **receipts** that must be taken into account are receipts which have been, during the action duration *(see Article 3)*:

- established (i.e. revenue that has been collected AND entered in the accounts)
- generated (i.e. revenue that has not yet been collected, but which has been generated) or

- confirmed (i.e. revenue that has not yet been collected, but for which the beneficiary has a commitment or written confirmation).

The following **are** considered **receipts**:

- income generated by the action *(i.e. any income generated by the action itself, including the sale of assets bought for the action and sold during the action duration)*

  Examples: *admission fee to a conference organised by the consortium; sale of equipment bought for the action.*

  Receipts from the sale of assets are capped at the amount of costs declared for the asset.

  Example:

  Machine bought for EUR 21 000 in year X, sold in year X + 4 (both within the action duration) for EUR 16 000.

  The machine was used at 50% for the action, and fully depreciated in 3 years (7 000 EUR/year, of which 3 500 EUR/year were charged to the action)

  Amount of receipts to be declared: 50% of 16 000 with a limit of 10 500 (3 x 3 500) = EUR 8 000

- financial contributions given by third parties specifically to be used for the action *(i.e. money given as a donation by a third party (a donor) to a beneficiary/linked third party specifically for being used for the action)*

- in-kind contributions provided by third parties free of charge specifically to be used for the action, if they have been declared as eligible costs *(i.e. not money, but an in-kind contribution free of charge given by a third party (a donor) specifically for being used for the action)*

  Examples: *the free use of equipment; the secondment of an expert without reimbursement*

  Receipts due to free of charge in-kind contributions are capped by the amount declared as third party costs for the contribution.

The following are **NOT** considered **receipts**:

- in-kind contributions given by a **third party (donor)** free of charge — if they were not given specifically to be used for the action

  Example: *A university professor whose costs are charged by the beneficiary university in the GA, but whose salary is paid by the ministry and not reimbursed by the university: This in-kind contribution from a third party (the ministry) is not to be considered a receipt, unless the professor has been specifically seconded by the ministry to the university to work for the action in question. In other words, if the university is free to decide the allocation of the professor's work, then his/her contribution is assimilated to an 'own resource' of the university and it is not a receipt.*

- financial contributions given by a third party (donor) specifically to be used for the action — if they may be used according to the donor's rules to cover also costs *other* than the eligible costs

  Example: *currency exchange losses*

- financial contributions given by a third party (donor) specifically to be used for the action — if the donor did not set the obligation to repay any unused amount at the end of the action

  In this case, the *full* amount of the financial contribution is considered not a receipt (not only the unused amount).

- financial contributions made **by one beneficiary to another** within the same action — since receipts are only contributions from *third parties*

  Conversely, such a financial contribution cannot either be declared as cost for the action.

  Example: *Beneficiary A (big company) in an innovation project (i.e. funded at 70%) decides to subsidise a small specialised SME by funding an additional 10% of the SME's costs in order to encourage it to participate in the action.*

– income generated by exploiting the results of the project *(e.g. the IPR)* — since successfully exploiting the results is one of the main objectives of the action

⚠ Receipts will be taken into account by the Commission/Agency only at the moment of the payment of the balance *(i.e. the final payment at the end of the action)*. They must be declared in the final report.

In many cases they will not affect the grant amount since they do not lead to a profit (at the level of the action). However, particularly in actions funded at 100%, they may have an impact and cause a reduction.

Examples:

1. *Eligible costs: 100 and grant amount: 70*

If receipts: 30 ➔ no impact

If receipts: 20 ➔ no impact

If receipts: 60 ➔ the grant amount will be reduced to 40.

2. *Eligible costs: 100 and grant amount: 100*

If receipts: 0 ➔ no impact;

If receipts: 20 ➔ the grant amount will be reduced to 80

Best practice: The potential implications of receipts should be addressed in the consortium agreement *(see Article 41.3)*.

➔ Amount resulting from Steps 1-3.

Step 4 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions (if any), the Commission/Agency will, for each beneficiary/linked third party, calculate the grant reductions at their level, add any reductions that must be made at action-level and then sum them up to a total amount for the consortium *(see Article 43)*.

This total amount of grant reductions for the consortium is then deducted from the maximum grant amount for the action set out in *Article 5.1*.

ℹ For more guidance on grant reductions*, see the Guidance on grant reductions*.

➔ Amount resulting from Step 4.

The **final grant amount** is the lower of the 2 (amount resulting from Steps 1-3 and amount resulting from Step 4).

Balance

Step 5 — **Calculation of the balance & Guarantee Fund release**

In order to calculate the balance, the Commission/Agency will deduct the total amount of pre-financing and interim payments made from the final grant amount.

If the final grant amount is *higher* than the payments already made, the balance will take the form of a payment. In addition, the Guarantee Fund contribution (5% that were kept from the pre-financing) will be released with a separate payment.

If the final grant amount is *lower* than the payments made, the balance will take the form of a recovery (amount overpaid needs to be paid back to the Commission/Agency; *see Article 44*). In this case, the amount to be paid back will be directly compensated against the Guarantee Fund release and if this amount is sufficient to cover the debt, the recovery process ends (instead the consortium will be paid the remainder of the Guarantee Fund contribution, if any is left). If the Guarantee Fund amount is not sufficient, further steps will be taken to recover the rest *(see below)*.

Step 6 — **Payment of the balance letter & debit note**

The Commission/Agency will inform the coordinator about the amount due to the consortium or the amount that needs to be paid back (payment of the balance letter).

If the final payment involves a grant reduction or recovery, there will be two letters: a pre-information letter (opening a contradictory procedure) and a confirmation letter *(see Articles 43 and 44)*.

If there is still an amount to be recovered after compensation with the Guarantee Fund release, the confirmation letter will include a debit note to the coordinator for the amount and the division of final grant amount table *(see below)*.

Recovery (if any)

Step 7a — **Recovery from the coordinator**

If the coordinator pays the debt by the date specified in the debit note, the recovery process ends.

If the coordinator does NOT repay the Commission/Agency by the date specified AND if it has NOT submitted the report on the distribution of payments, the Commission/Agency will pursue recovery against the coordinator alone (enforced recovery, *see below*).

Step 7b — **Recovery from the beneficiaries**

If the coordinator does NOT repay the Commission/Agency by the date specified, BUT has submitted the report on the distribution of payments, the Commission/Agency will:

- identify the beneficiaries that received funds in excess and
- calculate the amount each beneficiary owes to the Commission/Agency.

Step 7ba — **Identifying the beneficiaries with excess funding**

In order to identify the beneficiaries that received excess funding, the Commission/Agency will compare the amount each beneficiary *actually* received (report on the distribution of payments) with its *share of the final grant amount* (beneficiary's accepted EU contribution divided by total accepted EU contribution and obtained percentage then applied to final grant amount).

Beneficiary's final grant share formula:

{{{beneficiary's accepted costs

multiplied by

reimbursement rate}

divided by

accepted EU contribution calculated under Step 1}

multiplied by

final grant amount for the action}

This means that the final grant amount is redistributed between the beneficiaries in proportion to their accepted costs (especially important for overspent grants, i.e. where the consortium declared costs *above* the maximum grant amount limit and each beneficiary's accepted EU contribution must therefore be adjusted to bring it into line with the maximum grant amount) and then compared to the amounts they received from the coordinator.

Recovery will be pursued only against the beneficiaries with a negative result (i.e. excess of payments received over final grant amount share).

Step 7bb — **Division of the debt**

In order to calculate the amount each of those beneficiaries has to pay back, the Commission/Agency will split the amount to be recovered between them (in proportion to their relative share of the total payments in excess; division of final grant amount table).

Step 7bc — **Beneficiary recovery letter & debit note**

The Commission/Agency will cancel the debit note sent to the coordinator and inform the beneficiaries concerned about the amounts to be paid back, together with a debit note for each beneficiary (beneficiary recovery letter).

Step 8 — **Enforced recovery**

If the coordinator/beneficiaries do not honour the debit note within the deadline, the Commission/Agency will enforce its claim(s) by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- by drawing on the Guarantee Fund and then follow it up with a **debit note on behalf of** the **Guarantee Fund**, to continue the recovery procedure by:
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Examples for calculating the payment of the balance:

Case 1 (payment):

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 1 000 000.

Reimbursement rate: 100%.

Payments made (pre-financing and interim): EUR 900 000 (limit of 90% of the maximum grant amount).

Guarantee Fund contribution: 5% of EUR 1 000 000 = EUR 50 000.

Payments received: EUR 900 000 – EUR 50 000 = EUR 850 000.

Final grant amount:

Total accepted costs: EUR 1 045 000.

Application of the reimbursement rate: 100 % = EUR 1 045 000 (total accepted EU contribution).

Limit to the maximum grant amount: EUR 1 000 000.

No receipts/profit.

No grant reductions.

Final grant amount: EUR 1 000 000.

Balance & Guarantee Fund release:

Payments made: EUR 900 000.

Balance: EUR 1 000 000 (final grant amount) - EUR 900 000 (payments made) = EUR +100 000 (positive balance to be paid to the consortium).

Release of Guarantee Fund: EUR 50 000 (to be paid to consortium).

Amounts to be paid out to the consortium: EUR 100 000 (positive balance) + EUR 50 000 (Guarantee Fund release)

Case 2 (grant with terminated beneficiary):

Grant with three beneficiaries (A, B and C) and three reporting periods.

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100%.

Beneficiary A was terminated before the end of RP1 and the amount due calculated was EUR 62 500 EUR.

Payments made (pre-financing and interim): EUR 450 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 500 000 = EUR 25 000.

Payments received: EUR 450 000 - EUR 25 000 = EUR 425 000.

Final grant amount:

Total accepted costs: EUR 362 500.

Application of the reimbursement rate: 100% = EUR 362 500 (total accepted EU contribution).

Limit to maximum grant amount: EUR 362 500 (no limitation; costs below maximum grant amount).

No receipts/profit.

Amount resulting from Steps 1 to 3: EUR 362 500.

10% grant reduction beneficiary B: 10% of EUR 200 000 = EUR 20 000.

No other grant reductions.

Amount resulting from Step 4: 500 000 – 20 000 = EUR 480 000.

Lower amount of the two: EUR 362 500.

Final grant amount: EUR 362 500.

Balance & Guarantee Fund release:

Payments made: EUR 450 000.

Balance: EUR 362 500 (final grant amount) - EUR 450 000 (payments made) = EUR -87 500 (excess payments of EUR 87 500).

Offsetting against Guarantee Fund release: EUR 87 500 – EUR 25 000 = EUR -62 500.

Payment:

Amount to recovered from the consortium: EUR 62 500.

Case 3 (recovery – underspent grant):

Grant with four beneficiaries: A, B, C, D.

Maximum grant amount: EUR 3 000 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 800 000; B= EUR 1 200 000; C= EUR 600 000; D= EUR 400 000).

Reimbursement rate: 100 %.

Payments made (pre-financing and interim): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 3 000 000 = EUR 150 000.

Payments received: EUR 2 700 000 - EUR 150 000 = EUR 2 550 000.

Final grant amount:

Total accepted costs: EUR 2 430 000.

Application of the reimbursement rate: 100% = EUR 2 430 000 (total accepted EU contribution).

Limit to maximum grant amount: EUR 2 430 000 (no limitation; costs below maximum grant amount).

No receipts/profit.

Amount resulting from Steps 1 to 3: EUR 2 430 000.

10% grant reduction beneficiary B: 10% of EUR 1 200 000 = EUR 120 000.

No other grant reductions.

Amount resulting from Step 4: 3 000 000 - 120 000 = EUR 2 880 000.

Lower amount of the two: EUR 2 430 000.

Final grant amount: EUR 2 430 000 (underspent grant ➔ beneficiary shares: A= EUR 600 000; B= EUR 1 100 000; C= EUR 400 000; D= EUR 330 000).

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 430 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR -270 000 (excess payments of EUR 270 000).

Offsetting against Guarantee Fund release: EUR 270 000 – EUR 150 000 = EUR 120 000.

Recovery:

Amount to be recovered from the consortium: EUR 120 000 (negative balance of EUR 120 000 must be paid back by coordinator, otherwise Commission/Agency will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from coordinator:

The coordinator does not reimburse the Commission/Agency and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 400 000; B= EUR 1 200 000; C= EUR 600 000; D= EUR 350 000).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

A: EUR 600 000 (final grant share) - EUR 400 000 (payments received) = EUR 200 000 (no payment in excess)

B: EUR 1 100 000 (final grant share) - EUR 1 200 000 (payments received) = EUR -100 000 (excess payment of EUR 100 000)

C: EUR 400 000 (final grant share) - EUR 600 000 (payments received) = EUR -200 000 (excess payment of EUR 200 000)

D: EUR 330 000 (final grant share) - EUR 350 000 (payments received) = EUR -20 000 (excess payment of EUR 20 000).

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission/Agency.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 320 000.

B: 100 000/320 000 = 31.25 %.

C: 200 000/320 000 = 62.5 %.

D: 20 000/320 000 = 6.25 %.

Total to be recovered: EUR 120 000.

B: 31.25 % x 120 000 = EUR 37 500

C: 62.5 % x 120 000 = EUR 75 000

D: 6.25 % x 120 000 = EUR 7 500.

Case 4 (recovery – overspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 3 000 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 1 000 000; B= EUR 1 500 000; C= EUR 500 000)

Reimbursement rate: 100%.

Payments made (pre-financing and interim): EUR 2 700 000 (limit of 90 % of the maximum grant amount).

Guarantee Fund contribution: 5% of 3 000 000 = EUR 150 000.

Payments received: EUR 2 700 000 - EUR 150 000 = EUR 2 550 000.

Receipts:

Beneficiary A was sponsored for this project by a private company with an amount of EUR 60 000 dedicated to the reimbursement of the remuneration of one young researcher.

Beneficiary B (a university) received as in-kind contribution from its government the secondment of a scientist specifically assigned to the project. The salary of this seconded scientist (EUR 80 000) was declared as cost by this beneficiary, even if paid by the government.

Final grant amount:

Total accepted costs: EUR 2 500 000 direct costs (including EUR 200 000 for subcontracting) + EUR 575 000 for indirect costs (25 % flat rate on direct costs minus subcontracting) = EUR 3 075 000.

Application of the reimbursement rate: 100% = EUR 3 075 000 (total accepted EU contribution).

Limit to maximum grant amount: EUR 3 000 000.

Calculation of receipts and deduction of profit: Profit: EUR 3 140 000 (total accepted EU contribution + receipts : EUR 3 000 000 + EUR 60 000 + EUR 80 000) – EUR 3 075 000 (total accepted costs) = EUR 65 000

Amount after deducting profit: EUR 3 000 000 – EUR 65 000 = EUR 2 935 000.

Amount resulting from Steps 1 to 3: EUR 2 935 000.

10% grant reduction beneficiary A: 10% of EUR 1 000 000 = EUR 100 000.

No other grant reductions.

Amount resulting from Step 4: 3 000 000 - 100 000 = EUR 2 900 000.

Lower amount of the two: EUR 2 900 000.

Final grant amount: EUR 2 900 000.

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 900 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR +200 000 (positive balance to be paid to the consortium).

Release of Guarantee Fund: EUR 150 000 (to be paid to consortium).

Amounts to be paid out to the consortium: EUR 200 000 (positive balance) + EUR 150 000 (Guarantee Fund release)

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Commission/Agency on the basis of the final grant amount and the revised final grant amount *(see also Articles 5.4 and 44.1.3)*.

If the revised final grant amount is *lower* than the beneficiary's share of the final grant amount (beneficiary final grant share), the difference will be recovered.

How to calculate recoveries after payment of the balance:

Revised final grant amount

Step 1 — **Re-calculation of the accepted EU contribution**

In order to calculate the revised amount of accepted EU contribution for the beneficiary concerned, the Commission/Agency will calculate the revised amount of accepted costs for the beneficiary (i.e. eligible/not rejected costs declared in the financial statements; *see Articles 6 and 42*) and apply the reimbursement rate.

If the audit concerns a linked third party, the revised final grant amount will be calculated for its beneficiary.

➔ Amount resulting from Step 1.

Step 2 — **Grant reductions (substantial errors, irregularities or fraud or serious breach of obligations)**, if any

In order to calculate the amount of grant reductions, the Commission/Agency will calculate the grant reduction for the beneficiary concerned (if any; see *Article 43*).

This amount of grant reduction is then deducted from the beneficiary's maximum grant amount set out in Annex 2.

If the audit concerns a linked third party, the grant reduction will be calculated for the linked third party (i.e. deducted from its maximum grant amount), but the revised final grant amount will be calculated at beneficiary-level.

For beneficiaries that overspent (i.e. declared more costs at payment of the balance than their maximum grant amount), the reduction rate (percentage) will be applied directly to their share of the final grant amount and the resulting amount will be recovered (—short cut to ensure a proportionate result for beneficiaries that contributed more to the action than initially planned in the estimated budget; avoids disproportionate grant reductions compared to the real project participation; *see also Article 4.2*).

> For more guidance on grant reductions, *see the Guidance on grant reductions*.

➔ Amount resulting from Step 2.

The revised final grant amount is the lower of the two (amount resulting from Step 1 and amount resulting from Step 2).

Balance & recovery (if any)

Step 3 — **Calculation of the beneficiary balance**

In order to calculate if the beneficiary has to pay back any amounts, the Commission/Agency will compare the beneficiary's revised final grant amount with its final grant share *(see above)*.

Beneficiary's final grant share formula:

{{{beneficiary's accepted costs

multiplied by

reimbursement rate}

divided by

accepted EU contribution calculated under Step 1}

multiplied by

final grant amount for the action}

If the revised final grant amount is *lower* than its final grant share, the difference will be recovered.

If exceptionally the audit (or check, review or investigation) showed that the beneficiary made errors resulting in less cost declared than its eligible costs, there will be no recovery. Instead, the beneficiary will be allowed to submit corrected financial statements to claim the difference.

Step 4 — **Audit implementation letters & debit note**

The Commission/Agency will inform the beneficiary about the amounts put in question (audit implementation letter).

If the audit implementation involves a grant reduction or recovery (generally the case), there will be two letters: a pre-information letter (opening a contradictory procedure) and a confirmation letter *(see Articles 43 and 44)*.

If there is an amount to be recovered, the confirmation letter will include a debit note for the amount.

⚠ In case of European Court of Auditor audits, OLAF investigations and Member State judgments with a financial impact on the grant, similar procedures and letters will be used.

Step 5 — **Enforced recovery**

If the beneficiary does not honour the debit note within the deadline, the Commission/Agency will enforce its claim by one of the following *(see Article 44)*:

- by **offsetting** it

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

- by drawing on the Guarantee Fund and then follow it up with a **debit note on behalf of** the **Guarantee Fund**, to continue the recovery procedure by:
  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:
    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or
    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU.

Examples for calculating recoveries after payment of the balance:

Case 1 (recovery – underspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 200 000; C= EUR 100 000).

Reimbursement rate: 100 %.

Final grant amount:

Total accepted costs: EUR 187 500 + EUR 156 250 + EUR 150 000 = EUR 493 750

A: EUR 150 000 (direct costs) + EUR 37 500 (25 % flat rate for indirect costs) = EUR 187 500

B: EUR 125 000 (direct costs) + EUR 31 250 (25 % flat rate for indirect costs) = EUR 156 250

C: EUR 120 000 (direct costs) + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000

Application of the reimbursement rate: 100% = EUR 493 750 (total accepted EU contribution).

Limit to maximum grant amount: EUR 493 750 (no limitation; costs below maximum grant amount).

No receipts/profit.

No grant reductions

Final grant amount: EUR 493 750 (underspent grant ➔ beneficiary shares: A= 187 500 EUR; B= EUR 156 250; C= EUR 150 000).

Beneficiary revised final grant amount:

An audit concluded that the direct costs of beneficiary A were not eligible for an amount of EUR 30 000 and that there were issues with the visibility of EU funding and IPR.

Re-calculation of accepted EU contribution for beneficiary A: EUR 150 000 (direct costs) — EUR 30 000 (rejected direct costs) = EUR 120 000 + EUR 30 000 (25 % flat rate for indirect costs) = EUR 150 000.

Application of the reimbursement rate: 100% = EUR 150 000.

Amount resulting from Step 1: EUR 150 000.

10% grant reduction for beneficiary A: 10% of 200 000 = EUR 20 000.

Amount resulting from Step 2: 200 000 – 20 000 = EUR 180 000.

Lower amount of the two: EUR 150 000.

Beneficiary A revised final grant amount: EUR 150 000.

The other beneficiaries final grant amounts (i.e. their final grant shares) remain unchanged.

Beneficiary balance:

Balance: EUR 150 000 (revised final grant amount) - EUR 187 500 (final grant share) = EUR –37 500 (excess of EUR 37 500).

Recovery:

Amount to be recovered from beneficiary A: EUR 37 500 (negative balance of EUR 37 500 must be paid back by the beneficiary).

Case 2 (recovery – overspent grant):

Grant with three beneficiaries (A, B and C).

Maximum grant amount: EUR 500 000 (beneficiary maximum grant amounts in Annex 2: A= EUR 200 000; B= EUR 100 000; C= EUR 200 000).

Reimbursement rate: 100%.

Final grant amount:

Total accepted costs: EUR 200 000 + EUR 150 000 + EUR 250 000 = EUR 600 000

A: EUR 160 000 (direct costs) + EUR 40 000 (indirect costs) = EUR 200 000

B: EUR 120 000 (direct costs) + EUR 30 000 (indirect costs) = EUR 150 000

C: EUR 200 000 (direct costs) + EUR 50 000 (indirect costs) = EUR 250 000.

Application of the reimbursement rate: 100% = EUR 600 000 (total accepted EU contribution).

Limit to the maximum grant amount: EUR 500 000.

Final grant amount = EUR 500 000.

Beneficiary revised final grant amounts:

An audit concluded that direct costs of beneficiary A were not eligible for an amount of EUR 30 000.

Another audit concluded that direct costs of beneficiary C were not eligible for an amount of EUR 20 000 and that there were issues with the confidentiality obligations.

Calculation of the beneficiaries final grant shares:

A: (200 000/600 000) x 500 000 = EUR 166 667

B: (150 000/600 000) x 500 000 = EUR 125 000

C: (250 000/600 000) x 500 000 = EUR 208 333.

Beneficiary A:

Re-calculation of accepted EU contribution for beneficiary A: EUR 160 000 (direct costs) – EUR 30 000 (rejected costs) = EUR 130 000 + EUR 32 500 (25% flat rate for indirect costs) = EUR 162 500.

Application of the reimbursement rate: 100% = EUR 162 500.

No grant reductions

Beneficiary A revised final grant amount: EUR 162 500.

Beneficiary C:

Re-calculation of accepted EU contribution for beneficiary C: EUR 200 000 (direct costs) – 20 000 (rejected costs) = EUR 180 000 + EUR 45 000 ((25% flat rate for indirect costs) = EUR 225 000.

Application of the reimbursement rate: 100% = EUR 225 000.

Amount resulting from Step 1: EUR 225 000.

10% grant reduction beneficiary C: 10% of 200 000 = EUR 20 000.

Amount resulting from Step 2: 200 000 – 20 000 = EUR 180 000.

Lower amount of the two: EUR 180 000.

Beneficiary C revised final grant amount: EUR 180 000.

Beneficiary B's final grant amounts (i.e. its final grant amount share) remains unchanged.

Beneficiary balance:

Beneficiary A:

Balance: EUR 162 500 (revised final grant amount) - EUR 166 667 (final grant share) = EUR –4 167 (excess of EUR 4 167).

Beneficiary C:

Balance: EUR 180 000 (revised final grant amount) - EUR 208 333 (final grant share) = EUR -28 333 (excess of EUR 4 167).

Recovery:

Amount to be recovered from beneficiary A: EUR 4 167 (negative balance of EUR 4 167 must be paid back by the beneficiary).

Amount to be recovered from beneficiary C:

In principle: EUR 28 333 (negative balance according to normal calculation).

However, since normal calculation leads to disproportionate grant reductions for beneficiaries that overspent at payment of the balance: shortcut calculation (see above): 10% of EUR 208 333 = EUR 20 833.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

1. Checks

The Commission/Agency may — at any moment and without any time-limit — check any aspect relating to the grant.

Examples:

1. *After receiving the reports (see Article 20), the Commission checks the different documents (explanation of the work carried out, overview of the progress, explanation of the use of resources, etc.), for consistency with the description and work plan of the action.*

2. *The Agency performs a plagiarism check on documents submitted by the consortium.*

3. *After receiving information about misconducts concerning a certain beneficiary that participates in EU actions, the Commission checks all the grant agreements in order to see if it needs to take action.*

4. *After the end of the action, the Commission receives a complaint by one of the beneficiaries that another beneficiary does not respect its intellectual property obligations and decides to look into this allegation.*

The checks itself are **internal**. They may however have external effects, since the Commission/Agency may lead to a **request for information** *(see Article 17.1)* or it may take Chapter 6 measures in view of the results.

Example: *The beneficiaries did not clearly explain the allocation and use of resources in their periodic report. The Commission asks for more information by a certain date.*

The checks may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

The Commission/Agency may carry out checks using its own staff or with the assistance of external expert(s) or bodies — without asking the beneficiaries for approval before appointing them. In this case, the Commission/Agency will ensure that there is no conflict of interest by asking the expert(s) to sign a declaration.

If the check shows **ineligible costs** or serious **breach of obligations**, it may lead to cost rejection or grant reduction and, if necessary, recovery *(see Articles 42, 43 and 44)*. If a more in-depth examination is required, the Commission/Agency may start a review or audit.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in **meetings,** including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Project reviews

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out a review.

Reviews normally concern mainly the technical implementation of the action (i.e. its scientific and technological implementation), but may also cover financial and budgetary aspects or compliance with other obligations under the GA and may exceptionally also concern issues related to only one specific beneficiary.

They consist in an in-depth examination (often done with the help of independent experts) of the progress of the action, and in particular:

- the degree to which the work plan has been carried out and whether all deliverables were completed
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness
- the management procedures and methods of the action
- the beneficiaries' contributions and integration within the action
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

For some types of actions, they may be done regularly *(e.g. for the periodic reports related to a payment, to help the Commission/Agency to properly assess the action implementation and the work carried out by the beneficiaries)*.

They may also extend to third parties involved in the action (which is why beneficiaries must ensure that the Commission/Agency can exercise its rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-14*).

If the review shows **ineligible costs** or **substantial errors, irregularities or fraud** or serious **breach of obligations** (including non- or improper implementation of the action as described in Annex 1), it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

If carried out during the implementation of the action, a review may also recommend reorientations to the action.

2. Procedure

The review will be initiated by a **letter** sent to the coordinator (or, exceptionally, the beneficiary concerned) via the Participant Portal.

The letter will also mention the names of the independent experts that have been appointed (if any). The consortium may object to an expert, but only on the grounds of commercial confidentiality.

The review may include **on-the-spot visits** or a **review meeting** (on Commission/Agency premises or anywhere relevant for the action).

If there is a meeting, the invitation will indicate the documents that will be discussed, normally:

- Annex 1 (the contractual description of the action against which the assessment will be made)
- for periodic reviews: the periodic report(s) (technical and financial) for the period(s) under review (including documents related to financial/budgetary issues)
- deliverables that were due
- for final reviews: the final report and all periodic reports.

The results of the review will be recorded in a **review report**.

> The review report together with the Commission/Agency comments will be notified to the coordinator (or, exceptionally, the beneficiary concerned) for comments within 30 days (**contradictory review procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The Commission/Agency operational services (authorising officers) will analyse the comments received and decide on the follow-up, if any.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

1. Audits

The Commission/Agency may — at any moment and up until 2 years after the payment of the balance — carry out an audit.

⚠ **Record-keeping —** Once an audit has started, the beneficiary must keep ALL the records and supporting documents until the audit procedure AND its follow-up (including cost rejection, grant reduction, recovery and litigation) is completed.

Example: *If the beneficiary archives the paper copies of the original supporting documentation not on its premises, the documentation must be retrieved and sent there in time for the audit fieldwork.*

Audits normally concern mainly the financial implementation of the action by a beneficiary (i.e. financial and budgetary implementation), but may also cover technical aspects or compliance with other obligations under the GA.

They consist in an in-depth examination (by professional (external or Commission/Agency) auditors and according to the generally accepted audit standards) of the implementation of the action by the beneficiary.

They may also extend to third parties involved in the action and third parties receiving financial support or a prize (which is why beneficiaries must ensure that the Commission/Agency auditors can exercise their rights towards contractors, subcontractors, linked third parties or third parties providing in-kind contributions, by including appropriate clauses in their contracts with them; *see Articles 10-15*).

Examples:

1. *The Commission/Agency will audit **linked third parties**, as if they were beneficiaries. The audit will be carried out on the premises of the third party and all communication concerning the audit will be carried out directly with the linked third party (e.g. audit initiation letter, contradictory audit procedure). However, since the financial consequences would normally have to be borne by the linked third party's beneficiary (see Article 44), the Commission/Agency will also notify the beneficiary about the launching the audit, as well as about a summary of its conclusions.*

2. *The Commission/Agency may audit **third parties providing in-kind contributions** (free of charge or against payment), in the context of an audit of a beneficiary, in order to see if the costs claimed for the in-kind contribution are eligible. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the third party's premises, if necessary.*

3. *The Commission/Agency may audit **contractors** or **subcontractors**, in the context of an audit of a beneficiary, in order to:*

- *see if contracts/subcontracts were awarded in compliance with the requirements of the H2020 GA (ensuring best value for money or, if appropriate, the lowest price, absence of conflict of interest)*
- *see if payments made under the contract/subcontract match the costs declared by the beneficiary*
- *assess the technical work carried out by the subcontractor.*

The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to carry out checks on the contractor/subcontractor's premises, if necessary. The audit will not aim to check the contractors'/subcontractors' costs or accounts, because the remuneration they get is a set price, not a reimbursement of costs (except in cases of fraud).

4. *The Commission/Agency may audit **recipients of financial support** or **prizes**, in the context of an audit of a beneficiary, in order to see whether the eligibility conditions for the costs declared by the beneficiary are met. The audit procedure will formally be with the beneficiary and the beneficiary will be responsible for ensuring that the auditors have access to all necessary documents and to the recipient's premises, if necessary. The audit will normally not aim to assess the costs incurred by the recipients (since they are not relevant for the eligibility of the beneficiary's costs) — unless Annex 1 of the GA provides that the financial support must be given as reimbursement of the actual costs of the third parties.*

If the audit shows, **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and, in very serious cases, to exclusion and/or financial penalties *(see Article 45)*. In some cases, findings may result in the **acceptance** of additional costs (if the beneficiary declared them).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits will normally have no direct consequences for the beneficiaries that were audited; even if the actual costs turn out to be lower, this will not lead to a rejection of costs.

2. Procedure

The audit will be initiated by a **letter** sent to the beneficiary concerned (via the Participant Portal or by registered post with proof of delivery; *see Article 52*).

If the Commission/Agency uses an external audit firm, this letter will mention its name. The beneficiary may object on grounds of commercial confidentiality (together with the reasons why) and — if justified — the Commission/Agency may decide to appoint another external auditor (or, in exceptional circumstances, to carry out the audit itself).

The audit usually involves a **desk review** of the documents requested from the beneficiary and an **on-the-spot visit** (i.e. on the beneficiary's premises or on the site on which the action is being implemented). There may however also be audits that consist only in a desk review.

The auditors will request access to a wide range of records and documentation *(e.g. payslips, labour contracts, complete statutory accounts, etc.)* and will indicate how and when it must be provided (and in which format).

The beneficiary must provide the auditors with all requested information, records and supporting documents (in the format and within the deadline specified).

Example: *A hard copy list of records from the general ledger (accounting document) disclosing hundreds or thousands of transactions is impossible to process manually, therefore the auditors will normally require an electronic version.*

Objections based on data protection or confidentiality will NOT be accepted.

Where the records and documentation contain personal data, the Commission/Agency will process it in compliance with Regulation No 45/2001 and the beneficiary must inform the persons concerned about this processing *(see Article 39)*.

Confidential data will be processed in accordance with Article 36.

Failure to provide the requested information (in the requested format and within the specified deadline) will lead to the rejection of costs (and possibly other measures, such as recovery, suspension of payments, termination, administrative and financial penalties, etc.).

For on-the-spot audits, the beneficiary must allow access to its premises and ensure that all records and supporting documentation are readily available. This includes granting access to research facilities and interviewing the researchers that worked on the action.

The results of the audit will be recorded in an **audit report**.

The draft audit report will be sent to the beneficiary concerned for comments within 30 days (**contradictory audit procedure**). (This is NOT the contradictory procedure described in Article 42. It is a separate procedure that may, if necessary, be followed by a second contradictory procedure for cost rejection, grant reduction, etc. under Articles 41 to 46.)

The audit procedure will be closed (by the Commission/Agency auditors) with the **final audit report** and the **letter of audit conclusions** (LoC) — and the file will then be passed on to the Commission/Agency operational services (authorising officers) for the follow-up, if any.

⚠ If there are cost adjustments in favour of the EU budget to be made on the basis of the audit, please do not take any immediate action (do NOT deduct them from the next financial statement). If needed, the adjustments will be done by the Commission/Agency and you will be informed about them in the payment letter or audit implementation pre-information letter (with the possibility to take position).

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[41] and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

1. OLAF investigations

OLAF is the EU's anti-fraud office, responsible for investigating fraud against the EU budget.

If the Commission/Agency suspects that a beneficiary or third party involved in an action committed fraud or other illegal acts, it will inform OLAF, who may decide to investigate.

OLAF will send the outcome of the investigation to the Commission/Agency, who will then decide how to proceed.

If an OLAF investigation shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, it may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50),* to exclusion and/or financial penalties *(see Article 45),* as well as to criminal prosecution before the national authorities.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

1. ECA checks and audits

The European Court of Auditors (ECA) is the (entirely independent) external auditing body for all European institutions. As such, it may carry out audits on all recipients of EU funds (including beneficiaries, third parties involved in the action and recipients of financial support or prizes).

Depending on the outcome, the results of such an audit may be notified to the beneficiary.

If the Commission/Agency intends to reject costs on the basis of the findings of the Court of Auditors, it will inform the beneficiary and give it the possibility to make observations.

If an ECA check or audit shows **ineligible costs**, **substantial errors, irregularities or fraud** or serious **breach of obligations**, this may lead to suspension, termination, cost rejection, grant reduction and recovery *(see Articles 42-44, 47-50)* and to exclusion and/or financial penalties *(see Article 45)*.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION 2:** Not applicable.]*

1. Checks, reviews, audits and investigations for international organisations

Checks, reviews, audits and investigations may also be made with regard to beneficiaries that are **international organisations (IOs)**.

⚠ Checks, reviews, audits and investigations must however respect the privileges and immunities accorded to an international organisation by its constituent documents or international law.

If there is a specific agreement concluded with the international organisation (and this agreement covers checks, reviews, audits and investigations), the Commission/Agency will apply the agreement.

***Example:** A Financial and Administrative Framework Agreement (FAFA) signed between the European Union and the international organisation.*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the correction rate for extrapolation established by the *[Agency or the]*Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the **findings concern substantial errors, irregularities or fraud or serious breach of obligations,** the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Extension of findings (rejection and grant reduction)

If the Commission/Agency finds (typically in a review, audit or OLAF investigation) **substantial errors, irregularities or fraud** or serious **breach of obligations** which are **systemic** or **recurrent**, it may make a correction (cost rejection or grant reduction; *see Articles 42 and 43*) in:

- the grant, both for
  - reporting periods that where audited/reviewed and
  - reporting periods that were not audited/reviewed (extension of the findings)
- other grants of the beneficiary (extension of the findings).

'Recurrent' means an infringement found in several grants of the beneficiary (and therefore likely to also have occurred in the other grants of that beneficiary).

Examples (recurrent): *In several grants, the beneficiary claimed deductible VAT as an eligible cost; increased the remuneration of its personnel solely for its contracts with the Commission; did not clearly display the EU funding despite the GA's visibility requirements.*

'Systemic' means an infringement that is inherently related to the beneficiary's methodologies, accounting, management or internal control practices (and therefore, by its very nature, likely to have occurred in all other transactions of the beneficiary that are comparable/similar (i.e. governed by the same methodologies, accounting management or internal control practices, and thus part of the same 'system').

Examples (systemic): *The beneficiary does not keep records of a certain type of transactions; the beneficiary set up a fraudulent network to overcharge personnel costs .*

The findings may be extended both to *on-going* grants (i.e. grants for which the payment of the balance has not yet been carried out) and to *closed* grants — up to two years after the payment of the balance.

Findings may be extended to all other EU or Euratom grants awarded under similar conditions.

⚠ Findings will normally be extended only within one programme *(e.g. findings in an H2020 audit to all H2020 grants)* but they may exceptionally also be extended to similar programmes *(e.g. if justified by the nature of the findings and the similarity of the applicable grant agreements or in case of serious irregularities or fraud).*

2. Procedure

If findings are systemic or recurrent, this will already have been mentioned in the audit or review report and — like the other aspects of the report — they have been subject to the contradictory audit/review procedure.

If the findings also impact other EU/Euratom grants, the audit/review procedure will be followed by an extension procedure, to fix the list of impacted grants and ask the beneficiary's views on the method for correction. In order to minimise the administrative burden, this procedure is usually centralised.

Procedure for extension of findings:

Step 1 — After the end of the contradictory audit/review procedure, the Commission/Agency auditors send the letter closing the audit/review procedure (**letter of audit conclusions**), together with

- the final audit/review report
- the list of grants/reporting periods to which the audit findings will be extended
- an invitation to submit comments on the list of grants/reporting periods
- for cost rejection:
  - a request to submit revised financial statements for the grants/reporting periods on the list (via a specific form annexed to the letter of audit conclusions)
  - the proposed correction rate for extrapolation (if the beneficiary does not submit revised financial statements)
  - the conditions for external counter-audits to propose an alternative correction method *(see below)*
- for grant reduction: the proposed flat-rate for the correction.

The correction rate for cost rejection will normally correspond to the average correction rate calculated in the sample of audited grants (for the flawed cost category(ies) or even for the total costs claimed).

The flat-rate for grant reductions will normally be based on the relative importance of the tasks improperly implemented or the seriousness of the breach of obligations — compared to the action (i.e. calculated according to the principle of proportionality).

⚠ The rate will be used if:

- the beneficiary explicitly requests it

  Example: *if the beneficiary considers that the administrative workload related to submitting revised financial statements for all the grants affected would be disproportionate or impossible and so it decides to accept the correction rate.*

- the beneficiary does not submit revised financial statements or refuses to cooperate (in time)
- the Commission/Agency cannot approve the revised financial statements (because they do not properly reflect the audit/review findings)
- the Commission/Agency cannot accept the alternative correction method proposed by the beneficiary.

Step 2 — The beneficiary has 90 days to:

- submit comments on the list of grants

  If the beneficiary considers that some (or all) of the grants on the list are not affected, it must explain why. If the explanation is not sufficient, the Commission/Agency may request additional information or clarifications.

- submit revised financial statements (free of the errors or irregularities raised).

  Example: *An audit finds that the beneficiary claimed the deductible VAT as an eligible cost and qualifies this finding as recurrent. The beneficiary agrees with the audit conclusions. It submits revised financial statements correcting the VAT for each grant affected.*

- if it does not intend to submit revised financial statement, but disagrees with the proposed correction rate, the beneficiary may:
  - for cost rejection: present an **alternative correction method** (alternative correction rate), substantiated by an audit performed by an independent external auditor

    The purpose of the independent audit can ONLY be to determine a more precise error rate for the audit/review findings of the Commission/Agency (NOT to contest those findings themselves).

  - for grant reduction: present an **alternative correction method** (alternative flat rate), substantiated by a note explaining why the alternative rate is more appropriate than the rate proposed by the Commission/Agency.

⚠ The beneficiary must choose one method for the entire extension procedure, i.e. submit for all grants either revised financial statements or an alternative correction method.

⚠ The Commission/Agency has **full discretion** to accept or refuse the alternative correction method proposed by the beneficiary; there is NO entitlement to it.

After the extension procedure is completed, the list of grants and beneficiary position is handed to the operational services which are in charge of managing the concerned grants. They will decide on the actions to be taken in their grants.

The implementation will be done on the basis of the:

- revised financial statements — if the beneficiary sent revised statements and they were approved
- initially notified correction rate for extrapolation — if the beneficiary did not send any revised statements or they could not be approved
- alternative correction method — if the beneficiary sent an alternative method and it was accepted.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:** five]**[OPTION 2 for low value grants:** three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

1. Evaluations

The Commission/Agency may carry out **interim** and **final evaluations** of the actions for the monitoring and evaluation of the H2020 Programme implementation.

These evaluations have NO effect on the grant.

They are based on the performance indicators and issues specified in Annexes II and III to the H2020 Specific Programme. These performance indicators vary according to the specific programme's objectives. Performance indicators may be refined during the implementation of H2020.

Example:

Progress on the Specific Objective 'Leadership in enabling and industrial technologies' is evaluated on the basis of the three following indicators:

- *patent applications and patents awarded in the different enabling and industrial technologies,*
- *share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years),*
- *number of joint public-private publications.*

The necessary information will normally be taken from the questionnaire (that must be filled out as part of the periodic reports). However, the Commission/Agency may also address specific information requests to the coordinator (or the other beneficiaries).

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the **Code of Practice** annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

1. Code of Practice

Beneficiaries that are universities or other public research organisations must take measures to **implement** the principles set out the **Code of Practice**[44] annexed to the EU Recommendation on the management of intellectual property in knowledge transfer activities.

This is a **best effort obligation**: If not already done so, these beneficiaries must ensure that they consider the principles set out in Points 1 and 2 of the Code of Practice in the design and implementation of their IP management and knowledge transfer policies.

The Code consists of a set of general principles aiming to improve IP management and knowledge transfer by public research organisations by promoting exploitation and dissemination of research results (— with Point 1: Principles for an internal intellectual property policy and Point 2: Principles for a knowledge transfer policy)

[44] Available at http://europa.eu/legislation_summaries/research_innovation/general_framework/ri0007_en.htm.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Agreement on background

The beneficiaries must identify and agree on what constitutes **background for their action** (in order to be able to give access to it).

Best practice: Although not obligatory, beneficiaries are strongly advised to agree on background *before the GA is signed*, to ensure that they have access rights to what is needed for implementing the action (and then exploiting its results).

'Background' means any tangible or intangible input — from data to know-how, information or rights — that exists *before* the GA is signed and that is needed to implement the action or to exploit its results.

Examples: *prototypes; cell lines; patents; database rights*

For intellectual property rights, it suffices that the application was filed before the GA is signed. ('Intellectual property' being understood in the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967[45]).

Background is not limited to input owned, but potentially extends to anything the beneficiaries lawfully hold *(e.g. through a licence with the right to sub-licence)*. It also extends to input held by other parts of the beneficiary's organisation.

[45] Available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html.

> ***Example:*** *if a university department participates in the action, background could potentially be anything held by the university (unless the department has its own legal personality and is the beneficiary)*

The agreement may take **any form** *(e.g. positive list, negative list)*. It may be a separate agreement or may be part of the consortium agreement *(see Article 41)*.

If access to background is subject to **legal restrictions** or limits, the beneficiary must inform the other beneficiaries — before signing the GA *(see Article 25)*.

> ***Example:*** *Beneficiaries may agree to exclude specific background. Such an exclusion may be temporary (e.g. to permit the adequate protection of the background before providing access) or limited (e.g. to exclude only one or more specific beneficiaries). As background is by definition considered to be needed for implementation or exploitation, the impact of such exclusion on the action, particularly regarding an exclusion which does not have a temporary character, should be examined by the beneficiaries.*

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or ‘**associated country**’[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] For the definition, , see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948 . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

1. Access to background

The rules on **access to background** (including conditions and scope of access) are generally the same as for results *(see Article 31)*.

However, for background there is NO (or a more limited) obligation to give access, if there are **restrictions** or **limits** (legal or otherwise) and the beneficiary has informed the others — before acceding to the GA (or immediately when additional background is agreed on).

> ***Example:*** *A pre-existing agreement (e.g. an exclusive licence) which precludes the granting of access rights*

By contrast, if a beneficiary contracts on background later, it must ensure that it can comply with its access obligations under the GA.

Moreover, the **conditions for access** are slightly different. Access must be given:

- for the implementation of action tasks: the default rule is royalty-free

  However, if agreed by the beneficiaries before the GA is signed, for background other conditions may apply.

Example: *A beneficiary owns a novel technology needed by other beneficiaries for implementing their tasks under the action and the other beneficiaries do not bring the same level of background. In such case the beneficiaries may agree that access to the novel technology to implement the action will not be on a royalty-free basis.*

Best practice: If beneficiaries intend to deviate from the default rule, it is recommended that this is explained in detail in their proposal.

– for the exploitation of results: under fair and reasonable conditions *(see Article 31)*.

Also, there are NO **specific access rights** for EU institutions, Member States, Euratom, joint undertakings or third parties — except for the option for royalty-free access for users of research infrastructures in actions with trans-national or virtual access to research infrastructure.

Access rights are therefore normally limited to other beneficiaries and certain affiliated entities of other beneficiaries, unless otherwise agreed.

Example: *Beneficiary A used background from beneficiary B to generate its results. Beneficiary A would like to use its affiliated entity A established in a MS to exploit the results. For this, affiliated entity A needs access rights to beneficiary B's background.*

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

1. Ownership of results

Results belong normally to the beneficiary that produced them.

'Results' means the action's tangible outputs *(e.g. prototypes, micro-organisms)* and intangible outputs *(e.g. know-how, formulas),* as well as related rights (*e.g. patent rights and database rights*). Results do not include the outputs of activities not described in Annex 1, produced before the action starts, during its course or after it ends.

Record-keeping

Best practice: To avoid or resolve ownership disputes, beneficiaries should keep documents such as laboratory notebooks to show how and when they produced the results.

Specific cases (ownership of results):

Automatic joint ownership — If beneficiaries have jointly generated results and it is not possible to establish their respective contribution (or to separate them for protection), the beneficiaries automatically become joint owners.

In this case, the beneficiaries concerned must conclude a **joint ownership agreement** (in writing).

This agreement should cover in particular:

- specific conditions for granting licenses (if they are different from those already set out in the GA)
- criteria or principles for 'fair and reasonable compensation' to be provided to the other joint owners, if a non-exclusive license is granted to a third party (if appropriate)

  A ceiling for fair and reasonable compensation should be fixed only if the expected results can be determined with precision already before the action starts.
- how disputes will be settled *(e.g. via a mediator, applicable law, etc.)*.

Best practice: To make it easier to negotiate a joint-ownership agreement, the beneficiaries should include general principles on joint ownership already in the consortium agreement.

The joint ownership agreement will usually require further fine-tuning after the jointly-owned results are produced, in particular with regard to:

- how the ownership is divided *(e.g. equally or not)*
- if and how the joint results will be protected, including issues related to the cost of protection *(e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.)*, or to the sharing of revenues or profits
- how the joint results will be exploited and disseminated.

The joint owners automatically have the right under the GA to grant non-exclusive **licenses** to third parties against fair and reasonable compensation (without prior authorisation from the other joint owners) — unless otherwise provided in the joint ownership agreement.

The joint owner that intends to grant the licence must give the other joint owners at least **45 days advance notice** (together with sufficient information, to check if the proposed compensation is fair and reasonable). Such licenses may not include sub-licensing. Joint owners are free to agree on different arrangements in their joint-ownership agreement.

Joint owners may abandon joint ownership only after the jointly-owned results have been produced (new in Horizon 2020).

Example: *Once the results have been produced, the joint owners may transfer ownership to a single owner and agree on more favourable access rights (or on any other fair counterpart)*

Joint ownership by agreement — Outside the cases described above, the beneficiaries may also become joint owners if they specifically agree on it.

Example: *A beneficiary may decide that a part of its results will be owned jointly with its parent company or another third party. However, this requires a (partial) transfer of ownership, which is subject to the GA's rules on transferring ownership.*

EU/Euratom/Agency ownership to protect results — If valuable results are not protected *(e.g. if the official prosecution or renewal fees for a patent application are not paid*), the Commission/Agency may — under certain circumstances — assume ownership of the results.

2. Third parties with rights on results

The beneficiaries must ensure that they can fulfil their obligations under the GA regarding results, by making **arrangements** with any **third parties** that could claim rights to them *(e.g. subcontractors, linked third parties, international partners, employees, etc.)*.

Examples (third parties that may claim rights): *academic institutions in countries that have a kind of 'professor's privilege' system (according to which researchers may have some rights to the results of university research); employees or students who carry out work for the action (if they have rights under national law or their contract); beneficiaries for which linked third parties carry out a significant part of the work.*

Examples (arrangements): *transferring ownership to the beneficiary; granting access rights to the beneficiary with a right to sub-license.*

Specific cases (third parties with rights on results):

Joint research units (JRUs) — Where the internal arrangements of a JRU (*see Article 14*), state that any results produced by one member are owned jointly by all members, these other members are third parties that can claim rights on the results. In this case, the JRU member that is the beneficiary must ensure that it can fulfil its contractual obligations under the GA *(e.g. with regard to other beneficiaries' access rights)*.

Best practice: Beneficiaries that are members of a JRU should inform the other beneficiaries as soon as possible, to give them time to make, if needed, appropriate arrangements in the consortium agreement.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Protection of results

The beneficiaries must — for any results that can reasonably be expected to be commercially or industrially exploited —:

- examine the possibility of protecting them and
- if possible, reasonable and justified, **protect** them

even if this requires further research and development or private investment.

Example (no protection necessary): *if protection is impossible under EU or national law or not justified (in view of the (potential) commercial or industrial exploitation, the action's objective and other relevant elements, such as potential markets and countries in which competitors are located, whether additionally protecting a part of certain technology would bring significantly broader protection or not, etc.)*

Best practice: Beneficiaries should consider seeking expert advice to help them decide whether and how to protect results.

This obligation also applies to beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiaries are in principle free to choose any available **form** of protection.

Standard forms of protection:

- Patent
- Trademark
- Industrial design
- Copyright
- Trade-secret
- Confidentiality

The choice of the most suitable form should be made on the basis of the specificities of the action and the type of result (i.e. the form which offers the most adequate and effective protection). Although important for commercial and industrial exploitation, IP protection is not mandatory.

Examples (choice according to the type of result):

1. *For an invention: e.g. patent, confidential information.*

2. *For the design of a technology: e.g. industrial design, copyright.*

3. *For a website: e.g. industrial design, copyright, trademark.*

In some cases, it may be advisable to protect the invention by keeping it confidential, or to postpone the filing of a patent (or other IPR) application.

Example (better not to protect for the moment): *Keeping an invention temporarily confidential could allow further development of the invention while avoiding the negative consequences associated with premature filing (earlier priority and filing dates, early publication, possible rejection due to lack of support or industrial applicability, etc.).*

Costs related to protection may be eligible *(see Article 6.2.D.3).*

When deciding on protection, the beneficiaries must also consider the **other beneficiaries**' legitimate **interests**.

Any other beneficiary invoking legitimate interests must show how the decision would significantly harm it (especially commercially).

Example (harm): *The protection would lead to the disclosure of valuable background that is held by the other beneficiary (as a trade secret or flagged as confidential).*

Best practice: Although a beneficiary is not required to consult the other beneficiaries before deciding whether to protect a specific result it owns, beneficiaries can foresee arrangements (either in the consortium agreement or in separate agreements), to ensure that decisions on protection take due account of the interests of all beneficiaries concerned.

Protection should last for an appropriate **period** and have appropriate **territorial coverage** (in view of potential) commercial or industrial exploitation and other elements *(e.g. potential markets and countries in which potential competitors are located)*. Patent applications should identify the **rightful inventors**. Errors (or fraud) in identifying inventors may lead to the invalidation of patents.

Example (not rightful inventor): *an entity systematically designates a head of department as one of the inventors, although it is not true.*

2. Visibility of EU funding

Applications for protection must include the reference to EU funding set out in the GA — unless (technically or legally) impossible *(see Article 38)*.

Best practice: Where possible, beneficiaries should make this reference in the language of their application (using the text of the GA language version available on Participant Portal Reference Documents).

ARTICLE 28 — EXPLOITATION OF RESULTS

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Exploitation of results

The beneficiaries must take measures aiming to ensure **exploitatio**n of their results — either by themselves (*e.g. for further research or for commercial or industrial exploitation in its own activities*) or by others (other beneficiaries or third parties, *e.g. through licensing or by transferring the ownership of results*).

⚠ This is a **best effort obligation**: The beneficiaries must be proactive and take specific measures to ensure that their results are used (to the extent possible and justified).

The obligation applies only to beneficiaries receiving EU funding *(see Article 9)*.

Where possible, the measures should be consistent with the impact expected from the action and the plan for the exploitation and dissemination of the results.

If the GA provides for **additional exploitation obligations**, these must also be fulfilled. (Such additional exploitation obligations will already be mentioned in the work programme/call.)

Additional exploitation obligations apply to ALL beneficiaries.

If the GA includes the option for **information on standardisation**, the beneficiaries must moreover inform the Commission/Agency on any results that could contribute to European or international standards.

Example: *The results are produced in an area in which standards play an important role (such as in mobile communication, diagnostics or immunological diseases).*

For more guidance on dissemination and exploitation, *see the Participant Portal Online Manual.*

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the **obligation to protect results** in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018'];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1a for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) **[OPTION A for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme: data** which is **relevant for addressing a public health emergency**, if specifically requested by the [Commission][Agency] and within the deadline specified in the request]**[OPTION B**: not applicable];*

*(iii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

[additional OPTION for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme:** As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.]**]

***[OPTION 1b for health actions that do NOT participate in the Open Research Data Pilot, if foreseen in the work programme:** The [Commission][Agency] may require beneficiaries to:*

(a) deposit digital research data, which is generated in the action and relevant for addressing a public health emergency, in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user

(b) give specific access rights to third parties that need the digital research data to address the public health emergency (including the right to access, mine, exploit ad reproduce the data free of charge)

within the deadline specified in the [Commission][Agency]'s request.

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

[OPTION 1c for health actions targeting public health emergencies, if foreseen in the work programme: *The beneficiaries must deposit the digital research data generated in the action in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user, at the latest within 30 days after it has been generated.*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access, if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.**]***

[OPTION 2**: Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Dissemination of results

Unless it goes against their legitimate interests, the beneficiaries must — as soon as possible (but not before a decision on their possible protection) — **disseminate** their results (i.e. make them public).

Results that are disclosed too early (i.e. before the decision on their protection) run the risk being invalidated.

Example: *If a result is disclosed (in writing (including by e-mail) or orally (e.g. at a conference) before filing for protection — even to a single person who is not bound by secrecy or confidentiality obligations (typically someone from an organisation outside the consortium).*

NO dissemination at all may take place, if:

- the results need to be protected as a trade secret (i.e. confidential know-how) or
- dissemination conflicts with any other obligations under the GA *(e.g. personal data protection, security obligations, etc.)*.

Security obligations — Dissemination may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

Results that contain **EU-classified information**, can be disclosed only after approval by the Commission/Agency *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

The beneficiaries may choose the **form** for disseminating their results.

Standard forms of dissemination:

- website
- presentation at a scientific conference
- peer-reviewed publication

The dissemination measures should however be consistent with the 'plan for the exploitation and dissemination of the results' and proportionate to the impact expected from the action.

When deciding on dissemination, the beneficiaries must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to disseminate must give the other beneficiaries — unless otherwise agreed — at least **45 days advance notice** (together with sufficient information on the dissemination).

Any other beneficiary may **object** to dissemination — unless otherwise agreed — within **30 days** of receiving notification, if it can show that it would suffer significant harm (in relation to background or results). In this case, the results may not be disseminated — unless appropriate steps are taken to safeguard the interests at stake.

Examples (significant harm): *Disseminating the results would lead to disclosure of valuable background held by another beneficiary as a trade secret or would make protecting another beneficiary's results more difficult. Appropriate steps could include: omitting certain data or postponing dissemination until the results are protected.*

Best practice: Beneficiaries should foresee arrangements (either in the consortium agreement or in separate agreements) to ensure that decisions on dissemination take due account of the

interests of all beneficiaries concerned (and yet allow for publication of results without unreasonable delay).

If the GA provides for **additional dissemination obligations**, these must also be fulfilled. Such additional dissemination obligations will already be mentioned in the work programme/call.

For more guidance on dissemination and exploitation, *see the Participant Portal Online Manual.*

2. Open access to scientific publications

What? Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

'Peer-reviewed publications' means publications that have been evaluated by other scholars *(e.g. articles in scientific journals)*.

Other types of scientific publications, *such as non-peer-reviewed articles as well as monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

Open access means ensuring that, at the very least, such publications can be **read online**, **downloaded** and **printed** — via a repository for scientific publications.

Best practice: Open access has no impact on the other terms and conditions that apply to scientific publications *(e.g. as regards use, etc)*. However, in order to increase the utility of the publication, beneficiaries are encouraged to provide additional rights such as the right to copy, distribute, search, link, crawl and mine).

A 'repository for scientific publications' is an online archive. Beneficiaries are free to choose the repository; it can be institutional, subject-based or centralised.

Best practice: The Open Access Infrastructure for Research in Europe (OpenAIRE) links existing repositories. It is not obligatory for projects to deposit in OpenAIRE itself, but it is the recommended entry point for researchers deciding on a repository. OpenAIRE also offers support services for researchers, such as the National Open Access Desks. Other useful listings are the Registry of Open Access Repositories (ROAR), the Directory of Open Access Repositories (OpenDOAR) and OAPEN (for monographs). Beneficiaries should not choose a repository with rules which could conflict with open access.

Open access does NOT imply that the beneficiaries *are obliged to publish* their results; it only sets certain requirements that must be fulfilled if they do decide to publish them.

Open access can be provided through:

a) **gold open access** (**open-access publishing**)

'Gold open access means that open access is provided immediately via the publisher when an article is published, i.e. where it is published in open access journals or in 'hybrid' journals combining subscription access and open access to individual articles.

In gold open access, the payment of publication costs (article processing charges) is shifted from readers' subscriptions to (generally one-off) payments by the author. Such author processing costs may be eligible *(see Article 6.2.D.3)* — if incurred before the end of the action. Currently, an action for dealing with such costs incurred after the end of the action in FP7 is being piloted and further action in H2020 will be considered based on the outcome.

⚠ Although gold open access already ensures access via the publisher, the beneficiaries must nevertheless also provide open access via a repository *(see below)* in order to ensure the long-term preservation and availability of the publication.

b) **green open access** (self-archiving).

'Green open access' means that the published article or the final peer-reviewed manuscript is archived by the researcher (or a representative) in an online repository. Access to the article is often — but not necessarily — delayed (H2020 embargo period between 6 and 12 months; *see below*) as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download view fees during an exclusivity period.

Best practice: Authors are encouraged to retain their copyright and grant appropriate licences to publishers.

A template for an **open access clause** addendum which can be added to **publishing agreements** is available on the Participant Portal.

How? Open access to scientific publications involves four steps — which may or may not be taken at the same time.

Procedure for open access (scientific publications):

Step 1 — **Deposit**, in a repository for scientific publications, a machine-readable electronic copy of the published version of the **publication** (or the final peer-reviewed manuscript as accepted for publication).

This must be done as soon as possible (in some cases, the final version can be deposited before publication, *e.g. once accepted by the journal*) and at the latest on publication.

'Machine readable copy' means a format that can be used and understood by a computer; copies must be stored using text file formats that are either standardised or otherwise publicly known, so that anyone can develop new tools for working with them.

Best practice: Where possible, the article as published (in terms of layout, pagination, etc.) should be deposited.

Step 2 — Provide **open access** to the scientific **publication** — either as 'gold open access (i.e. via the publisher AND via the repository) or as 'green open access (i.e. via the repository only).

Open access must be given:

- in case of 'gold open access': at the latest on publication
- in all other cases: within 6 months (12 months for publications in the social sciences and humanities)

Step 3 — Ensure **open access**, via the repository, to certain **bibliographic metadata** that identify the publication

This is needed for visibility, traceability and monitoring.

It must be done in a standard format and include:

- the terms 'European Union (EU)' and 'Horizon 2020' or 'Euratom' and Euratom research and training programme 2014-18' (depending on the grant)
- the name of the action, acronym and grant number
- the publication date, and length of embargo period if applicable and

– a persistent identifier *(e.g. a stable digital object identifier which identifies the publication and links to an authoritative version)*.

Best practice: For ease of tracking, beneficiaries should also include the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601) in the funding acknowledgement field in their metadata.

The metadata compliance of the repository can be checked using OpenAIRE.

Step 4 — Aim to **deposit** at the same time, ideally in a data repository, the **research data** needed to validate the results in the deposited publication.

This is linked to rapid evolution of the concept of 'publication' in the digital era. The underlying data needed to validate the results presented in scientific publications is now seen as a crucial part of the publication and therefore an important element of scientific best practice.

⚠ Beneficiaries do NOT have to grant open access to the deposited underlying research data — unless they are participating in the Pilot on Open Research Data *(see below)*.

ℹ For more guidance on open access, *see the Participant Portal Online Manual.*

3. Open access to research data (Extended Open Research Data Pilot)

What? Beneficiaries of actions that participate in the Open Research Data Pilot must give **open, free-of-charge access** to the end-user to **digital research data** generated during the action (⚠ new in Horizon 2020).

⚠ As of the Work Programme 2017, the Open Research Data pilot has been extended to all thematic areas of Horizon 2020 (except ERC PoC actions, SME instrument Ph1 actions, ERA-NET Cofund actions that do not produce data, EJP Cofund actions, and prizes).

Participation is therefore now in principle **the default**. However, actions may **opt out** at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55)* —, if:

- participation is incompatible with the obligation to protect results *(see Article 27)*
- participation is incompatible with the security obligations *(see Article 37)*
- participation is incompatible with rules on protection of personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate/collect any research data or
- there are other legitimate reasons not to take part.

'Digital research data' is information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation; this includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Only data that is generated digitally *in the action* is concerned. Actions are encouraged to digitise any other data and provide open access to it, but they are not obliged to do so.

The pilot applies to **2 types** of digital research **data**:

– the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and

– other data and associated metadata, as specified by the beneficiaries themselves in their data management plan.

Examples: *curated data not directly attributable to a publication or raw data*

⚠ Beneficiaries may decide not to provide open access to specific datasets if this would go against other GA obligations *(e.g. to protect results or personal data)* or if the action's main objective, as described in Annex 1, would be jeopardised by giving open access to those specific datasets. In this case, the reasons must be explained in the data management plan, *see below*).

Open access to research data means taking measures to make it possible for third parties to **access, mine, exploit, reproduce** and **disseminate** data — via a research data repository.

A 'research data repository' means an online archive for research data; this can be subject-based/thematic, institutional or centralised.

Best practice: Useful listings of repositories include the Registry of Research Data Repositories (Re3data) and Databib. One key entry point for accessing and depositing related data and tools is Zenodo.

Actions participating in the pilot must draw up a **data management plan (DMP)** within the first 6 months of the project implementation.

The data management plan must support the management life-cycle for all data that will be collected, processed or generated by the action. It must cover how to make data findable, accessible, interoperable and re-usable (FAIR), including:

- the handling of data during and after the project
- what data will be collected, processed or generated
- what methodology and standards will be applied
- whether data will be shared / made open access (and how) and, if any, what data will not be shared / made open access (and why) and
- how data will be curated and preserved.

The data management plan should be updated (and become more precise) as the project evolves. New versions should be created whenever important changes to the project occur *(e.g. new data sets, changes in consortium policies, etc.),* at least as part of the mid-term review (if any) and at the end of the project.

ℹ For more guidance on data management plans (and a template), *see the H2020 proposal forms and the Participant Portal Online Manual.*

Costs related to the implementation of the Open Research Data pilot *(e.g. costs for providing open access, related research data management costs, data curation and data storage costs)* may be eligible *(see Article 6.2.D.3)*.

How? Open access to digital research data involves 3 steps:

Procedure for open access (research data):

Step 1 — **Deposit** the digital research data, preferably in a research data repository.

Step 2 — Provide **open access** by taking measures to enable users to access, mine, exploit, reproduce and disseminate the data free of charge *(e.g. for databases: by attaching an appropriate creative commons licence (CC-BY or CC0 tool) to the data; if the access/use is not subject to any rights: by indicating that no licence is needed)*.

Open access must not be given immediately; for data needed to validate the results presented in scientific publications, as soon as possible; for other data, beneficiaries are free to specify embargo periods for their data in the data management plan (as appropriate in their scientific area).

Step 3 — Provide **information**, via the repository, about **tools and instruments** for validating the results.

Where possible, the beneficiaries should provide those tools and instruments *(e.g. specialised software or software code, algorithms, analysis protocols, etc.).*

For more guidance on the research data pilot, see *the Participant Portal Online Manual.*

4. Data sharing for public health emergencies

If foreseen in the work programme/call, grant agreements for health actions will include specific contractual provisions concerning the sharing of research data for public health emergencies.

Public health emergencies are for instance:

- public health emergencies of international concern ('PHEIC') according to the World Health Organisation, or
- public health emergencies under Decision 1082/2013/EU, or
- public health emergencies under applicable national frameworks and regulations.

What? The data-sharing obligations for public health emergencies refer to any type of quality-controlled digital research data *(see point 3)* and associated metadata which is generated in the action and is relevant for the response to the public health emergency.

Personal data must be processed in accordance with applicable EU and national law (including international practices and standards; *see Article 39.2*).

For H2020 actions *targeting* public health emergencies, the beneficiaries must moreover:

- provide a data management plan (DMP) preferably with the proposal or at the latest before grant signature

  The data management plan should address the relevant aspects of making the data findable, accessible, interoperable and re-usable (FAIR), including:

  - what data the project will generate
  - whether and how the data will be made accessible for verification and re-use and
  - how it will be circulated and preserved.

  For more guidance on data management plans (and a template), *see the H2020 proposal forms and the Participant Portal Online Manual.*

- for relevant data (as agreed with the Commission/Agency): give free-of-charge access within 30 days after it has been generated
- for other data: give open access as soon as possible.

If agreed with the Commission/Agency, the open access obligation can exceptionally be replaced by special access rights to specific third parties that need the data to address the public health emergency.

In this case, the access rights must include the right to access, mine, exploit and reproduce the data free of charge (as further specified by the Commission/Agency, if needed) — but they may be used only for the access needed and only for addressing the public health emergency (i.e. limited both in scope and in time). Sub-licensing is only allowed if the beneficiary agrees.

For *other* H2020 actions, the special open access obligation (or the special access rights to specific third parties) is linked to a specific request by the Commission/Agency and limited to datasets agreed with the Commission/Agency.

5. Visibility of EU funding

Any dissemination of results (in any form), even when combined with other data, must include the reference to EU funding set out in the GA *(see Article 38*).

> **Best practice:** Where possible, beneficiaries should make this reference in the language of the dissemination activity (using the text of the GA language version available on Participant Portal Reference Documents).

Do NOT refer to EU funding when describing outputs of activities that are not described in Annex I, i.e. outputs developed outside the action (in other words for dissemination activities which do not concern results of the action).

> ⚠ **Combining H2020 & other EU grants —** If the outputs were developed in another EU-funded action (funded not by H2020, but another EU programme, including Structural Funds/ESIF Funds), do NOT forget the visibility obligations under those grant agreements.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

pending the [Commission][Agency] decision, within the period set out above;

if the [Commission][Agency] objects;

*until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

***[OPTION 2 for Euratom grants:** The Commission may **[OPTION:**— up to four years after the period set out in Article 3 —**]** object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

pending the Commission decision, within the period set out above;

if the Commission objects;

*until the conditions are complied with, if the Commission objection comes with conditions **]***

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

1. Transfers of ownership

The beneficiaries may **transfer ownership** of their results.

> ⚠ **Security obligations —** Transfer may be restricted/NOT possible for results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.
>
> ℹ For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual.*

The beneficiaries must however ensure that their **obligations** (regarding the results) apply to the **new owner** and that this new owner would pass them on in any subsequent transfer *(e.g. by including this in their arrangements with the new owner)*.

Obligations that must be extended to new owners:

- Joint ownership-related obligations *(see Article 26.2)*
- EU/Euratom/Agency's right to assume ownership, to protect results *(see Article 26.4)*
- Protection of results and visibility of EU funding *(see Article 27)*
- Exploitation of results and visibility of EU funding *(see Article 28)*
- Dissemination of results, open access and visibility of EU funding (see Article 29)
- Transfer and licensing of results *(see Article 30)*
- Access rights to result *(see Article 31)*.

When transferring ownership, they must also consider the **other beneficiaries'** legitimate **interests**.

The beneficiary that intends to make the transfer must give the other beneficiaries (that still have or still may request access rights) at least **45 days** (or less if agreed in writing) **advance notice** (together with sufficient information to allow them to properly assess the extent to which their access rights may be affected).

Any other beneficiary (with such access rights) may **object** to the transfer within **30 days** (or less if agreed in writing) of receiving notification, if it can show that it would adversely affect its access rights. In this case, the transfer may not take place, until the beneficiaries concerned reach an agreement.

The mere fact that the results concerned are transferred to a competitor is NOT in itself a valid reason for an objection. The beneficiary concerned must demonstrate the adverse effects on the exercise of its access rights.

Example (adverse effect): *Beneficiary A intends to transfer ownership of a new process it created during the course of an action to a competitor of beneficiary B. If beneficiary B shows that its access rights would be adversely affected by such a transfer (for instance, because the competitor has a proven track record of systematically legally challenging beneficiary B's claims), the transfer may not take place until the two beneficiaries reach an agreement.*

Specific cases (transfers of ownership of results):

Mergers & acquisitions (M&A) — If a transfer of ownership is not explicit (through an 'intended' transfer) but part of a take-over or merger of two companies, confidentiality constraints normally prevail (under M&A rules). Therefore, it may be necessary to inform the other beneficiaries only *after* the merger/acquisition took place (instead of *before*).

Specifically-identified third parties — The beneficiaries may (by prior written agreement) waive their right to object to transfers of ownership to a *specifically-identified* third party *(e.g. the mother company or an affiliate of one of them).* In this case, there is no need to inform them of such transfers in advance (and they do not have the right to object).

Before agreeing to such a global authorisation, beneficiaries should carefully consider the situation (and in particular the identity of the third party concerned), to determine if their access rights would be affected.

> ***Example:*** *For large industrial groups, it is sometimes clear from the beginning that all results produced will be transferred to another entity of the group, without being detrimental to the other beneficiaries (who agreed to the global authorisation).*

In security-related actions, transfers to third parties should only be decided on a case-by-case basis and should be handled with the greatest caution.

If the Commission/Agency has the right to object to transfers *(see point 3)*, the beneficiary must **formally notify in advance** (via the Participant Portal) any transfer to a specifically-identified third party established in a non-associated third country — and the Commission/Agency may object.

Joint research units (JRUs) — Where the internal arrangements of a JRU state that any results produced by one member are owned jointly by all members, the JRU member that is the beneficiary must ensure that it complies with the obligations under the GA on transfers (placing results under joint ownership of the JRU is a form of transfer).

Common legal structures — Common legal structures (CLS) (i.e. entities representing several other legal entities, *e.g. European Economic Interest Groupings (EEIG) or associations*) that are beneficiaries of an action may want to transfer ownership to one (or more) of their members. This is not prohibited; however the normal rules on transfers apply *(e.g. access rights have to remain available)*.

> **Best practice:** Beneficiaries that are members of a common legal structure are strongly advised to agree on specific arrangements with the other members of the CLS, in particular relating to ownership and access rights.

2. Granting licences

The beneficiaries may grant **licences** to their results.

They must however ensure that **access rights** can be exercised and that any **additional exploitation obligations** are complied with.

> *Exclusive* licences *(e.g. for commercial exploitation)* may be granted only if all other beneficiaries have waived their access rights and other access rights are preserved, *(e.g. the access rights of the EU, Member States and third parties; see Article 31)*.

3. Commission/Agency right to object to transfers or exclusive licensing

If the GA provides for this option, the Commission/Agency may **object** to transfers or *exclusive* licences (or, for Euratom grants, also *non-exclusive* licences) to third parties established in a non-associated third country.

> ⚠ As of the Work Programme 2018, the calls will normally already indicate if this option will be activated in the GAs. The option may however still be activated (without such indication):
>
> – for calls which do not fix the type of research and innovation activities ("bottom-up" calls, such as FET Open or MSCA) or
>
> – in other calls, exceptionally, if justified by the nature of the research and innovation activities or other action-related reasons.

Grounds for objection:

- Planned transfer/licence not in line with EU **competitiveness interests**

  Example: *if the transfer or licence would create a major competitive disadvantage for European companies or could make the results commercially unavailable on fair and reasonable conditions in the EU*

- Planned transfer/licence not consistent with **ethical principles**

  Example: *if the transfer or license could cause the results to be used in a way that is not in accordance with the fundamental ethical rules and principles recognised at EU and international level*

- Planned transfer/licence not consistent with **security considerations** (including, for Euratom grants, the Member States' defence interests under Article 24 of the Euratom Treaty).

  Example: *if the transfer or licence could make results considered significant from a security standpoint not readily available in the EU, or if security-sensitive results could fall into the hands of third parties that are considered a security risk*

This right does NOT apply to results generated by beneficiaries not receiving EU funding *(see Article 9)*.

The beneficiary must **formally notify** the Commission/Agency **in advance** (via the Participant Portal) of any planned transfer or exclusive licence (and, for Euratom grants, also of any non-exclusive licence).

A notification before the results are generated is allowed, if the specific results concerned (and the details of the transfer/licence) can already be identified.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).]

***[OPTION 2 for calls under Specific Objective 'Secure societies — Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION 3 for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

***[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[47], for the purposes of the complementary grant agreement(s) (see Article 2).]*

***[OPTION 1b for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

***[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

***[OPTION 1d for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]*

***[OPTION 2:** Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Access to results

What & When? The beneficiaries must provide **access to results**, if it is needed:

- by another beneficiary, for implementing action tasks or exploiting results
- by an affiliated entity of another beneficiary (established in a EU Member State or H2020 associated country), to exploit the results produced by the beneficiary to which it is affiliated — unless otherwise provided for in the consortium agreement.

There is NO definition of 'needed'. The beneficiary owning the results has to assess (on a case by case basis and taking into account the action's specificities), if the requesting beneficiary needs the access (and may refuse it, if it does not).

***Example (results needed for implementation)**: if without these results, action tasks could not be implemented, would be significantly delayed or would require significant additional financial or human resources.*

***Example (background needed for exploitation)**: if without these results, exploiting a result would be technically or legally impossible or if significant additional R&D work would have to be carried out outside of the action to develop an alternative equivalent solution.*

Best practice: To avoid conflicts, beneficiaries should agree *(e.g. in the consortium agreement)* on a common interpretation of what is needed.

The other beneficiaries may **waive their access rights**, provided that such a waiver is made in writing.

Best practice: Waivers should be made only on a case-by-case basis, once the results have been correctly identified, and should not be broader than what is actually necessary.

Examples:

***1.** If a waiver is made to allow for an exclusive licence, this waiver should not be broader than what is required for the purpose of the licence (regarding application fields, geographical coverage, etc.).*

***2.** If a waiver is made to allow for an exclusive licence, it may be wise that the beneficiaries agree that the waiver will lapse, if the license is not granted within a certain period or if the results concerned are not exploited by the licensee within a certain period.*

How? Access rights are not automatic; they must be **requested** (in writing).

Best practice: Beneficiaries may use their internal rules to specify how to make such written requests.

It may be requested even from beneficiaries who left the action before the end, under the same conditions as from active participants.

For affiliated entities (established in a EU Member State or H2020 associated country), access must be requested directly from the beneficiary owning the results. However, the beneficiary owning the results may agree to a different arrangement.

Access to results for exploitation may be requested up to one year after the period set out in Article 3 — unless the beneficiaries agreed on another time limit.

The **agreement** by the beneficiary owning the results (on the request for access) may be in any form (tacit, explicit, in writing or oral).

In case of **disagreement**, the requesting beneficiary can better substantiate its request, withdraw it or resort to the conflict resolution procedures foreseen by the consortium (*e.g. in the consortium agreement*).

If a conflict on access rights to results is likely to affect the action implementation, the beneficiaries must immediately **inform** the Commission/Agency *(see Article 17.2)*.

2. Conditions for access: Royalty free — Fair and reasonable conditions

Access must be given:

- for the implementation of action tasks: royalty-free
- for the exploitation of results: under fair and reasonable conditions

  'Fair and reasonable conditions' means appropriate conditions, including possible financial terms (i.e. monetary compensation), non-financial terms or royalty-free conditions, taking into account the specific terms of the granted access.

Fair and reasonable conditions includes also royalty-free conditions (⚠ new in Horizon 2020).

Examples (monetary compensation): *a lump sum, a royalty percentage, or a combination of both.*

Examples (non-financial terms): *a requirement to grant access to technology it has, or to agree on cooperation in a different field or in a future project.*

Best practice: Beneficiaries must agree on what constitutes fair and reasonable conditions, preferably in writing.

Royalty fees paid for access may be eligible **costs** *(see Article 6.2.D.3)*.

3. Scope of access: Sublicensing/Licensing — Additional access rights — More favourable terms — Additional conditions

The access rights set out in the GA **cover** only the **access needed**.

Access rights do NOT automatically give the right to the requesting beneficiary to **sub-licence**. (If this were the case, access rights to results would be extended — without consent — to virtually any company in the world, including the beneficiary's competitors).

Sub-licensing is only allowed if the beneficiary owning the results agrees — although such agreement should not be unduly refused, if the sublicensing is necessary. In this case the sub-licensing does not have to be royalty-free (even if the access rights concerned are) and can itself be made subject to specific conditions.

Examples:

1. *A university may need the right to sub-license access to results to third parties, to make it possible to derive value from its own results.*

2. *In large industrial groups it is quite common that research is conducted by one affiliate and exploitation by one or several other affiliates. Access rights enjoyed by the 'research affiliate' but not by the 'exploitation affiliate(s)' would raise problems for them.*

Best practice: The beneficiaries should agree on the terms and conditions of the sub-licensing generally and in writing (in the consortium agreement or separately).

Examples: *In such an agreement, they could foresee that sub-licensing could apply to the results (or part of them), but not to the background; sub-licensing could apply to affiliates of (some of) the beneficiaries, but not to other third parties.*

The beneficiaries remain free to grant **licenses** (including quasi-exclusive licenses) to their own results, as long as they can guarantee that all the access rights can be exercised. They can even grant an exclusive licence, if the other beneficiaries have waived their access rights.

Beneficiaries are free to grant **additional access** rights to results, beyond the rights foreseen in the GA.

Examples: *Additional access rights for third parties (e.g. affiliated entities not established in an EU Member State or H2020 associated country).*

Best practice: Such additional provisions may be included in the consortium agreement or in a separate agreement.

Access may also be granted on **more favourable** terms *(e.g. include the right to sub-licence)* or be made subject to **additional conditions** *(e.g. appropriate confidentiality obligations)*.

Example:

The beneficiary owning the results agrees that another beneficiary may sublicense its access rights to results to its affiliated entity.

Best practice: For legal certainty, beneficiaries should to specify these terms or conditions in writing.

Once obtained, access rights may be exercised as long as agreed by the concerned beneficiaries *(e.g. until the patent expires)*.

4. Specific access rights for EU institutions, bodies, offices or agencies and EU Member States

If the GA provides for this option, EU institutions, bodies, offices or agencies and/or EU Member States have specific access rights for policy purposes.

5. Specific access rights for Euratom and its joint undertakings

If the GA provides for this option, Euratom and its joint undertakings (such as the Fusion for Energy joint undertaking) have royalty-free access, for:

- developing, implementing and monitoring Euratom policies and programmes
- complying with Euratom's obligations under international research and cooperation agreements in the field of nuclear energy.

These access rights include the right to **sub-license** *(e.g. to third parties involved in such an international agreements)* or to give the results for use in public procurement, as long as they are only used for non-commercial and non-competitive purposes.

Example:

Euratom is part of the ITER agreement and is committed to disseminating information on technological solutions developed in the context of ITER projects, and to sharing them on a non-discriminatory basis with other ITER members and ITER itself. It does this by giving ITER and ITER members royalty-free licences, including the right to sub-license, for the intellectual property produced, so that they can publicly sponsor fusion and research programmes.

6. Specific access rights for third parties

If the GA provides for this option, there are specific access rights for third parties, i.e.:

- for beneficiaries of complementary grants (depending on the case, royalty-free or under fair and reasonable conditions)
- for third parties that need it for (cross-border) interoperability (depending on the case, royalty-free or under fair and reasonable conditions)
- for users of a research infrastructure in actions with trans-national or virtual access to research infrastructure under Article 16 (royalty-free).

  These access rights are limited to the research work of the user under the grant (i.e. what he needs for his research work while he uses the research infrastructure).

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the **European Charter** for Researchers and the **Code of Conduct** for the Recruitment of Researchers [48], in particular regarding:

- **working conditions**;
- transparent **recruitment** processes based on merit, and
- **career development**.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. European Charter and Code of Conduct for Researchers

The beneficiaries must take all measures to implement the principles set out in the European Charter for Researchers[46] and the Code of Conduct for their Recruitment.[47]

The **Charter** provides a framework for researchers' activities and career management, and includes obligations for researchers, employers and funders. The **Code of Conduct** provides for transparency to the recruitment and selection process, ensuring the equal treatment of all applicants. It includes obligations for employers and funders.

This is a **best effort obligation**: The beneficiaries must be proactive and take specific steps to address conflicts between their policies and practices and the principles set out in the Charter and Code of Conduct.

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

[46] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[47] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

2. Recruitment, working conditions and career development — Rights for the researchers

The beneficiaries must in particular implement the General Principles and Requirements of the Charter[48] and of the Code of Conduct[49] that relate to recruitment, working conditions and career development.

List of principles (relating to working conditions):

- Recruitment
- Transparency
- Judging merit
- Selection
- Variations in the chronological order of CVs
- Recognition of mobility experience
- Recognition of qualifications
- Seniority
- Postdoctoral appointments

According to these principles, beneficiaries should have a **clear policy for recruiting and selecting researchers**, which is publicly available and ensures that:

- all research vacancies and funding opportunities are publically advertised *(e.g. via the EURAXESS Jobs Portal[50])*
- vacancies and funding opportunities are also published in English
- vacancy announcements include a clear job description
- vacancy announcements include the requirements for the position or the funding opportunity, and the selection criteria
- there is an appropriate time period left between publication and the deadline for applications
- there are clear rules for the composition of the selection panels *(e.g. number and role of members, inclusion of experts from other (foreign) institutions, gender balance)*
- adequate feedback is given to applicants
- there is a complaint mechanism
- the selection criteria adequately value mobility, qualifications and experience, including qualifications and experience obtained in non-standard or informal ways.

These principles also apply to selection procedures that do not lead to formal employment relationship *(e.g. award of a research fellowship)*.

[48] Available at http://ec.europa.eu/euraxess/index.cfm/rights/europeanCharter
[49] Available at http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct
[50] Available at http://ec.europa.eu/euraxess/jobs

List of principles (relating to working conditions):

- Research freedom
- Accountability
- Non-discrimination
- Working conditions
- Research environment
- Funding and salaries (in particular, adequate social security)
- Stability and permanence of employment
- Gender balance
- Intellectual Property Rights
- Complaints/appeals and
- Participation in decision-making bodies.

List of principles (relating to career development):

- Career development
- Access to research training and continuous development (independently of the researcher's status)
- Value of mobility
- Access to career advice
- Supervision
- Evaluation/appraisal systems.

For more guidance on researcher rights, *see the Human Resources Strategy for Researchers tool.*

ARTICLE 33 — GENDER EQUALITY

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote **equal opportunities** between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Gender equality — Equal opportunities

The beneficiaries must aim — to the extent possible — for a gender balance at all levels of personnel assigned to the action, including at the supervisory and managerial levels.

This is a **best effort obligation**: The beneficiaries must:

- aim for the balanced participation of women and men in their research teams
- be proactive in ensuring gender balance among the individuals who are primarily responsible for carrying out the work (in accordance with the categories defined in the monitoring system).

Record-keeping — Beneficiaries should keep appropriate **documentation** about the steps taken and measures put in place *(see Article 18)*.

Examples (measures to promote equal opportunities): *transparency of recruitment and advancement processes, including gender-sensitive language in vacancies and job-descriptions; plans and conditions for career advancement; transparent wage classification and grading of jobs; development of leadership opportunities; gender planning and budgeting; gender impact assessment of new policies; climate surveys of institutions; adoption of family-friendly policies; promotion of mobility and dual-career couples.*

If a beneficiary cannot achieve the balanced participation of women and men in its team despite active recruitment efforts, the reasons should moreover be explained in the first **periodic technical report** and in the **final report** *(see Articles 20.3 and 20.4)*.

The Commission/Agency will verify compliance with this obligation, when monitoring the action implementation and in case of checks, reviews, audits and investigations *(see Article 22)*.

For more guidance on gender in research, *see the Participant Portal Online Manual.*

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following fundamental principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries

- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

The key sources of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Compliance to the ethical principles and legislation is ensured by the **H2020 ethics appraisal scheme** (i.e. the H2020 policy on ethics issues in research), which includes all of the following:

- ethics *self*-assessment (by the applicants, in their proposal)
- two-stage ethics review, with an ethics screening and, if necessary, an ethics assessment (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; *see Article 22*).

For more guidance on ethics, *see How to complete your ethics self-assessment, Research involving dual use items, Research focusing exclusively on civil applications, Potential misuse of research results and more generally, the Participant Portal Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State.

The beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that the research results cannot peripherally be useful in a military context. Research related to *dual-use* products or technologies (usually used for civilian purposes but with possible military applications) is not prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

In order to ensure the necessary level of research integrity, the beneficiaries must follow principles listed in this Article and ensure that the persons carrying out research tasks comply with the European Code of Conduct for Research Integrity[51] (i.e. follow the good research practices listed in this Code and refrain from any research integrity violations it describes).

Fundamental research integrity principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources

[51] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment
- **accountability** for the research from the idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

The Code constitutes a general reference framework and takes into account the legitimate interests of the beneficiaries (i.e. regarding IPRs and data sharing).

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply. In addition, beneficiaries should rely on local, national or discipline-specific guidelines, if such documents exist and are not contrary to the Code.

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define **ethics requirements** and include them as **deliverables** in Annex 1 of the GA.

Examples (ethics issues): *involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results*.

Examples (ethics deliverables): *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

Examples (other ethics requirements): *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

Best practice: When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18).*

The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

If the documents are not in English, the beneficiary may be asked to provide an English summary.

This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.

Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

The Commission/Agency may carry out **ethics checks, reviews or audits**, to ensure that the beneficiaries have properly implemented the ethics requirements and obtained the opinions/notifications/authorisations *(see Article 22)*.

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

Activities that involve human embryos (hE) or human embryonic stem cells (hESC) can only be funded, if:

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[52] (in particular, do NOT result in the destruction of human embryos)

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

[52] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

ARTICLE 35 — CONFLICT OF INTERESTS

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Conflicts of interests

The beneficiaries must ensure that the action is implemented impartially and objectively, as described in the GA. They must do their best to avoid conflicts of interest.

A ‘conflict of interests’ exists if **shared interests**:

- influenced the contract’s/subcontract’s selection/award procedure
- influenced the contract’s/subcontract’s price and this does not correspond to the market price or
- affected the action’s performance, as measured by the appropriate quality standards.

These interests may be:

- **economic interests** *(e.g. unjustified and preferential contracts or subcontracts with connected companies (not based on best value for money, technical merit, etc.))*

  Examples:

  1. *A beneficiary subcontracts work to another legal entity at above the market prices because it is a shareholder or has economic interests in this other legal entity.*

  2. *A university subcontracts work to a consultancy firm owned by a professor carrying out part of the work for the project in which the university participates.*

  3. *A university gives a preferential subcontract to its spin-off company: the contract is not based on the best value for money principle (i.e. the price is higher than the general market price for the same type of service).*

- **political or national affinity** *(e.g. beneficiaries or third parties are chosen, or research-related decisions are adopted, based on political considerations, connections or national affinity)*

Example: *The choice of an action's demonstration site is based on national affinities, not on the site's merits*.

- **family or emotional ties** *(e.g. contracts or subcontracts made with family members for their benefit)*

  Example: *A husband works for a beneficiary who subcontracts work to an SME owned by his wife.*

- **other shared interests**.

  Examples:

  1. *If a beneficiary or third party participates in the action not because of its technical capacity and objective merits, but because it has a close relationship with someone else working for the action, and this affects the action's implementation.*

  2. *If decisions made in the context of the action are taken not according to objective and impartial criteria, but because of these shared interests.*

  3. *If entities with close ties create a professional relationship with the intention of being part of the action in order to satisfy other interests, and as a result, the quality of the implementation is (or is likely to be) compromised.*

If there is a **(risk of) a conflict of interests**, the coordinator must **inform** the Commission/Agency (via the Participant Portal), so that steps can be taken to resolve or avoid it.

This may result in the Commission/Agency putting in place certain measures.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013, p.81).

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidentiality

The beneficiaries (and also the Commission/Agency) must — during the action and for four years afterwards — keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

This is a **minimum obligation**: Beneficiaries may extend the period and agree to additional confidentiality-related obligations among themselves *(for example, for access rights or third parties involved in the action)*.

Best practice: Beneficiaries should inform each other (and the Commission/Agency) about any laws that require disclosing confidential information (and to work together to minimise any negative effects).

A beneficiary may ask the Commission/Agency to extend the period. This request must explain why and clearly identify the confidential information.

Security obligations — Stricter confidentiality obligations apply for information that is **EU-classified** or results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the handling of classified information in EU research projects and, more generally, the Participant Portal Online Manual*.

The Commission/Agency will exchange confidential information with the European Court of Auditors (ECA), the European Anti-Fraud Office (OLAF) and other Agencies and H2020 funding bodies, to check double funding, pursue fraud and avoid plagiarism. (This is part of safeguarding the EU financial interests).

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2: *Not applicable**]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[51] — until it is declassified.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].**[OPTION 2:*** *Not applicable.**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable.**]***

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

1. Results with a security recommendation — EU-classified information

If the GA provides for (one of) these options, the beneficiaries must comply with the **security obligations** set out in this Article, in Annex 1 and in the other provisions of the GA *(see Articles 13 and 19)*.

The options will be inserted if the Commission/Agency finds during the selection procedure (security scrutiny) that the action raises security issues and must be subject to a security recommendation and/or EU-classification under Decision No 2015/444[53].

For more guidance on security obligations, *see the Guidelines for the classification of information in research projects, Potential misuse of research results and, more generally, the Participant Portal Online Manual.*

2. Activities involving dual-use goods

Beneficiaries that carry out activities involving dual-use goods must comply with applicable EU, national and international law, and in particular Regulation No 428/2009[54].

Moreover, the coordinator must — before the start of the activity for which it is needed — submit a **copy** of any **export** or **transfer licence**.

For more guidance on dual use goods, *see How to complete your ethics self-assessment* and *Research involving dual use items.*

[53] Commission Decision 2015/444/EC,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53).

[54] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1).

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION – VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and] Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is] [are]* not responsible for any use that may be made of the information it contains.

1. Communication activities (consortium) — Promoting the action and its results

The beneficiaries must promote the action and its result, with a **comprehensive communication plan** that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities (including a description and timing for each activity — throughout the action duration).

'Promoting the action' means providing targeted information to multiple audiences (including the media and the public), in a strategic and effective manner and possibly engaging in a two-way exchange

The beneficiaries are free to choose the type of communication activities[55].

Examples: *a press release for the general public at the start of the action; an interview in the local radio station after a major achievement of the action; an event in a shopping mall that shows how the outcomes of the action are relevant to our everyday lives; organising local workshops about the action, targeted at audiences for which the action is of interest; producing a brochure to explain the action's work to school or university students to show how interesting this specific research topic can be.*

The activities must however:

- be effective (i.e. suited to achieving the action's communication goals)
- be proportionate to the scale of the action *(e.g. activities carried out by a large-scale action with beneficiaries coming from several different countries and a large budget must be more ambitious than those of a beneficiary in a mono-beneficiary grant)*
- address audiences that go beyond the action's own community (including the media and the public).

Ad hoc efforts or mere dissemination of results are NOT sufficient. (Dissemination of results *(see Article 29)* cannot replace communication activities (or vice-versa); both provisions must be complied with.)

Moreover, the activities must make the research activities known to **multiple audiences** (in a way that they can be understood by non-specialists) and include the public policy perspective of EU research and innovation funding, by addressing aspects such as:

- transnational cooperation in a European consortium (i.e. how working together has allowed to achieve more than otherwise possible)
- scientific excellence
- contributing to competitiveness and to solving societal challenges
- impact on everyday lives *(e.g. creation of jobs, development of new technologies, better quality products, more convenience, improved life-style, etc.)*
- better use of results and spill-over to policy-makers, industry and the scientific community.

Any communication activity that is expected to have a **major media impact** (i.e. media coverage *(online and printed press, broadcast media, social media, etc.)* that will go beyond having a local impact and which could have the potential for national and international outreach) must be first **notified** to the Commission/Agency.

⚠ **Security obligations —** Information given may NOT include **EU-classified information** or information on results that are subject to **limited disclosure/dissemination** in Annex 1 of the GA *(see Article 37)*.

For more guidance on security obligations, *see the Guidelines for the classification of information in research projects and, more generally, the Participant Portal Online Manual.*

[55] For the definition of 'communication activities', *see the Glossary.*

The communication activities during the action must already be part of the proposal (either as a specific work package for communication or by including them in another work package; *see the H2020 proposal templates*) and be included in Annex 1 and 2.

For guidance on promoting the action, *see the Social media guide for EU funded R&I actions and the Participant Portal Online Manual.*

2. Visibility of EU funding

The beneficiaries must — during the action and afterwards — ensure the visibility of EU funding for any communication activity related to the action (including in electronic form, via social media, etc.) and on any infrastructure, equipment or major result (including prototypes) funded by the grant, by:

- displaying the **EU emblem**

AND

- including the **reference to EU funding** set out in the GA.

Best practice: Where possible, beneficiaries should make this reference in the language of the communication activity or, for infrastructure, equipment or major results, the official language(s) of the country where they are located (using the text of the GA language version available on Participant Portal Reference Documents).

The EU emblem and reference to EU funding must be displayed in a way that is easily visible for the public and with sufficient prominence (taking also into account the nature of the activity or object).

Examples: *a sticker or poster for equipment and major results, a plaque or billboard for infrastructure.*

For guidance on using the EU emblem, *see the Guide to using the EU emblem.*

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency; the]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of *[the Agency or]* the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency and the]* Commission will insert the following information:

> "© — [year] — [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the measures described in Chapter 6.

1. Communication activities (EU)

The Commission/Agency may use (free of charge) any (non-confidential and non-classified) information, documents and materials received from the beneficiaries, for its own communication and publicising activities.

> ***Examples (material):*** *summaries for publication (submitted as part of the reports), public deliverables and any other material, such as pictures or audio-visual material, provided by beneficiaries*
>
> ***Examples (communication activities):*** *using a picture or the publishable summary included in the final report submitted by the action to write a story about a particularly successful action for a Commission publication (e.g. Horizon - The EU Research & Innovation Magazine), or for speeches, etc.*
>
> ***Examples (publicising activities):*** *providing on an Commission/Agency website general information about the action such as its name, a project summary, the participating partners, the EU funding, etc.*

If the use would risk compromising legitimate interests, the beneficiary may request that the material is not used. This request must explain why and include the information, documents or material concerned.

If the Commission/Agency needs to edit or redraft the material, it will be careful not to distort any content.

Beneficiaries may ask the Commission/Agency to include a copyright notice *(e.g. by including such a notice in the material)*.

The beneficiaries must ensure that the Commission/Agency can use the documents or materials by making **arrangements** with any **third parties** that could claim rights to them.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the] Commission*

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the **'data controller'** of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have **recourse** at any time to the **European Data Protection Supervisor (EDPS)**.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

1. Processing of personal data (EU)

The Commission/Agency will process personal data in compliance with Regulation No 45/2001 and as set out in its Participant Portal privacy statements.

Personal data will be processed only for the purpose of implementing, managing and monitoring the GA or protecting EU/Euratom financial interests (including controls on eligibility of costs, proper implementation of the action and compliance with other obligations).

The level of detail of the data requested will be determined case-by-case and will be limited to what is necessary (for implementing, managing, monitoring and controlling the GA or protecting the EU financial interests).

When the Commission/Agency collects and processes personal data under the GA, national data protection law is NOT applicable and will NOT be accepted as a pretext for not complying with obligations under the GA.

Disclosure of staff data under the GA *(e.g. data requested by the Commission/Agency project officer or auditors)* is automatically justified under Article 5(c) of Regulation 45/2001.

The processing of personal data under the GA (manual or electronic) will be first **notified** (by the data controller) to the Commission/Agency Data Protection Officer (DPO).

The notifications are available via the Register of the DPO[56] (and describe the processing operations, legal basis, security safeguards, retention period, possible data transfer, etc.).

In addition, for processing that implies specific risks to the rights and freedoms of the data subjects (*e.g. processing of data relating to health*), the European Data Protection Supervisor (EDPS) will be consulted.

2. Right to access and correct personal data

Persons whose data is being processed (data subjects) can contact the data controller or the DPO (via the contact information in the privacy statement), to:

- correct errors in the data, block access or delete their data
- complain about the data collection and use, and claim compensation for any damage.

3. Complaints to the EDPS

Persons whose data is being processed by the Commission/Agency can lodge a complaint with the European Data Protection Supervisor (EDPS) (i.e. the independent supervisory authority for data processing by EU institutions).

Best practice: The beneficiaries should first contact the data controller (via the contact information in the privacy statement), since s/he might be able to solve the problem quickly.

[56] Available at http://ec.europa.eu/dpo-register/search.htm.

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the] Commission]*. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Processing of personal data (consortium)

The beneficiaries must process personal data under the GA in accordance with EU and national law on data protection (in particular, Directive 95/46/EC[57] and the corresponding national law).

⚠ The Directive is currently under revision. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

'**Personal data**' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of Directive 95/46/EC).

Examples (personal data): *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are considered NOT 'identifiable', if identifying them requires excessive effort.

Certain categories of data are more 'sensitive' than others, and these may only be processed according to specific rules. [58]

Examples (sensitive data): *racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, sexual orientation, etc*.

'**Processing of personal data'** means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection
- recording
- organisation and storage

[57] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[58] *See Article 8 of Directive 95/46/EC*.

- adaptation or alteration
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available
- alignment or combination
- blocking, deleting or destruction.

Examples (processing of personal data): *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

Under these laws, personal data must be processed according to certain principles and conditions that aim to ensure **data quality** and **confidentiality**.[59]

The beneficiaries must give their staff access to the personal data ONLY on a **need to know** basis, for carrying out their functions under the GA. This means that the beneficiaries must put in place adequate access controls and retention policies for the various categories of data they hold.

The beneficiaries must **inform their staff** (whose personal data are collected and processed by the Commission/Agency) about the disclosure of their data to the Commission/Agency (by providing them with the relevant Participant Portal privacy statement).

Examples:

1. *Before encoding staff data in the Participant Register or into a proposal, the beneficiary must provide the staff concerned with the privacy statement.*

2. *If in an ex-post audit, the Commission requests the names, CVs, time-sheets and salaries of the beneficiary's staff (to check the eligibility of personnel costs), the beneficiary must inform the staff concerned and provide them with the privacy statement.*

Processing of personal data is also part of the ethics obligations *(see Article 34).* Both provisions must be complied with.

[59] *See Articles 6, 16, 17 of Directive 95/46/EC.*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

1. Assignment of claims for payment

What? The beneficiaries may assign (i.e. transfer, sell or give) claims for payment (for work carried out under the action) to a third party, if the Commission/Agency has explicitly agreed in writing.

⚠ Assignments of rights under this Article are limited to ***claims for payment*** under Article 21. Transfers of other rights or obligations *(e.g. replacement of a beneficiary by the entity that bought it)* are governed by other provisions *(e.g. amendments; see Article 55)*.

⚠ Assignment has NO effect on the beneficiary's obligations under the GA; it remains **fully bound** by them.

Only *actual* (i.e. existing) claims for payment may be assigned (including pre-financing). Assignment is NOT possible for future claims.

How? Assignment of payment claims must be **requested**.

The request for approval must come from the coordinator, on behalf of the beneficiary concerned. It must be in writing and must explain the reasons for the assignment.

The Commission/Agency will assess the reasons given and approve or reject the request in writing.

Examples (reasonable requests for assignment):

1. *Assignment of a claim for payment for work carried out by a research laboratory sold after the end of the action (but before payment of the balance) by a beneficiary to another legal entity.*

2. *Assignment for the benefit of creditors in a bankruptcy procedure.*

If the assignment is linked to bankruptcy, the approval will be subject to compliance with national law.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— *RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES*] [— *RELATIONSHIP WITH PARTNERS OF A JOINT ACTION*]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES [— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

MONO-BENEFICIARY: ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

[OPTION to be used when the beneficiary is an European Research Infrastructure Consortium (ERIC)*[54] *without own resources: *As an exception, the beneficiary delegates the tasks set out above to [insert name of member of the ERIC]. The beneficiary retains sole responsibility for compliance with the obligations under the Agreement.]*

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The beneficiaries have full responsibility for **implementing the action** *(see Article 7)* and for **complying with the GA**.

This means that:

- each beneficiary must ensure that it complies with its obligations under the GA
- each beneficiary must ensure swift and proper implementation of the action (i.e. that there are no delays which can be attributed to it)
- each beneficiary is responsible (towards the Commission/Agency) for the tasks performed by its subcontractors and linked third parties
- the Commission/Agency is NOT responsible for the implementation of the action and has NO responsibility for the way in which the action is conducted (or any adverse consequences).

The beneficiaries are **jointly and severally liable for** the **technical implementation** of the action.

This means that the beneficiaries — including any new beneficiary introduced through an amendment — accept that they are together responsible for fully implementing the whole action — even if one of them withdraws.

If one of them **withdraws**, the remaining members of the consortium must carry out the action as set out in the GA — including the part that the defaulting beneficiary was supposed to carry out — unless the Commission/Agency expressly agrees otherwise (exceptional; only for specific reasons). They will have to do this without any additional funding (although — in case of beneficiary termination — the Guarantee Fund may intervene for the defaulting beneficiary; *see Article 50*).

> ***Example:*** *Legal entities A, B and C are members of a consortium that signed a GA with the Commission in order to carry out a research action. One year later, beneficiary C goes bankrupt. Beneficiaries A and B (or even only A or B) must carry out the entire action as described in Annex 1.*

The remaining beneficiaries may later take legal action against the defaulting beneficiary, in order to obtain compensation.

Moreover, the GA will have to be amended, in order to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary *(see Article 50)*.

In case of recovery, each beneficiary's **financial responsibility** is in principle limited to its own debt and undue amounts paid for costs declared by its linked third parties. It is only for the 5% contribution to the Guarantee Fund that financial responsibility is shared; *see Article 21.4*).

Specific cases (beneficiaries' responsibilities):

ERIC (European Research Infrastructure Consortium)[60]: If the beneficiary is an ERIC which does not have its own resources, it may exceptionally delegate the following responsibilities to one of its members:

- monitor that the action is implemented properly *(see Article 7)*
- inform about events or circumstances likely to affect significantly or delay the action

[60] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1).

implementation *(see Article 17.2)*
- submit deliverables and reports *(see Articles 19 and 20)*
- submit documents or information required

⚠ An ERIC using one of its members remains **fully responsible** for it under the GA.

MULTI-BENEFICIARY:

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the] Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and coordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION 1 for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.****]***

[OPTION 2: *Not applicable****]***

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

MONO-BENEFICIARY:

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[...]

41.5 Relationship with partners of a joint action — Coordination agreement

[…]

1. Division of roles and responsibilities — Roles and responsibilities within the consortium

The general division of roles and responsibilities within the consortium is as follows:

- the coordinator must coordinate and manage the grant and is the central contact point for the Commission/Agency
- the beneficiaries must all together contribute to a smooth and successful implementation of the grant (i.e. contribute to the proper implementation of the action, comply with their own obligations under the GA and support the coordinator in his obligations).

The beneficiaries must send all documents/information **via the coordinator** — unless, for specific cases, the Commission/Agency requests them to provide such information directly *(see Article 22)*.

Example:

In case of an audit, the beneficiaries must submit the documents requested directly to the auditors, if requested so.

2. The coordinator's roles and responsibilities

The coordinator is the **central contact point** for the Commission/Agency and represents the consortium (towards the Commission/Agency).

For this purpose, the GA imposes a number of specific coordination tasks.

Main coordination tasks:

- Monitor that the action is implemented properly
- Act as the intermediary for all communications — unless the Agreement specifies otherwise
- Request and review any documents or information required and verify their completeness and correctness

  The coordinator must check the quality of the documents submitted by the beneficiaries, including:

  - reviewing the individual financial statements from each beneficiary to verify consistency with the action tasks, as well as their completeness and correctness *(e.g. that the addition of the different costs declared by the beneficiary corresponds to the total amount declared, or that the 25% flat-rate for indirect costs is correctly calculated)*

    The coordinator is not, however, obliged to verify the *eligibility* of these costs (under Article 6) or to request justifications. Each beneficiary remains responsible for the cost it declares (both as regards eligibility and as regards sufficient records and supporting documents to substantiate them).
  - verifying that all the requested documents are submitted by the beneficiary *(e.g. the summary, the questionnaire etc.)*
  - verifying that the beneficiary submits the documents in the requested format
  - verifying that the technical information submitted by a beneficiary concerns its action tasks as described in Annex 1 (and not something unrelated to the action).
- Submit the deliverables and reports
- Distribute payments to the other beneficiaries, without unjustified delay
- Inform the Commission/Agency of the amounts paid to each beneficiary, if requested to do so *(see Article 44.1.2)*

The coordination tasks listed in Article 41.2 can normally NOT be subcontracted or outsourced to a third party (including linked third parties). They can NOT be carried out by other beneficiaries. (By contrast, the coordinator remains free — like any other beneficiary — to subcontract or use linked third parties for *other* tasks; *see Articles 13, 14*).

Specific cases (coordinator's responsibilities):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- they must have been granted the 'authorisation to administer'

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs (and those must include receiving and administering EU funds).

⚠ **Project management —** Coordination and administration tasks are considered **action tasks**.

⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

The costs of the entity may be declared by the coordinator as in-kind contributions (free of charge or against payment; *see Articles 6, 11 and 12*).

ERICs (European Research Infrastructure Consortia)[61] — Beneficiaries that are ERICs and do not have their own resources may exceptionally delegate the following coordination tasks to one of its members:

- monitor that the action is implemented properly *(see Article 7)*;
- act as intermediary for communications *(see Article 17)*;
- request and review documents or information required and verify completeness and correctness;
- submit deliverables and reports *(see Articles 19 and 20)*;

⚠ ERICs using one of their members remain **fully responsible** for it under the GA.

Scientific coordinator — Non-administrative coordination tasks (i.e. tasks not listed in this Article, *e.g. scientific coordination of the action*) can be carried out by any beneficiary.

Such a beneficiary may internally (i.e. within the consortium) be called 'scientific coordinator'. In the relationship with the Commission/Agency, it will however NOT be considered the action's coordinator (but one of the other beneficiaries).

Costs for scientific coordination can be eligible, if they comply with the eligibility conditions set out in Article 6.

3. Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must conclude a consortium agreement to ensure a smooth and successful project implementation — unless exceptionally provided otherwise in the work programme/call.

> **Best practice:** In view of their importance for avoiding disputes and ensuring a smooth implementation of the grant, the Commission/Agencies strongly recommend that every consortium sets up a consortium agreement, even if not mandatory.

The 'consortium agreement' is an agreement between members of the consortium, to set out their internal arrangements for implementing the grant. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (nor for any adverse consequences).

[61] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (OJ L 206, 08.08.2009, p.1)

The consortium agreement should **complement** the GA and must NOT contain any provision contrary to it (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

The consortium agreement should in principle be negotiated and concluded **before the signature of the GA** (i.e. each beneficiary should sign the consortium agreement before acceding to the GA). Otherwise, there is usually a serious risk that prolonged disagreement jeopardises the action. Of course, the consortium agreement does not have to remain the same during the lifetime of the action, it can be modified by the consortium at any moment.

The consortium agreement must be **in writing**. It may be a simple written agreement or take some other form *(e.g. a notarial deed or part of the statutes of a separate legal entity, such as a European Economic Interest Grouping, association or joint venture).*

> **Best practice:** The beneficiaries should carefully consider the advantages and disadvantages of the different legal forms, and choose the one that best fits the consortium's specific needs.

For guidance on consortium agreements, *see How to draw up your consortium agreement and the Participant Portal Online Manual*.

4. Relationship with complementary beneficiaries — Collaboration agreement

If the GA provides for this option, the beneficiaries must conclude a collaboration agreement to ensure a smooth and successful project implementation.

The option will be inserted ONLY for complementary actions *(see Article 2)*.

A 'collaboration agreement' is an agreement between the consortium and the beneficiaries of another complementary H2020 grant, to coordinate their work under the different GAs. It is purely internal; the EU/Euratom is not party and has NO responsibility for them (nor for any adverse consequences).

The beneficiaries of complementary grants must — through the collaboration agreement — create and participate in common boards and advisory structures, to decide on collaboration and synchronisation of the activities. These boards and advisory structures complement the governance of the project; they do not replace the consortium and other project governance mechanisms (if any).

5. Relationship with participants of a joint action — Coordination agreement

If the GA provides for this option, the beneficiaries must conclude a coordination agreement, to ensure a smooth and successful project implementation.

The option will be inserted ONLY for jointly funded actions *(see Article 2)*.

A 'coordination agreement' is an agreement between the consortium and the participants of the third country/international organisation (IO) action *(see Article 2)*. It is purely internal; the EU/Euratom is not party and has NO responsibility for it (or for any adverse consequences).

The coordination agreement should **complement** the GA and must NOT contain any provision contrary to them (or to the Rules for Participation Regulation No 1290/2013 or the Financial Regulation No 966/2012).

Moreover, it must be in line with the consortium agreement. It can NOT replace the consortium agreement (and vice versa).The coordination agreement should in principle be negotiated and concluded **before any work is begun**. The work programme/call may require that proposals include a draft coordination agreement.

The coordination agreement can take **various forms**, but a standard written agreement is most common.

For guidance on coordination agreements, *see How to draw up your coordination agreement and the Participant Portal Online Manual.*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the time of an interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Cost rejection

If the Commission/Agency finds **ineligible costs** *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)*, it will reject these costs (— in full, i.e. for the amount that is ineligible).

Cost rejections will be made for **violations of cost eligibility rules** (*see Articles 6, 8-16*) and will correspond to the amount that is ineligible.

Grounds for cost rejection (EU):

- **Costs** do **not comply with** the GA **eligibility rules (in this grant)**

  The Commission/Agency will reject costs, if they do not comply with the eligibility rules set out in Articles 6 and 8-16.

- **Costs** do **not comply with** the GA **eligibility rules (in other grants)**

  The Commission/Agency may also reject costs, if such ineligibility was found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the ineligibility is:
    - systemic or recurrent and
    - has a material impact on this grant.

Rejection of costs can take place at any moment — at the time of beneficiary termination, interim payment, payment of the balance or afterwards.

2. Procedure

The procedure differs according to the situation:

- if cost rejection leads to a recovery: there will be an *ex ante* **contradictory procedure**
- if cost rejection does NOT lead to a recovery: there will be NO *ex ante* contradictory procedure, but the possibility to object *ex post* to the rejection (**payment review procedure**).

In both cases, the Commission/Agency will explain which costs were rejected and why they were rejected. In both cases, beneficiaries can object and bring forward their arguments for disagreeing. The switch to the ex post payment review procedure allows the

Commission/Agency however to pay quickly without having to suspend the payment deadline (by postponing the discussion on the disputed costs).

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Payment review procedure:

Step 1 — The Commission/Agency informs the coordinator about the rejection of costs and notifies the amounts that will be paid out (**notification of amounts due**; *see Article 21.5)*.

Step 2 — If the beneficiaries disagree, the coordinator/beneficiary concerned has **30 days** to inform the Commission/Agency of its objections.

Step 3 — The Commission/Agency analyses the request for review and **informs** the coordinator of its **outcome**.

Depending on the moment when costs are rejected, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

- for rejections at the time of an interim payment or the payment of the balance: normally the coordinator
- for rejections after beneficiary termination and after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for its comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

If the Commission/Agency rejects costs at **beneficiary termination**, it will deduct the rejected amount from the costs the beneficiary declared in the termination report and calculate the amount due to the beneficiary. If the amount is lower than the (pre-financing and interim) payments received by the beneficiary, the Commission/Agency will recover the difference *(see Articles 44 and 50)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

If the Commission/Agency rejects costs at the moment of an **interim payment** or the **payment of the balance**, it will deduct them and calculate the amount to be paid accordingly *(see Articles 5.3 and 21)*.

If ineligible costs are found **in-between payments**, the Commission/Agency will reject them at the next payment (i.e. deduct the amount rejected from the costs declared in the next financial statement and calculate the amount to be paid accordingly; *see Article 21*).

If the Commission/Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the costs accepted for the beneficiary at the payment of the balance and calculate a **revised grant amount**. If the revised grant amount is lower than its share of the final grant amount, the Commission/Agency will **recover** the difference *(see Articles 5.4 and Article 44)*.

The detailed calculations for all cases are described in Article 21.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the time of the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* **redu**ces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Grant reduction

If the Commission/Agency finds *(in particular following a check, audit, extension of audit findings, review or OLAF investigation)* **substantial errors, irregularities or fraud** or **breach of obligations** under the GA or during the award procedure *(e.g. the action has not been properly implemented)*, it may reduce the grant in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations.

⚠ **Grant reductions** will be made (at beneficiary termination, at the end of the action or after the payment of the balance) for substantial errors, irregularities or fraud or serious breach of obligations, in proportion to the seriousness of the error, irregularity, fraud or breach *(e.g. in case of fraud the reduction may be up to a 100%)*.

⚠ If the issues are found before the end of the action, the beneficiaries must take all possible corrective steps to bring the action implementation back into line with the GA.

Grounds for grant reduction (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may make a grant reduction if a beneficiary has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Serious breach of obligations covers all kinds of non-compliance with GA obligations (including obligations during the award procedure).

  Example: *false declarations in the proposal form, in order to obtain EU funding*

  In practice, the most frequent breach is improper implementation of the action/non-compliance with Annex 1 GA (i.e. if the work performed does not correspond to the activities described in Annex 1). This will normally be examined on the basis of the periodic and final technical reports and, if needed, a project review.

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also make a grant reduction, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if:

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

3.0 Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol[62]).

Grant reduction can take place:

- at beneficiary termination
- at the payment of the balance or

[62] See judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128.

– after the payment of the balance.

3.0 Reduction at beneficiary termination was introduced explicitly with GA version 3.0. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination is possible for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 *(see above)*.

2. Procedure

The Commission/Agency will follow a **contradictory procedure.**

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)*.

Depending on the moment the reduction takes place, this procedure will be directed either at the **coordinator** or the **beneficiary concerned**:

– for reductions at beneficiary termination: normally with the beneficiary concerned

– for reductions at payment of the balance: normally the coordinator

– for reductions after payment of the balance: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must immediately inform the beneficiaries concerned offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments. It must also inform the other beneficiaries.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator in copy (in a way that preserves confidentiality).

⚠ **Information obligation** — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

3. Effects

If the Commission/Agency reduces the grant at **beneficiary termination**, it will calculate the reduction at beneficiary-level and calculate the amount due to the beneficiary. If the amount is lower than the (pre-financing and interim) payments received by the beneficiary, the beneficiary will have to pay back the difference *(see Articles 44 and 50)*.

Recovery at beneficiary termination during an ongoing action means that the beneficiary should pay back the amount to the *consortium*. If it doesn't, the Guarantee Fund will intervene and the Commission/Agency will then recover the amount for the Guarantee Fund.

If the Commission/Agency reduces the grant at the **payment of the balance**, it will calculate the reductions for each beneficiary and for the action (if any) and calculate the balance to be paid to the consortium (i.e. final grant amount) accordingly *(see Articles 5.3 and 21)*.

If the Commission/Agency reduces the grant **after the payment of the balance**, it will calculate the reduction for the beneficiary and compare the revised grant amount with its share of the final

grant amount. If the revised grant amount is lower, the Commission/Agency will recover the difference *(see Articles 5.4 and 44)*.

The detailed calculations for all cases are described in Article 21.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the **payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

MULTI-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action (see Article 57)** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the] Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION 2:** not applicable**];***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: 44.1.3 <u>Recovery of amounts after payment of the balance</u>

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[Commission][Agency*] will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the] Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION** 1 **if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:** if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**]** **[OPTION 2:** not applicable**]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the] Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies

MONO-BENEFICIARY: 44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

MONO-BENEFICIARY: 44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

[…]

MULTI-BENEFICIARY: 44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

[…]

1. Recovery of undue amounts

If it turns out that — due to early termination, cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings, review or OLAF investigation)* — the Commission/Agency has **paid too much**, it will recover the amount that is undue.

The Commission/Agency will **recover** the undue amounts from the beneficiary that owes the money (i.e. with a debt towards the Commission/Agency).

In case of recovery, each beneficiary's financial responsibility is normally limited to **its own debt** (including undue amounts paid for costs declared by **its linked third parties**, if any). Only the responsibility for the amount retained for the Guarantee Fund (i.e. the 5% withheld from the pre-financing; *see Article 21.4*) is shared.

If the Commission/Agency has requested **joint and several liability** of a **linked third party** *(see Article 14)*, it may recover also from the linked third party. The linked third party's financial responsibility (for the debt of the beneficiary) is limited to its maximum grant amount in Annex 2.

Grounds for recovery (EU):

- Commission/Agency **paid too much**

  The Commission/Agency will make a recovery, if the amounts paid out exceed the amounts that are due for the grant.

Recovery normally takes place only at **payment of the balance** or **afterwards**. Exceptionally, it can take place before, if a **beneficiary's participation is terminated**.

The Commission/Agency will recover after beneficiary termination if the beneficiary did not pay back to the coordinator the amounts it received in excess and — following this — the Guarantee Fund had to intervene *(see Article 50)*.

The Commission/Agency will recover at the payment of the balance if the sum of the pre-financing and the interim payments exceeds the final grant amount *(see Articles 5.3 and 21)*.

The Commission/Agency will recover after payment of the balance if — due to cost rejection or grant reduction *(in particular, following a check, audit, extension of audit findings or OLAF investigation)* — it finds out that it has paid in excess (or that the coordinator did not distribute the payments received; *see Article 5.4*).

The detailed calculations for all cases are described in *Article 21*.

2. Procedure

The basic procedure for recovery is almost always the same: After a **contradictory procedure**, the Commission/Agency claims repayment of the amounts and then enforces recovery.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it (**notification of amounts due**; *see Article 21.5)* and issues a debit note.

Enforced recovery:

If the coordinator/beneficiary concerned does not pay by the date set out in the debit note, the Commission or the Agency will **recover** the amount (with interest at the rate set out in Article 21.11), in one of the following ways:

- by **offsetting** it[63]

  'Offsetting' means to deduct the amount the debtor owes to the Commission/Agency from another amount that the Commission/Agency owes to debtor. With the offsetting both amounts are considered paid.

  ⚠ **Offsetting** is normally implemented as a **public law measure** (i.e. directly on the basis of Article 80(1) of the the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

  For the cases not covered by the Financial Regulation, offsetting will — exceptionally — be implemented as a purely **contractual measure** *(e.g. offsetting with Commission and Agency claims, offsetting against international organisations)*. In this case, the normal contractual means for dispute settlement apply (i.e. Article 272 TFEU action, arbitration, etc.; *see Article 57.2*).

  Normally, offsetting is carried out *after* the payment deadline has expired. However, in exceptional circumstances, the Commission or the Agency may offset before this date, in order to safeguard the EU financial interests.[64]

  If the offsetting takes place after the deadline for payment has expired, the interest must also be offset. The interest is normally offset first, before the principal amount.

- by drawing on the Guarantee Fund and then follow it with the **debit note on behalf of** the **Guarantee Fund** (to continue the recovery procedure):

  - if the Commission/Agency has requested joint and several liability from a linked third party: by **holding** the **linked third party liable**

  or

  - by either:

    - taking **legal action** in a national court or the European Court of Justice *(see Article 57.2)* or

    - adopting a **decision** that is **enforceable** within the meaning of Article 299 TFEU[65].[66]

      The decision describes the claim and its grounds, notes that the debtor has not paid (despite having been sent a debit note and reminders) and indicates the amount of the debt.

      ⚠ Enforceable decisions are **public law measures** (i.e. taken directly on the basis of Article 79(2) of the Financial Regulation No 966/2012). Therefore, the dispute settlement normally follows the public law remedies (i.e. Article 263 TFEU action; *see Article 57.2*).

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63 *See Article 80(1) of the Financial Regulation No 966/2012.*

64 *See Article 87 of the Rules of Application Regulation No 1268/2012.*

65 *See Article 299 TFEU:* Acts of the Council, the Commission or the European Central Bank which impose a pecuniary obligation on persons other than States, shall be enforceable. Enforcement shall be governed by the rules of civil procedure in force in the State in the territory of which it is carried out. The order for its enforcement shall be appended to the decision, without other formality than verification of the authenticity of the decision, by the national authority which the government of each Member State shall designate for this purpose and shall make known to the Commission and to the Court of Justice of the European Union. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority. Enforcement may be suspended only by a decision of the Court. However, the courts of the country concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

66 *See Article 79(2) of the Financial Regulation No 966/2012.*

This decision — duly endorsed with the order for enforcement issued by the competent authority in the Member State concerned — allows to have the debtor's **assets seized**.

The contradictory procedure will normally be **combined** with the **contradictory procedure** for cost rejection and/or grant reduction (if any).

Specific case (recoveries):

International organisations — Enforceable decisions under Article 299 TFEU (and other public law decisions) will NOT be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

Offsetting is — by contrast — a measure that may be taken in relation to international organisations, however NOT as public law measure (i.e. not on the basis of Article 80(1) of the Financial Regulation No 966/2012), but as a purely contractual measure (i.e. on the basis of Article 44 of the GA). Offsetting for international organisations will therefore be subject to the contractual means for dispute settlement (i.e. arbitration; *see Article 57.2*).

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

1. Administrative sanctions

If the Commission/Agency finds *(in particular, following a check, audit, review or OLAF investigation)* that a beneficiary is in an exclusion situation under Article 106(1) of the Financial Regulation No 966/2012, it may impose administrative sanctions (— in proportion to the seriousness of the misconduct).

Administrative sanctions (financial penalties and/or exclusion from future procurement contracts, grants and expert contracts) are **public law measures** (i.e. taken directly on the basis of Articles 106 and 131(4) of the Financial Regulation No 966/2012) that may be applied *in addition* to the contractual measures (i.e. cost rejection, grant reduction, recovery, suspension and termination), for **serious misconducts** *(substantial errors, irregularities or fraud, serious breach of obligations, bankruptcy, non-compliance with tax or social security obligations, grave professional misconduct, fraud, corruption, or criminal/illegal activity).*

Examples: *plagiarism; absence of time recording systems (although required); false declaration concerning SME status.*

The **maximum sanctions** are as follows:

- for exclusion: up to **5 years** from the date on which the Commission/Agency establishes the infringement, i.e. confirms the sanction and formally notifies this to the beneficiary.

  If, in that time, the beneficiary commits the same infringement again, the exclusion period may be extended to **10 years**.

- for financial penalties: between **2%** and **10%** of the maximum EU contribution to the beneficiary concerned according to the estimated budget (Annex 2) — depending on the seriousness of the infringement.

  If, within five years of the first infringement being established, the beneficiary commits the same infringement again, the rate may be increased to between **4%** and **20%**.

The decision to apply an administrative sanction may be **published** on the Commission/Agency websites (— together with the name of the person responsible for the misconduct, information on the misconduct and the duration of the exclusion and/or amount of the financial penalty).

When deciding on publishing this information or not, the Commission/Agency will take into account, in particular:

- the seriousness of the misconduct (including impact on the EU financial interest and image)
- the time that has elapsed since it took place
- the duration and recurrence of the misconduct

- the intention or degree of negligence and
- the measures taken by the beneficiary to remedy the situation.

2. Procedure

The Commission/Agency will follow the procedures set out in 106 of the Financial Regulation No 966/2012 (i.e. **contradictory procedure, panel, decision)**.

If the Commission/Agency imposes a financial penalty, it will also issue a debit note to **recover** the amount.

If the penalty is not paid by the date set out in the debit note, late-payment interest will be added to the amount to be recovered.

However, there is NO:

- intervention of the Guarantee Fund
- joint and several liability of linked third parties.

Specific case (administrative sanctions):

International organisations — Decisions on administrative sanctions (and other public law decisions) will not be taken against international organisations, where this would be contrary to the privileges and immunities accorded by their constituent documents or international law *(see Article 53.2)*.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

1. Liability for damages (EU)

The Commission/Agency can NOT be held liable if — in implementing the GA — its own services cause damage (to a beneficiary or third party).

Moreover, the Commission/Agency can NOT be held liable if — in implementing the GA — a beneficiary or third party involved in the action causes damage (to another beneficiary or third party).

Examples:

1. *An experiment carried out by a beneficiary leads to an accidental escape of pollutants into the local river.*

2. *A fire breaks out in a beneficiary's laboratory in the course of an experiment for the action.*

Subsidiary (secondary) liability is also excluded.

Non-liability extends to damages caused by third parties involved in the action (i.e. linked third parties, third parties providing in-kind contributions, subcontractors etc.; *see Article 8*).

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

1. Liability for damages (consortium)

If a beneficiary causes damage to the Commission/Agency (in implementing the action), the Commission/Agency may claim compensation).

Examples:

1. *Costs of legal proceedings borne by the Commission.*

2. *At a meeting on Commission premises, a beneficiary smokes and causes a fire.*

2. Procedure

The Commission/Agency will follow the normal procedure for damages claims (i.e. bringing an action for contractual damages before the European Court of Justice; not direct claim via a debit note).

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The Commission/Agency may stop the clock (suspend the deadline) if a payment request cannot be immediately approved, on the grounds listed in this Article.

Suspension of the payment deadline must be **distinguished** from **suspension of payments** *(see Article 48)*. Suspension of the payment deadline is an ad hoc measure regarding the request for payment. Suspension of payments is a measure to avoid making payments to a beneficiary which is, for example, suspected of serious misconducts.

Grounds for suspension of the payment deadline (EU):

- **Payment request** does **not comply with** the provisions of the **GA**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) do not fulfil the requirements set out in Article 20.

Examples: *the certificate on the financial statements does not comply with the template; inconsistencies in the technical report (meaning that the action cannot be assessed); the financial statement contains errors.*

- **Payment request** is **incomplete** or **requires clarification**

  The Commission/Agency may suspend the payment deadline, if the reports (or any of their documents) are incomplete or it needs additional information.

  Examples: *the reports, the certificate on the financial statement or other supporting documents are missing; the information in the periodic technical report is incomplete; additional information on the coordinator's new bank account is needed*

- **Doubts on the eligibility of costs** in the financial statements that require additional verifications

  The Commission/Agency may suspend the payment deadline, if it has doubts *(e.g. due to audit findings in other grants)* on the eligibility of the costs in the financial statements and additional checks, reviews, audits or investigations are needed.

  Example: *The costs claimed in the financial statements are not consistent with the action tasks described in the technical report.*

In practice, suspension is needed if there are issues with the payment request or with the costs declared which make it impossible for the Commission/Agency to comply with the **payment deadline** (i.e. for interim payments and payment of the balance: 90 days after payment request; *see Article 21*).

Suspension **starts** on the day the notification (announcing suspension) is sent to the coordinator (and **ends** on the day it is lifted).

Late payment without suspension of the payment deadline gives rise to late-payment interest for the beneficiaries *(see Article 21.11)*.

2. Procedure

The Commission/Agency will immediately formally notify the coordinator of the suspension of the payment deadline and explain the reasons why.

There is NO *ex ante* contradictory procedure. However, if the suspension exceeds **two months**, the coordinator may ask the Commission/Agency if the suspension is to be continued (i.e. ask to confirm it or lift it).

3. Effects

If the **issues** have been **resolved satisfactorily** *(e.g. the coordinator sent the requested information or re-submitted the report)* or the Commission/Agency has **finished** the necessary **verifications** *(e.g. an audit),* it will lift the suspension and formally notify the coordinator.

Suspension will normally last until it is possible to make all the necessary checks and verifications that are needed for the payment (*e.g. analysis of technical reports and financial statements, eligibility of claimed costs, calculation of amount to be paid, approval and authorisation of payment*).

With the lifting of the suspension, the remaining payment period starts to run again.

If a deadline has been suspended for several reasons, it will be lifted only when the consortium has satisfactorily addressed ALL the reasons.

ARTICLE 48 — SUSPENSION OF PAYMENTS

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

1. Suspension of payments (EU)

The Commission/Agency may suspend pre-financing, interim payments or the final payment (for one or more or for all beneficiaries), on the grounds listed in this Article.

⚠ **Suspension of payments** has NO impact on the action implementation. The consortium must continue to work on the action, while addressing the issues that have led to suspension of the payment; costs incurred during suspension of payments are in principle eligible.

Grounds for suspension of payments (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend payments, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend payments, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systemic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend all outstanding payments for the audited beneficiary until the issue is resolved.*

Suspension **starts** on the day the notification (confirming suspension) is sent to the coordinator (and **ends** on the day it is lifted).

If necessary, the consortium may also decide to:

- suspend the GA *(see Article 49)*
- terminate the GA or the participation of the beneficiary concerned *(see Article 50)*.

2. Procedure

Before suspending payments, the Commission/Agency will follow a **contradictory procedure**.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of suspension, this procedure will be directed either at the coordinator or the beneficiary concerned:

- suspension linked to the consortium: normally the coordinator
- suspension linked to a beneficiary *(e.g. simultaneous suspension of payments in several grants after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must make sure that the other members of the consortium are informed and ask for their comments.

If it is directed at the beneficiary, the Commission/Agency will inform the coordinator later on (in a way that preserves confidentiality).

> ⚠ **Information obligation** — Beneficiaries do not have to inform their coordinators or ask them to submit comments. However, they should inform them if there is the risk of a significant impact on the action *(see Article 17.2).*

3. Effects

During suspension, NO **individual financial statements** may be submitted for the beneficiary (or beneficiaries) concerned with the periodic reports (except with the report for the last reporting period).

Costs incurred (for continuing to implement the action during suspension) are eligible and may be included in the **next financial report**, after suspension has been lifted. They must be included in the periodic report for the last reporting period (— even if suspension is still ongoing).

Technical reports submitted during suspension must include the work of the beneficiaries concerned.

Example:

1 May:	*the Commission informs the coordinator of its intention to suspend interim payments for beneficiary B because an audit for other H2020 grants has detected systematic substantial errors in the calculation of its personnel costs.*
15 May:	*the coordinator comments that beneficiary B was not aware of its obligations in this respect.*
1 June:	*the Commission rejects the comments and confirms the suspension of payments for beneficiary B.*
1 July:	*the coordinator submits all reports except the individual financial statement for beneficiary B (covering an amount of EUR 75 000).*
10 August:	*the Commission pays for all beneficiaries except B.*
25 October:	*the Commission approves remedial measures taken by beneficiary B (correcting the substantial errors and submitting revised financial statements) and lifts the suspension. The costs of beneficiary B will be submitted in the next reporting period.*

If payments for one (or some) of the beneficiaries are still suspended at the end of the action, the Commission/Agency will make a partial payment of the balance for the amount that is not suspended (— but ONLY after having received all the necessary information for the final calculations for ALL consortium members, i.e. including the suspended beneficiaries).

> ⚠ The partial final payment is NOT the payment that closes the action. That payment will be made only after the payment suspensions are lifted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

1. GA suspension (consortium)

The beneficiaries may suspend the action (in full or in part), on the ground set out in this Article.

GA suspension may be used exceptionally if it is necessary to stop the action implementation, to fix specific problems. It should NOT be used in situations that cannot be resolved through a temporary interruption; in these cases, it may be better to terminate the GA *(see Article 50)*.

Ground for GA suspension (consortium):

- **Action can no longer be implemented (or becomes excessively difficult)**

  The beneficiaries may suspend the action (in full or in part), if implementation becomes impossible or excessively difficult.

  Example: *A fire devastates a beneficiary's laboratory, with most of the technical equipment and computers used for the action and containing the research results. The beneficiaries therefore request that the part of the action that is affected by this is suspended until the laboratory is restored.*

Suspension **starts** on the day the Commission/Agency receives the notification (and **ends** on the resumption date specified in the amendment after resumption).

⚠ **Information obligation** — Depending on the reasons for suspension, the beneficiaries may also have to take other measures under the GA *(e.g. **inform** the Commission/Agency under Article 17.2; **notify** a situation of force majeure under Article 51)*.

2. Procedure

The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal)

3. Effects

The beneficiaries must immediately take all the necessary steps to **limit the damage** and do their best to resume (i.e. continue) implementing the action as soon as possible.

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be incurred for the action, once action implementation is resumed.

If the **action can be continued** (resumed), the coordinator must notify it to the Commission/Agency by requesting an amendment to the GA.

The amendment must be requested in accordance with Article 55 *(e.g. it must be signed by the coordinator's LSIGN)*.

It sets the resumption date and adapts the grant to the new situation *(e.g. by extending the action duration, modifying Annexes 1 and 2, updating the reporting periods)*.

If the Commission/Agency approves the amendment, the suspension is lifted and will be resumed as from the **resumption date** set out in the amendment. The resumption date can be retroactive (i.e. back to the date when the problem stopped/issue was clarified).

Example: *The action was suspended on 24.03.2016 due to weather conditions. Once the conditions improve, the coordinator requests and amendment to lift the suspension (e.g. after 60 days, on 22.05.2016). Therefore, in accordance with Article 54 of the GA, the action will be resumed as from 23.05.2016.*

If the suspension is lifted and the action continues, the action's remaining budget can be used for action implementation. (Although it may be that the budget must be lowered in the amendment, to adapt the action to the new situation).

Example: *After the suspension, it is decided that not all the tasks described in Annex 1 will be implemented.*

If the **action** (or part of it) **can NOT be continued** (or the Commission/Agency does not approve the amendment; *see Article 55*), the GA (or the participation of one or more beneficiaries) may be terminated.

If the suspension leads to GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example: *The action starts on 1.1.2015 and is to last 36 months. The action's implementation is suspended for four months, from the date after the Commission is notified, 1.12.2015 to 31.3.2016 and the suspension leads to the GA termination. The eligible costs are:*

- *costs incurred from the action's start (1.1.2015) until the date of notification (30.11.2015)*
- *costs incurred for the submission of the first periodic report and the final report.*

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities, or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 <u>Procedure</u>

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the

Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (EU)

The Commission/Agency may suspend the action (in full or in part), on the grounds listed in this Article.

Grounds for GA suspension (EU):

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may suspend the action, if a beneficiary has committed or is suspected of having committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA

  Example: *false declarations in the proposal form, in order to obtain EU funding*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also suspend the action, if such substantial errors, irregularities or fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and
  - the substantial errors, irregularities or fraud or serious breach of obligations are:
    - systemic or recurrent and
    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that also affect all other GAs signed by the audited beneficiary. The Commission may suspend the audited beneficiary's part of the action until the issue is resolved.*

- **Loss of scientific or technological relevance**

  The Commission/Agency may suspend the action, if it needs time to assess whether the action has lost scientific or technological relevance.

  This may in particular be the case:

  - if a complete revision of Annex 1 is necessary to assess the impact of a request for amendment
  - if work has significantly deviated from the original work plan
  - if a key beneficiary leaves the action and the consortium needs time to find a replacement
  - after a check, audit or review of the action.

Example: *There are technical problems with implementing the work under an action as described in Annex 1, so the consortium proposes changes to the work to be carried out. This may jeopardise its technological relevance and the Commission decides to suspend its implementation and to carry out a review.*

Suspension **starts** 5 days after it is notified to the coordinator (or on a later date specified in the notification) and **ends** on the resumption date specified in the amendment signed by the Commission/Agency).

2. Procedure

Before suspending the GA, the Commission/Agency will follow a **contradictory procedure**.

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of suspension, this procedure will be directed either at the coordinator or the beneficiary concerned:

- suspension linked to the consortium: normally the coordinator
- suspension linked to a beneficiary *(e.g. simultaneous suspension of several grants after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must make sure that the other members of the consortium are informed and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform the coordinator later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If possible, the Commission/Agency will give an estimation of how long the suspension will be needed.

3. Effects

During suspension, **costs** incurred (for implementing the suspended part of the action) are NOT eligible *(see Article 6.5)*. Costs may again be declared for the action, once the action is resumed.

If the **action can be continued**, the Commission/Agency will lift the suspension and formally notify the coordinator (together with the suspension **end date**).

The suspension can be lifted retroactively (i.e. back to the date when the problem stopped/issue was clarified).

The coordinator must then request an amendment to the GA *(see Article 55)*, to set the **resumption date** in the tools and adapt the grant to the new situation *(e.g. by extending the action duration modifying Annexes 1 and 2, updating the reporting periods)*.

If the **action** (or part of it) **can NOT be continued**, the GA (or the beneficiary concerned) may be terminated.

If the suspension leads to the GA termination, NO further **costs** (incurred after the date of suspension) can be declared, except the costs for the reports *(see Article 6.1)*.

Example:

A key beneficiary is suspected of having declared as eligible personnel costs under the GA the costs of personnel employed by another company. The Commission suspends the implementation of the action in order to carry out checks. During that period of suspension, the beneficiary withdraws from the action. The consortium cannot find a replacement for this beneficiary and terminates the GA in accordance with Article 50.1.

The GA starts on 1.5.2015 and lasts 42 months.

The Commission suspends its implementation.

The coordinator confirms having received notification of the suspension on 18.3.2017.

The suspension takes effect on 23.3.2017.

On 23.6.2017, the consortium formally notifies the GA termination.

Only costs incurred from 1.5.2015 to 23.3.2017 and the costs of submitting the periodic report for the last reporting period and the final report are eligible.

The Commission will reject the ineligible personnel costs.

Ineligible **costs** will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'

The termination will **take effect** on the day specified in the notification**.**

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The beneficiaries have the right to terminate the GA.

GA termination should be a last-resort measure, if all efforts to continue the action fail.

If action implementation just becomes *temporarily* impossible or excessively difficult, it may be better not to terminate the GA, but to suspend it *(see Article 49)*. In this case, the GA would only be terminated if it turns out later that implementation cannot be resumed anymore.

Example: *A fire devastates a laboratory where most of the technical equipment and computers used in the action are stored. If the beneficiaries consider that the laboratory can be replaced and the action will still be correctly implemented, they may suspend implementation and resume it when the new laboratory is operational. However, if the action has been suspended and it is not possible to find a new laboratory and therefore it is impossible to resume the action, the beneficiaries may terminate the GA.*

Grounds for GA termination (consortium):

- **Any ground** that **justifies** early termination of the action

  The beneficiaries may terminate the GA in principle on any ground — as long as there is a good reason *(e.g. circumstances make its implementation impossible or excessively difficult; loss of the action's scientific or technological relevance; force majeure)*.

  Examples:

  1. *The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable.*

  2*. The consortium requests termination because the action was finished ahead of schedule.*

  If there are no legitimate reasons for discontinuing the action, the Commission/Agency **can NOT oppose**, but termination will be considered **improper**.

  ⚠ **Improper termination** of the GA may lead to a grant reduction (see *(see Articles 5.3 and 43)*.

  This will be the case, for instance, if:

  - the implementation of the action has become impossible or excessively difficult due to the beneficiaries' wilful misconduct or gross negligence
  - the reasons provided are based on changes in the strategic choices of the beneficiaries, not linked to any specific economic or operational difficulties
  - implementation would have been possible if the beneficiaries had made more (but still reasonable) efforts.

  Example: *The beneficiaries decide to terminate the GA due to internal communication and decision-making problems within the consortium, and notify the Commission via the coordinator. The Commission considers that these internal problems have jeopardised the action's implementation, but do not justify terminating the GA because they could have been solved within the consortium on the basis of the consortium agreement. This improper termination may lead to a grant reduction.*

2. Procedure

The coordinator must **formally notify** the Commission/Agency (via the Participant Portal) of the termination — on behalf of the other beneficiaries.

Best practice: Beneficiaries should contact the Commission/Agency beforehand, to discuss the termination.

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

The coordinator must — within 60 days — **submit** the necessary **reports** (i.e. a periodic report for the open reporting period until termination and the final report).

The Commission/Agency will **calculate** the **final grant amount** and the **payment of the balance** *(see Articles 5.3 and 21.4)*.

If the total amount of earlier payments (pre-financing payment and interim payments, if any) received before termination:

- is greater than the final grant amount, the balance is negative and will take the form of a recovery *(see Article 21.4 and 44.1.2)*.
- is lower than the final grant amount, the Commission/Agency will pay the balance *(see Article 21.4)*.

Only **costs** incurred *before* termination (i.e. generating event before the termination date; *see Article 6.1(a)*) are eligible — except for the:

- costs for the reports *(see Article 6.1)*

  Example: *The action's duration is 36 months. The starting date is 1.1.2016. The notified termination date is 1.5.2017. Therefore, only costs incurred in connection with the action from 1.1.2016 to 1.5.2017 (16 months) and the costs related to submission of the periodic report for the last reporting period and the final report are eligible*

- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

  Example: *One of the beneficiaries of the GA has a contract to carry out 8 tests during the action's duration. However, only three tests out of 8 are carried out before the GA is terminated. Therefore, only the costs related to these 3 tests carried out before termination may be eligible for the action.*

If the coordinator fails to submit the reports (within the 60 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the final grant amount is calculated. The Commission/Agency will NOT send a reminder and will NOT extend the deadline.

The detailed calculations are described in Article 21.

Termination has NO effect on the **provisions** that normally **continue to apply** after the end of the action.

Obligations that continue to apply after the GA is terminated:

- Keeping records and other supporting documentation *(Article 18.1)*
- Submitting the periodic report (for the open reporting period until termination) and the final report *(see Article 50.1.1 and 20)*
- Providing requested information and allow access to their sites and premises (for checks, reviews, audits, investigations or evaluations of the action's impact; *see Articles 22 and 23)*
- Complying with the rules on management of intellectual property, background and results *(see Section 3 of Chapter 4 of the GA)*
- Maintaining confidentiality *(see Article 36)*
- Complying with the security obligations (if applicable) *(see Article 37)*
- Promoting the action and giving visibility to the EU funding *(see Article 38)*
- No assignment of claims for payment *(see Article 40)*
- Chapter 6 measures (i.e. rejection of costs *(see Article 42)*, grant reduction *(see Article 43)*, recovery *(see Article 44)*.

MULTI-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

1. Beneficiary termination (consortium)

The beneficiaries may terminate the participation of a beneficiary (or of several beneficiaries), if:

- the beneficiary concerned requests it or
- the consortium decides to terminate the beneficiary's participation (using its internal decision-making procedures). In this case, the consortium must inform the beneficiary concerned, request the beneficiary's opinion in writing and provide it to the Commission/Agency (or — if the beneficiary didn't reply — provide proof that the beneficiary's opinion has been requested in writing).

Grounds for beneficiary termination (consortium):

- **Any ground** that **justifies** termination of the participation of the beneficiary

  The beneficiaries may terminate the participation of one of their consortium members in principle on any ground — as long as there is a good reason *(e.g. withdrawal by a beneficiary because due to a change in ownership; the beneficiary cannot implement its tasks in the same way; bankruptcy)*.

  For beneficiaries that are involved in **several EU GAs,** withdrawal from one GA does NOT necessarily imply that it has to also withdraw from the others.

  Information obligation — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2)*.

  If there are no legitimate reasons, the Commission/Agency **can NOT oppose** beneficiary termination, but it will be considered **improper**.

  Improper termination of the participation of a beneficiary may lead to GA termination *(see Article 50.3.1(c))* and/or to a grant reduction at the payment of the balance *(see Articles 5.3 and 43)*.

Termination extends to **linked third parties**. Terminating a beneficiary's participation implies that its linked third parties' may NOT continue participating in the action.

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in actions, like beneficiaries. Linked third parties can NOT however do more than the beneficiary they are linked to: If their beneficiary is terminated, they must also leave the action.

2. Procedure

The coordinator must **formally notify** the Commission/Agency of the termination (via the Participant Portal). At the same time, the coordinator must inform the beneficiary concerned (through the usual communication channels — in writing and offline).

The notification must include all the **information** set out in this Article (including the date the termination takes effect) and a **request for** an **amendment**.

Since for beneficiary termination the notification is combined with an amendment request, they must be submitted and signed by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3)*.

NO amendment is needed if the termination takes effect after the end of the action — unless it concerns the coordinator (since the coordinator has many obligations also after the end of the action, *e.g. submit the reports, receive the payment of the balance and distribute the payment among the beneficiaries*).

The amendment must be requested in accordance with Article 55.

If it is accepted, the GA will be amended to introduce the necessary changes (including, if necessary, the addition of new beneficiaries).

If it is rejected, the beneficiaries will have to make another proposal to the Commission/Agency. If a satisfactory solution cannot be found (i.e. the request for an amendment calls into question the decision awarding the grant or breaches the principle of the equal treatment of applicants), the GA may be terminated.

> ***Example:*** *A key beneficiary terminates its participation in the GA. The consortium cannot find a replacement and cannot continue implementing the action without one.*

The notification must specify the date on which termination will take effect (**termination date**).

This date must be a date after the notification: Terminations can**not** be **retroactive** (notably to be able to comply with the obligations and deadlines after termination; *see point 3*).

3. Effects

If the **GA continues** (i.e. it is amended), the remaining members of the consortium (and any new beneficiaries) have the responsibility for fully implementing the action as described in Annex 1 *(see Article 41.1)*. They must carry out the action (including the part that the defaulting beneficiary was supposed to carry out and without any additional funding to do so) — unless the Commission/Agency expressly agrees otherwise.

The coordinator must — within 30 days — **submit** the necessary **reports** (i.e. a report on the distribution of payments to the beneficiary concerned and a termination report).

In case of coordinator termination, the reports must be submitted by the new coordinator (to avoid problems with the payment). If the nomination of the new coordinator takes more time, the 30 days deadline may be extended.

The information contained in the beneficiary's termination report must also be included in the **periodic report** for the next reporting period.

The Commission/Agency will **calculate** the **amount due** to the terminated beneficiary:

- if the Commission/Agency owes amounts to the beneficiary, those amounts will be paid with the following payment to the consortium (interim or final)
- if the beneficiary owes, those amounts must be paid back to the consortium.

Only **costs** incurred before termination (i.e. generating event before the termination date *see Article 6.1(a)*) are eligible — except for the:

- costs for the termination report *(see Article 6.1)*
- costs for (the part of) contracts or subcontracts delivered before termination *(see Article 6.1)*.

If the coordinator fails to submit the *termination report* (within the 30 days of the date on which termination takes effect), costs that are not included in an approved periodic financial report will NOT be taken into account when the contribution is calculated. The Commission/Agency will NOT send a written reminder and will not extend the deadline.

If the coordinator fails to submit the *report on the distribution of payments*, the terminated beneficiary whose participation was terminated will NOT have to repay any amounts.

The detailed calculations are described in *Article 21*.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific cases (beneficiary termination):

Termination of the coordinator without its agreement — The decision to terminate the coordinator must be made by the rest of the consortium (according to its internal decision-making procedures). The notification and amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*) and the reports must be submitted by the new coordinator (to avoid problems with the payment). If needed, the 30 days deadline for submission of the reports can be extended *(see above)*.

Coordinator in bankruptcy/liquidation/administration (or similar) — In principle the coordinator must be changed. If the coordinator can no longer submit the request, the same procedure as for coordinator termination without its agreement should be used *(see above and Article 55)*.

Exceptionally, at the end of the action it may not be necessary to change the coordinator, but only its bank account if the administrator/liquidator accepts to do the final transfers of amounts.

MULTI-BENEFICIARY:

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable];*

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation):*** *the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable];*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**); see Article 22.5.2;

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks****][OPTION 2:*** *not applicable]*.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MONO-BENEFICIARY:

50.3 Termination of the Agreement, by the *[Commission][Agency]*

[…]

1. GA or beneficiary termination (EU)

The Commission/Agency may terminate the GA or the participation of one (or more) of the beneficiaries, on the **grounds** listed in this Article.

⚠ Beneficiary termination may lead to **GA termination**, if the Commission/Agency considers that the GA can NOT be continued *(see Article 50.3.1(c))*.

⚠ The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

Grounds for termination (EU):

- **Non-accession to the GA**

  The Commission/Agency may terminate the GA, if one (or more) beneficiaries did not accede to the GA (i.e. did not sign the Accession Form within 30 days after the entry into force of the GA or did not provide the requested declaration on joint and several liability).

  Non-accession of a beneficiary does NOT automatically lead to the GA termination; the consortium can find an alternative solution that ensures the proper implementation of the action without the beneficiary (and request an amendment; *see Article 55)*.

  In this case, the Commission/Agency will terminate the GA only if it considers the solution inappropriate or if the consortium no longer complies with the eligibility conditions set out General Annexes A and C to the H2020 Work Programme *(e.g. the rules regarding the minimum number of beneficiaries, their legal situation, or their place of establishment)*. [67]

  Examples:

  1. *Three entities from Poland, Portugal and France, are going to participate in a GA. The French beneficiary does not accede to the GA, and the other two beneficiaries fail to find a solution to this. The Commission terminates the GA because the conditions set out in the work programme/call are not met (i.e. the rule that three legal entities must take part).*

  2. *A key beneficiary does not take part in the action after all; the assessment of the action based on the award criteria announced in the call for proposals would have had a different result.*

- **Change in a beneficiary's situation**

  The Commission/Agency may terminate the participation of a beneficiary, if there has been a change to its (or one of its linked third parties') legal, financial, technical, organisational or ownership situation, that is likely to substantially affect or delay the action's implementation or calls into question the decision to award the grant.

  Such changes can be of any kind and can be triggered by the beneficiary itself or outside circumstances.

  Examples:

  1. *An action's key beneficiary is taken over by a non-European company (not entitled to participate due to security reasons). This substantially affects the action's implementation and the ownership, protection, exploitation and dissemination of the results. The Commission decides to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

  2. *The country in which one of the beneficiaries is established ceases to be an EU Member State. This means that the beneficiary is no longer eligible for funding and that the decision to award the grant is called into question. The Commission may decide to terminate the beneficiary's participation in the GA (or the GA if the other beneficiaries fail to find a solution to replace it).*

  ⚠ Costs become automatically ineligible as from the date of loss of eligibility *(see Article 6)*.

- **GA cannot be amended after termination** of a beneficiary's participation

  The Commission/Agency may terminate the GA, if it cannot be amended after termination of a beneficiary's participation because the necessary changes to the GA would call into

[67] *See also Article 8 of the Rules for Participation Regulation No 1290/2013.*

question the decision awarding the grant or breach the principle of the equal treatment of applicants; *see Article 55*).

The GA may be **directly terminated** if beneficiary termination would call into question the the decision awarding the grant or breach the principle of equal treatment of applicants.

- **Action can no longer be implemented**

The Commission/Agency may terminate the GA, if action implementation is prevented by *force majeure* or the action implementation is suspended and resumption is not possible or the necessary amendment is not acceptable *(see Articles 49 and 55)*.

Example:

1. *A fire devastates a laboratory where most of the technical equipment and computers with the action's research data are stored. The coordinator suspends the action's implementation to rebuild the laboratory. The Commission carries out a review after the force majeure takes place and concludes that the consortium can no longer implement the action. It therefore decides to terminate the GA.*

2. *A beneficiary that has the necessary background to work on the action and owns the installations where most of the work would be implemented decides to terminate its participation. The Commission decides to terminate the GA because continuing implementing the action without this beneficiary calls into question the decision awarding the grant.*

- **Bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings**

The Commission/Agency may terminate the participation of a beneficiary, if it is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law (since this normally implies that the beneficiary cannot carry out the work properly).

Example: *A coordinator informs the Commission that a beneficiary participating in a GA is insolvent. It does not notify beneficiary termination because it thinks that the beneficiary may continue implementing the action. The Commission considers that the beneficiary has not sufficient means to pursue implementation and terminates the beneficiary's participation.*

⚠ **Information obligation** — In case of **bankruptcy** (or similar), the beneficiary or the coordinator must immediately inform the Commission/Agency. Late information will be considered as a breach of the information obligation under the GA *(see Article 17.2).*

- **Professional misconduct**

The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has been found guilty of professional misconduct (proven by any means).

Example: *A legal entity's participation in a GA is terminated when a national investigation uncovers that it falsified the results of its clinical studies.*

- **Non-compliance with tax or social security obligations**

The Commission/Agency may terminate the participation of a beneficiary, if it has not fulfilled its obligations to pay social security contributions or taxes under national law (i.e. the law of the country in which it is established and those of the country where the action is implemented; *see Article 7*).

Example: *A national administration notifies to the Commission/Agency that a beneficiary did not pay social security contribution for its employees. If this beneficiary cannot prove that it paid these contributions or clarify the situation within a given deadline, the Commission may terminate its participation in the GA.*

- **Loss of scientific or technological relevance**

The Commission/Agency may terminate the GA, if the action has lost scientific or technological relevance.

Example: *A proposal on research on a new system based on recently discovered material is selected. After the action starts, a European scientific publication demonstrates that this material contains a chemical substance that irremediably harms human health. Therefore, the action cannot continue and the Commission decides to terminate the GA.*

- **Specific grounds for joint actions**

  For joint actions (i.e. actions funded following a joint or coordinated call with a third country or international organisation (IO); *see Article 2*), the Commission/Agency may terminate the GA, if:

  - the third country/IO action does not start by the date specified in Annex 1

    In this case, NO costs incurred by the consortium will be accepted. Any pre-financing provided to the consortium must be returned to the Commission/Agency in full.

  - the third country/IO action is terminated

  - the third country/IO action can no longer contribute to the subject of the GA.

    Example: *if the coordination agreement is not signed.*

- **Fraud, corruption or other criminal activities**

  The Commission/Agency may terminate the participation of a beneficiary, if it (or one of its representatives) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity.

  Example: *A legal entity's participation in several EU projects is terminated when its owner is convicted by national courts to have participated in large-scale drug trafficking.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in this grant)**

  The Commission/Agency may terminate the GA or the participation of a beneficiary, if a beneficiary (or one of its representatives) has committed substantial errors, irregularities or fraud or serious breach of obligations — either during the award procedure or under the GA.

  Example: *false declarations in the proposal form, in order to obtain EU funding; coordinator does not transfer payments to the other beneficiaries, but uses them for itself; coordinator does not submit the reports (despite a reminder); consortium does not inform the Commission/Agency about the receipt of a second grant for the same/similar proposal; review shows that action does not achieve its critical objectives and is way behind schedule and consortium submits a short-term implementation plan that is not acceptable; audit shows that beneficiary declared costs based on fake invoices; consortium does not provide requested information (despite a reminder); a check shows that scientific reports submitted by the consortium were almost entirely copied from the web (plagiarism); consortium does not submit an amendment request after beneficiary termination.*

- **Substantial errors, irregularities or fraud OR serious breach of obligations (in other grants)**

  The Commission/Agency may also terminate the GA or the participation of a beneficiary, if such substantial errors, irregularities- or, fraud or serious breach of obligations were found in *other* grants, if

  - the other grants were awarded under similar conditions and

  - the substantial errors, irregularities or fraud or serious breach of obligations are:

    - systemic or recurrent and

    - have a material impact on this grant.

  Example: *During an audit of other grants, the Commission detected systematic irregularities in the calculation of personnel costs that appear intentional and also affect all other GAs signed by the audited beneficiary. The Commission may terminate the participation of the audited beneficiary in the GA.*

- **Non-removal of a linked third party/international partner**

  The Commission/Agency may terminate the participation of a beneficiary if it refuses to remove one of its linked third parties or an international partner which is in one of the following situations:

  - bankruptcy, winding-up, administration, arrangement with creditors, suspension of business activities or other similar proceedings;

  - professional misconduct

  - non-compliance with tax or social security obligations

- fraud, corruption or other criminal activities
- substantial errors, irregularities or fraud or serious breach of obligations (in this grant or other grants).

3.0 This termination ground was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, beneficiary termination/linked third party removal was however already implicitly included in the different grounds of Article 50.3.3 (given that linked third parties have to fulfil the same conditions as the beneficiaries for participating in the action).

Before terminating (GA or beneficiary), the Commission/Agency may first suspend the GA *(see Article 49.2)*, to try to fix the problems and re-establish compliance with the GA. In this case, it will only terminate (the GA or a beneficiary) if the action cannot be resumed.

2. Procedure

Before GA or beneficiary termination, the Commission/Agency will follow a **contradictory procedure**

Contradictory procedure:

Step 1 — The Commission/Agency informs the coordinator/beneficiary concerned of its intention (and the reasons why), in a **pre-information letter**.

Step 2 — The coordinator/beneficiary concerned has **30 days** to submit observations. An extension may be granted on justified request — if submitted within the 30 days.

Step 3 — The Commission/Agency analyses the observations and either stops the procedure or **confirms** it.

Depending on the situation and type of termination, this procedure will be directed either at the coordinator or the beneficiary concerned:

- terminations linked to the consortium *(e.g. GA termination after a negative project review)*: normally the coordinator
- terminations linked to a beneficiary *(e.g. beneficiary termination or simultaneous termination of GAs after a beneficiary audit)*: normally the beneficiary concerned.

If it is directed at the coordinator, the coordinator must inform the other beneficiaries offline, via its usual communication channels *(e.g. e-mail, registered letters with proof of delivery, etc.)* and ask for their comments.

If it is directed at the beneficiary concerned, the Commission/Agency will inform coordinator later on (in a way that preserves confidentiality).

Information obligation — Beneficiaries normally do not have to inform their coordinators or ask them to submit comments. However, they should inform them, if there is the risk of a significant impact on the action *(see Article 17.2)*.

If a beneficiary is terminated on the basis of Article 50.3.1(e) (i.e. bankruptcy or similar), the Commission/Agency will also contact the liquidator/administrator (— as soon as possible after the termination is confirmed).

If it confirms termination, the Commission/Agency will specify the date on which termination will take effect **(termination date)**.

This date will be a date after the notification: Terminations can**not** be **retroactive** (notably to ensure the fulfilment of obligations and deadlines after termination; *see point 3*).

For some cases, the Commission/Agency may choose a future date (in order to give the beneficiaries the possibility to close the action). For the other cases *(e.g. termination under points (a), (d), (f), (i), (k), (l.i) and (m))*, the termination will take effect immediately, i.e. on the day after the coordinator receives the notification of the confirmation *(see Article 50.3.2)*.

3. Effects

The effects of **GA termination** are the same as when the beneficiaries terminate the GA *(see Article 50.1.2)*.

Only **costs** incurred before termination (i.e. generating event before the termination date; *see Article 6.1(a)*) are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Ineligible costs will be **rejected**. The **grant** may be **reduced**, if the termination is based on substantial errors, irregularities, fraud or serious breach of obligations (*for instance if the action has not been implemented properly; see Articles 5.3 and 43*). In certain cases, the Commission/Agency may also impose **administrative sanctions** (i.e. exclusion and/or financial penalties; *see Article 45*).

The effects of **beneficiary termination** are the same as when the beneficiaries terminate one of their partners *(see Article 50.2.2)*.

The detailed calculations are described in Article 21.

Termination has no effect on the **provisions** that normally **continue to apply** after the end of the action *(see Article 50.1)*.

Specific case:

Termination of the coordinator — The amendment request must be made by one of the beneficiaries (acting on behalf of the other beneficiaries; *see Article 55*) and the reports must be submitted by the new coordinator. If needed, the 60 days deadline for submission of the reports can be extended.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

1. Force majeure

What? In case of force majeure, a party will be excused from not fulfilling its obligations (i.e. there will be no breach of obligations under the GA and none of the adverse measures for breach of contract will be applied).

'Force majeure' relates to an extraordinary event or situation that is beyond the party's control and that prevents it from fulfilling its obligations under the GA.

Examples (force majeure): *An earthquake, terrorist attack or volcanic eruption; delay in delivering equipment due to floods in the region/country.*

Examples (not force majeure): *machine malfunctions, robberies; a subcontractor building a test site went bankrupt.*

The event or situation must be inevitable (despite the beneficiary's due diligence, i.e. level of care that can reasonably be expected from a beneficiary, in order to ensure the fulfilment of its obligations under the GA) and unforeseeable. Force majeure can NOT be used to justify situations caused by a beneficiary's negligence or by events that could reasonably have been anticipated.

The following cases are explicitly NOT considered force majeure:

- default of a service, defect in equipment or material or delays in making them available — unless they stem directly from a relevant case of force majeure
- labour disputes or strikes
- financial difficulties.

Personal reasons *(e.g. sickness)* or internal instructions are in general NOT considered as cases of force majeure.

If force majeure entails *extra* costs for the implementation of the action, it will normally be the beneficiaries that must bear them (since they were not budgeted and the maximum grant amount set out in Article 5.1 cannot be increased).

⚠ New in Horizon 2020: If a task could not be executed due to a situation of force majeure but certain costs were incurred for that task and could not have been avoided, those costs may still be eligible. This is different from FP7, where only costs for tasks that had actually been executed *up to* the date of the force majeure were eligible.

Example: *Airline tickets bought for a beneficiary to attend a meeting related to the action. The flight is cancelled due to a volcano eruption, making it impossible for the beneficiary to travel to the meeting. If the ticket costs fulfil the eligibility conditions set out under Article 6 of the GA, they are eligible, even if the beneficiary did not travel and did not take part in the meeting.*

Force majeure may lead to GA suspension *(see Article 49)* or GA termination *(see Article 50)*.

How? The coordinator must immediately **formally notify** the Commission/Agency (via the Participant Portal).

The beneficiary concerned must quickly put in place all possible **measures to limit** the **damage** caused by the force majeure, including measures to limit related costs.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal electronic exchange system and using the forms and templates provided there.

If — after the payment of the balance — the [Commission][Agency] finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

1. Communication between the parties — Participant Portal electronic exchange system

All communication between the consortium and the Commission/Agency – before and after the payment of the balance – must be in electronic form **via** the **Participant Portal**.

Beneficiaries will receive Participant Portal notifications even after the end of the action (and the LEARs are obliged to keep beneficiary contact data up to date, in order to ensure that the communication channels remain active).

The responsibility for opening notifications in time is with the beneficiaries.

Formal notifications are normally considered to have been **accessed 10 days after** they have been **sent** (— even not actually opened by recipient, *e.g. refusal of reception or omission*). Deadlines that are counted from the date of receipt are counted as of day eleven.

The same is in principle valid for formal notifications **after the payment of the balance** — except that the Commission/Agency will check that the notification has *actually* been accessed by the beneficiary (at any time, before or after the 10 days deadline). If it was not accessed, the Commission/Agency will send a second notification, this time on paper by registered post with proof of delivery. In that case, the deadlines will start to run from the date of receipt of the second notification.

4.0 The communication via the Participant Portal was extended to after the payment of the balance with GA version 4.0. For older grant agreements, it is in principle on paper, unless the beneficiary agrees to accept communication via the Participant Portal.

The Participant Portal offers different **functions**:

- viewing and changing the legal entity data in the Participant Register
- direct access to the necessary forms and electronic submission for reporting, deliverables and amendments
- contacting the Commission/Agency, via the messages function
- formal notifications
- where necessary, secured **electronic signatures** (*for instance, for signing the GA, accession to the GA, amendments and financial statements).*

It keeps **logs** of **all communication** and allows for **delivery** of formal notifications **with proof of receipt**.

All messages are recorded in the Participant Portal project file (with date and time).

Formal notifications are also recorded (with information on when they were sent and received, i.e. date and time the receiving party first accessed the notification, as indicated by the time stamp).

Access is limited to persons with a **user account** and **authorisation** to act for the beneficiary.

Authorisation and access are linked to the user role *(e.g. LEAR, PLSIGN or PFSIGN*).

Examples:

1. *Only Legal Signatories (PLSIGNs) may sign the GA and amendments.*

2. *Only Financial Statement Signatories (PFSIGNs) may sign the financial statements.*

3. *Only Primary Coordinator Contacts (PCoCos) and Coordinator Contacts (CoCo) may submit information to the Commission. The Primary Coordinator Contact can be changed only by the responsible (project) officer in the back-office, while the other roles can be managed by the participants themselves via the Portal. (In case of MSCA-IF the Supervisor identified in the proposal becomes the PCoCo, in ERC grants the PI identified in the proposal becomes the PCoCo.)*

4. *Only Participant Contacts (PaCos) may submit information to the coordinator. They cannot submit information directly to the Commission/Agency.*

5. *Only the Participant Contact(s) (PaCo, or PCoCo and CoCo(s) in case of the coordinator), Legal Signatory (PLSIGN) or Financial Signatory (PFSIGN) of the recipient beneficiary may access a formal notification for the first time (i.e. may formally receive it).*

6. *Task Managers (TaMa) may only complete and save web forms and upload documents related to their organisation's participation in the grant. They cannot submit information to the coordinator or the Commission.*

7. *Team Members (TeMe) have read-only access to project information. They cannot complete or save forms, nor submit information to the coordinator or the Commission/Agency.*

For more guidance on access and roles in the Participant Portal*, see the Participant Portal Online Manual.*

In principle, all communications from/to the Commission/Agency must normally go **via the coordinator** — unless the GA or other rules provide for direct communication with the other beneficiaries *(e.g. Articles 20, 22, 23, 30, 41, 55; OLAF Regulations No 883/2013 and No 2185/2996)*.

Specific cases (PP access rights):

Beneficiaries in bankruptcy — If during a beneficiary goes bankrupt during the action, the liquidator may be granted the necessary access rights in the Participant Portal, in order to complete the beneficiaries' obligations. If exceptionally necessary, the Commission/Agency can also agree to communication outside the Participant Portal electronic exchange system (i.e. via registered post or e-mails).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

1. Privileges and immunities

The Commission/Agency will not take measures against international organisations which would be contrary to the privileges and immunities accorded by their constituent documents or international law.

'**International organisation**' means intergovernmental organisations (other than the EU) with legal personality under international public law (including specialised agencies set up by international organisations).

Examples: *International Committee of the Red Cross (ICRC); International Federation of National Red Cross and Red Crescent Societies*

Thus in most cases (that is to say, unless the applicable legal texts provide otherwise), public law decisions cannot be applied to international organisations; only contractual measures will be taken.

Therefore, the Commission/Agency will not apply enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions (i.e. exclusion or financial penalties; *see Article 45*).

Similarly, offsetting will be applied only as a contractual measure on the basis of Article 44 GA (— never as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

By consequence, dispute settlement is normally limited to arbitration *(see Article 57.2)*. The public law remedies (i.e. Article 263 action) do not apply.

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], **periods expressed in days, months or years** are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L124, 8.6.1971, p.1)

1. Periods in days

A period expressed in days starts on the day following the triggering event and ends at midnight of the last day of the period. Days are **calendar days**.

Example: *Under Article 20.3, the coordinator must submit a periodic report within 60 days following the end of each reporting period.*
The action is divided into the following reporting periods:
RP1: from 1 March 2015 to 31 August 2016
RP2: from 1 September 2016 to 28 February 2017
Therefore, the deadline of 60 days for the first periodic report starts on 1 September 2016 and ends on 30 October 2016.
The deadline of 60 days for the second and last periodic report starts on 1 March 2017 and ends on 29 of April 2017.

2. Periods in months or years

Periods expressed in months or years end at midnight on the day with the same date as the day on which the period started, in the last month or year of the period.

Example: *Under Article 47, the Commission/Agency may suspend the payment deadline if a request for payment cannot be approved. The suspension takes effect on the day the Commission/Agency sends the notification. When the suspension exceeds two months, the coordinator may ask the Commission/Agency if it will continue. The Commission sent the notification for a grant payment deadline on 31 July 2016. Therefore, the suspension will have exceeded two months on 30 September 2016.*

If that day does not exist *(e.g. 31 of April)*, the period ends at midnight of the last day of that month (e.g. 30 of April).

Example: *Under Article 22.1.2, reviews may be started up to two years after the balance is paid. A grant's balance is paid on 29 February 2016. Therefore, the two-year period starts on 1 March 2016 and ends on 1 March 2018.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

When & What? An amendment is necessary whenever there is a need to **change** the GA (i.e. the core agreement and/or the Annexes).

⚠ The cases where an amendment is necessary are called 'amendment types' (AT); the amendment clauses are called 'AT clauses'.

⚠ The general terms and conditions of the GA can NOT be changed via an amendment. Only GA-specific data *(e.g. duration of the reporting periods, starting date, etc.)* and the options in the GA can be added, removed or updated via an amendment.

Examples:

1. *If the JRC should have been a beneficiary but then does not accede to the GA, the options related to the JRC will be removed.*

2. *If the JRC is added as a beneficiary during the action, the GA options related to the JRC will be added to the GA.*

3. *If a linked third party ends its participation, the option in Article 14.1 will be updated to set its 'end date of participation'.*

⚠ Amendments may NOT result in changes that — if known before awarding the grant — would have had an impact on the award decision. Those are mostly changes that:

- involve the consortium composition and have an impact on the eligibility criteria set out in General Annexes A and C to the Main Work Programme *(e.g. consortium of three entities established in three different Member States (BG, PL and FR) and replacement of the PL beneficiary by a BG beneficiary while the call required the representation in the consortium of at least three Member States)*
- involve changes to the action and/or its budget and affect the award criteria announced in the work programme/call *(e.g. the tasks in Annex 1 are changed so substantially that the action no longer corresponds to the scope of the call)*
- breach the principle of equal treatment of applicants
- do not comply with the rules applicable to the GA (i.e. Financial Regulation No 966/2012, Rules for Participation Regulation No 1290/2013, etc.) or with provisions of the GA itself *(e.g. amendment to subcontract tasks of the coordinator).*

⚠ **Information obligation — Changes** in the **name, address, legal form** and **organisation type** AND changes in the **legal, financial, technical, organisational** or **ownership situation** may or may not require an amendment *(see below)* — but they ALL trigger the information obligation under Article 17.2.

If such changes affect the implementation of the action and require an amendment, the Commission/Agency will examine the situation and inform the coordinator.

Examples (change that requires an amendment):

1. *Beneficiary A becomes bankrupt. It will be necessary terminate its participation and to amend the GA.*

2. *Beneficiary B moves from Europe to Australia during the action. The change of address implies that the beneficiary becomes not eligible for EU funding, so the GA will have to be amended to make it a 'beneficiary not receiving EU funding'.*

3. *Beneficiary C participates in an innovation action (IA) and loses its non-profit status during grant implementation. It will be necessary to amend the GA to change the reimbursement rate.*

Examples (change that does NOT require an amendment):

1. *Beneficiary D changes its name. The update in the Participant Register is sufficient; no amendment is needed.*

2. *Beneficiary E participates in an SME instrument action and loses its SME-status during grant implementation. No amendment is needed because there is an explicit exception in Article 53(2) of the Rules for Participation Regulation No 1290/2013.*

Normally amendments are done at the initiative of the consortium, but they may also be proposed by the Commission/Agency *(e.g. where errors need to be corrected; to change Annex 1 after a review of the action, etc.).*

The amended provisions **become an integral part of the GA**; all other provisions remain unchanged and continue to have full effect.

Sample list of cases where an amendment is necessary:

- **Removal of a beneficiary whose participation was terminated** due to **non-accession** to the GA or non-provision of the requested declaration on **joint and several liability** (**AT1**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary that never became part of the GA.

  How? The amendment is normally triggered by the beneficiaries.

In case of beneficiary termination (by the consortium), the notification of termination and amendment must be combined.

If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

The changes will be made ex tunc (i.e. since the beginning) since the beneficiary never participated in the grant.

If the beneficiary was participating with linked third parties/international partners, they will automatically be removed.

GA options for the beneficiary (and its linked third parties/international partners) are automatically removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Removal of a beneficiary whose participation was terminated** for **other reasons** (**AT2**; *see Article 50.2 and 50.3*)

  What? Removal of a beneficiary during the action.

  What not? There is NO need to request an amendment if termination takes effect *after* the end of the action *(see Article 3)* — unless the beneficiary concerned is the coordinator AND the amendment is necessary to comply with the obligation to submit the reports and distribute the payments.

  How? The amendment is normally triggered by the beneficiaries.

  In case of beneficiary termination (by the consortium), the notification of termination and amendment must be combined.

  If the coordinator is removed, the amendment has to propose a new coordinator (AT8).

  Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

  Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the request for amendment, the same procedure as for coordinator change without its agreement should be used.

  Changes will be made ex nunc (because the beneficiary participated in the grant up until termination and, moreover, many obligations are applicable after termination).

  The termination date will be added to the Preamble and the beneficiary will be entitled to submit costs until that date.

  If the beneficiary was participating with linked third parties/international partners, they will also have to be removed (with effect from the same date) and the end date of participation will be added to Article 14/Article 14a (AT5a/5b).

  By contrast, the GA options for the beneficiary (and its linked third parties/international partners) will NOT be removed/changed/become not applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

  Annexes 1 and 2 will normally have to be changed (AT21 and AT31).

- **Adding a new beneficiary** (**AT3**; *see Article 56.2*)

  What? Addition of a new beneficiary during the action.

  How? The amendment is normally triggered by the beneficiaries.

  The new beneficiary must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

  The accession date will be added to the Preamble of the GA and the beneficiary will be entitled to submit costs as from that date.

  The date must be selected in the Accession Form (attached to the amendment request). It is possible to choose between:

  - the date of signature of the Accession Form

- the date of entry into force of the amendment

OR

- a fixed date:
  - retroactive (before signature of the Accession Form)

  OR

  - future (after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that *both* can incur costs for a certain period.

Example: *The former beneficiary ends its participation on 1.6.2015, and the new beneficiary accedes to the GA on 1.5.2015.*

If the new beneficiary is participating with linked third parties/international partners, they will also have to be added (with effect from the same date) and the starting date of participation will be added to Article 14/Article 14a (AT6a/6b).

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, JRC, IO, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change of beneficiary due to partial takeover** (**AT4**; called 'partial transfer of rights and obligations' in FP7)

Transfer — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination *(see Article 50)* or addition of a new beneficiary *(see Article 56)*.

This amendment type should, however, NOT be used if the former beneficiary does NOT leave the consortium (but stays on as part of the consortium). In this case, simply use the amendment clause for addition of a new beneficiary (AT3).

What? Transfer due to partial takeover.

'Partial takeover' means that a part of the business of the beneficiary — including the GA — is taken over by (one or more) other entity(ies) (transfer of a business unit as a going concern, *e.g. partial acquisition, distribution of a business unit after dissolution/liquidation, division/demerger, etc.*).

'Partial acquisition' means that the original entity continues to exist, but that a new entity purchases a department, business unit, or similar (and absorbs or takes over part of the rights and obligations of the original entity). Thus, *some* of the rights and obligations (and contracts) of the original entity are transferred to the new entity. Since the beneficiary continues to exist as a legal entity and only some of its rights and obligations are affected, a case-by-case analysis is needed (and an amendment therefore necessary).

Example: *Company X sells its mobile phone division to company Z; all GAs where the mobile phone division of X was involved will be affected by the transfer of rights and obligations; other GAs where other divisions of company X work will not be affected.*

'Distribution of a business unit on dissolution/liquidation' means that the original entity disappears (due to dissolution or liquidation), but that (one or more) new entities purchase a department, business unit or similar (and absorb or take over part of the rights and obligations of the original entity). Since only *some* of the beneficiary's rights and obligations are transferred, a case-by-case analysis is needed (and an amendment therefore necessary).

'Division/demerger' means that the original entity disappears and several entities replace it; different parts of the original entity are transferred to the new entities (i.e. several partial transfers to different entities).

Examples:

1. *Company X has several ongoing grants. Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. For some GAs there will be a transfer of rights and obligations from X to Y, for other GAs it will be from X to Z.*

2. *Company Ω has an ongoing grant (covering some action tasks to be implemented by its engineering division and some action tasks to be implemented by other divisions). Company Ω is bought by two other companies (E and O), one of which absorbs the engineering division and the other the remaining divisions. There are two partial takeovers: one to company E and one to company O.*

What not? Simple sale of (one or more) assets of the beneficiary is NOT a 'partial takeover'; it does not involve the transfer of the GA, but — at most — a transfer of (some) action tasks if the beneficiary can no longer fulfil its action tasks. In this latter case, also the sale of assets will require an amendment, in order to terminate participation of the beneficiary and/or add a new beneficiary.

Example: *Company Ω implementing two different tasks in an action (engineering and testing) sells the engineering department to company E with the understanding that E will implement the engineering tasks of Ω in the action. The GA will have to be amended to add company E as a new beneficiary; company Ω remains beneficiary in the GA for the other action tasks (e.g. testing). (If company E is already a beneficiary in the GA, the GA must be amended only to modify Annexes 1 and 2 to adjust the action tasks and the budget; it is not be necessary to add E as new beneficiary).*

Best practice: In case of doubt, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

NO amendment is necessary for universal takeovers *(see below)*.

How? The amendment is normally triggered by the beneficiaries; if the Commission/Agency agrees, the new entity will replace the original entity as party to the GA (as new beneficiary).

'New beneficiary' is used here only for the purpose of the amendment; it can be either a new beneficiary joining the consortium or an already existing beneficiary who took over a part of the business of another beneficiary.

⚠The new beneficiary(ies) will (each) be fully **jointly and severally liable** with the former beneficiary for recoveries under Article 44. (By contrast: NO joint and several liability for debts linked to financial penalties and damages under Articles 45 and Article 46.)

If the new beneficiary joins the GA, it must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

If the partial takeover is governed by national law, the amendment request must clearly set out the legal situation and the consequences for the GA (both towards the Commission/Agency and towards the other beneficiaries). It must, in particular:

- explain the financial liability of the former beneficiary
- cite the applicable rules (with hyperlinks to the texts, if possible), and
- provide a copy of the takeover contract.

Best practice: In order to avoid multiple submission of documents, beneficiaries are recommended to upload the takeover contract in the Participant Register (via My Organisation page) and specify in the amendment request that the legal documents are available in the Participant Portal. This is particularly useful if several EU grant agreements or contracts are affected by a partial takeover.

The transfer date will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new beneficiary joins the action, the transfer date must be the same date as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification.

If the former beneficiary was participating with linked third parties/international partners, the new beneficiary will have to determine which of the former beneficiary's linked third parties/international partners stay on as linked third parties/international partners of the

new beneficiary (AT6a/6b) — all other linked third parties/international partners will be automatically removed.

The GA options for the beneficiary (and its linked third parties/international partners) will be added/changed/become applicable *(e.g. linked third party options, non-EU beneficiary, beneficiary receiving/not receiving EU funding)*.

Annexes 1 and 2 will also have to be changed (AT21 and AT31).

The former beneficiary does NOT need to submit any reports to the Commission/Agency. The financial statement for the open reporting period until transfer must be uploaded with the next periodic report either by the former beneficiary (for the time it was a beneficiary) or by the new one together with its own financial statement.

- **Removing a linked third party/international partner** (**AT5a/5b**; *see Articles 14 and 14a*)

  What? Removal of a linked third party/international partner during the action.

  How? The amendment is normally triggered by the beneficiaries.

  If requested by the Commission/Agency *(e.g. because of audit results or an OLAF investigation)*, the consortium MUST submit an amendment to remove a linked third party/international partner.

  > If the consortium does not follow-up this request, the Commission/Agency may **terminate** the participation of the *beneficiary* (and thereby also remove the linked third party/international partner).

  NO termination notification — Linked third parties/international partners can be removed by the consortium by simple amendment; no formal termination notification is required (termination notification applies only to beneficiaries; *see Article 50.2*)

  Changes will be made ex nunc (because the linked third party/international partner participated in the grant up until removal and, moreover, many obligations are applicable after termination).

  The end date of participation will be added to Article 14/14a.

  The date must be selected in the amendment request. It must be either a fixed date or 'the day after the submission of the amendment request'. The fixed date must be in the future (i.e. after the request: end of participation can NOT be retroactive).

  The GA options for the linked third party/international partner will normally NOT be removed/changed/become not applicable.

  Annexes 1 and 2 will have to be changed (AT21 and AT31).

- **Adding a linked third party/international partner** (**AT6a/6b**; *see Articles 14 and 14a*)

  What? Addition of a new linked third party/international partner during the action.

  How? The amendment is normally triggered by the beneficiaries.

  The new linked third party/international partner must first register (and get validated) in the Participant Register — unless it already has a validated participant identification code (PIC).

  The name of the linked third party/international partner and the starting date of participation will be added to Article 14/14a.

  The date must be selected in the amendment request. It is possible to choose between a fixed date or the 'date of entry into force of the amendment'. If the linked third party/international partner joins the action at the same time as the beneficiary, the starting date of participation must be the same date as the accession date of the beneficiary.

  The GA options for the linked third party/international partner will be added/changed/become applicable.

  Annexes 1 and 2 will also have to be changed (AT21 and AT31).

- **Change concerning a beneficiary/linked third party 'not receiving EU funding'** (**AT7a**; *see Article 9*)

What? If a beneficiary/linked third party — exceptionally — becomes eligible/not eligible for receiving EU funding during the action *(e.g. due to a change of establishment or a country changing eligibility status)* OR if it suddenly requests funding/zero funding, this change will normally require an amendment (to change Annex 1, Annex 2 and the options in Articles 9 and 57).

Examples:

1. *Beneficiary R moves from Europe to Australia and thus is no longer eligible for receiving EU funding. The GA must be amended. If R is participating with a linked third party M established in France, M will continue being eligible for funding.*

2. *The country in which beneficiary X is established leaves the EU (without an agreement ensuring continued eligibility). The beneficiary is therefore no longer eligible for funding and the GA may have to be amended (or terminated; see Article 50).*

3. *Beneficiary Y is eligible but signed the grant with zero funding. During the action the responsibilities within the consortium are shifted and beneficiary Y takes on a bigger role involving more costs. The other consortium members agree to adapt the budget and renounce to some funding in order to allow beneficiary Y to claim funding.*

⚠ Costs become automatically ineligible as from the date of loss of eligibility *(see Article 6)*.

How? This amendment can normally be triggered only by the Commission/Agency.

- **Change of coordinator (AT8)**

What? Replacement of the coordinator during the action *(e.g. because of financial difficulties)*.

Exceptionally, an amendment remains possible and necessary *after* the end of the action *(see Article 3)* — until the payment of the balance is paid out and distributed.

Coordinator in bankruptcy/liquidation/administration (or similar) — After the end of the action, if the coordinator can continue its participation with the bank account of the administrator/liquidator (i.e. termination and coordinator change not really needed), it is therefore exceptionally sufficient to change the bank account (AT40) without changing the coordinator.

What not? There is NO need to request an amendment for a change of the *person* in charge of the coordination of the project (since the person's name is not mentioned in the GA).

⚠ **Information obligation** — In case of a **change of person in charge of coordination**, the coordinator must — in addition to updating the data in the Participant Portal inform the Commission/Agency under Article 17.2).

How? The amendment is normally triggered by the beneficiaries.

If the new coordinator is not already a beneficiary of the GA, it must first accede to the GA as a new beneficiary (AT3).

The former coordinator may continue to participate in the action as a normal beneficiary or may terminate its participation (AT2).

Termination of the coordinator without its agreement — If the consortium terminates the coordinator without its agreement, it must provide proof of its decision to change the coordinator and nominate one of the beneficiaries to act on its behalf to request the amendment *(see Article 50.2 and below point 2).*

Coordinator in bankruptcy/liquidation/administration (or similar) — If the coordinator must be changed but can no longer submit the amendment request, the same procedure as for coordinator change without its agreement should be used.

The handover date will be added to the Preamble of the GA.

The date must be selected in the amendment request (fixed date or date of entry into force of the amendment).

It should normally be the date the new coordinator takes over the coordination tasks. If there was a gap (former coordinator leaves before new coordinator starts) there will be two different dates: the one for the former coordinator (when it stopped doing coordinator tasks — must be at the latest its termination date) and the one for the new coordinator (when it took over the coordinator tasks — must be after its accession date).

- **Change of the coordinator's bank account for payments (AT40)**

What? An amendment is necessary for all changes that imply a change to the account number/IBAN code.

Example: *The coordinator changes bank account.*

What not? NO amendment is necessary for a change of the name of the bank or name of the account holder; a change of the bank account data (and validation) in the Participant Portal Participant Register is sufficient.

How? The bank account data must first be updated in the Participant Register (and be validated).

- **Change of the starting date, action duration or reporting periods (AT23, AT24, AT25)**

What? Change of the action's schedule (starting date, action duration or reporting periods).

Example: *The GA for the action has a fixed starting date that is before the date on which the GA enters into force. Because of weather conditions, the consortium cannot start on that date and requests the Commission to change it.*

⚠ Even if the action is prolonged, the maximum grant amount *(see Article 5.1)* will NOT be increased.

How? An extension of the action must be requested *before* the action ends and will only be accepted in exceptional cases.

- **Changes to Annex 1 (description of the action) (AT21)**

What? Changes to the description of the action, in particular:

  - significant change of the action tasks *(e.g. if tasks are added/removed)* or of their division among the beneficiaries
  - changes concerning in-kind contributions provided by third parties (against payment or free of charge) or subcontracts

    Such changes could in principle also be made via simplified approval procedure *(see Articles 11, 12 and 13*); however, if the beneficiary requests an amendment, it will immediately know if the Commission/Agency agrees (or not). Without amendment, this decision is left for later and the Commission/Agency may reject the costs as ineligible later on (at the moment of the payment).
  - changes concerning the tasks to be carried out by linked third parties and related costs (including if a linked third party is removed)
  - significant changes to the plan for exploitation and dissemination (unless Annex 1 already foresees an update to be submitted with the periodic report)
  - changes concerning GA options (options are removed or added, *e.g. adding the options to provide trans-national access to research infrastructure requires normally a modification of Annex 1 and/or Annex 2)*
  - significant changes concerning deliverables *(e.g. changes of ethics requirements to align to ethical principles and legislation; adding/removing deliverables; changes in substance of a project output which is reflected in a deliverable, etc.)*.

What not? Changes to the due date of a deliverable normally do not require an amendment (except for certain deliverables, where timeliness is key)

- **Changes to Annex 2 and Annex 2a (estimated budget) or specific unit costs (AT31 and AT36)**

  What? Changes to the estimated budget, in particular:

  - a budget transfer of amounts between beneficiaries or between budget categories (or both) which are linked to a significant change in the action's work (i.e. Annex 1)
  - a budget transfer to a form of costs that is not used by the beneficiary (i.e. with 0 EUR costs in Annex 2) — except for transfer of amounts within the budget category A 'personnel costs' and for transfers to the budget category 'costs of internally invoiced goods and services'.

    Example:

    During the action implementation, the beneficiary decides to use the access costs for transnational access to research infrastructure unit cost. This requires an amendment to fix the unit cost and to move budget to budget category F.2.

  What not? There is NO need to request an amendment for changes covered by the budget transfers rule in Article 4.2 *(e.g. budget transfers within the personnel cost; see also below)*.

  How? The amendment is normally triggered by the beneficiaries.

  Best practice: If Annex 2a or specific unit costs need to be changed, the beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function).

Sample list of cases where NO amendment is needed:

- **Budget transfers not listed above**

  Transfers of amounts between beneficiaries or between budget categories (or both) do NOT require an amendment, provided that the action is implemented in line with Annex 1 *(see Article 4.2)*.

  Budget transfers within the personnel cost category and budget transfers to costs of internally invoiced goods and services are possible without having to amend the GA.

  Examples:

  1. *During the action implementation, a beneficiary that declared its direct personnel costs as actual costs decides to change this and instead to declare them as unit costs in accordance with its usual accounting practices (average personnel costs).*

  2. *An SME joins an on-going GA. The SME owner does not have a salary but incorrectly budgets its costs as actual personnel costs (category A.1). He realises the mistake and then switches to the unit costs for SME owners (category A.4).*

- **Change of name, address or other legal entity data (of beneficiaries/linked third parties)**

  Simple changes of name, legal form *(e.g. Ltd., S.A.)*, official registration number, address, VAT number do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is normally sufficient.

  Linked third parties/international partners — Since they normally do not have direct access to the Participant Register, linked third parties/international partners must inform their beneficiary who must inform the Commission/Agency. The data will then be updated by the Commission/Agency (and validated).

  If (exceptionally) the Commission/Agency considers that the registered change affects the implementation of the action, it will inform the coordinator (and instruct it to request an amendment or trigger itself an amendment, if needed).

  Example: Company R moves from Europe to Australia and this implies that the beneficiary is no longer eligible for EU funding. In such a case, the Commission will make an amendment to the GA to change the beneficiary status into 'beneficiary not receiving EU funding'.

  Short names have no legal value and only serve as easy identifiers in the GA. If needed, they can be changed in the context of an amendment initiated on other grounds.

  A change of the person that represent the coordinator for the purposes of signing the GA requires NO follow-up at all (not even a change in the Participant Register — since this name is only relevant at the moment of GA signature (not afterwards).

- **Change of beneficiary due to universal takeover** (called 'universal transfer of rights and obligations' in FP7).

  Transfers of the GA linked to a universal takeover (i.e. where the original entity is replaced by one new entity and all the rights and obligations — including the GA — are transferred to this new entity, *e.g. merger or full acquisition*) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is normally sufficient.

  Example: *Beneficiary X merges with another existing entity Y by:*

  - *becoming part of it (thus X and Y are together known as 'Y', and entity X ceases to exist) or*
  - *establishing a new separate legal entity (X and Y are together known as 'Z').*

  If — exceptionally — the Commission/Agency considers that the registered transfer affects the action implementation, it will inform the coordinator (and instruct it to request an amendment, if needed).

  Example:

  The legal form or type of organisation of the new entity differs from that of the former beneficiary or linked third party and this has an impact on the implementation of the action.

  Case 1: *The coordinator transfers all its rights and obligations to another legal entity. If this involves a change of the bank account number in Article 21.8, each GA in which it participates as coordinator must be amended to update this information (AT40).*

  Case 2: *A non-profit legal entity X is acquired by a big for-profit company Y; as a result of the acquisition Y assumes the rights and obligations of X in on-going innovation actions (IAs). The reimbursement rate applicable to Y in those on-going GAs will differ from that of X since the new beneficiary will not be entitled to a reimbursement rate of 100% (but only to a reimbursement rate of 70%). The GA must be amended to change the reimbursement rate (AT33) and the estimated budget (AT31).*
  For on-going RIA grants there will be no need to modify Annex 2 since the reimbursement rate is the same for all beneficiaries (100%).

Information obligation — In case of a **universal takeover**, the beneficiary must — in addition to updating the data in the Participant Register— inform the coordinator (offline) under Article 17.2, if the universal takeover could:

- significantly affect or delay the implementation of the action or the EU financial interests or
- affect the decision to award the grant or the compliance with requirements under the GA.

The coordinator must then inform the Commission/Agency (via the Participant Portal) and, if necessary, request an amendment.

The same applies if the universal takeover concerns a linked third party.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

2. Procedure

How? Amendment requests must be **prepared** by the requesting party (i.e. the coordinator or the Commission/Agency) directly in the Participant Portal.

Best practice: If none of the available amendment clauses fit, beneficiaries should contact the Commission/Agency (via the Participant Portal messaging function), to discuss the amendment.

⚠ Before the amendment request, new beneficiaries, new linked third parties or other new beneficiary data must have been registered and validated in the Participant Register.

Examples:

1. *A new beneficiary must be validated (legal entity validation). This means that the new beneficiary will first have to register in the Participant Register, be validated, appoint a LEAR, and provide the necessary information and supporting documents through the Participant Portal.*

2. *Validation of the new bank account, to change the bank account.*

⚠ The amendment request must include the necessary information and supporting documents. A signed and submitted amendment request can NOT be changed — only accepted, rejected or withdrawn. It is however possible to provide clarifications or additional information/documents.

ⓘ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

The **request** must be unambiguous and complete and submitted **in time** (i.e. sufficiently in advance to allow proper analysis and preparation before they are due to take effect and — generally — before the end of the action; *see Article 3*). Requests introduced AFTER the end of the action will be accepted only exceptionally, for very specific (duly substantiated) cases *(e.g. change of bank account, change of coordinator to make the payment of the balance)*.

The coordinator must ensure that it has the agreement of the consortium (in accordance with the internal decision-making processes, *e.g. unanimity, simple or qualified majority, etc. set out in the consortium agreement*).

Once completed, the request (with all its uploaded supporting documents) must be **submitted** and **signed** by the PLSIGN of the coordinator (on behalf of the other beneficiaries; *see Annex 3*).

Termination of the coordinator without its agreement — For change of coordinator without its agreement a special procedure applies: The other beneficiaries must nominate one of them to act on their behalf to notify termination and request the amendment. The nominated beneficiary must name a contact person responsible for the amendment.

Before it has been accepted or rejected, an amendment request may at any moment be **withdrawn**.

In order to **change** the amendment request, it must be withdrawn and re-submitted (changes to submitted requests are NOT possible).

Example: *The coordinator requests an amendment to change its bank account number and the reallocation of tasks in Annex 1 and of budget in Annex 2. Since the change of bank account is urgent because the Commission has to make the interim payment and the revision of the Annexes may require more time, the coordinator withdraws the request and makes a new request to change only the bank account and a second one to change the Annexes.*

A request containing several changes to the GA will be considered as one (and must either be agreed or rejected by the other party as a whole).

If the receiving party requests **additional information/documents**, a new deadline will apply, i.e. 45 days from receiving the additional information/documents.

Example: *The coordinator submits a request to add a new beneficiary with several linked third parties (see Article 14). The Commission requests a signed declaration for the joint and several liability of the linked third parties (Annex 3a). A new 45-day deadline for evaluation and validation will apply from the moment the Commission receives the declaration.*

The other party must — within **45 days** — **agree or disagree**.

The deadline may exceptionally be **extended** by the receiving party — for a period to be determined case-by-case —, if necessary for the assessment of the request *(e.g. a review is needed to assess the changes)*.

If **accepted** it will be **counter-signed** by the receiving party directly in the Participant Portal (for the consortium: by the PLSIGN of the coordinator).

If there is **no reaction** within the deadline, the request is considered to have been **rejected** (⚠ new in Horizon 2020: contrary to FP7, there is NO tacit approval of amendments). A new amendment request may however be submitted — even if it fully or partly repeats the initial request.

The amendment **enters into force** and is binding from the moment the receiving party has agreed to it (i.e. signed in the Participant Portal).

The amendment will **take effect** (i.e. the changes to the GA will start to apply) either:

- on the day of its entry into force (i.e. day of the last signature of the amendment) or
- on the specific date(s) indicated (and agreed) in the amendment.

The date should normally be *after* the entry into force of the amendment.

In justified cases it may — exceptionally — be *before* (retroactivity of the amendment). (In some cases, the GA itself provides for retroactivity.)

Examples (retroactivity allowed/foreseen in the GA):

1. *Where a new beneficiary is added to the GA (AT3), it must assume the rights and obligations from the accession date specified in the Accession Form. If this date is before the entry into force of the amendment, this retroactivity implies that its costs will be considered eligible as from the accession date (and not as from the entry into force of the amendment).*

2. *Following a suspension of the implementation of the action by the beneficiary or by the Commission, the suspension will be lifted with effect from the resumption date set out in the amendment (AT26). This date may be before the date on which the amendment enters into force (see Article 49.2.2).*

3. *If the amendment intends to correct an error (AT60), the change will be made with effect from entry into force of the GA (i.e. from the beginning).*

Depending on the amendment type, the date of taking effect may have an impact on the eligibility of costs.

An amendment request involving several changes, may take effect on different dates.

Example:

On 1 May 2016, the coordinator requests an amendment to change the bank account and to add a new beneficiary. The addition of the beneficiary takes effect from the date of its accession, as specified in the Accession Form (1 April 2016), while the change of bank account takes effect on a date agreed by the parties or on the date on which the amendment enters into force (i.e. 10 June 2016, the day it is signed by the receiving party).

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

1. Accession to the GA (beneficiaries mentioned in the Preamble)

All beneficiaries (except the coordinator) must accede to the GA by **signing** the **Accession Form** *(see Annex 3)* directly in the Participant Portal. They must do this **within 30 days** after the GA enters into force *(see Article 58)*.

Only the beneficiaries' legal signatories (PLSIGNs) may sign the Accession Forms.

Declarations on **joint and several liability** *(see Annex 3a)* must be signed by the linked third party *on paper* and send it to its beneficiary. The beneficiary must scan it and upload it in PDF format, before signing the Accession Form.

Without the declaration, it will NOT be able to accede to the GA (and thus NOT be considered a party to the GA).

Record-keeping — The beneficiary must keep the original of the linked third party in its files *(see Article 18.1.2)*.

Linked third parties do not become parties to the GA and therefore do NOT need to sign an Accession Form.

The coordinator is not obliged to **distribute hard copies of the GA** and Accession Form to the other beneficiaries (new in Horizon 2020). All documents are available in the Participant Portal project file.

Specific cases (accession):

JRC — If the JRC is beneficiary, it must sign Annex 3b as its Accession Form (instead of Annex 3).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

1. Addition of new beneficiaries (amendment)

In justified cases, the beneficiaries may request adding a new beneficiary.

The new beneficiary must comply with the eligibility criteria of the work programme/call, have sufficient operational and financial capacity to perform the proposed tasks, comply with the non-exclusion criteria and commit to implement the action under the same terms and conditions as the other beneficiaries.

Article 56 does not apply to *mono*-beneficiary actions. Mono-beneficiary actions can therefore NOT become multi-beneficiary actions.

How? The new beneficiary must:

- register in the Participant Register and be validated — unless it already has a validated participant identification code (PIC)
- sign the Accession Form (directly in Participant Portal)
- provide a declaration on joint and several liability of its linked third party (if required by the Commission/Agency).

The coordinator must request an **amendment** for adding a new beneficiary (*see Article 55*).

The Accession Form (attached to the amendment request) must specify the **accession date**. It must be either:

- the date of signature of the Accession Form
- the date of entry into force of the Amendment

OR

- a fixed date:
  - either retroactive (i.e. before signature of the Accession Form)

  OR
  - future (i.e. after signature of the Accession Form — this should be an exceptional case with a justification).

Handover period — If a new beneficiary joins to replace a beneficiary that leaves, the accession date may be set before the termination date (of the beneficiary that is replaced) — so that both can incur costs for a certain period.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned].****]***

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

1. Applicable law

As a general rule, H2020 GAs are subject to EU law (supplemented — where necessary — by Belgian law), for questions on their interpretation, application and validity.

Specific cases (applicable law):

International organisations (IOs) — If requested by the international organisation, the GA may provide for derogations:

Situation	Applicable law
For international organisations that do NOT accept any applicable law clause	No reference to any applicable law[68]. The applicable law will be determined by the Permanent Court of Arbitration *(see also point 2)*. According to the Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States, the applicable law are: – the rules of the organisation concerned – the law applicable to any agreement or relationship between the parties and – where appropriate, the general principles governing the law of

[68] *See Article 180(1) of the Rules of Application Regulation No 1268/2012.*

	international organisations and the rules of general international law.
For international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law)	The international organisation can choose any of the following combinations of applicable laws: – only EU law – only Belgian law – only other MS or EFTA country law – only general principles governing law of IOs + rules of general international law – EU law + MS or EFTA country law (except Belgium) – EU law + general principles governing law of IOs + rules of general international law – EU law + Belgian law + general principles governing law of IOs + rules of general international law – EU law + other MS or EFTA country law + general principles governing law of IOs + rules of general international law – Belgian law + general principles governing law of IOs + rules of general international law – other MS or EFTA country law + general principles governing law of IOs + rules of general international law

⚠ new in Horizon 2020: This is new compared to FP7, where (instead of a horizontal approach for all international organisations which cannot accept EU law) it was necessary to make specific provisions (special clause 3), in order to accommodate, for example, the participation of specialised agencies and international organisations of the UN family. It makes it easier for international organisations to participate in Horizon 2020.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not eligible for EU funding, which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. [OPTION for Agency grants: Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).]

1. Dispute settlement

As a general rule, H2020 GAs contain an Article 272 TFEU arbitration clause — referring **contractual disputes** (i.e. disputes on the interpretation, application or validity of the GA) to the European Court of Justice.

> An Article 272 action is ONLY possible once the Commission/Agency position is *final* (i.e. against confirmation letters, debit notes, etc.; NOT against audit reports, audit letters, pre-information letters, etc.).
>
> For Commission grants, actions must be brought against the Commission; for Agency grants, they must be brought against the Agency (information is available both in the Preamble of your GA and in SyGMa).

For disputes of public law nature (i.e. which concern **administrative sanctions**, **offsetting** or **enforceable decisions** under Article 299 TFEU; *see Articles 44, 45 and 46*), actions must be brought before the European Court of Justice under Article 263 TFEU (NOT before any other court and NOT under Article 272).

⚠ **Public law measures** must ALWAYS be brought to the European Court of Justice under Article 263 TFEU (including actions brought by non-EU beneficiaries or beneficiaries not receiving EU funding).

⚠ All procedures are organised in a way that the beneficiaries will always be **informed** about what they can do if they disagree (**means of redress** information in the letters).

Specific cases (dispute settlement):

Non-EU beneficiaries — For non-EU beneficiaries, contractual disputes are normally referred to the courts of Brussels, Belgium. They can NOT choose another forum. (So far NONE of the H2020 association agreements provides for the sole jurisdiction of the European Court of Justice.)

Disputes of public law nature remain before the European Court of Justice.

Beneficiaries not receiving EU funding — Beneficiaries not receiving EU funding which are not eligible (meaning from a third country not eligible for funding; *see Article 9*) are treated like non-EU beneficiaries (i.e. courts of Brussels), unless their national law explicitly provides that they cannot be subject to the jurisdiction of the Belgian courts. In this latter case (very exceptional), contractual disputes are referred to the Permanent Court of Arbitration.

Disputes of public law nature remain before the European Court of Justice.

International organisations — For international organisations, contractual disputes are referred to the Permanent Court of Arbitration (in line, for instance, with their PAGODA agreement, e.g. for the United Nations, the Financial and Administrative Framework Agreement (FAFA) with the United Nations[69]).

Disputes of public law will normally not arise, since international organisations are normally accorded immunity from public law decisions (under their constituent documents or international law). Such international organisations can therefore be subject only to contractual measures and to contractual dispute settlement (i.e. arbitration).

For this reason, the Commission/Agency will normally NOT adopt enforceable decisions under Article 299 TFEU *(see Article 44)* or decisions on administrative sanctions *(see Article 45).*

Similarly, offsetting will always be applied only as a contractual measure on the basis of Article 44 GA (NOT as a public law measure directly on the basis of Article 80(1) of the Financial Regulation No 966/2012).

For international organisations that have NO immunity, disputes of public law remain before the European Court of Justice.

[69] Financial and Administrative Framework Agreement concluded by the European Community, represented by the Commission, and the United Nations of 29.4.2003, as amended by Addendum No 1 of 22.1.2014 (C(2014) 238). Available at https://ec.europa.eu/europeaid/node/45445.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will **enter into force** on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

1. Entry into force

The GA enters into force when the last of the following two signs:

- the coordinator
- the Commission/Agency.

It is usually the Commission/Agency who signs last.

I.3 Issues applicable to particular countries

For countries for which it has carried out a formal assessment of specific situations or their legal framework, the Commission will keep record of its official position.

See the List of issues applicable to particular countries.

II. ERC MGAs

II.1 Background information and approach

The European Research Council (ERC) Model Grant Agreements are used for ERC actions only.

The ERC gives:

- 'frontier research grants', i.e.:
  - ERC Starting Grants (StG)
  - ERC Consolidator Grants (CoG)
  - ERC Advanced Grants (AdG)
  - ERC Synergy Grants (SyG)
- proof of concept grants (PoC), i.e.:
  - ERC PoC
  - ERC PoC Lump Sum Pilot
- ERC Low Value grants.

Frontier research actions use the H2020 ERC MGA. For ERC PoC, there are two specific MGAs: the standard ERC PoC MGA (based on actual costs reimbursement) and the ERC PoC Lump Sum Pilot MGA with a pre-fixed amount of EUR 150 000. A specific MGA also exists for ERC Low Value grants. Other ERC actions (coordination and support actions (CSA)) use the H2020 General MGA.

The ERC MGAs follow the General MGA for numbering and content, except for:

All ERC MGAs deviate from the General MGA as follows:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- The table of contents is adapted
- Cross-references in the footnotes are adapted

The H2020 ERC MGA deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 32 (Provisions on the working conditions for the PI and his/her team)
- Article 41.3 (Provisions on internal arrangements)

- Article 56 (Mono-beneficiary grant can become multi-beneficiary grant by addition of new beneficiaries)
- Article 56a (ERC-specific Article on portability)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statements

The H2020 ERC MGA PoC deviates from the General MGA as follows:

- Preamble (ERC principal beneficiary and name(s) of the PI(s))
- Article 5.2 (ERC specific reimbursement rate)
- Article 7.1 (ERC reference to work under the guidance of the PI)
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.3.1, 50.3.2., 50.3.3. (reference to single or multi reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC PoC specific articles on reporting and payment)
- Articles 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 41.3 (Provisions on internal arrangements)

The H2020 ERC MGA PoC Lump Sum Pilot deviates from the General MGA as follows:

- Preamble
- Article 4.2 (estimated lump sum breakdown and transfers)
- Article 5 (grant amount and form of grant
- Article 6 (not applicable)
- Article 7.1 (reference to PI supervision)
- Article 8 (resources to implement the action)
- Articles 9-12and 14a-16 (not applicable)
- Articles 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to single reporting/final report)
- Article 13 (subcontracting)
- Article 18 (keeping records)
- Articles 20 and 21 (specific reporting and payment provisions; only final report, no interim payments)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, (reference to the ERC funding, the ERC logo and the PI where necessary)
- Article 22 (specific procedure for extension of audit findings)
- Article 41.3 (Provisions on internal arrangements)
- Article 42 (not applicable)
- Article 47 (specific provision for suspension of payment deadline)
- Article 49 (specific provision for suspension of the action)
- Article 50 (specific provisions for termination)
- Article 56.3 (GA transfer for mono-MGAs)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3., 15 and 16, Annexes)* will not be shown.

For the ERC PoC Lump Sum Pilot MGA, the Articles where the only difference is the removal of references to eligibility of costs *(e.g. Article 14, 17.1, 22.5, 41.2 – removal of CFS —)* or rejection of costs *(e.g. Articles 14.2, 18.2, 22.6)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERC actions are added:

- Article 2 (ERC MGA actions; ERC MGA PoC actions)
- Article 4.1 (ERC MGA budget categories)
- Article 6 (ERC MGA eligible and ineligible costs)
- Article 8 (ERC MGA rules on third party involvement)

Since the ERC MGA and the standard ERC PoC MGA have a similar set-up (i.e. principal beneficiary, host institution, principal investigator) and provisions, the annotations of the standard ERC PoC MGA will be limited to major differences from the ERC MGA.

For the ERC PoC Lump Sum Pilot MGA, the annotations will focus mainly on differences arising from the cost models (lump sum versus actual costs reimbursement).

The annotations (for all three MGAs) are based on the multi-beneficiary version. The differences between multi and mono-beneficiary versions are marginal. For ERC PoC Lump Sum Pilot, there is a single MGA for both mono- and multi-beneficiary actions.

II.2 H2020 ERC MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the **principal beneficiary**':

[**full official name (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting [*and engaging*] the following

***[OPTION by default:** 'principal investigator':[4]*

*- [**Name**] [Date and place of birth]]*[5]

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

*- [**Name**] [Date and place of birth]*

*[and '**other principal investigator(s)**':*

*- [**Name**] [Date and place of birth]*

*- [**Name**] [Date and place of birth]].]*

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**] established in [official address in full] *[**OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**':*

*- [**Name**] [Date and place of birth]*

*- [**Name**] [Date and place of birth]*

[same for each beneficiary]

***[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).****].***

[OPTION for SyG*:* ***and other ERC grants with more than one principal investigator****: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.****]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Participants: Principal beneficiary — Beneficiaries — Host institution

In ERC grants, the coordinator is called '**principal beneficiary**'.

The '**host institution (HI)**' is the beneficiary that hosts (and normally also engages) the '**principal investigator (PI)**' for at least the duration of the action.

2. Participants: Principal investigator(s)

For ERC grants, the main researcher (i.e. the **principal investigator (PI)**) is named in the GA.

PIs can be of any **nationality**, if they intend to conduct research in an EU Member State or H2020 associated country and are hosted (and usually engaged) by a host institution that is based in an EU Member State or H2020 associated country.

Due to the key role of the PI, s/he can NOT be replaced by any other researcher during the action. Requests for amendments to change the PI will be rejected.

PI time commitments — The PI must comply with certain minimum requirements regarding working time on the action (fixed in Annex 1 and 2) and working time in an EU Member State or H2020 associated country (set out in the work programme/call).

The Agency must be informed before any change in employment or location of the PI.

Should the PI move to another host institution (in an EU Member State or H2020 associated country), the GA can be transferred to the new host institution (**portability**; *see Article 56a*). If the PI moves to an institution established in a non-associated third country, the GA may be terminated *(see Article 50.1 H2020 General MGA)*.

In case of breach, the Agency may terminate the GA or take any of the other Chapter 6 measures *(e.g. grant reduction, recovery of payments already made, etc.; see Articles 42-44, 47-50 H2020 General MGA).*

PIs do not become party to the GA, but they are the key actors in charge of the research activities. However, it is the host institution that subscribes to the financial and legal obligations under the GA — since it is the beneficiary.

Examples:

1. A PI can choose its own research team. This team is the research team *of* the PI and thus different from that of a network or consortium. The engagement of the team follows the rules of the beneficiary and its country.

2. PIs must be supported by their host institution during the entire action duration.

In order to govern their internal relationship (during the action), PIs and their host institutions must sign a **supplementary agreement (SA)** *(see Article 32)*. The supplementary agreement can NOT replace the employment/engagement contract and is not sufficient by itself.

Specific cases (PIs):

PI employed/engaged by a third party — Exceptionally, the PI may be employed/engaged not by the beneficiary but by a third party (from an EU Member State or H2020 associated country), i.e.:

- a third party that provides the PI as in-kind contribution or
- a linked third party *(see Article 8)*.

This must be specifically justified in the proposal and included in Annex 1.

In this case, the supplementary agreement *(see Article 32)* must be signed by the PI, the host institution AND the third party.

Retired PI — The PI may be retired.

Several PIs — ERC Synergy grants have several PIs (but only one principal beneficiary and one of the PIs that acts as 'correspondent PI'). Each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution (*see Article 56a*) a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC frontier research actions

What? ERC frontier research grants fund:

- ground-breaking, high-gain/high-risk research at the frontiers of knowledge ('frontier research') in any field of research (except nuclear energy), by one (or more) principal investigator(s) and their research team.

ERC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-STG)*.

For more information on ERC actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

For examples of successful ERC actions, see the *ERC website.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)] [and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERC MGA uses in principle the same budget categories as the General MGA.

Budget categories of the ERC MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
  - costs of internally invoiced goods and services
- indirect costs.

Thus, the ERC MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure
- direct costs of providing financial support to third parties
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

[…]

1. Reimbursement rate

How much? For ERC actions, the reimbursement rate is set at **100 %** *(see the ERC Work Programme)*.

2. Cost forms

For ERC actions, the **cost forms** are in principle the **same** as in the **General MGA** *(see Article 5 H2020 General MGA)*.

However, the ERC MGA does not use all the **unit costs** and **flat-rates** of the General MGA:

Like the General MGA, it uses the unit cost for personnel costs on the basis of the beneficiaries' usual accounting practices (average personnel costs), the unit costs for SME owners and beneficiaries that are natural persons without salary, the unit costs for internally invoiced goods and services and the flat-rate of 25% for indirect costs.[70]

It does NOT use the unit costs of category F 'specific cost categories' of the General MGA.

[70] See *Article 29(1) and 33(2) of the Rules for Participation Regulation No 1290/2013 and Commission Decision C(2013) 8197 of 3 December 2013 authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018). Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf.*

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions per budget category.

The ERC MGAs use in principle the same budget categories (**covering** the same **types of costs)** as the General MGA *(see Article 6 H2020 General MGA)* — with the exception of categories C. 'financial support to third parties' and F 'specific cost categories'.

The same **eligibility conditions** and **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

However, ERC grants have the following **specificities**:

– for category A 'personnel costs':

Costs for 'teaching buy-outs' — If the beneficiaries hire substitutes to perform some of the PI's duties that are not linked to the ERC grant *(e.g. teaching)*, these costs are NOT eligible.

PI employed/engaged by a third party — If the PI is employed/engaged by a third party (which thus pays his/her salary and seconds him/her to work on the premises of the beneficiary, for free or against reimbursement, the salary costs may be declared as direct personnel costs (if for free: under budget category A.1 'costs for employees (or equivalent)' (Article 6.2.A.1); if against payment: under budget category A.3 'seconded persons' (Article 6.2.A.3)).

– for category D 'other direct costs':

Recruitment costs — For ERC frontier research grants, recruitment costs, if clearly attributable to the action, are eligible as 'other direct costs', even for the unsuccessful candidates (because recruitment is part of the activities of such actions — unlike for actions under the General MGA or ERC PoC actions).

Purchase of scientific publications — Costs for scientific publications *(e.g. books, manuscripts, articles, digital copies, etc.)* may be eligible, if their direct link to the action and their necessity for the action is demonstrated.

Costs related to protection of the action's results — Are eligible. Given the increasing emphasis on the protection of inventions, the PIs are encouraged to protect their intellectual property rights properly. Costs related to protection of other intellectual property are NOT eligible.

Costs related to open access — Costs for open access to publications (including monographs) and to research data are eligible if incurred during the action duration. This includes costs charged by data repositories or data centres for the storage and maintenance of the research data generated by the action. With explicit agreement by the Agency, it can also include fees levied for a membership scheme (if this is a requirement for publishing with open access or if membership is a pre-condition for significantly lower article processing charges).

Costs related to scientists' visits — Short-term scientists' visits undertaken in the framework of an international agreement on scientific and technological cooperation (ERC Implementing Arrangements[71]) are eligible even if the scientist is not mentioned as a team member. Annex 1 does not need to be amended (i.e. the scientist and research visit do not need to be mentioned).

[71] See http://erc.europa.eu/implementing-arrangements

6.5 Ineligible costs

'**Ineligible costs**' are:

[…]

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[…]

1. Ineligible costs

The rules on **ineligible costs** are the same as in the General MGA *(see Article 6.5 H2020 General MGA)*.

Combining H2020 & other EU grants — ERC grants do NOT prevent **PIs** from applying independently (i.e. in their own name) for further EU funding for other actions or for the same action, but for costs that are not eligible (or not declared) under the ERC grant.

The fact that the funding rate for ERC grants is 100% does not mean that the grant pays for 100% of the costs of the ERC action. Therefore cost items not declared under the ERC grant may be covered by other EU funding.

For more information on how to combine EU funding from different programmes, *see the Participant Portal Online Manual (links to Regional funding).*

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERC actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

The PI must in principle, be hosted and engaged by the principal beneficiary. However, in exceptional cases, the PI can be engaged by a third party *(e.g. a third party that makes the PI available to work in the host institution; see Articles 11 and 12)*.

Example: *Research agencies that put the PIs at disposal of different universities.*

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, **for personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[…]

1. Records for personnel costs — Hours worked for the action

For ERC actions, the same rules on record-keeping apply as in the General MGA *(see Article 18 H2020 General MGA)*.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The beneficiary must— within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from the beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiary [*and linked third parties*] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary**: information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC)*;*]**[OPTION 2**: not applicable;**]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for the beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2.

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to its usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC actions, the principal beneficiary must submit both:

- a **periodic scientific report** after the end of each scientific reporting period (except the last one), with:
    - information about the scientific progress of the work
    - the achievements and results of the action, *such as publications and a declaration of any major change of scientific strategy*
    - information on whether and how open access has been provided to these results *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.
- a **final scientific report** at the end of the action, with:
    - the final results, achievements and conclusions of the action, and how they have been disseminated (including via scientific publications) *(see Article 29)*
    - a summary of the achievements of the action, for publication by the Agency.

Example: *For a five-year grant, there are two scientific reporting periods, so a 'periodic scientific report' is due for months 1-30 and a 'final scientific report' for months 31-60.*

In addition, the principal beneficiary must submit a **financial report** at the end of each financial reporting period, with:

- a narrative containing information on the eligible costs, including a breakdown of direct costs table and a budget follow-up table
- an individual financial statement
- a summary financial statement, created automatically by the IT system (on the basis of all financial statements submitted by the beneficiaries and linked third parties for the reporting period), which counts as the request of payment
- for the last financial reporting period only: a certificate on the financial statements (CFS).

Example: *For a five-year grant, there are four financial reporting periods, so a financial report is due for months 1-18, 19-36, 37-54 and 55-60.*

How? All reports must be prepared and submitted directly in the Participant Portal, *see Article 20 H2020 General MGA*).

2. Reporting periods

Like for the General MGA, ERC actions are divided into reporting periods.

The ERC MGA has, however, different reporting periods for financial and scientific reports.

Their length is defined in the signed GA. Normally, the financial reporting period is **18 months**, whereas scientific reports are due **halfway through** and at the **end** of the project.

> ***Example:*** *For a five-year grant, there are four financial reporting periods (months 1-18, 19-36, 37-54 and 55-60) and two scientific reporting periods (months 1-30 and 31-60).*

Reports must be submitted within 60 days after each period ends.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

[…]

1. Third parties with rights on results

For ERC actions, the same rules on third party rights apply as in the General MGA *(see Article 26 H2020 General MGA)*.

Due to the key role of the PI, it is however particularly important that agreements between the host institution and the PI allow the host institution to comply with its obligations under the GA — either by foreseeing a transfer of ownership to the host institution or by providing it with appropriate access rights (with a right to sub-license).

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING […]

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme)*: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in **the data management plan**;*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2: *Not applicable**]***

[…]

1. Open access to scientific publications

For ERC actions, the rules for open access to scientific publications are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

Beneficiaries must ensure **open, free-of-charge access** to the end-user to **peer-reviewed scientific publications** relating to their results.

> 'Peer-reviewed publications' means publications that have been evaluated by other scholars.
>
> Monographs, book chapters and other long-text publications are considered to be peer-reviewed, if the following conditions are fulfilled:
>
> – at least one independent expert (i.e. external to the publishing house) has reviewed the manuscript before acceptance for publication. For monographs in the strict sense (i.e. not edited collections), external review of a substantial part of the work is sufficient to be considered peer-reviewed
>
> – the external reviewer must not be a scientific series editor or a commercial editor related to the publication in question. For edited collections, it must not be the editor of the collection
>
> – PhD theses and habilitations for professorial degrees are considered peer-reviewed if they are formally published (because the review by external experts is generally part of the assessment of the candidate's research work for the PhD degree or the 'venia legendi').

⚠ Other types of publications, *such as non-peer-reviewed articles as well as non-peer reviewed monographs, books, conference proceedings and 'grey literature'* (i.e. informally published material not having gone through a standard publishing process, *e.g. reports*), are not covered by the open access obligation.

Best practice: However, to ensure fuller and wider access, beneficiaries are encouraged to provide open access also to these other types of scientific publications (where possible).

ERC grants have however the following **specificities**:

The ERC Scientific Council recommends the use of subject-specific repositories:

– for publications in the Life Sciences domain: Europe PubMed Central (http://europepmc.org)

– for publications in the Physical Sciences and Engineering domain: arXiv (http://arxiv.org).

If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo (http://zenodo.org). For monographs, book chapters and other long-text publications, the recommended repository is the OAPEN Library (http://oapen.org).

With explicit agreement by the Agency, the extended deadline for publications for grants in the social sciences and humanities domain (i.e. 12 months) can exceptionally be granted also for specific publications of grants in other domains, if the specific publication can be considered to relate to the social sciences and humanities. This must be requested within the 6 months originally foreseen.

Moreover, for publications after the end of the action, if beneficiaries cannot provide open access within the time limits set by Article 29.2 without incurring additional costs for gold open access, they may choose green open access with an extended embargo period which goes beyond six/twelve months.

Finally, the ERC MGA foresees lighter requirements for bibliographic metadata, focusing only on a persistent identifier (i.e. a stable address/marker to identify the publication, such as a digital object identifier (DOI)[72] or other systems).

Best practice: If the repository allows for this, beneficiaries of ERC grants are strongly encouraged to ensure that the bibliographic metadata also includes additional information such as the European Research Council (ERC) as funding source, the grant number, the title of the action and its acronym, the publication date, and the length of the embargo period (if applicable). For ease of tracking, beneficiaries should include the digital object identifier for the 'European Research Council' (http://dx.doi.org/10.13039/501100000781) in the funding acknowledgement field in their metadata, in addition to the digital object identifier for 'Horizon 2020' (http://dx.doi.org/10.13039/501100007601).

For more guidance, *see Open Access on the ERC website, the ERCEA Implementation Guidelines and the ERC Scientific Council's Open Access Guidelines for research results funded by the ERC.*

2. Open access to research data

This option will be inserted in the GA for ERC frontier research actions that participate in the Open Research Data Pilot (in line with provisions in the ERC Work Programme).

The rules on open access to research data are in principle the same as in the General MGA *(see Article 29 H2020 General MGA)*.

The ERC MGA has however the following **specificities**:

The data management plan (DMP) must address the following issues (the use of the ERC template is strongly recommended but not mandatory):

1. Making data Findable
2. Making data openly Accessible
3. Making data Interoperable
4. Increase data Re-use
5. Allocations of resources and data security

Moreover the DMP can provide justification for NOT ensuring open access to specific parts of the research data. For ERC actions, the exception allowing beneficiaries not to give access to specific parts of their research data applies not only if this would jeopardise the *main* objective of the action, but *any* one of the action objectives.)

For ERC frontier research actions, the main objective is always a purely scientific one. The justification for non-disclosure therefore does NOT need to be the scientific objective of the action but can refer to other objectives, such as the intended later commercialisation of the scientific findings.

A first version of the data management plan must be submitted within the first 6 months of the project implementation and should then be updated during the lifetime of the project, as needed.

[72] For more information, *see http://www.doi.org/.*

The beneficiaries may **opt out** of the pilot at any stage — both before signing the GA and afterwards (through an amendment; *see Article 55 H2020 General MGA)*. No reasons have to be provided for opting out. By opting out, they free themselves retroactively from the obligations associated with taking part in the pilot.

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator*[s]* and *[his/her][their]* team

The beneficiaries must respect the following **working conditions for the principal investigator*[s]* and *[his/her][their]* team**:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[OPTION for SyG **and other ERC grants with more than one principal investigator**: corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[OPTION for SyG **and other ERC grants with more than one principal investigator**: and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);
- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

[…]

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p.67).

1. Working conditions — Rights for the PI and his/her team

In view of the key role of the PI and his/her team in ERC actions, the ERC MGA foresees a series of obligations in order to guarantee best possible working conditions and scientific autonomy for them.

Main obligations (towards the PI):

- **Scientific autonomy**, to achieve the action's objectives under the best possible conditions, and within the time agreed
- **Competitive working conditions**, always in accordance with national law and institutional rules
- **Support for managing the action** *(e.g access to infrastructure; legal, financial and administrative support)*
- Access to and protection of **intellectual property rights**
- Allow and facilitate the transfer of the GA to another host institution (**grant portability**).

2. Supplementary agreement — Obligations on the PI

The ERC MGA foresees that the PI and its host institution must sign a supplementary agreement (SA), in order to formalise the commitments in the GA also towards the PI.

Main obligations (of the PI):

- **Supervision** of the scientific and technological implementation of the action
- Responsibility for the **scientific reporting** and contribution to the **financial reporting**
- Meeting the **time commitments** for implementing the action

The PI must ensure a sufficient time commitment and presence throughout the course of the project to guarantee its proper execution.

The two time commitment obligations are as follows:

- % of working time that the PI must work on the action
- % of working time that the PI must work in an EU Member State or H2020 associated country.

To be operational, these two percentages must be translated into working hours, i.e.:

- minimum number of hours that the PI must work in the action over its duration
- minimum number of hours that the PI must work in an EU Member State or H2020 associated country over the duration of the action.

The calculation should be done as follows:

Step 1 — For each year of the action, the percentages of PI commitment are applied to:

a) either the annual hours of a standard full time equivalent at the host institution, or

b) 1720 annual hours (this option must be used in all cases when it is not possible to determine the number of hours of a full time equivalent at the host institution).

The standard full time equivalent (or 1720 annual hours) works as a ceiling: they apply even if the PI works in total *more* hours (i.e. has other parallel affiliations, freelance activities or work-related obligations or works more hours on the action). In this case, the time commitment is capped at 100% and the hours are calculated on the standard full time equivalent (or 1720 annual hours).

By contrast, if the PI works in total *less* hours than the standard full time equivalent (or 1720 annual hours), the time commitment obligation will be reduced proportionally.

To do so, the percentage of PI commitment will be applied to the total work of the PI (instead of to options a) or b) above).

The total work of the PI will be determined by adding up all her/his hours of remunerated work, including under contracts with entities other than the host institution.

Example: *The % of PI commitment to the ERC action is 50%. The PI works 60 % part time at the host institution and has another contract with a different entity to work 350 hours over the year. A full time equivalent at the host institution works 1750 hours per year. The hours that the PI works in total are = 60 % of 1750 + 350 = 1 050 + 350 = 1 400. Since this amount is lower than the full time equivalent, the time commitment obligation will be: 1 400 x 50 % = 700*

Step 2 — Sum up the results for each year of Step 1 to get the total number of hours over the action duration.

The percentages must be reached for the overall action duration (NOT annually or per reporting period).

The PI's time commitments obligations must be fulfilled even if no personnel costs are charged for him/her to the project.

- Applying the host institution's usual management practices
- Informing the principal beneficiary immediately of any events or circumstances likely to affect the GA
- Ensure the **visibility of EU funding**

- Upholding the **intellectual property rights** of the host institution

  This obligation is not limited to *respecting* the host institution's intellectual property rights (IPRs). The PI must *actively* inform it if s/he becomes aware of any violations.

  Example: *The PI reads a research article and discovers a violation of the host institution's project IPRs. S/he is obliged to inform the host institution.*

- Maintaining **confidentiality**.

The 'supplementary agreement' is an agreement between the host institution and the PI, to set out their internal arrangements for implementing the grant.

It is **purely internal**; the EU/Euratom is NOT party and has NO responsibility for it (nor for any adverse consequences).

It should cover all the practical issues that may arise in the context of the grant implementation (in particular the ones listed in Article 32.1(b)) and must remain in place at least for the action duration *(see Article 3)* (— without any interruptions, even if the PI works only part-time on the ERC project).

It must NOT contain any provisions **contrary to the GA**. (Provisions that contradict the GA are considered void and cannot be opposed to the Agency.)

It can NOT replace an employment or engagement contract between the PI and its host institution (which remain necessary under national labour and social laws).

It must be concluded **before GA signature** (or in case of portability before submission of the amendment request) and a copy must be sent to the Agency.

A template [ODT format] for a model supplementary agreement is available. (The model is not mandatory; beneficiaries may use other clauses, provided they benefit the research action and do not contradict the GA.)

Specific cases (supplementary agreement):

PI employed/engaged by a third party — The supplementary agreement must be signed by the PI, the host institution *and* the third party.

Several PIs — For ERC Synergy grants (i.e. ERC frontier research grants with several PIs), each host institution must conclude a supplementary agreement with the PI(s) they engage.

No supplementary agreement — NO supplementary agreement is needed for ERC PoC grants.

PI entitled to sign the supplementary agreement — If the PI is entitled to sign the supplementary agreement on behalf of the host institution (because of his/her position in the institution), the supplementary agreement must be counter-signed by another person empowered by the institution. The principal investigator can NOT sign his/her own supplementary agreement for both parties.

Grant portability — If the GA is transferred to another host institution *(see Article 56a)*, a new supplementary agreement must be signed with the new host institution (and forwarded to the Agency). The new agreement must take effect from the grant transfer date (or before). The GA cannot be amended before the PI has sent the new supplementary agreement.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[…]

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC logo or any similar trademark or logo, either by registration or by any other means.

[…]

1. Visibility of EU funding

For ERC actions, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must however make **specific reference to the European Research Council (ERC)**. Thus, the clause acknowledging funding is slightly adapted and the beneficiaries must also use the ERC logo.

For more information on using the ERC logo, *see the ERC home page*

ARTICLE 56 — ACCESSION TO THE AGREEMENT

MULTI-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party]*.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of

MONO-BENEFICIARY: ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Addition of new beneficiaries

In justified cases, the beneficiary may request the addition of a new beneficiary.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added, the grant becomes a multi-beneficiary grant and ***[OPTION 1:*** *the preamble and the following Articles of the ERC Multi-beneficiary Model Grant Agreement will apply: […][…][…][same for further articles]****][OPTION 2:*** *the ERC Multi-beneficiary Model Grant Agreement will apply****]***.

1. Addition of new beneficiaries

For ERC actions, the rules on addition of beneficiaries are in principle the same as in the General MGA *(see Article 56 H2020 General MGA)*.

However, unlike the General MGA, ERC *mono*-beneficiary grants can become *multi*-beneficiary grants, by addition of a new beneficiary according to this provision.

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary *[OPTION for SyG and other ERC grants with more than one principal investigator: or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a request for amendment to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

1. Transfer of the GA (portability)

ERC grants can be **transferred** to a new host institution ('new beneficiary') — at any time during the action.

⚠ **Transfer** — The rights and obligations under the GA are transferred from the host institution to a new host institution — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former host institution remains fully responsible until the Agency has approved the amendment.

The transfer may be based on any **ground** that is beneficial for the PI and supports achieving the action's objectives.

The former host institution ('former beneficiary') may **oppose** a transfer only if it is not allowed under national law. It may however **negotiate** transfer conditions (including transfer of team members, intellectual property rights and equipment) with the new host institution, taking into account the views of the PI.

2. Procedure

The PI should first contact the host institution that signed the GA (i.e. the former host institution).

> ⚠ **Record-keeping**
> **Best practice:** Beneficiaries and PIs should keep records of the consultation and decision-making process for each portability case.

The former host institution must submit a **request for amendment** to the Agency.

For the amendment the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. If the new host institution joins the action, the transfer date must be the same date as the accession date. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new host institution (signed directly in the Participant Portal), the PI's justification letter and a supplementary agreement signed between the new host institution and the PI

The **financial reporting periods** will be automatically adapted to match the transfer date (unless the transfer date coincides with the end of a financial reporting period). **Scientific reporting** periods will usually remain unchanged (since the transfer normally has no effect on the scientific implementation of the action).

> ℹ For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The principal beneficiary must — within 60 days from either the transfer date or the date of signature of the amendment, whichever is the latest — submit:

- a financial report to the Agency (for the open period until transfer)
- a report on the distribution of payments (only in case of multi-beneficiary GA)
- if the costs reach the threshold set out in Article 20:, a certificate on the financial statement (CFS) (— even if this is not the last reporting period).

These documents will be used for calculating the interim payment due to the former beneficiary. The Agency will moreover instruct the former host institution to transfer the remaining pre-financing to the new host institution.

If the PI requests it, the Agency may require the former host institution to **transfer equipment** that was purchased and used exclusively for the action.

The former host institution may oppose this only if it is not possible under national law. It may however negotiate transfer conditions with the new host institution, taking into account the views of the PI.

Thus, the new host institution should make its best effort to buy the equipment fully used for the project. If it does so, it may declare the costs of this reimbursement (and any other related costs, i.e. dismantling, transfer and installation), if they fulfil the eligibility conditions set out in Article 6.

Specific cases (portability):

Several PIs— In ERC synergy grants (i.e. ERC frontier research grants with several PIs), each PI has the right to transfer his/her part of the action. They must inform and consult the other PIs, to ensure that the action's objectives can still be achieved.

Former host institution remains beneficiary — If certain team members (or equipment) stay with the former host institution, while the PI moves to a new host institution, the GA is transferred and changed into a multi-beneficiary grant agreement (allowing both the former host institution and the new host institution to participate in the grant). The former host institution stays on as beneficiary, the organisation that hosts and engages the PI is the new host institution. If the former host institution remains only for a limited time *(e.g. to ensure a smooth handover)*, it can then be terminated at a later stage, via a beneficiary termination *(see Article 50.2 H2020 General MGA)*.

II.3 H2020 ERC PoC MGA: Annotations

The H2020 ERC PoC MGA is very similar to the H2020 ERC MGA.

Like the ERC frontier research grants, the ERC PoC grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team *(Article 32 H2020 ERC MGA)*, no supplementary agreement and no grant portability *(Article 56a H2020 ERC MGA*).

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

What? ERC PoC funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2015-PoC)*.

For more information on ERC actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the report(s) set out in this Article. The financial report(s), include(s) the request(s) for payments.

The report(s) must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

[OPTION 1 by default (for actions with one RP): 20.2 Reporting periods

The action has one reporting period:

- RP: from month 1 to month [X]

20.3 Report — Request for payment of the balance

The principal beneficiary must — within 60 days following the end of the reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**';*

*(d) an '**individual financial statement**' (see Annex 4) from each beneficiary [and from each linked third party].*

The individual financial statement must detail the eligible costs (actual costs, unit costs, flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

*The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *that all the receipts have been declared (see Article 5.3.3).*

(e) ***[OPTION A if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION B:*** *not applicable;****]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for payment of the balance**;*

*(g) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).****]***

[OPTION 2 for actions with several RPs: 20.2 Reporting periods

The action is divided into the following reporting periods:

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1] to [the last month of the project].****]***

20.3 <u>Reports</u> — Requests for interim payments and payment of balance

The principal beneficiary must — within 60 days following the end of each reporting period — submit a report to the Agency.

*The **report** must include the following:*

(a) a summary for publication by the Agency;

*(b) an **overview of the progress of work** towards the objectives of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;*

*(c) detailed information on the costs declared, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';*

*(d) an **'individual financial statement'** (see Annex 4) from each beneficiary [and from each linked third party], for the reporting period concerned.*

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries [and linked third parties] must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the report for the next reporting period.

*The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).*

*Each beneficiary [and each linked third party] must **certify** that:*

- *the information provided is full, reliable and true;*
- *the costs declared are eligible (see Article 6);*
- *the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and*
- *for the last reporting period: that all the receipts have been declared (see Article 5.3.3);*

*(e) **[OPTION A if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);**][OPTION B:** not applicable;**]***

*(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last reporting period — the **request for payment of the balance**);*

(g) for the last reporting period only:

- *an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out;*
- *a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary [and linked third party], if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).**]***

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

The report(s) (including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the deadline for payment (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC PoC actions, the principal beneficiary must submit **periodic reports** — only one if there is one reporting period, otherwise one at the end of each reporting period.

The report(s) must include the all of the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be easy to read and understandable to a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of progress towards the action's objectives (or an overview of the action's results for the last reporting period)

- information on the eligible costs, including a table showing the breakdown of direct costs and a budget follow-up table

- an individual financial statement.

In addition, a summary financial statement, which counts as the request of payment, will be created automatically by the IT system, on the basis of all financial statements submitted by the beneficiaries and linked third parties for each reporting period.

Moreover, for the last reporting period, a certificate on the financial statements (CFS) will have to be added (if necessary).

How? All reports must be prepared and submitted directly in the Participant Portal *(see Article 20 H2020 General MGA*).

2. Reporting period(s)

ERC PoC actions normally have only **one reporting period** (with one pre-financing payment; *see Article 21*).

As a general rule, this single reporting period lasts **18 months** (and thus the entire action duration).

If provided in the GA, an ERC PoC action may however also have more reporting periods.

II.4 H2020 ERC PoC Lump Sum Pilot MGA: Annotations

Like the H2020 ERC PoC MGA, the H2020 ERC PoC Lump Sum Pilot MGA is very similar to the H2020 ERC MGA.

As the ERC frontier research grants, the ERC PoC Lump Sum Pilot grants have a principal beneficiary (who is also the host institution) and a principal investigator.

There are however NO specific provisions on the working conditions of the PI and his/her team, and there is no supplementary agreement *(Article 32 H2020 ERC MGA).* Furthermore, there is no right of the PI to portability of the grant *(Article 56a H2020 ERC MGA*) (although for mono-beneficiary grants there is the possibility, in duly justified cases, to transfer the grant to a new beneficiary; *see Article 56.3*).

Also, under the ERC PoC Lump Sum Pilot MGA the grant payment is based on pre-fixed lump sum amount and not on actual costs reimbursement.

The following annotations will only highlight the biggest differences. For the rest, the annotations to the ERC MGA apply *mutatis mutandis*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. ERC PoC actions

ERC PoC Lump Sum Pilot funds:

- a 'proof of concept' to verify the innovation potential of an idea from an ERC frontier research project.

ERC PoC Lump Sum Pilot grants can cover any activities that develop research output towards new commercial or societal applications *(e.g. making a 'business plan', technical issues and overall direction, intellectual property rights positioning and strategy, budgeting and other commercial parameters; connections to later stage funding; establishing a company; demonstration, testing, prototyping, piloting, design).*

ERC PoC Lump Sum Pilot grants can NOT cover activities under the ERC frontier research grant *(e.g. dissemination or publications of the results of the ERC frontier research action; pure research, especially research with no commercial potential)* or activities which are the result of research not performed under the ERC actions *(e.g. results of research not funded by the ERC action)*.

ERC PoC Lump Sum Pilot actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

ERC PoC Lump Sum Pilot actions are funded under Part I of Horizon 2020, 'European Research Council' *(e.g. ERC-2019-PoC)*.

For more information on ERC actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual, the ERC home page or the ERC Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The 'estimated lump sum breakdown' for the action is set out in Annex 2.

It contains the lump sum shares for the work per beneficiary *[and linked third party]*.

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiaries. It shows the amounts that the Agency commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 can be adjusted by transfers of amounts between the beneficiaries, but only via an amendment (see Article 55).

1. Estimated lump sum breakdown

Differently from the ERC frontier research grants and the standard ERC PoC, the ERC PoC Lump Sum Pilot grants do not have any budget categories. Instead, they have a lump sum (for multi-beneficiary grants, broken down per beneficiary).

For multi-beneficiary grants, the breakdown is used to determine:

- the share of the lump sum to which each beneficiary is entitled for the work
- the maximum amount for which each beneficiary is liable in case of improper implementation of the work.

Example: *On a grant involving three beneficiaries, the Agency carries out a review after the payment of the balance. The review concludes that 50% of the work attributed to beneficiary A was not implemented as indicated in Annex 1. On those grounds, the Agency decides to reduce the grant. According to Annex 2, EUR 50 000 was allocated to beneficiary A. Therefore, beneficiary A will be liable in proportion to its tasks or parts of the action not implemented (i.e. in case of a 50% reduction, beneficiary A will be liable for EUR 25 000).*

2. Lump sum share transfers

Unlike in the General MGA, transfers of ERC PoC Lump Sum Pilot shares are only possible via a formal amendment (i.e. increasing the share of a beneficiary and decreasing the share of another under a multi-beneficiary action).

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 150.000** (one hundred and fifty thousand euros).

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The ERC PoC Lump Sum Pilot MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant** *(see Decision C(2018) 5960)*.

The use of the lump sum will be set out in the ERC Work Programme.

The lump sum is a fixed amount of EUR 150 000 for each grant. This amount takes already into account the H2020 ERC funding rate.

There are no cost eligibility conditions. If the action is correctly implemented (in line with the description in Annex 1), the beneficiaries are entitled to receive the fixed lump sum amount.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** for the action and it can NOT be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum for the approved work and reduction for non-approved work

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum for the approved work and reduction for non-approved work

The amount of the lump sum corresponds to the lump sum shares (see Annex 2) declared by the beneficiaries *[and linked third parties]* for the approved work in the financial statement at the payment of the balance (see Article 20.4).

The grant is reduced (see Article 43) for the part of the work that has not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For ERC PoC Lump Sum Pilot grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation; see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For ERC PoC Lump Sum Pilot grants, the rules on the revised final grant amount are in principle the same as for the General MGA *(see Article 5.4 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services;
- use in-kind contributions provided by third parties against payment;
- use in-kind contributions provided by third parties free of charge;
- call upon subcontractors to implement action tasks described in Annex 1;
- call upon linked third parties to implement action tasks described in Annex 1;
- call upon international partners to implement action tasks described in Annex 1

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the ERC PoC Lump Sum Pilot MGA.

The General MGA rules on third party involvement are limited in PoC Lump Sum Pilot actions to subcontracting (*Article 13*) and linked third parties (*Article 14*).

The articles for purchases *(Article 10)* and in-kind contributions *(Articles 11* and *12)* are not applicable to the PoC Lump Sum MGA. Beneficiaries may make purchases and use any in-kind contributions from third parties following their internal practices but not subject to other rules (as long as they are needed to carry out the work of the action).

⚠ For all types of third party involvement (purchases, in-kind contributions, subcontracts and linked third parties), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Specific rules for subcontracting action tasks

Subcontracting may cover only a limited part of the action.

The tasks to be implemented for each subcontract must be set out in Annex 1. The Agency may however approve subcontracts not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the final report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).***]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for ERC PoC Lump Sum Pilot actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The ERC PoC Lump Sum Pilot MGA has however the following **specificities**:

The estimated subcontracting costs do NOT need to be included in Annex 1 or shown in the table of estimated costs in Annex 2 (there is no such table for the ERC PoC Lump Sum Pilot; Annex 2 is not the budget, but the estimated lump sum for mono-beneficiary grants/lump sum breakdown for multi-beneficiary grants). By contrast, the tasks to be subcontracted must still be indicated in Annex 1, as it happens in the General MGA.

The principles of best value for money and no conflict of interest are not explicitly mentioned in Article 13. Nonetheless, they must still be complied with and confirmed by the beneficiaries at proposal stage.

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations which occurred at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *[**OPTION 1 by default**: five]**[OPTION 2 for low value grants**: three]* years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

Records and other supporting documentation on the scientific and technical implementation of the action must be in line with the accepted standards in the respective field.

The beneficiaries do not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For ERC PoC Lump Sum Pilot actions, beneficiaries do not need to keep records on their actual costs; they only need to keep appropriate and sufficient evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 5 years after the balance is paid or longer if there are ongoing procedures (*such as audits, investigations or litigation)*. In this case, the evidence must be kept until the end of the respective procedure.

The records and supporting documentation must:

- refer to the implementation of the action, in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and
- prove that the tasks or part of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs actually incurred are NOT needed.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the final report set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action has one '**reporting period**':

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The principal beneficiary must submit — within 60 days following the end of the reporting period —the final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a **summary** for publication by the Agency.

(b) an **overview of the results** of the action, including the deliverables identified in Annex 1 and explanations justifying the differences between the work expected to be carried out in accordance with Annex 1 and that actually carried out.

(c) a '**breakdown of direct cost table**': not applicable

(d) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and each linked third party]*, for the reporting period.

The individual financial statement must declare the lump sum share indicated in Annex 2, for the work that was completed in the reporting period.

The beneficiaries may exceptionally also declare a partial lump sum share for the part of the work that was not completed (e.g. due to scientific or technical reasons), if agreed by the Agency.

Lump sum shares which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiaries *[and each linked third party]* must **certify** that:

– the information provided is full, reliable and true;

– the work has been completed and that the action in general has been properly implemented (see Article 7);

– the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(e) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(f) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the request for payment of the balance;

(g) a 'certificate **on the financial statements**': not applicable

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

Financial statements must be drafted in euro.

20.7 Language of reports

The final report (including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the final report submitted does not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the report and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For ERC PoC Lump Sum Pilot actions, the principal beneficiary must submit a **final report** at the end of the action.

The report must include the following:

- a summary for publication by the Agency

  The summary is a brief description of the action, presenting its objectives and the results achieved. It must be fit for publication and written in an easy to read language for a non-specialised audience. This will enable the Agency to publish it on the Commission's website right away.

  The principal beneficiary must ensure that material submitted to the Agency for publication does not include any confidential material.

- an overview of the results towards the action's objectives

- an individual financial statement.

The final report includes the completed work and the corresponding lump sum shares per beneficiary.

In principle, lump sum shares should be claimed only for work fully accomplished as described in Annex 1. However, if agreed by the Agency, the beneficiary may exceptionally declare partial lump sum shares for work not completed, for example, due to technical reasons.

Best practice: In case of doubt, the beneficiary should contact the Agency about work partially accomplished.

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that a new research methodology made the planned methodology obsolete. The new methodology could have been accepted via an amendment.*

- non-implementation linked to financial reasons

  Example: *The in-depth market study turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

How? The final report must be **prepared** by the **principal beneficiary** and the other **beneficiaries together**, directly in the Participant Portal).

In practice, the following steps will apply:

Step 1 — The principal beneficiary will indicate in the Participant Portal if the work foreseen in Annex 1 has been fully accomplished during the action duration.

Step 2 — The beneficiaries will have to sign individual financial statements to confirm proper implementation of their parts of the work and submit them to the principal beneficiary. All of them will be part of the final report.

Step 3 — The principal beneficiary will submit the final report to the Agency.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the 'Guarantee Fund'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)]) is not paid to the principal beneficiary, but kept by the Agency for the JRC.]*

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the lump sum for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares for the work declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The part of the work that has not been delivered or cannot be approved at the payment of the balance will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for the beneficiary, in the estimated lump sum breakdown (see Annex 2).

1. Payments to be made

ERC PoC Lump Sum Pilot actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid on approval of the final report.

2. Payment calculations — Amounts due — Recoveries

Beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Agency on the basis of the termination report, the payments already made and the report on the distribution of payments.

The rules follow those of the General MGA *(see Articles 21.3, 44.1.1, 50.2.2 and 50.3.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply takes into account the lump sum share for the beneficiary's accepted work.

Exceptionally, the Commission/Agency may accept also *part* of a lump sum share for work partially accomplished by the beneficiary.

Example for calculating the amount due at beneficiary termination:

Grant with three beneficiaries (A, B and C).
Maximum grant amount: EUR 150 000.
Lump sum share breakdown per beneficiary (Annex 2):

	Lump sum shares for the work	Total EU contribution
Beneficiary A	50 000	50 000
Beneficiary B	70 000	70 000
Beneficiary C	30 000	30 000
Total	150 000	150 000

The participation of beneficiary B is terminated before the end of the project. The reason for terminating its participation is the non-availability anymore of a biosafety level 4 laboratory which has been damaged by a fire during the course of the action and where proof of concept activities for the second virus should have been also performed. Therefore, this beneficiary cannot complete its tasks due to force majeure (see Article 51 H2020 General MGA). On those grounds, the Agency decides to accept for that beneficiary a part of the lump sum shares proportionate to the tasks carried out by the beneficiary in the action (e.g. 50%). According to the distribution of payment, the principal beneficiary had transferred EUR 50 000 as pre-financing to beneficiary B.

Amount due:

Lump sum shares for partly accepted work = EUR 70 000 – 50% of EUR 70 000 = EUR 35 000

Beneficiary B amount due: EUR 35 000.

Beneficiary balance:

Payments received by beneficiary B (according to the report on the distribution of payment): EUR 50 000.

Beneficiary B balance: EUR 35 000 (amount due) - EUR 50 000 (payment received) = - EUR 15 000

Since the payment received by Beneficiary B exceeds the amount of the lump sum share is entitled for its part of the work it has fully accomplished, there is a recovery of EUR 15 000 (see Article 50).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Agency on the basis of the financial statements, the final grant amount and the payment already made.

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares of the beneficiaries for the accepted work. Work partially accomplished due to scientific or technical reasons may exceptionally be accepted by the Agency.

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

Example: *The beneficiary argues that a new research methodology made the planned methodology obsolete. The new methodology could have been accepted via an amendment.*

- non-implementation linked to financial reasons

Example: *The in-depth market study turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

Step 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to ERC PoC Lump Sum Pilot grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Example for calculating the payment of the balance:

Grant with three beneficiaries (A, B and C).

Beneficiary A is in charge of scaling-up activities, beneficiary B is in charge of health and safety testing activities and beneficiary C is in charge of additional screening of target molecules as well as in charge of establishing a worldwide patent landscape mapping and an IPR strategy accordingly.

Maximum grant amount: EUR 150 000.

Lump sum share breakdown per beneficiary (Annex 2):

	Lump sum shares for the work	Total EU contribution
Beneficiary A	100 000	100 000
Beneficiary B	20 000	20 000
Beneficiary C	30 000	30 000
Total	150 000	150 000

Case 1:

At the end of the action, it appears that beneficiaries A and B fully completed their tasks. However beneficiary C completed only its tasks related to health and safety testing while it failed to establish a worldwide patent landscape mapping. The Agency decides to reduce by 10 % the lump sum share of beneficiary C corresponding to the proportion of the undelivered part of its work. In addition, the consortium breached its obligation to promote the action and its results under Article 38. The Agency decides to reduce the maximum grant amount by 10 % for that reason.

Final grant amount:

Lump sum share for accepted work of beneficiary A + Lump sum share for accepted work of beneficiary B + partial lump sum share for partly accepted work of beneficiary C = 100 000 + 20 000 + (30 000 – 10% of 30 000)

Amount resulting from Step 1: EUR 147 000

Grant reduction for other breaches: 10% grant reduction for the action = maximum grant amount – 10 % (reduction) = 150 000 – 15 000 = EUR 135 000.

Amount resulting from Step 2: EUR 135 000.

Lower amount of the two: EUR 135 000

Final grant amount: = EUR 135 000.

Case 2:

Work of beneficiary B and work of beneficiary C were not carried out (i.e. representing a total lump sum shares of EUR 50 000) and therefore the Agency reduced the grant accordingly.

Final grant amount:

Lump sum shares for accepted work: EUR 100 000

No grant reductions for other breaches.

Final grant amount: EUR 100 000 (➔ beneficiary shares: A = EUR 100 000; B = EUR 0; C = EUR 0)

Balance & Guarantee Fund release:

Payments made: EUR 127 500.

Balance: EUR 100 000 (final grant amount) - EUR 127 500 (payments made) = EUR - 27 500 (excess payments of EUR 27 500).

Offsetting against Guarantee Fund release: EUR 27 500 - EUR 7 500 (i.e. 5% of EUR 150 000) = EUR 20 000

Recovery:

Amount to be recovered from the consortium: EUR 20 000 (negative balance of EUR 20 000 must be paid back by the principal beneficiary, otherwise the Agency will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from the principal beneficiary:

The principal beneficiary does not reimburse the Agency and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 75 000; B= EUR 25 000; C = 27 500).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

*A: {(EUR 100 000 / (100 000 + 0) * 100 000 = EUR 100 000 (share in the final grant)} - EUR 75 000 (payments received) = EUR 25 000 (no payment in excess)*

*B: {0 / (100 000 + 0 + 0) * 100 000 = EUR 0 (share in the final grant)} - EUR 25 000 (payments received) = EUR – 25 000 (excess payment of EUR 25 000)*

*C: {0 / (100 000 + 0 + 0) * 100 000 = EUR 0 (share in the final grant)} - EUR 27 500 (payments received) = EUR – 27 500 (excess payment of EUR 27 500)*

Beneficiaries B and C received payment in excess of its EU contribution and will have to reimburse the Agency.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 52 500.

B: 25 000 /52 500 = 47.62 %.

C: 27 500 / 52 500 = 52.38 %.

Total to be recovered: EUR 20 000.

B: 47.62 % x 20 000 = EUR 9 524

C: 52.38 % x 20 000 = EUR 10 476

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 2 (Grant reductions) applies.

All other steps follow the General MGA *(see for the calculations Article 21 H2020 General MGA)*.

Examples for calculating recoveries after payment of the balance:

Case 1:

Grant with three beneficiaries (A, B, C).

Beneficiary A is in charge of scaling-up activities, beneficiary B is in charge of health and safety testing activities on 50 samples and beneficiary C is in charge of identifying application domains and establishing a market deployment strategy accordingly.

Maximum grant amount: EUR 150 000.

Lump sum share breakdown per beneficiary (Annex 2):

	Lump sum shares for the work	Total EU contribution
Beneficiary A	100 000	100 000
Beneficiary B	40 000	40 000
Beneficiary C	10 000	10 000
Total	150 000	150 000

Final grant amount:

Final grant amount: EUR 100 000 + EUR 40 000 + EUR 10 000 = EUR 150 000.

The Agency carries out a review on the action and finds out that beneficiary B carried out its health and safety testing activities on half of the number of samples foreseen (i.e. 25 out 50). The Agency therefore reduces the lump sum share of beneficiary B in proportion of the non-implemented work, i.e. 50% of EUR 40 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 40 000 (accepted lump sum shares) — EUR 20 000 (rejected lump sum shares) = EUR 20 000

Beneficiary B revised final grant amount: EUR 20 000.

The other beneficiaries final grant amounts (i.e. their final grant amount shares) remain unchanged.

Beneficiary balance:

The share of beneficiary B in the final grant amount = EUR 40 000 / 150 000 x 150 000 = EUR 40 000.

Balance: EUR 20 000 (revised final grant amount) – EUR 40 000 (final grant share) = EUR -20 000 (excess of EUR 20 000).

Recovery:

Amount to be recovered from beneficiary B: EUR 20 000 (negative balance of EUR 20 000 must be paid back by the beneficiary).

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

[…]

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

[…]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since (differently from ERC frontier research grants and the standard ERC PoC grants), ERC PoC Lump Sum Pilot grants do not use actual costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since beneficiaries have no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the implementation of the action (in particular full accomplishment of the work as described in Annex 1 of the GA), or on other aspects of the grant agreement, *such as promoting the action, visibility of EU funding, dissemination and exploitation of results, management of intellectual property, etc.*

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Agency or the Commission may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiaries that were audited.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **after termination of a beneficiary's participation, at the payment of the balance or afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** (including undue amounts paid by the Agency for lump sum shares declared by its linked third parties)***]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum grant amount indicated, for the linked third party, in the estimated lump sum breakdown (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter'** to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's approved lump sum share

[plus

its linked third parties' approved lump sum shares]},

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for the approved work calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

[…]

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{beneficiary's approved lump sum share

[plus

its linked third parties' approved lump sum shares]}

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for the approved work calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

[...]

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for ERC PoC Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(d) it does not comply with the provisions of the Agreement (see Article 20);

(e) the final report has not been submitted or is not complete or additional information is needed, or

(f) there is doubt about amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the final report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA *(see Article 47 H2020 General MGA)*.

The ERC PoC Lump Sum Pilot MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for ERC PoC Lump Sum Pilot grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work implementation).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

[…]

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20.4).

If the Agency does not receive the report within the deadline (see above), the lump sum will not be paid.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the report submitted and compliance with other obligations under the Agreement. Only part of the work completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

[…]

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the final report (see Article 20.4).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the payments received by the beneficiary exceed this amount.

Step 1 — Calculation of the lump sum share for the approved part of the work

If the beneficiary's part of the work is approved, the grant amount for the beneficiary corresponds to its lump sum share (see Annex 2) for the approved work declared in the termination report.

Only the part of the work completed by the beneficiary before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

[…]

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the report (see Articles 20.8 and 50.3.1(l)), the principal beneficiary may not submit any report after termination.If the Agency does not receive the report within the deadline (see above), the lump sum will not be paid.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the report submitted and compliance with other obligations under the Agreement. Only part of the work completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(a) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated lump sum breakdown (see Annexes 1and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the final report Article 20.4).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

The Agency will — on the basis of the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the pre-financing payment received by the beneficiary exceeds this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum share for the approved part of the work

If the beneficiary's part of the work is approved, the grant amount for the beneficiary corresponds to its lump sum share (see Annex 2) for the approved work declared in the termination report.

Only the part of the work completed by the beneficiary before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

1. GA termination (consortium or EU)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for ERC PoC Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21*).

2. Beneficiary termination (consortium or EU)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for ERC PoC Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the Agency has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

[…]

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

If a new beneficiary is added to a mono-beneficiary grant, the grant becomes a multi-beneficiary grant and the provisions will be applied accordingly.

Article 56.3 Transfer to a new beneficiary

In justified cases, the beneficiary of a mono-beneficiary grant may request the transfer of the action to a new beneficiary, provided that this would not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

For this purpose, the beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

The new beneficiary must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Transfer of the GA

In justified cases, ERC PoC Lump Sum Pilot mono-beneficiary grants can be **transferred** to a new beneficiary.

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (*Article 50*) or addition of a new beneficiary (*Article 56.2*).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains fully responsible until the Agency has approved the amendment.

The transfer may NOT entail changes to the GA which would call into question the decision to award the ERC PoC Lump Sum Pilot grant.

Example: *The Agency will not accept the transfer to a host institution established in a third country.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new beneficiary (signed directly in the Participant Portal) and the PI's justification letter.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 60 days from the transfer date or the date of signature of the amendment, whichever is the latest — a transfer report, with information on:

- the progress of the work and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to decide on how to split the lump sum share and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must also be uploaded later on with the final report (by the new beneficiary, together with its own financial statement).

The lump sum share will be split between the former beneficiary and the new beneficiary — on the basis of the part performed by the former beneficiary and the remaining part to be given to the new beneficiary. If the pre-financing received by the former beneficiary (see *Article 21*) exceeds the amount of its accepted lump sum share, the Agency will request the former beneficiary to transfer the difference to the new beneficiary.

The former and the new beneficiary must agree on arrangements, where necessary, concerning the transfer of the equipment, materials and/or services purchased for the principal investigator.

III. Marie Skłodowska-Curie Actions (MSCA) MGAs

III.1 Background information and approach

The Marie Skłodowska-Curie Actions (MSCA) Model Grant Agreements are used for grants for MSCA only, i.e.:

- MSCA-ITN
- MSCA-IF
- MSCA-RISE
- MSCA-COFUND and
- MSCA-SNLS.

The MSCA MGAs follow the General MGA for numbering and content, except for:

The H2020 MSCA-ITN MGA deviates from the General MGA — Multi as follows:

- Article 4.2 (MSCA-ITN specific conditions for budget transfers)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-ITN specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 21.7 (option for periodic instalments for distribution of payments by coordinator)
- Article 25.5 and 31.6 (access rights for researchers)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-IF MGA deviates from the General MGA — Mono as follows:

- Article 3 (notified starting date)
- Articles 4.2, 9-16, 41.4 and 41.5 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Articles 20.3 and 20.4 (options for reporting in case of only one RP; no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')
- Article 49.1 (MSCA-IF specific conditions for suspension of the action implementation)
- Article 50.3 (MSCA-IF specific conditions for termination)
- Article 55 (MSCA-IF specific conditions for amendments)
- Article 56a (MSCA-IF portability)

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-RISE MGA deviates from the General MGA — Multi as follows:

- Article 4.2 (specific conditions for budget transfer)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule)')
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9 - 16, 41.4 and 41.5 (not applicable)
- Article 18.1.2 (record keeping only for number of units declared)
- Article 19 (MSCA-RISE specific deliverables)
- Articles 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 and 31.6 (access rights for staff members)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 32 (MSCA specific obligations for recruitment and working conditions)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)
- Annexes 5 and 6 Not applicable

The H2020 MSCA-COFUND MGA deviates from the General MGA — Mono as follows:

- Article 4.2 (not applicable)
- Article 5.2 (specific reimbursement rate and form of costs)
- Article 5.3 (no 'Step 3 (reduction due to the no-profit rule))
- Article 6 (specific conditions for eligibility of costs)
- Article 8 (specific resources to implement the action)
- Articles 9-14, 16, 32, 41.4 and 41.5 (not applicable)
- Article 15 (provisions for support to or implementation of a programme)
- Article 18.1.2 (record keeping only for number of units declared and amounts paid to researchers)
- Article 19 (MSCA-COFUND specific deliverables)
- Article 20.4 (no certificate)
- Article 20.6 (currency for financial statement)
- Article 25.5 (access rights for the researcher)
- Articles 27.3, 28.2, 29.2, 29.4 and 38.1.2 (reference to MSCA funding)
- Article 38.1.1 (reference to 'mainstream media coverage')

- Annex 2 Model for the estimated budget for the action (specific)
- Annex 4 Model for the financial statement (specific)

The H2020 MSCA-SNLS MGA deviates from the General MGA — Mono as follows:

- Article 1 (linked grant)
- Article 4 (estimated lump sum breakdown, lump sum share transfers)
- Article 5 (maximum grant amount and form of grant)
- Article 6 (not applicable)
- Articles 9-16 (not applicable)
- Article 18 (special provisions for record-keeping)
- Articles 20, 21 (specific provisions for reporting and payments)
- Articles 23a-34 (not applicable)
- Article 37 (not applicable)
- Article 42 (not applicable)
- Article 44 (specific provisions for calculation of recoveries)
- Article 56 (not applicable)
- Article 56a (portability)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement
- Annexes 5 and 6 Not applicable

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 9-14, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for MSCA are added:

- Article 2 (MSCA-ITN; MSCA-IF; MSCA-RISE; MSCA-COFUND; MSCA-SNLS)
- Article 4.1 (MSCA-ITN budget categories; MSCA-IF budget categories ; MSCA-RISE budget categories; MSCA-COFUND budget categories; MSCA-SNLS estimated lump sum breakdown and lump sum share transfers)
- Article 8 (MSCA-ITN rules on third party involvement; MSCA-IF rules on third party involvement; MSCA-RISE rules on third party involvement; MSCA-COFUND rules on third party involvement; MSCA-SNLS rules on third party involvement)

III.2 H2020 MSCA-ITN MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-ITN actions

What? MSCA-ITN funds:

- joint research training and/or doctoral programmes for early-stage researchers (implemented by networks of beneficiaries from the academic and the non-academic sector from different countries).

MSCA-ITN takes the form of European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

MSCA-ITN are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-ITN-2015)*.

For more information on MSCA-ITN, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries.

This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[OPTION for all actions except EID with only two beneficiaries: *However, no more than 40% of the maximum grant amount (see Article 5.1) may be allocated to beneficiaries located in the same country or to any one international European interest organisation or international organisation.****]***

1. Budget categories

The MSCA-ITN MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-ITN MGA:

- costs for recruited researchers
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NOT** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary X was unable to implement six person-months, so the consortium informs REA of a redistribution of these months to beneficiary Y. REA agreed to this, but since beneficiary Y is located in a country where a higher country coefficient correction applies than in the country of beneficiary X, the budget transfer can only give 4.5 months to beneficiary Y.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for recruited researchers).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment *(see Article 55)* is required.

- correct application of the country correction coefficient

- the minimum and maximum recruitment durations per researcher

- for all actions except for EID with only two beneficiaries: a maximum of 40 % of the budget may be allocated to beneficiaries established in the same country (or to the same international European interest organisation or international organisation).

  The 40% is determined on the basis of the maximum grant amount.

  Example: *In an action with a maximum grant amount of EUR 3 000 000, beneficiaries from one country may not receive more than EUR 1 200 000 (= 40%). If the final grant amount is lower (e.g. because beneficiaries from other countries implement less person-months than expected) the original 40% ceiling of EUR 1 200 000 will be maintained (beneficiaries will not be penalised for the non-execution of person-months by other beneficiaries).*

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes (*e.g. to increase the salary of a researcher or to organise additional training activities)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes (*e.g. to increase the salary of a researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for recruited researchers** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Maximum grant amount

The maximum grant amount set out in this Article can NOT be exceeded.

For MSCA-ITN, the maximum grant amount is limited to a maximum unit cost equivalent of 540 person-months (and for EID with only two beneficiaries: 180 person-months).

2. Reimbursement rate

How much? For MSCA-ITN, the reimbursement rate is set at **100 %** *(see the H2020 Work Programme (section 3 MSCA))*.

3. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[73].

For MSCA-ITN, these are unit costs for:

- costs for recruited researchers: living allowance, mobility allowance and family allowance (if applicable)

[73] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they can NOT be changed.

The eligibility conditions are set out in *Article 6*.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5 H2020 General MGA*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for recruited researchers</u> (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researchers on the research training activities and

(ii) does not exceed 36 months (per researcher)*[;][, and]*

(iii) ***[OPTION for EID:** are, for each researcher, spent to at least 50% with one or more beneficiaries or partner organisations from the non-academic sector.**]***

(iv) ***[OPTION for EID:** if spent on inter-sectorial mobility between academic and non-academic beneficiaries (i.e. not partner organisations): are international (i.e. spent between beneficiaries established in different countries).]*

(v) ***[OPTION for EJD:** are, for at least two-thirds of the recruited researchers, spent in a joint, multiple or double degree programme with two or more beneficiaries or partner organisations stablished in EU Member States or associated countries.]*

(b) the recruited researchers comply with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

(ii) be employed for at least 3 months;

(iii) be employed full-time, unless the Agency has approved a part-time employment for personal or family reasons;

(iv) be working exclusively for the action;

(v) not have resided in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (and not have carried out their main activity (work, studies, etc.) in that country) – unless as part of a procedure for obtaining refugee status under the Geneva Convention[6].

For beneficiaries that are international European interest organisations or international organisations: not have spent with the beneficiary more than 12 months in the 3 years immediately before the recruitment date.

(vi) be — at the date of recruitment — an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);

(vii) ***[OPTION for 1 EJD:** be enrolled in a doctoral programme leading to the award of a joint, multiple or double degree in at least one EU Member State or associated country [;][.]**]***

(viii) ***[OPTION for 2 EID:** be enrolled in a doctoral programme.**]***

(c) the costs have been fully incurred for the benefit of the recruited researchers.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

The family allowance is due if the researcher has a family at the time of recruitment.

'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised) or dependent children who are actually being maintained by the researcher.

[6] 1951 Refugee Convention and the 1967 Protocol.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researchers, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)
- a monthly mobility allowance (A.2) — to cover costs related to their mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researchers, not professional costs (which are covered by budget category B.1 'research, training and networking costs')

AND

- a monthly family allowance (A.3) — for researchers with family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for each researcher; they can NOT be used to pay other researchers or other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

Example: *Costs for student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation can only be covered by the institutional unit costs.*

1.2 The costs must be **declared** as the unit costs fixed by Decision C(2017) 6855[74] and set out in Annex 2 and 2a of the GA.

This is currently:

– for the living allowance: **EUR 3 270** per researcher per month (person-month)

To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

The list of coefficients is published in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

On the basis of this list, the beneficiaries must determine the coefficient for each researcher when s/he is recruited — according to the country of recruitment. This coefficient normally does NOT change during the action (unless the researcher is formally employed — not only seconded to — by another beneficiary in another country during the action).

– for the mobility allowance: **EUR 600** per person-month

– for the family allowance: **EUR 500** per person-month.

For the latest information on the amounts and the country correction coefficients, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the periods of research training activities *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for researchers that:

  - are — at the date of recruitment — **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first 4 years (full time equivalent research experience) of their research career)

    '**Date of recruitment**' means the first day of the employment of the researcher for the purposes of the action (i.e. the starting date indicated in the employment contract/equivalent direct contract; *see Article 32)*. The Agency may however exceptionally accept a different date, if it is linked to the recruitment and justified *(e.g. by differences in the employment procedure in the country of recruitment)*.

[74] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

Example: *The date of the formal letter offering the position under the action or the date of the signature of the employment contract can also be accepted by the Agency as recruitment date.*

Years of '**research career**' are counted from the date on which the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- are recruited under an **employment contract/equivalent direct contract** (i.e. other contract with equivalent benefits and social security coverage), including:
  - sickness, parental, unemployment and invalidity benefits
  - pension rights and
  - benefits for accidents at work and occupational diseases.

  If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, beneficiaries may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:
  - sickness, parental and invalidity benefits and
  - benefits for accidents at work and occupational diseases.

  In this case, the living allowance will be reduced by 50%.

  The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

  Staff provided by a temporary work agency — Beneficiaries must always recruit researchers directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

- as a rule, be employed **full-time**

  Part-time employment can be accepted:
  - subject to prior approval by the Agency
  - on personal or family grounds only (i.e. not for professional reasons) and
  - if limited to a maximum of 50% of the time spent under the action.

  In the case of part-time employment, costs are reported as a pro-rata of the full-time unit cost.

  Example: *For one month of 50% part-time employment, 0.5 units should be reported.*

  ⚠ While it is not possible to request *part-time* employment for **professional reasons**, beneficiaries may — in exceptional cases — request an *interruption* of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

- **work exclusively** on the research training activities

  Work outside the action is not allowed. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities (and must be set out in Annex 1 of the GA).

- are supported for **at least 3 months**

  Person-months linked to shorter contracts will not be eligible.

However, this requirement is linked to the *duration of the contract* and not to the actual duration of the training. If the contract is set out for a longer duration, but the training is interrupted within the first three months for reasons not linked to the beneficiary *(e.g. because the researcher resigns)*, the costs may still be claimed.

- comply — at the date of recruitment — with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the recruiting beneficiary for more than 12 months in the 3 years immediately before the recruitment date (— unless the beneficiary is an 'international European interest organisation'[75] or international organisation, for whom the mobility rule is limited to time spent *with* them)

  The mobility rule applies only to the **first recruitment** under the action. For instance, it does not apply to beneficiaries or partner organisations to which the researcher is sent or seconded afterwards.

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[76] are NOT counted.

- for the doctoral programmes (EJD and EID): are enrolled in a **doctoral programme**

  For EJD:

  - the PhD-programme must lead to the award of:

    - a joint degree (i.e. a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries in which the degree-awarding institutions are located) or

    - a double or multiple degree (i.e. two or more separate national diplomas issued by two or more higher education institutions and recognised officially in the countries in which the degree-awarding institutions are located).

    in at least one EU Member State or H2020 associated country

  and

  - at least two-thirds of the recruited researchers must be enrolled in a joint, double or multiple degree programme within Europe, i.e. between two or more beneficiaries or partner organisations established in EU Member States or Horizon 2020 associated countries.

  The degree must not necessarily be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

- have been **fully incurred for** the benefit of the **researchers** (i.e. fully paid to the individuals for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowances must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

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[75] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[76] 1951 Refugee Convention and the 1967 Protocol.

Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researchers (gross amount).

MSCA-ITN researchers must NOT be requested to pay tuition fees for their research training and/or PhD degree programme (neither from their own funds, nor from the researcher unit cost). The costs that are usually covered by such tuition fees *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* can be reimbursed under category B 'institutional costs'.

The mobility and family allowances are due to the researchers for each month worked.

Mobility and family allowances can be paid to the researcher in various ways, *for example as*:

- *part of his/her salary*
- *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*
- *rental costs, directly paid or reimbursed by the beneficiary.*

Any form is acceptable, provided that:

- both sides agree
- it is allowed under national law

AND

- there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1 100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[77]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[78].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0.9 but this fluctuates from time to time. In order to ensure*

[77] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html.
[78] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm.

that the researcher receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0.87 and to make a payment to correct any underpayment at the end of the reporting period. The researcher is fully informed of this procedure at the time of recruitment.

The Agency will check if the allowances are used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

- for the family allowance: be incurred for researchers who have — at the date of the recruitment — a family, i.e.:
  - persons linked to them by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research training activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ Beneficiaries may declare a **maximum** of **36 person-months** per researcher. Person-months exceeding this number will be rejected by the Agency.

⚠ For EID: at least 50 % of the number of person-months declared for each researcher must have been spent in the non-academic sector.

This time does not have to be consecutive and may be split in time and between different beneficiaries/partner organisations/entities with a capital or legal link. The 50% must be reached by the end of the action (not before, *e.g. by the end of a specific reporting period*).

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary, *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 50% rule.

Inter-sectoral mobility between beneficiaries must be international (i.e. spent between beneficiaries established in different countries).

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence).*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researchers (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researchers' career development *(e.g. participation in conferences, trips related to work on the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - costs for visa-related fees and travel expenses
  - additional costs arising from each secondment of 6 months or less which require mobility from the place of residence *(e.g. travel and accommodation costs)*

    Example: *A researcher does doctoral research at a beneficiary in Italy for 36 months. During this time, she goes on a 4-month secondment to Poland. The beneficiary must cover her travel and accommodation costs in Poland for this 4-month period with the research, training and networking costs category.*
- management and indirect[79] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:
- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of a researcher or to organise additional training activities, to cover travel and accommodation costs for secondments of more than 6 months in line with the consortium internal arrangements)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of a researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[80] and set out in Annex 2 and 2a of the GA.

[79] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

This is currently:

- for research, training and networking costs: **EUR 1 800** per researcher per month (person-month)

- for management and indirect costs: **EUR 1 200** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[81] in the same period: only management costs, i.e. EUR 600 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for recruited researchers'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researchers.

Institutional costs (research, training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researchers are met. Person-months which are not eligible for budget category A 'costs for recruited researchers' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for recruited researchers:

- for the research, training and networking costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

- for the management and indirect costs:

  amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

[80] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[81] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), and in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon **entities with a capital or legal link** to the beneficiaries[7], to implement certain action tasks described in Annex 1 (i.e. hosting and training of researchers);
- call upon **partner organisations** to implement certain action tasks described in Annex 1 (i.e. hosting and training researchers during secondments).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[7] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-ITN allows the beneficiaries to use:

– entities with a capital or legal link to them

and

– partner organisations

to carry out work under the action (**third parties involved in the action**).

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-ITN grant (i.e. recruits the researchers), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-ITN action as entity with a capital or legal link implementing the research training activities, while the foundation or subsidiary participates as beneficiary (because it can recruit the researchers).

3. A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-ITN action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).

Entities with a capital or legal link may be used for hosting and training of researchers (including during secondments) — and can even implement ALL those activities under the action. But they can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary, tasks to be carried out and time spent with them).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as beneficiaries (for instance, be established in an EU Member State, H2020 associated country or third country listed in General Annex A to the H2020 Work Programme).

For more information on conditions for participation and funding, *see the H2020 Work Programme (section 3 MSCA).*

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers, but only during **secondments**.

Secondments — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country) in order to further enrich the training experience of the researchers.

They are limited to a **maximum of 30%** of the time that is declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researchers (only beneficiaries can recruit the researchers).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out and time spent with them).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations can be established anywhere (EU Member State, H2020 associated country or non-associated third country).

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have been granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-ITN uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for recruited researchers (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researchers.

[…]

1. Records and other supporting documentation

For MSCA-ITN, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researchers actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in *Article 32* were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researchers.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Agency.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after one year from the starting date of the action;
- organise a '**mid-term meeting**' between the beneficiaries, entities with a capital or legal link, partner organisations and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- establish a **supervisory board** of the network;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days after the recruitment of each researcher.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — within 30 days after the first year of the action — send to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

> **Best practice:** It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** after the recruitment date.

> It is important to give correct and complete information in the researcher declaration since the data will be automatically inserted in Annex 4 (financial statement), for calculating the living, mobility and family allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to background necessary for their research training activities under the action.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for researchers

The beneficiaries must — on a royalty-free basis — give access to the recruited researchers to results necessary for their research training activities under the action.

[…]

1. Access rights for researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA):*

The beneficiaries must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RECRUITED RESEARCHERS

32.1 Obligations towards recruited researchers

The beneficiaries must respect the following **recruitment and working conditions** for the researchers recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[16] and ensure that the researchers are aware of them;

(b) advertise and publish vacancies internationally, including on the web-sites requested by the Agency;

(c) recruit the researchers, following an open, transparent, impartial and equitable recruitment procedure, on the basis of:

(i) their scientific skills and the relevance of their research experience;

(ii) the impact of the proposed training on the researcher's career;

(iii) a fair gender representation (by promoting genuine equal access opportunities between men and women throughout the recruitment process);

(d) ensure that no conflict of interest exists in or arises from the recruitment;

(e) ensure that the researchers enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(f) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the starting date and duration of the research training activities under the action;

(ii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(v) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see *Article 17*);

(vi) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vii) the obligation of the researcher to maintain confidentiality (see Article 36);

(viii) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(g) assist the researchers in the administrative procedures related to their recruitment;

(h) inform the researchers about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(i) ensure that the researchers do not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiaries (or other entity mentioned in Annex 1);

(j) ensure that the researchers do not have to bear any costs for the implementation of the action as described in Annex 1;

(k) host the researchers at their premises (or at the premises of an entity with a capital or legal link);

(l) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(m) ensure that the researchers are adequately supervised;

(n) ensure that a career development plan is established and support its implementation;

(o) ensure an appropriate exposure to the non-academic sector;

(p) limit secondments to a maximum of 30% of the actual months spent implementing the research training activities under the action.

[…]

1. Recruitment and working conditions — Rights for the researchers

In view of the key role of the recruited researchers in MSCA-ITN, the MSCA-ITN MGA foresees a series of obligations in order to guarantee objective recruitment procedures and best possible working conditions.

Main obligations (towards the researcher):

- Advertise and **publish vacancies** internationally

  Beneficiaries must publish vacancies as widely as possible, including on the EURAXESS Jobs Portal[82]. They may also use their networks to ensure the widest possible dissemination of vacancies and information about the application process.

- Follow an open, transparent, impartial and equitable **recruitment procedure** (i.e. merit based, taking into account potential for their professional development and promoting equal access for women and men)

- Ensure that **no conflict of interest** exists in or arises from the recruitment (i.e. take or refrain from action, as appropriate, where the impartial and objective performance of recruitment duties is compromised for reasons involving:
  - family
  - emotional life
  - political or national affinity
  - economic interest or
  - any other shared interest)

- Ensure that the researchers enjoy at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position

- **Host** the researchers at their premises (or those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or ensure that this is provided by the entity with a capital or legal link).

[82] Available at http://ec.europa.eu/euraxess/

If the Agency finds that a beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.

- Ensure that the researchers are adequately **supervised**
- Ensure that a **career development plan** is established and support its implementation
- Ensure an appropriate **exposure to** the **non-academic sector**
- Ensure that **secondments** are **limited** to a **maximum** of **30 %** of the months declared for research training activities (i.e. the person-months for the researcher) — except in EID or EJD).

> ⚠ **Secondments** — For MSCA-ITN, secondments are (optional) additional periods of research training with another beneficiary or a partner organisation (from any country), in order to further enrich the training experience of the researchers *(see Article 8)*.

If the researcher unexpectedly leaves the action earlier (for reasons not linked to the beneficiary; *e.g. because s/he resigns*), the Agency may decide to nevertheless accept the costs — despite the 30% rule.

- Ensure that the researchers do NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiaries (or any other entity referred to in Annex 1)
- Ensure that the researchers do NOT have to bear **any costs** for the implementation of the action as described in Annex 1

  Recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training and/or PhD degree programme (*e.g. student registration,, access to student services (e.g. library, computing, etc.), teaching, supervision, examination and graduation)* neither from their own funds, nor from the researcher unit cost.
- Comply with the arrangements on **intellectual property rights**

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[83].
- **Assist** the researchers in the **administrative procedures** related to their recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[84].
- **Inform** the researchers about key elements of the grant

  Thus, beneficiaries must provide researchers with information on:
  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise them for the duration of the research training activities (including during secondments with other beneficiaries and/or partner organisations).

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:
  - the starting date of research training activities under the action and its duration
  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6.2 H2020 General MGA).*

[83] Available at https://www.iprhelpdesk.eu/.
[84] Available at http://ec.europa.eu/euraxess/.

The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

2. Employment contract — Obligations on the researchers

The MSCA-ITN GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researchers.

Main obligations (of the researchers):

- **Work exclusively** on the research training activities under the action

  This also means that a researcher can NOT hold two MSCA grants at the same time or engage in another professional activity or employment. Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from their beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** their beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  Researchers must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (consortium) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the

Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.3 H2020 MSCA-IF MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-IF actions

What? MSCA-IF funds:

- the recruitment of an experienced researcher for research training activities ('fellowship').

MSCA-IF take the form of European Fellowships (EF) and Global Fellowships (GF). European Fellowships include three additional funding strands: the 'Career Restart Panel', the 'Reintegration Panel' and the 'Society & Enterprise Panel'.

The MSCA-IF annotations are equally applicable to the Widening Fellowships *(see H2020 Work Programme (section 15 Spreading Excellence and Widening Participation))*.

MSCA-IF are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-IF-2014)*.

For more information on MSCA-IF, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [**insert number**] **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** the effective starting date notified by the beneficiary, which must be within [insert number] months from the date the Agreement enters into force] [**OPTION 3 if needed for the action:** [insert date]]*[4] ('**starting date of the action**').

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.

However, the MSCA-IF MGA provides for an additional option, where the actual starting date must be *notified* by the beneficiary (i.e. is not set by the Agency, but depends on the beneficiary).

In this case, there will be a **maximum deadline for notification** set out in Article 3 for both starting the action and notifying this to the Agency (normally 12 months from the entry into force of the GA).

The notification must be done directly in the Participant Portal.

Late notification will delay the pre-financing payment *(see Article 21.2 H2020 General MGA)*.

If the action does not start or the starting date is not notified in time, the Agency may terminate the GA *(see Article 50 H2020 General MGA)*.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-IF MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-IF MGA:

- costs for the recruited researcher
- institutional costs.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-IF is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the recruited researcher (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- The institutional unit cost should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (*including for GF outgoing phase; see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for the recruited researcher** (living, mobility and family allowances): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs and management and indirect costs): on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-IF, the reimbursement rate is set at **100 %** *(see the H2020 Work Programme (section 3 MSCA))*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[85].

For MSCA-IF, these are unit costs for:

- costs for the recruited researcher: living allowance, mobility allowance and family allowance (if applicable)
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[85] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 – ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs') if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(b) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant **can only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA : unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for the recruited researcher (A.1 Living allowance, A.2 Mobility allowance and A.3 Family allowance) are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the recruited researcher on the research training activities and

(ii) does not exceed *[**OPTION 1 by default:** 24] [**OPTION 2 for EF-CAR**: 36] [**OPTION 3 for GF**: 36]* months;

(b) the recruited researcher complies with the following conditions:

(i) be recruited by the beneficiary under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage, including periods of secondment to **'partner organisations'**;

(ii) be employed full-time, unless the Agency has approved a part-time employment for professional, personal or family reasons (see Article 55), and

(iii) be working exclusively for the action.

(c) the costs have been fully incurred for the benefit of the recruited researcher.

This latter condition is met if:

{{{**total remuneration costs** (salaries, social security contributions, taxes and other costs included in the remuneration under the employment contract or other direct contract) or **total fixed-amount fellowship costs** for the researcher during the action

plus

total mobility costs (household, relocation and travel expenses and, if they must be paid under national law, taxes, duties and social security contributions) for the researcher during the action}

plus

total family costs for the researcher during the action}

divided by

the number of actual units}.

is equal to or higher than the following amount:

{{amount per unit cost set out in Annex 2 as living allowance

plus

amount per unit cost set out in Annex 2 as mobility allowance}

plus

if it is due, amount per unit cost set out in Annex 2 as family allowance}.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the recruited researcher, by providing for:

- a monthly living allowance (A.1) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*)

- a monthly mobility allowance (A.2) — to cover costs related to his/her mobility *(e.g. relating to travel and accommodation)*

  This allowance covers *private* costs of the researcher, not professional costs (which are covered by category B.1 'research, training and networking costs').

AND

- a monthly family allowance (A.3) — if the researcher has family, to reduce family-related obstacles to researcher mobility.

⚠ **Budget flexibility** — There is NO flexibility as regards the *use* of the researcher unit costs (i.e. living, mobility and family allowances). They must be fully used for the researcher; they can NOT be used to pay other types of costs *(see Article 6.2.A(c))*.

What not? Management and indirect costs of the beneficiary are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017)6855 [86] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance: **EUR 4 880** for the researcher per month (person-month)

  To ensure equal treatment and purchasing power parity for all researchers, the amount for the living allowance is adapted per country, by applying a **country-specific correction coefficient**.

  The coefficient for the researcher is set by the Agency during grant preparation — on the basis of the list of coefficients of the H2020 Work Programme (section 3 MSCA) in force at the time of the call and according to the country of recruitment (i.e. the country of the beneficiary).

  For GF: there will be two different country-specific correction coefficients:

  - one for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
  - one for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

- for the mobility allowance: **EUR 600** per person-month

- for the family allowance: **EUR 500** per person-month.

ℹ For the latest information on the amounts and the country correction coefficients, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call*.

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for the researcher recruited under the action) and the costs are then automatically calculated by the IT system.

[86] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)

  Costs NOT incurred during the action implementation *(e.g. during maternity/parental leave)* are ineligible.

- be incurred for a researcher who:

  - is — at the date of the call deadline — an **experienced researcher** (i.e. have a doctoral degree OR have at least four years (full time equivalent research experience) of research career).

    Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

  - is recruited under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

    - sickness, parental, unemployment and invalidity benefits
    - pension rights and
    - benefits for accidents at work and occupational diseases

    If national law prevents it from recruiting the researcher under an employment contract/equivalent direct contract, the beneficiary may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

    - sickness, parental and invalidity benefits and
    - benefits for accidents at work and occupational diseases.

    In this case, the living allowance will be reduced by 50%.

    The social security coverage must be guaranteed for the entire action (i.e. also during optional secondments, if any, and for the GF outgoing phase).

    For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent coverage during the stay in the third country.

    Example: *A German university recruits the fellow for the total duration of the action (i.e. provides the main employment contract under the action) and sends him/her to a US university. Continuing the German social security during the stay in the US would be so expensive, that the beneficiary asks the US partner organisation to conclude an additional employment contract, in order to insure the researcher in the US.*

    Staff provided by a temporary work agency — The beneficiary must always recruit the researcher directly. Recruitments via other means *(e.g. temporary work agency)* are NOT allowed.

  - as a rule, be employed **full-time**

    Part-time employment can be accepted:

    - subject to prior approval by the Agency
    - on personal and family grounds

– on professional grounds (except during the outgoing phase for GF) in agreement with the beneficiary

– if limited to a maximum of 50% of the time spent under the action

Part-time employment for professional reasons can be requested in order to pursue supplementary activities, *such as creating a company, pursuing another research project, engaging in advanced studies not related to the MSCA grant, etc.* It cannot be requested in order to participate in another MSCA grant at the same time.

When part-time employment for professional reasons is accepted, the beneficiary must ensure reliable **time records** *(e.g. timesheets)* either on paper or in a computer-based time recording system.

In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

⚠ If NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

- **work exclusively** on the research training activities

  Work outside the action is NOT allowed (**—** unless part-time for professional reasons was approved). Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must not jeopardise the research activities (and must be set out in Annex 1 of the GA).

- have been **fully incurred for** the benefit of the **researcher** (i.e. fully paid to the individual for whom they are claimed)

  The beneficiary's costs (gross amount) for researcher remuneration, mobility and family allowance must be at least as high as the living, mobility and family allowances set out in Annex 2. Lower costs are considered as underpayment.

  Social security contributions and taxation (under national law) are to be counted as part of the beneficiary's costs for the recruited researcher (gross amount).

  The mobility and family allowances are due to the researchers for each month worked.

  Mobility and family allowances can be paid to the researcher in various ways, *for example as:*

  – *part of his/her salary*

  – *flight tickets for private travels, directly purchased or reimbursed by the beneficiary (work-related travels must be paid under category B.1 'research, training and networking costs')*

  – *rental costs paid or reimbursed by the beneficiary, etc.*

  Any form is acceptable, provided that:

  - both sides agree

  – it is allowed under national law

  AND

  – there is no underpayment.

Example: *Researcher X decides to rent an apartment of 750 EUR/month. If the beneficiary is willing to sign the rental agreement on behalf of the researcher and the researcher agrees with this form of payment, the beneficiary will use 750 EUR of the total amount of 1 100 EUR (mobility & family allowance) to pay the rent. The remaining 350 EUR must be paid as part of the salary (or in another acceptable form).*

Example: *Researcher Y intends to travel to his/her home country for the summer holidays. S/he requests the beneficiary to directly purchase the tickets for him/her, and the beneficiary agrees to do so. The tickets cost 450 EUR and the beneficiary pays the remaining 150 EUR of the mobility allowance as part of the salary (or in another acceptable form).*

⚠ Usually, payment as part of the salary is the **simplest** way to pay these allowances.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[87]
- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[88].

For ease of implementation, the monthly allowances for the recruited researcher can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researcher) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

Example: *Researcher X is recruited in a country outside the euro-zone. The average exchange rate is normally EUR 0,9 but this fluctuates from time to time. In order to ensure that the fellow receives a regular monthly income and to avoid exchange rate losses, the beneficiary chooses to apply a conservative exchange rate of EUR 0,87 and to make a payment to correct any underpayment at the end of the reporting period. The fellow is fully informed of this procedure at the time of recruitment.*

⚠ **Other conditions** — Although NOT formal cost eligibility conditions for MSCA-IF (because already checked by the Agency during the selection procedure), the recruited researcher must — at the date of the call deadline —:

- comply with the **mobility rule**, i.e. not have resided or carried out his/her main activity *(work, studies, etc.)* in the country of the beneficiary for more than 12 months in the 3 years immediately before to the call deadline (— unless the beneficiary is an 'international European interest organisations' or international organisations, for whom the mobility rule is limited to time spent *with* them)

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) are NOT counted.

  For EF Career Restart Panel, Reintegration Panel and Society & Enterprise Panel: specific mobility rule — not more than 3 years in the 5 years immediately before the call deadline

  For GF: the mobility rule is checked for the country of the partner organisation, not for the country of the beneficiary (i.e. where the outgoing phase takes place, not where the return phase takes place).
- for GF and EF Reintegration Panel: be nationals or **long-term residents** of a EU Member State or an H2020 associated country.

  'Long-term resident' means a period of legal and continuous residence in a EU Member States or H2020 associated countries for 5 or more consecutive years. Periods outside these countries will be taken into account if shorter than 6 consecutive months and all in all not more than 10 months.

[87] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html
[88] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

For EF Reintegration Panel: The long-term residence requirement will not apply to researchers who have obtained refugee status under the Geneva Convention (1951 Refugee Convention and the 1967 Protocol) in a EU Member State or H2020 associated country.

- for EF Career Restart Panel: not have been **active** in research for at least 12 months immediately before the call deadline

  'Active in research' means being employed or holding a scholarship. Parental leaves and unpaid leaves of absence will not be counted as periods of active engagement in research, even if a formal employment relationship exists during these periods. Publication activities or mere association to a university are not taken into account either.

- for the family allowance: have a **family**, i.e.
  - persons linked to the researcher by:
    - marriage or
    - a relationship with equivalent status to marriage (under the law of the country or region in which this relationship was formalised)

  or

  - dependent children who are actually being maintained by the researcher.

The Agency will check if the allowances are used fully for the benefit of the researcher. Any underpayments, if not corrected, may lead to a rejection of costs for the researcher.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

- for the living allowance:

  amount per unit *(see Annex 2)* **x** number of months actually spent by the researchers on the research activities ('number of implemented person-months')

- for the mobility allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

- for the family allowance:

  amount per unit *(see Annex 2)* **x** number of implemented person-months

⚠ The beneficiary may declare a **maximum** of **24 person-months** for the researcher (or **36 months** for GF and EF Career Restart Panel). Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the action, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by requesting an amendment to suspend the action; *see Article 49.1.1.2*).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence) and the action must be suspended.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the recruited researcher (living allowance, mobility allowance, family allowance; see above) are eligible.

1. Institutional costs (B.1): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training and networking activities that contribute directly to the researcher's career development *(e.g. participation in conferences, trips related to the work of the action, training, language courses, seminars, lab material, books, library records, publication costs)*
  - costs for research expenses
  - costs for visa-related fees and travel expenses
  - additional costs arising from secondments *(e.g. travel costs and accommodation costs for optional secondments)*
- management and indirect[89] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The institutional unit costs should be shared with entities with a capital or legal link which incurred costs for research training activities AND with partner organisations which incurred costs for hosting secondments (including for GF outgoing phase; *see Article 8*).
- The research, training and networking unit cost should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researcher or to organise additional training activities)*.
- The unit cost for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researcher)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[90] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 800** for the researcher per month (person-month)

[89] For the definition, *see Article 6.2 of the H2020 General MGA*: '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[90] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for management and indirect costs: **EUR 650** per person-month (if the beneficiary already receives an EU/Euratom operating grant[91] in the same period: only management costs, i.e. EUR 325 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

In practice, the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for the recruited researcher'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for the recruited researcher.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the recruited researcher are met. Person-months which are not eligible for budget category A 'costs for the recruited researcher' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without living allowance, etc.)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for the recruited researcher:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****]***.

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

[91] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon entities with a capital or legal link to the beneficiary[5], to implement certain action tasks described in Annex 1 (i.e. hosting and training of the researcher);
- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. hosting and training the researcher during secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

[5] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-IF allows the beneficiary to use:

– entities with a capital or legal link to it

and

– partner organisations

to carry out work under the action (**third parties involved in the action**).

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations).*

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to the beneficiary, which is neither limited to the action nor established for the sole purpose of its implementation).

Examples (entities with a capital or legal link):

1. *A university is beneficiary of an MSCA-IF grant (i.e. recruits the researcher), but part of the research training under the action takes place at its university hospital (which is part of the same structure, but a separate legal entity).*

2. *A large multi-national company (which uses a foundation or a subsidiary for all its HR management, including concluding the employment contracts and paying the staff) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation or subsidiary participates as beneficiary (because it is can recruit the researchers).*

3. *A university hospital (which is part of the public health system without legal personality on its own and which uses a foundation for its HR management) participates in an MSCA-IF action as entity with a capital or legal link implementing research training activities, while the foundation participates as beneficiary (because it can recruit the researchers).*

Entities with a capital or legal link may be used for hosting and research training of researchers (including during a secondment) — and can even implement ALL those activities under the action. But they can NOT recruit the researcher (only the beneficiary can recruit the researcher).

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of link with the beneficiary and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary (for instance, be established in an EU Member State or H2020 associated country).

Example: *For the EF Society & Enterprise Panel, the entities with a capital or legal link must also be from the non-academic sector.*

For more information on conditions for participation and funding, *see the H2020 Work Programme (section 3 MSCA).*

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to provide training and host researchers, but only during **a secondment**.

Secondments — For MSCA-IF, secondments are either:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country).

Optional secondments are limited to a **maximum of 3 months** (for actions with duration of up to 18 months) and **6 months** (for actions with duration of more than 18 months).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during a secondment.

Partner organisations can NOT recruit the researcher (only the beneficiary can recruit the researcher).

For GF: The third country partner organisation that hosts the beneficiary in the GF outgoing phase can (exceptionally) issue an additional employment contract to ensure equivalent social security coverage during the stay in the third country *(see Article 6)*.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations for optional secondments must be established in an EU Member State or H2020 associated country; partner organisations for GF outgoing phase must be established in a non-associated third country.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and that the costs for the recruited researcher (living allowance, mobility allowance, family allowance) have been fully incurred for the benefit of the researcher.

[…]

1. Records and other supporting documentation

For MSCA-IF, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contract (or other suitable documents, *e.g. fixed-fellowship agreement*)
- proof that:
  - the eligibility conditions for the researcher were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas, documents relating to recruitment procedure)*
  - the researcher actually worked on the action *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 32 were complied with
  - the living, mobility and family allowances (including the employer's compulsory social security payments) were fully paid to the researcher
  - in case of part-time for professional reasons, the work for the action has been reliably recorded *(through time-sheets, logbooks, counters etc.)*.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents will bear the **full risk** of cost rejection by the Agency.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give, access to the recruited researcher to results necessary for the research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees special access rights for him/her (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researcher **access** to both **background** AND **results** necessary for his/her research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** and **entities with a capital or legal link** (if any) give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR THE RECRUITED RESEARCHER

32.1 Obligations towards the recruited researcher

The beneficiary must respect the following **recruitment and working conditions** for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[12] and ensure that the researcher is aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the **employment contract**, other direct contract or fixed-amount-fellowship agreement (see Article 6) specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the monthly support for the researcher under this Agreement (in euro and, if relevant, in the currency in which the remuneration is paid);

(iv) the obligation of the researcher to work exclusively for the action;

(v) the obligation of the researcher not to receive for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(vi) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(vii) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(viii) the obligation of the researcher to maintain confidentiality (see Article 36);

(ix) the obligation of the researcher to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(x) *[OPTION for GF: the obligation of the researcher to carry out a mandatory return period of 12 months at the premises of the beneficiary;]*

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;
- the rights and obligations of the beneficiary toward the researcher under this Agreement;
- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency;

(f) ensure that the researcher does not receive, for activities carried out in the frame of the action, other incomes than those received from the beneficiary (or other entity mentioned in Annex 1);

(g) ensure that the researcher does not have to bear any costs for the implementation of the action as described in Annex 1;

(h) host the researcher at its premises (or at the premises of an entity with a capital or legal link);

(i) provide training and the necessary means for implementing the action (or ensure that such training and means are provided by entities with a capital or legal link);

(j) ensure that the researcher is adequately supervised;

(k) ensure that — at the beginning of the research training activities — a career development plan is established together with the supervisor;

(l) support the secondment of the researcher to a partner organisation in a Member State or associated country as set out in Annex 1:

- for actions with a duration up to 18 months: for a maximum of three months or
- for actions with a duration of more than 18 months: for a maximum of six months;

(m) ***[OPTION for GF:*** *support a maximum of 3 months spent by the researcher with the beneficiary (or an entity with a capital or legal link and/or a partner organisation) before the outgoing phase and the return of the researcher to the beneficiary (or an entity with a capital or legal link) to carry out a mandatory return period of 12 months.****]***

[…]

1. Recruitment and working conditions — Rights for the researcher

In view of the key role of the recruited researcher in MSCA-IF, the MSCA-IF MGA foresees a series of obligations in order to guarantee best possible working conditions.

Main obligations (towards the researcher):

- Ensure that the researcher enjoys at the place of the implementation at least the **same standards** and **working conditions** as those applicable to local researchers holding a similar position
- **Host** the researcher at its premises (or at those of an entity with a capital or legal link) and **provide training** as well as the necessary means for implementing the action (or to ensure that this is provided by the entity with a capital or legal link).

  If the Agency finds that the beneficiary is not supporting the research training activities in line with Annex 1 of the GA, it may reduce the grant.
- Ensure that the researcher is adequately **supervised**
- Ensure that — at the beginning of the research training activities — a **career development plan** is established and support its implementation
- **Support secondments** of the researcher (if any) and ensure that they are **limited** to a **maximum** of **3 months** (for actions of up to 18 months) or **6 months** (for actions of more than 18 months)

Secondments — For MSCA-IF, secondments can be:

- (optional) additional periods of research training with a partner organisation (from an EU Member State or H2020 associated country), in order to further enrich the training experience of the researcher

and/or

- for GF: (mandatory) outgoing phase with a partner organisation (from a third country) *(see Article 8)*

For GF: Also support time spent by the researcher with the beneficiary (or an entity with a capital or legal link and/or a partner organisation) before the outgoing phase (limited to a maximum of 3 months) and the researcher's return (mandatory return-period must always be 12 months)

- Ensure that the researcher does NOT receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

- Ensure that the researcher does NOT have to bear **any costs** for the implementation of the action as described in Annex 1

  The recruited researcher must NOT be requested to pay visa-related fees or tuition fees for the research training neither from his/her own funds, nor from the researcher unit cost.

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[92].

- **Assist** the researcher in the **administrative procedures** related to his/her recruitment *(e.g. helping with visa procedures or preparing the career development plan)*

  Assistance with relocating researchers can be obtained via *EURAXESS Services*[93].

- **Inform** the researcher about key elements of the grant

  Thus, the beneficiary must provide the researcher with information on:

  - basic facts about the Marie Skłodowska-Curie actions, to make the researcher aware that s/he is a **MSCA fellow**, including:
    - the researcher's rights and obligations and
    - where to look for details (MSCA website, Participant Portal, Marie Curie Alumni Association (MCAA), etc.)
  - the specific action in question *(e.g. planned secondments, events, etc.)* and
  - whom they have appointed to supervise him/her for the duration of the research training activities, including during optional secondments/GF outgoing phase with partner organisations.

  Moreover, the employment contract/equivalent direct contract (or fixed-amount-fellowship agreement) contract must clearly state:

  - the starting date of research training activities under the action and its duration

    The starting date and duration must match those in Article 3 of the GA.

  - the allowances that the researcher is entitled to receive (and if this is paid in a currency other than the euro, the exchange rate; *for the exchange rate, see Article 6).*

    The employment contract can state the total/annual salary — as long as it is possible to determine the monthly salary *(e.g. by dividing the annual salary by 12)*.

[92] Available at https://www.iprhelpdesk.eu/.
[93] Available at http://ec.europa.eu/euraxess/.

2. Employment contract — Obligations on the researcher

The MSCA-IF GA foresees that there must be an employment contract/equivalent direct contract (or fixed-amount-fellowship agreement), in order to formalise the commitments in the GA also towards the researcher.

Main obligations (of the researcher):

- **Work exclusively** on the research training activities

  This also means that a researcher can NOT hold two MSCA grants at the same time, or engage in another professional activity or employment — unless part-time employment for professional reasons has been approved (see Article 55). Complementary skills training *(e.g. teaching activity as part of the research training)* is possible, but must NOT jeopardise the research activities (and must be set out in Annex 1 of the GA).

- **Not** receive (for activities carried out in the frame of the action) **other incomes** than those received from the beneficiary (or any other entity referred to in Annex 1)

  Example: *If the researcher's allowances fall short of the legal minimum salary in the country in question, the beneficiary (or other entity in Annex 1) may pay a top-up to make up the difference.*

- **Inform** the beneficiary as soon as possible of any events or circumstances likely to affect the GA *(such as, significant changes to their career development plan or personal circumstances affecting the foreseen activities)*

- Comply with the arrangements related to the **intellectual property rights**

- Maintain **confidentiality**

- Ensure the **visibility of EU funding**

  The researcher must acknowledge funding under the MSCA grant in publications, communications or patent applications.

- Complete and submit — at the end of the training — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiary must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and

(b) include the following statement:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give it the right to exclusive use.

Moreover, it may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the actions are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the MSCA-IF beneficiary (in all actions except MSCA-IF Widening Fellowships) must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation by the beneficiary

49.1.1 Conditions — Procedure

49.1.1.1 The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

In this case, the beneficiary must immediately formally notify suspension to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.1.1.2 The beneficiary may request suspension of the action implementation (or any part of it) for **professional, personal or family reasons** (including parental leave).

For this purpose, the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55.

The suspension **will take effect** on the date set out in the amendment.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

[…]

1. GA suspension — Additional grounds for suspension: Professional, personal or family reasons (beneficiary)

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, the beneficiary in MSCA-IF actions may request suspension for professional, personal or family grounds of the recruited researcher *(including parental leave, long-term sick leave or another professional opportunity)*.

Suspension must be requested if the researcher is absent for more than 30 consecutive days (for reasons other than normal annual leave).

2. Procedure

The beneficiary must submit a request for amendment, indicating:

- the starting and (planned) end date of the suspension and
- the (planned) resumption date when the action will be resumed (i.e. automatically end date +1 day).

In principle, suspensions (other than for parental leave) should **not exceed 30 %** of the action duration.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

3. Effects

Costs incurred during the suspension are NOT eligible *(see Article 6.3)*.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

The beneficiary may, in particular, request a **change of the time spent on the action** (part-time employment) for professional, personal or family reasons (including parental leave).

[…]

1. Amendments — Additional ground for amendments: Change to part-time employment (beneficiary)

What? For MSCA-IF, the beneficiary may request an amendment to change the time the researcher spends on the action (i.e. from full-time to part-time, part-time to full-time or to a different percentage of part-time) — on professional, personal or family grounds (including parental leave).

If NOT possible to request *part-time* employment for **professional reasons**, beneficiaries may request a GA suspension to *interrupt* the employment *(see Article 49.1.1.2)*.

How? The amendment should be requested immediately (retroactive change is possible, if justified; *see Article 55 H2020 General MGA*).

The action duration will be automatically adapted (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months, so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working time; AT23 clause) and the reporting periods will be changed (to adapt them to the new action duration; AT25 clause).

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

The beneficiary may request that the research training activities are transferred to a new beneficiary, if there are serious reasons affecting its capacity to implement the action (without being entitled to any additional EU funding for doing so).

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher and its supervisor;
- a proposal for the necessary changes, including — if necessary — the appointment of the new supervisor and the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes in order to reallocate the tasks of the former beneficiary (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The maximum grant amount will be split between the former beneficiary and the new beneficiary, on the basis of the number of actual units in line with Article 6.

The former and the new beneficiary must agree on arrangements concerning the management of intellectual property rights and other issues under the Agreement.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-IF grants can be **transferred** to a new beneficiary.

⚠ **Transfer —** The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (Article 50) or addition of a new beneficiary (Article 56).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains **fully responsible** until the Agency has approved the amendment.

The transfer may be based on any **ground** that is linked to the beneficiary and affects objectives of the action (i.e. implementing the research training activities).

Examples: *Internal reorganisation affecting implementation of the action; dismantling of the research team involved in the action; departure of the supervisor from the beneficiary's premises; serious conflict between the researcher and the supervisor.*

Personal circumstances of the researcher *(e.g. other professional opportunities, personal or family commitments)* are NOT considered valid grounds for transferring the GA to a new beneficiary. These must be addressed by suspending the action *(see Article 49.1)* or a switch to part-time employment *(see Article 55)*.

The transfer may NOT entail changes to the GA which would call into question the decision to award the grant or breach the principle of equal treatment of applicants.

Example: *The transfer will not be accepted if the new beneficiary does not fulfil the eligibility conditions or does not have sufficient financial and operational capacity.*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The 'transfer date' should normally be the date the researcher starts working with the new beneficiary. In order to allow for full synchronisation of dates, chose the entry into force of the amendment (i.e. not a fixed date) as transfer date and put this date also as starting date in the employment contract for the researcher. If there is a gap in employment (between transfer date and employment starting date at the new beneficiary), request an amendment to suspend the action (AT82; must be done before the end of the action).

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the Agreement) of the new beneficiary (signed directly in the Participant Portal).

The **maximum grant amount/action duration** will be adapted to take into account the country correction coefficient of the new beneficiary.

⚠ The maximum grant amount *(see Article 5)* will **NOT** be **increased**.

If the new beneficiary is in a country with a lower country correction coefficient, the maximum grant amount *(see Article 5.1) will be lowered*.

If the new beneficiary is in a country with a higher country correction coefficient, the action duration will normally be adapted, so that the maximum grant amount can stay the same. If (exceptionally) the action duration is not changed, the beneficiary must top-up the salary of the researcher and pay the difference between the former and the new correction coefficient *(using e.g. the management and indirect costs or own funding)*.

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date or the date of signature of the amendment, whichever is the latest — a transfer report, with information on:

- the progress and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to check the eligible costs and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must also be uploaded later on with the next periodic report (by the new beneficiary, together with its own financial statement).

The maximum grant amount will be split between the former beneficiary and the new beneficiary — on the basis of the researcher months already spent with the former beneficiary.

The former and the new beneficiary must agree on arrangements, where necessary, concerning intellectual property and other issues.

III.4 H2020 MSCA-RISE MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-RISE actions

What? MSCA-RISE funds:

- the exchange of staff members (between beneficiaries or between a beneficiary and a partner organisation) for research and innovation activities ('secondments').

> **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

MSCA-RISE are multi-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-RISE-2014)*.

> For more information on MSCA-RISE, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*
>
> For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and **budget category** (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between the beneficiaries.

This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

1. Budget categories

The MSCA-RISE MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-RISE MGA:

- costs for seconded staff members
- institutional costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

The beneficiaries may redistribute person-months between *them* (as compared with the original planning set out in Annex 2). This redistribution can be done without requesting an amendment *(see Article 55 H2020 General MGA)* — provided that it does not imply a substantial change to the action as described in Annex 1.

⚠ The maximum grant amount *(see Article 5)* can however **NOT** be **increased**.

Best practice: The coordinator should **inform** the Agency in advance of any redistribution of person-months, in order to establish if an amendment is needed. Changes that only concern the consortium-internal arrangements on the redistribution of the unit costs for management and indirect costs do NOT need to be notified to the Agency.

Example: *Beneficiary A plans to second 24 person-months, but can finally only implement 22. At the same time, beneficiary B is able to implement 2 additional person-months compared to the original planning. In this case, the budget transfer between the beneficiaries is possible without an amendment.*

A redistribution of person-months will also have an impact on the institutional unit costs (since they are also paid according to the person-months declared for seconded staff members).

Redistributions are subject to the following:

- no impact on the action as described in Annex 1

  If the transfer of person-months implies a substantial change of Annex 1, a formal amendment is required.

- the minimum and maximum secondment duration.

Transfers between *budget categories* are formally NOT possible, because all budget categories are linked to the *same* person-months declared for the seconded staff (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

Budget flexibility — There is however some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs a staff member, to organise additional training activities or horizontal networking events)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **100 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**form of costs**'):

(a) for **costs for seconded staff members**: on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**') and

(b) for **institutional costs** (research, training and networking costs, management and indirect costs): on the basis of the amount per unit set out in Annex 2 **(unit costs**).

1. Reimbursement rate

How much? For MSCA-RISE, the reimbursement rate is set at 100% *(see the H2020 Work Programme (section 3 MSCA)).*

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[94].

For MSCA-RISE, these are unit costs for:

- costs for seconded staff members: top-up allowance
- institutional costs: research, training and networking costs and management and indirect costs.

These are fixed amounts that must be multiplied by the number of months the staff were seconded and spent on research and innovation activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[94] Commission Decision C(2017)6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiaries and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced grant amount following Step 3.

[…]

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in MSCA MGAs (Step 3 of Article 5.3 of the General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('eligible costs'), if:

(i) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units}.

(ii) the number of actual units complies with the following:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

⚠ ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiaries. They must keep sufficient supporting documents *(see Article 18)* to show that the person-months they declare are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. <u>Costs for seconded staff members</u> are eligible, if:

(a) the number of units declared:

(i) corresponds to the actual number of months spent by the seconded staff members on the research and innovation activities and

(ii) does not exceed 12 months (per seconded staff member);

(b) the seconded staff members comply — at the date of secondment — with the following conditions:

(i) be one of the following:

- an '**early stage researcher**' (i.e. in the first four years of his/her research career and not have a doctoral degree);
- an '**experienced researcher**' (i.e. in possession of a doctoral degree or have at least four years of research experience), or
- **administrative, managerial or technical staff** supporting research and innovation activities under the action, and

(ii) have been actively engaged in or linked to research and innovation activities for at least 1 month at the sending:

- beneficiary (or entity with a capital or legal link[6] to it and located in the same country), or
- partner organisation (or entity with a capital or legal link to it and located in the same country).

(c) the secondments comply with the following conditions:

(i) last at least 1 month and no longer than 12 months (per secondment);

(ii) be between different countries;

(iii) for secondments within the EU (or associated countries)[7]: be between different sectors (academic and non-academic)[8];

(iv) for secondments from EU (or associated countries): be from a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country) to a partner organisation (or entity with a capital or legal link) established in a non-EU Member State (or non-associated country), and

(v) for secondments to EU (or associated countries): be from a partner organisation (or entity with a capital or legal link) established in a country listed in General Annex A of the Main Work Programme to a beneficiary (or entity with a capital or legal link) established in a EU Member State (or associated country).

[6] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] For secondments for entities with a capital link or legal link to the beneficiaries or partner organisations: only the sector (academic or non-academic) of the beneficiary counts; the entity will be considered to belong to the same sector as their beneficiary.

1. Seconded staff costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the seconded staff members, by providing for:

- a monthly top-up allowance (A) — for travel, accommodation and subsistence costs relating to the secondment.

> ⚠ **Budget flexibility —** There is NO flexibility as regards the *use* of the seconded staff unit costs (i.e. top-up allowance). They must be fully used for the staff member (to cover the travel, accommodation and subsistence costs of the staff member); they can NOT be used to pay other staff members or other types of costs *(see Article 32)*.
>
> ⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

What not? Research, training and networking costs and management and indirect costs of the beneficiaries are not covered under this budget category; they are covered under category B 'institutional costs' (*Article 6.2.B*).

1.2 These costs must be **declared as** the unit cost fixed by Decision C(2017) 6855[95] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the top-up allowance: **EUR 2 100** per seconded staff member per month (person-month).

> ℹ For the latest information on the amount, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiaries must only indicate the number of implemented person-months (for staff members seconded under the action) and the costs are then automatically calculated by the IT system.

1.3 The costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- be incurred for staff members that — at the date of secondment —:
  - are one of the following three:
    - **early stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full time equivalent research experience) of their research career)
    - **experienced researchers** (i.e. have a doctoral degree OR at least four years (full time equivalent research experience) of research career), or

[95] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

- **administrative, managerial** or **technical staff supporting research and innovation activities** (i.e. actively involved in the R&D activities of the organisation and not with a purely administrative role).

  Examples (not eligible administrative, managerial or technical staff):

  1. *Ms B, employed by beneficiary B as an accountant, is not eligible for secondment as her tasks are not directly related to support research and innovation activities.*

  2. *Mr Y, employed by beneficiary/partner organisation Y and carrying out secretarial tasks, is not eligible for secondment because he is not directly involved in research and innovation activities.*

  Years of '**research career**' are counted from the date on which the researcher obtained the degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited or from where s/he is seconded) — even if a doctorate was never started or envisaged.

- have already been actively **engaged** in or **linked** to research and innovation activities at the premises of the sending beneficiary/partner organisation/entity with a capital or legal link, continuously for at least **1 month** (full time equivalent)

  Examples:

  1. *Mr Y is employed by/has a fellowship with/is a registered PhD candidate of beneficiary Y as from 1 January 2014; Mr Y will not be eligible for a secondment from 1 January 2014 but would be eligible for secondment as from 1 February 2014.*

  2. *Ms X is employed 50% part-time by beneficiary X as from 1 January 2014. Ms X will not be eligible for a secondment from 1 February 2014, but would be eligible for secondment as from 1 March 2014.*

  The type of relationship (employment contract, fellowship or other) is NOT relevant — as long as it:

  - complies with national law
  - complies with internal practices and
  - during the secondment: confers to the sending beneficiary/partner organisation/entity with a capital or legal link the necessary legal means in terms of controls and instructions to ensure the implementation of the activities in line with GA obligations.

    If this is not the case, the beneficiary/partner organisation/entity with a capital or legal link must conclude a contract which allows this (or a supplementary agreement) — before the secondment.

    Example: *A PhD-candidate can be seconded if s/he: has a contract allowing him/her to work full-time on the R&I activities of the action during the secondment under the instructions of the sending beneficiary/partner organisation/entity with a capital or legal link.*

- be incurred for secondments:

  - that last at **least 1 month** and **no longer than 12 months**

    Splitting into several periods is allowed.

    Example: *If a secondment is split into two-week periods, the person-month may be claimed (since the one-month minimum is satisfied). However, if the staff member participates only in the first two-week period and the second one never takes place, the beneficiary may not claim any person-months for the secondment.*

    Best practice: If the split is not already indicated in Annex 1, the coordinator should inform the Agency before the secondment.

    For the minimum duration, only splits within *secondments of* same staff, from same sending beneficiary/partner organisation to same hosting beneficiary/partner organisation can be added. Secondments from/to entities with a capital or legal link

will be counted as secondments from/to the beneficiaries/partner organisations they are linked to.

Example: *Two secondments of two weeks of the same staff member to different beneficiaries are not eligible since the minimum duration of 1 month is not reached.*

For the maximum duration, all secondments (and all splits) for the *same staff member* must be added.

- that are one of the following three:
  - secondments **between beneficiaries/entities with a capital or legal link** in different EU Member States (or H2020 associated countries) and between different sectors, i.e. academic and non-academic

    Both elements must be fulfilled (i.e. location in **different** EU Member States or H2020 associated **countries** AND **different sectors** (academic and non-academic sector).

    'Academic sector' means:

    - public or private higher education establishments awarding academic degrees
    - public or private non-profit research organisations whose primary mission is to pursue research or
    - international European interest organisations.

    'Non-academic sector' means any socio-economic actor not included in the academic sector.

  - secondments from a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country) **to** a **partner organisation/entity with a capital or legal link** in a third country

  OR

  - secondments **from** a **partner organisation/entity with a capital or legal link** in a third country listed in General Annex A to the H2020 Work Programme **to** a **beneficiary/entity with a capital or legal link** in an EU Member State (or H2020 associated country).

  Secondments from/to branches/departments of beneficiaries/partner organisations which are not separate legal entities are NOT eligible, if they are located in countries other than the country of their beneficiary/partner organisation.

  Examples:

  A and B exchange staff for 12 months within a RISE project. A sends 10 persons to B for one year (i.e. 120 person-months) and B sends the same number to A (also 120 person-months).

  Case 1: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country listed in General Annex A to the H2020 Work Programme.*
  A may claim 240 person-months (120 for its own staff and 120 for the staff seconded by the partner organisation).

  Case 2: *A is a beneficiary established in an EU Member State or H2020 associated country and B is a partner organisation established in a third country NOT listed in General Annex A to the H2020 Work Programme.*
  A may claim only 120 person-months (for its own staff; the person-months of the staff seconded by the partner organisation are not eligible).

  Case 3: *A and B are both beneficiaries established in an EU Member State or H2020 associated country.*
  They may each claim 120 person-months (for their own staff).

  If a person is a staff member of two or more organisations which participate in a RISE project, s/he can NOT be seconded *from* both organisations.

Example: *A researcher is both professor at the university and CEO of its own SME and both organisations are involved in a RISE project. This researcher can only be seconded from one of the two organisations.*

By contrast, a staff member can be seconded from one participating organisation *to* two or more participating organisations in a RISE project — as long as the total person-months per staff member do not exceed 12 *(see also Article 19)*.

⚠ **Other conditions** — Although NOT a cost eligibility condition for MSCA-RISE, but an 'other obligation' under Article 32:

- the top-up allowance must be fully used for the staff member (i.e. fully used to cover the travel, accommodation and subsistence costs of the staff member for whom it is claimed).

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the top-up allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the seconded staff members on the research and innovation activities (including travel) ('implemented person-months')

⚠ Beneficiaries may declare a **maximum** of **12 person-months** per seconded staff member. Person-months exceeding this number will be rejected by the Agency.

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *A staff member is seconded from a beneficiary to a partner organisation from 12 March to 25 August. The calculation is five months (from 12 March to 11 August) plus 14/30 (for the 14 days from 12 to 25 August). In this case, insert 5.47 as number of person-months.*

B. Institutional costs (B.1 Research, training and networking costs and B.2 Management and indirect costs) are eligible if the costs for the seconded staff members (see above) are eligible.

1. Institutional costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers**:

- research, training and networking costs (B.1) — for:
  - costs for training, transfer of knowledge and networking activities
  - costs for research expenses
- management and indirect[96] costs (B.2) — for the beneficiary's additional costs in connection with the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility —There is some flexibility as regards the *use* of the amounts received:

- Redistributions of institutional unit costs within the consortium are allowed, but should be done via an internal agreement.
- Institutional unit costs should also be shared with entities with a capital or legal link and partner organisations which incurred costs for hosting secondments *(see Article 8)*.
- Research, training and networking unit costs should be used for the research, training and networking activities foreseen in Annex 1, but unused amounts may be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.
- Unit costs for management and indirect costs should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to cover travel and subsistence costs of a staff member, to organise additional training activities or horizontal networking events)*.

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[97] and set out in Annex 2 and 2a of the GA.

This is currently:

- for research, training and networking costs: **EUR 1 800** per researcher per month (person-month)
- for management and indirect costs: **EUR 700** per person-month (for beneficiaries that already receive an EU/Euratom operating grant[98] in the same period: only management costs, i.e. EUR 350 — unless they can demonstrate that the operating grant does not cover any costs of the action; *see Article 6.2.E H2020 General MGA*).

[96] For the definition, *see Article 6.2 of the H2020 General MGA:* '**indirect costs**' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[97] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

[98] For the definition, *see Article 121(1)(b) of the Financial Regulation No 966/2012*: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting EU policy.

In practice the declaration of institutional costs for MSCA grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared under budget category A 'costs for seconded staff members'.

1.3 The **eligibility** of the institutional costs is directly linked to (and conditional on) the eligibility of the costs for seconded staff members.

Institutional costs (research training and networking costs, management and indirect costs) are eligible only if ALL the eligibility conditions for the seconded staff members are met. Person-months which are not eligible for budget category A 'costs for seconded staff members' are also not eligible for budget category B 'institutional costs'.

Institutional costs can NOT be claimed separately *(e.g. management and indirect costs cannot be claimed without top-up allowance)*.

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for seconded staff members:

– for the research, training and networking costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

– for the management and indirect costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the seconded staff unit cost)

⚠ **Budget flexibility** — Even if the consortium redistributes parts of the institutional unit costs, the reporting is always based on the implemented person-months.

6.3 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1), in particular costs incurred during suspension of the action implementation (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget), in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]*]*.*

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff);
- call upon entities with a capital or legal link to the beneficiaries or to partner organisations[9], to implement certain action tasks described in Annex 1 (i.e. seconding and hosting staff).

In this case, the beneficiaries retain sole responsibility towards the Agency for implementing the action.

[9] '**Entities with a capital or legal link**' are entities that have a link with the beneficiary or partner organisations, in particular, a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do NOT apply.

Instead, MSCA-RISE allows the beneficiaries to use:

– partner organisations

and

– entities with a capital or legal link to a beneficiary or a partner organisation

to carry out work under the action (**third parties involved in the action**).

Beneficiaries using third parties remain **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, beneficiaries should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article 1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiaries; no additional costs will be reimbursed by the Agency. (Beneficiaries are however encouraged to share the unit costs received with them.)

Partner organisations are third parties involved in the action without a (capital or legal) link to a beneficiary.

They may participate in the exchanges by seconding and hosting staff.

⚠ **Secondments —** For MSCA-RISE, secondments are the core activity of the action. They can be between beneficiaries/entities with a capital or legal link OR between beneficiaries/entities with a capital or legal link and partner organisations (from a third country).

They must have a **minimum** duration of **1 month** and a **maximum** duration of **12 months** (per seconded staff member).

The beneficiaries remain **fully responsible** for the action implementation (in accordance with the GA) during the secondments.

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Partner organisations must be established in a non-associated third country (i.e. not EU Member State or H2020 associated country).

Entities with a capital or legal link are similar to **linked third parties** under Article 14 of the H2020 General MGA (i.e. entities with a link to a beneficiary or a partner organisation — which is neither limited to the action nor established for the sole purpose of its implementation).

They may participate in the exchanges by seconding and hosting staff.

Their involvement must be clearly described in Annex 1 (in particular, name of the entity, type of the link with the beneficiary/partner organisation and tasks to be carried out).

Contrary to linked third parties under Article 14 of the H2020 General MGA, however, entities with a capital or legal link can NOT claim costs separately (since their costs are covered by the unit costs paid to the beneficiaries).

Entities with a capital or legal link must fulfil the same conditions for participation and funding under H2020 as the beneficiary/partner organisation they are linked to (for instance, if linked to a beneficiary: be established in an EU Member State or H2020 associated country; if linked to a partner organisation: be established in a non-associated third country AND be established in the same country as their beneficiary/partner organisation.

Examples (eligible entities with capital or legal link):

1. *University X (established in France) is part of a Joint Research Unit (JRU) with beneficiary Y (also established in France). Mr. X is employed by university X and is to be sent on a secondment to beneficiary Z. University X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

2. *SME X (established in Portugal) is a subsidiary of beneficiary Y (also established in Portugal). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. SME X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Ms. X.*

3. *Mr. X is formally employed by foundation X (established in Spain) which does the HR management for beneficiary Y (also established in Spain). Mr. X actually works with beneficiary Y and should be sent on a secondment to beneficiary Z. Foundation X will be considered as entity with a capital or legal link to beneficiary Y and can therefore second Mr. X.*

Examples (ineligible entities with capital or legal link):

1. *SME X (established in Germany) is a subsidiary of applicant Y (established in Greece). Ms. X is employed by SME X and is to be sent on a secondment to partner organisation Z. Since SME X is not established in the same country as applicant Y, it cannot act as entity with a capital or legal link for the purposes of a MSCA-RISE grant. Therefore, Ms X cannot be seconded.*

2. *University X (validated as academic; established in Sweden) is member of an association of universities (applicant Y; validated as non-academic). Mr. X is employed by university X and is to be sent on a secondment to applicant Z (validated as academic). University X cannot act as entity with a capital or legal link of applicant Y for the purposes of the MSCA-RISE grant because this would circumvent the inter-sector mobility rules (mix of academic and non-academic).*

ℹ For more information on conditions for participation and funding, *see the Main H2020 Work Programme (section 3 MSCA).*

Specific cases (third parties involved in the action):

Authorisation to administer — Coordinators that are secondary or higher education establishments and coordinators that are public bodies may exceptionally delegate the administration of the payments to another legal entity (third party), in most cases a foundation.

The third party must fulfil the following conditions:

- it must have granted an 'authorisation to administer' by the coordinator

AND

- it must be affiliated, controlled or set up by the coordinator in order to handle its administrative affairs, including receiving and administering EU funds.

> ⚠ **Project management** — Coordination and administration tasks are considered **action tasks**.
>
> ⚠ Coordinators using a third party with authorisation to administer remain **fully responsible** for it under the GA.

In this case, the option in Article 41.2(b) for authorisations to administer must be added to the grant agreement. The bank account number to be provided under Article 21.8 must be that of the entity with the authorisation to administer and the payments will be transferred directly to it. The entity must therefore be registered in the Participant Register and validated by the Commission/Agency. It will get its own PIC — although it is not a beneficiary.

Since MSCA-RISE uses unit costs, no additional costs arise for the action. The costs of the entity are covered by the unit costs paid to the coordinator *(see Article 6)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION
[…]

Art. 18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate **records and other supporting documentation** to prove the number of units declared.
[…]

1. Records and other supporting documentation

For MSCA-RISE, simplified rules on record-keeping apply: Beneficiaries only need to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- proof that:
  - the eligibility conditions for the seconded staff members were complied with *(e.g. CV showing the researcher's seniority, copies of diplomas)*
  - the secondment was eligible (*e.g. agreement on the secondment; travel documents and/or access rights for the host organisation's premises to show the duration; lab books, registration documents, scientific articles, library records to show research and innovation activities)*

    The nature of the records and supporting documents to be kept by the beneficiary must be adequate to show the duration of the secondments clearly and unequivocally.
  - the obligations set out in Article 32 were complied with

    Thus for the obligation to fully use the unit cost for seconded staff members (to cover their travel, accommodation and subsistence costs): the beneficiaries must keep proof of the amounts paid *(e.g. bank transfers to the staff member, travel tickets, hotel accommodation, etc.)*.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until these procedures end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents bear the **full risk** of cost rejection by the Agency.

Specific cases (record-keeping):

Documents for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must keep the documents for the staff of the partner organisation/entity with a capital or legal link.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must:

- submit a '**progress report**' within 30 days after the end of each year, except when the periodic and final reports are due;
- organise a '**mid-term meeting**' between the beneficiaries, partner organisations, entities with a capital or legal link and the Agency before the deadline for the submission of the report for RP 1 (reporting period 1);
- submit any other deliverables identified in Annex 1, in accordance with the timing and conditions set out in it.

The beneficiaries must:

- submit a '**researcher declaration**' within 20 days of the secondment of each seconded staff member.

19.2 Consequences of non-compliance

If a beneficiary or the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures provided for in Chapter 6.

1. Deliverable: Progress report

What & When? The coordinator must — after each year except if a periodic report is due (i.e. normally after the first and third year of the action) — submit to the Agency a progress report, to inform it about progress on the action.

How? The report must be uploaded directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The coordinator must — before the deadline for the periodic report for RP 1 — organise a mid-term meeting.

Best practice: It is good practice to send the Agency a draft version of the periodic report (in good time before the meeting).

3. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a 'researcher declaration' for each seconded staff member — within **20 days** from the start of the secondment.

It is important to give correct and complete information in the researcher declaration, since this information will be used to determine the eligibility of the person-months that are declared.

If a **secondment** is **split** in several stays of shorter duration, the researcher declaration must only be submitted once — at the beginning of the secondment — and indicate each split.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for one year, though split in two half-year periods. In this case, A has to submit the researcher declaration only at the beginning of the first period of secondment, indicating the split. No additional declaration is necessary for the second half.*

If a staff member is seconded to **more than one beneficiary/partner organisation** within the action duration, several researcher declarations must be submitted (within 20 days from the start date of each secondment). Secondments to entities with a capital or legal link will be counted as secondments to the beneficiary/partner organisation they are linked to and must therefore be covered by the same researcher declaration.

> ***Example:*** *Beneficiary A is sending Mr A to partner organisation B for half a year and to beneficiary C for half a year. In this case, the researcher declaration has to be submitted twice, each time within 20 days from the beginning of the secondment to a different beneficiary/partner organisation.*

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

Specific case (deliverables):

Researcher declaration for staff of the partner organisations and entities with a capital or legal link — For secondments from partner organisations/entities with a capital or legal link, it is the beneficiary that must submit the researcher declarations.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to background necessary for their research and innovation activities under the action.

[…]

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

[…]

31.6 Access rights for seconded staff members

The beneficiaries must — on a royalty-free basis — give access to the seconded staff members to results necessary for their research and innovation activities under the action.

[…]

1. Access rights for seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA*):

The beneficiaries must give the seconded staff members **access** to both **background** AND **results** necessary for their research and innovation activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by beneficiaries before they accede to the GA
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiaries in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

Beneficiaries must moreover ensure that **partner organisations** and **entities with a capital or legal link** give similar access.

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR SECONDED STAFF MEMBERS

32.1 Obligations towards seconded staff members

The beneficiaries must respect the following **recruitment and working conditions** for the seconded staff member under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[17] and ensure that the seconded staff members are aware of them;

(b) ensure that the rights and obligations of the seconded staff members remain unchanged during the secondment;

(c) ensure that seconded staff members are reintegrated after the secondment;

(d) ensure that the seconded staff members enjoy at the place of the implementation at least the same standards and working conditions as those applicable to local persons holding a similar position;

(e) ensure that the seconded staff members are covered by an appropriate medical insurance scheme;

(f) ensure that the staff members are seconded full-time;

(g) ensure that the seconded staff members have the relevant expertise for the action;

(h) inform the seconded staff members about:

- the description, conditions, location and the timetable for the implementation of the secondment under the action;
- the rights and obligations of the beneficiary toward the seconded staff members under this Agreement;
- the obligation of the seconded staff members to complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency;
- the arrangements related to the intellectual property rights between the beneficiary and the seconded staff members — during implementation of the secondment and afterwards;
- the obligation of the seconded staff members to maintain confidentiality (see Article 36);
- the obligation of the seconded staff members to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(i) assist the seconded staff members in the administrative procedures related to their secondment;

(j) use the costs of seconded staff members (see Article 6) to contribute to their subsistence and mobility.

(k) ensure that the seconded staff members do not have to bear any costs for the implementation of the action as described in Annex 1.

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[17] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Recruitment and working conditions — Rights for the seconded staff members

In view of the key role of the seconded staff members in MSCA-RISE, the MSCA-RISE MGA foresees a series of obligations in order to guarantee best possible working conditions for them.

Main obligations (towards the staff members):

- Ensure that the seconded staff members have the **relevant expertise** to participate in the action

  The profiles of the staff to be seconded must be in line with the tasks and objectives described in Annex 1.

- Ensure that the seconded staff members enjoy at least the **same standards** and **working conditions** at the place of secondment as those applicable to persons holding a similar position there

- Ensure that the seconded staff members are covered by an appropriate **medical insurance** scheme

- Ensure that the staff members are seconded **full-time.**

  For part-time staff members this may require a change of their relationship (i.e. conclude a contract or a supplementary agreement), to allow the secondment to be implemented on a full-time basis.

- Ensure that the **rights and obligations remain unchanged** during the secondment

  Secondments — For MSCA-RISE, secondments are the core activity of the action *(see Article 8)*.

  Beneficiaries and partner organisations must:

  - not penalise the staff members or reduce their rights due to the participation in the action and
  - in particular, since their normal remuneration is not covered by the grant (which is only a top-up allowance to cover the travel, accommodation and subsistence costs of the secondment), continue to pay them as before, according to their internal practices.

  Changes in favour of the seconded staff member are of course accepted.

- Ensure that the seconded staff members are **reintegrated** (into the beneficiary/partner organisation/entity with a capital or legal link) after the secondment, so as to allow for a transfer of knowledge and maximise the impact of the action (as regards knowledge-sharing and long-term collaboration)

- Comply with the arrangements on **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[99].

[99] Available at https://www.iprhelpdesk.eu/.

- **Assist** the seconded staff members in the **administrative procedures** related to their secondment *(e.g. helping with visa procedures)*
- **Inform** the staff member about key elements of the grant

  Beneficiaries must inform seconded staff members of all details concerning the secondment and the research and innovation activities *(such as description, conditions, location, and timetable for implementation)*.
- Ensure that the costs for seconded staff members are **fully used for** the benefit of the **seconded staff** members

  They can be:
  - paid directly to the seconded staff member in advance or via different instalments or
  - managed centrally by the beneficiary according to the specific needs of the secondment.
- Ensure that the seconded staff members do not have to bear **any costs** for the implementation of the action as described in Annex 1.

  The seconded staff members must NOT be requested to pay tuition fees for their research and innovation training neither from their own funds, nor from the staff member unit cost.

2. Obligations on the seconded staff members

Although they do not need to be explicitly reflected in their employment contract (or fellowship or other relationship), some of the basic obligations under the MSCA-RISE MGA must also be respected by the seconded staff members.

Main obligations (of the staff member):

- Comply with the arrangements related to the **intellectual property rights**
- Maintain **confidentiality**
- Ensure the **visibility of EU funding**

  Seconded staff members must acknowledge funding under the MSCA grant in publications, communications or patent applications.
- Complete and submit — at the end of the secondment — the evaluation questionnaire and — two years later — the follow-up questionnaire provided by the Agency.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (consortium) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiaries must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,* addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This

allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiaries must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.5 H2020 MSCA-COFUND MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

1. MSCA-COFUND actions

What? MSCA-COFUND funds:

- a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (— implemented by the beneficiary or a partner organisation).

MSCA-COFUND cover doctoral programmes for early-stage researchers (DP) and fellowship programmes for experienced researchers (FP).

MSCA-COFUND are mono-beneficiary actions.

They are funded under Part I of Horizon 2020, 'Marie Skłodowska-Curie actions' *(e.g. H2020-MSCA-COFUND-2014)*.

For more information on MSCA-COFUND, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the H2020 Work Programme (section 3 MSCA) and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down for the beneficiary, by **budget category** (see Articles 5, 6).

4.2 Budget transfers

Not applicable

1. Budget categories

The MSCA-COFUND MGA does not use the budget categories of the General MGA.

Budget categories of the MSCA-COFUND MGA:

- costs for researchers:
  - costs for researchers in programmes implemented by the beneficiary
  - costs of providing financial support to costs for researchers in programmes implemented by a partner organisation
- management costs.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

2. Budget transfers

Given that MSCA-COFUND is a mono-beneficiary action, there is NO redistribution of person-months between *beneficiaries*.

Transfers between *budget categories* are formally NOT possible because all budget categories are linked to the *same* person-months declared for the recruited researchers (and it is therefore technically not possible to move budgeted amounts from one budget category to another).

⚠ **Budget flexibility** — There is however some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may also be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses **50 %** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following form ('**form of costs**'):

(a) for **costs for researchers in a programme implemented by the beneficiary** (living allowance): on the basis of the amount(s) per unit set out in Annex 2 ('**unit costs**');

(b) for **costs of providing financial support to costs for researchers in a programme implemented by a partner organisation**: on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) and

(c) for **management costs**: on the basis of the amount per unit set out in Annex 2 (**unit costs**).

1. Reimbursement rate

How much? For MSCA-COFUND, the reimbursement rate is set at **50 %** *(see the H2020 Work Programme (section 3 MSCA))*.

2. Cost forms

The MSCA MGAs do not use the **cost forms** of the General MGA, but the **unit costs** set out in Decision C(2017) 6855[100].

For MSCA-COFUND, these are unit costs for:

- costs for researchers: living allowance
- management costs.

These are fixed amounts that must be multiplied by the number of months the recruited researchers spent on research training activities (person-months); they cannot be changed.

The eligibility conditions are set out in *Article 6*.

[100] Commission Decision C(2017) 6855 amending Decision C(2013) 8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 – Application of the reimbursement rate to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to eligible costs (unit costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 and 2 or
- the reduced maximum grant amount following Step 3.

1. Final grant amount

For MSCA, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since MSCA grants use only unit costs, there is NO reduction due to the no-profit rule in the MSCA MGAs (Step 3 in the Article 5.3 General MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

Unit costs are eligible ('**eligible costs**'), if:

(a) they are calculated as follows:

{amounts per unit set out in Annex 2

multiplied by

the number of actual units};

(b) the number of actual units complies with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

1. Eligible costs

The grant can **only reimburse eligible costs** (i.e. costs that comply with the general and specific conditions set out in this Article) ('**reimbursement of eligible costs grant**').

ONLY **eligible costs** may be entered into the estimated budget for the action *(see Article 4)* or declared in the financial statements *(see Article 20)*.

Record-keeping & burden of proof — The **burden of proof** for eligibility is on the beneficiary. It must keep sufficient supporting documents *(see Article 18)* to show that the person-months it declares are eligible.

Compliance with eligibility rules may be subject to a **check or audit** by the Commission/Agency. Any ineligible costs found will be **rejected** *(see Article 42)*.

Article 6.1 refers to general eligibility conditions, applicable per cost form (for MSCA: only unit costs; *see Article 5*).

Article 6.2 refers to specific eligibility conditions, applicable per budget category *(see Article 4)*.

2. General conditions for unit costs to be eligible

The general conditions for eligibility of unit costs are the same as in the General MGA *(see Article 6.1 H2020 General MGA)*.

6.2 Specific conditions for costs to be eligible

Costs are eligible, if they comply with the general conditions (see above) and the specific conditions set out below for each of the following two budget categories:

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The MSCA MGAs have their **own budget categories**, with their own **types of costs**, **eligibility conditions** and **calculation rules**.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

- types of costs covered by the budget category
- cost form under which the costs must be declared (for MSCA: unit costs)
- eligibility conditions
- how the costs must be calculated.

A. Costs for researchers ('living allowance')

A.1 **Costs for researchers in a programme implemented by the beneficiary** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

A.2. **Costs of providing financial support to costs for researchers in a programme implemented by a partner organisation** are eligible, if the number of units declared corresponds to the actual number of months spent by the researchers on the research training activities and if the conditions set out in Article 15.1.1 are met.

1. Researcher costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs for the researchers (recruited either by the beneficiary or by the partner organisation implementing the programme), by providing for:

- a monthly living allowance (A.1 or A.2) — to cover the employment or fixed-amount fellowship with social security coverage (i.e. gross amount, including compulsory deductions under national law, *such as employer/employee social security contributions and direct taxes*).

Budget flexibility — There is NO flexibility as regards the *use* of the researcher unit cost (i.e. living allowance). It must be fully used for each researcher; it can NOT be used to pay other researchers or other types of costs *(see Article 15)*.

What not? Other costs of the beneficiary are not covered. Management costs are covered under budget category B 'management costs' *(see Article 6.2.B)*. Other costs *(such as mobility and family allowances, research, training and networking costs, indirect costs)* are NOT eligible under the grant; they may be funded through other sources (including other EU programmes).

Combining H2020 & other EU grants — A MSCA-COFUND grant does NOT prevent the beneficiary or partner organisations from applying for further (non-H2020) EU funding for their programme — for costs that are not eligible (or not declared) under the MSCA-COFUND grant.

For more information on how to combine EU funding from different programmes, *see the Participant Portal Online Manual (links to Regional funding).*

1.2 The costs must be **declared as** the unit costs fixed by Decision C(2017) 6855[101] and set out in Annex 2 and 2a of the GA.

This is currently:

- for the living allowance:
  - for early-stage researchers in doctoral programmes: EUR 3 870 per researcher per month (person-month)

[101] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

– for experienced researchers in fellowship programmes: EUR 5 480 per person-month.

⚠ The unit cost that the beneficiary receives is however **EUR 1 935** and **EUR 2 740** respectively (because of the MSCA COFUND reimbursement rate).

ℹ For the latest information on the amounts, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of costs for MSCA grants is very simple and almost completely automatized: The beneficiary must only indicate the number of implemented person-months (for researchers recruited under the action) and the costs are then automatically calculated by the IT system.

1.3 Moreover, the costs (in practice for MSCA: the person-months) must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. the declared number of person-months must be linked to the implementation of the action, be incurred during the action duration, be identifiable and verifiable, etc.; *see Article 6.1*)
- fulfil the **additional** cost eligibility **conditions** set out in Article 15.1.1.

1.4 The **costs** are **calculated** (automatically by the IT system) as follows:

– for the living allowance:

amount per unit *(see Annex 2)* **x** number of months actually spent by the recruited researchers on the research training activities ('number of implemented person-months')

For **partial months** of recruitment, a pro-rata unit cost of 1/30 will be reimbursed for each day (for ease of implementation, each month is considered to have 30 days).

Example: *If the researcher spent 20 months and 15 days on the project, the calculation for the 15 days is: 15/30 = 0.5. In this case, insert 20.5 as number of person-months.*

Periods in which a researcher was **absent** for more than 30 consecutive days (for reasons other than normal annual leave) can NOT be charged to the action (and must be removed from the financial statement, by changing the researcher declaration).

Examples:

1. *If the researcher is absent for 30 consecutive days (or less), the costs incurred during this period can be charged to the action.*

2. *If the researcher is absent for 31 consecutive days (or more), no costs can be charged for this period (from the first day of the absence)*

B. Management costs are eligible if the costs of the researchers (living allowance; see above) are eligible.

1. Management costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** only the:

- management costs (B) — for direct costs of managing the action.

Project management — Coordination and administration tasks are considered **action tasks**.

Budget flexibility — There is some flexibility as regards the *use* of the amounts received:

- The management unit cost should be shared with partner organisations which incurred costs for the implementation of a programme or for hosting secondments *(see Article 8)*.
- The management unit cost should be used for the management of the action, but unused amounts may be used for other action-related purposes *(e.g. to increase the salary of the researchers)*.

What not? Other costs (such as research, training and networking costs AND indirect costs) are NOT eligible under the grant; they may be funded through OTHER sources (including other EU programmes).

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2017) 6855[102] and set out in Annex 2 and 2a of the GA.

This is currently:

- for management costs: EUR 650 per researcher per month (person-month).

The unit cost that the beneficiary receives is however **EUR 325** (because of the MSCA COFUND reimbursement rate).

For the latest information on the amount, *see the H2020 Work Programme (section 3 MSCA) in force at the time of the call.*

In practice, the declaration of management costs for MSCA-COFUND grants is completely automatized because the IT system automatically calculates them on the basis of the number of person-months declared for the researcher costs.

1.3 The **eligibility** of the management costs is directly linked to (and conditional on) the eligibility of the costs for researchers.

Management costs are eligible only if ALL the eligibility conditions for the researchers are met. Person-months which are not eligible for budget category A 'costs for researchers' are also not eligible for budget category B 'management costs'.

Management costs can NOT be claimed separately (i.e. management costs cannot be claimed without living allowance).

1.4 The **costs** are **calculated** (automatically by the IT system) like the costs for researchers:

[102] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf.

– for the management costs:

amount per unit *(see Annex 2)* **x** number of implemented person-months (declared for the researcher cost)

6.3 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (in Article 6.1 and 6.2);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget).

(c) ***[OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]****].***

6.4 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- call upon partner organisations to implement certain action tasks described in Annex 1 (i.e. implementing a doctoral or fellowship programme including recruiting researchers or hosting and training researchers during a secondment).

In this case, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For MSCA actions, the rules from the General MGA for third party involvement do not apply.

Instead, MSCA-COFUND allows the beneficiary to use:

– partner organisations

to carry out work under the action (**third parties involved in the action**).

A beneficiary using third parties remains **fully responsible** for them under the GA.

Best practice: In order to be able to fulfil this obligation, the beneficiary should make internal arrangements *(e.g. conclude partnership agreements with partner organisations)*.

Third parties involved in the action do not sign the GA *(see Article1 H2020 General MGA)*.

Their costs are considered already covered by the unit cost paid to the beneficiary; no additional costs will be reimbursed by the Agency. (The beneficiary is however encouraged to share the unit costs received with them.)

Partner organisations are third parties involved in the action without a (capital or legal) link to the beneficiary.

They may be used to:

– implement a doctoral or fellowship programme (i.e. recruit the researchers)

– provide training and hosting of researchers during a secondment *(see Article 15)*.

⚠ **Secondments —** For MSCA-COFUND, secondments can be:

- (optional) additional periods of research training with a partner organisation, in order to further enrich the training experience of the researchers

and/or

- for fellowship programmes similar to MSCA-IF GF: (mandatory) outgoing phase with a partner organisation (from a third country).

The beneficiary remains **fully responsible** for the action implementation (in accordance with the GA) also during secondments.

Partner organisations can recruit the researchers (and MUST do so if it is the partner organisation that implements the doctoral or fellowship programme; *see Article 15.1.1(b)*).

Their involvement must be clearly described in Annex 1 (in particular, tasks to be carried out).

They cannot claim costs separately (since their costs are covered by the unit costs paid to the beneficiary).

Partner organisations that implement a doctoral or fellowship programme must be established in an EU Member State, H2020 associated country, or third country listed in General Annex A to the *H2020 Work Programme*. Partner organisations hosting secondments can be established anywhere.

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

ARTICLE 15 — FINANCIAL SUPPORT TO OR IMPLEMENTATION OF A *[DOCTORAL] [FELLOWSHIP]* PROGRAMME

15.1 Rules for providing financial support to or implementation of a *[doctoral][fellowship]* programme

15.1.1 The beneficiary must ensure that the ***[doctoral][fellowship]* programme** (implemented by itself or a partner organisation) complies with the following conditions:

(a) **types of programme**:

[OPTION 1 for DPs: *The programme must concern research training activities for recruited researchers that lead to the award of a doctoral degree ('**doctoral programme**');**]***

[OPTION 2 for FPs: *The programme must concern fellowships for research training activities for recruited researchers ('**fellowship programme**').*

*For fellowships where the main part of the research training activity does not take place in an EU Member State or associated country[5], the return phase to an EU Member State or associated country may not be more than 50% of the total duration of the research training activity;**]***

(b) **categories of persons** that may be supported by the programme:

[OPTION 1 for DPs: *The doctoral programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**early-stage researchers**' (i.e. in the first four years of their research careers and not have a doctoral degree);*
- *show **transnational mobility** by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than 12 months in the 3 years immediately before the call deadline or recruitment — unless:*
  - *otherwise specified in Annex 1 for existing programme or*
  - *this time was as part of a procedure for obtaining refugee status under the Geneva Convention[6];*
- *are nationals or long-term residents of an EU Member State or associated country[7], in case of research training activities carried out in a country other than an EU Member State or associated country;*
- *fulfil any additional conditions set out in Annex 1.**]***

[OPTION 2 for FPs: *The fellowship programme must support researchers, who — at the date of the call deadline or recruitment —:*

- *are '**experienced researchers**' (i.e. in possession of a doctoral degree or have at least four years of research experience);*

- *show* **transnational mobility** *by carrying out the research training activities in a country (or — in case of international European interest organisations — with this organisation) where they have not resided or carried out their main activity for more than [**OPTION A by default:** 12 months in the 3][**OPTION B for actions with activities similar to the MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel:** 3 years in the 5] years immediately before to the call deadline or recruitment — unless:*

  - *otherwise specified in Annex 1 for existing programmes or;*

  - *this time was part of a procedure for obtaining refugee status under the Geneva Convention[8];*

- *are nationals or long-term residents of an EU Member State or associated country, in case of research training activities carried out in a country other than an EU Member State or associated country;*

- *fulfil any additional conditions set out in Annex 1.]*

Researchers that are already permanently employed by the entity where the research training activities take place may not be supported.

(c) **procedure and criteria for selecting researchers** in the programme:

[OPTION 1 for DPs: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, as described in Annex 1.*

*Vacancies must be internationally advertised and published (including on the web-sites requested by the Agency and must indicate the minimum gross salary to be offered to the researches, as set out in Annex 1).**]***

[OPTION 2 for FP: *Researchers must be selected following an open, transparent, merit-based, impartial and equitable selection procedure, based on international peer review, as described in Annex 1.*

The selection committee(s) must bring together diverse expertise, have an adequate gender balance and include members from other countries and with relevant experience to assess the candidates.

Fellowships must be granted via regular calls that are internationally advertised and published (including on the web-sites requested by the Agency) and have fixed deadlines or regular cut-off dates.

There must be no more than 4 deadlines or cut-off dates per year.

*The calls must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.**]***

(d) **conditions for the recruitment** of researchers under the programme:

- researchers must be recruited under an **employment contract** (or other direct contract with equivalent benefits, including social security coverage) or — if not otherwise possible under national law — under a fixed-amount-fellowship agreement with minimum social security coverage;

- researchers must be recruited for at least 3 months;

- ***[OPTION 1 for DPs:*** *for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 2 709.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 354.50;**]***

- ***[OPTION 2** for **FPs:** for researchers recruited under an employment contract (or other direct contract with equivalent benefits, including social security): the total remuneration costs (salaries, social security contributions, taxes and other costs included in the remuneration) for each researcher per month are equal to or higher than EUR 3 836;**]**.*

  *For researchers recruited under a fixed-amount-fellowship agreement: the total costs of each fixed-amount fellowship per month are equal to or higher than EUR 1 918.**]***

- researchers should not have to bear any costs for the implementation of the action as described in Annex 1.

15.1.2 In addition, the beneficiary must:

- for programmes implemented by itself:
  - take measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[9] and ensure that the researchers are aware or them;
  - ensure that researchers enjoy — wherever the research training activities take place — the same standards of safety and occupational health as those of local researchers holding a similar position;
  - ensure that researchers are provided with the means to carry out the research training activities (including the infrastructure, equipment and products);
  - ensure that researchers receive appropriate assistance in all administrative procedures before national authorities;
  - ensure that researchers are employed full-time, unless duly justified for reasons associated with personal or family reasons;
  - ensure that researchers work exclusively on the research training activities;
  - ensure that the research training activities (including activities raising ethical issues and research on human embryos or human embryonic stem cell) comply with the ethical principles set out in Article 34;
  - ensure that the researchers are informed that they are 'Marie Skłodowska-Curie fellows';
  - ensure that researchers are paid in accordance with their contract (employment contract, other direct contract or fixed-amount fellowship agreement);
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) complies with the provisions of this Agreement and specifies the research training activities;
  - ensure that the contract (employment contract, other direct contract or fixed-amount fellowship agreement) specifies arrangements relating to confidentiality and intellectual property rights (in particular to access to background, use of results, promoting the action) — during the research training activities and afterwards;
  - inform the researchers about their obligation to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — a follow-up questionnaire provided by the Agency;
  - ***[OPTIONS for DPs:** ensure a fair gender representation in the recruited researchers (by promoting genuine equal access opportunities between men and women throughout the recruitment process);*

- *appoint a supervisor with adequate experience to provide the researchers with academic support and a career plan.]*

- for programmes implemented by a partner organisation:

  - ensure that the partner organisation complies with the obligations set out in this Article and

  - ensure that the partner organisation allows that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the researchers will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to the application of any of the other measures provided for in Chapter 6.

[5] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[6] 1951 Refugee Convention and the 1967 Protocol.

[7] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[8] 1951 Refugee Convention and the 1967 Protocol.

[9] Commission Recommendation No 251/2005/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

1. Providing financial support — Implementing a doctoral/fellowship programme

MSCA-COFUND can provide support both for a programme implemented by the beneficiary itself or for a programme of a partner organisation (which the beneficiary funds by providing financial support).

'Providing financial support' means that the beneficiary passes on the EU support it receives via the MSCA-COFUND grant to the partner organisation that implements the doctoral/fellowship programme (also called 'cascade funding').

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Types of programme — Categories of persons

The beneficiary/partner organisation must implement one of the following **types of** research training **programme** supporting transnational mobility:

- doctoral programme (DP), i.e. a programme with research training activities for recruited early-stage researchers that leads to the award of a doctoral degree

  The degree does not necessarily need to be awarded within the action duration. However, if requested by the Agency, the beneficiary must be able to provide proof that the researcher actually received (or failed the examination for) the doctoral degree.

OR

- fellowship programme (FP), i.e. a programme with fellowships for recruited experienced researchers.

The **researchers** must — at the date of the call deadline or recruitment —:

- be one of the following two:

  - **early-stage researchers** (i.e. NOT have a doctoral degree AND be in the first four years (full-time-equivalent research experience) of their research career) or

  - **experienced researchers** (i.e. have a doctoral degree OR have at least four years (full-time-equivalent research experience) of research career).

  Years of '**research career**' are counted from the date when the researcher obtained a degree entitling him/her to embark on a doctoral programme (either in the country in which it was obtained or in which s/he is recruited) — even if the doctorate was never started or envisaged.

- comply with the **mobility rule**, i.e. not have resided or carried out their main activity *(work, studies, etc.)* in the country of the beneficiary/partner organisation for more than:

  - for fellowship programmes similar to MSCA-IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel: 3 years in the 5 years immediately before the recruitment date or call deadline

  - for all other programmes (doctoral programmes and other fellowship programmes): 12 months in the 3 years immediately before the recruitment date or call deadline

  — unless Annex 1 of the GA specifies otherwise for an already existing programme or the beneficiary/partner organisation is an 'international European interest organisation'[103], for whom the mobility rule is limited to time spent *with* them.

  Exceptions in Annex 1 are only possible for existing programmes (NO exceptions for new programmes).

  Short stays (such as holidays), compulsory national services (such as mandatory military service) and procedures for obtaining refugee status under the Geneva Convention[104] are NOT counted.

  Researchers are NOT eligible if they are already permanently employed by the entity where the research training activities take place.

- if the programme is implemented by a partner organisation established in a **third country** (only third countries listed in General Annex A to the H2020 Work Programme) or if a secondment to a partner organisation in a non-associated third country constitutes the ***main* part** of the research training activities: be nationals or **long-term residents** of a EU Member State or H2020 associated country.

[103] For the definition, *see Article 2.1(12) of the Rules for Participation Regulation No 1290/2013:* '**international European interest organisation**' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[104] 1951 Refugee Convention and the 1967 Protocol.

'Long-term resident' normally means a period of legal and continuous residence in EU Member States or H2020 associated countries for 5 or more consecutive years. Periods outside these countries will be taken into account if shorter than 6 consecutive months and all in all not more than 10 months.

For fellowship programmes similar to MSCA-IF EF Reintegration Panel: The long-term residence requirement will not apply to researchers who have obtained refugee status under the Geneva Convention[105] in a EU Member State or H2020 associated country.

NO other restrictions on researcher nationality or researcher origin or destination allowed.

3. Additional cost eligibility condition: Selection procedure

The beneficiary/partner organisation must select researchers in line with the following criteria:

- open
- transparent
- merit-based
- impartial
- equitable
- described in Annex 1 and
- for fellowship programmes: based on international peer review.

For doctoral programmes: the beneficiary/partner organisation must publish vacancies as widely as possible

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs[106])*.

Vacancies must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.

For fellowship programmes: the beneficiary/partner organisation must publish calls for proposals (with a **maximum** of **4** fixed deadlines or regular cut-off dates **per year**) as widely as possible:

- at international level and
- on web-sites requested by the Agency *(e.g. on EURAXESS Jobs)*.

The calls must indicate the minimum gross salary to be offered to the researchers, as set out in Annex 1.

4. Additional cost eligibility condition: Recruitment and working conditions

The beneficiary/partner organisation must recruit the researchers under an **employment contract/equivalent direct contract** (i.e. other direct contract with equivalent benefits and social security coverage), including:

- sickness, parental, unemployment and invalidity benefits

[105] 1951 Refugee Convention and the 1967 Protocol.
[106] Available at http://ec.europa.eu/euraxess/.

- pension rights and
- benefits for accidents at work and occupational diseases.

If national law prevents them from recruiting researchers under an employment contract/equivalent direct contract, the beneficiary/partner organisation may — exceptionally and subject to the Agency's prior agreement — offer a **fixed-amount fellowship** with minimum social security coverage, including:

- sickness, parental and invalidity benefits and
- benefits for accidents at work and occupational diseases.

In this case, the living allowance will be reduced by 50%.

The social security coverage must be guaranteed for the entire recruitment of the researcher (i.e. also during secondments, if any).

Staff provided by a temporary work agency — The beneficiary/partner organisation must always recruit researchers directly. Recruitments via other means *(e.g. temporary* work *agency)* are NOT allowed.

The researchers must be recruited for **at least 3 months**.

Researchers recruited under an employment contract/equivalent direct contract must receive a **minimum remuneration —** monthly **living allowance** (i.e. gross amount including salary, social security contributions, taxes and other costs included in the remuneration) and, if applicable, a single mobility allowance for the researcher to take up the doctoral or fellowship programme (to be funded through other sources) **—** of:

- for early-stage researchers (doctoral programmes): EUR 2 709
- for experienced researchers (fellowship programmes): EUR 3 836.

These amounts are halved for **fixed-amount fellowship agreements** (i.e. for early stage researchers EUR 1 354,50; for experienced researchers EUR 1 918).

Lower payments are considered as underpayment.

⚠ Since the MSCA-COFUND grant reimburses 50% of the researcher unit cost (i.e. EUR 1 935 and EUR 2 740 respectively), this means that the grant covers only a part of the minimum remuneration. The **beneficiary must bear** ('co-fund') the **difference** of **EUR 774** or **EUR 1096** per researcher.

It also means that there can be **NO budget flexibility**. The researcher unit cost must have been fully incurred for the benefit of the researcher (i.e. fully paid to the individual for whom they are claimed). There can be no amounts left (which the beneficiary could use for other action-related activities).

The total cost of the doctoral/fellowship programme, in particular the amounts to be provided for the benefit of the researchers and for the hosting organisation, must be specified in Annex 1.

A beneficiary with accounting in a **currency other than** the **euro** must ensure that — by the end of the doctoral/fellowship programme — the average monthly allowance (over the duration of the programme) respects the above-mentioned minimum.

Amounts to be paid in **other currencies** must be converted into euro as follows:

- if a daily rate is published in the C series of the *Official Journal of the European Union* for the currency in question: amounts must be converted into euro at the

average of the daily exchange rates published over the corresponding reporting period, as reported on the ECB website[107]

- if no daily rate is published: amounts must be converted at the average of the monthly accounting rates over the reporting period, using the currency converter on the Commission's website[108].

For ease of implementation, monthly allowances for the recruited researchers can be calculated using a **conservative exchange rate**, if a corrective payment is then made (to the researchers) immediately after the end of the reporting period. This must be clearly explained in the employment contract/equivalent direct contract or fixed-amount-fellowship agreement.

The Agency will check if the living allowance was used fully for the benefit of the researchers. Any underpayments, if not corrected, may lead to a rejection of costs (for that researcher).

Recruited researchers should not have to bear **any costs** for the implementation of the action as described in Annex 1.

For doctoral programmes: recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training and/or PhD programme *(e.g. student registration, access to student services (library, computing, etc.), teaching, supervision, examination and graduation)* neither from their own funds, nor from the researcher unit cost.

For fellowship programmes: the recruited researchers must NOT be requested to pay visa-related fees or tuition fees for their research training neither from their own funds, nor from the researcher unit cost.

5. 'Other obligations'

In addition to the additional cost eligibility conditions in Article 15.1.1, the beneficiary/partner organisation must comply with the following 'other obligations':

- the researchers must:
  - be **employed full-time**, unless duly justified for reasons associated with personal or family reasons.

    This also means that a researcher can NOT benefit from two MSCA grants at the same time.

    Part-time employment can be accepted:
    - subject to prior approval by the Agency
    - on personal and family grounds only (i.e. NOT for professional reasons) and
    - if limited to a maximum of 50% of the time spent under the action.

    In the case of part-time employment, costs are reported as pro-rata of the full-time unit cost.

    Example: *For one month of 50% part-time employment, 0.5 units should be claimed.*

    ⚠ While it is not possible to request part-time employment for **professional reasons**, the beneficiary may — in exceptional cases — request an interruption of the employment. If the Agency agrees (beforehand and in writing), there is no need for an amendment or GA suspension; it is sufficient NOT to declare the months not worked.

[107] Available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html.
[108] Available at http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm.

  - **work exclusively** on the research training activities carried out under the action (i.e. may not combine several activities)

    Complementary skills training *(e.g. a teaching activity as part of the research training)* is possible, but must NOT jeopardise the research training activities.

  - complete and submit — at the end of the training — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the Agency

- the contract must set out arrangements relating to **confidentiality** and **intellectual property rights**.

  Assistance with intellectual property rights can be obtained via the IPR Helpdesk[109].

- for doctoral programmes: the beneficiary/partner organisation must:

  - ensure **gender balance** regarding the recruited researchers

  - appoint a **supervisor** with adequate experience to provide the researchers with academic support and a career development plan.

[109] Available at https://www.iprhelpdesk.eu/.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

[…]

18.1.2 Records and other documentation to support the costs declared

The beneficiary must keep adequate **records and other supporting documentation** to prove the number of units declared and the total remuneration or fixed-amount fellowship costs of the recruited researchers.

[…]

1. Records and other supporting documentation

For MSCA-COFUND, simplified rules on record-keeping apply: The beneficiary only needs to keep appropriate and sufficient evidence to prove that the person-months declared are correct, i.e.:

- the employment contracts (or other suitable documents, *e.g. fixed-fellowship agreements*)
- proof that:
  - the eligibility conditions for the researchers were complied with *(e.g. CV showing the researchers' seniority, copies of diplomas, documents relating to selection procedure)*
  - the researchers actually worked on the project *(e.g. lab books, scientific articles, library records)*
  - the obligations set out in Article 15 were complied with
  - the minimum remuneration was paid to the researchers.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (3 years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ Costs that are not supported by appropriate and sufficient evidence may be **rejected** (and other measures described in Chapter 6 may be applied as well).

⚠ Beneficiaries that throw away supporting documents bear the full risk of cost rejection by the Agency.

Specific case (record-keeping):

Documents for a programme implemented by a partner organisation — For a programme implemented by a partner organisation, it is the beneficiary that must keep the documents also for the partner organisation.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must

- submit a '**researcher declaration**' within 20 days of the start of the research training activities, for each researcher;
- organise a **'mid-term meeting'** with the Agency;
- submit any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

1. Deliverable: Researcher declaration

What & When? The beneficiary must submit to the Agency a researcher declaration for each recruited researcher — within **20 days** of the start of the research training activities of the researcher.

It is important to give correct and complete information in the researcher declaration since the data will be automatically transmitted to Annex 4 (financial statement), for calculating the living allowance units. If the researcher declaration is not provided, it will NOT be possible to declare person-months for that researcher.

How? The researcher declarations must be prepared and submitted directly in the Participant Portal.

2. Deliverable: Mid-term meeting

What & When? The beneficiary must organise a mid-term meeting with the Agency to present the implementation of the action in the light of the schedule in Annex 1.

Best practice: Please contact the Agency for the timing.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

[…]

25.5 Access rights for the researcher

The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.

[…]

1. Access rights for the researcher

In view of the key role of the recruited researchers in MSCA-COFUND, the MSCA-COFUND MGA foresees special access rights for them (in addition to those of the General MGA; *see Articles 25 and 31 H2020 General MGA)*:

The beneficiary must give the recruited researchers **access** to both **background** AND **results** necessary for their research training activities.

> 'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
>
> – is held by the beneficiary before it accedes to the GA (i.e. before grant signature)
>
> – is needed to implement the action or exploit the results
>
> AND that
>
> – has been identified by the beneficiary in accordance with Article 24.
>
> 'Results' means any (tangible or intangible) output of the action, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action as well as any rights attached to it, including intellectual property rights.

The beneficiary must moreover ensure that **partner organisations** (if any) give similar access.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by the beneficiary

38.1.1 Obligation to promote the action and its results

The beneficiary must **promote the action** and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a **mainstream media coverage** the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No [number]."

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

[…]

1. Communication activities (beneficiary) — Promoting the action — Mainstream media coverage

For MSCA, the rules for promoting the action are in principle the same as in the General MGA *(see Article 38.1.1 H2020 General MGA)*.

However, the beneficiary must inform the Agency not only before a communication activity expected to have a *major* media impact, but before any activity expected to have **mainstream media coverage** (i.e. coverage in any forms of media, *e.g. print, TV, radio and electronic,*

addressing a non-specialist, non-scientific audience, *e.g. local, regional or national news*). This allows the Agency to ensure maximum publicity and to disseminate the coverage further — through social media, news updates, etc.

2. Visibility of EU funding

For MSCA, the same rules on visibility of EU funding apply as in the General MGA *(see Articles 27.3, 28.2, 29.4 and 38.1.2 H2020 General MGA)*.

In addition, the beneficiary must make specific reference to the MSCA grant. Thus, the clause acknowledging EU funding is slightly adapted.

III.6 H2020 MSCA-SNLS MGA: Annotations

ARTICLE 1 — SUBJECT OF THE GRANT AGREEMENT

ARTICLE 1 – SUBJECT OF THE AGREEMENT

[…] This grant is **linked** to another MSCA **grant** (number [insert number] — [insert acronym]).

1. Linked grant

MSCA-SNLS grants are always linked to another MSCA grant of the beneficiary (main grant – IF, ITN, RISE or Cofund).

The MSCA-SNLS provides support only to researchers or staff members with disabilities who are eligible under the linked MSCA GA.

Moreover, the MSCA-SNLS grant shares the fate of the main grant *(e.g. if the main grant is suspended or terminated, the MSCA-SNLS grant may also be suspended or terminated; see Articles 49.2 and 50.3)*.

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the acquisition of the special needs items or services described in Annex 1, which are needed to allow the concerned researcher or staff member to participate in the linked grant ('**action**').

2. Action: MSCA-SNLS

What? MSCA-SNLS grants fund additional costs that MSCA researchers and staff members with disabilities face due to the increased costs of their mobility during another MSCA action (main grant).

MSCA-SNLS is awarded for the acquisition of special needs items or services *(e.g. assistance by third persons, adaptation of work environment, additional travel/transportation costs)* to allow the recruited or seconded researcher/staff member to participate in the main MSCA action.

What not? Additional costs entailed by the recruited or seconded researcher/staff member but already covered by another source *(e.g. social security or health insurance)* cannot be funded under the MSCA-SNLS.

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The '**estimated lump sum breakdown**' for the action is set out in Annex 2.

It contains the lump sum shares, per work package (i.e. special needs items or services).

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiary. It shows the amounts that the Agency commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 cannot be adjusted by transfers of amounts between work packages (not even via an amendment; see Article 55).

1. Estimated lump sum breakdown

Since MSCA-SNLS grants do not use eligible costs, the MSCA-SNLS MGA does not have any budget categories. Instead, it has either a single lump sum or, if several special needs items or services are needed, a lump sum breakdown.

For technical reasons, each item or service must be considered a separate work package.

The breakdown is used to determine:

- the share of the lump sum to which the beneficiary is entitled for each work package.
- the maximum amount of grant reduction that can be applied for improper implementation of a work package.

Example: *Annex 2 sets out EUR 10 000 for work package 1 (WP1) – Special assistance services for the entire action duration (12 months). The Agency carries out a review on the grant and concludes that WP1 was not properly implemented because only part of the activities of that work package were actually carried out (i.e. assistance was provided for 11 months instead of 12 months). The Agency will reduce the grant in proportion to the improper implementation of WP1 up to a maximum of EUR 10 000 (the share of the lump sum allocated to that work package).*

2. Lump sum share transfers

Given that MSCA-SNLS is a mono-beneficiary action, there is NO redistribution between *beneficiaries*.

Transfers between *work packages* are NOT possible, because the lump sum shares have been fixed for each special needs item or service.

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)].

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The MSCA-SNLS MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum is set out in the H2020 Work Programme (section 3 MSCA).

The lump sum will be fixed taking into account the H2020 MSCA funding rates. This means that the lump sum fixed in Article 5 does not have to be multiplied again by the funding rate; it is already the net maximum EU funding.

The lump sum is one amount for the entire action. It will be limited to a maximum of EUR 60 000 per researcher/staff member and will be available as of 2019.

There are no cost eligibility conditions. If the action is correctly implemented, the beneficiary is entitled to receive the lump sum fixed in the GA.

The lump sum is deemed to cover ALL (direct and indirect) costs and cannot be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary are added together.

The grant is reduced (see Article 43) for all other work packages (i.e. all work packages that have not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For MSCA-SNLS grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation); see Article 43), it will calculate the '**revised final grant amount**'.

This amount is calculated by the Agency by reducing the grant in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For MSCA-SNLS grants, the rules on the revised final grant amount are also in principle the same as for the General MGA (see *Article 5.4 H2020 General MGA*).

However, since there is no reporting of costs, the calculations are different (see *Article 21*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services ;
- call upon subcontractors to implement action tasks described in Annex 1;

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Third parties involved in the action

For MSCA-SNLS actions, NEITHER the rules from the General MGA NOR from the MSCA main grant for third party involvement apply.

There are NO special rules for purchases or subcontracting. The beneficiary may make purchases or subcontract tasks if this is needed for the special needs items or services.

For all types of third party involvement (purchases and/or subcontracts), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiary must — for a period of three years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

Records and other supporting documentation on the implementation of the action must be in line with the accepted standards in the respective filed.

The beneficiary does not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For MSCA-SNLS actions, the beneficiary does not need to keep full records on its actual costs; it only needs to keep appropriate and sufficient evidence (documentation, records) that the special needs items or services were provided to the researcher/staff member as described in Annex 1.

The records and supporting documentation must also prove that:

- the eligibility conditions for the researcher/staff member as per MSCA main grant were complied with
- the special need(s) of the researcher/staff member was certified by a competent national authority.

By contrast, timesheets or invoices are NOT needed. The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 3 years (because not above 60 000 EUR) after the balance is paid or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit — within 60 days following the end of the reporting period — a final report.

The **final report** must include the following:

(a) a '**final technical report**' containing:

(i) an **overview of the results**.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

(ii) a summary for publication by the Agency: not applicable;

(iii) the answers to the '**questionnaire**': not applicable;

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4) which includes the **request for payment of the balance**.

The financial statement must declare the lump sum shares indicated in Annex 2, for the **work packages** that were completed.

If agreed by the Agency, the beneficiary may exceptionally also declare work packages that were not completed.

Lump sum shares which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the work packages have been completed and that the action in general has been properly implemented (see Article 7);

- the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

[…]

1. Reports

What & When? For MSCA-SNLS actions, the beneficiary must submit a **final periodic report** at the end of the action.

Each report is composed of a technical and a financial report, however, the financial report is not to declare costs but completed work packages and corresponding lump sum shares (one or more, depending on the number of special needs items or services which are covered by the grant).

In principle, lump sum shares should be claimed only for special needs items and services that were fully provided to the researcher/staff member concerned. However, if agreed by the Agency, the beneficiary may exceptionally declare partial lump sum shares for work packages that were not completed, for example, due to technical reasons or reasons related to the researcher/staff member.

Best practice: In case of doubt, the beneficiary should contact the Agency about partial work packages.

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that it did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the beneficiary to have enough time.*

- non-implementation linked to financial reasons

  Example: *The special needs service turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].*

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3) whichever is the latest.

*An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.**]***

[OPTION 2 if the JRC is the beneficiary: *The Agency will make a pre-financing payment of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)], within 30 days from the submission of a debit note from the JRC after the signature of the 'Arrangement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the Agency to the Guarantee Fund.**]***

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining lump sum shares for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Incomplete work packages, and work packages that have not been delivered or cannot be approved will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for the beneficiary, in the estimated lump sum breakdown (see Annex 2).

[…]

1. Payments to be made

MSCA-SNLS actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Agency on the basis of the financial statement, the final grant amount and the payments already made.

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares for the accepted work packages. Partial work packages can exceptionally be accepted (i.e. shares for work packages that were not

completed, for example due to technical reasons or reasons related to the researcher/staff member).

Examples:

1. *The beneficiary of an ongoing MSCA-SNLS GA cannot complete the pending work packages because the person providing assistance to the MSCA-RISE staff member with special mobility needs is no longer able to provide the service and the staff member in question does not want to replace his/her assistant. Therefore, the beneficiary requests termination of the MSCA-SNLS GA. The Agency decides to accept part of the lump sum shares for the uncompleted work packages that is proportionate to the tasks already carried out under the MSCA-SNLS action.*

2. *The participation of an early-stage researcher (ESR) with physical impairment has been terminated in the linked MSCA-ITN GA due to personal circumstances of the researcher (e.g. another professional opportunity). Given that the grounds for termination of the MSCA-SNLS are not linked to the beneficiary, the Agency decides to exceptionally accept partial work packages that were initiated but could not be fully completed. The Agency will however verify if the reported lump sum shares for the uncompleted work packages are proportionate to the tasks carried out.*

The Agency will **NOT** accept partial lump sum shares if:

- the situation could have been solved via an amendment.

  Example: *The beneficiary argues that it did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the beneficiary to have enough time.*

- non-implementation linked to financial reasons

  Example: *The special needs service turned out to be more expensive than initially expected and the beneficiary decided to provide less support than planned.*

Steps 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to MSCA-SNLS grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 4 (Grant reductions) applies.

All other steps follow the General MGA.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued relevance of the action.

[…]

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

[…]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since MSCA-SNLS grants do not use eligible costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since the beneficiary has no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the *technical* implementation of the action (in particular whether the special needs items and services have been provided to the researcher/staff member as described in Annex 1 of the GA).

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of the beneficiary to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiary.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[12] applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for MSCA-SNLS grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial report has not been submitted or is not complete or additional information is needed, or

(c) there is doubt about the amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA (see *Article 47 H2020 General MGA*).

The MSCA-SNLS MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for MSCA-SNLS grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work package implementation).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiary

49.1.1 Conditions

The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) the beneficiary or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2);

(c) not applicable;

(d) the action implementation of the linked grant (see Article 2) is suspended.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiary may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA (see *Article 49 H2020 General MGA*).

For *full* GA suspension (action is entirely suspended), all on-going work packages (i.e. special needs items or services) must be interrupted and no new work packages may be started.

For *partial* GA suspensions (suspension of specific work package(s)),, other work packages may be continued and new work packages may be started.

2. GA suspension — Additional ground for suspension: Suspension of main grant (EU)

In addition to the normal grounds for GA suspension *(see Article 49 H2020 General MGA)*, the Agency may suspend the MSCA-SNLS action if the main grant (to which the MSCA-SNLS grant is linked) is suspended.

> ***Example:*** *The beneficiary of an ongoing MSCA-IF grant has requested GA suspension for family grounds of the recruited researcher with visual impairment. The beneficiary has already fully adapted the main work environment but the adaptation of a small laboratory is still missing. The Agency will suspend the MSCA-SNLS GA until the MSCA-IF action will be resumed.*

ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

[…]

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no lump sum shares will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21) on the basis of the report submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiary's obligations (in particular Article 20, 22, 23, 36, 38, 40, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

If the Agency does not receive the report within the deadline (see above), no lump sum shares will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21) on the basis of the report submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the Agency.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 43 and 44) continue to apply.

1. GA termination

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for MSCA-SNLS grants there is no reporting of costs, the calculations are different *(see Article 21)*.

2. GA termination — Additional ground for termination: Termination of main grant or researcher/staff member's participation in main grant (EU)

In addition to the normal grounds for GA termination *(see Article 50.3 H2020 General MGA)*, the Agency may terminate the MSCA-SNLS action if the main grant or the researcher/staff member's participation in the main grant (to which the MSCA-SNLS grant is linked) is terminated.

Example: *The beneficiary of MSCA-COFUND grant has committed substantial errors and irregularities and the Agency has decided to terminate the GA. The MSCA-COFUND GA is linked to MSCA-SNLS GA which foresees the construction of multiple ramps at the premises of the beneficiary to create an accessible work environment. The termination of the MSCA-COFUND GA serves as a ground for termination of the MSCA-SNLS GA by the Agency.*

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

1. Amendments

The rules for amendments are the same as in the General MGA *(see Article 55 H2020 General MGA)*.

Given the parallelism of the MSCA-SNLS grants and the main grant, there may be a need to amend both in a synchronised manner.

> ***Example:*** *If the time spent by the researcher or staff member on the linked MSCA action is changed (e.g. for MSCA-IF from full-time to part-time), the duration of the MSCA-SNLS action may also have to be adapted accordingly.*

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY

56a.1 Conditions

If the linked grant (see Article 1) is transferred to a new beneficiary, the beneficiary may also request the transfer of this action.

56a.2 Procedure

The beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The request must include:

- the reasons why;
- the date the change takes effect;
- the opinion of the researcher or staff member;
- a proposal for the necessary changes, including the Accession Form for the new beneficiary (see Annex 3).

The change **will take effect** on the day set out in the amendment.

56a.3 Effects

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

In this case, the former beneficiary must:

- transfer immediately the remaining contribution to the new beneficiary and
- submit — within 30 days from the change — a '**transfer report**', containing an overview of the progress of the work and the individual financial statement (see Article 20).

The lump sum will be split between the former beneficiary and the new beneficiary, on the basis of the part performed by the former beneficiary and the remaining part to be given by the new beneficiary. If the pre-financing received by the former beneficiary (see Article 21) exceeds the amount of the lump sum recalculated for the former beneficiary, the Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing received in excess.

Where necessary, the former and the new beneficiary must agree on arrangements concerning the transfer of any equipment, materials and/or services purchased and used for the researcher or staff member concerned. The former beneficiary may object only on the basis that the transfer is technically not possible or not possible under national law.

If the Agency considers that the reasons provided do not justify the transfer, it will reject the request specifying the grounds for the rejection.

1. Transfer of the GA

MSCA-SNLS grant can be **transferred** to a new beneficiary if the main grant (MSCA-IF, MSCA-ITN, MSCA-RISE or MSCA-COFUND) is transferred to it.

Transfer of the main grant agreement may cover:

- 'transfer' in the sense of Article 56a MSCA-IF MGA
- change of beneficiary due to 'partial takeover'
- addition of a new beneficiary to the main grant, which will host the researcher/staff member with special needs.

Transfer — The rights and obligations under the GA are transferred from the beneficiary to a new beneficiary — without passing via termination (*Article 50*) or addition of a new beneficiary (*Article 56*).

NO transfer before the amendment has been accepted by the Agency. Transfers without a formal amendment are void and may result in GA termination. The former beneficiary remains fully responsible until the Agency has approved the amendment.

The transfer may NOT entail changes to the GA which would call into question the decision to award the MSCA-SNLS grant.

Example: *The transfer will not be accepted if the special needs item or service is eligible for funding by another source in the country of the new beneficiary (e.g. social security or health insurance system).*

2. Procedure

The former beneficiary must submit a **request for amendment** to the Agency.

For the amendment, the rules of the General MGA apply *(see Article 55 H2020 General MGA)*.

The **transfer date** will be added to the Preamble of the GA.

The date must be selected in the amendment request. The transfer date must be the same date as the accession date of the new beneficiary. Retroactive dates are allowed, but only in exceptional cases and with a specific justification *(see Article 55 H2020 General MGA)*.

The amendment request must include the Accession Form (i.e. the statement to take over all rights and obligations under the GA) of the new beneficiary (signed directly in the Participant Portal).

For more guidance on amendments, *see the Guide on amendment types & supporting documents and the Participant Portal Online Manual.*

3. Effects

The former beneficiary must submit — within 30 days from the transfer date — a transfer report, with information on:

- the progress of the work and
- the financial statement (for the open period until transfer).

This report is for information purposes only. The Agency will use it to decide on how to split the lump sum and instruct the former beneficiary to **transfer** the **remaining pre-financing** to the new beneficiary.

The financial statement for the open reporting period until transfer must be also uploaded with the final report (by the new beneficiary, together with its own financial statement).

The lump sum will be split between the former beneficiary and the new beneficiary — on the basis of the part performed by the former beneficiary and the remaining part to be given to the new beneficiary. If the pre-financing received by the former beneficiary (see *Article 21*) exceeds the amount of the lump sum recalculated for the former beneficiary, the Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing received in excess.

The former and the new beneficiary must agree on arrangements, where necessary, concerning the transfer of the equipment, materials and/or services purchased for the researcher/staff member.

IV. SME Instrument MGAs

IV.1 Background information and approach

The SME Instrument Model Grant Agreements are used for SME Instrument actions only, i.e.:

- SME Ph1 Lump Sum
- SME Ph2.

The SME Instrument MGAs follow the General MGA for numbering and content, except for:

The H2020 SME Ph1 Lump Sum MGA deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for SME Ph1)
- Article 8, 12, 14, 15, 16, 23a-33, 37, 39 (not applicable)
- Article 10 (SME Ph1 specific provision for purchase)
- Article 13 (SME Ph1 specific provision subcontracting)
- Article 18 (SME Ph1 specific provision for record-keeping)
- Article 20 (SME Ph1 specific reporting provisions)
- Article 21 (SME Ph1 specific payment provisions)
- Article 36 (SME Ph1 specific provision on confidentiality)
- Article 38 (SME Ph1 specific provision on promoting the action)
- Article 42 (SME Ph1 specific provision for lump-sum)
- Article 50 (SME Ph1 specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement

The H2020 SME Ph2 MGA deviates from the General MGA as follows:

- Article 5.2 (SME Ph2 specific provisions on reimbursement rate)
- Article 13 (SME Ph2 specific provisions on subcontracting)
- Article 26.3 (SME Ph2 ownership of results, rights of third parties)

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 11, 12, 14, 15, 16, 23a - 33, 37, 39 H2020 SME Ph1 Lump Sum MGA, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific explanation or interpretation for SME Instrument actions are added:

for SME Ph1 Lump Sum:
- Article 2 (SME Ph1 actions)
- Article 8 (SME Ph1 rules on third party involvement)

For SME Ph2:
- Article 2 (SME Ph2 actions)
- Article 4.1 (SME Ph2 budget categories)

- Article 6 (SME Ph2 eligible and ineligible costs)
- Article 8 (SME Ph2 rules on third party involvement)
- Article 20 (SME Ph2 reporting)

The annotations (for both Ph1 and Ph2) are based on the mono-beneficiary version, since it is the most common for SME Instrument actions. They normally also apply to multi-beneficiary grant agreements. Where there are significant differences (i.e. Articles 21, 41, 44 and 50), the multi-beneficiary version of the Article is shown.

IV.2 H2020 SME Ph1 Lump Sum MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (**'action'**), as described in Annex 1.

1. SME Instrument Ph1 Lump Sum actions

What? SME Instrument Ph1 Lump Sum funds:

- the feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service).

The feasibility study of Phase 1 should cover all topics that are necessary to assess quality and potential of the innovation idea *(e.g. risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept etc.)*.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above*; see General Annex G to the H2020 Work Programme*).

The implementation in Phase 2 must then focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

If provided for in the work programme/call, an SME Instrument Ph2 action may exceptionally concern pre-dominantly *research* activities. In this case, it will be funded with a GA based on the General MGA (instead of the SME Instrument Ph2 MGA).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, 'Innovation in SMEs' (*e.g. H2020-SMEINST-01-2016-2017)*.

For more information on SME Instrument Ph1 actions*, see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The SME Ph1 Lump Sum MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the SME Ph1 Lump Sum MGA:

- costs for the feasibility study (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The **maximum grant amount** is **EUR 50 000** (fifty thousand euros).

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses 70 % of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR 71 429 (seventy one thousand four hundred and twenty nine).

Eligible costs (see Article 6) for the costs for the feasibility study must be declared as the lump sum set out in Annex 2 (i.e. under the form of 'lump sum costs').

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The SME Ph1 Lump Sum MGA does not use the **cost forms** of the General MGA, but only the **lump sum** set out in Decision C(2013) 8198[110].

The lump sum has been set at EUR 71 429, to give a round amount of EUR 50 000 when the reimbursement rate of 70 % is applied. It is one amount (for the entire consortium).

The eligibility conditions are set out in Article 6. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

[110] Commission Decision C(2013) 8198 of 10 December 2013 authorising the reimbursement on the basis of a lump sum for SME Instrument Phase 1 actions under the Horizon 2020 Framework Programme. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

5.3 Final grant amount — Calculation

The final grant amount depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the beneficiary and approved by the Agency (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For SME Ph1 grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency;
- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For SME Ph1 grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, for SME Ph1 Lump Sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to grant *reduction*). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the feasibility study (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

1. Eligible costs

The SME Ph1 MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the feasibility study (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs for the feasibility study' **covers** the (direct and indirect costs) for the feasibility study for the innovation idea *(see Article 2)*.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the feasibility study. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the amount fixed by Decision C(2013) 8198[111] and indicated in Annex 2 of the GA (currently EUR 71 429 per action).

⚠ Since SME Ph1 grants have a **reimbursement rate** of **70%**, the lump sum that the beneficiaries receive is **EUR 50 000**.

In practice, the declaration of costs for SME Ph1 grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount of EUR 71 429 as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

[111] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-ph1_en.pdf.

6.2 Ineligible costs

'Ineligible costs' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU and Euratom budget.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6

1. Consequences of improper implementation

For SME Ph1 Lump Sum grants, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to grant *reduction*, but to the *ineligibility* of the costs (*see Article 6.1*).

If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10) and
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13).

In these cases, the beneficiary retains sole responsibility towards the Agency for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the SME Ph1 Lump Sum MGA.

The special rules from the General MGA on third party involvement are limited in SME Ph1 actions to purchases (Article 10) and subcontracting (Article 13).

⚠ The costs of purchases and subcontracts are **ALL covered** by the lump sum. NO other costs will be reimbursed.

In-kind contributions (Articles 11 and 12) and linked third parties (Article 14) or international partners (Article 14a) are NOT allowed (since it is a very simple action and moreover targeted at SMEs, the Agency expects the beneficiaries to implement the main part of the work — without relying on third parties).

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for SME Ph1 actions are in principle the same as in the General MGA *(see Article 10 H2020 General MGA)*.

Since SMEs are, by definition, not 'contracting authorities', there is however NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[112] or 2009/81/EC and the national legislation implementing them.

Moreover, the obligations in Article 10.1 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

[112] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for SME Ph1 actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph1 MGA has however the following **specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the estimated subcontracting costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

Since SMEs are not contracting authorities, there is also NO obligation as regards compliance with the EU public procurement Directives 2014/24/EU, 2014/25/EU[113] or 2009/81/EC and the national legislation implementing them.

[113] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Finally, the obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation to support the costs declared

The beneficiary must — for a period of three years after the balance is paid — keep adequate **records and other supporting documentation** to prove that the corresponding tasks or part of the action as described in Annex 1 have been implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as the lump sum.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For SME Ph1 actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

Examples: *Evidence means documentation that proves that the tasks were carried out. Describing all the tasks relating to the feasibility study is usually enough.*

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit the report

The beneficiary must submit to the Agency (see Article 52) the **final report** set out in this Article. This report includes the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting period

The action has one reporting period:

- RP1: from month 1 to month [X]

20.3 Periodic reports — Requests for interim payments

Not applicable

20.4 Final report — Request for payment of the balance

The beneficiary must submit to the Agency (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(i) an overview of the results;

(ii) the conclusions on the action;

(iii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing a '**financial statement**' (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the Agency.

The beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of report

The report (technical and financial final report, including the financial statement) must be submitted in the language of the Agreement.

[…]

1. Reports

What & When? At the end of the action, the beneficiary (for multi-beneficiary actions: the coordinator) must submit a **final periodic report**, containing a technical and a financial report.

2. Reporting period

SME Ph1 actions have only one reporting period (with one pre-financing payment; *see Article 21*).

3. Final financial report: Financial statement

The final financial statement (for multi-beneficiary actions: one common financial statement for the consortium) is automatically pre-filled by the system (with EUR 50 000 as final grant amount and EUR 71 429 as the total eligible costs of the action; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the beneficiary
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

The Agency will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the Agency, *the* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

SME Ph1 actions have only one reporting period *(see Article 20.2)*, with one pre-financing payment.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing payment for SME Ph1 actions is up to 50% of the maximum grant amount (i.e. up to EUR 25 000).

Payment of the balance

How much? The amount of the payment of the balance depends on the overall financial situation of the action, after calculation of the final grant amount *(see Article 5.3)*.

ARTICLE 36 — CONFIDENTIALITY

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

They may use confidential information to implement the Agreement.

The Agency may disclose confidential information also to its staff, other EU institutions and bodies.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Confidential information

The SME Ph1 MGA foresees lighter provisions on confidentiality than the General MGA.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Obligation to promote the action and its results — Information on EU funding — Obligation and right to use the EU emblem — Disclaimer excluding Agency and Commission responsibility — Agency and the Commission right to use materials, documents or information

The beneficiary must promote the action and its results.

Any communication activity related to the action must:

(c) display the EU emblem and

(d) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [number]".

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from the beneficiary (including in electronic form).

The right to use the beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

38.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Communication activities (consortium) — Promoting the action — Visibility of EU funding

The SME Ph1 MGA foresees lighter requirements for promoting the action and acknowledging EU funding.

ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the Agency

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the Agency immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submiting the deliverables and the report to the Agency (see Articles 19 and 20);

(d) submiting to the Agency in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(iii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iv) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and the report to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for SME Ph1 multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will —**at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the Agency will formally notify the beneficiary of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a **recovery**, the Agency will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the **payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for SME Ph1 Lump Sum grants the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*, improper implementation leads to the *ineligibility* of the costs (NOT grant *reduction*; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

Cost rejections will be made for **improper implementation** of the action (*see Article 7*).

If the feasibility study is incomplete and thus does not meet the intended objective or is of insufficient quality *(e.g. does not permit to assess the quality and potential of the innovation idea)*, ALL costs will be declared ineligible and there will be NO EU financial contribution.

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide required information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for SME Ph1 Lump Sum grants 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*, the grant can be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will —at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' **to the coordinator**:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Agency by the date in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the Agency.

The Agency will formally notify a **pre-information letter** **to the coordinator**:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The SME Ph1 multi-beneficiary MGA has, however, the following **specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Agency will recover ONLY from it.

Best practice: Beneficiaries should foresee internal arrangements to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement if:

(a) not applicable;

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable;

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (‘**extension of findings from other grants to this grant**’; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement, the Agency will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial sanctions (Article 45).

The beneficiary may not claim damages due to termination by the Agency (see Article 46).

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants) the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or the natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (‘**extension of findings from other grants to this grant**’; see Article 22.5.2);

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).
After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, 36, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, for SME Ph1 actions, improper termination by the beneficiaries will lead to a **100% reduction** of the grant.

2. Beneficiary termination (consortium)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the following **specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium together).

3. GA or beneficiary termination (EU)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the SME Ph1 multi-beneficiary MGA has the following **specificities**:

The request for amendment (which the coordinator must send 60 days after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IV.3 H2020 SME Ph2 MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** (**'action'**), as described in Annex 1.

1. SME Ph2 actions

What? SME Ph2 funds:

- the implementation of an innovation idea (including, prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through Phase 1 or another means.

The implementation of Phase 2 must focus on innovation activities *(e.g. demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication)* but may also include some research.

A project may be funded in Phase 2 even if it was not funded in Phase 1.

The innovation idea must have commercial potential and considerable novelty for its sector (i.e. for technological innovation ideas: 'technology readiness level' of 6 or above; *see General Annex G to the H2020 Work Programme*).

SME actions are normally mono-beneficiary actions, but can also be multi-beneficiary.

SME actions are funded under Part II of Horizon 2020, 'Innovation in SMEs' (*e.g. H2020-SMEINST-05-2016-2017)*.

For more information on SME Instrument Ph2 actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*).

[…]

1. Budget categories

The SME Ph2 MGA uses the same budget categories as the General MGA.

Budget categories of the SME Ph2 MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific cost categories (if option applies).

Thus, the SME Ph2 MGA does NOT have:

– personnel costs for providing trans-national access to research infrastructure

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **70%** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **if the beneficiary is a natural person** not receiving a salary (see Article 6.2, points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific costs category(ies)**: not applicable.

1. Reimbursement rate

How much? For SME Ph2 actions, the reimbursement rate is normally set at 70 % *(see General Annex D to the H2020 Work Programme)*.

If provided for in the work programme/call, an SME Ph2 action may exceptionally be funded at 100%, with a GA based on the General MGA (instead of the SME Ph2 MGA).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Eligible costs — Ineligible costs

The SME Ph2 MGA uses the **same budget categories** (covering the same **types of costs**) as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, since SMEs are by definition NO non-profit legal entities, they can NOT declare additional remuneration (under budget category A 'personnel costs'; *see Article 6.2.A.1 H2020 General MGA*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION – THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For SME Ph2 actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules [...][11].]*

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s);*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement." ***]***

[OPTION 1 only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries[12] and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[24].***]**

[OPTION 2 only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results as well as the background necessary to use the results — on a royalty-free basis — for its own use;*

- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic technical report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the* Agency *(see Article 37).]*

The beneficiary must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[11] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[12] For the definition, see Article 2.1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 of the Horizon 2020 Framework Programme Regulation No 1291/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

[13] See Articles 28 and 31(2)(a) of Directive 2004/18 replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. Subcontracting

The rules on subcontracting for SME Ph2 actions are similar to those of the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The SME Ph2 MGA has however the following **specificities**:

Subcontracting is NOT restricted to a limited part of the action.

Moreover, the Agency will assess compliance with best value for money during the *evaluation* of the proposal (and therefore be able to give higher security on subcontracts that are part of the proposal).

Assurance can only be given on subcontracts that are described in sufficient detail in the proposal.

For already awarded subcontracts: action task(s) that are subcontracted; key information on the award procedure; name of subcontractor, price and object; explanation why the subcontractor and the price are appropriate.

For future subcontracts: action task(s) to be subcontracted; estimated budget; procedure that will be followed to ensure best value for money.

Annex 1 will explicitly identify the subcontracts for which assurance is given by the Agency. (For these subcontracts, beneficiaries have assurance that compliance with best value for money will not be challenged in audits — unless it turns out that the beneficiary did not follow the procedure described or concealed information for the purpose of the approval).

Change to a subcontract — Subcontracts which were assessed during proposal evaluation (and for which assurance was granted) may be changed (via an amendment).

Best practice: Beneficiaries should contact the Agency (via the Participant Portal messaging function), if they intend to amend the grant to change a subcontract assessed during proposal evaluation.

The amendment request will not be agreed, if it would result in changes that — if known before awarding the grant — would have had an impact on the award decision *(see Article 55)*.

Example (acceptable): *the subcontractor went bankrupt*

Examples (not acceptable): *the action tasks subcontracted changed; increase of price of already awarded subcontracts.*

The Agency will examine the change to evaluate its impact on best value for money — and will either:

- grant assurance, on the basis of the justifications provided (similar to those used at the proposal stage)

OR

- refuse it (if it considers that the subcontract is not best value for money or if it cannot be assessed due to a lack of information).

⚠ Changes to a subcontract may only be done if the assurance on best value for money is granted by the Agency.

New subcontracts — New subcontracts (i.e. not already part of the proposal/Annex1), will be assessed by the Agency for best value for money during the amendment procedure.

⚠ If subcontracts are added not via a formal amendment but via the simplified approval procedure: there is NO assessment (and the beneficiary therefore bears the **full risk**).

Finally, for SME Ph2 actions, subcontracts must provide for the right of the beneficiaries to commercially exploit the results generated by subcontractors during the subcontract implementation (by way of transfer of the intellectual property rights, licence or other; *see Article 26.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the Agency (see Article 52) the technical and financial reports set out in this Article.

These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
- ***[****- RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to month [Z]*
- *[same for other RPs]*
- *RPN: from month [N+1]to [the last month of the project].****]***

[…]

1. Reporting periods

The reporting periods for SME Ph2 actions are normally the same as in the General MGA *(see Article 20.2 H2020 General MGA)*.

The reporting periods may however be shorter and more frequent than in other H2020 actions.

ARTICLE 26 — OWNERSHIP OF RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

[…]

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself and ensure its possibility to commercially exploit the results ('**freedom to operate**').

For this purpose, it must:

- in agreements with employees or third parties involved in the action (such as, for instance, subcontractors): retain the right to commercially exploit the results (at least for the forms of exploitation set out in the 'commercialisation plan'; see Annex 1), if necessary by agreeing to a licence and

- in all other cases: take measures to obtain, from the third parties, licences for the exploitation.

If obtaining the rights is impossible, the beneficiary must refrain from using third parties to generate the results.

[…]

1. Third parties with rights on results — Freedom to operate

'Freedom to operate' means being able to fully commercially exploit the action's results.

The beneficiaries must safeguard their freedom to operate in all agreements with employees and third parties involved in the action *(see Article 8 H2020 General MGA)*.

> ***Example:*** *in their agreements with subcontractors, beneficiaries must ensure their right to commercially exploit the results of work subcontracted, even if this involves using the subcontractor's IPR background.*

In addition, they may have to obtain licenses to commercially exploit the results from other third parties (i.e. third parties that are not participating in the action implementation).

> ***Example***: *if a third party that is not involved in the action owns IPRs that may stand in the way of commercially exploiting the results, the beneficiary must obtain the license for commercial exploitation.*

V. ERA-NET Cofund MGA

V.1 Background information and approach

The ERA-NET Cofund Model Grant Agreement is used for H2020 ERA-NET Cofund actions only.

The ERA-NET Cofund MGA follows the H2020 General MGA for numbering and content, except for:

The H2020 ERA-NET Cofund MGA deviates from the General MGA as follows:

- Article 3 (duration of ERA-NET Cofund actions: 60 months)
- Article 5.2 (ERA-NET Cofund specific reimbursement rate and forms of costs)
- Article 6.2 (ERA-NET Cofund specific conditions for eligibility of costs)
- Articles 8, 10, 11, 12, 13 (reference to 'transnational projects' instead of 'action')
- Article 15 (provisions for support to or implementation of trans-national projects for the co-funded call)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (ERA-NET Cofund specific deliverables)
- Article 20.1 – 20.5 (ERA-NET Cofund specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (ERA-NET Cofund specific payment provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of funds
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Articles 10-13, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for ERA-NET Cofund actions are added:

- Article 2 (ERA-NET Cofund actions)
- Article 4.1 (ERA-NET Cofund budget categories)
- Article 8 (ERA-NET Cofund rules on third party involvement).

V.2 H2020 ERA-NET Cofund MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***
	[OPTION if the JRC participates: *3b Administrative Arrangement****]***
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

ERA-NET Cofund uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities participating financially to the joint call for proposals MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8*).

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. ERA-NET Cofund actions

What? ERA-NET Cofund funds:

- a joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries).

  'Funded by the beneficiaries' means funded by providing financial support to third parties. This is normally the case if the beneficiaries are research funders and cash contributions are received from national programmes. In this case, the beneficiaries launch a call for proposals, resulting in grants for third parties. Most ERA-NET Cofund actions are implemented in this way.

  'Implemented by the beneficiaries' means that the beneficiaries implement the trans-national projects themselves. This is normally the case for governmental research organisations implementing a research programme based on institutional funding (i.e. not project-based funding). In this case, the co-funded call for proposals is based on in-kind contributions from their institutional funding and the beneficiaries then carry out the selected trans-national projects themselves, either fully or partially.

  Only one funded call per GA.

and

- optional: additional activities related to the coordination of national/regional research and innovation programmes.

  The additional activities must relate to the coordination of public research and innovation programmes and should focus on preparing and implementing joint activities (including other joint calls without EU co-funding; *see General Annex D to the H2020 Work Programme*).

  These activities must be *in addition* to implementing a joint call.

If the additional activities consist in additional calls without top-up funding from the EU, the requirements set out in Article 15 do NOT apply.

Normally, ERA-NET Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for sole participants *(see General Annex D to the H2020 Work Programme)*.

ERA-NET Cofund actions are funded in all Parts of Horizon 2020 *(e.g. FETPROACT-02-2017; SC5-33-2017)*.

For more information on ERA-NET Cofund actions*, see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action**: [insert date]]*[7] ('starting date of the action').

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement, or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

1. Action duration

For ERA-NET Cofund actions, the action duration is usually **60 months**. (This relatively long time is needed because these actions include call preparation, launch of the call, proposal submission and evaluation, the selection decision, and implementation of the selected transnational projects — which typically takes 36 months.)

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). Normally, the duration can NOT however exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Budget categories

The ERA-NET Cofund MGA uses its own budget categories.

Budget categories of the ERA-NET Cofund MGA:

- direct costs related to trans-national projects
  - direct costs of providing financial support to third parties implementing trans-national projects
  - direct costs for the implementation of trans-national projects by the beneficiaries:
    - direct personnel costs for the implementation of trans-national projects by the beneficiaries
      - costs for employees (or equivalent)
      - costs for natural persons working under a direct contract
      - costs of personnel seconded by a third party against payment
    - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
    - other direct costs for the implementation of trans-national projects by the beneficiaries
      - travel costs and related subsistence allowances
      - equipment costs
      - costs of other goods and services
      - capitalised and operating costs of large research infrastructure
- direct coordination costs for additional activities
- indirect costs.

Thus, the ERA-NET Cofund MGA does NOT have:

- personnel costs for SME owners without salary
- personnel costs for beneficiaries that are natural persons without salary
- personnel costs for providing trans-national or virtual access to research infrastructure
- specific cost categories.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…%**] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see in Annex 2)**.**

The **estimated eligible costs** of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **costs of providing financial support to third parties implementing trans-national projects**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for the implementation of trans-national projects by the beneficiaries**:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

(c) for **direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries**: as actually incurred costs (**actual costs**);

(d) for **other direct costs for the implementation of trans-national projects by the beneficiaries**:

- for costs of internally invoiced goods and services: on the basis of an mount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **direct coordination costs for additional activities**: on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(f) for **indirect costs**: on the basis of a flat-rate applied as set out in Point C of Article 6.2 ('**flat-rate costs**').

[…]

1. Maximum grant amount — Estimated eligible costs

The maximum grant amount and the estimated eligible costs are fixed in Article 5 at grant signature.

At the end of reporting period 1, the beneficiaries must however make an amendment, to adjust the initial budget (i.e. Annex 2, estimated eligible and, if needed, maximum grant amount) down to the amount justified by the selection list and the commitments to fund.

2. Reimbursement rate

How much? For ERA-NET Cofund, the reimbursement rate is currently set at **33 %** *(see General Annex D to the H2020 Work Programme)*.

3. Cost forms

The ERA-NET Cofund MGA, uses the same **cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

Cost forms of the ERA-NET Cofund MGA:

- **actual costs** for:
  - costs of providing **financial support**
  - **personnel** costs for implementing the trans-national projects (— unless declared as unit cost, *see below*)
  - **subcontracting** costs for implementing the trans-national projects
  - **other direct costs** for implementing the trans-national projects (— unless declared as unit cost, *see below*)
- **unit costs** for:
  - personnel costs calculated by the beneficiaries in accordance with their usual cost accounting practices (**average personnel costs**)
  - costs of **internally invoiced goods and services** calculated by the beneficiaries in accordance with their usual cost accounting practices
  - **coordination costs** for additional activities[114]
- **flat-rate costs** for:
  - **indirect costs**.

[114] Commission Decision C(2013) 8200 of 10 December 2013 authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct costs related to trans-national projects;
B. direct coordination costs for additional activities;
C. indirect costs.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point C below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The ERA-NET Cofund MGA has its **own budget categories**. Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — **for each budget category** — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs related to trans-national projects

A.1 **Direct costs of providing financial support to third parties implementing trans-national projects** are eligible if the conditions set out in Article 15.1.1 are met.

A.2 **Direct costs for the implementation of trans-national projects by the beneficiaries** are eligible, if they comply with the conditions set out in Article 15.1.1 and the following:

A.2.1 **Direct personnel costs for the implementation of trans-national projects by the beneficiaries**

Types of eligible personnel costs

A.2.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the implementation of trans-national projects (‘**costs for employees (or equivalent)**’). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[8] may also declare as personnel costs **additional remuneration** for personnel assigned to the implementation of trans-national projects (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary’s usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the implementation of trans-national projects is eligible up to the following amount:

(a) if the person works full time and exclusively on the implementation of trans-national projects during the full year: up to EUR 8 000;

(b) if the person works exclusively on the implementation of trans-national projects but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the implementation of trans-national projects: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the trans-national projects during the year}.

A.2.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the implementation of trans-national projects},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the implementation of trans-national projects under the conditions set out above (Point A.2.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.2.1.1,A.2.1.2 and A.2.1.3) : the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used.

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the implementation of trans-national projects may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.2.1.1 and A.2.1.2) **calculated in accordance with the beneficiary's usual cost accounting practices**: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories;

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and
- the hourly rate is calculated using the number of annual productive hours (see above).

A.2.2 **Direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

A.2.3 **Other direct costs for the implementation of trans-national projects by the beneficiaries**

A.2.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

A.2.3.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the trans-national projects implemented by the beneficiary and rate of actual use for the purposes of the transnational projects implemented by the beneficiary.

A.2.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the trans-national projects implemented by the beneficiary and in accordance with Article 10.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

A.2.3.4 **Capitalised and operating costs of 'large research infrastructure'**[9]***[OPTION 1 by default:*** *directly used for the trans-national projects implemented by the beneficiary are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the trans-national projects implemented by the beneficiary and the rate of actual use for the purposes of the trans-national projects implemented by the beneficiary, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

A.2.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:***:***

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

[8] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (**'Rules for Participation Regulation No 1290/2013'**) (OJ L 347, 20.1.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of Rules for Participation: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'

1. Costs for trans-national projects (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as direct costs related to trans-national projects:

- direct costs of providing financial support to third parties implementing trans-national projects
- direct costs for the implementation of trans-national projects by the beneficiaries:
  - direct personnel costs for the implementation of trans-national projects by the beneficiaries:
    - basic remuneration (basic salary and complements)
    - for non-profit legal entities: additional remuneration ('bonus payments')
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
  - direct costs of subcontracting for the implementation of trans-national projects by the beneficiaries
  - other direct costs for the implementation of trans-national projects by the beneficiaries:
    - travel and related subsistence allowances
    - equipment

- other goods and services
- costs of large research infrastructure.

What? These budget categories **cover** costs for the implementation of trans-national projects.

What not? They do not cover the costs for organising the calls (i.e. preparation of the call, selection of the projects etc.) or for additional coordination and networking activities of beneficiaries implementing trans-national project themselves. Such costs are NOT eligible under the ERA-NET grant.

> ⚠ The beneficiaries must use their own funds for such activities.

1.2 All costs must normally be **declared as** actual costs *(see Article 5.2(b))*.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

1.3 In principle, the same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The ERA-NET Cofund MGA has however the following **specificities**:

In some Articles, the conditions in the General MGA must be read as referring to 'trans-national projects' (instead of 'action').

Moreover, there are additional cost eligibility conditions in Article 15 for financial support to third parties *(e.g. selection procedure, compliance with national funding rules)*.

Finally, costs for financial support to third parties are usually eligible only AFTER the trans-national projects have ended.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA*).

B. Direct coordination costs for additional activities

Direct coordination costs for additional activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual years in which the beneficiary has carried out the 'additional activities' described in Annex 1.

Beneficiaries that implement transnational projects (partially or fully) themselves cannot declare direct coordination costs for additional activities.

1. Additional coordination costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the direct costs for additional activities related to the coordination of national/regional research and innovation programmes *(see also Article 2)*.

1.2 The costs must be **declared as** the unit cost fixed by Decision C(2013) 8200[115] and indicated in Annex 2 of the GA (currently **EUR 29 000** per beneficiary per year).

In practice, the declaration of costs for additional activities is very simple and almost completely automatized: The beneficiary must only indicate the number of years (during which such activities were implemented) and the costs are then automatically calculated by the IT system.

1.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be declared for the **additional coordination activities** described in Annex 1.

Costs for additional coordination activities are limited to the beneficiaries that carry out such activities.

Beneficiaries that implement trans-national projects can NOT declare any additional coordination costs.

1.4 They are **calculated** (automatically by the IT system) as follows:

amount per unit (EUR 29 000) **x** number of years in which additional activities were carried out

According to General Annex D to the H2020 Work Programme, the EU funding for coordination costs should not exceed 20 % of the maximum grant amount set out in Article 5.1.

If the additional activities are not properly implemented as described in Annex 1, the grant may be **reduced** *(see Articles 7 and 43)*.

Example: *Beneficiaries make only two meetings on general strategy.*

[115] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_era-net_cofund_en.pdf.

C. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points A and B above), from which are excluded:

(a) costs of subcontracting for the implementation of trans-national projects by the beneficiaries;

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

(c) costs of financial support to third parties implementing trans-national projects.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.[…]

[11] For the definition, see Article 121(1)(b) of the Financial Regulation: '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

1. Indirect costs (C.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The flat-rate is however calculated on the following eligible direct costs:

- direct costs for the implementation of trans-national projects by the beneficiaries
- direct coordination costs for additional activities.

'Direct costs of providing financial support to third parties implementing trans-national projects' are NOT included.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary for the implementation of the trans-national projects by the beneficiaries, they may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For ERA-NET Cofund actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing to the joint call for proposals can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action).

Use of **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12) or subcontractors (Article 13)) is ONLY allowed for beneficiaries/linked third parties that **implement trans-national projects**.

Linked third parties may participate in all activities under the action.

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

ARTICLE 15 — SUPPORT TO OR IMPLEMENTATION OF TRANS-NATIONAL PROJECTS

15.1 Rules for providing support to or implementation of trans-national projects

15.1.1 The beneficiaries must **provide financial support** to trans-national projects or **implement** such **projects** (partially or fully) themselves, in accordance with the following conditions:

(a) types of activity that qualify for financial support and persons or categories of persons that may receive financial support:

The projects must be **trans-national projects**, involving at least two independent entities from two different EU Member States or associated countries;

(b) **selection procedure** and criteria:

The projects must be selected following a single joint transnational call for proposals.

The beneficiaries must make the selection through a two-step procedure:

- Step 1: review at national or trans-national level
- Step 2: single international peer review.

Only entities that are eligible for funding under the national programmes involved in the joint call may be invited to Step 2.

In Step 2, the beneficiaries must evaluate proposals with the assistance of at least three **independent experts**, on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

Proposals must be ranked according to the evaluation results. The selection must be made on the basis of this **ranking**.

The selection procedure must be followed by an independent expert observer, who must make a report (see Article 20.2a);

(c) other conditions:

In the case of support to entities that are third parties, the beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Article 22 and 23 also towards the third parties receiving financial support.

Financial support to entities that are third parties must comply with **national funding rules**.

The **maximum amount of financial support** to a third party and the **criteria for** determining the **exact amount** under national funding rules are set out in Annex 1.

15.1.2 In addition, the beneficiaries must:

- publish a joint call on a dedicated webpage and promote it at national/regional level via their usual channels of communications to potential proposers;
- keep the joint call open for at least 60 days;
- take all lawful steps to ensure confidentiality of information and documents obtained during the evaluation and selection procedures of the joint call.

15.2 Consequences of non-compliance

If a beneficiary breaches its obligations under Article 15.1.1, the costs of the beneficiary for its financial support to the trans-national projects or for the implementation of its trans-national projects will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches its obligations under Article 15.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Providing financial support — Implementing trans-national projects

For ERA-NET Cofund actions, the beneficiaries may provide financial support to third parties (i.e pass on the EU support they receive via the ERA-NET Cofund grant to recipients that are not party to the GA, also called 'cascade funding').

In this case, the beneficiaries' activity consists in providing financial support, while it is the recipients (third parties) that actually implement the trans-national research and/or innovation projects.

The beneficiaries may however also choose to implement the projects themselves.

⚠ Article 15 contains both additional cost eligibility conditions (in Article 15.1.1) and 'other obligations' (in Article 15.1.2).

2. Additional cost eligibility condition: Trans-national projects

The projects must be trans-national (i.e. they must involve at least two independent entities from two different EU Member States or H2020 associated countries), both in case of:

- financial support to third parties and
- implementation of the projects by the beneficiaries themselves.

3. Additional cost eligibility condition: Two-step selection procedure

The beneficiaries must select the trans-national projects according to a two-step procedure, ensuring that:

- only entities that are eligible for funding under the national funding rules are invited to Step 2 and

- consortia can balance the requested funding and available funding per participating EU Member State and H2020 associated country between Steps 1 and 2.

4. Additional cost eligibility condition: Independent experts — Observer

In addition to expert evaluators, the beneficiaries must appoint an independent expert as an observer to verify that the selection procedure (and, in particular, the peer review evaluation and the ranking) meets the requirements of Article 15.

The observer's report must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

5. Additional cost eligibility condition: Ranking list(s) — Joint selection list

The beneficiaries must base their selection (**joint selection list**) on the order of the ranking list (or the ranking lists, if there are different topics).

If proposals have identical scores, the proposals coming from participating EU Member States or H2020 associated countries with still available funding can be given precedence, in order to maximise the number of selected projects.

The ranking list(s) and the joint selection list must be submitted by the coordinator, as part of the periodic report *(see Article 20.3)*.

6. Additional cost eligibility condition: Compliance with national funding rules

If the beneficiaries provide financial support to third parties, the support must comply with the applicable national funding rules.

The trans-national projects must have been implemented (by the recipients) in compliance with those rules.

Moreover, the beneficiaries must ensure that costs are checked and that their payments are made in compliance with those rules (and certify this; *see Article 20.4*).

7. Additional cost eligibility condition: Conditions for support set out in Annex 1 — Maximum amount of financial support

If the beneficiaries provide financial support to third parties, the beneficiaries may not exceed the maximum amount of financial support set out in Annex 1 and must apply the criteria set out in Annex 1 for fixing the exact amount of funding.

This information must already be part of the proposal *(see the proposal templates)*.

For both, the beneficiaries should rely on the applicable national funding rules. If the national rules do not specify a maximum amount, they must enter the amount of their part of the call budget.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- at least 30 days before the expected date of publication of the joint call: **information on the call** and its content;
- at the end of the selection: **information on each selected project** (including data on each participant and abstracts of the project proposal, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes;
- ***[OPTION 1 by default (two pre-financing payments):*** *in month 36 a '**progress report**' containing:*
  - *an **explanation of the work** carried out by the beneficiaries;*
  - *an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.*

    This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - *a **summary** for publication by the [Commission][Agency];**]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;**]***
- at the end of the action: **information on each implemented project** (including data on each participant and overview of the results, in a format specified by the *[Commission][Agency]*), for publication and evaluation purposes, and
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Information on each selected project — Information on each implemented project

What & When? For ERA-NET Cofund actions, the coordinator must — once the trans-national projects have been selected — submit to the Commission/Agency a list of all the projects with certain information.

> ***Example:*** *data on each participant and abstracts of the proposals*

This information must be updated by the coordinator at the end of the action, by submitting a list of all implemented projects, together with certain information.

> ***Example:*** *data on each participant and an overview of the results*

How? The information must be uploaded directly in the Participant Portal

2. Deliverable: Information on cumulative expenditure incurred

What & When? The coordinator must submit to the Commission/Agency — on a yearly basis — information on the cumulative expenditure incurred by the consortium

How? In practice, this mandatory declaration for ERA-NET Cofund *(see Article 20.5)* is handled as deliverable and must be uploaded directly in the Participant Portal.

It does NOT need to be set out in Annex 1 (since legally speaking the obligation is not based on Article 19 but on Article 20.5).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[19]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[20]]*
- *RP2: from month [X+1] to month [36]*
- *RP3: from month [37] to [the last month of the project]**]***

20.2a Periodic reports — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) the **ranking list(s)** of the projects;

(c) the **observers' report on the evaluation**;

(d) the **joint selection list** of the projects to be funded;

(e) from each beneficiary participating in the joint call, a formal and duly signed '**commitment on availability of funds**' (see Annex 7), and

(f) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment.**

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

(a) a ***periodic technical report*** *(see point (a) above) and*

(b) a ***statement on the use of the second pre-financing payment*** *(see Annex 8), including the* ***request for a third pre-financing payment****.*

The coordinator must certify that the information provided is full, reliable and true and that it can be substantiated by adequate supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22). ***]***

20.3 Request for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4), from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, in case of financial support to third parties, that it has been paid in compliance with the applicable national funding rules; see Article 15);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point A.2.1 of Article 6.2).

20.5 Information on cumulative expenditure incurred

In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the *[Commission][Agency]* by *[31 December][30 November]* each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.

[…]

[19] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.
[20] Month X should be the expected end of the selection procedure referred to in Article 15.1.1.

1. Reports

What & When? For ERA-NET Cofund actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- ranking list of the projects
- observer report on the evaluation

- joint selection list
- commitment on availability of funds (Annex 7)
- statement on the use of the previous pre-financing instalment (Annex 8).

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 8*).

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

ERA-NET Cofund actions are normally divided into 2 reporting periods with 2 pre-financing payments (or exceptionally 3 reporting periods with 3 pre-financing payments, if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment; *see Article 21*).

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

3. Information on cumulative expenditure incurred

Since reporting periods in ERA-NET Cofund actions normally exceed 18 months and ERA-NET Cofund grants are normally above EUR 5 000 000 with a pre-financing payment, all ERA-NET grants contain this clause.

The declaration is normally handled as deliverable *(see Article 19)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[…]

1. Payments to be made — No interim payments

ERA-NET Cofund actions normally are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because the Commission/Agency does not have sufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the trans-national projects) provides beneficiaries with the necessary funds to support or implement the trans-national projects.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since ERA-NET Cofund pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for ERA-NET Cofund actions are as follows:

- for the first pre-financing payment: between 10% and 30 % of the maximum grant amount
- for the second pre-financing payment: between 60 % and 80% of the maximum grant amount.

If the GA provides for a 3 pre-financing payments, then the amount is divided as follows:

- 30 % for the first pre-financing payment
- 30 % for the second pre-financing payment
- 30 % for the third pre-financing payment.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VI. PCP/PPI MGA

VI.1 Background information and approach

The PCP/PPI Model Grant Agreement is used for PCP/PPI actions only.

The PCP/PPI MGA follows the General MGA for numbering and content, except for:

The H2020 PCP-PPI MGA deviates from the General MGA as follows:

- Article 5.2 (PCP-PPI specific reimbursement rate and forms of costs)
- Article 6.2 (PCP-PPI specific conditions for eligibility of costs)
- Article 13 (specific provisions for subcontracting of the PCP R&D services/PPI innovative solutions)
- Article 15 (financial support to third parties not applicable)
- Article 19 (PCP-PPI specific deliverables)
- Article 20.1 – 20.5 (PCP-PPI specific reporting provisions)
- Article 21.1 – 21.3, 21.5 (PCP-PPI specific payment provisions)
- Article 23 (PCP-PPI specific impact evaluation provisions)

- Annex 2 Model for the estimated budget for the action
- Annex 4 Model for the financial statement
- Annex 7 Model for the commitment on availability of resources
- Annex 8 Model for the statement on the use of the previous pre-financing instalment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply or differ only in presentation *(e.g. Article 15, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for PCP/PPI actions are added:

- Article 2 (PCP/PPI actions)
- Article 4.1 (PCP/PPI budget categories)
- Article 8 (PCP/PPI rules on third party involvement).

VI.2 H2020 PCP/PPI MGA: Annotations

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[3],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[4],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[5],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[6]

and

on the other part,

1. 'the **coordinator**':

[**full official name (short name)**], [established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other **beneficiaries**, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number]],*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full] [**OPTION for beneficiaries with VAT:** VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)]*.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)]*.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1	Description of the action
Annex 2	Estimated budget for the action
	2a Additional information on the estimated budget
Annex 3	Accession Forms
	[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties]*
	[OPTION if the JRC participates: *3b Administrative Arrangement]*
Annex 4	Model for the financial statements
Annex 5	Model for the certificate on the financial statements
Annex 6	Model for the certificate on the methodology
Annex 7	Model for the commitment on availability of funds
Annex 8	Model for the statement on the use of the previous pre-financing payment

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[6] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Coordinator — Beneficiaries — Linked third parties — Third parties involved in the action

PCP/PPI uses in principle the same concepts for participants as the General MGA (i.e. coordinator, beneficiaries, linked third parties, etc).

However, all entities contributing financially to the PCP or PPI procurement budget MUST participate as beneficiaries or linked third parties in the GA (NOT as other third parties involved in the action; *see Article 8)*. They form the buyers group.

Linked third parties — Linked third parties are allowed to *fully* participate in the action, like beneficiaries. They will therefore be treated for many issues (including cost eligibility; see *Article 6.3 H2020 General MGA*) like beneficiaries.

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. PCP/PPI actions

What? PCP/PPI funds:

- one single joint public procurement of research and development (R&D) services (PCP) or one joint or several coordinated public procurements for innovative solutions (PPI)

AND

- related additional coordination and networking activities.

For PCP actions, it must be only one PCP per GA; for PPI actions, it can be one joint or several coordinated PPIs per GA.

The additional activities must relate to the joint call for tender, including coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities *(see General Annex D to the H2020 Work Programme)*.

> ***Examples:*** *activities that aim to remove barriers to introducing an innovative solution on the market (including standardisation, certification and regulation); activities that prepare the ground for cooperation on future PCP or PPI projects.*

Coordination activities needed to coordinate the PCP/PPI procurement are mandatory. Other additional activities are optional *(e.g. other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Normally, PCP/PPI grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex C and D to the H2020 Work Programme)*.

PCP/PPI actions are funded in all Parts of Horizon 2020 *(e.g. SEC-09-FCT-2017)*.

The possibility to have several coordinated PPIs was introduced with GA version 4.0 but is also open to older grant agreements.

For more information on PCP/PPI actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14 a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a)].]*

[…]

1. Estimated budget

When submitting the proposal with the estimated eligible costs for PCP/PPI actions, the consortium must decide who will pay the PCP/PPI subcontracts (and who may — by consequence — declare the subcontracting costs), i.e.:

- either the lead procurer (centralised payment; the consortium has a common jointly-committed budget; the lead procurer is mandated to sign the subcontracts and pays all subcontractors; *see Article 13*).

OR

- the members of the buyers group (the individual members of the buyers group pay the subcontractors pro rata; *see Article 13*).

2. Budget categories

The PCP/PPI MGA uses its **own budget categories**.

Budget categories of the PCP/PPI MGA:

- direct costs of PCP/PPI subcontracting

  These are the costs for procuring the R&D services (in the case of PCP) or the innovative solutions (in the case of PPI) (i.e. the estimated procurement price).

  Only the beneficiary(ies) that pay the PCP/PPI suppliers can declare PCP/PPI subcontracting costs. Who actually pays the PCP/PPI suppliers depends on the choice made by the consortium when submitting the estimated eligible costs: either the lead procurer or the members of the buyers group *(see Article 4)*.

- costs of related additional coordination and networking activities
  - direct personnel costs for related additional coordination and networking activities
    - costs for employees (or equivalent)
    - costs for natural persons working under a direct contract
    - costs of personnel seconded by a third party against payment
    - costs for SME owners without salary
    - costs for beneficiaries that are natural persons without salary

        - personnel costs for providing trans-national access to research infrastructure
    - direct costs of subcontracting for related additional coordination and networking activities
    - other direct costs for related additional coordination and networking activities
        - travel costs and related subsistence allowances
        - equipment costs
        - costs of other goods and services
        - capitalised and operating costs of large research infrastructure
    - indirect costs for related additional coordination and networking activities
    - specific cost categories (if option applies).

Thus, the PCP/PPI MGA does NOT have:

– direct costs of providing financial support to third parties.

⚠ The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **[…%]** of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct costs of *[PCP][PPI]* subcontracting**: as actually incurred costs ('**actual costs**');

(b) for **direct personnel costs for related additional coordination and networking activities** *[(excluding personnel costs covered by the unit cost under Point (f))]*[8]:

- as actually incurred costs (**actual costs**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[9]: as actually incurred costs (**actual costs**);

(d) for **other direct costs for related additional coordination and networking activities** *[(excluding other direct costs covered by the unit cost under Point (f))]*[10]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**unit costs**);
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities** *[(excluding indirect costs covered by the unit cost under Point (f))]*[11]: on the basis of a flat-rate applied as set out in Point B.4(a),(b) and (c) of Article 6.2 ('**flat-rate costs**');

(f) ***[OPTION 1 for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[12]] that are part of related additional coordination and networking activities:on the basis of the amount(s) per unit set out in Annex 2a*[13] ***(unit costs).]***

[OPTION 2: specific cost category(ies): *not applicable.**]***

[…]

8 To be used only if option in Point (f) is used.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; costs for 'clinical studies'; costs for 'energy efficiency measures in buildings'.
13 Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rates

How much? The PCP/PPI, normally uses the same reimbursement rates as the General MGA (**100%** for research and innovation actions (RIA) and **70% or 100%** for innovation actions (IA) actions; *see Article 5 H2020 General MGA*), unless the call provides exceptionally for another rate.

2. Cost forms

The PCP/PPI MGA uses the **same cost forms** as the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. Direct costs of *[PCP][PPI]* subcontracting
B. Costs for related additional coordination and networking activities

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point B.4 below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The PCP/PPI MGA has its **own budget categories.** Some of them **cover** however the **same types of costs** as the General MGA, with the same **eligibility conditions** and **calculation rules** *(see Article 6 H2020 General MGA)*.

For ease of reference, the annotations for Article 6.2 will summarise — for each budget category — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated.

A. Direct costs of *[PCP][PPI]* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

1. PCP/PPI subcontracting costs (A.): Types of costs — Form — Eligibility conditions — Calculation

1.1 What? This budget category **covers** the costs of the PCP/PPI procurement (i.e. the price paid and the related taxes; for VAT, *see Article 6.5*).

Only costs of R&D services or innovative solutions *subcontracted* by the beneficiaries are eligible. Costs related to R&D and innovation activities carried out by the beneficiaries *themselves* are NOT eligible in PCP/PPI actions.

What not? Indirect costs for the PCP subcontracting are not reimbursed.

1.2 These costs must be **declared as** actual costs (i.e. on the basis of the prices actually paid) *(see Article 5.2(a))*.

1.3 They must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, etc.; *see Article 6.1(a)*)
- be incurred for the **PCP/PPI subcontracting** described in Annex 1
- fulfil the **additional** cost eligibility **conditions** set out in Article 13.1.1.

1.4 There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred.

B. Costs for related additional coordination and networking activities are eligible up to EUR [(insert amount (insert amount in words)[14]], if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities** ***[(not covered by Point B.5]***

Types of eligible personnel costs

B.1.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the related additional coordination and networking activities ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[15] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

(b) if the person works exclusively on the related additional coordination and networking activities but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed;

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agree otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the related additional coordination and networking activities.

[**B.1.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories B.1.1, B.1.2, B.1.3 [and B.1.6]): the hourly rate is calculated *per full financial year* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of annual productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or option (iii) above, i.e.:

-fixed number of hours;

-standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for during each full financial year;

(b) for personnel costs declared on the basis of **unit** costs (i.e. budget categories B.1.1, B.1.2, B.1.4, B.1.5 [*and B.1.6*]): the hourly rate is one of the following:

- for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points B.1.4 and B.1.5 above), or

- for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices**,** if:

  - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

  - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information:

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** ***[(not covered by Point B.5)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3 **Other direct costs for related additional coordination and networking activities** ***[(not covered by Point B.5)]***

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

B.3.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the related additional coordination and networking activities and rate of actual use for the purposes of the related additional coordination and networking activities.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[16]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[17] ***[OPTION 1 by default:*** *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[18]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the related additional coordination and networking activities and the rate of actual use for the purposes of the additional coordination and networking activities, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 Grant Agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure): *Not applicable.****]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable****.]***

B.3.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

B.4 **Indirect costs for related additional coordination and networking activities** ***[(not included in Point B.5]***

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25 % of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 if Point B.5 applies and the unit cost covers indirect costs:*** *[unit costs under Article 5.2(f) and Point B.5]*[***OPTION 2***: *not applicable*]***]***.

Beneficiaries receiving an operating grant[19] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

B.5 ***[OPTION 1: [Insert name of specific cost category(ies) that are part of related additional coordination and networking activities][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION *1a* ***for specific unit costs (if foreseen by Commission decision and applicable to the grant):*** *[**Insert name of specific cost category**[20]] that are part of related additional coordination and networking activities are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units, [and if [insert additional eligibility conditions, if any]].***]***

[*same for each specific cost category****]***

[OPTION 2: *Not applicable****]***

[…]

[14] This amount must correspond to 30% for PCP and 50% for PPI of the estimated eligible costs set out in Article 5.2.

[15] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[16] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[17] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[18] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[19] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[20] Insert precise name of the cost (as in the Commission decision authorising the use of the unit cost). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

1. Additional coordination and networking costs (B.): Types of costs — Form — Eligibility conditions — Calculation

1.1 The beneficiaries may declare the following **types of costs** as costs for additional coordination and networking activities related to the joint call for tender:

- direct personnel costs for additional coordination and networking activities:
  - basic remuneration (basic salary and complements)
  - for non-profit legal entities: additional remuneration ('bonus payments')
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs of SME owners without salary
  - costs of beneficiaries that are natural persons not receiving a salary'
  - personnel costs for providing trans-national or virtual access to research infrastructure (if option applies)
- direct costs of subcontracting for additional coordination and networking activities
- other direct costs for additional coordination and networking activities:
  - travel and related subsistence allowances
  - equipment
  - other goods and services and
  - costs of large research infrastructure
- indirect costs for additional coordination and networking activities
- specific cost categories (if option applies).

1.2 All costs must normally be **declared as** actual costs.

Personnel costs (average personnel costs) and costs of internally invoiced goods and services may also be declared as unit cost in accordance with the usual cost accounting practices.

Personnel costs of beneficiaries that are SME owners or natural persons not receiving a salary MUST be declared as the unit cost fixed by Decision C(2013) 8197[116] and set out in Annex 2 and 2a of the GA.

This concerns only *beneficiaries* that are SMEs *(e.g. contracting authorities or contracting entities that are SMEs)*, not PCP/PPI subcontractors that are SMEs.

1.3 The same **eligibility conditions** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

The PCP/PPI MGA has however the following **specificities**:

[116] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_sme-owners_natural-persons-no-salary_en.pdf

The costs must be incurred by the beneficiaries for additional coordination and networking activities that are related to the joint call for tender *(e.g. coordination costs for preparing, managing monitoring and following-up the PCP/PPI procurement, costs for other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities)*.

Examples:

1. *The evaluation of the PCP or PPI tender is subcontracted or undertaken by in-house consultants under the responsibility of the consortium participants.*

2. *Resources or equipment for testing innovative solutions are made available by end-users of the targeted innovative solutions (in the form of action tasks undertaken by linked third parties or as in-kind contributions of third parties).*

3. *Costs for validation and testing of solutions provided by the subcontractors*.

1.4 The same **calculation rules** apply as in the General MGA *(see Article 6 H2020 General MGA)*.

According to General Annex D to the H2020 Work Programme, the costs of additional coordination and networking activities are eligible up to a maximum amount of 30% (for PCP)/50% (for PPI) of the total requested grant amount. For each GA, this ceiling is fixed in the GA *(see Article 6.2.B)*. Thus, the amount of EU funding for additional coordination and networking activities does NOT change, even if the costs actually incurred for PCP/PPI subcontracting end up being less than initially estimated (*e.g. if the buyers group is able to procure at a better price than it had budgeted*).

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the **appropriate resources** to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For PCP/PPI actions, generally the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

However, entities contributing financially to the joint procurement budget can only participate as beneficiaries or linked third parties (NOT as other third parties involved in the action). They form the buyers group.

Moreover, certain **third party resources** (i.e. purchasing of goods, works or services (Article 10), in-kind contributions (Articles 11 and 12)) are ONLY allowed for **additional coordination and networking activities**.

> ***Example:*** *Equipment needed for testing and validating solutions is provided by a third party as in-kind contribution.*

By contrast, **subcontracting** (Article 13) is possible both for PCP/PPI subcontracting and related additional coordination and networking activities.

Linked third parties (Article 14) may participate in all activities under the action.

In addition, PCP/PPI actions often have **other interested third parties** (preferred partners), which are neither lead procurer nor part of the buyers group nor linked third parties nor third parties providing in-kind contributions, but which have a special interest in closely following the PCP and may therefore be mentioned in Annex 1 (e.g. entities involved in the related additional networking activities; other potential buyers for the solutions that have expressed a special interest in the PCP/PPI).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

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13.1 ***[OPTION 1 for PCP: Rules for the pre-commercial procurement of research and development services***

13.1.1 The beneficiaries will award ***subcontracts*** *for the* ***PCP*** *research and development services ('**PCP R&D services**') that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the 'lead procurer' and the 'buyers group').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' ***must be set out in Annex 1****. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('**place of performance obligation**').*

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an **open market consultation**, which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1**: make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)[26];*
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*
- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*
- *describes the practical set-up for the implementation of the subcontracts;*
- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2:*** *make an* ***evaluation of the tenders****, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering* ***best value for money*** *and a* ***price corresponding to market conditions****.*

The ***framework agreements*** *(one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

The ***specific contracts*** *(one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4:*** *make a '****contract award notice****' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '****contract implementation stage****':*

(i) monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;

(ii) **ensure compliance with the planning of resources** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that the right of the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."****]***

[26] See Article 16(f) of Directive 2004/18/EC replaced by Article 14 of Directive 2014/24/EU, and Article 24(e) of Directive 2004/17/EC replaced by Article 32 of Directive 2014/25/EU..

1. PCP subcontracting

In PCP actions, the beneficiaries award PCP subcontracts for research and development services that are necessary to address a common challenge set out in Annex 1 (PCP R&D services). 'PCP

subcontract' thus means a contract for the purchase of R&D services (identified in Annex 1 as action task).

⚠ For the purposes of the GA, the suppliers selected as a result of the PCP/PPI call for tender are considered 'subcontractors' and the contracts with them are 'subcontracts'. They do NOT become beneficiaries of the GA.

Characteristics of subcontracting:

- Joint subcontracting by some or all of the beneficiaries and linked third parties (buyers group), with a joint procurement in 3 phases

  The **buyers group** is the group that finances and undertakes together the joint PCP procurement (i.e. normally the entities that need the purchased service/solution or central purchasing bodies).

  For PCP/PPI actions, it must normally be made up of:

  – a minimum of 2 public procurers (i.e. 'contracting authorities' or 'contracting entities' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[117])

    Any entity that fits the definition of a contracting authority or contracting entity as defined in those Directives is considered a public procurer — regardless of whether the EU public procurement Directives themselves apply or not.

    Example: *International entities such as European Research Infrastructure Consortia (ERICs) that fit as majority publicly owned entities the public procurement Directives definition of contracting authorities, but to which those Directives do not apply, are considered public procurers that can participate in the buyers group and are eligible for funding under PCP/PPI actions.*

  – that are established in two different EU Member States or H2020 associated countries *(see General Annex D to the H2020 Work Programme)*.

  This is in addition to the general minimum requirements for participation for Horizon 2020 actions (i.e. minimum of 3 independent legal entities established in different EU Member States or H2020 associated countries; *see General Annexes C and D to the H2020 Work Programme* — unless the work programme/call allows for the participation of sole participants).

  Procurers that are not public procurers, but provide services of public interest and share the same procurement need may also be part of the buyers group.

  Example: *a group of a minimum of two public hospitals from two different EU Member States or H2020 associated countries could be joined by a private hospital or NGO (e.g. Médecins sans frontiers).*

  The buyers group is NOT open to other types of procurers that are not providing services of public interest, even if they may share the same procurement need *(e.g. private company procurers like IBM or EADS that are not providing hospital services cannot be funded as buyers in the above example of a consortium of hospital procurers, even if they would be interested to procure the same software system as the hospital procurers)*.

  Such other entities may be involved in the action as:

[117] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- beneficiaries/linked third parties responsible for other action tasks related additional coordination and networking activities *(e.g. certification bodies, end-users)*
- third parties providing in-kind contributions

if they are not potential suppliers of solutions sought for by the procurement and have no other type of conflict of interest.

The PCP procurement is split in **3 phases** (solution design, prototyping, original development and testing of a limited set of 'first' products or services) which are implemented via 3 different specific contracts (under the overall PCP framework agreement).

The buyers group must select multiple competing subcontractors (with a minimum of 3 subcontractors for the first PCP phase). At the end of each phase, an intermediate evaluation will take place to identify the subcontractors that successfully completed the phase. A call-off will be made to select the subcontractors with the best value for money offers for the next phase.

In order to obtain a competitive supply chain as a result of the PCP, the buyers group must plan the budget distribution across the PCP phases so that there is enough budget for minimum 2 subcontractors in the last PCP phase 3.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

- Concerns **R&D services** addressing a **common challenge** (i.e. a specific procurement need that is part of the mid-to-long-term innovation plans of the buyers group).

The common challenge may have several facets or building blocks, as long as all the beneficiaries in the buyers group share the need for all of them and are willing to co-finance all of them.

If the common challenge is split in several sub-challenges on which different vendors can compete, the minimum requirements of 3 subcontractors for phase 1 and 2 for phase 3 applies per sub-challenge, in order to obtain a competitive supply chain for each sub-challenge.

The procurement must be for an R&D services contract (i.e. a contract with the objective to provide R&D services; *see also General Annex E to the H2020 Work Programme*).

If required for the provisioning of the R&D services and required by the procurement need of the buyers group, the PCP may include the purchase of supplies *(such as the limited volume of prototypes or first test-products resulting from the R&D)*.

Example: *A traffic authority may need to acquire more environmentally-friendly tarmac that was developed and installed during the PCP on a test strip of the road, because the old tarmac was destroyed during the PCP in order to test the new variant and the traffic authority needs to carry out further testing on the tarmac after the PCP is done*.

This does NOT extend to 'quantity production' or 'supply to establish commercial viability or to recover research and development costs' (— otherwise it will not be a an R&D services contract and it will not be exempted from the WTO GPA[118]).

Supplies can NOT constitute the majority of the contract value.

- All subcontracts paid from one common budget for the procurement (**common jointly-committed budget**)

This budget is based on the financial commitments of the beneficiaries and linked third parties in the buyers group and must correspond to the call-for-tender-budget (i.e. the estimated procurement price = estimated direct costs of PCP subcontracting; *see Articles 4 and 6.2.A*).

[118] PCP procurements are exempted from the WTO GPA (since according to Annex IV of the WTO GPA R&D services are excluded from the scope of the GPA, i.e. both from the national treatment obligation and from the non-discrimination obligation).

- Joint procurement procedure (i.e. joint call for tender, joint evaluation of offers and joint award) is coordinated and led by one beneficiary (**lead procurer**)

  The lead procurer may be part of the buyers group or not (i.e. it may also be a beneficiary that is NOT part of the buyers group).

  Example: *the lead procurer can be a central purchasing body that carries out the procurement for the buyers group, but does not contribute financially to the common jointly committed budget)*.

  The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[119].

- **Subcontracts signed** by the lead procurer, in the name and on behalf of the buyers group

  The lead procurer must be mandated by the buyers group in the joint procurement agreement.

  The subcontracts to be signed are:

  - a framework contract with each selected subcontractor, covering the whole PCP and
  - specific contracts with each selected subcontractor, for each PCP phase.

- **Subcontracts implemented** by the selected subcontractors (PCP implementation)

- **Subcontractors** are **paid** either by the lead procurer or (pro rata) by the members of the buyers group (based on their individual financial contribution to the jointly-committed budget), depending on the choice of the consortium when it submitted the estimated eligible costs *(see Article 4)*.

PCP subcontracting is NOT restricted to a limited part of the action (since the PCP subcontracting is the main goal of PCP actions).

There can only be one PCP per PCP action.

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (types of R&D services to be procured), the lead procurer, the buyers group and the common jointly-committed budget and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that the lead procurer has not changed and that the buyers group's commitments to the common jointly-committed budget are still valid — or whether

[119] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PCP subcontracting, there is NO simplified approval procedure (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Place of performance obligation

The majority (i.e. at least 50%) of the total amount of **work** done by the subcontractors for the PCP implementation (including the work of the main researchers) must be **performed in EU Member States** or **H2020 associated countries** (as defined in Article 25 H2020 General MGA).

This includes R&D and operational activities *(e.g. research, development, testing, certifying solutions, etc.)*.

The beneficiaries must require subcontractors to comply with this place of performance obligation, including when subcontractors subcontract work out themselves. This obligation must however be clearly set out in the Framework Agreement *(see below)*.

4. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

The beneficiaries must base the PCP subcontracts on the **best value for money** *(see Articles 10 and 13 H2020 General MGA)*.

The tenders for the PCP call for tender must therefore contain:

- a detailed offer for phase 1
- the goals, plans and unit price conditions for phases 2 and 3.

The offers for the call-offs for phase 2 and 3 must contain the detailed offer for phase 2 and phase 3. The price offered for phase 2 and 3 must be based on the unit prices in the framework agreement

The GA foresees additional rules, i.e. that:

- the price must correspond to **market conditions**

  This means that the price must normally be lower than the exclusive development price (since subcontractors obtain intellectual property ownership rights (IPRs)).

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and the lead procurer must formalise the PCP in a **joint procurement agreement** that:
    - specifies the working arrangements for the joint procurement *(e.g. division of tasks between the lead procurer and the buyers group; signature of the subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. the contributions of each member of the buyers group to the common jointly-committed budget; arrangements for financial transfers between buyers group and/or lead procurer for carrying out the PCP)*
    - specifies in-kind contributions provided by third parties

  - sets out other rights and obligations of the buyers group and lead procurer *(e.g. allocation of IPR-related rights resulting from the PCP; commitment to provide test environments)*

- the procurement must be preceded by an **open market consultation**

  This open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[120].

  A prior information notice (PIN) must be published in the Official Journal of European Union (OJEU) and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

- the procurement must be based on **common procurement specifications** prepared by the buyers group and the lead procurer

  These specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and take into account the feedback from the open market consultation (meaning that it should be refined based on this feedback, if needed).

  They must describe the functionality and performance requirements (including minimum requirements) that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders**.

  The request for tenders does not have to be published. It can be provided on request.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractors complied with these rules.

For more guidance and templates for the tender documents, *see the PCP procurement documents [ODT format].*

5. Additional cost eligibility condition: Minimum content of framework agreement and specific contracts

The beneficiaries must conclude a **framework agreement** (with each selected subcontractor) which sets out the framework conditions for all 3 phases of the PCP implementation, including:

[120] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

- the practical set-up of the implementation of the subcontracts, in particular:
  - the number, duration and budget of the PCP phases
  - the minimum number of expected subcontractors per PCP phase
  - the procedure for the intermediate evaluations after each PCP phase (in particular, the evaluation criteria and the weightings)
  - the process for monitoring of on-going R&D work and reporting obligations of subcontractors
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
  - the role and the rights and obligations of third parties involved in the implementation of the subcontracts
- the minimum requirements that subcontractors must comply with during the PCP implementation, in particular:
  - compliance with the definition of R&D services *(see General Annex E to the H2020 Work Programme)*
  - the obligation of the subcontractors to ensure that the majority of the R&D work (including the work of the main researchers) is located in the EU Member States or H2020 associated countries (place of performance obligation)
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights, in particular:
  - the ownership, by the subcontractors, of the intellectual property rights on the results that they generate
  - the right of the buyers to access to use the results — on a royalty-free basis — for their own internal use *(see General Annex E to the H2020 Work Programme)*
  - the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions and without the right to sub-licence

    This right serves as a safeguard to ensure a competitive supply chain (during or after the PCP action) in case of problems. It does NOT mean that every subcontractor will always and automatically be obliged to grant non-exclusive licenses to third parties to exploit its results.

    Examples (licences needed): *other providers working for the buyers group need access to the IPR to work for the buyers group; a PCP subcontractor abuses its monopoly situation*

  - the obligation of the subcontractors to transfer results (generated by subcontractors during the PCP implementation) to the buyers, if they fail to commercially exploit the results within the period set out in the framework agreement or use the results to the detriment of the public interest, including security interests *(see General Annex E to the H2020 Work Programme)*

    This right serves as a safeguard to ensure commercial exploitation in the public interest, in case the subcontractors fail to do so themselves. It will be for exceptional cases.
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderers and a project summary provided by the winning tenderers
  - after R&D has finished (and after consulting the subcontractors): summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP

The framework agreement remains binding for as long as subcontractors remain in the PCP (i.e. normally until the PCP subcontractor is no longer selected to continue for the next PCP phase).

The beneficiaries must conclude **specific contracts** (with each selected subcontractor and for each PCP phase) must set out the specific conditions applicable to each PCP phase, in particular:

- the details of the PCP R&D services purchased by each buyer
- quantity and
- price.

The phase 1 specific contract is signed (together with the framework agreement) with all the subcontractors selected for phase 1. After phase 1 is finished, a call-off to award the phase 2 specific contracts will be organised among the subcontractors who have successfully completed phase 1. After phase 2 is finished, a call-off to award at least two phase 3 contracts will be organised among the subcontractors who have successfully completed phase 2.

6. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PCP (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

7. 'Other obligation': Compliance with national procurement rules

The **EU public procurement Directives** 2014/24/EU, 2014/25/EU[121] and 2009/81/EC do **NOT apply** to the pre-commercial procurement of R&D services (because such services are exempted[122]).

However, beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of the EU public procurement Directives 2014/24/EU and 2014/25/EU[123]; *see Article 13 H2020 General MGA*) must implement the PCP procurement in compliance with provisions in **national laws on public procurement** that may be applicable to this type of R&D services contracts.

[121] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[122] *See Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.*

[123] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

[OPTION 2 for PPI: Rules for procurement of the PPI innovative solution(s)

*13.1.1 The beneficiaries will award **subcontracts** for procuring the '**PPI innovative solution(s)**' that are necessary to address the '**common challenge**' set out in Annex 1.*

The subcontracts must be awarded in one single joint (or several coordinated) procurement procedure(s) by the beneficiaries concerned (i.e. the 'buyers group' and the 'lead procurer').

The lead procurer must be a 'contracting authority' or 'contracting entity' as defined in Directives 2004/18/EC (or 2014/24/EU) and, 2004/17/EC (or 2014/25/EU).

*The 'buyers group', the 'lead procurer', the innovative solution(s) and their estimated cost **must be set out in Annex 1**. The estimated cost of PPI subcontracting per beneficiary must be set out in Annex 2.*

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).**]

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*
- *avoid any conflict of interest (see Article 35);*
- *allow for all communications (with potential tenderers, tenderers and subcontractors) to be made in English (and any additional language(s) they may have chosen).*

Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following **requirements**:*

*(a) For the '**preparation stage**':*

*(i) identify and agree (in writing) on their internal procedures for carrying out the joint (or coordinated) PPI procurement(s) ('**joint procurement agreement**');*

*(ii) **[OPTION 1 for PPI actions that are not limited to the procurement of the limited set of prototypes and/or test products developed during a preceding PCP action:** make an '**open market consultation**' inviting all interested economic operators to participate, which*

- *is published — two months in advance —by the lead procurer in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the [Commission][Agency], together with a list of Q&As raised during the open market consultation;**]***

[OPTION 2:** not applicable**]

*(iii) prepare **common tender specifications**, based on the needs analysis of the buyers group;*

*(b) For the '**procurement/tendering stage**':*

[OPTION 1 for PPI actions that are <u>not</u> limited to the procurement of a set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) '**contract notice**'(s), which:*

- *are published by the lead procurer (or beneficiary) in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specify a time-limit for receipt of tenders that is sufficient for the preparation of innovative bids.*

  The call(s) for tender must remain open for at least 60 days.

  The restricted procedure with shortened time-limit for receipt of tenders may not be used;
- *allow for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *are promoted and advertised widely;*
- *indicate how potential tenderers can obtain the tender documentation and the 'PPI request(s) for tenders';*

*and the **tender documentation** and **PPI request for tenders**.*

*(ii) **Step 2**: make one (or several) **evaluation(s) of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to **<u>best value for money</u>** criteria and ensuring that the price corresponds to **<u>market conditions</u>**;*

*(iii) **Step 3**: **award the <u>subcontract(s)</u>** to the tenderer(s) offering best value for money and a price corresponding to market conditions;*

*(iv) **Step 4**: make one (or several) '**contract award notice**'(s), which are published by the beneficiary or lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);**]***

[OPTION 2 for PPI actions that are limited to the procurement of the set of prototypes and/or test products developed during a preceding PCP action:

*(i) **Step 1**: make one (or several) **request(s) for offers** from at least **three providers**, which — in accordance with the negotiated procedure without publication as provided for in Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25//EU)[271] —:*

- *use technical specifications that are functional or performance based;*
- *avoid selection criteria based on restrictive qualification requirements or disproportionate financial guarantees;*
- *specify award criteria based on best value for money*

- *describe the practical set-up for the implementation of the subcontracts, in particular:*
  - *the types of subcontracts that will be concluded with successful tenderers (in particular whether a framework agreement with multiple economic operators will be used or not);*
- *describe the arrangements for intellectual property rights*
- *describe the arrangements for liability for damages;*

(iv) ***Step 2:*** *make one (or several)* ***evaluation(s) of the tenders*** *ranking them, on the basis of the common tender specifications (see above), according to* ***best value for money*** *criteria and ensuring that the price corresponds to* ***market conditions****;*

(v) ***Step 3: award the subcontracts*** *to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.****]***

*(c) For the '****contract implementation stage****':*

(i) monitor that the PPI innovative solutions are implemented compliance with the objectives of the action set out in Annex 1;

(ii) ensure ***compliance with the planning of resources*** *set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) ensure payment of the subcontractors.

The beneficiaries concerned must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the subcontractors.

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1 18, 34, 35, 36, 37, 38, 39 and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24/EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *'This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement.'****]***

[27] See Articles 28 and 31(2)(a) of Directive 2004/18/EU replaced by Article 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

1. PPI subcontracting

For PPI actions, beneficiaries award PPI subcontracts for procuring the innovative solutions that are necessary to address the common challenge set out in Annex 1 (PPI innovative solution(s)). 'PPI subcontract' thus means a contract for the purchase of innovative solutions (identified in Annex 1 as an action task).

The requirements for PPI subcontracting are generally similar as for PCP subcontracting.

However, PPI subcontracting has the following **specificities**:

The PPI procurement covers 2 phases (deployment and operational validation) — but there is no requirement to split the PPI procurement for those 2 phases in different contracts.

The beneficiaries may choose between implementing *one single* or *several coordinated* PPI procurements.

> For joint procurements, there is one joint PPI call for tender launched by the lead procurer and one joint evaluation of offers.
>
> For coordinated procurements, there are several separate PPI procurements carried out individually by the different procurers in the buyers group.

Moreover, the buyers group may select one or more subcontractors.

The common challenge does NOT concern R&D services, but the **supply** of **innovative goods** or **services**. The buyers group acts as a launch customer (early adopter) of innovative solutions that are not yet available on a large-scale commercial basis.

> PPI cannot include the procurement of R&D. Only procurement procedures that do not involve the procurement of R&D can be used for PPI *(e.g. innovation partnership procedure)*.
>
> Each PPI action focuses on one concrete common challenge and requires innovative solutions that are to a significant extent similar across countries, making it sensible to procure them together (i.e. the core functionality and performance characteristics must be the same; there may be additional local functionalities — due to differences in the local context of each individual procurer).

Also, there is a common budget for the procurement (**common jointly-committed budget**) only if the buyers group would like to centralise payments. Each buyer may alternatively manage a separate budget for the innovative solutions it buys.

Finally, the subcontracts are **not necessarily signed** by the **lead procurer**; there is not necessarily a **framework agreement**.

> The buyers group may choose between direct subcontracts or a framework agreement with specific contracts (with each selected subcontractor).
>
> For joint procurements:
>
> - the buyers group may mandate the lead procurer — in the joint procurement agreement — to sign the framework agreements and/or the specific contracts/direct subcontracts
> - if there is no mandate, the general rule is that:
> - framework agreement(s) must be signed by all members of the buyers group together
> - specific contracts must be signed by each buyer individually (for the innovative solution(s) it buys).

PPI subcontracting is not restricted to a limited part of the action (since the PPI subcontracting is the main goal of PPI actions).

⚠ Article 13.1 contains both additional cost eligibility conditions (in Article 13.1.1) and 'other obligations' (in Article 13.1.2).

2. Additional cost eligibility condition: Procurers, tasks and costs set out in Annexes 1 and 2 — No simplified approval procedure

Annexes 1 and 2 must clearly identify the common challenge (type of innovative solutions to be procured), the lead procurer, the buyers group, and the estimated costs per beneficiary, already at the moment of the signature of the GA. Any changes at a later stage *(e.g. after the preparation stage of the project)* are only possible through an amendment; *see Article 55*).

At the end of the preparation stage of the project, the consortium must confirm (in the periodic report; *see Article 20.3*) that lead procurer has not changed and that the buyers group's commitments to the budget for carrying out the PPI are still valid — or whether changes are needed, based on the feedback of the preparation stage of the project *(e.g. the open market consultation)*.

For PPI subcontracting, there is NO simplified approval procedure (contrary to the subcontracting of related additional coordination and networking activities; *see Article 13.2*).

3. Additional cost eligibility condition: Procurement procedure — Best value for money — Price corresponding to market conditions

Like for PCP subcontracts:

- the beneficiaries must base the PPI subcontracts on the **best price-quality ratio**
- the price must correspond to **market conditions**

AND

- a **specific procurement procedure** must be followed.

  The main elements of this procedure are as follows:

  - the buyers group and lead procurer must formalise the PPI in a **joint procurement agreement** that:
    - specifies the working arrangements *(e.g. division of tasks between the lead procurer and the buyers group; use of a framework agreement or not; signature of subcontracts, etc.)*
    - sets out the financial arrangements *(e.g. budget for the procurement committed per member of the buyers group; arrangements for financial transfers — if any — between members of the buyers group and/or lead procurer for carrying out the PPI)*
    - specifies in-kind contributions provided by linked third parties
    - sets out other rights and obligations of the buyers group and lead procurer *(e.g. IPR-related rights, commitments to provide test environments)*
  - the procurement must normally be preceded by an **open market consultation** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers).

    The open market consultation must be implemented as a 'technical dialogue' as defined in the EU public procurement Directives 2014/24/EU and 2014/25/EU[124].

[124] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).

A prior information notice (PIN) must be published in the Official Journal of the European Union and must be promoted widely, in particular via the websites specified by the Commission/Agency and the H2020 National Contact Points (NCPs).

The PIN must contain information on:

- the expected launch date for the call for tender

  This date must give potential tenderers sufficient time to adapt their production chain to reach the required functionality or performance requirements.

- whether verification of the market's readiness to deliver the requested quality/price (*e.g. via conformance testing, certification or quality labelling of solutions*) is planned before committing to procure and, if so, at what point in the process.

- the buyers group and the lead procurer must prepare '**common procurement specifications**

  The specifications must be based on an analysis of the buyers group's needs (i.e. the common challenge) and — if there was an open market consultation — take into account the feedback from that consultation.

  They must describe the functionality and performance requirements that solutions must meet, rather than prescribing a specific solution.

- the buyers group and the lead procurer must publish a **contract notice** to launch the **request for tenders** (— unless the PPI is limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers)

  The request for tenders should specify the arrangements for intellectual property rights *(see below)* and the buyers' right to publish summaries of the results and the subcontractors' identities.

  The request for tenders does not have to be published. It can be provided on request.

  For PPI limited to procuring a limited set of prototypes or test products resulting from a previous PCP action carried out by the same procurers, a request for offers from at least 3 providers (including the providers that successfully completed the last PCP phase in the PCP action) is sufficient.

- the buyers group and the lead procurer must **jointly evaluate** the tenders and make a **joint award** decision.

  In case of framework contracts/agreements, there may be multiple award decisions for different specific contracts that may be taken at the appropriate points in time during the framework contract/agreement by the procurers concerned.

Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

Example: *for contracts with a number of phases (such as design and build contracts) or contracts where different parts of the solution corresponding to different lots that need to be deployed at different times and/or by different procurers.*

Beneficiaries have to demonstrate — upon request — that the selection of the subcontractor complied with these rules.

For more guidance and templates for the tender documents*, see the PPI procurement documents [ODT format].*

4. Additional cost eligibility condition: Minimum content of subcontracts

The beneficiaries must conclude subcontract(s) that specify:

- the practical set-up of the implementation of the subcontracts, in particular:
  - the process for monitoring of on-going work and reporting obligations of subcontractors
  - the role and the rights and obligations of third parties involved in the PPI
  - the procedures for accounting and payments
  - an exclusion of contract renegotiations
- the minimum requirements that subcontractors must comply with during the PPI implementation, in particular:
  - implementation of the innovative solutions in accordance with the objectives of the action
  - additional national requirements, ethical and/or security requirements (if applicable)
- the arrangements for intellectual property rights (IPRs), in particular:
  - the ownership by the subcontractor(s) of the intellectual property rights on the results they generate — except in duly justified cases *(e.g. if the party that produced the results is not able to exploit them)*

  The intellectual property provisions described here are the minimum requirements that must be respected. Beneficiaries may — if appropriate — specify additional intellectual property provisions *(e.g. regarding access to background, licensing etc.)* if these:
    - do not conflict with their obligations under other Articles and
    - maximise the incentives for both beneficiaries and subcontractors to use, widely exploit and commercialise the results
- the right of the buyers to publish:
  - at the time of the contract award notice: the identity of the winning tenderer(s) and a project summary provided by the winning tenderer(s)
  - after the contract(s) has(have) finished (and after consulting the subcontractor(s)): summaries of the results as well as the identities of the subcontractor(s)
- the specific conditions for each buyer, in particular:
  - details of the innovative solutions purchased by each buyer
  - quantity and

– price.

If the beneficiaries choose a framework agreement with specific contracts (for the innovative solutions procured by each buyer), the specific conditions for each buyer must be in the specific contracts (and the rest in the framework agreement).

5. Additional cost eligibility condition: Compliance with the planning of resources

To ensure compliance with the resource planning (as set out in Annex 1), the beneficiaries must ensure the timely allocation of resources in order to implement the PPI (including allocating sufficient time and resources for testing solutions in real-life operational end-user environments).

Example: *testing facilities or equipment to be provided by the buyers group (or other beneficiaries or third parties)*.

6. 'Other obligation': Compliance with national procurement rules

Contrary to PCP, the **EU public procurement Directives** 2014/24/EU, 2014/25/EU[125] and 2009/81/EC normally **apply** to PPI procurements.

Therefore, the beneficiaries that are 'contracting authorities' or 'contracting entities' (within the meaning of Directives 2014/24/EU and 2014/25/EU[126]; see *Article 13 H2020 General MGA*) must — like in the General MGA — **also** comply with the applicable **national law on public procurement**.

[125] New directives in force since 2016:
Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ L 94, 28.3.2014, p. 65) and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p.65).
Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on public procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
Old directives:
Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).
Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

[126] Directive 2009/81/EC uses the definitions of Directives 2014/24/EU and 2014/25/EU *(see Article 1(17) of Directive 2009/81/EC)*.

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

*[**OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[28]]*

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment according to Article 55, if:

- they are specifically justified in the periodic or final technical report, and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

*[**OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.2.2 In addition, the beneficiaries must ensure that their obligations under Articles 35, 36, 38, and 46 also apply to the subcontractors.

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC (or 2014/24//EU) or as contracting entities within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

1. Subcontracting of related additional coordination and networking activities

For the subcontracting of related additional coordination and networking activities, the same rules apply as in the General MGA *(see Article 13 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation ***[OPTION for PCP:*** *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))****]***:
    - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders, for publication and evaluation purposes;
    - **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;
    - ***[OPTION for PCP: an assessment by the buyers group of the results achieved by each participating tenderer*** *in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP)****]****;*
- ***[OPTION 1 by default (two pre-financing payments):*** *the coordinator must submit in month [**Y**] a progress report containing:*
    - *a '**periodic summary technical report**' for publication by the [Commission][Agency];*
    - *an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1. This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;****]***

  [OPTION 2 in case of three pre-financing payments: *not applicable;****]***
- at the end of the action: **information on each subcontract financed by the procurement**, including data on each contractor that participated in the procurement, and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;
- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

[*In addition, the beneficiaries must:*

- *[**OPTION 1 for PCP:** at the end of the action: give a demonstration to the [Commission][Agency] of the test products resulting from the procured research and development services.]*
- *[**OPTION 2 for PPI:** at the end of the action: give a demonstration to the [Commission][Agency] of the innovative solution(s).]****]***

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverables: Information on the total number of bids received — Information on the evaluation of tenders — Information on each subcontract financed — Assessment of the results

What & When? For PCP/PPI actions, the coordinator must — after the end of the tender evaluation (and, for PCP actions, also after the evaluation for each PCP phase) — submit to the Commission/Agency information on:

- the total number of bids received
- the evaluation of tenders and
- the winning tenderer(s) and abstracts of the winning tenders (using the following template [ODT])

The information must be complemented by the coordinator at the end of the action (and, for PCP actions, also at the end of each PCP phase) by submitting an assessment of the results and conclusions (using the following template [ODT]).

How? The information must be submitted via the Participant Portal Continuous Reporting Module.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the requests for payments and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

[OPTION 1 by default (two pre-financing payments): *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[38]]*
- *RP2: from month [X+1] to [the last month of the project]**]***

[OPTION 2 in case of three pre-financing payments: *The action is divided into the following '**reporting periods**':*

- *RP1: from month 1 to month [X[39]]*
- *RP2: from month [X+1] to month [Y]*
- *RP3: from month [Y+1] to [the last month of the project]**]***

20.2a <u>Periodic reports</u> — Requests for second *[and third]* pre-financing payment*[s]*

The coordinator must submit a periodic report within 60 days following the end of the first reporting period.

The periodic report must include the following:

(a) a **periodic technical report** containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and other deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities[.][;]

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);**] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;**]***

(iii) a **summary** for publication by the *[Commission][Agency];*

(iv) the answers to the '**questionnaire**' covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on the outcome of the preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing payment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

[OPTION in case of three pre-financing payments: *The coordinator must submit a periodic report within 60 days following the end of the second reporting period.*

The periodic report must include the following:

*(a) a **periodic technical report** (see point (a) above) and*

*(b) a **statement on the use of the second pre-financing payment**, including the **request for a third pre-financing payment**.*

*The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).**]***

20.3 Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for all reporting periods.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

The individual financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party*;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**summary financial statement**' , created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

[…]

[38] Month X should be the end of the preparation phase and submission of second pre-financing request.
[39] Month X should be the end of the preparation phase and submission of second pre-financing request.

1. Reports

What & When? For PCP/PPI actions, the coordinator must submit a periodic report after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress

- summary for publication
- questionnaire (i.e. the structured information requested)
- call for tender documents (including contract notice, invitation to tender and procurement contracts)
- report on outcome of the preparation phase *(e.g. open market consultation)*
- commitment on availability of funds (Annex 7)

  This ensures that the PCP/PPI subcontracting costs are covered.
- statement on the use of the previous pre-financing instalment (Annex 8)

NO financial reporting during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes also the request for further pre-financing payments; only the first pre-financing payment is automatic; *see Annex 7*)

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

Normally, PCP/PPI actions are divided into 2 reporting periods (with 2 pre-financing payments; *see Article 21*). The first reporting period corresponds to the preparation of the joint procurement; the second reporting period corresponds to the implementation and follow-up of the joint procurement.

Actions will exceptionally be divided into 3 reporting periods (with 3 pre-financing payments), if the Commission/Agency does not have sufficient payment credits to pay the entire amount as a second pre-financing payment.

The first (and, if there are 2 pre-financing payments, also the second) reporting period triggers a periodic report.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payments — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* and transferred into the '**Guarantee Fund**'.

The *[Commission][Agency]* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] except if Articles 47 or 48 apply.

[OPTION in case of three pre-financing payments:** The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.**]

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

21.3 Interim payments — Amount — Calculation

Not applicable

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns the second *[or third]* pre-financing payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

[...]

1. Payments to be made — No interim payments

Normally, PCP/PPI actions are divided into 2 reporting periods *(see Article 20.2)* with 2 pre-financing payments (— unless the action is exceptionally divided into 3 reporting periods with 3 pre-financing payments because of insufficient payment credits).

There are NO interim payments, but the second pre-financing payment (after the end of the first reporting period, i.e. after the evaluation of the preparation stage of the PCP/PPI procurement) provides beneficiaries with the necessary funds to launch the PCP/PPI procurement.

The second (or third) pre-financing payment is NOT automatic but must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

In this statement, the beneficiaries must simply declare how much of the previous pre-financing was used up, not how much costs were incurred (since PCP/PPI pre-financing is NOT linked to financial reporting).

The balance is paid when the action ends (after the submission of financial reports).

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? Typically (and depending on the availability of EU budget credits), the amounts of the pre-financing payments for PCP/PPI actions are as follows:

- for the first pre-financing payment: the percentage of the maximum grant amount foreseen for the additional networking and coordination activities related to the preparation of the call for tender
- for the second pre-financing payment: if needed, up to 100% of the remaining part of the grant (minus the amount of the first pre-financing payment).

If the GA provides for a third pre-financing payment, the amounts will be adapted.

The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[the Agency and the]* Commission

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

1. Technical reviews

For PCP/PPI actions, the Commission/Agency may in particular carry out technical reviews at key milestone points during the action (*e.g. for PCP actions, at the transition from one PCP phase to the next)*.

VII. EJP Cofund MGA

VII.1 Background information and approach

The EJP Cofund Model Grant Agreement is used for European Joint Programme Cofund actions only.

The EJP Cofund MGA follows the General MGA for numbering and content, except for the following:

The H2020 EJP Cofund MGA deviates from the General MGA as follows:

- Article 3 (duration of EJP Cofund actions: 60 months)
- Article 5.2 (EJP Cofund specific reimbursement rate)
- Article 16 (provision on access to research infrastructures not applicable)
- Article 19 (EJP Cofund specific deliverables)
- Article 20.2, 20.2a, 20.3 (EJP Cofund specific reporting provisions)
- Article 21.1, 21.2, 21.5 (EJP Cofund specific payment provisions)

- Annex 7 Annual work plan for the next year
- Annex 8 Model for the statement on the use of the previous pre-financing payment

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in presentation *(e.g. Article 16, Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for EJP Cofund actions are added:

- Article 2 (EJP Cofund actions)
- Article 4.1 (EJP Cofund budget categories)
- Article 6 (EJP Cofund eligible and ineligible costs)
- Article 6.2.D.2 and F (Euratom Fusion EJP Cofund action durable equipment option and specific categories of costs)
- Article 8 (EJP Cofund rules on third party involvement).

VII.2 H2020 EJP Cofund MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. EJP Cofund actions

What? EJP Cofund funds:

- a joint programme of activities by coordinated national research and innovation programmes (— ranging from research and innovation to coordination and networking activities and including training, dissemination and financial support to third parties).

EJP does NOT fund individual projects or coordination networks.

Normally, EJP Cofund grants are multi-beneficiary grants; exceptionally they can be *mono*-beneficiary grants for 'sole participants' *(see General Annex D to the H2020 Work Programme)*.

EJP Cofund actions are funded in all Parts of Horizon 2020 and the Euratom Research and Training Programme *(e.g. NFRP7–2015; Fusion programme Cofund action (FEJP) in section B.1 Euratom Work Programme 2014-2015)*.

For more information on EJP Cofund actions, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

For more information on the conditions for participation and funding, *see the Participant Portal Online Manual or the General Annexes to the H2020 Work Programme and the call and topics pages of the call.*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The **duration of the action** will be **60 months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[7] (‘**starting date of the action**’).

[7] This date must be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application, except in duly justified exceptional cases as provided for in the basic act and the work programme (Article 130 FR).

1. Action duration

For EJP Cofund actions, the action duration is normally **60 months**.

If implementation of the action is justifiably delayed, the consortium may request an extension (i.e. request an amendment extending the action duration; *see Article 55*). The duration can however NOT exceed 72 months.

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and **budget category** (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)[and][international partners (see Article 14a].]*

[…]

1. Budget categories

The EJP Cofund MGA uses the same budget categories as the General MGA.

Budget categories of the EJP Cofund MGA:

- direct personnel costs
  - costs for employees (or equivalent)
  - costs for natural persons working under a direct contract
  - costs of personnel seconded by a third party against payment
  - costs for SME owners without salary
  - costs for beneficiaries that are natural persons without salary
- direct costs of subcontracting
- direct costs of providing financial support to third parties (if option applies)
- other direct costs
  - travel costs and related subsistence allowances
  - equipment costs
  - costs of other goods and services
  - capitalised and operating costs of large research infrastructure
- indirect costs
- specific categories of costs (if option applies).

For the FEJP action, there are moreover 3 additional specific cost categories:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Thus, the EJP Cofund MGA does NOT have:

- personnel costs for providing trans-national access to research infrastructure.

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORMS OF COSTS

[…]

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses [**…**]**%**[8] of the action's eligible costs (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost under Point (f))]*[11]: ***[OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][OPTION 2**: not applicable;**]***

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost under Point (f))]*[12]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION** 1 **for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] *(**unit costs**).]***

[OPTION 2: specific cost category(ies)**: not applicable.]

[…]

8 This must be the percentage (which can reach a maximum of up to 70%) foreseen in the work programme.
9 To be used only if option in Point (f) is used.
10 To be used only if option in Point (f) is used.
11 To be used only if option in Point (f) is used.
12 To be used only if option in Point (f) is used.
13 To be used only if option in Point (f) is used.

[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing transnational access to research infrastructures'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc.).

1. Reimbursement rate

How much? For EJP Cofund, the reimbursement rate is fixed in the work programme/call. It cannot exceed 70%[127].

2. Cost forms

For EJP Cofund actions, the **cost forms** are in principle the **same** as in the **General MGA** (i.e. actual costs, unit costs and flat rate costs; *see Article 5 H2020 General MGA*).

For the FEJP action, there are however 3 specific unit costs for category F 'specific cost categories':

- costs for mobility of personnel: daily subsistence allowance, monthly subsistence allowance and monthly family allowance
- costs for fellowships for researchers: monthly living allowance, mobility allowance and family allowance
- access costs for research infrastructure. [128]

[127] *See Article 28(5) of the Rules for Participation Regulation No 1290/2013.*

[128] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

[…]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION 2:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit costs:*** *[insert name(s) of specific cost category(ies)*[16]***]][OPTION 2: not applicable]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[…]

[16] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost/ lump-sum). For example: 'access costs for providing trans-national access to research infrastructure'; 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific conditions for costs to be eligible

Article 6.2 refers to specific eligibility conditions, applicable per budget category.

The EJP Cofund MGA uses in principle the **same budget categories** (covering the same **types of costs)** as the General MGA and the same **eligibility conditions** and **calculation rules** apply *(see Article 6 H2020 General MGA)*.

However, EJP grants have the following **specificities**:

- for category A 'personnel costs'

  Costs of students, PhDs and other researchers (under scholarship, internship or similar agreement) — Are eligible even if the agreement is training-oriented (or work-oriented but with a non-negligeable training component), the costs fulfil the eligibility conditions set out in Article 6 and Annex 1 explicitly includes the training activities.

- for category D.2 'equipment costs'

  There is a special cost category for the FEJP action: full purchase cost for JET equipment *(see below)*.

- for category F 'specific cost categories'

There are special cost categories for the FEJP action: specific cost categories *(see below)*.

The annotations below will be limited to these special cost categories for the FEJP action (and summarise — for each of them — the information necessary to establish the eligible costs, i.e.

1. types of costs covered by the budget category
2. cost form under which the costs must be declared (i.e. actual costs, unit costs, flat rate)
3. eligibility conditions
4. how the costs must be calculated).

D. Other direct costs ***[(not covered by Point F)]***

[…]

D.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]: *The* ***costs of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[OPTION (in addition to one of the two options above) to be used in accordance with the Euratom work programme 2014-2018*: The* ***costs of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand)* ***to be included in the JET facilities*** *are eligible, if:*

(a) the equipment, infrastructure or other assets to be purchased and the beneficiary purchasing it are identified in Annex 1 and in the annual work plans approved by the Commission (see Article 19.1)

(b) the costs of purchasing the equipment, infrastructure or other assets are capitalised or expensed by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practices, and

(c) the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.]

[…]

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

1. Equipment costs (D.): Types of costs — Form — Eligibility conditions — Calculation

This budget category applies to all EJP grants.

An additional option for full purchase costs for equipment for JET facilities will be inserted into the GA for the Fusion programme EJP Cofund action (FEJP).

As in the General MGA, the beneficiaries may normally declare the following **types of** equipment **costs** under category D.2 'equipment costs' *(see Article 6.2.D.2 H2020 General MGA)*:

one of the following:

- either **depreciation costs** of equipment, infrastructure or other assets
- or **purchase costs** of equipment, infrastructure or other assets (if option applies)

AND:

- costs of **renting or leasing** of equipment, infrastructure or other assets
- costs of equipment, infrastructure or other assets **contributed in-kind against payment**.

1.1 Equipment costs: Cost of purchasing equipment, infrastructure or other assets to be included in the JET facilities

1.1.1 What? This budget category **covers** the *full* purchase costs of equipment, infrastructure or other assets to be included in JET facilities (not only the depreciation costs for the relevant periodic report).

1.1.2 Equipment costs must be **declared** as actual costs *(see Article 5.2(d))*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for actual costs to be eligible (i.e. incurred during the action duration, necessary, linked to the action, recorded in the beneficiary's accounts, etc.; *see Article 6.1(a)*)
- concern equipment, infrastructure or other assets (new or second-hand) to be included in **JET facilities**

  'JET' means Joint European Torus, i.e. the experimental device for studying fusion relevant plasmas in operation at Culham, UK.

  'JET facilities' include, in particular, the JET device and auxiliary facilities *(such as the neutral beam test bed, the remote handling facility, and the active gas handling system)*.
- be **identified in Annex 1** and in the **annual work plans** approved by the Commission (*see Article 19.1*).
- be **capitalised** or **expensed** by the beneficiary in accordance with international accounting standards and the beneficiary's usual accounting practice
- fulfil the **additional** cost eligibility **conditions** set out in Article 10.1.1.

Costs of equipment, infrastructure or other assets (including depreciation costs) that are declared under this option, may not also be declared by another beneficiary or under another budget category. They may also not be declared under another EU or Euratom grant or contract (*see also Article 6.5(b)*).

1.1.4. There is no specific **calculation** method. The costs must correspond to the eligible costs actually incurred (i.e. the amount paid by the beneficiary for the supply of the equipment).

F. ***[OPTION 1: [Insert name of specific cost category(ies)]][OPTION 2 if no specific cost categories applicable to grant: Specific cost category(ies)]***

[OPTION 1a for specific unit costs (if unit costs foreseen by Commission decision and applicable to the grant): [insert name of specific cost category[22]] *are eligible if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of actual units,[and if [insert additional eligibility conditions if any]].]*

[same for each specific cost category]

[OPTION 2: *not applicable]*

[…]

[22] Insert precise name of the costs (as in the Commission decision authorising the use of the unit cost). For example: 'costs for clinical studies'; 'costs for energy efficiency measures in buildings', 'costs for mobility of personnel', 'costs for fellowships for researchers', 'access costs for research infrastructure'.

1. Specific cost categories (F.): Types of costs — Form — Eligibility conditions — Calculation

For this budget category, in principle the same rules apply as in the General MGA *(see Article 6 H2020 General MGA)*.

For the Fusion programme EJP Cofund action (FEJP), there are however 3 additional specific cost categories set out in Decision C(2013) 8201[129] available:

- costs for mobility of personnel
- costs for fellowships for researchers
- access costs for research infrastructure.

Double funding risk — Costs that are declared as a specific unit may NOT be declared (a **second time**) under another budget category *(for the costs that are covered, see below)*.

1.1 Specific cost category – costs for mobility of personnel (F.2)

1.1.1 What? This budget category **covers** direct costs for FEJP secondments of personnel (irrespective of their duration) to another research institution, in a location other than their normal place of employment, by providing for:

- a daily subsistence allowance
- a monthly subsistence allowance and
- a monthly family allowance.

[129] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

It may be used for secondments of personnel NOT *employed* by the beneficiary/linked third party, but with a contract with full social security coverage.

It may also be used for secondments of personnel provided in-kind by a third party *free of charge*.

It may NOT be used for mobility costs for personnel contributed in-kind *against payment (see below)*.

What not? This budget category does not cover the salary costs of the seconded personnel, other direct costs for the mobility *(e.g. extra costs incurred for the activities of the seconded persons)* or direct costs for managing the mobility. Such costs can be declared under another budget category (i.e. category A 'personnel costs' or D.3 'other goods and services'; *see Article 6.2.A, 6.2.D.3*).

It also does not cover indirect costs for managing the secondments. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; Article 6.2.E).

1.1.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[130] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the daily subsistence allowance: **EUR 127,65**, per individual per day

This amount is subject to a **country-specific correction coefficient** for the country (and in certain cases, the place) of the secondment (coefficient from 1 October 2013) (Belgium and Luxembourg = 100)[131]:

Country/place	Coefficient (%)	Country/place	Coefficient (%)
Austria	106,4	Italy	104,2
Bulgaria	58,4	*Italy Varese*	93,4
Croatia	80,0	Latvia	77,6
Cyprus	84,1	Lithuania	71,5
Czech Rep.	80,6	Malta	83,3
Denmark	135,3	Netherlands	105,3
Estonia	77,6	Poland	74,2
Finland	122,1	Portugal	83,5
France	117,7	Romania	68,8
Germany	95,8	Slovakia	79,7
Germany Bonn	94,1	Slovenia	85,3
Germany Karlsruhe	93,8	Spain	97,1
Germany Munich	106,4	Sweden	131,9
Greece	90,5	*Switzerland Geneva*	124,6
Hungary	78,3	*Switzerland Berne*	123,3
Ireland	110,6	United Kingdom	147,8
		UK Culham	112.5

[130] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.

[131] As set out in Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.4.2014, p. 12).

To ensure purchasing power parity, revised coefficients (based on 1 October 2015 values) are applied as from 1 January 2016:

Country/place	Coefficient	Country/place	Coefficient
Austria	105,9 %	Italy	99,4 %
Bulgaria	52,1 %	*Italy Varese*	92,2 %
Croatia	74,6 %	Latvia	74,2 %
Cyprus	77,3 %	Lithuania	69,0 %
Czech Rep.	73,4 %	Malta	84,5 %
Denmark	131,8 %	Netherlands	107,8 %
Estonia	78,0 %	Poland	71,8 %
Finland	119,7 %	Portugal	79,2 %
France	114,6 %	Romania	64,8 %
Germany	96,6 %	Slovakia	76,4 %
Germany Bonn	93,4 %	Slovenia	81,2 %
Germany Karlsruhe	93,8 %	Spain	90,2 %
Germany Munich	106,0 %	Sweden	127,9 %
Greece	79,9 %	*Switzerland*	142,4 %
Hungary	69,0 %		
Ireland	116,6 %	United Kingdom	166,9 %
		UK Culham	127,7 %

– for the monthly subsistence allowance: between **EUR 0 and 720,27**, per individual per month **—** depending on the distance between the place where the individual was working before and the place of secondment

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82,05**
> 300	**145,86**
> 500	**237,05**
> 800	**382,92**
> 1 300	**601,73**
> 2 000	**720,27**

This amount is subject to the country-specific correction coefficient *(see above)*.

– for the family allowance: **EUR 252,81**, per dependent child per month).

The European Commission may update these unit costs if the joint index based on inflation in Belgium and Luxembourg deviates from the 2014 baseline inflation index by 10 % or more. In this case, the FEJP GA will be **amended** (and the Annotated MGA will be revised accordingly).

As mentioned above, mobility costs for personnel contributed in-kind against payment must be declared as actual costs (of the beneficiary) under another budget category (i.e. category D.1 'travel'; *see Article 6.2.D.1*).

Best practice: Beneficiaries and third parties should use the rates fixed by Decision C(2013) 8201 for the mobility cost to be reimbursed to the third party and to pay this amount to the personnel *(see Article 11.1)*.

1.1.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)
- be incurred for the secondment of personnel (employed by the beneficiary or made available as an in-kind contribution by a third party) to:
  - a location other than the seconded person's place of employment and
  - one of the following:
    - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;
    - another beneficiary where the researcher carries out research activities described in Annex 1 or 7 or
    - a joint support unit created by the beneficiaries under the action
- have been **fully incurred for** the benefit of the **seconded personnel** (i.e. fully paid to the individuals, including during annual leave, special leave, sick leave and holidays)
- for the family allowance: be incurred for personnel accompanied during the secondment by dependent children (between 5 and 18 years), enrolled in regular full-time attendance at a primary or secondary school that charges tuition fees (registration and attendance fees).

1.1.4 They must be **calculated** as follows:

– for the daily subsistence allowance:

amount per unit (≈ EUR 127,65 **x** country coeff. corr.) **x** number of actual days of secondment

'**Day of secondment**' means each day of secondment that lasts more than 12 hours and is calculated as follows:

– the *base amount* is the time between the departure time and the return time of the main form of transport used for the secondment

– to this amount, add the following for each leg of the journey (outward and return):

  – for train travel: a maximum of 30 minutes for each leg

  – for air travel: a maximum of 2 hours for each leg.

NO extra time is added if the journey is by any means of transport other than train or plane.

Example:

The seconded person leaves her/his normal place of employment on a flight departing at 9:35 on Monday 3 April and returns on a flight that arrives at 10:35 on Wednesday 5 April.

*This amounts to **3 days of secondment**: Wednesday 5 April is also counted as exceeding 12 hours (00:00 until the flight arrival time of 10:35, plus 2 hours extra time = 12 hours 35 minutes).*

- for the monthly subsistence allowance:

  amount per unit (*see table above* **x** count. coef. corr.) **x** number of actual months of secondment

- for the family allowance:

  amount per unit (EUR 252,81) **x** number of actual months of secondment **x** number of dependent children

  The family allowance is paid for each full month of secondment in which the dependent child is between 5 and 18 years.

  '**Month of secondment**' means each *full month* of secondment (NO *pro-rata* payments for partial months of secondment).

  A full month can be one of the following two:

  - a **calendar month** *(e.g. 1 to 31 July inclusive)* or
  - a month **from the date the secondment starts** until the same date the following month (excluding the last day, *e.g. 3 July to 2 August)*.

  If a secondment starts on 31 January (or on 30 or 31 January in a leap year), it is considered to have been completed at midnight on 28 February (since there is never a 30 February and a 29 February only in leap years).

Examples for calculating unit costs for mobility of personnel:

1. *An employee with primary employment in Rome is seconded to the joint programme unit in Garching (Munich), Germany, from 1 January 2015 to 31 August 2016 (20 months). He is accompanied by one 6-year-old child, who is enrolled in a fee-paying primary school.*

*Daily subsistence allowance: 609 days * EUR 127,65 = EUR 77 738,85*

*Monthly subsistence allowance: 20 months * EUR 382,92 (800< distance >1 300) = EUR 7 658,40*

Subtotal = EUR 85 697,25

** correction coefficient (2016) of 106.0 % (Germany Munich) = EUR 90 839,09*

*Family allowance: 20 months * EUR 252,81 = EUR 5 056,20*

Total declared unit costs: EUR 95 895,29

2. *An employee with primary employment in Madrid is sent to a scientific project meeting at Culham, UK, for three days.*

*Daily subsistence allowance: 3 days * EUR 127,65 = EUR 382,95*

** correction coefficient (2016) of 127,7 % (Culham, UK) = EUR 489,03*

Total declared unit costs: EUR 489,03

1.2 Specific cost category – costs for fellowships for researchers (F.2)

1.2.1 <u>What?</u> This budget category **covers** direct costs for FEJP researcher fellowships, by providing for

- a monthly living allowance, with full social security coverage and unit costs (including all compulsory deductions) in accordance with applicable national legislation (gross amount)
- a monthly mobility allowance to cover additional costs, *e.g. relating to travel and accommodation* and
- a monthly family allowance to reduce family-related obstacles to researcher mobility.

What not? This budget category does not cover direct costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

It also does not cover indirect costs for managing the fellowships. Such costs can be declared under another budget category (i.e. category E 'indirect costs'; *see Article 6.2.E*).

1.2.2 The costs must be **declared as** the unit costs fixed by Decision C(2013) 8201[132] and set out in Annexes 2 and 2a of the GA.

This is currently:

– for the living allowance: **EUR 3 110** for early-stage researchers and **EUR 4 650** for experienced researchers, per fellow per month

This amount is subject to a 'country-specific correction coefficient' (based on the seven-year average of the relevant coefficient used between 2007 and 2013 for the FP7 Marie Skłodowska-Curie actions) [133]:

Country	Coefficient	Country	Coefficient
Austria	104,8%	Italy	106,7%
Belgium	100,0%	Lithuania	73,1%
Bulgaria	71,5%	Luxembourg	100,0%
Cyprus	91,8%	Latvia	75,9%
Czech Republic	83,8%	Malta	89,6%
Germany	98,8%	Netherlands	104,3%
Denmark	135,3%	Poland	76,4%
Estonia	78,3%	Portugal	89,1%
Greece	92,7%	Romania	68,3%
Spain	97,6%	Sweden	111,7%
Finland	116,6%	Slovenia	86,1%
France	111,0%	Slovakia	82,6%
Croatia	97,5%	United Kingdom	120,3%
Hungary	76,2%	Switzerland	113,1%
Ireland	113,5%		

– for the mobility allowance: **EUR 600**, per fellow per month

– for the family allowance: **EUR 500**, per fellow per month).

1.2.3 The costs must comply with the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, etc.; *see Article 6.1(b)*)

[132] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.
[133] As set out in H2020 Work Programme 2014-2015- 3. Marie Skłodowska-Curie Actions (MSCA) (p.53-54)

- be incurred for fellowships for (early-stage or experienced) researchers that are recruited under an employment contract or equivalent contract with full social security coverage that complies with the applicable social security legislation[134]

  'Early-stage researchers' means researchers that are — at the time of recruitment by the host organisation — in the first four years (full-time-equivalent research experience) of their research careers and have not been awarded a doctoral degree.

  'Experienced researchers' means researchers that have a doctoral degree or at least four years of full-time-equivalent research experience.

- have been **fully incurred for** the benefit of the **fellows** (i.e. fully paid to the individuals)

- for the family allowance: be incurred for fellows that have a family at the time of the recruitment

  'Family' means persons linked to the researcher by marriage (or a relationship with equivalent status to a marriage recognised by the legislation of the country where the relationship was formalised) or dependent children who are being actually maintained by the researcher.

1.2.4 They must be **calculated** as follows:

– for the living allowance:

amount per unit (≈ EUR 3 110/4 650 (**x** count. coef. corr.) **x** number of months actually spent by the fellows on the research training activities

– for the mobility allowance:

amount per unit (EUR 600) **x** number of months actually spent by the fellows on the research training activities

– for the family allowance:

amount per unit (EUR 500) **x** number of months actually spent by the fellows on the research training activities

These are calculated per individual per complete month (NO *pro-rata* payments).

Example for calculating unit costs for researchers fellowships:

A Belgian early-stage researcher with no family is starting a fellowship in Finland for 18 months as part of a PhD programme.

*Living allowance: 18 months * EUR 3 110 = EUR 55 980*

** correction coefficient of 116.6 % (Finland) = EUR 65 272.68*

*Mobility allowance: 18 months * EUR 600 = EUR 10 800*

No family allowance

Total declared unit costs: EUR 76 072.68

1.3 Specific cost category – access costs for research infrastructure (F.2)

1.3.1 **<u>What?</u>** This budget category **covers** direct and indirect access costs for providing FEJP access to research infrastructure (i.e. equipment and running costs of the installation and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc

[134] Council Regulation (EC) No 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 (OJ L 200, 7.6.2004, p. 1).

training needed by users to use the installation and for preparatory and closing activities needed to work on the installation).

⚠ This specific budget category must be distinguished from the general budget category D.4 **'capitalised and operating costs of large research infrastructure'** *(see Article 6.2.D.4 H2020 General MGA)*. FEJP beneficiaries that that have obtained a positive ex-ante assessment may opt between declaring costs under:

- category D.4 'capitalised and operating costs of large research infrastructure'

or

- category F.2 'access cost for research infrastructure'.

It may also be used for access to infrastructure provided by a third party *free of charge*.

It may NOT be used for infrastructure contributed in-kind *against payment (see below)*.

What not? Travel and subsistence costs for users to get access are not included in the access costs. (These costs can be reimbursed separately, under category D.1 'travel'; *see Article 6.2.D.1*).

1.3.2 If they are declared under this budget category, these costs must be **declared as** the unit cost calculated in accordance with Decision C(2013) 8201[135] and set out in Annexes 2 and 2a of the GA.

The precise unit cost is not pre-fixed by the Decision; it must be established for each access provider and installation — before signature of the FEJP GA.

The 'unit of access' to the installation must be identified (i.e. the unit used to measure the total quantity of access that the installation provides to its users)

The 'amount per unit of access' (EUR/unit of access) must be calculated according to the following formula:

$$\text{Amount per unit} = \frac{\text{average annual total access cost (over past two years}^{136})}{\text{average annual total quantity of access (over past two years}^{137})}$$

The averages must be based on:

- the beneficiary's certified or auditable historical data
- costs allocated to the installation according to the beneficiary's usual cost accounting practices and
- a period excluding times when the installation was not usable (out of order, under repair or undergoing long-term maintenance).

'Total quantity of access' means the units of access annually provided by the installation for the purposes of the activities referred to in Annex 1 of the GA (for the reference period years N-1 and N-2).

'Total access costs' is calculated on the basis of the following categories of eligible costs:

- direct costs incurred by the access provider for the 'annual total quantity of access to the installation', as recorded in the certified or auditable profit-and-loss accounts of the reference period (years N-1 and N-2) for:
  - personnel costs of administrative, technical and scientific staff directly assigned to keep the installation functioning normally and to support the users
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded to keep the installation functioning normally

[135] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_fusion_en.pdf.
[136] In exceptional and duly justified cases, the Commission may agree to a different reference period.
[137] In exceptional and duly justified cases, the Commission may agree to a different reference period.

— costs of consumables specifically used for the installation and the users' research work

— costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation

— costs of energy power and water supplied for the installation

— costs of general services specifically included in the access services provided *(e.g. library costs, shipping costs)*

— costs of software licences, internet connections or other electronic services for data management and computing where needed to provide access services

— costs of specific scientific services included in the access provided or needed for the provision of access

— depreciation costs of equipment, buildings and other assets (new or second-hand) that are part of the installation and were not purchased or built using EU/Euratom funds

— renting or leasing the equipment, buildings and other assets that are part of the installation

Costs calculated in accordance with the beneficiary's usual cost accounting practices are acceptable for personnel (average personnel costs) and internally invoiced goods and services — if this is the normal practice of the beneficiary.

– indirect costs for providing access to the installation equal to 25 % of the eligible direct costs, minus any costs of subcontracting (i.e. costs of contracts for maintenance and repair, installation management, scientific services and other electronic services)

and excluding:

– depreciation costs of infrastructure purchased or built using EU funds (Those costs are not eligible; *see also Article 6.5(b)*)

– travel and subsistence costs for users.

The unit cost can be changed only via an amendment to the agreement *(see Article 55)*.

As already mentioned above, access costs for installations contributed in-kind must be declared as actual costs under another budget category (i.e. category D.3 'other goods and services'; *see Article 6.2.D.3*).

Before signature of the FEJP GA, the beneficiaries can still opt for declaring the costs not as unit cost, but as actual costs *(see Article 6.2.A-E)*. (One cost form per installation and access provider.)

The use of unit costs for access activities is optional, i.e. each beneficiary/linked third party can decide independently whether to be reimbursed on the basis of unit costs or actual costs.

If a beneficiary has initially opted for actual costs, it may only change its choice to unit costs through an amendment to the agreement *(see Article 55)*.

1.3.3 The costs must fulfil the following **eligibility conditions**:

- fulfil the **general conditions** for unit costs to be eligible (i.e. units used during the action duration, necessary, linked to the action, correct calculation, etc.; *see Article 6.1(b)*)
- be incurred for providing access to research infrastructure to other beneficiaries

1.3.4 They must be **calculated** as follows:

amount per unit *(see Annex 2a GA)* **x** number of units of access actually provided to other beneficiaries

Example for calculating unit costs of access to research infrastructure:

An access provider considers that the unit of access to the installation is calendar days. It provided 200 days of access in year N-1 and 150 days in year N-2. The total cost of providing this access, calculated on the basis of the categories of costs indicated above and the beneficiary's usual cost-accounting practices, is EUR 50 000 000 for year N-1 and EUR 20 000 000 for year N-2.

Unit cost = EUR 35 000 000 (average annual total cost) / 175 days (average annual total access) = EUR 200 000 per day

If the access provider makes the installation available for the Fusion programme EJP Cofund action for 50 days in year N, the total to be declared under unit costs for research infrastructure for year N will be EUR 10 000 000.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

For EJP Cofund actions, the same rules on third party involvement apply as in the General MGA *(see Article 8 H2020 General MGA)*.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 90 days before the end of each reporting period:

  (a) the '**annual work plan for the next year**' (see Annex 7), for approval by the *[Commission][Agency]* and

  (b) a **summary progress report** *on* the activities carried out during the on-going reporting period

  This report must show how the activities proposed in the annual work plan for the next year ensure continuity with the work already carried out.

  If the *[Commission][Agency]* considers that the annual work plan for the next year does not comply with Annex 1, the coordinator must submit a revised version within 30 days from receiving formal notification.

  If the *[Commission][Agency]* considers that the revised annual work plan for the next year still does not comply with Annex 1, it may terminate the Agreement (see Article 50.3).

- the other '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

1. Deliverable: Annual work plan

What & When? For EJP Cofund actions, the coordinator must submit to the Commission/Agency — for each twelve-month period of the EJP — an annual work plan.

This plan contains a detailed description of the activities for that period, in line with the objectives and description of work set out in Annex 1. Thus, while Annex 1 may include the targeted areas for research or other activities, it is the annual work plan that will define and specify the activities and the deliverables.

Example:

Annex 1 of a EJP contains a work package dedicated to a series of irradiation experiments in a large research facility. The annual work plan for the first reporting period provides a detailed description of the planned experiments on the related materials and the expected milestones.

As the programme develops, additional irradiation capacity becomes available in year 3. Alternatively, the validation of previous results requires further work or other materials become interesting. The consortium proposes an annual work plan with additional experiments commencing in that reporting period.

An EJP consortium therefore has a certain flexibility to develop activities and use the allocated budget (as long as the proposed activities remain in line with the EJP objectives and description of work (Annex 1) as initially evaluated)

The annual work plan must be drawn up using the template in Annex 7.

The periods of the annual work plans coincide with the reporting periods *(see Article 20)*, but the work plans must be **submitted** 3 months (i.e. 90 days) in advance to allow for review by the Commission/Agency (— except for the annual work plan for the first reporting period, which must already be part of the proposal; *see the proposal templates*).

If the Commission/Agency considers that the proposed annual work plan does not comply with Annex 1, it will ask the coordinator to submit a **revised annual work plan** (— within 30 days from receiving the request).

How? The annual work plan must be uploaded directly in the Participant Portal.

2. Deliverable: Summary progress report

What & When? The annual work plan must be accompanied by a summary progress report.

The summary progress report should focus on how the activities proposed in the annual work plan ensure continuity with the work already carried out.

It should NOT contain an analysis of *all* activities carried out during the reporting period (since that is the purpose of two other documents that must be submitted as part of the periodic reports, i.e. the explanation of the work carried out and the overview of the progress; *see Article 20.3*).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36
- RP4: from month 37 to month 48
- RP5: from month 49 to month 60

20.2a Request for a second pre-financing payment

[OPTION 1 in case of two pre-financing payments: *The coordinator must submit — within 30 days following the end of the first reporting period — a* ***request for a second pre-financing payment****.*

*The request must be included in a '****statement on the use of the previous pre-financing payment****' (see Annex 8).****]***

[OPTION 2: *not applicable****]***

[…]

1. Reports

Like the General MGA, the EJP Cofund MGA foresees periodic reports for each reporting period (including the final one), with both a technical and a financial part *(see Article 20 H2020 General MGA)*.

2. Reporting periods

EJP Cofund actions are divided in **5** reporting periods of **12 months** each.

Each reporting period triggers a periodic report.

3. Request for a second pre-financing payment — Statement on the use of the previous pre-financing payment

The GA may provide for this option for large EJPs that need a second pre-financing payment (at the beginning of the second reporting period; *see Article 21)*.

Payment of further pre-financing payments is not automatic. It must be requested via a statement on the use of the first pre-financing payment *(see Annex 8)*.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a *[first]* **pre-financing payment**;
- *[a* **second pre-financing payment***, on the basis of the request for a second pre-financing payment (see Article 20);]*
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The *[Commission][Agency]* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a *[first]* pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.

From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to *[**OPTION 1 in case of a single pre-financing payment:** 5%][**OPTION 2 in case of two pre-financing payments:** 2,5%]* of the maximum grant amount (see Article 5.1), is retained by the Commission and transferred into the '**Guarantee Fund**'.

***[OPTION in case of a second pre-financing payment:** The [Commission][Agency] will — within 30 days from the request for a second pre-financing payment (see Article 20.2a) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 2.5% of the maximum grant amount (see Article 5.1), will be retained by the [Commission][Agency] and transferred into the Guarantee Fund.*

If the statement on the use of the previous pre-financing payment shows that less than 70% of the previous payment has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used. ***]***

[OPTION if the JRC is a beneficiary:** The parts of the pre-financing payments related to the Joint Research Centre (JRC) ([**insert amounts** (insert amounts in words)] are not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]

[…]

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns a *[second pre-financing payment,]* interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

1. Payments to be made

Normally, EJP Cofund actions are divided in 5 reporting periods *(see Article 20.2)*, with one pre-financing payment and interim payments for each reporting period.

Large EJPs may exceptionally benefit from a second pre-financing payment (at the beginning of the second reporting period).

Example (two pre-financing payments):

An EJP receives a grant with a maximum grant amount of EUR 30 million. A total pre-financing of EUR 8 million is agreed but is split into two pre-financings of EUR 4 million each.

First pre-financing = EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 ➔ net payment of EUR 3 250 000

Second pre-financing:

1a: *The coordinator submits a statement showing that at least EUR 2 275 000 (70% of the EUR 3 250 000) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 = net payment of EUR 3 250 000*

1b: *The coordinator submits a statement showing that EUR 1 950 000 (60% of the initial pre-financing) has been used to cover the costs of the action ➔ the second pre-financing will be EUR 4 000 000 – (EUR 2 275 000 – EUR 1 950 000) = EUR 3 675 000 with a Guarantee Fund retention of EUR 30 million x 2,5% = EUR 750 000 ➔ net payment of EUR 2 925 000*

The second pre-financing payment is NOT automatic but must be requested by the coordinator via a 'statement on the use of the first pre-financing payment' *(see Article 20)*.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? The pre-financing for EJP Cofund actions is normally 20% of the maximum grant amount set out in Article 5.1 (— unless it is exceptionally fixed higher or lower, to reflect the size and the needs of the EJP, the reimbursement rate in the work programme/call and/or the availability of EU budget credits)

If the GA foresees a second pre-financing payment, the Guarantee Fund retention (of 5% of the maximum grant amount) will be split between the two pre-financing payments.

⚠ The second/third pre-financing payment will be **reduced**, if — according to the statement on use of the previous pre-financing instalment — the previous pre-financing was **not fully used**:

- if 70% or more of the first/second pre-financing has been used: the second/third pre-financing is paid in full
- if less than 70% of the first/second pre-financing has been used: the second/third pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.

VIII. Framework Partnerships and Specific Agreements

VIII.1 Background information and approach

The H2020 FPA and H2020 SGA are used for framework partnerships and specific grants (under such framework partnerships) ONLY.

'**Framework partnerships**' are long-term co-operations that:

- pursue a mutual interest and common general objectives (that coincide with EU policy)
- have an action plan with actions that were defined and agreed jointly on the basis of the common general objectives and
- have an ongoing formal arrangement to implement (potential) actions (i.e. the FPA and SGAs).

Currently, framework partnerships are only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA)) and for PCP/PPI actions. Framework partnerships are currently not (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

4.0 As from GA 4.0 FPA/SGAs are also possible for PCP/PPI actions. This does NOT apply to older grant agreements.

> ⚠ The FPA/SGA therefore now covers both research and innovation actions or innovation actions *with* a PCP or PPI and PCP/PPI actions (separate type of action with PCP/PPI as *main* action task).

The FPA and SGA generally follow the General MGA for content, but with a different numbering:

Table of correspondence

Title of Article	FPA Article	SGA Article	MGA Article
CHAPTER 1 GENERAL			
SUBJECT OF THE AGREEMENT	1	1	1
CHAPTER 2 FRAMEWORK PARTNERSHIP			
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DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP	3		
RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP	4		
SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION	5		
TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF PARTICIPATION OF ONE OR MORE PARTNERS	6		
CHAPTER 3 SPECIFIC GRANTS			
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SECTION 2 SPECIFIC GRANTS			
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ELIGIBLE AND INELIGIBLE COSTS	11	5	6
SECTION 3 RIGHTS AND OBLIGATIONS OF THE PARTIES UNDER THE SPECIFIC GRANTS			
SUBSECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE SPECIFIC ACTIONS			
GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE SPECIFIC ACTIONS	12		7
RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS	13	6	8
IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING	14	7	9
PURCHASE OF GOODS, WORKS OR SERVICES	15	8	10
USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT	16	9	11
USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE	17	10	12
IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS	18	11	13
IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES	19	12	14
IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS	19a	12a	14a
FINANCIAL SUPPORT TO THIRD PARTIES	20	13	15
PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURES	22	14	16
SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION			
GENERAL OBLIGATION TO INFORM	23		17
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SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS OF THE SPECIFIC ACTIONS			

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OWNERSHIP OF RESULTS	32	18	26
PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING	33		27
EXPLOITATION OF RESULTS	34	18	28
DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING	35	18	29
TRANSFER AND LICENSING OF RESULTS	36	18	30
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SUBSECTION 4 OTHER RIGHTS AND OBLIGATIONS			
RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS	38		32
GENDER EQUALITY	39		33
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ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*	46		40
SECTION 4 DIVISION OF PARTNERS' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTICIPANTS OF A JOINT ACTION]*			
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CHAPTER 4 FINAL PROVISIONS			
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APPLICABLE LAW AND SETTLEMENT OF DISPUTES	63		57
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In addition, all references in the General MGA to 'beneficiary(ies)' must be read as referring to the 'partner(s)'.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that differ only in numbering or presentation *(e.g. Chapters 3 and 4; Annexes)* will not be shown.

By contrast, provisions that do not deviate from the General MGA, but that require clarification or a specific interpretation for the FPA or SGA are added:

- Article 9.1 (FPA-SGA budget categories)
- Article 10 (FPA-SGA maximum grant amount, form of grant, reimbursement rate, forms of costs, final grant amount, revised final grant amount)
- Article 11 (FPA-SGA eligible and ineligible costs)
- Article 13 (FPA-SGA rules on third party involvement)
- Article 63.2 (FPA/SGA rules on dispute settlement).

For more guidance on framework partnerships, *see the Participant Portal Online Manual and the H2020 grants fact sheets.*

VIII.2 H2020 FPA: Annotations

FRAMEWORK PARTNERSHIP AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Framework Partnership Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2]) ,]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Framework Partnership Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][5],

and

on the other part,

1. 'the **coordinator**':

[**full official name** (**short name**)**]**, established in [official address in full] ***[OPTION for partners with VAT**: VAT number [insert number],] [**OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding (see Article 14),]* represented for the purposes of signing the Framework Partnership Agreement by [function, forename and surname]

and the following other **partners** if they have signed their 'Accession Form' (see Annex 3 and Article 62):

2. [**full official name**] (**short name)**], established in [official address in full], ***[OPTION for partners with VAT:** VAT number [insert number],]*

*[**OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not receiving EU funding (see Article 14),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'partner' or 'partners' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties have agreed to enter into the framework partnership under the terms and conditions set out below.

The Framework Partnership Agreement is composed of:

Terms and Conditions

Annex 1 Action plan[6]

Annex 2 Model Specific Agreement

Annex 1 Description of the specific action

Annex 2 Estimated budget for the specific action

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

Annex 3 Accession Forms

[OPTION to be used if Article 19 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the certificate on the methodology

2 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
3 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
4 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
5 The person representing the *Commission/Agency* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 *'Mise en place de la Charte des ordonnateurs'*.
6 The action plan should include the common objectives of the parties and the types of activities covered under this framework partnership, that contribute to the achievement of those objectives.

1. Participants: Coordinator — Partners — Linked third parties — Third parties involved in the action

In FPAs and SGAs the beneficiaries are called '**partners**' (because technically speaking they become beneficiaries only once an SGA is signed).

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. However, partners/linked third parties that do not want to actively participate in a specific action, may participate as **partners not carrying out action tasks** and will not have to comply with most of the obligations under that SGA *(see Preamble SGA).*

Arrangements for signing the FPA are as follows:

- the coordinator signs the FPA directly
- the other partners sign the Accession Form *(see Article 62 FPA and Annex 3)*.

The documents must be signed directly in Participant Portal.

Amendments to the FPA (and the SGAs) will be signed by the coordinator on behalf of the other partners.

Applicants who accept the partnership by signing the FPA become partners to the Agreement and are **bound by** its **terms and conditions**.

Other entities involved in the partnership which do not sign the FPA (including entities linked to the partners) are considered as **third parties involved in the partnership**.

They are not bound by the terms and conditions of the FPA and SGA; conversely, the Commission/Agency has no obligation towards third parties.

Only linked third parties are normally involved in the framework partnership itself. Other third parties are normally only involved in the specific actions (**third parties involved in the specific actions**).

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

ARTICLE 1 — SUBJECT MATTER OF THE AGREEMENT

This Agreement establishes a long term cooperation ('**framework partnership**') and sets out its terms and conditions and the general terms and conditions and rights and obligations applicable to the specific grants that may be awarded by the *[Commission][Agency]* for the specific actions under the framework partnership.

CHAPTER 2 FRAMEWORK PARTNERSHIP

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

ARTICLE 2 — ACTION PLAN — AWARD OF SPECIFIC GRANTS — SPECIFIC AGREEMENTS

2.1 Action plan

The objectives and activities under the **framework partnership** are set out in the '**action plan**' in Annex 1.

2.2 Award of specific grants for specific actions — Specific Agreements

The *[Commission][Agency]* may award '**specific grants**' for actions to be implemented under the framework partnership ('**specific actions**').

[OPTION 1 by default: *In order to obtain proposals for specific grants, the [Commission][Agency] will consult the partners on the basis of [a* ***call for proposals****][an* ***invitation to submit a proposal****][7] [a call for proposals or an invitation to submit a proposal] that sets out the [selection and][8] award criteria it will apply. [This call will be [open to all the partners for which this type of activity is included in an FPA action plan] [open to all applicants meeting the announced criteria].] The partners are not obliged to respond to such consultations and may choose not to submit any proposal.****]***

[OPTION 2 if foreseen in the work programme: *The partners must* ***submit the proposals for specific grants*** *(consisting of [insert documents to be submitted with proposal]) [for [insert the name(s) of the activity]] by [the date(s) specified in the action plan][insert date].****]***

The *[Commission][Agency]* will decide on the award of the specific grants following an evaluation of the proposal *[and a competitive review across partners of different framework partnerships]*.

If the *[Commission][Agency]* decides to award a specific grant, it will propose the partners to conclude a '**Specific Agreement (SGA)**' (see Annex 2).

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the specific grant and agree to implement the specific action under their own responsibility and in accordance with the Framework Partnership Agreement and the Specific Agreement, with all the obligations and conditions they set out

Specific Agreements must be concluded before the end of the framework partnership (see Article 3).

After the end of the framework partnership or its termination, the Framework Partnership Agreement continues to apply to specific actions that are implemented under Specific Agreements which have entered into force before end of the duration.

[7] The invitation to submit a proposal is an option reserved:
- for monopoly situations or partners designated in the basic act;,
- for cases where work is carried out in a network with pre-determined partners under the conditions laid down in the basic acts or
- for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power, on condition that the actions concerned do not fall within the scope of a call for proposals.

[8] Use this option if you opt for an open call for proposals ('a call for proposals open to all applicants meeting the announced criteria').

1. Framework partnership — Action plan

What? Framework partnerships are long-term partnerships based on jointly agreed general objectives and a roadmap of actions (**action plan**).

The action plan should normally include at least the following:

- the objectives of the partnership (as set out in the work programme/call)
- the list of actions covered (including an indicative work plan)
- an explanation of how the actions will contribute to the achievement of the objectives
- the description of the partners
- key performance indicators
- information on the arrangements for intellectual property rights and open access (if relevant at FPA level)
- information on ethics and gender issues (if relevant).

The partnership is established in a FPA and implemented by SGAs for specific actions.

For this purpose, specific grants will be announced in work programmes/calls.

The FPA does NOT oblige the Commission/Agency to award specific grants.

Specific grants can be awarded only in line with the action plan.

The partners remain free to participate also in other calls for proposals organised by the Commission/Agency, in order to receive grants outside the action plan.

Framework partnerships can in principle be funded in all Parts of Horizon 2020.

4.0 Currently, they are however only open to actions under the General MGA (i.e. all kinds of research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA) *(e.g. H2020-FETFLAG-2014; H2020-EINFRA-2014-2)* and PCP- PPI actions; Framework partnerships are currently NOT (yet) open to ERANET, EJP, ERC, MSCA or SME Instrument specific actions.

2. Award of specific grants

The specific grants are awarded to partners through one or more of the following procedures (depending on which options were inserted in the FPA):

- **with competition (calls for proposals):**
  - **open to all partners** for which this type of activity is included in the FPA action plan

    Such calls are restricted to the consortia that have signed a FPA and compete for the specific grant.

    Example: *The Commission signs different FPAs. In the call for proposals for specific grants, it establishes that participation is restricted to applicants who have already signed an FPA. Consortia A and B have signed FPAs with the Commission – FPA-1 in the case of Consortium A and FPA-2 in the case of Consortium B. Following submission of the proposal and a positive evaluation, Consortium B is awarded the grant and signs an SGA with the Commission in the framework of FPA-2.*

  - **open to all applicants** meeting the criteria

Such calls are open to any legal entity that satisfies the criteria set out in the call for proposals.

- **without competition**:
  - **invitations to submit a proposal**

    Such invitations can only be issued in one of the following cases:

    - in monopoly situations or where partners are designated in the basic act
    - if work is carried out in a network with pre-determined partners under conditions laid down in the basic acts
    - for actions with specific characteristics that require a particular type of body on account of its technical competence, high degree of specialisation or administrative capacity, and do not fall within the scope of a call for proposals
  - **submission** of a proposal **by a certain date**

    This option can be included in the FPA only if it is provided for in the work programme/call.

    The date must be set out in the action plan or in Article 2 FPA.

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTERNSHIP

ARTICLE 3 — DURATION AND STARTING DATE OF THE FRAMEWORK PARTNERSHIP

The Framework Partnership Agreement is concluded for a period of [insert number] of months ([…]years)[9] as of its entry into force (see Article 64). This period cannot be extended.

[9] Not more than four years, except in duly justified exceptional cases (for instance, to align it with the duration of the framework programme) (Article 178 Rules of Application Regulation No 1268/2012).

1. Framework partnership starting date

The starting date of the framework partnership is fixed by the Commission/Agency in the FPA.

It is usually the first day of the month following the date on which the FPA enters into force. The FPA enters into force when the last party signs it *(see Article 64 FPA)*.

Example: *The FPA is signed by the coordinator on 30 December 2014 and by the Commission on 5 January 2015. The starting date of the partnership is 1 February 2015.*

2. Framework partnership duration

The framework partnership duration may not exceed four years, except in duly justified exceptional cases *(e.g. to align it with the duration of the Horizon 2020 Programme)*.

The FPA duration can NOT be extended (i.e. it is not possible to request an amendment extending the duration). The duration of an FPA only determines the moment up to which SGAs can be signed. The SGAs can still be implemented after the end of the framework partnership.

All SGAs must be signed before the end of the FPA.

⚠ Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA has ended.

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

ARTICLE 4 — RIGHTS AND OBLIGATIONS UNDER THE FRAMEWORK PARTNERSHIP

4.1 Obligation to properly implement the framework partnership

The partners must respect the objectives of the framework partnership and implement it as described in Annex 1 and endeavour to achieve those objectives also in the specific actions.

The partners must maintain relations of mutual co-operation and regular and transparent exchanges of information with the *[Commission][Agency]* on:

- the implementation and follow-up of the action plan and the specific grants and
- other matters of common interest related to the Framework Partnership Agreement.

The partners must implement the framework partnership in compliance with Articles 39, 40, 41, 42, 44, 45, 52 — *mutatis mutandis*.

4.2 Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The partners must have internal arrangements regarding their operation and co-ordination to ensure that the framework partnership and the specific actions are implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the partners, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a partner is in breach of its obligations) (see Subsection 3 of Chapter 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the partners.*

The consortium agreement must not contain any provision contrary to the Framework Partnership Agreement and the Specific Agreements.]

[OPTION 2:** Not applicable**]

1. Consortium agreement

As a general rule, the partners must conclude a FPA consortium agreement to ensure a smooth and successful implementation of the framework partnership and the specific actions (like for GAs; *see Article 41.3 H2020 General MGA*).

⚠ If necessary, the consortium may decide to have — in addition to the FPA consortium agreement — **specific consortium agreements for each SGA**. In this case, the consortium will need to ensure a mechanism to settle possible conflicts between the different consortium agreements.

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

ARTICLE 5 — SUSPENSION OF FRAMEWORK PARTNERSHIP IMPLEMENTATION

The parties may **suspend the implementation of the framework partnership** on the grounds and according to the procedure — *mutatis mutandis* — set out in Article 55.

If the framework partnership implementation is suspended, all specific actions are also suspended (see Article 55) — from the date of suspension of the framework partnership.

1. Suspension of framework partnership implementation

The rules on suspension of framework partnership implementation are similar to GA suspension *(see Article 49 H2020 General MGA)*.

FPA suspension automatically supends all on-going specific actions.

Amendments (to resume the action) after a suspension can NOT have the effect of extending the FPA duration set out in Article 3 FPA.). The duration of an FPA only determines the moment up to which SGAs can be signed An SGA can be implemented *after* the end of the framework partnership.

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

ARTICLE 6 — TERMINATION OF THE FRAMEWORK PARTNERSHIP AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE PARTNERS

6.1 Termination of the Agreement

The parties may terminate the Framework Partnership Agreement at any time.

The party terminating the Framework Partnership Agreement must formally notify termination to the other party, stating the date the termination will take effect. This date must be after the notification.

Termination of the Framework Partnership Agreement does not release the parties from their obligations under Specific Agreements which have entered into force before the date on which the termination takes effect, unless they have been terminated.

Neither party may claim damages due to termination by the other party.

6.2 Termination of the participation of one or more partners

The parties may terminate participation of one or more partners in the framework partnership on the grounds and according to the procedures — *mutatis mutandis* — set out in Article 56.2.1, 56.3.1 and 56.3.2.

The coordinator must submit a request for amendment (see Article 61) to adapt Annex 1 and, if necessary, the addition of one or more new partners (see Article 62).

If the request for amendment is rejected by the *[Commission][Agency],* the Framework Partnership Agreement may be terminated (see above).

Termination of participation in the framework partnership does not release the partner concerned from its obligations under Specific Agreements. It cannot however participate in specific actions awarded after the date on which the termination takes effect.

1. FPA termination

The FPA can be terminated at any time and on any grounds, without the need for a contradictory procedure between the parties.

⚠ FPA termination has NO effect on ongoing SGAs (— unless they are also terminated; *see Article 56 FPA and Article 20 SGA*). Certain provisions of the FPA will continue to apply for the on-going SGAs even if the FPA is terminated.

2. Beneficiary termination

The parties may terminate the participation of a partner in the framework partnership on similar grounds (and according to similar procedures) as their termination in actions *(see Article 50 H2020 General MGA)*.

⚠ **Different partners at FPA and SGA level (exceptional)** — Beneficiary termination may lead to a different consortium composition at FPA and SGA level — unless participation is ended on both levels (and for ALL SGAs).

This is one of the very few cases of a different consortium composition. Normally, consortium composition is the same, but partners/linked third parties can participate as partners not carrying out action tasks for certain specific actions.

Example: *A partner wants to terminate participation in the framework partnership because it no longer has interest in future SGAs (while it wants to finish the ongoing ones it has committed to).*

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 9 — ESTIMATED BUDGET AND BUDGET TRANSFERS

9.1 Estimated budget

The estimated budget for the specific actions is set out in Annex 2 to the Specific Agreements.

It contains the estimated eligible costs and the forms of costs, broken down by partner *[and linked third party]* and **budget category** (Articles 4, 5 , 6 SGA *[and Article 19 FPA]* It also shows, if applicable, the estimated costs of the partners not receiving EU funding, if applicable (see Article 7 SGA) and of the international partners (see Article 12a SGA).

[…]

1. Budget categories

The **budget categories** of the SGA will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the* ***budget categories*** *of the General MGA:*

- *direct personnel costs*
- *direct costs of subcontracting*
- *direct costs of providing financial support to third parties (if option applies)*
- *other direct costs*
- *indirect costs*
- *specific cost categories (if option applies) (see Article 4 H2020 General MGA).*

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

ARTICLE 10 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

10.1 Maximum grant amount

The maximum grant amount for the specific grants is set out in the Specific Agreements (see Article 4 SGA).

10.2 Form of grant, reimbursement rates and form(s) of costs

The form of the grant, reimbursement rate(s), estimated eligible costs and the form(s) of costs of the specific grants are set out in the Specific Agreements (see Article 4 SGA).

10.3 Final grant amount — Calculation

The final grant amount of a specific grant depends on the actual extent to which the specific action is implemented in accordance with the terms and conditions of the Framework Partnership Agreement and the Specific Agreement concerned.

This **amount** is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 17 SGA) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

10.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 4 SGA) are applied to the eligible costs (actual costs, unit costs, flat-rate costs and lump sum costs; see Article 5 SGA) declared by the partners *[and the linked third parties]* (see Article 16 SGA) and approved by the *[Commission][Agency]* (see Article 17 SGA).

10.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount (see Article 4 SGA), it will be limited to the latter.

10.3.3 Step 3 — Reduction due to the no-profit rule

The specific grant must not produce a profit.

'Profit' means the surplus of the amount obtained following Steps 1 and 2 plus the specific action's total receipts, over the specific action's total eligible costs.

The **'specific action's total eligible costs'** are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The **'specific action's total receipts'** are the consolidated total receipts generated during its duration (see Article 3 SGA).

The following are considered **receipts**:

(a) income generated by the specific action; if the income is generated from selling equipment or other assets purchased under the Specific Agreement, the receipt is up to the amount declared as eligible under the Specific Agreement;

(b) financial contributions given by third parties to the partner *[*or to a linked third party*]* specifically to be used for the specific action, and

(c) in-kind contributions provided by third parties free of charge specifically to be used for the specific action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the specific action's results (see Article 34);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 5 SGA);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3 of the Specific Agreement).

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

10.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the specific grant is reduced (see Article 49), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations in accordance with Article 49.2) from the maximum grant amount (see Article 4 SGA).

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

10.4 <u>Revised final grant amount</u> — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 28) — the *[Commission][Agency]* rejects costs (see Article 48) or reduces the specific grant (see Article 49), it will calculate the **'revised final grant amount'** for the partner concerned by the findings.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the partner concerned;
- in case of **reduction of the specific grant**: by calculating the concerned partner's share in the grant amount reduced in proportion to to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 49.2).

In case of **rejection of costs and reduction of the specific grant**: the revised final grant amount for the partner concerned will be the lower of the two amounts above.

1. Form of grant — Reimbursement rates — Cost form(s)

The form of grant, reimbursement rates and cost form(s) of the SGA will depend on the type of SGA used.

> ***Example:*** *For RIA, IA and CSA actions, the SGA will use the form of grant, reimbursement rates and* ***forms of costs*** *of the General MGA (see Article 4 SGA and Article 5 H2020 General MGA)*

2. Calculation of the final grant amount — Calculation of a revised final grant amount

Similarly, the rules on the calculation of the final grant amount and a revised final grant amount will depend on the type of SGA used.

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 11 — ELIGIBLE AND INELIGIBLE COSTS

11.1 Eligible Costs

The general and specific conditions for costs to be eligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.2 Ineligible costs

The conditions under which costs are considered ineligible under the specific grants are set out in the Specific Agreements (see Article 5 SGA).

11.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 48).

This may also lead to any of the other measures described in Section 5.

1. Eligible costs

The specific eligibility conditions, applicable per budget category, are set out in Article 5 SGA.

The SGA will use the **budget categories** that belong to the type of specific action, with the same **types of costs**, **eligibility conditions** and **calculation rules**.

Example: *For RIA, IA or CSA specific actions, the budget categories, types of costs, eligibility conditions and calculation rules of the General MGA will apply (see Article 5 SGA and Article 6 H2020 General MGA).*

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

ARTICLE 13 — RESOURCES TO IMPLEMENT THE SPECIFIC ACTIONS — THIRD PARTIES INVOLVED IN THE SPECIFIC ACTIONS

The rules on the resources to implement the specific actions and involvement of third parties in the action are set out in the Specific Agreements (see Article 6 SGA).

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules on third party involvement will depend on the type of SGA used.

Example: *For RIA, IA and CSA specific actions, the SGA will use the rules on third party involvement of the General MGA (see Article 8 H2020 General MGA).*

Linked third parties must already be identified in the FPA *(see Article 19 FPA)*. Their specific activities must then be set out in the specific actions.

Examples:

1. *Third parties making resources available against payment or free of charge (see Articles 9 and 10 FPA) must be identified in Annex I of the SGA.*

2. *Linked third parties carrying out specific action task must be identified in the FPA and also in Annex I of the relevant SGAs*

⚠ **Linked third parties —** Linked third parties are allowed to *fully* participate in the framework partnership and specific actions, like the partner they are linked to.

Linked third parties can NOT however do more than their partners: If a linked third party wants to participate in a specific action, its partner must also be active in that action (i.e. NOT be partner not carrying out action tasks). If the partner does not want to, the linked third party could itself become a partner of the FPA and SGA (— after the consortium composition is changed).

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

ARTICLE 62 — ACCESSION TO THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE SPECIFIC AGREEMENTS

62.1 Accession of the partners mentioned in the preamble

The other partners must accede to the Framework Partnership Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 58) — within 30 days after its entry into force (see Article 64). ***[OPTION if Article 19 applies and joint and several liability has been requested:*** *and for partners for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession to the Framework Partnership Agreement — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

All partners having acceded to the Framework Partnership Agreement must be part of the Specific Agreements. The partners will accede to the Specific Agreements by signature of the coordinator (see mandate in Annex 3).

They will assume the rights and obligations under the Agreements with effect from the date of their entry into force (see Article 64 and Article 21 SGA).

If a partner does not accede to the Framework Partnership Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action plan. This does not affect the *[Commission's][Agency's]* right to terminate the agreements (see Articles 6 and 56).

1. Accession to the FPA and SGAs

While the coordinator signs the FPA, the other partners must accede to the FPA by means of the Accession Forms.

In doing so, they mandate the coordinator:

- to submit and sign in their name and on their behalf any amendments to the framework
- to sign in their name and on their behalf any SGA that may be awarded.

⚠ The SGAs are signed ONLY by the coordinator. The other partners do NOT need to sign accession forms for the SGAs.

62.2 Addition of new partners

In justified cases, the partners may request the addition of a new partner.

For this purpose, the coordinator must submit a request for amendment of the Framework Partnership and the Specific Agreements in accordance with Article 61. It must include an Accession Form (see Annex 3) signed by the new partner in the electronic exchange system (see Article 58).

New partners must assume the rights and obligations under the Agreements with effect from the date of their accession specified in the Accession Form (see Annex 3).

1. Addition of a new partner

New partners can be added at any moment of the framework partnership.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. The new partner must therefore be added at both levels.

Before any SGA has been concluded, only the FPA must be amended.

Once an SGA has already been concluded, both the FPA and the SGA must be amended.

The coordinator must first submit a request for the FPA amendment (which will automatically include the change in the consortium composition for the SGAs — the new beneficiary is added (automatically) as 'inactive' to all signed SGAs under that FPA).

The coordinator must then request for each SGA a separate amendment to activate the new beneficiary *(e.g. to change Annex 1, Annex 2)*.

The conditions for accepting new partners are the same as under the General MGA *(see Article 56.2 H2020 General MGA)*.

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

ARTICLE 63 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

63.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Framework Partnership Agreement or a Specific Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU partners (except partners established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU partner(s) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for partners not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: As an exception, *for the following partners:*

- *[insert name of international organisation or partner not eligible for EU funding]*
- *[insert name of international organisation or partner not eligible for EU funding]*

[same for other partners that are international organisations or partner not eligible for EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Framework Partnership Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 50, 51 and 52), the partners must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must always be brought against the Commission (not against the Agency — even in Agency specific grants).

1. Dispute settlement

The rules on dispute settlement are similar to those of the General MGA *(see Article 57.2 H2020 General MGA)*.

However for FPAs, the Commission/Agency will determine already at FPA-level which partners must participate as 'beneficiaries not receiving EU funding' — because of a general issue with the jurisdiction clause (i.e. Belgian courts). Those beneficiaries can NEVER receive EU funding.

All other partners' status will be determined at SGA-level. Thus, partners from eligible countries (EU Member State, H2020 associated country or third country listed in General Annex A to the Main Work Programme) may participate as normal partners or as 'partners not receiving EU funding'. Partners from non-eligible countries may participate as 'partners not receiving EU funding' or — exceptionally — be granted funding.

VIII.3 H2020 SGA: Annotations

SPECIFIC AGREEMENT

NUMBER [insert number] — [insert acronym]

This '**Specific Agreement**' is between the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Specific Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name** (**short name**)],established in [official address in full], *[**OPTION for partners with VAT:** VAT number [insert number]], [**OPTION for coordinators not receiving EU funding:** as 'partner not receiving EU funding' (see Article 7),]* represented for the purposes of signing the Specific Agreement by [function, forename and surname],

and the following other **partners**, represented for the purposes of signing the Specific Agreement by the coordinator (see the mandate in Annex 3 FPA and Article 62 FPA):

2. [**full official name**] (**short name**)], established in[official address in full], *[**OPTION FOR partners with VAT:** VAT number [insert number]],*

***[OPTION for partners not carrying out action tasks under this SGA**: X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT:** VAT number [insert number]], as 'partner not carrying out action tasks',]*

***[OPTION for partners not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], [**OPTION for partners with VAT :** VAT number [insert number]], as 'partner not receiving EU funding' (see Article 7),]*

[same for each partner]

***[OPTION if the JRC is a partner:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the Administrative Arrangement (see Annex 5)]*.

By entering into the Specific Agreement ***[OPTION if the JRC is a partner:*** *or the Administrative Arrangement]*, the partners accept the grant and agree to implement the specific action, under their own responsibility and in accordance with the Framework Partnership Agreement and this Specific Agreement, with all the obligations and conditions they set out.

The Specific Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Additional information on the estimated budget

Annex 3 Model for the financial statements

Annex 4 Model for the certificate on the financial statements

[OPTION if the JRC participates: *Annex 5: Administrative Arrangement]*

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

1. Participants: Partners — Partners not carrying out action tasks under the SGA — Linked third parties

The partners of a SGA are generally the **same as the partners of the FPA** *(see Article 62.1 FPA)*.

Same partners at FPA and SGA level — Partners must generally be the same at FPA and SGA level. An entity that is not partner/linked third party in the FPA cannot become party in the SGA. Conversely, all partners/linked third parties to the FPA become parties to the SGA.

However, not all partners of a framework partnership must actively participate in all specific actions.

Partners (and linked third parties) who do NOT actively participate in a specific action are **partners not carrying out action tasks** under that Specific Agreement (and must be identified as such in the preamble to the SGA).

Partners not carrying out action tasks — They formally participate in the action as partners, but NOT with any action tasks or EU funding. In practice, most of the obligations therefore do not apply to them for that specific action.

Linked third parties — If a partner participates as not carrying out action tasks, its **linked third parties** get the same status. They can NOT actively participate in the specific action (— unless they themselves become partners of the FPA and SGA).

These partners are formally part of the consortium for the SGA (and are parties to this SGA, meaning that the coordinator signs also in their name).

They will be identified in Annex 1 as 'partners not carrying action tasks' (as they do not carry out any action tasks). Moreover, they will also be mentioned in Annex 2 with zero costs.

Formally, the rights and obligations under the FPA and SGA fully apply to them. In practice however, many of them *(e.g. implementation, deliverables, technical and financial reporting, keeping of supporting documents, financial or technical audits or reviews, IPR results, access to background and results of others, etc.)* are NOT applicable because these partners do not carry out action tasks and do not receive any EU funding. Other obligations remain relevant *(e.g. checks, information obligations, confidentiality)*.

SGAs are **signed** by the coordinator on behalf of the other partners *(see Article 62.1 FPA)*.

The documents must be signed directly in the Participant Portal.

The other partners do NOT need to sign Accession Forms.

Other entities involved in a specific action which do not sign the SGA (including **linked third parties**) are considered as **third parties involved in the specific action**.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the specific action will be [insert number] months as of *[OPTION 1 by default: the first day of the month following the date the Specific Agreement enters into force (see Article 21)] [OPTION 2 if needed for the action: insert date]* ('starting date of the action').

1. Action starting date

For MSCA-IF, the rules on the action starting date are in principle the same as in the General MGA *(see Article 3 H2020 General MGA)*.Normally, the SGA starting date should also be after the entry into force of the FPA (because one presumes the other). However, in justified cases, it is possible to exceptionally fix an SGA starting date before the entry into force of the FPA (i.e. retroactive).

If the consortium requests a starting date before the entry into force of the FPA, it assumes the risks implied by starting the action before the FPA and SGA are signed (in particular not being reimbursed for the costs incurred, *e.g. if the proposal is not successful or that the FPA/SGA are not signed*).

⚠ The SGA action starting date can in any case **NEVER** be **before** the **submission** of the SGA proposal.

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 17 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

17.7 Payments to the coordinator — Distribution to the partners

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the partners without unjustified delay.

Pre-financing may however be distributed only:

a) if the **minimum number of partners** set out in the call for proposals has acceded to the Framework and Specific Agreement (see Article 62 FPA) and

b) to partners that have entered into the Specific Agreement (see Article 62 FPA).

[…]

1. Minimum number of partners

The minimum number of partners generally depends on the type of specific action.

For SGAs, the minimum number of partners will be explicitly indicated in the call for proposals (or — if there is no call for proposals — in the work programme and the invitation to submit a proposal). The minimum numbers of partners refers to the partners implementing the specific action.

Same partners at FPA and SGA level — If a specific action requires more partners than are currently in the framework partnership, the FPA first needs to be enlarged.

IX. Lump Sum MGAs

IX.1 Background information and approach

The General Lump Sum Model Grant Agreement (H2020 General Lump Sum MGA) is used mainly for coordination and support actions (CSA) and, exceptionally, for research and innovation actions (RIA) and innovation actions (IA) — if the work programme/call provides for a lump sum grant.

Example: *H2020-INNOSUP-2014-5*

The Lump Sum Pilot Model Grant Agreement (H2020 Lump Sum Pilot MGA) is used in a limited number of cases provided for in the work programme/call.

Example: *Specific call within the Nanotechnologies, Advance Materials, Biotechnology and Advance Manufacturing and Processing topic DT-NMBP-20-2018*

The General Lump Sum MGA follows the General MGA for numbering and content, except for:

The H2020 General Lump Sum MGA deviates from the General MGA as follows:

- Article 4 (estimated budget of the action)
- Article 5 (maximum grant amount, form of grant and reimbursement rate)
- Article 6 (lump sum specific form of costs)
- Article 7 (specific provision for lump sum)
- Article 8 (specific provision for third parties)
- Articles 9, 11, 12, 16 (not applicable)
- Article 18 (specific provision for record-keeping)
- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 42 (specific provision for lump-sum)
- Article 44 (specific provisions for lump sum)
- Article 49 (specific provision for suspension of action implementation)
- Article 50 (specific provision for lump-sum)

- Annex 2 Model for the estimated budget for the action
- Annex 3 Accession form for beneficiaries
- Annex 4 Model for the financial statement
- Annex 7 Model for the request for further pre-financing payment(s)

The MGA Lump Sum Pilot follows the General MGA for numbering and content, except for:

The H2020 Lump Sum Pilot MGA deviates from the General MGA as follows:

- Article 4 (estimated lump sum breakdown and transfers)
- Article 5 (grant amount and form of grant)
- Article 6 (not applicable)
- Article 8 (resources to implement the action)
- Articles 10, 11, 12 (not applicable)
- Article 13 (subcontracting)
- Article 15 (financial support to third parties)
- Article 18 (keeping records)

- Article 20 (specific reporting provisions)
- Article 21 (specific payment provisions)
- Article 22 (specific procedure for extension of audit findings)
- Article 42 (not applicable)
- Article 47 (specific provision for suspension of payment deadline)
- Article 49 (specific provision for suspension of the action)
- Article 50 (specific provisions for termination)

- Annex 2 Estimated lump sum breakdown
- Annex 4 Model for the financial statement

The main difference between the General Lump Sum MGA and the Lump Sum Pilot MGA lies in the grant implementation mechanisms: the General Lump Sum MGA works with eligible costs and pre-financing payments (instead of interim payments); the Lump Sum Pilot MGA works with lump sum shares per work package and beneficiary (instead of eligible costs) and interim payments based on accomplished work packages.

The annotations will concentrate on differences in substance and interpretation that require explanation.

Parts that do not apply *(Articles 6, 10, 11, 12, 42 Lump Sum Pilot MGA)* or differ only in presentation *(e.g. Articles 4.2, 9, 11, 12, 16, 20.5, 21.3, 25.5 General Lump Sum MGA, Article 43.3 Lump Sum Pilot MGA, Annexes)* will not be shown.

For the Lump Sum Pilot MGA, the Articles where the only difference is the removal of references to eligibility of costs *(e.g. Article 14, 14a, 17.1, 22.5, 41.2 – removal of CFS —)* or rejection of costs *(e.g. Articles 14.2, 15.3, 16.3, 18.2, 22.6)* will not be shown.

The annotations are based on the multi-beneficiary version, since it is the most common for lump sum actions. Where there are significant differences (i.e. Articles 21, 41, 44, 49 and 50), the mono-beneficiary version of the Article is shown.

IX.2 H2020 Lump Sum MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the **action** entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. General Lump Sum actions

What? General Lump Sum grants fund (mainly) **coordination and support actions (CSA)** and (exceptionally) **research and innovation actions (RIA)** or **innovation actions (IA)** — if the work programme/call provides for it.

> For definitions and more information on CSA, RIA and IA actions, *see Article 2 of the H2020 General MGA, the Participant Portal Online Manual and the H2020 grants fact sheets.*

CSA, RIA and IA Lump Sum actions may be mono- or multi-beneficiary actions.

They can be funded in all Parts of Horizon 2020 *(e.g. H2020-INNOSUP-2014-5).*

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the budget category, the estimated eligible costs and the form of costs (see Articles 5 and 6).

4.2 Budget transfers

Not applicable

1. Budget category

The General Lump Sum MGA does not use the budget categories of the General MGA.

Since these grants consist in a single lump sum, there is only one budget category.

Budget category of the General Lump Sum MGA:

- costs (direct and indirect costs)

The budget categories are relevant for the estimated budget (Article 4 and Annex 2), forms of costs (Article 5), cost eligibility rules (Article 6.2) and the cost declarations (i.e. financial statements; Article 20 and Annex 4).

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATE AND FORM OF COSTS

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rate and form of costs

The grant reimburses *[**OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %** of the action's eligible costs] [**OPTION 2 for innovation actions (IA): 70%** of the action's eligible costs]*[8]*[**OPTION 3 for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared as the lump sum set out in Annex 2 (i.e. under the form of '**lump sum costs**').

[8] For the definition, see Article 2.1 (6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014 – 2020)' ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p. 81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

1. Maximum grant amount — Reimbursement rate — Cost forms

How much & which form? The General Lump Sum MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant**.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be set to give a round amount when the EU reimbursement rate is applied (— important if the reimbursement rate is not 100%). It is one amount (for the entire consortium).

The eligibility conditions are set out in *Article 6*. If the action is correctly implemented, the beneficiaries are entitled to receive this fixed amount of EU funding (lump sum).

⚠ The lump sum is deemed to cover ALL (direct and indirect) costs that are incurred for the action. NO other costs will be reimbursed.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the proper implementation of the action in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (lump sum costs; see Article 6) declared by the consortium and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or breach of obligations— Reduced maximum grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced maximum grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

In this case, the final grant amount will be the lower of the following two:

- the amount obtained in Step 1 or
- the amount obtained in Step 2.

1. Final grant amount

For General Lump Sum grants, the rules on the calculation of the final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since they are lump sum grants (and the amount declared is pre-filled by the system), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This **amount** is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]*;

- in case of **reduction of the grant**: in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

1. Revised final grant amount

For General Lump Sum grants, the rules on the calculation of the revised final grant amount are in principle the same as in the General MGA *(see Article 5.3 H2020 General MGA)*.

However, for General Lump Sum grants, improper implementation of the action leads to *ineligibility* of the costs (NOT to the *reduction* of the grant). Therefore, the grant reduction mentioned in this provision does not relate to improper implementation of the action (but only to other breaches and substantial errors, irregularities and fraud; *see Article 43*).

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 Eligible costs

Costs for the budget category:

A. Costs for the action (direct and indirect costs)

are eligible ('eligible costs'), if they correspond to the lump sum set out in Annex 2 and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.

6.2 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (see Article 6.1) and

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU and Euratom budget.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.3 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

1. Eligible costs

The General Lump Sum MGA has its **own budget category**, with its own **types of costs**, **eligibility conditions** and **calculation rules**.

2. Costs for the action (A.): Types of costs — Form — Eligibility conditions — Calculation

2.1 What? The budget category A 'costs' **covers** the (direct and indirect) costs for the action.

The lump sum is deemed to **cover ALL** (direct and indirect) **costs** that are incurred for the action. NO other costs will be reimbursed.

2.2 These costs must be **declared as** the **amount** set out in the work programme/call.

In practice, the declaration of costs for General Lump Sum grants is completely automatized. The coordinator only needs to sign and submit the financial statement (pre-filled by the IT system).

2.3 They must fulfil the following **eligibility conditions**:

- the action tasks must have been carried out as described in Annex 1.

2.4 NO **calculation** is necessary (since it is a fixed global amount).

By signing the financial statement (for multi-beneficiary actions: one common financial statement for the consortium; *see Article 20*), the beneficiaries automatically declare the amount set out in the work programme/call as the total eligible costs of the action (the amount is fixed and pre-filled by the IT system).

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary does not properly implement the action (or part of it), the corresponding costs will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any other obligation, the grant may be reduced (see Article 43).

This may also lead to any of the other measures described in Chapter 6.

1. Consequences of improper implementation

For General Lump Sum grants, 'improper implementation of the action not in accordance with Annex 1' does NOT lead to a *reduction* of the grant, but to the *ineligibility* of the costs (*see Article 6.1*).

> ⚠ If the action is not carried out as described in Annex 1, costs will be **rejected** proportionally to the tasks or parts of the action not implemented *(see Article 42)*.

By contrast, in case of other serious breaches the grant may be *reduced (see Article 43)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* for implementing the action.

1. Participants: Appropriate own resources — Use of third party resources — Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the General Lump Sum MGA.

The special rules from the General MGA on third party involvement are limited in General Lump Sum actions to purchases (*Article 10*), subcontracting (*Article 13*), linked third parties (*Article 14*) and international partners (*Article 14a*).

By contrast, there are NO special rules for in-kind contributions (Articles 11 and 12). Beneficiaries may use any in-kind contributions from third parties if they are needed to carry out the work of the action.

⚠ For all types of third party involvement (purchases, subcontracts, linked third parties, in-kind contributions), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[9] (or 2014/24/EU)[10] or 'contracting entities' within the meaning of Directive 2004/17/EC[11] (or 2014/25/EU)[12] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[9] Directive 2014/18/EC of the European Parliament and of the Council of 31 March 2014 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).
[10] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).
[11] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).
[12] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

1. Purchase of goods, works or services

The rules on contracts for the purchase of goods, works or services for General Lump Sum actions are almost identical to the General MGA *(see Article 13 H2020 General MGA)*.

The obligations in Article 10.1.1 are however NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for General Lump Sum actions are similar to the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The General Lump Sum MGA has however the following **specificities**:

The estimated subcontracting costs do NOT have to be included in Annex 1 or shown in the table of estimated costs of Annex 2 (since they are covered by the lump sum).

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[18]:*** *three]* years after the payment of the balance — keep adequate records and other supporting documentation to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep adequate records and documentation and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

1. Records and other supporting documentation

For General Lump Sum actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep the evidence (documentation, records) that the actions tasks (as described in Annex 1) were properly carried out.

The records and supporting documentation must:

- refer to the technical implementation of the action in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and

- prove that the tasks or parts of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs incurred are NOT needed.

The evidence must be verifiable, auditable and available.

It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the reports set out in this Article. These reports include the request for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]

[*- RP2: from month [X+1] to month [Y]*

- RP3: from month [Y+1] to month [Z]

[same for other RPs]

*- RPN: from month [N+1] to [the last month of the project].****]***

20.2a Periodic reports — Requests for further pre-financing payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**statement on the use of the previous pre-financing instalment**', including the **request for a further pre-financing payment** (Annex 7).

20.3. Requests for interim payments

Not applicable.

20.4 Final report — Request for payment of the balance

The coordinator must submit to the *[Commission][Agency]* (see Article 52) — within 60 days following the end of the reporting period — a final report, which includes the request for payment of the balance.

The **final report** must include the following:

(a) a '**final technical report**' containing a **summary** with:

(iv) an overview of the results;

(v) the conclusions on the action;

(vi) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements.

(b) a '**final financial report**' containing:

(i) a '**financial statement**' from the consortium (see Annex 4), which includes the **request for payment of the balance**.

The financial statement must detail the eligible costs (lump sum costs; see Article 6 and Annex 2).

Amounts which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

The consortium must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (i.e. that the action has been properly implemented; see Article 6);
- the costs (i.e. the proper implementation of the action) can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of the payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2 :*** *not applicable****]***

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

The financial statement must be drafted in euro.

20.7 Language of reports

The reports must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

1. Reports

What & When? For General Lump Sum actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Before the end of the action, these are only technical reports, with information on the technical implementation.

List of documents for the technical reports:

- explanation of the work carried out
- overview of the progress
- summary for publication
- questionnaire (i.e. the structured information requested)
- statement on the use of the previous pre-financing instalment

NO financial reporting is needed during the action (i.e. no financial statements before the final report). The coordinator only has to sign and submit a statement on the use of the previous pre-financing instalment (which includes the request for further pre-financing payments; *see Article 7*).

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

2. Reporting periods

General Lump Sum actions are normally divided into several reporting periods and each reporting period triggers a further pre-financing.

Each reporting period triggers a periodic report.

3. Final financial report: Financial statement

The financial statement (one common financial statement for the consortium) is automatically pre-filled by the system (with the amount set out in the work programme/call as final grant amount; *see Article 5*).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

MONO-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the beneficiary:

- a *[first]* **pre-financing payment;**
- *[a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);]*
- *[a **third pre-financing** payment, on the basis of the request for a third pre-financing payment (see Article 20);]*
- *[same for more pre-financing payments]*
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20)

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

[OPTION 1 by default: *The aim of the pre-financing is to provide the beneficiary with a float.*

It remains the property of the EU until the payment of the balance.

*The [Commission][Agency] will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest — make a first pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Article 48 applies.*

*From this amount, an amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the [Commission][Agency] and transferred into the '**Guarantee Fund**'.*

[OPTION in case of two pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

[OPTION in case of three pre-financing payments: *The [Commission][Agency] will — within 60 days after receiving the request (see Article 20) — make a third pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)], except if Articles 47 or 48 apply.*

*If the statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

[OPTION 2a if JRC is the beneficiary: *The [DG][Agency] will make a [first] pre-financing payment to the coordinator of EUR [**insert amount including the 5% to be paid to the Guarantee Fund** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*The JRC agrees that the amount of EUR [**insert amount: 5% of the grant amount intended for the JRC** (insert amount in words)], corresponding to its contribution to the Guarantee Fund (see Article 21.2), is transferred in its name by the [DG][Agency] to the Guarantee Fund.*

[OPTION if the JRC is the beneficiary and in case of two pre-financing payments: *The [DG][Agency] will make a second pre-financing payment to the coordinator of EUR [**insert amount** (insert amount in words)] within 30 days from the submission of a debit note from the JRC after the signature of the 'Agreement'.*

*If statement on the use of the previous pre-financing instalment shows that less than 70% of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70% threshold and the amount used.**]***

*[same for more pre-financing payments]**]***

The total amount of pre-financing payments must not exceed 90% of the maximum grant amount set out in Article 5.1

21.3 Interim payments — Amount — Calculation

Not applicable

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the beneficiary together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the beneficiary
    - is negative, it will be recovered from the beneficiary.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

21.5 Notification of amounts due

The *[Commission][Agency]* will formally notify to the beneficiary the amount due and specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

[…]

MULTI-BENEFICIARY: ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

pre-financing made}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered from the coordinator.

The amount to be paid may however be offset — without the coordinator's consent — against any other amount owed by the coordinator to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount set out in Article 5.1.

[…]

1. Payments to be made — No interim payments

General Lump Sum actions are divided into several reporting periods with pre-financing payments (each reporting period triggering a pre-financing instead of an interim payment).

> Only the first pre-financing payment is automatic. Further pre-financing payments must be requested by the coordinator via a statement on the use of the previous pre-financing payment *(see Article 20)*.

There are NO interim payments.

The balance is paid when the action ends.

2. Payment calculations — Amounts due — Recoveries?

Pre-financing payment

How much? There is no standard amount (or percentage) for pre-financing payments; the amount is fixed in each GA.

> The total amount of pre-financing can NOT exceed 90 % of the maximum grant amount *(see Article 5.1)*.
>
> The further (i.e. second/third/same for more) pre-financing payment(s) will be **reduced**, if — according to the statement on the use of the previous pre-financing payment — the previous pre-financing was **insufficiently used**:
>
> – if 70% or more of the previous pre-financing has been used: the next pre-financing is paid in full
>
> – if less than 70% of the previous pre-financing has been used: the next pre-financing will be reduced by an amount equal to the difference between the percentage actually used and 70%.
>
> ***Example:***
>
> *Consortium with a maximum grant amount of EUR 400 000 (100% reimbursement rate) and 3 reporting periods.*
> *90% limit of the maximum grant amount: EUR 360 000.*
> *3 Pre-financing payments: EUR 100 000; EUR 120 000 and EUR 140 000.*
> *Statement on the use of previous pre-financing submitted by the Consortium: 70% of the 1st pre-financing and 60% of the 2nd pre-financing payment.*
> *2nd pre-financing payment of EUR 120 000 is paid in full since the consortium used 70% of the 1st pre-financing;*
> *3rd pre-financing to the coordinator must be reduced because the consortium used only 60% of the 2nd pre-financing;*
> *Pre-financing actually used: EUR 120 000 * 60% = EUR 72 000*
> *70% of the 2nd pre-financing payment: EUR 120 000 * 70% = EUR 84 000*
> *Reduction due to 70% consumption rule: EUR 84 000 – EUR 72 000 = EUR 12 000*
> *3rd pre-financing paid to the consortium: EUR 140 000 – EUR 12 000 = EUR 128 000.*

Payment of the balance

How much? The amount of the payment of the balance depends on the overall financial situation at the end of the action, and in particular:

– the amount of pre-financing(s) already paid *(see Article 21 H2020 General MGA)*

– cost rejections (improper implementation of the action; *see Article 42)*

– grant reduction (other serious breaches or substantial errors, irregularities or fraud *see Article 43)*.

ARTICLE 41 — BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

MONO-BENEFICIARY: ARTICLE 41 —BENEFICIARY' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the *[Commission][Agency]*

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

(a) monitoring that the action is implemented properly (see Article 7);

(b) informing the *[Commission][Agency]* immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(c) submitting the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(d) submitting to the *[Commission][Agency]* in good time any documents or information required by it

and may not delegate or subcontract these tasks to any third party (including linked third parties).

41.2 Internal division of roles and responsibilities

Not applicable

[…]

MULTI-BENEFICIARY: ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- the data needed to draw up the technical report (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and the report to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Agency][Commission]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[…]

1. Division of roles and responsibilities — Responsibilities towards the Commission/Agency

The rules on internal division of roles and responsibilities are similar to the General MGA *(see Article 41 H2020 General MGA)*.

Since for General Lump Sum multi-beneficiary actions there is however only one (common) financial statement *(see Article 20)*, there is NO obligation for the beneficiaries to submit their own individual financial statements to the coordinator.

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (i.e. if the action as described in Annex 1 is not properly implemented; see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected proportionally to the tasks or parts of the action not implemented.

If the rejection of costs does not lead to a **recovery** (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs does not lead to a **recovery,** *[Commission][Agency]* will follow the contradictory procedure with '**pre-information letter**' set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

1. Rejection of ineligible costs

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for General Lump Sum grants the main cost eligibility condition refers to 'proper implementation of the action in accordance with Annex 1' *(see Article 6.1)*, improper implementation leads to the *ineligibility* of the costs (NOT *reduction* of the grant; *see also Article 7*). If the action is not carried out as described in Annex 1, the costs will be considered ineligible and rejected proportionally to the tasks or parts of the action not implemented.

⚠ 'Rejection of costs' will be made for **improper implementation** of the action (*see Article 7*).

ARTICLE 43 — REDUCTION OF THE GRANT

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if:

(a) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including submission of false information, failure to provide requested information, breach of ethical principles) or

(b) the beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

Improper implementation of the action as described in Annex 1 will not lead to a reduction of the grant but to a rejection of costs (see Article 42).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of the **payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

1. Reduction of the grant

The rules on rejection of ineligible costs are in principle the same as in the General MGA *(see Article 42 H2020 General MGA)*.

However, since for General Lump Sum grants 'proper implementation of the action in accordance with Annex 1' is an *eligibility* rule and does NOT lead to the *reduction* of the grant *(see also Articles 6.1 and 7)*, the grant can be reduced only in case of other serious breaches of obligations or substantial errors, irregularities or fraud*; see Article 43 H2020 General MGA).*

⚠ **Grant reductions** will be made for **substantial errors, irregularities or fraud** and **serious breaches of obligation other than proper implementation**.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

MONO-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If payment is not made by the date in the debit note, *[Agency or the]* Commission*]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or****][OPTION 2 :*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information** letter to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the] Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the] Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the beneficiary, in the estimated budget (see Annex 2) and/or]* ***[OPTION 2:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

MULTI-BENEFICIARY: ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will —**at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, *[the Agency or]* the Commission will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If the revised final grant amount (see Article 5.4) is lower than the final grant amount, the coordinator must repay the difference to the *[Commission][Agency]*.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the coordinator:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the [*Commission*][*Agency*] will **recover** the amount:

(a) by **offsetting** it — without the coordinator's consent — against any amounts owed to the coordinator by *[the Agency,]* the Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the coordinator the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party to the coordinator has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated for the consortium in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date *[the Agency or]* the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the coordinator, unless Directive 2007/64/EC applies.

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

The General Lump Sum multi-beneficiary MGA has, however, the following **specificities**:

Since the coordinator alone is financially responsible (for the entire grant), the Commission/Agency will recover ONLY from it.

> **Best practice:** Beneficiaries should foresee internal arrangements *(e.g. in the consortium agreement)* to redistribute the financial responsibility internally in the consortium in a fair way.

There is therefore also NO need for a report on the distribution of payments between beneficiaries.

Specific cases:

Coordinator with linked third party with joint and several liability — If a linked third party to the coordinator has accepted joint and several liability (see *Article 14 H2020 General MGA*), the Commission/Agency may also recover the amount unduly paid by holding the third party liable — up to the maximum EU contribution indicated for the consortium in the estimated budget (Annex 2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide requested information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment.

This date may be before the date on which the amendment enters into force.

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Article 43 and Article 44).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA (see *Article 49 H2020 General MGA)*.

The General Lump Sum MGA has, however, the following **specificities**:

Suspension of action implementation has NO specific impact on the eligibility of costs. Costs are eligible, if they fulfil the conditions set out in Article 6 — i.e. the action tasks must have been carried out as described in Annex 1.

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

MONO-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification

50.1.2 Effects

The beneficiary must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiary's obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement if:

(a) not applicable

(b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) not applicable

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) the beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][**OPTION 2:** not applicable]*;

(j) *[**OPTION 1 for joint actions (joint call with a third country or an international organisation):** the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][**OPTION 2:** not applicable]*;

(k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2).

*(n) **[OPTION 1**: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks][**OPTION 2**: not applicable].*

50.3.2 Procedure

Before terminating the Agreement, the *[Commission][Agency]* will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n)above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiary may not claim damages due to termination by the [Commission][Agency] (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

MULTI-BENEFICIARY: ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been 'terminated improperly'.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must submit — within 60 days from when termination takes effect — the final report (see Article 20).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

In case of **improper termination**, the grant will be reduced by 100% (see Article 43).

After termination, the beneficiaries' obligations (in particular Section 3 of Chapter 4, Articles 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the [Commission][Agency]

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**'; see Article 22.5.2);

(n) ***[OPTION 1****: despite a specific request by the [Commission][Agency], a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k) and to reallocate its tasks]****[OPTION 2****: not applicable].*

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or to beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect —, submit the final report (see Article 20).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report within the deadline (see above), no costs will be reimbursed.

The Agency will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), no costs will be reimbursed.

The *[Commission][Agency]* will calculate the final grant amount (see Article 5.3) and the balance (see Article 21), on the basis of the report submitted, the eligible costs and compliance with other obligations under the Agreement.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative and sanctions (Article 53).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 55), with a proposal for reallocation of the tasks (see Annex 1) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the [Commission][Agency] (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

1. GA termination (consortium)

The rules on GA termination are the same as in the General MGA *(see Article 50 H2020 General MGA)*.

2. Beneficiary termination (consortium)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the General Lump Sum multi-beneficiary MGA has the following **specificities**:

The notification must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

Moreover, if the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

3. GA or beneficiary termination (EU)

The rules on GA and beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, the General Lump Sum multi-beneficiary MGA has the following **specificities**:

The request for amendment (which the coordinator must send 60 after termination) must include a reallocation of the tasks (Annex 1), but NO reallocation of the estimated budget of the beneficiary concerned.

If the GA continues (i.e. it is amended), the termination of the beneficiary will NOT have any effect on the estimated budget (since there is a lump sum for the entire action, i.e. the consortium as a whole).

IX.3 H2020 Lump Sum Pilot MGA: Annotations

ARTICLE 2 — ACTION TO BE IMPLEMENTED

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the **action** entitled [**insert title of the action**] — [**insert acronym**] ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation): *The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

1. Lump Sum Pilot actions

What? Lump Sum Pilot grants are used in a limited number of cases provided for in the work programme/call. They can be research and **innovation actions (RIA)**, **innovation actions (IA)** or **coordination and support actions (CSA)**.

Examples: *Specific call within the Nanotechnologies, Advance Materials, Biotechnology and Advance Manufacturing and Processing topic DT-NMBP-20-2018, some R&I activities in the rail sector (e.g. topics S2R-CFM-IP5-01-2018 and S2R-CFM-CCA-01-2018).*

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

ARTICLE 4 — ESTIMATED LUMP SUM BREAKDOWN AND LUMP SUM SHARE TRANSFERS

4.1 Estimated lump sum breakdown

The '**estimated lump sum breakdown**' for the action is set out in Annex 2.

It contains the lump sum shares, per work package and beneficiary *[and linked third party]*.

The estimated lump sum breakdown does not prescribe how the EU contribution is to be used by the beneficiaries. It shows the amounts that the *[Commission][Agency]* commits to pay if the action is implemented properly, regardless of the costs actually incurred.

4.2 Lump sum share transfers

The estimated lump sum shares indicated in Annex 2 can be adjusted by transfers of amounts between beneficiaries and/or work packages, via an amendment (see Article 55).

Transfers between work packages are however possible only if:

- the work packages are not already completed (and declared in a financial statement);
- the transfers are justified by the technical and scientific implementation of the action and
- a review in accordance with Article 22.1.2 confirms that the amendment does not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

1. Estimated lump sum breakdown

Since Lump Sum Pilot grants do not use eligible costs, the Lump Sum Pilot MGA does not have any budget categories. Instead, it has a breakdown of the lump sum, per work package and beneficiary.

The breakdown is used to determine:

- the share of the lump sum to which each beneficiary is entitled for each work package

  Example: *Annex 2 sets out EUR 200 000 for work package 1 (WP1). The consortium completed WP1 in the first reporting period as described in Annex 1. Therefore, the consortium declares EUR 200 000 for WP1 in the periodic reports of period 1. If the Commission confirms that the WP1 was completed as described in Annex 1, it will include EUR 200 000 in the periodic payment.*

- the maximum amount for which each beneficiary is liable (grant reduction) in case of improper implementation of a work package

  Example: *In the example above, the Commission carries out a review on the grant in the last reporting period. The review concludes that WP1 was not properly implemented because only part of the activities of that work package were actually carried out. The Commission will reduce the grant in proportion to the improper implementation of WP1 up to a maximum of EUR 200 000 (the share of the lump sum allocated to that work package).*

- the maximum amount for which each beneficiary is liable in case of improper implementation of a work package.

Example: *In the example above, the Commission carries out a technical audit on the grant after the payment of the balance. The audit concludes that WP2 (value also EUR 200 000) was not implemented as indicated in Annex 1. On those grounds, the Commission decides to reduce the grant. Beneficiaries A and B were together responsible for carrying out WP2 (according to Annex 2 beneficiary A for EUR 150 000 and beneficiary B for EUR 50 000). Therefore, each beneficiary will be liable for their proportion of the work package (e.g. in case of a 50% reduction, beneficiary A for EUR 75 000 and Beneficiary B for EUR 25 000).*

2. Lump sum share transfers

Unlike in the General MGA, transfers of Lump Sum Pilot shares are only possible via a formal amendment.

The transfer may be:

- within the same work package (i.e. increasing the share of a beneficiary and decreasing the share of another)
- between work packages (i.e. increasing the share allocated to a work package and decreasing the share of another).

Transfers between work packages can only be accepted in exceptional circumstances, if duly justified and after a project review .

Transfers from or to a work package which the consortium has already declared as completed in a reporting period are NOT allowed.

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

ARTICLE 5 — GRANT AMOUNT AND FORM OF GRANT

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR** [**insert amount** (insert amount in words)].

5.2 Form of grant

The grant takes the **form** of a lump sum contribution for the implementation of the action.

1. Grant amount and form of grant

How much & which form? The Lump Sum Pilot MGA does not use the **cost forms** of the General MGA, but is a **lump sum grant** *(see Decisions C(2017)7149 and C(2017)7151)*.

The use of the lump sum will be set out in the work programme/call.

The lump sum will be fixed taking into account the H2020 funding rates. This means that the lump sum fixed in Article 5 does not have to be multiplied again by the funding rate; it is already the net maximum EU funding.

The lump sum is one amount for the entire consortium.

There are no cost eligibility conditions. If the action is correctly implemented (in line with the description in Annex 1), the beneficiaries are entitled to receive the fixed lump sum amount.

⚠ The lump sum is deemed to **cover ALL** (direct and indirect) **costs** for the action and it can NOT be increased.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21) — in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages and reduction of non-approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiaries *[and linked third parties]* are added together.

The grant is reduced (see Article 43) for all other work packages (i.e. all work packages that have not been delivered or cannot be approved at the payment of the balance).

5.3.2 Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is further reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than improper implementation; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Step 1 or
- the reduced grant amount following Step 2.

1. Final grant amount

For Lump Sum Pilot grants, the rules on the final grant amount are in principle the same as for the General MGA *(see Article 5.3 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

Moreover, since they are lump sum grants (and the amount declared cannot be higher than the amount fixed in Annex 2 anyways), there is NO need to calculate the:

- limit to the maximum grant amount or
- reduction due to the no-profit rule.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* reduces the grant (due to substantial errors, irregularities or fraud or serious breach of obligations including improper implementation; see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

1. Revised final grant amount

For Lump Sum Pilot grants, the rules on the revised final grant amount are in principle the same as for the General MGA *(see Article 5.4 H2020 General MGA)*.

However, since there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services;
- use in-kind contributions provided by third parties against payment;
- use in-kind contributions provided by third parties free of charge;
- call upon subcontractors to implement action tasks described in Annex 1;
- call upon linked third parties to implement action tasks described in Annex 1;
- call upon international partners to implement action tasks described in Annex 1

in accordance with the specific rules set out in Article 10 to 14a.

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

1. Participants: Appropriate own resources —Third parties involved in the action

The rules of the General MGA on third party involvement are only partly applicable to the Lump Sum Pilot MGA.

The General MGA rules on third party involvement are limited in Lump Sum Pilot actions to subcontracting (*Article 13*), linked third parties (*Article 14*) and international partners (*Article 14a*).

The articles for purchases (*Article 10*) and in-kind contributions (*Articles 11* and *12*) are not applicable to the Lump Sum Pilot MGA. Beneficiaries may make purchases and use any in-kind contributions from third parties following their internal practices but not subject to other rules (as long as they are needed to carry out the work of the action).

⚠ For all types of third party involvement (purchases, in-kind contributions, subcontracts, linked third parties and international partners), the **costs** are **ALL covered** by the lump sum. NO other costs will be reimbursed.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Specific rules for subcontracting action tasks

Subcontracting may cover only a limited part of the action.

The tasks to be implemented for each subcontract must be set out in Annex 1. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

***[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Subcontracting

The rules on subcontracting for Lump Sum Pilot actions are in principle the same as for the General MGA *(see Articles 8 and 13 H2020 General MGA)*.

The Lump Sum Pilot MGA has however the following **specificities**:

The estimated subcontracting costs do NOT need to be included in Annex 1 or shown in the table of estimated costs in Annex 2 (there is no such table for the Lump Sum Pilot; Annex 2 is not the budget, but the estimated lump sum breakdown). By contrast, the tasks to be subcontracted must still be indicated in Annex 1, as it happens in the General MGA

The principles of best value for money and no conflict of interest are not explicitly mentioned in Article 13. Nonetheless, they must still be complied with and confirmed by the beneficiaries at proposal stage.

The obligations in Article 13.1 are NOT considered to be additional cost eligibility conditions, but '*other obligations*'. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations which occurred at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[OPTION 1 to be used if foreseen in the work programme: *The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.*

*The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION 2: *Not applicable**]***

15.2 Financial support in the form of prizes

[OPTION 1 to be used if foreseen in the work programme: *The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.*

*The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION 2: *Not applicable**]***

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2: *Not applicable**]***

1. Financial support to third parties

The rules for financial support to third parties in Lump Sum Pilot actions are in principle the same as in the General MGA *(see Article 15 H2020 General MGA)*.

Thus, although the minimum conditions for granting financial support are not explicitly listed in Article 15 of the Lump Sum Pilot MGA, they must still be complied with (and confirmed by the beneficiaries at proposal stage).

Moreover, like under General MGA, the proposal must fix the criteria that the beneficiaries intend to apply for their cascading grants (i.e. no more than EUR 60 000 maximum amount per recipient, the criteria for determining the exact amount of support, the types of activities, the categories of recipients and the conditions for giving support) and this description will also become part of Annex 1 of the GA.

The obligations in Article 15.1 and 15.2 are NOT considered to be additional cost eligibility conditions, but *'other obligations'*. In case of breach, the Commission/Agency may therefore reduce the grant in proportion to the seriousness of the breach (instead of rejecting the costs).

The grant may also be reduced for breach of obligations at proposal stage *(see Article 43 H2020 General MGA)*.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants:*** *three]* years after the payment of the balance — keep adequate **records and other supporting documentation** to prove the proper implementation of the action.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance

Records and other supporting documentation on the scientific and technical implementation of the action must be in line with the accepted standards in the respective field.

The beneficiaries do not need to keep record about the costs actually incurred for implementing the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

1. Records and other supporting documentation

For Lump Sum Pilot actions, beneficiaries do not need to keep full records on their actual costs; they only need to keep appropriate and sufficient evidence (documentation, records) that the action tasks (as described in Annex 1) were properly carried out.

The evidence must be verifiable, auditable and available. It must be correctly archived — for at least 5 years after the balance is paid (three years for grants up to EUR 60 000) or longer if there are ongoing procedures *(such as audits, investigations or litigation)*. In this case, the evidence must be kept until they end.

The records and supporting documentation must:

- refer to the technical implementation of the action, in line with the accepted standards in the respective field *(see Article 18 H2020 General MGA)* and
- prove that the tasks or part of the action allocated to the beneficiary in Annex 1 were implemented properly *(see Article 18 H2020 General MGA)*.

By contrast, timesheets or invoices for costs actually incurred are NOT needed.

⚠ If the beneficiary cannot provide evidence of the proper implementation of the action, the grant may be **reduced** (and other measures described in Chapter 6 may be applied as well).

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

[…]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including work packages, milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must declare the lump sum shares indicated in Annex 2, for the **work packages** that were completed in the reporting period.

For the last reporting period, the beneficiaries may exceptionally also declare partial lump sum shares for work packages that were not completed (e.g. due to scientific or technical reasons), if agreed by the *[Commission][Agency]*.

Lump sum shares which are not declared in the financial statement will not be taken into account by the *[Commission][Agency]*.

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the work packages have been completed and that the action in general has been properly implemented (see Article 7);
- the proper implementation can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

(ii) an **explanation of the use of resources**: not applicable;

(iii) ***[OPTION** 1 **if the JRC is a beneficiary:** information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);**][OPTION 2:** not applicable;**]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action.

(b) a '**final financial report**' containing a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the financial statements for all reporting periods and including the **request for payment of the balance**.

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements

Financial statements must be drafted in euro.

[…]

1. Reports

What & When? For Lump Sum Pilot actions, the coordinator must submit a **periodic report** after the end of each reporting period (including the final one).

Each report is composed of a technical and a financial report (like in the General MGA). However, unlike in the General MGA, beneficiaries do not declare costs but their lump sum shares (as set out in Annex 2), for the work packages completed during that reporting period.

Work packages can be declared only once fully completed (as described in Annex 1). If a work package is carried out by several beneficiaries, they cannot declare it until all of them have completed it.

Example:

Grant for a consortium with a maximum grant amount of EUR 3 000 000 and the following breakdown per work package and beneficiary:

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Annex 1 of the grant agreement indicates that at the end of the first reporting period WP1, WP2 and WP3 should have been completed. WP4 and WP5 should have been initiated.

At the end of the first reporting period (RP1) the actual situation is as follows:

	WP1	WP2	WP3	WP4	WP5
Beneficiary A	Completed			Initiated	Initiated
Beneficiary B		Completed	Completed	Not initiated	
Beneficiary C	Completed	Initiated		Initiated	
Beneficiary D		Completed		Completed	

Since the beneficiaries can only declare completed work packages, they can only declare the amounts for WP1 and WP3. They cannot declare any amount for the WP2, WP4 or WP5, even if they are initiated, because they are not completed.

Partial work packages are allowed only in the following two situations:

- beneficiary termination — terminated beneficiaries may declare (in the termination report) shares for on-going work packages, provided that their part was completed in accordance with Annex 1 *(see Article 50)*.

- last reporting period — at the end of the action, beneficiaries may exceptionally also declare partial shares for work packages that were not completed, for example due to technical reasons.

Best practice: In case of doubt, the coordinator should contact the Commission/Agency about partial work packages.

⚠ The Commission/Agency will **NOT** accept partial lump sum shares in the last reporting period if:

- the situation could have been solved via an amendment

  Example: *The consortium argues that they did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the consortium to have enough time.*

- non-implementation is linked to financial reasons

  Example: *The project resulted to be more expensive than initially expected and the consortium decided to stop the work in some WPs.*

How? Each periodic report must be **prepared** by the **coordinator** and the other **beneficiaries together**, directly in the Participant Portal).

In practice, the following steps will apply for the financial part:

Step 1 — The coordinator will indicate in the Participant Portal which work packages have been fully accomplished during the reporting period.

Step 2 — The beneficiaries will have to sign individual financial statements to confirm proper implementation of those work package(s) and submit them to the coordinator. All of them will be part of the financial report for the reporting period concerned.

Step 3 — The coordinator will submit both the technical and the financial report to the Commission/Agency.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

[…]

21.3 Interim payments — Amount — Calculation

Interim payments pay the lump sum shares for work packages completed during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Work packages that have not been completed in time or cannot be approved at the time of an interim payment may be submitted (again) for the next reporting period (or any other future reporting period, after they have been completed).

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Calculation of the lump sum shares for the approved work packages

The amounts of the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiaries *[and linked third parties]* for the concerned reporting period are added together.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining lump sum shares for the implementation of the action.

If the total amount of earlier payments is greater than the **final grant amount** (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report and the lump sum shares and work packages declared. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

Incomplete work packages and work packages that have not been delivered or cannot be approved at the payment of the balance will reduce the grant (see Articles 5 and 43).

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum grant amount indicated, for that beneficiary, in the estimated lump sum breakdown (see Annex 2).

[…]

1. Payments to be made

The rules on payments are in principle the same as in the General MGA (one pre-financing payment, interim payments at the end of each reporting period, and a final payment of the balance).

2. Payment calculations — Amounts due — Recoveries?

Interim payments

How much? The amount of the interim payments will be calculated by the Commission/Agency on the basis of the financial statements and the payments already made.

The rules follow those of the General MGA *(see Article 21.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up the lump sum shares for the accepted work packages for this reporting period (the lump sum shares in Annex 2 already take into account the reimbursement rate; no need to apply it again). Partial work packages will NOT be accepted; the entire work package (i.e. work of all beneficiaries) needs to be done.

Beneficiary termination

How much? The amount due at beneficiary termination will be calculated by the Commission/Agency on the basis of the termination report, the payments already made and the report on the distribution of payments.

The rules follow those of the General MGA *(see Articles 21.3, 44.1.1, 50.2.2 and 50.3.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs, but simply sums up all the lump sum shares for the beneficiary's accepted work packages. Partial work packages can be accepted (i.e. shares for work packages where the beneficiary's part is completed).

Exceptionally, the Commission/Agency may accept also *part* of a lump sum share for a work package in which the beneficiary has not carried out all its tasks.

> ***Example:*** *The beneficiary requests terminating its participation in the action because a fire devastated its laboratory where most of the technical equipment and computers used for the action were located. Therefore, the beneficiary cannot complete its tasks in the on-going work packages due to force majeure (see Article 51 H2020 General MGA). On those grounds, the Commission decides to accept for that beneficiary a part of the lump sum shares for the on-going work packages proportionate to the tasks carried out by the beneficiary in those work packages.*

Not completed work packages (or not completed parts of them) can be finished and declared later on.

Example for calculating the amount due at beneficiary termination:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

The participation of beneficiary B is terminated before the end of the first reporting period. At the time when the termination takes effect beneficiary B had fully completed its tasks for WP2 and WP3 and initiated its tasks for WP4. The coordinator had transferred EUR 650 000 as pre-financing to beneficiary B.

Amount due:

Lump sum shares for accepted work packages: WP2 + WP3 = EUR 600 000.

Beneficiary B amount due: EUR 600 000.

Beneficiary balance:

Payments received by beneficiary B (according to the report on the distribution of payments): EUR 650 000.

Beneficiary B balance: EUR 600 000 (amount due) - EUR 650 000 (payments received) = EUR -50 000 (excess payments of EUR 50 000).

Recovery:

Amount to be recovered from beneficiary B: EUR 50 000 (negative balance of EUR 50 000 must be returned to the consortium; otherwise Commission/Agency will start a recovery procedure).

Payment of the balance

How much? The amount to be paid (or recovered) at payment of the balance (final payment) will be calculated by the Commission/Agency on the basis of the financial statements, the final grant amount, the payments already made and the report on the distribution of payments

The rules follow those of the General MGA *(see Articles 5.3, 21.4 and 44.1.2 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Calculation of the accepted EU contribution) does not apply the reimbursement rate to the eligible costs but simply sums up all the lump sum shares for the accepted work packages. Partial work packages can exceptionally be accepted (i.e. shares for work packages that were not completed, for example due to technical reasons).

The Commission/Agency will **NOT** accept partial lump sum shares in the last reporting period if:

- the situation could have been solved via an amendment

  Example: *The consortium argues that they did not have enough time to complete the WP. The duration of the action could have been extended via an amendment for the consortium to have enough time.*
- non-implementation is linked to financial reasons

  Example: *The project resulted to be more expensive than initially expected and the consortium decided to stop the work in some WPs.*

Steps 2 (Limit to the maximum grant amount) and 3 (Calculation of receipts & deduction of profit) do not apply to Lump Sum Pilot grants.

Step 4 (Grant reductions) relates to grant reductions for breaches *other* than non-implementation (because non-implementation is already taken into account for Step 1).

All other steps follow the General MGA.

Example for calculating the payment of the balance:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Case 1:

At the end of the action, WP7 was not completed as described in Annex 1. The Commission decides to reduce 50 % of WP7, corresponding to the proportion of the undelivered part of that work package. All other work packages were completed as described in Annex 1. In addition, the consortium breached an important confidentiality obligation under Article 36. The Commission decides to reduce the maximum grant amount by 10 % for that reason.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP2 + WP3 + WP4 + WP5 + WP6 + 50 % WP7 + WP8 = EUR 2 900 000.

Amount resulting from Step 1: EUR 2 900 000.

Grant reduction for other breaches: 10% grant reduction for the action = maximum grant amount – 10 % (reduction) = 3 000 000 – 300 000 = EUR 2 700 000.

Amount resulting from Step 2: EUR 2 700 000.

Lower amount of the two: EUR 2 700 000.

Final grant amount: = EUR 2 700 000.

Case 2:

The consortium decides to terminate the GA due to technical difficulties that result in the action no longer being viable. The termination takes effect before the end of the first reporting period. At the moment of termination the state of play of each work package is as follows:

	WP1	WP2	WP3	WP4	WP5	WP6, WP7, WP8
Beneficiary A	**Completed**			Initiated	Initiated	Not initiated
Beneficiary B		**Completed**	**Completed**	Not initiated		Not initiated
Beneficiary C	**Completed**	Not initiated		Not initiated		Not initiated
Beneficiary D		**Completed**		**Completed**		Not initiated

In the reports, the consortium justifies that for WP2 the work of beneficiary B and beneficiary D were fully accomplished in accordance with Annex 1, that the work of beneficiary C in this work package was ancillary and that beneficiary C stopped in fact collaborating in the action. On those grounds, the Commission accepts exceptionally 370 000 EUR for WP2.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP2 (part) + WP3 = 350 000 + 370 000 + 350 000 = EUR 1 070 000

No grant reductions for other breaches.

Final grant amount: EUR 1 070 000.

Case 3:

Work package 2 was not carried out (i.e. representing a total lump sum share of EUR 470 000) and therefore the Commission reduced the grant accordingly.

Final grant amount:

Lump sum shares for accepted work packages: WP1 + WP3 + WP4 + WP5 + WP6 + WP7 + WP8 = EUR 2 530 000.

No grant reductions for other breaches.

Final grant amount: EUR 2 530 000 (➔ beneficiary shares: A = EUR 1 150 000; B = EUR 650 000; C = EUR 430 000; D = EUR 300 000).

Balance & Guarantee Fund release:

Payments made: EUR 2 700 000.

Balance: EUR 2 530 000 (final grant amount) - EUR 2 700 000 (payments made) = EUR -170 000 (excess payments of EUR 170 000).

Offsetting against Guarantee Fund release: EUR 170 000 - EUR 150 000 = EUR 20 000

Recovery:

Amount to be recovered from the consortium: EUR 20 000 (negative balance of EUR 20 000 must be paid back by coordinator, otherwise Commission will start a recovery procedure against the beneficiaries that received excess funding).

Recovery from coordinator:

The coordinator does not reimburse the Commission and sends the report on the distribution of the payments among beneficiaries (distribution: A= EUR 977 500; B= EUR 765 000; C = EUR 450 500; D= EUR 357 000).

Recovery from beneficiaries:

Identifying the beneficiaries with excess funding:

*A: {(EUR 1 150 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 1 150 000 (share in the final grant)} - EUR 977 500 (payments received) = EUR 172 500 (no payment in excess)*

*B: {(EUR 650 000 / (1 150 000 + 650 000 + 430 000 +300 000)) * 2 530 000 = EUR 650 000 (share in the final grant)} - EUR 765 000 (payments received) = EUR -115 000 (excess payment of EUR 115 000)*

*C: {(430 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 430 000 (share in the final grant)} - EUR 450 500 (payments received) = EUR -20 500 (excess payment of 20 500)*

*D: {(300 000 / (1 150 000 + 650 000 + 430 000 + 300 000)) * 2 530 000 = EUR 300 000 (share in the final grant)} - EUR 357 000 (payments received) = EUR -57 000 (excess payment of EUR 57 000).*

Beneficiaries B, C and D received payments in excess of their EU contribution and will have to reimburse the Commission.

Beneficiary A will have to recover the money owed to it (if any) from the other beneficiaries in the consortium.

Division of the debt:

Relative share of total payments in excess:

Total payments made in excess = 192 500.

B: 115 000/192 500 = 59.74 %.

C: 20 500 /192 500 = 10.65 %.

D: 57 000/192 500 = 29.61 %.

Total to be recovered: EUR 20 000.

B: 59.74 % x 20 000 = EUR 11 948

C: 10.65 % x 20 000 = EUR 2 130

D: 29.61 % x 20 000 = EUR 5 922

Audit implementation after payment of the balance — Revised final grant amount

The amount to be recovered (or paid) after the final payment will be calculated by the Commission/Agency on the basis of the final grant amount and the revised final grant amount.

The rules follow those of the General MGA *(see Articles 5.4 and 44.1.3 H2020 General MGA)*, however with the following **specificities**:

Step 1 (Re-calculation of the accepted EU contribution) does not apply; only Step 2 (Grant reductions) applies.

All other steps follow the General MGA *(see for the calculations Article 21 H2020 General MGA)*.

Example for calculating recoveries after payment of the balance:

Grant with four beneficiaries (A, B, C, D).

Maximum grant amount: EUR 3 000 000.

Lump sum share breakdown per work package and beneficiary (Annex 2):

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	**Total**
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000

Case 1:

Final grant amount:

Final grant amount: EUR 1 150 000 + EUR 900 000 + EUR 530 000 + EUR 420 000 = EUR 3 000 000.

The Commission carries out a technical audit on the action and finds out that beneficiary B did not carry out its activities under the work package 4 (lump sum share EUR 50 000). The Commission therefore reduces the grant by EUR 50 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 900 000 (accepted lump sum shares) — EUR 50 000 (rejected lump sum shares) = EUR 850 000
Beneficiary B revised final grant amount: EUR 850 000.
The other beneficiaries final grant amounts (i.e. their final grant amount shares) remain unchanged.

Beneficiary balance:
The share of beneficiary B in the final grant amount = EUR 900 000 / 3 000 000 x 3 000 000 = EUR 900 000.
Balance: EUR 850 000 (revised final grant amount) – EUR 900 000 (final grant share) = EUR -50 000 (excess of EUR 50 000).
Recovery:
Amount to be recovered from beneficiary B: EUR 50 000 (negative balance of EUR 50 000 must be paid back by the beneficiary).

Case 2:

Same example as above, but in this case a reduction of the maximum grant amount had been performed at the time of the payment of the balance as follows: the consortium breached a confidentiality obligation under Article 36 and the Commission reduced the maximum grant amount by 10 % for that reason (i.e. EUR 3 000 000 – 10 % = EUR 2 700 000).

Final grant amount:

Final grant amount: = EUR 2 700 000.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for beneficiary B: EUR 900 000 (accepted lump sum shares) — EUR 50 000 (rejected lump sum shares) = EUR 850 000.

Beneficiary B revised final grant amount: EUR 850 000.

Beneficiary balance:

The share of beneficiary B in the final grant amount = EUR 900 000 / EUR 3 000 000 x EUR 2 700 000 = EUR 810 000.

Balance: EUR 850 000 (revised final grant amount) – EUR 810 000 (final grant share) = EUR 40 000 (no excess).

Recovery:
No recovery.

Case 3:

Final grant amount:

Final grant amount: EUR 1 150 000 + EUR 900 000 + EUR 530 000 + EUR 420 000 = EUR 3 000 000.

The Commission carries out a technical audit on the action and finds out that work package 8 (EUR 600 000) has not been implemented as described in Annex 1 and decides to reject it.

Beneficiary revised final grant amount:

Re-calculation of accepted EU contribution for the consortium & revised final grant amount:

Beneficiary A: 1 150 000 – 300 000 = EUR 850 000.

Beneficiary B: 900 000 – 150 000= EUR 750 000.

Beneficiary D: 420 000 - 150 000= EUR 270 000.

The EU contributions of beneficiary C remain unchanged.

Beneficiary balance:

The share of beneficiary A in the final grant amount = EUR 1 150 000.

The share of beneficiary B in the final grant amount = EUR 900 000.

The share of beneficiary D in the final grant amount = EUR 420 000.

Balance:

A: EUR 850 000 (revised final grant amount) - EUR 1 150 000 (final grant share) = EUR -300 000.

B: EUR 750 000 (revised final grant amount) - EUR 900 000 (final grant share) = EUR -150 000.

D: EUR 270 000 (revised final grant amount) - EUR 420 000 (final grant share) = EUR -150 000.

Recovery:

Amount to be recovered from beneficiary A: EUR 300 000 (negative balance of EUR 300 000 must be paid back by the beneficiary).

Amount to be recovered from beneficiary B: EUR 150 000 (negative balance of EUR 150 000 must be paid back by the beneficiary).

Amount to be recovered from beneficiary D: EUR 150 000 (negative balance of EUR 150 000 must be paid back by the beneficiary).

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

[…]

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

[…]

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement. […]

1. Checks, reviews and audits

The rules on checks, reviews and audits are in principle the same as in the General MGA *(see Article 22 H2020 General MGA)*.

However, since Lump Sum Pilot grants do not use eligible costs, their scope will differ as follows:

- there will be no *financial* checks, reviews, or audits to check costs (since beneficiaries have no obligation to document the costs incurred for the action, even if they remain subject to the accounting rules under the applicable national law).
- checks, reviews, and audits will focus on the *technical* implementation of the action (in particular full accomplishment of the work packages as described in Annex 1 of the GA), or on other aspects of the grant agreement, *such as promoting the action, visibility of EU funding, ethics and research integrity, dissemination and exploitation of results, management of intellectual property, etc.*

Specific cases (audits):

Audits for periodical assessment of simplified cost forms — The Commission/Agency may also audit the accounting records of beneficiaries to obtain general information about real costs of cost items for which it has fixed unit costs, flat-rate or lump sums (for statistical purposes or to gather data to assess the adequacy of its unit cost, flat rate or lump sum). Such audits have no consequences for the beneficiaries that were audited.

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — **after termination of a beneficiary's participation, at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for lump sum shares declared by its linked third parties)****]****,* except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(d) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(e) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum grant amount indicated, for the linked third party, in the estimated lump sum breakdown (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(f) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[34] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments, the *[Commission][Agency]* will:

(c) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's approved lump sum shares

[plus

its linked third parties' approved lump sum shares]},

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for approved work packages calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(d) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

[…]

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{beneficiary's approved lump sum shares

[plus

its linked third parties' approved lump sum shares]}

divided by

the total of all beneficiaries' *[and linked third parties']* lump sum shares for approved work packages calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

[...]

1. Recovery of undue amounts

The rules on recovery of undue amounts are in principle the same as in the General MGA *(see Article 44 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial report has not been submitted or is not complete or additional information is needed, or

(c) there is doubt about amounts requested for payment (including the need for a grant reduction) and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will take effect the day notification is sent by the [Commission][Agency] (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be lifted — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the [Commission][Agency] if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the [Commission][Agency] may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

1. Suspension of the payment deadline (EU)

The rules on the suspension of the payment deadline are in principle the same as in the General MGA *(see Article 47 H2020 General MGA)*.

The Lump Sum Pilot MGA has, however, the following **specificities**:

Since there are no cost eligibility conditions about which there could be doubts, the suspension ground for Lump Sum Pilot grants targets more generally any kinds of doubts about the amounts requested for payment (including doubts linked to work package implementation).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the [*Commission*][*Agency*] the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

During the suspension, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiaries may not claim damages due to suspension by the *[Commission] [Agency]* (see Article 46).

1. GA suspension (consortium or EU)

The rules on GA suspension are in principle the same as in the General MGA *(see Article 49 H2020 General MGA)*.

For *full* GA suspension (action is entirely suspended), all on-going work packages must be interrupted and NO new work packages may be started.

For *partial* GA suspensions other work packages may be continued and new work packages may be started(except for those covered by the suspension).

However, partial suspensions may have an indirect effect on other work packages, in the sense that it might not be possible to fully complete them (and thus not be possible to declare them for the reporting period — unless it is already the end of the action; *see Articles 20 and 21*).

Example: *A fire caused some damage to an equipment of a beneficiary which is used for a set of chemical 3D-analyses (large part of WP2) which are then needed for further experiments in WP4 and WP5. The consortium therefore requests that the part of the action that is affected (WP3) is suspended until the equipment is restored. The other beneficiaries may continue to work on the other work packages (WP4 and WP5). However, if these work packages cannot be fully completed at the end of the reporting period because the WP3 continues to be suspended, the lump sum shares for WP4 and WP5 cannot be declared by the beneficiaries.*

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

[…]

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the report within the deadline (see above), only lump sum shares included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate the final grant amount** (see Article 5.3) and the balance (see Article 21.4), on the basis of the reports submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

[…]

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work packages

The grant amount for the beneficiary is calculated by adding the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary *[and its linked third parties]* in the termination report.

Only lump sum shares for work packages fully completed by the beneficiary before termination will be approved — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the *[Commission][Agency]*

[…]

50.3.3 Effects

(b) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the report within the deadline (see above), only lump sum shares included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4), on the basis of the reports submitted and compliance with other obligations under the Agreement. Only lump sum shares for work packages fully completed before termination will be accepted — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

This does not affect the *[Commission][Agency]*'s right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(c) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(iv) a report on the distribution of payments to the beneficiary concerned;

(v) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated lump sum breakdown (see Annexes 1and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator, and

(vi) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work and the individual financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 56).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Calculation of the lump sum shares for the approved work

The grant amount for the beneficiary is calculated by adding the lump sum shares (see Annex 2) for the approved work packages declared by the beneficiary *[and its linked third parties]* in the termination report.

Only lump sum shares for work packages fully completed by the beneficiary before termination will be approved — unless exceptionally agreed otherwise by the *[Commission][Agency]*.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (due to substantial errors, irregularities or fraud or serious breach of obligations other than non-implementation of the action; see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

The amount due will be the lower of the two amounts.

[…]

1. GA termination (consortium or EU)

The rules on GA termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21*).

2. Beneficiary termination (consortium or EU)

The rules on beneficiary termination are in principle the same as in the General MGA *(see Article 50 H2020 General MGA)*.

However, since for Lump Sum Pilot grants there is no reporting of costs, the calculations are different *(see Article 21)*.

H2020 Programme

Fact sheets

Grants

Version 2.1
07 January 2020

Disclaimer
This document is aimed at assisting applicants and beneficiaries for Horizon 2020 funding. Its purpose is to explain the Horizon 2020 framework programme and the procedures to be followed. It is provided for information purposes only. Neither the EU Commission nor the EU Agencies can be held responsible for the use made of this document.

HISTORY OF CHANGES			
Version	**Publication Date**	**Change**	**Page**
1.0	03.02.2015	▪ Initial version	1
1.1	31.08.2015	▪ Small changes to improve usability for outside users ('work programme' replaced by 'call')	
2.0	22.12.2016	▪ Small corrections ▪ Update to 2016/2017 WP	
2.1	07.01.2020	▪ Update to VM4.0 / replace PP > FTP	

H2020 RIA & IA grants

Type of action & requirements:

General features/requirements for RIA and IA grants:

- Multi-beneficiary action
- Project:

  RIA (research and innovation actions): R&D to establish new knowledge or explore the feasibility of a new or improved technology, product, process, service or solution (including basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment)

  IA (innovation actions): innovation activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication)
- Maximum funding: None — unless specified in the call
- Maximum duration: None — unless specified in the call
- Subtypes: Lump sum grant possible if provided in the call

Beneficiaries (composition of the consortium):

- Minimum 3 beneficiaries from 3 different EU Member States (MS) or H2020 associated countries (AC)
- Additional beneficiaries/linked third parties from any country allowed (with EU funding, normally only if listed in General Annex A to the Main Work Programme)

Funding:

Type of grant: reimbursement of costs grant

Forms of costs:

Usually: actual costs + unit cost (average personnel costs; SME owners; specific unit costs, if option applies) + flat–rate costs (indirect costs)

For lump sum grants: lump sum

Budget categories:

Usually:

A. direct personnel costs

B. direct costs of subcontracting

C. direct costs of providing financial support to third parties (if option applies)

D. other direct costs

E. indirect costs

F. specific cost categories (if option applies)

For lump sum grants:

A. costs for the action (direct and indirect costs)

Funding rate:

RIA: 100% of eligible costs (unless the call provides exceptionally for another rate)

IA: 70% (100% for non-profit organisations) of eligible costs (unless the call provides exceptionally for another rate)

Evaluation:

Award criteria RIA and IA grants		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and credibility of the proposed methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
Extent that proposed work is beyond the state of the art, and demonstrates innovation potential (e.g. ground-breaking objectives, novel concepts and approaches, new products, services or business and organisational models) **Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge**	Any substantial impacts not mentioned in the work programme, that would enhance innovation capacity, create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits to society Quality of the proposed measures to: • Exploit and disseminate the project results (including management of IPR), and to manage research data where relevant • Communicate the project activities to different target audiences	
For IA: Weighting		
1	**1,5**	**1**

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Standard scoring: Each criterion is scored from 0 to 5. Individual thresholds for each criterion: 3/5; overall threshold: 10/15

For IA: scores are weighted

For two-stage calls: For stage 1-proposals, only the criteria 'excellence' and 'impact' will be evaluated and within those criteria only the aspects indicated in bold in *General Annex H of the Main Work Programme*. The threshold for each of the two individual criteria is 4. The overall threshold is dynamic (i.e. set at a level that allows the total requested budget of proposals admitted to stage 2 be as close as possible to 3 times and no less than 2.5 times the available budget).

Consortium agreement: Yes — unless otherwise provided in the call

Type of grant agreement: H2020 General MGA — Multi
H2020 MGA Lump sum — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 CSA grants

Type of action & requirements:

General features/requirements for CSA (coordination and support action) grants:

- Multi/mono-beneficiary action
- Project: accompanying measures such as standardization, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies (including design studies for new infrastructure and complementary activities of strategic planning, networking and coordination between programmes in different countries)
- Maximum funding: None — unless specified in the call
- Maximum duration: None — unless specified in the call
- Sub-types: Lump sum grant possible if provided in the call

Beneficiaries (composition of the consortium):

- Minimum 1 beneficiary from 1 EU Member State (MS) or H2020 associated country (AC)
- Additional beneficiaries/linked third parties from any country allowed (with EU funding, normally only if listed in General Annex A to the Main Work Programme)

Funding:

Type of grant: reimbursement of costs grant

Forms of costs:

Usually: actual costs + unit cost (average personnel costs; SME owners; specific unit costs, if option applies) + flat–rate costs (indirect costs)

For lump sum grants: lump sum

Budget categories:

Usually:

A. direct personnel costs
B. direct costs of subcontracting
C. direct costs of providing financial support to third parties (if option applies)
D. other direct costs
E. indirect costs
F. specific cost categories (if option applies)

For lump sum grants:

A. costs for the action (direct and indirect costs)

Funding rate: 100% of eligible costs (unless the call provides exceptionally for another rate)

Evaluation:

Award criteria CSA grants		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and** credibility of the proposed **methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
Quality of the proposed coordination and/or support measures	Quality of the proposed measures to: • Exploit and disseminate the project results (including management of IPR), and to manage research data where relevant • Communicate the project activities to different target audiences	

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Standard scoring: Each criterion is scored from 0 to 5. Scores are not weighted. Individual thresholds for each criterion: 3/5; overall threshold: 10/15

For two-stage calls: For stage 1-proposals, only the criteria 'excellence' and 'impact' will be evaluated and within those criteria only the aspects indicated in bold in General Annex H of the Main Work Programme. The threshold for each of the two individual criteria is 4. The overall threshold is dynamic (i.e. set at a level that allows the total requested budget of proposals admitted to stage 2 be as close as possible to 3 times and no less than 2.5 times the available budget).

Consortium agreement: Yes — unless otherwise provided in the work programme

Type of grant agreement: H2020 General MGA — Multi
H2020 General MGA — Mono
H2020 MGA Lump sum — Multi
H2020 MGA Lump sum — Mono

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 ERC frontier research grants

Type of action & requirements:

General features/requirements for ERC frontier research grants:

- Mono/multi-beneficiary action
- Project: any type of ground-breaking, high-gain/high-risk research at the frontiers of knowledge (frontier research) in any field of research (except nuclear energy) by a principal investigator and his/her research team
- Standard maximum funding:
  - Starting Grants: EUR 1 500 000
  - Consolidator Grants: EUR 2 000 000
  - Advanced Grants: EUR 2 500 000
- Maximum duration: 60 months (5 years)
- Beneficiaries may use linked third parties — to implement certain action tasks
- Sub-types: ERC Starting Grants, ERC Consolidator Grants, ERC Advanced Grants

ERC Starting Grants:

Beneficiaries:

- Minimum 1 beneficiary (host institution) from 1 EU Member State (MS) or H2020 associated country (AC)
- Additional beneficiaries/linked third parties from any country allowed, if participation is essential for carrying out the action
- Typical size: 1 beneficiary

PI:

- Only for PIs with between 2 and 7 years of research experience (after the first PhD)
- The beneficiary (host institution) must host (and normally also engage) the PI

ERC Consolidator Grants:

Beneficiaries:

- Minimum 1 beneficiary (host institution) from 1 MS/AC
- Additional beneficiaries/linked third parties from any country allowed, if participation is essential for carrying out the action
- Typical size: 1 beneficiary

PI:

- Only for PIs with between 7 and 12 years of experience (after the first PhD)
- The beneficiary (host institution) must host (and normally also engage) the PI

ERC Advanced Grants:

Beneficiaries:

- Minimum 1 beneficiary (host institution) from 1 MS/AC
- Additional beneficiaries/linked third parties from any country allowed, if participation is essential for carrying out the action
- Typical size: 1 beneficiary

PI:

- Only PIs that are active researchers with a track record of significant research achievements in the last 10 years
- The beneficiary (host institution) must host (and normally also engage) the PI

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: actual costs + unit cost (average personnel costs; SME owners) + flat–rate costs (indirect costs)

Budget categories:

A. direct personnel costs

B. direct costs of subcontracting

D. other direct costs

E. indirect costs

Funding rate: 100% of eligible costs

Evaluation:

Award criteria ERC frontier research grants		
Excellence	**Impact**	**Implementation**
Ground-breaking nature, ambition and feasibility of the research project	N/A	N/A
Intellectual capacity, creativity and commitment of the PI		

Evaluation procedure:

Standard submission procedure (one-stage submission), but two-step evaluation procedure.

Two step evaluation procedure: At step 1, the extended synopsis and the PI's track record and CV are assessed (not the full scientific proposal). At step 2, the complete version of the retained proposals is assessed (including the full scientific proposal). Proposals will be retained for step 2 based on the outcome of the evaluation at step 1 and a budgetary cut-off level of up to three times the evaluation panel's budget.

Scoring: Each proposal is marked on a scale from 1 (non-competitive) to 4 (outstanding), for each of the two elements of the award criterion. Marks are awarded with full or half-points. .

During the panel review, the proposals are scored by the panel as A, B or C:

For step 1:

A — sufficient quality to pass to step 2 of the evaluation

B — high quality but not sufficient to pass to step 2 of the evaluation

C — not of sufficient quality to pass to step 2 of the evaluation

For step 2:

A — fully meets the ERC's excellence criterion and is recommended for funding if sufficient funds are available

B — meets some but not all elements of the ERC's excellence criterion and will not be funded

Consortium agreement: No

Type of grant agreement: H2020 ERC MGA — Mono
H2020 ERC MGA — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 ERC PoC grants

Type of action & requirements:

General features/requirements for ERC PoC grants:

- Mono/multi-beneficiary action
- Project: 'proof of concept' to verify the innovation potential of ideas from ERC- funded frontier research projects
- Maximum funding: EUR 150 000
- Maximum duration: 18 months
- Beneficiaries may use linked third parties — to implement certain action tasks

Beneficiaries:

- Minimum 1 beneficiary (host institution) from 1 EU Member State (MS) or H2020 associated country (AC)
- Additional beneficiaries/linked third parties from any country allowed, if participation is essential for carrying out the action
- Typical size: 1 beneficiary

PI:

- Only for PIs that obtained an ERC frontier research grant
- The beneficiary (host institution) must host (and normally also engage) the PI

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: actual costs + unit cost (average personnel costs; SME owners) + flat–rate costs (indirect costs)

Budget categories:

A. direct personnel costs
B. direct costs of subcontracting
D. other direct costs
E. indirect costs

Funding rate: 100% of eligible costs

Evaluation:

Award criteria ERC PoC grants		
Excellence	**Impact**	**Implementation**
Innovation potential Move the output of research towards the initial steps of a process leading to a commercial or social innovation	**Generation of economic and/or societal benefits** Process resulting in a concrete application, including outlining a process of commercialisation or a process of generating social benefits	**Quality of the proof of concept plan** Reasonable and acceptable plan of activities against clearly identified objectives and towards establishing the feasibility of the project

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Scoring: Each criterion is scored as 'pass/fail' by peer reviewers. Proposals with a pass mark by a majority of peer reviewers for each of the three evaluation criteria is proposed for funding. If there is not enough budget for all proposals, they will be funded according to a ranking made by the peer reviewers.

Consortium agreement: No

Type of grant agreement: H2020 ERC MGA PoC — Mono
H2020 ERC MGA PoC — Mono

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 MSCA-ITN grants

Type of action & requirements:

General features/requirements for MSCA-ITN (Innovative Training Networks) grants:

- Multi-beneficiary action
- Action: collaborative research training and/or doctoral programmes for early-stage researchers (implemented by networks of universities, research institutions, research infrastructures, businesses, SMEs and other socio-economic actors from different countries)
- Maximum funding: 540 person-months per network (except for an EID with only 2 beneficiaries: maximum of 180 person-months)
- Maximum duration of the action: 48 months
- Only for 'early-stage researchers'
- Recruitment duration: 3 to 36 months
- Trans-national mobility required
- Maximum 40.0% of total budget to one country (except for EID with two beneficiaries)
- All beneficiaries must host and supervise recruited researchers
- Beneficiaries may use entities with a capital or legal link to them and partner organisations — to implement certain hosting and training tasks
- Sub-types: European Training Networks (ETN), European Industrial Doctorates (EID), European Joint Doctorates (EJD)

European Training Networks (ETN):

Beneficiaries & partner organisations:

- Minimum 3 beneficiaries from 3 different EU Member States (MS) or H2020 associated countries (AC)
- Additional beneficiaries/entities with a capital or legal link from MS, AC or third countries (TC) listed in General Annex A to the Main Work Programme allowed
- Partner organisations from any country allowed (for optional secondments)
- Typical size: 6-10 beneficiaries
- Participation of the non-academic sector expected

Recruitments & secondments:

- Researchers are typically enrolled in a doctoral programme
- Secondments of an individual researcher to other beneficiaries and/or partner organisations up to a maximum of 30% of the researcher's recruitment period

European Industrial Doctorates (EID):

Beneficiaries & partner organisations:

- Minimum 2 beneficiaries (1 academic + 1 non-academic (preferably enterprise)) from 2 different MS/AC
- Additional beneficiaries/entities with a capital or legal link from MS, AC or TC listed in General Annex A to the Main Work Programme allowed
- Partner organisations from any country allowed (for optional secondments)
- At least 1 academic beneficiary entitled to award doctoral degrees (if the beneficiary is not entitled, then it is sufficient he uses a partner organisation that is entitled)
- Typical size: 2-3 beneficiaries

Recruitments & secondments:

- Researchers must be enrolled in a doctoral programme
- Researchers must spend at least 50% of their time in the non-academic sector. This inter-sectoral mobility must be between participating organisations located in different countries. In addition, secondments to other beneficiaries/partner organisations up to a maximum of 30% of the recruitment period

European Joint Doctorates (EJD):

General:

- Joint doctoral programme (double, multiple or joint doctorates) with final degree awarded by institutions from at least 2 different countries

Beneficiaries & partner organisations:

- Minimum of 3 beneficiaries from 3 different MS/AC, which are entitled to award doctoral degrees or have transferred this right to a consortium/grouping of academic/research institutions to which they belong
- Minimum of 2 beneficiaries conferring the joint, double or multiple doctoral degree from MS/AC
- Additional beneficiaries/entities with a capital or legal link from MS, AC or TC listed in General Annex A to the Main Work Programme allowed
- Partner organisations from any country allowed (for optional secondments)
- Typical size: 4-8 beneficiaries

Recruitments & secondments:

- Researchers must be enrolled in the joint doctoral programme
- Secondments of the researchers to other beneficiaries and/or partner organisations up to a maximum of 30% of the researcher's recruitment period (in addition to the requirements of the joint doctoral programme)

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: unit costs

Budget categories:

A. Costs for recruited researchers

A.1 Living allowance: EUR 3 110 per person-month (multiplied by the correction coefficient of the country in which the researcher will be recruited)

A.2 Mobility allowance: EUR 600 per person-month

A.3 Family allowance (if family at the date of recruitment): EUR 500 per person-month

B. Institutional costs

B.1 Research, training and network costs: EUR 1 800 per person-month

B.2 Management and indirect costs: EUR 1 200 per person-month

Funding rate: 100% of eligible costs

Evaluation:

Award criteria MSCA-ITN grants		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality, innovative aspects and credibility of the research programme (including inter/multidisciplinary and intersectoral and, where appropriate, gender aspects)	Enhancing the **career perspectives** and **employability** of researchers and contribution to their **skills** development	**Coherence and effectiveness of the work plan,** including appropriateness of the allocation of **tasks and resources** (including awarding of the doctoral degrees for EID and EJD projects)
Quality and innovative aspects of the training programme (including transferable skills, inter/multidisciplinary and intersectoral and, where appropriate, gender aspects)	Contribution to **structuring doctoral/early-stage research training at the European level** and to strengthening **European innovation capacity**, including the potential for: **a)** meaningful contribution of the non-academic sector to the doctoral/research training, as appropriate to the implementation mode and	**Appropriateness of the management structures and procedures**, including quality management and risk management (with a mandatory joint governing structure for EID and EJD projects)

	research field **b)** developing sustainable joint doctoral degree structures (for EJD projects only)	
Quality of the supervision (including mandatory joint supervision for EID and EJD projects)	Quality of the proposed measures to exploit and **disseminate** the project results	Appropriateness of the **infrastructure** of the participating organisations
Quality of the proposed interaction between the participating organisations	Quality of the proposed measures to **communicate** the project activities to different target audiences	**Competences, experience and complementarity of the participating organisations and their commitment to the programme**
Weighting		
50%	**30%**	**20%**
Priority in case of *ex aequo*		
1	**2**	**3**

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Weighted scoring: Each criterion (not their individual elements) is scored from 0 to 5. Scores may be given with a resolution of one decimal place. Scores are weighted. Overall threshold: 70%

Special evaluation panels:

For EID and EJD, proposals are ranked in separate multidisciplinary panels with earmarked budgets.

Consortium agreement: Yes — mandatory **Type of grant agreement:** H2020 MGA MSCA-ITN — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 MSCA-IF grants

Type of action & requirements:

General features/requirements for MSCA-IF (Individual Fellowships) grants:

- Mono-beneficiary action
- Action: fellowship to support the career development of an experienced researcher through trans-national mobility (either moving within Europe (MS & AC) or coming to Europe, after a period elsewhere)
- Maximum funding and duration of the action: 24 person-months (EF)/36 person-months (GF)
- Only for 'experienced researchers'
- Recruitment duration: 12 to 24 months (EF)/12 to 36 months (GF)
- Trans-national mobility required
- The beneficiary may use entities with a capital or legal link to it and partner organisations — to implement certain hosting and training tasks
- Sub-types: European Fellowships (EF), Global Fellowships (GF)

European Fellowships (EF)

Beneficiaries & partner organisations:

- The beneficiary must be from an EU Member State (MS) or H2020 associated country (AC)
- For EF Society and Enterprise Panel: the beneficiary must also be an entity from the non-academic sector
- Entities with a capital or legal link from MS or AC (and for EF Society and Enterprise Panel: from non-academic sector) allowed
- Partner organisations from MS or AC allowed (for optional secondments)

Recruitments & secondments:

- For EF Reintegration Panel: the researcher must be a national/long-term resident of a MS/AC
- The beneficiary must recruit the researcher
- Secondment to an organisation in MS or AC possible (up to 3 months for a fellowship of 18 months and less and up to 6 months for a fellowship of more than 18 months)

Global Fellowships (GF)

Beneficiaries & partner organisations:

- The beneficiary must be from a MS/AC
- Entities with a capital or legal link from MS or AC allowed
- Partner organisations from third country (TC) (for GF outgoing phase) or from MS or AC (for optional secondments) allowed

Recruitments & secondments

- The researcher must be a national/long-term resident of a MS/AC
- The beneficiary must recruit the researcher and host him in the return phase
- Mandatory 12-24 month secondment to a partner organisation in a TC (outgoing phase) + mandatory 12 month return phase to a beneficiary in a MS/AC
- Additional secondment to an organisation in MS or AC possible (up to 6 months)

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: unit costs

Budget categories:

A. Costs for recruited researchers

A.1 Living allowance: EUR 4 650 per person-month (multiplied by the correction coefficient of the country in which the researcher will be recruited; except in GF, where in addition the coefficient of the TC involved is applied)

A.2 Mobility allowance: EUR 600 per person-month

A.3 Family allowance (if family at call deadline): EUR 500 per person-month

B. Institutional costs

B.1 Research, training and networking costs: EUR 800 per person-month

B.2 Management and indirect costs: EUR 650 per person-month

Funding rate: 100% of eligible costs

Evaluation:

Award criteria MSCA-IF grants		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality and credibility of the research/innovation project; level of novelty, appropriate consideration of inter/multidisciplinary and gender aspects	**Enhancing the potential and future career prospects of the researcher**	Coherence and effectiveness of **the work plan**
Quality and appropriateness of the training and of the two way **transfer of knowledge** between the researcher and the host	Quality of the proposed measures to exploit and **disseminate** the project results	Appropriateness of the allocation of **tasks and resources**
Quality of the supervision and of the integration in the team/institution	Quality of the proposed measures to **communicate** the project activities to different target audiences	Appropriateness of the **management structure and procedures**, including risk management
Capacity of the researcher to reach or re-enforce a position of professional maturity /independence		Appropriateness of the **institutional environment** (infrastructure)
Weighting		
50%	**30%**	**20%**
Priority in case of *ex aequo*		
1	**2**	**3**

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Weighted scoring: Each criterion (not their individual elements) is scored from 0 to 5. Scores may be given with a resolution of one decimal place. Scores are weighted. Overall threshold: 70%

Special evaluation panels:

For EF there are:

- 'Reintegration Panel' for researchers who wish to return to Europe to reintegrate in a longer-term research position
- 'Career Restart Panel' for researchers who want to resume research in Europe after a career break (of at least 12 months) and
- 'Society & Enterprise Panel' for researchers who seek to work on research and innovation projects in an organisation from the non-academic sector (earmarked budget for this panel)

Consortium agreement: Not applicable (mono-beneficiary action)

Type of grant agreement: H2020 MGA MSCA-IF — Mono

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 MSCA-RISE grants

Type of action & requirements:

General features/requirements for MSCA-RISE (Research and Innovation Staff Exchange) grants:

- Multi-beneficiary action
- Action: joint international and inter-sectorial exchange of research and innovation staff members ('secondments') between beneficiaries (and partner organisations)
- Maximum funding: 540 person-months
- Maximum duration of the action: 48 months
- Secondments duration: 1 to 12 months
- Secondments are not subject to a mobility rule
- Beneficiaries may use partner organisations or entities with a capital or legal link to them or to the partner organisations — for seconding and hosting staff members

Beneficiaries & partner organisations:

- Minimum 3 participating organisations (beneficiaries or partner organisations) from 3 different countries
- At least 2 beneficiaries from different EU Member States (MS) or H2020 associated countries (AC)
  - if 2 beneficiaries (from 2 different EU Member States (MS) or H2020 associated countries (AC)) + 1 partner organisation (from a third country (TC)): they can all be from the same sector
  - if 3 beneficiaries (located in different MS/AC): at least 1 of them must be from the academic sector and 1 from the non-academic sector
- Additional beneficiaries/entities with a capital or legal link from MS or AC allowed
- Additional partner organisations/entities with a capital or legal link from any TC allowed.

⚠ Entities with a capital or legal link must ALSO be established in the same country as their beneficiary/partner organisation.

Secondments:

- Secondments of staff members (early-stage researchers, experienced researchers and administrative, managerial or technical staff directly involved in the research and innovation activities under the action)
  - **between** beneficiaries in different MS/AC (or entities with a capital or legal link to them and located in the same country) and between different sectors, i.e. academic and non-academic or
  - **from** a beneficiary in a MS/AC (or an entity with a capital or legal link to it and located in the same country) **to** a partner organisation in a TC (or an entity with a capital or legal link to it and located in the same country) or
  - **from** a partner organisation in a TC listed in General Annex A to the Main Work Programme (or an entity with a capital or legal link to it and located in the same country) **to** a beneficiary in a MS/AC (or an entity with a capital or legal link to it and located in the same country)

  ⚠ The following is NOT funded:
  - secondments between organisations located in TCs or within the same MS/AC
  - secondments between two organisations of the same sector located in different MS/AC
  - secondments of staff from partner organisations located in TCs not listed in General Annex A to the Main Work Programme
- Staff can be of any nationality
- Staff must be actively engaged in/linked to research and/or innovation activities at the sending institution for at least six months (full-time equivalent) before the first period of secondment
- No secondments between different entities of the same institution, including subsidiaries/spin-offs etc.
- After a secondment, the seconded staff must be reintegrated

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: unit costs

Budget categories:

A. Costs for seconded staff members

A.1 Top-up allowance: EUR 2 000 per person-month

B. Institutional costs

B.1 Research, training and network costs: EUR 1 800 per person-month

B.2 Management and indirect costs: EUR 700 per person-month

Funding rate: 100% of eligible costs

Evaluation:

Award criteria MSCA-RISE grants		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality and credibility of the research/innovation project; level of novelty and appropriate consideration of inter/multidisciplinary, intersectoral and gender aspects	**Enhancing the potential and future career perspectives of the staff members**	**Coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources
Quality and appropriateness of knowledge sharing among the participating organisations in light of the research and innovation objectives	**Developing new and lasting research collaborations, achieving transfer of knowledge** between participating organisations and contribution to improving research and innovation potential at the European and global levels	**Appropriateness of the management structures and procedures**, including quality management and risk management
Quality of the proposed interaction between the participating organisations	Quality of the proposed measures to exploit and **disseminate** the project results	**Appropriateness of the institutional environment** (hosting arrangements, infrastructure)
	Quality of the proposed measures to **communicate** the project activities to different target audiences	**Competences, experience and complementarity** of the participating organisations and **their commitment to the project**
Weighting		
50%	**30%**	**20%**
Priority in case of *ex aequo*		
1	**2**	**3**

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Weighted scoring: Each criterion (not their individual elements) is scored from 0 to 5. Scores may be given with a resolution of one decimal place. Scores are weighted. Overall threshold: 70%

Consortium agreement: Yes —mandatory

Type of grant agreement: H2020 MGA MSCA-RISE — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 MSCA-COFUND grants

Type of action & requirements:

General features/requirements for MSCA-COFUND grants:

- Mono-beneficiary action
- Action: a regional, national or international doctoral or fellowship training programme for training, mobility and career development of researchers (implemented by the beneficiary or a partner organisation)
- Only for 'early-stage researchers' (DP) or 'experienced researchers' (FP)
- Recruitment duration: minimum 3 months (for DP: should correspond to typical time needed to complete a PhD in the country; for FP: typical duration: 12 to 36 months)
- Duration of the action: 36 to 60 months
- Trans-national mobility required
- The beneficiary may use partner organisations — to implement the programme or to implement certain hosting and training tasks during secondments
- Sub-types: Doctoral programmes (DP), Fellowship programmes (FP)

Doctoral programmes (DP)

Beneficiaries & partner organisations:

- The beneficiary must be from an EU Member State (MS) or H2020 associated country (AC)
- Partner organisations from MS, AC or third country (TC) listed in General Annex A to the Main Work Programme allowed (for implementing the DP)
- Partner organisations from any country allowed (for optional secondments)
- Entities with a capital or legal link NOT allowed

Recruitments & secondments

- The beneficiary and/or partner organisations implementing the DP must recruit and host the researchers
- If the research training activity is carried out in a TC, researchers must be nationals/long-term residents of a MS or AC
- Researchers must be recruited under an employment contract/equivalent direct contract or – if legally not possible – a fixed-amount fellowship (with a lower reimbursement for the beneficiary)
- Researchers must receive minimum monthly remuneration (for employment contract/equivalent direct contract: EUR 2 597 per month; for fixed-amount fellowship: EUR 1 298,50)
- Secondments to other organisations are possible and inter-sectoral secondments (academic to non-academic or vice versa) are encouraged

Fellowship programmes (FP)

Beneficiaries & partner organisations:

- The beneficiary must be from an EU Member State (MS) or H2020 associated country (AC)
- Partner organisations from MS, AC or TC listed in General Annex A to the Main Work Programme allowed (for implementing the FP)
- Partner organisations from any country allowed (for outgoing phase of FP similar to MSCA-IF GF and for optional secondments of FP)
- Entities with a capital or legal link are NOT allowed.

Recruitments & secondments

- The beneficiary and/or partner organisations implementing the FP must recruit and host the researchers
- If the research training activity is carried out in a TC, researchers must be nationals/long-term residents of a MS or AC
- Researchers must be recruited under an employment contract/equivalent direct contract or – if legally not possible – a fixed-amount fellowship (with a lower reimbursement for the beneficiary)

- Researchers must receive minimum monthly remuneration (for employment contract/equivalent direct contract: EUR 3 675 per month; for fixed-amount fellowship: EUR 1 837,50)
- Secondments to other organisations are possible and inter-sectoral secondments (academic to non-academic or vice versa) are encouraged
- If the main part of the research training activity does not take place in a MS/AC, the return phase may not be more than 50% of the total duration of the research training activity

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: unit costs

Budget categories:

A. Costs for recruited researchers

A.1 Living allowance:

for DP: EUR 1 855 per person-month (50% of 3 710 EUR)

for FP: EUR 2 625 per person-month (50% of 5 250 EUR)

B. Institutional costs

B.1 Management costs: EUR 325 per person-month (50% of 650 EUR)

Funding rate: 50% of eligible costs

Evaluation:

Award criteria MSCA-COFUND grants		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality of the selection / recruitment process for the researchers (transparency, composition and organisation of selection committees, evaluation criteria, equal opportunities)	Enhancing the **potential and future career perspectives** of researchers; **Strengthening human resources** on regional, national or international level	**Coherence, effectiveness and appropriateness of the work plan**
Quality of the research options offered by the programme in terms of science, interdisciplinarity, intersectorality and level of transnational mobility	**Aligning practices of participating organisations with the principles set out by the EU for human resources development in research and innovation**	**Appointment conditions of researchers**
Quality of career guidance and training, including supervision arrangements, training in transferable skills	Quality of the proposed measures to exploit and **disseminate** the results	**Competence of the participant** to implement the programme
	Quality of the proposed measures to **communicate** the results to different target audiences	
Weighting		
50%	**30%**	**20%**
Priority in case of *ex aequo*		
1	**2**	**3**

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Weighted scoring: Each criterion (not their individual elements) is scored from 0 to 5. Scores may be given with a resolution of one decimal place. Scores are weighted; overall threshold: 70%

Consortium agreement: Not applicable (mono-beneficiary action)

Type of grant agreement: H2020 MGA MSCA-COFUND — Mono

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

SME Instrument Phase 1 grants

Type of action & requirements:

General features/requirements for SME Instrument Phase 1 grants:

- Mono/multi-beneficiary action
- Project: making a feasibility study for an innovation idea (i.e. a 'proof of concept' or 'business plan' for new, altered or improved product, process or service)
- Maximum funding: EUR 50 000 (lump sum)
- Duration: ca 6 months

Beneficiaries:

- Minimum 1 beneficiary from 1 EU Member State (MS) or H2020 associated country (AC), which is a for-profit SME
- Additional beneficiaries must also be for-profit SMEs from a MS/AC
- Linked third parties NOT allowed

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: lump sum (EUR 50 000)

Budget categories:

A. Costs for the feasibility study (direct and indirect costs)

Funding rate: 70% of eligible costs (calculated in a way that the lump sum is 50 000)

Evaluation:

Award criteria SME Instrument Phase 1 grants		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and credibility of the proposed methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role

Extent that the proposed work is beyond the state of the art, and demonstrates innovation potential (e.g. ground-breaking objectives, novel concepts and approaches, new products, services or business and organisational models) **Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge**	Any substantial impacts not mentioned in the work programme, that would enhance innovation capacity, create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits for society Quality of the proposed measures to: • Exploit and disseminate the project results (including management of IPR), and to manage research data where relevant	
Weighting		
1	**1,5**	**1**

Evaluation procedure:

Call with multiple cut-off dates: There is an evaluation session after each cut-off date and after the final closure date (normally within a month). For each date, the submitted proposals are grouped, reviewed and ranked together. Evaluation results are made available immediately

Weighted scoring: Each criterion is scored from 0 to 5. Scores may be given with a resolution of one decimal place. Scores are weighted. Individual thresholds for each criterion: 4/5; overall threshold: 13/15

Consortium agreement: Yes (if multi-beneficiary)

Model Grant Agreement: H2020 MGA SME Ph1 — Mono
H2020 MGA SME Ph1 — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

SME Instrument Phase 2 grants

Type of action & requirements:

General features/requirements for SME Instrument Phase 2 grants:

- Mono/multi-beneficiary action
- Project: implementing an innovation project (including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication) — based on a strategic business plan either developed through phase 1 or another means
- Participants have to ensure 'freedom to operate'

Beneficiaries:

- Minimum 1 beneficiary from 1 EU Member State (MS) or H2020 associated country (AC), which is a for-profit SME
- Additional beneficiaries/linked third parties must also be for-profit SMEs from a MS/AC

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: actual costs + unit cost (average personnel costs; SME owners; specific unit costs, if option applies) + flat–rate costs (indirect costs)

Budget categories:

A. direct personnel costs
B. direct costs of subcontracting
D. other direct costs
E. indirect costs

Funding rate: 70% of eligible costs **—** unless otherwise provided in the call

Evaluation:

Award criteria SME Instrument Phase 2 grants		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and credibility of the proposed methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role

Extent that the proposed work is beyond the state of the art, and demonstrates innovation potential (e.g. ground-breaking objectives, novel concepts and approaches, new products, services or business and organisational models) **Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge**	Any substantial impacts not mentioned in the work programme, that would enhance innovation capacity, create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits to society Quality of the proposed measures to: • Exploit and disseminate the project results (including management of IPR), and to manage research data where relevant • Communicate the project activities to different target audiences	Best value for money of subcontracts is assessed
Weighting		
1	**1,5**	**1**

Evaluation procedure:

Call with multiple cut-off dates: There is an evaluation session after each cut-off date and after the final closure date (normally within a month). For each date, the submitted proposals are grouped, reviewed and ranked together. Evaluation results are made available immediately

Weighted scoring: Each criterion is scored from 0 to 5. Scores may be given with a resolution of one decimal place. Scores are weighted. Individual thresholds for 'excellence' and 'implementation' is 3/5 and for 'impact' 4/5; overall threshold: 12/15.

Consortium agreement: Yes (if multi-beneficiary)

Model Grant Agreement: H2020 SME Ph2 — Mono
H2020 SME Ph2 — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

ERA-NET Cofund grants

Type of action & requirements:

General features/requirements for ERA-NET Cofund grants:

- Multi-beneficiary action (exceptionally mono-beneficiary action for 'sole participants')
- Project: joint call for proposals for trans-national projects (and additional joint activities) by regional/national research and innovation programmes (— implemented or funded by the beneficiaries)
- Minimum funding: normally EUR 5 million
- Duration: 5 years

Beneficiaries (composition of the consortium):

- Minimum 3 beneficiaries from 3 different EU Member States (MS) or H2020 associated countries (AC), that are research funders (programme owners or programme managers)

  'Programme owners' are typically national/regional ministries or authorities responsible for defining, financing or managing national/regional research programmes.

  'Programme managers' are typically research councils, funding agencies or other national/regional organisations that implement research programmes under the supervision of the programme owners.
- Additional beneficiaries/linked third parties or partner organisations from any country allowed, if participation justified (with EU funding, normally only if listed in General Annex A to the Main Work Programme)
- Typical size: 10-30 beneficiaries

⚠ All entities that participate in the joint call for proposals must participate as beneficiaries/linked third parties.

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: actual costs + unit cost (average personnel costs; coordination costs for additional activities)) + flat–rate costs (indirect costs)

Budget categories:

A. Direct costs related to trans-national projects

A.1 Direct costs of providing financial support to third parties implementing trans-national projects

A.2 Direct costs for the implementation of trans-national projects by the beneficiaries

A.2.1 Direct personnel costs

A.2.2 Direct costs of subcontracting

A.2.3 Other direct costs

B. Direct coordination costs for of additional activities

C. Indirect costs

Funding rate: 33%

Evaluation:

Award criteria ERA-NET Cofund grants		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and credibility of the proposed methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
Level of ambition in the collaboration and commitment of the participants in the proposed ERA-NET action to pool national resources and coordinate their national/regional research programmes	Achievement of critical mass for the funding of trans-national projects by pooling of national/regional resources and contribution to establishing and strengthening a durable cooperation between the partners and their national/regional research programmes Quality of the proposed measures to: • Exploit and disseminate the project results (including management of IPR), and to manage research data where relevant. • Communicate the project, to activities to different target audiences	

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Standard scoring: Each criterion is scored from 0 to 5. Scores are not weighted. Individual thresholds for each criterion: 3/5; overall threshold: 10/15

Consortium agreement: Yes

Type of grant agreement: H2020 MGA ERA-NET Cofund — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 PCP/PPI grants

Type of action & requirements:

General features/requirements for PCP/PPI grants:

- Multi-beneficiary action (exceptionally mono-beneficiary action for 'sole participants')
- Project: public procurement of R&D services (PCP)/innovative solutions (PPI) and related additional coordination and networking activities

  The additional activities must relate to the call for tender; they include coordination and networking activities needed to prepare, manage and follow-up the PCP/PPI procurement and other coordination and networking activities to embed the PCP/PPI into a wider set of demand side activities

Beneficiaries (composition of the consortium):

- Minimum 3 beneficiaries established in different Member States (MS) or H2020 associated countries (AC) of which 2 must be public procurers

  'Public procurers' are legal entities that are 'contracting authorities' or 'contracting entities' according to the the EU public procurement Directives. (⚠ This includes also entities that fit the definition but to which these directives do not apply, *e.g ERICs*.)
- Additional beneficiaries/linked third parties from any country allowed, if participation justified (with EU funding, normally only if listed in General Annex A to the Main Work Programme)

  Examples: *end-users, certification bodies, experts that assist the procurers in the coordination and networking activities*

⚠ All entities that participate in the joint procurement must participate as beneficiaries/linked third parties. They form the 'buyers group'. *.)*

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: actual costs + unit cost (average personnel costs; SME owners; specific unit costs, if option applies) + flat–rate costs (indirect costs)

Budget categories:

A. Direct costs of PCP/PPI subcontracting

B. Costs of related additional and networking activities

B.1 Direct personnel costs for related additional coordination and networking activities

B.2 Direct costs of subcontracting for related additional coordination and networking activities

B.3 Other direct costs for related additional coordination and networking activities

B.4 Indirect costs for related additional coordination and networking activities

B.5 Specific cost categories (if option applies)

Funding rate:

PCP: 90% — unless otherwise provided in the call

PPI: 35%— unless otherwise provided in the call

The requested costs of coordination and networking activities may NOT exceed a certain percentage of the requested grant (PCP: 30%; PPI 50%).

Evaluation:

Award criteria PCP/PPI grants		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and credibility of the proposed methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
Progress beyond the state of the art in terms of the degree of innovation needed to satisfy the procurement need	Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global procurement markets Quality of the proposed measures to: • Exploit and disseminate the project results (including management of IPR), and to manage research data where relevant • Communicate the project, to activities to different target audiences More forward-looking concerted procurement approaches that reduce fragmentation of demand for innovative solutions	

Evaluation procedure:

Standard submission and evaluation procedure: one-stage submission + one-step evaluation)

Standard scoring: Each criterion is scored from 0 to 5. Scores are not weighted. Individual thresholds for each criterion: 3/5; overall threshold: 10/15

Consortium agreement: Yes

Type of grant agreement: H2020 MGA PCP/PPI— Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

EJP Cofund grants

Type of action & requirements:

General features/requirements for EJP Cofund grants:

- Multi-beneficiary action (exceptionally mono-beneficiary action for 'sole participants')
- Project: joint programme of activities by coordinated national research and innovation programmes, ranging from research and innovation to coordination and networking activities, and including training, dissemination and financial support to third parties.
- Maximum funding: none
- Maximum duration: 72 months (typical duration: 60 months)
- Annual work plan as specific standard deliverable

Beneficiaries (composition of the consortium):

- Minimum 5 beneficiaries from 5 different EU Member States (MS) or H2020 associated countries (AC), that own or manage national research and innovation programmes ('programme owners' or 'programme managers')
- Additional beneficiaries/linked third parties from any country allowed, if participation justified (with EU funding, normally only if listed in General Annex A to the Main Work Programme)

  Examples: *entities created to coordinate or integrate transnational research efforts, grouping funding from public and private sources*

Funding:

Type of grant: reimbursement of costs grant

Forms of costs: actual costs + unit cost (average personnel costs; SME owners; specific unit costs, if option applies) + flat–rate costs (indirect costs)

Budget categories:

A. direct personnel costs
B. direct costs of subcontracting
C. direct costs of providing financial support to third parties (if option applies)
D. other direct costs
E. indirect costs
F. specific cost categories (if option applies)

Funding rate: see call (maximum 70%)

Evaluation:

Award criteria EJP Cofund		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives **Soundness of the concept, and credibility of the proposed methodology**	**The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables Appropriateness of the management structures and procedures, including risk and innovation management Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the

		project to fulfil that role
Level of ambition in the collaboration and commitment of the participants in the proposed action to pool national resources and coordinate their national/regional research programmes	Critical mass in terms of proposed overall budget, maturity and degree of integration in the proposed research area as well as consistency of proposed activities with the development of a European Joint Programme towards a joint undertaking or other permanent structure in the proposed research area Effectiveness of the proposed measures to exploit and disseminate the programme's results and to communicate the programme	.

Evaluation procedure:

Standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Standard scoring: Each criterion is scored from 0 to 5. Scores are not weighted. Individual thresholds for each criterion: 3/5; overall threshold: 10/15

Additional conditions may be foreseen in the call.

Consortium agreement: Yes

Type of grant agreement: H2020 MGA EJP Cofund — Multi

For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

H2020 framework partnerships

What is a 'framework partnership'?

A 'framework partnership' is a long-term cooperation that sets out an action plan/work programme and the terms and conditions for receiving grants to implement them.

They are typically used when Commission intends to work with its partners on a regular basis or when there is the need of recurring grants during the funding programme period.

H2020 framework partnerships are currently open to research and innovation actions (RIA), innovation actions (IA) and coordination and support actions (CSA). They are NOT open to SME Instrument, ERC, ERANET, PCP/PPI, EJP or MSC actions and NOT to operating grants (— since Horizon 2020 does not give operating grants).

Framework partnerships set out in a 'framework partnership agreement (FPA)' and implemented through 'specific agreements (SGAs)'.

Types of action & requirements:

General features/requirements for framework partnerships:

- Multi-/mono-partner
- Maximum duration: 4 years (except in duly justified cases)

  Once set, the duration can NOT be extended.
- The action plan is implemented through SGAs
- No obligation to award/apply for specific grants
- The SGAs set out the budget and details for each action
- The procedure to award/apply for specific grants is set out in the FPA
- The SGAs must be signed before the end of the FPA
- Financial validation of the partners is done at the FPA level
- Suspension of the FPA imply automatic suspension of all SGAs
- FPA can be terminated at any time, but its termination does NOT necessarily lead to the termination of the on-going SGAs

Partners

- Partners in the FPA and SGAs must be the same

  ⚠ Partners that do not want to be active in a SGA can participate as inactive 'partner not receiving funding'.

  ⚠ New partners can be added, but they must first become part of the FPA and can only then be added to the SGAs.
- The coordinator for the FPA and all SGAs must be the same
- Linked third parties must already be identified in the FPA

Funding:

The FPA has no budget; the budget and rules on funding are set out in each SGA (and depend on the type of specific grant)

Evaluation:

Award criteria Framework Partnership Agreements		
Excellence	**Impact**	**Implementation**
Clarity and pertinence of the objectives	**The extent to which the action plan of the FPA would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**	Complementarity of the partners, and balance of expertise ; Potential for long term cooperation among the partners

Evaluation procedure:

FPA: standard submission and evaluation procedure (one-stage submission + one-step evaluation)

Standard scoring: Each criterion is scored from 0 to 5. Scores are not weighted. Individual thresholds for each criterion: 3/5; overall threshold: 10/15

SGA: procedure that is foreseen in FPA + procedure that applies to the type of specific grant

Consortium agreement: Yes — unless otherwise provided in the call

⚠ The consortium agreement is normally necessary at FPA level, but — if necessary — additional consortium agreements may have to be added at SGA level

Type of grant agreement: H2020 FPA and SGA — Multi
H2020 FPA and SGA — Mono

ℹ For more information, *see Article 3 of the H2020 Specific Programme, the H2020 work programmes and the AGA — Annotated Grant Agreement on the Funding & Tenders Portal.*

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Guidance

How to draw up your H2020 coordination agreement

Version 1.1

07 January 2020

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	23.02.2015	▪ Initial version
1.1	07.01.2020	▪ Updated to VM4.0 / PP > FTP references

IMPORTANT NOTICE

This document aims to assist **applicants/beneficiaries** in **drawing up** a **coordination agreement** for projects that are funded partly by Horizon 2020 and partly by a third country or international organisation (IO) (called 'jointly funded actions' or 'joint actions').

In view of the division into two grants, such projects may be more difficult to implement.

The coordination agreement should therefore set the **framework** for a successful project implementation (i.e. settle all issues that might hamper the smooth and seamless cooperation of the different actors for the different parts of the overall project).

It should in principle be negotiated and concluded **before any work is begun**.

⚠ The work programme/call may require that proposals already include a draft coordination agreement.

The coordination agreement is a private agreement between the beneficiaries of the two actions, to set out the rights and obligations amongst themselves. (⚠ It does NOT involve the European Commission/Agency or the third country/IO.)

It should **complement** the two grant agreements and must NOT contain any provision contrary to them. It must also be consistent with the Horizon 2020 consortium agreement.

You remain **fully responsible for your coordination agreement**. This document is necessarily general and may not address your specific needs. For complex questions, you should seek professional legal advice if needed.

Other information

⚠ This document is limited to the coordination agreement for Horizon 2020 projects that are 'jointly funded actions'.

For a more general overview of how Horizon 2020 grants work, *see the Online Manual*. For detailed information, *see the H2020 AGA — Annotated Grant Agreement* on the Funding & Tenders Portal.

Horizon 2020 terms are explained in the Glossary of the Funding & Tenders Portal.

If you need help, you can also contact the Research Enquiry Service helpdesk.

1. Drawing-up the coordination agreement: Typical issues and how to solve them

A coordination agreement is not a concept defined in law. Therefore, the agreement itself must spell out all the parties' rights and obligations.

In principle, the agreement may include any arrangements you wish to make, as long as they are not contrary to the two grant agreements and the Horizon 2020 Rules for Participation Regulation No 1290/2013[1]. It must also be consistent with the Horizon 2020 consortium agreement.

Issues that typically arise include:

- **Preamble**

  The preamble sets the scene and provides the context for the agreement.

  It may refer to the two grant agreements and/or to the call(s) for proposals and should include the names of the projects (and their acronyms).

- **Parties**

  The coordination agreement must identify all parties to the agreement (i.e. all participants involved both in the EU and in the third country/IO action).

- **Definitions**

  Defining specific terms in a 'definitions' section helps to avoid misunderstandings about the extent of a particular right or obligation.

  ⚠ Use the definitions of the Horizon 2020 Model Grant Agreements wherever possible. (No need to repeat them, a simple cross-reference is sufficient).

- **Internal organisation — Coordinating the projects**

  The coordination agreement should set out the rules for coordinating the projects, i.e.:

  - set-up and ways of working of coordination bodies
  - the powers and responsibilities of these bodies
  - voting rules.

  They should also say:

  - how often meetings will be held
  - how parties should communicate and correspond with each other and the coordination bodies
  - how the projects should be followed up and supervised.

  Set-up and ways of working. The coordination agreement should specify the

[1] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

powers and responsibilities, procedures and organisation of the coordination body(ies) *(e.g. composition and decision-making methods (unanimity or majority voting, voting and veto rights etc.))*.

The coordination agreement can set up several coordination bodies (*e.g. a steering committee, liaison committee and/or management committee, each of which may be made up of a number of different sub-committees, responsible for, for example, financial, technical or legal issues)*

The agreement could also include a provision for **creating other coordinating bodies** if needed.

In practice, the main work of the coordinating bodies often consists of day-to-day management tasks and representing the actions externally. It may be useful to select o**ne or more coordinators** among parties for these tasks.

⚠ To avoid lengthy procedures, the agreement may provide for **simplified approval processes** for certain types of decision.

Follow-up and supervision. The coordination agreement should provide that the coordinating body defines, assigns and adapts the tasks to be completed, checks the progress of the work, coordinates the research teams, coordinates the preparation of the reports *(e.g. the technical and financial reports)*, advises and directs changes to the work and provides a channel for formal communication between the parties.

- **Project implementation — Division of tasks**

The coordination agreement should cover matters such as

- the tasks assigned to each party (and how the tasks are linked and interdependent)
- the project schedule
- how changes can be made to the project
- the conditions under which other persons/organisations *(e.g. linked third parties, seconded persons or subcontractors)* are brought in to the project.

Project tasks. The coordination agreement should give a complete overview of all the project tasks and how they are divided between the parties.

You can do one of the following:

- include a **cross-reference** to the technical annexes of the two grant agreements
- **add** those technical annexes and describe what the actions involve
- **repeat and describe** the main points of the technical annexes, including:
    - the preliminary technical specifications
    - the desired technical results
    - the work to be completed and

- the tasks of each party.

Project schedule. The coordination agreement should specify how the tasks will be timed and coordinated (including when, where and how the resources required will be made available).

⚠ Avoid setting rigid timelines unless you are absolutely sure these can be met. The timeline could be interpreted as a commitment to completing certain tasks by specified dates, and you could be considered in breach if a deadline is not met. Instead, include **contingency plans** for delays or missed deadlines (and ensure proper follow-up and supervision by the coordination bodies).

Changes to the project. The coordination agreement should set out rules for managing technical changes to the project.

⚠ To avoid lengthy discussions, the agreement may provide for a **procedure** for making changes to the initial specifications (in particular for small technical changes, needed to adapt to changing circumstances).

- **Project budget — Contributions — Receipts**

The coordination agreement should address issues such as:

- project budget (financial plan)
- mutual payments and common expenses incurred by more than one party
- contributions
- how to make changes to the project budget.

⚠ Any specific arrangements must NOT conflict with the general rules set out in the two grant agreements.

Common expenses. The agreement should set out how to handle expenses incurred by more than one party *(e.g. for personnel or equipment)*. It could foresee:

- reimbursable advances paid to one party, and the method of reimbursement
- use of a joint account, and the arrangements for paying in funds
- the terms of payment for such costs
- the currency in which payments are to be made
- the effect of exchange rates and charges for bank transfers
- the payment of taxes and
- interest, if any is payable or has been earned on joint funds.

Contributions. The coordination agreement should set out in detail the contributions made by each party and whether these are made in cash or in kind.

The description will vary depending on the type of contribution:

- for persons: the total number of persons involved, the names of individuals with a critical role in the actions (a full list if possible), the qualifications held by these individuals, and whether they are seconded
- for equipment and facilities: the details of the equipment and facilities, the size of buildings, the amount of equipment, and the location of facilities
- for background or other information: the plans, manuals, calculations and prototypes, together with documents relating to the intellectual property rights held (if any)
- for financial contributions : the amounts.

⚠ If the project requires the parties to **second staff** to other organisations (often abroad), it may be necessary to draw up a second agreement, specifically for the secondment. This agreement could include information relating to, for example:

- work that needs to be done before the secondment
- accommodation
- interpreters
- working hours and conditions
- remuneration, arrangements for overtime, travel expenses or allowances and benefits in kind *(e.g. a car)*
- holidays
- medical care and other social security provisions *(e.g. life insurance and pension provision)*
- intellectual property rights
- employer's liability insurance
- visas
- applicable law and dispute settlement.

- **Intellectual property rights — Using and sharing results**

The coordination agreement should set out flexible and efficient rules to encourage and support cooperation between the parties as regards intellectual property. These should:

- facilitate implementation of the project
- protect and enable the best use of the results
- ensure the results are disseminated efficiently.

The rules may include identifying and agreeing on:

- protection, dissemination and exploitation of results
- how joint ownership will be managed

- any rules on access rights.

⚠ They must NOT conflict with the rules set out in the two grant agreements.

Protection, dissemination and exploitation of results. The coordination agreement should set out rules how results will be identified, reported, protected, disseminated and exploited (including, if appropriate, the details of a joint strategy, covering for instance arrangements for co-authoring of publications and measures to ensure the visibility of EU funding).

You should put in place a process to identify valuable results and to ensure that no information is disseminated before measures have been taken to protect these results. (⚠ Note that regimes for the protection of results may vary depending on where protection is sought.)

⚠ The rules must ensure that decisions on disseminating the results take due account of the interests of all beneficiaries affected, while still allowing (at least part of) the results to be disseminated without unreasonable delay.

Joint ownership. The coordination agreement should set out arrangements for the allocation of joint ownership and its terms of exercise.

The parties should agree, in particular, to:

- the **protection regime** (*e.g. when and how to protect the intellectual property rights, and who would bear the costs of doing so, including the potential costs of enforcement*) and
- the conditions **for the dissemination and exploitation** (including for licensing to other parties), with, *e.g. specified limits and potentially provisions for profit sharing*.

⚠ Rules on joint ownership are particularly important under the EU grant agreement, where jointly produced results which cannot be separated are — by default — jointly owned by the beneficiaries and they must agree (in writing) on the terms of exercise *(see Article 26 of the H2020 General MGA*). Alternatively, joint owners may conclude separate agreements for each case of joint ownership.

Access rights (licences and user rights). The coordination agreement should set out rules on access to background and results, if this is needed either for the parties to be able to carry out the actions or to be able to exploit the results produced in the course of the actions.

- **Confidentiality obligations**

The coordination agreement should set out the conditions under which the parties may disclose or use secret or confidential information. It should typically set out:

- a definition of what constitutes confidential information
- the confidentiality obligations (including their scope and duration)
- penalties for breach of confidentiality obligations (if necessary).

- **Liability, warranties & penalties — Financial responsibility for rejection of costs, reduction of the grant, recoveries and damages**

The coordination agreement must cover each party's liability for actions or omissions in the project (and possible guarantees, indemnities and penalties).

It should, in particular, cover:

- the procedure to be followed *(e.g. for serving the party with a warning, giving them the opportunity to object to the charge or to rectify the situation within a given period)*
- liability for damage caused and the related indemnification (and possible limitations of liability, including *force majeure*)
- possible penalties for non-compliance (stipulating clearly the terms of the penalties, *e.g. the amounts, the procedure for imposing a penalty and the interest due in cases of late payment*).

- **Boilerplate provisions**

'Boilerplate provisions' are standard contractual provisions included in agreements of all kinds. They set out the basic terms of an agreement, such as:

- its start and duration (i.e. entry into force and end (including early termination))

  You should in particular specify:

  - the duration of the coordination agreement in relation to the duration of the two grant agreements
  - the conditions for automatic renewal and extension (if any)
  - grounds for early termination and their consequences *(e.g. if the grant agreements are never signed, if the grant agreements are terminated early; if there are breaches of the coordination agreement, etc.)*
- methods for resolving disputes (in court, via arbitration or via mediation)
- the procedure for amendments (and the types of changes that require one)
- contact points for any correspondence
- the law applicable to the agreement.

Boilerplate provisions can also cover:

- waivers (which allow you to give up the right to sue the other parties for breach of a particular provision, without giving up any future claims under that provision)
- severability (which allows a court to remove a provision that isn't valid, while still keeping the rest of the agreement intact)
- assignments (which refers to your ability to sell or transfer your rights under the agreement to another party)
- force majeure (which means that no party is responsible for failures or delays if these are caused by circumstances beyond its reasonable control. These usually include:

- fire
- floods
- storm
- earthquakes
- war
- terrorism
- fuel shortages
- transport embargoes.

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8197 final

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018)

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to the Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Articles 5(2) and 18(3) thereof,

Having regard to the Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020), and in particular Articles 21, 26 and 27 thereof,

Having regard to the Council Regulation on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation, and in particular Article 6(1) thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union, and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union[1] contains detailed rules regarding unit costs,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme and of the Euratom Programme complementing Horizon 2020 needs to be reflected in its design, rules, financial management and implementation,

(3) Simpler funding rules should also serve the objective of an adequate participation of small and medium-sized enterprises (SME) in Horizon 2020 and in the Euratom Programme complementing Horizon 2020,

[1] Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

(4) The use of unit costs should therefore be authorised for personnel costs of SME owners and other natural persons not receiving a salary under the Horizon 2020 Framework Programme and under the Euratom Programme complementing Horizon 2020,

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants reimbursing eligible personnel costs declared by beneficiaries on the basis of unit costs is authorised for the reimbursement of the direct personnel costs of owners of small and medium-sized enterprises who are working on the action and who do not receive a salary, and for beneficiaries that are natural persons not receiving a salary, in actions under the Horizon 2020 Framework Programme for Research and Innovation and under the Euratom Research and Training Programme (2014-2018), for the reasons and under the conditions set out in the Annex.

Article 2

This Decision is subject to the final adoption of the Regulation of the European Parliament and the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), the Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020), the Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and the Council Decision establishing the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation by the legislative authority without significant modifications.

Done at Brussels, 10.12.2013

For the Commission
Máire GEOGHEGAN-QUINN
Member of the Commission

EN

ANNEX

1. Forms of grants and categories of costs covered

In accordance with Article 26 of the Regulation laying down the rules for participation and dissemination in Horizon 2020; '*owners of small and medium-sized enterprises who do not receive a salary and other natural persons who do not receive a salary may charge personnel costs on the basis of a unit cost*.'

Consequently, the grants under the Horizon 2020 Framework Programme and under the Euratom Programme complementing Horizon 2020 shall take the form of reimbursement on the basis of a unit cost declared by beneficiaries for either of the following categories of eligible costs:

(a) the eligible direct personnel costs of their owners, if the beneficiaries are small and medium-sized enterprises and their owners do not receive a salary;

(b) Their eligible direct personnel costs, if the beneficiaries are natural persons and they do not receive a salary.

Other eligible personnel costs for SMEs and other categories of eligible costs shall be reimbursed on the basis of eligible costs actually incurred or on the basis of unit costs, lump sums or flat-rate financing, or on the basis of a combination of those forms.

The unit cost to be declared by the beneficiaries shall be calculated in accordance with the method described in Section 3.

Personnel costs of SME owners of beneficiaries and personnel costs of beneficiaries that are natural persons not receiving a salary shall be eligible if they correspond to the amount per unit set out in in the estimated budget of the action (Annex 2 to the grant agreement) multiplied by the number of actual hours worked on the action.

2. Justification

2.1. Nature of the supported actions

Based on the simplification plan released by the European Commission in April 2010, the Commission is committed to put into place simplification measures to make the EU Research and Innovation Framework Programmes more attractive and more accessible to the best researchers and the most innovative companies, especially small and medium-sized enterprises (hereinafter referred to as SMEs).

Where SMEs and natural persons participate as beneficiaries in EU or Euratom research or innovation actions and perform tasks in accordance with the grant agreement, they – or for SMEs – their owners should be receive support for the work carried out, even if the value of the work is not registered as a cost in their accounts.

The funding on the basis of a unit cost is justified due to the difficulty to support SME owners who do not receive a salary and other natural persons who do not receive a salary for their personal involvement in the implemention of the actions. This difficulty is due to the fact that, in the absence of a salary, there is no actual cost recorded in the accounts of the beneficiary related to the work of these persons.

Therefore, in its Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 29 April 2010 entitled "Simplifying the implementation of the research framework programmes"[1], the Commission put forward simplification measures concerning, in particular, the use of scale-of-unit costs to determine the value of the work carried out in the Seventh Framework Programmes (FP7) by SME owners and other natural persons not receiving a salary.

Following this Communication the Commission adopted its Decision C(2011) 174 on three measures for simplifying the implementation of Decision No 1982/2006/EC of the European Parliament and of the Council and Council Decision No 970/2006/Euratom and amending Decisions C(2007) 1509 and C(2007) 1625, which establishes that under FP7 the European Union (hereinafter referred to as EU) financial contribution related to the own personal work of owners of SMEs who do not receive a salary and other natural persons who do not receive a salary shall be based on unit costs.

In line with Article 124(5) of Regulation (EC, Euratom) No 966/2012, and as part of the simplification measures proposed for Horizon 2020, its rules for participation and dissemination provide for the possibility of using a unit cost for the financing of the work of SME owners who do not receive a salary and other natural persons who do not receive a salary carried out in EU- and Euratom-funded research and innovation actions.

The EU and Euratom contribution related to the work of SME owners who do not receive a salary and other natural persons who do not receive a salary shall take the form of a unit cost in all grants for actions awarded under the Horizon 2020 Framework Programme, and the Euratom Research and Training Programme (2014-2018), in which direct personnel costs may be reimbursed as actual costs.

By doing so, the Commission aims at making more attractive and more accessible to the most innovative SMEs the EU and Euratom Research and Innovation Programmes.

2.2. Risks of irregularities and fraud and costs of control

The use of a unit cost to calculate the direct personnel costs for SME owners and other natural persons who do not receive a salary shall reduce the risk of irregularities, overstatements and fraud since they will be calculated in accordance with an established formula based on the Marie Skłodowska-Curie rates which has been proved very resistant to irregularities and fraud.

[1] COM(2010) 187 final.

The Commission will verify at the time of preparation of the grant, during the implementation of the action or afterwards (through checks, reviews or audits), compliance with the conditions to charge the unit cost, as well as the correct application of the formula.

3. Method to determine and update the amounts and amounts

Under FP7, the model grant agreements were modified to allow for the declaration of direct personnel costs for SME owners who do not receive a salary and other natural persons who do not receive a salary on the basis of unit costs corresponding to those applicable under the Marie Curie actions.

The use of Marie Curie unit costs (living allowances) has proved appropriate to achieve the policy objective of ensuring proper participation of SMEs in EU and Euratom research and innovation programmes and to guarantee the principle of equal treatment of beneficiaries.

This system shall thus be maintained under Horizon 2020 and the Euratom programme complementing Horizon 2020. To further simplify it, the unit cost for a reference category of researcher shall be used, i.e. experienced researchers under the Individual Fellowship (IF) actions, as calculated according to and specified in Commission Decision C(2013)8194 authorising the reimbursement on the basis of unit costs under Marie Skłodowska-Curie actions within the Horizon 2020 Framework Programme (2014-2020). The Commission decision provides for the application of a country-specific correction coefficient.

The unit cost for SME owners and other natural persons not receiving a salary shall be updated in accordance with the method specified in Commission Decision C(2013)8194.

The eligible direct personnel costs declared by beneficiaries that are SMEs for their owners not receiving a salary and by beneficiaries that are natural persons not receiving a salary shall be based on a unit cost per hour worked on the action to be calculated as follows:

{Monthly living allowance for experienced researchers under the IF actions calculated according to Commission Decision C(2013)8194 (including the country-specific correction coefficient) / 143 hours}

The value of the work of the SME owners and natural persons not receiving a salary shall be determined by multiplying the unit cost by the number of actual hours worked on the action.
The standard number of annual productive hours per SME owner and natural person is equal to 1 720 hours. The total number of hours declared, in a year, in EU and Euratom grants for one SME owner or natural person not receiving a salary may not be higher than the standard number of annual productive hours (1 720 hours).

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by the Financial Regulation.

Verification of compliance with those principles for the funding on the basis of unit costs of the work carried out by SME owners and other natural persons not receiving a salary is limited, since the value of their work are not personnel costs borne by the beneficiaries.

This exception is foreseen by Article 124(5) of Regulation (EC, Euratom) No 966/2012 and Article 26 of the Regulation laying down the rules for participation and dissemination in Horizon 2020.

However, the usual conditions for ensuring that the no-profit, co-financing and absence of double funding principles are complied with also apply to the unit costs to be declared for the work of SME owners and other natural personnel not receiving a salary:

- The number of units (researchers hours worked in the project) are identifiable and verifiable, and should be in particular supported by records and documentation;
- The unit cost covers only part of the eligible costs;
- The reimbursement rates mentioned in Article 22 of the Regulation laying down the rules for participation and dissemination in Horizon 2020 shall apply to the unit costs;
- Double funding is avoided by the specification/identification of the eligible costs.

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8199 final

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Articles 5(2)(a) thereof,

Having regard to the Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Articles 21, 24 and 27 thereof,

Having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union, and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union[2] contains detailed rules regarding unit costs,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be fully reflected in its design, rules, financial management and implementation,

(3) The Research Infrastructures Part of the Horizon 2020 Framework Programme, supports the provision to researchers of trans-national access to the research infrastructures they need for their research work,

(4) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of unit costs can simplify the calculation of reimbursement of these access costs, significantly decrease the workload of both the beneficiaries and the Commission as well as accelerate payment procedures,

(5) The use of unit costs should therefore be authorised for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme,

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[1] OJ L […], [date], p. […].

[2] Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants for reimbursement of eligible costs declared by beneficiaries on the basis of unit costs is authorised for the actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme, for the reasons and under the conditions set out in the Annex.

Article 2

This Decision is subject to the final adoption of the Regulation of the European Parliament and the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), the Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and the Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) by the legislative authority without significant modifications.

Done at Brussels, 10.12.2013

For the Commission
Máire GEOGHEGAN-QUINN
Member of the Commission

EN

ANNEX

1. Forms of grants and categories of costs covered

The grants under the Research Infrastructures Part of the Horizon 2020 Framework Programme shall take the form of reimbursement of either of the following eligible costs for trans-national access to research infrastructures:

(i) costs declared by beneficiaries on the basis of unit costs calculated on the basis of their historical data, or

(ii) costs actually and solely incurred for providing access to the *user groups* selected for support under the action, or

(iii) costs declared by beneficiaries on the basis of a combination of the forms of costs referred to in points (i) and (ii), if part of the eligible access costs, in particular eligible costs for the specific support to users, varies significantly between users.

Only one of the forms referred to in points (i), (ii) and (iii) may be used for one *installation*. No alternative use is allowed for one *installation.*

The categories of eligible costs covered by the unit costs referred to in point (i) are the eligible *access costs* as defined below, including direct and indirect costs:

- Direct costs for providing access to the *installation*:

  - Personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users.
  - Costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised).
  - Costs of consumables specifically used for the installation and the research work of the users.
  - Costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation.
  - Costs of energy power and water supplied for the installation.
  - Costs of general services when they are specifically included in the provided access services (library costs, shipping costs).
  - Costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services.
  - Costs of specific scientific services included in the access provided or needed for the provision of access.

- Indirect costs for providing access to the *installation*,

but excluding:

- All contributions to the capital investments of the infrastructure (including rental, lease or depreciation costs of buildings as well as depreciation and lease of instrumentation). Those costs are not eligible for the provision of access under the Research Infrastructures Part of the Horizon 2020 Framework Programme,
- Travel and subsistence costs to support the visits of users. Those costs shall be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs".

For that purpose, the following definitions shall apply:

(1) "installation" means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

(2) "access provider" means a beneficiary or a linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as specified in Annex I to the grant agreement.

(3) "user group" means a research team of one or more researchers to whom access to the installation is given under the action.

(4) "selected user" means a researcher within a user group.

(5) "access costs" are the costs incurred by the access provider for the provision of access. Access Costs cover the running costs of the *installation* and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the *installation* and for preparatory and closing activities that may be necessary to carry out user's work on the *installation*. Travel and subsistence costs incurred for supporting the visits of the *selected users* to the *installation* are not included in the *access costs*.

Other categories of eligible costs shall be reimbursed on the basis of eligible costs actually incurred or, for other direct personnel costs, on the basis of other unit costs or, for indirect costs, flat-rate financing**.**

The unit cost shall be calculated by beneficiaries in accordance with the method set out in Section 3 and shall be specified in the grant agreement to be used throughout the duration of the action. In exceptional and duly justified cases, it can be updated (with the agreement of the Commission and in accordance with the method in Section 3) through an amendment.

Costs for providing trans-national access to research infrastructures declared by beneficiaries on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in Annex 2 to the grant agreement multiplied by the number of actual units of access provided under the action and if the conditions set out in Article 16.1.1 of the grant agreement are met.

2. Justification

2.1. Nature of the supported actions

One of the most successful activities funded under the Research Infrastructures Part of the previous Research Framework Programmes is the provision, to selected *user groups*, of trans-national access to the best research infrastructures they need for their research work. The *user groups* are selected, under the actions funded by the Union, on the basis of the excellence of the proposed *user group*'s research projects.

The Union contribution mainly reimburses to the *access providers*, both the *access costs* for providing trans-national access to the selected *user groups* and the costs incurred for supporting the visits (travel and subsistence) of the *selected users* to the *installation*.

As some components of the *access costs* to the *installation* are caused only in part by the activities of the action (e.g. the running costs of the *installation*) it is not always possible to directly identify the specific *access costs* related to the provision of access to the *user groups* selected under the EU grant. A method to measure the use of the *installation* by the action must be defined to calculate the part of the *access costs* that can be attributed to the action for the trans-national access it provides. This method is given in Section 3.

In addition, in some cases, the access costs for the specific support to users may vary significantly between users. Those eligible costs could therefore be more effectively managed by separating them from the unit cost determined on the basis of averages. The eligible costs for trans-national access to a specific *installation* would in those cases be declared on the basis of unit costs covering only the categories of costs that are stable among all users and as actually incurred for the other categories of eligible access costs.

2.2. Risks of irregularities and fraud and costs of control

Section 1 defines the cost items to be used for the calculation of the unit cost. Moreover, capital investment of the research infrastructures will be explicitly excluded from the calculation of the unit cost and from the eligible *access costs* in general. This will minimise the risk of fraud as well as the risk that the Union contribution overpasses the eligible costs actually incurred for providing access to the *selected users*.

In addition, the infrastructures supported under the Research Infrastructures Part are usually owned and operated by large public research organisations which have their financial statements regularly analysed and certified by external or public auditors. The historical data can therefore be considered reliable.

When trans-national *access costs* are reimbursed on the basis of unit cost, the *access costs* to be charged to the grant will be easily identified by multiplying the unit cost by the number of units of access provided to the selected *user groups*. The costs of ex-post control will be minor as only records of access provisions must be verified as well as, in order to avoid double funding, the non-existence of other Union funding sources specifically covering the trans-national access and the travel and subsistence costs for the visits of *users* supported under the Horizon 2020 grant.

The use of a simplified method to support trans-national *access costs* therefore appears appropriate.

3. Method to determine and update the unit of cost

In order to measure the quantity of trans-national access to the *installation* supported under the Union grant the *access provider* will identify a unit of access to the *installation*. This unit of access shall also be used to measure the total quantity of access that the *installation* provides to all its users.

When eligible trans-national *access costs* for an *installation* are reimbursed on the basis of unit costs (only unit costs under point 1(i) or in combination with actual costs under point 1(iii)), the unit cost of a unit of access to the *installation* shall be agreed between the Commission and the *access provider.*

The unit cost shall be specified in the grant agreement and shall be defined on the basis of the average over the last two years[1] of the annual total *access costs* to the *installation*, for the categories covered by the unit cost, divided by the average over the last two years[2] of the total quantity of access to the *installation* annually provided, as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total } \textit{access costs} \textbf{ to the } \textit{installation}}{\textbf{average total quantity of access to the } \textit{installation} \textbf{ annually provided}}$$

The average amounts shall be based on certified or auditable historical data of the beneficiary (or the linked third party) over the last 2 years (years N-1 and N-2)[3] and allocated to the concerned *installation* according to the beneficiary's usual cost accounting practices. The average over the last two years of the *access costs* and quantity of access to the *installation* shall not include periods where the *installation* was not usable because out of order, or under repair or maintenance.

3.1 Calculation of the unit cost

The 'total quantity of access to the *installation*' shall include all the units of access annually provided by the installation, included access financed by the Union under previous grant agreements, if any.

The 'total *access costs* to the *installation*' shall be:

- the direct costs incurred by the beneficiary (or the linked third party) for the provision of access to the *installation*, as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2)[4] for the concerned categories of direct costs.

  By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices.

  If eligible costs for access to an *installation* are declared by beneficiaries exclusively on the basis of unit costs (point 1(i)), costs for all the categories of eligible direct costs referred to in Section 1 may be taken into account.

  If eligible costs for access to an *installation* are declared by beneficiaries as a combination of unit costs and of costs actually incurred (point 1(iii)), only costs for the eligible categories of direct costs referred to in Section 1 that are not reimbursed on an actual cost basis may be taken into account.

- the eligible indirect costs for the access to the *installation*, equal to 25% of the direct costs referred to above (amounts for the categories taken into account in the unit costs, i.e. excluding the categories reimbursed on an actual cost basis) minus any costs of subcontracting (amounts referred to above for the categories "costs of contracts for maintenance and repair", "costs of contracts for installation management", "costs of scientific services" and "cost for other electronic services").

The *access costs* to the *installation* shall exclude all contributions to the capital investments of the infrastructure as well as travel and subsistence costs to support the visits of users (see Section 1).

[1] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[2] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[3] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[4] Unless exceptionally agreed otherwise by the Commission

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by Regulation (EC, Euratom) No 966/2012.

Provision of trans-national access under the Research Infrastructures grants is not expected to generate revenue or to be specifically funded by third donors. The unit cost should not exceed the actual eligible costs as its calculation is based on the certified or auditable historical costs incurred to provide access. In addition, the exclusion of capital investment from the calculation of the unit cost will ensure that access providers contribute with their own resources to the support of *users-groups* selected under the grants, thus complying with the co-financing and no-profit principles.

Double funding is avoided by the specification/identification of eligible costs detailed in Section 1. Compliance with the specification method of eligible costs is checked through controls during the proposal evaluation phase, on the application of the methodology for the calculation of the unit cost, as well as through ex-post controls on the existence of other Union funding sources specifically covering the trans-national access and travel and subsistence costs of *users* supported under the Union grant.

Finally, the costs of building the infrastructure may have been supported by the Union. The risk of double funding is minimised by the ineligibility of depreciation costs (and of all capitalised costs) for the provision trans-national access under the Research Infrastructures Part.

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8196 final

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Article 5(2)(c) thereof,

Having regard to the Regulation (EU) No 1290/2013 of 11.12.2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Articles 21, 24 and 27 thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[2], and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012[3] contains detailed rules regarding lump sums, unit costs and flat-rate financing.

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be fully reflected in its design, rules, financial management and implementation.

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of unit costs is necessary to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures.

(4) It is necessary to use Union funding to promote innovative energy efficient activities in buildings going beyond the national energy targets.

(5) The use of unit costs should therefore be authorised for actions on energy efficiency measures in buildings under the Energy Challenge of the Horizon 2020 Framework Programme,

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1 OJ L 347, 201.12.2013, p.1

2 OJ L 298, 26.10.2012, p. 1.

3 Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants for reimbursement of eligible costs declared by beneficiaries on the basis of unit costs is authorised for the actions on energy efficiency measures in buildings under the Energy Challenge actions of the Horizon 2020 Framework Programme, for the reasons and under the conditions set out in the Annex.

Article 2

This Decision is subject to the final adoption of the Regulation of the European Parliament and the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), the Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and the Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) by the legislative authority without significant modifications.

Done at Brussels,

For the Commission
Member of the Commission

Brussels, 10.12.2013

C(2013) 8196 final

ANNEX

ANNEX

1. Forms of grants and categories of costs covered

The grants for the Energy challenge actions within the Horizon 2020 Framework Programme shall take the form of reimbursement of eligible costs for the demonstration of additional energy efficiency measures in buildings declared by beneficiaries on the basis of unit costs.

The following shall be considered "additional energy efficiency measures":

(a) for new buildings: those measures which are implemented to make the building more energy efficient than would have been required under the applicable national legislation;

(b) for refurbished buildings: those measures which are implemented to make the building more energy efficient than would have been required under the applicable national legislation or than would have been the case for the refurbishment of such a building using current practices if there is no national regulation applicable.

The categories of eligible costs covered by the unit costs are the following:

– Costs of purchasing equipment, infrastructures and other assets directly necessary for the demonstration of additional energy efficiency measures in buildings (e.g. costs of purchasing elements to build or refurbish buildings such as new isolation, new ventilation system, windows, doors, heating elements, system controlling the system);

– Costs of subcontracting the works necessary for the demonstration of additional energy efficiency measures in buildings.

Indirect costs for the demonstration of additional energy efficiency measures in buildings are not eligible (the 25% flat-rate financing shall not apply to the eligible costs declared on the basis of unit costs for additional energy efficiency measures in buildings). Fluids are not eligible either.

Other categories of eligible costs shall be reimbursed on the basis of eligible costs actually incurred or, for direct personnel costs, on the basis of unit costs or, for indirect costs, flat-rate financing.

The amounts of the unit costs to be declared by the beneficiaries shall be calculated in accordance with the method described in Section 3.

2. Justification

2.1. Nature of the supported actions

Substantial energy savings in buildings can derive from simultaneous interventions on all the building components where energy can be saved. National regulations on buildings define the minimum specifications these components must meet.

Demonstration projects including energy efficient buildings, in order to be eligible for Community funding, must adopt measures going beyond the national regulations or beyond the market practice if there is no national regulation applicable (e.g. for refurbishment of buildings).

Community funding has to be based on those costs directly related to "additional energy efficiency measures".

Innovation is a prerequisite for Horizon 2020 projects. The innovation in buildings may be linked either to the integration of the different technologies, components or systems and/or to the improvements in the individual technologies which are to be demonstrated in the projects.

The difficulty of using actual cost

The following aspects make it practically impossible to determine the eligible costs on the basis of actual costs per construction item:

(a) one and the same building components may function differently, depending on the way it is incorporated and interacts with other components in the building; most of the time innovation is not linked to a single specific building component but to the interacting effects of design, installation and management of all those building components, including non-technological measures. Consequently, energy efficiency in buildings is not related to the actual cost of individual building components but to the way these components are used in a given context;

(b) a critical mass of interventions in buildings is often necessary (e.g. the Horizon 2020 Smart Cities and Communities projects) for the full-size demonstration that has an impact and is visible at a European level; in a Smart Cities and Communities project, a large number of buildings, forming a district or a whole city containing a high number of flats/offices, is affected in each one of the communities participating in the projects; in such situations the control of the performance has to be established with the help of global certification (based on surface built and building specifications);

(c) not all demonstration buildings, even in the same community, have the same characteristics, or are built or refurbished using the same specifications; in combination with the large number of buildings involved, it is practically impossible to audit and verify specific components of each building separately;

(d) there are constraints set by the accounting systems of the beneficiaries which do not allow differentiation between innovative elements and regular building costs. Instead the buildings are depreciated as one entity over several decades.

Conversely, statistical data (reference study period: 30 years, dated 10.2013, sources: DFIU, EE, ÖÖW) are available on the price to be paid for the refurbishment of a building to save 1 kWh, which is the standard output of the actions to be supported under the Energy Challenge within the Horizon 2020 Framework Programme (for the means of verification of the outputs, see Section 2.2).

2.2. Risks of irregularities and fraud and costs of control

The unit cost in building-related research projects has been used by the Commission in the Sixth and Seventh framework programmes (Concerto projects, in parts of the Public Private Partnership for Energy Efficient Buildings projects and the Smart Cities and Communities projects).

Past experience shows that this significantly simplifies the management of the projects for contractors and the carrying out of controls.

The specifications per type demonstration building are set out in the technical annex of the grant agreements (Annex 1). For the calculation of the Union contributions, the periodic reports are a prerequisite for any payment based on unit costs. Those reports shall be accompanied by 'handover certificate' certifying the actual specifications of the buildings constructed or refurbished, their surface area and address. The certificate is signed by a competent person from the consortium.

Given the specificity of the buildings where many of its components are hidden (e.g. insulation materials) and given the large building numbers and surface areas concerned in the demonstration projects, extensive technical audits on site would prove very costly and practically impossible.

The use of unit cost in this type of projects has a small extra cost, mainly related to the preparation of the 'handover certificates' by the contractors and their checking against the specifications provided by the Commission.

3. Method to determine the amounts

The unit cost applicable to the demonstration of actions involving energy efficient buildings related projects under Horizon 2020 shall:

– apply per m² of eligible conditioned gross floor area (excluding parts of the buildings which are not affected by the measures, e.g. garages);

– be calculated according to the following formula:

{standard cost in EUR to save 1 kWh * estimated total kWh saved per m² per year * standard payback period in years}

with:

- the standard cost to save 1 kWh being EUR 0.1, in accordance with the statistical data (reference study period: 30 years, dated 10.2013, sources: DFIU, EE, ÖÖW);
- the estimated total kWh saved per m² per year being determined at proposal level, using the model table established by the Commission and supported by detailed information on the interventions to be made to the building envelope. It shall be determined with reference to the estimated value of the energy which the additional energy efficiency measures will save. The estimated value of the energy saved shall be determined on the basis of the estimated reduction in the overall energy demand of the building, calculated on the basis of the "additional energy efficiency proposed measures" over a period of a maximum of 10 years. The above estimated value of the energy saved due to the "additional energy efficiency measures" shall be divided by the surface area of the building;
- the standard payback period for the investment (eligible costs) related to energy efficient measures being 10 years. According to statistical information on the payback periods of building projects supported by the Commission, the average payback period is 30 years. However, the use of a standard period of 10 years enables to cover most of the buildings and limits the risks that the grant exceeds the net costs of investment over the standard payback period.

The amount of the unit cost per eligible m² for the demonstration of additional energy efficiency measures in buildings under Horizon 2020 shall thus be:

EUR { estimated total kWh saved per m² per year }

This amount per eligible m² shall apply for the full duration of Horizon 2020, unless it does not prove appropriate anymore. In such a case, it will be adjusted by a new Commission decision.

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by the Financial Regulation.

The implementation of additional energy efficiency measures in buildings is not expected to generate revenue (only to save costs) or to be specifically funded by third donors. In addition, the unit cost should not exceed – on average - the actual eligible costs as its calculation is based on the low range for averages obtained statistically.

The co-financing principle will be complied with by application of the reimbursement rate applicable to Energy Challenge actions, as well as the ineligibility of certain cost items (e.g. costs of fluids, indirect costs for the demonstration of the energy efficiency measures in buildings).

Double funding is avoided by the specification/identification of eligible costs detailed in Section 1. Compliance with the specification method of eligible costs is checked through controls, during the proposal evaluation phase as well as through ex-post controls on the existence of other Union funding sources specifically covering the demonstration of the same additional energy efficiency measures in buildings.

DECISION authorising the use of unit costs for the actions involving virtual access under the Research Infrastructures Part of the Horizon 2020 Framework Programme

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)[1], and in particular Articles 5(2)(a) thereof,

Having regard to the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)"[2], and in particular Articles 25 and 33 thereof,

Having regard to the Regulation (EU, Euratom) No 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union[3], and in particular Articles 125 and 181 thereof,

Whereas:

(1) Article 181 of Regulation (EU, Euratom) No 2018/1046 contains detailed rules regarding unit costs,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be fully reflected in its design, rules, financial management and implementation,

(3) The Research Infrastructures Part of the Horizon 2020 Framework Programme, supports the provision to researchers of virtual access to the research infrastructures they need for their research work,

(4) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of unit costs can simplify the calculation of reimbursement of these access costs, significantly decrease the workload of both the beneficiaries and the Commission as well as accelerate payment procedures,

(5) The use of unit costs should therefore be authorised for actions involving virtual access under the Research Infrastructures Part of the Horizon 2020 Framework Programme,

THE FOLLOWING HAS BEEN DECIDED:

Sole Article

The use of eligible costs declared by recipients of Union funds on the basis of unit costs is authorised for the actions involving virtual access under the Research Infrastructures Part of the Horizon 2020 Framework Programme, for the reasons and under the conditions set out in the Annex.

[1] OJ L 347 of 20.12.2013, p.104
[2] OJ L 347 of 20.12.2013, p. 81
[3] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p.1).

Done at Brussels,

(e-Signed)

Jean-Eric Paquet
Director General of DG RTD

Roberto Viola
Director General of DG CONNECT

Annex

1. Form[s] of Union contribution and categories of costs covered

The grants under the Research Infrastructures Part of the Horizon 2020 Framework Programme shall take the form of reimbursement of either of the following eligible costs for virtual access to research infrastructures:

(i) costs declared by beneficiaries on the basis of unit costs calculated on the basis of their historical data, or

(ii) costs actually and solely incurred for providing virtual access to *users* under the action, or

(iii) costs declared by beneficiaries on the basis of a combination of the forms of costs referred to in points (i) and ii), if part of the eligible access costs varies significantly and cannot be represented by its average.

Only one of the forms referred to in points (i), (ii) and (iii) may be used for one *installation* under the action. No alternative use is allowed for one *installation*.

The categories of eligible costs covered by the unit costs referred to in point (i) are the eligible *virtual access costs* as defined below, including direct and indirect costs:

- Direct costs for providing virtual access to the *installation*:
  - Personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the *installation* and to the support of the *users*.
  - Costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the *installation* (if not capitalised).
  - Costs of consumables specifically used for the *installation*.
  - Costs of contracts for *installation* management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the *installation*.
  - Costs of energy power and water supplied specifically for the *installation*.
  - Costs of software licence, internet connection or other electronic services for data management and computing supplied specifically for the *installation* when they are needed to provide virtual access services.
  - Costs of specific scientific services included in the access provided or needed for the provision of virtual access by the *installation*.
- Indirect costs for providing access to the *installation* equal to 25% of the direct costs referred to above,

but excluding:

- All contributions to the capital investments of the infrastructure (including rental, lease or depreciation costs of buildings as well as depreciation and lease of instrumentation). Those costs are not eligible for the provision of virtual access under the Research Infrastructures Part of the Horizon 2020 Framework Programme unless otherwise specified in the Work Programme, in which case only the portion used to provide virtual access under the action can be eligible;
- All ineligible costs as referred to in the Art 6.5 of the H2020 MGA.

For that purpose, the following definitions shall apply:

(1) "installation" means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

(2) "access provider" means a beneficiary or a third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as specified in Annex I to the grant agreement.

(3) "user" means a researcher or any other stakeholder that meets the eligibility conditions established by the research infrastructure, to whom virtual access to the installation is provided under the action.

(4) "virtual access costs" are the costs incurred by the *access provider* for the provision of virtual access. Virtual Access Costs cover the running costs of the *installation* and the costs for logistical, technological and scientific support to *users*' access, including costs for preparatory and closing activities that may be necessary to provide the requested services.

Other categories of eligible costs shall be reimbursed on the basis of eligible costs actually incurred or, for other direct personnel costs, on the basis of other unit costs or, for indirect costs, flat-rate financing**.**

The unit cost shall be calculated by beneficiaries in accordance with the method set out in Section 3 and shall be specified in the grant agreement to be used throughout the duration of the action. In duly justified cases, in particular when there are significant variations in the costs for providing access, it can be updated (with the agreement of the Commission and in accordance with the method in Section 3) through an amendment.

Costs for providing virtual access to research infrastructures declared by beneficiaries on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in Annex 2 to the grant agreement multiplied by the number of actual units of virtual access provided under the action and if the conditions set out in Article 16.2 of the grant agreement are met.

2. Justification

2.1. Nature of the supported actions

A successful activity funded under the Research Infrastructures Part of the previous Research Framework Programmes is the provision to researchers of virtual access to the best digital resources they need for their research work.

The Union contribution reimburses to the *access providers* the *access costs* for providing virtual access under the grant.

As some components of the *virtual access costs* to the *installation* are caused only in part by the activities of the action (e.g. the running costs of the *installation*) it is not always possible to directly identify the specific *virtual access costs* related to the provision of virtual access under the EU grant. A method to measure the use of the *installation* by the action must be defined to calculate the part of the *virtual access costs* that can be attributed to the action for the virtual access it provides. This method is given in Section 3.

In addition, in some cases, part of the access costs for providing access to a same digital resource may vary significantly according to the request. Those eligible costs could therefore be more effectively managed by separating them from the unit cost determined on the basis of averages. The eligible costs for virtual access to a specific *installation* would in those cases be declared on the basis of unit costs covering only the categories of costs that are stable for all the requests of access and as actually incurred for the other categories of eligible access costs.

2.2. Risks of irregularities and fraud and costs of control

Section 1 defines the cost items to be used for the calculation of the unit cost. Moreover, unless otherwise specified in the Work Programme, capital investment of the research infrastructures will be explicitly excluded from the calculation of the unit cost and from the eligible *virtual access costs* in general. This will minimise the risk of fraud as well as the risk that the Union contribution overpasses the eligible costs actually incurred for providing virtual access under the action.

In addition, the infrastructures supported under the Research Infrastructures Part of the Horizon 2020 Framework Programme, are mostly owned and operated by large public research organisations which have their financial statements regularly analysed and certified by external or public auditors. The historical data can therefore be considered reliable.

When *virtual access costs* are reimbursed on the basis of unit cost, the *virtual access costs* to be charged to the grant will be easily identified by multiplying the unit cost by the number of units of access provided under the action. The costs of ex-post control will be minor as only records of access provisions must be verified as well as, in order to avoid double funding, the non-existence of other Union funding sources specifically covering the virtual access provided under the Horizon 2020 action.

The use of a simplified method to support *virtual access costs* therefore appears appropriate.

3. Method to determine and update the unit of cost

In order to measure the quantity of virtual access to the installation supported under the Union grant the *access provider* will identify a unit of access to the installation. This unit of access shall also be used to measure the total quantity of access that the installation provides to all its *users*.

When eligible *virtual access costs* for an installation are reimbursed on the basis of unit costs (only unit costs under point 1(i) or in combination with actual costs under point 1(iii)), the unit cost of a unit of access to the installation shall be agreed between the Commission and the *access provider*.

The unit cost shall be specified in the grant agreement and shall be defined on the basis of the total cost over the last year[4] for *virtual access costs* to the installation, for the categories covered by the unit cost, divided by the total quantity of access to the installation provided over the last year[5], as follows:

$$\textbf{Unit cost} = \frac{\textbf{total } \textit{virtual access costs} \textbf{ to the } \textit{installation} \textbf{ over the last year}}{\textbf{total quantity of virtual access to the } \textit{installation} \textbf{ provided over the last year}}$$

[4] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[5] In exceptional and duly justified cases, the Commission may agree to use a different reference period.

The use of the last year as the reference period to determine the unit cost instead of an average of more than one year is justified by the fast evolving nature of the technologies underlying the *installations*.

The total *virtual access costs* shall be based on certified or auditable historical data of the beneficiary (or the linked third party) over the last year (year N-1)[6] and allocated to the concerned *installation* according to the beneficiary's usual cost accounting practices. The calculation over the last year of the *access costs* and quantity of access to the *installation* shall not include periods where the *installation* was not usable because out of order, or under repair or maintenance.

3.1 Calculation of the unit cost

The 'total quantity of virtual access to the *installation*' shall include all the units of access annually provided by the installation, included access financed by the Union under previous grant agreements, if any.

The 'total *virtual access costs* to the *installation*' shall be:

- the direct costs incurred by the *access provider* for the provision of access to the *installation*, as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1)[7] for the concerned categories of direct costs.

  By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices.

  If eligible costs for access to an *installation* are declared by *access provider*s exclusively on the basis of unit costs (point 1(i)), costs for all the categories of eligible direct costs referred to in Section 1 may be taken into account.

  If eligible costs for access to an *installation* are declared by *access provider*s as a combination of unit costs and of costs actually incurred (point 1(iii)), only costs for the eligible categories of direct costs referred to in Section 1 that are not reimbursed on an actual cost basis may be taken into account.

- the eligible indirect costs for the access to the *installation*, equal to 25% of the direct costs referred to above (amounts for the categories taken into account in the unit costs, i.e. excluding the categories reimbursed on an actual cost basis) minus any costs of subcontracting.

The *access costs* to the *installation* shall exclude all contributions to the capital investments of the infrastructure unless otherwise specified in the Work Programme, in which case only the portion used to provide virtual access under the action can be eligible (see Section 1).

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by Regulation (EU, Euratom) No 2018/1046 and Regulation (EU) No 1290/2013. The Commission will apply the applicable co-financing rate at payment application stage.

Provision of virtual access of actions under the Research Infrastructures part of Horizon 2020 is not expected to generate revenue or to be specifically funded by third donors. The unit cost

[6] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[7] Unless exceptionally agreed otherwise by the Commission.

should not exceed the actual eligible costs as its calculation is based on the certified or auditable historical costs incurred to provide access. In addition, when applicable, the exclusion of capital investment from the calculation of the unit cost will ensure that *access provider*s contribute with their own resources to the provision of access under the action, thus complying with the co-financing and no-profit principles.

Double funding is avoided by the specification/identification of eligible costs detailed in Section 1. Compliance with the specification method of eligible costs is checked through controls during the proposal evaluation phase, on the application of the methodology for the calculation of the unit cost, as well as through ex-post controls on the existence of other Union funding sources specifically covering the virtual access provided under the Union action.

Finally, the costs of building the infrastructure may have been supported by the Union. The risk of double funding is minimised by the general ineligibility of depreciation costs (and of all capitalised costs) for the provision of virtual access under the Research Infrastructures Part.

Electronically signed on 05/02/2019 14:29 (UTC+01) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563

EUROPEAN
COMMISSION

Brussels, 25.11.2016
C(2016) 7553 final

COMMISSION DECISION

of 25.11.2016

modifying the Commission decision of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme

COMMISSION DECISION

of 25.11.2016

modifying the Commission decision of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Article 10 thereof,

Having regard to Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020)[2], and in particular Articles 25 and 33 thereof,

Having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[3], and in particular Article 124 thereof,

Whereas:

(1) On 7 March 2014 the Commission adopted a decision authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme,

(2) This Commission decision gives the beneficiaries the opportunity to declare their costs following either an actual cost system or the unit cost system described therein,

(3) Since the adoption of the Commission Decision, the applicants and beneficiaries concerned have raised concerns related to its practical implementation,

(4) The main obstacle identified concerns the obligation to apply either the unit cost method or the actual costs method for all categories of costs without any flexibility,

(5) A modification of the conditions set out in the Annex to the Commission decision is needed to introduce such flexibility,

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[1] OJ L 347, 20.12.2013, p. 104
[2] OJ L 347, 20.12.2013, p. 81
[3] OJ L 298, 26.10.2012, p.1

HAS DECIDED AS FOLLOWS:

Sole Article

The Annex of Commission decision C(2014) 1393 of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme is replaced by the Annex to this decision.

Done at Brussels, 25.11.2016

For the Commission
Carlos MOEDAS
Member of the Commission

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ANNEX

1. Form of costs and categories of costs covered

A 'clinical study' is defined for the purpose of this decision as any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients or study participants. It includes but is not limited to clinical studies and clinical trials in the sense of the Clinical Trials Regulation EU No 536/2014 and, in so far as it remains applicable, the Clinical Trials Directive 2001/20/EC.

Beneficiaries of grants under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme may determine the costs of clinical studies according to the following forms:

(i) Unit costs per patient or study participant calculated on the basis of their historical data, or

(ii) Cost actually incurred.

A grant may involve the conduct of several clinical studies, and each clinical study may be conducted by several entities. Hence, the grant agreement may foresee different forms for the costs of clinical studies per beneficiary or third party, under the following conditions:

- For the costs of personnel directly assigned to the conduct of clinical studies, each beneficiary or third party may only choose one of the forms (i) or (ii) .

NB This decision does not apply to personnel costs for horizontal tasks carried out by beneficiaries or third parties participating in the clinical study, such as study monitoring or study coordination tasks (these tasks are covered by provisions of the Grant Agreement).

- For categories (b) to (d) of direct eligible costs referred to in Part 2, beneficiaries and third parties may choose either of the forms (i) or (ii) for each cost item.

Unit costs per patient or participant will be specific to each beneficiary or third party and in each case only represent a proxy of their specific categories of costs (a) to (d) referred to in Part 2 below.

The unit costs shall be specified in the grant agreement to be used throughout the duration of the action. The proposal as well as the grant agreement should also specify the costs of the clinical study that will be determined as actual costs.

Costs of clinical studies declared by beneficiaries on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in Annex 2 to the grant agreement multiplied by the number of actual units (patients or study participants) included in the clinical studies conducted under the action.

Third parties may contribute in kind to the action by making data obtained from patients or study participants enrolled in the clinical studies available to a beneficiary or linked third party. The related costs shall also take one of the forms referred to in points (i) and (ii) for the purpose of determining:

- the maximum amount of the eligible costs that the beneficiaries may declare, if the data are contributed against payment,
- the eligible costs that the beneficiaries may declare, if the data are contributed free of charge.

The categories of eligible costs covered by the unit costs referred to in point (i) are defined below:

- Direct costs of clinical studies:

(a) Personnel costs of doctors and other medical personnel and technical personnel (including data managers) directly assigned to the conduct of the clinical study;

(b) Costs of consumables specifically used for the conduct of the clinical study;

(c) Costs of the medical equipment specifically used for the conduct of the clinical study, corresponding to:

- the depreciation costs
- the other costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair);

(d) Costs of other specific service contracts necessary for the conduct of the clinical study (including data analysis, if subcontracted);

- Indirect costs of the clinical study

The categories of eligible costs covered by the unit costs exclude the travel and subsistence costs of patients or study participants. Those costs will be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs".

Other categories of eligible costs not covered by the present decision shall be reimbursed on the basis of:
-eligible costs actually incurred or,
-for other direct personnel costs, on the basis of other unit costs or,
-for other indirect costs, flat-rate financing.

2. Method to determine the unit costs

The amounts of the unit costs per patient or study participant are determined *as the sum of the amounts of the unit cost components defined in points (a) to (e) below*, corresponding to the categories of eligible costs defined in Part 1, for each beneficiary or third party identified in the grant agreement and each clinical study.

Each beneficiary or third party shall determine the direct costs by reference to their historical costs and the estimated resources consumed per task and per patient or participant.

The beneficiary and the third party shall use as historical costs the costs recorded in their certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant proposal).

The estimation of resources at the time of submission of the grant proposal shall be based on the applicable protocol for the clinical study and must be the same for all members of the consortium involved in one clinical study.
Those resources shall be indicated in the grant proposal and will be assessed by the experts evaluating the proposals.

The choice of form of costs (unit costs or actual costs per cost category or sub-category) has to be made at the time of the proposal submission. The resulting unit costs shall also be included in the grant proposal and in the Annex 2 to the grant agreement. However, the unit cost can be modified through an amendment to the grant agreement in the following cases:

- if there is a change in the protocol (e.g. due to requests from competent authorities, regulatory agencies or ethics committees) during the implementation of the action which results in a change of the estimation of resources needed to calculate the unit costs. In such a case, the Commission may ask the advice of independent experts for the assessment of the necessity of the resources.

- if an error occurred in the identification of costs recorded in the beneficiary's certified or auditable accounts for year N-1 (last closed financial year at the time of submission of the proposal) or wrong application of points (a) to (d) below.

Under no circumstances may such modifications result in a substantial change to the grant proposal or in an increase of the maximum amount of the grant specified in the grant agreement.

In case of any amendment the historical costs shall still be the costs recorded in the certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the proposal) of the concerned beneficiary or the third party

The Commission has the right to verify that these costs comply with the requirements defined in points (a) to (d) below and to correct the unit costs in case of non-compliance.

(a) Personnel costs of medical and technical personnel directly assigned to the conduct of the clinical study

The amount of the unit cost component ‘personnel costs’ is determined for each task described in the protocol as follows:

*{Average hourly cost for **Doctors** X Estimated number of hours worked by doctors for each task described in the protocol and for each patient or study participant*

+ Average hourly cost for ***Other medical personnel*** *X Estimated number of hours worked by other medical personnel for each task described in the protocol and for each patient or study participant*

+ Average hourly cost for ***Technical personnel*** *X Estimated number of hours worked by technical personnel for each task described in the protocol and for each patient or study participant}*

with

Average hourly cost for Doctors *= Certified or auditable total personnel costs for Doctors for year N-1 / {1720 X number of full-time equivalent for the personnel category Doctors for year N-1}*

Average hourly cost for Other medical personnel *= Certified or auditable total personnel costs for other medical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Other medical personnel for year N-1}*

Average hourly cost for Technical personnel *= Certified or auditable total personnel costs for technical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Technical personnel for year N-1}*

and

Total personnel costs *= Actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act (see conditions set out in Article 6.2.A.1 of the model Horizon 2020 grant agreement).*

The use of hourly costs determined according to another methodology, including according to the beneficiary's or third party's usual cost accounting practices, is not allowed.

(b) Costs of consumables specifically used for the conduct of the clinical study

The amount of the unit cost component 'costs of consumables' is determined for each task described in the protocol as follows:

{Average price per item for the first category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ Average price per item for the second category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ Average price per item for the third category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ idem for each category of consumables specifically used in the clinical study}

with

Average price per item for a category of consumables used in the clinical study *= Certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned / Total number of items purchased in year N-1 for the category of consumables concerned*

and

Total costs of purchase of the consumables *= Total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary or third party for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

(c) Costs of the medical equipment specifically used for the conduct of the clinical study

The amount of the unit cost component 'costs of medical equipment' is determined for each task described in the protocol as follows:

{Average cost of depreciation and of directly related services for the first category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ Average cost of depreciation and of directly related services for the second category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ Average cost of depreciation and of directly related services for the third category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ idem for each category of equipment specifically used in the clinical study}

with

Average cost of depreciation and directly related services per unit of use *= {Certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + Certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned} / Total capacity in year N-1*

and

Total depreciation costs *= Total depreciation allowances as recorded in the beneficiary's or third party's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + Total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees (see conditions set out in Article 6.2.D.2 of the model Horizon 2020 grant agreement).*

Total costs of purchase of services *= Total value of the contracts concluded by the beneficiary or third party (including related duties, taxes and charges such as non-deductible VAT) for services delivered in year N-1 for the functioning of the equipment, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

Total capacity *= Total time of use of the equipment expressed in hours, days or months and supported by evidence or the number of accesses to the equipment, for which supporting evidence may take the form of records or electronic log of units-of-access provision.*

The total capacity must take due account of real constraints (e.g. opening hours), but must reflect the equipment full capacity and include any time during which the equipment is usable but not used or any unit of access available but not used.

(d) Costs of other specific contracts necessary for the conduct of the clinical study

The amount of the unit cost component 'costs of other specific contracts' is determined for each task described in the protocol as follows:

{Average cost of the first specific service necessary for the conduct of the clinical study per patient or study participant

+ Average cost of the second specific service necessary for the conduct of the clinical study per patient or study participant

+ Average cost of the third specific service necessary for the conduct of the clinical study per patient or study participant

+ idem for each specific service necessary for the conduct of the clinical study}

with

Average cost of a specific service per patient or study participant *= Certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies / Total number of patients or participants included in the clinical studies for which the specific service was delivered in year N-1*

and

Total costs of purchase of a service *= Total value of the contracts concluded by the beneficiary or third party (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

(e) Indirect costs

The amount of the unit cost component 'indirect costs' is determined for each task described in the protocol by applying a flat rate of 25% of the sum of the unit cost components referred to in points (a), (b) and (c) above (excluding the unit cost component referred to in point (d) above and the costs of resources made available by third parties which are not used on the premises of the beneficiary, as well as financial support to third parties, as set out in Article 29(1) of Regulation (EU) No 1290/2013).

3. Justification

3.1. Nature of the supported actions

Clinical studies are the essential link in the translation of new knowledge generated by basic research into new health products, services and interventions. Without clinical studies, the validity of these products, services and interventions cannot be tested and proven, to the disadvantage of patients, citizens and the competitiveness of the European health sector.

Over the course of 7th Framework Programme for Research and Development (FP7) approximately one fifth of all projects in the 'Health' theme included clinical studies, with a significant rise in number in the last years of FP7 implementation. As Horizon 2020 gives greater emphasis to innovation than previous programmes, the percentage of funding allocated to clinical studies is likely to increase.

(a) Problems related to the determination of actual costs of clinical studies

The precise quantification of costs resulting from clinical studies is difficult. Clinical studies consist of a large number and variety of different elements, such as repeat hospitalisations or outpatient clinic visits (themselves including a number of elements ranging from receptionist's time to meals and laundry), a variety of individual doctors', nurses' and technicians' time, study drugs and auxiliary drugs as well as laboratory and imaging tests. These costs are incurred in the health and care settings (hospitals, clinics, etc.) which are at the present time relatively inexperienced beneficiaries of Framework Programmes and the accounting systems of which are frequently not equipped to track these costs.

The problem for beneficiaries required to follow the H2020 rules regarding actual costs is in proving the allocation of actual resources needed to perform clinical studies. Such proof would be both time consuming and in some cases not possible due to the unsuitability of beneficiaries' accounting systems and management practices.

(b) Alternatives and consultation of stakeholders

In industry- or academically-funded clinical studies, hospitals are typically therefore reimbursed a lump sum per patient, calculated on the basis of a rough estimation of the actual costs. In large industrial trials this amount often includes a profit margin for the hospital or the participating doctors, whereas in academically-funded clinical studies, this amount usually does not cover the full costs and requires additional subsidy.

A number of stakeholders have called upon the Commission to adopt a similar approach for EU-funded clinical studies:
- A June 2012 note of the League of European Research Universities (LERU)1 requests among other changes trial-specific "flat rates per patient";
- A September 2013 workshop with representatives of three major German University Hospitals, the German National Contact Point and Clinical Research Organisations confirmed the urgent need to simplify the funding rules for clinical studies and welcomed the idea presented by the Commission (outlining the option in this Commission decision) as potential solution;
- The Commission also presented different options to the group of national experts at its meeting of 11 October 2013. Representatives of Member States also recognised the urgent need to simplify the accounting for clinical studies. The feedback received from most of the experts participating in this group is positive in respect to the option of declaring a 'unit cost per patient or participant involved in the study' as described in this decision;
- Numerous individual requests and meetings with project coordinators and hospital participants in FP7 projects have raised similar issues and potential solutions, which are the basis of the option proposed in this decision.

(c) Impact on grant management

Using unit costs considerably simplifies, streamlines and reduces the time needed for the financial management of projects, both at the Commission and beneficiary levels. A unit-cost system substantially decreases the number of recovery orders and de-commitments. It also significantly decreases the workload of the Commission or Agency when analysing cost statements and consequently speeds up the payment procedure. Furthermore, it implies additional simplifications at beneficiary level in terms of reporting requirements.

In summary, this approach provides simplification through:
- less complex funding rules contributing to easier understanding of actions;
- greater predictability for beneficiaries making their participation in the corresponding actions more attractive;
- less administrative burden for checking at the payment stage, reducing costs for the contracting authority and facilitating productivity gains;
- simplified reporting requirements (no certification of financial statement to be provided by beneficiaries for those costs);
- easier ex-post analysis and further reductions of the risk of error.

The use of unit costs is justified by the difficulty in determining the allocation of resources and is considered as an appropriate form of financing in order to simplify the administrative burden and financing conditions of supported actions. A unit-cost approach provides the opportunity to emphasise the quality of results. Moreover, the use of unit costs represents a further simplification for applicants ensuring certainty and transparency of funding levels.

3.2. Risks of irregularities and fraud and costs of control

The Financial Regulation (FR2) requires that the DGs and Agencies establish anti-fraud measures in their individual Internal Control Systems. In June 2011, the Commission adopted its first Anti–Fraud Strategy (CAFS) in which it requested the Commission Services to set up or update their sectorial Anti-Fraud Strategies. For the area of research the Anti-Fraud Strategy (RAFS) was adopted in December 2012. The RAFS builds strongly on and complements the CAFS by demonstrating how elements of the corporate strategy are addressed in the area of research. The sectorial strategy outlines some key principles of combating fraud, with a special focus on challenges which are common to the services of the research family and coordination mechanisms, which should ensure that strategic priorities are implemented in a most effective and coherent manner throughout the whole family.

The unit costs system is much simpler compared with the actual costs systems regarding the declaration of costs. As a consequence, the intrinsic risk on legality and regularity errors in cost claims leading to unjustified EU funding is very low and therefore the control and audit mechanism is lighter and less costly than in a system based on actual costs.

Reporting and control for clinical studies will focus on the realisation of the supported activity and the achieved results rather than on the resources allocated to the project, reducing the workload and scope for error of both participants and the Commission or Agency. The monitoring system will be set up in a manner ensuring efficiency and cost-effectiveness of the controls.

In fact, the unit costs will be subject to subsequent verification and audit to determine only the following:
- whether the number of patients or participants declared by the beneficiary corresponds to the number of patients or participants actually participating in the study, and
- whether the beneficiary has used the accounting data referred to in Part 2 for the determination of the unit costs set out in Annex 2 to the grant agreement.

However, the Commission will neither control the allocation of resources already agreed at the time of signature of the grant agreement nor the actual costs for the categories of eligible costs referred to in Part 1.

These controls will help the prevention of fraud while being simple and comprehensible both for the Commission or Agency and for the beneficiaries.

4. No-profit and co-financing principles and absence of double financing

The methodology for determining the unit cost per patient or participant included in the study described in Part 2 ensures respect for the no-profit and co-financing requirements and the absence of double financing of costs.

The clinical study is not expected to generate revenue or to be specifically funded by third donors. The unit cost per patient or participant set out in the grant agreement will not exceed the actual eligible costs as the calculation of the direct cost components will be based on

certified or auditable costs of a study which costs are recorded in the last closed accounts of the beneficiary. Furthermore, the funding for indirect costs is limited to 25% of the total direct eligible costs, excluding direct eligible costs for subcontracting. Therefore, the profit is a priori excluded and the remaining indirect costs are financed by the beneficiaries.

The reimbursement rate set out in the grant agreement will apply to the costs of clinical studies declared on the basis of unit costs.

The Commission avoids double funding by making checks at the time of evaluation and finalisation of the grant agreement that the costs falling under the categories covered by the unit costs, as referred to in Part 1, are not indicated in another budget category. A clear description of the activities covered by the unit cost will be included in the proposal and in the Technical Annex to the grant agreement, which will enable the Commission or Agency to reconcile the estimated eligible costs with the activities to be carried out. Similar checks will be performed during and after implementation of the grant agreement.

Funding based on unit costs encourages the recipient to use resources in an economical manner, given that the grant agreement is based on pre-established rates - without further adjustment of the amount of the grant based on the actual expenditure.

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 2.4
15 February 2023

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK
1.5	28.06.2018	▪ Update of the explanations for France
1.6	26.06.2019	▪ Update of the explanations for France and Spain
2.0	07.01.2020	▪ Update to VM4.0
2.1	26.05.2020	▪ Update of the explanations for Hungary
2.2	21.06.2021	▪ Update of the explanations for Hungary
2.3	30.07.2021	▪ Update of the explanations for Hungary
2.4	15.02.2023	▪ Update to of the explanations for France (Prime de participation à la recherche scientifique abolished).

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique [abolished since 01.09.2017]	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	

Bonuses	Prime de charges administratives	
Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Salaries	Indemnité de départ à la retraite	Eligible within the limits set by law or mandatory collective agreement
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Taxes	Crédit Impôt Recherche	It is **not** a receipt of the action

	(CIR)	
Taxes	Contribution à l'Agefiph due à l'obligation d'emploi des travailleurs handicapés	It is an **ineligible** cost
Hungary		
Taxes	Act CLV/2011 concerning contributions to vocational training and training support	Costs up to the amount foreseen in the national legislation are **eligible** cost
Taxes	KATA	Mandatory KATA that the beneficiary paid for staff fulfilling the conditions of article 6.2.A.2 can be included in the calculation of their hourly rates.
Taxes	KIVA	The part of the KIVA that is calculated on the personnel costs is an eligible item than can be included in the calculation of the hourly rates.
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.

Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
Spain		
Contributions	Bonificación Seguridad Social del personal investigador (Real Decreto 475/2015)	The *bonificación* is an **ineligible** cost
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the

		beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue should be deleted.**
- **For options *[*in square brackets*]*: choose the option that applies. (Options not chosen and the brackets should be deleted.)**
- **For fields in [grey in square brackets]: enter the appropriate data (and take out the grey colour and the brackets).**

This template is NOT IT-supported. It must be prepared manually (by choosing and deleting the options/entering the appropriate data) and uploaded in SyGMa as attachment to the grant agreement.

For the 'unit cost tables': either fill them out manually or use currently existing tables from Annex 1 or the proposal.

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{the monthly living allowance for researchers in MSCA-IF actions / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The monthly living allowance and the country-specific correction coefficients are set out in the Work Programme (section 3 MSCA) in force at the time of the call:

- for calls *before* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 650**
  - for the country-specific correction coefficients: see Work Programme 2014-2015 and Work Programme 2016-2017 (available on the Participant Portal Reference Documents page)
- for calls *under* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 880**
  - for the country-specific correction coefficients: see Work Programme 2018-2020 (available on the Participant Portal Reference Documents page)

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment): For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- beneficiary/linked third party [short name]: EUR [insert amount]
- beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] ***]***

Estimated number of units: see Annex 2

Marie Skłodowska-Curie unit costs

2. MSCA-IF/MSCA-ITN unit costs

Costs for the recruited researcher(s) — Living allowance

Units: months spent by the researcher(s) on the research training activities ('person-months')

Amount per unit *: see Annex 2

* Amount calculated as follows:
{the monthly living allowance for researchers in MSCA-IF/MSCA-ITN actions
multiplied by
country-specific correction coefficient of *[OPTION by default:* the country in which the researcher is recruited*][OPTION for IF-global fellowship:* the country where the partner organisation hosting the researcher during a secondment is located (for the outgoing phase) and the country in which the researcher is recruited (for the return phase)*]*}

The monthly living allowance and the country-specific correction coefficients are set out in the Work Programme (section 3 MSCA) in force at the time of the call:

- for calls *before* Work Programme 2018-2020:
  - for the monthly living allowance:
    - IF: **EUR 4 650**
    - ITN: **EUR 3 110**
  - for the country-specific correction coefficients: see Work Programme 2014-2015 and Work Programme 2016-2017 (available on the Participant Portal Reference Documents page)
- for calls *under* Work Programme 2018-2020:
  - for the monthly living allowance:
    - IF: **EUR 4 880**
    - ITN: **EUR 3 270**
  - for the country-specific correction coefficients: see Work Programme 2018-2020 (available on the Participant Portal Reference Documents page).

Estimated number of units: see Annex 2

Costs for the recruited researcher(s) — Mobility allowance

Units: months spent by the researcher(s) on the research training activities ('person-months')

Amount per unit[1]: see Annex 2

Estimated number of units: see Annex 2

Costs for the recruited researcher(s) — Family allowance

Units: months spent by the researcher(s) on the research training activities ('person-months')

Amount per unit[2]: see Annex 2

Estimated number of units: see Annex 2

Institutional costs — Research, training and networking costs

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[1] Same amount for all beneficiaries.
Amount for the mobility allowance set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[2] Same amount for all beneficiaries.
Average based on the amount for the family allowance set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call (half of the number of units with family, half without).

Units: months spent by the researcher(s) on the research training activities ('person-months')

Amount per unit[3]: see Annex 2

Estimated number of units: see Annex 2

Institutional costs — Management and indirect costs

Units: months spent by the researcher(s) on the research training activities ('person-months')

Amount per unit[4]: see Annex 2

Estimated number of units: see Annex 2

3. MSCA-RISE unit costs

Costs for seconded staff members — Top-up allowance

Units: months spent by the seconded staff member(s) on the research and innovation activities ('person-months')

Amount per unit[5]: see Annex 2

Estimated number of units: see Annex 2

Institutional costs — Research, training and networking costs

Units: months spent by the seconded staff member(s) on the research and innovation activities ('person-months')

Amount per unit[6]: see Annex 2

Estimated number of units: see Annex 2

Institutional costs — Management and indirect costs

Units: months spent by the seconded staff member(s) on the research and innovation activities ('person-months')

Amount per unit[7]: see Annex 2

Estimated number of units: see Annex 2

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[3] Same amount for all beneficiaries.
Amount for research, training and networking costs set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[4] Same amount for all beneficiaries.
Amount for management and indirect costs set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[5] Same amount for all beneficiaries.
Average based on the amount for the top-up allowance set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[6] Same amount for all beneficiaries.
Average based on the amount for research, training and networking costs set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[7] Same amount for all beneficiaries.
Average based on the amount for management and indirect costs set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

4. MSCA-COFUND unit costs

Costs for researchers (Living allowance)

Units: months spent by the researchers on the research training activities ('person-months')

Amount per unit[8]: see Annex 2

Estimated number of units: see Annex 2

Management costs

Units: months spent by the researchers on the research training activities ('person-months')

Amount per unit[9]: see Annex 2

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

5. Costs for energy efficiency measures in buildings

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m² per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

Unit cost table (energy efficiency measures unit cost)[10]

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

[8] Same amount for all beneficiaries.
Average based on the amount for the living allowance set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[9] Same amount for all beneficiaries.
Average based on the amount for management costs set out in the H2020 Work Programme (section 3 MSCA) in force at the time of the call.

[10] Data from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.

Research infrastructure unit cost

6. Access costs for providing trans-national access to research infrastructure

Units[11]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[12])}}{\text{average annual total quantity of access to the installation (over past two years[13])}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[14]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

Clinical studies unit cost

7. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each sequence (if any), clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for the cost components of each task, as follows:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

$$\frac{\{\text{certified or auditable total personnel costs for doctors for year N-1}\}}{\{1720 * \text{number of full-time-equivalent for doctors for year N-1}\} \text{ multiplied by } \text{estimated number of hours to be worked by doctors for the task (per participant)}\}}$$

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

$$\frac{\{\text{certified or auditable total personnel costs for other medical personnel for year N-1}\}}{\{1720 * \text{number of full-time-equivalent for other medical personnel for year N-1}\}}$$

[11] Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.
[12] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
[13] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
[14] Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)}

For personnel costs of technical personnel: 'average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1

{1720 * number of full-time-equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1

total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)}

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)}

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1

total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1}

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}}

multiplied by

25%}

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

Unit cost table: clinical studies unit cost[15]

Task, Direct cost categories	**Resource per patient**	**Costs year N-1 Beneficiary 1 [short name]**	**Costs year N-1 Linked third party 1a [short name]**	**Costs year N-1 Beneficiary 2 [short name]**	**Costs year N-1 Linked third party 2a [short name]**	**Costs year N-1 Third party giving in-kind contributions 1 [short name]**
Sequence No. 1						
Task No. 1 Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						

[15] Same table as in proposal and Annex 1.

Task No. 1 XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

I

ERA-NET Cofund unit cost

8. Direct coordination costs for additional activities

Units: number of years in which the additional activities were carried out by each beneficiary/linked third party

Amount per unit (EUR/year): EUR 29 000 per year

Estimated number of units: see Annex 2

EJP Euratom Fusion unit costs

9. Costs for mobility of personnel

Daily subsistence allowance

Units: days spent by the personnel on secondment

Amount per unit*: see (for each beneficiary/linked third party and secondment) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 127.65
multiplied by
country-specific correction coefficient of the place of secondment}

Country-specific correction coefficients until 31 December 2015[16]:

Country/place	**Coefficient (%)**	**Country/place**	**Coefficient (%)**
Austria	106.4	Italy	104.2
Bulgaria	58.4	*Italy Varese*	93.4
Croatia	80.0	Latvia	77.6
Cyprus	84.1	Lithuania	71.5
Czech Rep.	80.6	Malta	83.3
Denmark	135.3	Netherlands	105.3
Estonia	77.6	Poland	74.2
Finland	122.1	Portugal	83.5
France	117.7	Romania	68.8
		Slovakia	79.7
Germany	95.8	Slovenia	85.3
Germany Bonn	94.1	Spain	97.1
Germany Karlsruhe	93.8		
Germany Munich	106.4	Sweden	131.9
Greece	90.5	*Switzerland Geneva*	124.6
Hungary	78.3	*Switzerland Berne*	123.3
Ireland	110.6		
		United Kingdom	147.8
		UK Culham	112.5

Country-specific correction coefficients as from 1 January 2016[17]:

Country/place	**Coefficient (%)**	**Country/place**	**Coefficient (%)**
Austria	105.9	Italy	99.4
Bulgaria	52.1	*Italy Varese*	92.2
Croatia	74.6	Latvia	74.2
Cyprus	77.3	Lithuania	69.0
Czech Rep.	73.4	Malta	84.5
Denmark	131.8	Netherlands	107.8
Estonia	78.0	Poland	71.8

[16] For the 'estimated budget (Annex 2)': country coefficient for UK Culham (i.e. 112.5%) should be used. (⚠ For the 'financial statements', the amount must be adjusted according to the actual place of secondment.)
The country-specific coefficient is based on Regulation (EU) No 423/2014 of the European Parliament and of the Council of 16 April 2014 adjusting with effect from 1 July 2012 the remuneration and pensions of officials and other servants of the European Union and the correction coefficients applied thereto (OJ L 129, 30.04.2014, p. 12).
Revised coefficients (based on 1 October 2015 values) will be applied as from 1 January 2016 through an amendment to the grant agreement.

[17] For the 'estimated budget (Annex 2)': country coefficient for UK Culham (i.e. 127.7%) should be used. (⚠ For the 'financial statements', the amount must be adjusted according to the actual place of secondment.)
The revised country coefficients are based on the 2015 update of the remuneration and pensions of the officials and other servants of the European Union and the correction coefficients applied thereto (OJ C 415, 15.12.2015, p.4). The revised coefficients were introduced into the EJP Euratom Fusion grant agreement through an amendment.

Finland	119.7	Portugal	79.2
France	114.6	Romania	64.8
Germany	96.6	Slovakia	76.4
Germany Bonn	93.4	Slovenia	85.3
Germany Karlsruhe	93.8	Spain	97.1
Germany Munich	106.0	Sweden	131.9
Greece	79.9	*Switzerland*	142.4
Hungary	69.0		
		United Kingdom	166.9
Ireland	116.6	*UK Culham*	127.7

Estimated number of units: see (for each beneficiary/linked third party and secondment) the 'unit cost table' attached

Monthly subsistence allowance

Units: months spent by the personnel on secondment

Amount per unit*: see (for each beneficiary/linked third party and secondment) the 'unit cost table' attached

* Amount calculated as follows:

{[insert amount from the table below, depending on the distance between the place where the individual was working before the secondment and the place of secondment] [18]:

Distance between place of employment and place of secondment (km)	Monthly allowance (EUR)
0 – 150	**0**
> 150	**82.05**
> 300	**145.86**
> 500	**237.05**
> 800	**382.92**
> 1 300	**601.73**
> 2 000	**720.27**

multiplied by
country-specific correction coefficient of the place of secondment}

For the country-specific correction coefficient, see above (daily subsistence allowance)[19].

Estimated number of units: see (for each beneficiary/linked third party and secondment) the 'unit cost table' attached

Family allowance

Units: months spent on secondment

Amount per unit*: see (for each beneficiary/linked third party and secondment) the 'unit cost table' attached

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[18] For the 'estimated budget (Annex 2)': the distance between the place of employment and UK Culham should be used. (⚠ For the 'financial statements', the amount must be adjusted according to the actual place of secondment.)

[19] For the 'estimated budget (Annex 2)': the country coefficient for UK Culham (i.e. 112.5% until 31.12.2015 or 127.7% from 01.01.2016) should be used. (⚠ For the 'financial statements', the amount must be adjusted according to the actual place of secondment.)

* Amount calculated as follows:
{EUR 258.81 x number of dependent children[20]**}**

Estimated number of units: see (for each beneficiary/linked third party and secondment) the 'unit cost table' attached

Unit cost table (EJP Fusion mobility unit cost)

Short name beneficiary/linked third party	Secondment (name*, destination, duration**)	Type of unit cost	Unit	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
[insert short name of beneficiary/linked third party]	NN, UK Culham, 3 days	Daily subsistence allowance	days		3	
		Monthly subsistence allowance	months		0	
		Family allowance	months		0	
	NN, UK Culham, 3 months (= 90 days)	Daily subsistence allowance	days		90	
		Monthly subsistence allowance	months		3	
		Family allowance	months		3	
	NN, UK Culham, 8 months (= 240 days)	Daily subsistence allowance	days		240	
		Monthly subsistence allowance	months		8	
		Family allowance	months		8	
	NN, UK Culham, 20 days	Daily subsistence allowance	days		20	
		Monthly subsistence allowance	months		0	
		Family allowance	months		0	
	…					
[insert short name of beneficiary/linked third party]	NN, UK Culham, 25 months (= 750 days)	Daily subsistence allowance	days		750	
		Monthly subsistence allowance	months		25	
		Family allowance	months		25	
	NN, UK Culham, 15 days	Daily subsistence allowance	days		15	
		Monthly subsistence allowance	months		0	
		Family allowance	months		0	
	NN, UK Culham, 8 months (= 240 days)	Daily subsistence allowance	days		240	
		Monthly subsistence allowance	months		8	
		Family allowance	months		8	
	…					
…		Daily subsistence allowance	days			
		Monthly subsistence allowance	months			
		Family allowance	months			
		Daily subsistence allowance	days			
		Monthly subsistence allowance	months			

[20] For the 'estimated budget (Annex 2)': an average should be used. (⚠ For the 'financial statements', the number of children (and months) must be adjusted according to the actual family status at the moment the secondment starts.)

		Family allowance	months			
		Daily subsistence allowance	days			
		Monthly subsistence allowance	months			
		Family allowance	months			
		Daily subsistence allowance	days			
		Monthly subsistence allowance	months			
		Family allowance	months			
		Daily subsistence allowance	days			
		Monthly subsistence allowance	months			
		Family allowance	months			

* For the 'estimated budget': NN should be used. (For the 'financial statements', NN should be changed to the real name.)
** For the 'estimated budget': count 30 days per month. (For the 'financial statements', the number of days and months must be adapted according to the actual duration of the secondment — according to the calculation explained in the H2020 AGA – Annotated Grant Agreement published on the Participant Portal.)

10. Costs for fellowships for researchers

Living allowance

Units: months spent by the fellow on fellowship

Amount per unit*: see (for each beneficiary/linked third party and fellowship) the 'unit cost table' attached

* Amount calculated as follows:
{/**EUR 3 110** (for early-stage researcher(s))/ /**EUR 4 650** (for experienced researcher(s))/
multiplied by
country-specific correction coefficient of the country of the fellowship}

Country-specific correction coefficient[21]:

Country	**Coefficient**	**Country**	**Coefficient**
Austria	104.8 %	Italy	106.7 %
Belgium	100.0 %	Lithuania	73.1 %
Bulgaria	71.5 %	Luxembourg	100.0 %
Cyprus	91.8 %	Latvia	75.9 %
Czech Republic	83.8 %	Malta	89.6 %
Germany	98.8 %	Netherlands	104.3 %
Denmark	135.3 %	Poland	76.4 %
Estonia	78.3 %	Portugal	89.1 %
Greece	92.7 %	Romania	68.3 %
Spain	97.6 %	Sweden	111.7 %
Finland	116.6 %	Slovenia	86.1 %
France	111.0 %	Slovakia	82.6 %
Croatia	97.5 %	United Kingdom	120.3 %
Hungary	76.2 %		
Ireland	113.5 %	Switzerland	113.1 %

Estimated number of units: see (for each beneficiary/linked third party and fellowship) the 'unit cost table' attached

Mobility allowance

Units: months spent by the fellow on fellowship

Amount per unit[22]: **EUR 600**

Estimated number of units: see (for each beneficiary/linked third party and fellowship) the 'unit cost table' attached

Family allowance

Units: months spent by the fellow on fellowship

Amount per unit[23]: **EUR 500**

Estimated number of units: see (for each beneficiary/linked third party and fellowship) the 'unit cost table' attached

Unit cost table (EJP Fusion fellowship unit cost)

Short name beneficiary/linked third party	Fellowship (name, type of fellow, destination, duration)	Type of unit cost	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
[insert short name of beneficiary/linked third party]	NN, early stage researcher, Belgium, 3 months	Living allowance	XX EUR	3	
		Mobility allowance	600	3	
		Family allowance	500	3	
	NN, early stage researcher, Belgium, 15 months	Living allowance	XX EUR	15	
		Mobility allowance	600	15	
		Family allowance	500	15	
	NN, experienced researcher, Belgium, 9 months	Living allowance	XX EUR	9	
		Mobility allowance	600	9	
		Family allowance	500	9	
	…				
[insert short name of beneficiary/linked third party]	NN, experienced researcher, Belgium, 20 months	Living allowance	XX EUR	20	
		Mobility allowance	600	20	
		Family allowance	500	20	
	NN, early stage researcher, Belgium, 8 months	Living allowance	XX EUR	8	
		Mobility allowance	600	8	
		Family allowance	500	8	
	NN, experience researcher, Belgium, 7 months	Living allowance	XX EUR	7	
		Mobility allowance	600	7	
		Family allowance	500	7	
	…				
…		Living allowance	XX EUR		
		Mobility allowance	600		
		Family allowance	500		
		Living allowance	XX EUR		
		Mobility allowance	600		
		Family allowance	500		
		Living allowance	XX EUR		
		Mobility allowance	600		
		Family allowance	500		

[22] Same for all beneficiaries/linked third parties.
[23] Same for all beneficiaries/linked third parties.

11. Access costs for research infrastructure

Units[24]: see (for each beneficiary/linked third party and installation) the 'unit cost table' attached

Amount per unit*: see (for each beneficiary/linked third party and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[25])}}{\text{average annual total quantity of access to the installation (over past two years[26])}}$$

Estimated number of units: see (for each beneficiary/linked third party and installation) the 'unit cost table' attached

Unit cost table (EJP Fusion access to research infrastructure unit cost)

Short name beneficiary/linked third party	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

HISTORY OF CHANGES		
Version	**Date**	**Change**
1.0	18.12.2014	▪ Initial version
2.1	01.10.2015	▪ Small changes
3.0	14.12.2015	▪ Introduction of Annex 2a in ERANET Cofund grants. ▪ Small changes (hyperlink to AGA, taking out of colour codes, etc.)
4.0	31.08.2016	▪ MSCA unit cost aligned to IT implementation (as standard reference document) ▪ Examples in tables (clinical studies and EJP Fusion) changed into H2020 blue. ▪ Annex updated to MGA v4.0
5.0	25.05.2018	▪ Checked against MGA v5.0 (no changes needed).

[24] Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.
[25] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
[26] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2013

laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 173, 183, and the second paragraph of Article 188 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the Court of Auditors ([1]),

Having regard to the opinion of the European Economic and Social Committee ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ("Horizon 2020") is established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council ([4]). That Regulation needs to be complemented by rules for participation in indirect actions undertaken under Horizon 2020, and for exploitation and dissemination of the results of those actions.

(2) Horizon 2020 should be implemented with a view to contributing directly to creating industrial leadership, growth and employment as well as citizens' welfare in Europe, and should reflect the strategic vision of the Commission Communication of 6 October 2010 entitled "Europe 2020 Flagship Initiative Innovation", in which the Commission commits itself to radically simplify access for participants.

(3) Horizon 2020 should support the achievement and functioning of the European Research Area in which researchers, scientific knowledge and technology circulate freely, by strengthening cooperation both between the Union and the Member States, and among the Member States, in particular through the application of a coherent set of rules.

(4) The rules for participation, exploitation and dissemination in Horizon 2020 laid down in this Regulation ("the Rules") should adequately reflect the recommendations of the European Parliament in its resolution of 11 November 2010 on simplifying the implementation of the Research Framework Programmes ([5]), and of the Council with regard to the simplification of the administrative and financial requirements of the research framework programmes. The Rules should provide continuity to the simplification measures already implemented under Decision No 1982/2006/EC of the European Parliament and of the Council ([6]). They should take up the recommendations made in the final report of the Expert Group entitled 'Interim Evaluation of the 7th Framework Programme' of 12 November 2010 and they should enable further progress in reducing the administrative burden for participants and the complexity of the financial provisions in order to facilitate participation and reduce the number of financial errors. The Rules should also duly reflect the concerns raised and recommendations made by the research community resulting from the debate initiated by the Commission Communication of 29 April 2010 entitled "Simplifying the implementation of the research framework programmes", and the subsequent Green Paper of 9 February 2011 entitled "From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation funding".

(5) The interim evaluation of Horizon 2020 should include an evaluation of the new funding model, including its impact on funding levels, on participation in Horizon 2020 and on the attractiveness of Horizon 2020.

(6) The Commission or the relevant funding body should ensure that guidance and information is made available to all potential participants at the time of publication of the call for proposals.

([1]) OJ C 318, 20.10.2012, p. 1.
([2]) OJ C 181, 21.6.2012, p. 111.
([3]) Position of the European Parliament of 21 November 2013 (not yet published in the Official Journal)
([4]) Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014 to 2020) and repealing Decision 1982/2006/EC (See page 104 of this Official Journal).
([5]) OJ C 74E, 13.3.2012, p. 34.
([6]) Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

(7) In order to ensure coherence with other Union funding programmes, Horizon 2020 should be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council [1], and Commission Delegated Regulation (EU) 1268/2012 [2], taking due account of the specific nature of research and innovation activities.

(8) An integrated approach should be ensured by bringing together activities covered by the Seventh Framework Programme for research, technological development and demonstration activities (2007-2013) adopted by Decision No 1982/2006/EC, the Competitiveness and Innovation Framework Programme established by Decision No 1639/2006/EC of the European Parliament and of the Council [3] and the European Institute of Innovation and Technology (the EIT) established by Regulation (EC) No 294/2008 of the European Parliament and of the Council [4] to make participation easier, create a more coherent set of instruments and increase the scientific and economic impact, while avoiding duplication and fragmentation. Common rules should apply in order to ensure a coherent framework which should facilitate participation in programmes receiving Union financial contributions from the budget of Horizon 2020, including participation in programmes managed by the EIT, joint undertakings or any other structures under Article 187 of the Treaty on the Functioning of the European Union (TFEU), and participation in programmes undertaken by Member States pursuant to Article 185 TFEU.

However, flexibility to adopt specific rules should be ensured when justified by the specific needs of the respective actions. In order to take into account the specific operating needs as identified in the framework of the relevant basic act of the bodies set up under Article 187 TFEU, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure the simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(9) Actions which fall within the scope of this Regulation should respect fundamental rights and observe the principles acknowledged in particular by the Charter of Fundamental Rights of the European Union. Such actions should be in conformity with any legal obligation including international law and with any relevant Commission decisions such as the Commission notice of 28 June 2013 [5], as well as with ethical principles, which include avoiding any breach of research integrity.

(10) In line with the objectives of international cooperation as set out in Articles 180 and 186 TFEU, the participation of legal entities established in third countries and of international organisations should be promoted. The implementation of the Rules should be in conformity with the measures adopted in accordance with Articles 75 and 215 TFEU and should be in compliance with international law. Moreover, the implementation of the Rules should duly take into account the conditions for the participation of Union entities in third countries' corresponding programmes.

(11) The Rules should provide a coherent, comprehensive and transparent framework to ensure the most efficient implementation possible, taking into account the need for easy access by all participants through simplified procedures, in particular with regard to micro-, small-, and medium-sized enterprises (SMEs). The financial assistance from the Union could be provided in various forms.

(12) In line with the principle of transparency and in addition to the publicity requirement set out in Regulation (EU, Euratom) No 966/2012 and in Regulation (EU) No 1268/2012, the Commission should publish open calls for proposals on the internet pages of Horizon 2020, through specific information channels, and should ensure their wide dissemination, including via national contact points and upon request in accessible formats, where practicable.

(13) The selection and award criteria laid down in this Regulation should be applied in a transparent way and based on objective and measurable parameters, taking into account the overall aim of Horizon 2020 to achieve a well-functioning European Research Area.

(14) In general, the period between the final date for the submission of complete proposals and the signing of grant agreements with applicants or notifying grant decisions to them should be shorter than the period provided for in Regulation (EU, Euratom) No 966/2012. In duly justified cases and for actions of the European Research Council a longer period should be allowed.

[1] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

[2] Commission Delegated Regulation (EU) No 1268/2012 of 29.10.2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

[3] Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) (OJ L 310, 9.11.2006, p. 15).

[4] Regulation (EC) No 294/2008 of the European Parliament and of the Council of 11 March 2008 establishing the European Institute of Innovation and Technology (OJ L 97, 9.4.2008, p. 1).

[5] OJ C 205, 19.7.2013, p. 9.

(15) The Commission should continue its efforts to simplify the procedures in ways made possible by the improvement of IT systems, such as the further expansion of the portal for participants which should function as the single entry point from the moment of publication of the calls for proposals, through submission of proposals, until implementation of the action, with the aim of establishing a one-stop shop. The system may also provide feedback to applicants on the progress and the timeline of their applications.

(16) The handling of confidential data and classified information should be governed by all relevant Union law, including the Institutions' internal rules, such as Commission Decision 2001/844/EC, ECSC, Euratom [1] which lays down the provisions on security of European Union classified information.

(17) It is necessary to establish the minimum conditions for participation, both as a general rule and with regard to the specificities of the actions under Horizon 2020. In particular, rules should be laid down regarding the number of participants and their places of establishment. In the case of an action without the participation of an entity established in a Member State, the attainment of the objectives laid down in Articles 173 and 179 TFEU should be pursued.

(18) Pursuant to Council Decision 2001/822/EC [2], legal entities of overseas countries and territories are eligible to participate in Horizon 2020 subject to the specific conditions laid down in the latter.

(19) The Commission should consider the timings of calls for proposals and requests for information taking into account, where possible, standard holiday periods.

(20) In the case of unsuccessful proposals, the Commission should give feedback to the applicants concerned.

(21) Clear and transparent mechanisms to develop calls for proposals on specific topics should enable a level playing field, increase the attractiveness of Horizon 2020 and increase participation.

(22) The Commission should in all aspects of Horizon 2020 act in accordance with the principles of the European Code of Good Administrative Behaviour as set out in the annex to Commission Decision 2000/633/EC, ECSC, Euratom [3].

(23) It is appropriate to establish the terms and conditions for providing Union funding to participants in actions under Horizon 2020. In order to reduce the complexity of the existing funding rules, a simplified cost reimbursement system should be adopted with enhanced use of lump sums, flat rates and unit costs.

(24) The reimbursement rates in this Regulation are referred to as maximums in order to comply with the non-profit requirement and the co-financing principle, and to allow participants to request a lower rate. In principle, the reimbursement rates should however be 100 % or 70 %.

(25) The OECD definitions regarding Technological Readiness Level (TRL) should be taken into account in the classification of technological research, product development and demonstration activities.

(26) Specific challenges in the area of research and innovation should be addressed through new forms of funding such as prizes, pre-commercial procurement, public procurement of innovative solutions, the SME Instrument and the Fast Track to Innovation actions, which require specific rules.

(27) In order to maintain a level playing field for all undertakings active in the internal market, funding provided by Horizon 2020 should be designed in accordance with State aid rules so as to ensure the effectiveness of public spending and prevent market distortions such as crowding-out of private funding, the creation of ineffective market structures or the preservation of inefficient firms. Care should be taken to ensure that funding of innovation actions neither distorts competition nor leads to market interference without sufficient cause.

(28) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, ensuring an appropriate balance between trust and control.

(29) In accordance with Regulation (EU, Euratom) No 966/2012, the Rules should provide the basis for a wider acceptance of the usual cost accounting practices of the beneficiaries.

[1] 2001/844/EC,ECSC,Euratom: Commission Decision of 29 November 2001 amending its internal Rules of Procedure (OJ L 317, 3.12.2001).

[2] Council Decision 2001/822/EC of 27 November 2001 on the association of the overseas countries and territories with the European Community ('Overseas Association Decision') (OJ L 314, 30.11.2001, p. 1).

[3] 2000/633/EC, ECSC, Euratom: Commission Decision of 17 October 2000 amending its Rules of Procedure (OJ L 267, 20.10.2000, p. 63).

(30) The participant Guarantee Fund set up under Regulation (EC) No 1906/2006 of the European Parliament and of the Council [1] and managed by the Commission has proved to be an important safeguard mechanism which mitigates the risks associated with the amounts due and not reimbursed by defaulting participants. Therefore, a new participant Guarantee Fund ("the Fund") should be established. In order to ensure more efficient management and better coverage of participants' risk, the Fund should cover actions under the programme set up under Decision No 1982/2006/EC, under the programme set up by Council Decision 2006/970/Euratom [2], under the programme set up by Council Decision 2012/93/Euratom [3] as well as actions under Horizon 2020 and Regulation (Euratom) No 1314/2013 of the Council [4]. Programmes managed by entities other than Union funding bodies should not be covered by the Fund.

(31) In order to enhance transparency, the names of experts that have assisted the Commission or relevant funding bodies in the application of this Regulation should be published. Where the publication of the name would endanger the security or integrity of the expert or would unduly prejudice his or her privacy, the Commission or funding bodies should be able to refrain from the publication of such names.

(32) Personal data relating to the experts should be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council [5].

(33) Rules governing the exploitation and dissemination of results should be laid down to ensure that participants protect, exploit and disseminate those results as appropriate, and to provide for the possibility of additional exploitation conditions in the European strategic interest. Participants that have received Union funding, and that plan to exploit the results generated with such funding primarily in third countries not associated with Horizon 2020, should indicate how the Union funding will benefit Europe's overall competitiveness (reciprocity principle), as set out in the grant agreement.

(34) In the case of research with the potential for further development into a novel medical technology (such as drugs, vaccines and medical diagnostics), measures should be taken to ensure the immediate exploitation and dissemination of the results, where appropriate.

(35) Despite the success of existing Union debt and equity financial instruments for research, development, innovation and growth, access to risk finance remains a key issue, in particular for innovative SMEs. In order to allow their most effective use, debt and equity financial instruments should be allowed to be combined with each other and with grants funded under the Union budget, including under Horizon 2020. Moreover, the Commission should, in particular, ensure continuity of the Risk-Sharing Finance Facility (RSFF) set up under Decision No 1982/2006/EC and the early stage part of the High-Growth and Innovative SME Facility (GIF1) set up under Decision No 1639/2006/EC within their succeeding debt and equity financial instruments under Horizon 2020, respectively the 'Union loan & guarantee service for Research and innovation' and the 'Union Equity Instruments for research and innovation'. In this context, revenues and repayments generated by any of those financial instruments should directly benefit the financial instruments set up under Horizon 2020.

(36) The Commission should ensure sufficient complementarities between the SME instrument under Horizon 2020 and the financial instruments under Horizon 2020 and the COSME programme established under Regulation (EU) No 1287/2013 of the European Parliament and of the Council [6], as well as with schemes and instruments set up jointly with Member States, such as the Eurostars Joint Programme [7].

(37) For reasons of legal certainty and clarity, Regulation (EC) No 1906/2006 should be repealed,

[1] Regulation No 1906/2006/EC of the European Parliament and of the Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013) (OJ L 391, 30.12.2006, p. 1).

[2] Council Decision 2006/970/Euratom of 18 December 2006 concerning the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007 to 2011) (OJ L 400, 30.12.2006, p. 60).

[3] 2012/93/Euratom: Council Decision of 19 December 2011 concerning the Framework Programme of the European Atomic Energy Community for nuclear research and training activities (2012 to 2013) (OJ L 47, 18.2.2012, p. 25).

[4] Regulation (Euratom) No 1314/2013 of the Council on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing Horizon 2020 - the Framework Programme for Research and Innovation (See page 948 of this Official Journal).

[5] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

[6] Regulation (EU) No 1287/2013 of the European Parliament and of the Council of 11 December 2013 establishing a Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (COSME) (2014 - 2020) and repealing Decision No 1639/2006/EC (See page 33 of this Official Journal).

[7] Decision No 743/2008/EC of the European Parliament and of the Council of 9 July 2008 on the Community's participation in a research and development programme undertaken by several Member States aimed at supporting research and development performing small and medium-sized enterprises (OJ L 201, 30.7.2008, p. 58).

HAVE ADOPTED THIS REGULATION:

TITLE I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down specific rules for participation in indirect actions undertaken under Regulation (EU) No 1291/2013, including participation in indirect actions funded by funding bodies in accordance with Article 9(2) of that Regulation.

This Regulation also lays down the rules governing the exploitation and dissemination of results.

2. Subject to the specific rules laid down in this Regulation, the relevant rules of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012 shall apply.

3. Regulation (EC) No 294/2008 or any basic act which entrusts budget implementation tasks to a funding body under Article 185 TFEU may establish rules which depart from those laid down in this Regulation. In order to take into account their specific operating needs and subject to the rules established in the relevant basic act, the Commission shall be empowered to adopt delegated acts in accordance with Article 56, with regard to funding bodies set up under Article 187 TFEU concerning:

(a) the conditions for participation in calls for proposals issued by funding bodies established in the area of aeronautics with a view to reducing the minimum number of participants set out in Article 9(1);

(b) the eligibility for funding as set out in Article 10, allowing funding bodies established in the area of bio-based industries and of innovative medicines to limit the eligibility for funding to specific types of participants;

(c) the rules governing exploitation and dissemination of results, allowing funding bodies established in the area of innovative medicines to:

(i) extend the possibilities of transfer and licensing of results and background for affiliated entities, purchasers and any successor entity, in accordance with the grant agreement and without the consent of other participants referred to in Article 44(1) and (2);

(ii) allow for specific agreements for access rights to background for developing results for commercialisation or commercialising results themselves (direct exploitation) referred to in Article 48(2) to (4);

(iii) complement the rules by introducing provisions on ownership and access to data, knowledge and information which are outside of the objectives of an action and which are not needed for implementing and exploiting the action (sideground) referred to in Article 41(2) and Articles 45 to 48;

(iv) extend rules on exploitation to other purposes than implementing the action (research use) or developing results for commercialisation or commercialising results themselves (direct exploitation) referred to in Article 48;

(v) set out specific criteria for allowing sub-licensing from one participant to another participant in the same action referred to in Article 46(2);

(vi) extend, under the conditions defined in the consortium agreement referred to in Article 24(2), the access rights of participants, their affiliated entities and third parties as licensees to results or background for purposes other than implementing the action (research use) under appropriate conditions including financial terms, or developing results for commercialisation or commercialising results themselves (direct exploitation), as referred to in Articles 46 to 48;

(vii) make access rights for direct exploitation conditional upon the agreement of the participants concerned, as referred to in Article 48;

(viii) render optional the dissemination through scientific publication in the form of open access, as referred to in Article 43(2);

(d) the funding of the actions, allowing funding bodies in the area of electronic components and systems to apply reimbursement rates different to those set out in Article 28(3) in cases where one or more Member States co-fund a participant or an action.

A funding body entrusted with budget implementation tasks under points (i) or (ii) of point (c) of Article 58(1) of Regulation (EU, Euratom) No 966/2012, may apply rules which depart from those laid down in this Regulation, subject to the consent of the Commission, if its specific operating needs so require. The Commission shall give its consent in such cases only if those rules are in compliance with the general principles established in this Regulation.

4. This Regulation shall not apply to direct actions carried out by the Joint Research Centre (JRC).

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions apply:

(1) 'access rights' means rights to use results or background under the terms and conditions laid down in accordance with this Regulation;

(2) 'affiliated entity' means any legal entity that is under the direct or indirect control of a participant, or under the same direct or indirect control as the participant, or that is directly or indirectly controlling a participant. Control may take any of the forms set out in Article 8(2);

(3) 'associated country' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No 1291/2013;

(4) 'background' means any data, know-how or information whatever its form or nature, tangible or intangible, including any rights such as intellectual property rights, which is: (i) held by participants prior to their accession to the action; (ii) needed for carrying out the action or for exploiting the results of the action; and (iii) identified by the participants in accordance with Article 45;

(5) 'basic act' means a legal act adopted by the Union institutions in the form of a regulation, a directive or a decision within the meaning of Article 288 TFEU which provides a legal basis for the action;

(6) 'innovation action' means an action primarily consisting of activities directly aimed at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication;

(7) 'coordination and support action' means an action consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure, and may also include complementary activities of networking and coordination between programmes in different countries;

(8) 'dissemination' means the public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium;

(9) 'exploitation' means the use of results in further research activities other than those covered by the action concerned, or in developing, creating and marketing a product or process, or in creating and providing a service, or in standardisation activities;

(10) 'fair and reasonable conditions' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged;

(11) 'funding body' means a body or authority, other than the Commission, as referred to in point (c) of Article 58(1) of Regulation (EU, Euratom) No 966/2012, to which the Commission has entrusted budget implementation tasks in accordance with Article 9(2) of Regulation (EU) No 1291/2013;

(12) 'international European interest organisation' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe;

(13) 'legal entity' means any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations;

(14) 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members;

(15) 'participant' means any legal entity carrying out an action or part of an action under Regulation (EU) No 1291/2013 having rights and obligations with regard to the Union or another funding body under this Regulation;

(16) 'programme co-fund action' means an action funded through a grant the main purpose of which is supplementing individual calls or programmes funded by entities, other than Union funding bodies, managing research and innovation programmes. A programme co-fund action may also include complementary activities of networking and coordination between programmes in different countries;

(17) 'pre-commercial procurement' means the procurement of research and development services involving risk-benefit sharing under market conditions, and competitive development in phases, where there is a clear separation of the research and development services procured from the deployment of commercial volumes of end-products;

(18) 'public procurement of innovative solutions' means procurement where contracting authorities act as a launch customer for innovative goods or services which are not yet available on a large-scale commercial basis, and may include conformity testing;

(19) 'results' means any tangible or intangible output of the action, such as data, knowledge or information, that is generated in the action, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights;

(20) 'SME' means micro-, small- and medium-sized enterprises, as defined in Commission Recommendation 2003/361/EC ([1]);

(21) 'work programme' means the document adopted by the Commission for the implementation of the specific programme in accordance with Article 5 of Council Decision 2013/743/EU of 3 December 2013 ([2]);

(22) 'work plan' means the document similar to the Commission work programme adopted by funding bodies entrusted with part of the implementation of Horizon 2020 in accordance with Article 9(2) of Regulation (EU) No 1291/2013.

([1]) Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

([2]) Council Decision 2013/743/EU of 11 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014 - 2020) (See page 965 of this Official Journal).

2. For the purposes of this Regulation, an entity which does not have legal personality under the applicable national law shall be considered as being assimilated to a legal entity provided that the conditions set out in Article 131(2) of Regulation (EU, Euratom) No 966/2012 and Article 198 of Regulation (EU) No 1268/2012 are complied with.

3. For the purposes of this Regulation, grant recipients shall not be considered to be funding bodies.

Article 3

Confidentiality

Subject to the conditions established in the implementing agreements, decisions or contracts, any data, knowledge and information communicated as confidential in the framework of an action shall be kept confidential, taking due account of Union law regarding the protection of and access to classified information.

Article 4

Information to be made available

1. Without prejudice to Article 3, the Commission shall, upon request, make available to the Union institutions, bodies, offices or agencies, any Member State or associated country, any useful information in its possession concerning results generated by a participant in an action that has received Union funding, provided that both the following conditions are met:

(a) the information concerned is relevant to public policy;

(b) the participants have not provided sound and sufficient reasons for withholding the information concerned.

In actions under the specific objective 'Secure societies - Protecting freedom and security of Europe and its citizens', the Commission shall upon request make available to Union institutions, bodies, offices or agencies or to Member States' national authorities any useful information in its possession concerning results generated by a participant in an action that has received Union funding. The Commission shall notify the participant of such communication. Where a Member State or Union institution, body, office or agency requests the communication of information, the Commission shall also notify such communication to all Member States.

2. The provision of information pursuant to paragraph 1 shall not be deemed to transfer to the recipient any rights or obligations of the Commission or of the participants. However, the recipient shall treat any such information as confidential unless it becomes public or is made available publicly by the participants, or unless it was communicated to the Commission without restrictions concerning confidentiality. The Commission rules on security shall apply regarding classified information.

Article 5

Guidance and information for potential participants

In accordance with Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012, the Commission or the relevant funding body shall ensure that sufficient guidance and information is made available to all potential participants at the time of publication of the call for proposals, in particular the applicable model grant agreement.

TITLE II

RULES FOR PARTICIPATION

CHAPTER I

General provisions

Article 6

Forms of funding

In accordance with Article 10 of Regulation (EU) No 1291/2013, funding may take one or several of the forms provided for by Regulation (EU, Euratom) No 966/2012, in particular grants, prizes, procurement or financial instruments.

Article 7

Legal entities that may participate in actions

1. Any legal entity, regardless of its place of establishment, or international organisation may participate in an action provided that the conditions laid down in this Regulation have been met, together with any conditions laid down in the relevant work programme or work plan.

2. The relevant work programme may restrict the participation in Horizon 2020 or parts thereof of legal entities established in third countries where conditions for the participation of legal entities from Member States, or of their affiliated entities established in a third country, in the third country's research and innovation programmes are considered to be prejudicial to the Union's interests.

3. The relevant work programme or work plan may exclude entities unable to provide satisfactory security guarantees, including as regards personnel security clearance if justified by security reasons.

4. The JRC may participate in actions with the same rights and obligations as a legal entity established in a Member State.

Article 8

Independence

1. Two legal entities shall be regarded as independent of each other where neither is under the direct or indirect control of the other or under the same direct or indirect control as the other.

2. For the purposes of paragraph 1, control may, in particular, take either of the following forms:

(a) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;

(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

3. For the purposes of paragraph 1, the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50 % of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;

(b) the legal entities concerned are owned or supervised by the same public body.

CHAPTER II

Grants

Section I

Award procedure

Article 9

Conditions for participation

1. The following minimum conditions shall apply:

(a) at least three legal entities shall participate in an action;

(b) three legal entities shall each be established in a different Member State or associated country; and

(c) the three legal entities referred to in point (b) shall be independent of each other within the meaning of Article 8.

2. For the purposes of paragraph 1, where one of the participants is the JRC, or an international European interest organisation or an entity created under Union law, it shall be deemed to be established in a Member State or associated country other than any Member State or associated country in which another participant in the same action is established.

3. By way of derogation from paragraph 1, the minimum condition shall be the participation of one legal entity established in a Member State or associated country, in the case of:

(a) European Research Council (ERC) frontier research actions;

(b) the SME instrument, where the action has a clear European added value;

(c) programme co-fund actions; and

(d) justified cases provided for in the work programme or work plan.

4. By way of derogation from paragraph 1, in the case of coordination and support actions and training and mobility actions, the minimum condition shall be the participation of one legal entity.

5. Where appropriate and duly justified, work programmes or work plans may provide for additional conditions according to specific policy requirements or to the nature and objectives of the action, including inter alia conditions regarding the number of participants, the type of participant and the place of establishment.

Article 10

Eligibility for funding

1. The following participants are eligible for funding from the Union:

(a) any legal entity established in a Member State or associated country, or created under Union law;

(b) any international European interest organisation;

(c) any legal entity established in a third country identified in the work programme.

2. In the case of a participating international organisation or in the case of a participating legal entity established in a third country, neither of which are eligible for funding according to paragraph 1, funding from the Union may be granted provided that at least one of the following conditions is fulfilled:

(a) the participation is deemed essential for carrying out the action by the Commission or the relevant funding body;

(b) such funding is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and the international organisation or, for entities established in third countries, the country in which the legal entity is established.

Article 11

Calls for proposals

1. Calls for proposals shall be issued in accordance with Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/12, taking account in particular of the need for transparency and non-discrimination, and for flexibility appropriate to the diverse nature of the research and innovation sectors.

2. As an exception and without prejudice to the other cases provided for in Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012, calls for proposals shall not be issued for coordination and support actions and programme co-fund actions to be carried out by legal entities identified in the work programmes or work plans provided that the action does not fall within the scope of a call for proposals.

3. In accordance with the relevant rules of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012, sufficient time periods for preparing proposals shall be provided, with reasonable notice of upcoming calls for proposals through the publication of a work programme and a reasonable time period between the publication of a call for proposals and the deadline for submitting a proposal.

Article 12

Joint calls with third countries or with international organisations

1. Joint calls for proposals with third countries or their scientific and technological organisations and agencies or with international organisations may be issued to jointly fund actions in priority areas of common interest and expected mutual benefit where there is a clear added value for the Union. Proposals shall be evaluated and selected through joint evaluation and selection procedures to be agreed upon. Such evaluation and selection procedures shall ensure compliance with the principles set out in Title VI of Regulation (EU, Euratom) No 966/2012 and involve a balanced group of independent experts appointed by each party.

2. Legal entities receiving funding from the Union shall conclude a grant agreement with the Union or the relevant funding body. That grant agreement shall include a description of the work to be done by those participants and by the participating legal entities from the third countries involved.

3. Legal entities receiving funding from the Union shall conclude a coordination agreement with the participating legal entities receiving funding from the relevant third countries or international organisations.

Article 13

Proposals

1. Proposals shall include a draft plan for the exploitation and dissemination of the results, where provided for in the work programme or work plan.

2. Any proposal for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States concerned as well as details of the ethical approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States concerned.

3. A proposal which contravenes ethical principles or any applicable legislation, or which does not fulfil the conditions set out in Decision No 2013/743/EU, in the work programme, in the work plan or in the call for proposals may be excluded from the evaluation, selection and award procedures at any time.

4. Where relevant and specified in the work programme or the work plan, proposals shall explain how and to what extent gender analysis is relevant to the content of the intended project.

Article 14

Ethics review

1. The Commission shall systematically carry out ethics reviews for proposals raising ethical issues. That review shall verify the respect of ethical principles and legislation and, in the case of research carried out outside the Union, that the same research would have been allowed in a Member State.

2. The Commission shall make the process of the ethics review as transparent as possible and ensure that it is carried out in a timely manner avoiding, where possible, the resubmission of documents.

Article 15

Selection and award criteria

1. The proposals submitted shall be evaluated on the basis of the following award criteria:

(a) excellence;

(b) impact;

(c) quality and efficiency of the implementation.

2. Only the criterion referred to in point (a) of paragraph 1 shall apply to proposals for ERC frontier research actions.

3. The criterion referred to in point (b) of paragraph 1 may be given a higher weighting for proposals for innovation actions.

4. The work programme or work plan shall lay down further details of the application of the award criteria laid down in paragraph 1, and specify weightings and thresholds.

5. The Commission shall take into account the possibility of a two-stage submission procedure provided for in Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012, where appropriate and consistent with the objectives of the call for proposals.

6. Proposals shall be ranked according to the evaluation results. The selection shall be made on the basis of that ranking.

7. The evaluation shall be carried out by independent experts.

8. In the case of a legal entity referred to in Article 11(2) or in other duly justified exceptional circumstances, the evaluation may be carried out in a manner derogating from paragraph 7. In each case of such evaluation the Commission shall provide the Member States with detailed information on the evaluation procedure used and its outcome.

9. In cases where the requested funding from the Union for the action is equal or superior to EUR 500 000, the Commission or the relevant funding body shall, by means compatible with national law, verify in advance the financial capacity of only the coordinators. Furthermore, whenever there are grounds to doubt the financial capacity of the coordinator or other participants on the basis of available information, the Commission or the relevant funding body shall verify their financial capacity.

10. The financial capacity shall not be verified either in respect of legal entities whose viability is guaranteed by a Member State or an associated country or in respect of higher and secondary education establishments.

11. Financial capacity may be guaranteed by any other legal entity, whose financial capacity shall in turn be verified in accordance with paragraph 9.

Article 16

Evaluation review procedure

1. The Commission or the relevant funding body shall provide a transparent evaluation review procedure for applicants which consider that the evaluation of their proposal has not been carried out in accordance with the procedures set out in this Regulation, the relevant work programme, work plan or the call for proposals.

2. A request for review shall relate to a specific proposal, and shall be submitted by the coordinator of the proposal within 30 days of the date on which the Commission or the relevant funding body informs the coordinator of the evaluation results.

3. The Commission or the relevant funding body shall be responsible for the examination of the request referred to in paragraph 2. The examination shall cover only the procedural aspects of the evaluation, and not the merits of the proposal.

4. An evaluation review committee composed of Commission staff or of staff of the relevant funding body shall provide an opinion on the procedural aspects of the evaluation process. It shall be chaired by an official of the Commission or of the relevant funding body, from a department other than that responsible for the call for proposals. The committee may recommend one of the following:

(a) re-evaluation of the proposal primarily by evaluators not involved in the previous evaluation;

(b) confirmation of the initial evaluation.

5. On the basis of the recommendation referred to in paragraph 4, a decision shall be taken by the Commission or the relevant funding body and notified to the coordinator of the proposal. The Commission or the relevant funding body shall take such decision without undue delay.

6. The review procedure shall not delay the selection process of proposals which are not the subject of requests for review.

7. The review procedure shall not preclude any other actions the participant may take in accordance with Union law.

Article 17

Enquiries and complaints

1. The Commission shall ensure the existence of a procedure for participants to make enquiries or complaints about their involvement in Horizon 2020.

2. The Commission shall ensure that information on how to register concerns, enquiries or complaints is made available to all participants and is published on-line.

Article 18

Grant agreement

1. The Commission shall, in close cooperation with the Member States, draw up model grant agreements between the Commission or the relevant funding body and the participants in accordance with this Regulation. If a significant modification of a model grant agreement is required, the Commission shall, in close cooperation with the Member States, revise it as appropriate.

2. The Commission or the relevant funding body shall enter into a grant agreement with the participants. The removal or substitution of an entity before signature of the grant agreement shall be duly justified.

3. The grant agreement shall establish the rights and obligations of the participants and of either the Commission or the relevant funding body in compliance with this Regulation. It shall also establish the rights and obligations of legal entities which become participants during the implementation of the action, as well as the role and tasks of a consortium coordinator.

4. On the basis of a requirement in a work programme or work plan, the grant agreement may establish rights and obligations of the participants with regard to access rights, exploitation and dissemination, in addition to those laid down in this Regulation.

5. The grant agreement shall, where appropriate and to the extent possible, reflect the general principles laid down in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, principles of research integrity, the Commission Recommendation on the management of intellectual property in knowledge transfer activities, the Code of Practice for universities and other public research institutions as well as the gender equality principle laid down in Article 16 of Regulation (EU) No 1291/2013.

6. The grant agreement shall, where appropriate, contain provisions ensuring the respect of ethical principles, including the establishment of an independent ethics board and the right of the Commission to carry out an ethics audit by independent experts.

7. In duly justified cases, specific grants for actions may form part of a framework partnership in accordance with Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012.

Article 19

Grant decisions

Where appropriate, and in duly justified cases, the Commission, in accordance with Article 121(1) of Regulation (EU, Euratom) No 966/2012, or the relevant funding body, may notify grant decisions instead of entering into grant agreements. The provisions of this Regulation referring to grant agreements shall apply mutatis mutandis.

Article 20

Time to grant

1. In accordance with Article 128(2) of Regulation (EU, Euratom) No 966/2012, calls for proposals shall specify the planned date by which all applicants shall be informed of the outcome of the evaluation of their application and the indicative date for the signature of grant agreements or the notification of grant decisions.

2. The dates referred to in paragraph 1 shall be based on the following periods:

(a) for informing all applicants of the outcome of the scientific evaluation of their application, a maximum period of five months from the final date for submission of complete proposals;

(b) for signing grant agreements with applicants or notifying grant decisions to them, a maximum period of three months from the date of informing applicants they have been successful.

3. The periods referred to in paragraph 2 may be exceeded for actions of the ERC and in exceptional, duly justified cases, in particular where actions are complex, where there is a large number of proposals or where requested by the applicants.

4. Participants shall be given reasonable time to submit the information and documentation required for the signature of the grant agreement. The Commission shall make decisions and requests for information as promptly as possible. Where possible, resubmission of documents shall be avoided.

Article 21

Time to Pay

Participants shall be paid in a timely manner in accordance with Regulation (EU, Euratom) No 966/2012. When a payment has been made to the coordinator, the Commission or the relevant funding body shall notify the participants thereof.

Article 22

Secure electronic system

All exchanges with participants, including the conclusion of grant agreements, the notification of grant decisions and any amendments thereto, may be made through an electronic exchange system set up by the Commission or by the relevant funding body, as stipulated in Article 179 of Regulation (EU) No 1268/2012.

Section II

Implementation

Article 23

Implementation of actions

1. Participants shall implement actions in compliance with all the conditions and obligations set out in this Regulation, Regulation (EU, Euratom) No 966/2012, Regulation (EU) No 1268/2012, Decision 2013/743/EU, the work programme or work plan, the call for proposals and the grant agreement.

2. Participants shall make no commitments which are incompatible with this Regulation or the grant agreement. Where a participant fails to comply with its obligations regarding the technical implementation of the action, the other participants shall comply with the obligations without any additional Union funding unless the Commission or the relevant funding body expressly relieves them of that obligation. In the event of a participant defaulting, the Commission may, in accordance with point (a) of Article 39(3) transfer the amount due from the Participant Guarantee Fund referred to in Article 38 to the coordinator of the action. The financial responsibility of each participant shall be limited to its own debt subject to the provisions relating to the Participant Guarantee Fund. Participants shall ensure that the Commission or the relevant funding body is informed in due time of any event which might significantly affect the implementation of the action or the interests of the Union.

3. Participants shall implement the action and shall take all necessary and reasonable measures to that end. They shall have the appropriate resources as and when needed for carrying out the action. Where it is necessary for the implementation of the action, they may call upon third parties, including subcontractors, to carry out work under the action or may use resources made available by third parties by means of contributions in kind, according to the conditions set out in the grant agreement. Participants shall retain responsibility towards the Commission or the relevant funding body and towards the other participants for the work carried out.

4. The award of subcontracts for carrying out certain elements of the action shall be limited to the cases provided for in the grant agreement and to duly justified cases that could not be clearly foreseen at the time of entry into force of the grant agreement.

5. Third parties other than subcontractors may carry out work under the action under the conditions laid down in the grant agreement. The third party and the work to be carried out by it shall be identified in the grant agreement.

Costs incurred by those third parties may be deemed eligible if the third party meets all the following conditions:

(a) it would be eligible for funding if it were a participant;

(b) it is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action;

(c) it is identified in the grant agreement;

(d) it abides by the rules applicable to the participant under the grant agreement with regard to eligibility of costs and control of expenditure;

(e) it accepts joint and several liability with the participant for the Union contribution corresponding to the amount declared by the third party, if required by the Commission or the relevant funding body.

6. Third parties may also make available resources to a participant by means of contributions in kind to the action. Costs incurred by third parties in relation to such contributions which are made free of charge are eligible for funding provided they meet the conditions established in the grant agreement.

7. The action may involve financial support to third parties under the conditions established in Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012. The amounts referred to in point (c) of Article 137(1) of Regulation (EU, Euratom) No 966/2012 may be exceeded where it is necessary to achieve the objectives of an action.

8. The action carried out by participants which are contracting authorities within the meaning of Directive 2004/17/EC of the European Parliament and of the Council ([1]), Directive 2004/18/EC of the European Parliament and of the Council ([2]) and Directive 2009/81/EC of the European Parliament and of the Council ([3]) may involve or have as their primary aim the pre-commercial procurement and procurement of innovative solutions, where provided for in a work programme or a work plan and required for its implementation. In such cases, the rules set out in Article 51(2), (4) and (5) of this Regulation shall apply to the procurement procedures carried out by the participants.

9. Participants shall comply with national legislation, regulations and ethical rules in the countries where the action will be carried out. Where appropriate, participants shall seek the approval of the relevant national or local ethics committees prior to the start of the action.

10. Work using animals shall be carried out in accordance with Article 13 TFEU and shall comply with the requirement to replace, reduce and refine the use of animals for scientific purposes in accordance with Union law and in particular with Directive 2010/63/EU of the European Parliament and of the Council ([4]).

Article 24

Consortium

1. The members of any consortium wishing to participate in an action shall appoint one of them to act as coordinator, which shall be identified in the grant agreement. The coordinator shall be the principal point of contact between the members of the consortium in relations with the Commission or the relevant funding body, unless specified otherwise in the grant agreement, or in the event of non-compliance with its obligations under the grant agreement.

2. The members of a consortium participating in an action shall conclude an internal agreement ("the consortium agreement") establishing their rights and obligations with respect to the implementation of the action in compliance with the grant agreement, except in duly justified cases provided for in the work programme or work plan or call for proposals. The Commission shall publish guidelines on the main issues that may be addressed by participants in the consortium agreement.

3. The consortium agreement may stipulate inter alia the following:

(a) the internal organisation of the consortium;

(b) the distribution of the Union funding;

(c) rules on dissemination, use and access rights, additional to those in Title III, Chapter I of this Regulation, and to the provisions in the grant agreement;

(d) arrangements for settling internal disputes;

(e) liability, indemnification and confidentiality arrangements between the participants.

([1]) Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1).

([2]) Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (OJ L 134, 30.4.2004, p. 114).

([3]) Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC (OJ L 216, 20.8.2009, p. 76).

([4]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

The members of the consortium may make any arrangements in the consortium they deem fit to the extent that those arrangements are not in conflict with the grant agreement or this Regulation.

4. The consortium may propose to add or remove a participant or change the coordinator in accordance with the relevant provisions of the grant agreement, provided that the change is in conformity with the conditions for participation, does not adversely affect the implementation of the action and is not contrary to the principle of equal treatment.

Section III

Forms of grants and funding rules

Article 25

Forms of grants

Grants may take any of the forms provided for in Article 123 of Regulation (EU, Euratom) No 966/2012, taking into account the objectives of the action.

Article 26

Eligibility of costs

1. Conditions for eligibility of costs are defined in Article 126 of Regulation (EU, Euratom) No 966/2012. Costs incurred by third parties under the action may be eligible according to the provisions of this Regulation and of the grant agreement.

2. Ineligible costs are those not complying with the conditions of paragraph 1, including, in particular, provisions for possible future losses or charges, exchange losses, costs related to return on capital, costs reimbursed in respect of another Union action or programme, debt and debt service charges and excessive or reckless expenditure.

Article 27

Direct eligible personnel costs

1. Without prejudice to the conditions laid down in Article 26, direct eligible personnel costs shall be limited to salaries plus social security charges and other costs included in the remuneration of personnel assigned to the action, arising from national law or from the employment contract.

2. Without prejudice to the conditions laid down in Article 26, additional remuneration to personnel of participants that are non-profit legal entities assigned to the action, including payments on the basis of supplementary contracts regardless of their nature, may also be considered as direct eligible personnel costs, up to the amount set out in paragraph 3, if they fulfil the following additional conditions:

(a) it is part of the usual remuneration practices of the participant and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and of general application by the participant, independent of the source of funding used.

3. Additional remuneration may be eligible up to EUR 8 000 per year and per person. In relation to a person not working exclusively for the action, a limit per hour shall apply. The limit per hour shall be calculated by dividing EUR 8 000 by the number of annual productive hours calculated in accordance with Article 31.

Article 28

Funding of the action

1. The funding of an action shall not exceed the total eligible costs minus the receipts of the action.

2. The following shall be considered as receipts of the action:

(a) resources made available by third parties to the participants by means of financial transfers or contributions in kind free of charge, the value of which has been declared as eligible costs by the participant, provided that they have been contributed by the third party specifically to be used in the action;

(b) income generated by the action, except income generated by the exploitation of the results of the action;

(c) income generated from the sale of assets purchased under the grant agreement up to the value of the cost initially charged to the action by the participant.

3. A single reimbursement rate of the eligible costs shall be applied per action for all activities funded therein. The maximum rate shall be fixed in the work programme or work plan.

4. The Horizon 2020 grant may reach a maximum of 100 % of the total eligible costs, without prejudice to the co-financing principle.

5. The Horizon 2020 grant shall be limited to a maximum of 70 % of the total eligible costs for innovation actions and programme co-fund actions.

By way of derogation from paragraph 3, the Horizon 2020 grant may, for innovation actions, reach a maximum of 100 % of the total eligible costs for non-profit legal entities, without prejudice to the co-financing principle.

6. The reimbursement rates determined in this Article shall also apply in the case of actions where flat rate, unit or lump-sum financing is fixed for the whole or part of the action.

Article 29

Indirect costs

1. Indirect eligible costs shall be determined by applying a flat rate of 25 % of the total direct eligible costs, excluding direct eligible costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the beneficiary, as well as financial support to third parties.

2. By way of derogation from paragraph 1, indirect costs may be declared in the form of a lump sum or unit costs when provided for in the work programme or work plan.

Article 30

Evaluation of the funding levels

The interim evaluation of Horizon 2020 shall include an evaluation of the impact of the various features introduced by the new funding levels laid down in Articles 27, 28 and 29 of this Regulation, with the aim of evaluating whether the new approach has led to undesired situations adversely affecting the attractiveness of Horizon 2020.

Article 31

Annual productive hours

1. Eligible personnel costs shall cover only the actual hours worked by the persons directly carrying out work under the action. Evidence regarding the actual hours worked shall be provided by the participant, usually through a time recording system.

2. For persons working exclusively for the action, no time recording is required. In such cases, the participant shall sign a declaration confirming that the person concerned has worked exclusively for the action.

3. The grant agreement shall contain:

(a) the minimum requirements for the time recording system;

(b) the option to choose between a fixed number of annual productive hours and the method for establishing the number of annual productive hours to be used for the calculation of the hourly personnel rates, taking account of the participant's usual accounting practices.

Article 32

Owners of SMEs and natural persons without a salary

The owners of SMEs who do not receive a salary, and other natural persons who do not receive a salary, may charge personnel costs on the basis of a unit cost.

Article 33

Unit costs

1. In accordance with Article 124 of Regulation (EU, Euratom) No 966/2012, the Commission may establish methods to determine unit costs based on:

(a) statistical data or similar objective means;

(b) auditable historical data of the participant.

2. Direct eligible personnel costs may be financed on the basis of unit costs determined according to the participant's usual cost accounting practices, provided that they comply with the following cumulative criteria:

(a) they are calculated on the basis of the total actual personnel costs recorded in the participant's general accounts which may be adjusted by the participant on the basis of budgeted or estimated elements according to the conditions defined by the Commission;

(b) they comply with Articles 26 and 27;

(c) they ensure compliance with the non-profit requirement and the avoidance of double funding of costs;

(d) they are calculated with due regard to Article 31.

Article 34

Certificate on the financial statements

The certificate on the financial statements shall cover the total amount of the grant claimed by a participant under the form of reimbursement of actual costs and under the form of unit costs referred to in Article 33(2), excluding the amounts declared on the basis of lump sums, flat rates and unit costs other than those determined according to the participant's usual cost accounting practices. The certificate shall be submitted only when that amount is equal to or greater than EUR 325 000 at the time of claiming the payment of the balance of the grant.

Article 35

Certificate on the methodology

1. Participants that calculate and claim direct personnel costs on the basis of unit costs in accordance with Article 33(2) may submit to the Commission a certificate on the methodology. That methodology shall comply with the conditions set out in Article 33(2) and meet the requirements of the grant agreement.

2. Where the Commission accepts a certificate on the methodology, it shall be valid for all actions financed under Regulation (EU) No 1291/2013 and the participant shall calculate and claim costs on the basis of it. Once the Commission has accepted a certificate on the methodology, it shall not attribute any systemic or recurrent error to the accepted methodology.

Article 36

Certifying auditors

1. The certificates on the financial statements and on the methodology referred to in Articles 34 and 35 shall be established by an independent auditor qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council [1] or similar national regulations, or by a competent and independent public officer in whom the relevant national authorities have vested the legal capacity to audit the participant and who has not been involved in the preparation of the financial statements.

2. Upon request by the Commission, the Court of Auditors or the European Anti-fraud Office (OLAF), the auditor who delivers the certificate on the financial statements and on the methodology shall grant access to the supporting documents and audit working papers on the basis of which a certificate on the financial statements or on the methodology was issued.

Article 37

Cumulative funding

An action for which a grant from the Union budget has been awarded may also give rise to the award of a grant on the basis of Regulation (EU) No 1291/2013, provided that the grants do not cover the same cost items.

Section IV

Guarantees

Article 38

Participant Guarantee Fund

1. A participant guarantee fund (the "Fund") is hereby established and shall cover the risk associated with non-recovery of sums due to the Union under actions financed through grants by the Commission under Decision No 1982/2006/EC and by the Commission or Union funding bodies under "Horizon 2020" according to the rules set out in this Regulation. The Fund shall replace and succeed the Participant Guarantee Fund set up under Regulation (EC) No 1906/2006.

2. The Fund shall be operated in accordance with Article 39. Any financial interest generated by the Fund shall be added to the Fund and shall serve exclusively for the purposes set out in Article 39(3).

3. Where interest is insufficient to cover the operations described in Article 39(3), the Fund shall not intervene and the Commission or the relevant Union funding body shall recover directly from participants or third parties any amount owed.

4. The Fund shall be considered a sufficient guarantee under Regulation (EU, Euratom) No 966/2012. No additional guarantee or security may be accepted from participants or imposed upon them except in the case described in paragraph 3 of this Article.

5. Participants in actions under Horizon 2020 whose risk is covered by the Fund shall make a contribution of 5 % of the Union funding for the action. At the end of the action the amount contributed to the Fund shall be returned to the participants, via the coordinator.

6. The rate of the participants' contribution to the Fund set out in paragraph 5 may be reduced on the basis of the interim evaluation of Horizon 2020.

Article 39

Operation of the Fund

1. The Fund shall be managed by the Union, represented by the Commission acting as executive agent on behalf of the participants, in accordance with the conditions established by the grant agreement.

The Commission may manage the Fund directly or entrust the financial management of the Fund either to the European Investment Bank or to an appropriate financial institution ("the depository bank"). The depository bank shall manage the Fund pursuant to the instructions of the Commission.

2. The participants' contribution to the Fund may be offset from the initial pre-financing and be paid to the Fund on behalf of the participants.

3. Where amounts are due to the Union by a participant, the Commission may, without prejudice to penalties which may be imposed on the defaulting participant, take either of the following actions:

[1] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

(a) transfer, or order the depository bank to transfer, directly the amount due from the Fund to the coordinator of the action. That transfer shall be made after the termination or withdrawal of the participation of the defaulting participant if the action is still ongoing and if the remaining participants agree to implement it according to the same objectives. Amounts transferred from the Fund shall be regarded as Union funding;

(b) recover effectively that amount from the Fund.

The Commission shall issue a recovery order against that participant or third party to the benefit of the Fund. The Commission may adopt to that end a recovery decision in accordance with Regulation (EU, Euratom) No 966/2012.

4. The amounts recovered shall constitute revenue assigned to the Fund within the meaning of Article 21(4) of Regulation (EU, Euratom) No 966/2012. Once the implementation of all grants whose risk is covered by the Fund is complete, any sums outstanding shall be recovered by the Commission and entered into the budget of the Union, subject to decisions of the legislative authority.

CHAPTER III

Experts

Article 40

Appointment of independent experts

1. The Commission and, where appropriate, funding bodies may appoint independent experts to evaluate proposals in accordance with Article 15 or to advise on or assist with:

(a) the evaluation of proposals;

(b) the monitoring of the implementation of actions carried out under Regulation (EU) No 1291/2013 as well as of previous Research and/or Innovation Programmes;

(c) the implementation of Union research and innovation policy or programmes including Horizon 2020, as well as the achievement and functioning of the European Research Area;

(d) the evaluation of Research and Innovation Programmes;

(e) the design of the Union research and innovation policy, including the preparation of future programmes.

2. Independent experts shall be chosen on the basis of their skills, experience and knowledge appropriate to carry out the tasks assigned to them. In cases where independent experts have to deal with classified information, the appropriate security clearance shall be required before appointment.

Independent experts shall be identified and selected on the basis of calls for applications from individuals and calls addressed to relevant organisations such as research agencies, research institutions, universities, standardisation organisations, civil society organisations or enterprises with a view to establishing a database of candidates.

The Commission or the relevant funding body may, if deemed appropriate and in duly justified cases, select in a transparent manner any individual expert with the appropriate skills not included in the database.

When appointing independent experts, the Commission or the relevant funding body shall take appropriate measures to seek a balanced composition within the expert groups and evaluation panels in terms of various skills, experience, knowledge, geographical diversity and gender, and taking into account the situation in the field of the action. Where appropriate, private-public sector balance shall also be sought.

The Commission or the relevant funding body may call upon the advice of advisory bodies for the appointment of independent experts. In the case of ERC frontier research actions, the Commission shall appoint experts on the basis of a proposal from the Scientific Council of the ERC.

3. The Commission or the relevant funding body shall ensure that an expert faced with a conflict of interest in relation to a matter on which the expert is required to provide an opinion does not evaluate, advise or assist on the specific matter in question.

4. All exchanges with independent experts, including the conclusion of contracts for their appointment and any amendment thereto, may be done through electronic exchange systems set up by the Commission or by the relevant funding body as stipulated in Article 287(4) of Regulation (EU) No. 1268/2012.

5. The names of experts appointed in a personal capacity, who have assisted the Commission or the funding bodies in implementation of Regulation (EU) No 1291/2013 and Decision 2013/743/EU shall be published, together with their area of expertise, at least once a year on the internet site of the Commission or the relevant funding body. Such information shall be collected, processed and published in accordance with Regulation (EC) No 45/2001.

TITLE III

RULES GOVERNING THE EXPLOITATION AND DISSEMINATION OF RESULTS

CHAPTER I

Grants

Section I

Results

Article 41

Ownership of results

1. Results shall be owned by the participant generating them.

2. Where participants in an action have jointly generated results, and where their respective contribution to the joint results cannot be ascertained, or where it is not possible to separate such joint results for the purpose of applying for, obtaining or maintaining the relevant intellectual property rights protection, they shall have joint ownership of those results. The joint owners shall establish an agreement regarding the allocation and terms of exercise of that joint ownership in accordance with their obligations under the grant agreement. The joint owners may agree not to continue with joint ownership but decide on an alternative regime, inter alia by transferring their ownership shares to a single owner with access rights for the other participants, once the results have been generated.

Unless otherwise agreed in the joint ownership agreement, each joint owner shall be entitled to grant non-exclusive licences to third parties to exploit the jointly owned results, without any right to sub-license, subject to the following conditions:

(a) prior notice shall be given to the other joint owners;

(b) fair and reasonable compensation shall be provided to the other joint owners.

3. If employees or any party working for a participant are entitled to claim rights to the results generated, the participant concerned shall ensure that it is possible for those rights to be exercised in a manner compatible with its obligations under the grant agreement.

Article 42

Protection of results

1. Where results are capable of or may reasonably be expected to be capable of commercial or industrial exploitation, the participant owning those results shall examine the possibility of protecting them. The participant shall, if possible, reasonable and justified given the circumstances, adequately protect them for an appropriate period of time and with an appropriate territorial coverage, having due regard to its legitimate interests, and the legitimate interests, particularly the commercial interests, of the other participants in the action.

2. Where a participant that has received Union funding intends not to protect results generated by it for reasons other than impossibility under Union or national law or the lack of potential for commercial or industrial exploitation, and unless the participant intends to transfer them to another legal entity established in a Member State or associated country in view of their protection, it shall inform the Commission or the relevant funding body before any dissemination relating to those results takes place. The Commission, on behalf of the Union, or the relevant funding body may, with the consent of the participant concerned, assume ownership of those results and take the necessary steps for their adequate protection.

The participant may refuse consent only if it demonstrates that its legitimate interests would suffer significant harm. No dissemination relating to those results may take place until the Commission or the relevant funding body has taken a decision not to assume ownership of the results or has decided that it will assume ownership and has taken the necessary steps to ensure their protection. The Commission or the relevant funding body shall make such decision without undue delay. The grant agreement shall lay down time-limits in this respect.

3. Where a participant that has received Union funding intends to abandon the protection of results or intends not to seek the extension of such protection for reasons other than the lack of potential for commercial or industrial exploitation within a period that shall not exceed five years following the payment of the balance, it shall inform the Commission or the relevant funding body, which may continue or extend protection by assuming ownership thereof. The participant may refuse consent only if it demonstrates that its legitimate interests would suffer significant harm. The grant agreement shall lay down time-limits in this respect.

Article 43

Exploitation and dissemination of results

1. Each participant that has received Union funding shall use its best efforts to exploit the results it owns, or to have them exploited by another legal entity, in particular through the transfer and licensing of results in accordance with Article 44.

Any additional exploitation obligations shall be laid down in the grant agreement. In the case of research with the potential to address major societal challenges, additional exploitation obligations may include licensing on non-exclusive terms. Any such additional obligations shall be indicated in the work programme or work plan.

2. Subject to any restrictions due to the protection of intellectual property, security rules or legitimate interests, each participant shall through appropriate means disseminate the results it owns as soon as possible. The grant agreement may lay down time-limits in this respect.

Any additional dissemination obligations shall be laid down in the grant agreement and indicated in the work programme or work plan.

With regard to the dissemination of results through scientific publications, open access shall apply under the terms and conditions laid down in the grant agreement. Costs relating to open access to scientific publications that result from research funded under Horizon 2020, incurred within the duration of an action, shall be eligible for reimbursement under the conditions of the grant agreement. With due regard to Article 18 of Regulation (EU) No 1291/2013, the grant agreement shall not stipulate conditions regarding open access to publications which would result in additional publishing costs after the completion of an action.

With regard to the dissemination of research data, the grant agreement may, in the context of the open access to and the preservation of research data, lay down terms and conditions under which open access to such results shall be provided, in particular in ERC frontier research and FET (Future and Emerging Technologies) research or in other appropriate areas, and taking into consideration the legitimate interests of the participants and any constraints pertaining to data protection rules, security rules or intellectual property rights. In such cases, the work programme or work plan shall indicate if the dissemination of research data through open access is required.

Prior notice of any dissemination activity shall be given to the other participants. Following notification, a participant may object if it demonstrates that its legitimate interests in relation to its results or background would suffer significant harm by the intended dissemination. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard those legitimate interests. The grant agreement shall lay down time-limits in this respect.

3. For the purposes of monitoring and dissemination by the Commission or the relevant funding body, participants shall provide any information on their exploitation and dissemination related activities, and provide any documents necessary in accordance with the conditions laid down in the grant agreement. Subject to the legitimate interests of the participants which have provided the information, such information shall be made publicly available. The grant agreement shall, inter alia, lay down time-limits with respect to such reporting obligations.

4. All patent applications, standards, publications or any other dissemination, including those in electronic form, relating to results shall, if possible, include a statement, which may include visual means, that the action received financial support from the Union. The terms of that statement shall be established in the grant agreement.

Article 44

Transfer and licensing of results

1. Where a participant transfers ownership of results, it shall pass on its obligations under the grant agreement regarding those results to the transferee, including the obligation to pass them on in any subsequent transfer.

Without prejudice to confidentiality obligations arising from laws or regulations in the case of mergers and acquisitions, where other participants still enjoy access rights or may still request the granting of access rights to the results to be transferred, a participant which intends to transfer the results shall give prior notice to the other participants, together with sufficient information concerning the intended new owner of the results, to permit the other participants to analyse the effect of the intended transfer on the possible exercise of their access rights.

Following notification, a participant may object to the transfer of ownership if it demonstrates that the intended transfer would adversely affect the exercise of its access rights. In such a case, the transfer may not take place until agreement has been reached between the participants concerned. The grant agreement shall lay down time-limits in this respect.

The other participants may by prior written agreement waive their right to prior notice and to object to transfers of ownership from one participant to a specifically identified third party.

2. Provided that access rights to the results can be exercised, and that any additional exploitation obligations are complied with by the participant which owns the results, the latter may grant licences or otherwise grant the right to exploit them to any legal entity, including on an exclusive basis. Exclusive licences for results may be granted subject to consent by all the other participants concerned that they will waive their access rights thereto.

3. With regard to results which are generated by participants that have received Union funding, the grant agreement may provide that the Commission or the relevant funding body may object to transfers of ownership or to grants of an exclusive licence to third parties established in a third country not associated with Horizon 2020, if it considers that the grant or transfer is not in accordance with the interests of developing the competitiveness of the Union economy, or is inconsistent with ethical principles or security considerations.

In such cases, the transfer of ownership or grant of exclusive licence shall not take place unless the Commission or the relevant funding body is satisfied that appropriate safeguards will be put in place.

Where appropriate, the grant agreement shall provide that the Commission or the relevant funding body is to be notified in advance of any such transfer of ownership or grant of an exclusive licence. The grant agreement shall lay down time-limits in this respect.

Section II

Access rights to background and results

Article 45

Background

Participants shall identify the background for their action in any manner in a written agreement.

Article 46

Access rights principles

1. Any request to exercise access rights or any waiving of access rights shall be made in writing.

2. Unless otherwise agreed by the owner of the results or background to which access is requested, access rights shall not include the right to sub-license.

3. Participants in the same action shall inform each other before their accession to the grant agreement of any legal restriction or limit to granting access to their background. Any agreement concluded thereafter by a participant regarding background shall ensure that any access rights may be exercised.

4. The termination of the participation in an action shall not affect the obligation of such a participant to grant access under the terms and conditions established in the grant agreement.

5. The consortium agreement may stipulate that where a participant defaults on its obligations and such default is not remedied, such a defaulting participant shall no longer enjoy access rights.

Article 47

Access rights for implementation

1. A participant shall enjoy access rights to the results of another participant in the same action if those results are needed by the former to carry out its work under the action.

Such access shall be granted on a royalty-free basis.

2. A participant shall enjoy access rights to background of another participant in the same action if this background is needed by the former to carry out its work under the action, and subject to any restrictions or limits pursuant to Article 46(3).

Such access shall be granted on a royalty-free basis, unless otherwise agreed by the participants before their accession to the grant agreement.

Article 48

Access rights for exploitation

1. A participant shall enjoy access rights to the results of another participant in the same action if those results are needed by the former to exploit its own results.

Subject to agreement, such access shall be granted under fair and reasonable conditions.

2. A participant shall enjoy access rights to background of another participant in the same action if this background is needed by the former to exploit its own results, and subject to any restrictions or limits pursuant to Article 46(3).

Subject to agreement, such access shall be granted under fair and reasonable conditions.

3. An affiliated entity established in a Member State or associated country shall, unless otherwise provided for in the consortium agreement, also have access rights to results and, subject to any restrictions or limits pursuant to Article 46(3), to background under fair and reasonable conditions if those results and background are needed to exploit the results generated by the participant to which it is affiliated. Such access rights shall be requested and obtained directly from the participant owning the results or background unless otherwise agreed in accordance with Article 46(2).

4. A request for access under paragraphs 1, 2 or 3 may be made up to one year after the end of the action, unless the participants agree on a different time-limit.

Article 49

Access rights for the Union and the Member States

1. The Union institutions, bodies, offices or agencies shall, for the duly justified purpose of developing, implementing and monitoring Union policies or programmes, enjoy access rights solely to the results of a participant that has received Union funding. Such access rights are limited to non-commercial and non-competitive use.

Such access shall be granted on a royalty-free basis.

2. Regarding actions under the specific objective 'Secure societies - Protecting freedom and security of Europe and its citizens' set out in Part III of Annex I to Regulation (EU) No 1291/2013, Union institutions, bodies, offices and agencies, as well as Member States' national authorities, shall, for the purpose of developing, implementing and monitoring their policies or programmes in this area, enjoy the necessary access rights to the results of a participant that has received Union funding. Such access rights shall be limited to non-commercial and non-competitive use. Such access rights shall be granted on a royalty-free basis and upon bilateral agreement defining specific conditions aimed at ensuring that those rights will be used only for the intended purpose and that appropriate confidentiality obligations will be in place. Such access rights shall not extend to the participant's background. The requesting Member State, Union institution, body, office or agency shall notify all Member States of such requests. The Commission rules on security shall apply regarding classified information.

TITLE IV

SPECIFIC PROVISIONS

Article 50

Prizes

1. Union funding may take the form of prizes as defined in Title VII of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012.

2. Any prize awarded shall be conditional upon the acceptance of the appropriate publicity obligations. Regarding the dissemination of results, Title III of this Regulation shall apply. The work programme or work plan may contain specific obligations regarding exploitation and dissemination.

Article 51

Procurement, pre-commercial procurement and public procurement of innovative solutions

1. Any procurement carried out by the Commission on its own behalf or jointly with Member States shall be subject to the rules on public procurement set out in Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No 1268/2012.

2. Union funding may take the form of pre-commercial procurement or the procurement of innovative solutions carried out by the Commission or the relevant funding body on its own behalf or jointly with contracting authorities from Member States and associated countries.

The procurement procedures:

(a) shall comply with the principles of transparency, non-discrimination, equal treatment, sound financial management, proportionality, with competition rules and, where applicable, with Directives 2004/17/EC, 2004/18/EC and 2009/81/EC, or, where the Commission acts on its own behalf, with Regulation (EU, Euratom) No 966/2012;

(b) may provide for specific conditions such as the place of performance of the procured activities being limited for pre-commercial procurement, to the territory of the Member States and of countries associated to Horizon 2020 where duly justified by the objectives of the actions;

(c) may authorise the award of multiple contracts within the same procedure (multiple sourcing);

(d) shall provide for the award of the contracts to the tender(s) offering best value for money.

3. Unless otherwise stipulated in the call for tenders, results generated by procurement carried out by the Commission shall be owned by the Union.

4. Specific provisions regarding ownership, access rights and licensing shall be laid down in the contracts regarding pre-commercial procurement to ensure maximum uptake of the results and to avoid any unfair advantage. The contractor generating results in pre-commercial procurement shall own at least the attached intellectual property rights. The contracting authorities shall enjoy at least royalty-free access rights to the results for their own use and the right to grant, or require the participating contractors to grant, non-exclusive licences to third parties to exploit the results under fair and reasonable conditions without any right to sub-license. If a contractor fails to commercially exploit the results within a given period after the pre-commercial procurement as identified in the contract, it shall transfer any ownership of the results to the contracting authorities.

5. Specific provisions regarding ownership, access rights and licensing may be laid down in the contracts regarding public procurement of innovative solutions to ensure maximum uptake of the results and to avoid any unfair advantage.

Article 52

Financial Instruments

1. Financial instruments may take any of the forms referred to in, and shall be implemented in accordance with, Title VIII of Regulation (EU, Euratom) No 966/2012 and may be combined with each other and with grants funded under the Union budget, including under Regulation (EU) No 1291/2013.

2. By way of derogation from the second subparagraph of Article 140(6) of Regulation (EU, Euratom) No 966/2012, both revenues and annual repayments generated by a financial instrument established under Regulation (EU) No 1291/2013 shall be assigned, in accordance with Article 21(4) of Regulation No 966/2012, to that financial instrument.

3. By way of derogation from the second subparagraph of Article 140(6) of Regulation (EU, Euratom) No 966/2012, both revenues and annual repayments generated by the Risk Sharing Finance facility set up under Decision No 1982/2006/EC and the early stage part of the High-Growth and Innovative SME Facility (GIF1) set up under Decision No 1639/2006/EC, shall be assigned, in accordance with Article 21(4) of Regulation (EU, Euratom) No 966/2012, to the succeeding financial instruments under Regulation (EU) No 1291/2013.

Article 53

SME Instrument

1. Only SMEs may apply for calls for proposals issued under the dedicated SME instrument referred to in Article 22 of Regulation (EU) No 1291/2013. They may cooperate with other companies, and with research organisations or universities.

2. Once a company has been validated as an SME, that legal status shall be assumed to prevail for the entire duration of the project, even in cases where the company, due to its growth, later exceeds the ceilings of the SME definition.

3. In the case of the SME instrument or grants by funding bodies or by the Commission targeting SMEs, the grant agreement may lay down specific provisions, in particular on ownership, access rights, exploitation and dissemination.

Article 54

Fast Track to Innovation

1. In accordance with Article 7, any legal entity may participate in a Fast Track to Innovation ("FTI") action. Actions funded under FTI shall be innovation actions. The FTI call shall be open to proposals relating to any technology field under the specific objective "Leadership in enabling and industrial technologies" set out in point 1 of Part II of Annex I to Regulation (EU) No 1291/2013 or to any of the specific objectives under the priority "Societal challenges" set out in points 1 to 7 of Part III of Annex I to that Regulation.

2. Proposals may be submitted at any time. The Commission shall set three cut-off dates per year to evaluate proposals. The period between a cut-off date and signature of the grant agreement or notification of the grant decision shall not exceed six months. Proposals shall be ranked according to the impact, quality and efficiency of implementation and excellence, with the criterion of impact given a higher weighting. No more than five legal entities shall participate in any one action. The amount of the grant shall not exceed EUR 3 million.

Article 55

Other specific provisions

1. In the case of actions involving security-related activities, the grant agreement may lay down specific provisions, in particular on pre-commercial public procurement, procurement of innovative solutions, changes to the consortium's composition, classified information, exploitation, dissemination, open access to research publications, transfers and licences of results.

2. In the case of actions to support existing or new research infrastructures, the grant agreement may lay down specific provisions relating to users of the infrastructure and to the users' access to them.

3. In the case of ERC frontier research actions, the grant agreement may lay down specific provisions, in particular on access rights, portability and dissemination, or relating to participants, researchers and any party concerned by the action.

4. In the case of training and mobility actions, the grant agreement may lay down specific provisions on commitments relating to the researchers benefiting from the action, ownership, access rights and portability.

5. In the case of coordination and support actions, the grant agreement may lay down specific provisions, in particular on ownership, access rights, exploitation and dissemination of results.

6. In the case of the Knowledge and Innovation Communities of the EIT, the grant agreement may lay down specific provisions, in particular on ownership, access rights, exploitation and dissemination.

TITLE V

FINAL PROVISIONS

Article 56

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 1(3) shall be conferred on the Commission for the duration of Horizon 2020.

3. The delegation of power referred to in Article 1(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 1(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 57

Repeal and transitional provisions

1. Regulation (EC) No 1906/2006 is repealed with effect from 1 January 2014.

2. Without prejudice to paragraph 1, this Regulation shall not affect the continuation or modification, including the total or partial termination, of the actions concerned, until their closure, or until the award of financial assistance by the Commission or funding bodies under Decision No 1982/2006/EC or any other legislation applying to that assistance on 31 December 2013, which shall continue to apply to the actions concerned until their closure.

3. Any sums from the participant Guarantee Fund set up by Regulation (EC) No 1906/2006 as well as all its rights and obligations shall be transferred to the Fund as of 31 December 2013. The participants in actions under Decision No 1982/2006/EC signing grant agreements after 31 December 2013 shall make their contribution to the Fund.

Article 58

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 11 December 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
V. LEŠKEVIČIUS

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8199 final

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme

***EXTRACT OF* COMMISSION DECISION**

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Articles 5(2)(a) thereof,

Having regard to the Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Articles 21, 24 and 27 thereof,

Having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union, and in particular Article 124 thereof,

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants for reimbursement of eligible costs declared by beneficiaries on the basis of unit costs is authorised for the actions involving trans-national access under the Research Infrastructures Part of the Horizon 2020 Framework Programme, for the reasons and under the conditions set out in the Annex.

Article 2

This Decision is subject to the final adoption of the Regulation of the European Parliament and the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), the Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and the Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) by the legislative authority without significant modifications.

Done at Brussels, 10.12.2013

For the Commission
Máire GEOGHEGAN-QUINN
Member of the Commission

[1] OJ L 347, 20/12/2013, p. 104.

ANNEX

1. Forms of grants and categories of costs covered

The grants under the Research Infrastructures Part of the Horizon 2020 Framework Programme shall take the form of reimbursement of either of the following eligible costs for trans-national access to research infrastructures:

(i) costs declared by beneficiaries on the basis of unit costs calculated on the basis of their historical data, or

(ii) costs actually and solely incurred for providing access to the *user groups* selected for support under the action, or

(iii) costs declared by beneficiaries on the basis of a combination of the forms of costs referred to in points (i) and (ii), if part of the eligible access costs, in particular eligible costs for the specific support to users, varies significantly between users.

Only one of the forms referred to in points (i), (ii) and (iii) may be used for one *installation*. No alternative use is allowed for one *installation.*

The categories of eligible costs covered by the unit costs referred to in point (i) are the eligible *access costs* as defined below, including direct and indirect costs:

- Direct costs for providing access to the *installation*:
  - Personnel cost of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users.
  - Costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation (if not capitalised).
  - Costs of consumables specifically used for the installation and the research work of the users.
  - Costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards (if not capitalised) specifically incurred for the functioning of the installation.
  - Costs of energy power and water supplied for the installation.
  - Costs of general services when they are specifically included in the provided access services (library costs, shipping costs).
  - Costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services.
  - Costs of specific scientific services included in the access provided or needed for the provision of access.
- Indirect costs for providing access to the *installation*,

but excluding:

- All contributions to the capital investments of the infrastructure (including rental, lease or depreciation costs of buildings as well as depreciation and lease of instrumentation). Those costs are not eligible for the provision of access under the Research Infrastructures Part of the Horizon 2020 Framework Programme,

- Travel and subsistence costs to support the visits of users. Those costs shall be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs".

For that purpose, the following definitions shall apply:

(1) "installation" means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

(2) "access provider" means a beneficiary or a linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as specified in Annex I to the grant agreement.

(3) "user group" means a research team of one or more researchers to whom access to the installation is given under the action.

(4) "selected user" means a researcher within a user group.

(5) "access costs" are the costs incurred by the access provider for the provision of access. Access Costs cover the running costs of the *installation* and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the *installation* and for preparatory and closing activities that may be necessary to carry out user's work on the *installation*. Travel and subsistence costs incurred for supporting the visits of the *selected users* to the *installation* are not included in the *access costs*.

Other categories of eligible costs shall be reimbursed on the basis of eligible costs actually incurred or, for other direct personnel costs, on the basis of other unit costs or, for indirect costs, flat-rate financing**.**

The unit cost shall be calculated by beneficiaries in accordance with the method set out in Section 3 and shall be specified in the grant agreement to be used throughout the duration of the action. In exceptional and duly justified cases, it can be updated (with the agreement of the Commission and in accordance with the method in Section 3) through an amendment.

Costs for providing trans-national access to research infrastructures declared by beneficiaries on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in Annex 2 to the grant agreement multiplied by the number of actual units of access provided under the action and if the conditions set out in Article 16.1.1 of the grant agreement are met.

3. Method to determine and update the unit of cost

In order to measure the quantity of trans-national access to the *installation* supported under the Union grant the *access provider* will identify a unit of access to the *installation*. This unit of access shall also be used to measure the total quantity of access that the *installation* provides to all its users.

When eligible trans-national *access costs* for an *installation* are reimbursed on the basis of unit costs (only unit costs under point 1(i) or in combination with actual costs under point 1(iii)), the unit cost of a unit of access to the *installation* shall be agreed between the Commission and the *access provider.*

The unit cost shall be specified in the grant agreement and shall be defined on the basis of the average over the last two years[2] of the annual total *access costs* to the *installation*, for the

[2] In exceptional and duly justified cases, the Commission may agree to use a different reference period.

categories covered by the unit cost, divided by the average over the last two years[3] of the total quantity of access to the *installation* annually provided, as follows:

$$\textbf{Unit cost} = \frac{\textbf{average annual total } \textit{access costs} \textbf{ to the } \textit{installation}}{\textbf{average total quantity of access to the } \textit{installation} \textbf{ annually provided}}$$

The average amounts shall be based on certified or auditable historical data of the beneficiary (or the linked third party) over the last 2 years (years N-1 and N-2)[4] and allocated to the concerned *installation* according to the beneficiary's usual cost accounting practices. The average over the last two years of the *access costs* and quantity of access to the *installation* shall not include periods where the *installation* was not usable because out of order, or under repair or maintenance.

3.1 Calculation of the unit cost

The 'total quantity of access to the *installation*' shall include all the units of access annually provided by the installation, included access financed by the Union under previous grant agreements, if any.

The 'total *access costs* to the *installation*' shall be:

- the direct costs incurred by the beneficiary (or the linked third party) for the provision of access to the *installation*, as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2)[5] for the concerned categories of direct costs.

  By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices.

  If eligible costs for access to an *installation* are declared by beneficiaries exclusively on the basis of unit costs (point 1(i)), costs for all the categories of eligible direct costs referred to in Section 1 may be taken into account.

  If eligible costs for access to an *installation* are declared by beneficiaries as a combination of unit costs and of costs actually incurred (point 1(iii)), only costs for the eligible categories of direct costs referred to in Section 1 that are not reimbursed on an actual cost basis may be taken into account.

- the eligible indirect costs for the access to the *installation*, equal to 25% of the direct costs referred to above (amounts for the categories taken into account in the unit costs, i.e. excluding the categories reimbursed on an actual cost basis) minus any costs of subcontracting (amounts referred to above for the categories "costs of contracts for maintenance and repair", "costs of contracts for installation management", "costs of scientific services" and "cost for other electronic services").

The *access costs* to the *installation* shall exclude all contributions to the capital investments of the infrastructure as well as travel and subsistence costs to support the visits of users (see Section 1).

[3] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[4] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[5] Unless exceptionally agreed otherwise by the Commission

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Template

for essential information to be provided for proposals including clinical trials/studies/investigations/cohorts

Version 2.0
15 December 2016

HISTORY OF CHANGES			
Version	**Publication Date**	**Change**	**Page**
1.1 2017 callsV1	July 2016	▪ Introduction: Update on specific call topics and on stage-1 proposals ▪ Minor changes in sections 1.2.1, 1.2.2, 1.5, 1.6 (addition of cumulative efficacy information) 1.7.2, 1.7.3, and 1.7.7. ▪ Annex 2: Deletion of one 'mandatory deliverable' ▪ Editorial changes	
2.0 2017 callsV2	15.12.2016	▪ Title: Addition of reference to cohort studies ▪ Introduction: Update on specific call topics and including specification of applicability for IMI2 JU topics ▪ Minor changes in sections 1.2.2, 1.2.3, 1.4, 1.5 and 1.7.4 (additional references to guidelines and methodical specifications) ▪ Annex 2: Addition of data protection requirements and more specific guidance ▪ Editorial changes	

Template for essential information to be provided for proposals including clinical trials/studies/investigations/cohorts

This template only concerns you if your proposal contains a clinical trial/study/investigation! In the following, clinical trials/studies/investigations/cohorts are collectively referred to as 'clinical studies'[1]

Clinical studies have a number of methodological and regulatory specificities. Information on these issues is crucial for evaluators to assess the scientific quality of the proposal. The following guidance should help applicants to provide this essential information on clinical studies in a standardised format.

Applicability:

For **Horizon 2020 collaborative research:**

Single-stage- and stage-2 proposals: The use of this template is mandatory for all clinical studies[1] included in a single-stage- or stage-2 proposal submitted to topics[2] PM-02-2017, PM-07-2017, PM-08-2017, PM-10-2017, PM-11-2016-2017, HCO-07-2017. For these topics, you will have the possibility to upload the completed template as a separate part of your application in the submission system.

Stage-1 proposals: In the limited frame of a stage-1 proposal not all methodological details of clinical studies can be fully elaborated. Depending on the characteristics of the study, however, key aspects of study design and conduct have to be convincingly addressed already at stage 1. This template cannot be uploaded as a separate document at stage 1, but relevant aspects of this information should be integrated in part B of the stage 1 proposal template.

For **IMI2:**
Single-stage and **stage-2** proposals: The use of this template is mandatory for all clinical studies. You can upload the completed template as a separate part of your application in the submission system.
Stage-1 proposals: see under Horizon 2020 collaborative research

For each clinical study performed within the scope of the proposal, information on the issues listed below should be provided, compiled into one single document per proposal based on this template[3].

[1] A 'clinical study' is defined for the purpose of this template as any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients. It includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EC)
[2] For proposals containing clinical studies submitted to topics *not* listed here you may use the points listed below as an orientation and provide this information normally in section B.3.1. of the proposal. If required, the table provided in section 1.9 of this template on unit costs can in this case be provided in section 3.4 ('Resources to be committed') of part B of the proposal.
[3] If the proposal contains more than one clinical study, each study should be described in its own main chapter (1.1, 1.2, 1.3…; 2.1, 2,2…; 3.1… etc.) as indicated in the example below.

Each section must be shortly and concisely described. **In case one or more issues do not apply to a particular study, please briefly explain/justify.**

When the requested information is currently not available (e.g. a clinical study is planned for a later stage of the project and will be based on data from prior studies) the source of this data and/or the applied methodology should be described.

Information provided in this template does not need to be repeated elsewhere in the proposal, but can be referred to.

There are no page limitations for this template, but explanations should be as concise as possible.

Information outside the scope of this template will not be taken in account in the proposal evaluation. No other chapters or annexes (containing e.g. complete study protocols) can be added to this template. Section headings should not be changed.

Ethics considerations have to be addressed in the appropriate section of the proposal. Similarly, risks and contingency plans have to be addressed in the respective section of the proposal (part B.3.2 and table 3.2.a) (not in this template!). If contingency plans are not outlined in the proposal (and the grant agreement), your grant agreement might be terminated and/or the EU/IMI2 JU contribution significantly reduced should a study not proceed as planned.

Three **mandatory deliverables** have to be implemented in the proposal for each clinical study included in the proposal. Further information on the mandatory deliverables can be found in Annex 2.

1 Clinical study No. 1

1.1 Identifier

Title, short title or unique identifier.

1.2 Study design and endpoints

1.2.1 Study design

Brief description of the objectives or hypotheses and concise description of the selected study design.

1.2.2 Primary and secondary endpoint(s)

Description of the primary and secondary endpoints/outcome measures (and how these relate to the objectives). For observational studies please refer also to other variables relevant to the study objectives, such as potential confounding variables and effect measure modifiers.

1.2.3 Relevant guidance documents

References to guidance documents relevant to the study, e.g. guidelines by/of

(a) Scientific societies and advisory bodies e.g. addressing:

- *Best practice of treatments / standard-of-care*

- *Good Clinical Practice* [4]
- *Good (Pharmaco)epidemiological Practice* [5]

(b) *Health Technology Assessment agencies / EUnetHTA*

(c) *Regulatory bodies (e.g. the European Medicines Agency, EMA[6]). For studies addressing development and/or optimisation of pharmacological therapies the following guidelines may have an impact on the later scientific/regulatory value and applicability of results:*

- *Clinical efficacy and safety guidelines for the evaluation of medicines in disease areas - e.g diabetes (CPMP/EWP/1080/00 Rev. 1) or oncology (EMA/CHMP/EWP/205/95/Rev.4)*
- *General guidelines e.g. addressing clinical pharmacology and pharmacokinetics (e.g. bioanalytical methods validation EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2 or pharmacokinetics in paediatric population EMEA/CHMP/EWP/147013/2004)*
- *Methodological guidelines - e.g. statistical principles for clinical crials (CPMP/ICH/363/96) or clinical trials in small populations (CHMP/EWP/83561/2005)*

1.3 Scientific advice / protocol assistance / communication with regulatory / competent authorities / ethics committees

If scientific advice/protocol assistance from a competent/regulatory authority has been requested, please provide the full text answer of the authority (or a comprehensive summary) in this section of the document. If the answer is not yet available provide an explanation of the current status. Please also include in this section any other relevant correspondence or minutes of meetings with regulatory authorities or ethics committees such as requested or granted approvals of clinical trial applications. Clearly define the regulatory / ethics status and requirements for the study according to national and EU regulations.

1.4 Subjects/population(s)

Definition of study population(s) by inclusion and exclusion criteria. Please discuss appropriate inclusion of women and special populations, such as children and elderly (with defined age groups). If there are populations specifically excluded, please justify.

Definition of sub-populations if subgroup analysis is intended.

[4] e.g. Good Clinical Practice Guidelines from ICH

[5] e.g. *Guidelines for Good Pharmacoepidemiology Practices* from ISPE, *Good Practices for Outcomes Research* from ISPOR or *Good Epidemiological Practice* from IEA

[6] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000043.jsp&mid=WC0b01ac05800240cb

1.5 Statistic analysis plan(ning) and power calculation

Definition and justification (power calculation) of sample size, definition of statistical methods and planning of statistical analysis (including stopping guidelines and/or procedures to control sources of bias and their influence on results, if relevant).

1.6 Cumulative safety and efficacy information

1.6.1 *Cumulative safety information*

Concise information on safety and tolerability of study interventions: e.g. pre-clinical data from in-vitro or in-vivo studies; data from previous clinical studies; data from (pharmaco-)vigilance systems or other sources.

1.6.2 Cumulative efficacy information

Concise information on efficacy of study interventions based on (pre-)clinical data.

1.7 Conduct

1.7.1 Schedule for study conduct including timelines for key study milestones[7]

In this section, include a (realistic!) planning of the schedule for the study conduct, including provisions and timelines for ethics and other administrative approvals. As a minimum, include realistic planning and timing for the key study milestones below. Dates for key study milestones are defined relative to the starting date of the project (i.e. month 1, month 6 etc.):

- *First Patient (or study subject), First Visit (FPFV):*
- *Last Patient (or study subject), First Visit:*
- *Last Patient (or study subject), Last Visit:*
- *End of Study (including follow-up and data analysis):*

1.7.2 Description of recruitment strategy

Description of the recruitment strategy, including realistic estimates of the expected recruitment rate (subjects per month/per centre) based on available data.

1.7.3 Description and assignment of intervention

Please describe the intervention(s) tested and methods for allocation and blinding.

1.7.4 Study management, study monitoring, data and sample management

Please include a description of

- *Planned strategy for study / trial management,*
- *Study monitoring plan (monitoring visits, level of source data verification, etc.)*
- *Adverse event reporting*

[7] Key study milestones will be scrutinised during the time course of the project. Significantly delayed key study milestones (e.g. FPFV) might lead to the termination of the grant agreement.

- *Data collection and management (including mechanisms to ensure data quality, completeness and integrity)*
- *Sample management*

1.7.5 Sponsor, coordinating centre(s) and committees

Please specify the trial sponsor. Specify the role of the coordinating centre(s) and different committees (e.g. Data Safety Monitoring Board, Independent Data Monitoring Committee, etc.).

1.7.6 Study medication

If a study medication (investigational and non investigational medicinal products) is required, please provide information on whether manufacturing and / or labelling of the study medication is required and which plans and / or commitments are in place for this.

1.7.7 Clinical centres

Specification of criteria for site selection and indicative list of clinical centres / recruitment centres planned to be involved in the clinical study.

1.8 Orphan designation

If orphan designation has been granted provide the reference of the Commission Decision. If orphan designation has been requested but not granted, provide an update on the current status.

1.9 'Unit costs per patient' for clinical trials / studies / investigations

Commission Decision C(2016) 7553[8] *authorises the use of unit costs for clinical studies.* ***The use of unit costs is an alternative to the use of actual costs. Its use is voluntary, i.e. each beneficiary can decide whether to be reimbursed on the basis of unit costs or of actual costs for a given clinical study.*** *Beneficiaries can use different forms of reimbursement (unit costs or actual costs) for different clinical studies. Costs that are covered by unit costs cannot be declared as actual costs.* ***If no beneficiary intends to use unit costs, this section of the template does not need to be completed!***

When a beneficiary intends to use unit costs, the ***detailed and complete*** *calculation must be provided in Table(s) X.9 of this template (see below). The direct costs must be determined by estimating the* resources *used per task and per patient or subject and using its historical costs for these resources. The beneficiary must estimate the* resources *used specifically per patient for the conduct of the clinical study (i.e. personnel costs of doctors, other medical personnel and technical personnel; costs of medical equipment and costs of other service contracts) on the basis of the protocol for the clinical study. The resource estimate must be the same for all members of the consortium using unit costs in a particular study.*

The beneficiary must use as historical costs the costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application). The amount of unit costs per patient is fixed in the grant agreement for the entire duration of the project, without adjustment for inflation.

[8] (http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit_costs_clinical_studies.pdf)

For detailed information please refer to Annex 1 of this document and/or to *Commission Decision C(2016) 7553*

The resources and costs identified will be evaluated by independent experts as part of the evaluation of the proposal.

If unit costs are to be used, the estimation of resources and historical costs must be provided in the following table as part of this document.

Text in blue font (examples) must be replaced by concrete estimations of resources and historical costs.

Table X.9: Unit cost declaration for (identifier, see 1.1)

Task, Direct cost categories	Resource per patient	Costs in year N-1 Benef.[a] 1 (short name)	Costs in year N-1 Benef.[a] 2 (short name)
Task No. 1 *Blood sample*			
(a) Personnel costs: - Doctors			
- Other Medical Personnel	*Phlebotomy (nurse), 10 minutes*	*8,33 EUR[b]*	*11,59 EUR[b]*
- Technical Personnel	*Sample Processing (lab technician), 15 minutes*	*9,51 EUR[b]*	*15,68 EUR[b]*
(b) Costs of consumables:	*Syringe*	*XX EUR*	*XX EUR*
	Cannula	*XX EUR*	*XX EUR*
	Blood container	*XX EUR*	*XX EUR*
(c) Costs of the medical equipment:	*Use of -80° deep freezer, 60 days*	*XX EUR*	*XX EUR*
….	*Use of centrifuge, 15 minutes*	*XX EUR*	*XX EUR*
(d) Services			
Task No. X *…*			
…			
Total amount:		*XX EUR*	*XX EUR*

[a]Beneficiary, linked third parties or third parties contributing in kind to the clinical study: The estimated unit costs have to be presented per beneficiary, linked third party or third party contributing in kind to the clinical study. Please add columns for additional participants if needed.

[b]Costs incurred in another currency shall be converted into Euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), determined over the corresponding year N-1. If no daily Euro exchange rate is published in the Official Journal of the European Union for the currency in question, conversion shall be made at the average of the monthly accounting rates established by the Commission and published on its website (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), determined over the corresponding year N-1.

Direct costs of activities carried out centrally by one (or a limited number of) beneficiary/ies for all patients/study subjects (or the patients/study subjects at several beneficiaries), such as a site monitoring or trial insurance should be reimbursed based on actual costs.

2 Clinical study No. 2 (if applicable)

2.1 Identifier

Title, short title or unique identifier.

etc.

3 Clinical study No. 3 (if applicable)

Etc.

Annex 1: Method to determine the unit costs

(a) Personnel costs of medical and technical personnel directly assigned to the conduct of the clinical study

The amount of the unit cost component 'personnel costs' is determined for each task described in the protocol as follows:

*{Average hourly cost for **Doctors** X Estimated number of hours worked by doctors for each task described in the protocol and for each patient or subject*

*+ Average hourly cost for **Other medical personnel** X Estimated number of hours worked by other medical personnel for each task described in the protocol and for each patient or subject*

+ Average hourly cost for ***Technical personnel*** *X Estimated number of hours worked by technical personnel for each task described in the protocol and for each patient or subject}*

with

Average hourly cost for Doctors *= Certified or auditable total personnel costs for Doctors for year N-1 / {1720 X number of full-time equivalent for the personnel category Doctors for year N-1}*

Average hourly cost for Other medical personnel *= Certified or auditable total personnel costs for other medical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Other medical personnel for year N-1}*

Average hourly cost for Technical personnel *= Certified or auditable total personnel costs for technical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Technical personnel for year N-1}*

and

Total personnel costs *= Actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act*
(see conditions set out in Article 6.2.A.1 of the model grant agreement).

The use of hourly costs determined according to another methodology, including according to the beneficiary's usual cost accounting practices, is not allowed.

(b) Costs of consumables specifically used for the conduct of the clinical trial

The amount of the unit cost component 'costs of consumables' is determined for each task described in the protocol as follows:

{Average price per item for the first category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or subject

+ Average price per item for the second category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or subject

+ Average price per item for the third category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or subject

+ idem for each category of consumables specifically used in the clinical study}

with

Average price per item for a category of consumables used in the clinical study *= Certified or auditable total costs of purchase of the consumables in year N-1 for the category of*

consumables concerned / Total number of items purchased in year N-1 for the category of consumables concerned

and

Total costs of purchase of the consumables *= Total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests*

(see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement)

(c) Costs of the medical equipment specifically used for the conduct of the clinical study

The amount of the unit cost component 'costs of medical equipment' is determined for each task described in the protocol as follows:

{Average cost of depreciation and of directly related services for the first category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or subject

+ Average cost of depreciation and of directly related services for the second category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or subject

+ Average cost of depreciation and of directly related services for the third category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or subject

+ idem for each category of equipment specifically used in the clinical study}

with

Average cost of depreciation and directly related services per unit of use *= {Certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + Certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned} / Total capacity in year N-1*

and

Total depreciation costs *= Total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + Total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees*
(see conditions set out in Article 6.2.D.2 of the model Horizon 2020 grant agreement)

Total costs of purchase of services *= Total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for services delivered in year N-1 for the functioning of the equipment, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests*
(see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement)

Total capacity *= Total time of use of the equipment expressed in hours, days or months and supported by evidence or the number of accesses to the equipment, for which supporting evidence may take the form of records or electronic log of units-of-access provision.*

The total capacity must take due account of real constraints (e.g. opening hours), but must reflect the equipment full capacity and include any time during which the equipment is usable but not used or any unit of access available but not used.

(d) Costs of other specific contracts necessary for the conduct of the clinical study

The amount of the unit cost component 'costs of other specific contracts' is determined for each task described in the protocol as follows:

{Average cost of the first specific service necessary for the conduct of the clinical study per patient or subject

+ Average cost of the second specific service necessary for the conduct of the clinical study per patient or subject

+ Average cost of the third specific service necessary for the conduct of the clinical study per patient or subject

+ idem for each specific service necessary for the conduct of the clinical study}

with

Average cost of a specific service per patient or subject *= Certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies / Total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1*

and

Total costs of purchase of a service *= Total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests*

(see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement)

(e) Indirect costs

The amount of the unit cost component 'indirect costs' is determined for each task described in the protocol by applying a flat rate of 25 % of the sum of the unit cost components referred to in points (a), (b) and (c) above (excluding the unit cost component referred to in point (d) above and the costs of resources made available by third parties which are not used on the premises of the beneficiary, as well as financial support to third parties, as set out in Article 29(1) of Regulation (EU) No 1290/2013).

Annex 2: Mandatory deliverables for clinical studies

For each clinical study, the following mandatory deliverables (with the indicated title and scope as defined) have to be included in the proposal:

1. **'First study subject approvals package'**
   (prior to enrolment of first study subject):
   a. Final version of study protocol as approved by first regulator / ethics committee(s) (no need to change deliverable if later amendments)
   b. Registration number of clinical study in a WHO- or ICMJE- approved registry that also allows later posting of study results.
   c. Approvals required for invitation / enrolment of **first** subject in at least one clinical centre (if applicable): ethics committees, national competent authorities and copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority. If the position of a Data Protection Officer is established, its opinion/confirmation that all data collection and processing will be carried out according to EU and national legislation
2. **'Midterm recruitment report'**

   Deliverable to be scheduled for the time point when 50% of the study population is expected to have been recruited. The report shall include an overview of recruited subjects by study site, potential recruiting problems and, if applicable, a detailed description of implemented and planned measures to compensate delays in the study subject recruitment.
3. **'Report on status of posting results'**

   Report on the status of posting results in the study registry/ies (including timelines when final posting of results is scheduled after end of funding period). To be scheduled for the time of expected results posting or for the last months of the project, whichever comes earlier.

This document will be available soon.

The list of research infrastructures targeted by call H2020-INFRADEV-2014-2015 under topic "INFRADEV-3-2015 - Individual implementation and operation of ESFRI projects" have been included in the updated Work Programme 2014-2015. They are:

- ELIXIR, EPOS and the European Spallation Source
- BBMRI, CESSDA, CLARIN, CTA, DARIAH, ECCSEL, EISCAT-3D, ELI, EMSO, the European Social Survey, SHARE and SKA

Please refer to the Work Programme for details.

EUROPEAN COMMISSION

H2020 Programme

Guidance

Grant reductions

Version 1.0
27 February 2018

IMPORTANT NOTICE

This document aims to provide guidance to **Commission/Agency services** for deciding on **grant reductions** in the context of the H2020 programme.

It will not be applied mechanically, but provides for a common framework of parameters that will allow to harmonise practices and reach proportionate results adapted to each individual case.

This document has been endorsed by Commission Decision (2018)1017.

It should also be used by H2020 funding bodies.

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	27.02.2018	▪ Initial version

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1. Background

The Horizon 2020 model grant agreements (MGAs) provide for a set of measures to be taken in case of grant agreement violations ('Chapter 6 measures').

These measures can lead to rejection of costs and/or to grant reduction (i.e. a reduction of the grant amount fixed in the estimated budget, Annex 2[1]).

Reductions may be applied in cases of *(see Article 43 MGA)*:

- substantial errors, irregularities or fraud[2]
- serious breach of obligations under the GA or during the award procedure, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles, etc.
- systemic or recurrent errors, irregularities or fraud/serious breach of obligations in other grants that have a material impact on the grant (i.e. extension of findings from other grants– *see also Article 22.5.2 MGA*).

This guidance establishes a methodology to ensure that grant reductions are applied in a coherent and proportionate manner by all Commission, Agency services implementing H2020 — and thus in line with the general principles of proportionality and equal treatment of beneficiaries.[3]

2. When can reductions be applied?

Grant reductions can be applied after beneficiary termination[4], at the payment of the balance or afterwards (but NOT in interim payments).

According to Article 43 MGA, grant reductions can be made only for ***sufficiently serious*** cases, i.e. if there is proof of *substantial* errors, irregularities, fraud or *serious* breaches of obligations (during the award procedure or during the implementation of the GA).

> ***Examples (reduction):*** *fraud/substantial irregularities; submission of false information; breach of ethical principles; partial or improper implementation of the action (e.g. one of the 3 test plants was not built, and several testing activities were not carried out); breach of the obligation to ensure open access to all peer-reviewed scientific publications relating to results; breach of the obligation to display the EU emblem; incorrect handling of EU-classified information; plagiarism.*

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[1] This is the grant amount *committed* for the action (i.e. the maximum grant amount), not the grant amount actually *paid* (i.e. the final grant amount). The first is set out in the GA and linked to the budget of the action; the second is linked to the costs accepted.

[2] Reduction for substantial errors, irregularities or fraud was introduced as explicit contractual ground with GA version 3.0. For older grant agreements, grant reduction on these grounds was however also possible directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (and in very exceptional cases involving fraud schemes also on the basis of Article 1116 of the Belgian Code Civil — as annulation ab initio pour dol- ; see judgment of 12 July 2016, Commission/Thales, T-326/13, points 119-128).

[3] See Article 135(4) and (8) of the Financial Regulation No 966/2012.

[4] Only for GAs signed from version 3.0 onward. For older grant agreements, there is NO grant reduction at beneficiary termination for serious breach of contract (since explicitly NOT foreseen). By contrast, grant reduction at beneficiary termination possible for substantial errors, irregularities or fraud — directly on the basis of Article 135(4) and (5) of the Financial Regulation No 966/2012 (see footnote 2).

This means that grant reduction should NOT be applied in cases where the errors or breach of obligations have no significant impact on the action or the EU financial interests or image.

Examples (no reduction): *minor delays/deviations in the technical work foreseen in Annex 1 (e.g. a deliverable is slightly delayed because the researcher responsible is on sick leave; a scientific test has to be redone at a later time due to meteorological conditions).*

3. How much? — Calculation & reduction rates

Grant reductions must be **proportionate** to the seriousness of the errors, irregularities or fraud or breach of obligations.[5]

They will be **calculated** by applying the reduction rate to the maximum grant amount fixed in the GA. The resulting amount will be deducted from the maximum grant amount to calculate the reduced grant amount (*see Article 5.3.4 MGA)*.

This calculation will observe the following **principles**:

1. The reduction will normally be calculated:

   - on the defaulting beneficiary/ies (**beneficiary-level**)

     The percentage will be applied to the maximum grant amount fixed in Annex 2 for the beneficiary/ies concerned.

   - on all the beneficiaries together (**action-level**), if:

     - all beneficiaries are together responsible for not complying with the obligation AND the breach cannot be attributed to one (or several) of them, or

     - very serious errors, irregularities or fraud put into question the funding of the entire action.

     The percentage will be applied to the maximum grant amount fixed in Article 5.1 and Annex 2 for the action.

   Examples (reduction on all beneficiaries):

   1. *A review shows an improper implementation of the action which cannot be attributed to individual beneficiaries.*

   2. *The consortium set up a fraud network to systematically overstate costs (i.e. fraud or very serious errors/irregularities that justify a reduction).*

2. The **reduction rate** (percentage) will normally be based on this reduction rate matrix.

REDUCTIONS	Gravity/impact					
	1 (Lowest)	2	3	4	5	6 (Highest)

[5] See Article 43.2 H2020 General MGA.

Type of breach	Fraud		N/A	N/A	N/A	N/A	75 %	100 %
	Substantial errors or irregularities		N/A	N/A	25%	50 %	75 %	100 %
	Obligations during the award procedure		5%	10%	25%	50%	75%	100%
	GA obligations	Principal obligation	N/A	10%	25%	50%	75%	100 %
		Secondary obligation	5%	10 %	25%	50 %	N/A	N/A
	Improper implementation		Value of part improperly implemented					

The table fixes the range of reduction rates that can be attributed to a type of breach. Fields marked as N/A do not apply to that type of breach.

Examples: *For example, any case of fraud will automatically be a minimun gravity of 5 (i.e. 75 % reduction); it cannot be qualified as gravity 1 to 4. Substantial errors or irregularities will automatically be qualified as 3 or above and breach of principal obligations automatically as 2 or above. By contrast, breaches of secondary obligations can never reach a gravity of more than 4.*

Specific case:

Improper implementation (Art 7 MGA) — If the breach consists in the improper implementation of the action, the reduction will not be based on a fixed percentage from the matrix, but on the value of the improperly implemented part (— usually by looking at the amount that was budgeted/declared for it). The reduction will be proportional to the improper implementation (i.e. the degree of non/bad quality implementation).

The rate will be chosen on the basis of the type of breach *(e.g. fraud, principal or secondary GA obligation, obligation during the award procedure, etc.)* and its gravity *(e.g. obligation only partially or totally disregarded, impact on the action/EU financial interests/image, aggravating and mitigating factors, etc.)*.

GA obligations other than proper implementation are grouped into 'principal' and 'secondary' in the catalogue of GA obligations in Annex 1 to this document.

Aggravating factors:

- The Commission/Agency has already warned the beneficiary about the breach (*e.g. at the end of the first reporting period, external audit, etc.)*.
- The beneficiary has shown bad faith or intentionality.

- The beneficiary failed to co-operate with the Commission/Agency.
- Reputational damage for the Commission/Agency.
- Long duration or recurrence of the breach of the obligation.
- Existence of other breaches with same or lower percentage.

Mitigating factors:

- The beneficiary has remedied the situation on its own initiative (following a warning from the Commission/Agency).
- The beneficiary has taken precautionary measures (on its own initiative or following a warning from the Commission/Agency) to prevent similar breaches in the future.
- The beneficiary was in good faith and the rules were not entirely clear.
- The beneficiary has co-operated with the Commission/Agency throughout the proceedings.
- The project delivered very good results (not applicable to fraud cases).

If there are **several breaches** for a beneficiary in the same grant, only the highest rate decided for each of those breaches will be applied for the reduction at beneficiary-level. If there are several breaches in the same grant at action-level, only the highest rate decided for each of those breaches will be applied for the reduction at action-level. Reductions at beneficiary-level may accumulate with reductions at action-level.

Example:

1. *Beneficiary A has committed 3 breaches (10%, 50% and 25%). The RAO will apply a single reduction of 50 %. (The other breaches should be counted as aggravating factor when determining the rates.)*

2. *Beneficiary B has committed 2 breaches (10% and 70 000 EUR for improper implementation). The RAO will apply the single reduction of 70 000 EUR if the amount for the other breach is less.*

If the matrix gives a **disproportionate** result *(e.g. for beneficiaries with very large maximum grant amounts)*, it will be lowered down to the next lower level.

If there is **force majeure**, there is no breach (according to Article 51 MGA), and therefore there is no reduction.

⚠ The percentages for grant reductions must be distinguished from flat-rates for cost rejection *(e.g. the correction rates for extrapolation in Article 22.5.3.1 H2020 General MGA or OLAF correction rates for ineligible costs)*. Those flat-rates are used to quantify ineligible costs (not for grant reductions).

3. The **reduction base** is the maximum grant amount that is fixed in the grant agreement.

For reductions at *beneficiary-level*, this is normally the beneficiary's maximum grant amount; for reductions at *action-level*, this is the maximum grant amount for the consortium *(see Annex 2 and Article 5.1 MGA)*.

Specific cases:

Reductions at beneficiary termination — For reductions at beneficiary termination, the reduction rate will not be applied to the beneficiary's maximum grant amount, but to a pro rata temporis[6] part of it (to ensure *effet utile*, since the 'lower of the two amounts' rule would often render grant reductions redundant — because rarely higher than the non-declared costs).

Pro rata temporis part of the maximum grant amount:

{beneficiary's maximum grant amount *(see Annex 2)*
multiplied by
{months of participation
divided by
total action duration (months)}**}**

Reductions after payment of the balance for overspending beneficiary — For reductions after payment of the balance for a beneficiary that overspent (i.e. declared more costs than its maximum grant amount), the reduction rate will be applied directly to the beneficiary's share in the final grant amount and that same amount will be recovered from the beneficiary. This ensures a proportionate result for beneficiaries that contributed more to the action than initially planned in the estimated budget (avoids disproportionate grant reductions compared to the *real* project budget at payment of the balance).

4. At payment of the balance, the calculation may need to be done **several times** (once for each defaulting beneficiary/linked third party and once for the action, if any) and all amounts must be summed up to give the total amount of grant reduction that flows into the final payment calculation. Reductions at beneficiary-level may accumulate with a reduction at action-level.

5. If grant reduction takes place at the same time as cost rejection, only one of the two measures will have a financial impact. This is because both resulting amounts (grant amount after rejection and grant amount after reduction) will be compared and only the **lower of the two amounts** will be taken into account for the final grant amount *(see Articles 5 and 50 MGA)*.

6. Not all grant reductions will automatically lead to a recovery. Recovery depends on the overall payment calculation and whether the beneficiary received more than was due (after the grant reduction; *see Article 44 MGA*).

7. **Linked third parties** will be treated like beneficiaries (*mutatis mutandis*). Grant reductions will be calculated on the linked third party's maximum grant amount (with the exception set out above). For the purpose of recoveries, linked third parties are looked at together with their beneficiary.

For detailed explanations and sample calculations, *see Article 21 H2020 AGA — Annotated Model Grant Agreement*.

[6] The pro rata temporis part is portion of the beneficiary's maximum grant amount that corresponds to its period of participation (i.e. until termination).

4. How? — Procedure

Grant reductions are subject to a **contradictory procedure** (which will take place for each grant agreement before the reduction is implemented, i.e. at beneficiary termination, at payment of the balance or afterwards; *see Articles 21 and 43 MGA*).

For on-going grants, the beneficiary will moreover be informed at the time when the breach is discovered (via an audit implementation/review **information letter**).

A Coordination Panel will be set up to ensure that grant reductions are applied in a consistent and coherent manner. The panel must be consulted for any case involving several responsible authorising officers. If the RAO decides to deviate from the opinion of the panel it must duly justify its decision.

The RAO must also consult OLAF before initiating the contradictory procedure or informing the beneficiary if:

- OLAF is investigating the beneficiary or is assessing the possibility to open an investigation (OLAF's selection process);
- The RAO envisages sending the case to OLAF.

In those cases, any disclosure of information to the beneficiary in the context of the contradictory procedure or information letter requires the prior agreement by OLAF.

5. Combinations with other measures for breach of contract

Depending on the case, grant reduction may have to be combined with other Chapter 6 measures *(e.g. suspension of payments, termination, administrative sanctions: exclusion and/or financial penalties, etc.)*.

The principle of proportionality has to be respected in all cases. Moreover, if grant reduction takes place at the same time as cost rejection, only one of the two measures will have a financial impact *(see point 3.5 above)*.

Annex 1

Catalogue of GA obligations

This table presents the GA obligations (other than proper implementation) in two main groups:

- corporate: obligations which are equal for all programmes
- sectoral: obligations which are specific for one or several programmes *(e.g. IPR provisions in research)*

and classifies them as principal or secondary.

The list below ONLY concerns reductions *based on the GA* (i.e. 'serious breach of obligations under the GA').

GA obligations leading to rejection of costs are not included precisely because their breaches result in rejection of (quantified) amounts. Therefore, they do not need to be classified as principal or secondary to use the reduction rate matrix in order to be quantified.

The obligation to properly implement the action (i.e. obligation to implement the action as foreseen in Annex 1 and obligation to implement the action well — good quality; *see Article 7*) is not included because the grant reduction does not depend on the qualification into principal or secondary, but on the value of the improperly implemented part.

Obligations that might be breached during the award procedure are not included because they are too varied to be catalogued.

Corporate obligations (in all EU MGAs)

EU GA obligations		Type
Article 7: Obligation to implement the action in compliance with all legal obligations under applicable EU, international and national law		case by case
Article 10.1.2, 13.1.2: Obligation to comply with the public procurement rules (for beneficiaries that are contracting authorities/entities)		case by case (see also DG BUDG Guidelines)
Article 13.1.2, 14.1.2, 15.1.2, 15.2..2: Obligation to ensure that GA provision apply to third parties (subcontractors, linked third parties, third parties receiving financial support		Principal
Article 17:	Obligations to provide information upon request	case-by-case
	Obligation to keep information in BR updated and inform about events and circumstances likely to affect the grant	Principal
Article 18: Obligation to keep reliable records and supporting documents		Principal
Article 19: Obligation to submit deliverables		Principal
Article 20: Obligation to submit technical and financial reports		Principal
Article 21.7: Obligation to distribute payments		Principal
Article 22: Obligation to cooperate for audits and investigations		Principal
Article 23: Obligation to cooperate for action impact evaluations		Secondary

Article 35:	Obligation to avoid conflict of interest	Principal
	Obligation to notify conflict of interest	Secondary
Article 36: Obligation to maintain confidentiality		Principal
Article 38.1:	Obligation to promote the action and its results	Principal
Article 38.2:	Visibility of EU funding	Principal
Article 39: Obligation to comply with EU and national law on data privacy		Secondary
Article 50.1 and 50.2: Obligation not to terminate without good reasons (otherwise improper)		Secondary

Sector-specific obligations

H2020 GA Obligations		Type
Article 13 PCP/PPI: Obligations concerning the PCP/PPI subcontracting		Principal
Article 15 ERANET Cofund: Obligations concerning the rules for providing support to or implementation of trans-national projects		Principal
Article 15.1.2 MSCA-COFUND:	Obligation to take measures to implement the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers	Principal
	Obligations concerning the rules on recruitment and working conditions for researchers	Principal
	Other obligations	Secondary
Article 16.1.2: Additional obligations for access providers		Secondary
Article 23a: Obligation to take measures to implement Code of Practice on the management of intellectual property in knowledge transfer activities		Secondary
Article 24: Obligation to agree on background		Principal
Article 25: Obligation to give access to background		Principal
Article 26: Obligations regarding ownership of results		Principal
Article 27:	Obligation to protect results	Principal
	Information on EU funding	Principal
Article 28:	Obligation to exploit the results	Principal
	Additional exploitation obligations	Principal

	Obligations regarding standards	Principal
Article 29:	Obligation to disseminate results	Principal
	Additional dissemination obligations	Principal
	Obligations on open access to scientific publications	Principal
	Obligations on open access to research data	Principal
	Visibility of EU funding	Principal
Article 30: Obligations on transfer and licensing of results		Principal
Article 31: Obligation to give access to results		Principal
Article 32: Obligation to take measures to implement the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers		Principal
Article 32 ERC: Obligations concerning the working conditions for the PI and his/her team		Principal
Article 32 MSCA-ITN, MSCA-IF and MSCA-RISE:	Obligation to take measures to implement the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers	Principal
	Obligations concerning the rules on recruitment and working conditions for researchers/seconded staff members	Principal
Article 33: Gender equality		Secondary
Article 34: Obligation to comply with ethical principles including plagiarism		Principal
Article 37:	Obligation to protect classified information	Principal
	Obligation to comply with security requirements	Principal
	Obligation to comply with EU, national and international law on dual-use goods or dangerous materials and substances (if applicable)	case-by-case basis
Article 49.1 MSCA-IF: Obligations concerning action suspension (only for the reasons set out in the GA)		Principal
Article 56a ERC: Obligations concerning transfer of the GA to a new beneficiary (portability)		Principal
Article 56a MSCA-IF: Obligations concerning transfer of the GA to a new beneficiary		Principal

OPEN ACCESS PUBLISHING AGREEMENT

- **Instructions and footnotes in blue should be deleted.**
- **For options *[*in square brackets*]*: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

ADDENDUM

(To be filled out by the beneficiary/author and the publisher. This model is not mandatory but reflects the obligations for the beneficiary under the H2020 grant agreements. It can be supplemented by further provisions agreed between the parties, provided they are compatible with the Grant Agreement. The Commission/Agency takes no responsibility for the use of this model.)

This '**Addendum**' is **between** the following parties:

on the one part,

1. the publisher

[full official name (short name)], established in [official address in full], represented by [….],

and

on the other part,

1. 'the corresponding author':

[full name], [official address in full], represented by [….]

and the following **other authors**

2. **[full name]**, [official address in full], represented by [….]

3. **[full name]**, [official address in full], represented by [….]

[same for each author].

With this Addendum, the **parties agree** to **complement** and **amend** the attached Publication Agreement concerning the publication [insert name of publication] in the Journal [insert name of journal] with the following open access clause:

Open access

The author(s) retain(s) the right to:

a) deposit a machine-readable electronic copy of the published version or the final manuscript (after peer review) in an institutional, centralised and/or subject-based repository

b) provide open access (i.e. free-of-charge access to the electronic copy to anyone) through this repository:

   (i) immediately, if the publication itself is published 'open access' (i.e. if an electronic version is also available free of charge to the reader via the publisher) or

   (ii) within *[*6*][*12 *]*[1] months after publication.

In case of conflicting provisions, this Addendum takes precedence over the Publication Agreement.

All other provisions of the Publishing Agreement remain unchanged.

This Addendum enters into force on the day of the last signature.

[OPTION if addendum signed after publication: It takes effect on [insert publication date].*]*

SIGNATURES

For the authors:

name date signature

name date signature

name date signature

For the publisher:

date signature stamp

Done in two originals, in English

History of changes		
Version	**Publication date**	**Change**
1.0	20.03.2017	▪ Initial version

[1] Choose 12 months for publications in the social sciences and humanities and 6 months for publications in other domains.

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EUROPEAN COMMISSION
Directorate-General for Migration and Home Affairs

H2020 Programme

Guidance

Guidelines for the classification of information in research projects

Version 2.2
07 January 2020

IMPORTANT NOTICE

This document aims to assist **national experts** with the security scrutiny of H2020 proposals, inform **applicants** on how information will be EU-classified and help **Commission staff** to decide about the sensitivity of their call for proposals.

⚠ This guidance concerns solely protective measures to be taken to preserve the confidentiality of security-sensitive information in H2020 research projects. Other aspects *(e.g. data protection, ethical issues, dual-use, etc.)* are covered in other parts of the evaluation procedure.

⚠ Pending the adoption of implementing rules for Commission Decision 2015/444 on the security rules for protecting EU classified information, certain provisions in this guide are still based on Commission Decision 2001/844. In the absence of new guidelines they should continue to be applied.

Under the new security rules, all classification markings must now be written in FR/EN format *(e.g. RESTREINT UE/EU RESTRICTED)*.

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	11.07.2013	▪ Initial version
2.0	23.02.2015	▪ DGT and LS redraft
2.1	21.10.2016	▪ Change of title. Small changes. ▪ LS validation of new sections 3.8 and 3.9
2.2	07.01.2020	▪ Updated to VM 4.0 / PP > FTP. Updated GoFund links. Change of header (PP Document to EU grants)

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1. When and for how long must information be classified?

Under the Decision 2015/444[1], information must be classified if its **unauthorised disclosure could adversely impact the interests** of the EU or of one (or more) of its Member States.

> ***Example:*** *some of the information produced by a project could potentially be used to plan terrorist attacks or avoid detection of criminal activities*

To minimise costs and restrictions caused by classifying project information, the classification will be for a limited time — after which classification will be reviewed and possibly downgraded, declassified or even extended.

⚠ Classification of information may be combined with other **security recommendations (REC)** *(e.g. limited dissemination, creation of a security advisory group, limiting the level of detail, using a fake scenario, excluding the use of classified information, etc.).*

2. Classification levels

There are four **levels of classification**:[2]

- TRÈS SECRET UE/EU TOP-SECRET **(TS-UE)**

  ⚠ TRÈS SECRET UE/EU TOP-SECRET is NOT used for the security scrutiny of research proposals.

- SECRET UE/EU SECRET (**SEC-UE**)

  Use this classification for information which could *seriously harm* essential EU or national interests.

  > ***Example:*** *threatening of life or the serious prejudicing of public order or individual security and liberty*

- CONFIDENTIEL UE/EU CONFIDENTIAL **(CON-UE)**

  Use this for information which could *harm* essential EU or national interests.

  > ***Example:*** *inception of damage to the operational effectiveness or security of a Member State or other State's forces or to the effectiveness of valuable security or intelligence operations*

- RESTREINT UE/EU RESTRICTED **(RES-UE)**

Use this for information which could be **disadvantageous** to those interests.

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[1] *See Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53.)*

[2] *See. Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53.)*

Example: *information which could potentially make it more difficult to maintain the operational effectiveness or security of Member States or other State's forces*

3. How to classify information?

The classification of information produced by research projects will normally depend on two parameters:

- the **subject-matter** of the research:
  - **explosives**
  - **CBRN**
  - **critical infrastructure and utilities**
  - **border security**
  - **intelligent surveillance**
  - **terrorism**
  - **organised crime**
  - **digital security**
  - **space**

AND

- the **type** of the research/results and whether it is being done in simulated environments (*e.g. serious gaming, etc.)* or in real world experimentation
  - **threat assessments** (i.e. estimation of the likelihood of a malicious act against an asset, with particular reference to factors such as intention, capacity and potential impact)
  - **vulnerability assessments** (i.e. description of gaps or weaknesses in networks, services, systems, assets, operations or processes which can be exploited during malicious acts, and often contain suggestions to eliminate or diminish these weaknesses)
  - **specifications** (i.e. exact guidelines on the design, composition, manufacture, maintenance or operation of threat substances or countermeasure substances, technologies and procedures)
  - **capability assessments** (i.e. description of the ability of an asset, system, network, service or authority to fulfil its intended role — and in particular the capacity of units, installations, systems, technologies, substances and personnel that have security-related functions to carry these out successfully)
  - **incidents/scenarios** (i.e. detailed information on real-life security incidents and potential threat scenarios:

- on past incidents (often including details not otherwise publicly available, demonstrating the real-life effects of particular attack methods or security gaps which have since been addressed)
- on devised scenarios (commonly derived directly from existing vulnerabilities, but normally with a lower level of detail, particularly of the attack preparation phase)).

⚠ These categories are not exhaustive, and may overlap.

3.1 Explosives research

What?

'**Explosives**' are solid or liquid substances (or mixtures of substances) which are capable — by chemical reaction — of producing gas at such a temperature, pressure and speed as to cause damage to the surroundings.[3]

How to deal with threat assessments?

Information on *e.g. the availability of precursors, the manufacturing capabilities of adversaries and the effectiveness of explosives they produce* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL. If it adds value *(e.g. by prioritising these threats)*, it should be classified SECRET UE/EU SECRET.

How to deal with vulnerability assessments?

Assessments of *e.g. current capacity to detect explosives and mitigate explosions (which may include a critical analysis of existing practices or extant abilities)* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with specifications?

Specifications relating to explosives may refer to threat substances or to countermeasures.

Specifications for the manufacture, safe handling or chemical and operational characteristics of threat substances should be classified CONFIDENTIEL UE/EU CONFIDENTIAL. This includes in principle recipes for homemade explosives (HMEs). If the recipes have been validated or experimentally assessed, they should however be classified SECRET UE/EU SECRET. HME recipes that were already publicly available when the applicants applied for funding *(such as manufacturing instructions published on the internet)* do not need to be classified.

The name, chemical characteristics and operation of inhibitors used in countermeasures should be classified CONFIDENTIEL UE/EU CONFIDENTIAL. Research on the removal or attempted removal of inhibitors should be classified SECRET UE/EU SECRET.

The design, characteristics, operation and requirements of, and prototypes for, key functional devices used as components in detection *(such as samplers, sensors, lasers and lidars)* should be classified RESTREINT UE/EU RESTRICTED. Details of soft detection methods, such as data mining, online HME resources discovery and social media analysis techniques, should also be classified RESTREINT UE/EU RESTRICTED.

The design, characteristics and operation of, and prototypes for, chemical or physical mitigation and containment countermeasures should be classified RESTREINT UE/EU RESTRICTED.

Information concerning forensic methods and procedures, such as protocols for forensic sampling, methods of forensic analysis and detailed information on crime scene procedures should be classified RESTREINT UE/EU RESTRICTED.

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[3] *See Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC, 1999/45/EC and amending Regulation (EC) No 1907/2006. (O.J. L 35, 31.12.2008, p. 1-1355)*

How to deal with capability assessments?

Detailed information or test reports on the capabilities of beyond the state-of-the-art detection subsystems *(such as spectroscopic subsystems)* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL. Demonstrations of systems in selected scenarios, evaluations of detection devices and assessments of the performance of mitigation and neutralisation methods should be classified RESTREINT UE/EU RESTRICTED.

How to deal with incidents/scenarios?

Detailed scenarios (and any risk analysis or guidance tools that feature detailed scenarios), potential consequences or responses should be classified RESTREINT UE/EU RESTRICTED, as should detailed accounts of individual real-life incidents which may contain information not publicly available. Incident information to which value has been added *(e.g. itemised attack databases, matrices of IED events or detailed analyses of numerous incidents)* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

3.2 CBRN research

What?

'**CBRN**' means chemical, biological, radiological or nuclear substances and materials.

CBRN research covers research on:

- malicious use of CBRN ('preventive CBRN research') and
- preparedness and response to accidental, man-made or natural incidents.

How to deal with threat assessments?

Threat assessment information, which usually concern the availability of threat substances and the hazard that individual substances pose to European and national security, should be classified RESTREINT UE/EU RESTRICTED.

How to deal with vulnerability assessments?

Vulnerability refers mainly to the ability to detect and neutralise CBRN threat substances; this may include assessments of the susceptibility of certain organisms to particular threat substances. Such research should be classified RESTREINT UE/EU RESTRICTED. Vulnerability assessments that take a system-of-systems approach (incorporating gap analyses of a wide range of infrastructures, countermeasures and operations) should be classified SECRET UE/EU SECRET.

How to deal with specifications?

CBRN research referring to specifications for threat substances (their manufacture, characteristics, operation and effects) or to countermeasures (their design, operation and requirements) should be classified as follows:

Detailed information on threat substances *(e.g. toxicity and dose response information)* that is beyond the state-of-the-art should be classified RESTREINT UE/EU RESTRICTED.

Information on CBRN countermeasures (detection devices, treatment devices and forensic tools) should be classified as follows:

The design, proofs of concept, characteristics, operation and requirements of, and prototypes for, key functional devices for use in detection *(such as samplers, plastic scintillators and sensors)* should be classified RESTREINT UE/EU RESTRICTED. Systems-level information *(such as operating systems, platforms, software and algorithms)* should also be classified RESTREINT UE/EU RESTRICTED.

The design, proofs of concept, characteristics, operation and requirements of, and prototypes for, key functional devices for use in treatment, if precise, should be classified RESTREINT UE/EU RESTRICTED, as should detailed operational information on treatment processes.

The design, proofs of concept, characteristics, operation and requirements of, and prototypes for, key functional devices, tools, processes, protocols or systems with forensic functions *(such as discriminating between strains or determining whether CBRN substances have been intentionally introduced)* should be classified RESTREINT UE/EU RESTRICTED.

How to deal with capability assessments?

Assessments, demonstrations or test reports on the capabilities of beyond the state-of-the-art CBRN detection or neutralisation devices in laboratory or simulated environments should be classified RESTREINT UE/EU RESTRICTED.

Demonstration and test reports, or other detailed information, on the performance of beyond the state-of-the-art CBRN detection or neutralisation devices in real-life environments *(such as identifiable water treatment plants)* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

Other capability-related information *(such as analyses of detection limits, evaluations of particular systems software or detailed examples of use cases)* should be classified RESTREINT UE/EU RESTRICTED.

How to deal with incidents/scenarios?

Databases on CBRN incidents, analyses of the factors influencing the impact and course of past CBRN events and detailed information on possible CBRN scenarios should be classified RESTREINT UE/EU RESTRICTED.

Detailed information on possible CBRN scenarios based on specific, identifiable, real-life settings should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

3.3 Critical infrastructure and utilities research

What?

'**Critical infrastructures and utilities**' are assets and systems *(e.g. buildings and urban areas; energy, water, transport and communications networks; supply chains; financial infrastructures, etc.)* which are essential for maintaining vital social functions *(health, safety, security, economic or social well-being)*[4].

How to deal with threat assessments?

Analyses of man-made threats to infrastructure should be classified RESTREINT UE/EU RESTRICTED. If they add value *(e.g. by prioritising threats)*, they should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with vulnerability assessments?

Detailed gap analyses intrinsic to specific infrastructure and assessments of current security systems, technologies and processes and other extant security solutions should be classified RESTREINT UE/EU RESTRICTED. If they add value *(e.g. by including criticality analyses, highly detailed case studies, vulnerability modelling of supply systems or vulnerability assessment methodologies)* they should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

Given the specific threat of terrorist attacks on aviation infrastructure, vulnerability analyses of both passenger and cargo security solutions and processes should also be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with specifications?

The design, specifications and operation of software tools and platforms to prevent and detect attacks on infrastructure and the design, specifications and operation of architectural security solutions for utilities should be classified RESTREINT UE/EU RESTRICTED.

Detailed detection techniques for early-warning and event analysis *(such as those for use in public transport and urban environments)* and the definition of the data sources to be used should be classified RESTREINT UE/EU RESTRICTED.

Information on sensor networks *(such as those used to identify potential incidents in energy grids, ICT systems or water supply systems)* should be classified RESTREINT UE/EU RESTRICTED. Automated analysis of sensor data, the algorithms used and detailed information on other qualitative and quantitative tools to detect security threats should be classified RESTREINT UE/EU RESTRICTED.

Detailed specifications of organisational and operational processes regarding distribution networks and supply chains *(such as postal systems)* should be classified RESTREINT UE/EU RESTRICTED.

Again, given the higher threat level, the design, specifications and operation of beyond the state-of-the-art screening and detection systems for aviation purposes should be classified CONFIDENTIEL UE/EU CONFIDENTIAL, as should detailed

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[4] *See Council Directive 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection (OJ L 345, 23.12.2008, p. 77)*

information on airport checkpoint design and procedures. Detailed information on air cargo supply chains should be classified RESTREINT UE/EU RESTRICTED, like other supply chains.

How to deal with capability assessments?

Reports on the performance of systems installed in infrastructure *(such as power plants or water treatment plants)* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

The performance of completed detection and security systems in simulated environments *(such as demonstrations of early-warning systems or physical security solutions for buildings)* should be classified RESTREINT UE/EU RESTRICTED.

The capabilities of aviation detection equipment and processes in simulated environments should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with incidents/scenarios assessments?

Detailed information on scenarios and incidents involving attacks on critical infrastructure should be classified RESTREINT UE/EU RESTRICTED. If it adds value *(e.g. by including in-depth quantitative analyses of the potential or actual consequences (human, functional or financial) of such actions)*, it should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

3.4 Border security research

What?

'**Border security**' covers, for instance:

- monitoring of authorised crossing points, including the verification of legal entry of persons into a territory and the inspection of persons, objects and vehicles to detect and prevent threats to security
- monitoring of unauthorised crossing points

⚠ It concerns the EU as a whole, the Schengen area, individual EU countries and possibly associated countries.

How to deal with threat assessments?

Threat analyses should be classified RESTREINT UE/EU RESTRICTED. If they add value *(e.g. by prioritising the threats)*, they should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with vulnerability assessments?

In-depth gap analyses, user requirements or detailed inventories of existing capabilities in border security systems, assets, technologies, operations or processes should be classified RESTREINT UE/EU RESTRICTED. If they add value *(e.g. by including criticality analyses or highly detailed case studies)*, they should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with specifications?

Detailed information on the design, characteristics, operation and requirements of, and prototypes for, key functional devices for use in border security, such as sensors and radars, should be classified RESTREINT UE/EU RESTRICTED.

Systems information *(such as the functional or technical architecture, operating systems, platforms, software and algorithms)* should be classified RESTREINT UE/EU RESTRICTED.

Information on the design, characteristics, pattern recognition, operation and requirements of X-ray devices, specifically those used on cargo, should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

Detailed information on operational processes should be classified RESTREINT UE/EU RESTRICTED. This includes information on communication and interoperability *(such as frequencies used, data rates and communication protocols)*.

How to deal with capability assessments?

Reports on the performance of key functional devices *(such as sensors or radars)* and of completed systems in simulated environments should be classified RESTREINT UE/EU RESTRICTED. Evaluations of the performance of key functional devices and systems installed in real-life sites should also be classified RESTREINT UE/EU RESTRICTED.

Detailed information on the capabilities of X-ray scanning equipment used on cargo *(such as detection limits)* should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with incidents/scenarios?

Detailed information on previous incidents or in-depth scenarios for potential events should be classified RESTREINT UE/EU RESTRICTED.

3.5 Intelligent surveillance research

What?

'**Intelligent surveillance**' means the use of pattern recognition and other artificial intelligence techniques to analyse data obtained from more conventional security devices, with the aim of identifying behaviour deemed suspicious or anomalous with regard to the given legal and social context.

How to deal with…

⚠ Classification is currently not foreseen in this area. This may change in the future.

3.6 Terrorism research

What?

'**Terrorism**' refers to criminal offences committed with one (or more) of the following goals:

- seriously intimidating a population
- unduly compelling a government or international organisation to perform or abstain from performing any act
- seriously destabilising or destroying the fundamental political, constitutional, economic or social structures of a country or international organisation.[5]

How to deal with threat assessments?

Threat assessments of terrorist organisations should be classified RESTREINT UE/EU RESTRICTED.

How to deal with vulnerability assessments?

Detailed evaluations of the current capacity of law enforcement staff to predict, detect, understand and respond to terrorist strategies, attacks and activity should be classified RESTREINT UE/EU RESTRICTED. General assessments of the vulnerability of urban locations to terrorist attack should also be classified RESTREINT UE/EU RESTRICTED. *(See also Explosives and CBRN.)*

How to deal with specifications?

Information on four main types of law-enforcement measures to counter terrorism should generally be classified RESTREINT UE/EU RESTRICTED:

- prediction: anticipating the decisions, behaviour, strategies, attacks and other activities of terrorist groups (including any techniques for predicting terrorist actions, *such as decision-making and behavioural models*)
- detection: identifying terrorist operatives and their activities or plans *(e.g. through operational activities such as intelligence-gathering)* and technical information on detection devices *(such as sensors, pattern recognition, algorithms and operating systems)*
- understanding: obtaining detailed information on processes such as radicalisation *(e.g. through case studies of radicalised individuals and conceptual models detailing the radicalisation process, including information such as psychological indicators)*
- response: action based on the three previous categories *(e.g. operational and strategic information)*.

[5] *See Council Framework Decision of 13 June 2002 on Combating Terrorism U.N. Doc. 2002/475/JHA, (OJ L 164 22.6.2002, p. 3-7).*

How to deal with capability assessments?

This covers:

- law enforcement agencies' capabilities to predict, detect and respond to terrorist activities in light of the potential advances detailed in specific projects
- the capabilities of individual state-of-the-art prediction and detection techniques and systems
- the capabilities of intervention programmes, particularly with regard to radicalisation
- the technological and operational ability of law enforcement personnel to respond to terrorist activities.

Detailed information on the performance of integrated systems to predict, detect, understand and respond to terrorism, in simulated environments, should be classified RESTREINT UE/EU RESTRICTED, as should information on the operating and technological capabilities of law enforcement personnel.

Information on the performance of integrated systems to predict, detect, understand and respond to terrorism, in real-life environments, should be classified CONFIDENTIEL UE/EU CONFIDENTIAL.

How to deal with incidents/scenarios?

Detailed information on previous terrorist attacks and detailed scenarios of potential attack strategies should be classified RESTREINT UE/EU RESTRICTED.

3.7 Organised crime research

What?

'**Organised crime**' means a structured association of more than two persons acting together to commit serious offences to obtain, directly or indirectly, financial or other material benefits.[6]

How to deal with threat assessments?

Assessments of the threat(s) of organised crime should be classified RESTREINT UE/EU RESTRICTED.

How to deal with vulnerability assessments?

Detailed information on gaps in existing systems, tools and methodologies for predicting and detecting organised criminal activities should be classified RESTREINT UE/EU RESTRICTED.

How to deal with specifications?

The following specifications of measures to predict, detect and respond to organised crime should be classified RESTREINT UE/EU RESTRICTED:

- the identification and prioritisation of indicators
- detailed information on factors which influence the development of organised crime
- detailed specifications of technical countermeasures *(e.g. the design, prototypes, characteristics, operation and requirements of key functional tools and systems and information on the software and algorithms employed)*
- detailed information on the operational processes or strategies used by law enforcement personnel to respond to organised criminal acts.

How to deal with capability assessments?

Assessments of the capabilities of law enforcement personnel to predict and detect organised criminal activities including:

- detailed information or test reports on the capabilities of beyond the state-of-the-art detection subsystems *(such as intelligent surveillance systems)*
- demonstrations of systems and evaluations of detection devices, in both simulated and real-life environments
- assessments of the performance of prediction methods and models

should be classified RESTREINT UE/EU RESTRICTED.

Technical, operational and strategic capabilities of law enforcement personnel to respond to organised crime should also be classified RESTREINT UE/EU RESTRICTED

[6] *See Council Framework Decision 2008/841/JHA (OJ L 300, 11.11.2008, p.42-45).*

How to deal with incidents/scenarios

Detailed information on previous incidents or representative scenarios of organised crime should be classified RESTREINT UE/EU RESTRICTED.

3.8 Digital security research

What?

'**Digital security**' covers a wide range of research topics linked to security aspects of ICT components, devices, systems and services, communication protocols and networks (including technological and procedural measures to ensure confidentiality, integrity and availability of information).

How to deal with…

Usually there is no need to classify proposals in the area of digital security research, because In most cases ICT systems (or the measures to ensure their security) do not need any classification.

Particular attention should, however, be paid in the following areas:

- vulnerability assessments — During the research activities, projects may come upon previously unknown vulnerabilities ('zero-day vulnerabilities'); in this case, responsible disclosure is required.
- use-case risk assessment — Depending on the type of use-case and the context *(e.g. critical infrastructure)*, the results of information security risk assessments, (especially if obtained in operational or near operational environments) may include certain threats and/or vulnerabilities that require classification.
- governmental cryptology — Classification might be necessary (but research in this area does not fall within the scope of H2020).

Moreover, classification may be needed if the research extends to security sensitive information that is stored within ICT systems. In this case, the classification must be made in accordance with the rules for that area *(e.g. explosives, CBRN, critical infrastructure and utilities, border security, etc.; see above and below)*.

The need for classification of digital security research will be examined for each proposal on a case-by-case basis.

3.9 Space research

What?

'**Space research**' covers research activities in the field of space (*e.g. satellite navigation, earth observation, satellite communication, space surveillance and tracking and space exploration*).

These activities may use or generate classified information. They will therefore be assessed during the security scrutiny procedure, mainly on the basis of the GNSS classification guide[7].

[7] *This is a RESTREINT UE/EU RESTRICTED document, which will be made available to the national experts during the security scrutiny (in accordance with the applicable security rules).*

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance

Social media guide for EU funded R&I projects

Version 1.1
07 January 2020

IMPORTANT NOTICE

This guide shows you how to use social media in Horizon 2020 projects.

More guidance

- Funding & Tenders Portal Online Manual
- Communicating EU research & innovation – Guidance for project participants

You can also take specialised **training** on this topic.
For example: EASME webinar (1 hour) – Increase the impact of your project communication

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	06.04.2018	▪ Initial version
1.1	07.01.2020	▪ Updated to VM 4.0 / PP > FTP. GoFund links update

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1. Why use social media?

Social media allow you to reach an extremely wide — but also targeted — audience, maximising the impact and successful exploitation of your research results.

Communicating vs Disseminating

Social media can be used for both communication and dissemination (both of which are mandatory for all Horizon 2020 projects).

But what is the **difference** between these 2 activities?

COMMUNICATION	DISSEMINATION
Covers the **whole project** (including results)	Covers project **results only**
Starts at the **outset** of the project	Happens only once **results are available**
Multiple audiences Beyond the project's own community, including the media and general public. Multiplier effect.	**Specialist audiences** Groups that may use the results in their own work, including peer groups, industry, professional organisations, policymakers
Informing and **engaging with society**, to show how it can benefit from research	Enabling the **take-up** and **use** of **results**
Legal reference Grant Agreement Article **38.1**	*Legal reference* Grant Agreement Article **29**

Other benefits of social media

- manage your **reputation** and wield **influence** in debates on science and innovation with a wider audience
- build networks to help you **find new research partners** among colleagues and potential graduate students, accessing additional expertise from all over the world
- **informally pre-review works in progress**, gaining consensus on and/or feedback about your work
- **crowdfund** research
- recruit **volunteers**.

2. First steps

To decide whether or not to use social media for your project, you should properly understand how it works.

So on launching your project:

- **analyse the pros and cons** of using social media for your project ('SWOT' and 'PEST' analysis)
- identify your target **audience**
- ask yourself if you can reach them using social media (which **platforms**?)
- identify which consortium partner would be **best to lead** this.

3. Other rules you must follow

As well as this guide, you should also consult the following articles of the Grant Agreement:

- Article 19 — Submission of deliverables
- Article 20 — Reporting — Payment requests
- Article 29 — Dissemination of results — Open access — Visibility of EU funding
- Article 34 — Ethics and research integrity
- Article 37 — Security-related obligations
- Article 38 — Promoting the action — Visibility of EU funding
- Article 39 — Processing of personal data.

Acknowledging EU funding

All communication related to the project *(including electronic communication, using social media, etc.)* and all infrastructure, equipment or major results funded under the grant must:

(a) display the **EU emblem**[1]

and

(b) include the following **text**:

> *This project has received funding from the [European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018] under grant agreement No [number].*

[1] High-resolution emblems: http://europa.eu/about-eu/basic-information/symbols/flag

Exceptions

When the Commission or Agency in question request (or agree) that you do otherwise, or when it may simply not be possible.

In this case you should find alternative ways to mention the EU funding.

Thus, for instance, since Twitter has a 160 character limit for profile information, we recommend you use the following sentence as your bio or alternatively pinned tweet/post:

*This project receives funding from the **@EU_H2020** Research & Innovation Programme. Any related tweets reflect only the views of the project owner.*

4. Your strategy?

To avoid potentially wasting time with unfocused, open-ended use of social media, decide on a detailed **social media strategy**, as part of your project's communication and dissemination plan.

This should cover the following points:

- **WHERE**

  — which accounts and platforms will you use?

- **WHO?**

  — who in your consortium who will be in charge of social media?

  — who is your target audience?

- **HOW?**

  — what impact do you want to have and how will you assess this?

  — which language(s) will you use for your target audience?

- **WHAT?**

  — which content do you want to share?

  — how much time will you need to commit to this task?

- **WHEN**

  — what is the right time to share your content?

  — how often you should post on your account?

4.1 Choosing your platform(s)

EU-funded projects mostly use Twitter, Facebook, LinkedIn, Google+, Instagram and Pinterest (with most preferring Twitter).

Twitter

What can you post?

Text of up to **280** characters. This excludes media attachments (photos, images, videos, etc.) and quoted tweets (displaying someone else's tweet within your own) but includes links (a URL is always altered to 23 characters).

How can you use it?

To share short comments, make announcements that can instantaneously reach a large audience or retweet relevant content.

You can also use **Twitter groups** to cluster a group of projects on a similar topic.

Facebook

What can you post?

Text (no character limit), photos, GIFs, videos, links, etc.

How can you use it?

To showcase your project and results in an informal, highly accessible way.

Instead of using an individual account, Facebook profile, to share project information, we'd recommend one of these 2 options:

- **Facebook page**

  The most convenient way to promote your project on Facebook, allowing you to post a variety of content including pictures, videos, event invitations or reports, as well as links to presentations or available multimedia material. Facebook pages have **fans** who like the page, not friends. A page has also the advantage to allow for several nominated users under different types of profiles (admin, editor, reviewer).

- **Facebook group**

  Mostly used for exchanges among members (individuals). Unlike Facebook pages, where only the page administrator can post, anybody previously approved can share content with the group.

LinkedIn

What can you post?

Text (no character limit), photos, GIFs, videos, links, etc.

How can you use it?

A networking site for professionals, it can be used for groups and has established networks on specific topics. Several projects have chosen LinkedIn to create new groups, share content and connect with already established groups.

Instagram

What can you post?

Pictures only.

How can you use it?

As a self-standing repository of all the project-related images you want to publicise, separate from your own project website.

On Instagram and similar platforms, the pictures are more searchable and visible, and you have no storage restrictions.

YouTube and Vimeo

What can you post?

Audio-visual content.

4.2 Creating an account

To start communicating with a large audience at the earliest opportunity, set up the social media accounts for your project as soon as it starts. This will also enable you to access and track all project-related messages throughout the entire project.

Alternatively, you could use other social media channels, such as the accounts of beneficiary organisations and institutions, or even the accounts of the researchers involved in the project.

Once the project account is set up, these other accounts can act as multipliers of information. In this case, you should create a **project hashtag** to group conversations related to your topic. For this, it is crucial to work with communications managers at universities and research institutes.

⚠ Don't forget to let your Project Officer know as soon as you open your social media accounts.

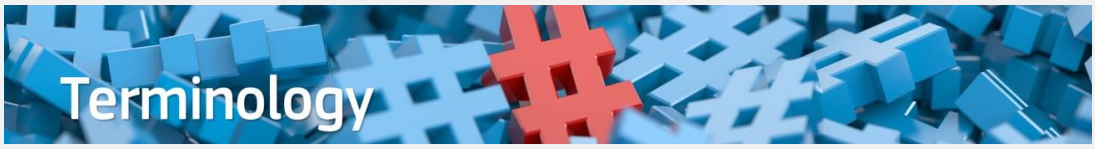

Hashtag #

Added in front of any word or phrase in a post, this makes it easier for users to locate specific content or themes.

Examples: #innovation, #OpenScience, #H2020

Using a hashtag makes the keyword or phrase in the post searchable. It is like a label that clusters and links similar content, the same way keywords do when scientific papers are published.

Why use hashtags?

- To **increase outreach** — enabling you to join bigger, topic-specific conversations.
- To **capitalise on existing trends** — finding emerging hashtags to boost your research with the right audience.

- To **consolidate and group content** — helping those who took part in an event search for related coverage using the event's hashtag.
- To **encourage interaction** — bringing new opinions and views into a discussion about a specific topic.

Handle @

Unique user name mainly used to identify a person or a project's account.

It always starts with the **@** symbol, followed by a name or phrase to identify the account. For example, the European Commission's Twitter handle is @EU_Commission.

How to use handles

- To send a **direct reply** to someone, by starting your message with their handle.
- To **link to someone else's account** (known as a 'mention') by using their handle elsewhere in your post. This will link your post to the mentioned user's account.

4.3 Deciding who is in charge

All beneficiaries are welcome to contribute to the project's social media activities, but you need to **designate one person to oversee** all of this.

We suggest you specify who this is in your communication and dissemination plan. They will set up and manage social media accounts, centralise the information to be shared and communicate with the audience, including replying to messages.

The ideal person for this could be the beneficiary staff member who already handles communication tasks.

Regular exchanges of information between the frontline project staff and the communication and dissemination team can help ensure the project is promoted adequately, by enabling the social media manager to draft relevant content and post it on time.

To reach the widest possible audience, we recommend you identify other individuals in your consortium who are already using social media. Invite them to retweet and share the project's posts and relevant content with the appropriate audiences.

4.4 Identifying & building your audience

Which audience?

You must define clearly the target audience you want to reach through social media — *e.g. researchers, entrepreneurs, policymakers, young people*. This determines the **message** you want to convey, and how.

You need to **adapt your message** to the audience: think of what information your intended reader could be looking for and aim to give them that information, **customising** the language and content instead of posting just for the sake of it. This makes it more likely that people will read and retweet your content, expanding your audience.

Building an audience

Building a social media community that shares the same interests and is involved in similar projects is crucial for boosting the visibility of your content and increasing the number of people who read your posts. You can do this by:

- retweeting
- replying to others' tweets
- quote-tweeting information about your project
- start an online discussion, *e.g. by asking questions*.

Connecting with other Horizon 2020 beneficiaries

Projects under the same call often share goals and are aimed at similar audiences. By connecting and clustering with likeminded beneficiaries — *for example, by following their account, retweeting or replying to their posts or tagging them* — you can attract each other's followers and fans, enlarging your community of interested individuals and organisations.

Follow the European Commission social media channels

We also generally encourage beneficiaries to play an active role in Horizon 2020 communication and dissemination campaigns launched by the European Commission.

European Commission social media channels

The social media platforms the Commission and its agencies use can help you expand your audience by sharing your posts.

Try the following:

- Add **#H2020** to your tweets. Be part of the online conversation about Horizon 2020 and your tweets become searchable.
- Tag **@EU_H2020** in your tweets. Relevant posts are sometimes shared on EU social media accounts.

Full list of relevant hashtags/handles (for a selection of these, *see Appendix*).

Align all your communication channels

To avoid confusing your audience, and improve access to your content, and interconnections based on it — be consistent in linking together all your social media project accounts and the project website, also by naming them consistently.

- To improve your **search engine ranking**, create a connection between your social media and your project website, e*.g. by posting 'live' tweets and Facebook posts on the project website*.
- Make sure all your **offline information** on your project *(leaflets, flyers, publications, etc.)* includes prominent reference to all the online sources.

4.5 Risks of social media

When using social media, like with any other means of communication, special attention should be paid to the content shared.

It is up to each consortium to determine which information to keep private and which to publish, where and to what extent.

People who want to 'steal' information might see social media platforms as fertile hunting grounds. However, plagiarism is nothing new, so it's not a reason not to use social media.

That said, you should be aware of the following risks, and take the necessary precautions:

- **Internet bots/social media bots**

  Automatically generated messages designed to advocate certain ideas/campaigns aimed at manipulating public opinion and work against a project/consortium.

- **Online trolls**

  These spread negative messages, causing other followers/friends to lose interest in/stop following your project.

- **Privacy/data breaches**

  This means disclosing any research involving private content without the explicit consent of the data owner. Breaching online privacy rules can result in liability.

- **Information leakage**

  This means a loss of intellectual property. It is for the content owner to decide what to post or share.

- **Security breaches**

  All social media platforms have their own privacy and data protection policies. Read them carefully.

  ⚠ EU-classified information may under no circumstances be used in social media. Special security rules apply.

- **Targeted spam**

  Fake messages used to obtain confidential information.

⚠ To protect your project and yourself, all consortium members should agree on an **internal code of social media conduct**, covering all the above points.

4.6 Measure impact and performance

Impact criteria

With social media, you can assess in detail how well your post has been received, from the moment you publish it to days and months afterwards.

We suggest that you **create your own criteria** to measure impact. To do so, you can choose from many free social media analysis tools, such as:

- **Twitter Analytics**
- **Facebook Insights**

You should also build these into **key performance indicators** for your social media strategy, so you can compare the impact you initially expected to have with the intermediate and final results.

Which criteria to choose?

Generally speaking, you can measure dozens of different metrics on social media, but there is still no single criterion that gives a constructive measurement of the impact of using social media.

This makes it particularly difficult to assess the impact of doing so for scientific projects — but you can identify specific indicators that best fit the area of research covered by your project, and keep track of these.

Indicators can include the following quantitative and qualitative aspects:

- **Quantitative**

  Number of clicks, likes, shares, tags, video views, new followers, profile visits, engagement rates, cost per result, uses of your hashtag and influence of the accounts that use it etc.

- **Qualitative**

  Types of comments received, their tone, the number of people they reached, the types of followers, impressions, traffic data, ratings, word clouds etc.

  They can also include new collaborations, product commercialisation, appreciation for research, as well as greater knowledge among specialists and the general public. You can also perform a sentiment analysis, to understand the opinions expressed and their emotional tone.

Monitoring & reporting

Monitoring your social media accounts and assessing their effectiveness — ideally every month — gives you a wealth of data to identify trends and refocus your activities if necessary.

Using your pre-defined criteria, analyse what works and what doesn't, and use this knowledge to adjust your strategy and plan ahead.

When **reporting** on your communication and dissemination activities to the EU (through the periodic reports), include information about your social media accounts, activities, achievements and impacts.

4.7 Appropriate style, content and tone

Below are some tips to help you **hold the reader's attention** (as well as being accurate, fair and consistent) — vital in today's crowded social media landscape.

Style

- Minimise the use of **abbreviations**, except generally recognised acronyms and accepted hashtags.
- Limit the number of **technical words** that only experts are likely to understand. Instead try to use layman's terms.
- Use **visual aids** in your tweets as much as possible, and tag relevant handles.
- Keep your posts **short, clear and catchy** — 3 sentences at most on Facebook.
- Use software to help you avoid **typos and grammar mistakes**.
- Convey **emotions** with your posts (but don't go overboard, or undermine your content's credibility with excessive hype or clichéd promotional phrasing).
- Publish content in other **languages**, to reach local communities.

Content

- Before you post, **ask yourself if you would be interested** in reading this, or clicking the link to know more.
- **Vary the content** — include a picture, video, GIF, infographic, link or poll to enliven the text. The image credit should be put next to the picture.
- **Visual content** (as above) is very effective as it conveys a lot of information in an appealing, easily digestible way.
- **Share information** about your project results and final products, new papers and scientific publications, events, conferences and training courses, breaking news and hashtags relevant to your project, etc.
- Highlight the project's **impacts** and its contribution to society.
- Tag appropriate **handles**, to ensure your content reaches the widest audience possible.
- Make sure everything you post is **accurate** — nobody wants to follow an unreliable information source!
- **Events** – keep in mind that live posts or pictures of events may not necessarily be relevant content for people who did not attend. They are more likely interested in the **outcomes** of such events *(minutes, reports, links to presentations and interviews, etc.)*.

Tone

- Use **appropriate, inoffensive language** (this is how you will get responses and stimulate debate).
- Be **receptive to your readers' arguments** — if you don't agree, defend your position without being rude.
- Gain/maintain **credibility** by sharing worthwhile, relevant content and show respect for other cultures and ideas, online as well as offline.

- Be aware that **libel and defamation** laws apply.

SOME TIPS FOR TWITTER USERS

- Create your **project handle and hashtag** (if necessary) and use them consistently throughout the overall project implementation.
- Leverage any **existing social media presence**.

  If the host institution, researchers, team members or other relevant organisations already have a strong, well established social media presence, get all these parties to **communicate information about your project**, on the basis of an editorial schedule that you create. This will help you reach already existing audiences.
- Use handles, such as **@EU_H2020** in your tweets to maximise your visibility and be recognised as part of the H2020 community.
- Include **emojis** in your tweets.
- Twitter is becoming increasingly **visual** — post pictures, videos, GIFs or data visualisations to spark interest.
- Make **Twitter lists** to categorise your accounts into themes, or sign up for already existing lists. These lists can serve as channels for receiving news in your policy area and provide you with pools of people/organisations who can share your posts, if you tag them or message them directly.
- Share images and **tag other Twitter accounts** (up to 10), to build a relationship with your audience and make them aware (the account tagged receives a notification) of content that might interest them, in the hope that they might want to retweet it.

SOME TIPS FOR FACEBOOK USERS

- Distinguish between and **use the different types of page appropriately**: Facebook profile, Facebook page, Facebook group, Facebook event.
- **Vary your content** (pictures, videos, polls, links…) and **tag** other profiles and pages in your posts, to reach a wider audience.
- Use **Facebook Analytics** to track the performance of your page.

4.8 When should you post?

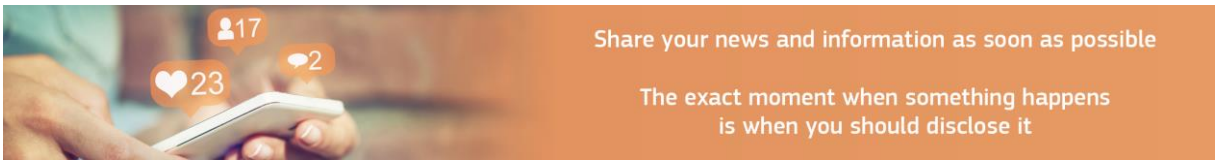

Right at the start, in your strategy, include an **editorial calendar** and plan how often you should post.

Posting for the general public and media

You can share your information and news *(using pictures, (live) videos, short messages, key quotes, etc.)* **at the exact moment they are taking place**, for example:

- when you have a project **breakthrough**, reach a (genuine) milestone or get results
- when your project is featured at a **conference** or **event**
- when you are presenting your project at an **exhibition fair stand**
- when a new **press release** is published

⚠ **Don't wait** until you have all the details or the full story (you can post this later). Acting immediately is vital to gain momentum and get your event, result, etc. into online discussions.

⚠ Tweets cannot replace full articles and press releases about your project's achievements. But they can link to more detailed information available on other platforms, making your content more visible.

Posting for stakeholders/target audience

Alert your followers when your scientific papers have been **peer-reviewed** and **published:**

- use the **@EU_H2020** tag for maximum impact
- **link** to your paper/article
- **tag your publisher**, to reach a wider audience (ask your publisher and repository in advance what specific authorisations and agreements you must adhere to)
- post links to recently-published **related scientific articles** (to reach journalists who might cover the story, or other researchers you can have relevant scientific discussions with).

Timetable for posting on events

Messaging can vary, depending on the event and its target audience, but some standard steps and timing apply to all cases:

At least **6 weeks** in advance: Tell your Project Officer you've decided to organise an event. Decide what hashtags you're going to use and start sharing content alongside them. To make your event more visible, look into using any additional means of communication that the Commission or other EU online platforms provide.

At least **1 month** in advance: Create web content and start promoting it on your project's social media account using the event hashtag. Prepare an event image to

share on tweets. Engage in conversations about similar topics and involve your audience by asking questions and using the relevant handles.

Several **days** before the event: Prepare a list of useful, relevant Twitter handles for participants to engage with before and during the event, such as event speakers and participants. Create a list of posts to tweet during the event. You can schedule your tweets using a social media dashboard such as Hootsuite.

During the event: Live-tweet with interesting pictures, tag/mention people, promote the relevant hashtag and ask participants to join the conversation. Tweet related content, scientific studies, published papers, web content, always including your hashtag.

> Live-tweeting provides engaging, concise content for people who couldn't attend an event, either in real time or later by searching for the conference hashtag to catch up on the key moments and discussions *(by looking at photos, videos and links and reading key discussion points from throughout the day)*.
>
> ⚠ For live-tweeting to be successful, you need to have your **pre-prepared handles and posts** to hand. **Don't sacrifice clarity, accuracy or key messages** for the sake of speed — or you will lose followers.

After the event: During the days following the event, monitor your impact and keep tweeting relevant content with your own hashtag (if any).

Tools you can use

Twitter Moments — This gives you maximum flexibility in managing the posts related to your event. Moments are customised sections you can create on your project's Twitter account, to display content related to an event and keep it separate from the rest of the posts. This makes it more visible and traceable.

Facebook event — This is an online platform dedicated to a particular event, where you can share information and invite people.

⚠ When **reporting officially** on your event, it is not enough to just copy-paste your tweets or social media pages. Nor should you replace in-depth reports on conferences, or minutes you are asked for the periodic report, with a list of posts.

Making the best use of social media

- make an **analysis of strengths, weaknesses**, opportunities and threats (SWOT) in relation to using social media for your project
- make a **social media strategy** and plan ahead right from the start
- choose the social media **platforms** and **accounts** that are most relevant to your project
- clarify **who is doing what** in your consortium
- define your goals, target **audience**, policy and **messages**
- plan how you are going to **measure your impact**
- be **consistent** across all your communication channels
- share **project-related content only**, using an appropriate style
- **vary** the types of content you post *(text, pictures, videos, polls, links, etc.)*
- **engage** with your audience using replies, retweets or tags
- **connect** with other EU-funded projects and the European Commission social media channels
- use **@EU_H2020** and **#H2020** in your tweets to maximise their visibility
- follow the news and use **trending hashtags**
- **monitor** your social media channels to measure the impact you're having
- **share** the social media activities and analysis for your project with your **Project Officer**, in the deliverables and periodic reports.

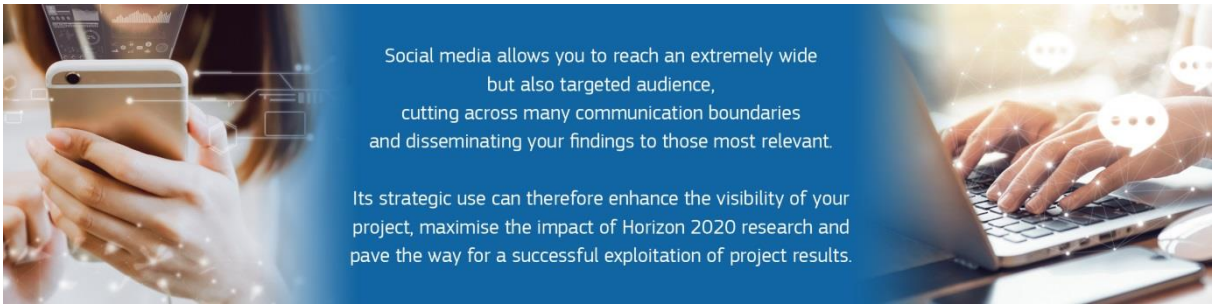

Appendix

Sample Twitter handles & hashtags

Twitter handles:

@EU_H2020

@MSCActions

@Mariecurie_alum

@mariescurie_ire

@TNavracsicsEU

@Net4Mobility

@FET_eu

@EU_Growth

@EUHomeAffairs

@EU_TrustSec

@OpenAccessEC

@DG_Connect

@DigitalAgendaEU

@EU_Agri

@EUClimateAction

@Energy4Europe

@INEA_EU

@EU_ENV

@EU_MARE

@Transport_EU

@ERC_Research

@EU_EASME

@IMI_JU

@cleansky_ju

@fch_ju

@BBI2020

@ECSEL_JU

@Shift2Rail_JU

@SESAR_JU

Twitter hashtags:

#H2020

#MSCA

#MarieCurious

#MSCAjobalert

#MSCA20

#EUbudget4results

#Bioeconomy

#EIPagri

#ePrivacy

#cybersecurity

#SecurityUnion

#openaccess

#DSMeu

Sample Facebook & LinkedIn pages

Facebook pages:

- https://www.facebook.com/Marie.Curie.Actions
- https://www.facebook.com/FET.europe
- https://www.facebook.com/DigitalSingleMarket
- https://www.facebook.com/pages/EGov-Infso
- https://www.facebook.com/EUScienceInnov
- https://www.facebook.com/EU.Growth
- https://www.facebook.com/EUAgri

LinkedIn pages:

- HORIZON 2020 Framework Programme for Research and Innovation
- H2020 MARIE CURIE Actions Fellowship & Research Grants, PhD Careers and R&D Jobs
- INEA - Innovation and Networks Executive Agency
- EASME - EU projects & partner search
- EASME - Environment projects & partner search
- BBI JU - Bio-based Industries Joint Undertaking

Other channels:

- https://www.youtube.com/EUScienceInnovation
- https://www.youtube.com/user/Horizon2020YourViews
- https://www.youtube.com/user/EuropeanResearchArea
- https://www.youtube.com/user/JRCaudiovisuals
- You Tube BBI JU - Bio-Based Industries
- https://www.youtube.com/c/DigitalSingleMarketEU
- https://www.instagram.com/digitalsinglemarket/
- https://www.pinterest.com/eucommission/digitalsinglemarket/

ALL EU social networks

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Guidance

How to draw up your H2020 consortium agreement

Version 2.2
07 January 2020

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	n/a	▪ Initial version
2.1	02.03.2015	▪ LS review
2.2	07.01.2020	▪ Updated to VM4.0 / PP > FTP references

IMPORTANT NOTICE

This document aims to assist **applicants/beneficiaries** in **drawing up** a **consortium agreement** for Horizon 2020 projects (— mandatory for all multi-beneficiary projects, unless the call/work programme provides otherwise).

The consortium agreement should set the framework for a successful project implementation (i.e. settle all issues that might hamper the smooth and seamless cooperation of the different actors for the different parts of the project).

It should in principle be negotiated and concluded **before signing the grant agreement**.

Figure 1 — consortium agreement time-line diagram

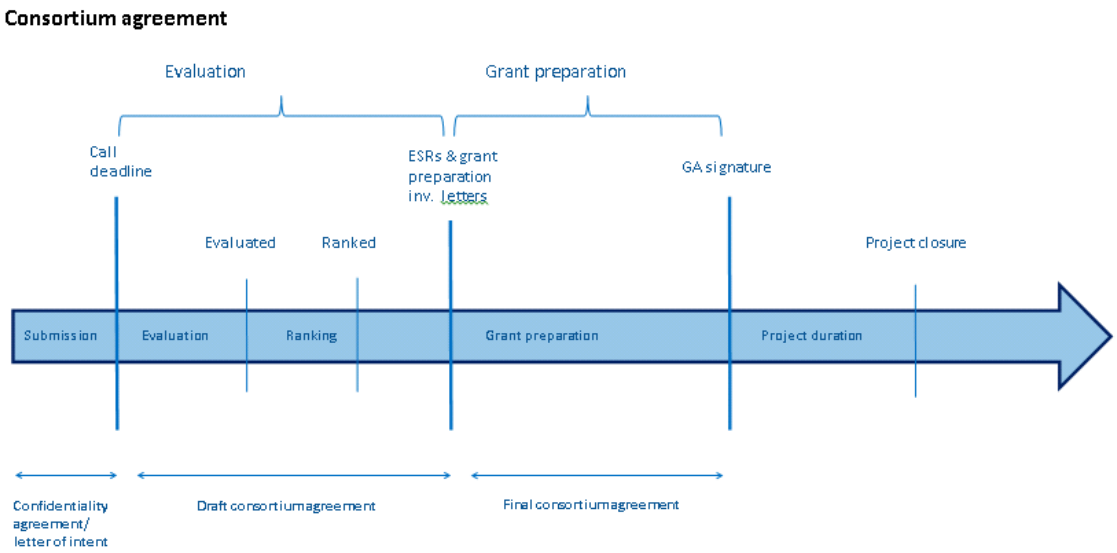

The consortium agreement is a private agreement between the beneficiaries, to set out the rights and obligations amongst themselves. (⚠ It does NOT involve the European Commission/Agency.)

It should **complement** the grant agreement and must NOT contain any provision contrary to it.

You remain **fully responsible for your consortium agreement**. This document is necessarily general and may not address your specific needs. For complex consortia, you should seek professional legal advice if needed.

Other information

⚠ This document is limited to the consortium agreement for H2020 projects.

For a more general overview of how Horizon 2020 grants work, *see the Online Manual*. For detailed information, *see the H2020 AGA — Annotated Grant Agreement* on the Funding & Tenders Portal.

A comprehensive list of Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' page of the Funding & Tenders Portal.

Horizon 2020 terms are explained in the Glossary of the Funding & Tenders Portal.

If you need help, you can also contact the Research Enquiry Service helpdesk.

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2.1 Typical issues & how to address them 8

1. Proposal phase: Preparing the consortium

During the proposal phase, you will need to **commit yourselves to** a common **project** and draw up a joint **proposal**.

You will need to:

- **share important information** about the state of play of your research, your approach to the project, and the goals that your proposal is to meet
- negotiate your project's technical and commercial specifications

  ⚠ Avoid focusing too much on specific internal policies or strategies.
- share information about your operational capacity (to see how it complements others' capacity), pre-existing intellectual property ('background'), etc.
- submit information on your operational capacity to the Commission/Agency
- choose a **name for your project**
- **prepare the consortium agreement** (preferably by drafting an outline or draft consortium agreement)

1.1 Typical issues & how to address them

Typical issues arising at the proposal stage include the **commitment** to the project, the **confidentiality** of the information shared and the choice of a **name or acronym** for the project.

- **Formalising the commitment**

  During the proposal phase (and before submitting the proposal), you should **formalise your negotiations** (through a '**letter of intent**' or as part of a '**confidentiality agreement**'; *see below*). This will give you some legal certainty. It will also facilitate cooperation and the exchange of information.

  > 'Letters of intent' or 'memoranda of understanding' are agreements outlining the framework for negotiations between applicants, usually drawn up at the outset of negotiations on involvement in a project.
  >
  > A letter of intent is not usually legally binding, but applicants could include some binding rules *(e.g. confidentiality obligations)*. Even if non-binding, a letter of intent is more formal than a 'gentlemen's agreement', which is often unwritten. Signing a letter of intent is an official sign that the applicants have a shared interest in achieving a given result, and may make a successful outcome more likely.

  The letter of intent (or confidentiality agreement) should set out:

  - the shared intentions (i.e. taking part and the substance of the proposal)
  - rules on communication, sharing information, confidentiality and reporting (unless included in a separate confidentiality agreement)
  - the conditions of termination.

This gives the parties a framework for further negotiations. Moreover, it allows the coordinator to declare that all applicants have explicitly consented to:

- taking part and
- the substance of the proposal.

- Sharing information — Confidentiality issues

Sharing information between applicants entails a risk of it being disclosed or used for the wrong purpose.

To avoid any such misuse, applicants should commit themselves (either in the letter of intent or in a separate confidentiality agreement) to honouring certain confidentiality obligations. They should accept restrictions on:

- using confidential information
- disclosing it.

'Confidentiality agreements' are agreements that set out the conditions under which applicants may disclose or use secret or confidential information *(e.g. the research idea for the project)*.

The confidentiality agreement should typically set out:

- a definition of what constitutes confidential information
- the confidentiality obligations (including their scope and duration)
- penalties for breach of confidentiality obligations (if necessary)

Confidentiality obligations: scope. The confidentiality agreement should set out that it is permissible to pass on confidential information shared among applicants to a specified circle of persons/organisations, on a '**need to know' basis** and subject to certain **conditions**.

Applicants may, for instance, need to share confidential information with identified '**linked third parties**' that will participate in the project (i.e. non-consortium organisations with which they have links)**.**

⚠ Define the concept of 'linked third party' using the definitions in the Model Grant Agreement, to make it clear which organisations or individuals are subject to confidentiality obligations.

To avoid requiring the linked third parties to sign confidentiality obligations, you can guarantee that any confidentiality obligations to which you are subject also apply to your linked third parties (as defined in the confidentiality agreement).

When establishing confidentiality obligations, remember that the links between a linked third party and an applicant may be severed. (For instance, the entity could be sold or merged with another organisation. You could stipulate that in such cases the entity concerned must return any confidential information it has received.)

Similarly, applicants may need to disclose information to **employees** or **other staff**.

Although employees often have a duty of confidentiality to their employer under national labour law, they should be made aware of their specific obligations to keep this information confidential.

You should explicitly guarantee that employees or other staff with whom the information is shared will keep it confidential.

Employees' confidentiality obligations should preferably continue after they stop working for you, if national law allows this.

Confidentiality obligations: duration. The confidentiality agreement should set the time-limit of the confidentiality obligations (typically starting from either the date on which the agreement takes effect or the date on which the confidential information was given).

Penalties for breach of confidentiality. A breach of confidentiality may cause significant damage but the damage may be difficult to prove. To prevent this, you may wish to include a contractual penalty in the confidentiality obligations (if allowed under national law).

- **Project name — Trademark issues**

At the proposal stage, you and your fellow applicants must choose a name and acronym for your project.

It must not be one that can be confused with existing names.

Moreover, your choice may be limited by other rights *(e.g. trademarks and domain names)*.

⚠ Avoid choosing a project name or acronym that is identical or similar to another organisation's registered trademark or domain name, especially if it is active in the same area. This is especially important if you and your partner(s) plan to make commercial use of the name or acronym later on.

You can use certain tools to search for previously registered trademarks or domain names.

There are free search tools for **trademarks**, provided by the EU Office for Harmonisation in the Internal Market (OHMI) and by the World Intellectual Property Organisation (WIPO). You can also contact your national intellectual property office.

For **domain names**, you can check your suggested project name in the WHOIS database.

- **Preparing the consortium agreement**

Draft consortium agreement. Even at the proposal stage you should at least draw up a draft consortium agreement. This enables you to discuss and agree on how to handle important (and often sensitive) matters. The draft can then be used as a starting point for further discussions if the proposal is

accepted.

The draft agreement should give a first idea on:

- project implementation and division of tasks
- internal organisation and management of the consortium and user rights on the Funding & Tenders Portal
- project budget and distribution of EU funding
- additional rules on rights and obligations related to background and results
- liability, indemnification and confidentiality arrangements between the beneficiaries
- boilerplate provisions: duration, termination, communication, applicable law, settlement of internal disputes etc.

2. Grant preparation phase: Drawing up the consortium agreement

Successful proposals will be invited to 'grant preparation'.

In this phase, any preliminary agreements you have made should be replaced by a consortium agreement that should be concluded before the grant agreement is signed.

2.1 Typical issues & how to address them

The consortium agreement allows you, as consortium members, to agree on any specific details not covered by the grant agreement, such as the organisation of work, intellectual property management, liability, and future exploitation and dissemination of results.

A consortium agreement is not a concept detailed further in law. Therefore, the agreement itself must spell out all the parties' rights and obligations.

In principle, the agreement may include any arrangements you wish to make, as long as they are not contrary to the grant agreement and the Horizon 2020 Rules for Participation Regulation No 1290/2013[1].

Model consortium agreements are available from different sources.

Note that these have NOT been developed or endorsed by the Commission.

For more information on model consortium agreements, *see the IPR Helpdesk*.

[1] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Issues that typically arise include:

- **Preamble**

  The preamble sets the scene and provides the context for the agreement.

  It may refer to any agreements previously made by the parties, such as a letter of intent or confidentiality agreement, and may refer to the grant agreement and/or to the call for proposals.

- **Parties — Involvement of third parties**

  The consortium agreement should give the official name for each member of the consortium ('parties to the agreement' — the corresponding term in the grant agreement is 'beneficiaries').

  You might also like to add other interested parties to the consortium agreement, in addition to the beneficiaries *(e.g. linked third parties)*, in particular if they will carry out tasks during the project.

- **Definitions**

  Defining specific terms in a 'definitions' section helps to avoid misunderstandings about the extent of a particular right or obligation.

  ⚠ Use the definitions of the H2020 Model Grant Agreements wherever possible. (No need to repeat them, a simple cross-reference is sufficient).

- **Internal organisation — Managing the consortium**

  The bulk of the consortium agreement normally concerns 'governance'.

  Since a consortium, by definition, involves several different parties, often from different Member States and with different languages and customs, the rules on efficiently managing and organising the consortium should be set out clearly. Proper management of the consortium is needed to achieve results and to efficiently disseminate and exploit these results.

  Provisions on governance usually cover:

  - set-up and ways of working of coordination and management bodies
  - the powers and responsibilities of these bodies
  - voting rules.

  They may also say:

  - how often meetings will be held
  - how parties should communicate and correspond with each other and the management bodies
  - how the project should be followed up and supervised
  - what rules will apply if a partner wants to leave the consortium or if a new party wants to join when the project has already started.

The larger the consortium, the more detailed the management rules need to be.

Managing user rights on the Funding & Tenders Portal. The consortium agreement should define the roles and Funding & Tenders Portal user rights (for project information and project management tasks, *e.g. filling in forms, uploading documents, submitting information and signing documents)*.

The consortium can assign most of the required user rights to anyone it considers necessary, and revoke them if necessary.

The consortium agreement should include provisions on managing and maintaining user rights assigned to persons involved in the project, so that information isn't accessed inappropriately and all transactions are appropriately authorised. These provisions should cover what happens when persons leave or change role in the project or in the organisation, and what happens if applicants/beneficiaries end their involvement with the project.

For more information on Funding & Tenders Portal roles and user rights, *see the Online Manual*.

- **Project implementation — Division of tasks**

The consortium agreement should cover matters such as:

- the tasks assigned to each party
- the project schedule
- how changes can be made to the project
- the conditions under which other persons/organisations *(e.g. linked third parties, seconded persons or subcontractors)* are brought in to the project.

- **Project budget — Contributions — Receipts**

The consortium agreement should address issues such as:

- distribution by the coordinator of the payments received by the Commission/Agency
- contributions
- receipts.

Any specific arrangements must NOT conflict with the general rules set out in the grant agreement.

Contributions. The agreement should set out in detail the contributions made by each consortium member and whether these are made in cash or in kind.

Receipts. In the consortium agreement, you should also consider the potential implications of contributions and income received, since, when these qualify as receipts, they will be considered at project-level, (and NOT at

beneficiary-level, as it was under FP7). A beneficiary's income may mean the grant for the project is reduced because of the non-profit rule *(see Article 5.3.3 of the H2020 General MGA)*. Therefore, if such receipts are expected, the consortium agreement should set out how this will be managed.

- **Intellectual property rights — Exploitation and dissemination of results**

The consortium agreement should set out flexible and efficient rules to encourage and support cooperation between the beneficiaries as regards intellectual property. They may include agreeing on:

- the background *(e.g. positive or negative list)*
- protection, dissemination and exploitation of results
- how joint ownership will be managed
- transfers of ownership provisions
- any additional rules on access rights
- how third party involvement will be managed.

⚠ They must NOT conflict with the rules set out in the grant agreement.

Protection, dissemination and exploitation of results. The consortium agreement should set out rules how results will be identified, reported, protected, disseminated and exploited.

You should put in place a process to identify valuable results. The grant agreement requires a beneficiary to notify the other beneficiaries before disseminating results which allows you to review the content before it is disseminated and, if appropriate and justified, to seek protection for the results. (⚠ Note that regimes for the protection of results may vary depending on where protection is sought.).

Parties may have different interests as regards the dissemination of results. Some parties may have an interest in publishing them *(e.g. in dissertations or scientific papers)*; others may wish to keep them confidential (to gain or maintain a competitive advantage).

⚠ The rules should ensure that decisions on disseminating the results take due account of the interests of all beneficiaries affected, while still allowing (at least part of) the results to be disseminated without unreasonable delay.

Joint ownership. If two or more beneficiaries jointly produce results in the project, and you can neither identify each beneficiary's contribution nor separate the results to protect them, the beneficiaries will jointly own the results (default regime under Article 26 of the H2020 General MGA). The grant agreement requires joint owners to agree (in writing) on the terms of their joint ownership. You could do this in the consortium agreement.

⚠ If results are jointly created and you do NOT want the default joint

ownership scheme, you can agree on a different ownership scheme (*e.g. making one party the owner of the results, and giving the others the right to access them)*. This can only be done once the results have been generated.

Third party involvement. If you need help from other parties (including linked third parties) to carry out the project or to exploit its results, the consortium agreement should explicitly cover this, especially if they will play a significant role.

You may need to put in place additional rules *(e.g. additional confidentiality obligations or additional access rights)* and you must ensure that any agreements you make with these persons/organisations allow you to meet your obligations under the grant agreement and the consortium agreement.

- **Confidentiality obligations**

The consortium agreement should set out the conditions under which the parties may disclose or use secret or confidential information *(see above)*. It should typically set out:

- a definition of what constitutes confidential information
- the confidentiality obligations (including their scope and duration)
- penalties for breach of confidentiality obligations (if necessary).

- **Liability, warranties & penalties — Financial responsibility for rejection of costs, reduction of the grant, recoveries and damages**

Liability. The consortium agreement should cover each party's liability for actions or omissions in the project (and possible guarantees, indemnities and penalties).

It should, in particular, cover:

- the procedure to be followed *(e.g. for serving the party with a warning, giving them the opportunity to object to the charge or to rectify the situation within a given period)*
- liability for damage caused and the related indemnification (and possible limitations of liability, including *force majeure*)
- possible penalties for non-compliance (stipulating clearly the terms of the penalties, *e.g. the amounts, the procedure for imposing a penalty and the interest due in cases of late payment*).

⚠ Again, consortium members may have different interests. Some parties may be reluctant to participate in the project without a reasonable cap on liability (especially if they are not able to build up sufficient financial reserves to deal with cases where it must pay damages, which is normally the case particularly for small enterprises, start-ups and non-profit research institutions); others may be reluctant to participate if there is no liability.

When limiting liability in a consortium agreement you should check whether the applicable national law allows liability to be limited in the way envisaged. (In many countries, for instance, excluding liability for fraud or wilful misconduct is not allowed.)

You should also decide whether or not you will guarantee in the consortium agreement that your background or results do not infringe third party rights. (Although there is always a certain degree of risk in making this kind of guarantee since it is almost impossible to check worldwide whether someone else's intellectual property rights may come into conflict.)

The arrangements in the consortium agreement could include a specific conflict resolution system for potential disputes.

Rejection of costs, reduction of the grant and recoveries. Although it does not happen very often, the Commission/Agency may reject the costs declared by the consortium or reduce the grant (normally after an audit). In this case, the grant agreement defines the way the financial responsibility is normally shared between the beneficiaries (*see Articles 42, 43 and 44 of the H2020 General MGA*).

⚠ If you would like to share financial responsibility between members of the consortium differently, this should be done via the consortium agreement.

Damages. Under the grant agreement, each beneficiary is liable for the damages it causes to the Commission/Agency *(see Article 46 of the H2020 General MGA)*.

⚠ If you would like to share financial responsibility between members of the consortium differently, this should be done via the consortium agreement.

- **Boilerplate provisions**

'Boilerplate provisions' are standard contractual provisions included in agreements of all kinds. They set out the basic terms of an agreement, such as:

- its start and duration (i.e. entry into force and end (including early termination))
- methods for resolving disputes (in court, via arbitration or via mediation)
- the procedure for amendments (and the types of changes that require one)
- contact points for any correspondence
- the law applicable to the agreement.

Boilerplate provisions can also cover:

- waivers (which allow you to give up the right to sue the other parties

for breach of a particular provision, without giving up any future claims under that provision)

- severability (which allows a court to remove a provision that isn't valid, while still keeping the rest of the agreement intact)
- assignments (which refers to your ability to sell or transfer your rights under the agreement to another party)

  You may decide to prohibit any assignment of rights, or to allow rights only to be assigned to affiliated entities, etc.
- force majeure (which means that no party is responsible for failures or delays if these are caused by circumstances beyond its reasonable control). These usually include:
  - fire
  - floods
  - storm
  - earthquakes
  - war
  - terrorism
  - fuel shortages
  - transport embargoes.

European Commission

EU Grants

Guidance
Amendment types & supporting documents

Version 5.1
06 December 2018

IMPORTANT NOTICE

This document is designed to help **beneficiaries of EU grants which** are managed via the EU Participant Portal (EU Funding & Tenders Portal) with their **amendment requests**, i.e. to list the supporting documents and show how amendment clauses ('AT-clauses') are typically combined.

It covers all types of amendments that are currently supported by the Participant Portal Amendment tool.

Further guidance can be found in Article 55 of the H2020 AGA — Annotated Grant Agreement (— also valid for programmes outside H2020).

⚠ If you have any doubt, contact us (via your Participant Portal account) before finalising your amendment request.

Other information

For detailed information on amendments,

For a broader overview, see the Participant Portal Online Manual.

A comprehensive list of all reference documents (including legislation, work programme and templates) can be found on Participant Portal Reference Documents.

Terms are explained in the Participant Portal Participant Portal Glossary.

If necessary, you can also contact the Research Enquiry Service.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	25.11.2016	▪ Initial version
2.0	n/a	▪ Not applicable
3.0	n/a	▪ Not applicable
4.0	n/a	▪ Version numbering aligned to MGA version. ▪ Instructions on colour coding corrected. ▪ MGA v4.0 changes introduced.
5.0	23.07.2018	▪ Checked against MGA v5.0 and H2020 Lump Sum Pilot (no changes needed).
5.1	06.12.2018	▪ Correction of mistake on handover date and instructions on change of coordinator without its agreement in AT8.

Grey = clauses that can be activated only by the EU (Automatic – only PO can change system data, Selected by EU or On-demand).

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		▪ Correction of mistake in AT31 (H2020 IA instruction not only for GAs before version 4.0) ▪ Clarification in AT 33 (examples linked to H2020 and AGRI Promo) ▪ Change of option instruction for AT36 ▪ Addition of instructions on sick leave for AT82

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AMENDMENT TYPES & SUPPORTING DOCUMENTS

⚠ This document lists the amendment types (AT-clauses) and shows **mandatory combinations** and combinations that are often used together (**other combinations**). Additional combinations may be needed to suit your case.

The list of supporting documents covers required documents for the clause in question AND its mandatory combinations. For those linked to other combinations, see those other clauses.

For any questions related to an amendment request, please contact us immediately (via your Participant Portal account) so that we can see how to solve the problem. Incomplete or incorrect amendment requests will have to be rejected and re-submitted (it is not possible to change amendment requests, once signed).

Clauses are implemented as:

1. Automatic (change of system data automatically triggers AT-clause)
2. Selected by EU (AT-clause can be selected by the EU Project Officer)
3. On-demand (AT-clause can be selected only via Helpdesk – please contact your Project Officer).

Clauses in grey are open only to the EU (and can therefore NOT be activated by you). Please contact us.

For changes linked to errors/mistakes, ONLY clause AT60 may be used. Please contact us.

STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			

[1] The instructions also apply to FPA/SGA amendments – unless specifically indicated.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
Changes concerning the beneficiaries & linked third parties/affiliated entities[2]				
1	**Removal of beneficiary whose participation was terminated due to:** – **non-accession to GA or** – **H2020: non-provision of declaration on joint and several liability**	**Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (FPA: Annex 1 FPA; SGA: ---) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA: ---; SGA: ---) **Supporting documents:** 1) Updated Annex 1 2) Updated Annex 2 (including Annex 2a, if necessary) 3) H2020 ERC: PI motivation letter	**Other combinations:** - Addition of a new beneficiary (AT3) - Addition of a linked third party/affiliated entity (AT6a) - H2020: Addition of an international partner (AT6b) - GAs with different reimbursement rates at beneficiary-level: Change of the reimbursement rate (AT33)	**AT1 —** AT1 serves to remove a beneficiary that never became part of the GA. The end date must always be retroactive (back to the beginning of the GA). Do NOT combine with AT5a, 5b, 7a (not needed because changes already part of AT1). **Linked third parties/affiliated entities and international partners —** If a beneficiary is terminated all its linked third parties/affiliated entities and international partners will automatically also be removed (with the same effective date as the beneficiary) — as part of AT1 (AT1 foresees the removal, no need to combine AT1 with AT5a, AT5b and AT7a). **Mono-beneficiary GAs —** AT1 does not apply (because the entire GA will be terminated). FPA/SGA — AT1 can ONLY be used at FPA-level (because NO SGA can be signed before the problems at FPA level have been solved).

[2] For H2020: linked third parties
For non-H2020: affiliated entities/linked third parties (it means the same, but the label was changed for grants signed after GA version 4.0.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
2	**Removal of a beneficiary whose participation was terminated for other reasons** **Termination by the beneficiaries**	**Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (FPA: Annex 1 FPA; SGA: Annex 1 SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA: ---; SGA: Annex 2 SGA) - Removal of a linked third party/affiliated entity (if any) (AT5a) - H2020: Removal of an international partner (if any) (AT5b) **Supporting documents:** 1) Notification of partner termination, with: – opinion of beneficiary whose participation is terminated (or proof that its opinion has been requested) – supporting documents to justify the termination (if any; *e.g. proof of bankruptcy or similar situation; letter from liquidator; court decision etc*) – for coordinator termination/change without its agreement: decision of the consortium on:	**Other combinations:** - Addition of a new beneficiary (AT3) - Addition of a linked third party/affiliated entity (AT 6) - Change of the coordinator (if necessary) (AT8) - GAs with different reimbursement rates at beneficiary-level: Change of the reimbursement rate (AT33) - Change of the bank account for payments (if termination concerns the coordinator) (AT40)	**AT2 —** AT2 serves to remove a beneficiary during the grant. The end date must be the same in the termination notification and the amendment request ('termination date'). The termination date can NOT be retroactive. **Linked third parties/affiliated entities and international partners —** If a beneficiary is terminated all its linked third parties/affiliated entities and international partners must also be removed (with the same effective date as the beneficiary) — via AT5a and 5b. **No withdrawal of termination —** The termination notification is legally binding (i.e. takes effect) even if the amendment request is withdrawn or rejected. If you would like to withdraw a partner termination before its effective date, contact us. After the effective date of termination has passed, the termination can be "undone" only via a formal amendment to re-enter the participant (AT3). **Mono-beneficiary GAs —** AT2 does not apply (because there is only termination of the entire GA). **Mandatory coordinator change —** In case of

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
		– termination and change of the coordinator – nomination of one of the beneficiaries to act on behalf of the consortium *(e.g. approved consortium meeting minutes; e-mail exchange confirming agreement; scanned copy of signed paper agreement)* – H2020 ERC: PI motivation letter 2) Amendment request with: – updated Annex 1, with proposal for change/reallocation of tasks – updated Annex 2 (including Annex 2a, if necessary) with estimated budget of the beneficiary concerned by termination ⚠ Notification and amendment request are combined in one document. ⚠ Within 30 days after termination takes effect, the coordinator will also have to		termination of the coordinator (by the consortium or the EU), the amendment request must ALWAYS be combined with AT8 to appoint a new coordinator (– as long as the final payment is not yet paid out). A coordinator change (AT8) may also be needed if after the end of the action (both after the end date or after GA termination by the consortium or the EU) the coordinator is no longer in a position to fulfil its role *(e.g. liquidation)* (– and the final payment is not yet paid out). **Coordinator termination/change without its agreement —** A special procedure applies *(see AT8)*. FPA/SGA — AT2 at FPA-level does not automatically lead to partner termination in the SGAs. The consortium composition at FPA and SGA-level will therefore exceptionally be different. (Important for cases where a partner wants to terminate participation because he does not anymore want to participate in future actions but would like to finish the on-going SGAs.)

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			

		submit:
		– a report on the distribution of the payments made to the beneficiary concerned
		– if termination during the action duration: termination report, with:
		  – an overview of the progress of the work (of what has been achieved up until that point)
		  – an overview of the use of resources
		  – the beneficiary's individual financial statement
		  – an certificate on the financial statement (CFS) (if necessary)		

	Termination by the EU	**Supporting documents:** 1) updated Annex 1 with proposal for change/reallocation of tasks 2) updated Annex 2 (including Annex 2a, if necessary) 3) H2020 ERC: PI motivation letter ⚠ Within 60 days after termination takes effect, the coordinator will also have to submit:		

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			

		– a report on the distribution of payments made to the beneficiary concerned
		– if termination during the action duration: termination report, with:
		  – an overview of the progress of the work (of what has been achieved up until that point)
		  – an overview of the use of resources
		  – the beneficiary's individual financial statement
		  – a certificate on the financial statement (CFS) (if necessary)		

3	**Addition of a new beneficiary**	**Requirements:** - New beneficiary (and its linked third parties/affiliated entities) must have been validated in the Participant Register - H2020: New international partners of the beneficiary must be registered in the Participant Register (but no validation is needed) **Mandatory combinations:** - Change of Annex 1 (if change/ reallocation of tasks and changes to the use of resources are necessary) (AT21) (FPA: Annex 1 FPA;	**Other combinations:** - Removal of a beneficiary (AT1,2) - Removal of a linked third party/affiliated entity (AT5a) - H2020: Removal of an international partner (AT5b) - Change of the coordinator (if necessary) (AT8)- GAs with different reimbursement rates at beneficiary-level: Change of the reimbursement rate (AT33) - H2020 GAs: Joint and several liability of a	**AT3 —**AT3 serves to add a beneficiary during the grant. Do NOT use AT3 for addition of a beneficiary to an ERC mono-beneficiary GA (use AT72) The starting date must be the same in the Accession Form and the amendment request. The starting date can be retroactive. It can be a fixed date, or linked to the date of the signature of the Accession Form or the date of entry into force of the amendment.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
		SGA: ---) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA: ---; SGA: ---) - Addition of a linked third party/affiliated entity (if any) (AT6a) - H2020: Addition of an international partner (if any) (AT6b) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 (including Annex 2a, if necessary) 3) declaration of honour (DoH), signed in the electronic exchange system 4) Accession Form (Annex 3), signed in the electronic exchange system 5) for the linked third party(ies)/affiliated entities: legal documents proving the link to the beneficiary (statutes, financial data, agreement, decree, citation of the applicable rules with hyperlinks to the texts, etc) 6) if new beneficiary is the JRC: Administrative Arrangement multi (Annex 3b), signed in the electronic exchange system 7) for H2020 ERC GAs: PI motivation letter	linked third party (if requested by the EU) (AT39a)	**FPA/SGA** — AT3 at FPA-level automatically leads to addition in all SGAs (as inactive partner). ⚠ For costs to become eligible, those partners must also be activated (via AT7b – Change concerning the participation with or without action tasks and AT21 and 31 to redistribute action tasks and budget).

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
4	**Change of beneficiary due to partial takeover**	**Requirements:** - New beneficiary (and linked third parties/affiliated entities) must have been validated in the Participant Register - H2020: New international partners of the beneficiary must be registered in the Participant Register (but no validation is needed) **Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (FPA&SGA: Annex 1 FPA and SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA&SGA: Annex 2 SGA) - Addition of a linked third party/affiliated entity (AT6a) - H2020: Addition of an international partner (AT6b) **Supporting documents:** 1) legal documents proving the transfer of rights and obligations (takeover contract, court decision, declaration, etc; citation of the applicable rules with hyperlinks to the texts) and summary description of legal situation and consequences for the GA (including financial liability rules)	**Other combinations:** - GAs with different reimbursement rates at beneficiary-level: Change of the reimbursement rate (AT33) - H2020: Joint and several liability of a linked third party (if requested by the EU) (AT39a) - Change of the bank account for payments (if takeover concerns the coordinator) (AT40)	**AT4 —** AT4 serves to adapt the GA to a partial takeover (i.e. when a part of the business of the beneficiary — including the GA — is taken over as a going concern by (one or more) other entity(ies), *e.g. partial acquisition, distribution of a business unit after dissolution/liquidation, division/demerger, etc.; see H2020 AGA — Annotated Grant Agreement, art.55*). The new beneficiary must comply with all eligibility rules. The end date of the former beneficiary and starting date of the new beneficiary can NOT overlap (transfer of participation with single 'transfer date'). Do NOT use AT4: • if the former beneficiary does NOT leave the consortium (use AT3 – addition of a beneficiary) • if the former beneficiary has NOT yet acceded to the GA, i.e. if partial transfer happens during GA signature and the beneficiary concerned has not yet signed its Accession Form (use AT1 – removal of a beneficiary and AT3 – addition of a beneficiary) • for ERC portability and MSCA transfer of the GA (use AT71 and AT84). Normally AT4 does not imply a change of

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
		⚠ In order to avoid multiple submissions, beneficiaries are recommended to upload the legal documents proving/explaining the takeover in the Participant Portal Organisation Register (via My Organisation page) and to specify this in the amendment request. 2) updated Annex 1 with proposal for change/reallocation of tasks 3) updated Annex 2 (including Annex 2a, if necessary) 4) if the new beneficiary joins the consortium: declaration of honour (DoH), signed in the electronic exchange system Accession Form (Annex 3), signed in the electronic exchange system 5) for the linked third party(ies)/affiliated entities: legal documents proving the link to the beneficiary (statutes, financial data, agreement, decree, citation of the applicable rules with hyperlinks to the texts, etc)		reporting periods (AT25). Do NOT combine with AT2, AT3, AT5a, AT5b, AT7a (not needed because all the necessary changes are already part of AT4). ⚠ Contact us before preparing your amendment (mandatory). **Automatic transfer of beneficiaries —** AT4 makes an automatic transfer and includes all the necessary changes (no combination with AT2 – removal of beneficiary, AT3 – addition of beneficiary). **NO automatic transfer of linked third parties/affiliated entities/international partners —** AT4 automatically removes the linked third parties/affiliated entities/international partners of the former beneficiary (→ no combination with AT5a and 5b – removal of linked third parties/affiliated entities/ international partners). Linked third parties/affiliated entities/ international partners that should continue with the new beneficiary need to be added manually (via AT6a and 6b – addition of linked third parties/affiliated entities/ international partners). **Automatic coordinator transfer —** If the former beneficiary is coordinator and this role should NOT go to the new beneficiary (but to another

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
				one), the consortium must first change the coordinator via AT8 and then apply AT4 for the partial transfer. Both can be done in the same amendment, but it is important to follow this sequence of changes. FPA/SGA — AT4 at FPA-level automatically leads to replacement in all SGAs (as active or inactive partner, depending on the status of the former partner)
5a	**Removal of a linked third party/affiliated entity**	**Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (FPA: Annex 1 FPA; SGA: Annex 1 SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA: ---; SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 (including Annex 2a, if necessary) 3) H2020 ERC: PI motivation letter	**Other combinations:** - Removal of a beneficiary (AT2) - GAs with different reimbursement rates at beneficiary-level: Change of the reimbursement rate (AT33)	**AT5a —** AT5a serves to remove a linked third party during the grant. If linked to the removal of its beneficiary, the linked third party's end date must be the same as the end date of the beneficiary. The end date can NOT be retroactive. We will NOT directly terminate linked third parties/affiliated entities, but will request the consortium to remove them. Do NOT combine with AT1 (use only AT1 because that clause already includes all the necessary changes. DO combine with AT2. FPA/SGA — AT5a at FPA-level does not automatically lead to removal in the SGAs. The consortium composition at FPA and SGA-level will therefore exceptionally be different. (Same

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
				approach as with AT2 – Removal of a beneficiary. If the beneficiary stays on to finish an on-going SGA also its linked third parties/affiliated entities must be able to stay on)
5b	ONLY for H2020: **Removal of an international partner**	**Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (for FPA: Annex 1 FPA; for SGA: Annex 1 SGA) - Change of Annex 2 (AT31) (FPA: ---; SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 3) H2020 ERC: PI motivation letter	**Other combinations:** - Removal of a beneficiary (AT2)	**AT5b —** AT5b serves to remove an international partner during the grant. If linked to the removal of its beneficiary, the partner's end date must be the same as the end date of the beneficiary. The end date can be retroactive. We will NOT directly terminate international partners, but will request the consortium to remove them (automatic removal only if their beneficiary is terminated). Do NOT combine with AT1 (use only AT1 because that clause already includes all the necessary changes). DO combine with AT2. FPA/SGA — AT5b at FPA-level does not automatically lead to removal in the SGAs. The consortium composition at FPA and SGA-level will therefore exceptionally be different. (Same approach as with AT2 – Removal of a beneficiary. If the beneficiary stays on to finish an on-going SGA, its international partners must be able to stay as well).

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
6a	**Addition of a linked third party/affiliated entity**	**Requirements:** - New linked third party/affiliated entity must have been validated in the Participant Register **Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (FPA: Annex 1 FPA; SGA: ---) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA: ---; SGA: ---) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 (including Annex 2a, if necessary) 3) legal documents proving the link to the beneficiary (statutes, financial data, agreement, decree, citation of the applicable rules with hyperlinks to the texts, etc) 4) H2020 ERC: PI motivation letter	**Other combinations:** - Addition of a beneficiary (AT3) - GAs with different reimbursement rates at beneficiary-level: Change of the reimbursement rate (AT33) - H2020: Joint and several liability of a linked third party (if requested by the EU) (AT39a)	**AT6a —** AT6a serves to add a linked third party during the grant. If linked to the addition of a new beneficiary, the linked third party's starting date must be the same as the starting date of the beneficiary ('accession date'). The starting date can be retroactive. FPA/SGA — AT6a at FPA-level automatically leads to addition in all SGAs (as inactive linked third party/affiliated entity). ⚠ For costs to become eligible, those entities must also be activated (via AT7b – Change concerning the participation with or without action tasks and AT21 and 31 to redistribute action tasks and budget).
6b	ONLY for H2020: **Addition of an international partner**	**Requirements:** - New international partner must be registered in the Participant Register (but no validation is needed) **Mandatory combinations:** - Change of Annex 1 (if change/reallocation		**AT6b —**AT6b serves to add an international partner during the grant. If linked to the addition of a new beneficiary, the partner's starting date must be the same as the starting date of the beneficiary ('accession date'). The starting date can be retroactive.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
		of tasks and changes to the use of resources are necessary) (AT21) (FPA: Annex 1 FPA; SGA: ---) - Change of Annex 2 (AT31) (FPA: ---; SGA: -) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 3) H2020 ERC: PI motivation letter		International partners need to have a PIC (i.e. be registered in the Participant Register), but do NOT need to be validated. ⚠ This clause can also be used by GAs before version 4.0. (They can use AT6b to introduce international partners). FPA/SGA — AT6b at FPA-level automatically leads to addition in all SGAs (as inactive linked third party/affiliated entity). ⚠ For costs to become eligible, those entities must also be activated (via AT7b – Change concerning the participation with or without action tasks and AT21 and 31 to redistribute action tasks and budget).
7a	ONLY for programmes with 'beneficiaries not receiving funding': **Change concerning the participation with or without funding**	**Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (SGA: Annex 1 SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 (including Annex 2a, if necessary)	**Other combinations:** - Change of dispute settlement forum (AT51b)	**AT7a —** AT7a serves to change the status of 'beneficiary not receiving funding'. ⚠ AT7a is reserved for very exceptional cases and is for most cases open only to the EU. Only 'zero funding ' to 'funding' & vs can be changed by the consortium. For all other cases, contact us in case of an issue. The clause will be activated depending on the impact of the status change and the need to reflect it in the grant agreement, *e.g. if a beneficiary becomes ineligible during the project*. It will NOT be combined with AT1, 2, 3, 4, 5a, 6a and 7b (only those clauses will be used because

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
				they already include all the necessary changes). Combination with AT51b is extremely rare because it applies only to changes into 'not eligible for funding' and requires that the national law explicitly excludes jurisdiction of the Belgian courts. FPA/SGA — Status changes in FPA/SGAs are more complicated because they need to be coordinated with clause AT51b (change of dispute settlement forum): Changes into 'eligible for funding' are only possible for partners that do not have the arbitration clause in the FPA (if a change is needed, use first AT51b and then AT7a). Changes into 'not eligible for funding' normally do not require any change of the dispute settlement forum (normally: Belgian courts). However, if needed, the dispute settlement forum can be changed in the FPA (via AT60, to include the partner in the list of partners not receiving funding and change the dispute settlement clause into arbitration).
7b	ONLY for FPA/SGAs: **Change concerning the participation with or without action tasks**	**Mandatory combinations:** - SGAs: Change of Annex 1 SGA (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) - SGAs: Change of Annex 2 SGA (including Annex 2a, if necessary) (AT31)		**AT7b —** AT7b serves to activate an 'inactive partner' for a specific SGA.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
		Supporting documents: 1) updated Annex 1 SGA 2) updated Annex 2 SGA 3) H2020 ERC: PI motivation letter		
Changes concerning the coordinator				
8	**Change of the coordinator/ ERC principal beneficiary**	**Requirements:** - Bank account must have been validated in the Participant Register **Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary (AT21) (FPA&SGA: Annex 1 FPA and SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (FPA&SGA: Annex 2 SGA) - Change of bank account (AT40) **Supporting documents:** 1) updated Annex 1 (including overview of the progress of the work done till the change) 2) updated Annex 2 (including Annex 2a, if necessary) 3) for coordinator change without its agreement: decision of the consortium	**Other combinations:** - Removal of a beneficiary (if the former coordinator leaves the consortium) (AT2) - Removal of a linked third party/affiliated entity (if the former coordinator leaves the consortium) (AT5a) - H2020: Removal of an international partner (if the former coordinator leaves the consortium) (AT5b) - Addition of a new beneficiary (if the new coordinator did not already participate in the consortium) (AT3) - Addition of a linked third party/affiliated entity (for the new coordinator if he did not already participate in the consortium) (AT6a) - H2020: Addition of an international partner (AT6b) - H2020: Change of the 'authorisation to	**AT8 —** AT8 serves to replace the coordinator during the grant. AT8 must ALWAYS be used when the coordinator is changed. (It is not automatically included in any other clause.) The 'handover date' should normally be the date the new coordinator takes over the coordinator tasks. If there is a gap (former coordinator leaves before new coordinator starts) you need to choose two different dates: the one for the former coordinator (when it stopped doing coordinator tasks — must be at the latest its termination date) and the one for the new coordinator (when it takes over the coordinator tasks — must be after its accession date). **Mono-beneficiary GAs —** AT8 does not apply (because there is no coordinator). **Mandatory coordinator change —** The

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
		to: – change the coordinator (and who should be the new coordinator) – nominate one of the beneficiaries to act on behalf of the consortium to request the amendment *(e.g. approved consortium meeting minutes; e-mail exchange confirming agreement; scanned copy of signed paper agreement)* 4) H2020 ERC: new supplementary agreement (SA) 5) H2020 ERC: PI motivation letter	administer' (AT9a) - H2020 ERC: Change of the reporting periods (unless the handover date coincides with the end of a financial reporting period) (AT25)	coordinator must be changed whenever it is no longer in a position to fulfil its role *(for instance when it is terminated due to liquidation)* — even after the end of the action if the final payment is not yet paid out. **Coordinator in bankruptcy/liquidation —** If the coordinator can no longer make the amendment itself, use same procedure as for coordinator change without its agreement *(see below)*. If the coordinator can continue its participation with the bank account of the administrator/ liquidator (i.e. termination not possible/not needed), it is exceptionally sufficient to change the bank account without changing the coordinator *(see AT40)*. **Coordinator change without its agreement —** A special procedure applies. The other beneficiaries must nominate one of them to act on their behalf (for the amendment). The nominated beneficiary must name a contact person responsible for the amendment (PCoCo). The nominated beneficiary should in principle be the one that will take over the coordinator role (new coordinator). We will need proof of the consortium nomination *(e.g. approved consortium meeting minutes; e-mail exchange confirming agreement; scanned copy of signed paper*

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
				agreement). Contact us before preparing your amendment (mandatory). FPA/SGA — AT8 at FPA-level automatically leads to coordinator change in all SGAs.
9a	ONLY for H2020: **Change of the delegation of coordinator tasks (authorisation to administer)**	**Requirements:** - Bank account must have been validated in the Participant Register **Mandatory combinations:** - Change of bank account (AT40) **Supporting documents:** 1) Proof of authorisation to administer		**AT9a —** AT9a serves to replace the entity with a delegation to administer certain coordinator tasks *(e.g. payments)*. This clause is needed only for H2020 GAs because the entity is explicitly mentioned in the GA. (For other programmes, payments can be administered by another entity without explicit reference in the GA – the coordinator can simply use the bank account of the entity.)
9b	ONLY for H2020: **Change of the delegation of coordinator tasks (ERIC member with delegation)**	**Requirements:** - Bank account must have been validated in the Participant Register **Mandatory combinations:** - Change of bank account (AT40) **Supporting documents:** 1) Proof of authorisation to administer		

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
Changes concerning the framework partnership				
11	ONLY for FPAs: **Change of the framework partnership acronym**			
12	ONLY for FPAs: **Change of Annex 1 (action plan/implementation strategy)**	**Supporting documents:** 1) updated Annex 1 FPA		
13	ONLY for FPAs: **Change of the procedure for awarding specific grants**			**AT13 —** AT13 serves to change the procedure for awarding specific grants. ⚠ AT13 is reserved for very exceptional cases (since the new procedure must remain in line with the procedure announced in the work programme/call for proposals) and is open only to the EU. Contact us in case of an issue.
14	ONLY for FPAs: **Resuming the framework partnership after suspension**	**Mandatory combinations:** - FPAs: Resuming the specific action(s) (SGAs) after a suspension of the action implementation (AT26) - FPAs: Change of Annex 1 FPA (if needed) (AT12) **Supporting documents:** 1) updated Annex 1 FPA		**AT14 —** AT14 serves to resume the framework partnership, if it was formally suspended. For resuming the SGAs, AT14 must be combined with AT26. The duration of the FPA can NOT be extended, but an SGA can be extended beyond the duration of the FPA (because FPA duration only serves as a limit for signing new SGAs). ⚠ Contact us before preparing your amendment (mandatory).

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
Changes concerning the action or action implementation				
21	**Change of Annex 1 (description of the action)**	**Mandatory combinations:** - Change of Annex 2 (if change of estimated budget necessary) (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 1 (including for H2020 SME Ph2 changes of subcontracts: updated table with detailed information on the subcontract(s) (section 4 of the proposal template)) 2) updated Annex 2 (including Annex 2a, if necessary) 3) H2020 ERC: Letter from PI justifying the changes to Annex 1	**Other combinations:** - Removal of a beneficiary (AT1, 2) - Removal of a linked third party/affiliated entity (AT5a) - H2020: Removal of an international partner (AT5b) - Addition of a new beneficiary (AT3) - Addition of a linked third party/affiliated entity (AT6a) - H2020: Addition of an international partner (AT6b)	**AT21 —** AT21 serves to adjust the description of the action (DoA) if there are significant changes to the project *(see H2020 AGA — Annotated Grant Agreement, art.55)* ⚠ Don't forget to double-check/make the changes also in the SyGMa screens in the Continuous Reporting Module and Periodic Reporting (if open). **H2020 SME Ph2 —** For a change of a subcontract, contact us before preparing your amendment (mandatory). **H2020 —** Changes to the option for additional access rights for interoperability are only possible are only possible if the H2020 Work Programme allows for flexibility regarding the conditions for access and these conditions change (i.e. from 'fair and reasonable conditions' to 'royalty-free' - or vice-versa).
22	**Change of action title and/or acronym**			
23	**Change of action duration**	**Mandatory combinations:** - Change of Annex 1 (AT21) (SGA: Annex 1	**Other combinations:** - Change of the action starting date (AT24)	**AT23 —** AT23 is one of the clauses that serve to adjust the action schedule (starting date, action

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
		SGA) - Change of the reporting periods (AT25) **Supporting documents:** 1) updated Annex 1 2) H2020 ERC: PI motivation letter	- Change of the reporting periods (AT25)	duration or reporting periods) to a change of circumstances in the project. FPA/SGA — The starting date of the FPA can NOT be anticipated, but the SGA may exceptionally be retroactive (and start before FPA; *e.g. at the beginning, if both FPA and SGA were opened with the same call*). The duration of the FPA can NOT be extended, but an SGA can be extended beyond the duration of the FPA (because FPA duration only serves as a limit for signing new SGAs). H2020 EJP — The action duration is maximum 72 months.
24	**Change of action starting date**		**Other combinations:** - Change of the action duration (AT23) - Change of the reporting periods (AT25) - Change of Annex 1 (if needed) (AT21)	**AT24 —** AT24 is one of the clauses that serve to adjust the action schedule (starting date, action duration or reporting periods) to a change of circumstances in the project.
25	**Change of reporting periods**	**Mandatory combinations:** - Change of Annex 1 (AT21) (SGA: Annex 1 SGA) **Supporting documents:** 1) updated Annex 1	**Other combinations:** - Change of the action duration (AT23) - Change of the action starting date (AT24)	**AT25 —** AT25 is one of the clauses that serve to adjust the action schedule (starting date, action duration or reporting periods) to a change of circumstances in the project. Closed reporting periods can NOT be changed.

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
		2) H2020 ERC: PI motivation letter		H2020 SME Ph1—There is only one RP. H2020 ERA-NET — Reporting periods can be extended but no new reporting periods can be added H2020 EJP — Use EJP fixed reporting periods. If the extension of duration is six months or less, the 5th reporting period should be extended. If the extension of the duration is six months or more, an additional 6th reporting period should be added.
25a	ONLY for non-H2020: **Changes to the special conditions for carrying out action activities**		**Other combinations:** - Change of Annex 1 (if change/reallocation of action tasks and changes to use of resources necessary) (AT21)	**AT25a —** AT25a serves to adjust the options for special conditions to a change of circumstances in the project. For changes due to mistakes (when choosing the options during GA preparation or a previous amendment), use AT60. Contact us before preparing your amendment (mandatory).
26	**Resuming the action after suspension**	**Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) (SGA: Annex 1 SGA) - Change of Annex 2 (including Annex 2a, if	**Other combinations:** - Change of the action duration (AT23) - Change of the reporting periods (AT25) - Removal of a beneficiary (AT2) - Removal of a linked third party/affiliated	**AT26 —** AT26 serves to resume the grant, if it was formally suspended. The suspension is lifted from the resumption date set out in the amendment. For GA suspensions decided by the EU, the resumption date must be the same as the

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
		necessary) (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 3) H2020 ERC: PI motivation letter	entity (AT5a) - H2020: Removal of an international partner (AT5b) - Addition of a new beneficiary (AT3) - Addition of a linked third party/affiliated entity (AT6a) - H2020: Addition of an international partner (AT6b) - Resuming the framework partnership after suspension (AT14)	suspension end date set out in the lifting of suspension letter. The resumption date/suspension end date can be retroactive (i.e. back to the date when the problem stopped/issue was clarified). AT26 must normally be accompanied by an amendment AT25 to adapt the reporting periods (merge or extend RPs, as needed) and AT23 to extend the action duration (if more time is needed to complete the project). FPA/SGA — If suspension should be lifted both for FPA and for SGAs, AT26 must be combined with AT14. If the suspension of the SGA was due to the suspension of the FPA, the SGA can only be resumed if the FPA is first resumed (via AT14). The duration of the FPA can NOT be extended, but an SGA can be extended beyond the duration of the FPA (because FPA duration only serves as a limit for signing new SGAs).
28	ONLY for H2020: **Change of the participation in the Open Research Data Pilot**		- Change of Annex 1 (if needed) (AT21) (SGA: Annex 1 SGA)	**AT28 —** AT28 serves to adjust the option for participation in the pilot to a change of circumstances in the project. ⚠ Changes to the participation are possible ONLY if participation is not mandatory in the H2020 Work Programme.
29	ONLY for H2020: **Change of the EU right to object to**	**Mandatory combinations:** - Change of Annex 1 (if change to plan for		**AT29 —** AT29 serves to adjust the option for EU objections to a change of circumstances in the

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
	transfers or licensing	the exploitation and dissemination of results is necessary) (AT21) (SGA: Annex 1 SGA) **Supporting documents:** 1) updated Annex 1		project/policy. ⚠ AT29 is reserved for exceptional cases and is open onl y to the EU. Contact us in case of an issue.
30	ONLY for H2020: **Change concerning the security context**	**Mandatory combinations:** - Change of Annex 1 (if needed) (AT21) (SGA: Annex 1 SGA) **Supporting documents:** 1) updated Annex 1		**AT30 —** AT30 serves to adjust the security to a change of circumstances in the project/security context. ⚠ Contact us before preparing your amendment (mandatory).
Changes concerning the financial aspects of the grant				
31	**Change of Annex 2 (estimated budget)**	**Mandatory combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) (SGA: Annex 1 SGA) **Supporting documents:** 1) updated Annex 2 (including Annex 2a, if necessary) 2) updated Annex 1 3) H2020 ERC: PI motivation letter	- H2020: Joint and several liability of a linked third party (if requested by the EU) (AT39a) - GAs with different reimbursement rates at beneficiary -level: Change of the reimbursement rate (AT33)	**AT31 —** AT31 serves to adapt the estimated budget to the real project implementation *(see H2020 AGA — Annotated Grant Agreement, art.55)*. ⚠ It is recommended to adapt Annex 2 at the end of the action, because the maximum grant amounts in the estimated budget will be used for the calculation of grant reductions (if any). ⚠ For a change of Annex 2a, contact us before preparing your amendment (mandatory). H2020 IA —If a beneficiary/linked third party changes its status from non-profit to for-profit, its

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
				reimbursement rate will have to be updated.
32a	**Change of the maximum grant amount (decrease)**	**Mandatory combinations:** - Change of Annex 2 (AT31) (FPA/SGA: Annex 2 SGA) - Change of the estimated eligible costs (AT34) - Change of the pre-financing (if not yet paid) (AT38) - H2020: Change of the contribution to the Guarantee Fund (if pre-financing not yet paid) (AT39) **Supporting documents:** 1) updated Annex 2	**Other combinations:** - Change of Annex 1 (if change/reallocation of action tasks and changes to use of resources necessary) (AT21) - Change of the funding rate (AT33)	**AT32a —** AT32a serves to lower the maximum grant amount for the action (i.e. the amount mentioned in Article 5.1 GA). **H2020** — If the maximum grant amount is decreased, the contribution to the PGF will only be changed if the pre-financing is not yet paid (i.e. if it is not yet retained from the pre-financing) **Non-H2020** — NO change to the pre-financing guarantee (since not linked to the maximum grant amount, but to the financial viability). **JRC** — NO change to the JRC AA multi. (Change only needed if change of pre-financing; *see AT38*.)
32b	**Change of the maximum grant amount (increase)**	**Mandatory combinations:** - Change of Annex 2 (AT31) (FPA/SGA: Annex 2 SGA) - Change of the estimated eligible costs (AT34) **Supporting documents:** 1) updated Annex 2	**Other combinations:** - Change of Annex 1 (if change/reallocation of action tasks and changes to use of resources necessary) (AT21) - Change of the funding rate (AT33) - Change of the pre-financing (AT38) - Change of the contribution to the Guarantee Fund/pre-financing guarantee (AT39)	**AT32b —** AT32b serves to raise the maximum grant amount for the action (i.e. the amount mentioned in Article 5.1 GA). ⚠ The maximum grant amount can normally NOT be *increased*. AT32b is therefore open only to the EU. Contact us in case of an issue. **Low value grants** — An increase to above 60 000 EUR implies the automatic activation of the options for high value grants *(e.g. no profit rule,*

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
				longer deadlines for audits, etc). H2020 — If the maximum grant amount is increased, the EU may decide to also increase the pre-financing/ contribution to the PGF, but it will only be changed if the pre-financing is not yet paid (i.e. if it is not yet retained from the pre-financing) Non-H2020 — NO change to the pre-financing guarantee (since not linked to the maximum grant amount, but to the financial viability). JRC — NO change to the JRC AA multi. (Change only needed if change of pre-financing; *see AT38*.)
33	**Change of the funding rate**	**Mandatory combinations:** - Change of Annex 2 (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 2	**Other combinations:** *Case 1: consortium change* - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) - Removal of a beneficiary (AT1,2) - Addition of a new beneficiary (AT3) - Removal of a linked third party/affiliated entity (AT5a) - Addition of a linked third party/affiliated entity (AT6a) *Case 2: increase of maximum grant amount (⚠ absolutely exceptional)*	**AT33 —** AT33 serves to lower or raise the funding rate for the participants, for instance to adapt it to consortium changes that make the text in Article 5.2 GA incorrect *(e.g. for H2020: if a beneficiary/linked third party leaves or loses its profit/non-profit status; for AGRI Promo: the beneficiary/linked third party's country loses its macro-economic assistance status)* ⚠ AT33 is reserved for exceptional cases and is open only to the EU. Contact us in case of an issue. Consortium changes can impact the funding rate only in EU programmes that exceptionally allow

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
			- Change of Annex 1 (if change/reallocation of action tasks and changes to the use of resources are necessary) (AT21) - Change of the maximum grant amount (AT32b) - Change of the estimated eligible costs (AT34) - Change of the pre-financing (AT38) - Change of the contribution to the Guarantee Fund/pre-financing guarantee (AT39)	for several funding rates at participant-level (i.e. different funding rates for different beneficiaries/linked third parties/affiliated entities, *e.g. H2020 and AGRI Promo*); the clause will therefore only be activated in certain situations and for certain types of actions. H2020 — This clause is mainly for consortium changes in GAs before version 4.0. As from version 4.0, the wording of Article 5.2 has been simplified so that consortium/situation changes remain without impact on Article 5.2
34	**Change of the estimated eligible costs**	**Mandatory combinations:** - Change of Annex 2 (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 2	**Other combinations:** - Change of Annex 1 (if change/reallocation of action tasks and changes to the use of resources are necessary) (AT21) - Change of the maximum grant amount (AT32a and b) - Change of the pre-financing (if not yet paid) (AT38) - H2020: Change of the contribution to the Guarantee Fund (if pre-financing not yet paid) (AT39)	**AT34 —** AT34 serves to lower or raise the estimated eligible costs for the action (i.e. the amount mentioned in Article 5.2 GA). Non-H2020 — NO change to the pre-financing guarantee (since not linked to the estimated eligible costs, but to the financial viability). H2020 ERA-NET — There will be an automatic amendment after RP1 to adjust the initial EU contribution (down to the amount justified by the selection list and the commitments to fund)
35	ONLY for non-H2020 programmes with SEP flexible indirect cost rates: **Change of the indirect cost**	**Mandatory combinations:** - Change of Annex 2 (AT31) (SGA: Annex 2 SGA)	**Other combinations:** - Change of the maximum grant amount (AT32a and b)	**AT35 —** AT35 serves to lower or raise the indirect cost rate for the participants (i.e. the percentage mentioned in Article 6.2 GA).

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
	rate	- Change of the estimated eligible costs (AT34) **Supporting documents:** 1) updated Annex 2	- Change of the pre-financing (if not yet paid) (AT38)	⚠ AT35 is reserved for very exceptional cases and is open only to the EU. Contact us in case of an issue. Change of the indirect cost rate is only possible if it was below the maximum ceiling of the call and the EU Financial Regulation (and the change cannot go above this ceiling). All participants must keep the same indirect cost rate (beneficiaries and linked third parties/affiliated entities; mandatory). **Recalculations & adjustments —** If the amendment is retroactive (standard case), the beneficiaries may adjust previous financial statements (to add costs that were incurred AFTER the change date, i.e. normally beginning of the action because retroactive back to the beginning of the action).
36	ONLY for programmes with specific unit costs/lump sums: **Change concerning specific cost categories (specific unit costs/lump sums)**		**Other combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) - Change of Annex 2 (including Annex 2a, if necessary) (AT31)	**AT36 —** AT36 serves to adjust the options for specific unit costs/lump sums to a change of circumstances in the project *(see H2020 AGA — Annotated Grant Agreement, art.55)*. ⚠ Contact us before preparing your amendment (mandatory). **Recalculations & adjustments —** If the amendment is retroactive (exception), the beneficiaries may adjust previous financial

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AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
				statements (to add costs that were incurred AFTER the change date).
36a	ONLY for programmes with full purchase cost option: **Change concerning the full purchase cost option for equipment**		**Other combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) - Change of Annex 2 (including Annex 2a, if necessary) (AT31)	**AT36a —** AT36a serves to adjust the options for reimbursement of equipment costs to a change of circumstances in the project. ⚠ Contact us before preparing your amendment (mandatory). **Recalculations & adjustments —** If the amendment is retroactive (exception), the beneficiaries may adjust previous financial statements (to add costs that were incurred AFTER the change date).
37a	**Change concerning financial support**		**Other combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) - Change of Annex 2 (including Annex 2a, if necessary) (AT31)	**AT37a —**AT37a serves to adjust the options for financial support to third parties to a change of circumstances in the project. For changes due to mistakes (when choosing the options during GA preparation or a previous amendment), use AT60. ⚠ Contact us before preparing your amendment (mandatory).
37b	**Change concerning financial support in the form of prizes**		**Other combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) - Change of Annex 2 (including Annex 2a, if necessary) (AT31)	**AT37b —**AT37b serves to adjust the options for financial support to third parties to a change of circumstances in the project. For changes due to mistakes (when choosing the options during GA preparation or a previous amendment), use AT60.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
				⚠ Contact us before preparing your amendment (mandatory).
38	**Change of the pre-financing**	**Mandatory combinations:** - if JRC participates: Changes to Annex 3b (JRC AA multi) (AT53) **Supporting documents:** 1) for JRC: Administrative Arrangement (Annex 3b), signed in the PP electronic exchange system		**AT38 —** AT38 serves to add, lower or raise the pre-financing for the action (i.e. the amount mentioned in Article 21.2/16.2 GA). ⚠ AT38 is reserved for exceptional cases and is open only to the EU. Contact us in case of an issue. A change of the pre-financing has normally NO impact on the maximum grant amount. A change of the pre-financing has NO impact on the contribution to the Guarantee Fund/pre-financing guarantee (since those are not linked to the pre-financing, but to the maximum grant amount/financial viability).
39	H2020: **Change of the contribution to the Guarantee Fund** Non-H2020: **Change of the pre-financing guarantee**	**Mandatory combinations:** - if JRC participates: Changes to Annex 3b (JRC AA multi) (AT53) **Supporting documents:** 1) for JRC: Administrative Arrangement (Annex 3b), signed in the electronic exchange system		**AT39 —** AT39 serves to add, lower or raise the Guarantee Fund contribution/pre-financing guarantee for the action (i.e. the amount mentioned in Article 21.2/16.2 GA). ⚠ AT39 is reserved for very exceptional cases and is open only to the EU. Contact us in case of an issue. H2020 — The contribution to the PGF can normally NOT be changed if the pre-financing is already paid (because the contribution is made via deduction from the pre-financing payment).

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
				Non-H2020 — New pre-financing guarantees may be introduced if there are doubts about the financial viability of a new beneficiary. RFCS — The pre-financing guarantees are at beneficiary-level and linked to the pre-financing payment for the beneficiary. Therefore AT39 must normally be combined with AT38.
39a	Only for H2020: **Joint and several liability of a linked third party**	**Supporting documents:** 1) 'declaration of joint and several liability of the linked third parties' (Annex 3a), signed and scanned	**Other combinations:** - Addition of a new beneficiary (AT3) - Change of beneficiary due to partial takeover (AT4) - Addition of a linked third party (AT6a) - Change of Annex 2 (estimated budget) (AT31)	**AT6b —**AT39a serves to add joint and several liability of a linked third party (if requested by the EU, *e.g. because a new beneficiary enters the grant; the financial capacity of an existing beneficiary changes during the project implementation; a new linked third party is added; a change of the estimated budget in Annex 2; a change in the distribution of work in Annex 1, etc*).
40	**Change of the bank account for payments**	**Requirements:** - Bank account must have been validated in the Participant Register	**Other combinations:** - Change of the coordinator (AT8) - H2020: Change of the 'authorisation to administer' (AT9a)	**AT40 —** AT40 serves to adjust the bank account information (number/IBAN) to a simple change of bank account or coordinator/or delegation change *(see AT8 and AT9a/9b)*. **Coordinator in liquidation —** If the coordinator is in bankruptcy/liquidation/under administration, AT40 may exceptionally be used without AT8, if termination is not possible/not needed and the coordinator participates with the bank account of

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	
No	Name			
				the administrator/liquidator.
…				
49a	ONLY for H2020: **Change concerning trans-national access to research infrastructure**	**Mandatory combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) (SGA: Annex 1 SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 (including Annex 2a, if necessary)	**Other combinations:** - Removal of a beneficiary (AT 1,2) - Removal of a linked third party (AT5a) - Addition of a new beneficiary (AT3) - Addition of a linked third party (AT6a)	**AT49a —** AT49a serves to adjust the options for trans-national access to research infrastructure to a change of circumstances in the project. For changes due to mistakes (when choosing the options during GA preparation or a previous amendment), use AT60. Contact us before preparing your amendment (mandatory).
49b	ONLY for H2020: **Change concerning virtual access to research infrastructure**	**Mandatory combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) (SGA: Annex 1 SGA) - Change of Annex 2 (including Annex 2a, if necessary) (AT31) (SGA: Annex 2 SGA) **Supporting documents:** 3) updated Annex 1 updated Annex 2 (including Annex 2a, if necessary)	**Other combinations:** - Removal of a beneficiary (AT 1,2) - Removal of a linked third party (AT5a) - Addition of a new beneficiary (AT3) - Addition of a linked third party (AT6a)	**AT49b —** AT49b serves to adjust the options for virtual access to research infrastructure to a change of circumstances in the project. For changes due to mistakes (when choosing the options during GA preparation or a previous amendment), use AT60. Contact us before preparing your amendment (mandatory).
…				

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
Other changes				
51a	**Change of the applicable law**	**Supporting documents:** 1) documents proving IO status		**AT51a —** AT51a serves to adjust the options for the applicable law of international organisations (IOs) to a change of situation/policy of the beneficiary. ⚠ Changes to the applicable law are possible ONLY if there is a change of situation which justifies a different applicable law. Do NOT combine with AT1, 2, 3, 4, 7a (use only those clauses because they already include all the necessary changes). Do NOT combine with AT5a, 6a (because applicable law is not linked to linked third parties/affiliated entities). Do NOT combine with AT5b, 6b (because applicable law is not linked to international partners). ⚠ Contact us before preparing your amendment (mandatory).
51b	**Change of the dispute settlement forum**	**Supporting documents:** documents proving IO status/establishment/impossibility to be subject to Belgian courts under national law		**AT51b —** AT51b serves to adjust the options for the dispute settlement forum to a change of situation of the beneficiary. ⚠ Changes to the dispute settlement forum are possible ONLY if there is a change of situation which justifies a different forum. Do NOT combine with AT1, 2, 3, 4, 7a (use only those clauses because they already include all the

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
				necessary changes). Do NOT combine with AT5a, 6a (because dispute settlement forum is not linked to linked third parties/affiliated entities). Do NOT combine with AT5b, 6b (because dispute settlement forum is not linked to international partners). For changes due to mistakes (when setting the dispute settlement forum during GA preparation or a previous amendment), use AT60. ⚠ Contact us before preparing your amendment (mandatory). **Arbitration —** For non-IOs arbitration is open ONLY to beneficiaries which are not eligible for funding, which participate as beneficiaries NOT receiving funding AND which according to their national law CANNOT be subject to the Belgian courts. FPA/SGA — AT51b may have to be combined with AT7a if there is a change of status (participation with or without funding).
52	ONLY for GAs before version 4.0: **Change of the EU address**			⚠ AT52 is open only to the EU. This clause is needed only for GAs before version 4.0. As from version 4.0, EU address changes

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
				remain without impact.
53	ONLY for multi-beneficiary GAs: **Changes to Annex 3b (JRC Administrative Arrangement —Multi)**	**Supporting documents:** 1) Administrative Arrangement (Annex 3b), signed in the electronic exchange system		⚠ Changes in the administrative arrangement may also have an impact on the GA itself (e.g. change of pre-financing amount for JRC).
54	ONLY for H2020: **Change concerning complementary grants**	**Supporting documents:** 1) updated Annex 1 (SGA: Annex 1 SGA)	**Other combinations:** - Change of Annex 1 (AT21)	**AT54 —** AT54 serves to adjust the options for complementary grants to a change of situation. ⚠ AT54 is open only to the EU. Contact us in case of an issue.
55	ONLY for H2020: **Change concerning joint actions**	**Supporting documents:** 1) updated Annex 1 (SGA: Annex 1 SGA)	**Other combinations:** - Change of Annex 1 (AT21)	**AT55 —** AT55 serves to adjust the options for joint actions to a change of situation. ⚠ AT55 is open only to the EU. Contact us in case of an issue.
56	**Change of the beneficiary short name**			**AT56 —** AT56 serves to reflect name changes of the beneficiary also in the short name that is used for the GA. ⚠ This AT-clause is optional. Legally speaking NO amendment is needed (because short names have no legal value and only serve as easy identifiers in the GA and the IT tools). But AT56 allows beneficiaries to correct their short name in a grant agreement without having to initiate an amendment on other grounds.
…				

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			
60	GENERAL ERROR CLAUSE: **Change due to an error/mistake**			**AT60 —** AT60 is a general default clause to correct mistakes/errors that happened during GA preparation or a previous amendment OR to update GAs to retroactive MGA changes that require a different text/new option in the GA. ⚠ AT60 is open only to the EU. Contact us in case of an issue. We will instruct you how to proceed.
Special cases				
61	**Transfer of the Grant Agreement to an executive agency/the Commission**			⚠ AT61 is open only to the EU.
62	**Changes due to updates to the Model Grant Agreement**			⚠ AT62 is open only to the EU.
63	ONLY for mono-beneficiary GAs: **Change of the JRC Administrative Arrangement — Mono (JRC GA Preamble)**			
65	GENERAL MANUAL AMENDMENT CLAUSE: **Changes via general manual amendment clause**			**AT65 —** AT65 is a general default clause to allow for amendments in atypical (or not-yet-IT - supported) cases. ⚠ AT65 is open only to the EU. Contact us in case of an issue. We will instruct you how to proceed.

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STANDARD AT-CLAUSES (ALL MGAS, INCLUDING FPA/SGA[1])				
AT-clauses		Mandatory combinations & supporting documents	Other combinations	⚠
No	Name			

SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
H2020 ERC MGAs				
71	**Transfer of (part of) the Grant Agreement to a new beneficiary (portability)** (H2020 ERC General)	**Requirements:** - New host institution and new linked third parties (if applicable) must have been validated in the Participant Register – Bank account must have been validated in the Participant Register **Mandatory combinations:** - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) - Change of Annex 2 (AT31) - Change of principal beneficiary (if	**Other combinations:** - Addition of a linked third party (AT6a) - Addition of an international partner (AT6b)	**AT71 —** AT71 serves to adapt the GA if the PI transferred to a new host institution (portability). The new host institution must comply with all eligibility rules. The end date of the former beneficiary and starting date of the new beneficiary can NOT overlap (transfer of participation with single 'transfer date'). ⚠ For a retroactive transfer date, contact us before preparing your amendment (mandatory). AT71 can only be used for ERC MGAs. AT71 does NOT work for ERC PoC GAs or ERC low value GAs.

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	
No	Name			
		necessary) (AT8) - Change of bank account (if necessary) (AT40) - Change of the reporting periods (unless the transfer date coincides with the end of a financial reporting period) (AT25) **Supporting documents:** 1) PI motivation letter (including the reasons of the request, the added value for the scientific output of the project and detailing the results of the conducted research up to the time of the transfer) 2) new signed supplementary agreement (SA) between PI and new host institution 3) updated Annex 1 4) updated Annex 2 7) if the new host institution joins the consortium: Accession Form (Annex 3), signed in the electronic exchange system 8) if requested by Agency: declaration of joint and several liability of the linked third parties (Annex 3a), signed and scanned 9) if new host institution is the JRC: Administrative Arrangement (Annex		The former host institution may stay or leave the grant. The new host institution may already be part of the grant or join it.

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
		3b), signed in the electronic exchange system ⚠ Within 60 days after the transfer takes effect or the signature of the amendment (whichever is the latest), the principal beneficiary must also submit: – a financial report (for the open period until transfer) – for multi-beneficiary GAs: a report on the distribution of payments		
72	**Addition of a new beneficiary** (H2020 ERC General Mono)	Same combinations, requirements and supporting documents as for AT3		**AT72 —** AT72 serves to adapt a mono-beneficiary GA which is made into a multi-beneficiary GA (by addition of a second beneficiary).
73	**Change of PI data** (H2020 ERC General and PoC)	**Supporting documents:** 1) documents proving the statement (such as a passport, ID) 2) request letter from the host institution		**AT73 —** AT73 serves to adapt the PI data to a change of situation *(e.g. name change due to marriage/divorce)*, ⚠ AT73 is open only to the EU. Contact us in case of an issue. AT73 may NOT be used to change the PI. For changes due to mistakes, AT60 is to be used.
H2020 MSCA MGAs				
81	**Change of the action**			**AT81 —** AT81 is one of the clauses that serve to adjust the

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
	starting date (H2020 MSCA-IF)			action schedule to a change of circumstances in the project — in a way that preserves the maximum number of researcher-months promised for the grant (together with suspension and change of working time). AT81 can only be used for MSCA-IF GAs (for other MSCA grants, use AT24). ⚠ If you need to shorten the action and lower the number of researcher-months, please notify an early termination of the GA (and indicate the fellowship end-date). ⚠ If the action starting date is incorrect, you must change that *before* notifying early termination**.**
82	**Suspension for professional, personal or family reasons (including parental leave)** (H2020 MSCA-IF)			**AT82 —** AT82 is one of the clauses that serves to adjust the action schedule to a change of circumstances in the project/researcher *(including sick leave of more than 30 consecutive days)* — in a way that preserves the maximum number of researcher-months promised for the grant (together with change of starting date and working time). ⚠ If you need to shorten the action and lower the number of researcher-months, please notify an early termination of the GA (and indicate the fellowship end-date).
83	**Change of the time spent on the action for professional, personal or family reasons** (H2020 MSCA-IF)	**Mandatory combinations:** - Change of the action duration (to extend the action in line with the part-time regime, i.e. transform the full-time-equivalent number of months into the real number of months), so that the maximum grant amount can stay the same and the costs can be declared at the pro-rata of the working		**AT83 —** AT83 is one of the clauses that serves to adjust the action schedule to a change of circumstances in the project — in a way that preserves the maximum number of researcher-months promised for the grant (together with suspension and change of starting date). ⚠ If you need to shorten the action and lower the number of researcher-months, please notify an early termination of the GA (and indicate the fellowship end-date).

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
		time) (AT23) - Change of the reporting periods (to adapt them to the new action duration) (AT25)		
84a	**Transfer of the GA to a new beneficiary** (H2020 MSCA-IF)	**Mandatory combinations:** For all changes: - Change of Annex 1 (if change/reallocation of tasks and changes to the use of resources are necessary) (AT21) - Change of Annex 2 (always including Annex 2a) (AT31) - Change of bank account (AT40) If the new beneficiary is in a country with a lower correction coefficient: - Change of the maximum grant amount (to reduce it to reflect the lower country coefficient) (AT32a) - Change of the estimated eligible costs (to adapt it to the new maximum grant amount) (AT34) - Change of the pre-financing (if not already paid out) (AT38) - Change to the contribution to the Guarantee Fund (if pre-financing not already paid out) (AT39) If the new beneficiary is in a country with a higher correction coefficient: - Change of the action duration (to		**AT84a —** AT84a serves to adapt the GA if the researcher transfers to a new beneficiary. The new beneficiary must comply with all eligibility rules. The end date of the former beneficiary and starting date of the new beneficiary can NOT overlap (transfer of participation with single 'transfer date'). The former beneficiary always leaves the grant and the new beneficiary always enters the grant (because MSCA-IF is a mono-beneficiary action, so there are no other beneficiaries). ⚠ The 'transfer date' should normally be the date the researcher starts working with the new beneficiary. In order to allow for full synchronisation of dates, chose the entry into force of the amendment (i.e. not a fixed date) as transfer date and put this date also as starting date in the employment contract for the researcher. If there is a gap in employment (between transfer date and employment starting date at the new beneficiary), request an amendment to suspend the action (AT82; must be done before the end of the action).

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
		reduce it, so that the maximum grant amount can stay the same) (AT23) - Change of the reporting periods (to adapt them to the new action duration) (AT25) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 (always; because either change of maximum grant amount or change of person months) 3) researcher's opinion 4) former supervisor's opinion 5) Accession Form (Annex 3), signed in the electronic exchange system (= declaration of commitment from the new beneficiary) ⚠ Within 30 days after the transfer takes effect or the signature of the amendment (whichever is the latest), the former beneficiary must also submit: – a transfer report, with: – an overview of the progress of the work (of what has been achieved up until that point) – the former beneficiary's individual financial statement (for the open period until transfer)		

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
84b	**Transfer of the GA to a new beneficiary** (H2020 MSCA-SNLS)	**Requirements:** - New host institution must have been validated in the Participant Register – Bank account must have been validated in the Participant Register **Mandatory combinations:** For all changes: - Change of Annex 1 (if change/reallocation of tasks are necessary) (AT21) - Change of Annex 2 (AT31) - Change of bank account (AT40) **Supporting documents:** 1) updated Annex 1 2) updated Annex 2 3) researcher's opinion 4) former supervisor's opinion 5) Accession Form (Annex 3), signed in the electronic exchange system (= declaration of commitment from the new beneficiary) ⚠ Within 30 days after the transfer takes effect, the former beneficiary must also submit: – a transfer report, with:		**AT84b —** AT84b serves to adapt the MSCA-SNLS GA if the researcher of the linked MSCA grant changes host institution. Compliance with the eligibility rules will be checked in the linked grant. The transfer date (end and starting date) must be the same as in the linked grant. The former beneficiary always leaves the grant and the new beneficiary always enters the grant (because MSCA-SNLS is a mono-beneficiary action, so there are no other beneficiaries).

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
		– an overview of the progress of the work (of what has been achieved up until that point) – the former beneficiary's individual financial statement (for the open period until transfer)		
H2020 COFUND MGAs				
91	**Change of equipment costs** (H2020 EJP)	**Mandatory combinations:** - Change of Annex 1 (if changes to the use of resources are necessary) (AT21) - Change of Annex 2 (AT31) **Supporting documents:** 1) updated Annex 1 (including Annex 7, if necessary) 2) updated Annex 2		
92	**Change of pre-financing** (H2020 ERA-NET, PCP/PPI)	**Mandatory combinations:** - if JRC participates: Changes to Annex 3b (JRC AA multi) (AT53) **Supporting documents:** 1) for JRC: Administrative Arrangement (Annex 3b), signed in the PP electronic exchange system		**AT92 —** AT92 serves to lower or raise the pre-financing for the action (i.e. the amount mentioned in Article 21.2/16.2 GA). ⚠ AT92 is reserved for exceptional cases and is open only to the EU. Contact us in case of an issue. A change of the pre-financing has normally NO impact on the maximum grant amount.

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SPECIAL AT-CLAUSES (ONLY IN SOME TYPES OF MGAS)				
AT-clauses		Mandatory combinations and supporting documents	Other combinations	⚠
No	Name			
				A change of the pre-financing has NO impact on the contribution to the Guarantee Fund/pre-financing guarantee (since not linked to the pre-financing, but to the maximum grant amount/financial viability).
RFCS MGA				
301	**Change of pre-financing** (RFCS)	**Mandatory combinations:** - if JRC participates: Changes to Annex 3b (JRC AA multi) (AT53) **Supporting documents:** 1) for JRC: Administrative Arrangement (Annex 3b), signed in the PP electronic exchange system		**AT301 —** AT301 serves to add, lower or raise the pre-financing for each beneficiary (i.e. the amount mentioned in Article 21.2 GA). ⚠ AT301 is reserved for exceptional cases and is open only to the EU. Contact us in case of an issue. A change of the pre-financing has normally NO impact on the maximum grant amount. A change of the pre-financing has NO impact on the pre-financing guarantee (since those are not linked to the pre-financing, but to the maximum grant amount/financial viability).
302	**Change of the pre-financing guarantee** (RFCS)	**Mandatory combinations:** - if JRC participates: Changes to Annex 3b (JRC AA multi) (AT53) **Supporting documents:** 2) for JRC: Administrative Arrangement (Annex 3b), signed in the PP electronic exchange system		**AT302 —** AT302 serves to add, lower or raise the pre-financing guarantee for each beneficiary (i.e. the amount mentioned in Article 21.2 GA). ⚠ AT39 is reserved for very exceptional cases and is open only to the EU. Contact us in case of an issue. Non-H2020 — New pre-financing guarantees may be introduced if there are doubts about the financial viability of a new beneficiary.

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Open Access Guidelines for research results funded by the ERC

– revised February 2016 –

ERC SCIENTIFIC COUNCIL – FEBRUARY 2016

The mission of the European Research Council (ERC) is to support excellent research in all fields of science and scholarship. The main outputs of this research are new knowledge, ideas and understanding, which the ERC expects its researchers to publish in peer-reviewed articles and monographs.

The ERC considers that providing *free online access* to these materials is the most effective way of ensuring that the fruits of the research it funds can be accessed, read, and used as the basis for further research.

Open access to research publications

The ERC therefore supports the principle of open access to the published output of research as a fundamental part of its mission.

Accordingly, the European Research Council:

- *requests* that an electronic copy of any research article, monograph or other research publication that is supported in whole, or in part, by ERC funding be deposited in a suitable repository immediately upon publication. Open access should be provided as soon as possible and in any case no later than six months after the official publication date. For publications in the Social Sciences and Humanities domain a delay of up to twelve months is acceptable.
- *strongly encourages* ERC funded researchers to use discipline-specific repositories for their publications. A list of recommended repositories is provided in Appendix 1. If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo[1].

[1] http://www.zenodo.org/

archived

- *reminds* ERC funded researchers that open access fees are eligible costs that can be charged against ERC grants, provided they are incurred during the duration of the project.
- *asks* Host Institutions to cover open access fees of any research publications supported in whole, or in part, by ERC funding, arising after the end of the project.

Research data management and sharing

The European Research Council supports the basic principle of Open Access to research data. It therefore

- *recommends* to all its funded researchers that they follow best practice by retaining files of all the research data they have produced and used during the course of their work, and that they be prepared to share these data with other researchers whenever they are not bound by copyright restrictions, confidentiality requirements, or contractual clauses.

To further this principle, the ERC is following, and participating in, developments in this area both to help create an appropriate professional environment to collect, structure and store data, to arrive at suitable protocols to gain access to data and to identify appropriate repositories for research data in different disciplines and domains.

The European Research Council considers that, given the fast evolving practices in this area and the extreme diversity of situations, as well as the different approaches in different disciplines, it would be premature at this time to ask ERC funded researchers to make a binding commitment to open research data right at the start of their project. Nevertheless, the ERC continues to strongly encourage all ERC funded researchers to seek to establish and practice good research data management in accordance with the current best practices in their respective fields and to share their data with other researchers in a responsible way.

This document has been drawn up to provide guidance to ERC funded researchers and their Host Institutions[2]. It will be reviewed periodically.

[2] These guidelines are complementary to Special Clause 39 of the FP7 ERC Model Grant Agreement / to the Horizon 2020 ERC Model Grant Agreement, which detail the legal obligations of the beneficiary with regard to open access, where applicable.

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Appendix 1: Recommended discipline-specific open access repositories

The recommended repository for Life Sciences is Europe PubMed Central[3]; and for Physical Sciences and Engineering arXiv[4] is recommended. The ERC Scientific Council is currently not recommending any specific repository for Social Sciences and Humanities. However, it is reviewing existing practices and open access infrastructures in this domain and may make recommendations in the future.

Appendix 2: Recommended repository for monographs and book chapters

The recommended repository for monographs, book chapters and other long-text publications is the OAPEN Library[5].

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[3] http://europepmc.org
[4] http://arxiv.org/
[5] http://oapen.org

European Research Council
Executive Agency

Established by the European Commission

Horizon 2020
European Union Funding
for Research & Innovation

European Research Council (ERC)

Guidelines on

Implementation of Open Access to Scientific Publications and Research Data

in projects supported by the European Research Council under Horizon 2020

Version 1.1
21 April 2017

HISTORY OF CHANGES			
Version	**Publication Date**	**Change**	**Page**
1.0	25.08.2016	▪ Initial version	
1.1	21.04.2017	▪ Link to ERC Data Management Plan template was included in the Guidelines	2

Open Access to Publications

According to the ERC Scientific Council's Open Access Guidelines[1]:

"The mission of the European Research Council (ERC) is to support excellent research in all fields of science and scholarship. The main outputs of this research are new knowledge, ideas and understanding, which the ERC expects its researchers to publish in peer-reviewed articles and monographs. The ERC considers that providing free online access *to these materials is the most effective way of ensuring that the fruits of the research it funds can be accessed, read, and used as the basis for further research.* […] *The ERC therefore supports the principle of open access to the published output of research as a fundamental part of its mission."*

Under Horizon 2020, beneficiaries of ERC grants[2] must ensure **open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results**. The detailed requirements on open access to publications are contained in the Horizon 2020 ERC Model Grant Agreement (Article 29.2).

Research Data Management and Sharing

Concerning **research data**, the ERC Scientific Council's Open Access Guidelines further explain:

"The European Research Council supports the basic principle of Open Access to research data. It therefore recommends *to all its funded researchers that they follow best practice by retaining files of all the research data they have produced and used during the course of their work, and that they be prepared to share these data with other researchers whenever they are not bound by copyright restrictions, confidentiality requirements, or contractual clauses."*

Beneficiaries of ERC grants funded under the Work Programme 2016 may opt-in, on an individual and voluntary basis, **to the Horizon 2020 Pilot on Open Research Data** in order to facilitate access, re-use and preservation of research data generated during their research work. Beneficiaries choosing this option should carefully check the additional obligations that apply to projects that opt-in to the Pilot as described in Article 29.3 of the ERC Model Grant Agreement under Horizon 2020. As of the Work Programme 2017 the Pilot on Open Research Data is being extended to cover all thematic areas of Horizon 2020 and open access becomes the default setting for the research data generated. The beneficiaries may still opt out at any stage, freeing themselves from any obligations regarding the open access to digital research data generated in the action. Please also see ERC Data Management Plan template [ODT format].

[1] Open Access Guidelines for research results funded by the ERC (revised February 2016)
[2] except for ERC Low-value Grants

Implementation

Open access to peer-reviewed scientific publications

Article 29.2 of the Grant Agreement sets out detailed legal requirements on open access to scientific publications: under Horizon 2020, **each beneficiary must ensure open access – via a repository – to all peer-reviewed scientific publications** relating to the project's results (including not only journal articles but also conference proceedings and long-text publications such as monographs, book chapters, edited volumes, etc.). Access has to be provided either to the published version or the final peer-reviewed manuscript accepted for publication.
To meet this requirement, beneficiaries must ensure that these publications can be read online, downloaded and printed (free of charge, online access to any user). Beneficiaries are also encouraged to provide for further rights that could make them even more useful (e.g., right to copy, distribute, search, link, crawl and mine).

The open access to publications mandate comprises 3 steps:

1. Depositing publications in repositories (online archive)
2. Selecting the open access route (green or gold open access)
3. Providing open access to publications

These steps are explained in more detail below. They may or may not occur simultaneously, depending on the selected open access route and whether an embargo period applies.

Step 1 – Depositing publications in repositories

Beneficiaries are required to deposit an electronic copy of the publication in a suitable repository. Publications must be "machine-readable", that is in a format that can be used and understood by a computer. They must therefore be stored in text file formats that are either standardised or otherwise publicly known so that anyone can develop new tools for working with the documents. Thus, scanned versions of printed publications do not fulfil this requirement.

Depositing is mandatory regardless of the open access mode selected. It must be done as soon as possible and at the latest upon publication.

The beneficiary must also aim to deposit at the same time as the publication the research data needed to validate the results presented in the deposited scientific publications ('underlying data'), ideally in a data repository. This is strongly encouraged but not mandatory[3]. Beneficiaries are also invited to grant open access to this data, but they are not obliged to do so.

ERC strongly encourages ERC funded researchers to use discipline-specific repositories for their publications.

- For Life Sciences the recommended repository is Europe PubMed Central. For Physical Sciences and Engineering arXiv is recommended. The ERC is currently not recommending any specific repository for Social Sciences and Humanities.

[3] However, note that for projects that take part in the Open Research Data Pilot the deposit and the provision of open access to the data underlying publications IS mandatory. This is explained further down in these guidelines.

- The recommended repository for monographs, book chapters and other long-text publications is the OAPEN Library.
- If there is no appropriate discipline specific repository, researchers should make their publications available in institutional repositories or in centralized ones, such as Zenodo.

Venues such as Research Gate or Academia.edu that require users to register in order to access content do not count as repositories. The posting of publications on a personal, institutional or project specific webpage or the deposit in a publically accessible Dropbox account is not sufficient to satisfy the requirements either.

Step 2 – Selecting the open access route

Beneficiaries select one of the two main routes towards open access to publications, both equally valid:

1. **Green open access (self-archiving):** The published work or the final peer-reviewed manuscript that has been accepted for publication is made freely and openly accessible by the author, or a representative, in an online repository. Some publishers request that open access be granted only after an embargo period has elapsed.
2. **Gold open access (open access publishing):** The published work is made available in open access mode by the publisher immediately upon publication. The most common business model is based on one-off payments by authors (commonly called APCs – article processing charges – or BPCs – book processing charges). The costs of gold open access publications are eligible costs that can be charged against ERC grants, provided the costs are incurred during the duration of the project.

Step 3 – Providing open access to deposited publications

Beneficiaries must **ensure open access to the deposited version** of their publications via the chosen repository. Open access should be provided as soon as possible and in any case no later than six months after the official publication date. For publications in the Social Sciences and Humanities domain a delay of up to twelve months is acceptable. For publications that have been published in gold open access, open access to the deposited version has to be provided immediately upon publication.

For publications issued after the end of the action, if beneficiaries cannot provide open access within the maximum acceptable embargo period without incurring additional costs for gold open access, green open access with a longer embargo period is accepted.

To be able to easily find the deposited publication, beneficiaries must also ensure open access – via the repository – to the bibliographic metadata that identify the deposited publication. This metadata must include a persistent identifier (such as the Digital Object Identifier, DOI) in order to allow easy and persistent referencing.

The European Commission encourages authors to retain their copyright and grant adequate licences to publishers. Creative Commons offers useful licensing solutions (e.g. CC BY). This type of licence is a good legal tool for providing open access in its broadest sense.

Open access to research data

In Horizon 2020 the European Commission has been encouraging open access to and reuse of digital research data generated by Horizon 2020 projects **through the Open Research Data Pilot** (ORD Pilot), following FAIR data principles - all research data should be Findable, Accessible, Interoperable and Reusable (FAIR). Examples of research data include statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images.

Under the pilot, open access should be provided to the data needed to validate the results presented in scientific publications. Other data is also covered as specified in the data management plan.

The legal requirements for projects participating in this ORD Pilot are set out in Article 29.3 of the Grant Agreement: the beneficiary must deposit the data in a research data repository so that it is possible to access, mine, exploit, reproduce and disseminate the data, free of charge for any user. For ERC Work Programme 2016 projects, Article 29.3 will be only included in the Grant Agreement if the beneficiary has opted-in the ORD Pilot. Starting from ERC Work Programme 2017 projects, Article 29.3 will be included in the Grant Agreement as the default[4].

After the project has started, beneficiaries of the ERC projects participating in the ORD Pilot have to formulate a **Data Management Plan (DMP)**, a brief plan to define what data sets the project will generate or process, whether and how these data will be made accessible, and how they will be curated, stored and preserved. The DMP should also provide information on the measures taken to safeguard and protect sensitive data.

For ERC projects, the data management plan must address following issues:
1. Making data **F**indable,
2. Making data openly **A**ccessible,
3. Making data **I**nteroperable,
4. Increase data **R**e-use,
5. Allocation of recourses and data security

The data management plan will also have to specify if certain datasets remain closed and the reasons for not giving access should be given (for instance, if one of the project objectives would be jeopardised by providing open access to certain data or some of the generated data are considered sensitive, etc.).

A first version of the data management plan must be submitted within the first six months of the project implementation. It should be updated and completed (i.e. become more precise) as the project evolves.

No additional funding is provided for data management activities for those deciding to participate in the pilot. Costs relating to open access to research data will be eligible as part of the grant, **independent from the participation in the pilot,** provided the general eligibility conditions specified in the Grant Agreement are followed.

[4] **ERC proof of concept"** grants are excluded from the ORD Pilot

Participants of the Open Research Data Pilot need to take the following three steps:

1. Deposit research data needed to validate the results presented in scientific publications, including associated metadata, in the repository as soon as possible. Also other data (for instance data not directly attributable to a publication, or raw data), including associated metadata, should be deposited – that is, according to the individual judgement by each project, specified in the data management plan.

2. Take measures to enable third parties to access, mine, exploit, reproduce and disseminate (free of charge for any user) this research data, for instance by attaching a Creative Commons Attribution Licence (CC BY) to the data deposited, or by waiving all interests associated to copyright and database protection using the CC0 tool.

   The EUDAT B2SHARE tool includes a built-in license wizard that facilitates the selection of an adequate license for research data.

3. Provide information via the chosen repository about the tools available in order for the beneficiaries to validate the results, e.g. specialised software or software code, algorithms and analysis protocols. Where possible, these tools or instruments should be provided.

Opting out of the ORD Pilot

Participation in the ORD Pilot is flexible in the sense that it does not mean that all research data needs to be open, following the approach "as open as possible, as closed as necessary". Furthermore, beneficiaries also have the possibility to opt out of this Pilot completely at any stage (before or after the grant signature), thereby freeing themselves retroactively from the associated obligations. In this case, Article 29.3 will be removed from the Grant Agreement. Beneficiaries of ERC actions can provide a reason for opting out (but are not required to do so).

References and support

- Guidelines issued by the ERC Scientific Council: Open Access Guidelines for researchers funded by the ERC (revised February 2016)
- ERC Model Grant Agreement for frontier research grants
- Horizon 2020 Annotated Grant Agreement - ERC specific annotations to Articles 29.2 and 29.3 (pages 363 – 365)
- Open Access section of the ERC website
- Repositories for publications recommended by the ERC Scientific Council:
  - Europe PubMed Central
  - arXiv
  - OAPEN library
  - Zenodo

On the basis of the experience gained, the ERC Executive Agency will continue to provide guidance via the update of these guidelines. Specific issues may also be covered through dedicated FAQ.

If you have any question on open access or the Open Research Data Pilot in the context of ERC projects, do not hesitate to contact the ERC open access support team at ERC-OPEN-ACCESS@ec.europa.eu.

EUROPEAN
COMMISSION

Brussels, 18.9.2018
C(2018) 5960 final

COMMISSION DECISION

of 18.9.2018

on authorising the use of reimbursement on the basis of a lump sum for ERC Proof of Concept actions under the Horizon 2020 Framework Programme for Research and Innovation

COMMISSION DECISION

of 18.9.2018

on authorising the use of reimbursement on the basis of a lump sum for ERC Proof of Concept actions under the Horizon 2020 Framework Programme for Research and Innovation

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation (EU) No 1291/2013 of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Article 10 thereof,

Having regard to the Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)[2], and in particular Article 28.6 thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[3], and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union[4] contains detailed rules regardinglumps sums,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be reflected in its design, rules, financial management and implementation,

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of lump sums is appropriate to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures,

(4) The use of lump-sum financing should therefore be authorised for actions under the Horizon 2020 Framework Programme,

HAS DECIDED AS FOLLOWS:

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1 OJ L 2013, 20.12.2013, p. 104-173.

2 OJ L 2013, 20.12.2013, p. 81-103

3 OJ L 2012, 26.10.2012, p. 1-96

4 Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

Article 1

The use of grants reimbursing eligible costs on the basis of a lump sum is authorised for ERC Proof of Concept actions under the Horizon 2020 Framework Programme for Research and Innovation (2014-2018), for the reasons and under the conditions set out in the Annex.

Done at Brussels, 18.9.2018

For the Commission
Carlos MOEDAS
Member of the Commission

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ANNEX

1. Form of grant and categories of costs covered

Grants to be awarded under the action Proof of Concept of Horizon 2020 ('ERC PoC action'), ERC Work programmes 2019 and 2020, shall exclusively take the form of a standard lump sum pre-fixed by the Commission.

ERC Proof of Concept grants concern activities aimed at verifying the innovation potential of ideas arising from ERC funded projects (e.g. by validating results, clarifying IPR or knowledge transfer strategies, making market analysis, etc.).

This lump sum will cover the beneficiaries' following direct and indirect eligible costs for such actions: personal costs, subcontracting, other direct costs and indirect costs.

Indirect costs are included as a flat-rate of 25% to the direct cost categories that qualify for indirect costs under the H2020 rules.

The amount of the lump sum for each grant is fixed at 150.000 EUR following the methodology set out in Section 3.

The applicants must also provide in their proposal a breakdown of the lump sum showing the share per beneficiary (and linked third party). This estimated lump sum breakdown will become part of the grant agreement (Annex 2).

The lump sum will be paid by the Agency, if the action has been properly implemented in accordance with Annex 1 of the grant agreement (and provided that all other obligations under the grant agreement have been complied with).

2. Justification

Simplification as a central aim of the Horizon 2020 Framework Programme needs to be reflected in its design, rules, financial management and implementation.

Lump sum funding, when compared to reimbursement of actual costs, provides considerable simplification potential. It removes all obligations on cost reporting and financial audits, thus removing a major part of the administrative burden on beneficiaries and enabling efficiency gains in the implementation of Horizon 2020. At the same time, lump sum funding strongly increases the focus on the quality of the scientific-technical performance and output of projects rather than on accounting compliance. This is desirable in Horizon 2020 in order to improve the quality of results and their exploitation.

Furthermore, lump sums are fully in line with the Commission's initiative Budget Focused on Results and the underlying principles of the proposal for the revision of the Financial Regulation.

2.1. Appropriateness of lump sum costs with regard to the nature of the actions to be supported under the action Proof of Concept in the ERC Work Programmes 2019 and 2020

The action is part of a pilot exercise for a pre-defined fixed lump-sum and has been chosen because of the homogenous nature of the ERC PoC projects for which a lump-sum scheme would imply significant administrative simplification. The costs of the Proof of Concept projects can be well estimated on the basis of the ERC historical data and therefore these projects are appropriate for this pilot.

2.2. The risks of irregularities and fraud and costs of control

The Agency will verify at the time of preparation of the grant, during the implementation of the action or afterwards (through technical checks, reviews or audits), compliance with the conditions for using lumps sums.

As a direct consequence of removing all obligations on cost reporting and financial ex-post audits, financial error rates will be minimised.

Pre-financing will follow the standard H2020 rules and will be fixed in the grant agreement, 5% of the lump sum is retained as contribution to the Guarantee Fund.

There is no reporting of actual costs, and there are normally no financial checks, reviews or audits. Beneficiaries have no obligation vis-à-vis the Agency to document costs incurred for the action but they remain subject to the accounting rules under the applicable national laws.

Checks, reviews, and audits will focus on the technical implementation of the action, in particular on the fulfilment of the conditions for releasing lump sums, or on other aspects of the grant agreement such as ethics and research integrity, dissemination and exploitation of results, management of intellectual property and gender equality.

If such controls reveal that the conditions for payment of the lump sum had not been met (e.g. the action had not been completed) and that an undue payment was made to a beneficiary, the Agency is entitled to recover up to the amount of the grant.

3. Method to determine the amount of the lump sum

According to Article 124(2) of Regulation (EC, Euratom) No 966/2012, the method chosen to determine the lump sum may be based on "statistical data or similar objective means".

The ERC PoC action has been implemented since 2011 and there is a consolidated experience on the main objectives and structure of the related projects.

The projects to be funded aim at turning research outputs into a commercially or socially valuable proposition. A typical ERC PoC action includes one single activity which consists in verifying the innovation potential of ideas arising from ERC funded projects, e.g. by validating results, clarifying IPR or knowledge transfer strategies, identifying customers and societal benefits.

The projects have a duration of 18 months.

In order to establish the amount of the pre-fixed lump sum, the statistical data of all H2020 funded PoC projects were analysed. At the date of calculation, September 2017, the database consisted of 441 H2020 PoC projects, of which 143 were already closed.

These projects had comparable objectives and were also comparable in terms of their eligible costs, EU funding and total costs.

The analysis focused on the budget and resources allocated to the projects.

The projects belonged to the following calls for proposals:

1. H2020: ERC Proof of Concept 2014;
2. H2020: ERC Proof of Concept 2015;
3. H2020: ERC Proof of Concept 2016.

3.1. Statistical analysis

Graph 1 summarises the budget request of all funded H2020 PoC projects (441 individual projects) at the proposal stage:

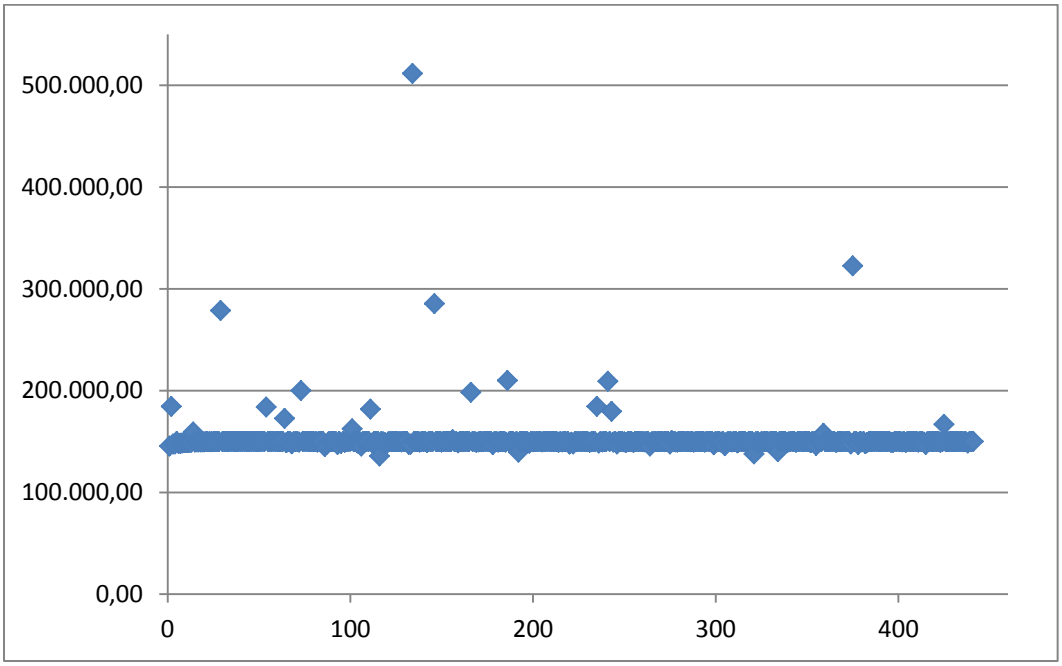

Table 2: Average and median estimated costs of the H2020 441 individual project proposals

Average:	152,382 euro

Median:	149,995 euro

The analysis showed that some beneficiaries indicated a higher planned budget for their projects despite of the maximum available EU contribution for a PoC project (150,000 euro). This resulted in a higher amount for the average size of a planned project, but a typical request for a PoC project is close to the current maximum of 150,000 euro.

Table 3: Evolution of total projects costs in € of H2020 143 completed and paid PoC projects

RESULTS	
Completed projects (Final payments processed)	143
average maximum EU contribution as per GA	148.948,83
average accepted eligible costs	146.758,80
median maximum EU contribution as per GA	149.967,00
median accepted eligible costs	150.000,00

The table shows that the typical accepted cost for a H2020 PoC project is eventually 150,000 euro.

Analysing the data, the following aspects also need to be taken into account:

- The financial reporting system allows the beneficiaries to report all their eligible costs, even higher costs, if that is the case, than the maximum EU contribution. Though, beneficiaries do not report them systematically, as they know that they will be reimbursed up to the maximum EU contribution, typically 150,000 euro.

- The data of all the 178 projects financed from the FP7 programme were also analysed. They showed similar characteristics as of the 441 H2020 projects, i.e. the grant agreements had a typical (median) maximum EU contribution of 149,759 euro and the typical size of eligible costs reached 148,762 euro.

3.2. Summary

Taking into consideration that:

- the typical amount of a PoC project is estimated at 150,000 euro by the beneficiaries and

- the typical amount of costs accepted at the stage of final reports is 150,000 euro and

- the magnitude of refused claimed costs is not significant,

it is proposed to use a lump sum of 150,000 euro pre-fixed by the Commission for the implementation of the ERC PoC action.

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by the Financial Regulation.

The usual conditions for ensuring that the no-profit, co-financing and absence of double funding principles are complied with also apply to lump sum costs:

- The lump sum is based on statistical data;
- The risk of profit is limited because the lump sum is fixed at the typical funding level of previous ERC PoC projects, and because there is traditionally high over-subscription in ERC PoC calls for proposals. Applicants will therefore face high competition, which is a factor discouraging proposals with a lower value;
- The reimbursement rate of 100% as set out in Article 28 of the H2020 Rules for Participation is reflected in the calculation of the lump sum;
- Double-funding is avoided by the fact that the beneficiaries are requested to describe in a narrative way the resources planned to use for the implementation of the project. In addition, the lump sum will cover all direct and indirect eligible costs of the action;
- Proposals will be evaluated according to the standard Horizon 2020 evaluation procedures with the help of outside experts. These experts will assess the quality of the proposals in terms of the excellence of their innovation potential, of the expected effects or benefits to the economy, society, culture, public policy or services as well as the quality and efficiency of the proof of concept plan.

DECISION

of XXX

amending Commission Decision C(2013)8194 authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska- Curie actions under the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (Text with EEA relevance)[1], and in particular Article 57 thereof,

Having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union ('Financial Regulation')[2], amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 and in particular Article 279(2) thereof,

Whereas:

(1) The special needs allowance for Marie Skłodowska-Curie Actions (MSCA) under Horizon 2020 is implemented through a pilot scheme of dedicated low-value lump sum grants - "Special Needs Lump Sums" (SNLS). This arrangement has proven to lead to an excessive administrative burden and disproportionate management costs for this additional grant cycle. This has prompted a change of approach for Horizon Europe.

(2) The Horizon 2020 implementation of the special needs allowance via lump sum grants should therefore be replaced by a unit cost top-up to the institutional unit cost integrated in the main MSCA action in which the person concerned participates.

(3) Decision C(2013)8194 should therefore be amended in accordance with Article 50(2) of the internal rules for the implementation of the Commission section of the general budget of the European Union[3], by which authorising decisions adopted prior to the entry into force of Regulation (EU, Euratom) 2018/1046 should be amended using the same procedure as set out in the second paragraph of that article.

HAS DECIDED AS FOLLOWS:

Sole Article

The Annex to Decision C(2013)8194 is replaced by the text in the Annex to this Decision.

Done at Brussels, xxx

Themis CHRISTOPHIDOU
Director-General

[1] OJ L 170, 12.5.2021, p. 1.
[2] OJ L 193, 30.7.2018, p1.
[3] Commission Decision C(2022)9304.

EN

ANNEX

Introduction

In order to make the Union's research and innovation system more competitive on a global scale, Horizon 2020 aims *inter alia* at reinforcing and extending the excellence of the Union's science base and at consolidating the European Research Area. Europe needs a strong and creative human resource base, mobile across countries and sectors, with the right combination of skills to innovate and to convert knowledge and ideas into products and services for economic and social benefit. Global mobility for research purposes in a constantly challenging economic environment which competes for the best brains and ideas has a price which needs to be paid if Europe wants to remain at the forefront of innovation and secure prosperity for its people.

In support of this aim, the Marie Skłodowska-Curie actions provide excellent and innovative research training as well as attractive career and knowledge-exchange opportunities through cross-border and cross-sector mobility of researchers to best prepare them to face current and future societal challenges. By doing so, the Marie Skłodowska-Curie actions ensure optimum development and dynamic use of Europe's intellectual capital in order to generate, develop and transfer new skills, knowledge and innovation and, thus, to realise its full potential across all sectors and regions.

1. Form of financing and categories of costs covered

In line with the recommendations of the FP7 Marie Curie actions interim evaluation covering the years 2007 to 2011[4], the contribution to costs of researchers/seconded staff members and institutional costs incurred by beneficiaries in Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme shall exclusively take the form of reimbursement of eligible costs declared on the basis of unit costs.

The use of unit costs applies to the following four actions:

Action	Acronym	Description
1. Innovative Training Networks	ITN	Support for doctoral and early-stage training: - European Training Networks - European Industrial Doctorates - European Joint Doctorates
2. Individual Fellowships	IF	Support for experienced researchers undertaking international and inter-sector mobility: - European Fellowships - Global Fellowships

[4] FP7 Marie Curie Actions Interim Evaluation, Final Report, 7.02.2013, p. 112: "Although due to the very wide use of flat rates in general MCA are regarded as very user-friendly as far as financial management is concerned, application of real costs for a rather minor share of overall MCA expenditure has a negative impact on the consistency and overall clarity of the financial management arrangements. Therefore in order to further simplify MCA administrative provisions it would be important to harmonise financial management procedures and to switch to the full use of standardised costs".

Action	Acronym	Description
3. Research and Innovation Staff Exchange	RISE	International and inter-sectorial cooperation through the exchange of staff
4. Co-funding of programmes	COFUND	Co-funding of regional, national and international programmes: - doctoral programmes - fellowship programmes

All the eligible costs incurred in the framework of those actions shall be reimbursed on the basis of unit costs, in accordance with the following system:

Categories of eligible costs / Marie Skłodowska-Curie Action	Costs of researchers/seconded staff members (1)				Institutional costs (2)	
	Living allowance (a)	**Mobility allowance (b)**	**Family allowance (c)**	**Top-up allowance (d)**	**Research, training and networking costs (a)**	**Management and indirect costs[5] (b)**
ITN	**Unit cost per person/month**	**Unit cost per person/month**	**Unit cost per person/month**	**Ineligible**	**Unit cost per person/month**	**Unit cost per person/month**
IF	**Unit cost per person/month**	**Unit cost per person/month**	**Unit cost per person/month**	**Ineligible**	**Unit cost per person/month**	**Unit cost per person/month**
RISE	**Ineligible**	**Ineligible**	**Ineligible**	**Unit cost per person/month**	**Unit cost per person/month**	**Unit cost per person/month**
COFUND	**Unit cost per person/month (one for early-stage researchers and one for experienced researchers)**	**Ineligible**	**Ineligible**	**Ineligible**	**Ineligible**	**Unit cost per person/month (indirect costs not covered)**

(1) For ITN, IF and COFUND – costs of researchers

(a) Living allowances payable to the individual early-stage or experienced researchers recruited under an employment contract/contract with full social security coverage and complying with the social security legislation applicable[6]. These amounts include all compulsory deductions under national applicable legislation.

To ensure equal treatment of, and purchasing power parity for, researchers working all over the world, the amount of the unit costs for living allowances for ITN and IF are determined per country by applying a country-specific correction coefficient.

(b) For ITN and IF, a mobility allowance payable to the individual researcher to cover additional mobility-related costs such as travel and accomodation.

(c) For ITN and IF, a family allowance payable to the individual eligible researcher to reduce family-related obstacles to researcher mobility.

For RISE – costs of seconded staff members

(d) A top-up allowance payable to the individual seconded staff member to cover travel, accomodation and subsistence costs related to the secondment.

5 Including, where applicable the special needs top-up.

6 Council Regulation (EC) No 883/2004 of 29 April 2004, OJ L 166, 30.04. 2004, p. 1.

(2) Institutional costs

(a) Costs related to the training and research expenses of researchers as well as costs related to the transfer of knowledge and networking.

(b) Costs related to managing a project and, for ITN, IF and RISE, indirect costs.

(c) Where applicable, costs related to special needs to provide financial support for the specific costs entailed by recruited or seconded persons whose long-term physical, mental, intellectual or sensory impairments are such that their participation in MSCA actions would not be possible without this additional support.

The amounts of the unit costs to be used shall be calculated in accordance with the method described in Section 3.

2. Justification

Recurring to unit costs considerably simplifies, streamlines and reduces the time needed for the financial management of projects, both at Commission/Research Executive Agency (REA) as well as beneficiary level. Compared to the 'traditional' system of calculating the grant amount on a detailed budget of estimated actual eligible costs per cost category, a unit-cost system is not only more cost-effective and economically sound than item-based budgeting: it significantly shortens the time needed to calculate grant amounts, avoids amendments related to budget variations and substantially decreases the number of recovery orders and de-commitments. It also significantly decreases the workload of the management body and consequently speeds up the payment procedure. Furthermore, it implies additional simplifications at beneficiary level both in terms of application and reporting requirements.

In summary, this approach provides simplification through:

(a) less complex funding rules contributing to easier readability of actions;

(b) greater predictability for grant beneficiaries making the actions more attractive;

(c) less administrative burden for checking at the payment stage reducing overheads for the contracting authority and facilitating productivity gains;

(d) simplified reporting requirements (no certification or financial statement to be provided by beneficiaries);

(e) easier ex-post analysis (riders related to budget variations will be avoided; payment based on predetermined output or result) and further reductions of the risk of error.

Marie Skłodowska-Curie actions are particularly suited to the utilisation of unit costs given their successful implementation in a similar way for the past seven years (under the FP7 PEOPLE Specific Programme 2007-2013). Consequently, the Commission has a data base of final grants reimbursing unit costs as well as a study on which to base its assessment.

2.1. Nature of the supported actions

The **Innovative Training Networks (ITN)** aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit. The ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced

career perspectives in both the academic and non-academic sectors through international, interdisciplinary and inter-sector mobility combined with the innovation-oriented mind-set.

The goal of **Individual Fellowships (IF)** is to enhance the creative and innovative potential of experienced researchers wishing to diversify their individual competence in terms of skill acquisition at multi- or interdisciplinary level through advanced training, international and intersectoral mobility. IF provide opportunities to acquire new knowledge and to work on research in a European context (Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

The **RISE** scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa) for the advancement of science and development of innovation. The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

The **COFUND** scheme aims at stimulating regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions. This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sector mobility of researchers at all stages of their career.

In order to offer attractive working conditions for researchers from all over the world, the system of so-called Marie Skłodowska-Curie rates was established under the 4th Framework Programme for Research and Technological Development (1994-1998) as a benchmark against the most favourable national researcher mobility grants in Europe and beyond. Since then, these rates have been progressively refined and fine-tuned as well as periodically updated to stay competitive and realistic; in particular, measures have been taken to allow for researchers' salary adaptations due to pay increases and/or inflation and to ensure that the reimbursement levels are in line with, and do not exceed, real costs incurred by host organisations.

All supported projects will be funded through an output-based unit cost system. The recourse to unit costs is justified by the very high number of applications[7] and is considered as an appropriate form of financing in order to simplify the administrative burden and financing conditions of supported projects. While a budget-based approach involves complex rules related to budget transfers and variations with project implementation subsequently entailing a lot of accounting compliance, a unit-cost approach provides the opportunity to put added weight on the quality of the results as well as on the impact of the support. Such an approach also leads to more qualitative projects with verifiable results in line with the objectives of the Marie Skłodowska-Curie actions rather than emphasising the financial and administrative aspects of the research training, career development and knowledge exchange. Moreover, the sole use of unit costs represents a further simplification for applicants ensuring certainty and transparency of funding levels in case of selection and proper implementation of the project.

2.2. Risks of irregularities and fraud and costs of control

[7] Over the seven-year period of FP7, more than 50 000 applications were submitted under calls related to Marie Curie actions, with roughly 42 000 applications for individual fellowships and almost 6 000 for initial training networks alone.

The extended use of simplified forms of grants under Marie Skłodowska-Curie actions may imply certain risks of irregularities and fraud. Therefore, the importance of having effective internal control procedures for fraud prevention and reporting of irregularities is increased.

Regulation (EU, Euratom) No 966/2012[8] requires that the DGs and Agencies establish anti-fraud measures in their individual Internal Control Systems. According to that Regulation, the financial statement must provide information regarding existing and planned fraud prevention and protection measures in order to prevent any risk of fraud or irregularity which might affect the Union's financial interests. In 2010, the REA started implementing its first Anti-Fraud Strategy. In addition, controls to prevent and detect fraud have been included in all parts of the Internal Control Systems of the REA. In June 2011, the Commission adopted its first Anti–Fraud Strategy (CAFS) in which it requested the Commission Services to set up or update their sectorial Anti-Fraud Strategies. For the area of research the Anti-Fraud Strategy (RAFS) was adopted in December 2012. The RAFS builds strongly on and complements the CAFS by demonstrating how elements of the corporate strategy are addressed in the area of research. The sectorial strategy outlines some key principles of combating fraud, with a special focus on challenges which are common to the services of the research family and coordination/collaboration mechanisms, which should ensure that strategic priorities are implemented in a most effective and coherent manner throughout the whole family. In parallel with the setup of RAFS and taking into account this new element, the REA reviewed its own strategy by fully endorsing the RAFS and by complementing it with an Anti-Fraud Approach, to stress that the CAFS and RAFS remain the key strategic documents for anti-fraud activity in the REA. While CAFS and RAFS focus on the strategic positioning of anti-fraud activities, the main purpose of the REA's Anti-Fraud Approach is to translate the strategic priorities into measures which are addressing risks that are particularly relevant for the operations managed by the agency. The Approach identifies various areas where the REA could improve the effectiveness of its fraud prevention and detection capacity, thereby supporting implementation and awareness-raising activities. The Approach is accompanied by an action plan with clear deliverables; it also introduces an anti-fraud team in the REA which will considerably strengthen the anti-fraud activity within the agency and the collaboration on anti-fraud matters with the Commission services and OLAF.

Reporting and control in Marie Skłodowska-Curie actions will focus on the implementation of the supported activity and the achieved results rather than on the eligibility of costs incurred, reducing the workload and scope for error of both participants and managing body. The whole monitoring system is set up in a manner so as to ensure efficiency and cost-effectiveness of the controls. The REA will be exclusively responsible for management aspects of the Marie Skłodowska-Curie actions such as on-site project visits. In addition, the possibilities for ex-post controls will be extended which can further guarantee the sufficient quality of the outputs.

As statistically proven over the seven-year period of the 7th Framework Programme for Research and Development (FP7) and due to its clear-cut nature, the system of Marie Skłodowska-Curie rates is very resistant to irregularities and fraud. In fact, the FP7 PEOPLE specific programme remained much simpler compared to other FP7 specific programmes when it comes to the financing modalities for mobility grants. As a consequence, the intrinsic risk on legality and regularity errors in cost claims leading to unjustified Union funding has been very low and does thus not justify additional control and audit mechanism nor their costs.

In order to further reduce the risks, participants shall continue to be required to incur the full researcher unit costs (in ITN, IF and RISE actions) for the exclusive benefit of the researchers

[8] Articles 32 and 66(2) of Regulation (EU, Euratom) No 966/2012 and Article 19 of Commission Delegated Regulation (EU) No 1268/2012.

so that – in line with the policy objective of the Marie Skłodowska-Curie actions to promote better employment conditions – these researchers have a guaranteed minimum allowance during their mobility experience. For COFUND actions, a co-funding rate of 50% will be applied to the researcher unit cost. Beneficiaries shall be required to pay the fellow at least 70% of the researcher unit cost which shall include both the EU contribution (corresponding to 50% of the researcher unit cost) and the beneficiary's own contribution (corresponding to at least 20% of the researcher unit cost). In fact, the researcher unit costs remain subject to subsequent verification and audit to determine that actual allowances paid to the researchers (and related employers' social security charges) are equal to, or exceed, the unit costs defined in the grant agreement. Experience from FP6/FP7 project management has demonstrated that the occurrence and impact of errors of underpayment of researchers remains fairly low[9]. Moreover, where such underpayments are discovered, beneficiaries have been and shall continue to be required to make additional payments to the researchers concerned (rather than repaying the difference back to the Union budget).

3. Methodology to determine and update the amounts

Calls for proposals before the mid-term review (H2020 Work Programmes 2014-2015 and 2016-2017)

In order to determine the amounts of the researcher and institutional unit costs, reliable historical data of eligible costs were collected from 9 131[10] signed Marie Curie projects financed under FP7 between 2007 and 2013. The unit costs applicable to the Marie Skłodowska-Curie actions under Horizon 2020 are based on the seven-year average of the Marie Curie rates applicable under FP7[11] and the findings of the FP7 Marie Curie actions interim evaluation as well as the MORE2 study[12]:

(a) the average monthly living allowance paid to an experienced researcher[13] receiving an individual fellowship in the Marie Curie individual-driven actions amounts to EUR 4 657. An analysis of all programmes supported by the Marie Curie COFUND action leads to a similar figure for the average monthly living allowance paid to experienced researchers with an employment contract.

(b) The average monthly mobility allowance paid to a researcher receiving an individual fellowship in the Marie Curie individual-driven actions amounts to EUR 586.

(c) The average monthly family allowance paid to a researcher receiving an individual fellowship in the Marie Curie individual-driven actions amounts to EUR 300. According to the MORE2 study, "[w]hen asked for explicit reasons for their non-mobility, researchers rank personal and family reasons as being most important … While this is an important barrier to overcome when embarking upon an international

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9 The available figures show that the residual error rate in financial transactions for the People Programme for the period 2009-2013 is 0.6%, i.e. far below the materiality threshold of 2.0% and not even one fifth of the overall residual error rate of all FP7 Programmes managed by the Research Executive Agency in that period. This confirms the low inherent risk of the People Programme.

10 629 ITN, 3 212 IEF, 797 IOF, 977 IIF, 1 089 CIG, 495 ERG, 958 IRG, 315 IAAP, 527 IRSES and 132 COFUND projects as of 3rd October 2013.

11 The specific requirements of Marie Curie actions under FP7 imply that the rates set out by the Commission for researchers' allowances correspond to at least the actual eligible costs incurred by the beneficiaries.

12 MORE2 – Support for continued data collection and analysis concerning mobility patterns and career paths of researchers: Deliverable 8 – Final report MORE2, August 2013.

13 Experienced researcher (ER) = researcher with a doctoral degree or at least four years of full-time equivalent research experience.

research period, it is an even more important factor which convinces researchers not to travel… [W]omen …see more barriers regarding personal and or family reasons [than men]"[14].

(d) the average monthly flat rate per exchanged staff member in the Marie Curie IRSES action amounts to EUR 1 867 (excluding the additional long-distance allowance). According to the findings of the FP7 Marie Curie actions interim evaluation, "there is a clear demand for higher flat rates in IRSES and additional funding to cover the networking (workshops, seminars, conferences and similar events) costs incurred by the action's beneficiairies"[15].

(e) as evidenced by the FP7 Marie Curie actions interim evaluation, Marie Curie actions "funding allocated to cover research and training costs [for projects selected between 2007 and 2010] is less sufficient than the allocation to cover living and mobility costs"[16]. As a consequence, the Commission decided to raise these monthly unit costs for the years 2011 to 2013 to EUR 1 800 for the ITN and IAPP actions and to EUR 800 for individual-driven actions.

(f) the average monthly Union contribution to management and overhead costs in Marie Curie multi-beneficiary projects[17] amounts to EUR 1 200 which is equivalent to 19.1% of the final costs linked to supported researchers, their training and networking as reported by beneficiaries; according to the findings of the FP7 Marie Curie actions interim evaluation, "the fact that the management budget and overheads are not fixed in advance (but rather depend on total or direct costs of the project) causes additional difficulties for the beneficiary in planning administrative project arrangements"[18].

(g) the average monthly Union contribution to the management of COFUND projects offering employment contracts amounts to EUR 335 (excluding indirect costs such as overheads).

As a consequence, the following unit costs, expressed in person-months and corresponding to the country-specific correction factor of 100% applicable to Belgium and Luxembourg, shall be applicable to the Marie Skłodowska-Curie calls for proposals launched under the Horizon 2020 Work Programmes 2014-2015[19] and 2016-2017[20]:

(1) Costs of researchers/seconded staff members

(a) The monthly living allowance for experienced researchers eligible for an individual fellowship in IF actions shall be fixed at EUR 4 650. According to the MORE2 study[21], the salary of an early-stage researcher (R1) is equivalent to 66.9% of the one earned by an experienced researcher (R2). Consequently, the monthly living allowance for early-stage researchers in ITN actions shall be set at EUR 3 110.

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14 MORE2 – Final report MORE2, August 2013, p. 169 and p. 171.

15 FP7 Marie Curie Actions Interim Evaluation, Final Report, 7.02.2013, p. 123.

16 FP7 Marie Curie Actions Interim Evaluation, Final Report, 7.02.2013, p. 105.

17 Eligible management costs are reimbursed on an actual cost basis under FP7, up to 10% of the EU contribution. Overhead costs are eligible on the basis of a flat-rate of 10% of the eligible direct costs under FP7.

18 FP7 Marie Curie Actions Interim Evaluation, Final Report, 7.02.2013, p. 106.

19 Commission Decision C(2014)4995 of 22 July 2014.

20 Commission Decision C(2016)4614 of 25 July 2016.

21 MORE2 – Remuneration – Cross-Country Report (WP4), April 2013, p. 39-42.

To ensure equal treatment of, and purchasing power parity for, researchers working all over the world, these living allowances are subject to a country-specific correction coefficient. The applicable coefficient is the 7-year average of the respective country-specific coefficient used between 2007 and 2013 for the FP7 Marie Curie actions. This average country-coefficient shall automatically be revised after 4 years based on the average of the 2010-2016 country-specific coefficients to make sure that researchers' purchasing power parity stays comparable irrespective of the country they are conducting their research in.

(b) The monthly mobility allowance shall be fixed at EUR 600.

(c) In order to "ensure effective equal opportunities for the mobility of male and female researchers, including through specific measures to remove barriers"[22], the monthly family allowance shall be fixed at EUR 500.

(d) The monthly top-up allowance for seconded staff members in RISE actions shall be fixed at EUR 2 000.

(e) The researcher unit cost applicable to COFUND actions and subject to a 50% co-funding rate shall be set as the sum of both the living and mobility allowances listed above, i.e. at EUR 3 710 per month for early-stage researchers and EUR 5 250 per month for experienced researchers. This unit cost shall be used exclusively as contribution to the living allowance of the researcher. Other researcher-related cost items (such as the mobility and family allowances) are ineligible under Horizon 2020 and may be funded through other sources including Union programmes other than Horizon 2020.

(2) Institutional unit costs

(a) The unit cost related to the training and research expenses of researchers as well as to the costs related to the transfer of knowledge and networking shall be fixed at EUR 1 800 per month for ITN and RISE actions and at EUR 800 per month for IF actions.

(b) The unit cost related to managing and running a project (management and indirect costs) shall be fixed at EUR 1 200 per month for ITN actions, at EUR 650 per month for IF actions and at EUR 700 per month for RISE actions.

For collaborative projects, this unit cost represents 20% of the costs linked to supported researchers, their training and networking. For mono-beneficiary projects, the unit cost is 10% of the costs linked to supported researchers, their training and networking. This is in line with, and slightly below, FP7 Marie Curie actions statistical data on actual eligible costs reported by beneficiaries.

In case a beneficiary already receives an operating grant financed by the EU or Euratom budget in the same period, indirect costs are ineligible unless the beneficiary can demonstrate that the operating grant does not cover any costs of the action in question. The analysis of FP7 Marie Curie actions statistical data showed that on average the amount of indirect costs was equal to the amount of management costs. Therefore, the unit cost applicable to beneficiaries in receipt

[22] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC, OJ L 347, 20.12.2013, p. 129.

of an operating grant shall be half of the amount determined in the first paragraph of point 3(2)(b) above.

The institutional unit cost applicable to COFUND actions and subject to a 50% co-funding rate shall be set at EUR 650 per month. It covers only the management costs of the programme. Other institutional cost items (such as training and research expenses of researchers, costs related to the transfer of knowledge and networking as well as indirect costs such as overheads) are ineligible under Horizon 2020 and may be funded through other sources including Union programmes other than Horizon 2020.

Marie Skłodowska-Curie Actions pay particular attention to accessibility and inclusion of researchers with disabilities. In order to facilitate and encourage their participation in MSCA actions, the Horizon 2020 Work Programme 2018-2020 introduced a new special needs allowance to provide financial support for the specific costs incurred by recruited or seconded persons whose long-term physical, mental, intellectual or sensory impairments are such that their participation in MSCA actions would not be possible without this additional support.

The special needs allowance for Marie Skłodowska-Curie Actions under Horizon 2020 is implemented through a pilot scheme of dedicated low-value lump sum grants - SNLS. The grants are limited to a maximum of EUR 60 000 per researcher/staff member. Only beneficiaries of MSCA ongoing actions can participate in SNLS calls, because the SNLS grant is conditioned on the participation of the person in an MSCA action. A separate SNLS grant agreement linked to the main MSCA grant is signed for each researcher/staff member.

However, this arrangement has proven to lead to an excessive administrative burden and disproportionate management costs for this additional grant cycle and it has prompted a change of approach under Horizon Europe.

It is therefore appropriate that the Horizon 2020 implementation of the special needs allowance is aligned with the Horizon Europe approach. To this end, the Horizon 2020 lump sum grant methodology should be replaced by a unit cost top-up to the institutional unit cost integrated in the main MSCA action in which the person concerned participates.

As a consequence, in order to further simplify the implementation of the Special Needs Scheme (SNS), to streamline the procedure and to reduce the administrative burden, it is necessary to authorise the use of unit contributions comparable to those outlined in the Decision of 11 March 2021 authorising the use of lump sum contributions and unit contributions for Marie Skłodowska-Curie actions under the Horizon Europe Programme [23]. This change of approach is justified by the fact that the unit cost top-up to the institutional unit cost would be linked to the main MSCA action, and therefore it will apply to the same action and final beneficiaries.

[23] Decision of 11 March 2021 authorising the use of lump sum contributions and unit contributions for Marie Skłodowska-Curie actions under the Horizon Europe Programme

Where the SNS applies, it shall be implemented as a top-up increasing the amount of the unit cost related to managing and running the project, starting from the approval of the request for the allowance until the end of the action duration.

The top-up amount per month shall be calculated as follows:

{{Total amount of authorised SNS allowance for the action}

divided by

{the number of person-months starting from the approval of the request for the SNS allowance until the end of the action duration (*'remaining person-months'*) }}

The total authorised special needs amount for the action is determined based on the needs of each specific case up to a maximum of EUR 60 000 per researcher/staff member.

Marie Skłodowska-Curie action	**Costs of researchers/seconded staff members** **person/month**			**Institutional unit cost** **person/month**	
	Living allowance	**Mobility allowance**	**Family allowance**	**Research, training and networking costs**	**Management and indirect costs**[24]
Innovative Training Networks	EUR 3 110 for early-stage researchers	EUR 600	EUR 500	EUR 1 800	EUR 1 200
Individual Fellowships	EUR 4 650 for experienced researchers	EUR 600	EUR 500	EUR 800	EUR 650
Co-funding of regional, national and international programmes	50% of EUR 3 710 for early-stage researchers 50% of EUR 5 250 experienced researchers	N/A	N/A	N/A	50% of EUR 650 for management costs only
	Top-up allowance			**Research, training and networking costs** (no change)	**Management and indirect costs**[25] (no change)
Research and Innovation Staff Exchange	EUR 2 000 for seconded staff members			EUR 1 800	EUR 700

[24] Where applicable increased by the SNS top up.
[25] Where applicable increased by the SNS top up.

The assessment of the present methodology was developed on the basis of a statistically robust set of data. However, the lack of real cost data in the future urges the Commission to use other similar objective means in order to keep the approved methodology up-to-date. As a method of revision, the Commission shall organise a mid-term review of the adopted unit costs compared to real costs and researchers' salary development in Europe and beyond. This is foreseen to be conducted *inter alia* through a consultancy study including survey among a sample of selected beneficiaries for a given period. The sample should cover each category and should focus, as far as possible, on those that have received their payment of the balance. Beneficiaries should be asked to provide details, certified by a declaration on their honour, of their initial budgets and the final real costs with an assurance that they will not be used for challenging the pre-determined amount of the unit costs. The revision will allow updating the researcher and institutional unit costs. Furthermore and in order to guarantee continuity and stability, the Commission reserves the right to automatically update the above unit costs once the joint index based on national Belgian and Luxembourg inflation[26] deviates from the 2014 baseline inflation index by 10%.

Calls for proposals after the mid-term review (H2020 Work Programmes 2018-2020)[27]

Based on the results of the mid-term review[28], the unit cost for researchers/seconded staff members must be updated as follows (for the calls for proposals launched under the H2020 Work Programme 2018-2020[29]):

Marie Skłodowska-Curie action	**Costs of researchers/seconded staff members** **person/month**			**Institutional unit cost** **person/month**	
	Living allowance	**Mobility allowance** (no change)	**Family allowance** (no change)	**Research, training and networking costs** (no change)	**Management and indirect costs**[30] (no change)
Innovative Training Networks	EUR 3 270 for early-stage researchers	EUR 600	EUR 500	EUR 1 800	EUR 1 200
Individual Fellowships[31]	EUR 4 880 for experienced researchers	EUR 600	EUR 500	EUR 800	EUR 650
Co-funding of regional, national	50% of EUR 3 870 for	N/A	N/A	N/A	50% of EUR 650 for

26 As used for the Method for adjusting salaries and pensions of European Union staff.

27 These unit costs will not lead to additional increase of the budgetary requests for MSCA; the indicative budgets will remain as foreseen in the Work Programme 2018-2020 (subject to adoption/annual budgetary procedures).

28 Mid-term review of Marie Skłodowska-Curie actions unit costs, Final report, February 2017, https://publications.europa.eu/en/publication-detail/-/publication/0f44192e-5499-11e7-a5ca-01aa75ed71a1/language-en/format-PDF/source-31288412.

29 To be adopted in October 2017.

30 Where applicable increased by the SNS top up.

31 By analogy, these unit costs shall apply to the Individual Fellowships implemented under the *Spreading Excellence and Widening Participation* part of H2020 Work Programme 2018-2020.

Marie Skłodowska-Curie action	Costs of researchers/seconded staff members person/month			Institutional unit cost person/month	
and international programmes	early-stage researchers 50% of EUR 5 480 experienced researchers				management costs only
	Top-up allowance			**Research, training and networking costs** (no change)	**Management and indirect costs**[32] (no change)
Research and Innovation Staff Exchange	EUR 2 100 for seconded staff members			EUR 1 800	EUR 700

The mid-term review was made by an external consultancy between May 2016 and January 2017. In order to collect data on real costs, the study conducted a survey consisting of 162 interviews with 83 fellows and 79 coordinators of ongoing projects[33] selected from the 2014 Marie Skłodowska-Curie actions calls. It ensured a broad geographical balance and coverage of all four actions and all cost categories. In parallel, an analysis of trends in researchers' salaries was undertaken and was based on the MORE2 study on mobility patterns and career paths of researchers[34] and internationally comparable data[35].

The final study report recommended to maintain the existing methodology, but to adjust the amounts of the researchers/seconded staff members unit costs (while maintaining the amount of the other unit costs).

For the researchers/seconded staff members unit cost, the survey of fellows and coordinators found that the monthly allowances (living, mobility and family) for both early-stage and experienced researchers are largely competitive in the majority of countries. Other data sources showed however that researchers' salaries have increased over the period 2014-2017 broadly in line with inflation[36]. In order to take account of this change, the study recognised the need to increase the monthly living allowance for both early-stage and experienced researchers by 5%. This was calculated on the basis of Belgian inflation over the years 2014-2017[37]. The updated amounts were rounded to the nearest ten. The same method for updating was recommended to be applied to the monthly top-up allowance for seconded staff members as it aims to cover costs of living associated with secondments.

32 Where applicable increased by the SNS top up.

33 It is important to note that none of the Marie Skłodowska-Curie projects had received their payment of the balance at the time of the study.

34 https://euraxess.ec.europa.eu/content/more2-study-mobility-patterns-and-career-paths-researchers-2013.

35 Mid-term review of Marie Skłodowska-Curie actions unit costs, Final study report, February 2017, p. 12-13.

36 Mid-term review of Marie Skłodowska-Curie actions unit costs, Final study report, February 2017, p. 40, p. 72 and p.74-75.

37 The Belgian inflation rate was used as a proxy as is the case with the Method for adjusting salaries and pensions of European Union staff. Luxembourg was not taken into account as no data were available on researchers' salaries for the period in question.

For the research, training and networking unit costs, the study concluded that they were appropriate, with the majority of coordinators reporting that they were adequate. In general, their level was deemed competitive compared to the budgets available to similar researchers[38]. Furthermore, data showed that coordinators as well as researchers were able to avoid any negative impact on their research by tapping into other sources of funding.

For the other institutional unit costs, the study found that although they did not fully cover the real costs incurred, institutions were able to draw from other funding sources. Thus, there is no evidence that the current level of the unit costs prohibits or discourages institutions from participating in the Marie Skłodowska-Curie actions. This is also supported by the fact that the number of applications continues to grow.

The study also found no clear evidence that the institutional unit costs were higher than actual costs, in particular when considering the intended flexibility in relation to the use of unused amounts for other action-related purposes.

The institutional unit costs therefore seem adequate and do not need to be adjusted.

The Commission will continue to closely monitor the unit costs to ensure that they respect the no-profit, co-financing and absence of double funding principles, remain sufficiently competitive and attractive to excellent researchers and institutions.

Furthermore, in order to guarantee continuity and stability, the Commission reserves the right to automatically update the above unit costs once the joint index based on national Belgian and Luxembourg inflation[39] deviates from the 2017 baseline inflation index by more than 10%.

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by Regulation (EU, Euratom) No 966/2012.

Projects funded in the Marie Skłodowska-Curie actions are not expected to generate revenue or to receive contributions specifically assigned to the eligible costs described in Section 1.

In addition, due to the participants' obligation to incur at least the rates for researcher costs in ITN, IF and RISE actions and to incur at least 70% of the researcher cost in COFUND actions (which is subject to a Union co-funding rate of 50%), the possibility to make profit on researcher costs (due to the use of unit costs of more than 100% of the real costs) is excluded. Furthermore, statistical analyses and simulations have been carried out to ensure that all the unit costs, and notably the institutional ones, would on average be comparable to, but below a possible Commission contribution to incurred real costs, which guarantees that there is no possibility for profit under this cost category.

The emphasis in managing grant agreements/decisions in the application of unit costs is placed on the quality and level of achievement of measurable objectives, and therefore focused on results rather than inputs.

Financing on the basis of unit costs where an analysis of the cost base has been made ex-ante introduces an incentive for the beneficiary to use resources as economically as possible, as the final grant is based on the pre-established rates in function of the nature and implementation of the action, without further adjustments of the grant amount based on actual expenditure. Moreover, applying pre-established rates offers advantages in terms of transparency, predictability and equal treatment of beneficiaries.

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38 Mid-term review of Marie Skłodowska-Curie actions unit costs, Final study report, February 2017, p. 72.

39 As used for the Method for adjusting salaries and pensions of European Union staff.

The rules governing COFUND action foresee an overall maximum amount of co-financing of EUR 10 million per beneficiary and call as well as a maximum Union co-financing rate of 50%. The required level of co-financing (regional, national, international, beneficiaries' own resources, etc.) and the fact that the unit costs cover only part of the total eligible costs ensure that the no-profit rule is properly respected. Detailed guidelines and additional trainings will be provided to the management body staff and selection experts.

Double funding is effectively prevented through controls at the evaluation stage by the REA and the Commission. Marie Skłodowska-Curie actions draw clear division lines between actions and avoid that the same activity can be undertaken in different actions by the same participants. Double funding is also avoided by the specification/identification of eligible costs which are detailed in Section 1.

Electronically signed on 29/06/2023 21:53 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8198 final

COMMISSION DECISION

of 10.12.2013

authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme

COMMISSION DECISION

of 10.12.2013

authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Article 18 thereof,

Having regard to the Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Articles 21 and 24 thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[1] (hereinafter referred to as the 'Financial Regulation'), and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union[2] contains detailed rules regarding lump sums,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be reflected in its design, rules, financial management and implementation,

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of lump sums is necessary to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures,

(4) The use of a lump sum should therefore be authorised for the SME Instrument phase 1 actions,

[1] OJ L 298, 26.10.2012, p. 1.

[2] Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants for reimbursement of eligible costs declared by beneficiaries on the basis of a lump sum is authorised for SME INSTRUMENT Phase 1 actions under the Horizon 2020 Framework Programme, for the reasons and under the conditions set out in the Annex.

Article 2

This Decision is subject to the final adoption of the Regulation of the European Parliament and the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), the Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and the Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) by the legislative authority without significant modifications.

Done at Brussels, 10.12.2013

For the Commission
Máire GEOGHEGAN-QUINN
Member of the Commission

EN

ANNEX

1. Form of grants and categories of costs covered

The dedicated SME INSTRUMENT Phase 1 grants within the Horizon 2020 Framework Programme shall exclusively take the form of reimbursement of eligible costs declared by beneficiaries on the basis of a lump sum.

The Phase 1 grants cover the costs of the "feasibility study: business innovation plan" which can be the basis for applying for funding under Phase 2 of the dedicated SME instrument.

The eligible costs to be declared under the lump sum for Phase 1 are the eligible direct and indirect costs of the development of a feasibility study, which can relate to both in-house work and external advice such as IPR assessment, legal matters, technological analysis, business advice, market studies, etc.

Costs for the feasibility study declared as a lump sum shall be **eligible** if they correspond to the lump sum set out in the estimated budget for the action (Annex 2 of the grant agreement) and if the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1 of the grant agreement.

Therefore, the categories of eligible costs to be declared on the basis of the lump sum are all the eligible costs of the Phase 1 activities (feasibility study: business innovation plan), i.e.:

- Costs of personnel directly assigned to the feasibility study;
- Travel costs and related subsistence allowances necessary for the feasibility study;
- Costs of subcontracting necessary for the feasibility study;
- Depreciation costs for equipment directly used for the feasibility study;
- Costs of other goods and services directly used for the feasibility study;
- Indirect costs.

The amount of the lump sum shall be calculated in accordance with the methodology set out in Section 3 and is set out in Section 3.

2. Justification

2.1 Appropriateness of lump sum costs with regard to the nature of the dedicated SME instrument phase 1 actions

The dedicated SME instrument addresses the needs of internationally oriented SMEs by providing funding for early stage high-risk research and innovation with a clear European added value, thereby stimulating innovations, including eco-innovations and social innovations, and increasing private sector commercialisation for research results.

It will provide funding in three phases:

- Phase 1 funding for a "Concept and feasibility assessment" to explore the scientific and technical feasibility and the commercial potential of a new idea (proof of concept) in order to develop an innovation project. A positive outcome of this assessment will allow for funding under the following phase(s).
- Phase 2 "R&D, demonstration, market replication", will support research and development with a particular focus on demonstration activities (testing, prototype, scale-up studies, design, piloting innovative processes, products and services, performance verification etc.) and market replication.
- Phase 3 "Commercialisation" will not provide direct funding other than support activities, but aims to facilitate access to private capital and innovation enabling environments.

The dedicated SME instrument responds to the demand for a funding mechanism that is better aligned to the strategic needs of innovative SMEs.

The objective is to provide a SME-friendly instrument that is characterised by a very short time-to-grant corresponding to the short innovation cycles in companies and provides for a simplified and resource-efficient management, in particular for Phase 1 of the SME instrument corresponding to the smaller risks/funding involved.

The outcome of Phase 1 will be a business innovation plan including an innovation strategy based on the feasibility study.
A standard approach for the eligibility of costs on the basis of a fixed lump sum is chosen based on the following assumptions:

(1) SMEs usually do not have all necessary abilities and knowledge in-house to address the different parts of a feasibility study for an innovation action (i.e. IPR assessment, market study, etc.), but they innovate in cooperation with others. Depending on the size of the company, sector or other variables, the in-house competences and capacities as well as the scope and type of external advice and help needed may vary. It may come from different sources and on different matters (IPR, legal matters, technological, business advice, market studies, etc). The standard approach ensures minimum burden for beneficiaries and a flexible way to meet their needs to implement the project.

(2) The SME instrument covers different areas of science and knowledge and encourages cross-fertilisation. It also encompasses a broad geographical area where prices/costs are different. It is necessary to follow a standard approach:

- to simplify the implementation,
- to encourage cross-border collaboration among SMEs and with other innovators, and
- to facilitate the relations with other companies, experts or external advice from different areas of knowledge or sectors

As a conclusion, due to the standardisation of the project type and project result and the need to speed up project management, it is appropriate to estimate "ex ante" the standard project cost and to use a lump sum cost for phase 1 of the SME instrument. It is a simplification measure that will facilitate support to SMEs and attract innovative SMEs to participate, in particular those that have not participated before.

2.2 The risks of irregularities and fraud and costs of control

The risk of fraud and cost of controls of the triggering event for the eligible lump sum cost are minimal, since the proper implementation of the action is easy to verify.
In addition, through the award process independent experts assess the feasibility study and validate that the envisaged output corresponds to the value of the grant.

Conversely, the costs of control of the actual eligible costs of the feasibility study activities are high (many personnel-intensive tasks are involved). Controlling the actual eligible costs would not be cost-effective in view of the amount of the grant (€50,000, see below), which constitutes a rather low financial risk.

Pre financing will not exceed 50% of the total amount of the grant, of which EUR 2 500 are retained as contribution to the Guarantee Fund. The maximum financial risk of the EU is therefore up to EUR 25 000 per grant for the cases where the output is not delivered or where the delivered output does not achieve the minimum quality or content required.

3. Method to determine the amount of the lump sum

The support in Phase 1 shall be provided in the form of reimbursement of eligible costs declared on the basis of a lump sum. According to Article 124(2) of Regulation (EC, Euratom) No 966/2012, the method chosen to determine the lump sum may be based on "statistical data or similar objective means".
The average eligible costs of producing the "feasibility study: business innovation plan " have been objectively estimated. Due to the different thematic areas of implementation of the SME instrument, Commission services have estimated standard costs, which cover the general expenses of the development of a feasibility study.

3.1. Calculation of standard costs

The estimation of the eligible costs is done assuming that one or two experts (full time equivalents) are needed for 6 months (corresponding to 120 or 240 necessary working days) for the purpose of delivering the feasibility study funded under Phase 1 (see also Point 3.2(a)). The implementation of phase 1 shall not modify the cost structure or the payroll of the SME. Some of the activities will be subcontracted; some others will be implemented by the SME in-house.

The standard approach implies to use as a baseline for calculating the honorarium set for independent experts, a rate of EUR 450/day, as specified in the appointment letter to experts. This approach is independent of the country or region or the field of expertise.

According to this calculation the overall eligible costs of experts for the output of Phase 1 vary between EUR 54 000 and EUR 108 000. This amount reflects the total eligible costs of the development of a feasibility study.

3.2. Comparative analysis of the financing arrangements under existing similar schemes

The comparative analysis is based on the following similar schemes:

- United Kingdom SBRI (hereinafter, UK SBRI) phase 1 "proposals concentrate on proving the scientific, technical and commercial feasibility of the proposed project."[1]
- Netherlands SBIR (hereinafter, NL SBIR) phase 1: Phase 1 is a feasibility study[2]
- United States SBIR: Phase I is the start-up phase. "Approximately 6 months support exploration of the technical merit or feasibility of an idea or technology"[3]
- Sweden, Research and Growth programme grants a feasibility study[4]

a) Time to deliver (duration of the action)

On the basis of the experience of similar schemes, the time to produce a feasibility study for Phase 1 of the SME instrument is estimated at 6 months.
Similar schemes:

- UK SBRI, the time to develop a feasibility study in this phase is 6 months[5]
- NL SBIR stipulates 6 months for the feasibility study[6]
- US SBIR, the time to develop its phase 1 is up to 6 months[7]
- Sweden, Research and Growth programme; the time to develop the feasibility study is from 3 to 6 months[8].

[1]Technology Strategy Board. SBRI. United Kingdom. https://www.innovateuk.org/documents/1524978/1814018/SBRI+brochure/57cd28aa-2676-4acb-afa6-37d13eaa9b2e

[2]ERAWATCH. Netherlands. http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/nl/supportmeasure/support_mig_0005

[3]U.S. Small Business Administration. http://www.sba.gov/content/small-business-innovation-research-program-sbir http://www.sba.gov/content/small-business-innovation-research-program-sbir

[4]ERAWATCH. Sweden. http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/se/supportmeasure/support_mig_0007

[5] Technology Strategy Board. SBRI. United Kingdom. https://www.innovateuk.org/documents/1524978/1814018/SBRI+brochure/57cd28aa-2676-4acb-afa6-37d13eaa9b2e

[6] ERAWATCH. Netherlands. http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/nl/supportmeasure/support_mig_0005

[7] U.S. Small Business Administration http://www.sbir.gov/applicants; http://www2.ed.gov/programs/sbir/index.html

b) Financial contributions awarded

- UK SBRI, the amount for phase 1 is up to EUR 118 000 (GBP 100 000).
- NL SBIR, the amount for phase 1 is EUR 50 000
- US SBIR, the amount for phase 1 is approximately EUR 110 000 (USD 150 000)
- Sweden, Research and Growth; the amount for the feasibility study is up to EUR 46 000

The above estimations contain provision for direct and indirect costs.

3.3. Amount of the lump sum

Taking into consideration the average of the standard eligible costs estimated in Point 3.2 (b), the cost of the development of a feasibility study is at least EUR 70 000.

In order to avoid the risk of fraud and to protect the financial interest of the Union, the eligible costs of the development of the feasibility study shall remain in the low range of the estimated amount and, below the average of similar funding schemes, i.e. around EUR 70 000. Applying the usual co-financing rate of the 70 %,% to the lump sum considered as appropriately reflecting the underlying eligible costs (EUR 70 000), the amount of the grant is EUR 49 000.

For the sake of simplification, the amount of the lump sum to be declared as eligible costs is fixed at EUR 71 429, leading to an amount of the grant of EUR 50 000 (for mono- and multi-beneficiary grants).

The amount of EUR 71 429 shall apply for the full duration of Horizon 2020, unless it does not prove appropriate anymore. In such a case, it will be adjusted by a new Commission decision.

4. No-profit and co-financing principles and absence of double financing

The following elements limit the risk of profit:

- The use of the low range for the assessment of standard costs;
- The application of the standard 70% reimbursement rate;
- The absence of revenue generated from the Phase 1 action.

It may in addition be noted that Article 125(4) of the Financial Regulation exempts low value grants (grants lower than or equal to EUR 60 000) from the no-profit principle.

[8] ERAWATCH. Sweden http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/se/supportmeasure/support_mig_0007

The co-financing principle is complied with by application of the reimbursement rate to the eligible costs declared as a lump sum.

The grant takes exclusively the form of reimbursement of costs declared as eligible on the basis of the lump sum, which renders void the risk of double financing due to the declaration of the same costs as eligible under different budget categories. In addition, the specificity of the activities funded under the SME Instrument Phase 1 limits the risks that other Union-funded grants are awarded for the same action.

Finally, the proposal for Phase 1 containing the information concerning the envisaged feasibility study is evaluated with the help of independent experts, who will assess the quality and validate that the expected output corresponds to the value of the grant. This means all projects will also be scrutinised by 'expert opinion', which relies on subject matter experts to assess the quality of the feasibility study. Expert opinion is a recognised methodology for cost estimation[9]. The expert opinion as a cost estimation method, also known as engineering judgment, is widely used in matters of scientific technology. The use of expert opinion is as accurate as other methods[10].

[9] GAO-07-1134SP Cost Assessment Guide: Best Practices for Estimating and Managing Program Costs. United States Government Accountability Office. July 2007.

[10] Expert judgement in cost estimating: Modelling the reasoning process. Christopher Rush & Rajkumar Roy. Department of Enterprise Integration. School of Industrial Manufacturing and Science. Cranfield University. UK. *Concurrent Engineering December 2001 vol. 9 no. 4 271-284*

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8200 final

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for ERA-NET Cofund actions under the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Article 20(2) thereof,

Having regard to the Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Articles 21 and 27 thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union [1], and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union contains detailed rules regarding unit costs.

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be reflected in its design, rules, financial management and implementation.

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of unit costs is necessary to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures.

(4) The use of a unit cost should therefore be authorised for direct coordination costs of additional activities in ERA-NET Cofund actions.

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants for reimbursement of eligible costs declared by beneficiaries on the basis of unit costs is authorised for the ERA-NET Cofund actions under the Horizon 2020 Framework Programme, for the reasons and under the conditions set out in the Annex.

[1] OJ L 298, 26.10.2012, p. 1.

Article 2

This Decision is subject to the final adoption of the Regulation of the European Parliament and the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), the Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and the Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) by the legislative authority without significant modifications.

Done at Brussels, 10.12.2013

For the Commission
Máire GEOGHEGAN-QUINN
Member of the Commission

ANNEX

1. Forms of grants and categories of costs covered

The grants for the ERA-NET Cofund actions under the Horizon 2020 Framework Programme shall take the form of reimbursement of eligible costs declared by beneficiaries on the basis of unit costs for the coordination of their additional activities. Additional activities are joint activities other than those related to the co-funded joint call.

As set out in the work programme and model grant agreement for the ERA-NET Cofund actions, coordination costs for additional activities carried out by beneficiaries that implement transnational projects (partially or fully) themselves are not eligible.

The categories of eligible costs covered by the unit costs are the direct eligible coordination costs of the additional activities, i.e.:

- Personnel costs of staff directly assigned to the coordination of the additional activities;
- Travel costs and related subsistence allowances necessary for the coordination of the additional activities;
- Costs of subcontracting for the coordination of additional activities;
- Depreciation costs for equipment directly used for the coordination of additional activities;
- Costs of goods and services directly used for the coordination of additional activities.

As set out in the work programme and model grant agreement for the ERA-NET Cofund actions, the costs of coordination of the co-funded joint call (activities related to the preparation, implementation and follow-up of the co-funded call) are not eligible.

Other categories of eligible costs (i.e. costs of financial support to third parties implementing trans-national projects and costs for the implementation of trans-national projects by the beneficiaries) shall be reimbursed on the basis of eligible costs actually incurred or, for indirect costs (including indirect costs of coordination of additional activities), on the basis of flat-rate financing.

The amount of the unit costs to be declared by the beneficiaries shall be calculated in accordance with the method set out in Section 3.

2. Justification

2.1. Nature of the supported actions

ERA-NET Cofund under Horizon 2020 is based on the merger of the former ERA-NET actions (Union support to coordination and management costs) and ERA-NET Plus actions

(Union support to the funding of transnational projects) and is implemented by using 'programme co-fund actions'. It is designed to support public-public-partnerships in their preparation, establishment of networking structures, design, implementation and coordination of joint activities as well as Union topping-up of a trans-national call for proposals. It allows for programme collaboration in any part of the entire research-innovation cycle.

The main and compulsory activity of the ERA-NET Cofund under Horizon 2020 is the implementation of a single co-funded joint call for proposals that leads to the funding of trans-national research and innovation projects. The call is normally based on a call for proposals resulting in grants (financial support) to third parties, but may also cover calls for proposals of governmental research organisations carrying out trans-national projects partially or fully themselves. The Union contribution to the costs for support to trans-national projects is limited to support awarded following one call per grant agreement. The costs for activities related to the preparation, implementation and follow-up of the co-funded call are not eligible.

In addition to the co-funded call, the consortia may implement other joint activities. The activities supported by the grant based on unit costs under this decision must be related to the coordination of public research and innovation programmes and should focus on the preparation and implementation of joint activities including other joint calls without Union co-funding. Those additional activities are similar to the activities which have been carried out in the ERA-NETs under FP6 and FP7 (i.e. activities which were not supported by Union co-funding of calls).

2.2. Risks of irregularities and fraud and costs of control

The progress reports provided by the beneficiaries in ERA-NET actions will include information on the contribution from each beneficiary to the additional activities. The actual implementation of those additional activities is easy to verify. The risk of irregularities or fraud is thus very low. In case of doubt, the coordinator and the Commission may request supporting documents substantiating their implementation.

Conversely, the costs of control of the actual eligible costs of coordination of the additional activities are high (many personnel-intensive tasks are involved).

Therefore, since the amount per beneficiary per year is limited, the reimbursement of eligible coordination costs on the basis of unit costs ensures a low risk of irregularity or fraud while keeping in line with the objective of simplification (less reporting obligations) and cost-effectiveness of controls.

3. Method to determine the amounts

The unit cost to be applied under Horizon 2020 is determined by reference to statistical data (historical data reported by beneficiaries under FP6), i.e. the cost statements for final reporting of a representative sample (around 30%) of the 71 ERA-NET projects under FP6.

Under FP6, the participants could submit proposals with a cost distribution and overall costs according to the needs of the consortium. Under FP7, the maximum Union contribution per ERA-NET was pre-defined in the work programme (between EUR 1 and 3 million), which had a strong influence on the amount and distribution of coordination costs. In addition, since most FP7 ERA-NET grant agreements are not closed yet (no final payment), the sample from

FP7 would be very small. Therefore, in order to make a reference to unbiased data, only projects under FP6 have been taken into account.

The amount of the unit cost is based on the coordination costs declared (and approved for the final payment) in the financial management reports per beneficiary and per year. Under FP6 (and FP7) the Union contribution was limited to the reimbursement of actual direct costs and a flat rate of 7% applied to them for indirect costs. The flat rate for indirect costs covered only part of the actual indirect costs of the beneficiaries.

For the calculation of the unit costs, the 7% indirect costs included in the Union contribution were deducted in order to determine the Union contribution to actual direct costs. The extreme amounts, i.e. the lowest and highest 10%, were excluded from the sample.

The result for the average amount of actual direct costs for coordination is EUR 29 783.

Since these direct costs include costs for subcontracting of around 4.5% for the sample used, this amount has been adjusted to compensate for these subcontracting costs.

The unit cost for eligible direct coordination costs of additional activities per beneficiary per year is therefore fixed at EUR 29 000, to which the flat rate of 25% for indirect costs under Horizon 2020 is to be applied.

The amount to be reimbursed (per beneficiary per year) is determined by applying the reimbursement rate applicable to ERA-NET actions (normally 33%) to the unit cost. As a consequence, the maximum reimbursement of direct and indirect costs of coordination of additional activities per beneficiary per year will be EUR 11 962,50.

The horizontal Annex to the Horizon 2020 work programme also specifies that the Union contribution to coordination costs for additional activities through the reimbursement of unit costs should not exceed 20% of the total Union contribution to the action.

The amount of EUR 29 000 per beneficiary per year shall apply for the full duration of Horizon 2020, unless it does not prove appropriate anymore. In such a case, it will be adjusted by a new Commission decision.

4. No-profit and co-financing principles and absence of double financing

As explained above, the reimbursement of direct coordination costs on the basis of the unit costs only corresponds to a fraction of what was paid to participants in the past, since the reimbursement rate is reduced from 100% to 33%. The method for calculation thus ensures that there can be no risk of participants getting a profit out of the payment of coordination costs for additional activities.

As regards the receipts generated by an action, the obligation to deduct the receipts from statistical (historical) data does not apply here as there is no receipt in ERA-NET actions.

As provided for in the ERA-NET model grant agreement, only the following categories of costs are eligible for co-funding from the Union:

- Costs of coordination of additional activities;
- Costs related to the trans-national projects. Where those costs are the costs of financial support to third parties, the costs of the trans-national projects are clearly and easily separated from the coordination costs. This ensures that no costs related to the trans-national projects can be charged under coordination costs.

This separation is more difficult to ensure where the costs are incurred by beneficiaries carrying out the trans-national projects themselves. Therefore, in order to avoid double financing, this decision and the ERA-NET Cofund model grant agreement specify that beneficiaries carrying out the trans-national project themselves may not declare eligible coordination costs under any form (including no eligible coordination cost on the basis of unit costs).

EN

EURATOM

WORK PROGRAMME 2014 – 2015

Revised

(European Commission C(2014)5009 of 22 July 2014)

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Introduction

The Euratom Research and Training Programme (2014-18)[1] complements the Horizon 2020[2] in the field of nuclear research and training. Its general objective is to pursue nuclear research and training activities with an emphasis on continually improving nuclear safety and radiation protection, notably to contribute to the long-term decarbonisation of the energy system in a safe, efficient and secure way. By contributing to these objectives, the Euratom Programme shall reinforce outcomes under the three priorities of the Horizon 2020: excellent science, industrial leadership, and societal challenges.

The indirect actions of the Euratom Programme are focused on two areas: nuclear fission and radiation protection, and fusion research aiming to developing magnetic confinement fusion as an energy source.

As requested by the Council in June 2011, Euratom activities in the area of nuclear fission and radiation protection have been thoroughly reviewed, in the context of the post-Fukushima era. In 2012, DG Research and Innovation (RTD), commissioned[3] the Interdisciplinary Study "Benefits and Limitations of Nuclear Fission for a Low Carbon Economy"[4], which was presented at the 2013 Symposium of the same title co-organised by the European Commission (EC) and the European Economic and Social Committee (EESC). The Council was informed in June 2013 on the conclusions and recommendations made by the high level experts and various stakeholders involved in this Study. These conclusions and recommendations, which notably point out the need for a further focusing on nuclear safety and improved interaction with civil society, constitute the backbone of the research direction proposed in this work programme for fission and radiation protection.

Euratom has been at the centre of the European fusion research effort since the very start of the endeavour to develop magnetic confinement fusion as an energy source. The Euratom Framework Programmes in the fusion domain have ensured that research in fusion science and technology carried out in national fusion laboratories across Europe, also involving collaborative activities with third countries, is coordinated and largely integrated. Instruments such as Contracts of Association (under Art. 10 of the Euratom Treaty) have provided Community support to all Member States and Switzerland as fully associated third country to develop a solid basis in fusion science. More recently, the European Fusion Development Agreement (EFDA) has, through a range of instruments, added a multilateral dimension to fusion research activities, in particular regarding the exploitation of JET, as well as providing a common focus for cooperation with our international partners. However, the current instruments all expire at the end of 2013, and while recognising the achievements to date, it is clear that the challenges ahead require a new programme structure promoting enhanced

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1 Council Regulation on the Research and Training Programme of the European Atomic Energy Community (2014-2018)

2 Council and EP regulation on Horizon 2020

3 In cooperation with Directorates General Joint Research Centre (JRC), Energy (ENER), Development and Cooperation (DEVCO) and Education and Culture (EAC) for defining the terms of reference and guidance to experts.

4 http://www.eesc.europa.eu/?i=portal.en.events-and-activities-symposium-on-nuclear-fission-forum

integration across Europe in order to ensure the success of ITER and electricity generation from a 'DEMO' device around the middle of the XXI Century. The basis for this effort is the Fusion roadmap ('Fusion Electricity – A roadmap to the realisation of fusion energy'[5]), endorsed by the EFDA members in autumn 2012. The principal aim of the present work programme in this respect is to provide Community support to the joint programme of activities implemented by the national fusion laboratories in line with the Fusion roadmap over the period 2014-2018[6]. International cooperation remains a crucial part of these activities and will continue to be implemented under the various multilateral frameworks (OECD/IEA, IAEA, etc.), as well as through the bilateral Euratom cooperation agreements with third countries that, under the provisions of the Euratom Treaty, cover all international collaborative activities between EU entities and the third countries in question. Fusion research in Europe is the best example Europe can offer of a unified research programme, and it is imperative to retain this unity in the new approach.

[5] http://www.efda.org/2013/01/bringing-fusion-electricity-to-the-grid/

[6] The present Work Programme is considered as a 5-year programme in respect of the actions proposed in Section B.1 – Fusion Joint Programme and Section B.5 - Contract for the operation of JET, for which it constitutes the financing decision.

SECTION A: CALL FOR PROPOSALS *(H2020-NFRP-2014/2015)*

Activities concerning the nuclear fission and radiation protection presented in this Work Programme are in line with the Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community Framework for the Nuclear Safety of Nuclear Installations and with the Commission Proposal of 13 June 2013 for a revised Directive (COM(2013) 343), the Council Directive (2011/70/Euratom) of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste[7], and the Commission Proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (COM(2012) 242 final).

The activities funded by this Work Programme have been developed in accordance with the Council Regulation on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020. They are organised in five main sections:

A. Support safe operation of nuclear systems
B. Contribute to the development of solutions for the management of ultimate radioactive waste
C. Foster Radiation Protection
D. Cross-cutting aspects for nuclear fission and radiation protection
E. Support the development of nuclear competences at Union level and socio-economic aspects.

It should be noted that socio-economic issues are also addressed within each of the first four sections, as well as trans-national access to research infrastructures, where appropriate.

International cooperation with third countries is promoted through bilateral Euratom cooperation agreements, but also multilateral initiatives such as those established by the United Nations (UN) or the Organisation for Economic Co-operation and Development (OECD). Reference to international cooperation is specifically mentioned in each of the work programme sections, where considered more particularly pertinent, but this is not restrictive. The detailed provisions are available at Horizon 2020 web page[8]. Dissemination of activities in this work programme through scientific publications will be encouraged.

[7] OJ L199/48, 2.8.2011

[8] http://ec.europa.eu/research/horizon2020/index_en.cfm

Proposals are invited against the following topics:

A - Support Safe Operation of Nuclear Systems

NFRP 1 – 2014: Improved safety design and operation of fission reactors

Specific challenge: The European Union (EU) has a strong leadership in reactor design and operation responding to stringent safety requirements from regulators and seeks to foster convergence of nuclear safety approaches. The EU is also at the forefront of the development of innovative reactor designs with even higher safety characteristics. Today's major research challenge is evidently to reinforce research cooperation on reactor safety at EU level and worldwide.

Scope: At EU level, this reinforced cooperation will, first of all, involve Members States' national research programmes while also taking into account the priorities of the strategic research and innovation agenda of SNETP[9] and NUGENIA[10]. The Euratom funding will be devoted to supporting the continuous improvement of nuclear safety of the existing reactor fleet and to optimising the safety characteristics in the design of future reactors, e.g. by implementation of passive safety features and by increasing the redundancy and diversity or by performing experimental tests and developing advanced simulation tools. The focus will be on actions increasing the knowledge basis on reactor life-time management issues relevant to safety (e.g. integrity of structural components, containment, irradiation and corrosion issues, …), as well as on those promoting safety culture and providing guidance for severe accident management (especially on issues arising after the Fukushima accident e.g. safety of fuel storage, hydrogen explosion, containment behaviour, corium/debris coolability and interactions, …). The Euratom funding will be dedicated to topics where national programme priorities converge and where European added value is obvious and maximised. International cooperation activities would be beneficial in this area and will be considered during evaluation.

Expected impact: In the short term, this action will provide the knowledge basis for developing robust national and EU policies in the field of nuclear reactor safety, while also helping interacting with stakeholders and civil society on nuclear reactor safety. In the medium term this research will further improve the safety of nuclear reactors in Europe and worldwide through increased resistance of safety relevant equipment and better safety culture. It will also reinforce the EU strong leadership in reactor design and operation responding to stringent safety requirements from regulators and seek to foster European cooperation on nuclear safety approaches. In so doing, the EU will remain at the forefront of the development of innovative reactor designs with even higher safety characteristics.

Type of action: Research and innovation actions.

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[9] Sustainable Nuclear Energy Technology Platform
[10] Nuclear Generation II and III Association

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 3 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 2 – 2014: Tool for the fast and reliable prediction of severe accident progression and anticipation of the source term of a nuclear accident

Specific Challenge: The fast and reliable prediction of severe accident progression and the anticipation of the source term in case of severe accident is of paramount importance for the protection of people in triggering the appropriate response to a nuclear emergency. The need to improve the tools for predicting the plant status and the source term has been identified as a priority following the Fukushima accident as it gives input to accident management strategies and for dose projection caused by atmospheric releases.

Scope: For use in emergency operation centres, this tool should be adapted to all types of reactors in operation or foreseeable in the EU. Furthermore, this tool should be able to predict the different possible accidental scenarios and provide results in a fast and user-friendly way. Such tool should start with minimal input data from nuclear power plants but be able to incorporate additional refinement as more information becomes available in order to improve predictions. It should also rely on state of the art knowledge on severe accident phenomenology and mitigation measures in order to give results with enough accuracy, confidence and reduced uncertainties. International cooperation with notably Japan, the United States of America, Ukraine and the Russian Federation would be beneficial in this area and will be considered during evaluation.

Expected impact: This research will first of all lead to reinforcing nuclear safety through improved accident management procedures that will ensure a faster and site specific response to nuclear emergencies. The tool to be developed is also to be used for the further assessment of existing severe accident management guidelines. It will improve the availability and reliability of dose projection caused by atmospheric releases following a nuclear accident and respond to the need identified as a priority following the Fukushima accident. In the long term, it is also expected that this research will lead to a further exchange of approaches in this domain at EU level and to the reinforcing of EU leadership in reactor safety technology and nuclear emergency management.

Type of action: Research and innovation actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 2 and 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 3 – 2014: New innovative approaches to reactor safety

Specific challenge: Some very innovative reactor safety concepts are investigated, which could become breakthrough options if their scientific and practical maturity is demonstrated. The Euratom research, with its focus on safety and reliability and optimal waste management, should also consider such possible breakthrough options.

Scope: The aim will be to allow promising designs to move from the Technology Readiness Level (TRL) 1 to TRL 3, or from TRL 2 to TRL 3 as defined in Annex to this work programme. Focus will be on the proof of concept regarding safety (e.g. passive safety systems and new approaches to severe accidents management), reliability and quality assurance (e.g. industrial standards). Advanced experimental and numerical simulation tools to evaluate the viability and performance should support this research. It should be undertaken in close cooperation with industry and regulators whose involvement is indispensable at an early stage of design. International cooperation could be beneficial in this area.

Expected impact: This action will offer top-level scientists a level playing field for highly innovative ideas enabling them to demonstrate the feasibility of advanced safety concepts. It will open-up new avenues towards reactor safety design. In the medium / long term, this action should lead to new orientation and breakthrough in nuclear safety.

Type of action: Research and innovation actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 2 and 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

B - Contribute to the Development of Solutions for the Management of Ultimate Radioactive Waste

NFRP 4 – 2014: EU concerted development of Member State research on radioactive waste management

Specific Challenge: The Radioactive Waste Management Directive (2011/70/Euratom), which was adopted in 2011, requires each Member State to *inter alia* carry out research activities. Member States' research in this field is aligned with national timeframes to implementing technical solutions for geological disposal facilities. The immediate challenge is to address uncertainties about the safety of such facilities, to build a sound safety case, special attention being paid to stakeholders' concerns regarding all ultimate radioactive waste materials to be disposed of. It is also necessary to maintain scientific competence to demonstrate the safe operation of facilities. Taking into account the scope of IGDTP, this action should exploit synergies between industry, implementers, Technical Safety Organisations (TSO), policy makers and the research community.

Scope: The aim is to develop synergies and increase coordination of national research programmes in the field of management of spent fuel and radioactive waste. This action includes the reviewing of all strategic aspects linked to a stepwise move to joint programming in this field. For this purpose, it should seek to involve as many entities as possible that are active in the management and disposal of radioactive waste, notably most relevant public or industry-funded research programmes, industry, implementers, TSO and policy makers while not confusing their respective roles.

Expected impact: This action will lead to the further integration of the concerned research community and hence help maintaining and developing EU leadership in knowledge and expertise for innovative and publicly acceptable radioactive waste management solutions. Moreover, it will further reinforce and make more effective the interaction at EU level between industry, implementers, TSO, policy makers and the research community, which is of particular importance for the implementing of solutions for the final disposal of radioactive waste.

Type of action: Coordination and Support Actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 0,7 and 1.5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 5 – 2015: Supporting the licensing of geological repositories

Specific challenge: Interaction between regulatory authorities, their TSO and national radioactive waste management organisations is essential in the context of the licensing process of underground repositories. These interactions are aimed at developing a common understanding on reviews of license applications. They also are aimed at identifying and developing the necessary scientific competence for actors in this field to fulfil their respective roles.

Scope: While recognising independence and distinct responsibilities of the various actors above mentioned, their interactions should be further deepened for the identification of research priorities. This action would include exchange on criteria and guidance on the review of licence application and the interpretation of standards. Due account should be taken of existing and planned initiatives at international level. Outreach activities of main findings should also be part of the activity.

Expected impact: This action will lead to exchange of regulatory review methods and competence in regulatory functions, thereby easing and accelerating the licensing process. This work will also help consolidating the knowledge base and stimulate its sharing amongst all stakeholders including the public at large, which is central to the implementing of solutions for the long-term safety of geological repositories.

Type of action: Coordination and Support Actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 0,8 and 1,2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 6 – 2014: Supporting the implementation of the first-of-the-kind geological repositories

Specific challenge: Substantial progress has been made over the last decades in RD&D for the management and disposal of radioactive waste in Europe. The EU has established a world-wide leading position in the field. By 2015, three Member States (Finland, Sweden, possibly also France) should have submitted an application for authorisation to build and operate an underground repository, in particular for high level and long-lived radioactive waste and spent fuel. In view of the operation of these facilities planned by 2025, it is essential to address the remaining key technical and scientific issues of common interest. In particular, research should improve the knowledge base for the safety case including the development of monitoring strategies, also taking into account stakeholder's concerns.

Scope: Priority topics of IGD-TP[11] should be considered as well as those of public waste management oriented research programmes. EU funding will be dedicated to topics where national programme priorities converge and where European added value is obvious and maximised. The joint implementation of this research at pan-European level would help develop and maintain the necessary competences. The involvement of non-technical stakeholders and socio-economic experts is required notably in view of extensive communication with and dissemination towards the public and all stakeholders. Interaction with non-EU organisations active in the field could be beneficial.

Expected impact: This research and development work shall contribute to resolve the key remaining technical issues for the actual implementation of the planned geological disposal projects in the EU. Hence it will demonstrate the EU leadership in this domain. The involvement of countries with programmes in their initial state alongside the three most advanced ones should stimulate and foster the cooperation amongst EU Member States at large and facilitate steps towards decision making and implementation of underground repositories, in particular for high level and long-lived radioactive waste and spent fuel in more Member States.

Type of action: Research and innovation actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 3 and 6 million would allow this specific challenge to be

[11] Implementing Geological Disposal Technology Platform

addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

C - Foster Radiation Protection

NFRP 7 – 2015: Integrating radiation research in the European Union

Specific Challenge: Radiation protection aims at protecting people and the environment from the potentially harmful effects of ionising radiation. It is of particular interest in the context of the rehabilitation of contaminated territories following an accident, as well as the protection of people and the environment during normal operation. The deep understanding of the effects of ionising radiations is also necessary for drawing maximum benefits from the adequate use of these in medical and industrial applications. Contrary to high dose, the risks from low dose of radiation, including its interaction with other risk factors, are poorly understood. A reinforced multidisciplinary approach to research and innovation is considered as essential to further develop the knowledge base in this field. This approach should encompass a number of basic scientific disciplines besides the specific disciplines pertaining to radiation protection so far, such as emergency preparedness, radioecology or the medical use of ionising radiation. It will require cooperation of the entire European research community concerned with a view to exploit to the best extend the synergistic aspects amongst these different disciplines.

Scope: This activity will build on the Strategic Research Agendas of MELODI[12], NERIS[13] and ALLIANCE[14], while also making use of other existing expertise in Europe, notably regarding dosimetry (EURADOS[15]) and the medical use of ionising radiation. EU funding will specifically be devoted to supporting the further integration, at EU level, of radiation protection research, with due attention to the interaction and synergies to be established between the various areas of expertise, in particular biology, biophysics, epidemiology, dosimetry and modelling. These disciplines are pivotal for research on medical exposures and the optimisation of the use of, and protection from ionising radiation in this field. Attention should also be paid to the development of advanced knowledge on the biology and bio-kinetics of medical radioisotopes and to the understanding of the effects of naturally occurring radiation (and the optimisation of the protection thereof), which also contribute to radiation protection basic science. This activity will also address the improvement of knowledge on the effects of ionising radiation on living beings (radioecology) both during the normal operation of nuclear installations and after an accident, which would be needed to further develop mutually compatible European tools and innovative approaches on nuclear emergency management and

[12] Multidisciplinary European Low Dose Initiative
[13] European Platform on preparedness for nuclear and radiological emergency response and recovery, http://www.eu-neris.net/
[14] European Radioecology Alliance http://www.er-alliance.org/about-us/alliance-activities/
[15] European Radiation Dosimetry Group, http://www.eurados.org/

environmental remediation. Due attention will be paid to research and innovation necessary for supporting the successful transposition and implementation of the revised European Basic Safety Standards[16], which will require changes in national regulations and practices that should be done in a co-ordinated manner in order to optimise protection and avoid duplication. Euratom funding should benefit all European institutes involved in the research on radiation protection related issues. Finally, this activity will also aim at accelerating and improving the developing of competences in radiation protection with a special focus on radiation protection culture and at addressing the challenge of communicating results in radiation protection to non-specialist audiences such as policy decision makers and the public at large. Considerations such as gender and age are of relevance in this field of activity and will have to be addressed, notably as part of research on individual sensitivity to radiation. Moreover, gender and age balance in the composition of project teams should be sought. International cooperation could be beneficial in this area.

Expected Impact: This action will lead to the better integrating of the radiation protection scientific community at EU level, leading to a better coordination of research efforts and the provision of more consolidated and robust science-based policy recommendations to decision makers in this area. In the long term, these efforts will translate into additional or improved practical measures in view of the effective protection of people and the environment.

Type of action: Programme Co-fund Action (European Joint Programme).. Financial support to third parties may be one of the main objectives of the action. General details on the form of funding are provided in Annex 1.D.

Evaluation Criteria: The standard evaluation criteria for a European Joint Programme (Programme co-fund action) apply. For the details see Annex 1.D and 1.G

Additional information: In line with the nature of the action as a proposed European Joint Programme, the Commission considers that proposals requesting a contribution from the Euratom of between EUR 18,5 and 19,5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

D – Cross-cutting aspects for Nuclear Fission and Radiation Protection

NFRP 8 – 2015: High density uranium fuel and targets for the production of medical radioisotopes

Specific Challenge: A shortage of Molybdenum-99 has occurred mainly as a result of the low availability of research reactor facility and of the extensive replacement of highly enriched

[16] Commission proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, COM (2012)242 final

uranium fuel by low enriched one to address nuclear proliferation concerns. This has been at the origin of the European Observatory on the Supply of Medical Radioisotopes[17], created in order to organise the availability of this essential radiopharmaceutical product.

Research and innovation should be undertaken to support the replacement of highly enriched uranium fuel and targets by low enriched and high density ones. The issue for the fuel is the sufficient performance and safe operation of the reactor, notably for preserving the fuel elements from meltdown, e.g. in using an appropriate conditioning. The issue for the targets is to achieve a sufficient number of fission reactions that produce Molybdenum-99 and to get a high quality pharmaceutical product.

Scope: This research and innovation will focus on developing new kinds of high density uranium fuel and targets bearing in mind their thermal, mechanical and chemical behaviour and their suitability for use in different research reactors. This will involve *inter alia* the investigation of heat resistance, preserved microstructure, reduced oxidation and thermal fatigue of high density fuel and targets by appropriate coating. Fuel and target fabrication will be studied in view of testing their properties under thermal stress before and after irradiation. International cooperation could be beneficial in this area.

Impact: The cost effective supply of high density and low enriched uranium fuel and targets will allow the more efficient use of research reactors in Europe for the purpose of energy research and the production of medical radioisotopes like Molybdenum-99. This will contribute to the addressing of key challenges of Horizon 2020 in the sectors of energy and health. The principal impact of this action will be the prevention of future crises in the supply of Molybdenum-99.

Type of action: Research and innovation actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 9 – 2015: Transmutation of minor actinides (Towards industrial application)

Specific Challenge: The elimination or transmutation of minor actinides is a key to the sustainability of the back-end of the fuel cycle. Further research is needed in order to demonstrate the feasibility of transmutation of high-level waste at industrial scale. Advanced experimental tests as well as numerical simulation tools will be required to conduct this interdisciplinary research encompassing basic as well as applied sciences. The technological and economic performance of transmutation in a fast neutron facility should also take into

[17] http://ec.europa.eu/energy/nuclear/radiation_protection/medical/doc/observatory_mission.pdf

account the other possible uses of the equipment, e.g. for the production of radioisotopes or material testing for nuclear fission and fusion applications.

Scope: This research should contribute to the further development of state-of-the-art critical or sub-critical fast neutron installations for transmutation. Due consideration should be given to the actual effectiveness of the transmutation process, as for example by using accelerator driven systems, as well as the safety and reliability of the facility and the demonstration of the industrial feasibility of the process. The development of innovative fuel and targets for the transmutation of minor actinides should also be considered in this proposal, as well as the development of advanced experiments and numerical simulation tools. Full advantage should be taken of existing knowledge and competence. International cooperation could be beneficial in this area.

Expected impact: Even if a final repository would still be needed, the partitioning and transmutation would drastically reduce the radiotoxicity, the heat production and package volume of high-level radioactive wastes, thereby easing the long-term safety of a final repository. This research will allow pursuing this objective by using state-of-the-art technology, notably in terms of efficiency and safety of the process.

Type of action: Research and innovation actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 7 and 9 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

E - Support the development of nuclear competences at Union level and socio-economic aspects

NFRP 10 – 2014: Education and training (Bologna and Copenhagen processes)

Specific challenge: One of the main goals of Euratom from its inception in developing research and training programmes is to maintain nuclear expertise by generating knowledge (research) and developing competences (training). A key concern of industry and policy makers (in particular, regulators) world-wide is that human resources could be at risk, especially because of high retirement expectations and low renewal rates in countries with a tradition of nuclear installations and a strong need for further specialised training in emerging nuclear energy countries. More specifically, within the EU, the nuclear education and training community is faced with the challenges of lifelong learning and cross border mobility. This action should be undertaken under the umbrella of the Technology Platforms and other authoritative expert bodies concerned.

Scope: Special attention is to be devoted to the further implementation, in the nuclear and relevant medical and industrial sectors, of the EU policies stemming from the Bologna and

Copenhagen processes[18]. Education and training organisations (notably at university or equivalent level) are invited to submit proposals in close collaboration with the "end–users", i.e. industry, research and regulatory organisations. A special effort should be devoted to the development of European Masters and summer schools for the continuous professional development of researchers and other private/public actors. The implementation of the action will need coordination involving research and educational institutions, practitioners in the respective area, regulators, equipment manufacturers and stakeholders from different Member States. Particular attention shall be paid to gender balance in the composition of project teams.

Expected impact: This activity will accelerate and optimise the development of competences in the nuclear area with a special focus on nuclear safety culture and radioactive waste management. It will contribute to the creation and transfer not only of knowledge but also of skills and competences in a well-focused and practical manner. In the long term, it will contribute to improving the safety and radiation protection culture and hence, the safety of nuclear installations in the EU.

Type of action: Coordination and Support Actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 1 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 11 – 2015: Modelling and analysing the energy system, its transformation and impacts.

This action is addressed under the item LCE 21 - 2015 of the Horizon 2020 – Energy Challenge Work Programme 2014-2015 'Social, environmental and economic aspects of the energy system'. Applications should be submitted to that programme. The deadline for submitting project proposals under this topic may differ from the deadline for the Euratom Work Programme 2014-2015, and is indicated in the Energy Challenge Work Programme 2014-2015.

NFRP 12 – 2014: Nuclear developments and interaction with society

Specific Challenge:

Perception by and engagement with civil society regarding nuclear applications is a challenging issue. This has been highlighted particularly in the interdisciplinary study and the

[18] Bologna process (1999) for academic education (European Credit Transfer and accumulation System/ ECTS), providing a robust basis for Euromaster programmes and doctoral schools, the Copenhagen process (2002) for Vocational Education and Training (European Credit System for VET/ECVET), fostering the synergy between the worlds of education / training and of work / industry

symposium on "Benefits and Limitations of Nuclear Fission for a Low Carbon Economy". A large body of knowledge of past successes and failures in interacting with civil society in the implementing of nuclear projects exist in the form of books and studies, press articles, government reports, radio and TV broadcasts, the memory of projects stakeholders, etc. The aim of this activity is to exploit to the best extent this information in view of shedding light on the last sixty years of developments of nuclear in Europe and a number of other major nuclear stakeholder countries, clarifying the context within which certain decisions were made, identifying the factors which influenced projects' success or failure in gaining engagement of the civil society and ultimately, help improving communication and interaction with civil society for the benefit of all public and private stakeholders concerned.

Scope:

This research shall be composed of a coherent and representative set of "case studies" regarding nuclear developments and projects, over the last sixty years, in the EU and abroad (USA, Russia, Ukraine, Japan) and related international cooperation where appropriate. These cases shall be examined also taking account of the broader context (economic, political, institutional…) within which decisions were taken regarding the main energy sources for electricity production. The focus shall be on nuclear energy applications but a number of case studies shall also be selected outside the power sector, i.e. in relation to medical and industrial (e.g. agri-business) applications.

In a first phase, historians shall provide the core facts and figures, based on available documents and other sources of information, complemented as appropriate by field investigations, notably interviews of major players with regard to the selected developments and projects. This should result in a well-organised and documented database and historical record.

The second phase shall bring-in additional experts, i.e. communication specialists, sociologists or psychologists of organisations, philosophers and other such specialists in order to analyse and interpret this information from the perspective of furthering the understanding of the mechanisms for effective interaction with civil society regarding nuclear applications and projects, including the factors underlying perception, participation and engagement.

In the third and last phase, the results shall be presented and discussed with industry, associations, policy makers and representatives of the civil society.

The research team will need to demonstrate the absence of conflict of interest and its ability to conduct this study in complete independence from developments in the nuclear domain. The team will however need to demonstrate the appropriate breadth of expertise and experience needed in view of conducting such type of investigation. A fully detailed work plan of the desk and fieldwork, established and agreed with all main performers involved in the project, will have to be presented to the EC for approval within the first eight months of the project.

Expected impact: This research should contribute to the understanding of factors triggering the societal engagement with nuclear energy and other nuclear applications and provide insights to decision makers and other stakeholders regarding interaction with civil society. This should

help the implementing of future nuclear projects, primarily in energy production, but similarly in areas such as food processing, nuclear medicine, emergency management or radioactive waste management. It should also reinforce the links between the nuclear research community and the social sciences and humanities, and help with the disseminating and understanding of nuclear research and knowledge.

Type of action: Research and innovation actions.

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 2 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 13 – 2015: Fostering the network of National Contact Points

Specific challenge: Facilitate trans-national co-operation between National Contact Points (NCPs) on Nuclear Fission and Radiation Protection with a view to identifying and sharing good practices and raising the general standard of support to programme applicants, taking into account the diversity of actors that make up the constituency of this Programme.

Scope: Support will be given to a consortium of formally nominated NCPs in the area of Nuclear Fission Safety and Radiation Protection (Euratom). The activities will be tailored according to the nature of the area, and the priorities of the NCPs concerned. Various mechanisms may be included, such as benchmarking, joint workshops, enhanced cross-border brokerage events, specific training linked to this field as well as to gender dimension of Research and Innovation, and twinning schemes. Special attention will be given to enhance the competence of NCPs, including helping less experienced NCPs rapidly acquire the know-how accumulated in other countries.

The focus throughout should be on issues specific to Nuclear fission and radiation protection, and should not duplicate actions foreseen in the NCP network for quality standards and horizontal issues under 'Science with and for Society'.

Only NCPs from EU Member States, Associated Countries which have been officially appointed by the relevant national authorities are eligible to participate in and receive funding for this action.

The consortium should have a good representation of experienced and less experienced NCPs.

Submission of a single proposal is encouraged. NCPs from EU Member States or Associated Countries choosing not to participate as a member of the consortium should be identified and the reason explained in the proposal. These NCPs are nevertheless invited and encouraged to participate in the project activities (e.g. workshops), and the costs incurred by the consortium for such participation (e.g. travel costs paid by the consortium) may be included in the estimated budget and be eligible for funding by the Commission.

The Commission will only fund one proposal under this topic.

Expected impact:

- An improved and professionalised NCP service across Europe, thereby helping simplify access to Euratom fission 2014-2018 calls, lowering the entry barriers for newcomers, and raising the average quality of proposals submitted.
- A more consistent level of NCP support services across Europe.

Type of action: Coordination and support action

Additional information: The Commission considers that proposals requesting a contribution from the Euratom of between EUR 0,3 and 0,5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 14 – 2014: Regional initiative aiming at nuclear research and training capacity building

Specific challenge: Maintaining competence in fission safety remains of interest for a number of Member States especially in the Baltic and Eastern European region. Discussions have started at these various regional levels with the aim to develop jointly sustainable applications of fission for e.g. new and safer research reactor technology, radioactive waste management and training and education in these fields.

Scope: The aim is to support the exchange of scientific staff and the sharing of equipment, knowledge and competences between private and/or public research laboratories within the region and with similar organisations in other EU Member States. This action should take advantage of and develop synergies with on-going and future Euratom projects in particular those offering access to research infrastructures in conjunction with education and training. A strong involvement of appropriate public bodies from the Member States concerned is essential, as well as links with relevant platforms such as SNETP and IGD-TP. This action should also aim at examining how Structural Funds could possibly be mobilised to further develop regional cooperation in the area.

Expected impact: The capacity building at regional level for nuclear research and training through cooperation and networking will reduce regional disparity in the European Union. Such effort will reinforce the EU excellence in fission relevant applications and in particular in nuclear safety and radioactive waste management.

Type of action: Coordination and Support Actions.

Additional information: In line with the nature of the action, the Commission considers that proposals requesting a contribution from the Euratom of between EUR 1 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 15 – 2015: Specific support to the work of the Sustainable Nuclear Energy Technology Platform

Specific challenge: The Sustainable Nuclear Energy Technology Platform (SNETP) has been recognised as a European Technology Platform (ETP) by the European Commission in the context of the upcoming "Strategy for European Technology Platforms: ETP 2020". SNETP rests on three main pillars: (i) the NUGENIA association addressing the safety of existing light-water reactors; (ii) ESNII (European Sustainable Nuclear Industrial Initiative) dealing with the safety of fast reactors with associated strategies of spent nuclear fuel management and waste minimization, and (iii) nuclear safety of plants not restricted to electricity production. The major challenge of SNETP is to continue to integrate the R&I in nuclear safety at European Level in the global context taking due account of the various stakeholders' concerns

Scope: The Euratom funding will be devoted to specific studies, data collection and analysis activities and workshops for the further development of technology roadmaps, implementation plans and deployment strategies as well as to the dissemination of the platform activities to the various stakeholders. Due attention is to be paid in this regard to the recent SET Plan initiatives for integrating the different energy roadmaps (nuclear and non-nuclear). Activities should aim at fostering collaboration between ETPs to address cross-sectorial challenges between fission, fusion and non-nuclear energy sources as put forward at SET Plan level, notably on materials and education and training. Euratom will not cover secretariat and other running costs of the platform as it should be self-financed for these needs.

Expected impact: This action will help SNETP to further structure – content-wise - its activities. It will also help better situating the development of nuclear energy in the broader context of the relevant Horizon 2020 societal challenges, and hence help disseminating the platform's activities to the policy-makers and stakeholders.

Type of action: Coordination and Support Actions.

Additional information: In line with the nature of the action, the Commission considers that proposals requesting a contribution from the Euratom of between EUR 0,4 and 0,6 million would allow this specific support action to be undertaken appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

The conditions related to this topic are provided at the end of this call and in the Annex 1.

NFRP 16 – 2015: Supporting the licensing of Western nuclear fuel for reactors of VVER design operating in the EU.

SPECIFIC CHALLENGE: Attempts were made to diversify the nuclear fuel supply for Russian pressurized water reactors (VVER). Although successful at some nuclear power plants

operated in the EU it was abandoned for different reasons. As many as 16 VVERs are operating in the EU (essentially in the new Member States) and another 15 in Ukraine where feedback is also available on the potential safety issues. The diversification of fuel supply in EU VVER plants would be relevant for greater security of energy supply. However, the licensing in the EU of VVER reactor fuel assemblies manufactured by a new supplier requires a full range of safety evaluations for which R&D is to be carried out at EU level, involving industrial and regulatory (or TSO) experts.

SCOPE: This activity will build on the experience gained in different VVER plants in the EU and on well-documented irradiation campaign results (either past or on-going). It should aim at establishing all necessary safety analyses, tests and procedures in view of the further licensing of VVER fuel manufactured by Western suppliers, with due consideration to international safety standards. This would involve the assessment of accident safety cases produced by operators and their evaluation by regulatory authorities with the help of their TSOs. A strong cooperation between countries with experience in such adaptation of fuel type and other countries concerned shall be established. This cooperation initiative should allow reinforcing as quickly as possible the European capabilities in this domain. This activity to be fully relevant should consider different Western fuel sources.

EXPECTED IMPACT: This action contributes to the security of supply of nuclear fuel for VVER reactors operating in the EU by supporting the diversification of fuel sources in the short / medium term in full compliance with nuclear safety standards.

TYPE OF ACTION: Research and Innovation action

ADDITIONAL INFORMATION: In line with the nature of the action, the Commission considers that proposals requesting a contribution of between EUR 1 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Conditions for the call

Opening date(s)[19]: 11/12/2013 for topics NFRP 1-15,

25/07/2014 for topic NFRP 16

Deadline(s) [20]:

Topics NFRP 1-15	17/09/2014 at 17.00.00 Brussels time
Topic NFRP 16	20/11/2014 at 17.00.00 Brussels time

Indicative budget:

EUR 48.46 million from the 2014 budget

EUR 39.41 million from the 2015 budget[21]

Topics	2014 EUR million	2015 EUR million
NFRP 1	18.80	
NFRP 2	3.00	
NFRP 3	6.00	
NFRP 4	1.10	
NFRP 5		1.00
NFRP 6	14.60	
NFRP 7		19.00
NFRP 8		5.00
NFRP 9		8.00
NFRP 10		4.00
NFRP 12	2.50	
NFRP 13		0,37
NFRP 14	2.00	
NFRP 15		0.50
NFRP 16	0.46	1.54

All topics - single stage procedure

Eligibility and admissibility conditions: The conditions are described in parts B and C of the Annex 1 to the work programme, with the following exceptions:

NFRP 7	Please read carefully the provisions under Annex 1.D (European Joint Programme (EJP) Co-fund Action).

[19] The Director-General responsible may decide to open the call up to one month prior to or after the envisaged date of opening

[20] The Director-General responsible may delay this deadline by up to two months.

[21] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

Evaluation criteria, scoring and threshold: The criteria, scoring and threshold are described in part G of the Annex 1 to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part G of the Annexes.

The full evaluation procedure is described in the relevant guide[22] published on the Participant Portal.

Indicative timetable for evaluation and grant agreement:

	Information on the outcome of the evaluation (*single stage*)	Indicative date for the signing of grant agreements
All topics	Maximum 5 months from the final date for submission	Maximum 3 months from the date of informing applicants

Consortia agreements: In line with the Rules for Participation and the Model Grant Agreement, participants in Research and Innovation Actions or in Innovation Actions are required to conclude a consortium agreement prior to grant agreement.

[22] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

SECTION B: OTHER ACTIONS[23, 24]

B.1: Fusion Joint Programme

Specific challenge: The ultimate challenge of fusion research is the realisation of electricity generation from magnetic confinement fusion within a reasonable time horizon. Though the challenge of fusion electricity is considerable, the present consensus in Europe is that a DEMO device could be generating electricity for the grid around the middle of this Century. On the critical path towards this achievement is the successful demonstration in ITER of 'burning fusion plasmas' at reactor scale, which is expected towards the end of the 2020s. The fusion research effort must therefore be focused on the success of ITER and enabling Europe to be in a position to exploit the results of ITER in order to progress to the next stage of actual electricity production in a DEMO facility. The various activities and missions that are needed in this effort are presented in the EFDA roadmap. The EFDA members (national fusion laboratories) have defined a joint programme of activities to fulfil the missions in the roadmap. The research builds on the efforts supported under previous Euratom Framework Programmes, including the related cooperation with international organisations and third countries. In this regard, all opportunities offered by international cooperation, such as the pooling of resources and sharing of risks, should continue to be pursued. In the spirit of joint programming, increased cooperation and exchange of information between EU Member States regarding their international activities would enable the establishing of a fully coherent European strategy on international cooperation founded on the main European assets and aligned to the objectives and missions of the EFDA roadmap.

Scope: The Commission invites the consortium of national labs to submit a proposal for a joint programme implementing the EFDA roadmap over the years 2014-18. The proposal for the joint programme should include details as described in Annex 1.D (European Joint Programme). All current EFDA members (plus prospective member from Croatia, as a new Member State) should have the opportunity to be partners in the consortium. Special attention should be paid to ensuring the broadest possible participation of labs, in particular smaller ones, commensurate with their available competencies and the requirements of the roadmap. An appropriate governance structure should be established to ensure effective implementation of the joint programme in line with the roadmap. This should involve centralised management and coordination functions, and similar arrangements to those in place under EFDA may be considered, in particular a Programme Manager and supporting unit (separate from the administrative effort required by the consortium coordinator). The supporting unit may be constituted at one or more locations, though an appropriate secondment scheme should be established that can attract suitably qualified staff from the consortium partners. The issue of education and training is crucial for the further development of fusion, and the proposal should

[23] The budget amounts for 2014 are subject to the availability of the appropriations provided for in the draft budget for 2014 after the adoption of the budget for 2014 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

[24] The budget amounts for 2015 are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2015.

clearly lay out the vision for these activities and allocate appropriate resources. The FuseNet Association, which has emerged from an action supported under Euratom Seventh Framework Programme, brings together a range of stakeholders, not only national labs and universities but also industry, and could play an important part in shaping the future education & training landscape in fusion. Under the Euratom 2013 fusion research programme, the Commission launched FUTTA, a pilot project to investigate the requirements for the establishment of a fusion technology transfer office. Recommendations from this project should be addressed under the new joint programme as part of the innovation aspects of the consortium's activities and mentioned in the plan for the exploitation and dissemination of results. In the past, public information and awareness-raising activities in the field of fusion energy and related research was an important part of the European effort, and this should be maintained in the new joint programme. In view of the recognised importance of the mobility of researchers in the fusion programme, the proposal should foresee support to mobility to cover the cost of travel and subsistence under the new programme. Rules similar to those in force under the current Mobility Agreement between EFDA Members may be adopted by the consortium. The scientific exploitation of JET should be fully included in the work programme/plan presented in the proposal, though the operation of JET will be funded via a separate bilateral operation contract between the Commission and CCFE. As part of the joint programme, support for other facilities can be included if the activities are necessary for the implementation of the roadmap. The full cost of purchasing equipment (the "durable equipment") to be specifically used as additions to JET and not in the control of the purchasing or contributing beneficiary, may be eligible under the conditions set out in the grant agreement. In particular, the durable equipment to be purchased under these conditions shall be included in Annex 1 and in the Annual Work Plan of the action and shall be purchased in accordance with Article 10 of the Model Grant Agreement.

Early involvement of industry in the implementation of the roadmap is considered essential and the appropriate interaction with industry and integration of industrial activities should be part of the proposal. For this, appropriate contacts with the Fusion Industry Innovation Forum (FIIF) should be ensured. In view of the expiry of EFDA at the end of 2013, the proposal should indicate how the previous records, reports and IT servers/systems will be maintained and kept accessible by the consortium partners and the Commission for a period of at least 5 years (related costs can be eligible costs under the Grant Agreement for the co-fund action). In this regard, and during the transition phase, the new supporting unit would be expected also to deal with legacy EFDA tasks that are currently managed by the EFDA Close Support Unit (CSU). The proposal should describe how the crucial issue of international cooperation, where relevant to the objectives of the roadmap, will be addressed in the joint programme. Efficient and effective cooperation between all European actors in the fusion area, including F4E, must be clearly addressed by the consortium. Support to third parties will be an important part of the action and will be necessary to achieve the objectives of the action. The proposal should also address the other issues mentioned in the general guidance for proposal submission.

Expected impact: The joint programme will be an unprecedented research effort focused on the key challenges towards exploitation of fusion as an energy source. It dispels the myth that

fusion energy is always '50 years away' and represents a concerted and effective cooperative initiative between national fusion laboratories at the cutting edge of science and technology. The co-fund action will enable significant Euratom funding to be contributed to this effort, and in doing so continue to leverage the national support for fusion that has been the hallmark of the Euratom fusion programme to date. This effort is long term, building on many years of successful European research in this field and will be typified by incremental but significant progress in a wide range of specific research activities over the period of Horizon 2020 and beyond. The fundamental guiding document is the roadmap to fusion electricity, which will also need updating and revising at regular intervals, at the same time reinforcing the integrated nature of this joint effort, both at the level of fusion labs and Member States. The most important impact over the next five years will be the contribution to the success of ITER, which is the single critical path in the roadmap and the focus of the majority of the resources in the joint programme. In the longer term, progress towards DEMO and eventual power plants will represent important opportunities for European industry in general, and current activities under the roadmap will also have clear impacts in these areas, with the new structure of the fusion programme enabling all relevant actors to position themselves accordingly. Impacts must be tangible, and maintaining the goal-oriented philosophy of the roadmap, with clear milestones, is crucial in this respect. Furthermore, as the fusion effort moves from one of fundamental science to more applied and engineering sciences, the possibilities for spin-off applications and technologies is increasing and will also represent a significant additional impact by the end of Horizon 2020 – there are already concrete examples of such spin-offs, and the FUTTA project mentioned above could be an important precursor needed to support and promote the expected future growth.

Type of action: Grant to identified beneficiaries - Programme co-fund action (European Joint Programme).

Activities to be funded: see Annex 1.D

Beneficiary: The beneficiaries for this grant are: see Annex 2.

Rate of co-financing: The Euratom contribution will be limited to a maximum of 55%[25] of the total eligible costs of the action. Reimbursement of the eligible costs related to the action, in accordance with the conditions set out in the grant agreement, including reimbursement of actually incurred costs, lump sums, unit costs or flat rates, as the case may be, in accordance with the relevant Commission decisions[26].

Indicative budget: EUR 457.77 million committed in annual instalments over the 5 years, 2014-18 (EUR 77.36 million from the 2014 budget).

Eligibility conditions: The standard eligibility conditions for a European Joint Programme (Programme co-fund action) apply. For the details see Annex 1.C and 1.D.

[25] The precise co-fund rate will be mentioned in the Grant Agreement

[26] Commission Decision (C(2013)8201) for authorising the reimbursement of unit costs for the Fusion Programme Co-Fund Action under the Research and Training Programme of Euratom (2014-2018) complementing Horizon 2020.

Evaluation criteria: The standard evaluation criteria for a European Joint Programme (Programme co-fund action) apply. For the details see Annex 1.G.

Submission and evaluation procedure: The proposal can be submitted between 1 January 2014 (10:00 Brussels local time) and 31 March 2014 (17:00 Brussels local time). No proposal page limits are imposed. The evaluation will be performed within 3 months of the submission of the proposal. A panel of independent experts will be used, including from outside Europe. In view of the unique nature of this evaluation, and in line with the provisions of Rules for Participation, individuals with the appropriate expertise may be selected from outside the database.

Indicative time to inform: Maximum 5 months from the final date for submission

Indicative time to grant: Maximum 3 months from the date of informing applicants
Start date of the action and eligibility of costs: In view of the necessity to maintain continuity following the activities programmed under the Euratom Framework Programme 2012-2013, the action is expected to start on 1 January 2014. In accordance with Council Regulation on the Research and Training Programme of the European Atomic Energy Community (2014-2018) costs incurred in implementation of the action will be eligible as from 1 January 2014 even if the relevant proposal is submitted after that date.

Consortium agreement: All partners must sign a Consortium Agreement establishing the roles and responsibilities of the partners and the governance structure for the joint programme.

B.2: External expertise

B.2.1: This action will support the use of appointed independent experts for the evaluation of project proposals and, where appropriate, for the monitoring of running projects, and for the ex-post evaluation of the Euratom Seventh Framework Programme (2007-2011) and the Euratom Framework Programme (2012-2013), in accordance with Article 6(2) of the Council decision (2012/93/Euratom) of 19 December 2011 concerning the Framework Programme of the European Atomic Energy Community for nuclear and training activities (2012-13).

Type of action: Expert contracts

Indicative timetable: First Quarter of 2014 – fourth Quarter of 2015

Indicative budget: EUR 0.43 million from the 2014 budget (2/3 for fission, 1/3 for fusion).

B.2.2: This action will support the use of appointed experts for assisting the Commission with the design of the Euratom fission research programme with respect to issues such as the safety aspects of nuclear fuel supply, equipment and related know-how, energy interdependencies and the management of spent nuclear fuel.

Type of action: Expert contracts

Indicative timetable: Third Quarter of 2014 – fourth Quarter of 2015

Indicative budget: EUR 0.15 million from the 2014 budget for fission and EUR 0.15 million form the 2015 budget for fission.

B.3: Supporting access to Jules Horowitz reactor

Specific Challenge: One of the roles of the Euratom Framework Programme is to facilitate access to the key research infrastructures for Euratom researchers. One of the key types of infrastructures in the area of nuclear science and technology is the Materials Testing Reactor (MTR), such as the Jules Horowitz Reactor (JHR). The JHR is expected to start operating in 2017 and has advanced material testing capabilities (high neutron flux irradiation, on-line instrumentation, flexibility of operation conditions) that are consistent with the current state-of-the-art experimental and numerical simulation techniques, including in relation to fusion. It also has the high level of safety that is mandatory for state of the art research reactors.

Scope: The objective is to acquire additional reserved and secure access rights to JHR in order to ensure future Euratom projects have ready access to this unique irradiation facility when in operation and for a period of 30 years. These access rights are intended to be used in particular by any European laboratory/organisation located in a Member State and/or in Associated Countries. The distribution of these rights to deserving projects or laboratories will be the responsibility of Euratom through its participation in the JHR Consortium Governing Board.

Expected impact: This effort will first of all secure access to Euratom researchers to the most up-to-date MTR in the EU. More generally speaking, it will enable Euratom to fulfil several of its key objectives in nuclear safety and nuclear systems, notably material testing, research and education and training in this area.

Type of action: Public procurement - service contract.

Indicative timetable: Third quarter of 2015

Indicative budget: EUR 15 million from the 2015 budget

B.4: Prize - Innovation SOFT

Specific challenge: Within energy research, fusion encompasses innovation in the domains of physics and technology in a wide variety of specialisations. The researchers in Europe are constantly challenging the science and improving the technology thereby creating the conditions for innovation, much of which can be exploited in other science and industrial sectors for the benefit of European society. A fundamental basis of the Euratom Programme complementing Horizon 2020 is to support innovation. In this context the researcher plays a critical role. This prize is being offered to highlight and reward the excellence in innovation that can be found in the fusion research programme as well as the quality of the researchers and industries involved.

Scope: There are no specific categories for this prize. The participant(s) is free to submit an application concerning any physics or technology innovation that has been or is being developed in the European fusion research programme and that has a market potential or has been taken up (or recognised) by industry to be further developed for the market. The Jury evaluating submissions will consist of a group of independent experts appointed by the Commission knowledgeable in innovative processes and technology transfer from business and academia. The Jury will submit to the Commission the selected 1st, 2nd and 3rd placed

winners who will receive 15,000, 10,000 and 5,000 Euros respectively. The winners will be announced at the SOFT conference in September 2014.

Expected impact: By awarding the 'European Prize for Innovation in fusion research' the Commission will showcase innovations in this research sector and give visibility to the most dynamic, forward-looking and innovative researchers, research teams or industrial participants. This visibility will provide the greater potential for valorisation with the subsequent rewards that this brings to the EU both economically and socially. Furthermore, presenting these awards will stimulate the research community to develop a stronger innovation and entrepreneur culture in the European fusion programme.

Type of action: The form of funding will be through prizes to a total value of EUR 0.030 million.

Eligibility criteria:

- The contestant must be a researcher, research team or industrial participant benefitting from Euratom financial support, and be resident in an EU Member State or a Euratom Associated Country. Example of proof: details of a specific contract associated to the Euratom fusion research programme; copy of any official document of identification (passport, driving licence etc.). If you are not an EU citizen, you must present a document proving your residency in the EU or an Associated Country (e.g. a copy of your visa or work permit).
- The researcher, research team or industrial participant has acquired permission from the owner of the intellectual property rights to submit an application. The owner of the IPR should comment on the state of the IPR: free or contractually embedded, and name of eventual contractor/s.
- The contestant's submission will consist of a complete application for the 'European Prize for Innovation in fusion research' including:
    - a technical description of the innovation;
    - a state of the art assessment of the innovation (using publically available patent data base such as the EPO Espacenet);
    - an account, in general terms, of the market potential for the exploitation of the innovation;
    - the contribution that the prize could provide for the exploitation of the innovation.

For the detailed information on the general conditions, applicable law, exclusion criteria, please refer to the Rules of Contest for prizes in Annex 1.

Contestants can at any time be required to submit official proof to support claims made under any of the above eligibility criteria.

Award criteria:

- The originality and replicability: the idea is innovative and the result of lateral thinking and proves to be original and first-of-a-kind used in the industry or in the domain of application.

- Technical analysis applied: the application will need to include patent information on the state of the art in the associated technology field (using publically available patent data base such as the EPO Espacenet).
- Clarity: the concept must be clear, logical and well-illustrated.
- The planned use of the prize money: the application should present an awareness of all relevant innovation aspects and include identification of the market needs and business opportunities and where this prize could contribute to the successful exploitation and further development of the innovation.

Funding scheme: Prize - 1st prize: EUR 0.015 million, 2nd prize: EUR 0.010 million and 3rd prize: EUR 0.005 million from the 2014 budget.

Date of publication of the contest: 1 January 2014, 12:00:00 Brussels local time

Date of opening of the contest: 1 January 2014, 12:00:00 Brussels local time

Deadline to submit applications: 16 April 2014, 17:00:00 Brussels local time

Announcement of winners: September 2014

Evaluation procedure: The evaluation of the application is carried out by the Commission with the assistance of up to 4 independent experts.

In a first step a committee of Commission staff will carry out a pre-screening of all received applications. Each application will be evaluated against the eligibility and award criteria outlined in the Euratom 2014/2015 Work Programme.

In a second step, independent experts perform the evaluation on a personal basis, not as representatives of their employer, their country or any other entity. They sign an expert contract, including a declaration of confidentiality and absence of conflict of interest before starting their work. Confidentiality rules must be adhered to at all times, before, during and after the evaluation.

The Commission reserves the right not to select a winner if no suitable entries are received or proposed by the jury.

The Commission allocates the applications to individual experts, taking account of the fields of expertise of the experts, and the absence of conflicts of interest.

At the beginning of the evaluation, the experts will be briefed by the Commission on the evaluation procedure, the experts' responsibilities, the issues involved in the particular area/objective, and other relevant matters.

B.5: Contract for the operation of JET

Specific challenge: After a comprehensive assessment of the JET programme and future contribution by an independent committee of experts, it was recommended that a full characterisation of the 'ITER-like wall' should be undertaken, including final tritium experiments, in order to support the operation and licensing activities in ITER. To this end, the reference scenario for the operation of JET is exploitation until 2017, with closure during 2018.

The main role of JET will be to mitigate the risk of delays in ITER by providing comprehensive knowledge about the start-up plasma regimes and the necessary operating techniques and diagnostics that will ensure safe operation and high performance.

Scope: JET will be operated through a bilateral contract between the Commission and the Culham Centre for Fusion Energy (CCFE). CCFE will be responsible for the operation and maintenance of the JET facilities on behalf of the Commission. The Commission will then provide the JET facilities as an in-kind contribution to the consortium of EFDA members who will in turn manage and implement the experimental programme that will be defined in the annual work programme of the consortium in line with the European fusion roadmap. In this respect, it is the responsibility of the consortium to decide which experiments should be carried out, and the related costs eligible for reimbursement under the co-fund action.

Expected impact: The JET programme is dedicated to the support of ITER physics, technology and licensing activities. Its current programme of characterisation and validation of the ITER-like wall and the future tritium experiments are expected to ensure a smooth start-up to ITER operation as well as facilitating the ITER licensing process thereby minimising risks of costly delays in reaching ultimate objectives.

Type of action: This action requires the continued operation of the JET facilities and depends on the technical and administrative competence of CCFE. A bilateral contract between the Commission and CCFE under Article 10 of the Euratom Treaty will be concluded to provide the Commission support. In accordance with the provisions of the Euratom Research and Training Programme 2014-18 (refer to footnote 1) this may include the secondment of Commission staff.

Indicative date of signature: 1st quarter 2014

Indicative budget: EUR 250 million committed in annual instalments over the 5 years, 2014-18 (EUR 63.00 million from the 2014 budget).

B.6: Contribution to the Organisation for Economic Co-operation and Development (Nuclear Energy Agency) / Secretariat for the GIF

USA, UK, France, Brazil, Japan, Korea, South Africa, Argentina and Canada signed the Charter of the Generation-IV International Forum (GIF) in July 2001, with the purpose of satisfactorily addressing nuclear safety, waste, proliferation and public perception concerns. Euratom signed the Charter on 30 July 2003 by a decision of the Commission pursuant to Article 101(3) of the Euratom Treaty. Switzerland, the Russian Federation and the People's Republic of China signed later on. A Framework Agreement (FA) for collaboration on R&D, setting the framework conditions for subsequent system and project arrangements, has been concluded subsequently. The Charter was originally for duration of 10 years, and in 2011 the signatories unanimously prolonged this duration indefinitely. The FA depository is the OECD Secretary General. The EU Council approved the accession of the Euratom to the FA in its Decision no. 14121/05, Brussels, 8 November 2005, and Euratom formally acceded in May 2006. Accession brings with it certain obligations, including the co-funding of the GIF technical secretariat activities carried out by the NEA. The level of this funding from each

signatory was established by the GIF Policy Group (PG) at its meeting in Beijing, China, 23-24 October 2008, and revised recently at the GIF PG meeting in Beijing, 16-17 May 2013.

Type of action: Subscription for operation of the GIF Secretariat for the years 2014- 2015, in the form of a "subscription", in accordance with Article 121(2)(d) of the Financial Regulation and Article 173 of its Rules of Application.

Indicative timetable: First half of 2014

Indicative budget: EUR 0.3 million from the 2014 budget.

SECTION C: BUDGET OVERVIEW

Item	2014 Budget EUR million	**2015 Budget[27] EUR million**
Calls		
Call H2020-NFRP-2014/2015 Nuclear Fission and Radiation Protection	*48.46* *from 08.030102*	*39.41* *From 08.030102*
Other Actions		
B.1 Fusion Joint Programme	*77.36* *of which 65.94 from 08.030101 and 11.42 from 08.035001*	*72.15* *from 08.030101*
B.2 External expertise	*0.58* *of which 0.10 from 08.030102, 0.05 from 08.030101and 0.43 from 08.035001*	*0.15* *from 08.030102*
B.3 Supporting access to Jules Horowitz Reactor		*15.00* *from 08.030102*
B.4 Prize – Innovation SOFT	*0.03* *from 08.035001*	
B.5 Contract for operation of JET	*63.00* *of which 43.74 from 08.030102 and 19.26 from 08.035001*	*50.00* *from 08.030101*
B.6 Secretariat for the GIF	*0.30* *from 08.030102*	
Estimated total budget	*189.73*	***176.71***

[27] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

Overview of the 2014-2018 appropriations that will be committed for the 2014-2018 grant to support the Fusion Joint Programme and the contract for the operation of the JET.						
Item	2014 Budget (EUR million)	2015 Budget (EUR million)	2016 Budget (EUR million)	2017 Budget (EUR million)	2018 Budget (EUR million)	TOTAL
Fusion Joint Programme	77.36	72.15	82.00	101.56	124.63	457.70
Contract for operation of JET	63.00	50.00	50.00	50.00	37.00	250
TOTAL	140.36	122.15	132.00	151.56	161.63	707.70

ANNEXES

Annex 1: General Conditions

A. List of countries, and applicable rules for funding

B. Standard admissibility conditions for grant proposals, and related requirements

C. Standard eligibility criteria

D. Types of action: specific provisions and funding rates

E. Technology readiness levels (TRL)

F. Rules of Contest (RoC) for Prizes

G. Evaluation

H. Budget flexibility.

I. Classified Information

J. Financial support to third parties

Annex 2: Consortium members for fusion programme co-fund grant

Annex 1: General Conditions

A. List of countries, and applicable rules for funding

Legal entities established in the following countries and territories will be eligible to receive funding through the Euratom Research and Training Programme (2014-18) complementing Horizon 2020:

- The Member States of the European Atomic Energy Community, including their overseas departments;
- The Overseas Countries and Territories (OCT) linked to the Member States[28]:
  - Anguilla, Aruba, Bermuda, Bonaire, British Virgin Islands, Cayman Islands, Curaçao, Falkland Islands, French Polynesia, Greenland, Montserrat, New Caledonia, Pitcairn Islands, Saba, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, Turks and Caicos Islands, Wallis and Futuna.
- The Countries associated to the Euratom Research and Training Programme (2014-18) complementing Horizon 2020[29]: the latest information on which countries are associated, or in the process of association, to the Euratom Research and Training Programme complementing Horizon 2020 can be found in the Online Manual[30].

Legal entities established in countries not listed above will be eligible for funding when such funding is explicitly foreseen in the relevant call text.

International European interest organisations[31] will also be eligible to receive funding from the Euratom Research and Training Programme (2014-18) complementing Horizon 2020.

In addition, legal entities established in countries not listed above and international organisations will be eligible for funding:

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and an international organisation or a third country:
- When the Commission deems participation of the entity essential for carrying out the action funded through the Euratom Research and Training Programme (2014-18) complementing Horizon 2020.

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[28] Entities from Overseas Countries and Territories (OCT) are eligible for funding under the same conditions as entities from the Member States to which the OCT in question is linked

[29] Signed an agreement with the Euratom as identified in the Council Regulation on the Euratom Research and Training Programme complementing Horizon 2020.

[30] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/international-cooperation_en.htm

[31] These are international organisations, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

B. Standard admissibility conditions for grant proposals, and related requirements

1. To be considered admissible, a proposal must be:

(a) Submitted in the electronic submission system before the deadline given in the call conditions;

(b) Readable, accessible and printable.

2. Incomplete proposals may be considered inadmissible. This includes the requested administrative data, the proposal description, and any supporting documents specified in the call. The following supporting documents will be required to determine the operational capacity, unless otherwise specified:

- A curriculum vitae or description of the profile of the persons who will be primarily responsible for carrying out the proposed research and/or innovation activities;
- A list of up to five relevant publications and/or products or services (including widely-used datasets or software), or other achievements relevant to the call content;
- A list of up to five relevant previous projects or activities, connected to the subject of this proposal;
- A description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work;
- A description of any third parties that are not represented as project partners, but who will nonetheless be contributing towards the work (e.g. providing facilities, computing resources)

3. Proposals shall include a draft plan for the exploitation and dissemination of the results, unless otherwise specified in the call conditions. The draft plan is not required for proposals at the first stage of two-stage procedures.

4. Page limits will apply to proposals. The limits will be clearly set out in the electronic submission system. If a submitted proposal exceeds the limits, the applicant will receive an automatic warning, and will be advised to re-submit a version that conforms. After the relevant call deadline, excess pages in any over-long proposals will be automatically overprinted with a “watermark”. Expert evaluators will be instructed to disregard these excess pages.

No page limits will apply to proposals for European Joint Programme (EJP) Co-fund actions.

C. Standard eligibility criteria

All proposals must conform to the conditions set out in the Rules for Participation.

Furthermore, in this work programme, the following conditions apply unless they are supplemented or modified in the call conditions.

A proposal will only be considered eligible if:

(a) its content corresponds, wholly or in part, to the topic description against which it is submitted, in the relevant work programme part;

(b) it complies with the eligibility conditions set out below, depending on the type of action.

	Eligibility conditions[32, 33, 34]
Research & innovation action	At least three legal entities. Each of the three shall be established in a different Member State or associated country. All three legal entities shall be independent of each other.
Innovation action	At least three legal entities. Each of the three shall be established in a different Member State or associated country. All three legal entities shall be independent of each other
Coordination & support action	At least one legal entity established in a Member State or associated country.
European Joint Programme (EJP) Co-fund action	At least five legal entities. Each of the five shall be established in a different Member State or associated country. All five legal entities shall be independent of each other.[35] Eligible participants in EJP Co-fund actions are legal entities owning or mandated to manage national research and innovation programmes[36].

[32] The eligibility criteria formulated in Commission notice Nr. 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp.9-11) shall apply for all actions under this Work Programme , including with respect to third parties receiving financial support in the cases where the respective action involves financial support to third parties by grant beneficiaries in accordance with Article 137 of the EU's Financial Regulation, notably Programme Co-Fund actions.

[33] Some entities from third countries are covered by the Council sanctions in place and are not eligible to participate in the Euratom Research and Training Programme (2014-18) complementing Horizon 2020. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm

[34] Given that the EU does not recognise the illegal annexation of Crimea and Sevastopol, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate in any capacity. This criterion also applies in cases where the respective action involves financial support given by grant beneficiaries to third parties established in the Autonomous Republic of Crimea or the city of Sevastopol in accordance with Article 137 of the EU's Financial Regulation. Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, this Work Programme shall be revised.

[35] EJP co-fund actions support coordinated national research and innovation programmes. In line with the objective of transnational integration though a critical mass of resources, the required minimum number of participants is higher than the one provided in the Horizon 2020 Rules for Participation.

[36] It is appropriate that core participation in EJP co-fund actions is limited to entities that can fully participate through their contribution of national and regional programmes: programme owners, typically national ministries/regional authorities responsible for defining, financing or managing programmes carried out at national or regional level or 'programme managers' (such as research councils or funding agencies) or other entities that implement national or regional research and innovation programmes under the mandate of the programme owners. Beyond the minimum participants, other legal entities may participate if justified by the

Note:

In the case of Programme Co-fund Actions (European Joint Programmes), sole participants formed by several legal entities (e.g. European Economic Interest Grouping, associations) are eligible if the above-mentioned minimum conditions are satisfied by the legal entities forming together the sole participant.

nature of the action, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from public and private sources.

D. Types of action: specific provisions and funding rates[37,38]

Research and innovation actions

Description: Action primarily consisting of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment.

Projects may contain closely connected but limited demonstration or pilot activities aiming to show technical feasibility in a near to operational environment.

Funding rate: 100%

Innovation actions

Description: Action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

A 'demonstration or pilot' aims to validate the technical and economic viability of a new or improved technology, product, process, service or solution in an operational (or near to operational) environment, whether industrial or otherwise, involving where appropriate a larger scale prototype or demonstrator.

A 'market replication' aims to support the first application/deployment in the market of an innovation that has already been demonstrated but not yet applied/deployed in the market due to market failures/barriers to uptake. 'Market replication' does not cover multiple applications in the market of an innovation[39] that has already been applied successfully once in the market. 'First' means new at least to Europe or new at least to the application sector in question. Often such projects involve a validation of technical and economic performance at system level in real life operating conditions provided by the market.

Projects may include limited research and development activities.

Funding rate: 70% (except for non-profit legal entities, where a maximum rate of 100% applies)

Coordination and support actions

Description: Actions consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services,

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[37] Eligible costs for all types of action are in accordance with the Financial Regulation and the Rules for Participation. In addition, as training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their proposal such activity and the following corresponding estimated costs that may be eligible for the Euratom funding:

i. Costs of delivering the training (personnel costs if the trainers are employees of the beneficiary or subcontracting if the training is outsourced);
ii. Accessory direct costs such as travel and subsistence costs, if the training is delivered outside the beneficiary's premises;
iii. Remuneration costs for the researchers attending the training, in proportion to the actual hours spent on the training (as personnel costs).

[38] Participants may ask for a lower rate.

[39] A new or improved technology, product, design, process, service or solution.

policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure and may also include complementary activities of strategic planning, networking and coordination between programmes in different countries.

Funding rate: 100%

European Joint Programme (EJP) Co-fund Action

The "programme co-fund action" aims at supplementing individual calls or programmes funded by entities, other than Union bodies, managing research and innovation programmes. The following types of programme co-fund actions are supported in the Euratom Work Programme 2014-15:

- European Joint Programme ('EJP'): co-funding of coordinated national research and innovation programmes.

The specific features applicable to the EJP are described below.

European Joint Programme

The European Joint Programme ('EJP') under Horizon 2020 is a co-fund action designed to support coordinated national research and innovation programmes. The EJP aims at attracting and pooling a critical mass of national resources on objectives and challenges of Horizon 2020 and at achieving significant economies of scales by adding related Horizon 2020 resources to a joint effort.

The EJP does not promote types of activities or forms of coordination, but relies on modalities and processes agreed by the coordinated national programmes and related actors.

Eligibility

The minimum number of participants in EJPs is five independent legal entities from different Member States or associated countries owning or managing national research and innovation programmes:

a) Programme owners, typically national ministries/regional authorities responsible for defining, financing or managing programmes carried out at national or regional level.

b) Programme 'managers' (such as research councils or funding agencies) or other entities that implement national or regional research and innovation programmes under the supervision of the programme owners.

The participation of programme managers has to be mandated by the national/regional authorities in charge.

In addition to the minimum conditions, other legal entities may participate if justified by the nature of the action, in particular entities created to coordinate or integrate transnational research efforts, grouping funding from both national and private sources.

Sole participants may be eligible if the above-mentioned specific conditions for eligible EJP partners are satisfied. A sole participant forming a sole legal entity shall explicitly indicate which of its 'members' are either programme owners or programme managers in the proposed action, and indicate for these members the respective national/regional programmes which are at the disposal of the proposed EJP action.

Justification for additional eligibility criteria: In line of the objective of transnational integration though a critical mass of resources, the required minimum number of participants is higher than the one provided in the Horizon 2020 Rules for Participation. In addition, such participants must be established in different Member States or associated countries in order to further establish an appropriate level of cooperation and integration. Finally, EJP actions support coordination and future integration of national

research and innovation programmes. It is appropriate that core participation in these actions is limited to entities that can fully participate through their contribution of national and regional programmes.

Activities funded

The main activity of the action is the implementation of a joint programme of activities to attain objectives common to Horizon 2020, ranging from research to coordination and networking activities, including training activities, demonstration and dissemination activities, support to third parties etc.

The Euratom funding can be used to enhance and expand the activities of existing coordinated programmes or create new ones, provided they aim at attaining the objectives of a European transnational joint-programme established by the EJP consortium.

The EJP will identify the objectives, work and the schedules of activities to be carried out in this context. It will be necessary to provide a detailed description of these activities for the initial and each successive twelve-month periods of the EJP, as the joint programme develops in line with the initial objectives. An Annual Work Programme, combined with a progress report on previous achievements will be a key deliverable for the implementation of the EJP on a rolling basis. It will be submitted and approved by the Commission prior to commencement of activities for each reporting period:

- Initial Proposal Submission: Description of overall objectives and schedule of proposed activities, together with 1st Annual Work Programme;

- Periodic Reporting: an update to the Annual Work Programme will be submitted three months before the end of the relevant reporting period – after evaluation and possible revision further to Commission comments, the Annual Work Programme will be agreed prior to the start of the next reporting period.

The Euratom contribution takes the form of a grant consisting of a reimbursement of the eligible costs related to the action, in accordance with the conditions set out in the grant agreement and relevant Commission decisions, including reimbursement of actually incurred costs, lump sums, unit costs or flat rates[40]. Financial support provided to third parties as part of the joint programme implementation, for example through calls for proposals or under otherwise defined conditions (cascade grants), is also eligible for reimbursement.

In accordance with the Decisions concerning Horizon 2020 and the Regulation laying down the rules for the participation and dissemination in Horizon 2020, the provisions of Article 137(1 (c)) of the Regulation no 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union and Article 210a of the Commission Delegated Regulation no. 1268/2012, shall not be applicable with regard to the financial support provided by the participants in the EJP to third parties participating in actions selected following calls for proposals launched under the EJP when the financial support to third parties is a primary aim of the action or necessary to achieve its objectives.

[40] Commission Decision (C(2013)8201) for authorising the reimbursement of unit costs for the Fusion Programme Co-Fund Action under the Research and Training Programme of Euratom (2014-2018) complementing Horizon 2020.

The Euratom contribution will be limited to 70% of the total eligible costs of the action, unless otherwise specified in the work programme, in line with the objective of achieving a balanced funding of the EJP from the Euratom and participating public programmes.

Evaluation

The standard evaluation criteria of excellence, impact, and quality and efficiency of the implementation apply, as set out in the Horizon 2020 Rules for Participation and indicated in Annex 1.G to this work programme.

The level of ambition in the collaboration and commitment of the participants in the proposed action to pool national resources and coordinate their national/regional research programmes will be assessed under the excellence criterion.

Critical mass in terms of proposed overall budget, maturity and degree of integration in the proposed research area as well as consistency of activities with the development of the European Joint Programme towards a joint undertaking or other permanent structure in the proposed research area will be evaluated under the impact criterion.

Duration of the action

The total duration of the action should normally not exceed 5 years.

E. Technology readiness levels (TRL)

Where a topic description refers to a TRL, the following definitions apply, unless otherwise specified:

- TRL 1 – basic principles observed
- TRL 2 – technology concept formulated
- TRL 3 – experimental proof of concept
- TRL 4 – technology validated in lab
- TRL 5 – technology validated in relevant environment
- TRL 6 – technology demonstrated in relevant environment
- TRL 7 – system prototype demonstration in operational environment
- TRL 8 – system complete and qualified
- TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

F. Model Rules of Contest (RoC) for Prizes

This annex provides a model for the Rules of Contest that will be published for Prizes under this Work Programme.

1. Objectives pursued

As already specified in the Work Programme.

2. Expected results

As already specified in the Work Programme.

3. Award criteria

As already specified in the Work Programme, or, if the Work Programme only provides essential award criteria, then specific award criteria detailing the essential award criteria shall be provided.

4. Arrangements and final dates for the registration of contestants, if required, and arrangements and final dates for the submission of entries

Required entry forms and deadlines for submission. Registration of contestants can apply only to inducement prizes.

5. Amount of prize(s) including specific amount for each prize, if applicable

6. Arrangement for the payment of the prize to the winner after its award

7. Conditions for cancellation of the contest, if any

The Commission has to right to terminate the contest before its closing date without any obligation to indemnify contestants in case the objective of the contest has been achieved by a non-registered or non-eligible contestants.

The Commission has the right to decide not to award any prize if no entries are received or if no entries are to be awarded by the contest jury.

8. Conditions for participation

The contestant must not have received any other Union prize before that is the subject of the current contest.

All information given by the contestant in the entry must be correct and complete.

8.1. Eligibility criteria

As already specified in the Work Programme, or, if the Work Programme only provides essential eligibility criteria, then specific eligibility criteria detailing the essential eligibility criteria shall be provided.

8.2. Exclusion criteria

Contestants will be excluded from participating in the contest if they fall under any of the following situations[41]:

The contestant:

a) is bankrupt or being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

b) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of res judicata;

c) has been guilty of grave professional misconduct proven by any means which the European Union bodies can justify including by decisions of the European Investment Bank and international organisations;

d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the authorising officer responsible and those of the country where the activity is to be implemented;

e) has been the subject of a judgement which has the force of res judicata for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the Union's financial interests;

f) is subject to an administrative penalty for being guilty of misrepresenting the information required as a condition of participation in a procurement procedure or another grant award procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts or agreements covered by the Union's budget.

Natural person with power of representation, decision-making or control over one of the contestants that are legal entities, must not be in the situations referred to in b) and e) above:

Contestants must:

g) have no conflict of interests in connection with the prize; a conflict of interests could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;

h) inform the European Commission, without delay, of any situation considered a conflict of interests or which could give rise to a conflict of interests;

i) have not been granted and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves

[41] Contestants which are in one of the situations referred to in Article 106(1) and Articles 107, 108 and 109 of the Financial Regulation are excluded from participating in the contest.

corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to the award of the prize;

In case of award of a prize, the following evidence shall be provided upon request and within the time limit set by the European Commission:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the contestant is a legal person and the national legislation of the country in which the contestant is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the contestant.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the contestant is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in the two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

If the contestant is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the European Commission.

8.3 Sole liability of contestants

The Commission may not be held responsible for any claim relating to the activities carried out in the framework of the contest by the contestant. The Commission shall not be held liable for any damage caused or sustained by any of the contestants, including any damage caused to third parties as a consequence of or during the implementation of the activities related to the contest.

8.4. Checks and audits

The contestants accept that, if they are awarded a prize, the Commission, OLAF and the Court of Auditors may carry out checks and audits in relation to the contest and the received prize.

8.5. Publicity

8.5.1. Publicity by the winner of the prize

The contestants accept, if they are awarded a prize, to promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

Unless the Commission requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) must:
(a) display the EU emblem and
(b) include the following text:

"*This action has been awarded the prize [name of the prize] from the Euratom Research and Training Programme"*.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of its obligations, the winner of the prize may use the EU emblem without first obtaining approval from the Commission. This does not, however, give it the right to exclusive use. Moreover, the winner of the prize may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

8.5.2. Publicity by the Commission

The Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from the winner of the prize (including in electronic form).

The Commission will publish the name of the winner, its locality, the amount of the prize and its nature and purpose and that the contestant may request the Commission to waive such publication if disclosure risks threatening its security and safety or harm its commercial interest.

Photos and videos taken by the Commission either in preparation of the award ceremony or during the award ceremony are the sole property of the Commission.

8.6 Processing of personal data

Registration and submission of entry shall be made in writing, which implies by letter or by electronic means (as specified in the rules of the contest), provided that they are non-discriminatory in nature and ensure integrity, confidentiality and protection of personal data. All personal data contained in the entry shall be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council (OJ L8 of 12.01.2001, p1) on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Such data shall be processed by the Controller solely in connection with the implementation and follow-up of the entry of the winner, without prejudice to a possible transmission to the bodies in charge of a monitoring or inspection task in accordance with European Community and European Union legislation.

Contestants may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the Controller, via the contact person announced in the rules of the contest. Please send in addition a scanned copy of your letter to the email address announced in the rules of the contest.

Contestants may, at any time, lodge a complaint against the processing of their personal data with the European Data Protection Supervisor.

The Commission shall be authorised to publish, in whatever form and on or by whatever medium, the following information:

- The name of winner(s);
- The locality of winner(s);
- The general purpose of the activities of the winner(s) in relation to the award of the prize, in the form of the summary provided by the winner(s);
- The amount of the prize awarded.

8.7 Applicable law and competent jurisdiction

The contest is governed by the applicable Union law complemented, where necessary, by the law of Belgium. The General Court or, on appeal, the Court of Justice of the European Union, shall have sole jurisdiction to hear any dispute between the Union and any participant concerning the interpretation, application or validity of the rules of this contest, if such dispute cannot be settled amicably.

If international organisations are eligible, this general rule may be complemented by the special conditions proposed in the model grant agreement on dispute settlement - arbitration and applicable law.

8.8 Applicability of penalties

By virtue of Article 212 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and with due regard to the principle of proportionality, a contestant which has committed irregularities or fraud, has made false declarations shall be liable to:

(a) administrative penalties consisting of exclusion from all contracts, grants and contests financed by the Union budget for a maximum of five years from the date on which the infringement is established and confirmed following a contradictory procedure with the contestant; and/or

(b) financial penalties of 2% to 10% of the value of the prize.

In the event of another infringement within five years following the establishment of the first infringement, the period of exclusion under point (a) may be extended to 10 years and the range of the rate referred to in point (b) may be increased to 4% to 20%.

8.9. Dissemination and exploitation obligations

Obligations regarding dissemination of results laid down in Title III of the rules for participation and dissemination in Horizon 2020 (Regulation 1290/2013) apply as well as any additional rules provided in the Work Programme.

G. Evaluation

Selection Criteria

a) *Financial capacity:* In line with the Financial Regulation and the Rules for Participation. At the proposal stage, coordinators will be invited to complete a self-assessment using an on-line tool.

b) *Operational capacity*: As a distinct operation, carried out during the evaluation of the award criterion 'Quality and efficiency of the implementation', experts will indicate whether the participants meet the selection criterion related to operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).

Award criteria

Experts will evaluate on the basis of the criteria 'excellence', impact and quality and efficiency of the implementation'. The aspects to be considered in each case depend on the types of action as set out in the table below, unless stated otherwise in the call conditions.

Type of action	**Excellence** The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic/other action description in the work programme/call for proposals:	**Impact** The extent to which the outputs of the project should contribute at the European and/or International level to:	**Quality and efficiency of the implementation** The following aspects will be taken into account:
All types of action	**Clarity and pertinence of the objectives;** Credibility of the proposed approach	**The expected impacts listed in the work programme under the relevant topic**	Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks and resources; Complementarity of the participants within the consortium (when relevant); Appropriateness of the management structures and procedures, including risk and innovation management.

Research and innovation; **Innovation**	**Soundness of the concept, including trans-disciplinary considerations, where relevant;** **Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art (e.g. ground-breaking objectives, novel concepts and approaches);**	Enhancing innovation capacity and integration of new knowledge; Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets; Any other environmental and socially important impacts (not already covered above); Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	
Coordination & support actions	**Soundness of the concept;** **Quality of the proposedcoordination and/or support measures**	Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, disseminate and to manage research data where relevant	
EJP Co-fund	Level of ambition in the collaboration and commitment of the participants in the proposed action to pool national resources and coordinate their national/regional research programmes.	Critical mass in terms of proposed overall budget, maturity and degree of integration in the proposed research area as well as consistency of proposed activities with the development of a European Joint Programme towards a joint undertaking or other permanent structure in the proposed research area. Effectiveness of the proposed measures to exploit and disseminate the programme's results and to communicate the programme	

Note

Unless otherwise specified in the call conditions:

(a) Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For full proposals each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.

(b) For Innovation actions, to determine the ranking, the score for the criterion 'impact' will be given a weight of 1.5.

(c) For the evaluation of first-stage proposals under a two-stage submission procedure, only the criteria 'excellence' and 'impact' will be evaluated. Within these criteria, only the aspects in bold will be considered. The threshold for both individual criteria will be 4.

Priority order for proposals with the same score

Unless the call conditions indicate otherwise, the following method will be applied.

As part of the evaluation by independent experts, a panel review will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated above. A ranked list will be drawn up for every indicative budget shown in the call conditions.

If necessary, the panel will determine a priority order for proposals which have been awarded the same score within a ranked list. Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the call fiche. The following approach will be applied successively for every group of *ex aequo* proposals requiring prioritisation, starting with the highest scored group, and continuing in descending order:

(i) Proposals that address topics not otherwise covered by more highly-ranked proposals, will be considered to have the highest priority.

(ii) These proposals will themselves be prioritised according to the scores they have been awarded for the criterion *excellence*. When these scores are equal, priority will be based on scores for the criterion *impact.* In the case of Innovation actions this prioritisation will be done first on the basis of the score for *impact*, and then on that for *excellence*.

If necessary, any further prioritisation will be based on the following factors, in order: size of budget allocated to SMEs; gender balance among the personnel named in the proposal who will be primarily responsible for carrying out the research and/or innovation activities.

If a distinction still cannot be made, the panel may decide to further prioritise by considering how to enhance the quality of the project portfolio through synergies between projects, or other factors related to the objectives of the call or to Horizon 2020 in general. These factors will be documented in the report of the Panel.

(iii) The method described in (ii) will then be applied to the remaining *ex aequos* in the group.

H. Budget flexibility

Budgetary figures given in this work programme are indicative. Unless otherwise stated, final budgets may vary following the evaluation of proposals. The final figures may vary by up to 20% with respect to those indicated in this work programme for the following budgeted activities:

- Total expenditure for each call for proposals;
- Any repartition of the call budget within a call, up to 20% of the total expenditure of the call;
- Evaluation and monitoring, up to 20% of the total expenditure for all these activities;
- Each other individual action not implemented through calls for proposals

I. Classified Information

In the case of actions involving security-related activities special provisions for classified information (as defined in Commission Decision 2001/844/EC, ECSC, Euratom) will be taken in the grant agreement, as necessary and appropriate.

Proposals should not contain any classified information. However, it is possible that the output of an action ('Foreground') needs to be classified, or that classified inputs ('Background') are required. In such cases proposers have to ensure and provide evidence of the adequate clearance of all relevant facilities. Consortia have to clarify issues such as e.g. access to classified information or export or transfer control with the national authorities of their Member States/Associated Countries prior to submitting the proposal. Proposals need to provide a draft security classification guide, indicating the expected levels of classification. Appropriate arrangements will have to be included in the consortium agreement.

Topics in the work programme that are most likely to lead to classified projects include the following reference:

"Projects addressing this topic may involve the use of classified background information (EU or national) or the production of security sensitive foreground information. As such, certain project deliverables may require security classification. The final decision on the classification of projects is subject to the security evaluation."

This applies primarily to the Secure Societies challenge, but the provisions may appear in other parts. These references do not however preclude a different assessment following the security scrutiny. To that effect positively evaluated proposals involving sensitive or classified information will be flagged to the members of the Secure Societies Programme Committee configuration and dealt with according to its Rules for Procedure.

J. Financial support to third parties

Where this possibility is indicated under the relevant topic, proposals which foresee a financial support to third parties[42] shall clearly detail the objectives and the results to be obtained and include at least the following elements:

- a closed list of the different types of activities that qualify for financial support,

- the persons or categories of persons which may receive financial support,

- the criteria for awarding financial support

- the criteria for calculating the exact amount of the financial support,

- the maximum amount to be granted to each third party (may not exceed EUR 60 000 for each third party unless it is necessary to achieve the objectives of the action)

The financial support may also take the form of a prize awarded following a contest organised by the beneficiary.

In such case proposals shall clearly detail at least the following elements:

- the conditions for participation;

- the award criteria;

- the amount of the prize;

- the payment arrangements.

Further boundary conditions regarding the above listed elements or other elements may be laid down in the relevant call allowing a financial support to third parties.

The grant beneficiary must ensure that recipients of the financial support allow the Commission, the European Anti-fraud Office and the Court of Auditors to exercise their powers of control, on documents, information, even stored on electronic media, or on the final recipient's premises.

[42] Art 137 of the Financial Regulation

Annex 2: Consortium members for fusion programme co-fund grant

List of legal entities nominated by Member States or Associated countries to participate in the Fusion Joint Programme in accordance with Annex 1, point (i) of the Council Regulation on the Research and Training Programme (2014-18) of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 - The Framework programme for Research and Innovation. This list may be amended in the grant agreement if a Member State or Associated country decides to designate a different participant.

Member state and Associated state	**Address of participating entity**
Austria	Österreichische Akademie der Wissenschaften, Kegelgasse 27/13, 1030 Wien
Belgium	Ecole Royale Militaire, Laboratoire de Physique des Plasmas, 30, Avenue de la Renaissance, B - 1000 Bruxelles (to be confirmed)
Bulgaria	Institute for Nuclear Research and Nuclear Energy - Bulgarian Academy of Science, Boul. Tzarigradsko Chaussee 72 BG - 1784 Sofia
Croatia	"Ruder Boskovic" Institute Bijenicka 54, HR-10000 Zagreb, Croatia
Cyprus	Dept. of Mechanical and Manufacturing Engineering, University of Cyprus Kallipoleos St., PO Box 20537 CY -1678 Nicosia
Czech Republic	Institute of Plasma Physics, Academy of Sciences of the Czech Republic Za Slovankou 3, CR-182 00 Praha 8
Denmark	Technical University of Denmark, Department of Physics DTU Risø Campus Frederiksborgvej 399, P.O. Box 49 Building 129, DK-4000 Roskilde
Estonia	University of Tartu, Institute of Physics 142 Riia Street, EE - 51014 Tartu

Finland	Tekes, Finnish Funding Agency for Technology and Innovation Kyllikinportti 2, Helsinki P.O. Box 69 FIN-00101 HELSINKI
France	Institut de Recherche sur la Fusion par confinement Magnétique (IRFM), CEA - Cadarache F - 13108 Saint Paul Lez Durance CEDEX
Germany	Forschungszentrum Jülich GmbH, Institut für Plasmaphysik Postfach 1913, D - 52425 Jülich
	Karlsruhe Institute of Technology, Campus Nord Hermann-von-Helmholtz-Platz 1, D – 76344 Eggenstein-Leopoldshafen
	The Max-Planck Institut für Plasmaphysik, Boltzmannstrasse 2 85 748 Garching (Coordinator of the consortium)
Greece	National Technical University of Athens School of Electrical and Computer Engineering 9, Iroon, Polytechniou St. GR – 157 73 Zografou - Athens
Hungary	Hungarian Academy of Sciences Wigner Research Centre for Physics P.O. Box 49 HU-1525 Budapest
Ireland	Plasma Research Laboratory, Dublin City University – DCU, Glasnevin EI - Dublib
Italy	ENEA - C.R.E. Frascati, Via Enrico Fermi 45, C.P. 65 I - 00044 Frascati (Roma)
Latvia	Institute of Solid State Physics, University of Latvia 8 Kengaraga Str., LV - 1063 Riga
Lithuania	Lithuanian Energy Institute 3 Breslaujos str., LT-44403 Kaunas
Luxembourg	GRADEL S.A., 38 route de Luxembourg, L-8440, Steinfort
Malta	
Netherlands	DIFFER – Dutch Institute for Fundamental Energy Research Edisonbaan 14, Postbus 1207 NL - 3430 BE Nieuwegein
Poland	The Institute of Plasma Physics and Laser Microfusion IPPLM 23 Hery street, 01-497 Warszawa
Portugal	Instituto de Plasmas e Fusão Nuclear, Instituto Superior Técnico Av. Rovisco Pais, 1049-001 Lisboa

Romania	National Institute for Laser, Plasma and Radiation Physics Atomistilor, No. 409, PO Box MG-36, 077125 Magurele, Bucharest,
Slovakia	Faculty of Mathematics and Physics Comenius University Mlynska dolina F-2 SK - 842 15 Bratislava
Slovenia	Jozef Stefan Institute Jamova 39, SL - 1000 Ljubljana
Spain	Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas (CIEMAT) Avenida Complutense 40 E - 28040 Madrid
Sweden	Vetenskapsrådet Klarabergsviadukten 3 Box 1035, SE-101 38 Stockholm
The Swiss Confederation	Ecole Polytechnique Fédérale de Lausanne EPFL CRPP Bâtiment PPB Station 13 CH CH - 1015 Lausanne
United Kingdom	The United Kingdom Atomic Energy Authority Culham Centre for Fusion Energy, Culham Science Centre GB - Abingdon, OX14 3DB

EUROPEAN
COMMISSION

Brussels, 10.12.2013
C(2013) 8201 final

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for Fusion programme co-fund action under the Research and Training Programme of the European Atomic Energy Community (2014-2018)

COMMISSION DECISION

of 10.12.2013

authorising the use of reimbursement on the basis of unit costs for Fusion programme co-fund action under the Research and Training Programme of the European Atomic Energy Community (2014-2018)

THE EUROPEAN COMMISSION,

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to the Council Regulation on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 - The Framework Programme for Research and Innovation, and in particular Articles 6 and 7 thereof,

Having regard to the Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), and in particular Articles 21, 24 and 27 thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union (hereinafter referred to as the 'Financial Regulation'), and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012[1] contains detailed rules regarding unit costs,

(2) Simplification as a central aim of the Euratom Programme complementing Horizon 2020 needs to be fully reflected in its design, rules, financial management and implementation,

(3) Simpler funding rules reduce the administrative costs for participation in the Fusion programme co-fund action and contribute to the prevention and reduction of financial errors. In this respect, the use of unit costs is necessary to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures,

(4) The use of a unit costs should therefore be authorised to reimburse costs for mobility of personnel, costs of fellowships for researchers and costs of access to research infrastructures in Euratom Fusion programme co-fund action,

[1] Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

HAS DECIDED AS FOLLOWS:

Article 1

The use of a grant for reimbursement of eligible costs declared by beneficiaries on the basis of unit costs is authorised for the Fusion programme co-fund action under the Euratom Programme complementing Horizon 2020, for the reasons and under the conditions set out in the Annex.

Article 2

This Decision is subject to the final adoption of the Council Regulation establishing the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation by the legislative authority without significant modifications.

Done at Brussels, 10.12.2013

For the Commission
Máire Geoghegan-Quinn
Member of the Commission

EN

ANNEX

1. Forms of grant and categories of costs covered

The grant for the Euratom Fusion programme co-fund action shall take the form of reimbursement of eligible costs declared by beneficiaries:

(a) on the basis of unit costs for the eligible costs of mobility of personnel;

(b) on the basis of unit costs for the eligible costs of fellowships for researchers;

(c) either on the basis of unit costs or as costs actually incurred for the eligible access costs to research infrastructures. For one *installation,* the eligible access costs shall be declared either on the basis of unit costs or as actually incurred. No combination is allowed.

The categories of eligible costs to be declared on the basis of the unit costs are set out in point 1.1 for the eligible costs of mobility of personnel, in point 1.2 for the eligible costs of fellowships for researchers and point 1.3 for the eligible access costs to research infrastructures.

Other categories of eligible costs than those referred to in points 1.1, 1.2 and 1.3 shall be reimbursed on the basis of eligible costs actually incurred or, for other direct personnel costs, on the basis of unit costs or, for indirect costs, flat-rate financing.

The amounts of the unit costs to be declared for the mobility of personnel shall be calculated in accordance with the method described in point 3.1 and are set out in point 3.1. They shall be updated in accordance with the method in point 3.1 through an amendment of the grant agreement.

The amounts of the unit costs to be declared for the fellowships for researchers shall be calculated in accordance with the method described in point 3.2 and are set out in point 3.2.

The amounts of the unit costs to be declared for the access to research infrastructures shall be calculated in accordance with the method described in point 3.3 and shall be specified in the grant agreement to be used throughout the duration of the action. In exceptional and duly justified cases, they may be updated (with the agreement of the Commission and in accordance with the method in point 3.3) through an amendment of the grant agreement.

1.1 Costs for mobility of personnel

The **unit costs of mobility of personnel** cover the following categories of costs:

- a daily subsistence allowance to cover for the costs of living payable to the individual (employee of the beneficiary) who is seconded to a different research institution than the one of the beneficiary where she/he has an employment contract or a contract with full social security coverage,
- a monthly subsistence allowance payable to the individual (employee of the beneficiary) who is seconded to a different research institution than the one of the beneficiary where she/he has an employment contract or a contract with full social security coverage to cover for the costs of housing,

- a monthly family allowance (per child) to be paid to the seconded personnel that has children following a primary or secondary education courses to cover for the tuition fees of the children.

The management costs for the mobility of personnel shall be reimbursed on the basis of eligible costs actually incurred.

The 25% flat-rate financing for indirect costs shall not apply to the unit costs for the mobility of personnel.

Costs of mobility of personnel declared as unit cost shall be **eligible** if:

(i) they correspond to the amount per unit set out in the estimated budget of the action (Annex 2 to the grant agreement) multiplied by the number of actual days or months of secondment and

- the secondment is made to a location other than the employee of beneficiary' place of employment and

- is made to one of the following:

  - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation;

  - another beneficiary where the researcher carries out research activities described in Annex 1 or 7, or

  - a joint support unit created by the beneficiaries under the action;

(ii) the costs have been fully incurred for the benefit of the seconded personnel.

1.2 Costs for fellowships for researchers

The unit costs for fellowships for researchers cover the following categories of costs:

- living allowances payable to the individual early-stage or experienced researchers recruited under an employment contract/ contract with full social security coverage by the beneficiary and complying with the social security legislation applicable[1]. These amounts include all compulsory deductions under national applicable legislation,
- a mobility allowance payable to the individual researcher to cover additional mobility-related costs such as travel and accomodation,
- a family allowance payable to the individual eligible researcher to reduce family-related obstacles to researcher mobility.

The management costs for the fellowships for researchers shall be reimbursed on the basis of eligible costs actually incurred.

The 25% flat-rate financing for indirect costs shall not apply to the unit costs for the fellowships for researchers.

[1] Council Regulation (EC) N° 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 and Corrigendum, OJ L 200, 7.6.2004, p. 1 (883/2004).

Costs of fellowships for researchers declared as unit cost shall be **eligible** if:

(i) they correspond to the amount per unit set out in the estimated budget of the action (Annex 2 to the grant agreement) multiplied by the number of actual months spent by the fellows on the research training activities;

(ii) the costs have been fully incurred for the benefit of the fellows.

1.3 Costs of access to research infrastructures

The unit costs for access to research infrastructures cover the eligible *access costs,* as defined below, for providing access to research infrastructure to other beneficiaries:

- Direct costs for providing access to the *installation*:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the *installation* and to the support of the users,
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the *installation*,
  - costs of consumables specifically used for the installation and the research work of the users,
  - costs of contracts for *installation* management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the *installation*;
  - costs of energy power and water supplied for the installation,
  - costs of general services when they are specifically included in the provided access services (library costs, shipping costs),
  - costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services,
  - costs of specific scientific services included in the access provided or needed for the provision of access,
  - depreciation costs of the equipment, buildings and other assets (new or second-hand) that are part of the *installation* and that were not purchased or built using Union funds as well as the costs of renting or leasing the equipment, buildings and other assets that are part of the *installation*,
- Indirect costs for the access to the *installation,*

but excluding

- travel and subsistence costs to support the visits of users. Those costs shall be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs".

For the access costs to research infrastructures, the following definitions shall apply:

1) "installation": means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more *installations*.
2) "access provider": means a *beneficiary* or *linked third party* that is in charge of providing access to one or more research infrastructures *or installations*, or part of them, as specified in Annex I to the grant agreement.
3) "user group": means a research team of one or more researchers to whom access to the *installation is* given under the action covered by the *grant agreement*.

4) "access costs": are the costs incurred by the *access provider* for the provision of access. They cover the running costs of the *installation* and the costs for logistical, technological and scientific support to users' access, including costs for ad-hoc training needed by users to use the *installation* and for preparatory and closing activities that may be necessary to carry out user's work on the *installation*. Travel and subsistence costs incurred by users to have access to the *installation* are not included in the *access costs*.

Costs of access to research infrastructure declared one the basis of unit costs shall be **eligible** if they correspond to the amount per unit set out in the estimated budget of the action (Annex 2 to the grant agreement) multiplied by the number of actual units of access provided to other beneficiaries.

2. Justification

2.1 Nature of the supported actions

Euratom Fusion programme co-fund action will be an important research effort whose objective is the implementation of the roadmap to fusion electricity through a joint pooling of resources for building in the future the DEMO device that could generate electricity for the grid by 2050. Therefore, it will involve researchers from all the Member States and associated third countries such as Switzerland that will need to join their efforts and participate in joint experimental campaigns at different locations. It will also require the exploitation of different research infrastructures, from the Member States and from associated third countries, which were identified in the fusion roadmap as important for the development of fusion research.

Recurring to unit costs considerably simplifies, streamlines and reduces the time needed for the financial management of projects, both at Commission as well as beneficiary level. Compared to the 'traditional' system of calculating the grant amount on a detailed budget of eligible costs per cost category, a unit-costs system is not only more cost-effective and economically sound than item-based budgeting: it significantly shortens the time needed to calculate grant amounts, avoids amendments related to budget variations and substantially decreases the number of recovery orders and de-commitments. It also significantly decreases the workload of the management body and consequently speeds up the payment procedure. Furthermore, it implies additional simplifications at beneficiary level in terms of both application and reporting requirements.

In summary, this approach provides simplification through:

- less complex funding rules contributing to easier readability of actions;
- greater predictability for grant beneficiaries making the actions more attractive;
- less administrative burden for checking at the payment stage reducing overheads for the contracting authority and facilitating productivity gains;
- simplified reporting requirements (no certification or financial statement to be provided by beneficiaries);
- easier ex-post analysis (riders related to budget variations will be avoided; payment based on predetermined output or result) and further reductions of the risk of error.

Considering the complexity and the novelty of the Fusion programme co-fund action, it is recommendable to offer to the beneficiaries the possibility to use unit costs for declaring eligible costs under those categories that could otherwise lead to complicated calculations and might deter the beneficiaries from doing certain activities such as going on mobility.

Therefore, the use of unit costs is suitable for these activities because it increases predictability for the beneficiaries and consequently increases the attractiveness of the action.

2.1.1 Mobility of personnel

The implementation of the fusion roadmap requires that researchers from all the Members States that take part in the fusion joint programme should be able to participate actively in joint activities and to experiments at the fusion research facilities existing in the Member States or in associated third countries such as Switzerland. In addition, the scientific exploitation of the JET facilities that the Commission entrusted to the beneficiaries of fusion joint programme will require the presence of researchers from all the Member States and associated third countries as Switzerland to come to Culham and stay during long periods while the experiments take place. In addition, the technical follow up of the joint programme will require setting up support units that will assist the programme manager. It is important that the personnel that will collaborate in these research units are selected based on their qualifications and a simplified system for payment of their living costs during the period they are on mobility is in place, ensuring also their equal treatment as far of those costs of living are concerned.

In this respect, it is important to have a mobility scheme in the joint programme for personnel of the beneficiaries that need to be seconded to a location different from his/her place of employment, such as when:

- the researcher is seconded to an organisation different than her/his employer, for taking part in experiments to be done in the research infrastructure managed by this organisation;

- the researcher is seconded to another beneficiary for carrying out research activities provided in Annex I of the grant;

- the personnel is seconded to the support units that the Consortium may create for assisting the programme manager in the implementation of the joint programme.

As for the method of calculation of the unit costs for subsistence allowances, it was decided to use one similar to that applied for the secondment to the Commission of national experts[2], considering that, as in those cases, the personnel of the participants to the fusion joint programme working at another location is seconded in the interest of the service.

Therefore, it is proposed that the person on mobility shall receive a specific subsistence daily allowance and a monthly subsistence allowance as well as a monthly family allowance to cover for the costs for tuition fees of the schooled children. This family allowance does not apply for national experts referred to in Commission Decision C(2008)6866 because the right of the seconded national experts to enrol their children in European schools covers it. Since this right could not be conferred on the personnel of the beneficiaries of the Consortium, it is proposed that a family allowance covers the costs for the tuition fees for enrolling the children in European schools or other schools. To calculate the value of this family allowance it is used the value of the education allowance accorded to Euratom civil servants and other servants of the Euratom according to the Staff Regulations[3]. The reason for using the education allowance as a model for calculating the family allowance is that both fulfil the same

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[2] Commission Decision C(2008)6866 of 12.11.2008 laying down rules on the secondment to the Commission of national experts and national experts in professional training.

[3] Regulation no.31 (EEC), 11(EAEC) laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community.

objective, respectively to cover for the education costs incurred for enrolling the children to a school similar to the European School.

The advantages of using for the calculation of the unit costs for mobility of personnel in the fusion joint programme the same system of allowances used by the Commission for seconded national experts and adding it the value of the education allowance used by the Commission are that they are based on trustworthy statistical data that the Commission itself uses to determine the amount for secondment and education allowances. This way it is ensured the reliability of the statistical data used for the calculation of unit costs and of the method of calculation.

To ensure purchasing power parity for researchers working all over the Member States, the daily and monthly subsistence allowances are subject to a country-specific correction coefficient that are used by the Commission for calculating the daily subsistence allowance for seconded national experts and that are fixed by the Council according of the Article 64 of the Staff Regulations.

For the unit costs for the mobility of personnel to be eligible, beneficiaries will be required to incur the full unit costs (sum of the daily and monthly subsistence and family allowances) for the exclusive benefit of the seconded personnel.

2.1.2 Fellowship for researchers

The operation of DEMO device will require that professionals with specific training are available to run and maintain the device. For this reason, it is necessary that in parallel with the development of the knowledge for the building of DEMO device, qualified people be trained for the operation in the future of DEMO. Therefore, a system of fellowships similar to that used for Marie Skłodowska-Curie ITN and IF fellowships that ensures the mobility of researchers at the different research infrastructures but that is meant for goal oriented training shall be in place under Horizon 2020. This system of training already existed under the previous Euratom Framework Programme (FUSENET project) ensuring that a critical mass of fusion researchers are available for running the DEMO device when it will function. The use of unit costs for fellowships similar to the ones used by the Marie Skłodowska-Curie system ensures that reliable statistical data exist for the calculation of the unit costs and that the same structure of research unit costs applies as in the case of Marie Skłodowska-Curie fellowships.

As for Marie Skłodowska-Curie fellowships, for the unit costs for living, mobility and family allowances to be eligible, beneficiaries shall continue to be required to incur the full researcher unit costs (sum of the living, mobility and family allowances) for the exclusive benefit of the researchers.

2.1.3 Access to research infrastructures

The fusion roadmap indicated several research infrastructures that need to be exploited for ensuring that all the alternatives for producing fusion energy are taken into account. For ensuring that these infrastructures are available for the research experiments requested for the implementation of the activities under the fusion joint programme, it is proposed that the costs for the use of these infrastructures during the experiments necessary for the implementation of the joint programme can be reimbursed as unit costs per unit of access to these research infrastructures. For the calculation of these unit costs it will be used the same methodology proposed in Horizon 2020 for the calculation of unit costs for access to research infrastructures.

As some components of the *access costs* to the *installation* that form the research infrastructures are caused only in part by the activities of the joint programme (e.g. the running costs of the *installation*), it is not always possible to directly identify the specific *access costs* related to the provision of access under the grant for the activities of the fusion joint programme. Therefore, a method to measure the use of the *installation* by the fusion joint programme must be defined to calculate the part of the *access costs* that can be attributed to the fusion joint programme for the access it provides. This method is given in point 3. The use of this method for the calculation of access to the research infrastructures will simplify for the participants the calculation of their costs being in line with the simplification purposes of Horizon 2020.

2.2. Risks of irregularities and fraud and costs of control

The risks of irregularities and fraud regarding the data used by the participants to establish the unit costs are very low considered that all the beneficiaries are public research organisations having their financial statements regularly analysed and certified by external or public auditors. Point 1 and the methodology in point 3 define precisely cost items to be used for the calculation of the unit costs, as well as the conditions under which they can be used.

Also, for the unit costs for mobility, the use of the Commission system for seconded experts will avoid that the costs included in the calculation are arbitrary or established in a fraudulent manner. The use of a simplified method to calculate the allowances for people on mobility will ensure compliance with the recommendations of the internal audit report on fusion that suggested simplifying the rules for determination of the payment of EU contribution to allow easier checking and avoid double funding.

As for the unit costs for fellowships, the verification of the outputs will be focused on the realisation of the supported activities and the achieved results. In addition, it has been demonstrated by the seven-year period of the 7th Framework Programme for Research and Development (FP7) that the system of Marie Skłodowska-Curie rates proved to be very resistant to irregularities and fraud. For this reason, it was decided to use the same system for Fusion training programme under the FUSENET project in Euratom 7th Framework Programme and to continue it in the fusion joint programme under Horizon 2020.

Regarding unit costs for access to research infrastructures, the access costs to be charged to the grant will be easily identified by multiplying the unit costs by the number of units of access provided for the joint programme. The costs of ex-post control will be minor as only records of access provisions must be verified as well as, in order to avoid double funding, the non-existence of other Union funding sources specifically covering the access supported under the Fusion programme co-fund action.

In conclusion the use of a simplified method to support access costs appears appropriate.

3. Method to determine the amounts and update the amounts

3.1. Mobility unit costs

In order to determine the amounts of the mobility unit costs, it will be taken into account the value of the allowances paid according to the rules on secondment to the Commission of national experts and national experts in professional training provided providing by the Commission Decision C(2008)6866 of 12.11.2008 and the values of the education allowance paid to Euratom civil servants and other servants of Euratom according to the EU Staff

Regulations. Since this system has not been applied before, it takes as a reference the values applying on 1 October 2013.

According to this Commission Decision, the daily subsistence allowance is of EUR 127.65.

The monthly subsistence allowance varies according to the distance between the place where the employee was working for his/her employer at the time of secondment and the place of secondment.

Distance between place of employment and place of secondment (km)	Amount in euros
0 – 150	0
> 150	82.05
> 300	145.86
> 500	237.05
> 800	382.92
> 1300	601.73
> 2000	720.27

The place of employment is the location where the employee was performing his or her work before his or her secondment.

The monthly subsistence allowance is due for each full month spent on secondment (no pro-rata is allowed).

The daily and monthly subsistence allowances do not include the salary that the employee receives from his employer and any indirect costs.

The family allowance will be calculated based on education allowance paid by the Commission to the Euratom civil servants and other servants of Euratom. It will be paid to the employee who is accompanied during the secondment by his or her dependent children who are enrolled in a regular full-time attendance at a primary or secondary school for each full month spent on secondment (no pro-rata is allowed) and for each dependent child that is at the moment of secondment at least 5 years old and no more than 18 years old and is in regular full-time attendance at a primary or secondary school that charges fees (registration and attendance fees). The family allowance shall cover the registration and attendance fees at educational establishments. The amount will be of EUR 252.81 per month for each dependent child, such as it is applies for Euratom civil servants and other servants of Euratom, at the value applies in 1 October 2013.

The unit costs will be expressed in person-months and corresponding to the country-specific correction factor of 100% applicable to Belgium and Luxembourg.

To ensure purchasing power parity for researchers working at different facilities in the Member States or associated third countries, the daily and monthly subsistence allowances are subject to a country-specific correction coefficient pursuant to Article 64 of the Staff

Regulations. The applicable coefficient is the one applicable at 1 October 2013. This country-coefficient will be revised after 2 years on the basis of the cooeficient applicable on 1 October 2015 to make sure that employee' purchasing power parity stays comparable irrespective of the country they are seconded. The revised amounts will be applicable as from 1 January 2016 through an amendment to the grant agreement and it will be applied until the end of the grant agreement. The allowances shall be payable for periods of mission, annual leave, special leave, sick leave and holidays.

As a method of revision and in order to guarantee continuity and stability, the Commission reserves the right to automatically update the above unit costs once the joint index based on national Belgian and Luxembourg inflation[4] deviates from the 2014 baseline inflation index by 10%.

3.2. Unit costs for fellowships for researchers

The unit costs for fellowships are calculated according to the method used by Marie Skłodowska-Curie actions under Horizon 2020 for calculating researchers unit costs. Their value is calculated based on the seven-year average of the Marie Curie rates applicable under FP7, the MORE2 study and the findings of the FP7 Marie Curie actions interim evaluation. The use of this method is due to the fact that it provides reliable historical data of eligible costs and that, as for Marie Skłodowska-Curie actions, beneficiaries are required to incur those allowances for the exclusive benefit of the researchers.

Therefore, the following unit costs, expressed in person-months and corresponding to the country-specific correction factor of 100% applicable to Belgium and Luxembourg, shall be applicable for fellowships selected as of 1 January 2014 under the Fusion programme co-fund action:

- Living allowance payable to the individual early-stage or experienced researchers recruited under an employment contract/contract with full social security coverage and complying with the social security legislation applicable[5]. These amounts include all compulsory deductions under national applicable legislation.

  The living allowance for experienced researchers eligible for an individual fellowship is fixed at EUR 4 650. The living allowance for early-stage researchers is fixed at EUR 3 110.

  To ensure purchasing power parity for researchers working in different Member States or associated third countries, the above living allowance is subject to a country - specific correction coefficient. The applicable coefficient is the 7-year average of the respective country-specific coefficient used between 2007 and 2013 for the FP7 Marie Curie Actions. The automatic revision after 4 years of the average country-coefficient as foreseen for the Marie Skłodowska-Curie actions under Horizon 2020 does not apply to the unit costs for fellowships for researchers under the fusion joint programme.
- The mobility allowance which is fixed at EUR 600.
- The family allowance which is fixed at EUR 500.

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4 As used for the Method for adjusting salaries and pension of Union staff.

5 Council Regulation (EC) N° 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 and Corrigendum, OJ L 200, 7.6.2004, p. 1 (883/2004).

The unit costs for fellowships for researchers will be set as the sum of the living and mobility allowances listed above, and, if applicable, the family allowance.

The above unit costs do not include any management costs or indirect costs.

3.3. Unit costs of access to research infrastructures

In order to measure the quantity of access to the *installation* supported under the fusion joint programme, the *access provider* will identify a unit of access to the *installation*. This unit of access shall also be used to measure the total quantity of access that the *installation* provides to all its users.

When eligible *access costs* for an *installation* are reimbursed on the basis of unit costs, the unit cost of a unit of access to the *installation* shall be agreed between the Commission and the *access provider.*

The unit cost shall be specified in the grant agreement and shall be defined on the basis of the average over the last two years[6] of the annual total *access costs* to the *installation* for the categories covered by the unit costs, divided by the average over the last two years[7] of the total quantity of access to the *installation* annually provided, as follows:

$$\textbf{Unit costs} = \frac{\textbf{average annual total } \textit{access costs} \textbf{ to the } \textit{installation}}{\textbf{average total quantity of access to the } \textit{installation} \textbf{ annually provided}}$$

The average amounts shall be based on certified or auditable historical data of the beneficiary (or the linked third party) over the last 2 years (years N-1 and N-2)[8] and allocated to the concerned installation according to the beneficiary's usual cost accounting practices in case the installation has less than 2 years of operation. The average over the last two years of the access costs and quantity of access to the installation shall not include periods where the *installation* was not usable because out of order, or under repair or maintenance.

For the calculation of the unit costs:

- The 'total quantity of access to the *installation*' shall include all the units of access annually provided by the access provider to the *installation* for performing the activities described in Annex I of the grant agreement.
- The 'total *access costs* to the *installation*' shall be:
    - the direct costs incurred by the beneficiary (or its linked third party) for the provision of access to the *installation*, as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2)[9] for all the categories of eligible direct costs referred to in point 1. By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices.
    - the eligible indirect costs for the access to the *installation*, equal to 25% of the direct costs referred to above minus any costs of subcontracting (amounts referred to above for the categories "costs of contracts for maintenance and repair", "costs of contracts for installation management", "costs of scientific services" and "cost for other electronic services").

[6] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[7] In exceptional and duly justified cases, the Commission may agree to use a different reference period
[8] In exceptional and duly justified cases, the Commission may agree to use a different reference period
[9] Unless exceptionally agreed otherwise by the Commission.

The *access costs* to the *installation* shall exclude the depreciation costs of the infrastructure if its purchase or building was supported by Union funds as well as travel and subsistence costs to support the visits of users (see point 1).

4. No-profit and co-financing principles and absence of double financing

The methodologies described in point 3 comply with the principles of no-profit, co-financing and absence of double funding as required by Regulation (EC, Euratom) No 966/2012 .

The activities funded under the fusion joint programme are not expected to generate revenue or to be specifically funded by third donors. Furthermore, the unit costs for mobility and fellowships correspond to the minimum costs to be incurred by the benefciaries. Finally, for access unit costs, the calculation of the unit costs is based on certified or auditable historical eligible costs incurred by the beneficiaries to provide access.

The use of units of costs is respecting the principle of co-financing because according to the Euratom Work Programme by being subject to the maximum reimbursement rate of 70% of the total eligible costs of the programme co-fund action.

Double funding is avoided by the specification/identification of eligible costs detailed in point 1.

The main risk of double financing concerns the financing of the same costs for the operation of the research infrastructure from different Union funding sources. However, with the methodology put in place that accounts only for the units of use of the research infrastructure for the fusion joint programme, this risk is low. Furthermore, the Commission shall check thoroughly whether the costs of building the infrastructure have been supported by the Union and, if so, that the depreciation costs have not been taken into account by the beneficiary under the Fusion programme co-fund action.

Ref. Ares(2019)533012 - 30/01/2019

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

The Director-General

DECISION

authorising the use of unit costs for the Fusion programme co-fund action under the Research and Training Programme of the European Atomic Energy Community 2019-2020

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to the Council Regulation (Euratom) 2018/1563 of 15 October 2018 on the Research and Training Programme of the European Atomic Energy Community (2019-2020)[1] complementing the Horizon 2020 Framework Programme for Research and Innovation, and repealing Regulation (Euratom No 1314/2013), and in particular Articles 6 and 7 thereof,

Having regard to the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)"[2] , and particular Articles 25 and 33 thereof,

Having regard to Regulation (EU, Euratom) No 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union[3], and in particular Articles 125 and 181 thereof,

Whereas:

(1) Commission Decision C(2013) 8201 authorised the use of unit costs for the fusion programme co-fund action to facilitate the mobility of researchers in the programme for the implementation of the fusion roadmap and the access to research infrastructures;
(2) The 2019-2020 Euratom Programme has the same objectives as the Euratom Programme 2014-2018 and thus the programme co-fund action through the EUROfusion grant will be continued;
(3) It is necessary to maintain in the programme the same level of mobility of researchers and access to research infrastructures.

THE FOLLOWING HAS BEEN DECIDED:

Article 1

The use of eligible costs declared by recipients of Union funds on the basis of unit costs for the Fusion programme co-fund action is authorised under the Research and Training Programme of the European Atomic Energy Community (2019-2020), for the reasons and under the conditions set out in the Annex.

[1] OJ L 262, 19.10.2018, p.1.
[2] OJ L 347, 20.12.2013, p. 81.
[3] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p.1).

Article 2

The decision shall apply from 1 January 2019.

Done at Brussels,

Jean-Eric Paquet

Annex

1. Forms of Union contribution and categories of costs covered

Recipients of Union funds in the Fusion programme co-fund action (Grant Agreement – 633053), under the Research and Training Programme of the European Atomic Energy Community (2019-2020), shall declare the eligible costs on the basis of the following:

(a) unit costs for the eligible costs of mobility of personnel;

(b) either unit costs or as costs actually incurred for the eligible access costs to research infrastructures. For one installation, the eligible access costs shall be declared either on the basis of unit costs or as actually incurred. No combination is allowed.

Other categories of costs shall be reimbursed on the basis of eligible costs actually incurred or:

– for other direct personnel costs: on the basis of unit costs where applicable;

– for indirect costs: flat-rate financing.

The categories of eligible costs covered by the unit costs referred in poinst (a) and (b) above are set out in point 1.1 for the eligible costs of mobility of personnel and point 1.2 for the eligible access costs to research infrastructures.

The amounts of the unit costs to be declared for the mobility of personnel shall be calculated in accordance with the method described in point 3.1. They shall be updated in accordance with the method in point 3.1 through an amendment of the grant agreement.

The amounts of the unit costs to be declared for the access to research infrastructures shall be calculated in accordance with the method described in point 3.2 and shall be specified in the grant agreement to be used throughout the duration of the action. In exceptional and duly justified cases, they may be updated (with the agreement of the Commission and in accordance with the method in point 3.2) through an amendment of the grant agreement.

1.1 Unit costs for mobility of personnel

The unit costs related to mobility of personnel within the Fusion programme co-fund action include the following categories of costs:

- a daily subsistence allowance to cover for the costs of living payable to the individual (employee of the beneficiary) who is seconded to a different research institution than the one of the beneficiary where she/he has an employment contract or a contract with full social security coverage,
- a monthly subsistence allowance payable to the individual (employee of the beneficiary) who is seconded to a different research institution than the one of the beneficiary where she/he has an employment contract or a contract with full social security coverage to cover for the costs of housing,
- a monthly family allowance (per child) to be paid to the seconded personnel that has children following a primary or secondary education courses to cover for the tuition fees of the children.

The management costs for the mobility of personnel shall be reimbursed on the basis of eligible costs actually incurred.

The 25% flat-rate financing for indirect costs shall not apply to the unit costs for the mobility of personnel.

Costs of mobility of personnel declared as unit cost shall be eligible if:

(i) they correspond to the amount per unit set out in the estimated budget of the action (Annex 2 to the grant agreement) multiplied by the number of actual days or months of secondment and

- the secondment is made to a location other than the beneficiary's employee place of employment and

- is made to one of the following:

  - an organisation where the researcher takes part in experiments using a research infrastructure of that organisation,

  - another beneficiary, to the ITER Organization or to the European Joint Undertaking for ITER and the Development of Fusion Energy (Fusion for Energy), where the researcher carries out research activities described in Annex 1 or 7,

  - a joint support unit created by the beneficiaries under the action.

(ii) the costs have been fully incurred for the benefit of the seconded personnel.

1.2 Costs of access to research infrastructures

The unit costs for access to research infrastructure cover the eligible access costs, as defined below, for providing access to research infrastructure to other beneficiaries:

- Direct costs for providing access to the installation:
  - personnel costs of administrative, technical and scientific staff directly assigned to the functioning of the installation and to the support of the users,
  - costs of contracts for maintenance and repair (including specific cleaning, calibrating and testing) specifically awarded for the functioning of the installation,
  - costs of consumables specifically used for the installation and the research work of the users,
  - costs of contracts for installation management, including security fees, insurance costs, quality control and certification, upgrading to national and/or EU quality, safety or security standards specifically incurred for the functioning of the installation;
  - costs of energy power and water supplied for the installation,

- costs of general services when they are specifically included in the provided access services (library costs, shipping costs),
- costs of software licence, internet connection or other electronic services for data management and computing when they are needed to provide access services,
- costs of specific scientific services included in the access provided or needed for the provision of access,
- depreciation costs of the equipment, buildings and other assets (new or second-hand) that are part of the installation and that were not purchased or built using Union funds as well as the costs of renting or leasing the equipment, buildings and other assets that are part of the installation,

- Indirect costs for the access to the installation,

but excluding

- travel and subsistence costs to support the visits of users. Those costs shall be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs".

Costs of access to research infrastructure declared on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in the estimated budget of the action (Annex 2 to the grant agreement) multiplied by the number of actual units of access provided to other beneficiaries.

2. Justification

2.1 Nature of the supported actions

The Commission Decision C(2013) 8201 authorised the use of unit costs for the fusion programme co-fund action to facilitate the mobility of researchers in the programme for the implementation of the fusion roadmap and the access to research infrastructures. In accordance with the Annex 1(i) of the Euratom Research and Training Programme 2019-2020, the EUROfusion European Joint Programme (grant agreement – 633053), awarded under Regulation (Euratom) No 1314/2013 will continue to be funded under the Euratom Research and Training Programme 2019-2020. Since the Euratom Programme 2019-2020 has the same objectives as the Euratom Programme 2014-2018 and the programme co-fund action through the EUROfusion grant will be continued, it is necessary to maintain the same level of mobility of the researchers as well as access to research infrastructures.

2.2. Risks of irregularities and fraud and costs of control

The system of unit costs for mobility of researchers and access to research infrastructures was subject to several audits and evaluations in the Euratom Programme 2014-2018. It was proven during the controls that the use of a simplified method of calculation of the allowances for people on mobility simplifies the payment of Union contribution to ensure easier checking and avoid double funding. As for the access to research infrastructures, the ex-post audit controls proved the nonexistence of other Union funding for covering access supported under the Fusion programme co-fund action.

For all these reasons, the use of unit costs for these two types of costs appears appropriate and needs to be continued in the Euratom Programme 2019-2020.

3. Method to determine and update the amount of the Union contribution in the form of unit costs

3.1 Mobility unit costs

Since the Euratom Programme 2019-2020 is a continuation of the previous Programme, it is proposed to use the same method for determining the amounts of the mobility unit costs as in the Commission Decision C(2013) 8201. Accordingly, the unit costs will be calculated based on the allowances paid to the national experts and national experts in professional training provided the Commission Decision C(2008) 6866 of 12.11.2008. As for the values of the education allowance, it was proposed to use the values used for the allowance paid to Euratom civil servants and other servants of Euratom according to the EU staff Regulations. The values in force as of 1 January 2018 are taken as reference values.

The daily subsistence allowance is of EUR 138,15.

The monthly subsistence allowance varies according to the distance between the place where the employee was working for his/her employer at the time of secondment and the place of secondment.

Distance between place of employment and place of secondment (km)	Amount in euros
0 – 150	0
> 150	88.80
> 300	157.86
> 500	256.55
> 800	414.42
> 1300	651.23
> 2000	779.52

The place of employment is the location where the employee was performing his or her work before his or her secondment.

The monthly subsistence allowance is due for each full month spent on secondment (no pro-rata is allowed).

The daily and monthly subsistence allowances do not include the salary that the employee receives from his employer and any indirect costs.

The family allowance will be calculated based on education allowance paid by the Commission to the Euratom civil servants and other servants of Euratom. It will be paid to the employee who is accompanied during the secondment by his or her dependent children. The children has to be enrolled in a full-time attendance primary or secondary school that charges fees (registration and attendance fees). The allowance paid for each full month spent on secondment (no pro-rata is allowed) and for each dependent child that is at the moment of secondment at least 5 years old and no more than 18 years old. The family allowance shall cover the registration and attendance fees at educational establishments. The amount will be of EUR 273, 60 per month for each dependent child.

The unit costs will be expressed in person-months and corresponding to the country-specific correction factor of 100% applicable to Belgium and Luxembourg.

To ensure purchasing power parity for researchers working at different facilities in the Member States or associated third countries, the daily and monthly subsistence allowances are subject to a country-specific correction coefficient pursuant to Article 64 of the Staff Regulations. The applicable coefficient is the one applicable at 1 January 2018. The allowances shall be payable for periods of mission, annual leave, special leave, sick leave and holidays.

3.2. Access to research infrastructures unit costs

In order to measure the quantity of access to the installation, the *access provider* will identify a unit of access to the *installation*. This unit of access shall also be used to measure the total quantity of access that the *installation* provides to all its users.

When eligible *access costs* for an *installation* are reimbursed on the basis of unit costs, the unit cost of a unit of access to the *installation* shall be agreed between the Commission and the *access provider.*

The unit cost shall be specified in the grant agreement and shall be defined on the basis of the average over the last two years[4] of the annual total *access costs* to the *installation* for the categories covered by the unit costs, divided by the average over the last two years[5] of the total quantity of access to the *installation* annually provided, as follows:

$$\textbf{Unit costs} = \frac{\textbf{average annual total } \textit{access costs} \textbf{ to the } \textit{installation}}{\textbf{average total quantity of access to the } \textit{installation} \textbf{ annually provided}}$$

The average amounts shall be based on certified or auditable historical data of the beneficiary (or the linked third party) over the last 2 years (years N-1 and N-2)[6] and allocated to the concerned installation according to the beneficiary's usual cost accounting practices in case the installation has less than 2 years of operation. The average over the last two years of the access costs and quantity of access to the installation shall not include periods where the *installation* was not usable because out of order, or under repair or maintenance.

For the calculation of the unit costs:

[4] In exceptional and duly justified cases, the Commission may agree to use a different reference period.
[5] In exceptional and duly justified cases, the Commission may agree to use a different reference period
[6] In exceptional and duly justified cases, the Commission may agree to use a different reference period

- The 'total quantity of access to the *installation*' shall include all the units of access annually provided by the access provider to the *installation* for performing the activities described in Annex I of the grant agreement.
- The 'total *access costs* to the *installation*' shall be:
    - the direct costs incurred by the beneficiary (or its linked third party) for the provision of access to the *installation*, as recorded in the certified or auditable profit and loss accounts of the reference period (years N-1 and N-2)[7] for all the categories of eligible direct costs referred to in point 1. By way of exception, the direct personnel costs to be used may be those calculated by the beneficiary in accordance with its usual cost accounting practices.
    - the eligible indirect costs for the access to the *installation*, equal to 25% of the direct costs referred to above minus any costs of subcontracting (amounts referred to above for the categories "costs of contracts for maintenance and repair", "costs of contracts for installation management", "costs of scientific services" and "cost for other electronic services").

The *access costs* to the *installation* shall exclude the depreciation costs of the infrastructure if its purchase or building was supported by Union funds as well as travel and subsistence costs to support the visits of users.

4. **Sound financial management and co-financing principles and absence of double financing**

The methodologies described in point 3 comply with the principles of no-profit, co-financing and absence of double funding as required by Regulation (EC, Euratom) No 966/2012.

The activities funded under the Fusion programme co-fund action are not expected to generate revenue or to be specifically funded by third donors. Furthermore, the unit cost for mobility corresponds to the minimum costs to be incurred by the beneficiaries. Finally, for access unit costs, the calculation of the unit costs is based on certified or auditable historical eligible costs incurred by the beneficiaries to provide access.

The use of units of costs is respecting the principle of co-financing because according to the Euratom Work Programme by being subject to the maximum reimbursement rate of 70% of the total eligible costs of the programme co-fund action.

Double funding is avoided by the specification/identification of eligible costs detailed in point 1. The main risk of double financing concerns the financing of the same costs for the operation of the research infrastructure from different Union funding sources. However, with the methodology put in place that accounts only for the units of use of the research infrastructure for the Fusion programme co-fund action, this risk is low. Furthermore, the Commission shall check thoroughly whether the costs of building the infrastructure have been supported by the Union and, if so, that the depreciation costs have not been taken into account by the beneficiary under the action.

[7] Unless exceptionally agreed otherwise by the Commission.

Electronically signed on 30/01/2019 09:11 (UTC+01) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563

EN

HORIZON 2020

WORK PROGRAMME 2014 – 2015

3. Marie Skłodowska-Curie Actions

Revised

This Work Programme was adopted on 10 December 2013. The parts that relate to 2015 (topics, dates, budget) have, with this revised version, been updated. The changes relating to this revised part are explained on the Participant Portal.

(European Commission Decision C (2014)4995 of 22 July 2014)

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Introduction

This part of the Work Programme contributes to developing the new knowledge and enhancing the skills of people behind research and innovation, this being one of the key drivers identified in the strategy for the first three years of Horizon 2020.

The Marie Skłodowska-Curie actions ensure excellent and innovative research training as well as attractive career and knowledge-exchange opportunities through cross-border and cross-sector mobility of researchers, to better prepare them for current and future societal challenges.

The Marie Skłodowska-Curie actions are open to all domains of research and innovation addressed under the Treaty on the Functioning of the European Union, from basic research up to market take-up and innovation services. Research and innovation fields as well as sectors are chosen freely by the applicants in a fully bottom-up manner.

The Marie Skłodowska-Curie actions are open to researchers and innovation staff at all stages of their career, as well as to universities, research institutions, research infrastructures, businesses, and other socio-economic actors from all countries, including third countries under the conditions defined in Horizon 2020 Rules for Participation and in part A of the General Annexes to the Work Programme. Attention is paid to encouraging the strong participation of industry, in particular SMEs, for the successful implementation and impact of the Marie Skłodowska-Curie actions.

The Marie Skłodowska-Curie actions support researchers to establish themselves on a more stable career path and to ensure that they can achieve an appropriate work/life balance, taking into account their family situation. The principles of the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers[1] (Charter and Code) promoting open recruitment and attractive working and employment conditions are recommended to be endorsed and applied by all the funded participants.

Mobility is a key requirement in the Marie Skłodowska-Curie actions. Researchers receive funding on the condition that they move from one country to another to broaden or deepen their competences.

Marie Skłodowska-Curie actions pay particular attention to gender balance. In line with the Charter and Code, all Marie Skłodowska-Curie proposals are encouraged to take appropriate measures to facilitate mobility and counter-act gender-related barriers to it. Equal opportunities are to be ensured, both at the level of supported researchers and that of decision-making/supervision. In research activities where human beings are involved as subjects or end-users, gender differences may exist. In these cases the gender dimension in the research content has to be addressed as an integral part of the proposal to ensure the highest level of scientific quality.

As training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their proposals such activity.

[1] Commission recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, C(2005) 576 of 11.3.2005.

To further enhance dissemination and public engagement, beneficiaries of the Marie Skłodowska-Curie actions are required to plan suitable public outreach activities.

A novelty in Horizon 2020 is the Open Research Data Pilot which aims to improve and maximise access to and re-use of research data generated by projects. While certain Work Programme parts and areas have been explicitly identified as participating in the Pilot on Open Research Data, individual actions funded under the other Horizon 2020 parts and areas can choose to participate in the Pilot on a voluntary basis. The use of a Data Management Plan is required for projects participating in the Open Research Data Pilot. Further guidance on the Open Research Data Pilot is made available on the Participant Portal.

Call for Marie Skłodowska-Curie Innovative Training Networks (ITN)

H2020-MSCA-ITN-2014

Objective:

The Innovative Training Networks (ITN) aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit.

ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced career perspectives in both the academic and non-academic sectors through international, interdisciplinary and intersectoral mobility combined with an innovation-oriented mind-set.

Scope:

ITN supports competitively selected joint research training and/or doctoral programmes, implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs, and other socio-economic actors from different countries across Europe and beyond.

Partnerships take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

Each programme should have a clearly identified supervisory board co-ordinating network-wide training and establishing active and continuous communication and exchange of best practice among the partners to maximise the benefits of the partnership.

The programme should exploit complementary competences of the participants, and enable networking activities, the organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and the career development of researchers.

Training responds to well identified needs in defined research areas, with appropriate references to interdisciplinary fields. It should be primarily focused on scientific and technological knowledge through research on individual, personalised projects.

In order to increase the employability of the researchers, the research training should be complemented by the meaningful exposure of each researcher to the non-academic sector and by substantial training modules addressing key transferable skills common to all fields (e.g. entrepreneurship, management and financing of research activities and programmes, management of intellectual property rights, other exploitation methods of research results, ethical aspects, communication, standardisation and societal outreach). The training follows the EU Principles for Innovative Doctoral Training[2].

In EID and EJD, enrolment in a doctoral programme and the creation of a joint governance structure - with joint admission (EJD only), selection, supervision, monitoring and assessment procedures - is mandatory. In the case of EJD, the successful completion of the programme must result in the award of joint, double or multiple doctoral degrees.

[2] http://ec.europa.eu/euraxess/index.cfm/services/researchPolicies.

Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance. Joint supervision of the researchers is mandatory for EJD and for EID, and encouraged in ETN. In EID, the joint supervision of the researcher must be ensured by at least one supervisor from the academic sector and one supervisor from the non-academic sector.

A Career Development Plan should be established jointly by the supervisor(s) and the early-stage researcher recruited by the selected network. In addition to research objectives, this plan comprises the researcher's training and career needs, including planning for publications and participation in conferences.

Expected impact:

- ITN will create and contribute to high-quality innovative research and doctoral training, build capacity, and have a structuring effect throughout Europe and beyond.
- Through research training provided by the institutions from different countries, sectors and disciplines, this action will trigger cooperation between organisations from the academic and non-academic sectors.
- It will enhance skills development and knowledge-sharing, enhancing researchers' employability and providing them with new career perspectives.
- ITN will shape future generations of entrepreneurial researchers capable of contributing effectively to the knowledge-based economy and society.
- In the long term, it will also raise the attractiveness of research careers and encourage young people to embark on this career path.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[3]

Deadline(s): 09 April 2014 at 17.00.00 Brussels time[4]

Indicative budget: EUR 405.18 million from the 2014 budget. Of this amount, EUR 25.5 million is allocated to European Industrial Doctorates and EUR 30 million is allocated to European Joint Doctorates.

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

[3] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[4] The Director-General responsible may delay this deadline by up to two months.

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Participants in ETN and EJD resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on research training and career development.

Call for Marie Skłodowska-Curie Individual Fellowships (IF)

H2020-MSCA-IF-2014

Objective:

The goal of Individual Fellowships is to enhance the creative and innovative potential of experienced researchers wishing to diversify their individual competence in terms of skill acquisition through advanced training, international and intersectoral mobility.

Individual Fellowships provide opportunities to acquire and transfer new knowledge and to work on research in a European context (EU Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

Scope:

Support is foreseen for individual, trans-national fellowships awarded to the best or most promising researchers for employment in EU Member States or Associated Countries, based on an application made jointly by the researcher and host organisation in the academic or non-academic sectors.

Fellowships are either European Fellowships or Global Fellowships. European Fellowships are held in EU Member States or Associated Countries and are open to researchers either coming to Europe or moving within Europe. The researcher must comply with the rules of mobility in the country where the European Fellowship is held. Global Fellowships are based on a secondment to a third country and a mandatory 12 month return period to a European host. The researcher must comply with the rules of mobility in the country where the Global Fellowship secondment takes place, not for the country of the return phase.

Return and reintegration of researchers into a longer term research position in Europe, including in their country of origin, is supported via a separate multi-disciplinary reintegration panel of the European Fellowships. For the reintegration panel, there shall be mobility into Europe.

Support to individuals to resume research in Europe after a career break, e.g. after parental leave, is ensured via a separate multi-disciplinary career restart panel of the European Fellowships. To qualify for the career restart panel, researchers must not have been active in research for at least 12 months immediately prior to the deadline for submission.

Researchers receiving an Individual Fellowship may opt to include a secondment phase in Europe, notably in the non-academic sector, within the overall duration of their fellowship. For a fellowship of 18 months or less, the secondment phase may last up to three months. For a fellowship of more than 18 months, the secondment phase may last up to six months. The secondment phase can be a single period or be divided into shorter mobility periods. The secondment should significantly add to the impact of the fellowship.

A Career Development Plan should be established jointly by the supervisor(s) and the researcher. In addition to research objectives, this plan comprises the researcher's training and career needs, including training on transferable skills, planning for publications and participation in conferences.

Expected impact:

- Individual Fellowships are expected to add significantly to the development of the best and most promising researchers active in Europe, in order to enhance and maximise their contribution to the knowledge-based economy and society.
- The action will also strengthen the contact network of both the researcher and the host organisation.
- The fellowship will contribute to realising the full potential of researchers and to catalysing significant development in their careers in both the academic and non-academic sectors.
- Some researchers will be resuming a research career in Europe after a break, or reintegrating within Europe after living abroad.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 12 March 2014[5]

Deadline(s): 11 September 2014 at 17.00.00 Brussels time[6]

Indicative budget: EUR 240.50 million from the 2014 budget. Of this amount, EUR 29 million is allocated to Global Fellowships.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A curriculum vitae of the researcher;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

[5] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[6] The Director-General responsible may delay this deadline by up to two months.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 10 pages, excluding the CV of the researcher and the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Not applicable - this is a mono-beneficiary action.

Call for Marie Skłodowska-Curie Research and Innovation Staff Exchange (RISE)

H2020-MSCA-RISE-2014

Objective:

The RISE scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa) for the advancement of science and the development of innovation.

The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

Scope:

RISE involves organisations from the academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Associated Countries) and outside Europe (third countries).

Support is provided for the development of partnerships in the form of joint research and innovation activities between the participants. This is aimed at knowledge sharing via international as well as intersectoral mobility, based on secondments of research and innovation staff (exchanges) with an in-built return mechanism.

The organisations constituting the partnership contribute directly to the implementation of the joint research and innovation activities by seconding and/or hosting eligible staff members.

The proposed research and innovation activities should exploit complementary competences of the participants, as well as other synergies, and enable networking activities, organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and career development for research and innovation staff members.

Activities can focus either on one dimension of mobility (intersectoral / international), or include a combination of both.

Exchanges can be for both early-stage and experienced researchers' levels and can also include administrative, managerial and technical staff supporting the research and innovation activities of the proposal.

Support for the exchanges between institutions in the EU Member States and Associated Countries covers only intersectoral secondments.

Exchanges with institutions from third countries can be intersectoral secondments as well as secondments within the same sector.

No secondments between institutions located in third countries or within the same EU Member State or Associated Country can be supported.

Expected impact:

- Research and innovation activities under RISE are expected to build or enhance new and existing networks of international and intersectoral cooperation. They will significantly

strengthen the interaction between organisations in the academic and non-academic sectors, and between Europe and third countries.

- In terms of knowledge sharing and broad skills development, they will better align different cultures and expectations, with a view to a more effective contribution of research and innovation to Europe's knowledge economy and society.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[7]

Deadline(s): 24 April 2014 at 17.00.00 Brussels time[8]

Indicative budget: EUR 70 million from the 2014 budget.

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.

[7] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[8] The Director-General responsible may delay this deadline by up to two months.

The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement: Participants in actions resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on staff exchanges.

Call for Marie Skłodowska-Curie Co-funding of regional, national and international programmes (COFUND)

H2020-MSCA-COFUND-2014

Objective:

The COFUND scheme aims at stimulating regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions.

This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

Scope:

Each proposal funded under the COFUND scheme shall have a sole participant that will be responsible for the availability of the necessary matching funds to execute the proposal.

Participants submit multi-annual proposals for new or existing doctoral programmes or fellowship programmes that may be run at regional, national or international level. The evaluation is organised in two different panels: A) Doctoral programmes and B) Fellowship programmes. Support cannot be awarded to researchers who are already permanently employed at the host organisation.

Doctoral programmes address the development and broadening of the research competencies of early-stage researchers. The training follows the EU Principles on Innovative Doctoral Training. Collaboration with a wider set of partners, including from the non-academic sector, which may provide hosting or secondment opportunities or training in research or transferable skills, as well as innovative elements of the proposed programme, will be positively taken into account during the evaluations. Each researcher must be enrolled in a doctoral programme. Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance.

Fellowship programmes fund individual research training and career development fellowships for experienced researchers. The programmes supported should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between the researchers applying. The selections should be based on open, widely advertised competition, with transparent international peer review and the selection of candidates on merit. Mobility types supported by fellowship programmes may be similar to the ones supported under Marie Skłodowska-Curie Individual Fellowships. On top of transnational mobility, applicants are encouraged to include elements of cross-sectoral mobility into their programmes. Fellowship programmes should be based on individual-driven mobility, i.e., researchers should be able to freely choose a research topic and the appropriate host organisation fitting their individual needs.

Limitations regarding the researchers' origin and destination should be avoided. Given that the aim of the co-funded fellowship programmes is the support of individual fellows, research teams will not be funded.

Proposed fellowship programmes are encouraged to cover all research disciplines ("bottom-up"), but can also focus on specific disciplines. In this case the range of covered disciplines

should allow reasonable flexibility for the researchers. Programmes that prioritise specific research disciplines based on national or regional Research and Innovation Strategies for Smart Specialisation (RIS3 strategies) will also be supported.

Researchers supported under this scheme should comply with the mobility rules of the Marie Skłodowska-Curie actions. Existing programmes can deviate from this rule if duly justified in the proposal by the applicant.

Expected impact:

The COFUND scheme will on a voluntary basis exploit synergies between European Union actions and those at regional and national level, as well as with other actions at international level. The scheme will have a leverage effect on regional, national or international funding programmes for early-stage researchers and experienced researchers. This impact is expected to extend to:

1. enabling the relevant regional, national and international actors to contribute significantly to the development within their own setting of high quality human resources, by introducing and/or further developing the trans-national dimension of their offers;

2. increasing the numerical and/or qualitative impact, in terms of supported researchers or working/employment conditions;

3. combating fragmentation in terms of objectives, evaluation methods and working conditions of regional, national or international offers in this area.

Type of action: Marie Skłodowska-Curie COFUND (Programme Co-fund Action).

CONDITIONS FOR THIS CALL

Opening date: 10 April 2014[9]

Deadline(s): 02 October 2014 at 17.00.00 Brussels time[10]

Indicative budget: EUR 80.00 million from the 2014 budget. Of this amount, EUR 30 million is allocated to Doctoral Programmes.

The European Union contribution has maximum overall of EUR 10 million to a single applicant legal entity for one call. Participants having benefited from COFUND under previous calls (under Seventh Framework Programme or under Horizon 2020) will explain in their proposals how the latest proposal relates to and goes beyond the earlier grant and provide evidence for its quality (e.g., if possible, by external evaluations).

[9] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[10] The Director-General responsible may delay this deadline by up to two months.

Duration: Selected programmes will have a duration of 36 to 60 months from the starting date specified in the Agreement. This duration includes also the time that is needed to select or recruit the researchers.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be responsible for carrying out the proposed work;
- A description of administrative resources to implement the programme;
- A description of partner organisations who will be contributing towards the work by hosting researchers.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: A maximum length of the proposal is of 30 pages. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Not applicable - this is a mono-beneficiary action.

Call for European Researchers' Night (NIGHT)

H2020-MSCA-NIGHT-2014

Objective:

The European Researchers' Night aims to bring researchers closer to the general public and to increase awareness of research and innovation activities, with a view to supporting the public recognition of researchers, creating an understanding of the impact of researchers' work on citizen's daily life, and encouraging young people to embark on scientific careers.

Scope:

The European Researchers' Night takes place yearly, typically on the last Friday of the month of September, and is the occasion for a Europe-wide public and media event for the promotion of research careers, in particular towards young people and their parents. Supported events can start early Friday afternoon and last until early morning the following day.

Activities focus on the general public, addressing and attracting people regardless of the level their scientific background, with a special focus on pupils and students. Activities can combine education aspects with entertainment, especially when adressing young audience. They can take various forms, e.g. hands-on experiments, science shows, simulations, debates, games, competitions, quizzes, etc.

Each proposal should set up at least one European corner. Activities should be organised with researchers actively involved and directly in contact with the public. They should promote the European dimension and gender balance in research and innovation. Involvement of researchers funded by Horizon 2020, including Marie Skłodowska-Curie actions, is encouraged.

Participants can be any legal entity in the EU Member States and Associated Countries, and/or if relevant, constitute a partnership at regional, national or international level.

Expected impact:

- The European Researchers' Night will raise awareness of the importance of research careers. It will make the general public better understand the central role of researchers and the key benefits that they bring to society.
- The scheme will help to tackle the existing stereotypes about researchers and their profession.
- In the long term, it will convince young people that research careers are fascinating and will stimulate them to embark on research careers.

Type of action: Coordination and support action. The funding rate for this call is provided in part D of the General Annexes.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[11]

Deadline(s): 04 March 2014 at 17.00.00 Brussels time[12]

Indicative budget: EUR 8.00 million from the 2014 budget.

Duration: The maximum duration of support will be two years from the starting date specified in the Agreement. The Agreement should cover two editions of the Night, in successive years. One single edition of the Night may also be considered.

Eligibility and admissibility conditions: The conditions are described in parts B and C of the General Annexes to the work programme. The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide[13] published on the Participant Portal. .
- Proposal page limits and layout: The maximum length of the proposal is 30 pages. There is no automatic check in the system. Experts will be instructed to disregard any excess pages in each section in which the maximum number of pages is indicated.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).
- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.
Consortium agreement:
Participants in actions resulting from this call are NOT required to conclude a consortium agreement.

[11] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[12] The Director-General responsible may delay this deadline by up to two months.

[13] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

Call for Trans-national cooperation among Marie Skłodowska-Curie National Contact Points (NCP)

H2020-MSCA-NCP-2014

Objective:

Facilitate trans-national co-operation between National Contact Points (NCPs) for the Marie Skłodowska-Curie actions (MSCA), with a view to identifying and sharing good practices and raising the general standard of support to applicants, taking into account the diversity of actors.

Scope:

Support will be given to a consortium of formally nominated NCPs in the area of MSCA. The activities will be tailored according to the nature of the area, and the priorities of the NCPs concerned. Various mechanisms may be included, such as benchmarking, joint workshops, enhanced cross-border brokerage events, training sessions linked to MSCA as well as to gender dimension of Research and Innovation, twinning schemes, etc. Special attention will be given to enhancing the competence of MSCA NCPs, including helping less experienced NCPs rapidly acquire the know-how accumulated in other countries. It will be also encouraged to build up cooperation with other networks to increase visibility to potential beneficiaries, especially in the non-academic sector.

The focus throughout should be on issues specific to MSCA and should not duplicate actions foreseen in the NCP network for quality standards and horizontal issues under 'Science with and for Society'.

Only NCPs host organisations from EU Member States, Associated Countries, and third countries which have been officially appointed by the relevant national authorities are eligible to participate in and receive funding for this action.

The consortium should have a good representation of experienced and less experienced NCPs.

Submission of a single proposal is encouraged. NCPs from EU Member States or Associated Countries choosing not to participate as a member of the consortium should be identified and the reason explained in the proposal. These NCPs are nevertheless invited and encouraged to participate in the project activities (e.g. workshops), and the costs incurred by the consortium for such participation (e.g. travel costs paid by the consortium) may be included in the estimated budget and be eligible for funding by the Commission.

The Commission will only fund one proposal under this topic.

Expected impact:

- An improved and professionalised NCP service across Europe, therefore helping simplify access to Horizon 2020 calls, lowering the entry barriers for newcomers, and raising the average quality of submitted proposals.
- A more consistent level of NCP support services across Europe.

Type of action: Coordination and support action. The funding rate for this call is provided in part D of the General Annexes.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[14]

Deadline(s): 02 April 2014 at 17.00.00 Brussels time[15]

Indicative budget: EUR 1.50 million from the 2014 budget.

Duration: The maximum duration of support will be three years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The conditions are described in parts B and C of the General Annexes to the work programme. The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide[16] published on the Participant Portal.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Participants in actions resulting from this call are NOT required to conclude a consortium agreement.

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[14] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[15] The Director-General responsible may delay this deadline by up to two months.

[16] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

Call for Marie Skłodowska-Curie Innovative Training Networks (ITN)

H2020-MSCA-ITN-2015

Objective:

The Innovative Training Networks (ITN) aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit.

ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced career perspectives in both the academic and non-academic sectors through international, interdisciplinary and intersectoral mobility combined with an innovation-oriented mind-set.

Scope:

ITN supports competitively selected joint research training and/or doctoral programmes, implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs, and other socio-economic actors from different countries across Europe and beyond.

Partnerships take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

Each programme should have a clearly identified supervisory board co-ordinating network-wide training and establishing active and continuous communication and exchange of best practice among the partners to maximise the benefits of the partnership.

The programme should exploit complementary competences of the participants, and enable networking activities, the organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and the career development of researchers.

Training responds to well identified needs in defined research areas, with appropriate references to interdisciplinary fields. It should be primarily focused on scientific and technological knowledge through research on individual, personalised projects.

In order to increase the employability of the researchers, the research training should be complemented by the meaningful exposure of each researcher to the non-academic sector and by substantial training modules addressing key transferable skills common to all fields (e.g. entrepreneurship, management and financing of research activities and programmes, management of intellectual property rights, other exploitation methods of research results, ethical aspects, communication, standardisation and societal outreach). The training follows the EU Principles for Innovative Doctoral Training[17].

In EID and EJD, enrolment in a doctoral programme and the creation of a joint governance structure - with joint admission (EJD only), selection, supervision, monitoring and assessment

[17] http://ec.europa.eu/euraxess/index.cfm/services/researchPolicies.

procedures - is mandatory. In the case of EJD, the successful completion of the programme must result in the award of joint, double or multiple doctoral degrees.

Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance. Joint supervision of the researchers is mandatory for EJD and for EID, and encouraged in ETN. In EID, the joint supervision of the researcher must be ensured by at least one supervisor from the academic sector and one supervisor from the non-academic sector.

A Career Development Plan should be established jointly by the supervisor(s) and the early-stage researcher recruited by the selected network. In addition to research objectives, this plan comprises the researcher's training and career needs, including planning for publications and participation in conferences.

Expected impact:

- ITN will create and contribute to high-quality innovative research and doctoral training, build capacity, and have a structuring effect throughout Europe and beyond.
- Through research training provided by the institutions from different countries, sectors and disciplines, this action will trigger cooperation between organisations from the academic and non-academic sectors.
- It will enhance skills development and knowledge-sharing, enhancing researchers' employability and providing them with new career perspectives.
- ITN will shape future generations of entrepreneurial researchers capable of contributing effectively to the knowledge-based economy and society.
- In the long term, it will also raise the attractiveness of research careers and encourage young people to embark on this career path.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 02 September 2014[18]

Deadline(s): 13 January 2015 at 17.00.00 Brussels time[19]

Indicative budget: EUR 370.00 million from the 2015 budget. Of this amount, EUR 25 million is allocated to European Industrial Doctorates and EUR 28 million is allocated to European Joint Doctorates.[20]

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

[18] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[19] The Director-General responsible may delay this deadline by up to two months.

[20] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Participants in ETN and EJD resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on research training and career development.

Call for Marie Skłodowska-Curie Individual Fellowships (IF)

H2020-MSCA-IF-2015

Objective:

The goal of Individual Fellowships is to enhance the creative and innovative potential of experienced researchers wishing to diversify their individual competence in terms of skill acquisition through advanced training, international and intersectoral mobility.

Individual Fellowships provide opportunities to acquire and transfer new knowledge and to work on research in a European context (EU Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

Scope:

Support is foreseen for individual, trans-national fellowships awarded to the best or most promising researchers for employment in EU Member States or Associated Countries, based on an application made jointly by the researcher and host organisation in the academic or non-academic sectors.

Fellowships are either European Fellowships or Global Fellowships. European Fellowships are held in EU Member States or Associated Countries and are open to researchers either coming to Europe or moving within Europe. The researcher must comply with the rules of mobility in the country where the European Fellowship is held. Global Fellowships are based on a secondment to a third country and a mandatory 12 month return period to a European host. The researcher must comply with the rules of mobility in the country where the Global Fellowship secondment takes place, not for the country of the return phase.

Return and reintegration of researchers into a longer term research position in Europe, including in their country of origin, is supported via a separate multi-disciplinary reintegration panel of the European Fellowships. For the reintegration panel, there shall be mobility into Europe.

Support to individuals to resume research in Europe after a career break, e.g. after parental leave, is ensured via a separate multi-disciplinary career restart panel of the European Fellowships. To qualify for the career restart panel, researchers must not have been active in research for at least 12 months immediately prior to the deadline for submission.

Researchers receiving an Individual Fellowship may opt to include a secondment phase in Europe, notably in the non-academic sector, within the overall duration of their fellowship. For a fellowship of 18 months or less, the secondment phase may last up to three months. For a fellowship of more than 18 months, the secondment phase may last up to six months. The secondment phase can be a single period or be divided into shorter mobility periods. The secondment should significantly add to the impact of the fellowship.

A Career Development Plan should be established jointly by the supervisor(s) and the researcher. In addition to research objectives, this plan comprises the researcher's training and career needs, including training on transferable skills, planning for publications and participation in conferences.

Expected impact:

- Individual Fellowships are expected to add significantly to the development of the best and most promising researchers active in Europe, in order to enhance and maximise their contribution to the knowledge-based economy and society.
- The action will also strengthen the contact network of both the researcher and the host organisation.
- The fellowship will contribute to realising the full potential of researchers and to catalysing significant development in their careers in both the academic and non-academic sectors.
- Some researchers will be resuming a research career in Europe after a break, or reintegrating within Europe after living abroad.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 12 March 2015[21]

Deadline(s): 10 September 2015 at 17.00.00 Brussels time[22]

Indicative budget: EUR 215.00 million from the 2015 budget. Of this amount, EUR 27 million is allocated to Global Fellowships.[23]

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A curriculum vitae of the researcher;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

[21] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[22] The Director-General responsible may delay this deadline by up to two months.

[23] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 10 pages, excluding the CV of the researcher and the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Not applicable - this is a mono-beneficiary action.

Call for Marie Skłodowska-Curie Research and Innovation Staff Exchange (RISE)

H2020-MSCA-RISE-2015

Objective:

The RISE scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa) for the advancement of science and the development of innovation.

The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

Scope:

RISE involves organisations from the academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Associated Countries) and outside Europe (third countries).

Support is provided for the development of partnerships in the form of joint research and innovation activities between the participants. This is aimed at knowledge sharing via international as well as intersectoral mobility, based on secondments of research and innovation staff (exchanges) with an in-built return mechanism.

The organisations constituting the partnership contribute directly to the implementation of the joint research and innovation activities by seconding and/or hosting eligible staff members.

The proposed research and innovation activities should exploit complementary competences of the participants, as well as other synergies, and enable networking activities, organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and career development for research and innovation staff members.

Activities can focus either on one dimension of mobility (intersectoral / international), or include a combination of both.

Exchanges can be for both early-stage and experienced researchers' levels and can also include administrative, managerial and technical staff supporting the research and innovation activities of the proposal.

Support for the exchanges between institutions in the EU Member States and Associated Countries covers only intersectoral secondments.

Exchanges with institutions from third countries can be intersectoral secondments as well as secondments within the same sector.

No secondments between institutions located in third countries or within the same EU Member State or Associated Country can be supported.

Expected impact:

- Research and innovation activities under RISE are expected to build or enhance new and existing networks of international and intersectoral cooperation. They will significantly

strengthen the interaction between organisations in the academic and non-academic sectors, and between Europe and third countries.

- In terms of knowledge sharing and broad skills development, they will better align different cultures and expectations, with a view to a more effective contribution of research and innovation to Europe's knowledge economy and society.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 06 January 2015[24]

Deadline(s): 28 April 2015 at 17.00.00 Brussels time[25]

Indicative budget: EUR 80 million from the 2015 budget.[26]

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

[24] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[25] The Director-General responsible may delay this deadline by up to two months.

[26] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement: Participants in actions resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on staff exchanges.

Call for Marie Skłodowska-Curie Co-funding of regional, national and international programmes (COFUND)

H2020-MSCA-COFUND-2015

Objective:

The COFUND scheme aims at stimulating regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions.

This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

Scope:

Each proposal funded under the COFUND scheme shall have a sole participant that will be responsible for the availability of the necessary matching funds to execute the proposal.

Participants submit multi-annual proposals for new or existing doctoral programmes or fellowship programmes that may be run at regional, national or international level. The evaluation is organised in two different panels: A) Doctoral programmes and B) Fellowship programmes. Support cannot be awarded to researchers who are already permanently employed at the host organisation.

Doctoral programmes address the development and broadening of the research competencies of early-stage researchers. The training follows the EU Principles on Innovative Doctoral Training. Collaboration with a wider set of partners, including from the non-academic sector, which may provide hosting or secondment opportunities or training in research or transferable skills, as well as innovative elements of the proposed programme, will be positively taken into account during the evaluations. Each researcher must be enrolled in a doctoral programme. Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance.

Fellowship programmes fund individual research training and career development fellowships for experienced researchers. The programmes supported should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between the researchers applying. The selections should be based on open, widely advertised competition, with transparent international peer review and the selection of candidates on merit. Mobility types supported by fellowship programmes may be similar to the ones supported under Marie Skłodowska-Curie Individual Fellowships. On top of transnational mobility, applicants are encouraged to include elements of cross-sectoral mobility into their programmes. Fellowship programmes should be based on individual-driven mobility, i.e., researchers should be able to freely choose a research topic and the appropriate host organisation fitting their individual needs.

Limitations regarding the researchers' origin and destination should be avoided. Given that the aim of the co-funded fellowship programmes is the support of individual fellows, research teams will not be funded.

Proposed fellowship programmes are encouraged to cover all research disciplines ("bottom-up"), but can also focus on specific disciplines. In this case the range of covered disciplines

should allow reasonable flexibility for the researchers. Programmes that prioritise specific research disciplines based on national or regional Research and Innovation Strategies for Smart Specialisation (RIS3 strategies) will also be supported.

Researchers supported under this scheme should comply with the mobility rules of the Marie Skłodowska-Curie actions. Existing programmes can deviate from this rule if duly justified in the proposal by the applicant.

Expected impact:

The COFUND scheme will on a voluntary basis exploit synergies between European Union actions and those at regional and national level, as well as with other actions at international level. The scheme will have a leverage effect on regional, national or international funding programmes for early-stage researchers and experienced researchers. This impact is expected to extend to:

1. enabling the relevant regional, national and international actors to contribute significantly to the development within their own setting of high quality human resources, by introducing and/or further developing the trans-national dimension of their offers;

2. increasing the numerical and/or qualitative impact, in terms of supported researchers or working/employment conditions;

3. combating fragmentation in terms of objectives, evaluation methods and working conditions of regional, national or international offers in this area.

Type of action: Marie Skłodowska-Curie COFUND (Programme Co-fund Action).

CONDITIONS FOR THIS CALL

Opening date: 14 April 2015[27]

Deadline(s): 01 October 2015 at 17.00.00 Brussels time[28]

Indicative budget: EUR 80.00 million from the 2015 budget. Of this amount, EUR 30 million is allocated to Doctoral Programmes.[29]

The European Union contribution has maximum overall of EUR 10 million to a single applicant legal entity for one call. Participants having benefited from COFUND under previous calls (under Seventh Framework Programme or under Horizon 2020) will explain in their proposals how the latest proposal relates to and goes beyond the earlier

[27] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[28] The Director-General responsible may delay this deadline by up to two months.

[29] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

grant and provide evidence for its quality (e.g., if possible, by external evaluations).

Duration: Selected programmes will have a duration of 36 to 60 months from the starting date specified in the Agreement. This duration includes also the time that is needed to select or recruit the researchers.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be responsible for carrying out the proposed work;
- A description of administrative resources to implement the programme;
- A description of partner organisations who will be contributing towards the work by hosting researchers.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: A maximum length of the proposal is of 30 pages. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:

Not applicable - this is a mono-beneficiary action.

Other actions (not subject to calls for proposals) [30]

1. External expertise

This action will support the use of appointed independent experts for the evaluation of project proposals and, where appropriate, for the monitoring of running projects.

Type of action: Expert contracts

Indicative timetable: Throughout the 2014 and 2015. The implementation is linked to the schedule of the calls.

Indicative budget: EUR 10 217 498 from the 2014 budget and EUR 10 067 659 from the 2015 budget.

2. Support for EU Presidency events

Support for two EU Presidency events in the area of mobility, training and careers of researchers.

The Italian Presidency conference will raise awareness of challenges associated with the training of the next generation of researchers and will allow the sharing of best practices in the area of research career development.

The Luxembourg Presidency conference will provide a suitable forum for discussing the COFUND scheme and in particular, the leverage effect on regional, national or international funding programmes for early-stage researchers and experienced researchers: how to foster excellence in researchers' training, mobility and career development. This will be addressed from different perspectives while highlighting challenges and best practices.

Legal entity:

On the condition that the incoming Italian Presidency confirms their intentions, the EU Presidency event in Italy would be implemented through a grant to the appropriate authorities (The Italian Ministry of Education, Universities and Research - Ministero dell'Istruzione, dell'Università e della Ricerca, Piazza Kennedy 20, 00144 ROMA, Italy) that will cooperate with other institutions of the country for the organisation of the event.

On the condition that the incoming Luxembourg Presidency confirms their intentions, the EU Presidency event in Luxembourg would be implemented through a grant to the appropriate authorities (Fonds National de la Recherche Luxembourg, 6, rue Antoine de Saint-Exupéry, B.P. 1777 L-1017 Luxembourg) that will cooperate with other institutions of the country for the organisation of the event.

Type of action: Grant to identified beneficiary - Coordination and support action.

[30] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The standard evaluation criteria, thresholds, weighting for award criteria and the maximum rate of co-financing for this type of action are provided in parts C, D and H of the General Annexes.

Indicative timetable: First semester of 2014 for the grant to identified beneficiary for the Italian Presidency. First semester of 2015 for the grant to identified beneficiary for the Luxembourg Presidency.

Indicative budget: EUR 150 000 from the 2014 budget (Italian Presidency event) and EUR 150 000 from the 2015 budget (Luxembourg Presidency event).

3. Studies

To study aspects of high relevance for the successful implementation of the Marie Skłodowska-Curie Actions: dual careers in research, promotion measures of research careers towards potential future researchers, career restart in research, industrial doctorates.

Type of action: Public Procurement - Framework contract. Maximum two specific contracts.

Indicative timetable: Third quarter of 2014 for the first specific contract and second quarter of 2015 for the second specific contract.

Indicative budget: EUR 350 000 from the 2014 budget and EUR 100 000 from the 2015 budget.

4. Alumni services

To further increase the impact of the Marie Skłodowska-Curie actions, networking between Marie Skłodowska-Curie researchers (current and past) will be enhanced through the implementation of alumni services.

Type of action: Public Procurement – existing Framework contract. Maximum two specific contracts.

Indicative timetable: Third quarter of 2014 and third quarter of 2015.

Indicative budget: EUR 567 000 from the 2014 budget and EUR 550 000 from the 2015 budget.

5. Events and outreach 2015

During 2015 the Commission intends to organise several events (conferences and workshops) dedicated to the Marie Skłodowska-Curie actions, to contribute to leading research conferences and other events as well as to inform about the programme's results, thus raising awareness with relevant target groups and stakeholders about the programme's impact and its new developments. For this, maximum 10 specific contracts will be concluded via existing framework contracts for the support measures.

Type of action: Public Procurement - Framework contract.

Indicative timetable: First quarter of 2015 for the first specific contract and fourth quarter of 2015 for the last specific contract.

Indicative budget: EUR 400 000 from the 2015 budget.

Budget

Calls	*2014 Budget EUR million*[31]	**2015**[32] **Budget EUR million**
Call H2020-MSCA-ITN-2014 Marie Skłodowska-Curie Innovative Training Networks	*405.18* *from 15 03 01 01*	-
Call H2020-MSCA-IF-2014 Marie Skłodowska-Curie Individual Fellowships	*240.50* *from 15 03 01 01*	-
Call H2020-MSCA-RISE-2014 Marie Skłodowska-Curie Research and Innovation Staff Exchange	*70.00* *from 15 03 01 01*	-
Call H2020-MSCA-COFUND-2014 Marie Skłodowska-Curie Co-funding of regional, national and international programmes	*80.00* *from 15 03 01 01*	-
Call H2020-MSCA-NIGHT-2014 European Researchers' Night	*8.00* *from 15 03 01 01*	-
Call H2020-MSCA-NCP-2014 Trans-national cooperation among Marie Skłodowska-Curie National Contact Points	*1.50* *from 15 03 01 01*	-
Call H2020-MSCA-ITN-2015 Marie Skłodowska-Curie Innovative Training Networks	-	370.00 *from 15 03 01 01*
Call H2020-MSCA-IF-2015 Marie Skłodowska-Curie Individual Fellowships	-	215.00 *from 15 03 01 01*
Call H2020-MSCA-RISE-2015 Marie Skłodowska-Curie Research and Innovation Staff Exchange	-	80.00 *from 15 03 01 01*
Call H2020-MSCA-COFUND-2015 Marie Skłodowska-Curie Co-funding of regional, national and international	-	80.00 *from 15 03 01 01*

[31] The budget figures given in this table are rounded to two decimal places.

[32] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

programmes		
Other Actions		
Expert contracts	*10.22* *from 15 03 01 01*	10.07 *from 15 03 01 01*
Grant to identified beneficiary - EU Presidency events	*0.15* *from 15 03 01 01*	0.15 *from 15 03 01 01*
Public Procurement - Studies	*0.35* *from 15 03 01 01*	0.10 *from 15 03 01 01*
Public procurement – Alumni services	*0.57* *from 15 03 01 01*	0.55 *from 15 03 01 01*
Events and outreach activities	-	0.40 *from 15 03 01 01*
Estimated total budget	***816.47***	**756.27**

Contribution to Horizontal activities (08.020500 in 2014 and 2015)		
Dissemination activities (see Part 17 of the work programme)	*0.61*	0.63
Corporate communication (see Part 17 of the work programme)	*0.32*	_
Estimated total budget for the horizontal activities	***0.93***	**0.63**
Estimated total budget including horizontal activities	***817.40***	**756.90**

Eligibility conditions

PROPOSAL

A proposal will only be considered eligible if it complies with the minimum participation and any other eligibility conditions set out below, depending on the type of action.

PARTICIPANTS

Participants will comply with the applicable rules for funding as set out in part A of the General Annexes to the work programme.

The eligibility criteria formulated in Commission notice Nr 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp. 9-11) shall apply for all actions under this part of the Work Programme, including with respect to partner organisations, third parties receiving financial support in the cases where the respective action involves financial support to third parties by grant beneficiaries in accordance with Article 137 of the EU's Financial Regulation, notably Programme Co-Fund action.

Some entities from third countries are covered by the Council sanctions in place and are not eligible to participate in Union programmes. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.

For the purpose of determining eligibility, where one of the participants is an international European interest organisation or the EU's Joint Research Centre or an entity created under Union law, it shall be deemed to be established in an EU Member State or Associated Country other than any EU Member State or Associated Country in which another participant in the same proposal is established.

Participants are organisations from the academic or the non-academic sector. These two sectors are defined as follows:

Academic sector

Academic sector consists of public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations[33].

Non-academic sector

Non-academic sector includes any socio-economic actor not included in the academic sector and fulfilling the requirements of the Horizon 2020 Rules for Participation.

[33] For the purpose of this document, international European interest organisations shall be understood as defined in article 2 of the Horizon 2020 Rules for Participation.

Participants can be divided in two groups based on their level of participation:

- Beneficiaries: signatory to the agreement

  Beneficiaries are full partners with complete responsibility for executing the proposed programme and other requirements of the project. They contribute directly to the implementation of the research training programme by appointing, supervising, hosting and training researchers.[34] They may also provide secondment opportunities.

- Partner organisations: non-signatory of the agreement

  Partner organisations are non-beneficiary organisations contributing to the project by providing training and hosting researchers[35] during secondments. Partner organisations do not employ researchers within the project[36]. Partner organisations shall include a letter of commitment in the proposal to ensure their real and active participation in the proposed network. The experts will be instructed to disregard the contribution of any partner organisations for which no such evidence of commitment is submitted.

Consortia involving partner organisations are encouraged to sign a partnership agreement to regulate the relationship between participants. These partnership agreements shall be in compliance with the obligations laid down in the Agreement.

In **Individual Fellowships (IF)**, the beneficiary shall be a participant located in an EU Member State or Associated Country and employing the researcher during the project.

Innovative Training Networks (ITN) can take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD). They must be created by at least three beneficiaries (or at least two for EID) located in three different EU Member States or Associated Countries. Above this minimum, the participation of institutions from any country or organisation is possible under the conditions provided by the Horizon 2020 Rules for Participation.

In the case of EID, at least one beneficiary must be entitled to award doctoral degrees[37] and at least one beneficiary must come from the non-academic sector, primarily enterprises. For EJD, at least three beneficiaries must be entitled to award doctoral degrees.[38]

The overall Union contribution for ITN is limited to the recruitment of a maximum 540 person-months. For EID with only two participants, this limit is set to 180.

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[34] In the framework of COFUND, beneficiaries may also fund doctoral programmes or fellowship programmes for researchers.

[35] In the framework of RISE, "researchers" refers to staff members.

[36] In the framework of COFUND, this restriction does not apply.

[37] Every time the document refers to doctoral degrees, this means that the degrees have to be recognised as such by the relevant authorities of the country or countries concerned.

[38] For EJD, at least two institutions conferring a joint, double or multiple doctoral degree must be established in an EU Member State and/or Associated Country.

Not more than 40% of the requested EU contribution shall be dedicated to hosts in the same country (except for EID).

Participants in the **Research and Innovation Staff Exchange (RISE)** shall be established in at least three different countries of which at least two must be EU Member States or Associated Countries. If all participants are from the same sector (either only academic or only non-academic), at least one participant must be from a third country. Above this minimum, the participation of institutions from any country or organisation is possible under the conditions provided by the Horizon 2020 Rules for Participation.

The overall European Union contribution for RISE is limited to the secondment of a maximum 540 person-months.

Participants in the Marie Skłodowska-Curie **Co-funding of regional, national and international programmes (COFUND)** shall be legal entities established in an EU Member State or Associated Country that fund or manage doctoral programmes or fellowship programmes for researchers. International European interest organisations that fund or manage doctoral programmes or fellowship programmes for researchers can also participate in this action.

RESEARCHERS

Researchers may be of any nationality. Researchers receive support on the condition that they move from one country to another to broaden or deepen their competences.

Global Fellowships and the Reintegration Panel in IF are open to nationals or long-term residents of EU Member States and Associated Countries. Long-term residence means a period of full-time research activity of at least 5 consecutive years.

Supported researchers fall into two categories: early-stage or experienced researchers:

Early-stage researchers (ESR) shall at the time of recruitment (ITN, COFUND) or secondment (RISE) by the host organisation, be in the first four years (full-time equivalent research experience) of their research careers and have not been awarded a doctoral degree.

Experienced researchers (ER) shall, at the time of the relevant deadline for submission of proposals (IF), recruitment (COFUND) or secondment (RISE) by the host organisation, be in possession of a doctoral degree or have at least four years of full-time equivalent research experience.

Full-time equivalent research experience is measured from the date when a researcher obtained the degree which would formally entitle him or her to embark on a doctorate, either in the country in which the degree was obtained or in the country in which the researcher is recruited or seconded, irrespective of whether or not a doctorate is or was ever envisaged.

Mobility rules:

At the time of the relevant deadline for submission of proposals (IF), or recruitment by the host organisation (ITN), researchers shall not have resided or carried out their main activity (work , studies, etc) in the country of their host organisation for more than 12 months in the 3 years immediately prior to the reference date. Compulsory national service and/or short stays

such as holidays are not taken into account. As far as international European interest organisations or international organisations are concerned, this rule does not apply to the hosting of eligible researchers. However the appointed researcher shall not have spent more than 12 months in the 3 years immediately prior to the reference date, depending on the action, in the same appointing organisation.

In the Career Restart Panel and the Reintegration Panel in IF, researchers shall not have resided or carried out their main activity in the country of their host organisation for more than 3 years in the 5 years immediately prior to the relevant deadline for submission of proposals.

Staff members in RISE are researchers (ESR and ER), administrative, managerial and technical staff supporting the research and innovation activities of the project. They shall be actively engaged in or linked to research and/or innovation activities for at least six months (full-time equivalent) at the sending institution prior to the first period of secondment. Secondments in RISE are not subject to the mobility rules.

Duration of support

The support granted to eligible researchers (including staff members in RISE) will cover the following periods:

1. ITN: 3-36 months
   Researchers in EID shall spend at least 50% of their time in the non-academic sector

2. IF European: 12-24 months
   IF Global: 12-24 months for the outgoing phase plus 12 month return phase in Europe

3. RISE: 1-12 months
   Secondments may be split into several stays not exceeding 12 months in total and not going beyond the project duration. The splits must be justified and considered beneficial for the transfer of knowledge activities.
   The exchanged staff members should be guaranteed full reintegration into the sending institution thus maximising the impact of the action for knowledge sharing and long-term collaboration.

4. COFUND: minimum 3 months
   Researchers in COFUND shall not be recruited for less than 3 months.

Award criteria

The award criteria against which proposals will be judged are set out in Article 14 of the Horizon 2020 Rules for Participation.

The purpose of this section is to set out specifications for the criteria, weightings and ex-aequo priority order applied to calls for proposals in Marie Skłodowska-Curie actions.

Evaluation scores will be awarded for each of the criteria, and not their individual elements. Each criterion will be scored from 0 to 5. Scores with a resolution of one decimal place may be awarded. The total score will be subject to a threshold of 70%.

A proposal that contravenes fundamental ethical principles, fails to comply with the relevant security procedures, or which does not fulfil any other of the conditions set out in the specific programme, the work programme or in the call for proposals shall not be selected. Such a proposal may be excluded from the award procedure at any time. Details of the procedure to be followed are given in the Commission rules mentioned above.

Table 1: Award Criteria, Weightings and ex-aequo Priority Order

1. ITN - Marie Skłodowska-Curie Innovative Training Networks		
Excellence	**Impact**	**Implementation**
Quality, innovative aspects and credibility of the research programme (including inter/multidisciplinary and intersectoral aspects)	**Enhancing research- and innovation-related human resources, skills, and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources (including awarding of the doctoral degrees for *EID* and *EJD* projects)
Quality and innovative aspects of the training programme (including transferable skills, inter/multidisciplinary and intersectoral aspects)	**Contribution to structuring doctoral / early-stage research training at the European level and to strengthening European innovation capacity, including the potential for**: **a)** meaningful contribution of the non-academic sector to the doctoral/research training, as appropriate to the implementation mode and research field **b)** developing sustainable joint doctoral degree structures (for *EJD* projects only)	**Appropriateness of the management structures and procedures**, including quality management and risk management (with a mandatory joint governing structure for *EID* and *EJD* projects)

Quality of the supervision (including mandatory joint supervision for *EID* and *EJD* projects)	Effectiveness of the proposed measures for **communication** and **dissemination of results**	**Appropriateness of the infrastructure of the participating organisations**
Quality of the proposed interaction between the participating organisations		**Competences, experience and complementarity of the participating organisations and their commitment to the programme**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

2. IF - Marie Skłodowska-Curie Action: Individual Fellowships		
Excellence	**Impact**	**Implementation**
Quality, innovative aspects and credibility of the research (including inter/multidisciplinary aspects)	**Enhancing research- and innovation-related human resources, skills and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources
Clarity and quality of transfer of knowledge/training for the development of researcher in light of the research objectives	Effectiveness of the proposed measures for **communication** and **results dissemination**	**Appropriateness of the management structures and procedures**, including quality management and risk management
Quality of the supervision and the hosting arrangements		**Appropriateness of the institutional environment** (infrastructure)
Capacity of the researcher to reach or re-enforce a position of professional maturity in research		**Competences, experience and complementarity** of the participating organisations **and institutional commitment**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

3. RISE - Marie Skłodowska-Curie Action: Research and Innovation Staff Exchange		
Excellence	**Impact**	**Implementation**
Quality, innovative aspects and credibility of the research (including inter/multidisciplinary aspects)	**Enhancing research- and innovation-related human resources, skills and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources
Clarity and quality of knowledge sharing among the participants in light of the research and innovation objectives.	**To develop new and lasting research collaborations, to achieve transfer of knowledge** between research institutions and to improve research and innovation potential at the European and global levels	**Appropriateness of the management structures and procedures**, including quality management and risk management
Quality of the interaction between the participating organisations	Effectiveness of the proposed measures for **communication** and **results dissemination**	**Appropriateness of the institutional environment** (infrastructure)
		Competences, experience and complementarity of the participating organisations **and institutional commitment**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

4. COFUND - Marie Skłodowska-Curie Action: Co-funding of regional, national and international programmes		
Excellence	**Impact**	**Implementation**
Quality of the selection / recruitment process for the researchers (transparency, composition and organisation of selection committees, evaluation criteria, equal opportunity)	**Enhancing research- and innovation-related human resources, skills and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence, effectiveness and appropriateness of the work plan**
Quality of the research options offered by the programme in terms of science, interdisciplinarity, intersectorality and level of transnational mobility	**Impact of the programme on aligning practices at participating organisations with principles set out by the EU for the human resources development in research and innovation**	**Appointment conditions of researchers**
Quality of career guidance and training, including supervision arrangements, training in transferable skills	Effectiveness of the proposed measures for **communication** and **results dissemination of the programmes**	**Competence of the participant** to implement the programme
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

Evaluation procedure

In Marie Skłodowska-Curie ITN, IF and RISE, proposals are allocated to one of the eight main evaluation panels: Chemistry (CHE), Social Sciences and Humanities (SOC), Economic Sciences (ECO), Information Science and Engineering (ENG), Environment and Geosciences (ENV), Life Sciences (LIF), Mathematics (MAT), Physics (PHY). In ITN, separate multidisciplinary panels will be created for the European Industrial Doctorates (EID) and the European Joint Doctorates (EJD). In IF, separate multidisciplinary panels will be created for the Career Restart Panel (CAR) and the Reintegration Panel. COFUND evaluation will be organised in two different panels: Doctoral programmes and Fellowship programmes.

For each panel a ranked list is established. The distribution of the indicative budget of the call will be proportional to the number of eligible proposals received in each panel, except where a specific budget for a multidisciplinary panel has been fixed in the call. If the budget allocated to any panel exceeds the requirements of all proposals positively evaluated[39] in that panel, the excess budget will be reallocated to the other panels based on the distribution as above. Equally, if the allocated funding to a panel is insufficient to fund the highest ranked proposal in that panel, the necessary budget will be transferred from the other panels based on the distribution as above, in order to ensure that the highest ranked proposal can be funded.

Proposals will not be evaluated anonymously. Proposals may be evaluated remotely.

As part of the evaluation by independent experts, a panel review will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated in this work programme.

If necessary, the panel will determine a priority order for proposals which have been awarded the same score within a ranked list. When the total scores are equal, priority will be based on scores for individual award criteria. For each action the priority order of the criteria is detailed in table 1 of the section on award criteria.

If necessary, any further prioritisation will be based on other appropriate characteristics, to be decided by the panel, related to the contribution of the proposal to the European Research Area and/or general objectives mentioned in the work programme (e.g. intersectoral mobility, international co-operation, favourable employment and working conditions).

Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the call fiche.

The full evaluation procedure is described in the relevant guide[40] published on the Participant Portal.

[39] Measured as proposals having passed all relevant evaluation thresholds.

[40] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

European Union contribution and applicable rates

The host organisation shall appoint each eligible researcher under an employment contract / contract with full social security coverage (including sickness, parental, unemployment and invalidity benefits, pension rights, benefits in respect of accidents at work and occupational diseases) except where national regulation prohibits this possibility.

Table 2 gives the yearly reference rates for calculating the living allowances of each eligible researcher. The amounts per year are given in Euros per category of researchers who are recruited under an employment contract/ contract with full social security coverage complying with the social security legislation applicable[41]. These amounts include all compulsory deductions under national applicable legislation.

Table 2: Yearly reference rates for living allowances under employment contracts (Correction Coefficient index 100)[42]

Researchers Categories	EUR/year
Early-stage researchers	37 320
Experienced researchers	55 800

When an employment contract cannot be provided, the host organisation shall recruit the researcher under a status equivalent to a fixed-amount fellowship. The rates applicable in these cases, which shall be duly justified, will be 50% of the rates for researchers under an employment contract. The host organisation shall ensure that researchers enjoy minimum social security coverage.

The host organisation receiving the Union funding under Table 2 above shall pay to the selected researchers a minimum contribution according to these reference allowances, taking into account all compulsory deductions under national legislation in the context of the project. The host organisation may pay a top-up to the eligible researchers in order to complement this contribution.

In addition to the living allowance, a mobility allowance and a family allowance will be paid for some categories of researchers as specified in Table 3. In this context family is defined as persons linked to the researcher by (i) marriage, or (ii) a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised; or (iii) dependent children who are actually being maintained by the researcher.

[41] Council Regulation (EC) N° 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 and Corrigendum, OJ L 200, 7.6.2004, p. 1 (883/2004)

[42] Rates for individual countries are obtained by applying to these reference rates the respective correction coefficients as listed in Table 4.

The various rates from Tables 2 and 3 apply to researchers devoting themselves to their project on a full-time basis (pro-rata for parts of years). In exceptional cases where researchers, in agreement with the host organisation and with prior approval by the Research Executive Agency, execute their project on a part-time basis, the rates will apply proportionally without the possibility that the total amounts will exceed those that apply for full-time equivalent periods. The same principle will also apply in case of split of a project into several distinct periods.

Table 3: Structure of the European Union contribution

The EU contribution under the Marie Skłodowska-Curie actions is based on unit costs expressed in person-months. They have been established in line with the methodology set up by the Commission Decision n° C(2013) 8194[43] and are indicated in EUR.

Marie Skłodowska-Curie Action	**Researcher unit cost**** **person/month**			**Institutional unit cost**** **person/month**	
	Living allowance*	**Mobility allowance**	**Family allowance**	**Research, training and networking costs**	**Management and indirect costs**
Innovative Training Networks	**3 110**	**600**	**500**	**1 800**	**1 200**
Individual Fellowships	**4 650**	**600**	**500**	**800**	**650**

* A country correction coefficient applies to the living allowance. This coefficient is the one applicable to the country of the researcher's host organisation as listed in Table 4.
** These unit costs will be subject to a funding rate of 100% (Article 28.4 of the Rules for Participation).

[43] COMMISSION DECISION authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme

Marie Skłodowska-Curie Action	**Staff member unit cost**** **Top-up allowance** **person/month**	**Institutional unit cost**** **person/month**	
		Research, training and networking costs	**Management and indirect costs**
Research and Innovation Staff Exchange	**2 000**	**1 800**	**700**

** These unit costs will be subject to a funding rate of 100% (Article 28.4 of the Rules for Participation).

Marie Skłodowska-Curie Action	**Researcher unit cost***** **person/month**		**Institutional unit cost***** **person/month**
Co-funding of regional, national and international programmes	**Early-stage researchers**	**3 710**	**650**
	Experienced researchers	**5 250**	

***These unit costs will be subject to a co-funding rate of 50% (Article 28.3of the Rules for Participation).

The EU contribution for the co-funding of regional, national and international programmes (COFUND) shall be used exclusively as contribution to the management of the programme and to the living allowance of the researchers, which is exclusively for the benefit of the researchers appointed under the project and includes all compulsory deductions under national legislation. Other cost items (such as research costs, travel and mobility allowances, indirect costs) may be funded through other resources including EU programmes other than Horizon 2020. Applicants shall specify in their proposal the amounts that will be provided for the benefit of the researcher and for the organisation that is hosting the researcher. This information will be needed for the expert evaluators to assess the adequateness of employment and working conditions of the researchers.

The researcher unit costs will be reduced by 50% in case that the researchers are recruited under a status equivalent to a fixed-amount fellowship.

The living and mobility allowances provided by the programmes for the benefit of the researchers

- recruited under an employment contract shall in no case be lower than EUR 2 597 (ESR) and EUR 3 675 (ER);
- recruited under a status equivalent to a fixed-amount fellowships shall in no case be lower than EUR 1 298.50 (ESR) and EUR 1 837.50 (ER).

TABLE 4: COUNTRY CORRECTION COEFFICIENTS (CCC)

Country Code[44]	CCC
AT	104.8%
BE	100.0%
BG	71.5%
CY	91.8%
CZ	83.8%
DE	98.8%
DK	135.3%
EE	78.3%
EL	92.7%
ES	97.6%
FI	116.6%
FR	111.0%
HR	97.5%
HU	76.2%
IE	113.5%
IT	106.7%
LT	73.1%
LU	100.0%
LV	75.9%
MT	89.6%
NL	104.3%
PL	76.4%
PT	89.1%
RO	68.3%
SE	111.7%
SI	86.1%
SK	82.6%
UK	120.3%
AL	76.1%
BA	73.6%
CH	113.1%
FO	134.1%
IL	108.7%
IS	116.6%
LI	110.0%
MD	61.1%
ME	66.9%
MK	68.4%
NO	131.9%
RS	67.1%
TR	86.6%
AM	89.9%
AO	114.6%
AR	58.5%
AU	105.0%
AZ	93.0%
BB	116.6%
BD	47.2%
BF	93.8%
BJ	92.6%
BM	151.5%
BO	51.3%
BR	92.0%
BW	55.3%
BY	65.0%
BZ	75.3%
CA	86.4%
CD	127.6%
CF	114.3%
CG	124.9%
CI	102.0%
CL	67.1%
CM	103.3%
CN	85.0%
CO	76.6%
CR	76.7%
CU	83.8%
CV	76.4%
DJ	93.4%
DO	66.9%
DZ	81.7%
EC	68.8%
EG	48.6%
ER	61.2%
ET	85.2%
FJ	68.1%
GA	113.1%
GE	89.5%
GH	68.2%
GM	67.7%
GN	60.4%
GT	78.8%
GW	102.7%
GY	58.9%
HK	93.8%
HN	69.0%
HT	108.7%
ID	75.3%
IN	52.8%
JM	94.9%
JO	75.5%
JP	115.9%
KE	78.1%
KG	83.1%
KH	70.5%
KR	105.2%
KZ	100.2%
LA	77.7%
LB	86.4%

[44] ISO 3166 alpha-2, except for Greece and the United Kingdom (EL and UK used respectively instead of GR and GB).

LK	61.6%
LR	100.1%
LS	56.7%
LY	60.0%
MA	83.5%
MG	80.0%
ML	90.4%
MR	64.5%
MU	72.7%
MW	76.0%
MX	70.4%
MY	71.6%
MZ	71.6%
NA	68.3%
NC	128.9%
NE	87.9%
NG	92.4%
NI	57.3%
NP	73.5%
NZ	94.1%
PA	57.0%
PE	75.5%
PG	83.0%
PH	65.8%
PK	49.4%
PS	100.4%
PY	71.9%
RU	115.5%

RW	87.3%
SA	84.8%
SB	93.3%
SD	65.1%
SG	102.5%
SL	85.2%
SN	86.2%
SR	50.6%
SV	74.3%
SY	74.8%
SZ	56.8%
TD	125.3%
TG	88.7%
TH	65.0%
TJ	64.9%
TL	78.3%
TN	70.5%
TO	85.0%
TT	74.1%
TW	83.6%
TZ	65.2%
UA	92.3%
UG	65.7%
US	99.4%
UY	75.3%
UZ	51.4%
VE	70.0%
VN	51.1%

VU	112.6%
WS	75.8%
XK	58.6%
YE	68.1%
ZA	55.8%
ZM	66.4%
ZW	47.2%

EC Decisions on Lump Sum Pilot of Horizon 2020	See page below
C(2017) 7149 of 27 October 2017: Commission Decision on authorising the use of reimbursement on the basis of a lump sum for the eligible costs of actions under the Horizon 2020 Framework Programme for Research and Innovation, Topic DT-NMBP-20-2018: A digital 'plug and produce' online equipment platform for manufacturing.	2
C(2017) 7151 of 27 October 2017: Commission Decision on authorising the use of reimbursement on the basis of a lump sum for the eligible costs of actions under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018).	11

EUROPEAN
COMMISSION

Brussels, 27.10.2017
C(2017) 7149 final

COMMISSION DECISION

of 27.10.2017

on authorising the use of reimbursement on the basis of a lump sum for the eligible costs of actions under the Horizon 2020 Framework Programme for Research and Innovation, Topic DT-NMBP-20-2018: A digital 'plug and produce' online equipment platform for manufacturing

COMMISSION DECISION

of 27.10.2017

on authorising the use of reimbursement on the basis of a lump sum for the eligible costs of actions under the Horizon 2020 Framework Programme for Research and Innovation, Topic DT-NMBP-20-2018: A digital 'plug and produce' online equipment platform for manufacturing

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation (EU) No 1291/2013 of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Article 10 thereof,

Having regard to the Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)[2], and in particular Article 28.6 thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[3], and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union[4] contains detailed rules regarding lump sums,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme needs to be reflected in its design, rules, financial management and implementation,

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of lump sums is appropriate to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures,

(4) The use of lump-sum financing should therefore be authorised for actions under the Horizon 2020 Framework Programme,

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1 OJ L 2013, 20.12.2013, p. 104-173.

2 OJ L 2013, 20.12.2013, p. 81-103

3 OJ L 2012, 26.10.2012, p. 1-96

4 Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants reimbursing eligible costs on the basis of a lump sum is authorised for Topic DT-NMBP-20-2018: A digital 'plug and produce' online equipment platform for manufacturing under the Horizon 2020 Framework Programme for Research and Innovation (2014-2018), for the reasons and under the conditions set out in the Annex.

This Decision shall apply from the entry into force of this Decision.

Done at Brussels, 27.10.2017

For the Commission
Carlos Moedas
Member of the Commission

EN
ANNEX

1. Form of grant and categories of costs covered

Grants to be awarded under the topic DTY-NMBP-20-2018: A digital 'plug and produce' online equipment platform for manufacturing" of Horizon 2020 work programme 2018-2020 shall exclusively take the form of a standard lump sum pre-fixed by the Commission.

This lump sum will cover the beneficiaries' direct and indirect eligible costs for the project (i.e. design and development of an ICT platform and experimentation of the platform by companies in the manufacturing sector).

These costs must be shown in the proposals, via a description of resources, a detailed cost estimate per work package and per beneficiary and linked third party and a detailed budget table.

This detailed budget should show the costs of each beneficiary in the following categories:

- Direct personal costs
- Other direct costs
- Direct costs of subcontracting
- Direct costs of providing financial support to third parties
- Indirect costs

It may include only costs that would be eligible for an actual costs grant and must exclude costs that are ineligible under the H2020 rules.

Indirect costs should be calculated by applying a flat-rate of 25% to the direct cost categories that qualify for indirect costs under the H2020 rules.

The applicants must also provide in their proposal a breakdown of the lump sum showing the share per work package (and, within each work package, the share assigned to each beneficiary and linked third party). This estimated lump sum breakdown will become part of the grant agreement (Annex 2).

The proposal must describe, for each work package, the activities that are covered by the lump sum share.

The amount of the lump sum for each grant is fixed at 7.5 million euro, following the methodology set out in Section 3.

Payments do not depend on the costs actually incurred.

The lump sum will be paid by the Commission, if the corresponding work packages of the action have been properly implemented in accordance with Annex 1 of the grant agreement (and provided that all other obligations under the grant agreement have been complied with).

Lump sums whose conditions have been fully met during a reporting period are paid to the coordinator.

Lump sums whose conditions have not been fully met during a reporting period are not paid, but could be paid in the subsequent reporting period if the conditions are fully met.

Lump sums whose conditions are not met in any reporting period are not paid and the grant is reduced by an amount up to the value of the lump sums concerned following a contradictory procedure with the coordinator or beneficiary concerned.

2. Justification

Simplification as a central aim of the Horizon 2020 Framework Programme needs to be reflected in its design, rules, financial management and implementation.

Lump sum funding, when compared to reimbursement of actual costs, provides considerable simplification potential. It removes all obligations on cost reporting and financial audits, thus removing a major part of the administrative burden on beneficiaries and enabling efficiency gains in the implementation of Horizon 2020. At the same time, lump sum funding strongly increases the focus on the scientific-technical performance and output of projects. This is desirable in Horizon 2020 in order to improve the quality of results and their exploitation.

Furthermore, lump sums are fully in line with the Commission's initiative Budget Focused on Results and the underlying principles of the proposal for the revision of the Financial Regulation.

2.1. Appropriateness of lump sum costs with regard to the nature of the actions to be supported under the topic DT-NMBP-20-2018: A digital ‘plug and produce' online equipment platform for manufacturing

The actions are part of a pilot exercise for a pre-defined fixed lump-sum and have been chosen because of the substantial industrial participation, including SMEs for which a lump-sum scheme would imply significant administrative simplification. The cost of the type of projects, digital online platforms, can be well estimated based on the envisaged output of the projects and therefore they are appropriate for this pilot.

2.2 The risks of irregularities and fraud and costs of control

The Commission will verify at the time of preparation of the grant, during the implementation of the action or afterwards (through technical checks, reviews or audits), compliance with the conditions for using lumps sums.

As a direct consequence of removing all obligations on cost reporting and financial ex-post audits, financial error rates will be minimised.

Pre-financing will follow the standard H2020 rules, and will be fixed in the grant agreement, 5% of the lump sum is retained as contribution to the Guarantee Fund.

There is no reporting of actual costs, and there are normally no financial checks, reviews, or audits. Beneficiaries have no obligation vis-à-vis the Commission/Agency to document costs incurred for the action but they remain subject to the accounting rules under the applicable national law.

Checks, reviews, and audits will focus on the technical implementation of the action, in particular on the fulfilment of the conditions for releasing lump sums, or on other aspects of the grant agreement such as ethics and research integrity, dissemination and exploitation of results, management of intellectual property, and gender equality.

If such controls reveal that the conditions for payment of the lump sum had not been met (e.g. a particular work package had not been completed), and that an undue payment was made to a beneficiary, the Commission is entitled to recover up to the amount of the grant.

3. Method to determine the amount of the lump sum

The projects to be funded under the topic in question aim to create a digital market place for manufacturing equipment and related services. The users of the online platform are both suppliers and customers of manufacturing equipment in various sectors (the majority of them SMEs) and they should be able to easily connect to it. The main activities of the projects involve the design and development of an ICT platform and its validation by users and suppliers.

In order to establish the amount of the fixed lump sum, 14 EU-funded projects with comparable objectives and structure were identified and analysed.

These projects had comparable objectives (addressing the creation of ICT platforms and networks in the manufacturing domain with the involvement of users and/or suppliers). They were also comparable in terms of their activities, EU funding and total costs.

For the statistical analysis, the activities were grouped in four activity domains according to a typical ICT platform design, development and operation pattern, namely:

A. BUSINESS ANALYSIS (market analysis, technical requirements and applicable standards);
B. TECHNICAL DEVELOPMENT (software creation and testing);
C. OPERATION (experimentation including the involvement of end-users); and
D. HORIZONTAL ACTIVITIES (project management and administration, dissemination and training).

The analysis focused on the activities and resources the projects allocated to each of the domains.

The projects belonged to the following calls for proposals:

1. FP7: FoF-ICT-2013.7.1 - Application experiments for robotics and simulation

2. FP7: FoF-ICT-2013.7.2 - Equipment assessment for sensor and laser based applications
3. H2020: FoF-09-2015 - ICT Innovation for Manufacturing SMEs (I4MS)
4. H2020: FoF-12-2017 - ICT Innovation for Manufacturing SMEs (I4MS).

3.1 Statistical analysis

Table 1 summarises the project costs and EU funding for the 14 projects (and shows averages of project costs, EU funding and resources in person-months for the following groups of projects):

- all 14 projects together;
- all projects excluding the projects selected under the 1st call, who are least representative in terms of project costs and efforts; and
- 3 projects selected under the most recent, 4th call. These projects resemble best the envisaged projects under the topic.

Call	Project	Acronym	Total	EU Funding	Person-Months
1: FP7: FoF-ICT-2013.7.1 Application experiments for robotics and simulation	608849	EuRoC	22,726,345.00	16,500,000.00	
	608886	CloudSME	5,362,934.00	4,496,630.00	
	609100	CloudFlow	8,839,150.00	6,623,000.00	
	609029	FORTISSIMO	22,003,118.00	16,000,000.00	
2: FP7: FoF-ICT-2013.7.2 Equipment assessment for sensor and laser based applications	609046	LASHARE	15,154,157.00	11,200,000.00	
	609306	INTEFIX	10,253,513.00	7,500,000.00	
	609355	APPOLO	14,555,771.00	11,000,000.00	
3: H2020: FoF-09-2015 ICT Innovation for Manufacturing SMEs (I4MS)	680431	ReconCell	6,306,457.00	5,561,569.00	
	680481	FORTISSIMO 2	11,421,307.00	10,000,000.00	
	680633	BEinCPPS	9,517,642.00	8,000,000.00	
	680734	HORSE	8,865,871.25	7,945,601.00	
4: H2020: FOF-12-2017 ICT Innovation for Manufacturing SMEs (I4MS)	767498	MIDIH	8,524,832.50	8,000,000.00	
	767642	L4MS	8,764,549.64	8,000,000.00	
	768892	ClaudiFacturing	9,465,573.00	8,698,548.77	
Average all projects			**11,554,372.89**	**9,251,810.63**	**1,064**
Average all projects except call 1			**10,282,967.34**	**8,590,571.88**	**878**
Average projects under call 4			**8,918,318.38**	**8,232,849.59**	**712**
Lump-sum proposed action			**10,000,000.00**	**7,500,000.00**	**800**

Table 1. Total costs, EU-funding, and person months in 14 signed grants that are representative of the grants to be awarded under the topic "Digital Plug & produce online equipment platform manufacturing"

The amount of the pre-fixed lump sum is based on the above averages.

The EU funding of the envisaged projects is estimated at 7.5 million euro which is slightly lower than the average EU funding of the analysed projects, resulting in a ratio between project budget and EU funding of 4:3. The calculation of this ratio is based on:

(a) the equivalence with the standard Horizon 2020 cost-based funding rules for innovation actions (IA), namely maximum 100% funding for non-profit beneficiaries and maximum 70% funding for profit-making beneficiaries and

(b) the expectation that a large majority of the beneficiaries, including the end-user participants, will be profit-making organisations.

This is because of the industry-oriented nature of the topic, and the fact that roughly one third of the activities are earmarked for activities to be carried out by industrial end-users.

Table 2 shows the split of efforts across the 4 activity groups. This allows to compare the activities of the analysed projects to the envisaged projects under the topic. All analysed project have activities in all four groups, but the projects selected under the earlier calls have less focus on ICT platform design and development and more focus on the actual operation and experiments. The projects under the 4th call include both the design and development of ICT platforms and the operation of the platform, including substantial involvement of end-users. The split of efforts of these projects is expected to be quite similar for the projects under the topic.

	Average effort repartition in %			Estimated effort repartition %
Activity Group	**All calls**	**calls 2,3 and 4**	**call 4 only**	**Lump sum pilot call**
A. BUSINESS ANALYSIS	13	16	21	about 20
B. TECHNICAL DEVELOPMENT	23	23	25	about25
C. OPERATION	47	42	35	about 35
D. HORIZONTAL ACTIVITIES	18	20	19	about 20

Table 2. Distribution of staff efforts across four activity domains in the 14 representative grants analysed.

The analysed projects are a representative sample for the analysis. Despite the variation of resources allocated to activity domains (which depend on the scope of each project), the analysis shows a convergence towards a more homogeneous distribution of activity domains, EU funding and total project costs in projects funded under the later calls.

3.3 Amount of the lump sum

Based on this analysis, it is expected that projects with an estimated budget in the order of 10 million euro should be able to achieve the objectives of the topic.

Since it is expected that a large majority of the beneficiaries will be profit-making organisations (industry-oriented nature of the pilot), that roughly one third of the activities are earmarked for activities to be carried out by industrial end-users, and considering that reimbursement rates for H2020 innovation actions are 70% for profit organisations and 100%

for non-profit organisations, a fixed lump-sum of 7.5 million euro (corresponding to an average 75% reimbursement of costs) should be able to mobilise resources of ca. 10 million euro, which is comparable to similar projects funded under Horizon 2020.

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by the Financial Regulation.

The usual conditions for ensuring that the no-profit, co-financing and absence of double funding principles are complied with also apply to lump sum costs:

- The lump sum is based on statistical data;
- The risk of profit is limited because the lump sum was fixed at lower level than average funding to similar projects, and because there is traditionally high over-subscription in similar calls for proposals. Applicants will therefore face high competition, which is a factor discouraging proposals with a lower value;
- The co-financing principle is complied with, since the lump sum was fixed by taking into account the reimbursement rates (70% and 100%; provided for in Article 28 of the H2020 Rules for Participation), and the extent to which both types of beneficiaries (for-profit and not-for-profit beneficiaries) are expected to participate;
- Double funding is avoided by identifying the project costs that are covered by the lump sum (detailed budget is part of the proposal);
- Proposals will be evaluated according to the standard Horizon 2020 evaluation procedures with the help of outside experts. These experts will assess the quality of the proposals in terms of scientific and technological excellence, expected impact and quality and efficiency of the implementation. The experts will also check the budget estimate and look whether the value of the activities and expected outputs corresponds to the estimated budget and if the resources proposed and the split of lump sum shares allows achieving these activities and expected outputs.

EUROPEAN
COMMISSION

Brussels, 27.10.2017
C(2017) 7151 final

COMMISSION DECISION

of 27.10.2017

on authorising the use of reimbursement on the basis of a lump sum for the eligible costs of actions under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018)

COMMISSION DECISION

of 27.10.2017

on authorising the use of reimbursement on the basis of a lump sum for the eligible costs of actions under the Horizon 2020 Framework Programme for Research and Innovation and under the Research and Training Programme of the European Atomic Energy Community (2014-2018)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to the Regulation (EU) No 1291/2013 of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Article 10 thereof,

Having regard to the Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)[2], and in particular Article 28.6 thereof,

Having regard to the Council Regulation (Euratom) No 1314/2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation[3], and in particular Article 6(1) thereof,

Having regard to Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[4] and in particular Article 124 thereof,

Whereas:

(1) Article 182 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union[5] contains detailed rules regarding lump sums,

(2) Simplification as a central aim of the Horizon 2020 Framework Programme and of the Euratom Programme complementing Horizon 2020 needs to be reflected in its design, rules, financial management and implementation,

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of lump

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1 OJ L 2013, 20.12.2013, p. 104-173.

2 OJ L 2013, 20.12.2013, p. 81-103

3 OJ L-2013,16.12.2013 p..948-964

4 OJ L 2012, 26.10.2012, p. 1-96

5 Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

sums is appropriate to simplify the calculation of grant amounts, to significantly decrease the workload of both the beneficiaries and the Commission as well as to accelerate payment procedures,

(4) The use of lump-sum financing should therefore be authorised for actions under the Horizon 2020 Framework Programme and under the Euratom Programme complementing Horizon 2020,

HAS DECIDED AS FOLLOWS:

Article 1

The use of grants reimbursing eligible costs on the basis of a lump sum is authorised for all actions under the Horizon 2020 Framework Programme for Research and Innovation and under the Euratom Research and Training Programme (2014-2018), for the reasons and under the conditions set out in the Annex.

This Decision shall apply from the entry into force of this Decision.

Done at Brussels, 27.10.2017

For the Commission
Carlos MoedasMember of the Commission

EN

ANNEX

1. Form of grant and categories of costs covered

Grants under the Horizon 2020 Framework Programme and under the Euratom Programme complementing Horizon 2020 may take the form of a lump sum, for calls or topics specified in the Horizon 2020 Work Programme 2018-2020.
This lump sum will determined for each grant by the Commission/Agency on the basis the following principles:

(a) The lump sum must be an approximation of the beneficiaries' underlying actual costs;
(b) The applicants must propose the amount of the lump sum on the basis of their estimated direct and indirect project costs and in accordance with the method described in Section 3;
(c) The proposal must show the costs and categories of costs covered by the lump sum, may contain only costs that would be eligible for an actual costs grant and must exclude costs that are ineligible under the H2020 rules;
(d) The Commission/Agency will apply the method in Section 3 to fix the lump sum, based on the proposal and the evaluation result.
(e) The H2020 25% flat rate for indirect costs and reimbursement rates are included in the calculation of the lump sum (see Section 3).

Payments do not depend on the costs actually incurred.

The lump sum will be paid by the Commission/Agency, if the corresponding work packages of the action have been properly implemented in accordance with Annex 1 of the grant agreement (and provided that all other obligations under the grant agreement have been complied with).

Lump sums whose conditions have been fully met during a reporting period are paid to the coordinator.

Lump sums whose conditions have not been fully met during a reporting period are not paid, but could be paid in the subsequent reporting period if the conditions are fully met.

Lump sums whose conditions are not met in any reporting period are not paid and the grant is reduced by an amount up to the value of the lump sums concerned following a contradictory procedure with the coordinator or beneficiary concerned.

2. Justification

Simplification as a central aim of the Horizon 2020 Framework Programme and of the Euratom Programme complementing Horizon 2020 needs to be reflected in its design, rules, financial management and implementation.

Lump sum funding, when compared to reimbursement of actual costs, provides considerable simplification potential. It removes all obligations on cost reporting and financial audits, thus removing a major part of the administrative burden on beneficiaries and enabling efficiency gains in the implementation of Horizon 2020. At the same time, lump sum funding strongly increases the focus on the scientific-technical performance and output of projects. This is desirable in Horizon 2020 in order to improve the quality of results and their exploitation.

Furthermore, lump sums are fully in line with the Commission's initiative Budget Focused on Results and the underlying principles of the proposal for the revision of the Financial Regulation.

2.1 Risks of irregularities and fraud and costs of control

The Commission/Agency will verify at the time of preparation of the grant, during the implementation of the action or afterwards (through technical checks, reviews or audits), compliance with the conditions for using lumps sums.

As a direct consequence of removing all obligations on cost reporting and financial ex-post audits, financial error rates will be minimised.

Pre-financing will follow the standard H2020 rules, and will be fixed in the grant agreement, 5% of the lump sum is retained as contribution to the Guarantee Fund.

There is no report of actual costs, and there are normally no financial checks, reviews, or audits. Beneficiaries have no obligation vis-à-vis the Commission/Agency to document costs incurred for the action but they remain subject to the accounting rules under the applicable national law.

Checks, reviews, and audits will focus on the technical implementation of the action, in particular on the fulfilment of the conditions for releasing lump sums, or on other aspects of the grant agreement such as ethics and research integrity, dissemination and exploitation of results, management of intellectual property, and gender equality.

If such controls reveal that the conditions for payment of the lump sum had not been met (e.g. a particular work package had not been completed), and that an undue payment was made to a beneficiary, the Commission/Agency is entitled to recover up to the amount of the grant.

3. Method to determine the amount of the lump sum

3.1 Grant proposal

(a) The applicants must provide in their proposal a breakdown of the lump sum showing the share per work package (and, within each work package, the share assigned to each beneficiary and linked third party);

(b) The proposal must describe the activities that are covered by each work package;

(c) Proposals for lump sum grants must contain the resources and a detailed cost estimate per work package and per beneficiary and linked third party.

(d) The applicants must fill in a detailed budget table which shows the costs of each beneficiary in the following categories:

- personnel costs, separately for each category of staff;
- costs of providing financial support to third parties, when the possibility is provided for in the topic;
- travel costs;
- costs of equipment, infrastructure, and other assets (depreciation costs);
- costs for consumables;
- costs of other goods and services;
- capitalised and operating costs of 'large research infrastructure', when the possibility is provided for in the topic;
- costs of internally invoiced goods and services;
- costs of subcontracting

It may include only costs that would be eligible for an actual costs grant and must exclude costs that are ineligible under the H2020 rules.

Beneficiaries must make a declaration that they have followed their own accounting practices for the preparation of the budget.

Indirect costs should be calculated by applying a flat rate of 25% to the direct cost categories that qualify for indirect costs under the H2020 rules.

3.2 Evaluation

(a) Proposals will be evaluated according to the standard Horizon 2020 evaluation procedures with the help of outside experts. The experts will assess the quality of the proposals in terms of scientific and technological excellence, expected impact and quality and efficiency of the implementation. Experts with the necessary financial know-how will also check the budget estimate and look whether the resources proposed and the split of lump sum shares allows achieving the activities and expected outputs. Experts should check that proposals include the declaration by beneficiaries of having used their own accounting practices. For each work package, the budget estimate will be assessed for accuracy and appropriateness in view of the proposed resources. For this, the experts will consult statistical data on costs and resources from previously funded, comparable projects provided by the Commission/Agency.

(b) Following proposal evaluation, the authorising officer may adapt estimated cost items that appear unjustified or not in line with the requirements in point 3.1 above (including in case of recommendations from the expert evaluators). If cost items are adapted, the lump sum and the lump sum breakdown are modified accordingly during grant preparation.

(c) The final lump sum is included in the grant agreement as the maximum grant amount. It is calculated by applying the reimbursement rate set out in the H2020 rules to the total estimated eligible costs in the detailed budget table.

4. No-profit and co-financing principles and absence of double financing

The methodology described in Section 3 complies with the principles of no-profit, co-financing and absence of double funding as required by the Financial Regulation.

The usual conditions for ensuring that the no-profit, co-financing and absence of double funding principles are complied with, also apply to lump sums:

- The cost estimate in the grant proposal is detailed and subject to an in-depth check by the evaluation committee to ensure it represents an approximation of actual eligible costs as described in points 3.1 and 3.2.
- The reimbursement rates set out in Article 28 of the H2020 Rules for Participation are reflected in the calculation of the lump sum.
- Double funding is avoided by identifying the project costs that are covered by the lump sum.
- Proposals will be evaluated according to the standard Horizon 2020 evaluation procedures with the help of outside experts, and according to the principles presented in section 3.2.

Ethics and data protection

14 November 2018

Disclaimer
This document has been drafted by a panel of experts at the request of the European Commission (DG Research and Innovation) and aims at raising awareness in the scientific community, and in particular with beneficiaries of EU research and innovation projects. It does not constitute official EU guidance. Neither the European Commission nor any person acting on their behalf can be made responsible for the use made of it.

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I. Introduction

Data protection is both a central issue for research ethics in Europe and a fundamental human right. It is intimately linked to autonomy and human dignity, and the principle that everyone should be valued and respected. For this principle to guide the development of today's information society, data protection must be rigorously applied by the research community.

The right to data protection is enshrined in the EU Charter of Fundamental Rights and the Treaty on the Functioning of the European Union, which give effect to individuals' right to privacy by providing them with control over the way information about them is collected and used.[1]

In research settings, data protection imposes obligations on researchers to provide research subjects with detailed information about what will happen to the personal data that they collect. It also requires the organisations processing the data to ensure the data are properly protected, minimised, and destroyed when no longer needed.

Depending on the setting or information in question, the failure to protect personal data against loss or misuse can have devastating consequences for the data subjects. It may also have serious legal, reputational and financial consequences for the data controller and/or processor.[2] Many recent examples of unethical research practices have involved the unauthorised collection and/or (mis)use of personal data, resulting in enforcement action by regulators.

While individual EU-funded research projects processing personal data must comply with EU and national data protection laws, the objective of this guidance note is to ensure that, in addition to respecting legal obligations, all projects are guided by ethical considerations and the values and principles on which the EU is founded.

Particular attention should be paid to research involving special categories of data (formerly known as 'sensitive data'), profiling, automated decision-making, data-mining techniques, big-data analytics and artificial intelligence, as such processing operations may pose higher risks to the rights and freedoms of data subjects (see Table 1). The increasing impact of these and other new technologies on our everyday lives and activity is reflected in the letter and spirit of the EU's 2016 General Data Protection Regulation GDPR).

While the EU's ethics review process is primarily concerned with ethics issues, your project must demonstrate compliance with the GDPR. However, the fact that your research is legally permissible does not necessarily mean that it will be deemed *ethical*.

Crucially, if your research proposal involves the processing of any personal data, whatever method is used, you – and all of your partners, collaborators and service providers – must, if called upon, be able to demonstrate compliance with both legal and ethical requirements. Such requests could come from data subjects, funding agencies or data protection supervisory authorities.

When developing and implementing your proposal, it is your responsibility to identify the appropriate legal provisions and ensure compliance. All EU projects processing personal information about identifiable human research subjects are subject to the GDPR. The principle of accountability is central to the GDPR and requires data processors to establish and document data protection compliance processes. Comprehensively addressing data protection issues in your research proposal, which will become part of your contract if selected for funding, can make an important contribution to the accountability of the project.

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1 Article 8, EU Charter of Fundamental Rights.

2 Regulators may impose fines of up to €20 million or 4 % of the global turnover of the entity (whichever is higher).

Note that in addition to the GDPR, national legislation or related EU measures could also apply to your research:

- if your proposal uses data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences, Directive (EU) 2016/680 may also apply;
- if your project uses personal data generated or processed by electronic networks (e.g. data relating to 'cookies', internet usage or electronic network traffic), the EU's e Privacy Directive (currently under revision) may also apply;
- EU Member States have laid down their own rules on data processing, e.g. the processing of special categories of data (such as genetic, biometric and/or health data) may be subject to additional national legal requirements, such as prior notification of regulators or data protection authorities. It is your responsibility to ensure that your research complies with the data protection laws in all the Member States in which your research data are processed, as well as the GDPR.[3]

[3] See in particular Articles 9(4), 8 and 89(3) GDPR.

[Box 1] Key issues, concepts and definitions

'**Personal data'** are defined extremely broadly and include **'any information relating to an identified or identifiable natural person'**. An **'identifiable natural person'**, or **'data subject'**, is **'one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'** (Article 4(1) GDPR).

Personal data include data such as internet protocol (IP) addresses (unique identifiers that can be used to identify the owner of devices connected to the internet) and data from 'smart meters' monitoring energy usage by addresses linked to identifiable persons.

'Special categories of personal data' (formerly known as 'sensitive data') are subject to more stringent data-protection safeguards. They include ' **personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation'**(Article 9(1) GDPR).

If your project involves the processing of special categories of data, it is more likely to raise significant ethics issues. You must therefore justify the inclusion of this kind of data in your project.

The definition of **'data processing'** is very broad. It includes **'any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction'** (Article 4(2) GDPR).

It is highly likely that if your project involves any data about identifiable persons, even if they are not directly participating in the research, you are processing personal data and must comply with EU and national law. Only data that have been fully and irreversibly anonymised are exempt from these requirements. Importantly, while **pseudonymisation** can provide individual data subjects with a degree of protection and anonymity, pseudonymised data still fall within the scope of personal data because it is possible to re-identify the data subject (see below).

Even if your project is using only **anonymised data**, the origin or acquisition of the data may still raise significant ethics issues.

The GDPR places obligations on both:

- the **'data controller'**, which **'alone, or jointly with others, determines the purposes and means of the processing of personal data'**; and
- the **'data processor'**, which **'processes personal data on behalf of the controller'**.

You must ensure that any partners, contractors or service providers that process research data at your request and on your behalf comply with the GDPR and the H2020 ethics standards. Where you share with consortium partners the responsibility for processing personal data collected in the course of your research project, your project may have **joint data controllers**. In this case, you and your partners must set out your respective responsibilities in an agreement available to data subjects and provide them with a single point of contact.

II. Identifying and addressing ethics issues in your research proposal

All research proposals that involve the processing of personal data must provide information about the data protection provisions in their proposal. It is more likely that your project raises higher ethics risks if it involves:

- Processing of 'special categories' of personal data (formerly known as 'sensitive data');
- processing of personal data concerning children, vulnerable people or people who have not given their consent to participate in the research;
- complex processing operations and/or the processing of personal data on a large scale and/or systematic monitoring of a publicly accessible area on a large scale;
- data processing techniques that are invasive and deemed to pose a risk to the rights and freedoms of research participants, or techniques that are vulnerable to misuse; and
- collecting data outside the EU or transferring personal data collected in the EU to entities in non-EU countries.

[Table 1] Indicators of data processing operations that may entail higher ethics risks

Types of personal data	* racial or ethnic origin * political opinions, religious or philosophical beliefs * genetic, biometric or health data * sex life or sexual orientation * trade union membership
Data subjects	* children * vulnerable people * people who have not given their explicit consent to participate in the project
Scale or complexity of data processing	* large-scale processing of personal data * systematic monitoring of a publicly accessible area on a large scale * involvement of multiple datasets and/or service providers, or the combination and analysis of different datasets (i.e. big data)
Data-collection or processing techniques	* privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals) * using camera systems to monitor behaviour or record sensitive information * data mining (including data collected from social media networks), 'web crawling' or social network analysis * profiling individuals or groups (particularly behavioural or psychological profiling) * using artificial intelligence to analyse personal data * using automated decision-making that has a significant impact on the data subject(s)
Involvement of non-EU countries	* transfer of personal data to non-EU countries * collection of personal data outside the EU

Further indicators of the kinds of project and data-processing operation that may be considered higher-risk are provided throughout this note (see in particular the sections on data protection impact assessments and profiling, tracking, surveillance, automated decision-making and big data).

If your research entails higher-risk data processing, you must provide a detailed analysis of the ethics issues raised by your project methodology. This should comprise:

- an overview of all planned data collection and processing operations;
- identification and analysis of the ethics issues that these raise; and
- an explanation of how you will mitigate these issues in practice.

You must ensure that these issues are duly included and addressed in the research protocol that you submit to your research ethics committee. You may also be required to conduct a data protection impact assessment (DPIA) in line with Article 35 GDPR and supplementary guidance on DPIAs (see below).

If your institution has appointed a data protection officer (DPO), you should involve them in all stages of your project and seek their advice on data privacy issues. This will help in the implementation of your proposal and grant agreement (EU grants are subject to full compliance with data privacy rules).

Where complex, sensitive or large-scale data processing is envisaged or data are to be transferred outside the EU, you should consult the DPO on the compatibility of the data protection arrangements with the host institution's policies and applicable legislation.

You should include the opinion and/or advice of the DPO in your proposal. If your host institution does not have a DPO, it is recommended that you seek the advice of a suitably qualified expert.

III. Pseudonymisation and anonymisation

One of the best ways to mitigate the ethical concerns arising from the use of personal data is to anonymise them so that they no longer relate to identifiable persons. Data that no longer relate to identifiable persons, such as aggregate and statistical data, or data that have otherwise been rendered anonymous so that the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law.

However, even if you plan to use only anonymised datasets, your proposal may still raise significant ethics issues. These could relate to the origins of the data or the manner in which they were obtained. You must therefore specify the source of the datasets you intend to use in your proposal and address any ethics issues that arise. You must also consider the potential for misuse of the research methodology or findings, and the risk of harm to the group or community that the data concern.

Where it is necessary to retain a link between the research subjects and their personal data, you should, wherever possible, pseudonymise the data in order to protect the data subject's privacy and minimise the risk to their fundamental rights in the event of unauthorised access. Pseudonymisation and anonymisation are not the same thing and it is important that you are aware of the difference between them, as the GDPR requires you to use them wherever possible or feasible (Article 89 GDPR).

[Box 2] Pseudonymisation and anonymisation: understanding the difference

Pseudonymisation entails substituting personally identifiable information (such as an individual's name) with a unique identifier that is not connected to their real-world identity, using techniques such as coding or hashing. However, if it is possible to re-identify the individual data subjects by reversing the pseudonymisation process, data protection obligations still apply. They cease to apply only when the data are fully and irreversibly anonymised.

Anonymisation involves techniques that can be used to convert personal data into anonymised data. Anonymisation is increasingly challenging because of the potential for re-identification.

Re-identification is the process of turning pseudonymised or anonymised data back into personal data by means of data matching or similar techniques.

While anonymised data are no longer considered personal data, anonymisation processes are challenging, particularly where large datasets containing a wide range of personal data are concerned. This is because it is very difficult to create fully anonymous datasets that retain the granular information needed for research purposes.[4] As far as your research proposal is concerned, if there is a significant prospect of re-identification of persons whose data have been collected, the information should be treated as personal data. It is difficult to assess the risk of re-identification with absolute certainty and you should always err on the side of caution. A growing body of case studies and research publications in which individuals are identified from 'anonymous' datasets has demonstrated the fundamental constraints to anonymisation as a technique to protect the privacy of individuals.

If you intend to anonymise the data you collect for use in your research project, the timing of the anonymisation process is paramount. You are collecting 'anonymised' data only if the anonymisation happens at the point and time at which the data are collected from the research subject, so that no personal data are actually processed. If anonymisation takes place at a later stage, e.g. you intend to remove personally identifiable information during the transcription of audio recordings or at the point at which survey data are fed into a database, the raw data are still personal data and your proposal must include provisions for their protection up until the point at which they are deleted or rendered anonymous.

In some instances, your host institution, funding body or publisher may require you to keep the raw data for auditing, accountability or research integrity purposes. There may be other scenarios in which a host institution has a raw dataset which it makes available to its researchers and partners in anonymised form. In these instances, while the recipients of the anonymised data may – subject to the mitigation of the risk of re-identification – be exempt from data protection requirements, the host institution is still processing personal data and must therefore ensure appropriate protection for the raw (personal) data. This includes technical and organisational measures to protect the data and the means to identify the data subjects (e.g. the keys, codes or applications used to anonymise the data) against unauthorised access or use. If you are in any doubt as to the adequacy of the technique(s) that you intend to use, you should seek advice from your DPO or a suitably qualified expert. As noted below (see Box 5), for sensitive or complex processing scenarios involving pseudonymisation or anonymisation, it may even be necessary to conduct a DPIA in order to ensure an appropriate level of data protection and minimise risk to the data subjects' rights.

[4] See also *Opinion 05/2014 on anonymisation techniques*, Article 29 Working Party (adopted 10 April 2014).

IV. Data protection by design and default

To innovate ethically and responsibly, researchers and developers have long been encouraged to apply the concept of 'privacy by design', which provides a framework for focusing the design of systems, databases and processes on respect for data subjects' fundamental rights. A wider concept of 'data protection by design', now included in the GDPR, requires data controllers to implement appropriate technical and organisational measures to give effect to the GDPR's core data-protection principles (articles 5 and 25 GDPR). Data protection by design is one of the best ways to address the ethics concerns that arise from your research proposal at the design stage of your project.

In a research and development context, measures to achieve data protection by design could include:

- the pseudonymisation or anonymisation of personal data;
- data minimisation (see Box 3);
- applied cryptography (e.g. encryption and hashing);
- using data-protection focused service providers and storage platforms; and
- arrangements that enable data subjects to exercise their fundamental rights (e.g. as regards direct access to their personal data and consent to its use or transfer).

When considering whether and how to apply the principle of data protection by design, you should take into account:

- the nature, scope, context and purposes of processing;
- the severity of the risks to the data subjects' fundamental rights should you fail to protect their information; and
- the cost and availability of the technologies and applications you may need.

You must apply the principle of data protection by design where it could mitigate the ethics risks raised by the data processing in your research project, and explain in your research proposal how this will be achieved. This approach is underscored by the principle of data protection by default. **Wherever you have the possibility to enhance the level of data protection afforded to your research subjects, you should apply such measures by default rather than just considering them or making them available as an optional extra.**

Where your research involves complex, sensitive or large-scale data processing, your proposal should include a description of the measures you will take to apply the principles of data protection by design and default, and/or to enhance security so as to prevent unauthorised access to personal data or equipment.

[Box 3] Data minimisation

Data processing must be lawful, fair and transparent. **It should involve only data that are necessary and proportionate** to achieve the specific task or purpose for which they were collected (Article 5(1) GDPR).

You should therefore **collect only the data that you need to meet your research objectives**. Collecting personal data that you do not need for your research project may be deemed unethical and unlawful.

If you are in any doubt as to whether you actually need all of the data you intend to collect, you should **conduct a data minimisation review**. This should be designed and conducted by the research team to ensure that data are collected on a **'need to know' basis**, i.e. the data are required for a specific purpose that is relevant and limited to your project's objectives and methodology.

Data minimisation applies not only to the amount of personal data collected, but also to the extent to which they may be accessed, further processed and/or shared, the purposes for which they are used, and the period for which they are kept. You must minimise the processing as far as possible.

If you are unable fully to identify the purpose of the data processing at the time of data collection or you need to keep the data beyond the duration of your project, **you must explain and justify the data collection and retention arrangements**.

You must also explain how you will apply the principles of data minimisation and data protection by design in practice. In particular, you must ensure that:

- you pseudonymise or anonymise the data wherever possible (see Box 2);
- the data are securely stored; and
- where appropriate, policies and procedures are established to limit the use of the data and protect the fundamental rights of the data subjects.

V. Informed consent to data processing

Informed consent is the cornerstone of research ethics. It requires you to explain to research participants what your research is about, what their participation in your project will entail and any risks that may be involved. Only after you have conveyed this information to the participants – and they have fully understood it – can you seek and obtain their express permission to include them in your project (Articles 4(11) and 7 GDPR).[5]

In principle, living individuals should not be the subject of a research project without being informed, even in the relatively rare cases where research methods, conditions or objectives dictate that they are not made fully aware of the nature of the study until its completion. However, the advent of the internet and the widespread use of social media platforms and other ICTs have dramatically expanded opportunities for researching human behaviour without the express consent of the subjects. In turn, this has created a range of ethical dilemmas and challenges for the research community.

Whenever you collect personal data directly from research participants, you must seek their informed consent by means of a procedure that meets the minimum standards of the GDPR. This requires consent to be given by a clear affirmative act establishing a freely given, specific, informed

[5] For research involving clinical trials, data processing should also comply with Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

and unambiguous indication of the subject's agreement to the processing of their personal data.[6] This may take the form of a written statement, which may be collected by electronic means, or an oral statement.

Wherever possible, this process should be integrated into a broader informed consent procedure that meets the standards set out in the Commission's *Guidance note on informed consent*. However, for projects involving particularly complex or sensitive data-processing operations, or intrusive methods such as behavioural profiling, audio/video recording or geo-location tracking, you should implement a specific informed consent process covering the data-processing component of your project.

You must keep records documenting the informed consent procedure, including the information sheets and consent forms provided to research participants, and the acquisition of their consent to data processing. These may be requested by data subjects, funding agencies or data protection supervisory authorities.

For consent to data processing to be 'informed', the data subject must be provided with detailed information about the envisaged data processing in an intelligible and easily accessible form, using clear and plain language. As a minimum, this should include:

- the identity of the data controller and, where applicable, the contact details of the DPO;
- the specific purpose(s) of the processing for which the personal data will be used;
- the subject's rights as guaranteed by the GDPR and the EU Charter of Fundamental Rights, in particular the right to withdraw consent or access their data, the procedures to follow should they wish to do so, and the right to lodge a complaint with a supervisory authority;
- information as to whether data will be shared with or transferred to third parties and for what purposes; and
- how long the data will be retained before they are destroyed.

The data subjects must also be made aware if data are to be used for any other purposes, shared with research partners or transferred to organisations outside the EU (see article 13 GDPR).

As with any research project involving human subjects, **if the data processing entails potential risks to the data subjects' rights and freedoms, they must be made aware of these risks during the informed consent procedure**.

The consent process(es) and the information you give to the data subjects should cover all the data-processing activities related to their participation in your research. From a research ethics perspective, and in accordance with the principles of fair and transparent data processing, if you intend to use or make their data available for future research projects, it is best practice to obtain their additional, explicit consent to the secondary use of the data.[7] If you do plan to use the data in

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[6] See also Article 7 GDPR and *Guidelines on consent under Regulation 2016/679*, Article 29 Working Party (adopted 28 November 2017).

[7] e.g. 'A university research department conducts an experiment analysing changes of mood on 50 subjects. These are required to register in an electronic file their thoughts every hour, at a given time. The 50 persons gave their consent for this particular project, and this specific use of the data by the university. The research department soon discovers that electronically logging thoughts would be very useful for another project focused on mental health, under the coordination of another team. Even though the university, as controller, could have used the same data for the work of another team without further steps to ensure lawfulness of processing that data, given that the purposes are compatible, the university informed the subjects and asked for new consent, following its research ethics code and the principle of fair processing' (*Handbook on European data protection law: 2018 edition*, EU Fundamental

multiple projects or for purposes other than your research, you must give the data subjects the opportunity to opt out of the further processing operation(s).

If in the course of your research project you wish to make any significant changes to your methodology or processing arrangements that have a bearing on the data subjects' rights or the use of their data, you must make them aware of the intended changes, and seek and obtain their express consent; it is not enough to offer them the opportunity to opt out. This must be done *before* you make the changes.

If your project involves complex and large-scale data processing, if you plan to use the data in multiple projects or for multiple purposes, or if it is not possible fully to identify the purpose of the data processing at the time of data collection, it may be appropriate to use a consent management application. Various service providers now offer ethically robust, secure informed consent platforms that can help you to manage, document and evidence your consent processes.

VI. Collecting data on children

All research involving children and young people raises significant ethics issues, as they may be less aware of the risks and consequences of their participation. This is also true as regards the processing of their personal data.

If your research project involves collecting data from children, you must follow the *EC Guidance note on informed consent*, in particular the provisions on obtaining the consent of a parent/legal representative and, where appropriate, the assent of the child. As that guidance makes clear, it is imperative that any information you address to a child is in age-appropriate and plain language that they can easily understand. You must also apply the principle of protection by design to research data concerning children and minimise the collection and processing of their data as far as possible.

The GDPR establishes special safeguards for children in relation to 'information society services', a broad term covering all internet service providers, including social media platforms.[8] These include a requirement for *verified* parental consent in respect of information society services offered directly to children aged under 16. Individual Member States may provide for this threshold to be lowered to 13. If you are collecting data from children using ICTs (e.g. from social media platforms or apps), you must ensure that you observe the national and EU law safeguards and explain in your proposal how you will obtain and verify the parent/legal representative's consent.

VII. Use of previously collected data ('secondary use')

As noted above, some of the most high-profile breaches of ethics standards have concerned the use of data collected for one purpose and then used for other research or targeting processes, without the knowledge or consent of the data subject. If you are processing personal data in your research without the express consent of the data subjects, you must explain how you will obtain the data, justify their use in your project and ensure that the processing is fair to the data subject.

If the collection or use of data raises specific ethics issues (e.g. as regards consent and transparency, privacy and the rights and expectations of the data subjects), you must provide a detailed overview

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Rights Agency, European Court of Human Rights, Council of Europe and European Data Protection Supervisor (2018); http://fra.europa.eu/en/publication/2018/handbook-european-data-protection-law).

[8] See also Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

of the planned data collection and processing operations and **explain how the ethics concerns will be mitigated**.

If you are using data that are publicly available, you must provide details of the source(s) and confirm that the data are openly and publicly accessible and may be used for research purposes. You must also do this where the data you intend to use have been manifestly made public by the data subject (see Box 4).

[Box 4] Using 'open source' data

The fact that some data are publicly available does not mean that there are no limits to their use.

On the contrary, **if you take 'open source' personal data about identifiable persons and create new records or files/profiles, you are processing personal data about them** and must have a lawful/legitimate basis for doing so.

You must ensure that the data processing is fair to the data subject and that their fundamental rights are respected.

If your research project uses **data from social media networks** and you do not intend to seek the data subjects' explicit consent to the use of their data, you must assess whether those persons actually intended to make their information public (e.g. in the light of the privacy settings or limited audience to which the data were made available).

It is not enough that the data be accessible; they must have been made public to the extent that the data subjects do not have any **reasonable expectation of privacy**. **You must also ensure that your intended use of the data complies with any terms and conditions published by the data controller**.

If you are in any doubt as to what you can and cannot do with this kind of data, you should seek advice from your DPO or a suitably qualified expert and include their opinion in your proposal.

If you intend to use personal data that were collected from a previous research project, you must provide details regarding the initial data collection, methodology and informed consent procedure. You must also confirm that you have permission from the owner/manager of the dataset(s) to use the data in your project.

Where the planned use of data is predicated on the 'legitimate interests' of the data controller, the nature and purpose of the dataset must be set out in detail, together with the safeguards (e.g. anonymisation or pseudonymisation techniques) that warrant its use in your project.[9]

If your intended data processing is based on national legislation or international regulations authorising your research, or a demonstrable overriding public interest (e.g. public health, social protection) allows you to use a particular dataset, your proposal must make reference to the relevant Member State or Union law or policy.

In principle, if you are using personal data provided to you by a third party and the data subjects have not expressly consented to its use in research projects, you must, in accordance with the GDPR, inform them that you have acquired the data and what you will be using them for (art.14 GDPR). You must also provide them with the same basic information about the data processing and their rights

[9] According to the GDPR, '[t]he legitimate interests of a controller, including those of a controller to which the personal data may be disclosed, or of a third party, may provide a legal basis for processing, provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, taking into consideration the reasonable expectations of data subjects based on their relationship with the controller'. See also recital 47 and Article 89 GDPR.

as data subjects that you are obliged to provide to people you are collecting data from directly (see section V). These requirements do not apply only where it is not possible or would involve a disproportionate effort to contact the data subjects. However, in such cases you must implement appropriate safeguards, including technical and organisational measures to ensure respect for the principle of data minimisation (see Box 3) and protect the subjects' fundamental rights. Crucially, the GDPR requires that pseudonymisation or anonymisation techniques (see above) be implemented wherever viable (article 89 GDPR).

VIII. Data protection impact assessments

The risk-based approach to data processing upon which the GDPR is predicated can help researchers with complex, sensitive or large-scale data processing requirements to identify and address the ethics issues that arise from their methods and objectives.

The DPIA is a process designed to assess the data-protection impacts of a project, policy, programme, product or service and, in consultation with relevant stakeholders, to ensure that remedial actions are taken as necessary to correct, avoid or minimise the potential negative impacts on the data subjects.

Under the GDPR, a DPIA is mandatory for processing operations that are likely to 'result in a high risk to the rights and freedoms of natural persons'(art.35). These include in particular:

- a 'systematic and extensive' analysis of personal data in the context of automated processing, including profiling, where this has a significant effect on the data subject;
- large-scale processing of 'special categories' of personal data, or of personal data relating to criminal convictions and offences; or
- a systematic monitoring of a publicly accessible area on a large scale.

The EU's Article 29 Working Party (WP29) has produced a longer list of scenarios in which it is likely to be necessary to conduct a DPIA (see Box 5). The European Data Protection Board and national data protection supervisory authorities are expected to clarify further those processing operations for which DPIAs are mandatory. It is your responsibility to check whether you are required to conduct a DPIA in accordance with EU or Member State rules.

If your research objectives and methods require you to conduct a DPIA in accordance with the GDPR, then provision for this must be made in your proposal. This includes details of how, when and by whom the assessment will be conducted.

Crucially, if the DPIA indicates that the envisaged processing would result in a high risk to people's rights and freedoms in the absence of measures taken by the controller to mitigate the risk, you must seek the advice of your data protection supervisory authority as to whether the envisaged processing is permissible(art.36 GDPR).This may in turn have a significant bearing on the viability of your research proposal and must therefore be addressed in your risk assessment.

If you are unsure as to whether you are required to conduct a DPIA, you should seek advice from your DPO or a suitably qualified expert, and include their opinion in your proposal. Even if you are not required to conduct a DPIA in accordance with the GDPR, it is good practice to conduct such an assessment in order to ascertain and minimise risk wherever the envisaged data processing is complex, large-scale or sensitive.

Regardless of whether a DPIA is required or conducted, if the data processing that you envisage raises significant ethics concerns, you must provide a thorough evaluation of those risks in your proposal. As a minimum, this should include the risk of unethical conduct or harm to the wellbeing

or interests of research participants at both individual (e.g. research participants, their associates or other third parties) and group level (e.g. the potential for adverse impacts on the community that the data concern).

When assessing the ethical issues arising from your research, you must consider the risk of discrimination, stigmatisation, data breaches (i.e. exposing the identity or sensitive data of individuals or damaging their reputation through a breach of confidentiality), threats to the safety or security of participants and the potential for misuse of the research methodology or findings.

[Box 5] Scenarios in which you should conduct a data protection impact assessment

WP29 considers that **processing operations raising multiple data-protection concerns are more likely to present a high risk to the rights and freedoms of data subjects, and therefore require a DPIA**, regardless of the measures, which the controller intends to adopt. The Article 29 guidance note[10] gives the following examples:

Examples of processing	Possible Relevant criteria	DPIA likely to be required?
A hospital processing its patients' genetic and health data (hospital information system).	- Sensitive data or data of a highly personal nature - Data concerning vulnerable data subjects - Data processed on a large-scale	Yes
The use of a camera system to monitor driving behaviour on highways. The controller envisages to use an intelligent video analysis system to single out cars and automatically recognise license plates.	- Systematic monitoring. - Innovative use or applying technological or organisational solutions	Yes
A company systematically monitoring its employees' activities, including the monitoring of the employees' work station, internet activity, *etc*.	- Systematic monitoring - Data concerning vulnerable data subjects	Yes
The gathering of public social media data for generating profiles.	- Evaluation or scoring - Data processed on a large scale - Matching or combining of datasets - Sensitive data or data of a highly personal nature	Yes
An institution creating a national level credit rating or fraud database.	- Evaluation or scoring - Automated decision making with legal or similar significant effect - Prevents data subject from exercising a right or using a service or a contract - Sensitive data or data of a highly personal nature	Yes
Storage for archiving purpose of pseudonymised personal sensitive data concerning vulnerable data subjects of research projects or clinical trials	- Sensitive data - Data concerning vulnerable data subjects. - Prevents data subjects from exercising a right or using a service or a contract	Yes

[10] *Guidelines on data protection impact assessment (DPIA) and determining whether processing is 'likely to result in a high risk' for the purposes of Regulation 2016/679*, Article 29 Working Party (last revised and adopted 4 October 2017).

IX. Profiling, tracking, surveillance, automated decision-making and big data

The widespread use and vast research and development potential of information and communication technologies has created a new range of ethical challenges. These include potentially adverse or unforeseen consequences for individual data subjects, specific communities and society at large. These may relate to the implications of combining and analysing different datasets, the potential for misuse of applications, or the risk of institutionalised discrimination.

If your research project involves these techniques, you must provide a detailed analysis of the ethics issues raised by your methodology. This should comprise:

- an overview of all planned data collection and processing operations;
- identification and analysis of the ethics issues that these raise; and
- an explanation of how these issues will be addressed to mitigate them in practice.

If human participants are involved in your research, you must ensure that robust informed consent procedures are in place. **Your research involves human participants if you recruit them directly, or if your research activities consist of actively involving, influencing, manipulating or directing people in any way.**

If your project involves the large-scale processing of personal data using techniques such as data-mining, 'web crawling' or social network analysis, you should address both the ethics implications of the research methods and the GDPR compatibility of the data processing.

If your project involves the automated processing or profiling of personal data (see Box 6), your proposal should address the ethical implications of the objectives, methods and expected outcomes. You should also consider the legal, social and ethical impacts of any big-data analysis,[11] in particular its potential impact on people's right to equal treatment and non-discrimination.[12]

If your project involves developing or using technology that may be used for the surveillance or tracking of individuals, it may fall within the scope of the EC dual-use regulation (428/2009) , or be vulnerable to misuse. In such cases, you must consult the EC Guidance note-Research involving dual use items and/or EC Guidance note- Potential misuse of research.

If your project entails the intensive monitoring or tracking of research participants, for example with regard to their movements, behaviour, activities or emotions, your proposal must explain what measures will be taken to protect both their personal data and fundamental rights.

If the goal of the project is to develop surveillance technologies or techniques for law enforcement purposes, your proposal should explain why the surveillance can be deemed necessary and proportionate in a democratic society, in accordance with EU values, principles and laws.

As noted above, this kind of research may require a DPIA in accordance with the GDPR or supplementary guidance issued by supervisory authorities. If your planned research activities entail multiple or particularly complex ethics issues that cannot be resolved at the proposal stage, or subsequently through a DPIA, your proposal should make provision for a broader ethical impact assessment, which should in turn be subject to review by your research ethics committee or other appropriate body.

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[11] See also *Guidelines on the protection of individuals with regard to the processing of personal data in a world of big data (Big Data Guidelines)*, Council of Europe (January 2017).

[12] Article 21, EU Charter of Fundamental Rights.

[Box 6] Automated processing and profiling

The GDPR includes specific safeguards related to the automated processing or 'profiling' of personal data that has, or is likely to have, a significant legal or material impact on the data subject (article 22 GDPR). Profiling and its impact are expressly linked to evaluation and scoring: **the more intrusive the profiling and the greater the potential effect of the result, the more likely it is to raise significant ethical and fundamental rights issues**. The GDPR safeguards are designed to enable the data subject to:

- understand that they are subject to profiling;
- know the logic behind the processing and any envisioned consequences of such processing;
- object to or opt out of the processing; and
- contest or seek human intervention in respect of the automated decision reached.

As research or development projects (rather than real-world applications), your activities may not have a significant legal or material impact on the data subject. However, in accordance with the principles of data protection by design and responsible research and innovation, **you must consider the automated processing and profiling safeguards required by the GDPR at the project development stage**. If you intend or expect your methodology to be used more widely (e.g. in a product, application or research context), you must develop the requisite safeguards.

Profiling safeguards include the use of proven and reliable mathematical and statistical methods, methods to ensure that data are as accurate as possible, and the development of models and techniques to minimise the risk of error or discriminatory effect. **Transparency and accountability to research participants are particularly important** and the GDPR also requires you to **provide data subjects with information on the automated processing, profiling and assessment, and recourse for those affected to obtain an explanation and challenge the decision reached**.

X. Data security

Whenever and however you collect personal data, you have both ethical and legal obligations to ensure that participants' information is properly protected. This is fundamental to safeguarding their rights and freedoms, and minimising the ethics risks related to the data processing.

The GDPR requires all data controllers and processors to implement appropriate technical and organisational measures to ensure a level of data security that is commensurate to the risks faced by the data subjects in the event of unauthorised access to, or disclosure, accidental deletion or destruction of, their data (art.32 GDPR).

Your proposal should provide details of the technical and organisational measures that will be implemented to protect the personal data processed in the course of your research, e.g. with reference to your host institution's and research partners' data protection and information security policies. Such measures may include the pseudonymisation and encryption of personal data, and policies and procedures to ensure the confidentiality, integrity, availability and resilience of processing systems.

Where higher-risk processing is envisaged (e.g. involving special categories or large-scale data), you should explain clearly how you will ensure an enhanced level of data security. In these scenarios, it is important that you choose appropriate research methods and data-processing tools (see Box 7).

This is vital where your research involves research subjects who are vulnerable or may be rendered vulnerable because of their participation in your research project. This may be the case, e.g. if you are collecting data on sensitive political issues or communicating with people in countries with repressive governments. Almost all communication is vulnerable to surveillance and interception,

but some channels are more susceptible than others. Wherever you believe there is a heightened risk to researchers and research participants, you should ensure that your communications are secure from unauthorised access.

[Box 7] Data security: 10 do's and don'ts

Do

- ✓ use GDPR-compliant tools to collect, process and store research subjects' personal data;
- ✓ take communications security seriously, and devise and implement dedicated protocols for your project as necessary;
- ✓ check the terms and conditions of all of the service providers you use (software, applications, storage, etc.) to process personal data within your project, in order to identify and mitigate risks to the data subjects;
- ✓ encrypt your research data and/or the devices on which they are stored, and ensure that keys/passwords are appropriately protected; and
- ✓ consult your DPO or a suitably qualified expert for advice on how to achieve a level of data security that is commensurate to the risks to your data subjects.

Don't

- ✗ collect data on a personal device such as a smartphone without ensuring that they are properly protected (e.g. consider the implications of automatic back-ups to the cloud, and the device's security features);
- ✗ use free services that may use your participants' data for their own purposes in lieu of payment, or collect data or communicate with research participants via social media platforms without first assessing the data protection implications;
- ✗ use unencrypted email, SMS or insecure 'voice over IP' platforms to communicate with vulnerable participants or those who may be subject to state surveillance;
- ✗ expose personal data to unauthorised access or use when accessing them remotely (e.g. by using insecure wifi connections) or travelling to countries where your devices may be inspected or seized; and
- ✗ assume that your research partners, collaborators or service providers have appropriate information security and data protection policies without checking that this is the case.

XI. Transfer of personal data to non-EU countries

Sending participants' personal data to partners, collaborators or service providers outside the EU raises ethical and legal issues that can be difficult to address in practice. Researchers based outside the EU may be subject to different ethical rules and their treatment of the data may fall short of EU standards.

Few non-EU countries have received an 'adequacy determination' from the European Commission indicating that they have a data protection framework offering a level of protection equivalent to that provided under EU law.[13] This means that your research subjects' data may not be adequately protected or may even be used in ways that undermine their fundamental rights. The EU requires that its ethics standards apply to all of the research it funds, regardless of the country in which it takes place. The transfer of personal data from non-EU countries is subject to strict data protection requirements under Chapter V GDPR.

[13] The list of countries covered by a Commission adequacy determination is available at: https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en

You **do not actually have to 'send' the data to a non-EU country for these provisions to apply**; if one of your partners or service providers is located outside the EU and is able to access the personal data you have collected, this amounts to a 'data transfer' in the context of the GDPR. You must give details of all envisaged data transfers to non-EU countries in your proposal. You must also ensure that the recipients of the data ensure the same level of data protection as is required under EU law.

For data transfers to non-EU countries to be lawful they must be predicated on one of the following grounds:

- the explicit consent of the data subject (which requires them to be informed in advance of any such transfers);
- an 'adequacy determination' by the European Commission in respect of the country in question;
- a data-transfer agreement containing EC standard contractual clauses giving effect to EU data protection law; or
- binding corporate rules covering both sender and recipient and approved by a national supervisory authority.

These requirements apply to all personal data transfers, regardless of the sensitivity of the data.

From a research ethics perspective, the transfer of research participants' data to non-EU countries should in principle always be based on their informed consent, which must be sought and obtained in accordance with the guidance set out above.

If your research proposal envisages the transfer of participants' data to non-EU countries without their express consent of the data subjects, then your proposal must clarify the legal basis for any such transfer. In such cases, you should seek the advice of your host institution's DPO as to the legality of the data transfer and include their opinion in your proposal. If your host institution does not have a DPO, you should seek the advice of a suitably qualified expert.

XII. Collection of personal data outside the European Union

Collecting personal data from research subjects in non-EU countries raises similar ethical issues, but these may be amplified by the need to ensure that the participants are:

- wholly comfortable with being part of a research project conducted by researchers from outside their own country;
- aware of what will happen to their data; and
- not subject to any undue pressure to participate.

As noted above, the EU's ethics requirements apply to all EU-funded research, irrespective of where it takes place. Similarly, the GDPR applies to all data-processing operations conducted by data controllers based in the EU, irrespective of where the processing takes place. This means that, even if you are collecting personal data outside the EU, you must still ensure and be able to demonstrate compliance with EU law.

You also have to comply with the laws of the country in which you are conducting your research, including any national data-protection laws. For example, you may be under an obligation to notify or seek permission for your research from national authorities or data protection regulators . Further authorisations may be required to transfer personal data outside the country in which the research takes place. 'Data sovereignty' provisions may even prohibit the transfer of certain kinds of information, such as health or patient data, out of the country.

It is your responsibility to determine what legal obligations apply to any research you conduct outside the EU and to take whatever action is necessary to comply with them. You must also be able to demonstrate compliance upon request. Again, if you are unsure as to how to handle issues related to international data transfers, you should seek the advice of your host institution's DPO, or a suitably qualified expert, and include their opinion in your proposal.

[Box 8] Checklist: international data transfers

Transferring personal data out of the EU

- ✓ ensure that any international data transfers fulfil at least one of the relevant conditions in Chapter V GDPR;
- ✓ check that any third-party services you intend to use (e.g. survey tools, data analytics, cloud storage, etc.) are incorporated in an EU Member State or legally represented in the EU in accordance with the GDPR;
- ✓ adopt legally binding and enforceable agreements with partners or service providers prior to data transfers;
- ✓ prohibit the onward transfer of personal data by members of your consortium and any other recipients outside the framework of such agreements; and
- ✓ implement appropriate organisational and technical measures to ensure that personal data are transferred securely.

Collecting personal data in non-EU countries

- ✓ ensure that processing, notification, consent and accountability provisions meet GDPR standards;
- ✓ identify any further data protection requirements in applicable laws in the country in which data are to be collected and explain in your proposal how you will comply with them;
- ✓ if applicable, ensure that research participants understand and consent to the export of the personal data they provide to an EU Member State or an non-EU country;
- ✓ use pseudonymisation or anonymisation techniques to minimise the risk to data subjects;
- ✓ implement appropriate organisational and technical measures to ensure that personal data are transferred securely.

XIII. Deletion and archiving of data

You may keep the personal data you collect only as long as it necessary for the purposes for which they were collected, or in accordance with the established auditing, archiving or retention provisions for your project. These must be explained to your research participants in accordance with informed consent procedures.

Recent high-profile cases involving the misuse of personal data have stemmed from data controllers' failure to delete personal data and ensure that third parties to whom the data were provided had done the same in accordance with the agreed terms of their use.

As soon as your research data are no longer needed, or subject to an established retention period, you must securely delete the data in their entirety and make sure that they cannot be recovered. Data retained for auditing processes should be stored securely and further processed for those purposes only.

If research data are held in the cloud or by a third-party service provider, you should ensure that it has securely deleted the data together with any back-ups. If data have been shared with partners or transferred to third parties in the course of your project, you should ensure that they have deleted the data, unless they have a legitimate basis for retaining them.

XIV. Data protection officers and other sources of help

If your institution has appointed a DPO, it is recommended that you seek their advice as to your data protection obligations and how to meet them. You must ensure that the DPO's contact details are made available to all the data subjects involved in your research.

If your project raises complex data protection issues due to the sensitivity of the data, or the scale or nature of the processing involved, you should consider appointing a data protection specialist/adviser to your project or research ethics board. If your host institution does not have a DPO, you should seek the advice of a suitably qualified expert in the preparation of your proposal and/or appoint such an expert to your project if necessary.

If you need help and advice addressing the broader ethics issues raised by the data processing in your project, you should contact the relevant institutional bodies or services (e.g. research office or research ethics committee) in your university or institution, relevant national bodies, members of your consortium, or colleagues in your personal network who may have relevant expertise and experience.

If you are uncertain about any aspects of ethics in your research, you should consider appointing an ethics advisor or engaging an ethics mentor to provide advice, oversee the ethical concerns in your research and ensure that it is fully ethically compliant.

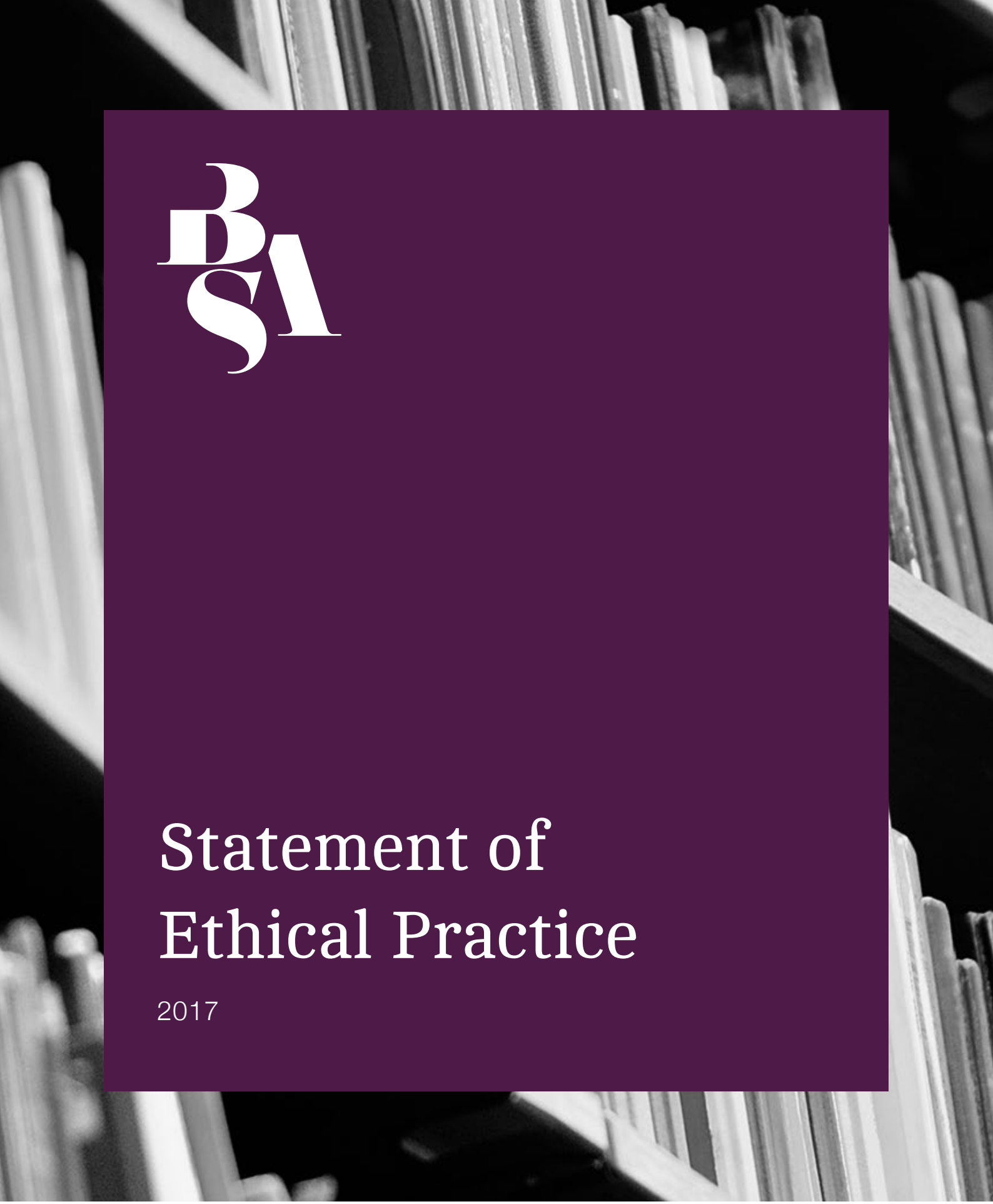

Statement of Ethical Practice

2017

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BRITISH SOCIOLOGICAL ASSOCIATION

BSA Statement of Ethical Practice

This statement forms part of a set of guidelines which relate to a variety of important aspects of professional sociology.

The British Sociological Association gratefully acknowledges the use made of the generic ethics principles produced by the Academy of Social Sciences. We also acknowledge the ethical codes and statements of the Social Research Association, the American Sociological Association, the Association of Social Anthropologists of the UK and the Commonwealth, and the British Psychological Society.

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1. The purpose of the statement is to make both BSA members and other sociologists aware of the ethical issues that may arise as they fulfil their varied professional obligations as sociologists and to encourage them to take responsibility throughout for their own ethical practice.

2. The statement does not, therefore, provide a set of recipes for resolving ethical choices or dilemmas (in the context of potentially conflicting interests of the various parties involved), but recognizes that it may be necessary to make such choices, drawing on fundamental principles (congruent with those set out by AcSS).

3. Sociologists work within a wide range of settings (not just in academic sociology departments, but in a variety of adjacent disciplinary departments and research centres, with many sociologists also working outside academia). Their role may encompass the following:

    - Administrative duties – within their own institution (such as staff and student recruitment, management – including annual appraisals for line-managed staff members – mentoring, policy development, serving on ethics committees, discharging of responsibilities involved in REF – or equivalent exercises, serving on committees making decision about allocation of internal research funding). Sociologists may operate at a range of levels within institutions, including acting as Vice-chancellors, Principals, Deans, and Heads of Department, and members of Senate, Academic Boards, and Boards of Study. When engaged in these activities sociologists should be aware of institutional practices, as well as BSA guidelines and should seek to foster debate where any differences or conflicts are seen to arise between recommended practice.

    - Professional activities (such as reviewing for funding bodies, serving on grant awarding panels, reviewing for journals, serving on editorial boards – as members or editors – reviewing for publishers, providing references for job applicants, publicizing, fundraising and engaging with potential sponsors).

- Teaching and supervision (of sociology students at any level), including examining at undergraduate and postgraduate levels (within and across institutions), involving acting as external examiner, and validating courses. In some situations the boundary between training, teaching and research can be blurred and sociologists need to consider carefully the ethical implications of their practice.

- Primary research (whether this involves empirical or theoretical engagement) including supervision of more junior staff, providing interim and final reports to funders, conducting of data collection/generation, submitting ethics applications, ensuring secure data storage, archiving of data, disseminating research findings – through conference papers, seminars, public events, academic and popular publications, and via the media, including social media). In the field of empirical research, in particular, methodological developments continually raise new issues or constellations of issues that require regular review, perhaps involving updating of guidelines. Hence, these guidelines are supplemented by more detailed statements relating to ethical conduct in relation to visual sociology, online research and the use of social media (See Digital Research Annexe for further information.).

4. The strength of this statement and its binding force rest ultimately on active discussion, reflection, and continued use by sociologists. In addition, the statement will help to communicate the professional position of sociologists to others – especially those directly involved or affected by the activities of sociologists.

A working group lead by BSA Publications Director Rosaline Barbour undertook the updating of the *BSA Statement of Ethical Practice*. Their efforts included updating the existing statement (drafted in 2002 and published in 2004) and the inclusion of a new annexe addressing digital research ethics. Our thanks to this working group:

Rosaline Barbour (Trustee), Daniel Conway, Huw Davies, Robert Dingwall, Susan Halford, Christine Hine, Christina Hotz, Wendy Martin, Gabriel Newfield and Lisa Suguira. John Oates also contributed in an advisory capacity. We also thank the authors, anonymous and named, who have contributed case studies on the various aspects of research ethics for sociologists.

The strength of this statement and its binding force rest ultimately on active discussion, reflection, and continued use by sociologists.

Professional Integrity

5. Sociologists have a responsibility both to safeguard the proper interests of those involved in or affected by their work, and to share their analyses/report their findings accurately and truthfully. They need to consider the effects of their involvements and the consequences of their work or its misuse for those they study and other interested parties. Sociologists should note that there are national laws and administrative regulations (for example Data Protection Acts, the Human Rights Act, copyright and libel laws) which may affect the conduct of their research, data distribution and storage, publication, rights of research subjects, of sponsors and employers etc.

6. While recognising that training and skills are necessary for sociological practice – and, particularly for conduct of social research – sociologists should themselves recognise the boundaries of their professional competence. They should not accept work of a kind that they are not qualified to carry out. They should be clear about the limits of their detachment from and involvement in their areas of study. (Also see points 43-45)

7. In their relations with the media, sociologists should have regard for the reputation of the discipline and refrain from offering expert commentaries in a form that would appear to give credence to material that, as researchers, they would regard as comprising inadequate or tendentious evidence.

Conducting Research

8. Sociologists as researchers should satisfy themselves that the studies they undertake are worthwhile and that the techniques proposed are appropriate.

9. Although sociologists, like other researchers, are committed to the advancement of knowledge, that goal does not, of itself, provide an entitlement to override the rights of others.

10. Social researchers face a range of potential risks to their safety. Safety issues need to be considered in the design and conduct of social research projects and procedures should be adopted to reduce the risk to researchers, including, importantly, any research assistants employed.

11. Sociologists, when they carry out research, enter into personal and moral relationships with those they study, be they individuals, households, social groups or corporate entities.

Relationships with Research Participants

12. Sociologists have a responsibility to ensure that the physical, social and psychological well-being of research participants is not adversely affected by the research. They should strive to protect the rights of those they study, their interests, sensitivities and privacy, while recognising the difficulty of balancing potentially conflicting interests.

13. Because sociologists study the relatively powerless as well as those more powerful than themselves, research relationships are frequently characterised by disparities of power and status. Despite this, research relationships should be characterised, whenever possible, by trust and integrity.

Covert Research

14. There are serious ethical and legal issues in the use of covert research but the use of covert methods may be justified in certain circumstances. For example, difficulties arise when research participants change their behaviour because they know they are being studied. Researchers may also face problems when access to spheres of social life is closed to social scientists by powerful or secretive interests.

15. However, covert methods violate the principles of informed consent and may invade the privacy of those being studied. Covert researchers might need to take into account the emerging legal frameworks surrounding the right to privacy. Participant or non-participant observation in non-public spaces or experimental manipulation of research participants without their knowledge should be resorted to only where it is impossible to use other methods to obtain essential data.

16. In such studies it is important to safeguard the anonymity of research participants. Ideally, where informed consent has not been obtained prior to the research, it should be obtained post-hoc.

Consent

17. In some cases, where the public interest dictates otherwise and particularly where power is being abused, obligations of trust and protection may weigh less heavily. Nevertheless, these obligations should not be discarded lightly.

18. As far as possible participation in sociological research should be based on the freely given informed consent of those studied. This implies a responsibility on the sociologist to explain in appropriate detail, and in terms meaningful to participants, what the research is about, who is undertaking and financing it, why it is being undertaken, and how it is to be distributed and used.

Sociologists have a responsibility to ensure that the physical, social and psychological well-being of research participants is not adversely affected by the research.

19. It should also be borne in mind that in some research contexts, especially those involving field research, it may be necessary for the obtaining of consent to be regarded, not as a once-and-for-all prior event, but as a process, subject to renegotiation over time. In addition, particular care may need to be taken during periods of prolonged fieldwork where it is easy for research participants to forget that they are being studied.

20. In some situations access to a research setting is gained via a ´gatekeeper´. In these situations members should adhere to the principle of obtaining informed consent directly from the research participants to whom access is required, while at the same time taking account of the gatekeepers´ interest.

21. Since the relationship between the research participant and the gatekeeper may continue long after the sociologist has left the research setting, care should be taken not to compromise existing relationships within the research setting.

22. Research participants should be made aware of their right to refuse participation whenever and for whatever reason they wish.

23. In many of its forms, social research intrudes into the lives of those studied. While some participants in sociological research may find the experience a positive and welcome one, for others, the experience may be disturbing. Even if not harmed, those studied may feel wronged by aspects of the research process. This can be particularly so if they perceive apparent intrusions into their private and personal worlds, or where research gives rise to false hopes, uncalled for self-knowledge, or unnecessary anxiety.

24. It is incumbent upon sociologists to be aware of the possible consequences of their research. Wherever possible they should attempt to anticipate, and to guard against, consequences for research participants that can be predicted to be harmful. Sociologists, as researchers, are not absolved from this responsibility by the consent given by research participants.

25. Social researchers should consider carefully the possibility that the research experience may be a disturbing one and should attempt, where necessary, to find ways to minimise or alleviate any distress caused to those participating in research. It should be borne in mind that decisions made on the basis of research may have effects on individuals as members of a group, even if individual research participants are protected by confidentiality and anonymity.

Anonymity and Confidentiality

26. Research participants should understand how far they will be afforded anonymity and confidentiality and should be able to reject the use of data-gathering devices such as tape recorders and video cameras. Anonymity can also be compromised by the use of photographs and, particularly, online platforms and social media (including platforms such as Facebook – see Ethics Guidelines and Collated Resources for Digital Research).

27. Sociologists should be careful, on the one hand, not to give unrealistic guarantees of confidentiality and, on the other, not to permit communication of research films or records to audiences other than those to which the research participants have agreed.

28. Researchers should clarify whether – and, if so, the extent to which – research participants are allowed to see transcripts of interviews and field notes and to alter the content, withdraw statements, to provide additional information or to add glosses on interpretations. Since they contain comments from all participants, focus group transcripts should be treated with particular caution and careful thought should be given before sharing these. (See Ethics Guidelines and Collated Resources for Digital Research.)

Research with Vulnerable People and Groups

29. Special care should be taken where research participants are particularly vulnerable by virtue of factors such as age, disability, their physical or mental health. Researchers will need to take into account the legal and ethical complexities involved in those circumstances where there are particular difficulties in eliciting fully informed consent. In some situations proxies may need to be used in order to gather data. Where proxies are used, care should be taken not to intrude on the personal space of the person to whom the data ultimately refer, or to disturb the relationship between this person and the proxy. Where it can be inferred that the person about whom data are sought would object to supplying certain kinds of information, that material should not be sought from the proxy.

30. Research involving children requires particular care. The consent of the child should be sought in addition to that of the parent. Researchers should use their skills to provide information that could be understood by the child, and their judgement to decide on the child´s capacity to understand what is being proposed. Specialist advice and expertise should be sought where relevant. Researchers should have regard for issues of child protection and make provision for the potential disclosure of abuse (see also section on Obligations, Roles and Rights).

Data Storage and Archiving

31. Appropriate measures should be taken to store research data in a secure manner. Members should have regard to their obligations under the Data Protection Act. Where appropriate and practicable, methods for preserving anonymity should be used including the removal of identifiers, the use of pseudonyms and other technical means for breaking the link between data and identifiable individuals. Members should also take care to prevent data being published or released in a form that would permit the actual or potential identification of research participants without prior written consent of the participants. Potential informants and research participants, especially those possessing a combination of attributes that make them readily identifiable, may need to be reminded that it can be difficult to disguise their identity without introducing an unacceptably large measure of distortion into the data. In some situations, presenting findings by way of hypothetical composite and/or partially fictionalised case studies can address this issue.

32. Where there is a likelihood that data may be shared with other researchers, the potential uses to which the data might be put must be discussed with research participants and their consent obtained for the future use of the material.

33. Social researchers also need to comply with the archiving requirements of funders. (See also sections on Obligations, Roles and Rights and Contractual Obligations).

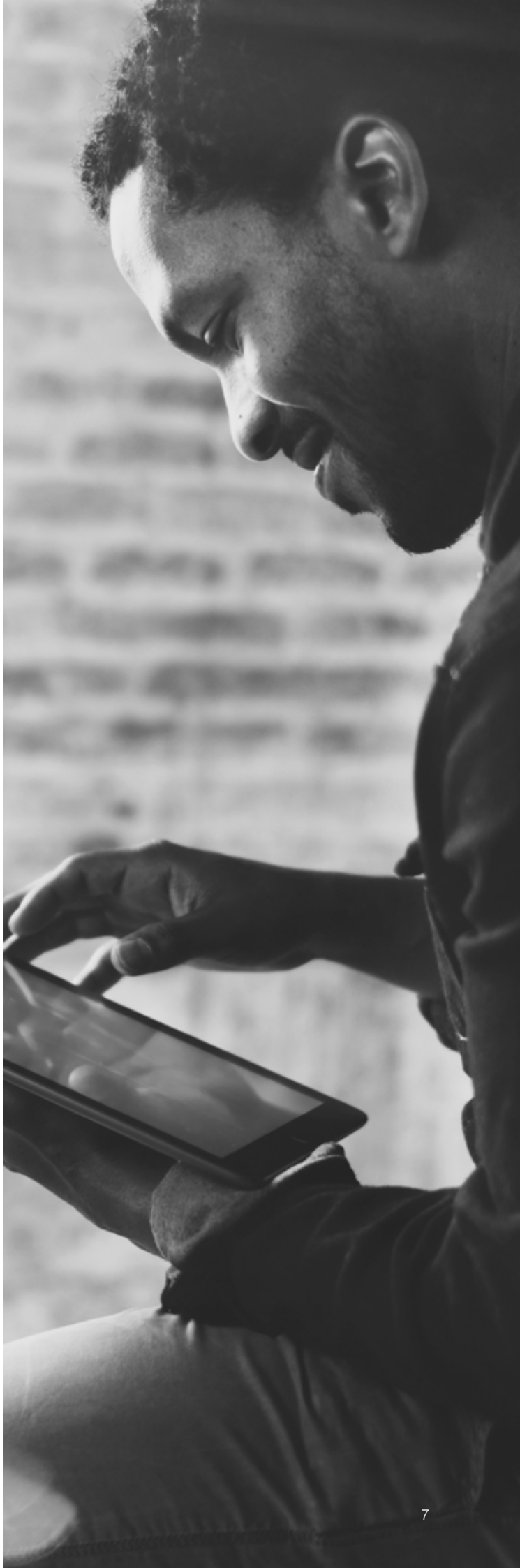

Distribution and Publication of Research

34. Sociologists should be aware that they have some responsibility for the use to which their data may be put and for how the research is to be distributed. Discharging that responsibility may on occasion be difficult, especially in situations of social conflict, competing social interests or where there is unanticipated misuse of the research by third parties.

35. Clarification should be given to research participants regarding the degree to which they will be consulted prior to publication. Where possible, participants should be offered feedback on findings, for example in the form of a summary report.

36. When making notes, filming or recording for research purposes (generating visual/online materials), sociologists should make clear to research participants the purpose of the notes, filming or recording, and, as precisely as possible, to whom it will be communicated. It should be recognised that research participants have contractual and/or legal interests and rights in data, recordings and publications. (See Digital Research Annexe for further information.)

Obligations, Roles and Rights

37. Guarantees of confidentiality and anonymity given to research participants must be honoured, unless there are clear and overriding reasons to do otherwise – for example in relation to the abuse of children. Other people, such as colleagues, research staff or others, given access to the data must also be made aware of their obligations in this respect. By the same token, sociologists should respect the efforts taken by other researchers to maintain anonymity.

38. Research data given in confidence do not enjoy legal privilege; that is they may be liable to subpoena by a court and research participants should be informed of this.

39. There may be fewer compelling grounds for extending guarantees of privacy or confidentiality to public organisations, collectivities, governments, officials or agencies than to individuals or small groups. Nevertheless, where guarantees have been given they should be honoured, unless there are clear and compelling public interest reasons not to do so.

Research data given in confidence do not enjoy legal privilege; that is they may be liable to subpoena by a court and research participants should be informed of this.

40. A common interest exists between sponsor, funder and sociologist as long as the aim of the social inquiry is to advance knowledge, although such knowledge may only be of limited benefit to the sponsor and the funder. That relationship is best served if the atmosphere is conducive to high professional standards.

41. Sociologists should ensure that sponsors and/or funders appreciate the obligations that sociologists have not only to them, but also to society at large, research participants and professional colleagues and the sociological community. The relationship between sponsors or funders and social researchers should be such as to enable social inquiry to be undertaken professionally. In research projects involving multiple funders or inter-disciplinary teams, members should consider circulating this Statement to colleagues as an aid to the discussion and negotiation of ethical practice.

42. Research should be undertaken with a view to providing information or explanation rather than being constrained to reach particular conclusions or prescribe particular courses of action.

43. Sociologists should clarify in advance the respective obligations of funders/sponsors and researchers where possible in the form of a written contract. They should refer the sponsor or funder to the relevant parts of the professional code to which they adhere and should also be careful not to promise or imply acceptance of conditions which are contrary to their professional ethics or competing research commitments.

44. Where some or all of those involved in the research are also acting as sponsors and/or funders of research the potential for conflict between the different roles and interests should also be made clear to them.

45. Sociologists should also recognise their own general or specific obligations to the sponsors whether contractually defined or only the subject of informal and often unwritten agreements. They should be honest and candid about their qualifications and expertise, the limitations, advantages and disadvantages of the various methods of analysis and data sources, and should exercise discretion with respect to confidential information obtained from sponsors.

46. Sociologists should also try not to conceal factors that are likely to affect satisfactory conditions or the completion of a proposed research project or contract.

47. During their research sociologists should avoid, where they can, actions which may have deleterious consequences for sociologists who come after them or which might undermine the reputation of sociology as a discipline.

Contractual Obligations

48. When acting as commissioned researchers or commentators, sociologists should not accept contractual conditions that are contingent upon a particular outcome/expression of a particular view or set of findings from a proposed empirical inquiry or review. A conflict of obligations may also occur if the funder requires particular methods to be used.

49. Sociologists should clarify, before signing the contract, how far they are entitled to be able to disclose the source of their funds, the personnel, aims and purposes of the project.

50. Sociologists should also clarify their right to publish and distribute the results of their research.

51. There is an obligation for sociologists to ensure that sponsors grasp the implications of the choice between alternative research methods, guarding privileged information and negotiating problematic sponsorship.

52. In the course of discharging their duties as researchers or commentators, sociologists may be furnished with information by the funder who may legitimately require it to be kept confidential. Methods and procedures that have been utilised to produce published data should not, however, be kept confidential unless otherwise agreed.

53. When negotiating sponsorships sociologists should be aware of the requirements of the law with respect to the ownership of and rights of access to data.

54. In some political, social and cultural contexts some sources of funding and sponsorship may be contentious. Candour and frankness about the source of funding may create problems of access or co-operation for the social researcher but concealment may have serious consequences for colleagues, the discipline and research participants. The emphasis should be on maximum openness.

55. Where sponsors and funders also act directly or indirectly as gatekeepers and control access to participants, researchers should not delegate to gatekeepers the responsibility to protect participants' interests. Sociologists should be wary of inadvertently disturbing the relationship between participants and gatekeepers, since that will continue long after the researcher has left.

56. Sociologists have a responsibility to notify the sponsor and/or funder of any proposed departure from the terms of reference of the proposed change in the nature of the contracted research/commissioned report/review/commentary.

57. A research study should not normally be undertaken where it is anticipated that resources will be inadequate.

58. When financial support or sponsorship has been accepted, sociologists must make every reasonable effort to complete the proposed research/report/review/commentary on schedule, including reports to the funding source.

59. Sociologists should seek to distribute their research findings/share their analyses as widely as possible and, where required, make their research data available to other researchers via appropriate archives.

60. Sociologists should normally avoid restrictions on their freedom to publish or otherwise broadcast research findings.

Sociologists should normally avoid restrictions on their freedom to publish or otherwise broadcast research findings.

Draft

Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research

2010

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A. Foreword

The aim of this guidance note is to provide applicants and evaluators of Social Sciences and Humanities research projects with advice and practical guidance on dealing with the ethical aspects of Social Sciences and Humanities research. In an effort to better understand the problems associated with ethics review of social sciences and humanities projects, this document examines the main points that need to be considered in order to write a complete, accurate and robust grant application.

The document is based on discussions among twenty-eight Ethics Experts with previous experience in Ethics Screening, Review and Audit at European Commission and was chaired by Prof. Margit Sutrop and Prof. Carmen Florea. The discussion took place from September to December 2010 via the SINAPSE system and was followed by an experts' meeting in Brussels on the 8th of December 2010.

Much of the following advice is already published, and thus can be found in many books, articles and documents. However, we hope that summarizing this in one document will help both applicants and reviewers to get a quick overview of the fundamental ethical issues of Social Sciences and Humanities research.

Acknowledgments

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Ursula Huws	Sam Panicker
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B. Introduction

Ethics is as an integral part of EU funded research projects

Ethics is an integral part of research: it is only by getting the ethics right that research excellence can be achieved.[1] As ethics is considered to be central to scientific integrity, the European Commission has made ethics review an integral component of research evaluation procedure. All research projects that have successfully passed the scientific evaluation are subject to an ethical evaluation.[2] A system of Ethics Screening has been implemented, delegated to individual Programs, Remote and Central Reviews, Follow-up and Audit, organized mainly by the Ethics Sector of DG-RTD (Directorate-General for Research and Innovation, Unit L3 – Governance and Ethics), and accompanied by increased training programs for both applicants and Commission staff.

The ethical review process at the European Commission shows that there is a lack of awareness of how one should deal with the ethical issues in Social Sciences and Humanities (SSH) research proposals. Either the applicants lack the requisite knowledge of ethics, have low awareness of how ethical principles should apply to their research, or they do not know how to demonstrate their awareness of ethical issues.

Some common reasons include:

- Failure to show any significant appreciation of the potential ethical issues of the study.
- Failure to notice that voluntary informed consent is the accepted norm of conduct for all kinds of research on human subjects; failure to give a detailed description of how the informed consent process will be implemented.
- Failure to provide appropriate documentation supporting the proposed research from the ethics and regulatory side.
- Failure to describe in detail what kind of measures of privacy and data protection will be implemented.
- Failure to assess the potential risks associated with the project and to plan measures to avoid or minimize them.

As the number of proposals in the field of Social Sciences and Humanities (SSH) is rapidly increasing and their ethical dimension is either not evident or insufficiently elaborated, there is a

[1] Ethics for Researchers. Facilitating Research Excellence in FP7 (2007). ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-for-researchers.pdf

[2] On the Ethics Review and the FP7 Ethics Framework see: ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-review-fp7-ethics-framework_en.ppt

clear need to give guidance to applicants as well as to the reviewers of SSH research projects. The aim of this note of guidance is not to teach SSH researchers how to do ethically correct science. We leave this role to the professional societies and research communities who are intensively debating the ethical issues of their specific research fields and developing their own ethical guidelines and codes of conduct. [3] We are optimistic in this respect, as during the past decades there appears to be a heightened interest in the ethical considerations in the SSH research. However, ethical awareness varies considerably both among different disciplines and different national contexts.

Another problem expressed recently is that in many cases the ethical guidelines used by the ethical review boards are better suited to medical/bio-medical research than to SSH research; members of ethical review boards are unfamiliar with SSH research methods and protocols. Professional associations of SSH have expressed their concerns and pointed out that if standard rules and procedures are followed in a blanket manner on the assumption that the same ethical principles apply in the same way to all research fields, this will do more harm than good (it may heighten the risk to the participants of research instead of protecting them, and even stop socially important research).[4] Thus, a deeper understanding of the peculiarities of the ethical considerations of SSH is needed and this should lead to improved guidance for protecting the rights and welfare of participants in various types of SSH research.

Ethical issues in SSH research involving human participants involve considerations that are as diverse as the range of disciplines and fields that constitute these sciences. The term SSH refers to the scientific study of behavioral, cultural, and social phenomena, carried out in a variety of disciplinary and interdisciplinary fields ranging from anthropology, economics, psychology, political science and sociology to archaeology, history, linguistics, literary studies and education research, among others. The methodological approaches in these sciences include surveys and questionnaires, focus groups and interviews, direct observation, physiological manipulations and recordings, standardised tests, descriptive methods, laboratory and field experiments, economic analyses, statistical modelling, ethnography, and evaluation.[5] In some fields of SSH research, as for example in behavioural studies, minimal physical intervention (e.g. taking blood samples etc) may also take place. As today's research is becoming more and more interdisciplinary, it is impossible to

[3] An extensive analysis of the ethical codes of over 250 SSH professional associations was carried out between 2001 and 2003 in the framework of the EC funded RESPECT project.

[4] Raymond De Vries, Debra A. DeBruin, Ethics Review of Social, Behavioral, and Economic Research: Where Should We Go from Here? *Ethics&Behavior*, 14 (2004): 351-68.

[5] Felice J. Levine, Paula R. Skedsvold, Behavioral and Social Science Research. In E. J. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, D. Wendler, *The Oxford Textbook of Clinical Research Ethics*. Oxford: Oxford University Press, 2008, pp. 336-355.

draw a strict line between SSH research and other kinds of research. Thus, the ethical considerations of SSH research are neither easy to characterize, nor can they be broken down into a single pattern that is universally applicable to the variety of research methods used in SSH while remaining globally responsive to the myriad of issues under study (ranging from daily life circumstances to those marked by various sensitivities).

The ongoing discussions concerning ethical issues within SSH research community highlight the fact that the developmental, creative and interpretative nature of research in these fields requires particular attentiveness to ethical dilemmas and tensions.[6] Ethical rules should not be followed or required blindly by the ethical review panels; rather one should take into account the variety of methodologies and research contexts. The researchers and evaluators should recognize the complexity of ethical decision-making in SSH research and be aware that ethical principles may frequently be in tension or contradiction with each other. These guidelines do not attempt to resolve these choices by prioritizing one principle over the others but instead, offer a framework in which individual ethical decision-making should take place.

This note of guidance does not give definitive answers but it gives examples of likely areas SSH researchers have to explore in their grant application. We hope that this will help the applicants to prepare the ethics section of the EU grant proposal and reviewers to carry out a smooth and fair ethical review of SSH projects. The document will also highlight some of the peculiarities of the ethical considerations of SSH research, outline common ethical dilemmas that are encountered in SSH research and suggest ways of dealing with them. In this sense it is intended to be both an educational tool for the research community and a stimulus for further discussions.

C. Underlying ethical principles

Avoidance of exploitation, just distribution of benefits and burden, beneficence, respect for persons, respect for human dignity, scientific validity, social value, the rights and interests of research participants are overarching **ethical principles** of any scientific research. From the stage of research design to the dissemination of research outcomes these principles should be taken into account when identifying and dealing with the ethical issues raised by a particular research. To become operational these ethical principles should be translated into tools and procedures that can and should vary, depending on the field of research and sometimes even its context. These tools and procedures (such as informed consent, data protection and privacy, impact of the research results)

[6] Mark Garner, Christine Raschka, Peter Sercombe, Sociolinguistic Minorities, Research and Social Relationships, *Journal of Multilingual and Multicultural Development*, 27 (2006): 61-78

form the basis of the ethical issues section provided in the Guide for Applicants and research proposals submitted for funding under the FP7, as well as for the ethical review process organized by the European Commission.

Six points to consider when you complete the ethical section of the application form:

Demonstrate that you are aware of the ethical issues raised by the methodology of your research and describe the suitable measures taken to appropriately address these issues.

Complete the Ethical Issues Table, which serves to identify any ethical aspects of the proposed research. You must complete this Table even if there are no ethical issues raised by your proposal. If you answer "yes" to any of the questions from the Ethical Issues Table you should provide a comprehensive discussion of how the identified issues will be addressed.

In the Ethical Annex you must discuss separately the following aspects:

- describe the ethical issues raised by the objectives of your research, its results, the potential consequences of the research outcomes and how you will address these issues effectively;
- describe the steps to be taken for the proposed research to meet the ethical standards of FP7 and the legal and ethical requirements of the country where the research will be performed;
- specify clearly where the research will be carried out and which competent authorities will be contacted to approve the study. Identify whether or not such authorities are in place and have the competencies to assess SSH research. Refer to the national and international relevant legislation and regulation and state explicitly how your research proposal would meet the ethical and legal exigencies of these documents.

If your research proposal raises highly sensitive issues (such as observation of people or research among illiterate people) it is advisable to include an independent ethics advisor or an independent ethics advisory board. In cases of major potential ethical challenges, a work package on ethics can be proposed.

You should address informed consent, data protection and privacy issues in a

comprehensive manner.

A proper assessment of potential risks (for individuals and communities/society alike), as well as a plan of minimizing potential harm should be included in the proposal.

D. Objectives and implications of SSH research. Minimizing harm, maximising benefit

The ethical review of all scientific projects starts with the question of whether the objectives of research raise any ethical questions. From the scientific point of view, every research project has to address the question of why the planned research has to be carried out, whether there is any new knowledge to be gained and whether it is worth spending the time and money to obtain it. A justification for conducting any proposed research project is a way of demonstrating that the research will offer benefits to scientific understanding, to policy and/or to practice that makes the resources spent on the proposed research worthwhile.[7] From the ethical point of view, asking about the justification of the objectives evokes the ethical concern that social interests or the paternalistic impulses of the scientific community should not override individual interests. The contemporary debate on participants' rights and the protection of human subjects of research is grounded in Nuremberg, as a reaction to the oppressive history of eugenics and the Nazi scientists' experiments carried out in the "public interest". The respect for autonomy and the principle of informed consent have been introduced into research ethics after World War II in order to protect individual participants in research from possible harm. Since the 1990s attempts are made to balance to balance individual rights and the public interest/common good as it has been suggested by communitarian-minded critics that people's individual freedom should be limited in order to promote some kind of public good (health, scientific knowledge, or security).

It is often claimed that SSH research is less likely to involve risk for human participants than biomedical research, which has far greater potential for physical injury, harm or adverse reaction. Whereas it is true that the potential for physical harm or inconvenience is rare in SSH research, sometimes there may be potential for psychological, social, economic, or legal harm.[8] Thus, the assessment of risks and benefits still comes into play in planning and implementing SSH research.

[7] Ron Iphofen, *Ethical Decision-Making in Social Research. A Practical Guide*, London: Palgrave Macmillan, 2009, p. 19.

[8] A good overview of these harms and ameliorative measures have been produced by Joan E. Sieber, a member of the Social and Behavioral Sciences Working Group on Human Research Protections. Risk and Harm. 2004. http://www.aera.net/humansubjects/risk-harm.pdf

In order to protect the human subjects involved in SSH research, one has to understand the differences between SSH research and biomedical research, and be able to recognize the likely risks and harms associated with such research. While in some instances, the research activity itself could produce psychological discomfort or harm, in most cases the biggest risk in SSH research relates to the disclosure of a person's identity and insufficient protection of private information which may then lead to discrimination or stigmatization.[9] Thus, the main effort should be devoted to safeguarding subjects' privacy and the confidentiality of the data processed in SSH research. It should be kept in mind that certain groups may be more vulnerable to harm from having information they provided be linked to them (illegal immigrants, victims of home violence, prostitutes, HIV-positive employees, etc). In these cases, standard procedures for obtaining written informed consent may be harmful to the subjects instead of offering protection and therefore need to be replaced by other measures of protection.

In preparing the ethics section, researchers should provide an assessment of risks, stating explicitly what kinds of harm might occur, the actual likelihood of subjects actually incurring such harm, and the available methods of ameliorating it. According to the UK Economic and Social Research Council,[10] the following research would normally be considered as entailing more than minimal risk: research involving potentially vulnerable groups and people unable to consent; research involving sensitive topics and which might induce psychological stress, anxiety or humiliation; research involving deception; research where the safety of the researcher may be in question; research involving respondents through the Internet, in particular where visual images are used, and where sensitive issues are discussed or where participants and other individuals may be identifiable in the visual images used or generated.

It would be also important to distinguish between risks related to the research subjects, groups and the society as well as to the researchers themselves. Whereas there are many situations where SSH research can be said to be analogous to the biomedical research model, where research also often involves investigating the circumstances of vulnerable groups, there are many kinds of social research where the model of the powerful well-informed researcher and the vulnerable research subject does not apply. On the contrary, the balance of power and knowledge may be reversed. Examples might include research involving interviews with high-ranking political figures carried out by political scientists or research involving interviews with senior managers in transnational

[9] Felice J. Levine, Paula R. Skedsvold, "Behavioral and Social Science Research". In E. J. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, D. Wendler, *The Oxford Textbook of Clinical Research Ethics*. Oxford: Oxford University Press, 2008, pp. 336-355.

[10] Economic and Social Research Council (ESRC) Framework for Research Ethics (UK, 2010). (http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf)

corporations carried out within the fields of business or organisational studies. Extending to such powerful figures the right to withhold or withdraw consent (which is clearly appropriate for vulnerable and ill-informed research subjects) can leave SSH researchers seriously disadvantaged, without even the most basic rights to make enquiries by other social groups, such as investigative journalists, or even ordinary citizens who might confront such figures at public meetings.

Even more importantly, there are many situations of social research where the personal interests of individual research subjects may be subordinated to more general social and collective interests. Examples of this involve the research into criminal behaviour, such as drug-dealing, human trafficking, child abuse or more mundane crimes such as tax avoidance or benefit fraud. In such cases any attempt to obtain informed consent in advance will of course seriously compromise the value of research. Even when a research topic does not involve activities that are formally defined as criminal, it may involve investigation of anti-social activities (such as playground bullying, binge drinking, xenophobic name-calling, football hooliganism, insensitive treatment of the handicapped, etc.) in situations where the research cannot be effective if the research subjects are formally notified in advance of the topic of the research, asked to sign consent forms, etc.

Thus, it is important not to apply the ethical principles (e.g. respect for autonomy and informed consent) in a blanket manner on the assumption that all research subjects are vulnerable. There is therefore a need for informed professional ethical judgement on how SSH research should be carried out in which the risks and benefits of participation in the research to individuals are carefully balanced against the risks and benefits to society as a whole.

Outline the anticipated benefits of conducting the research.

Describe the research findings which will help deliver better services, add value, change policy/practice or offer improved value for money.

Explain whether (and if so, how) the research will be of direct benefit to the site/organisation/community in which it is being conducted.

Explain the feasibility of implementing any findings.

Outline any harm that might occur, the actual likelihood of subjects actually incurring such harm, and the available methods of ameliorating the harm.

How will unforeseen or adverse events in the course of research be managed? (e.g. do you have procedures to deal with any disclosures from vulnerable participants, do you have procedures to deal with disclosures of criminal behaviour?)

Useful links to consider potential risks in SSH research:

http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf

http://www.aera.net/humansubjects/risk-harm.pdf

See Project Risk Assessment Matrix in Ron Iphofen. *Ethical Decision-Making in Social Research. A Practical Guide*. London: Palgrave Macmillan, 2009.

E. Methodology and research ethics in SSH

SSH research poses specific ethical issues in terms of **methodology**. This derives primarily from the research methods employed (for example quantitative, qualitative and observational studies). Research methods in social sciences and humanities are dynamic, progressive and developmental, therefore unforeseen risks at the beginning of a research could arise during the course of a study. It is recommended that researchers in SSH take a more systematic approach to risk assessment. The risk-based assessment should clearly consider not only individuals, but also give equal

consideration to society-based risks.

Particular emphasis should be placed on issues of data protection and privacy, the process of obtaining Informed Consent, stigmatization and discrimination. These aspects are highly relevant from an ethical perspective because research in SSH is often carried out over long periods of time and outside institutional settings; it focuses on time limited events, public behaviour, and contentious/stigmatized behaviour. It is within this context and along these lines that applicants should consider their proposed methodology carefully and in great detail. Given that SSH research involves very different degrees of interactions/intrusions with/on the research participants the ethical review of such proposals would be facilitated if these aspects are considered appropriately.

Of special importance are the ethical issues raised in qualitative research, the process of which is characterized by dynamic and evolving analytical approaches, as in ethnography, discourse analysis or oral history. During such studies, researchers act in a variety of social contexts and over long period of time. It is therefore difficult to anticipate at the beginning of the study all ethical issues that could arise; some of them become evident only in the course of research.

Another area of ethical concern pertains to the observational research that is central to much socio-psychological research. Observational approaches can vary (focused, participant, invasive/intrusive, visible, covert/overt; recorded rigorously using audio/visual methods or hand written notes compiled after the event). Researchers should ask themselves several questions concerning the research setting (e.g., is it public or private?), the behaviour under scrutiny (in a public or private setting), the way data is collected (recorded or not), and whether or not the protection of participants is ensured. For example, in the case of participatory observation it is advisable that the researcher have the skill and experience to ensure that there is nothing about their personal attributes that offends or intimidates the subjects.[11] When employing observational approaches in their study, researchers should devise a risk-management plan in case "sometimes does go wrong" in order to minimize/avoid the harm that might be inflicted on those observed. It has been observed that an ethical situationism tailored to the specific contexts and the development of study during the various phases of research could help researchers deal with the ethical issues encountered.[12] In this type of research, which usually includes fieldwork, the way relationships between researchers and research participant are established and how these develop during the course of the study must all be given equal consideration.

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[11] Iphofen, Krayer, and Robinson, Reviewing and Reading Social Care Research: From Ideas to Findings, Bangor University, 2009, pp. 211-221.

[12] Rachel Hurdley, In the Picture or Off the Wall? Ethical Regulation, Research Habitus, and Unpeopled Ethnography, *Qualitative Inquiry*, 16 (2010): 517-28

All research proposals employing deception in research should give a strong justification for the use of this research method, demonstrating that there are no undisclosed risks (that are more than minimal), and including an assessment of the impact of the study. Researchers undertake an enormous responsibility when using deception with respect to the potential risks incurred by participants. In case deception is used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred both researchers and participants.[13]

F. Participating in SSH research

Human participation in SSH research is not obligatory and should be given proper justification. Whenever initiating a study in this field, researchers should consider the following: inclusion of adults, of children, of vulnerable groups (such as prisoners, immigrants, people with decreased mental capacity etc.). Applicants must justify the inclusion of these individuals/groups according to the main research objectives of the proposal. Special consideration should be given to vulnerable populations. Adopting a protective guardianship concerning the participation of members of such groups may not always be the best way to go. Depending on the nature of this involvement and the implications of the research results for the wellbeing of these individuals and the communities they belong to, appropriate measures should be in place in order to deal with the ethical concerns raised by the participation of such people. Participatory research is one such measure. When illiterate people are approached in order to obtain their participation in the research, it is often advisable to assess whether obtaining their consent in an ongoing and collaborative manner would ensure an ethical treatment of such participation.

On the other hand, there seem to be many cases of research – e.g. studies of behaviour in public places or the use of social media – where practices of obtaining consent are not truly relevant: therefore researchers should devise strategies of dealing with the ethical issues in accordance with the research questions, the status of existing knowledge / state-of-the-art and the availability of existing qualitative or quantitative data.

Researchers must recognize the right of the participants to withdraw from the investigation whenever and for whatever reason they wish. In all such circumstances researchers must examine their own actions to assess whether they have contributed to the decision to withdraw and whether a change of approach might persuade the participants to re-engage.

[13] For example, Respect Code of ethics (www.respectproject.org/code) suggests that deception should be used only when there is no other ethically sound way of collecting accurate and appropriate data.

However, these are not the only ethical dilemmas that arise during this recruitment stage. Political or legal sensitivities, issues of coercion and/or undue influence should also be considered by the researchers. It should also be remembered that sometimes research in social sciences and humanities is dominated by different degrees of interactions and status between the researchers and the research participant (as for example when interviewing political leaders when conducting a study on political sciences).

Researchers in SSH such as archaeologists, historians, or art historians should also take into account the ethical aspects involved in the study of human remains. Attention has been called to the way public display of human remains might affect local communities and the preservation of cultural heritage. Ideas of protecting posthumous interests and the vital importance of ancestral human remains and sites where such remains are kept have surfaced in the debates of the last decades and found their way into various codes of ethics and international documents.[14]

Selecting, Recruiting, Retaining and Releasing Participants

Are you planning primary research or secondary research? Specify which research methods you are planning to use.

Who will be the research participants?

What are the inclusion and exclusion criteria?

How, where, and by whom will participants be identified, approached and recruited?

Are research participants selected equitably? Will any unequal relationships exist between anyone involved in the recruitment and the potential participants?

Is there a need for participants to be de-briefed? By whom?

Can participants opt out?

Researchers must consider the ethical implications not only for those participating in their research,

[14] T. M. Wilkinson, Last Rights: the Ethics of Research on the Dead, *Journal of Applied Philosophy*, 19 (2002): 31-41. Useful guidance on how to deal with human remains can also be found in the Codes of Ethics adopted at the World Archaeological Congress, 1990, in The Vermillion Accord on Human Remains adopted in 1989 and the Tanaki Makau-ran Accord on the Display of Human remains and Sacred Objects adopted in 2006.

but also for the research team. Conflicts of interest and integrity of the researcher (freedom of the researcher, responsibility of the researcher, the possibility of pressure from some political groups or government to have access to certain results-- for example in sociology) should also be considered. Scientific integrity and proper conduct are essential for individual researchers and must also prevail in the functioning of the research teams. Research misconduct refers to falsification of results, fabrication of data and plagiarism; this has been identified as an ethical issue in the context of EU funded research and integrated into the EU's ethics oversight (screening, reviewing and auditing).[15] Other moral, ethical and legal aspects worth considering are those concerning participation of students, the relationship among the members of the research team and the scientific responsibility towards research colleagues. The results of a focus group discussion conducted to identify specific ethical issues in the humanities revealed that because of the social and interactional nature of this type of research, interpersonal relationships are of high importance. On the one hand there is the responsibility to remain objective when assessing research results, but given the inherent subjectivity of these results (such as in performing arts or musicology), researchers are confronted with other ethical tensions. Similarly, supervisors of students should try to balance the need for guidance and mentorship with the necessity to allow students to freely develop their own research interests. Ethical tensions concern issues of intellectual property, protection of the sources of information and of the data obtained.[16]

The research team should pay attention to the following aspects:

- scientific integrity and academic freedom must govern the functioning of the research team
- scientific responsibility is at the core of any research enterprise
- involvement of students in research experiments is subject to same ethical requirements as the other research participants
- refer to the European Charter for Researchers, The Code of Conduct for the Recruitment of Researchers and the relevant professional codes

Useful link: http://europa.eu.int/comm/research/rtdinfo/index_en.html

[15] Johannes Rath, A Comprehensive Strategy on How to Minimize Research Misconduct and the Potential Misuse of Research in EU Funded Research, 2010. (http://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf)

[16] Cheryl K. Stenmark & Alison L. Antes & Laura E. Martin & Zhanna Bagdasarov & James F. Johnson & Lynn D. Devenport & Michael D. Mumford, Ethics in the Humanities: Findings from Focus Groups, *Journal of Academic Ethics*, (published online November 2010, Springer)

G. Obtaining informed consent

Informed consent: this is the most critical part in SSH research and a very detailed informed consent is a crucial requirement in SSH research. Although informed consent procedures are primarily derived from a human biomedical research model, there are nevertheless important aspects that SSH researchers must take into account. For example, the power relationship between the investigator and research participants, the vulnerability of the population under study, the impact of the research results on individuals and communities, with particular emphasis placed on avoiding stigmatization and discrimination. All relevant aspects from this list should be given thorough consideration in research protocols.

The process of obtaining Informed Consent (IC) is neither easy, nor is it necessarily time limited. SSH researchers must pay close attention to the way research participants are approached. In many cases consent is obtained from family or community leaders only to approach individuals, but this should not substitute an individually obtained consent. In case of people not able to consent (e.g. children), parents/legal representatives consent and children`s assent are necessary. Many times, particularly when research consists of fieldwork, obtaining informed consent might not be a one-time event, but should rather be regarded as an ongoing process, which might evolve differently from what was anticipated before beginning research.

When seeking to obtain individual, written consent from research participants, researchers should take into account the cultural and ethical norms of the population(s) under study. In case a written consent does not respond to the ethical norms of those studied, the applicant must provide alternative ways of obtaining consent (such as recording the oral consent, the presence of witnesses, all procedures used must be documented). In case of participants who for any reason are not fully capable of understanding and expressing their will, the IC should be replaced by other robust protective measures. Sometimes the collection of written informed consent may bring participants under danger as their anonymity will no longer be guaranteed.

In case of observational studies, reasonable IC should be obtained from all participants, and approval from the gatekeepers before the beginning of the study; if individuals cannot be identified, then individual consent might be sought after the study is finished. Depending on the nature of the study, observation of people in a completely public environment might not require consent, but researchers have to demonstrate that their study would in no way alter the usual behaviour of those under scrutiny and that their privacy would be respected.

As has been detailed above, deception raises complex ethical issues, particularly because it impacts

the informed consent process, one of the most important safeguarding mechanisms for participation in research. The applicants should clearly describe the exact content of the "modified truth" or the "misleading information" that is going to be used, whilst at the same time specifying that these deviations from the truth will not impose any short or long term hazard for the participating subject. By the end of the study, researchers should undertake the obligation to reveal to the participants the misleading information that was used during their involvement in the protocol and explain to them the necessity of its use. Clear justification is needed for the use of deception; ideally participants should be informed afterwards about the deception and why it was deployed. It is better to provide less information on any informed consent form rather than providing misleading information on this form.

In SSH research it can be permissible or even encouraged that consent be renegotiated should the inquiry move in unanticipated new directions. The methodological limitations on gaining "fully informed" consent would have to be made clear at the outset.

While it is not essential to submit the informed consent documents to the European Commission in your grant application, you need to demonstrate a good understanding of the issues in your ethics section. Ideally, you can include a sample informed consent document and Information Sheet which contains information about who will be the researchers, sources of the funding, aims/purpose of the study, how subjects will be selected and recruited, research procedures, risks/discomfort anticipated, who will benefit from the study, how findings will be disseminated (incl. feedback to the participants), steps taken to protect the privacy and confidentiality of the data.

In the process of obtaining informed consent you should keep in mind the following questions:

Will the voluntary informed consent be sought?

How will consent be gained and/or recorded and by whom?

How will the competence of participants to give informed consent be determined?

What information will participants be given about the research? Does the information sheet contain all the information participants need?

Will the participants be informed that participation is voluntary, that consent can be refused, and that withdrawal is possible at any time?

If the study is being undertaken in a developing country, where written consent is not common practice, detail what practices you will apply to obtain informed consent (e.g. with witnesses, following local customs, having it video or audio recorded etc).

Are there any reasons for not seeking consent?

Is there any need for incomplete disclosure? Would some form of deception be used? Would this harm the research participants, the researchers and/or society in general in any way?

If your research changes, how will consent be renegotiated?

As the process of obtaining Informed Consent is complex and since it is considered one of the most important safeguarding mechanisms in research, the sections of the Ethical Issues Table also refer to children and vulnerable adults. If you are involving children in your research you should devise appropriate strategies of informing them about their participation (for example by using audio or video materials, posters, flyers, suitable to their age and understanding). Children who are capable of forming their own views should be granted the right to express their views freely in all matters affecting them, commensurate with their age and maturity.

In the case of participants whose age, intellectual capability or other vulnerable circumstance may limit the extent to which they can be expected to understand and agree voluntarily to undertake their role, researchers must also seek the collaboration and approval of those who act in guardianship (e.g. parents) or as 'responsible others'.

If participants may experience distress or discomfort in the research process you should take necessary steps to reduce the sense of intrusion and take care of the participants well-being (e.g., when interviewing on the topic of the death of close relatives, or an experience of violence, a psychologist should be provided for support).

Children and vulnerable adults

Will any vulnerable subjects be recruited, (e.g. children, people with disabilities, elderly, pregnant women, prisoners, armed services personnel, immigrants etc.)?

If you are using vulnerable subjects justify this and explain exactly what procedures will

be undertaken.

Justify how many subjects will be used in your study and give inclusion and exclusion criteria.

Specify exactly what information you will collect and what you will do with it.

Specify how informed consent/assent will be obtained.

State any expected harm and benefit to the vulnerable subjects.

If you use vulnerable adults with reduced capacity to consent (e.g. elderly patients in a residential home with advanced Alzheimer's), particular attention should be given to how informed consent will be obtained, and support provided, if necessary.

Children should be facilitated to give fully informed consent.

Ensure that the best interests of the child will be your primary consideration.

Ensure that researchers and any collaborators or research assistants and students under their supervision comply with legal requirements in relation to working with children or vulnerable young people and adults.

Special attention should be paid when making photos, audio and video recordings and other communication materials that depict vulnerable populations, (e.g. children) produced in the research projects.

Useful link concerning child protection and safeguarding policy www.ahgtm.ac.uk

H. Protecting personal data and privacy

Researchers must consider protection of personal data, but also data that refer to/is or has been obtained from various settings (such as cultural heritage, public space, video and audio recordings, mapping etc.). There are three different categories to which data protection refer: the users, the providers and the environment. All these different aspects must be taken into account when devising mechanisms for data protection in the course of research (including publication of findings and dissemination to the general public). There is an internationally recognized and globally accepted standard (such as ISO/IEC 27001:2005) that can be used by SSH researchers.

It is not always possible to anticipate the ways in which data obtained will be used, therefore

informing research participants at the beginning of the study about the uses of the data they provide will not always be sufficient to safeguard their interests and to protect them; ongoing communication with them is therefore highly recommended.[17] Researchers in social sciences and humanities must consider the ethical implications of this aspect.

There are different understandings of privacy in different cultural contexts. Privacy is a contested concept: it is the right to be left alone, but it can also be something positioned at the interface between private life and public life. It entails a dynamic relationship between private persons in different situations and different degrees of interaction. It is crucial to respect the privacy of research participants, but in SSH research there are other relevant rights' holders the researchers should consider. It is therefore important to detail the purpose of the research according to the different understandings and legal definitions of privacy.[18] For example in "covert research," researchers should take into account the meanings of public and private in the contexts they are studying. Covert observation should only proceed if researchers can demonstrate clear benefits of the research, when no other research approach seems possible and when it is reasonably certain that no one will be harmed or suffer as a result of the observation.

Researchers must ensure that data is kept securely and that the form of any publication, including publication on the Internet, neither directly nor indirectly leads to a breach of agreed confidentiality and anonymity. In some rare cases there may be a need to override agreements on confidentiality and anonymity (e.g. if maintaining confidentiality agreements facilitates continuation of illegal behaviour which has come to light in the course of the research). In such circumstances the researchers must carefully consider making disclosure to the appropriate authorities. Insofar as it does not undermine disclosure, researchers must appraise the participants or their guardians or responsible others of their intentions and reasons for disclosure.

[17] Pamela Innes, Ethical Problems in Archival Research: Beyond Accessibility, *Language and Communication,* 30 (2010): 198-203

[18] For the legal definition of this concept see The Universal Declaration of Human Rights Article 12 and Article 8 of the European Convention on Human Rights.

Maintaining Privacy and Confidentiality

What type of data will be collected? Justify if any personal data will be collected. State that only relevant data will be collected and this will not be more than what is needed for the research study.

Describe in detail all data protection measures, providing evidence that the confidentiality of the participants will be ensured according to the relevant EU standards (see e.g. EU Directive 95/46/EC).

Have you considered anonymity and confidentiality? Clarify whether the data will be anonymised (link to the data will be destroyed) or coded (the data will be reversible). Explain how you will ensure data protection and how any link to the research participants will be handled if not fully anonymised.

If the data will not be anonymised, explain why you cannot anonymise the data (e.g. you need to recontact the participants or do follow-up in case of long-term study). If the data will be coded, describe the coding system, and who will have access to the code. Confirm that it cannot be tracked back to individuals unless essential for the study.

How will you store your collected data? Explain how and where the data will be stored and for how long?

How will data be disposed of and after how long? Explain what will happen with the data after the completion of the research.

If using secondary data, does the consent from the primary data cover further analysis? If not, explain how new consent will be obtained for the reuse of the data.

Explain if any information could lead to stigmatization, depending on how it is collected.

Useful document: Caroline Gans-Combe, Data Protection and Privacy Ethical Guidelines

http://cordis.europa.eu/fp7/ethics_en.html (click on Privacy in the Ethics checklist)

I. Research in non EU-Countries (Developing Countries)

Non-EU countries, especially developing countries (DCs) represent a very wide and constantly changing, variety of situations. Many of the ethical issues that are specific to these countries originate from the potential vulnerability of local stakeholders

Some overall considerations apply to all research projects in DCs:

1.The research must be responsive to the needs of the country where it is carried out (e.g. the study must have value for the welfare of the intended participants, their community, and/or their country). This issue is of critical relevance for emerging and developing countries.
2. Sensitivity must be shown to local conditions. Explain how your research proposal fits into local customs and practices.
3. It is also important to indicate how the results of your research can be applied in the developing country.
4. Ideally your application will also be able to show that you are helping build local capacities by conducting research in developing countries and by bringing something extra to the community.
5. If appropriate, state that you are planning to discuss in advance the planned research and dissemination of the results with relevant parties in the developing society.
6. The research needs to adhere to FP7 ethics requirements and the research must abide by relevant local and international laws and guidelines.
7. As for doing research in non-EU countries, you also need the approval of the host countries which will judge the ethical acceptability of the research in accord with the customs and traditions of the society concerned.
Useful document on how to do research in developing countries can be found at:

ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf

J. Ethical review process. Ethical approvals

Applicants should identify the relevant national/local legislation and guidelines concerning data protection and human participation in research. They should also mention whether local ethical committees are in place and whether or not ethical approval is required in the country where the research will be carried out. In case such committees do not exist, the applicant should refer to the ethical principles that would govern the proposed research and the relevant international legislation and regulation to be followed (such as the European Charter for Researchers, The European Charter of Fundamental Rights etc.)

In some but not all countries there are special ethics committees for dealing with SSH research projects. If EC requires ethical approval of the local/national ethics committee, this may cause a situation where SSH projects will be examined by ethics committees set up for assessing projects in biomedical research. Their competence may not allow giving a fair judgment of the ethical aspects of SSH projects. On the other hand, the clear requirement to obtain the approval also for SSH projects may speed up the process of establishing the ethical committees for research in SSH.

Given the developmental nature of SSH research prior approval is not always the best solution. Particularly qualitative research may need "flexible protocols", where the research is adapted according to a stepwise approach, depending on interim findings from focus groups, surveys, questionnaires etc. Such projects could be approved, but only if the researchers define limits of the flexibility and describe how they will handle new problems as they occur, such as privacy or exploitation. Interim reporting on a regular basis or as /when ethical challenges emerge is a normal requirement. The applicants could also be required to establish ethical boards to oversee the conduct of the study, including interim results, subject attrition, unanticipated events, etc. before changes are made to the approved protocol. This might not be possible in traditional ethnographic studies but may be applicable to community-based research. In research projects involving observational approaches, observation schedules should be drafted. They must be clearly structured to allow for easy data recording-issues of anonymity and confidentiality: links between sources of data and individual cases must be anonymised immediately and known only to those permitted. When deception is used, the Ethics Review Board should thoroughly examine the potential of any hazardous consequences for the subjects and in case of a negative conclusion, grant permission for this particular manipulation. It is advisable that applicants include ongoing ethical monitoring in the management section of the project.

Local ethics committees and authorizations of competent bodies

Specify if your research already has been given ethical approval at the local or national level. If so, it will aid your application to submit a copy of this approval in your application. If not, specify which Ethics Committee is most appropriate for your research. Have you considered the time you need to gain ethics approval?

In case of multinational research, ethical approvals for the planned research should be obtained from the ethical committee of the country of the researcher as well as from the committees where the research (or parts of the research) will be

performed.

Have you considered what legislation your project will need to abide by?

How will the ethics aspects of the project be monitored throughout its course?

If the research methodology, techniques or protocols that will be used within the project will raise complex sensitive ethical issues, it is advisable to appoint an expert in ethics or an independent ethics advisory board, or in case of major potential ethical challenges, include a work package on ethics.

Useful link for the Ethics Review and the FP7 Ethics Framework at http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl

K. Recommendations

As a result of online discussions among the experts involved in the ethical review system set up by the European Commission, the 8th December 2010 workshop devoted to the ethical issues in SSH and the opinions formulated by external experts, the following list of recommendations emerged:

1. In what concerns The Ethical Review Boards:

- the composition of the ethical review boards should be interdisciplinary, thus ensuring that the peculiarities of SSH research would benefit of appropriate consideration during the review process.

- As effective local/national structures have been put in place for the ethical review of biomedical projects, the imperative is to outline similar procedures for projects in SSH area

national or regional ethical committees to assess and approve SSH research projects should be established

- the ethical review boards should check whether or not legal and ethical obligations were considered by the applicants

- EC should initiate training courses for national/local ethical review committees

- Competent authorities in each countries should be encouraged to adopt a uniform assessment. Networking among ethical committees could significantly contribute to the development of such uniform assessment.

2. In what concerns The Ethical Issues Table:

- it should be modified so as to more fully reflect the daily research questions encountered in SSH

research

- it should be devised as follows: clinical/non clinical research; impact of the research results (psychologically, socially etc).; the use of data in public domain; research involving indigenous population; observing people, internal ethical review system in your institution; vulnerable population (in terms of legal and/or economic status, age, gender, etc.), data protection and privacy, informed consent process, discrimination and stigmatization, dual use/misuse, misconduct, research activities in developing countries or countries with emerging economies

- two separate questions should be introduced: genetic information and personal data; and quantitative/qualitative data;

- methodology and management of ethical issues

- this relevant checklist should be put on the website; it should be responsive and adaptable; the same checklist should be used by the applicants and the reviewers

In what concerns The Guide for Applicants:

- it would be desirable to have an ethical checklist included in Part A of the proposal and in Part B the ethical issues being integrated into the state-of-the art discussion, methodology, management of the project, risk contingency plan and dissemination

- it should be highlighted in the application forms that in order for an application to be considered complete and eligible, the applicant must provide details on the ethical issues raised by his/her proposal

- it should include guidance notes on addressing ethical issues in SSH research

guidelines should be addressed to both policy makers and national/local authorities

- the applicants are encouraged to follow the terms of national or disciplinary-specific ethical codes in the conduct of their research (for example RESPECT Code of Practice)

In what concerns the Raising Awareness Process:

- development of promotional material for SSH researchers

- specific/standardized educational training programmes through the National Contact Points (NCPs)

- training for commission staff on handling ethical issues in SSH research

- supporting documents for SSH researchers should be available on the Cordis website, but also be presented at the information days (at national and EU level)

- case studies reflecting the experience of the present FP7 funded projects should be presented in training workshops and online

- EU Member States should be encouraged to introduce legal regulation of the use of data about identifiable individuals for the purpose of research, including bodies to supervise and enforce the regulation, if such regulations do not already exist

- professional bodies should be involved through the National Contact Points to participate actively in the training programmes and workshops

- the coordinators of current FP7 projects could be requested to comment on their experience (obtaining ethical approvals, including ethics in their research strategy, experience of ethical audit etc.). This experience could be used as best practice/case studies to be included in the training programmes

- include links in the CORDIS "Find a Document" list, relevant DG websites, national research references, sectoral research associations

- printed materials: applicant guides, good practices and flyers to distribute at events

L. Reading materials and links

Supporting documents for preparing the Ethical Issues Section of your grant application

One of the key EU web pages to review is Sinapse http://europa.eu/sinapse/sinapse/**.** This has all the latest documents related to research on humans as well as guidelines for researchers.

Getting through Ethics Review http://cordis.europa.eu/fp7/ethics_en.html

The EU gets tough on ethics. ftp://ftp.cordis.europa.eu/pub/fp7/docs/technology-ireland.pdf

Ethics Review and the FP7 Ethics Framework ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-review-fp7-ethics-framework_en.ppt

Ethics for Researchers. Facilitating Research Excellence in FP7 (2007). ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-for-researchers.pdf

Integrating Ethics in EU Research. ftp://ftp.cordis.europa.eu/pub/fp7/docs/integrating-ethics.pdf

A Comprehensive Strategy of how to minimize research misconduct and the potential misuse of research in EU funded research ftp://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf

Charter of Fundamental Rights of the European Union (2000) http://www.europarl.europa.eu/charter/default_en.htm

The European Charter for Researchers. The Code of Conduct for the Recruitment of Researchers (2005). http://ec.europa.eu/euraxess/index.cfm/rights/index

Professional guidelines and codes of conduct

A list of the most well-known codes of ethics of international professional associations in social research, collected in the framework of the EU-funded RESPECT project is available at: http://www.respectproject.org/ethics/412ethics.pdf

Academy of Criminal Justice Science. *Code of Ethics* (2000). http://www.acjs.org/pubs/167_671_2922.cfm

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Association of Social Anthropologists of the UK and Commonwealth. *Ethical Guidelines for Good Research Practice* (1999). http://www.nomadit.net/asatest/ethics/guidelines.htm

Australian Government, National Health and Medical Research Council, Australian Research Council, and Australian Vice-Chancellors' Committee. *National Statement on Ethical Conduct in Human Research* (2007). http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e72-jul09.pdf

Australian Market and Social Research Society (AMSRS). *Code of Professional Behaviour* http://www.mrsa.com.au/files/Code_of_Professional_Behaviour.pdf

British Educational Research Association (BERA). *Revised Ethical Guidelines for Educational Research* (2004). http://www.bera.ac.uk/files/guidelines/ethica1.pdf

British Society of Criminology. *Code of Ethics for Researchers in the field of Criminology* (2006). http://www.britsoccrim.org/codeofethics.htm

British Sociological Association. *Statement of Ethical Practice for the British Sociological Association* (2002). http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm

Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2010). http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

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Council on Social Work Education. National Statement on Research Integrity in Social Work (2006). http://www.cswe.org/cms/17157.aspx

Economic and Social Research Council (ESRC, UK). *Framework for Research Ethics* (2010). http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf

ESOMAR. *Tape and Video Recording and Client Observation of Interviews and Group Discussions* (1996). http://www.esomar.org/uploads/pdf/ESOMAR_Codes&Guidelines_TapeAndVideoResearc

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The Ethics Committee of the British Psychological Society. *Code of Ethics and Conduct.* (2009). http://www.ucl.ac.uk/educationalpsychology/resources/BPS%20Code_of_Ethics_Conduct.pdf

European Federation of Psychologists' Associations. *Meta-Code of Ethics* (1995, revised 2005). http://www.efpa.eu/download/54fb9f885725e219c3aa3a7db1eb69a8

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Society for Research in Child Development. *Ethical Standards for Research with Children* (2007). http://www.srcd.org/index.php?option=com_content&task=view&id=68&Itemid=499

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11. Nicholas H. Steneck. Fostering Integrity in Research: Definitions, Current Knowledge, and Future Directions. *Science and Engineering Ethics*, 12 (2006): 53–74

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Please find the new, updated version of this document in an editable file format under the following hyperlink:

http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/tmpl_decl_excl-work_en.odt

Please find the new, updated version of this document in an editable file format under the following hyperlink:

http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/tmpl_time-records_en.odt

EN

HORIZON 2020

WORK PROGRAMME 2014 – 2015

3. Marie Skłodowska-Curie Actions

Revised

This Work Programme was adopted on 10 December 2013. The parts that relate to 2015 (topics, dates, budget) have, with this revised version, been updated. The changes relating to this revised part are explained on the Participant Portal.

(European Commission Decision C (2014)4995 of 22 July 2014)

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Introduction

This part of the Work Programme contributes to developing the new knowledge and enhancing the skills of people behind research and innovation, this being one of the key drivers identified in the strategy for the first three years of Horizon 2020.

The Marie Skłodowska-Curie actions ensure excellent and innovative research training as well as attractive career and knowledge-exchange opportunities through cross-border and cross-sector mobility of researchers, to better prepare them for current and future societal challenges.

The Marie Skłodowska-Curie actions are open to all domains of research and innovation addressed under the Treaty on the Functioning of the European Union, from basic research up to market take-up and innovation services. Research and innovation fields as well as sectors are chosen freely by the applicants in a fully bottom-up manner.

The Marie Skłodowska-Curie actions are open to researchers and innovation staff at all stages of their career, as well as to universities, research institutions, research infrastructures, businesses, and other socio-economic actors from all countries, including third countries under the conditions defined in Horizon 2020 Rules for Participation and in part A of the General Annexes to the Work Programme. Attention is paid to encouraging the strong participation of industry, in particular SMEs, for the successful implementation and impact of the Marie Skłodowska-Curie actions.

The Marie Skłodowska-Curie actions support researchers to establish themselves on a more stable career path and to ensure that they can achieve an appropriate work/life balance, taking into account their family situation. The principles of the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers[1] (Charter and Code) promoting open recruitment and attractive working and employment conditions are recommended to be endorsed and applied by all the funded participants.

Mobility is a key requirement in the Marie Skłodowska-Curie actions. Researchers receive funding on the condition that they move from one country to another to broaden or deepen their competences.

Marie Skłodowska-Curie actions pay particular attention to gender balance. In line with the Charter and Code, all Marie Skłodowska-Curie proposals are encouraged to take appropriate measures to facilitate mobility and counter-act gender-related barriers to it. Equal opportunities are to be ensured, both at the level of supported researchers and that of decision-making/supervision. In research activities where human beings are involved as subjects or end-users, gender differences may exist. In these cases the gender dimension in the research content has to be addressed as an integral part of the proposal to ensure the highest level of scientific quality.

As training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their proposals such activity.

[1] Commission recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, C(2005) 576 of 11.3.2005.

To further enhance dissemination and public engagement, beneficiaries of the Marie Skłodowska-Curie actions are required to plan suitable public outreach activities.

A novelty in Horizon 2020 is the Open Research Data Pilot which aims to improve and maximise access to and re-use of research data generated by projects. While certain Work Programme parts and areas have been explicitly identified as participating in the Pilot on Open Research Data, individual actions funded under the other Horizon 2020 parts and areas can choose to participate in the Pilot on a voluntary basis. The use of a Data Management Plan is required for projects participating in the Open Research Data Pilot. Further guidance on the Open Research Data Pilot is made available on the Participant Portal.

Call for Marie Skłodowska-Curie Innovative Training Networks (ITN)

H2020-MSCA-ITN-2014

Objective:

The Innovative Training Networks (ITN) aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit.

ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced career perspectives in both the academic and non-academic sectors through international, interdisciplinary and intersectoral mobility combined with an innovation-oriented mind-set.

Scope:

ITN supports competitively selected joint research training and/or doctoral programmes, implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs, and other socio-economic actors from different countries across Europe and beyond.

Partnerships take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

Each programme should have a clearly identified supervisory board co-ordinating network-wide training and establishing active and continuous communication and exchange of best practice among the partners to maximise the benefits of the partnership.

The programme should exploit complementary competences of the participants, and enable networking activities, the organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and the career development of researchers.

Training responds to well identified needs in defined research areas, with appropriate references to interdisciplinary fields. It should be primarily focused on scientific and technological knowledge through research on individual, personalised projects.

In order to increase the employability of the researchers, the research training should be complemented by the meaningful exposure of each researcher to the non-academic sector and by substantial training modules addressing key transferable skills common to all fields (e.g. entrepreneurship, management and financing of research activities and programmes, management of intellectual property rights, other exploitation methods of research results, ethical aspects, communication, standardisation and societal outreach). The training follows the EU Principles for Innovative Doctoral Training[2].

In EID and EJD, enrolment in a doctoral programme and the creation of a joint governance structure - with joint admission (EJD only), selection, supervision, monitoring and assessment procedures - is mandatory. In the case of EJD, the successful completion of the programme must result in the award of joint, double or multiple doctoral degrees.

[2] http://ec.europa.eu/euraxess/index.cfm/services/researchPolicies.

Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance. Joint supervision of the researchers is mandatory for EJD and for EID, and encouraged in ETN. In EID, the joint supervision of the researcher must be ensured by at least one supervisor from the academic sector and one supervisor from the non-academic sector.

A Career Development Plan should be established jointly by the supervisor(s) and the early-stage researcher recruited by the selected network. In addition to research objectives, this plan comprises the researcher's training and career needs, including planning for publications and participation in conferences.

Expected impact:

- ITN will create and contribute to high-quality innovative research and doctoral training, build capacity, and have a structuring effect throughout Europe and beyond.
- Through research training provided by the institutions from different countries, sectors and disciplines, this action will trigger cooperation between organisations from the academic and non-academic sectors.
- It will enhance skills development and knowledge-sharing, enhancing researchers' employability and providing them with new career perspectives.
- ITN will shape future generations of entrepreneurial researchers capable of contributing effectively to the knowledge-based economy and society.
- In the long term, it will also raise the attractiveness of research careers and encourage young people to embark on this career path.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[3]

Deadline(s): 09 April 2014 at 17.00.00 Brussels time[4]

Indicative budget: EUR 405.18 million from the 2014 budget. Of this amount, EUR 25.5 million is allocated to European Industrial Doctorates and EUR 30 million is allocated to European Joint Doctorates.

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

[3] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[4] The Director-General responsible may delay this deadline by up to two months.

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Participants in ETN and EJD resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on research training and career development.

Call for Marie Skłodowska-Curie Individual Fellowships (IF)

H2020-MSCA-IF-2014

Objective:

The goal of Individual Fellowships is to enhance the creative and innovative potential of experienced researchers wishing to diversify their individual competence in terms of skill acquisition through advanced training, international and intersectoral mobility.

Individual Fellowships provide opportunities to acquire and transfer new knowledge and to work on research in a European context (EU Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

Scope:

Support is foreseen for individual, trans-national fellowships awarded to the best or most promising researchers for employment in EU Member States or Associated Countries, based on an application made jointly by the researcher and host organisation in the academic or non-academic sectors.

Fellowships are either European Fellowships or Global Fellowships. European Fellowships are held in EU Member States or Associated Countries and are open to researchers either coming to Europe or moving within Europe. The researcher must comply with the rules of mobility in the country where the European Fellowship is held. Global Fellowships are based on a secondment to a third country and a mandatory 12 month return period to a European host. The researcher must comply with the rules of mobility in the country where the Global Fellowship secondment takes place, not for the country of the return phase.

Return and reintegration of researchers into a longer term research position in Europe, including in their country of origin, is supported via a separate multi-disciplinary reintegration panel of the European Fellowships. For the reintegration panel, there shall be mobility into Europe.

Support to individuals to resume research in Europe after a career break, e.g. after parental leave, is ensured via a separate multi-disciplinary career restart panel of the European Fellowships. To qualify for the career restart panel, researchers must not have been active in research for at least 12 months immediately prior to the deadline for submission.

Researchers receiving an Individual Fellowship may opt to include a secondment phase in Europe, notably in the non-academic sector, within the overall duration of their fellowship. For a fellowship of 18 months or less, the secondment phase may last up to three months. For a fellowship of more than 18 months, the secondment phase may last up to six months. The secondment phase can be a single period or be divided into shorter mobility periods. The secondment should significantly add to the impact of the fellowship.

A Career Development Plan should be established jointly by the supervisor(s) and the researcher. In addition to research objectives, this plan comprises the researcher's training and career needs, including training on transferable skills, planning for publications and participation in conferences.

Expected impact:

- Individual Fellowships are expected to add significantly to the development of the best and most promising researchers active in Europe, in order to enhance and maximise their contribution to the knowledge-based economy and society.
- The action will also strengthen the contact network of both the researcher and the host organisation.
- The fellowship will contribute to realising the full potential of researchers and to catalysing significant development in their careers in both the academic and non-academic sectors.
- Some researchers will be resuming a research career in Europe after a break, or reintegrating within Europe after living abroad.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 12 March 2014[5]

Deadline(s): 11 September 2014 at 17.00.00 Brussels time[6]

Indicative budget: EUR 240.50 million from the 2014 budget. Of this amount, EUR 29 million is allocated to Global Fellowships.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A curriculum vitae of the researcher;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

[5] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[6] The Director-General responsible may delay this deadline by up to two months.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 10 pages, excluding the CV of the researcher and the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Not applicable - this is a mono-beneficiary action.

Call for Marie Skłodowska-Curie Research and Innovation Staff Exchange (RISE)

H2020-MSCA-RISE-2014

Objective:

The RISE scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa) for the advancement of science and the development of innovation.

The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

Scope:

RISE involves organisations from the academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Associated Countries) and outside Europe (third countries).

Support is provided for the development of partnerships in the form of joint research and innovation activities between the participants. This is aimed at knowledge sharing via international as well as intersectoral mobility, based on secondments of research and innovation staff (exchanges) with an in-built return mechanism.

The organisations constituting the partnership contribute directly to the implementation of the joint research and innovation activities by seconding and/or hosting eligible staff members.

The proposed research and innovation activities should exploit complementary competences of the participants, as well as other synergies, and enable networking activities, organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and career development for research and innovation staff members.

Activities can focus either on one dimension of mobility (intersectoral / international), or include a combination of both.

Exchanges can be for both early-stage and experienced researchers' levels and can also include administrative, managerial and technical staff supporting the research and innovation activities of the proposal.

Support for the exchanges between institutions in the EU Member States and Associated Countries covers only intersectoral secondments.

Exchanges with institutions from third countries can be intersectoral secondments as well as secondments within the same sector.

No secondments between institutions located in third countries or within the same EU Member State or Associated Country can be supported.

Expected impact:

- Research and innovation activities under RISE are expected to build or enhance new and existing networks of international and intersectoral cooperation. They will significantly

strengthen the interaction between organisations in the academic and non-academic sectors, and between Europe and third countries.

- In terms of knowledge sharing and broad skills development, they will better align different cultures and expectations, with a view to a more effective contribution of research and innovation to Europe's knowledge economy and society.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[7]

Deadline(s): 24 April 2014 at 17.00.00 Brussels time[8]

Indicative budget: EUR 70 million from the 2014 budget.

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.

[7] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[8] The Director-General responsible may delay this deadline by up to two months.

The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement: Participants in actions resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on staff exchanges.

Call for Marie Skłodowska-Curie Co-funding of regional, national and international programmes (COFUND)

H2020-MSCA-COFUND-2014

Objective:

The COFUND scheme aims at stimulating regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions.

This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

Scope:

Each proposal funded under the COFUND scheme shall have a sole participant that will be responsible for the availability of the necessary matching funds to execute the proposal.

Participants submit multi-annual proposals for new or existing doctoral programmes or fellowship programmes that may be run at regional, national or international level. The evaluation is organised in two different panels: A) Doctoral programmes and B) Fellowship programmes. Support cannot be awarded to researchers who are already permanently employed at the host organisation.

Doctoral programmes address the development and broadening of the research competencies of early-stage researchers. The training follows the EU Principles on Innovative Doctoral Training. Collaboration with a wider set of partners, including from the non-academic sector, which may provide hosting or secondment opportunities or training in research or transferable skills, as well as innovative elements of the proposed programme, will be positively taken into account during the evaluations. Each researcher must be enrolled in a doctoral programme. Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance.

Fellowship programmes fund individual research training and career development fellowships for experienced researchers. The programmes supported should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between the researchers applying. The selections should be based on open, widely advertised competition, with transparent international peer review and the selection of candidates on merit. Mobility types supported by fellowship programmes may be similar to the ones supported under Marie Skłodowska-Curie Individual Fellowships. On top of transnational mobility, applicants are encouraged to include elements of cross-sectoral mobility into their programmes. Fellowship programmes should be based on individual-driven mobility, i.e., researchers should be able to freely choose a research topic and the appropriate host organisation fitting their individual needs.

Limitations regarding the researchers' origin and destination should be avoided. Given that the aim of the co-funded fellowship programmes is the support of individual fellows, research teams will not be funded.

Proposed fellowship programmes are encouraged to cover all research disciplines ("bottom-up"), but can also focus on specific disciplines. In this case the range of covered disciplines

should allow reasonable flexibility for the researchers. Programmes that prioritise specific research disciplines based on national or regional Research and Innovation Strategies for Smart Specialisation (RIS3 strategies) will also be supported.

Researchers supported under this scheme should comply with the mobility rules of the Marie Skłodowska-Curie actions. Existing programmes can deviate from this rule if duly justified in the proposal by the applicant.

Expected impact:

The COFUND scheme will on a voluntary basis exploit synergies between European Union actions and those at regional and national level, as well as with other actions at international level. The scheme will have a leverage effect on regional, national or international funding programmes for early-stage researchers and experienced researchers. This impact is expected to extend to:

1. enabling the relevant regional, national and international actors to contribute significantly to the development within their own setting of high quality human resources, by introducing and/or further developing the trans-national dimension of their offers;

2. increasing the numerical and/or qualitative impact, in terms of supported researchers or working/employment conditions;

3. combating fragmentation in terms of objectives, evaluation methods and working conditions of regional, national or international offers in this area.

Type of action: Marie Skłodowska-Curie COFUND (Programme Co-fund Action).

CONDITIONS FOR THIS CALL

Opening date: 10 April 2014[9]

Deadline(s): 02 October 2014 at 17.00.00 Brussels time[10]

Indicative budget: EUR 80.00 million from the 2014 budget. Of this amount, EUR 30 million is allocated to Doctoral Programmes.

The European Union contribution has maximum overall of EUR 10 million to a single applicant legal entity for one call. Participants having benefited from COFUND under previous calls (under Seventh Framework Programme or under Horizon 2020) will explain in their proposals how the latest proposal relates to and goes beyond the earlier grant and provide evidence for its quality (e.g., if possible, by external evaluations).

[9] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[10] The Director-General responsible may delay this deadline by up to two months.

Duration: Selected programmes will have a duration of 36 to 60 months from the starting date specified in the Agreement. This duration includes also the time that is needed to select or recruit the researchers.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be responsible for carrying out the proposed work;
- A description of administrative resources to implement the programme;
- A description of partner organisations who will be contributing towards the work by hosting researchers.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: A maximum length of the proposal is of 30 pages. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Not applicable - this is a mono-beneficiary action.

Call for European Researchers' Night (NIGHT)

H2020-MSCA-NIGHT-2014

Objective:

The European Researchers' Night aims to bring researchers closer to the general public and to increase awareness of research and innovation activities, with a view to supporting the public recognition of researchers, creating an understanding of the impact of researchers' work on citizen's daily life, and encouraging young people to embark on scientific careers.

Scope:

The European Researchers' Night takes place yearly, typically on the last Friday of the month of September, and is the occasion for a Europe-wide public and media event for the promotion of research careers, in particular towards young people and their parents. Supported events can start early Friday afternoon and last until early morning the following day.

Activities focus on the general public, addressing and attracting people regardless of the level their scientific background, with a special focus on pupils and students. Activities can combine education aspects with entertainment, especially when adressing young audience. They can take various forms, e.g. hands-on experiments, science shows, simulations, debates, games, competitions, quizzes, etc.

Each proposal should set up at least one European corner. Activities should be organised with researchers actively involved and directly in contact with the public. They should promote the European dimension and gender balance in research and innovation. Involvement of researchers funded by Horizon 2020, including Marie Skłodowska-Curie actions, is encouraged.

Participants can be any legal entity in the EU Member States and Associated Countries, and/or if relevant, constitute a partnership at regional, national or international level.

Expected impact:

- The European Researchers' Night will raise awareness of the importance of research careers. It will make the general public better understand the central role of researchers and the key benefits that they bring to society.
- The scheme will help to tackle the existing stereotypes about researchers and their profession.
- In the long term, it will convince young people that research careers are fascinating and will stimulate them to embark on research careers.

Type of action: Coordination and support action. The funding rate for this call is provided in part D of the General Annexes.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[11]

Deadline(s): 04 March 2014 at 17.00.00 Brussels time[12]

Indicative budget: EUR 8.00 million from the 2014 budget.

Duration: The maximum duration of support will be two years from the starting date specified in the Agreement. The Agreement should cover two editions of the Night, in successive years. One single edition of the Night may also be considered.

Eligibility and admissibility conditions: The conditions are described in parts B and C of the General Annexes to the work programme. The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide[13] published on the Participant Portal. .
- Proposal page limits and layout: The maximum length of the proposal is 30 pages. There is no automatic check in the system. Experts will be instructed to disregard any excess pages in each section in which the maximum number of pages is indicated.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).
- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.
Consortium agreement:
Participants in actions resulting from this call are NOT required to conclude a consortium agreement.

[11] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[12] The Director-General responsible may delay this deadline by up to two months.

[13] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

Call for Trans-national cooperation among Marie Skłodowska-Curie National Contact Points (NCP)

H2020-MSCA-NCP-2014

Objective:

Facilitate trans-national co-operation between National Contact Points (NCPs) for the Marie Skłodowska-Curie actions (MSCA), with a view to identifying and sharing good practices and raising the general standard of support to applicants, taking into account the diversity of actors.

Scope:

Support will be given to a consortium of formally nominated NCPs in the area of MSCA. The activities will be tailored according to the nature of the area, and the priorities of the NCPs concerned. Various mechanisms may be included, such as benchmarking, joint workshops, enhanced cross-border brokerage events, training sessions linked to MSCA as well as to gender dimension of Research and Innovation, twinning schemes, etc. Special attention will be given to enhancing the competence of MSCA NCPs, including helping less experienced NCPs rapidly acquire the know-how accumulated in other countries. It will be also encouraged to build up cooperation with other networks to increase visibility to potential beneficiaries, especially in the non-academic sector.

The focus throughout should be on issues specific to MSCA and should not duplicate actions foreseen in the NCP network for quality standards and horizontal issues under 'Science with and for Society'.

Only NCPs host organisations from EU Member States, Associated Countries, and third countries which have been officially appointed by the relevant national authorities are eligible to participate in and receive funding for this action.

The consortium should have a good representation of experienced and less experienced NCPs.

Submission of a single proposal is encouraged. NCPs from EU Member States or Associated Countries choosing not to participate as a member of the consortium should be identified and the reason explained in the proposal. These NCPs are nevertheless invited and encouraged to participate in the project activities (e.g. workshops), and the costs incurred by the consortium for such participation (e.g. travel costs paid by the consortium) may be included in the estimated budget and be eligible for funding by the Commission.

The Commission will only fund one proposal under this topic.

Expected impact:

- An improved and professionalised NCP service across Europe, therefore helping simplify access to Horizon 2020 calls, lowering the entry barriers for newcomers, and raising the average quality of submitted proposals.
- A more consistent level of NCP support services across Europe.

Type of action: Coordination and support action. The funding rate for this call is provided in part D of the General Annexes.

CONDITIONS FOR THIS CALL

Opening date: 11 December 2013[14]

Deadline(s): 02 April 2014 at 17.00.00 Brussels time[15]

Indicative budget: EUR 1.50 million from the 2014 budget.

Duration: The maximum duration of support will be three years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The conditions are described in parts B and C of the General Annexes to the work programme. The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide[16] published on the Participant Portal.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Participants in actions resulting from this call are NOT required to conclude a consortium agreement.

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[14] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[15] The Director-General responsible may delay this deadline by up to two months.

[16] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

Call for Marie Skłodowska-Curie Innovative Training Networks (ITN)

H2020-MSCA-ITN-2015

Objective:

The Innovative Training Networks (ITN) aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit.

ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced career perspectives in both the academic and non-academic sectors through international, interdisciplinary and intersectoral mobility combined with an innovation-oriented mind-set.

Scope:

ITN supports competitively selected joint research training and/or doctoral programmes, implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs, and other socio-economic actors from different countries across Europe and beyond.

Partnerships take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

Each programme should have a clearly identified supervisory board co-ordinating network-wide training and establishing active and continuous communication and exchange of best practice among the partners to maximise the benefits of the partnership.

The programme should exploit complementary competences of the participants, and enable networking activities, the organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and the career development of researchers.

Training responds to well identified needs in defined research areas, with appropriate references to interdisciplinary fields. It should be primarily focused on scientific and technological knowledge through research on individual, personalised projects.

In order to increase the employability of the researchers, the research training should be complemented by the meaningful exposure of each researcher to the non-academic sector and by substantial training modules addressing key transferable skills common to all fields (e.g. entrepreneurship, management and financing of research activities and programmes, management of intellectual property rights, other exploitation methods of research results, ethical aspects, communication, standardisation and societal outreach). The training follows the EU Principles for Innovative Doctoral Training[17].

In EID and EJD, enrolment in a doctoral programme and the creation of a joint governance structure - with joint admission (EJD only), selection, supervision, monitoring and assessment

[17] http://ec.europa.eu/euraxess/index.cfm/services/researchPolicies.

procedures - is mandatory. In the case of EJD, the successful completion of the programme must result in the award of joint, double or multiple doctoral degrees.

Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance. Joint supervision of the researchers is mandatory for EJD and for EID, and encouraged in ETN. In EID, the joint supervision of the researcher must be ensured by at least one supervisor from the academic sector and one supervisor from the non-academic sector.

A Career Development Plan should be established jointly by the supervisor(s) and the early-stage researcher recruited by the selected network. In addition to research objectives, this plan comprises the researcher's training and career needs, including planning for publications and participation in conferences.

Expected impact:

- ITN will create and contribute to high-quality innovative research and doctoral training, build capacity, and have a structuring effect throughout Europe and beyond.
- Through research training provided by the institutions from different countries, sectors and disciplines, this action will trigger cooperation between organisations from the academic and non-academic sectors.
- It will enhance skills development and knowledge-sharing, enhancing researchers' employability and providing them with new career perspectives.
- ITN will shape future generations of entrepreneurial researchers capable of contributing effectively to the knowledge-based economy and society.
- In the long term, it will also raise the attractiveness of research careers and encourage young people to embark on this career path.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 02 September 2014[18]

Deadline(s): 13 January 2015 at 17.00.00 Brussels time[19]

Indicative budget: EUR 370.00 million from the 2015 budget. Of this amount, EUR 25 million is allocated to European Industrial Doctorates and EUR 28 million is allocated to European Joint Doctorates.[20]

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

[18] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[19] The Director-General responsible may delay this deadline by up to two months.

[20] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Participants in ETN and EJD resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on research training and career development.

Call for Marie Skłodowska-Curie Individual Fellowships (IF)

H2020-MSCA-IF-2015

Objective:

The goal of Individual Fellowships is to enhance the creative and innovative potential of experienced researchers wishing to diversify their individual competence in terms of skill acquisition through advanced training, international and intersectoral mobility.

Individual Fellowships provide opportunities to acquire and transfer new knowledge and to work on research in a European context (EU Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

Scope:

Support is foreseen for individual, trans-national fellowships awarded to the best or most promising researchers for employment in EU Member States or Associated Countries, based on an application made jointly by the researcher and host organisation in the academic or non-academic sectors.

Fellowships are either European Fellowships or Global Fellowships. European Fellowships are held in EU Member States or Associated Countries and are open to researchers either coming to Europe or moving within Europe. The researcher must comply with the rules of mobility in the country where the European Fellowship is held. Global Fellowships are based on a secondment to a third country and a mandatory 12 month return period to a European host. The researcher must comply with the rules of mobility in the country where the Global Fellowship secondment takes place, not for the country of the return phase.

Return and reintegration of researchers into a longer term research position in Europe, including in their country of origin, is supported via a separate multi-disciplinary reintegration panel of the European Fellowships. For the reintegration panel, there shall be mobility into Europe.

Support to individuals to resume research in Europe after a career break, e.g. after parental leave, is ensured via a separate multi-disciplinary career restart panel of the European Fellowships. To qualify for the career restart panel, researchers must not have been active in research for at least 12 months immediately prior to the deadline for submission.

Researchers receiving an Individual Fellowship may opt to include a secondment phase in Europe, notably in the non-academic sector, within the overall duration of their fellowship. For a fellowship of 18 months or less, the secondment phase may last up to three months. For a fellowship of more than 18 months, the secondment phase may last up to six months. The secondment phase can be a single period or be divided into shorter mobility periods. The secondment should significantly add to the impact of the fellowship.

A Career Development Plan should be established jointly by the supervisor(s) and the researcher. In addition to research objectives, this plan comprises the researcher's training and career needs, including training on transferable skills, planning for publications and participation in conferences.

Expected impact:

- Individual Fellowships are expected to add significantly to the development of the best and most promising researchers active in Europe, in order to enhance and maximise their contribution to the knowledge-based economy and society.
- The action will also strengthen the contact network of both the researcher and the host organisation.
- The fellowship will contribute to realising the full potential of researchers and to catalysing significant development in their careers in both the academic and non-academic sectors.
- Some researchers will be resuming a research career in Europe after a break, or reintegrating within Europe after living abroad.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 12 March 2015[21]

Deadline(s): 10 September 2015 at 17.00.00 Brussels time[22]

Indicative budget: EUR 215.00 million from the 2015 budget. Of this amount, EUR 27 million is allocated to Global Fellowships.[23]

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A curriculum vitae of the researcher;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

[21] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[22] The Director-General responsible may delay this deadline by up to two months.

[23] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: The maximum length of the proposal is 10 pages, excluding the CV of the researcher and the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:
Not applicable - this is a mono-beneficiary action.

Call for Marie Skłodowska-Curie Research and Innovation Staff Exchange (RISE)

H2020-MSCA-RISE-2015

Objective:

The RISE scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa) for the advancement of science and the development of innovation.

The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

Scope:

RISE involves organisations from the academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Associated Countries) and outside Europe (third countries).

Support is provided for the development of partnerships in the form of joint research and innovation activities between the participants. This is aimed at knowledge sharing via international as well as intersectoral mobility, based on secondments of research and innovation staff (exchanges) with an in-built return mechanism.

The organisations constituting the partnership contribute directly to the implementation of the joint research and innovation activities by seconding and/or hosting eligible staff members.

The proposed research and innovation activities should exploit complementary competences of the participants, as well as other synergies, and enable networking activities, organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and career development for research and innovation staff members.

Activities can focus either on one dimension of mobility (intersectoral / international), or include a combination of both.

Exchanges can be for both early-stage and experienced researchers' levels and can also include administrative, managerial and technical staff supporting the research and innovation activities of the proposal.

Support for the exchanges between institutions in the EU Member States and Associated Countries covers only intersectoral secondments.

Exchanges with institutions from third countries can be intersectoral secondments as well as secondments within the same sector.

No secondments between institutions located in third countries or within the same EU Member State or Associated Country can be supported.

Expected impact:

- Research and innovation activities under RISE are expected to build or enhance new and existing networks of international and intersectoral cooperation. They will significantly

strengthen the interaction between organisations in the academic and non-academic sectors, and between Europe and third countries.

- In terms of knowledge sharing and broad skills development, they will better align different cultures and expectations, with a view to a more effective contribution of research and innovation to Europe's knowledge economy and society.

Type of action: Marie Skłodowska-Curie action.

CONDITIONS FOR THIS CALL

Opening date: 06 January 2015[24]

Deadline(s): 28 April 2015 at 17.00.00 Brussels time[25]

Indicative budget: EUR 80 million from the 2015 budget.[26]

Duration: The maximum duration of support will be four years from the starting date specified in the Agreement.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be primarily responsible for carrying out the proposed work;
- A description of any significant infrastructure or any major items of technical equipment, relevant to the proposed work;
- A description of any partner organisations that are not represented as beneficiaries, but who will nonetheless be contributing towards the work.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

[24] The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of opening.

[25] The Director-General responsible may delay this deadline by up to two months.

[26] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

- Proposal page limits and layout: The maximum length of the proposal is 30 pages, excluding the annexes. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement: Participants in actions resulting from this call are NOT required to conclude a consortium agreement, as the main focus of activities is on staff exchanges.

Call for Marie Skłodowska-Curie Co-funding of regional, national and international programmes (COFUND)

H2020-MSCA-COFUND-2015

Objective:

The COFUND scheme aims at stimulating regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions.

This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

Scope:

Each proposal funded under the COFUND scheme shall have a sole participant that will be responsible for the availability of the necessary matching funds to execute the proposal.

Participants submit multi-annual proposals for new or existing doctoral programmes or fellowship programmes that may be run at regional, national or international level. The evaluation is organised in two different panels: A) Doctoral programmes and B) Fellowship programmes. Support cannot be awarded to researchers who are already permanently employed at the host organisation.

Doctoral programmes address the development and broadening of the research competencies of early-stage researchers. The training follows the EU Principles on Innovative Doctoral Training. Collaboration with a wider set of partners, including from the non-academic sector, which may provide hosting or secondment opportunities or training in research or transferable skills, as well as innovative elements of the proposed programme, will be positively taken into account during the evaluations. Each researcher must be enrolled in a doctoral programme. Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance.

Fellowship programmes fund individual research training and career development fellowships for experienced researchers. The programmes supported should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between the researchers applying. The selections should be based on open, widely advertised competition, with transparent international peer review and the selection of candidates on merit. Mobility types supported by fellowship programmes may be similar to the ones supported under Marie Skłodowska-Curie Individual Fellowships. On top of transnational mobility, applicants are encouraged to include elements of cross-sectoral mobility into their programmes. Fellowship programmes should be based on individual-driven mobility, i.e., researchers should be able to freely choose a research topic and the appropriate host organisation fitting their individual needs.

Limitations regarding the researchers' origin and destination should be avoided. Given that the aim of the co-funded fellowship programmes is the support of individual fellows, research teams will not be funded.

Proposed fellowship programmes are encouraged to cover all research disciplines ("bottom-up"), but can also focus on specific disciplines. In this case the range of covered disciplines

should allow reasonable flexibility for the researchers. Programmes that prioritise specific research disciplines based on national or regional Research and Innovation Strategies for Smart Specialisation (RIS3 strategies) will also be supported.

Researchers supported under this scheme should comply with the mobility rules of the Marie Skłodowska-Curie actions. Existing programmes can deviate from this rule if duly justified in the proposal by the applicant.

Expected impact:

The COFUND scheme will on a voluntary basis exploit synergies between European Union actions and those at regional and national level, as well as with other actions at international level. The scheme will have a leverage effect on regional, national or international funding programmes for early-stage researchers and experienced researchers. This impact is expected to extend to:

1. enabling the relevant regional, national and international actors to contribute significantly to the development within their own setting of high quality human resources, by introducing and/or further developing the trans-national dimension of their offers;

2. increasing the numerical and/or qualitative impact, in terms of supported researchers or working/employment conditions;

3. combating fragmentation in terms of objectives, evaluation methods and working conditions of regional, national or international offers in this area.

Type of action: Marie Skłodowska-Curie COFUND (Programme Co-fund Action).

CONDITIONS FOR THIS CALL

Opening date: 14 April 2015[27]

Deadline(s): 01 October 2015 at 17.00.00 Brussels time[28]

Indicative budget: EUR 80.00 million from the 2015 budget. Of this amount, EUR 30 million is allocated to Doctoral Programmes.[29]

The European Union contribution has maximum overall of EUR 10 million to a single applicant legal entity for one call. Participants having benefited from COFUND under previous calls (under Seventh Framework Programme or under Horizon 2020) will explain in their proposals how the latest proposal relates to and goes beyond the earlier

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grant and provide evidence for its quality (e.g., if possible, by external evaluations).

Duration: Selected programmes will have a duration of 36 to 60 months from the starting date specified in the Agreement. This duration includes also the time that is needed to select or recruit the researchers.

Eligibility and admissibility conditions: The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme. The admissibility conditions are described in part B of the General Annexes to the work programme, with the following exception:

The following supporting documents will be required to determine the operational capacity:

- A description of the profile of the persons who will be responsible for carrying out the proposed work;
- A description of administrative resources to implement the programme;
- A description of partner organisations who will be contributing towards the work by hosting researchers.

Evaluation criteria: The selection and award criteria for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

Evaluation procedure: The evaluation procedure for Marie Skłodowska-Curie actions apply. Please read the dedicated section in this part of the work programme.

- Proposal page limits and layout: A maximum length of the proposal is of 30 pages. Experts will be instructed to disregard any excess pages.
The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). Ensure that the font type chosen is clearly readable (e.g. Arial or Times New Roman).

- Indicative timetable for evaluation and grant agreement:
Information on the outcome of the evaluation (*one stage*): Maximum 5 months from the final date for submission.
Indicative date for the signing of grant agreements: Maximum 3 months from the date of informing applicants.

Consortium agreement:

Not applicable - this is a mono-beneficiary action.

Other actions (not subject to calls for proposals) [30]

1. External expertise

This action will support the use of appointed independent experts for the evaluation of project proposals and, where appropriate, for the monitoring of running projects.

Type of action: Expert contracts

Indicative timetable: Throughout the 2014 and 2015. The implementation is linked to the schedule of the calls.

Indicative budget: EUR 10 217 498 from the 2014 budget and EUR 10 067 659 from the 2015 budget.

2. Support for EU Presidency events

Support for two EU Presidency events in the area of mobility, training and careers of researchers.

The Italian Presidency conference will raise awareness of challenges associated with the training of the next generation of researchers and will allow the sharing of best practices in the area of research career development.

The Luxembourg Presidency conference will provide a suitable forum for discussing the COFUND scheme and in particular, the leverage effect on regional, national or international funding programmes for early-stage researchers and experienced researchers: how to foster excellence in researchers' training, mobility and career development. This will be addressed from different perspectives while highlighting challenges and best practices.

Legal entity:

On the condition that the incoming Italian Presidency confirms their intentions, the EU Presidency event in Italy would be implemented through a grant to the appropriate authorities (The Italian Ministry of Education, Universities and Research - Ministero dell'Istruzione, dell'Università e della Ricerca, Piazza Kennedy 20, 00144 ROMA, Italy) that will cooperate with other institutions of the country for the organisation of the event.

On the condition that the incoming Luxembourg Presidency confirms their intentions, the EU Presidency event in Luxembourg would be implemented through a grant to the appropriate authorities (Fonds National de la Recherche Luxembourg, 6, rue Antoine de Saint-Exupéry, B.P. 1777 L-1017 Luxembourg) that will cooperate with other institutions of the country for the organisation of the event.

Type of action: Grant to identified beneficiary - Coordination and support action.

[30] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The standard evaluation criteria, thresholds, weighting for award criteria and the maximum rate of co-financing for this type of action are provided in parts C, D and H of the General Annexes.

Indicative timetable: First semester of 2014 for the grant to identified beneficiary for the Italian Presidency. First semester of 2015 for the grant to identified beneficiary for the Luxembourg Presidency.

Indicative budget: EUR 150 000 from the 2014 budget (Italian Presidency event) and EUR 150 000 from the 2015 budget (Luxembourg Presidency event).

3. Studies

To study aspects of high relevance for the successful implementation of the Marie Skłodowska-Curie Actions: dual careers in research, promotion measures of research careers towards potential future researchers, career restart in research, industrial doctorates.

Type of action: Public Procurement - Framework contract. Maximum two specific contracts.

Indicative timetable: Third quarter of 2014 for the first specific contract and second quarter of 2015 for the second specific contract.

Indicative budget: EUR 350 000 from the 2014 budget and EUR 100 000 from the 2015 budget.

4. Alumni services

To further increase the impact of the Marie Skłodowska-Curie actions, networking between Marie Skłodowska-Curie researchers (current and past) will be enhanced through the implementation of alumni services.

Type of action: Public Procurement – existing Framework contract. Maximum two specific contracts.

Indicative timetable: Third quarter of 2014 and third quarter of 2015.

Indicative budget: EUR 567 000 from the 2014 budget and EUR 550 000 from the 2015 budget.

5. Events and outreach 2015

During 2015 the Commission intends to organise several events (conferences and workshops) dedicated to the Marie Skłodowska-Curie actions, to contribute to leading research conferences and other events as well as to inform about the programme's results, thus raising awareness with relevant target groups and stakeholders about the programme's impact and its new developments. For this, maximum 10 specific contracts will be concluded via existing framework contracts for the support measures.

Type of action: Public Procurement - Framework contract.

Indicative timetable: First quarter of 2015 for the first specific contract and fourth quarter of 2015 for the last specific contract.

Indicative budget: EUR 400 000 from the 2015 budget.

Budget

Calls	*2014 Budget EUR million*[31]	**2015**[32] **Budget EUR million**
Call H2020-MSCA-ITN-2014 Marie Skłodowska-Curie Innovative Training Networks	*405.18* *from 15 03 01 01*	-
Call H2020-MSCA-IF-2014 Marie Skłodowska-Curie Individual Fellowships	*240.50* *from 15 03 01 01*	-
Call H2020-MSCA-RISE-2014 Marie Skłodowska-Curie Research and Innovation Staff Exchange	*70.00* *from 15 03 01 01*	-
Call H2020-MSCA-COFUND-2014 Marie Skłodowska-Curie Co-funding of regional, national and international programmes	*80.00* *from 15 03 01 01*	-
Call H2020-MSCA-NIGHT-2014 European Researchers' Night	*8.00* *from 15 03 01 01*	-
Call H2020-MSCA-NCP-2014 Trans-national cooperation among Marie Skłodowska-Curie National Contact Points	*1.50* *from 15 03 01 01*	-
Call H2020-MSCA-ITN-2015 Marie Skłodowska-Curie Innovative Training Networks	-	370.00 *from 15 03 01 01*
Call H2020-MSCA-IF-2015 Marie Skłodowska-Curie Individual Fellowships	-	215.00 *from 15 03 01 01*
Call H2020-MSCA-RISE-2015 Marie Skłodowska-Curie Research and Innovation Staff Exchange	-	80.00 *from 15 03 01 01*
Call H2020-MSCA-COFUND-2015 Marie Skłodowska-Curie Co-funding of regional, national and international	-	80.00 *from 15 03 01 01*

[31] The budget figures given in this table are rounded to two decimal places.

[32] The budget amounts for 2015 are subject to the availability of the appropriations provided for in the draft budget for 2015 after the adoption of the budget for 2015 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

programmes		
Other Actions		
Expert contracts	*10.22* *from 15 03 01 01*	10.07 *from 15 03 01 01*
Grant to identified beneficiary - EU Presidency events	*0.15* *from 15 03 01 01*	0.15 *from 15 03 01 01*
Public Procurement - Studies	*0.35* *from 15 03 01 01*	0.10 *from 15 03 01 01*
Public procurement – Alumni services	*0.57* *from 15 03 01 01*	0.55 *from 15 03 01 01*
Events and outreach activities	-	0.40 *from 15 03 01 01*
Estimated total budget	***816.47***	**756.27**

Contribution to Horizontal activities (08.020500 in 2014 and 2015)		
Dissemination activities (see Part 17 of the work programme)	*0.61*	0.63
Corporate communication (see Part 17 of the work programme)	*0.32*	_
Estimated total budget for the horizontal activities	***0.93***	**0.63**
Estimated total budget including horizontal activities	***817.40***	**756.90**

Eligibility conditions

PROPOSAL

A proposal will only be considered eligible if it complies with the minimum participation and any other eligibility conditions set out below, depending on the type of action.

PARTICIPANTS

Participants will comply with the applicable rules for funding as set out in part A of the General Annexes to the work programme.

The eligibility criteria formulated in Commission notice Nr 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp. 9-11) shall apply for all actions under this part of the Work Programme, including with respect to partner organisations, third parties receiving financial support in the cases where the respective action involves financial support to third parties by grant beneficiaries in accordance with Article 137 of the EU's Financial Regulation, notably Programme Co-Fund action.

Some entities from third countries are covered by the Council sanctions in place and are not eligible to participate in Union programmes. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.

For the purpose of determining eligibility, where one of the participants is an international European interest organisation or the EU's Joint Research Centre or an entity created under Union law, it shall be deemed to be established in an EU Member State or Associated Country other than any EU Member State or Associated Country in which another participant in the same proposal is established.

Participants are organisations from the academic or the non-academic sector. These two sectors are defined as follows:

Academic sector

Academic sector consists of public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations[33].

Non-academic sector

Non-academic sector includes any socio-economic actor not included in the academic sector and fulfilling the requirements of the Horizon 2020 Rules for Participation.

[33] For the purpose of this document, international European interest organisations shall be understood as defined in article 2 of the Horizon 2020 Rules for Participation.

Participants can be divided in two groups based on their level of participation:

- Beneficiaries: signatory to the agreement

  Beneficiaries are full partners with complete responsibility for executing the proposed programme and other requirements of the project. They contribute directly to the implementation of the research training programme by appointing, supervising, hosting and training researchers.[34] They may also provide secondment opportunities.

- Partner organisations: non-signatory of the agreement

  Partner organisations are non-beneficiary organisations contributing to the project by providing training and hosting researchers[35] during secondments. Partner organisations do not employ researchers within the project[36]. Partner organisations shall include a letter of commitment in the proposal to ensure their real and active participation in the proposed network. The experts will be instructed to disregard the contribution of any partner organisations for which no such evidence of commitment is submitted.

Consortia involving partner organisations are encouraged to sign a partnership agreement to regulate the relationship between participants. These partnership agreements shall be in compliance with the obligations laid down in the Agreement.

In **Individual Fellowships (IF)**, the beneficiary shall be a participant located in an EU Member State or Associated Country and employing the researcher during the project.

Innovative Training Networks (ITN) can take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD). They must be created by at least three beneficiaries (or at least two for EID) located in three different EU Member States or Associated Countries. Above this minimum, the participation of institutions from any country or organisation is possible under the conditions provided by the Horizon 2020 Rules for Participation.

In the case of EID, at least one beneficiary must be entitled to award doctoral degrees[37] and at least one beneficiary must come from the non-academic sector, primarily enterprises. For EJD, at least three beneficiaries must be entitled to award doctoral degrees.[38]

The overall Union contribution for ITN is limited to the recruitment of a maximum 540 person-months. For EID with only two participants, this limit is set to 180.

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[34] In the framework of COFUND, beneficiaries may also fund doctoral programmes or fellowship programmes for researchers.

[35] In the framework of RISE, "researchers" refers to staff members.

[36] In the framework of COFUND, this restriction does not apply.

[37] Every time the document refers to doctoral degrees, this means that the degrees have to be recognised as such by the relevant authorities of the country or countries concerned.

[38] For EJD, at least two institutions conferring a joint, double or multiple doctoral degree must be established in an EU Member State and/or Associated Country.

Not more than 40% of the requested EU contribution shall be dedicated to hosts in the same country (except for EID).

Participants in the **Research and Innovation Staff Exchange (RISE)** shall be established in at least three different countries of which at least two must be EU Member States or Associated Countries. If all participants are from the same sector (either only academic or only non-academic), at least one participant must be from a third country. Above this minimum, the participation of institutions from any country or organisation is possible under the conditions provided by the Horizon 2020 Rules for Participation.

The overall European Union contribution for RISE is limited to the secondment of a maximum 540 person-months.

Participants in the Marie Skłodowska-Curie **Co-funding of regional, national and international programmes (COFUND)** shall be legal entities established in an EU Member State or Associated Country that fund or manage doctoral programmes or fellowship programmes for researchers. International European interest organisations that fund or manage doctoral programmes or fellowship programmes for researchers can also participate in this action.

RESEARCHERS

Researchers may be of any nationality. Researchers receive support on the condition that they move from one country to another to broaden or deepen their competences.

Global Fellowships and the Reintegration Panel in IF are open to nationals or long-term residents of EU Member States and Associated Countries. Long-term residence means a period of full-time research activity of at least 5 consecutive years.

Supported researchers fall into two categories: early-stage or experienced researchers:

Early-stage researchers (ESR) shall at the time of recruitment (ITN, COFUND) or secondment (RISE) by the host organisation, be in the first four years (full-time equivalent research experience) of their research careers and have not been awarded a doctoral degree.

Experienced researchers (ER) shall, at the time of the relevant deadline for submission of proposals (IF), recruitment (COFUND) or secondment (RISE) by the host organisation, be in possession of a doctoral degree or have at least four years of full-time equivalent research experience.

Full-time equivalent research experience is measured from the date when a researcher obtained the degree which would formally entitle him or her to embark on a doctorate, either in the country in which the degree was obtained or in the country in which the researcher is recruited or seconded, irrespective of whether or not a doctorate is or was ever envisaged.

Mobility rules:

At the time of the relevant deadline for submission of proposals (IF), or recruitment by the host organisation (ITN), researchers shall not have resided or carried out their main activity (work , studies, etc) in the country of their host organisation for more than 12 months in the 3 years immediately prior to the reference date. Compulsory national service and/or short stays

such as holidays are not taken into account. As far as international European interest organisations or international organisations are concerned, this rule does not apply to the hosting of eligible researchers. However the appointed researcher shall not have spent more than 12 months in the 3 years immediately prior to the reference date, depending on the action, in the same appointing organisation.

In the Career Restart Panel and the Reintegration Panel in IF, researchers shall not have resided or carried out their main activity in the country of their host organisation for more than 3 years in the 5 years immediately prior to the relevant deadline for submission of proposals.

Staff members in RISE are researchers (ESR and ER), administrative, managerial and technical staff supporting the research and innovation activities of the project. They shall be actively engaged in or linked to research and/or innovation activities for at least six months (full-time equivalent) at the sending institution prior to the first period of secondment. Secondments in RISE are not subject to the mobility rules.

Duration of support

The support granted to eligible researchers (including staff members in RISE) will cover the following periods:

1. ITN: 3-36 months
   Researchers in EID shall spend at least 50% of their time in the non-academic sector

2. IF European: 12-24 months
   IF Global: 12-24 months for the outgoing phase plus 12 month return phase in Europe

3. RISE: 1-12 months
   Secondments may be split into several stays not exceeding 12 months in total and not going beyond the project duration. The splits must be justified and considered beneficial for the transfer of knowledge activities.
   The exchanged staff members should be guaranteed full reintegration into the sending institution thus maximising the impact of the action for knowledge sharing and long-term collaboration.

4. COFUND: minimum 3 months
   Researchers in COFUND shall not be recruited for less than 3 months.

Award criteria

The award criteria against which proposals will be judged are set out in Article 14 of the Horizon 2020 Rules for Participation.

The purpose of this section is to set out specifications for the criteria, weightings and ex-aequo priority order applied to calls for proposals in Marie Skłodowska-Curie actions.

Evaluation scores will be awarded for each of the criteria, and not their individual elements. Each criterion will be scored from 0 to 5. Scores with a resolution of one decimal place may be awarded. The total score will be subject to a threshold of 70%.

A proposal that contravenes fundamental ethical principles, fails to comply with the relevant security procedures, or which does not fulfil any other of the conditions set out in the specific programme, the work programme or in the call for proposals shall not be selected. Such a proposal may be excluded from the award procedure at any time. Details of the procedure to be followed are given in the Commission rules mentioned above.

Table 1: Award Criteria, Weightings and ex-aequo Priority Order

1. ITN - Marie Skłodowska-Curie Innovative Training Networks		
Excellence	**Impact**	**Implementation**
Quality, innovative aspects and credibility of the research programme (including inter/multidisciplinary and intersectoral aspects)	**Enhancing research- and innovation-related human resources, skills, and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources (including awarding of the doctoral degrees for *EID* and *EJD* projects)
Quality and innovative aspects of the training programme (including transferable skills, inter/multidisciplinary and intersectoral aspects)	**Contribution to structuring doctoral / early-stage research training at the European level and to strengthening European innovation capacity, including the potential for**: **a)** meaningful contribution of the non-academic sector to the doctoral/research training, as appropriate to the implementation mode and research field **b)** developing sustainable joint doctoral degree structures (for *EJD* projects only)	**Appropriateness of the management structures and procedures**, including quality management and risk management (with a mandatory joint governing structure for *EID* and *EJD* projects)

Quality of the supervision (including mandatory joint supervision for *EID* and *EJD* projects)	Effectiveness of the proposed measures for **communication** and **dissemination of results**	**Appropriateness of the infrastructure of the participating organisations**
Quality of the proposed interaction between the participating organisations		**Competences, experience and complementarity of the participating organisations and their commitment to the programme**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

2. IF - Marie Skłodowska-Curie Action: Individual Fellowships		
Excellence	**Impact**	**Implementation**
Quality, innovative aspects and credibility of the research (including inter/multidisciplinary aspects)	**Enhancing research- and innovation-related human resources, skills and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources
Clarity and quality of transfer of knowledge/training for the development of researcher in light of the research objectives	Effectiveness of the proposed measures for **communication** and **results dissemination**	**Appropriateness of the management structures and procedures**, including quality management and risk management
Quality of the supervision and the hosting arrangements		**Appropriateness of the institutional environment** (infrastructure)
Capacity of the researcher to reach or re-enforce a position of professional maturity in research		**Competences, experience and complementarity** of the participating organisations **and institutional commitment**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

3. RISE - Marie Skłodowska-Curie Action: Research and Innovation Staff Exchange		
Excellence	**Impact**	**Implementation**
Quality, innovative aspects and credibility of the research (including inter/multidisciplinary aspects)	**Enhancing research- and innovation-related human resources, skills and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources
Clarity and quality of knowledge sharing among the participants in light of the research and innovation objectives.	**To develop new and lasting research collaborations, to achieve transfer of knowledge** between research institutions and to improve research and innovation potential at the European and global levels	**Appropriateness of the management structures and procedures**, including quality management and risk management
Quality of the interaction between the participating organisations	Effectiveness of the proposed measures for **communication** and **results dissemination**	**Appropriateness of the institutional environment** (infrastructure)
		Competences, experience and complementarity of the participating organisations **and institutional commitment**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

4. COFUND - Marie Skłodowska-Curie Action: Co-funding of regional, national and international programmes		
Excellence	**Impact**	**Implementation**
Quality of the selection / recruitment process for the researchers (transparency, composition and organisation of selection committees, evaluation criteria, equal opportunity)	**Enhancing research- and innovation-related human resources, skills and working conditions to realise the potential of individuals and to provide new career perspectives**	**Overall coherence, effectiveness and appropriateness of the work plan**
Quality of the research options offered by the programme in terms of science, interdisciplinarity, intersectorality and level of transnational mobility	**Impact of the programme on aligning practices at participating organisations with principles set out by the EU for the human resources development in research and innovation**	**Appointment conditions of researchers**
Quality of career guidance and training, including supervision arrangements, training in transferable skills	Effectiveness of the proposed measures for **communication** and **results dissemination of the programmes**	**Competence of the participant** to implement the programme
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

Evaluation procedure

In Marie Skłodowska-Curie ITN, IF and RISE, proposals are allocated to one of the eight main evaluation panels: Chemistry (CHE), Social Sciences and Humanities (SOC), Economic Sciences (ECO), Information Science and Engineering (ENG), Environment and Geosciences (ENV), Life Sciences (LIF), Mathematics (MAT), Physics (PHY). In ITN, separate multidisciplinary panels will be created for the European Industrial Doctorates (EID) and the European Joint Doctorates (EJD). In IF, separate multidisciplinary panels will be created for the Career Restart Panel (CAR) and the Reintegration Panel. COFUND evaluation will be organised in two different panels: Doctoral programmes and Fellowship programmes.

For each panel a ranked list is established. The distribution of the indicative budget of the call will be proportional to the number of eligible proposals received in each panel, except where a specific budget for a multidisciplinary panel has been fixed in the call. If the budget allocated to any panel exceeds the requirements of all proposals positively evaluated[39] in that panel, the excess budget will be reallocated to the other panels based on the distribution as above. Equally, if the allocated funding to a panel is insufficient to fund the highest ranked proposal in that panel, the necessary budget will be transferred from the other panels based on the distribution as above, in order to ensure that the highest ranked proposal can be funded.

Proposals will not be evaluated anonymously. Proposals may be evaluated remotely.

As part of the evaluation by independent experts, a panel review will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated in this work programme.

If necessary, the panel will determine a priority order for proposals which have been awarded the same score within a ranked list. When the total scores are equal, priority will be based on scores for individual award criteria. For each action the priority order of the criteria is detailed in table 1 of the section on award criteria.

If necessary, any further prioritisation will be based on other appropriate characteristics, to be decided by the panel, related to the contribution of the proposal to the European Research Area and/or general objectives mentioned in the work programme (e.g. intersectoral mobility, international co-operation, favourable employment and working conditions).

Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the call fiche.

The full evaluation procedure is described in the relevant guide[40] published on the Participant Portal.

[39] Measured as proposals having passed all relevant evaluation thresholds.

[40] See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

European Union contribution and applicable rates

The host organisation shall appoint each eligible researcher under an employment contract / contract with full social security coverage (including sickness, parental, unemployment and invalidity benefits, pension rights, benefits in respect of accidents at work and occupational diseases) except where national regulation prohibits this possibility.

Table 2 gives the yearly reference rates for calculating the living allowances of each eligible researcher. The amounts per year are given in Euros per category of researchers who are recruited under an employment contract/ contract with full social security coverage complying with the social security legislation applicable[41]. These amounts include all compulsory deductions under national applicable legislation.

Table 2: Yearly reference rates for living allowances under employment contracts (Correction Coefficient index 100)[42]

Researchers Categories	EUR/year
Early-stage researchers	37 320
Experienced researchers	55 800

When an employment contract cannot be provided, the host organisation shall recruit the researcher under a status equivalent to a fixed-amount fellowship. The rates applicable in these cases, which shall be duly justified, will be 50% of the rates for researchers under an employment contract. The host organisation shall ensure that researchers enjoy minimum social security coverage.

The host organisation receiving the Union funding under Table 2 above shall pay to the selected researchers a minimum contribution according to these reference allowances, taking into account all compulsory deductions under national legislation in the context of the project. The host organisation may pay a top-up to the eligible researchers in order to complement this contribution.

In addition to the living allowance, a mobility allowance and a family allowance will be paid for some categories of researchers as specified in Table 3. In this context family is defined as persons linked to the researcher by (i) marriage, or (ii) a relationship with equivalent status to a marriage recognised by the legislation of the country where this relationship was formalised; or (iii) dependent children who are actually being maintained by the researcher.

[41] Council Regulation (EC) N° 883/2004 of 29 April 2004, as amended by Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009, Commission Regulation (EU) No 1244/2010 of 9 December 2010 and Corrigendum, OJ L 200, 7.6.2004, p. 1 (883/2004)

[42] Rates for individual countries are obtained by applying to these reference rates the respective correction coefficients as listed in Table 4.

The various rates from Tables 2 and 3 apply to researchers devoting themselves to their project on a full-time basis (pro-rata for parts of years). In exceptional cases where researchers, in agreement with the host organisation and with prior approval by the Research Executive Agency, execute their project on a part-time basis, the rates will apply proportionally without the possibility that the total amounts will exceed those that apply for full-time equivalent periods. The same principle will also apply in case of split of a project into several distinct periods.

Table 3: Structure of the European Union contribution

The EU contribution under the Marie Skłodowska-Curie actions is based on unit costs expressed in person-months. They have been established in line with the methodology set up by the Commission Decision n° C(2013) 8194[43] and are indicated in EUR.

Marie Skłodowska-Curie Action	**Researcher unit cost**** **person/month**			**Institutional unit cost**** **person/month**	
	Living allowance*	**Mobility allowance**	**Family allowance**	**Research, training and networking costs**	**Management and indirect costs**
Innovative Training Networks	**3 110**	**600**	**500**	**1 800**	**1 200**
Individual Fellowships	**4 650**	**600**	**500**	**800**	**650**

* A country correction coefficient applies to the living allowance. This coefficient is the one applicable to the country of the researcher's host organisation as listed in Table 4.
** These unit costs will be subject to a funding rate of 100% (Article 28.4 of the Rules for Participation).

[43] COMMISSION DECISION authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme

Marie Skłodowska-Curie Action	**Staff member unit cost**** **Top-up allowance** **person/month**	**Institutional unit cost**** **person/month**	
		Research, training and networking costs	**Management and indirect costs**
Research and Innovation Staff Exchange	**2 000**	**1 800**	**700**

** These unit costs will be subject to a funding rate of 100% (Article 28.4 of the Rules for Participation).

Marie Skłodowska-Curie Action	**Researcher unit cost***** **person/month**		**Institutional unit cost***** **person/month**
Co-funding of regional, national and international programmes	**Early-stage researchers**	**3 710**	**650**
	Experienced researchers	**5 250**	

***These unit costs will be subject to a co-funding rate of 50% (Article 28.3of the Rules for Participation).

The EU contribution for the co-funding of regional, national and international programmes (COFUND) shall be used exclusively as contribution to the management of the programme and to the living allowance of the researchers, which is exclusively for the benefit of the researchers appointed under the project and includes all compulsory deductions under national legislation. Other cost items (such as research costs, travel and mobility allowances, indirect costs) may be funded through other resources including EU programmes other than Horizon 2020. Applicants shall specify in their proposal the amounts that will be provided for the benefit of the researcher and for the organisation that is hosting the researcher. This information will be needed for the expert evaluators to assess the adequateness of employment and working conditions of the researchers.

The researcher unit costs will be reduced by 50% in case that the researchers are recruited under a status equivalent to a fixed-amount fellowship.

The living and mobility allowances provided by the programmes for the benefit of the researchers

- recruited under an employment contract shall in no case be lower than EUR 2 597 (ESR) and EUR 3 675 (ER);
- recruited under a status equivalent to a fixed-amount fellowships shall in no case be lower than EUR 1 298.50 (ESR) and EUR 1 837.50 (ER).

TABLE 4: COUNTRY CORRECTION COEFFICIENTS (CCC)

Country Code[44]	CCC
AT	104.8%
BE	100.0%
BG	71.5%
CY	91.8%
CZ	83.8%
DE	98.8%
DK	135.3%
EE	78.3%
EL	92.7%
ES	97.6%
FI	116.6%
FR	111.0%
HR	97.5%
HU	76.2%
IE	113.5%
IT	106.7%
LT	73.1%
LU	100.0%
LV	75.9%
MT	89.6%
NL	104.3%
PL	76.4%
PT	89.1%
RO	68.3%
SE	111.7%
SI	86.1%
SK	82.6%
UK	120.3%
AL	76.1%
BA	73.6%
CH	113.1%
FO	134.1%
IL	108.7%
IS	116.6%
LI	110.0%
MD	61.1%
ME	66.9%
MK	68.4%
NO	131.9%
RS	67.1%
TR	86.6%
AM	89.9%
AO	114.6%
AR	58.5%
AU	105.0%
AZ	93.0%
BB	116.6%
BD	47.2%
BF	93.8%
BJ	92.6%
BM	151.5%
BO	51.3%
BR	92.0%
BW	55.3%
BY	65.0%
BZ	75.3%
CA	86.4%
CD	127.6%
CF	114.3%
CG	124.9%
CI	102.0%
CL	67.1%
CM	103.3%
CN	85.0%
CO	76.6%
CR	76.7%
CU	83.8%
CV	76.4%
DJ	93.4%
DO	66.9%
DZ	81.7%
EC	68.8%
EG	48.6%
ER	61.2%
ET	85.2%
FJ	68.1%
GA	113.1%
GE	89.5%
GH	68.2%
GM	67.7%
GN	60.4%
GT	78.8%
GW	102.7%
GY	58.9%
HK	93.8%
HN	69.0%
HT	108.7%
ID	75.3%
IN	52.8%
JM	94.9%
JO	75.5%
JP	115.9%
KE	78.1%
KG	83.1%
KH	70.5%
KR	105.2%
KZ	100.2%
LA	77.7%
LB	86.4%

[44] ISO 3166 alpha-2, except for Greece and the United Kingdom (EL and UK used respectively instead of GR and GB).

LK	61.6%
LR	100.1%
LS	56.7%
LY	60.0%
MA	83.5%
MG	80.0%
ML	90.4%
MR	64.5%
MU	72.7%
MW	76.0%
MX	70.4%
MY	71.6%
MZ	71.6%
NA	68.3%
NC	128.9%
NE	87.9%
NG	92.4%
NI	57.3%
NP	73.5%
NZ	94.1%
PA	57.0%
PE	75.5%
PG	83.0%
PH	65.8%
PK	49.4%
PS	100.4%
PY	71.9%
RU	115.5%

RW	87.3%
SA	84.8%
SB	93.3%
SD	65.1%
SG	102.5%
SL	85.2%
SN	86.2%
SR	50.6%
SV	74.3%
SY	74.8%
SZ	56.8%
TD	125.3%
TG	88.7%
TH	65.0%
TJ	64.9%
TL	78.3%
TN	70.5%
TO	85.0%
TT	74.1%
TW	83.6%
TZ	65.2%
UA	92.3%
UG	65.7%
US	99.4%
UY	75.3%
UZ	51.4%
VE	70.0%
VN	51.1%

VU	112.6%
WS	75.8%
XK	58.6%
YE	68.1%
ZA	55.8%
ZM	66.4%
ZW	47.2%

In addition to this 2012 report, AOIR has also produced a 2002 report to assist researchers in making decisions about internet research. Available at: http://www.aoir.org/reports/ethics.pdf

Ethical Decision-Making and Internet Research:

Recommendations from the AoIR Ethics Working Committee (Version 2.0)

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INTRODUCTION AND BACKGROUND

The work represented in this document emerges from theoretical, empirical, and field research conducted by members of the Association of Internet Researchers, including members of the AoIR Ethics Working Group.

The first version of the AoIR Ethical Decision-Making document was released in 2002, after two years of international and cross-disciplinary collaboration. The document and its guidelines emerged from a series of extensive dialogues among experienced researchers facing and resolving ethical issues in internet research, philosophers, and other members of AoIR's international, interdisciplinary community. The intention was to develop guidelines from the bottom up -- i.e., out of the day-to-day practices of researchers in a wide range of disciplines, countries and contexts, in contrast to a more usual top-down approach that tries to provide a universal set of norms, principles, practices, and regulations. This approach was crucial because the enterprise of internet research is expansive -- that is, globally informed -- but also situated in innumerable locales. The 2002 document has subsequently received much use, and has been cited and used in a wide range of publications by a diverse number of disciplines. The AoIR Guidelines document has also been used by research ethics boards (REBs) and institutional review boards (IRBs) when making decisions about internet research-based protocols.[1]

Purpose and Audience

While the first AoIR document enjoyed extensive use, much has changed in the field of Internet Studies since 2002. The scope and contexts of internet research have been dramatically expanded through the continuing global diffusion of the internet into nearly every country in the world, as facilitated through a growing array of devices (including game consoles, internet-enabled phones and other mobile devices) and ever-increasing bandwidth; rapidly expanding suites of new communication applications; and the increasingly seamless interweaving of online and offline activities and experiences. Alongside these developments, the literature of internet research ethics has grown considerably, providing us with a far more extensive range of theoretical resources and practical examples to help recognize and guide ethical reflection.

The AoIR ethics working committee, with extensive feedback from AoIR membership including at workshops conducted annually at the AoIR internet research conferences, from 2005 through the present, has developed this 2012 version in an effort to recognize and respond to the array of changing technologies and ongoing developments that affect the ethics of internet research. We emphasize that no set of guidelines or rules is static; the fields of internet research are dynamic and heterogeneous. This dynamism is reflected in the fact that as of the time of this writing, no official guidance or “answers” regarding internet research ethics have been adopted at any national or international level.

This document aligns with and extends the first AoIR document. This document represents a series of considerations designed to support and inform those responsible for making decisions about the ethics of internet research. And, while primarily directed at researchers, it provides a resource for a wide audience of other stakeholders such as review boards, ethicists, and students, by providing a current discussion of important ethical issues and pertinent literature in the field.

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Limitations, or What This Document is Not

In this document, we do not reiterate the many specific rules of governmental or institutional research policies, as these are well documented and widely available. We also do not include specific disciplinary best practices or codes of ethics, as this document seeks to function at the macro-level.[2]

Although we identify current internet technologies and contexts, we acknowledge that technologies themselves change rapidly. Therefore, this document is designed to emphasize processes for decision-making and questions that can be applied to ever-changing technological contexts.

At its most fundamental level, we recognize that ethical decision-making interweaves one's fundamental world view (ontology, epistemology, values, etc), one's academic and political environment (purposes), one's defining disciplinary assumptions, and one's methodological stances. Decision making occurs at many junctures in the cycle of inquiry, including research design, research conduct, and research production and dissemination. Because of the complexity of ethical decision making in individual cases, this document focuses on general principles, illustrating their application using some examples from the many possible ethical issues that may arise.

What is Internet Research?

The internet is a social phenomenon, a tool, and also a (field) site for research. Depending on the role the internet plays in the research project or how it is conceptualized by the researcher, different epistemological, logistical and ethical considerations will come into play. The term "Internet" originally described a network of computers that made possible the decentralized transmission of information. Now, the term serves as an umbrella for innumerable technologies, devices, capacities, uses, and social spaces. Within these technologies, many ethical and methodological issues arise and as such, internet research calls for new models of ethical evaluation and consideration.

Because the types of interaction and information transmission made possible by the internet vary so widely, researchers find it necessary to define the concept more narrowly within individual studies. This is complicated by the fact that studies of and on the internet cut across all academic disciplines.

This document uses the following working definitions:

Internet research encompasses inquiry that:

(a) utilizes the internet to collect data or information, e.g., through online interviews, surveys, archiving, or automated means of data scraping;
(b) studies how people use and access the internet, e.g., through collecting and observing activities or participating on social network sites, listservs, web sites, blogs, games, virtual worlds, or other online environments or contexts;
(c) utilizes or engages in data processing, analysis, or storage of datasets, databanks, and/or repositories available via the.
(d) studies software, code, and internet technologies
(e) examines the design or structures of systems, interfaces, pages, and elements

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(f) employs visual and textual analysis, semiotic analysis, content analysis, or other methods of analysis to study the web and/or internet-facilitated images, writings, and media forms.
(g) studies large scale production, use, and regulation of the internet by governments, industries, corporations, and military forces.

Internet research is not machine specific or dependent, and we recognize the impact of smart devices and increased mobility on internet activities. It is important to note that definitions of and experiences with these contexts vary widely. Technological convergence collapses many contexts and categories in evolving and sometimes surprising ways. The internet mediates everyday life in industrialized and developing cultures, whether or not we are actively accessing the web. Thus, internet research should be considered in its broadest sense.

GENERAL ETHICAL GUIDELINES

Principles of research ethics and ethical treatment of persons are codified in a number of policies and accepted documents, such as the UN Declaration of Human Rights, the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. At their core, the basic tenets shared by these policies include the fundamental rights of human dignity, autonomy, protection, safety, maximization of benefits and minimization of harms, or, in the most recent accepted phrasing, respect for persons, justice, and beneficence. While originally stemming from the biomedical contexts, these principles have been adapted beyond these early contexts and rise above disciplines and methodologies. We accept them as basic to any research endeavor. These basic principles provide a starting point for a range of ethical considerations that occur at various junctures of any specific research project. Different ethical issues become salient as the researcher develops research questions, seeks and gains access to individuals and/or information, manages and protects personally identifiable information, selects analytical tools, and represents the data through dissemination, in published reports, conference presentations, or other venues.[3]

Key guiding principles

We find the following principles to be fundamental to an ethical approach to internet research:

> The greater the vulnerability of the community / author / participant, the greater the obligation of the researcher to protect the community / author / participant.
>
> Because 'harm' is defined contextually, ethical principles are more likely to be understood inductively rather than applied universally. That is, rather than one-size-fits-all pronouncements, ethical decision-making is best approached through the application of practical judgment attentive to the specific context (what Aristotle identified as phronesis[4]).
>
> Because all digital information at some point involves individual persons, consideration of principles related to research on human subjects may be necessary even if it is not immediately apparent how and where persons are involved in the research data.
>
> When making ethical decisions, researchers must balance the rights of subjects (as authors, as research participants, as people) with the social benefits of research and researchers' rights to conduct research. In different contexts the rights of subjects may outweigh the benefits of research.

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Ethical issues may arise and need to be addressed during all steps of the research process, from planning, research conduct, publication, and dissemination.

Ethical decision-making is a deliberative process, and researchers should consult as many people and resources as possible in this process, including fellow researchers, people participating in or familiar with contexts/sites being studied, research review boards, ethics guidelines, published scholarship (within one's discipline but also in other disciplines), and, where applicable, legal precedent.[5]

Guidelines versus codes

Ethical conundrums are complex and rarely decided along binary lines. There is much grey area in ethical decision-making. More than one set of norms, values, principles and usual practices can be seen to legitimately apply to the issue(s) involved. It becomes difficult to make judgments as to which set(s) apply, especially when one set conflicts with another in some way. This forces the researcher to determine which is more relevant in a given context or at particular junctures during the course of the study. We emphasize that ethical concepts such as harm, vulnerability, respect for persons, and beneficence are not just regulatory hurdles to be jumped through at the beginning stages of research, but concepts that ground ethical inquiry. As such, they should be assessed and considered throughout each stage of the research. Multiple judgments are possible, and ambiguity and uncertainty are part of the process.

We advocate guidelines rather than a code of practice so that ethical research can remain flexible, be responsive to diverse contexts, and be adaptable to continually changing technologies. When one considers that ethical assessments are always operationalized via some sort of practice (method), and also contextualized institutionally and/or geographically, it becomes clearer that an adaptive, inductive approach can yield potentially more ethically legitimate outcomes than a simple adherence to a set of instantiated rules. The emphasis on a process approach highlights the researcher's responsibility for making such judgments and decisions within specific contexts and, more narrowly, within a specific research project. Hence, this 2012 version of the AoIR Ethical Decision Making document adheres to the same underlying principles as the first: a dialogic, case-based, inductive, and process approach to ethics.

We strongly urge that people who use this document in their work contribute a synopsis or case study of how they used it, whether it was in fact useful, and whether they might change anything about it. In this way, we can more fully appreciate the range of approaches to ethical research practice and continue to build a robust and diverse collection of best practices. This growing compendium of resources can be accessed at http://ethics.aoir.org/.

A PROCESS APPROACH TO ETHICAL DECISION MAKING IN INTERNET RESEARCH

At each juncture of a research project, different ethical issues become relevant. Decisions about gaining access to a site for data collection are different from decisions about how to interact with participants or whether or not informed consent is needed. Once these issues have been resolved, further ethical quandaries will arise as one makes decisions about how to store data, whether or not

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to use actual quotes in published reports, or how to represent one's findings for various audiences. This section is designed to help guide one's considerations through the process of ethical assessment. We begin by outlining three major issues that arise repeatedly in discussions about ethical practice in internet research: Human subjects, private/public, and data/persons. This is followed by a brief discussion of a fourth issue for researchers: The tension between top down regulatory models and case based, situated approaches. Finally in this section, we provide a detailed list of questions that can help raise awareness of ethical considerations throughout a research project. Note that the appendices provide further tools to think with, including a list of frequently asked questions and a heuristic chart that lays out an array of questions arising in studies of particular contexts/venues or with particularly types of information or data produced or retrieved from those contexts.

Major tensions/considerations

Operational definitions of ethical concepts and appropriate research conduct vary widely, within and across disciplines. This is not unique to internet research, but describes an inherent quality of any ethical discussion. Our research community has learned over the past two decades that internet research requires individuals and institutions alike to confront many irresolvable contradictions and tensions. Many competing interests must be negotiated by researchers, ethics review boards, and institutions.

Human Subjects: The concept of 'human subjects' is a persistent and contentious example of a dialectical tension between disciplinary/regulatory models and context-specific sensibilities. The term 'human subject' as applied to the consideration of research ethics emerged from early responses to harmful treatment of persons in medical experiments[6]. It persists as a guiding concept for ethical social research, yet has been long critiqued for being ill-suited for models of inquiry that follow non-biomedical procedures for interacting with people or don't interact directly with people at all, for example, studying published texts.[7] Many regulatory bodies across the world[8] have dealt with these issues by creating different levels of ethics board review based on the idea that some research might be exempt from review or require only limited review. The definition of 'human subject' has become, unfortunately, a litmus test for whether or not one needs to undergo ethical review before conducting research. In internet research, 'human subject' has never been a good fit for describing many internet-based research environments.[9] Ongoing debates among our community of scholars illustrate a diverse, educated range of standpoints on the answers to the question of what constitutes a 'human subject.' We agree with other regulatory bodies that the term no longer enjoys the relatively straightforward definitional status it once did.[10] As a community of scholars, we maintain the stance that when considered outside a regulatory framework, the concept of 'human subject' may not be as relevant as other terms such as harm, vulnerability, personally identifiable information, and so forth. We encourage researchers to continue vigorous and critical discussion of the concept of 'human subject,' both as it might be further specified in internet-related research or as it might be supplanted by terms that more appropriately define the boundaries for what constitutes inquiry that might be ethically challenging.

Public/Private: Individual and cultural definitions and expectations of privacy are ambiguous, contested, and changing. People may operate in public spaces but maintain strong perceptions or expectations of privacy.[11] Or, they may acknowledge that the substance of their communication is public, but that the specific context in which it appears implies restrictions on how that information is -- or ought to be -- used by other parties.[12] Data aggregators or search tools make information accessible to a wider public than what might have been originally intended. In mediated contexts,

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as Nissenbaum points out, "what people care most about is not simply restricting the flow of information but ensuring that it flows appropriately" (2010, p. 2). As noted in the 2002 version of these AOIR ethics guidelines, privacy is a concept that must include a consideration of expectations and consensus. Social, academic, or regulatory delineations of public and private as a clearly recognizable binary no longer holds in everyday practice. When conducting research within such shifting terrains, when there is no consensus, or even assumption of consensus, Nissenbaum's concept of contextual integrity (2010) is a valuable construct.

Data(Text)/Persons: The internet complicates the fundamental research ethics question of personhood. Is an avatar a person? Is one's digital information an extension of the self? In the U.S. regulatory system, the primary question has generally been: Are we working with human subjects or not? If information is collected directly from individuals, such as an email exchange, instant message, or an interview in a virtual world, we are likely to naturally define the research scenario as one that involves a person. If the connection between the object of research and the person who produced it is indistinct, there may be a tendency to define the research scenario as one that does not involve any persons. This may oversimplify the situation--the question of whether one is dealing with a human subject is different from the question about whether information is linked to individuals: Can we assume a person is wholly removed from large data pools? For example, a data set containing thousands of tweets or an aggregation of surfing behaviors collected from a bot is perhaps far removed from the persons who engaged in these activities. In these scenarios, it is possible to forget that there was ever a person somewhere in the process that could be directly or indirectly impacted by the research. Yet there is considerable evidence that even 'anonymised' datasets that contain enough personal information can result in individuals being identifiable. Scholars and technologists continue to wrestle with how to adequately protect individuals when analysing such datasets (Sweeny, 2009; Narayanan & Shmatikov, 2008, 2009). These are important considerations because they link to the fundamental ethical principle of minimizing harm. Does the connection between one's online data and his or her physical person enable psychological, economic, or physical, harm? One way of evaluating the extent to which these ethical dilemmas may be hidden is to focus on the way that procedures for data collection or analysis extract data from lived experience.

These three issues represent ongoing tensions for internet research. Although we as researchers might like straightforward answers to questions such as "Will capturing a person's Tweets cause them harm?" or "Is a blog a public or private space?" and we as authors of this document might like to supply answers, the uniqueness and almost endless range of specific situations defy attempts to universalize experience or define in advance what might constitute harmful research practice. We take the position that internet research involves a number of dialectical tensions that are best addressed and resolved at the stages they arise in the course of a research study. In saying so, we reiterate the value of a casuistic or case-based approach.

Top-down versus bottom-up approaches to ethics: This case based approach is complicated by the fact that most of us will grapple with other sets of tensions beyond the specifics of the research context we are studying: ethical versus legal considerations, regulatory-driven versus context-specific models for ethical approaches, and top-down versus bottom-up decision making. These tensions should be acknowledged and considered, even if there are no easy resolutions.

For example, when acknowledging the tension between regulation-driven and context-specific considerations, it may be useful to consider that while regulations or disciplinary traditions are intended to encourage ethical practice, they can also inadvertently function to restrict the researcher

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by making universal declarations and *a priori* determinations about what constitutes harm and what will cause harm. This is often done by identifying particular categories of persons who are vulnerable, or by implying that by gaining informed consent, harm may somehow be mitigated. We agree that in certain extreme situations, there will be broad consensus about whether certain actions were ethical or not. Yet we also agree as a community of researchers that in most social situations, the issues and ethics are more fuzzy.

One must also balance the need to predict what ethical consequences might occur with the need to be open to how ethical issues emerge during the research process. In the United States, for example, most scholars are required to gain approval of institutional review boards (IRB) prior to conducting research. One is asked to make many decisions about possible ethical issues in advance of one's study. This can be daunting. Foreseeing harms or risks associated with a research project is always difficult, given that individuals and groups are unique, situations change, research directions can shift, and continually-evolving technologies may alter the ethical situation. On the other hand, researchers working without the direct approval of ethics review boards in countries where these are not a part of the research process have different responsibilities and may have additional challenges to face.

The challenge for researchers remains: how to balance contextual requirements with disciplinary, institutional, legal, cultural, or other constraints.

We offer the following detailed sets of questions to prompt reflection about ethical decision making within the specific confines of one's study. These are intended, along with the appendices, as tools to engage with prior to, during, and after the research process.

Internet Specific Ethical Questions

The list below begins with common questions asked in the course of a research project. The bullet points represent more specific considerations that arise in internet-related contexts.

How is the context defined and conceptualized?

- Does the research definition of the context match the way owners, users, or members might define it?[13] (Parameters such as 'culture,' 'person,' 'data set,' and 'public text' each carry different ethical expectations for researchers)
- Are there distinctions between local contextual norms for how a venue is conceptualized and jurisdictional frameworks (e.g., Terms of Service, other regulations)? For example, if the TOS defines the space as off limits for researchers but the individuals want to participate in public research of this space, what risk might exist for either the researcher or individuals involved?[14]
- What are the ethical expectations users attach to the venue in which they are interacting, particularly around issues of privacy? Both for individual participants as well as the community as a whole?

How is the context (venue/participants/data) being accessed?

- How are participants / authors situated in the context?
- How are participants/authors approached by the researcher?
- How is the researcher situated in the context?[15]
- If access to an online context is publicly available, do members/participants/authors perceive the context to be public? What considerations might be necessary to accommodate

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'perceived privacy'[16] or the notion that individuals might care more about the appropriate flow of information as defining it as public or private[17]?

Who is involved in the study?

- What are the ethical expectations of the community/participants/authors?
- What is the ethical stance of the researcher? (For example, a mismatch between the ethical stance of the researcher and the community/participant/author may create ethical complications).[18]
- What are the ethical traditions of researchers' and/or author/participants' cultures or countries?
- If research data is housed in a repository for reuse, how might individuals or communities be affected later? For example, data collected for one purpose might be reused later for a different purpose but the researcher's relationship with the community from which the data came no longer exists. What possible risk or harm might result from reuse and publication of this information?[19]

What is the primary object of study?

- What are the ethical expectations commonly associated with these types of data? (For example, working with aggregated, de-identified data carries different ethical expectations than working with interview data.)
- Does the object of analysis include persons or texts beyond the immediate parameters outlined by the study? What are the potential ethical consequences and how might these be addressed? (For example, collecting data from a blog often includes comments; collecting data from one social media stream reveals links to people or data outside the specific scope of the study.)
- If information collected in the course of a study can be linked back to an individual by means of internet search or other technology, what process will the researcher use to determine how that information will be treated? (For example, many challenges surround the responsible use of images and video). To what extent might data be considered by participants to be personal and private, or public and freely available for analysis and re-publication?
- What other questions might arise as a result of the particular context from which this data was collected?

How are data being managed, stored, and represented?

- What method is being used to secure and manage potentially sensitive data?
- What unanticipated breaches might occur during or after the collection and storage of data or the production of reports?[20] (For example, if an audience member recorded and posted sensitive material presented during an in-house research presentation, what harms might result?
- If the researcher is required to deposit research data into a repository for future use by other researchers (or wishes to do so), what potential risks might arise? What steps should be taken to ensure adequate anonymity of data or to unlink this data from individuals?
- What are the potential ethical consequences of stripping data of personally identifiable information?
- How might removal of selected information from a dataset distort it such that it no longer represents what it was intended to represent?
- If future technologies (such as automated textual analysis or facial recognition software) make it impossible to strip personally identifiable information from data sets in

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repositories, what potential risks might arise for individuals? Can this be addressed by the original researcher? If so, how? How will this impact subsequent researchers and their data management?

How are texts/persons/data being studied?

- Does one's method of analysis require exact quoting and if so, what might be the ethical consequence of this in the immediate or long term? (For example, would quoting directly from a blog cause harm to the blogger and if so, could another method of representation be less risky?[21])
- What are the ethical expectations of the research community associated with a particular approach (e.g, ethnographic, survey, linguistic analysis)?
- Do one's disciplinary requirements for collecting, analyzing, or representing information clash with the specific needs of the context? If so, what are the potential ethical consequences?

How are findings presented?

- What immediate or future risk might occur by using exact-quoted material in published reports? (For example, while a participant might not think his or her information is sensitive now, this might change in five years. What protections might be put in place to anticipate changing perceptions?[22])
- Are individuals adequately protected in pre-publication reports, such as workshops, conferences, or informal meetings?[23]
- Could materials be restricted because of copyright? (For example, many countries have strong restrictions on using screenshots or images taken from the web without permission. Certain sites have restrictions in their terms of service. Whereas there may be allowances for the scholarly use of copyrighted materials without permission, such as the U.S. doctrine of fair use, this is not a guarantee of protection against copyright infringement.)

What are the potential harms or risks associated with this study?

- What is the potential harm or risk for individuals, for online communities, for researchers, for research?
- Are risks being assessed throughout the study as well as in advance of the study? (Harm is only certain after it occurs. Thus, a priori assessments of risk might be useful but inadequate[24]).
- How are the concepts of 'vulnerability' and 'harm' being defined and operationalized in the study? How are risks to the community/author/participant being assessed?
- How is vulnerability determined in contexts where this categorization may not be apparent?
- Would a mismatch between researcher and community/participant/author definitions of 'harm' or 'vulnerability' create an ethical dilemma? If so, how would this be addressed?
- What harms--to life, to career, to reputation--may occur from the research? (e.g., would the research "out" an LGBTQ individual who is not publicly out and perhaps cause them to lose their jobs? Would the research cause someone to face criminal or civil penalties?)
- What possible privacy-related harms may occur? For example, might online groups disband or individuals cease to use an online support group or withdraw from blogging activities because of the presence of researchers;[25] Might individuals be upset that their perceived privacy has been violated;[26] might individuals object to having their writing or speech anonymised, preferring to remain known and public in any published results?
- Who or what else could cause harm to the author/participant beyond the researcher?

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- Are we acting in ways that minimizes risk?
- Does our research adequately protect the researcher as well as the community/author/participant?

What are potential benefits associated with this study?

- Who benefits from the study - do the potential participants? If not, what greater benefit justifies the potential risks?
- Is the research aiming at a good or desirable goal?
- Can we be sure the data collected from online sites, fora, communities, is "legitimate" and "valuable"?[27]

How are we recognizing the autonomy of others and acknowledging that they are of equal worth to ourselves and should be treated so?

- Will informed consent be required from participants?
- If so, what procedures to obtain consent will be followed? (E.g., print or digital signatures, virtual consent tokens, click boxes or waiver of documented consent)[28]
- Will consent be obtained just from individuals or from communities and online system administrators?
- In situations whereby consent is desired but written informed consent is impossible (or in regulatory criteria, impracticable) or potentially harmful, will procedures or requirements be modified?
- What harm might result from asking for consent, or through the process of asking for consent?[29]
- What ethical concerns might arise if informed consent is not obtained?
- If an ethics board deems no consent is required, will the researcher still seek subjects'/participants' consent in a non-regulatory manner?
- If informed consent is warranted, how will the researcher ensure that participants are truly informed?

What particular issues might arise around the issue of minors or vulnerable persons?

- Are minors being excluded from the study because of the difficulties of getting ethical permission to study them?
- In situations where identity, age, and ability of the participant is unknown or hidden, and harm cannot be determined as an a priori category based on known vulnerability of participant, how will harm be considered as an ethical concern and operationalized in the study?
- How are minors identified as 'minors' in contexts where demographic information is not required? What harm might result from asking (or not asking) for participants to reveal their age?
- How will parental or guardian consent be obtained in addition to assent where required by research regulations? What risks might arise in this particular consent process? (for any or all parties, including the minor, the parents, and the researcher)?

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CONCLUSION

This document provides a basic overview of internet research considerations. It advocates a process approach to ethics, which emphasizes the importance of addressing and resolving ethical issues as they arise in each stage of the project. We also advocate a casuistic, or case based approach, which attends to the specific needs of each case. Rather than prescribing a set of approved practices, we have deliberately chosen to suggest a characteristic range of questions that should be asked by internet researchers as well as those responsible for oversight of such research.

Guidelines such as these should not be considered complete or final. More than two decades of research practice provide multiple examples of ethical complications, unique solutions, and best practices. To continue to build, rather than reinvent the wheel, we believe it is vital for researchers to maintain a strong awareness of previous scholarship. To help in this endeavor, we provide a diverse bibliography in Appendix 3. We also recognize that as internet researchers encounter new venues, contexts, inter/actions, and tools, additional issues, questions, and responses will inevitably arise, either as variations of those mentioned in this document or as distinctively new. We encourage researchers to contribute synopses of their ethical challenges or specific case studies to our web-based compendium of cases. [website link here]. Our intent is that this document will remain useful in those new contexts in so far as it suggests starting points and possible analogies for raising new questions and developing new responses.

At the same time, we anticipate that as this document comes into use, it may help researchers further identify its limits as they encounter new contexts and ethical issues that emerge in the ongoing evolution of both the internet and our multifaceted efforts to research the communicative engagements these technologies make possible. We intend this document to serve both as a first way of addressing contemporary ethical challenges and as an occasion for inviting further critical evaluation and ongoing dialogical development of internet research ethics.

In sum, we hope this document will prove helpful to researchers, ethicists, and others concerned with the important ethical challenges of internet research, and the Association of Internet Researchers remains grateful for further critical comment and examples that help to carry our dialogues onward from this point.

ENDNOTES

[1] See Buchanan and Ess (2009), who found that U.S. based IRBs referred most regularly to the Code of

[2] For example, the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP); U.S. Copyright Law, Norway's National Committee for Research Ethics in the Sciences and the Humanities (NESH); the EU Data Privacy Protection Act represent specific guidelines; each country and/or region maintains specific and changing guidelines. See also Privireal, which examines "the implementation of the Data Protection Directive 95/46/EC" in relation to research ethics and law (http://privireal.group.shef.ac.uk/content/rec/countries.php). We refer to some of these in Appendix 3 (the wiki-based bibliography located at http://ethics.aoir.org), but our listing is not all-inclusive. Readers should consult their professional and discipline-specific codes of conduct or practice, as well as extant regulation, to ensure they are acting in accordance with their disciplinary and jurisdictional bounds.

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[3] As one example, copyright laws vary by country and in the digital age, complexities in copyright laws have grown. Copyright is one particular issue that bridges legal and ethical realms, and is a matter of consideration in internet research. In some disciplines, for example, linguistics, copyright laws are more significant concerns than human subjects regulations. For more information on copyright law by country, see http://en.wikipedia.org/wiki/Category:Copyright_law_by_country
[4] For further discussion of phronesis as applied to internet research ethics and to digital media ethics, see for example Ess (2009) and McKee and Porter (2009).
[5] For example, in addition to general ethical principles, researchers must be aware of legal requirements in the countries implicated in the research. This can create important and potentially unresolvable tensions that should be acknowledged. While guidelines and regulations are intended to encourage ethical practice, they can also inadvertently function to restrict the researcher by making universal declarations and a priori determinations about what constitutes harm and what will cause harm. This is often done by identifying particular categories of persons who are vulnerable, or by implying that by gaining informed consent, harm may somehow be mitigated. We agree that in certain extreme situations, there will be broad consensus about whether certain actions are ethical or not. Yet we also agree as a community of researchers that in most social situations, the issues and ethics are more fuzzy. It can be difficult if not impossible to predict beforehand what might cause immediate or eventual harm, whether or not someone is vulnerable, or even whether or not we can call something a 'human subject.' Hence the need for deliberation.
[6] E.g., the Tuskegee syphilis experiments:
http://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment
[7] Manipulation and close study of information generated by social media networks certainly constitutes a different research environment than sticking a needle into a volunteering person in a medical laboratory. On the other hand, entire communities have felt harm from use of their DNA data more than a decade after it was collected and anonymously aggregated. Interacting with a person in a face-to-face interview seems to raise different considerations than interviewing a person in an anonymous chatroom. Yet, anonymous members of online communities have felt harm after researchers published reports about what they perceived to be private community activities. Blogs are often considered public, published texts. On the other hand, users have described their blogs as a part of their identity, not to be treated as simply publicly accessible data.
[8] For a fairly comprehensive listing of these, see
http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html
[9] Should authors be considered human subjects? Should studies based on observation of people in public be scrutinized with the same criteria as studies involving drug testing?
[10] The AoIR discussion list and archives (http://listserv.aoir.org/listinfo.cgi/air-l-aoir.org) provide many examples of researchers seeking advice from a world-wide community.
[11] This is widely discussed in ethics and internet research literature. A particularly keen analysis appears in Sveningsson (2003), and is modified/expanded somewhat in McKee & Porter (2009). The ethical parameters for collecting information in online public spaces are ambiguous and contested. Hudson and Bruckman (2004) found that while it might be widely considered ethically acceptable to capture and analyze interactions and conversations in a public square without consent, this model did not match the expectations of their participants in real time chatrooms, who felt strongly that "one may not ethically record an otherwise ephemeral medium without consent from participants" (p.118). Bassett & O'Riordan (2002) note that this sort of mismatch can occur in many ways: In the same online space or in the same online group, some users may believe their words are important public documents and they should receive credit as authors while others might believe their contributions are private, deserving anonymity. Likewise, the service provider, operator of an online forum, or terms of service may state that the content is public, yet individuals

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perceive the space to be private. Cases by authors such as Bromseth (2002), Gajjala (2004), and Ikonomidis Svedmark & Nyberg (2009) illustrate the difficulties these issues can pose for the researcher.

[12] For example, youth interviewed by boyd and Marwick (2011, p.6) felt angry that their Facebook information was used by teachers and administrators in a school-wide public presentation to illustrate the dangers of posting private information in public spaces. They knew the information was relatively public. It was the manner in which it was used that violated their expectations of privacy.

[13] See for example Hudson & Bruckman (2004); Gajjala (2004); Ikonomidis Svedmark & Nyberg (2009); Baker (2009).

[14] See for example Chee, Taylor, & de Castell (2012).

[15] See for example Markham (2009).

[16] For further discussion of this, see for example Sveningsson (2003), Sveningsson-Elm (2009) and McKee & Porter (2009).

[17] For further discussion, see Nissenbaum (2010).

[18] See Ayers (2003).

[19] A case involving blood and DNA samples taken from the Havasupai Indian tribe in Arizona provides an illustration of the complexities of informed consent, misuse of data/samples, and community harms resultant from biomedical research. See http://www.whoownsyourbody.org/havasupai.html

[20] See for example Sweeny (2003); Zimmer (2010).

[21] See for example Ikonomidis Svedmark & Nyberg (2009).

[22] Markham (2012) makes the case for revising or refashioning data to resonate with the situation without using direct quotes to protect privacy.

[23] CF Footnote 18.

[24] Traditional notions of harm or risk come from the medical or biomedical models of research, which can often predict with more accuracy how a particular medical or psychological procedure can affect a research participant. Regulatory language around the issue of risk and harm may be predicated on such medical models, which are often different from social research environments, where potential risks or harms may not be clearly foreseeable. Likewise, in inductive or qualitative research frameworks, procedures for interaction with contexts or persons are added or modified in situ, so that the risks associated with particular methods may only be known at later stages of the research. Risk and harm in less formalized research frameworks can arise in many stages of the project, from data collection to analysis to presentation of research.

[25] See for example Bromseth (2002); Kraut et al., (2004).

[26] CF Footnote 8

[27] For example, Karpf (2012) notes: "Spambots, commercial incentives, proprietary firewalls, and noisy indicators all create serious challenges for the researcher."

[28] Although in some cases, traditional informed consent procedures may be warranted, in other cases, these may not be the most ethically sensitive approach. As recommended by the 2010 AOIR Ethics workshop: "Informed consent may happen at different points throughout a study, Sometimes it may be more ethical to get informed consent at the end when you want to present a specific case study or quote an individual or focus on a particular element. Therefore, informed consent should be always an inductive process" (Buchanan, Markham, & Ess, 2010).

[29] See for example Stern (2003); Ikonomidis Svedmark (2010).

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APPENDIX 1:
Charting Ethical Questions By Data And Type

This figure is intended to provide a reference guide for researchers and research reviewers to recognize where a particular research project might fit in the internet research continuum, in what specific type of venue a project exists, what types of information/data may be derived from these contexts, and what common ethical questions have been asked within these contexts.

This graphic is best viewed as a conceptual heuristic, as the categories overlap and merge. The first column lists the types of information that might be collected. These data types are not tied to certain internet spaces or genres, such as blogs, email, or the web, but cut across all contexts. The second column lists specific types of contexts. Again, because categories continue to converge, we have organized this column by major interaction type, rather than specific type of interface. The third column lists certain key ethical questions that might be raised. Notably, there are varying ways to conceptualize or define each of the contexts mentioned and varying ways to perceive one's research in or of these contexts. Two people can be utilizing the same technological context and yet have very different perspectives on it. These distinctions are also blurred as technologies converge and become less obvious as a part of everyday life.

Researchers and review boards can refer to this chart as a guide or checklist of considerations when writing or reviewing research proposals, developing methodological approaches for a particular study, designing specific protocols, and so forth. Ideally, a researcher should be able to answer these questions and justify those responses within the context of his or her research question, discipline, specific internet venue or context, and region or jurisdiction.

Note: This is shown as a small graphic on the following page. A higher resolution PDF is available at: http://ethics.aoir.org/reports/2012aoirgraphic.pdf

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This chart provides a useful starting point for internet researchers to consider ethics. Convergence of technologies and capacities continues to break down the strict boundaries between these categories. Not intended to provide answers, this graphic promotes consideration of a range of issues and questions that may become relevant in the course of any internet related research.

Types of Data collected	Types of Venues/Contexts	Commonly asked questions about ethical practice
Interactions, behaviors, transactions • Hyperlinks • Comments or Recommendations • File or Information Sharing (file or snippet) • Forwarding /Replying • Interpersonal Interactions, conversations • Networks (e.g., maps visualizing communication flow or strength of relations between persons)	**Direct communication** (formal or informal interviews via real-time or asynchronous text, audio, or visual)	How is protection of autonomy of participant/author achieved through informed consent or protection of vulnerable persons? How can researcher ensure that author/participant understands and agrees that content or interaction may be used for research purposes? Is the communication archived or easily searchable and retrievable? Is the data subject to open data laws or regulations? How long does the third party provider or ISP preserve the data and where? Could privacy be achieved through anonymization of email content and/or header information?
	Special Interest Forums (email- or web-based conversations and archives, e.g., threaded discussion forums, chatrooms)	How do terms of service (TOS) articulate privacy of content and/or how it is shared with 3rd parties? Regardless of TOS, what are community or individual norms and/or expectations for privacy? Does the author/subject consider personal network of connections sensitive information? Is the data easily searchable and retrievable? If the content of a subject's communication were to become known beyond the confines of the venue being studied – would harm likely result? Is the conversation thread or forum perceived as public or private by the author(s)/subject(s)? How is profile, location, or other personally identifying information used or stored by researcher? Is the data easily searchable and retrievable? How is informed consent or protection of privacy achieved? How are vulnerable persons identified and protected? If non-active archives are used, how is vulnerability or harm defined and how are potential or actual subjects protected?
Production, presentation, performance • Texts (e.g., authored texts, naturally occurring discourse, interview transcripts) • Images (presented or produced by user or captured by researcher) • Video (presented or produced by user or captured by researcher) • Audio (presented or produced by user or captured by researcher) • User motions and movements (any and all activities produced or presented by user and/or captured by researcher) • Configurations or personalization of devices	**Social Networking** (e.g., LinkedIn, google+, Facebook, Twitter, Tumblr, Flickr, FourSquare)	How do the terms of service articulate privacy of content and/or how it is shared with 3rd parties? Does the author/participant consider personal network of connections sensitive information? How is profile or location information used or stored by researcher? Does author/participant understand and agree to interaction that may be used for research purposes? Does research purpose and design balance possible conflicts between participant and researcher perceptions of public/private and sensitive/nonsensitive? Does the dissemination of findings protect confidentiality? Is the data easily searchable and retrievable? If the content of a subject's communication was ever linked to the person, would harm likely result?
	Personal spaces/ blogs (e.g., homepages, blogs, youtube, and all forms of multimedia presentation)	Could analysis, publication, redistribution, or dissemination of content harm the subject in any way? If the content of a subject's communication were to become known beyond the confines of the venue being studied would harm likely result? Does the author/participant consider personal network of connections sensitive information? Does author/participant consider the presentation of information or venue to be private or public? Do the terms of service conflict with ethical principles? Is the author/subject a minor?
Locations and movements • Physical locations (GPS) • Physical movements • Surfing behaviors	**Avatar-based social spaces , virtual worlds, and online gaming spaces** (e.g., Second Life, SIMs, MUDS/MOOS, MPORPG)	Should these virtual worlds be considered "public"? What constitutes "privacy" in such places? Should avatars be considered as persons and afforded the same protections as human subjects? Will the process of requesting consent itself cause harm? How and when should consent be sought? What requires consent? To what extent do users perceive their interactions and communication to be private in these spaces? How do Terms of Service specify researcher presence, anonymity of users, and privacy/ confidentiality? To what extent and in what ways could research activities interfere with or compromise a user's play or outcomes in the game? How should researchers juggle their own multiple roles? Could data be used to identify a user's physical location and other sensitive demographic information?
Archived information • Demographic information • Bookmark collections • Discussion archives • Data banks • Transaction logs • Clickstream data • Trace data	**Commercial Web Services** (e.g., Google, AOL, Yahoo, Bing, MSN, SurveyMonkey, Cloud Storage)	What are the participant/author's expectations of privacy? Is the data easily searchable and retrievable? Is the data subject to open data laws or regulations? Does the service's privacy policy contradict ethical principles? What measures safeguard data at the site of data collection? How long will the data be stored on the servers? Does this contradict the time frame indicated by the researcher or institutional policies? What happens to the data after the researcher completes work on the service? How are the data destroyed? How will cross-border data be handled if IP addresses are considered by one country to fall under privacy regulations?
	Databanks/ Repositories	Where is the data stored? How long will the data exist in the repository? What consent or permission might be needed for subsequent data use? Does the remixing/mashing of data enable identification of individual or group identities or enable any additional risks to participants? In the case of shared data, what conditions were placed on data use by the original researcher, if any? Regardless of conditions, what ethical responsibilities may require consideration by later users? What mechanisms are in place to ensure appropriate data provenance and ownership? How will images/audio be effectively anonymized?

Created by Annette Markham as Appendix 1, AOIR Guidelines: Ethical Decision Making and Internet Research Ethics: 2012. Original document located at http://ethics.aoir.org/

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APPENDIX 2:
Regional resources and/or FAQs
can be found online at : http://ethics.aoir.org/

APPENDIX 3:
Bibliography of resources, categorized by topic area
can be found online at: http://ethics.aoir.org/

APPENDIX 4:
Case Studies
can be found online at: http://ethics.aoir.org/

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DECISIONS

COUNCIL DECISION

of 3 December 2013

establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC

(Text with EEA relevance)

(2013/743/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 182(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with a special legislative procedure,

Whereas:

(1) In accordance with Article 182(3) of the Treaty on the Functioning of the European Union (TFEU), the Framework Programme for Research and Innovation 2014-2020 ("Horizon 2020"), established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 [3], is to be implemented through a specific programme which determines the specific objectives and rules for their implementation, fixes its duration and provides for the means deemed necessary.

(2) The general objective of Horizon 2020 should be pursued through three priorities dedicated to generating excellent science ("Excellent science"), creating industrial leadership ("Industrial leadership") and tackling societal challenges ("Societal challenges"). The general objective should also be pursued through the specific objectives "Spreading excellence and widening participation" and "Science with and for society". Those priorities and specific objectives should be implemented by means of a specific programme setting out one Part for each of the three priorities, one Part for the specific objective "Spreading excellence and widening participation", one Part for the specific objective "Science with and for society" and one Part for the non-nuclear direct actions of the Joint Research Centre (JRC).

(3) All Horizon 2020 priorities and specific objectives should include an international dimension. International cooperation activities should be maintained at least at the level of the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) ("Seventh Framework Programme"), adopted by Decision No 1982/2006/EC of the European Parliament and of the Council [4].

(4) While Regulation (EU) No 1291/2013 sets out the general objective of Horizon 2020, the priorities and the broad lines of the specific objectives and activities to be carried out, the specific programme should define the specific objectives and the broad lines of the activities which are specific to each of the Parts. The provisions on implementation set out in Regulation (EU) No 1291/2013 apply fully to the specific programme, including those relating to ethical principles.

(5) Each Part should be complementary to and implemented in a coherent way with the other Parts of the specific programme.

[1] OJ C 181, 21.6.2012, p. 111.
[2] OJ C 277, 13.9.2012, p. 143.
[3] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (See page 104 of this Official Journal).
[4] Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

(6) There is a critical need to reinforce, widen and extend the excellence of the Union's science base and to ensure a supply of world-class research and talent to secure Europe's long term competitiveness and well-being. The priority "Excellent science" should support the activities of the European Research Council (ERC) on frontier research, future and emerging technologies, Marie Skłodowska-Curie actions and European research infrastructures. These activities should aim at building competence in the long term, focusing strongly on the next generation of science, systems and researchers, and providing support for emerging talent from across the Union and from associated countries. Union activities to support excellent science should help consolidate the European Research Area (ERA) and make the science system of the Union more competitive and attractive on a global scale.

(7) Research actions carried out under the priority "Excellent science" should be determined according to the needs and opportunities of science. The research agenda should be set in close liaison with the scientific community. Research should be funded on the basis of excellence.

(8) The ERC should replace and succeed the ERC established by Commission Decision 2007/134/EC [1]. It should operate according to the established principles of scientific excellence, autonomy, efficiency and transparency.

(9) In order to maintain and increase the Union's industrial leadership there is an urgent need to stimulate private sector research and development and innovation investment, promote research and innovation with a business driven agenda and accelerate the development of new technologies which will underpin future businesses and economic growth. The priority "Industrial leadership" should support investments in excellent research and innovation in key enabling technologies and other industrial technologies, facilitate access to risk finance for innovative companies and projects, and provide Union-wide support for innovation in micro, small and medium-sized enterprises (SMEs).

(10) Space research and innovation, which is a shared competence of the Union, should be included as a coherent element in the priority "Industrial leadership" in order to maximise the scientific, economic and societal impact and to ensure an efficient and cost-effective implementation.

(11) Addressing the major societal challenges identified in the Europe 2020 strategy for smart, sustainable and inclusive growth ("Europe 2020 strategy") requires major investments in research and innovation to develop and deploy novel and breakthrough solutions that have the necessary scale and scope. These challenges also represent major economic opportunities for innovative companies and therefore contribute to the Union's competitiveness and employment.

(12) The priority "Societal challenges" should increase the effectiveness of research and innovation in responding to key societal challenges by supporting excellent research and innovation activities. Those activities should be implemented using a challenge-based approach which brings together resources and knowledge across different fields, technologies and disciplines. Social sciences and humanities research is an important element for addressing all of the challenges. The activities should cover the full range of research and innovation, including innovation-related activities such as piloting, demonstration, test-beds, and support for public procurement, pre-normative research and standard setting, and market uptake of innovations. The activities should support directly the corresponding sectoral policy competences at Union level, where appropiate. All challenges should contribute to the overarching objective of sustainable development.

(13) There should be an appropriate balance between small and large projects within the priority "Societal challenges" and the specific objective "Leadership in enabling and industrial technologies".

(14) The specific objective "Spreading excellence and widening participation" should fully exploit the potential of Europe's talent pool and ensure that the benefits of an innovation-led economy are both maximised and widely distributed across the Union in accordance with the principle of excellence.

(15) The specific objective "Science with and for society" should build effective cooperation between science and society, foster the recruitment of new talent for science, and pair scientific excellence with social awareness and responsibility.

(16) As an integral part of Horizon 2020, the JRC should continue to provide independent customer-driven scientific and technical support for the formulation, development, implementation and monitoring of Union policies. In order to achieve its mission the JRC should carry out research of the highest quality. In carrying out the direct actions in accordance with its mission, the JRC should place particular emphasis on areas of key concern for the Union, namely smart, inclusive and sustainable growth, and the headings "Security and citizenship" and "Global Europe" of the Multiannual Financial Framework for 2014-2020.

[1] Commission Decision 2007/134/EC of 2 February 2007 establishing the European Research Council (OJ L 57, 24.2.2007, p. 14).

(17) The direct actions of the JRC should be implemented in a flexible, efficient and transparent manner, taking into account the relevant needs of the users of the JRC and the needs of Union policies, and respecting the objective of protecting the financial interests of the Union. Those research actions should be adapted, where appropriate, to those needs and to scientific and technological developments and should aim to achieve scientific excellence.

(18) The JRC should continue to generate additional resources through competitive activities, including participation in the indirect actions of Horizon 2020, third party work and, to a lesser extent, the exploitation of intellectual property.

(19) The specific programme should complement the actions carried out in the Member States as well as other Union actions which are necessary for the overall strategic effort for the implementation of the Europe 2020 strategy.

(20) Pursuant to Council Decision 2001/822/EC ([1]), legal entities of the overseas countries and territories are eligible to participate in Horizon 2020 subject to the specific conditions laid down in the latter.

(21) In order to ensure that the specific conditions for the use of the finance facilities reflect market conditions, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to adapt or define further the specific conditions for use of the finance facilities. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a timely and appropriate transmission of relevant documents to the Council.

(22) In order to ensure uniform conditions for the implementation of the specific programme, implementing powers should be conferred on the Commission to adopt work programmes for the implementation of the specific programme.

(23) The implementing powers relating to the work programmes for the priorities "Excellent science", "Industrial leadership" and "Societal challenges" and for the specific objectives "Spreading excellence and widening participation" and "Science with and for society" should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([2]).

(24) The Board of Governors of the JRC, set up by Commission Decision 96/282/Euratom ([3]), has been consulted on the scientific and technological content of the specific programme on the non-nuclear direct actions of the JRC.

(25) For reasons of legal certainty and clarity, Council Decision 2006/971/EC ([4]), Council Decision 2006/972/EC ([5]), Council Decision 2006/973/EC ([6]), Council Decision 2006/974/EC ([7]) and Council Decision 2006/975/EC ([8]) should be repealed,

HAS ADOPTED THIS DECISION:

TITLE I

GENERAL PROVISIONS

Article 1

Subject matter

This Decision establishes the specific programme implementing Regulation (EU) No 1291/2013 and determines the specific objectives for Union support to the research and innovation activities set out in Article 1 of that Regulation as well as the rules for implementation.

([1]) Council Decision 2001/822/EC of 27 November 2001 on the association of the overseas countries and territories with the European Community ("Overseas Association Decision") (OJ L 314, 30.11.2001, p. 1).

([2]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

([3]) Commission Decision 96/282/Euratom of 10 April 1996 on the reorganization of the Joint Research Centre (OJ L 107, 30.4.1996, p. 12).

([4]) Council Decision 2006/971/EC of 19 December 2006 concerning the specific programme: 'Cooperation' implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 86).

([5]) Council Decision 2006/972/EC of 19 December 2006 concerning the specific programme: 'Ideas' implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 243).

([6]) Council Decision 2006/973/EC of 19 December 2006 concerning the specific programme 'People' implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 272).

([7]) Council Decision 2006/974/EC of 19 December 2006 on the specific programme: 'Capacities' implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 299).

([8]) Council Decision 2006/975/EC of 19 December 2006 concerning the specific programme to be carried out by means of direct actions by the Joint Research Centre under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 368).

Article 2

Establishment of the specific programme

1. The specific programme implementing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (the 'specific programme') is hereby established for the period from 1 January 2014 to 31 December 2020.

2. In accordance with Article 5(2), (3) and (4) of Regulation (EU) No 1291/2013, the specific programme shall consist of the following Parts:

(a) Part I 'Excellent science';

(b) Part II 'Industrial leadership';

(c) Part III 'Societal challenges';

(d) Part IV 'Spreading excellence and widening participation';

(e) Part V 'Science with and for society';

(f) Part VI 'Non-nuclear direct actions of the Joint Research Centre (JRC)'.

Article 3

Specific objectives

1. Part I 'Excellent science' shall strengthen the excellence of European research in accordance with the priority "Excellent science" set out in point (a) of Article 5(2) of Regulation (EU) No 1291/2013 by pursuing the following specific objectives:

(a) strengthening frontier research, through the activities of the European Research Council (ERC) ("The European Research Council (ERC)");

(b) strengthening research in future and emerging technologies ("Future and Emerging Technologies (FET)");

(c) strengthening skills, training and career development, through the Marie Skłodowska-Curie actions ("Marie Skłodowska-Curie actions");

(d) strengthening European research infrastructures, including e-infrastructures ("Research infrastructures").

The broad lines of the activities for those specific objectives are set out in Part I of Annex I.

2. Part II 'Industrial leadership' shall strengthen industrial leadership and competitiveness in accordance with the priority 'Industrial leadership' set out in point (b) of Article 5(2) of Regulation (EU) No 1291/2013 by pursuing the following specific objectives:

(a) boosting Europe's industrial leadership through research, technological development, demonstration and innovation in the following enabling and industrial technologies ("Leadership in enabling and industrial technologies"):

(i) information and communication technologies ("ICT");

(ii) nanotechnologies;

(iii) advanced materials;

(iv) biotechnology;

(v) advanced manufacturing and processing;

(vi) space;

(b) enhancing access to risk finance for investing in research and innovation ("Access to risk finance");

(c) increasing innovation in SMEs ("Innovation in SMEs").

The broad lines of the activities for those specific objectives are set out in Part II of Annex I.

There shall be specific conditions for use of finance facilities under the specific objective in point (b) of the first subparagraph. Those conditions are set out in section 2 of Part II of Annex I.

The Commission shall be empowered to adopt delegated acts in accordance with Article 11 concerning the modifications of the share of investment from the Equity facility of Horizon 2020 of the total Union investment in expansion and growth-stage investments regarding the financial instruments referred to in section 2 of Part II of Annex I.

3. Part III 'Societal challenges' shall contribute to the priority 'Societal challenges' set out in point (c) of Article 5(2) of Regulation (EU) No 1291/2013 by pursuing research, technological development, demonstration and innovation actions which contribute to the following specific objectives:

(a) improving the lifelong health and well-being of all ("Health, demographic change and well-being");

(b) securing sufficient supplies of safe, healthy and high quality food and other bio-based products, by developing productive, sustainable and resource-efficient primary production systems, fostering related ecosystem services and the recovery of biological diversity, alongside competitive and low-carbon supply, processing and marketing chains ("Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy");

(c) making the transition to a reliable, affordable, publicly accepted, sustainable and competitive energy system, aiming at reducing fossil fuel dependancy in the face of increasingly scarce resources, increasing energy needs and climate change ("Secure, clean and efficient energy");

(d) achieving a European transport system that is resource-efficient, climate- and environmentally-friendly, safe and seamless for the benefit of all citizens, the economy and society ("Smart, green and integrated transport");

(e) achieving a resource- and water-efficient and climate change resilient economy and society, protection and sustainable management of natural resources and ecosystems and a sustainable supply and use of raw materials, in order to meet the needs of a growing global population within the sustainable limits of the planet's natural resources and ecosystems ("Climate action, environment, resource efficiency and raw materials");

(f) fostering a greater understanding of Europe, providing solutions and supporting inclusive, innovative and reflective European societies in a context of unprecedented transformations and growing global interdependencies ("Europe in a changing world – Inclusive, innovative and reflective societies");

(g) fostering secure European societies in a context of unprecedented transformations and growing global interdependencies and threats, while strengthening the European culture of freedom and justice ("Secure societies – Protecting freedom and security of Europe and its citizens").

The broad lines of the activities for those specific objectives are set out in Part III of Annex I.

4. Part IV 'Spreading excellence and widening participation' shall contribute to the specific objective "Spreading excellence and widening participation" set out in Article 5(3) of Regulation (EU) No 1291/2013 by fully exploiting the potential of Europe's talent pool and ensuring that the benefits of an innovation-led economy are both maximised and widely distributed across the Union in accordance with the principle of excellence.

The broad lines of the activities for this specific objective are set out in Part IV of Annex I.

5. Part V 'Science with and for society' shall contribute to the specific objective "Science with and for society" set out in Article 5(3) of Regulation (EU) No 1291/2013 by building effective cooperation between science and society, recruiting new talent for science and pairing scientific excellence with social awareness and responsibility.

The broad lines of the activities for this specific objective are set out in Part V of Annex I.

6. Part VI 'Non-nuclear direct actions of the Joint Research Centre (JRC)' shall contribute to all of the priorities set out in Article 5(2) of Regulation (EU) No 1291/2013 with the specific objective of providing customer-driven scientific and technical support to Union policies.

The broad lines of the activities for this specific objective are set out in Part VI of Annex I.

7. The specific programme shall be assessed in relation to results and impact as measured against performance indicators.

Further details on the key performance indicators are set out in Annex II.

Article 4

Budget

1. In accordance with Article 6(1) of Regulation (EU) No 1291/2013, the financial envelope for the implementation of the specific programme shall be EUR 74 316,9 million.

2. The amount referred to in paragraph 1 of this Article shall be distributed among the six Parts set out in Article 2(2) of this Decision in accordance with Article 6(2) of Regulation (EU) No 1291/2013. The indicative budgetary breakdown for the specific objectives set out in Article 3 of this Decision and the maximum overall amount of the contribution to the actions of the JRC are set out in Annex II to Regulation (EU) No 1291/2013.

3. No more than 5 % of the amounts referred to in Article 6(2) of Regulation (EU) No 1291/2013 for Parts I to V of the specific programme shall be for the Commission's administrative expenditure. The Commission shall ensure that during the programme its administrative expenditure will decrease and it will endeavour to reach a target of 4,6 % or less in 2020. These figures shall be subject to review as part of the Horizon 2020 interim evaluation as laid down in Article 32(3) of Regulation (EU) No 1291/2013.

4. Where necessary, appropriations may be entered in the budget beyond 2020 to cover technical and administrative expenses, in order to enable the management of activities not yet completed by 31 December 2020.

TITLE II

IMPLEMENTATION

Article 5

Work programmes

1. The specific programme shall be implemented by work programmes.

2. The Commission shall adopt common or separate work programmes for the implementation of Parts I to V of the specific programme referred to in points (a) to (e) of Article 2(2), except for the implementation of the actions under the specific objective "The European Research Council (ERC)", referred to in point (a) of Article 3(1). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 10(4).

3. The work programmes for the implementation of the actions under the specific objective "The European Research Council (ERC)" referred to in point (a) of Article 3(1), as established by the Scientific Council under point (b) of Article 7(2), shall be adopted by the Commission, by means of an implementing act, in accordance with the advisory procedure referred to in Article 10(3). The Commission shall depart from the work programme established by the Scientific Council only when it considers that it is not in accordance with the provisions of this Decision. In that case, the Commission shall adopt the work programme by means of an implementing act in in accordance with the examination procedure referred to in Article 10(4). The Commission shall duly motivate this measure.

4. The Commission shall adopt a separate multi-annual work programme, by means of an implementing act, for Part VI of the specific programme referred to in point (f) of Article 2(2). This work programme shall take into account the opinion provided by the Board of Governors of the JRC referred to in Decision 96/282/Euratom.

5. The work programmes shall take account of the state of science, technology and innovation at national, Union and international level and of relevant policy, market and societal developments. They shall contain, where appropriate, information on coordination with research and innovation activities carried out by Member States (including their regions), including in areas where there are joint programming initiatives. They shall be updated where appropriate.

6. The work programmes for the implementation of Parts I to V referred to in points (a) to (e) of Article 2(2) of this Decision shall set out the objectives pursued, the expected results, the method of implementation and their total amount, including indicative information on the amount of climate-related expenditure, where appropriate. They shall also contain a description of the actions to be financed, an indication of the amount allocated to each action, an indicative implementation timetable, as well as a multi-annual approach and strategic orientations for the following years of implementation. They shall include for grants the priorities, the selection and award criteria and the relative weight of the different award criteria and the maximum rate of funding of the total eligible costs. They shall also indicate any additional exploitation and dissemination obligations for participants, in accordance with Article 43 of Regulation (EU) No 1290/2013 [1] of the European Parliament and of the Council. They shall allow for strategic top-down as well as bottom-up approaches, as appropriate, that address the objectives in innovative ways.

In addition, those work programmes shall contain a section which identifies the cross-cutting issues as referred to in Article 14 and under the subtitle "Cross-cutting issues and support measures in Horizon 2020" in Annex I to Regulation (EU) No 1291/2013, across two or more specific objectives both within the same priority or across two or more priorities. Those actions shall be implemented in an integrated manner.

7. The Commission shall adopt, by means of implementing acts, in accordance with the examination procedure referred to in Article 10(4) the following measures:

(a) the decision on the approval of the funding of indirect actions, where the estimated amount of the Union contribution under the specific programme is equal to or more than EUR 2,5 million, with the exception of actions under the specific objective "European Research Council (ERC)" referred to in point (a) of Article 3(1) of this Decision and with the exception of actions funded under the "Fast Track to Innovation" pilot, referred to in Article 24 of Regulation (EU) No 1291/2013;

[1] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)' and repealing Regulation (EC) No 1906/2006 (See page 81 of this Official Journal).

(b) the decision on the approval of the funding of actions involving the use of human embryos and human embryonic stem cells and of actions under the specific objective "Secure societies – Protecting freedom and security of Europe and its citizens" referred to in point (g) of Article 3(3);

(c) the decision on the approval of the funding of actions, where the estimated amount of the Union contribution under the specific programme is equal to or more than EUR 0,6 million for actions under the specific objective "Europe in a changing world – Inclusive, innovative and reflective societies" referred to in point (f) of Article 3(3) and for actions under the specific objectives "Spreading excellence and widening participation" and "Science with and for society" referred to in Article 3(4) and (5) respectively;

(d) the drawing up of the terms of reference for the evaluations provided for in Article 32 of Regulation (EU) No 1291/2013.

Article 6

European Research Council

1. The Commission shall establish a European Research Council ("ERC"), which shall be the means of implementing the actions under Part I 'Excellent science' which relate to the specific objective "The European Research Council (ERC)", referred to in point (a) of Article 3(1) of this Decision. The ERC shall succeed the ERC set up by Decision 2007/134/EC.

2. The ERC shall be composed of the independent Scientific Council provided for in Article 7 and the dedicated implementation structure provided for in Article 8.

3. The ERC shall have a President who shall be chosen from among senior and internationally respected scientists.

The President shall be appointed by the Commission following a transparent recruitment process involving an independent dedicated search committee, for a term of office limited to four years, renewable once. The recruitment process and the candidate selected shall have the approval of the Scientific Council.

The President shall chair the Scientific Council and shall ensure its leadership and liaison with the dedicated implementation structure, and represent it in the world of science.

4. The ERC shall operate according to the principles of scientific excellence, autonomy, efficiency, effectiveness, transparency and accountability. It shall ensure continuity with ERC actions conducted under Decision 2006/972/EC.

5. The activities of the ERC shall support research carried out across all fields by individual and transnational teams in competition at the European level. ERC frontier research grants shall be awarded on the sole criterion of excellence.

6. The Commission shall act as the guarantor of the autonomy and integrity of the ERC and shall ensure the proper execution of the tasks entrusted to it.

The Commission shall ensure that the implementation of the ERC actions is in accordance with the principles set out in paragraph 4 of this Article as well as with the overall strategy for the ERC, referred to in point (a) of Article 7(2), established by the Scientific Council.

Article 7

Scientific Council

1. The Scientific Council shall be composed of scientists, engineers and scholars of the highest repute and appropriate expertise, of both women and men in different age groups, ensuring a diversity of research areas and acting in their personal capacity, independent of extraneous interests.

The members of the Scientific Council shall be appointed by the Commission, following an independent and transparent procedure for their identification agreed with the Scientific Council, including a consultation of the scientific community and a report to the European Parliament and the Council.

Their term of office shall be limited to four years, renewable once, on the basis of a rotating system which shall ensure the continuity of the work of the Scientific Council.

2. The Scientific Council shall establish:

(a) the overall strategy for the ERC;

(b) the work programme for the implementation of the ERC activities;

(c) the methods and procedures for peer review and proposal evaluation on the basis of which the proposals to be funded are determined;

(d) its position on any matter which from a scientific perspective may enhance achievements and impact of the ERC and the quality of the research carried out;

(e) a code of conduct addressing, inter alia, the avoidance of conflict of interests.

The Commission shall depart from the positions established by the Scientific Council in accordance with points (a), (c), (d), and (e) of the first subparagraph only when it considers that the provisions of this Decision have not been respected. In that case, the Commission shall adopt measures to maintain continuity in the implementation of the specific programme and the achievements of its objectives, setting out the points of departure from the Scientific Council positions and duly motivating them.

3. The Scientific Council shall act in accordance with the mandate set out in section 1.1 of Part I of Annex I.

4. The Scientific Council shall act exclusively in the interest of achieving the specific objective "The European Research Council (ERC)", referred to in point (a) of Article 3(1), according to the principles set out in Article 6(4). It shall act with integrity and probity and carry out its work efficiently and with the greatest possible transparency.

Article 8

Dedicated implementation structure

1. The dedicated implementation structure shall be responsible for the administrative implementation and programme execution, as described in section 1.2 of Part I of Annex I. It shall support the Scientific Council in the conduct of all of its tasks.

2. The Commission shall ensure that the dedicated implementation structure follows strictly, efficiently and with the necessary flexibility the objectives and requirements of the ERC alone.

TITLE III

FINAL PROVISIONS

Article 9

Monitoring and information on implementation

1. The Commission shall annually monitor and report on the implementation of Horizon 2020 in accordance with Article 31 of Regulation (EU) No 1291/2013 and Annex III to this Decision.

2. The Commission shall regularly inform the Committee referred to in Article 10 of the overall progress of the implementation of the indirect actions of the specific programme to allow the Committee to provide early appropriate input on the preparation of the work programmes, in particular the multi-annual approach and strategic orientations, and shall provide it with timely information on all actions proposed or funded under Horizon 2020 as specified in Annex IV.

Article 10

Committee procedure

1. The Commission shall be assisted by a committee (the Programme Committee). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. The committee shall meet in different configurations as set out in Annex V, having regard to the subject matter to be discussed.

3. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

5. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Article 11

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3(2) shall be conferred on the Commission for the duration of Horizon 2020.

3. The delegation of power referred to in Article 3(2) may be revoked at any time by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it to the Council.

5. A delegated act adopted pursuant to Article 3(2) shall enter into force only if no objection has been expressed by the Council within a period of two months of notification of that act to the Council or if, before the expiry of that period, the Council has informed the Commission that it will not object. That period shall be extended by one month at the initiative of the Council.

6. The European Parliament shall be informed of the adoption of delegated acts by the Commission, or any objection formulated to them, or of the revocation of the delegation of powers by the Council.

Article 12

Repeal and transitional provisions

1. Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC are repealed with effect from 1 January 2014.

2. However, actions initiated under the Decisions referred to in paragraph 1 of this Article and financial obligations related to actions pursued under those Decisions shall continue to be governed by those Decisions until their completion. Where necessary, any remaining tasks of the Committees established by the Decisions referred to in paragraph 1 of this Article shall be undertaken by the Committee referred to in Article 10.

3. The financial allocation for the specific programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the specific programme and the measures covered by Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC.

Article 13

Entry into force

This Decision shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Article 14

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 3 December 2013.

For the Council
The President
E. GUSTAS

ANNEX I

BROAD LINES OF THE ACTIVITIES

Common elements for the indirect actions

1. PROGRAMMING

1.1. *General*

Regulation (EU) No 1291/2013 provides a set of principles in order to foster a programmatic approach whereby activities contribute in a strategic and integrated way to its objectives and in order to ensure strong complementarities with other related policies and programmes across the Union.

The indirect actions of Horizon 2020 will be implemented through the forms of funding provided for in Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ([1]), in particular grants, prizes, procurement and financial instruments. All forms of funding will be used in a flexible manner across all general and specific objectives of Horizon 2020, with their use being determined on the basis of the needs and the specificities of the particular specific objective.

Particular attention will be paid to ensuring a balanced approach to research and innovation, which is not only limited to the development of new products and services on the basis of scientific and technological breakthroughs, but which also incorporates aspects such as the use of existing technologies in novel applications, continuous improvement and non-technological and social innovation. Only a holistic approach to innovation can at the same time tackle societal challenges and give rise to new competitive businesses and industries.

In particular for the priority "Societal challenges" and the specific objective "Leadership in enabling and industrial technologies", there will be a particular emphasis on research and innovation activities complemented with activities which operate close to the end-users and the market, such as demonstration, piloting or proof-of-concept. This will also include, where appropriate, activities in support of social innovation, and support to demand side approaches such as pre-standardisation or pre-commercial procurement, procurement of innovative solutions, standardisation and other user-centered measures to help accelerate the deployment and diffusion of innovative products and services into the market. In addition, there will be sufficient room for bottom-up approaches to call for proposals, and activities in work programmes will be defined in broad terms. There will be open, light and fast schemes under each of the challenges and technologies to provide Europe's best researchers, entrepreneurs and enterprises with the opportunity to put forward breakthrough solutions of their choice.

Detailed priority setting during the implementation of Horizon 2020 will entail a strategic approach to programming of research, using modes of governance aligning closely with policy development yet cutting across the boundaries of traditional sectoral policies. This will be based on sound evidence, analysis and foresight, with progress measured against a robust set of performance indicators. This cross-cutting approach to programming and governance will allow effective coordination between all specific objectives of Horizon 2020 and will allow to address challenges which cut across them, such as sustainability, climate change, social sciences and humanities or marine sciences and technologies.

Priority setting will equally be based on a wide range of inputs and advice. It will include, where appropriate, groups of independent experts set up specifically to advise on the implementation of Horizon 2020 or any of its specific objectives. These expert groups shall show the appropriate level of expertise and knowledge in the covered areas and a variety of professional backgrounds, including academia, industry and civil society involvement. Advice on the identification and design of strategic priorities by the European Research Area and Innovation Committee (ERAC), other ERA-related Groups and the Enterprise Policy Group (EPG) shall, where appropriate, also be taken into consideration.

Priority setting may also take into account the strategic research agendas of European Technology Platforms, Joint Programming Initiatives or inputs from the European Innovation Partnerships. Where appropriate, public-public partnerships and public-private partnerships supported through Horizon 2020 will also contribute to the priority setting process and to the implementation, in line with Regulation (EU) No 1291/2013. Regular interactions with end-users, citizens and civil society organisations, through appropriate methodologies such as consensus conferences, participatory technology assessments or direct engagement in research and innovation processes, will also be a cornerstone of the priority setting process.

([1]) Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

As Horizon 2020 is a programme for seven years, the economic, societal and policy context in which it will operate may change significantly during its life-time. Horizon 2020 needs to be able to adapt to these changes. Under each of the specific objectives, there will therefore be the possibility to include support for activities beyond the descriptions set out below, where this is duly justified to address major developments, policy needs or unforeseen events.

Activities supported under the different Parts and their specific objectives should be implemented in a way that ensures complementarity and consistency among them, as appropriate.

1.2. *Access to risk finance*

Horizon 2020 will help companies and other types of entities gain access to loans, guarantees and equity finance via two facilities.

The Debt facility will provide loans to single beneficiaries for investment in research and innovation; guarantees to financial intermediaries making loans to beneficiaries; combinations of loans and guarantees, and guarantees or counter-guarantees for national, regional and local debt-financing schemes. It will include a SME window targeting research and innovation (R&I) driven SMEs with loan amounts that complement finance to SMEs by the Loan Guarantee Facility under the Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (COSME) (2014-2020).

The Equity facility will provide venture and/or mezzanine capital to individual enterprises in the early stage (start-up window). The facility will also have the possibility to make expansion and growth-stage investments in conjunction with the Equity Facility for Growth under COSME, including in funds-of-funds.

These facilities will be central to the specific objective 'Access to risk finance' but may, where relevant, also be used across all other specific objectives of Horizon 2020.

The Equity facility and the SME window of the Debt facility will be implemented as part of two Union financial instruments that provide equity and debt to support R&I and growth of SMEs, in conjunction with the equity and debt facilities under COSME.

1.3. *Communication, exploitation and dissemination*

A key added value of research and innovation funded at the Union level is the possibility to disseminate, exploit and communicate results on a continent-wide scale to enhance their impact. Horizon 2020 will therefore include, under all of its specific objectives, dedicated support to dissemination (including through open access to scientific publications), communication and dialogue actions, with a strong emphasis on communicating results to end-users, citizens, academia, civil society organisations, industry and policy makers. To this extent, Horizon 2020 may make use of networks for information transfer. Communication activities undertaken in the context of Horizon 2020 will promote the fact that the results were obtained with the support of Union funding and will also seek to raise public awareness on the importance of research and innovation by means of publications, events, knowledge repositories, databases, websites or a targeted use of social media.

2. COMPLEMENTARITIES, CROSS-CUTTING ISSUES AND SUPPORT MEASURES

Horizon 2020 is structured around the objectives defined for its three priorities: "Excellent science", "Industrial leadership" and "Societal challenges". Particular attention will be paid to ensuring adequate coordination between these priorities and fully exploiting the synergies generated between all specific objectives to maximise their combined impact on the higher level policy objectives of the Union. The objectives of Horizon 2020 will therefore be addressed through a strong emphasis on finding efficient solutions, going well beyond an approach based simply on traditional scientific and technological disciplines and economic sectors.

Cross-cutting actions will be promoted across Part I 'Excellent Science', Part II 'Industrial Leadership', Part III 'Societal Challenges', Part IV 'Spreading excellence and widening participation' and Part V 'Science with and for society' to develop jointly new knowledge, future and emerging technologies, research infrastructures and key competences. Research infrastructures will also be leveraged for broader usage in society, for example in public services, promotion of science, civil security and culture. Furthermore, priority setting during implementation for the direct actions of the JRC and the activities of the European Institute of Innovation and Technology (EIT) will be adequately coordinated with the other parts of Horizon 2020.

Furthermore, in many cases, contributing effectively to the objectives of Europe 2020 and the flagship initiative "Innovation Union" will require solutions to be developed which are interdisciplinary in nature and therefore cut across multiple specific objectives of Horizon 2020. Horizon 2020 includes specific provisions to incentivise such cross-cutting actions, including by an efficient bundling of budgets. This includes also for instance the possibility for the priority "Societal challenges" and the specific objective "Leadership in enabling and industrial technologies" to make use of the provisions for financial instruments and the dedicated SME instrument.

Cross-cutting actions will also be vital in stimulating the interactions between the priority "Societal challenges" and the specific objective "Leadership in enabling and industrial technologies", needed to generate major technological breakthroughs. Examples of where such interactions may be developed are: the domain of eHealth, smart grids, intelligent transport systems, mainstreaming of climate actions, nanomedicine, advanced materials for lightweight vehicles or the development of bio-based industrial processes and products. Strong synergies will therefore be fostered between the priority "Societal challenges" and the development of generic enabling and industrial technologies. This will be explicitly taken into account in developing the multi-annual strategies and the priority setting for each of these specific objectives. It will require that stakeholders representing the different perspectives are fully involved in the implementation, and in many cases it will also require actions which bring together funding from the specific objective "Leadership in enabling and industrial technologies" and the relevant specific objectives of the priority "Societal challenges".

Particular attention will also be paid to the coordination of activities funded through Horizon 2020 with those supported under other Union funding programmes, such as the Common Agricultural Policy, the Common Fisheries Policy, the Life Programme, the Erasmus+ programme or the Health for Growth Programme and the Union's external and development funding programmes. This includes an appropriate articulation with the cohesion policy in the context of national and regional R&I strategies for smart specialisation, where support to capacity-building for research and innovation at regional level may act as a 'stairway to excellence', the establishment of regional centres of ex cellence may help close the innovation divide in Europe, or support to large-scale demonstration and pilot line projects may aid in achieving the objective of generating industrial leadership in Europe.

A. *Social sciences and humanities*

Social sciences and humanities research will be fully integrated into each of the specific objectives of Horizon 2020. This will include ample opportunities for supporting such research through the specific objectives "The European Research Council (ERC)", "Marie Skłodowska-Curie actions" or "Research infrastructures".

To this end, social sciences and humanities will also be mainstreamed as an essential element of the activities needed to enhance industrial leadership and to tackle each of the societal challenges. For the latter, this includes: understanding the determinants of health and optimising the effectiveness of healthcare provision; supporting policies empowering rural areas; researching and preserving Europe's cultural heritage and richness; promoting informed consumer choices; creating an inclusive digital ecosystem based on knowledge and information; robust decision making on energy policy and in ensuring a consumer-friendly European electricity grid and a transition to a sustainable energy system; supporting evidence-based transport policy and foresight; supporting climate change mitigation and adaptation strategies, resource efficiency initiatives and measures towards a green and sustainable economy; and understanding cultural and socio-economic aspects of security, risk and management issues (including legal and human rights aspects).

In addition, the specific objective 'Europe in a changing world - Inclusive, innovative and reflective societies' will support social sciences and humanities research into issues of a horizontal nature such as the creation of smart and sustainable growth, social, cultural and behavioural transformations in European societies, social innovation, innovation in the public sector or the position of Europe as a global actor.

B. *Science and society*

The relationship and interaction between science and society as well as the promotion of responsible research and innovation, science education, science communication and culture shall be deepened and public confidence in science and innovation reinforced by activities of Horizon 2020 favouring the informed engagement of and a dialogue with citizens and civil society in research and innovation.

C. *Gender*

Promoting gender equality in science and innovation is a commitment of the Union. In Horizon 2020, gender will be addressed as a cross-cutting issue in order to rectify imbalances between women and men and to integrate a gender dimension in research and innovation programming and content.

D. *SMEs*

Horizon 2020 will encourage and support the increased participation of SMEs in an integrated way across all specific objectives.

In addition to the establishment of better conditions for SMEs to participate in Horizon 2020, in accordance with Article 22 of Regulation (EU) No 1291/2013, dedicated measures set out under the specific objective 'Innovation in SMEs' (dedicated SME instrument) shall be applied in the specific objective 'Leadership in enabling and industrial technologies' and in the priority 'Societal challenges'. This integrated approach should lead to a minimum of 20 % of their total combined budgets going to SMEs.

Particular attention shall be paid to the adequate representation of SMEs in public-private partnerships referred to in Article 25 of Regulation (EU) No 1291/2013.

E. *Fast Track to Innovation (FTI)*

FTI will reduce the time from idea to market significantly and is expected to increase the participation of industry and first-time applicants in Horizon 2020.

FTI, as set out in Article 24 of Regulation (EU) No 1291/2013, will support innovation actions under the specific objective "Leadership in enabling and industrial technologies" and under the priority "Societal challenges", with a bottom-up-driven logic on the basis of a continuously open call, and "time to grant" not exceeding six months. FTI will contribute to innovation in Europe, underpinning the Union's competitiveness.

F. *Widening participation*

The research and innovation potential of the Member States, despite some recent convergence, remains very different, with large gaps between "innovation leaders" and "modest innovators". Activities shall help close the research and innovation divide in Europe by promoting synergies with the European Structural and Investment Funds (ESI Funds) and also by specific measures to unlock excellence in low performing research, development and innovation (RDI) regions, thereby widening participation in Horizon 2020 and contributing to the realisation of the ERA.

G. *International cooperation*

International cooperation with partners in third countries is necessary to address effectively many specific objectives defined in Horizon 2020, in particular those relating to Union external and development policies and international commitments. This is the case for all the societal challenges addressed by Horizon 2020, which are common in nature. International cooperation is also essential for frontier and basic research in order to capture the benefits from emerging science and technology opportunities. Promoting R&I staff mobility at an international scale is therefore crucial to enhance this global cooperation. Activities at international level are equally important to enhance the competitiveness of European industry by promoting the take-up and trade of novel technologies, for instance through the development of worldwide standards and interoperability guidelines, and by promoting the acceptance and deployment of European solutions outside Europe. All international activities should be supported by an efficient and fair knowledge transfer framework which is critical for innovation and growth.

The focus of international cooperation in Horizon 2020 will be on cooperation with three major country groupings:

(1) industrialised and emerging economies;

(2) enlargement and neighbourhood countries; and

(3) developing countries.

Where appropriate, Horizon 2020 will promote cooperation at bi-regional or multilateral level. International cooperation in research and innovation is a key aspect of the Union's global commitments and has an important role to play in the Union's partnership with developing countries, such as progressing towards the achievement of the United Nations' Millennium Development Goals.

Article 27 of Regulation (EU) No 1291/2013 sets out the general principles for participation of legal entities from third countries and of international organisations. As research and innovation in general benefit largely from an openness towards third countries, Horizon 2020 will continue with the principle of general openness while encouraging reciprocal access to third country programmes. Where appropriate, and in particular to safeguard European interest as regards intellectual property, a more cautious approach may be adopted.

In addition, a range of targeted actions will be implemented taking a strategic approach to international cooperation on the basis of common interest, priorities and mutual benefit and promoting coordination and synergies with Member States' activities. This will include a mechanism for supporting joint calls and the possibility of co-funding programmes together with third countries or international organisations. Synergies with other Union policies will be sought.

Strategic advice from the Strategic Forum for International Scientific and Technological Cooperation (SFIC) will continue to be sought.

Without prejudice to other collaboration opportunities, examples of areas where such strategic international cooperation may be developed are:

(a) the continuation of the European & Developing Countries Clinical Trials Partnership (EDCTP2) on clinical trials for medical interventions against HIV, malaria, tuberculosis and neglected diseases;

(b) support by way of an annual subscription to the Human Frontier Science Programme (HFSP) to allow non-G7 Member States to fully benefit from the funding provided by the HFSP;

(c) international consortium on rare diseases, with a number of Member States and third countries. The aim of this initiative is to develop by 2020 diagnostic tests for most rare diseases and 200 new therapies for rare diseases;

(d) support to the activities of the International Knowledge-Based Bio-Economy Forum and the EU-US Task Force on Biotechnology Research as well as collaborative links with relevant international organisations and initiatives, such as global research alliances on agricultural greenhouse gases and on animal health;

(e) contribution to multilateral processes and initiatives, such as the Intergovernmental Panel on Climate Change (IPCC), the Intergovernmental Platform on Biodiversity and Ecosystem Services (IPBES), and the Group on Earth Observations (GEO);

(f) the Space Dialogues between the Union and the United States and Russia, the two major space faring nations, is an extremely valuable one and forms the basis for the establishment of strategic cooperation in space partnerships;

(g) the implementing arrangement between the Union and the United States for cooperative activities in the field of Homeland Security/Civil Security/Research, signed on 18 November 2010;

(h) cooperation with developing countries, including from Sub-Saharan Africa, in the field of decentralised energy production for poverty alleviation;

(i) continuation of research collaboration with Brazil on new generation of biofuels and other uses of biomass.

In addition, dedicated horizontal activities will be supported in order to ensure the coherent and effective development of international cooperation across Horizon 2020.

H. *Sustainable development and climate change*

Horizon 2020 will encourage and support activities towards exploiting Europe's leadership in the race to develop new processes and technologies promoting sustainable development, in a broad sense, and combating climate change. Such a horizontal approach, fully integrated in all Horizon 2020 priorities, will help the Union to prosper in a low-carbon, resource-constrained world while building a resource-efficient, sustainable and competitive economy.

I. *Bridging from discovery to market application*

Bridging actions throughout Horizon 2020 are aimed at bringing discovery to market application, leading to exploitation and commercialisation of ideas whenever appropriate. The actions should be based on a broad innovation concept and stimulate cross-sectoral innovation.

J. *Cross-cutting support measures*

The cross-cutting issues will be supported by a number of horizontal support measures, including support to: enhancing the attractiveness of the research profession, including the general principles of the European Charter for Researchers, as set out in the Commission Recommendation of 11 March 2005 ([1]); strengthening the evidence base and the development of and support for ERA (including the five ERA initiatives) and the flagship initiative "Innovation Union"; recognising top performing Horizon 2020 beneficiaries and projects in the different fields through symbolic awards; improving framework conditions in support of the flagship initiative "Innovation Union", including the principles of the Commission Recommendation on the management of intellectual property ([2]), and exploring the possibility of setting up an European Intellectual Property Rights valorisation instrument; and administration and coordination of international networks for excellent researchers and innovators, such as European Cooperation in Science and Technology (COST).

3. PARTNERING

For achieving sustainable growth in Europe, the contribution of public and private players must be optimised. This is essential for consolidating the ERA and for delivering on the "Innovation Union", "the Digital Agenda for Europe", and other Europe 2020 flagship initiatives. Furthermore, responsible research and innovation requires that best solutions be derived from interactions between partners having various perspectives but common interests.

Horizon 2020 includes scope and a clear set of criteria for setting up public-public and public-private partnerships. Public-private partnerships can be based on a contractual arrangement between public and private actors and can in limited cases be institutionalised public-private partnerships, such as Joint Technology Initiatives (JTIs) and other joint undertakings.

Existing public-public and public-private partnerships may receive support from Horizon 2020, provided they address Horizon 2020 objectives, contribute to realising the ERA, meet the criteria laid down in Horizon 2020 and have shown to make significant progress under the Seventh Framework Programme.

Initiatives under Article 185 TFEU supported under the Sixth Framework Programme of the European Community for research, technological development and demonstration activities ("the Sixth Framework Programme"), adopted by Decision No 1513/2002/EC of the European Parliament and of the Council ([3]), and/or under the Seventh Framework Programme for which further support may be provided under the above conditions include: the European & Developing Countries Clinical Trials Partnership (EDCTP), Ambient Assisted Living Joint Programme (AAL), Baltic Sea Research and Development Programme (BONUS), the Eurostars Programme and the European Metrology Research Programme (EMRP). Further support may also be provided to the European Energy Research Alliance (EERA) established under the European Strategic Energy Technology Plan (SET Plan). Joint Programming Initiatives may be supported by Horizon 2020 through the instruments referred to in Article 26 of Regulation (EU) No 1291/2013, including through initiatives under Article 185 TFEU.

Joint Undertakings established in the Seventh Framework Programme under Article 187 TFEU for which further support may be provided under the above conditions are: the Innovative Medicines Initiative (IMI), Clean Sky, Single European Sky ATM Research (SESAR), the Fuel Cells and Hydrogen Joint Undertaking (FCH) and the Electronic Components and Systems for European Leadership Joint Technology Initiative (ECSEL).

Other public-private partnerships supported under the Seventh Framework Programme for which further support may be provided under the above conditions are: Factories of the Future, Energy-efficient Buildings (EeB), European Green Cars Initiative and Future Internet. Further support may also be provided to the European Industrial Initiatives (EIIs) established under the SET Plan.

Further public-public partnerships and public-private partnerships may be launched under Horizon 2020 where they meet the defined criteria.

([1]) OJ L 75, 22.3.2005, p. 67.
([2]) Commission Recommendation on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations (C(2008) 1329, of 10.4.2008).
([3]) Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) (OJ L 232, 29.8.2002, p. 1).

PART I

EXCELLENT SCIENCE

1. EUROPEAN RESEARCH COUNCIL (ERC)

The ERC will promote world-class frontier research. Research at and beyond the frontiers of current understanding is both of critical importance to economic and social welfare, and an intrinsically risky venture, progressing on new and most challenging research areas and characterised by an absence of disciplinary boundaries.

In order to stimulate substantial advances at the frontiers of knowledge, the ERC will support individual teams to carry out research in any field of basic scientific and technological research which falls within the scope of Horizon 2020, including engineering, social sciences and the humanities. As appropriate, specific target groups (e.g. starting researchers/emerging teams) may be taken into account, following the objectives of the ERC and needs for efficient implementation. Particular attention will be paid to emerging and fast-growing areas at the frontier of knowledge and at the interface between disciplines.

Independent researchers of any age and gender, including starting researchers making the transition to being independent research leaders in their own right, from any country in the world will be supported to carry out their research in Europe.

The ERC shall give particular priority to assisting the best starting researchers with excellent ideas to make the transition to independence by providing adequate support at the critical stage when they are setting up or consolidating their own research team or programme. The ERC will also continue to provide appropriate levels of support for established researchers.

An "investigator-driven" approach will be followed. This means that the ERC will support projects carried out by researchers on subjects of their choice within the scope of calls for proposals. Proposals will be evaluated on the sole criterion of excellence as judged by peer review, taking account of excellence in new groups, starting researchers, as well as established teams, and paying particular attention to proposals which are highly pioneering and involve correspondingly high scientific risks.

The ERC will operate as an autonomous science-led funding body consisting of an independent Scientific Council, supported by a lean and cost-effective dedicated implementation structure.

The Scientific Council will establish the overall scientific strategy and will have full authority over decisions on the type of research to be funded.

The Scientific Council will establish the work programme to meet the ERC's objectives based on its scientific strategy as set out below. It will establish the necessary international cooperation initiatives in line with its scientific strategy, including outreach activities to increase the visibility of the ERC for the best researchers from the rest of the world.

The Scientific Council will continuously monitor the operation of the ERC and its evaluation procedures and consider how best to achieve its broader objectives. It will develop the ERC's mix of support measures as necessary to respond to emerging needs.

The ERC will aim for excellence in its own operations. The administrative and staff costs for the ERC relating to the Scientific Council and the dedicated implementation structure will be consistent with lean and cost-effective management. Administrative expenditure will be kept to a minimum, consistent with ensuring the resources necessary for world-class implementation, in order to maximise funding for frontier research.

ERC awards will be made and grants operated according to simple, transparent procedures that maintain the focus on excellence, encourage initiative and combine flexibility with accountability. The ERC will continuously look for further ways to simplify and improve its procedures in order to ensure that these principles are met.

Given the unique structure and role of the ERC as a science-led funding body the implementation and management of the activities of the ERC will be reviewed and evaluated on an ongoing basis with the full involvement of the Scientific Council to assess its achievements and to adjust and improve procedures and structures on the basis of experience.

1.1. *The Scientific Council*

In order to carry out its tasks, as set out in Article 7, the Scientific Council will:

(1) Scientific strategy:

— establish the overall scientific strategy for the ERC, in the light of scientific opportunities and European scientific needs;

— on a permanent basis, in accordance with the scientific strategy, ensure the establishment of the work programme and necessary modifications, including calls for proposals and criteria and, as may be required, the definition of specific target groups (e.g. starting/emerging teams);

(2) Scientific management, monitoring and quality control:

— as appropriate, from a scientific perspective, establish positions on implementation and management of calls for proposals, evaluation criteria, peer review processes including the selection of experts, the methods for peer review and proposal evaluation and the necessary implementing rules and guidelines, on the basis of which the proposal to be funded will be determined under the supervision of the Scientific Council, and establish positions on any other matter affecting the achievements and impact of the ERC's activities and the quality of the research carried out, including the principal provisions of the ERC Model Grant Agreement;

— monitor quality of operations and evaluate implementation and achievements and make recommendations for corrective or future actions.

(3) Communication and dissemination:

— assure transparency in communication with the scientific community, key stakeholders and the general public on the ERC's activities and achievements;

— regularly report to the Commission on its own activities.

The Scientific Council has full authority over decisions on the type of research to be funded and is the guarantor of the quality of the activity from the scientific perspective.

Where appropriate, the Scientific Council shall consult with the scientific, engineering and scholarly community, regional and national research funding agencies and other stakeholders.

The members of the Scientific Council shall be compensated for the tasks they perform by means of an honorarium and, where appropriate, reimbursement of travel and subsistence expenses.

The President of the ERC will reside in Brussels for the duration of the appointment and devote most of his/her working time ([1]) to ERC business. He/she will be remunerated at a level commensurate with the Commission's top management.

The Scientific Council shall elect from amongst its members three Vice-Chairs who shall assist the President in its representation and the organisation of its work. They may also hold the title of Vice-President of the ERC.

Support will be provided to the three Vice-Chairs to ensure adequate local administrative assistance at their home institutes.

1.2. *Dedicated implementation structure*

The dedicated implementation structure will be responsible for all aspects of administrative implementation and programme execution, as provided for in the work programme. It will, in particular, implement the evaluation procedures, peer review and selection process in accordance with the strategy established by the Scientific Council and will ensure the financial and scientific management of the grants.

The dedicated implementation structure will support the Scientific Council in the conduct of all of its tasks as set out above, provide access to the necessary documents and data in its possession, and keep the Scientific Council informed of its activities.

([1]) In principle at least 80 %.

In order to ensure an effective liaison with the dedicated implementation structure on strategy and operational matters, the leadership of the Scientific Council and the Director of the dedicated implementation structure will hold regular coordination meetings.

The management of the ERC will be carried out by staff recruited for that purpose, including, where necessary, officials from the Union institutions, and will cover only the real administrative needs in order to assure the stability and continuity necessary for an effective administration.

1.3. *Role of the Commission*

In order to fulfil its responsibilities as set out in Articles 6, 7 and 8 the Commission will:

— ensure the continuity and renewal of the Scientific Council and provide support for a standing Identification Committee for the identification of future Scientific Council members;

— ensure the continuity of the dedicated implementation structure and the delegation of tasks and responsibilities to it taking into account the views of the Scientific Council;

— appoint the Director and the Senior Staff of the dedicated implementation structure taking into account the views of the Scientific Council;

— ensure the timely adoption of the work programme, the positions regarding implementing methodology and the necessary implementing rules as provided by the ERC Rules of Submission and the ERC Model Grant Agreement, taking into account the positions of the Scientific Council;

— regularly inform and consult the Programme Committee on the implementation of the ERC activities.

2. FUTURE AND EMERGING TECHNOLOGIES

Future and Emerging Technologies (FET) activities will concretise different logics of intervention, from completely open to varying degrees of structuring of topics, communities and funding, structured around three strands - FET Open, FET Proactive and FET Flagships.

2.1. *FET Open: fostering novel ideas*

Supporting a large set of early stage, high-risk visionary science and technology collaborative research projects is necessary for the successful exploration of new foundations for radically new future scientific knowledge and technologies. By being explicitly non-topical and non-prescriptive, this activity allows for new ideas, whenever they arise and wherever they come from, within the broadest spectrum of themes and disciplines, and it actively stimulates creative out-of-the-box thinking. Nurturing such fragile ideas requires an agile, risk-friendly and highly interdisciplinary research approach, going well beyond the strictly technological realms. Attracting and stimulating the participation of new high-potential actors in research and innovation, such as young researchers and high-tech SMEs, is also important for nurturing the scientific and industrial leaders of the future.

2.2. *FET Proactive: nurturing emerging themes and communities*

Novel areas and themes need to be matured, by working towards structuring emerging communities and supporting the design and development of transformative research themes. The main benefits of this structuring yet explorative approach are emerging novel areas that are not yet ready for inclusion in industry research roadmaps, and building up and structuring of research communities around them. It makes the step from collaborations between a small number of researchers, to a cluster of projects that each address aspects of a research theme and exchange results. This will be done in close association with the priorities "Industrial leadership" and "Societal challenges".

2.3. *FET Flagships: pursuing grand interdisciplinary scientific and technological challenges*

Research initiatives within this strand are science- and technology-driven, large-scale, multidisciplinary and built around a visionary unifying goal. They tackle grand science and technology challenges requiring cooperation among a range of disciplines, communities and programmes. The scientific and technological advance should provide a strong and broad basis for future innovation and economic exploitation, as well as novel benefits for society of a potential high impact. The overarching nature and magnitude implies that they can only be realised through a collaborative long-term and sustained effort.

2.4. *Specific implementation aspects*

A FET Advisory Board, including scientists and engineers of the highest repute and expertise, will provide stakeholder input on the overall scientific and technological strategy, including advice on the definition of the work programme.

FET will continue to be science- and technology-led, supported by a light and efficient implementation structure. Simple administrative procedures will be adopted to maintain the focus on excellence in science-driven technological innovation, encourage initiative and combine speed in decision-making and flexibility with accountability. The most appropriate approaches will be used for probing the FET research landscape (e.g. portfolio analysis) and for involving communities of stakeholders (e.g. consultations). The aim will be for continuous improvement and for the search for further ways to simplify and improve procedures in order to ensure that these principles are met. Assessments of the effectiveness and impact of the FET activities will be carried out, complementing those at programme level.

Given its mission of fostering science-driven research towards future technologies, FET strives to bring together actors from science, technology and innovation, including, where appropriate, users, and to the extent possible from both public and private sectors. FET should therefore play an active and catalytic role in stimulating new thinking, new practices and new collaborations.

FET Open groups activities for an entirely bottom-up search for promising new ideas. The high risk implied by each such idea is countered by exploring many of them. Efficiency in terms of time and resources, low opportunity cost for the proposers, and undisputable openness to non-conventional and interdisciplinary ideas are the key characteristics for these activities. Light and fast continuously open submission schemes will seek for promising new high-risk research ideas and will include tracks for new and high-potential innovation actors such as young researchers and high-tech SMEs. To complement FET Open activities, activities under the priorities "Industrial Leadership" and "Societal Challenges" may foster radically new use of knowledge and technologies.

FET Proactive will regularly open calls on several high-risk, high-potential innovative themes, funded at such a level that several projects can be selected. These projects will be supported by community building actions that foster activities such as joint events, development of new curricula and research roadmaps. The selection of themes will take into account excellence in science-driven research towards future technologies, potential for creating a critical mass and impact on science and technology.

A number of large-scale focused initiatives (FET Flagships) could be implemented subject to the positive outcome of FET preparatory projects. They should be based on open partnerships that enable the voluntary combination of Union, national and private contributions, with a balanced governance that allows programme owners to have appropriate influence, as well as a large degree of autonomy and flexibility in the implementation, enabling the Flagship to follow closely a broadly supported research roadmap. The selection of topics to be implemented as Flagships will be based on scientific and technologial excellence and will take into account the unifying goal, the potential impact, the integration of stakeholders and resources under a cohesive research roadmap and, where appropriate, the support from stakeholders and national/regional research programmes. These activities shall be realised using the existing funding instruments.

Activities in the three FET strands are complemented by networking and community-based activities for creating a fertile and vibrant European base for science-driven research towards future technologies. They will support the future developments of the FET activities, foster the debate on implications of new technologies, and accelerate impact.

3. MARIE SKŁODOWSKA-CURIE ACTIONS

3.1. *Fostering new skills by means of excellent initial training of researchers*

Europe needs a strong and creative human resource base, mobile across countries and sectors, with the right combination of skills to innovate and to convert knowledge and ideas into products and services for economic and social benefit.

This will be achieved in particular by structuring and raising excellence in a substantial share of the high-quality initial training of early stage researchers and doctoral candidates throughout Member States and associated countries including, where appropriate, participation from third countries. By equipping early stage researchers with a diversity of skills that will allow them to face current and future challenges, the next generation of researchers will benefit from enhanced career perspectives in both public and private sectors, thereby enhancing also the attraction of young people to research careers.

The action will be implemented through support to Union-wide competitively selected research training programmes implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs and other socio-economic actors from different countries across Europe and beyond. Single institutions able to provide the same enriching environment will also be supported. Flexibility in the implementation of the objectives will have to be ensured in order to address the different needs. Typically, successful partnerships will take the form of research training networks that may offer innovative types of training such as joint or multiple doctoral degrees or industrial doctorates, while single institutions will usually be involved in innovative doctoral programmes. Industrial doctorates are an important element to foster an innovative spirit among researchers and create closer links between industry and academia. In this frame, support is foreseen for the best early stage researchers from any country to join these excellent programmes, which may include, inter alia, mentoring to transfer knowledge and experience.

These training programmes will address the development and broadening of core research competences, while equipping researchers with a creative mind, an entrepreneurial outlook and innovation skills that will match the future needs of the labour market. The programmes will also provide training in transferable competences such as team-work, risk-taking, project management, standardisation, entrepreneurship, ethics, intellectual property rights (IPR), communication and societal outreach which are essential for the generation, development, commercialisation and diffusion of innovation.

3.2. *Nurturing excellence by means of cross-border and cross-sector mobility*

Europe has to be attractive for the best researchers, European and non-European alike. This will be achieved in particular by supporting attractive career opportunities for experienced researchers in both public and private sectors and by encouraging them to move between countries, sectors and disciplines to enhance their creative and innovative potential.

Funding will be given to the best or most promising experienced researchers, regardless of their nationality, who want to develop their skills through a transnational or international mobility experience. They can be supported along all the different stages of their career, including the most junior ones just after their doctoral degree or equivalent experience. These researchers will receive funding on the condition that they move from one country to another to broaden or deepen their competences in universities, research institutions, research infrastructures, businesses, SMEs or other socio-economic actors of their choice (e.g. civil society organisations), working on research and innovation projects fitting their personal needs and interests. They will be encouraged to move from public to private sector or vice versa through the support of temporary postings. This should enhance the innovativeness of the private sector and promote cross-sector mobility. Part-time opportunities allowing combined positions in both public and private sectors will also be supported to enhance the transfer of knowledge between sectors and also to encourage the creation of start-ups. Such tailor-made research opportunities will help promising researchers to become fully independent and to facilitate career moves between public and private sectors.

In order to fully exploit the existing potential of researchers, possibilities to be trained and to acquire new knowledge in a third-country high-level research institution, to restart a research career after a break and to (re)integrate researchers into a longer term research position in Europe, including their country of origin, after a transnational/international mobility experience covering return and reintegration aspects will also be supported.

3.3. *Stimulating innovation by means of cross-fertilisation of knowledge*

Societal challenges are becoming more and more global and cross-border and cross-sector collaborations are crucial to successfully face them. Sharing of knowledge and ideas from research to market (and vice versa) is therefore vital and can only be achieved through the connection of people. This will be promoted through the support of flexible exchanges of highly skilled R&I staff between sectors, countries and disciplines.

European funding will support exchanges of R&I staff within partnerships of universities, research institutions, research infrastructures, businesses, SMEs and other socio-economic actors among Europe, as well as between Europe and third countries to reinforce international cooperation. It will be open to R&I staff at all career levels, from the most junior (post-graduate) to the most senior (management), including also administrative and technical staff.

3.4. *Increasing structural impact by co-funding the activities*

Stimulating regional, national or international programmes to foster excellence and to spread best practices of the Marie Skłodowska-Curie Actions in terms of European-wide mobility possibilities for researchers' training, career development and staff exchange will increase the numerical and structural impact of the Marie Skłodowska-Curie Actions. This will also enhance the attractiveness of the centres of excellence across Europe.

This will be achieved by co-funding new or existing regional, national and international programmes, both public and private, to open up to and provide for international, intersectoral and interdicisplinary research training, as well as cross-border and cross-sector mobility of R&I staff at all stages of their career.

This will allow the exploitation of synergies between Union actions and those at regional and national level, combating fragmentation in terms of objectives, evaluation methods and working conditions of researchers. In the framework of co-funding activities, use of employment contracts will be strongly promoted.

3.5. *Specific support and policy actions*

To meet the challenge efficiently it will be essential to monitor progress. The Marie Skłodowska-Curie actions will support the development of indicators and the analysis of data related to researchers' mobility, skills, careers and gender equality with a view to identifying gaps and barriers in these actions and to increasing their impact. These activities will be implemented by seeking synergies and close coordination with the policy support actions on researchers, their employers and funders carried out under the specific objective 'Europe in a changing world - Inclusive, innovative and reflective societies'. Specific actions will be funded to support initiatives to raise awareness on the importance of the research career and to disseminate research and innovation results emanating from work supported by the Marie Skłodowska-Curie actions.

To further increase the impact of the Marie Skłodowska-Curie actions, the networking between Marie Skłodowska-Curie researchers (current and past) will be enhanced through a strategy of alumni services. These will range from supporting a forum for contact and exchange between the researchers, providing possibilities for exploring collaborations and job opportunities, to the organisation of joint events and the involvement of the fellows in outreach activities as ambassadors for the Marie Skłodowska-Curie actions and for the ERA.

3.6. *Specific implementation aspects*

The Marie Skłodowska-Curie actions will be open to training and career development activities within all domains of research and innovation addressed under the TFEU, from basic research up to market take-up and innovation services. Research and innovation fields as well as sectors will be chosen freely by the applicants.

To benefit from the worldwide knowledge base, the Marie Skłodowska-Curie actions will be open to R&I staff, as well as to universities, research institutions, research infrastructures, businesses and other socio-economic actors from all countries, including third countries, under the conditions defined in Regulation (EU) No 1290/2013.

Throughout all the activities described above, attention will be paid to encourage a strong participation of enterprises, in particular SMEs, as well as of other socio-economic actors in the successful implementation and impact of the Marie Skłodowska-Curie actions. A long-term collaboration between higher education, research organisations and the public and private sectors, taking into account the protection of intellectual property rights, is promoted throughout all Marie Skłodowska-Curie actions.

The Marie Skłodowska-Curie actions will be developed in close synergy with other programmes supporting these policy objectives, including the Erasmus+ programme and the Knowledge and Innovation Communities (KICs) of the EIT.

The possibility is retained, if specific needs arise, to target certain activities under the Marie Skłodowska-Curie actions regarding specific societal challenges, types of research and innovation institutions, or geographical locations in order to respond to the evolution of Europe's requirements in terms of skills, research training, career development and knowledge sharing.

In order to be open to all sources of talent, general measures to overcome any distortions in the access to the grants will be ensured, for example by encouraging equal opportunities for male and female researchers in all Marie Skłodowska-Curie actions and by benchmarking gender participation. In addition, the Marie Skłodowska-Curie actions will support researchers to get established on a more stable career path and to ensure that they can achieve an appropriate work/life balance, taking into account their family situation, and to facilitate resuming a research career after a break. The principles of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers promoting open recruitment and attractive working conditions are recommended to be endorsed and applied by all funded participants.

To further enhance dissemination and public engagement, beneficiaries of the Marie Skłodowska-Curie actions may be required to plan suitable outreach activities to the general public. This plan will be assessed during the evaluation process as well as during the project follow-up.

4. RESEARCH INFRASTRUCTURES

The activities will aim at developing excellent European research infrastructures for 2020 and beyond, fostering their innovation potential and human resources and reinforcing European policy. Coordination with the cohesion funding sources will be pursued to ensure synergies and a coherent approach for the development of the research infrastructures. Synergies with the Marie Sklodowska-Curie actions will be encouraged.

4.1. *Developing the European research infrastructures for 2020 and beyond*

4.1.1. Developing new world-class research infrastructures

The aim is to facilitate and support the preparation, implementation, long-term sustainability and efficient operation of the research infrastructures identified by the European Strategy Forum on Research Infrastructures (ESFRI) and of other world-class research infrastructures, which will help Europe to respond to grand challenges in science, industry and society. This objective will address specifically those infrastructures that are planning to set up, are setting up or have set up their governance, e.g. on the basis of the European Research Infrastructure Consortium (ERIC) or any equivalent structure at European or international level.

The Union funding will contribute to, as appropriate:

(a) he preparatory phase of future infrastructures (e.g. detailed construction plans, legal arrangements, multiannual planning, and early engagement of industry);

(b) the implementation phase (e.g. research and development (R&D) and engineering work jointly with industry and users, and development of Regional Partner Facilities [1] aiming at a more balanced development of the ERA); and/or

(c) the operation phase (e.g. access, data handling, outreach, training and international cooperation activities).

This activity will also support design studies for new research infrastructures through a bottom-up approach.

4.1.2. Integrating and opening existing national and regional research infrastructures of European interest

The aim is to open up, where appropriate, key national and regional research infrastructures to all European researchers, from both academia and industry, and to ensure the optimal use and joint development of these infrastructures.

The Union will support networks and clusters that bring together and integrate, on European scale, key national research infrastructures. Funding will be provided to support, in particular, the transnational and virtual access of researchers and the harmonisation and improvement of the services that the infrastructures provide.

4.1.3. Development, deployment and operation of ICT-based e-infrastructures [2]

The aim is to achieve by 2020 a world-leading capability in networking, computing and scientific data in a single and open European space for online research where researchers enjoy leading-edge, ubiquitous and reliable services for networking and computing, and seamless and open access to e-Science environments and global data resources.

To achieve this goal, support will be given to: global research and education networks providing advanced, standardised and scalable inter-domain services on-demand; grid and cloud infrastructures providing virtually unlimited computational and data processing capacity; an ecosystem of supercomputing facilities, advancing towards exascale; a software and service infrastructure, e.g. for simulation and visualisation; real-time collaborative tools; and an interoperable, open and trusted scientific data infrastructure.

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[1] A Regional Partner Facility (RPF) is a research infrastructure of national or regional importance in terms of socio-economic returns, training and attracting researchers and technicians, that is recognised as a partner to a pan-European ESFRI or other world-class research infrastructure. The quality of the RPF, including the level of its scientific service, management and access policy, must meet the same standards required for pan-European research infrastructures.

[2] As all research becomes computer- and data-intensive, access to state-of-the-art e-infrastructures has become essential for all researchers. For example GÉANT connects 40 million users in over 8 000 institutions across 40 countries, whereas the European Grid Infrastructure is the world's largest distributed computing infrastructure with over 290 sites in 50 countries. Relentless progress in ICT and the increasing needs of science for computing and processing massive amounts of data pose major financing and organisational challenges for ensuring seamless services to researchers.

4.2. *Fostering the innovation potential of research infrastructures and their human resources*

4.2.1. Exploiting the innovation potential of research infrastructures

The goal is to stimulate innovation both in the infrastructures themselves and in industries, such as the supplier and user industry.

To this end, support will be provided to:

(a) R&D partnerships with industry to develop Union capacities and industrial supply in high-tech areas such as scientific instrumentation or ICT;

(b) pre-commercial procurement by research infrastructure actors to drive forward innovation and act as early adopters or developers of cutting-edge technologies;

(c) stimulate the use of research infrastructures by industry, e.g. as experimental test facilities or knowledge-based centres; and

(d) encourage the integration of research infrastructures into local, regional and global innovation ecosystems.

The Union actions will also leverage the use of research infrastructures, in particular e-infrastructures, for public services, social innovation, culture, education and training.

4.2.2. Strengthening the human capital of research infrastructures

The complexity of research infrastructures and the exploitation of their full potential require adequate skills for their managers, engineers and technicians, as well as users.

The Union funding will support the training of staff managing and operating research infrastructures of pan-European interest, the exchange of staff and best practices between facilities, and the adequate supply of human resources in key disciplines, including the emergence of specific education curricula. Synergies with the Marie Skłodowska-Curie actions will be encouraged.

4.3. *Reinforcing European research infrastructure policy and international cooperation*

4.3.1. Reinforcing European policy for research infrastructures

The aims are to exploit synergies between national and Union initiatives by setting up partnerships between relevant policy makers, funding bodies or advisory groups (e.g. ESFRI, e-Infrastructure Reflection Group (e-IRG), EIROforum organisations, and national public authorities), to develop complementarities and cooperation between research infrastructures and activities implementing other Union policies (such as regional, cohesion, industrial, health, environment, employment, or development policy), and to ensure coordination between different Union funding sources. Union actions will also support survey, monitoring and assessment of research infrastructures at Union level, as well as relevant policy studies and communication tasks.

Horizon 2020 will facilitate the efforts of the Member States to optimise their research facilities by supporting an up-to-date Union-wide database on openly accessible research infrastructures in Europe.

4.3.2. Facilitating strategic international cooperation

The aim is to facilitate the development of global research infrastructures, i.e. research infrastructures that require funding and agreements on a global scale. The aim is also to facilitate the cooperation of European research infrastructures with their non-European counterparts, ensuring their global interoperability and reach, and to pursue international agreements on the reciprocal use, openness or co-financing of infrastructures. In this respect due account will be taken of the recommendations of the Carnegie Group of Senior Officials on Global Research Infrastructures. Attention will also be given to ensure adequate Union participation in coordination with international bodies such as the United Nations (UN) or the Organisation for Economic Cooperation and Development (OECD).

4.4. *Specific implementation aspects*

During implementation independent expert groups will be consulted, as well as stakeholders and advisory bodies, such as ESFRI and the e-IRG.

The implementation will follow a three-pronged approach: bottom-up where the exact content and partnership of projects are not known; targeted where the specific research infrastructures and/or communities addressed are well-defined; and named beneficiaries, for example where a contribution to operational costs is provided to (a consortium of) infrastructure operator(s).

The aims of the activity lines set out under sections 4.2 and 4.3 shall be pursued by dedicated actions, as well as within the actions developed under section 4.1, when appropriate.

PART II

INDUSTRIAL LEADERSHIP

1. LEADERSHIP IN ENABLING AND INDUSTRIAL TECHNOLOGIES

General

The successful mastering, integration and deployment of enabling technologies by European industry is a key factor in strengthening Europe's productivity and innovation capacity and ensuring Europe has an advanced, sustainable and competitive economy, global leadership in high-tech application sectors and the ability to develop effective and sustainable solutions for societal challenges taking into account, inter alia, user needs. Innovation activities will be combined with R&D, as an integral part of the funding.

An integrated approach to Key Enabling Technologies

A major component of the specific objective 'Leadership in Enabling and Industrial Technologies' are Key Enabling Technologies (KETs), defined as micro- and nanoelectronics, photonics, nanotechnology, biotechnology, advanced materials and advanced manufacturing systems. Many innovative products incorporate several of these technologies simultaneously, as single or integrated parts. While each technology offers technological innovation, the accumulated benefit from the numerous interactions of KETs and other industrial enabling technologies and their combinations can also lead to technological leaps. Tapping into cross-cutting key enabling technologies will enhance product competitiveness and impact, stimulate growth and jobs and provide new opportunities to tackle societal challenges. The numerous interactions of these technologies will therefore be exploited. Dedicated support will be provided for larger-scale pilot line and demonstrator projects to be implemented in various environments and conditions.

This will include KETs and cross-cutting KET (multi KETs) activities that bring together and integrate various individual technologies, resulting in technology validation in an industrial environment to a complete and qualified system, ready or close to enter the market. Strong private sector involvement in such activities and the demonstration of how project results will contribute to market value for the Union will be a prerequisite, and implementation could therefore take the form of public-private partnerships. To this extent and through the Horizon 2020 implementation structure, a joint work programme for cross-cutting KET activities will be developed. Taking into account market needs and the requirements of the societal challenges, it will aim at providing generic KETs and multi KETs building blocks for different application areas, including societal challenges. In addition, synergies will be sought, where appropriate, between KET activities and the activities under the cohesion policy framework in the context of national and regional R&I strategies for smart specialisation, as well as with the EIT, the European Investment Bank (EIB) and, where appropriate, with the Member States driven activities under the Joint Programming Initiatives.

Specific implementation aspects

Innovation activities will include the integration of individual technologies; demonstrations of capacities to make and deliver innovative products, systems, processes and services; user and customer pilots to prove feasibility and added value; and large-scale demonstrators to facilitate market take-up of the research results. Adequate focus will be given to small and medium scale projects. Furthermore, implementation under this Part will encourage the involvement of small and medium-sized research teams, also contributing to a more active participation of SMEs.

Various individual technologies will be integrated, resulting in technology validation in an industrial environment to a complete and qualified system, ready for the market. Strong private sector involvement in such activities will be a prerequisite, including public-private partnerships.

Demand-side actions will complement the technology push of the research and innovation initiatives. These include making the best use of public procurement of innovation; developing appropriate technical standards and technical activities in support of standardisation and regulation; private demand and engaging users to create more innovation-friendly markets.

For nanotechnology and biotechnology in particular engagement with stakeholders and the general public will aim to raise the awareness of benefits and risks. Safety assessment and the management of overall risks in the deployment of these technologies will be systematically addressed. Where appropriate, social sciences and humanities will contribute to taking into account user needs preferences and acceptance as well as ensuring societal engagement and informed consumers' choice.

The activities supported under this specific objective will complement support for research and innovation in enabling technologies, which may be provided by national or regional authorities under the Cohesion Policy Funds, within the framework of smart specialisation strategies.

This specific objective shall, as part of the funding of actions, also support technology transfer activities (both at national and regional level), including the development of international and regional innovation clusters, to promote more effective linkages between universities and the industry.

Strategic international cooperation initiatives will be pursued in areas of mutual interest and benefit with leading partner countries. Of particular, but not exclusive, interest for enabling and industrial technologies are:

— access to world-leading scientific and technological expertise;

— the development of global standards;

— the removal of bottlenecks in industrial exploitation, R&D collaboration and conditions for trade;

— the safety of nanotechnology-based and biotechnology-based products and the long-term impact of their use;

— the development of materials and methods to reduce energy and resource consumption;

— industry-led, collaborative international initiatives within the manufacturing community; and

— the interoperability of systems.

1.1. *Information and Communication Technologies (ICT)*

A number of activity lines will target ICT industrial and technological leadership challenges along the whole value chain and cover generic ICT research and innovation agendas, including notably:

1.1.1. A new generation of components and systems: Engineering of advanced, embedded and energy- and resource-efficient components and systems

The objective is to maintain and reinforce European leadership in technologies related to advanced, embedded, energy-and resource-efficient and robust components and systems. It also includes micro-nano-bio systems, organic electronics, large area integration, underlying technologies for the Internet of Things (IoT) ([1]), including platforms to support the delivery of advanced services, sensors, smart integrated systems, embedded and distributed systems, systems of systems and complex systems engineering.

1.1.2. Next generation computing: Advanced and secure computing systems and technologies, including cloud computing

The objective is to leverage European assets in processor and system architecture, interconnect and data localisation technologies, cloud computing, parallel computing, modelling and simulation software for all market segments, including engineering applications (such as uncertainty quantification, risk analysis and decision in engineering).

1.1.3. Future Internet: Software, hardware, infrastructures, technologies and services

The objective is to reinforce the competitiveness of European industry in developing, mastering and shaping the next generation Internet that will gradually replace and surpass the current Web, fixed and mobile networks and service infrastructures, and enable the interconnection of trillions of devices (IoT) across multiple operators and domains that will change the way we communicate, access and use knowledge. This includes R&I on networks, software, processes and services, cyber security, privacy, reliability and trust, wireless ([2]) communication and all optical networks, immersive interactive multimedia and the connected enterprise of the future.

([1]) Internet of Things will be coordinated as a cross-cutting issue.
([2]) Including space-based networks.

1.1.4. Content technologies and information management: ICT for digital content and for cultural and creative industries

The objective is to strengthen Europe's position as provider of products and services based on individual and business creativity. It will do so by providing professionals and citizens with new tools to create, access, exploit, preserve and re-use all forms of digital content in any language and to model, analyse and visualise vast amounts of data (big data), including linked data. This includes new technologies for arts, language, learning, interaction, digital preservation, web design, content access, analytics and media; and intelligent and adaptive information management systems based on advanced data mining, machine learning, statistical analysis and visual computing technologies.

1.1.5. Advanced interfaces and robots: Robotics and smart spaces

The objective is to reinforce European scientific and industrial leadership in industrial and service robotics, cognitive and communicative systems, advanced interfaces and smart spaces, and sentient machines, building on increases in computing and networking performance and progress in the ability to design and build systems that can learn, self-assemble, adapt and react or that optimise human-machine interactions. Where appropriate, the systems developed and advancements in the state of the art should be validated in real-world environments.

1.1.6. Micro- and nanoelectronics and photonics: Key enabling technologies related to micro- and nanoelectronics and to photonics, covering also quantum technologies

The objective is to take advantage of the excellence of Europe in these key enabling technologies and support and further enhance the competitiveness and market leadership of its industry. Activities will also include research and innovation on design, advanced processes, pilot lines for fabrication, related production technologies and demonstration actions to validate technology developments and innovative business models as well as underlying next generation technologies exploiting advances in quantum physics.

These six major activity lines are expected to cover the full range of needs taking into account the competitiveness of European industry on a global scale. These would include industrial leadership in generic ICT-based solutions, products and services needed to tackle major societal challenges as well as application-driven ICT research and innovation agendas which will be supported together with the relevant societal challenge. In view of the ever increasing advancement of technology in all areas of life, the interaction between humans and technology will be important in this respect, and part of the application-driven ICT research mentioned above. Research with a user-centred perspective will contribute to the development of competitive solutions.

Included under each of these six major activity lines are also ICT-specific research infrastructures, such as living labs for experimentation, and infrastructures for underlying key enabling technologies and their integration in advanced products and innovative smart systems, including equipment, tools, support services, clean rooms and access to foundries for prototyping.

This should be implemented in a way that ensures complementarity and consistency with the specific objective "Research infrastructures" under the priority "Excellent Science".

Activities will support research and development of ICT systems in full respect of the fundamental rights and freedoms of natural persons and in particular their right to privacy.

1.2. *Nanotechnologies*

1.2.1. Developing next generation nanomaterials, nanodevices and nanosystems

Development and integration of knowledge of nanoscale phenomena at the cross-roads of different scientific disciplines, aiming at fundamentally new products and systems enabling sustainable solutions in a wide range of sectors.

1.2.2. Ensuring the safe and sustainable development and application of nanotechnologies

Advancing scientific knowledge of the potential impact of nanotechnologies on health or on the environment for pro-active, science-based governance of nanotechnologies, and providing validated scientific tools, methods and platforms for hazard, exposure and risk assessment and management along the entire life cycle of nanomaterials and nanosystems, including standardisation issues.

1.2.3. Developing the societal dimension of nanotechnology

Addressing the human and physical needs of nanotechnology deployment and focusing on governance of nanotechnology for societal and environmental benefit, including communication strategies to ensure social engagement.

1.2.4. Efficient and sustainable synthesis and manufacturing of nanomaterials, components and systems

Focusing on new flexible, scalable and repeatable unit operations, smart integration of new and existing processes, including technology convergence such as nanobiotechnology, as well as up-scaling to enable sustainable high precision large-scale production of products and flexible and multi-purpose plants that ensure the efficient transfer of knowledge into industrial innovation.

1.2.5. Developing and standardisation of capacity-enhancing techniques, measuring methods and equipment

Focusing on the underpinning technologies, supporting the development and market introduction of safe complex nanomaterials and nanosystems, including nanometrology, characterisation and manipulation of matter at the nanoscale, modelling, computational design and advanced engineering at the atomic level.

1.3. *Advanced materials*

1.3.1. Cross-cutting and enabling materials technologies

Research on materials by design, functional materials, multifunctional materials with higher knowledge content, new functionalities and improved performance, such as self-repairing or biocompatible materials, self-assembling materials, novel magnetic materials and structural materials, for innovation in all industrial sectors, particularly for high value markets, and including the creative industries.

1.3.2. Materials development and transformation

Research and development to ensure efficient, safe and sustainable development and scale-up to enable industrial manufacturing of future design-based products towards a "no-waste" management of materials in Europe, e.g. in the metal, chemical or biotechnological industries, and to improve the understanding of material degradation mechanisms (wear, corrosion and mechanical reliability).

1.3.3. Management of materials components

Research and development for new and innovative techniques for materials, components and systems, joining, adhesion, separation, assembly, self-assembly and the disassembling, decomposition and deconstruction of material components, and management of life-cycle costs and environmental impacts through novel use of advanced materials technology.

1.3.4. Materials for a sustainable, resource-efficient and low-emission industry

Developing new products and applications, business models and responsible consumer behaviour that increase the use of the renewable resources for sustainable applications, reduce energy demand in the product's entire life cycle and facilitate low-emission production, as well as process intensification, recycling, depollution, materials for energy storage and materials with potential for high added value from waste and remanufacture.

1.3.5. Materials for creative industries, including heritage

Applying design and the development of converging technologies to create new business opportunities, including the preservation and restoration of Europe's heritage and materials with historical or cultural value, as well as novel materials.

1.3.6. Metrology, characterisation, standardisation and quality control

Promoting technologies such as characterisation, non-destructive evaluation, continuous assessing and monitoring and predictive modelling of performance for progress and impact in materials science and engineering.

1.3.7. Optimisation of the use of materials

Research and development to investigate substitution and alternatives to the use of materials, including addressing the challenge of raw materials through tailor-made materials or the substitution of scarce, critical or dangerous materials, and innovative business model approaches and identification of critical resources.

1.4. *Biotechnology*

1.4.1. Boosting cutting-edge biotechnologies as a future innovation driver

The objective is to lay the foundations for the European industry to stay at the front line of innovation, also in the medium and long term. It encompasses the development of emerging technology areas such as synthetic biology, bioinformatics and systems biology, as well as exploiting the convergence with other enabling technologies such as nanotechnology (e.g. bionanotechnology), ICT (e.g. bioelectronics) and engineering technology. These and other cutting-edge fields deserve appropriate measures in terms of research and development to facilitate effective transfer and implementation into new applications.

1.4.2. Biotechnology-based industrial products and processes

The objective is twofold: on the one hand, enabling the European industry (e.g. chemical, health, mining, energy, pulp and paper, fibre-based products and wood, textile, starch, and food processing industries) to develop new products and processes meeting industrial and societal demands using preferably environmentally friendly and sustainable production methods and competitive and enhanced biotechnology-based alternatives to replace established ones; on the other hand, harnessing the potential of biotechnology for detecting, monitoring, preventing and removing pollution. It includes R&I on novel enzymes with optimised biocatalyst functions, enzymatic and metabolic pathways, industrial scale bio-process design, integration of bio-processes in industrial production processes, advanced fermentation, up- and down-stream processing, and gaining insight on the dynamics of microbial communities. It will also encompass the development of prototypes for assessing the techno-economic feasibility as well as the sustainability of the developed products and processes.

1.4.3. Innovative and competitive platform technologies

The objective is to develop platform technologies (e.g. genomics, meta-genomics, proteomics, metabolomics, molecular tools, expression systems, phenotyping platforms and cell-based platforms) triggering leadership and competitive advantage on a wide number of economic sectors having econonomic impact. It includes aspects such as underpinning the development of bio-resources with optimised properties and applications beyond conventional alternatives; enabling exploration, understanding and exploitation in a sustainable manner of terrestrial and marine biodiversity for novel applications, bio-based products and processes; and sustaining the development of biotechnology-based healthcare solutions (e.g. diagnostics, biologicals, and bio-medical devices).

1.5. *Advanced Manufacturing and Processing*

1.5.1. Technologies for Factories of the Future

Promoting sustainable industrial growth by facilitating a strategic shift in Europe from cost-based manufacturing to an approach based on the creation of high added value products and ICT-enabled intelligent and high performance manufacturing in an integrated system. This requires addressing the challenge of producing more, while consuming less material, using less energy and generating less waste and pollution aiming at high ecological efficiency. The focus will be on the development and integration of the adaptive production systems of the future, with particular emphasis on the needs of European SMEs, in order to achieve advanced and sustainable manufacturing systems and processes. Focus shall also be on methodologies for enhancing flexible, safe and smart production where adequate levels of automation are applied in worker-friendly environments.

1.5.2. Technologies enabling energy-efficient systems and energy-efficient buildings with a low enviromental impact

Reducing energy consumption and CO_2 emissions by the development and deployment of sustainable construction technologies and systems and by the implementation and replication of measures for an increased uptake of energy-efficient systems and materials in new, renovated and retrofitted buildings. Life-cycle considerations and the growing importance of design-build-operate concepts will be key factors in addressing the challenge of a transition to near-zero-energy buildings in Europe by 2020 and the realisation of energy-efficient districts through the engagement of the wide stakeholder community.

1.5.3. Sustainable, resource-efficient and low-carbon technologies in energy-intensive process industries

Increasing the competitiveness of process industries, such as chemical, cement, pulp and paper, glass, minerals or non-ferrous metals and steel industries, by drastically improving resource and energy efficiencies and reducing the environmental impact of such industrial activities. Focus will be on the development and validation of enabling technologies for innovative substances, materials and technological solutions for low-carbon products and less energy-intensive processes and services along the value chain, as well as on the adoption of ultra-low carbon production technologies and techniques, to achieve specific greenhouse gas emission intensity reductions.

1.5.4. New sustainable business models

Cross-sectoral cooperation in concepts and methodologies for knowledge-based, specialised production can boost learning in organisations, creativity and innovation with a focus on business models in customised approaches that can adapt to the requirements of globalised value chains and networks, changing markets, and emerging and future industries. This includes addressing sustainable business models by covering the whole lifecycle of the product and process.

1.6. *Space*

In the field of space research, action at Union level will be carried out in conjunction with the space research activities of the Member States and the European Space Agency (ESA), aiming at building up complementarity among different actors.

1.6.1. Enabling European competitiveness, non-dependence and innovation of the European space sector

The objective is to maintain a globally leading role in space by safeguarding and further developing a cost-effective, competitive and innovative space industry (including SMEs) and research community and by fostering space-based innovation.

1.6.1.1. Safeguard and further develop a competitive, sustainable and entrepreneurial space industry and research community and strenghten European non-dependance in space systems

Europe is playing a leading role in space research and in the development of space technologies and is continually developing its own operational space infrastructures (e.g. the Galileo programme and the Copernicus programme). In fact, European industry has established itself as an exporter of first class satellites and other space-related technologies. Nevertheless, this position is challenged by competition from other major space powers. The objective of this measure is the development of a research base by providing continuity in space research and innovation programmes, for example by a sequence of smaller and more frequent in-space demonstration projects. This will allow Europe to develop its industrial base and space research and technological development (RTD) community, thereby contributing to advancing beyond the current state of the art and to its non-dependence from imports of critical technologies.

Standardisation should be supported in order to optimise the investments and to develop access to market.

1.6.1.2. Boost innovation between space and non-space sectors

A number of challenges in space technologies have parallels to terrestrial challenges, for example in the fields of aeronautics, energy, environment, telecommunications and ICT, natural resource exploration, sensors, robotics, advanced materials, security and health. These commonalities offer opportunities for early co-development, in particular by SMEs, of technologies across space and non-space communities, including non-space industries, potentially resulting in breakthrough innovations more rapidly than achieved in spin-offs at a later stage. Exploitation of existing European space infrastructure should be stimulated by promoting the development of innovative products and services based on remote sensing, geo-positioning or other types of satellite enabled data. Europe should furthermore reinforce the incipient development of an entrepreneurial space sector, where appropriate, by well targeted measures, including support for space technology transfer initiatives.

1.6.2. Enabling advances in space technologies

The objective is to develop advanced and enabling space technologies and operational concepts from idea to demonstration in space.

The ability to access space and to develop, maintain and operate space systems in Earth orbit and beyond are vital to the future of European society. The necessary capabilities require research and innovation investments in a multitude of space technologies (e.g. for launchers and other vehicles, satellites, robotics, instruments and sensors) and in operational concepts from idea to demonstration in space. Europe is currently one of the three leading space powers mainly driven by investments by Member States through ESA and national programmes, but compared to the level of investment in space R&D in the United States (e.g. about 20 % of the total NASA budget) the European focus in future space technologies and applications needs to be strengthened along the entire chain:

(a) low technology readiness level (TRL) research, often relying heavily on key enabling technologies, with the potential of generating breakthrough technologies with terrestrial applications;

(b) improvement of existing technologies, e.g. through miniaturisation, higher energy efficiency, and higher sensor sensitivity;

(c) demonstration and validation of new technologies and concepts in the space and terrestrial analogue environments;

(d) mission context, e.g. analysis of the space environment, ground stations, protecting space systems and infrastructure against damage or destruction from collision with debris or other space objects, as well as the effects of space weather events including solar flares (Space Situational Awareness, SSA), fostering innovative data gathering and transmission and sample archiving infrastructure;

(e) satellite communication, advanced navigation and remote sensing technologies, covering the research essential for future generations of Union space systems (e.g. Galileo and Copernicus).

1.6.3. Enabling exploitation of space data

The objective is to ensure more extensive utilisation of space data from existing, archived and future European missions in the scientific, public and commercial domain.

Space systems produce information which often cannot be acquired in any other way. Despite world-class European missions, publication figures show that data from European missions are not as likely to be used as data from US missions. A considerably increased exploitation of data from European satellites (scientific, public or commercial) can be achieved if further effort is made for the processing, archiving, validation, standardisation and sustainable availability of space data from European missions as well as to support the development of new information products and services resulting from those data and, where appropriate, in combination with data from ground-based observations. Innovations in data acquisition and processing, data fusion, and data dissemination and interoperability, in particular promotion of access to and exchange of earth science data and metadata, utilising also innovative ICT-enabled forms of collaboration, can ensure a higher return on investment of space infrastructure and contribute to tackling societal challenges. Calibration and validation of space data (for individual instruments, between instruments and missions, and with respect to in-situ objects) are key factors in the efficient use of space data in all domains, and there is a need to enhance the standardisation of space-derived data and reference frames.

Data access and exploitation of space missions is a matter that requires global coordination. For Earth observation data, harmonised approaches and best practices are partly achieved in coordination with the intergovernmental organisation Group on Earth Observation (GEO), aiming to sustain a Global Earth Observation System of Systems (GEOSS), in which the Union participates, namely by fully exploiting the Copernicus programme. A fast introduction of these innovations into the relevant application and decision making processes will be supported. This includes as well the exploitation of data for further scientific investigation.

1.6.4. Enabling European research in support of international space partnerships

The objective is to support the European research and innovation contribution to long term international space partnerships.

Although space information provides great local benefits, space undertakings have a fundamentally global character. This is particularly clear for the cosmic threat to Earth and space systems. The loss of satellites due to space weather and space debris is estimated to cost around EUR 100 million a year. Equally global are many space science and exploration projects. The development of cutting-edge space technology is increasingly taking place within such international partnerships, making access to such international projects an important success factor for European researchers and industry. The Union contribution to such global space endeavours needs to be defined in long-term strategic roadmaps (10 years and more), aligning with the Union's space policy priorities, and in coordination with the Member States and internal European partners, such as ESA and National Space Agencies, and, when relevant, with international partners and with the space agencies of space-faring nations.

1.6.5. Specific implementation aspects

The implementation priorities of space research and innovation under Horizon 2020 are in line with the Union's space policy priorities as defined by the Space Council and in the Commission Communication of 4 April 2011 entitled "Towards a space strategy for the European Union that benefits its citizens". The implementation will, where appropriate, be based on strategic research agendas developed in consultation with the Member States and National Space Agencies, ESA, stakeholders from European space industry (including SMEs), academia, technology institutes and the Space Advisory Group. As regards the participation in international undertakings, the research and innovation agenda will be defined in collaboration with European stakeholders and international partners (e.g. NASA, ROSCOSMOS and JAXA).

The application of space technologies shall be supported through the respective specific objectives of the priority "Societal challenges", where appropriate.

2. ACCESS TO RISK FINANCE

Horizon 2020 will set up two facilities (the 'Equity facility' and the 'Debt facility'), composed of various windows. The Equity facility and the SME window of the Debt facility will be implemented in interdependence with COSME, as part of two Union Financial Instruments that provide equity and debt to support R&I and growth of SMEs.

The Equity facility and the Debt facility may, where appropriate, allow pooling of financial resources with Member States or regions willing to contribute part of the ESI Funds allocated to them, in accordance with Regulation (EU) No 1303/2013 of the European Parliament and of the Council [1].

Instead of providing for instance loans, guarantees or equity directly to final beneficiaries, the Commission will delegate to financial institutions the provision of support via, in particular, risk-sharing, guarantee schemes and equity and quasi-equity investments.

2.1. *Debt facility*

The Debt facility will provide loans to single beneficiaries for investment in R&I; (counter-) guarantees to financial intermediaries providing loans to beneficiaries; combinations of loans and (counter-) guarantees; and guarantees and/or counter-guarantees for national or regional debt-financing schemes. The Debt facility will undertake maturity enhancement activities, and it will support the dedicated SME Instrument, subject to the level of demand (see section 3 'Innovation in SMEs' of Part II). Provisions from the Debt facility may be combined, with the possible addition of grants (including lump sums), with provisions from the Equity facility in one or more integrated schemes. Soft loans, convertible loans, subordinated loans, participating loans, leasing loans and securitisation may also be possible.

As well as providing loans and guarantees on a market-driven, first-come, first-served basis, the Debt facility will target, under a series of compartments, particular policies and sectors. Ring-fenced budgetary contributions for this purpose may, where appropriate, come from:

(a) other parts of Horizon 2020, notably Part III 'Societal challenges';

(b) other frameworks, programmes and budget lines in the general budget of the Union;

(c) particular regions and Member States that wish to contribute with resources available from the Cohesion Policy Funds; and

(d) specific entities (such as Joint Technology Initiatives) or initiatives.

Such budgetary contributions may be made or topped up at any time during the course of Horizon 2020.

Risk-sharing and other parameters may vary within policy or sector compartments, provided their values or states comply with the common rules for debt instruments. Furthermore, compartments may have specific communications strategies within the overall promotional campaign for the Debt facility. In addition, specialist intermediaries at national level may be used if specific expertise is needed to assess prospective loans in the domain of a particular compartment.

The SME window under the Debt facility shall target R&I-driven SMEs and small mid-caps with loan amounts exceeding EUR 150 000, thus complementing finance to SMEs by the Loan Guarantee Facility under COSME. The SME window of the Debt facility shall also cover loans below EUR 150 000 for R&I-driven SMEs and small mid-caps.

The leverage of the Debt facility - defined as the total funding (i.e. Union funding plus contribution from other financial institutions) divided by the Union financial contribution - is expected to range from an average 1,5 to 6,5, depending on the type of operations involved (level of risk, target beneficiaries, and the particular debt financial instrument facility concerned). The multiplier effect - defined as the total of investments made by supported beneficiaries divided by the Union financial contribution - is expected to be 5 to 20, again depending on the type of operations involved.

[1] Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Council Regulation (EC) No 1083/2006 (See page 320 of this Official Journal.).

2.2. *Equity facility*

The Equity facility will focus on early-stage venture capital funds and public and private funds-of-funds providing venture capital and/or mezzanine capital to individual portfolio enterprises. These enterprises may, in addition, seek debt financing from financial intermediaries implementing the Debt facility. Furthermore, the Equity facility will also explore possibilities to support business angels and other potential sources of equity finance. This could also include support at the phase 3 stage of the SME instrument subject to the level of demand, as well as to technology transfer (including the transfer of research results and inventions stemming from the sphere of public research to the productive sector, for example through proof-of-concept).

The Equity facility will also have the possibility to make expansion and growth-stage investments in conjunction with the Equity Facility for Growth (EFG) under COSME (this includes investments in funds-of-funds with a broad investor base and includes private institutional and strategic investors as well as national public and semi-public financial institutions). In the latter case, the investment from the Equity facility of Horizon 2020 shall not exceed 20 % of the total Union investment except in cases of multi-stage funds, where funding from EFG and the Equity facility of Horizon 2020 will be provided on a pro rata basis, based on the funds' investment policy. Like the EFG, the Equity facility shall avoid buy-out or replacement capital intended for the dismantling of an acquired enterprise. The Commission may decide to amend the 20 % threshold in light of changing market conditions.

The Union Equity Financial Instrument for SMEs' R&I and growth referred to in the first paragraph of section 2 should be of an appropriate size and scale to back innovative companies from the earliest stage through to growth and expansion, in an integrated approach.

Investment parameters will be set in such a way that specific policy objectives, including the targeting of particular groups of potential beneficiaries, can be achieved while still preserving the market-oriented, demand-driven approach of this instrument.

The Equity facility may be supported by budgetary contributions from:

(a) other parts of Horizon 2020;

(b) other frameworks, programmes and budget lines in the general budget of the Union;

(c) particular regions and Member States; and

(d) specific entities or initiatives.

The leverage of the Equity facility - defined as the total funding (i.e. Union funding plus contribution from other financial institutions) divided by the Union financial contribution - is expected to be around 6, depending on market specificities, with an expected multiplier effect - defined as the total of investments made by supported beneficiaries divided by the Union financial contribution - of, on average, 18.

2.3. *Specific implementation aspects*

The implementation of the two facilities will be delegated to the European Investment Bank Group (EIB and the European Investment Fund (EIF)) and/or to other financial institutions that may be entrusted with the implementation of financial instruments in compliance with Regulation (EU, Euratom) No 966/2012. Their design and implementation will be aligned with the general provisions for financial instruments set out in that Regulation and with more specific operational requirements to be set out in Commission guidance. The use of financial instruments must have a clear European added value and should provide leverage and function as a complement to national instruments.

Financial intermediaries, selected by entrusted entities for the implementation of financial instruments pursuant to Article 139(4) of Regulation (EU, Euratom) No 966/2012 on the basis of open, transparent, proportionate and non-discriminatory procedures, may include private financial institutions as well as governmental and semi-governmental financial institutions, national and regional public banks as well as national and regional investment banks.

Their elements may be combined, with the possible addition of grants (including lump sums), in one or more integrated schemes supporting particular categories of beneficiary or special-purpose projects, such as SMEs and mid-caps with growth potential, or the large-scale demonstration of innovative technologies.

Their implementation will be supported by a set of accompanying measures. These may include technical assistance for financial intermediaries involved in assessing the eligibility of loan applications or the value of knowledge assets; investment-readiness schemes covering incubating, coaching and mentoring SMEs and fostering their interaction with potential investors; measures to raise the awareness of venture capital firms and business angels of the growth potential of innovative SMEs involved in Union funding programmes; schemes to attract private investors to support the growth of innovative SMEs and mid-caps; actions to improve cross-border and multi-country debt and equity financing; schemes for encouraging philanthropic foundations and individuals to support R&I; and schemes to foster corporate venturing and encourage the activities of family offices and business angels.

Bodies such as regional authorities, SMEs associations, chambers of commerce and relevant financial intermediaries may be consulted, as appropriate, in relation to the preparation and implementation of these activities.

Complementarity will be ensured with the facilities of COSME.

3. INNOVATION IN SMES

3.1. *Mainstreaming SME support, especially through a dedicated instrument*

SMEs will be supported across Horizon 2020. For this purpose, to participate in Horizon 2020, better conditions for SMEs shall be established. In addition, a dedicated SME instrument is targeted at all types of innovative SMEs showing a strong ambition to develop, grow and internationalise. It will be provided for all types of innovation, including non-technological, social and service innovations, given each activity has a clear European added value. The objective is to help fill the gap in funding for early stage high-risk research and innovation, stimulate breakthrough innovations and increase private-sector commercialisation of research results.

All specific objectives of the priority "Societal challenges" and the specific objective "Leadership in enabling and industrial technologies" shall apply the dedicated SME instrument and allocate an appropriate amount to it, to reach the minimum goal of 20 % of total combined budgets for all specific objectives of the priority "Societal challenges" and the specific objective 'Leadership in enabling and industrial technologies' being devoted to SMEs.

Only SMEs will be allowed to apply for funding and support. They can form collaborations according to their needs, including for subcontracting research and development work. Projects must be of clear interest and potential benefit to SMEs and have a clear European dimension.

The SME instrument will cover all fields of science, technology and innovation in a bottom-up approach within a given societal challenge or enabling technology so as to leave sufficient room for all kinds of promising ideas, notably cross-sector and interdisciplinary projects, to be funded.

The SME instrument will operate under a single centralised management system, light administrative regime and a single entry point. It shall be implemented primarily in a bottom-up manner through a continuously open call.

The SME instrument will provide simplified and staged support. Its three phases will cover the whole innovation cycle. Transition from one phase to the next will be seamless, provided that the SME project has proven to be worth further funding during a previous phase. There is no obligation for applicants to sequentially cover all three phases. At the same time each phase will be open to all SMEs:

— Phase 1: Concept and feasibility assessment:

SMEs will receive funding to explore the scientific or technical feasibility and the commercial potential of a new idea (proof of concept) in order to develop an innovation project. A positive outcome of this assessment, in which the linkage between project-topic and potential user/buyer needs is an important issue, will allow for funding under the following phase(s).

— Phase 2: R&D, demonstration, market replication:

With due attention to the innovation voucher concept, research and development will be supported with a particular focus on demonstration activities (testing, prototype, scale-up studies, design, piloting innovative processes, products and services, validation, performance verification etc.) and market replication encouraging the involvement of end users or potential clients. Innovation Vouchers will promote the participation of young entrepreneurs.

— Phase 3: Commercialisation:

This phase will not provide direct funding other than support activities, but aims to facilitate access to private capital and innovation enabling environments. Links to the financial instruments (see section 2 'Access to Risk Finance' of Part II) are foreseen, for example by giving SMEs that have successfully completed phases 1 and/or 2 priority within a ring-fenced volume of financial resources. SMEs will also benefit from support measures such as networking, training, coaching and advice. In addition, this phase may connect to measures promoting pre-commercial procurement and procurement of innovative solutions.

Uniform promotion, implementation and monitoring of the SME instrument across Horizon 2020 will ensure easy access for SMEs. Relying on existing SME support networks, such as the Europe Enterprise Network and other innovation service providers, a mentoring scheme for the beneficiary SMEs shall be established to accelerate impact from the support provided. In addition, links will be explored with relevant national and/or regional intermediaries to ensure an efficient implementation of the mentoring scheme.

A dedicated body of stakeholders and experts in SME research and innovation will be set up with view to promoting and accompanying the specific SME measures of Horizon 2020.

3.2. *Specific support*

3.2.1. Support for research-intensive SMEs

A specific action will promote transnational market-oriented innovation of R&D performing SMEs. It targets research-intensive SMEs in any sectors that also need to demonstrate their capability to commercially exploit the project results.

The action will cover the entire field of science and technology with a bottom-up approach to fit the needs of R&D performing SMEs.

The action will be implemented by an Article 185 TFEU initiative building on the Eurostars Programme and reorienting it along the lines stated in its interim evaluation.

3.2.2. Enhancing the innovation capacity of SMEs

Transnational activities assisting the implementation of and complementing the SME specific measures across Horizon 2020 will be supported, notably to enhance the innovation capacity of SMEs. Activities may include awareness raising, information and dissemination, training and mobility activities, networking and exchange of best practices, developing high quality innovation support mechanisms and services with strong Union added value for SMEs (e.g. intellectual property and innovation management, knowledge transfer, innovative use of ICT and e-skills in SMEs), as well as assisting SMEs to connect to research and innovation partners across the Union, allowing them to spin in technology and develop their innovation capacity. Intermediary organisations representing groups of innovative SMEs shall be invited to conduct cross-sectoral and cross-regional innovation activities with SMEs having mutually reinforcing competences, in order to develop new industrial value chains.

These activities shall be coordinated with similar national measures when appropriate. Close cooperation with the National Contact Point (NCP) Network is envisaged. Synergies with Union cohesion policy will be sought in the context of national and regional innovation strategies for smart specialisation.

A reinforced link with the Enterprise Europe Network (EEN) (under COSME) is envisaged ensuring its coordination with the National Contact Points. The support could range from improved information and advisory services through mentoring, coaching and partner search activities for SMEs wishing to develop cross-border innovation projects, to providing innovation support services. This will consolidate the 'one stop shop' approach of the Enterprise Europe Network to supporting SMEs, together with a strong regional and local presence of the network.

3.2.3. Supporting market-driven innovation

These activities will support transnational market-driven innovation in view of enhancing the innovation capacity of SMEs by improving the framework conditions for innovation as well as tackling the specific barriers preventing the growth of innovative SMEs with potential for fast growth. Specialised innovation support (on e.g. exploitation of intellectual property, networks of procurers, support to technology transfer offices, and strategic design) and reviews of public policies in relation to innovation will be supported.

PART III

SOCIETAL CHALLENGES

1. HEALTH, DEMOGRAPHIC CHANGE AND WELL-BEING

Effective health promotion, supported by a robust evidence base, prevents disease, contributes to well-being and is cost-effective. Promotion of health, active ageing, well-being and disease prevention also depend on an understanding of the determinants of health, on effective preventive tools, such as vaccines, on effective health and disease surveillance and preparedness, and on effective screening programmes.

Successful efforts to prevent, detect early, manage, treat and cure disease, disability, frailty and reduced functionality are underpinned by the fundamental understanding of their causes, processes and impacts, as well as factors underlying good health and well-being. Improved understanding of health and disease will demand close linkage between fundamental, clinical, epidemiological and socio-economic research. Effective sharing of data and the linkage of these data with real-world large-scale cohort studies is also essential, as is the translation of research findings into the clinic, in particular through the conduct of clinical trials.

It is a societal challenge to adjust to the further demands on health and care sectors due to the ageing population. If effective health and care is to be maintained for all ages, efforts are required to improve and speed up decision making in prevention and treatment provision, to identify and support the dissemination of best practice in the health and care sector, to raise awareness and to support integrated care. A better understanding of ageing processes and the prevention of age-related illnesses are the basis for keeping European citizens healthy and active throughout the course of their lives. Similarly important is the wide uptake of technological, organisational and social innovations empowering older persons, persons with chronic diseases as well as disabled persons, to remain active and independent. Doing so will contribute to increasing their physical, social, and mental well-being and lengthening the duration thereof.

This specific objective should address in the relevant activities chronic conditions and diseases including but not limited to: cardiovascular disease, cancer, metabolic diseases and risk factors including diabetes, chronic pain, neurological, neurodegenerative, mental health and substance use disorders, rare diseases, overweight and obesity, autoimmune diseases, rheumatic and musculo-skeletal disorders and various diseases affecting different organs as well as acute conditions and various functional limitations. Likewise infectious diseases, including but not limited to HIV/AIDS, tuberculosis and malaria, neglected and poverty related diseases and animal-borne diseases, emerging epidemics, re-emerging infectious diseases (including water-related diseases) as well as the threat of increasing anti-microbial resistance and occupational diseases and work related disorders should be addressed.

Personalised medicine should be developed in order to suit preventive and therapeutic approaches to patient requirements, and must be underpinned by the early detection of disease.

All of these activities will be undertaken in such a way as to provide support throughout the research and innovation cycle, strengthening the competitiveness of the European based industries and development of new market opportunities. Support will be given to translational approaches that integrate several steps of the innovation process in the health care industry.

Specific activities are described below.

1.1. *Understanding health, well-being and disease*

1.1.1. Understanding the determinants of health, improving health promotion and disease prevention

A better understanding of the determinants of health is required in order to provide evidence for effective health promotion and disease prevention, and will also allow the development of comprehensive health and well-being indicators in the Union based on existing data sources and indicator systems. Environmental, behavioural (including life-style), psychological, organisational, cultural, socio-economic, biological and genetic factors, in their broadest senses, will be studied. Approaches will include the long term study of cohorts and their linkage with data derived from "omics" research, systems bio-medicine including relevant applications of systems biology and other methods.

In particular, a better understanding of the environment as a determinant of health will require an interdisciplinary approach integrating amongst others human-relevant molecular biological, epidemiological and toxicological approaches and resultant data to study the modes of action of various chemicals, combined exposures to pollutants and other

environmental and climate-related stressors, to perform integrated toxicological testing and to seek alternatives to animal testing. Innovative approaches to exposure assessment are needed using new-generation biomarkers based on 'omics' and epigenetics, human biomonitoring, personal exposure assessments and modelling to understand combined, cumulative and emerging exposures, integrating socio-economic, cultural, occupational, psychological and behavioural factors. Improved links with environmental data using advanced information systems will be supported.

In this way, existing and planned policies and programmes can be assessed and policy support provided. Similarly, improved behavioural interventions, prevention and education programmes can be developed, including those pertaining to health literacy in nutrition, physical activity, vaccination and other primary care interventions.

1.1.2. Understanding disease

There is a need for an improved understanding of health and disease, throughout the human life cycle, so that new and better prevention measures, diagnosis, treatments and rehabilitation measures can be developed. Interdisciplinary, basic and translational research on the patho-physiology of disease is essential to improve the understanding of all aspects of disease processes, including a re-classification of normal variation and disease based on molecular data, and to validate and use research results in clinical applications.

Underpinning research will encompass and encourage development and use of new tools and approaches for the generation of biomedical data and will include bio-imaging, "omics", high throughput and systems medicine approaches. These activities will demand close linkage between fundamental and clinical research and with long term cohort studies (and the corresponding research domains) as described above. Close links with research and medical infrastructures (databases, bio-banks etc.) will also be required for standardisation, storage, sharing and access to data, which are all essential for maximising data utility and for stimulating more innovative and effective ways of analysing and combining datasets.

1.1.3. Improving surveillance and preparedness

Human populations are under threat from new and emerging infections, including of zoonotic origin, as well as from those which result from drug resistance to existing pathogens and from other direct and indirect consequences of climate change and from the international movement of people. New or improved methods for surveillance, diagnosis, early warning networks, health service organisation and preparedness campaigns are needed for the modelling of epidemics and for effective pandemic response. Efforts to maintain and enhance capabilities to combat drug-resistant infectious diseases are also needed.

1.2. *Preventing disease*

1.2.1. Developing effective prevention and screening programmes and improving the assessment of disease susceptibility

The development of prevention and screening programmes depends on the identification of early biomarkers (including functional and behavioural) of risk and of disease onset, and their design should be informed by internationally accepted criteria. Their deployment depends on the testing and validation of screening methods and programmes. Knowledge should be generated and methods developed for identifying individuals and populations at a clinically relevant increased risk of disease. Identifying individuals and populations at high risk of disease will allow personalised, stratified and collective strategies for efficacious and cost-effective disease prevention to be developed.

1.2.2. Improving diagnosis and prognosis

An improved understanding of health, disease and disease processes throughout the life cycle is needed to develop new and more effective diagnostics and theranostics. Innovative and existing methods, technologies and tools will be developed with the goal of significantly improving disease outcomes through earlier, more accurate diagnosis and prognosis and by allowing for accessible, more patient-adapted, treatment.

1.2.3. Developing better preventive and therapeutic vaccines

There is a need for more effective preventive and therapeutic interventions and vaccines and evidence-based vaccination schemes for an expanded range of diseases, including poverty-related diseases such as HIV/AIDS, tuberculosis, malaria and neglected infectious diseases and also for other major diseases. This relies on a better understanding of disease and disease processes and their consequent epidemics and on clinical trials and associated studies being undertaken.

1.3. *Treating and managing disease*

1.3.1. Treating disease, including developing regenerative medicine

There is a need to support the improvement of cross-cutting support technologies for drugs, biotherapies, vaccines and other therapeutic approaches, including transplantation, surgery, gene and cell therapy and nuclear medicine; to increase success in the drug and vaccine development process (including alternative methods to replace classical safety and effectiveness testing, e.g. the development of new methods); to develop regenerative medicine approaches, including approaches based on stem cells; to develop new biopharmaceuticals, including therapeutic vaccines; to develop improved medical and assistive devices and systems; to improve palliative therapies; to maintain and enhance the ability to combat disease and undertake medical interventions that depend on the availability of effective and safe antimicrobial drugs; and to develop comprehensive approaches to treat co-morbidities at all ages and avoid polypharmacy. These improvements will facilitate the development of new, more efficient, effective, sustainable and personalised treatments for disease and for the management of disability and frailty, including advanced therapies and cellular therapies for the treatment of chronic diseases.

1.3.2. Transferring knowledge to clinical practice and scalable innovation actions

Clinical trials are an important means to transfer biomedical knowledge to application in patients, and support for these will be provided, as well as for the improvement of their practice. Examples include the development of better methodologies to allow trials to focus on relevant population groups, including those suffering from other concomitant diseases and/or already undergoing treatment; the determination of comparative effectiveness of interventions and solutions; and enhancing the use of databases and electronic health records as data sources for trials and knowledge transfer. Pre-clinical and/or clinical development of designated orphan drugs will be supported. Similarly, support for the transfer of other types of interventions, such as those related to independent living, into real world environments will be provided.

1.4. *Active ageing and self-management of health*

1.4.1. Active ageing and independent and assisted living

Multidisciplinary advanced and applied research and innovation with socioeconomic, behavioural, gerontological, digital and other sciences is needed for cost-effective user-friendly solutions for active, independent and assisted daily living (in the home, the workplace, public spaces, etc.) for the ageing population and people with disabilities taking into account gender differences. This applies in a variety of settings and for technologies and systems and services enhancing quality of life and human functionality including mobility, smart personalised assistive technologies, service and social robotics, and ambient assistive environments. Research and innovation pilots to assess implementation and wide uptake of solutions will be supported. Involvement of end-users, user communities and formal/informal carers will be emphasised.

1.4.2. Individual awareness and empowerment for self-management of health

Empowering individuals to improve and manage their health throughout life will result in more cost-effective health and care systems by enabling the management of chronic disease outside institutions and improving health outcomes. This requires research into socio-economic factors and cultural values, behavioural and social models, attitudes and aspirations in relation to personalised health technologies, mobile and/or portable tools, new diagnostics, sensors and devices for monitoring and personalised services including but not limited to nanomedicine-based tools which promote a healthy lifestyle, well-being, mental health, self-care, improved citizen/healthcare professional interaction, personalised programmes for disease and disability management to, inter alia, enhance patients' autonomy, as well as support for knowledge infrastructures. Solutions will be developed and tested with the use of open innovation platforms such as large-scale demonstrators for social and service innovation.

1.5. *Methods and data*

1.5.1. Improving health information and better use of health data

The integration of infrastructures and information structures and sources (including those derived from cohort studies, protocols, data collections, indicators, health examination surveys etc.) as well as the standardisation, interoperability, storage, sharing of and access to data, will be supported to enable such data to be sustainable in the long-term and properly exploited. Attention should be given to data processing, knowledge management, modelling, visualisation, ICT-security and privacy-related issues. In particular, availability of information and data on negative results and adverse effects of treatment need to be improved.

1.5.2. Improving scientific tools and methods to support policy making and regulatory needs

There is a need to support research, development, integration and use of scientific tools, methods and statistics for rapid, accurate and predictive assessment of the safety, efficacy and quality of health interventions and technologies including new drugs, biologics, advanced therapies and medical devices. This is particularly relevant for new developments in domains concerning biopharmaceuticals, vaccines, antimicrobials, cell/tissue and gene therapies, organs and transplantation, specialist manufacturing, biobanks, new medical devices, combination products, diagnostic/treatment procedures, genetic testing, interoperability and e-health, including privacy aspects. Similarly, support for improved risk assessment methodologies, compliance frameworks, testing approaches and strategies relating to environment and health is required. There is also a need to support the development of relevant methods for assisting the assessment of ethical aspects of the above-mentioned domains.

1.5.3. Using in-silico medicine for improving disease management and prediction

Computer simulation-based medical systems using patient-specific data and building on systems medicine approaches and physiological modelling can be used to predict susceptibility to disease, disease evolution and the likely success of medical treatments. Model-based simulation can be used to support clinical trials, predictability of treatment response, and the personalisation and optimisation of treatment.

1.6. *Health care provision and integrated care*

1.6.1. Promoting integrated care

Supporting the management of chronic disease, including patients with disabilities, outside institutions also depends on improved cooperation between the providers of health and social or informal care. Research and innovative applications will be supported for decision making based on distributed information addressing both physical and mental health, including psychosocial aspects, and for providing evidence for large-scale deployments and market exploitation of novel solutions, including interoperable tele-health and tele-care services. Particularly in the context of demographic change, research and innovation to improve the organisation of long-term care delivery as well as policy and management innovation will also be supported. Implementing new and integrated care solutions shall aim at personal empowerment and enhancement of existing capabilities as well as concentrate on compensation of deficits.

1.6.2. Optimising the efficiency and effectiveness of healthcare provision and reducing inequalities by evidence-based decision making and dissemination of best practice, and innovative technologies and approaches

There is a need to support the development of a systemic approach to health technology assessment and health economics, as well as the gathering of evidence and dissemination of best practice and innovative technologies and approaches in the health and care sector, including ICT and e-health applications. Comparative analyses of the reform of public health systems in Europe and in third countries and assessments of their mid- to long-term economic and social impacts will be supported. Analyses of future health workforce needs both in terms of numbers and required skills in relation to new patterns of care will be supported. Research on the evolution of health inequalities, on their interplay with other economic and social inequalities and on the effectiveness of policies aiming to reduce them in Europe and beyond will be supported. Finally, there is a need to support the assessment of patient safety solutions and quality assurance systems, including the role of patients.

1.7. *Specific implementation aspects*

Implementation of this specific objective will include support for knowledge and technology transfer and other forms of dissemination, for large-scale piloting and demonstration actions, and for standardisation. In this way, market deployment of products and services will be accelerated, and scalable solutions for Europe and beyond will be validated. Such actions will not only support European industrial competitiveness and the involvement of innovative SMEs but will require the active involvement of all stakeholders. Synergies with other relevant programmes and activities, both public and private, at Union, national and international levels will be sought. In particular, synergies with activities developed in the context of the Health for Growth Programme will be sought.

The Scientific Panel for Health will be a science-led stakeholder platform which elaborates scientific input concerning this societal challenge. It will provide a coherent scientific focused analysis of research and innovation bottlenecks and opportunities related to this societal challenge, contribute to the definition of its research and innovation priorities, and encourage Union-wide scientific participation in it. Through active cooperation with stakeholders, it will help to build capabilities and to foster knowledge sharing and stronger collaboration across the Union in this field.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and relevant public-public and public-private partnerships.

Appropriate links with the actions of relevant European Innovation Partnerships and the relevant aspects of the research and innovation agendas of European Technology Platforms will also be established.

2. FOOD SECURITY, SUSTAINABLE AGRICULTURE AND FORESTRY, MARINE, MARITIME AND INLAND WATER RESEARCH, AND THE BIOECONOMY

2.1. *Sustainable agriculture and forestry*

Appropriate knowledge, tools, services and innovations are necessary to support more productive, environmentally friendly resource-efficient and resilient agriculture and forestry systems that supply sufficient food, feed, biomass and other raw materials and deliver ecosystems services while at the same time protecting biodiversity and supporting the development of thriving rural livelihoods. Research and innovation will provide options for integrating agronomic and environmental goals into sustainable production, thus: increasing productivity and resource efficiency, including water use efficiency, of agriculture; increasing the safety of animal and plant production; reducing agricultural greenhouse gas emissions; reducing the production of waste; reducing leaching of nutrients and other chemical inputs from cultivated lands into terrestrial and aquatic environments; decreasing dependence from international plant derived protein imports to Europe; increasing the level of diversity in primary production systems; and fostering the recovery of biological diversity.

2.1.1. Increasing production efficiency and coping with climate change, while ensuring sustainability and resilience

Activities will enhance productivity as well as the adaptive capacity of plants, animals and production systems to cope with rapidly changing environmental/climatic conditions and increasingly scarce natural resources. The resulting innovations will help to move towards a low energy, low emission and low waste economy and to reduce natural resources demand along the entire food and feed supply chain. In addition to contributing to food security, new opportunities will be created for the use of biomass and by-products from agriculture for a wide range of non-food applications.

Multi-disciplinary approaches will be sought to improve the performance of plants, animals and micro-organisms, while ensuring efficient resource use (water, land, soil, nutrients, energy and other inputs) and the ecological integrity of rural areas. Emphasis will be placed on integrated and diverse production systems and agronomic practices, including the use of precision technologies and ecological intensification approaches to benefit both conventional and organic agriculture. Also urban greening will be promoted, with new forms of agriculture, horticulture and forestry in urban and peri-urban areas. These shall be considered by addressing new requirements for plant characteristics, cultivation methods, technologies, marketing and urban design, in relation with human health and well-being, environment and climate change. Genetic improvement of plants and animals for adaptation, health and productivity traits will call for all appropriate conventional and modern breeding approaches and for preservation and better use of genetic resources.

Due attention will be given to soil management for increasing the productivity of crops. Bearing in mind the overall objective of ensuring high quality and safe food production, plant and animal health will be promoted. Activities in the area of plant health and plant protection will increase knowledge and support the development of integrated environmentally friendly pest management strategies, products and tools to prevent the introduction of pathogens, control pest and diseases and reduce yield losses at pre- and post-harvest levels. In the area of animal health, strategies for the eradication or effective management of diseases, including zoonoses, and research on antimicrobial resistance will be promoted. Integrated control of disease, parasites and pests will be strengthened, starting from a better understanding of host-pathogen interactions, to surveillance, diagnostics and treatments. Studying the effects of practices on animal welfare will help meet societal concerns. The above listed areas will be underpinned by more fundamental research to address relevant biological questions as well as to support the development and implementation of Union policies and supported by adequate assessment of their economic and market potential.

2.1.2. Providing ecosystem services and public goods

Agriculture and forestry are unique systems delivering commercial products but also wider societal public goods (including cultural and recreational value) and important ecological services such as functional and in-situ biodiversity, pollination, water storage and regulation, soil functions, landscape, erosion reduction, resilience to flooding and droughts and carbon sequestration / greenhouse gas mitigation. Research activities will contribute to a better understanding of the complex interactions between primary production systems and ecosystems services and will support the provision of these public goods and services, through the delivery of management solutions, decision-support tools and the assessment

of their market and non-market value. Specific issues to be dealt with include the identification of rural and (peri-)urban farming/forest systems and landscape patterns likely to achieve these goals. Shifts in the active management of agricultural systems - including the use of technologies and change of practices - will increase greenhouse gas mitigation and the adaptive capacity of the agriculture sector to the adverse effects of climate change.

2.1.3. Empowerment of rural areas, support to policies and rural innovation

Development opportunities for rural communities will be mobilised by strengthening their capacity for primary production and delivery of ecosystems services as well as by opening avenues for the production of new and diversified products (including food, feed, materials and energy) which meet the increasing demand for low-carbon short-chain delivery systems. Socio-economic research and science and society studies along with the development of new concepts and institutional innovations is needed to ensure cohesion of rural areas and prevent economic and social marginalisation, foster diversification of economic activities (including the service sector), ensure appropriate relations between rural and urban areas, as well as facilitate knowledge exchange, demonstration, innovation and dissemination and foster participatory resource management. Also, there is a need to look at ways in which public goods in rural areas can be converted into local/regional socio-economic benefits. Innovation needs defined at regional and local levels will be complemented by cross-sectoral research actions at international, inter-regional and European levels. By providing the necessary analytical tools, indicators, integrated models and forward-looking activities, research projects will support policy makers and other actors in the implementation, monitoring and assessment of relevant strategies, policies and legislation, not only for rural areas but for the whole bioeconomy. Tools and data are also required to allow for proper assessment of potential trade-offs between various types of resource use (land, water, soil, nutrients, energy and other inputs) and bioeconomy products. Socio-economic and comparative assessment of farming/forestry systems and their sustainability performance will be addressed.

2.1.4. Sustainable forestry

The aim is to sustainably produce bio-based products ecosystems, services (including water-related and climate-mitigation services) and sufficient biomass, with due consideration to economical, ecological and social aspects of forestry as well as to regional differences. Overall, activities in the forestry sector will seek to promote multi-functional forests which deliver a variety of ecological, economic, and social benefits. Activities will focus on the further development of sustainable forestry systems which can address societal challenges and demands, including forest owners' needs, by putting in place multifunctional approaches that reconcile the need for delivering smart, sustainable and inclusive growth taking into account climate change. These sustainable forestry systems are instrumental in the strengthening of forest resilience and biodiversity protection and the need to meet the increased biomass demand. This will need to be underpinned by research on tree health and on forest protection and restoration from fire.

2.2. *Sustainable and competitive agri-food sector for a safe and healthy diet*

Consumer needs for safe, healthy, high quality and affordable food have to be addressed, while considering the impacts of food consumption behaviour and food and feed production on human health, the environment and the global ecosystem. Food and feed security and safety, the competitiveness of the European agri-food industry and the sustainability of food production, supply and consumption will be addressed, covering the whole food chain and related services, whether conventional or organic, from primary production to consumption. This approach will contribute to achieving food safety and security for all Europeans and eradication of hunger in the world; decreasing the burden of food- and diet-related diseases by promoting the shift towards healthy and sustainable diets, via consumer education and innovations in agriculture and the food industry; reducing water and energy consumption in food processing, transport and distribution; reducing food waste by 50 % by 2030; and achieving a broad diversity of healthy, high quality and safe food for all.

2.2.1. Informed consumer choices

Consumer preferences, attitudes, needs, behaviour, lifestyle and education as well as the cultural component of food quality will be addressed, and communication between consumers and the food chain research community and its stakeholders will be enhanced in order to improve public understanding of food production generally and to enable informed choice, sustainable and healthy consumption and their impacts on production, inclusive growth and quality of life, especially of vulnerable groups. Social innovation will respond to societal challenges, and innovative predictive models and methodologies in consumer science will deliver comparable data and lay the ground for responses to Union policy needs.

2.2.2. Healthy and safe foods and diets for all

Nutritional needs, a balanced diet and the impact of food on physiological functions and on physical and mental performance will be addressed as well as the links between diet, demographic trends (such as ageing) and chronic diseases and disorders. Dietary solutions and innovations leading to improvements in health and well-being will be identified. Chemical and microbial food and feed contamination, risks and exposures as well as allergens will be analysed, assessed, monitored, controlled and traced throughout the food, feed and drinking water supply chains from production and storage to processing, packaging, distribution, catering, and preparation at home. Food safety innovations, improved tools for risk and risk-benefit assessment and for risk communication and improved food safety standards to be implemented throughout the food chain will lead to enhanced consumer trust and protection in Europe. Globally improved food safety standards will also help to strengthen the competitiveness of the European food industry.

2.2.3. A sustainable and competitive agri-food industry

The needs for the food and feed industry to cope with social, environmental, climate and economic change from local to global will be addressed at all stages of the food and feed production chain, including food design, processing, packaging, process control, waste reduction, by-product valorisation and the safe use or disposal of animal by-products. Innovative and sustainable resource-efficient technologies and processes as well as diversified, safe, healthy, affordable and high quality products will be generated and underpinned with science-based evidence. This will strengthen the innovation potential of the European food supply chain, enhance its competitiveness, create economic growth and employment and allow the European food industry to adapt to changes. Other aspects to address are traceability, logistics and services, socio-economic and cultural factors, animal welfare and other ethical issues, the resilience of the food chain against environmental and climate risks, the limitation of negative impacts of food chain activities and of changing diets and production systems on the environment.

2.3. *Unlocking the potential of aquatic living resources*

One of the main features of living aquatic resources is that they are renewable and their sustainable exploitation relies on in-depth understanding and a high degree of quality and productivity of the aquatic ecosystems. The overall objective is to manage aquatic living resources to maximise social and economic benefits/returns from Europe's oceans, seas and inland waters.

This includes the need to optimise the sustainable contribution of fisheries and aquaculture to food security in the context of the global economy and to reduce the Union's heavy dependence on seafood imports (approximately 60 % of total European seafood consumption depends on import, and the Union is the world's largest importer of fisheries products), and to boost marine and maritime innovation through biotechnologies to fuel smart "blue" growth. In line with current policy frameworks, in particular the Integrated Maritime Policy and the Marine Strategy Framework Directive ([1]), research activities will underpin the ecosystem approach to the management and exploitation of natural resources, while enabling sustainable use of marine goods and services, and the 'greening' of the sectors involved.

2.3.1. Developing sustainable and environmentally friendly fisheries

The new Common Fisheries Policy, the Marine Strategy Framework Directive and the Union's 2020 Biodiversity Strategy call for European fisheries to be more sustainable, competitive, and environmentally friendly. The move towards an ecosystem approach to fisheries management will require an in-depth understanding of marine ecosystems. New insights, tools and models will be developed to improve understanding of what makes marine ecosystems healthy and productive and to assess, evaluate and mitigate the impact of fisheries on marine ecosystems (including deep sea). New harvest strategies and technologies will be developed which provide services to society while maintaining healthy marine ecosystems. The socio-economic effects of management options will be measured. The effects and adaptation to environmental changes, including climate change, will also be investigated along with new assessment and management tools to deal with risk and uncertainty. Activities will support research on the biology, genetics and dynamics of fish populations, on the role of key species in the ecosystems, on fishing activities and their monitoring, on fishing sector behaviours and adaptation to new markets (e.g. eco-labelling) and on fishing industry involvement in decision making. The shared use of maritime space with other activities, particularly in the coastal zone, and its socio-economic impact will also be addressed.

([1]) Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

2.3.2. Developing competitive and environmentally friendly European aquaculture

Sustainable aquaculture has a large potential for the development of healthy, safe and competitive products tailored to consumer needs and preferences as well as for environmental services (bioremediation, land and water management etc.) and energy production but it needs to be fully realised in Europe. Knowledge and technologies will be strengthened in all aspects of domestication of established species and diversification for new species while taking into account the interactions between aquaculture and the aquatic ecosystems in order to reduce the impact of aquaculture on the environment, and the effects of climate change and how the sector can adapt to them. Continuation of research efforts is particularly needed on health and diseases of farmed aquatic organisms (including prevention and mitigation tools and methods), on nutrition issues (including development of alternative tailor-made ingredients and feeds for aquaculture), and on reproduction and breeding which are among the main obstacles in the sustainable development of European aquaculture. Innovation will also be promoted for sustainable production systems inland, on the coastal zone and offshore. The specificities of the European ultra-periphery will also be taken into account. Emphasis will also be given to understanding the social and economic dimensions of the sector to underpin cost- and energy-efficient production matching with the market and consumer demands, while ensuring competitiveness and attractive prospects for investors and producers.

2.3.3. Boosting marine and maritime innovation through biotechnology

More than 90 % of the marine biodiversity remains unexplored, offering a huge potential for discovery of new species and applications in the field of marine biotechnologies, which is foreseen to generate a 10 % annual growth for this sector. Support will be given to further explore and exploit the large potential offered by marine biodiversity and aquatic biomass to bring new innovative and sustainable processes, products and services on the markets with potential applications in sectors including chemical and material industries, fisheries and aquaculture, and pharmaceutical, energy supply and cosmetic industries.

2.4. *Sustainable and competitive bio-based industries and supporting the development of a European bioeconomy*

The overall objective is to accelerate the conversion of fossil-based European industries to low-carbon, resource-efficient and sustainable ones. Research and innovation will provide the means to reduce the Union's dependency on fossil fuels and contribute to meeting its energy and climate change policy targets for 2020 (10 % of transport fuels from renewables and a 20 % reduction of greenhouse gas emissions). Estimates conclude that a shift to biological raw materials and biological processing methods could save up to 2,5 billion tons of CO_2 equivalent per year by 2030, increasing markets for bio-based raw materials and new consumer products substantially. Reaping these potentials requires building a broad knowledge base and developing relevant (bio)technologies, focusing mainly on three essential elements: a) transforming current fossil-based processes by resource- and energy-efficient biotechnology-based ones; b) establishing reliable, sustainable and appropriate supply chains of biomass, byproducts and waste streams and a wide network of biorefineries throughout Europe; and c) supporting market development for bio-based products and processes, taking account of the associated risks and benefits. Synergies will be sought with the specific objective 'Leadership in Enabling and Industrial Technologies'.

2.4.1. Fostering the bioeconomy for bio-based industries

Major progress towards low-carbon, resource-efficient and sustainable industries will be supported through discovery and exploitation of terrestrial and aquatic biological resources, while minimising adverse environmental impacts and water footprint, for example through the establishment of closed circuits of nutrients, including between urban and rural areas. Potential trade-offs between the various uses of biomass should be examined. Activities should focus on non-food-competitive biomass and also consider the sustainability of related land use systems. The development of bio-based products and biologically active compounds for industries and consumers with novel qualities, functionalities and improved sustainability will be targeted. The economic value of renewable resources, biowaste and by-products will be maximised through new and resource-efficient processes, including the transformation of urban biowaste into agricultural inputs.

2.4.2. Developing integrated biorefineries

Activities will be supported to boost sustainable bioproducts, intermediates and bioenergy/biofuels, predominantly focusing on a cascade approach, prioritising the generation of high added value products. Technologies and strategies will be developed to assure the raw material supply. Enhancing the range of types of biomass for use in second and third generation biorefineries, including forestry, biowaste and industrial by-products, will help avoid food/fuel conflicts and support economic and environmentally friendly development of rural and coastal areas in the Union.

2.4.3. Supporting market development for bio-based products and processes

Demand-side measures will open new markets for biotechnology innovation. Standardisation and certification at Union and international levels is needed for, amongst others, determination of bio-based content, product functionalities and biodegradability. Methodologies and approaches to life-cycle analysis need to be further developed and continuously adapted to scientific and industrial advances. Research activities supporting product and process standardisation (including harmonisation of international standards) and regulatory activities in the field of biotechnology are considered essential for supporting the creation of new markets and for realising trade opportunities.

2.5. *Cross-cutting marine and maritime research*

The aim is to increase the impact of Union seas and oceans on society and economic growth through the exploitation of marine resources as well as the use of different sources of marine energy and the wide range of different uses that is made of the seas. Activities shall focus on cross-cutting marine and maritime scientific and technological challenges with a view to unlocking the potential of seas and oceans across the range of marine and maritime industries, while protecting the environment and adapting to climate change. A strategic coordinated approach for marine and maritime research across all challenges and priorities of Horizon 2020 will also support the implementation of relevant Union policies to help deliver key blue growth objectives.

Due to the multidisciplinary nature of marine and maritime research, close coordination and joint activities with other parts of Horizon 2020, especially the specific objective "Climate action, environment, resource efficiency and raw materials" of the priority "Societal challenges", will be pursued.

2.5.1. Climate change impact on marine ecosystems and maritime economy

Activities will be supported to increase the current understanding of the functioning of marine ecosystems and the interactions between oceans and the atmosphere. This will increase the ability to assess the role of the oceans on climate and the impact of climate change and ocean acidification on marine ecosystems and coastal areas.

2.5.2. Developing the potential of marine resources through an integrated approach

Boosting long-term, sustainable maritime growth and creating synergies across all maritime sectors requires an integrated approach. Research activities will focus on preserving the marine environment as well as on the impact of maritime activities and products on non-maritime sectors. This will allow advances in the field of eco-innovation, such as new products, processes and the application of management concepts, tools and measures, to assess and mitigate the impact of human pressures on the marine environment in order to advance towards a sustainable management of maritime activities.

2.5.3. Cross-cutting concepts and technologies enabling maritime growth

Advances in cross-cutting enabling technologies (e.g. ICT, electronics, nanomaterials, alloys, biotechnologies, etc.) and new developments and concepts in engineering will continue to enable growth. Activities will allow major breakthroughs in the field of marine and maritime research and ocean observation (e.g. deep-sea research, observing systems, sensors, automated systems for monitoring of activities and surveillance, screening marine biodiversity, marine geohazards and remotely operated vehicles). The aim is to reduce the impact on the marine environment (e.g. underwater noise and introduction of invasive species and pollutants from sea and land) and to minimise the carbon foot-print of human activities. Cross-cutting enabling technologies will underpin the implementation of marine and maritime Union policies.

2.6. *Specific implementation aspects*

Beyond the general sources of external advice, specific consultations will be sought from the Standing Committee on Agricultural Research (SCAR) on a range of issues, including strategic aspects through its foresight activity and the coordination of agricultural research between national and Union levels. Appropriate links with the actions of relevant European Innovation Partnerships and the relevant aspects of the research and innovation agendas of European Technology Platforms will also be established.

The impact and dissemination of research results will be actively supported through specific actions on communication, knowledge exchange and the involvement of various actors all along the projects. Implementation will combine a wide range of activities, including substantial demonstration and pilot activities. Easy and open access to research results and best practices will be fostered.

The specific support to SMEs will allow for an increased participation of farms, fishermen and other types of SMEs in research and demonstration activities. The specific needs of the primary production sector for innovation support services and outreach structures will be taken into account. Implementation will combine a wide range of activities, including knowledge exchange actions where the involvement of farmers or other primary producers and intermediaries will be actively ensured in view of summarising the research needs of end-users. Easy and open access to research results and best practices will be fostered.

Support to standardisation and regulatory aspects will be used to help accelerate market deployment for novel bio-based goods and services.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and relevant public-public and public-private partnerships.

Synergies with and further deployment by other Union funds related to this societal challenge, such as the European Agricultural Fund for Rural Development (EAFRD) and the European Maritime and Fisheries Fund (EMFF), will be sought.

Forward-looking activities will be undertaken across the sectors of the bioeconomy, including the development of data bases, indicators and models addressing global, European, national and regional dimensions. A European bioeconomy observatory shall be developed for mapping and monitoring Union and global research and innovation activities including technology assessment, developing key performance indicators, and monitoring innovation policies in the bioeconomy.

3. SECURE, CLEAN AND EFFICIENT ENERGY

3.1. *Reducing energy consumption and carbon footprint by smart and sustainable use*

The energy sources and consumption patterns of Europe's industries, transport systems, buildings, districts, towns and cities are largely unsustainable, leading to significant environmental and climate change impacts. Real-time energy management for new and existing near-zero-emission, near-zero-energy and positive energy buildings, retrofitted buildings as well as active buildings, highly efficient industries and mass take-up of energy-efficient approaches by companies, individuals, communities, cities and districts will require not only technological advances, but also non-technological solutions such as new advisory, financing and demand management services and input from the behavioural and social sciences while at the same time taking into account questions of public acceptance. In this way improved energy efficiency may provide one of the most cost-effective ways to reduce energy demand, thereby enhancing security of energy supply, reducing environmental and climate impacts and boosting competitiveness. To meet these challenges the further development of renewable energies and the tapping of energy efficiency potentials are important.

3.1.1. Bringing to mass market technologies and services for a smart and efficient energy use

Reducing energy consumption and eliminating energy waste, while providing the services that society and economy need, requires not only that more efficient, cost-competitive, environmentally friendly and smarter equipment, products and services are brought to mass market but also the integration of components and devices in such a way that they cooperate to optimise the overall energy use of buildings, services and industry.

To ensure full adoption and full benefits for consumers (including the possibility for them to monitor their own consumption), energy performance of these technologies and services needs to be customised and optimised for and in their application environments. This requires researching, developing and testing innovative ICT and monitoring and control techniques as well as demonstration projects and pre-commercial deployment activities to ensure interoperability and scalability. Such projects should aim to contribute to significantly reducing or optimising the overall energy consumption and energy costs by developing common procedures to collect, collate and analyse energy consumption and emissions data to improve the measurability, transparency, public acceptability, planning and visibility of energy use and its environmental impacts. Security and privacy by design to protect monitoring and control techniques should be safeguarded in these processes. Developing platforms and applying them for verifying the stability of such systems will help to ensure reliability.

3.1.2. Unlocking the potential of efficient and renewable heating-cooling systems

A substantial share of energy is consumed for heating or cooling purposes across the Union, and the development of cost-effective and efficient technologies and system integration techniques, such as network connectivity with standardised languages and services in this area, would have a major impact in reducing energy demand. This requires research and

demonstration of new design techniques and systems and components for industrial, commercial and residential applications, for example in decentralised and district supply of hot water, space heating and cooling. This should encompass different technologies, such as solar, thermal, geothermal, biomass, heat pumps, combined heat and power, and recovery of waste energy, and meet the requirements of near-zero-energy buildings and districts and support smart buildings. Further breakthroughs are needed, in particular, in storage for thermal energy from renewable energy sources and to foster the development and deployment of efficient combinations of hybrid heating and cooling systems, for centralised and de-centralised applications.

3.1.3. Fostering European Smart Cities and Communities

Urban areas are one of the largest consumers of energy in the Union and emit a correspondingly large share of greenhouse gases, while generating a substantial amount of air pollutants. At the same time, urban areas are affected by decreasing air quality and climate change and have to develop their own mitigation and adaptation strategies. Finding innovative energy solutions (e.g. energy efficiency, electricity and heating and cooling supply systems, and integration of renewables in the built environment), integrated with transport systems, smart construction and urban planning solutions, waste and water treatment as well as ICT solutions for the urban environment is therefore crucial in the transformation towards a low-carbon society. Targeted initiatives in support to the convergence of industrial value chains of the energy, transport and ICT sector for smart urban applications need to be envisaged. At the same time, new technological, organisational, planning and business models need to be developed and tested at full scale according to the needs and means of cities and communities and their citizens. Research is also needed to understand the social, environmental, economic and cultural issues that are involved in this transformation.

3.2. *Low-cost, low-carbon electricity supply*

Electricity will play a central role in the establishment of an environmentally sustainable low-carbon economy. Renewable energy sources lie at the core of this development. The uptake of low-carbon electricity generation is too slow due to the high costs involved. There is a pressing need to find solutions that reduce costs significantly, with enhanced performance, sustainability and public acceptance to accelerate the market deployment of low-cost, reliable and low-carbon electricity generation. Activities shall focus on research, development and full scale demonstration of innovative renewables, including small and micro-scale energy systems, efficient, flexible and low-carbon emission fossil power plants and carbon capture and storage, or CO_2 re-use technologies.

3.2.1. Developing the full potential of wind energy

The objective for wind energy is to reduce the cost of electricity production of onshore and offshore wind by up to about 20 % by 2020 compared to 2010, to increasingly move offshore, and to enable proper integration in the electricity grid. The focus will be on the development, testing and demonstration of next generation wind energy conversion systems of larger scale (including innovative energy storage systems), higher conversion efficiencies and higher availabilities for both on- and offshore (including remote locations and hostile weather environments) as well as new serial manufacturing processes. Environmental and biodiversity aspects of wind energy development will be taken into account.

3.2.2. Developing efficient, reliable and cost-competitive solar energy systems

The cost of solar energy, covering photovoltaics (PV) and concentrating solar power (CSP), should be halved by 2020 compared to 2010, if it is to substantially increase its share of the electricity market.

For PV, this will need further research on, inter alia, novel concepts and systems as well as demonstration and testing of mass production with a view to large-scale deployment and building integration of PV.

For CSP, the focus will be on developing ways to increase efficiency while reducing costs and environmental impact, enabling industrial up-scaling of demonstrated technologies by building first-of-a-kind power plants. Solutions to efficiently combine the production of solar electricity with water desalination will be tested.

3.2.3. Developing competitive and environmentally safe technologies for CO_2 capture, transport, storage and re-use

Carbon capture and storage (CCS) is a key option that has to be widely deployed on a commercial scale at global level to meet the challenge of a decarbonised power generation and low-carbon industry by 2050. The objective is to minimise the extra-cost of CCS in the power sector for coal-fired, gas-fired and oil-shale fired power plants compared to equivalent plants without CCS and energy intensive industrial installations.

Support will be given, in particular, to demonstrate the full CCS chain for a representative portfolio of different capture, transport, storage and re-use technology options. This will be accompanied by research to further develop these technologies and to deliver more competitive capture technologies, improved components, integrated systems and processes, safe geological storage and rational solutions and public acceptance for the re-use of captured CO_2 to enable the commercial deployment of CCS technologies for fossil fuel power plants and other carbon-intensive industries going into operation after 2020. Support will also be given to clean coal technologies as technologies complementary to CCS.

3.2.4. Developing geothermal, hydro, marine and other renewable energy options

Geothermal, hydro, and marine energy as well as other renewable energies can contribute to the decarbonisation of the European energy supply while enhancing its flexibility to variable production and use of energy. The objective is to further develop and bring to commercial maturity cost-effective and sustainable technologies, enabling large-scale deployment at an industrial scale including grid integration. Enhanced geothermal systems is a technology that should be further researched, developed and demonstrated notably in the fields of exploration, drilling and heat production. Ocean energies such as tidal, current or wave energy and osmotic power offer zero-emission and predictable energy and can also contribute to the development of the full potential of offshore wind energy (combination of marine energies). Research activities should include laboratory scale innovative research into low-cost reliable components and materials in a high corrosion, biofouling environment as well as demonstrations under the varied conditions found in European waters.

3.3. *Alternative fuels and mobile energy sources*

Meeting Europe's energy and CO_2 reduction goals also requires the development of new fuels and mobile energy sources. This is particularly important to meet the challenge of smart, green and integrated transport. Value chains for these technologies and alternative fuels are not sufficiently developed and must be accelerated to demonstration scale.

3.3.1. Making bioenergy more competitive and sustainable

The objective for bioenergy is to bring to commercial maturity the most promising technologies, to permit large-scale, sustainable production of advanced biofuels of different value chains in a bio-refinery approach for surface, maritime and air transport, and highly efficient combined heat and power and green gas from biomass and waste, including CCS. The aim is to develop and demonstrate the technology for different bioenergy pathways at different scales, taking account of differing geographical and climate conditions and logistical constraints, while minimising negative environmental and social impacts linked to land use. Longer term research will support the development of a sustainable bioenergy industry beyond 2020. These activities will complement upstream (e.g. feedstock, bio-resources) and downstream (e.g. integration into vehicle fleets) research activities carried out in other relevant specific objectives of the priority "Societal challenges".

3.3.2. Reducing time to market for hydrogen and fuel cell technologies

Fuel cells and hydrogen have a great potential to contribute to addressing energy challenges facing Europe. Bringing these technologies to market competitiveness will require significant cost decrease. As an illustration the cost of fuel cell systems for transportation will have to be reduced by a factor of ten over the next 10 years. To do so, support will be given to demonstrations and pre-commercial deployment activities for portable, stationary and micro-stationary, transport applications and the related services, as well as long-term research and technology development to build up a competitive fuel cell chain and a sustainable hydrogen production and infrastructure across the Union. Strong national and international cooperation is needed to enable market breakthroughs of a sufficient scale, including the development of appropriate standards.

3.3.3. New alternative fuels

There is a range of new options with long term potential, such as powdered metal fuel, fuel from photosynthetic micro-organisms (in water and land environments) and from artificial photosynthesis mimics and solar fuels. These new paths may offer potential for more efficient energy conversion and more cost-competitive and sustainable technologies. Support will be given notably to bring these new and other potential technologies from laboratory to demonstration scale size in view of pre-commercial demonstration by 2020.

3.4. *A single, smart European electricity grid*

Electricity networks have to respond to three interrelated challenges to enable a consumer-friendly and increasingly decarbonised electricity system: creating a pan-European market; integrating a massive increase of renewable energy sources; and managing interactions between millions of suppliers and customers (where increasingly households will be both), including owners of electrical vehicles. Future electricity networks will play a key role for the transition to a decarbonised energy system, while providing additional flexibility and cost benefits to the consumers. The overriding goal by 2020 is to transmit and distribute about 35 % [1] of electricity from dispersed and concentrated renewable energy sources.

A strongly integrated research and demonstration effort will support the development of new components, technologies, and procedures which will respond to the particularities of both the transmission and distribution side of the grid, as well as flexible energy storage.

All options to successfully balance energy supply and demand must be considered to minimise emissions and costs. New smart energy grid technologies, back-up and balancing technologies enabling higher flexibility and efficiency, including conventional power plants, new grid components to improve the transmission capacity and quality as well as the reliability of grids have to be developed. New power systems technologies and a bi-directional digital communication infrastructure must be researched and integrated into the electricity grid as well as used to establish smart interactions with other energy grids. This will contribute to better planning, monitoring, control and secure operation of networks, including standardisation issues, in normal and emergency conditions as well as to managing the interactions between suppliers and customers and to transporting, managing and trading energy flow. For the deployment of future infrastructure, indicators and cost benefit analysis should take into account energy system-wide considerations. In addition, synergies between smart grids and telecommunication networks will be maximised in order to avoid duplication of investments, to increase safety and to accelerate the take up of smart energy services.

Novel energy storage means (including both batteries and large scale storage means such as power-to-gas) and vehicle systems will provide the required flexibility between production and demand. Improved ICT technologies will further increase the flexibility of electricity demand by providing customers (industrial, commercial and residential) with the necessary automation tools. Security, reliability and privacy are important issues here as well.

New planning, market and regulatory designs need to drive the overall efficiency and cost-effectiveness of the electricity supply chain and interoperability of infrastructures as well as the emergence of an open and competitive market for smart energy grid technologies, products and services. Large-scale demonstration projects are needed to test and validate solutions and assess the benefits for the system and for individual stakeholders, before deploying them across Europe. This should be accompanied by research to understand how consumers and businesses react to economic incentives, behavioural changes, information services and other innovative opportunities provided by smart grids.

3.5. *New knowledge and technologies*

Novel, more efficient and cost-competitive as well as clean, safe and sustainable energy technologies will be required for the long term. Progress should be accelerated through multi-disciplinary research and joint implementation of pan-European research programmes and world-class facilities to achieve scientific breakthroughs in energy-related concepts and enabling technologies (e.g. nano-science, material science, solid state physics, ICT, bio-science, geosciences, computation and space). Safe and environmentally sustainable unconventional gas and oil resources exploration and production as well as the development of innovations in future and emerging technologies will also be supported, where appropriate.

Advanced research will also be needed to provide solutions to adapt energy systems to changing climatic conditions. Priorities may be adjusted to new scientific and technological needs and opportunities or newly-observed phenomena which could indicate promising developments or risks to society and which may emerge during the course of implementation of Horizon 2020.

3.6. *Robust decision making and public engagement*

Energy research should support and be strongly aligned with the energy policy. Extensive knowledge and research on the uptake and use of energy technologies and services, infrastructure, markets (including regulatory frameworks) and consumer behaviour is required to provide policy makers with robust analyses. Support will be given, in particular

[1] Commission Staff Working Document SEC(2009) 1295 accompanying the Communication on "Investing in the Development of Low Carbon Technologies (SET-Plan)" (COM(2009) 519 final).

in the frame of the Commission's Information System for the SET-Plan (SETIS), to develop robust and transparent theories, tools, methods, models and forward-looking and perspective scenarios to assess the main economic and social issues related to energy; to build databases and scenarios for an enlarged Union and for the assessment of the impact of energy and energy-related policies on the security of supply, consumption, the environment, natural resources, climate change, society and competitiveness of the energy industry; and to carry out socio-economic research activities as well as science in society studies.

Taking advantage of the possibilities offered by web and social technologies, and consumer behaviour, including that of vulnerable consumers such as persons with disabilities and behavioural changes, will be studied in open innovation platforms such as living labs and large-scale demonstrators for service innovation as well as through panel surveys, while ensuring privacy.

3.7. *Market uptake of energy innovation - building on Intelligent Energy Europe (IEE)*

Innovative market uptake and replication solutions are essential for the roll-out of new energy technologies in time and through a cost-effective implementation. In addition to technology-driven research and demonstration, this requires actions with clear Union added value aiming to develop, apply, share and replicate non-technological innovations with a high leverage factor in the Union's sustainable energy markets across disciplines and levels of governance.

Such innovations will focus on creating favourable market conditions at regulatory, administrative and financing level for low-carbon, renewable and energy-efficient technologies and solutions. Support will be given to measures facilitating the energy policy implementation, preparing the ground for roll-out of the investments, supporting capacity-building and acting on public acceptance. Attention will also be given to innovation for the smart and sustainable use of existing technologies.

Research and analysis repeatedly confirm the crucial role of the human factor in the success and failure of sustainable energy policies. Innovative organisational structures, the dissemination and exchange of good practices and specific training and capacity-building actions will be encouraged.

3.8. *Specific implementation aspects*

The priority setting for the implementation of the activities in this societal challenge is led by the need to strengthen energy research and innovation at the European level. A main aim will be to support the implementation of the research and innovation agenda of the Strategic Energy Technology Plan (SET Plan) ([1]) to achieve the objectives of the Union's energy and climate change policy. The SET Plan roadmaps and implementation plans will therefore provide a valuable input for the formulation of the work programmes. The SET Plan governance structure will be used as a principle basis for strategic priority setting and the coordination of energy research and innovation across the Union.

The non-technological agenda will be guided by the Union's energy policy and legislation. The enabling environment for mass deployment of demonstrated technological and service solutions, processes and policy initiatives for low-carbon technologies and energy efficiency across the Union shall be supported. This may involve support to technical assistance for the development and roll-out of energy efficiency and renewable energy investments.

In the field of market uptake, activities shall build upon and further enhance those undertaken within the Intelligent Energy Europe (IEE) programme.

Partnering with European stakeholders will be important to share resources and implement joint activities. It may be envisaged, on a case-by-case basis, that existing European Industrial Initiatives (EIIs) of the SET Plan are turned into formalised public-private partnerships, if considered appropriate, to increase the level and coherence of funding and to stimulate joint research and innovation actions among both public and private stakeholders. Consideration will be given to provide support, including with Member States, to alliances of public research performers, in particular the European Energy Research Alliance (EERA) established under the SET Plan to pool public research resources and infrastructures to address critical research areas of European interest. International coordination actions shall support the SET Plan priorities according to the variable geometry principle, taking account of countries' capabilities and specificities. Appropriate links with the actions of relevant European Innovation Partnerships and the relevant aspects of the research and innovation agendas of European Technology Platforms will also be established.

([1]) COM(2007) 723.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and relevant public-public and public-private partnerships. Activities shall also focus on increasing the support and promoting the involvement of SMEs.

The Commission's Information System for the SET Plan (SETIS) will be mobilised to develop, together with stakeholders, key performance indicators (KPIs) to monitor the progress of implementation. These KPIs will be revised on a regular basis to account of the latest developments. More broadly, implementation under this societal challenge will seek to improve the coordination of relevant Union programmes, initiatives and policies, such as cohesion policy, in particular through the national and regional strategies for smart specialisation, and the emission trading schemes (ETS), for example concerning support to demonstration projects.

4. SMART, GREEN AND INTEGRATED TRANSPORT

4.1. *Resource-efficient transport that respects the environment*

Europe has set a policy target of achieving a 60 % reduction of CO_2 by 2050 compared to 1990 levels. It aims at halving the use of 'conventionally-fuelled' cars in cities and achieving virtually CO_2-free city logistics in major urban centres by 2030. Low-carbon fuels in aviation should reach 40 % by 2050, and CO_2 emissions from maritime bunker fuels should be reduced by 40 % by 2050 ([1]) compared to 2005 levels.

It is essential to reduce this environmental impact through targeted technological improvement, bearing in mind that each mode of transport faces varying challenges and is characterised by specific technology integration cycles.

Research and innovation will substantially contribute to the development and take up of the necessary solutions for all transport modes, which will drastically reduce transport emissions that are harmful to the environment (such as CO_2, NO_x, SO_x and noise), lower the dependence of transport on fossil fuels, and hence reduce transport impact on biodiversity and climate change and preserve natural resources.

This will be done through work on the following specific activities:

4.1.1. Making aircraft, vehicles and vessels cleaner and quieter will improve environmental performance and reduce perceived noise and vibration

The activities in this domain will focus on the end products, but will also address lean and ecological design and manufacturing processes, considering the entire life cycle process and with recyclability integrated in the design phase. Activities will also cover the upgrading of existing products and services by integration of new technologies.

(a) Developing and accelerating the take-up of cleaner and quieter propulsion technologies is important for reducing or eliminating impacts on climate and health of European citizens, e.g. CO_2, noise and pollution from transport. New and innovative solutions are necessary, based on electric engines and batteries, hydrogen and fuel cells, gas-powered engines, advanced architectures and technologies in engines or hybrid propulsion. Technological breakthroughs will also help improve the environmental performance of traditional and new propulsion systems.

(b) Exploring options for the use of low emission alternative energies will help reduce the consumption of fossil fuels. This includes using sustainable fuels and electricity from renewable energy sources in all modes of transport including aviation, reducing fuel consumption through energy harvesting or diversified energy supply and other innovative solutions. New holistic approaches will be pursued encompassing vehicles, energy storage, energy supply, fuelling and charging infrastructure, including vehicle-to-grid interfaces and innovative solutions for the use of alternative fuels.

(c) Improving the overall performance of aircraft, vessels and vehicles by reducing their weight and lowering their aerodynamic hydrodynamic or rolling resistance by using lighter materials, leaner structures and innovative design will contribute to lower fuel consumption.

([1]) Commission White Paper on "Roadmap to a Single European Transport Area – Towards a competitive and resource efficient transport system" (COM(2011) 144 final).

4.1.2. Developing smart equipment, infrastructures and services

This will help optimise transport operations and reduce resource consumption. The focus will be on solutions for the efficient planning, design, use and management of airports, ports, logistic platforms and surface transport infrastructures, as well as on autonomous and efficient maintenance, monitoring and inspection systems. New policies, business models, concepts, technologies and IT solutions are to be adopted to increase capacity. Particular attention will be given to the climate resilience of equipment and infrastructures, cost-efficient solutions based on a life-cycle approach, and the wider take-up of new materials and technologies allowing for more efficient and lower cost maintenance. Attention will also be paid to accessibility, user friendliness and social inclusiveness.

4.1.3. Improving transport and mobility in urban areas

This will benefit a large and increasing share of the population which lives and works in cities or uses them for services and leisure. New mobility concepts, transport organisation, multimodal accessibility models, logistics, provision of innovative vehicles and urban public services and planning solutions need to be developed and tested, which will contribute to reduce congestion, air pollution and noise and improve the efficiency of urban transport. Public and non-motorised transport as well as other resource-efficient transport options for passengers and freight should be developed as a real alternative to the use of private motor vehicles, supported by greater use of intelligent transport systems as well as by innovative supply and demand management. Special emphasis shall be given to the interaction between the transport system and other urban systems.

4.2. *Better mobility, less congestion, more safety and security*

Relevant European transport policy goals aim to optimise performance and efficiency in the face of growing demands for mobility, to make Europe the safest region for aviation, railways and waterborne transport and to move towards the target of zero fatalities in road transport by 2050 and of halving the road casualties by 2020. By 2030,30 % of road freight transport over 300 kilometres should shift to rail and waterborne transport. A seamless, accessible, affordable, user-oriented and efficient pan-European transport of people and goods, also internalising external costs, requires a new European multimodal transport management, information and payment system, as well as efficient interfaces between long distance and urban mobility networks.

A better European transport system will contribute to a more efficient use of transport, improve the quality of life of citizens and support a healthier environment.

Research and innovation will make important contributions to these ambitious policy goals through activities in the following specific activities:

4.2.1. A substantial reduction of traffic congestion

This can be achieved by implementing an intelligent, multi-modal and fully intermodal 'door-to-door' transport system and by avoiding unnecessary use of transport. This means promoting greater integration between transport modes, the optimisation of transportation chains and better integrated transport operations and services. Such innovative solutions will also facilitate accessibility and passenger choices, including for the ageing population and vulnerable users, and provide opportunities to reduce congestion by improving incident management and the development of traffic optimisation schemes.

4.2.2. Substantial improvements in the mobility of people and freight

This can be achieved through the development, demonstration and widespread use of intelligent transport applications and management systems. This entails planning demand analysis and management, information and payment systems that are interoperable Europe-wide, and the full integration of information flows, management systems, infrastructure networks and mobility services into a new common multi-modal framework based on open platforms. This will also ensure flexibility and rapid responses to crisis events and extreme weather conditions by reconfiguring travel and haulage across modes. New positioning, navigation and timing applications, made possible through the Galileo and the European Geostationary Navigation Overlay Service (EGNOS) satellite navigation systems, will be instrumental in achieving this objective.

(a) Innovative air traffic management technologies will contribute to a step-change in safety and efficiency with rapidly increasing demand, to achieve improved punctuality, to reduce time spent in travel-related procedures at airports and to achieve resilience in the air transport system. The implementation and further development of the 'Single European Sky' will be supported with research and innovation activities providing solutions for increased automation and

autonomy in air traffic management and aircraft operation and control, better integration of air and ground components, and novel solutions for the efficient and seamless handling of passengers and freight throughout the transport system.

(b) For waterborne transport, improved and integrated planning and management technologies will contribute to the emergence of a 'Blue Belt' in the seas around Europe, improving port operations, and to a suitable framework for inland waterways.

(c) For rail and road, the optimisation of network management and interoperability will improve the efficient use of infrastructure and make cross-border operations easier. Comprehensive cooperative road traffic management and information systems will be developed, relying on vehicle-to-vehicle and vehicle-to-infrastructure communication.

4.2.3. Developing new concepts of freight transport and logistics

This can reduce pressure on the transport system and the environment and improve safety and freight capacity. The activities can, for example, combine high performance and low environmental impact vehicles with smart, secure on-board and infrastructure-based systems. This should be based on an integrated logistics approach in the field of transport. Activities will also support the development of the e-Freight vision of a paperless freight transport process, where electronic information flows, services and payments are linked to physical freight flows across transport modes.

4.2.4. Reducing accident rates, fatalities and casualties and improving security

This will be achieved by addressing aspects inherent to the organisation, management and monitoring of performance and risk of transport systems and by focusing on the design, manufacturing and operations of aircraft, vehicles, vessels, infrastructures and terminals. The focus will be on passive and active safety, preventive safety and enhanced automation and training processes to reduce the risk and impact of human errors. To better anticipate, assess and mitigate the impact of weather, natural hazards and other crisis situations, special tools and techniques will be devised. Activities will also focus on the integration of security aspects in the planning and management of passenger and freight flows, on the conception of aircraft, vehicles and vessels, on traffic and system management and on the design of transport infrastructures and of freight and passenger terminals. Intelligent transport and connectivity applications may also provide useful tools for enhanced security. Activities will also focus on improving the safety of all road users, especially those at greatest risk, particularly in urban areas.

4.3. *Global leadership for the European transport industry*

By staying ahead in technological development and improving the competitiveness of existing manufacturing processes, research and innovation will contribute to growth and highly skilled jobs in the European transport industry, in the face of growing competition. At stake is the further development of the competitiveness of a major economic sector that directly represents 6,3 % of the Union gross domestic product (GDP) and employs nearly 13 million people in Europe. Specific objectives include the development of the next generation of innovative and environmentally friendly air, waterborne and land transport means, ensuring sustainable manufacturing of innovative systems and equipment and preparing the ground for future transport means, by working on novel technologies, concepts and designs, smart control systems, efficient development and production processes, innovative services and certification procedures. Europe aims at becoming the world leader in efficiency, environmental performance and safety in all modes of transport and at enhancing its leadership in global markets both for end-products as well as for subsystems.

Research and innovation will focus on the following specific activities:

4.3.1. Developing the next generation of transport means as the way to secure market share in the future

It will help enhance European leadership in aircraft, high speed trains, conventional and (sub)urban rail transport, road vehicles, electromobility, passenger cruise ships, ferries and specialised high technology ships and maritime platforms. It will also spur the competitiveness of European industries in upcoming technologies and systems and support their diversification towards new markets, including in sectors other than transport. This includes the development of innovative safe and environmentally friendly aircraft, vehicles and vessels that incorporate efficient propulsion systems, high performance and intelligent operation and control systems.

4.3.2. On-board, smart control systems

These are needed to realise higher levels of performance and system integration in transport. Appropriate interfaces for communications between aircraft, vehicles, vessels and infrastructures in all relevant combinations will be developed, taking into account impacts of electromagnetic fields, with a view to defining common operational standards. They may include delivering traffic management and user information direct to in-vehicle devices, supported by reliable real-time traffic data on road conditions and congestion from the same devices.

4.3.3. Advanced production processes

These will allow customisation, lower lifecycle cost and development time and facilitate the standardisation and certification of aircraft, vehicles and vessels as well as their components, equipment and related infrastructure. Activities in this area will develop fast and cost-efficient design and manufacturing techniques, including assembly, construction, maintenance and recycling, through digital tools and automation, and capacity to integrate complex systems. This will foster competitive supply chains able to deliver with short time to market and reduced costs without compromising operational safety and security. Transport applications of innovative materials are also a priority both for environmental and competitiveness goals as well as for increased safety and security.

4.3.4. Exploring entirely new transport concepts

This will help enhance Europe's competitive edge in the longer term perspective. Strategic multidisciplinary research and proof-of-concept activities shall address innovative transport systems solutions. This will include fully automated and other new types of aircraft, vehicles and vessels with long term potential and high environmental performance as well as new services.

4.4. *Socio-economic and behavioural research and forward-looking activities for policy making*

Actions to support policy analysis and development including gathering evidence to understand behaviour on spatial, socio-economic and wider societal aspects of transport are necessary to promote innovation and create a shared evidence base to meet the challenges raised by transport. Activities will target the development and implementation of European research and innovation policies for transport and mobility, prospective studies and technology foresight, and strengthening of the ERA.

Understanding local and regional specificities, user behaviour and perceptions, social acceptance, impact of policy measures, mobility, changing needs and patterns, evolution of future demand, business models and their implications are of paramount importance for the evolution of the European transport system. Scenario development taking into account societal trends, evidence on causalities, policy objectives and technology foresight in a 2050 perspective will be carried out. In view of better understanding the links between territorial development, social cohesion and the European transport system, robust models are needed on which sound policy decisions can be taken.

Research will focus on how to reduce social and territorial inequalities in access to mobility and on how to improve the position of vulnerable transport users. Economic issues must also be addressed, focusing on ways to internalise the externalities from transport across modes, as well as taxation and pricing models. Prospective research is needed to assess future requirements for skills and jobs, research and innovation development and uptake as well as transnational cooperation.

4.5. *Specific implementation aspects*

The activities will be organised in such a way as to allow for an integrated and mode-specific approach as appropriate. Multiannual visibility and continuity will be necessary in order to take into account the specificities of each transport mode and the holistic nature of challenges as well as relevant aspects of the strategic research and innovation agendas of European Technology Platforms.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and the relevant public-public and public-private partnerships. Appropriate links with the actions of relevant European Innovation Partnerships will also be established. Activities shall also focus on increasing the support and promoting the involvement of SMEs.

5. CLIMATE ACTION, ENVIRONMENT, RESOURCE EFFICIENCY AND RAW MATERIALS

5.1. *Fighting and adapting to climate change*

Current CO_2 concentrations in the atmosphere are close to 40 % higher than those at the start of the industrial revolution and at the highest levels experienced in the last 2 million years. Non-CO_2 greenhouse gases also contribute to climate change and are playing an increasingly significant role. Without decisive action, climate change could cost the world at least 5 % of GDP each year, and up to 20 % under some scenarios. In contrast, with early and effective action the net costs could be limited to around 1 % of GDP per year. Meeting the 2 °C target and avoiding the worst impacts of climate change will require developed countries to cut greenhouse gas emissions by 80-95 % by 2050 compared to 1990 levels.

The aim of this activity is therefore to develop and assess innovative, cost-effective and sustainable adaptation and mitigation measures and strategies, targeting both CO_2 and non-CO_2 greenhouse gases and aerosols, and underlining both technological and non-technological green solutions, through the generation of evidence for informed, early and effective action and the networking of the required competences.

To achieve this, research and innovation will focus on the following:

5.1.1. Improving the understanding of climate change and the provision of reliable climate projections

Better understanding of the causes and evolution of climate change and more accurate climate projections are crucial for the society to protect lives, goods and infrastructures and ensure effective decision making and adequate mitigation and adaptation options. It is essential to further improve the scientific knowledge base of climate drivers, processes, mechanisms, feedbacks and thresholds associated with the functioning of terrestrial, marine and polar ecosystems and the atmosphere. Improved understanding will also allow more accurate detection of climate change and attribution to natural and anthropogenic causal factors. Improved reliability of climate projections and predictions at pertinent temporal and spatial scales will be supported via the improvement of measurements and via the development of more accurate scenarios and models, including fully coupled Earth-system models taking into account paleoclimate history.

5.1.2. Assessing impacts and vulnerabilities and developing innovative cost-effective adaptation, risk prevention and management measures

There is incomplete knowledge on the ability of society, economy and ecosystems to adapt to climate change. Effective, equitable and socially acceptable measures towards a climate-resilient environment, economy and society require the integrated analysis of current and future impacts, vulnerabilities, population exposure, risks and their management, second order effects such as migration and conflicts, costs and opportunities associated with climate change and variability, taking into account extreme events and related climate-induced hazards and their recurrence. This analysis will also be developed on the adverse impacts of climate change on biodiversity, ecosystems and ecosystem services, water resources, infrastructures and economic and natural assets. Emphasis will be placed on the most valuable natural ecosystems and built environments, as well as key societal, cultural and economic sectors across Europe. Actions will investigate the impacts and growing risks for human health stemming from climate change, climate-induced hazards and increased greenhouse gas concentrations in the atmosphere. Research will evaluate innovative, equitably distributed and cost-effective adaptation responses to climate change, including the protection and adaptation of natural resources and ecosystems, and related effects, to inform and support their development and implementation at all levels and scales. This will also include the potential impacts, costs, risks and benefits of geo-engineering options. The complex interlinkages, conflicts and synergies of adaptation and risk-prevention policy choices with other climate and sectoral policies will be investigated, including impacts on employment and the living standards of vulnerable groups.

5.1.3. Supporting mitigation policies, including studies that focus on impact from other sectoral policies

The Union's transition to a competitive, resource-efficient and climate change resilient economy and society by 2050 requires the design of effective and long-term low-emission strategies and major advancements in our capacity to innovate. Research will assess the environmental and socio-economic risks, opportunities and impacts of climate change mitigation options. It will also assess impact from other sectoral policies. Research will support the development and validation of new climate-energy-economy models, taking into account economic instruments and relevant externalities, with the aim of testing mitigation policy options and low-carbon technology pathways at different scales and for

the key economic and societal sectors at Union and global level. Actions will facilitate technological, institutional and socio-economic innovation by improving the links between research and application and between entrepreneurs, end users, researchers, policy makers and knowledge institutions.

5.2. *Protecting the environment, sustainably managing natural resources, water, biodiversity and ecosystems*

Societies face a major challenge to establish a sustainable balance between human needs and the environment. Environmental resources, including water, air, biomass, fertile soils, biodiversity and ecosystems, and the services they provide underpin the functioning of the European and global economy and quality of life. Global business opportunities related to natural resources are expected to amount to over EUR 2 trillion by 2050 ([1]). Despite this, ecosystems in Europe and globally are being degraded beyond nature's ability to regenerate them, and environmental resources are being over-exploited and even destroyed. For example, 1 000 km^2 of some of the most fertile soils and valuable ecosystems are lost every year in the Union, while a quarter of fresh water is wasted. Continuing these patterns is not an option. Research must contribute to reversing the trends that damage the environment and to ensuring that ecosystems continue to provide the resources, goods and services that are essential for well-being, economic prosperity and sustainable development.

The aim of this activity is therefore to provide knowledge and tools for the management and protection of natural resources, achieving a sustainable balance between limited resources and the present and future needs of society and the economy.

To achieve this, research and innovation will focus on the following:

5.2.1. Furthering our understanding of biodiversity and the functioning of ecosystems, their interactions with social systems and their role in sustaining the economy and human well-being

Human action may trigger changes in the environment that are irreversible and which alter the character of ecosystems and their biodiversity. It is vital to anticipate these risks by assessing, monitoring and forecasting the impact of human activities on the environment, including land use change, and environmental changes on human well-being. Research on marine (from coastal zones to the deep sea including the sustainability of marine resources), polar, fresh-water, terrestrial and urban ecosystems, including groundwater dependent ecosystems, will improve our understanding of the complex interactions between natural resources and social, economic, and ecological systems, including natural tipping points, and the resilience, or fragility, of human and biological systems. It will examine how biodiversity and ecosystems function and react to anthropogenic impacts, how they can be restored, and how this will affect economies and human well-being. It will also investigate solutions for addressing resource challenges in the European and international context. It will contribute to policies and practices that ensure that social and economic activities operate within the limits of the sustainability and adaptability of ecosystems and biodiversity.

5.2.2. Developing integrated approaches to address water-related challenges and the transition to sustainable management and use of water resources and services

Freshwater availability and quality have become global issues with far-reaching economic and social implications. With ever-growing demand for different and often conflicting uses (e.g. agriculture, industry, recreational activities, public services, ecosystems and landscape maintenance, environmental restoration and enhancement), increased resource vulnerability exacerbated by climate and global change, urbanisation, pollution and over-exploitation of freshwater resources, maintaining and improving water quality and availability, and mitigating the impact of human activities on fresh water ecosystems is becoming a critical challenge for the users of water in various sectors as well as for aquatic ecosystems.

Research and innovation will address these pressures and provide integrated strategies, tools, technologies and innovative solutions to meet current and future needs. It will aim to develop appropriate water management strategies, improve water quality, cope with imbalances between water demand and availability or supply at different levels and scale, close the water cycle, promote sustainable end-user behaviour and address water-related risks whilst sustaining the integrity, structure and functioning of the aquatic ecosystems in line with the prevailing Union policies.

([1]) Estimates developed by PricewaterhouseCoopers for "sustainability-related global business opportunities in natural resources (including energy, forestry, food and agriculture, water and metals)" and WBCSD (2010) Vision 2050: The New Agenda for Business, World Business Council for Sustainable Development: Geneva, URL: http://www.wbcsd.org/web/projects/BZrole/Vision2050-FullReport_Final.pdf

5.2.3. Providing knowledge and tools for effective decision making and public engagement

Social, economic and governance systems still need to address both resource depletion and the damage to ecosystems. Research and innovation will underpin policy decisions needed to manage natural resources and ecosystems so as to avoid, or adapt to, disruptive climate and environmental change and to promote institutional, economic, behavioural and technological changes that ensure sustainability. Research will thus underpin the development of systems to value biodiversity and ecosystem services, including understanding the stock of natural capital and the flow of ecosystems services. Emphasis will be put on critical policy-relevant ecosystems and ecosystem services, such as fresh water, seas and oceans (including coastal areas), forests, polar regions, air quality, biodiversity, land use and soil. The resilience of societies and ecosystems to pollutants and pathogens and to catastrophic events, including natural hazards (such as seismic and volcanic, flooding and droughts) and forest fires, will be supported through improving capacities for forecasting, early warning and assessing vulnerabilities and impacts, including the multi-risk dimension. Research and innovation will thus provide support for environmental and resource efficiency policies, and options for effective evidence-based governance within safe operating limits. Innovative ways will be developed to increase policy coherence, resolve trade-offs and manage conflicting interests and to improve public awareness of research results and the participation of citizens in decision making.

5.3. *Ensuring the sustainable supply of non-energy and non-agricultural raw materials*

Sectors such as construction, chemicals, automotive, aerospace, machinery and equipment, which have a combined added value in excess of EUR 1 000 billion and provide employment for some 30 million people, all depend on access to raw materials. The Union is self-sufficient in construction minerals. Nonetheless, whilst the Union is one of the world's largest producers of certain industrial minerals, it remains a net importer of most of them. Furthermore, the Union is highly dependent on imports of metallic minerals and is totally import dependent for some critical raw materials.

Recent trends indicate that demand for raw materials will be driven by the development of emerging economies and by the rapid diffusion of key enabling technologies. Europe has to ensure a sustainable management and secure a sustainable supply of raw materials from inside and outside its borders for all sectors that depend on access to raw materials. Policy targets for critical raw materials are outlined in the Commission's Raw Materials Initiative ([1]).

The aim of this activity is therefore to improve the knowledge base on raw materials and develop innovative solutions for the cost-effective and environmentally friendly exploration, extraction, processing, re-use, recycling and recovery of raw materials and for their substitution by economically attractive and environmentally sustainable alternatives with a lower environmental impact.

To achieve this, research and innovation will focus on the following:

5.3.1. Improving the knowledge base on the availability of raw materials

The assessment of the long-term availability of global and Union resources, including access to urban mines (landfills and mining waste), coastal-sea and deep-sea resources (e.g. the sea-bed mining of rare earth minerals), and the associated uncertainties will be improved. This knowledge will help society reach a more efficient use, recycling and reuse of scarce or environmentally harmful raw materials. It will also develop global rules, practices and standards governing economically viable, environmentally sound and socially acceptable resource exploration, extraction and processing, including practices in land use and marine spatial planning on the basis of an ecosystems approach.

5.3.2. Promoting the sustainable supply and use of raw materials, including mineral resources, from land and sea, covering exploration, extraction, processing, re-use, recycling and recovery

Research and innovation is needed over the entire life cycle of materials, in order to secure an affordable, reliable and sustainable supply and management of raw materials essential for European industries. Developing and deploying economically viable, socially acceptable and environmentally friendly exploration, extraction and processing technologies will boost the efficient use of resources. This will include mineral resources, from land and sea, and will also exploit the potential of urban mines. New and economically viable and resource-efficient recycling and materials recovery technologies, business models and processes, including closed-loop processes and systems, will also contribute to reducing the

([1]) COM(2008) 699 final.

Union's dependence on the supply of primary raw materials. This will include the need for longer use, high-quality recycling and recovery, and the need to drastically reduce resource wastage. A full life-cycle approach will be taken, from the supply of available raw materials to end of life, with minimum energy and resource requirements.

5.3.3. Finding alternatives for critical raw materials

In anticipation of the possible reduced global availability of certain materials, due for example to trade restrictions, sustainable substitutes and alternatives for critical raw materials, with similar functional performance, will be investigated and developed. This will reduce the Union's dependence on primary raw materials and improve the impact on the environment.

5.3.4. Improving societal awareness and skills on raw materials

The necessary move to a more self-reliant and resource-efficient economy will require cultural, behavioural, socio-economic, systemic and institutional change. In order to address the growing problem of skills shortage in the Union's raw materials sector, including the European mining industry, more effective partnerships between universities, geological surveys, industry and other stakeholders will be encouraged. It will also be essential to support the development of innovative green skills. In addition there is still limited public awareness of the importance of domestic raw materials for the European economy. To facilitate the necessary structural changes, research and innovation will aim to empower citizens, policy-makers, practitioners and institutions.

5.4. *Enabling the transition towards a green economy and society through eco-innovation*

The Union cannot prosper in a world of ever increasing resource consumption, environmental degradation and biodiversity loss. Decoupling growth from the use of natural resources requires structural changes in how such resources are used, re-used and managed, while safeguarding our environment. Eco-innovations will enable us to reduce pressure on the environment, increase resource efficiency, and put the Union on the path to a resource- and energy-efficient economy. Eco-innovation also creates major opportunities for growth and jobs, and increases European competitiveness within the global market, which is estimated to grow to a trillion Euro market after 2015 ([1]). 45 % of companies have already introduced some type of eco-innovation. It has been estimated that around 4 % of eco-innovations led to more than a 40 % reduction of material use per unit of output ([2]), highlighting the great future potential. However, it is not uncommon that highly promising and technically advanced eco-innovative technologies, processes, services and products do not reach the market due to pre-commercialisation challenges and do not realise their full environmental and economic potential as their scaling up and market introduction are perceived as too risky by private investors.

The aim of this activity is therefore to foster all forms of eco-innovation that enable the transition to a green economy.

To achieve this, research and innovation will focus on the following:

5.4.1. Strengthening eco-innovative technologies, processes, services and products, including exploring ways to reduce the quantities of raw materials in production and consumption, overcoming barriers in this context and boosting their market uptake

All forms of eco-innovation, both incremental and radical, combining technological, organisational, societal, behavioural, business and policy innovation, and strengthening the participation of civil society, will be supported. This will underpin a more circular economy, while reducing environmental impacts, increasing environmental resilience and taking account of rebound effects on the environment and potentially on other sectors. This will include user-driven innovation, business models, industrial symbiosis, product service systems, product design, full life cycle and cradle-to-cradle approaches as well as exploring ways to reduce the quantities of raw materials in production and consumption, and overcoming barriers in this context. The potential to move to more sustainable patterns of consumption will be addressed. The aim will be

([1]) European Parliament, Policy Department, Economic and Scientific Policy "Eco-innovation - putting the EU on the path to a resource and energy efficient economy; Study and briefing notes", March 2009.
([2]) Eco-innovation Observatory "The Eco-Innovation Challenge - Pathways to a resource-efficient Europe - Annual Report 2010", May 2011.

to improve resource efficiency by reducing, in absolute terms, inputs, waste and the release of harmful substances (e.g. those indicated under Regulation (EC) No 1907/2006 of the European Parliament and of the Council [1]) along the value chain and to foster re-use, recycling and resource substitution.

Emphasis will be given to facilitate the transition from research to market, involving industry and notably start-ups and innovative SMEs, civil society organisations and end-users, from the development of prototypes and demonstration of technical, social and environmental performance, up to the first application and market replication of eco-innovative techniques, products, services or practices of Union relevance. Actions will contribute to removing barriers to the development and wide application of eco-innovation, creating or enlarging markets for the solutions concerned and improving the competitiveness of Union enterprises, especially SMEs, on world markets. Networking among eco-innovators will also seek to enhance the dissemination and exploitation of knowledge and link supply with demand better.

5.4.2. Supporting innovative policies and societal changes

Structural and institutional changes are needed to enable the transition towards a green economy and society. Research and innovation will address the main barriers to societal and market change and will aim to empower consumers, business leaders and policy makers to adopt innovative and sustainable behaviour, with contributions from social sciences and humanities. Robust and transparent tools, methods and models to assess and enable the main economic, societal, cultural and institutional changes needed to achieve a paradigm shift towards a green economy and society will be developed. Research will explore how to promote sustainable lifestyles and consumption patterns, encompassing socio-economic research, behavioural science, user engagement and public acceptance of innovation, as well as activities to improve communication and public awareness. Full use will be made of demonstration actions.

5.4.3. Measuring and assessing progress towards a green economy

It is necessary to develop robust indicators at all appropriate spatial scales that are complementary to GDP, methods and systems to support and assess the transition towards a green economy and the effectiveness of relevant policy options. Driven by a life-cycle approach, research and innovation will improve the quality and availability of data, measurement methods and systems relevant to resource efficiency and eco-innovation and facilitate the development of innovative offset schemes. Socio-economic research will provide a better understanding of the root causes of producer and consumer behaviour and thus contribute to the design of more effective policy instruments to facilitate the transition to a resource-efficient and climate change resilient economy. Moreover, technology assessment methodologies and integrated modelling will be developed to support resource efficiency and eco-innovation policies at all levels, while increasing policy coherence and resolving trade-offs. The results will enable the monitoring, assessment and reduction in material and energy flows involved in production and consumption, and will enable policy-makers and businesses to integrate environmental costs and externalities into their actions and decisions.

5.4.4. Fostering resource efficiency through digital systems

Innovations in information and communication technologies can constitute a key tool to support resource efficiency. To achieve this objective, modern and innovative ICT will contribute to significant efficiency gains in productivity, notably through automated processes, real time monitoring and decision support systems. The use of ICT will aim to accelerate a progressive dematerialisation of the economy, by increasing the shift towards digital services, and to facilitate changes of consumption behaviours and business models through the use of the ICT of the future.

5.5. *Developing comprehensive and sustained global environmental observation and information systems*

Comprehensive environmental observation and information systems are essential to ensure the delivery of the long-term data and information required to address this societal challenge. These systems will be used to monitor, assess and predict the condition, status and trends of the climate, natural resources including raw materials, terrestrial and marine (from coastal zones to deep sea) ecosystems and ecosystem services, as well as to evaluate low-carbon and climate mitigation and adaptation policies and options across all sectors of the economy. Information and knowledge from these systems will be used to stimulate the smart use of strategic resources, to support the development of evidence-based policies, to foster new environmental and climate services, and to develop new opportunities in global markets.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Capabilities, technologies and data infrastructures for Earth observation and monitoring must build on advances in ICT, space technologies and enabled networks, remotely sensed observations, novel in situ sensors, mobile services, communication networks, participatory web-service tools and improved computing and modelling infrastructure, with the aim of continuously providing timely and accurate information, forecasts and projections. Free, open and unrestricted access to interoperable data and information will be encouraged, as well as the effective and, if required, secure storage, management and dissemination of research results. Activities shall help define future operational activities of the Copernicus programme and enhance the use of Copernicus data for research activities.

5.6. *Cultural heritage*

Cultural heritage assets are unique and irreplaceable in their tangible form as well as in their intangible value, cultural significance and meaning. They are a major driver of societal cohesion, identity and well-being, and they contribute significantly to sustainable growth and job creation. However, Europe's cultural heritage is subject to deterioration and damage, further exacerbated by increasing exposure to human activities (e.g. tourism) and extreme weather events resulting from climate change as well as due to other natural hazards and disasters.

The aim of this activity is to provide knowledge and innovative solutions, through adaptation and mitigation strategies, methodologies, technologies, products and services for the preservation and management of tangible cultural heritage in Europe at risk from climate change.

To achieve this, multidisciplinary research and innovation will focus on the following:

5.6.1. Identifying resilience levels via observations, monitoring and modelling

New and improved damage assessment, monitoring and modelling techniques will be developed to improve the scientific knowledge base of the impact on cultural heritage of climate change and other environmental and human risk factors. The knowledge and understanding generated with the help of scenarios, models and tools, including analysis of the perception of value, will help provide a sound scientific basis for the development of resilience strategies, policies and standards, within a coherent framework for risk assessment and management of cultural heritage assets.

5.6.2. Providing for a better understanding on how communities perceive and respond to climate change and seismic and volcanic hazards

Research and innovation will, through integrated approaches, develop resource-efficient solutions for prevention, adaptation and mitigation, involving innovative methodologies, technologies, products and services for the preservation of cultural heritage assets, cultural landscapes and historic habitats.

5.7. *Specific implementation aspects*

Activities will enhance the Union's participation in and financial contribution to multilateral processes and initiatives, such as the Intergovernmental Panel on Climate Change (IPCC), the Intergovernmental Platform on Biodiversity and Ecosystem Services (IPBES), and the Group on Earth Observations (GEO). Cooperation with other major public and private research funders as well as with major research networks will improve global and European research efficiency and contribute to global research governance.

Scientific and technological cooperation will contribute to the United Nations Framework Convention on Climate Change (UNFCCC) global technology mechanism and facilitate technology development, innovation and transfer in support of climate adaptation and the mitigation of greenhouse gases.

Building on the outcomes of the UN Rio+20 Conference, a mechanism will be explored to systematically collect, collate and analyse scientific and technological knowledge on key sustainable development and green economy issues, which will include a framework for measuring progress. This will complement existing scientific panels and bodies and seek synergies with them.

Research actions under this societal challenge will contribute to Copernicus operational services by providing a developmental knowledge base for Copernicus.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and relevant public-public and public-private partnerships.

Approriate links with the actions of relevant European Innovation Partnerships and the relevant aspects of the research and innovation agendas of European Technology Platforms will also be established.

Specific measures will ensure that results from Union research and innovation in the fields of climate, resource efficiency and raw materials are used downstream by other Union programmes, such as the LIFE programme, ESI Funds, and external cooperation programmes.

Activities will also, inter alia, build upon and enhance those undertaken in the Eco-Innovation Programme.

Actions will also provide the continuous analysis of scientific and technological progress in the Union and its major partner countries and regions, an early investigation of market opportunities for new environmental technologies and practices, and foresight for research and innovation policy.

6. EUROPE IN A CHANGING WORLD - INCLUSIVE, INNOVATIVE AND REFLECTIVE SOCIETIES

This section includes research and innovation activities contributing to make societies more inclusive, innovative and reflective, and also specific measures supporting particular cross-cutting issues mentioned in this societal challenge ([1]).

6.1. *Inclusive societies*

Current trends at play in European societies bring with them opportunities for a more united Europe but also risks and challenges. These opportunities, risks and challenges need to be understood and anticipated in order for Europe to evolve with adequate solidarity and cooperation at social, economic, political, educational and cultural levels, taking into account an increasingly interconnected and interdependent world.

In this context, the objective is to understand, analyse and develop social, economic and political inclusion, as well as inclusive labour markets, combat poverty and marginalisation, enhance human rights, digital inclusiveness, equality, solidarity and inter-cultural dynamics by supporting cutting-edge science, interdisciplinary research, development of indicators, technological advances, organisational innovations, development of regional innovation clusters and new forms of collaboration and co-creation. Research and other activities shall support the implementation of the Europe 2020 strategy as well as other relevant Union policies. Social sciences and humanities research has a leading role to play in this context. Specifying, monitoring, assessing and addressing the objectives of European strategies and policies will require focused research that allows policy makers to analyse and assess the impact and effectiveness of envisaged measures, in particular in favour of social inclusion. To this end, full societal inclusion and participation must encompass all areas of life and all ages.

The following specific objectives will be pursued to understand and foster or implement:

6.1.1. The mechanisms to promote smart, sustainable and inclusive growth

Europe has developed a specific and rather unique combination of economic progress, social policies aimed at a high level of social cohesion, humanistic shared cultural values embracing democracy and the rule of law, human rights, respect and preservation of diversity, as well as the promotion of education and science, arts and humanities as fundamental drivers of social and economic progress and well-being. The constant quest for economic growth carries a number of important human, social, environmental and economic costs. A smart, sustainable and inclusive growth in Europe implies substantial changes in the way growth and societal well-being are defined, measured (including through the measurement of progress beyond the commonly used GDP indicator), generated and sustained over time.

([1]) Without prejudice to the budget allocated to this societal challenge.

Research will analyse the development of citizen participation, sustainable lifestyles, cultural understanding and socio-economic behaviours and values and how they relate to paradigms, policies and to the functioning of institutions, communities, markets, firms, governance and belief systems in Europe and their relations with other regions and economies. It will develop tools for a better assessment of the contextual and mutual impacts of such evolutions, compare public policies against the variety of challenges across Europe, and analyse policy options and decision making mechanisms in areas such as employment, taxation, inequalities, poverty, social inclusion, education and skills, community development, competitiveness and the internal market with a view to understanding the new conditions and opportunities for greater European integration and the role of its social, cultural, scientific and economic components and synergies as sources of comparative Union advantages at world level.

Demographic change due to ageing societies and migration movements will be analysed in terms of its implications for growth, the labour market and well-being. In this context, to be able to tackle the challenge of future growth, it is important to take into account the different components of knowledge, focusing research on learning, education and training issues, or on the role and place of young people in the society. Research will also develop better tools for assessing sustainability impacts of different economic policies. It will also analyse how national economies evolve and which forms of governance at European and international level could help prevent macro-economic imbalances, monetary difficulties, fiscal competition, unemployment and employment problems and other forms of societal, economic and financial disorders. It will take into account the growing interdependencies between Union and global economies, markets and financial systems and resulting challenges for institutional development and public administration. Against the background of the European public debt crisis, emphasis will also be put on research to define the framework conditions for stable European financial and economic systems.

6.1.2. Trusted organisations, practices, services and policies that are necessary to build resilient, inclusive, participatory, open and creative societies in Europe, in particular taking into account migration, integration and demographic change

Understanding social, cultural and political transformations in Europe requires the analysis of changing democratic practices and expectations as well as of the historical evolution of identities, diversity, territories, religions, cultures, languages and values. This includes a good understanding of the history of European integration. Research will seek to identify ways to adapt and improve the European welfare systems, public services and the broader social security dimension of policies in order to achieve cohesion and gender equality, to foster participatory, open and creative societies and to promote social and economic equality and intergenerational solidarity. Research will analyse how societies and politics become more European in a broad sense through evolutions of identities, cultures and values, the circulation of knowledge, ideas and beliefs and combinations of principles and practices of reciprocity, commonality and equality, paying particular attention to migration, integration and demographic change. It will analyse how vulnerable populations (e.g. Roma) can participate fully in education, society and democracy, notably through the acquisition of various skills and the protection of human rights. The analysis of how political systems evolve and also respond to the above-mentioned social evolutions will thus be central.

Research will also address the evolution of key systems that provide underlying forms of human and social bonds, such as family, work, education and employment, and help to combat social inequalities, exclusion and poverty.Social cohesion and fair and reliable justice, education, democracy, tolerance and diversity are factors that need to be carefully considered with a view to identifying and better exploiting European comparative advantages at world level and to providing improved evidence-based support to policies. Research will take into account the importance of mobility and migration, including intra-European flows, and demography in the future development of European policies.

In addition, understanding the strains and opportunities arising from the uptake of ICT, both at individual and collective levels, is important in order to open new paths of inclusive innovation. Given the increasing socio-economic importance of digital inclusion, research and innovation actions will promote inclusive ICT solutions and the effective acquisition of digital skills leading to the empowerment of citizens and a competitive workforce. Emphasis will be given to new technological advances that will enable a radical improvement in personalisation, user-friendliness and accessibility through a better understanding of citizen, consumer and user behaviours and values, including persons with disabilities. This will require an "inclusion by design" research and innovation approach.

6.1.3. Europe's role as a global actor, notably regarding human rights and global justice

Europe's distinct historical, political, social and cultural system is increasingly confronted with the impact of global changes. In order to further develop its external action in its neighbourhood and beyond and its role as a global actor, Europe has to improve its capacities for defining, prioritising, explaining, assessing and promoting its policy

objectives in interaction with other world regions and societies to further cooperation or prevent or solve conflicts. In this regard, it also has to improve its capacities for anticipating and responding to the evolution and impacts of globalisation. This requires a greater understanding of and learning from the history, cultures and political-economic systems of other world regions, as well as of the role and influence of transnational actors. Finally, Europe also has to contribute effectively to global governance and global justice, in key domains like trade, development, work, economic cooperation, environment, education, gender equality and human rights, defence and security. This implies the potential to build new capacities whether in terms of tools, services, systems and instruments of analysis or in terms of diplomacy in formal and informal international arena with governmental and non-governmental actors.

6.1.4. The promotion of sustainable and inclusive environments through innovative spatial and urban planning and design

80 % of Union citizens live today in and around cities, and inadequate urban planning and design can thus have tremendous consequences on their lives. Understanding how they function for all citizens, as well as understanding their design, liveability and their attractiveness to, inter alia, investment and skills, is critical to Europe's success in creating growth, jobs and a sustainable future.

European research and innovation should provide tools and methods for a more sustainable, open, innovative and inclusive urban and peri-urban planning and design; a better understanding of the dynamics of urban societies and social changes and of the nexus of energy, environment, transport and land-use, including the interplay with surrounding rural areas; an improved understanding of design and use of public space within cities, also in the context of migration, to improve social inclusion and development and reduce urban risks and crime; new ways to reduce pressures on natural resources and stimulate sustainable economic growth while improving the quality of life of European urban citizens; and a forward-looking vision on the socio-ecological transition towards a new model of urban development reinforcing Union cities as hubs of innovation and centres of job creation and social cohesion.

6.2. *Innovative societies*

The Union share of global knowledge production remains considerable, yet its socio-economic impacts need to be maximised. Efforts will be made to increase the efficiency of research and innovation policies and their transnational policy synergies and coherence. Innovation will be addressed in a wide sense, including large-scale policy, social-, user- and market-driven innovation. The experience and innovative power of creative and cultural Industries will be taken into account. These activities will support the achievement and functioning of the ERA and in particular the Europe 2020 flagship initiatives 'Innovation Union' and the 'Digital Agenda for Europe'.

The following specific objectives will be pursued:

6.2.1. Strengthening the evidence base and support for the Innovation Union and ERA

In order to assess and prioritise investments and strengthen the Innovation Union and the ERA, the analysis of research, education and innovation policies, systems and actors in Europe and third countries as well as the development of indicators, data and information infrastructures will be supported. Forward-looking activities and pilot initiatives, economic and gender analysis, policy monitoring, mutual learning, coordination tools and activities and the development of methodologies for impact assessment and evaluations will also be needed, exploiting direct feedback from stakeholders, enterprises, public authorities, civil society organisations and citizens. This analysis should be conducted in coherence with studies on higher education systems in Europe and third countries within the Erasmus+ programme.

To ensure a single market for research and innovation, measures to incentivise ERA compatible behaviour will be implemented. Activities underpinning policies related to the quality of research training, mobility and career development of researchers will be supported, including initiatives to provide for mobility services, open recruitment, women's participation in the sciences, researchers' rights and links with global researcher communities. These activities will be implemented seeking synergies and close coordination with the Marie Skłodowska-Curie Actions under the priority 'Excellent science'. Institutions presenting innovative concepts for the rapid implementation of ERA principles, including the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, the Commission Recommendation on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research institutions ([1]), will be supported.

([1]) COM(2008) 1329 final, 10.4.2008.

As regards coordination of policies, a facility for policy advice will be set up to make expert policy advice available to national authorities when defining their National Reform Programmes and research and innovation strategies.

To implement the Innovation Union flagship initiative, there is also a need to support market-driven innovation, open innovation, public sector and social innovation in view of enhancing the innovation capacity of firms and fostering European competitiveness. This will require improving the overall framework conditions for innovation as well as tackling the specific barriers preventing the growth of innovative firms. Powerful innovation support mechanisms (such as improved cluster management, public-private partnerships and network cooperation), highly specialised innovation support services (on e.g. IP management/exploitation, networking of IPR owners and users, innovation management, entrepreneurship skills, and networks of procurers) and reviews of public policies in relation to innovation will be supported. Issues specific to SMEs will be supported under the specific objective 'Innovation in SMEs'.

6.2.2. Exploring new forms of innovation, with special emphasis on social innovation and creativity, and understanding how all forms of innovation are developed, succeed or fail

Social innovation generates new goods, services, processes and models that meet societal needs and create new social relationships. As means of innovation are constantly changing, further research is needed into the development of all forms of innovation and the way innovation meets the needs of society. It is important to understand how social innovation and creativity may lead to change in existing structures, practices and policies and how they can be encouraged and scaled-up. It is important to assess the impact of on-line platforms on networking citizens. Support will also be given to the use of design in companies, networking and experimentation of the use of ICT for improving learning processes, as well as to networks of social innovators and social entrepreneurs. Research will also focus on the processes of innovation and how they develop, succeed or fail (including risk taking and the role of different regulatory environments).

It will be essential to promote innovation in order to foster efficient, open and citizen-centric public services (e.g. eGovernment). This will require multidisciplinary research on new technologies and large-scale innovation related in particular to digital privacy, interoperability, personalised electronic identification, open data, dynamic user interfaces, lifelong learning and e-learning platforms, distributed learning systems, citizen-centric public service configuration and integration and innovation driven by users, including in social sciences and the humanities. Such actions will also address social network dynamics and crowd-sourcing and smart-sourcing for co-production of solutions addressing social problems, based, for example, on open data sets. They will help to manage complex decision making, in particular the handling and analysis of huge quantities of data for collaborative policy modelling, simulation of decision making, visualisation techniques, process modelling and participatory systems as well as to analyse changing relationships between citizens and the public sector.

Specific measures shall be developed to involve the public sector as an agent for innovation and change, at national and Union level, in particular through policy support and cross-border innovation measures at the widest geographical level enabling the smart use of ICT in and by public administrations for seamless delivery of public services for citizens and businesses.

6.2.3. Making use of the innovative, creative and productive potential of all generations

Activities will contribute to exploring Europe's opportunities to innovate in terms of new products and technologies, improved services and new business and social models adapted to the changing demographic structure of the society. Activities will enhance taking advantage of the potential of all generations by fostering the development of smart policies to make active ageing a reality in an evolving intergenerational context and by supporting the integration of the generations of young Europeans in all domains of social, political, cultural and economic life, taking into account, amongst others, perception of opportunities for innovation in the context of high unemployment in many Union regions.

6.2.4. Promoting coherent and effective cooperation with third countries

Horizontal activities will ensure the strategic development of international cooperation across Horizon 2020 and address cross-cutting policy objectives. Activities to support bilateral, multilateral and bi-regional policy dialogues in research and innovation with third countries, regions, international fora and organisations will facilitate policy exchange, mutual learning and priority setting, promote reciprocal access to programmes and monitor the impact of cooperation. Networking and twinning activities will facilitate optimal partnering between research and innovation actors on both sides and improve competencies and cooperation capacity in less advanced third countries. Activities will promote

coordination of Union and national cooperation policies and programmes, as well as joint actions of Member States and associated countries with third countries in order to enhance their overall impact. Finally, the European research and innovation 'presence' in third countries will be consolidated and strengthened, notably by exploring the creation of European virtual 'science and innovation houses', the provision of services to European organisations extending their activities into third countries, and the opening of research centres, established jointly with third countries, to organisations or researchers from other Member States and associated countries.

6.3. *Reflective societies - Cultural heritage and European identity*

The aim is to contribute to an understanding of Europe's intellectual basis, its history and the many European and non-European influences, as an inspiration for our lives today. Europe is characterised by a variety of different peoples (including minorities and indigenous people), traditions and regional and national identities as well as by different levels of economic and societal development. Migration and mobility, media, industry and transport contribute to the diversity of views and lifestyles. This diversity and its opportunities should be recognised and considered.

European collections in libraries, including digital ones, archives, museums, galleries and other public institutions have a wealth of rich, untapped documentation and objects for study. These archival resources, together with intangible heritage, represent the history of individual Member States but also the collective heritage of a Union that has emerged through time. Such materials should be made accessible, also through new technologies, to researchers and citizens to enable a look to the future through the archive of the past. Accessibility and preservation of cultural heritage in these forms is needed for the vitality of the living engagements within and across European cultures now and contributes to sustainable economic growth.

The focus of activities shall be the following:

6.3.1. Studying European heritage, memory, identity, integration and cultural interaction and translation, including its representations in cultural and scientific collections, archives and museums, to better inform and understand the present by richer interpretations of the past

The activities will contribute to a critical analysis of how a European tangible and non-tangible heritage has developed over time, including language, memories, practices, institutions and identities. They will include studies of the interpretations and practices of cultural interactions, integration and exclusion.

An intensified European integration process has underlined that a wider European identity sphere exists – one which complements other types of identities in Europe. A broad spectrum of evidence and testimonies of European identity spheres can be found in European and non-European scientific collections, archives, museums, libraries and cultural heritage sites. They offer materials and documents which enable greater understanding of identity building processes that allow reflections about social, cultural or even economic processes that contribute to past, actual and future forms of European identity. The objective is to develop innovations and to use and analyse objects and/or documentation in cultural and scientific collections, archives and museums to improve our understanding of how European identity can be traced, constructed or debated.

The issues of multilingualism, translation and circulation of ideas across Europe and from and to Europe and how they form part of a common European intellectual heritage will be explored.

6.3.2. Researching into European countries' and regions' history, literature, art, philosophy and religions and how these have informed contemporary European diversity

Cultural diversity is an important facet constituting Europe's singularity and providing a source of strength, dynamism and creativity. The activities will address the contemporary European diversity and how this diversity is shaped by history while also helping to analyse how such diversity is conducive to new intercultural developments, or even tensions and conflicts. The role of arts, media, landscapes, literature, languages, philosophy and religions, in relation to this diversity, will be central as they offer various interpretations of the social, political and cultural realities and influence the visions and practices of individuals and social actors.

6.3.3. Researching Europe's role in the world, the mutual influence and ties between the world regions, and a view from outside on European cultures

The activities will address the complexity of the socio-economic and cultural links between Europe and other world regions and assess the potential for improved intercultural exchanges and dialogues taking into account broader social, political and economic developments. They will help to analyse the development of various views in Europe on other world regions and vice versa.

6.4. *Specific implementation aspects*

In order to promote an optimal combination of approaches, cooperation between this societal challenge and the priority "Industrial Leadership" shall be established in the form of cross-cutting actions targeting the field of interaction between humans and technology. Technological innovation based on ICT will play an important role in enhancing the productivity and engaging the creativity of citizens from all generations in an innovative society.

Implementation under this societal challenge will also enjoy the support of administration and coordination of international networks for excellent researchers and innovators such as COST and EURAXESS, and therefore also contribute to the ERA.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and relevant public-public and public-private partnerships.

Appropriate links with the actions of relevant European Innovation Partnerships and the relevant aspects of the research and innovation agendas of European Technology Platforms will also be established.

Research and innovation actions under this societal challenge will contribute to implementing the Union's international research and innovation cooperation activities, by engaging more strategically in science, technology and innovation cooperation with its main third country partners. In this regard, the Strategic Forum for International Scientific and Technological Cooperation (SFIC) will continue to give strategic advice to the Council and the Commission on the international dimension of the ERA.

7. SECURE SOCIETIES - PROTECTING FREEDOM AND SECURITY OF EUROPE AND ITS CITIZENS

The Union, its citizens and its international partners are confronted with a range of security threats and challenges like crime, terrorism and mass emergencies due to man-made or natural disasters. These can span across borders and aim at physical targets or the cyberspace. Attacks against critical infrastructures, networks and Internet sites of public authorities and private entities not only undermine the citizen's trust but may seriously affect essential sectors such as energy, transport, health, finance or telecommunications.

In order to anticipate, prevent and manage these threats, it is necessary to develop and apply innovative technologies, solutions, foresight tools and knowledge, stimulate cooperation between providers and users, find civil security solutions, improve the competitiveness of European security, industry and services, including ICT, and prevent and combat the abuse of privacy and breaches of human rights in Internet and elsewhere, while ensuring European citizens' individual rights and freedom.

The coordination and improvement of the security research and innovation area will thus be an essential element and will help to map present research efforts, including foresight, and improve relevant legal conditions and procedures for coordination, including pre-normative activities.

Activities within this societal challenge shall have an exclusive focus on civil applications and will follow a mission-oriented approach, promote efficient cooperation of end-users, industry and researchers, and integrate the relevant societal dimensions whilst complying with ethical principles. They will support the Union's policies for internal and external security, including the Common Foreign and Security Policy and its Common Security and Defence Policy, and improve cyber security, trust and privacy in the Digital Single Market. The activities will include a focus on the research and development of the next generation of innovative solutions, by working on novel concepts and designs, and interoperable standards. This will be done by developing innovative technologies and solutions that address security gaps and lead to a reduction in the risk from security threats.

The following specific objectives will be pursued:

7.1. *Fighting crime, illegal trafficking and terrorism, including understanding and tackling terrorist ideas and beliefs*

The ambition is both to avoid an incident and to mitigate its potential consequences. This requires new technologies and capabilities for fighting and preventing crime (including cyber crime), illegal trafficking and terrorism (including cyber terrorism), including understanding causes and impacts of radicalisation and violent extremism, and tackling terrorist ideas and beliefs to also avoid aviation-related threats.

7.2. *Protecting and improving the resilience of critical infrastructures, supply chains and transport modes*

New technologies, processes, methods and dedicated capabilities will help to protect critical infrastructures (including in urban areas), systems and services which are essential for the proper functioning of society and economy (including communications, transport, finance, health, food, water, energy, logistic and supply chain, and environment). This will include analysing and securing public and private critical networked infrastructures and services against any type of threats, including aviation-related threats. This will also include protection of maritime transport routes.

7.3. *Strengthening security through border management*

Technologies and capabilities are also required to enhance systems, equipments, tools, processes, and methods for rapid identification to improve land, marine and coastal border security and management, including both control and surveillance issues, while exploiting the full potential of the European Border Surveillance System (EUROSUR). These will be developed and tested considering their effectiveness, compliance with legal and ethical principles, proportionality, social acceptability and the respect of fundamental rights. Research will also support the improvement of the integrated European border management, including through increased cooperation with candidate, potential candidate and European Neighbourhood Policy countries.

7.4. *Improving cyber security*

Cyber security is a prerequisite for people, business and public services in order to benefit from the opportunities offered by the Internet or any other additional data networks and communication infrastructures. It requires providing an improved security for systems, networks, access devices, software and services, including cloud computing, while taking into account the interoperability of multiple technologies. Research and innovation will be supported to help prevent, detect and manage real-time cyber-attacks across multiple domains and jurisdictions, and to protect critical ICT infrastructures. The digital society is in full development with constantly changing uses and abuses of the Internet, new ways of social interaction, new mobile and location-based services and the emergence of the Internet of Things (IoT). This requires a new type of research which should be triggered by the emerging applications, usage and societal trends. Nimble research initiatives will be undertaken, including pro-active R&D, to react quickly to new contemporary developments in trust and security. Particular attention should be given to the protection of children, as they are highly vulnerable to the emerging forms of cyber crime and abuse.

Work here should be conducted in close co-ordination with the ICT strand of the priority "Industrial Leadership".

7.5. *Increasing Europe's resilience to crises and disasters*

This requires the development of dedicated technologies and capabilities to support different types of emergency management operations in crises and disaster situations (such as civil protection, fire fighting, environmental contamination, marine pollution, civil defence, development of medical information infrastructures, rescue tasks, and disaster recovery processes) as well as law enforcement. Research will cover the whole crisis management chain and societal resilience, and support the establishment of a European emergency response capacity.

7.6. *Ensuring privacy and freedom, including in the Internet, and enhancing the societal legal and ethical understanding of all areas of security, risk and management*

Safeguarding the human right of privacy, including in the digital society, will require the development of privacy-by-design frameworks and technologies to underpin new products and services. Technologies will be developed allowing users to control their personal data and its use by third parties, as well as tools to detect and block illegal content and data breaches and to protect human rights on-line, preventing that the behaviour of individuals or groups is limited by unlawful searching or profiling.

Any new security solution and technology needs to be acceptable to the society, comply with Union and international law, and be effective and proportionate in identifying and addressing the security threat. It is therefore essential to understand the socioeconomic, cultural, and anthropological dimensions of security, the causes of insecurity, the role of media and communication and the citizen's perceptions better. Ethical and legal issues and protection of human values and fundamental rights will be addressed, as well as risk and management issues.

7.7. *Enhancing standardisation and interoperability of systems, including for emergency purposes*

Pre-normative and standardisation activities will be supported across all mission areas. Attention will be paid to standardisation gaps and on the next generation of tools and technologies. Activities across all mission areas will also address the integration and interoperability of systems and services, including aspects such as communication, distributed architectures and human factors, including for emergency purposes.

7.8. *Supporting the Union's external security policies, including through conflict prevention and peace-building*

New technologies, capabilities and solutions are required to support the Union's external security policies in civilian tasks, ranging from civil protection to humanitarian relief, border management or peace-keeping and post-crisis stabilisation, including conflict prevention, peace-building and mediation. This will require research on conflict resolution and restoration of peace and justice, on early identification of factors leading to conflict and on the impact of restorative justice processes.

This also requires promoting interoperability between civilian and military capabilities in civilian tasks ranging from civil protection to humanitarian relief, border management or peace-keeping. This will include technological development in the sensitive area of dual-use technologies to enhance interoperability between civil protection and military forces and amongst civil protection forces worldwide, as well as reliability, organisational, legal and ethical aspects, trade issues, protection of confidentiality and integrity of information and traceability of all transactions and processing.

7.9. *Specific implementation aspects*

Whereas research and innovation activities will have an exclusive focus on civil applications, coordination with the activities of the European Defence Agency (EDA) will be actively pursued in order to strengthen cooperation with EDA, notably through the already established European Framework Cooperation (EFC), recognising that there are areas of dual-use technology. Coordination mechanisms with relevant Union agencies, such as the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (FRONTEX), European Maritime Safety Agency (EMSA), European Union Agency for Network and Information Security (ENISA) and European Police Office (Europol), will also be further strengthened in order to improve the coordination of Union programmes and policies in the field of both internal and external security, and of other Union initiatives.

Taking into account the particular nature of security, specific arrangements will be put in place with regards to programming and governance, including arrangements with the Committee referred to in Article 10. Classified or otherwise sensitive information related to security will be protected, and particular requirements and criteria for international cooperation may be specified in work programmes. This will also be reflected in the programming and governance arrangements for the specific objective "Secure societies - Protecting freedom and security of Europe and its citizens" (including the comitology aspects).

PART IV

SPREADING EXCELLENCE AND WIDENING PARTICIPATION

The aim is to fully exploit the potential of Europe's talent pool and ensure that the benefits of an innovation-led economy are both maximised and widely distributed across the Union in accordance with the principle of excellence.

There are significant disparities across Europe in research and innovation performance which need to be addressed with specific measures. These measures will aim at unlocking excellence and innovation and will be distinct from, and where appropriate complementary and synergistic with, policies and actions of the ESI Funds. They include:

(a) Teaming of excellent research institutions and low performing RDI regions: Teaming aims at the creation of new (or significant upgrade of existing) centres of excellence in low performing RDI Member States and regions. It will focus on the preparatory phase for setting up or upgrading and modernising such an institution, facilitated by a teaming process with a leading counterpart in Europe, including supporting the development of a business plan. A commitment of the recipient region or Member State (e.g. support via ESI Funds) is expected. Subject to the quality of the business plan, the Commission may provide further seed financial support for the first steps of implementation of the centre.

Building links with innovative clusters and recognising excellence in low performing RDI Member States and regions, including through peer reviews and awarding labels of excellence to those institutions that meet international standards, will be considered;

(b) Twinning of research institutions: Twinning aims at significantly strenghtening a defined field of research in an emerging institution through links with at least two internationally-leading institutions in a defined field. A comprehensive set of measures underpinning this linkage would be supported (e.g. staff exchanges, expert visits, short-term on-site or virtual trainings, and workshops; conference attendance; organisation of joint summer school type activities; dissemination and outreach activities);

(c) 'ERA Chairs': Establishing 'ERA Chairs' aims at attracting outstanding academics to institutions with a clear potential for research excellence, in order to help these institutions fully unlock this potential and hereby create a level playing field for research and innovation in the ERA. This will include institutional support for creating a competitive research environment and the framework conditions necessary for attracting, retaining and developing top research talent within these institutions. Possible synergies with ERC activities should be explored;

(d) Policy Support Facility: This will aim at improving the design, implementation and evaluation of national/regional research and innovation policies. It will offer expert advice to public authorities at national or regional level on a voluntary basis, covering the needs to access the relevant body of knowledge, to benefit from the insight of international experts, to use state-of-the-art methodologies and tools, and to receive tailor-made advice;

(e) Supporting access to international networks for excellent researchers and innovators who lack sufficient involvement in European and international networks. This will include support provided through COST;

(f) Strengthening the administrative and operational capacity of transnational networks of National Contact Points (NCPs), including through training, financial and technical support, while improving the framework for the operation of NCPs and the flow of information between them and the Horizon 2020 implementation bodies, so that NCPs can provide better support to potential participants.

PART V

SCIENCE WITH AND FOR SOCIETY

The aim is to build effective cooperation between science and society, to recruit new talent for science and to pair scientific excellence with social awareness and responsibility.

The strength of the European science and technology system depends on its capacity to harness talent and ideas from wherever they exist. This can only be achieved if a fruitful and rich dialogue and active cooperation between science and society is developed to ensure a more responsible science and to enable the development of policies more relevant to citizens. Rapid advances in contemporary scientific research and innovation have led to a rise of important ethical, legal and social issues that affect the relationship between science and society.

Improving the cooperation between science and society to enable a widening of the social and political support to science and technology in all Member States is an increasingly crucial issue which the current economic crisis has greatly exacerbated. Public investment in science requires a vast social and political constituency sharing the values of science, educated and engaged in its processes and able to recognise its contributions to knowledge, society and economic progress.

The focus of activities shall be to:

(a) make scientific and technological careers attractive to young students, and foster sustainable interaction between schools, research institutions, industry and civil society organisations;

(b) promote gender equality, in particular by supporting structural changes in the organisation of research institutions and in the content and design of research activities;

(c) integrate society in science and innovation issues, policies and activities in order to integrate citizens' interests and values and to increase the quality, relevance, social acceptability and sustainability of research and innovation outcomes in various fields of activity from social innovation to areas such as biotechnology and nanotechnology;

(d) encourage citizens to engage in science through formal and informal science education, and promote the diffusion of science-based activities, namely in science centres and through other appropriate channels;

(e) develop the accessibility and the use of the results of publicly-funded research;

(f) develop the governance for the advancement of responsible research and innovation by all stakeholders (researchers, public authorities, industry and civil society organisations), which is sensitive to society needs and demands, and promote an ethics framework for research and innovation;

(g) take due and proportional precautions in research and innovation activities by anticipating and assessing potential environmental, health and safety impacts;

(h) improve knowledge on science communication in order to improve the quality and effectiveness of interactions between scientists, general media and the public.

PART VI

NON-NUCLEAR DIRECT ACTIONS OF THE JOINT RESEARCH CENTRE (JRC)

The JRC shall contribute to the general objective and priorities of Horizon 2020 by providing scientific and technical support to Union policies, in collaboration with relevant national and regional research stakeholders, where appropriate. The JRC activities will be conducted taking into account relevant initiatives at the level of regions, Member States or the Union, within the perspective of shaping the ERA.

1. EXCELLENT SCIENCE

The JRC will carry out research to enhance the scientific evidence base for policy making and to examine emerging fields of science and technology, including through an exploratory research programme.

2. INDUSTRIAL LEADERSHIP

The JRC will contribute to innovation and competitiveness through:

(a) continuing to contribute to the strategic orientation and science agenda of relevant instruments of indirect research, such as European Innovation Partnerships as well as public-private partnerships and public-public partnerships;

(b) support to knowledge and technology transfer through definition of appropriate intellectual property rights frameworks for different research and innovation instruments, and promotion of cooperation in knowledge and technology transfer among large public research organisations;

(c) contributions to facilitating the use, standardisation and validation of space technologies and data, in particular to tackle the societal challenges.

3. SOCIETAL CHALLENGES

3.1. *Health, demographic change and well-being*

The JRC will contribute to the harmonisation of methods, standards, and practices in support of Union legislation targeting health and consumer protection through:

(a) assessment of risks and opportunities of new technologies and chemicals, including nanomaterials, in food, feed and consumer products; development and validation of harmonised measurement, identification and quantification methods, integrated testing strategies and state-of-the-art tools for toxicological hazard assessment, including alternative methods to animal testing; assessment of health effects of environmental pollution;

(b) development and quality assurance of health testing and screening practices, including genetic testing and cancer screening.

3.2. *Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy*

The JRC will support the development, implementation and monitoring of European agriculture and fisheries policies, including food security and development of the bioeconomy through:

(a) establishment of a global system and tools for crop forecasting and monitoring of crop productivity; support to improve short- to mid-term outlooks of agricultural commodities, including the predicted effects of climate change;

(b) contribution to biotechnological innovation and improved resource efficiency to produce 'more with less' through techno-economic analyses and modelling;

(c) scenario modelling for decision making in agricultural policies and analyses of policy impact at macro/regional/micro levels; analysis of the impact of the "CAP towards 2020" ([1]) on developing/emerging economies;

(d) further development of methods for fisheries control and enforcement and traceability of fish and fish products; development of robust ecosystem health indicators and bioeconomic modelling to better understand the direct effects (e.g. fishing) and indirect effects (climate change) of human activities on the fish stock dynamics, the marine environment, and their socio-economic impact.

3.3. *Secure, clean and efficient energy*

The JRC will focus on the 20-20-20 climate and energy targets and the Union's transition to a competitive low-carbon economy by 2050 with research on technological and socio-economic aspects of:

(a) security of energy supply, in particular as regards links and interdependencies with the extra-European energy supply and transmission systems; mapping indigenous primary and external energy sources and infrastructures on which Europe depends;

(b) energy/electricity transmission networks, in particular modelling and simulation of trans-European energy networks, analysis of smart/super grid technologies, and real-time simulation of power systems;

(c) energy efficiency, in particular methodologies for monitoring and assessing the achievements of energy efficiency policy instruments, techno-economic analysis of the use of energy-efficient technologies and instruments and of smart grids;

(d) low-carbon technologies (including safety of nuclear energy in the Euratom programme), in particular performance assessment and pre-normative research of prospective low-carbon technologies; analysis and modelling of drivers and barriers of their development and deployment; assessment of renewable resources and bottlenecks, such as critical raw materials, in the supply chain of low-carbon technologies; continuous development of the Information System for the SET-Plan (SETIS) and related activities.

3.4. *Smart, green and integrated transport*

The JRC will support the 2050 goals of a competitive, smart, resource-efficient and integrated transport system for safe and secure transport of people and goods through laboratory studies, modelling and monitoring approaches on:

(a) strategic low-carbon transport technologies for all transport modes, including road transport electrification and alternative fuelled aircrafts/vessels/vehicles, and further development of a Commission internal clearing house for collecting and disseminating information on relevant technologies; availability and costs of non-fossil based fuels and energy sources, including impacts of electrified road transport on electricity grids and electricity generation;

([1]) COM(2010) 672 final.

(b) clean and efficient vehicles, in particular definition of harmonised test procedures and assessment of innovative technologies in terms of emissions, conventional and alternative fuel efficiency and safety; developing improved methodologies for emission measurements and environmental pressures calculations; coordinating and harmonising emissions inventorying and monitoring activities at European level;

(c) smart mobility systems to achieve secure, intelligent and integrated mobility, including techno-economic assessment of new transport systems and components, applications for improved traffic management and contribution to the design of an integrated approach to transport demand and management:

(d) integrated transport safety, in particular provision of tools and services for collecting, sharing and analysing incidents and accidents information in the aviation, maritime and land transport sectors; enhancing accidents prevention through analysis and crossmodal safety lessons while contributing to cost savings and efficiency gains.

3.5. *Climate action, environment, resource efficiency and raw materials*

The JRC will contribute to the greening of Europe, security of resource supply and a global sustainable management of natural resources through:

(a) enabling access to interoperable environmental data and information through the further development of standards and interoperability arrangements, geo-spatial tools and innovative information communication technology infrastructures such as the Infrastructure for Spatial Information in the European Union (INSPIRE), and other Union and global initiatives;

(b) measuring and monitoring key environmental variables and assessing the state and change of natural resources by further developing indicators and information systems contributing to environmental infrastructures; assessing ecosystem services, including their valuation and climate change effects;

(c) developing an integrated modelling framework for sustainability assessment based on thematic models such as soil, land use, water, air quality, biodiversity, greenhouse gas emissions, forestry, agriculture, energy and transport, also addressing effects of and responses to climate change;

(d) supporting Union development policy goals by promoting technology transfer, monitoring of essential resources (such as forests, soils, and food supplies), and research to limit the impact of climate change and the environmental impacts of resource use, and to resolve trade-offs in the competition for land as between the production of food or energy and biodiversity;

(e) integrated assessment related to sustainable production and consumption policies, including security of supply of strategic raw materials, resource efficiency, low-carbon and clean production processes and technologies, products and services development, consumption patterns and trade. Further development and integration in policy analyses of Life Cycle Assessment;

(f) integrated impact analysis of options for climate change mitigation and/or adaptation based on the development of a quantitative tool set of models at regional and global scale, ranging from the sectoral to the macro-economic level.

3.6. *Europe in a changing world - Inclusive, innovative and reflective societies*

The JRC will contribute to the goals of the flagship initiative "Innovation Union" and the heading "Global Europe" of the Multiannual Financial Framework for 2014-2020 through the following activities:

(a) comprehensive analyses of drivers and barriers of research and innovation, and development of a modelling platform for the assessment of their micro- and macro-economic impacts;

(b) contributions to the monitoring of the implementation of the flagship initiative "Innovation Union" via scoreboards, development of indicators etc., and operation of a public information and intelligence system to host relevant data and information;

(c) operation of a public information and intelligence platform for assisting national and regional authorities with smart specialisation; quantitative economic analysis of the spatial pattern of economic activity, in particular addressing economic, social and territorial disparities and changes in the pattern in response to technological developments;

(d) econometrics and macro-economic analysis of the reform of the financial system to contribute to maintain an efficient Union framework for financial crisis management; continuing to provide methodological support for monitoring of Member State budget positions in relation to the Stability and Growth Pact;

(e) monitoring the functioning of the ERA and analysing drivers of and barriers to some of its key elements (such as mobility of researchers and opening up of national research programmes) and proposing relevant policy options; continuing to play an important role in the ERA through networking, training, opening its facilities and databases to users in Member States and in candidate and associated countries;

(f) developing quantitative economic analysis of the Digital Economy; carrying out research on the impact of information and communication technologies on the goals of the Digital Society; studying the impact of sensitive security issues on the lives of individuals (Digital Living).

3.7. *Secure societies - Protecting freedom and security of Europe and its citizens*

The JRC will contribute to the goals of the heading "Security and Citizenship" of the Multiannual Financial Framework for 2014-2020 through the following activities:

(a) focusing on identification and assessment of the vulnerability of critical infrastructures (including global navigation systems and financial markets); improvement of tools for fighting fraud against the general budget of the Union and for maritime surveillance; operational performance assessment of technologies for or affecting personal identity (digital identity);

(b) enhancing the Union's capacity for disaster risk reduction and management of natural and man-made disasters notably through the development of global multi-hazard early warning and risk management information systems, making use of Earth observation technologies;

(c) continueing to provide tools for the assessment and management of global security challenges such as terrorism and non-proliferation (chemical, biological, radiological and nuclear (in the Euratom programme)) and threats arising from socio-political instability and communicable diseases; new areas to be addressed include vulnerability and resilience to emerging or hybrid threats, e.g. accessibility to raw materials, piracy, resource scarcity/competition and effects of climate change on occurrence of natural disasters.

4. SPECIFIC IMPLEMENTATION ASPECTS

In line with the priorities of the heading "Global Europe" of the Multiannual Financial Framework for 2014-2020, the JRC will strengthen scientific cooperation with key international organisations and third countries (e.g. UN bodies, OECD, United States, Japan, Russia, China, Brazil, and India) in areas having a strong global dimension such as climate change, food security, or nanotechnologies. This cooperation will be coordinated closely with international cooperation activities of the Union and the Member States.

In order to provide an enhanced service to policy making, the JRC will further develop its capacity to analyse and provide cross-sectoral policy options and to carry out related impact assessments. This capacity will be supported in particular through strengthening of:

(a) modelling in key areas (e.g. energy and transport, agriculture, climate, environment, and economics); the focus will be on both sectoral and integrated models (for sustainability assessments), and it will cover scientific-technical as well as economic aspects;

(b) forward-looking studies which will provide analyses of trends and events in science, technology and society and on how these may affect public policies, influence innovation, and reinforce competitiveness and sustainable growth; this would enable the JRC to draw attention to issues that may require future policy intervention and to anticipate customers' needs.

The JRC will strengthen its support to the standardisation process and standards as a horizontal component in support of European competitiveness. Activities will include pre-normative research, development of reference materials and measurements, and harmonisation of methodologies. Five focal areas have been identified (energy; transport; the flagship initiative "Digital Agenda"; security and safety (including nuclear in the Euratom programme); and consumer protection). Moreover, the JRC will continue to promote dissemination of its results and provide support on the management of intellectual property rights to Union institutions and bodies.

The JRC will establish a capacity in behavioural sciences to support the development of more effective regulation, complementing JRC activities in selected fields such as nutrition, energy efficiency and product policies.

Socio-economic research will be part of the activities in relevant areas such as the flagship initiative "Digital Agenda", sustainable production and consumption or public health.

In order to fulfil its mission as reference centre for the Union, to continue to play a vital role in the ERA, and to enter into new fields of research, it is essential that the JRC disposes of state-of-the-art infrastructure. The JRC will continue its renovation and refurbishment programme to ensure compliance with applicable environmental and safety and security regulations, and it will invest into scientific infrastructure, including the development of modelling platforms, facilities for new areas such as genetic testing, etc. Such investments will be done in close coordination with the roadmap of ESFRI and take into account existing facilities in the Member States.

ANNEX II

PERFORMANCE INDICATORS

The following table specifies a number of key indicators for assessing the results and impacts of the specific objectives of Horizon 2020. These key indicators may be refined during the implementation of Horizon 2020.

1. PART I. PRIORITY 'EXCELLENT SCIENCE'

Indicators for the specific objectives:

— European Research Council (ERC)

  — Share of publications from ERC-funded projects which are among the top 1 % highly cited per field of science

— Future and Emerging Technologies (FET)

  — Publications in peer-reviewed high impact journals

  — Patent applications and patents awarded in Future and Emerging Technologies

— Marie Skłodowska-Curie actions

  — Cross-sector and cross-country circulation of researchers, including PhD candidates

— Research infrastructures (including eInfrastructures)

  — Number of researchers who have access to research infrastructures through Union support

2. PART II. PRIORITY 'INDUSTRIAL LEADERSHIP'

Indicators for the specific objectives:

— Leadership in enabling and industrial technologies

  — Patent applications and patents awarded in the different enabling and industrial technologies

  — Share of participating firms introducing innovations new to the company or the market (covering the period of the project plus three years)

  — Number of joint public-private publications

— Access to risk finance

  — Total investments mobilised via debt financing and venture capital investments

  — Number of organisations funded and amount of private funds leveraged

— Innovation in SMEs

  — Share of participating SMEs introducing innovations new to the company or the market (covering the period of the project plus three years)

  — Growth and job creation in participating SMEs

3. PART III. PRIORITY 'SOCIETAL CHALLENGES'

Indicators for the specific objectives:

— For all societal challenges:

  — Publications in peer-reviewed high impact journals in the area of the various societal challenges

— Patent applications and patents awarded in the area of the various societal challenges

— Number of prototypes and testing activities

— Number of joint public-private publications

Moreover, for each of the challenges, progress shall be assessed against the contribution to the specific objectives which are detailed in Annex I to Regulation (EU) No 104/2013.

4. PART VI. NON-NUCLEAR DIRECT ACTIONS OF THE JOINT RESEARCH CENTRE (JRC)

Indicators for the specific objective:

— Number of occurrences of tangible specific impacts on European policies resulting from technical and scientific support provided by the JRC

— Number of peer reviewed publications in high impact journals

ANNEX III

MONITORING

The Commission will monitor the implementation of Horizon 2020 and in particular the following:

1. Contribution to the realisation of the ERA
2. Widening participation
3. SMEs' participation
4. Social sciences and humanities
5. Science and society
6. Gender
7. International cooperation
8. Sustainable development and climate change, including information on climate change related expenditure
9. Bridging from discovery to market application
10. Digital Agenda
11. Private sector participation
12. Funding for public-private and public-public partnerships
13. Communication and dissemination
14. Participation patterns of independent experts

ANNEX IV

Information to be provided by the Commission in accordance with Article 9(2)

1. Information on individual projects, enabling the monitoring of the entire lifetime of each proposal, covering in particular:

   — submitted proposals,

   — evaluation results for each proposal,

   — grant agreements,

   — completed projects.

2. Information on the outcome of each call and project implementation, covering in particular:

   — results of each call,

   — outcome of negotiations on grant agreements,

   — project implementation, including payment data and outcome of projects.

3. Information on programme implementation, including relevant information at the level of the framework programme, the specific programme, each specific objective and related themes and the JRC, as well as the synergies with other relevant Union programmes.

4. Information on the execution of the Horizon 2020 budget, including information on commitments and payments for initiatives under Articles 185 and 187 TFEU.

ANNEX V

Programme Committee configurations

List of configurations [1] of the Programme Committee in accordance with Article 10(2):

1. Strategic configuration: Strategic overview of the implementation of the whole programme, coherence across the different parts of the programme and cross-cutting issues including the specific objectives "Spreading excellence and widening participation" and "Science with and for society".

Part I — Excellence Science:

2. European Research Council (ERC), Future and Emerging Technologies (FET) and Marie Skłodowska-Curie Actions (MSCA)

3. Research infrastructures

Part II — Industrial Leadership:

4. Information and communication technologies (ICT)

5. Nanotechnologies, Advanced materials, Biotechnology, Advanced manufacturing and processing

6. Space

7. SMEs and Access to risk finance

Part III — Societal Challenges:

8. Health, demographic change and well-being

9. Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy

10. Secure, clean and efficient energy

11. Smart, green and integrated transport

12. Climate action, environment, resource efficiency and raw materials

13. Europe in a changing world – Inclusive, innovative and reflective societies

14. Secure societies – Protecting Freedom and security of Europe and its citizens

[1] With a view to facilitating the implementation of the programme, for each meeting of the Programme Committee as defined in the agenda, the Commission will reimburse, in accordance with its established guidelines, the expenses of one representative per Member State, as well as one expert/adviser per Member State for those agenda items where a Member State requires specific expertise.

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidelines to the Rules on

Open Access to Scientific Publications
and
Open Access to Research Data
in Horizon 2020

Version 3.2
21 March 2017

HISTORY OF CHANGES			
Version	**Date**	**Change**	**Page**
2.1	15.02.2016	▪ The guide was also published as part of the Online Manual with updated and simplified content	all
3.0	26.07.2016	▪ This version has been updated to reflect the extension of the Open Research Data Pilot	all
3.1	25.08.2016	▪ Link added to specific guidelines to projects funded by European Research Council	3
3.2.	21.03.2017	▪ Change in title of the document and clarification of its purpose ▪ Provision of an optional model addendum to publication agreements in order support compliance with Horizon 2020 embargo periods (based on a similar document for FP7)	1,3,7

These guidelines explain the rules on open access to scientific peer reviewed publications and research data that beneficiaries have to follow in projects funded or co-funded under Horizon 2020.

Note that these guidelines do not apply to their full extent to actions funded by the European Research Council (ERC). For information and guidance concerning implementation of Open Access and the Open Research Data Pilot at the ERC, please see the Guidelines on the Implementation of Open Access to Scientific Publications and Research Data in projects supported by the European Research Council under Horizon 2020 or contact erc-open-access@ec.europa.eu.

1. WHAT IS OPEN ACCESS?

Open access (OA) refers to the practice of providing online access to **scientific information** that is free of charge to the end-user and reusable. 'Scientific' refers to all academic disciplines. In the context of research and innovation, 'scientific information' can mean:

1. peer-reviewed scientific research articles (published in scholarly journals) or
2. research data (data underlying publications, curated data and/or raw data).

1. Peer-reviewed scientific research articles

Open access to scientific publications means free online access for any user. Although there are no legally binding definitions of 'access' or 'open access' in this context, authoritative definitions of open access appear in key political declarations including:

- the 2002 Budapest Declaration
- the 2003 Berlin Declaration

Under these definitions, '**access**' includes not only basic elements - the right to read, download and print – but also the right to copy, distribute, search, link, crawl and mine.

The 2 main routes to open access are:

A. **Self-archiving / 'green' open access** – the author, or a representative, archives (deposits) the published article or the final peer-reviewed manuscript in an online repository before, at the same time as, or after publication. Some publishers request that open access be granted only after an embargo period has elapsed.

B. **Open access publishing / 'gold' open access** - an article is immediately published in open access mode. In this model, the payment of publication costs is shifted away from subscribing readers.
The most common business model is based on one-off payments by authors. These costs, often referred to as Article Processing Charges (APCs) are usually borne by the researcher's university or research institute or the agency funding the research.
In other cases, the costs of open access publishing are covered by subsidies or other funding models.

Misconceptions about open access to scientific publications

In the context of research funding, open access requirements do not imply an obligation to publish results. The decision to publish is entirely up to the grant beneficiaries. Open access becomes an issue *only if* publication is chosen as a means of dissemination.

Moreover, open access does not affect the decision to exploit research results commercially, e.g. through patenting. The decision on whether to publish through open access must come after the more general decision on whether to publish directly or to first seek protection.

This is illustrated in the chart at the end of this section, which shows open access to scientific publication and research data in the wider context of dissemination and exploitation.

For more information, see the European IPR Helpdesk factsheet "Publishing vs. patenting".

2. Research data

Open access to research data

Refers to the right to access and reuse digital research data under the terms and conditions set out in the Grant Agreement.

Research data

Refers to information, in particular facts or numbers, collected to be examined and considered as a basis for reasoning, discussion, or calculation.

In a research context, examples of data include statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images. The focus is on research data that is available in digital form.

Users can normally access, mine, exploit, reproduce and disseminate openly accessible research data free of charge.

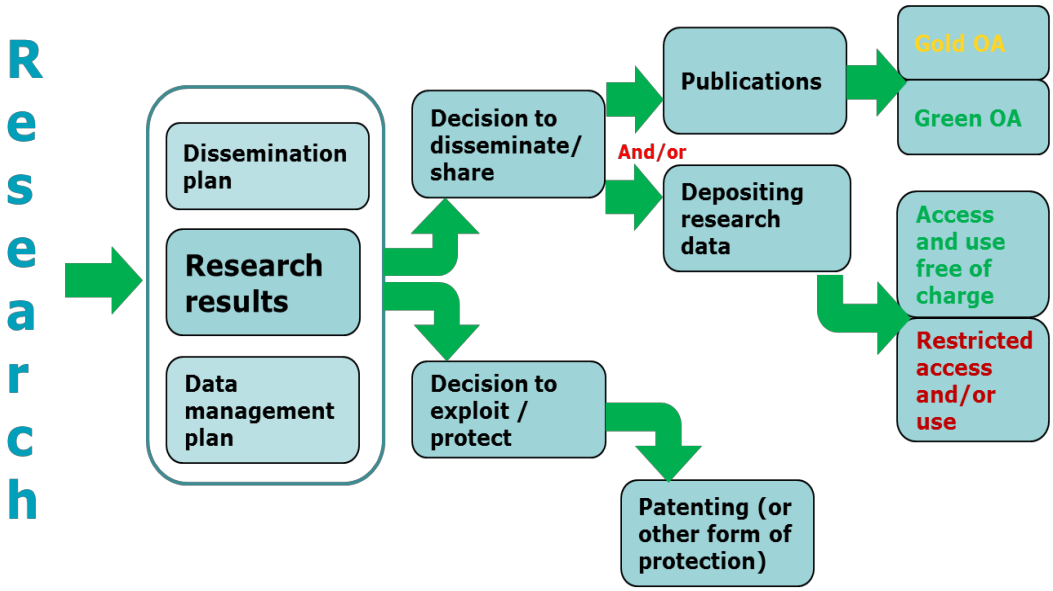

Graph: Open access to scientific publication and research data in the wider context of dissemination and exploitation

2. WHY HAVE OPEN ACCESS TO PUBLICATIONS AND DATA IN HORIZON 2020?

Modern research builds on extensive scientific dialogue and advances by improving earlier work. The Europe 2020 strategy for a smart, sustainable and inclusive economy underlines the central role of knowledge and innovation in generating growth. Broader access to scientific publications and data therefore helps to:

- **build on previous research results** (improved quality of results)
- **encourage collaboration** and avoid duplication of effort (greater efficiency)
- **speed up innovation** (faster progress to market means faster growth)
- **involve citizens and society** (improved transparency of the scientific process).

This is why the EU wants to improve access to scientific information and to boost the benefits of public investment in research funded under Horizon 2020.

The Commission considers that there should be no need to pay for information funded from the public purse each time it is accessed or used. Moreover, it should benefit European businesses and the public to the full.

This means making publicly-funded scientific information available online, at no extra cost, to European researchers, innovative industries and the public, while ensuring that it is preserved in the long term.

Under Horizon 2020, the legal basis for open access is laid down in the Framework Programme and its Rules for Participation. These principles are translated into specific requirements in the Model Grant Agreement and in the Horizon 2020 work programmes.

The Annotated Model Grant Agreement provides specific explanations of the Model Grant Agreement. These guidelines build on these documents.

3. MANDATE ON OPEN ACCESS TO PUBLICATIONS

Article 29.2 of the Model Grant Agreement sets out detailed legal requirements on open access to scientific publications: under Horizon 2020, **each beneficiary must ensure open access to all peer-reviewed scientific publications** relating to its results.

To meet this requirement, beneficiaries must, at the very least, ensure that any scientific peer-reviewed publications can be read online, downloaded and printed.

Since any further rights - such as the right to copy, distribute, search, link, crawl and mine - make publications more useful, beneficiaries should make every effort to provide as many of these options as possible.

Peer-reviewed publications are those assessed by other scholars. Peer review is typically, though not exclusively, organised by the journal or publisher to which an article or manuscript is submitted. However, new approaches are expected to become more prevalent in years to come.

The dominant type of **scientific publication** is the journal article. Grant beneficiaries are also strongly encouraged to provide open access to other types of scientific publications including:

- monographs
- books
- conference proceedings
- grey literature (informally published written material not controlled by scientific publishers, e.g. reports).

The open access mandate comprises 2 steps:

1. depositing publications in repositories
2. providing open access to them

These steps are explained in more detail below. They may or may not occur simultaneously, depending on whether open access publishing ('gold' open access) or self-archiving ('green' open access) is used, and, in the case of self-archiving, depending on the embargo period (if any).

Step 1 - Depositing publications in repositories

Beneficiaries must deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications. This must be done as soon as possible and at the latest upon publication.

This step applies **even where open access publishing** (**'gold' open access**) **is chosen** to ensure that the article is preserved in the long term.

'Machine-readable electronic copy' - publications must be in a format that can be used and understood by a computer. They must be stored in text file formats that are either standardised or otherwise publicly known so that anyone can develop new tools for working with the documents.

In some cases, the final version of an article can be deposited *before publication*, for example at the time when the article is accepted by the journal. The latest acceptable time to deposit a publication is the date of publication.

Where possible, the version deposited should be identical to the published version (in layout, pagination, etc.).

A repository for scientific publications is an **online archive**. Institutional, subject-based and centralised repositories are all acceptable choices. Repositories that claim rights over deposited publications and preclude access are not.

The Open Access Infrastructure for Research in Europe (OpenAIRE) is the recommended entry point for researchers to determine what repository to choose. It also offers support services for researchers, such as the National Open Access Desks. Other useful listings of repositories are:

- Registry of Open Access Repositories (ROAR)
- Directory of Open Access Repositories (OpenDOAR)

Article 29.2 of the Model Grant Agreement also mentions that beneficiaries must aim to deposit at the same time as the publication the research data needed to validate the results presented in the deposited scientific publications (**'underlying data'**), ideally in a data repository. Note that this requirement is not related to the openness of the data but to data management – openness of research data is addressed in article 29.3 of the Model Grant Agreement as explained in point 4 below.

Step 2 - Providing open access to publications

After depositing publications beneficiaries must ensure open access to those publications via the chosen repository.

Beneficiaries can choose one of two main ways to meet this requirement:

1. **Self-archiving / 'green' OA**: beneficiaries can deposit the final peer-reviewed manuscript in a repository of their choice. They must ensure open access to the publication within at most 6 months (12 months for publications in the social sciences and humanities).
   To provide support concerning compliance with Horizon 2020 embargo periods the Commission offers a model amendment to publishing agreements, which are often signed between authors and publishers. This model is not mandatory but reflects the obligations for the beneficiary under the H2020 grant agreements. It can be supplemented by further provisions agreed between the parties, provided they are compatible with the Grant Agreement. The Commission/Agency takes no responsibility for the use of this model.

2. **Open access publishing / 'gold' OA**: researchers can also publish in open access journals, or in hybrid journals that both sell subscriptions and offer the option of making individual articles openly accessible.
   Monographs can also be published either on a purely open access basis or using a hybrid business model.
   'Article processing charges' are eligible for reimbursement during the duration of the project (as other costs defined in Article 6.2.D.3 of the Model Grant Agreement). As stated, the article must also be made accessible through a repository upon publication.

   The **costs** of 'gold' open access publications incurred once a project is completed cannot be refunded from that project's budget. However, a mechanism is being piloted to address the issue of open access publication charges incurred once a grant agreement with the Commission has expired. This pilot project, funded under the OpenAIRE2020 project, supports open access publications arising from completed FP7 projects. Detailed information and conditions to apply for reimbursements is provided in the OpenAIRE FP7 Post-Grant Open Access Pilot Application Guidelines.

Beneficiaries must also provide open access, through the repository, to the **bibliographic metadata** that identify the deposited publication. These must be in a standard format and must include the following:

- terms *["European Union (EU)" & "Horizon 2020"]["Euratom" & Euratom research & training programme 2014-2018"]*
- name of the action, acronym and grant number
- publication date, the length of the embargo period (if applicable) and a persistent identifier.

The purpose of the bibliographic metadata requirement is to make it easier to find publications and ensure that EU funding is acknowledged. Information on EU funding must therefore be included as part of bibliographic metadata so that Horizon 2020 can be properly monitored, statistics produced, and the programme's impact assessed.

To monitor any embargo periods, the publication date and embargo period must be provided. The persistent identifier (for example a Digital Object Identifier) identifies the publication. It enables a link to be provided to an authoritative version of the publication.

In all cases, the Commission encourages authors to retain their **copyright** and grant adequate licences to publishers. Creative Commons offers useful licensing solutions. This type of licence is a good legal tool for providing open access in its broadest sense.

Where possible, contributors should also be uniquely identifiable, and data uniquely attributable, through **identifiers** which are persistent, non-proprietary, open and interoperable (e.g. through leveraging existing sustainable initiatives such as ORCID for contributor identifiers and DataCite for data identifiers).

4. EXTENDED PILOT ON OPEN ACCESS TO RESEARCH DATA

The Commission has enabled access to and reuse of research data generated by Horizon 2020 projects through the Open Research Data Pilot (ORD Pilot). As stated in the 2017 work programme, the **pilot is being extended to cover all thematic areas** as described below. This is indicated in the general introduction of the work programme, the specific work programmes and in the General Annex L.

The legal requirements for participating projects are set out in Article 29.3 of the Model Grant Agreement, included by default in the Grant Agreement (but can be removed by opting out – see below).

Open research data will be monitored throughout Horizon 2020 with a view to further developing the Commission's policy on open science.

Opting out – partially or entirely

By extending the pilot, open access becomes the default setting for research data generated in Horizon 2020.

However, not all data can be open. Projects can therefore opt out at any stage (either before or after signing the grant) and so free themselves retroactively from the obligations associated with the conditions – if:

- participation is incompatible with the obligation to protect results that can reasonably be expected to be commercially or industrially exploited
- participation is incompatible with the need for confidentiality in connection with security issues
- participation is incompatible with rules on protecting personal data
- participation would mean that the project's main aim might not be achieved
- the project will not generate / collect any research data or
- there are other legitimate reasons (*you can enter these in a free-text box at the proposal stage*).

The Commission's approach can therefore be described as "*as open as possible, as closed as necessary*".

⚠ Important: Participation in the Open Research Data Pilot is **not** part of the project evaluation.

In other words, proposals will not be penalised for opting out.

During the lifetime of a project, a total opt-out is possible for any of the reasons highlighted above. In this case, Article 29.3 is removed from the Grant Agreement via an amendment.

Alternatively, projects can also choose to keep selected datasets or even all data closed for any of the reasons above, via their Data Management Plan.

For more information, and a template, please see the Guidelines on data management in Horizon 2020.

Exceptions for instruments

The Open Research Data Pilot will apply to all *thematic areas* of Horizon 2020 from the **start of the 2017 work programme**.

However, not all *instruments* are suitable for research data sharing. The following instruments are excluded:

- **"co-fund" and "prizes" instruments**
- **"ERC proof of concept" grants**
- **"ERA-Nets" that do not produce data**
- **SME instrument, phase 1**

Coordination and support actions are included in the Open Research Data Pilot, as many of them produce relevant data.

For 2-stage calls, information on participation in the Pilot will be requested only at stage 2.

⚠ In summary, participating in the Open Research Data Pilot does not necessarily mean opening up all research data. Rather, the focus of the Pilot is on encouraging good data management as an essential element of research best practice.

Types of data covered

1. **the 'underlying data'** (the data needed to validate the results presented in scientific publications), including the **associated metadata** (i.e. metadata describing the research data deposited), **as soon as possible**
2. **any other data** (for instance curated data not directly attributable to a publication, or raw data), including the **associated metadata**, **as specified and within the deadlines laid down in the DMP** – that is, according to the individual judgement by each project/grantee.

What are the requirements of the Open Research Data Pilot?

Projects must meet the following requirements:

Step1 - they must deposit the research data described above, preferably in a research data repository. These are online research data archives, which may be subject-based/thematic, institutional or centralised. Useful listings of repositories include the Registry of Research Data Repositories and Databib. The Open Access Infrastructure for Research in Europe (OpenAIRE) provides additional information and support on linking publications to underlying research data. Some repositories like Zenodo (an OpenAIRE and CERN collaboration), allows researchers to deposit both publications and data, while providing tools to link them. Zenodo and some other repositories as well as many academic publishers also facilitate linking publications and underlying data through persistent identifiers and data citations.

Step 2 – as far as possible, projects must then take measures to enable third parties to access, mine, exploit, reproduce and disseminate (free of charge for any user) this research data.
One straightforward and effective way of doing this is to attach Creative Commons Licences (CC BY or CC0) to the data deposited.
The EUDAT B2SHARE tool includes a built-in license wizard that facilitates the selection of an adequate license for research data.

At the same time, projects should provide **information** via the chosen repository about the tools available to the beneficiaries that are needed to validate the results, e.g. specialised software or software code, algorithms and analysis protocols. Where possible, they should provide these **instruments** themselves.

Periodic reporting

Check further details on how to fill in reporting tables for publications, deliverables and the process for continuous reporting in the Participant Portal's grant management system.

Incentives / supporting measures

Costs related to open access are eligible as part of the grant, if they fulfil the general eligibility conditions specified in the Grant Agreement.

You can also find specific technical and professional support services through the OpenAIRE and EUDAT2020 projects.

5. FURTHER INFORMATION AND HELP

- Horizon 2020 programmes
- European Commission Open Access Policy (Open Science)
- Further activities on Open Access (Digital Agenda)
- Horizon 2020 General Model Grant Agreement

- Horizon 2020 Annotated Grant Agreement – for Articles 29.2 and 29.3
- Press release – open access to research results
- OpenAIRE

Questions about open access?

E-mail the Commission

E-mail the ERC

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidelines on FAIR Data Management in Horizon 2020

Version 3.0
26 July 2016

History of changes			
Version	**Date**	**Change**	**Page**
2.1	15.02.2016	▪ the guide was also published as part of the Online Manual with updated and simplified content	all
3.0	26.07.2016	▪ This version has been updated in the context of the extension of the Open Research Data Pilot and related data management issues ▪ New DMP template included	all 6

1. Background – Extension of the Open Research Data Pilot in Horizon 2020

⚠ Please note the distinction between open access to scientific peer-reviewed ***publications*** and open access to research ***data***:

- **publications** – open access is an *obligation* in Horizon 2020.
- **data** – the Commission is running a flexible pilot which has been extended and is described below.

See also the guideline: Open access to publications and research data in Horizon 2020.

This document helps Horizon 2020 beneficiaries make their research data **findable, accessible, interoperable and reusable** (**FAIR**), to ensure it is soundly managed. Good research data management is not a goal in itself, but rather the key conduit leading to knowledge discovery and innovation, and to subsequent data and knowledge integration and reuse.

Note that these guidelines do not apply to their full extent to actions funded by the ERC. For information and guidance concerning Open Access and the Open Research Data Pilot at the ERC, please read the Guidelines on the Implementation of Open Access to Scientific Publications and Research Data in projects supported by the European Research Council under Horizon 2020.

The Commission is running a flexible pilot under Horizon 2020 called the Open Research Data Pilot (ORD pilot). The ORD pilot aims to improve and maximise access to and re-use of research data generated by Horizon 2020 projects and takes into account the need to balance openness and protection of scientific information, commercialisation and Intellectual Property Rights (IPR), privacy concerns, security as well as data management and preservation questions.

In the 2014-16 work programmes, the ORD pilot included only selected areas of Horizon 2020. Under the revised version of the 2017 work programme, the Open Research Data pilot has been extended to cover all the thematic areas of Horizon 2020.

While open access to research data thereby becomes applicable by default in Horizon 2020, the Commission also recognises that there are good reasons to keep some or even all research data generated in a project closed.

The Commission therefore provides robust *opt-out* possibilities at any stage, that is

- during the application phase
- during the grant agreement preparation (GAP) phase and
- after the signature of the grant agreement.

The ORD pilot applies primarily to the data needed to validate the results presented in scientific publications. Other data can also be provided by the beneficiaries on a voluntary basis, as stated in their Data Management Plans. Costs associated with open access to research data, can be claimed as eligible costs of any Horizon 2020 grant.

Participation in the ORD pilot is not part of the evaluation of proposals. In other words, proposals are not evaluated more favourably because they are part of the pilot and are not penalised for opting out of the pilot.

For more on open access to research data, please also consult the H2020 Annotated Model Grant Agreement.

> ⚠ Participating in the ORD Pilot does not necessarily mean opening up all your research data. Rather, the ORD pilot follows the principle "**as open as possible, as closed as necessary**" and focuses on encouraging sound data management as an essential part of research best practice.

2. Data Management Plan – general definition

Data Management Plans (DMPs) are a *key element* of good data management. A DMP describes the data management life cycle for the data to be collected, processed and/or generated by a Horizon 2020 project. As part of making research data findable, accessible, interoperable and re-usable (FAIR), a DMP should include information on:

- the handling of research data during and after the end of the project
- what data will be collected, processed and/or generated
- which methodology and standards will be applied
- whether data will be shared/made open access and
- how data will be curated and preserved (including after the end of the project).

A DMP is required for all projects participating in the extended ORD pilot, unless they opt out of the ORD pilot. However, projects that opt out are still encouraged to submit a DMP on a voluntary basis.

3. Proposal, submission & evaluation

> ⚠ Whether a proposed project participates in the ORD pilot or chooses to opt out does not affect the evaluation of that project. In other words, proposals will not be penalized for opting out of the extended ORD pilot.

Since participation in the ORD pilot is not an evaluation criterion, the proposal is **not** expected to contain a fully developed DMP. However, good research data management as such should be addressed under the impact criterion, as relevant to the project. Your application should address the following issues:

- What standards will be applied?
- How will data be exploited and/or shared/made accessible for verification and reuse? If data cannot be made available, why?
- How will data be curated and preserved?

Your policy should also:

- reflect the current state of consortium agreements on data management
- be consistent with exploitation and Intellectual Property Rights (IPR) requirements

You should also ensure resource and budgetary planning for data management and include a deliverable for an initial DMP at month 6 at the latest into your proposal.

4. Research data management plans during the project life cycle

Once a project has had its funding approved and has started, you **must submit a first version of your DMP** (as a deliverable) within the first 6 months of the project. The Commission provides a DMP template in annex, the use of which is recommended but voluntary.

The DMP needs to be **updated** over the course of the project whenever significant changes arise, such as (but not limited to):

- new data
- changes in consortium policies (e.g. new innovation potential, decision to file for a patent)
- changes in consortium composition and external factors (e.g. new consortium members joining or old members leaving).

The DMP should be updated as a minimum in time with the periodic evaluation/assessment of the project. If there are no other periodic reviews foreseen within the grant agreement, then such an update needs to be made in time for the final review at the latest. Furthermore, the consortium can define a timetable for review in the DMP itself.

Periodic reporting

For general information on periodic reporting please check the following sections of the online manual

- How to fill in reporting tables for publications, deliverables
- Process for continuous reporting in the grant management system.

5. Support

Reimbursement of costs

Costs related to open access to research data in Horizon 2020 are eligible for reimbursement during the duration of the project under the conditions defined in the H2020 Grant Agreement, in particular Article 6 and Article 6.2.D.3, but also other articles relevant for the cost category chosen.

Data Management Plan

A DMP **template** is provided in Annex I. While the Commission does not currently offer its own online tool for data management plans, beneficiaries can generate DMPs online, using tools that are compatible with the requirements set out in Annex 1 (see also section 7 of Annex I).

ANNEX 1

Horizon 2020 FAIR Data Management Plan (DMP) template

Version: 26 July 2016

Introduction

This Horizon 2020 FAIR DMP template has been designed to be applicable to any Horizon 2020 project that produces, collects or processes research data. You should develop a **single DMP for your project** to cover its overall approach. However, where there are specific issues for individual datasets (e.g. regarding openness), you should clearly spell this out.

FAIR data management

In general terms, your research data should be 'FAIR', that is findable, accessible, interoperable and re-usable. These principles precede implementation choices and do not necessarily suggest any specific technology, standard, or implementation-solution.

This template is not intended as a strict technical implementation of the FAIR principles, it is rather inspired by FAIR as a general concept.

More information about FAIR:

FAIR data principles (FORCE11 discussion forum)

FAIR principles (article in Nature)

Structure of the template

The template is a **set of questions** that you should answer with a level of detail appropriate to the project.

It is not required to provide detailed answers to all the questions in the first version of the DMP that needs to be submitted by month 6 of the project. Rather, the DMP is intended to be *a living document* in which information can be made available on a finer level of granularity through updates as the implementation of the project progresses and when significant changes occur. Therefore, DMPs should have a clear version number and include a timetable for updates. As a minimum, the DMP should be updated in the context of the periodic evaluation/assessment of the project. If there are no other periodic reviews envisaged within the grant agreement, an update needs to be made in time for the final review at the latest.

In the following the main sections to be covered by the DMP are outlined. At the end of the document, Table 1 contains a summary of these elements in bullet form.

This template itself may be updated as the policy evolves.

1. Data Summary

What is the purpose of the data collection/generation and its relation to the objectives of the project?

What types and formats of data will the project generate/collect?

Will you re-use any existing data and how?

What is the origin of the data?

What is the expected size of the data?

To whom might it be useful ('data utility')?

2. FAIR data

2. 1. Making data findable, including provisions for metadata

Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

What naming conventions do you follow?

Will search keywords be provided that optimize possibilities for re-use?

Do you provide clear version numbers?

What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

2.2. Making data openly accessible

Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.

Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for *opting out.*

How will the data be made accessible (e.g. by deposition in a repository)?

What methods or software tools are needed to access the data?

Is documentation about the software needed to access the data included?

Is it possible to include the relevant software (e.g. in open source code)?

Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

Have you explored appropriate arrangements with the identified repository?

If there are restrictions on use, how will access be provided?

Is there a need for a data access committee?

Are there well described conditions for access (i.e. a machine readable license)?

How will the identity of the person accessing the data be ascertained?

2.3. Making data interoperable

Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organisations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

2.4. Increase data re-use (through clarifying licences)

How will the data be licensed to permit the widest re-use possible?

When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

How long is it intended that the data remains re-usable?

Are data quality assurance processes described?

Further to the FAIR principles, DMPs should also address:

3. Allocation of resources

What are the costs for making data FAIR in your project?

How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

Who will be responsible for data management in your project?

Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

4. Data security

What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

Is the data safely stored in certified repositories for long term preservation and curation?

5. Ethical aspects

Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

6. Other issues

Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

7. Further support in developing your DMP

The Research Data Alliance provides a Metadata Standards Directory that can be searched for discipline-specific standards and associated tools.

The EUDAT B2SHARE tool includes a built-in license wizard that facilitates the selection of an adequate license for research data.

Useful listings of repositories include:

- Registry of Research Data Repositories
- Some repositories like Zenodo, an OpenAIRE and CERN collaboration), allow researchers to deposit both publications and data, while providing tools to link them.
- Other useful tools include DMP online and platforms for making individual scientific observations available such as ScienceMatters.

SUMMARY TABLE 1

FAIR Data Management at a glance: issues to cover in your Horizon 2020 DMP

This table provides a summary of the Data Management Plan (DMP) issues to be addressed, as outlined in Annex I. You should refer to the annex and the main text of the guidelines for further guidance.

DMP component	Issues to be addressed
1. Data summary	• State the purpose of the data collection/generation • Explain the relation to the objectives of the project • Specify the types and formats of data generated/collected • Specify if existing data is being re-used (if any) • Specify the origin of the data • State the expected size of the data (if known) • Outline the data utility: to whom will it be useful
2. FAIR Data 2.1. Making data findable, including provisions for metadata	• Outline the discoverability of data (metadata provision) • Outline the identifiability of data and refer to standard identification mechanism. Do you make use of persistent and unique identifiers such as Digital Object Identifiers? • Outline naming conventions used • Outline the approach towards search keyword • Outline the approach for clear versioning • Specify standards for metadata creation (if any). If there are no standards in your discipline describe what type of metadata will be created and how

2.2 Making data openly accessible	• Specify which data will be made openly available? If some data is kept closed provide rationale for doing so • Specify how the data will be made available • Specify what methods or software tools are needed to access the data? Is documentation about the software needed to access the data included? Is it possible to include the relevant software (e.g. in open source code)? • Specify where the data and associated metadata, documentation and code are deposited • Specify how access will be provided in case there are any restrictions
2.3. Making data interoperable	• Assess the interoperability of your data. Specify what data and metadata vocabularies, standards or methodologies you will follow to facilitate interoperability. • Specify whether you will be using standard vocabulary for all data types present in your data set, to allow inter-disciplinary interoperability? If not, will you provide mapping to more commonly used ontologies?
2.4. Increase data re-use (through clarifying licences)	• Specify how the data will be licenced to permit the widest reuse possible • Specify when the data will be made available for re-use. If applicable, specify why and for what period a data embargo is needed • Specify whether the data produced and/or used in the project is useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why • Describe data quality assurance processes • Specify the length of time for which the data will remain re-usable
3. Allocation of resources	• Estimate the costs for making your data FAIR. Describe how you intend to cover these costs • Clearly identify responsibilities for data management in your project • Describe costs and potential value of long term preservation

4. Data security	• Address data recovery as well as secure storage and transfer of sensitive data
5. Ethical aspects	• To be covered in the context of the ethics review, ethics section of DoA and ethics deliverables. Include references and related technical aspects if not covered by the former
6. Other	• Refer to other national/funder/sectorial/departmental procedures for data management that you are using (if any)

EN

Horizon 2020

Work Programme 2016 - 2017

3. Marie Skłodowska-Curie Actions

Important notice on the second Horizon 2020 Work Programme

This Work Programme covers 2016 and 2017. The parts of the Work Programme that relate to 2017 (topics, dates, budget) have, with this revised version, been updated. The changes relating to this revised part are explained on the Participant Portal.

(European Commission Decision C(2016)4614 of 25 July 2016)

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Introduction

This part of the Work Programme contributes to developing the new knowledge and enhancing the skills of people behind research and innovation, this being one of the key drivers identified in the strategy for the first three years of Horizon 2020.

The Marie Skłodowska-Curie actions ensure excellent and innovative research training as well as attractive career and knowledge-exchange opportunities through cross-border and cross-sector mobility of researchers, to better prepare them for current and future societal challenges.

The Marie Skłodowska-Curie actions are open to all domains of research and innovation addressed under the Treaty on the Functioning of the European Union, from basic research up to market take-up and innovation services[1]. Research and innovation fields as well as sectors are chosen freely by the applicants in a fully bottom-up manner.

The Marie Skłodowska-Curie actions are open to researchers and innovation staff at all stages of their career, irrespective of age. They are open to universities, research institutions, research infrastructures, businesses, and other socio-economic actors, including civil society organisations, from all countries, including third countries under the conditions defined in the Horizon 2020 Rules for Participation Regulation No 1290/2013 and in part A of the General Annexes to the Work Programme. Attention is paid to encouraging the strong participation of industry, in particular SMEs, for the successful implementation and impact of the Marie Skłodowska-Curie actions.

The Marie Skłodowska-Curie actions support researchers to establish themselves on a more stable career path and to ensure that they can achieve an appropriate work/life balance, taking into account their family situation.

Mobility is a key requirement in the Marie Skłodowska-Curie actions. Researchers receive funding on the condition that they move from one country to another to broaden or deepen their competences.

The principles of the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers[2] (Charter and Code) promoting open recruitment and attractive working and employment conditions should be applied by all the funded participants.

Principles of research integrity - as set out, for instance, in the European Code of Conduct for Research Integrity – will apply throughout all Marie Skłodowska-Curie actions.

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[1] Proposals falling within the scope of the Annex I of the Euratom Treaty shall be submitted to relevant calls under the Euratom Framework Programme.

[2] Commission Recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, C(2005) 576 of 11.3.2005.

The Marie Skłodowska-Curie actions endorse the Horizon 2020 Responsible Research and Innovation (RRI) cross-cutting issue, engaging society, integrating the gender and ethical dimensions, ensuring the access to research outcomes and encouraging formal and informal science education. All applicants to the Marie Skłodowska-Curie calls are encouraged to adopt an RRI approach into their proposals.

The ethical dimension of the activities undertaken should be analysed and taken into account, including relevant socio-economic implications. This implies the respect of ethical principles and related legislation during the implementation. Whenever possible, the activities should also include in their objectives a better understanding and handling of the ethical aspects as well as the promotion of the highest ethical standards in the field and among the actors and stakeholders.

The Marie Skłodowska-Curie actions pay particular attention to gender balance. In line with the Charter and Code, all Marie Skłodowska-Curie proposals are encouraged to take appropriate measures to facilitate mobility and counter-act gender-related barriers to it. Equal opportunities are to be ensured in the implementation of the actions by a balanced participation of women and men, both at the level of supported researchers and that of decision-making/supervision/management structure. In research activities where human beings are involved as subjects or end-users, gender differences may exist. In these cases the gender dimension in the research content has to be addressed as an integral part of the proposal to ensure the highest level of scientific quality.

As training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their proposals such activity.

To further enhance dissemination and public engagement, beneficiaries of the Marie Skłodowska-Curie actions are required to plan suitable public outreach activities. In this way, they can also contribute to the cross-cutting objectives of Horizon 2020, such as climate action, sustainable development and biodiversity.

The following applies for all calls with opening dates falling between 14/10/2015 and 25/07/2016 inclusive:

A novelty in Horizon 2020 is the Pilot on Open Research Data which aims to improve and maximise access to and re-use of research data generated by projects. Applicants to the Marie Skłodowska-Curie actions may participate in the Open Research Data Pilot on a voluntary basis. Participation in the Pilot is not taken into account during the evaluation procedure. In other words, proposals will not be evaluated favourably because they are part of the Pilot. More information can be found under General Annex L of the work programme.

A further new element in Horizon 2020 is the use of Data Management Plans (DMPs) detailing what data the project will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. The use of a DMP is required for projects participating in the Open Research Data Pilot. Other projects are invited to submit a DMP if relevant for their planned research. Only funded projects are required to submit a DMP.

Further guidance on the Pilot on Open Research Data and Data Management is available on the Participant Portal.

The following applies for all calls with an opening date on or after 26/07/2016:
Grant beneficiaries under this work programme part will engage in research data sharing by default, as stipulated under Article 29.3 of the Horizon 2020 Model Grant Agreement (including the creation of a Data Management Plan). Participants may however opt out of these arrangements, both before and after the signature of the grant agreement. More information can be found under General Annex L of the work programme.

Marie Skłodowska-Curie Innovative Training Networks

H2020-MSCA-ITN-2016

MSCA-ITN-2016: Innovative Training Networks

Objective: The Innovative Training Networks (ITN) aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit.

ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, incorporating the elements of Open Science and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced career perspectives in both the academic and non-academic sectors through international, interdisciplinary and intersectoral mobility combined with an innovation-oriented mind-set.

Scope: ITN supports competitively selected joint research training and/or doctoral programmes, implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs, and other socio-economic actors from different countries across Europe and beyond.

Partnerships take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

Each programme should have a clearly identified supervisory board co-ordinating network-wide training and establishing active and continuous communication and exchange of best practice among the partners to maximise the benefits of the partnership.

The programme should exploit complementary competences of the participating organisations, and enable sharing of knowledge, networking activities, the organisation of workshops and conferences.

Training responds to well identified needs in defined research areas, with appropriate references to inter- and multidisciplinary fields and follows the EU Principles for Innovative Doctoral Training. It should be primarily focused on scientific and technological knowledge through research on individual, personalised projects.

In order to increase the employability of the researchers, the research training should be complemented by the meaningful exposure of each researcher to the non-academic sector.

Secondments of the researcher to other beneficiaries and partner organisations are encouraged.

Substantial training modules, including digital ones, addressing key transferable skills common to all fields and fostering the culture of Open Science, innovation and entrepreneurship will be supported.

In order to reflect on the changing nature of research, training should prepare early-stage researchers for an increased research collaboration and information-sharing made possible by new technologies (e.g. collaborative tools, open access, raw data, etc.).

A Career Development Plan should be established jointly by the supervisor(s) and the early-stage researcher recruited by the selected network. In addition to research objectives, this plan comprises the researcher's training and career needs, including planning for publications and participation in conferences.

Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance. Joint supervision of the researchers is mandatory for EJD and for EID, and encouraged in ETN. In EID, the joint supervision of the researcher must be ensured by at least one supervisor from the academic sector and one supervisor from the non-academic sector. These arrangements will be taken into account during the evaluation of the proposal.

In EID and EJD, fellowships offered to early-stage researchers should lead to a doctoral degree. EJD result in joint[3], double or multiple doctoral degrees[4] awarded by institutions from at least two different countries.

In EID and EJD, enrolment in a doctoral programme and the creation of a joint governance structure - with joint admission (EJD only), selection, supervision, monitoring and assessment procedures - is mandatory. These arrangements will be taken into account during the evaluation of the proposal.

Expected Impact:

At researcher level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia (leading in the longer-term to more successful careers)
- Increase in higher impact R&I output and more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Enhanced cooperation and better transfer of knowledge between sectors and disciplines
- Improvement in the quality of training programmes and supervision arrangements
- Creation of new networks and enhanced quality of existing ones

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[3] Joint degree – a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries where the degree-awarding institutions are located.

[4] Double or multiple degree - two or more national diplomas issued by two or more higher education institutions and recognised officially in the countries where the degree-awarding institutions are located.

- Boosting R&I capacity among participating organisations
- Increased internationalisation of participating organisations

At system level:

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- More structured and innovative doctoral training, enhanced implementation of the European Charter and Code and the EU Principles for Innovative Doctoral Training
- Stronger links between the European Research Area (ERA) and the European Higher Education Area (EHEA), notably through supporting the knowledge triangle between research, innovation and education
- Improvement in the working and employment conditions for doctoral candidates in Europe
- Increased societal and economic relevance of European higher education
- Strengthening Europe's human capital base in R&I with a new generation of more entrepreneurial and highly-skilled early career researchers
- Increase in Europe's attractiveness as a leading research destination, accompanied by a rise in the numbers of talented researchers attracted and retained from abroad
- Better quality research and innovation contributing to Europe's competitiveness and growth

Type of Action: European Industrial Doctorates, European Joint Doctorates, European Training Networks

Conditions for the Marie Skłodowska-Curie Innovative Training Networks call
Opening date(s), deadline(s), indicative budget(s):[5]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2016	
Opening: 15 Oct 2015		
MSCA-ITN-2016 (MSCA-ITN-ETN)	322.00	12 Jan 2016
MSCA-ITN-2016 (MSCA-ITN-EID)	25.00	
MSCA-ITN-2016 (MSCA-ITN-EJD)	28.00	
Overall indicative budget	375.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the General Annexes to the work programme. The award criteria, scoring and threshold for Marie

[5] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.

Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

Marie Skłodowska-Curie Individual Fellowships

H2020-MSCA-IF-2016

MSCA-IF-2016: Individual Fellowships

Objective: The goal of the Individual Fellowships is to enhance the creative and innovative potential of experienced researchers, wishing to diversify their individual competence in terms of skill acquisition through advanced training, international and intersectoral mobility.

Individual Fellowships provide opportunities to acquire and transfer new knowledge and to work on research and innovation in a European context (EU Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

Scope: Support is foreseen for individual, trans-national fellowships awarded to the best or most promising researchers of any nationality, for employment in EU Member States or Associated Countries. It is based on an application made jointly by the researcher and the beneficiary in the academic or non-academic sectors.

Only one proposal per individual researcher will be evaluated.

Fellowships take the form of European Fellowships or Global Fellowships. European Fellowships are held in EU Member States or Associated Countries and are open to researchers either coming to Europe from any country in the world or moving within Europe. The researcher must comply with the rules of mobility in the country where the European Fellowship is held.

Return and reintegration of researchers into a longer term research position in Europe, including in their country of origin, is supported via a separate multi-disciplinary reintegration panel of the European Fellowships. For the reintegration panel, there shall be mobility into Europe.

Support to individuals to resume research in Europe after a career break, e.g. after parental leave, is ensured via a separate multi-disciplinary career restart panel of the European Fellowships. To qualify for the career restart panel, researchers must not have been active in research for at least 12 months immediately prior to the deadline for submission.

Researchers seeking to work on research and innovation projects in an organisation from the non-academic sector will be supported via a separate multi-disciplinary society and enterprise panel of the European Fellowships. The objective of this panel is to facilitate career moves between the academic and non-academic sectors and to open attractive career opportunities for researchers outside academia.

Global Fellowships are based on a secondment to a third country and a mandatory 12 month return period to a European host. The researcher must comply with the rules of mobility in the

country where the Global Fellowship secondment takes place, not for the country of the return phase.

Researchers receiving an Individual Fellowship may opt to include a secondment phase in Europe, notably in the non-academic sector, within the overall duration of their fellowship. For a fellowship of 18 months or less, the secondment phase may last up to three months. For a fellowship of more than 18 months, the secondment phase may last up to six months. The secondment phase can be a single period or be divided into shorter mobility periods. The secondment should significantly add to the impact of the fellowship.

A Career Development Plan should be established jointly by the supervisor(s) and the researcher. In addition to research or innovation objectives, this plan comprises the researcher's training and career needs, including training on transferable skills, planning for publications and participation in conferences.

Expected Impact:

At researcher level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia
- Increase in higher impact R&I output, more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Enhanced cooperation and stronger networks
- Better transfer of knowledge between sectors and disciplines
- Boosting of R&I capacity among participating organisations

At system level:

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- Strengthening of Europe's human capital base in R&I with more entrepreneurial and better trained researchers
- Better communication of R&I results to society
- Increase in Europe's attractiveness as a leading destination for R&I
- Better quality research and innovation contributing to Europe's competitiveness and growth

Type of Action: CAR – Career Restart panel, RI – Reintegration panel, SE - Society and Enterprise panel, Standard EF, GF - Global Fellowships

Conditions for the Marie Skłodowska-Curie Individual Fellowships call

Opening date(s), deadline(s), indicative budget(s):[6]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2016	
Opening: 12 Apr 2016		
MSCA-IF-2016 (MSCA-IF-EF-CAR) MSCA-IF-2016 (MSCA-IF-EF-RI) MSCA-IF-2016 (MSCA-IF-EF-ST)	179.71	14 Sep 2016
MSCA-IF-2016 (MSCA-IF-EF-SE)	10.00	
MSCA-IF-2016 (MSCA-IF-GF)	29.00	
Overall indicative budget	218.71	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

[6] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the General Annexes to the work programme. The award criteria, scoring and threshold for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 10 pages, excluding the CV of the researcher and the annexes.

Consortium agreement: Not applicable - this is a mono-beneficiary action.

Marie Skłodowska-Curie Research and Innovation Staff Exchange

H2020-MSCA-RISE-2016

MSCA-RISE-2016: Research and Innovation Staff Exchange

Objective: The RISE scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa).

The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

Scope: RISE involves organisations from the academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Associated Countries) and outside Europe (third countries).

Support is provided for the development of partnerships in the form of a joint research and innovation project. This is aimed at knowledge sharing via international as well as intersectoral mobility, based on secondments of research and innovation staff (exchanges) with an in-built return mechanism.

The organisations constituting the partnership contribute directly to the implementation of a joint research and innovation project by seconding and/or hosting eligible staff members. Secondments shall always take place between legal entities independent from each other[7].

RISE should exploit complementary competences of the participating organisations, as well as other synergies, and enable networking activities, organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and career development for research and innovation staff members.

RISE projects can focus either on one dimension of mobility (intersectoral / international), or include a combination of both.

Exchanges can be for both early-stage and experienced researchers' levels and can also include administrative, managerial and technical staff directly involved in the research and innovation activities of the proposal.

Support for the exchanges between institutions within Europe (EU Member States and Associated Countries) covers only intersectoral secondments.

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[7] Independence in the meaning of Article 8 of the Horizon 2020 Rules for Participation.

Exchanges with institutions from and to third countries can be intersectoral as well as within the same sector.

Secondments between institutions located in third countries or within the same EU Member State or Associated Country will not be supported.

Expected Impact:

At staff member level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia
- Increase in higher impact R&I output, more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Enhanced cooperation and transfer of knowledge between sectors and disciplines
- Strengthening of international and intersectoral collaborative networks
- Boosting of R&I capacity among participating organisations

At system level:

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- Strengthening of Europe's human capital base in R&I
- Increase in Europe's attractiveness as a leading destination for R&I
- Better quality R&I contributing to Europe's competitiveness and growth

Type of Action: RISE

Conditions for the Marie Skłodowska-Curie Research and Innovation Staff Exchange call

Opening date(s), deadline(s), indicative budget(s):[8]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2016	
Opening: 08 Dec 2015		
MSCA-RISE-2016 (MSCA-RISE)	80.00	28 April 2016
Overall indicative budget	80.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the General Annexes to the work programme. The award criteria, scoring and threshold for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

[8] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

Marie Skłodowska-Curie Co-funding of regional, national and international programmes

H2020-MSCA-COFUND-2016

MSCA-COFUND-2016: Co-funding of regional, national and international programmes

Objective: The COFUND scheme aims to stimulate regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions.

This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

Scope: Each proposal funded under the COFUND scheme shall have a sole beneficiary that will be responsible for the availability of the necessary matching funds to execute the proposal.

Applicants submit multi-annual proposals for new or existing doctoral programmes or fellowship programmes which are expected to have an impact on enhancing research- and innovation related human resources on regional, national or international level.

Applicants having benefited from COFUND under previous calls (under the Seventh Framework Programme or under Horizon 2020) will explain how their proposal adds value in relation to previous grant(s). This can also take the form of increased networking with organisations in less represented countries or capacity building measures there.

Researchers supported under this scheme shall comply with the mobility rules of the Marie Skłodowska-Curie actions.

Limitations regarding the researchers' origin and destination should be avoided. Support cannot be awarded to researchers who are already permanently employed by the organisation hosting them.

Proposed programmes are encouraged to cover all research disciplines ("bottom-up"), but can also focus on specific disciplines. In this case the range of covered disciplines should allow reasonable flexibility for the researchers.

Programmes that prioritise specific research disciplines based on national or regional Research and Innovation Strategies for Smart Specialisation (RIS3 strategies) can also be supported. Synergies with the European Structural & Investment Funds (ESIF) are encouraged.

COFUND takes the form of:

A) Doctoral programmes

Doctoral programmes address the development and broadening of the research competencies of early-stage researchers. The training follows the EU Principles on Innovative Doctoral Training. Collaboration with a wider set of partner organisations, including from the non-academic sector, which may provide hosting or secondment opportunities or training in research or transferable skills, as well as innovative elements of the proposed programme, will be positively taken into account during the evaluation.

Each researcher must be enrolled in a doctoral programme. Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance.

B) Fellowship programmes

Fellowship programmes fund individual research training and career development fellowships for experienced researchers. The programmes supported should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between the researchers applying. The selections should be based on open, widely advertised competition, with transparent international peer review and the selection of candidates on merit. Mobility types supported by fellowship programmes may be similar to the ones supported under Marie Skłodowska-Curie Individual Fellowships. On top of transnational mobility, applicants are encouraged to include elements of cross-sectoral mobility into their programmes. Fellowship programmes should be based on individual-driven mobility, i.e., researchers should be able to freely choose a research topic and the appropriate organisation to host them, fitting their individual needs.

Given that the aim of the co-funded fellowship programmes is the support of individual fellows, research teams will not be funded.

Expected Impact:

At researcher level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia (leading in the longer-term to more successful careers)
- Increase in higher impact R&I output, more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Development of high quality human resources
- Boosting R&I capacity among participating organisations
- Enhanced cooperation and transfer of knowledge between sectors and disciplines
- Strengthening of international and intersectoral collaborative networks

At system level:

- Aligning of practices and policies in the context of the EU Human Resources Strategy for Researchers, enhanced implementation of the European Charter and Code and the

EU Principles for Innovative Doctoral Training at regional, national or international level

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- Improvement in the working and employment conditions for researchers in Europe at all levels of their career, starting from the doctoral stage
- Strengthening of Europe's human capital base in R&I
- Increase in Europe's attractiveness as a leading destination for R&I
- Better quality R&I contributing to Europe's competitiveness and growth

Type of Action: Doctoral programmes, Fellowship programmes

Conditions for the Marie Skłodowska-Curie Co-funding of regional, national and international programmes call

Opening date(s), deadline(s), indicative budget(s):[9]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2016	
Opening: 14 Apr 2016		
MSCA-COFUND-2016 (MSCA-COFUND-DP)	30.00	29 Sep 2016
MSCA-COFUND-2016 (MSCA-COFUND-FP)	50.00	
Overall indicative budget	80.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the General Annexes to the work programme. The award criteria, scoring and threshold for Marie

[9] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.

Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Not applicable - this is a mono-beneficiary action.

European Researchers' Night

H2020-MSCA-NIGHT-2016

MSCA-NIGHT-2016: European Researchers' Night

Objective: The European Researchers' Night aims to bring researchers closer to the general public and to increase awareness of research and innovation activities, with a view to supporting the public recognition of researchers, creating an understanding of the impact of researchers' work on citizen's daily life, and encouraging young people to embark on research careers.

Scope: The European Researchers' Night takes place yearly, typically on the last Friday of the month of September, and is the occasion for a Europe-wide public and media event for the promotion of research careers, in particular towards young people and their families. Supported events can start on Friday and last until early morning the following day.

Activities focus on the general public, addressing and attracting people regardless of the level of their scientific background, with a special focus on pupils and students. Activities can combine education aspects with entertainment, especially when addressing young audience. They can take various forms, e.g. hands-on experiments, science shows, simulations, debates, games, competitions, quizzes, etc.

Where appropriate, engagement with educational institutions should be sought in order to encourage formal and informal science education with the aim to improve the scientific knowledge base.

Each proposal should set up at least one European corner. Activities should be organised with researchers actively involved and directly in contact with the public. They should promote the European dimension and gender balance in research and innovation. Involvement of researchers funded by Horizon 2020, including the Marie Skłodowska-Curie actions, is encouraged.

Participants can be any legal entity in the EU Member States and Associated Countries, and/or if relevant, constitute a partnership at regional, national or international level. The maximum duration of support will be two years from the starting date specified in the grant agreement. Proposal should cover two editions of the Night, in successive years. One single edition of the Night may also be considered.

Applicants not retained due to lack of funding may be granted the status of associated events.

Expected Impact:

- Increased awareness among the general public of the importance of research and innovation and more favourable general attitude towards its public funding
- Better understanding of the key benefits that research brings to society
- Reduction in the stereotypes about researchers and their profession
- Increase, in the long term, of people taking up research careers

Type of Action: Coordination and support action

Conditions for the European Researchers' Night call

Opening date(s), deadline(s), indicative budget(s):[10]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2016	
Opening: 15 Oct 2015		
MSCA-NIGHT-2016 (CSA)	8.00	13 Jan 2016
Overall indicative budget	8.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The conditions are described in parts B and C of the General Annexes to the work programme.

Evaluation criteria, scoring and threshold: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation Procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide published on the Participant Portal.

[10] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

Marie Skłodowska-Curie Innovative Training Networks

H2020-MSCA-ITN-2017

MSCA-ITN-2017: Innovative Training Networks

Objective: The Innovative Training Networks (ITN) aim to train a new generation of creative, entrepreneurial and innovative early-stage researchers, able to face current and future challenges and to convert knowledge and ideas into products and services for economic and social benefit.

ITN will raise excellence and structure research and doctoral training, extending the traditional academic research training setting, incorporating the elements of Open Science and equipping researchers with the right combination of research-related and transferable competences. It will provide enhanced career perspectives in both the academic and non-academic sectors through international, interdisciplinary and intersectoral mobility combined with an innovation-oriented mind-set.

Scope: ITN supports competitively selected joint research training and/or doctoral programmes, implemented by partnerships of universities, research institutions, research infrastructures, businesses, SMEs, and other socio-economic actors from different countries across Europe and beyond.

Partnerships take the form of collaborative European Training Networks (ETN), European Industrial Doctorates (EID) or European Joint Doctorates (EJD).

Each programme should have a clearly identified supervisory board co-ordinating network-wide training and establishing active and continuous communication and exchange of best practice among the partners to maximise the benefits of the partnership.

The programme should exploit complementary competences of the participating organisations, and enable sharing of knowledge, networking activities, the organisation of workshops and conferences.

Training responds to well identified needs in defined research areas, with appropriate references to inter- and multidisciplinary fields and follows the EU Principles for Innovative Doctoral Training. It should be primarily focused on scientific and technological knowledge through research on individual, personalised projects.

In order to increase the employability of the researchers, the research training should be complemented by the meaningful exposure of each researcher to the non-academic sector.

Secondments of the researcher to other beneficiaries and partner organisations are encouraged.

Substantial training modules, including digital ones, addressing key transferable skills common to all fields and fostering the culture of Open Science, innovation and entrepreneurship will be supported.

In order to reflect on the changing nature of research, training should prepare early-stage researchers for an increased research collaboration and information-sharing made possible by new technologies (e.g. collaborative tools, open access, raw data, etc.).

A Career Development Plan should be established jointly by the supervisor(s) and the early-stage researcher recruited by the selected network. In addition to research objectives, this plan comprises the researcher's training and career needs, including planning for publications and participation in conferences.

Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance. Joint supervision of the researchers is mandatory for EJD and for EID, and encouraged in ETN. In EID, the joint supervision of the researcher must be ensured by at least one supervisor from the academic sector and one supervisor from the non-academic sector. These arrangements will be taken into account during the evaluation of the proposal.

In EID and EJD, fellowships offered to early-stage researchers should lead to a doctoral degree. EJD result in joint[11], double or multiple doctoral degrees[12] awarded by institutions from at least two different countries.

In EID and EJD, enrolment in a doctoral programme and the creation of a joint governance structure - with joint admission (EJD only), selection, supervision, monitoring and assessment procedures - is mandatory. These arrangements will be taken into account during the evaluation of the proposal.

Expected Impact:

At researcher level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia (leading in the longer-term to more successful careers)
- Increase in higher impact R&I output and more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Enhanced cooperation and better transfer of knowledge between sectors and disciplines
- Improvement in the quality of training programmes and supervision arrangements
- Creation of new networks and enhanced quality of existing ones

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[11] Joint degree – a single diploma issued by at least two higher education institutions offering an integrated programme and recognised officially in the countries where the degree-awarding institutions are located.

[12] Double or multiple degree - two or more national diplomas issued by two or more higher education institutions and recognised officially in the countries where the degree-awarding institutions are located.

- Boosting R&I capacity among participating organisations
- Increased internationalisation of participating organisations

At system level:

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- More structured and innovative doctoral training, enhanced implementation of the European Charter and Code and the EU Principles for Innovative Doctoral Training
- Stronger links between the European Research Area (ERA) and the European Higher Education Area (EHEA), notably through supporting the knowledge triangle between research, innovation and education
- Improvement in the working and employment conditions for doctoral candidates in Europe
- Increased societal and economic relevance of European higher education
- Strengthening Europe's human capital base in R&I with a new generation of more entrepreneurial and highly-skilled early career researchers
- Increase in Europe's attractiveness as a leading research destination, accompanied by a rise in the numbers of talented researchers attracted and retained from abroad
- Better quality research and innovation contributing to Europe's competitiveness and growth

Type of Action: European Industrial Doctorates, European Joint Doctorates, European Training Networks

Conditions for the Marie Skłodowska-Curie Innovative Training Networks call
Opening date(s), deadline(s), indicative budget(s):[13]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2017	
Opening: 15 Sep 2016		
MSCA-ITN-2017 (MSCA-ITN-ETN)	370.00	10 Jan 2017
MSCA-ITN-2017 (MSCA-ITN-EID)	28.00	
MSCA-ITN-2017 (MSCA-ITN-EJD)	32.00	
Overall indicative budget	430.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the

[13] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.
The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

General Annexes to the work programme. The award criteria, scoring and threshold for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

Marie Skłodowska-Curie Individual Fellowships

H2020-MSCA-IF-2017

MSCA-IF-2017: Individual Fellowships

Objective: The goal of the Individual Fellowships is to enhance the creative and innovative potential of experienced researchers, wishing to diversify their individual competence in terms of skill acquisition through advanced training, international and intersectoral mobility.

Individual Fellowships provide opportunities to acquire and transfer new knowledge and to work on research and innovation in a European context (EU Member States and Associated Countries) or outside Europe. The scheme particularly supports the return and reintegration of researchers from outside Europe who have previously worked here. It also develops or helps to restart the careers of individual researchers that show great potential, considering their experience.

Scope: Support is foreseen for individual, trans-national fellowships awarded to the best or most promising researchers of any nationality, for employment in EU Member States or Associated Countries. It is based on an application made jointly by the researcher and the beneficiary in the academic or non-academic sectors.

Only one proposal per individual researcher will be evaluated.

Fellowships take the form of European Fellowships or Global Fellowships. European Fellowships are held in EU Member States or Associated Countries and are open to researchers either coming to Europe from any country in the world or moving within Europe. The researcher must comply with the rules of mobility in the country where the European Fellowship is held.

Return and reintegration of researchers into a longer term research position in Europe, including in their country of origin, is supported via a separate multi-disciplinary reintegration panel of the European Fellowships. For the reintegration panel, there shall be mobility into Europe.

Support to individuals to resume research in Europe after a career break, e.g. after parental leave, is ensured via a separate multi-disciplinary career restart panel of the European Fellowships. To qualify for the career restart panel, researchers must not have been active in research for at least 12 months immediately prior to the deadline for submission.

Researchers seeking to work on research and innovation projects in an organisation from the non-academic sector will be supported via a separate multi-disciplinary society and enterprise panel of the European Fellowships. The objective of this panel is to facilitate career moves between the academic and non-academic sectors and to open attractive career opportunities for researchers outside academia.

Global Fellowships are based on a secondment to a third country and a mandatory 12 month return period to a European host. The researcher must comply with the rules of mobility in the

country where the Global Fellowship secondment takes place, not for the country of the return phase.

Researchers receiving an Individual Fellowship may opt to include a secondment phase in Europe, notably in the non-academic sector, within the overall duration of their fellowship. For a fellowship of 18 months or less, the secondment phase may last up to three months. For a fellowship of more than 18 months, the secondment phase may last up to six months. The secondment phase can be a single period or be divided into shorter mobility periods. The secondment should significantly add to the impact of the fellowship.

A Career Development Plan should be established jointly by the supervisor(s) and the researcher. In addition to research or innovation objectives, this plan comprises the researcher's training and career needs, including training on transferable skills, planning for publications and participation in conferences.

Expected Impact:

At researcher level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia
- Increase in higher impact R&I output, more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Enhanced cooperation and stronger networks
- Better transfer of knowledge between sectors and disciplines
- Boosting of R&I capacity among participating organisations

At system level:

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- Strengthening of Europe's human capital base in R&I with more entrepreneurial and better trained researchers
- Better communication of R&I results to society
- Increase in Europe's attractiveness as a leading destination for R&I
- Better quality research and innovation contributing to Europe's competitiveness and growth

Type of Action: CAR – Career Restart panel, RI – Reintegration panel, SE - Society and Enterprise panel, Standard EF, GF - Global Fellowships

Conditions for the Marie Skłodowska-Curie Individual Fellowships call

Opening date(s), deadline(s), indicative budget(s):[14]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2017	
Opening: 11 Apr 2017		
MSCA-IF-2017 (MSCA-IF-EF-CAR) MSCA-IF-2017 (MSCA-IF-EF-RI) MSCA-IF-2017 (MSCA-IF-EF-ST)	205.00	14 Sep 2017
MSCA-IF-2017 (MSCA-IF-EF-SE)	10.00	
MSCA-IF-2017 (MSCA-IF-GF)	33.70	
Overall indicative budget	248.70	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie

[14] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.
The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the General Annexes to the work programme. The award criteria, scoring and threshold for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 10 pages, excluding the CV of the researcher and the annexes.

Consortium agreement: Not applicable - this is a mono-beneficiary action.

Marie Skłodowska-Curie Research and Innovation Staff Exchange

H2020-MSCA-RISE-2017

MSCA-RISE 2017: Research and Innovation Staff Exchange

Objective: The RISE scheme will promote international and inter-sector collaboration through research and innovation staff exchanges, and sharing of knowledge and ideas from research to market (and vice-versa).

The scheme fosters a shared culture of research and innovation that welcomes and rewards creativity and entrepreneurship and helps to turn creative ideas into innovative products, services or processes.

Scope: RISE involves organisations from the academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Associated Countries) and outside Europe (third countries).

Support is provided for the development of partnerships in the form of a joint research and innovation project. This is aimed at knowledge sharing via international as well as intersectoral mobility, based on secondments of research and innovation staff (exchanges) with an in-built return mechanism.

The organisations constituting the partnership contribute directly to the implementation of a joint research and innovation project by seconding and/or hosting eligible staff members. Secondments shall always take place between legal entities independent from each other[15].

RISE should exploit complementary competences of the participating organisations, as well as other synergies, and enable networking activities, organisation of workshops and conferences to facilitate sharing of knowledge, new skills acquisition and career development for research and innovation staff members.

RISE projects can focus either on one dimension of mobility (intersectoral / international), or include a combination of both.

Exchanges can be for both early-stage and experienced researchers' levels and can also include administrative, managerial and technical staff directly involved in the research and innovation activities of the proposal.

Support for the exchanges between institutions within Europe (EU Member States and Associated Countries) covers only intersectoral secondments.

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[15] Independence in the meaning of Article 8 of the Horizon 2020 Rules for Participation.

Exchanges with institutions from and to third countries can be intersectoral as well as within the same sector.

Secondments between institutions located in third countries or within the same EU Member State or Associated Country will not be supported.

Expected Impact:

At staff member level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia
- Increase in higher impact R&I output, more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Enhanced cooperation and transfer of knowledge between sectors and disciplines
- Strengthening of international and intersectoral collaborative networks
- Boosting of R&I capacity among participating organisations

At system level:

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- Strengthening of Europe's human capital base in R&I
- Increase in Europe's attractiveness as a leading destination for R&I
- Better quality R&I contributing to Europe's competitiveness and growth

Type of Action: RISE

Conditions for the Marie Skłodowska-Curie Research and Innovation Staff Exchange call

Opening date(s), deadline(s), indicative budget(s):[16]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2017	
Opening: 01 Dec 2016		
MSCA-RISE 2017 (MSCA-RISE)	80.00	05 Apr 2017
Overall indicative budget	80.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the General Annexes to the work programme. The award criteria, scoring and threshold for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

[16] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.
The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

Marie Skłodowska-Curie Co-funding of regional, national and international programmes

H2020-MSCA-COFUND-2017

MSCA-COFUND-2017: Co-funding of regional, national and international programmes

Objective: The COFUND scheme aims to stimulate regional, national or international programmes to foster excellence in researchers' training, mobility and career development, spreading the best practices of Marie Skłodowska-Curie actions.

This will be achieved by co-funding new or existing regional, national, and international programmes to open up to, and provide for, international, intersectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

Scope: Each proposal funded under the COFUND scheme shall have a sole beneficiary that will be responsible for the availability of the necessary matching funds to execute the proposal.

Applicants submit multi-annual proposals for new or existing doctoral programmes or fellowship programmes which are expected to have an impact on enhancing research- and innovation related human resources on regional, national or international level.

Applicants having benefited from COFUND under previous calls (under the Seventh Framework Programme or under Horizon 2020) will explain how their proposal adds value in relation to previous grant(s). This can also take the form of increased networking with organisations in less represented countries or capacity building measures there.

Researchers supported under this scheme shall comply with the mobility rules of the Marie Skłodowska-Curie actions.

Limitations regarding the researchers' origin and destination should be avoided. Support cannot be awarded to researchers who are already permanently employed by the organisation hosting them.

Proposed programmes are encouraged to cover all research disciplines ("bottom-up"), but can also focus on specific disciplines. In this case the range of covered disciplines should allow reasonable flexibility for the researchers.

Programmes that prioritise specific research disciplines based on national or regional Research and Innovation Strategies for Smart Specialisation (RIS3 strategies) can also be supported. Synergies with the European Structural & Investment Funds (ESIF) are encouraged.

COFUND takes the form of:

A) Doctoral programmes

Doctoral programmes address the development and broadening of the research competencies of early-stage researchers. The training follows the EU Principles on Innovative Doctoral Training. Collaboration with a wider set of partner organisations, including from the non-academic sector, which may provide hosting or secondment opportunities or training in research or transferable skills, as well as innovative elements of the proposed programme, will be positively taken into account during the evaluation.

Each researcher must be enrolled in a doctoral programme. Attention is paid to the quality of supervision and mentoring arrangements as well as career guidance.

B) Fellowship programmes

Fellowship programmes fund individual research training and career development fellowships for experienced researchers. The programmes supported should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between the researchers applying. The selections should be based on open, widely advertised competition, with transparent international peer review and the selection of candidates on merit. Mobility types supported by fellowship programmes may be similar to the ones supported under Marie Skłodowska-Curie Individual Fellowships. On top of transnational mobility, applicants are encouraged to include elements of cross-sectoral mobility into their programmes. Fellowship programmes should be based on individual-driven mobility, i.e., researchers should be able to freely choose a research topic and the appropriate organisation to host them, fitting their individual needs.

Given that the aim of the co-funded fellowship programmes is the support of individual fellows, research teams will not be funded.

Expected Impact:

At researcher level:

- Increased set of skills, both research-related and transferable ones, leading to improved employability and career prospects both in and outside academia (leading in the longer-term to more successful careers)
- Increase in higher impact R&I output, more knowledge and ideas converted into products and services
- Greater contribution to the knowledge-based economy and society

At organisation level:

- Development of high quality human resources
- Boosting R&I capacity among participating organisations
- Enhanced cooperation and transfer of knowledge between sectors and disciplines
- Strengthening of international and intersectoral collaborative networks

At system level:

- Aligning of practices and policies in the context of the EU Human Resources Strategy for Researchers, enhanced implementation of the European Charter and Code and the

EU Principles for Innovative Doctoral Training at regional, national or international level

- Increase in international, interdisciplinary and intersectoral mobility of researchers in Europe
- Improvement in the working and employment conditions for researchers in Europe at all levels of their career, starting from the doctoral stage
- Strengthening of Europe's human capital base in R&I
- Increase in Europe's attractiveness as a leading destination for R&I
- Better quality R&I contributing to Europe's competitiveness and growth

Type of Action: Doctoral programmes, Fellowship programmes

Conditions for the Marie Skłodowska-Curie Co-funding of regional, national and international programmes call

Opening date(s), deadline(s), indicative budget(s):[17]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2017	
Opening: 05 Apr 2017		
MSCA-COFUND-2017 (MSCA-COFUND-DP)	30.00	28 Sep 2017
MSCA-COFUND-2017 (MSCA-COFUND-FP)	50.00	
Overall indicative budget	80.00	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The admissibility conditions are described in part B of the General Annexes to the work programme. The eligibility conditions for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation criteria, scoring and threshold: The selection criteria are described in part H of the

[17] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.
The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

General Annexes to the work programme. The award criteria, scoring and threshold for Marie Skłodowska-Curie actions apply. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

Evaluation Procedure: The evaluation procedure for Marie Skłodowska-Curie actions applies. Please read the dedicated section in the Marie Skłodowska-Curie part of the work programme.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Not applicable - this is a mono-beneficiary action.

Trans-national cooperation among Marie Skłodowska-Curie National Contact Points

H2020-MSCA-NCP-2017

MSCA-NCP-2017: MSCA National Contact Points

Objective: Facilitate trans-national co-operation between National Contact Points (NCPs) for the Marie Skłodowska-Curie actions (MSCA), with a view to identifying and sharing good practices and raising the general standard of support to applicants, taking into account the diversity of actors.

Scope: Support will be given to a consortium of formally nominated NCPs in the area of MSCA. The activities will be tailored according to the nature of the area, and the priorities of the NCPs concerned. Various mechanisms may be included, such as benchmarking, joint workshops, enhanced cross-border brokerage events, training sessions linked to MSCA as well as to Responsible Research and Innovation, twinning schemes, etc. Special attention will be given to enhancing the competence of MSCA NCPs, including helping less experienced NCPs rapidly acquire the know-how accumulated in other countries. It will also be encouraged to build up cooperation with other networks to increase visibility to potential beneficiaries, especially in the non-academic sector.

The focus throughout should be on issues specific to MSCA and should not duplicate actions foreseen in the NCP network for quality standards and horizontal issues under 'Science with and for Society'.

Only NCP organisations from EU Member States, Associated Countries, and third countries which have been officially appointed by the relevant national authorities are eligible to participate in and receive funding for this action.

The consortium should have a good representation of experienced and less experienced NCPs.

Submission of a single proposal is encouraged. NCPs from EU Member States, Associated Countries or third countries choosing not to participate as a member of the consortium are nevertheless invited and encouraged to participate in the project activities (e.g. workshops), and the costs incurred by the consortium for such participation (e.g. travel costs paid by the consortium) may be included in the estimated budget and be eligible for funding by the Commission.

The Commission will only fund one proposal under this topic. The maximum duration of support will be three years from the starting date specified in the grant agreement.

Expected Impact:

- An improved and professionalised NCP service across Europe, therefore helping simplify access to Horizon 2020 calls, lowering the entry barriers for newcomers, and raising the average quality of submitted proposals.
- A more consistent level of NCP support services across Europe.

Type of Action: Coordination and support action

Conditions for the Trans-national cooperation among Marie Skłodowska-Curie National Contact Points call

Opening date(s), deadline(s), indicative budget(s):[18]

Topics (Type of Action)	Budgets (EUR million)	Deadlines
	2017	
Opening: 10 Jan 2017		
MSCA-NCP-2017 (CSA)	1.50	04 May 2017
Overall indicative budget	1.50	

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

Eligibility and admissibility conditions: The conditions are described in parts B and C of the General Annexes to the work programme.

Evaluation criteria, scoring and threshold: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme

Evaluation Procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

[18] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.
The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The full evaluation procedure is described in the relevant guide published on the Participant Portal.

	The maximum length of a proposal is 30 pages, excluding the annexes.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

Other actions[19]

1. Evaluation of the Marie Skłodowska-Curie actions

To assess the long-term impact of the Marie Curie Actions under the Seventh Framework Programme and the first results and outcomes of the Marie Skłodowska-Curie actions under Horizon 2020.

One specific contract will be concluded.

Type of Action: Public Procurement – existing Framework Contract

Indicative timetable: First quarter of 2016

Indicative budget: EUR 0.50 million from the 2016 budget

2. Alumni services

To further increase the impact of the Marie Skłodowska-Curie actions, networking between Marie Skłodowska-Curie researchers (current and past) will be enhanced through the implementation of alumni services. This could be extended to include Marie Skłodowska-Curie supervisors.

For this purpose, one renewable service contract will be concluded.

Type of Action: Public Procurement

Indicative timetable: Third quarter of 2016, renewable in 2017

Indicative budget: EUR 1.10 million from the 2016 budget and EUR 1.10 million from the 2017 budget

3. Events and outreach

During 2016 and 2017, the Commission intends to organise several events (conferences and workshops) dedicated to the Marie Skłodowska-Curie actions, and to contribute to leading research conferences. Moreover, a dedicated campaign will be organised to take a novel approach in communication of research and to disseminate results of the Marie Skłodowska-Curie-funded projects to the general public.

For this, maximum 10 specific contracts will be concluded.

[19] The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

Type of Action: Public Procurement – existing Framework Contract(s).

Indicative timetable: Throughout 2016 and 2017.

Indicative budget: EUR 0.57 million from the 2016 budget and EUR 0.33 million from the 2017 budget

4. Studies

To provide in-depth analysis of various aspects relevant for the successful implementation of the Marie Skłodowska-Curie actions: mobility aspects, impact of the SME participation in the programme,.

Maximum two specific contracts.

Type of Action: Public Procurement – existing Framework Contract.

Indicative timetable: Throughout 2016 and 2017.

Indicative budget: EUR 0.40 million from the 2016 budget

5. External expertise

This action will support the use of appointed independent experts for the monitoring of running actions under Horizon 2020 and FP7 where appropriate. A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity who act independently and in the public interest.

Type of Action: Expert Contracts.

Indicative timetable: Throughout 2016 and 2017.

Indicative budget: EUR 0.80 million from the 2016 budget and EUR 1 million from the 2017 budget.

6. Presidency conference(s)

A MSCA Presidency conference will be organised by the Maltese Presidency. The action will be implemented through a grant to the Ministry for Education and Employment (MCST) of Malta. The conference will be part of the official series of Maltese Council of the EU Presidency conferences. The grant will be awarded to the competent Ministry, which is best placed to organise such a conference due to its expertise and administrative power.

Legal entities: Ministry for Education and Employment (MCST) of Malta, Malta

Type of Action: Grant to identified beneficiary - Coordination and support actions

Indicative timetable: May 2017

Indicative budget: EUR 0.15 million from the 2016 budget

Budget[20]

	Budget line(s)	2016 Budget EUR million	2017 Budget EUR million
Calls			
H2020-MSCA-ITN-2016		375.00	
	from 15.030101	*375.00*	
H2020-MSCA-IF-2016		218.71	
	from 15.030101	*218.71*	
H2020-MSCA-RISE-2016		80.00	
	from 15.030101	*80.00*	
H2020-MSCA-COFUND-2016		80.00	
	from 15.030101	*80.00*	
H2020-MSCA-NIGHT-2016		8.00	
	from 15.030101	*8.00*	
H2020-MSCA-ITN-2017			430.00
	from 15.030101		*430.00*
H2020-MSCA-IF-2017			248.70

[20] The budget figures given in this table are rounded to two decimal places.
The budget amounts for the 2017 budget are subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget 2017 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

	from 15.030101		*248.70*
H2020-MSCA-RISE-2017			80.00
	from 15.030101		*80.00*
H2020-MSCA-COFUND-2017			80.00
	from 15.030101		*80.00*
H2020-MSCA-NCP-2017			1.50
	from 15.030101		*1.50*
Other actions			
Public Procurement		2.57	1.43
	from 15.030101	*2.57*	*1.43*
External Expertise		*0.80*	*1.00*
	from 15.030101	*0.80*	*1.00*
Presidency conference(s)		*0.15*	
	from 15.030101	*0.15*	
Estimated total budget		**765.23**	**842.63**

Eligibility conditions for Marie Skłodowska-Curie actions

Proposal

A proposal will only be considered eligible if it complies with the eligibility conditions set out in this section, depending on the type of MSC action.

Participating organisations

1. Marie Skłodowska-Curie actions must fulfil the **minimum conditions concerning participating organisations**:

- For **IF**:

  The beneficiary must be a legal entity located in an EU Member State or Horizon 2020 associated country and must employ and supervise the researcher during the action.

  In addition to the above, for IF European Fellowship (EF) **Society and Enterprise Panel**, the beneficiary must be an entity from the non-academic sector.

- For **ITN**:

  For **ITN European Training Networks (ETN)** and **ITN European Joint Doctorates (EJD)**: the consortium must be composed of at least three beneficiaries located in three different EU Member States or Horizon 2020 associated countries. All three legal entities must be independent of each other.

  In order to reach the objectives of EJD, at least three beneficiaries must be entitled to award doctoral degrees[21]. A beneficiary from the academic sector, which has transferred the right of awarding a doctoral degree to a consortium/grouping of academic/research institutions to which it belongs to, is also eligible. Letters of commitment to award the joint, double or multiple doctoral degrees must be included in the proposal.

  For **ITN European Industrial Doctorates (EID)**: the consortium must be composed of at least two independent beneficiaries located in two different EU Member States or Horizon 2020 associated countries.

  Given the nature of EID, at least one beneficiary must be from the academic sector and at least one beneficiary must come from the non-academic sector, primarily enterprises. Should none of the academic beneficiaries be entitled to award a doctoral degree[22], a university or a consortium/grouping of academic/research institutions entitled to award a doctoral degree must be associated to the project as a partner organisation.

  For all ITN: all beneficiaries are required to host at their premises and supervise recruited researchers.

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[21] For EJD, at least two institutions conferring a joint, double or multiple doctoral degree must be established in an EU Member State and/or associated country.

[22] Every time the document refers to doctoral degrees, this means that the degrees have to be recognised as such by the relevant authorities of the country or countries concerned.

The overall EU contribution for ITN actions is limited to a maximum of 540 person-months. For EID with only two beneficiaries, this limit is set to 180 person-months.

Not more than 40.0% of the requested EU contribution may be allocated to beneficiaries in the same country or to any one international European interest organisation or international organisation (except for EID with only two beneficiaries).

- For **RISE**: the consortium must be created by at least three legal entities, independent of each other and established in at least three different countries. At least two of them must be beneficiaries located in an EU Member State or Horizon 2020 associated country. If all participating organisations are from the same sector (i.e. either only academic or only non-academic), there must be at least one partner organisation from a third country. Above this minimum, the participation of beneficiaries/partner organisations from any country is possible under the conditions provided by the Horizon 2020 Rules for Participation Regulation No 1290/2013.

  For RISE actions, only legal entities that are established in EU Member States or Horizon 2020 associated countries can be beneficiaries; only legal entities that are established in third countries can be partner organisations.

  The overall EU contribution for RISE actions is limited to a maximum 540 person-months.

- For **COFUND**: the beneficiary must be a legal entity established in an EU Member State or Horizon 2020 associated country that funds or manages doctoral programmes or fellowship programmes for researchers.

2. In addition, the following rules apply:

- The eligibility criteria formulated in Commission notice Nr 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp. 9-11) apply for all actions under this part of the Work Programme, including to partner organisations and to third parties that receive financial support under the action (in accordance with Article 137 of the Financial Regulation No 966/2012), notably COFUND.

- Natural or legal persons, groups or non-State entities which are covered by the Council sanctions in force are not eligible to participate in EU programmes. (Please see the consolidated list of persons, groups and entities subject to EU sanctions, available at:

  http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.)

- Given that the EU does not recognise the illegal annexation of Crimea and Sevastopol, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate in any capacity. This criterion also applies in cases where the action involves financial support given by grant beneficiaries to third parties established in the Autonomous Republic of Crimea or the city of Sevastopol (in accordance with Article 137 of the Financial Regulation No 966/2012). Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, this Work Programme will be revised.

⚠ *Note*:

1. Once the minimum eligibility conditions are fulfilled and provided that the conditions laid down in this Work Programme are met, any other organisation from any country may participate – under the conditions set out in Part A of the General Annexes to the Work Programme.

2. For the minimum eligibility conditions: if one of the participants is an ***international European interest organisation****, the EU's* ***Joint Research Centre (JRC)*** *or an* ***'entity created under Union law'*** *(see Article 9(2) of the Horizon 2020 Rules for Participation Regulation), it shall be considered to be established in an EU Member State or Horizon 2020 associated country other than the EU Member States / Horizon 2020 associated countries in which the other participants are established.*

3. The following ***definitions*** *apply:*

'Beneficiaries' *are the legal entities that sign the grant agreement and have the responsibility for the proper implementation of the action. They contribute directly to the implementation of the research, transfer of knowledge and training activities. Depending on the type of MSC action, this involves recruiting, supervising, hosting, training*[23] *or seconding researchers or managing and funding programmes.*

'Partner organisations' *contribute to the implementation of the action, but do not sign the grant agreement. Partner organisations may not employ the researchers under the action*[24]*.*

Partner organisations identified in the proposal must include a letter of commitment[25] *(with the proposal) to ensure their real and active participation in the network. (The contribution of any partner organisations for which no such evidence of commitment is submitted will not be taken into account during evaluation).*

When partner organisations are involved, beneficiaries are encouraged to sign a partnership agreement with them (for the internal relationship between participating organisations). These partnership agreements must comply with the grant agreement.

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[23] For ITN and IF: If it is necessary to implement the action, the beneficiaries may call upon entities with a capital or legal link to the beneficiaries to implement certain action tasks described in Annex 1 of the grant agreement (see Article 8 to the Model Grant Agreement). The involvement of such entities must be clearly described in the proposal and will be assessed as part of the evaluation.

[24] For COFUND and the IF Global Fellowships outgoing phase, this restriction does not apply: In COFUND, partner organisations implementing the action can employ the researchers. In IF Global Fellowships, the outgoing host partner organisation can conclude an additional employment contract with the researcher to ensure adequate medical/social insurance in the outgoing country.

[25] Except in IF for partner organisations located in EU Member States or associated countries.

'Academic sector' *means public or private higher education establishments awarding academic degrees, public or private non-profit research institutes whose primary mission is to pursue research, and international European interest organisations*[26].

'Non-academic sector' *means any socio-economic actor not included in the academic sector and fulfilling the requirements of the Horizon 2020 Rules for Participation. This includes all fields of future workplaces of researchers, from industry to business, government, civil society organisations, cultural institutions, etc.*

Recruited researchers / seconded staff

1. ITN, IF and COFUND actions must include the recruitment of researchers (for ITN and IF: they must be recruited by the beneficiary; for COFUND: they can be recruited by a partner organisation).

RISE actions must include the secondment of staff members.

2. Supported researchers and staff members may be of any nationality. They must move from one country to another to broaden or deepen their competences.

For IF Global Fellowships (GF) and the European Fellowships (EF) Reintegration Panel: the researchers must be nationals or long-term residents of EU Member States and Horizon 2020 associated countries. Long-term residence means a period of full-time research activity in the EU or Horizon 2020 associated countries of at least 5 consecutive years.

3. For ITN, IF and COFUND: supported **researchers must be** either early-stage or experienced researchers, depending on the action:

- For ITN and COFUND Doctoral Programmes (DP): researchers must be **early-stage researchers (ESR)**, i.e. at the date of recruitment (ITN) or at the date of recruitment or the deadline of the co-funded programme's call (COFUND DP), be in the first four years (full-time equivalent research experience) of their research careers and have not been awarded a doctoral degree.
- For IF and COFUND Fellowship Programmes (FP): researchers must be **experienced researchers (ER)**, i.e. at the date of the call deadline (for IF) or at the date of recruitment or the deadline of the co-funded programme's call (for COFUND FP), be in possession of a doctoral degree[27] or have at least four years of full-time equivalent research experience.

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[26] 'International European interest organisation' means an international organisation, the majority of whose members are EU Member States or Horizon 2020 associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe (see Article 2.1(12) of the Horizon 2020 Rules for Participation Regulation No 1290/2013).

[27] A medical doctor degree will not be accepted by itself as equivalent to a doctoral degree. To be considered as experienced researchers, medical doctors need to provide the certificates of a doctoral degree or information on their research experience.

⚠ *Note*:

'Full-time equivalent research experience' *is measured from the date when the researcher obtained the degree entitling him/her to embark on a doctorate (either in the country in which the degree was obtained or in the country in which the researcher is recruited or seconded) – even if a doctorate was never started or envisaged.*

For RISE: supported **staff members must be** (early-stage or experienced) researchers or administrative, managerial or technical staff supporting the research and innovation activities under the action. They must be actively engaged in or linked to research and/or innovation activities for at least six months (full-time equivalent) at the sending institution[28], before the first period of secondment.

4. For ITN, IF and COFUND: researchers must comply with the **mobility rule**[29].

Researchers may not have resided or carried out their main activity (work, studies, etc.) in the country of their host organisation for more than 12 months in the 3 years immediately before the reference date: the call deadline (IF), or recruitment (ITN) or either of these two points in time (COFUND).

For 'international European interest organisations' or 'international organisations', the researchers may not have spent more than 12 months in the 3 years immediately before the call deadline/recruitment, in the same appointing organisation.

For the IF Society and Enterprise Panel, Career Restart Panel and Reintegration Panel or equivalent activities under COFUND, researchers may not have resided or carried out their main activity in the country of their host organisation for more than 3 years in the 5 years immediately before the reference date.

Compulsory national service, short stays such as holidays and time spent as part of a procedure for obtaining refugee status under the Geneva Convention[30] are not taken into account.

For RISE: secondments are not subject to a mobility rule.

5. The minimum/maximum duration of the funded recruitment/secondment is:

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[28] If it is necessary to implement the action, the beneficiaries/partner organisations may call upon entities with a capital or legal link to the beneficiaries/partner organisations, to implement certain action tasks described in Annex 1 of the grant agreement (see Article 8 to the Model Grant Agreement). The involvement of such entities must be clearly described in the proposal and will be assessed as part of the evaluation.

[29] Existing programmes applying for COFUND can deviate from this rule if duly justified in the proposal by the applicant.

[30] 1951 Refugee Convention and the 1967 Protocol.

- For ITN:

  Recruitment/fellowship duration: 3-36 months

  Secondments are possible for up to 30% of the fellowship duration (except for EID and EJD – where time spent at other participating organisations, in line with the proposal description, is not affected by this limitation).

  For ITN EID, researchers must spend at least 50% of their time in the non-academic sector. This inter-sectoral mobility has to be between participating organisations located in different countries.

- For IF:

  IF European Fellowships (EF): recruitment/fellowship duration: 12-24 months

  IF Global Fellowships (GF): recruitment/fellowship duration: 24-36 months (12-24 months for the outgoing phase plus 12 month return phase in Europe)

- For RISE:

  Secondment duration: 1-12 months

  Secondments may be split into several stays not exceeding 12 months in total and not going beyond the project duration. The splits must be justified and considered beneficial for the transfer of knowledge activities.

  The exchanged staff members must be guaranteed reintegration into the sending institution, thus maximising the impact of the action for knowledge sharing and long-term collaboration.

- For COFUND:

  Recruitment/fellowship duration: minimum 3 months
  For programmes where the main part of the research training activity does not take place in an EU Member State or an Horizon 2020 associated country, the return phase to a Member State/associated country may not be more than 50% of the total duration of the research training activity.

Duration of the action

The maximum duration of the action will be the following:

- For ITN: 48 months from the starting date set out in the grant agreement.
- For IF: equals the duration of support granted to the researcher.
- For RISE: 48 months from the starting date set out in the grant agreement.
- For COFUND: 60 months from the starting date set out in the grant agreement.

For ITN and COFUND, the maximum duration also includes the time that is needed to recruit or select the researchers.

Evaluation rules for Marie Skłodowska-Curie actions

Award criteria, scores and weighting

1. Proposals will be evaluated by experts, on the basis of the **award criteria** 'excellence', 'impact' and 'quality and efficiency of the implementation' (see Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013).

The aspects to be considered in each case and the **weighting** depend on the type of Marie Skłodowska-Curie action as set out in the tables below.

2. Evaluation **scores** will be awarded for each of the criteria, and not their individual elements. Each criterion will be scored from 0 to 5. Scores with a resolution of one decimal place may be awarded. The total score will be subject to a threshold of 70%.

3. If necessary, the panel will determine a **priority order** for proposals which have been awarded the same score within a ranked list. When the total scores are equal, priority will be based on scores for individual award criteria. For each action the priority order of the criteria is detailed in the tables below.

If necessary, any further prioritisation will be based on other appropriate characteristics, to be decided by the panel, related to the contribution of the proposal to the European Research Area (ERA) and/or general objectives mentioned in the work programme (e.g. intersectoral mobility, international co-operation, favourable employment and working conditions).

Whether or not such a prioritisation is carried out will depend on the available budget or other call conditions.

ITN: Marie Skłodowska-Curie Innovative Training Networks		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality, innovative aspects and credibility of the research programme (including inter/multidisciplinary, intersectoral and, where appropriate, gender aspects)	Enhancing the **career perspectives** and **employability** of researchers and contribution to their **skills** development	**Coherence and effectiveness of the work plan**, including appropriateness of the allocation of **tasks and resources,** (including awarding of the doctoral degrees for *EID* and *EJD* projects)
Quality and innovative aspects of the training programme (including transferable skills, inter/multidisciplinary, intersectoral and, where appropriate, gender aspects)	Contribution to **structuring doctoral / early-stage research training at the European level** and to strengthening **European innovation capacity**, including the potential for:	**Appropriateness of the management structures and procedures**, including quality management and risk management (with a mandatory joint governing structure for EID and EJD projects)

	a) meaningful contribution of the non-academic sector to the doctoral/research training, as appropriate to the implementation mode and research field **b)** developing sustainable joint doctoral degree structures (for *EJD* projects only)	
Quality of the supervision (including mandatory joint supervision for *EID* and *EJD* projects)	Quality of the proposed measures to exploit and **disseminate** the project results	Appropriateness of the **infrastructure** of the participating organisations
Quality of the proposed interaction between the participating organisations	Quality of the proposed measures to **communicate** the project activities to different target audiences	**Competences, experience and complementarity of the participating organisations and their commitment to the programme**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

IF: Marie Skłodowska-Curie Individual Fellowships		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality and credibility of the research/innovation project; level of novelty, appropriate consideration of inter/multidisciplinary and gender aspects	**Enhancing the potential and future career prospects of the researcher**	Coherence and effectiveness of **the work plan**
Quality and appropriateness of the training and of the two way **transfer of knowledge** between the researcher and the host	Quality of the proposed measures to exploit and **disseminate** the project results	Appropriateness of the allocation of **tasks and resources**

Quality of the supervision and of the integration in the team/institution	Quality of the proposed measures to **communicate** the project activities to different target audiences	Appropriateness of the **management structure and procedures**, including risk management
Capacity of the researcher to reach or re-enforce a position of professional maturity/independence		Appropriateness of the **institutional environment** (infrastructure)
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

RISE: Marie Skłodowska-Curie Research and Innovation Staff Exchange		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality and credibility of the research/innovation project; level of novelty and appropriate consideration of inter/multidisciplinary, intersectoral and gender aspects	**Enhancing the potential and future career perspectives of the staff members**	**Coherence and effectiveness of the work plan,** including appropriateness of the allocation of tasks and resources
Quality and appropriateness of knowledge sharing among the participating organisations in light of the research and innovation objectives.	**Developing new and lasting research collaborations, achieving transfer of knowledge** between participating organisations and contribution to improving research and innovation potential at the European and global levels	**Appropriateness of the management structures and procedures**, including quality management and risk management
Quality of the proposed interaction between the participating organisations	Quality of the proposed measures to exploit and **disseminate** the project results	**Appropriateness of the institutional environment** (hosting arrangements, infrastructure)
	Quality of the proposed measures to **communicate** the project activities to different target audiences	**Competences, experience and complementarity** of the participating organisations **and their commitment to the project**
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

COFUND: Marie Skłodowska-Curie Co-funding of regional, national and international programmes		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Quality of the selection / recruitment process for the researchers (transparency, composition and organisation of selection committees, evaluation criteria, equal opportunities)	Enhancing the **potential and future career perspectives** of researchers; **Strengthening human resources** on regional, national or international level	**Coherence, effectiveness and appropriateness of the work plan**
Quality of the research options offered by the programme in terms of science, interdisciplinarity, intersectorality and level of transnational mobility	**Aligning practices of participating organisations with the principles set out by the EU for human resources development in research and innovation**	**Appointment conditions of researchers**
Quality of career guidance and training, including supervision arrangements, training in transferable skills	Quality of the proposed measures to exploit and **disseminate** the results	**Competence of the participant** to implement the programme
	Quality of the proposed measures to **communicate** the results to different target audiences	
50%	**30%**	**20%**
Weighting		
1	**2**	**3**
Priority in case of *ex aequo*		

Evaluation procedure

1. In ITN, IF and RISE, proposals will normally be **evaluated by** one of eight 'main evaluation **panels**': Chemistry (CHE), Social Sciences and Humanities (SOC), Economic Sciences (ECO), Information Science and Engineering (ENG), Environment and Geosciences (ENV), Life Sciences (LIF), Mathematics (MAT), Physics (PHY).

For ITN European Industrial Doctorates (EID) and European Joint Doctorates (EJD), proposals will be ranked in specific multidisciplinary panels.

For IF, there are – in addition to the main evaluation panels – three separate multidisciplinary panels: Society and Enterprise Panel (SE), Career Restart Panel (CAR) and the Reintegration Panel (RI).

In COFUND, the evaluation will be organised in two different panels: Doctoral programmes (DP) and Fellowship programmes (FP).

Each panel establishes a ranked list.

The distribution of the indicative budget of the call will be proportional to the number of eligible proposals received in each panel, except where a specific budget for a multidisciplinary panel has been fixed in the call. If the budget allocated to any panel exceeds the requirements of all proposals positively evaluated[31] in that panel, the excess budget will be reallocated to the other panels based on the distribution as above. Equally, if the allocated funding to a panel is insufficient to fund the highest ranked proposal in that panel, the necessary budget will be transferred from the other panels based on the distribution as above, in order to ensure that the highest ranked proposal can be funded.

2. Proposals will not be evaluated anonymously.

3. Proposals may be evaluated remotely.

4. In ITN and IF, the consensus score for each award criterion may be the average of the corresponding scores attributed by the individual expert evaluators.

5. As part of the evaluation by independent experts, a panel review will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated in this work programme.

The full evaluation procedure is described in the relevant guide published on the Participant Portal.

[31] Measured as proposals having passed all relevant evaluation thresholds.

EU contribution and applicable unit costs

The EU contribution under the Marie Skłodowska-Curie actions is based on unit costs expressed in person-months. They have been established in line with the methodology set up by Commission Decision No C(2013) 8194[32].

1. ITN / IF / COFUND

The beneficiary (beneficiary or partner organisation in COFUND) must recruit each eligible researcher under an employment contract or 'equivalent direct contract' with full social security coverage (including sickness, parental, unemployment and invalidity benefits, pension rights, benefits in respect of accidents at work and occupational diseases) except where national legislation prohibits this possibility.

When an employment contract cannot be provided, the beneficiary (beneficiary or partner organisation in COFUND) must recruit the researcher under a 'fixed-amount fellowship'. In this case, the living allowance[33] will be halved and the beneficiary must ensure that the researcher enjoys minimum social security coverage.

ITN / IF

The yearly reference rates for calculating the living allowance of researchers recruited under an employment contract/ equivalent direct contract are:

- for early-stage researchers (ITN): 37 320 EUR/year
- for experienced researchers (IF): 55 800 EUR/year

The above amounts include all compulsory deductions under national legislation. Rates for individual countries are obtained by applying the country correction coefficients of table 2.

The beneficiary must pay to the recruited researchers at least the reference allowances (minus all compulsory deductions under national legislation in the context of the project). A top-up may be paid to the researchers in order to complement this contribution.

In addition to the living allowance, the beneficiary must pay a mobility allowance and for some categories of researchers, a family allowance, as specified in table 1. In this context family is defined as persons linked to the researcher by (i) marriage, or (ii) a relationship with equivalent status to a marriage recognised by the legislation of the country or region where this relationship was formalised; or (iii) dependent children who are actually being maintained by the researcher.

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[32] COMMISSION DECISION authorising the use of reimbursement on the basis of unit costs for Marie Skłodowska-Curie actions under the Horizon 2020 Framework Programme

[33] Researcher unit cost in case of COFUND

The rates from table 1 apply to researchers devoting themselves to their project on a full-time basis (pro-rata for parts of years). In cases where researchers, in agreement with the beneficiary and with prior approval by the Research Executive Agency (REA), implement their project on a part-time basis due to personal or family reasons, the rates will apply proportionally without the possibility that the total amounts will exceed those that apply for full-time equivalent periods. The same principle will also apply in case of a split of a project into several distinct periods.

COFUND

The EU contribution is limited to EUR 10 million per beneficiary per call.

Table 1 specifies the researcher unit cost and the institutional unit cost for the co-funding of regional, national and international programmes. The EU contribution must be used exclusively as contribution to the management of the programme and to the living allowance of the researchers, which is solely for the benefit of the researchers appointed under the programme and includes all compulsory deductions under national legislation. Other cost items (such as research costs, travel, family and mobility allowances, indirect costs) may be funded through other resources including EU programmes other than Horizon 2020.

Applicants must specify in their proposal the total cost of the proposal and in particular, the amounts that will be provided for the benefit of the researcher and for the organisation that is hosting the researcher. This information will be needed to evaluate the adequateness of employment and working conditions of the researchers.

The remuneration, i.e. the living allowance (salaries, social security contributions, taxes and other costs included in the remuneration), and the mobility allowance for the benefit of the researchers must be:

- for researchers recruited under an employment contract: not lower than EUR 2 597 (for early-stage researchers) and EUR 3 675 (for experienced researchers);
- for researchers recruited under a fixed-amount fellowship: not lower than EUR 1 298.50 (for early-stage researchers) and EUR 1 837.50 (for experienced researchers).

2. RISE

The top-up allowance specified in table 1 must be solely for the benefit of the seconded staff member.

Table 1: EU contribution [in EUR]

Marie Skłodowska-Curie Action	Researcher unit cost person/month			Institutional unit cost person/month	
	Living allowance*	Mobility allowance	Family allowance	Research, training and networking costs	Management and indirect costs
Innovative Training Networks	3 110	600	500	1 800	1 200
Individual Fellowships	4 650	600	500	800	650

* A country correction coefficient applies to the living allowance. This coefficient is the one applicable to the country of the beneficiary, as listed in Table 2. The only exception are IF Global Fellowships with two different country correction coefficients:

- for the outgoing phase: the coefficient of the country where the researcher is hosted (i.e. the country of the partner organisation)
- for the return phase: the coefficient of the country where the researcher returns to (i.e. the country of the beneficiary).

Marie Skłodowska-Curie Action	Staff member unit cost Top-up allowance person/month	Institutional unit cost person/month	
		Research, training and networking costs	Management and indirect costs
Research and Innovation Staff Exchange	2 000	1 800	700

Marie Skłodowska-Curie Action	Researcher unit cost person/month		Institutional unit cost person/month
Co-funding of regional, national and international programmes	Early-stage researchers	1 855**	325**
	Experienced researchers	2 625**	

** This figure represents the EU contribution, as established in Commission Decision No C(2013) 8194

Table 2: Country correction coefficients (CCC) for ITN and IF living alllowances

For countries where the correction coefficient is not indicated, the Commission will decide on a case-by-case basis.

Country Code[34]	CCC
EU Member States	
AT	104.8%
BE	100.0%
BG	71.5%
CY	91.8%
CZ	83.8%
DE	98.8%
DK	135.3%
EE	78.3%
EL	92.7%
ES	97.6%
FI	116.6%
FR	111.0%
HR	97.5%
HU	76.2%
IE	113.5%
IT	106.7%
LT	73.1%
LU	100.0%
LV	75.9%
MT	89.6%
NL	104.3%
PL	76.4%
PT	89.1%
RO	68.3%
SE	111.7%
SI	86.1%
SK	82.6%
UK	120.3%
Horizon 2020 associated countries	
AL	76.1%
BA	73.6%
CH	113.1%
FO	134.1%
GE	89.5%
IL	108.7%
IS	116.6%
MD	61.1%
ME	66.9%
MK	68.4%
NO	131.9%
RS	67.1%
TN	70.5%
TR	86.6%
UA	92.3%
Third countries	
AM	89.9%
AO	114.6%
AR	58.5%
AU	105.0%
AZ	93.0%
BB	116.6%
BD	47.2%
BF	93.8%
BJ	92.6%
BM	151.5%
BO	51.3%
BR	92.0%
BW	55.3%
BY	65.0%
BZ	75.3%
CA	86.4%
CD	127.6%
CF	114.3%
CG	124.9%
CI	102.0%
CL	67.1%
CM	103.3%
CN	85.0%
CO	76.6%
CR	76.7%
CU	83.8%
CV	76.4%
DJ	93.4%
DO	66.9%
DZ	81.7%
EC	68.8%
EG	48.6%
ER	61.2%
ET	85.2%
FJ	68.1%
GA	113.1%
GH	68.2%
GM	67.7%
GN	60.4%
GT	78.8%

[34] ISO 3166 alpha-2, except for Greece and the United Kingdom (EL and UK used respectively instead of GR and GB).

GW	102.7%
GY	58.9%
HK	93.8%
HN	69.0%
HT	108.7%
ID	75.3%
IN	52.8%
JM	94.9%
JO	75.5%
JP	115.9%
KE	78.1%
KG	83.1%
KH	70.5%
KR	105.2%
KZ	100.2%
LA	77.7%
LB	86.4%
LI	110.0%
LK	61.6%
LR	100.1%

LS	56.7%
LY	60.0%
MA	83.5%
MG	80.0%
ML	90.4%
MR	64.5%
MU	72.7%
MW	76.0%
MX	70.4%
MY	71.6%
MZ	71.6%
NA	68.3%
NC	128.9%
NE	87.9%
NG	92.4%
NI	57.3%
NP	73.5%
NZ	94.1%
PA	57.0%
PE	75.5%

PG	83.0%
PH	65.8%
PK	49.4%
PS	100.4%
PY	71.9%
RU	115.5%
RW	87.3%
SA	84.8%
SB	93.3%
SD	65.1%
SG	102.5%
SL	85.2%
SN	86.2%
SR	50.6%
SV	74.3%
SY	74.8%
SZ	56.8%
TD	125.3%
TG	88.7%
TH	65.0%

TJ	64.9%
TL	78.3%
TO	85.0%
TT	74.1%
TW	83.6%
TZ	65.2%
UG	65.7%
US	99.4%
UY	75.3%
UZ	51.4%
VE	70.0%
VN	51.1%
VU	112.6%
WS	75.8%
XK	58.6%
YE	68.1%
ZA	55.8%
ZM	66.4%
ZW	47.2%

PCP REQUEST FOR TENDERS

⚠ **This document is designed to help beneficiaries of H2020 pre-commercial procurement (PCP) grants to draw up the request for tenders to be published in the EU Official Journal (via the TED (tenders electronic daily) website).**
It shows the information and provisions that need to be included in order to ensure compliance with the obligations under the H2020 grant agreement.

- **Instructions and footnotes in blue should be deleted**
- **For options *[*in square brackets*]*, choose the option that applies (options not chosen and the brackets should be deleted)**
- **For fields in [grey in square brackets], enter the appropriate data (and take out the grey colour and the brackets)**

Disclaimer: This template is aimed at assisting H2020 PCP grant beneficiaries. It is provided for information purposes only and is not intended to replace consultation of professional legal advice. It can be used as a starting point to draw up the requests for tenders, but beneficiaries remain responsible for adapting it to their situation and checking full compliance with national law.

Neither the European Commission nor its Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

PCP REQUEST FOR TENDERS [Project acronym] — [full name of project]

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Annex 4 Templates for exclusion and compliance criteria (if needed, *e.g. declaration of honour for exclusion criteria, absence of conflict of interest and absence of incompatible other public financing*)

Annex 5 Tender form (optional; only needed if the request for tenders does not specify the information requested from tenderers for each of the award criteria)

Annex 6 Template for reports or deliverables (optional; only needed if the request for tenders does not specify the minimum information contractors are required to submit in the reports or deliverables)

1. General context

1.1 Pre-commercial procurement (PCP)

Explain the general context:

This procurement is a **pre-commercial procurement (PCP)**.

PCP means that public procurers challenge innovative players on the market, via an open, transparent and competitive process, to develop new solutions for a technologically demanding mid- to long-term challenge that is in the public interest and requires new R&D services.

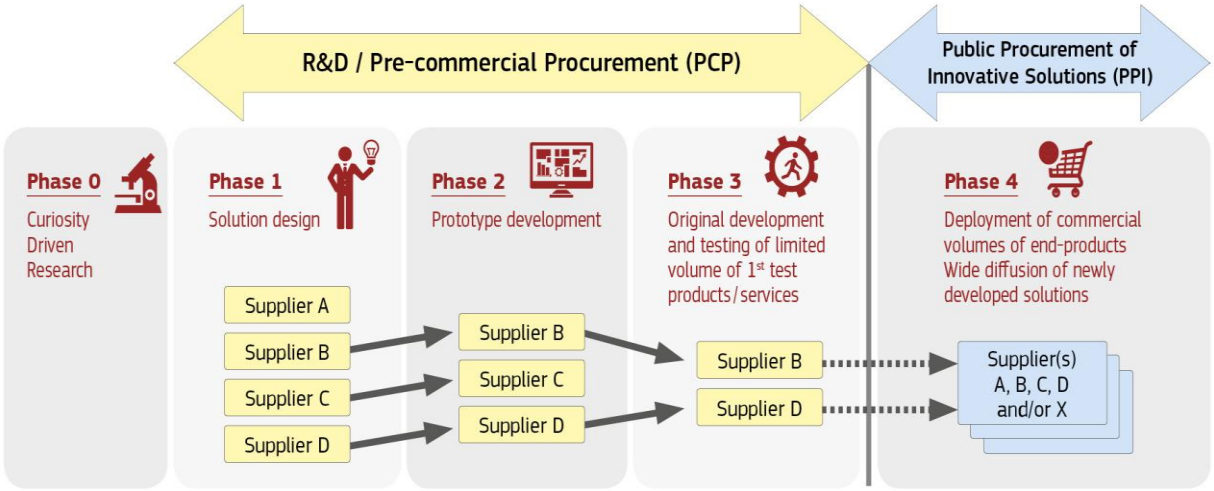

PCP is characterised by the following four **features**:

- ✕ Competitive development in phases to identify the solutions offering the best value for money

PCP targets situations that require radical innovation or R&D and for which there are typically no solutions on or close to the market yet. Different competing providers may have different ideas for solutions to the problem. As R&D is yet to take place, there is not yet any proof as to which of these potential alternative solutions would best meet customers' needs.

PCP therefore awards R&D contracts to a number of competing contractors at the same time, in order to compare different approaches to solving the problem. It thus offers innovators an opportunity to show how well their solution compares with others. It also allows a first customer test reference to be obtained from countries of the procurers that will test the solutions.

The R&D is split into three phases (solution design, prototyping, original development and testing of a limited set of 'first' products or services). Evaluations after each phase progressively identify the solutions that offer the best value for money and meet the customers' needs. This phased approach allows successful contractors to improve their offers for the next phase based on lessons learnt and feedback from procurers in the previous phase. Using a phased approach with gradually growing contract sizes per phase also makes it easier for smaller companies to participate in the PCP and enables SMEs to grow their business step-by-step with each phase.

Depending on the outcome of the PCP, procurers may or may not decide to follow-up the PCP with a public procurement to deploy the innovative solutions (PPI).

- ✕ Public procurement of R&D services

PCP addresses mid- to long-term public procurement needs for which either no commercially stable solutions yet exist on the market, or existing solutions exhibit structural shortcomings that it requires further R&D to resolve. PCP is a way for procurers to trigger the market to develop new solutions that address these shortcomings. PCP focuses on specific identified needs and provides customer feedback to businesses from the early stages of R&D. This improves the likelihood of commercial exploitation of the newly developed solutions.

PCP is explained in the PCP communication COM/2007/799 and the associated staff working document SEC/2007/1668. The R&D services can cover research and development activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards. R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs.[1] It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements.

✕ Open, transparent, non-discriminatory approach — No large-scale deployments

PCP is open to all operators on equal terms, regardless of the size, geographical location or governance structure. There is, however, a place of performance requirement that they must perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon 2020 associated countries.

Any subsequent public procurement of innovative solutions (PPI), for the supply of commercial volumes of the solutions, will be carried out under a separate procurement procedure. Providers that did not take part in this PCP (or were not chosen to go through as far as the last phase) will thus still be able to compete on an equal basis in any subsequent procurement looking for contractors to provide a solution on a commercial scale.

✕ Sharing of IPR-related risks and benefits under market conditions

PCP procures R&D services at market price, thus providing contractors with a transparent, competitive and reliable source of financing for the early stages of their research and development. Giving each contractor the ownership of the IPRs attached to the results it generates during the PCP means that they can widely exploit the newly developed solutions commercially. In return, the tendered price must contain a financial compensation for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price must be the 'non-exclusive development price'; see section 4.5.4). Moreover, the procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.

ⓘ For more information, see PCP on the Europa website.

1.2 Exemption from EU procurement directives, the WTO Government Procurement Agreement (GPA) and EU state aid rules

Explain that the PCP procurement is exempted from the EU procurement directives, the WTO Government Procurement Agreement (GPA) and the EU state aid rules:

[1] See also Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

This procurement procedure is exempted from the **EU public procurement directives** because procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).[2]

It is also exempted from the **WTO Government Procurement Agreement (GPA)** because this Agreement does not cover R&D services[3] (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement).

The procurement does not constitute state aid under the **EU state aid rules**[4] because it follows an open, transparent, competitive procedure with risk- and benefit-sharing at market price. (The division of all rights and obligations (including IPRs) and all selection and award criteria for all phases are published at the outset; the PCP is limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors are not given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.)

1.3 EU funding

Explain that the PCP procurement is part of an EU project:

This PCP procurement is part of a project that is funded by the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No [insert number] — [insert project acronym] (see [insert project website]).

[*OPTION if the procurement also receives funding from other EU programmes (e.g. has member(s) of the buyers group whose financial contribution to the PCP budget is co-financed by e.g. the European Structural and Investment Funds (ESIF) instead of Horizon 2020):* Moreover, it receives funding from the *[OPTION for EU programmes:* European Union's [insert name of EU programme]*][OPTION for national programmes co-funded by the EU (e.g. by Regional Funds, Agricultural Funds):* [insert name of national programme] co-financed by the European Union*]*:

- [insert beneficiary name and grant agreement number and acronym].***]***

The procurement must therefore comply with the rules imposed by the EU Horizon 2020 grant agreement ***[****OPTION if procurement also receives funding from other EU programmes:* and with the rules imposed by the EU [insert name of other EU programme(s) from which funding is received] programme*][*grant*]***].

ⓘ For more information, see 'innovation procurement' and 'links to regional policy' in the Participant Portal Online Manual.

⚠ **Attention:** The EU is not participating as a contracting authority in this procurement.

1.4 Overview: contracting, budget and schedule

1.4.1 Total budget and budget distribution (per phase)

Explain the budgetary set-up, specifying in particular:

- the total budget for the PCP

[2] See Article 16(f) of Directive 2004/18/EC (Article 14 of Directive 2014/24/EU), Article 24(e) of Directive 2004/17/EC (Article 32 of Directive 2014/25/EU) and Article 13(f)(j) of Directive 2009/81/EC.

[3] See the EU's Annex IV of Appendix I to the WTO GPA.

[4] See Point 33 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

- the maximum budget per phase (and per lot, where applicable)
- the maximum budget per tender per phase (and per lot, where applicable)
- the 'minimum' number of contractors that are expected to be selected per phase (and per lot, where applicable)
- the maximum duration per phase.

Provide for the flexibility to transfer leftover budget from one phase to the next phase in case you receive offers with lower price than expected: For phases 1 and 2, contracts are funded until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. As leftover budget from the previous phase will be transferred to the next phase, the total budget available for phases 2 and 3 may eventually be higher than stated here (but the maximum budget per contractor for phases 2 and 3 will remain the same). The lower the average price of tenders, the more contracts can be awarded. The total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria.

Note:

State the minimum instead of the maximum expected number of contractors, to allow more contracts than initially expected to be awarded if there are more high quality tenders at cheaper prices than expected.

Ensure that the budget distribution of the PCP:

- starts with minimum of three contractors and ends with a minimum of two contractors in the last phase
- contains a minimum of three phases that between them cover the entire PCP lifecycle: solution exploration; prototyping; initial development and testing of a limited set of first products or services. (If needed, each phase may be split up into more phases, *e.g. in complex PCPs*.)

1.4.2 Contracting approach

Explain the contracting approach:

The PCP is implemented by means of a framework agreement with specific contracts for each of the R&D phases (altogether 'contracts').

Following the tendering stage, a framework agreement and a specific contract for phase 1 are expected to be awarded to a minimum of [indicate number: minimum 3] contractors.

A call-off will be organised for phase 2, with the aim of awarding a minimum of [indicate number] phase 2 contracts. Only offers from contractors that successfully completed phase 1 will be eligible for phase 2. The procurers will validate the phase 2 prototypes [identify the site: in the procurer's labs or the contractors' lab].

A second call-off will be organised for phase 3, with the aim of awarding a minimum of [indicate number: minimum 2] phase 3 contracts. Only offers from contractors that successfully completed phase 2 will be eligible for phase 3. Phase 3 field-testing is expected to take place [insert where *(e.g. at all the sites where procurers of the buyers group are based)*].

The framework agreement sets all the framework conditions for the entire duration of the PCP (covering all the phases). There will be no renegotiation. The framework agreement remains binding for the duration of all phases for which contractors remain in the PCP. Tenderers that are awarded a framework agreement will also be awarded a specific contract for phase 1 (evaluation of tenders for the framework agreement and phase 1 are combined). Tenderers are therefore asked not only to submit their detailed offer for phase 1 in their tender, but also to state their goals, and to outline their plans (including price conditions) for phases 2 and 3, thus giving specific details of the steps that would lead to commercial exploitation of the R&D results.

Provide a brief overview of the overall timing of the PCP (including the expected start and finish dates) and of the individual phases.

Indicate clearly (in this section and in the time schedule table below) if:

- the offers for the next phase will be requested together with the end-of phase deliverables for the previous phase (In this case all contractors of the previous phase will be invited to make offers for the next phase, successful completion of the previous phase is evaluated before evaluating the offers for the next phase, to determine which offers are eligible to proceed to the evaluation of offers for the next phase)

or if

- the offers for the next phase will be requested only *after* the end-of phase deliverables of the previous phase and after the contractors have been informed of successful completion of the previous phase (In this case only the contractors that successfully completed the previous phase will be invited to make offers for the next phase.)

1.4.3 Time schedule

Explain the planned time schedule:

Planned time schedule	
Date	**Activity**
	First tender procedure (framework agreement and phase 1 contracts)
[dd.mm.yyyy]	Publication of contract notice in TED
…	Deadline for requesting tender documents
	Deadline for submitting questions about tender documents
	Deadline for lead procurer to publish replies to questions (Q&A document)
	Deadline for submission of tenders for the framework agreement and phase 1
	Opening of tenders
	Tenderers notified of decision on awarding contracts
	Signing of framework agreements and phase 1 specific contracts
	Publication of contract award notice in TED
	Implementation of phase 1
	Start of phase 1
	Names of winning phase 1 contractors and their project abstracts sent to EU and published on [insert acronym] PCP project website
	Visit of phase 1 contractors to the premises(s) of the procurer(s) to learn about the operational boundary conditions governing the design of targeted solutions
	Deadline for phase 1 interim milestone(s)/interim deliverable(s)
	Visit(s) of the phase 1 supervisor/monitoring team to the contractor's premises to check completion of milestone(s)/interim deliverable(s)
	Feedback from phase 1 supervisor/monitoring team on phase 1 interim milestone(s)/interim deliverable(s)
	Interim payments (if applicable)
	Deadline for phase 1 final milestone(s)/final report/deliverable(s)

	Assessment of phase 1 final milestone(s)/final report/deliverable(s)
	Phase 1 contractors notified as to whether they have completed this phase satisfactorily and successfully
	End of phase 1
	Payment of balance for phase 1 to contractors that completed this phase satisfactorily
	Second tender procedure (call-off for phase 2)
	Launch call-off for phase 2 (only offers from contractors that successfully completed phase 1 are eligible)
	Deadline for submitting questions on phase 2 call-off documents
	Deadline for lead procurer to circulate replies to questions to phase 2 bidders
	Deadline for submitting phase 2 offers
	Opening of phase 2 offers
	Contractors notified of decision on awarding phase 2 contracts
	Signing of phase 2 specific contracts
	Implementation phase 2
	Start of phase 2
	Names of winning phase 2 contractors and their project abstracts published on [insert acronym] PCP project website and sent to EU
	Visit of phase 2 contractors to the premises(s) of the procurer(s), where applicable
	Deadline for phase 2 interim milestone(s)/deliverable(s)
	Visit(s) of the phase 2 supervisor/monitoring team to the contractor's premises to check completion of interim milestone(s)/deliverable(s)
	Feedback from phase 2 supervisor/monitoring team on phase 2 interim milestone(s)/deliverable(s)
	Interim payments (if applicable)
	Lab testing of the prototype developed during phase 2
	Feedback from phase 2 supervisor/monitoring team on lab testing of the prototype
	Deadline for submission of phase 2 final milestone(s)/final report /deliverable(s)
	Demonstration of prototype for the EU technical review of phase 2
	Assessment of phase 2 final milestone(s)/final report/deliverable(s)
	Phase 2 contractors notified as to whether they have completed this phase satisfactorily and successfully
	End of phase 2
	Payment of balance for phase 2 to contractors that completed this phase satisfactorily
	Third tender procedure (call-off for phase 3)

	Launch call-off for phase 3 (only offers from contractors that successfully completed phase 2 are eligible)
	Deadline for submitting questions about phase 3 call-off documents
	Deadline for lead procurer to circulate replies to questions to phase 3 bidders
	Deadline for submitting phase 3 offers
	Opening of phase 3 offers
	Contractors notified of decision to award phase 3 contracts
	Signing of phase 3 specific contracts
	Implementation phase 3
	Start of phase 3
	Names of winning phase 3 contractors and their project abstracts published on [insert acronym] PCP project website and sent to EU
	Visit of phase 3 contractors to premises(s) of procurer(s), where applicable
	Deadline for phase 3 interim milestone(s)/deliverable(s)
	Visit(s) of the phase 3 /monitoring team to the contractor's premises to check completion of phase 3 interim milestone(s)/deliverable(s)
	Feedback from phase 3 monitoring supervisor/monitoring team on phase 3 interim milestone(s)/deliverable(s)
	Interim payments (if applicable)
	Field-testing of products/services developed during phase 3
	Feedback from phase 3 supervisor/monitoring team on field-testing of the products/services
	Deadline for submission of phase 3 final milestone(s)/final report/ deliverable(s)
	Final demonstration of products/services developed during phase 3 (including to EU representatives)
	Assessment of phase 3 final milestone(s)/final report/deliverable(s)
	Phase 3 contractors notified as to whether they have completed this phase satisfactorily and successfully
	End of phase 3
	Summary of the lessons learnt and the results achieved by each contractor during the PCP sent to EU for publication purposes.
	Payment of balance for phase 3 to contractors that completed this phase satisfactorily

2. Procurer(s) *[*and other parties involved in the PCP*]*

Explain the procurer set-up:

This procurement relates to a joint PCP that will be carried out by the following **lead procurer**: [name and country of the lead procurer]

The lead procurer is appointed to coordinate and lead the joint PCP, and to sign and award the framework agreement and the specific contracts for all phases of the PCP, in the name and on behalf of the following **buyers group**:

- [name and country of the member 1 of the buyers group]
- [name and country of the member 2 of the buyers group]
- …

The lead procurer is *[*not*]* part of the buyers group.

The procurers in the buyers group have the following background/profile/responsibilities for:

- [name 1]: [insert responsibilities]
- [name 2]: [insert responsibilities]
- ……

Explain the responsibilities the procurers in the buyers group have in their respective countries with regards to setting the acquisition and/or regulatory strategy for the innovative solutions. *(For example, a regional health procurer should explain here for how many hospitals in his region he is responsible to procure solutions, how many patients are served by these hospitals, how many of these patients are affected by the problem that the PCP aspires to solve etc. A regional ministry of health should explain for how many citizens (e.g. specific types of patients) it is defining regulations that affect the deployment of solutions in the healthcare sector in its region.)*

[For PCPs with third parties providing in-kind contributions to the PCP, add: The following entities are not in the buyers group but participate as **third parties giving in-kind contributions** to the lead procurer and/or buyers group for the purpose of carrying out the PCP:

- [name, country]
- [name, country]
- …

Provide a short description of the responsibilities of the third parties, the type of resources they will put at the disposal of the PCP, and the rights and obligations that the third parties will assume with respect to the PCP, *e.g. the type of information they will have access to, and whether they will participate in certain parts of the PCP implementation such as testing*. Explain that they will not assume rights to results or IPRs.*]*

[For PCPs with preferred partners, add: The following entities are participating as **preferred partners** with an interest in the PCP, but without being part of the buyers group or giving in-kind contributions for carrying out the PCP:

- [name, country]
- [name, country]
- [name, country]

Explain briefly how the preferred partners will be kept informed about the PCP, what type of information concerning the PCP they will have access to and whether they will attend certain parts of the PCP implementation such as product demonstrations and testing. Explain that they will not assume rights to results or IPRs.]

Note:

Lead procurer — Beneficiary of the EU grant that represents the buyers group for the funded procurement (and is also part of the 'buyers group' if it contributes to the PCP procurement budget).

Buyers group — Beneficiaries of the EU grant that form the group of procurers that contribute to the PCP procurement budget.

For procurers that participate in the EU grant as sole participants (i.e. entities representing several members, *e.g. a central purchasing body, a European research infrastructure consortium or a European regional cooperation group*), indicate which of the members contribute to the PCP procurement budget.

Third parties that provide in-kind contributions to the PCP — Entities that are neither lead procurer nor members of the buyers group but that participate in the EU grant as third parties giving in-kind contributions to the PCP.

Preferred partners — Entities that are neither lead procurer, nor members of the buyers group, nor third parties providing in-kind contributions to the PCP, but that have a special interest in closely following the PCP. They may be beneficiaries/linked third parties involved in the EU grant *(e.g. those involved in 'related additional networking activities')* or they may be other entities that are not involved in the EU grant *(e.g. other procurers on the market that are potential buyers for the solutions and have expressed an interest in closely following the PCP)*.

3. Description of services to be procured

3.1 Motivation for the PCP

Explain the drivers that motivated the procurer(s) to launch the PCP, in particular:

- how the PCP fits into the strategy and plans of the procurer(s) to improve the quality and efficiency of the services of public interest that the procurer(s) is/are responsible for (*e.g. Procurer A is responsible for the care of x thousands of elderly persons in his region, the elderly population will increase by y % by 2020 whilst elderly care budgets are under pressure. Procurer A is therefore planning to re-organise/modernize its elderly care provisioning system with the new solutions to be developed by the PCP, in order to provide elderly care z % more efficiently and effectively by 2020*)
- whether the motivation(s) for carrying out the PCP are linked to regulatory requirements and/or the need for standardisation or certification.

3.2 Preparation for the PCP

Provide information about any preparatory activities undertaken to fine-tune the scope of the PCP that tenderers should be aware of *(e.g. the outcome of the open market consultation, horizon scanning, prior analysis of the products currently available or under development in ongoing R&D projects and end-user surveys)* before the publication of the contract notice.

Provide details about the open market consultation (*e.g. how it was conducted, where and when it was held, an internet link and a link to the prior information notice (PIN) published*).

Summarise clearly the lessons learnt, in particular the reasons why the currently available solutions don't meet the procurement need.

3.3 PCP challenge

Explain the common challenge to be addressed and the scope of the R&D services to be procured:

This procurement is for **R&D services** to develop **solutions** to tackle the following **challenge**: [specify briefly the subject and scope of this PCP, *e.g. improving the energy efficiency of buildings*] *[OPTION for PCPs with sub-challenges:* and the following sub-challenges: [specify the sub-challenges]*]*

This is a common challenge shared by all procurers in the buyers group. *[OPTION for PCPs with sub-challenges:* All sub-challenges are shared by all members of the buyers group.*]*

The **main quality/efficiency improvements** sought for: [indicate the target quality/efficiency and/or functionality/performance improvements, compared to the current best available solutions, *e.g. 30 % energy efficiency improvement, interoperability*]

[*OPTION for PCPs that include the purchase of some of the R&D results:* The PCP includes the **purchase** of a limited set of *[***prototype(s)***] [*and*][*or*] [*first test products or services*]* resulting from the R&D.

Explain clearly who is procuring which/how many prototypes/test products and where and when they need to be delivered.***]***

Note:

Ensure that the target quality/efficiency improvements clearly enable to make a step-change beyond what currently available solutions are able to deliver. Use functional or performance-based specifications, including technical minimum requirements that innovative solutions must meet, rather than prescribing a specific solution. Take into account your analysis on the shortcomings of solutions available on the market, the analysis of the needs of the buyers group and the outcome of the open market consultation. Alert tenderers as far as possible to any specific requirements of the subsequent phases *(e.g. for phase 2: local technical and safety conditions where prototype testing is planned to take place at one of the procurers' labs; for phase 3: local technical, ethics and safety/security requirements for field-testing)*. Provide the metrics or indicators that will be used to compare, at the end of each PCP phase, to what extent each competing solution has made progress towards reaching the targets.

For PCPs that include the purchase of a limited set of prototype(s) or first test products or services resulting from the R&D, specify why these are needed for R&D purposes (*e.g. if the existing solution used by the procurers has to be destroyed in order to test the new solutions developed during the PCP and/or the procurers need to carry out further testing of the newly developed solutions after the PCP is finished)*. Specify which and how many prototypes or first products are to be procured.

3.4 Expected outcomes (per phase)

Describe the objectives, their associated output and results and the tasks to be carried out (milestones and deliverables) for each of the three phases:

Expected outcomes					
Phase 1					
	Objective:	Perform research to: 1. elaborate the solution design and determine the approach to be taken to develop the new solutions and 2. demonstrate the technical, financial and commercial feasibility of the proposed concepts and approach to meet the procurement need			
	Output and results:				
	Milestones and deliverables		**By when?**	**How?**	**Output and results**
	Milestones:	M1.1) [milestone 1.1]	[dd.mm.yyyy]	[*e.g.sent by email to lead procurer, on-site visit*]	…

		M1.2) [milestone 1.2]	…	…	…
		…..			
	Deliverables:	D1.1)[deliverable 1.1]			
		D1.1a)[interim deliverable 1.1a]			
		D1.1b)[interim deliverable 1.1b]			
		D1.2)[deliverable 1.2]			
		D1.3)[deliverable 1.3]			
		D1.3a)[interim deliverable 1.3a]			
		D1.4)[deliverable 1.4]			
		…			
Phase 2					
	Objective:	Develop, demonstrate and validate prototypes in lab conditions			
	Output and results:				
	Milestones and deliverables		**By when?**	**How?**	**Output and results**
	Milestones:	M2.1) [milestone 2.1]	[dd.mm.yyyy]	[*e.g.sent by email to lead procurer, on-site visit*]	…
		M2.2) [milestone 2.2]	…	…	
		…..			
	Deliverables:	D2.1)[deliverable 2.1]			
		D2.1a)[interim deliverable 2.1a]			
		D2.1b)[interim deliverable 2.1b]			
		D2.2)[deliverable 2.2]			
		D2.3)[deliverable			

		2.3]			
		D2.3a)[interim deliverable 2.3a]			
		D2.4)[deliverable 2.4]			
		…			
	Points to be addressed in report:				
Phase 3					
	Objective:	Original development and field-testing of a limited set of first *[products] [services]* (the test series)			
	Output and results:				
	Milestones and deliverables		**By when?**	**How?**	**Output and results**
	Milestones:	M3.1) [milestone 3.1]	[dd.mm.yyyy]	[*e.g.sent by email to lead procurer, on-site visit*]	
		M3.2) [milestone 3.2]	…		
		…..			
	Deliverables:	D3.1)[deliverable 3.1]			
		D3.1a)[interim deliverable 3.1a]			
		D3.1b)[interim deliverable 3.1b]			
		D3.2)[deliverable 3.2]			
		D3.3)[deliverable 3.3]			
		D3.3a)[interim deliverable 3.3a]			
		D3.4)[deliverable 3.4]			
		…			
	Points to be addressed in report:				

Specify the tasks and expected outcomes of each milestone and deliverable in more detail:

M1.1)

M1.2) …

D1.1)

D1.2) …

Note:

Do not forget to include the following deliverables:

- for each end-of phase deliverable, a section that explains the IPR measures taken by the contractor to protect the results and lists the names and location of personnel that carried out the R&D activities
- at the start of phase 1, phase 1 project abstracts (in the format required by the EU for publication)
- at the end of phase 1, a summary of the main results achieved by each contractor and conclusions from phase 1 (in the format required by the EU for publication)
- at the start of phase 2, phase 2 project abstracts (in the format required by the EU for publication)
- at the end of phase 2, a summary of the main results achieved by each contractor and conclusions from phase 2 (in the format required by the EU for publication)
- at the end of phase 2, a demonstration to the EU of the prototypes developed during phase 2
- at the start of phase 3, phase 3 project abstracts (in the format required by the EU for publication)
- at the end of phase 3, a summary of the main results achieved by each contractor and conclusions from the PCP in the format required by the EU for publication)
- a deadline by which the contractors must agree on the text for the summary of overall lessons learnt and results achieved from the PCP, for publication
- at the end of phase 3, a final demonstration to the EU of the final products or services developed during the three phases.

For phase 2, specify whether prototype validation is expected to be done at the premises of the procurer(s) or the contractor. In case of PCPs with lots, clarify if there is a need for validating prototypes of contractors from different lots together (to test dependencies between lots and to ensure that building blocks developed in different lots will ultimately work together as expected).

For phase 3, provide information on the site(s) where the testing of the test series will take place and its timing. State clearly how many solutions each contractor is expected to develop for the limited test series. Specify whether contractors need to set aside resources for testing the solutions on the premises of all the procurers in the buyers group. Indicate whether they need to plan to have resources available to carry out testing sequentially or in parallel at the different sites. In case of PCPs with lots, clarify if there is a need for field testing of products/services developed by contractors in different lots together (to test dependencies between lots and to ensure that building blocks developed in different lots ultimately work together as expected).

3.5 IPR — Commercial exploitation of the results — Declaration of pre-existing rights

Ownership of results (foreground)

Each contractor keeps ownership of the IPRs attached to the results it generates during the PCP implementation. The tendered price is expected to take this into account (see section 4.5.4).

The ownership of the IPRs will be subject to the following:

- the members of the buyers group have the right to:
  - access results, on a royalty-free basis, for their own use
  - grant (or to require the contractors to grant) non-exclusive licences to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license)
- the contractors will have to transfer ownership of the IPRs to the members of the buyers group if they fail to comply with their obligation to commercially exploit the results (see below) or use the results to the detriment of the public interest, including security interests.

Commercial exploitation of results

*[*The market potential is estimated at [insert available figures for the expected size and type of the potential total market size, i.e. beyond the procurers alone].*]*

The contractors are expected to commercially exploit the results of the R&D undertaken in the PCP within a period of [insert number of years (minimum of four years after the end of the EU grant)] years after the end of the framework agreement.

Provide information about:

- whether contractors are required to undertake specific activities beyond product development to commercially exploit the results, *e.g. certification of solutions or contribution to standardisation;*
- activities that the procurers themselves plan to undertake to help remove barriers to the introduction onto the market of the solutions to be developed during the PCP *(e.g. promotion of R&D results among other procurers, contribution made by the demand side to regulation, standardisation, and certification)*

The feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria (see section 4.5.3).

Declaration of pre-existing rights (background)

The ownership of pre-existing rights remains unchanged by the PCP.

In order to be able to distinguish clearly between results and pre-existing rights (and to establish which pre-existing rights are held by whom):

- tenderers are requested to list the pre-existing rights for their proposed solution in their offers (see section 4.5.3)
- procurers and contractors will establish a list of respective pre-existing rights to be used — before the start of the contract.

[OPTION for lead procurers, members of the buyers group and third parties providing in-kind contributions to the PCP that do NOT hold any relevant background: The lead procurer and members of the buyers group *[*and third parties providing in-kind contributions to the PCP*]* do not hold any pre-existing rights relevant to the PCP contracts.*]*

[OPTION for lead procurers, members of the buyers group and third parties providing in-kind contributions to the PCP that hold relevant background: The following members of the buyers group and/or lead procurer and/or third parties providing in-kind contributions to the PCP hold the following pre-existing relevant rights: [list all pre-existing rights held by the lead procurer or by members of the buyers group that tenderers should be aware about to prepare their offer — and specify those that are available for use and those that must be used to build upon for carrying out the R&D for the PCP]*]*

The framework agreement contains a provision that describes in more detail the rights and obligations of the different parties regarding the pre-existing rights and results.

Note: Note that some of the IPR-related terms used in this document (e.g. background) do not necessarily have the same meaning as in the EU grant agreement.

4. Conditions of tender

4.1 Eligible tenderers, joint tenders and subcontracting

Explain that the call for tenders is open to all operators (companies or other type of legal entities):

Participation in the tendering procedure is **open** on equal terms to **all types of operators from any country,** regardless of their geographic location, size or governance structure.

Tenders may be submitted by a **single entity** or in collaboration with others. The latter can involve either submitting a **joint tender** or subcontracting, or a combination of the two approaches.

For joint tenders:

- explain that the group of tenderers must assume joint and several liability for the performance of the contract
- require that the group of tenderers must mandate one of them with the power to sign the framework agreement and specific contracts provide in their name and on their behalf ('lead contractor')

For subcontracting:

- specify if there are restrictions on the allowed amount(s) that can be subcontracted
- indicate the provisions of national law that apply to subcontracting
- explain that the tender must mention which parts of the contract will be subcontracted
- specify that the contractors remain fully liable to the buyers group for the performance of the contract (and that subcontracts must therefore reflect the rules of the EU grant agreement, *including as relates to the place of performance, the definition of R&D services, confidentiality, results and IPRs, the visibility of EU funding, conflicts of interest, language, obligation to provide information and keep records, audits and checks by the EU, the processing of personal data, liability for damages and ethics and security requirements*).

Participation in the open market consultation is not a condition for submitting a tender.

⚠ **Attention:**

There will, however, be a requirement relating to the place of performance of the R&D services (see below).

For phases 2 and 3, participation is limited to tenderers that successfully completed the preceding phase.

4.2 Exclusion criteria

List the exclusion criteria and the evidence to be provided that will be used for the evaluation of the tender.

The exclusion criteria are as follows:

Exclusion criteria	Evidence
Include conflict of interest and all mandatory (and if applicable, optional) exclusion criteria according to national law.	Specify the required evidence for each criterion.
A) Conflict of Interest	A) a declaration of honour for 'absence of conflict of interest'
B) …	

⚠ Tenderers that do not comply with these criteria will be excluded.

Explain each exclusion criterion in more detail:

A) Conflict of interest

Tenderers that are subject to a conflict of interest may be excluded. If there is a potential conflict of interest, tenderers must immediately notify the lead procurer in writing.

A conflict of interest is any situation where the impartial and objective implementation of the evaluation of tenders and/or implementation of the contract is compromised for reasons relating to economic interests, political or national affinity, family, personal life *(e.g. family of emotional ties)* or any other shared interest.

⚠ **Attention:** If an actual or potential conflict of interest arises at a later stage (i.e. during the implementation of the contract), the contractor must contact the lead procurer, who is required to notify the EU and to take steps to rectify the situation. The EU may verify the measures taken and require additional information to be provided and/or further measures to be taken.

B) …

4.3 Selection criteria

List the selection criteria and the evidence to be provided:

The selection criteria are as follows:

Selection criteria	Evidence
A) Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs	Description of the capacity, materials and equipment that are available to the tenderer for research, prototyping and limited production and supply of the first set of products or services Description of the financial and organisational structures that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results
B) …	

⚠ Tenderers that do not comply with these criteria will be excluded.

Explain each selection criterion in more detail:

A) Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs

Tenderers must have:

- the capacity, tools, material and equipment to:
  - carry out research and lab prototyping
  - produce and supply a limited set of first products or services and demonstrate that these products or services are suitable for production or supply in quantity and to quality standards defined by the procurers
- the financial and organisational structures to
  - manage, exploit and transfer or sell the results of the PCP (including tangible and intangible results, such as new product designs and IPRs)
  - generate revenue by marketing commercial applications of the results (directly or through subcontractors or licensees).

B) ...

⚠ **Attention:** Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

Note:

Avoid selection criteria that are based on disproportionate qualification and financial guarantee requirements *(e.g. with regard to references from past customers, references for professional or technical qualifications and minimum turnover)*. Instead, use the business plan as one of the award criteria for deciding whether to award a contract (i.e. by requiring tenderers to show that they are able, during the PCP, to gradually build up sufficient financial capacity to successfully market their results).

4.4 Compliance criteria

List the compliance criteria and the evidence to be provided. Explain that the offers for each phase will be evaluated against the compliance criteria A to E.

Tenders must comply with the following compliance criteria:

Compliance criteria	Evidence
A) Compliance with the definition of R&D services	
B) Compatibility with other public financing	

C) Compliance with the requirements regarding the place of performance of the contract	
D) Compliance with ethics requirements	
E) Compliance with security requirements	
Additional compliance criteria for the call-off for phase 2	
X) …	
Additional compliance criteria for the call-off for phase 3	
X) …	

⚠ Tenders that do not comply with these criteria will be excluded.

Explain each compliance criterion in more detail:

A) Compliance with the definition of R&D services

Tenders that go beyond the provision of R&D services will be excluded.

R&D covers fundamental research, industrial research and experimental development, as per the definition given in the EU R&D&I state aid framework[5]. It may include exploration and design of solutions and prototyping up to the original development of a limited volume of first products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and to demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards.[6] R&D does not include quantity production or supply to establish commercial viability or to recover R&D costs. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements. The purchase of commercial volumes of products or services is not permitted.

The definition of services means that the value of any products covered by the contract must be less than 50 % of the total value of the PCP framework agreement.

Specify the evidence to be provided to demonstrate compliance with this criterion.

The following evidence is required:

- the financial part of the offer for the framework agreement must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement
- the financial part of the offer for each phase must give a breakdown of the price for that phase in terms of units and unit prices for every type of item in the contract, distinguishing clearly the units and unit prices for items that concern products
- the offers for all three phases may include only items needed to address the challenge in question and to deliver the R&D services described in the request for tenders
- the offers for all three phases must offer services matching the R&D definition above
- the total sum of the value of products offered in each phase and all previous phases must be less than 50 % of the total value of the framework agreement

[5] See Point 15 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

[6] See Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

- …

B) Compatibility with other public financing

Tenders that receive public funding from other sources will be excluded if this leads to double public financing or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules.

Specify the evidence to be provided to demonstrate compliance with this criterion. Require for example a declaration of honour for absence of other incompatible public financing.

C) Compliance with requirements relating to the place of performance of the contract

Tenders will be excluded if they do not meet the following requirements relating to the place of performance of the contract:

- At least [add percentage — minimum 50 %] of the total value of activities covered by the framework agreement must be performed in the EU Member States or H2020 associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or H2020 associated countries.
- At least [add percentage — minimum 50 %] of the total value of activities covered by each specific contract for each PCP phase must be performed in the EU Member States or in H2020 associated countries. The principal R&D staff working on each specific contract must be located in the EU Member States or H2020 associated countries.

The percentage is calculated as the part of the total monetary value of the contract that is allocated to activities performed in the EU Member States or in other countries associated to Horizon 2020. All activities covered by the contract are included in the calculation, i.e. all R&D and operational activities that are needed to perform the R&D services *(e.g. research, development, testing and certifying solutions)*. This includes all activities performed under the contract by contractors and, if applicable, their subcontractors.

The principal R&D staff are the main researchers, developers and testers responsible for leading the R&D activities covered by the contract.

The countries associated to Horizon 2020 are those listed as associated countries in the Participant Portal Online Manual[7].

Both percentages must be set at a minimum of 50 % to ensure that tenders that do not go through to phase 2 or 3 still satisfy the place of performance requirement.

Specify the evidence to be provided to demonstrate compliance with this criterion:

The following evidence is required:

- the financial part of the offer must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement and give a breakdown of the price for the current phase in terms of units and unit prices (hours and unit price per hour), for every type of item in the contract *(e.g. junior and senior researchers)*
- a list of staff working on the specific contract (including for subcontractors), indicating clearly their role in performing the contract (i.e. whether they are principal R&D staff or not) and the location (country) where they will carry out their tasks under the contract
- a confirmation or declaration of honour that, where certain activities forming part of the contract are subcontracted, subcontractors will be required to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that has to be performed in the EU Member States or in countries participating in Horizon 2020 is respected

[7] List of H2020 associated countries.

- …

D) Ethics and research integrity

Tenders will be excluded if they:

- do not comply with the following rules:
  - ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity[8], and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
  - applicable international, EU and national law
- include plans to carry out activities that are prohibited in all Member States or in a country outside the EU (where those activities are allowed)
- include activities whose aim is to:
  - carry out human cloning for reproductive purposes
  - modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads)
  - create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer
- include activities that do not focus exclusively on civil applications
- *[OPTION if EU grant agreement contains ethics requirements that affect the PCP contracts:* do not comply with the following ethics requirements:
  - [insert the ethics requirements from Annex I to the EU grant agreement]*]*.

If the tender involves activities that raise ethical issues, the tenderer must submit an ethics self-assessment that:

- describes how the tender meets the legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out
- explains in detail how the tenderer intends to address the ethical issues identified, in particular as regards:
  - objectives *(e.g. dealing with vulnerable populations and dual-use goods[9])*
  - methodology *(e.g. involvement of children and related consent procedure and protection of data collected)*
  - the potential impact *(e.g. issues relating to the dual use of goods, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing and malevolent use of results)*.

ⓘ For information on ethics issues, see the guidance for EU grant beneficiaries How to complete your ethics self-assessment.

⚠ **Attention:**

[8] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

[9] See Article 2(1) EU export control Regulation No 428/2009.

Call-offs for phases 2 and 3 may request that this information be updated in the offers submitted for these phases.

Before starting the particular task that raises ethical issues, contractors must provide a copy of:

- any ethics committee opinion required under national law; and
- any notification or authorisation for activities raising ethical issues required under national law.

The framework agreement contains a provision on ethics.

E) Security

Tenders will be excluded if they do not:

- comply with:
  - EU, national and international law on dual-use goods or dangerous materials and substances
  - *[OPTION if EU grant agreement provides for a security classification that affects the PCP contracts:* the security aspect letter (SAL) annexed to the EU grant agreement and Decision No 2015/444[10]*]*
  - *[OPTION if EU grant agreement contains security recommendations that affect the PCP contracts:* the following security recommendations:
    - [insert the security recommendations from Annex I to the EU grant agreement]*]*

Tenders themselves must not contain any classified information.

If the output of activities or results proposed in the tender raise security issues or uses EU-classified information, the tenderer must show that these issues are being handled correctly. In such a case, tenderers are required to ensure and to provide evidence of the adequate clearance of all relevant facilities. They must examine any issues (*such as those relating to access to classified information or export or transfer control*) with the national authorities before submitting their offer. Tenders must include a draft security classification guide (SCG), indicating the expected levels of security classification.

⚠ **Attention:**

If necessary for the tender procedure or for performing the contract itself, contractors will be requested to ensure appropriate security clearance for third parties *(e.g. for external experts needed to evaluate the proposal)*.

Call-offs for phases 2 and 3 may request that this security information be updated in the offers submitted for that phase.

Before starting the particular task that raises security issues, contractors must provide a copy of any export or transfer licences required under EU, national or international law.

The framework agreement and/or the specific contracts contain a provision on security.

F)…

[10] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information

⚠ **Attention:** Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

4.5 Award criteria

Specify the award criteria (and sub-criteria, where applicable), weightings and thresholds for each of the three phases:

Award criteria	Maximum points	Thresholds	Weighting
Phase 1			
Technical quality criteria			
A) [insert technical quality criterion 1]			
B) [insert technical quality criterion 2]			
C) [insert technical quality criterion 3]			
D)…			
Total technical quality criteria			
Price			
Phase 2			
Technical quality criteria			
A) [insert technical quality criterion 1]			
B) [insert technical quality criterion 2]			
C) [insert technical quality criterion 3]			
D)…			
Total technical quality criteria			
Price			
Phase 3			
Technical quality criteria			
A) [insert technical quality criterion 1]			
B) [insert technical quality criterion 2]			
C) [insert technical quality criterion 3]			
D)…			
Total technical quality criteria			
Price			

Explain each award criterion in more detail:

A) …

B)…

⚠ **Attention:**

Additional sub-criteria may be added for the call-offs for phases 2 and 3, as a way of making the award criteria more precise, provided that they do not substantially change the existing criteria.

Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

Note:

The award criteria must ensure that the procurer gets the best value for money. It is therefore not permitted to use either lowest price as the sole criteria, without taking quality into account, or highest quality as the sole criteria, without taking price into account.

Set the technical quality and price award criteria, weightings and thresholds so as to favour the most economically advantageous tenders. Define the thresholds per criterion and the total threshold.

Pay particular attention to the weighting given to price. It should be sufficiently high to avoid this criteria being neutralised in the evaluation. *(For example, a weighting of less than 20 out of 100 for price is too low for it to have a significant effect on the result.)*

State clearly whether all the award criteria will be evaluated by examining the written tender or whether some award criteria will be evaluated on the basis of hearings with or presentations to the evaluation committee.

4.6 Submission content and format

4.6.1 Submission and format of tenders, tender closing time

Explain the formal requirements that tenders must meet (including the address for submission of the tender, the deadline for submission of the tender and requirements relating to the presentation of the offer and its packaging).

State that all tenders must:

- contain administrative, technical and financial sections
- indicate their minimum validity period (from submission)
- be signed.

Specify that tenders that do not comply with the formal requirements will automatically be rejected.

Explain that more detailed information about the final layout requirements for the phase 2 and 3 offers will be provided in the call-off.

4.6.2 Administrative section of the tender

List the information that must be included in this section of the tender (including the documentary evidence necessary to identify the tenderer and to evaluate the tender against the exclusion, selection and compliance criterion B and — for joint tenders — the mandate for the lead contractor).

Mention that the lead procurer may request clarification or additional evidence where there is any doubt.

Explain that more detailed information for the phase 2 and 3 offers will be provided in the call-offs.

4.6.3 Technical section of the tender

Explain what the technical section of the tender must include:

Tenders must include a **technical offer**, containing:

- a technical plan that outlines: 1. the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and performance; and 2. technical details of how this would be implemented
- a draft business plan that explains the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market
- a list of the pre-existing rights (background) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed
- a risk assessment and risk mitigation strategy
- a reply to the question "Does this tender involve **ethical issues**? (YES/NO)" and if YES, an ethics self-assessment, with explanations how the ethical issues will be addressed (see section 4.2)
- a reply to the question "Does this tender involve: activities or results that may raise **security issues** and/or **EU-classified information**[11] as background or results? (YES/NO)" and if YES information on how these issues will be addressed (see section 4.2)
- …

⚠ **Attention:**

Tenders failing to meet these requirements will be excluded.

The technical part must provide a *detailed* technical offer for phase 1 (including an explanation of the methodology, a work plan and details of deliverables and milestones), and must specify the plans for and objectives of the subsequent phases 2 and 3 and beyond (including a plan for commercial exploitation of the results).

Explain how the technical section of the tender should be drafted (possibly by providing a template).

State that the information provided in the technical section of the tender will be used to evaluate the tenders, on the basis of the technical award criteria and the compliance criteria A, D and E.

Explain that more detailed information for the phase 2 and 3 offers (in particular on the technical implementation plan, updated business plan and list of IPRs) will be provided in the call-offs.

4.6.4 Financial section of the tender

Explain what the financial section of the tender must include:

The tender must include a detailed **financial offer** specifying:

- binding **unit prices** for all items needed for carrying out phase 1 and for items that are expected to be needed for phases 2 and 3 (given in euros, excluding VAT but including any other taxes and duties)

[11] See Decision 2015/444/EC, Euratom on the provisions on security of EU-classified information.

- a fixed **total price** for phase 1 and an estimated total price for phases 2 and 3, broken down to show unit prices and the number of each unit needed to carry out phase 1 (given in euros, excluding VAT but including any other taxes and duties).

In addition, the financial section must include:

- a **price breakdown** that shows the price for R&D services and the price for supplies of products (to demonstrate compliance with the definition of R&D in compliance criterion A)
- a **price breakdown** that shows the location or country in which the different categories of activities are to be carried out *(e.g. x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour)* (to demonstrate compliance with the requirement relating to place of performance in compliance criterion C)
- the **financial compensation** valuing the allocation of ownership of the **IPRs** generated during the PCP to the tenderer, either:
    - *[OPTION if the procurers choose 'ex ante' valuation of the IPRs:* by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e. the price that would have been quoted were IPR ownership to be transferred to the procurers)*]*
    - *[OPTION if the procurers choose 'ex post' valuation of the IPRs:* by confirming the tenderer's agreement with the chosen royalty scheme specified by the procurers, including the percentage of royalties that contractors will have to pay on sales/profits made from commercial exploitation of the IPRs*]*

  in order to ensure compliance with the EU R&D&I state aid framework.

⚠ **Attention:** The unit prices quoted for each category of items *(e.g. hourly rates for junior and senior researchers, developers and testers)* remain binding for all phases (i.e. for the duration of the framework agreement).

Explain how the financial section of the tender should be written.

Explain whether and according to which formula unit prices can be indexed for phases 2 and 3.

Explain that the financial compensation for IPRs must reflect the market value of the benefits received (i.e. the opportunity that the IPRs offer for commercial exploitation) and the risks assumed by the contractor *(e.g. the cost of maintaining IPRs and bringing the products onto the market)*.

State that the information provided in the financial section of the tender will be used to evaluate the tenders on the basis of the price award criteria and the compliance criteria A and C.

Explain that more detailed information for the phase 2 and 3 offers will be provided in the call-off. The price for phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the framework agreement. Where new units/unit prices *(e.g. for new tasks or equipment)* are subsequently added to the phase 2 or 3 offers, they will become binding for the remaining phases.

Similar price breakdowns will be requested for the call-offs for phase 2 and 3.

Note:

Indicate which VAT regime(s) apply. If all contractors will be paid by the lead procurer (centralised payments), it will be the VAT regime of the lead procurer. If all contractors will be paid by each member of the buyers group individually (pro rata to its contribution to the PCP procurement budget; decentralised payments), it will be the VAT regime for each member of the buyers group for its share of the payment.

4.7 Other tender conditions

4.7.1 Signed tenders

A signed tender will be considered to constitute a firm, irrevocable, unchangeable and binding offer from the tenderer.

The signature of an authorised representative will be considered as the signature of the tender (and will be binding on the tenderer or, for joint tenders, the group of tenderers).

4.7.2 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure (including EU-classified information[12]).

4.7.3. Language

Tenders as well as offers for phase 2 and 3 call-offs must be submitted in English *[*and [insert additional language(s), if any]*]*.

Deliverables must be submitted in English *[*and [insert additional language(s), if any]*].*

Communication (relating to either the tender procedure or the implementation of the contract) must be carried out in English *[*or [add additional language(s), if any]*]*.

Note:

Indicate specific language requirements, if necessary (for example, if certain tasks need to be carried out in cooperation with third parties locally, *e.g. for field-testing with end-users who may speak only the local language*).

4.7.4 Cancellation of the tender procedure

The procurers may, at any moment, cease to proceed with the tender procedure and cancel it.

The procurers reserve the right not to award any contracts at the end of the tender procedure.

The procurers are not liable for any expense or loss the tenderers may have incurred in preparing their offer*[*, except for [insert if mandatory limits under national law]*].*

5. Process rules and information

5.1 Opening of tenders

Describe the composition of the opening committee, i.e. the number and type of members, without giving their names.

Specify which points will be checked during the opening of tenders, in particular in relation to compliance with the conditions on the content and format of the offer (see above).

[12] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information.

State that tenders not complying with the formal requirements will be excluded from the tender evaluation.

Give the date for the opening of the tenders and explain how tenderers can participate.

For phases 2 and 3, explain any differences in the composition of the opening committee or in the procedure.

5.2 Evaluation of tenders

Describe the composition of the evaluation committee (and its panels, where applicable), i.e. specify:

- whether the evaluation committee is the same as the opening committee
- the number and type of members, without giving their names
- whether, in addition to the lead procurer and the members of the buyers group, there will be independent experts on the committee *(e.g. technical experts on the subject, financial experts for evaluating the commercial viability of the solutions proposed or ethical or security experts)*.

The evaluation committee will evaluate the tenders, carrying out the following four steps:

Step 1 — Checking whether the tenderer is not in one of the situations covered by the exclusion criteria

Step 2 — For tenderers passing Step 1, assessing whether the tenderer has the capacities necessary to perform the contract, on the basis of the selection criteria

Step 3 — For tenderers passing Step 2, evaluating the tender based on the compliance criteria

Step 4 — For tenders passing Step 3, evaluating the tender based on the award criteria

Explain the tasks of the chair and the members (and the different panels, where applicable).

Specify which members will be involved in the different steps of the evaluation.

Describe how the committee (and its panels) will work *(e.g. when and how they will meet)*, and explain the process to be used for making decisions at each of the different steps *(e.g. decision by unanimity)*.

Explain the system for scoring, qualitative appraisal and ranking *(e.g. starting from a first round of individual evaluations and concluding with a final agreed qualitative appraisal; the scoring for each tender and the final ranking list of all tenders agreed by the lead procurer and the buyers group)*.

Specify the type of feedback tenderers will receive from the evaluation of their tender.

For phases 2 and 3, explain any differences in the composition of the evaluation committee or in the procedure (Highlight in particular that the evaluation of offers for phase 2 has only two steps: evaluating the offers based on the compliance and award criteria.)

Note:

The buyers group and the lead procurer must evaluate the tenders and offers for the call-offs for phase 2 and 3 jointly and must make a *joint* award decision.

Avoid potential conflicts of interest.

⚠ Please note that, for each phase and each tender received, the procurer must send an evaluation form to the Commission or its agency as part of the deliverables to be submitted at the

end of the tender evaluation. (It should include: the final scores awarded, a qualitative appraisal per evaluation criterion, minutes of the evaluation meeting and the final ranking list)

5.3 Communication — Q&A

The Q&A from the open market consultation can be found on [indicate the website where the Q&A from the open market consultation phase can be found].

For further questions, you may contact [the lead procurer via email and/or by other means] in English [and any additional languages chosen by the lead procurer and buyers group] until [insert date].

The summary of all questions and answers will be presented in an anonymised Q&A document that will be published on [indicate the website where the Q&A will be uploaded] in English [and any additional languages chosen by the lead procurer and buyers group] (final version planned for [insert date]). For phases 2 and 3, the answers will not be published, but distributed to all contractors that successfully completed the previous phase.

Unless otherwise instructed, please do not use any other contact addresses or contact any other persons in connection with this procurement.

5.4 Procedures for appeal

Specify:

- the names of the appeal and mediation bodies foreseen under the national law applicable to the lead procurer and the time periods for filing a complaint and the different stages of dispute settlement.

6. Conditions of the contracts

Successful tenderers will be requested to sign both a framework agreement and specific contracts for phases 1, 2 and 3 (see the models given in Annexes 1 and 2).

6.1. Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, deliverables and output or results) for the phase.

Each contractor will be assigned a main contact person (their supervisor) from the monitoring team appointed by the procurers.

There will be regular monitoring meetings between contractor and the supervisor/monitoring team.

Explain how often they will take place, how they will be conducted (physical meetings or remote/online meetings), and what they will involve. The contractors could be asked to discuss the results achieved in the preceding period and present their updated work plan; the monitoring team or supervisor could visit the contractor's premises to periodically monitor progress; the contractors could visit the procurer's premises (in particular at the start of a phase to get to know better the operational environment that solutions need to be designed for). Clarify that the contractor must cover its own costs and thus foresee personnel and travel budgets in its offer. In case of PCPs with lots, clarify if and when there will be meetings that involve contractors from the different lots to sort out dependencies between lots and to ensure that building blocks under development in different lots will ultimately work together as expected.

The monitoring team *[*or supervisor*]* will provide regular feedback to contractors after meetings or visits.

Explain how and when this will take place and how this will allow contractors to continuously improve the way in which their solutions address the problem set out in the PCP description.

6.2. Payments based on satisfactory completion of milestones and deliverables of the phase

Payments corresponding to each PCP phase will be subject to the *satisfactory* completion of the deliverables and milestones for that phase.

Satisfactory completion will be assessed by an assessment committee composed of [describe the composition of the assessment committee, without mentioning their names].

Satisfactory completion will be assessed according to the following requirements:

- if the work corresponding to that milestone / deliverable has been carried out
- if a reasonable minimum quality has been delivered
- if the reports have been submitted on time
- if the monies have been allocated to the planned objectives
- if the monies have been allocated and the work has been carried out according to the compliance criteria (place of performance, public funding and R&D definition criteria)

and

- if the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective phase)

'Reasonable minimum quality' of a report means that:

- the report can be read by somebody who is familiar with the topic, but not an expert
- the report gives insight in the tasks performed in and the results
- the report is made using the end of phase report form or (if applicable) the milestone report form and the requirements of this form have been met
- …

'Reasonable minimum quality' of a demonstration (for phase 2 or 3) means:

- the demonstration can be understood by somebody who is familiar with the topic, but not an expert (for instance, somebody with operational but not technical knowledge)
- the demonstration shows how the innovation works, how it can be used and (if applicable) how it is operated and maintained
- the demonstration is accessible to parties appointed by the procurers, unless these are direct competitors of the contractor
- ...

Satisfactory completion in each of the phases does not mean successful completion. (A PCP could, for instance, be satisfactorily completed even if it concludes that the innovation is not feasible.)

The assessment will consider the efforts made by contractors to take into account the feedback from the supervisor or the monitoring team.

Specify the terms of approval for deliverables (for reports and demonstrations respectively), in particular how many days the contractor has to approve/request modifications/reject deliverables, how many days the contractor has to resubmit deliverables.

Where the assessment committee judges the completion of deliverables or milestones to be unsatisfactory, [explain what happens, in particular the possible consequences in terms of reducing or withdrawing payments for that deliverable and/or terminating the contract].

Invoices must be submitted *[*to the lead procurer*][*pro-rata to each member of the buyers group*]*.

[*OPTION in case pro-rata payments are used:* For every payment the contractors must create [insert a number equal to the amount of members in the buyers group] number of invoices, dividing the amount of the payment over the invoices for the different members of the buyers group, according to the following distribution:

- [insert percentage that equals the ratio between the financial contribution of member X of the buyers group to the total PCP subcontracting cost (including the applicable VAT in country X) and the total PCP subcontracting cost (including VAT)] percent of the payment to be invoiced to [insert name of member X of the buyers group]]
- […] percent of the payment to be invoiced to [insert name of member Y of the buyers group]]
- …

Note: In an example of a buyers group with 3 procurers, each procurer must contribute the same amount (including VAT) to the total PCP subcontracting cost (i.e. for each payment 3 invoices equal to one third of the total payment amount; one invoice to each of the 3 procurers). ***]***

Contractors' invoices must provide:

- a **price breakdown** showing the price for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D in compliance criterion A)

- a **price breakdown** showing the location or country in which the different categories of activities were performed *(e.g. x hours of senior researchers in country L at y euro/hour, a hours of junior developers in country M at b euro/hour)* (in order to demonstrate compliance with the requirement relating to the place of performance in compliance criterion C).

Explain when payments will be made. Provide information on the amounts of the pre-instalments and interim payments (where applicable) and the payment of the balance.

6.3. Eligibility for the next phase based on successful completion of the phase

Eligibility for participation in the next phase will be subject to *successful* completion of the current phase.

Successful completion of a phase will be assessed by the assessment committee against the following requirements:

- if all milestones have been successfully completed

- if the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency improvements which the procurers set forward for the innovative solutions to achieve)

- if the results of the R&D are considered to be promising

- …

'Promising' means:

- for phase 1, that the feasibility is convincing

- for phase 2, that the feasibility, the applicability in an operational setting and the potential impact of the product is convincing

Note: Note the difference between satisfactory completion (requirement for payment) and successful completion (prerequisite for passing from one phase to the next).

6.4. Finalisation of phase 3: link with possible follow-up PPI procurement

A new call for tenders will be launched for any follow-up public procurement of innovative solutions (PPI) to deploy a commercial volume of innovative solutions.

If possible, please provide an indicative schedule for the procurement process that the procurers in the buyers group would organise for deploying commercial volumes of the solutions, were the PCP to be completed successfully.

Annex 1

PCP Framework Agreement

Disclaimer: This annex is aimed at assisting H2020 PCP grant beneficiaries. It is provided for information purposes only and is not intended to replace consultation of professional legal advice. It can be used as a starting point to draw up the framework agreement, but beneficiaries remain responsible for adapting it to their situation and checking full compliance with the applicable law. Neither the European Commission nor its Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

In order to comply with the conditions of the EU grant agreement, the framework agreements should contain at least the following elements/provisions:

PREAMBLE

This is a framework agreement ("agreement') between the following parties:

on the one part,

the "lead procurer", [insert details of the lead procurer],

acting in the name and on behalf of the *[*other*]* members of the buyers group:

1. [insert the details of the members of the buyers group (NOT of preferred partners or third giving in-kind contributions to the PCP!)]

2.

and on the other hand, the "contractor", [insert details of the contractor],

[*OPTION for joint tenders:* acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]

2.

The members of the group of tenderers are hereafter collectively referred to as the "contractor" and will be jointly and severally liable vis-à-vis the lead procurer for the performance of this agreement and the specific contracts.***]***

The lead procurer, buyers group and the contractor(s) shall be referred to together as "parties", unless otherwise specified.

By signing this agreement the parties agree to implement the pre-commercial procurement in accordance with the agreement and all the obligations it sets out.

The agreement is composed of:

- Preamble

- Terms and Conditions

Annex 1 Request for tenders

Annex 2 Contractor's tender

TERMS AND CONDITIONS

In order to comply with the conditions of the EU grant, the framework agreements should contain at least the following provisions:

Article 1 — Subject of the agreement

This framework agreement defines the general terms and conditions for the implementation of the PCP procurement of R&D services set out in Article XX and for the specific contracts that will be awarded for each of the 3 PCP phases.

Article XX — Duration

Define the duration for the framework agreement and starting and end date for the implementation of the tasks.

Specify that the period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

Article XX — R&D services to be provided

The contractor shall provide the R&D services (tasks, deliverables and milestones) to develop solutions to tackle the challenge set out in the tender and the specific contracts.

Article XX — Pricing, payment and accounting

The price for the R&D services to be implemented for each PCP phase will be set out in the specific contracts.

The prices shall be based on the binding unit prices in the tender and the following price conditions:

- if new units/unit prices are added to phase 2 or 3 offers, they shall become binding for the remaining phases
- … specify the other price conditions

Specify the payment and invoicing conditions that will apply. Ensure consistency with the request for tenders/tender (if needed via cross-references).

[*OPTION in case there are preferred partners and third parties providing in-kind contributions to the PCP:* **Article XX — Participation of preferred partners and third parties providing in-kind contributions to the PCP)**

Complete as applicable to the specificities of the PCP. Name the preferred partners and third parties providing in-kind contributions to the PCP and explain the boundary conditions for their participation, i.e. the rights and responsibilities with respect to the provisions under the agreement and specific contracts.

Pay particular attention to clearly set out the rules for participating in testing /monitoring/evaluation of results, confidentiality, processing of personal data and communication.

Specify also clearly IPR-related rights *(e.g. access rights to results needed to follow the implementation of the PCP)* or obligations of preferred partners and third parties providing in-kind contributions to the PCP *(e.g. access rights to pre-existing rights, sideground or results (foreground) needed by contractors to implement the PCP or exploit its results).****]***

Article XX — Ownership of the results (foreground), pre-existing rights (background) and sideground (including intellectual and industrial property rights)

Include provisions that clarify the rights and obligations related to pre-existing rights (background), sideground and results (foreground) for:

- procurers,
- contractors and
- their subcontractors (if any).

Note:

Such provisions may not conflict with the obligations of the lead procurer and the buyers group under the EU grant.

Third parties providing in-kind contributions to the PCP and preferred partners should be covered in the Article on participation of preferred partners and third parties providing in-kind contributions.

Provide definitions, notably for:

- 'results (i.e. foreground)' means any tangible or intangible output, such as data, knowledge or information, that is generated in the PCP, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights ('attached IPRs' or 'IPRs attached to the results').

  'Generated in the PCP' means in activities described in the PCP framework agreement and specific contracts.

- 'pre-existing rights (i.e. background)' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('background IPRs') — that is held prior to the signing of the framework agreement, and identified by the parties involved in the PCP as background and is needed to implement the PCP or exploit the results of the PCP.

- 'sideground' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('sideground IPRs') — that is generated during the timespan of the PCP but not in the PCP and is needed to implement the PCP or to exploit the results of the PCP.

  'Not generated in the PCP' means not generated in activities described in the PCP framework agreement or specific contracts.

- 'fair and reasonable conditions' means appropriate conditions, including financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access (for example, the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged).

Provide for the rights and obligations in relation to results. Specify:

- that each contractor that generates results **owns** the attached IPRs

- who will **own results that are not IPRs** *(e.g. prototypes and first products resulting from the R&D, design, prototype and first product/service specifications, simulations, data models, drawings, source code)*

- that each contractor is responsible for the **management** (including protection) of its IPRs and bears the costs associated with this

- that the lead procurer and the buyers group have the right to **monitor** the management of the IPRs

- that the contractors must inform the buyers group (via the lead procurer) of results that can be **exploited**, regardless of whether they can be protected or not, within [insert number] days from when they are generated. The information submitted to the lead procurer must include information about the contents of the results, the confirmation by the contractor to protect them and the planned timing for protection.

- that if a contractor does not seek **protection** for results that should be protected, the buyers group has the right to request (via the lead procurer) that the results are transferred to them

- that the contractors grant to the members of the buyers group irrevocable, royalty-free, non-exclusive, world-wide **access** rights to use the results, for their own purposes (for IPRs: until their expiry date)

- that, for results that are an implementation of design specifications into simulations, prototypes, demonstrators or first products /services, those access rights are limited to a duration of [insert duration] years and to the following purposes for fulfilling the R&D objectives of the PCP: [specify those purposes for your PCP]

  Note: The limitation of the scope and duration of the access rights (to 'what is needed by the members of the buyers group to fulfil the R&D objectives of the PCP') is needed for the PCP to remain an 'R&D procurement' where the 'procurers do not retain all the benefits' and thus be exempted from the WTO rules and the EU public procurement directives.

- that the members of the buyers group have *[*the right to grant*] [*the right to require the contractors to grant — within a reasonable time period specified in the request —*]* **non-exclusive licences to third parties** to commercially or non-commercially exploit the results under fair and reasonable conditions, without the right to sub-license

- that the contractors may grant non-exclusive licences to third parties allowing them to exploit the results (or otherwise give the right to exploit them) — unless this impedes the access rights of the buyers group

- that the contractors may **transfer ownership** of their results — unless this is prohibited (or restricted) by the security obligations and provided that they ensure that their obligations (in respect of the results) apply to the new owner and that this new owner is obliged to pass them on in any subsequent transfer *(e.g. by including a requirement to do so in their arrangements with the new owner)*

  Note: You may foresee a right of first refusal for the members of the buyers group to buy the results.

  You should also foresee a procedure for transfers when there are members of the buyers group that still have (or may still request) access rights to the results (*e.g. that the contractor must give them at least 45 days advance notice of its intention to transfer ownership of the results and that this notification must include sufficient information on the new owner to enable the members of the buyers group to assess the effects on their access rights. Any member of the buyers group may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. Should an objection be raised, the transfer may not take place until agreement has been reached between the parties concerned).*

- whether the contractor is required to deposit copies of results *(e.g. the source code and design specifications)*, *for example, under an ESCROW agreement designed to guarantee the buyers group continued access to results in the case of financial bankruptcy of the contractor (or any of its subcontractors)*.

Provide for the rights and obligations concerning pre-existing rights (background) and sideground. Specify:

- rules regarding **ownership** of pre-existing rights and sideground (normally remains unchanged)

- that the parties must inform each other about the generation of/changes in pre-existing rights and sideground within [insert number] days from the generation /change

- that the contractors introducing background must within [define period *e.g. 2 weeks*] of the signing of the PCP framework agreement provide the lead procurer with a **list of the pre-existing rights** it holds and/or has access to *(e.g. via its subcontractors)* (at the

date of the agreement) and a list of the software necessary for the operation of the prototype and first *[*products*][*services*]* that will be developed during the PCP, specifying which software is closed source software. An updated list (to the extent necessary) must be provided with each bid for the next phase

- the **access** that the parties must grant each other to each other's pre-existing rights and sideground for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes *(normally at least to the buyers group)*

  Note: Don't forget to fix conditions for access that are fair and reasonable to all parties, e*.g. — if appropriate for your PCP —*

  - *on a royalty-free, non-exclusive basis, access to each other's background, for carrying out the tasks assigned to them in the PCP*
  - *under fair and reasonable conditions and on non-exclusive basis, access to each other's background, for exploitation of results generated in the PCP and for using the results for their own purposes*
  - *under fair and reasonable conditions and on non-exclusive basis, access to each other's sideground, for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes*

Note:

Don't forget to foresee:

- rules that define third party rights and obligations with respect to the above points on results, pre-existing rights and sideground (in the Article on participation of preferred partners and third parties providing in-kind contributions)
- rules on subcontractor rights and obligations with respect to the above points on results, pre-existing rights and sideground *(e.g. that the contractors must ensure that they comply with their obligations under the framework agreement and specific contracts if they use subcontractors; that they must obtain all necessary rights (transfer, licences or other) from subcontractors, as if they were generated by themselves in order to be able to respect their obligations under the framework agreement; that they should refrain from using subcontractors if obtaining those rights needed to respect their obligations under the framework agreement is impossible)*

You may specify additional intellectual property provisions, provided they:

- do not conflict with the obligations of the lead procurer and the buyers group under the EU grant agreement and
- help lead procurers, the buyers group and contractors to implement the PCP and exploit the results.

Article XX — Confidentiality

The parties shall keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed. This applies during the implementation of the framework agreement and up to [insert number of years (minimum 4 years after the end of the EU grant)] years after the end of the framework agreement.

If information has been identified as confidential only orally, it shall be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

The parties may disclose confidential information to their staff or to third parties involved in the PCP implementation only if:

(a) they need to be aware of this information in order to implement the PCP activities under the framework agreement and specific contracts; and

(b) they are bound by an obligation of confidentiality.

The confidentiality obligations cease to apply if:

(a) the disclosing party agrees to release the other party from the obligation;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was produced without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation; or

(e) the disclosure of the information is required by EU or national law.

This does not change the security obligations, which still apply. Stricter confidentiality obligations apply for information that is EU-classified or subject to a security recommendation.

Note:

If the duration of the EU grant agreement is longer than foreseen (i.e. if the action duration is extended), you must also extend the confidentiality obligation for the framework agreement (via an amendment).

Article XX — Promotion, publicity and communication

XX.1 The contractor shall undertake communication activities to create publicity about its participation to the procurement, and to promote the objectives and the results of the R&D carried out under the PCP (in particular, to other potential customers beyond the lead procurer and buyers group with the objective to achieve commercial exploitation of the results (see Article XX – Commercial exploitation of results)).

All communication activities shall comply with the applicable confidentiality and security restrictions.

During the implementation of the contract and for a period of [insert number] *[*years*][*months*]* after the end of the contract, the contractor shall inform the lead procurer [indicated number] days in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the services or results. Information on communication activities expected to have a major media impact shall be provided sufficiently in advance to allow the lead procurer to inform the EU.

All communication activities (including in electronic form and via social media) and infrastructure, equipment and major results financed by the PCP shall display the EU emblem and include the following text:

- for communication activities: 'This is part of the [acronym of the EU grant] project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme';

- for infrastructure, equipment and major results: 'This [infrastructure][equipment][insert type of result] is part of the [acronym of EU grant] project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme'.

When displayed together with another logo, the EU emblem shall have appropriate prominence. The contractor may use the EU emblem without first obtaining approval from the EU. This does not, however, give the contractor the right to exclusive use. Moreover, the contractor may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

All communication activities shall indicate that they reflect only the author's views.

XX.2 The lead procurer and the buyers group may use, for the purposes of communication and publicity, all information relating to the PCP, documents (notably summaries) and deliverables, and

any other material (such as pictures or audiovisual material) from the contractor (including in electronic form).

The lead procurer and the buyers group may, in particular, publish the names of the participating contractors and their project abstracts, the summaries of the main results from the R&D and the lessons learnt during the PCP *(e.g. relating to the feasibility of the different approaches to meeting the procurers' requirements that were explored, and the lessons learnt for potential future use of the solutions proposed)*.

This does not change the confidentiality obligations under Article XX.

Moreover, before publishing this information, the lead procurer and the buyers group shall consult the contractor, in order to avoid harm to legitimate business interests *(e.g. regarding aspects of the solutions that could be IPR-protected)* or distortion of competition.

XX.3 The EU may use, for the purposes of communication and publicity, information relating to the PCP, documents (notably summaries) and deliverables, and any other material (such as pictures or audiovisual material) from the contractor (including in electronic form).

If the EU's use of these materials, documents or information would risk compromising legitimate interests, the contractor may, however, ask the lead procurer to request the EU not to use it.

The right to use the contractor's materials, documents and information includes:

(a) use for its own purposes (in particular, making them available to staff working for the EU (including for the European Commission, EU executive agencies, other EU institutions, bodies, offices or agencies) or for EU Member State institutions or bodies; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) editing or redrafting for the purposes of communication and publicity (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts *(e.g. audio or video files)*, dividing into parts or using in a compilation);

(d) translation;

(e) giving access in response to individual requests made under Regulation EC No 1049/2001, without the right to reproduce or exploit;

(f) storage in paper, electronic or other form;

(g) archiving, in line with applicable rules on document management, and

(h) authorising third parties to act on its behalf or sub-licensing the modes of use set out in points (b), (c), (d) and (f) to third parties if needed for the purposes of communication and publicity.

If the right of use is subject to rights of a third party (including the contractor's staff), the contractor shall ensure that it obtains the necessary approval from the third parties concerned).

Article XX — Commercial exploitation of results

The contractor shall, for at least [insert number of years (minimum 4 years after the end of the EU grant)] years after the end of the framework agreement, take measures to ensure that its results are exploited commercially (directly or indirectly, in particular through transfer or licensing).

If the contractor fails to commercially exploit the results within this period (or uses the results to the detriment of the public interest, including security interests), the buyers group has the right to require that ownership of the results be transferred to them.

'Failure to commercially exploit results' means not marketing a commercial application of the results (directly or indirectly, through a subcontractor or licensee).

Note:

Set the period of time allowed in such a way as to give contractors a fair and reasonable amount of time to exploit the results in the relevant sector. This will ensure that the potential for marketing the product or service is valued correctly (an appropriate length of time would typically be longer than 4 years, *e.g. 5 years*). The period should take account of the fact that: 1. the contractors need to start producing the good or service in quantity and to invest in large scale promotion activities; and 2. the potential first customers, public procurers, generally take time to prepare and launch a PPI after the PCP has been completed.

If the duration of the EU grant is longer than foreseen (i.e. if the action duration is extended), you must also extend the obligation on the commercial exploitation the framework agreement (via an amendment).

Article XX — Conflicts of interest

XX.1 The contractor shall take all measures necessary to prevent a situation arising where the impartial and objective implementation of the framework agreement or a specific contract is compromised for reasons involving economic interests, political or national affinity, family, personal life or any other shared interest.

XX.2 The contractor shall notify the lead procurer without delay of any situation constituting or likely to lead to a conflict of interest (including changes of ownership) and shall immediately take all steps necessary to rectify this situation.

The lead procurer may instruct the contractor to take specific measures to remedy the situation.

Article XX — Ethics and research integrity

XX.1 The contractor shall carry out the tasks assigned to it in the framework agreement and in the specific contracts in compliance with:

(a) ethical principles (including the highest standards of research integrity) and

(b) applicable international, EU and national law.

The contractor may not carry out activities that are prohibited in all EU Member States in a country outside the EU (where those activities are allowed).

The contractor may not carry out activities whose aim is to:

(a) carry out human cloning for reproductive purposes;

(b) modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads); or

(c) create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The contractor may not carry out activities that do not focus exclusively on civil applications.

The contractor shall respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[13].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;

[13] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that contractor must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — as much as possible and taking into account the legitimate interest of the contractor — access to research data, in order to enable research to be reproduced ;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid conflicts of interest and misrepresentation of credentials or other research misconduct.

XX.2 Before starting any activity that raises an ethical issue, the contractor shall submit to the lead procurer a copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

[OPTION if EU grant agreement contains ethics requirements that concern the PCP contracts: XX.3 In addition, the contractor shall comply with the following ethics requirements:

- [insert the ethics requirements from Annex I to the EU grant agreement].*]*

Article XX — Security related obligations

[OPTION if the contracts involve dual-use goods or dangerous materials or substances: XX.X Activities involving dual-use goods or dangerous materials and substances shall comply with applicable EU, national and international law.

Before starting the activity, the contractor shall provide the lead procurer with a copy of any export or transfer licences required.*]*

[OPTION if the EU grant agreement provides for a security classification that affects the PCP contracts: XX.X Classified information shall be treated in accordance with the security aspect letter (SAL) annexed to the EU grant agreement and EU Decision No 2015/544[14] until it is declassified.

[14] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information.

Tasks involving classified information may not be subcontracted without prior written approval from the lead procurer.

The contractor shall inform the lead procurer of any changes relating to security and, if necessary, request an amendment to the framework agreement.*]*

[OPTION if the EU grant agreement contains security recommendations restricting disclosure or dissemination that affect the PCP contracts: XX.X The following results may be disclosed or disseminated only if the contractors have first obtained written approval from the lead procurer:

- [insert the results subject to a security recommendation restricting disclosure or dissemination from Annex I to the EU grant agreement].*]*

[OPTION if the EU grant agreement contains other security recommendations that affect the PCP contracts: XX.X In addition, the contractor shall comply with the following security recommendations:

- [insert the security recommendations from Annex I to the EU grant agreement].*]*

Article XX — Processing of personal data

XX.1 The lead procurer and the buyers group shall process personal data in compliance with the applicable EU and national law on data protection.

XX.2 The contractor shall process personal data in compliance with the applicable EU and national law on data protection (including as relates to authorisations and notification requirements).

The contractor may grant its staff access to data only in so far as is strictly necessary for implementing, managing and monitoring the framework agreement and specific contracts.

The contractor must inform the staff whose personal data are collected and processed by the lead procurer, the buyers group and/or the EU. For this purpose, the contractor must provide them with the privacy statements of the lead procurer, the buyers group and the EU, before transmitting their data. If explicit prior consent from the subjects of the data is needed, the contractor must obtain such consent.

Article XX — Obligation to provide information and keep records

XX.1 The contractor must, at any time during the implementation of the framework agreement and specific contracts or afterwards, provide any information requested by the lead procurer or the buyers group in relation to the agreement or contracts.

XX.2 The contractor must keep, for a period of up to [insert number of years (minimum 5 years after the end of the EU grant agreement)] years after the end of the framework agreement, records and other supporting documentation relating to its implementation or the implementation of the specific contracts.

This obligation includes records and other supporting documentation on scientific and technical implementation (in line with the accepted standards in the field) and on the price charged and the costs incurred by the contractor.

The contractor must keep the original documents. Digital and digitalised documents are considered originals if they are authorised under national law.

Should there be ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims (including against the lead procurer or buyers group), the contractor must keep the records and other supporting documentation relating to the implementation of the framework agreement and specific contracts until the end of these procedures.

Article XX — EU checks, reviews, audits and investigations

Should the EU (including as represented by the European Court of Auditors or the European Anti-Fraud Office (OLAF)) decide to carry out a check, review, audit or investigation, the contractor must make available all information, records and other supporting documents relating to the implementation of the framework agreement and specific contracts.

Should there be an on-the-spot visit, the contractor must allow access to its premises and must ensure that the information requested is readily available.

Article XX — EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the lead procurer and buyers group), the contractor must make available all information, records and other supporting documents relating to the implementation of the framework agreement and specific contracts.

Article XX — Breach of contract

Set out the consequences in case of breach of contract (in line with the law applicable to the contract).

Don't forget provisions on partial/improper implementation of tasks and breach of other obligations.

Include a section on liability for damages:

XX.1 The contractor must compensate the lead procurer and the buyers group if they are held liable by the EU for damage it sustained as a result of the implementation of the framework agreement or a specific contract or because it was not implemented properly.

XX.2 The EU cannot be held liable for any damage caused to the contractor or caused by the contractor in connection with the implementation of the framework agreement or a specific contract.

Article XX — Amendments

Include a provision on amendments. Specify that they must be made in writing.

Include a clause that the amendment may not have the purpose or the effect of making changes to the contracts which might call into question the decision awarding the contracts or result in unequal treatment of tenderers.

Article XX — Interpretation

Include a provision specifying that the terms set out in the framework agreement have precedence over those in annexes and that the terms set out in Annex 1 (request for tenders) have precedence over those set out in Annex 2 (contractor's tender).

Specify that the same applies to the specific contracts.

Article XX — Applicable law and dispute settlement

Choose:

- *the law applicable to the framework agreement and to the specific contracts*
- *the dispute settlement mechanisms, in particular the competent court or other dispute settlement mechanisms (e.g. arbitration or mediation, if allowed under national law) and the deadlines to respect.*

Article XX — Entry into force

Define the entry into force *(e.g. upon signature of the last party)*

SIGNATURES

The lead procurer signs for the buyers group and — in case of joint tenders — the lead contractor for the group of contractors (see also section 4.1 of the request for tenders).

Annex 2

PCP Specific contract for phase *[*1*][*2*][*3*]*

Disclaimer: This annex is aimed at assisting H2020 PCP grant beneficiaries. It is provided for information purposes only and is not intended to replace consultation of professional legal advice. It can be used as a starting point to draw up the specific contracts, but beneficiaries remain responsible for adapting it to their situation and checking full compliance with the applicable law. Neither the European Commission nor its Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

Specific contracts must contain at least the following elements/provisions:

PREAMBLE

Similar set-up as the framework agreement: Lead procurer concludes and signs in in the name and on behalf of the members of the buyers group.

Annex the contractor's offer.

TERMS AND CONDITIONS

Article 1 — Subject of the contract

This specific contract defines the specific terms and conditions for the implementation of the PCP procurement of R&D services set out in Article XX — for the *[*1st*][*2rd*][*3rd*]* PCP phase.

Article XX — Duration

Specify the duration of the specific contract and starting and end date for the implementation of the tasks.

Specify that the period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

Article XX — R&D services to be provided

The contractor shall provide the R&D services (tasks, deliverables and milestones) set out in the offer for this phase.

Specify the scope of the specific contract (i.e. which phase and which lot, if any).

Specify the individuals in charge of carrying out the R&D activities for the specific contract and their location (country where they carry out the R&D activities).

Article XX — Price and payment arrangements

The price to be paid by *[*the lead procurer*][*the members of the buyers group*]* for the R&D services set out in Article XX shall be *[*EUR*][*other currency*]* [amount in figures and in words].

Specify the amounts of pre-instalments and interim payments (if applicable) and final payment in figures and words. In case of pro rata payments by the different members of the buyers group split the amount pro rata per member of the buyers group according to their contribution to the total PCP subcontracting cost (with and without VAT).

Specify which invoice for which payment x the contractor has to send to whom (to the lead procurer or to the individual members of the buyers group) after approval of deliverable x. Specify how many days after receipt of the invoice (the lead procurer or to the individual members of the buyers group) will make the payment(s) to the contractor.

Specify the contractor's bank account details and the currency in which payments will be made.

Article XX — Security related obligations

Add a provision on security if specifically needed for the phase and not already covered by the provision in the framework agreement.

Article XX — Entry into force

Specify the entry into force date.

SIGNATURES

Same as for framework agreement: The lead procurer signs for the buyers group and — in case of joint tenders — the lead contractor for the group of contractors.

HISTORY OF CHANGES		
VERSION	PUBLICATION DATE	CHANGE
1.0	09.03.2016	Initial version

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 1.1
1 July 2016

History of changes

Version	Date	Change	Page
1.0	30.10.2015	▪ Initial version	
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia	3, 5

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as *basic remuneration* if: – it is paid in accordance with the applicable national law; and – recipients and individual amounts are determined on the basis of objective criteria established and documented at least in the internal regulations of the beneficiary; and – the event triggering the bonus is NOT the participation in the H2020 action (otherwise the bonus would be *additional remuneration*); and – there is no bias in the award of the bonus resulting in a systemic overcharging of EU actions compared with non EU-actions.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	
Bonuses	Prime de responsabilités pédagogiques	

Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May **NOT** be declared as personnel costs. However, they may be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests. If the contract remunerates also other activities on top of the work in the H2020 action (i.e. it is not exclusive for the H2020 action), the beneficiary cannot charge any part of that contract as *direct cost* unless: – the contract fixes a specific amount to be paid for the work in the H2020 action, or – there is other direct measurement of the cost corresponding to the work in the H2020 action (example: the contract sets a price of 100 € per test and 50 tests have been done for the H2020 action). Otherwise that contract would be considered indirect cost (covered by the 25 % flat-rate).
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost

Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **additional remuneration** under H2020. As such it is subject to the specific eligibility conditions applicable to additional remuneration.
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as *basic remuneration* if: – it is paid in accordance with the applicable national law; and – recipients and individual amounts are determined on the basis of objective criteria established and documented at least in the internal regulations of the beneficiary; and – the event triggering the bonus is NOT the participation in the H2020 action (otherwise the bonus would be *additional remuneration*); and – there is no bias in the award of the bonus resulting in a systemic overcharging of EU actions compared with non EU-actions.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May **NOT** be declared as personnel costs. However, they may be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests. If the contract remunerates also other activities on top of the work in the H2020 action (i.e. it is not exclusive for the H2020 action), the beneficiary cannot charge any part of that

		contract as *direct cost* unless: – the contract fixes a specific amount to be paid for the work in the H2020 action, or – there is other direct measurement of the cost corresponding to the work in the H2020 action (example: the contract sets a price of 100 € per test and 50 tests have been done for the H2020 action). Otherwise that contract would be considered indirect cost (covered by the 25 % flat-rate).
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	**Qualify as basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 1.2
25 November 2016

HISTORY OF CHANGES			
Version	**Publication Date**	**Change**	**Page**
1.0	30.10.2015	▪ Initial version	
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia	
1.2	25.11.2016	▪ Update of the explanations for The Netherlands	5

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as *basic remuneration* if: – it is paid in accordance with the applicable national law; and – recipients and individual amounts are determined on the basis of objective criteria established and documented at least in the internal regulations of the beneficiary; and – the event triggering the bonus is NOT the participation in the H2020 action (otherwise the bonus would be *additional remuneration*); and – there is no bias in the award of the bonus resulting in a systemic overcharging of EU actions compared with non EU-actions.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	
Bonuses	Prime de responsabilités pédagogiques	

Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May **NOT** be declared as personnel costs. However, they may be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests. If the contract remunerates also other activities on top of the work in the H2020 action (i.e. it is not exclusive for the H2020 action), the beneficiary cannot charge any part of that contract as *direct cost* unless: – the contract fixes a specific amount to be paid for the work in the H2020 action, or – there is other direct measurement of the cost corresponding to the work in the H2020 action (example: the contract sets a price of 100 € per test and 50 tests have been done for the H2020 action). Otherwise that contract would be considered indirect cost (covered by the 25 % flat-rate).
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost

Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **additional remuneration** under H2020. As such it is subject to the specific eligibility conditions applicable to additional remuneration.
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 1.4
26 October 2017

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	
Bonuses	Prime de responsabilités	

	pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered

		by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if:

		– this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 1.3
21 April 2017

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	
Bonuses	Prime de responsabilités	

	pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost

Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).

European Commission

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 1.5
28 June 2018

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK
1.5	28.06.2018	▪ Update of the explanations for France

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	

Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Taxes	Crédit Impôt Recherche (CIR)	It is **not** a receipt of the action
Italy		
Workforce	Contratto a progetto	May be declared as personnel costs if they fulfil

contracts	(co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary

	amount is set up in the functional salary or the personal salary	entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 1.6
26 June 2019

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK
1.5	28.06.2018	▪ Update of the explanations for France
1.6	26.06.2019	▪ Update of the explanations for France and Spain

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	

Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Salaries	Indemnité de départ à la retraite	Eligible within the limits set by law or mandatory collective agreement
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Taxes	Crédit Impôt Recherche (CIR)	It is **not** a receipt of the action

Taxes	Contribution à l'Agefiph due à l'obligation d'emploi des travailleurs handicapés	It is an **ineligible** cost
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is

		eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
Spain		
Contributions	Bonificación Seguridad Social del personal investigador (Real Decreto 475/2015)	The *bonificación* is an **ineligible** cost
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 2.0
07 January 2020

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK
1.5	28.06.2018	▪ Update of the explanations for France
1.6	26.06.2019	▪ Update of the explanations for France and Spain
2.0	07.01.2020	▪ Update to VM4.0

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	

Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Salaries	Indemnité de départ à la retraite	Eligible within the limits set by law or mandatory collective agreement
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Taxes	Crédit Impôt Recherche (CIR)	It is **not** a receipt of the action

Taxes	Contribution à l'Agefiph due à l'obligation d'emploi des travailleurs handicapés	It is an **ineligible** cost
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is

		eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
Spain		
Contributions	Bonificación Seguridad Social del personal investigador (Real Decreto 475/2015)	The *bonificación* is an **ineligible** cost
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 2.2
21 June 2021

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK
1.5	28.06.2018	▪ Update of the explanations for France
1.6	26.06.2019	▪ Update of the explanations for France and Spain
2.0	07.01.2020	▪ Update to VM4.0
2.1	26.05.2020	▪ Update of the explanations for Hungary
2.2	21.06.2021	▪ Update of the explanations for Hungary

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	

Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Salaries	Indemnité de départ à la retraite	Eligible within the limits set by law or mandatory collective agreement
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Taxes	Crédit Impôt Recherche (CIR)	It is **not** a receipt of the action

Taxes	Contribution à l'Agefiph due à l'obligation d'emploi des travailleurs handicapés	It is an **ineligible** cost
Hungary		
Taxes	Act CLV/2011 concerning contributions to vocational training and training support	Costs up to the amount foreseen in the national legislation are **eligible** cost
Taxes	KATA	Mandatory KATA that the beneficiary paid for staff fulfilling the conditions of article 6.2.A.2 can be included in the calculation of their hourly rates.
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		

Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
Spain		
Contributions	Bonificación Seguridad Social del personal investigador (Real Decreto 475/2015)	The *bonificación* is an **ineligible** cost
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working

		time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on

List of issues applicable to particular countries

Version 2.1
26 May 2020

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
1.3	21.04.2017	▪ Update of the explanation for France, Italy and Slovenia
1.4	26.10.2017	▪ Update of the explanations for France and UK
1.5	28.06.2018	▪ Update of the explanations for France
1.6	26.06.2019	▪ Update of the explanations for France and Spain
2.0	07.01.2020	▪ Update to VM4.0
2.1	26.05.2020	▪ Update of the explanations for Hungary

List of issues applicable to particular countries

Category	Issue	Reply
Belgium		
Taxes	Exonération partielle du précompte professionnel des chercheurs Gedeeltelijke vrijstelling van bedrijfsvoorheffing voor onderzoekers	This is an **eligible** cost provided that: – it is reinvested in research; and – it is not used to reduce the costs of the project.
Czech Republic		
Bonuses	Bonuses included in the salary statement	Bonuses whose amount is set up in the salary statement, and thereby become an unconditional salary entitlement for the employee, can be considered as mandatory complements to the basic salary and **qualify as basic remuneration** under H2020.
France		
Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	

Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Salaries	Indemnité de départ à la retraite	Eligible within the limits set by law or mandatory collective agreement
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
Taxes	Taxe sur les salaires	It is an **eligible** cost
Taxes	Versement transport	It is an **eligible** cost
Taxes	Participation des employeurs à l'effort de construction	It is an **ineligible** cost
Taxes	Crédit Impôt Recherche (CIR)	It is **not** a receipt of the action

Taxes	Contribution à l'Agefiph due à l'obligation d'emploi des travailleurs handicapés	It is an **ineligible** cost
Hungary		
Taxes	Act CLV/2011 concerning contributions to vocational training and training support	Costs up to the amount foreseen in the national legislation are **eligible** cost
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive (IRAP)	IRAP is an **ineligible** cost
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have

		to be deducted from the eligible costs claimed by the beneficiary.
Portugal		
Taxes	Tributação autónoma (TA)	This is an eligible cost, provided that: – the cost to which the TA is applied is eligible, – the tax is non-deductible for the beneficiary.
Slovakia		
Bonuses	The personal complement whose amount is set up in the functional salary or the personal salary	Qualifies as **basic remuneration** under H2020 provided that they are unconditional salary entitlements for the employee.
Slovenia		
Bonuses	Work performance resulting from increased workload due to special projects	Qualifies as **basic remuneration** if it is paid in accordance with the Public Sector Salary System Act and the level of remuneration is not higher than the level of remuneration paid in projects funded by national schemes. If it is higher, the excess qualifies as **additional remuneration**.
Spain		
Contributions	Bonificación Seguridad Social del personal investigador (Real Decreto 475/2015)	The *bonificación* is an **ineligible** cost
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and – the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance on
List of issues applicable to particular countries

Version 2.3
30 July 2021

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	30.10.2015	▪ Initial version
1.1	01.07.2016	▪ Update of the explanations for France and Slovenia
1.2	25.11.2016	▪ Update of the explanations for The Netherlands
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List of issues applicable to particular countries

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Bonuses	Prime de recherche	Qualifies as part of the *basic remuneration* if the bonus is paid to the employee regardless if he/she is involved or not in specific projects.
Bonuses	Indemnité spécifique pour fonctions d'intérêt collectif	
Bonuses	Prime de participation à la recherche scientifique	
Bonuses	Prime d'encadrement doctoral et de recherche	
Bonuses	Prime de recherche et d'enseignement supérieur	
Bonuses	Prime d'enseignement supérieur	
Bonuses	Prime informatique	
Bonuses	Indemnité de résidence	
Bonuses	Supplément familial de traitement	
Bonuses	Prime de charges administratives	

Bonuses	Prime de responsabilités pédagogiques	
Bonuses	Indemnité d'administration et de technicité	
Bonuses	Indemnités forfaitaires pour travaux supplémentaires	
Bonuses	Prime de fonctions et de résultats	
Bonuses	Intéressement des salariés	
Salaries	Participation des salariés aux résultats de l'entreprise	It is an **eligible** cost
Salaries	Allocation d'assurance pour les travailleurs involontairement privés d'emploi (also known as Provision Perte Emploi, Allocation Retour à l'Emploi or Allocation Perte d'Emploi).	When employers have entrusted the management of the insurance benefit to an external entity (i.e. pole emploi), eligibility is limited to the proportion of payments actually made to this entity during a given year. When employers manage themselves the insurance benefit, eligibility is limited to the proportion of payments actually made during a given year.
Salaries	Indemnité de départ à la retraite	Eligible within the limits set by law or mandatory collective agreement
Contributions	Contribution au fonds national d'aide au logement (Fnal)	It is an **eligible** cost
Taxes	Taxe d'apprentissage	It is an **eligible** cost
Taxes	Participation à la formation professionnelle continue	It is an **eligible** cost
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Taxes	Versement transport	It is an **eligible** cost
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Taxes	Crédit Impôt Recherche (CIR)	It is **not** a receipt of the action

Taxes	Contribution à l'Agefiph due à l'obligation d'emploi des travailleurs handicapés	It is an **ineligible** cost
Hungary		
Taxes	Act CLV/2011 concerning contributions to vocational training and training support	Costs up to the amount foreseen in the national legislation are **eligible** cost
Taxes	KATA	Mandatory KATA that the beneficiary paid for staff fulfilling the conditions of article 6.2.A.2 can be included in the calculation of their hourly rates.
Taxes	KIVA	The part of the KIVA that is calculated on the personnel costs is an eligible item than can be included in the calculation of the hourly rates.
Italy		
Workforce contracts	Contratto a progetto (co.co.pro.) Contratto di collaborazione coordinata e continuativa (co.co.co.) Assegni di Ricerca	May be declared as personnel costs if they fulfil the conditions of article 6.2.A.2, in particular that the person factually works under conditions similar to those of an employee. If the costs are eligible as personnel costs, the time worked for the H2020 action must be supported by relevant supporting documents (see Article 18.1.2). If they do not fulfil the conditions, the costs may still be eligible as: – Subcontracting: if the activities covered by the contract are part of the tasks of the action detailed in Annex 1 (e.g.: the contract is to produce deliverable X, to work on work package Z, to carry out research work for the H2020 action) – Purchase of services: if the activities covered by the contract are not part of the tasks of the action. In both cases the award of the contract must fulfil the specific eligibility conditions (Article 10 or Article 13), including that the contract must be awarded ensuring best value for money and no conflict of interests.
Taxes	Imposta regionale sulle attività produttive	IRAP is an **ineligible** cost

	(IRAP)	
Netherlands		
Taxes	WBSO: fiscale regeling voor research en development	The tax credit has no impact on the eligibility of the personnel costs triggering it. The rebate on wage tax and social security contributions under this scheme does not have to be deducted from the eligible costs claimed by the beneficiary.
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Spain		
Contributions	Bonificación Seguridad Social del personal investigador (Real Decreto 475/2015)	The *bonificación* is an **ineligible** cost
United Kingdom		
Productive hours	Transparent Approach to Costing (TRAC)	The annual productive hours established by TRAC (e.g. 1650) may be used as the standard productive hours for the purpose of calculating the hourly rates (option 3 'standard annual productive hours') if: – this is the usual cost accounting practice of the beneficiary; and

		– the TRAC number is at least 90 % of the standard annual workable hours of the beneficiary (based on the national working time legislation, the applicable collective labour agreement or the employment contracts).
Taxes	Apprenticeship Levy	It is an **eligible** cost

EUROPEAN
COMMISSION

Brussels, 25.11.2016
C(2016) 7553 final

COMMISSION DECISION

of 25.11.2016

modifying the Commission decision of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme

COMMISSION DECISION

of 25.11.2016

modifying the Commission decision of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)[1], and in particular Article 10 thereof,

Having regard to Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020)[2], and in particular Articles 25 and 33 thereof,

Having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[3], and in particular Article 124 thereof,

Whereas:

(1) On 7 March 2014 the Commission adopted a decision authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme,

(2) This Commission decision gives the beneficiaries the opportunity to declare their costs following either an actual cost system or the unit cost system described therein,

(3) Since the adoption of the Commission Decision, the applicants and beneficiaries concerned have raised concerns related to its practical implementation,

(4) The main obstacle identified concerns the obligation to apply either the unit cost method or the actual costs method for all categories of costs without any flexibility,

(5) A modification of the conditions set out in the Annex to the Commission decision is needed to introduce such flexibility,

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[1] OJ L 347, 20.12.2013, p. 104
[2] OJ L 347, 20.12.2013, p. 81
[3] OJ L 298, 26.10.2012, p.1

HAS DECIDED AS FOLLOWS:

Sole Article

The Annex of Commission decision C(2014) 1393 of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme is replaced by the Annex to this decision.

Done at Brussels, 25.11.2016

For the Commission
Carlos MOEDAS
Member of the Commission

EN

ANNEX

1. Form of costs and categories of costs covered

A 'clinical study' is defined for the purpose of this decision as any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients or study participants. It includes but is not limited to clinical studies and clinical trials in the sense of the Clinical Trials Regulation EU No 536/2014 and, in so far as it remains applicable, the Clinical Trials Directive 2001/20/EC.

Beneficiaries of grants under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme may determine the costs of clinical studies according to the following forms:

(i) Unit costs per patient or study participant calculated on the basis of their historical data, or

(ii) Cost actually incurred.

A grant may involve the conduct of several clinical studies, and each clinical study may be conducted by several entities. Hence, the grant agreement may foresee different forms for the costs of clinical studies per beneficiary or third party, under the following conditions:

- For the costs of personnel directly assigned to the conduct of clinical studies, each beneficiary or third party may only choose one of the forms (i) or (ii) .

NB This decision does not apply to personnel costs for horizontal tasks carried out by beneficiaries or third parties participating in the clinical study, such as study monitoring or study coordination tasks (these tasks are covered by provisions of the Grant Agreement).

- For categories (b) to (d) of direct eligible costs referred to in Part 2, beneficiaries and third parties may choose either of the forms (i) or (ii) for each cost item.

Unit costs per patient or participant will be specific to each beneficiary or third party and in each case only represent a proxy of their specific categories of costs (a) to (d) referred to in Part 2 below.

The unit costs shall be specified in the grant agreement to be used throughout the duration of the action. The proposal as well as the grant agreement should also specify the costs of the clinical study that will be determined as actual costs.

Costs of clinical studies declared by beneficiaries on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in Annex 2 to the grant agreement multiplied by the number of actual units (patients or study participants) included in the clinical studies conducted under the action.

Third parties may contribute in kind to the action by making data obtained from patients or study participants enrolled in the clinical studies available to a beneficiary or linked third party. The related costs shall also take one of the forms referred to in points (i) and (ii) for the purpose of determining:

- the maximum amount of the eligible costs that the beneficiaries may declare, if the data are contributed against payment,
- the eligible costs that the beneficiaries may declare, if the data are contributed free of charge.

The categories of eligible costs covered by the unit costs referred to in point (i) are defined below:

- Direct costs of clinical studies:

(a) Personnel costs of doctors and other medical personnel and technical personnel (including data managers) directly assigned to the conduct of the clinical study;

(b) Costs of consumables specifically used for the conduct of the clinical study;

(c) Costs of the medical equipment specifically used for the conduct of the clinical study, corresponding to:

- the depreciation costs
- the other costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair);

(d) Costs of other specific service contracts necessary for the conduct of the clinical study (including data analysis, if subcontracted);

- Indirect costs of the clinical study

The categories of eligible costs covered by the unit costs exclude the travel and subsistence costs of patients or study participants. Those costs will be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs".

Other categories of eligible costs not covered by the present decision shall be reimbursed on the basis of:
-eligible costs actually incurred or,
-for other direct personnel costs, on the basis of other unit costs or,
-for other indirect costs, flat-rate financing.

2. Method to determine the unit costs

The amounts of the unit costs per patient or study participant are determined *as the sum of the amounts of the unit cost components defined in points (a) to (e) below*, corresponding to the categories of eligible costs defined in Part 1, for each beneficiary or third party identified in the grant agreement and each clinical study.

Each beneficiary or third party shall determine the direct costs by reference to their historical costs and the estimated resources consumed per task and per patient or participant.

The beneficiary and the third party shall use as historical costs the costs recorded in their certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant proposal).

The estimation of resources at the time of submission of the grant proposal shall be based on the applicable protocol for the clinical study and must be the same for all members of the consortium involved in one clinical study.
Those resources shall be indicated in the grant proposal and will be assessed by the experts evaluating the proposals.

The choice of form of costs (unit costs or actual costs per cost category or sub-category) has to be made at the time of the proposal submission. The resulting unit costs shall also be included in the grant proposal and in the Annex 2 to the grant agreement. However, the unit cost can be modified through an amendment to the grant agreement in the following cases:

- if there is a change in the protocol (e.g. due to requests from competent authorities, regulatory agencies or ethics committees) during the implementation of the action which results in a change of the estimation of resources needed to calculate the unit costs. In such a case, the Commission may ask the advice of independent experts for the assessment of the necessity of the resources.

- if an error occurred in the identification of costs recorded in the beneficiary's certified or auditable accounts for year N-1 (last closed financial year at the time of submission of the proposal) or wrong application of points (a) to (d) below.

Under no circumstances may such modifications result in a substantial change to the grant proposal or in an increase of the maximum amount of the grant specified in the grant agreement.

In case of any amendment the historical costs shall still be the costs recorded in the certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the proposal) of the concerned beneficiary or the third party

The Commission has the right to verify that these costs comply with the requirements defined in points (a) to (d) below and to correct the unit costs in case of non-compliance.

(a) Personnel costs of medical and technical personnel directly assigned to the conduct of the clinical study

The amount of the unit cost component ‘personnel costs’ is determined for each task described in the protocol as follows:

*{Average hourly cost for **Doctors** X Estimated number of hours worked by doctors for each task described in the protocol and for each patient or study participant*

+ Average hourly cost for ***Other medical personnel*** *X Estimated number of hours worked by other medical personnel for each task described in the protocol and for each patient or study participant*

+ Average hourly cost for ***Technical personnel*** *X Estimated number of hours worked by technical personnel for each task described in the protocol and for each patient or study participant}*

with

Average hourly cost for Doctors *= Certified or auditable total personnel costs for Doctors for year N-1 / {1720 X number of full-time equivalent for the personnel category Doctors for year N-1}*

Average hourly cost for Other medical personnel *= Certified or auditable total personnel costs for other medical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Other medical personnel for year N-1}*

Average hourly cost for Technical personnel *= Certified or auditable total personnel costs for technical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Technical personnel for year N-1}*

and

Total personnel costs *= Actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act (see conditions set out in Article 6.2.A.1 of the model Horizon 2020 grant agreement).*

The use of hourly costs determined according to another methodology, including according to the beneficiary's or third party's usual cost accounting practices, is not allowed.

(b) Costs of consumables specifically used for the conduct of the clinical study

The amount of the unit cost component 'costs of consumables' is determined for each task described in the protocol as follows:

{Average price per item for the first category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ Average price per item for the second category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ Average price per item for the third category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ idem for each category of consumables specifically used in the clinical study}

with

Average price per item for a category of consumables used in the clinical study *= Certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned / Total number of items purchased in year N-1 for the category of consumables concerned*

and

Total costs of purchase of the consumables *= Total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary or third party for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

(c) Costs of the medical equipment specifically used for the conduct of the clinical study

The amount of the unit cost component 'costs of medical equipment' is determined for each task described in the protocol as follows:

{Average cost of depreciation and of directly related services for the first category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ Average cost of depreciation and of directly related services for the second category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ Average cost of depreciation and of directly related services for the third category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ idem for each category of equipment specifically used in the clinical study}

with

Average cost of depreciation and directly related services per unit of use *= {Certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + Certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned} / Total capacity in year N-1*

and

Total depreciation costs *= Total depreciation allowances as recorded in the beneficiary's or third party's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + Total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees (see conditions set out in Article 6.2.D.2 of the model Horizon 2020 grant agreement).*

Total costs of purchase of services *= Total value of the contracts concluded by the beneficiary or third party (including related duties, taxes and charges such as non-deductible VAT) for services delivered in year N-1 for the functioning of the equipment, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

Total capacity *= Total time of use of the equipment expressed in hours, days or months and supported by evidence or the number of accesses to the equipment, for which supporting evidence may take the form of records or electronic log of units-of-access provision.*

The total capacity must take due account of real constraints (e.g. opening hours), but must reflect the equipment full capacity and include any time during which the equipment is usable but not used or any unit of access available but not used.

(d) Costs of other specific contracts necessary for the conduct of the clinical study

The amount of the unit cost component 'costs of other specific contracts' is determined for each task described in the protocol as follows:

{Average cost of the first specific service necessary for the conduct of the clinical study per patient or study participant

+ Average cost of the second specific service necessary for the conduct of the clinical study per patient or study participant

+ Average cost of the third specific service necessary for the conduct of the clinical study per patient or study participant

+ idem for each specific service necessary for the conduct of the clinical study}

with

Average cost of a specific service per patient or study participant *= Certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies / Total number of patients or participants included in the clinical studies for which the specific service was delivered in year N-1*

and

Total costs of purchase of a service *= Total value of the contracts concluded by the beneficiary or third party (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

(e) Indirect costs

The amount of the unit cost component 'indirect costs' is determined for each task described in the protocol by applying a flat rate of 25% of the sum of the unit cost components referred to in points (a), (b) and (c) above (excluding the unit cost component referred to in point (d) above and the costs of resources made available by third parties which are not used on the premises of the beneficiary, as well as financial support to third parties, as set out in Article 29(1) of Regulation (EU) No 1290/2013).

3. Justification

3.1. Nature of the supported actions

Clinical studies are the essential link in the translation of new knowledge generated by basic research into new health products, services and interventions. Without clinical studies, the validity of these products, services and interventions cannot be tested and proven, to the disadvantage of patients, citizens and the competitiveness of the European health sector.

Over the course of 7th Framework Programme for Research and Development (FP7) approximately one fifth of all projects in the 'Health' theme included clinical studies, with a significant rise in number in the last years of FP7 implementation. As Horizon 2020 gives greater emphasis to innovation than previous programmes, the percentage of funding allocated to clinical studies is likely to increase.

(a) Problems related to the determination of actual costs of clinical studies

The precise quantification of costs resulting from clinical studies is difficult. Clinical studies consist of a large number and variety of different elements, such as repeat hospitalisations or outpatient clinic visits (themselves including a number of elements ranging from receptionist's time to meals and laundry), a variety of individual doctors', nurses' and technicians' time, study drugs and auxiliary drugs as well as laboratory and imaging tests. These costs are incurred in the health and care settings (hospitals, clinics, etc.) which are at the present time relatively inexperienced beneficiaries of Framework Programmes and the accounting systems of which are frequently not equipped to track these costs.

The problem for beneficiaries required to follow the H2020 rules regarding actual costs is in proving the allocation of actual resources needed to perform clinical studies. Such proof would be both time consuming and in some cases not possible due to the unsuitability of beneficiaries' accounting systems and management practices.

(b) Alternatives and consultation of stakeholders

In industry- or academically-funded clinical studies, hospitals are typically therefore reimbursed a lump sum per patient, calculated on the basis of a rough estimation of the actual costs. In large industrial trials this amount often includes a profit margin for the hospital or the participating doctors, whereas in academically-funded clinical studies, this amount usually does not cover the full costs and requires additional subsidy.

A number of stakeholders have called upon the Commission to adopt a similar approach for EU-funded clinical studies:
- A June 2012 note of the League of European Research Universities (LERU)1 requests among other changes trial-specific "flat rates per patient";
- A September 2013 workshop with representatives of three major German University Hospitals, the German National Contact Point and Clinical Research Organisations confirmed the urgent need to simplify the funding rules for clinical studies and welcomed the idea presented by the Commission (outlining the option in this Commission decision) as potential solution;
- The Commission also presented different options to the group of national experts at its meeting of 11 October 2013. Representatives of Member States also recognised the urgent need to simplify the accounting for clinical studies. The feedback received from most of the experts participating in this group is positive in respect to the option of declaring a 'unit cost per patient or participant involved in the study' as described in this decision;
- Numerous individual requests and meetings with project coordinators and hospital participants in FP7 projects have raised similar issues and potential solutions, which are the basis of the option proposed in this decision.

(c) Impact on grant management

Using unit costs considerably simplifies, streamlines and reduces the time needed for the financial management of projects, both at the Commission and beneficiary levels. A unit-cost system substantially decreases the number of recovery orders and de-commitments. It also significantly decreases the workload of the Commission or Agency when analysing cost statements and consequently speeds up the payment procedure. Furthermore, it implies additional simplifications at beneficiary level in terms of reporting requirements.

In summary, this approach provides simplification through:
- less complex funding rules contributing to easier understanding of actions;
- greater predictability for beneficiaries making their participation in the corresponding actions more attractive;
- less administrative burden for checking at the payment stage, reducing costs for the contracting authority and facilitating productivity gains;
- simplified reporting requirements (no certification of financial statement to be provided by beneficiaries for those costs);
- easier ex-post analysis and further reductions of the risk of error.

The use of unit costs is justified by the difficulty in determining the allocation of resources and is considered as an appropriate form of financing in order to simplify the administrative burden and financing conditions of supported actions. A unit-cost approach provides the opportunity to emphasise the quality of results. Moreover, the use of unit costs represents a further simplification for applicants ensuring certainty and transparency of funding levels.

3.2. Risks of irregularities and fraud and costs of control

The Financial Regulation (FR2) requires that the DGs and Agencies establish anti-fraud measures in their individual Internal Control Systems. In June 2011, the Commission adopted its first Anti–Fraud Strategy (CAFS) in which it requested the Commission Services to set up or update their sectorial Anti-Fraud Strategies. For the area of research the Anti-Fraud Strategy (RAFS) was adopted in December 2012. The RAFS builds strongly on and complements the CAFS by demonstrating how elements of the corporate strategy are addressed in the area of research. The sectorial strategy outlines some key principles of combating fraud, with a special focus on challenges which are common to the services of the research family and coordination mechanisms, which should ensure that strategic priorities are implemented in a most effective and coherent manner throughout the whole family.

The unit costs system is much simpler compared with the actual costs systems regarding the declaration of costs. As a consequence, the intrinsic risk on legality and regularity errors in cost claims leading to unjustified EU funding is very low and therefore the control and audit mechanism is lighter and less costly than in a system based on actual costs.

Reporting and control for clinical studies will focus on the realisation of the supported activity and the achieved results rather than on the resources allocated to the project, reducing the workload and scope for error of both participants and the Commission or Agency. The monitoring system will be set up in a manner ensuring efficiency and cost-effectiveness of the controls.

In fact, the unit costs will be subject to subsequent verification and audit to determine only the following:
- whether the number of patients or participants declared by the beneficiary corresponds to the number of patients or participants actually participating in the study, and
- whether the beneficiary has used the accounting data referred to in Part 2 for the determination of the unit costs set out in Annex 2 to the grant agreement.

However, the Commission will neither control the allocation of resources already agreed at the time of signature of the grant agreement nor the actual costs for the categories of eligible costs referred to in Part 1.

These controls will help the prevention of fraud while being simple and comprehensible both for the Commission or Agency and for the beneficiaries.

4. No-profit and co-financing principles and absence of double financing

The methodology for determining the unit cost per patient or participant included in the study described in Part 2 ensures respect for the no-profit and co-financing requirements and the absence of double financing of costs.

The clinical study is not expected to generate revenue or to be specifically funded by third donors. The unit cost per patient or participant set out in the grant agreement will not exceed the actual eligible costs as the calculation of the direct cost components will be based on

certified or auditable costs of a study which costs are recorded in the last closed accounts of the beneficiary. Furthermore, the funding for indirect costs is limited to 25% of the total direct eligible costs, excluding direct eligible costs for subcontracting. Therefore, the profit is a priori excluded and the remaining indirect costs are financed by the beneficiaries.

The reimbursement rate set out in the grant agreement will apply to the costs of clinical studies declared on the basis of unit costs.

The Commission avoids double funding by making checks at the time of evaluation and finalisation of the grant agreement that the costs falling under the categories covered by the unit costs, as referred to in Part 1, are not indicated in another budget category. A clear description of the activities covered by the unit cost will be included in the proposal and in the Technical Annex to the grant agreement, which will enable the Commission or Agency to reconcile the estimated eligible costs with the activities to be carried out. Similar checks will be performed during and after implementation of the grant agreement.

Funding based on unit costs encourages the recipient to use resources in an economical manner, given that the grant agreement is based on pre-established rates - without further adjustment of the amount of the grant based on the actual expenditure.

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Guidance

How to complete your simap forms for PCPs

Version 1.0

9 March 2016

Disclaimer

This document is aimed at assisting H2020 PCP grant beneficiaries. It is provided for information purposes only and is not intended to replace consultation of professional legal advice. Neither the Commission nor its Agencies (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

IMPORTANT NOTICE

This document is designed to help **Horizon 2020 beneficiaries** that implement pre–commercial procurement (PCP) grants (or beneficiaries of normal H2020 grants with PCP) to fill out the simap standard forms for public procurement for the following types of document: prior information notices (PINs) for the open market consultation, contract notices and contract award notices (to be published in the Official Journal via the TED — tenders electronic daily website).

Our approach

It provides **instructions** and **standard text** to be used.

Instructions are in blue.

Recommended text is in black.

Data to be added is shown in [grey in square brackets].

Options are shown in *[italics square brackets]*.

Other information

For a more general overview of how Horizon 2020 grants work, see the Online Manual. For detailed information, see the H2020 AGA — Annotated Grant Agreement.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the Participant Portal reference documents page.

Horizon 2020 terms are explained in the Participant Portal Glossary.

In case of doubt, please consult professional legal advice or contact the Horizon 2020 Helpdesk.

Simap acronym comes from the information system for public procurement (fr. système d'information pour les marchés publics).

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	09.03.2016	▪ Initial version

PCP PRIOR INFORMATION NOTICE (PIN) FOR THE OPEN MARKET CONSULTATION

Use the English version of the simap standard form that is most appropriate for your type of organisation:

- **for lead procurers in the public sector: 'Prior information notice'**
- **for lead procurers in the utilities sector: 'Periodic indicative notice — utilities'.**
- **for lead procurers in the defence and security sector: 'Prior information notice for contracts in the field of defence and security'**

In addition to English, you may publish the PIN (or a summary) in any other language(s).

⚠ **Do not forget that a copy of the PIN must be submitted as a deliverable to the Commission or the agency acting on its behalf at the latest five days before publication (i.e. five days before the date of dispatch of the PIN notice — *see Article 19 H2020 PCP-PPI MGA*).**

European Union

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Prior information notice

Directive 2004/18/EC

For lead procurers in the utilities sector the header contains additional information. Select 'no' (for both questions, i.e. no call for competition and no reduction of the time limits for tenders).

Section I: Contracting authority

I.1) Name, addresses and contact point(s)

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address(es): *(if applicable)* General address of the contracting authority: *(URL)* Address of the buyer profile: *(URL)*		
Further information can be obtained from ◯ The above mentioned contact point(s)	◯ Other (*please complete Annex A.I*)	

In the contact points section, give the contact details of the lead procurer.

In the internet addresses section, give the project website if you do not want to use the general website of the lead procurer. Use the address of the lead procurer's buyer profile.

I.2) Type of the contracting authority

◯ Ministry or any other national or federal authority, including their regional or local sub-divisions ◯ National or federal agency/office ◯ Regional or local authority ◯ Regional or local agency/office	◯ Body governed by public law ◯ European institution/agency or international organisation ◯ Other: *(please specify)*

This section is to be filled in ONLY if the lead procurer is a contracting authority (i.e. NOT a contracting entity).

I.3 Main activity

☐ General public services ☐ Defence ☐ Public order and safety ☐ Environment ☐ Economic and financial affairs ☐ Health	☐ Housing and community amenities ☐ Social protection ☐ Recreation, culture and religion ☐ Education ☐ Other: *(please specify)*

Select the lead procurer's main activities.

I.4) Contract award on behalf of other contracting authorities

The contracting authority is purchasing on behalf of other contracting authorities: ◯ yes ◯ no *(if yes, information on those contracting authorities can be provided in Annex A)*

Select 'yes'.

The contact details of all members of the buyers group must be given in Annex A.I) 'Address of the other contracting authority on behalf of which the contracting authority is purchasing'.

Section II.B: Object of the contract – Supplies or services

Complete subsection II.B for services (not II.A for works; PCP is a procurement of R&D *services*).

II.1) Title attributed to the contract by the contracting authority:

Use this title: 'Pre–commercial procurement (PCP) to buy R&D (research and development) services to [specify in a few words the subject and scope of this PCP *e.g. improving the energy efficiency of buildings*]'.

Use this text:

This PIN announces an open market consultation and provides information at an early stage on the expected starting date and purchase volume for the [insert project acronym] pre-commercial procurement (PCP) which:

- targets the following challenge: [insert challenge]

and

- looks for the following types of solutions: [insert types of solutions].

II.2) Type of contract and place of delivery or of performance *choose one category only – supplies or services – which corresponds most to the specific object of your contract or purchase(s)*	
◯ Supplies	◯ Services Service category No: [ ][ ] *(Please see Annex C1 for service categories)*
Main place of performance or of delivery:	
NUTS code [ ][ ][ ][ ][ ] NUTS code [ ][ ][ ][ ][ ]	NUTS code [ ][ ][ ][ ][ ] NUTS code [ ][ ][ ][ ][ ]

Select 'Services' (not 'Supplies; PCP is an R&D *services* contract).

For lead procurers in the public or utilities sector: use 'research and development services' category 8.

For lead procurers in the defence and security sector: use 'research and development services' category 14.

Do NOT fill out the other fields (main site or location of delivery/performance, NUTS code).

⚠ Do not choose any other category and make sure that your procurement complies with the category 8/14 — otherwise your procurement will not be exempted from the EU procurement directives.

II.3) Information on framework agreement The notice involves the establishment of a framework agreement: ◯ yes ◯ no

Select 'yes'.

For lead procurers in the public or utilities sector, this information has to be given in Section II.4. 'Short description of the contract/nature and quantity or value of supplies or services'.

II.4) Short description of nature and quantity or value of supplies or services: *(in each of the service categories)* *(if known, give figures only)* Estimated cost excluding VAT: [ ] Currency: [ ][ ][ ] *or* Range: between [ ] and [ ] Currency: [ ][ ][ ]

Use this text:

Procurement

What is this? The aim of this procurement is to trigger new solutions to be developed and tested to address the following common challenge (i.e. a challenge faced by all the organisations in the buyers group): [specify briefly the subject and scope of this PCP *e.g. improving the energy efficiency of buildings*].

The main technical challenges to be addressed are: [indicate the main target quality/efficiency and/or functionality/performance improvements compared to the current state-of-the art technology, e.g. 30 % energy efficiency improvement, interoperability].

The selected operators will retain ownership of the intellectual property rights (IPRs) that they generate during the PCP and will be able to use them to exploit the full market potential of the developed solutions i.e. beyond the buyers group.

*[*The market potential is estimated at [insert available figures about the potential total market size, i.e. beyond the procurers alone].*]*

[OPTION for PCP with lots: The procurement will be divided into the following lots:

- lot 1: [insert name of the sub-challenge to which the lot corresponds]
- lot 2:
- …*]*

Who is procuring? The procurement will be carried out jointly by the following organisations (the buyers group): [insert names of the members of the buyers group] (see [insert project website]). [Add name of lead procurer] will act as the lead procurer and will coordinate and lead the joint procurement in the name and on behalf of the other organisations.

How does it work? The procurement will take the form of a pre-commercial procurement (PCP) under which R&D service contracts will be awarded to a number of R&D providers in parallel in a phased approach. This will make it possible to compare competing alternative solutions.

Each selected operator will be awarded a framework agreement that covers three R&D phases.

The three phases are:

- solution design
- prototyping
- original development and validation and testing of a limited set of first products or services.

After each phase, intermediate evaluations will be carried out to progressively select the best of the competing solutions. The contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.

Testing is expected to take place in [add the locations where testing is expected to take place, in particular test locations of the members of the buyers group and other additional test locations]. This testing may also serve as a first customer test reference for the contractors.

[OPTION for PCP with lots: The phased approach with parallel contracts and intermediate evaluations will be followed within each lot.*]*

When will it take place? The procurement is expected to start in [add expected starting date of the PCP] and end in [add expected completion date of the PCP].

Open market consultation

In preparation for this PCP, **all interested operators** are **invited** to take part in an **open market consultation** (regardless of their geographic location, the size or governance structure of their organisation).

The open market consultation will provide you with an overview on the procurement objectives, the PCP process and the main clauses of the contract. You will also have the opportunity to ask questions.

It will be held in English *[*and [add additional language(s), if any]*]*.

The open market consultation will be organised in the form of a [insert the format *e.g. meeting, online meeting, webinar or online Q&A forum, or a combination of those*] that will be held:

- when: [insert date and time or period]

  ⚠ Choose the timing in such a way that you ensure that this PIN is published two months before the start of the open market consultation.

- where: [insert venue *e.g. via the project website*].

*[*Please register by [insert date].*]*

[OPTION if bidders are allowed to supply additional confidential information in a face-to-face meeting during the open market consultation: Please indicate *[*by [insert date]*][*together with the registration for the open market consultation*]* if you want to supply (under a non-disclosure agreement) additional confidential information that you do not wish to reveal in public during the open market consultation.*]*

⚠ Procurers must ensure equal treatment to all interested economic operators also in face-to-face meetings. Such meetings can therefore only be used to *listen* to the economic operators, but may not be used to *give* any additional information to the economic operators (except information also provided to all other operators)

[OPTION if for example a questionnaire is used: Please submit the following information [insert information, *e.g. questionnaire*] by [insert date].*]*

Note:

You can participate in the PCP call for tender even if you did not participate in the open market consultation.

Offers will be accepted in English *[*and [insert additional language(s), if any]*]*. All communication (before, during and after the procurement) will be carried out in English *[*and [add additional language(s), if any]*]*.

All information provided during the open market consultation and other background information will be published online in English *[*and [add additional language(s), if any]*]* on the project website ([insert the project website]).

More information:

Please see:

- the project website ([insert address])
- the section on PCP on the Europa website (http://ec.europa.eu/digital-agenda/en/innovation-procurement).

Provide any other relevant information.

Give the estimated total value of the PCP contract (without VAT).

Lots *(for information about lots, use Annex B as many times as there are lots)* This contract is divided into lots: ◯ yes ◯ no

For PCPs with lots select 'yes'.

II.5) Common procurement vocabulary (CPV)		
	Main vocabulary	Supplementary vocabulary *(if applicable)*
Main object	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
Additional object(s)	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]

Use CPV 73100000 for R&D services and additional other CPVs, if relevant to the object of the contract *(e.g. CPV for medical equipment if the PCP is for medical equipment-related R&D, CPV for software development services if software-related R&D is needed).*

II.6) Scheduled date for start of award procedures *(if known)*
[ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*

Enter the date.

II.7) Information about Government Procurement Agreement (GPA)
The contract is covered by the Government Procurement Agreement (GPA): ◯ yes ◯ no

Select 'no'.

II.8) Additional information: *(if applicable)*

Provide any other relevant additional information.

Section III: Legal, economic, financial and technical information

III.1) Conditions relating to the contract

III.1.1) Main financing conditions and payment arrangements and/or reference to the relevant provisions governing them: *(if known, provide information only in the case of works contracts)*

III.2) Conditions for participation

III.2.1) Information about reserved contracts *(if applicable)*
☐ The contract is restricted to sheltered workshops
☐ The execution of the contract is restricted to the framework of sheltered employment programmes

Complete if applicable. Avoid conditions that might unduly restrict participation.

The options for reserved contracts do not apply.

Section VI: Complementary information

VI.1) Information about European Union funds

The contract is related to a project and/or programme financed by European Union funds ◯ yes ◯ no
(if yes) Reference to project(s) and/or programme(s):

Select 'yes'.

Use this text:

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No [insert number] — [insert project acronym] (see [insert project website]).

[OPTION if the procurement also receives funding from other EU programmes (e.g. has member(s) of the buyers group whose financial contribution to the PCP budget is co-financed by the European Structural and Investment Funds (ESIF) instead of Horizon 2020): This procurement also receives funding from the *[OPTION for EU programmes:* European Union's [insert name of EU programme]*][OPTION for national programmes co-funded by the EU (e.g. by Regional Funds, Agricultural Funds):* [insert name of national programme] co-financed by the European Union*]:*

- [insert the beneficiary's name and the grant agreement number and acronym].*]*

The EU has given a grant for this procurement but is not participating as a contracting authority in the procurement.

VI.2) Additional information: *(if applicable)*

The PCP procurement is exempted from the WTO Government Procurement Agreement (GPA), the EU public procurement directives and the national laws that implement them (because it concerns the procurement of R&D services where the benefits do not accrue exclusively to the contracting *[*authority*][*entity*]* for its use in the conduct of its own affairs).

This PIN is published to announce an open market consultation on a future procurement procedure. The PIN is not a commitment to procure.

VI.3) Information on general regulatory framework

Relevant governmental Internet sites where information can be obtained

Tax legislation: *(URL)*

Environmental protection legislation: *(URL)*

Employment protection and working conditions: *(URL)*

For additional details about relevant governmental services where information can be obtained on taxes, environmental protection, employment protection and working conditions, please fill Annex A.II-IV (if applicable)

Complete if applicable

VI.4) Date of dispatch of this notice: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

Enter the date.

Appendix

Periodic indicative notice being a call for competition or aiming at reducing time-limits for the receipt of tenders

If the notice aims at reducing time-limits for receipt of tenders, the information in this appendix shall be supplied if available

For lead procurers in the public or utilities sector: do NOT fill in the appendix of the form (it does not apply to PCP open market consultations).

Annex A

Additional addresses and contact points

I) Addresses and contact points from which further information can be obtained

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete if applicable.

II) Address, contact points and internet site of the relevant government service from which information can be obtained about taxes

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete if applicable.

III) Address, contact points and internet site of the relevant government service from which information can be obtained about environmental protection

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete if applicable.

IV) Address, contact points and internet site of the relevant government service from which information can be obtained about employment protection and working conditions

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete, if applicable.

V) Address of the other contracting authority on behalf of which the contracting authority is purchasing

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:

(Use Annex A Section V as many times as needed)

Give contact details for all members of the buyers group.

Annex B

Information about lots

This annex relates to

Section II.A: Object of the contract – *(Works)* ◯

Section II.B: Object of the contract – *(Supplies or services)* ◯

Title attributed to the contract by the contracting authority:

Lot No: [ ][ ][ ] **Lot title:**

1) Short description:			
2) Common procurement vocabulary (CPV)			
	Main vocabulary	Supplementary vocabulary *(if applicable)*	
Main object	[ ][ ].[ ][ ].[ ][ ].[ ]–[ ]	[ ][ ][ ][ ]–[ ]	[ ][ ][ ][ ]–[ ]
Additional object(s)	[ ][ ].[ ][ ].[ ][ ].[ ]–[ ]	[ ][ ][ ][ ]–[ ]	[ ][ ][ ][ ]–[ ]
	[ ][ ].[ ][ ].[ ][ ].[ ]–[ ]	[ ][ ][ ][ ]–[ ]	[ ][ ][ ][ ]–[ ]
	[ ][ ].[ ][ ].[ ][ ].[ ]–[ ]	[ ][ ][ ][ ]–[ ]	[ ][ ][ ][ ]–[ ]
	[ ][ ].[ ][ ].[ ][ ].[ ]–[ ]	[ ][ ][ ][ ]–[ ]	[ ][ ][ ][ ]–[ ]

3) Quantity or scope:

(if known, give figures only) Estimated cost excluding VAT: [ ] Currency: [ ] [ ] [ ]
or
Range: between [ ] and [ ] Currency: [ ] [ ] [ ]

4) Indication about different date for start of award procedures and/or duration of contract *(if applicable)*
Scheduled date for start of award procedures: *(if known)* [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

Duration in months: [ ][ ] *or* in days: [ ][ ][ ][ ] (from the award of the contract)
or (if known)
Scheduled date for
start of works: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*
completion of works: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

5) Additional information about lots:

(Use this Annex as many times as there are lots)

Complete if the PCP involves lots.

PCP CONTRACT NOTICE

Use the English version of the simap standard form that is most appropriate for your type of organisation:

- **for lead procurers in the public sector: 'Contract notice'**
- **for lead procurers in the utilities sector: 'Contract notice — utilities'**
- **for lead procurers in the field of defence and security: 'Contract notice for contracts in the field of defence and security'**

In addition to English, you may publish the contract award notice (or a summary) in any other language(s).

⚠ **Do not forget that a copy of the contract notice must be submitted as a deliverable to the Commission or the agency acting on its behalf at the latest 30 days before publication of the notice (i.e. 30 days before the date of dispatch of the contract notice — *see Article 19 H2020 PCP-PPI MGA*).**

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Contract notice

Directive 2004/18/EC

Section I: Contracting authority

I.1) Name, addresses and contact point(s)

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address(es): *(if applicable)* General address of the contracting authority: *(URL)* Address of the buyer profile: *(URL)* Electronic access to information: *(URL)* Electronic submission of tenders and requests to participate: *(URL)* *Please use Annex A to provide more detailed information*		
Further information can be obtained from ◯ The above mentioned contact point(s) ◯ Other *(please complete Annex A.I)*		
Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained from ◯ The above mentioned contact point(s) ◯ Other *(please complete Annex A.II)*		
Tenders or requests to participate must be sent to ◯ The above mentioned contact point(s) ◯ Other *(please complete Annex A.III)*		

In the contact points section, give the contact details of the lead procurer.

In the internet addresses section, give the project website if you do not want to use the general website of the lead procurer. Use the address of the lead procurer's buyer profile.

I.2) Type of the contracting authority

◯ Ministry or any other national or federal authority, including their regional or local sub-divisions ◯ National or federal agency/office ◯ Regional or local authority ◯ Regional or local agency/office	◯ Body governed by public law ◯ European institution/agency or international organisation ◯ Other: *(please specify)*

This section is to be filled in ONLY if the lead procurer is a contracting authority (i.e. NOT a contracting entity).

I.3) Main activity

☐ General public services ☐ Defence ☐ Public order and safety ☐ Environment ☐ Economic and financial affairs ☐ Health	☐ Housing and community amenities ☐ Social protection ☐ Recreation, culture and religion ☐ Education ☐ Other: *(please specify)*

Select the lead procurer's main activities.

I.4) Contract award on behalf of other contracting authorities

The contracting authority is purchasing on behalf of other contracting authorities: ◯ yes ◯ no *(if yes, information on those contracting authorities can be provided in Annex A)*

Select 'yes'.

The contact details of all members of the buyers group must be given in Annex A.I) 'Address of the other contracting authority on behalf of which the contracting authority is purchasing'.

Section II: Object of the contract

II.1) Description

II.1.1) Title attributed to the contract by the contracting authority:

Use this title: 'Pre–commercial procurement (PCP) to buy R&D (research and development) services to [specify in a few words the subject and scope of this PCP *e.g. improving the energy efficiency of buildings*]'

II.1.2) Type of contract and location of works, place of delivery or of performance *(choose one category only – works, supplies or services – which corresponds most to the specific object of your contract or purchase(s))*		
◯ Works	◯ Supplies	◯ Services
☐ Execution ☐ Design and execution ☐ Realisation, by whatever means of work, corresponding to the requirements specified by the contracting authorities	◯ Purchase ◯ Lease ◯ Rental ◯ Hire purchase ◯ A combination of these	Service category No: [ ][ ] *Please see Annex C1 for service categories*
Main site or location of works, place of delivery or of performance:		
NUTS code [ ][ ][ ][ ][ ] NUTS code [ ][ ][ ][ ][ ]	NUTS code [ ][ ][ ][ ][ ] NUTS code [ ][ ][ ][ ][ ]	

Select 'Services'.

For lead procurers in the public or utilities sector: use 'research and development services' category 8.

For lead procurers in the defence and security sector: use 'research and development services' category 14.

Do NOT fill out the other fields (main site or location of delivery/performance, NUTS code).

⚠ Do not choose any other category and make sure that your procurement complies with the category 8/14 — otherwise your procurement will not be exempted from the EU procurement directives.

II.1.3) Information about a public contract, a framework agreement or a dynamic purchasing system (DPS)

☐ The notice involves a public contract
☐ The notice involves the establishment of a framework agreement
☐ The notice involves the setting up of a dynamic purchasing system (DPS)

Select 'The notice involves the establishment of a framework agreement'.

II.1.4) Information on framework agreement *(if applicable)*

◯ Framework agreement with several operators
Number [ ][ ][ ]
or
(if applicable) maximum number [ ][ ][ ] of participants to the framework agreement envisaged

◯ Framework agreement with a single operator

Select 'Framework agreement with several operators'.

State the minimum number of framework agreements that you plan to award (according to the request for tenders, there should be one per selected operator). For PCPs with lots, enter the total minimum number of framework agreements counted across all the lots.

Duration of the framework agreement
Duration in years: [ ][ ] or in months: [ ][ ][ ]

Justification for a framework agreement, the duration of which exceeds four years:

Enter the duration.

If the framework agreement exceeds four years for lead procurers in the public or utilities sector or seven years for lead procurers in the defence and security sector, give reasons why.

Estimated total value of purchases for the entire duration of the framework agreement *(if applicable, give figures only)*

Estimated value excluding VAT: [ ] Currency: [ ][ ][ ]
or
Range: between [ ] and [ ] Currency: [ ][ ][ ]

Frequency and value of the contracts to be awarded: *(if known)*

Give the total estimated value of the PCP framework agreement (excluding VAT) in euros/other currency and indicate the value and frequency (i.e. timing) of the specific contracts planned for each phase of the PCP.

II.1.5) Short description of the contract or purchase(s):

Use this text:

What is this? The aim of this procurement is to trigger new solutions to be developed and tested to address the following common challenge (i.e. a challenge faced by all the organisations in the buyers group): [specify briefly the subject and scope of this PCP *e.g. improving the energy efficiency of buildings*].

The main quality/efficiency improvements to be achieved are: [indicate the main target quality/efficiency and/or functionality/performance improvements compared to the current state-of-the art technology, *e.g. 30 % energy efficiency improvement, interoperability*].

The selected contractors will retain ownership of the intellectual property rights (IPRs) that they generate during the PCP and will be able to use them to exploit the full market potential of the solutions developed, i.e. beyond the buyers group alone). *[*The market potential is estimated at [insert available figures about the total potential market size, beyond the procurers alone].*]*

[OPTION for PCP with lots: The procurement will be divided into the following lots:

- lot 1: [insert name of the sub-challenge to which the lot corresponds]
- lot 2:
- …*]*

Who is procuring? The procurement will be carried out jointly by the following organisations (the buyers group): [insert names of the members of the buyers group] (see [insert project website]). [Add name of lead procurer] will act as the lead procurer and will coordinate and lead the joint procurement in the name and on behalf of the other organisations.

*[*In addition, there will be [explain briefly if there are third parties or preferred partners that will cooperate with the buyers group during the PCP. *For example, third parties that are putting resources at the disposal of the procurer(s) for the purpose of implementing the PCP (e.g. test sites, equipment or staff) or other procurers from other European countries that have indicated an interest in the PCP and that will be informed of the progress and results of the PCP (the preferred partners)*].*]*

How does it work? The procurement will take the form of a pre-commercial procurement (PCP) with a phased approach, under which R&D service contracts will be awarded to a number of R&D providers in parallel, in order to be able to compare competing alternative solutions.

Each selected operator will conclude a framework agreement that covers three R&D phases.

The three phases are:

- solution design
- prototyping
- original development and validation and testing of a limited set of first products or services.

After each phase, intermediate evaluations will be carried out to progressively select the best competing solutions. The contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.

Testing is expected to take place in [add the locations where testing is expected to take place, in particular test locations of the members of the buyers group and other additional test locations]. This testing may also serve as a first customer test reference for the contractors.

[OPTION for PCP with lots: The phased approach with parallel contracts and intermediate evaluations will be followed for each lot.*]*

When will it take place? The procurement is expected to start in [add expected starting date of the PCP] and end in [add expected completion date of the PCP].

Proposals may be submitted in English *[*and [insert additional language(s), if any]*]*. All communication (before, during and after the procurement) can be made in English *[*and [add additional language(s), if any]*]*.

For **more information** see:

- the project website ([insert address])
- the open market consultation Q&A (see [insert address]
- the PCP section on the Europa website (http://ec.europa.eu/digital-agenda/en/innovation-procurement)

or contact:

- [insert email address or interactive web address].

Please ensure that interested operators can ask questions about the procurement and tender documents and give them sufficient time to do so.

II.1.6) Common procurement vocabulary (CPV)		
	Main vocabulary	Supplementary vocabulary *(if applicable)*
Main object	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
Additional object(s)	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]

Use CPV 73100000 for R&D services and additional other CPVs, if relevant to the object of the contract *(e.g. CPV for medical equipment if the PCP is for medical equipment, CPV for software development services if software-related R&D is needed).*

II.1.7) Information about Government Procurement Agreement (GPA)
The contract is covered by the Government Procurement Agreement (GPA): ◯ yes ◯ no

Select 'no'.

II.1.7) Information about subcontracting *(if applicable)*

☐ The tenderer has to indicate in the tender any share of the contract it may intend to subcontract to third parties and any proposed subcontractor, as well as the subject-matter of the subcontracts for which they are proposed. *(if applicable)*

☐ The tenderer has to indicate any change occurring at the level of subcontractors during the execution of the contract. *(if applicable)*

☐ The contracting authority/entity may oblige the successful tenderer to award all or certain subcontracts through the procedure set out in Title III of Directive 2009/81/EC.

☐ The successful tenderer is obliged to subcontract the following share of the contract through the procedure set out in Title III of Directive 2009/81/EC: minimum percentage: [ ][ ],[ ] (%), maximum percentage: [ ][ ],[ ] (%) of the value of the contract.
(The maximum percentage may not exceed 30% of the value of the contract)

☐ The successful tenderer is obliged to specify which part or parts of the contract it intends to subcontract beyond the required percentage and to indicate the subcontractors already identified. *(if applicable)*

For lead procurers in the defence and security sector: complete if applicable.

II.1.8) Lots *(for information about lots, use Annex B as many times as there are lots)*

This contract is divided into lots: ◯ yes ◯ no

(if yes) Tenders may be submitted for
◯ one lot only ◯ one or more lots ◯ all lots

For PCPs with lots: select 'yes'.

Select 'Tenders may be submitted for all lots'.

II.1.9) Information about variants
Variants will be accepted ◯ yes ◯ no

Select 'no'.

II.2) Quantity or scope of the contract

II.2.1) Total quantity or scope: *(including all lots, renewals and options, if applicable)*

(if applicable, give figures only)
Estimated value excluding VAT: [ ] Currency: [ ][ ][ ]
or
Range: between [ ] and [ ] Currency: [ ][ ][ ]

Select 'Estimated value excluding VAT' and insert the value of the whole PCP (excluding VAT) in euros.

II.2.2) Information about options *(if applicable)*
Options ◯ yes ◯ no
(if yes) Description of these options:

(if known) Provisional timetable for recourse to these options:
in months: [ ][ ] *or* in days: [ ][ ][ ][ ] (from the award of the contract)

Complete if applicable

II.2.3) Information about renewals *(if applicable)*
This contract is subject to renewal ◯ yes ◯ no
Number of possible renewals: *(if known)* [ ][ ][ ] *or* Range: between [ ][ ][ ] and [ ][ ][ ]

(if known) In the case of renewable supplies or service contracts, estimated timeframe for subsequent contracts:
in months: [ ][ ] *or* in days: [ ][ ][ ][ ] (from the award of the contract)

Select 'no'.

II.3) Duration of the contract or time limit for completion

Duration in months: [ ][ ] *or* in days: [ ][ ][ ][ ] (from the award of the contract) *or* Starting [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)* Completion [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

Enter the duration of the framework agreement (from award to end).

Section III: Legal, economic, financial and technical information

III.1) Conditions relating to the contract

III.1.1) Deposits and guarantees required: *(if applicable)*
III.1.2) Main financing conditions and payment arrangements and/or reference to the relevant provisions governing them:
III.1.3) Legal form to be taken by the group of economic operators to whom the contract is to be awarded: *(if applicable)*
III.1.4) Other particular conditions *(if applicable)* The performance of the contract is subject to particular conditions ◯ yes ◯ no *(if yes)* Description of particular conditions:

Complete as applicable. You can refer to the tender documents for further information.

Avoid conditions that might unduly restrict participation (in particular disproportionate financial guarantees and restrictions on the legal form of operators).

III.2) Conditions for participation

III.2.1) Personal situation of economic operators, including requirements relating to enrolment on professional or trade registers
Information and formalities necessary for evaluating if the requirements are met:

III.2.2) Economic and financial ability	
Information and formalities necessary for evaluating if the requirements are met:	Minimum level(s) of standards possibly required: *(if applicable)*

III.2.3) Technical capacity	
Information and formalities necessary for evaluating if the requirements are met:	Minimum level(s) of standards possibly required: *(if applicable)*
III.2.4) Information about reserved contracts *(if applicable)* ☐ The contract is restricted to sheltered workshops ☐ The execution of the contract is restricted to the framework of sheltered employment programmes	

Complete as applicable. You can refer to the tender documents for further information.

Avoid conditions that might unduly restrict participation (in particular disproportionate qualification and financial guarantee requirements *e.g. references from past customers and minimum turnovers*).

The options for reserved contracts do not apply.

III.3) Conditions specific to services contracts

III.3.1) Information about a particular profession Execution of the service is reserved to a particular profession ◯ yes ◯ no *(if yes)* Reference to the relevant law, regulation or administrative provision:
III.3.2) Staff responsible for the execution of the service Legal persons should indicate the names and professional qualifications of the staff responsible for the execution of the service ◯ yes ◯ no

Complete as applicable.

Avoid undue restrictions that might unduly restrict participation to the procurement.

Section IV: Procedure

IV.1) Type of procedure

IV.1.1) Type of procedure	
◯ Open	
◯ Restricted	
◯ Accelerated restricted	Justification for the choice of accelerated procedure:
◯ Negotiated	Some candidates have already been selected (if appropriate under certain types of negotiated procedures) ◯ yes ◯ no *(if yes, provide names and addresses of economic operators already selected under Section VI.3 Additional information)*
◯ Accelerated negotiated	Justification for the choice of accelerated procedure:
◯ Competitive dialogue	

For lead procurers in the public or utilities sector: select 'open'.

For lead procurers in the defence and security sector: select 'negotiated'.

In Section VI.3 Additional information, you will have to state that this procurement is exempted from the EU public procurement directives and the national laws that implement them (i.e. it is not an open and negotiated procedure subject to the EU public procurement directives. The choice here must be made for formal reasons only, because it is mandatory for filling out the form).

IV.1.2) Limitations on the number of operators who will be invited to tender or to participate *(restricted and negotiated procedures, competitive dialogue)*

Envisaged number of operators [ ] [ ] [ ]
or
Envisaged minimum number [ ] [ ] [ ] and (*if applicable*) maximum number [ ] [ ] [ ]

Objective criteria for choosing the limited number of candidates:

Leave blank.

IV.1.3) Reduction of the number of operators during the negotiation or dialogue *(negotiated procedure, competitive dialogue)*
Recourse to staged procedure to gradually reduce the number of solutions to be discussed or tenders to be negotiated ◯ yes ◯ no

Leave blank.

IV.2) Award criteria

IV.2.1) Award criteria *(please tick the relevant box(es))*

◯ Lowest price

or

◯ The most economically advantageous tender in terms of

◯ the criteria stated below *(the award criteria should be given with their weighting or in descending order of importance where weighting is not possible for demonstrable reasons)*

◯ the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document

Criteria	Weighting	Criteria	Weighting
1. [ ]	[ ]	6. [ ]	[ ]
2. [ ]	[ ]	7. [ ]	[ ]
3. [ ]	[ ]	8. [ ]	[ ]
4. [ ]	[ ]	9. [ ]	[ ]
5. [ ]	[ ]	10.[ ]	[ ]

Select 'the most economically advantageous tender' and one of the two other options ('the criteria stated below' OR 'the criteria stated in the specifications in the invitation to tender').

If you select the first option ('the criteria stated below'), you must indicate the criteria and their weighting in the table.

IV.2.2) Information about electronic auction

An electronic auction will be used ◯ yes ◯ no

(if yes, if appropriate) Additional information about electronic auction:

Select 'no'.

IV.3) Administrative information

IV.3.1) File reference number attributed by the contracting authority: *(if applicable)*

Complete if applicable.

IV.3.2) Previous publication(s) concerning the same contract ◯ yes ◯ no

(if yes)

◯ Prior information notice ◯ Notice on a buyer profile

Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*

☐ Other previous publications *(if applicable)*

Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*

Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*

Select 'yes'.

Select 'Prior information notice' and provide information on the PIN announcing the open market consultation.

Select 'Other previous publications' and provide information (if applicable).

IV.3.3) Conditions for obtaining specifications and additional documents or descriptive document *(in the case of a competitive dialogue)*
Time limit for receipt of requests for documents or for accessing documents
Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)* Time: [ ][ ] : [ ][ ]

Payable documents ◯ yes ◯ no
(if yes, give figures only) Price: [ ] Currency: [ ][ ][ ]
Terms and method of payment:

Set the deadline for receiving requests for documents and for accessing documents so that you allow sufficient time for interested operators to obtain all relevant specifications and additional documents.

Do not use 'descriptive documents' (the procurement does not use the competitive dialogue procedure).

Select 'no' for payable documents.

IV.3.4) Time limit for receipt of tenders or requests to participate
Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)* Time: [ ][ ] : [ ][ ]

Specify a deadline that gives operators at least two months.

IV.3.5) Date of dispatch of invitations to tender or to participate to selected candidates *(if known, in the case of restricted and negotiated procedures, and competitive dialogue)*
Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

Leave blank.

IV.3.6) Language(s) in which tenders or requests to participate may be drawn up
◯ Any EU official language
◯ Official EU language(s):
☐ Other:

Select English and any other language(s) chosen by the buyers group. (These languages may or may not be official EU languages; *e.g. for members from H2020 associated countries*).

IV.3.7) Minimum time frame during which the tenderer must maintain the tender
until: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*
or
Duration in months: [ ][ ][ ] *or* in days: [ ][ ][ ] (from the date stated for receipt of tender)

Complete as applicable.

IV.3.8) Conditions for opening tenders
Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)* Time: [ ][ ] : [ ][ ]
(if applicable) Place: [ ]
Persons authorised to be present at the opening of tenders *(if applicable)* ◯ yes ◯ no
(if yes) Additional information about authorised persons and opening procedure:

Complete as applicable.

Section VI: Complementary information

VI.1) Information about recurrence *(if applicable)*

This is a recurrent procurement ◯ yes ◯ no

(if yes) Estimated timing for further notices to be published:

Select 'no'.

VI.2) Information about European Union funds

The contract is related to a project and/or programme financed by European Union funds ◯ yes ◯ no

(if yes) Reference to project(s) and/or programme(s):

Select 'yes'.

Use this text:

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No [insert number] — [insert project acronym] (see [insert project website]).

[OPTION if the procurement also receives funding from other EU programmes (i.e. has member(s) of the buyers group whose financial contribution to the PCP budget is co-financed by European Structural and Investment Funds (ESIF) instead of Horizon 2020): This procurement receives funding from the *[OPTION for EU programmes:* European Union's [insert name of EU programme]*][OPTION for national programmes co-funded by the EU (e.g. by Regional Funds, Agricultural Funds):* [insert name of national programme] co-financed by the European Union*]*:

– [insert beneficiary name and grant agreement number and acronym].***]***

VI.3) Additional information: *(if applicable)*

Use this text:

This contract notice invites interested operators to submit tenders to the procurement.

Note:

Participation in the open market consultation held as part of the preparation for this procurement is not a prerequisite for submitting a tender.

The EU has given a grant for this procurement but is not participating as a contracting authority in the procurement.

This procurement is exempted from the WTO Government Procurement Agreement (GPA), the EU public procurement directives and the national laws that implement them. This is because it concerns the procurement of R&D services where the benefits do not accrue exclusively to the contracting authority for its use in the conduct of its own affairs.

Publication of this contract notice in the EU Official Journal is not to be understood as a waiver of this exemption. Publication is made on a voluntary basis and the procurement will not follow the procedures under the EU public procurement directives, but rather the procedure described in the tender documentation.

(The *[*open*][*negotiated*]* procedure was chosen in Section IV.1.1) 'Procedure' for formal reasons only. This is because it is not possible to publish a contract notice without selecting one of the listed procedures.

More information:

see:

- the project website (see [insert address])
- the open market consultation Q&A (see [insert address])
- the section on PCPs on the Europa website (http://ec.europa.eu/digital-agenda/en/innovation-procurement)

or contact:

- [insert email address or interactive web address]

Provide other additional information (if applicable).

Please ensure that interested operators can ask questions about the procurement and tender documents and give them sufficient time to do so.

VI.4) Procedures for appeal

VI.4.1) Body responsible for appeal procedures		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:
Body responsible for mediation procedures *(if applicable)*		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:

Give the names of the appeal and mediation bodies foreseen under the national law applicable to the lead procurer.

Depending on the country, this may or may not be the same body that is competent when the EU procurement directives do apply.

Do NOT leave this section blank (otherwise you risk multiple complaints procedures in different countries).

VI.4.2) Lodging of appeals *(please fill in heading VI.4.2 or if need be, heading VI.4.3)* Precise information on deadline(s) for lodging appeals:

Use the following text:

The procurement is exempted from the EU public procurement directives (including the EU procurement remedies Directives 89/665/EEC and 92/13/EEC — *see above*) and the national laws that implement them.

Publication of this notice in the Official Journal is not to be understood as a waiver of this exemption by the contracting authority.

VI.4.3) Service from which information about the lodging of appeals may be obtained		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:

Give the contact details of a contact person at the lead procurer.

Make sure that this contact person has sufficient information about the context and background of the procurement.

VI.5) Date of dispatch of this notice: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

Enter the date.

Annex A

Additional addresses and contact points

I) Addresses and contact points from which further information can be obtained

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete if applicable.

II) Addresses and contact points from which specifications and additional documents can be obtained

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete if applicable.

III) Addresses and contact points to which tenders/requests to participate must be sent

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address: *(URL)*		

Complete if applicable.

IV) Address of the other contracting authority on behalf of which the contracting authority is purchasing

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:

(Use Annex A Section IV as many times as needed)

Give contact details for all members of the buyers group.

Annex B

Information about lots

Title attributed to the contract by the contracting authority:

Lot No: [ ][ ][ ] **Lot title:**

1) Short description:		
2) Common procurement vocabulary (CPV)		
	Main vocabulary	Supplementary vocabulary *(if applicable)*
Main object	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
Additional object(s)	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]

3) Quantity or scope:
(if known, give figures only) Estimated cost excluding VAT: [ ] Currency: [ ][ ][ ] *or* Range: between [ ] and [ ] Currency: [ ][ ][ ]
4) Indication about different date for duration of contract or starting/completion *(if applicable)* Duration in months: [ ][ ] or in days: [ ][ ][ ][ ] (from the award of the contract) *or* Starting [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)* Completion [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*
5) Additional information about lots:

(Use this Annex as many times as there are lots)

Complete if the PCP is with lots.

PCP CONTRACT AWARD NOTICE

Use the English version of the simap standard form that is appropriate for your type of organisation:

- **for lead procurers in the public sector: 'Contract award notice'**
- **for lead procurers in the utilities sector: 'Contract award notice — utilities'**
- **for lead procurers in the field of defence and security: 'Contract award notice for contracts in the field of defence and security'**

In addition to English, you may publish the contract award notice (or a summary) in any other language(s).

⚠ **Do not forget that a copy of the published contract award notice should be submitted to the Commission or the agency acting on its behalf as part of the deliverables at the end of the tender evaluation *(see Article 19 H2020 PCP-PPI MGA)*.**

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Contract award notice

Directive 2004/18/EC

Section I: Contracting authority

I.1) Name, addresses and contact point(s)

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:
Contact point(s): For the attention of:		Telephone:
E-mail:		Fax:
Internet address(es): *(if applicable)* General address of the contracting authority: *(URL)* Address of the buyer profile: *(URL)* Electronic access to information: *(URL)* Electronic submission of tenders and requests to participate: *(URL)*		

In the contact points section, give the contact details of the lead procurer.

In the internet addresses section, give the project website if you do not want to use the general website of the lead procurer. Use the address of the lead procurer's buyer profile.

I.2) Type of the contracting authority

◯ Ministry or any other national or federal authority, including their regional or local sub-divisions ◯ National or federal agency/office ◯ Regional or local authority ◯ Regional or local agency/office	◯ Body governed by public law ◯ European institution/agency or international organisation ◯ Other: *(please specify)*

This section is to be filled in ONLY if the lead procurer is a contracting authority (i.e. NOT a contracting entity).

I.3) Main activity

☐ General public services ☐ Defence ☐ Public order and safety ☐ Environment ☐ Economic and financial affairs ☐ Health	☐ Housing and community amenities ☐ Social protection ☐ Recreation, culture and religion ☐ Education ☐ Other: *(please specify)*

Select the lead procurer's main activities.

I.4) Contract award on behalf of other contracting authorities

The contracting authority is purchasing on behalf of other contracting authorities: ◯ yes ◯ no *(if yes, information on those contracting authorities can be provided in Annex A)*

Select 'yes'.

The contact details of all the members of the buyers group must be given in Annex A.I) 'Address of the other contracting authority on behalf of which the contracting authority is purchasing'.

Section II: Object of the contract

II.1) Description

II.1.1) Title attributed to the contract

Use the following title: 'Pre–commercial procurement (PCP) to buy R&D (research and development) services to [specify in a few words the subject and scope of this PCP *e.g. improving the energy efficiency of buildings*]'

II.1.2) Type of contract and location of works, place of delivery or of performance *(choose one category only – works, supplies or services – which corresponds most to the specific object of your contract or purchase(s))*		
◯ Works	◯ Supplies	◯ Services
☐ Execution ☐ Design and execution ☐ Realisation, by whatever means of work, corresponding to the requirements specified by the contracting authorities	◯ Purchase ◯ Lease ◯ Rental ◯ Hire purchase ◯ A combination of these	Service category No: [ ][ ] *Please see Annex C1 for service categories* In case of contracts for service categories 17 to 27 – see Annex C1 – do you agree to the publication of this notice? ◯ yes ◯ no
Main site or location of works, place of delivery or of performance:		
NUTS code [ ][ ][ ][ ][ ] NUTS code [ ][ ][ ][ ][ ]	NUTS code [ ][ ][ ][ ][ ] NUTS code [ ][ ][ ][ ][ ]	

Select 'Services'. For lead procurers in the public or utilities sector: use 'research and development services' category 8.

For lead procurers in the defence and security sector: use 'research and development services' category 14.

Do NOT fill out the other fields (main site or location of delivery/performance, NUTS code)

⚠ Do not choose any other category and make sure that your procurement complies with the category 8/14 — otherwise your procurement will not be exempted from the EU procurement directives.

II.1.3) Information about a framework agreement or a dynamic purchasing system (DPS)

☐ The notice involves the establishment of a framework agreement

☐ The notice involves contract(s) based on a dynamic purchasing system (DPS)

Select 'the notice involves the signature of a framework agreement'.

II.1.4) Short description of the contract or purchase(s):

Use the following text:

On [enter date of the publication of the contract notice], a contract notice was published as part of the EU project [insert project acronym] to purchase R&D services from a number of R&D providers in parallel. The aim was to compare competing alternative solution approaches to address the following challenge: [specify briefly the subject and scope of this PCP e.g. improving the energy efficiency of buildings]. The procurement was announced to be in the form of a pre-commercial procurement (PCP) with a phased approach, i.e. a framework agreement covering three R&D phases:

- solution design
- prototyping
- original development and validation and testing of a limited set of first products or services.

After each phase, intermediate evaluations are carried out to progressively select the best competing solutions. The contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.

The procurement is carried out jointly by the following organisations [insert names of the members in the buyers group] (see [insert project website]). [Add name of lead procurer] was appointed as lead procurer and will coordinate and lead the joint procurement in the name and on behalf of the other organisations.

A total budget of [enter the total estimated budget for the PCP that was announced in the contract notice] was earmarked for awarding the contracts to a minimum of:

- [enter minimum number of R&D providers that were expected to start phase 1 as announced in the contract notice] contractors for phase 1
- [enter minimum number of R&D providers that were expected to start phase 2 as announced in the contract notice] contractors for phase 2 and
- [enter minimum number of R&D providers that were expected to start phase 3 as announced in the contract notice] contractors for phase 3.

[*OPTION 1 if NOT enough proposals offering adequate value for money were received to start the PCP:* It was decided not to start the procurement and consequently not to award any contracts because [explain the reason, *e.g. insufficient proposals scored above the minimum requirement or insufficient proposals were received to start the PCP*].***]***

[*OPTION 2 if the PCP went ahead as planned:*

[OPTION 2a for PCP without lots: [Enter name of the lead procurer] has signed contracts with [enter number of R&D providers that were awarded a framework agreement (and specific contract for phase 1)] contractors to start phase 1.*]*

[OPTION 2a for PCP with lots: For lot [number of lot], [enter name of the lead procurer] has signed contracts with [enter number of R&D providers that were awarded a framework agreement (and specific contract for phase 1)] contractors to start phase 1.*]]*

[OPTION if the number of contracts awarded is below the minimum number announced in the contract notice: The number of contracts awarded remained below the number announced in the contract notice because [explain why this is the case *e.g. insufficient proposals were received to award more contracts or the other proposals did not score above the minimum requirement*]*]*

The abstracts of the winning tenders are available on [insert project website].

The PCP is expected to start in [enter expected start date for phase 1] and end in [add expected completion date for phase 3].

II.1.5) Common procurement vocabulary (CPV)		
	Main vocabulary	Supplementary vocabulary *(if applicable)*
Main object	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]
Additional object(s)	[ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ] [ ][ ].[ ][ ].[ ][ ].[ ][ ]-[ ]	[ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ] [ ][ ][ ][ ]-[ ]

Use CPV 73100000 for R&D services and add other CPVs, if relevant to the object of the contract *(e.g. CPV for medical equipment if the PCP is for medical equipment, CPV for software development services if software-related R&D is needed)*.

II.1.6) Information about Government Procurement Agreement (GPA)
The contract is covered by the Government Procurement Agreement (GPA): ◯ yes ◯ no

Select 'no'.

II.2) Total final value of contract(s)

II.2.1) Total final value of contract(s) *(Please give, using figures, only total final value, including all contracts, lots, renewals and options. For information about individual contracts, please fill section V. Award of contract)*			
	Excluding VAT	Including VAT	VAT rate (%)
Value: [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] Currency: [ ][ ][ ] *or*	◯	◯	at [ ][ ],[ ]
Lowest offer [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] and highest offer [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] Currency: [ ][ ][ ] taken into consideration	◯	◯	at [ ][ ],[ ]

Indicate the total final value of all framework agreements awarded, across all lots (if applicable), in euros/other currency (totalling the prices of the contracts that were awarded for phase 1 and the maximum total budgets planned for phases 2 and 3).

Details on the value of the individual framework agreements must be given in Section V. 'Award of contract'.

Section IV: Procedure

IV.1) Type of procedure

IV.1.1) Type of procedure	
◯ Open ◯ Restricted ◯ Accelerated restricted ◯ Competitive dialogue	◯ Negotiated with a call for competition ◯ Accelerated negotiated ◯ Negotiated without a call for competition ◯ Award of a contract without prior publication of a contract notice in the Official Journal of the European Union (in the cases listed in Section 2 of Annex D1) Justification for the award of the contract without prior publication of a contract notice in the Official Journal of the European Union (OJEU): *please complete Annex D1*

For lead procurers in the public or utilities sector: select 'open'.

For lead procurers in the defence and security sector: select 'negotiated'.

In Section IV.3 Additional information, you must state that this procurement is exempted from the EU public procurement directives and the national laws that implement them (i.e. this is not an open and negotiated procedure subject to the EU public procurement directives. The choice here must be made for formal reasons only because it is mandatory for filling out the form).

IV.2) Award criteria

IV.2.1) Award criteria *(please tick the relevant box(es))*

◯ Lowest price
or
◯ The most economically advantageous tender in terms of

Criteria	Weighting	Criteria	Weighting
1. [ ]	[ ]	6. [ ]	[ ]
2. [ ]	[ ]	7. [ ]	[ ]
3. [ ]	[ ]	8. [ ]	[ ]
4. [ ]	[ ]	9. [ ]	[ ]
5. [ ]	[ ]	10.[ ]	[ ]

Select 'The most economically advantageous tender'.

IV.2.2) Information about electronic auction
An electronic auction has been used ◯ yes ◯ no

Select 'no'.

IV.3) Administrative information

IV.3.1) File reference number attributed by the contracting authority: *(if applicable)*

Complete if applicable.

IV.3.2) Previous publication(s) concerning the same contract ◯ yes ◯ no
(if yes, please fill in the appropriate boxes)
◯ Prior information notice ◯ Notice on a buyer profile
Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*
◯ Contract notice ◯ Simplified contract notice on a dynamic purchasing system
Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*
☐ Voluntary ex ante transparency notice
Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*
☐ Other previous publications *(if applicable)*
Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*
Notice number in the OJEU: [ ][ ][ ][ ]/S [ ][ ][ ]–[ ][ ][ ][ ][ ][ ][ ] of [ ][ ]/[ ][ ]/[ ][ ][ ][ ] *(dd/mm/yyyy)*

Select 'yes'.

Select 'Prior information notice' and provide information on the PIN announcing the open market consultation.

Select 'Contract notice' and provide information on the contract notice.

Select 'Other previous publications' and provide information (if applicable).

Section V: Award of contract

Contract No: [ ][ ][ ] **Lot No:** [ ][ ][ ] **Lot title:**

Section V: Award of contract

This section must be filled out as many times as needed, i.e. for every contractor that was awarded a framework agreement (and a phase 1 contract). For PCPs with lots, the section must be filled out for every lot AND every contractor that was awarded a framework agreement (and a phase 1 contract).

V.1) Date of contract award decision: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

V.2) Information about offers Number of offers received: [ ][ ][ ] Number of offers received by electronic means: [ ][ ][ ]

If the PCP is with lots, use the number of proposals received for the lot in question.

V.3) Name and address of economic operator in favour of whom the contract award decision has been taken		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:

Give the name and address of the operator that won the contract in question.

V.4) Information on value of contract *(give figures only)*			
	Excluding VAT	Including VAT	VAT rate (%)
Initial estimated total value of the contract *(if applicable)* Value: [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] Currency: [ ][ ][ ]	○	○	at [ ][ ],[ ]
Total final value of the contract Value: [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] Currency: [ ][ ][ ]	○	○	at [ ][ ],[ ]
or Lowest offer [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] and highest offer [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ],[ ][ ] Currency: [ ][ ][ ] taken into consideration	○	○	at [ ][ ],[ ]
If annual or monthly value: *(please give)* Number of years: [ ][ ] *or* Number of months: [ ][ ]			

Give the initial estimated total value of the contract in euros/other currency (totalling the price offered by the operator that won the contract in question for phase 1 and the maximum budget planned for phases 2 and 3).

V.5) Information about subcontracting
The contract is likely to be sub-contracted ◯ yes ◯ no

(if yes, give figures only) Value or proportion of the contract likely to be sub-contracted to third parties:
Value excluding VAT: [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] [ ][ ][ ] , [ ][ ] Not known: ☐
Currency: [ ][ ][ ] Proportion [ ][ ] , [ ] (%)

Short description of the value/proportion of the contract to be sub-contracted: *(if known)*

(Use this section as many times as needed)

Section VI: Complementary information

VI.1) Information about European Union funds

The contract is related to a project and/or programme financed by European Union funds ◯ yes ◯ no
(if yes) Reference to project(s) and/or programme(s):

Select 'yes'.

Use this text:

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No [insert number] — [insert project acronym] (see [insert project website]).

[OPTION if the procurement also receives funding from other EU programmes (i.e. has member(s) of the buyers group whose financial contribution to the PCP budget is co-financed by European Structural and Investment Funds (ESIF) instead of Horizon 2020): This procurement receives funding from the *[OPTION for EU programmes:* European Union's [insert name of EU programme]*][OPTION for national programmes co-funded by the EU (e.g. by Regional Funds, Agricultural Funds):* [insert name of national programme] co-financed by the European Union*]*:

– [insert beneficiary name and grant agreement number and acronym].***]***

VI.2) Additional information: *(if applicable)*

Use this text:

Note:

The EU has given a grant for this procurement but is not participating as a contracting authority in it.

The procurement is exempted from the WTO Government Procurement Agreement (GPA), the EU public procurement directives and the national laws that implement them. This is because it

concerns the procurement of R&D services where the benefits do not accrue exclusively to the contracting authority for its use in the conduct of its own affairs.

Publication of this notice in the EU Official Journal is not to be understood as a waiver of this exemption. It is made on a voluntary basis and the procurement will not follow the procedures under the EU public procurement directives, but rather the procedure described in the tender documentation.

(The *[*open*][*negotiated*]* procedure was chosen in Section IV.1.1) 'Procedure' for formal reasons only. This is because it is not possible to publish a contract award notice without selecting one of the listed procedures.

Provide other additional information (if applicable).

VI.3) Procedures for appeal

VI.3.1) Body responsible for appeal procedures		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:

Body responsible for mediation procedures *(if applicable)*		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:

Give the names of the appeal and mediation bodies foreseen under the national law applicable to the lead procurer.

Depending on the country, this may or may not be the same body that is competent when the EU procurement directives do apply.

Do NOT leave this section blank (otherwise you risk multiple complaints procedures in different countries).

VI.3.2) Lodging of appeals *(please fill in heading VI.3.2 or, if need be, heading VI.3.3)* Precise information on deadline(s) for lodging appeals:

Use the following text:

The procurement is exempted from the EU public procurement directives (including the EU procurement remedies Directive 2007/66/EC and 92/13/EEC - *see above*) and the national laws that implement them.

Publication of this notice in the Official Journal is not to be understood as a waiver of this exemption by the contracting authority.

VI.3.3) Service from which information about the lodging of appeals may be obtained		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: *(URL)*		Fax:

Give the contact details of a contact person at the lead procurer.

Make sure this person has sufficient information about the context and background of the procurement.

VI.4) Date of dispatch of this notice: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] *(dd/mm/yyyy)*

Enter the date.

Annex A

Additional addresses and contact points

I) Address of the other contracting authority on behalf of which the contracting authority is purchasing

Official name:		National ID: *(if known)*
Postal address:		
Town:	Postal code:	Country:

(Use this section as many times as needed)

Give contact details for all members of the buyers group.

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The European Code of Conduct for Research Integrity

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Preamble

Research is the quest for knowledge obtained through systematic study, thinking, observation, and experimentation. While different disciplines may use different approaches, they each share the motivation to increase our understanding of ourselves and the world in which we live. Therefore, "The European Code of Conduct for Research Integrity" applies to research in all scientific and scholarly fields.

Research is a common enterprise, carried out by many different actors in academic, industry, and other settings. It involves collaboration, direct or indirect, which often transcends social, political, and cultural boundaries. It is underpinned by the freedom to define research questions and develop theories, gather empirical evidence, and employ appropriate methods in an impartial way. Therefore, research draws on the work of the community of researchers and should develop independently of pressure from commissioning parties and from ideological, economic, or political interests.

Research integrity is crucial to preserving the trustworthiness of the research system and its results. It encompasses the basic responsibility of the research community to formulate the principles of research, to define the criteria for proper research behaviour, to maximise the quality, reliability, and robustness of research and its results, and to respond adequately to threats to, or violations of, good research practices. Research results in this context include, but are not limited to, publications, data, metadata, protocols, code, software, images, artefacts, and other research materials and methods. The primary purpose of this European Code of Conduct is to help realise this responsibility and to serve the research community as a framework for self-regulation.

The research community encompasses a broad range of stakeholders including individual researchers, research teams, and research support staff. It also includes the institutions and organisations that enable research, such as research performing organisations, research funders, academies, learned societies, editors and publishers, and other relevant bodies. The European Code of Conduct describes professional, legal, societal, ethical, and moral responsibilities of the different actors in different settings, including those who define and implement the priorities and criteria for research funding, assessment, and publication. It acknowledges the role of institutions and organisations in facilitating good research practices through appropriate policies, processes, resources, and infrastructure.

Interpretation of the values and principles that regulate research may be affected by social, political, or technological developments and by changes in the research environment. Such changes since the 2017 edition of the European Code of Conduct include the development and application of technologies in research in new ways,

and the use and impact of social media to share and disseminate research results. The 2023 edition also takes account of changes in data management practices, the General Data Protection Regulation (GDPR), and recent developments in Open Science and research assessment. The 2023 edition of the European Code of Conduct also reflects a new awareness of the importance of research culture in enabling research integrity and implementing good research practices.

An effective European Code of Conduct for the research community promotes an ethical mindset. Its principles are relevant across the research system and in all disciplines and are applicable to publicly funded and private research. It can be the basis for local, national, and discipline-specific policies and guidelines, and applies to existing and new research practices such as citizen science or participatory research. Each stakeholder within the research community needs to take active responsibility for observing and promoting these practices and the principles that underpin them.

This document is an updated version of the 2017 edition of the European Code of Conduct for Research Integrity, developed by the European Federation of Academies of Sciences and Humanities (ALLEA). It is updated periodically to take account of evolving concerns and emerging areas so that it can continue to be fit for purpose in guiding the research community towards good research practice.

1. Principles

Good research practices are based on fundamental principles of research integrity. They guide individuals, institutions, and organisations in their work as well as in their engagement with the practical, ethical, and intellectual challenges inherent in research.

These principles include:

- ***Reliability*** in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources.

- ***Honesty*** in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way.

- ***Respect*** for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment.

- ***Accountability*** for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider societal impacts.

2. Good Research Practices

This section describes good research practices in the following contexts:

- Research Environment
- Training, Supervision, and Mentoring
- Research Procedures
- Safeguards
- Data Practices and Management
- Collaborative Working
- Publication, Dissemination, and Authorship
- Reviewing and Assessment

2.1 Research Environment

- Research institutions and organisations promote awareness and resource incentives to ensure a culture of research integrity.

- Research institutions and organisations create an environment of mutual respect and promote values such as equity, diversity, and inclusion.

- Research institutions and organisations create an environment free from undue pressures on researchers that allows them to work independently and according to the principles of good research practice.

- Research institutions and organisations demonstrate leadership in clear policies and procedures on good research practice and the transparent and proper handling of suspected research misconduct and violations of research integrity.

- Research institutions and organisations actively support researchers who receive threats and protect bona fide whistle-blowers, taking into account that early career and short-term employed researchers may be particularly vulnerable.

- Research institutions and organisations support appropriate infrastructure for the generation, management, and protection of data and research materials in all their forms that are necessary for reproducibility, traceability, and accountability.

2.2 Training, Supervision, and Mentoring

- Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology, analysis, dissemination, and communication.

- Research institutions and organisations develop appropriate and adequate training in ethics and research integrity to ensure that all concerned are made aware of the relevant codes and regulations and develop the necessary skills to apply these to their research.

- Senior researchers, research leaders, and supervisors mentor their team members, lead by example, and offer specific guidance and training to properly develop and structure their research activities.

- Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity.

2.3 Research Procedures

• Researchers take into account the state-of-the-art in relevant fields when developing research ideas.

• Researchers design, carry out, analyse, and document research in a careful, transparent, and well-considered manner.

• Research protocols take account of, and are sensitive to, relevant differences among research participants, such as age, gender, sex, culture, religion, worldview, ethnicity, geographical location, and social class.

• Researchers make proper and conscientious use of research funds.

• Researchers share their results in an open, honest, transparent, and accurate manner, and respect confidentiality of data or findings when legitimately required to do so.

• Researchers report their results and methods, including the use of external services or AI and automated tools, in a way that is compatible with the accepted norms of the discipline and facilitates verification or replication, where applicable.

2.4 Safeguards

• Researchers, research institutions, and organisations comply with relevant codes, guidelines, and regulations.

• Researchers handle research participants and subjects (be they human, animal, cultural, biological, environmental, or physical) and related data with respect and care, and in accordance with legal provisions and ethical principles.

• Researchers have due regard for the health, safety, and welfare of the community, of collaborators, and others connected with their research.

• Researchers recognise and weigh potential harms and risks relating to their research and its applications and mitigate possible negative impacts.

• Researchers overseeing projects that cross professional boundaries, such as citizen science or participatory research, take responsibility for ensuring research integrity standards, oversight, training, and safeguards.

2.5 Data Practices and Management

• Researchers, research institutions, and organisations ensure appropriate stewardship, curation, and preservation of all data, metadata, protocols, code, software, and other research materials for a reasonable and clearly stated period.

• Researchers, research institutions, and organisations ensure that access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Reusable) for data management.

• Researchers, research institutions, and organisations are transparent about how to access and gain permission to use data, metadata, protocols, code, software, and other research materials.

• Researchers inform research participants about how their data will be used, reused, accessed, stored, and deleted, in compliance with GDPR.

• Researchers, research institutions, and organisations acknowledge data, meta-data, protocols, code, software, and other research materials as legitimate and citable products of research.

• Researchers, research institutions, and organisations ensure that any contracts or agreements relating to research results include equitable and fair provisions for the management of their use, ownership, and protection under intellectual property rights.

2.6 Collaborative Working

• All partners in research collaborations take responsibility for the integrity of the research and its results.

• All partners in research collaborations formally agree at the outset, and monitor and adapt as necessary, the goals of the research and the process for communicating their research as transparently and openly as possible.

• All partners in research collaborations formally agree at the outset, and monitor and adapt as necessary, the expectations and standards concerning research integrity, the laws and regulations that will apply, protection of the intellectual property of collaborators, and procedures for handling conflicts and possible cases of misconduct.

• All partners in research collaborations are consulted and formally agree on submissions for publication of research results and other forms of dissemination or exploitation of the results.

2.7 Publication, Dissemination, and Authorship

• Authors formally agree on the sequence of authorship, acknowledging that authorship itself is based on: (1) a significant contribution to the design of the research, relevant data collection, its analysis, and/or interpretation; (2) drafting and/or critical reviewing the publication; (3) approval of the final publication; and (4) agreeing to be responsible for the content of the publication, unless specified otherwise in the publication.

• Authors include an 'Author Contribution Statement' in the final publication, where possible, to describe each author's responsibilities and contributions.

• Authors acknowledge important work and contributions of those who do not meet the criteria for authorship, including collaborators, assistants, and funders who have enabled the research.

• Authors disclose any financial and non-financial conflicts of interest as well as sources of support for the research or the publication.

• Authors and publishers promptly issue corrections or retract publications, if necessary, the retraction processes are clear and the reasons stated, and authors are given credit for issuing corrections post-publication.

• Authors, research institutions, publishers, funders, and the research community acknowledge that negative results can be as relevant as positive findings for publication and dissemination.

• Authors are accurate and honest in their communication to colleagues, policymakers, and society at large.

• Authors are transparent in their communication, outreach, and public engagement about assumptions and values influencing their research as well as the robustness of the evidence, including remaining uncertainties and knowledge gaps.

• Authors adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal, or in any other publication form, including preprint servers.

2.8 Reviewing and Assessment

• Researchers take seriously their commitment and responsibility to the research community through refereeing, reviewing, and assessment, and this work is recognised and rewarded by researchers, research institutions, and organisations.

• Researchers, research institutions, and organisations review and assess submissions for publication, funding, appointment, promotion, or reward in a transparent and justifiable manner, and disclose the use of AI and automated tools.

• Reviewers and editors declare any actual or perceived conflicts of interest and, when necessary, withdraw from involvement in discussion and decisions on publication, funding, appointment, promotion, or reward.

• Reviewers maintain confidentiality unless there is prior approval for disclosure.

• Reviewers and editors respect the rights of authors and applicants, and seek permission to make use of the ideas, data, or interpretations presented.

• Researchers, research institutions, and organisations adopt assessment practices that are based on principles of quality, knowledge advancement, and impact that go beyond quantitative indictors and take into account diversity, inclusiveness, openness, and collaboration where relevant.

3. Violations of Research Integrity

It is of crucial importance that researchers master the knowledge, methodologies, and ethical practices associated with their field. Failing to follow good research practices violates professional responsibilities. It damages the research processes, degrades relationships among researchers, undermines trust in and the credibility of research, wastes resources, and may expose research participants and subjects, users, society, or the environment to unnecessary harm.

3.1 Research Misconduct and other Unacceptable Practices

Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorisation) in proposing, performing, or reviewing research, or in reporting research results:

- ***Fabrication*** is making up data or results and recording them as if they were real.

- ***Falsification*** is manipulating research materials, equipment, images, or processes, or changing, omitting, or suppressing data or results without justification.

- ***Plagiarism*** is using other people's work or ideas without giving proper credit to the original source.

There are further violations of good research practice that distort the research record or damage the integrity of the research process or of researchers. In addition to violations of the good research practices set out in this European Code of Conduct, examples of other unacceptable practices include, but are not confined to:

- Allowing funders, sponsors, or others to jeopardise independence and impartiality in the research process or unbiased reporting of the results.

- Misusing seniority to encourage violations of research integrity or to advance one's own career.

- Delaying or inappropriately hampering the work of other researchers.

- Misusing statistics, for example to inappropriately suggest statistical significance.

- Hiding the use of AI or automated tools in the creation of content or drafting of publications.

- Withholding research data or results without justification.

- Chopping up research results with the specific aim of increasing the number of research publications ('salami publications').

- Citing selectively or inaccurately.

- Expanding unnecessarily the bibliography of a study to please editors, reviewers, or colleagues, or to manipulate bibliographic data.

- Manipulating authorship or denigrating the role of other researchers in publications.

- Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('self-plagiarism').

- Establishing, supporting, or deliberately using journals, publishers, events, or services that undermine the quality of research ('predatory' journals or conferences and paper mills).

- Participating in cartels of reviewers and authors colluding to review each other's publications.

- Misrepresenting research achievements, data, involvement, or interests.

- Accusing a researcher of misconduct or other violations in a malicious way.

- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.

In their most serious forms, unacceptable practices are sanctionable, but at the very least every effort must be made to prevent, discourage, and stop them through training, supervision, and mentoring and through the development of a positive and supportive research environment.

3.2 Dealing with Violations and Allegations of Misconduct

National and institutional guidelines differ as to how violations of good research practice and allegations of misconduct are handled. However, it is always in the interest of society and the research community that violations are handled in a fair, consistent, and transparent fashion. The following principles need to be incorporated into any investigation process:

- Anyone accused of research misconduct is presumed innocent until proven otherwise.

- Investigations are fair, comprehensive, and conducted expediently, without compromising accuracy, objectivity, or thoroughness.

- The parties involved in the investigation declare any conflict of interest that may arise during the investigation.

- Measures are taken to ensure that investigations are carried through to a conclusion.

- Investigations are conducted confidentially in order to protect those involved.

- Institutions protect the rights of bona fide whistle-blowers during investigations and ensure that their career prospects are not endangered.

- General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity.

- Persons accused of research misconduct are given full details of the allegation(s) and are allowed a fair process for responding to allegations and presenting evidence.

- Investigations into research misconduct consider the role of both individuals and institutions contributing to the breach of good research practice.

- Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.

- Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.

Annex 1: Key Resources

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Annex 2: Revision Process

The original European Code of Conduct for Research Integrity was developed in 2011 by the European Federation of Academies of Sciences and Humanities (ALLEA) and the European Science Foundation (ESF). From the start, the European Code of Conduct has been conceived as a living document that will be reviewed and revised as necessary to take account of evolving concerns and emerging areas, so that it can continue to serve the research community as a framework for good research practices.

A new version of the European Code of Conduct for Research Integrity was developed in 2017 by ALLEA. This revision was motivated by developments in, among others, the European research funding and regulatory landscapes, institutional responsibilities, communication and dissemination, the use of social media, review procedures, open access publishing, the use of repositories, and citizen involvement in research. The revision included extensive consultation among major stakeholders in European research, both public and private, to ensure a sense of shared ownership.

The present document is a revision of the 2017 European Code of Conduct for Research Integrity. This edition contains revisions to ensure that the European Code of Conduct remains fit for purpose and relevant to all disciplines and emerging areas of research or research practices. It takes account of changes in data management practices, the General Data Protection Regulation (GDPR), and recent developments in Open Science and research assessment. The changes reflect a new awareness of the importance of research culture in enabling research integrity and implementing good research practices. They also reflect greater awareness in the research community of mechanisms of discrimination and exclusion and the responsibility of all actors to promote equity, diversity, and inclusion.

Annex 3: List of Stakeholders

ALLEA would like to thank all stakeholder organisations and projects who generously provided detailed and insightful written feedback during the consultation process:

- Association of Learned and Professional Society Publishers (ALPSP)
- Committee on Publication Ethics (COPE)
- Conference of European Schools for Advanced Engineering Education and Research (CESAER)
- EU-LIFE
- European Association of Research and Technology Organisations (EARTO)
- European Association of Research Managers and Administrators (EARMA)
- European Chemical Society (EuChemS)
- European Commission
- European Group on Ethics in Science and New Technologies (EGE)
- European Industrial Research Management Association (EIRMA)
- European Molecular Biology Organization (EMBO)
- European Network of Research Ethics Committees (EUREC)
- European Network of Research Integrity Offices (ENRIO)
- European Physical Society (EPS)
- European University Association (EUA)
- EuroScience
- FoodDrinkEurope
- Global Young Academy (GYA)
- HYBRIDA
- International Association of Scientific, Technical and Medical Publishers (STM)
- League of European Research Universities (LERU)
- Open Access Scholarly Publishers Association (OASPA)
- Path2Integrity
- PRO-Ethics
- Responsible Open Science in Europe (ROSiE)
- Science Europe
- Standard Operating Procedures for Research Integrity (SOPs4RI)
- TechEthos
- The Guild
- UK Publishers Association
- Young European Research Universities Network (YERUN)

A detailed summary of the stakeholder feedback process and how this informed the 2023 revision can be found at https://allea.org/code-of-conduct/.

Annex 4: ALLEA Permanent Working Group on Science and Ethics

The ALLEA Permanent Working Group on Science and Ethics (PWGSE) is concerned with a wide range of 'internal' (within the research community) and 'external' (relations between science and society) issues. Since ethical considerations have been an essential component in the consolidation of a united Europe, and also in the creation of ALLEA, the PWGSE was established to bring together experts from academies across Europe and provide them with a platform for continuous debate on research ethics and research integrity.

The PWGSE has been extending its capacities and activities during recent years, in order to adequately fulfil its mission of collective deliberation on topics such as research integrity, ethics education in science and research training, ethics of scientific policy advice, trust in science, scientific misconduct, and plagiarism, among others.

Further topics recently addressed include ethical issues of open access publishing, reforming research assessment, and research on digital and (bio)medical technologies. Additionally, the group provides expertise for Horizon 2020 Science with and for Society (SwafS) and Horizon Europe WIDERA projects concerned with research ethics and integrity, and supports ALLEA membership of the TechEthos project, which addresses the ethics of new and emerging technologies with high socio-economic impact.

The PWGSE meets regularly and has also convened thematic meetings in wider settings, typically in partnerships with other relevant transnational organisations. The members of the PWGSE drew on their extensive network of experts and institutions for the successful execution of the revision process of "The European Code of Conduct for Research Integrity".

Members of the ALLEA Permanent Working Group on Science and Ethics

Maura Hiney (Chair) – Royal Irish Academy, ***Drafting Group***

László Fésüs – Hungarian Academy of Sciences

Göran Hermerén – Royal Swedish Academy of Letters, History and Antiquities, ***Drafting Group***

Lisa Maria Herzog – Global Young Academy, ***Drafting Group***

Anne Ruth Mackor – Royal Netherlands Academy of Arts and Sciences

Anne Sophie Meincke – Austrian Academy of Sciences

Bertil Emrah Oder – Bilim Akademisi (The Science Academy, Turkey)

Deborah Oughton – Norwegian Academy of Science and Letters, ***Drafting Group***

Roger Pfister – Swiss Academies of Arts and Sciences

Pere Puigdomènech – Royal Academy of Sciences and Arts of Barcelona, Institute for Catalan Studies (Spain)

Michael Quante – Union of German Academies of Sciences and Humanities

Nils-Eric Sahlin – Royal Swedish Academy of Letters, History and Antiquities

Camilla Serck-Hanssen – Norwegian Academy of Science and Letters

Raivo Uibo – Estonian Academy of Sciences

Els Van Damme – Royal Academy of Sciences, Letters and Arts of Belgium, ***Drafting Group***

Krista Varantola – Council of Finnish Academies, ***Drafting Group (Chair)***

Support to the PWGSE and Drafting Group: Mathijs Vleugel (ALLEA Secretariat)

More information about the ALLEA Permanent Working Group on Science and Ethics can be found at https://allea.org/research-integrity-and-research-ethics/.

ALLEA – All European Academies

ALLEA, the European Federation of Academies of Sciences and Humanities, represents more than 50 academies from nearly 40 EU and non-EU countries. Since its foundation in 1994, ALLEA speaks on behalf of its members on European and international stages, promotes science as a global public good, and facilitates scientific collaboration across borders and disciplines.

Academies are self-governing bodies of distinguished scientists drawn from all fields of scholarly inquiry. They contain a unique human resource of intellectual excellence, experience, and multidisciplinary knowledge dedicated to the advancement of science and scholarship in Europe and the world.

Jointly with its members, ALLEA seeks to improve the conditions for research, to provide the best independent and interdisciplinary science advice available, and to strengthen the role of science in society. In doing so, ALLEA channels the expertise of European academies for the benefit of the research community, decision-makers, and the public. Outputs include science-based advice in response to topics that are critical to society as well as activities to encourage scientific cooperation, reasoning, and values through public engagement.

ALLEA is a not-for-profit association and remains fully independent from political, religious, commercial, or ideological interests.

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European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Communicating EU research and innovation guidance for project participants

Version 1.0
25 September 2014

Disclaimer:
This document is aimed at assisting applicants and beneficiaries for Horizon 2020 funding. Its purpose is to explain the Horizon 2020 framework programme and the procedures to be followed. Please note that the final version of this document is still under discussion and may still change.

Research and Innovation

Communicating EU research and innovation guidance for project participants

Communication, why?

Communication, dissemination and exploitation — a team working on H2020 project is called upon to take part in various activities that will bring their research to the attention of as many relevant people as possible.

What we call here 'communication' is more than just an additional reporting burden. Europe's future economic growth and jobs will increasingly have to come from innovation in products, services and business models. With this in mind, communication about European research projects should aim to demonstrate the ways in which research and innovation is contributing to a European 'Innovation Union' and account for public spending by providing tangible proof that collaborative research adds value by:

- showing **how European collaboration has achieved more than would have otherwise been possible**, notably in achieving scientific excellence, contributing to competitiveness and solving societal challenges;
- showing **how the outcomes are relevant to our everyday lives**, by creating jobs, introducing novel technologies, or making our lives more comfortable in other ways;
- **making better use of the results**, by making sure they are taken up by decision-makers to influence policy-making and by industry and the scientific community to ensure follow-up.

There is an enormous difference between communication strategically planned with these objectives in mind and ad hoc efforts for the sake of meeting contractual requirements. How often do we hear people say 'let's make a video to inform everyone' before giving any thought to what is to be achieved? How often do we resort to facts and figures, assuming they will be enough to convince people? Your contractual obligations are important, but communication is not an end in itself and **quality** is expected. We hope this guide will help you avoid some common mistakes:

Common mistakes: non-strategic communication	Better practice: strategic communication
Focus on media before message	Targets, audience and message clarified before deciding on the media
Creative people come up with a 'cool' idea	Creative people plan to achieve desired outcomes
'Why' or 'what' questions are left unanswered	Objectives are clearly defined

What's in it for you?

With a little creativity, strategic communication can help publicise your work in such a way that you will profit. Suitably framed messages can help to:

- Increase the **success rate of your proposal** (provided you have a good communication and dissemination plan);
- Draw the attention of national governments, regional authorities and other public and private funding sources to the **need for and ultimate benefits of (your) research**;
- Attract the interest of potential **partners**;
- Encourage **talented students and scientists** to join your partner institutes and enterprises;
- Enhance your **reputation** and visibility at local, national and international level;
- Help the search for financial backers, licensees or industrial implementers to **exploit your results**;
- Generate **market demand** for the products or services developed.

This short guide will help you attain these outcomes. You will be inspired by some good practices emanating from fellow project coordinators. And you will find a helpful checklist for improving your own communication activities right from the start of your project.

Finally, the European Commission will be only too pleased to spread the word about the good work of the projects it is supporting. Once you have some worthwhile material available, there are many ways in which we can help you pass on the message.

Good practices from projects like yours

'Communication is a way to keep all partners actively involved in the project'
Jan Willem Gunnink, project coordinator, COMET:

'For me it's only natural to put considerable effort into communicating the outcomes of our work. We receive massive amounts of taxpayers' money to carry out fantastic projects. Letting the public know how this money is spent is an obvious obligation. In addition, many of our consortium partners share a commercial interest in exploiting our results. So we invest up to 10% of our resources in communication and dissemination activities.

The communication plan that we drafted at the start of our project includes a variety of tools and ideas to help ensure that Europe's manufacturing industries quickly understand the objectives of our COMET project and the potential impact of using robots for cost-effective, high precision manufacturing in factories of the future. It also includes the consortium's procedures for disseminating information: partners always get the chance to check whether the information is correct or perhaps confidential.

Communication is certainly a way to keep all partners actively involved in the project. We decided to invest in small gadgets and materials with the project's name on them. You'd be surprised of the effect a simple sticker displaying the project's name on a robot can have. Similarly, we made sure that banners with the project's name were available right from the beginning.

Most of the work is carried out jointly with the marketing department of the coordinating company, but we do ask all work package leaders to contribute a little to generating noise around our project. For example, they each submit one 'tweet' a month for our Twitter account. We also have about 1000 subscribers to a digital newsletter and we make sure all partners get their share of visibility. This is resulting in numerous expressions of interest in our products. I think it's somehow similar to how washing powder is advertised: show up everywhere and it pays off.

The best advertisement, however, is demonstrating a working product. This spring we will organise what we call 'open training days' in several countries. Anyone interested will be welcome to learn about our work and see a demonstration of what our advanced robots can do. Communication is not something that you give to someone as a task on the side; it's really one of the most important aspects of running a successful project.'

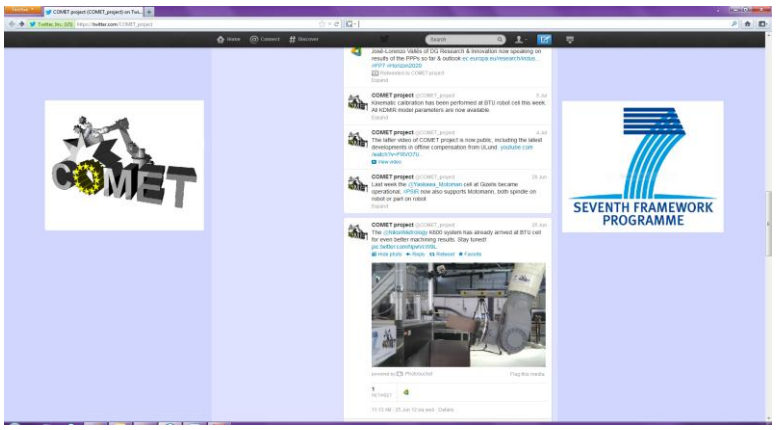

Twitter feed: https://twitter.com/COMET_project

‘People are even taking it on themselves to call our scientists’
Marilou Ramos Pamplona, project coordinator, Lupa:

‘In our project, we use information about dogs’ genetics to improve our understanding of diseases that occur in both dogs and humans. For the collection of DNA samples our scientists spend a lot of time communicating with dog owners, breeding clubs, vets and people at dog shows.

Our communication activity is very decentralised, as it must take into account the specifics of each of the twelve countries that we work in. All of our scientists have direct access to flyers and posters. They keep an eye on relevant events in their regions, contact dog shows to ask for a booth and talk to as many dog owners and breeders as they can.

We publish information about our work in popular journals for pet lovers, all the way through the project and as soon as results become available. In our articles, we ask people to submit samples and we explain our findings. Those can be used to screen dogs for particular diseases, so they are of interest to this same community. The scientific credibility of our findings obviously relies on our research basis. Our communication with the broader public is never secondary to publishing in high-profile journals like *Nature* or *Science*. Quite the contrary: we issue a press release for general publications whenever our work is taken up by journals of good standing.

A prerequisite of communication is to acquire a good understanding of the ways your target audience will respond to your message. Some dog lovers fear that our research might hurt dogs. Dealing with animal welfare issues right at the start of our presentations helps to ensure a positive response. I am impressed to see that our approach does not just encourage people to let us take DNA samples; they are even taking it on themselves to call the scientists whenever they find a disease in one of their breeds.’

It is worthwhile to collaborate with others to amplify your work

Michele Cocco, project coordinator, Argomarine:

'Our project deals with signalling oil spills and predicting their evolution. Rather than focusing exclusively on the small circle of scientists working in this field, we have also tried to involve people to whom the preservation of the marine environment — and hence our project — is relevant. For example, we have been organising local workshops with coastguards and municipalities. We have also produced an applet for smartphones that can be used by people at sea — like recreational sailors, fishermen and scuba divers — to report oil spills when they find any.

Sending out a press release is a good way to promote these actions. For us, it was helpful to include a link to a video clip that introduced our work. We hired professionals for that, so that the imagery and style were very accessible. Professionals have also recently helped us in creating a social media presence, which has definitely increased our visibility. I think it would be advisable to dedicate a budget to this type of assistance right from the start of a project.

Being active in communication meant that I, as the coordinator, encouraged all the partners to think about what we could do. It also means having the contacts and resources to react in a timely and efficient way whenever something happens that could be relevant to your work. In our case, right after the accident with the Costa Concordia ship, the partners discussed whether we could somehow respond. Since one of the main concerns at the time was possible oil leakages, we decided to make a simulation and issued a press release. This resulted in plenty of reactions.

Finally, we found it worthwhile to profit from existing meetings and conferences and to collaborate with others to amplify our work. As an example, our final workshop will take place at the Maritime Days, where thousands of people will be present. We have also established contacts with another EU-funded research project working on a closely related topic. I expect that we will organise a cross-project demonstration soon.'

Project video: http://youtu.be/_5biJLVZjxg

The key to a successful media campaign is in the planning

Colin Smith (media officer) and Emile Greenhalgh (project coordinator), STORAGE:

'The STORAGE project has attracted quite a lot of attention, ranging from *Der Spiegel* to the *New York Times*. As a result, there has been considerable interest in the technologies being developed and the subsequent impact they could have on future automotive applications (and beyond). In fact, Volvo has estimated that the advertising exposure from the STORAGE project has been worth € 112 million, from the press release (January 2010) up to May 2011. If you set that off against the cost, it is good value for money! To give an idea of what it involves for a team of researchers:

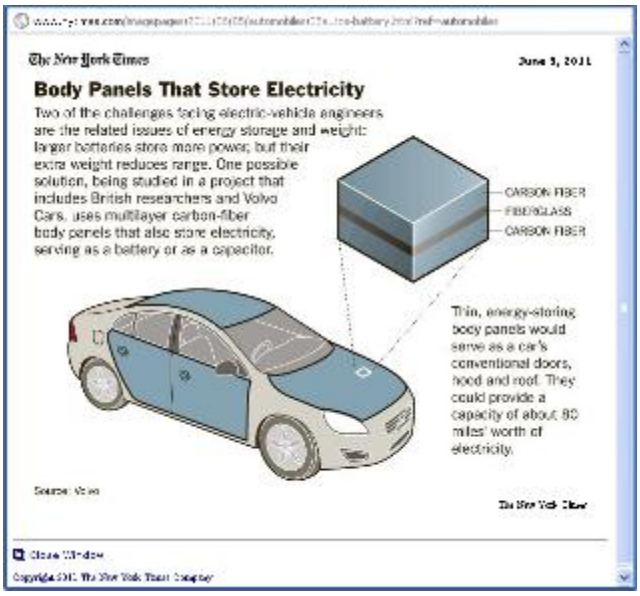

- Initial meeting (1 hour) — This involves meeting with your press officer to discuss the project. The press officer will need to take notes for the press release and work out the campaign timeline.
- Editing process (1 hour) — A draft release will come back to you for approval. You will need to look at the release to ensure the copy is accurate.
- Speaking to the press — As a rule of thumb, always remember that broadcast (TV) will take the most time and online media may take the least amount of time as they tend to use press releases verbatim.
- Interviews (1-2 hours) — If your story has a really interesting visual element, always remember that the broadcast press may want to come and interview you in a lab. You may need to invest extra time preparing the lab for filming.
- Long-term support — Be prepared to put some long-term support into your press campaign if it has been very successful, as you may get further coverage in other countries over a longer period of time. You may also get calls for collaborations and enquiries about your research from funders and other stakeholders. Develop a plan for responding to enquiries in a timely way. For example, a web page you can refer people to, which will reduce the time spent repeating general information to callers.

After issuing our press release, we received a huge number of queries from the press as well as approaches from industry for more information about STORAGE. For example, we received an invitation and funding to visit Singapore and Canada (Montreal), organised by the FCO to present the technologies to researchers and industries in these countries, with the aim of initiating future collaborations. Similarly, exposure from STORAGE led to the project coordinator being invited by Tourism London to represent London.

If we were to give a single tip for future project coordinators, it would be this: the key to a successful media campaign is in the planning. Before you even begin a campaign, it is important that the key people involved all agree on the answers to the following:

- What do we want to achieve with this publicity? For example, do we want more students to apply to our department? Do we want funding? Do we want the public to learn about this interesting area of research and innovation?
- Who are our audiences? Are they schoolchildren, other academics, policymakers, business, industry or the general public interested in science?
- How will we achieve our objectives?'

‘It is very important to know who you want to reach’

Oscar Valdemoros Tobia, project coordinator, EPOSbed:

‘Small and medium-sized companies do not always have a lot of resources. I am doing a large share of the communication work myself, together with the person in charge of marketing and communication at our company. Despite this restraint, our project has been quite successfully communicated, not least because we profited a lot from the support we got from European and local authorities.

As an example, we closely involved local politicians in our project. When the head of a public institution comes to visit your factory, he will automatically be followed by the press. In this way it was easier for us to get press coverage. It is important to involve decision-makers and politicians anyway, inviting them to your meetings and keeping them informed, because they can help pave the way for your next steps. In our case, this helped us to arrange for the real-life testing of our product in a public hospital.

The European Commission supported us by introducing our work to Euronews, who produced a professional video about EPOSbed. We simply distributed the video and uploaded it to our YouTube channel. This has resulted in calls from throughout Europe, and also from North America and Brazil.

The technologies we use are complex — our medical beds rely on artificial intelligence — but that doesn’t mean that it’s impossible to explain our work to people. The bed we developed has a clear medical significance. It can, for example, be used by people who are homebound and do not receive full-time care. Anyone can grasp the actual application of the technology.

One thing I learned through working on this project is that it is very important to know who you want to reach. You need to focus your efforts on a clear target audience to maximise your investment. We spent a considerable amount of time and money on attending one large European exhibition. Although it did give us wide exposure, the people there were mostly from academia. We have realised that it is more important for us at this stage to go to places where we can find potential customers. I now prefer going to trade fairs instead.’

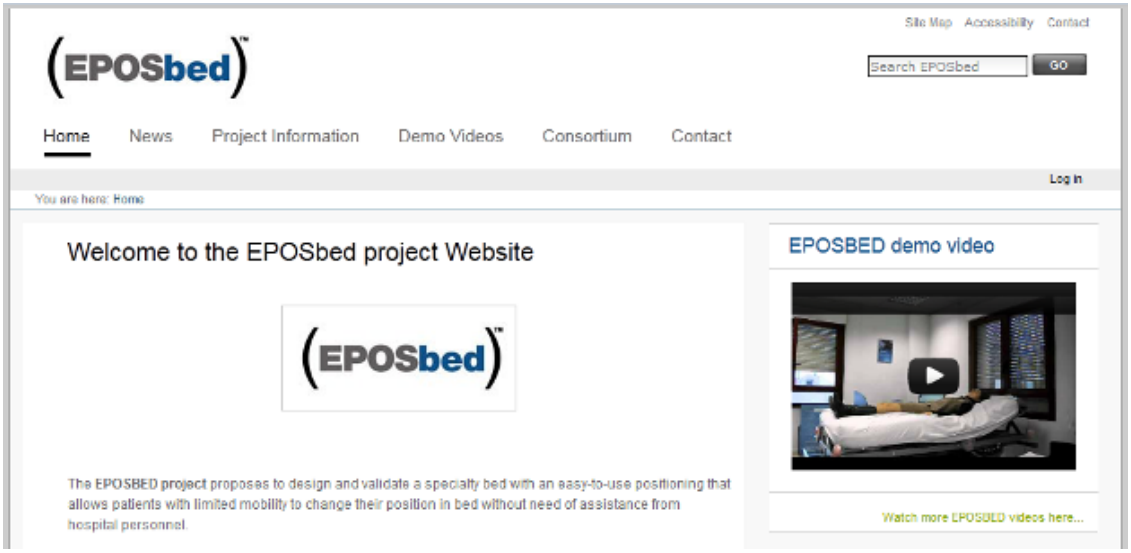

Website: http://eposbed.pera.com/

Build your own communication strategy – a checklist

A. Ensure good management

1 Have resources been allocated (time and money)?

- Does your proposal include a work package on communication?
- Have you prepared a communication strategy and timeline?
- Does the communication element of the project involve all consortium partners (and their respective staff, including researchers)?
- Is there awareness that communication is a continuous process, not a one-time effort when the project ends?
- Are you ready for the unexpected? Have you thought about how to respond effectively to such things as publication in high-ranking journals or a sudden new event related to the project's theme?

2 Are professional communicators involved?

- Have resources been allocated to professional assistance with the drafting of press releases, graphic design, maintenance of the website and other communication tasks? Larger institutions usually have an in-house capacity for this.
- Have you considered taking any training in the field of communication or including a communication expert in your team?

A word of warning

When working with external professionals, the costs of hiring them need to be justifiable economically and in terms of effectiveness. Shopping around among several service providers can assure best value for money.

We are aware that from time to time participants in projects funded under the framework programmes are contacted — often by telephone — by organisations seeking **payment in return for publishing** information on the work being done in their projects. As with 'cold calling' in general, the claims and assertions made should be treated with appropriate caution before deciding on the best course of action. Contrary to some of the 'sales pitches' used, **these publications and their services have not been endorsed by the Commission**. Common tactics to secure business include vague references to high-level contributions from decision-makers, or making project participants believe that their activities have been singled out on account of special merit, which may not be the case.

3 Is continuity ensured?

- Are there any arrangements to ensure that information will not be lost once the project comes to an end?
- Does the project provide for any feedback loops back to the European Commission that can help with amplifying the message, for example by notifying an event, or before publishing a press release?

B. Define your goals and objectives

1 Are there any goals and objectives?

- Have the final and intermediate communication aims of the project been specified, what impact is intended, what reaction or change is expected from the target audience? For example:
    - Receiving feedback or engaging in dialogue
    - Influencing the attitudes of decision-makers
    - Having people make a decision or take action
    - Ensuring that the project outcomes will be taken into production

2 Are your goals and objectives neither too ambitious nor too weak?

- Is there a deadline by which the goals should be achieved, taking into account different stages of the research and possible intermediary outcomes?
- Are the objectives specific and measurable, rather than vague? Does the project envisage ways of measuring its communication efforts and impact? For example:
  - Evidence of debates in the media
  - Evidence of new funders for your area
  - Evidence of transfer of research and innovation into practice (patents, prototypes, licenses)
  - Number and turnover of new products, practices or procedures developed, based on your research outcomes
  - Number of articles in the press
  - Number of people asking for feedback or more information
  - Number of references in scientific publications
  - Participation in project events and seminars
  - Speaker evaluations from conference presentations
  - Survey of end-users
  - Trends in website visits

C. Pick your audience

1 Is your audience well defined?

- Is each target audience a relatively homogenous group of people (not: 'the public at large' or 'all stakeholders')?
- Can the indicated audiences be further specified? For example: from 'the general public' to 'female citizens commuting by train to work in one of the EU-10 countries' or from 'decision-makers' to 'Europarliamentarians involved in the design of the new transport policy 2013'.

2 Does it include all relevant target groups?

- Can your audience help you reach your objectives?
  - Who has an interest in your research?
  - Who can contribute to your work?
  - Who would be interested in learning about the project's findings?
  - Who could or will be affected directly by the outcomes of the research?
  - Who are not directly involved, but could have influence elsewhere?
- Does the project aim to address both a direct audience and intermediaries to reach more people?
- What about the possibility of audiences at local, regional, national and European level?
- Is the audience external (not restricted to consortium partners)?

For each audience, you should work on a distinct strategy using targeted messages, means and language.

D. Choose your message

1 Is it news?

- Why do we need to know? What will change? What solutions are you offering? What makes the issue urgent? What are the consequences if no action is taken?
- Have you tried to stir your audience's imagination and emotions?
- How does your work relate to everyday life? Does it link to any broader societal issue? Rather than focusing only on the provision of factual information, is your project research positioned within a broader socio-economic and policy context, so that it will be easier to explain the results and their relevance to policymakers and citizens?

Tell a story, don't just list facts

A story is an effective way to make people remember your message. Why not tell one to disseminate your results?

Which stories work best? A good story consists of a succession of events with a beginning, a middle and an end, a scene setter and a plot, a climax and a conclusion, all of this in a rich context. It is hence more than a list of results achieved. A good story is one with which others can identify, with the project content as a basis, and focused on a person (for example: the researcher). Such stories also allow your message to be conveyed through shared values that will touch people's hearts and provoke emotion, and the promise of a better future.

You have forgotten how to tell a story? There are plenty of resources on the internet to help you. Just search for 'storytelling'.

2 Are you connecting to what your audience wants to know? See through your audience's eyes:

- What do they already know about the topic?
- What do they think about it?
- Do they need information and/or persuasion?
- Have you tested your message?

3 Are you connecting to your own communication objectives?

E. Use the right medium and means

1 Do they reach the audience?

- Are you working at the right level (local, regional, national)?
- Are you using dissemination partners and multipliers? Dissemination partners can help amplify and multiply a message. Rather than aiming to build an audience from scratch, the project should indicate which partners to use and how.

2 Do they go beyond the obvious?

- If input or contributions are needed, are there mechanisms in place to make communication interactive so as to obtain responses?
- Are you taking into account the different ways to communicate?

Examples of interpersonal , two-way communication	**Examples of mass media, one-way communication**
- Dialogues, face-to-face conversation - Group discussions - Conferences - Brokerage events - School visits - Tours - Round tables - Exhibitions - Meetings - Workshops - Open days - Demonstrations and prototypes - Telephone calls - E-mail information service (question and answer) - Internet debate	- Newspapers and magazines - Press releases - Newsletters - Manuals - Brochures, booklets, flyers - Letters - Radio - Television - Video - Posters - Stickers - Banners - Billboards - Website - Policy briefs
Smaller audience, lower costs, more effort (more effect?!) Interactive, good for acquiring input Flexible (easy to change tone, strategy and content)	Potentially large audience Uses the credibility of the mass media

F. Evaluate your efforts

- Go back to your goals and objectives. Have they been reached? What lessons have you learned?

How can we help you?

Whether your project is organising a public event or press demonstration, or has just delivered a set of exciting results: the European Commission may be able to help you spread the word. Do not forget to inform your Project Officer about interesting topics, news and events concerning your project. We can help raise your profile. In addition, several freely accessible tools are at your disposal:

Publications

Horizon Magazine http://horizon-magazine.eu/	HORIZON is the EU Research & Innovation e-magazine. It is covering the latest developments in EU funded research and innovation, communicating the priorities and achievements of EU-funded research, its impact on citizens' lives and its contribution to the EU goals of smart and sustainable growth. It is written by independent journalists on behalf of DG Research & Innovation and is updated at least three times a week with new articles.	For story suggestions or questions to the editor, e-mail: RTD-PUBLICATIONS@ec.europa.eu
Project stories https://ec.europa.eu/programmes/horizon2020/en/newsroom/551/	Articles about selected EU-funded research projects, which led to breakthroughs, discoveries and world-firsts by taking great ideas from the lab to the market, at the same time contributing to economic growth and creating jobs, and tackling societal challenges.	Please contact your Project Officer about any interesting project outcomes. Furthermore a journalist contracted by the European Commission may contact you.
research*eu results magazine www.cordis.europa.eu/research-eu/magazine_en.html	This print magazine features highlights from the EU-funded research and development projects. It is published 10 times per year in English, and covers mainly the research areas of biology and medicine, Social sciences and humanities, energy and transport, environment and society, IT and telecommunications, industrial technologies and space.	Please contact your Project Officer about any interesting project outcomes. Furthermore a journalist contracted by the European Commission may contact you.
research*eu focus www.cordis.europa.eu/research-eu/research-focus_en.html	This print magazine covers in each issue a specific topic of research interest. It features articles on EU policies, initiatives, programmes and projects related to research and technological development and their exploitation. It is published at irregular intervals up to six times a year in English. Exceptionally, it may be available in other European languages as well.	Please contact your Project Officer about any interesting project outcomes. A journalist contracted by the European Commission may contact you.
Newsletters www.ec.europa.eu/research/index.cfm?pg=publications&lg=en	Newsletters are published by the European Commission for different research areas.	Please contact your Project Officer to get more information on how to publish something in a specific newsletter.
Co-publications or editorial partnerships	The European Commission works with private publishers and international organisations to promote the dissemination of relevant publications. Scientific publications and books, including conference proceedings, may be co-published in this way.	Please contact your Project Officer to discuss the possibilities.

Audiovisual

Futuris Magazine http://www.euronews.net/sci-tech/futuris/	Short documentary-style television magazine in various languages, appearing at least 22 times on the EuroNews channel throughout Europe.	EuroNews has editorial independence, but we are in contact with them to suggest good stories. Since it is television, this is interesting for visually appealing projects and demonstration activities. Please contact your Project Officer if you would like your project to be put forward.

Events

Events on the Commission's Research & Innovation website www.ec.europa.eu/research/index.cfm?pg=conferences&filter=all	This website displays research and innovation-related conferences and events.	You can submit an event by using the "Suggest an event" functionality which is available on the left-hand side of the website.
Events on the CORDIS website www.cordis.europa.eu/news/home_en.html	This website displays research-related conferences and events.	Submitting an event requires one-time registration on the CORDIS website
Conferences and events organised by the European Commission	Throughout the year, the European Commission (co-organises a variety of conferences, both in Brussels and elsewhere. These may include exhibition areas or sessions at which you could present your work.	Please contact your Project Officer if you have suitable exhibition items (prototypes, demonstrators)

Open access scientific publishing

Openaire www.openaire.eu	The Open Access Infrastructure for Research in Europe is an electronic gateway for peer-reviewed articles and other important scientific publications (pre-prints or conference publications).	You may submit your publications to www.openaire.eu

Online news

Headlines on the Commission's Research & Innovation website www.ec.europa.eu/research/infocentre/all_headlines_en.cfm	Headlines report on recent developments in research and innovation in Europe and beyond and are devoted purely to projects. Suitable stories to be published on the site are selected on a daily basis.	You may submit your news (by means of a press release, event announcement or otherwise) via CORDIS wire http://cordis.europa.eu/wire
CORDIS Wire http://cordis.europa.eu/wire/	CORDIS Wire provides registered users with a simple interface to publish articles on the CORDIS website's News and Events service. All articles are moderated by CORDIS editors before publication.	Requires one-time registration at http://cordis.europa.eu/wire

Sources and resources

This list includes a number of sources that we have found useful as a starting point. It is by no means exhaustive. In fact, it is likely that guides dealing specifically with your research field exist. A quick search or a check with your national academy of sciences may also reveal guides on scientific communication that have been written in your language.

- **AAAS (American Association for the Advancement of Science)**
  http://communicatingscience.aaas.org/
  The AAAS Center for Public Engagement with Science and Technology provides resources for scientists and engineers, to help researchers communicate more broadly with the public. *Communicating Science: Tools for Scientists and Engineers* includes learning the basics of communication, how-to tips for working with reporters, strategies for using online media effectively, and more.

- **British Science Association 'Collective Memory'**
  http://collectivememory.britishscienceassociation.org/
  The Collective Memory is a database of evaluations of a diverse range of science communication initiatives. Explore the database to learn about past successes, pick up useful tips for planning events and read about various types of evaluation.

- **Carrada, Giovanni** (2006), *A Scientist's Survival Kit; Communicating Science. EU Publications Office, Luxembourg.*

- **European Commission** (2004), *European Research - A guide to successful communications*. EU Publications Office, Luxembourg.

- **European Commission** (2008). *Scientific evidence for policymaking*. Publications Office, Luxembourg.

- **European Commission** (2010). *Communicating research for evidence-based policymaking*. A practical guide for researchers in socio-economic sciences and humanities. Publications Office, Luxembourg.

- **European Science Events Association (Eusea)**
  http://www.eusea.info/
  The European association for organisations for European Science Communication Events (SCE). It is a platform to exchange experiences about the organisation of such informal learning events in Europe.

- **Story Collider**
  http://storycollider.org (podcasts)
  From finding awe in Hubble images to visiting the doctor, science is everywhere in our lives. Whether we wear a white lab coat or haven't seen a test tube since eighth grade, science affects and changes us. We all have a story about science, and at The Story Collider, we want to hear those stories.

- **UK Royal Society** (2006), *Communicating the results of new scientific research to the public – Science and the public interest*.
  Focusing in particular on the ins and outs of communicating about risk and probability.

- **Voice of Young Science** (2006). *Standing up for science. A guide to the media for early career scientists.* Sense about Science, London.

DECISION authorising the use of lump sum contributions and unit contributions for Marie Skłodowska-Curie actions under the Horizon Europe Programme

HISTORY OF CHANGES		
VERSION	PUBLICATION DATE	CHANGE
1.0	15.03.2021	Initial version (Ares (2021)1857830)
2.0	20.07.2023	Changes made to initial version of 15 March 2021 via amending Decision of 20 July 2023 (Ares(2023)5064589) , i.e.: • Updated section 3.2.3: Removed sentence "*For one off costs, the number of months shall correspond to 1.*" • Updated footnotes 13,28, and 30: Specified the methodology applicable to calculate the special needs allowance.
3.0	17.05.2024	• Versioning table: Added version 2.0 and the related changes brought to the initial version of 15 March 2021 by amending Decision of 20 July 2023 • Updated title of section 3.2, i.e. added "and update" • Introduced a subheading under section 3.2.1, i.e. "*Calls for proposals before the mid-term review (calls under Horizon Europe Work Programme 2021-2022 and 2023 calls under Horizon Europe Work Programme 2023-2024)*" • Added footnote 26 "*The monthly living allowance is subject to adjustment based on the country-specific correction coefficient to ensure equal treatment and purchasing power parity for all researchers"* under section 3.2.1 • (Previous) section 3.2.4 moved up to became new section 3.2.2 and (previous) section 3.2.2 moved done to became new section 3.2.5Added "<u>for calls under Horizon Europe Work Programme 2021-2022 and 2023 calls under Horizon Europe Work Programme 2023-2024</u>" above the table in section 3.2.2

		• Created new section 3.2.3 (new unit contributions amounts, methodology and justification) and (previous) section 3.2.3 moved done to became new section 3.2.6 • Created new section 3.2. (methodology to calculate the Country-specific Correction Coefficients) (Previous) section 3.2. moved down to became new section 3.2.7 • Introduced in section 3.2. a clarification on updating the unit contributions in case of high inflation • Updated section 3.2.1: Added scope of application of unit costs authorised before the mid-term review on p 16 Moved paragraph related to the country specific correction coefficient from point (1)(a) to section 3.2.4 • Added footnote 28 Update section 3.2.: • Reworded the beginning of the first sentence. Replaced “salary” by “long-term allowance”
4.0	10.07.2025	• Introduced a new action – Choose Europe for Science • Update all the relevant sections of the Decision to include Choose Europe for Science, including introducing new unit contributions for this action, namely Choose Europe for Science COFUND allowance, long-term leave allowance, and special needs allowance in the following sections: 1; 1.2(3); 2.1; 3.2.3; 3.2.4; 4.
5.0	dd.mm.2025	• Revised the preamble with an updated reference and footnote to the new 2024 EU Financial Regulation. • Updated the following sections to include references to lump sum contributions for the Support to the Marie Curie Alumni Association: , 1(a), 2, 2.1, 3.1, 4. • Section 3.2.2 and section 3.2.3 were merged. It affected the numbering of the

		subsequent sections i.e. 3.2.4 became 3.2.3; 3.2.5 became 3.2.4; 3.2.6 became 3.2.5; 3.2.7 became 3.2.6 • Updated the following sections to include references to the new Choose Europe for Science 2027: 1.2(1), 1.2(2), 1.2(3)(a), 3.2.2, 3.2.4, 4. • Deleted the word "onwards" in section 3.2.3. • Added a title for the summary table for the 2024 calls under Horizon Europe Work Programme 2023-2024 and for MSCA COFUND Choose Europe for Science as from Horizon Europe Work Programme 2025 in section 3.2.3. • Added a new paragraph and summary table in section 3.2.2., outlining the biennial adjustment of the unit contributions for MSCA Doctoral Networks, MSCA Postdoctoral Fellowships, MSCA Staff Exchanges, MSCA COFUND, as well as the new unit contribution scheme for Choose Europe for Science under the Horizon Europe Work Programme 2026-2027. Added a footnote in the same table specifying that the COFUND call of 2027 will only cover doctoral programmes. • Added "2025" for Choose Europe for Science 2025 in sections: 1.2(3)(a) and 4. • Deleted "COFUND" after Choose Europe for Science in the following sections: preamble, 1(b), 1.2(3), 12.1, 3.2.3, 4. • Deleted "types of" in preamble (2). • Replaced "Instead" with "The" in section 3.1. • Clarified the frequency of adjusting the unit contributions in line with inflation, allowing the Commission to biennially update the unit contributions based on the recommendation of the 2024 mid-term review in the following sections: preamble (6), 3.2.2, 3.2.6. • Clarified the frequency of adjusting the country-specific correction coefficients (CCCs) in line with inflation, allowing

		the Commission to biennially update the CCCs based on the recommendation of the 2024 mid-term review in section 3.2.3. • Rephrased the relevant paragraph in section 3.2.6, to allow the Commission to adjust all the unit contributions annually in line with the Belgian and Luxembourg inflation of the previous years by adding “all”, “annually”, and changing “2023” to “previous year’s”. • Added a clarification regarding the Eurostat methodology to determine the country-specific coefficient in section 3.2.3.

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation– and in particular Articles 21 and 36(6) thereof,

Having regard to the Council Decision establishing the specific programme implementing Horizon Europe – the Framework Programme for Research and Innovation – and in particular Article 2(1) rationale for Marie Skłodowska-Curie actions, Annex I, Pillar I Excellent Science thereof,

Having regard to the Council Regulation establishing the Research and Training Programme of the European Atomic Energy Community for the period 2021-2025 complementing Horizon Europe – the Framework Programme for Research and Innovation, and repealing the Council Regulation (Euratom) No 2018/1563 of 15 October 2018, and in particular Articles 6 and 9 thereof,

Having regard to Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union[1], and in particular Articles 125 and 184 thereof,

Whereas:

(1) Simplification as a central aim of the Horizon Europe Framework Programme needs to be reflected in its design, rules, financial management and implementation.

(2) In order to further simplify the implementation of Marie Skłodowska-Curie actions under the Horizon Europe Framework Programme, it is necessary to authorise the use of lump sum contributions and unit contributions for the following actions: MSCA Doctoral Networks, MSCA Postdoctoral Fellowships, MSCA Staff Exchanges, MSCA COFUND, MSCA Choose Europe for Science, MSCA and Citizens, and Support to the Marie Curie Alumni Association.

(3) Simpler funding rules reduce the administrative costs for participation and contribute to the prevention and reduction of financial errors. In this respect, the use of lump sum contributions and unit contributions is necessary to simplify the calculation of grant amounts, leading to a significant decrease in the workload of both beneficiaries and the granting authority as well as to accelerated payment procedures.

(4) The amending Decision of 20 July 2023 introduced minor changes to Decision of 15 March 2021 authorising the use of lump sum contributions and unit contributions for Marie Skłodowska-Curie actions under the Horizon Europe Programme.

(5) For ease of reference and consolidation purpose, amending Decision of 20 July 2023 should be integrated into the Decision of 15 March 2021.

[1] Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast)

(6) Following a mid-term review of the MSCA lump sum and unit contributions, it is appropriate to increase the monthly living allowance and mobility allowance in MSCA Doctoral Networks and Postdoctoral Fellowships, the top-up allowance in MSCA Staff Exchanges and the COFUND allowance in MSCA COFUND, as well as to adjust the methodology to calculate the country-specific correction coefficients applicable to the living allowances to take account of the high inflation during 2021-2023.

THE FOLLOWING HAS BEEN DECIDED:

Sole Article

The use of the Union contribution in the form of lump sum contributions and unit contributions is authorised for Marie Skłodowska-Curie actions (Doctoral Networks, Postdoctoral Fellowships, Staff Exchanges, COFUND, Choose Europe for Science, MSCA and Citizens, Support to the Marie Curie Alumni Association, under the Horizon Europe Framework Programme, for the reasons and under the conditions set out in the Annex.

Done at Brussels,

Pia AHRENKILDE HANSEN
Director-General

Annex

1. Forms of Union contribution and categories of costs covered

The Union contribution for Marie Skłodowska-Curie actions (MSCA) under the Horizon Europe Framework programme shall exclusively take the form of lump sum contributions and unit contributions, as follows:

a) costs for the implementation of MSCA and Citizens European Researchers' Night actions and Support to the Marie Curie Alumni Association under the Horizon Europe Work Programme 2026-2027 shall take the form of lump sum contributions;

b) costs for recruited researchers/seconded staff members and institutional costs in MSCA Doctoral Networks, Postdoctoral Fellowships, Staff Exchanges, COFUND and Choose Europe for Science actions shall take the form of unit contributions.

1.1. Categories of eligible costs covered by the lump sum contributions

The categories of eligible costs covered by the lump sum contributions are the following:

a) direct costs: personnel costs, subcontracting costs, purchase costs and other cost categories (e.g. financial support to third parties);

b) indirect costs.

The amounts of the lump sum contributions to be used shall be calculated in accordance with point 3.

1.2. Categories of eligible costs covered by the unit contributions

The categories of eligible costs covered by the unit contributions are the following:

(1) Costs of recruited researchers/seconded staff members

For MSCA Doctoral Networks, Postdoctoral Fellowships and Choose Europe for Science 2027 costs of recruited researchers

(a) A **living allowance** to cover personnel costs for the employment of researchers with full social security coverage.

(b) A **mobility allowance** to cover additional, private mobility-related costs, e.g. travel and accommodation costs.

(c) A **family allowance** to contribute to mobility-related costs of researchers with family obligations.

(d) A **long-term leave allowance** to cover personnel costs incurred by the beneficiaries in case of the researchers' leave, including maternity, paternity, parental, sick or special leave.

(e) A **special needs allowance** to contribute to the additional costs for the acquisition of special needs items and services for researchers with disabilities[2], e.g. assistance by third persons, adaptation of work environment, additional travel/transportation costs.

For MSCA Staff Exchanges – costs of seconded staff members

(a) A **top-up allowance** to contribute to travel, accommodation and subsistence costs related to the secondment.

(b) A **special needs allowance** to contribute to the additional costs for the acquisition of special needs items and services for staff members with disabilities[3], e.g. assistance by third persons, adaptation of work environment, additional travel/transportation costs.

(2) Institutional costs

For MSCA Doctoral Networks, Postdoctoral Fellowships, Staff Exchanges and Choose Europe for Science 2027

(a) Costs related to the **training and research** expenses of researchers/staff members as well as costs related to the **transfer of knowledge and networking** activities, e.g. costs for participation in conferences, trips related to work on the action, training or language courses, seminars, lab material, books, library records, publication costs, visa-related fees and travel expenses.

(b) Costs related to the **management** of the action (e.g. personnel costs for project management/coordination) and **indirect costs**.

(3) Costs of recruited researchers and institutional costs for MSCA COFUND and Choose Europe for Science 2025

(a) A **COFUND allowance and COFUND Choose Europe for Science allowance** to contribute to:

i. costs of the researchers including the personnel costs for employment with full social security coverage, as well as the private mobility-related costs (e.g. travel and accommodation costs) and, if applicable, the mobility-related costs of researchers with family obligations, and/or

ii. costs related to the training, research expenses, transfer of knowledge and networking activities of researchers (e.g. costs for participation in conferences, trips related to work on the action, training or language courses, seminars, lab material, books, library records, publication costs, visa-related fees and travel expenses), as well as costs of managing the action (e.g. personnel costs for project management) and indirect costs.

(b) A **long-term leave allowance** to contribute to the personnel costs incurred by the beneficiary in case of the researchers' leave, including maternity, paternity, parental, sick or special leave.

[2] Long-term physical, mental, intellectual, or sensory impairments.
[3] Idem.

(c) A **special needs allowance** to contribute to the additional costs for the acquisition of special needs items and services for researchers with disabilities[4], e.g. assistance by third persons, adaptation of work environment, additional travel/transportation costs.

The amounts of the unit contributions to be used shall be calculated in accordance with point 3.

2. Justification

The use of lump sum and unit contributions considerably simplifies, streamlines and reduces the time needed for the financial management of actions, both at granting authority as well as beneficiary levels. The European Court of Auditors has highlighted the potential of lump sums, as a major step to decrease administrative burden for beneficiaries and has already called for an intensification of the testing on lump sums in the course of Horizon 2020[5].

Marie Skłodowska-Curie actions proved to be particularly suited to the use of unit contributions, given their successful implementation under Horizon 2020 and FP7. Consequently, the Commission has confirmed experience with, and a very solid database of, final grants using a reimbursement system based on unit contributions, as well as evidence from two studies on which to base its assessment.

The European Researchers' Night, on the other hand, has been financed on a real-cost basis throughout the 7th Framework Programme and Horizon 2020. This led to a heavy administrative burden, with substantial resources allocated to planning and reporting of financial inputs. The adoption of lump sum contributions for the European Researchers' Night under the MSCA and Citizens action is in line with the objective of simplification at both MSCA and Horizon Europe level. It will allow a better allocation of resources to the activities, a stronger focus on the outputs and results of the funded actions but also lead to a reduction of the management and indirect costs[6].

Similarly, the Support to the Marie Curie Alumni Association has historically been funded via grants based on actual costs. This led to a considerable administrative burden for the Association, diverting time and resources to extensive financial planning and reporting. By transitioning to lump sum financing, the Association can more effectively allocate resources directly to its core activities. This shift will enhance the overall efficiency and effectiveness of the association's operations and align with the objective of simplification under Horizon Europe.

2.1. Nature of the supported actions

MSCA Doctoral Networks aim to train creative, entrepreneurial, innovative and resilient doctoral candidates and will raise the attractiveness and excellence of doctoral training in Europe. They will equip researchers with the right combination of research-related and transferable competences and provide them with enhanced career perspectives in both the

[4] Idem.

[5] See Special report available at: https://www.eca.europa.eu/Lists/ECADocuments/SR18_28/SR_HORIZON_2020_EN.pdf

[6] The Commission supports this assessment based on evidence provided by the consultancy study implemented in view of Horizon Europe. Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020, p. 95: "Introducing a lump sum system for the NIGHT action would contribute to simplified management of the projects and reduction of the administrative burden to beneficiaries, which would have a direct impact on the reduction of project management and indirect costs."

academic and non-academic sectors through international, interdisciplinary and inter-sectoral mobility combined with an innovation-oriented mind-set.

The goal of **MSCA Postdoctoral Fellowships** is to enhance the creative and innovative potential of researchers holding a PhD who wish to acquire new skills through advanced training, international, interdisciplinary and inter-sectoral mobility.

MSCA Staff Exchanges promote innovative international, inter-sectoral and interdisciplinary collaboration in research and innovation through exchanging research, technical, administrative and managerial staff, and sharing knowledge and ideas at all stages of the innovation chain, and help turn ideas into innovative products, services or processes.

MSCA COFUND co-finances new or existing doctoral programmes and postdoctoral fellowship schemes at national, regional or international level with the aim to spread the best practices of the MSCA including international, inter-sectoral and interdisciplinary research training, as well as transnational and cross-sectoral mobility of researchers at all stages of their career.

MSCA Choose Europe for Science co-finances talent recruitment programmes that will provide researchers holding a doctoral degree with excellent research, teaching and/or management opportunities to lead them to concrete and attractive career prospects. This will have an impact on the enhancement of human resources in R&I at institutional, regional, national or international level.

MSCA and Citizens, through the **European Researchers' Night**, aims to bring research and researchers closer to the public at large, to increase awareness of research and innovation activities, to boost public recognition of science and research education, to show the role of the researcher in and for the society and economy, and the impact of researchers' work on citizens' daily lives, as well as to raise the interest of young people for research and scientific careers.

Support to the Marie Curie Alumni Association funds a global network of researchers and professionals who have benefitted from MSCA funding. The Association promotes lifelong career development, networking, and advocacy enabling alumni to act as MSCA ambassadors and promoters within global and innovation community, supporting diverse career trajectories within and beyond research. It fosters collaboration across disciplines and career stages, facilitates discussions on science policy in Europe, and enhances public engagement with research. It also carries out surveys and provides valuable feedback to the European Commission on the MSCA programme and related policies.

At the outset of Horizon 2020, the MSCA unit cost system was adopted by Commission Decision[7] on the basis of statistically robust historical data. Following a mid-term review[8], the rates of the living allowance and top-up allowance were updated based on the evidence provided by a consultancy study[9]. For Horizon Europe, the MSCA funding modalities were

[7] Commission Decision C(2013)8194 of 27.11.2013: http://ec.europa.eu/transparency/regdoc/rep/3/2013/EN/3-2013-8194-EN-F1-1.PDF

[8] Commission Decision C(2017)6855 of 16.10.2017: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[9] Mid-term review of Marie Skłodowska-Curie actions unit costs, Final study report, February 2017: https://publications.europa.eu/en/publication-detail/-/publication/0f44192e-5499-11e7-a5ca-01aa75ed71a1/language-en/format-PDF/source-31288412

again reviewed through a second consultancy study[10], to ensure that the MSCA continue to offer competitive, attractive and appropriate rates to researchers and organisations, and to provide evidence for the establishment of a) additional unit costs for two new cost categories, and b) simplified contributions for the European Researchers' Night in the form of lump sums.

The use of unit contributions is justified by the very high number of applications and has proved to be an appropriate form of financing to simplify the administrative burden and financing conditions of supported actions. While actual cost-based grants involve complex rules related to budget transfers and variations with project implementation subsequently entailing a lot of accounting compliance, a unit cost-based approach provides the opportunity to put added weight on the quality of the results as well as on the impact of the support. Such an approach also leads to more qualitative actions with verifiable results in line with the objectives of the MSCA rather than emphasising the financial and administrative aspects of the research training, career development, knowledge exchange and outreach. Moreover, the use of unit contributions leads to simplification for applicants, ensuring certainty and transparency of funding levels in case of selection and proper implementation of the action.

Similarly, the use of lump sum contributions for the European Researchers' Night under MSCA and Citizens appears justified and appropriate. The administrative burden and workload related to the financial reporting in Horizon 2020 proved to be disproportionate. The simplified management of the lump sum-based grants will have a direct impact on the reduction of management and administrative costs[11]. As a consequence, the resources will be allocated more efficiently to the activities, outputs and results of the funded actions, improving their quality and exploitation. At the same time, beneficiaries will face less complex financial reporting, and the number of adjustments arising from ex-post audits should be reduced.

Lump sum contributions are also the most appropriate form of funding for the Support to the Marie Curie Alumni Association, based on experience with the two grants based on actual costs and feedback from the Association. Similarly to the MSCA and Citizens action, the administrative burden associated with the financial reporting based on actual costs have been deemed excessive for the Association and have diverted time away from the Association`s primary activities of promoting scientific collaboration and networking. Transitioning to lump sum funding will enable more efficient management of resources, allowing for a better allocation of resources to the activities and a stronger focus on the outputs and results of the funded actions.

2.2. Risks of irregularities and fraud and costs of control

The extended use of simplified forms of grants under the MSCA may imply certain risks of irregularities and fraud. Therefore, it is still important to have effective internal control procedures for fraud prevention and reporting of irregularities.

Reporting and control in MSCA will focus on the implementation of the supported activity and the achieved results rather than on the eligibility of costs incurred, reducing the workload

[10] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: https://op.europa.eu/en/publication-detail/-/publication/8900e099-8a89-11ea-812f-01aa75ed71a1/language-en

[11] Up to an average of 30%. Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020, p. 95.

and scope for fraud or error of both participants and managing body. The whole monitoring system is set up in a manner to ensure efficiency and cost-effectiveness of the controls. The European Research Executive Agency will be exclusively responsible for management aspects of the MSCA, encompassing several measures to ensure compliance of beneficiaries with contractual obligations, including on-site visits and reinforced monitoring of actions. In addition, the possibilities for ex-post controls further guarantees the sufficient quality of the outputs and reducing the opportunity for error or fraud.

As statistically proven over the seven-year period of Horizon 2020, and due to its clear-cut nature, the funding system of MSCA is very resistant to irregularities and fraud. In fact, the MSCA remained much simpler compared to other Horizon 2020 instruments when it comes to the financing modalities for mobility grants. As a consequence, the intrinsic risk on legality and regularity errors in cost claims leading to unjustified Union funding has been very low and does thus not justify additional control and audit mechanism nor their costs.

3. Method to determine and update the amount of the Union contribution in the form of lump sum contributions and unit contributions

In order to determine the amounts of the EU contribution for all MSCA actions in Horizon Europe, the Commission launched a study[12] to review the unit cost system used in Horizon 2020. The study was implemented between June 2019 and February 2020. The objectives of the study were to: (i) review the existing unit costs and determine the future rates ensuring that they remain competitive, attractive and appropriate for both researchers and institutions; (ii) establish new unit contributions for additional cost categories, notably costs to be borne by the employer in case of maternity, paternity, parental, sick or special leave and costs arising from special needs of researchers/staff members with disabilities[13]; and (iii) analyse historical data of the European Researchers' Night and recommend the most appropriate simplified form of contribution and determine its amount.

3.1. Method to determine the amount of the lump sum contributions

Notwithstanding the fact that historical data on European Researchers' Night actions implemented under FP7 and Horizon 2020 has been analysed, it was concluded that a fixed lump sum would not be appropriate. This is because the costs of the action have been found to vary widely (from EUR 30 000 to over EUR 200 000), with 85% of the final amounts falling between EUR 50 000 and EUR 150 000. This was considered too wide a variation on which to base an average amount. While additional analysis showed that it could be possible to derive differentiated amounts based on the size of the event, it was also felt that the outputs for the events on which the differentiated amount could be paid would be too difficult to reliably demonstrate by the beneficiary and carried a high risk of errors and consequent grant reductions/rejections. This risk for the beneficiary lead to the conclusion that pre-fixed lump sum contributions are not appropriate for the action.

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[12] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: https://op.europa.eu/en/publication-detail/-/publication/8900e099-8a89-11ea-812f-01aa75ed71a1/language-en

[13] Under Horizon 2020, where applicable, the additional costs arising from disabilities of researchers/seconded staff members are (partially) covered by a Special Needs Scheme allowance (SNS). From 2019 until 2021, the SNS was subject to a lump sum allowance paid through a linked Coordination and Support Action (CSA). As from 2022, the SNS is subject to a unit cost top-up mechanism calculated as follows: {{Total amount of authorised SNS allowance for the action} divided by {the number of person-months starting from the approval of the request for the SNS allowance until the end of the action duration (*'remaining person-months'*)}}. In both cases, the SNS allowance can amount to a maximum of EUR 60 000 per researcher/staff member.

Based on the positive experience with the lump sum implementation of the MSCA and Citizens action, along with experience from the two previous Support to the Marie Curie Alumni Association grants based on actual costs and feedback received from the Association, it was concluded that a fixed lump sum would not be appropriate for the Support to the Marie Curie Alumni Association. The experience has shown that the annual cost for the action can vary which would make it difficult to establish a fixed lump sum.Therefore, the same methodology used for the MSCA and Citizens will apply to determine the amount of lump sum contributions for the Support to the Marie Curie Alumni Association.

The method to determine the amount of the lump sum contributions for the MSCA and Citizens action and the Support to the Marie Curie Alumni Association shall be based on the estimated budget of the beneficiary as follows:

Applicants shall propose the amount of the lump sum contribution on the basis of their estimated actual direct and indirect costs. They shall provide a breakdown of the lump sum contribution showing the share per work package and, within each work package, the share assigned to each beneficiary and affiliated entity (if any). The proposal shall describe in detail the activities covered by each work package and all related resources.

For the MSCA and Citizens action, if applicants intend to organise two editions of the European Researchers' Night, they shall indicate as well the total costs per edition.

The detailed cost estimation per work package and per beneficiary and affiliated entity (if any) shall include only costs that would be considered eligible in an actual costs grant. Ineligible costs shall not be included. Applicants shall declare that they have followed their own accounting practices for the preparation of the estimated budget.

The estimated eligible costs for the action shall be broken down by budget category:

- A. Personnel costs
- B. Subcontracting costs
- C. Purchase costs
- D. Other cost categories
- E. Indirect costs.

Indirect costs shall be calculated by applying a flat rate of 25% to the direct cost categories that qualify for the calculation of indirect costs under the Horizon Europe rules.

Proposals shall be evaluated according to the standard Horizon Europe procedures with the help of independent expert evaluators. The experts shall assess the quality of the proposals in terms of excellence, expected impact and quality and efficiency of the implementation. For each work package, experts with the necessary financial knowhow shall, in addition, check the budget estimate on the basis of relevant benchmarks on costs and resources such as market prices, statistical data or historical data and assess whether the resources proposed and the split of lump sum shares allows achieving the activities and expected outputs.

Following proposal evaluation, the authorising officer will establish the amount of the lump sum taking into account the findings of the assessment carried out (including in case of recommendations from the expert evaluators). If cost items are adapted, the lump sum contribution and the lump sum breakdown shall be modified accordingly during grant preparation.

The final lump sum contribution shall be included in the grant agreement as the maximum grant amount. It shall be calculated by applying a maximum of 100% funding rate to the total estimated eligible costs in the detailed budget table, in compliance with Article 34 of the Horizon Europe Rules for Participation.

3.2. Method to determine and update the unit contributions

3.2.1. Method to update the unit costs authorised in Horizon 2020

Calls for proposals before the mid-term review (calls under Horizon Europe Work Programme 2021-2022 and 2023 calls under Horizon Europe Work Programme 2023-2024)

The unit costs applicable to the MSCA Innovative Training Networks (ITN), Individual Fellowships (IF), Research and Innovation Staff Exchange (RISE) and Co-funding of regional, national and international programmes (COFUND) at the outset of Horizon 2020 were based on reliable historical data of eligible costs collected from actions financed under FP7 between 2007 and 2013, as well as on the findings of the FP7 Marie Curie actions interim evaluation and the MORE2 study[14]. As a method of revision, a mid-term review was organised through a consultancy study comparing the adopted unit costs to real costs and researchers' salary development in Europe and beyond[15]. Based on the study findings, the existing methodology was maintained, but the researchers and seconded staff members unit costs were adjusted to specifically increase the monthly living allowance (for MSCA ITN and IF researchers), as well as the monthly top-up allowance (for MSCA RISE seconded staff members) by 5%, calculated on the basis of Belgian inflation over the years 2014-2017[16].

In view of establishing the rates of the unit contributions in Horizon Europe, the Commission organised a second review of the existing unit costs through a new consultancy study (constituting an 'expert judgement' for the purposes of Article 181 of the Financial Regulation). The study entailed a large survey involving 2 690 individual researchers and 1 223 organisations from Horizon 2020 MSCA projects[17], as well as interviews with representatives from universities, stakeholder organisations and MSCA National Contact Points. The survey ensured a balanced geographical coverage, and adequately represented all MSCA actions and scientific fields, paying due attention to the gender balance of the surveyed researchers. Additionally, the study also performed desk research to collect information on researchers' salaries and research costs and compare the MSCA unit costs to other competitive fellowships programmes. Evidence was gathered through review of literature and EU sources, including Euridyce[18] and the MORE3 study[19].

The study confirmed the relevance and soundness of the methodology and structure of the existing MSCA unit costs. Overall, it concluded that the funding provided by the MSCA appeared competitive compared to other programmes and generally appropriate in relation to

[14] MORE2 – Support for continued data collection and analysis concerning mobility patterns and career paths of researchers: Deliverable 8 – Final report MORE2, August 2013.

[15] The study also encompassed an analysis of trends in researchers' salaries based on the MORE2 study on mobility patterns and career paths of researchers and internationally comparable data. Mid-term review of Marie Skłodowska-Curie actions unit costs, Final study report, February 2017, p. 12-13.

[16] Commission Decision C(2017)6855 of 16.10.2017: http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit-costs_msca_en.pdf

[17] ITN, IF, RISE and COFUND researchers and beneficiaries. A significant number of projects involved in the survey were completed, i.e. they had already received the payment of the balance. Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: p. 102.

[18] https://eacea.ec.europa.eu/national-policies/eurydice/home_en

[19] https://www.more3.eu/

real research expenditures. However, to remain attractive in the future, while at the same time maintaining its appropriateness and ensuring the respect of the sound financial management principle, the study recommended to update the units for the recruited researchers and for the seconded staff members, and at the same time to partially rebalance the contribution to institutional costs.

The study found that the rates of the **living allowance** in MSCA ITN and IF were, overall, competitive and attractive under Horizon 2020. However, to maintain researchers' purchasing power under Horizon Europe, and in line with the recommendations arising from the previous mid-term review, the study recommended to update the living allowances in both MSCA Doctoral Networks and Postdoctoral Fellowships based on the Belgian inflation over the years 2018-2020 by 4%[20]. The updated amounts were rounded to the nearest ten. At the same time, the study also confirmed the country-specific correction coefficients to be a valid adjustment tool to ensure equal treatment and purchasing power parity, based on a well-established methodology and, overall, corresponding well to the differences in living costs and the levels of purchasing power in different countries.

The study also highlighted how in some circumstances organisations have to top up the EU contribution in order to achieve competitive and attractive level of remuneration for the fellows. This is particularly relevant for the most expensive regions in Europe, and generally due to comparatively high relocation and rental costs. Evidence shows as well that such mobility-related costs are notably high in comparison to the researcher's overall income, when s/he has family obligations. Therefore, while the study advised to keep the **mobility allowance** unchanged, it also recommended to significantly increase the **family allowance** for MSCA Doctoral Networks and Postdoctoral Fellowships by approximately 30% (or by EUR 160), calculated as the difference between the perceived lack of income reported by MSCA researchers without (EUR 50 on average) and those with family obligations (EUR 210 on average)[21]. The recommended increase will support further the MSCA principles of inclusiveness, fairness and gender-balance, and will be budget-efficient by benefitting a targeted share of the MSCA researchers' population.

With regard to the **top-up allowance**, the amount set for MSCA RISE under Horizon 2020 appeared insufficient to fully support secondments to expensive regions of staff members coming from lower-income countries. The study quantified EUR 300 as the additional amount needed to ensure attractiveness of the rates for secondments from low-income third countries. However, the study also highlighted the need to weigh this amount against the level of overall attractiveness of the rates for all types of secondments. In the light of all these considerations, the study recommended an increase of the top-up allowance for the Horizon Europe Staff Exchanges scheme by up to 10%[22].

As per the **researchers' unit costs in COFUND**, the study found that the attractiveness of the scheme in Horizon 2020 was affected by the need to co-fund the actions in order to ensure that fellows receive the required minimum remuneration. The latter proved to be particularly

[20] The review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe refers to a forecasted inflation rate of 5.5% (see Final report, April 2020, p. 75). The 4% is calculated on the basis of the 2020 annual inflation rate for Belgium, available at the beginning of November 2020 (Eurostat, Euro indicators, 152/2020 - 16 October 2020).

[21] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: p. 49.

[22] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: p. 52.

costly in low-income countries, including the so-called Widening Countries[23]. The study therefore recommended to increase the contribution to the researchers' costs in order to cover in full the required minimum remuneration. At the same time, it confirmed the appropriateness of the methodology to determine such a remuneration as 70% of the sum of the living and mobility allowances of researchers funded under MSCA Doctoral Networks and Postdoctoral Fellowships.

For the **institutional unit costs**, the study found that, overall, the Horizon 2020 rates are appropriate and deemed attractive and competitive by participating organisations. The answers to the survey did not reveal differences in terms of satisfaction among different country groups or scientific areas. Nevertheless, the analysis of real cost data collected through the survey and emerged from the desk research showed that the level of funding under Horizon 2020 offers margin for adaptations, which allow to distribute the MSCA budget in a fairer and more balanced way among the schemes and within the single actions.

The study compared the **research, training and networking costs** provided in Horizon 2020 **ITN and IF** actions and found that the ones in IF are comparatively less adequate in relation to real costs. While a higher contribution for ITN actions is necessary in view of the higher training needs, the difference between the two schemes is not justified in full as experienced/postdoctoral researchers typically incur higher costs for e.g. publishing. In the light of this finding, the study recommended to decrease by EUR 200 the contribution to research, training and networking costs in MSCA Doctoral Networks, and to increase by an equivalent amount the contribution to the same costs in MSCA Postdoctoral Fellowships. For the **management and indirect costs**, the study did not find grounds for a change.

For the institutional unit costs provided for **RISE** actions under Horizon 2020, different results emerged, especially in consideration of the particular nature of the action. The study showed that the unit costs for **management and indirect costs** appear to be too low compared to the real costs incurred by the participating organisations. It therefore suggested a possible increase of such a contribution by up to EUR 500[24]. At the same time, the study also highlighted that funding provided for **research, training and networking costs**, frequently used to increase the top-up allowance in Horizon 2020 RISE actions, could be reduced in MSCA Staff Exchanges, notably as this scheme would focus under Horizon Europe more on the added value of the research collaboration than on the research itself. Therefore, these two categories of institutional unit costs could be rebalanced for the MSCA Staff Exchanges by up to EUR 500.

Finally, with regard to the contribution to **management costs** in **COFUND**, the study concluded that this contribution could be eliminated in Horizon Europe, to compensate for the increased contribution to the researchers' costs.

On the basis of these considerations, the following unit contributions, expressed in person-months and corresponding to the country-specific correction coefficient of 100% for Belgium and Luxembourg, are applicable to the Marie Skłodowska-Curie Actions calls under Horizon Europe Work Programme 2021-2022 and 2023 calls under Horizon Europe Work Programme 2023-2024:

[23] Low R&I performing countries as defined under Article 2 of Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation.

[24] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: p. 76. The data analysis shows that real costs will still be higher compared to the EU contribution.

(1) **Contributions for recruited researchers/seconded staff members:**

(a) The monthly **living allowance**[25] for researchers recruited under an employment contract or equivalent direct contract in Doctoral Networks and Postdoctoral Fellowships shall be fixed at EUR 3 400 and EUR 5 080 respectively.

In the exceptional case of recruitment under a fixed-amount fellowship agreement with minimum social security coverage, the living allowance shall be reduced by 50%.

(b) The monthly **mobility allowance** shall be fixed at EUR 600.

(c) The monthly **family allowance** shall be fixed at EUR 660.

(d) The monthly **top-up allowance** for seconded staff members in Staff Exchanges shall be fixed at EUR 2 300.

(2) **Institutional contributions**

(a) The unit contribution related to the training and research expenses of researchers as well as to the costs related to the transfer of knowledge and networking (i.e. **research, training and networking contribution**) shall be fixed at EUR 1 600 per month for Doctoral Networks, at EUR 1 000 per month for Postdoctoral Fellowships, and at EUR 1 300 per month for Staff Exchanges.

(b) The unit contribution related to managing and running the action (i.e. **management and indirect contribution**) shall be fixed at EUR 1 200 per month for Doctoral Networks, at EUR 650 per month for Postdoctoral Fellowships and at EUR 1 000 per month for Staff Exchanges.

In case a beneficiary already receives an operating grant financed by the EU or the Euratom budget in the same period, indirect costs are ineligible, unless the beneficiary can demonstrate that the operating grant does not cover any costs of the action grant in question. The analysis of FP7 Marie Curie statistical data showed that on average the amount of indirect costs was equal to the amount of management costs. Therefore, the unit contribution applicable to beneficiaries in receipt of an operating grant shall be half of the amount determined in the first paragraph of point 3.2.1(2)(b) above.

The contributions for recruited researchers/seconded staff members and the institutional contributions include a 100% funding rate in compliance with Article 34 of the Horizon Europe Rules for Participation.

(3) **COFUND allowance**

This monthly unit contribution shall be set at EUR 2 800 (i.e. 4 000 x 70% funding rate) for doctoral researchers and EUR 3 980 (i.e. 5 680 x 70% funding rate) for postdoctoral researchers, i.e. as the sum of the living and mobility allowances listed above. This unit shall be used as contribution to the remuneration, mobility and, when

[25] The monthly living allowance is subject to adjustment based on the country-specific correction coefficient to ensure equal treatment and purchasing power parity for all researchers.

applicable, family costs of the researchers, as well as to the costs related to training, research, transfer of knowledge and networking, and the costs related to managing and running the action, provided that the researchers, recruited under an employment contract or equivalent direct contract, receive a minimum remuneration of at least EUR 2 800 (for doctoral programmes) and EUR 3 980 (for postdoctoral programmes). The minimum remuneration requirement shall be fulfilled even if the remuneration costs are fully funded from other sources (including other EU programmes).

In the exceptional case of recruitment under a fixed-amount fellowship agreement with minimum social security coverage, the COFUND allowance shall be reduced by 50%.

The COFUND allowance may be used in full to provide financial support to third parties.

Summary table of the unit contributions applicable to MSCA Doctoral Networks, Postdoctoral Fellowships, Staff Exchanges and COFUND for calls under Horizon Europe Work Programme 2021-2022 and 2023 calls under Horizon Europe Work Programme 2023-2024:

Marie Skłodowska-Curie Action	**Contributions for recruited researchers/ seconded staff members (in person/month)**					**Institutional contributions (in person/month)**		**Contributions for recruited researchers and institutional contributions (in person/month)**
	Living allowance	**Mobility allowance**	**Family allowance**	**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance**
Doctoral Networks	EUR 3 400	EUR 600	EUR 660	EUR 4 000 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 600	EUR 1 200	N/A
Postdoctoral Fellowships	EUR 5 080	EUR 600	EUR 660	EUR 5 680 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 000	EUR 650	N/A
	Top-up allowance			**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance**
Staff Exchanges	EUR 2 300			N/A	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 300	EUR 1 000	N/A
	Living allowance			**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance**
COFUND	N/A			EUR 2 800 or 3 980 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500,	N/A	N/A	EUR 2 800 for doctoral programmes or EUR 3 980 for

			35 500, 47 500 or 60 000 x (1/number of months)			postdoctoral programmes

3.2.2. Method to update the unit costs authorised in Horizon Europe

Calls for proposals after the mid-term review (as from 2024 calls under Horizon Europe Work Programme 2023-2024 onwards)

A third review of the MSCA lump sum and unit contributions (mid-term review)[26] was performed by external service providers between May 2023 and October 2023 to assess the extent to which the unit contributions matched the real costs.

The contractor conducted a survey[27] that was completed by over 5500 of MSCA researchers and 1000 coordinators of MSCA projects as well as expert interviews and desk research on trends in researchers' salaries and other categories of costs relevant for the MSCA.

The mid-term review study determined that the MSCA unit contributions remain relatively competitive and attractive compared to other fellowship schemes. However, it was established that the overall purchasing power parity of the MSCA allowances has decreased due to the rise in inflation since the start of Horizon Europe.

It became apparent that in certain countries the **living allowance rates** in MSCA DN and PF are not considered to be as competitive as they used to, while in some cases they do not meet the salary levels set out in collective agreements.[28] As a result, some organisations had to complement the EU contribution to reach national salary levels or to guarantee competitive remuneration to researchers.

The study therefore recommended adjusting the living allowance according to the cumulative Belgian HICP inflation rate over the period from January 2021 to October 2023 by 18%. It also recommended biennial updates of the living allowance to respond to trends in inflation and to ensure competitiveness and attractiveness of the programme.

While the study advised to keep the **family allowance** unchanged due to its significant increase by approximately 30% at the start of Horizon Europe, it also recommended adjusting the **mobility allowance** by 18% on the basis of Belgian inflation over the years 2021-2023 to cover the substantial rise in rent prices and one-off relocation costs, particularly affecting researchers with families.

When it comes to the **top-up allowance** for MSCA SE, the surveyed staff did not consider the current top-up allowance as sufficient to cover their costs linked to the secondment. This issue was especially pronounced for researchers going from lower income countries to EU non-widening countries and high-income third countries.

As with the living allowances, the study concluded that the decrease in satisfaction is primarily linked to inflation, which has had a severe impact on travel, accommodation and subsistence costs. The study therefore recommended increasing the top-up allowance by 18% in line with inflation in Belgium during the period 2021-2023. It also recommended biennial

[26] Review of the MSCA lump sum and unit contributions, Final report, February 2024 https://data.europa.eu/doi/10.2766/344144

[27] The survey covered projects funded under Horzion Europe and H2020 that did not fall within the scope of the previous study. The sample of the respondents represents a broad geographical coverage that is proportionate to the overall participation in MSCA.

[28] This is particularly the case in some EU non-widening countries (e.g., Austria, Belgium, France, the Netherlands), associated non-widening countries (e.g., Norway) and high-income third countries (e.g., the US and Switzerland).

updates of the top-up allowances to respond to trends in inflation and to ensure competitiveness and attractiveness of the programme.

In relation to the **COFUND allowance**, the study established that the high inflation over the past few years is also hindering the competitiveness and attractiveness of the COFUND allowance particularly in high-income countries and recommended increasing the allowance by 18% in line with inflation during the period 2021-2023. It also recommended biennial updates of the COFUND allowance to respond to trends in inflation and to ensure competitiveness and attractiveness of the programme.

Although Choose Europe for Science was not part of the mid-term study as it was introduced in Horizon Europe Work Programme 2023-2025, the amount of the **COFUND Choose Europe for Science allowance** was set as the sum of the MSCA Postdoctoral Fellowships living allowance and mobility allowance, which were subject to assessment in the mid-term review study.

More precisely, the EU contribution consists of a sum of the mobility allowance and the living allowance at a rate that is applicable to the MSCA Postdoctoral Fellowships, namely EUR 6700 for the first phase (24 or 36 months) while in the second phase of the project the beneficiary institution must cover the remaining 24 months of the project.

The COFUND Choose Europe for Science allowance operates in the same manner as the COFUND allowance in terms of the possibility to use it across all cost categories.

While the inflation had a negative impact on **research, training and networking** unit contribution, the survey results indicated that the MSCA beneficiaries have a significant capacity to provide additional funding, especially when it comes to research and training activities. Furthermore, the satisfaction of researchers with research, training and networking unit contribution remains extremely high. In view of the limited budget of the MSCA programme and the increase in the researchers' unit contributions, the research, training and networking unit contribution shall remain unchanged.

As to the **management and indirect unit contributions**, the study found that the level of satisfaction is decreasing due to the high inflation and increase in prices, particularly affecting the Doctoral Networks. In this regard, around one third of the surveyed organisations reported having secured additional funds to cover the increased costs. Nevertheless, the study found that most organisations had no issue with providing additional resources if necessary.

Considering the above and given that the recommended increase in living allowances and top-up allowance would have a positive spillover effect for institutions such as the lesser need to complement researchers' salaries, the study recommended to keep the institutional unit contributions unchanged for all actions.

The Commission will continue to closely monitor the unit contributions to ensure that they respect sound financial management, the co-financing and absence of double funding principles, remain sufficiently competitive and attractive to excellent researchers and institutions.

Based on the results of the mid-term review[29], the unit contributions for MSCA Doctoral Networks, MSCA Postdoctoral Fellowships, MSCA Staff Exchanges and MSCA COFUND as from 2024 calls under Horizon Europe Work Programme 2023-2024 and for MSCA

[29] Review of the MSCA lump sum and unit contributions, Final report, February 2024 https://data.europa.eu/doi/10.2766/344144

Choose Europe for Science 2025 as from Horizon Europe Work Programme 2025, the unit contributions are as follows:

Summary table of the unit contributions applicable to MSCA Doctoral Networks, Postdoctoral Fellowships, Staff Exchanges and COFUND for 2024 and 2025 calls under Horizon Europe Work Programme 2023-2025 and for MSCA Choose Europe for Science as from Horizon Europe Work Programme 2025

Marie Skłodowska-Curie Action	**Contributions for recruited researchers/ seconded staff members (in person/month)**					**Institutional contributions (in person/month)**		**Contributions for recruited researchers and institutional contributions (in person/month)**
	Living allowance	**Mobility allowance**	**Family allowance**	**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**
Doctoral Networks	EUR 4 010	EUR 710	EUR 660	EUR 4 720 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 600	EUR 1 200	N/A
Postdoctoral Fellowships	EUR 5 990	EUR 710	EUR 660	EUR 6 700 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 000	EUR 650	N/A
	Top-up allowance			**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**
Staff Exchanges	EUR 2 710			N/A	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 300	EUR 1 000	N/A
	Living allowance			**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**
COFUND	N/A			EUR 3 300 or 4 700 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	N/A	N/A	EUR 3 300 for doctoral programmes or EUR 4 700 for postdoctoral programmes
Choose Europe for Science 2025	N/A			EUR 6 700 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	N/A	N/A	EUR 6 700

For the Horizon Europe Work Programme 2026-2027, the Choose Europe for Science action has been transformed into a unit contribution scheme that is aligned with the Postdoctoral Fellowships, in response to stakeholder feedback received regarding the Choose Europe 2025 call.

Moreover, in line with point 3.2.6. and considering the continuing high levels of inflation, the need to maintain attractive working conditions for funded researchers and the feedback received from Member States, the Commission has adjusted the unit contributions according to the cumulative Belgian HICP inflation rate over the period since the last update (October 2023) to June 2025 by 6% for MSCA Doctoral Networks, MSCA Postdoctoral Fellowships, MSCA Staff Exchanges, MSCA COFUND, Choose Europe for Science 2027 under the Horizon Europe Work Programme 2026-2027 as follows:

Summary of the unit contributions for MSCA Doctoral Networks, MSCA Postdoctoral Fellowships, MSCA Staff Exchanges, MSCA COFUND and Choose Europe for Science 2027 under the Horizon Europe Work Programme 2026-2027

Marie Skłodowska-Curie Action	**Contributions for recruited researchers/ seconded staff members (in person/month)**					**Institutional contributions (in person/month)**		**Contributions for recruited researchers and institutional contributions (in person/month)**
	Living allowance	**Mobility allowance**	**Family allowance**	**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**
Doctoral Networks	EUR 4 250	EUR 710	EUR 660	EUR 4960 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 600	EUR 1 200	N/A
Postdoctoral Fellowships	EUR 6 350	EUR 710	EUR 660	EUR7060 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 000	EUR 650	N/A
	Top-up allowance			**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**
Staff Exchanges	EUR 2 870			N/A	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 300	EUR 1 000	N/A
	Living allowance			**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**

Marie Skłodowska-Curie Action	Contributions for recruited researchers/ seconded staff members (in person/month)					Institutional contributions (in person/month)		Contributions for recruited researchers and institutional contributions (in person/month)
COFUND[30]	N/A			EUR 3 500 or 4 980 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	N/A	N/A	EUR 3 500 for doctoral programmes or 4980 for postdoctoral programmes
	Living allowance	**Mobility allowance**	**Family allowance**	**Long-term leave allowance**	**Special needs allowance**	**Research, training and networking contribution**	**Management and indirect contribution**	**COFUND allowance/ COFUND Choose Europe for Science allowance**
Choose Europe for Science 2027	EUR 6 350	EUR 710	EUR 660	EUR7060 x % covered by the beneficiary	EUR 3 000, 4 500, 6 000, 9 500, 13 000, 18 500, 27 500, 35 500, 47 500 or 60 000 x (1/number of months)	EUR 1 000	EUR 650	N/A

3.2.3. Method to determine the country-specific correction coefficients (CCCs)

Calls for proposals before the mid-term review (calls under Horizon Europe Work Programme 2021-2022 and 2023 calls under Horizon Europe Work Programme 2023-2024)

To ensure equal treatment of, and purchasing power parity for, researchers working all over the world, these living allowances shall be subject to a country-specific correction coefficient. The applicable coefficient is the 7-year average of the respective country-specific coefficient ("weighting") used between 2014 and 2020 and applied to remuneration of EU staff worldwide to adjust for differences in price level of consumer goods and services in the duty station (Intra-EU or Extra-EU) by reference to base city (Brussels and Luxembourg)[31]. The country-specific correction coefficients and details on the Eurostat methodology for calculating coefficients for Intra and Extra-EU duty stations are published on the Eurostat website.[32] This average country-specific coefficient was revised after 4 years to make sure that researchers' purchasing power parity stays comparable irrespective of the country where they are conducting research.

Calls for proposals after the mid-term review (as from 2024 calls under Horizon Europe Work Programme 2023-2024 onwards)

The mid-term review study found that over a third of the survey respondents consider that country-specific amounts following the application of the **country-specific correction**

[30] Note that the 2027 COFUND Call (HORIZON-MSCA-2027-COFUND-01) will only cover doctoral programmes.

[31] Article 64 of the Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community.

[32] For intra-EU duty stations, see:
https://ec.europa.eu/eurostat/databrowser/view/prc_colc_tot/default/table?lang=en
For extra-EU duty stations, see:
https://ec.europa.eu/eurostat/databrowser/view/prc_colc_ext/default/table?lang=en

coefficients (CCCs) applicable to the MSCA living allowance are too low and do not reflect the actual cost of living in the host countries.

The study also showed that the methodology used until 2023 for the country-specific correction coefficients based on the 7-year average of the CCCs used to adjust the remuneration of EU staff in different duty stations worldwide was not responsive and sufficiently agile to account for rapid and unexpected spikes in prices and costs of living in different countries.

For this reason, the MSCA CCCs shall be calculated **on the basis of 3-year average**, rather than the 7-year average used to calculate the CCCs at the start of this Multiannual Financial Framework (MFF) to better reflect the constantly changing costs of living and respond in a timely manner to sudden increases in labour costs. Following the recommendation of the study, the Commission reserves the right to biennially revise the average country-specific correction coefficient to ensure that researchers' purchasing power parity stays comparable irrespective of the country where they are conducting research. Moreover, the study recommended aligning the calculation of the CCCs **for the countries associated to Horizon Europe and several other third countries** that host large number of MSCA fellows with the methodology determining the CCCs for remuneration of EU staff based in EU. Unlike the methodology of the CCCs for salaries of EU staff stationed in third countries, the intra-EU calculation takes into account accommodation costs, which represent a major expense for MSCA researchers.

In case there is no reliable data to determine a CCC based on the standard methodology outlined above, the Commission will compare other CCCs in a given region to the last reliable data for the country in question to establish an appropriate CCC.

3.2.4. Method to determine the long-term leave allowance

The 2020 review of MSCA actions unit costs in preparation for Horizon Europe showed that when institutions had to pay a maternity, paternity, parental, sick or special leave benefit, the amount of the benefit was a percentage of the salary received by the researcher[33]. Variations of this share occur across Europe, depending on the national legislation or collective agreements. While a single rate cannot be identified, it appears appropriate to determine the amount of the long-term leave allowance on the basis of the researcher's remuneration. The study recommended to calculate the long-term leave allowance as a share of the living allowance. However, evidence obtained through grant management shows that the mobility allowance is included in the salary of the researchers in a significant majority of the cases.

Therefore, to cover the beneficiaries' additional pay obligations in a fair and equitable way, the long-term leave allowance shall be established as the sum of both the living and mobility allowances. This amount shall be further adjusted based on a percentage factor, corresponding to the share of the long-term leave allowance covered by the beneficiary and subsequently multiplied by the duration of the benefit.

On the basis of these considerations, the long-term leave allowance shall be calculated as follows:

{(long-term leave allowance (i.e. living allowance + mobility allowance))

[33] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: p. 79 ff.

x (% of long-term leave allowance incurred by the beneficiary (=costs incurred by the beneficiary/long-term leave allowance))

x (number of months)}

The living and mobility allowances referred above shall be those established for Doctoral Networks, Postdoctoral Fellowships and Choose Europe for Science 2027 respectively. In COFUND and Choose Europe for Science 2025, the basis for the long-term leave allowance shall be the COFUND allowance (i.e. 70% of the sum of the respective living and mobility allowances applicable to Doctoral Networks and Postdoctoral Fellowships) and the COFUND Choose Europe for Science allowance (i.e. the sum of the living and mobility allowances applicable to Postdoctoral Fellowships).

The number of months in the above formula shall correspond to the duration of the beneficiary's payment obligations for the leave.

The long-term leave allowance shall cover absences longer than 30 consecutive days.

3.2.5. Method to determine the special needs allowance

In order to establish a special needs allowance based on unit contribution, the study performed an analysis of costs incurred for researchers/staff members with disabilities (e.g. long-term physical, mental, intellectual or sensory impairments), participating in training and research activities[34]. The analysis took also into account the data from the two MSCA Special Needs Lump Sums cut-offs implemented under Horizon 2020[35], as well as the advice of the experts involved in the survey. The study confirmed that the very wide variety of disabilities corresponds to an equally wide variety of items and services and related costs. The costs per item or service vary across EU Member States and depend on several other factors such as type and severity of the disability, services available in the host country, researcher's household composition, and, ultimately, specific need(s) of the individual. However, evidence shows that these costs can be grouped according to the average cost of the items or services considered. On this basis, the study elaborated a list of categories established on quantitative and qualitative data, each corresponding to a range of costs, as follows:

Category	Range (in EUR)	Median value (in EUR)
I	3 000[36] – 5 999	4 500
II	6 000 – 12 999	9 500
III	13 000 – 23 999	18 500

[34] Review of Marie Skłodowska-Curie actions unit costs in preparation for Horizon Europe, Final report, April 2020: p. 82 ff.

[35] Under Horizon 2020, where applicable, the additional costs arising from disabilities of researchers/seconded staff members are (partially) covered by a Special Needs Scheme allowance (SNS). From 2019 until 2021, the SNS was subject to a lump sum allowance paid through a linked Coordination and Support Action (CSA). As from 2022, the SNS is subject to a unit cost top-up mechanism calculated as follows: {{Total amount of authorised SNS allowance for the action} divided by {the number of person-months starting from the approval of the request for the SNS allowance until the end of the action duration (*'remaining person-months'*) }} In both cases, the SNS allowance can amount to a maximum of EUR 60 000 per researcher/staff member.

[36] Evidence gathered by the study showed that funding lower than EUR 3 000 would be needed in very few cases, and that organisations would be willing to cover such small amounts from their own funds.

Category	Range (in EUR)	Median value (in EUR)
IV	24 000 – 30 999	27 500
V	31 000 – 39 999	35 500
VI	40 000 – 54 999	47 500
VII	55 000 – 65 000	60 000[37]

The above categories indicate where the beneficiaries' expenses related to each recruited researcher with a disability may fall, covering low-value and widely available items, more expensive services and technological equipment, medium and extensive infrastructure adaptations, a very specific item and a combination of them (from different categories). In view of establishing a unit contribution for these types of costs, the study proposed to set for each of the above categories a rate at either the lowest or the median value of each range of costs[38].

However, two additional elements shall be taken into account: 1) the existing margins due to different price levels of special needs items or services across countries, and 2) the impact that fluctuations in the order of EUR 1 000 – 2 000 have at the lower end of the scale of the categories. Therefore, in order to ensure that the established units are not too distant from the actual expenses, both the lower and the median values of categories I, II and III above shall be used.

In view of the above considerations, the special needs allowance shall be based on one of the following units:

(a) EUR 3 000
(b) EUR 4 500
(c) EUR 6 000
(d) EUR 9 500
(e) EUR 13 000
(f) EUR 18 500
(g) EUR 27 500
(h) EUR 35 500
(i) EUR 47 500
(j) EUR 60 000

The triggering event for the payment of the special needs allowance will be the recruitment or secondment of a fellow with disabilities whose long-term physical, mental, intellectual or sensory impairments are certified by a competent national authority and of such nature that his/her participation in the action would not be possible without the special needs items or services.

[37] Expenses higher than EUR 60 000 were quoted once in the study's survey, while a number of data points were above 55 000. The highest rate will be set at EUR 60 000 also in consideration of the maximum support available for the Special Needs Scheme (SNS) allowance formerly known as the Special Needs Lump Sum (SNLS) allowance under Horizon 2020.
[38] Median values are indicated in brackets for each of the categories listed above.

Beneficiaries shall claim the closest lower rate per researcher/staff member compared to the estimated actual costs of his/her special needs, so that the co-financing principle and compliance with the funding rates provided for in Article 34 of the Horizon Europe Rules for Participation are reasonably ensured *a priori*. Requests for special needs allowance may be assessed by independent external experts on a case-by-case basis, in order to further ensure compliance with the principle of sound financial management. Where this assessment shows that the needs described do not match the category of allowance proposed, the expert may recommend that the category of need be changed to reflect the description.

Costs lower than EUR 3 000 and higher than EUR 60 000 shall not be reimbursed through the special needs allowance. The amount of the monthly unit contribution shall be calculated as follows:

{(special needs unit x

(1/number of months)}

The number of months in the formula above shall correspond to the number of months the special needs items or services were used or produced for implementing the action, depending on the nature of the items or services. For one-off costs, the number of months shall correspond to 1.

3.2.6. Method to keep the lump sum contributions and unit contributions up to date

The Commission shall continue to closely monitor the lump sum and unit contributions to ensure that they respect the sound financial management and co-financing principles, do not contribute to double financing and remain sufficiently competitive and attractive for excellent researchers and institutions.

Considering the unexpectedly high rates of inflation over the past few years and the need to ensure adequacy of the unit contributions, and as recommended by the mid-term review study, the Commission reserves the right to biennially adjust the unit contributions for recruited researchers or seconded staff taking into account the joint index based on national Belgian and Luxembourg inflation. Furthermore, the Commission reserves the right to update all above unit contributions annually via an amendment of this Decision if the joint index based on national Belgian and Luxembourg inflation deviates from the previous year's baseline inflation index by more than 10%.

4. Sound financial management and co-financing principles and absence of double financing

The methodology described in point 3 complies with the sound financial management and co-financing principles and ensures the absence of double financing as required by Regulation (EU, Euratom) No 2018/1046.

Sound financial management is ensured because the costs have been estimated as a reliable proxy of the real costs incurred. Statistical analyses, simulations and studies have been carried out to ensure that all the unit contributions, and notably the institutional ones, would on average be comparable to, but below a possible EU contribution to incurred real costs. Actions funded by the MSCA are not expected to generate revenue. Moreover, because the costs are estimated to be below real costs, it also ensures that the co-financing principle is respected.

The methodologies for the new long-term leave and special needs allowances also comply with the co-financing principle. For the long-term leave allowance, the unit contribution shall not be higher than the share of the researcher's remuneration paid by the beneficiary. For the special needs allowance, beneficiaries shall claim lower costs compared to those incurred. Furthermore, the proposed methodology is not prone to the variations of costs for the same item or service depending on the country of the beneficiary. Similar to the other unit contributions in MSCA, beneficiaries shall keep records and other supporting documents to prove that the triggering event took place and that the specific eligibility conditions in the grant agreement are complied with.

With regard to the lump sum contributions for the European Researchers' Night under MSCA and Citizens and Support to the Marie Curie Alumni Association, the cost estimate in the proposal shall be detailed and subject to an in-depth check by the evaluation committee to ensure that it represents an approximation of the actual eligible costs, as described in point 3.1 above. The independent expert evaluators shall assess the breakdown of shares and ensure that the described activities correspond well to the estimated budget. Compliance with the co-financing principle is further ensured where the EU contribution covers partially the total costs of the events. Double funding is avoided by identifying the project costs that are covered by the lump sum contributions.

The COFUND scheme foresees an overall maximum amount of co-financing of EUR 10 million per beneficiary and call as well as a maximum funding rate of 70%. The required level of co-financing (regional, national, international, beneficiaries' own resources, etc.) and the fact that the unit contribution covers only part of the total eligible costs ensure compliance with the above-mentioned principles.

The Choose Europe for Science 2025 action has an overall maximum amount of co-financing of EUR 3.5 million per beneficiary. During the initial phase (i.e. 24 months for 48-month fellowships and 36 months for 60-month fellowships) the EU provides a minimum contribution for living and mobility costs for the researchers and the beneficiary must provide all other project-related costs. During the second phase of the action, all project-related costs will be provided by the beneficiary (regional, national, international, beneficiaries' own resources, etc.).

The Choose Europe for Science 2027 action has an overall maximum amount of co-financing of EUR 5 million per beneficiary. During the EU-funded phase (i.e. 24 months for 48-month fellowships and 36 months for 60-month fellowships), the EU provides the living allowance, mobility allowance, family allowance, long-term leave as well as special needs allowances, if applicable, for the researchers as well as institutional contributions. During the phase fully funded by the beneficiary, all project-related costs will be provided by the beneficiary from other sources (regional, national, international, beneficiaries' own resources, etc.).

Finally, double funding is effectively prevented through controls at the evaluation, grant agreement preparation, implementation, interim and final payment stages by the granting authority and the Commission. The MSCA draw clear dividing lines between actions and avoid that the same activity can be undertaken in different actions by the same participants. Double funding is also avoided by identifying the eligible cost categories per scheme, as detailed in point 1.

Electronically signed on 16/12/2025 19:06 (UTC+01) in accordance with Article 11 of Commission Decision (EU) 2021/2121

European Research Council
Executive Agency

Established by the European Commission

Horizon 2020
European Union Funding
for Research & Innovation

European Research Council (ERC)

Multi-Beneficiary Model Grant Agreement

ERC Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants

(H2020 ERC MGA — Multi)

Version 5.0
18 October 2017

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	○ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	○ The main changes compared to version 1 of the model grant agreement are as follows: – Article 20.6 "Currency for financial statements and conversion into euro" to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" to give the possibility to the beneficiaries to receive the pre-financing payment 10 days prior to the starting date of the action. – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem and the ERC logo " to ensure more visibility of the European Research Council (ERC) funding under the European Union's Horizon 2020 research and innovation programme for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ○ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
3.0	20.07.2016	○ The main changes compared to version 2.1 of the model grant agreement are as follows: – Introduction of the option for Co-Principle Investigator (Co-PI) for all ERC Frontier Research grants, where the action is carried out under the guidance of more than one principle investigator. – Article 4.2 'Budget transfers': increased budget flexibility for beneficiaries, which may transfer amounts between forms of costs within the direct personnel costs budget category without an amendment to the grant agreement even if they did not foresee that form of cost in Annex 2. – Article 6.2.A 'Direct personnel costs' to take into account to a larger extent the usual cost accounting practices of the beneficiaries by allowing them to calculate the hourly rate not only per full financial year but also per month. – Article 29.3 'Open access to research data' in order to align the ERC MGAs to the rules on open access of general H2020 MGA. – Article 34.1 'Obligation to comply with ethical and research integrity principles' in order to underline the standards of research integrity that beneficiaries must respect. – Article 34.2 'Activities raising ethical issues' in order to simplify the beneficiaries' reporting obligations on ethics before the beginning of an activity raising an ethical issue. – Article 36.1 'General obligation to maintain confidentiality' in order to allow broader access to confidential information in the case of the Commission/Agency staff, other EU institutions and bodies. – Article 48 'Suspension of payments' extends the possibility for the Commission/Agency to suspend the payment of the balance only for one or more beneficiaries.

		– Articles 48 'Suspension of payments', 49 'Suspension of action implementation', 50.3 'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency' in order to clarify that for confidentiality reasons and to protect the personal data, in case of audits, reviews, investigations etc., the Commission/Agency will carry out the contradictory procedure directly with the beneficiary concerned (in this case the coordinator will also be informed). – Article 50.3 'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency': the Commission/Agency may terminate the participation of a beneficiary if it did not request an amendment to the grant agreement to terminate the participation of its linked third party which is under the same conditions as a beneficiary for which the participation may be terminated. For instance, the linked third party is bankrupt. Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
4.0	27.02.2017	○ The main changes compared to version 3.0 of the model grant agreement are under: – Article 6.2.A "Direct personnel costs" – Article 6.2.A.2 'Personnel costs for natural persons working under a direct contract with the beneficiary' – Article 6.2.D.5 'Direct costs internally invoiced' – Article 6.2.E 'Indirect costs' – New Article 14a 'Implementation of action tasks by international partners' – Article 52.1 'Forms and means of communication' ○ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
5.0	18.10.2017	○ The main changes compared to version 4.0 of the model grant agreement are under: – Article 34 'Ethics and research integrity' to align the provisions on ethical and]research integrity principles to the new European Code for Research Integrity adopted ALLEA (All European Academies). ○ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

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MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1]
ERC STARTING GRANTS, CONSOLIDATOR GRANTS AND ADVANCED GRANTS[2]
(H2020 ERC MGA — MULTI)

Introductory remark

H2020 ERC MGA — Multi deviates from the General MGA— Multi as follows:

Generally:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- Annexes 2 (with two parts A and B) and 4 are different
- The table of contents is adapted
- Cross-references in the footnotes are adapted

In specific Articles:

- Preamble
- Article 5.2
- Article 7.1
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 32 (Provisions on the working conditions for the Principal Investigator)
- Article 41.3 (Provisions on internal arrangements)
- Article 56a (ERC specific Article on portability)

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **Text in grey indicates that text which appears in the H2020 General MGA does not apply in this grant agreement.**

- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the principal beneficiary':

[**full official name (short name)**] established in [official address in full] ***[OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),**]*** represented for the purposes of signing the Agreement by [function, forename and surname], hosting *[and engaging]* the following ***[OPTION by default: 'principal investigator':*** [4]

- *[**Name**][Date and place of birth]**]***[5]

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 *'Mise en place de la Charte des ordonnateurs'*.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[OPTION for SyG and other ERC grants with more than one principal investigator: *'**corresponding principal investigator**':*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]].**]***

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **[full official name]** **[short name]** established in [official address in full] ***[OPTION for beneficiaries with VAT:*** *VAT number [insert number]],* ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *hosting [and engaging] the '**other principal investigator(s)**' :*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding: *X. [full official name (short name)], established in [official address in full]* ***[OPTION for beneficiaries with VAT****: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),**]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the* ***Joint Research Centre (JRC)*** *established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC).**]***.

[OPTION for SyG and other ERC grants with more than one principal investigator*: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]***

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:*** *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');

- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[7] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

[7] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3 *[and A.6]*): the hourly rate is calculated *per full financial year,* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or

- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.1, A.2, A.4, A.5 *[and A.6]*): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[8]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

[8] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

D.5 Costs of internally invoiced goods and services directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

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[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

[11] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

The beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator*[s]*.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 in accordance with Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.3, 20.4, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**:[insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION B, to be used if the beneficiary/ coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 20.4, 23a and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.4, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION 1 by default**:*

*these beneficiaries]**[OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

***[additional OPTION for beneficiaries requesting zero funding:** If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION 2:** Not applicable**]

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[12]**]

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

[12] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[13] (or 2014/24/EU[14]) or 'contracting entities' within the meaning of Directive 2004/17/EC[15] (or 2014/25/EU[16]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services. The costs will appear in the accounts of the beneficiaries and will be considered as costs incurred by them (see Article 6.1 and 6.2).

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

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[13] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[14] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[15] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

[16] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243)

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[17]]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

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[17] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[18] and **third parties with a legal link to a beneficiary**[19] ('**linked third parties**') may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
  [same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

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[18] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not constitute in themselves control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[19] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following **international partners**[20] may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.2, 35, 36, 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[20] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION 2:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the principal beneficiary — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[21]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

[21] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions (‘**certificate on the methodology**’). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The principal beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the principal beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must — within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and

- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for each beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from10 days before the starting date of the action (see Article 3) whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)]) is not paid to the principal beneficiary, but kept by the Agency for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary, together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

  - is positive, it will be paid to the principal beneficiary,

  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the principal beneficiary the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the principal beneficiary — Distribution to the beneficiaries

Payments will be made to the principal beneficiary.

Payments to the principal beneficiary will discharge the Agency from its payment obligation.

The principal beneficiary must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][22]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the

[22] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the principal beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the principal beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the principal beneficiary may be terminated (see Article 50).

Such breaches may also lead to the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 17. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of

deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The principal beneficiary or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Agency or the Commission will formally notify the review report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission or the Agency in justified cases.

The '**final audit report**' will take into account observations by the principal beneficiary or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [23]and No 2185/96[24] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot

[23] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[24] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[25], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION 2:** Not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘**extension of findings from this grant to other grants**’).

[25] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The Agency or the Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors, irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Agency or the Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants:*** *three]* years after the payment of the balance.

The evaluation is considered to start on the date of the formal notification to the principal beneficiary or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The principal beneficiary or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[26].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

[26] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘**agreement on background**’).

‘**Background**’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the internal arrangements, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[27] established in an EU Member State or '**associated country**'[28], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

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[27] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[28] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership **agreement**, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 Agency ownership, to protect results

26.4.1 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after

the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 Agency ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the Agency may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

"The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiaries concerned must — up to four years after the period set out in Article 3 — inform the Agency.****]***

If results are incorporated in a standard, the beneficiaries concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard have received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme): *Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in the **data management plan;***

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1,

*would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2:** Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem, the ERC logo and

(b) include the following text:

> "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****]*** ***[OPTION 2:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

[OPTION 1 for EU grants: *The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*

(b) *the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*

- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*

- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the Agency decision, within the period set out above;*

- *if the Agency objects;*

- *until the conditions are complied with, if the Agency objection comes with conditions.]*

[OPTION 2:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the internal arrangements, access to results must also be given — under fair and reasonable conditions (see Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

[OPTION 2:** Not applicable**]

31.6 Access rights for principal investigator*[s]*

The beneficiaries must — on a royalty-free basis — give access to the principal investigator*[s]* to results needed for *[his/her][their]* activities under the action.

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator[s] and [his/her][their] team

The beneficiaries must respect the following working conditions for the principal investigator*[s]* and *[his/her][their]* team:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[29] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding]* principal investigator to supervise the scientific and technological implementation of the action ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary and the other*

[29] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

principal investigator(s)] immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);

- any personal grounds affecting the implementation of the action;

- any changes in the information that was used as a basis for signing the supplementary agreement;

- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[30].

This implies compliance with the following fundamental principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;

- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;

- **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

[30] European Code of Conduct for Research Integrity of ALLEA (All European Academies) http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the principle beneficiary to the Agency (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU’s financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[31], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

[31] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in “Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)” (OJ L 347, 20.12.2013 p.81).

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

*For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities), —inform the coordinator, which must request written approval from the Agency.****]***

*In case of change to the security context, the beneficiaries must inform the coordinator which must immediately inform the Agency and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL) and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[32] *— until it is declassified.*

[32] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the Agency.

*In case of change to the security context, the beneficiaries must inform the coordinator which must immediately inform the Agency and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2:** Not applicable**]

37.3 Activities involving dual-use goods or dangerous materials and substances

***[OPTION 1 if applicable to the grant:** Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the Agency (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2:** Not applicable**]

37.4 Consequences of non-compliance

***[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable:** If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC Logo and

(b) include the following text:

> For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC Logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC Logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency and Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency and the Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from any beneficiary or principal investigator (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the Agency's or the Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency or the Commission not to use it (see Article 52).

The right to use a beneficiary's or principal investigator's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001[33], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary and the principal investigator), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries or the principal investigator), the Agency or the Commission will insert the following information:

[33] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

"© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Research Council Executive Agency (ERCEA) and the *[European Union (EU)][Euratom]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 45/2001[34] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency or the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the Agency and Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

[34] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Agency or the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the principal beneficiary (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:
   (i) keep information stored in the Participant Portal Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the principal beneficiary immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the principal beneficiary in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the scientific reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **principal beneficiary** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The principal beneficiary may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the principal beneficiary is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the principal beneficiary: *As an exception, the principal beneficiary delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The principal beneficiary retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries

The beneficiaries must have '**internal arrangements**' regarding their operation and co-ordination, covering all aspects of their cooperation and implementation of the action, to ensure the action is implemented properly (including decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *(including for disputes between the principal investigators and between them and the beneficiaries)****]*** and division of responsibilities for cases of rejection of costs or reduction of the grant).

The internal arrangements must not contain any provision contrary to this Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will — after **termination of the participation of a beneficiary,** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, see Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the rejection of costs does not lead to a recovery (see Article 44), the Agency will formally notify the principal beneficiary or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The principal beneficiary or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Agency will follow the contradictory procedure with 'pre-information letter' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs after **termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary *[and its linked third parties]* in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant, if:

(a) a beneficiary (or a natural person who has power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles), or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the principal beneficiary or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant after **termination of the participation of a beneficiary,** it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the Agency for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency or the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[35] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

[35] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the* Agency*:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the principal beneficiary has not distributed amounts received (see Article 21.7), the Agency will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]* ***[OPTION 2:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Agency or the Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the scientific reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the scientific or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles), or

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the Agency will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the Agency will formally notify the principal beneficiary or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency will formally notify the principal beneficiary or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The principal beneficiary must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The principal beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the principal beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the principal beneficiary or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the principal beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The principal beneficiary or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may — with the agreement of the principal investigator*[s]* — terminate the Agreement.

The principal beneficiary must formally notify termination to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the open reporting period until termination; see Article 20.3) and

(ii) the final scientific report (see Article 20.3).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic financial report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the principal beneficiary, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The principal beneficiary must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the principal beneficiary's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;

- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);

- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

- a report on the distribution of payments to the beneficiary concerned and

- if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, scientific organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the principal beneficiary (see Article 49.1) and either:

(i) resumption is impossible or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business

activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action— with respect to the state of the art — is no longer of scientific or technological relevance or no longer has any breakthrough potential ;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) ***[OPTION 1:*** *despite a specific request by the Agency, a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l), (m) or (n) and to reallocate its tasks****][OPTION 2:*** *not applicable****]****;*

(o) *[a][the]* principal investigator is no longer in a position to continue working under the action.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the principal beneficiary or beneficiary concerned (with copy to the

[OPTION for SyG and other ERC grants with more than one principal investigator: *corresponding**]*** principal investigator):

- **informing** of its intention to terminate and the reasons why, and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding**]*** principal investigator) **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding**]*** principal investigator) that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii), (n) and (o) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the last open reporting period until termination) (see Article 20.3) and

(ii) a final scientific report (see Article 20.2).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.6 and 50.3.1(l)), the principal beneficiary may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must, within 60 days from when termination takes effect, submit:

- a report on the distribution of payments to the beneficiary concerned;

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case the request for amendment must propose a new principal beneficiary, and

- if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment, and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then

pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,

- was not due to error or negligence on their part (or on the part of third parties involved in the action), and

- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,

- labour disputes or strikes, or

- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the Agency finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The Agency will formally notify the principal beneficiary and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the official mailing address indicated on the Agency's website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[36], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

[36] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The principal beneficiary submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of principal beneficiary is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of principal beneficiary without its agreement: the opinion of the principal beneficiary (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned]].*

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]* ***[****by the law of [Belgium][[insert name of another Member State or EFTA country]]****]*** *[and, where appropriate,] [by the general principles governing the law of international organisations and the rules of general international law]*
- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]* ***[****by the law of [Belgium][[insert name of another Member State or EFTA country]]****]*** *[and, where appropriate,] [by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the Agency and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not receiving EU funding because not eligible for EU funding (see Article 9) which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.**]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the principal beneficiary, depending on which is later.

SIGNATURES

For the principal beneficiary	For the Agency
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

ⓘ print format A4 landscape

MODEL ANNEX 2 FOR ERC MGA — MULTI

PART A: BUDGET TABLE FOR BENEFICIARY [name]/LINKED THIRD PARTY [name]

Please enter duration in months [1] ➔ :	

Please indicate the % of working time the PI dedicates to the project over the period of the grant ➔:	
OPTION for SyG and other ERC grants with more than one principal investigator:	
Name of PI 1:	**% of working time the PI dedicates to the project over the period of the grant ➔:**
Name of PI 2:	**% of working time the PI dedicates to the project over the period of the grant ➔:**

Estimated eligible costs (per budget category)	**month … to …**	**month … to …**	**month … to …**	**month … to …**	**Total**
A. Direct Personnel costs:					
P.I.					-
Senior Staff					-
Post docs					-
Students					-
Other					-
Total Personnel:	-	-	-	-	-
D. Other Direct Costs:					
D.1 Travel					-
D.2 Equipment					-
D.3 Other goods and services (i.e. consumables, publications)					-
D.4 Costs of large research infrastructure					-
Total Other Direct Costs:	-	-	-	-	-
Total Direct Costs:	-	-	-	-	-
E. Indirect Costs (25% of Direct Costs)					-
B.Subcontracting Costs (No indirect costs)					-
Costs of in-kind contributions not used on premises (No indirect costs)					-
Total Estimated Budget (by reporting period and total):	-	-	-	-	-

[1] **Duration of the action (see Article 3)**

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MODEL ANNEX 2 FOR H2020 ERC MGA — MULTI

PART B: ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)									EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs		E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/ international partners
Form of costs[5]	Actual	Unit[6]	Unit[7]		Actual	Actual	Unit[8]	Flat-rate[9] 25%							
	a	Total b	No hours	Total c	d	e	Total f	g=0,25x(a+b+c+e+f-l)	h = a+b+c+d+e+f+g	i	j	k	l	Yes/No	
1 [short name beneficiary]															
[short name linked third party]															
[short name linked third party not eligible for funding]															
[short name linked third party requesting zero funding]															
[short name international partner]															
Total beneficiary															
2 [short name beneficiary]															
[short name linked third party]															
Total beneficiary															
X [short name beneficiary not eligible for funding][10]															
X [short name beneficiary requesting zero funding][10]															
[short name linked third party][11]															
Total beneficiary															
Total consortium															

[1] See Article 6 for the eligibility conditions

[2] Indirect costs covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] See Article 5 for the forms of costs

[6] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[7] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[8] Unit and costs per unit: calculated according to the beneficiary's usual accounting practice.

[9] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

[10] See Article 9 for beneficiaries not receiving funding

[11] Only for linked third parties that receive-funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{the monthly living allowance for researchers in MSCA-IF actions / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The monthly living allowance and the country-specific correction coefficients are set out in the Work Programme (section 3 MSCA) in force at the time of the call:

- for calls *before* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 650**
  - for the country-specific correction coefficients: see Work Programme 2014-2015 and Work Programme 2016-2017 (available on the Participant Portal Reference Documents page)
- for calls *under* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 880**
  - for the country-specific correction coefficients: see Work Programme 2018-2020 (available on the Participant Portal Reference Documents page)

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment: For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] *]*

Estimated number of units: see Annex 2

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new principal beneficiary (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number]]*, (*['the beneficiary']['the principal beneficiary']*), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][principal beneficiary]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the principal beneficiary] **and** the European Research Council Executive Agency (ERCEA ('the Agency'), *under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the principal beneficiary** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.**]

By signing this Accession Form, the beneficiary accepts the grant and agrees to *[**OPTION: for new principal beneficiaries:** take on the obligations and role of principal beneficiary and to]* implement it in accordance with the Agreement, with all the obligations and conditions it sets out *[**OPTION for new beneficiaries:,** as from [insert date] [the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date')** [**additional OPTION for change of beneficiary due to partial takeover**:, and with joint and several liability for undue amounts paid to [insert short name of former beneficiary] (i.e. recoveries)] — if the [Commission][Agency] agrees with the request for amendment**]**.*

SIGNATURE

For the beneficiary/new beneficiary/new principal beneficiary:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the Agency)

[**full official name of the entity affiliated or linked to the beneficiary (short name)**], established in [official address in full], ***[OPTION for linked third parties with VAT:*** *VAT number [insert number]]* ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], established in [official address in full], ***[OPTION for beneficiaries with VAT:*** *VAT number [insert number]]* ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the Agency by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the Agency, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

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MODEL ANNEX 4 FOR H2020 ERC MGA — MULTI

FINANCIAL STATEMENT FOR BENEFICIARY [name]/ LINKED THIRD PARTY [name] FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)										Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs			E. Indirect costs[2]	Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that			D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Unit	Flat-rate[5] 25%						
	a	Total b	No hours	Total c	d	e	*[f]*	Total g	h=0,25x(a+b+c+e+*[f]*+g -n)	i = a+b+c+d+e+*[f]* +g+h	j	k	l	m	n
[short name beneficiary/linked third party]															

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less.

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The principal beneficiary must submit to the Agency the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the principal beneficiary the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission, the Agency, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;

- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission the Agency, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission the Agency, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement
[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices' declared of

[sum of total actual costs and total unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the *[Commission] [Agency]* in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The *[Commission] [Agency]* may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation, , the Beneficiary's usual remuneration practice for projects funded under national funding schemes …); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *'ADDITIONAL REMUNERATION' MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.* *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE QUALIFIES AS "ADDITIONAL REMUNERATION" AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	methodology was consistently used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-17 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary;	14) The natural persons worked under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed..	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the employment conditions of staff in the same category to compare costs and; ○ any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	15) The results of work carried out belong to the Beneficiary, or if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself.	
		16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		17) The costs were supported by audit evidence and registered in the accounts.	
	For personnel seconded by a third party and included in the sample (not subcontractors) To confirm standard factual findings 18-21 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: ○ their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; ○ if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the	18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		19) The results of work carried out belong to the Beneficiary, or if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	*If personnel is seconded against payment:* 20) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 22-27 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total	22) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	number of hours worked was calculated and that the contracts specified the annual workable hours.	23) Productive hours were calculated annually.	
	If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.	24) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
	BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS: ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.*	*If the Beneficiary applied method B.* 25) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary. 25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	*If the Beneficiary applied method C.* 26) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		Beneficiary.	
		27) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal	28) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied] *For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 29) The Beneficiary used the Commission-approved metho-dology to calculate hourly rates. It corresponded to the organisation's usual cost	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; o (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	accounting practices and was applied consistently for all activities irrespective of the source of funding. *For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 30) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary. *For option II concerning individual hourly rates:* 31) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined. 31.2) The hourly rates do not include additional remuneration.	
A.4	**TIME RECORDING SYSTEM**	32) All persons recorded their time	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		33) Their time-records were authorised at least monthly by the project manager or other superior.	
		34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	36) The exclusive dedication is supported by a declaration signed by the Beneficiary and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 37-41 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium;	37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		39) The subcontracts were not awarded to other Beneficiaries of the consortium.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		41) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; **b)** the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	42) All minimum conditions were met	
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there*	43) Costs were incurred, approved and reimbursed in line with the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).	Beneficiary's usual policy for travels.	
		44) There was a link between the trip and the action.	
		45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		46) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery	47) Procurement rules, principles and guides were followed.	
		48) There was a link between the grant agreement and the asset charged to the action.	
		49) The asset charged to the action was traceable to the accounting records and the underlying documents.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		51) The amount charged corresponded to the actual usage for the action.	
		52) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual	53) Contracts for works or services did not cover tasks described in Annex 1.	
		54) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		55) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	56) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
		57) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 58-59 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 60 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 60 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	58) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report. 59) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 60) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
D.5	**Costs of internally invoiced goods and services** **The Auditor sampled cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 61-65 listed in the next column, the Auditor:	61) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs); ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding; ○ verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of internally invoiced goods and services (see Article 6 GA); ○ verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, and correspond to objective and verifiable information. ○ verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services. ○ verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.	62) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding.	
		63) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.	
		64) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.	
		65) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.	
E	**USE OF EXCHANGE RATES**		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	66) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	67) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options *[in italics in square brackets]*: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission*[, the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[2] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;

[2] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

2. Brief description of the time recording system in place;
3. An example of the time records used by the *[Beneficiary] [Linked Third Party]*;
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the *[Beneficiary] [Linked Third Party]* and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the *[Beneficiary] [Linked Third Party]* in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the *[Beneficiary] [Linked Third Party]* in connection with Article 18.1.2 of the Agreement;
- may not be used by the *[Beneficiary] [Linked Third Party]* or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the *[Beneficiary] [Linked Third Party]*.

No conflict of interest[3] exists between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[3] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget in the same	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 full-time equivalents are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s), complemented by other employees irrespective of their assignments until he has reached 10 employees.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).

Please explain any discrepancies in the body of the Report.

Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 employees referred to under Section C: Personnel costs, and verified in particular:

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[1]].* *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the*	✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Auditor: - *...]*	reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]

[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Grants Manual - Section on: Proposal submission and evaluation

(sections III.5, III.6, IV.1, IV.2)

Version 1.4

28 May 2015

History of changes

Version	Date	Changes
1.1	23.05.2014	▪ New annotations regarding hyperlinks and references ▪ Updated chapters on "Ethics review" and "Security scrutiny"
1.2	15.01.2015	▪ Complaints point was added to Submit a proposal section
1.3	22.04.2015	▪ Table of content updated
1.4	28.05.2015	▪ The response deadline to complaints about failed submission is specified in the AoR

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III.5 Submit a proposal

Differences to FP7

- ✕ recommendations of experts limited
- ✕ 'negotiation' replaced by 'grant preparation'

Summary

This section explains:

- how you can submit a proposal

Key points

- We will treat your proposal **confidentially**, as well as any related information, data, and documents we receive from you.

  We will ensure that the process of handling and evaluating proposals is carried out in a confidential manner.

  External experts are also bound by an obligation of confidentiality.

  You too should avoid taking any actions that could jeopardise confidentiality. You must not attempt to discuss your proposal with persons you believe may act as expert evaluator for the Commission/Agency.

- Your proposal is archived under **secure** conditions at all times. After the evaluation and signature of any subsequent grant agreement, all copies are destroyed except those required for archiving or auditing purposes.

  Your proposal should not contain any information that is 'EU classified' under the rules on security of information in the Commission internal Rules of Procedure *(see also Guide for classification)*.

- We will process **personal data** in accordance with Regulation No 45/2001 and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Commission/Agency (publicly accessible in the DPO register).

- Once the coordinator (or sole applicant) has submitted a proposal, you will not hear from us until the proposal has been evaluated, unless:
  - we need to contact you (usually through the coordinator) to clarify matters such as eligibility or to request additional information
  - we need more information, or supporting documents, for legal entity validation, financial viability check, ethics review or security scrutiny
  - you have made an enquiry or a complaint or
  - the evaluation process involves hearings.

- For details on your call see the call topic information.

- There is a Helpdesk available to deal with issues relating to the electronic submission of proposals.

  For information on how to register concerns or enquiries please look on the Participant Portal.

- To **contact us** please use only the electronic exchange system (i.e. the 'My Area' section of the Participant Portal).

1. Before proposal submission

1.1 Draft proposals

The coordinator can enter draft proposals in the 'Electronic Submission Service' of the Participant Portal (accessible via the topic page of your call), using the forms and templates provided there.

ⓘ For tips on the ethics self-assessment, see How to complete your ethics self-assessment.

1.2 Mock evaluation

As part of the topic information for your call, you will find a link to the evaluation forms similar to those used by our experts for the evaluation of your proposal.

It is strongly recommended that you use these forms to assess the strengths and weaknesses of your proposal before you submit it. Ideally, ask a disinterested colleague to carry out a mock evaluation.

1.3 Checklist for submission

Before the coordinator (or sole applicant) officially submits the proposal, check that:

- your proposal fulfils the conditions set out in the call
- the proposal (both the administrative forms and technical annex) is complete, readable, accessible and printable
- the requested declarations have been made
- all consortium members have:
  - obtained access to the electronic exchange system (i.e. the 'My Area' section of the Participant Portal) *(see section III.3)*
  - registered in the Beneficiary Register.

Rules:
- ✕ Art 15 RfP
- ✕ WP/call

Specific schemes:
- ✕ two-stage submission schemes
- ✕ continuous submission schemes
- ✕ multi-step evaluation schemes

2. Submitting your proposal

Proposals must be submitted by the coordinator **on-line** via the Electronic Submission Service of the Participant Portal and before the call deadline.

Specific cases:

For **two-stage submission schemes**, you must submit a 'short outline proposal' for the first stage and you will be invited to submit your 'full proposal' for the second stage, if you pass the first-stage evaluation. The full proposal must be consistent with the short outline proposal and may not differ substantially.

Some calls may be **continuously open for submission** at any time. In these cases, the call will set intermediate or final closure dates and specify whether:

- the evaluation of proposals will be carried out within one month of that date
- proposals will be evaluated individually as they arrive and ranked after the next intermediate or final closure date.

⚠ If you miss an intermediate closure date, the proposal will be evaluated in the next evaluation session.

We will record the date and time the coordinator submits the proposal, and immediately send a confirmation e-mail to all applicants.

If you have not received this e-mail, it is because the proposal has not been submitted.

If you miss the call deadline, your proposal will be disregarded by the system and we will not consider it as submitted.

The system carries out basic verification checks for completeness of the proposal, internal data consistency, virus infection file types, size limitations etc.

⚠ The system will check page limits in specific parts of the proposal and, if necessary, suggest that you shorten it. After the deadline, unless otherwise indicated in the call, any excess pages will be overprinted with a 'watermark', indicating to evaluators that these pages must be disregarded.

Before the call deadline, the coordinator may replace the proposal with new proposals. We will only keep for evaluation the most recent version submitted.

After the call deadline, changes or additions are no longer possible, unless we ask you to clarify any obvious clerical errors on your part.

After the call deadline (or intermediate or final closure date for continuous submission schemes), the system will issue an e-receipt which will be available to all participants via the Participant Portal; it will contain

- the full proposal incl. proposal title, acronym and unique proposal identifier (proposal number)
- the name of the relevant programme part and call identifier and
- the date and time of receipt (i.e. the call deadline).

⚠ If during the final days of the submission process there is a fault in the system, we may decide to extend the call deadline accordingly.

3. After proposal submission

3.1 Access by the Commission/Agency

We have no access to the proposal before the call deadline. However, so that we can plan the evaluation process and meet the deadline for informing you of the outcome, we will ask you consent to access certain information before the call deadline:

- the call title and the topic for which the proposal is submitted
- the title of the proposal, summary information, keywords
- the identity codes of your organisation(s)
- for Marie Skłodowska-Curie actions: the relevant panel.

⚠ A disclaimer will inform you that we will be accessing this information and we will give you the opportunity to refuse access.

Some calls allowing for **continuous submission** may indicate that proposals will be evaluated individually as they arrive. They will be ranked after the closure date specified in the call. In those cases, we may access your proposal from the moment of submission.

3.2 Withdrawing a proposal

The coordinator can subsequently withdraw your proposal – the guidance documents will explain how to do this.

3.3 Multiple proposals

If the coordinator submits a number of similar proposals, we may ask him to choose one or more of them to be withdrawn.

3.4 Complaints

If you think that the submission of your proposal was not entirely successful due to a technical error on the side of the Commission, the coordinator may lodge a complaint through the IT Helpdesk on the Participant Portal. For the complaint to be admissible it must be filed **within 4 calendar days** following that of the call closure. You will receive an acknowledgement of receipt the same or next working day.

You should *secure a PDF version of all the B-parts and annexes of your proposal holding a time stamp* (file attributes listing the date and time of creation and last modification) that is prior to the call deadline dd/mm/yyyy:hh:mm , as well as any proof of the alleged failure (e.g. screen shots). Later in the procedure you may be requested by the IT Helpdesk to provide these items. Please, note that any information regarding the proposal will be treated in a strictly confidential manner.

In order that a complaint would be upheld, the IT audit trail (application log files and access log files of the EC IT-systems involved) must show that there was indeed a technical problem at the EC side which prevented you from submitting (or resubmitting) the proposal using the electronic submission system.

You will be notified about the outcome of the treatment of your complaint as soon as possible and at latest within the time indicated in the acknowledgment of receipt (AoR). If a decision cannot be reached in this term you will receive a holding reply.

If your complaint is upheld, the secured files (provided by you to the IT helpdesk), for which the investigation has demonstrated that technical problems at the EC side prevented (re)submitting, will be used as a reference for accepting the proposal for subsequent evaluation. In absence of such documents, the version present in the IT system will be evaluated.

III.6 Admissibility & Eligibility check

Rules:
- Art 131(2) FR
- Art 201 RAP
- Art 7-10 RfP
- WP/call

Summary

This section explains how and why the Commission/Agency:
- checks admissibility and eligibility of the proposal

1. Admissibility & eligibility check

We will check your proposal for inadmissibility (against the standard admissibility conditions set out in General Annex B to the Main Work Programme and, if relevant, the specific conditions on admissibility set out in the work programme for your call).

To be considered admissible, a proposal must be:

- submitted in the Electronic Submission System before the deadline given in the call conditions
- readable, accessible and printable.

Incomplete proposals may be considered inadmissible. This includes the requested administrative data, the proposal description, and any supporting documents specified in the call. General Annex B to the Main Work Programme lists the necessary supporting documents.

In case of an 'obvious clerical error' *(e.g. omission to submit evidence or information on a non-substantial element of the proposal)*, we may first ask you to provide the missing information or supporting documents.

⚠ If the missing information or document would substantially change the proposal, it will not be taken into account.

We will also check your proposal for ineligibility (against the standard eligibility criteria set out in General Annexes A and C to the Main Work Programme and the specific eligibility conditions set out in the work programme for your call).

Example: *Research & innovation actions (RIA) require, for instance, a minimum of three independent legal entities established in different Member States or associated countries*[1].

Your proposal must also correspond to the topic description for your call.

ⓘ For more information on participation of third country participants, see section on cross-cutting issues (international cooperation).

Specific cases:

In the case of two-stage submission schemes, an eligibility check is carried out at first stage. At second stage, we will check that the eligibility conditions are still complied with.

If your Marie Skłodowska-Curie action proposal is ineligible for call you submitted it for, but eligible in another open call, we will transfer to that call.

[1] Further conditions may be set out in the work programme.

2. Outcome of the admissibility & eligibility check

If your **proposal** is considered **inadmissible** or **ineligible**, we will inform your coordinator (via a 'proposal rejection letter' sent through the electronic exchange system), together with the reasons why and how to appeal.

If the proposal is (for the moment) eligible, but you are not, we will inform you and your coordinator (via an '**applicant rejection letter**' sent through the electronic exchange system).

IV From evaluation to grant signature

IV.1 Evaluation of proposals and operational capacity check

Rules:
- Art 128(2), 131(3), 132(1,2), 133 FR
- Art 202, 203, 204 RAP
- Art 15, 40 RfP
- WP/call

Summary

This section explains how the Commission/Agency
- chooses its experts
- evaluates your operational capacity
- evaluates your proposal (on its scientific merit)
- establishes its ranked list

Key points

- We will evaluate your proposal with the help of independent external experts.
- We will be guided by the following:
  - **Excellence** ⏩ Proposals must demonstrate high quality in relation to the topics and criteria set out in the calls.
  - **Transparency** ⏩ Funding decisions must be based on clearly described rules and procedures, and applicants should receive adequate feedback on the outcome of the evaluation.
  - **Fairness and impartiality** ⏩ All proposals submitted in response to a call are treated equally and evaluated impartially on their merits, irrespective of their origin or the identity of the applicants.
  - **Efficiency and speed** ⏩ Evaluation, award and grant preparation should be done as quickly as possible without compromising quality or neglecting the rules.
  - **Ethics and security** ⏩ Proposals must not contravene fundamental ethical principles or relevant security procedures.

1. Evaluation and operational capacity

If your proposal is admissible and eligible (or if admissibility and/or eligibility cannot immediately be determined), it will be evaluated by independent experts on its scientific merits.

All proposals within a call (or within a coherent part of a call) are evaluated together.

Specific cases:

For **two-stage submission schemes**, there is a first-stage and a second-stage evaluation (against the evaluation criteria for each stage). In a two-stage submission scheme, proposals must pass all thresholds to pass to the second stage.

For **continuous submission schemes**, there is normally an evaluation session after the intermediate or final closure dates (normally within a month). The work programme/call may provide for evaluation when the proposals arrive. In this case they are all ranked after the intermediate or final closure date and evaluation results are made available immediately.

If the work programme/call provides for a **combination of continuous submission scheme and two-stage submission scheme**, the first-stage short outline proposals may be evaluated on a continuous basis when they are received and the full proposal will be evaluated after the intermediate closure date for the second-stage evaluation.

For '**multi-step evaluations**', different experts may be examining the different criteria. Proposals failing a threshold score may not progress to the next step.

To evaluate your capability, the experts will also give an opinion on your operational capacity to implement the action.

2. Evaluation by independent experts

In order to ensure that only proposals of the highest quality are selected for funding, we rely on **independent experts** for the evaluation of proposals ('evaluators').

How are the evaluators selected? We appoint independent evaluators for each call from the database of experts. When selecting evaluators, we look for:

- a high level of skill, experience and knowledge in the relevant areas *(e.g. project management, innovation, exploitation, dissemination and communication)*

and, provided the above condition can be satisfied, a balance in terms of:

- skills, experience and knowledge
- geographical diversity
- gender
- where appropriate, the private and public sectors, and
- an appropriate turnover from year to year.

In principle, your proposal will be examined initially by at least three experts (in many cases, five or more).

Specific case:

For the first stage in two-stage submission schemes and for low-value grants, it may be that only two experts are used.

Additional **ethics exper**ts will be appointed for the ethics review.

In addition, the evaluation process may be followed by one or more **independent observers**:

- to observe the practical workings of the evaluation process
- to give independent advice on:
  - the conduct and fairness of the evaluation sessions
  - the application of the award criteria
  - ways in which the procedures could be improved

but

- not to express views on the proposals or the other experts' opinions.

Experts that have a **conflict of interests** will be excluded by us.

We consider that a conflict of interest exists, if an expert:

- was involved in the preparation of a proposal
- benefits directly or indirectly if a proposal is accepted
- has a close family or personal relationship with any person representing an applicant
- is a director, trustee or partner or is in any way involved in the management of an applicant
- is employed or contracted by one of the applicants or any named subcontractors

  Such an expert may, however, exceptionally be invited to take part in the evaluation session, if all of the following apply:

  - the expert works in a different department/laboratory/institute from where the action is to be carried out
  - the bodies operate with a high degree of autonomy and
  - such a role is justified by the requirement to appoint the best available experts and by the limited size of the pool of qualified experts (and this is documented).
- is a member of an advisory group (set up by the Commission to advise on the preparation of EU or Euratom Horizon 2020 work programmes) in an area related to the call
- is a National Contact Point (NCPs) or persons directly working for the Enterprise Europe Network (EEN)
- is a member of a programme committee

We will decide whether a conflict of interest exists — taking account of the objective circumstances, available information and related risks — when an expert:

- was employed by one of the applicants in the last three years
- is involved in a contract or grant agreement, grant decision, membership of management structures *(e.g. member of management or advisory board etc.)* or research collaboration with an applicant or a fellow (or had been so in the last three years)
- is in any other situation that could cast doubt on their ability to participate in the evaluation of the proposal impartially (or that could reasonably appear to do so in the eyes of an external third party).

We will publish on the "Reference Documents" page of the Participant Portal at least once a year the list of experts who have assisted us together with their area of expertise.

3. Award criteria — Scoring — Thresholds

Your proposal will be evaluated against the following **award criteria**:

- excellence,
- impact and
- quality and efficiency of implementation

and according to the **weighting** and **thresholds** that are set out in the work programme (General Annex H to the Main Work Programme).

In order to be considered for funding, your proposal must score above a certain threshold for each criterion, and above an overall threshold.

Thresholds may vary according to the work programme.

Specific case:

For two-stage submission schemes, thresholds and the maximum overall score may vary between the first and the second stage.

For each criterion, your proposal will be given **scores** of 0 to 5 (half marks are possible), as follows:

0 — The proposal fails to address the criterion or cannot be assessed due to missing or incomplete information (unless the result of an 'obvious clerical error')

1 — Poor: the criterion is inadequately addressed or there are serious inherent weaknesses

2 — Fair: the proposal broadly addresses the criterion but there are significant weaknesses

3 — Good: the proposal addresses the criterion well but with a number of shortcomings

4 — Very good: the proposal addresses the criterion very well but with a small number of shortcomings

5 — Excellent: the proposal successfully addresses all relevant aspects of the criterion; any shortcomings are minor.

The maximum overall score is therefore 15.

Exception:

⚠ For the Marie Skłodowska-Curie (MSC) actions and SME instrument, scores with a resolution of one decimal place may be awarded.

⚠ If the work programme/call provides for a weighting factor, this will be used to determine the final ranking.

⚠ Proposals will be evaluated on their own merit, and not their potential should certain changes be made. Proposals with an inflated budget are likely to receive a lower score.

4. Evaluation process

The evaluation process has **three phases**:

Phase 1 — Individual evaluation

Phase 2 — Consensus group

Phase 3 — Panel review

Before starting the evaluation process, the **experts are briefed** on:

- the evaluation processes and procedures (including selection and award criteria)
- the content of the R&I topics under consideration
- the terms of their contract *(e.g. confidentiality, impartiality, conflicts of interest, completing tasks and approving reports, penalties for non-compliance)*
- disregarding excess pages
- the need to evaluate proposals as they were submitted, rather than their potential should certain changes be made.

  ⚠ In Horizon 2020, there will no scope for recommending improvements to proposals (including improvements on the budget). In particular, proposals with a significantly inflated budget, taking into account cost efficiency considerations, will receive a lower score and may not pass the threshold.

4.1 Phase 1 — Individual evaluation

Each expert carries out an evaluation and prepares an '**individual evaluation report (IER)**' with comments and scores for each criterion.

They also indicate if the proposal:

- falls entirely outside the scope of the part of the call which they are evaluating or
- involves security issues that will need further scrutiny.

4.2 Phase 2 — Consensus group

The individual experts then form a 'consensus group' to come to a common view and agree on comments and scores (in a '**consensus report**').

Specific cases:

If foreseen in the work programme/call, an arithmetic average (i.e. median or mean value) of the individual scores may be taken as the consensus score *(e.g. for the first stage of two-stage submission schemes, SME Instrument actions)*.

The 'mean' is the total score of the experts, divided by the number of experts.

The 'median' is found by arranging all the scores from lowest value to highest value and picking the middle one *(e.g. the median of {3, 5, 9} is 5)*.

If there is an even number of experts, then there is no single middle value; the median is then the mean of the two middle scores *(e.g. the median of {3, 5, 7, 9} is (5 + 7) / 2 = 6)*.

If foreseen in the work programme/call the consensus report may consist in a **collation of the individual evaluation reports** or extracts from them *(e.g. the first stage of two-stage submission schemes; SME Instrument actions)*

⚠ If you have submitted your proposal to the Commission/Agency previously under Horizon 2020 or any other programme in the past two years, and if the work programme topics and criteria were comparable, the moderator of the consensus group may give a copy of the previous Evaluation Summary Report *(see below)* to the experts.

The group has an impartial 'moderator' (normally a Commission/Agency staff member), who:

- seeks a consensus and
- ensures that proposals are evaluated fairly, in line with the criteria.

If a consensus group cannot reach a common view, the consensus report will set out both the majority view and the dissenting views.

⚠ In some cases we may ask additional experts to examine the proposal, to establish whether a clear majority view exists.

4.3 Phase 3 — Panel review

Finally, a panel will review all the proposals within a call, or part of a call, to:

- make sure that the consensus groups have been consistent in their evaluations
- if necessary, propose a new set of marks or comments and
- resolve cases where a minority view was recorded in the consensus report.

There will be **no** panel review:

- the evaluation concerns stage 1 proposals in a two-stage submission schemes
- the Work Programme/call provides for an exception
- if there are sufficient funds to support all the proposals that passed the relevant thresholds.

Specific case:

There will also be no separate panel review if the same consensus group has examined all the proposals. In this case their final review will be done together with the consensus reports. This is considered to constitute the panel review.

The panel review is guided by a 'panel chairperson' (normally a Commission/Agency staff member) who must ensure fair and equal treatment of the proposals. A rapporteur (who may also be the chair) may be appointed to draft the panel report.

As part of the panel deliberations, the Commission/Agency may organise **hearings with the applicants** to:

- clarify the proposals and help the panel establish their final assessment and scores or
- improve the experts' understanding of the proposal.

The call documents will indicate if hearings will be organised.

Invitations to hearings are sent only to the coordinators of proposals with consensus scores above the individual and overall thresholds and, in some cases, also to those whose proposals passed the individual thresholds, but fell short of the overall threshold.

Hearings may not be used to modify proposals.

You may only provide explanations and clarifications in response to questions submitted to you in advance.

⚠ You may choose not to attend the hearing and to reply only in writing.

The panel may invite additional experts to clarify particular issues requiring specific expertise.

These experts may not take position on the proposal as a whole.

Hearings are usually held in Brussels, but may also be conducted by a written procedure, via telephone, or by video-conference.

The '**panel report**' includes the '**evaluation summary report (ESR)**' for each proposal (based on the consensus report, including comments and scores, and taking into account the panel's deliberations and any new scores or comments considered necessary), with explanations and a list of proposals passing all thresholds, along with a final score, ('**panel ranked list**') and, where necessary, the panel's recommendations for a priority order for proposals in the event of equal scores, using the procedure set out in the work programme.

⚠ You will receive a copy of your evaluation summary report, when you will be informed of the outcome of the evaluation by the experts.

Exception:

For two-stage submission schemes, the ESR of the first stage will not be sent to successful first stage applicants, unless this is provided for in the Work Programme/call. (In such schemes, successful applicants will receive the grant information letter and ESR at the end of the second/last stage; at the end of the first stage, they will only be informed about the outcome and, if applicable, be invited to submit their full proposal.)

5. Outcome of the evaluation: Commission/Agency ranked list — Operational capacity check

We will rank the proposals that passed the thresholds according to the results of the evaluation by the experts ('Commission/Agency ranked list').

This ranked list consists of:

- a main list (proposals proposed for funding)
- normally also a reserve list (in case proposals are withdrawn, excluded or extra funding becomes available)
- a list of proposals that cannot be funded because of insufficient budget.

In addition, we will make a list of proposals that didn't pass the thresholds or has been found to be ineligible *(e.g. out of scope)*.

If — on the basis of this ranking and the available budget — your proposal is on the main list, we will **invite you to the grant preparation stage** (via a 'grant information letter' sent through the electronic exchange system).

Specific case:

For two-stage submission schemes, if you successfully pass the first stage, you will receive the information letter at the end of the second stage; at the end of the first stage, you will be informed that your short outline proposal has been successfully evaluated and only be invited to submit your full proposal.

⚠ This is not a commitment that we will fund your project.

You will receive this letter within 5 months of the call deadline.

If your proposal is put on a **reserve list**, we will **inform** your coordinator and let him/her know of any subsequent change.

If your **proposal** has **not** been **retained** for funding, we will inform your coordinator (via a 'proposal rejection letter' sent through the electronic exchange system), together with the reasons why and how to appeal.

If the proposal is retained for funding, but **you may not participate** *(e.g. because you are found to have insufficient operational capacity or to be ineligible)*, we will inform you and your coordinator (via an 'applicant rejection letter' sent through the electronic exchange system).

IV.2 Grant preparation

IV.2.1 Ethics review (ethics screening and ethics assessment)

Rules:
- ✕ Art 19 H2020 FP Reg
- ✕ Art 13(2,3), 14 RfP

Summary

This section explains how and why the Commission/Agency makes an
- ethics review.

Key points

- During proposal submission, you are asked to fill out the 'ethics self-assessment' for your proposal.

  This consists of:

  – the 'ethics issue table' in Part A of the proposal templates and

  – 'ethics self-assesment' in Part B of the proposal templates (i.e. a description of how the identified ethics issue is addressed and how it complies with applicable laws.

- We will check if your proposal **complies with ethical principles** (including research integrity) and **applicable international, EU and national law**.

  All proposals will be screened for ethics issues ('**ethics screening**').

  Proposals raising serious or complex ethics issues must undergo an '**ethics assessment**' *(e.g. proposals involving the use of human embryonic stems cells (hESCs); significant research integrity issues)*.

- Proposals that contravene ethical principles may be excluded at any time.

1. Ethics review

In parallel to the evaluation (or soon after), we will check — with the help of independent ethics experts — if your proposal complies with ethical principles and relevant legislation.

2. Ethics issues

Although the main focus is on the ethical dimension *(e.g. human rights and protection of human beings, animal protection and welfare, data protection and privacy, environmental protection, malevolent use of research results)*, we will also look at 'research integrity' issues *(e.g. fabrication, falsification or plagiarism, including misrepresenting credentials and authorship improprieties)*.

3. Ethics review process

The ethics review process has **one or two stages**:

Stage 1 — Ethics screening

Stage 2 — Ethics assessment

All proposals will go through an ethics review process (made up of one or two consecutive steps, depending on whether or not ethics issues are confirmed, whether they are adequately addressed as well as their severity and complexity).

We will start the **ethics screening** by flagging any ethics issues that are not already indicated in the ethics self-assessment of your proposal and then examine whether they are adequately handled.

Exception:

Proposals involving the use of human embryonic stems cells (hESCs) must always undergo an ethics assessment (without ethics screening).

Example (ethics issues): *impact on human beings, environment or animal welfare; processing of personal data; fabrication and falsification of date (plagiarism).*

If your proposal raises serious or complex ethics issues, it will have to also undergo an **ethics assessment** (i.e. a more in-depth analysis).

Example (serious ethics issues that require ethics assessment): *severe intervention on humans; multiple and interconnected ethics issues; lack of appropriate ethics framework in the country where the research will be conducted, etc.*

⚠ We may contact you during the ethics review, if we need more information or supporting documents.

4. Outcome of the ethics review: Ethics opinion

The ethics review culminates in one or more **ethics reports** (one for the ethics screening and one for the ethics assessment, if necessary) with an **ethics opinion**.

These ethics reports may:

- grant **ethics clearance** (for proposals that are 'ethics-ready', i.e. respect ethical principles and applicable law)
- grant **conditional ethics clearance** (for proposals where the experts make the clearance subject to conditions (i.e. 'ethics requirements') to be fulfilled before the signature of the grant agreement or to be included in the grant agreement)

  The conditions may include:

  - regular reporting
  - appointing an independent ethics advisor or board (that may notably be tasked to report to the Commission/Agency on the compliance with the ethics requirements)

  - an ethics check or audit
  - submission of further information/documents
  - necessary adaptation of the methodology to comply with ethical principles and relevant legislation
- recommend an **ethics assessment**, or
- **refuse** ethics clearance.

The reports may also contain ethics recommendations.

During an ethics assessment, the experts may request a **second ethics assessment**, if they consider that the elements submitted do not allow them to provide an opinion.

If the report is **positive** (clearance or conditional clearance) or recommends an ethics assessment, it will be sent to your coordinator (via the electronic exchange system).

If the report is **negative** (no ethics clearance), we will inform your coordinator (via a 'proposal rejection letter' sent through the electronic exchange system), together with the reasons why and how to appeal.

IV.2.2 Security scrutiny

Summary

This section explains how and why the Commission/Agency makes a:

- security scrutiny

Key points

- If your project deals with information that is 'EU-classified' under the Commission internal Rules of Procedure, we will check how you propose to deal with information *(see General Annex J to the Main Work Programme)*.

  ⓘ For more information on 'EU classification', see the Guide for classification.

  ⚠ The security scrutiny is not a fully-fleged security check on all potentially security-relevant aspects of a proposal; it is limited to identifying actions that involve security-sensitive information (and classifying them and their deliverables as 'classified deliverables').

  The security scrutiny does not concern other issues or 'activities involving dual-use goods or dangerous materials and substances'.

- Security scrutiny will be used for most parts of Societal Challenge 7 — Secure Societies calls, but it may also apply to other proposals.

1. Security scrutiny

If your proposal deals with information that is 'EU-classified' under the Commission internal Rules of Procedure[2], it will have to undergo security scrutiny.

2. Proposals subject to security scrutiny

Your project will be subject to security scrutiny if:

- you apply for funding under the Societal Challenge 7 — Secure Societies and your proposal falls under areas described in the Guide for classification
- you declare in the proposal that it is 'security-sensitive', i.e. concerns EU-classified information
- the topic is flagged in the Work Programme as potentially resulting in security-sensitive projects
- the Commission/Agency detects or suspects that:
  - classified information is, or may be, used as background and/or
  - it is planned that some results will be classified.

[2] Commission Decision 2001/844/EC, ECSC, Euratom amending the Commission's internal Rules of Procedure (OJ L 317, 3.12.2001, p. 1–55). Available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001D0844-20050202&qid=1395937087333&from=EN.

3. Documents and information to be provided

Unless you have already included them in your proposal, we will contact you to request the following:

- a 'Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG) [3]', covering
  - the level of classification of background information (and the formal written authorisation by the competent security authorities to use this information);
  - the classified results (including which participant will have access to what information).
- a copy of the 'Facility Security Clearances (FSC)' (or of the FSC request).

  ⚠ The validity of the FSC may be checked by the Commission Security Directorate through the appropriate formal channel with the national security authorities (NSAs) involved.

4. Security scrutiny process

The '**security scrutiny committee**' will check:

- the level of sensitivity of your proposal and
- that you have properly addressed all the security aspects.

This committee will give a **recommendation** on the level of 'EU classification' that is necessary.

If classification is required, the Security Aspect Letter (SAL)' and 'Security Classification Guide (SCG)' will become 'security requirements' in Annex 1 to the grant agreement. It will be EU-classified at the level of the highest classification of the information used/produced by the action as indicated in the 'security aspects letter (SAL)' and 'security classification guide (SCG)')

If the proposal is too sensitive to be financed because you do not have the appropriate experience, skills or permissions to guarantee security of the information, we will refuse funding.

If we **refuse funding**, will inform your coordinator (via a 'proposal rejection letter' sent through the electronic exchange system), together with the reasons why and how to appeal.

⚠ If the reasons for rejection are themselves 'EU classified', we cannot include them in the rejection letter.

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[3] *See Section 27 of Commission Decision 2001/844/EC, ECSC, Euratom. Available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006D0548&from=EN.*

Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities

Preface

The Internet has fundamentally changed the practical and economic realities of distributing scientific knowledge and cultural heritage. For the first time ever, the Internet now offers the chance to constitute a global and interactive representation of human knowledge, including cultural heritage and the guarantee of worldwide access.

We, the undersigned, feel obliged to address the challenges of the Internet as an emerging functional medium for distributing knowledge. Obviously, these developments will be able to significantly modify the nature of scientific publishing as well as the existing system of quality assurance.

In accordance with the spirit of the Declaration of the Budapest Open Access Initiative, the ECHO Charter and the Bethesda Statement on Open Access Publishing, we have drafted the Berlin Declaration to promote the Internet as a functional instrument for a global scientific knowledge base and human reflection and to specify measures which research policy makers, research institutions, funding agencies, libraries, archives and museums need to consider.

Goals

Our mission of disseminating knowledge is only half complete if the information is not made widely and readily available to society. New possibilities of knowledge dissemination not only through the classical form but also and increasingly through the open access paradigm via the Internet have to be supported. We define open access as a comprehensive source of human knowledge and cultural heritage that has been approved by the scientific community.

In order to realize the vision of a global and accessible representation of knowledge, the future Web has to be sustainable, interactive, and transparent. Content and software tools must be openly accessible and compatible.

Definition of an Open Access Contribution

Establishing open access as a worthwhile procedure ideally requires the active commitment of each and every individual producer of scientific knowledge and holder of cultural heritage. Open access contributions include original scientific research results, raw data and metadata, source materials, digital representations of pictorial and graphical materials and scholarly multimedia material.

Open access contributions must satisfy two conditions:

1. The author(s) and right holder(s) of such contributions grant(s) to all users a free, irrevocable, worldwide, right of access to, and a license to copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship (community standards, will continue to provide the mechanism for enforcement of proper attribution and responsible use of the published work, as they do now), as well as the right to make small numbers of printed copies for their personal use.

2. A complete version of the work and all supplemental materials, including a copy of the permission as stated above, in an appropriate standard electronic format is deposited (and thus published) in at least one online repository using suitable technical standards (such as the Open Archive definitions) that is supported and maintained by an academic institution, scholarly society, government agency, or other well established organization that seeks to enable open access, unrestricted distribution, inter operability, and long-term archiving.

Supporting the Transition to the Electronic Open Access Paradigm

Our organizations are interested in the further promotion of the new open access paradigm to gain the most benefit for science and society. Therefore, we intend to make progress by

- encouraging our researchers/grant recipients to publish their work according to the principles of the open access paradigm.
- encouraging the holders of cultural heritage to support open access by providing their resources on the Internet.
- developing means and ways to evaluate open access contributions and online journals in order to maintain the standards of quality assurance and good scientific practice.
- advocating that open access publication be recognized in promotion and tenure evaluation.
- advocating the intrinsic merit of contributions to an open access infrastructure by software tool development, content provision, metadata creation, or the publication of individual articles.

We realize that the process of moving to open access changes the dissemination of knowledge with respect to legal and financial aspects. Our organizations aim to find solutions that support further development of the existing legal and financial frameworks in order to facilitate optimal use and access.

Signatories:

On behalf of the German research organisations (in alphabetical order):

Hans-Jörg Bullinger 22 October 2003
President of the Fraunhofer Society

Karl Max Einhäupl 22 October 2003
Chairman des Wissenschaftsrates

Peter Gaehtgens 22 October 2003
President of the Hochschulrektorenkonferenz

Peter Gruss 22 October 2003
President of the Max Planck Society

Hans-Olaf Henkel 22 October 2003
President Leibniz Association

Walter Kröll 22 October 2003
President Helmholtz Association

Ernst-Ludwig Winnacker 22 October 2003
President German Research Foundation

Further national & international Signatories:

Bernard Larrouturou 22 October 2003
Director General, Centre National de la Recherche Scientifique (CNRS)

Jürgen Mittelstraß 22 October 2003
President, Academia Europaea

Paolo Galluzzi 22 October 2003
Director, Istituto e Museo di Storia della Scienza, Florence

Christian Bréchot 22 October 2003
Director General, Institut National de la Santé
et de la Recherche Médicale (INSERM)

Yehuda Elkana 22 October 2003
President and Rector, Central European University, Budapest

Jean-Claude Guédon 22 October 2003
Open Society Institute

Martin Roth 22 October 2003

Director General, Staatliche Kunstsammlungen, Dresden

Friedrich Geisselmann 22 October 2003
Head of the Deutscher Bibliotheksverband

José Miguel Ruano Leon 22 October 2003
Minister of Education, Cultura y Deportes Gobierno de Canarias

Dieter Simon 22 October 2003
President, Berlin-Brandenburg Academy of Sciences and Humanities

Jens Braarvig 22 October 2003
Director, Norwegian Institute of Palaeography and Historical Philology

Peter Schirmbacher 22 October 2003
CEO of the Deutsche Initiative für Netzwerkinformation

Status 22 October 2003 (conference end)

The actual status of signatories can be viewed at
http://www.oa.mpg.de/openaccess-berlin/signatories.html

L. Conditions related to open access to research data

Where indicated in the introduction of the work programme participants will engage in research data sharing, according to Article 29.3 of the Horizon 2020 Model Grant Agreement(s). This means that beneficiaries must deposit and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate, free of charge for any user: (1) data needed to validate the results presented in scientific publications ('underlying data'); and (2) other data as specified by the beneficiaries in their Data Management Plan (DMP, see below).

Projects can "opt-out" of these provisions before or after the signature of the grant agreement (thereby freeing themselves from the associated obligations) on the following grounds:

a) Incompatibility with the Horizon 2020 obligation to protect results that are expected to be commercially or industrially exploited

b) Incompatibility with the need for confidentiality in connection with security issues

c) Incompatibility with rules on protecting personal data

d) Incompatibility with the project's main aim

e) If the project will not generate / collect any research data, or

f) If there are other legitimate reasons not to provide open access to research data

Any costs related to the implementation of these provisions are eligible for reimbursement during the duration of the grant.

A proposal will not be evaluated more favourably if the consortium agrees to share its research data, nor will it be penalised if it opts-out.

Further information on open access to research data is available on the Participant Portal.

A Data Management Plan (DMP) details what data the project will generate, how it will be exploited and made accessible for verification and re-use, and how it will be curated and preserved. The use of a Data Management Plan is obligatory for all projects that do not opt-out. Projects that opt-out are also strongly encouraged to submit a Data Management Plan if relevant for their planned research. Further information on Data Management Plans is available on the Participant Portal.

EN

Horizon 2020

Work Programme 2016 - 2017

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and

1. General Introduction

Important notice on the second Horizon 2020 Work Programme

This Work Programme covers 2016 and 2017. The parts of the Work Programme that relate to 2017 (topics, dates, budget) have, with this revised version, been updated. The changes relating to this revised part are explained on the Participant Portal.

(European Commission Decision C(2017)2468 of 24 April 2017)

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General Introduction

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1.1 Overview and summary

The Horizon 2020 Programme strongly supports the three strategic priorities[1] of Open Innovation, Open Science, and being Open to the World.

Open innovation is about combining diverse sources of knowledge to innovate, underpinned by networked, multi-collaborative innovation systems and involving researchers, entrepreneurs, investors, users, governments and civil society. Favouring Open Innovation means encouraging the capitalisation of results from European research and innovation. Open Science includes moving forward on the need for more open access to research results and the underlying data. The Commission is therefore extending its Open Research Data Pilot to cover all thematic areas of Horizon 2020 whilst maintaining robust opt-out options. Open Science also entails the need for new initiatives to strengthen research integrity for policy makers, research funders, research institutions and researchers. Open to the World means to engage more in science diplomacy and in global scientific and technological collaboration to remain relevant and competitive, and to lead the way in developing global research and innovation partnerships to address global challenges.

Horizon 2020 spans seven years (2014 to 2020), and is the biggest EU Research and Innovation funding programme ever. The Horizon 2020 Specific Programme is implemented through two-year work programmes setting out funding opportunities under the different parts through calls for proposals containing topics, and the other actions such as public procurements.

The 'General Introduction' to the second Horizon 2020 Work Programme covering the years 2016-17 explains the context in which the Work Programme was developed, and contains guidance to help those submitting proposals for EU research funding.

This second Work Programme is completely new in terms of content, building on the achievements of the first Horizon 2020 Work Programme which was for 2014-15, and which received an overwhelmingly positive response with strong demand from the research and innovation stakeholder communities.

Through this new Work Programme, Horizon 2020 will continue to fund researchers and innovators at the cutting edge of their fields working on the latest breakthroughs; it will support projects across the cycle from research to innovation; it will create opportunities to build research teams in Member States where the innovation and research potential is underexploited; it will encourage the training of researchers including exchanges of researchers between industry and academia; it will take a strategic approach to international cooperation in research and innovation; and through a suite of financial instruments it will help to plug the gap between innovative research and its exploitation.

In determining the contents of this Work Programme in line with the Horizon 2020 Specific Programme, the Commission has continued with its strategic programming process which was begun with the first Horizon 2020 Work Programme. The aim is to maximise the impact of the available EU funding through an integrated, coherent, evidence-based implementation.

On this basis, criteria used for selecting the priorities to be supported in the Work Programme 2016-2017 were: the maximising of EU added value; addressing and anticipating research and innovation key trends and areas of high potential for world-class breakthroughs; providing

[1] Speech of Commissioner Carlos Moedas on 'Open Innovation, Open Science, Open to the World', at conference, 'A new start for Europe: Opening up to an ERA of Innovation', Brussels, 22 June 2015.

strong potential for impact and uptake and leverage of industry and SME participation, by addressing the demand side, tackling barriers to innovation and market deployment and uptake, and building collaborations between industry, businesses, universities and research institutions; providing genuinely cross-cutting approaches and embedding key novelties such as covering the full research and innovation cycle, social science and humanities, gender aspects, and climate and sustainable development; improving international cooperation by focusing on key strategic and targeted areas of common interest and mutual benefit one example of which being Euro-Mediterranean cooperation in the field of Research and Innovation, including the work done to date by the PRIMA initiative participating States.

The strategic programming approach takes into account new intelligence on scientific, technological, economic, market, and social trends and foresight, as well as emerging policy needs. It has involved extensive consultations, notably through the Horizon 2020 Programme Committee and advisory structures.

In line with the strategic objectives for the Work Programme and to provide clear information to proposers, wherever possible guidance has been provided for each topic in the Work Programme on the order of EU financial contribution which the Commission considers would allow the relevant specific challenge to be addressed appropriately.

The Horizon 2020 Work Programme 2016-17 comprises 20 parts, including one on Dissemination, Exploitation and Evaluation, and the General Annexes, which set out the funding opportunities under the different parts of the programme. These describe the overall objectives, the respective calls, and the topics within each call. Each topic describes the specific challenge to be addressed, the scope of the activities to be carried out, and the expected impacts to be achieved.

Proposals can be submitted in the calls for proposals shown on the Participant Portal.

The General Annexes, part 20 of the Work Programme, have been revised and updated with respect to those for the 2014-15 Work Programme, and contain: a list of countries eligible for funding, and applicable rules; standard admissibility criteria and related conditions; standard eligibility criteria; types of action: specific provisions for innovation procurement; rules of contest for Prizes; a description of Technology Readiness Levels (TRL); a description of the evaluation criteria; a note on budget flexibility; classified information; and financial support to third parties.

This Work Programme continues with the approach of the first Horizon 2020 Work Programme to have fewer calls and topics, as compared with Framework Programme 7 (FP7). These are generally broader and encompass a range of possible approaches. In most cases more than one possible action is envisaged for a particular topic. The Work Programme reflects the strong challenge-based approach of Horizon 2020, allowing applicants to have considerable freedom to come up with innovative solutions.

This Work Programme incorporates improvements based on the lessons learned from the first Horizon 2020 Work Programme, notably in the need to continue with the open approach to calls; better use of the new instruments promoting innovation in the Work Programme cycle; reinforcing the broad approach to innovation extending beyond technological and research-based innovation and including social innovation and user innovation; promoting SME participation in calls for collaborative projects and other grant-based instruments; promoting the SME instrument; proactive integration of social sciences and humanities aspects; improved addressing of the gender dimension; better targeting of potential international cooperation; reinforcing the quality of proposal evaluation; and standards for feedback to applicants.

Further efforts in particular have been made to ensure cross-cutting issues (e.g. social sciences and humanities, gender, international strategy) have been mainstreamed in each of the different parts of the Work Programme, ensuring an integrated approach.

This Work Programme makes further progress on streamlining the presentation, with access via the web, and tools to allow ease of access including smart searches.

While this Work Programme covers the large majority of the funding available under Horizon 2020, it is complemented by the separate Work Programmes for the European Research Council, Euratom, the Joint Research Centre, as well as the Strategic Innovation Agenda for the European Institute of Innovation and Technology (EIT).

1.2 Political context

Although there are positive signs, the EU still has a long way to go before it overcomes the effects of the economic crisis and the high unemployment rate, especially amongst young people, remains the biggest concern and challenge in many Member States. The five point strategic agenda for the Union in times of change set by the European Council and followed up by the Commission's agenda for jobs, growth, fairness and democratic change is a strong response to the challenges we face, namely by strengthening our global competitiveness, stimulating investments from both public and private sources, promoting growth and creating new and sustainable jobs for the benefit of the economy and citizens.

The agenda of the Commission sets out ten policy areas on which the EU needs to focus its efforts over the next years. This includes maximising the opportunities and assets of the EU by fully exploiting the potential of the single market as well as of international markets and reinforcing its global attractiveness as a place of production, investment, education and living, thus delivering benefits for all by promoting a climate of entrepreneurship, job creation and social fairness. In the present context the migration challenge also requires new research and innovation actions and a better integration of displaced researchers in Europe.

Research and innovation represent major drivers to both stimulate and leverage investment, providing new solutions and the knowledge which will help to deliver the Commission's agenda. By coupling research and innovation, and its emphasis on excellent science, industrial leadership and tackling societal challenges, Horizon 2020 will: mobilise innovative financial instruments; facilitate investment in research infrastructures and skills; maintain and reinforce a high-performing primary sector and industrial base; enhance the use of digital technologies and ICT solutions; capitalise on and promote further our existing strengths in renewables and energy efficiency; contribute to combatting cross-border crime and terrorism while also guaranteeing fundamental rights and values and protecting Europeans' personal data; provide new insights for policy-making towards reversing inequalities and promoting fairness; enhance collaborations between the public and private sectors in delivering innovation; and maximise potential synergies with the European Structural and Investment Funds at national and regional level.

1.3 Key priorities for 2016-2017

On the basis of the strategic programming process, including a broad consultation of stakeholders, and the Horizon 2020 Specific Programme, key priorities for 2016-2017 have been identified. In alignment with the Commission's agenda, the Work Programme for 2016-2017 will contribute to the Jobs, Growth and Investment Package helping to strengthen

Europe's global competitiveness, create new and sustainable jobs and promote growth. All the calls for proposals and activities will contribute substantially to this policy area as well as contributing in broader terms to one or more of the other policy areas.

A new Boost for Jobs, Growth and Investment

Investments will cover both the immediate need to engage the re-industrialisation of Europe as well as the longer-term objective of building solid knowledge needed for the next wave of innovative breakthroughs. A substantial number of Horizon 2020 activities, including innovative forms of financing, are in particular targeted at mobilising additional public and private investment in the European economy and thereby help promote a climate of entrepreneurship and job creation. Investment in researcher skills and competences relevant for the evolving needs of both public and private employers will at the same time respond to the increasing demand for the best talent and will also contribute to strengthening Europe's competitiveness. In particular the following activities are prominent elements contributing to the Jobs, Growth and Investment Package in both the short and longer term:

- As part of the **Innovation Investment Package** representing an investment worth over EUR 22 billion, seven **Public-Private Partnerships** (PPPs) relevant to industry in the fields of innovative medicine, fuel cells and hydrogen, aeronautics, bio-based industries, electronic components and systems, railways, and EU air traffic management system, address strategic technologies that underpin growth and jobs in key European sectors and can help make the EU a more attractive location for international companies to invest and innovate. Complementarity of the work programme with all these activities has been sought to ensure synergies, while avoiding overlaps. These PPPs are complemented by a similar level of investment in **contractual Public Private Partnerships** (cPPPs) implemented through the work programme, on Factories of the Future (FoF); Energy-efficient buildings (EeB); European Green Vehicles Initiative (EGVI); Sustainable Process Industry (SPIRE); Advanced 5G Network Infrastructure (5G); Robotics; Photonics; High Performance Computing (HPC), and Big Data Value and the recently adopted Cybersecurity, to develop new technologies, products and services which will have a substantial impact on the competitiveness of EU industry, and the creation of new high-skilled jobs in Europe.
- Further investments through **financial instruments,** targeted in particular to small and medium-sized enterprises (SMEs), will contribute to the availability of a wider range of debt and equity financing products and facilities to support research and innovation; a stronger venture capital and wider equity industry; the increased involvement of business angels, crowd-funding platforms and philanthropic foundations in funding research and innovation; and more investment in technology transfer. Synergies with the European Fund for Strategic Investments (EFSI) will be promoted.
- Through the European Research Council (ERC), the most talented and creative individual researchers and their teams will be able to investigate the best ideas, based on **excellence**, and carry out frontier research of the highest quality which could lead to new innovative breakthroughs. (this is the subject of a different Work Programme)
- Investing in the skills and competences of the **next generation of excellent researchers** to enable them to face current and future challenges remains the main focus of the Marie Skłodowska-Curie actions. Innovative approaches to research training with exposure to the non-academic sector and the stimulation of

interdisciplinary, international and inter-sector mobility will be particularly promoted. The Societal Challenges and Leading and Enabling Industrial Technologies (LEITs) will contribute to the new skills and competences needed to deliver on innovation, growth and participation in a modern society.

- **Future and emerging technologies** activities help to create in Europe a fertile ground for responsible and dynamic multi-disciplinary collaborations and for kick-starting new European research and innovation eco-systems around them. These will be the seeds for future industrial leadership and for tackling societal challenges in new ways.
- The development, implementation and sustainable operation of pan-European **research infrastructures** help Europe to respond to grand challenges in science and society and boost the productivity and competitiveness of our economy. In this context, e-infrastructures become crucial as a cross-cutting support layer in the storage, transmission and processing of the surging volumes of data. Access to modern and world-class research infrastructures is important for Europe's ability to create cutting-edge research, educate, retain and attract the best research talent and connect researchers globally. Furthermore, partnerships with industry and SMEs on key technologies need to be exploited to foster innovation and create new market opportunities.
- **Closing the research and innovation divide** to bring innovations to all corners of the EU will remain a key objective, in particular through the new actions on Teaming, Twinning and ERA Chairs.

A substantial number of activities across the work programme are dedicated to support **EU manufacturing**. The '4th Industrial Revolution' which is underway, will bring dramatic changes in our working and living environments due to the rapid development of IT infrastructure and the linking of the physical and the virtual worlds to form cyber-physical systems. The digitalisation of industry is also giving a new impetus to all types of firms to develop capabilities to provide services, further blurring boundaries between goods and services. The range of innovative new product-service systems that service providers and manufacturers can offer is already increasing. This offers huge potential for increasing flexibility and productivity, but also resource efficiency and new ways to sustainability in the production and service sector, as well as in everyday life. It is a unique chance for clean, safe and smart "made in Europe".

Other important activities include a call to enhance the innovation capacity of SMEs and the SME Instrument, whose main focus in 2016-2017 will be on facilitating market uptake of innovation, including in international markets and through facilitated access to risk finance and synergies with national or regional support programmes; and the Fast Track to Innovation pilot aimed at reducing the time from idea to market and thus accelerating the development of innovative products, processes and services. In line with the key objective of simplification, the SME instrument is implemented (Industrial Leadership and Societal Challenge pillars) in a predominately bottom-up manner.

A Connected Digital Single Market

Digitalisation offers huge potential for Europe's economy and society. It influences the way we work, communicate and live and empowers customers and end-users in unprecedented ways. It enables new services and innovative business models and modifies the value chains and networks in all sectors of the economy. We need to step up our effort to make much better use of the economic opportunities digitalisation provides. Promising new developments

within the digital domain will be addressed in the next work programme, thereby facilitating the creation of new infrastructures and platforms to experiment, pilot and demonstrate new ways of doing things with consumers and users based on their needs and behaviour, while at the same time addressing the concerns of citizens in areas such as cyber security and trust. Activities will also help boost digital skills and learning across society, including the development and use of language technologies. The following activities will in particular contribute to key knowledge and innovative solutions and support the creation of secure digital ecosystems for fast growth and competitive leadership in key industrial sectors:

- The Internet is accelerating innovation, reshaping established industries, facilitating new ways of doing business, and transforming social behaviours. An integrated response to the technology challenges and innovation needs is required to position Europe at the forefront of the Internet developments. The **Internet of Things** call will allow complementing technology developments with large-scale pilots in a number of societal challenges, thus demonstrating actual solutions in real-life settings.
- **Automated Road Transport** drives a paradigm shift in the automotive sector, with decisive implications for the competitiveness of the European industry. It will improve drastically safety and reduce congestion, while contributing to increase energy efficiency and decrease emissions. The call will address component development, human-machine interactions, testing of vehicles and integration with infrastructure, as well as transition scenarios, standards, user behaviour and acceptance.
- ICT-driven transformations bring opportunities across many important sectors but also vulnerabilities to critical infrastructures and services, which can have significant consequences on the functioning of society, economic growth and the technological innovation potential of Europe. The **Digital Security** call will address these issues through innovative approaches and will be complemented by actions on privacy and ethics recognising the importance of protecting our fundamental right to data protection. Topics will be contributing to the objectives of the recently established cybersecurity cPPP.
- Data sets continue to grow larger and more complex. This trend calls for new and better techniques for extracting, managing, analysing and sharing both data and the results of data analyses, while respecting the privacy rights of individuals and the needs for government and corporate confidentiality. Activities on **Big Data** will help accelerate the progress of scientific discovery and innovation, and foster the development of Europe's data-driven economy emphasising a cross-cutting approach, as the research challenges for big data span across many scientific and technical domains, with promising application prospects in numerous areas such as health, energy, transport, climate action, culture, manufacturing and government, the development and use of language technologies, and spanning both goods and services.

In addition, a call will contribute to maintain and develop the EU position for leading edge technology in key areas such as electronics, photonics, embedded systems, computing, robotics, network technologies and systems or content technologies. Access to research data increases returns from public investment, reinforces open scientific inquiry, and enhances the quality and efficiency of scientific research and innovation, thus providing better business opportunity. The Open Research Data approach will facilitate, through the use of data management plans, access, re-use and preservation of research data resulting from the projects stemming from the work programme.

A Resilient Energy Union with a Forward-Looking Climate Change Policy

There is a strong political will for Europe to move towards an energy secure, competitive, climate resilient and low-carbon economy, become the world number one in renewable energies and to lead the global fight against climate change. This transition is dependent on a forward-looking multi-disciplinary climate change and energy policy that addresses the challenges and opportunities of limiting the increase in global temperature to below two degrees Celsius above pre-industrial levels up to 2050 and beyond. This transition goes hand in hand with other key political objectives, significantly enhancing energy efficiency by 2030 and beyond, ensuring affordable energy prices, reducing greenhouse gas emissions by at least 40% by 2030, increasing the security of our energy system at all levels, and increasing resilience of the energy system to climate change and ensuring its adaptation to the impacts of new consumer behaviours and energy system evolution.

Activities under this work programme will help play a major role in mobilising Europe's research excellence to generate innovative solutions, trigger additional public and private investments, to build European industrial capacities for developing supply chains that are resilient to global competition, to allow active participation of citizens, and at the same time providing a strong response against global warming and other climatic changes. The consumer must play a foremost role in all transitions to the new energy system and be provided with all necessary tools and information to keep costs at a reasonable level. Some of the main contributing activities concern:

- The **Smart and Sustainable Cities** call aims to bring together cities, industry and citizens to improve urban socio-economic functioning through sustainable integrated energy and transport solutions, and to develop business models, innovative financing modalities and appropriate governance modes for integrated solutions. Large scale demonstration projects will be launched in cities, as 'living laboratories' for deployment, testing, replication and scaling up of innovative systemic and yet locally attuned solutions and thus provide evidence for economically, socially and environmentally viable alternatives to tackle simultaneously the various challenges which cities are faced with. This will help make the EU a world leader of a new market for sustainable energy solutions.
- The call on **Energy Efficiency** will give a strong boost in research and innovation investments to remove current technological and market uptake obstacles, by addressing the most pertinent technology-related issues across the energy value chain and non-technology issues. Particular attention will be given to the building area offering the biggest potential for improvement and to improving access to finance.
- The **Competitive Low-carbon Energy** call underpins the commitment to diversify energy sources and for Europe to secure a world-leading position in renewable energies by further advancing renewable electricity and heating/cooling technologies, smart electricity grids combined with storage technologies, the integration and optimisation of the EU energy system, the development of sustainable biofuels and alternative fuels, the decarbonisation of the fossil fuel-based power sector, as well as non-technological challenges such as new financing and business models.
- Activities for moving **towards a low-carbon Europe** will aim at steering a longer-term, broad, multi-disciplinary effort to come to an authoritative view on the most favourable scenarios and options for the decarbonisation of Europe by 2050. Actions will design feasible and cost-effective technological and non-technological options of

deep decarbonisation pathways and address the consequences of those pathways with respect to the production and consumption of goods and services as well as the societal consequences and trade-offs in Europe and beyond. Support to the development of a pan-European market for cutting-edge customised climate services will enable public and private sector actors to mitigate climate risks, increase resilience, and take advantage of business opportunities. Activities within the **Blue Growth** call will also address the impact of climate change on the Arctic, and knock-on effects for Europe and beyond.

A Deeper and Fairer Internal Market with a Strengthened Industrial Base

The internal market is one of Europe's best assets in times of increasing globalisation and provides a strong basis for our companies and industry to thrive in the global economy. To reach its full potential, European industry needs to combine advanced manufacturing with sustainability and the solutions developed for societal challenges. This Work Programme will contribute to maintaining and reinforcing a strong and high-performing European industrial base and primary sector. The research and innovation activities will help maintain our global leadership in strategic sectors with high-value jobs by stimulating investment in new technologies, processes and business models, easing access to finance and up-scaling investment in the development of innovative skills. In particular, the following activities will contribute to this:

- The **Industry 2020 in the Circular Economy** call will contribute to boosting and renewing Europe's industrial capacities and the real economy, while ensuring economic, environmental and social sustainability, in the context of the circular economy, and providing the basis to the transition towards a smart, dynamic, competitive, resource-efficient and low-carbon European industrial economy. Systemic solutions will be examined, developed and demonstrated throughout value chains, while addressing all influencing factors. While the engagement of industry is essential, full societal success will depend upon a systemic approach, including new production, consumption and behaviour patterns, with strong multi-stakeholder and multi-disciplinary involvement and engagement of civil society.
- As an investment in strategies for earlier and more effective prevention, diagnosis and treatments, and for organising healthcare systems in a more efficient and sustainable way, the call on **Promoting healthy ageing and personalised healthcare** will enable the EU to better understand the determinants of health, keep its population healthier for longer, preserve quality of life, deliver better healthcare at lesser costs and provide European life sciences industries, including SMEs, with a competitive edge that can secure growth and jobs.
- In a context of growing demand for resources and competition, sustainably capturing and demonstrating the potential of seas and oceans is critical to turn this potential into an asset for Europe. In the **Blue Growth** call, targeted innovation in our seas and oceans will demonstrate the commercial application of new technologies (marine bio-refineries, deep sea mining, multi-purpose floating platforms, new medicines) while respecting sea and ocean ecosystems, and maximise synergies with activities funded at national and regional level. This has the potential to provide more jobs, growth, renewable energy sources as well as climate-smart and ecosystem solutions. Important contributions to bring technologies to readiness level for commercial applications for

the generation of renewable energy in the marine environment (tidal, wind) in potential synergy with other sectors will also be provided.

- The **Sustainable Food Security** call will address resilience and resource efficiency in the primary sectors (agriculture, forestry, fisheries and aquaculture) and in the related up- and downstream industries to ensure the food and nutritional security of EU citizens. Investments in innovation will support stability and competitiveness of the agri-food chains, such as the food industry, the largest EU manufacturing industry. This call will also help to safeguard and make efficient use of the natural capital as the basis of primary sectors, while factoring in climate and environmental challenges. Finally, the call will explore innovative approaches in the food value chain to empower citizens to change towards sustainable and healthy food consumption patterns and lifestyles.
- The **Mobility for Growth** call will contribute to further strengthening transport's role as the artery of the single market and vital contributor to EU competitiveness. It will support the world leadership of many of the Union's transport manufacturing companies, while seeking cost-effective long term solutions to key challenges, notably enhancing safety and reducing transport's dependency on fossil fuels. It will focus in particular on technology development and innovative solutions that will allow cleaner and smarter means of transport, as well as better inter-modal integration, improving the efficiency and resilience of logistics chains, and allowing greater choice to passengers. This will use ICT solutions that will in turn drive more efficient use of existing infrastructure with substantial safety improvements and energy savings.

Key enabling technologies (KETs) supporting the development of new goods, industrial processes and services as well as product-service systems, and including cross-cutting KET actions, with the potential to create unforeseen advances and new markets, will also help strengthen Europe industrial base. Calls on innovation and business opportunities in the rural sector, and bio-based innovation for sustainable goods and services will also contribute to this policy area.

Calls and activities in vital areas such as satellite navigation, earth observation and satellite communication will help Europe to reap the benefits of European investments in the space sector and in doing so stimulate smart growth and provide opportunities for highly-skilled jobs. This is a long-term challenge that requires a long-term approach that must encompass several areas such as security of supply of component technologies, industry capability and technology readiness as well as space situational awareness to cope with threats such as space orbital debris (including space surveillance and tracking).

A Stronger Global Actor, Towards a New Policy on Migration, and An Area of Justice and Fundamental Rights Based on Mutual Trust

The strong international cooperation dimension of research and innovation in Horizon 2020 will contribute to the policy area, *A Stronger Global Actor*. **International cooperation calls** and **targeted initiatives** relating to societal challenges or LEITs, developed on the basis of country/region roadmaps[2] and international policy dialogues with key partners, will contribute

[2] Report on the implementation of the strategy for international cooperation in research and innovation of 11 September 2014 – COM(2014)567 final.

to strengthening competitiveness, effectively tackling common societal challenges, supporting EU external policies, reinforcing the European presence in partner countries and boosting research and innovation cooperation. The call **Engaging together globally** will investigate major challenges to the EU's role as a global actor so as to promote the clout of the EU, make it a strong partner in its neighbourhood, and engage with global strategic partners. The Border and external security part of the **Security** call will support the Union's external security policies in its civilian tasks, ranging from civil protection to humanitarian relief, peace-keeping and post-crisis stabilisation, including conflict prevention, peace-building and mediation.

This call will also contribute to the policy area, Towards a New Policy on Migration. Europe needs to manage migration better, in all aspects, as shown by the recent events in the Mediterranean. The call will support border control authorities in their efforts to ensure the security of the EU external borders, whilst at the same time facilitating the legitimate flow of people and goods. Research will also be carried out on the origins of migrations from the EU neighbouring countries and from the 'neighbours of the neighbours'. Topics will address the increasing influence of radical movements and its impacts on asylum seeking and migration paths.

The **Reversing inequalities call** will also support the European Agenda on **Migration**. It will include a Social Platform on migration and asylum as well as a European and cross-national comparative research on migration Platform. The questions of employability, skills and labour market integration of migrants will also be addressed in this call that will cover both third country migration and internal EU migration. Evidence-based recommendations will provide insights on migration, humanitarian assistance and development cooperation policies. The significance of cultural and core values for the migration challenge will be part of the call **Understanding Europe**.

The combat against cross-border crime and terrorism is a common European responsibility. The EU needs to crack-down on organised crime, such as human trafficking, smuggling and cybercrime. The Fight against crime and terrorism part of the **Security** call, will contribute to the policy area, *An Area of Justice and Fundamental Rights Based on Mutual Trust,* by developing new technologies and innovative capabilities for fighting and preventing crime (including cyber-crime), illegal trafficking, and terrorism (including cyber-terrorism), and for understanding and tackling terrorist ideas and beliefs, while guaranteeing fundamental rights and values, including procedural rights and the protection of personal data. The call **Understanding Europe** will also contribute to this policy area by exploring the challenges to European shared values and legitimacy, its historical, educational and cultural backgrounds.

1.4 Cross-cutting and other key features

While the majority of the calls for proposals pertain to one objective of the *Specific Programme*, the Work Programme 2016-2017 also contains focus area calls covering more than one objective. Focus areas address key areas of political relevance and societal concern to provide better solutions and enhance impacts through stronger integration across different Work Programme parts, in particular between the LEITs and the societal challenges. Those calls are targeted and evidence-based, and are set to provide sufficient scale and scope to achieve a critical mass of support on the basis of clearly defined objectives and impacts. They concern the following nine calls for proposals: Internet of Things; Automated Road Transport; Digital Security; Smart and Sustainable Cities, Energy Efficiency, Competitive Low-carbon Energy, Industry 2020 in the Circular Economy; Blue Growth; and Sustainable Food Security. The calls for proposals for Internet of Things, Industry 2020 in the Circular

Economy and Smart and Sustainable Cities are in a separate Work Programme part. In addition to the priorities mentioned above, the following aspects are embedded across the whole Work Programme within the calls for proposals and activities.

Substantial support for **innovation** and close-to-markets activities such as prototyping, testing, demonstrating, piloting, large-scale product validation and market replication will be provided. Demand side approaches will be reinforced, including further support to pre-commercial procurement and public procurement for innovation in suitable areas, in particular in the societal challenges, as well as policy tools and instruments to foster the market uptake of innovations, namely regulations and standard-setting. New forms and sources of innovation will be piloted, and a broad approach to innovation reinforced with more emphasis on aspects such as process, organisational, value chain, business model innovation, user-driven innovation (including service and design), social innovation and public sector innovation.

One other important instrument to be used is **inducement prizes.** They offer a reward to the first or best solution achieving a pre-set ambitious technological and societal target. These prizes are output-oriented and can attract new talents, entrepreneurs and innovators, mobilising additional private investment for research and innovation and raising interest among the general public. At least one to two major inducement prizes are expected to be launched per year.

Further steps have been made to fully integrate Social Sciences and Humanities (SSH) in Horizon 2020 to solve complex societal challenges. Learning from the first experiences, SSH integration was addressed upstream in the strategic programming for 2016-2017 so that it becomes an integral part of the conceptual design and improves the quality of calls for proposals. It also widens the scope of the integration to cover a broader range of both social sciences and humanities to better understand and contextualise the development of certain (technological) solutions.

Horizon 2020 funded activities will support the relationships between science and society through the promotion of **Responsible Research and Innovation** (**RRI**) as a cross-cutting issue as well as through Part 16 of the Work Programme, *'Science with and for society'*. Included in this are actions aimed at increasing public awareness, improving the scientific knowledge base, and encouraging formal and informal science education.

The exchange of skills of artists and creative people with entrepreneurs and technologists will also be promoted. In the ICT area in particular, the STARTS (S&T&ARTS) activity will push for silo-breaking research and innovation practices via collaboration between Science and Technology and the Arts. STARTS will encourages Horizon 2020 projects to dedicate, whenever appropriate, resources to artistic and other creativity-enhancing practices for instance for exploration of technological limits via art installations, developing unexpected uses of technology, testing of unusual technical solutions, and for working on social acceptance.

All applicants are invited to explore whether and how the **gender dimension in research content** is relevant to their research, including where appropriate specific studies and training. In addition, **gender equality** is promoted in all parts of Horizon 2020 including gender balance at all levels of personnel involved in projects. Gender equality issues are also reinforced in the Excellent Science parts of the Horizon 2020 Work Programme dedicated to the ERC and MSCA.

International cooperation ensures that European partners have access to talent and resources wherever they are located; that they can tackle global societal challenges effectively; that EU companies participate in global value chains and can access new and emerging markets and helps strengthen the EU's position as a major global player. Horizon 2020 is fully open to participation of entities from across the globe, and many topics are flagged as being specifically relevant for international cooperation, identifying upfront the targeted area and partner country or region. Where appropriate financial incentives are offered to ensure that the right international partners are attracted.

The approach to **climate action and sustainable development**, in support of the 35% and 60% respective expenditure targets, has been pursued and strengthened through upfront mainstreaming during strategic programming, and then during the development of the content of the Work Programme as well as in plans for monitoring of the project implementation. Climate action and sustainable development form some of the key objectives of a number of calls under the societal challenges and LEITs.

As reflected in the **expected impact statements** of the calls for proposals, impact together with excellence are important elements of the Work Programme. Clearer and stronger expected impacts are an important aspect of the presentation of the Work Programme. Where appropriate, this includes aspects such as business potential, service orientation, understanding of user and customer needs, and skills development.

Also important are the **potential synergies with European Structural and Investment Funds (ESIF)** which will be promoted. The European Structural and Investment Funds (ESIF) will invest some €90 billion in innovation and research in the period 2014-2020 and therefore, Art. 20 of the Horizon 2020 Regulation and Article 37 Rules for Participation encourage **synergies between Horizon 2020 and other European Union funds, such as ESIF.**

Synergy aims to strengthen the impact of both Horizon 2020 and ESIF funds. Examples could be the development and equipment of research and innovation infrastructures, or the fostering of innovation skills through ESIF that enable the participation in a Horizon 2020 project, or the transfer of knowledge and technologies resulting from Horizon 2020 projects to firms that can, through ESIF funding develop it further, test, prototype, etc. ESIF can also be used to expand the support and advisory services for potential Horizon 2020 participants, or help deploy innovative solutions emanating from Horizon 2020, e.g. through public procurement in the fields of environment, transport, health and energy.

Applicants are invited to identify the smart specialisation fields of their EU Member State or region (see*:* http://s3platform.jrc.ec.europa.eu/eye-ris3) and explore the potential for synergies with the relevant Managing Authorities in charge of the ESIF in their territory (see: http://ec.europa.eu/regional_policy/indexes/in_your_country_en.cfm).

Horizon 2020 enables EU-wide competition to select the best proposals, thereby raising levels of excellence and providing visibility for leading research and innovation. The European Structural and Investment Funds (ESIF) could for example support those project proposals evaluated as excellent but which could not be funded because of insufficient Horizon 2020 budget, whenever in line with ESIF smart specialisation priorities and Cohesion/national rules. To facilitate this process, a 'Seal of excellence' was provided as of November 2015 to above-threshold, not-funded proposals under the SME instrument.

This action will be complemented by a strong 'mobilisation' campaign towards regions/countries (through the established Community of Practice) to include funding schemes that would be 'Seal-of-Excellence-friendly' in implementing their ESIF co-funded

Operational Programmes (meaning that they would create favourable conditions for those proposals that had been already granted a 'Seal of Excellence' by the Commission services)."

Under Horizon 2020, the **evaluation and monitoring of research and innovation activities** will continue to be of instrumental importance, ensuring that the programme implementation is performant to achieve its objectives and maximises Union added value and impact.

1.5 Communication, open access to research results and a new emphasis on data management

This Work Programme continues the new approach under Horizon 2020 to communication and to access provided to research results and to data management.

First, actions shall develop and implement a comprehensive communication plan to ensure a high visibility of the funded actions and help to maximise the impact of results.

1.5.1. Open access to scientific peer reviewed publications

Second, as in previous Work Programmes, and following the policy outlined in the Horizon 2020 Regulation and the provisions of the Model Grant Agreement (article 29.2.) , beneficiaries must ensure that *peer-reviewed scientific publications* resulting from Horizon 2020 are made open access i.e. that free of charge online access for the user is provided. Beneficiaries must also aim to deposit the publication in a repository and must also aim to *deposit* at the same time the research data needed to validate the results presented in scientific publications. Further information on the Open Access in Horizon 2020 is made available on the Participant Portal.

15.2. Open access to research data and research data management

Third, a novelty in Horizon 2020 is the *Open Research Data Pilot* (ORD pilot) which aims to improve and maximise access to and re-use of research data generated by projects. As of the Work Programme 2017 this ORD pilot is being extended to cover *all thematic areas of Horizon 2020* in order to "make open research data the default option", as announced in the Communication 'a European Cloud Initiative – Building a competitive data and knowledge economy in Europe'. This is indicated in the introduction of the thematic work programmes[3] Otherwise the setup of the ORD pilot remains the same and is described in Article 29.3 of the Horizon 2020 Model Grant Agreement(s) or its equivalent.

The Open Research Data Pilot applies to the data needed to validate the results presented in scientific publications. Additionally, projects can chose to make other data available for open access and need to describe their approach in a Data Management Plan (DMP, see below).

As stipulated in the Horizon 2020 Rules for Participation (Regulation No 1290/2013 of the European Parliament and of the Council of 11 December 2013) the Commission takes into consideration the legitimate interests of the participants and any constraints pertaining to data

[3] Note that some *instruments* are excluded, namely those co-fund actions that do not produce data, prizes, ERC proof of concept instruments, and the SME instrument Phase I.

protection rules, security rules or intellectual property rights. It provides robust possibilities for projects to partially or entirely opt-out of open access to research data before or after4 the signature of the grant agreement (see general annex L).

It needs to be stressed that in the evaluation phase, proposals will **not** be evaluated more favourably because they engage in data sharing, and will not be penalised for opting out.

Participating projects will receive dedicated support. In particular, any costs related to open access to research data and related data management and data sharing costs (including the creation of a DMP) will be reimbursed and specific technical and professional support services will be provided.

Further information on research data sharing is made available on the Participant Portal.

Fourth, a further new element in Horizon 2020 is the use of Data Management Plans (DMPs) detailing what data the project will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. Ideally, the DMP should address the relevant aspects of making data FAIR – findable, accessible, interoperable and re-usable.

The use of a Data Management Plan is required for all Horizon 2020 projects, except if they opt-out of sharing their research data for one of the reasons indicated in general annex L. Note that a DMP is **not** required at submission stage. Rather, projects must provide a first version of the DMP within the first six months of the project (as a deliverable), to be updated as appropriate. Further information on Data Management Plans is made available on the Participant Portal.

The open access mandate as well as the policy on data management plans will be reviewed in the context of the Horizon 2020 Interim evaluation which is due to be completed before the end of 2017.

Horizon 2020 may contribute financially to corporate communication in 2016 in accordance with article 28 of the Regulation establishing the Programme. This contribution would cover the corporate communication of the Union's political priorities to the extent that they are related to the general objective of the Programme

1.6 Complementarity with other Work Programmes

Complementing this Work Programme are the direct research activities carried out by the Joint Research Centre through its own Work Programme, the indirect actions of the Euratom Programme and of the ERC, the joint actions of the Public-Public Partnerships (P2Ps), and the work of the European Institute of Innovation and Technology (EIT) in its efforts to build Knowledge and Innovation Communities (KICs).

1.7 Key websites

The key websites to help those submitting proposals for Horizon 2020 funding and for information are:

[4] Once the project has started, opt-outs are possible via an amendment (to remove article 29.3. of the grant agreement) or by explaining why datasets are kept closed in the Data Management Plan. The latter is preferable, since it is a more flexible approach.

- the Participant Portal (incorporates a powerful search facility for the Work Programme) at http://ec.europa.eu/research/participants/portal/desktop/en/home.html
- Participant Portal Glossary http://ec.europa.eu/research/participants/portal/desktop/en/support/reference_terms.html
- the Horizon 2020 site on Europa at http://ec.europa.eu/programmes/horizon2020/
- the Community Research and Development and Information Service (CORDIS) at http://cordis.europa.eu/

H2020 Programme

Multi-Beneficiary General Model Grant Agreement

(H2020 General MGA — Multi)

Version 5.0
18 October 2017

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	▪ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	▪ The main changes compared to version 1 of the model grant agreement are as follows: - Article 20.6 "Currency for financial statements and conversion into euro" in order to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); - Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" in order to give the possibility to the consortium to receive the pre-financing payment at an earlier date, namely 10 days prior to the starting date of the action. - Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem" in order to ensure more visibility of EU funding for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
3.0	20.07.2016	▪ The main changes compared to version 2.1 of the model grant agreement are as follows: - Article 4.2 *'Budget transfers':* increased budget flexibility for beneficiaries, which may transfer amounts between forms of costs within the direct personnel costs budget category without an amendment to the grant agreement even if they did not foresee that form of cost in Annex 2. - Article 6.2.A *'Direct personnel costs'* to take into account to a larger extent the usual cost accounting practices of the beneficiaries by allowing them to calculate the hourly rate not only per full financial year but also per month. - Article 20.3 *'Period reports – Requests for interim payment'* : the technical report submitted by the coordinator must also indicate the communication activities. - Article 34.1 *'Obligation to comply with ethical and research integrity principles'* in order to underline the standards of research integrity that beneficiaries must respect. - Article 34.2 *'Activities raising ethical issues'* in order to simplify the beneficiaries' reporting obligations on ethics before the beginning of an activity raising an ethical issue. - Article 36.1 *'General obligation to maintain confidentiality'* in order to allow broader access to confidential information in the case of the Commission/Agency staff, other EU institutions and bodies. - Article 48 *'Suspension of payments'* extends the possibility for the Commission/Agency to suspend the payment of the balance only for one or more beneficiaries. - Articles 48 *'Suspension of payments'*, 49 *'Suspension of action implementation'*, 50.3 *'Termination of the Agreement*

		or the participation of one of more beneficiaries by the Commission/Agency' in order to clarify that for confidentiality reasons and to protect the personal data, in case of audits, reviews, investigations etc., the Commission/Agency will carry out the contradictory procedure directly with the beneficiary concerned (in this case the coordinator will also be informed). - Article 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'* : the Commission/Agency may terminate the participation of a beneficiary if it did not request an amendment to the grant agreement to terminate the participation of its linked third party which is under the same conditions as a beneficiary for which the participation may be terminated. For instance, the linked third party is bankrupt. Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
4.0	27.02.2017	▪ The main changes compared to version 3.0 of the model grant agreement are under: - Article 6.2.A "Direct personnel costs" - Article 6.2.A.2 'Personnel costs for natural persons working under a direct contract with the beneficiary' - Article 6.2.D.5 'Direct costs internally invoiced' - Article 6.2.E 'Indirect costs' - New Article 14a 'Implementation of action tasks by international partners' - Article 52.1 'Forms and means of communication' Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
5.0	18.10.2017	▪ The main changes compared to version 4.0 of the model grant agreement are under: - Article 29.3 'Open access to research data' to provide for third party access to research data in health actions in cases of public health emergencies; - Article 34 'Ethics and research integrity' to align the provisions on ethical and]research integrity principles to the new European Code for Research Integrity adopted ALLEA (All European Academies). ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

EUROPEAN COMMISSION
DG/EXECUTIVE AGENCY

[Directorate]
[Unit][Director]

GENERAL MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1] (H2020 GENERAL MGA — MULTI)

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

***[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]*

***[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], **[OPTION for beneficiaries with VAT:** VAT number [insert number],] as 'beneficiary not receiving EU funding' (see Article 9),]*

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)].*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it

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[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties]*

[OPTION if the JRC participates: *3b Administrative Arrangement]*

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].]*

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]*

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of ***[OPTION 1 by default:*** *the first day of the month following the date the Agreement enters into force (see Article 58)]* ***[OPTION 2 if needed for the action:*** *[insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be***

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

used if Article 9 or 14a applies: *It also shows the estimated costs of the [beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Moreover, lump sums set out in Annex 2 can never be adjusted.]*

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %*** *of the action's eligible costs]* ***[OPTION 2 for innovation actions (IA)***[7]***: 100%*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[8] *and* ***70%*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]* ***[OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA: […%]*** *of the action's eligible costs]* ***[OPTION B for IA: […%]*** *of the eligible costs for beneficiaries [and linked*

[7] For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[8] For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

third parties] that are non-profit legal entities[9] *and […%] of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]]* (see Article 6) (‘**reimbursement of eligible costs grant**’) (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms (‘**forms of costs**’):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[10]:

- as actually incurred costs (‘**actual costs**’) or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (‘**unit costs**’).

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[11]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[12]: *[**OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][**OPTION 2**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[13]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (‘**unit costs**’);

- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[14]: on the basis of a flat-rate applied as set out in Article 6.2, Point E (‘**flat-rate costs**’);

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[9] For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: ‘**non-profit legal entity**’ means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[10] To be used only if option in Point (f) is used.

[11] To be used only if option in Point (f) is used.

[12] To be used only if option in Point (f) is used.

[13] To be used only if option in Point (f) is used.

[14] To be used only if option in Point (f) is used.

(f) ***[OPTION 1a for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a*[16] *(**unit costs**).]*

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): *for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

[OPTION 2: specific cost category(ies): *not applicable.]*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

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[15] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[16] Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc).

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:** direct costs of providing financial support to third parties;] **[OPTION 2:** not applicable;**]***
D. other direct costs;
E. indirect costs;

F. ***[OPTION 1 for specific unit[/lump sum] costs:*** *[insert name(s) of specific cost category(ies)*[17]***]][OPTION 2:*** *not applicable]*.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs *[(not covered by Point F)]*

<u>Types of eligible personnel costs</u>

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[18] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

[17] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[18] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises (‘**SME owners**’), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of ‘beneficiaries that are natural persons**’ not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

*[A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]]*

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3 *[and A.6]*): the hourly rate is calculated *per full financial year*, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.1, A.2, A.4, A.5 *[and A.6]*): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting ***[(not covered by Point F)]*** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.]*

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]*

C. Direct costs of providing financial support to third parties ***[(not covered by Point F)]***

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.]*

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.]*

[OPTION 2*: Not applicable]*

D. Other direct costs ***[(not covered by Point F)]***

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.]*

D.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[19]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.]*

[19] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).]*

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).]*

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.]*

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]*

D.4 **Capitalised and operating costs of 'large research infrastructure'**[20] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[21]*);*

[20] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[21] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.]

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable]*

[OPTION 3 to be used if foreseen in the work programme: *Not applicable]*

D.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

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computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 to be used if Article 15 applies:*** *costs of providing financial support to third parties [and][;]]****[OPTION 2****: not applicable;]*

(d) ***[OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]]* ***[OPTION 2:*** *not applicable.]*

Beneficiaries receiving an operating grant[22] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

F. ***[OPTION 1: [Insert name of specific cost category(ies)[23]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]***

[OPTION 1a for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): *[**Insert name of specific cost category**] are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of units [and if [insert eligibility conditions, if any]].]*

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category*] are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]*

[same for each specific cost category]

[OPTION 2: *Not applicable]*

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: Costs incurred by linked third parties *are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.]*

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[22] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[23] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

***[OPTION 2:** Not applicable]*

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action*[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: **9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding**

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 in accordance with Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.]

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.]

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.]

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

***[additional OPTION for beneficiaries requesting zero funding:** If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION 2:** Not applicable]*

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

***[OPTION:** In addition, if the value of the purchase exceeds EUR […], the beneficiaries must comply with the following rules: […].[24]]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[25] (or 2014/24/EU[26]) or 'contracting entities' within the meaning of Directive

[24] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

2004/17/EC[27] (or 2014/25/EU[28]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

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[25] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[26] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. (OJ L 94, 28.03.2014, p. 65).

[27] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[28] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR […], the beneficiaries must comply with the following rules: […].*[29]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

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[29] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a ***request for tenders*** *from at least* ***three providers*** *(including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[30]*.]*

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[30] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).]*

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following ***affiliated entities***[31] *and* ***third parties with a legal link to a beneficiary***[32] *(****'linked third parties'****) may implement the action tasks attributed to them in Annex 1:*

[31] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION 2:** Not applicable]*

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following international **partners**[33] may implement the action tasks attributed to them in Annex 1:*

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;

(b) the legal entities concerned are owned or supervised by the same public body.

[32] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

[33] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

- *will not be reimbursed and*

- *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36, 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION 2:** Not applicable]*

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

***[OPTION 1 to be used if foreseen in the work programme:** 15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.]

***[OPTION 2:** Not applicable]*

15.2 Financial support in the form of prizes

***[OPTION 1 to be used if foreseen in the work programme:** 15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.]

***[OPTION 2:** Not applicable]*

15.3 Consequences of non-compliance

***[OPTION 1 to be used if 15.1 and/or 15.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION 2:** Not applicable]*

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) categories of users that may have access:

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*

- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country[36] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;

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[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[35] '**Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[36] For the definition, see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]**[OPTION for Euratom grants:*** *Article 5 of*

(c) procedure and criteria for selecting user groups:

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a ***selection panel*** *set up by the access providers.*

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]*[37]***]***.

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*

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*Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (‘**H2020 Euratom Research and Training Programme Regulation No 1314/2013**’) (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[37] If the authorising officer considers necessary to give priority to certain categories of users.

- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.]*

***[OPTION 2:** Not applicable]*

16.2 Rules for providing virtual access to research infrastructure

***[OPTION 1 for virtual access to research infrastructure:** '**Access providers**'[38] must provide access to research infrastructure or installations[39] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.]

***[OPTION 2:** Not applicable]*

16.3 Consequences of non-compliance

***[OPTION 1 to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION 2:** Not applicable]*

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[38] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[39] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[40]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep

[40] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]*

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception*,* for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

***[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]*

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1]to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);]****[OPTION 2:*** *not applicable;]*

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a

total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[41]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.]

[OPTION 2: *Not applicable]*

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

[41] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)]) is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.]*

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][42]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;

- the beneficiary bears the cost of transfers charged by its bank;

- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

[42] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [43]and No 2185/96[44] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

[43] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[44] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[45], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION 2:** Not applicable;]*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘**extension of findings from this grant to other grants**’).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

[45] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

The *[Agency or the]* Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the *[Agency or the]* Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors, irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[46].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘**agreement on background**’).

[46] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[47] established in an EU Member State or '**associated country**'[48], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

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[47] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[48] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.]****[OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.]

[OPTION 2: *Not applicable;]*

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.]*

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards,*

the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].]

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.]*

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.]*

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).]*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018"];

- the name of the action, acronym and grant number;

- the publication date, and length of embargo period if applicable, and

- a persistent identifier.

29.3 Open access to research data

***[OPTION 1a for actions participating in the Open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications, as soon as possible;

*(ii) **[OPTION A for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme:** data which is relevant for addressing a public health emergency, if specifically requested by the [Commission][Agency] and within the deadline specified in the request]**[OPTION B:** not applicable];*

(iii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

***[additional OPTION for health actions that participate in the Open Research Data Pilot, if foreseen in the work programme:** As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.]]*

***[OPTION 1b for health actions that do NOT participate in the Open Research Data Pilot, if foreseen in the work programme:** The [Commission][Agency] may require beneficiaries to:*

(a) deposit digital research data, which is generated in the action and relevant for addressing a public health emergency, in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user

or

(b) give specific access rights to third parties that need the digital research data to address the public health emergency (including the right to access, mine, exploit and reproduce the data free of charge)

within the deadline specified in the [Commission][Agency]'s request.

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.]

[OPTION 1c for health actions targeting public health emergencies, if foreseen in the work programme: *The beneficiaries must deposit the digital research data generated in the action in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user, at the latest within 30 days after it has been generated.*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access, if the [Commission][Agency] agrees to replace the open access obligation by special access rights for third parties that need the research data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.]

[OPTION 2: *Not applicable;]*

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)]* ***[OPTION 2:*** *not applicable].*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*

(b) *the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*

- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.]*

[OPTION 2 for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —] object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions.]*

[OPTION 3: *Not applicable]*

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).]

[OPTION 2 for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens': *The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

[OPTION 3 for Euratom grants: *The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.]

31.6 Access rights for third parties

[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme*: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries*[49]*, for the purposes of the complementary grant agreement(s) (see Article 2).]*

[OPTION 1b for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.]*

[49] '**Complementary beneficiary**' means a beneficiary of a complementary grant agreement.

[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

[OPTION 1d for trans-national access to research infrastructure: *The access provider must give the users royalty-free access to the results needed to implement the action.]*

[OPTION 2: *Not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[50], in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

[50] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[51].

This implies compliance with the following fundamental principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;

- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;

- **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

[51] European Code of Conduct for Research Integrity of ALLEA (All European Academies) http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the *[Commission][Agency]* (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[52], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

[52] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).]

[OPTION 2: *Not applicable]*

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[53] *— until it is declassified.*

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].

[53] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

***[OPTION 2:** Not applicable]*

37.3 Activities involving dual-use goods or dangerous materials and substances

***[OPTION 1 if applicable to the grant:** Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.]

***[OPTION 2:** Not applicable]*

37.4 Consequences of non-compliance

***[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable:** If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION 2:** Not applicable]*

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and]* Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is][are]* not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency,* the*]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) translation;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[54], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Agency or the]* Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency or the]* Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the]* Commission

[54] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[55] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the]* Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

[55] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.]*

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[56] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The*

[56] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

coordinator retains sole responsibility for compliance with the obligations under the Agreement.]

41.3 Internal arrangements between beneficiaries — Consortium agreement

***[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement**: The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

***[OPTION 2:** Not applicable]*

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION 1 for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.]

***[OPTION 2:** Not applicable]*

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

The coordination agreement must not contain any provision contrary to the Agreement.]

***[OPTION 2:** Not applicable]*

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the time of an **interim payment**, **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented]*.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21)..

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[57] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[57] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up*

*to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]**[OPTION 2:** not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[*Commission*][Agency]* will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]* ***[OPTION 2:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No

966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission] [Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3), must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new

situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1]****[OPTION 2:*** *not applicable]*;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action]****[OPTION 2:*** *not applicable]*;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks]****[OPTION 2:*** *not applicable]*.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of

the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary .

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a

debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the *[Commission][Agency]* finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons,

each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.]*

[OPTION 2: *Not applicable]*

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[58], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;

[58] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

- the appropriate supporting documents, and

- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline , the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned]].*

[additional OPTION for international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary][by the law of [Belgium][insert name of another Member State or EFTA country]][and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary][by the law of [Belgium][insert name of another Member State or EFTA country]][and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

[same for other international organisations].]

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.]*

[additional OPTION for international organisations and for beneficiaries not receiving EU funding because not eligible for EU funding (see Article 9) which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or beneficiaries not eligible for EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).]*

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

For the *[Commission][Agency]*

[forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

① print format A4 landscape

MODEL ANNEX 2 FOR H2020 GENERAL MGA — MULTI

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)													EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	*[F. Costs of ...]*			Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*	A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of ...]*[5]		*[F.2 Costs of ...]*[5]					Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/International partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%	Unit[11]		*[Unit][Lump sum]*[12]							
	a	Total b	No hours	Total c	d	*[e]*	f	Total g	h = 0,25 x (a+b+c+f+g+*[i1]*[13] +*[i2]*[13] -n)	No units	Total *[i1]*	Total *[i2]*	j = a+b+c+d+*[e]* +f+g+h +*[i1]* +*[i2]*	k	l	m	n	Yes/No	
1 [short name beneficiary]																			
[short name linked third party]																			
[short name linked third party not eligible for funding]																			
[short name linked third party requesting zero funding]																			
[short name international partner]																			
Total beneficiary																			
2 [short name beneficiary]																			
[short name linked third party]																			
Total beneficiary																			
X [short name beneficiary not eligible for funding][14]																			
X [short name beneficiary requesting zero funding][14]																			
[short name linked third party][15]																			
Total beneficiary																			
Total consortium																			

[1] See Article 6 for the eligibility conditions

[2] Indirect costs already covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.

[6] See Article 5 for the forms of costs

[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice

[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[9] Unit and costs per unit : calculated according to the beneficiary's usual accounting practices.

[10] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E).

[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).

[12] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)

[13] Only specific unit costs that do not include indirect costs

[14] See Article 9 for beneficiaries not receiving funding

[15] Only for linked third parties that receive funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{the monthly living allowance for researchers in MSCA-IF actions / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The monthly living allowance and the country-specific correction coefficients are set out in the Work Programme (section 3 MSCA) in force at the time of the call:

- for calls *before* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 650**
  - for the country-specific correction coefficients: see Work Programme 2014-2015 and Work Programme 2016-2017 (available on the Participant Portal Reference Documents page)
- for calls *under* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 880**
  - for the country-specific correction coefficients: see Work Programme 2018-2020 (available on the Participant Portal Reference Documents page)

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment): For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] *]*

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

[OPTION if specific unit cost applicable to the grant: 2. Costs for energy efficiency measures in buildings

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m^2 per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

Unit cost table (energy efficiency measures unit cost)[59]

Short name beneficiary/linked third party	BEST No	Cost Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

]

Research infrastructure unit cost

[OPTION if specific unit cost applicable to the grant: 3.1 Access costs for providing trans-national access to research infrastructure

Units[60]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[61])}}{\text{average annual total quantity of access to the installation (over past two years[62])}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[63]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

[59] Data from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.
[60] Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.
[61] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
[62] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
[63] Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

]

[OPTION if specific unit cost applicable to the grant: 3.2 Access costs for providing virtual access to research infrastructure

Units[64]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{total virtual access costs to the installation (over the last year}^{65}\text{)}}{\text{total quantity of virtual access to the installation (over the last year}^{66}\text{)}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (virtual access to research infrastructure unit cost)[67]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

]

Clinical studies unit cost

[OPTION if specific unit cost is applicable to the grant: 4. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each sequence (if any), clinical study and beneficiary/linked third party) the 'unit cost table' attached

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for the cost components of each task, as follows:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

$$\frac{\{\text{certified or auditable total personnel costs for doctors for year N-1}\}}{\{1720 * \text{number of full-time-equivalent for doctors for year N-1}\}}$$

64 Unit of access fixed by the access provider in proposal.

65 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

66 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

67 Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

multiplied by
estimated number of hours to be worked by doctors for the task (per participant)}

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1

{1720 * number of full-time-equivalent for other medical personnel for year N-1}
multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)}

For personnel costs of technical personnel: 'average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1

{1720 * number of full-time-equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1

total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)}

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)}

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1

total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1}

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}

multiplied by

25%}

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

Unit cost table: clinical studies unit cost[68]

Task, Direct cost categories	**Resource per patient**	**Costs year N-1 Beneficiary 1 [short name]**	**Costs year N-1 Linked third party 1a [short name]**	**Costs year N-1 Beneficiary 2 [short name]**	**Costs year N-1 Linked third party 2a [short name]**	**Costs year N-1 Third party giving in-kind contributions 1 [short name]**
Sequence No. 1						
Task No. 1 Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						

[68] Same table as in proposal and Annex 1.

…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1 XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

]

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new coordinator (short name**)], established in [official address in full], ***[OPTION for beneficiaries with VAT:*** *VAT number [insert number],]* ('the beneficiary' or 'the coordinator'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become ***[beneficiary][coordinator]*** No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the coordinator] **and** *[the European Union ('the EU', represented by the European Commission ('the Commission')] [the European Atomic Energy Community ('Euratom'), represented by the European Commission ('the Commission'),][[the [Research Executive Agency (REA)][European Research Council Executive Agency (ERCEA)][Innovation and Networks Executive Agency (INEA)][Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the power delegated by the European Commission ('the Commission'),]*

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the coordinator *to submit and sign in its name and on its behalf any* ***amendments*** *to the Agreement, in accordance with Article 55.]*

By signing this Accession Form, the beneficiary accepts the grant and agrees to ***[OPTION: for new coordinators:*** *take on the obligations and role of coordinator and to]* implement it in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:,*** *as from [insert date][the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date'**) [**additional OPTION for change of beneficiary due to partial takeover:**, and with joint and several liability for undue amounts paid to [insert short name of former beneficiary] (i.e. recoveries)] — if the [Commission][Agency] agrees with the request for amendment]*.

SIGNATURE

For the beneficiary/new beneficiary/new coordinator:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary, if Article 14 applies and linked third party liability has been requested by the [Commission][Agency])

[**full official name of the entity affiliated or linked to the beneficiary (short name)**] , established in [official address in full], ***[OPTION for linked third parties with VAT:*** *VAT number [insert number]]* ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], established in [official address in full], ***[OPTION for beneficiaries with VAT:*** *VAT number [insert number]]* ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the *[Commission][Agency]* by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the *[Commission][Agency]*, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

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MODEL ANNEX 4 FOR H2020 GENERAL MGA — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)														Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs			E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of …]*		*[F.2 Costs of …]*		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Unit	Flat-rate[5] 25%	Unit		*[Unit][Lump sum]*						
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	Total h	i=0,25 x (a+b+c+f+*[g]* + h+ *[j1]*[6] +*[j2]*[6] -p)	No units	Total *[j1]*	Total *[j2]*	k = a+b+c+d+*[e]* +*f* +*[g]* +h+ i + *[j1]* +*[j2]*	l	m	n	o	p
[short name beneficiary/linked third party]																			

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less,

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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TERMS OF REFERENCE FOR AN INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission *[Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission*[, the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission *[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above*.]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the *[Commission] [Agency]* in evaluating whether the *[Beneficiary's] [Linked Third Party's]* costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the *[Commission] [Agency]* in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the *[Commission] [Agency]* for any other purpose, nor may it be distributed to any other parties. The *[Commission] [Agency]* may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation, the Beneficiary's usual remuneration practice for projects funded under national funding schemes…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *'ADDITIONAL REMUNERATION' MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.* *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE QUALIFIES AS "ADDITIONAL REMUNERATION" AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-17 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	14) The natural persons worked under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed.	
		15) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		results were generated by itself.	
		16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		17) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 18-21 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll;	18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		19) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself..	
		If personnel is seconded against payment: 20) The costs declared were supported with documentation and recorded in the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o any other document that supports the costs declared (e.g. invoices, etc.).	Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 22-27 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable	22) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	
		23) Productive hours were calculated annually.	
		24) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A**. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B**. THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C**. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method B.* 25) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary. 25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).	
		If the Beneficiary applied method C. 26) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		27) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates;	28) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 29) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; o (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 30) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 31) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined. 31.2) The hourly rates do not include additional remuneration.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	32) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		33) Their time-records were authorised at least monthly by the project manager or other superior.	
		34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	36) The exclusive dedication is supported by a declaration signed by the Beneficiary and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 37-41 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		39) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		41) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	42) All minimum conditions were met	

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).	43) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		44) There was a link between the trip and the action.	
		45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		46) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures;	47) Procurement rules, principles and guides were followed.	
		48) There was a link between the grant agreement and the asset charged to the action.	
		49) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	o they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		51) The amount charged corresponded to the actual usage for the action.	
		52) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with	53) Contracts for works or services did not cover tasks described in Annex 1.	
		54) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		55) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	
		56) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.	58) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	In the cases that a positive ex-ante assessment has been issued *(see the standard factual findings 58-59 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 60 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 60 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly.	
		60) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
D.5	**Costs of internally invoiced goods and services** **The Auditor sampled cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 61-65 listed in the next column, the Auditor: o obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs); o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding; o verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of	61) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice.	
		62) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding.	
		63) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary's accounts, excluding any ineligible cost or costs included in other	

	internally invoiced goods and services (see Article 6 GA); o verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, and correspond to objective and verifiable information. o verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services. o verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.	budget categories. 64) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service. 65) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm),*	66) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	67) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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TERMS OF REFERENCE FOR AN AUDIT ENGAGEMENT FOR A METHODOLOGY CERTIFICATE IN CONNECTION WITH ONE OR MORE GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').].*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[1] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

[1] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[2] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[2] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *…]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 employees are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s) complemented by other employees irrespective of their assignments until he has reached 10 employees.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
(including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget in the same period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- …]*	✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
<u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90 % of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:**

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 employees referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
present certificate[1]]. *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- …]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[official name of the *[Beneficiary] [Linked Third Party]****]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature of the*** *[Beneficiary] [Linked Third Party]****>***	***[official name of the Auditor]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature*** *of the Auditor****>***

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Associated Countries

Association to Horizon 2020 is governed by Article 7 of the Horizon 2020 Regulation. Legal entities from Associated Countries can participate under the same conditions as legal entities from the Member States. Association to Horizon 2020 takes place through the conclusion of an International Agreement.

As of 01 January 2017, the following countries are associated to Horizon 2020:

- **Iceland**
- **Norway**
- **Albania**
- **Bosnia and Herzegovina**
- **North Macedonia**
- **Montenegro**
- **Serbia**
- **Turkey**
- **Israel**
- **Moldova**
- **Switzerland**
- **Faroe Islands**
- **Ukraine**
- **Tunisia**
- **Georgia**
- **Armenia**

Association Agreements with all of the above countries have either entered into force or are provisionally applicable; all Agreements apply retroactively from 1 January 2014 (i.e. from the beginning of Horizon 2020) except for the Agreement with Switzerland, which is retroactively applicable as of 15 September 2014 (see below for detailed information), the Agreement with Ukraine which is applicable as from 17 August 2015, the Agreements

with Tunisia and Georgia which are applicable as from 1 January 2016 and the Agreement with Armenia which is applicable as from 7 November 2016.

Following the ratification of the Protocol on the extension to Croatia of the Free Movement of Persons Agreement between the EU and Switzerland by the Swiss Federal Council on 16 December 2016, **as of 1 January 2017** Switzerland **is associated to the whole of Horizon 2020, Euratom Programme 2014-2018 and the activities carried out by Fusion for Energy.** This means that for all grant agreements signed as from 1 January 2017 onwards Swiss legal entities will be treated as entities from an Associated Country.

During the period from 15 September 2014 to 31 December 2016 the association of Switzerland to Horizon 2020 covered the following parts of the Programme: the "Excellent Science" pillar, containing the European Research Council, Future and Emerging Technologies, Research Infrastructures and the Marie Skłodowska-Curie actions; the actions under the specific objective "Spreading excellence and widening participation". During that period Switzerland was also associated to the entire Euratom Programme and the activities carried out by the European Joint Undertaking for ITER and the Development of Fusion for Energy for 2014-2020. In other Horizon 2020 priorities that are not listed directly above, **for all actions where the grant agreements were signed before 1 January 2017** Swiss legal entities continue to participate with a status of non-associated third country entities.

For more information, please see the information note on http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-hi-swiss-part_en.pdf

Given that the EU does not recognise the illegal annexation of Autonomous Republic of Crimea and the City of Sevastopol, under the terms of the Horizon 2020 Association Agreement with **Ukraine**, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate. Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, the Agreement will be revised accordingly. The same applies in relation to the association of Ukraine to the **Euratom Programme.** For more information on the association of Ukraine to the Euratom Programme, please see the information note on http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-euratom-hi-ukraine-part_en.pdf

The Horizon 2020 Association Agreement with **Armenia** does not provide for retroactive application. However, Armenian legal entities can participate in all Horizon 2020 actions funded **from the 2016 budget** (calls for proposals, calls for tenders, contests, JRC activities etc.) with the status of entities from an Associated Country as of the entry into force of the Association Agreement.

Note that, unlike in FP7, **Liechtenstein** does not intend to associate to Horizon 2020.

History of changes		
Version	**Publication Date**	**Change**
1.1	26.02.2014	▪ Updates on the participation conditions for Faroe Islands and Switzerland
1.2	19.05.2014	▪ Update on the countries associated with H2020: Norway and Iceland
1.3	11.06.2014	▪ Update on the participation status of Faroe Islands
1.4	15.07.2014	▪ Update on the countries associated with H2020: Albania, Bosnia and Herzegovina, Former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova
1.5	12.09.2014	▪ Update on the association of Switzerland to parts of Horizon 2020
1.6	23.10.2014	▪ Update on the countries associated with H2020: Israel
1.7	5.12.2014	▪ New update on association of Switzerland to parts of Horizon 2020
1.8	17.12.2014	▪ Update on the countries associated with H2020: Faroe Islands
1.9	02.02.2015	▪ Update on status of the association of Ukraine to H2020
1.10	22.04.2015	▪ General clarifications and up-date on signature of the Horizon 2020 Association Agreement with Ukraine
1.11	17.08.2015	▪ Update on the countries associated with H2020: Ukraine
1.12	01.12.2015	▪ General clarifications and up-date on signature of the Horizon 2020 Association Agreement with Tunisia
1.13	17.02.2016	▪ Update on the participation status of Georgia and Armenia
1.14	14.04.2016	▪ Update on the countries associated with H2020: Tunisia
1.15	29.04.2016	▪ Update on the countries associated with H2020: Georgia
1.16	19.05.2016	▪ Update on the participation status of Armenia
1.17	08.11.2016	▪ Update on the countries associated with H2020: Armenia
1.18	02.12.2016	▪ Information on Ukraine
1.19	20.12.2016	▪ Update on the participation status of Switzerland
1.20	27.02.2019	▪ Update on the denomination of North Macedonia

ALLEA

ALL European Academies

Ethics Education in Science

Statement by the ALLEA Permanent Working Group on Science and Ethics

Statement by the
ALLEA Permanent Working Group on Science and Ethics

Final version: September 2013
Valuable feedback from many member academies on an earlier version of this statement is gratefully acknowledged.

Members
Göran Hermerén (Chair) - Royal Swedish Academy of Letters, History and Antiquities
Anna Benaki - Academy of Athens
Anne Fagot-Largeault - Académie des Sciences, France
Jože Trontelj - Slovenian Academy of Sciences
Kirsti Strøm Bull - Norwegian Academy of Science and Letters
Krista Varantola - Council of Finnish Academies
László Fésüs - Hungarian Academy of Sciences
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Pavel Kratochvíl - Academy of Sciences of the Czech Republic
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Statement on Ethics Education in Science

Trust in the scientific enterprise and in the conduct of scientific research is fundamental for fruitful interaction within the scientific community as well as between it and society at large.

At the present time, perhaps more than ever, researchers need to be able to take decisions based on a solid legal, ethical and scientific understanding of the subject matter and its potential implications for science and society.

ALLEA argues in this statement that societies need to set aside or create resources (time, human resources, knowledge banks etc.), so as to ensure that all research is conducted by individuals who have the necessary literacy in ethics.

Ethics education in science should cover both internal and external research ethics, both canons of good research practice and ethical aspects of the relations between science and society.

To ensure that practitioners of science and research have robust guidance when they seek to follow the principles and commitments of their fields, universities and research institutes should provide a continuously updated education in ethics in all fields of scientific research.

The recommendations in this statement are addressed to universities, academies and other research-performing organisations with the responsibility of educating and employing researchers, as well to the governments and other funders who ultimately have to ensure that their funds, public or private, are used by beneficiaries who show full respect for the principles of responsible conduct of research.

The document is divided into two parts. This first part presents general principles and recommendations. The second part, with practical examples and references to on-line resources, will follow later.

1. WHY ETHICS EDUCATION IN SCIENCE?

In this context ‘science‘ is used in a wide sense and includes the natural sciences, the social and behavioural sciences and the humanities. Scientific research aims to produce new, systematic knowledge. It is increasingly collaborative, competitive and global, using – and developing – new technologies and progressing rapidly.

New ethical challenges are raised by scientific developments. The challenges facing contemporary science and the complex relations between science and society highlight the need to be aware of the responsibilities of scientists. In view of recent events and debates, education in research ethics needs to be strengthened to ensure trust and confidence in scientific research.

Scientists have many different roles: as researchers, supervisors, evaluators and peer reviewers. Sometimes they are asked to give advice to governments and institutions. The ethical principles apply to all these roles.

(Principle 1) The challenges facing contemporary science and the complex relations between science and society highlight the responsibilities of scientists.

(Principle 2) Ethics education in science makes the responsibilities of scientists explicit and examines ways of meeting them.

The ethics of science should be an integral part of the education and training of all scientists. A positive attitude towards reflection, alertness and awareness of the ethical dilemmas early career researchers may encounter in their professional life is important. Also senior scientists, research leaders and researchers have a responsibility to promote and integrate research ethics in their own teaching. Thus, ethical training should be part of a researcher’s career from beginning to end. Standards change, methods change, responsibilities change – everyone needs to keep up-to-date.

2. INTERNAL AND EXTERNAL ASPECTS OF RESEARCH ETHICS

The study of ethics can provide guidance not only for individual lives, but also in developing the insight and competence that communities need in order to face present and future challenges. But 'ethics' is used in many senses.

The field of research ethics is wider than the concerns raised by research integrity. There is more than one relevant distinction here, and different terminologies are used. One such distinction, already mentioned in previous ALLEA documents [ALLEA, Annual Report 2003], has been stated as follows:

"The external category of problems refers to questions such as:

• What justifies the choice of the research topic? Is it worth knowing what we investigate?

• Is scientific research truly sufficiently independent (of clients, interested parties, sponsors)?

• How far does the researcher's responsibility extend in respect of what is being done with his results?

• Is there a need for 'no go' or 'go slow' decisions in certain cases on the ground of ethical objections to implications or consequences of insights generated by the research? One may think of stem cell research, xenotransplantation, research into dangerous viruses, nuclear fusion or fission etc.

Internal social/ethical problems in science all refer to undesirable or unacceptable behaviour by scientists.

The following are relevant:

• negligent behaviour in regard of human or animal research subjects,

• careless or inaccurate communication with the general public and the media,

• disregard of the rules of good practice when publishing, quoting and evaluating research, and

• violation of the norms of scientific integrity.

The next part of this paper shall concentrate on this type of internal unethical behaviour - the violation of scientific norms of integrity". (Drenth 2006)

This distinction expresses two kinds of responsibility in science: the responsibility for the moral quality of our work (internal morality) and the

responsibility for its use or abuse by external parties (mostly in politics, but also business). Ethics education in science should cover both aspects of scientists' ethical responsibility: responsible conduct in research itself; and the socio-ethical context of research, focusing on ethical issues concerning the relations between science and society.

Considering the complexity and sensitivity of ethical problems in life sciences (which will mark this century), the key ethical issues of biomedical research on human beings need to be emphasised, including the protection of the dignity of human beings, problems of free and informed consent and the primacy of the human person versus the interests of science or society. The fight for these principles has not yet been won. But research in the social and behavioural sciences, too, raises intriguing ethical issues; this is true also of the humanities.

Research integrity deals with problems that are typically tackled in national or international guidelines for responsible conduct in research and for handling alleged misconduct in the research process and in the publication of research results, including research fraud, publication ethics and misconduct concerning other activities such as the ethics of applications for financial support and the ethics of scientific evaluations of science.

The relevant norms are defined and established through the scientific community itself and the ideal of research integrity has its roots in the autonomy of science. Here also protection of whistle-blowers is taken into account – as well as recommendations on how to report cases of suspected misconduct.

External research ethics, on the other hand, deals with other types of ethical issues in research, in particular with respect to the relationship between the researcher and the research subject and between the researcher and society (individuals and institutions) outside the research community. The problems include, more specifically, for example, risks and benefits of the design and implementation of clinical trials that include experiments involving human beings, human biological materials or experiments on animals, which are regulated somewhat differently in many countries. It includes issues like the responsible application and use of research results, possible restrictions on research on the ground of ethical objections, including possible consequences of research insights (dual use of research). External research ethics also covers the legal framework that sets the field-specific norms, as well as the protection of

basic rights and values like human rights.

Violations of internal and external ethical rules are usually handled in different ways. But some of the recommendations below are relevant for research ethics in both of these senses.

The fact that the way research integrity is managed or mismanaged will have effects on trust and confidence in science, and hence have external effects, is no objection to this distinction. Similarly, conflicts of interest and lack of independence can appear in both internal and external research ethics, but again that is no objection to this distinction.

Cross-border exchanges - political, economic, social and scientific - pose challenges to many legal and ethical norms and values. In external research ethics there are differences between countries. However, there are also many joint policies in effect at the European level. This is reflected in the Charter of Fundamental Rights of European citizens and in several EU directives that member states are obliged to transpose into national law, including the data protection directive, the clinical trials directive, the biotech directive and the cells and tissues directive.

Results of scientific research can be of immense significance for large-scale societal choices. Some of these choices are regulated by law, others not. The relations between ethics and law are complex and it is difficult to draw a sharp line between ethics and 'soft law', as codified in international codes and conventions and which deals with issues in internal as well as external research ethics.

(Principle 3) The responsibilities of scientists include awareness of and ability to deal with issues concerning research integrity and research ethics in a wider sense.

(Principle 4) Ethics education in science focuses on clarifying these responsibilities and on promoting responsible conduct of research.

(Principle 5) The ethical responsibilities of scientists are to be integrated into the curriculum of scientific education and learned as part of the mastery of the specific field of research itself.

These principles are relevant for science in the wide sense, that is, the natural sciences, the social and the behavioural sciences and the humanities. ALLEA is aware that not everything can be stated in principles and rules. There is a culture, an ethos, in science from which you learn by paradigmatic examples and role models. Mentors play an important role in the training of early career researchers.

3. AIMS AND MEANS OF ETHICS EDUCATION IN SCIENCE

To ensure that practitioners of science have robust guidance when they seek to follow the internal and external principles of research ethics in their fields, universities and research institutions should provide a continuously updated education in ethics in all fields of scientific research.

Scientists will benefit from training in ethics and in critical examination of arguments, as well as from training in understanding and applying the values that underlie and justify national and international guidelines and declarations in research ethics.

The new challenges for advanced science in society at large require the development of, and respect for, norms and standards for all scientific fields. Here it is essential to distinguish between subject-specific standards and general research integrity standards.

Training in research ethics should be specific to the discipline, whereas this is less essential for training in issues related to research integrity and internal research ethics. Criteria that define good scientific practice are by no means self-evident – but they can be taught and learned.

(Principle 6) Ethics education in science aims to fully incorporate awareness of the ethical aspects of the decisions and choices that scientists – in a wide sense – face in their work.

The general aim of education in both internal and external research ethics is to increase early career researchers' awareness of the ethical dimensions of their work and to improve their skills in critical examination of arguments offered for or against different positions. Researchers are not only an object of ethical regulations, but as agents are the subjects of their own ethical responsibility in this field of action as well. Therefore the ability to examine ethical arguments is essential.

To be successful, ethics education presupposes that the teachers are aware of the choices facing scientists in their work and that the scientists are familiar enough with concerns, concepts and traditions in ethics to make possible a meaningful dialogue on ethical issues in research.

The most important ability conveyed through good ethics training is argumentation. A 'rational argument' is not just a set of statements

designed to sway an opponent, the way advertising and some forms of rhetoric do. The ability to construct good arguments and to distinguish good arguments from bad ones is something early career researchers can and will learn.

(Principle 7) Ethics education in science focuses on the critical examination of arguments and the assumptions they are based on, as well as on the rational justification of ethical decisions taken.

To be able to argue rationally and to examine arguments critically – including in situations where there are conflicts of interest and in newly emerging fields of science – researchers must have developed a competence in ethics and be able to use it to deal with the issues they face.

Early career researchers need to develop sensitivity for the risks and benefits of the results and products of research, as well as for the possibility of potential dual uses, for instance. As an example, recent virological discoveries may lead to the production of new vaccines and at the same time be used for biological warfare or pollute our environment.

General principles of good scientific practice constitute a core element of research ethics relevant for all academic disciplines. Mandatory courses should give early career researchers the opportunity to learn to specify these principles, apply them to problems in different fields of research and to discuss grey zones of scientific practice.

(Principle 8) The means of ethics education include seminars and lectures, examining and discussing real cases collected from scientific practice.

The means of ethics education include seminars and lectures focused on real cases, recent as well as past, collected from scientific practice. Subject-specific cases are to be collected and shared with other teachers. Such a bank of examples needs to be updated on a regular basis. Different modules can be combined in several ways, according to the wishes of the teaching institution or the funding organisation.

The crucial importance of case studies is emphasised. All parts of research ethics education should allow for sufficient time for the discussion of such cases and for sharing personal experiences. Group work will give an opportunity to learn how to argue and to balance conflicting norms in an appropriate manner.

(Principle 9) Subject-specific cases should be collected and shared with other teachers, and they should be updated on a regular basis.

Moreover, without basic knowledge in ethics and training in developing argumentative skills, early career researchers may not be able to question some of the problematic practices they may come across during their career.

(Principle 10) Ethics education will empower early career researchers to understand the difference between what is and is not ethically acceptable, and prevent them from making mistakes they would later regret because of the adverse consequences for others, for science and for their own career.

In some cases, ethics is already included in the research curriculum, in others it is not. This has to be taken into account in considering ways of introducing and developing ethics in the research curriculum.

Ethics education will also prepare early career researchers to participate actively in debates about the consequences of their scientific activity and respond to those who have concerns about it. With additional training, scientists could also serve the scientific community by working in ethics committees and internal review boards.

The scientific competence and personal integrity of thesis supervisors is a decisive factor in both the research and the ethics education of early career researchers.

4. RECOMMENDATIONS

The previous sections describe the rationale for and relevance of research ethics in the context of modern scientific research, as well as the aims and methods of such education. 'Scientific research' is used in a wide sense and includes the natural sciences, the social and behavioural sciences and the humanities. In this section a list of recommendations to universities, research institutes, academies and funding organisations is presented.

It is recommended that all institutions responsible for the establishment and operation of graduate and doctoral research education include education in research ethics in their curricula. Such education should be specific and relevant to the research field concerned. It should also deal with good conduct and honesty in publishing as well as with several other problems mentioned in this statement, including the ethical issues raised by controversies over intellectual property rights.

It is recommended that these institutions create conditions so that such education in research ethics is perceived and performed as an important part of research training. Mastery of the key skills conveyed by research ethics education are to be seen as one entry requirement for successful high-quality research.

Universities and research institutes responsible for the funding of graduate and doctoral research training need to see to it that appropriate high-quality staff in research ethics is made available.

The requirements in the ethics curriculum should emerge from discussions among the leading scientists and research ethicists in a given field, and be revised on a regular basis in the light of scientific advances and new international guidelines.

National Academies, as associations of leading scholars and assemblies of leading research institutes, bear a special responsibility for spearheading this process. They are well placed to promote and guide debates and decisions across all research fields by arranging workshops, symposia and conferences, in particular those of an interdisciplinary character. When public debate emerges on ethical issues in science, the National Academies should make their voice heard.

Where national debates between stakeholders are necessary in order to achieve a consensus, Academies have the convening power to provide a neutral platform to discuss processes and a meaningful distribution of tasks and roles.

It is recommended that high-quality teaching materials for students and teachers in research ethics be developed at a national, European and even global level, taking into account advanced methodologies and reflecting the latest scientific advances and challenges.

It is also recommended that centres of information and expertise be used or established at national and international level and that relevant resources (textbooks, case studies, etc) be collected and made digitally accessible. These centres could function as regular meeting places for exchange among professionals, curriculum developers and teachers and as a basis from which to develop cooperative ventures.

In order to ensure the highest possible quality of education in research ethics, it is essential that the teachers in research ethics have competences in both research ethics and the scientific field in question.

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Ethical Aspects of Open Access: A Windy Road

WORKSHOP REPORT

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Foreword

Ever since the Berlin Declaration in 2003 marked a milestone in the proliferation of open access publishing, the topic has attracted large interest among the scientific community and beyond. The idea to provide results of research funded by taxpayer money free of charge to the general public is as simple as it is enticing. Yet, in the past 15 years, a variety of different models and forms of access have created a vast, and at times confusing, system leading to uncertainty among the research community about this, at its heart, very laudable development.

The advent of open access coincides with increasing pressures on the academic community to publish or perish, whereby researchers feel the need to publish as many research articles in as many impactful journals as possible in order to further their careers. Predatory journals have taken advantage of these existential pressures and prey on researchers to circumvent established practices of good research conduct.

However, open access is here to stay, as the European Commission's plans to publish all of the research funded within its research framework programmes in open access by 2020 clearly show.

It is therefore high time to think about improving open access publishing, to develop stronger mechanism against fraud, and to enable researchers to freely share the fruits of their labour with their peers and the general public.

This report on ethical aspects of open access summarises the outcomes of a workshop which was attempting to do exactly that. Throughout the various presentations, given by a variety of stakeholders, solutions from different angles are provided. We are deeply grateful to our hosts, the Royal Flemish Academy of Belgium for Science and the Arts, for welcoming us in Brussels, to all of our speakers, who have made invaluable contributions to the topic, to the audience for their lively and interesting participation, and to the members of the ALLEA Permanent Working Group on Science & Ethics on whose initiative this workshop came to be.

We do hope that this report can serve the reader as a comprehensive overview on the state of the ethical debate on open access and the various actors involved in the process to achieve that European research will in the future be as accessible as possible.

Professor Göran Hermerén
Chair of ALLEA Permanent Working Group on Science & Ethics

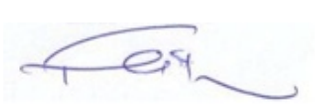

Professor László Fésüs
Lead workshop organiser; member of ALLEA Permanent Working Group on Science & Ethics

Keynote - Ethical Aspects of Open Access Publishing

László Fésüs, Hungarian Academy of Sciences

The rise of open access publishing in the past 15 years or so has been a laudable development in general, though lack of clear guidelines and absent harmonisation procedures on how to publish correctly in open access and with whom have provided a breeding ground for unacceptable and unethical publishing practices.

This presentation will reflect on the trends and developments in open access publishing; the ethical concerns and issues derived from open access publishing; and the reaction of the scientific community to these challenges.

Trends and Developments in Open Access Publishing

Open access cannot be looked at in isolation. Rather it is a development that went hand in hand with the digitisation of academic research and, more recently, the involvement of Big Data. Increasingly this enables researchers to collaborate more easily across national boundaries and academic disciplines. At the same time, scientific output is shifting away from the Western World, as evidenced by the fact that there are now more scientific papers published in China than in the United States (US National Science Foundation, 2018). Involving more people in the scientific endeavour, spread across more disciplines and countries, undoubtedly is beneficial to the quality of research. Yet, an ever-growing system with little to no regulation may either lead to confusion among researchers or to questionable business practices, both of which we can find in the open access world.

open access publishing has become a global industry based on the gold access publishing model, with the Directory of Open Access Journals (DOAJ) estimating that there are currently around 10.000 OA journals in existence.

Nevertheless, the growth of open access publishing has not exactly proceeded as anticipated or predicted. According to a 2017 analysis, only around 15% of journals publish all accepted articles as open access (Else, 2018) - financed by charging per-article fees to authors – and just less than half have adopted a 'hybrid' model of publishing, whereby they make papers immediately free to read for a fee.

In 2011, it was predicted (in a presentation made by Peter Binfield, of PLoS to the Society of Scholarly Publishing meeting in 2011) that 50% of STM (Science, Technology, Medicine) publications would be published by around 100 megajournals in open access by now. However, the actual number is closer to a mere 3% of STM publications. Open access publishing has created an explosion of titles, most of which seem to be competing for a small slice of a fixed pie (Davis, 2018). This competition has only stiffened further with the arrival of big publishing houses in open access. Arguably, open access had its roots in a reaction against the very monopoly of those big publishers, yet by their sheer market force and competitive advantage, they have managed to assert themselves in the

field of open access publishing. "The small number of elite journals with far more submissions than they can possibly handle in their toll-access flagship can use this cascading model to reassert themselves in the marketplace" (Esposito, 2015).

It has to be emphasised that rigorous quality control, information, dissemination, innovative technologies in publishing and archiving are not free, somebody has to bear the costs. The more selective the editorial process is, the more costly it becomes to publish high quality journals. "In the absence of external support, an open access journal has to be either selective and expensive, or inexpensive but less selective. Highly selective journals running in the open access mode struggle to break even, whereas large-volume, low-selectivity open access publishing generates substantial profit" (Leptin, 2012).

Research funding organisations across Europe have in many cases mandated or at least announced a preference for open access publishing for research projects financed by them. However, this preference raises the question of which form of open access is referred to and, if the answer is the gold access model, whether diverting funds from the actual research in order to pay for article processing charges (APC) - levied by journals to allow immediate open access - is the right way to go.

Research institutions and universities now face the dilemma that, if all of their research groups' publications were to be published in the gold access model, the costs for APCs would far exceed their annual budgets for journal subscriptions.

Two trends and expectations in response to this dilemma can be observed:

1. Research-intensive institutions would pay the lion's share and this would subsidise free access for less research-intensive institutions and the pharmaceutical industry. This may lead to questionable dominance of scientific publishing by richer institutions.

2. The 'green' model of OA publishing emerged, requiring authors to deposit their manuscript or its accepted version in a public repository within a predetermined period of time.

The article is generally made available free of charge after an embargo period which may vary depending on the research funders: mostly either 6 months to 1 year in the natural sciences and between 1 to 2 years in the social sciences and humanities.

Uncertainty about open access publishing models makes compliance cumbersome for researchers. Open access mandates (gold or green, different repository requirements, reporting) set by institutions, funders and governments differ in various countries.

The European Council Conclusion 9526/16 agreed to support the transition to immediate open access as default by 2020 without embargoes (or with as short as possible embargoes), without financial and legal barriers, taking into account the diversity within the scientific community. Though, the transition process seems to be lasting a lot longer than expected, and it is not likely to be concluded before there is a uniform agreement on which form of open access publishing should be adopted across Europe. The recent announcement of several European research funders, called Plan S, to mandate scientists they fund to publish only in full open access journals from 2020 might accelerate this process.

Ethical Issues and Concerns

As seen above, the advent of open access has been a confusing, de-centralised enterprise with an absence of regulations and guidelines, leading to a number of ethical issues faced by those active in the scientific endeavor.

Ethical issues include, but are not limited to:

1. Possibility of restriction in academic freedom
2. Emergence of APC figure as a measure of quality
3. Mushrooming of bogus ('predatory') journals
4. Increased use of bogus journals
5. Hybrid journals – 'double dipping'

Researchers may find themselves in a situation where they are restricted to publish their work in channels they consider less appropriate. This could happen either via administrative open access mandates requiring publication with a certain model of open access, or via the limited availability of funds for APCs.

Depending on the size of earmarked APC funds in their institution or country, researchers may not have equal opportunity compared to some of their peers to freely publish their results as they see fit for the advancement of their research careers.

These elements may endanger the freedom of science and the principle of equal opportunity, and further widen the already existing gap in research output between countries, including Member States of the European Union.

In certain areas, we run the danger of linking the value of scientific results to the amount of APCs charged for open access publication. APCs cannot and should not be regarded as a quality measure for scientific work, as it creates false and artificial criteria for the assessment of scientific excellence.

The emergence of bogus or predatory journals is a regrettable development to take advantage of the lack of clear guidelines in open access publishing, and it is yet another symptom of the pressure many researchers face concerning the 'publish-or-perish' mentality often applied to career advancement. According to research done by Shen & Björk in 2015, 8,000 predatory journals published around 400,000 articles.

Predatory journals often name nonexistent people as their editors and editorial board members and claim ownership of articles that they have plagiarised from other publications. Sloppy or no archiving of articles is commonplace. Typically, these publishers spam professional email lists, broadly soliciting article submissions for the clear purpose of gaining additional income.

Read more about poor editorial standards in this sting operation conducted by John Bohannon and published in Science (2013, 342) -> *Who's Afraid of Peer Review?*

http://science.sciencemag.org/content/342/6154/60

Read more about the recruitment of fake editors in this study by Piotr Sorokowski, Emanuel Kulczycki, Agnieszka Sorokowska, and Katarzyna Pisanski published in NATURE (2017, 543) -> *Predatory journals recruit fake editors.*

https://www.nature.com/news/predatory-journals-recruit-fake-editor-1.21662

Researchers may find themselves more compelled to publish in a predatory journal to seemingly more easily disseminate their work, yet they do so at the cost of solid editorial standards such as comprehensive peer-review. Others may be duped by predatory journals or follow poor guidance by colleagues.

Increasing number of researchers are tempted to pay and then expect lower standards by publishing their findings in bogus open access journals which lack quality control in order to increase their personal career. This has resulted in misuse of funds for self-promotion, increasing number of inaccurate

or even fabricated results in the scientific literature, and misleading scientific claims. Many researchers are just deceived by predatory journals or are simply unaware of the difference between bogus and quality open access journals. Even those who recognise a potential problem can fall victim. Predatory journals are becoming increasingly adept at appearing legitimate (Moher et al, 2017).

Problems associated with open access publishing also touch upon business ethics. A large proportion of the traditional subscription journals became hybrid journals, publishing an increasing number of open, freely accessible papers online for which publishers collect APCs, in addition to the subscription payments - for the same journals - received from libraries and licensing consortia. This is often called 'double dipping'. Unless publishers introduce a transparent system which decreases subscription payment in proportion to collected APCs, they will be blamed for exploitation of the publishing system to gain extra profit.

> The above problems pose both a financial as well as an ethical problem, as was described in the study by David Moher et al. published in NATURE (549, 2017) -> *Stop this waste of people and money*
>
> https://www.nature.com/news/stop-this-waste-of-people-animals-and-money-1.22554

The repercussions of such unethical business practices and poor publication standards come to the detriment of the entire scientific community. Rattled by scandals and irreproducible research, it is unsurprising that the public would begin to lose trust in scientific output, resulting in a rejection of science and ultimately in a reduction of research funding.

Reaction by the Scientific Community

It should be made very clear that some of the issues open access faces with regards to unethical behaviour must not reflect on its commendable merit of enabling easier and less restrictive access to scientific publications as a whole.

The responsibility lies with all stakeholders in open access publishing to ensure that the core principles of scientific publishing are abided by. These are the critical, high quality and independent evaluation of scientific claims and the secure archiving of validated research.

The academic community must therefore arrive at a common understanding of open access which simultaneously provides equal opportunities for researchers regardless of their location or discipline, and which does not violate or threaten academic freedom.

Furthermore, in the absence of a centralised governing body, it is up to the community to monitor the publishing scene and communicate with each other where to publish and which journals to avoid.

Members of the scientific community should be encouraged to participate in such monitoring activities, to report misconducts and to support activities which regularly list, based on well-defined criteria, credible and bogus ('predatory') publishers and journals.

Recommendations by Moher et al (2017):

» Publishers, research institutions and funders should issue explicit warnings against illegitimate publishers.

» Funders and research institutions should prohibit the use of funds to support predatory journal publications; make sure that researchers

are trained in how to select appropriate journals when submitting their work; audit where grantees, faculty members and research staff publish.

» When seeking promotion or funding, researchers should include a declaration that their CV is free of predatory publications.

» Before approving a study, ethics committees should ask researchers to declare in writing their willingness to work with their institutional resources, such as librarians, to ensure they do not submit to any journals without reviewing evidence-based criteria for avoiding these journals.

To identify predatory journals it is advisable to follow the 13 characteristics to identify predatory journals as laid out by Shamseer et al (2017, see box). Additionally, it may be worthwhile checking Cabell's Index, a website currently listing around 4,000 journals on a blacklist of predatory journals; 65 criteria are used to determine whether a journal is predatory and a white list is also available. The Directory of Open Access Journals (www.doaj.org) also provides useful information about credibility of OA journals.

Salient evidence-based characteristics of potential predatory journals as described by Shamseer et al (2017)

1. The scope of interest includes non-biomedical subjects alongside biomedical topics.
2. The website contains spelling and grammar errors.
3. Images are distorted/fuzzy, intended to look like something they are not, or which are unauthorised.
4. The homepage language targets authors.
5. The Index *Copernicus Value* is promoted on the website.
6. Description of the manuscript handling process is lacking.
7. Manuscripts are requested to be submitted via email.
8. Rapid publication is promised.
9. There is no retraction policy.
10. Information on whether and how journal content will be digitally preserved is absent.
11. The Article processing/publication charge is very low (e.g., < $150 USD).
12. Journals claiming to be Open Access either retain copyright of published research or fail to mention copyright.
13. The contact email address is non-professional and non-journal affiliated (e.g. @yahoo.com).

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Editorial Responsibility In The Open Access World

Chris Graf, Committee on Publication Ethics/ Wiley

The guiding question of this presentation is concerned with the responsibilities of editorial staff in the open access world. After all, as we move from a traditional subscription access world to an open access world, editorial responsibility is still all about quality.

In order to achieve this quality assurance, COPE suggests 10 core practices which journal editors and journal publishers should - or even must - adhere to. In addition to these core practices, there are a number of further actions which could be taken to tackle some of the challenges today's research and publishing ecosystem presents to editorial staff. Adhering to transparent and clearly defined standards helps journals to both create a better understanding within the research community regarding the reasons why these practices are needed, while simultaneously increasing the quality and accessibility of the scientific output.

These core practices are supplemented by a wealth of resources that elaborate in-depth on many of these processes, all of which are available on the COPE website. As the research endeavour varies slightly from institution to institution, and even more so between countries, it is of paramount importance to consider the core practices alongside existing national and international codes of conduct for research.

Yet if COPE stopped at just the provision of these core practices that would not suffice in a research publishing industry that has seen dramatic changes over the past few years. One such example of an unintended consequence has been the increasing prevalence of fake reviewers, accompanied by increasing recognition that the peer-review process could be improved. For entrepreneurs who understand the intense pressure researchers face to publish a large body of work in as short a time as

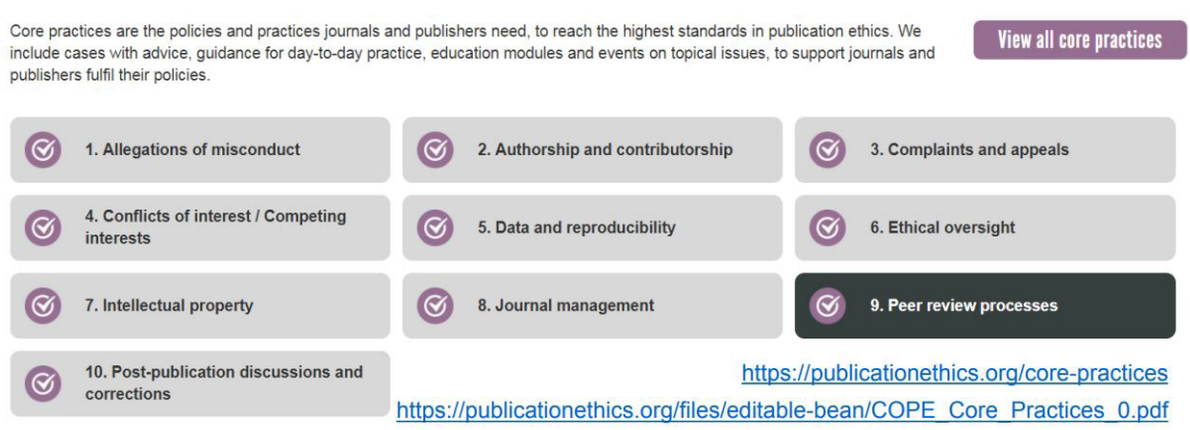

COPE's Core Practices (https://publicationethics.org/files/editable-bean/COPE_Core_Practices_0.pdf)

possible, the incentive to create services that tempt researchers wittingly or unwittingly to engage with fake reviewers in exchange for money becomes more intense and alluring.

Most researchers do not seek to publish their work in dubious journals, yet the pressure to publish in order to advance their academic careers, coupled with a notable absence of mechanisms to identify reliable and unreliable peer-reviewed publishers, can easily lead to less-than-desirable publishing outcomes. To assist the researchers as well as the editors, COPE provides an overview of potential red flags which, if occurring concurrently, should lead to a more thorough investigation of the reviewer's credentials. The list can be accessed here: https://publicationethics.org/files/COPE%20PR_Manipulation_Process.pdf

Open access has come up with a variety of different publishing models, which are added to the already existing models in established publishing houses. However, regardless of their subscription model, high publishing standards and requirements regarding the scientific merit of an academic publication must remain the same.

To date, COPE has avoided mentioning predatory journals or black lists; rather, COPE's focus is on what good practice looks like so as to encourage clean editorial work. One major way of doing that is to refer researchers to resources which can help them make good decisions regarding where to publish their research, such as 'think.check.submit' (https://thinkchecksubmit.org/), which guides researchers through the process of assessing the appropriate publishing outlet to submit their research paper. While reputable journals and publishers will usually have solid practices in place to ensure the quality of their published research, it may at times be the case that those standards slip or that they are simply no longer fit for their purpose. As such, COPE includes a sanction process where its members fail to meet the 10 core practices and need to demonstrate better practice.

Beyond Editorial Responsibilities

Together with DOAJ (https://doaj.org/), OASPA (https://oaspa.org/) and WAME (http://www.wame.org/), COPE has developed a document which highlights the 16 principles of transparency and best practice in research publishing[1]. These principles are used to vet membership applications. Some of those principles apply to business practices, such as:

1. **Website**: A journal's website, including the text that it contains, shall demonstrate that care has been taken to ensure high ethical and professional standards. It must not contain information that might mislead readers or authors, including any attempt to mimic another journal/publisher's site.

An 'Aims & Scope' statement should be included on the website and the readership should be clearly defined. There should be a statement on what a journal will consider for publication including authorship criteria (e.g., not considering multiple submissions, redundant publications) to be included. ISSNs should be clearly displayed (separate for print and electronic).

2. **Name of journal**: The Journal name shall be unique and not be one that is easily confused with another journal or that might mislead potential authors and readers about the Journal's origin or association with other Journals.

1 Taken from COPE/DOAJ/OASPA/WAME (2018), Principles of Transparency and Best Practice in Research Publishing, version 3. Emphasis speaker. https://publicationethics.org/resources/guidelines-new/principles-transparency-and-best-practice-scholarly-publishing

3. **Ownership and management**: Information about the ownership and/or management of a journal shall be clearly indicated on the journal's website. Publishers shall not use organizational or journal names that would mislead potential authors and editors about the nature of the journal's owner.

4. **Governing body**: Journals shall have editorial boards or other governing bodies whose members are recognized experts in the subject areas included within the journal's scope. The full names and affiliations of the journal's editorial board or other governing body shall be provided on the journal's website.

5. **Author fees**: Any fees or charges that are required for manuscript processing and/or publishing materials in the journal shall be clearly stated in a place that is easy for potential authors to find prior to submitting their manuscripts for review or explained to authors before they begin preparing their manuscript for submission. If no such fees are charged that should also be clearly stated.

6. **Revenue sources**: Business models or revenue sources (e.g., author fees, subscriptions, advertising, reprints, institutional support, and organizational support) shall be clearly stated or otherwise evident on the journal's website. Publishing fees or waiver status should not influence editorial decision making.

7. **Direct marketing:** Any direct marketing activities, including solicitation of manuscripts that are conducted on behalf of the journal, shall be appropriate, well targeted, and unobtrusive. Information provided about the publisher or journal is expected to be truthful and not misleading for readers or authors.

Many bad practices relate to pretending to be something that you are not; how a journal is governed, owned and managed, and who is involved; fees must be transparent and upfront and a description how the journal makes money must be provided.

The World is Changing, What Are We Doing About It?

One of the problems, and subsequent criticisms, many research publications run into is their lack of reproducibility, a feature so common that it is generally referred to as the reproducibility crisis. Rather than focusing on the immense difficulty of reproducing an experiment 1-to-1, we ought to instead rethink how we approach the research methods.

One way to do that would be an expansion, or rather re-application, of the peer review process at an early stage of the research process. Researchers could first have their methods validated; these would then be transparently registered, and this would allow for peer review of the research methods before the results of the research are known, a model called Registered Reports (https://www.bps.org.uk/news-and-policy/we-are-working-wiley-improve-replicability-and-transparency-research). Registered Reports would enable researchers to present their research design and get feedback on how to improve their research design. If researchers adhere to these suggestions, journals would more readily agree to publish their research once it has been conducted. It is an 'in principle' acceptance before the research is carried out, but at the same time ensures good research practice while reducing the temptation to oversell the outcomes of any given research project.

Methods are only one part on the quest to improve research; another aspect is data. Data is particularly

susceptible to contain errors, which may range from simple typos to incorrect structures, all of which could result in useless research outcomes. By using data validation, such as this free Wiley service to validated ^{13}C NMR data (https://www.wsslabs.com), researchers can enter their data and have it validated based on previous data readings from different researchers who used the same technique. The programme will then provide a certificate which can be submitted to the publisher alongside the final research. It is worth noting, however, that data validation may only work in fields with comparable research procedures, such as chemistry or related fields in the natural sciences.

Consider What We Aspire To

Science is like an orchestra, in which many people contribute in different ways to a greater purpose. This means that the median impact factor of research publications is far below that of NATURE publications, which are the equivalent to achieving 'rock star' status in the science world. We need to be aware of this discrepancy and keep in mind that, for the vast majority of research, transparency is more important than excitement. This in turn means that transparency must be increased and that being transparent must be made as easy and as rewarding to researchers as possible.

A publication by Brian Nosek and colleagues on promoting an open research culture (Nosek et al, 2015) describes the TOP guidelines to aim for research transparency in eight standards and on three levels. The standard is widely endorsed in the research community, yet its implementation is lacking. The authors of this report recognise this project and, in collaboration with the Center for Open Science, devised a workshop on TOP part 2, resulting in the preprint here (https://doi.org/10.31219/osf.io/sm78t) which aims to make the recommendations from TOP part 1 implementable.

In the end, what we need to aspire to is embracing the idea that being a part of a 'research orchestra' is as rewarding as being a 'science rock star'.

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Open Data: Balancing Transparency with Resilience

Stephan Lewandowsky, University of Bristol

This presentation highlighted the vital importance of transparency and open data for the success of open access as a publishing model. It is crucial that the transformation and implementation of transparency and open data is driven by the scientific community. This is presuming that if scientists fail to come up with suitable ways to make their data accessible while at the same time protecting it from undue use, other institutions with less-than-noble goals might do it for them. Such institutions could include private businesses, but might also come in the form of government agencies regulating open access.

Transparency and open data are essential and, at least on the surface, its harmful potential may not always be immediately obvious to the untrained eye. Though, when we talk about these two terms, we need to consider their full implications, which go far beyond just making data available. Whether we like it or not, transparency and open data are political or, with the right spin imposed on it, can be politicised.

This presentation therefore lays out several situations where transparency and open data may be employed to abuse, misrepresent, or mislead individuals or even society at large.

In particular the focus will be on:

1: Intentions of people requesting data

2: Questions surrounding consent and ethics

3: The competence of people who request data

4: Cherry-picking of research results to suit an agenda

In order to contextualise the above 4 issue areas, it is crucial to understand what makes transparency and open data political, who has vested interests, and how politicisation of scientific research is used to create uncertainty in the greater population in order to further someone's agenda.

Publicly funded scientists, especially if they are held to the high standards as laid out in the chapter on editorial responsibility, will have undergone lengthy procedures before, during, and after their research to ensure that their datasets are not only sound, but also in accordance with the FAIR (Findable, Accessible, Interoperable, Reusable) principles.

This means that their data should be made available for scrutiny by external channels, regardless of their ability to pass a scientific judgement on this data. Privately funded research, by contrast, is generally exempted from such disclosures.

This may lead to cases as described in Cataldo, Bero & Malone (2010), in which the tobacco industry used raw access data and re-analysed it with different parameters to make the dangers of tobacco-related morbidity and mortality disappear.

On the other side of the spectrum, scientists may find themselves accused of withholding data, despite ample evidence to the contrary. (Compare: Gianelli 1998).

Both of these scenarios, reinterpreting data and casting doubt over the integrity of the researcher, serve the same purpose: to create uncertainty over the validity of the research produced. This uncertainty is generally not one that affects the

scientific community, which has sufficient means in and of itself to navigate such a conflict, but rather it is aimed at the general public. The assumption is that as long as the general public believes there is a disagreement among scientists about certain issues (climate change, tobacco, vaccinations), no decisive legislation can be taken in favour of one position or the other. In matters concerning public health, this does not only jeopardise the reputation of the researcher whose data was misused, but often times it comes as a direct detriment to the population who is misled.

In the turn towards open access, scientists therefore need to be keenly aware of the implications that making their data open and transparent may have when used nefariously. Levy & Merritt Johns (2016) put it even more strongly when they speak about the weaponisation of transparency in science and governance.

1. Intentions of People Requesting Data

Depending on whom you ask the question of whether the intentions of the people/institutions requesting the data matter or not, you might get a variety of responses. While open data advocates, as well as industry representatives requesting data from publicly funded research for their own research, would argue that intentions should not matter, many researchers in public health would disagree.

The issue at hand is whether people or institutions who request access to data should disclose any conflicts of interest that may arise from using that data, since data can be, and has been, used selectively to suit a certain narrative. As mentioned above, the scientific community will usually not be fooled by these cases for longer periods of time; the existing checks and balances will eventually override any harm done by the misrepresentation of data. However, the question of intention becomes more complex when it pertains to the use of data to shape public opinion and, perhaps more importantly, public policy.

If data is interpreted in a way that omits certain aspects of the dataset or outright dismisses them, then doubt is cast on the validity of the entire research. As such, the appearance of a scientific debate is created on a topic in which there is actually widespread scientific consensus. Climate change is a clear example of a topic where an insignificant minority of scientists oppose the commonly accepted position of anthropogenic climate change. The public is now confronted with two diametrically opposed positions, neither of which they may fully understand due to their complexity. All they know is that one is vastly more inconvenient than the other. What we end up with is a situation of public indecisiveness, which lasts as long as this faux scientific debate remains unresolved. Before a resolution is found, no meaningful public policy response will be formulated. In the case of tobacco, control legislation was delayed significantly as a result of an apparent scientific 'debate' (Proctor, 2011).

2. Questions Surrounding Consent and Ethics

Any research conducted in which human beings are the research subjects relies on their explicit consent to partake in the research. Researchers need to ensure the confidentiality of their research subjects' data and need to make sure that they are not individually identifiable. However, for a variety of reasons, full anonymity often proves difficult to achieve, leaving a backdoor open for potential abuse via 'creative' interpretation of results. There is a need to carefully think about the implications of consent. Consentees may not realise entirely what their consent may entail if their data has to

be made openly available and is therefore possibly subject to abuse. For the research community, this poses some difficult questions: how to ensure that research subjects are aware of knock-on effects of their consent for one particular study? If they do understand the possible knock-on effects, would they give their consent to this study, or to any other study in the future?

Open data is, by its very nature, susceptible to abuse. There is a real danger that consent given for one particular study is misused in further studies by other researchers or political operatives, without specifically re-requesting consent for further use.

3. The Competence of People Who Request Data

While scientists operate in an institutional context governed by different committees and boards that ensure thorough quality assurance of their research projects, open data means that someone without a scientific background can re-analyse scientifically sound data and arrive at different or wrong conclusions. This would not, in and of itself, represent the biggest of problems. However, enabled by modern communication technologies, it has become ever more simple to reach a global audience via podcasts, social media and the like, which are easily accessible online. In a way, communication technology can equally amplify the voices of the scientists and the voices of the laymen playing scientists. Sometimes the non-scientists may even drown out the scientists with more 'catchy' or fear-mongering results. For the general public, it may at times be difficult to differentiate the validity of findings published in journal articles versus other less scrutinised means of dissemination. In this, the role of the media must not be understated, as their only vested interest is selling papers, which is best done by creating controversy. Smith et al. (2007) investigated this phenomenon by looking at UK MMR vaccination rates and its relation to sustained negative, but false, coverage of the effects of MMR vaccinations on children.

4. Cherry-picking of Research Results to Suit an Agenda

In line with the responsibilities laid out in chapter 2, researchers are now expected to conform to high-quality standards in the conduct of their research. They ought to pre-register their hypotheses and their analysis, against which the data will be evaluated to ensure that they did not cherry-pick results or outcome measures. Yet, the same is not done for those who request data. As a general rule, if you look at enough data for long enough, you will be able to find a data set that suits your agenda. Previous points above highlight that sometimes only very little spin is required to obfuscate the original meaning of a data set.

Requiring an analysis plan as a condition to access data is both in accordance with the *Accessible* component of the FAIR principle, which allows for moderation of access, and it would allow to better protect sensitive data by providing a measure to guard against improper usage.

Conclusion

There is no doubt that science needs to be open and transparent. However, there is an important distinction to be made between a scientific debate and the public debate. Conflating the two, intentionally or unintentionally, can lead to uncertainty and indecisiveness in the public perception, with, at its worst, harmful outcomes for the population.

We need to recognise that openness and transparency facilitate science, but they also aid in the dissemination of noise, nonsense, commercial interests, and political propaganda. The scientific community needs to be acutely aware of this and cannot cast it aside.

A solution is to create a balance between the researchers and their data on the one hand, and the users requesting the data on the other. This would provide a symmetrical structure, wherein the people requesting the data must show that they are competent enough to appropriately use them. This must go hand in hand with institutionalised mechanisms of accountability, such as independent national arbitration boards that decide on data availability or, in contested cases, can provide independent re-analyses.

Pre-registration of intended uses by the requesting party would be another step towards better use of open data.

At all times, the consent of the research subjects needs to be observed and the consentee needs to be aware of the full implications of their consent.

To protect against undue accusations of withholding data, the peer review process should include a determination of whether all data has been made available and used appropriately.

Transparency and open data are at the core of good research practice, though the above challenges remain and require innovative solutions from within the scientific community.

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Questionable and Unethical Publishers: How to Spot Them and Enable Researchers to Avoid Being Trapped

Lars Bjørnshauge, Directory of Open Access Journals

Since the advent of the Budapest Convention on open access 15 years ago, two concurrent publishing models in open access have emerged, the green model and the gold model. While distinctly different in the kind of access they provide to the end user, both are considered open access formats, leading to widespread confusion among the research community. Gold open access is providing immediate access to the final published version in fully open access journals, be it with or without article publishing charges (APC), most articles are published with APCs, but the majority of open access Journals are operated without APCs. Green open access provides access to earlier versions of the papers archived in open access repositories, often after an embargo period defined by the publisher.

This presentation will examine the issue of questionable publishing, which is not restricted to open access publishing, yet its ongoing confusion on terminology provides a fertile environment for publishers to engage in questionable behaviour. This chapter will therefore look at what constitutes questionable publishing, what drives it, and how to detect questionable journals.

What Constitutes Questionable Publishing

Over the past years, we have witnessed a growing understanding within the research community, but also among policy-makers, that the accessibility of research results is conducive to the creation of better scholarship. Yet we are still lacking the incentives to effectively distribute and provide access to the knowledge created through research. Decision makers and research funders still accept that research results are not readily available in open access immediately after publication. In recent years, however, an increasing number of research funders have moved to recommend and even require that the research they are funding is published in open access, but they still leave it up to the researcher to choose where and how (open/not open) to publish it. What is needed, thus, is a re-thinking within the funding community to better get to grips with how the research they are funding is actually accessible for the research community on a global scale and specify the requirements in terms of compliant publishing channels. This means that a paper should be available immediately out in the open, including the underlying data as well as any software that was used to obtain this data. Publishing needs to be perceived, in a way, as the responsibility of the academic community, much like academic freedom is considered paramount for good research design.

Bohannon (2013) in his study *Who's Afraid of Peer Review?* somewhat infamously published results showing that multiple open access journals fell for a sting to publish fake research, leading to questions around their approach to peer-review. However,

recalling the main idea of this chapter that questionable publishing is not restricted to open access publishing, only one year later, Van Noorden (2014) broke the news that legacy publishers had to withdraw more than 120 papers which were proven to have been computer-generated. Questionable publishing is therefore not exclusive to open access publishing, but the business model of open access, where it is relatively easy to set up a journal and solicit articles, has certainly made it easier to engage in questionable practices. Regardless of the shape these questionable practices may take, they are the ones that are considered, as coined by Beall, 'predatory journals'.

Yet, the term predatory may itself not be entirely applicable, or at least not only to the journals that are commonly chastised with the term. If we assume that predation in the publishing industry is based on the interest to make a profit, then exploiting the divide between libraries (that typically pay for subscriptions) and scholars (who typically expect and demand access to those subscriptions) in order to make extraordinarily high profits could be considered predatory conduct. In the same way, continuing to raise prices at several times the rate of inflation, even as those increases cause direct injury to libraries by robbing them of budget flexibility or even make it impossible for them to continue providing resources, is very much driven by an interest to make a bigger profit. However, both of these practices are commonplace, even for publishing houses which are not generally considered predatorial. Though, blame should not fall on the publishing industry. Instead, academia should re-assess their thinking to outsource the dissemination of their intellectual production without service level agreements to a third-party, the publishers.

As such, the term 'predatory publishers' should not be used, as its terminology is unclear. In the same way as the terms 'illegitimate publishers', 'deceptive publishers', and 'unethical publishers' all touch on certain aspects that are wrong within open access publishing, but none can be globally applicable. Thus, the term 'questionable publishers' provides a more accurate and realistic description.

Directory of Open Access Journals (DOAJ) definition of questionable publishers:

Questionable publishers are publishers who are not living up to reasonable standards in terms of content, services, transparency and business behaviour.

Indubitably, questionable publishers are a problem. The question remains, however, just how big of a problem they really are. Shen & Björk (2015) estimated that at the time of their investigation, around 8.000 questionable journals containing about 420,000 papers existed. A similar study conducted by Crawford (2017) came to the conclusion that many of those journals are actually empty. He came to the conclusion that there are 3275 (active) journals, with about 121,000 articles published in them.

In their analysis, Shen & Björk noticed that questionable publishers originate and are spread throughout the world, with India being the single largest country of origin at 27.1%. The same holds true for the authors, with India being home to about 34.7% of all authors publishing in questionable formats.

What Drives Questionable Publishing

In the assessment of questionable publishing practices, five main drivers can be identified:

1. Ignorance

2. Aggressive marketing
3. Publish-or-perish
4. Research Assessment
5. Exclusion

Ignorance

At times, researchers show a stunning lack of attention to the fate of their paper. It appears as if all available energy was used up in the production of the research, only to then ignore entirely what happens with their papers afterwards. This may derive from ignorance around peer-review, archiving, indexing, and the like. In principle, this means that a solid research product may be published on a platform whose quality standard is far below the quality standard used in the production of the research.

Aggressive Marketing

Researchers often find themselves aggressively targeted by scientific journals' marketing campaigns urging them to publish their research in their journal. Ease of access to publishing, thus, becomes an alluring prospect in a career-driven world. Especially, when considering the third point in this list.

Publish-or-Perish

In order to advance their academic careers, researchers are now keenly aware of the need to include as many publications as possible on their CV, regardless of their individual merit. Unfortunately, in too many cases, this behaviour still pays off with better career prospects, while there are few, if any, repercussions to be feared when publishing in those journals. Particularly researchers in the Global South may be tempted to pay money to have their research published if it ends up enabling them to get a better CV.

Research Assessment

While some blame lies with the researchers, it is perhaps more important to note that those in charge of assessing the merits of a scientific publication often fail to comply with their obligation to thoroughly ensure that the journal in which the research was published actually is of sufficient quality itself. Research assessment cannot be done only by looking at the number of publications of a researcher, or an impact factor of a journal, but must focus on the actual research.

Exclusion

In line with the finding of Shen & Björk, there seems to be a certain bias by dominant indexing platforms, such as Scopus or Web of Science, against research that was not produced in the Global North. In response, researchers from the Global South often feel the need to find a workaround to get published.

First and foremost, those managing or funding research need to re-think how they evaluate the research they govern. Research assessment can only be based on the actual content of the research, and not on any other metric, such as impact factor or number of publications.

Institutions that issue mandates to publish the research they fund in open access should develop mechanisms to guide researchers to assess the various publishing channels. One way to do that could be by creating and disseminating lists of accredited publishing channels, which is what more and more governmental institutions and authorities do.

Another aspect, closely related to the concept of research integrity, is publishing literacy. Knowing how and where to publish, and how to share must be an integral part of researcher's training.

How to Spot Questionable Publishers/ Journals

In its most basic form, the 5 minute check as outlined by Gavia (2012) can serve as a comprehensive starting point to identify the black sheep in the publishing community.

The DOAJ does not seek to primarily exclude those with questionable publishing practices. Rather, it aims to promote open access journals that behave in line with the Principles of Transparency in Scholarly Publishing (https://doaj.org/bestpractice), which the DOAJ co-developed with the Committee on Publication Ethics (COPE), the open access Scholarly Publishers Association (OASPA), and the World Association of Medical Editors (WAME.), to assist journals to become attractive publishing channels.

When a journal applies for listing in the DOAJ, the journal needs to both adhere to these principles as well as be able to respond to no less than 54 questions concerning the policies and working mechanisms of the journal before they can be included in the DOAJ. These questions ensure that the journal is in line with quality assurance guidelines accepted in the community and include questions about the editorial board, the peer review process, archiving/ preservation, plagiarism, openness, licensing and copyright, re-use rights, and charges.

In this process, it may well be that a publisher does not satisfy every single criteria at the moment of application. However, the DOAJ is keen to support these publishers to improve their internal structures. A single appearance of a shady practice does not in and of itself warrant exclusion from the DOAJ. Rather this prompts communication with

The 5 Minute check to assess the credibility of a journal -> Gavia Library

- Competent web-site?
- Mass e-mails asking for editors and submissions?
- In the DOAJ? – if not: worrying
- Usage statistics?
- Staple in the discipline?
- Misspelled journal titles?
- Journal launch dates – many at the same time?
- Empty shells- no/few articles?

the journal to help and advice in improving the journals' practices. It is the accumulation of several bad practices which arouses suspicion and will lead to rejection.

However, there are also a number of bad practices which should raise red flags among those dealing with journals. If a journal displays inappropriate marketing practices such as email spamming; if it has a title that includes 'International', 'American', or 'European'; if it is very broad in scope; if it displays fake impact factors; if it advertises quick publishing; if it has a low publication fee; if it has little to no quality control of articles; and if it has a low or no standard for peer-review, suspicions over the integrity of the journal are justified.

Blacklists

Blacklists are incomplete by definition and susceptible to legal challenges as well as personal bias. This stigmatises publishers rather than help them get better (Neylon, 2017).

Whitelists

Whitelists (lists of accredited journals) may be a better tool in that regard. They show that a journal abides by certain standards. These standards can be used as a basis for research evaluation, rewards system, promotion and resource allocation. In other words, if you do not publish in an accredited publisher, you may not get support for APCs. The aim must be to steer researchers towards using whitelisted journals rather than avoiding blacklisted journals.

The 16 principles of transparency in scholarly publishing as described by COPE, OASPA, WAME, and the DOAJ

1. Peer review process
2. Governing Body
3. Editorial team/contact
4. Author fees
5. Copyright
6. Identification of and dealing with allegations of research misconduct
7. Ownership and management
8. Website
9. Name of journal
10. Conflicts of interest
11. Access
12. Revenue sources
13. Advertising
14. Publishing schedule
15. Archiving
16. Direct marketing

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https://www.allea.org/wp-content/uploads/2018/02/LBjoersnahuge_Questionable-and-Unethical-Publishers-How-To-Sport-Them-and-Enable-Researchers-To-Avoid-Being-Trapped.pdf

Research Assessment In Open Science

Michele Garfinkel, European Molecular Biology Organization

This presentation is concerned with how a shift towards open science would fundamentally impact research assessment and, subsequently, the prospects of career academicians. At the very heart of scientific publishing, as defined by the National Research Council of the National Academies (2004) of the United States, lies the intention to move science forward. The act of publishing is a quid pro quo in which authors receive credit and acknowledgement in exchange for disclosure of their scientific findings. This method of disseminating scientific findings has been proven and tested for decades and constitutes the foundation of the modern scientific publishing industry.

The caveat, as this presentation points out, is that publishing in a renowned journal and achieving a high impact factor, i.e. number of citations, has arguably become in and of itself the most important metric to assess the quality of scientists. The result has been an academic industry in which scientists at all career levels, though particularly young scientists, feel the pressure to publish a large volume of publications as quickly as possible, a development known as 'publish-or-perish'.

In the transition towards open science and particularly open access, this publish or perish culture has at times led to questionable publishing practices. Scientists may feel the need to publish their research in journals with high visibility and impact or in journals without due respect for appropriate quality assurance and peer-review, the latter of which is undermining the trustworthiness of their own research as well as that of the scientific community as a whole.

This presentation thus intends to highlight what the purpose of publicising scientific information should be, as well as to point out methods which would enable it to better achieve its intended goals, namely to improve the overall quality of published scientific output.

Regardless of which shape the scientific publication comes in (be it open access, the traditional subscription-based model, and even preprints) there are certain core principles that need to be met in order to meet the quality standards of scientific publications.

The 11 core principles that EMBO bases its scientific publishing on have strongly influenced the 'Declaration on Research Assessment – DORA', which was adopted in 2012 and has since become a global initiative covering all scientific disciplines as well as key stakeholders in the scientific landscape. The single most pertinent recommendation from this declaration vis-à-vis research assessment is "the need to eliminate the use of journal-based metrics, such as Journal Impact Factors, in funding, appointment, and promotion considerations." The declaration makes it very clear that "Journal Impact Factors should not be used as a surrogate measure of the quality of individual research articles to assess an individual scientist's contributions, or in hiring, promoting, or funding decisions." The reality, however, shows that Journal Impact Factors have become exactly that: a convenient means to

EMBO 11 core principles

1. Transparent review
2. Scooping Protection
3. Referee Cross-Commenting
4. Single Round
5. Fast Process
6. Source Data
7. Approachable Editors
8. Informed Evaluation
9. Manuscript Transfers
10. Flexible Formatting
11. Pre-publication screening

judge the perceived merit of a scientific publication, for both researchers and assessors. This is not to say that metrics-based assessments are not useful per se, though it still needs to be figured out how to meaningfully integrate them in the research assessment process. The problem that arises for the assessors is that the alternative - a thorough review - is expensive and time-consuming and therefore, given the volume of publication, often too cumbersome or even outright impossible.

This leads to the question: if impact factor and other metrics-based assessments should be discarded as a means to judge researchers (and it seems that increasing open access publishing may make them somewhat redundant anyway), what are better ways to assess research in the future?

One approach which has gained some traction has been the use of preprint servers such as ArXiv/BioRxiv, where scientists can upload their final, though still pre-peer-review, articles online to invite comments. Reservations towards the use of preprint servers come mostly from researchers who may be afraid to make their research known before their name can be officially attached to it because of fears that they could be scooped. This is a legitimate concern, and any system focussing on preprint servers must take scooping protection into consideration. At EMBO, this means that if you submit a preprint, or a regular article submission for that matter, and someone else publishes a similar research afterwards, the original article shall still be printed, provided it satisfies all other quality standards.

Preprints may be the future of research. Researchers, as the authors of their papers, should have control over their publications. As it stands currently, peer-review on preprints is not at all times a formalised process yet, though there is some indication that the community is moving towards formalising it. Nevertheless, there is little doubt that preprints encourage openness and, it is expected, honest behaviour. As such, it may be integral to the improvement of research integrity.

One aspect that still needs to be addressed is the sustainability of preprint servers. This question revolves around ownership of the respective servers and how to ensure that articles remain accessible even after the owner no longer exists. This is a question primarily of funding and of maintaining those servers, which in the end does create some costs.

Providing the opportunity to publish a research article preprint is very much shaped and driven by the suppliers of research infrastructures. However, their provision is a moot point without better training for research practitioners. Despite

intensifying efforts on the European level, many practitioners still lack the basic skills to conduct research properly, including vital aspects such as data management plans, use of controls and the like. The onus to communicate and provide these trainings to research practitioners - particularly those at the beginning of their careers - is on the institutes, but also on the supervising positions.

A further aspect obfuscating the assessment of research is the high number of authors many collaborative research projects contain. There is little doubt that modern research, especially in the natural sciences, would not be possible without large teams, often in collaborative efforts between research institutes. Yet a list of authors does not indicate to which extent an individual researcher has contributed to a given paper. For example, senior professors may use this system to bolster their bibliographies and their impact factor, by appearing on research papers without a significant contribution, while technicians and data managers may receive no credit for their work on a particular research problem. A potential solution would be a simple rebranding away from the term 'authorship' and in favour of the term 'contributorship'. It is of paramount importance in the assessment of research and researchers to know precisely who did what and who was responsible for any given research project. As such, existing platforms like CASRAI (www.casrai.org) supplemented by the use of ORCID (www.orcid.org) identifiers could help in establishing a system in which it is possible to assess not only the quality of someone's research but also to assess the quality of their individual contribution to that research.

Conclusion

The transition towards open science offers the opportunity to do away with some long-standing mechanisms of research assessment, such as the use of Journal Impact Factors. More open and honest means of scientific publishing, coupled with a reform of the academic research assessment system, would allow researchers to publish their research open access without jeopardising their career prospects. Researchers need to be able to put their unpublished research on preprint servers for scrutiny without the fear of having their research scooped by someone else. Preprints may be the future of scientific publishing, provided that questions of sustainability are solved and that the researchers themselves receive adequate guidance in their use. Furthermore, the system of authorship needs to be reformed to better depict the individual researchers' contributions.

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Dealing with the Challenges of Openness – Stakeholder Perspectives

Lidia Borrell-Damian, European University Association
Maud Evrard, Science Europe
Göran Hermerén, Royal Swedish Academy of Letters, History and Antiquities
Martin Stokhof, European Research Council
Marcel Swart, Young Academy of Europe
Stuart Taylor, Royal Society
Moderation: Maura Hiney, Royal Irish Academy

Reflecting on the presentations made earlier that day, this diverse panel, consisting of representatives from science funders, performers, young researchers, and the academies, was asked to respond to two questions: "What is the positive impact of open access in your sector?" and "if there are specific actions in your sector that are already or will be undertaken to mitigate some of the challenges mentioned throughout the workshop". Afterwards, the discussion was widened to include all participants of the workshop. For reasons of conciseness, the following text compiles the relevant responses under the separate headings of the original two questions.

What is the Positive Impact of Open Access in Your Sector?

The panel was unanimous that, by and large, open access has/will have overwhelmingly positive impacts on their respective sectors. The panel acknowledged that open access still has challenges and shortcomings but stressed that there needs to be a shift towards open access as part of a wider reform of academic publishing and research assessment, including an adaptation of the peer-review system to ensure the quality of publications in an open access world.

Regarding the positive impacts of open access, it was pointed out that any assessment of open access needs to recognise that, as it stands, only about a quarter of research articles published worldwide are immediately available to read. In a majority of cases the outputs of research, often publically funded, are hidden behind paywalls or, at the very least, access is restricted by embargo periods. This means that the current model of academic publishing erects significant monetary barriers to anyone trying to access cutting edge knowledge. To researchers in well-endowed research systems this might be merely a nuisance, but to researchers coming from low income research systems, this effectively prevents them from utilising the most up to date knowledge in their fields.

Therefore, the panel agreed that enabling more researchers to access more research outputs more readily will undoubtedly increase the speed of scientific progress worldwide. In this sense, open access contributes greatly to facilitating borderless research across geographic and disciplinary boundaries. It was also noted that open access articles have higher download rates and reach a greater readership. In practical terms this means that in times of crisis (such as during the Zika virus

outbreak) open access can hasten the dissemination of knowledge and ultimately help to find a solution more quickly. As such, it is generally expected that open access will also lead to an increase in scientific output. However, in order to enable researchers to take full advantage of open access, a research-friendly copyright reform is needed. A particularly crucial tool in this regard is text and data mining, which would allow researchers to trawl and exploit more information than they otherwise could by conventional means.

The accessibility of open access not only has the benefit of a faster dissemination of scientific knowledge, but can increase transparency in research. Increased readership goes hand in hand with increased scrutiny and a quicker correction of the research record in cases of inaccuracies in content or interpretation. In an open access system, it is easier for researchers to make their research visible, which is an incentive to ensure that their research methods and conduct are beyond reproach. As such, it is assumed that increased transparency would enhance overall trust in research, a particularly welcome and pertinent development given the ongoing debates around fake science, which have been introduced in previous presentations.

For early career academics, open access is one of the most important recent developments in research. This group is particularly affected by the publish-or-perish culture, resulting in the need to publish as many papers as quickly as possible to further their careers. Young researchers are simultaneously excited about the prospects of easier pathways to getting published and increasing visibility, but they are also apprehensive about the implications of open access on research assessment. Young researchers in particular feel the pressure to publish in high impact journals, which are assumed to indicate high quality through excellent peer review. However, because of the way in which the journal impact factor is calculated (citations over time), some of the newer open access journals have yet to achieve high impact factors.

With open access, there is an opportunity for comprehensive reform of the peer-review system as we know it, but this must go hand in hand with quality. Moving away from high-impact, journal-centric publishing, to, for example, open peer review, not only challenges the current system, but the way in which research is currently evaluated. With ever larger volumes of publications, assessing a researcher based on citation rates of papers and the impact factor of the journals in which they publish has long been a favoured proxy of quality in higher education and, so far, viable alternatives are few and far between. That said, open access opens the way for other quality measures but much work remains to be done in this area of second generation metrics.

In conclusion, the community feels that open access will go a long way to improving openness of research as well as its transparency for peers and the public. However, it was also clear that successful implementation of open access needs concurrent reforms in the peer-review and research assessment systems.

Are there specific actions in your sector which have already been, or will soon be, undertaken to mitigate some of the challenges mentioned this morning?

In addressing this question, the panel highlighted a variety of different actions that need to be taken in order to make open access successful. However, it was agreed that sectors cannot advance the open access agenda in isolation. As such, the panel agreed that any action taken by one sector to further the open access agenda needs to be holistic and take account of its feasibility for other sectors. Ultimately, what is needed is a long-term change in

the culture around academic publishing and career progression. Despite its very obvious implications on a large section of academic life, open access does not yet enjoy the level of awareness within the community that would be required to effectively overhaul the system.

To further highlight the need for awareness raising, the panellists cited excerpts from the European University Association's annual survey on open access (https://eua.eu/downloads/publications/open%20access%202016-2017%20eua%20survey%20results.pdf), which further illustrate that many active researchers are just not aware of open access and its benefits. The simple conclusion that can be drawn from this is that, no matter how beneficial open access may be, as long as the researchers who are publishing do not know about it, the entire endeavour is more or less pointless. open access needs to be community-driven since funding agencies and the like depend on their community, not vice-versa.

As the panel agreed about the need for a long-term culture change, the steps needed in order to facilitate this development became the focus of the discussion. As a foremost priority, it was considered essential to train young researchers in academic publishing as soon as they enter the academic system. They need to be taught that the current publication system is outdated and become aware of the benefits of open access. However, for a successful uptake of open access, it is vital that they are not only shown the benefits of open access, but they also require assurances that publishing in an entirely new system will not have detrimental effects on their career progression. Some of the guidelines required to help researchers navigate this complex web of open access publication already exist. Institutions like the aforementioned Think.Check.Submit or the DOAJ clearly show how and where to publish open access.

In order to provide these reassurances, several different actors need to contribute their share. Universities and other research performing institutions will have to set up clear and harmonised guidelines on open access publishing within their institutions, which include guidance on data management, legal aspects, and storing and sharing of publications. These adaptations need to be supported by funding agencies which should encourage open access publishing wherever possible. Encouraging open access publishing, however, will only be successful if the publishing industry also embraces open access. This might be the most demanding step in the whole process, as it would turn a long-standing and universally accepted model of academic publishing on its head since trying to squeeze open access into the traditional publishing model runs the danger of trying to combine two mutually exclusive publishing models without any assurances that they go together.

Once the above conditions have all been met, the remaining issue - and not at all a trivial one - is how to reform the research assessment system. As it stands, research assessment is intimately linked to the prestige of high impact publication, often expressed as Journal Impact Factor. In order for open access to be widely applicable and desirable, research assessment and academic publishing need to be decoupled. This would require a rethinking of the rewards system for researchers, including providing recognition for good open access publishing practices. Additionally, a welcome side effect of a reformed publishing model would be a reduction in so-called 'salami slicing', a term used to describe the practice of publishing multiple articles out of essentially the same research in order to bolster bibliographies and impact factor. It was noted that other parts of the world such as North America appear to put less emphasis on impact factors and the like without detrimental effects to research quality.

In conclusion, there are a wide range of activities already underway that will contribute to mitigating some of the unresolved questions in open access. However, a concerted effort between all stakeholders is required to avoid duplication of work, seamless implementation and, most of all, an open access publishing system that works for all research disciplines and researchers from all backgrounds.

Workshop Programme

9:00	Welcome/Short introduction	Welcome: KVAB President Joos Vandewalle Welcome/Introduction: Chair of Permanent Working Group Science & Ethics, Göran Hermerén
9:15	Outcomes of ICSU Open Data in Science Workshop, summing up	Roger Pfister, Swiss Academies of Arts and Sciences Find the ICSU Workshop Report at: http://euro-isc.org/thematic_work/opendata/
9:25	Keynote – Ethical Aspects of Open Access Publishing *Followed by Q&A*	Laszló Fesüs, Hungarian Academy of Sciences
09:55	Editorial Responsibility in the Open Access world *Followed by Q&A*	Chris Graf, Committee Of Publication Ethics - COPE/ Wiley
10:25	Open Data: balancing transparency with resilience *Followed by Q&A*	Stephan Lewandowsky, University of Bristol
11:25	Questionable and Unethical Publishers: How to spot them and enable researchers to avoid being trapped *Followed by Q&A*	Lars Bjørnshauge, Directory of Open Access Journals
12:15	Research Assessment in Open Science *Followed by Q&A*	Michele Garfinkel, EMBO
13:45	Dealing with the Challenges of Openness: Stakeholder Perspectives	Lidia Borrell-Damian, European University Association Maud Evrard, ScienceEurope Göran Hermerén, Royal Swedish Academy of Letters, History and Antiquities Martin Stokhof, European Research Council Marcel Swart, Young Academy of Europe Stuart Taylor, Royal Society Moderation: Maura Hiney, Royal Irish Academy

The ALLEA Permanent Working Group on Science & Ethics

The ALLEA Permanent Working Group on Science and Ethics (PWGSE) is concerned with a wide range of issues, both 'internal' (within the scientific community) and 'external' (relations between science and society). Since ethical considerations have been an essential component in the consolidation of a united Europe, and also in the creation of ALLEA, the PWGSE was established to bring together experts from academies across Europe and provide them with a platform for continuous debate on research ethics and research integrity.

The PWGSE has been extending its capacities and activities during recent years, in order to adequately fulfil its mission of collective deliberation on topics such as research integrity, ethics education in science and research training, ethics of scientific policy advice, trust in science, scientific misconduct, and plagiarism, among others.

Further issues recently addressed include dual use of research outcomes, ethical aspects of risks, science and human rights, support for higher education and research in Palestine, research on human embryos, synthetic biology, nanotechnologies etc. Additionally, the group provides expertise for the Horizon 2020 funded ENERI project (European Network of Research Ethics and Research Integrity), which aims to train experts in ethics related issues and to harmonise research integrity infrastructures across Europe.

The PWGSE meets regularly and has also convened thematic meetings in wider settings, typically in partnerships with other relevant organisations such as the European Commission, the European Science Foundation (ESF), the International Council for Science (ICSU), and UNESCO, among many others. The members of the PWGSE drew on its extensive network of experts and institutions for the successful execution of the revision process of "The European Code of Conduct for Research Integrity".

Members of the ALLEA Permanent Working Group on Science and Ethics

- Göran Hermerén (Chair) – Royal Swedish Academy of Letters, History and Antiquities
- Maura Hiney – Royal Irish Academy
- László Fésüs – Hungarian Academy of Sciences
- Roger Pfister – Swiss Academies of Arts and Sciences
- Els Van Damme – Royal Academies for Science and the Arts of Belgium
- Martin van Hees – Royal Netherlands Academy of Arts and Sciences
- Krista Varantola – Council of Finnish Academies
- Anna Benaki – Academy of Athens (Greece)

- Anne Fagot-Largeault – Académie des Sciences (France)
- Michael Quante – Union of the German Academies of Sciences and Humanities
- Bertil Emrah Oder – Bilim Akademisi (The Science Academy, Turkey)
- Pere Puigdomenech – Royal Academy of Sciences and Arts of Barcelona / Institute for Catalan Studies (Spain)
- Deborah Oughton – Norwegian Academy of Science and Letters
- Zbigniew Szawarski – Polish Academy of Sciences
- Raivo Uibo – Estonian Academy of Sciences

About ALLEA

ALLEA is the European Federation of Academies of Sciences and Humanities. It was founded in 1994 and brings together almost 60 Academies of Sciences and Learned Societies from over 40 countries in the Council of Europe region. ALLEA is financed by annual dues from its Member Academies and remains fully independent from political, religious, commercial or ideological interests.

Member Academies operate as learned societies, think tanks, or research performing organisations. They are self-governing communities of leaders of scholarly enquiry across all fields of the natural sciences, the social sciences and the humanities. ALLEA therefore provides access to an unparalleled human resource of intellectual excellence, experience and expertise. Furthermore, its integrative membership structure comprises Academies from both EU and non–EU member states in Europe.

ALLEA seeks to contribute to improving the framework conditions under which science and scholarship can excel. Jointly with its Member Academies, ALLEA is in a position to address the full range of structural and policy issues facing Europe in science, research and innovation. In doing so, it is guided by a common understanding of Europe, bound together by historical, social and political factors as well as for scientific and economic reasons.

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Perspectives on *'Conflicts of interest'*

A report of a one-day workshop held by the Academy of Medical Sciences on 27 November 2015

The Academy of Medical Sciences

Disclaimer
This report does not represent a formal Academy of Medical Sciences position on conflicts of interest. Rather this document is a summary of the wide-ranging discussions that took place at the workshop and does not necessarily represent the views of all participants. The report of this meeting will feed into the Academy's workstream on '*How can we all best use evidence to judge the potential benefits and harms of medicines?*'.[1]

We would welcome feedback on the report. For further information, please contact Rachel Brown, Policy Officer at the Academy of Medical Sciences (rachel.brown@acmedsci.ac.uk, 020 3176 2184).

We are most grateful to Professor Onora O'Neill CH CBE HonFRS FBA FMedSci for Chairing this workshop, and for all individuals who contributed to the meeting and the report.

All web references were accessed in January/February 2016

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1. Led by Professor Sir John Tooke FMedSci, the workstream also includes workshops on evaluating evidence in health and communicating evidence about medicines. For further information, please see: http://www.acmedsci.ac.uk/policy/policy-projects/how-can-we-all-best-use-evidence/

Perspectives on *'Conflicts of interest'*

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Executive summary

Actual and perceived conflicts of interest undermine confidence in the generation and interpretation of scientific evidence. The financial relationship between industry and academics has come under particular scrutiny, although conflicts of interest can be financial and non-financial, direct and indirect.

The *'Conflicts of interest'* workshop was held on 27 November 2015 as part of the Academy of Medical Sciences' wider project exploring the question '*How can we all best use evidence to judge the potential benefits and harms of medicines?*'. It brought together representatives from academia, clinical practice, the pharmaceutical industry, other areas of business, the legal sector, patient support organisations, the media, and other interested parties to discuss how sources of funding (or other potential conflicts of interest) might impact on the generation or interpretation of medical evidence, and how conflicts can be effectively managed. The discussions were wide-ranging, and although the meeting was not designed to reach a consensus on all topics, several key themes emerged.

The distinction between interests and conflicts of interest is important. It was widely agreed that **an interest in itself does not always inherently present a conflict** as conflicts are context dependent. For example, whether the funding source for academic research (e.g. industry or government) presents a conflict of interest will depend on the degree of influence that the funder has on the design, analysis, and publication of the research as well as the personal benefit (e.g. financial) derived by the researcher. Public declarations of interests, regularly updated, provide tools for assessing whether a conflict of interest might arise in a specific decision-making situation or during the generation of evidence.

Conflicts of interest are important to recognise as they are one potential source of bias in the medical evidence base. However, **care should be taken not to routinely conflate conflicts of interest with bias**. Conflicts do not inherently lead to bias, and other sources of bias also exist, for example sub-conscious 'cognitive biases'.

Much of the discussion during the workshop centered on the **mechanisms by which both real and perceived conflicts of interest could be managed** in order to safeguard against this potential source of bias.

In decision-making situations, not including individuals with particular interests (e.g. those with industry funding) could remove an important source of expertise, potentially leading to committees and advisory groups lacking sufficient knowledge or experience. It was generally agreed, therefore, that efforts should focus on the management of conflicts of interest rather than on their avoidance. While in some cases it may be necessary to remove a conflicted individual from the decision-making process, in other cases the decision-making processes could accommodate input from individuals declaring a conflict of interest. In this case their input should be subject to scrutiny and group discussion. While the onus is on individuals to identify potential conflicts arising from an interest, which management mechanism is ultimately required should be determined by those responsible for the decision-making process. In any case, **the simple act of declaring an interest should not lead to a false reassurance that any resulting conflict has been managed effectively;** more active steps are necessary.

With respect to the generation of evidence, a couple of participants argued that the impact (and perceived impact) of commercial conflicts of interest on the medical evidence base was so serious that they need to be eliminated completely, for example by preventing direct financial connections between industry and academia. Many were concerned, however, that this could damage what some see to be beneficial outcomes of the relationship between academia and industry, such as the accelerated development of new products that benefit patients. A number of participants felt that an **agreed framework** to define what constitutes a conflict of interest and to provide guidance on their management in the context of academic-industry relationships would be beneficial. This would be similar to those already established in many companies and professional bodies within the wider public sector. Although the precise form this framework could take was not agreed - particularly whether it would be prescriptive or establish high level principles - many participants felt a body such as the Academy of Medical Sciences would be well placed to develop it.

Some participants raised concern that a person's interests (even in cases where any conflicts are appropriately managed) were sometimes being incorrectly used - particularly in the media - as a proxy for bias or as a means by which to undermine the credibility of research. As an example, it was suggested that it would be beneficial, particularly for the public, if the **rationale behind the value of industry-academia collaborations were communicated more effectively**, something that some participants felt has to date been neglected.

This report does not represent a formal Academy of Medical Sciences position on conflicts of interest. Rather this document reflects the wide-ranging discussions that took place at the workshop. The report of this meeting will feed into the Academy's workstream on '*How can we all best use evidence to judge the potential benefits and harms of medicines?*'.[2]

We would welcome feedback on the report.

References and notes

2. Led by Professor Sir John Tooke FMedSci, the workstream also includes workshops on evaluating evidence in health and communicating evidence about medicines. For further information, please see: http://www.acmedsci.ac.uk/policy/policy-projects/how-can-we-all-best-use-evidence/

Introduction

Evidence-based medicine is fundamentally dependent on the availability of high-quality evidence to guide decision-making. Concerns have been expressed that parts of the medical evidence base is biased because of flaws at multiple stages of the evidence generation and analysis pathway, and during the downstream interpretation of such evidence. Although various sources of bias exist, conflicts of interest may represent one factor contributing to this bias.

Many major funders of medical research - including research councils, medical charities, and Government departments such as the Department of Business, Innovation and Skills and the Department of Health - have stressed the importance of closer working between academia and industry in order to accelerate the translation of research to generate patient benefits and greater wealth for the country. The Academy recognises that these relationships will be increasingly important as the process of drug development evolves to limit the time and cost associated with late stage failures in drug development. More precise definition of potential drug targets derived from academically driven discovery science and experimental medicine will be core features of such a strategy.

On the other hand, there are concerns that commercial interests may jeopardise the development of a reliable evidence base on which to base health policy-making and clinical decision-making. Commercial pressures may influence what research is carried out, how it is carried out, whether and how it is disseminated, and the analysis of evidence in decision-making. With closer links between academia and industry, there are concerns that these pressures may also influence those working within the academic sector.

On 27 November 2015, the Academy of Medical Sciences held a one-day workshop on *'Conflicts of interest'* as part of a wider Academy project exploring the question *'How can we all best use evidence to judge the potential benefits and harms of medicines?'*.[3] Led by Professor Sir John Tooke FMedSci, this wider project has already hosted a workshop on '*Evaluating evidence in health*' which discussed the strengths and limitations of different forms of evidence and further explored the opportunities to enhance the generation and use of medical evidence, and its communication to wider groups.[4] The wider project is also organising a meeting on communicating evidence about medicines. [5] The *'Conflicts of interest'* workshop brought together representatives from academia, clinical practice, the pharmaceutical industry, other areas of business, the legal sector, patient support organisations, the media, and other interested parties to discuss how sources of funding (or other potential conflicts of interest) might impact on the generation or interpretation of medical evidence, and how conflicts can be effectively managed. The discussions held at this meeting will be used to inform the report that is produced as part of the wider *'How can we all best use evidence to judge the potential benefits and harms of medicines?'* workstream. We would welcome feedback on this report as a means to gather further views on this topic.

After an introductory presentation by Baroness Onora O'Neill of Bengarve CH CBE HonFRS FBA FMedSci, Emeritus Professor of Philosophy, University of Cambridge, and Chair of the Equality and Human Rights Commission, the workshop was organised around three panel sessions with short presentations from invited speakers. Each panel discussion was followed by audience discussion. Annex 1 provides details of the workshop agenda and list of attendees, and Annex 2 summarises speakers' presentations. The following is a summary of the main points raised by participants during discussions; they do not necessarily represent the views of the Academy and should not be taken as agreed outputs from the workshop.

References and notes

3. The Academy of Medical Sciences. *How can we all best use evidence to judge the potential benefits and harms of medicines?* http://www.acmedsci.ac.uk/policy/policy-projects/how-can-we-all-best-use-evidence/
4. The Academy of Medical Sciences. *Evaluating evidence in health workshop.* http://www.acmedsci.ac.uk/more/events/evaluating-evidence-in-health/
5. The Academy of Medical Sciences. *Communicating evidence about medicines workshop*. http://www.acmedsci.ac.uk/policy/policy-projects/communicating-evidence-workshop/

Overview: Introductory presentation by Baroness O'Neill

Introducing the workshop, Baroness O'Neill made the clear case for the importance of managing conflicts of interest in public decision-making. Decision-making, she suggested, can bear upon both public goods and individual goods; it is important that individuals do not influence decision-making to favour their own interests over these goods.

Reflecting on the 'Nolan principles', established to guide behaviour in public life, Baroness O'Neill suggested it is reasonable to expect public figures to act in the public interest rather than on the basis of self-interest.[6] While individuals with public responsibility might be expected to take it upon themselves to act with professionalism and integrity, systems and procedures can also be put in place to encourage and support good practice.

Baroness O'Neill argued that individuals with interests do not inherently have a conflict of interest as these are context dependent. However, the first step in avoiding or mitigating the impact of conflicts of interest is for individuals to identify all their interests, thereby facilitating the identification of those that might present a conflict. Such a 'declaration of interests' should be made public, readily accessible, and regularly kept up to date. There are many possible types of interest, some pecuniary (such as salary or other direct financial support, share holdings, and hospitality) and some not (individuals may, for example, have an interest in an institution, particularly if they hold a governance role).

However, it is not always easy to decide what constitutes an interest. Difficult areas include indirect financial interest (such as financial interests held by a spouse or family member) and levels of hospitality (being bought an occasional coffee probably does not constitute an interest, while a day out at a major sporting event almost certainly does, but many examples may fall between these extremes). It may also be unclear when an interest ceases to exist – individuals may retain an interest even when their formal association has ended, but the exact period may vary considerably from case to case.

Nonetheless, everyone has interests of some kind and it would be a mistake to consider only financial interests when formulating lists of interests. For example, the pressure to publish and other academic pressures on career progression can create interests. Interests may also arise if individuals stand to gain financially from increasing personal visibility (for example, in traditional or social media). Many organisations provide guidelines on what they consider it appropriate to declare. Baroness O'Neill suggested it was generally advisable to err on the side of caution and to declare interests if in any doubt.

Public declarations of interests provide tools for assessing whether a conflict of interest might arise in a specific decision-making situation. However, it is only a first step and because it is relatively easy to achieve, there are dangers that the transparent declaration of an interest alone becomes a proxy for having fulfilled conflict of interest obligations. Instead, when a potential conflict is identified appropriate actions should be taken to manage it.

There is a particular onus on committee chairs or others with responsibility for a decision-making process to be mindful of potential conflicts of interest and to ensure that the appropriate steps are taken to manage them. They have a duty to protect the integrity of the decision-making process. While that may mean excluding conflicted individuals from discussions, it may also mean allowing their input while recognising its potential to be influenced by their interests. Allowing input may be particularly important in situations where decision-making relies on expert knowledge but it has proved difficult to identify experts without any conflicts of interest.

Baroness O'Neill concluded by pointing out that financial conflicts of interest are just one possible factor potentially biasing the health evidence base. In particular, researchers (or others with an interest in a product) may have an emotional attachment that subconsciously influences their thinking or behaviour. Such 'cognitive biases' may simply reflect 'wishful thinking' on the part of a researcher rather than a conscious desire to subvert evidence generation or analysis. However, while acknowledging the undoubted influence of cognitive biases, she suggested that it is challenging for conflict of interest measures to be the main mechanism for minimising all bias in the medical evidence base. Some issues are better dealt with through other mechanisms addressing the methodologies of health evidence generation and evaluation. It is important, she suggested, that managing conflicts of interest is not seen as a way of solving all problems of bias in the health evidence base.

References and notes

6. https://www.gov.uk/government/publications/the-7-principles-of-public-life

What constitutes an interest and when do interests present a conflict?

Following the introductory presentation, participants engaged in further discussion about interests and their distinction from conflicts of interest.

There was widespread agreement that this distinction is important, with many reiterating that in many situations an interest does not pose a conflict of interest. There was also support for the public declaration of interests as a first step in the identification of those that may pose a conflict in a particular situation. Declarations of financial interests should detail not only the source of funding, but also the size of the contribution and what the money was used for. Many participants felt that such a process should be practiced more widely, and all parties involved in evidence generation, analysis or dissemination – such as researchers, journalists, commentators, medical journals, and others – should routinely declare their interests. It was however noted that care should be taken to balance complete transparency with the risk of over-disclosure, which could lead to pertinent information being lost among a mass of irrelevant detail or to the normalisation of conflicts of interest within the community. Deciding which interests to declare and which might be considered conflicts requires judgment on the part of the individual; in doing so it may be helpful to consider the perceptions of 'a reasonable person'.

When are conflicts of interest 'real' and what is the impact?

- Using industry funding as an example, it was noted that whether a particular interest gives rise to a conflict depends in part on the nature of the relationship with industry (for example, whether a researcher has complete freedom to analyse and publish findings), the scale of industry support, and how that support is used (for example, whether it benefits researchers personally, is used to support their research, or is donated to charity).
- Nonetheless, there is published evidence that researchers with industry links are more likely to publish favourable findings on medicinal products.[7,8] Similarly, one panellist detailed a study on academic researchers' comments in the media during the recent swine flu epidemic which revealed that those with reported conflicts of interests were more likely to make heightened risk assessments and promote the use of antiviral drugs.[9]
- Therefore, conflicts of interest are one factor potentially contributing to bias in the medical evidence base, and can influence all stages of evidence generation and evaluation, including the choice and framing of research questions, the design of experimental studies, the disclosure of results, and the analysis of evidence. Participants were keen, however, to emphasise that conflicts of interest do not inevitably lead to bias: conflicts can be managed and an individual may still be able to maintain objectivity despite having relevant interests.
- In addition to the role of industry in the funding of academic research, one participant raised a concern about industry's attempts to build relationships with influential medical academics ('key opinion leaders') who hold positions of influence and authority.[10]
- As well as true conflicts of interest, perceived conflicts of interest can also be damaging, particularly to an organisation's reputation. This may again encourage organisations to adopt a cautious approach to minimise and manage even remote risks of conflicts of interest.

References and notes

7. Perlis RH, *et al*. (2005). *Industry sponsorship and financial conflict of interest in the reporting of clinical trials in psychiatry*. Am J Psychiatry **162**(10):1957–60.
8. Wang AT, *et al*. (2010). *Association between industry affiliation and position on cardiovascular risk with rosiglitazone: cross sectional systematic review*. BMJ **340**:c1344.
9. Mandeville KL, *et al.* (2014). *Academics and competing interests in H1N1 influenza media reporting.* J Epidemiol Community Health **68**(3):197–203.
10. Moynihan R. (2008). *Key opinion leaders: independent experts or drug representatives in disguise?* BMJ **336**(7658):1402–3.

Mechanisms to manage and mitigate the impact of conflicts of interest

Following short presentations from invited speakers (see Annex 2), extensive discussion centered on both the avoidance and the management of conflicts of interest in the context of evidence generation and decision-making as means to safeguard against this potential source of bias.

Managing conflicts of interest during evidence generation

- One speaker suggested that conflicts of interest had such insidious effects on the generation of evidence that they needed to be eliminated entirely by removing all direct financial connections between companies and researchers.
- It was suggested that companies could contribute to a central fund which would support independent evaluations of products (e.g. phase III trials) and comparative studies that individual companies would be unlikely to conduct. The Italian Medicines Agency (AIFA) was highlighted as one organisation that had introduced a scheme along these lines (although some queried how sustainable the scheme is).[11] Some 5% of the marketing budget of pharmaceutical companies operating in Italy is used to support such studies.
- Another historical example given was an initiative run by the British Thoracic Society beginning in the inter-war years on behalf of the Medical Research Council (MRC), particularly to evaluate treatments for tuberculosis: UK doctors were reluctant to work directly with industry on trials, so the Society acted as an intermediary, deciding which treatments merited further evaluation.
- However, other participants questioned whether it was desirable – or feasible – to eliminate close academia–industry interactions entirely, reiterating that there are mutual benefits to industry and academia working together, and that in the long run patients benefited from more rapid development of medicines.
- Participants felt it would be useful to have a supportive framework in place to provide guidelines on responsibilities and good practice in industry-academia relationships. Such guidelines could provide clarity on best practice for industry-funded research in academia (e.g. independent design of research, full disclosure of results), detail what could be considered a conflict of interest, and advise on how issues relating to conflicts of interests should be dealt with. Some participants felt that such a governance framework should focus on general principles or values, while others suggested a more rules-based framework (including definitions on the precise value at which industry funding could become a conflict) would be valuable.
- It was suggested that a body such as the Academy of Medical Sciences would be well placed to develop such a framework or 'code of conduct' to cover interactions between industry, academics, and higher education institutions. Medical journals should also be involved in this process, so that there is clarity regarding the processes that need to be followed in order for journals to consider publication of findings.
- Such guidelines would need to take account of the international nature of medical research. Ideally, the principles adopted and approaches used would be consistent across different countries.[12]
- It was more specifically noted that the publication of contractual arrangements between academia and industry would enhance transparency, encourage the adoption of good practice, and provide reassurance about key principles such as academic freedom to analyse and publish data.

Managing conflicts of interest during decision-making processes

- Excluding individuals with particular interests (e.g. industry funding) from decision-making committees could remove an important source of knowledge and experience from discussions. Excessively robust rules to avoid conflicts of interest could also unwittingly hamper attempts to include the patient voice in discussions, as patient groups often receive charitable industry support.
- There is a similar argument that such rules could mean that the dissemination of evidence, for example through the media, would fall to individuals who lack the relevant expertise.
- Therefore, rather than attempting to avoid conflicts of interest by severing all connections between interested stakeholders, a better approach may be to establish transparent and robust mechanisms to manage potential conflicts of interest should they arise.
- While the first step is the declaration of interests, thereby facilitating the identification of conflicts, the simple act of declaring an interest should not lead to a false reassurance that any resulting conflict has been managed effectively; more active steps are necessary.
- For example, in some cases mechanisms such as leaving the room may be needed to limit the potential impact of conflicts of interest on decision-making processes. It is not always necessary, however, to go to such extents. Other mechanisms exist that support full and open debate, with participants declaring their interests in advance and presenting their perspective for independent scrutiny by others in the decision-making group.
- Examples were given where such mechanisms were used to reach agreement in highly contentious areas (including nuclear waste disposal: Nirex adapted a 'group consensus elicitation methodology' to facilitate discussions and achieve agreement between stakeholders with very different interests).[13]
- Such mechanisms highlight the important role played by the 'process owner', or committee Chair, who has the responsibility to ensure that good conflicts of interest practice is followed in order to ensure a reliable decision is reached.

Conflicts of interest: the need for greater public communication

- Several participants expressed concern that the media in particular use conflicts of interest as a short-hand heuristic to undermine the authority of individuals by implying that their contributions are inevitably unreliable or biased.
- Others described how researchers can be unfairly labelled as having conflicts of interest despite having complete independence to design and carry out industry-funded studies and publish their findings (Box 1).
- It was widely felt that academics face conflicting pressures since the Government, funders, and their institutions promote closer contact with industry, but some commentators and the public subsequently criticise them or devalue their input because they are considered too closely connected to industry. It was noted that this could discourage researchers from contributing to evidence appraisal or public discussions even though they have valuable knowledge and experience.

Box 1: Food industry funding

To what extent does food industry funding of research create conflicts of interest?

The food industry has been accused of wielding excessive influence on policy-making. In early 2015, a series of features in the *BMJ* suggested that industry funding was being used systematically to distort the evidence base and to influence the thinking of academics involved in public policy-making.[14] It was argued that there was a *'network of relationships between key public health experts and the sugar industry'* and that *'these sorts of links create bias… [and] weaken public health efforts to tackle the harmful effects of sugar on the diet'*.

These *BMJ* articles reflect concerns that the food industry has undue influence on policy-making. They imply that any form of industry funding creates conflicts of interest and has the potential to influence the thinking or behaviour of individuals with an advisory role in policy-making.

Some researchers believe that encouraging relationships between academics and industry may help promote a commercial environment in which health-encouraging behaviours can develop. Others argued that there are many ways in which academics can receive funding from industry, and it is debatable whether all of these can be truly considered conflicts of interest. Indeed, in response to such criticism, several scientists involved in academic research part-funded by industrial contributions have pointed out instances where all industry funding had been declared, had been used to support research rather than personal remuneration, represented only a very small proportion of total research funding, and where the researchers had been fully responsible for study design and analysis, and maintained an independent right to publish any data regardless of the findings.[15]

- The inappropriate use of conflicts of interest as a proxy for bias or unreliability could also exclude some patient organisations from important forums, or pressure them to decline a potentially important source of income.
- Further still, concern was raised that a disproportionate focus on conflicts of interest has the potential to detract attention from more valid underlying issues around the evidence and its interpretation (Box 2).
- It was noted that this situation may have arisen because the reasoning behind encouraging close ties between industry and academia (i.e. to accelerate medical innovation and translation of research) has not been communicated effectively to the general public. It was felt that those who support such collaboration should take greater responsibility for communicating their reasoned benefits to the media and wider public.
- Being entirely open about interests, and the precise situations in which conflicts of interest arise, may lead to a more nuanced public understanding of what they mean in practice and aid in the proper critical appraisal of evidence. Journalists and commentators should be similarly open about their interests.

Box 2: e-cigarettes evidence appraisal

A recent analysis of evidence relating to e-cigarettes has led some to question how conflicts of interest considerations are being used.

A group of researchers recently undertook a 'comparative harm analysis' of e-cigarettes and conventional nicotine-containing products such as cigarettes, concluding that the former were considerably less harmful than the latter.[16] This analysis was cited prominently in a report from Public Health England, which argued in favour of e-cigarettes as a health-improvement measure.[17]

The group included some members with e-cigarette industry connections. However, it used a methodology (multi-criteria decision analysis, MCDA) based on an objective criteria-based framework enabling expert opinion to be discussed and challenged in an open forum.

Nevertheless, the group's work was subject to both a critical *Lancet* editorial and a commentary in the *BMJ.*[18,19] Both focused heavily on the make-up of the analysis group and possible bias owing to their perceived conflicts of interest, as well as the fact that the project's funders received support from the tobacco industry.

As well as arguing that the MCDA approach is a good way of minimising the impact of conflicts of interest, members of the group have also suggested that the focus on conflicts of interest in the critical commentaries failed to address the substantive issues raised in the original analysis or provide any alternative assessment of the evidence.[20]

References and notes

11. The Italian Medicines Agency. http://www.agenziafarmaco.com/en/node/4111
12. Amongst other reasons, the need for such a framework to be international in nature is in recognition of the finding that UK researchers are highly collaborative and rates of international co-authorship are high. UK Department of Business, Innovation and Skills (BIS). (2013). *International Comparative Performance of the UK Research Base – 2013.* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/263729/bis-13-1297-international-comparative-performance-of-the-UK-research-base-2013.pdf
13. A procedure for data elicitation in support of performance assessments.(Nirex report N/132). 2006. Harwell: United Kingdom Nirex Ltd.
14. Gornall J. (2015). S*ugar: spinning a web of influence*. BMJ **350**:h231; h215; h219; h220
15. The Guardian. (2015). *Obesity advisor rejects conflict of interest claim.* http://www.theguardian.com/society/2015/feb/11/obesity-adviser-rejects-conflict-of-interest-claim

16. Nutt DJ *et al*. (2014). *Estimating the harms of nicotine-containing products using the MCDA approach.* Eur Addict Res. **20**(5):218–25.
17. McNeill A, et al. (2015). E-cigarettes: an evidence update. London: Public Health England.
18. McKee M, Capewell S. (2015). *Evidence about electronic cigarettes: a foundation built on rock or sand?* BMJ **351**:h4863. doi:10.1136/bmj.h4863.
19. Anon. (2015). *E-cigarettes: Public Health England's evidence-based confusion*. Lancet **386**(9996): 829.
20. Nutt DJ. (2015). *Evidence about electronic cigarettes: a foundation built on rock or sand? Reply.* BMJ **351**:h4863; http://drugscience.org.uk/blog/2015/08/27/blinded-smoke-why-do-e-cigarettes-provoke-such-irrational-reactions/

Concluding remarks

The *'Conflicts of interest'* workshop demonstrated that this topic remains an impassioned area of divergent views.

A few participants felt strongly that there are serious, systemic flaws in the processes used to acquire, analyse, and disseminate medical evidence, and that conflicts of interest are a fundamental contributor to such bias. Others reasoned that conflicts of interest are just one source of bias, and it is therefore better to consider them in a more restricted sense and use additional mechanisms to address wider issues relating to the integrity of the medical evidence base.

Regardless, there is clearly a tension between calls for greater engagement between academia and industry on the one hand, and public concern regarding the pervasive impact of conflicts of interest on the other. Some call for complete disengagement to preserve the independence of academia and to eliminate any scope for conflicts of interest to influence evidence generation and analysis; others argue that disengagement would itself be damaging to medical progress.

There was a widespread sense that the public is currently being ill-served by a focus on conflicts of interest that is being exploited to (in many cases inappropriately) undermine individuals without addressing underlying points of substance. While it is undoubtedly important to recognise and manage conflicts of interest, over-zealous interpretation can also be damaging – for example by leading to the exclusion of knowledgeable voices from discussions which in turn can lead to decision-making becoming dependent on groups lacking sufficient knowledge and expertise.

While participants disagreed on the degree to which conflicts of interest can be minimised or eliminated, there was a widespread feeling that a governance framework needs to be developed to establish and promote good practice in industry–academia relationships. Such a document could also support more effective communication with the public about the nature of conflicts of interest and the medical evidence base.

The exploratory discussions held at this *'Conflicts of interest'* workshop will feed into the Academy of Medical Science's wider workstream on '*How can we all best use evidence to judge the potential harms and benefits of medicines?*' and its final report.[21]

References and notes

21. Led by Professor Sir John Tooke FMedSci, the workstream also includes workshops on evaluating evidence in health and communicating evidence about medicines. For further information, please see: http://www.acmedsci.ac.uk/policy/policy-projects/how-can-we-all-best-use-evidence/

Annex I Agenda and participants list

Friday 27 November 2015, 09.00 – 17.00
Academy of Medical Sciences, 41 Portland Place, London, W1B 1QH (John Newsom-Davis Council Chamber)

09.00 – 09.30	**Registration**
Introductory session: What constitutes an interest and when do they present a conflict?	
09.30 – 09.40	**Welcome from the Chair** **Baroness Onora O'Neill CH CBE HonFRS FBA FMedSci**, Emeritus Professor of Philosophy, University of Cambridge
09.40 – 10.00	**Dealing with interests** **Baroness Onora O'Neill CH CBE HonFRS FBA FMedSci**, Emeritus Professor of Philosophy, University of Cambridge
10.00 – 10.45	**Q&A and discussion** Chair: **Baroness Onora O'Neill CH CBE HonFRS FBA FMedSci**, Emeritus Professor of Philosophy, University of Cambridge • What constitutes an interest? • When and why should interests be declared? • How to identify when an interest presents a conflict? • What actions should be taken when a conflict is identified?
10.45 – 11.00	**Refreshment break**
Panel discussion sessions: What actions should be taken when conflicting interests are identified?	
11.00 – 12.30	**Panel discussion 1: Interests when funding studies, and generating and analysing findings** Chair: **Professor Jonathan Montgomery**, Chair, Health Research Authority; Chair, Nuffield Council on Bioethics; Professor of Healthcare Law, University College London Panellists: • Funding body: **Dr Tony Peatfield**, Director of Corporate Affairs, Medical Research Council • Industry: **Wendy Harrison**, Ethics and Compliance Programme Director, Shell • Systematic reviews: **Sir Iain Chalmers FMedSci**, Co-founder, Cochrane Collaboration; Co-ordinator, James Lind Initiative

12.30 – 13.15	**Lunch**
13.15 – 14.45	**Panel discussion 2: Interests when disseminating findings** Chair: **Professor Dame Nicky Cullum DBE FMedSci**, Professor of Nursing, University of Manchester Panellists: • Publishing: **Dr Fiona Godlee**, Editor in Chief, The BMJ • Researcher: **Dr Kate Mandeville**, Wellcome Trust Clinical Research Fellow, London School of Hygiene and Tropical Medicine • Media: **Fiona Fox OBE**, Chief Executive, Science Media Centre • Industry: **Dr Marilyn Metcalf**, Senior Director, Benefit Risk Evaluation, GlaxoSmithKline
14.45 – 15.00	**Refreshments**
15.00 – 16.30	**Panel discussion 3: Interests when using evidence to inform practice/policy** Chair: **Baroness Onora O'Neill CH CBE HonFRS FBA FMedSci**, Emeritus Professor of Philosophy, University of Cambridge Panellists: • Third sector: **Tracey Brown**, Director Sense About Science • Regulatory sector: **Jonathan Mogford**, Policy Director, Medicines and Healthcare products Regulatory Agency • Patient group: **Jeremy Taylor**, Chief Executive, National Voices • Consumer Champion: **Nick Ross**, President, HealthWatch
16.30 – 17.00	**Identification of key questions and uncertainties, and/or common principles, in declaring and managing interests** Chair: **Baroness Onora O'Neill CH CBE HonFRS FBA FMedSci**, Emeritus Professor of Philosophy, University of Cambridge
17.00	**Close**

- Michael Blastland*, Journalist
- Eleanor Boddington, Senior Legal Counsel, Wellcome Trust
- Tracey Brown, Director, Sense about Science
- Professor Nancy Cartwright FBA[†], Professor of Philosophy, Durham University and University of California
- Sir Iain Chalmers FMedSci, Co-founder, Cochrane Collaboration; Co-ordinator, James Lind Library
- Professor Sir Rory Collins FRS FMedSci, Professor of Medicine and Epidemiology; Head of the Nuffield Department of Population Health, University of Oxford
- Professor Dame Nicky Cullum DBE FMedSci[†], Professor of Nursing, University of Manchester

- Professor David Delpy CBE FRS FREng FMedSci, Professor of Biomedical Optics, University College London; Chairman, Defence Scientific Advisory Council; Chair, UK Quantum Technologies
- Dr Jon Fistein, Head of Clinical Ethics and Data, Medical Research Council
- Phillipa Foster-Back CBE, Director, Institute of Business Ethics
- Fiona Fox OBE, Chief Executive, Science Media Centre
- Dr Fiona Godlee, Editor in Chief, BMJ
- Dr Stephanie Harriman, Medical Editor, BioMed Central
- Wendy Harrison, Ethics and Compliance Programme Director, Shell
- Dr Farah Jameel, General Practitioner; Member of the GP Clinical and Prescribing sub-committee, British Medical Association
- Professor Susan Jebb, Professor of Diet and Population Health, University of Oxford
- James Lawford Davies, Solicitor, Hempsons
- Dr Kate Mandeville, Wellcome Trust Clinical Research Fellow, London School of Hygiene and Tropical Medicine
- Dr Marilyn Metcalf, Senior Director Benefit Risk Evaluation, GlaxoSmithKline
- Jonathan Mogford, Policy Director, Medicines and Healthcare products Regulatory Agency
- Professor Jonathan Montgomery*, Chair, Health Research Authority; Chair, Nuffield Council on Bioethics; Professor of Healthcare Law, University College London
- Dr Jo O'Leary, Head of Innovation and Skills Delivery Unit, Biotechnology and Biological Sciences Research Council
- Baroness Onora O'Neill CH CBE HonFRS FBA FMedSci (Chair)*, Emeritus Professor of Philosophy, University of Cambridge;
- Dr Tony Peatfield, Director of Corporate Affairs, Medical Research Council
- Professor Lawrence Phillips, Emeritus Professor of Decision Sciences, London School of Economics and Political Science
- Professor Mark Philp, Director of Research (History), University of Warwick; Chair, Research Advisory Board to the UK Committee on Standards in Public Life
- Charmaine Roberts, Funding Policy and Governance Manager, Strategy and Research Funding, Cancer Research UK
- Dr Elizabeth Robertson, Director of Research, Breast Cancer Now
- Nick Ross, President, HealthWatch
- Professor Sir Michael Rutter CBE FRS FBA FMedSci*†, Professor of Developmental Psychopathology, King's College London; Chair of the 'Methods of evaluating evidence' Working Group, Academy of Medical Sciences
- Dr Daniel Schiff, Board Member, International Association of Scientific, Technical and Medical Publishers; Vice President and Publisher, Journals, Thieme
- Heather Simmonds, Director, Prescription Medicines Code of Practice Authority
- Derek Stewart OBE, Associate Director for Patient and Public Involvement, National Institute for Health Research Clinical Research Network
- Tony Sumner, Founding Director, Patient Voices
- Dr Ed Sykes, Senior Press Manager and Head of Mental Health and Neuroscience, Science Media Centre; Chair, Stempra
- Jeremy Taylor, Chief Executive, National Voices
- Aileen Thompson, Executive Director of Communications, Association of the British Pharmaceutical Industry
- Dr Matina Tsalavouta, Head of Communications and Public Engagement, Rothamsted Research
- Professor John Uff CBE, Barrister, Keating Chambers
- Dr David Warriner, Clinical Research Fellow, University of Sheffield

Secretariat

- Dr Rachel Brown, Policy Officer, Academy of Medical Sciences
- Dr Claire Cope, Senior Policy Officer, Academy of Medical Sciences

- Elizabeth Gothard, Policy Intern, Academy of Medical Sciences
- Nick Hillier, Director of Communications, Academy of Medical Sciences
- Ian Jones, Independent science writer
- Dr Rachel Quinn, Director of Policy, Academy of Medical Sciences

* Member of the Academy's Oversight Group on 'How can we all best use evidence to judge the potential benefits and harms of medicines?'
† Member of the Academy's Working Group on '*Methods of evaluating evidence*'

Annex II Summary of panel presentations

Panel 1: Interests when funding studies, and generating and analysing findings

Dr Tony Peatfield, Director of Corporate Affairs, Medical Research Council (MRC), provided a funders' perspective, based on the principles and practices adopted by the MRC (most of which are likely to be shared by other research councils and major funders).

Dr Peatfield identified three stages in the grant review process when conflicts of interest are important. Recently, applicants have begun to be asked if they have pecuniary or other interests in the research they are proposing or its outcomes. Potential reviewers are asked to declare their interests, which are borne in mind when reviewers are selected or their reviews received (it can be difficult to identify reviewers without any relevant interests). Well-established procedures exist for decision-making panel meetings, with conflicted members leaving the room for particular discussions or not being sent paperwork. Panel chairs have an important role to play in ensuring good practice is followed, and all actions are formally recorded.

Dr Peatfield argued that transparency and established procedures are crucial, but are only part of the solution to ensure that conflicts do not bias decision-making; individual judgement is necessary as it is difficult to impose hard and fast rules. To some degree, trust is required as it can be challenging to identify hidden interests.

Wendy Harrison, Ethics and Compliance Programme Director at Shell, provided an industry perspective from a different business sector, Oil and Gas. An important cornerstone of Shell's Ethics and Compliance programme is for staff to avoid both real and perceived conflicts of interest – even the latter may be damaging in terms of a company's reputation and loss of public trust.

Shell is a large global company and has to consider the complexity of both the cultural context in which business is being conducted – accepted practices may vary widely between countries – and the many different types of people engaging with external contractors. It does however apply one Code of Conduct globally.

Although it necessarily deals with complex issues, Shell has aimed for simplicity in its Code of Conduct, with a focus on specific risk factors, how problems can be avoided, and where to seek advice.[22] Its Code of Conduct combines a set of values, mandatory rules, and guidance (such as *'don't get involved in situations where the average person may question your objectivity'* and *'don't make decisions based on personal considerations'*) with a supportive framework that encourages staff to identify potential interests (including a conflicts of interest register) and to raise them with their manager when appropriate. A manager can decide how to handle the situation or escalate and seek advice from compliance officers. Although hard and fast rules are again difficult to define, specific guidance and financial thresholds are provided in areas such as corporate hospitality.

However, given there are many grey areas, the general principles and supportive framework for identifying and managing conflicts of interest is important. She suggested that a similar framework might be useful in the medical sciences.

Sir Iain Chalmers FMedSci, Co-founder of the Cochrane Collaboration and Coordinator of the James Lind Initiative, emphasised the importance of the reliability of the evidence generated by medical research, and the potential for patients to be harmed because of biases, perceived or real, in the evidence base. The ultimate goal of eliminating these biases is better health.

He argued that biases have been introduced within medical academia because of systemic flaws in the way that evidence is generated and evaluated. He felt that this issue has not received the attention it deserves, and commented that many, including the Academy of Medical Sciences, have long been too accepting of its existence. He suggested that conflicts of interest were one source of such bias and detailed there is a large body of evidence showing that papers from authors with industry funding tend to publish more favourable assessments of commercial products.

As steps in the right direction, Sir Iain identified a workshop organised by the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) on biased reporting of animal research, and a recent report from the Academy on reproducibility and reliability of biomedical research, an outcome of a symposium organised in partnership with the MRC, Biotechnology and Biological Sciences Research Council (BBSRC) and the Wellcome Trust and led by Professor Dorothy Bishop FRS FBA FMedSci.[23,24] Nevertheless, he maintained his argument that much more needs to be done, especially to tackle conflicts of interest in senior levels of medical academia.

Panel 2: Interests when disseminating findings

Dr Fiona Godlee, Editor in Chief of the *BMJ*, emphasised the importance of an unbiased evidence base open to independent scrutiny, and suggested that we are some way from achieving these objectives. She argued that financial conflicts of interest were distorting all stages of evidence generation and analysis, including the framing of research questions, the design of research, whether or not findings were published, and access to data.

Dr Godlee highlighted a 2009 report from the US Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice,* which argued that researchers should not undertake research in which they had a financial interest.[25] The *BMJ* has a policy of not publishing studies funded by the tobacco industry, is likely to introduce a similar policy for research funded by the food and drink industry, and is considering how to handle studies supported by the pharmaceutical and medical device industry. She also argued that research conducted by researchers in academia should be subject to the same scrutiny and challenge as that carried out by industry-based scientists.

Dr Godlee also argued that conflicts of interest also apply to authors of commentary and review articles, and authors had a responsibility to declare such interests. The *BMJ* has gone a step further and instigated a 'zero tolerance' policy to conflicts of interest for authors of its clinical educational articles, refusing to publish such articles from authors with a relevant financial conflict of interest.

In terms of possible solutions, she suggested that pharmaceutical companies should not be allowed to directly evaluate their own products. Instead they could contribute to a central fund that would support independent research on their products. A small-scale initiative along these lines has been established by the Italian Medicines Agency (AIFA).[26]

Dr Kate Mandeville, Wellcome Trust Clinical Research Fellow at the London School of Hygiene and Tropical Medicine, described her studies identifying a correlation between researchers' conflicts of interest and the viewpoints expressed in the media about the recent UK swine flu epidemic and use of antiviral drugs.

Dr Mandeville and colleagues examined newspaper coverage of the swine flu epidemic and analysed the interests of all academics quoted. The studies revealed that academics were widely called upon to comment – they were the most common voice after ministers of health – but those with industry interests were significantly more likely to stress high-impact pandemic scenarios and to promote the use of antiviral drugs.[27]

Dr Mandeville suggested that academics are seen as trusted and independent sources of information, but public trust could be compromised if conflicts of interest are not declared and could be perceived to be influencing their thinking. She suggested that scientists should be open in declaring their interests and journalists should seek to identify whether any conflicts exist.

Fiona Fox OBE, Chief Executive of the Science Media Centre, argued that the malicious misuse of conflicts of interest were beginning to discourage scientists from engaging with the public through the mainstream media, and that they were being used as a tool to undermine public confidence in scientists.

She emphasised that some of the media exposure of conflicts of interest have been truly revelatory and in the public interest, changing the way scientists behave in a positive way. However, she suggested that an unfortunate situation was developing in which any link with industry was automatically seen as evidence of bias, rendering viewpoints of some of the best scientists as unreliable. This could have damaging consequences on the quality of public debate, with potential consequences for public health. Furthermore, commentators dismissing input as 'tainted' on the basis of conflicts of interest may themselves have undeclared conflicts of interests, such as membership of single issue campaign groups. The upshot, she argued, was that knowledgeable experts were sometimes being unfairly criticised for having industry connections, even when there is no evidence these connections affected their scientific findings or advice. Meanwhile, less expert opinion from potentially conflicted commentators was being presented by some sections of the media as more credible and subjected to less rigorous scrutiny. As an example, she explained that if the public place greater trust in celebrity campaigners (despite their good intentions) than senior academics with industry connections, this could lead to poor decision-making.

To address this issue, the Science Media Centre is promoting a culture of openness. Every scientist who issues a comment declares their conflicts of interest, and material provided at press briefings provides a full disclosure of relevant speakers' interests. The Science Media Centre also encourages journalists to be skeptical and questioning, and challenges weak associations about links to industry. Finally, she argued that, although academics were being encouraged to work with industry, the rationale for this policy has not been communicated well to journalists or the public, and needs to be communicated more effectively.

Dr Marilyn Metcalf, Senior Director of Benefit Risk Evaluation at GlaxoSmithKline (GSK), provided a perspective from the pharmaceutical industry. She suggested that biases were intrinsic to everyone – they are simply a fact of human nature. Standards and processes applicable to all interested parties can be put in place to minimise the risk that these biases influence decision-making.

GSK, she suggested, had taken steps to promote robust processes of evidence generation and analysis. It is a supporter of the AllTrials initiative which has called for full disclosure of all clinical trials and publication of clinical trial data, and has developed a platform to provide bona fide researchers with access to GSK clinical trial data (with due regard to participants' privacy rights).[28,29] It is also actively conducting collaborative research in pre-competitive spaces and continues to engage with patients, for example to identify trial endpoints that matter to patients.

Panel 3: Interests when using evidence to inform practice/policy

Tracey Brown, Director of Sense About Science, suggested that the current focus on conflicts of interest is doing the public a disservice. She argued that the public is, in many areas, apparently comfortable with the idea that industry pays for research and development of new products (and would be unlikely to favour increased taxes or a reduction in other public spending to replace this with public funding).

She also summarised a range of questions that members of the public typically have about new scientific developments, such as *'should we worry?'*, *'what do scientists actually know?'*, *'do all scientists agree?'*, and *'is it a proper study and how can I tell?'* She suggested that the focus on conflicts of interest is not addressing these questions. Indeed, it is proving a distraction and not helping the public get to grips with the reliability of research findings or cases of actual, rather than alleged, bias. Furthermore, there is a risk of 'false reassurance' if a lack of conflicts of interest was seen as a proxy for trustworthiness.

She argued that there is a need for more engagement with the public about what is gained by academia–industry partnerships and the nature of the conflicts of interest that might thereby arise. Strong institutional leadership is needed to support researchers who are increasingly expected to work with industry but can then find themselves subject to public criticism. This should include specifying the ideal contract for protecting research from funder interests. Currently, she suggested, there is huge variation in practice between institutions. Standard guidelines would encourage the spread of good practice and enable researchers and institutions to demonstrate how their work sits within an approved governance framework. The public would then be able to question whether such standards were in operation and move on to issues of substance about the value of the research itself.

Jonathan Mogford, Policy Director at the Medicines and Healthcare products Regulatory Agency (MHRA), discussed the implications of conflicts of interest for regulatory agencies. Conflicts of interest, he suggested, form part of a wider set of governance questions and also need to be seen in an international context.

Decision-making in regulatory agencies relies heavily on scientific advice from expert committees. Selection processes for membership of expert committees need to be mindful of the potential risks

posed by conflicts of interest but it is also important that committees have the expertise to make truly informed decisions.

Regulatory agencies are now typically drawing on a wider set of resources to inform decision-making, including 'real world' data, raising new conflicts of interest issues. However, he also argued that it is important that conflicts of interest policies and procedures do not only have a negative or excluding function, and that enabling mechanisms also need to be put in place to ensure appropriate input into decision-making. He also noted that it is essential that there is professional and public confidence in regulatory processes, emphasising the importance of the integrity of the evidence base used to inform decision-making and of transparency in decision-making procedures.

Mr Mogford suggested that transparency and clear practical guidance were required to manage conflicts of interest. Importantly, however, these provided a tool to support good governance, and there were limits to what could be achieved even by careful management of conflicts of interest. There is also a risk that over-zealous application of conflicts of interest could be counterproductive, in terms of eliminating input from experts whose knowledge would benefit the process. Furthermore, he suggested, conflicts of interest policies would not provide a mechanism to counter deliberate acts of subterfuge or law-breaking.

Jeremy Taylor, Chief Executive of National Voices, provided a patient group perspective. His organisation has worked with the Association of the British Pharmaceutical Industry (ABPI) to develop a set of guidelines for charities working with industry. A key principle of these guidelines is that it can be appropriate for charities to collaborate with industry and receive industry funding, but they need to be transparent, exercise caution and consider any possible implications for their independence and reputation.

Mr Taylor noted that NHS England's Patient and Public Voice Advisory Group, which feeds into specialised commissioning policy, had been asking members to declare potential conflicts of interest, casting its net very widely (for example, to include interests of family members and friends). He suggested that there was an important distinction between declaring and managing conflicts of interest on the one hand, and seeking to eliminate them on the other. A focus on the latter risks excluding individuals or organisations that could make a useful contribution to decision-making.

More generally, he pointed out that companies and patients affected by a condition naturally have a shared interest in developing new treatments, and in ensuring these treatments are implemented. At what point, he asked, does this natural alignment of interests become a conflict of interests?

Mr Taylor also noted that the absence of conflicts of interest does not automatically mean an individual is unbiased. People might for example have strong views either in favor of or against medical models of care and pharmacological approaches, based on their own values, experience or other personal factors.

Nick Ross, Honorary President of HealthWatch, argued that subconscious cognitive biases pose a significant threat to the reliability of the scientific evidence base for medicines. He suggested that many individuals have a considerable emotional investment in their work, and naturally hope that their efforts will have practical impact. These perfectly natural desires may subconsciously

influence their thinking – they may genuinely believe they are acting in the public interest or interpreting evidence impartially.

To guard against these natural tendencies, it is important that mechanisms exist to minimise sources of bias in medical evidence. Industry needs to acknowledge the importance of methodologies such as formalised protocols, full data release, and other mechanisms that support impartial assessment of an unbiased evidence base. He also argued that it would be beneficial for individuals and organisations to publish details of the measures they have taken to minimise and manage conflicts of interest.

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152/2020 - 16 October 2020

September 2020

Annual inflation down to -0.3% in the euro area

Down to 0.3% in the EU

The **euro area** annual inflation rate was -0.3% in September 2020, down from -0.2% in August. A year earlier, the rate was 0.8%. **European Union** annual inflation was 0.3% in September 2020, down from 0.4% in August. A year earlier, the rate was 1.2%. These figures are published by **Eurostat, the statistical office of the European Union**.

The lowest annual rates were registered in **Greece** (-2.3%), **Cyprus** (-1.9%) and **Estonia** (-1.3%). The highest annual rates were recorded in **Poland** (3.8%), **Hungary** (3.4%) and **Czechia** (3.3%). Compared with August, annual inflation fell in thirteen Member States, remained stable in seven and rose in seven.

In September, the highest contribution to the annual **euro area** inflation rate came from food, alcohol & tobacco (+0.34 percentage points, pp), followed by services (+0.24 pp), non-energy industrial goods (-0.08 pp) and energy (-0.81 pp).

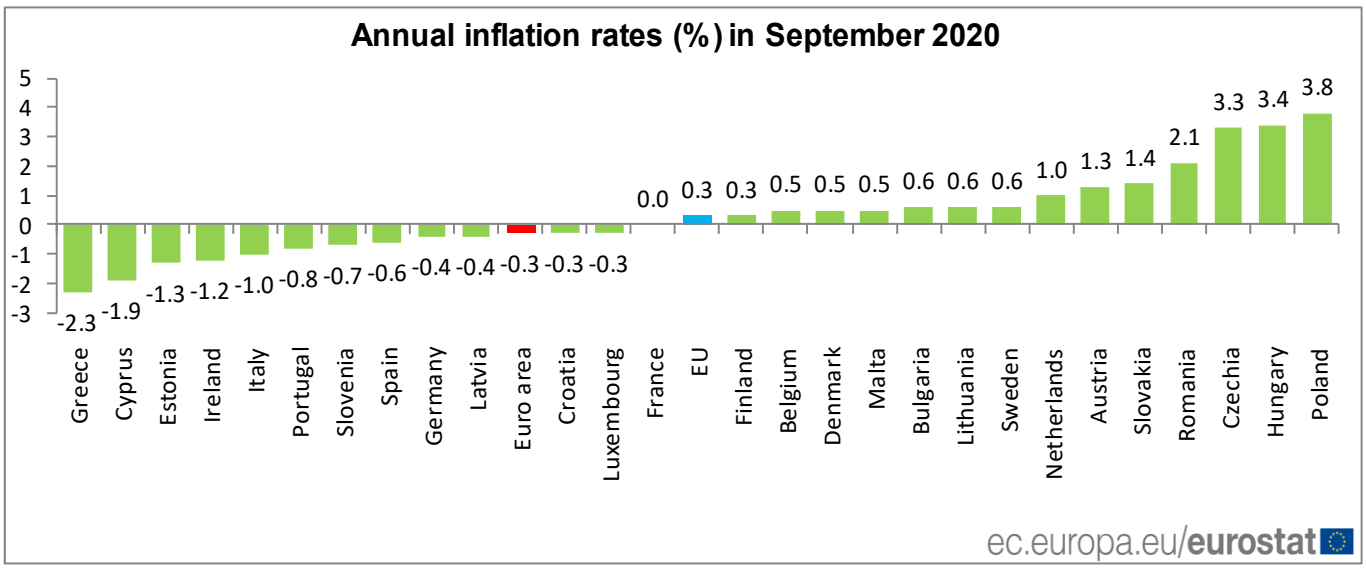

Inflation rates (%) measured by the HICP

	Annual rate							Monthly rate
	Sep 19	Apr 20	May 20	Jun 20	Jul 20	Aug 20	Sep 20	Sep 20
Euro area	0.8	0.3	0.1	0.3	0.4	-0.2	**-0.3**	0.1
EU	1.2	0.7	0.6	0.8	0.9	0.4	**0.3**	0.0
Belgium	0.6	0.0	-0.2	0.2	1.7	-0.9	**0.5**	0.8
Bulgaria	1.6	1.3	1.0	0.9	0.4	0.6	**0.6**	-1.2
Czechia	2.6	3.3	3.1	3.4	3.6	3.5	**3.3**	-0.6
Denmark	0.4	-0.1	-0.2	0.2	0.4	0.4	**0.5**	-0.2
Germany	0.9	0.8	0.5	0.8	0.0	-0.1	**-0.4**	-0.4
Estonia	2.2	-0.9	-1.8	-1.6	-1.3	-1.3	**-1.3**	-0.1
Ireland	0.6	-0.3	-0.8	-0.6	-0.6	-1.1	**-1.2**	-0.4
Greece	0.2	-0.9	-0.7	-1.9	-2.1	-2.3	**-2.3**	1.5
Spain	0.2	-0.7	-0.9	-0.3	-0.7	-0.6	**-0.6**	0.4
France	1.1	0.4	0.4	0.2	0.9	0.2	**0.0**	-0.6
Croatia	0.6	-0.1	-0.7	-0.4	-0.6	-0.4	**-0.3**	-0.1
Italy	0.2	0.1	-0.3	-0.4	0.8	-0.5	**-1.0**	0.9
Cyprus	-0.5	-1.2	-1.4	-2.2	-2.0	-2.9	**-1.9**	-0.8
Latvia	2.3	-0.1	-0.9	-1.1	0.1	-0.5	**-0.4**	-0.1
Lithuania	2.0	0.9	0.2	0.9	0.9	1.2	**0.6**	0.3
Luxembourg	1.1	-0.8	-1.6	-0.4	0.1	-0.2	**-0.3**	-0.2
Hungary	2.9	2.5	2.2	2.9	3.9	4.0	**3.4**	-0.5
Malta	1.6	1.1	0.9	1.0	0.7	0.7	**0.5**	-1.3
Netherlands	2.7	1.0	1.1	1.7	1.6	0.3	**1.0**	-0.4
Austria	1.2	1.5	0.6	1.1	1.8	1.4	**1.3**	1.0
Poland	2.4	2.9	3.4	3.8	3.7	3.7	**3.8**	0.2
Portugal	-0.3	-0.1	-0.6	0.2	-0.1	-0.2	**-0.8**	0.8
Romania	3.5	2.3	1.8	2.2	2.5	2.5	**2.1**	-0.4
Slovenia	1.7	-1.3	-1.4	-0.8	-0.3	-0.7	**-0.7**	-0.2
Slovakia	3.0	2.1	2.1	1.8	1.8	1.4	**1.4**	0.0
Finland	1.0	-0.3	-0.1	0.1	0.7	0.3	**0.3**	0.0
Sweden	1.3	-0.2	0.1	0.9	0.7	1.0	**0.6**	0.1
United Kingdom	1.7	0.8	0.5	0.6	1.0	0.2	**:**	:
Iceland	2.8	-0.1	0.9	0.3	-0.1	0.9	**1.4**	-0.8
Norway	1.5	0.6	1.1	1.3	1.4	1.6	**1.4**	0.4
Switzerland	0.1	-1.0	-1.0	-1.3	-1.2	-1.4	**-1.1**	-0.1

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Source dataset: prc_hicp_manr

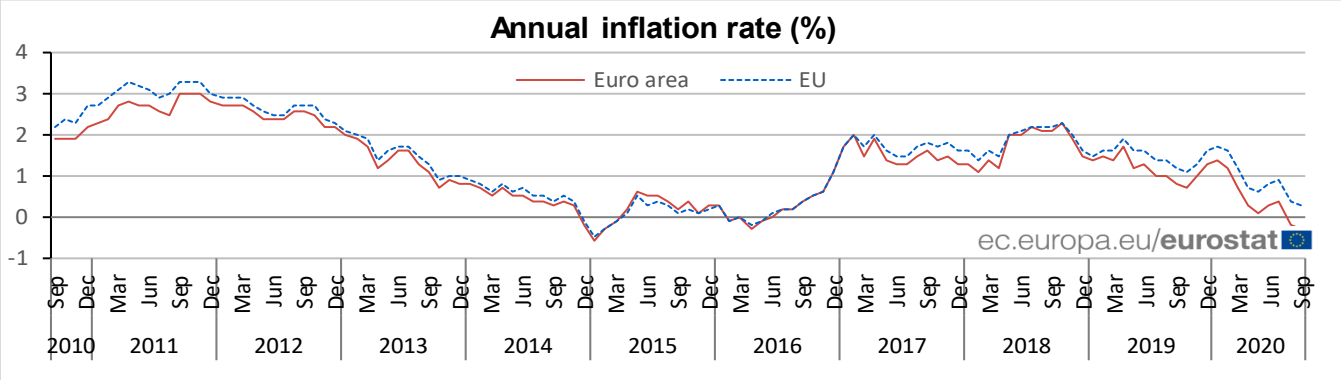

Euro area inflation rate (%), selected aggregates

	Weights (‰)	Annual rate							Monthly rate
	2020	Sep 19	Apr 20	May 20	Jun 20	Jul 20	Aug 20	Sep 20	Sep 20
All-items HICP	**1000.0**	**0.8**	**0.3**	**0.1**	**0.3**	**0.4**	**-0.2**	**-0.3**	**0.1**
All-items excluding: > energy	901.5	1.1	1.4	1.4	1.3	1.4	0.7	**0.6**	0.1
> energy, unprocessed food	857.1	1.2	1.1	1.2	1.1	1.3	0.6	**0.4**	0.1
> energy, food, alcohol & tobacco	710.8	1.0	0.9	0.9	0.8	1.2	0.4	**0.2**	0.2
> energy, seasonal food	876.5	1.2	1.2	1.2	1.1	1.3	0.6	**0.4**	0.1
> tobacco	977.2	0.8	0.2	0.0	0.1	0.2	-0.3	**-0.5**	0.1
Food, alcohol & tobacco	190.7	1.6	3.6	3.4	3.2	2.0	1.7	**1.8**	-0.2
> processed food, alcohol & tobacco	146.3	1.8	2.3	2.4	2.3	1.6	1.5	**1.4**	-0.3
> unprocessed food	44.5	0.7	7.6	6.7	6.0	3.1	2.3	**3.1**	0.5
Energy	98.5	-1.8	-9.7	-11.9	-9.3	-8.4	-7.8	**-8.2**	-0.4
Non-energy industrial goods	262.1	0.2	0.3	0.2	0.2	1.6	-0.1	**-0.3**	2.8
Services	448.7	1.5	1.2	1.3	1.2	0.9	0.7	**0.5**	-1.2

Contributions to the euro area annual inflation rate (pp), selected aggregates

	Contributions						
	Sep 19	Apr 20	May 20	Jun 20	Jul 20	Aug 20	Sep 20
Food, alcohol & tobacco	0.29	0.67	0.64	0.60	0.38	0.33	**0.34**
> processed food, alcohol & tobacco	0.26	0.34	0.35	0.34	0.24	0.23	**0.20**
> unprocessed food	0.03	0.33	0.30	0.26	0.14	0.10	**0.14**
Energy	-0.18	-0.97	-1.20	-0.93	-0.83	-0.77	**-0.81**
Non-energy industrial goods	0.06	0.09	0.06	0.05	0.42	-0.03	**-0.08**
Services	0.66	0.52	0.59	0.55	0.42	0.30	**0.24**

Source dataset: prc_hicp_ctrb

Geographical information

The **euro area** consists of Belgium, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Austria, Portugal, Slovenia, Slovakia and Finland.

The **European Union** includes Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland and Sweden.

The euro area and European Union data refer to the respective country compositions at a specific point in time. Changes in the composition of these aggregates are incorporated using a chain index formula. For more information on this, please read this note.

Methods and definitions

Annual inflation is the change of the price level between the current month and the same month of the previous year. **Monthly inflation** is the change of the price level between the current month and the previous month.

A **contribution** shows how much of the annual inflation rate comes from a particular component of the HICP. The contributions are calculated according to a method which ensures their additivity (allowing for rounding).

Data collection for HICP has been affected by the COVID-19 crisis in all countries. Eurostat and the Member States' national statistical institutes have agreed a set of procedures to estimate prices that could not be collected due to mobility restrictions or closures of outlets. All information about these procedures is available on the Eurostat website section on inflation.

Revisions and timetable

A flash estimate of euro area inflation is issued at the end of each reference month. The euro area flash estimate for September 2020, published on 2 October 2020, was -0.3%.

The next flash estimate of euro area inflation with data for October 2020 is scheduled for 30 October 2020.

For more information

Eurostat website section on inflation

Eurostat database section on inflation

Eurostat Statistics Explained article on inflation in the euro area

Eurostat metadata on inflation

Eurostat €-indicators release calendar

European Statistics Code of Practice

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EN 2018

NO 28

Special Report

The majority of simplification measures brought into Horizon 2020 have made life easier for beneficiaries, but opportunities to improve still exist

(pursuant to Article 287(4), second subparagraph, TFEU)

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AUDIT TEAM

The ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was carried out by Audit Chamber IV Regulation of markets and competitive economy, headed by ECA Member Neven Mates. The audit was led by ECA Member Alex Brenninkmeijer, supported by Raphael Debets, Head of Private Office and Di Hai, Private Office Attaché; Paul Stafford, Principal Manager; Daniela Hristova, Head of Task; Wayne Codd, Juan Antonio Vázquez Rivera and Marco Montorio, Auditors.

From left to right: Raphael Debets, Di Hai, Wayne Codd, Alex Brenninkmeijer, Paul Stafford, Daniela Hristova, Marco Montorio, Juan Antonio Vázquez Rivera.

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Commission's replies

ABBREVIATIONS AND ACRONYMS

AMGA	Annotated Model Grant Agreement
CIP	Competitiveness and Innovation Framework Programme
CSC	Common Support Centre
DG CNECT	Commission Directorate-General for Communications Networks, Content and Technology
DG RTD	Commission Directorate-General for Research and Innovation
EASME	Executive Agency for Small and Medium-Sized Enterprises
EARTO	European Association of Research and Technology Organisations
ECA	European Court of Auditors
EIT	European Institute of Innovation and Technology
EUA	European University Association
EP	European Parliament
FP7	Seventh Framework Programme
FP9	Ninth Framework Programme
H2020	Horizon 2020 (the Eighth Framework Programme)
IA	Innovation Action
JRC	Joint Research Centre
MGA	Model Grant Agreement
NCP	National Contact Point
REA	Research Executive Agency
RES	Research Enquiry Service
RTO	Research and Technology Organisation
SME	Small and medium-sized enterprises
SMEI	Small and medium-sized enterprise Instrument
TRL	Technology readiness level
UEAPME	European Association of Craft, Small and Medium-sized Enterprises

GLOSSARY

Annotated Model Grant Agreement (AMGA): a user guide for applicants and beneficiaries that summarises and explains the terms of the General Model Grant Agreement (GMGA) and the various specific Model Grant Agreements for Horizon 2020.

Applicant: Person or organisation (individually or grouped) requesting EU funding.

Beneficiary: Person or organisation (individually or grouped) awarded EU funding in the form of a grant.

Briefing Paper: ECA's Briefing Paper of March 2018, "A contribution to simplification of EU research programme beyond Horizon 2020".

Call for proposals: Procedure for inviting applicants to submit project proposals, with the aim of receiving EU funding. There are several types of calls (with special submission or evaluation schemes): 2-stage calls; calls with multiple cut-off dates; and invitations to submit a proposal.

Cascade funding: A European Commission mechanism through which grant beneficiaries can distribute funds via sub-grants to third parties outside the consortium.

Common Support Centre: A Commission directorate centralising all support services in research and innovation.

Europe 2020: A ten-year strategy proposed by the European Commission on 3 March 2010 to advance the economy of the European Union (replacing the Lisbon Strategy for 2000-2010). The main objective is "smart, sustainable, inclusive growth" with greater coordination of national and EU policy.

Ex ante controls: Relate to preventive checks carried out either before grant signature or before payment.

Ex post controls: Relate to checks carried out after payment has been made.

Framework Programme (FP): The Framework Programme is the EU's main instrument for research funding in Europe. The FP is proposed by the European Commission and adopted by Council and the European Parliament following co-decision procedure.

FP7: The Seventh Framework Programme.

H2020: The Eight Framework Programme.

Horizon 2020 dashboard: online presentation of implementation data of Horizon 2020, accessible via the Participant Portal.

Inducement prizes: a type of simplified cost option with financial contribution given as a reward following a contest.

Innovation Union: One of the seven flagship initiatives of the Europe 2020 strategy.

Lump sums: a type of simplified cost option with pre-determined amounts to be reimbursed when pre-defined project goals or milestones are reached, with no need for reporting of actual costs incurred by the participant.

Multi-annual financial framework (MFF): Multi-year EU budget, fixing the priorities and parameters for EU spending for consecutive periods of 5-7 years.

National Contact Point (NCP): A national structure set up in an EU Member State or another country participating in Horizon 2020 to give applicants personalised support on the spot and in their own languages.

Participant Portal: The Participant Portal is an internet platform for electronic administration of EU-funded research and innovation projects, which hosts the services for managing grant proposals and projects throughout their lifecycle.

Project officer: An EU official with responsibility for managing the EU's interest in a project; the main contact point for beneficiaries. Normally follows a project from beginning to end, with a key role in all relevant decisions affecting the project (payments, amendments, reviews, etc.).

Research and Innovation family: Commission DGs, Executive Agencies (EAs) and Joint Undertakings (JUs).

Research Enquiry Service: An online service provided by the Commission to answer questions from applicants and beneficiaries about European research in general and about the validation process of legal entities.

Rules for participation: Specific funding rules for Horizon 2020, set out in Regulation (EU) No 1290/2013.

Small and medium-sized enterprises (SMEs): companies employing fewer than 250 staff and with an annual turnover not exceeding 50 million euro and/or an annual balance sheet total not exceeding 43 million euro (defined in Article 2 of the annex to Recommendation 2003/361/EC).

Technology readiness level: A measurement scale developed by NASA to assess the maturity of a particular technology. Used mainly to assess the readiness of individual technological components to operate in a larger technology system. On a scale from 1 to 9, TRL 1 corresponds roughly to basic research, TRLs 2-4 to applied research, TRLs 5-6 to applied research/development, TRLs 7-8 to demonstration and TRL 9 to full-scale deployment.

Time to grant: defined as the administrative period between submission of a proposal and signature of the grant agreement, marking the official start of a project.

EXECUTIVE SUMMARY

I. Horizon 2020 is the eighth EU framework programme for research and innovation. With a budget of 76.4 billion euro for the period 2014 to 2020, it ranks as the world's biggest public research and innovation programme.

II. Horizon 2020 has an impact on a wide range of EU policies and is managed by a number of Commission's Directorates General, which adds to its complexity. In Horizon 2020, the Commission has simplified its rules and procedures, speeded up the "time to grant", streamlined IT systems, reduced the number of funding schemes and provided clearer guidance and more legal certainty to beneficiaries.

III. We assessed whether the Commission's simplification measures had reduced the administrative burden of beneficiaries. We examined whether the design of the measures was based on previous evaluations and feedback from stakeholders. We carried out a survey of beneficiaries of Horizon 2020 grants to assess their perceptions of the positive and negative impact of those measures in terms of reducing the administrative burden on them.

IV. We found that the majority of the Commission's simplification measures have been effective in reducing the administrative burden for beneficiaries in Horizon 2020, although not all actions produced the desired result and opportunities to improve still exist. Stability in the rules is also important; beneficiaries are able to adapt to complexity but frequent modifications to guidance can cause confusion and uncertainty.

V. We found that the Commission drew on its experience of managing previous framework programmes to identify where simplification was needed. New organisational and horizontal structures, notably the creation of the Common Support Centre (CSC), were a major contribution to simplification. This led to more coherent implementation of the programme.

VI. The Research Enquiry Service, providing advice and support to applicants and participants, was not incorporated into the CSC. Although improved since FP7, there are other channels answering queries, meaning that consistent treatment of cases could not be guaranteed. National Contact Points also offer varying levels of support and guidance.

VII. Support tools, such as the Participant Portal, were improved. The introduction of electronic signatures led to simplified grant award and management for applicants and beneficiaries. However, some technical improvements are still required. Similarly, although the grants manual offers comprehensive and detailed information, it is difficult to navigate, especially for inexperienced beneficiaries.

VIII. The "time to grant", from application to signature of a grant agreement, has been reduced significantly thanks to electronic management and withdrawal of the negotiation stage, but the opportunities to reduce the administrative burden have not been fully exploited. Only a fraction of calls for proposals employs two-stage evaluation. This has an impact in particular on unsuccessful applicants. Moreover, the Seal of Excellence, intended to help the best of the unsuccessful proposals find funding elsewhere, has not yet been effective.

IX. Attempts to simplify rules on personnel costs have not had the intended results and these remain complex for beneficiaries, leading to errors in cost declarations. Some negative side-effects emerged from the new approaches adopted, and subsequent adjustments introduced have caused some confusion and legal uncertainty. Increasing reliance on usual cost accounting practices, in particular for personnel costs, could reduce the administrative burden. New simplified cost options, such as lump sums and inducement prizes, have the potential to reduce the administrative burden, but they have not yet been sufficiently tested by the Commission.

X. The creation of a Common Audit Service and a new audit strategy have reduced the audit burden compared to FP7, but variable quality in outsourced audits can lead to frustration and confusion for beneficiaries.

XI. We recommend that the Commission should:

(a) better communicate with applicants and beneficiaries;

(b) intensify testing of lump sums;

(c) explore greater use of two-stage proposal evaluations;

(d) re-examine remuneration conditions for expert evaluators;

(e) increase recognition of the Seal of Excellence;

(f) ensure stability for rules and guidance for participants;

(g) improve quality of outsourced audits;

(h) further simplify tools and guidance for SMEs.

INTRODUCTION

What is Horizon 2020?

1. Horizon 2020 is the eighth EU framework programme for research and innovation. With a budget of 76.4 billion euro[1] for the period 2014 to 2020, it ranks as the world's biggest public research and innovation programme.

2. Horizon 2020 has its origins in the priorities of the Europe 2020 strategy. It is built around three main pillars and two specific objectives covering a large range of topics (see ***Figure 1***). It provides funding to researchers, research institutes, universities, private companies (both large companies and SMEs) and public bodies either individually or in consortia, engaged in collaborative research projects.

3. The programme has a particular focus on SMEs. The European Commission targets the participation of SMEs, both in collaborative projects and through the new SME Instrument, which was designed specifically for highly innovative smaller companies.

4. The cross-cutting nature of research and innovation and its impact on a wide range of EU policies shapes the Horizon 2020 mode of management. The Commission's Research and Innovation Directorate General (DG RTD) manages the programme together with eight other Directorates General[2]. Parts of the budget can be the responsibility of more than one DG. In all, 22 different bodies[3] implement the Horizon 2020 budget.

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[1] Updated H2020 budget after the establishment of the European Fund for Strategic Investments (EFSI) and including the Euratom Research & Training Programme.

[2] DG RTD, DG CNECT, DG GROW, DG EAC, DG AGRI, DG MOVE, DG HOME, DG ENER and the JRC.

[3] Commission executive agencies, public-public partnerships between the EU and Member States, public-private partnerships with industry, the European Investment Bank and the European Institute of Innovation and Technology (EIT).

Figure 1 - Horizon 2020 architecture

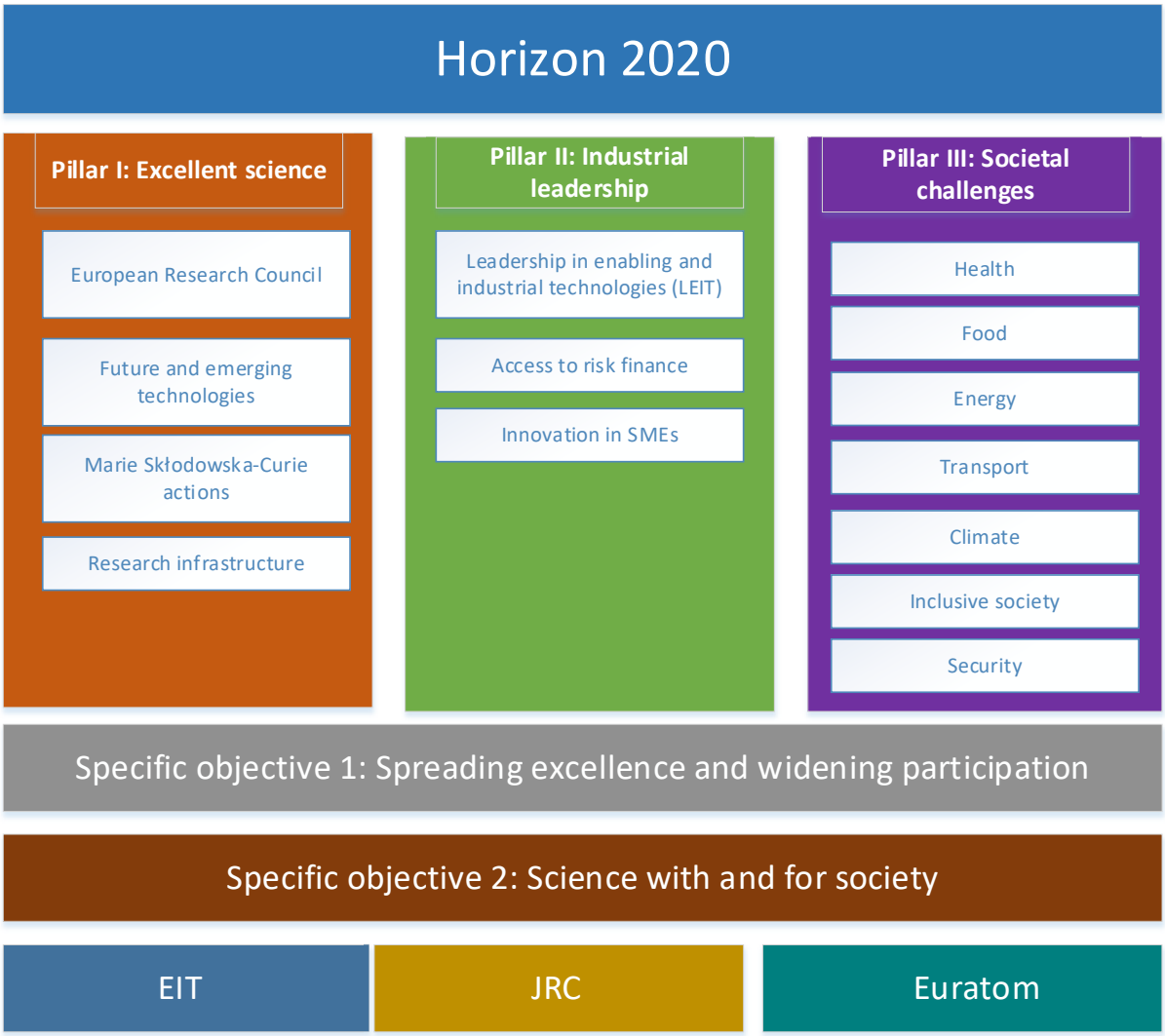

Source: ECA.

A history of EU research and innovation funding

5. European funding for research activities began under the first Community treaties and was extended in 1983 with the establishment of the "first Community framework programme for research" (FP1).

6. Since then, successive framework programmes have become a major part of research cooperation in Europe, growing progressively in size, scope and ambition. ***Figure 2*** shows the evolution of European research funding since the first programme.

Figure 2 - Evolution of research funding 1984-2020

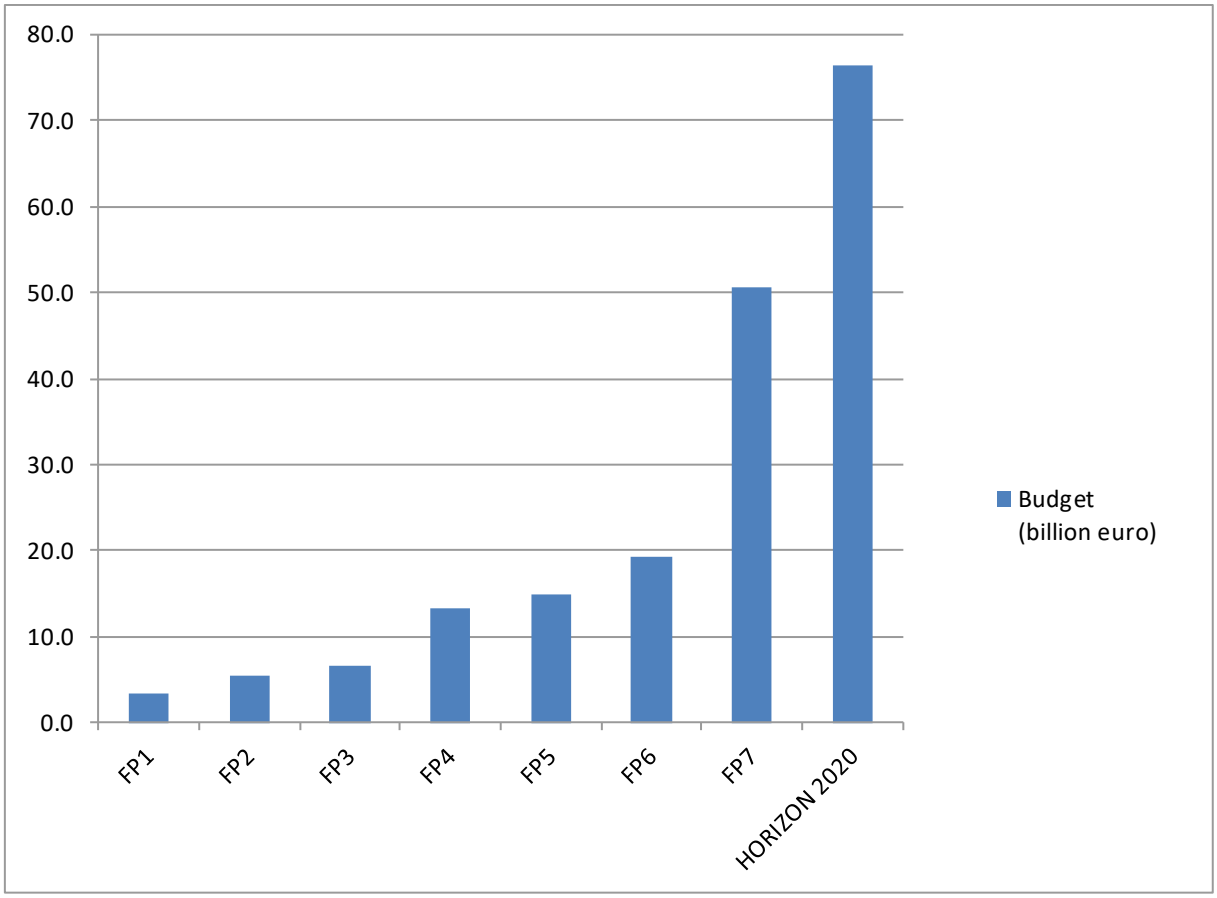

Source: ECA.

7. As the eighth programme, Horizon 2020 is an important implementing tool for the Innovation Union, one of seven flagship initiatives of the Europe 2020 strategy[4]. Horizon 2020 combines all research and innovation funding previously provided through the Seventh Framework Programme (FP7), the innovation-related activities of the Competitiveness and Innovation Framework Programme (CIP) and the European Institute of Innovation and Technology (EIT).

Summary of the most recent simplification initiatives

8. The simplification of EU research and innovation funding has been on the agenda for many years, with industry, academia and researchers across Europe seeking simpler

[4] http://ec.europa.eu/research/innovation-union/index.cfm

administrative rules, better communication with the European Commission, legal certainty and consistency. The Commission has been criticised for its unclear guidance to beneficiaries, lengthy time to grant, complex funding rules and ineffective grant management procedures.

9. With Horizon 2020, simplification became a central aim[5]. The European Commission proposed changes designed to simplify the rules governing EU research and innovation funding.

10. These changes included: establishing a single set of rules, harmonising the grant management processes and streamlining the supporting IT systems, reducing the number of programmes, increasing coherence and clarity of rules, setting clearer priority objectives and indicators, providing more coherent cost-eligibility rules, simplifying forms of grants and reduced times to grant and pay (see ***Figure 3***).

Figure 3 – Principal Horizon 2020 simplification measures

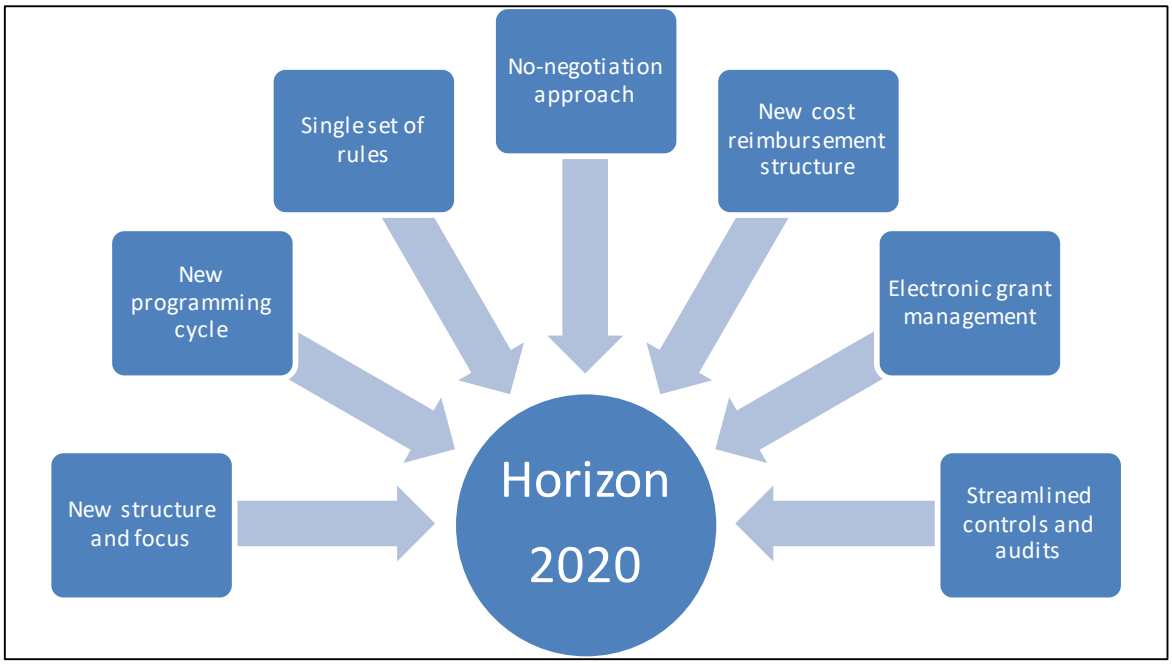

Source: ECA.

[5] See recital 20 to Regulation No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 104).

AUDIT SCOPE AND APPROACH

Audit scope

11. This special report is the latest in a series of ECA publications concentrating on the Framework Programme for research and innovation. This includes a forward-looking briefing paper "A contribution to simplification of EU research programme beyond Horizon 2020" published in March 2018. The ECA decided to carry out this audit in time for the preparation of the next innovation and research Framework Programme.

12. In this audit, we asked "Have the Horizon 2020 simplification measures taken by the Commission been effective in reducing the administrative burden of beneficiaries?". To answer this question, we examined whether the Commission's measures were designed on the basis of previous evaluations and feedback from stakeholders. We surveyed beneficiaries of the Horizon 2020 programme to assess the positive and negative impact of those measures.

Approach

13. We examined information from a wide range of sources:

(a) We reviewed and analysed legal bases, guidelines, evaluation and monitoring reports, position papers and other documentation with a bearing on simplification;

(b) We discussed the simplification measures with the relevant Commission departments[6] and representatives of three umbrella organisations[7]; we also attended a meeting of the national contact points and a stakeholders' meeting organised by the Common Support Centre.

14. In February 2018 we sent an online survey to 32 918 contacts from 20 797 organisations granted Horizon 2020 funding. The survey covered the period from the start of

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[6] DG RTD, DG CNECT and REA.

[7] EARTO, UEAPME, EUA.

the programme in 2014 to January 2018 and comprised 59 questions. We asked the beneficiaries for their views on the effectiveness of the simplification measures, including, where applicable, how the programme compared with FP7. We received 3 598 replies. To obtain more detailed information to support the survey results, we conducted meetings with eight final beneficiaries (two SMEs, two universities, one large private enterprise and three RTOs).

OBSERVATIONS

The Commission drew on its experience of previous programmes to identify which simplification measures were needed

15. It is important, when preparing a new Framework Programme, to make a thorough analysis and evaluation of the predecessor programmes. The Commission should evaluate whether policies and spending activities are fit for purpose and have delivered the desired changes to European business and citizens. The results of the evaluation should help the Commission to decide whether EU actions can be continued unchanged or need modification.

16. The legal base for FP7 required the Commission to continually and systematically monitor implementation of the Programme[8]. We found that the Commission had prepared annual monitoring reports during the implementation of FP7 in which it regularly analysed, in detail, participation patterns, implementation issues and the situation with regard to the simplification process.

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[8] Article 7 of Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

17. In line with the interinstitutional agreement on better law-making[9], the Commission also sought feedback from key stakeholders via a range of consultation channels (see ***Box 1***).

18. The Commission summarised stakeholders' input to a wide public consultation in its "Green Paper on a Common Strategic Framework for EU Research and Innovation Funding". The green paper identified simplification as a "top priority in order to make EU research and innovation funding generate more impact and be more attractive to participants"[10].

19. In the impact assessment accompanying the Horizon 2020 set of legislative proposals[11], the Commission defined the need for further simplification in research and innovation funding, set specific and operational objectives for the next programming period, analysed four policy options and eventually proposed Horizon 2020 as the most appropriate option to achieve the objectives set.

20. We conclude that the simplification measures undertaken by the European Commission in Horizon 2020 are the result of an analysis of previous framework programmes, in particular its immediate predecessor FP7.

Box 1 - Consultations with stakeholders and interested parties in preparation for Horizon 2020

- FP6 ex-post evaluation, February 2009;
- FP7 interim evaluation, November 2010;
- Public consultation on Green Paper describing the Common Strategic Framework for Research and Innovation, June 2011;
- Public consultation on the successor to the Competitiveness and Innovation Framework Programme (CIP), November 2011;
- CIP: interim and final evaluations, ex-ante evaluations and impact assessment studies for the ICT-PSP, IEE and innovation-related parts of the Entrepreneurship and Innovation Programme;

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[9] 2003/C 321/01 in force until 12/04/2016 and replaced by 32016Q0512(01) (OJ L 123, 12.5.2016).

[10] European Commission, "Green Paper on a Common Strategic Framework for EU Research and Innovation Funding", June 2011.

[11] SEC(2011) 1427 final of 30.11.2011.

- Large stakeholder conferences on the successor to the CIP (January 2011) and the Common Strategic Framework (June 2011);
- Expert panels and stakeholder conferences on the European Research Council, Marie Curie, EIT, etc.;
- EU Presidencies: Lund conference on the future of EU research (Sweden, July 2009); FP7 interim evaluation conference (Hungary, February 2011);
- Wide range of position papers on future EU research and innovation funding during EU budget preparations;
- Thematic stakeholder consultations: ICT, transport, health, biotechnology, space;
- Discussions with representatives of national administrations (CIP Joint Management Committees meeting, meetings of EIP Management Committee).

Source: European Commission.

The main changes to achieve simplification were through design, organisation and supporting tools

The Common Support Centre is a major step towards coherent implementation of Horizon 2020

21. Programme management is defined as the centralised coordinated management of a programme to achieve the programme's strategic objectives and benefits[12]. The shared services concept is one way to gain such centralised coordinated management.

22. In our special report on FP7[13] we criticised the Commission's management and found that the Research Clearing Committee, established by the managing Directorates-general to enhance legal certainty and equal treatment of beneficiaries, failed to identify all divergent practices in FP7 implementation.

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[12] Project management Institute, "A Guide to the Project Management Body of Knowledge (PMBOK Guide)", Fourth edition.

[13] Special Report No 2/2013 "Has the Commission ensured efficient implementation of the seventh framework programme for research?".

23. The Commission streamlined the management approach for Horizon 2020 by setting up a new directorate, the Common Support Centre (CSC), in 2014. By centralising horizontal support services in research and innovation, the CSC ensures that all bodies in the Research and Innovation family (Commission DGs, executive agencies and joint undertakings) apply the Horizon 2020 legislation in a coherent manner.

24. The CSC's tasks are presented in ***Figure 4***.

Figure 4 - Common Support Centre tasks

Source: ECA.

25. The Commission put in place a variety of tools to facilitate participation in Horizon 2020, increase awareness and strengthen consistent application of its rules. Some of these tools, such as the Participant Portal, the Annotated Model Grant Agreement (AMGA), the Horizon 2020 online manual and FAQs, fall under the direct responsibility of the CSC; others, such as the National Contact Points (NCPs), are for the Member States to appoint. The Research Enquiry Service and IT Helpdesk are mainly run by the Research Executive Agency (REA) and

DG DIGIT respectively. The CSC only provides the second-level helpdesks for the subjects under its responsibility.

26. We asked the beneficiaries we surveyed whether they were satisfied with the support tools. Overall, respondents showed a high level of satisfaction, ranging from 45 % of respondents considering the Enterprise Europe Network to be fit for purpose, up to 86 % for the Participant Portal (see ***Figure 5***).

Figure 5 – Survey respondents' satisfaction with support tools

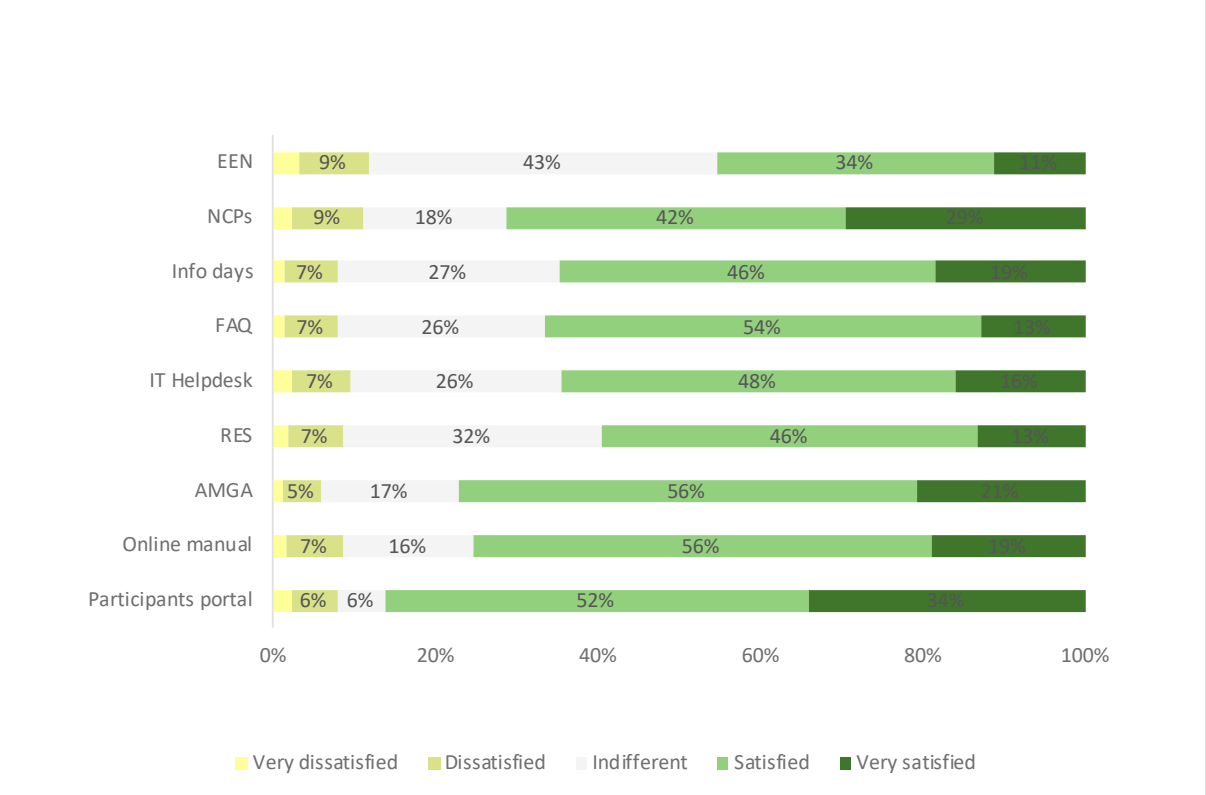

Source: ECA survey, March 2018.

27. The CSC started its activity with clear objectives (see ***Figure 6***)[14]. Since its establishment in 2014, it has made great efforts to improve the Participant Portal and has frequently updated and expanded the AMGA. A legal and financial helpdesk can now answer questions from beneficiaries (via the Research Enquiry Service) and other Commission departments.

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[14] Commission Decision C(2014) 2656 final on the operating rules for the Common Support Centre for Horizon 2020, the Framework Programme for Research and Innovation (2014-2020).

Another step towards simplification was the adoption of the Common Audit Strategy and a common ex ante control strategy.

28. The introduction of an electronic grant management workflow was among the most significant simplification achievements in Horizon 2020. Another positive element, especially appreciated by the NCPs, was the practice retained from FP7 of organising roadshows in the Member States, at which the CSC makes presentations to beneficiaries, NCPs and certifying auditors on various legal and financial issues.

Figure 6 – Common Support Centre: objectives vs. achievements

Source: ECA.

29. Thus the CSC took the lead in the process of simplification. In the areas under its remit, it has harmonised the rules for participation, developed a new audit strategy and improved the IT tools for grant management and reporting. However, not all support services have been brought under CSC control, leading to a risk of inconsistent advice and interpretation being provided to beneficiaries. This issue is discussed below in respect of two communication tools.

Beneficiaries appreciate the communication and feedback channels but some still report inconsistent treatment and varying levels of service

30. Effective communication and a functioning feedback system are prerequisites for coherent application of the rules for participation and the consistent treatment of beneficiaries. A failure in communication can negatively impact a project. The CSC has several channels, outlined below, for communicating with, and receiving feedback from, beneficiaries on the functioning and implementation of the Framework Programme.

Research Enquiry Service

31. The Commission put the Research Enquiry Services (RES) in place during FP7 to facilitate communication with and effective feedback from the beneficiaries of research and innovation funding. RES replaced a system of 60 functional mailboxes and is accessible from the Participant Portal, but also through other channels, such as the Horizon 2020 Europa website. The tool plays the role of a helpdesk, where potential and current Horizon 2020 beneficiaries can seek methodological, technical and legal support throughout the life-cycle of their projects.

32. Currently, the Research Executive Agency manages RES. Part of the service is executed by the Europe Direct Contact Centre (EDCC)[15]. EDCC has a wider scope, answering queries about a range of EU policies, not only Horizon 2020.

33. The EDCC answers questions using information which can be found in publicly available sources, and more complicated questions are answered with input from the appropriate Commission services.

34. In our survey, we asked beneficiaries to evaluate the quality of RES. More than half of the respondents who expressed an opinion considered that RES is generally a useful and fit-for-purpose tool.

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[15] Under a contract with DG COMM.

35. On the subject of RES, respondents highlighted two main issues: on one hand, the timeliness of the replies to beneficiaries, and on the other, the lack of thoroughness (some replies are taken directly from the Commission guidance).

36. We found that despite the CSC's general aim to centralise common services, RES has a decentralised structure. In practice RES is supported by 36 different helpdesks hosted by a range of DGs and executive agencies. Questions that cannot be answered by the external contractor (56 % in 2017) are forwarded to the REA team or directly to one of the 36 helpdesks. Every month the REA team of three check all responses provided by the external contractor and the decentralised helpdesks for both quality and categorisation.

37. We also found that, in addition to the service provided by RES, certain executive agencies (e.g. EASME) use other functional mailboxes. Other departments (e.g. DG CNECT) reply via social media. In such cases, it is hard for either REA or the CSC to exercise any control over replies.

38. We used the survey to ask beneficiaries whether, if they had participated in more than one Horizon 2020 project, identical or equivalent situations had been treated inconsistently. 36 % of respondents replied that this was the case. The most common inconsistencies related to the interpretation of financial rules (20 %), reporting requirements (18 %) and project evaluations (17 %).

39. The Commission set up a dedicated RES back-office to handle notifications of possible inconsistencies. However, we found that 82 % of the respondents who had experienced cases of inconsistent treatment were not aware of this service. As a result the Commission is rarely informed about inconsistencies and cannot always prepare the appropriate remedial measures.

40. Although RES was improved with the programming of Horizon 2020, the alternative channels through which queries and replies can be exchanged means that consistency of information still cannot be guaranteed.

National Contact Points

41. The network of NCPs serves as an important conduit between the Commission and beneficiaries. The Commission considers it to be "the main structure for providing practical information and assistance to potential participants"[16]. It also enables the Commission to obtain feedback from beneficiaries. NCP support can be especially helpful for SMEs and newcomers to the programme, whose relative lack of expertise may threaten the success of their applications.

42. In order to ensure consistency in the support which NCPs offer to applicants and beneficiaries of research funding, in 2013 the Commission produced the "Minimum standards and guiding principles for National Contact Points"[17]. This document provides a common reference for all participating countries and defines the NCPs` core functions and the mechanisms for cooperation between them and the Commission.

43. The Member States and associate countries appoint NCPs. Although NCPs are not under the direct responsibility of the Commission, the Commission DGs in charge of different parts of the programme organise meetings with them to discuss policy developments, procedural aspects, and the content of calls for proposals. The CSC also organises meetings with legal and financial NCPs to present the latest developments.

44. In our survey, we asked beneficiaries about their experience of the NCPs. The overall opinion of the NCPs' work was positive (71 % of respondents considered the NCP support to be fit-for-purpose), but the level of appreciation differed from one country to another. Dissatisfaction with the NCPs' quality of service ranged from 4 % to 25 % in different Member States; most concerns related to their degree of preparedness and availability.

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[16] http://ec.europa.eu/research/participants/data/support/20131125_NCP%20Minimum%20standards.pdf.

[17] http://ec.europa.eu/research/participants/data/support/20131125_NCP%20Minimum%20standards.pdf.

45. We conclude that, although beneficiaries are generally satisfied with their NCPs, there are significant differences between participating countries in terms of the technical support and guidance they provide, which reduces the usefulness of the network for beneficiaries.

The Participant Portal simplifies grant management for beneficiaries

46. The Participant Portal is the main interface between the Commission and the beneficiaries of research and innovation funding. It should facilitate grant application and management for applicants and beneficiaries. It represents a gateway to the various systems (proposal submission tool, project management tool, notification system) facilitating stakeholders' participation and is intended to be the one-stop shop for efficient paperless grant management.

47. The Commission made its first release of the Participant Portal during FP7. However, at that time only a limited number of services were available for beneficiaries.

48. Since the start of Horizon 2020, the CSC has introduced new tools and functionalities which have improved the quality of Portal services. These include "partner search service" (for finding partners for collaboration on future projects), the possibility of filling out the forms in any browser, and a platform that is HTML5-compliant.

49. More than 85 % of the respondents to our survey were satisfied with the Portal and recognised the efforts made by the CSC to enhance its functions. In terms of accessibility, the current Portal is a considerable improvement over FP7, where each tool required separate access and log-ins. It has become a single reference point covering a large number of services. Beneficiaries also praised the introduction of an electronic signature function, which has considerably reduced the administrative burden in Horizon 2020.

50. However, we found that, some beneficiaries had experienced difficulties with system slowdown, navigation between a confusing or excessive number of screens, pop-ups, etc. These beneficiaries reported that such problems generated additional work and took time to resolve.

51. Moreover, newcomers to EU funding schemes, in particular SMEs, found it difficult to deal with the complexity of the Commission's IT tools. For example in one of our visits, the

beneficiary SME reported having experienced difficulties with the Portal and needing an external consultant to input all required information and documentation in the tool.

Commission guidance (AMGA) is comprehensive but difficult to use and frequent changes have led to uncertainty

52. Regulation (EU) No 1290/2013 establishing the rules for participation[18] in Horizon 2020 requires the Commission to provide sufficient guidance and information to all potential participants at the time of publication of the call for proposals, in particular the applicable model grant agreement.

53. The Annotated Model Grant Agreement (AMGA) has one clear strength with significant impact on simplification: it focuses all guidance related to Horizon 2020 in a single document. In 750 pages, using examples of best practice, specific cases and exceptions, the AMGA explains each article of the General Model Grant Agreement (GMGA) and specific model agreements. In contrast, FP7 guidance was dispersed among separate rulebooks for each part of the programme. Some 77 % of the respondents to our survey considered the AMGA to be a fit-for-purpose tool.

54. We asked for views on the AMGA in our survey. Respondents said that the guidance had the advantage of being very comprehensive and detailed. However, they expressed concern about its excessive length and complexity and pointed to the difficulty of navigating between the different sub-sections of a document in pdf format.

55. Since the release of the initial version in December 2013, the MGA has been modified six times and the AMGA has been through 18 updates. Although informed about these changes, beneficiaries expressed a number of concerns about the consequences of this (see ***Figure 7***). Nevertheless, most respondents to the survey and beneficiaries interviewed

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[18] Article 5 of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for participation and dissemination in Horizon 2020 (OJ L 347, 20.12.2013, p. 81).

stated that they would find it easier to cope with such updates if they were scheduled at fixed intervals to cater for needs emerging during the implementation of Horizon 2020.

Figure 7 - Impact of the frequent updates of MGA and AMGA

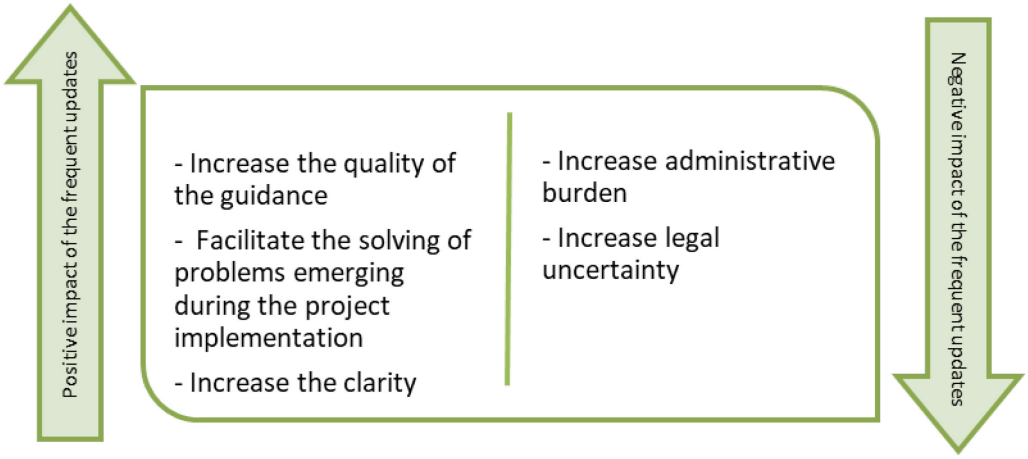

Source: ECA.

New initiatives with potential for simplification have not yet been fully tested and evaluated

Lump sums and prizes

56. Encouraged by the European Parliament[19] and the Council[20], before launching MFF 2014-2020 and Horizon 2020 the Commission started exploring the possibility of simplifying

[19] P7_TA (2010)0401, European Parliament resolution of 11 November 2010 on simplifying the implementation of the Research Framework Programmes (2010/2079(INI)).

[20] Conclusions of the 3016th Competitiveness Council meeting, Brussels, 26 May 2010.

grant management through innovative, simplified cost options. The legal basis for the use of lump-sum funding and inducement prizes is given by the 2012 Financial Regulation[21].

57. The use of simplified cost options under Horizon 2020 has been limited, with prizes being used to support a small number of initiatives[22] and lump sums being used to support: (i) SME Instrument 1 projects, (ii) a restricted number of accompanying measures and (iii) two pilot calls[23] for multi-beneficiary projects and the special needs support under the Marie Skłodowska-Curie Actions included in the 2018-2020 work programme.

58. As of September 2018, the two lump sum pilots were still ongoing and conclusive evidence was not yet available from the analysis of full project life cycles.

59. Through our survey and during on-site visits, we asked Horizon 2020 beneficiaries and umbrella associations if they would welcome a more extensive use of these simplified cost options and what they perceived to be the major advantages and drawbacks.

60. The answers to our survey reveal that these simplified cost options are seen as a viable alternative to traditional cost reimbursement. ***Figure 8*** shows that 74 % of respondents would welcome the wider use of lump sums, while 49 % favour the introduction of inducement prizes.

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[21] Regulation (EU, Euratom) No 966/2012 of 25 October 2012 on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p. 1).

[22] The total value of prizes is approximately 0.11 % of the Horizon 2020 budget.

[23] Call DT-NMBP-20-2018 (one-stage). Call SC1-BHC-15-2018 (two-stage).

Figure 8 - Opinions on the more extensive use of lump sums and inducement prizes

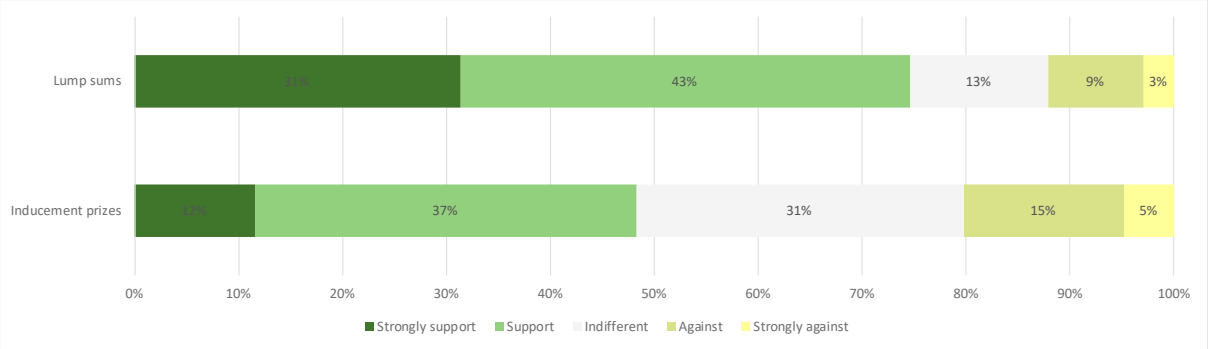

Source: ECA survey, March 2018.

61. The perception of simplified cost options varies according to the type of beneficiaries and is in particular dependent on their level of experience[24]. More experienced beneficiaries are less inclined towards the wider adoption of both lump sums and inducement prizes (see ***Figure 9***).

Figure 9 - Opinion on a more extensive use of lump sums and inducement prizes, by level of experience (number of Horizon 2020 projects)

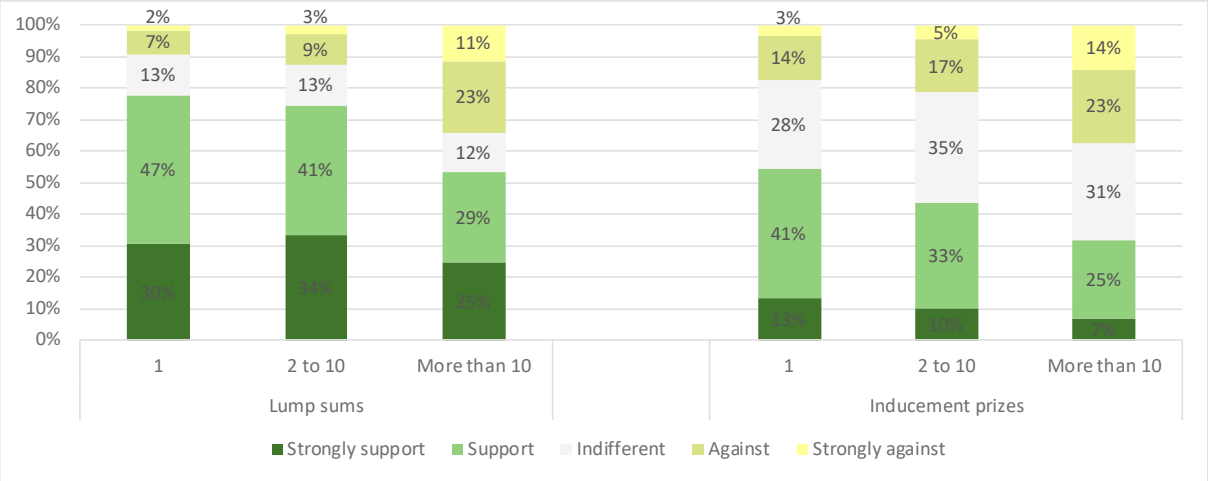

Source: ECA survey, March 2018.

62. Notwithstanding the generally positive view, beneficiaries expressed some concerns about lump sums and prizes, highlighting perceived risks and pointing to the fact that these

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[24] Measured here as the number of Horizon 2020 projects that the beneficiary has been involved in.

simplified cost options might not be suitable for all types of projects. These concerns were shared by the beneficiaries and NCPs we interviewed (see ***Annex I***).

63. Simplified cost options could reduce the administrative burden and the occurrence of errors for Horizon 2020 grants, enabling beneficiaries to focus on scientific goals while managing projects in a more flexible way. However, they may not be suitable for all types of research and innovation projects, and the Commission does not yet have sufficient evidence from its pilot testing.

64. As stated in our March 2018 briefing paper, funding schemes based on lump-sum payments, if properly designed, could also encourage a greater participation by all types of beneficiary groups (including SMEs and new entrants).

Cascade funding

65. Cascade funding works by providing a mechanism for grant beneficiaries to distribute Horizon 2020 funds to third parties in the form of sub-grants (following a call for proposal) or prizes. This shifts the administrative burden from the Commission to the beneficiary responsible for managing the calls for sub-grants.

66. The Horizon 2020 beneficiary or consortium publishes its own calls for proposals to attract specific groups of potential beneficiaries, especially start-ups and SMEs, and provides grants ranging from 50 000 euro to 150 000 euro per third party. Cascade funding was piloted under FP7; under Horizon 2020 the European Commission is making increasing use of this mechanism.

67. In our survey, we asked whether using cascade funding under Horizon 2020 had resulted in a lower administrative burden compared to FP7. A small majority (52 %) of respondents who expressed an opinion replied that cascade grants had little or no effect in this regard, whereas 39 % agreed that the burden was lower compared to FP7. ***Figure 10*** shows how the perception of cascade funding varied with experience: 23 % of respondents involved in more than ten Horizon 2020 projects considered that cascade funding had reduced their administrative burden, whereas for 26 % administration had increased.

Figure 10 - Cascade grants reduced the administrative burden compared to FP7, by level of experience (number of Horizon 2020 projects)

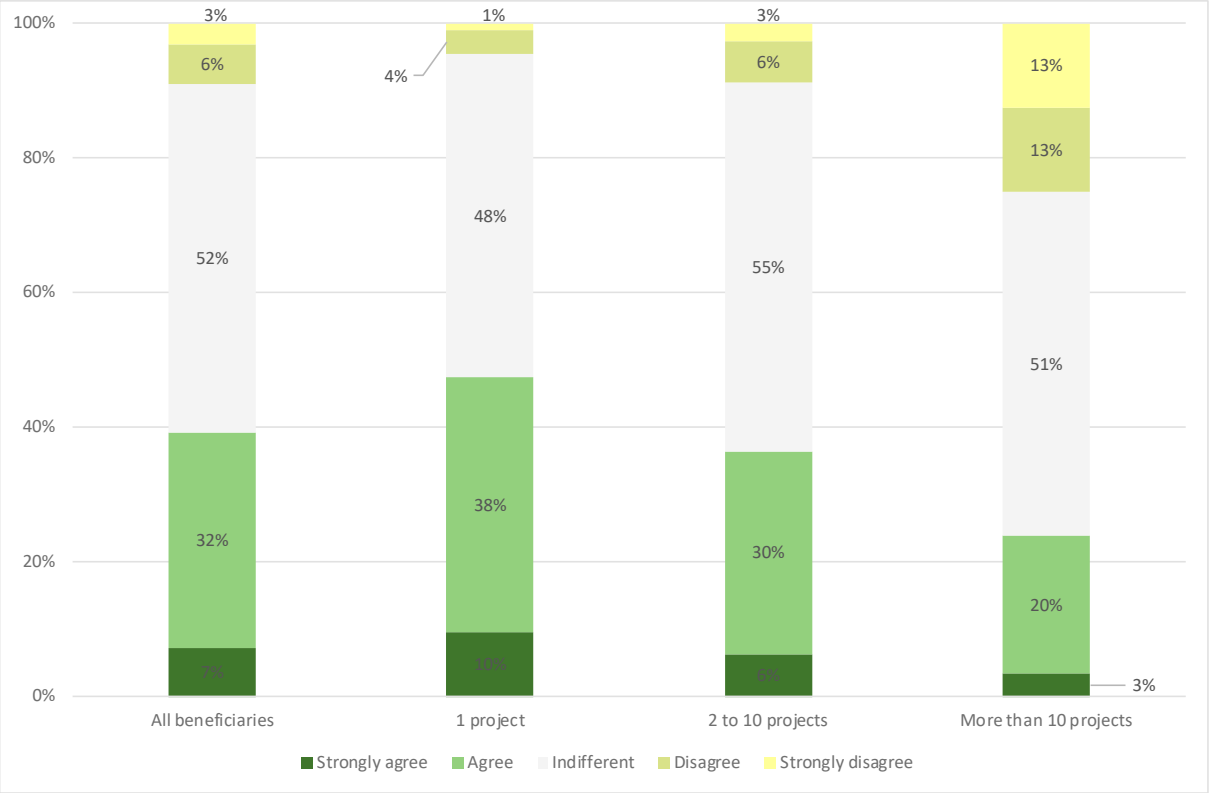

Source: ECA survey, March 2018.

68. We found that the guidance issued by the Commission[25] has not provided enough clarity to beneficiaries on how to manage the calls for cascade grants. In addition, the interviewed beneficiaries were uncertain about the type of regulation they had to apply when designing their call for proposals and when providing grants to third parties.

69. The Commission has not assessed the cascade funding mechanism ex post to determine whether it has effectively and efficiently achieved the intended outcomes.

Obtaining a grant is faster but opportunities to reduce administrative burden have not been fully exploited

70. A balance needs to be struck between, on the one hand, minimising the time, effort and money spent in submitting a proposal and, on the other, presenting enough information to

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[25] Guidance note on financial support to third parties under Horizon 2020.

allow the Commission to compare applications and identify the best proposals for funding. Simplification of the proposal procedure is especially important given the low success rate for applications, where only one in eight proposals receives funding[26].

Figure 11 - Proposal preparation effort in Horizon 2020 compared to FP7, by funding scheme and role in project

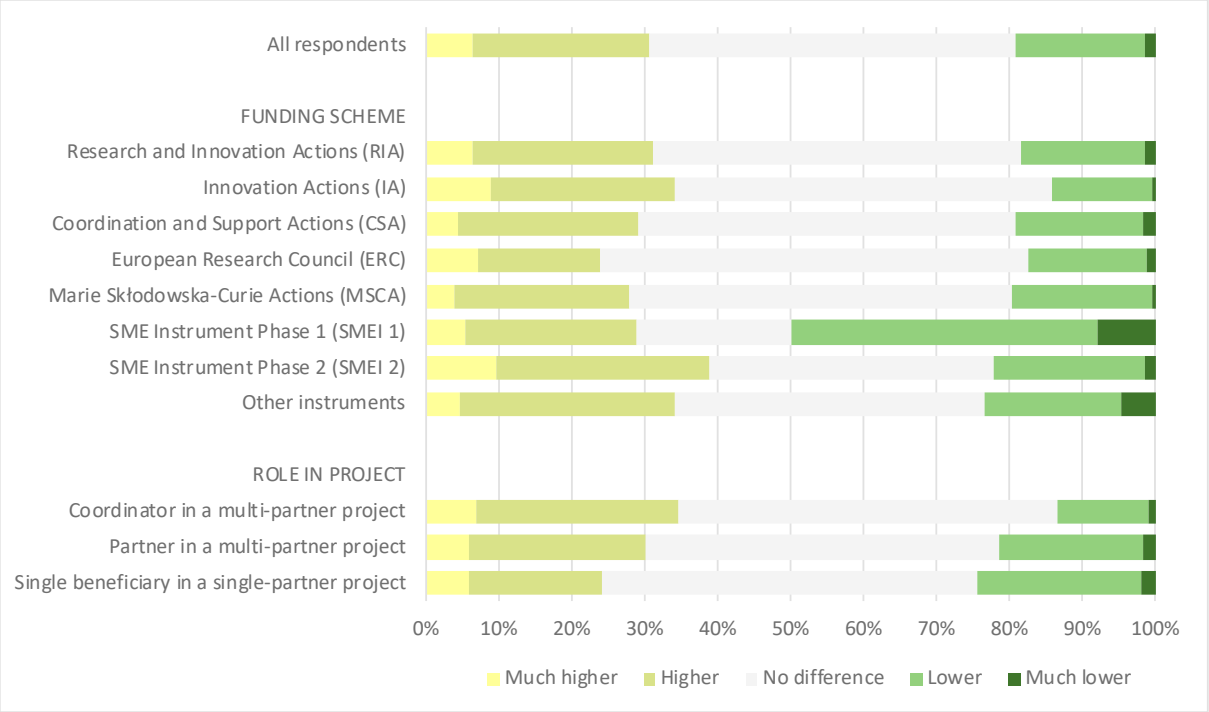

Source: ECA survey, March 2018.

71. In our survey we asked beneficiaries to compare FP7 and Horizon 2020 in terms of the administrative workload of preparing proposals. Among the respondents able to make a comparison (see ***Figure 11***), 30 % reported a greater workload, 20 % a lower workload, and around half reported no difference at all. SMEI-1 beneficiaries reported the greatest improvement, with half of these respondents considering their current burden to be lower or much lower than for FP7. However, SMEI-1 was a new instrument for Horizon 2020, and in FP7 the "Research for the benefit of SMEs" action appeared under a different funding scheme. Project coordinators reported a larger increase in workload than other

[26] European Commission, "Horizon 2020 in full swing - Three years on - Key facts and figures 2014-2016", December 2017.

beneficiaries; this is a consequence of the move to centralise project coordination and interaction with the Commission at their level under Horizon 2020.

Withdrawal of negotiation stage has speeded up the time to grant

72. One of the changes introduced under Horizon 2020 was the withdrawal of the 'negotiation stage', which had previously taken place between the selection of a proposal for funding and the signing of the grant agreement. In Horizon 2020, projects are to be implemented in the form proposed.

73. The respondents to the survey and the interviewed beneficiaries were broadly in favour of the no-negotiation approach. At the same time, a minority considered that removing negotiations limited the possibility of improving projects and increased the likelihood of amendments to a grant agreement after signature.

74. The purpose of removing the negotiation stage was to accelerate the launch of funded projects. The indicator "time to grant" is defined as the time elapsed between the close of a call and the signing of the grant agreement, marking the official start of the project. The Horizon 2020 rules for participation provide for a maximum time to grant of eight months[27]. Reducing the length of this process is important both for unsuccessful applicants, which will need to make alternative arrangements as quickly as possible, and for successful ones, which may be trying to bring a product to market ahead of competitors.

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[27] Article 20 of Regulation (EU) No 1290/2013: "up to five months to inform applicants whether a proposal has been accepted, followed by a maximum of three months to sign the grant agreement".

Figure 12 - Average time to grant in days, by programming period

	FP6 (2002–2006)[1]	FP7 (2007–2013)[2]	Horizon 2020 (2014–2017)[3]
Time to grant	347	309	191

[1] Average number of days from call deadline to grant signature.

[2] Average number of days from call deadline to grant signature (except ERC).

[3] Average number of days from call deadline to grant signature (except ERC).

Source: European Commission.

75. Withdrawal of the negotiation stage, together with the increased use of electronic document transmission and signature, has significantly shortened the time to grant compared to FP7 and FP6 (see ***Figure 12***).

Wider use of the two-stage approach could reduce costs for the large number of unsuccessful applicants

76. In accordance with Article 15(5) of the rules for participation[28], Horizon 2020 employs both one and two-stage evaluation processes. In the two-stage approach, coordinators submit short proposals for initial evaluation, with successful applicants then invited to submit a full proposal. After a second evaluation, a ranked list is forwarded to the Commission for selection. In Horizon 2020, around 10 % of all full proposals have arrived via the two-stage approach[29].

77. The two-stage approach can help applicants avoid devoting unnecessary effort to developing detail in ultimately unsuccessful project proposals. However, for some projects the two-stage process may be too slow, with the risk that products arrive on the market later than those of competitors. The Commission estimates that a second stage of evaluation

[28] ”The Commission shall take into account the possibility of a two-stage submission procedure […], where appropriate and consistent with the objectives of the call for proposals.”

[29] SWD(2017) 220 final– “In-depth interim evaluation of Horizon 2020”.

adds around three months to the process, as well as creating additional administrative costs for the Commission.

78. The respondents to our survey generally considered that a two-stage evaluation would reduce the overall workload of submission, with public bodies showing strongest support (see ***Figure 13***). Some of the beneficiaries we interviewed felt that much of the work of preparing a proposal lay in setting up a consortium and developing the basic idea in enough detail to minimise the risk of rejection, rather than in writing the proposal itself; for them, a two-stage approach would not make much difference to the workload. Others expressed the concern that stage one approval would be delayed, making preparations for the second stage necessary in any case and negating any potential resource-saving.

Figure 13 - Preference for one- or two-stage evaluations, by type of respondent

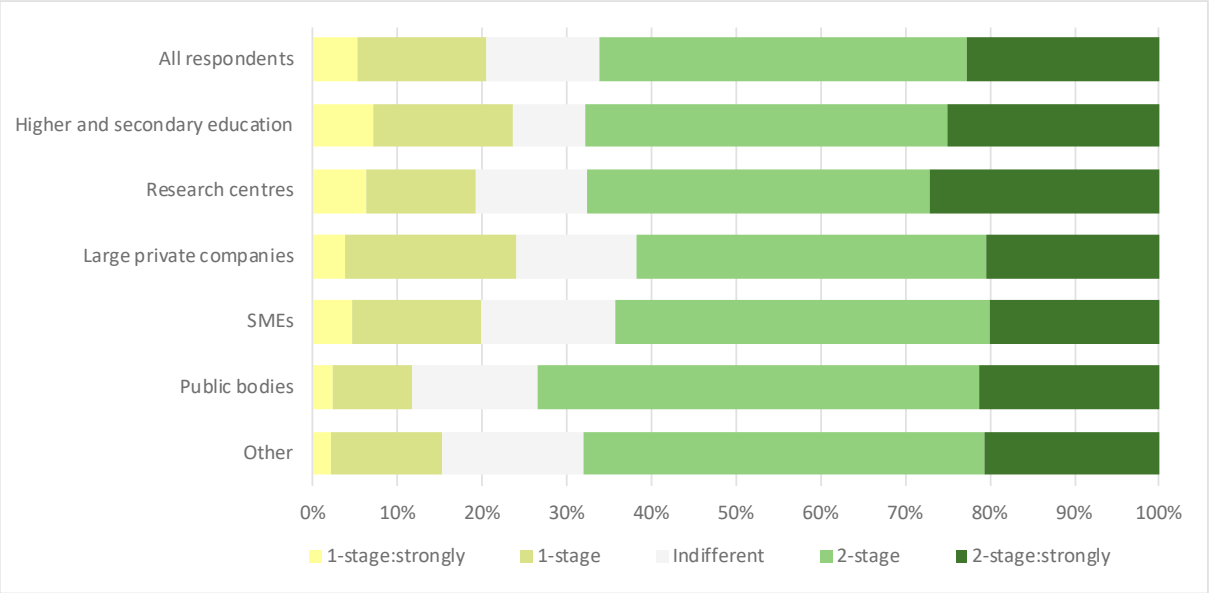

Source: ECA survey, March 2018.

79. Many applicants invest a lot of time and money in developing ultimately unsuccessful proposals. The beneficiaries we consulted generally agreed that this problem could be reduced by expanding the use of two-stage evaluations, but only where any associated delays in time to grant did not create other disadvantages.

Concerns remain about the quality of evaluations and feedback to unsuccessful applicants

80. High-quality evaluation of proposals made against appropriate criteria, although only indirectly linked to simplification, is essential to help ensure that the best projects are funded and the aims of Horizon 2020 achieved. Unsuccessful applicants should be given informative feedback with reasons for the outcome to assist them with future proposals.

81. Admissible and eligible proposals are evaluated against set criteria by at least three independent experts. Each evaluator awards scores for excellence, impact and quality and efficiency of implementation, based on award criteria published in the Horizon 2020 work programme. The "panel of evaluators" produces a summary report on all the proposals received; the Commission then uses this to draw up a list for funding.

Evaluations

82. The Research Executive Agency (REA) manages and contracts all independent experts involved in Horizon 2020, though selection is made by individual DG units (or Agency) for each call, drawing from the database of 120 000 registered experts (experts register themselves in the database and no endorsement, approval or quality check is implied). This database is established from an open-ended call for experts. The Commission is obliged to publish annually the list of evaluators used. Refreshment and rotation rules apply. For example, at least 25 % of experts for a call should not have been involved in the previous three years. REA also monitors the number of completely new evaluators.

83. In a DG RTD survey of evaluators[30], 44 % of evaluators replied that they had been compensated for less time than they had actually needed and spent. Allocating insufficient time to an evaluation can substantially compromise its quality.

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[30] Evaluation of the operation of REA (2012-2015) Final Report, 2016.

84. Most respondents to our survey of beneficiaries considered the evaluation criteria to be suitable, with only 17 % expressing a negative opinion. However, some beneficiaries questioned whether the experts had sufficient technical knowledge in the field. The Commission's own mid-term evaluation of Horizon 2020[31] concluded that the quality of the evaluation process at the time should be improved.

85. Adequate remuneration is needed in order to recruit qualified evaluators so that proposals are correctly assessed and that the best proposals are selected and funded.

86. Experts are paid based on a rate per working day which has not been updated since 2007. They spend an average of 5.6 hours per single evaluation[32], which we consider insufficient for an evaluator to read thoroughly and make a high-quality evaluation of a proposal.

87. As a result, there is a risk that insufficient remuneration dissuades qualified individuals from taking part in the evaluation process. Allocating insufficient time for the evaluation can have the same effect and/or compromise the quality of the evaluation.

Feedback

88. Feedback to applicants on the outcome of unsuccessful proposals should simplify their work when developing subsequent proposals and contributes to the overall quality of the Horizon 2020 programme.

89. Coordinators and participant contacts are informed about the evaluation outcome through a results letter. Though 46 % of survey respondents stated that quality of feedback had improved from FP7 to Horizon 2020 (see ***Figure 14***), interviews with beneficiaries and comments received in our survey expressed concerns about the quality of feedback on

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[31] SWD(2017) 221 final, "In-depth interim evaluation of Horizon 2020", Annex 1.

[32] SWD(2017) 220 final, "In-depth Interim Evaluation of Horizon 2020", May 2017.

evaluations. One in five survey respondents felt there had been a decline in quality between FP7 and Horizon 2020. The Commission's interim evaluation of Horizon 2020[33] also reported that 34 % of respondents assessed feedback quality to be "poor" or "very poor".

Figure 14 – Opinions on evaluation feedback in Horizon 2020 compared to FP7

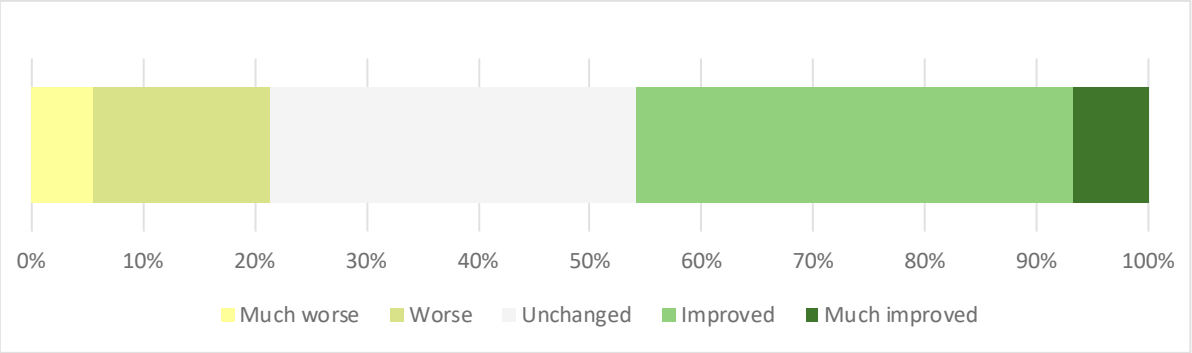

Source: ECA survey, March 2018.

90. A common complaint from beneficiaries, both to the Commission and in the survey comments, was that, having first been unsuccessful, they had resubmitted a proposal for a subsequent call, including changes based on evaluator feedback, but had received a lower score than before. However, the call may have been different from the previous one, or the original idea may have become less innovative over time.

The Seal of Excellence has not met expectations

91. The "Seal of Excellence" is a quality label awarded to project proposals which, having satisfied the selection and award criteria for Horizon 2020 funding and been ranked above a predefined quality threshold, could not ultimately be funded due to budget constraints. The aim is to help Seal of Excellence holders obtain funds for these proposals from other national, European or international programmes, without having the additional administrative burden of resubmitting proposals. The Commission launched the Seal of Excellence initiative in October 2015. The initiative was first piloted in the SME Instrument and in 2016 extended to Marie Skłodowska-Curie Individual fellowships.

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[33] SWD(2017) 220 final "In-depth Interim Evaluation of Horizon 2020", May 2017.

92. In our survey, we asked recipients of a Seal of Excellence whether the label had helped them to obtain funds from other sources. We found that the Seal of Excellence was not universally recognised: only 15 % of respondents replied that it had helped them obtain another type of funding (see ***Figure 15***).

93. We found that, despite the information campaign undertaken by the Commission, the lack of success of the Seal of Excellence is due to: (i) the lack of recognition by other funding institutions; (ii) the lack of clear guidance on how to use the label; and (iii) the lack of alignment between national and other EU programmes and Horizon 2020 regarding topics, selection and award criteria or evaluation processes.

94. In addition, at the time the Commission launched the Seal of Excellence, effective mechanisms of cooperation with other funding schemes had not yet been established and there was insufficient clarity on the application of state aid rules to the public funds supporting Seal of Excellence projects. It did not clarify the applicability of state aid rules until 2017[34].

95. The Commission collects country data on Seal of Excellence support schemes (see ***Figure 15***). In our survey, we enquired about recipients' access in each country to alternative sources of funding. The responses show that, all in all, access to other sources is still limited in the EU Member States. The Commission does not have data on the number of Seal of Excellence projects funded by other programmes in each country.

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[34] Commission Staff Working Document "Explanatory note of the Commission services on the application of State Aid Rules to national and regional funding schemes that offer alternative support to SME Instrument project proposals with a Horizon 2020 'Seal of Excellence'", January 2017.

Figure 15 – Usefulness of the Seal of Excellence

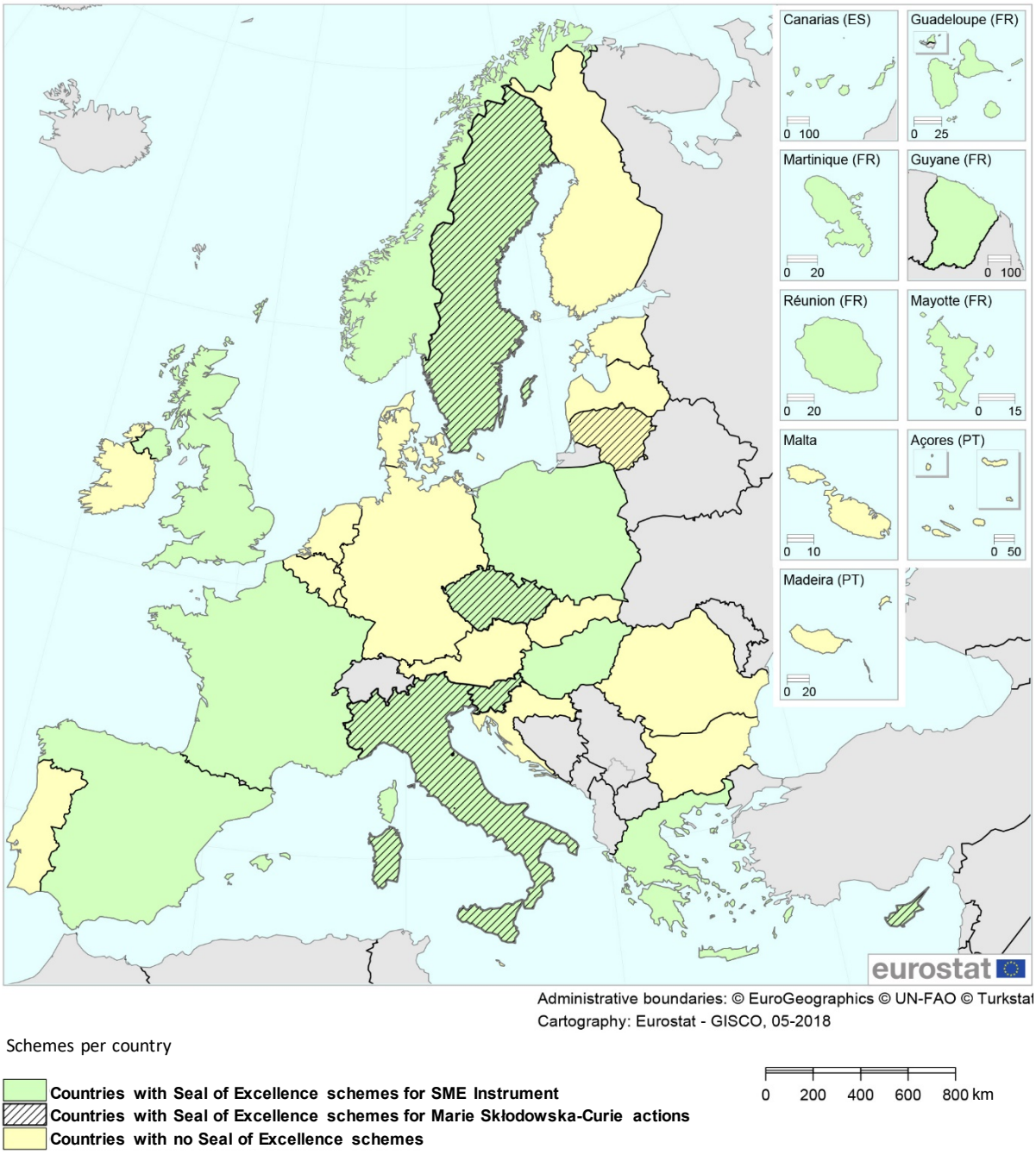

Source: Eurostat.

96. As stated in our March 2018 briefing paper, the absence of a proper coordination mechanism between Horizon 2020 and other European and national programmes limited the impact of the Seal of Excellence in helping beneficiaries to find alternative sources of funding. It therefore failed to ease the burden of applying for research funding.

Reporting and auditing project costs

The rules on personnel costs were simplified, but some changes have created difficulties for beneficiaries and personnel costs remain principal major source of error

97. Personnel costs are a key cost category, accounting on average for approximately 45 % of the total costs of Horizon 2020 research projects.

98. In our survey and on-site visits, we asked Horizon 2020 beneficiaries whether they appreciated the simplification introduced under Horizon 2020 for the calculation and reporting of personnel costs, and whether there was still a need and scope to reduce the administrative burden in this area.

99. The majority of respondents approved of the changes made in Horizon 2020 regarding personnel costs. ***Figure 16*** summarises the opinions they expressed about:

- the changes to the overall methodology for calculating personnel costs;
- the easing of time-recording requirements (e.g. abolition of time-recording obligations for staff working exclusively on a Horizon 2020 project);
- the acceptance of monthly hourly rates alongside annual hourly rates;
- the use of average personnel costs calculated by beneficiaries;
- the use of unit costs for SME owners and natural persons without a salary;
- the acceptance of supplementary payments of up to 8 000 euro per person per year for non-profit organisations.

Figure 16 - The simplification measures introduced under Horizon 2020 reduced the administrative burden compared to FP7

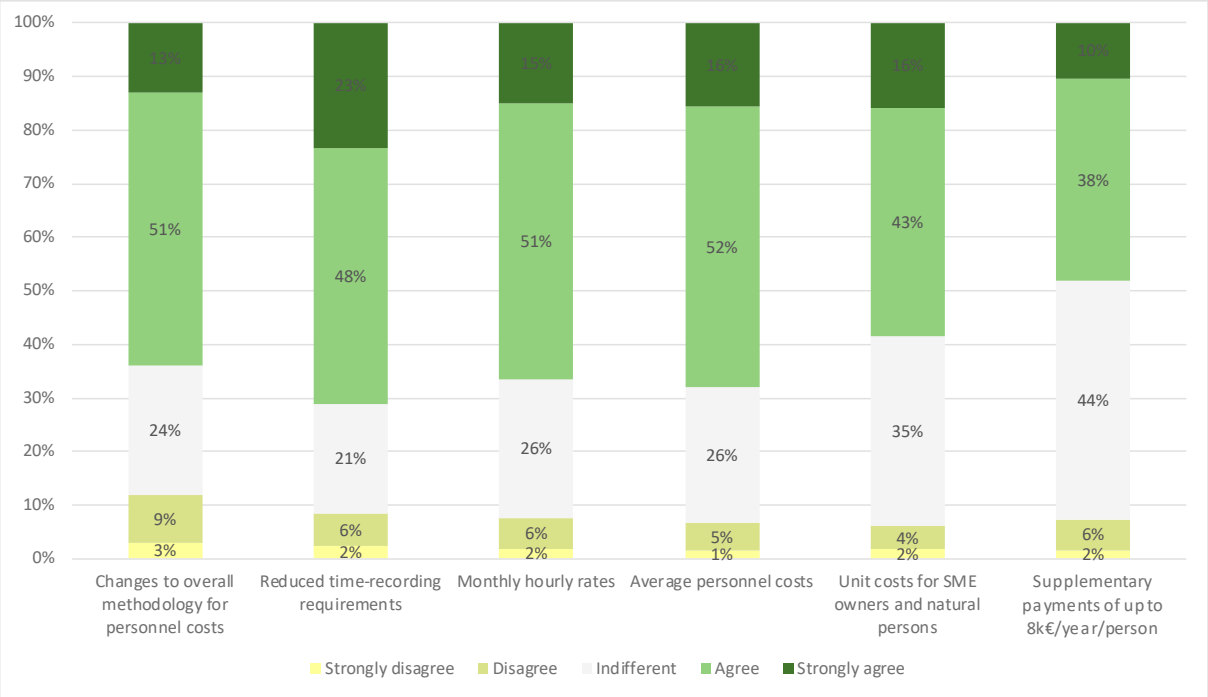

Source: ECA survey, March 2018.

100. A closer look at the results of our survey shows that:

- opinions depend on the experience of respondents with Horizon 2020 projects[35], with more experienced beneficiaries generally showing less appreciation for the changes introduced;

- when asked which measures introduced under Horizon 2020 have *increased* the administrative burden for the reporting of project costs, most of the respondents pointed to measures linked to the calculation and reporting of personnel costs;

- when asked where simplification was most needed for FP9, respondents named the reporting of personnel costs.

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[35] Measured as the number of Horizon 2020 projects that the beneficiary has been involved in.

101. Furthermore, 41 % of the respondents to our survey declared that they needed to run a specific time-recording system to manage their Horizon 2020 projects, with no significant reduction compared to FP7.

102. The most frequent complaints expressed by beneficiaries and other stakeholders (such as NCPs and associations) related to:

- the use of detailed timesheets showing a split by work package;
- the cumbersome recalculations that some beneficiaries have to make to reconcile staff salaries with Horizon 2020 rules;
- the frequent introduction of changes throughout the implementation of Horizon 2020;
- difficulties in applying the concept of additional remuneration.

103. Following the Commission's first audits of Horizon 2020 projects, 68 % of all subsequent adjustments were linked to the improper reporting of personnel costs[36]. The vast majority (65 % of the total) concerned the calculation of personnel costs *per se* (notably, incorrect calculation of productive hours, incorrect remuneration costs, incorrect time claimed for a given activity, missing timesheets, incorrect additional remuneration), while the remainder (3 % of the total) were linked to personnel costs being reported as unit costs[37].

104. 70 % of respondents who expressed an opinion consider that, compared to FP7, Horizon 2020 rules on reimbursement of project costs rely more on the acceptance of usual cost accounting practices. However, the share of beneficiaries who do not see a difference in the level of acceptance of the usual cost accounting practices between FP7 and Horizon 2020 remains high.

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[36] The ECA also finds errors of this nature and reports on them in its Annual Reports.

[37] Presentation *Audits and Financial issues,* NCP meeting, 14-15 March 2018.

105. Increasing reliance on usual cost accounting practices, in particular for personnel costs, could reduce the administrative burden.

The audit burden has decreased but beneficiaries face inconsistent treatment in outsourced ex post audits

106. The principles of control and audit of Horizon 2020 expenditure are defined in the Horizon 2020 regilation[38]. They aim to ensure (i) an appropriate balance between trust and control and (ii) an audit process in line with the principles of economy, efficiency and effectiveness in order to minimise the audit burden on participants.

Figure 17 – The Commission's financial control and audit strategy in Horizon 2020

Certificate of Financial Statements (CFS)	Ex ante checks on the cost claims performed by Project and Finance Officers	Ex post audits on a sample of grants paid
• ex ante checks based on agreed-upon procedures performed by independent auditors contracted by the beneficiaries • a CFS has to be provided whenever a payment above 325 000 euro is requested (reimbursement of actual costs and some unit costs)	• review of the use of resources • plausibility checks • analysis of deviations between initial budget and implementation • analysis of the CFS and ex ante certification of cost methodologies	•7 % of all Horizon 2020 expenditure will be subject to an ex post audit •this is not a regulatory requirement •there was no such limit under FP7

Source: ECA.

107. In line with the ECA's recommendations[39], the Commission has centralised the design and implementation of the Horizon 2020 audit strategy through the Common Audit Service (CAS) using a single representative sample across Horizon 2020, and has taken a more risk-based audit strategy[40].

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[38] Article 29 of Regulation (EU) No 1291/2013 establishing Horizon 2020.

[39] See our special report 2/2013.

[40] Horizon 2020 Ex post Audit Strategy, DG RTD 9.11.2015.

108. In our survey, we asked beneficiaries to give their views about the Horizon 2020 control and audit burden. 53 % of respondents replied that the overall audit burden in Horizon 2020 had decreased compared to FP7, and only 14 % stated that it had increased. Two thirds of respondents also replied that the audit burden should be further reduced.

109. The beneficiaries we interviewed appreciated the new Common Audit Service as a means of ensuring consistency. However, some respondents to the survey complained that there was still no consistency in the control and audit process. In their view, inconsistencies may result from frequent changes to the AMGA, as auditors were sometimes unaware of retroactive amendments or did not know which version of the AMGA to apply.

110. The Commission has a framework contract with independent external audit firms for around 80 % of Horizon 2020 ex post audits, with the Commission itself performing the remaining 20 %. The Commission concluded the first ex post audits of Horizon 2020 projects in 2017.

111. Beneficiaries we met during our on-the-spot visits and at workshops criticised the work of some external audit firms. The most common complaints concerned the quality of work, the auditors' limited knowledge of the programme and the time taken to produce audit reports. NCPs made the same criticisms at an event organised by the Commission[41] and in interviews.

112. We found that the creation of a common audit service and the new audit strategy have reduced the audit burden for beneficiaries. However, we also found that there is room for improvement in the quality of outsourced ex post audits.

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[41] 11th Meeting of the Horizon 2020 NCPs for Legal and Financial Matters, Brussels 14-15 March 2018.

SME participation has increased but barriers remain

113. Supporting SMEs is one of the Commission's priorities in the current programming period, and it has encouraged SMEs to participate in all areas of Horizon 2020. It designed the SME Instrument[42], recently incorporated into the European Innovation Council pilot, to facilitate SME access to research and innovation funding.

114. Despite increased participation by SMEs in Horizon 2020, we found that they have experienced difficulties both during the application process and when implementing their research and innovation projects. SMEs that were new to EU funding schemes found it difficult to understand the regulatory requirements with regard to the grants. The length and comprehensiveness of the AMGA is particularly burdensome for SMEs who do not have dedicated staff to deal with the interpretation of EU guidelines and reporting.

115. We found that SMEs rely heavily on external consultants to overcome the difficulties they encounter in the preparation of their proposals. This is especially the case for single-beneficiary projects in SMEI phases 1 and 2 (see ***Box 2***).

Box 2 – Use of external consultants in proposal preparation and project reporting

•36 % of the respondents to our survey said that they required help from external consultants during the proposal preparation phase. The figure varied according to the respondents' experience (less experienced beneficiaries used external support more often), the type of respondent and the funding scheme. SMEs operating alone are particularly reliant on external consultants, especially in SMEI phases 1 and 2 (see ***Figure 18***).

[42] Under the SME instrument companies can apply for two distinct non-related phases, depending on the technological maturity of their innovative projects. In phase 1 each project receives 50 000 euro for a feasibility study; if selected, in phase 2 each project can receive up to 2.5 million euro to finance innovation activities.

Figure 18 - Use of external consultants to prepare proposals, by funding scheme

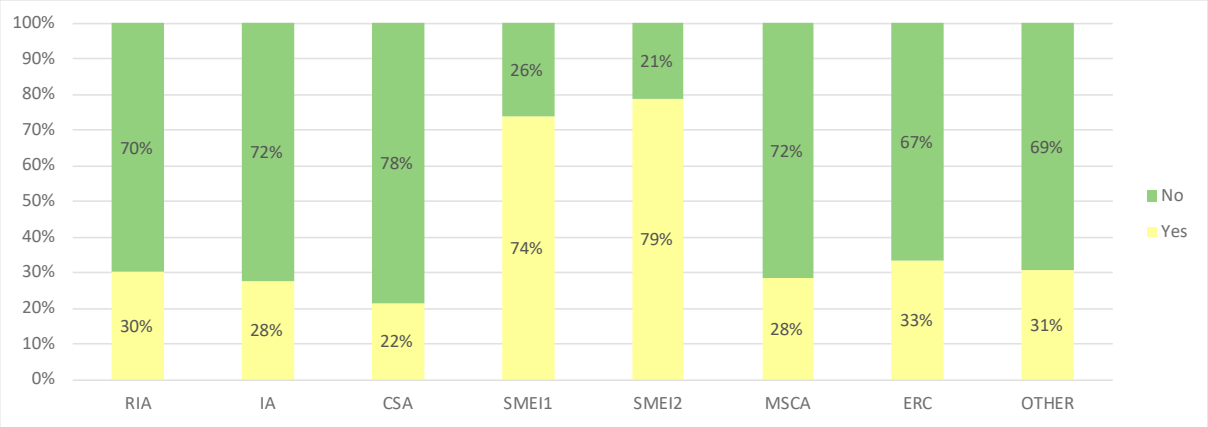

Source: ECA survey, March 2018.

• The main reason for using external consultants to prepare proposal was to increase the chances of success, followed by the need to manage the administrative complexity of the process. More than half of respondents preferred to use external consultants rather than internal resources for this purpose, with a minority turning to consultants for scientific and technical support.

• External consultants were less used during project implementation than for proposal preparation. Nevertheless, almost one third of SMEs stated that they made some use of external consultants for project management and reporting. The figure increased to approximately 50 % for single-beneficiary SMEs in SMEI phases 1 and 2.

• Most respondents believed that the need for external consultants either remained the same or increased from FP7 to Horizon 2020, both for proposal preparation and for project implementation.

• When asked about the fees paid to external consultants (as a percentage of total funding), the median value reported by the respondents was 5 % for proposal preparation and 5 % for project implementation.

• The need for external consultants during the proposal preparation phase is a barrier to entry to Horizon 2020 for SMEs which cannot afford the related costs. This is particularly serious for newcomers since, given their lack of experience, they are especially in need of external help.

CONCLUSIONS AND RECOMMENDATIONS

116. The majority of simplification measures taken by the Commission have been effective in reducing the administrative burden for beneficiaries in Horizon 2020, although not all

actions produced the desired result and opportunities to improve still exist. Replying to our survey, beneficiaries expressed the need for more user-friendly guidance and tools and for further testing of the appropriateness and usability of new funding schemes. Stability in the rules is also important; beneficiaries are able to adapt to complexity but frequent modifications to guidance can cause confusion and uncertainty.

Organisational efforts to simplify

117. The simplification measures introduced by the Commission for Horizon 2020 were a result of its analysis of previous Framework Programmes (in particular FP7) and feedback from key stakeholders. The creation of the Common Support Centre was a major contribution to simplification, notably through the harmonisation of the rules for participation, a new audit strategy and IT solutions for grant management and reporting (see ***paragraphs 15 to 29***).

118. Many applicants and beneficiaries still consider that they are treated inconsistently during the application process and the implementation of their projects. Despite the Commission's efforts to improve communication, there is limited awareness of the dedicated back-office tool, established by the Commission for the reporting of inconsistent treatment. Moreover, we found that the work of the Research Enquiry Service (RES), in parallel with the other existing channels, is too fragmented to guarantee consistency (see ***paragraphs 30 to 40***).

119. NCPs provide useful assistance to applicants and beneficiaries, helping to ensure consistent application of Horizon 2020 legislation, but we found significant differences in the level of technical support and guidance provided by the NCPs in the various Member States (see ***paragraphs 41 to 45***).

120. The support tools developed by the Commission to facilitate the implementation of research and innovation programmes have undergone significant improvements since the beginning of Horizon 2020 and are appreciated by beneficiaries. However, there were some technical issues with the Participant Portal (see ***paragraphs 46 to 51***), and the Commission manual on research and innovation (AMGA), which aims to provide comprehensive guidance, has evolved into a complex and long document. Frequent modifications of the

AMGA added to the overall administrative burden and sometimes increased legal uncertainty for the beneficiaries (see ***paragraphs 52 to 55***).

Recommendation 1 – better communication with applicants and beneficiaries

The Commission should improve its channels for communication with grant applicants and beneficiaries by:

(i) establishing better procedures and controls with regard to the performance of the helpdesk functions, and in particular of RES, and raising awareness of the tools through which beneficiaries can report inconsistent treatment during the application process or during the implementation of their projects.

(ii) resolving the remaining technical issues affecting the Participant Portal, improving its design and facilitating navigation and the search function.

(iii) work with Member States to improve the methodological and technical guidance to the NCPs so that they provide the necessary quality of service to potential beneficiaries of research and innovation funding.

These measures should be in place by the start of 2021.

121. Simplified cost options – lump sums and inducement prizes – have potential for reducing the administrative burden linked to the full life cycle of a Horizon 2020 project. A large majority of beneficiaries support further use of lump sums. However, they may not suit all types of research and innovation projects and evidence from pilot testing is necessary before deploying them on a larger scale (see ***paragraphs 56 to 69***).

Recommendation 2 – intensify testing of lump sums

The Commission should intensify the testing of simplified cost options, and in particular lump sums, by:

(i) analysing and reporting on the outcome of the calls already launched under Horizon 2020 as soon as the first results are available;

(ii) launching new pilot initiatives on a larger scale to identify the most suitable types of project, assess possible drawbacks and design appropriate remedies.

These measures should be put in place immediately.

Launching a project

122. Only 20 % of respondents to our survey considered that the Commission's simplifications had actually reduced the administrative burden associated with applying for funding. Half of the respondents reported that the effort involved in developing a proposal was unchanged (see ***paragraphs 70 to 71***).

123. Most respondents were satisfied that withdrawal of the negotiation stage had eased the burden, though a significant minority took the opposing view. The lack of formal negotiation was seen as speeding up the process, and fine-tuning remains possible in the grant agreement. Those unhappy with the removal of this stage considered that amendments to the grant agreement after signature were now more likely (see ***paragraphs 72 to 75***).

124. Applicants regret the effort spent in developing long proposals which are found to be of good quality but not good enough to be funded. Wider use of two-stage calls would reduce the burden, according to respondents, but would only be suitable for those scientific fields and market sectors where the additional stage would not delay the arrival of project results on the market (see ***paragraphs 76 to 79***).

Recommendation 3 – explore greater use of two-stage proposal evaluations

The Commission should identify a greater number of topics where the use of two-stage proposal evaluations could reduce the administrative burden for unsuccessful applicants, while maintaining the shortest possible time to grant if speed in reaching the market is critical.

This measure should be in place by the start of 2021.

125. Most respondents considered the evaluation criteria for assessment of proposals to be appropriate. However, some beneficiaries were concerned that experts might not have sufficient technical knowledge to ensure quality in evaluations, especially in multi-

disciplinary projects. Furthermore, evaluators may not be given sufficient time to evaluate lengthy and challenging proposals and the daily remuneration rate has remained unrevised since 2007. A significant number of beneficiaries reported dissatisfaction with the quality of evaluation feedback, which could frustrate their efforts to improve subsequent proposals (see ***paragraphs 80 to 90***).

Recommendation 4 – re-examine remuneration conditions for expert evaluators

The Commission should update the daily remuneration rate and reassess the time needed for experts to carry out reliable evaluations of project proposals.

This measure should be in place by the end of 2019.

126. The Seal of Excellence has had only limited impact at national level, as it is not universally recognised in the Member States. It has not adequately reduced the burden on applicants with good proposals (see ***paragraphs 91 to 96***).

Recommendation 5 – increase recognition of the Seal of Excellence

The Commission should:

(i) establish proper mechanisms in the design of the next Framework Programme to facilitate the recognition of excellent research projects by the various EU and national funding schemes.

(ii) work to build synergies between programmes so as to increase the likelihood that projects awarded the Seal of Excellence can more easily access other funding sources;

(iii) produce appropriate guidance on how to use the Seal of Excellence.

These measures should be in place by the start of 2021.

Reporting and auditing project costs

127. The majority of respondent beneficiaries appreciated the measures introduced in Horizon 2020 to simplify the calculation and reporting of personnel costs. However, some negative side-effects arose, and adjustments made during the Programme's implementation have caused some confusion and legal uncertainty. The calculation and reporting of

personnel costs remains the main area in which further simplification would help beneficiaries by reducing administrative requirements. Increasing reliance on usual cost accounting practices, in particular for personnel costs, could reduce the administrative burden (see ***paragraphs 97 to 105)***.

Recommendation 6 – stability for rules and guidance for participants

The Commission should:

(i) maintain continuity in the rules for participation between Framework Programmes wherever possible;

(ii) minimise adjustments to the guidance during implementation of the Framework Programme;

(iii) simplify time-sheets to avoid unnecessary reporting of effort by work package ;

(iv) explore the possibility of more widely accepting the usual cost accounting practices, notably for personnel costs.

These measures should be in place by the start of 2021.

128. For Horizon 2020, the Commission put in place an audit strategy based on a more risk-driven approach than for previous framework programmes. We found that the new strategy has reduced the audit burden for beneficiaries. However, we also found that the quality of the ex post audits which are carried out by external audit firms could be improved. The ex post audit process is still considered too long (see ***paragraphs 106 to 112***).

Recommendation 7 – improve quality of outsourced ex-post audits

The Commission should:

(i) improve its mechanisms for examining the quality of outsourced ex post audits, and;

(ii) speed up such audits.

These measures should be in place for by the start of 2021.

SME participation

129. SME participation has increased in Horizon 2020 compared to FP7. However, we found that some SMEs have experienced difficulties both during the application process and when implementing their research and innovation projects. The practice of using external consultants is common in the preparation of proposals, notably for the SME Instrument and, to a lesser extent, project management and reporting. This practice has increased, moreover, from FP7 to Horizon 2020. One of the main reasons for seeking external support is to manage the complexity of the programme. The lengthy guidance created an additional burden for SMEs (see ***paragraphs 113 to 115***).

Recommendation 8 – further simplify tools and guidance for SMEs

The Commission should further simplify its tools and guidance in such a way that they impose a minimal burden on SMEs, and especially on start-ups without the resources and staff to deal with their complexity. In particular, the Commission should consider issuing an abridged version of the guidance (AMGA) for SMEs and newcomers.

These measures should be in place by the start of 2021.

This Report was adopted by Chamber IV, headed by Mr Neven MATES, Member of the Court of Auditors, in Luxembourg at its meeting of 2 October 2018.

For the Court of Auditors

Klaus-Heiner LEHNE

President

ANNEX

THE RISKS OF SIMPLIFIED COST OPTIONS, AS PERCEIVED BY BENEFICIARIES

- Lump sums and prizes might be more suitable for smaller, high-TRL (technologically mature) projects with clearly defined deliverables, less suitable for larger, more basic research projects, which are inherently riskier.

- The evaluation of project achievements will be critical and the Commission will need to rely upon skilled sector-competent reviewers (often difficult to find).

- Linking payments to the achievement of scientific results could mean beneficiaries receiving no funding for research work actually done.

- Unless lump sums are indexed to national labour costs, project coordinators might be tempted to select project partners based on labour cost considerations rather than scientific excellence. This could create geographic imbalances in favour of countries where labour costs are lower.

- Project and consortium management will be more complex. Tensions could emerge in project consortia (especially in large multi-beneficiary projects) due to higher financial interdependencies among project partners (e.g. the entire consortium might not receive funding if one partner underperforms). If not addressed properly, this issue could make well-established consortia more reluctant to involve new, potentially unreliable partners, in particular SMEs.

- Prizes might favour certain players. Smaller ones will not have the resources to perform research projects without pre-financing or a reasonable assurance of being financed ex-post. Public bodies, such as many universities and research centres, cannot take the risk associated with failing to win a prize (after having carried out the research project) and cannot launch a research project without financial backing.

REPLIES OF THE COMMISSION TO THE SPECIAL REPORT OF THE EUROPEAN COURT OF AUDITORS

"THE MAJORITY OF SIMPLIFICATION MEASURES BROUGHT INTO HORIZON 2020 HAVE MADE LIFE EASIER FOR BENEFICIARIES, BUT OPPORTUNITIES TO IMPROVE STILL EXIST"

EXECUTIVE SUMMARY

VIII. The Seal of Excellence has up to now more than 30 seal support schemes in place in 15 countries. The Commission accepts, however, that further development is necessary. See for details the Commission's reply in paragraph 91.

X. The Common Audit Service has stepped up its efforts to ensure that all audits are carried out effectively. The external firms are closely monitored and controlled via meetings, training, daily instructions and guidance.

XI. The Commission accepts all the recommendations.

OBSERVATIONS

Common Commission reply to paragraphs 35 and 36.

The contractor replies in 3 working days and the reports 2016/2017 contain information on the time to reply per helpdesk (with average at 7.5 days).

The decentralised structure allows the most competent service to reply to the specific enquiry directly. The 36 thematic helpdesks ensure input from staff with the appropriate professional expertise in a particular area, depending on technical specificities and characteristics of the schemes. This set-up adds consistency and coherence.

In a very limited number of cases where incorrect information has been given to participants, these are corrected by the RES back-office in REA with a corrective e-mail sent to the participant.

66. On the basis of the Financial Regulation[1], cascading grants may not exceed EUR 60.000 for each third party, unless it is necessary to achieve the objectives of the action. The Commission emphasises that the figures quoted in the text refer to a specific area of the work programme (ICT).

Common Commission reply to paragraphs 92 to 96.

The Seal of Excellence was a first concrete attempt to create concrete synergies with the ESIF. It has had a certain level of success, with 35 schemes put in place in 15 Member States. However, the Commission accepts that the impact has been limited.

The Commission has taken a number of steps in Horizon 2020 to improve the potential impact of the scheme:

- Extension in 2016 to MSCA

- Adoption in early January 2017 of an Explanatory note on the application of State Aid Rules relating to the Seal of Excellence

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[1] Regulation (EU, Euratom) No 966/2012 of 25 October 2012 on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p. 1).

- Establishment of a Community of practice, bringing together more than 200 funding bodies

- Publication of guidance notes

Nevertheless, the constraints identified by the ECA, especially the freedom for national and ESIF programmes to choose whether to recognise or not the Seal, remains a problem.

The proposals for the next generation of programmes will further facilitate synergies between the EU Research Framework Programme, the ESIF and other EU programmes, and national and Regional Programmes. The experience from the Seal of Excellence has been a major contributor to these new provisions.

109. The Common Audit Service put in place a Quality Control Cell that review all the audit reports, at draft and final levels, and ensures consistency with the rules in force and with previous audit opinions on the same issues.

111. The Common Audit Service has put great emphasis on ensuring that audits are carried on a consistent basis and to a high quality. The external firms are closely monitored and controlled via meetings, trainings, daily instructions and guidance.

Common Commission reply to paragraphs 113 and 114.

The Commission notes that there has been a considerable increase in participation by SMEs, which shows the success of Horizon 2020 in attracting and supporting them.

In FP7, SME participation was 17% of relevant expenditure, with €4.9bn of EU contribution over the seven years. In H2020, by July 2018, SME participation was 24% of the relevant expenditure, well above the target of 20%, with an EU contribution of €5.6bn in just four years.

CONCLUSIONS AND RECOMMENDATIONS

118. On the Participant Portal, participants can report on an inconsistency issue through the web submit form of the RES.

The decentralised structure allows the most competent service to reply to the specific enquiry directly. The 36 thematic helpdesks ensure input from staff with the appropriate professional expertise in a particular area, This set-up adds consistency and coherence.

There is also a quality control operated by the Research Enquiry Service (RES) back-office at REA.

Recommendation 1- better communication with applicants and beneficiaries

The Commission accepts this recommendation.

Recommendation 2 – intensify testing of lump sums

The Commission accepts this recommendation.

123. In FP7 the average number of amendments per grant was 0.99. The preliminary figure for H2020 is 0.60. There is therefore no evidence that the “no-negotiation” approach has increased the likelihood of amendments to a grant agreement after signature.

Recommendation 3 - explore greater use of two-stage proposal evaluations

The Commission accepts this recommendation.

Recommendation 4 – re-examine remuneration conditions for expert evaluators

The Commission accepts this recommendation.

126. Today, there are 35 Seal of Excellence schemes operating in 15 countries. The Commission accepts that there is further potential to be exploited. Additional provisions have been included for

the next generation of programmes. However, Member States will still have no obligation to recognise the seal of excellence, this is their own choice.

Recommendation 5 – increase recognition of the Seal of Excellence

The Commission accepts this recommendation.

Recommendation 6 – stability for rules and guidance for participants

The Commission accepts this recommendation.

128. See Commission replies to paragraphs 109 and 112.

Recommendation 7 – improve quality of outsourced ex post audits

The Commission accepts this recommendation.

Recommendation 8 – further simplify tools and guidance for SMEs

The Commission accepts this recommendation.

Event	Date
Adoption of Audit Planning Memorandum (APM) / Start of audit	12.12.2017
Official sending of draft report to Commission (or other auditee)	19.7.2018
Adoption of the final report after the adversarial procedure	2.10.2018
Commission's (or other auditee's) official replies received in all languages	31.10.2018

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The simplification of EU research and innovation funding has been on the agenda for many years, with industry, academia and researchers across Europe seeking simpler administrative rules, better communication with the European Commission, legal certainty and consistency. With Horizon 2020, the Commission introduced changes designed to simplify the rules in this area. Our audit examined whether these changes have been effective in reducing the administrative burden for beneficiaries. We concluded that the majority of the simplification measures have been effective, although not all actions produced the desired result and opportunities to improve still exist. Beneficiaries need more user-friendly guidance and tools, and the Commission has to further test the appropriateness and usability of new funding schemes. Stability in the rules is also important and, while beneficiaries are able to adapt to complexity, frequent modifications to guidance can cause confusion and uncertainty.

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European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

ERC Multi-beneficiary model grant agreement for Starting Grants (StG), Consolidator Grants (CoG), Advanced Grants (AdG) and Synergy Grants (SyG)

(ERC Multi-beneficiary)

Version 1.0
11 December 2013

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

Research and Innovation

EN

[*EUROPEAN COMMISSION/Executive Agency*]
DG

Directorate
Unit

ERC MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR STARTING GRANTS (StG), CONSOLIDATOR GRANTS (CoG), ADVANCED GRANTS (AdG) AND SYNERGY GRANTS (SyG) (ERC MULTI-BENEFICIARY)[1]

Introductory remark for publication on the Participant Portal only

The ERC Multi-beneficiary Model Grant Agreement deviates from the General Model Grant Agreement as follows:

Generally:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- Annexes 2 (with two parts A and B) and 4 are different
- The table of contents is adapted
- Cross-references in the footnotes are adapted

In specific Articles:

- Preamble
- Article 5.2
- Article 7.1
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 32 (Provisions on the working conditions for the Principal Investigator)
- Article 41.3 (Provisions on internal arrangements)
- Article 56a (ERC specific Article on Portability)

[1] ERC Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

- **Footnotes in yellow will appear in the text generated by the IT system for signature (since they contain definitions or references to legal documents). The other footnotes will not stay in the text (since they are internal instructions only).**
- **Text in grey indicates that text which figures in the Multi-beneficiary General MGA is not applicable.**
- **For options [*in italics, in square brackets*]: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

- **Information on formatting:**

  styles

CHAPTER	**style 'Chapter'**
SECTION	**style 'Section'**
SUBSECTION	**style 'Subsection'**
ARTICLE 1	**style 'Article'**
4.1 Estimated budget	**style 'Subarticle'**
Text (without list)	**style 'Normal'**
Table of Content levels (black)	**style 'TOC 1', 'TOC 2', 'TOC 3', 'TOC 4', 'TOC 5'**

Footnotes: Paragraph - special (hanging 0,5) ('Times New Roman', '10 pt')

attention: text with a list must be formatted manually ('Times New Roman', '12 pt', 'Justified')

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],

and

on the other part,

1. 'the principal beneficiary':

[full official name] [short name] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the

Agreement by [function, forename and surname], hosting *[and engaging]* the following ***[OPTION by default: 'principal investigator'**:*

- *[**Name**][Date and place of birth]**]***

***[OPTION for SyG: 'corresponding principal investigator'**:*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]].**]***

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **[full official name]** **[short name]** [legal form] [official registration No] [official address in full] [VAT number*], **[OPTION for SyG:** hosting [and engaging] the '**other principal investigator(s)**' :*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC).**].***

[OPTION for SyG**: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement

the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

Annex 4 Model financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[2] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

[2] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

The beneficiaries may not however:

- ***[OPTION if lump sum foreseen in Article 5.2**: adjust amounts set out as lump sums in Annex 2;]***

- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs *for the action* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for activities in Point (f))]*[3]:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for activities in Point (f))]*[4]: as actually incurred costs (**actual costs**);

(c) *not applicable;*

[3] To be used only if option in Point (f) is used.
[4] To be used only if option in Point (f) is used.

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]* [5]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]* [6]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

[(f) [OPTION for specific categories of costs if unit costs foreseen by Commission decision: *for* ***costs of [insert cost category or activity***[7]*]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[8]*[or*
- *as a combination of the two].**]***

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision: *for* ***costs of [insert cost category or activity****]: as the lump sum set out in Annex 2 ('**lump sum costs**').**]***

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the Agency (see Article 21).

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5 To be used only if option in Point (f) is used.

6 To be used only if option in Point (f) is used.

7 Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.

8 To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper

implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:* *direct costs of providing financial support to third parties;*] [*OPTION:* *not applicable*;]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision*: *costs of [insert cost category or activity*[9]*]*]**.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs *[(not included in Point F)]*

<u>Types of eligible personnel costs</u>

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[10] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

[9] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: costs of 'providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

[10] For the definition, see Article 2.1(10a) of Regulation (EU) No XX/2013 of the European Parliament and of the Council of XX laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L XX, XX, p.XX) ('**Rules for Participation Regulation No XX/2013**'): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[*A.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

<u>Calculation</u>

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

C. Direct costs of providing financial support to third parties *[(not included in Point F)]* *[**OPTION to be used if Article 15 applies:** are eligible if the conditions set out in Article 15 are met.][**OPTION**: not applicable]*

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

D.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

[OPTION (alternative to option above) to be used if foreseen in the work programme[11]: *The* ***cost of purchasing equipment***, ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.]*

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).]*

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.]*

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]*

[11] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[12] *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[13]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.**]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.**]***

[OPTION to be used if foreseen in the work programme: *not applicable.**]***

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

*(c) [**OPTION to be used if Article 15 applies:** costs of providing financial support to third parties][**OPTION**: not applicable]**[**and*

[12] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[13] For the definition see Article 2(f) of Regulation (EU) No XXX/2013 of the European Parliament and of the Council of XX 2013 establishing H2020 - The Framework Programme for Research and Innovation (2014-2020): '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

(d) ***OPTION if Point F applies and the unit or lump sum cost includes indirect costs:*** *[unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]****]****.*

Beneficiaries receiving an operating grant[14] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

(a) *declared as* ***unit costs****: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

(b) *[declared as* ***actual costs****: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

(c) *[declared as a* ***combination of the two****: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity] *are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]****]***

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.****]***

[OPTION: *not applicable****]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

[14] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('**Financial Regulation No 966/2012**'): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

The beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

*Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 [**OPTION:** with the exception of additional exploitation obligations], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

*Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.**]***

[OPTION: *not applicable**]***

9.2 Consequences of non-compliance

[*If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).*

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION: *not applicable**]***

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[15]]***

The beneficiaries must ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[16] or 'contracting entities' within the meaning of Directive 2004/17/EC[17] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services. The costs will appear in the accounts of the beneficiaries and will be considered as costs incurred by them (see Article 6.1 and 6.2).

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[15] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[16] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[17] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[18]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering best value for money;*

[18] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for offers** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [19].**]***

***[OPTION only for actions involving PCP:** The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

[19] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).]*

The beneficiaries must ensure that the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ XXX).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ XXX).

[OPTION: *14.1.1 The following* ***affiliated entities***[22] *and* ***third parties with a legal link to a beneficiary***[23] *(‘****linked third parties****’) may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary] [****OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary] [****OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Commission and the Agency*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.*

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.****]***

[OPTION: *not applicable****]***

14.2 Consequences of non-compliance

[*If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

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[22] For the definition see Article 2.1(2) Rules for Participation Regulation No XX/2013: ‘**affiliated entity**’ means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[23] ‘**Third party with a legal link to a beneficiary**’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION:** not applicable]*

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 Obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any information requested in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the principal beneficiary — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[24]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

[24] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('Rules of Application Regulation No 1268/2012'): '**low value grants**' are lower or equal to EUR 60 000.

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Agency, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2****: for* ***lump sum costs****: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.****]***

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The principal beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the principal beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) scientific and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the Agency in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must — within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for each beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days *[**OPTION:** from the entry into force of the Agreement (see Article 58)] [**OPTION:** from the starting date of the action (see Article 3)] [**OPTION:** from the 45th day before the starting date of the action (see Article 3)]*.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

[OPTION if the JRC is a beneficiary:** Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the principal beneficiary, but kept by the Agency for the JRC.**]

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 – Application of the reimbursement rate

Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary, together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the principal beneficiary,

    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget) up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the principal beneficiary the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the principal beneficiary — Distribution to the beneficiaries

Payments will be made to the principal beneficiary.

Payments to the principal beneficiary will discharge the Agency from its payment obligation.

The principal beneficiary must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][25]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

[25] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the principal beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the principal beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the principal beneficiary may be terminated (see Article 50).

Such breaches may also lead to the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission and the Agency

22.1.1 Right to carry out checks

The Commission or the Agency will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission or the Agency may be assisted by external persons or bodies.

The Commission or the Agency may also request additional information in accordance with Article 17. The Commission or the Agency may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Commission or the Agency may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission or the Agency may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission or the Agency may request beneficiaries to provide such information to it directly.

The principal beneficiary or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission or the Agency will formally notify the review report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Commission or the Agency may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission or the Agency may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission or the Agency may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Commission or the Agency will formally notify the draft audit report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission or the Agency in justified cases.

The '**final audit report**' will take into account observations by the principal beneficiary or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission or the Agency may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [26]and No 2185/96[27] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[28], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

[26] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[27] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[28] Regulation (EU, EURATOM) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, EURATOM)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission or the Agency may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission or the Agency will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Commission or the Agency on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission or the Agency in justified cases.

The Commission or the Agency will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission or the Agency does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission or the Agency accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission or the Agency intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission or the Agency does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission or the Agency accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission or the Agency may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]****[OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the principal beneficiary or beneficiaries.

The Commission or the Agency may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The principal beneficiary or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission or the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[29].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

[29] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the internal arrangements, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[30] established in an EU Member State or '**associated country**'[31], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

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[30] For the definition, see footnote 22.

[31] For the definition, see Article 2.1(3) Rules for Participation Regulation No XX/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No XX/2013 of the European Parliament and of the Council of XX establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ XXX) ('**Horizon 2020 Framework Programme Regulation No XX/2013**').

Article 7 of the Horizon 2020 Framework Programme Regulation No XX/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.]

***[OPTION:** not applicable]*

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership **agreement**, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU] [Agency]* ownership, to protect results

26.4.1 *[The EU][[The* Agency*]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][The* Agency*]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][the* Agency*]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiaries concerned must — up to four years after the period set out in Article 3 — inform the Agency.****]***

If results are incorporated in a standard, the beneficiaries concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard have received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

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29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme): *Regarding the digital research data generated in the action ('**data**'), the beneficiaries must take appropriate measures to ensure open access, including:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(ii) other data, including associated metadata, as specified is Annex 1;

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

[OPTION:** not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem, the ERC logo and

(b) include the following text:

> "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****]*** ***[OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

[OPTION for EU grants: *The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the Agency decision, within the period set out above;*
- *if the Agency objects;*
- *until the conditions are complied with, if the Agency objection comes with conditions.****]***

[OPTION: *not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the internal arrangements, access to results must also be given — under fair and reasonable conditions (see Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).]

***[OPTION for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member*

States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.***]**

31.6 Access rights for third parties

The beneficiaries must — on a royalty-free basis — give access to the principal investigator*[s]* to results needed for *[his/her][their]* activities under the action.

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator[s] and [his/her][their] team

The beneficiaries must respect the following working conditions for the principal investigator*[s]* and *[his/her][their]* team:

- take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[32] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure

[32] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75).

that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

- enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

  (i) the obligation of the beneficiary to meet its obligations under the Agreement;

  (ii) the obligation of the *[**OPTION for SyG:** corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[**OPTION for SyG:** and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

  (iii) the obligation of the *[**OPTION for SyG:** corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[**OPTION for SyG:** and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

  (iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

  (v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

  (vi) the obligation of the principal investigator to inform the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

    - a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);

    - any personal grounds affecting the implementation of the action;

    - any changes in the information that was used as a basis for signing the supplementary agreement;

    - any changes in the information that was used as a basis for awarding the grant;

  (vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

  (viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a)

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[33] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the principal beneficiary must submit (see Article 52) to the Agency copy of:

(a) any ethics committee opinion required under national law and

[33] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the principal beneficiary must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The principal beneficiary must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: *Activities involving research on human embryos or human embryonic stem cells may be carried out only if:*

- *they are set out in Annex 1 or*

- *the principal beneficiary has obtained explicit approval (in writing) from the Agency (see Article 52).**]***

[OPTION**: not applicable**]

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(b) need to know to implement the Agreement and

(c) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for participation Regulation No XXX/2013[34], the Commission must moreover make available information on the results to

[34] Regulation (EU) No XX/2013 of the European Parliament and of the Council of XX laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L XX, XX, p. XX).

other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the principal beneficiary — which must request written approval from the Agency.****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '**security requirements**' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the Agency.

*The beneficiaries must inform the principal beneficiary — which must immediately inform the Agency — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION:** not applicable**]

37.3 Activities involving dual-use goods or dangerous materials and substances

***[OPTION:** Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the principal beneficiary must submit to the Agency (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION:** not applicable**]

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the European Union emblem and the ERC Logo and

(b) include the following text:

"This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC Logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC Logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem and the ERC Logo or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from any beneficiary or principal investigator (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the Agency's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency not to use it (see Article 52).

The right to use a beneficiary's or principal investigator's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

If the right of use is subject to rights of a third party (including personnel of the beneficiary and the principal investigator), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries or the principal investigator), the Agency will insert the following information:

"© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Agency]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency

Any personal data under the Agreement will be processed by the Agency under Regulation No 45/2001[35] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the Agency's websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the Agency.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the principal beneficiary (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

[35] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the principal beneficiary immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the principal beneficiary in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the scientific reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the Agency under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency.

(b) The **principal beneficiary** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The principal beneficiary may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the principal beneficiary is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the principal beneficiary: *As an exception, the principal beneficiary delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The principal beneficiary retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries

The beneficiaries must have '**internal arrangements**' regarding their operation and co-ordination, covering all aspects of their cooperation and implementation of the action, to ensure the action is implemented properly (including decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement ***[OPTION for SyG:*** *(including for disputes between the principal investigators and between them and the beneficiaries)****]*** and division of responsibilities for cases of rejection of costs or reduction of the grant).

The internal arrangements must not contain any provision contrary to this Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the scientific reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the principal beneficiary or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The principal beneficiary or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement as set out in Articles 21.3 or 21.4. (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the principal beneficiary or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the Agency for costs declared by its linked third parties)****]****,* except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[36] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

[36] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the* Agency*:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the principal beneficiary has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify

to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]* ***[OPTION:*** *not applicable]*

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the Agency may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the Agency may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the Agency.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and

- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the Agency can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the scientific reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the sceintific or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the Agency will formally notify the principal beneficiary:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the principal beneficiary.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the Agency resumes payments, the principal beneficiary may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The principal beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the principal beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the principal beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the principal beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The principal beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may — with the agreement of the principal investigator*[s]* — terminate the Agreement.

The principal beneficiary must formally notify termination to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the open reporting period until termination; see Article 20.3) and

(ii) the final scientific report (see Article 20.3).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic financial report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the principal beneficiary, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The principal beneficiary must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the principal beneficiary's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

- a report on the distribution of payments to the beneficiary concerned and
- if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

The Agency will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the Agency). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then

pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, scientific organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the principal beneficiary (see Article 49.1) and either:

(i) resumption is impossible or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action— with respect to the state of the art — is no longer of scientific or technological relevance or no longer has any breakthrough potential ;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION:*** *not applicable****];***

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION:*** *not applicable****];***

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**');

(n) *[a][the]* principal investigator is no longer in a position to continue working under the action.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator):

- **informing** of its intention to terminate and the reasons why, and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator) **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator) that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the principal beneficiary.

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the last open reporting period until termination) (see Article 20.3) and

(ii) a final scientific report (see Article 20.2).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.6 and 50.3.1(l)), the principal beneficiary may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must, within 60 days from when termination takes effect, submit:

- a report on the distribution of payments to the beneficiary concerned;

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case the request for amendment must propose a new principal beneficiary, and

- if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the Agency). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see

Article 6). Costs relating to contracts due for execution only after termination are not eligible.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment, and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and

- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the Agency — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency's websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or

- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The Agency will formally notify the principal beneficiary and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the following address:

[*European Commission*]*[name of the Agency]*
[*Directorate-General*]*[Department]* [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[37], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

[37] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The principal beneficiary submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of principal beneficiary is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of principal beneficiary without its agreement: the opinion of the principal beneficiary (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the Agency has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary ***[OPTION for SyG:*** *or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

Upon request by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. [***OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned]*]

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the Agency and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the Agency relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

The arbitral award will be binding on all parties and will not be subject to appeal.]

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the principal beneficiary, depending on which is later.

SIGNATURES

For the principal beneficiary	For the Agency
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

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MODEL ANNEX 2 FOR ERC MULTI-BENEFICIARY

PART A: BUDGET TABLE FOR BENEFICIARY [name]/LINKED THIRD PARTY [name]

Please enter duration in months [1] ➔ :	

Please indicate the % of working time the PI dedicates to the project over the period of the grant ➔:

Estimated eligible costs (per budget category)	month ... to ...	month ... to ...	month ... to ...	month ... to ...	Total
A. Direct Personnel costs:					
P.I.					-
Senior Staff					-
Post docs					-
Students					-
Other					-
Total Personnel:	-	-	-	-	-
D. Other Direct Costs:					
D.1 Travel					-
D.2 Equipment					-
D.3 Other goods and services (i.e. consumables, publications)					-
D.4 Costs of large research infrastructure					-
Total Other Direct Costs:	-	-	-	-	-
Total Direct Costs:	-	-	-	-	-
E. Indirect Costs (25% of Direct Costs)					-
B.Subcontracting Costs (No indirect costs)					-
Costs of in-kind contributions not used on premises (No indirect costs)					-
Total Estimated Budget (by reporting period and total):	-	-	-	-	-

[1] **Duration of the action (see Article 3)**

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MODEL ANNEX 2 FOR ERC MULTI-BENEFICIARY

PART B: ESTIMATED BUDGET FOR THE ACTION

ANNEX 2

	Estimated eligible* costs (per budget category)								EU contribution		
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs	E. Indirect costs	Total costs	Reimbursement rate %	Maximum EU contribution **	Maximum grant amount
	A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services D.4 Costs of large research infrastructure					
Form of costs* **	Actual	Unit ①	Unit ②		Actual	Actual	Flat-rate ③				
			XX EUR/hour				25%				
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)=0,25x((a)+(b)+(c)+(e)-(k))	(g) = (a)+(b)+(c)+(d)+(e)+(f)	(h)	(i)	(j)
Beneficiary 1											
Linked third party 1a											
Linked third party 1b											
...											
Total Beneficiary 1											
Beneficiary 2											
Linked third party 2a											
Linked third party 2b											
...											
Total Beneficiary 2											
...											
Total Consortium											

	Additional information	
	Information for indirect costs :	Information for auditors:
	Costs of in-kind contributions not used on premises	Declaration of costs under Point D.4
	(k)	Yes/No
Beneficiary 1		
Linked third party 1a		
Linked third party 1b		
...		
Total Beneficiary 1		
Beneficiary 2		
Linked third party 2a		
Linked third party 2b		
...		
Total Beneficiary 2		
...		
Total Consortium		

* See Article 6 for conditions for costs to be eligible
** This is the theoretical amount of EU contribution if the reimbursement rate is applied to *all* the budgeted costs. The theoretical amount of EU contribution for the action is capped by the maximum grant amount.
*** See Article 5 for forms of costs
① unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
② unit : hours worked on the action; cost per unit : XX EUR
③ flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under Point F if they include indirect costs

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary**], [short name] [legal form], [official registration No], established in [official address in full] [VAT number], ('the beneficiary'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become beneficiary ('insert beneficiary no ..')

in Agreement No [insert agreement number] ('the Agreement')

between [full official name of the principal beneficiary] **and** the European Research Council Executive Agency (ERCEA ('the Agency'), *under the power delegated by the European Commission ('the Commission'),]*
for the action entitled [insert title of the action (insert acronym)].

and mandates

the principal beneficiary to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the Agency)

[**full official name of the entity affiliated or linked to the beneficiary**], [short name of the entity], [legal form], [official registration No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary], [short name], [legal form], [official registration No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the Agency by the beneficiary under grant agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex II).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the Agency, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

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MODEL ANNEX 4 FOR ERC MULTI-BENEFICIARY

FINANCIAL STATEMENT FOR BENEFICIARY [name]/ LINKED THIRD PARTY [name]

	Eligible* costs (per budget category)									Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs		E. Indirect costs	Total costs	Receipts	Reimbursement rate %	Maximum EU contribution **	Requested EU contribution	Information for indirect costs :
	A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services	D.4 Costs of large research infrastructure			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs* **	Actual	Unit ①	Unit ②		Actual	Actual	Actual	Flat-rate ③						
			XX EUR/hour					25%						
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)	(g)=0,25x((a)+(b)+(c)+(f)-(m))	(h) = (a)+(b)+(c)+(d)+(e)+(f)+(g)	(i)	(j)	(k)	(l)	(m)

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘThe beneficiary/linked party must declare all eligible costs, even if - for actual costs, unit costs and flat-rate costs - they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts not declared in the individual financial statement will not be taken into account by the Agency

* See Article 6 for conditions for costs to be eligible
** This is the theoretical amount of EU contribution if the reimbursement rate is applied to *all* the reported costs. At the payment of the balance, the theoretical amount of EU contribution for the action is capped by the maximum grant amount.
*** See Article 5 for forms of costs
① unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
② unit : hours worked on the action; cost per unit : XX EUR
③ flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under Point F if they include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[38] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

[38] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

1.1 Subject of the engagement

The principal beneficiary must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the principal beneficiary the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commissionsets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[39]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Federation of Accountants (IFAC);
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

[39] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IFAC.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*]. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[40] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices]
EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

[40] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.
….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**'*

('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.

- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[41] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

[41] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	
		7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT: *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied:	10) The personnel costs included in the Financial Statement were calculated in	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	subcontractors).	instructions).	
	To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	
		17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	For personnel seconded by a third party and included in the sample (not subcontractors) To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results;	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; ○ if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; ○ any other document that supports the costs declared (e.g. invoices, etc.).	20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that:	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated.	hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
	If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours.	24) Productive hours were calculated annually.	
	If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.	25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
	BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS: ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR*	*If the Beneficiary applied method B.* 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	
		If the Beneficiary applied method C. 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.	documents provided by the Beneficiary.	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2.	*For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 30) The Beneficiary used the Commission-approved metho-dology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
	<u>"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":</u> *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *<u>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates:	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ;	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor	38) The use of claimed subcontracting costs was foreseen in Annex I and costs were declared in the Financial Statements under the subcontracting category.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex I; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o ~~there were signed agreements between the Beneficiary and the subcontractor~~;	40) The subcontracts were not awarded to other Beneficiaries of the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ there was evidence that the services were provided by subcontractor;	consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex I; **b)** the financial support to third parties was agreed in Annex I of the Agreement and the other provisions on financial support to third parties included in Annex I were respected.	43) All minimum conditions were met	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The asset charged to the action was traceable to the accounting records and the underlying documents.	
		51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		52) The amount charged corresponded to the actual usage for the action.	
		53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that:	54) Contracts for works or services did not cover tasks described in Annex 1.	
		55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case	equipment.	
		56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	
		57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
		58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,**	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD. *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').].*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*

- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[42]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Federation of Accountants (IFAC);
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*]. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission, *[the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

[42] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IFAC.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[43] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;

[43] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs, why they are reasonable and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[44] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[44] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.
C. **Personnel costs** General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements, were reasonable and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly	to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s).

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. If method B is applied XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. If method C is applied XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year. **Factual finding:** General 12. The Beneficiary applied a number of productive hours consistent with method A or B detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. If method B is applied 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. If method C is applied 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates	**Procedure**

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- ...]*	✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum

[45] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[45]].* *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- ...]*	requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager in reasonable time. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the *[Beneficiary] [Linked Third Party]****]***
[name and title of authorised representative]
[dd Month yyyy]
<Signature of the *[Beneficiary] [Linked Third Party]****>***

[official name of the Auditor]

[name and title of authorised representative]
[dd Month yyyy]
<Signature *of the Auditor>*

European Research Council
Executive Agency

Established by the European Commission

H2020[1] MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR ERC GRANTS[2] (H2020 ERC MGA — MULTI)

Introductory remark

The ERC MGA — Multi deviates from the General MGA— Multi as follows:

Generally:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- Annexes 2 (with two parts A and B) and 4 are different
- The table of contents is adapted
- Cross-references in the footnotes are adapted

In specific Articles:

- Preamble
- Article 5.2
- Article 7.1
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 32 (Provisions on the working conditions for the Principal Investigator)
- Article 41.3 (Provisions on internal arrangements)
- Article 56a (ERC specific Article on portability)

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **Text in grey indicates that text which appears in the General MGA — Multi is not applicable in this grant agreement.**

- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

The main changes compared to version 1 of the model grant agreement are as follows:

- Article 20.6 "Currency for financial statements and conversion into euro" to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects);
- Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" to give the possibility to the beneficiaries to receive the pre-financing payment 10 days prior to the starting date of the action.
- Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem and the ERC logo " to ensure more visibility of the European Research Council (ERC) funding under the European Union's Horizon 2020 research and innovation programme for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action.

Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the principal beneficiary':

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 *'Mise en place de la Charte des ordonnateurs'*.

[**full official name (short name)**] [legal form] [official registration No] established in [official address in full] [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname], hosting *[and engaging]* the following ***[OPTION by default: 'principal investigator'**:* [4]

- *[**Name**][Date and place of birth]**]***[5]

***[OPTION for SyG: 'corresponding principal investigator'**:*

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]].**]***

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **[full official name] [short name]** [legal form] [official registration No] [official address in full] [VAT number*], **[OPTION for SyG:** hosting [and engaging] the '**other principal investigator(s)**' :*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC).**]***.

[OPTION for SyG**: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.
[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[7] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

[7] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[8]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

[8] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.****]***

[OPTION to be used if foreseen in the work programme: *Not applicable****.]***

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[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 141.1.****]***

[OPTION: *Not applicable****]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

[11] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

*[(c) **OPTION for cost categories explicitly excluded in the work programme:** [insert name of excluded cost category]].*

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

The beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*

- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.3, 20.4, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION 2, to be used if the beneficiary/ coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 20.4, 23a and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.4, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

***[OPTION:** Not applicable]*

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[12]]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[13] or 'contracting entities' within the meaning of Directive 2004/17/EC[14] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

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[12] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[13] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[14] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services. The costs will appear in the accounts of the beneficiaries and will be considered as costs incurred by them (see Article 6.1 and 6.2).

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[15]***]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report, and

[15] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).****]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following ***affiliated entities***[16] *and* ***third parties with a legal link to a beneficiary***[17] *('****linked third parties****') may implement the action tasks attributed to them in Annex 1:*

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[16] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:

- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:

(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or

(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not constitute in themselves control relationships:

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name_)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;

(b) the legal entities concerned are owned or supervised by the same public body.

[17] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the principal beneficiary — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[18]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The principal beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the principal beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods**':

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must — within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and

- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for each beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from10 days before the starting date of the action (see Article 3) whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the principal beneficiary, but kept by the Agency for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary, together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the principal beneficiary,

    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the principal beneficiary the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the principal beneficiary — Distribution to the beneficiaries

Payments will be made to the principal beneficiary.

Payments to the principal beneficiary will discharge the Agency from its payment obligation.

The principal beneficiary must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][19]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the principal beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

[19] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the principal beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the principal beneficiary may be terminated (see Article 50).

Such breaches may also lead to the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 17. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The principal beneficiary or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Agency or the Commission will formally notify the review report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission or the Agency in justified cases.

The '**final audit report**' will take into account observations by the principal beneficiary or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [20]and No 2185/96[21] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[22], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

[20] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[21] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[22] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘**extension of findings from this grant to other grants**’).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments

(see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the Agency or the Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Agency or the Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Agency or the Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Agency or the Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]* ***[OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the principal beneficiary or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The principal beneficiary or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[23].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

[23] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the internal arrangements, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[24] established in an EU Member State or ‘**associated**

[24] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: ‘**affiliated entity**’ means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

‘Control’ may take any of the following forms:

country'[25], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;

(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;

(b) the legal entities concerned are owned or supervised by the same public body.-

[25] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership **agreement**, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 Agency ownership, to protect results

26.4.1 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 Agency ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the Agency may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiaries concerned must — up to four years after the period set out in Article 3 — inform the Agency.****]***

If results are incorporated in a standard, the beneficiaries concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard have received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

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29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme): *Regarding the digital research data generated in the action (‘**data**’), the beneficiaries must take appropriate measures to ensure open access, including:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(ii) other data, including associated metadata, as specified is Annex 1;

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

[OPTION:** Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem, the ERC logo and

(b) include the following text:

> "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****]*** ***[OPTION:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

[OPTION for EU grants: *The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the Agency decision, within the period set out above;*
- *if the Agency objects;*
- *until the conditions are complied with, if the Agency objection comes with conditions.**]***

[OPTION:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the internal arrangements, access to results must also be given — under fair and reasonable conditions (see Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).]

31.6 Access rights for principal investigators

The beneficiaries must — on a royalty-free basis — give access to the principal investigator*[s]* to results needed for *[his/her][their]* activities under the action.

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator[s] and [his/her][their] team

The beneficiaries must respect the following working conditions for the principal investigator*[s]* and *[his/her][their]* team:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[26] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[**OPTION for SyG:** corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[**OPTION for SyG:** and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[**OPTION for SyG:** corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[**OPTION for SyG:** and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);

[26] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

- any personal grounds affecting the implementation of the action;
- any changes in the information that was used as a basis for signing the supplementary agreement;
- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*
- provide a statement to the principal beneficiary ***[OPTION for SyG:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[27] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

[27] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the principal beneficiary must submit (see Article 52) to the Agency copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the principal beneficiary must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The principal beneficiary must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[28], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the Agency.****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[28] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '**security requirements**' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the Agency.

*The beneficiaries must inform the coordinator — which must immediately inform the Agency — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).**]***

[OPTION: *Not applicable**]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the Agency (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION: *Not applicable**]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC Logo and

(b) include the following text:

> For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC Logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC Logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from any beneficiary or principal investigator (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the Agency's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency not to use it (see Article 52).

The right to use a beneficiary's or principal investigator's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001[29], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

If the right of use is subject to rights of a third party (including personnel of the beneficiary and the principal investigator), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries or the principal investigator), the Agency will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Research Council Executive Agency (ERCEA) under conditions."

[29] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 45/2001[30] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency or the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement(s) (SSPS)' that are published on the Agency and Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the service specific privacy statement(s) (SSPS) (see above), before transmitting their data to the Agency or the Commission.

39.3 Consequences of non-compliance

[30] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

If a beneficiary breaches any of its obligations under Article 39.2, the Agency or the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the principal beneficiary (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the principal beneficiary immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the principal beneficiary in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the scientific reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **principal beneficiary** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The principal beneficiary may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the principal beneficiary is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the principal beneficiary: *As an exception, the principal beneficiary delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The principal beneficiary retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries

The beneficiaries must have '**internal arrangements**' regarding their operation and co-ordination, covering all aspects of their cooperation and implementation of the action, to ensure the action is implemented properly (including decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement ***[OPTION for SyG:*** *(including for disputes between the principal investigators and between them and the beneficiaries)****]*** and division of responsibilities for cases of rejection of costs or reduction of the grant).

The internal arrangements must not contain any provision contrary to this Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the principal beneficiary or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The principal beneficiary or

beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the principal beneficiary or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the Agency for costs declared by its linked third parties)**]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency or the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article*

*14), by **holding the third party liable** up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or**][OPTION:** not applicable;**]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[31] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

[31] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the* Agency*:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the principal beneficiary has not distributed amounts received (see Article 21.7), the Agency will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the Agency may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the Agency or the Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the Agency.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and

- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the Agency can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the scientific reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the sceintific or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the Agency will formally notify the principal beneficiary:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency will formally notify the principal beneficiary.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the Agency resumes payments, the principal beneficiary may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The principal beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the principal beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the principal beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the principal beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The principal beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may — with the agreement of the principal investigator*[s]* — terminate the Agreement.

The principal beneficiary must formally notify termination to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the open reporting period until termination; see Article 20.3) and

(ii) the final scientific report (see Article 20.3).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic financial report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the principal beneficiary, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The principal beneficiary must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the principal beneficiary's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

- a report on the distribution of payments to the beneficiary concerned and

- if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

The Agency will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the Agency). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

- termination takes effect after an interim payment and

- the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, scientific organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the principal beneficiary (see Article 49.1) and either:

(i) resumption is impossible or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action— with respect to the state of the art — is no longer of scientific or technological relevance or no longer has any breakthrough potential ;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**');

(n) *[a][the]* principal investigator is no longer in a position to continue working under the action.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator):

- **informing** of its intention to terminate and the reasons why, and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator) **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator) that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the principal beneficiary.

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the last open reporting period until termination) (see Article 20.3) and

(ii) a final scientific report (see Article 20.2).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.6 and 50.3.1(l)), the principal beneficiary may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must, within 60 days from when termination takes effect, submit:

- a report on the distribution of payments to the beneficiary concerned;

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case the request for amendment must propose a new principal beneficiary, and

- if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the Agency). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see

Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

    - termination takes effect after an interim payment, and

    - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

    In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and

- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated— before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or

- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The Agency will formally notify the principal beneficiary and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the following address:

[*European Commission]*[*name of the Agency]*
[*Directorate-General]*[*Department]* [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[32], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

[32] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The principal beneficiary submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of principal beneficiary is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of principal beneficiary without its agreement: the opinion of the principal beneficiary (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary ***[OPTION for SyG:*** *or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned]]*.

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].**]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the Agency and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.**]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.**]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring

action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the principal beneficiary, depending on which is later.

SIGNATURES

For the principal beneficiary
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

For the Agency
[forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

print format A4 landscape

MODEL ANNEX 2 FOR H2020 ERC MGA — MULTI

PART B: ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)								EU contribution		
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs	E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*					
Form of costs[5]	Actual	Unit[6]	Unit[7]		Actual	Actual	Flat-rate[8]				
			XX EUR/hour				25%				
	a	Total b	No hours	Total c	d	e	f=0,25x(a+b+c+e-k)	g = a+b+c+d+e+f	h	i	j
1 [short name beneficiary]											
[short name linked third party]											
[short name linked third party not receiving EU funding]											
...											
Total beneficiary											
2 [short name beneficiary]											
[short name linked third party]											
...											
Total beneficiary 2											
X [short name beneficiary not receiving EU funding][9]											
[short name linked third party][10]											
...											
Total beneficiary											
...											
Total consortium											

	Additional information		
	Information for indirect costs :	Information for auditors:	Other information:
	Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
	k	Yes/No	
1 [short name beneficiary]			
[short name linked third party]			
[short name linked third party not receiving EU funding]			
...			
Total beneficiary			
2 [short name beneficiary]			
[short name linked third party]			
...			
Total beneficiary			
X [short name beneficiary not receiving EU funding]			
[short name linked third party]			
...			
Total beneficiary			
...			
Total consortium			

[1] See Article 6 for the eligibility conditions

[2] The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] See Article 5 for the forms of costs

[6] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[7] Unit : hours worked on the action; cost per unit (hourly rate) : [...] EUR

[8] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

[9] See Article 9 for beneficiaries not receiving EU funding

[10] Only for linked third parties that receive EU funding

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new principal beneficiary (short name)**][legal form], [official registration No], established in [official address in full] [VAT number], (*['the beneficiary']['the principal beneficiary']*), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][principal beneficiary]* ('insert official registration no ..')

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the principal beneficiary] **and** the European Research Council Executive Agency (ERCEA ('the Agency'), *under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the principal beneficiary *to submit and sign in its name and on its behalf any* ***amendments*** *to the Agreement, in accordance with Article 55.**]***

By signing this Accession Form, the beneficiary accepts the grant and agrees to ***[OPTION: for new principal beneficiaries:*** *take on the obligations and role of principal beneficiary and to]* implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:*** *as from [date] if the [Commission][Agency] agrees with the request for amendment]*.

SIGNATURE

For the beneficiary/new beneficiary/new principal beneficiary:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the Agency)

[**full official name of the entity affiliated or linked to the beneficiary (short name)**][legal form], [official registration No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)][legal form], [official registration No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the Agency by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the Agency, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 ERC MGA — MULTI

FINANCIAL STATEMENT FOR BENEFICIARY [name]/ LINKED THIRD PARTY [name] FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)									Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs		E. Indirect costs[2]	Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit XX EUR/hour		Actual	Actual	Actual	Flat-rate[5] 25%						
	a	Total b	No hours	Total c	d	e	*[f]*	g=0,25x(a+b+c+*[f]* -m)	h = a+b+c+d+e+*[f]* +g	i	j	k	l	m
[short name beneficiary/linked third party]														

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, if the 90% limit (see Article 21) is reached, etc).

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[33] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The principal beneficiary must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the principal beneficiary the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[33] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commissionsets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[34]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[34] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[35] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement
[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[35] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[36] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[36] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	
		7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
	(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR; *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u>	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	
		17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours'	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.	correctly applied.	
	BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS: ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.*	*If the Beneficiary applied method B.* 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	
		If the Beneficiary applied method C. 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2.	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES": *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically)	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*).	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	subcontracting category.	
		39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		40) The subcontracts were not awarded to other Beneficiaries of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; **b)** the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	43) All minimum conditions were met	
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table);	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	
		50) The asset charged to the action was traceable to the accounting records and the underlying documents.	
		51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value).	52) The amount charged corresponded to the actual usage for the action.	
	The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular:	54) Contracts for works or services did not cover tasks described in Annex 1.	
		55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	
		57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	In the cases that a positive ex-ante assessment has been issued *(see the standard factual findings 59-60 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	described in the positive ex-ante assessment report. 60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	CORRESPONDING REPORTING PERIOD. *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[37]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[37] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[38] submitted thereafter.

[38] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;

5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[39] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[39] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].* X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.].* For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u>	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates.	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[40]]. *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- ...]*	effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[40] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**

[official name of the *[Beneficiary] [Linked Third Party]****]***
[name and title of authorised representative]
[dd Month yyyy]
<Signature of the *[Beneficiary] [Linked Third Party]>*

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
<Signature *of the Auditor>*

European Research Council
Executive Agency

Established by the European Commission

Horizon 2020
European Union Funding
for Research & Innovation

European Research Council (ERC)

Multi-Beneficiary Model Grant Agreement

ERC Starting Grants, Consolidator Grants and Advanced Grants

(H2020 ERC MGA — Multi)

Version 3.0
20 July 2016

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	▪ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	▪ The main changes compared to version 1 of the model grant agreement are as follows: – Article 20.6 "Currency for financial statements and conversion into euro" to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" to give the possibility to the beneficiaries to receive the pre-financing payment 10 days prior to the starting date of the action. – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem and the ERC logo " to ensure more visibility of the European Research Council (ERC) funding under the European Union's Horizon 2020 research and innovation programme for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
3.0	20.07.2016	▪ The main changes compared to version 2.1 of the model grant agreement are as follows: – ntroduction of the option for Co-Principle Investigator (Co-PI) for all ERC Frontier Research grants, where the action is carried out under the guidance of more than one principle investigator. ○ Article 4.2 *'Budget transfers':* increased budget flexibility for beneficiaries, which may transfer amounts between forms of costs within the direct personnel costs budget category without an amendment to the grant agreement even if they did not foresee that form of cost in Annex 2. ○ Article 6.2.A *'Direct personnel costs'* to take into account to a larger extent the usual cost accounting practices of the beneficiaries by allowing them to calculate the hourly rate not only per full financial year but also per month. ○ Article 29.3 *'Open access to research data'* in order to align the ERC MGAs to the rules on open access of general H2020 MGA. ○ Article 34.1 *'Obligation to comply with ethical and research integrity principles'* in order to underline the standards of research integrity that beneficiaries must respect. ○ Article 34.2 *'Activities raising ethical issues'* in order to simplify the beneficiaries' reporting obligations on ethics before the beginning of an activity raising an ethical issue. ○ Article 36.1 *'General obligation to maintain confidentiality'* in order to allow broader access to confidential information in the case of the Commission/Agency staff, other EU

		institutions and bodies. ○ Article 48 *'Suspension of payments'* extends the possibility for the Commission/Agency to suspend the payment of the balance only for one or more beneficiaries. ○ Articles 48 *'Suspension of payments'*, 49 *'Suspension of action implementation'*, 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'* in order to clarify that for confidentiality reasons and to protect the personal data, in case of audits, reviews, investigations etc., the Commission/Agency will carry out the contradictory procedure directly with the beneficiary concerned (in this case the coordinator will also be informed). ○ Article 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'*: the Commission/Agency may terminate the participation of a beneficiary if it did not request an amendment to the grant agreement to terminate the participation of its linked third party which is under the same conditions as a beneficiary for which the participation may be terminated. For instance, the linked third party is bankrupt. Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

European Research Council
Executive Agency

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MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1]
ERC STARTING GRANTS, CONSOLIDATOR GRANTS AND ADVANCED GRANTS[2]
(H2020 ERC MGA — MULTI)

Introductory remark

H2020 ERC MGA — Multi deviates from the General MGA— Multi as follows:

Generally:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- Annexes 2 (with two parts A and B) and 4 are different
- The table of contents is adapted
- Cross-references in the footnotes are adapted

In specific Articles:

- Preamble
- Article 5.2
- Article 7.1
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 32 (Provisions on the working conditions for the Principal Investigator)
- Article 41.3 (Provisions on internal arrangements)
- Article 56a (ERC specific Article on portability)

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **Text in grey indicates that text which appears in the H2020 General MGA does not apply in this grant agreement.**

- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the principal beneficiary':

[**full official name (short name)**] established in [official address in full] ***[OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting *[and engaging]* the following ***[OPTION by default: 'principal investigator':*** [4]

- *[**Name**] [Date and place of birth]]*[5]

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 *'Mise en place de la Charte des ordonnateurs'*.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

***[OPTION for SyG and other ERC grants with more than one principal investigator:** 'corresponding principal investigator':*

- *[**Name**] [Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**] [Date and place of birth]*
- *[**Name**] [Date and place of birth]].**]***

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name**] [**short name**] [official address in full] ***[OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**' :*

- *[**Name**] [Date and place of birth]*

- *[**Name**] [Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC).**]***.

[OPTION for SyG and other ERC grants with more than one principal investigator**: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[7] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

[7] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is calculated *per full financial year,* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[8]: *The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

[8] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.**]***

[OPTION 2 to be used if foreseen in the work programme:** Not applicable.**]

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

F. Specific cost category(ies)

[10] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[11] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 141.1.****]***

[OPTION 2: *Not applicable****]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom

budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period*[.][;]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

The beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);

- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.3, 20.4, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION B, to be used if the beneficiary/ coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 20.4, 23a and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.4, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION 2: *Not applicable**]***

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[12]***]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

[12] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[13] (or 2014/24/EU[14]) or 'contracting entities' within the meaning of Directive 2004/17/EC[15] (or 2014/25/EU[16]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services. The costs will appear in the accounts of the beneficiaries and will be considered as costs incurred by them (see Article 6.1 and 6.2).

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[13] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[14] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18EC (OJ L 94, 28.03.2014, p. 65).

[15] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

[16] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243)

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[17]***]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).****]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC (or 2014/24/EU) or ‘contracting entities’ within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

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[17] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following ***affiliated entities***[18] *and* ***third parties with a legal link to a beneficiary***[19] *(‘****linked third parties****’) may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [****OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name_)], affiliated or linked to [short name of the beneficiary] [****OPTION if joint and several liability has been requested:****, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
  [same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

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[18] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: ‘**affiliated entity**’ means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not constitute in themselves control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[19] ‘**Third party with a legal link to a beneficiary**’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the principal beneficiary — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[20]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries

[20] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The principal beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the principal beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods'**:

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must — within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and

- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for each beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from10 days before the starting date of the action (see Article 3) whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the principal beneficiary, but kept by the Agency for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary, together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

  - is positive, it will be paid to the principal beneficiary,

  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the principal beneficiary the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the principal beneficiary — Distribution to the beneficiaries

Payments will be made to the principal beneficiary.

Payments to the principal beneficiary will discharge the Agency from its payment obligation.

The principal beneficiary must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][21]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the principal beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

[21] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the principal beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the principal beneficiary may be terminated (see Article 50).

Such breaches may also lead to the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 17. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal

beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The principal beneficiary or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Agency or the Commission will formally notify the review report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission or the Agency in justified cases.

The '**final audit report**' will take into account observations by the principal beneficiary or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [22]and No 2185/96[23] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[24], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

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[22] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[23] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[24] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION 2:** Not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘**extension of findings from this grant to other grants**’).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The Agency or the Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors, irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Agency or the Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the principal beneficiary or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The principal beneficiary or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[25].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

[25] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘**Fair and reasonable conditions**’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the internal arrangements, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[26] established in an EU Member State or '**associated country**'[27], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

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[26] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[27] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership **agreement**, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 Agency ownership, to protect results

26.4.1 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time

inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 Agency ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the Agency may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiaries concerned must — up to four years after the period set out in Article 3 — inform the Agency.****]***

If results are incorporated in a standard, the beneficiaries concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard have received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme): *Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in the **data management plan;***

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2: *Not applicable**]***

29.4 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem, the ERC logo and

(b) include the following text:

> "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****]*** ***[OPTION 2:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

[OPTION 1 for EU grants: *The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*

(b) *the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*

- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the Agency decision, within the period set out above;*
- *if the Agency objects;*
- *until the conditions are complied with, if the Agency objection comes with conditions.]*

[OPTION 2:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the internal arrangements, access to results must also be given — under fair and reasonable conditions (see Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

[OPTION 2:** Not applicable**]

31.6 Access rights for principal investigators

The beneficiaries must — on a royalty-free basis — give access to the principal investigator*[s]* to results needed for *[his/her][their]* activities under the action.

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator[s] and [his/her][their] team

The beneficiaries must respect the following working conditions for the principal investigator*[s]* and *[his/her][their]* team:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[28] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding]* principal investigator to supervise the scientific and technological implementation of the action ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

[28] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);

- any personal grounds affecting the implementation of the action;

- any changes in the information that was used as a basis for signing the supplementary agreement;

- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[29].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;

[29] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.

- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;

- ensure objectivity, accuracy and impartiality when disseminating the results;

- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3****]*** as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced;

- make the necessary references to their work and that of other researchers;

- refrain from practicing any form of plagiarism, data falsification or fabrication;

- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the principle beneficiary to the Agency (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[30], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[30] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

*For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities), —inform the coordinator, which must request written approval from the Agency.****]***

*In case of change to the security context, the beneficiaries must inform the coordinator which must immediately inform the Agency and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL) and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[31] *—until it is declassified.*

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the Agency.

*In case of change to the security context, the beneficiaries must inform the coordinator which must immediately inform the Agency and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION 1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

[31] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

*Before the beginning of the activity, the coordinator must submit to the Agency (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2:** Not applicable**]

37.4 Consequences of non-compliance

***[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable:** If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC Logo and

(b) include the following text:

For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC Logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC Logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency and Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency and the Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from any beneficiary or principal investigator (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the Agency's or the Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency or the Commission not to use it (see Article 52).

The right to use a beneficiary's or principal investigator's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other

graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001[32], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary and the principal investigator), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries or the principal investigator), the Agency or the Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Research Council Executive Agency (ERCEA) and the *[European Union (EU)][Euratom]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 45/2001[33] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

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[32] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[33] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

Such data will be processed by the '**data controller**' of the Agency or the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the Agency and Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Agency or the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the principal beneficiary (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the principal beneficiary immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the principal beneficiary in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the scientific reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **principal beneficiary** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The principal beneficiary may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the principal beneficiary is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the principal beneficiary: *As an exception, the principal beneficiary delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The principal beneficiary retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries

The beneficiaries must have '**internal arrangements**' regarding their operation and co-ordination, covering all aspects of their cooperation and implementation of the action, to ensure the action is implemented properly (including decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *(including for disputes between the principal investigators and between them and the beneficiaries)****]*** and division of responsibilities for cases of rejection of costs or reduction of the grant).

The internal arrangements must not contain any provision contrary to this Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will — after **termination of the participation of a beneficiary,** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, see Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the rejection of costs does not lead to a recovery (see Article 44), the Agency will formally notify the principal beneficiary or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The principal beneficiary or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Agency will follow the contradictory procedure with 'pre-information letter' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs after **termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary *[and its linked third parties]* in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement

or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant, if:

(a) a beneficiary (or a natural person who has power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles), or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the principal beneficiary or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant after **termination of the participation of a beneficiary,** it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the Agency for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency or the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[34] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

[34] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the* Agency*:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the principal beneficiary has not distributed amounts received (see Article 21.7), the Agency will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Agency or the Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the scientific reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the scientific or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles), or

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the Agency will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the Agency will formally notify the principal beneficiary or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency will formally notify the principal beneficiary or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The principal beneficiary must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The principal beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the principal beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the principal beneficiary or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the principal beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The principal beneficiary or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may — with the agreement of the principal investigator*[s]* — terminate the Agreement.

The principal beneficiary must formally notify termination to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the open reporting period until termination; see Article 20.3) and

(ii) the final scientific report (see Article 20.3).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic financial report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the principal beneficiary, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The principal beneficiary must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the principal beneficiary's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

- a report on the distribution of payments to the beneficiary concerned and

- if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, scientific organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the principal beneficiary (see Article 49.1) and either:

(i) resumption is impossible or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action— with respect to the state of the art — is no longer of scientific or technological relevance or no longer has any breakthrough potential ;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) despite a specific request by the Agency, a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties that is in one of the situations under points (e), (f), (g), (k), (l), (m) or (n) and to reallocate its tasks;

(o) *[a][the]* principal investigator is no longer in a position to continue working under the action.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding****]*** principal investigator):

- **informing** of its intention to terminate and the reasons why, and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding****]*** principal investigator) **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding****]*** principal investigator) that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii), (n) and (o) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the last open reporting period until termination) (see Article 20.3) and

(ii) a final scientific report (see Article 20.2).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.6 and 50.3.1(l)), the principal beneficiary may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must, within 60 days from when termination takes effect, submit:

- a report on the distribution of payments to the beneficiary concerned;

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for

amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case the request for amendment must propose a new principal beneficiary, and

- if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment, and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or

- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The Agency will formally notify the principal beneficiary and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the following address:

[European Commission][Name of the Agency]
[Directorate-General [complete]
[Street name and number]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[35], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

[35] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

The principal beneficiary submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of principal beneficiary is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of principal beneficiary without its agreement: the opinion of the principal beneficiary (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned]].*

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]* ***[****by the law of [Belgium][[insert name of another Member State or EFTA country]]****]*** *[and, where appropriate,] [by the general principles governing the law of international organisations and the rules of general international law]*
- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]* ***[****by the law of [Belgium][[insert name of another Member State or EFTA country]]****]*** *[and, where appropriate,] [by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the Agency and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for non-EU beneficiaries not receiving EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or non-EU beneficiary not receiving EU funding]*
- *[insert name of international organisation or non-EU beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiary not receiving EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take

place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the principal beneficiary, depending on which is later.

SIGNATURES

For the principal beneficiary	For the Agency
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

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MODEL ANNEX 2 FOR H2020 ERC MGA — MULTI

PART B: ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)								EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs	E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
Form of costs[5]	Actual	Unit[6]	Unit[7]		Actual	Actual	Flat-rate[8] 25%							
	a	Total b	No hours	Total c	d	e	f=0,25x(a+b+c+e-k)	g = a+b+c+d+e+f	h	i	j	k	Yes/No	
1 [short name beneficiary]														
[short name linked third party]														
[short name linked third party not receiving EU funding]														
Total beneficiary														
2 [short name beneficiary]														
[short name linked third party]														
Total beneficiary 2														
X [short name beneficiary not receiving EU funding][9]														
[short name linked third party][10]														
Total beneficiary														
Total consortium														

[1] See Article 6 for the eligibility conditions

[2] The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] See Article 5 for the forms of costs

[6] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[7] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[8] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

[9] See Article 9 for beneficiaries not receiving EU funding

[10] Only for linked third parties that receive EU funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{{ EUR 4,650 / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

Country-specific correction coefficient (in force at the time of the call):

EU Member States

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AT	104.8%	DK	135.3%	HR	97.5%	LV	75.9%	SE	111.7%
BE	100.0%	EE	78.3%	HU	76.2%	MT	89.6%	SI	86.1%
BG	71.5%	EL	92.7%	IE	113.5%	NL	104.3%	SK	82.6%
CY	91.8%	ES	97.6%	IT	106.7%	PL	76.4%	UK	120.3%
CZ	83.8%	FI	116.6%	LT	73.1%	PT	89.1%		
DE	98.8%	FR	111.0%	LU	100.0%	RO	68.3%		

H2020 associated countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AL	76.1%	FO	134.1%	LI	110.0%	MK	68.4%	TR	86.6%
BA	73.6%	IL	108.7%	MD	61.1%	NO	131.9%		
CH	113.1%	IS	116.6%	ME	66.9%	RS	67.1%		

Other countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AM	89.9%	CU	83.8%	JP	115.9%	NI	57.3%	TJ	64.9%
AO	114.6%	CV	76.4%	KE	78.1%	NP	73.5%	TL	78.3%
AR	58.5%	DJ	93.4%	KG	83.1%	NZ	94.1%	TN	70.5%
AU	105.0%	DO	66.9%	KH	70.5%	PA	57.0%	TO	85.0%
AZ	93.0%	DZ	81.7%	KR	105.2%	PE	75.5%	TT	74.1%
BB	116.6%	EC	68.8%	KZ	100.2%	PG	83.0%	TW	83.6%
BD	47.2%	EG	48.6%	LA	77.7%	PH	65.8%	TZ	65.2%

BF	93.8%	ER	61.2%	LB	86.4%	PK	49.4%	UA	92.3%
BJ	92.6%	ET	85.2%	LK	61.6%	PS	100.4%	UG	65.7%
BM	151.5%	FJ	68.1%	LR	100.1%	PY	71.9%	US	99.4%
BO	51.3%	GA	113.1%	LS	56.7%	RU	115.5%	UY	75.3%
BR	92.0%	GE	89.5%	LY	60.0%	RW	87.3%	UZ	51.4%
BW	55.3%	GH	68.2%	MA	83.5%	SA	84.8%	VE	70.0%
BY	65.0%	GM	67.7%	MG	80.0%	SB	93.3%	VN	51.1%
BZ	75.3%	GN	60.4%	ML	90.4%	SD	65.1%	VU	112.6%
CA	86.4%	GT	78.8%	MR	64.5%	SG	102.5%	WS	75.8%
CD	127.6%	GW	102.7%	MU	72.7%	SL	85.2%	XK	58.6%
CF	114.3%	GY	58.9%	MW	76.0%	SN	86.2%	YE	68.1%
CG	124.9%	HK	93.8%	MX	70.4%	SR	50.6%	ZA	55.8%
CI	102.0%	HN	69.0%	MY	71.6%	SV	74.3%	ZM	66.4%
CL	67.1%	HT	108.7%	MZ	71.6%	SY	74.8%	ZW	47.2%
CM	103.3%	ID	75.3%	NA	68.3%	SZ	56.8%		
CN	85.0%	IN	52.8%	NC	128.9%	TD	125.3%		
CO	76.6%	JM	94.9%	NE	87.9%	TG	88.7%		
CR	76.7%	JO	75.5%	NG	92.4%	TH	65.0%		

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment: For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] ***]***

Estimated number of units: see Annex 2

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new principal beneficiary (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number]]*, (*['the beneficiary']['the principal beneficiary']*), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][principal beneficiary]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the principal beneficiary] **and** the European Research Council Executive Agency (ERCEA ('the Agency'), *under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the principal beneficiary** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.**]

By signing this Accession Form, the beneficiary accepts the grant and agrees to *[**OPTION: for new principal beneficiaries:** take on the obligations and role of principal beneficiary and to]* implement it in accordance with the Agreement, with all the obligations and conditions it sets out *[**OPTION for new beneficiaries:,** as from [insert date] [the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date')** [**additional OPTION for change of beneficiary due to partial takeover**:, and with joint and several liability for undue amounts paid to [insert short name of former beneficiary] (i.e. recoveries)] — if the [Commission][Agency] agrees with the request for amendment**]***.

SIGNATURE

For the beneficiary/new beneficiary/new principal beneficiary:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the Agency)

[**full official name of the entity affiliated or linked to the beneficiary (short name)**], established in [official address in full], *[**OPTION for linked third parties with VAT:** VAT number [insert number]]* ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number]]* ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the Agency by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the Agency, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 ERC MGA — MULTI

FINANCIAL STATEMENT FOR BENEFICIARY [name]/ LINKED THIRD PARTY [name] FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)									Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs		E. Indirect costs[2]	Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Flat-rate[5] 25%						
	a	Total b	No hours	Total c	d	e	*[f]*	g=0,25x(a+b+c+e+*[f]* -m)	h = a+b+c+d+e+*[f]* +g	i	j	k	l	m
[short name beneficiary/linked third party]														

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less.

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The principal beneficiary must submit to the Agency the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the principal beneficiary the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission, the Agency, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;

- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission the Agency, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission the Agency, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement
[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the *[Commission] [Agency]* in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The *[Commission] [Agency]* may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
	(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR; *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	methodology was consistently used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices,	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	
		15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting records, etc.).	17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR*	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	(THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE). ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	documents provided by the Beneficiary. 26.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).	
		If the Beneficiary applied method C. 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
		28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u>	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; o (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. <u>*"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":*</u>	rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2. *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	*For option II concerning individual hourly rates:* 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 32.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined.	
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ;	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	were consistent with the presences/absences recorded in HR-records.	
		36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: ○ the use of subcontractors was foreseen in Annex 1; ○ subcontracting costs were declared in the subcontracting category of the Financial Statement; ○ supporting documents on the selection and award procedure were followed; ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio,	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium;	40) The subcontracts were not awarded to other Beneficiaries of the consortium.	
	o there were signed agreements between the Beneficiary and the subcontractor;	41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
	o there was evidence that the services were provided by subcontractor;	42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to**	43) All minimum conditions were	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	third parties and sampled _____ cost items selected randomly (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; **b)** the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	met	
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	
		50) The asset charged to the action was traceable to the accounting records and the underlying documents.	
		51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		52) The amount charged corresponded to the actual usage for the action.	
		53) No ineligible costs or excessive or reckless expenditure were declared. 54)	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio,	55) Contracts for works or services did not cover tasks described in Annex 1.	
		56) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		57) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	
		58) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
		59) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),*	60) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	
		61) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	62) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	63) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	64) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options *[in italics in square brackets]*: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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(1) Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission*[, the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

(2) Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[2] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;

[2] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

2. Brief description of the time recording system in place;
3. An example of the time records used by the *[Beneficiary] [Linked Third Party]*;
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the *[Beneficiary] [Linked Third Party]* and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the *[Beneficiary] [Linked Third Party]* in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the *[Beneficiary] [Linked Third Party]* in connection with Article 18.1.2 of the Agreement;
- may not be used by the *[Beneficiary] [Linked Third Party]* or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the *[Beneficiary] [Linked Third Party]*.

No conflict of interest[3] exists between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[3] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget).	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
<u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).

Please explain any discrepancies in the body of the Report.

Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular:

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[1]].* *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the*	✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Auditor: - *...]*	reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]

[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

European Research Council
Executive Agency

Established by the European Commission

Horizon 2020
European Union Funding
for Research & Innovation

European Research Council (ERC)

Multi-Beneficiary Model Grant Agreement

ERC Starting Grants, Consolidator Grants and Advanced Grants

(H2020 ERC MGA — Multi)

Version 4.0
27 February 2017

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	▪ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	▪ The main changes compared to version 1 of the model grant agreement are as follows: – Article 20.6 "Currency for financial statements and conversion into euro" to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" to give the possibility to the beneficiaries to receive the pre-financing payment 10 days prior to the starting date of the action. – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem and the ERC logo " to ensure more visibility of the European Research Council (ERC) funding under the European Union's Horizon 2020 research and innovation programme for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
3.0	20.07.2016	▪ The main changes compared to version 2.1 of the model grant agreement are as follows: – ntroduction of the option for Co-Principle Investigator (Co-PI) for all ERC Frontier Research grants, where the action is carried out under the guidance of more than one principle investigator. ○ Article 4.2 *'Budget transfers':* increased budget flexibility for beneficiaries, which may transfer amounts between forms of costs within the direct personnel costs budget category without an amendment to the grant agreement even if they did not foresee that form of cost in Annex 2. ○ Article 6.2.A *'Direct personnel costs'* to take into account to a larger extent the usual cost accounting practices of the beneficiaries by allowing them to calculate the hourly rate not only per full financial year but also per month. ○ Article 29.3 *'Open access to research data'* in order to align the ERC MGAs to the rules on open access of general H2020 MGA. ○ Article 34.1 *'Obligation to comply with ethical and research integrity principles'* in order to underline the standards of research integrity that beneficiaries must respect. ○ Article 34.2 *'Activities raising ethical issues'* in order to simplify the beneficiaries' reporting obligations on ethics before the beginning of an activity raising an ethical issue. ○ Article 36.1 *'General obligation to maintain confidentiality'* in

		order to allow broader access to confidential information in the case of the Commission/Agency staff, other EU institutions and bodies. ○ Article 48 *'Suspension of payments'* extends the possibility for the Commission/Agency to suspend the payment of the balance only for one or more beneficiaries. ○ Articles 48 *'Suspension of payments'*, 49 *'Suspension of action implementation'*, 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'* in order to clarify that for confidentiality reasons and to protect the personal data, in case of audits, reviews, investigations etc., the Commission/Agency will carry out the contradictory procedure directly with the beneficiary concerned (in this case the coordinator will also be informed). ○ Article 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'*: the Commission/Agency may terminate the participation of a beneficiary if it did not request an amendment to the grant agreement to terminate the participation of its linked third party which is under the same conditions as a beneficiary for which the participation may be terminated. For instance, the linked third party is bankrupt. Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
4.0	27.02.2017	▪ The main changes compared to version 3.0 of the model grant agreement are under: – Article 6.2.A "Direct personnel costs" – Article 6.2.A.2 'Personnel costs for natural persons working under a direct contract with the beneficiary' – Article 6.2.D.5 'Direct costs internally invoiced' – Article 6.2.E 'Indirect costs' – New Article 14a 'Implementation of action tasks by international partners' – Article 52.1 'Forms and means of communication' ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

European Research Council
Executive Agency

Established by the European Commission

MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1]
ERC STARTING GRANTS, CONSOLIDATOR GRANTS AND ADVANCED GRANTS[2]
(H2020 ERC MGA — MULTI)

Introductory remark

H2020 ERC MGA — Multi deviates from the General MGA— Multi as follows:

Generally:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- Annexes 2 (with two parts A and B) and 4 are different
- The table of contents is adapted
- Cross-references in the footnotes are adapted

In specific Articles:

- Preamble
- Article 5.2
- Article 7.1
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 32 (Provisions on the working conditions for the Principal Investigator)
- Article 41.3 (Provisions on internal arrangements)
- Article 56a (ERC specific Article on portability)

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **Text in grey indicates that text which appears in the H2020 General MGA does not apply in this grant agreement.**

- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the principal beneficiary':

[**full official name (short name)**] established in [official address in full] ***[OPTION for beneficiaries with VAT**: VAT number [insert number]]*, ***[OPTION for principal beneficiary not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname], hosting *[and engaging]* the following ***[OPTION by default: 'principal investigator':*** [4]

- *[**Name**] [Date and place of birth]]*[5]

[OPTION for SyG and other ERC grants with more than one principal investigator: 'corresponding principal investigator':

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 *'Mise en place de la Charte des ordonnateurs'*.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

- *[**Name**] [Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**] [Date and place of birth]*
- *[**Name**] [Date and place of birth]].**]***

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **[full official name] [short name]** established in [official address in full] *[**OPTION for beneficiaries with VAT:** VAT number [insert number]], **[OPTION for SyG and other ERC grants with more than one principal investigator:** hosting [and engaging] the '**other principal investigator(s)**' :*

- *[**Name**] [Date and place of birth]*

- *[**Name**] [Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)], established in [official address in full] [**OPTION for beneficiaries with VAT**: VAT number [insert number]], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC).**]**.*

[OPTION for SyG and other ERC grants with more than one principal investigator**: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 or 14a applies:** It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9)] [and] [international partners (see Article 14a)].]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');

- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[7] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

[7] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3 *[and A.6]*): the hourly rate is calculated *per full financial year,* as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}.

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or

- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespectively of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) during each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.1, A.2, A.4, A.5 *[and A.6]*): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[8]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

[8] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.**]***

[OPTION 2 to be used if foreseen in the work programme: *Not applicable.**]***

D.5 Costs of internally invoiced goods and services directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

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[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

[11] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action *[.][;]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

The beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator*[s]*.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 in accordance with Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.3, 20.4, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**:[insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION B, to be used if the beneficiary/ coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 20.4, 23a and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 14, 18.1.2, 20.4, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION 1 by default**:*

*these beneficiaries]**[OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

***[additional OPTION for beneficiaries requesting zero funding:** If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION 2:** Not applicable**]

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[12]**]

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

[12] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[13] (or 2014/24/EU[14]) or 'contracting entities' within the meaning of Directive 2004/17/EC[15] (or 2014/25/EU[16]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services. The costs will appear in the accounts of the beneficiaries and will be considered as costs incurred by them (see Article 6.1 and 6.2).

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

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[13] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[14] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.03.2014, p. 65).

[15] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

[16] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243)

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[17]]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified information:** Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

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[17] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[18] and **third parties with a legal link to a beneficiary**[19] ('**linked third parties**') may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name_)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
  [same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

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[18] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not constitute in themselves control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[19] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following **international partners**[20] may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.2, 35, 36, 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

[20] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION 2:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the principal beneficiary — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[21]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

[21] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The principal beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the principal beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project]*.***]***

The principal beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods'**:

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must — within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);

- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and

- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for each beneficiary *[and linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from10 days before the starting date of the action (see Article 3) whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)]) is not paid to the principal beneficiary, but kept by the Agency for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary, together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

  - is positive, it will be paid to the principal beneficiary,

  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the principal beneficiary the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the principal beneficiary — Distribution to the beneficiaries

Payments will be made to the principal beneficiary.

Payments to the principal beneficiary will discharge the Agency from its payment obligation.

The principal beneficiary must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][22]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the

[22] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the principal beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the principal beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the principal beneficiary may be terminated (see Article 50).

Such breaches may also lead to the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 17. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of

deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The principal beneficiary or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Agency or the Commission will formally notify the review report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission or the Agency in justified cases.

The '**final audit report**' will take into account observations by the principal beneficiary or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [23]and No 2185/96[24] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot

[23] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[24] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[25], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION 2:** Not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘**extension of findings from this grant to other grants**’).

[25] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The Agency or the Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors, irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Agency or the Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:*** *five]* ***[OPTION 2 for low value grants:*** *three]* years after the payment of the balance.

The evaluation is considered to start on the date of the formal notification to the principal beneficiary or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The principal beneficiary or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[26].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

[26] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘**agreement on background**’).

‘**Background**’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the internal arrangements, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[27] established in an EU Member State or '**associated country**'[28], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

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[27] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[28] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership **agreement**, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 Agency ownership, to protect results

26.4.1 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after

the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 Agency ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the Agency may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

"The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiaries concerned must — up to four years after the period set out in Article 3 — inform the Agency.****]***

If results are incorporated in a standard, the beneficiaries concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

"Results incorporated in this standard have received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

29.3 Open access to research data

[OPTION 1 for actions participating in the Open Research Data Pilot (in line with the provisions in the ERC work programme): *Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified in the **data management plan;***

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1,

*would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2:** Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem, the ERC logo and

(b) include the following text:

> "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

[OPTION 1 for EU grants: *The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*

(b) *the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*

- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*

- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the Agency decision, within the period set out above;*

- *if the Agency objects;*

- *until the conditions are complied with, if the Agency objection comes with conditions.]*

[OPTION 2:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the internal arrangements, access to results must also be given — under fair and reasonable conditions (see Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

[OPTION 2:** Not applicable**]

31.6 Access rights for principal investigator*[s]*

The beneficiaries must — on a royalty-free basis — give access to the principal investigator*[s]* to results needed for *[his/her][their]* activities under the action.

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator[s] and [his/her][their] team

The beneficiaries must respect the following working conditions for the principal investigator*[s]* and *[his/her][their]* team:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[29] — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding]* principal investigator to supervise the scientific and technological implementation of the action ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary and the other*

[29] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

principal investigator(s)] immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);

- any personal grounds affecting the implementation of the action;

- any changes in the information that was used as a basis for signing the supplementary agreement;

- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[30].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;

[30] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

- ensure objectivity, accuracy and impartiality when disseminating the results;

- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3****]*** as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced;

- make the necessary references to their work and that of other researchers;

- refrain from practicing any form of plagiarism, data falsification or fabrication;

- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the principle beneficiary to the Agency (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[31], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

[31] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

*For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities), —inform the coordinator, which must request written approval from the Agency.****]***

*In case of change to the security context, the beneficiaries must inform the coordinator which must immediately inform the Agency and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL) and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[32] *— until it is declassified.*

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the Agency.

*In case of change to the security context, the beneficiaries must inform the coordinator which must immediately inform the Agency and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION 1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the Agency (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[32] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

[OPTION 2:** Not applicable**]

37.4 Consequences of non-compliance

***[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable:** If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC Logo and

(b) include the following text:

> For communication activities: "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC Logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC Logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency and Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency and the Commission are not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency and the Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency and the Commission may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material received from any beneficiary or principal investigator (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the Agency's or the Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency or the Commission not to use it (see Article 52).

The right to use a beneficiary's or principal investigator's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency, the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001[33], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency or the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary and the principal investigator), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries or the principal investigator), the Agency or the Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Research Council Executive Agency (ERCEA) and the *[European Union (EU)][Euratom]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 45/2001[34] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency or the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

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[33] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[34] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the Agency and Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Agency or the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the principal beneficiary (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the principal beneficiary immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the principal beneficiary in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the scientific reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **principal beneficiary** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The principal beneficiary may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the principal beneficiary is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the principal beneficiary: *As an exception, the principal beneficiary delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The principal beneficiary retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries

The beneficiaries must have '**internal arrangements**' regarding their operation and co-ordination, covering all aspects of their cooperation and implementation of the action, to ensure the action is implemented properly (including decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *(including for disputes between the principal investigators and between them and the beneficiaries)****]*** and division of responsibilities for cases of rejection of costs or reduction of the grant).

The internal arrangements must not contain any provision contrary to this Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Agency will — after **termination of the participation of a beneficiary,** at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant**, see Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the rejection of costs does not lead to a recovery (see Article 44), the Agency will formally notify the principal beneficiary or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The principal beneficiary or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Agency will follow the contradictory procedure with 'pre-information letter' set out in Article 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs after **termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary *[and its linked third parties]* in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Agency may — **after termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — reduce the grant, if:

(a) a beneficiary (or a natural person who has power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles), or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the principal beneficiary or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant after **termination of the participation of a beneficiary,** it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the Agency for costs declared by its linked third parties)****]****,* except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency or the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[35] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

[35] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the* Agency*:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the principal beneficiary has not distributed amounts received (see Article 21.7), the Agency will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency or the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Agency or the Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the scientific reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the scientific or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles), or

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the Agency will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the Agency will formally notify the principal beneficiary or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency will formally notify the principal beneficiary or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The principal beneficiary must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The principal beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the principal beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the principal beneficiary or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the principal beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The principal beneficiary or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may — with the agreement of the principal investigator*[s]* — terminate the Agreement.

The principal beneficiary must formally notify termination to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the open reporting period until termination; see Article 20.3) and

(ii) the final scientific report (see Article 20.3).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic financial report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the principal beneficiary, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The principal beneficiary must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the principal beneficiary's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

- a report on the distribution of payments to the beneficiary concerned and
- if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, scientific organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the principal beneficiary (see Article 49.1) and either:

(i) resumption is impossible or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action— with respect to the state of the art — is no longer of scientific or technological relevance or no longer has any breakthrough potential ;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) ***[OPTION 1:*** *despite a specific request by the Agency, a beneficiary does not request— through the coordinator— an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l), (m) or (n) and to reallocate its tasks****][OPTION 2:*** *not applicable****];***

(o) *[a][the]* principal investigator is no longer in a position to continue working under the action.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding****]*** principal investigator):

- **informing** of its intention to terminate and the reasons why, and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding****]*** principal investigator) **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify the principal beneficiary or beneficiary concerned (with copy to the ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *corresponding****]*** principal investigator) that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii), (n) and (o) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the last open reporting period until termination) (see Article 20.3) and

(ii) a final scientific report (see Article 20.2).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.6 and 50.3.1(l)), the principal beneficiary may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must, within 60 days from when termination takes effect, submit:

- a report on the distribution of payments to the beneficiary concerned;

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case the request for amendment must propose a new principal beneficiary, and

- if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual

financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the Agency.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Agency will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the

Guarantee Fund to pay the principal beneficiary and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment, and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the Agency finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The Agency will formally notify the principal beneficiary and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the official mailing address indicated on the Agency's website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[36], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The principal beneficiary submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of principal beneficiary is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;

[36] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

- the appropriate supporting documents, and

- for a change of principal beneficiary without its agreement: the opinion of the principal beneficiary (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary ***[OPTION for SyG and other ERC grants with more than one principal investigator:*** *or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned]]*.

[additional OPTION for international organisations that would accept an applicable law clause but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]* ***[****by the law of [Belgium][[insert name of another Member State or EFTA country]]****]*** *[and, where appropriate,] [by the general*

principles governing the law of international organisations and the rules of general international law]

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]* ***[****by the law of [Belgium][[insert name of another Member State or EFTA country]]****]*** *[and, where appropriate,] [by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations]****.]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the Agency and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the principal beneficiary, depending on which is later.

SIGNATURES

For the principal beneficiary	For the Agency
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

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MODEL ANNEX 2 FOR H2020 ERC MGA — MULTI

PART B: ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)									EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs		E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding/ international partners
Form of costs[5]	Actual	Unit[6]	Unit[7]		Actual	Actual	Unit[8]	Flat-rate[9] 25%							
	a	Total b	No hours	Total c	d	e	Total f	g=0,25x(a+b+c+e+f-l)	h = a+b+c+d+e+f+g	i	j	k	l	Yes/No	
1 [short name beneficiary]															
[short name linked third party]															
[short name linked third party not eligible for EU funding]															
[short name linked third party requesting zero EU funding]															
[short name international partner]															
Total beneficiary															
2 [short name beneficiary]															
[short name linked third party]															
Total beneficiary 2															
X [short name beneficiary not eligible for EU funding][10]															
X [short name beneficiary requesting zero EU funding][10]															
[short name linked third party][11]															
Total beneficiary															
Total consortium															

[1] See Article 6 for the eligibility conditions

[2] Indirect costs covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] See Article 5 for the forms of costs

[6] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[7] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[8] Unit and costs per unit: calculated according to the beneficiary's usual accounting practice

[9] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

[10] See Article 9 for beneficiaries not receiving EU funding

[11] Only for linked third parties that receive EU funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{{ EUR 4,650 / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

Country-specific correction coefficient (in force at the time of the call):

EU Member States

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AT	104.8%	DK	135.3%	HR	97.5%	LV	75.9%	SE	111.7%
BE	100.0%	EE	78.3%	HU	76.2%	MT	89.6%	SI	86.1%
BG	71.5%	EL	92.7%	IE	113.5%	NL	104.3%	SK	82.6%
CY	91.8%	ES	97.6%	IT	106.7%	PL	76.4%	UK	120.3%
CZ	83.8%	FI	116.6%	LT	73.1%	PT	89.1%		
DE	98.8%	FR	111.0%	LU	100.0%	RO	68.3%		

H2020 associated countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AL	76.1%	FO	134.1%	LI	110.0%	MK	68.4%	TR	86.6%
BA	73.6%	IL	108.7%	MD	61.1%	NO	131.9%		
CH	113.1%	IS	116.6%	ME	66.9%	RS	67.1%		

Other countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AM	89.9%	CU	83.8%	JP	115.9%	NI	57.3%	TJ	64.9%
AO	114.6%	CV	76.4%	KE	78.1%	NP	73.5%	TL	78.3%
AR	58.5%	DJ	93.4%	KG	83.1%	NZ	94.1%	TN	70.5%
AU	105.0%	DO	66.9%	KH	70.5%	PA	57.0%	TO	85.0%
AZ	93.0%	DZ	81.7%	KR	105.2%	PE	75.5%	TT	74.1%
BB	116.6%	EC	68.8%	KZ	100.2%	PG	83.0%	TW	83.6%
BD	47.2%	EG	48.6%	LA	77.7%	PH	65.8%	TZ	65.2%

BF	93.8%	ER	61.2%	LB	86.4%	PK	49.4%	UA	92.3%
BJ	92.6%	ET	85.2%	LK	61.6%	PS	100.4%	UG	65.7%
BM	151.5%	FJ	68.1%	LR	100.1%	PY	71.9%	US	99.4%
BO	51.3%	GA	113.1%	LS	56.7%	RU	115.5%	UY	75.3%
BR	92.0%	GE	89.5%	LY	60.0%	RW	87.3%	UZ	51.4%
BW	55.3%	GH	68.2%	MA	83.5%	SA	84.8%	VE	70.0%
BY	65.0%	GM	67.7%	MG	80.0%	SB	93.3%	VN	51.1%
BZ	75.3%	GN	60.4%	ML	90.4%	SD	65.1%	VU	112.6%
CA	86.4%	GT	78.8%	MR	64.5%	SG	102.5%	WS	75.8%
CD	127.6%	GW	102.7%	MU	72.7%	SL	85.2%	XK	58.6%
CF	114.3%	GY	58.9%	MW	76.0%	SN	86.2%	YE	68.1%
CG	124.9%	HK	93.8%	MX	70.4%	SR	50.6%	ZA	55.8%
CI	102.0%	HN	69.0%	MY	71.6%	SV	74.3%	ZM	66.4%
CL	67.1%	HT	108.7%	MZ	71.6%	SY	74.8%	ZW	47.2%
CM	103.3%	ID	75.3%	NA	68.3%	SZ	56.8%		
CN	85.0%	IN	52.8%	NC	128.9%	TD	125.3%		
CO	76.6%	JM	94.9%	NE	87.9%	TG	88.7%		
CR	76.7%	JO	75.5%	NG	92.4%	TH	65.0%		

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment: For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] ***]***

Estimated number of units: see Annex 2

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new principal beneficiary (short name)**] established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number]]*, (*['the beneficiary']['the principal beneficiary']*), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][principal beneficiary]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the principal beneficiary] **and** the European Research Council Executive Agency (ERCEA ('the Agency'), *under the power delegated by the European Commission ('the Commission'),]*

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the principal beneficiary *to submit and sign in its name and on its behalf any* ***amendments*** *to the Agreement, in accordance with Article 55.]*

By signing this Accession Form, the beneficiary accepts the grant and agrees to *[**OPTION: for new principal beneficiaries:** take on the obligations and role of principal beneficiary and to]* implement it in accordance with the Agreement, with all the obligations and conditions it sets out *[**OPTION for new beneficiaries:,** as from [insert date] [the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date')** [**additional OPTION for change of beneficiary due to partial takeover**:, and with joint and several liability for undue amounts paid to [insert short name of former beneficiary] (i.e. recoveries)] — if the [Commission][Agency] agrees with the request for amendment**]**.*

SIGNATURE

For the beneficiary/new beneficiary/new principal beneficiary:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the Agency)

[**full official name of the entity affiliated or linked to the beneficiary (short name)**], established in [official address in full], *[**OPTION for linked third parties with VAT:** VAT number [insert number]]* ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number]]* ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the Agency by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the Agency, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 ERC MGA — MULTI

FINANCIAL STATEMENT FOR BENEFICIARY [name]/ LINKED THIRD PARTY [name] FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)										Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs			E. Indirect costs[2]	Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that			D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Unit	Flat-rate[5] 25%						
	a	Total b	No hours	Total c	d	e	*[f]*	Total g	h=0,25x(a+b+c+e +*[f]*+g -n)	i = a+b+c+d+e+*[f]* +g+h	j	k	l	m	n
[short name beneficiary/linked third party]															

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less.

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The principal beneficiary must submit to the Agency the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the principal beneficiary the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission, the Agency, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;

- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission the Agency, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission the Agency, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement
[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the *[Commission] [Agency]* in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The *[Commission] [Agency]* may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation, , the Beneficiary's usual remuneration practice for projects funded under national funding schemes …); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *'ADDITIONAL REMUNERATION' MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.* *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE QUALIFIES AS "ADDITIONAL REMUNERATION" AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	methodology was consistently used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary;	14) The natural persons worked under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed..	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the employment conditions of staff in the same category to compare costs and; ○ any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	15) The results of work carried out belong to the Beneficiary, or if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself.	
		16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		17) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: ○ their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; ○ if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the	18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		19) The results of work carried out belong to the Beneficiary, or if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	*If personnel is seconded against payment:* 20) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total	22) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	number of hours worked was calculated and that the contracts specified the annual workable hours.	23) Productive hours were calculated annually.	
	If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.	24) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
	BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS: ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.*	*If the Beneficiary applied method B.* 25) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary. 25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	*If the Beneficiary applied method C.* 26) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		Beneficiary.	
		27) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal	28) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 29) The Beneficiary used the Commission-approved metho-dology to calculate hourly rates. It corresponded to the organisation's usual cost	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; o (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	accounting practices and was applied consistently for all activities irrespective of the source of funding. *For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 30) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary. *For option II concerning individual hourly rates:* 31) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined. 31.2) The hourly rates do not include additional remuneration.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	32) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		33) Their time-records were authorised at least monthly by the project manager or other superior.	
		34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	36) The exclusive dedication is supported by a declaration signed by the Beneficiary and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		39) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		41) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; **b)** the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	42) All minimum conditions were met	
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the*	43) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	total, whichever number is the highest). The Auditor inspected the sample and verified that: ○ travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; ○ travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; ○ no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).	travels.	
		44) There was a link between the trip and the action.	
		45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		46) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: ○ the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; ○ they were correctly allocated to the action (with supporting documents such as delivery	47) Procurement rules, principles and guides were followed.	
		48) There was a link between the grant agreement and the asset charged to the action.	
		49) The asset charged to the action was traceable to the accounting records and the underlying documents.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		51) The amount charged corresponded to the actual usage for the action.	
		52) No ineligible costs or excessive or reckless expenditure were declared. 53)	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual	54) Contracts for works or services did not cover tasks described in Annex 1.	
		55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
		58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	
		60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly.	
		61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
D.5	**Costs of internally invoiced goods and services** **The Auditor sampled cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 62-66 listed in the next column, the Auditor:	62) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs); ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding; ○ verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of internally invoiced goods and services (see Article 6 GA); ○ verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and verifiable information. ○ verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services. ○ verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.	63) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding.	
		64) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.	
		65) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.	
		66) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	67) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	68) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options *[in italics in square brackets]*: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission*[, the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[2] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;

[2] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

2. Brief description of the time recording system in place;
3. An example of the time records used by the *[Beneficiary] [Linked Third Party]*;
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the *[Beneficiary] [Linked Third Party]* and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the *[Beneficiary] [Linked Third Party]* in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the *[Beneficiary] [Linked Third Party]* in connection with Article 18.1.2 of the Agreement;
- may not be used by the *[Beneficiary] [Linked Third Party]* or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the *[Beneficiary] [Linked Third Party]*.

No conflict of interest[3] exists between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[3] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 full-time equivalents are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s), complemented by other employees irrespective of their assignments until he has reached 10 employees.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
for the purpose of implementing the EU or Euratom budget in the same period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90 % of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	<u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[1]].*	The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: - *...]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

European Commission

H2020 Model Grant Agreement for ERC Starting Grants, Consolidator Grants and Advanced Grants — Multi (H2020 ERC MGA — Multi)

Version 2.1
1. October 2015

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

Research and Innovation

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	▪ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	▪ The main changes compared to version 1 of the model grant agreement are as follows: – Article 20.6 "Currency for financial statements and conversion into euro" to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" to give the possibility to the beneficiaries to receive the pre-financing payment 10 days prior to the starting date of the action. – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem and the ERC logo " to ensure more visibility of the European Research Council (ERC) funding under the European Union's Horizon 2020 research and innovation programme for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

European Research Council
Executive Agency

Established by the European Commission

H2020[1] MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR ERC STARTING GRANTS, CONSOLIDATOR GRANTS AND ADVANCED GRANTS[2] (H2020 ERC MGA — MULTI)

Introductory remark

H2020 ERC MGA — Multi deviates from the General MGA— Multi as follows:

Generally:

- 'Coordinator' is replaced by 'principal beneficiary' (also in the Annexes)
- *[Agency][Commission]* is replaced by 'Agency'
- References to/options for Euratom are taken out
- 'Technical report(s)' is replaced by 'scientific report(s)'
- Annexes 2 (with two parts A and B) and 4 are different
- The table of contents is adapted
- Cross-references in the footnotes are adapted

In specific Articles:

- Preamble
- Article 5.2
- Article 7.1
- Articles 11.1, 12.1, 13.1, 50.1.1, 50.1.2., 50.2.2, 50.3.1, 50.3.2., 50.3.3. (reference to financial or scientific reporting where necessary)
- Articles 15 and 16 (not applicable)
- Articles 20 and 21 (ERC specific articles on reporting and payment)
- Articles 25.4, 26.3, 27.3, 28.2, 29.2, 29.3, 29.4, 31.4, 31.6, 38.1.2, 38.2.1 (reference to the ERC funding, the ERC logo and the Principal Investigator where necessary)
- Article 32 (Provisions on the working conditions for the Principal Investigator)
- Article 41.3 (Provisions on internal arrangements)
- Article 56a (ERC specific Article on portability)

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] ERC grants (i.e. Starting Grants, Consolidator Grants, Advanced Grants and Synergy Grants) fund excellent investigators and their research teams for ground-breaking, high-gain/high-risk research at the frontiers of knowledge.

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **Text in grey indicates that text which appears in the General MGA — Multi is not applicable in this grant agreement.**

- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname][3],

and

on the other part,

1. 'the principal beneficiary':

[**full official name (short name)**] [legal form] [official registration No] established in [official address in full] [VAT number], ***[OPTION for principal beneficiary not receiving EU funding:*** *as 'beneficiary not receiving EU funding' (see Article 9),* ***]*** represented for the purposes of signing the Agreement by [function, forename and surname], hosting *[and engaging]* the following ***[OPTION by default: 'principal investigator':*** [4]

- *[**Name**] [Date and place of birth]* ***]***[5]

[OPTION for SyG: 'corresponding principal investigator':

[3] The person representing the Agency must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.2.2001 *'Mise en place de la Charte des ordonnateurs'*.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

- *[**Name**][Date and place of birth]*

*[and '**other principal investigator(s)**':*

- *[**Name**][Date and place of birth]*
- *[**Name**][Date and place of birth]].**]***

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **[full official name]** **[short name]** [legal form] [official registration No] [official address in full] [VAT number*], **[OPTION for SyG:** hosting [and engaging] the '**other principal investigator(s)**' :*

- *[**Name**][Date and place of birth]*

- *[**Name**][Date and place of birth]*

[same for each beneficiary]

[OPTION for beneficiaries not receiving EU funding:** X. [full official name (short name)] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)].*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the principal beneficiary ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC).**]***.

[OPTION for SyG**: Unless otherwise specified, references to 'principal investigator' or 'principal investigators' include the corresponding principal investigator.**]

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it, under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

[OPTION if one of the unit costs applies: *2a Additional information on the estimated budget****]***

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the Agency: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the beneficiaries' *[and linked third parties']* eligible costs for the action (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2)**.**

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);

(c) **for direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) for **specific cost category(ies)**: not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the Agency (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Agency.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Agency rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[7] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

[7] For the definition, see Article 2.1(14) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 ***[OPTION by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[8]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

[8] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[9] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[10]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.**]***

[OPTION to be used if foreseen in the work programme: *Not applicable.**]***

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

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[9] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[10] For the definition see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

(a) costs of subcontracting *[and]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[11] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 141.1.****]***

[OPTION: *Not applicable****]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

[11] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

The beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the principle beneficiary and does not have linked third parties receiving EU funding: *Chapter 3, Articles*

*10 to 14, 18.1.2, 20.3, 20.4, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

***[OPTION 2, to be used if the beneficiary/ coordinator not receiving EU funding has linked third parties receiving EU funding:** Chapter 3, Articles 10 to 14, 20.4, 23a and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

***[OPTION 3, to be used if the beneficiary not receiving EU funding IS the principle beneficiary and does not have linked third parties receiving EU funding:** Chapter 3, Articles 10 to 14, 18.1.2, 20.4, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.**]***

[OPTION:** Not applicable**]

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[12]]***

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[13] or 'contracting entities' within the meaning of Directive 2004/17/EC[14] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed

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[12] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[13] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[14] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

equipment, infrastructure or other assets or other contributed goods and services. The costs will appear in the accounts of the beneficiaries and will be considered as costs incurred by them (see Article 6.1 and 6.2).

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Agency may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[15]***]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic financial report, and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the Agency (see Article 37).****]***

[15] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[16] and **third parties with a legal link to a beneficiary**[17] (**'linked third parties'**) may implement the action tasks attributed to them in Annex 1:*

[16] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not constitute in themselves control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[17] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name_)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the

costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the principal beneficiary — which must immediately inform the Agency and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[18]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

[18] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Agency may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The principal beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the principal beneficiary breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The principal beneficiary must submit to the Agency (see Article 52) the scientific and financial reports set out in this Article. The financial report includes the requests for payments.

The reports must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Scientific reporting — Reporting periods

The action is divided into the following '**scientific reporting periods**':

- SRP1: from month 1 to month [X]
- ***[****- SRP2: from month [X+1] to month[Y]*
- *SRP3: from month [Y+1] to month [Z]*
- *[same for other SRPs]*
- *final SRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must submit to the Agency a:

- '**periodic scientific report**' within 60 days after the end of each period (except the last one) and

- '**final scientific report**' within 60 days after the end of the last reporting period.

The **periodic scientific report** must include:

(a) information about the **scientific progress** of the work;

(b) **achievements and results** of the action, such as publications and a declaration of any major change of scientific strategy;

(c) information on whether and how open access has been provided to these results (see Article 29);

(d) a summary of the achievements of the action for publication by the Agency.

The **final scientific report** must:

(a) present the **final results, achievements and conclusions** of the action, and how they have been disseminated (including via scientific publications) (see Article 29);

(b) contain a summary of the achievements of the action, for publication by the Agency.

20.3 Financial reporting — Payment requests — Reporting periods

The action is divided into the following '**financial reporting periods'**:

- FRP1: from month 1 to month [X]
- ***[****- FRP2: from month [X+1] to month[Y]*
- *FRP3: from month [Y+1] to month [Z]*
- *[same for other FRPs]*
- *final FRP: from month [N+1] to [the last month of the project].****]***

The principal beneficiary must — within 60 days after the end of each period — submit to the Agency a '**financial report**' for each reporting period.

The **financial report** must contain:

(a) information on the eligible costs, including a '**breakdown of direct costs table**' and a '**budget follow-up table**';

(b) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]* for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in a financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The final financial statements must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(c) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Agency to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(d) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including the **request for interim payment** (or — for the last financial reporting period — the **request for payment of the balance**);

(e) for the last financial reporting period only: a '**certificate on the financial statements**' (see Annex 5) for each beneficiary *[and linked third party]*, if it requests a total

contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.4 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.5 Language of reports

All reports (scientific and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.6 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the principal beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the principal beneficiary:

- one **pre-financing payment;**

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The Agency will — except if Article 48 applies — make the pre-financing payment to the principal beneficiary within 30 days, either from the entry into force of the Agreement (see Article 58) or from10 days before the starting date of the action (see Article 3) whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the Agency from the pre-financing payment and transferred into the '**Guarantee Fund**'.

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the principal beneficiary, but kept by the Agency for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the principal beneficiary the amount due as interim payment within 90 days from receiving the financial report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

Step 1 — Application of the reimbursement rate

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the Agency (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount specified in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the financial report and the final scientific report (see Article 20), except if Articles 47 or 48 apply.

Payment is subject to the approval of the financial and final scientific reports. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the principal beneficiary, together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the principal beneficiary,

    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Agency will formally notify to the principal beneficiary the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Agency will make all payments in euro.

21.7 Payments to the principal beneficiary — Distribution to the beneficiaries

Payments will be made to the principal beneficiary.

Payments to the principal beneficiary will discharge the Agency from its payment obligation.

The principal beneficiary must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][19]

[19] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the principal beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the principal beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the principal beneficiary may be terminated (see Article 50).

Such breaches may also lead to the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Agency and the Commission

22.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 17. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The principal beneficiary or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Agency or the Commission will formally notify the review report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the principal beneficiary or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the principal beneficiary or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The principal beneficiary or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the principal beneficiary or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission or the Agency in justified cases.

The '**final audit report**' will take into account observations by the principal beneficiary or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [20]and No 2185/96[21] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[22], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

[20] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[21] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[22] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the Agency or the Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Agency or the Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Agency or the Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Agency or the Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]* ***[OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the principal beneficiary or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The principal beneficiary or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[23].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

[23] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘**agreement on background**’).

‘**Background**’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the internal arrangements, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[24] established in an EU Member State or '**associated country**'[25], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

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[24] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.-

[25] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

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identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

Unless otherwise agreed in the joint ownership **agreement**, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel and the principal investigator[s])

If third parties (including personnel and the principal investigator*[s]*) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results for a beneficiary, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 Agency ownership, to protect results

26.4.1 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Agency and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Agency takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The Agency may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Agency at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Agency decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 Agency ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the Agency may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Agency requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiaries concerned must — up to four years after the period set out in Article 3 — inform the Agency.****]***

If results are incorporated in a standard, the beneficiaries concerned must — unless the Agency requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard have received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication, which must include a persistent identifier.

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29.3 Open access to research data

[OPTION for grants wishing to participate on a voluntary basis in the open Research Data Pilot in the framework of an ERC frontier research action (if opt-in option provided for by the ERC work programme): *Regarding the digital research data generated in the action (‘**data**’), the beneficiaries must take appropriate measures to ensure open access, including:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(ii) other data, including associated metadata, as specified is Annex 1;

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of one of the action objectives, as described in Annex 1,

*would be jeopardised by making those specific parts of the research data openly accessible. In this case, the Annex 1 must contain the reasons for not giving access.**]***

[OPTION:** Not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem, the ERC logo and

(b) include the following text:

> "This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC logo without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Agency right to object to transfers or licensing

[OPTION for EU grants: *The Agency may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the Agency considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the Agency before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Agency may request additional information.

If the Agency decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the Agency decision, within the period set out above;*
- *if the Agency objects;*
- *until the conditions are complied with, if the Agency objection comes with conditions.**]***

[OPTION:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the internal arrangements, access to results must also be given — under fair and reasonable conditions (see Article 25.3) — to affiliated entities established in

an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

[OPTION by default for EU grants: *The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).***]**

31.6 Access rights for principal investigators

The beneficiaries must — on a royalty-free basis — give access to the principal investigator*[s]* to results needed for *[his/her][their]* activities under the action.

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — WORKING CONDITIONS FOR THE PRINCIPAL INVESTIGATOR*[S]* AND *[HIS/HER][THEIR]* TEAM

32.1 Obligations towards the principal investigator[s] and [his/her][their] team

The beneficiaries must respect the following working conditions for the principal investigator*[s]* and *[his/her][their]* team:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[26] — in particular regarding working conditions,

[26] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

transparent recruitment processes based on merit and career development — and ensure that the principal investigator*[s]*, researchers and third parties involved in the action are aware of them;

(b) enter — before signature of the Agreement — into a '**supplementary agreement**' with the*[ir]* principal investigator, that specifies:

(i) the obligation of the beneficiary to meet its obligations under the Agreement;

(ii) the obligation of the *[**OPTION for SyG:** corresponding]* principal investigator to supervise the scientific and technological implementation of the action *[**OPTION for SyG:** and the obligation of the other principal investigator(s) to supervise the scientific and technological implementation of their part of the action and to contribute to the overall proper implementation of the action]*;

(iii) the obligation of the *[**OPTION for SyG:** corresponding]* principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the financial reporting *[**OPTION for SyG:** and the obligation of the other principal investigator(s) to contribute to the scientific and financial reporting]*;

(iv) the obligation of the principal investigator to meet the time commitments for implementing the action as described in Annex 1;

(v) the obligation of the principal investigator to apply the beneficiary's usual management practices;

(vi) the obligation of the principal investigator to inform the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary and the other principal investigator(s)]* immediately of any events or circumstances likely to affect the Agreement (see Article 17) , such as:

- a planned transfer of the action (or part of it) to a new beneficiary (see Article 56a);

- any personal grounds affecting the implementation of the action;

- any changes in the information that was used as a basis for signing the supplementary agreement;

- any changes in the information that was used as a basis for awarding the grant;

(vii) the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

(viii) the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary during the implementation of the action and afterwards;

(ix) the obligation of the principal investigator to maintain confidentiality (see Article 36);

(x) for a transfer of the action (or part of it) to a new beneficiary (see Article 56a): the obligation of the principal investigator to:

- propose to the principal beneficiary *[**OPTION for SyG:** and, where applicable, to his/her beneficiary]* (in writing) to what extent the action will be transferred and the details of the transfer arrangement *[**OPTION for SyG:** and, if the transfer is done by (one of) the other principal investigator(s), the obligation of the corresponding principal investigator to verify that the principal investigator has informed his/her beneficiary and the principal beneficiary];*

- provide a statement to the principal beneficiary *[**OPTION for SyG:** and, where applicable, his/her beneficiary]* with the detailed results of the research up to the time of transfer;

(xi) the right of the Commission and the Agency, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 also towards the principal investigator;

(xii) the applicable law and the country in which disputes must be settled;

(c) provide the principal investigator*[s]* with a copy of the signed Agreement;

(d) guarantee the principal investigator*[s]* scientific independence, in particular for the:

(i) use of the budget to achieve the scientific objectives;

(ii) authority to publish as senior author and invite as co-authors those who have contributed substantially to the work;

(iii) preparation of scientific reports for the action;

(iv) selection and supervision of the other team members (hosted *[and engaged]* by the beneficiary or other legal entities), in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices;

(v) possibility to apply independently for funding;

(vi) access to appropriate space and facilities for conducting the research;

(e) provide — during the implementation of the action — research support to the principal investigator*[s]* and the*[ir]* team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research);

(f) support the principal investigator*[s]* and provide administrative assistance, in particular for the:

(i) general management of the work and his/her team

(ii) scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator*[s];*

(iii) financial reporting, especially providing timely and clear financial information;

(iv) application of the beneficiary's usual management practices;

(v) general logistics of the action;

(vi) access to the electronic exchange system (see Article 52);

(g) inform the principal investigator*[s]* immediately (in writing) of any events or circumstances likely to affect the Agreement (see Article 17);

(h) ensure that the principal investigator*[s]* enjoy*[s]* adequate:

(i) conditions for annual, sickness and parental leave;

(ii) occupational health and safety standards;

(iii) insurance under the general social security scheme, such as pension rights;

(i) allow the transfer of the Agreement to a new beneficiary ('portability'; see Article 56a).

32.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[27] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the principal beneficiary must submit (see Article 52) to the Agency copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

[27] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

If these documents are not in English, the principal beneficiary must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The principal beneficiary must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the Agency may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Agency may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[28], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

[28] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the Agency.****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the Agency.

*The beneficiaries must inform the coordinator — which must immediately inform the Agency — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

***[OPTION:** Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the Agency (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION:** Not applicable**]

37.4 Consequences of non-compliance

***[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable:** If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Agency (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem and the ERC logo

Unless the Agency requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the European Union emblem and the ERC Logo and

(b) include the following text:

For communication activities: “This project has received funding from the European Research Council (ERC) under the European Union’s Horizon 2020 research and innovation programme (grant agreement No [number])”.

For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement No [number])".

When displayed together with another logo, the EU emblem and the ERC Logo must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem and the ERC Logo without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem, the ERC Logo or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Agency responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Agency

38.2.1 Right to use beneficiaries' materials, documents or information

The Agency may use, for its own communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material such as pictures or audio-visual material that it receives from any beneficiary or principal investigator (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the Agency's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Agency not to use it (see Article 52).

The right to use a beneficiary's or principal investigator's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating

through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation (EC) No 1049/2001[29], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of exploitation set out in points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

If the right of use is subject to rights of a third party (including personnel of the beneficiary and the principal investigator), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries or the principal investigator), the Agency will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Research Council Executive Agency (ERCEA) under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 45/2001[30] and according to the 'notifications of the processing

[29] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[30] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency or the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement(s) (SSPS)' that are published on the Agency and Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the service specific privacy statement(s) (SSPS) (see above), before transmitting their data to the Agency or the Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Agency or the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the principal beneficiary (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the principal beneficiary immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the principal beneficiary in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the scientific reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

(b) The **principal beneficiary** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(iv) submit the deliverables and reports to the Agency (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Agency of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Agency.

The principal beneficiary may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the principal beneficiary is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the principal beneficiary: *As an exception, the principal beneficiary delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The principal beneficiary retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries

The beneficiaries must have '**internal arrangements**' regarding their operation and co-ordination, covering all aspects of their cooperation and implementation of the action, to ensure the action is implemented properly (including decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement ***[OPTION for SyG:*** *(including for disputes between the principal investigators and between them and the beneficiaries)****]*** and division of responsibilities for cases of rejection of costs or reduction of the grant).

The internal arrangements must not contain any provision contrary to this Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The Agency will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the Agency rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the principal beneficiary or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The principal beneficiary or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary

financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The Agency may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a '**pre-information letter**' to the principal beneficiary or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Agency reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Agency will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Agency will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the Agency for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the principal beneficiary), the Agency will claim back the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency or the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[31] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Agency will formally notify a '**pre-information letter**' to the principal beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the principal beneficiary to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the principal beneficiary to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the principal beneficiary a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the principal beneficiary does not repay the Agency by the date in the debit note and has not submitted the report on the distribution of payments: the Agency or the Commission will **recover** the amount set out in the debit note from the principal beneficiary (see below).

If the principal beneficiary does not repay the Agency by the date in the debit note, but has submitted the report on the distribution of payments: the Agency will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

[31] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the principal beneficiary}.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the* Agency*:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]****[OPTION:*** *not applicable;]*

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Agency.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Agency* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the Agency multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the principal beneficiary has not distributed amounts received (see Article 21.7), the Agency will also recover these amounts.

The Agency will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to

the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The Agency or the Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the Agency:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the Agency may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the Agency or the Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the Agency.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and

- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the Agency can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, the Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the scientific reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Agency will formally notify the principal beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the principal beneficiary may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the sceintific or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Agency may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the Agency will formally notify the principal beneficiary:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency will formally notify the principal beneficiary.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the Agency resumes payments, the principal beneficiary may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The principal beneficiary must immediately formally notify to the Agency the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the principal beneficiary must immediately formally notify the Agency and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Agency

49.2.1 Conditions

The Agency may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the principal beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the principal beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The principal beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 46).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may — with the agreement of the principal investigator*[s]* — terminate the Agreement.

The principal beneficiary must formally notify termination to the Agency (see Article 52), stating:

(a) the reasons why and

(b) the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the open reporting period until termination; see Article 20.3) and

(ii) the final scientific report (see Article 20.3).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic financial report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible. Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the principal beneficiary, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The principal beneficiary must formally notify termination to the Agency (see Article 52) and inform the beneficiary concerned.

If the principal beneficiary's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the principal beneficiary. In this case, the request for amendment must propose a new principal beneficiary.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The principal beneficiary must — within 30 days from when termination takes effect — submit:

- a report on the distribution of payments to the beneficiary concerned and
- if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement will be **amended** to introduce the necessary changes (see Article 55).

The Agency will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the Agency). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

    - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

    - in all other cases (in particular if termination takes effect after the period set out in Article 3), the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

    - if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

        - termination takes effect after an interim payment and

        - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

    In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

50.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, scientific organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the principal beneficiary (see Article 49.1) and either:

(i) resumption is impossible or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action— with respect to the state of the art — is no longer of scientific or technological relevance or no longer has any breakthrough potential ;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**');

(n) *[a][the]* principal investigator is no longer in a position to continue working under the action.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator):

- **informing** of its intention to terminate and the reasons why, and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator) **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify the principal beneficiary (with copy to the ***[OPTION for SyG:*** *corresponding****]*** principal investigator) that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the principal beneficiary.

50.3.3 Effects

(a) for **termination of the Agreement**:

The principal beneficiary must — within 60 days from when termination takes effect — submit:

(i) a periodic financial report (for the last open reporting period until termination) (see Article 20.3) and

(ii) a final scientific report (see Article 20.2).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.6 and 50.3.1(l)), the principal beneficiary may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the Agency (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The principal beneficiary must, within 60 days from when termination takes effect, submit:

- a report on the distribution of payments to the beneficiary concerned;

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the principal beneficiary. In this case the request for amendment must propose a new principal beneficiary, and

- if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, information on the eligible costs (including a breakdown of direct costs table), the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Agency will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the Agency). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the principal beneficiary the amount unduly received. The Agency will formally notify the amount unduly received and request the beneficiary concerned to repay it to the principal beneficiary within 30 days of receiving notification. If it does not repay the principal beneficiary, the Agency will draw upon the Guarantee Fund to pay the principal beneficiary and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44).

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the Agency will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit

note, the Guarantee Fund will pay to the Agency the amount due and the Agency will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former principal beneficiary, it must repay the new principal beneficiary the amount unduly received, unless:

  - termination takes effect after an interim payment, and

  - the former principal beneficiary has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the Agency will formally notify a **debit note** to the former principal beneficiary. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Agency the amount due. The Agency will then pay the new principal beneficiary and notify a debit note on behalf of the Guarantee Fund to the former principal beneficiary (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Agency does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Agency does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the principal beneficiary did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the principal beneficiary.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated— before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The Agency will formally notify the principal beneficiary and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Agency** must be sent to the following address:

[*European Commission]*[*name of the Agency]*
[*Directorate-General]*[*Department]* [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[32], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

[32] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The principal beneficiary submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of principal beneficiary is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of principal beneficiary without its agreement: the opinion of the principal beneficiary (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into

force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and, for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party****]***.

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the principal beneficiary must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the principal beneficiary must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 56a — TRANSFER OF THE AGREEMENT TO A NEW BENEFICIARY — PORTABILITY OF THE GRANT

56a.1 Conditions

[The][A] principal investigator may request the transfer of the action (or his/her part of it) to a new beneficiary, provided that the objectives of the action remain achievable.

The principal beneficiary ***[OPTION for SyG:*** *or, where applicable, his/her beneficiary]* may object only on the basis that the transfer is not possible under national law.

56a.2 Procedure

The principal beneficiary must formally notify a **request for amendment** to the Agency (see Article 55).

56a.3 Effects

The former beneficiary must agree with the principal investigator and the new beneficiary on a plan to transfer the intellectual property rights under the Agreement to the new beneficiary

The Agency will request the former beneficiary to transfer to the new beneficiary any part of the pre-financing (see Article 21) not covered by an approved financial report.

If requested by the principal investigator, the Agency may require the former beneficiary to transfer to the new beneficiary the equipment purchased and used exclusively for the action (against reimbursement of the costs that have not yet been depreciated). The former beneficiary may object only on the basis that the transfer is not possible under national law.

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium *[**OPTION for international organisations that do not accept application of Union law:** except for [insert name(s) of the international organisations concerned]]*.

[OPTION for international organisations that accept application of Union law but not Belgian law:** For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].**]

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)**: As an exception, if such a dispute is between the Agency and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.**]

***[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice:** As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the principal beneficiary, depending on which is later.

SIGNATURES

For the principal beneficiary	For the Agency
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

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MODEL ANNEX 2 FOR H2020 ERC MGA — MULTI

PART B: ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)								EU contribution				Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs	E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]		Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*							Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
Form of costs[5]	Actual	Unit[6]	Unit[7]		Actual	Actual	Flat-rate[8] 25%								
	a	Total b	No hours	Total c	d	e	f=0,25x(a+b+c+e-k)	g = a+b+c+d+e+f	h	i	j		k	Yes/No	
1 [short name beneficiary]												**1 [short name beneficiary]**			
[short name linked third party]												**[short name linked third party]**			
[short name linked third party not receiving EU funding]												**[short name linked third party not receiving EU funding]**			
												...			
Total beneficiary												**Total beneficiary**			
2 [short name beneficiary]												**2 [short name beneficiary]**			
[short name linked third party]												**[short name linked third party]**			
												...			
Total beneficiary 2												**Total beneficiary**			
X [short name beneficiary not receiving EU funding][9]												**X [short name beneficiary not receiving EU funding]**			
[short name linked third party][10]												**[short name linked third party]**			
												...			
Total beneficiary												**Total beneficiary**			
												...			
Total consortium												**Total consortium**			

[1] See Article 6 for the eligibility conditions

[2] The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] See Article 5 for the forms of costs

[6] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[7] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[8] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

[9] See Article 9 for beneficiaries not receiving EU funding

[10] Only for linked third parties that receive EU funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate')*:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary]

* Amount calculated as follows:
{[insert amount for MSC-IF living allowance of the Main Work Programme — MSCA in force at the time of the call] / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

Country correction coefficient: [insert the country-specific correction coefficient table for MSC actions of the Main Work Programme — MSCA in force at the time of the call]

Estimated number of units: see Annex 2

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new principal beneficiary (short name)**][legal form], [beneficiary No], established in [official address in full] [VAT number], (*[‘the beneficiary’][‘the principal beneficiary’]*), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][principal beneficiary]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] (‘the Agreement’)

between [full official name of the principal beneficiary] **and** the European Research Council Executive Agency (ERCEA (‘the Agency’)*, under the power delegated by the European Commission (‘the Commission’),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the principal beneficiary *to submit and sign in its name and on its behalf any* ***amendments*** *to the Agreement, in accordance with Article 55.**]***

By signing this Accession Form, the beneficiary accepts the grant and agrees to ***[OPTION: for new principal beneficiaries:*** *take on the obligations and role of principal beneficiary and to]* implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:,*** *as from [insert date] [the date of signature of the Accession Form][the date of entry into force of the amendment] (**‘accession date’**) — if the [Commission][Agency] agrees with the request for amendment]*.

SIGNATURE

For the beneficiary/new beneficiary/new principal beneficiary:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the Agency)

[**full official name of the entity affiliated or linked to the beneficiary (short name)**][legal form], [beneficiary No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)][legal form], [beneficiary No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the Agency by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the Agency, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

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MODEL ANNEX 4 FOR H2020 ERC MGA — MULTI

FINANCIAL STATEMENT FOR BENEFICIARY [name]/ LINKED THIRD PARTY [name] FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)									Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	D. Other direct costs		E. Indirect costs[2]	Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Flat-rate[5] 25%						
	a	Total b	No hours	Total c	d	e	*[f]*	g=0,25x(a+b+c+*[f]* -m)	h = a+b+c+d+e+*[f]* +g	i	j	k	l	m
[short name beneficiary/linked third party]														

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, if the 90% limit (see Article 21) is reached, etc).

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting and costs of in-kind contributions not used on premises (see Article 6.2.E)

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[33] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The principal beneficiary must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the principal beneficiary the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[33] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[34]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[34] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[35] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement
[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[35] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[36] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[36] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); ○ recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
	(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR; *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	methodology was consistently used in all H2020 actions. 11) The employees were charged under the correct category. 12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts. 13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors). To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices,	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions). 15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary). 16) The results of work carried out belong to the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting records, etc.).	17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR*	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	(THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).	Beneficiary.	
	C. *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.*	*If the Beneficiary applied method C.* 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor:	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2.	*For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
	<u>"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":</u> *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *<u>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		40) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; **b)** the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	43) All minimum conditions were met	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table);	50) The asset charged to the action was traceable to the accounting records and the underlying documents.	
		51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
	The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value).	52) The amount charged corresponded to the actual usage for the action.	
	The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	53) No ineligible costs or excessive or reckless expenditure were declared. 54)	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting	55) Contracts for works or services did not cover tasks described in Annex 1.	
		56) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE*	57) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 58) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups. 59) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report.*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.	*The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	60) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	
		61) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly.	
		62) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	63) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	64) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options *[in italics in square brackets]*: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[37]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[37] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[38] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;

[38] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[39] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[39] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
for the purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[40]].*	internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

[40] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: *- ...]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]

[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

Multi-beneficiary General Model Grant Agreement

Version 1.0
11 December 2013

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

Research and Innovation

[*EUROPEAN COMMISSION/Executive Agency*]
DG
Directorate
Unit

MULTI-BENEFICIARY GENERAL MODEL GRANT AGREEMENT

- **Footnotes in yellow will appear in the text generated by the IT system for signature (since they contain definitions or references to legal documents). The other footnotes will not stay in the text (since they are internal instructions only).**
- **Text in grey indicates that text which figures in the Multi-beneficiary General MGA is not applicable in the Mono-beneficiary General MGA.**
- **For options [*in italics, in square brackets*]: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

- **Information on formatting:**

  styles

CHAPTER	**style 'Chapter'**
SECTION	**style 'Section'**
SUBSECTION	**style 'Subsection'**
ARTICLE 1	**style 'Article'**
4.1 Estimated budget	**style 'Subarticle'**
Text (without list)	**style 'Normal'**
Table of Content levels (black)	**style 'TOC 1', 'TOC 2', 'TOC 3', 'TOC 4', 'TOC 5'**

Footnotes: Paragraph - special (hanging 0,5) ('Times New Roman', '10 pt')

attention: text with a list must be formatted manually ('Times New Roman', '12 pt', 'Justified')

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[1],]*

[1] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission'),**]

[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission'),**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[2]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][legal form], [official registration No], established in [official address in full] [VAT number],

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the administrative arrangement (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the administrative arrangement]*, the beneficiaries accept the grant and agree to implement

[2] The person representing the *[Commission][Agency]* must be an authorising officer (by delegation or sub-delegation) designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative arrangement****]***

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** insert date]*[3] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:*** *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

[3] This date must always be the first day of a month and it must be later than the date of entry into force of the agreement unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

- ***[OPTION if lump sum foreseen in Article 5.2**: adjust amounts set out as lump sums in Annex 2;]***

- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research actions: 100 %** of the action's eligible costs] [**OPTION for innovation actions**[4] **if all beneficiaries and all linked third parties are non-profit legal entities**[5]**: 100%** of the action's eligible costs][**OPTION for innovation actions if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the other beneficiaries [and linked third parties][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding personnel costs for the activities in Point (f))]*[6]:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

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[4] *For the definition, see Article 2.1(5a) of the Rules for Participation Regulation (EU) No XX/2013: 'innovation action' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.*

[5] *For the definition, see Article 2.1(10a) Rules for Participation Regulation (EU) No XX/2013: 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.*

[6] To be used only if option in Point (f) is used.

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs for the activities in Point (f))]*[7]: as actually incurred costs (**actual costs**);

(c) ***[OPTION to be used if Article 15 applies**: for **direct costs of providing financial support to third parties** [(excluding costs of financial support given under the activities in Point (f))]*[8]*: as actually incurred costs (**actual costs**);][OPTION**: not applicable;]***

(d) for **other direct costs** *[(excluding other direct costs for the activities in Point (f))]*[9]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs for the activities in Point (f))]*[10]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

*[(f) **[OPTION for specific categories of costs if unit costs foreseen by Commission decision:** for **costs of [insert cost category or activity**[11]]:*

- *on the basis of the amount(s) per unit set out in Annex 2 (**unit costs**) [or]*
- *[as actually incurred costs (**actual costs**)]*[12]*[or*
- *as a combination of the two].]*

[OPTION for specific categories of costs if lump sum costs foreseen by Commission decision:** for **costs of [insert cost category or activity**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]]

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

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[7] To be used only if option in Point (f) is used.
[8] To be used only if option in Point (f) is used.
[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump-sum. For example: costs of 'providing transnational access to research infrastructures'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'.
[12] To be used only if the Commission decision authorising the use of the unit cost allows that the beneficiary chooses between actual or unit cost.

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. **[*OPTION to be used if Article 15 applies:** direct costs of providing financial support to third parties;**] [*OPTION:** not applicable*;**]**
D. other direct costs;
E. indirect costs;
F. **[*OPTION for specific categories of costs if unit costs foreseen by Commission decision**: costs of [insert cost category or activity*[13]*]***]**.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs *[(not included in Point F)]*

<u>Types of eligible personnel costs</u>

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[14] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

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[13] Insert precise name of the costs as in the Commission decision authorising the use of the unit cost or lump sum. For example: costs of 'providing trans-national access to research infrastructure'; costs of 'clinical studies'; costs of 'energy efficiency measures in buildings'

[14] For the definition, see Article 2.1(10a) of Regulation (EU) No XX/2013 of the European Parliament and of the Council of XX laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L XX, XX, p.XX) ('**Rules for Participation Regulation No XX/2013**'): '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting *[(not included in Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

C. Direct costs of providing financial support to third parties *[(not included in Point F)]* ***[OPTION to be used if Article 15 applies:*** *are eligible if the conditions set out in Article 15 are met.]* ***[OPTION****: not applicable]*

D. Other direct costs *[(not included in Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

D.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.****]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[15]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.****]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).****]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

[15] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

D.4 ***[OPTION by default:*** *The* ***capitalised and operating costs of 'large research infrastructure'***[16] *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[17]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.****]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *not applicable.****]***

[OPTION to be used if foreseen in the work programme: *not applicable****.]***

E. Indirect costs *[(not included in Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION to be used if Article 15 applies:*** *costs of providing financial support to third parties][****OPTION****: not applicable]****[****and*

[16] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[17] For the definition see Article 2(f) of Regulation (EU) No XXX/2013 of the European Parliament and of the Council of XX 2013 establishing H2020 - The Framework Programme for Research and Innovation (2014-2020): '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

(d) ***OPTION if Point F applies and the unit or lump sum cost includes indirect costs:*** *[unit costs under Article 5.2(f) and Point F below)][lump sum costs under Article 5.2(f) and Point F below]****]****.*

Beneficiaries receiving an operating grant[18] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[F. OPTION for specific categories of costs if unit costs foreseen by Commission decision: Costs of [insert cost category(ies) or activity(ies)]

Costs of [insert cost category or activity]:

(a) *declared as* ***unit costs****: are eligible if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units, and if [insert eligibility conditions];*

(b) *[declared as* ***actual costs****: are eligible, if they comply with the conditions set out above (Points A to [D][E]) [and if [insert eligibility conditions];]*

(c) *[declared as a* ***combination of the two****: if the part declared as actual costs fulfils the conditions for actual costs and the part declared as unit costs fulfils the conditions for unit costs].*

[same for each specific category of costs]

[OPTION for specific lump sum costs (i.e. costs which may be/have to be declared as lump sum costs) if foreseen by Article 5.2(f)): Costs of [insert cost category or activity] *are eligible if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]****]***

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: *Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.****]***

[OPTION: *not applicable****]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* —

[18] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('**Financial Regulation No 966/2012**'): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

[OPTION for beneficiaries not receiving EU funding: *Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*

- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

*Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 26.4, 28.1 [**OPTION:** with the exception of additional exploitation obligations], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.*

They will not be subject to financial checks, reviews and audits under Article 22.

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.]

***[OPTION:** not applicable]*

9.2 Consequences of non-compliance

[If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION:** not applicable]*

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

***[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].[19]]*

[19] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[20] or 'contracting entities' within the meaning of Directive 2004/17/EC[21] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

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[20] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[21] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[22]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

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[22] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a ***request for offers*** *from at least* ***three providers*** *(including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC* [23]***.]***

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').****]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified deliverables: *Classified deliverables may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

[23] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

The beneficiaries must ensure that the Commission *[and the Agency]*, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

[OPTION: *14.1.1 The following* ***affiliated entities***[24] *and* ***third parties with a legal link to a beneficiary***[25] *('****linked third parties****') may implement the action tasks attributed to them in Annex 1:*

[24] For the definition see Article 2.1(2) Rules for Participation Regulation No XX/2013: '**affiliated entity**' means any legal entity that:
- is under the direct or indirect control of a beneficiary, or
- is under the same direct or indirect control as the beneficiary, or
- directly or indirectly controls a beneficiary.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity or
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities do not constitute control relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[25] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity], affiliated or linked to [name or acronym of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked entities]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

*14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.**]***

[OPTION:** not applicable**]

14.2 Consequences of non-compliance

***[**If any obligation under Article 14.1.1 is breached, the costs of the third party will be ineligible (see Article 6) and will be rejected (see Article 42).*

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

***[OPTION to be used if foreseen in the work programme:** 15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION:** not applicable**]

15.2 Financial support in the form of prizes

***[OPTION to be used if foreseen in the work programme:** 15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that the Commission [and the Agency], the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION:** not applicable**]

15.3 Consequences of non-compliance

***[**If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

***[OPTION trans-national access to research infrastructure:** 16.1.1 '**Access providers**'[26] must provide access to research infrastructure or installations[27] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) categories of users that may have access:

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*

- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that will disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;

(c) procedure and criteria for selecting user groups:

[26] **'Access provider'** means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[27] '**Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a ***selection panel*** *set up by the access providers.*

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]****]***[28].

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.****]***

[OPTION: *not applicable****]***

[28] If the authorising officer considers necessary to give priority to certain categories of users.

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: *'**Access providers**'*[29] *must provide access to research infrastructure or installations*[30] *in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting or identifying the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION: *not applicable**]***

16.3 Consequences of non-compliance

[*If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *not applicable**]***

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 Obligation to provide information upon request

[29] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[30] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

The beneficiaries must provide — during implementation of the action or afterwards — any information requested in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]****[OPTION for low value grants[31]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

[31] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('Rules of Application Regulation No 1268/2012'): '**low value grants**' are lower or equal to EUR 60 000.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the *[Commission][Agency]*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these

conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *[Commission][Agency]* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*[;][.]*

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and*

information on the users (including names, nationality and home institutions).] ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure****];***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the Commission to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[32]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the*

[32] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

[Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.

This information is required for the [Commission's][Agency's] accounting purposes and will not be used to calculate the final grant amount.]

***[OPTION:** not applicable]*

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days from the starting date of the action (see Article 3) or from the entry into force of the Agreement (see Article 58), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 – Application of the reimbursement rates

Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the Commission or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][33]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

[33] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission *[and the Agency]*

22.1.1 Right to carry out checks

The Commission *[or the Agency]* will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission *[or the Agency]* may be assisted by external persons or bodies.

The Commission *[or the Agency]* may also request additional information in accordance with Article 17. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including

information on the use of resources). The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Commission *[or the Agency]* may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission *[or the Agency]* may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission *[or the Agency]* may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Commission *[or the Agency]* will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission *[or the Agency]* in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission *[or the Agency]* may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [34]and No 2185/96[35] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[36], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court*

[34] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[35] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[36] Regulation (EU, EURATOM) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, EURATOM)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION:** not applicable]*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission *[or the Agency]* may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission *[or the Agency]* will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Commission *[or the Agency]* on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission *[or the Agency]* in justified cases.

The Commission *[or the Agency]* will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission *[or the Agency]* does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission *[or the Agency]* accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission *[or the Agency]* intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission *[or the Agency]* does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission [*or the Agency*] accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission *[or the Agency]* may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]**[OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission *[or the Agency]* may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission *[or the Agency]* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[37].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

[37] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[38] established in an EU Member State or '**associated country**'[39], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

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[38] For the definition, see footnote 24.

[39] For the definition, see Article 2.1(3) Rules for Participation Regulation No XX/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in Article 7 of Regulation (EU) No XX/2013 of the European Parliament and of the Council of XX establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ XXX) ('**Horizon 2020 Framework Programme Regulation No XX/2013**').
Article 7 of the Horizon 2020 Framework Programme Regulation No XX/2013 sets out the conditions for association of non-EU countries to Horizon 2020.

25.5 Access rights for third parties

[OPTION for access to research infrastructures: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give access to the users to the background of the access provider needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *not applicable****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018"]*;

- the name of the action, acronym and grant number;

- the publication date, and length of embargo period if applicable, and

- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION:** not applicable**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.****]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —****]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions.* ***]***

[OPTION: *not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

[OPTION for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens': *The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

[OPTION for Euratom grants: *The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme*: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries*[40]*, for the purposes of the complementary grant agreement(s) (see Article 2).**]***

[OPTION for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]***

[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for*

[40] '**Complementary beneficiary**' means a beneficiary of a complementary grant agreement.

interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

[OPTION for access to research infrastructures: *The access provider must give the users access to the results, if needed to implement the action.]*

[OPTION: *not applicable]*

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[41], in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

[41] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[42] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

[42] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

[OPTION for activities potentially involving research on human embryos or human embryonic stem cells: *Activities involving research on human embryos or human embryonic stem cells may be carried out only if:*

- *they are set out in Annex 1 or*

- *the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).**]***

[OPTION**: not applicable**]

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(b) need to know to implement the Agreement and

(c) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for participation Regulation No XXX/2013[43], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

[OPTION: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *not applicable****]***

37.2 Classified deliverables

[OPTION: *Activities related to 'classified deliverables' (see Annex 1) must comply with the '**security requirements**' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the [Commission][Agency].

[43] Regulation (EU) No XX/2013 of the European Parliament and of the Council of XX laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L XX, XX, p. XX).

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary — request for Annex 1 to be amended (see Article 55).**]***

[OPTION:** not applicable**]

37.3 Activities involving dual-use goods or dangerous materials and substances

***[OPTION:** Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION:** not applicable**]

37.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating

through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[44], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][Agency]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Commission][Agency]*

Any personal data under the Agreement will be processed by the *[Commission][Agency]* under Regulation No 45/2001[45] and according to the 'notifications of the processing

[44] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[45] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

operations' to the Data Protection Officer (DPO) of the *[Commission][Agency]* (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *[Commission][Agency]* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *[Commission's][Agency's]* websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Commission][Agency]*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *[Commission][Agency]*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES *[— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES] [— RELATIONSHIP WITH PARTNERS OF A JOINT ACTION]*

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *[Commission][Agency]* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Commission][Agency]*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*

- *settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION:** not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*

- *settlement of disputes.*

The coordination agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*

- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** not applicable**]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:**, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented**]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the

periodic or final summary financial as set out in Articles 21.3 or 21.4. statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]****,* except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable, and/or****]***

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from

the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[46] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Commission][Agency]* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

[46] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Commission][Agency]* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable****]***

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Commission][Agency]* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[and Article 106a of the Euratom Treaty]* (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Commission][Agency]* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make

other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until

termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

- the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1.****][OPTION:*** *not applicable****];***

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION:*** *not applicable****];***

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary

concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *[Commission][Agency]* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Commission's][Agency's]* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or

- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission*][*name of the Agency*]
[*Directorate-General*][*Department*] [complete]
[*Directorate* [*complete*]]
Unit [complete]

[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[47], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

[47] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

[OPTION if Article 14 applies and joint and several liability has been requested: *If the [Commission][Agency] has requested joint and several liability of a linked third party, the beneficiary to which it is linked must also submit — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.]*

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium. [***OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned]*]

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the rules of the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *For the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

disputes with the [Commission][Agency] relating to the Agreement must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

The arbitral award will be binding on all parties and will not be subject to appeal.]

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator	For the *[Commission][Agency]*
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

① print format A4 landscape

MODEL ANNEX 2 FOR GENERAL MGA - MULTI-BENEFICIARY

ESTIMATED BUDGET FOR THE ACTION

ANNEX 2

	Estimated eligible* costs (per budget category)												EU contribution				Additional information	
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs	E. Indirect costs	*[F. Costs of …]*			Total costs	Reimbursement rate %	Maximum EU contribution ***	Maximum grant amount		Information for indirect costs :	Information for auditors:
	A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services D.4 Costs of large research infrastructure		*[F.1 Costs of …] **	*[F.2 Costs of …]**							Costs of in-kind contributions not used on premises	Declaration of costs under Point D.4
Form of costs****	Actual	Unit ①	Unit ② XX EUR/hour		Actual	Actual	Actual	Flat-rate ③ 25%	Unit ④ XX EUR/hour		Unit ⑤							
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)	(g)=0,25x((a)+(b)+(c)+(f)+[(h1)]⑥+[(h2)]⑥-(m))	No units	Total (h1)	Total (h2)	(i) = (a)+(b)+(c)+(d)+(e)+(f)+(g)+(h1)+(h2)	(j)	(k)	(l)		(m)	Yes/No
Beneficiary 1																**Beneficiary 1**		
Linked third party 1a																**Linked third party 1a**		
Linked third party 1b																**Linked third party 1b**		
…																**…**		
Total Beneficiary 1																**Total Beneficiary 1**		
Beneficiary 2																**Beneficiary 2**		
Linked third party 2a																**Linked third party 2a**		
Linked third party 2b																**Linked third party 2b**		
…																**…**		
Total Beneficiary 2																**Total Beneficiary 2**		
…																**…**		
Total Consortium																**Total Consortium**		

* See Article 6 for conditions for costs to be eligible
** Depending on its type, this cost will or will not include indirect costs.
Costs that include indirect costs are: costs of energy efficiency measures in buildings, costs of providing trans-national access to research infrastructure and costs of clinical studies.
*** This is the theoretical amount of EU contribution if the reimbursement rate is applied to *all* the budgeted costs. The theoretical amount of EU contribution for the action is capped by the maximum grant amount.
**** See Article 5 for forms of costs
① unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
② unit : hours worked on the action; cost per unit : XX EUR
③ flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under Point F if they include indirect costs
④ unit : … ; costs per unit : XX EUR
⑤ unit : ….. costs per unit …… (the units,the costs per unit and the estimated number of units will be agreed with the beneficiaries in a separate document that becomes part of Annex 2 of their grant agreement)
⑥ only unit costs **not including indirect costs** to be added

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary**], [short name] [legal form], [official registration No], established in [official address in full] [VAT number], ('the beneficiary'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become beneficiary ('insert beneficiary no ..')

in Agreement No [insert agreement number] ('the Agreement')

between [full official name of the coordinator] **and** *[the European Union ('the EU', represented by the European Commission ('the Commission'] [the European Atomic Energy Community ('Euratom'), represented by the European Commission ('the Commission'),]**[***[the [Research Executive Agency (REA)][European Research Council Executive Agency (ERCEA)][Innovation and Networks Executive Agency (INEA)][Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the power delegated by the European Commission ('the Commission'),***]***

for the action entitled [insert title of the action (insert acronym)].

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the [Commission][Agency])

[**full official name of the entity affiliated or linked to the beneficiary**], [short name of the entity], [legal form], [official registration No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary], [short name], [legal form], [official registration No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the *[Commission][Agency]* by the beneficiary under grant agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex II).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the *[Commission][Agency]*, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR GENERAL MGA - MULTI-BENEFICIARY

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]*

	Eligible* costs (per budget category)													Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs	*[F. Costs of …]*			Total costs	Receipts	Reimbursement rate %	Maximum EU contribution ***	Requested EU contribution	Information for indirect costs :
	A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services	D.4 Costs of large research infrastructure		*[F.1 Costs of …] **	*[F.2 Costs of …]**			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs**	Actual	Unit ①	Unit ② XX EUR/hour		Actual	Actual	Actual	Actual	Flat-rate ③ 25%	Unit ④ XX EUR/unit		Unit ⑤						
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)	(g)	(h)=0,25x((a)+(b)+(c)+(f)+ (g)+ [(i1)]⑥+[(i2)]⑥-(o))	No units	Total (i1)	Total (i2)	(j) = (a)+(b)+(c)+(d)+(e)+(f)+(g)+(h)+(i1)+(i2)	(k)	(l)	(m)	(n)	(o)

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ The beneficiary/linked party must declare all eligible costs, even if - for actual costs, unit costs and flat-rate costs - they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*

* See Article 6 for conditions for costs to be eligible
** Depending on its type, this cost will or will not include indirect costs.
Costs that include indirect costs are: costs of energy efficiency measures in buildings, costs of providing trans-national access to research infrastructure and costs of clinical studies.
*** This is the theoretical amount of EU contribution if the reimbursement rate is applied to *all* the reported costs. At the payment of the balance, the theoretical amount of EU contribution for the action is capped by the maximum grant amount.
**** See Article 5 for forms of costs
① unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
② unit : hours worked on the action; cost per unit : XX EUR
③ flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under Point F if they include indirect costs
④ unit : … ; costs per unit : XX EUR
⑤ unit : ….. costs per unit …… (the units and the costs per unit are set out in Annex 2 of the grant agreement)
⑥ only unit costs **not including indirect costs** to be added

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME 5

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[48] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[48] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commissionsets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[49]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Federation of Accountants (IFAC);
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*]. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[49] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IFAC.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[50] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[50] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.
….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.
….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[51] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[51] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
	(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR; *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors). To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices,	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	
		15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting records, etc.).	17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not exceed the third party's cost as	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated.	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
	If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours.	24) Productive hours were calculated annually.	
	If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.	25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
	BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS: ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS*	*If the Beneficiary applied method B.* 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE). ***C**. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method C.* 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
		28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor:	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. *<u>"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *<u>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex I; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and	38) The use of claimed subcontracting costs was foreseen in Annex I and costs were declared in the Financial Statements under the subcontracting category. 39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	40) The subcontracts were not awarded to other Beneficiaries of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex I; b) the financial support to third parties was agreed in Annex I of the Agreement and the other provisions on financial support to third parties included in Annex I were respected.	43) All minimum conditions were met	
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there*	44) Costs were incurred, approved and reimbursed in line with the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	
		50) The asset charged to the action was traceable to the accounting records and the underlying documents.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		52) The amount charged corresponded to the actual usage for the action.	
		53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment;	54) Contracts for works or services did not cover tasks described in Annex 1.	
		55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: ○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
		58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report. 60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	is highest): *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	figures.	
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME …….. 5

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[52]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Federation of Accountants (IFAC);
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*]. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[52] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IFAC.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[53] submitted thereafter.

[53] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs, why they are reasonable and how they are based on objective and verifiable information;

5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[54] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[54] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements, were reasonable and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].* X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.].* For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A or B detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
number is reduced proportionately. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[55]].*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of

[55] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: *- ...]*	productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager in reasonable time. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

EUROPEAN COMMISSION
DG/EXECUTIVE AGENCY

[Directorate]
[Unit][Director]

GENERAL MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1] (H2020 GENERAL MGA — MULTI)

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

The main changes compared to version 1 of the model grant agreement are as follows:

- Article 20.6 "Currency for financial statements and conversion into euro" in order to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects);
- Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" in order to give the possibility to the consortium to receive the pre-financing payment at an earlier date, namely 10 days prior to the starting date of the action.
- Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem" in order to ensure more visibility of EU funding for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action.

Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

***[OPTION 3:** the [**Research Executive Agency (REA)**] [**European Research Council Executive Agency (ERCEA)**] [**Innovation and Networks Executive Agency (INEA)**] [**Executive Agency for Small and Medium-sized Enterprises (EASME)**] ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],]*

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][legal form], [official registration No], established in [official address in full] [VAT number],

---

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

[OPTION for beneficiaries not receiving EU funding: *X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]***

[same for each beneficiary]

[OPTION if the JRC is a beneficiary: *and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)**]***.

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:*** *and the Joint Research Centre (JRC)**]***.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:*** *or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties**]***

[OPTION if the JRC participates: *3b Administrative Arrangement**]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)**: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2**: Lump sums set out in Annex 2 can never be adjusted.**]

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action's eligible costs] [**OPTION for innovation actions (IA)**[7]**, if all beneficiaries and all linked third parties are non-profit legal entities**[8]**: 100%** of the action's eligible costs][**OPTION for innovation actions (IA), if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs][**OPTION for innovation actions(IA), if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities][**OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

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[7] For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[8] For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[9] To be used only if option in Point (f) is used.

[10] To be used only if option in Point (f) is used.

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[11]: ***[OPTION to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][**OPTION**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2*[15] *(**unit costs**).]*

***[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant):** for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

***[OPTION: specific cost category(ies):** not applicable.]*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

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[11] To be used only if option in Point (f) is used.

[12] To be used only if option in Point (f) is used.

[13] To be used only if option in Point (f) is used.

[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc).

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;**] [OPTION:*** *not applicable;**]***
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit[/lump sum] costs****: [insert name(s) of specific cost category(ies)*[16]*]**][OPTION:*** *not applicable**]***.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs *[(not covered by Point F)]*

<u>Types of eligible personnel costs</u>

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[**A.6 [**OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.] [**OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.]**]

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

C. Direct costs of providing financial support to third parties *[(not covered by Point F)]* *[**OPTION to be used if Article 15 applies:** are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]*

*[**OPTION**: Not applicable]*

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

D.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they*

were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.****]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable****]***

[OPTION to be used if foreseen in the work programme: *Not applicable****]***

E. Indirect costs *[(not covered by Article Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

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[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION to be used if Article 15 applies:*** *costs of providing financial support to third parties [and][;]]**[OPTION**: not applicable;]*

(d) ***[OPTION if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]]* ***[OPTION:*** *not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

F. ***[OPTION: Insert name of specific cost category(ies)[22]][OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]***

[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant): *[**Insert name of specific cost category**] are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]***

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant): *[**Insert name of specific cost category**] are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]***

[same for each specific cost category]

[OPTION: *Not applicable**]***

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: Costs incurred by linked third parties *are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.**]***

[OPTION: *Not applicable**]***

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[21] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period*[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION 2, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

***[OPTION:** Not applicable]*

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[23]]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] or 'contracting entities' within the meaning of Directive 2004/17/EC[25] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

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[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[26]***]***

[26] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided.

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [27].**]***

Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[27] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

[OPTION only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*
- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').****]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[28] and **third parties with a legal link to a beneficiary**[29] ('**linked third parties**') may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [ishort name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

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[28] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[29] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

***[OPTION to be used if foreseen in the work programme:** 15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION:** Not applicable**]

15.2 Financial support in the form of prizes

***[OPTION to be used if foreseen in the work programme:** 15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION:** Not applicable**]

15.3 Consequences of non-compliance

***[OPTION to be used if 15.1 and/or 15.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: *16.1.1 '**Access providers**'[30] must provide access to research infrastructure or installations[31] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) categories of users that may have access:

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*

- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country[32] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;

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[30] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[31] '**Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[32] For the definition, see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.****]***

(c) procedure and criteria for selecting user groups:

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a ***selection panel*** *set up by the access providers.*

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]****]***[33].

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*

[33] If the authorising officer considers necessary to give priority to certain categories of users.

- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.**]***

[OPTION:** Not applicable**]

16.2 Rules for providing virtual access to research infrastructure

***[OPTION virtual access to research infrastructure:** '**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** Not applicable**]

16.3 Consequences of non-compliance

***[OPTION to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[35] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[36]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible

[36] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);]* ***[OPTION for providing access to virtual services:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]*

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial

statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[37]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION: *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

[37] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days *either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest*.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 – Application of the reimbursement rates

Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the coordinator

    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][38]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;

- the beneficiary bears the cost of transfers charged by its bank;

- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which

[38] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [39]and No 2185/96[40] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during

[39] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[41], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable;**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

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[40] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[41] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘**extension of findings from this grant to other grants**’).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected .

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the *[Agency or the]* Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the *[Agency or the]* Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the *[Agency or the]* Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the *[Agency or the]* Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the *[Agency or the]* Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]****[OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[42].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

[42] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[43] established in an EU Member State or '**associated country**'[44], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

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[43] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[44] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *Not applicable;****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border*

interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).]

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018"]*;

- the name of the action, acronym and grant number;

- the publication date, and length of embargo period if applicable, and

- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION:** Not applicable;**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if

it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —**]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*

- *if the Commission objects;*

- *until the conditions are complied with, if the Commission objection comes with conditions.* ***]***

[OPTION: *Not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

***[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and*

31.3 — access to their results to complementary beneficiaries[45]*, for the purposes of the complementary grant agreement(s) (see Article 2).**]***

[OPTION for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.**]***

[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.**]***

[OPTION for trans-national access to research infrastructure: *The access provider must give the users royalty-free access to the results needed to implement the action.**]***

[OPTION: *Not applicable**]***

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[46], in particular regarding:

- working conditions;

[45] '**Complementary beneficiary**' means a beneficiary of a complementary grant agreement.

[46] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

- transparent recruitment processes based on merit, and

- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[47] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

[47] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the *[Commission][Agency]* (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(b) need to know to implement the Agreement and

(c) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[48], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[48] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary — request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *Not applicable****]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION: *Not applicable****]***

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[49], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

[49] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][insert the name of the Agency]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *Agency and the]* Commission

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[50] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement(s) (SSPS)' that are published on the *[Agency and]* Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

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[50] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the]* Commission. For this purpose, they must provide them with the service specific privacy statement(s) (SSPS) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the 'Beneficiary Register' (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the] Commission*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION: *Not applicable****]***

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work programme*: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*

- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*

- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** Not applicable**]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:****, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented****]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[51] applies.

44.1.2 Recovery at payment of the balance

[51] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**,

minus

{pre-financing and interim payments received by the beneficiary}**}**.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator**}**.

If payment is not made by the date specified in the debit note, the *[*Commission*][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[*Commission*][Agency]* will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[*Commission*][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Agency or the]* Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission] [Agency]* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make

other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

- termination takes effect after an interim payment and

- the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION:*** *not applicable****];***

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION:*** *not applicable****];***

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and

- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or

- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission][name of the Agency]*
[*Directorate-General][Department]* [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[52], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

[52] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline , the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned]]*.

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according

to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.**]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).**]***

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator	For the *[Commission][Agency]*
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

ⓘ print format A4 landscape

MODEL ANNEX 2 FOR H2020 GENERAL MGA — MULTI

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)												EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs	E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]		Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*		*[F.1 Costs of …]*[5]	*[F.2 Costs of …]*[5]							Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Flat-rate[9]	Unit[10]		Unit[11]								
			XX EUR/hour					25%	XX EUR/unit										
	a	Total b	No hours	Total c	d	*[e]*	f	g = 0,25 x (a+b+c+f+ *[h1]*[12]+*[h2]*[12]-m)	No units	Total *[h1]*	Total *[h2]*	i = a+b+c+d+*[e]* +f+g+*[h1]*+*[h2]*	j	k	l		m	Yes/No	
1 [short name beneficiary]																**1 [short name beneficiary]**			
[short name linked third party]																**[short name linked third party]**			
[short name linked third party not receiving EU funding]																**[short name linked third party not receiving EU funding]**			
…																**…**			
Total beneficiary																**Total beneficiary**			
2 [short name beneficiary]																**2 [short name beneficiary]**			
[short name linked third party]																**[short name linked third party]**			
…																**…**			
Total beneficiary																**Total beneficiary**			
X [short name beneficiary not receiving EU funding][13]																**X [short name beneficiary not receiving EU funding]**			
[short name linked third party][14]																**[short name linked third party]**			
…																**…**			
Total beneficiary																**Total beneficiary**			
…																**…**			
Total consortium																**Total consortium**			

[1] See Article 6 for the eligibility conditions

[2] The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.

[6] See Article 5 for the forms of costs

[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[8] Unit : hours worked on the action; cost per unit (hourly rate) : […] EUR

[9] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs

[10] Unit : […] ; costs per unit : […] EUR

[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)

[12] Only specific unit costs that do not include indirect costs

[13] See Article 9 for beneficiaries not receiving EU funding

[14] Only for linked third parties that receive EU funding

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new coordinator (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], ('the beneficiary' or 'the coordinator'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][coordinator]* ('insert official registration no ..')

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the coordinator] **and** *[the European Union ('the EU', represented by the European Commission ('the Commission')] [the European Atomic Energy Community ('Euratom'), represented by the European Commission ('the Commission'),]**[**[the [Research Executive Agency (REA)][European Research Council Executive Agency (ERCEA)][Innovation and Networks Executive Agency (INEA)][Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the coordinator *to submit and sign in its name and on its behalf any* ***amendments*** *to the Agreement, in accordance with Article 55.**]***

By signing this Accession Form, the beneficiary accepts the grant and agrees to ***[OPTION: for new coordinators:*** *take on the obligations and role of coordinator and to]* implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:*** *as from [date] if the [Commission][Agency] agrees with the request for amendment]*.

SIGNATURE

For the beneficiary/new beneficiary/new coordinator:

[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary, if Article 14 applies and linked third party liability has been requested by the [Commission][Agency])

[**full official name of the entity affiliated or linked to the beneficiary (short name)**], [legal form], [official registration No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], [legal form], [official registration No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the *[Commission][Agency]* by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the *[Commission][Agency]*, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 GENERAL MGA — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)													Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*		*[F.1 Costs of …]*				Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit XX EUR/hour		Actual	Actual	Actual	Actual	Flat-rate[5] 25%	Unit XX EUR/unit		Unit						
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	h=0,25 x (a+b+c+f+*[g]* + *[i1]*[6] +*[i2]*[6] - o)	No units	Total *[i1]*	Total *[i2]*	j = a+b+c+d+*[e]* +f +*[g]* +h+*[i1]* +*[i2]*	k	l	m	n	o
[short name beneficiary/linked third party]																		

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, if the 90% limit (see Article 21) is reached, etc).

[4] See Article 5 for the form of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[53] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[53] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[54]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[54] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[55] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[55] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[56] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[56] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	
		7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
	(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR; *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u>	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	
		17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit;	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method B.* 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	
		If the Beneficiary applied method C. 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
		28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. *<u>"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *<u>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE*	accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.	*For option II concerning individual hourly rates:* 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system.	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).	36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	If the persons are working exclusively for the action and without time records For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	*(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		40) The subcontracts were not awarded to other Beneficiaries of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*).	43) All minimum conditions were met	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.		

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	
		50) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy. 52) The amount charged corresponded to the actual usage for the action. 53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular:	54) Contracts for works or services did not cover tasks described in Annex 1. 55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. 56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,**	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[57]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[57] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[58] submitted thereafter.

[58] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;

5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[59] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[59] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
for the purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[60]].*	internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

[60] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: *- ...]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

European Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020

H2020 General Model Grant Agreement — Multi (H2020 General MGA — Multi)

Version 2.1
1 October 2015

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

Research and Innovation

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	▪ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	▪ The main changes compared to version 1 of the model grant agreement are as follows: – Article 20.6 "Currency for financial statements and conversion into euro" in order to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" in order to give the possibility to the consortium to receive the pre-financing payment at an earlier date, namely 10 days prior to the starting date of the action. – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem" in order to ensure more visibility of EU funding for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

EUROPEAN COMMISSION
DG/EXECUTIVE AGENCY

[Directorate]
[Unit][Director]

GENERAL MULTI-BENEFICIARY MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1] (H2020 GENERAL MGA — MULTI)

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], ***[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),**]*** represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number],

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**] [legal form], [official registration No], established in [official address in full] [VAT number], as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

---

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

[OPTION if one of the unit costs applies: *2a Additional information on the estimated budget****]***

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action] — [insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION if needed for the action:** [insert date]]*[6] (‘**starting date of the action**’).

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The ‘**estimated budget**’ for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be used if Article 9 applies:** It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2**: Lump sums set out in Annex 2 can never be adjusted.**]

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The ‘**maximum grant amount**’ is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[**OPTION for research and innovation actions (RIA): 100 %** of the action’s eligible costs] [**OPTION for innovation actions (IA)**[7]**, if all beneficiaries and all**

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

linked third parties are non-profit legal entities[8]***: 100%*** *of the action's eligible costs]**[OPTION for innovation actions (IA), if all beneficiaries and all linked third parties are profit legal entities: 70%** of the action's eligible costs]**[OPTION for innovation actions(IA), if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%** of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and **70%** of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities]**[OPTION for exceptional cases if foreseen in the work programme: […%]** of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[11]: ***[OPTION to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][**OPTION**: not applicable;]*

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7 For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

8 For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

9 To be used only if option in Point (f) is used.

10 To be used only if option in Point (f) is used.

11 To be used only if option in Point (f) is used.

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2*[15] *(**unit costs**).]*

[OPTION for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): *for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

[OPTION: specific cost category(ies): *not applicable.]*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

---

[12] To be used only if option in Point (f) is used.

[13] To be used only if option in Point (f) is used.

[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[15] Annex 2 must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION to be used if Article 15 applies:*** *direct costs of providing financial support to third parties;]* ***[OPTION:*** *not applicable;]*
D. other direct costs;
E. indirect costs;
F. ***[OPTION for specific unit[/lump sum] costs****: [insert name(s) of specific cost category(ies)*[16]*]]****[OPTION:*** *not applicable]*.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[*A.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

<u>Calculation</u>

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

C. Direct costs of providing financial support to third parties *[(not covered by Point F)]* *[**OPTION to be used if Article 15 applies:** are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]*

*[**OPTION**: Not applicable]*

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

D.2 ***[OPTION by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

[OPTION (alternative to option above) to be used if foreseen in the work programme[18]: *The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).**]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services **for providing trans-national access to research infrastructure** are eligible only if also the conditions set out in Article 16.1.1 are met.**]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services **for providing virtual access to research infrastructure** are eligible only if also the conditions set out in Article 16.2 are met.**]***

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION by default:*** *directly used for the action are eligible, if:*

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[20]);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.**]***

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics):** Not applicable**]

[OPTION to be used if foreseen in the work programme:** Not applicable**]

E. Indirect costs *[(not covered by Article Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION to be used if Article 15 applies:** costs of providing financial support to third parties [and][;]][**OPTION**: not applicable;]*

(d) ***[OPTION if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:** [unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION:** not applicable.]*

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that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

F. *[OPTION: [Insert name of specific cost category(ies)[22]][OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]*

[OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category] *are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].]***

[OPTION for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category] *are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]***

[same for each specific cost category]

[OPTION: *Not applicable]***

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: Costs incurred by linked third parties *are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.]***

[OPTION: *Not applicable]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

[21] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period*[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION 1, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION 2, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION 3, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION by default**: these beneficiaries][**OPTION if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.***]**

[OPTION:** Not applicable]***

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[23]]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] or 'contracting entities' within the meaning of Directive 2004/17/EC[25] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

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[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[26]***]***

[OPTION for actions involving PCP or PPI: *In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

[26] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC [27].**]***

***[OPTION only for actions involving PCP:** The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

[27] See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').***]**

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[OPTION for classified results: *Classified results may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).***]**

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**[28] and **third parties with a legal link to a beneficiary**[29] ('**linked third parties**') may implement the action tasks attributed to them in Annex 1:*

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [ishort name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

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[28] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[29] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

***[OPTION to be used if foreseen in the work programme:** 15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION:** Not applicable**]

15.2 Financial support in the form of prizes

***[OPTION to be used if foreseen in the work programme:** 15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.]

***[OPTION:** Not applicable]*

15.3 Consequences of non-compliance

***[OPTION to be used if 15.1 and/or 15.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

***[OPTION:** Not applicable]*

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

***[OPTION trans-national access to research infrastructure:** 16.1.1 '**Access providers**'[30] must provide access to research infrastructure or installations[31] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

[30] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[31] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) categories of users that may have access:

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*

- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country[32] is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;

(c) procedure and criteria for selecting user groups:

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

*The user groups must be selected by a **selection panel** set up by the access providers.*

[32] For the definition, see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:** Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.**][OPTION for Euratom grants:** Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('**H2020 Euratom Research and Training Programme Regulation No 1314/2013**') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.**]***

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION:** In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]**][33].

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.**]***

[OPTION:** Not applicable**]

16.2 Rules for providing virtual access to research infrastructure

***[OPTION virtual access to research infrastructure:** '**Access providers**'[34] must provide access to research infrastructure or installations[35] in accordance with the following conditions:*

[33] If the authorising officer considers necessary to give priority to certain categories of users.

(a) access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION:** Not applicable**]

16.3 Consequences of non-compliance

***[OPTION to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION:** Not applicable**]

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

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[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[35] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION by default:*** *five]* ***[OPTION for low value grants[36]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

[36] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.**]***

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.**]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

[OPTION for providing access to trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****]***
[OPTION for providing access to virtual services: *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible,*

information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months[37]***:*** *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the start date of the action.*

[37] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.**]***

[OPTION:** Not applicable**]

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *[Commission][Agency]*, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 – Application of the reimbursement rates

Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries

[and the linked third parties] (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

- is positive, it will be paid to the coordinator
- is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Address of branch: […]
Full name of the account holder: […]

Full account number (including bank codes): […]
[IBAN code: […]][38]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

[38] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory**

audit procedure'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [39]and No 2185/96[40] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[41], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION:** Not applicable;**]

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[39] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[40] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[41] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected .

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the *[Agency or the]* Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the *[Agency or the]* Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the *[Agency or the]* Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the *[Agency or the]* Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the *[Agency or the]* Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION by default:*** *five]****[OPTION for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[42].

[42] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[43] established in an EU Member State or '**associated**

[43] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

country'[44], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION: *Not applicable;****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is

[44] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to

four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.****]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).****]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018"]*;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

*(ii) other data, including associated metadata, as specified and within the deadlines laid down in the '**data management plan**' (see Annex 1);*

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION:** Not applicable;**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated with Horizon 2020 and

(b) the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*

- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*

- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*

- *if the [Commission][Agency] objects;*

- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.**]***

[OPTION for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —**]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*

- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*

- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions.* ***]***

[OPTION: *Not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an

EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

*This does not change the security obligations in Article 37, which still apply.**]***

***[OPTION for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries[45], for the purposes of the complementary grant agreement(s) (see Article 2).]

[OPTION for additional access rights for interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION:** under fair and reasonable conditions (see Article 25.3)][**OPTION:** on a royalty-free basis] — access to their results needed for interoperability.]

***[OPTION for additional access rights for cross-border interoperability if foreseen in the work programme:** The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

*Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]***

[OPTION for trans-national access to research infrastructure:** The access provider must give the users royalty-free access to the results needed to implement the action.]

[OPTION:** Not applicable]

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

[45] '**Complementary beneficiary**' means a beneficiary of a complementary grant agreement.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[46], in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

[46] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[47] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *[Commission][Agency]* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

[47] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the *[Commission][Agency]* (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(b) need to know to implement the Agreement and

(c) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[48], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

[48] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION if applicable to the grant: *'Results with a security recommendation' (see Annex 1) may be disclosed or disseminated only under the conditions set out in Annex 1.*

*Before disclosing such results to a third party (including linked third parties, such as affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the [Commission][Agency].****]***

[OPTION: *Not applicable****]***

37.2 Classified results

[OPTION if applicable to the grant: *Activities related to 'classified results' (see Annex 1) must comply with the '****security requirements****' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the [Commission][Agency].

*The beneficiaries must inform the coordinator — which must immediately inform the [Commission][Agency] — of any changes in the security context and — if necessary — request for Annex 1 to be amended (see Article 55).****]***

[OPTION: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION: *Not applicable****]***

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION: *Not applicable**]***

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Commission][Agency]* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Commission][Agency]*

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Commission][Agency]* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *[Commission's][Agency's]* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Commission][Agency]* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Commission][Agency]* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[49], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Commission][Agency]*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Commission][Agency]* will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *[European Union (EU)][Euratom][insert the name of the Agency]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *Agency and the]* Commission

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[50] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their

[49] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[50] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

personal data to the data controller, via the contact point indicated in the 'service specific privacy statement(s) (SSPS)' that are published on the *[Agency and]* Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the]* Commission. For this purpose, they must provide them with the service specific privacy statement(s) (SSPS) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the 'Beneficiary Register' (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*

- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*

- *settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION:** Not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*

- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*

- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION:** Not applicable**]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *[Commission][Agency]* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:**, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented**]***.

If the *[Commission][Agency]* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the *[Commission][Agency]* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *[Commission][Agency]* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *[Commission][Agency]* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *[Commission][Agency]* reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[51] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

[51] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[*Commission*][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)**}**.

If the coordinator has not distributed amounts received (see Article 21.7), the *[*Commission*][Agency]* will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[*Commission*][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *[Commission][Agency]* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *[Agency or the]* Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *[Commission][Agency]*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *[Commission][Agency]* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages — Calculation

The amount the *[Commission][Agency]* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *[Commission][Agency]* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *[Commission][Agency]* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date in the debit note;

(b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission] [Agency]* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. When the *[Commission][Agency]* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION:*** *not applicable****]***;

(j) ***[OPTION for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary *[and its linked third parties]* and approved by the *[Commission][Agency]*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

    In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,

- was not due to error or negligence on their part (or on the part of third parties involved in the action), and

- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,

- labour disputes or strikes, or

- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[*European Commission][name of the Agency]*
[*Directorate-General][Department]* [complete]
[*Directorate [complete*]]
Unit [complete]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[52], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

[52] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into

force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline , the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium ***[OPTION for international organisations that do not accept application of Union law:*** *except for [insert name(s) of the international organisations concerned]]*.

[OPTION for international organisations that accept application of Union law but not Belgian law: *For [insert name(s) of the international organisations concerned], the Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the*

*[Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.**]***

[OPTION for beneficiaries that are international organisations and for beneficiaries not receiving EU funding, established in a non-EU or associated country and which according to their national law cannot be subject to the jurisdiction of the European Court of Justice: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not receiving EU funding]*
- *[insert name of international organisation or beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or beneficiary not receiving EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

*The arbitral award will be binding on all parties and will not be subject to appeal.**]***

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).**]***

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator	For the *[Commission][Agency]*
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

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MODEL ANNEX 2 FOR H2020 GENERAL MGA — MULTI

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)												EU contribution				Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs	E. Indirect costs[2]	*[F. Costs of ...]*			Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]		Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services [D.4 Costs of large research infrastructure]		*[F.1 Costs of ...]*[5]	*[F.2 Costs of ...]*[5]							Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Flat-rate[9] 25%	Unit[10]		Unit[11]								
	a	Total b	No hours	Total c	d	*[e]*	f	g = 0,25 x (a+b+c+f+ *[h1]*[12]+*[h2]*[12]-m)	No units	Total *[h1]*	Total *[h2]*	i = a+b+c+d+*[e]*+f+g+*[h1]*+*[h2]*	j	k	l		m	Yes/No	
1 [short name beneficiary]																**1 [short name beneficiary]**			
[short name linked third party]																**[short name linked third party]**			
[short name linked third party not receiving EU funding]																**[short name linked third party not receiving EU funding]**			
Total beneficiary																**Total beneficiary**			
2 [short name beneficiary]																**2 [short name beneficiary]**			
[short name linked third party]																**[short name linked third party]**			
Total beneficiary																**Total beneficiary**			
X [short name beneficiary not receiving EU funding][13]																**X [short name beneficiary not receiving EU funding]**			
[short name linked third party][14]																**[short name linked third party]**			
Total beneficiary																**Total beneficiary**			
Total consortium																**Total consortium**			

[1] See Article 6 for the eligibility conditions

[2] The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.

[6] See Article 5 for the forms of costs

[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice

[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[9] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs

[10] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).

[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)

[12] Only specific unit costs that do not include indirect costs

[13] See Article 9 for beneficiaries not receiving EU funding

[14] Only for linked third parties that receive EU funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a /SME owner//beneficiary that is a natural person/ not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate')*:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary]

* Amount calculated as follows:
{[insert amount for MSC-IF living allowance of the Main Work Programme — MSCA in force at the time of the call] / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

Country correction coefficient: [insert the country-specific correction coefficient table for MSC actions of the Main Work Programme — MSCA in force at the time of the call]

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

2 Costs for energy efficiency measures in buildings

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m^2 per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' *attached*

Unit cost table (energy efficiency measures unit cost)[53]

Short name beneficiary/linked third party	BEST No	Cost Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

Research infrastructure unit cost

3. Access costs for providing trans-national access to research infrastructure

Units[54]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[55])}}{\text{average annual total quantity of access to the installation (over past two years[56])}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[57]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

Clinical studies unit cost

4. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

53 Data will be taken from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.

54 Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

55 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

56 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

57 Data will be taken from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

Amount per unit*: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for each task described in the protocol, as follows:

{Task 1
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}
[same for all other tasks]}

Unit cost components calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':

{'average hourly cost for doctors', i.e.:

$$\frac{\text{certified or auditable total personnel costs for doctors for year N-1}}{\text{\{1720 * number of full-time equivalent for the personnel category doctors for year N-1\}}}$$

multiplied by
estimated number of hours worked by doctors for the task (per patient/subject)}

For unit cost component 'personnel costs of other medical personnel':

{'average hourly cost for other medical personnel', i.e.:

$$\frac{\text{certified or auditable total personnel costs for other medical personnel for year N-1}}{\text{\{1720 * number of full-time equivalent for the personnel category other medical personnel for year N-1\}}}$$

multiplied by
estimated number of hours worked by other medical personnel for the task (per patient/subject)}

For unit cost component 'personnel costs of technical personnel':

{average hourly cost for technical personnel, i.e.:

$$\frac{\text{certified or auditable total personnel costs for technical personnel for year N-1}}{\text{\{1720 * number of full-time equivalent for the personnel category technical personnel for year N-1\}}}$$

multiplied by
estimated number of hours worked by technical personnel for the task (per patient/subject)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc)

For each category of consumables:

{'average price per item', i.e.:

{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned

total number of items purchased in year N-1 for the category of consumables concerned}

multiplied by

estimated number of items used for the task (per patient/subject)}

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:

{'average cost of depreciation and directly related services per unit of use', i.e.:

{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}

total capacity in year N-1

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)}

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value-for-money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:

'average cost of a specific service per patient or subject', i.e.:

certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies

total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%

multiplied by

{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}}

The following must be excluded:

- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and

- costs of providing financial support to third parties (if any).

Unit cost table: clinical studies unit cost[58]

[Insert name of clinical study]							
Tasks and unit cost components		**Resources per patient**	**Amount per unit for beneficiary /linked third party 1 [insert short name]**	**Amount per unit for beneficiary /linked third party 2 [insert short name]**	**Amount per unit for beneficiary/linked third party 3 [insert short name]**		**…**
						in-kind contributions by third party*	
Task No. 1 Blood sample							
Personnel costs	doctors	----	0	0	0	0	
	other medical personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,55 EUR	9,76 EUR	
	technical personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	13,77 EUR	12,35 EUR	
Costs of consumables	Category 1	Syringe, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Cannula, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Blood container, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	…						
Costs of medical equipment	Category 1	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	
	….						
Costs of other specific services	Category 1						
	Category 2						
	…						
Indirect costs							
Task No. 2							
…							

58 Same table as in proposal and Annex 1.

Total amount per unit			XX EUR	XX EUR	XX EUR	XX EUR**	
Estimated No of units (patients/subjects participating in the study)			XX	XX	XX	XX	
Total unit cost for beneficiary/linked third party (total cost per unit x estimated no of units)			XX EUR	XX EUR	XX EUR		

* Use costs of third party making in-kind contribution.
** Capped at payment to third party, if any.

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new coordinator (short name)**] [legal form], [beneficiary No], established in [official address in full] [VAT number], ('the beneficiary' or 'the coordinator'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][coordinator]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the coordinator] **and** *[the European Union ('the EU', represented by the European Commission ('the Commission')] [the European Atomic Energy Community ('Euratom'), represented by the European Commission ('the Commission'),]**[**[the [Research Executive Agency (REA)][European Research Council Executive Agency (ERCEA)][Innovation and Networks Executive Agency (INEA)][Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the coordinator *to submit and sign in its name and on its behalf any* ***amendments*** *to the Agreement, in accordance with Article 55.**]***

By signing this Accession Form, the beneficiary accepts the grant and agrees to ***[OPTION: for new coordinators:*** *take on the obligations and role of coordinator and to]* implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:,*** *as from [insert date][the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date'**) — if the [Commission][Agency] agrees with the request for amendment]*.

SIGNATURE

For the beneficiary/new beneficiary/new coordinator:

[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary, if Article 14 applies and linked third party liability has been requested by the [Commission][Agency])

[**full official name of the entity affiliated or linked to the beneficiary (short name)**], [legal form], [beneficiary No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], [legal form], [beneficiary number No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the *[Commission][Agency]* by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the *[Commission][Agency]*, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 GENERAL MGA — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)													Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*		*[F.1 Costs of …]*	*[F.1 Costs of …]*			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Flat-rate[5] 25%	Unit		Unit						
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	h=0,25 x (a+b+c+f+*[g]* + *[i1]*[6] +*[i2]*[6] o)	No units	Total *[i1]*	Total *[i2]*	j = a+b+c+d+*[e]* +f+*[g]* +h+*[i1]* +*[i2]*	k	l	m	n	o
[short name beneficiary/linked third party]																		

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, if the 90% limit (see Article 21) is reached, etc).

[4] See Article 5 for the form of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[59] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of_actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[59] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[60]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[60] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[61] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[61] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.
….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.
….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[62] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[62] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT: *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used. 9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions. 11) The employees were charged under the correct category. 12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts. 13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices,	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions). 15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary). 16) The results of work carried out belong to the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting records, etc.).	17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR*	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	(THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).	Beneficiary.	
	C. *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.*	*If the Beneficiary applied method C.* 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor:	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. *<u>"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *<u>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</u>* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		40) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	43) All minimum conditions were met	

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	
		50) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		52) The amount charged corresponded to the actual usage for the action.	
		53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular:	54) Contracts for works or services did not cover tasks described in Annex 1.	
		55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	
		57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,**	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME …….. 5

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[63]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[63] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[64] submitted thereafter.

[64] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;

5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[65] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[65] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.
C. **Personnel costs**	**Procedure:**

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget).	*The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
<u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
90 % of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	<u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
appropriate]; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[66]].* *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the*	The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:**

[66] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Beneficiary they should be listed here below and reported as exception by the Auditor: - *...]*	20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature of the** [Beneficiary] [Linked Third Party]>*

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
***<Signature** of the Auditor>*

H2020 Programme

Multi-Beneficiary General Model Grant Agreement

(H2020 General MGA — Multi)

Version 3.0
20 July 2016

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	– Initial version

2.0 & 2.1	01.10.2014
	01.10.2015
		– The main changes compared to version 1 of the model grant agreement are as follows:
		  – Article 20.6 "Currency for financial statements and conversion into euro" in order to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects);
		  – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" in order to give the possibility to the consortium to receive the pre-financing payment at an earlier date, namely 10 days prior to the starting date of the action.
		  – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem" in order to ensure more visibility of EU funding for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action.
		– Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

3.0	20.07.2016	– The main changes compared to version 2.1 of the model grant agreement are as follows:
		  – Article 4.2 *'Budget transfers':* increased budget flexibility for beneficiaries, which may transfer amounts between forms of costs within the direct personnel costs budget category without an amendment to the grant agreement even if they did not foresee that form of cost in Annex 2.
		  – Article 6.2.A *'Direct personnel costs'* to take into account to a larger extent the usual cost accounting practices of the beneficiaries by allowing them to calculate the hourly rate not only per full financial year but also per month.
		  – Article 20.3 *'Period reports – Requests for interim payment'* : the technical report submitted by the coordinator must also indicate the communication activities.
		  – Article 34.1 *'Obligation to comply with ethical and research integrity principles'* in order to underline the standards of research integrity that beneficiaries must respect.
		  – Article 34.2 *'Activities raising ethical issues'* in order to simplify the beneficiaries' reporting obligations on ethics before the beginning of an activity raising an ethical issue.
		  – Article 36.1 *'General obligation to maintain confidentiality'* in order to allow broader access to confidential information in the case of the Commission/Agency staff, other EU institutions and bodies.
		  – Article 48 *'Suspension of payments'* extends the possibility for the Commission/Agency to suspend the payment of the balance only for one or more beneficiaries.
		  – Articles 48 *'Suspension of payments'*, 49 *'Suspension of action implementation'*, 50.3 *'Termination of the Agreement*

		or the participation of one of more beneficiaries by the Commission/Agency' in order to clarify that for confidentiality reasons and to protect the personal data, in case of audits, reviews, investigations etc., the Commission/Agency will carry out the contradictory procedure directly with the beneficiary concerned (in this case the coordinator will also be informed). – Article 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'* : the Commission/Agency may terminate the participation of a beneficiary if it did not request an amendment to the grant agreement to terminate the participation of its linked third party which is under the same conditions as a beneficiary for which the participation may be terminated. For instance, the linked third party is bankrupt. Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

EUROPEAN COMMISSION
DG/EXECUTIVE AGENCY

[Directorate]
[Unit][Director]

GENERAL MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1] (H2020 GENERAL MGA — MULTI)

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU', represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]*

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], **[OPTION for beneficiaries with VAT:** VAT number [insert number],] as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it

---

[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be***

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

used if Article 9 applies: *It also shows the estimated costs of the beneficiaries not receiving EU funding (see Article 9).]*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Moreover, lump sums set out in Annex 2 can never be adjusted.****]***

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA): 100 %*** *of the action's eligible costs]* ***[OPTION 2 for innovation actions (IA)[7], if all beneficiaries and all linked third parties are non-profit legal entities[8]: 100%*** *of the action's eligible costs]****[OPTION 3 for innovation actions (IA), if all beneficiaries and all linked third parties are profit legal entities: 70%*** *of the action's eligible costs]****[OPTION 4 for innovation actions(IA), if some beneficiaries or linked third parties are non-profit legal entities and some are profit legal entities: 100%*** *of the eligible costs of [the beneficiaries][and][linked third parties] that are non-profit legal entities and* ***70%*** *of the eligible costs of the beneficiaries [and linked third parties] that are profit legal entities]****[OPTION 5 for***

[7] For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[8] For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

exceptional cases if foreseen in the work programme: *[**…%**] of the action's eligible costs]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[9]:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[10]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[11]: *[**OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][**OPTION 2**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[12]: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[13]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) ***[OPTION 1a for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[14]]: on the basis of the amount(s) per unit set out in Annex 2a*[15] ***(unit costs).]***

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[9] To be used only if option in Point (f) is used.
[10] To be used only if option in Point (f) is used.
[11] To be used only if option in Point (f) is used.
[12] To be used only if option in Point (f) is used.
[13] To be used only if option in Point (f) is used.
[14] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.
[15] Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc).

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): *for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

[OPTION 2: specific cost category(ies): *not applicable.]*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;

- the units must be necessary for implementing the action or produced by it, and

- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:** direct costs of providing financial support to third parties;**] [OPTION 2:** not applicable;**]***
D. other direct costs;
E. indirect costs;
F. ***[OPTION 1 for specific unit[/lump sum] costs**: [insert name(s) of specific cost category(ies)*[16]*]][OPTION 2:** not applicable**]**.*

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

[16] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

A. Direct personnel costs *[(not covered by Point F)]*

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[17] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

[17] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[*A.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

<u>Calculation</u>

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)**}**.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is calculated *per full financial year*, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

C. Direct costs of providing financial support to third parties *[(not covered by Point F)]*

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

D.2 ***[OPTION 1 by default**: The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.**]***

***[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[18]:** The **cost of purchasing equipment**, **infrastructure** or **other assets** (new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.**]***

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).**]

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure:** As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).**]

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

[18] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

D.4 **Capitalised and operating costs of 'large research infrastructure'**[19] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[20]*);*

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('****ex-ante assessment****');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.****]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable****]***

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[19] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[20] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[OPTION 3 to be used if foreseen in the work programme: *Not applicable****]***

E. Indirect costs *[(not covered by Article Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) *[**OPTION 1 to be used if Article 15 applies:** costs of providing financial support to third parties [and][;]][**OPTION 2**: not applicable;]*

(d) *[**OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:** [unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]] [**OPTION 2:** not applicable.]*

Beneficiaries receiving an operating grant[21] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

F. *[OPTION 1: [Insert name of specific cost category(ies)[22]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]*

[OPTION 1a for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): *[**Insert name of specific cost category**] are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual units [and if [insert eligibility conditions, if any]].**]***

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): *[**Insert name of specific cost category**] are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.**]***

[same for each specific cost category]

[OPTION 2: *Not applicable****]***

[21] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[22] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: Costs incurred by linked third parties *are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

[OPTION 2: *Not applicable****]***

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU

or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period*[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);

- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: 9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*

- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: insert short name of the beneficiary].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION 1 by default**: these*

beneficiaries] ***[OPTION 2 if more than one of the three options apply to the grant****: insert short name of the beneficiary]*.

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.****]***

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[23]***]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[24] (or 2014/24/EC[25]) or 'contracting entities' within the meaning of Directive

[23] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

2004/17/EC[26] (or 2014/25/EC[27]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

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[24] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[25] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. (OJ L 94, 28.03.2014, p. 65).

[26] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[27] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[28]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

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[28] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a ***request for tenders*** *from at least* ***three providers*** *(including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[29]***.]***

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').****]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[29] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following ***affiliated entities***[30] *and* ***third parties with a legal link to a beneficiary***[31] *(****'linked third parties'****) may implement the action tasks attributed to them in Annex 1:*

[30] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

***[OPTION 1 to be used if foreseen in the work programme:** 15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[31] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION 2:** Not applicable**]

15.2 Financial support in the form of prizes

***[OPTION 1 to be used if foreseen in the work programme:** 15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION 2:** Not applicable**]

15.3 Consequences of non-compliance

[OPTION 1 to be used if 15.1 and/or 15.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'[32] must provide access to research infrastructure or installations[33] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) categories of users that may have access:

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*

[32] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[33] '**Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country[34] *is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

(c) procedure and criteria for selecting user groups:

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a ***selection panel*** *set up by the access providers.*

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*

- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]****]***[35].

(d) other conditions:

[34] For the definition, see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.****]***

[35] If the authorising officer considers necessary to give priority to certain categories of users.

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.**]***

[OPTION 2:** Not applicable**]

16.2 Rules for providing virtual access to research infrastructure

***[OPTION 1 for virtual access to research infrastructure:** '**Access providers**'[36] must provide access to research infrastructure or installations[37] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2:** Not applicable**]

16.3 Consequences of non-compliance

[36] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[37] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[OPTION 1 to be used if 16.1 and/or 16.2 are applicable: *If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[38]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

[38] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2****: for* ***lump sum costs****: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.****]***

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

***[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]*

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[- RP2: from month [X+1] to month [Y]
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
- RPN: from month [N+1]to [the last month of the project].]

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not

declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[39]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.**]***

[OPTION 2: *Not applicable**]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

[39] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)] is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.**]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the coordinator

    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: […]
Full name of the account holder: […]
Full account number (including bank codes): […]
[IBAN code: […]][40]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

[40] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [41]and No 2185/96[42] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[43], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews audits and investigations.*

*This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.**]***

[OPTION 2:** Not applicable;**]

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

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[41] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[42] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[43] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The *[Agency or the]* Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the *[Agency or the]* Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors, irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:*** *five]**[OPTION 2 for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[44].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

[44] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘**agreement on background**’).

‘**Background**’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘**request for access**’).

‘**Access rights**’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[45] established in an EU Member State or '**associated country**'[46], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

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[45] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[46] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable;****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

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identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].****]***

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.****]***

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set*

*out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.**]***

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).**]***

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018"];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1 for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(ii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2:** Not applicable;**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****]*** ***[OPTION 2:*** *not applicable****]***.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*

(b) *the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.]*

[OPTION 2 for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —****]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*

- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions.]*

[OPTION 3:** Not applicable**]

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

***[OPTION 2 for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens':** The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

***[OPTION 3 for Euratom grants:** The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

***[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme**: The beneficiaries must give — under the conditions set out in Article 31.2 and*

31.3 — access to their results to complementary beneficiaries[47]*, for the purposes of the complementary grant agreement(s) (see Article 2).**]***

[OPTION 1b for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.**]***

[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.*

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

[OPTION 1d for trans-national access to research infrastructure: *The access provider must give the users royalty-free access to the results needed to implement the action.**]***

[OPTION 2: *Not applicable**]***

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[48], in particular regarding:

[47] '**Complementary beneficiary**' means a beneficiary of a complementary grant agreement.

[48] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;

[49] European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.

- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3****]*** as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced ;

- make the necessary references to their work and that of other researchers;

- refrain from practicing any form of plagiarism, data falsification or fabrication;

- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the *[Commission][Agency]* (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[50], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[50] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).****]***

[OPTION 2: *Not applicable****]***

37.2 Classified information

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/*444*[51] *— until it is declassified.*

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].

[OPTION 2: *Not applicable****]***

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION 1 if applicable to the grant: *Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.****]***

[OPTION 2: *Not applicable****]***

37.4 Consequences of non-compliance

[51] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable: *If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and]* Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is][are]* not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency,* the*]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) translation;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[52], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Agency or the]* Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency or the]* Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the*[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the]* Commission

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[53] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

[52] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

[53] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the]* Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[54] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*

[54] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*

- *settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[OPTION 2:** Not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION 1 for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*

- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION 2:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*

- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*

- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the time of an **interim payment**, **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant (**see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:**, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented**]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21)..

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]****,* except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[55] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

[55] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[*Commission*][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[*Commission*][Agency]* will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[*Commission*][Agency]* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Commission][Agency]* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission] [Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3), must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false declaration, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the

beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

- the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

(i) resumption is impossible, or

(ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) despite a specific request by the *[Commission][Agency]*, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the

participation of one of its linked third parties that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the

beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,

- was not due to error or negligence on their part (or on the part of third parties involved in the action), and

- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,

- labour disputes or strikes, or

- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the following address:

[European Commission][Name of the Agency]
[Directorate-General [complete]**]**
[Street name and number]
[Post code, town and country]

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[56], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

[56] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline , the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned]****]****.*

[additional OPTION for international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles*

governing the law of international organisations and the rules of general international law]

[same for other international organisations].]

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.]*

[additional OPTION for international organisations and for non-EU beneficiaries not receiving EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or non-EU beneficiary not receiving EU funding]*
- *[insert name of international organisation or non-EU beneficiary not receiving EU funding]*

[same for other beneficiaries that are international organisations or non-EU beneficiary not receiving EU funding]

such disputes must — if they cannot be settled amicably — be referred to arbitration. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against enforceable decisions must be brought against the Commission (not against the Agency).]*

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

For the *[Commission][Agency]*

[forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

① print format A4 landscape

MODEL ANNEX 2 FOR H2020 GENERAL MGA — MULTI

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)												EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs	E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*		*[F.1 Costs of …]*[5]		*[F.2 Costs of …]*[5]					Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Flat-rate[9] 25%	Unit[10]		*[Unit][Lump sum][11]*							
	a	Total b	No hours	Total c	d	*[e]*	f	g = 0,25 x (a+b+c+f+ *[h1]*[12]+*[h2]*[12]-m)	No units	Total *[h1]*	Total *[h2]*	i = a+b+c+d+*[e]* +f+g+*[h1]* +*[h2]*	j	k	l	m	Yes/No	
1 [short name beneficiary]																		
[short name linked third party]																		
[short name linked third party not receiving EU funding]																		
Total beneficiary																		
2 [short name beneficiary]																		
[short name linked third party]																		
Total beneficiary																		
X [short name beneficiary not receiving EU funding][13]																		
[short name linked third party][14]																		
Total beneficiary																		
Total consortium																		

[1] See Article 6 for the eligibility conditions

[2] The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.

[6] See Article 5 for the forms of costs

[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice

[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[9] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs

[10] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).

[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)

[12] Only specific unit costs that do not include indirect costs

[13] See Article 9 for beneficiaries not receiving EU funding

[14] Only for linked third parties that receive EU funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{{ EUR 4,650 / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

Country-specific correction coefficient (in force at the time of the call):

EU Member States

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AT	104.8%	DK	135.3%	HR	97.5%	LV	75.9%	SE	111.7%
BE	100.0%	EE	78.3%	HU	76.2%	MT	89.6%	SI	86.1%
BG	71.5%	EL	92.7%	IE	113.5%	NL	104.3%	SK	82.6%
CY	91.8%	ES	97.6%	IT	106.7%	PL	76.4%	UK	120.3%
CZ	83.8%	FI	116.6%	LT	73.1%	PT	89.1%		
DE	98.8%	FR	111.0%	LU	100.0%	RO	68.3%		

H2020 associated countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AL	76.1%	FO	134.1%	LI	110.0%	MK	68.4%	TR	86.6%
BA	73.6%	IL	108.7%	MD	61.1%	NO	131.9%		
CH	113.1%	IS	116.6%	ME	66.9%	RS	67.1%		

Other countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AM	89.9%	CU	83.8%	JP	115.9%	NI	57.3%	TJ	64.9%
AO	114.6%	CV	76.4%	KE	78.1%	NP	73.5%	TL	78.3%
AR	58.5%	DJ	93.4%	KG	83.1%	NZ	94.1%	TN	70.5%
AU	105.0%	DO	66.9%	KH	70.5%	PA	57.0%	TO	85.0%
AZ	93.0%	DZ	81.7%	KR	105.2%	PE	75.5%	TT	74.1%
BB	116.6%	EC	68.8%	KZ	100.2%	PG	83.0%	TW	83.6%
BD	47.2%	EG	48.6%	LA	77.7%	PH	65.8%	TZ	65.2%
BF	93.8%	ER	61.2%	LB	86.4%	PK	49.4%	UA	92.3%
BJ	92.6%	ET	85.2%	LK	61.6%	PS	100.4%	UG	65.7%
BM	151.5%	FJ	68.1%	LR	100.1%	PY	71.9%	US	99.4%

BO	51.3%	GA	113.1%	LS	56.7%	RU	115.5%	UY	75.3%
BR	92.0%	GE	89.5%	LY	60.0%	RW	87.3%	UZ	51.4%
BW	55.3%	GH	68.2%	MA	83.5%	SA	84.8%	VE	70.0%
BY	65.0%	GM	67.7%	MG	80.0%	SB	93.3%	VN	51.1%
BZ	75.3%	GN	60.4%	ML	90.4%	SD	65.1%	VU	112.6%
CA	86.4%	GT	78.8%	MR	64.5%	SG	102.5%	WS	75.8%
CD	127.6%	GW	102.7%	MU	72.7%	SL	85.2%	XK	58.6%
CF	114.3%	GY	58.9%	MW	76.0%	SN	86.2%	YE	68.1%
CG	124.9%	HK	93.8%	MX	70.4%	SR	50.6%	ZA	55.8%
CI	102.0%	HN	69.0%	MY	71.6%	SV	74.3%	ZM	66.4%
CL	67.1%	HT	108.7%	MZ	71.6%	SY	74.8%	ZW	47.2%
CM	103.3%	ID	75.3%	NA	68.3%	SZ	56.8%		
CN	85.0%	IN	52.8%	NC	128.9%	TD	125.3%		
CO	76.6%	JM	94.9%	NE	87.9%	TG	88.7%		
CR	76.7%	JO	75.5%	NG	92.4%	TH	65.0%		

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment): For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] ***]***

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

[OPTION if specific unit cost applicable to the grant: **2. Costs for energy efficiency measures in buildings**

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m² per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

Unit cost table (energy efficiency measures unit cost)[57]

Short name beneficiary/linked third party	BEST No	Cost Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

]

[57] Data from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.

Research infrastructure unit cost

[OPTION if specific unit cost applicable to the grant: 3. Access costs for providing trans-national access to research infrastructure

Units[58]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[59])}}{\text{average annual total quantity of access to the installation (over past two years[60])}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[61]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

]

Clinical studies unit cost

[OPTION if specific unit cost is applicable to the grant: 4. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for each task described in the protocol, as follows:

{Task 1

{unit cost component 'personnel costs'

+ unit cost component 'costs of consumables'

[58] Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

[59] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

[60] In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

[61] Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}

+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}

[same for all other tasks]}

Unit cost components calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':

{'average hourly cost for doctors', i.e.:

$$\frac{\text{certified or auditable total personnel costs for doctors for year N-1}}{\text{\{1720 * number of full-time equivalent for the personnel category doctors for year N-1\}}}$$

multiplied by

estimated number of hours worked by doctors for the task (per patient/subject)}

For unit cost component 'personnel costs of other medical personnel':

{'average hourly cost for other medical personnel', i.e.:

$$\frac{\text{certified or auditable total personnel costs for other medical personnel for year N-1}}{\text{\{1720 * number of full-time equivalent for the personnel category other medical personnel for year N-1\}}}$$

multiplied by

estimated number of hours worked by other medical personnel for the task (per patient/subject)}

For unit cost component 'personnel costs of technical personnel':

{average hourly cost for technical personnel, i.e.:

$$\frac{\text{certified or auditable total personnel costs for technical personnel for year N-1}}{\text{\{1720 * number of full-time equivalent for the personnel category technical personnel for year N-1\}}}$$

multiplied by

estimated number of hours worked by technical personnel for the task (per patient/subject)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc)

For each category of consumables:

{'average price per item', i.e.:

$$\frac{\text{\{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned}}{\text{total number of items purchased in year N-1 for the category of consumables concerned\}}}$$

multiplied by

estimated number of items used for the task (per patient/subject)}

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for

consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:

{'average cost of depreciation and directly related services per unit of use', i.e.:

$$\frac{\{\text{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned} + \text{certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}\}}{\text{total capacity in year N-1}}$$

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)}

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value-for-money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:

'average cost of a specific service per patient or subject', i.e.:

$$\frac{\text{certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies}}{\text{total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1}}$$

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%
multiplied by
{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}}

The following must be excluded:

- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

Unit cost table: clinical studies unit cost[62]

[62] Same table as in proposal and Annex 1.

[Insert name of clinical study]							
Tasks and unit cost components		**Resources per patient**	**Amount per unit for beneficiary /linked third party 1 [insert short name]**	**Amount per unit for beneficiary /linked third party 2 [insert short name]**	**Amount per unit for beneficiary/linked third party 3 [insert short name]**		**…**
						in-kind contributions by third party*	
Task No. 1 Blood sample							
Personnel costs	doctors	----	0	0	0	0	
	other medical personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,55 EUR	9,76 EUR	
	technical personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	13,77 EUR	12,35 EUR	
Costs of consumables	Category 1	Syringe, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Cannula, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Blood container, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	…						
Costs of medical equipment	Category 1	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	
	….						
Costs of other specific services	Category 1						
	Category 2						
	…						
Indirect costs							
Task No. 2							
…							
Total amount per unit			**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR****	

Estimated No of units **(patients/subjects participating in the study)**	XX	XX	XX	XX	
Total unit cost for beneficiary/linked third party **(total cost per unit x estimated no of units)**	XX EUR	XX EUR	XX EUR		

* Use costs of third party making in-kind contribution.

** Capped at payment to third party, if any.

/

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new coordinator (short name)**], established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number],]* ('the beneficiary' or 'the coordinator'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][coordinator]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the coordinator] **and** *[the European Union ('the EU', represented by the European Commission ('the Commission'] [the European Atomic Energy Community ('Euratom'), represented by the European Commission ('the Commission'),]**[**[the [Research Executive Agency (REA)][European Research Council Executive Agency (ERCEA)][Innovation and Networks Executive Agency (INEA)][Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.**]

By signing this Accession Form, the beneficiary accepts the grant and agrees to *[**OPTION: for new coordinators:** take on the obligations and role of coordinator and to]* implement it in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:,** as from [insert date]*[the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date'**) [**additional OPTION for change of beneficiary due to partial takeover:**, and with joint and several liability for undue amounts paid to [insert short name of former beneficiary] (i.e. recoveries)] — if the [Commission][Agency] agrees with the request for amendment**]***.

SIGNATURE

For the beneficiary/new beneficiary/new coordinator:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary, if Article 14 applies and linked third party liability has been requested by the [Commission][Agency])

[**full official name of the entity affiliated or linked to the beneficiary (short name)**] , established in [official address in full], ***[OPTION for linked third parties with VAT:*** *VAT number [insert number]]* ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], established in [official address in full], ***[OPTION for beneficiaries with VAT:*** *VAT number [insert number]]* ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the *[Commission][Agency]* by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the *[Commission][Agency]*, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)													Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*		*[F.1 Costs of …]*	*[F.1 Costs of …]*			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Flat-rate[5] 25%	*[Unit][Lump sum]*		Unit						
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	h=0,25 x (a+b+c+f+*[g]* + *[i1]*[6] +*[i2]*[6] - o)	No units	Total *[i1]*	Total *[i2]*	j = a+b+c+d+*[e]* +f +*[g]* +h+*[i1]* +*[i2]*	k	l	m	n	o
[short name beneficiary/linked third party]																		

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less,

[4] See Article 5 for the form of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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TERMS OF REFERENCE FOR AN INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission*[, the Agency],* the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission *[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement
[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT: *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices,	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	
		15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting records, etc.).	17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT*	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE). ***C**. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.*	Beneficiary. 26.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).	
	'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.	*If the Beneficiary applied method C.* 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
		28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; o (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. <u>*"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":*</u> *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE*	Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates:	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2. *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 32.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined.	
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system.	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).	36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	If the persons are working exclusively for the action and without time records For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment).	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	*collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		40) The subcontracts were not awarded to other Beneficiaries of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met:	43) All minimum conditions were met	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.		

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	
		50) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy. 52) The amount charged corresponded to the actual usage for the action. 53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment; o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive	54) Contracts for works or services did not cover tasks described in Annex 1. 55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. 56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)***,**	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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TERMS OF REFERENCE FOR AN AUDIT ENGAGEMENT FOR A METHODOLOGY CERTIFICATE IN CONNECTION WITH ONE OR MORE GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[1] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

[1] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[2] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[2] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since [dd Month yyyy]. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy].	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
(including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
<u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90 % of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:**

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
present certificate[1]]. *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- ...]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[official name of the *[Beneficiary] [Linked Third Party]****]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature of the*** *[Beneficiary] [Linked Third Party]>*	***[official name of the Auditor]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature*** *of the Auditor>*

Swiss participation in Horizon 2020

(version January 2017)

This information sheet contains FAQ and explanations concerning the status of Switzerland and of entities established in Switzerland in relation to Horizon 2020 after 1 January 2017 and in the period of 'partial' association, i.e. between 15 September 2014 and 31 December 2016.

On 16 December 2016 the Swiss Federal Council ratified the Protocol on the extension to Croatia of the Free Movement of Persons Agreement between the EU and Switzerland. That means that in accordance with Article 13(6) of the Agreement associating Switzerland to Horizon 2020, as of 1 January 2017 the Association Agreement with Switzerland continues to apply and is expanded to cover the **whole of Horizon 2020**, Euratom Programme 2014-2018 and activities carried out by Fusion for Energy.

The FAQ below outline in Section I in more detail what the aforementioned means in practice regarding the period as of 1 January 2017 onwards. Section II of this information sheet contains additional explanations and FAQ concerning the status of Switzerland during the period of 'partial' association between 15 September 2014 and 31 December 2016.

I Period as of 1 January 2017 onwards

1. What is the status of Swiss legal entities in Horizon 2020 projects for grant agreements (GAs) signed as from 1 January?

As from 1 January 2017 Switzerland is associated to the entire Horizon 2020. In practical terms this means that for all Horizon 2020 projects for which the GA is signed as from 1 January the Swiss participants are automatically eligible for funding and may count towards the minimum number of participants required for a project (see the eligibility criteria for funding and participation under Regulation 1290/2013 on Horizon 2020 Rules for participation).

2. Will this affect the status of Swiss legal entities in on-going projects?

The status of Swiss legal entities in all on-going projects, for which the GAs have already been signed before 1 January 2017 remains unchanged.

3. What are the typical rights and obligations of Switzerland, as a fully associated country to H2020?

As an associated country to the whole of Horizon 2020, Switzerland has the right to send observers to meetings of all the different configurations of the committee which is responsible for the implementation of H2020. It also has the right to send observers to the Board of Governors of the JRC and the right to participate in all ERA related bodies as an observer.

Switzerland is obliged to pay a financial contribution to the Union budget calculated on the basis of a ratio between its GDP and the sum of the Member States of Union GDP in line with the terms of the Association Agreement.

4. What about Switzerland's participation as a State in Art. 185 and Art. 187 initiatives under Horizon 2020?

Regarding actions under Art. 185 and Art. 187 initiatives in Horizon 2020, as of 1 January 2017 Switzerland is to be treated as an Associated Country and therefore participate in these initiatives. As a consequence, Switzerland is entitled to participate in the legal structures created in conformity with the decisions and regulations that have been adopted for these initiatives.

5. What about participation of Swiss entities in actions under Art. 185 and Art. 187 initiatives in Horizon 2020?

As of 1 January 2017 Swiss entities are to be treated as entities from an Associated Country in relation to participation in Art 185 and Art 187 initiatives and they will be eligible for participation and funding in accordance with the conditions set out in the Horizon 2020 Rules for Participation in conjunction with the relevant basic acts. In relation to already on-going projects, i.e. where GAs following the calls launched by respective Article 185 and 187 initiatives were signed before 1 January 2017, the status of Swiss legal entities remains unaffected. This means that in such on-going projects they will continue to be treated as entities from a non-associated third country.

II Period from 15 September 2014 to 31 December 2016 ('partial' association)

During this period, the participation of Switzerland with an associated country status covered actions under:

- the "Excellent Science" pillar (the 1st pillar), containing the European Research Council, Future and Emerging Technologies, Research Infrastructures and the Marie Skłodowska-Curie actions;
- the specific objective "Spreading excellence and widening participation";
- the Euratom Programme; and
- the activities carried out by the European Joint Undertaking for ITER and the Development of Fusion for Energy for 2014-2020.

In all other parts of the Horizon 2020 programme, Switzerland had to be considered as a non-associated third country participant until 1 January 2017. For more information on

funding for Swiss participants in such projects by the Swiss government, please see: http://www.h2020.ch/.

In relation to cooperation for fusion activities under the Euratom Programme the new agreement replaced the 1978 Fusion Cooperation Agreement.

The FAQ below outline in more detail what the aforementioned means in practice regarding the period from 15 September 2014 to 31 December 2016.

1. For which Horizon 2020 priorities were the Swiss entities treated as entities from an Associated Country between 15 September 2014 and 31 December 2016?

During that period Swiss legal entities could participate with a status of entities from an Associated Country in actions under the 1st pillar of Horizon 2020, namely the European Research Council, future and emerging technologies, Marie Skłodowska-Curie actions and research infrastructures as well as in actions under the specific objective "Spreading excellence and widening participation". The same applied to calls under the Research and Training Programme of the European Atomic Energy Community (the Euratom Programme) complementing Horizon 2020.

2. What did it mean in practice?

Between 15 September 2014 and 31 December 2016 the Swiss participants could participate as entities from an Associated Country in the parts of Horizon 2020 described above and for which the submission deadline was after or on 15 September 2014. In practical terms that meant that for these calls the Swiss participants were automatically eligible for funding and counted towards the minimum number of participants required for a project (eligibility criteria). The same principle applied for the Euratom Programme.

3. What about Swiss legal entities status in other priorities of Horizon 2020 between 15 September 2014 and 31 December 2016?

During that period Swiss legal entities continued being eligible for participation in all actions under Horizon 2020, other than those covering the 1st pillar, as entities from any industrialised third country not associated to Horizon 2020. That meant that in actions under the Industrial Leadership and Societal Challenges pillars of Horizon 2020, Swiss participants were not automatically eligible for funding and did not count towards the minimum number of participants required for a project (eligibility criteria) if the GA was signed before 1 January 2017.

H2020 Programme

Multi-Beneficiary General Model Grant Agreement

(H2020 General MGA — Multi)

Version 4.0
27 February 2017

Disclaimer
This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	11.12.2013	▪ Initial version
2.0 & 2.1	01.10.2014 01.10.2015	▪ The main changes compared to version 1 of the model grant agreement are as follows: – Article 20.6 "Currency for financial statements and conversion into euro" in order to allow beneficiaries with accounts in other currencies than euro to convert into euro all costs incurred independently of the currency in which they were incurred (similar to FP7 projects); – Article 21.2 "Pre-financing payment – Amount – Amount retained for the Guarantee Fund" in order to give the possibility to the consortium to receive the pre-financing payment at an earlier date, namely 10 days prior to the starting date of the action. – Article 38.1.2 "Information on EU funding – Obligation and right to use the EU emblem" in order to ensure more visibility of EU funding for any communication activity related to any infrastructure, equipment used and to major results of a H2020 action. ▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
3.0	20.07.2016	▪ The main changes compared to version 2.1 of the model grant agreement are as follows: – Article 4.2 *'Budget transfers':* increased budget flexibility for beneficiaries, which may transfer amounts between forms of costs within the direct personnel costs budget category without an amendment to the grant agreement even if they did not foresee that form of cost in Annex 2. – Article 6.2.A *'Direct personnel costs'* to take into account to a larger extent the usual cost accounting practices of the beneficiaries by allowing them to calculate the hourly rate not only per full financial year but also per month. – Article 20.3 *'Period reports – Requests for interim payment'* : the technical report submitted by the coordinator must also indicate the communication activities. – Article 34.1 *'Obligation to comply with ethical and research integrity principles'* in order to underline the standards of research integrity that beneficiaries must respect. – Article 34.2 *'Activities raising ethical issues'* in order to simplify the beneficiaries' reporting obligations on ethics before the beginning of an activity raising an ethical issue. – Article 36.1 *'General obligation to maintain confidentiality'* in order to allow broader access to confidential information in the case of the Commission/Agency staff, other EU institutions and bodies. – Article 48 *'Suspension of payments'* extends the possibility for the Commission/Agency to suspend the payment of the balance only for one or more beneficiaries. – Articles 48 *'Suspension of payments'*, 49 *'Suspension of*

		action implementation', 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'* in order to clarify that for confidentiality reasons and to protect the personal data, in case of audits, reviews, investigations etc., the Commission/Agency will carry out the contradictory procedure directly with the beneficiary concerned (in this case the coordinator will also be informed). – Article 50.3 *'Termination of the Agreement or the participation of one of more beneficiaries by the Commission/Agency'* : the Commission/Agency may terminate the participation of a beneficiary if it did not request an amendment to the grant agreement to terminate the participation of its linked third party which is under the same conditions as a beneficiary for which the participation may be terminated. For instance, the linked third party is bankrupt. Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.
4.0	27.02.2017	▪ The main changes compared to version 3.0 of the model grant agreement are under: – Article 6.2.A "Direct personnel costs" – Article 6.2.A.2 'Personnel costs for natural persons working under a direct contract with the beneficiary' – Article 6.2.D.5 'Direct costs internally invoiced' – Article 6.2.E 'Indirect costs' – New Article 14a 'Implementation of action tasks by international partners' – Article 52.1 'Forms and means of communication' Other minor drafting changes and corrections of clerical mistakes can be viewed in a version with tracked changes.

EUROPEAN COMMISSION
DG/EXECUTIVE AGENCY

[Directorate]
[Unit][Director]

GENERAL MODEL GRANT AGREEMENT FOR THE HORIZON 2020 PROGRAMME[1] (H2020 GENERAL MGA — MULTI)

- **Footnotes in blue will not appear in the text generated by the IT system for signature (since they are internal instructions only).**
- **For options *[in italics, in square brackets]*: the applicable option must be chosen in the IT system. Options not chosen will automatically either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiaries to easily spot that a specific rule applies).**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **The IT system will generate a data sheet confirming the options chosen and the data entered.**

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

***[OPTION 1**: the **European Union** ('the EU'), represented by the European Commission ('the Commission')[2],]*

***[OPTION 2:** the **European Atomic Energy Community** ('Euratom'), represented by the European Commission ('the Commission')[3],]*

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) ('**H2020 Framework Programme Regulation No 1291/2013**') (OJ L 347, 20.12.2013 p.104).

[2] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[3] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[OPTION 3:** the **[Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)]** ('the Agency'), under the powers delegated by the European Commission ('the Commission')[4],**]

represented for the purposes of signature of this Agreement by [[function, [Directorate-General, Directorate, Unit] [Department]], [forename and surname],[5]

and

on the other part,

1. 'the coordinator':

[**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],] **[OPTION for coordinators not receiving EU funding:** as 'beneficiary not receiving EU funding' (see Article 9),]* represented for the purposes of signing the Agreement by [function, forename and surname]

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. [**full official name (short name)**], established in [official address in full], ***[OPTION for beneficiaries with VAT:** VAT number [insert number],]*

[OPTION for beneficiaries not receiving EU funding:** X. [**full official name (short name)**], established in [official address in full], **[OPTION for beneficiaries with VAT:** VAT number [insert number],] as 'beneficiary not receiving EU funding' (see Article 9),**]

[same for each beneficiary]

***[OPTION if the JRC is a beneficiary:** and X. the **Joint Research Centre (JRC)** established in [official address in full], if it signs the 'Administrative Arrangement' (see Annex 3b)**]**.*

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator ***[OPTION if the JRC participates:** and the Joint Research Centre (JRC)**]**.*

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form ***[OPTION if the JRC is a beneficiary:** or the Administrative Arrangement]*, the beneficiaries accept the grant and agree to implement it

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[4] Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

[5] The person representing the Commission/Agency must be an authorising officer (by delegation or sub-delegation), designated in accordance with document 60008 of 22.02.2001 '*Mise en place de la Charte des ordonnateurs*'.

under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the [Commission][Agency]: *3a Declaration on joint and several liability of linked third parties****]***

[OPTION if the JRC participates: *3b Administrative Arrangement****]***

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED *[— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]*

The grant is awarded for the action entitled **[insert title of the action]** — **[insert acronym]** ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work programme: *The grant is a '**complementary grant**' to [the grant agreement(s) under the call(s) for proposals [call identifier(s): H2020 — theme —]] [the following complementary grant agreement(s) No(s):*

- *[insert number] [insert acronym]*
- *[insert number] [insert acronym]].**]***

[OPTION for joint actions (joint call with a third country or an international organisation)*: The action is a '**jointly funded action**' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.**]***

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***[insert number]*** **months** as of *[**OPTION 1 by default:** the first day of the month following the date the Agreement enters into force (see Article 58)] [**OPTION 2 if needed for the action:** [insert date]]*[6] ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary *[(and linked third party)]* and budget category (see Articles 5, 6, *[and 14]*). ***[OPTION to be***

[6] This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the authorising officer, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

used if Article 9 or 14a applies: *It also shows the estimated costs of the [beneficiaries not receiving EU funding (see Article 9)][and][international partners (see Article 14a)].**]***

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

[OPTION if lump sum foreseen in Article 5.2*: Moreover, lump sums set out in Annex 2 can never be adjusted.**]***

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR [insert amount** (insert amount in words)**]**.

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***[OPTION 1 for research and innovation actions (RIA) and coordination and support actions (CSA): 100 %*** *of the action's eligible costs****] [OPTION 2 for innovation actions (IA)***[7]***: 100%*** *of the eligible costs for beneficiaries [and linked third parties] that are non-profit legal entities*[8] *and* ***70%*** *of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities****] [OPTION 3 for exceptional cases if foreseen in the work programme: [OPTION A for RIA and CSA: […%]*** *of the action's eligible costs] [****OPTION B for IA: […%]*** *of the eligible costs for beneficiaries [and linked*

[7] For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" ('**Rules for Participation Regulation No 1290/2013**') (OJ L 347, 20.12.2013 p.81): '**innovation action**' means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

[8] For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

third parties] that are non-profit legal entities[9] *and [...%] of the eligible costs for beneficiaries [and linked third parties] that are profit legal entities]]* (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **[insert amount** (insert amount in words)**]**.

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs** *[(excluding direct personnel costs covered by the unit cost[/lump sum] under Point (f))]*[10]:

- as actually incurred costs ('**actual costs**') or

- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs of subcontracting** *[(excluding subcontracting costs covered by the unit cost[/lump sum] under Point (f))]*[11]: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** *[(excluding costs of financial support covered by the unit cost[/lump sum] under Point (f))]*[12]: *[**OPTION 1 to be used if Article 15 applies**: as actually incurred costs (**actual costs**);][**OPTION 2**: not applicable;]*

(d) for **other direct costs** *[(excluding other direct costs covered by the unit cost[/lump sum] under Point (f))]*[13]:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');

- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs** *[(excluding indirect costs covered by the unit cost[/lump sum] under Point (f))]*[14]: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

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[9] For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[10] To be used only if option in Point (f) is used.

[11] To be used only if option in Point (f) is used.

[12] To be used only if option in Point (f) is used.

[13] To be used only if option in Point (f) is used.

[14] To be used only if option in Point (f) is used.

(f) ***[OPTION 1a for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant):*** *for [**insert name of specific cost category(ies)**[15]]: on the basis of the amount(s) per unit set out in Annex 2a*[16] ***(unit costs).]***

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): *for [**insert name of specific cost category(ies)**]: as the lump sum set out in Annex 2 ('**lump sum costs**').]*

[OPTION 2: specific cost category(ies): *not applicable.]*

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *[Commission][Agency]* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

[15] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[16] Annex 2a must clearly show, for each beneficiary (and linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc).

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *[Commission][Agency]*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *[Commission][Agency]* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *[Commission][Agency]* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *[Commission][Agency]* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs *[or lump-sum costs]*) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs:***

(i) the eligible amount is equal to the amount set out in Annex 2, and

*(ii) the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.**]***

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. ***[OPTION 1 to be used if Article 15 applies:** direct costs of providing financial support to third parties;**] [OPTION 2:** not applicable;**]***
D. other direct costs;
E. indirect costs;

F. ***[OPTION 1 for specific unit[/lump sum] costs**: [insert name(s) of specific cost category(ies)*[17]*]][OPTION 2:** not applicable**]**.*

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs *[(not covered by Point F)]*

<u>Types of eligible personnel costs</u>

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[18] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

[17] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[18] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**'), who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of** '**beneficiaries that are natural persons**' not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

[*A.6 [****OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.] [****OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.]****]***

<u>Calculation</u>

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3 *[and A.6])*: the hourly rate is calculated *per full financial year*, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}**}**

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.1, A.2, A.4, A.5 *[and A.6]*): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting *[(not covered by Point F)]* (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: *Subcontracting costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Subcontracting costs* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

C. Direct costs of providing financial support to third parties *[(not covered by Point F)]*

[OPTION 1a to be used if Article 15.1 applies: *C.1* ***Direct costs of providing financial support*** *are eligible if the conditions set out in Article 15.1.1 are met.****]***

[OPTION 1b to be used if Article 15.2 applies: *C.2* ***Direct costs of providing financial support in the form of prizes*** *are eligible if the conditions set out in Article 15.2.1 are met.****]***

[OPTION 2*: Not applicable****]***

D. Other direct costs *[(not covered by Point F)]*

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: *Travel costs* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

D.2 ***[OPTION 1 by default****: The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

*The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.****]***

[OPTION 2 (alternative to option above) to be used if foreseen in the work programme[19]: *The* ***cost of purchasing equipment****,* ***infrastructure*** *or* ***other assets*** *(new or second-hand) (as recorded in the beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.*

The ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

The costs of equipment, infrastructure or other assets ***contributed in-kind against payment*** *are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.****]***

[19] To be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work programme.

[OPTION (in addition to one of the two first options above) for trans-national access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national access to research infrastructure (see Article 16.1).****]***

[OPTION (in addition to one of the two first options above) for virtual access to research infrastructure, unless the work programme explicitly allows capital investments for virtual access to research infrastructure: *As an exception, the beneficiaries must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing virtual access to research infrastructure (see Article 16.2).****]***

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services* ***for providing trans-national access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.1.1 are met.****]***

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services* ***for providing virtual access to research infrastructure*** *are eligible only if also the conditions set out in Article 16.2 are met.****]***

D.4 **Capitalised and operating costs of 'large research infrastructure'**[20] ***[OPTION 1 by default:*** *directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[21]*);*

[20] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[21] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

*(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.**]***

[OPTION 2 for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): *Not applicable**]***

[OPTION 3 to be used if foreseen in the work programme: *Not applicable**]***

D.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

E. Indirect costs *[(not covered by Point F)]*

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

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computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

(a) costs of subcontracting *[and][;]*

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises *[and][;]*

(c) ***[OPTION 1 to be used if Article 15 applies:*** *costs of providing financial support to third parties [and][;]****][OPTION 2****: not applicable;]*

(d) ***[OPTION 1 if Article 6.2.F applies and the specific unit cost[/lump sum] cost covers indirect costs:*** *[unit costs under Articles 5.2(f) and 6.2.F.][lump sum costs under Articles 5.2(f) and 6.2.F.]****] [OPTION 2:*** *not applicable.****]***

Beneficiaries receiving an operating grant[22] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

F. ***[OPTION 1: [Insert name of specific cost category(ies)[23]][OPTION 2 if no specific cost categories applicable to the grant: Specific cost category(ies)]***

[OPTION 1a for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): *[****Insert name of specific cost category****] are eligible, if they correspond to the amount per unit set out in Annex 2a multiplied by the actual number of units [and if [insert eligibility conditions, if any]].****]***

[OPTION 1b for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): *[****Insert name of specific cost category****] are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.****]***

[same for each specific cost category]

[OPTION 2: *Not applicable****]***

6.3 Conditions for costs of linked third parties to be eligible

[OPTION 1 to be used if Article 14 applies: Costs incurred by linked third parties *are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.****]***

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[22] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

[23] Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[OPTION 2:** Not applicable**]

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary *[or linked third party]),* if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *[Commission][Agency]*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *[Commission][Agency]* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action*[;][.]*

[(c) ***OPTION for cost categories explicitly excluded in the work programme:*** *[insert name of excluded cost category]]*.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the *[Commission][Agency]* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

[OPTION 1 for beneficiaries not receiving EU funding: **9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding**

*Beneficiaries that [are not eligible for EU funding][or][request zero funding] ('**beneficiaries not receiving EU funding**') must implement the action tasks attributed to them in Annex 1 in accordance with Article 7.1.*

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

[OPTION A, to be used if the beneficiary not receiving EU funding IS NOT the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to[**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22.**]***

[OPTION B, to be used if the beneficiary/coordinator not receiving EU funding has linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*Articles 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EU funds.*

*[These beneficiaries][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.**]***

[OPTION C, to be used if the beneficiary not receiving EU funding IS the coordinator and does not have linked third parties receiving EU funding: *Chapter 3, Articles 10 to 15, 18.1.2, 20.6, 23a, 26.4, 27.2, 28.1 [**OPTION:** (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 and 40 do not apply to [**OPTION 1 by default**: these beneficiaries][**OPTION 2 if more than one of the three options apply to the grant**: [insert short name of the beneficiary]].*

*[They][The beneficiary] will not be subject to financial checks, reviews and audits under Article 22 for [their][its] own costs.***]**

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

[additional OPTION for beneficiaries requesting zero funding: *If a beneficiary requesting zero funding receives funding later on (through an amendment; see Article 55), all obligations will apply retroactively.]*

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation in the Agreement may be terminated (see Article 50).

*Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.***]**

[OPTION 2: *Not applicable***]**

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION: *In addition, if the value of the purchase exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[24]***]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[25] (or 2014/24/EC[26]) or 'contracting entities' within the meaning of Directive

[24] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

2004/17/EC[27] (or 2014/25/EC[28]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

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[25] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[26] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. (OJ L 94, 28.03.2014, p. 65).

[27] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[28] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *[Commission][Agency]* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

[OPTION:** In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiaries must comply with the following rules: [...].*[29]]***

***[OPTION for actions involving PCP or PPI:** In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiaries must follow a transparent and non-discriminatory procedure, including at least the following:*

*(a) an '**open market consultation**' published in the Official Journal of the European Union via a '**prior information notice (PIN)**' and promoted and advertised widely;*

*(b) a '**contract notice**' allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*

*(c) a '**request for tenders**' based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*

*(d) an objective and non-discriminatory **evaluation** of the tenders and **award** of subcontract(s) to the tender(s) offering **best value for money**;*

*(e) a '**contract award notice**' published in the Official Journal of the European Union.*

The beneficiaries must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

> *"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No [number]). The EU is however not participating as a contracting authority in this procurement."**]***

***[OPTION 1 only for actions involving PPI:** Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

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[29] If the authorising officer decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EU contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The authorising officer may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP action, the beneficiaries do not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, they must make a ***request for tenders*** *from at least* ***three providers*** *(including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC (or 2014/24/EU) and 2004/17/EC (or 2014/25/EU)*[30]***.]***

[OPTION 2 only for actions involving PCP: *The subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

*The beneficiaries must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').****]***

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *[Commission][Agency]* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[30] See Articles 28 and 31(2)(a) of Directive 2004/18/EC replaced by Articles 26 and 32(3)(a) of Directive 2014/24/EU and Article 40(3)(b) of Directive 2004/17/EC replaced by Article 50(b) of Directive 2014/25/EU.

[OPTION for classified information: *Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the [Commission][Agency] (see Article 37).****]***

The beneficiaries must ensure that *[the Agency,]* the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION 1: 14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following ***affiliated entities***[31] *and* ***third parties with a legal link to a beneficiary***[32] *(****'linked third parties'****) may implement the action tasks attributed to them in Annex 1:*

[31] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:

- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*
- *[name of the entity (short name)], affiliated or linked to [short name of the beneficiary] [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]*

[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

[OPTION 1: 14a.1 Rules for calling upon international partners to implement part of the action

*The following international **partners**[33] may implement the action tasks attributed to them in Annex 1:*

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;

(b) the legal entities concerned are owned or supervised by the same public body.

[32] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

[33] 'International partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

- *[name of the entity (short name)], international partner of [short name of the beneficiary]*
- *[name of the entity (short name)], international partner of [short name of the beneficiary]*

[same for more international partners]

The costs of the international partners are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant.*

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their international partners.

The beneficiaries must ensure that their obligations under Articles 18.1.1, 20.3(a), 20.4(a), 35, 36, 38 also apply to their international partners.

14a.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

***[OPTION 1 to be used if foreseen in the work programme:** 15.1.1 The beneficiaries must provide financial support in accordance with the conditions set out in Annex 1.*

At a minimum, these conditions must include:

(a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

(b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

*15.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.**]***

[OPTION 2:** Not applicable**]

15.2 Financial support in the form of prizes

***[OPTION 1 to be used if foreseen in the work programme:** 15.2.1 The beneficiaries must provide prizes in accordance with the conditions described in Annex 1.*

At a minimum, these conditions must include:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize, and

(d) the payment arrangements.

The beneficiaries must ensure that [the Agency,] the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

*15.2.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.**]***

[OPTION 2:** Not applicable**]

15.3 Consequences of non-compliance

***[OPTION 1 to be used if 15.1 and/or 15.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION 1 for trans-national access to research infrastructure: *16.1.1 '**Access providers**'*[34] *must provide access to research infrastructure or installations*[35] *in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) categories of users that may have access:

*Trans-national access must be provided to selected '**user-groups**', i.e. teams of one or more researchers (users) led by a '**user group leader**'.*

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*

- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country[36] *is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex 1;*

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[34] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

[35] '**Installation'** means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

[36] For the definition, see 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in ***[OPTION for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION for Euratom grants:*** *Article 5 of*

(c) procedure and criteria for selecting user groups:

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

The user groups must be selected by a ***selection panel*** *set up by the access providers.*

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiaries, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: *In addition, the beneficiaries must comply with the following additional rules for the selection of user groups: [...]*[37]***]***.

(d) other conditions:

The access provider must request written approval from the [Commission][Agency] (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*

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*Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (‘**H2020 Euratom Research and Training Programme Regulation No 1314/2013**’) (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.**]***

[37] If the authorising officer considers necessary to give priority to certain categories of users.

- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.**]***

[OPTION 2:** Not applicable**]

16.2 Rules for providing virtual access to research infrastructure

***[OPTION 1 for virtual access to research infrastructure:** '**Access providers**'[38] must provide access to research infrastructure or installations[39] in accordance with the following conditions:*

(a) access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

*The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiaries, unless otherwise specified in Annex 1.**]***

[OPTION 2:** Not applicable**]

16.3 Consequences of non-compliance

***[OPTION 1 to be used if 16.1 and/or 16.2 are applicable:** If a beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If a beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

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[38] '**Access provider**' means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

[39] '**Installation**' means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *[Commission][Agency]* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

(i) changes in its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties and*

(ii) changes in the name, address, legal form, organisation type of its linked third parties;]

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants[40]:*** *three]* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *[Commission][Agency]* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. ***[OPTION for trans-national access to research infrastructure:*** *This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.****]*** Beneficiaries do not need to identify the actual eligible costs covered or to keep

[40] For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): '**low value grants**' are lower or equal to EUR 60 000.

or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries *[and linked third parties]* may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate*[;][.]*

(d) ***[OPTION if lump sum foreseen in Article 5.2**: for **lump sum costs**: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiaries do not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]***

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *[Commission][Agency]* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception**,** for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

[OPTION to be added if Article 14 applies**: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *[Commission][Agency]* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month [X]
[*- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]
[same for other RPs]
*- RPN: from month [N+1]to [the last month of the project].****]***

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities*[.][;]*

[OPTION for trans-national access to research infrastructure: *The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);****] [OPTION for virtual access to research infrastructure:*** *The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;****]***

(iii) a **summary** for publication by the *[Commission][Agency]*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary *[and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiaries *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary *[and from each linked third party]*, for the reporting period concerned;

(iii) ***[OPTION 1 if the JRC is a beneficiary:*** *information on the amount of each interim payment and payment of the balance to be paid by the [Commission][Agency] to the Joint Research Centre (JRC);****][OPTION 2:*** *not applicable;****]***

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary *[and for each linked third party]*, if it requests a

total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

[OPTION 1 for grants above EUR 5 million with reporting periods beyond 18 months[41]: *In addition to the reporting requirements set out above (Article 20.1 to 20.3), the coordinator must inform the [Commission][Agency] by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiaries from the starting date of the action.*

*This information is required for the Commission's accounting purposes and will not be used to calculate the final grant amount.****]***

[OPTION 2: *Not applicable****]***

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries *[and linked third parties]* with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *[and linked third parties]* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the *[Commission][Agency]* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

[41] To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the *[Commission][Agency]* may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment;**

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR [**insert amount** (insert amount in words)].

The *[Commission][Agency]* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR [**insert amount** (insert amount in words)], corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *[Commission][Agency]* from the pre-financing payment and transferred into the '**Guarantee Fund**'

[OPTION if the JRC is a beneficiary: *Moreover, the part of the pre-financing payment related to the Joint Research Centre (JRC) ([**insert amount** (insert amount in words)]) is not paid to the coordinator, but kept by the [Commission][Agency] for the JRC.****]***

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *[Commission][Agency]* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *[Commission][Agency]* in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiaries *[and the linked third parties]* (see Article 20) and approved by the *[Commission][Agency]* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *[Commission][Agency]* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *[Commission][Agency]* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the *[Agency, the]* Commission or an*[other]* executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *[Commission][Agency]* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *[Commission][Agency]* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *[Commission][Agency]* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]][42]

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *[Commission][Agency]* bears the cost of transfers charged by its bank;

- the beneficiary bears the cost of transfers charged by its bank;

- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *[Commission][Agency]* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *[Commission][Agency]* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

[42] BIC or SWIFT code applies to for countries if the IBAN code does not apply.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The *[Agency or the]* Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the *[Agency or the]* Commission may be assisted by external persons or bodies.

The *[Agency or the]* Commission may also request additional information in accordance with Article 17. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The *[Agency or the]* Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The *[Agency or the]* Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The *[Agency or the]* Commission may request beneficiaries to provide such information to it directly

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The *[Agency or the]* Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the *[Agency or the]* Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The *[Agency or the]* Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts *[or lump sums]*.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 [43]and No 2185/96[44] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

[43] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[44] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[45], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

***[OPTION 1 for international organisations**: In conformity with its financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), may undertake, including on the spot, checks, reviews, audits and investigations.*

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union.]

***[OPTION 2:** Not applicable;]*

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

[45] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

The *[Agency or the]* Commission may extend findings from other grants to this grant (‘**extension of findings from other grants to this grant**’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The *[Agency or the]* Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the *[Agency or the]* Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the *[Agency or the]* Commission in justified cases.

The *[Agency or the]* Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors, irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the *[Agency or the]* Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The *[Agency or the]* Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The *[Agency or the]* Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *[EU][Euratom]* programme.

Evaluations may be started during implementation of the action and up to ***[OPTION 1 by default:*** *five]****[OPTION 2 for low value grants:*** *three]* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The *[Agency or the]* Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *[Commission][Agency]* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[46].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘**agreement on background**’).

[46] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[47] established in an EU Member State or '**associated country**'[48], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

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[47] For the definition, see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[48] For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: '**associated country**' means a non EU-country (third country) which is party to an international agreement with the Union, as identified in ***[OPTION 1 for EU grants:*** *Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.****][OPTION 2 for Euratom grants:*** *Article 5 of Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation ('****H2020 Euratom Research and Training Programme Regulation No 1314/2013****') (OJ L 347, 20.12.2013, p. 948) . Article 5 sets out the conditions for association of non-EU countries to Horizon 2020.]*

[OPTION 1 for trans-national access to research infrastructure: *The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.*

*The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.****]***

[OPTION 2: *Not applicable;****]***

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *[EU][Euratom][Agency]* ownership, to protect results

26.4.1 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *[Commission][Agency]* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the *[Commission][Agency]* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *[The EU][Euratom][The Agency]* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *[Commission][Agency]* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *[Commission][Agency]* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *[EU][Euratom][Agency]* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *[the EU][Euratom][the Agency]* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work programme: *In addition, the beneficiaries must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.****]***

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

[OPTION for results that could contribute to standards if foreseen in the work programme: *If results could reasonably be expected to contribute to European or international standards,*

the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the [Commission][Agency].]

If results are incorporated in a standard, the beneficiary concerned must — unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work programme: *In addition, the beneficiaries must comply with the additional dissemination obligations set out in Annex 1.]*

[OPTION for additional dissemination obligations for interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.]*

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work programme: *Moreover, the beneficiaries must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).]*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *[Commission][Agency]* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms ["European Union (EU)" and "Horizon 2020"]["Euratom" and Euratom research and training programme 2014-2018"];
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

***[OPTION 1 for actions participating in the open Research Data Pilot**: Regarding the digital research data generated in the action ('**data**'), the beneficiaries must:*

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(ii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

*As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.**]***

[OPTION 2:** Not applicable;**]

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [Number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *[Commission][Agency]* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *[Commission][Agency]* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licences

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) ***[OPTION 1 if additional exploitation obligations in Annex 1:*** *the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)****] [OPTION 2:*** *not applicable****]****.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *[Commission][Agency]* right to object to transfers or licensing

[OPTION 1 for EU grants: *The [Commission][Agency] may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:*

(a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*

(b) *the [Commission][Agency] considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

A beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the [Commission][Agency] before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The [Commission][Agency] may request additional information.

If the [Commission][Agency] decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the [Commission][Agency] decision, within the period set out above;*
- *if the [Commission][Agency] objects;*
- *until the conditions are complied with, if the [Commission][Agency] objection comes with conditions.]*

[OPTION 2 for Euratom grants: *The Commission may* ***[OPTION:****— up to four years after the period set out in Article 3 —****]*** *object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:*

(a) it is to a third party established in a non-EU country not associated to the Euratom research and training programme 2014-2018, and

(b) the Commission considers that the transfer or licence is not in line with the EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.

Security considerations include the defence interests of the Member States under Article 24 of the Euratom Treaty.

A beneficiary that intends to transfer ownership or grant a licence must formally notify the Commission before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The Commission may request additional information.

If the Commission decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- *pending the Commission decision, within the period set out above;*
- *if the Commission objects;*
- *until the conditions are complied with, if the Commission objection comes with conditions.]*

[OPTION 3: *Not applicable****]***

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

***[OPTION 1 by default for EU grants**: The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.*

Such access rights are limited to non-commercial and non-competitive use.

*This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).**]***

[OPTION 2 for calls under Specific Objective 'Secure societies - Protecting freedom and security of Europe and its citizens': *The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices and agencies as well as EU Member States' national authorities, necessary for developing, implementing or monitoring their policies or programmes in this area.*

Such access rights are limited to non-commercial and non-competitive use.

Access is conditional on an agreement to define specific conditions ensuring that:

(a) the access will be used only for the intended purpose and

(b) appropriate confidentiality obligations are in place.

The requesting EU Member State or EU institution, body, office or agency must inform all other EU Member States of such a request.

This does not change the security obligations in Article 37, which still apply.]

[OPTION 3 for Euratom grants: *The beneficiaries must give access to their results — on a royalty-free basis — to the European Atomic Energy Community (Euratom) and its joint undertakings, for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with third countries and international organisations.*

*As an exception to Article 31.1, such access rights include the right to authorise third parties to use the results in public procurement and the right to sublicense and are limited to non-commercial and non-competitive use.**]***

31.6 Access rights for third parties

[OPTION 1a for additional access rights for complementary grants if foreseen in the work programme*: The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries*[49]*, for the purposes of the complementary grant agreement(s) (see Article 2).**]***

[OPTION 1b for additional access rights for interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and [**OPTION A:** under fair and reasonable conditions (see Article 25.3)][**OPTION B:** on a royalty-free basis] — access to their results needed for interoperability.**]***

[OPTION 1c for additional access rights for cross-border interoperability if foreseen in the work programme: *The beneficiaries must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to their results needed for*

[49] '**Complementary beneficiary**' means a beneficiary of a complementary grant agreement.

interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.

Beneficiaries must give access to software components under an EU public licence (or compatible licences) and must comply with any additional requirements set out in in Annex 1.]

[OPTION 1d for trans-national access to research infrastructure: *The access provider must give the users royalty-free access to the results needed to implement the action.****]***

[OPTION 2: *Not applicable****]***

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[50], in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

[50] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[51].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — ***[OPTION for actions participating in the Open Research Data Pilot:*** *in addition to the open access obligations under Article 29.3****]*** as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced ;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;

[51] European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the *[Commission][Agency]* (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic

interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the *[Commission][Agency]* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *[Commission][Agency]* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the *[Commission][Agency]* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *[Commission][Agency]* may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU’s financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[52], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

[OPTION 1 if applicable to the grant: *The beneficiaries must comply with the 'security recommendation(s)' set out in Annex 1.*

For security recommendations restricting disclosure or dissemination, the beneficiaries must — before disclosure or dissemination to a third party (including linked third parties, such as affiliated entities) — inform the coordinator, which must request written approval from the [Commission][Agency].

[52] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

*In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55).**]***

[OPTION 2:** Not applicable**]

37.2 Classified information

***[OPTION 1 if applicable to the grant:** The beneficiaries must comply with the security classification set out in Annex 1 ('security aspect letter (SAL)' and 'security classification guide (SCG)').*

Information that is classified must be treated in accordance with the security aspect letter (SAL) and Decision No 2015/444[53] — until it is declassified.

Action tasks involving classified information may not be subcontracted without prior explicit written approval from the [Commission][Agency].

In case of changes to the security context, the beneficiaries must inform the coordinator, which must immediately inform the [Commission][Agency] and, if necessary, request for Annex 1 to be amended (see Article 55)].

[OPTION 2:** Not applicable**]

37.3 Activities involving dual-use goods or dangerous materials and substances

***[OPTION 1 if applicable to the grant:** Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.*

*Before the beginning of the activity, the coordinator must submit to the [Commission][Agency] (see Article 52) a copy of any export or transfer licences required under EU, national or international law.**]***

[OPTION 2:** Not applicable**]

37.4 Consequences of non-compliance

***[OPTION 1 to be used if 37.1, 37.2 and/or 37.3 are applicable:** If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).*

*Such breaches may also lead to any of the other measures described in Chapter 6.**]***

[OPTION 2:** Not applicable**]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

[53] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information.

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *[Commission][Agency]* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *[Commission][Agency]* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> For communication activities: "This project has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *[European Union's Horizon 2020 research and innovation programme][Euratom research and training programme 2014-2018]* under grant agreement No [number]".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *[Commission][Agency]*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *[Agency and]* Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *[Agency and the]* Commission *[is][are]* not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *[Agency and the]* Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The *[Agency and the]* Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the *[Agency's or the]* Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *[Agency or the]* Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *[Agency,* the*]* Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) translation;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[54], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

[54] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the *[Agency or the]* Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *[Agency or the]* Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *[[name of the Agency] and the] [European Union (EU)][Euratom]* under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *[Agency and the]* Commission

Any personal data under the Agreement will be processed by the *[Agency or the]* Commission under Regulation No 45/2001[55] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *[Agency or the]* Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *[Agency or the]* Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the *[Agency and]* Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

[55] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *[Agency or the]* Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the *[Agency or the]* Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *[Commission][Agency]* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *[COMMISSION][AGENCY]*

The beneficiaries may not assign any of their claims for payment against the *[Commission][Agency]* to any third party, except if approved by the *[Commission][Agency]* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *[Commission][Agency]* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *[Commission][Agency]*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibilities towards the *[Commission][Agency]*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to

any additional EU funding for doing so), unless the *[Commission][Agency]* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself *[and its linked third parties]* and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *[Agency or the]* Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *[Agency or the]* Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *[Commission][Agency]* (in particular, providing the *[Commission][Agency]* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *[Commission][Agency]* and verify their completeness and correctness before passing them on to the *[Commission][Agency]*;

(iv) submit the deliverables and reports to the *[Commission][Agency]* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *[Commission][Agency]* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *[Commission][Agency]*.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

[OPTION to be used when the coordinator is a secondary or higher education establishment or public body and there is an 'authorisation to administer' given to a third party created, controlled or affiliated to the coordinator: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(v) and (vi) above to [insert name of third party with an authorisation to administer]. The coordinator retains sole responsibility for the EU contribution and for compliance with the obligations under the Agreement.****]***

[OPTION to be used when the coordinator is an European Research Infrastructure Consortium (ERIC)[56] without own resources: *As an exception, the coordinator delegates the tasks set out in Point 2(b)(i) to (iv) above to [insert name of member of the ERIC]. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.****]***

41.3 Internal arrangements between beneficiaries — Consortium agreement

[OPTION 1 to be used, unless the work programme specifies that there is no need for a consortium agreement*: The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '****consortium agreement****' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

[56] See Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 08.08.2009, p.1).

[OPTION 2:** Not applicable**]

41.4 Relationship with complementary beneficiaries — Collaboration agreement

***[OPTION 1 for complementary grants if foreseen in the work programme**: The beneficiaries must conclude a written 'collaboration agreement' with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:*

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

*The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.**]***

[OPTION 2:** Not applicable**]

41.5 Relationship with partners of a joint action — Coordination agreement

***[OPTION 1 for joint actions (joint call with a third country or an international organisation)**: The beneficiaries must conclude a '**coordination agreement**' with the partners of the third country or international organisation action (see Article 2), covering for instance:*

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*
- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

*The coordination agreement must not contain any provision contrary to the Agreement.**]***

[OPTION 2:** Not applicable**]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, at the time of an **interim payment**, **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant (**see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full ***[OPTION if lump sum foreseen in Article 5.2:**, except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented**]***.

If the rejection of costs does not lead to a recovery (see Article 44), the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *[Commission][Agency]* of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the *[Commission][Agency]* will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the *[Commission][Agency]* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the *[Commission][Agency]* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *[Commission][Agency]* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The *[Commission][Agency]* may — **after termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21)..

43.3 Effects

If the *[Commission][Agency]* reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the *[Commission][Agency]* reduces the grant **at the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *[Commission][Agency]* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *[Commission][Agency]* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *[Commission][Agency]* will — after **termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt ***[OPTION if Article 14 applies:*** *(including undue amounts paid by the [Commission][Agency] for costs declared by its linked third parties)****]***, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *[Commission][Agency]* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[57] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *[Commission][Agency]* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

[57] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note and has not submitted the report on the distribution of payments: the *[Agency or the]* Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *[Commission][Agency]* by the date in the debit note, but has submitted the report on the distribution of payments: the *[Commission][Agency]* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****][OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) *[, Article 106a of the Euratom Treaty]* and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *[Commission][Agency]*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *[Commission][Agency]* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

[plus

its linked third parties' costs declared in the final summary financial statement and approved by the [Commission][Agency] multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned]}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the *[*Commission*][Agency]* will also recover these amounts.

The *[Commission][Agency]* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *[Commission][Agency]* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *[Agency or the]* Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *[Agency, the]* Commission or an*[other]* executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *[Agency or the]* Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund.** The *[Agency or the]* Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) ***[OPTION 1 if Article 14 applies and joint and several liability has been requested by the [Commission][Agency]:*** *if a linked third party has accepted joint and several liability (see Article 14), by* ***holding the third party liable*** *up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or****] [OPTION 2:*** *not applicable;****]***

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU)

[, Article 106a of the Euratom Treaty] and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *[Agency or the]* Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the *[Agency or the]* Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *[Commission][Agency]*

The *[Commission][Agency]* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *[Commission][Agency]* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *[Commission][Agency]* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *[Commission][Agency]* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *[Commission][Agency]* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *[Commission][Agency]* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *[Commission][Agency]* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *[Commission][Agency]* may — at any moment — suspend payments, in whole or in part and for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar

conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the *[Commission][Agency]* will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *[Commission][Agency]*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *[Commission] [Agency]* will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3), must not contain any individual financial statements from the beneficiary concerned *[and its linked third parties]*. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *[Commission][Agency]* the suspension (see Article 52), stating:

- the reasons why and

- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *[Commission][Agency]*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *[Commission][Agency]* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *[Commission][Agency]*

49.2.1 Conditions

The *[Commission][Agency]* may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *[Commission][Agency]* (see Article 46).

Suspension of the action implementation does not affect the *[Commission's][Agency's]* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52), stating:

- the reasons why and

- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *[Commission][Agency]* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *[Commission][Agency]* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and

- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *[Commission][Agency]* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *[Commission][Agency]*

50.3.1 Conditions

The *[Commission][Agency]* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

  (i) resumption is impossible, or

  (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1****][OPTION 2:*** *not applicable****]***;

(j) ***[OPTION 1 for joint actions (joint call with a third country or an international organisation)****: the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action****][OPTION 2:*** *not applicable****]***;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) ***[OPTION 1:*** *despite a specific request by the [Commission][Agency], a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks****][OPTION 2:*** *not applicable****]***.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *[Commission][Agency]* will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *[Commission][Agency]* of the measures to ensure compliance with the obligations under the Agreement.

If the *[Commission][Agency]* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *[Commission][Agency]* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *[Commission][Agency]* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *[Commission's][Agency's]* right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the *[Commission][Agency]* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *[Commission][Agency]* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *[Commission][Agency]*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *[Commission][Agency]* will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary *[and its linked third parties]* in the termination report and approved by the *[Commission][Agency]*.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the *[Commission][Agency]* will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary .

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *[Commission][Agency]* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *[Commission][Agency]* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the *[Commission][Agency]* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due and the *[Commission][Agency]* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44) ;

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

  In this case, the *[Commission][Agency]* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *[Commission][Agency]* the amount due. The *[Commission][Agency]* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *[Commission][Agency]* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *[Commission][Agency]* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,

- was not due to error or negligence on their part (or on the part of third parties involved in the action), and

- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,

- labour disputes or strikes, or

- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and

- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the *[Commission][Agency]* finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *[Agency and]* Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or

- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

[insert URL]

The *[Commission][Agency]* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *[Commission][Agency]*** must be sent to the official mailing address indicated on the *[Commission's][Agency's]* website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION 1 for all international organisations: *Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the [insert name of international organisation(s)] by its constituent documents or international law.****]***

[OPTION 2: *Not applicable****]***

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[58], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

[58] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *[Commission][Agency]* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *[Commission][Agency]* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58) ***[OPTION if Article 14 applies and joint and several liability has been requested:*** *and for beneficiaries for which the [Commission][Agency] has requested joint and several liability of a linked third party, by also submitting — at accession — a declaration on joint and several liability (see Annex 3a) signed by the third party.****]***

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline , the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *[Commission's][Agency's]* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

[additional OPTION for international organisations that do not accept any applicable law clause: *As an exception, there is no applicable law for [insert name(s) of the international organisations concerned]****]****.*

[additional OPTION for international organisations that would accept an applicable law clause, but not the standard clause (EU + Belgian law): *As an exception, the Agreement is governed by a different applicable law for the following beneficiaries:*

- *[insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*
- *insert name(s) of the international organisations concerned]: [by the applicable EU law][, supplemented if necessary]****[****by the law of [Belgium][insert name of another Member State or EFTA country]****]****[and, where appropriate,][by the general principles governing the law of international organisations and the rules of general international law]*

*[same for other international organisations].****]***

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

[additional OPTION for non-EU beneficiaries (except beneficiaries established in an associated country with an association agreement to Horizon 2020 that stipulates sole jurisdiction of the European Court of Justice)*: As an exception, if such a dispute is between the [Commission][Agency] and [insert non-EU beneficiary(ies) name(s)], the competent Belgian courts have sole jurisdiction.****]***

[additional OPTION for international organisations and for beneficiaries not eligible for EU funding which according to their national law cannot be subject to the jurisdiction of the Belgian courts: *As an exception, for the following beneficiaries:*

- *[insert name of international organisation or beneficiary not eligible for EU funding]*
- *[insert name of international organisation or beneficiary not eligible for EU funding]*

[same for other beneficiaries that are international organisations or beneficiaries not eligible for EU funding]

*such disputes must — if they cannot be settled amicably — be referred to arbitration. Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator. The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply. The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party. The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English. The arbitral award will be binding on all parties and will not be subject to appeal.****]***

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. ***[OPTION for Agency grants:*** *Actions against offsetting and enforceable decisions must be brought against the Commission (not against the Agency).****]***

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *[Commission][Agency]* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator	For the *[Commission][Agency]*
[function/forename/surname] [electronic signature]	[forename/surname] [electronic signature]
Done in [English] on [electronic time stamp]	Done in [English] on [electronic time stamp]

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MODEL ANNEX 2 FOR H2020 GENERAL MGA — MULTI

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)													EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	*[F. Costs of ...]*			Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs :	Information for auditors:	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*	A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of ...]*[5]		*[F.2 Costs of ...]*[5]					Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding/International partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%	Unit[11]		*[Unit][Lump sum]*[12]							
	a	Total b	No hours	Total c	d	*[e]*	f	Total g	h = 0,25 x (a+b+c+f+g-*[i1]*[13]-*[i2]*[13] n)	No units	Total *[i1]*	Total *[i2]*	j = a+b+c+d+*[e]* +f+g+h +*[i1]* +*[i2]*	k	l	m	n	Yes/No	
1 [short name beneficiary]																			
[short name linked third party]																			
[short name linked third party not eligible for EU funding]																			
[short name linked third party requesting zero EU funding]																			
[short name international partner]																			
Total beneficiary																			
2 [short name beneficiary]																			
[short name linked third party]																			
Total beneficiary																			
X [short name beneficiary not eligible for EU funding][14]																			
X [short name beneficiary requesting zero funding][14]																			
[short name linked third party][15]																			
Total beneficiary																			
Total consortium																			

[1] See Article 6 for the eligibility conditions

[2] Indirect costs already covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This *theoretical* amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).

[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.

[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.

[6] See Article 5 for the forms of costs

[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice

[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).

[9] Unit and costs per unit : calculated according the beneficiary's usual accounting practice.

[10] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs

[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).

[12] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)

[13] Only specific unit costs that do not include indirect costs

[14] See Article 9 for beneficiaries not receiving EU funding

[15] Only for linked third parties that receive EU funding

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*]/[*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{{ EUR 4,650 / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

Country-specific correction coefficient (in force at the time of the call):

EU Member States

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AT	104.8%	DK	135.3%	HR	97.5%	LV	75.9%	SE	111.7%
BE	100.0%	EE	78.3%	HU	76.2%	MT	89.6%	SI	86.1%
BG	71.5%	EL	92.7%	IE	113.5%	NL	104.3%	SK	82.6%
CY	91.8%	ES	97.6%	IT	106.7%	PL	76.4%	UK	120.3%
CZ	83.8%	FI	116.6%	LT	73.1%	PT	89.1%		
DE	98.8%	FR	111.0%	LU	100.0%	RO	68.3%		

H2020 associated countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AL	76.1%	FO	134.1%	LI	110.0%	MK	68.4%	TR	86.6%
BA	73.6%	IL	108.7%	MD	61.1%	NO	131.9%		
CH	113.1%	IS	116.6%	ME	66.9%	RS	67.1%		

Other countries

country	coefficient	country	coefficient	country	coefficient	country	coefficient	country	coefficient
AM	89.9%	CU	83.8%	JP	115.9%	NI	57.3%	TJ	64.9%
AO	114.6%	CV	76.4%	KE	78.1%	NP	73.5%	TL	78.3%
AR	58.5%	DJ	93.4%	KG	83.1%	NZ	94.1%	TN	70.5%
AU	105.0%	DO	66.9%	KH	70.5%	PA	57.0%	TO	85.0%
AZ	93.0%	DZ	81.7%	KR	105.2%	PE	75.5%	TT	74.1%
BB	116.6%	EC	68.8%	KZ	100.2%	PG	83.0%	TW	83.6%
BD	47.2%	EG	48.6%	LA	77.7%	PH	65.8%	TZ	65.2%
BF	93.8%	ER	61.2%	LB	86.4%	PK	49.4%	UA	92.3%
BJ	92.6%	ET	85.2%	LK	61.6%	PS	100.4%	UG	65.7%
BM	151.5%	FJ	68.1%	LR	100.1%	PY	71.9%	US	99.4%

BO	51.3%	GA	113.1%	LS	56.7%	RU	115.5%	UY	75.3%
BR	92.0%	GE	89.5%	LY	60.0%	RW	87.3%	UZ	51.4%
BW	55.3%	GH	68.2%	MA	83.5%	SA	84.8%	VE	70.0%
BY	65.0%	GM	67.7%	MG	80.0%	SB	93.3%	VN	51.1%
BZ	75.3%	GN	60.4%	ML	90.4%	SD	65.1%	VU	112.6%
CA	86.4%	GT	78.8%	MR	64.5%	SG	102.5%	WS	75.8%
CD	127.6%	GW	102.7%	MU	72.7%	SL	85.2%	XK	58.6%
CF	114.3%	GY	58.9%	MW	76.0%	SN	86.2%	YE	68.1%
CG	124.9%	HK	93.8%	MX	70.4%	SR	50.6%	ZA	55.8%
CI	102.0%	HN	69.0%	MY	71.6%	SV	74.3%	ZM	66.4%
CL	67.1%	HT	108.7%	MZ	71.6%	SY	74.8%	ZW	47.2%
CM	103.3%	ID	75.3%	NA	68.3%	SZ	56.8%		
CN	85.0%	IN	52.8%	NC	128.9%	TD	125.3%		
CO	76.6%	JM	94.9%	NE	87.9%	TG	88.7%		
CR	76.7%	JO	75.5%	NG	92.4%	TH	65.0%		

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment): For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] ***]***

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

[OPTION if specific unit cost applicable to the grant: **2. Costs for energy efficiency measures in buildings**

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m² per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

Unit cost table (energy efficiency measures unit cost)[59]

Short name beneficiary/linked third party	BEST No	Cost Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

]

[59] Data from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.

Research infrastructure unit cost

[OPTION if specific unit cost applicable to the grant: 3. Access costs for providing trans-national access to research infrastructure

Units[60]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[61])}}{\text{average annual total quantity of access to the installation (over past two years[62])}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[63]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

]

Clinical studies unit cost

[OPTION if specific unit cost is applicable to the grant: 4. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for each task described in the protocol, as follows:

{Task 1

{unit cost component 'personnel costs'

+ unit cost component 'costs of consumables'

60 Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

61 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

62 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

63 Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}

+ Task 2
{unit cost component 'personnel costs'
+ unit cost component 'costs of consumables'
+ unit cost component 'costs of medical equipment'
+ unit cost component 'costs of other specific services'
+ unit cost component 'indirect costs'}

[same for all other tasks]}

Unit cost components calculated as follows:

Unit cost component '**personnel costs**' (i.e. 'personnel costs of doctors' + 'personnel costs of other medical personnel' + 'personnel costs of technical personnel')

For unit cost component 'personnel costs of doctors':

{'average hourly cost for doctors', i.e.:

$$\frac{\text{certified or auditable total personnel costs for doctors for year N-1}}{\{1720 * \text{number of full-time equivalent for the personnel category doctors for year N-1}\}}$$

multiplied by

estimated number of hours worked by doctors for the task (per patient/subject)}

For unit cost component 'personnel costs of other medical personnel':

{'average hourly cost for other medical personnel', i.e.:

$$\frac{\text{certified or auditable total personnel costs for other medical personnel for year N-1}}{\{1720 * \text{number of full-time equivalent for the personnel category other medical personnel for year N-1}\}}$$

multiplied by

estimated number of hours worked by other medical personnel for the task (per patient/subject)}

For unit cost component 'personnel costs of technical personnel':

{average hourly cost for technical personnel, i.e.:

$$\frac{\text{certified or auditable total personnel costs for technical personnel for year N-1}}{\{1720 * \text{number of full-time equivalent for the personnel category technical personnel for year N-1}\}}$$

multiplied by

estimated number of hours worked by technical personnel for the task (per patient/subject)}

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act

Unit cost component '**costs of consumables**' (i.e. 'costs of consumables category 1 + 'costs of consumables category 2' + 'costs of consumables category 3', etc)

For each category of consumables:

{'average price per item', i.e.:

$$\frac{\{\text{certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned}}{\text{total number of items purchased in year N-1 for the category of consumables concerned}\}}$$

multiplied by

estimated number of items used for the task (per patient/subject)}

'total costs of purchase of the consumables' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for

consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**costs of medical equipment**' (i.e. 'costs of medical equipment category 1' + 'costs of medical equipment category 2' + 'costs of medical equipment category 3', etc.)

For each category of medical equipment:

{'average cost of depreciation and directly related services per unit of use', i.e.:

$$\frac{\{\text{certified or auditable total depreciation costs in year N-1 for the category of equipment concerned} + \text{certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}\}}{\text{total capacity in year N-1}}$$

multiplied by

estimated number of units of use of the equipment for the task (per patient/subject)}

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value-for-money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

Unit cost component '**costs of other specific services**' (i.e. 'costs of contracts for specific service 1' + 'costs of contracts for specific service 2' + 'costs of contracts for specific service 3', etc.)

For each category of specific service:

'average cost of a specific service per patient or subject', i.e.:

$$\frac{\text{certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies}}{\text{total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1}}$$

'total costs of purchase of a service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests

Unit cost component '**indirect costs**'

{25%
multiplied by
{unit cost component 'personnel costs' + unit cost component 'costs of consumables' + unit cost component 'costs of medical equipment'}}

The following must be excluded:

- costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises and
- costs of providing financial support to third parties (if any).

Unit cost table: clinical studies unit cost[64]

[64] Same table as in proposal and Annex 1.

[Insert name of clinical study]							
Tasks and unit cost components		**Resources per patient**	**Amount per unit for beneficiary /linked third party 1 [insert short name]**	**Amount per unit for beneficiary /linked third party 2 [insert short name]**	**Amount per unit for beneficiary/linked third party 3 [insert short name]**		**…**
						in-kind contributions by third party*	
Task No. 1 Blood sample							
Personnel costs	doctors	----	0	0	0	0	
	other medical personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,55 EUR	9,76 EUR	
	technical personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	13,77 EUR	12,35 EUR	
Costs of consumables	Category 1	Syringe, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Cannula, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Blood container, 1	XX EUR	XX EUR	XX EUR	XX EUR	
	…						
Costs of medical equipment	Category 1	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	
	Category 2	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	
	….						
Costs of other specific services	Category 1						
	Category 2						
	…						
Indirect costs							
Task No. 2							
…							
Total amount per unit			**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR****	

Estimated No of units **(patients/subjects participating in the study)**	**XX**	**XX**	**XX**	**XX**	
Total unit cost for beneficiary/linked third party **(total cost per unit x estimated no of units)**	**XX EUR**	**XX EUR**	**XX EUR**		

* Use costs of third party making in-kind contribution.

** Capped at payment to third party, if any.

]

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

[**Full official name of the beneficiary/new beneficiary/new coordinator (short name)**], established in [official address in full], *[**OPTION for beneficiaries with VAT:** VAT number [insert number],]* ('the beneficiary' or 'the coordinator'), represented for the purpose of signing this Accession Form by [forename and surname, function],

hereby agrees

to become *[beneficiary][coordinator]* No [insert beneficiary no]

in Grant Agreement No [insert agreement number] ('the Agreement')

between [full official name of the coordinator] **and** *[the European Union ('the EU', represented by the European Commission ('the Commission'] [the European Atomic Energy Community ('Euratom'), represented by the European Commission ('the Commission'),]**[**[the [Research Executive Agency (REA)][European Research Council Executive Agency (ERCEA)][Innovation and Networks Executive Agency (INEA)][Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the power delegated by the European Commission ('the Commission'),**]***

for the action entitled [insert title of the action (insert acronym)].

[OPTION for beneficiaries/new beneficiaries: and mandates

the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.**]

By signing this Accession Form, the beneficiary accepts the grant and agrees to *[**OPTION: for new coordinators:** take on the obligations and role of coordinator and to]* implement it in accordance with the Agreement, with all the obligations and conditions it sets out ***[OPTION for new beneficiaries:,** as from [insert date]*[the date of signature of the Accession Form][the date of entry into force of the amendment] (**'accession date'**) [**additional OPTION for change of beneficiary due to partial takeover:**, and with joint and several liability for undue amounts paid to [insert short name of former beneficiary] (i.e. recoveries)] — if the [Commission][Agency] agrees with the request for amendment**]***.

SIGNATURE

For the beneficiary/new beneficiary/new coordinator:
[function/forename/surname]
[electronic signature]

Done in [English] on [electronic time stamp]

ANNEX 3a

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary, if Article 14 applies and linked third party liability has been requested by the [Commission][Agency])

[**full official name of the entity affiliated or linked to the beneficiary (short name)**] , established in [official address in full], ***[OPTION for linked third parties with VAT:*** *VAT number [insert number]]* ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to beneficiary No [insert number] [full official name of the beneficiary (short name)], established in [official address in full], ***[OPTION for beneficiaries with VAT:*** *VAT number [insert number]]* ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the *[Commission][Agency]* by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EU contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the *[Commission][Agency]*, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 GENERAL MGA — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)														Receipts				Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs			E. Indirect costs[2]	*[F. Costs of …]*			Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of …]*		*[F.2 Costs of …]*		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Unit	Flat-rate[5] 25%	Unit		*[Unit][Lump sum]*						
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	Total h	i=0,25 x (a+b+c+f+*[g]* + h+ *[j]*[6] +*[j2]*[6] -p)	No units	Total *[j1]*	Total *[j2]*	k = a+b+c+d+*[e]* +f +*[g]* +h+ i + *[j1]* +*[j2]*	l	m	n	o	p
[short name beneficiary/linked third party]																			

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less,

[4] See Article 5 for the form of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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TERMS OF REFERENCE FOR AN INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission *[Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission*[, the Agency],* the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission *[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we
[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

<u>The Report</u>

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.
….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.
….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation, the Beneficiary's usual remuneration practice for projects funded under national funding schemes…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *'ADDITIONAL REMUNERATION' MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.* *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS QUALIFIES AS "ADDITIONAL REMUNERATION" AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	14) The natural persons worked under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed.	
		15) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		results were generated by itself.	
		16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		17) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll;	18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		19) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself..	
		If personnel is seconded against payment: 20) The costs declared were supported with documentation and recorded in the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ any other document that supports the costs declared (e.g. invoices, etc.).	Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: ○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable	22) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	
		23) Productive hours were calculated annually.	
		24) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C.*** *THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method B.* 25) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary. 25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).	
		If the Beneficiary applied method C. 26) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		27) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <u>II) For individual hourly rates:</u> The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates;	28) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	
		For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC): 29) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; ○ (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month.	activities irrespective of the source of funding.	
	"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES": *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 30) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
	HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS: *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	*For option II concerning individual hourly rates:* 31) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined. 31.2) The hourly rates do not include additional remuneration.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	32) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		33) Their time-records were authorised at least monthly by the project manager or other superior.	
		34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	36) The exclusive dedication is supported by a declaration signed by the Beneficiary and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		39) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		41) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	42) All minimum conditions were met	

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).	43) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		44) There was a link between the trip and the action.	
		45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		46) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures;	47) Procurement rules, principles and guides were followed.	
		48) There was a link between the grant agreement and the asset charged to the action.	
		49) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	○ they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) ○ they were entered in the accounting system; ○ the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		51) The amount charged corresponded to the actual usage for the action.	
		52) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: ○ the contracts did not cover tasks described in Annex 1; ○ they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); ○ the goods were not placed in the inventory of durable equipment; ○ the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with	53) Contracts for works or services did not cover tasks described in Annex 1.	
		54) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	
		55) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	
		56) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.	58) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	In the cases that a positive ex-ante assessment has been issued *(see the standard factual findings 59-60 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 60) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
D.5	**Costs of internally invoiced goods and services** **The Auditor sampled cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 62-66 listed in the next column, the Auditor: ○ obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs); ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding; ○ verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of	61) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. 62) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding. 63) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary's accounts, excluding any ineligible cost or costs included in other	

	internally invoiced goods and services (see Article 6 GA); ○ verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and verifiable information. ○ verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services. ○ verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.	budget categories.	
		64) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.	
		65) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.	
		66) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE*	67) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	CORRESPONDING REPORTING PERIOD. *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	68) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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TERMS OF REFERENCE FOR AN AUDIT ENGAGEMENT FOR A METHODOLOGY CERTIFICATE IN CONNECTION WITH ONE OR MORE GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[1] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

[1] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[2] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[2] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since [dd Month yyyy]. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy].	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *...]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 employees are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s) complemented by other employees irrespective of their assignments until he has reached 10 employees.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
(including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget in the same period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- ...]*	✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
<u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90 % of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *...]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:**

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
present certificate[1]]. *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- ...]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[official name of the *[Beneficiary] [Linked Third Party]****]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature of the*** *[Beneficiary] [Linked Third Party]>*	***[official name of the Auditor]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature*** *of the Auditor>*

EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Association of Ukraine to the Euratom Research and Training Programme (2014-2018)

Version 1.1
02 December 2016

The Agreement for scientific and technological cooperation between the European Atomic Energy Community and the Government of Ukraine associating Ukraine to the Euratom Research and Training Programme (2014-2018) was signed in Brussels on 27 June 2016 and entered into force on 28 October 2016.

According to the terms of this Agreement, Ukrainian legal entities can participate in indirect actions for nuclear fission, safety and radiation protection of the Programme, as well as in the activities of the Joint Research Centre, **funded from the 2016 budget and onwards**, as entities from an Associated Country (i.e. under the same conditions as those applicable to legal entities of Member States).

The Agreement also provides for participation of Ukrainian legal entities as entities from an Associated Country in indirect actions for fusion research and development of the Programme **funded from the 2017 budget and onwards** in the framework of the EUROfusion consortium's activities. The Euratom fusion energy research programme is implemented through a 'European Joint Programme (EJP) co-fund action', to which only legal entities established or designated by Member States and Associated Countries to the Euratom Research and Training Programme (2014-2018) can participate.

Given that the EU does not recognise the illegal annexation of Autonomous Republic of Crimea and the City of Sevastopol, under the terms of this Agreement, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate. Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, the Agreement will be revised accordingly.

History of changes

Version	Publication Date	Change
1.0	29.08.2016	▪ Initial version
1.1	02.12.2016	▪ Entry into force of the Agreement associating Ukraine to the Euratom Research and Training Programme (2014-2018)

Open Access: The problem landscape from an ethical perspective

László Fésüs

Hungarian Academy of Sciences and University of Debrecen
Hungary

Ethical Aspects of Open Access: A Windy Road. Brussels February 1st, 2018

Science publishing has dramatically changed in the past 15 years

- advanced digital technologies,
- the rise of interdisciplinary and collaborative research,
- appearance of big data science,
- growing scientific community worldwide (China, Brasil, India..),
- advances in search tools (Mendeley, Google, ..),
- alternative peer view practices,
- Preprint services (BioRxiv)
- Evolving new measures of merit (downloads, Altmetrics, faculty 1000, …),
- Novel business models

- **Open access publishing** from aspirational to commonplace

Trends and Developments in Open Access Publishing - global industry

Open access scientific publishing have *grown into a global industry*

based on a “gold” publishing model

where the authors pay article processing charge (APC) for immediate access

instead of institutional subscriptions with access to published scientific papers

The Directory of Open Access Journals (www. doaj.org) listed

more than 10 000 open-access journals in 2017

Trends and Developments in Open Access Publishing - costs and selectivity

Rigorous quality control, information dissemination, innovative technologies in publishing and archiving are not free, somebody has to bear the costs.

The more selective the editorial process is the more costly it becomes to publish high quality journals.

"In the absence of external support, an open access journal has to be either selective and expensive, or inexpensive but less selective.

Currently, **highly selective journals** running in the open access mode **struggle to break even**, whereas **large-volume, low-selectivity** open access publishing **generates substantial profit**"
Maria Leptin (director of EMBO): Open Access – pass the buck. Science editorial 2012, 335:1279.

Trends and Developments in Open Access Publishing - mega journals, ~3% of all STM outputs

PLOS ONE

Scientific Reports

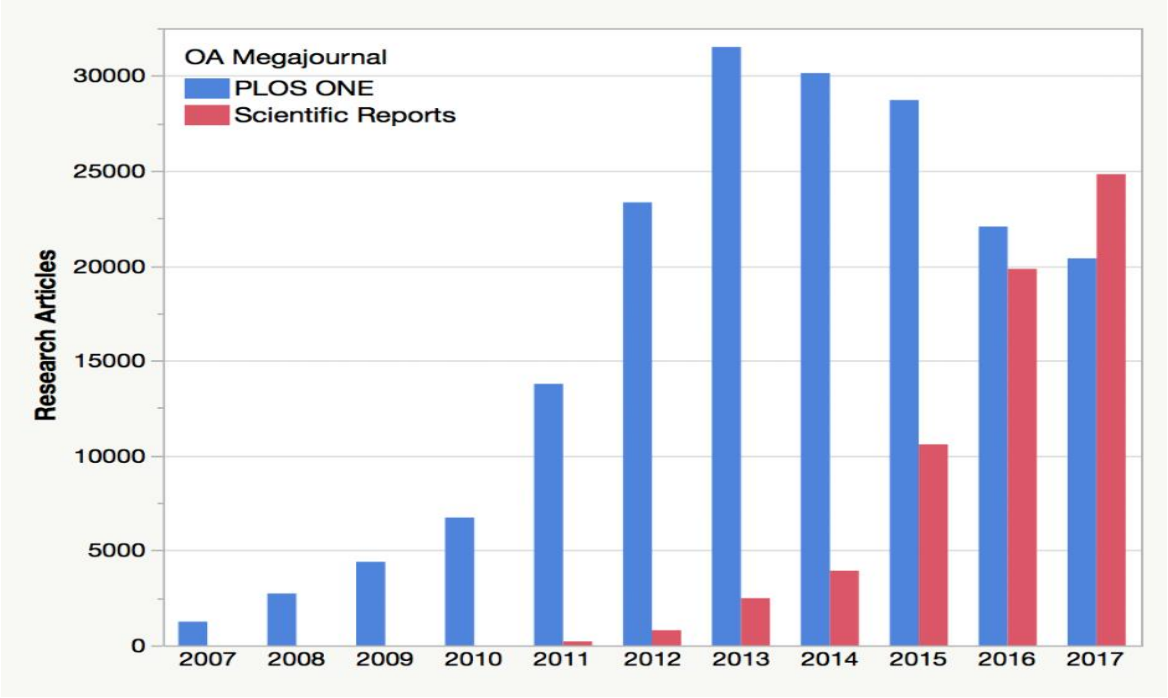

BioMed Central (Springer Nature)

Hindawi

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iScience (Cell Press – Elsevier)

Phil Davis „The future of OA megajournals"
Scholarly Kitchen January 2018.
„OA publishing has created an explosion of titles, most of which seem to be competing for a small slice of a fixed pie."

„Embeddedness of journal prestige and reputation in academic practices means there is likely a limit to open access megajournal growth."

Trends and Developments in Open Access Publishing - the lucrative cascading

NATURE

Nature Journals - 50 with „Nature" label, 26 with NPJ label hybrid OA

Nature Communications gold OA

Communications (Biology, Chemistry, Physics) gold OA

Scientific Reports gold OA Scientific Data gold OA

Big publishers of elite brand journals coopting gold OA

„The small number of elite journals with far more submissions than they can possibly handle in their toll-access flagship can use this cascading model to reassert themselves in the marketplace." *Joseph Esposito Scholarly Kitchen 2015*

Trends and Developments in Open Access Publishing - funders

Several global and national funders have mandated or preferred open-access publishing providing significant extra funds for gold OA

- often without guidance about journal selection

Open access to research publications. Independent advice. The Adam Tickell report. *https://www.gov.uk/government/publications/open-access-to-research-independent-advice*

Trends and Developments in Open Access Publishing - resources

The question has been raised whether at times of limited resources it is wise diverting funds from research in order to support gold open-access publishing parallel with paying subscriptions to journals.

There is a **new dilemma** for many research institutions and universities: assuming that all articles from their research groups was published with gold open access it would have cost significantly more than their annual budget for journal subscription

Research-intensive institutions would pay most and this would subsidize free access for **less-research-intensive** institutions and the **pharmaceutical industry**.
This may lead to **questionable dominance** of scientific publishing by the rich institutions.

Trends and Developments in Open Access Publishing - green OA

Until now research funders, intergovernmental agencies and governments have not found the solution to finance the costs of gold open access publishing of all scientific results.
T*he "green" mode of OA* publishing emerged requiring authors to deposit their manuscript or its accepted version in a public repository within a predetermined period of time.

The article is generally made available free of charge after an **embargo period** which may vary depending on funders:
mostly either 6 months or 1 year in natural sciences and 1 or 2 years in humanities.

Open access mandates (gold or green, different repository requirements, reporting) set by institutions, funders and governments **differ** in various countries and are often contradictory, even confusing, making **compliance cumbersome** with administrative burden.

Trends and Developments in Open Access Publishing - European Union Resolution

Council Conclusions on the Transition Towards an Open Science System (2016):

„AGREES to further promote the mainstreaming of open access to scientific publications by continuing to support a transition to immediate open access as the default by 2020, using the various models possible and in a cost - effective way,

without embargoes or with as short as possible embargoes,
and without financial and legal barriers,
taking into account the diversity in research systems and disciplines,
and that open access to scientific publications should be achieved in full observance of the principle that no researcher should be prevented from publishing."

Unexpected Consequences in Open Access Publishing - ethical issues

Possibility of restriction in academic freedom

Emergence of APC figure as a measure of quality?

Mushrooming of bogus („predatory) journals”

Increased use of bogus journals

Hybrid journals – „double dipping”

Ethical issues in Open Access Publishing – Academic freedom

Researchers may be restricted in academic freedom to publish where they consider it best

- administrative open access mandates

- limited availability of funds for Article Processing Charges (APCs).

This may **endanger freedom of science** and the principle of equal opportunity and **increase the already existing gap** in research output between countries, including member states of the European Union.

Depending on the size of earmarked APC funds in their institution or country they may not have equal opportunity compared to peers to publish their results as they find it most beneficiary for their research carrier

Ethical issues in Open Access Publishing – False criteria of excellence

There is a potential danger of linking value of scientific results and publications to amounts of APCs charged for OA publication that is creating an artificial and false criteria of excellence.

APC figure as a quality measure must be strictly avoided

Ethical issues in Open Access Publishing – bogus („predatory”) journals

Researchers have initiated and participated in setting up open access journals for carrier advances and /or financial gains.

A large proportion of these journals (a rough estimate of 8000 in 2015*) lacks editorial quality control and victimize researchers by intentionally misleading authors, readers, and the scientific community at large. They are often called **“predatory journals”**

They often name nonexistent people as their editors and editorial board members and claim ownership of articles that they have plagiarized from other publications. Sloppy or no archiving.

Typically, these publishers **spam professional email lists**, broadly soliciting article submissions for the clear purpose of gaining additional income.

Shen & Björk, BMC Med.* ***13,* *230 (2015).*

Ethical issues in Open Access Publishing – bogus („predatory”) journals

The *Science* Sting

Science *4 October 2013:* ***Vol. 342 no. 6154*** *pp. 60-65*

Who's Afraid of Peer Review? *By John Bohannon*

Dozens of open-access journals targeted in an elaborate *Science* sting accepted a spoof research article, raising questions about peer-review practices in much of the open-access world.

The journalist created variations of a credible but mundane scientific paper with such grave errors that a competent peer reviewer should easily identify it as flawed and un-publishable.
They were submitted to 304 Open Access Journals: **more than half accepted it.**

Ethical issues in Open Access Publishing – bogus („predatory”) journals

Predatory journals recruit fake editor

An investigation finds that dozens of academic titles offered ‘Dr Fraud’ — a sham, unqualified scientist — a place on their editorial board.

NATURE | Vol 543, pp 481-483, 2017

*Piotr Sorokowski, Emanuel Kulczycki, Agnieszka Sorokowska& Katarzyna Pisan*ski

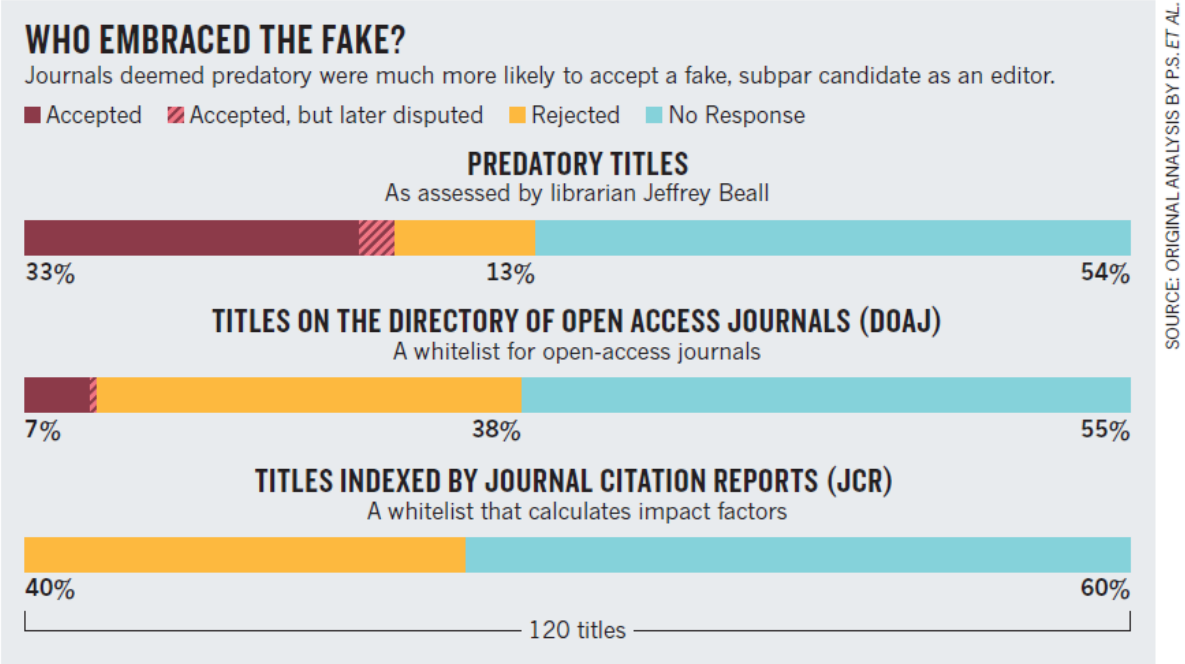

PUBLISHING PROBLEM

Spot the predator

Excerpts from e-mails from journals accepting and rejecting a fake, unqualified candidate.

TITLES THAT ACCEPTED THE FAKE

- “… as an editor, you have to publish some of your research articles with the Journal”
- “If you want to start a new journal… you will get 30% of the revenue earned thru you”
- “It’s our pleasure to add your name as our editor in chief for this journal with no responsibilities”

„The open-access movement, although noble in its intent, has been an unwitting host to these parasitic publishers.”

Ethical issues in Open Access Publishing – bogus („predatory”) journals

SOURCE: A. MANCA *ET AL. LANCET* **390**, 734–735 (2017)

TREND WATCH

Increasing numbers of suspected ‘predatory’ journals in neurology, neuroscience and rehabilitation are having their articles indexed in PubMed, finds a survey (A. Manca *et al. Lancet* **390,** 734–735; 2017). Predatory journals do not provide standard services such as peer review but charge publication fees. The survey used a catalogue of questionable open-access journals called Beall’s list, which is now offline, and tracked how many had articles indexed in PubMed. The proportions for all fields grew from October 2016 to April 2017.

PREDATORY JOURNALS INDEXED IN PUBMED

The proportion of suspected ‘predatory’ open-access journals* in the fields of neuroscience, neurology and rehabilitation indexed in PubMed increased over a six-month period.

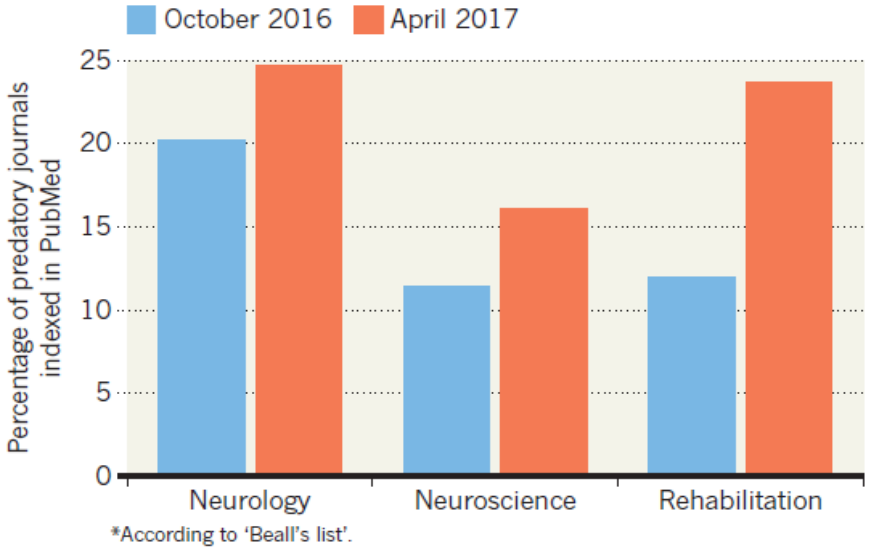

*According to ‘Beall’s list’.

Predatory journals are becoming increasingly adept at appearing legitimate.
Moher et al, Nature 549, 23, 2017

Ethical issues in Open Access Publishing – Temptation to publish in bogus OA journals

Increasing number of researchers are tempted to pay and then expect lower standards by publishing their findings in bogus open access journals which lack quality control.

This has resulted in

misuse of funds for self-promotion,

increasing number of false or even fabricated results in the scientific literature,

appearance of misleading scientific claims.

Many researchers are just duped by the predatory journals or simply unaware of the difference between bogus and quality open access journals.

Even those who recognize a potential problem can fall victim.

Ethical issues in Open Access Publishing – Temptation to publish in bogus OA journals

Stop this waste of people, animals and money

Predatory journals indeed have shoddy reporting and include papers from wealthy nations..

David Moher, Larissa Shamseer, Kelly Kobey et al.

NATURE | Vol 549, pp 23-25, 2017

"In our view, publishing in predatory journals is unethical."

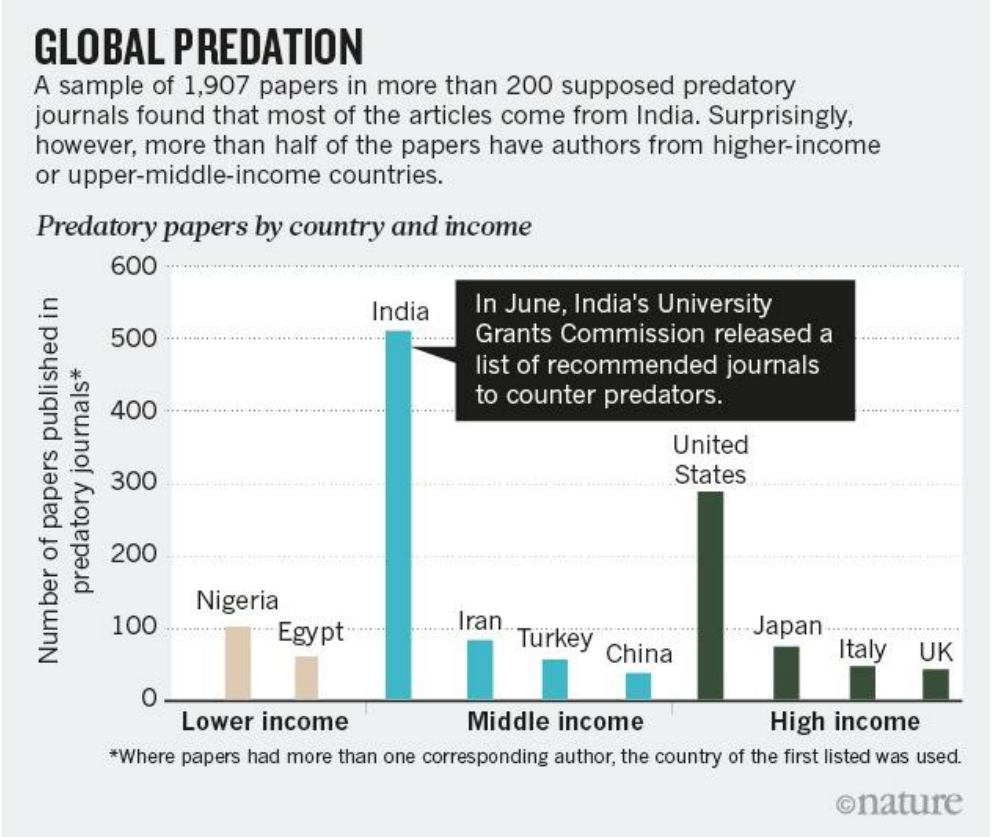

Articles failed to report key information necessary for readers to assess, reproduce and build on the findings.

They contained data from more than 2 million individuals and over 8,000 animals.

The problem is more urgent than many realize

Ethical issues in Open Access Publishing – business ethics

Most of the traditional subscription journals became hybrid journals publishing increasing number of online open, freely accessible papers for which publishers collect APCs in addition to the subscription payments for the same journals received from libraries and licensing consortia.

This is often called “double dipping”

Unless publishers introduce a transparent system which decreases subscription payment in proportion to collected APCs they will be blamed for exploitation of the publishing system to gain extra profit.

Ethical issues in Open Access Publishing – loss of public trust

News about corrupted open access journals weakens trust of the public in science

At a time

„…when neglect of science by public officials and frequent denial of scientific thinking in many quarters seem to call into question … scientific progress.” *Rush Holt Science editorial* January 26, 2018

- Deepens reproducibility crisis
- May lead to reductions in research funding
- Generate unfounded negative publicity for open access publishing in general

Reactions to unintended consequences of open access publishing

Responding to ethical concerns in Open Access Publishing

Decisions of all stakeholders on open access publishing must be based primarily on protecting the core principles of scientific publishing:

Critical, high quality and independent evaluation of scientific claims

Secure archiving of validated research

Responding to ethical concerns in Open Access Publishing

Open access mandates, procedures in distribution and administration of funds for APCs should be formulated in such a way that they

- do not violate academic freedom
- guarantee equal opportunities for researchers.

Responding to ethical concerns in Open Access Publishing

Systematic monitoring of open access journals are necessary to identify and publicly list

- **Credible open access journals**
- **bogus and „predatory" journals**

Members of the scientific community should be encouraged to participate in such monitoring activities, to report misconducts and to support activities which regularly list, based on well-defined criteria, of credible and bogus („predatory") publishers and journals.

Responding to ethical concerns in Open Access Publishing

Directory of Open Access Journals (DOAJ); the *Who's Who* of credible open-access journals

Jeffrey Beall' list: Potential, possible, or probable predatory scholarly open-access publishers; in 2016 the number was close to 2000.
The site was shut down by the owner in January 2017.

Cabell's index

Scholarly services firm Cabell's International in Beaumont, Texas, launched a blacklist of „predatory" academic journals;: lists about 4,000 journals — available only to paying subscribers. The company uses a set of 65 criteria to judge whether journals are predatory. It **also publishes a 'whitelist'** of trustworthy journals, to which about 800 institutions subscribe.

Responding to ethical concerns in Open Access Publishing

Salient evidence-based characteristics of potential predatory journals

1. The scope of interest includes non-biomedical subjects alongside biomedical topics
2. The website contains spelling and grammar errors
3. Images are distorted/fuzzy, intended to look like something they are not, or which are unauthorized
4. The homepage language targets authors
5. The Index Copernicus Value is promoted on the website
6. Description of the manuscript handling process is lacking
7. Manuscripts are requested to be submitted via email
8. Rapid publication is promised
9. There is no retraction policy
10. Information on whether and how journal content will be digitally preserved is absent
11. The Article processing/publication charge is very low (e.g., < $150 USD)
12. Journals claiming to be open access either retain copyright of published research or fail to mention copyright
13. The contact email address is non-professional and non-journal affiliated (e.g. @yahoo.com)

Shamseer et al. BMC Med 15:28, 2017

Responding to ethical concerns in Open Access Publishing

Institutional research evaluations and assessment committees should pay close attention to quality of publications appearing in open access journals when these are considered in procedures for promotion and funding decisions.

Responding to ethical issues in Open Access Publishing -Recommendations

Publishers, research institutions and funders should issue **explicit warnings against illegitimate publishers**.

Funders and research institutions should **prohibit the use of funds to support predatory journal publications**; make sure that **researchers are trained** in how to select appropriate journals when submitting their work; and **audit** where grantees, faculty members and research staff publish.

When seeking promotion or funding, researchers should include a declaration that their **CV is free of predatory publications**.

Before approving a study, **ethics committees** should ask researchers to declare in writing their willingness to work with their institutional resources, such as librarians, to ensure they do not submit to any journals without reviewing evidence-based criteria for avoiding these titles.

Moher et al, Nature 549, 23, 2017

Responding to ethical concerns in Open Access Publishing

Good practices in OA publishing and unaccepted behaviours are defined and included in codes of conduct for research integrity.

The European
Code of Conduct for
Research Integrity
REVISED EDITION

2017

2. Good Research Practices

2.7 Publication and Dissemination

.

- Authors ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the general public , and in traditional and social media

.

- Researchers adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal or in any other alternative publication form.

3. Violations of Research Integrity

3.1 Research Misconduct and other Unacceptable Practices

.

- Establishing or supporting journals that undermine the quality control of research (‘predatory journals’).

Thank you for your attention

Open data: Balancing transparency with resilience

Stephan Lewandowsky

University of Bristol and University of Western Australia

@STWorg

stephan.lewandowsky@bristol.ac.uk

Brussels 1 February 2018

Transparency and Open Data are Essential

- Because if we (as a community) don't act, others will do it for us
- Recent UK Parliament inquiry hinted at government action (Video of hearing)
- U.S. NIH currently seeks to reclassify all basic research as clinical trials (Washington Post)

Transparency and Open Data are Essential

- But we need to consider their full implications
- Transparency and open data are political
- Transparency can be weaponized:
  - intentions of people who request data
  - consent and ethics
  - competence of people who request data
  - communication platforms
  - cherry-picking

Open Data is Political

- U.S. data access act 1998 (and 2000)
  - all data from federally funded projects available
  - data disseminated by government must adhere to act's definition
  - citizens can cha
  - "influential data reanalysis by "q
  - privately funde disclosure

- The acts were drafted by the tobacco industry and allies
- Implementation was overseen by tobacco industry
- Most challenges launched by lobbyists or industry not public
- Many regulations delayed

(Baba et al., 2005, *American Journal of Public Health*)

ELSEVIER

Journal of Clinical Epidemiology 63 (2010) 841–853

Journal of Clinical Epidemiology

"A delicate diplomatic situation": tobacco industry efforts to gain control of the Framingham Study

Janine K. Cataldo[a,*], Lisa A. Bero[b], Ruth E. Malone[c]

[a]*Department of Physiological Nursing—Gerontology, University of California San Francisco, San Francisco, CA, USA*
[b]*Department of Clinical Pharmacy and Health Policy, University of California San Francisco, San Francisco, CA, USA*
[c]*Department of Social and Behavioral Sciences, University of California San Francisco, San Francisco, CA, USA*

Accepted 30 January 2010

- Tobacco industry used access to raw data for re-analysis by industry consultant
- Tobacco-related morbidi
  disappeared

- Lead (paint, gasoline)
- PVC
- Any type of pollution

Open Data may Never be Open Enough

- Lamar Smith (R-TX), Chair of the House of Representatives Science Committee
- Issued subpoena in 2016 to National Oceanic and Atmospheric Administration (NOAA) …
- … for climate data th
available (via Google

- The catchphrase ‘‘secret science’’ to advocate for data disclosure discussed by the tobacco industry as early as 1998 (Gianelli, 1998)

Commentary

BIG DATA & SOCIETY

Big Data & Society
January–June 2016: 1–6
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sagepub.com/journalsPermissions.nav
DOI: 10.1177/2053951715621568
bds.sagepub.com
SAGE

When open data is a Trojan Horse: The weaponization of transparency in science and governance

Karen EC Levy[1] and David Merritt Johns[2]

- Transparency can be weaponized:
  - intentions of people who request data
  - consent and ethics
  - competence of people who request data
  - communication platforms
  - cherry-picking

I. Do Intentions Matter?

- Open Data advocates: No
- Tobacco industry: No, why?
- Public health researchers: Absolutely yes!

Nefarious Intentions and Science

- Dr. Smith publishes a paper suggesting interference causes forgetting.
- Dr. Jones requests data from Dr. Smith and discovers that it is actually leprechauns that caused the forgetting.
- Dr. Jones is Dr. Smith's ex-spouse and recently lost a bitter custody batt
children and a hamster.
- Ultimately the scientific
the issue.

- Egos are bruised
- Careers hampered
- But no (not much?) lasting harm done

Nefarious Intentions and Public Policy

- Dr. Smith publishes a paper suggesting that Product X causes cancer.
- Dr. Jones, who works for Manufacturer X, requests data and purports to discover that cancer is caused by “dispositional factors” rather than Product X.
- Ultimately the scientific community resolves the issue.

But massive harm is done

Scientific Debate ≠ Public Debate

nature climate change

ARTICLES

PUBLISHED ONLINE: 28 OCTOBER 2012 | DOI: 10.1038/NCLIMATE1720

The pivotal role of perceived scientific consensus in acceptance of science

Stephan Lewandowsky*, Gilles E. Gignac and Samuel Vaughan

- The appearance of a scientific debate, whether real or not, prolongs public indecisiveness.
- Tobacco control legislation was delayed by decades due to *appearance* of scientific debate.

Aspirin and Reye's Syndrome (e.g., Michaels & Monforton, 2005)

- In children with viral infections, Aspirin consumpt
syndrome
- 1 in 3 chil

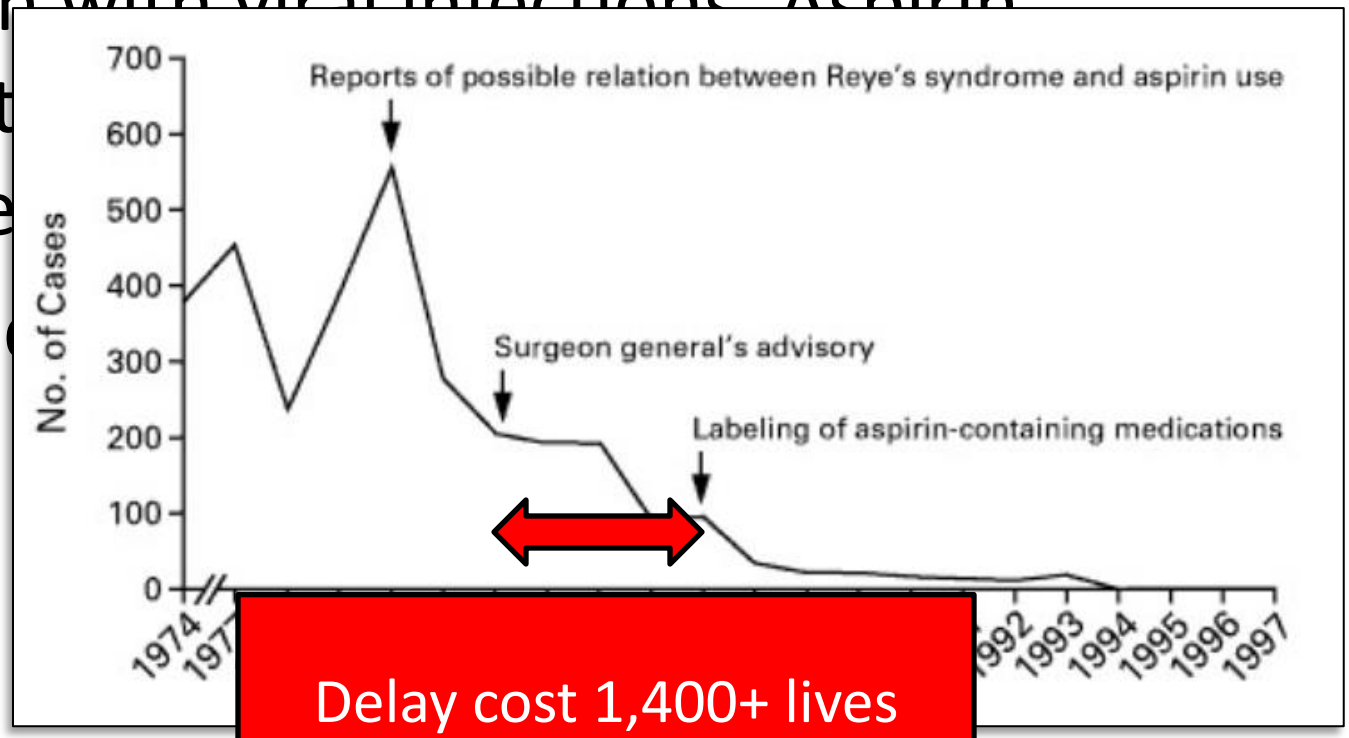

Delay cost 1,400+ lives (Author of *Data Quality Act* a key figure in delay)

I. Do Intentions Matter?

- Open Data advocates: No
- Tobacco industry: No, why?
- Public health researchers: Absolutely yes!

Now you know why they say that

II. Consent and Ethics

- Medical or clinical research
  - patient confidentiality
  - anonymization can be difficult
  - even de-linking is insufficient unless the linking key has been destroyed or is held by another institution (U.K. data protection act)
  - consent may have been given for one stated purpose of a study only

Consent: Exploring Implications

- Ms. Jones consents to participate in an experiment that observes the effect of WM training on IQ
- The experimenter collects the usual covariates and demographics such as gender and ethnicity
- The Ku-Klux-Klan rea
  and discovers that bl
  higher IQ overall but
  training

- The *Kluxer's Trumpet* headline: "No matter how much you train them, they cannot get smarter"

Consent: Exploring Implications

- Ms. Jones consents to participate in an experiment that observes the effect of WM training on IQ
- Suppose Ms. Jones was black
  - did she realize what she consented to?
  - would she have given consent if she knew this could happen?
  - given what happened, would she ever consent again?
  - note that anonymity is not

If data are open, they are open to abuse

Concerns are Being Articulated

Sydes *et al. Trials* (2015) 16:104
DOI 10.1186/s13063-015-0604-6

TRIALS

METHODOLOGY Open Access

Sharing data from clinical trials: the rationale for a controlled access approach

Matthew R Sydes*, Anthony L Johnson, Sarah K Meredith, Mary Rauchenberger, Annabelle South and Mahesh KB Parmar

Abstract

Background: The move towards increased transparency around clinical trials is welcome. Much focus has been on under-reporting of trials and access to individual patient data to allow independent verification of findings. There are many other good reasons for data sharing from clinical trials. We describe some key issues in data sharing, including the challenges of open access to data. These include issues in consent and disclosure; risks in identification, including

III. Does Competence Matter?

- Researchers operate in an institutional context
  - ethics boards
  - data management plans
  -
  -
- M
  Ce
  -
  -

Consideration of the Platforms

- Dr. Smith publishes a paper suggesting that Product X causes cancer.
- Dr. Jones, who works for Manufacturer X, requests data and discovers that cancer is caused by “dispositional factors” rather than Product X.
- Dr. Jones and Manufacturer X publish analysis on blogs and Twitter. The Daily Mail picks it up.
- Ultimately the scientific community resolves the issue.

U.K. MMR Vaccination Rates
(Smith et al., 2007)

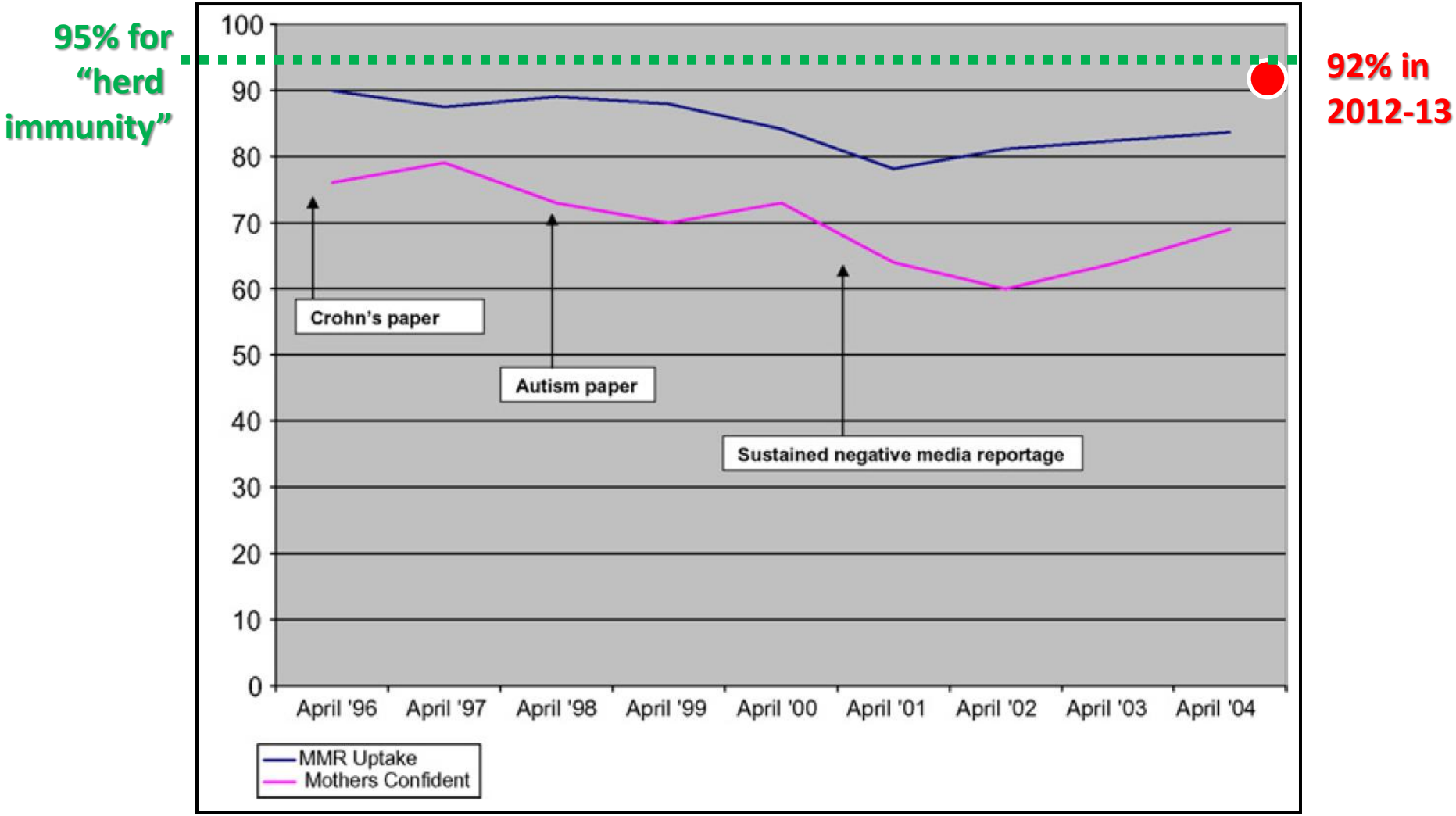

IV. Cherry-Picking

- We urge scientists to preregister hypotheses and analysis plans to guard against cherry-picking of results or outcome measures.
- We do not keep track of the Ku-Klux-Klan requesting 90 data sets with a racial-identifier variable
- So they can trumpet the one result that yields the “desired” racial differences

What Does this Add up to?

- Science should be open and transparent
- But there is a distinction between science on the one hand, and noise, nonsense, commercial interests, or political propaganda on the other
- Openness and transparency facilitate science, but they also aid in the dissemination of noise, nonsense, commercial interests, and political propaganda

Solutions? Symmetry

- People who request data must be competent and must operate in an institutional context of accountability
- People who request data must preregister their intentions (and conform to them)
- Participants' consent must be considered
- Data availability (and limits) should be enshrined in peer-review record at the time of publication to avoid later controversy

Don't let transparency damage science

Stephan Lewandowsky and **Dorothy Bishop** explain *(Nature,* **2016***, 529*, 459-461)

Importance of Competence

- U.K. Medical Research Council's guidelines: "The custodian [of the data] must ensure that the group [receiving the data] accepts a duty of confidence and protects confidentiality through training procedures, etc, to the same standards as the custodian."

C O P E 20TH ANNIVERSARY 1997-2017

Editorial responsibility in the open access world

COPE: Promoting integrity in research and its publication

Chris Graf, Co-Chair, COPE, Committee on Publication Ethics, at the ALLEA workshop, Ethical Aspects of Open Access: A Windy Road, January 2018. ORCID ID: 0000-0002-4699-4333.

Disclosure: CG volunteers for COPE, Committee on Publication Ethics. CG works for Wiley.

It’s still all about quality

Research and research publishing is changing fast. But it’s (still) really all about quality. With the backdrop of COPE’s 10 Core Practices, I’ll share thoughts on what some editors, journals, and publishers are doing to embrace and help lead that change, with examples of how new approaches to methods validation and data validation are being added into the editorial process. I’ll argue that transparency from journals is one way we can help researchers understand why reputable journals are valuable for them as authors and as readers. And I’ll suggest that it’s time to think carefully about what we aspire to, without losing sight of what matters most about research quality, so that we can help more researchers to express and communicate their research in the best possible way.

Agenda

COPE's Core practices

Support quality, actively

- Methods validation
- Data validation

Increase transparency

What we could aspire to

These are my personal observations, which may or may not reflect COPE's position

COPE’s Core Practices

COPE assists editors of scholarly journals and publishers - as well as other parties, such as institutions - in their work to preserve and promote the integrity of the scholarly record through policies and practices. COPE describes these in 10 “Core Practices”. COPE's Core Practices should be considered alongside specific national and international codes of conduct for research.

https://publicationethics.org/core-practices

Journals and publishers should have robust and well-described, publicly documented practices in all the following areas

Core practices are the policies and practices journals and publishers need, to reach the highest standards in publication ethics. We include cases with advice, guidance for day-to-day practice, education modules and events on topical issues, to support journals and publishers fulfil their policies.

View all core practices

- 1. Allegations of misconduct
- 2. Authorship and contributorship
- 3. Complaints and appeals
- 4. Conflicts of interest / Competing interests
- 5. Data and reproducibility
- 6. Ethical oversight
- 7. Intellectual property
- 8. Journal management
- 9. Peer review processes
- 10. Post-publication discussions and corrections

https://publicationethics.org/core-practices

https://publicationethics.org/files/editable-bean/COPE_Core_Practices_0.pdf

publicationethics.org

COPE flowcharts: How to spot manipulation of the peer review process

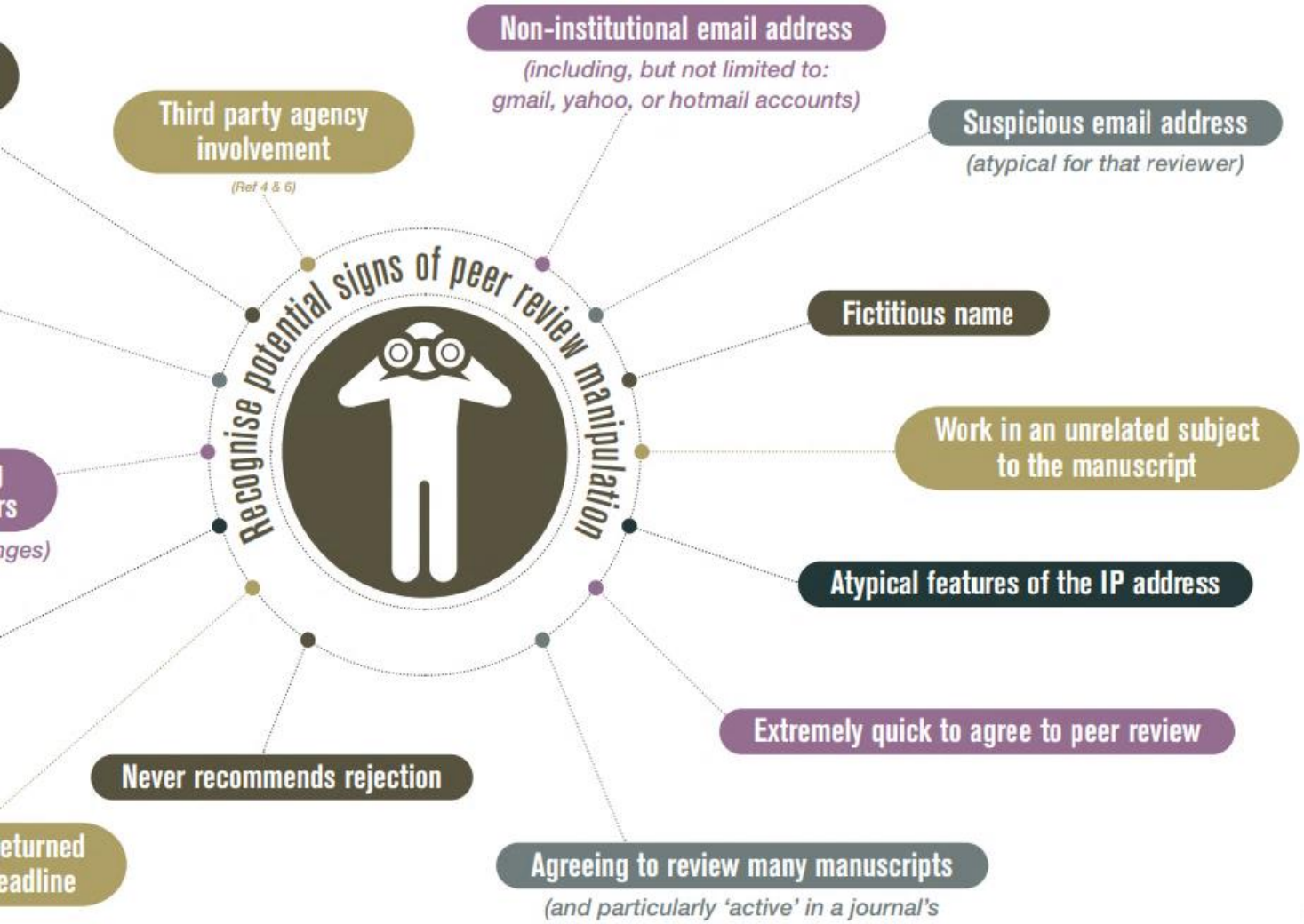

Fake reviewers

The retractions earlier this year of 107 cancer papers were arguably a case of identity fraud. These 107 papers were retracted after the publisher discovered that their peer review process had been compromised by fake peer reviewers.

It's not clear that the researchers involved did this wittingly. It may have been the fault of a third-party they paid to help with language editing and submission, to help them get their work published.

Resource: COPE guide (to the left) to spotting manipulations in peer review.

https://publicationethics.org/files/COPE%20PR_Manipulation_Process.pdf
http://retractionwatch.com/2017/04/20/new-record-major-publisher-retracting-100-studies-cancer-journal-fake-peer-reviews/

The same standards apply

The same publication ethics standards defined by our core practices are expected of all COPE members, irrespective of their business model.

COPE supports and aims to inspire good practice amongst our members. We support campaigns that help researchers to make good journal choices, like think.check.submit. We have a sanctions process for occasions where our members need to demonstrate better practice. COPE doesn't often refer to blacklists or predatory journals, and explains more in "The changing face and future of publication ethics"

Beyond editorial responsibilities

The 16 Principles of Transparency from COPE, DOAJ, OASPA, and WAME include some specifics about business responsibilities (beyond editorial responsibilities).

https://publicationethics.org/files/Principles_of_Transparency_and_Best_Practice_in_Scholarly_Publishingv3.pdf

Principles of Transparency

This version
Published 15 January 2018

Version 2
Published 22 June 2015

Version 1
Published 10 January 2014

1. Website: A journal's website, including the text that it contains, shall demonstrate that care has been taken to ensure high ethical and professional standards. It must not contain information that might mislead readers or authors, including any attempt to mimic another journal/publisher's site.

An 'Aims & Scope' statement should be included on the website and the readership clearly defined. There should be a statement on what a journal will consider for publication including authorship criteria (e.g., not considering multiple submissions, redundant publications) to be included. ISSNs should be clearly displayed (separate for print and electronic).

2. Name of journal: The Journal name shall be unique and not be one that is easily confused with another journal or that might mislead potential authors and readers about the Journal's origin or association with other journals.

...

4. Ownership and management: Information about the ownership and/or management of a journal shall be clearly indicated on the journal's website. Publishers shall not use organizational or journal names that would mislead potential authors and editors about the nature of the journal's owner.

5. Governing body: Journals shall have editorial boards or other governing bodies whose members are recognized experts in the subject areas included within the journal's scope. The full names and affiliations of the journal's editorial board or other governing body shall be provided on the journal's website.

...

8. Author fees: Any fees or charges that are required for manuscript processing and/or publishing materials in the journal shall be clearly stated in a place that is easy for potential authors to find prior to submitting their manuscripts for review or explained to authors before they begin preparing their manuscript for submission. If no such fees are charged that should also be clearly stated.

...

14. Revenue sources: Business models or revenue sources (e.g., author fees, subscriptions, advertising, reprints, institutional support, and organizational support) shall be clearly stated or otherwise evident on the journal's website. Publishing fees or waiver status should not influence editorial decision making.

...

16. Direct marketing: Any direct marketing activities, including solicitation of manuscripts that are conducted on behalf of the journal, shall be appropriate, well targeted, and unobtrusive. Information provided about the publisher or journal is expected to be truthful and not misleading for readers or authors.

https://publicationethics.org/files/Principles_of_Transparency_and_Best_Practice_in_Scholarly_Publishingv3.pdf

Note: The slides from here on are personal observations, which may or may not reflect COPE's position or recommendations

Support quality, actively

What about working in new ways?

- Methods validation
- Data validation

John Schmidt's Top 5 solutions for the replication crisis

"Total vaporization of the Earth by an exploding sun *would* solve the replication crisis

Also: Zombies, deep impact, demons, ignoring it

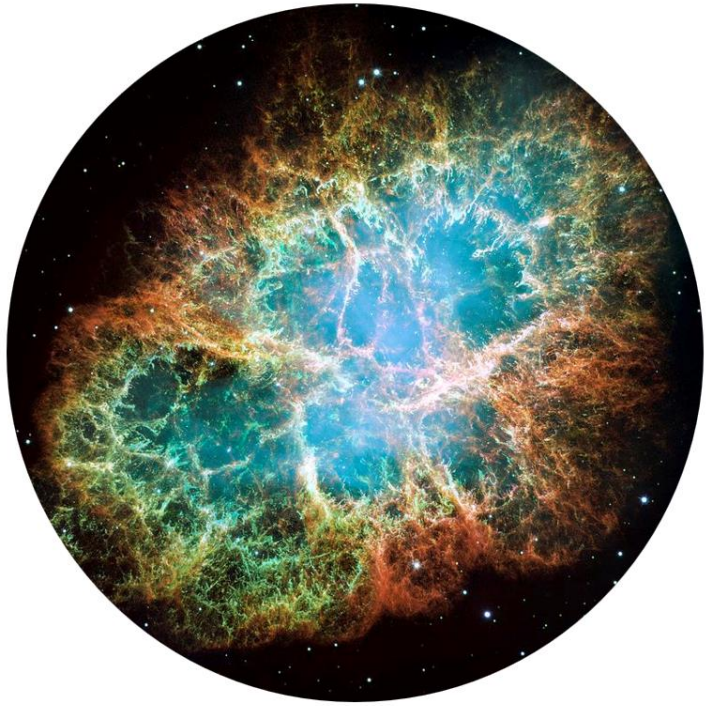

https://medium.com/@InOurLabs/top-five-real-solutions-to-the-replication-crisis-a2607a83d46f

Image credit: Public domain image, with acknowledgement to NASA and STScI https://en.wikipedia.org/wiki/Supernova

A quality problem: Methods

Daryl O'Connor on Registered Reports at *Journal of Neuropsychology,* edited by Martin Edwards

Methods validation: Registered Reports

"Registered Reports will increase the transparency of our science and allow peer review of research before results are known... improving the quality of our research protocols, that will ultimately improve the robustness of our evidence base

Disclosure: Wiley publishes *J Neuropsychology* for BPS
https://www.bps.org.uk/news-and-policy/we-are-working-wiley-improve-replicability-and-transparency-research

https://cos.io/rr/

8 Answers about Registered Reports, an Interview with David Mellor from Center for Open Science
https://hub.wiley.com/community/exchanges/discover/blog/2017/12/05/8-answers-about-registered-reports-research-preregistration-and-why-both-are-important

A quality problem: Data

Perhaps 50% of published ^{13}C NMR datasets contain errors. Some are simple typos. Others are completely incorrect structures, where a chemist thinks they've made one structure but actually they've made something different.

An example of new ways to validate data

Data validation

Wiley Smart Spectra Repository (SSR) is a tool for research validation. It helps researchers publish higher-quality, correct data.

SSR checks if a chemical structure and the submitted ^{13}C NMR data are consistent and shows where errors might be.

https://www.wsslabs.com

Disclosure: This is a Wiley service

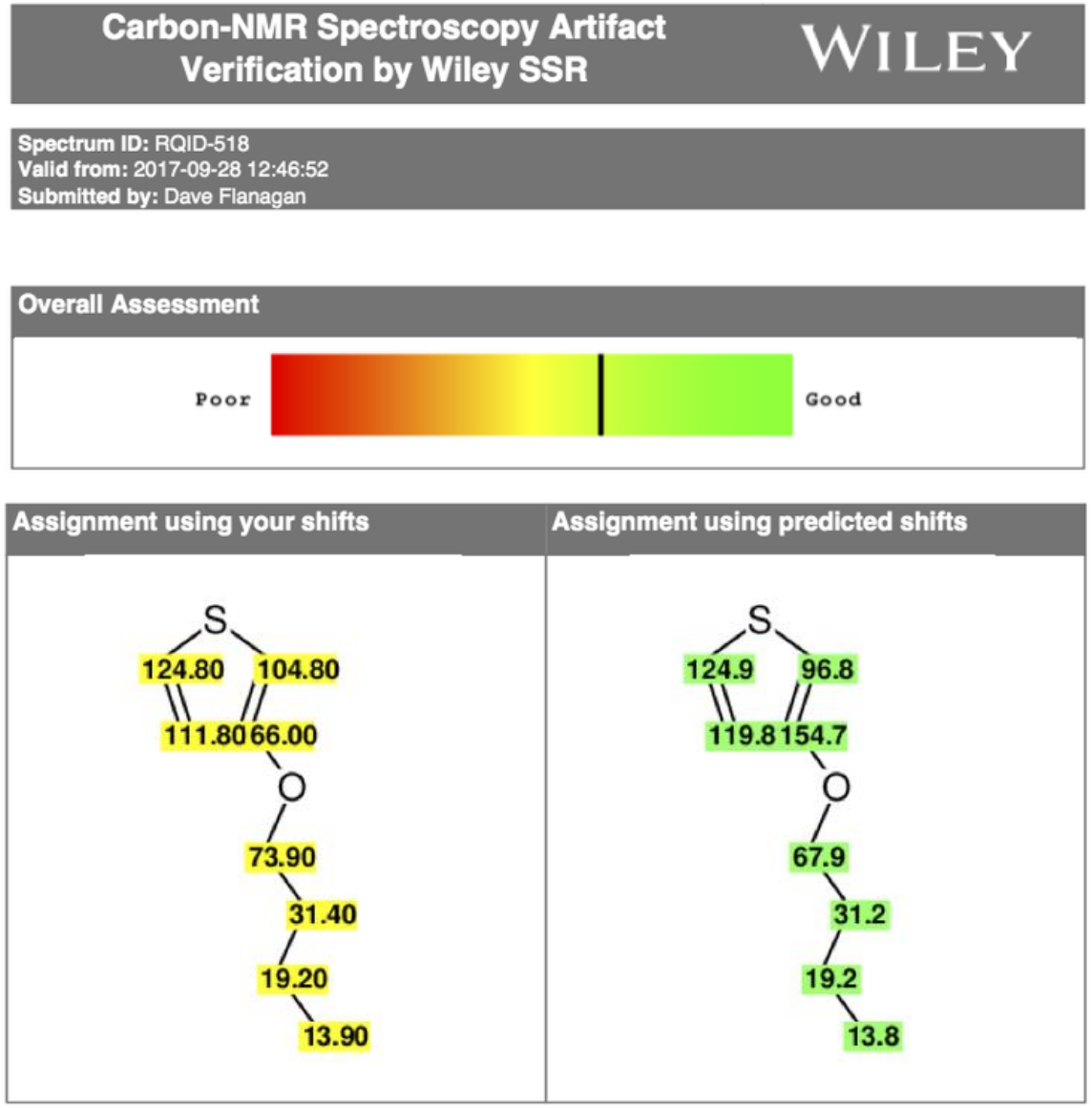

Consider what we aspire to

On rock stars and orchestras and new ways to think about quality

Rock stars

Nobel prizes

6

Nature articles

821

40.137 Nature Magazine's Impact Factor

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Orchestras

Academics and post docs

17million

1,803,249

research articles in Scopus

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Increase transparency

Make being transparent easy and rewarding for researchers

https://publicationethics.org/news/research-integrity-and-how-buy-persian-carpet-top-guidelines-part-2

Carpets

In “The art of buying a carpet,” Simon Busch suggests that a wise carpet buyer checks a carpet’s knot count (“You will find much truth under the carpet: turn it over”), examines its fibre (silk and wool, or something else?), and takes a close look at its colour (“Bend the carpet so as to expose individual threads from the base to the tip.”)

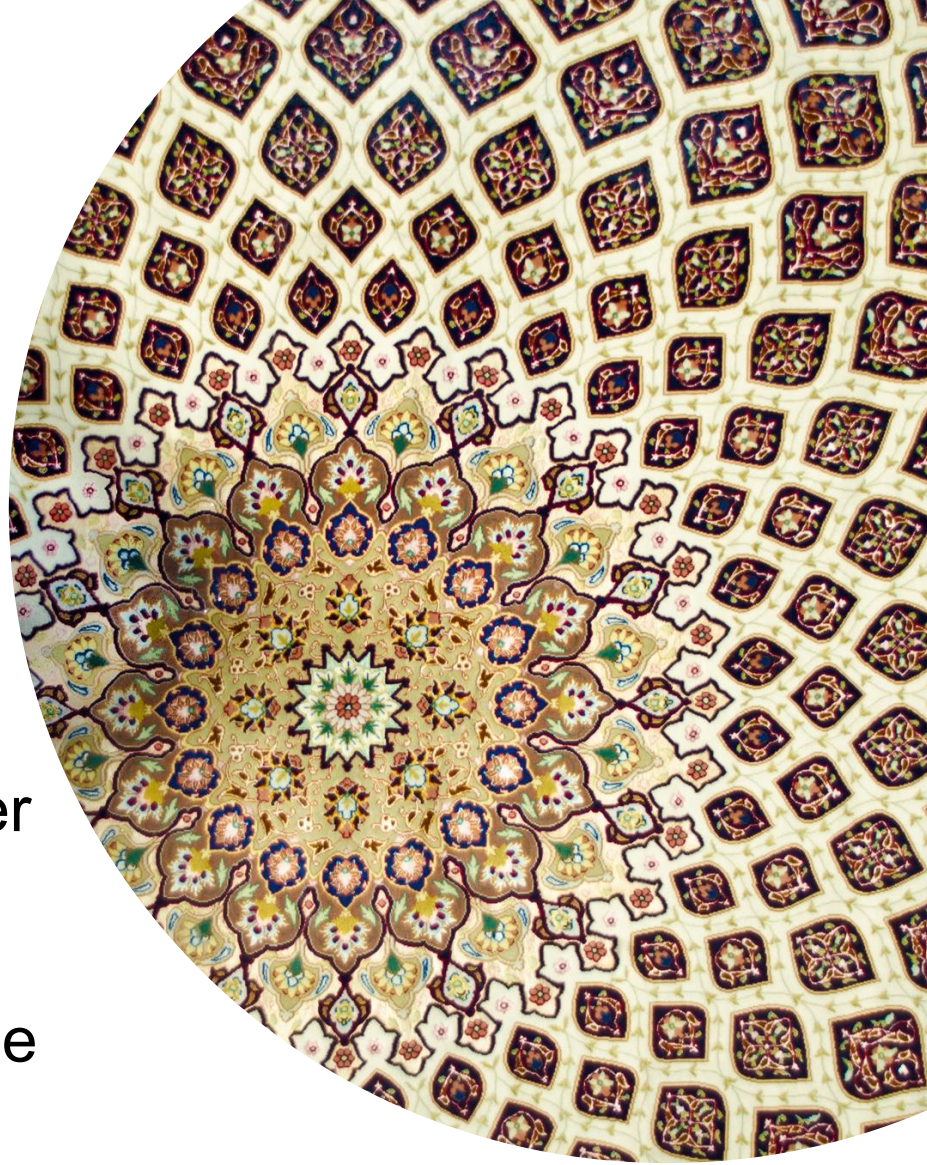

Picture by Garry Knight (Flickr: Persian Carpet) CC BY-SA 2.0 at https://commons.wikimedia.org/wiki/File%3APersian_Carpet.jpg
https://publicationethics.org/news/research-integrity-and-how-buy-persian-carpet-top-guidelines-part-2

The same is true for research

When research authors share and cite their data; describe their methods in detail; make their materials available; and share information about their analysis then other people can check the knot count, fibre, and colour of that particular research project.

https://publicationethics.org/news/research-integrity-and-how-buy-persian-carpet-top-guidelines-part-2

TOP, part 2: An ongoing draft

"Promoting an open research culture," published by Nosek and colleagues in *Science*, presents the Transparency and Openness Promotion guidelines: How to aim for research transparency in 8 standards and 3 levels. TOP is widely endorsed. But not widely implemented. This is where TOP part 2 picks up.

And it is in draft now (January 2018) for you at this link: https://docs.google.com/document/d/1NI6P4M2UKekXoZuFR2uuQ2Tj1xf0WrThn86H5XOR1uY

In the open access world editorial responsibility is still all about quality

But maybe we need to aspire to a kind of quality that works members of orchestras (as well as for Taylor Swift)

Thank you!

publicationethics.org

About COPE (appendix 1)

publicationethics.org

12,000+ members, 100+ countries

- As an organization, COPE's role is to assist editors of scholarly journals and publisher/owners in their endeavour to **preserve and promote the integrity of the scholarly record** through policies and practices that reflect the current best principles of transparency as well as integrity.
- COPE is a membership organization. Our members are primarily editors of **journals and publishers** although we are currently exploring expanding our membership. Part of this potential expansion is being explored with a pilot project with **five universities around the world**.
- COPE operates, manages and governs the organization with a small group of paid employees and a large **group of very active volunteers** who serve on the trustee board and council.

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legal responsibilities for COPE

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Appoint

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- Trustee

Free markets (appendix 2)

publicationethics.org

Led by an invisible hand

“In [a free economy] there is one and only one social responsibility of business—to use its resources and engage in activities designed to increase its profits *so long as it stays within the rules of the game*.

It is the responsibility of the rest of us to establish a framework of law such that an individual in pursuing his own interest is, to quote Adam Smith again, ‘led by an invisible hand to promote an end which was no part of his intention.’

Corporate Social Responsibilty: Friedman's View https://bfi.uchicago.edu/news/feature-story/corporate-social-responsibilty-friedmans-view Quoting Capitalism and Freedom, University of Chicago Press, 2002 Fortieth Anniversary Edition, p 133

Picture by http://www.thefamouspeople.com/profiles/milton-friedman-167.php [CC BY-SA 4.0 (https://creativecommons.org/licenses/by-sa/4.0)], via Wikimedia Commons

“We need a culture of responsibility for the integrity of the literature… it’s not just the job of editors

Ginny Barbour, 2012—2017 COPE Chair

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Research assessment in open science

Michele Garfinkel, PhD
Manager, EMBO Science Policy Programme

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About EMBO

- European Molecular Biology Organization (Maria Leptin, Director)
- Founded 1964, Heidelberg, DE
- Funded by the European Molecular Biology Conference
  - 31 Member and Associate Member States
  - 2 Cooperation Agreements
- *Advancing policies for a world-class European research environment*

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Programmes

- Members
- Fellowships
- Young Investigators
- Courses and Workshops
- Science Policy
- Scientific publishing: EMBO Press

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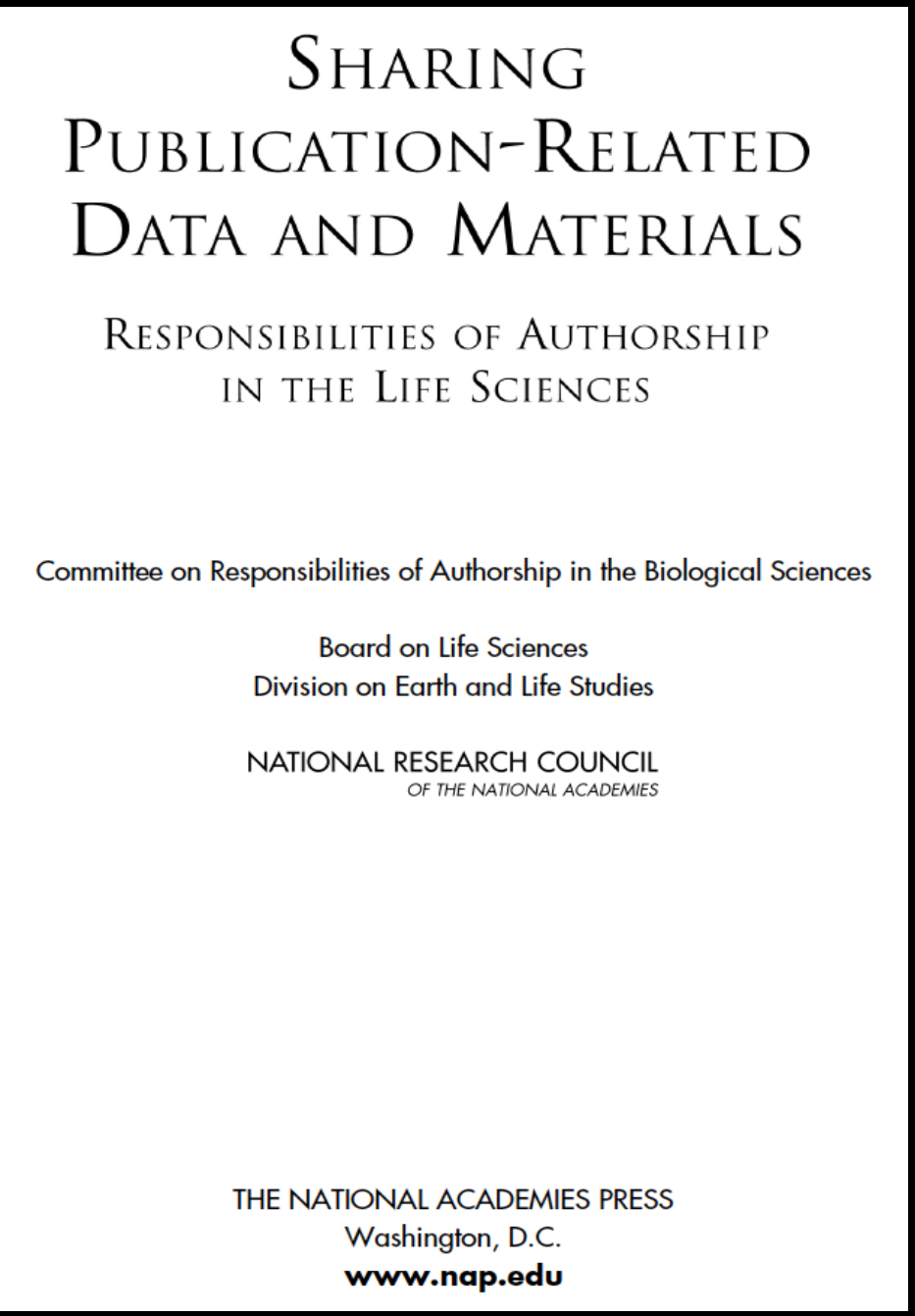

SHARING PUBLICATION-RELATED DATA AND MATERIALS

RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES

Committee on Responsibilities of Authorship in the Biological Sciences

Board on Life Sciences
Division on Earth and Life Studies

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OF THE NATIONAL ACADEMIES

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Scientific publishing

The publication of scientific information is intended to move science forward. More specifically, the act of publishing is a *quid pro quo* in which authors receive credit and acknowledgment in exchange for disclosure of their scientific findings.

THE EMBO JOURNAL

EMBO reports

molecular systems biology OPEN ACCESS

EMBO Molecular Medicine OPEN ACCESS

Core principles and services

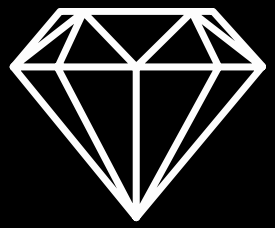

TRANSPARENT PROCESS

1. Transparent review
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3. Referee Cross-Commenting
4. Single Round
5. Fast Process
6. Source Data
7. Approachable Editors
8. Informed Evaluation
9. Manuscript Transfers
10. Flexible Formatting
11. Pre-publication screening

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San Francisco

DORA

Declaration on Research Assessment

San Francisco DORA
Declaration on Research Assessment

DORA | About DORA | Sign The Declaration | Media Inquiries | Inspiration and Good Practices

The San Francisco Declaration on Research Assessment (DORA), initiated by the American Society for Cell Biology (ASCB) together with a group of editors and publishers of scholarly journals, recognizes the need to improve the ways in which the outputs of scientific research are evaluated. The group met in December 2012 during the ASCB Annual Meeting in San Francisco and subsequently circulated a draft declaration among various stakeholders. DORA as it now stands has benefited from input by many of the original signers listed below. It is a worldwide initiative covering all scholarly disciplines. We encourage individuals and organizations who are concerned about the appropriate assessment of scientific research to sign DORA.

The Declaration

There is a pressing need to improve the ways in which the output of scientific research is evaluated by funding agencies, academic institutions, and other parties. To address this issue, a group of editors and publishers of scholarly journals met during the Annual Meeting of The American Society for Cell Biology (ASCB) in San Francisco, CA, on December 16, 2012. The group developed a set of recommendations, referred to as the San Francisco Declaration on Research Assessment. We invite interested parties across all scientific disciplines to indicate their support by adding their names to this Declaration. The outputs from scientific research are many and varied, including: research articles reporting new knowledge, data, reagents, and software; intellectual property; and highly trained young scientists. Funding agencies, institutions that employ scientists, and scientists themselves, all have a desire, and need, to assess the quality and impact of scientific outputs. It is thus imperative that scientific output is measured accurately and evaluated wisely.

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Organization Signers

Total: 438

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General Recommendation

1. Do not use journal-based metrics, such as Journal Impact Factors, as a surrogate measure of the quality of individual research articles, to assess an individual scientist's contributions, or in hiring, promotion, or funding decisions.

For funding agencies

2. Be explicit about the criteria used in evaluating the scientific productivity of grant applicants and clearly highlight, especially for early-stage investigators, that the scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.
3. For the purposes of research assessment, consider the value and impact of all research outputs (including datasets and software) in addition to research publications, and consider a broad range of impact measures including qualitative indicators of research impact, such as influence on policy and practice.

For institutions

4. Be explicit about the criteria used to reach hiring, tenure, and promotion decisions, clearly highlighting, especially for early-stage investigators, that the scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.
5. For the purposes of research assessment, consider the value and impact of all research outputs (including datasets and software) in addition to research publications, and consider a broad range of impact measures including qualitative indicators of research impact, such as influence on policy and practice.

For publishers

6. Greatly reduce emphasis on the journal impact factor as a promotional tool, ideally by ceasing to promote the impact factor or by presenting the metric in the

context of a variety of journal-based metrics (e.g., 5-year impact factor, EigenFactor [8], SCImago [9], *h*-index, editorial and publication times, etc.) that provide a richer view of journal performance.

7. Make available a range of article-level metrics to encourage a shift toward assessment based on the scientific content of an article rather than publication metrics of the journal in which it was published.
8. Encourage responsible authorship practices and the provision of information about the specific contributions of each author.
9. Whether a journal is open-access or subscription-based, remove all reuse limitations on reference lists in research articles and make them available under the Creative Commons Public Domain Dedication [10].
10. Remove or reduce the constraints on the number of references in research articles, and, where appropriate, mandate the citation of primary literature in favor of reviews in order to give credit to the group(s) who first reported a finding.

For organizations that supply metrics

11. Be open and transparent by providing data and methods used to calculate all metrics.
12. Provide the data under a licence that allows unrestricted reuse, and provide computational access to data, where possible.
13. Be clear that inappropriate manipulation of metrics will not be tolerated; be explicit about what constitutes inappropriate manipulation and what measures will be taken to combat this.
14. Account for the variation in article types (e.g., reviews versus research articles), and in different subject areas when metrics are used, aggregated, or compared.

For researchers

15. When involved in committees making decisions about funding, hiring, tenure, or promotion, make assessments based on scientific content rather than publication metrics.
16. Wherever appropriate, cite primary literature in which observations are first reported rather than reviews in order to give credit where credit is due.
17. Use a range of article metrics and indicators on personal/supporting statements, as evidence of the impact of individual published articles and other research outputs [11].
18. Challenge research assessment practices that rely inappropriately on Journal Impact Factors and promote and teach best practice that focuses on the value and influence of specific research outputs.

San Francisco DORA
Declaration on Research Assessment

What it does *not* say

- Metrics based research assessment is wrong
- JIF is useless
- Citations are a flawed metric
- There is a simple alternative
- Publishers are to blame
- Metrics providers are to blame

Publishing/policy interface

- Preprint servers
  - ArXiv/BioArXiv
  - ASAPbio
- Assessing contributors of data (microattribution) (extend DORA?)
- Identification of authors and contributors
- Formal and informal post-publication review

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- High Energy Physics - Lattice (**hep-lat** new, recent, find)
- High Energy Physics - Phenomenology (**hep-ph** new, recent, find)
- High Energy Physics - Theory (**hep-th** new, recent, find)
- Mathematical Physics (**math-ph** new, recent, find)
- Nonlinear Sciences (**nlin** new, recent, find)
  includes: Adaptation and Self-Organizing Systems; Cellular Automata and Lattice Gases; Chaotic Dynamics; Exactly Solvable and Integrable Systems; Pattern Formation and Solitons
- Nuclear Experiment (**nucl-ex** new, recent, find)
- Nuclear Theory (**nucl-th** new, recent, find)
- Physics (**physics** new, recent, find)
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- General Relativity and Quantum Cosmology (**gr-qc** new, recent, find)
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Cooperation And Liaison Between Universities And Editors (CLUE): Recommendations On Best Practice

Elizabeth Wager, Sabine Kleinert, Michele Garfinkel, Volker Bähr, Ksenija Baždarić, Michael Farthing, Chris Graf, Zoë Hammatt, Lyn Horn, Susan King, Debra Parrish, Bernd Pulverer, Paul Taylor, Gerrit van Meer

doi: https://doi.org/10.1101/139170

This article is a preprint and has not been peer-reviewed [what does this mean?].

Abstract | Info/History | Metrics | Preview PDF

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ASAPbio is a scientist-driven initiative to promote transparency and innovation in life sciences communication.

News

Meeting on Transparency, Recognition, and Innovation in Peer Review in the Life Sciences

Fraud or Beautification?

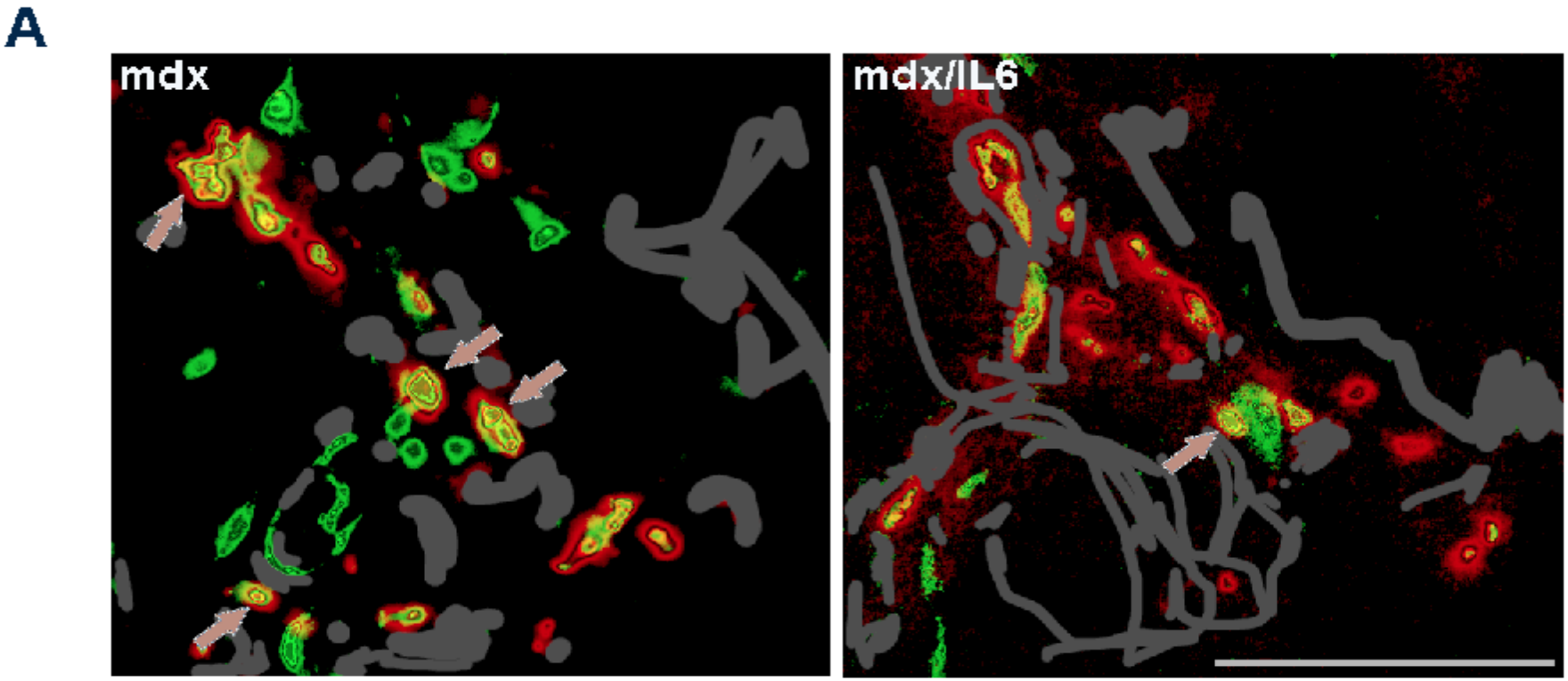

EMM submission

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	pre-pub check	% 'issues'
2013	215	20.9
2014	289	20.4

Level	Attributes	Action	%
I	cosmetic aberrations or mistakes with supporting source data and satisfactory author explanation.	allow revision no report to institution	12
II	data 'beautification' and undeclared manipulation that changes conclusions; available source data or new data	may allow revision, may report to institution	8
III	image manipulation with digital obfuscation (splicing, cloning, insertion, selective deletion); no explanation; no source data	reject and report	<0.5

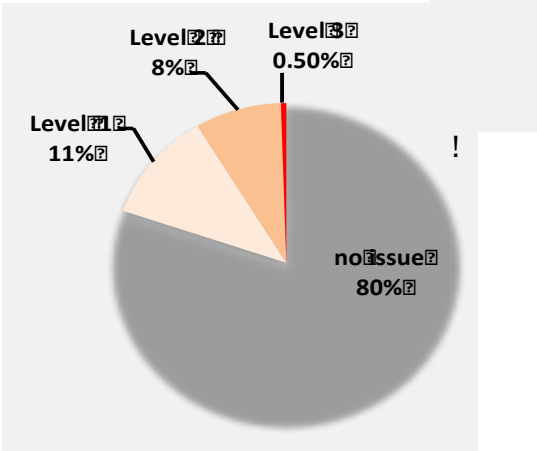

!

request source data without providing details

Need for training

Date: March 11, 2015 1:22:05 PM GMT+01:00
To: Michele Garfinkel <michele.garfinkel@embo.org>

Dear Michele,

[redacted]

In addition, I am currently attending the course on research integrity; I am more or less half way to do the test. It is a great course; although I have been doing research for more than 15 years, I was not aware of many important details. I am ashamed in admitting that I have sometimes followed and witnessed incorrect research conduct, without even noticing. Of course I haven't done anything evil, but in the future I will pay more attention. I think that more education, at all levels, is needed to get the research community aware and more attentive to Research Integrity.

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Main page Recent changes Navigate by Filter by Search

Contributor Roles

A high-level classification of the diverse roles performed in the work leading to a published research output in the sciences. Its purpose to provide transparency in contributions to scholarly published work, to enable improved systems of attribution, credit, and accountability.

Sub-elements

1. Contributor Roles/Conceptualization
2. Contributor Roles/Data curation
3. Contributor Roles/Formal analysis
4. Contributor Roles/Funding acquisition
5. Contributor Roles/Investigation
6. Contributor Roles/Methodology
7. Contributor Roles/Project administration
8. Contributor Roles/Resources
9. Contributor Roles/Software
10. Contributor Roles/Supervision
11. Contributor Roles/Validation
12. Contributor Roles/Visualization
13. Contributor Roles/Writing – original draft
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Consortia Advancing Standards in Research Administration Information: Contributor Roles Taxonomy

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Wed 2018-01-31
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Five Key Takeaways from ORCID's First Consortia Workshop

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LATEST NEWS

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Tue 2018-01-30
Five Key Takeaways from ORCID's First Consortia Workshop

Michele Garfinkel

ORCID ID

https://orcid.org/0000-0001-8946-7907

What or who needs to be responsible?

- The system?
- The individual?
- “Science”?
- Scientists?

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Asilomar 1975

ROLLING STONE, JUNE 19, 1975

THE PANDORA'S BOX CONGRESS

By Michael Rogers

140 Scientists Ask: Now that We Can Rewrite the Genetic Code, What Are We Going To Say?

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DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Questionable and Unethical Publishers: How to spot them and enable researchers to avoid being trapped

ALLEA Workshop

Ethical Aspects of Open Access: A Windy Road

Brussels February 1st 2018

Lars Bjørnshauge

lars@doaj.org

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Agenda

- Questionable publishers
  - What are we taking about
  - Getting the numbers right
- The Drivers
- Tools to detect questionable journals
  - Blacklists?
  - Whitelists!
  - Empowering researchers to make clever decisions

Questionable or unethical publishers

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Questionable publishing is not a phenomenon that is specific to Open Access publishing!

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October 2013

NEWS

Who's Afraid of Peer Review?

John Bohannon

Dozens of open-access journals targeted in an elaborate *Science* sting accepted a spoof research article, raising questions about peer-review practices in much of the open-access world.

February 2014

NATURE | NEWS

Publishers withdraw more than 120 gibberish papers

Conference proceedings removed from subscription databases after scientist reveals that they were computer-generated.

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Questionable publishers

- Predatory publishers – (Beall)

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Definition

- Definition of predatory:
  - inclined or intended to injure or exploit others for personal gain or profit (Merriam-Webster)

- A predatory publisher can then be described as
  - a publisher who intends to injure or exploit others for personal gain or profit.

-

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- Consider this:

- "Does exploiting the divide between libraries (that typically pay for subscriptions) and scholars (who typically use the subscriptions) in order to make extraordinary high profits constitute predatory conduct?"

- or this:

- "Does continuing to raise prices at several times the rate of inflation, even as those increases cause direct injury to libraries by robbing them of budget flexibility or even make it impossible for them to continue to provide resources – does that constitute predatory publishing?"

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Questionable publishers – many names:

- ~~Predatory publishers – (Beall)~~
- Illegitimate publishers – no law regulating academic publishing
- Deceptive publishers
- Unethical publishers

- In DOAJ we call them:
- **Questionable publishers**

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Our definition:
Questionable publishers is publishers, who are not living up to reasonable standards in terms of content, services, transparency and business behavior.

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The numbers

- Questionable publishers is a problem!!
- But how big a problem is it??
- Shen & Björk (2014): 8.000 journals/420.000 papers
- Crawford (2014): 3275 (active) journals/121.000
- But it is still a problem!!

- Shen & Björk: https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-015-0469-2
- Crawford: https://walt.lishost.org/2017/04/the-problems-with-shenbjorks-420000/

Main Results
country of publishers

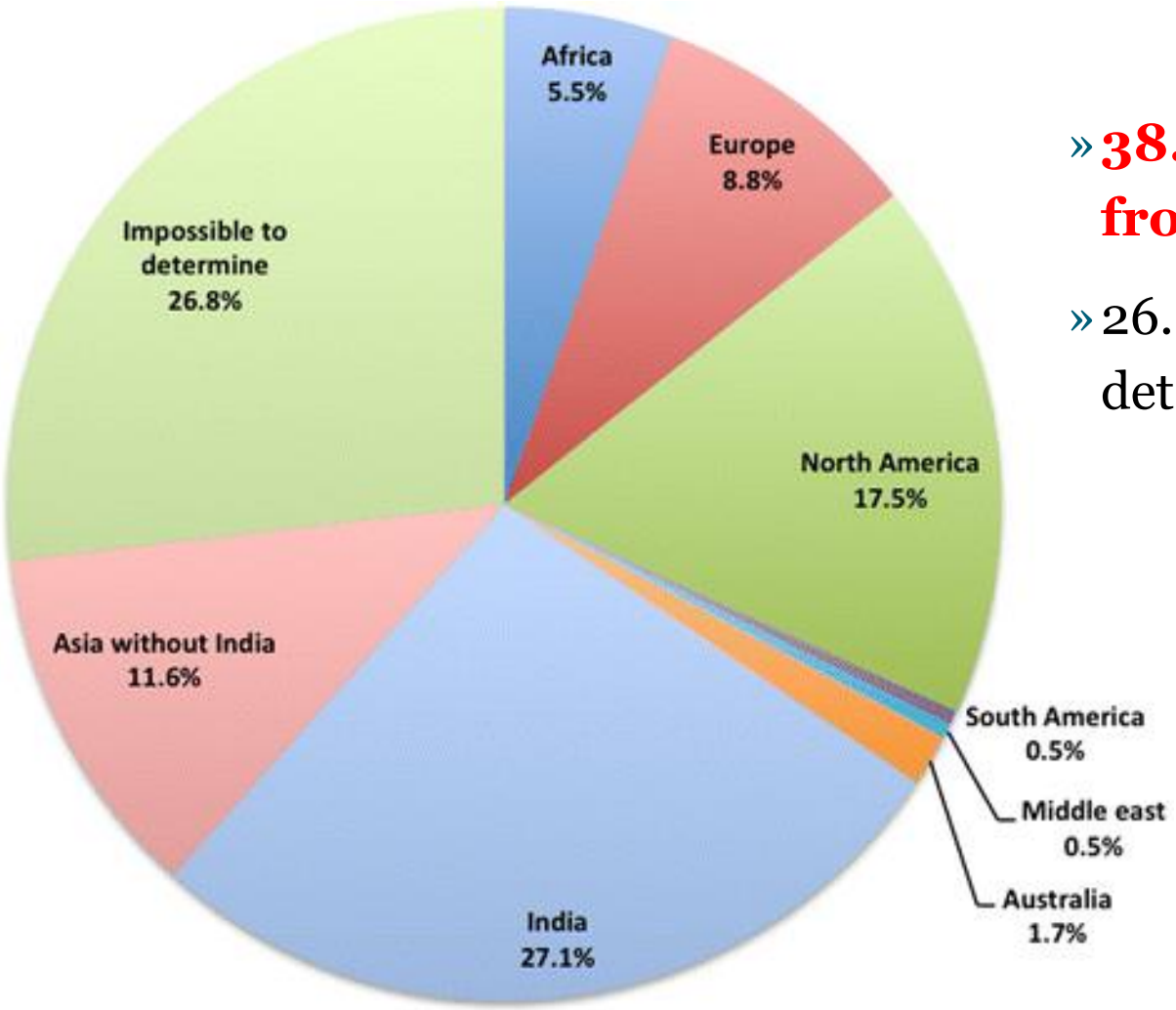

- **38.7% -Asia (27.1% from India)**
- 26.8% -Impossible to determine

from Shen & Björk)

Main Results country of authors

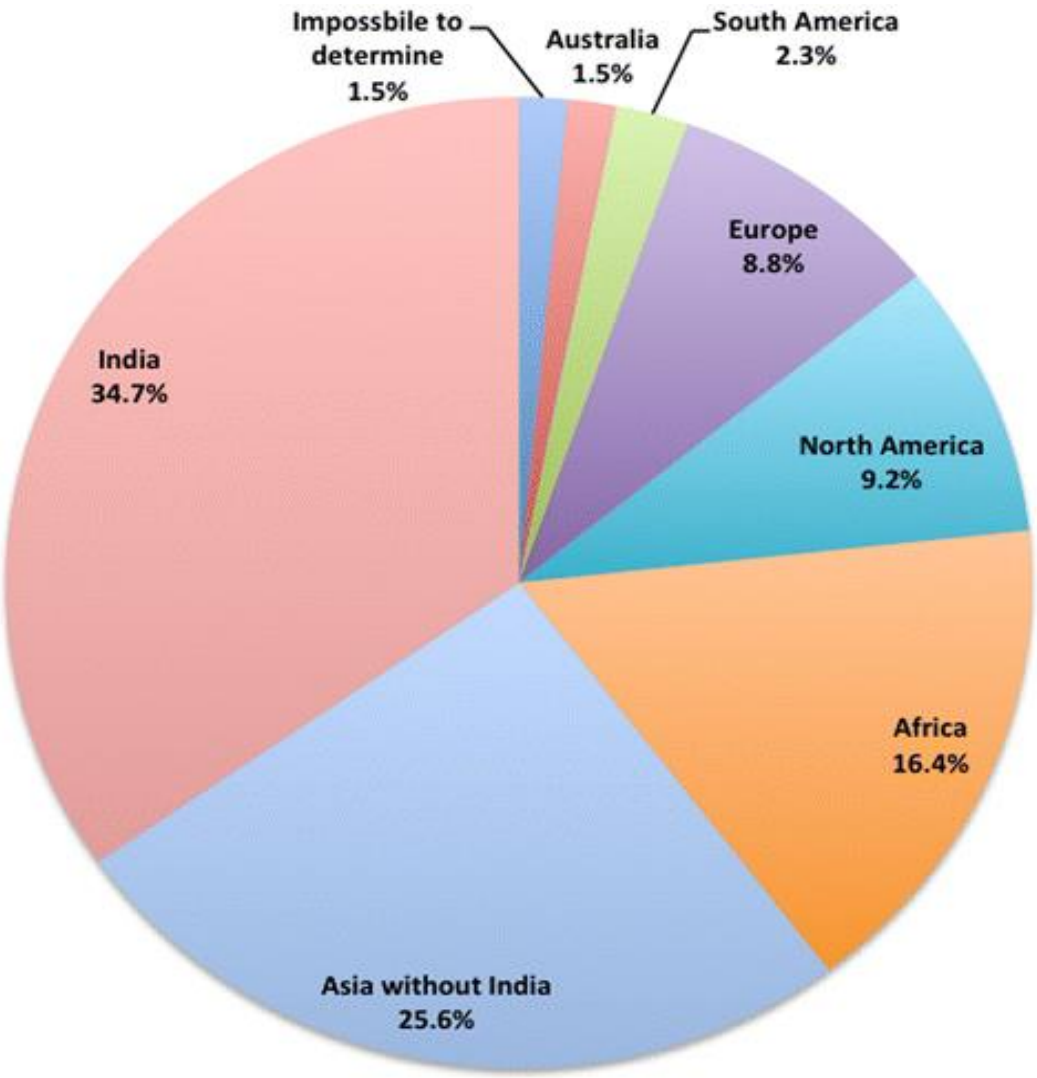

- **60.3% - Asia (34.7% from India)**
- 16.4% - Africa

from Shen & Björk)

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The Drivers

- Why are researchers publishing in questionable journals?
  - Ignorance – lack of attention to the faith of the paper
  - Aggressive marketing cheats researchers
  - Publish or Perish – get something on my C.V. – subito! – pays off!
  - Research Assessment – decision makers counting beans!
  - Exclusion

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Reducing the attraction

- Research managers/funders/decision makers:
  - Research assessment based on actual assessment of the research!!
  - OA-publishing mandates
  - Lists of accredited publishing channels!?
- Professors/PI/research managers:
  - Make Publishing Literacy an integral part of (training in) Research Integrity

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How to spot Questionable Publishers/Journals

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The 5 minute check

- Competent web-site?
- Mass e-mails asking for editors and submissions?
- In the DOAJ? – if not: worrying
- Usage statistics?
- Stable in the discipline?
- Misspelled journal titles?
- Journal launch dates – many at the same time?
- Empty shells- no/few articles?

- Check list from Gavia Library (the library loon) -http://gavialib.com/2012/04/assessing-the-scamminess-of-a-purported-open-access-publisher/– april 2012

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The 5 minute check

- Regularly publishing?
- Many “Edited volumes”?
- Quality of writing, copyediting and typesetting?
- Archiving arrangement?
- Editorial Board – identifiable?
- Other financial support – only relying on APCs?
- Relevant Advertising?
- Running many/expensive conferences?

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How we spot them!

- How does DOAJ detect questionable journals?
- Our approach is based on:
  - the Principles of Transparency and Best Practice in Scholarly Publishing

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

We will help out!

- COPE, OASPA, WAME & DOAJ:

Principles of Transparency and Best Practice in Scholarly Publishing

Introduction

The Committee on Publication Ethics, the Directory of Open Access Journals, the Open Access Scholarly Publishers Association, and the World Association of Medical Editors are scholarly organizations that have seen an increase in the number of membership applications from both legitimate and non-legitimate publishers and journals. Our organizations have collaborated in an effort to identify principles of transparency and best practice that set apart legitimate journals and publishers from non-legitimate ones and to clarify that these principles form part of the criteria on which membership applications will be evaluated.

These criteria are largely derived from those developed by the Directory of Open Access Journals. Note that additional membership criteria may also be used by each of the scholarly organizations. The organizations intend to share information in order to develop lists of legitimate journals and publishers. We do not intend to develop or publish a list of publishers or journals that failed to demonstrate they met the criteria for transparency and best practice.

This is a work in progress and we welcome feedback on the general principles and the specific criteria. Background on the organizations is below.

- https://doaj.org/bestpractice

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

The Principles

1. **Peer review process**
2. **Governing Body**
3. **Editorial team/contact**
4. **Author fees**
5. **Copyright**
6. **Identification of and dealing with allegations of research misconduct**
7. **Ownership and management**
8. **Web site**.
9. **Name of journal**
10. **Conflicts of interest**
11. **Access**
12. **Revenue sources**
13. **Advertising**
14. **Publishing schedule**
15. **Archiving**
16. **Direct marketing**

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

The application form

- The new application form:
- http://doaj.org/application/new

DOAJ Journal Application Form

All the information provided will help our Editorial Team with their assessment, to help them make an informed decision based on the information that you provide.

If you know a journal that should be in DOAJ, please contact the publisher and ask them to complete this form.

BEFORE YOU START, please remember that **all** the content of the journal you are applying about **must** be available **immediately** upon publication.

Basic Journal Information

1) Journal Title *

2) URL *

3) Alternative Title

4) Journal ISSN (print version) *

Only provide the print ISSN if your journal has one, otherwise leave this field blank. Write the ISSN with the hyphen "-" e.g. 1234-4321.

5) Journal ISSN (online version) *

Write the EISSN with the hyphen "-" e.g. 1234-4321.

6) Publisher *

Quality and Transparency of the Editorial Process

34) What is the URL for the Editorial Board page? *

The journal must have either an editor or an editorial board with at least 5 clearly identifiable members and affiliation information. We may ask for affiliation information and email addresses as part of our checks.

35) Please select the review process for papers *

36) Enter the URL where this information can be found *

This field is optional if you have selected "None" above.

37) What is the URL for the journal's Aims & Scope *

Capture a Rectangul

We are asking about…

- The editorial board
- The peer review process
- Archiving/preservation
- Plagiarism
- Openness
  - Licensing and copyright
  - Re-use rights
- Charges
- … and much, much more

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Editorial ”quality”

- **QUALITY AND TRANSPARENCY OF THE EDITORIAL PROCESS**

- The journal must have an editor or an editorial board, all members must be easily identified
- Specification of the review process
  - Editorial review, Peer review., Blind peer review, Double blind peer review, Open Peer Review, Other
- Statements about aims & scope clearly visible
- Instructions to authors shall be available and easily located
- Screening for plagiarism?
- Time from submission to publication

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Editorial issues

Quality and Transparency of the Editorial Process

34) What is the URL for the Editorial Board page? *

The journal must have either an editor or an editorial board with at least 5 clearly identifiable members including affiliation information and email addresses.

35) Please select the review process for papers *

36) Enter the URL where this information can be found *

This field is optional if you have selected "None" above.

Specify what kind of reveiw process is applied: Editorial review, Peer Review, Blind Peer Review, Double Blind Peer Review, Open Peer Review

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Openness

- Openness, Reuse& Remixing rights, Licensing, Copyrights and Permissions!

How Open is the Journal?

Please remember that **all** the content of the journal you are applying about **must** be available **immediately** upon publication.

42) What is the URL for the journal's Open Access statement? *

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Reuse/remix

45) Does the journal allow reuse and remixing of its content, in accordance with a CC license? *

- ○ CC-BY
- ○ CC-BY-NC
- ○ CC-BY-NC-ND
- ○ CC-BY-ND
- ○ CC-BY-SA
- ○ No
- ◉ Other

For more information go to http://creativecommons.org/licenses/

46) Which of the following does the content require? (Tick all that apply.)

- ☐ Attribution
- ☐ No Commercial Usage
- ☐ No Derivatives
- ☐ Share Alike

47) Enter the URL on your site where your license terms are stated

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Licensing

47) Enter the URL on your site where your license terms are stated

48) Does the journal allow readers to 'read, download, copy, distribute, print, search, or link to the full texts' of its articles? *

- Yes
- No

From the Budapest Open Access Initiative's definition of Open Access

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Copyright and permissions

Copyright and Permissions

50) Does the journal allow the author(s) to hold the copyright without restrictions? *

- ○ Yes
- ○ No
- ◉ Other

51) Enter the URL where this information can be found *

52) Will the journal allow the author(s) to retain publishing rights without restrictions? *

- ○ Yes
- ○ No
- ○ Other

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Archiving/Preservation

- Archiving is important – too many OA-journals do not have an archiving arrangement

23) What digital archiving policy does the journal use? *

- [ ] No policy in place
- [ ] LOCKSS
- [ ] CLOCKSS
- [ ] Portico
- [ ] PMC/Europe PMC/PMC Canada
- [ ] A national library
- [ ] Other

Select all that apply. Institutional archives and publishers' own online archives are not valid

24) Enter the URL where this information can be found *

This field is optional if you have only selected "No policy in place" above

25) Does the journal allow anyone to crawl the full-text of the journal? *

- ( ) Yes
- ( ) No

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Plagiarism etc

39) Does the journal have a policy of screening for plagiarism? *

- (●) Yes
- ( ) No

If "No" proceed to question below

40) Enter the URL where this information can be found *

41) What is the average number of weeks between submission and publication? *

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Charges

13) Does the journal have article processing charges (APCs)? *

- (●) Yes
- ( ) No

If "No" proceed to question below

14) Amount *

15) Currency *

16) Does the journal have article submission charges? *

- ( ) Yes
- (●) No

If "No" proceed to question below

21) Does the journal have a waiver policy (for developing country authors etc)? *

- (●) Yes
- ( ) No

22) Enter the URL where this information can be found *

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

How we spot them!

How does DOAJ detect questionable journals?

- Low publishing quality
  - Journal name, website, fees, peer review, publisher, ownership, volume of articles, advertisements, prominent soliciting for editors, ambiguous company address, many journals and few articles
- Low scientific quality
  - focus, format, self-citations, plagiarism
- Malpractice
  - false claims, hidden costs, spamming authors, wrong information,

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and more….

- Inappropriate marketing practices
  - Spam emails
- Journal titles with “International”, “American” or “European”
- Very broad scope, multidiscplinary
- Fake impact factors
- Advertise very quick publishing
- Advertise a relative low publication fee
- No or little quality control of articles
- Low-standard peer review process or even don’t have peer review at all

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But!!

- It is the complete assessment of the journal/publisher that forms the final picture.
- A minor set of shortcomings isn't enough ”evidence” to label someone a Questionable Publisher.
- Shortcomings often based on lack of knowledge!
- We are in it to help honest publishers do a better job!!

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Blacklists?

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Beall´s list:

- Maintained by one (1) person, a serials librarian,
- with remarkable ignorance about just serials,
- who explicitly dislike OA and
- operates as prosecutor, judge and jury in one person

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About Blacklists

- Not only are blacklists incomplete by definition
- They are highly susceptible to legal challenge and vulnerable to personal bias.
- Scholars should be able to decide for themselves what is a good venue from which to communicate their work
- (Cameron Neylon: https://cameronneylon.net/blog/blacklists-are-technically-infeasible-practically-unreliable-and-unethical-period/)

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- The Blacklist approach:
  - Stigmatize publishers/journals
- The DOAJ approach:
  - assist publishers to improve and become more transparent, and keep Questionable Publishers out!

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Whitelists

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Accredited Publishing Channels

- An increasing number of Governments and Research Funders are developing Lists of Accredited Publishing Channels as a basis for
  - Research evaluation
  - Rewards systems and promotion
  - Resource allocation
- In case Open Access Policies or Mandates are in place many look to DOAJ for good Open Access Journals

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Promoting OA journals in National Whitelists

- Examples:
- The Science Europe Recommendations:
  - DOAJ recognized in line with Web of Science and Scopus
- The Nordic Research Councils collaborate on a whitelist and supports DOAJ
- Indonesia and other countries
- Many universities have DOAJ listing as a criteria for supporting APC payments for their researchers

Vetenskapsrådet

THE NORDIC LIST

An international collaborative tool for publication analysis with relevance for open access

Collaboration with DOAJ

- In March 2017 a collaboration was started between DOAJ and the Nordic List consortium
- The consortium would like to use DOAJ as a partner in evaluating open access policies of publications channels
- This is an attempt to increase the effectivness of the Nordic collaboration and also to be able to highlight good practice in publishing

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

More help to researchers to avoid Questionable Publishers

It´s easy: encourage them to think!!!

THINK CHECK SUBMIT

Choose the right journal for your research

Home Think Check Submit About FAQ

Think. Check. Submit. is a campaign to help researchers identify trusted journals for their research. It is a simple checklist researchers can use to assess the credentials of a journal or publisher.

THINK CHECK SUBMIT

Choose the right journal for your research

THINK

Are you submitting your research to a trusted journal?
Is it the right journal for your work?

- More research is being published worldwide.
- New journals are launched each week.
- Stories of publisher malpractice and deception are also on the rise.
- It can be challenging to find up-to-date guidance when choosing where to publish.

How can you be sure the journal you are considering is the right journal for your research?

THINK CHECK SUBMIT

Choose the right journal for your research

CHECK

Reference this list for your chosen journal to check if it is trusted.

- Do you or your colleagues know the journal?
  – Have you read any articles in the journal before?
  – Is it easy to discover the latest papers in the journal?

- Can you easily identify and contact the publisher?
  – Is the publisher name clearly displayed on the journal website?
  – Can you contact the publisher by telephone, email, and post?

- Is the journal clear about the type of peer review it uses?

- Are articles indexed in services that you use?

- Is it clear what fees will be charged?
  – Does the journal site explain what these fees are for and when they will be charged?

THINK CHECK SUBMIT

Choose the right journal for your research

CHECK

- Do you recognise the editorial board?
  – Have you heard of the editorial board members?
  – Do the editorial board mention the journal on their own websites?

- Is the publisher a member of a recognized industry initiative?
  – Do they belong to the Committee on Publication Ethics (COPE) ?
  – If the journal is open access, is it listed in the Directory of Open Access Journals (DOAJ) ?
  – If the journal is open access, does the publisher belong to the Open Access Scholarly Publishers' Association (OASPA) ?
  – Is the journal hosted on one of INASP's Journals Online platforms (for journals published in Bangladesh, Nepal, Sri Lanka, Central America and Mongolia) or on African Journals Online (AJOL, for African journals)?
  – Is the publisher a member of another trade association?

THINK CHECK SUBMIT

SUBMIT

If you can answer 'yes' to most or all of the questions on the list.

Complete the check list and submit your article only if you are happy you can answer 'yes' to most or all of the questions.

- You need to be confident your chosen journal will have a suitable profile among your peers to enhance your reputation and your chance of gaining citations.
- Publishing in the right journal for your research will raise your professional profile, and help you progress in your career.
- Your paper should be indexed or archived and be easily discoverable.
- You should expect a professional publishing experience where your work is reviewed and edited.
- Only then should you submit your article.

THINK CHECK SUBMIT

Choose the right journal for your research

ABOUT

Contributing organizations:

- Asian Council of Science Editors (ACSE)
- Association of Learned & Professional Society Publishers (ALPSP)
- Committee on Publication Ethics (COPE)
- Directory of Open Access Journals (DOAJ)
- INASP
- ISSN International Centre
- Ligue des Bibliothèques Européennes de Recherche – Association of European Research Libraries (LIBER)
- Open Access Scholarly Publishers Association (OASPA)
- SPARC Europe
- International Association of STM Publishers (STM)
- UKSG

THINK CHECK SUBMIT

Choose the right journal for your research

LANGUAGE

- Arabic
- Catalan
- Chinese (Simplified)
- Chinese (Traditional)
- Czech
- Farsi
- French
- German
- Greek
- Hindi
- Indonesian
- Italian
- Japanese
- Kazakh
- Korean
- Lithuanian
- Mongolian
- Portuguese
- Romanian
- Russian
- Slovak
- Spanish
- Ukrainian
- Tamil
- Thai
- Vietnamese

http://thinkchecksubmit.org/

and of course:
Check DOAJ – if the journals is not listed, then:

Take Care!!

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

DOAJ – some numbers (Jan 2018)

- Number of Journals in DOAJ: 11.023
- Number of Articles linked in DOAJ: 2.867.844
- Number of Countries represented: 123
- Rejection Rate: 47%
- Number of Publishers (Journals) inadmissible for 1 year or more: 316 (3123)
- List of journals removed: https://docs.google.com/spreadsheets/d/183mRBRqs2jOyP0qZWXN8dUd02D4vL0Mov_kgYF8HORM/edit#gid=0
- Number of new Applications /Month: >300

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

How we work!

- DOAJ Core team:
  - Managing Director
  - Operations Manager
  - Project and Communications Manager
  - Editor-in-Chief
  - Senior Managing Editor
  - 6 Managing Editors

  - PLUS

DOAJ DIRECTORY OF OPEN ACCESS JOURNALS

Volunteers and Ambassadors

- 50+ Voluntary Editors/Associate Editors working unpaid a few hours/week – distributed in editorial groups managing 20+ languages
- 20 Ambassadors recruited to
  - Promote DOAJ
  - Handle applications of journals to be listed in DOAJ
  - Promote best publishing practice and
  - Help identifying and spotting questionable and unethical publishers
- Ambassadors are
  - based in China, India, Russia, Egypt, Ethiopia, Burkina Faso, Algeria, South Africa and Mexico, Indonesia & Korea – covering Asia, Middle East, Africa and Latin America

three-tier evaluation proces

Associate Editors: reviewing applications, communicate with publishers, recommend inclusion/rejection

Editors: allocating applications to Associate Editors, recommend inclusion/rejection

Managing Editors: allocate applications to Editors & decide on inclusion/rejection

DOAJ – much more than a list of journals!

- A global list of peer-reviewed Open Access journals – all subjects and languages
  - journals undergo evaluation based on a set of criteria
  - 11.000 titles (January 2018)
- An aggregation of article level metadata
  - Publishers upload article metadata into DOAJ
  - 73% of the journals do so
  - Currently 2.867.000 records
- All DOAJ services and data are free for all to use, download and re-use

DOAJ is aggregating article level metadata

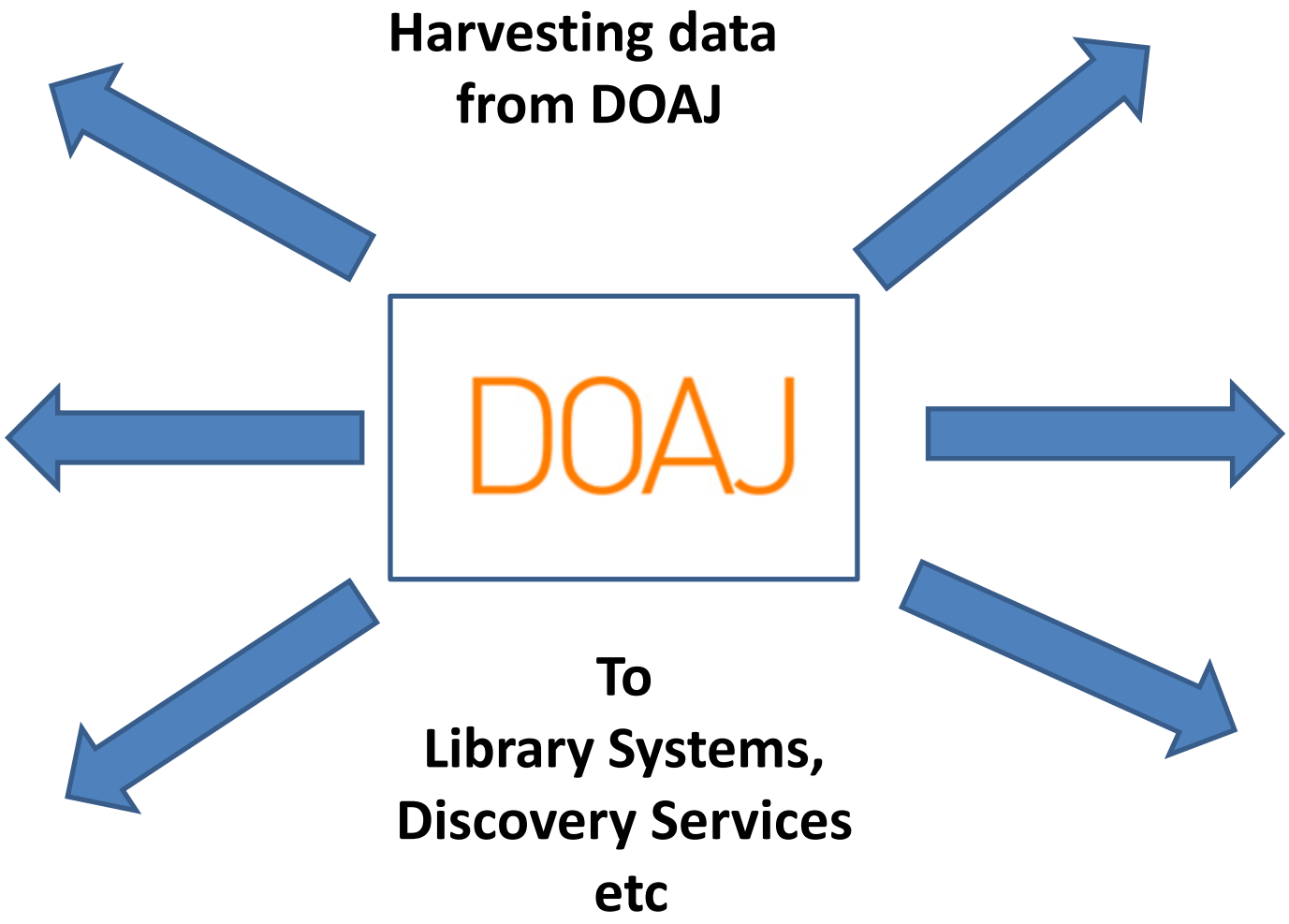
Harvesting data
from DOAJ
DOAJ
To
Library Systems,
Discovery Services
etc

Collaboration!

- COPE, OASPA, WAME – the Principles of Transparency and Best Practice of Scholarly Publishing
- Keepers' Registry – certified archiving organizations
- (OJS) PUBLIC KNOWLEDGE PROJECT
- RESEARCH4LIFE – screening OA-journals
- ISSN
- OASPA, STM, ALPSP, LIBER etc:

THINK CHECK SUBMIT

- www.thinkchecksubmit.org

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DOAJ depends entirely on donations

SUPPORT DOAJ

Become a member or make a donation

DOAJ Membership is recommended for those who can support the DOAJ with an annual fixed contribution (annual automatic payment). Members are listed on the DOAJ Membership page, can use their DOAJ membership status and our logo for marketing activities. You may also make a donation of any amount that you wish (invoiced annually) and be listed as a DOAJ Supporter. If you publish or own an Open Access journal, you may prefer to become a Publisher Member. You will be listed on our Publisher Members page and will receive our newsletter.

https://doaj.org/membership

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- ALLEA Members supporting DOAJ:
  - Austrian Academy of Sciences
  - Several of the centres in the network of the Hungarian Academy of Sciences
  - The Royal Netherlands Academy of Arts and Sciences

  - Interested in supporting the work we do?
  - Contact lars@doaj.org

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Thanks to :,

All the Library Consortia, Universities, Research Funders and Publishers and our Sponsors for the financial support to DOAJ!

And thank you for listening!

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APS physics
BRILL
cogent • oa
Copernicus Publications The Innovative Open Access Publisher
DE GRUYTER OPEN
Dovepress
EBSCO
edp sciences
eLIFE
ELSEVIER
ExLibris The bridge to knowledge
frontiers
Hindawi
IOP Publishing
ISSN INTERNATIONAL STANDARD SERIAL NUMBER
JMIR Publications The Leading eHealth Publisher
Karger Open access
LUND UNIVERSITY
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ingenta OPEN
Taylor & Francis Group an informa business
Thieme
WILEY
Wolters Kluwer
ADRI Perkumpulan AHLI & DOSEN REPUBLIK INDONESIA

EUA
European University Association

OPEN ACCESS
2016-2017 EUA SURVEY
RESULTS

By Rita Morais
and Lidia Borrell-Damian

FEBRUARY 2018

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European University Association asbl

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OPEN ACCESS

2016-2017 EUA SURVEY

RESULTS

By Rita Morais

and Lidia Borrell-Damian

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The authors would like to thank the members of the EUA Expert Group Science 2.0/ Open Science for their contribution to the EUA Open Access Survey and the present report. Special thanks are extended to Professor Jean-Pierre Finance, Chair of the Expert Group, for his insights on the evolution of open access across European universities and for the ongoing support to the development of this report.

1. Preface

EUA continues to strongly support Open Science, particularly in view of the renewed ambition of several European states and the European Commission to achieve Open Access to scientific publications by 2020.

In this context, the following questions remain unsolved and pertinent:

- How to engage researchers in new methods and tools based on Open Science in a quicker and more globalised way;
- How to speed up regulatory processes to ensure a higher degree of fairness and simplification in terms of copyright, text and data mining and Open Access to research data;
- How to control the costs of accessing publications (pay to read and/or pay to publish), especially counting on the expectation that an increase in the number of Open Access journals should lead to a decrease in the cost of subscriptions;
- How to increase fairness in the evaluation of scientific papers;
- How to transform research assessment (and thus the management of researchers' careers) by departing from the hypocrisy of the journal impact factor.

Over the years, EUA has developed studies and policy positions on these relevant topics and addressed them to national and European political leaders, as well as to university leaders (for example, EUA Statement on Open Science to EU Institutions and National Governments and Recommendations to University Leaders on Open Access to Research Publications and on Research Data Management and Text and Data Mining).

The EUA positions are informed and shaped by the expertise of long-standing and dedicated working groups (Expert Group on Science 2.0/Open Science, High-Level Group on Big Deals), but also by surveys addressed to European universities through the national rectors' conferences. Thus, these surveys, as well as those carried out in other thematic areas (University Autonomy Scorecard, Bologna Process, etc.), reinforce the position of EUA as a relevant monitoring centre of the European higher education and research systems.

It is in this context that EUA publishes the present report on the outcomes of the third wave of its Open Access Survey addressed to European universities. While the 2015-2016 survey gathered 169 responses, the rate doubled in the 2016-2017 edition, reaching 338 universities. Only 107 universities took part in the survey conducted in 2015-2016.

The reader will find evident stability in the percentages reported for the main indicators. In addition to the increase in responses, this suggests a positive evolution of universities towards Open Access (institutional policies on Open Access, the existence of institutional or shared repositories, linkages with OpenAIRE). At the same time, the reader will see that some important aspects of Open Access are still at a very low implementation level. For example, only 20% of articles published via a peer review mechanism are freely accessible.

Beyond the analysis of the annual evolution of Open Access to scientific publications in European universities, the 2016-2017 report also includes a section on research data management and Open Access to research data. In this area, however, the progress of universities is still somewhat feeble.

I am convinced this new report will help universities, researchers and librarians to better understand the current state of play in Open Access.

I warmly thank the EUA team responsible for the report for their excellent work.

Prof. Jean-Pierre Finance

Chair of the EUA Expert Group on Science 2.0/Open Science

1. Introduction

Open science, particularly open access to research publications and research data, is developing fast on many fronts including legal and technical aspects. This is likely to have a lasting impact on how science is conducted, used and disseminated. The dual role of European and national authorities, and universities, is to contribute to shaping the evolution of open access policies and to adapt practices to new developments. One major stakeholder initiative at EU-level is the Open Science Policy Platform (OSPP), of which EUA is a member.

European universities have a critical role in making open access a reality by 2020, as proposed in the Amsterdam Call for Action on Open Science. The European University Association (EUA) has been monitoring universities' progress in this area since 2007 and, more recently, has intensified this work with the Expert Group on Science 2.0/Open Science. The EUA Roadmap on Open Access to Research Publications sets the agenda for the association's open access activities. The priorities identified in this roadmap include monitoring European universities' open access policies.

The EUA Open Access Survey of European universities is now in its third round. Started in 2014, the first survey focused on how far institutional open access policies had been implemented. It has since been refined and re-launched every year. The report of the outcomes of the 2015-2016 EUA Survey on Open Access was published in June 2017. This report presents the results of the 2016-2017 survey. This third wave gathered 338 responses from universities and higher education institutions across 39 European countries, which represents a 100% increase from the 2015-2016 response rate. For the first time, the 2016-2017 survey also focused on research data management and open access to research data, in addition to open access to research publications.

The outcomes of this survey have informed EUA work on open science and are reflected in the major policy recommendations issued during 2017, as indicated in the preface.

EUA will continue to conduct its annual open access survey to monitor progress in this important area and to better support members as they make the transition to open access

2. Methodology and Participants

The 2016-2017 Open Access Survey included 27 questions grouped into three main sections:

- The Institution and the Respondent
- Institutional Policies and Strategies for Open Access to Research Publications
- Research Data Management and Open Access to Research Data

Like previous EUA OA Surveys, the 2016-2017 questionnaire included both open- and closed-ended questions, covering topics such as the characteristics of institutional open access policies and infrastructure, awareness of open access initiatives, drivers and barriers to open access and potential actions.

The *Research Data Management and Open Access to Research Data* section built on the outcomes of the 2015-2016 survey and, for the first time, included exploratory, open questions focusing on the skills required for research data management and open access to research data.

The survey was open from 25 November 2016 until 31 March 2017. Only one response per institution was accepted.

Figure 1. Number of respondent institutions per country

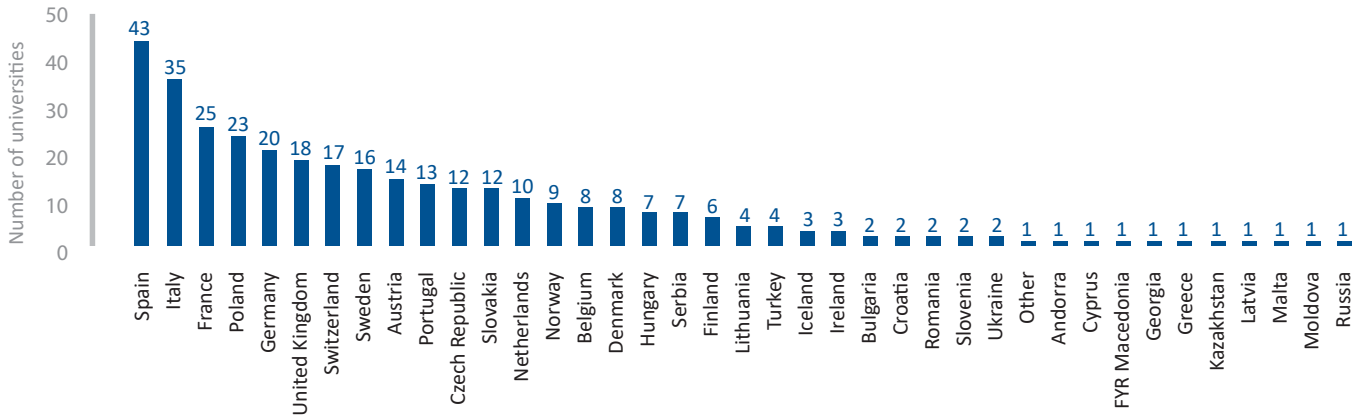

The previous edition of the EUA Open Access Survey, conducted in 2015-2016, received responses from 169 institutions in 33 European countries[1]. The first wave of this survey, which was conducted back in 2014, collected 106 responses from 30 European countries. These figures indicate a 100% increase in the response rate from the 2015-2016 to the 2016-2017 surveys. It is also worth noting that 107 institutions participated in both the surveys conducted in 2015-2016 and 2016-2017 and that 36 institutions participated in the three waves of the EUA Open Access Survey (2014, 2015-2016, 2016-2017).

While the response rate for all EUA Open Access Surveys reflects the diversity of EUA membership, both in terms of geographical spread and university size, it is not possible to use the results reported to generalise about other institutions due to the nature of the data (convenience sample[2]).

This report focuses on the results of the 2016-2017 EUA Open Access Survey. Where appropriate and relevant, a comparison with the results of the 2015-2016 survey is provided.

1 The results of the 2015-2016 EUA Open Access Survey are available on the EUA website.
2 Convenience sampling is a type of non-probability sampling in which participants are selected because of their accessibility or proximity to the researcher. All EUA members were invited to take part in the EUA Open Access Survey. The sample comprises participating institutions.

3. Open Access to Research Publications

This chapter focuses on the degree of implementation of institutional open access policies to research publications. It covers a variety of topics, such as repositories, drivers and barriers to self-archiving, institutional awareness of open access and actions needed to further promote open access to research publications.

3.1. Institutional policies

Over 50% of the institutions surveyed stated they had implemented an open access policy to research publications and 21% reported being in the process of developing and implementing an open access policy over the next year. Globally, over nine out of ten universities indicated having an open access policy, being in the process of developing one or planning its development (Figure 2).

However, about 7% indicated that they were not planning to develop an institutional open access policy. The main reasons given related to the low priority given to open access by the institution, the lack of funds for open access costs (e.g. to establish and/or maintain a repository) and low levels of open access knowledge.

Figure 2. Institutional policy on open access to research publications

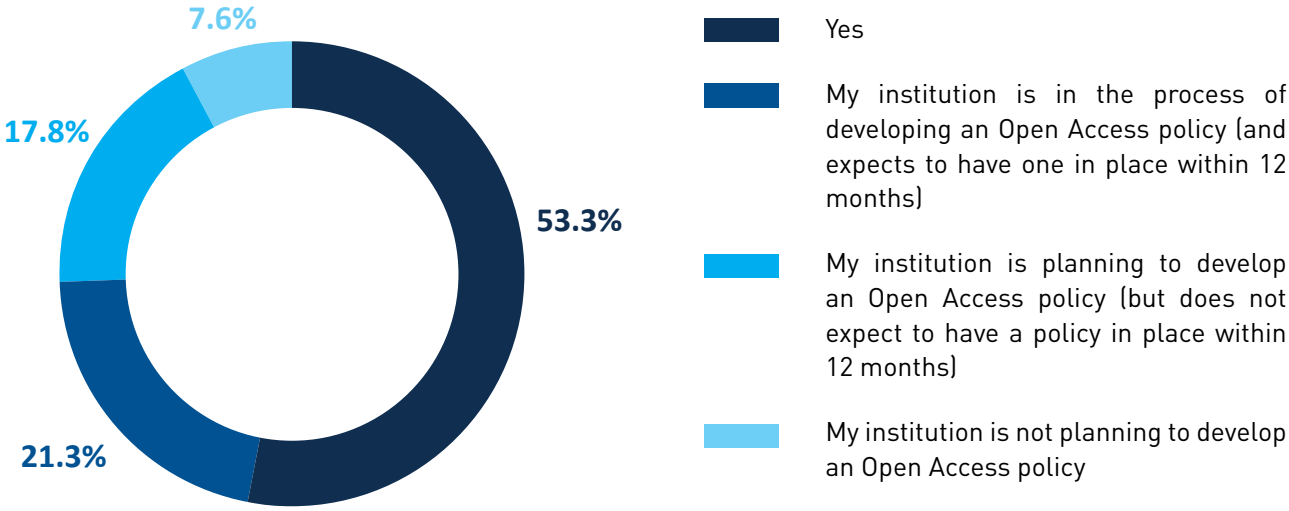

Number of respondents: 338/338.

Comparison with 2015-2016 results:

The results of the 2015-16 survey showed a similar pattern: 55.6% of the institutions reported having implemented an open access policy, 23.7% indicated being in the process of developing one and 17.2% were planning to develop an open access policy but did not expect it to be in place within 12 months.

The most common measures used at institutions with or developing an open access policy, are recommendations for researchers to self-archive their publications (60.2%) and activities and training to raise awareness about open access to research publications (54.1%). Mandatory policies linked to internal performance evaluation or external review procedures are still much less common (about 12%).

Figure 3. Elements of institutional policies on Open Access to research publications

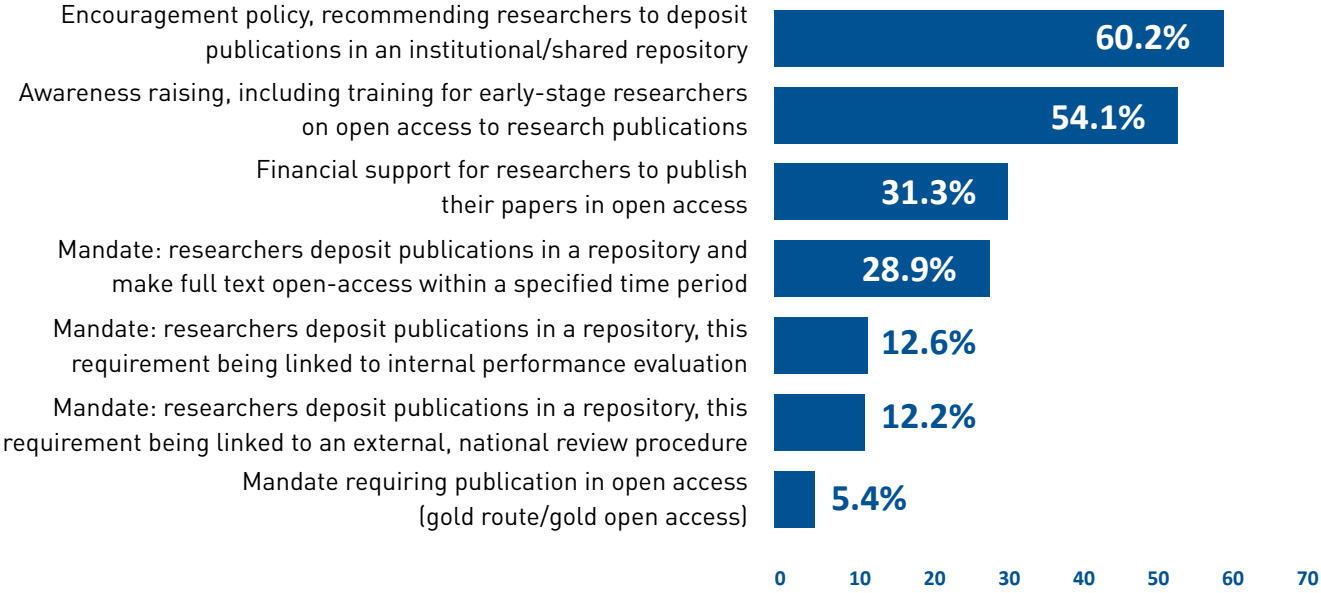

Notes: this question only applies to universities that replied "yes", "my institution is in the process of developing an Open Access policy" or "my institution is planning to develop an Open Access policy" in Figure 2. The sub-sample for this question is 312.

Multiple-choice question. Number of respondents 294/312.

Comparison with the 2015-2016 results:

The results of the survey conducted in 2015-2016 showed a similar pattern in terms of the use of recommendations for self-archiving (64.1% vs. 60.2% in 2016-2017). Institutional self-archiving requirements linked to internal performance evaluation were reported by a similar proportion of institutions in 2015-2016 and 2016-2017 (11.5% vs. 12.6%). However, financial support for researchers to publish their articles in open access increased between 2015-2016 and 2016-2017 (24.4% vs. 31.3%).

Almost 60% of the institutions with an existing policy on open access to research publications have registered their repository in ROARMAP (Figure 4).

Figure 4. Percentage of institutional repositories registered in the Registry of Open Access Repository Mandates and Policies (ROARMAP)

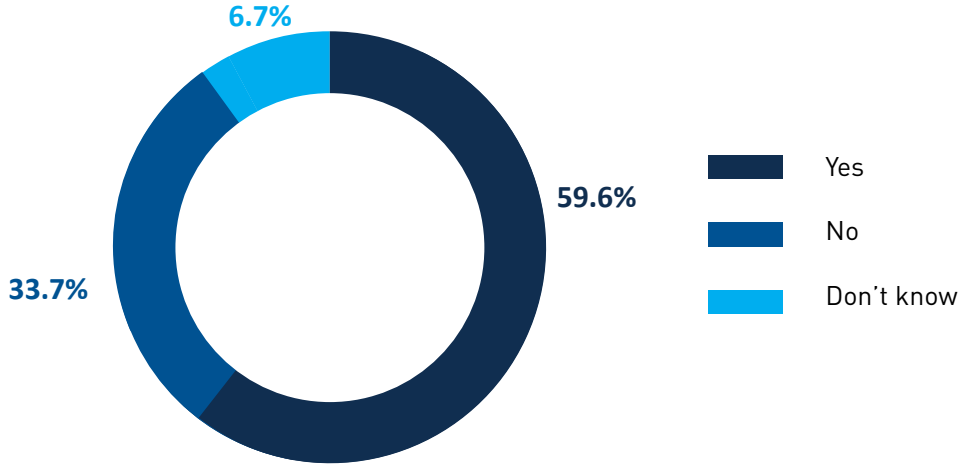

Notes: this question only applies to universities that replied "yes" in Figure 2. The sub-sample for this question is 180. Number of respondents: 178/180.

Comparison with 2015-2016 results:

The pattern of responses in 2016-2017 and the previous year are very similar: in both cases, almost 60% of institutions had registered their open access policy in ROARMAP and around 35% did not.

3.1.1. Repositories and deposit rates

This section includes information about the existence and use of institutional repositories, software used, participation in the OpenAIRE portal and deposit rate evolution.

As shown in Figure 5, nearly three out of four institutions have a repository and about 10% participate in a shared repository. Almost 14% of the universities surveyed lacked both an institutional and a shared repository.

Figure 5. Existence of an institutional/shared repository

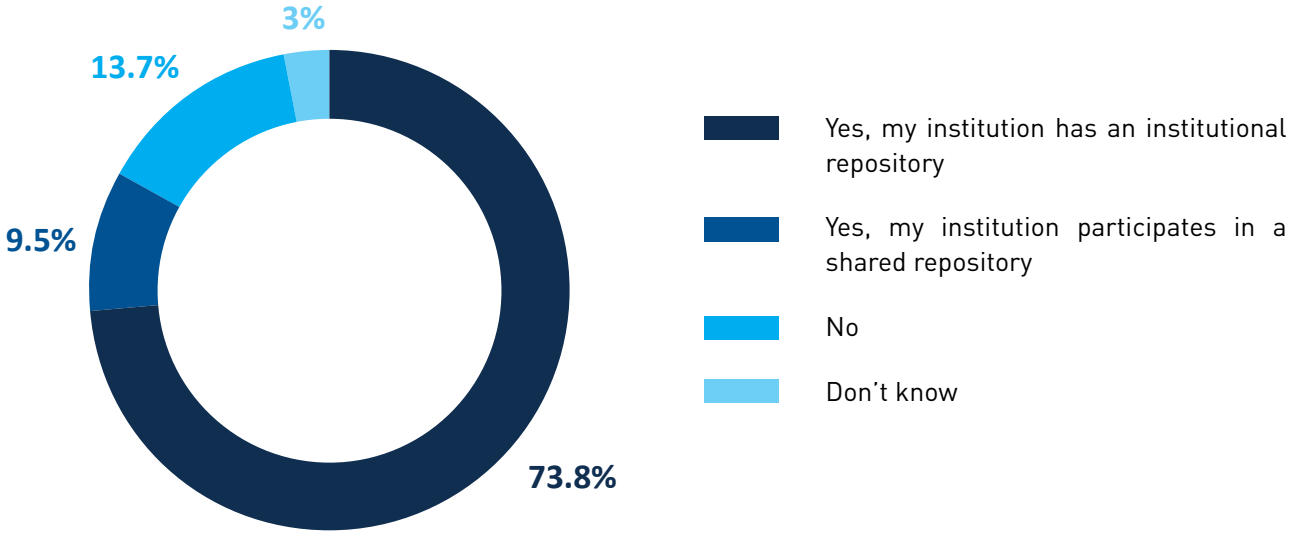

Number of respondents: 336/338.

Comparison with 2015-2016 results:

The results of the 2015-2016 survey were similar to those of 2016-2017 in terms of the institutions' own repositories or participation in shared repositories. In 2015-2016, almost 77% of universities had their own repository and about 12% participated in a shared repository. The number of institutions that did not participate in a shared repository or have their own increased from 9.5% in 2015-2016 to 13.7% in 2016-2017.

Repository software and aggregation

DSpace was the software most frequently used by institutions with either their own repositories or participating in a shared repository (Table 1).

Table 1. Repository software

	Percentage
DSpace	45.5
Eprints	8.6
In-house software (e.g.part of the institutional information system)	7.2
Fedora	5
Invenio	2.5
Opus	1.4
Digital Commons	0.7
Other	23.4
Don't know	5.9

Notes: this question only applies to universities that replied "yes, my institution has an institutional repository" or "my institution participates in a shared repository" in Figure 5. The sub-sample for this question is 280. Number of respondents: 278/280.

The 'Other' category covers a wide variety of software. For example, some institutions used HAL, Iris, DiVA and Pure.

Almost seven out of ten institutions' repositories were aggregated by the OpenAIRE portal (Figure 6). Between 37% and 38% of these repositories used OpenAIRE Basic or OpenAIRE 3.0 (Table 2).

Figure 6. Institutional repository aggregated by the OpenAIRE[3] portal/infrastructure

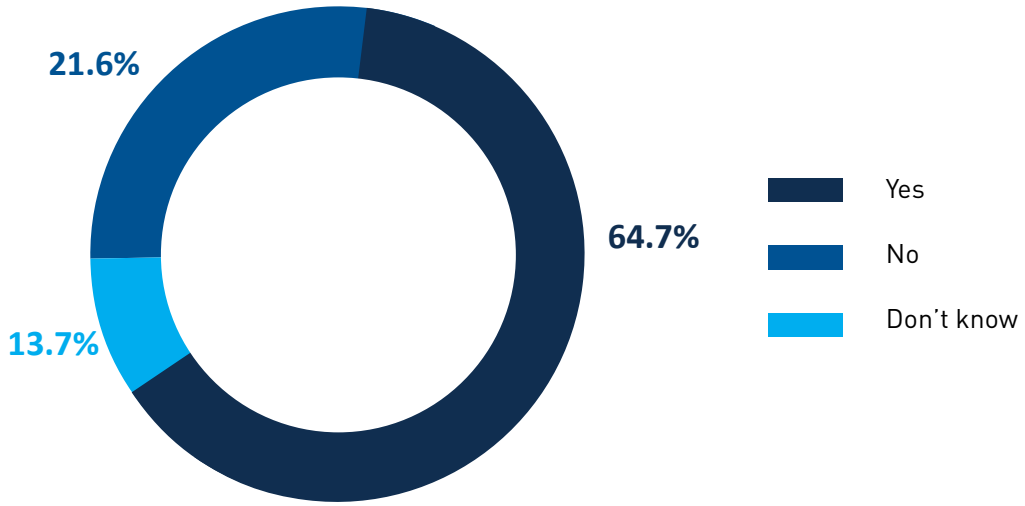

Notes: Notes: this question only applies to universities that replied "yes, institutional repository" or "yes, shared repository" in Figure 5. The sub-sample for this question is 280. Number of respondents: 278/280.

Table 2. Institutional repository compatibility with OpenAIRE infrastructure

	Percentage
OpenAIRE Basic (DRIVER OA)	38.2
OpenAIRE 2.0 (EC funding)	4.7
OpenAIRE 2.0+ (DRIVER OA, EC funding)	20.6
OpenAIRE 3.0 (OA, funding)	36.5

Notes: this question only applies to universities that replied "yes" in Figure 6. The sub-sample for this question is 180. Number of respondents: 170/180.

Comparison with 2015-2016 results:

In 2016-2017, DSpace continued to be the most frequently used software, at 45% of institutions; in 2015-2016 this figure had been 51%. The proportion of repositories aggregated by the OpenAIRE portal was also similar, at 62% in 2015-2016 and 65% in 2016-2017.

3 www.openaire.eu

3.1.2. Drivers and barriers to self-archiving by researchers

To encourage researchers to self-archive their publications in the institutional or shared repository, a very high proportion of universities considered it was important to increase the visibility of research (89.5%) and the number of citations (87.2%, Figure 7). Over seven out of ten institutions indicated that research funding requirements were also critically important to increasing self-archiving.

Figure 7. Importance of different factors in encouraging researchers to self-archive research publications in a repository (green route/green open access)

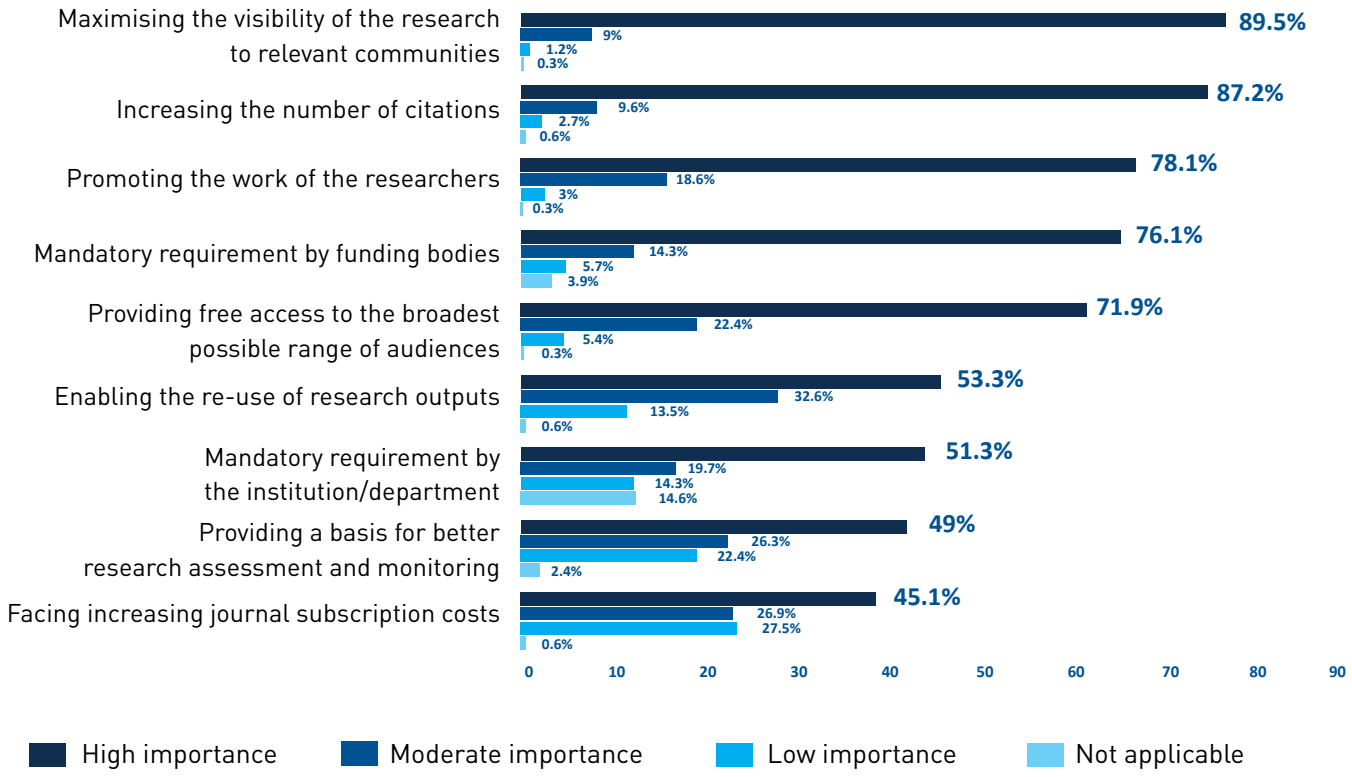

Notes: number of respondents: 335/338, except for the items, "Maximising the visibility of research," "Enabling the use of research outputs," and "Promoting the work of researchers," which had 334/338.

Comparison with 2015-2016 results:

The 2015-2016 survey showed a similar pattern of results. A very high proportion of universities (between 70%-80%) indicated that the most important reasons encouraging self-archiving were: maximising research visibility, increasing the number of citations, promoting researchers' work and mandatory requirements by funding bodies.

When looking at researchers' concerns about self-archiving (Figure 8), most institutions placed greatest importance on factors related to the importance of publishing in conventional journals (81.7%), which is probably related to research assessment. Uncertainties about copyright (75.1%), publisher policies (71.9%) and the reputation of open access publications (69.1%) were also frequently cited.

Figure 8. Researchers' concerns about self-archiving publications in a repository (green route/green open access)

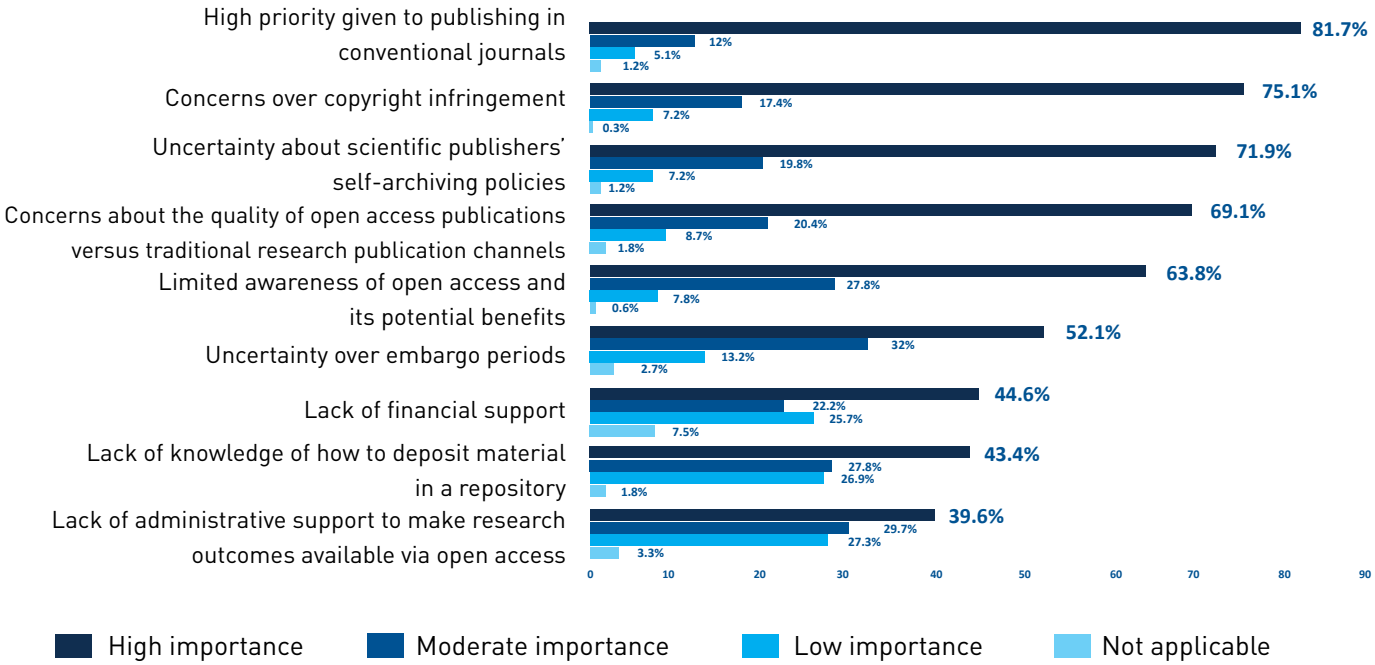

Notes: number of respondents: 334/338, except items "Lack of administrative support to make research outcomes available via open access," and "Concerns about the quality of open access publications versus traditional research publication channels," which had 333/338.

Comparison with 2015-2016 results:

The question used in the 2015-2016 survey asked universities to indicate the frequency of different researchers' concerns. The list of potential concerns was also more limited than in the 2016-2017 survey. Despite these differences, uncertainty about scientific publishers' policies and concerns about copyright infringement ranked among the most frequent/important researcher concerns regarding self-archiving in both survey waves.

3.1.3. Institutional monitoring of open access to research publications

Universities were asked about the share of peer-reviewed open access publications (including journal articles, monographs/books, proceedings/conference papers) authored from members of the institution between 1 January 2013 and 31 December 2015. This question was open to all institutions surveyed, irrespective of whether the institution had an open access policy (Table 3). The results were analysed both for the overall sample and for the sub-sample of institutions with an existing open access policy. Only the overall sample results are presented below, as the outcomes for both samples were identical.

Table 3. Estimated percentage of peer-reviewed research publications (including journal articles, monographs/books, proceedings/conference papers) authored by members of the institution between 1 January 2013 and 31 December 2015 (all institutions)

	Deposit in the institutional /shared repository (green open access) (% of institutions)	Open access publishing (gold open access) (% of institutions)
Less than 20%	59.6	69.6
20-40%	22.7	19.9
40-60%	4.9	3.9
60-80%	7.6	3.3
More than 80%	5.3	3.3

Notes: number of responses: green open access = 225/338, gold open access = 157/338.

A 60-70% majority of institutions reported that less than 20% of their peer-reviewed research publications were available in open access, either through the green or gold route. In addition, over eight in ten universities indicated that a maximum of 40% of their publications were available in open access (repositories - green route, or open access publishing - gold route), which indicates that most peer-reviewed publications from the institutions surveyed are still not available in open access.

It is also worth noting that several institutions were unable to reply to this question as the institution lacked mechanisms for collecting and/or analysing open access publication data.

Comparison with 2015-2016 results:

The 2015-2016 and 2016-2017 results are broadly equivalent. In both survey waves, most institutions reported that less than 20% of their peer-reviewed publications were available in open access, whether via repositories (60% of universities in both 2015-2016 and 2016-2017) or open access publishing (80% in 2015-2016 vs. 70% in 2016-2017). The most relevant difference was found in the proportion of institutions with between 20-40% of their publications available through open access publishing – in 2015-2016 this was the case for only 8.5% of universities, but in 2016-2017 the proportion increased to 20%.

Effectiveness of institutional open access policies

Almost 60% of universities with an existing open access policy indicated an increase in the deposit rates in the institutional/shared repository (Figure 9). Almost 11% of these institutions indicated no increase in deposits and about 32% indicated that they did not know whether deposit rates had increased since they had adopted an open access policy.

Figure 9. Increase in the deposit rate of publications in the institutional/shared repository after adopting an institutional policy on open access to research publications

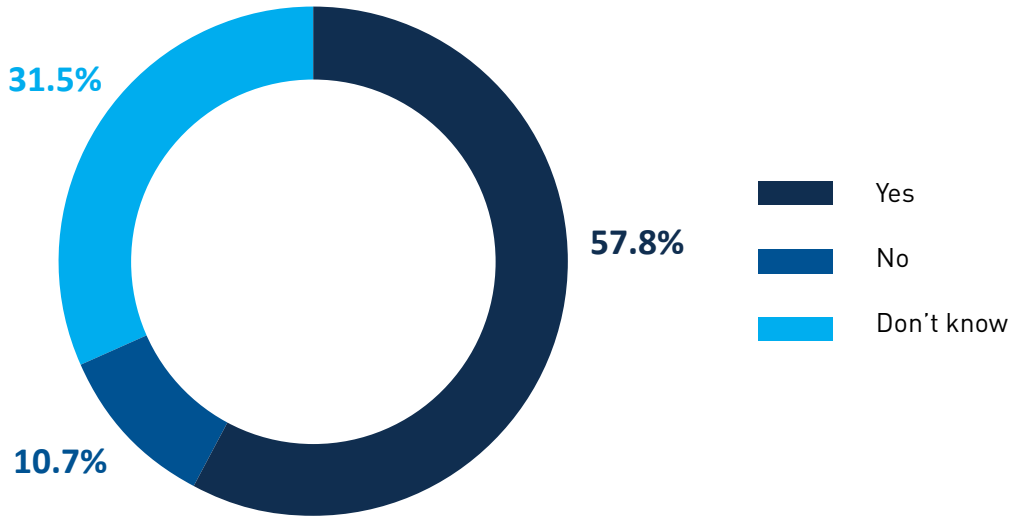

Notes: this question only applied to universities that indicated they had an institutional policy in place (Figure 2). The sub-sample for this question is 180. Number of respondents: 178/180.

Comparison with 2015-2016 results:

The 2015-2016 and 2016-2017 results are identical. In both survey waves, about 60% of institutions with an open access policy indicated an increase in repository deposit rates. Importantly, around 30% of the universities in both survey waves reported they had no information about the evolution of deposit rates in the institutional or shared repository.

Institutions that reported an increase in the deposit rate after adopting an open access policy were asked to provide more information about the evolution in depositing journal articles, monographs/books, proceedings/conference papers (all peer-reviewed) and doctoral theses.

One hundred and three institutions reported an increase in deposit rates following adoption of an open access policy (Figure 7). The year in which this group of universities adopted their open access policy is shown in Table 4. A few institutions implemented their open access policies in the early 2000's, but most adopted open access policies between 2010-2015.

Table 4. Year of institution-wide adoption of the open access policy (institutions reporting an increase in deposit rates since policy adoption)

Year	Number of institutions
2000	1
2005	1
2006	2
2007	3
2008	5
2009	3
2010	9
2011	12
2012	9
2013	10
2014	12
2015	18
2016	7
Non-response	11
Total	**103**

Only a limited number of these 103 institutions provided figures for both current deposit rates and those at the time of the policy adoption. The data collected is presented in Figure 10. The very limited response rate means that the results can only be interpreted as an indication of the situation at these institutions[4].

Figure 10: Evolution in the deposit rates of publications in the institutional/shared repository

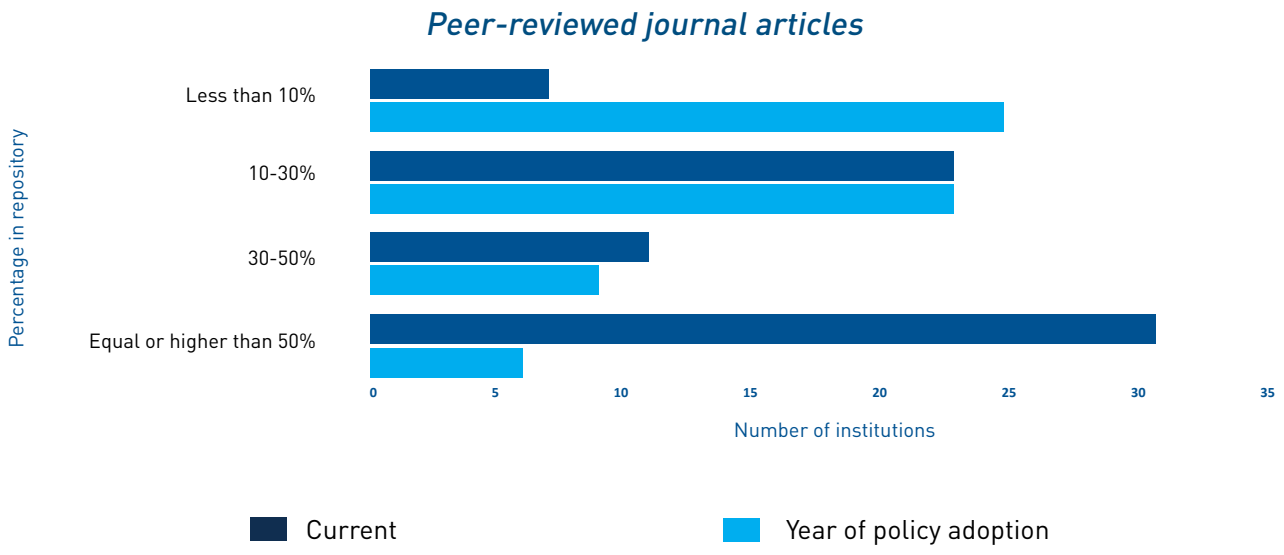

4 A similar analysis was performed for the data reported in the EUA OA Survey 2015-2016.

Peer-reviewed monographs/books

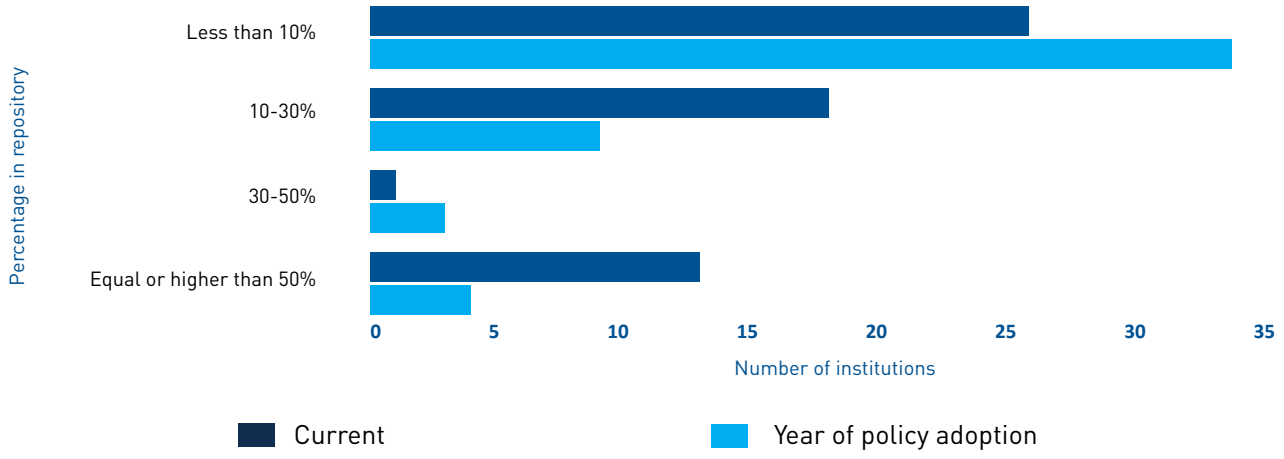

Peer-reviewed proceedings/conference papers

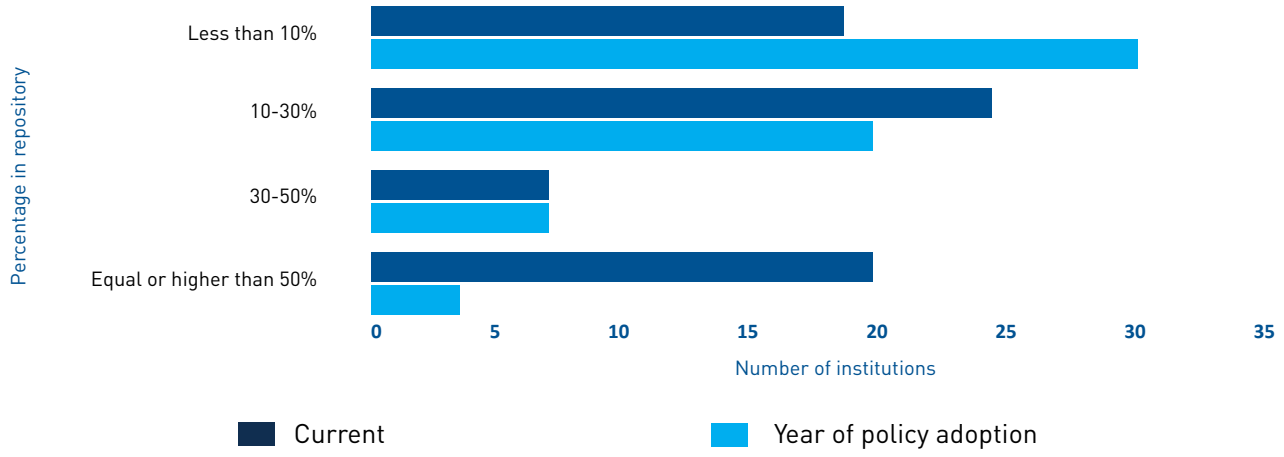

Doctoral theses

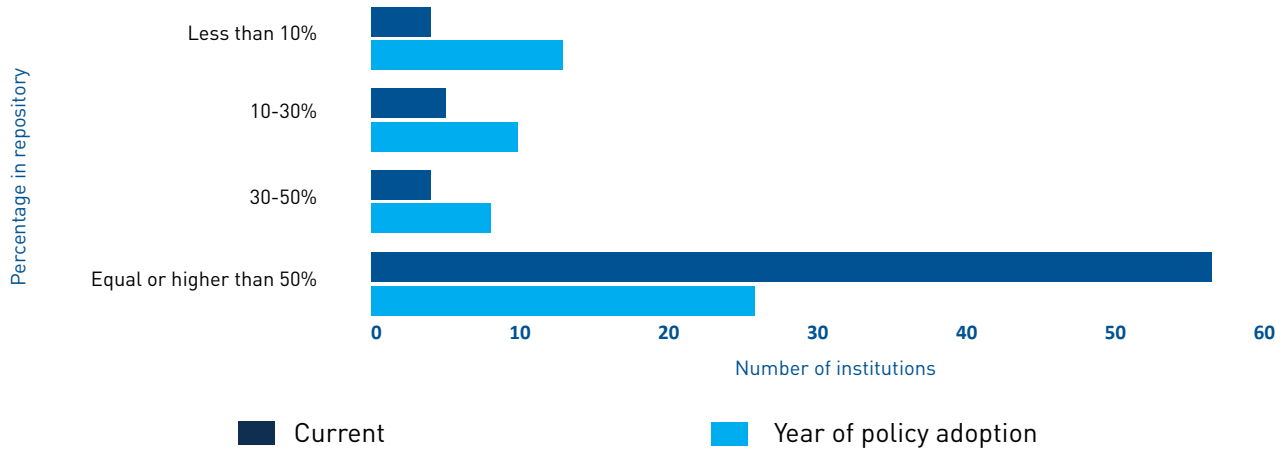

Notes: number of responses: journal articles (year of policy adoption = 63/103, current = 72/103); monographs/books (year of policy adoption = 50/103, current= 58/103); proceedings/conference papers (year of policy adoption = 52/103, current = 60/103); doctoral theses (year of policy adoption = 57/103, current = 70/103).

Most universities surveyed indicated having up to 30% of their peer-reviewed articles, monographs and conference papers in the repository when institutional policies were implemented. A higher number of institutions reported that 50% or more of their doctoral theses were deposited in the repository. After an open access policy was adopted, more institutions reported deposit rates equal to or above 50% in all types of publications, especially in peer-reviewed journal articles and doctoral theses. Monographs/books and, to a lesser extent, conference papers, are more frequently deposited at rates of up to 30%.

The evolution of deposit rates in institutional/shared repositories was also analysed by looking at the increase in deposit rates from the year of policy adoption to date. Deposit rates in the year of policy adoption were subtracted from current deposit rates, for each separate publication type. The results are expressed as percentage points and shown in Figure 11.

Figure 11. Increase in deposit rates per publication type (in percentage points, pp)

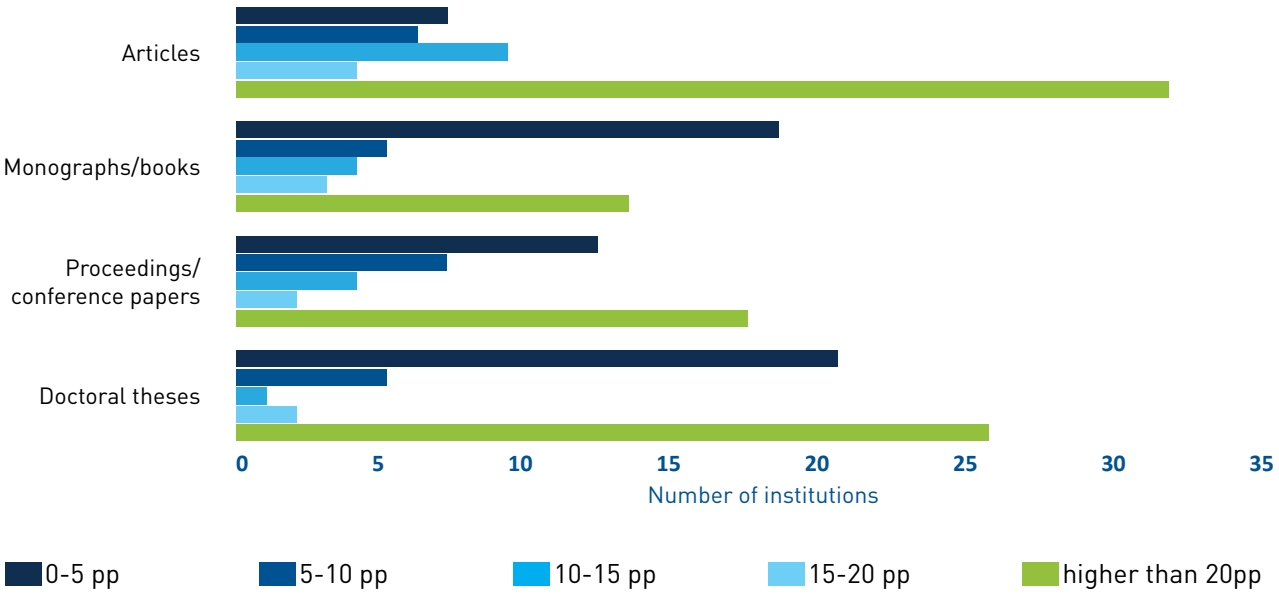

Notes: number of responses: articles = 57/103, monographs/books = 43/103, proceedings/conference papers = 42/103, doctoral theses = 53/103. Only institutions that provided data for both current deposit rates and deposit rates in the year of policy adoption were included in the analysis.

For all types of publications, except articles, most institutions reported either a modest (between 0-5 pp) or a more significant increase (more than 20 pp). Only a few universities reported moderate increases (between 5 and 20 pp). However, for peer-reviewed articles, a clear majority of universities indicated deposits had increased by more than 20 pp after adopting an open access policy. Deposit rates for doctoral theses also increased by more than 20 pp at most universities.

3.2. Institutional awareness of and financial support for open access

The survey included questions about levels of awareness of different aspects of open access among different groups, namely institutional leadership, librarians, early-stage researchers (e.g. doctoral candidates, post-docs) and researchers (e.g. faculty).

As shown in Figure 12, librarians were seen as having the best knowledge of scientific publishers' open access policies – 86.3% of institutions considered their knowledge as 'good' or 'very good', followed by institutional leadership at 53.9%, and early-stage researchers and researchers at 31% each. It is also worth noting that around 40% of institutions assessed both groups of researchers awareness of publishers' policies as 'neither good nor bad'.

Figure 12. Awareness of scientific publishers' open access policies among different university populations

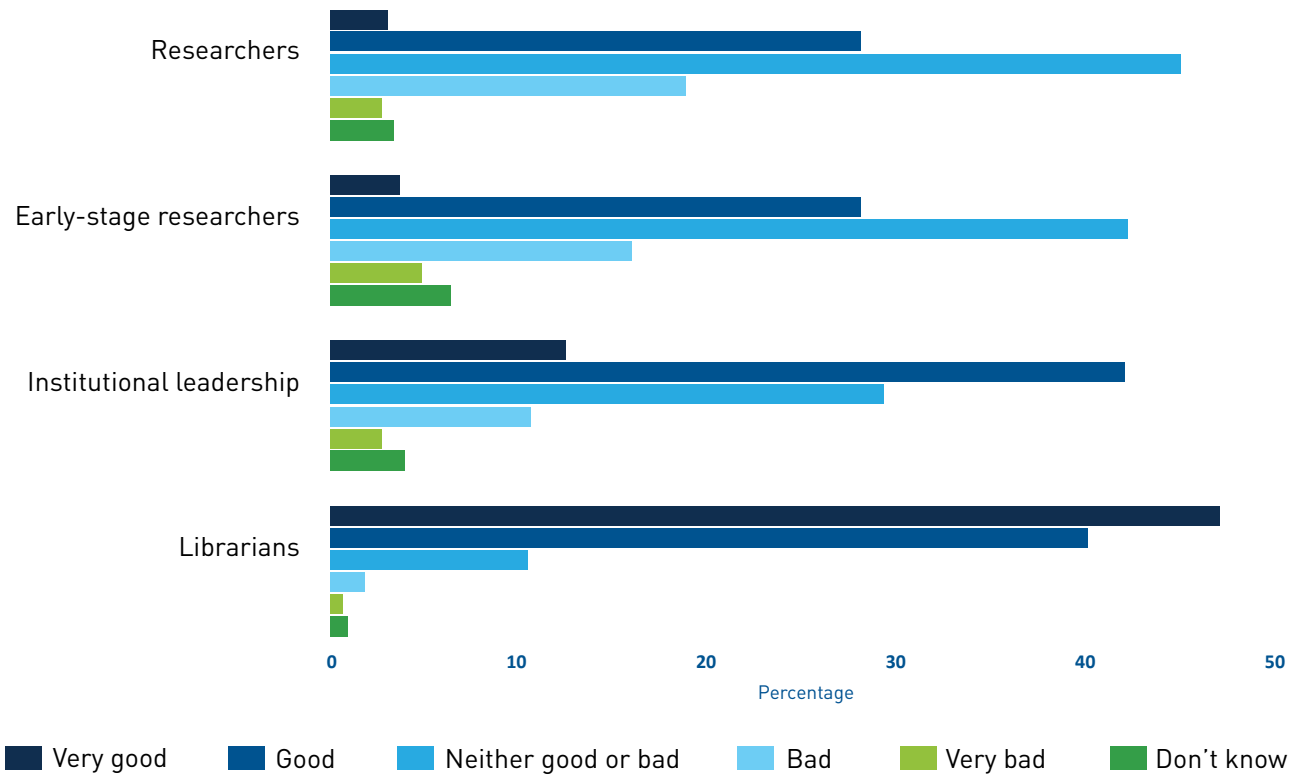

Notes: number of respondents: 335/338, except for institutional leadership and researchers with 334/338. 'Early researchers' means doctoral candidates and post-docs and 'researchers' means faculty and other research professionals.

Librarians and the institutional leadership were again seen to have the best knowledge of the open access rules defined in Horizon 2020 (Figure 13). Librarians were seen to have 'good' or 'very good' knowledge by 66.3% of the respondents and institutional leadership achieved 46.5% in these categories. However, knowledge of the open access rules set out in Horizon 2020 was assessed in a negative way ('very bad' or 'bad') with early-stage researchers scoring 30% and established researchers 22.6% by the institutions surveyed.

Figure 13. Awareness of the open access rules defined in Horizon 2020 - the current EU framework programme for research and innovation

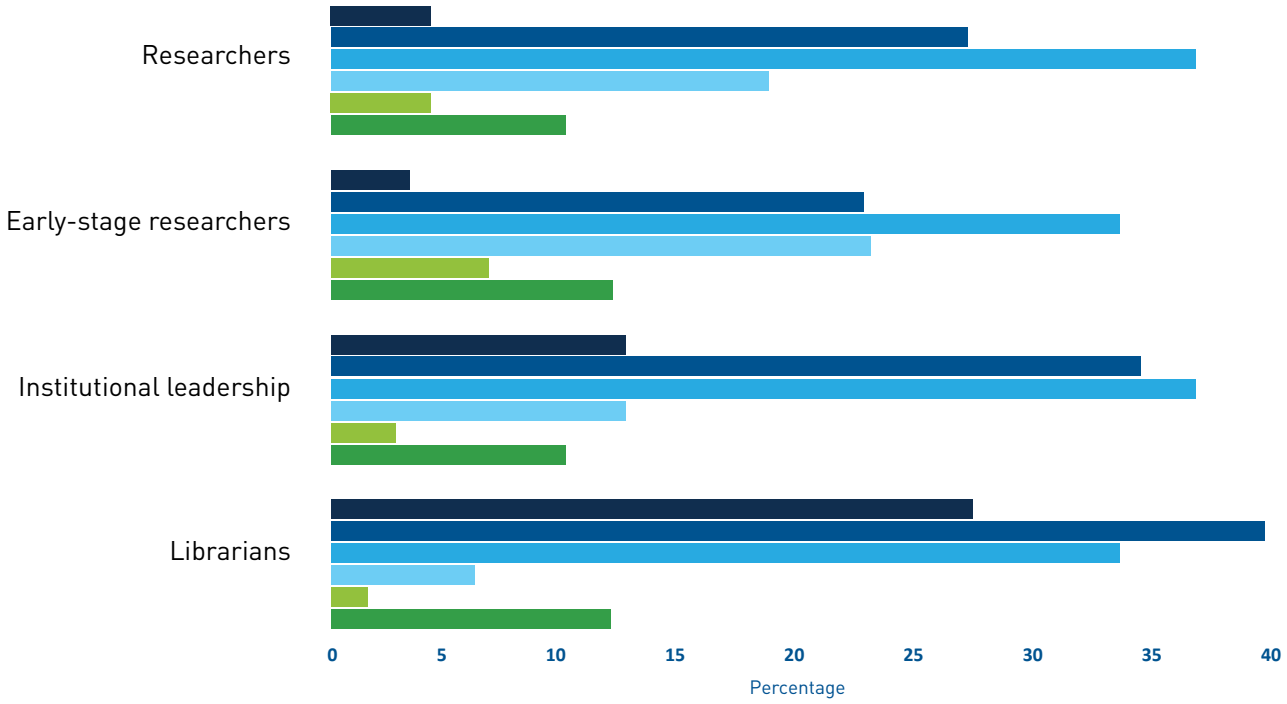

Notes: number of respondents: 331/338, except for librarians with 333/338 and researchers with 332/338. 'Early researchers' means doctoral candidates and post-docs and 'researchers' means faculty and other research professionals.

Comparison with 2015-2016 results:

The results of the 2015-2016 survey are consistent with 2016-2017. In 2015-2016, librarians and institutional leaders were considered most knowledgeable about publishers' open access policies (88.1% of universities considered librarians awareness to be 'good' or 'very good' and institutional leaders scored 54% in these categories) and about the Horizon 2020 open access rules (e.g. 70% of universities indicated librarians awareness 'good' or 'very good').

The 2015-2016 survey did not distinguish between researchers and early-stage researchers; nevertheless, by and large, 'researchers' were considered as being least aware of publishers' open access policies and the Horizon 2020 open access rules.

Overall, most universities considered that open access is important or very important for all professional groups (Figure 14). Open access was considered as being highly strategically important for librarians at almost 86.6% of the institutions surveyed, while the same was true for 60.6% of institutional leadership. Between 35-40% of institutions considered open access strategically important for both groups of researchers.

Figure 14. The strategic importance of open access at the university

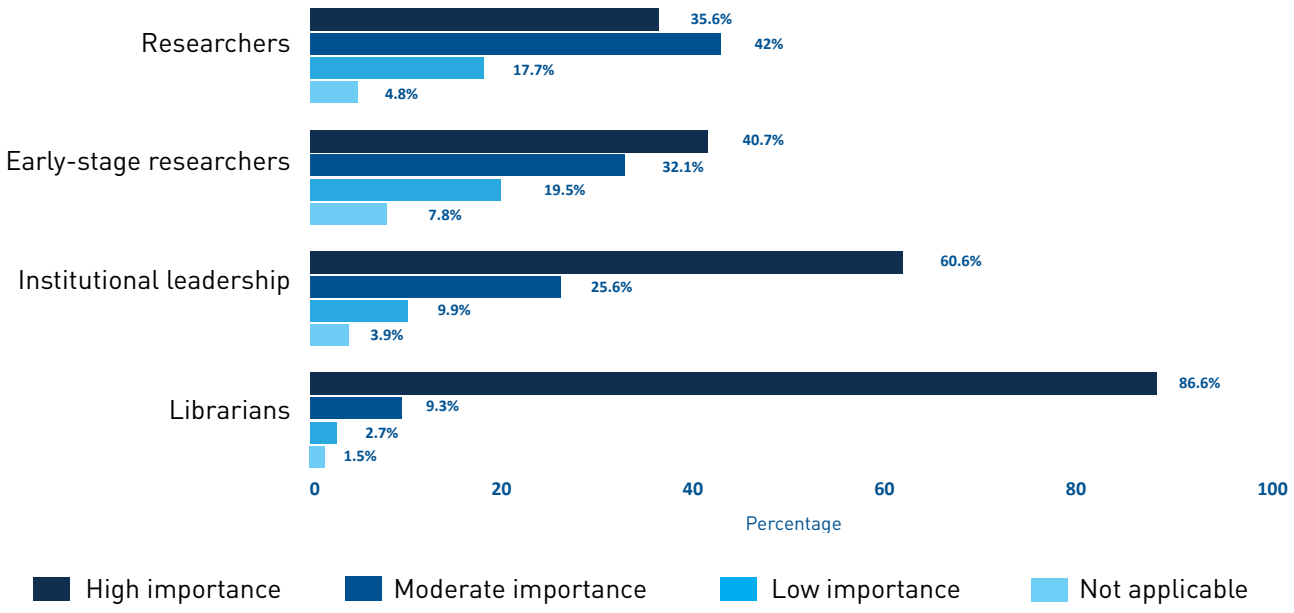

Notes: number of respondents: 334/338, except for institutional leadership with 333/338 and librarians with 335/338. 'Early researchers' means doctoral candidates and post-docs and 'researchers' means faculty and other research professionals.

Financial support to open access to research publications

Over half of the institutions surveyed indicated they could access both European and national funding, in addition to the institution's own budget, to support open access to research publications (Figure 15).

Figure 15. Sources of funding to support open access to research publications

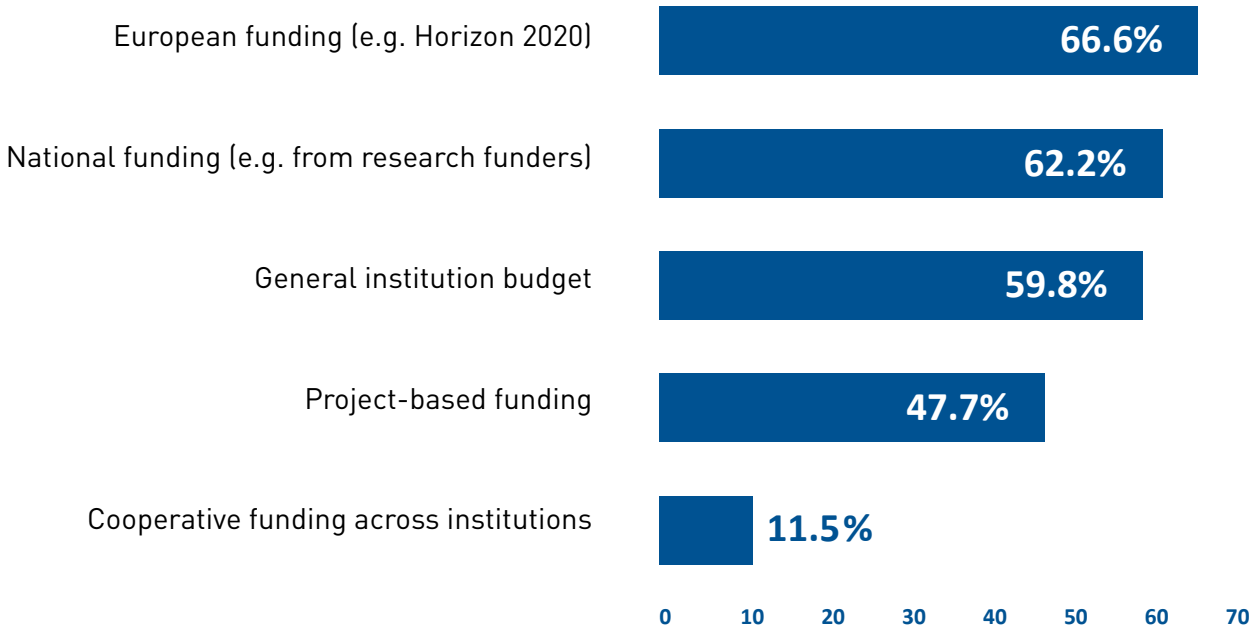

Number of respondents: 323/338. Multiple-choice question.

3.3. National and European actions to promote open access to research publications

Figure 16 shows the proportion of universities that strongly agreed with different national and European actions in the area of open access to research publications. Coordinated engagement and negotiations with scientific publishers to improve contractual conditions and secure greater transparency on costs were seen as the most relevant areas at both national and European levels.

Activities to raise awareness about open access and share good practices on institutional open access policies were generally considered more important at national than at European level.

Figure 16. National and European priorities for open access to research publications

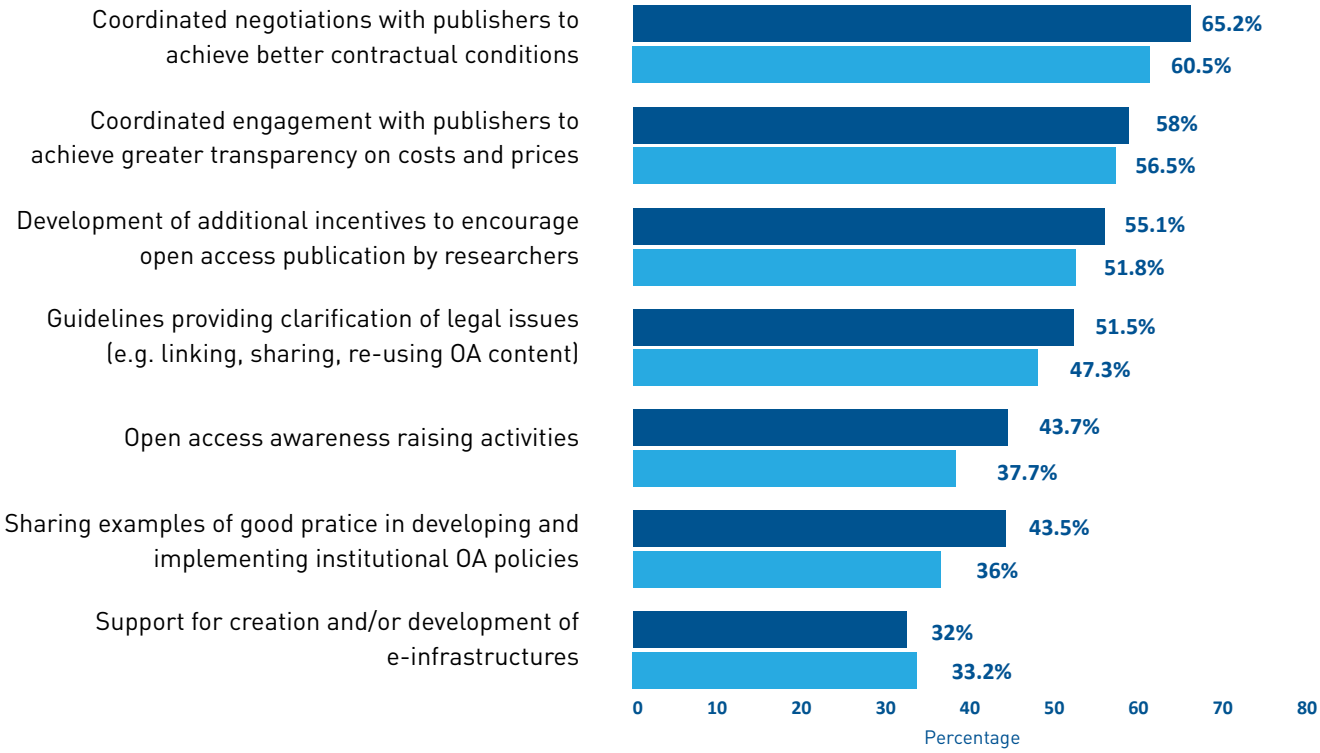

Notes: the chart displays the percentages of 'strongly agree' responses. Number of respondents: between 329 and 334/338.

Comparison with 2015-2016 results:

The 2015-2016 survey included a more limited list of items than the 2016-2017 version. In 2015-2016, the two actions perceived as most important (between 56-58%) at both national and European levels were: the development of more incentives for researchers and the provision of guidelines clarifying legal matters.

4. Research Data Management and Open Access to Research Data

The 2016-2017 survey included a dedicated section on research data management and open access to research data. The 2015-2016 survey had only considered open access to research data. Distinguishing between these concepts in 2016-2017 allowed a more detailed understanding of the different levels of development of research data management and open access to research data at institutions across Europe.

4.1. Institutional guidelines, awareness and organisational structures

Only about 19% of the institutions surveyed had an institutional research data management policy (Figure 17); 19.6% of the institutions indicated that they had informal guidelines in place. Consequently, almost six out of ten universities reported having no RDM guidelines.

Figure 17. Existence of institutional guidelines for research data management

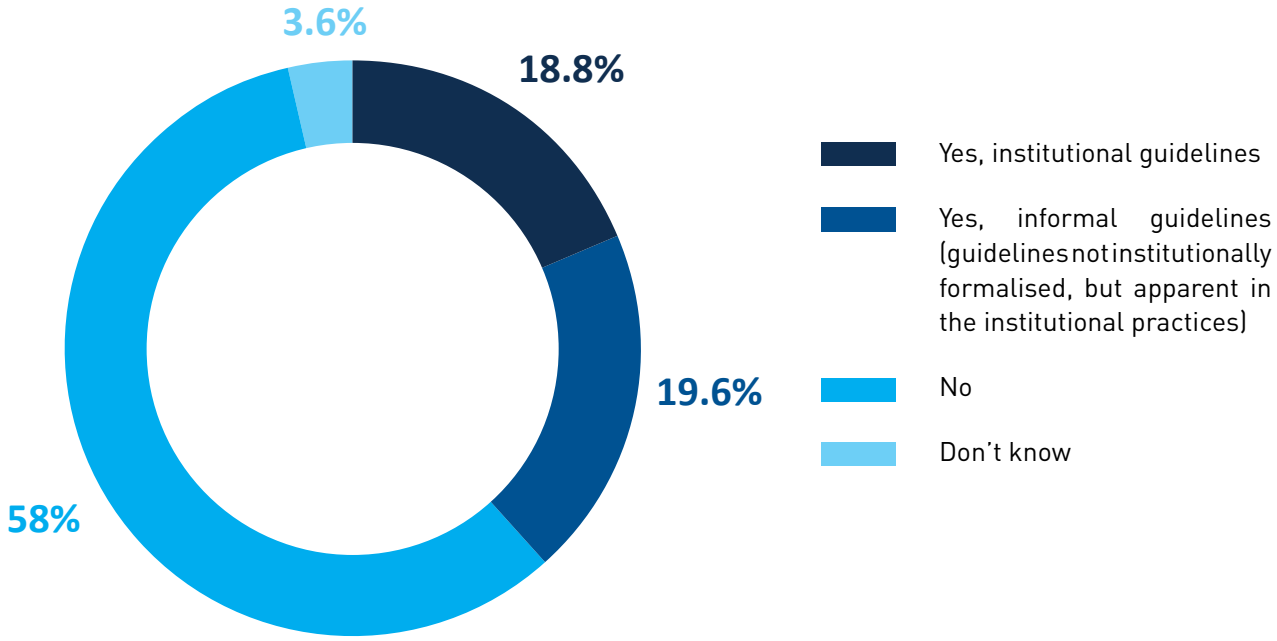

Number of respondents: 336/338.

The vast majority of institutions with research data management guidelines (including informal principles) had developed recommendations. Over half of the institutions also included data storage provisions and information about legal aspects (Figure 18).

Figure 18. Elements covered by institutional guidelines for research data management

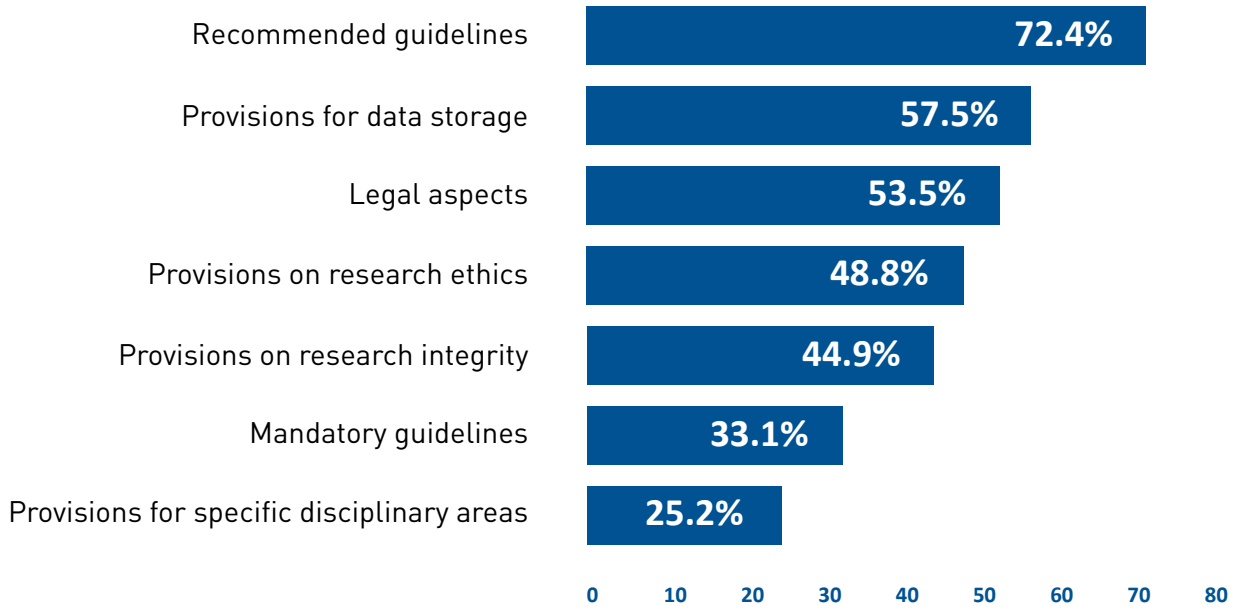

Notes: multiple-choice question. Number of respondents: 127/129. Only the institutions that answered "Yes, institutional guidelines" or "Yes, informal guidelines" in Figure 17 were included in this analysis.

A lower proportion of institutions reported the existence of formal or informal guidelines for open access to research data (27.7%; Figure 19). Almost seven out of ten institutions indicated not having any guidelines for open access to research data in place.

Figure 19. Existence of institutional guidelines for open access to research data

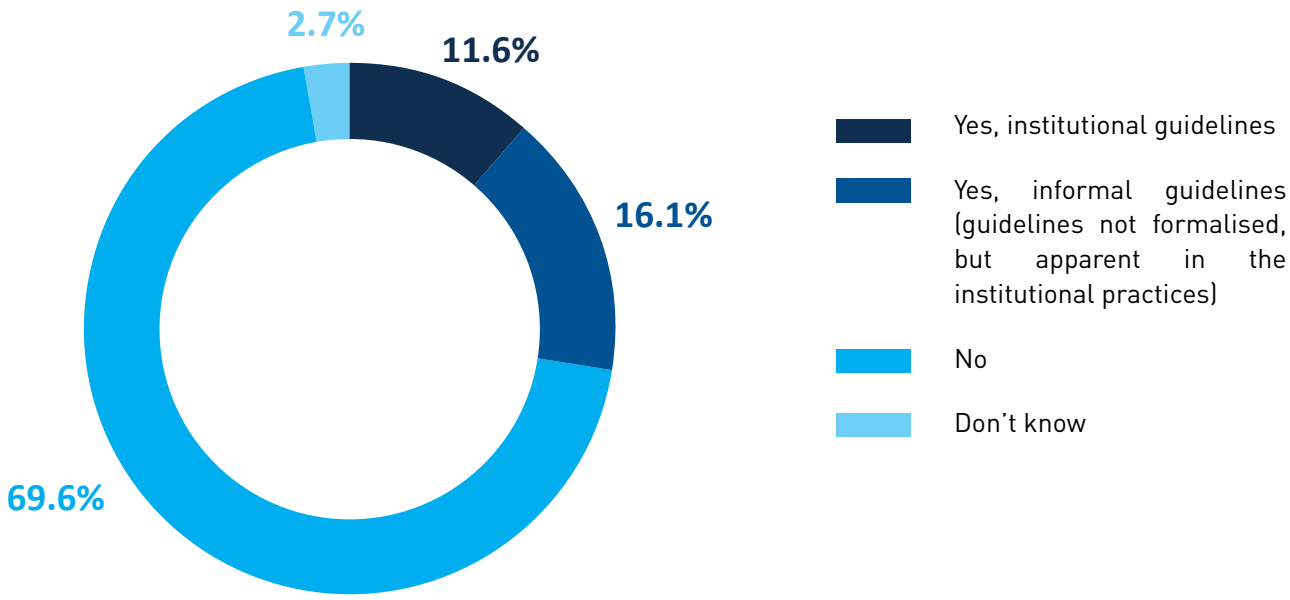

Number of respondents: 336/338.

Like institutional guidelines for research data management, the most common elements of guidelines for open access to research data were: recommendations, provisions for data storage and legal issues (Figure 20). Provisions for specific disciplines and licenses were seldom mentioned.

Figure 20. Elements included in institutional guidelines for open access to research data

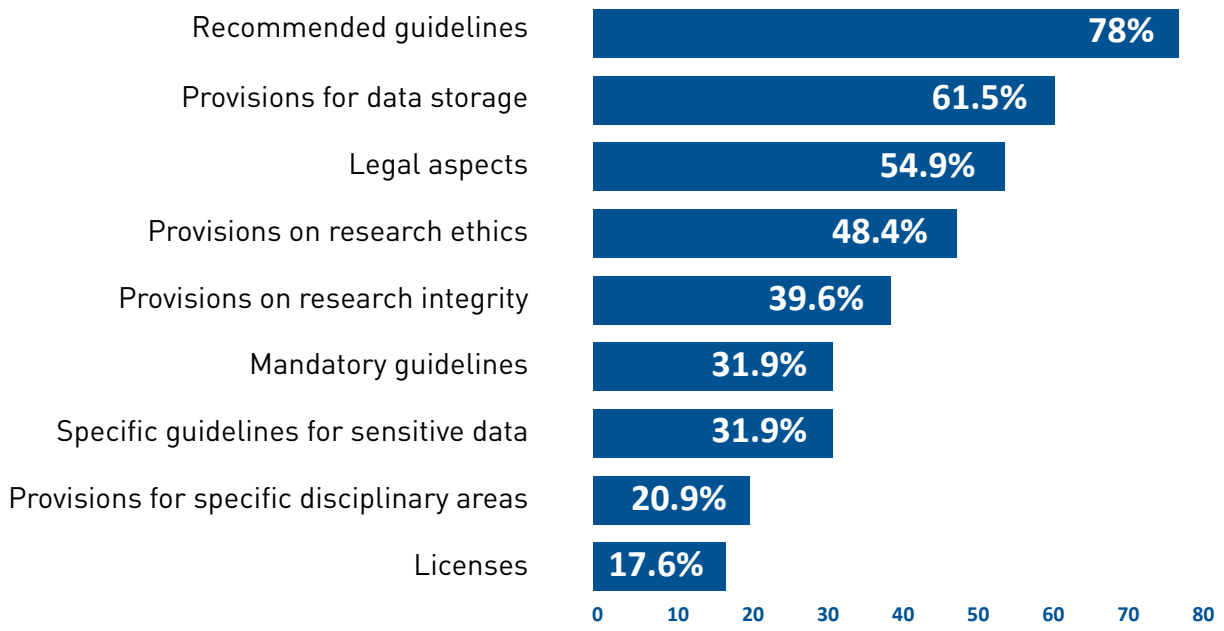

Notes: multiple-choice question. Number of respondents: 91/93. Only the institutions that indicated "Yes, institutional guidelines" or "Yes, informal guidelines" in Figure 19 were included in this analysis.

Comparison with 2015-2016 results:

The 2015-2016 survey only included questions focusing on open access to research data. The total proportion of institutions reporting formal or informal guidelines in 2015-2016 was 24.8%. 72.2% reported having no such guidelines in place. These figures are broadly consistent with those observed in 2016-2017.

Awareness of the Horizon 2020 Open Research Data Pilot

Institutions were also asked about different university populations' awareness of the Horizon 2020 Open Research Data Pilot (Figure 21). These were generally low, particularly among early-stage researchers and researchers. About 19% of institutions considered librarians' awareness as 'very bad' or 'bad'. This figure increased to 28.0% for institutional leadership, 37.2% for researchers and 43.2% for early-stage researchers.

Figure 21. Awareness of the Horizon 2020 Open Research Data Pilot

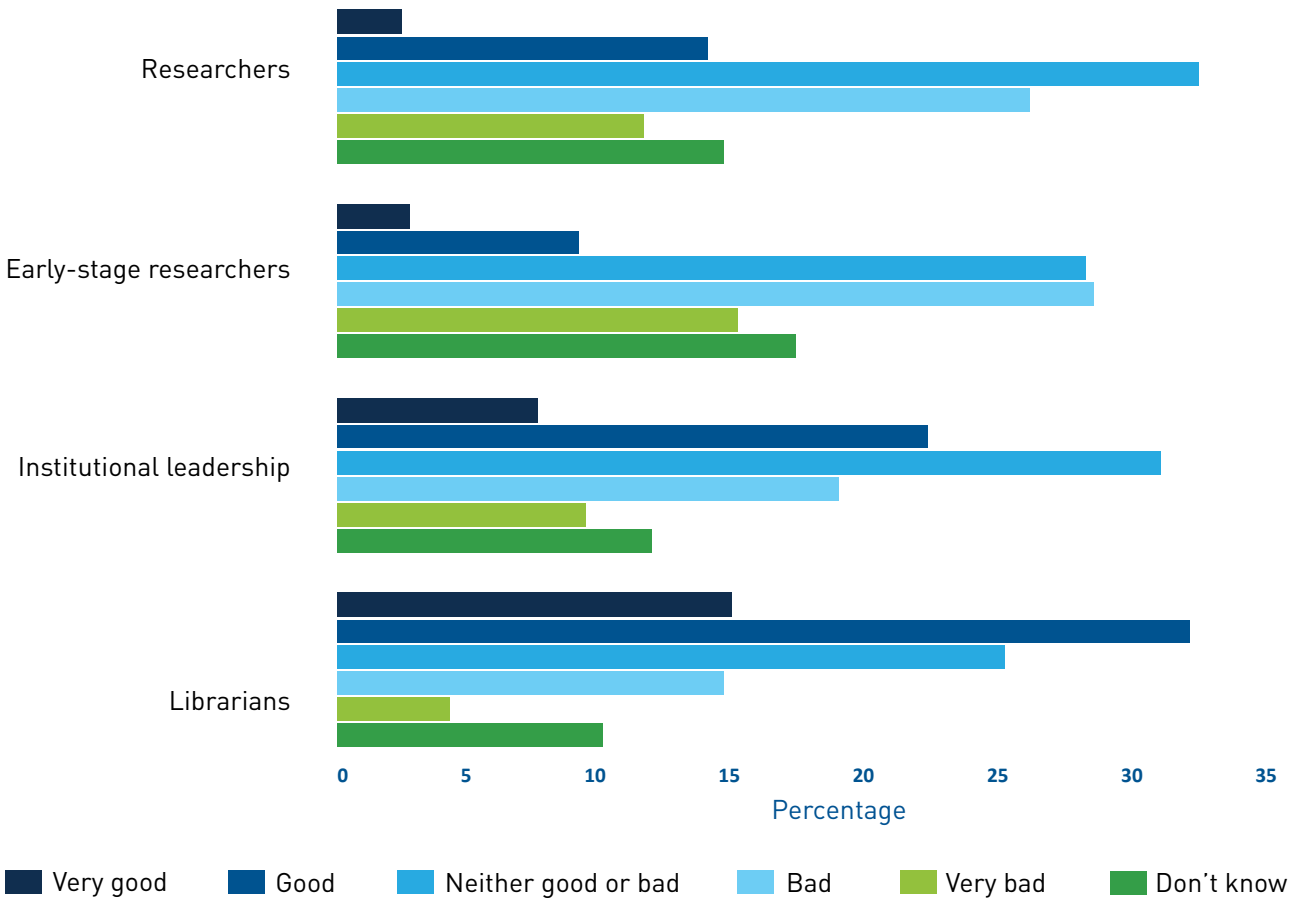

Notes: number of respondents: 333/338, except for institutional leadership with 332/338. 'Early researchers' means doctoral candidates and post-docs and 'researchers' means faculty and other research professionals.

Comparison with 2015-2016 results:

The results of the 2015-2016 survey are consistent with those in 2016-2017. In 2015-2016, librarians and institutional leaders were considered to have most knowledge about the Horizon 2020 Open Research Data Pilot (49.7% of universities considered librarians' awareness 'good' or 'very good'. For institutional leaders, this figure was about 35%). As a group, researchers were considered least aware of the Horizon 2020 Open Research Data Pilot.

Reasons for a lack of guidelines for research data management and/or open access to research data

Universities with no policies or guidelines for research data management and/or open access to research data indicated that this was most often due to the absence of national guidelines and a general lack of awareness of the importance of these areas (Figure 22). Lack of infrastructure and expertise, the absence of dedicated funding or research funding requirements, and the technical complexity of research data management and open access to research data, all make a relevant contribution to the absence of institutional policies. Interestingly, about a quarter of institutions also mention negative open access stereotypes.

Figure 22. Reasons for the absence of institutional guidelines for research data management and/or open access to research data

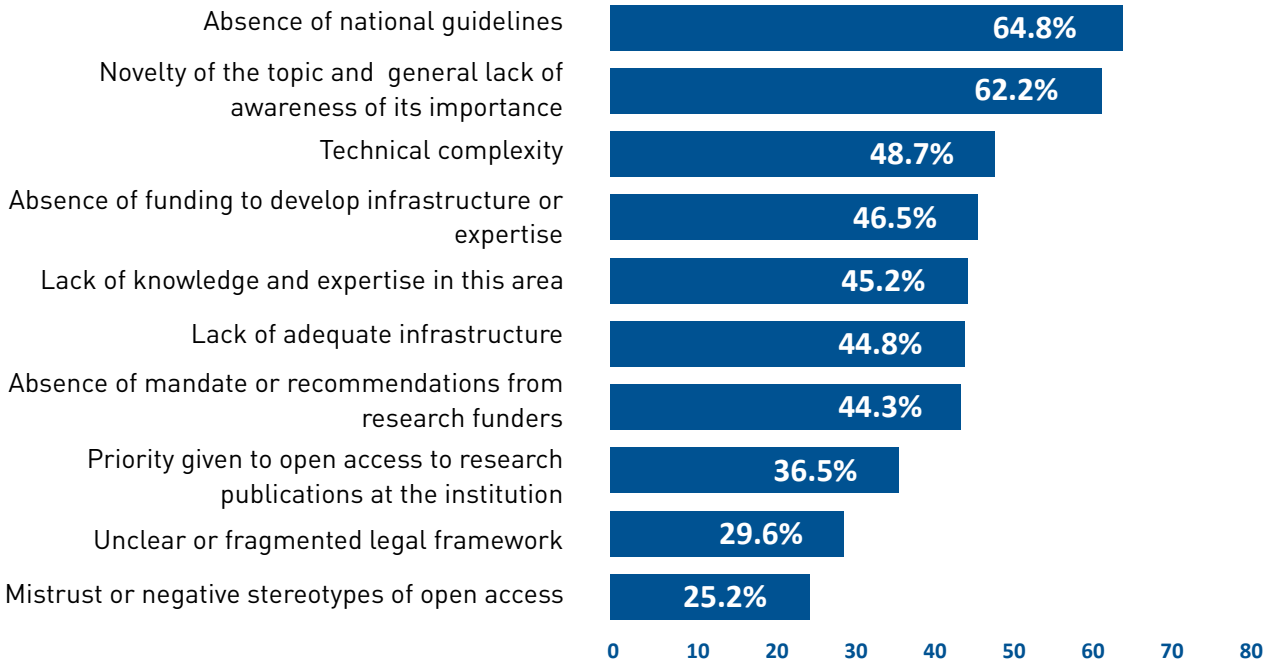

Notes: multiple-choice question. Number of respondents: 230/244. Only those institutions that answered 'No' in Figure 17 or 19 were included in this analysis.

Organisational structures

Universities were also asked about the existence of open research data working groups or committees. As shown in Figure 23, less than one quarter of the institutions surveyed reported the existence of such structures.

Figure 23. Establishment of a permanent open research data working group or committee

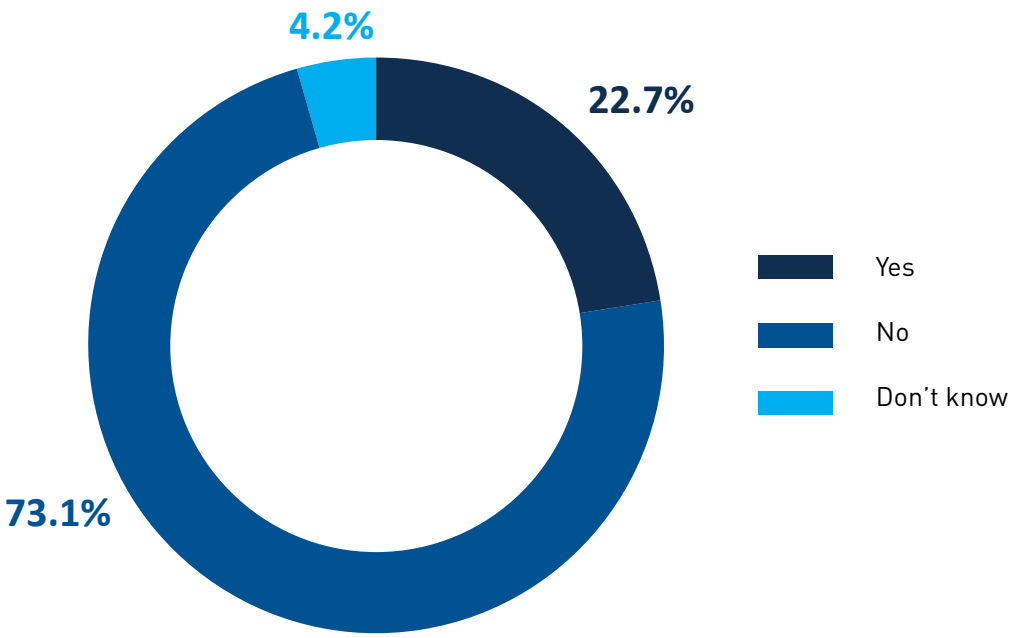

Number of respondents: 331/338.

Universities also reported the composition of the governance structure responsible for research data management and/or open access to research data at institutional level (Figure 24). The library handled these topics at over seven out of ten institutions. High-level institutional management, research administration bodies and the ICT department were also involved at over 40% of the institutions. The legal department and data protection office were less often involved.

Figure 24. Governance structure responsible for research data management and/or open access to research data at institutional level

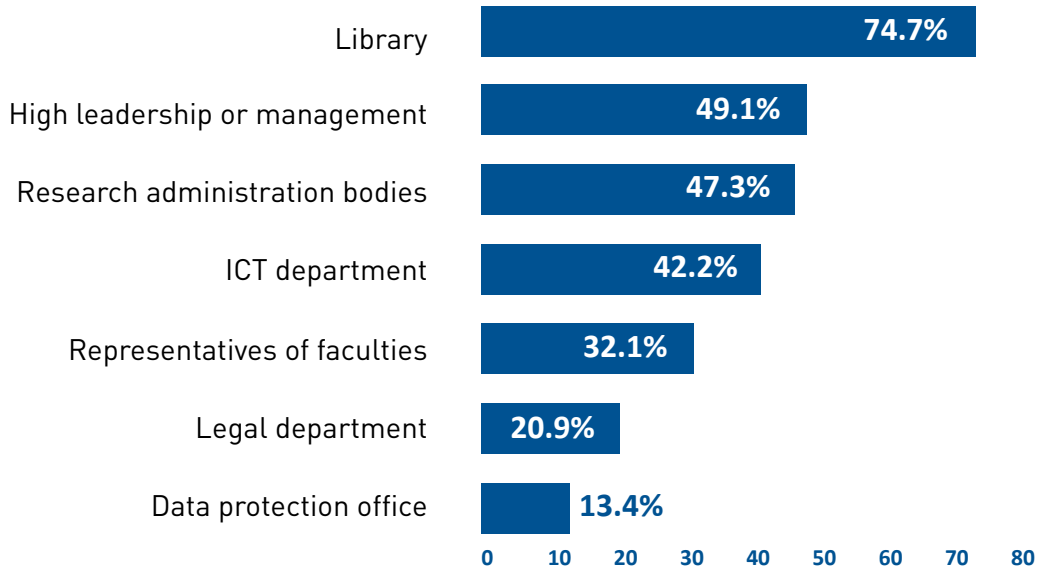

Notes: multiple-choice question. Number of respondents: 277/338.

4.2. Research data management and open access to research data infrastructure and resources

Slightly over a third of the institutions stated that they used either internal or internal and external repositories for research data management and/or open access to research data (Figure 25). A quarter of universities reported using an external, trusted repository (e.g. identified through re3data.org).

Figure 25. Infrastructure used for research data management and/or open access to research data

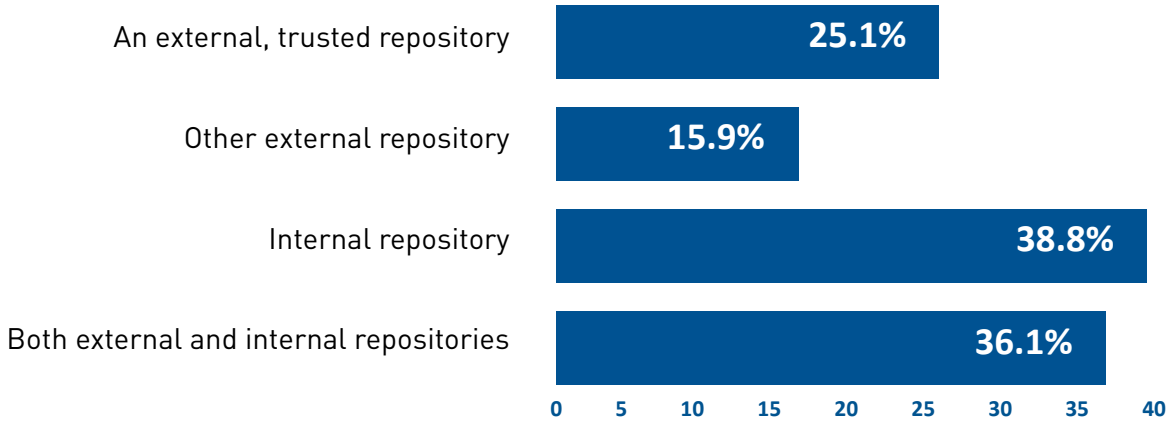

Number of respondents: 263/338.

Institutions were asked to indicate the type of resources they needed to streamline research data management activities, including data creation, data storage and data curation. The resources identified can be grouped into the following three broad categories:

A. Human resources

- Need for skilled, specialist support staff (e.g. data stewards, ICT personnel, administrative support, archive staff, library staff).
- Need to train existing staff.
- Need to increase staff numbers.

B. Technical resources

- Data repositories.
- Appropriate e-infrastructure.
- Appropriate software (e.g. open source software, in-house solutions).

C. Transversal needs

- Sustainable funding for human resources and technical e-infrastructure.
- Awareness raising activities/research data management advocacy for different. institutional groups: university leadership, faculty management and researchers.
- Awareness raising activities about the importance of research data management and how it can be applied in different scientific fields (taking into account their specificities).
- Clear university research data management policies and guidelines, including legal considerations. University policies and guidelines should also include provisions for different scientific fields.
- Guidance for drafting data management plans.
- Institutional strategy on data storage that considers eventual changes to support and accommodate growth.
- Research data management coordination at institutional level.

Research data management and open access to research data skills

Universities identified several skills and other requirements needed to implement research data management and open access to research data at institutional level:

- Legal skills, including knowledge of copyright, licensing, data privacy, data protection.
- Technical skills: data experts or library staff with specific training on:
    - Metadata
    - Data storage, management, data curation, data preservation
    - Technical standards
    - Data sharing
    - Data archiving.

- Technical skills: IT experts with the skills to develop e-infrastructure.
- Increase researchers' skills in areas such as: data visualisation, data mining, and data quality.
- Professionals with a knowledge of national and European research data management/ open access policies and data standards.
- Professionals who can advise researchers on the technical, organisational and operational aspects of research data management.
- Mechanisms for coordination between researchers, librarians and other technical staff.
- Mechanisms for research data management/open access coordination across the institution.

Examples:

"Training, both administrative staff and researchers in data management, curation and quality, support for archiving research data, tools for metadata creation and management, efforts to drive cultural change, etc." (A Finnish Institution)

"Training or recruiting more technical, library and legal staff to extend and improve the support service. Soft skills training and eLearning programs to help research teams understand new requirements. DMPonline tools more specifically designed to meet H2020 requirements." (An Italian Institution)

"The most critical and underdeveloped issues are user-friendly data environments during the research stage, funding research data management costs per project/ discipline (is there actually a viable business case for FAIR-based research data management in each discipline and how to deal with this), and related to this, what is the general applicability, viability (costs) and consequences of the rather complex FAIR Research Data Management principles (what does interoperable actually mean in real life at what costs), avoiding mistakes with Open Access publishing (e.g., is CC-BY license actually a good idea for data, shades of access is what most researchers find (more) acceptable (...) Researchers often don't know what is expected of them. A typical researcher comment is, "Do they now also expect us to become data scientists, I don't have the time or money for that even if I wanted to." Representatives/contact persons working for funders are often unable to provide clear answers about what is reasonably expected (especially in relation to what is or not eligible for funding), which leads to further confusion. Access and licensing alternatives that balance the interests of all parties involved), researcher awareness (the open science message/propaganda does not work for all researchers, broaden the discourse), and when and why should data stewards enter the research data management process (again at what cost)." (A Dutch Institution)

Virtually all of the institutions surveyed indicated a greater or lesser possession of the skills identified above. For example, the vast majority of institutions have legal and technical (both IT and library-related) skills available, distributed among their library, legal, research and IT services. What is needed is more specialist training for current staff, as well as more time for staff to work on research data management and open access to data. Several institutions indicated they would need more funding to be able to recruit more staff to work on these areas. Institutions also indicated they would need more professionals with knowledge and skills covering the different areas relevant to research data management and open access to data (e.g. IT skills, legal knowledge, data management skills).

Institutions were also asked about the support that researchers, including doctoral candidates, who are interested in open access to research data, receive. The open-ended answers provided were classified into different categories, which are presented below. The proportion of universities that indicated a response in each category is also provided. It is important to note that about 26% of institutions do not currently provide support to researchers interested in open access to research data, but they are planning to do so in the near future.

A. **Support services provided by library or other specialised staff, typically on a one-to-one basis**. Such support typically focuses on legal issues, technical help (e.g. archiving, managing data, open access to data, advice on data repositories, information about policies relevant to research data management and/or open access to data) (20.8%).

B. A **dedicated office or service** supporting researchers is available at some institutions. Examples include an open access office, helpdesk, research data management support desk, university data centre. Support typically focuses on technical issues, legal matters and information about relevant policies (9.9%).

C. **Training for researchers and support staff** (e.g. research data management workshops, H2020) provided on a regular basis or ad hoc on demand (22.6%).

D. **Training for graduate students**, including doctoral candidates: some institutions provide courses, workshops or specialist training about open science, research data management, legal and ethical matters (22.6%). A few institutions provide doctoral candidates with individual support to create data management plans.

E. **Information events** focusing on research data management and/or open access to research data (6.7%).

F. **Institutional website** with information about research data management and open access to research data, blogs, newsletters (13%).

G. **Specific financial support for researchers**, including doctoral candidates, to attend events on open access to research data and/or for open access publications (1.8%).

Examples:

"Support for writing grant applications, support for creating a data management plan, legal advice (IPR), advice on where to deposit data. Awareness raised via websites, seminars." (A Dutch Institution)

"The university encourages open access publication by researchers to increase author and institutional visibility and to extend free access to research outcomes. The doctoral school has a course." (A Romanian Institution)

"The Research Data Management Group provides guidance and advice. Researchers have access to the recently established skills development program, which also covers topics relating to open access to data. In 2017, research support staff will also receive training that will help them provide local support to researchers interested in sharing their data openly. In terms of promotion, the Research Data Management Group achieve this through training and by organising events, attending departmental meetings and also by engaging in institutional discussions around the topic." (A Norwegian Institution)

4.3. Barriers to research data management and open access to research data

Institutions identified a wide range of institutional level barriers to research data management and open access to research data (Figure 26). Different scientific cultures and the absence of national guidelines were identified as major barriers by over six out of ten institutions. A combination of scarce institutional resources, inherent technical complexity and low awareness of the benefits of research data management and open access to research data were the factors most identified as institutional barriers.

Figure 26. Institutional barriers to promoting research data management and/or open access to research data

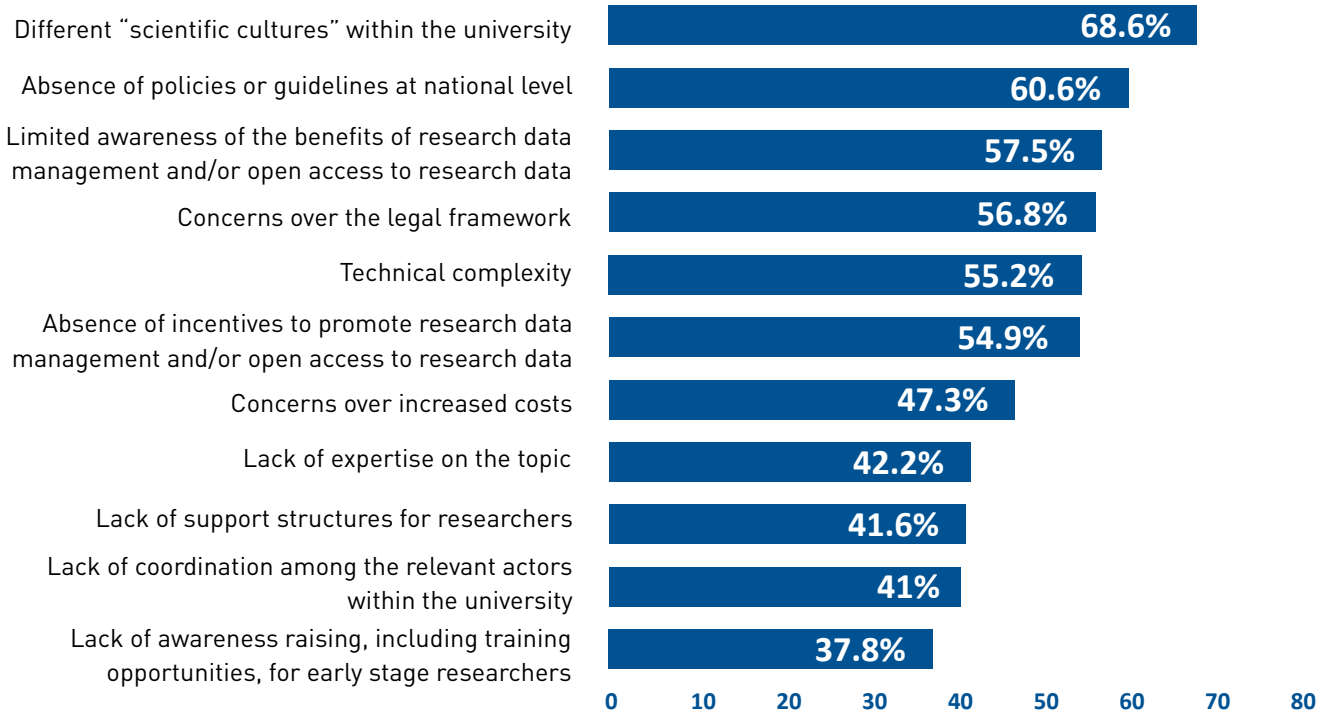

Notes: multiple-choice question. Number of respondents: 315/338.

4.4. National and European actions to promote research data management and open access to research data

Most universities considered that it was important to carry out most courses of action at both national and European levels (Figure 27). Almost 70% of the institutions saw the creation of policies and guidelines as most relevant to supporting universities make the transition to research data management and open access to research data. The exchange of best practices, research data quality assurance, raising awareness in these areas and developing clear technical standards were also considered very important measures to promote the take-up of research data management and open access to research data. Activities to raise awareness and train early-stage researchers in open access to research data seemed particularly important at national level (43.0% of the institutions).

Figure 27. Importance of different actions to help institutions make the transition to research data management and open access to research data

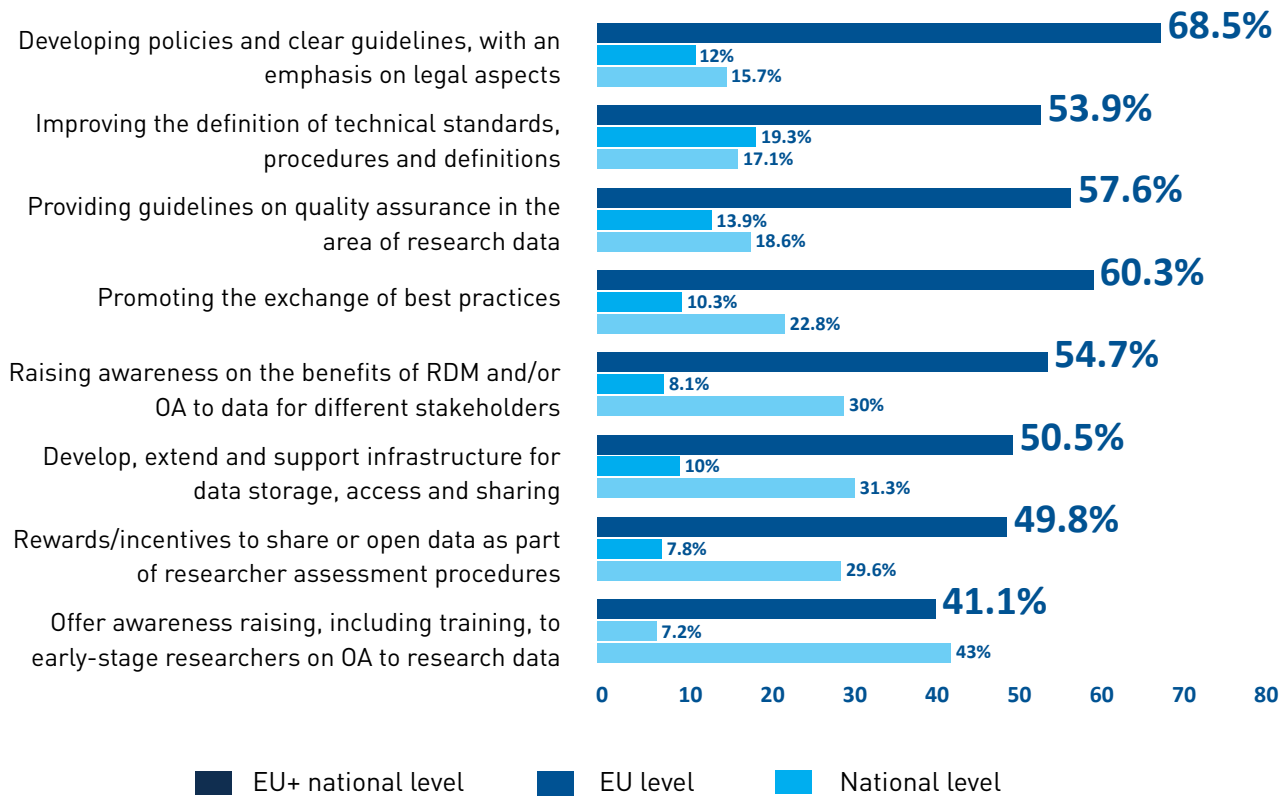

Number of respondents: between 319-324/338.

5. Conclusions

The results of the 2016-2017 EUA Open Access Survey show that a growing number of European universities are making progress in the transition towards open access to research publications. The survey outcomes also indicate that while some research data management and open access to research data initiatives are being undertaken, progress is at a less mature stage.

MAIN OUTCOMES REGARDING OPEN ACCESS TO RESEARCH PUBLICATIONS

- More than nine out of ten universities indicated the existence or planned implementation of an institutional open access policy.
- Most policies involve recommendations that researchers self-archive publications and include provisions to raise awareness and provide training in open access. Policies that link open access to research assessment are seldom reported.
- While three out of four universities indicated having an institutional repository, many still lack the technical or procedural means to ascertain the deposit rate for different publication types (e.g. peer-reviewed journal articles, conference proceedings).
- Universities, particularly institutional leadership (61%) and librarians (87%), saw open access as an important strategic area. For researchers and early-stage researchers, this figure dropped to 35%-40%.
- Universities called for European and national initiatives focusing on negotiations with scientific publishers to achieve better contractual conditions and greater transparency regarding costs.

These results are largely in line with those reported in the 2015-2016 EUA Open Access Survey. It is interesting to note the consistency in the result patterns across the various survey waves, this despite the growing number of institutions participating. In fact, 400[5] different institutions completed the 2015-2016 and 2016-2017 EUA Open Access surveys combined – about half of the association's members. This shows the increasing importance European universities ascribe to the area of open access.

5 Participation in both the 2015-2016 and 2016-2017 surveys = 107 institutions, participation in the 2015-2016 survey alone = 62 institutions, participation in the 2016-2017 survey alone = 231 institutions.

MAIN OUTCOMES REGARDING RESEARCH DATA MANAGEMENT AND OPEN ACCESS TO RESEARCH DATA

- Six out of ten institutions had no research data management guidelines in place.
- Seven out of ten institutions had no open access to research data guidelines in place.
- Institutions that lacked research data management and open access to research data guidelines, indicated that this was mainly due to the absence of national guidelines and the novelty of the topic. ¬
- Universities underlined the need for specific human and technical resources (skilled and specialist staff), data repositories, appropriate e-infrastructure and software to streamline research data management.
- To improve open access to research data, universities indicated the need for clear university policies, including provisions for different scientific fields, and for sustainable funding outlooks to develop human resources and technical infrastructure.
- Universities observed that the specific skills needed for research data management and open access to research data must span diverse areas, including legal, data and technical aspects. Institutional coordination is also critical, as relevant skills are typically scattered across different units, departments and staff members.
- Universities called for policies on research data management and open access to research data at national and European levels, with an emphasis on quality assurance and legal matters. Best practice exchange was also considered critical at both national and European levels.

Policy implications

The results of this survey contain relevant information for shaping European and national developments in open access and open science. Achieving full open access to research publications by 2020 will require greater engagement by all of the relevant stakeholders.

The results of the EUA Open Access Survey show that only about 12% of those institutions developing or with an existing policy on open access to research publications have mandatory policies linked to internal performance evaluation or external review procedures. More than seven out of ten institutions indicated that a research funding requirement is needed to increase self-archiving. **Mandatory policies at both research funding bodies and universities could accelerate the transition to open access research publications**.

A large proportion of institutions with a policy on open access to research publications do not have mechanisms to collect and analyse data about the number of publications in the institution's repository or published in open access journals. There is therefore a **need for monitoring mechanisms that allow institutions to assess their progress**.

Greater researcher engagement is also critical. The results of both the 2015-2016 and 2016-2017 EUA Open Access Surveys clearly indicate that librarians and institutional leaders are most knowledgeable about open access. Researchers and early-stage researchers are, however, considered as having the lowest awareness of publishers' open access policies, Horizon 2020 open access rules and the Horizon 2020 Open Data Research Pilot. This situation certainly needs to change if open access to both research publications and research data is to become a reality in the next few years. These results are also relevant to the EU Open Science policy debate, i.e., the European Open Science Cloud. **Raising researcher awareness of open access and open research data is a crucial prerequisite for making data available in an open and FAIR way as envisioned for the European Open Science Cloud**.[6]

The EUA Open Access Survey identified frequent barriers to research data management and open access to research data. These included a combination of limited financial resources, technical complexities, diverse disciplinary cultures and an absence of policies and sufficient guidelines at national and European level. These **economic, technical, scientific and cultural challenges need to be addressed, and ultimately solved for the European Open Science Cloud to succeed**.

Another critical factor in making open access a reality is the need for both universities and research funders to include open science practices as part of researchers' performance evaluation and as a criteria for funding research proposals. Changes to research assessment practices that depart from over-reliance on the journal impact-factor and move towards multi-dimensional assessment criteria are crucial to providing incentives for researchers to engage in open science practices (e.g. open access to research outcomes). Criticism about using journals' impact factor as the main criterion to assess researchers and a call for more complex assessment approaches is gaining traction. Examples include the San Francisco Declaration on Research Assessment (DORA declaration), which dates back to 2012 and is now signed by more than 11,000 individuals and 500 organisations, including EUA. The European Commission is also working on this area and has recently published a report outlining a set of recommendations for European and national authorities on how to embed open science practices in research career assessments (Evaluation of Research Careers fully acknowledging Open Science Practices. Rewards, incentives and/or recognition for researchers practicing Open Science). **Universities and research funders must change their assessment practices, moving away from the impact factor, and providing incentives for researchers to engage in open science practices**.

6 High Level Expert Group on the European Open Science Cloud, Brussels: DG RTD 2016, available online at https://ec.europa.eu/research/openscience/pdf/realising_the_european_open_science_cloud_2016.pdf; Mark D. Wilkinson et al., The FAIR Guiding Principles for scientific data management and stewardship, in: Scientific Data 3 (2016), DOI: 10.1038/sdata.2016.18, available online at https://www.nature.com/articles/sdata201618.pdf.

The results of this survey have informed recent EUA initiatives in Open Science, namely the EUA Statement on Open Science to EU Institutions and National Governments, the recommendations for university leaders and National Rectors' Conferences on open access to research publications and on Research Data Management and Text and Data Mining. In these documents, EUA has called on all relevant stakeholders to develop the necessary framework conditions to enable the rapid transition towards open access to research publications and to accelerate the progress of European universities in developing policies, structures and skills in the areas of research data management, open access to research data and text and data mining.

EUA will continue to develop initiatives to assess progress in the transition towards open access, namely through new waves of the EUA Open Access Survey. EUA will also continue to support its members take up new open science challenges, including those related to legislative developments (e.g. copyright), citizen science, research assessment, and skills and rewards for open science.

The European University Association (EUA) is the representative organisation of universities and national rectors' conferences in 47 European countries. EUA plays a crucial role in the Bologna Process and in influencing EU policies on higher education, research and innovation. Thanks to its interaction with a range of other European and international organisations EUA ensures that the independent voice of European universities is heard wherever decisions are being taken that will impact their activities.

The Association provides a unique expertise in higher education and research as well as a forum for exchange of ideas and good practice among universities. The results of EUA's work are made available to members and stakeholders through conferences, seminars, website and publications.

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144/2020 - 2 October 2020

Flash estimate - September 2020

Euro area annual inflation down to -0.3%

Euro area annual inflation is expected to be -0.3% in September 2020, down from -0.2% in August according to a flash estimate from **Eurostat, the statistical office of the European Union**.

Looking at the main components of euro area inflation, food, alcohol & tobacco is expected to have the highest annual rate in September (1.8%, compared with 1.7% in August), followed by services (0.5%, compared with 0.7% in August), non-energy industrial goods (-0.3%, compared with -0.1% in August) and energy (-8.2%, compared with -7.8% in August).

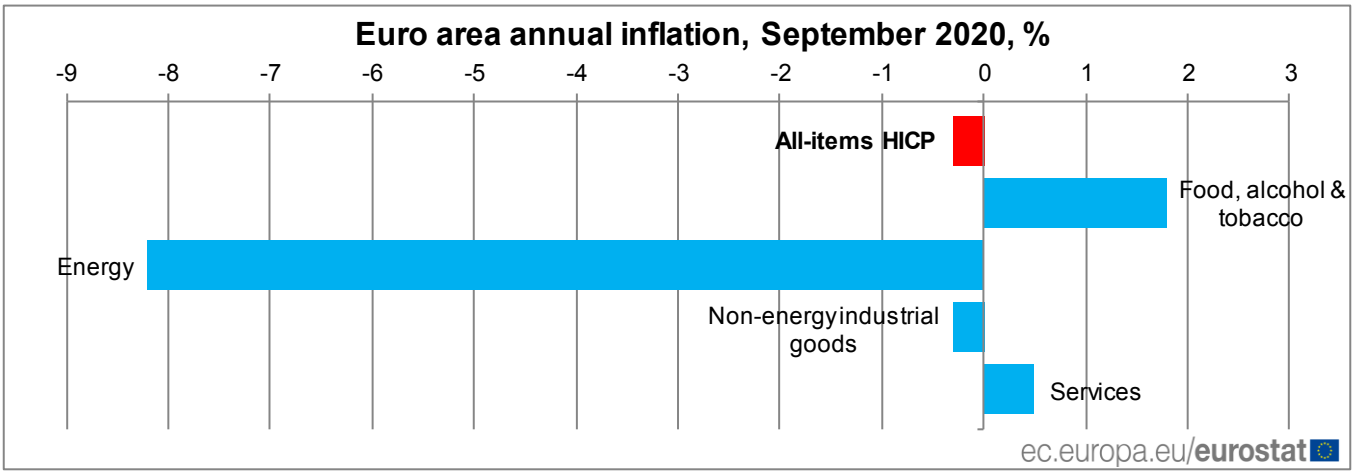

Euro area annual inflation and its components, %

	Weights (‰)	Annual rate							Monthly rate
	2020	Sep 19	Apr 20	May 20	Jun 20	Jul 20	Aug 20	Sep 20	Sep 20
All-items HICP	1000.0	0.8	0.3	0.1	0.3	0.4	-0.2	**-0.3e**	0.1e
All-items excluding: > energy	901.5	1.1	1.4	1.4	1.3	1.4	0.7	**0.6e**	0.2e
> energy, unprocessed food	857.1	1.2	1.1	1.2	1.1	1.3	0.6	**0.4e**	0.1e
> energy, food, alcohol & tobacco	710.8	1.0	0.9	0.9	0.8	1.2	0.4	**0.2e**	0.2e
Food, alcohol & tobacco	190.7	1.6	3.6	3.4	3.2	2.0	1.7	**1.8e**	-0.1e
> processed food, alcohol & tobacco	146.3	1.8	2.3	2.4	2.3	1.6	1.5	**1.4e**	-0.3e
> unprocessed food	44.5	0.7	7.6	6.7	6.0	3.1	2.3	**3.1e**	0.5e
Energy	98.5	-1.8	-9.7	-11.9	-9.3	-8.4	-7.8	**-8.2e**	-0.4e
Non-energy industrial goods	262.1	0.2	0.3	0.2	0.2	1.6	-0.1	**-0.3e**	2.8e
Services	448.7	1.5	1.2	1.3	1.2	0.9	0.7	**0.5e**	-1.2e

e estimate

Inflation rates (%) measured by the HICP

	Annual rate							Monthly rate
	Sep 19	Apr 20	May 20	Jun 20	Jul 20	Aug 20	Sep 20	Sep 20
Belgium	0.6	0.0	-0.2	0.2	1.7	-0.9	**0.5e**	0.8e
Germany	0.9	0.8	0.5	0.8	0.0	-0.1	**-0.4e**	-0.4e
Estonia	2.2	-0.9	-1.8	-1.6	-1.3	-1.3	**-1.3e**	-0.2e
Ireland	0.6	-0.3	-0.8	-0.6	-0.6	-1.1	**-1.1e**	-0.3e
Greece	0.2	-0.9	-0.7	-1.9	-2.1	-2.3	**-2.3e**	1.4e
Spain	0.2	-0.7	-0.9	-0.3	-0.7	-0.6	**-0.6e**	0.4e
France	1.1	0.4	0.4	0.2	0.9	0.2	**0.0e**	-0.6e
Italy	0.2	0.1	-0.3	-0.4	0.8	-0.5	**-0.9e**	1.0e
Cyprus	-0.5	-1.2	-1.4	-2.2	-2.0	-2.9	**-1.9e**	-0.8e
Latvia	2.3	-0.1	-0.9	-1.1	0.1	-0.5	**-0.4e**	-0.1e
Lithuania	2.0	0.9	0.2	0.9	0.9	1.2	**0.6e**	0.3e
Luxembourg	1.1	-0.8	-1.6	-0.4	0.1	-0.2	**-0.3e**	-0.2e
Malta	1.6	1.1	0.9	1.0	0.7	0.7	**0.5e**	-1.3e
Netherlands	2.7	1.0	1.1	1.7	1.6	0.3	**1.0e**	-0.4e
Austria	1.2	1.5	0.6	1.1	1.8	1.4	**:**	:
Portugal	-0.3	-0.1	-0.6	0.2	-0.1	-0.2	**-0.7e**	0.8e
Slovenia	1.7	-1.3	-1.4	-0.8	-0.3	-0.7	**-0.7e**	-0.2e
Slovakia	3.0	2.1	2.1	1.8	1.8	1.4	**1.5e**	0.1e
Finland	1.0	-0.3	-0.1	0.1	0.7	0.3	**0.5e**	0.2e

e estimate : not available Source dataset: prc_hicp_manr

Geographical information

The **euro area** consists of Belgium, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Austria, Portugal, Slovenia, Slovakia and Finland.

The euro area data refer to the country composition at a specific point in time. Changes in the composition of the euro area are incorporated using a chain index formula.

Methods and definitions

Annual inflation is the change of the price level between the current month and the same month of the previous year. **Monthly inflation** is the change of the price level between the current month and the previous month.

Data collection for HICP has been affected by the COVID-19 crisis in all euro area countries. Eurostat and the Member States' national statistical institutes have agreed a set of procedures to estimate prices that could not be collected due to mobility restrictions or closures of outlets. All information about these procedures is available on the Eurostat website section on inflation.

Revisions and timetable

The euro area inflation flash estimate is issued at the end of each reference month.

The complete set of harmonised indices of consumer prices (HICP) for the euro area, EU and Member States is released around the middle of the month following the reference month. The next release with full data for September 2020 is scheduled for 16 October 2020.

For more information

Eurostat website section on inflation

Eurostat database section on inflation

Eurostat Statistics Explained article on inflation in the euro area

Eurostat metadata on inflation

Eurostat €-indicators release calendar

European Statistics Code of Practice

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This document has been updated.

You may find the most recent version here:
http://ec.europa.eu/research/participants/data/support/ncp/h2020-standards-principles_en.pdf

Please update your bookmarks accordingly.

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WORKSHOP

Ethical Aspects of Open Access: A Windy Road

Organised by ALLEA and hosted by the Royal Flemish Academy of Belgium for Science and the Arts (KVAB)

Thursday, 1 February 2018
9:00 - 15:20

Location

Palais des Académies/ Paleis der Academiën
Rue Ducale 1/ Hertogsstraat 1
1000, Brussels

Room: Espace Roi Baudouin (Throne Building)

Ethical Aspects of Open Access: A Windy Road

Facilitating access to research is a shared interest of the academic community. Open Access enables researchers to present their results more easily, opens up opportunities for researchers and institutions who cannot afford to subscribe to scientific journals, and allows for an easier use of publications in the classroom. But there are also unintended consequences. In some cases the costs have to be paid by individual researchers or institutions who cannot do so. Furthermore, it has led to an increase of predatory journals, retractions, and fake editors. How are these problems to be dealt with, or rather, how can the opportunities be maximised and the threats minimised? These questions will be addressed at this workshop, which involves eminent experts from across Europe and from all relevant sectors involved in or affected by the on-going debate on open access publishing.

PROGRAMME

9:00 - 9:15

Welcome and Introduction

Joos Vandewalle, KVAB President

Göran Hermerén, Chair of ALLEA Permanent Working Group Science and Ethics

9:15 - 9:30

Open Data in Science: Outcomes of the European Members of ICSU Workshop

Roger Pfister, Swiss Academies of Arts and Sciences

9:30 - 10:00

Open Access: The Problem Landscape from an Ethical Perspective

László Fésüs, Hungarian Academy of Sciences

Followed by Q&A

10:00 - 10:30

Editorial Responsibility in the Open Access World: Best Practices

Chris Graf, Committee on Publication Ethics (COPE)

Followed by Q&A

10:30 - 11:00	*Coffee Break*
11:00 - 11:30	**Open Data: Balancing Transparency with Resilience** Stephen Lewandowsky, University of Bristol *Followed by Q&A*
11:30 - 12:00	**Questionable and Unethical Publishers: How to Spot them and Enable Researchers to Avoid Being Trapped** Lars Bjørnshauge, Directory of Open Access Journals *Followed by Q&A*
12:00 - 12:30	**Open Access and Assessing Research Performance** Michele Garfinkel, EMBO *Followed by Q&A*
12:30 - 13:30	*Lunch*
13:30 - 15:10	**Stakeholder Perspectives: Dealing with the Challenges of Openness** Panel discussion moderated by Maura Hiney, Royal Irish Academy
15:10-15:20	**Wrap-up and Closing** Göran Hermerén, Chair of ALLEA Permanent Working Group Science and Ethics

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Koninklijke Vlaamse Academie van België voor Wetenschappen en Kunsten

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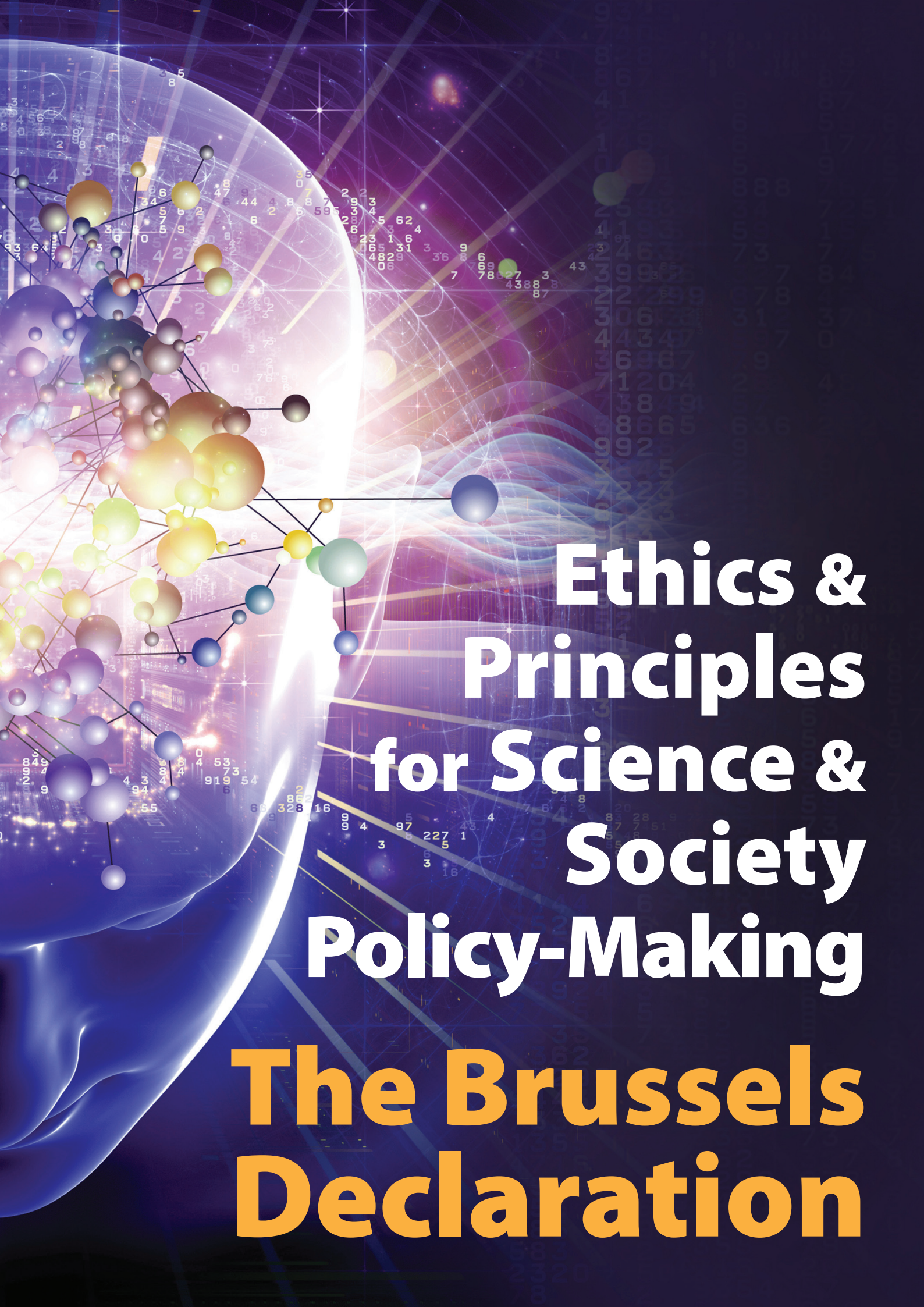

Ethics & Principles for Science & Society Policy-Making

The Brussels Declaration

Ethics & Principles for Science & Society Policy-Making

The Brussels Declaration

Text adopted on 17th February, 2017 during an announcement symposium at the American Association for the Advancement of Science's Annual Meeting (AAAS) held in Boston, USA. *(Published in the EuroScientist Journal the same day and disseminated to all Elsevier publications.)*

PREAMBLE

With the encouragement and support of all participating organisations, public and industry scientists, representatives of science-led civil society groups and particularly those many individuals assuming leadership roles in steering this independent initiative, we the participants of the five Consultation Events held from 2012 - 2016 adopt the present Brussels Declaration on Ethics and Principles for Science and Society Policy-Making.

This bottom-up initiative began as a genuine attempt by the scientific community to question the robustness of science-led policy-making worldwide. The features that set it apart are its purposeful five-year process, its multidisciplinary approach, its openness to all stakeholders, the numbers and range of groups involved, and the quality of the dialogue and inputs achieved. Taking harm reduction science as the most powerful case-study to encourage both engagement and examination of how decisions are made, the spotlight has been on the processes themselves, not the public health imperatives. Nevertheless, our discussions uncovered major concerns and these searching questions persist.

During the latter part of our process when presenting interim findings at global conferences, our collective was able to convince the organisers of the *World Science Forum* to equally call for greater concerted effort towards establishing universal ethics and principles. Thus, in line with the outcomes of the 1999 World Conference on Science (WCS) and taking into account the 2011 Budapest Declaration on the New Era of Global Science and the 2013 Rio de Janeiro Declaration on Science for Global Sustainable Development, our Co-Chairs helped draft Article IV of the 2015 World Science Forum's Budapest Declaration on the Enabling Power of Science entitled 'Scientific Advice for Policies'. This calls for: ***"…concerted action of scientists and policy-makers to define and promulgate universal principles for developing and communicating science to inform and evaluate policy based on responsibility, integrity, independence, and accountability."***

Our document brings together the findings from a series of five consultation events and symposia at global conferences from 2012 - 2016, in which more than 300 individuals from 35 countries examined how power operates in science and society (see annex).

We believe that science is relevant to politics, policy and power because it is based on evidence and gets it right most of the time. In what some now call our 'post-factual' society, however, with its cauldron of competing interests, knowledge is ever more complex, contingent and contested.

Right now, the 'playbook' at the boundary of science, society and public policy is being re-written, by multiple groups with multiple mandates and agendas.

The story of this five-year experiment is rich with tales of scepticism and walk-outs, but also of unbridled support and positivity. Our case-study presentations and discussions examined the science behind science-policy making, making it clear that 'truth' has today become a moveable feast, a mask of legitimacy often worn by those seeking power, but a mask which often bears no relation to reality.

Most policy decisions are informed by evidence provided by experts. All too often, who those experts are, how they are chosen and how reliable their advice really is, is open to question. The hard truth for the champions of scientific evidence is that facts will not reverberate as much as fear or emotion. People know that smoking kills but they still do it. Similarly, policy-makers know, as Kofi Annan put it, that 'drugs have harmed many people but bad government policies have harmed many more', but they still make those policies. We tried to uncover why?

The added-value of our expertise-gathering was that we took a deliberately bottom-up approach, focusing on the view from the grass-roots level and working with carefully selected influencers from a range of relevant fields – politicians, science advisers, chief scientific officers from industry, civil society leaders, medical doctors, professors, science editors etc. By merging traditional scientific and political 'elites' with 'scientific citizenship' and robust third-party science, our group effort identified promising alternatives based not on more top-down authority or even certainty, but on greater methodological trust.

Citizens have every right to ask who the experts are, how they are chosen and what the veracity of their advice is. The career professional scientific class must be more open. It is important that all stakeholders – society at large and those individuals or companies that may be affected by new policy – are able to be involved in the process. For all these actors and stakeholders, the scientific community included, the key requirement is transparency and honesty. Without these, trust is impossible. And without trust, public dialogue and effective policy-making are the losers.

We call upon all stakeholders – governments, scientists, industry and the public at large – to cooperate in a joint effort to ensure reliable, evidence-based policy-making for the benefit of society as a whole. The alternative, in our view, is a continued dangerous slide into the realm of policy-biased evidence.

This Brussels Declaration proposes a twenty-point blueprint for a set of ethics and principles to inform work at the boundary between science, society and policy. **Its sole purpose is to boost understanding of how power operates and to explain why evidence plus dialogue rarely equals (as one might expect) good decisions and laws.** Above all, we make the case for a broad, multi-stakeholder and multi-disciplinary approach promoting greater integrity and accountability. Our main recommendation for promoting public dialogue and better understanding is not only greater transparency and scrutiny, but genuine inclusivity.

We offer our Brussels Declaration for public comment as an attempt to provide guidelines for incorporating scientific progress into the policy-making that affects all areas of our lives.

We renew our commitment towards the responsible and ethical use of scientific knowledge in addressing the grand challenges of humankind.

We call for concerted action and will continue mobilising the international community to play its role to advance the use of this Brussels Declaration to support global and national initiatives.

Above all, our five-year journey has convinced all concerned, more than ever, that it is in all our interests that we benefit from ***'evidence-based policy-making'*** rather than suffer ***'policy-biased evidence'.***

**Details of all five consultation events and supporting symposia held at global conferences 2012 – 2016, their set-up logic, participant lists, working groups, presentations, plus the thematic thought-leader essays generated etc. can be found at: www.sci-com.eu*

SUMMARY:

SECTION 1: SCIENCE AND POLICY – A CRUCIAL RELATIONSHIP

1. Science is a fundamental pillar of knowledge-based societies
2. Science can help provide the evidence base for public policy
3. Sound public policy is crucial for the direction and priorities of science
4. The dialogue between science and policy is never straight-forward

SECTION 2: WHAT WE EXPECT FROM THE SCIENTIFIC COMMUNITY

5. The integrity of science needs to be clear and the integrity of scientists providing advice must be unimpeachable
6. The full range of scientific disciplines should be included; notably, the social sciences can play a key role in improving how the public may react or adapt
7. Scientists must learn to use established communication channels for providing policy advice more effectively and be less aloof and perhaps less arrogant
8. Scientists must listen and respond to criticism

SECTION 3: WHAT WE EXPECT FROM THE POLICY-MAKING COMMUNITY

9. Policy-makers must listen, consult and be held accountable
10. Ethical consideration of the impact of policy decisions is crucial
11. Policy-makers have to challenge science to deliver on public investment
12. Policy-makers should be willing to justify decisions, particularly where they deviate from independent scientific advice
13. Policy-makers should acknowledge the potential for bias and vested interests contrary to the scientific consensus

SECTION 4: WHAT WE EXPECT FROM THE PUBLIC, MEDIA, INDUSTRY AND INTEREST GROUPS

14. The public plays a critical role in influencing policy and must be included in the decision-making process
15. Industry is an investor in knowledge generation and science and has every right to have its voice heard
16. Interest groups similarly have every right to have their voice heard as guardians of the common good or legitimate sectoral interests
17. Advice from any source to policy-making must acknowledge possible bias

SECTION 5: WHAT NEEDS TO CHANGE: HOW SCIENTIFIC ADVICE & GREATER INCLUSIVITY NEED TO BE INTEGRATED MORE EFFECTIVELY

18. Scientific advice must be more involved in all stages of the policy-making process
19. Policy-making must learn to cope with the speed of scientific development and include greater foresight and policy anticipation
20. Societal investment in science will always require priority-setting; nevertheless, advances in public health deserve special attention

SECTION 1:
SCIENCE AND POLICY – A CRUCIAL RELATIONSHIP

1. Science is a fundamental pillar of knowledge-based societies:

Science provides a vital source of innovation, technological development and new ideas that change the way citizens and policy-makers perceive the world. It can both benefit and pose risks to the human condition. Scientists provide an interpretation of factual evidence, acknowledging that the interpretation may change as new knowledge is gathered. The application of science is not without risks and uncertainties, and these factors should be openly acknowledged and identified. Above all, we must not lose sight of the fact that science is also a value to society in its own right, forming the basis of judgement and insight while expanding the frontiers of knowledge. As such it cannot, and must not, be judged only in utilitarian, economic terms. In return, excellence and integrity must be taken very seriously by the scientific community in order to retain trust.

2. Science can help provide the evidence base for public policy:

In a complex, inter-connected society, there is a growing need for evidence and expertise to inform policy-making. Scientific evidence is one among many types of advice that inform the decision-making process. Others include ethical values, cultures, politics and the impact any decision has on other areas of policy. But science occupies a unique position in the support it can offer to policy formation. This is a responsibility – and a value – that must be taken seriously by scientists and non-scientists alike.

3. Sound public policy is crucial for the direction and priorities of science:

Policy for science is distinct from science to inform public policy. But there are overlaps. More often than not, science advice and science communication stand apart from the classical academic reputational system. Both are under-prioritised in academic careers. How funding and other resources are allocated to different areas of research can have a major impact on the questions and priorities which are addressed by the scientific community. Laws and policies may even prohibit the funding of science for certain topics in ways that are unrelated to evidence, for example, in vitro fertilisation or surrogacy.

4. The dialogue between science and policy is never straight-forward:

Policy-makers have multiple sources of solicited and unsolicited advice. Scientific evidence is not always welcomed by policy-makers, which can lead to it being ignored or distorted. Even when it is invited to speak, science does not always speak with one voice. Where judgement is necessary on competing scientific assessments, transparency is essential. Above all, there needs to be greater awareness that scientific uncertainties are likely to be perceived differently by different stakeholders. Building trust and ensuring transparency demands that citizens are engaged and consulted in developing the scientific advice, and in ensuring the integrity of those providing the advice. Scientific citizenship is not an a la carte add-on option.

SECTION 2:
WHAT WE EXPECT FROM THE SCIENTIFIC COMMUNITY

5. The integrity of science needs to be clear and the integrity of scientists providing advice must be unimpeachable:

Scientists and those who make use of their work have a duty to ensure that the results of scientific research are reproducible and transparent. Vested interests can be beneficial but must be disclosed and conflicts of interest avoided or managed appropriately. The integrity and quality of that which science produces should be rigorously monitored and nurtured, by underpinning it with continuous and effective peer review, plus open quality assurance. Conclusions should be based on evidence. If scientists accept funding from special interest groups (including industry, not-for-profit organisations or government) the relationship must be open, known to all stakeholders and especially the general public. For example, several governments fund charities – often in former colonies – which, in turn, use public funding to lobby government.

6. The full range of scientific disciplines should be included; notably, the social sciences can play a key role in improving how the public may react or adapt:

Science and society all too often remain poles apart. Breaking down silos and including the full range of scientific disciplines will help scientists understand their role in society. Their collective wisdom is essential in helping policy-makers get things right. Science must accept that such inputs are often required ad-hoc, as there is not always time for tailor-made studies or optimal solutions. The focus should be on humane, ethical and sound science. Neither can science advice ever be accurate or actionable unless social psychology and humanities studies are fully factored in. For example, key determinants such as information selection, confirmation bias, pluralistic ignorance, extremism, polarisation, decision-making etc. require greater attention.

7. Scientists must learn to use established communication channels for providing policy advice more effectively and be less aloof and perhaps less arrogant:

Scientists must accept the responsibility to translate their scientific knowledge into forms that are understandable for society at large – especially where they are funded by public money. They need to be less aloof, perhaps even less arrogant, and engage with all appropriate communication channels to inform genuine public debate and provide effective policy advice. In so doing, science must enhance its voice, be courageous in policy debates, and get better organised to 'gang up' and ensure more accurate representation of its findings. In particular, scientists need to understand that policy-makers have to constantly weigh up the pros and cons of every decision. By developing comparative analyses of choices based on scientific evidence, more pragmatic choices will be possible. Ultimately this will require a greater understanding of, and earlier engagement with, the general public, private sector and non-governmental organisations, who are equal stakeholders.

8. Scientists must listen and respond to criticism:

The dialogue between science and society requires mutual trust and respect. All too often it can be portrayed as a 'science versus society' arm-wrestle with zero room for understanding or compromise. Scientists need to convey the best current evidence while acknowledging the limits of science and listening and responding seriously to criticism. Scientists must justify their recommendations and better engage when faced with such argument and criticism. "Trust me, I'm a scientist" does not, and should not convince. Scrutiny matters too and discounting 'citizen science' is erroneous. Where there are disagreements as to the interpretation of scientific data this should be acknowledged and addressed. Scientists need to recognise that they are advocates with vested interests too – in their case, in their own science.

SECTION 3:
WHAT WE EXPECT FROM THE POLICY-MAKING COMMUNITY

9. Policy-makers must listen, consult and be held accountable:

Policy-makers should be receptive to independent and transparent scientific advice, even when this advice is uncomfortable. Scientists should have the opportunity to provide input at all relevant stages of the policy-making process and hold it to scrutiny, while accepting that there may be stages that are not science-relevant. Policy-makers should pose questions in a timely fashion, as the quality and value of advice given may be compromised by a demand for unrealistically fast responses.

Although policy-makers may be restricted in the level of expertise or tools they have at their disposal, they should keep their door open and include the private and corporate sectors, civil society groups and NGOs in public dialogue on scientific evidence. A system for alerting policy-makers to hazards and potential mistakes should be integral.

But the bottom line must be that, while the inherent uncertainty in research has to be recognised, when policy-makers fail to take on board what the evidence is telling us, they must be held accountable for their inactions as much as for their actions. For example, differing policy responses to cannabis or alcohol harm reduction. The highly publicised opposing views of the Canadian and U.S. Surgeon Generals on e-cigarettes are a case in point.

10. Ethical consideration of the impact of policy decisions is crucial:

Ethical consideration of the human impact of policy decisions is crucial and should be an integral part of decision-making. For example, how do we differentiate between the responsibilities of individuals to look after themselves and the powers of states to look after their citizens? Inevitably, occasions arise where a purely scientific assessment may harm society, or particular groups in society.

Concerns for human dignity, respect for plurality, solidarity and justice, and even practicality, can all be crucial for the ultimate acceptance of policy, yet seem unscientific, or even anti-scientific, to some. Policy-makers, of course, have a responsibility to address areas that are complex, which require compromise and pragmatism, and where the selected response may therefore run counter to scientific 'purity'. Where policy does not respond directly to scientific findings, policy-makers must accept a responsibility to give clear explanations and reasoning.

11. Policy-makers have to challenge science to deliver on public investment:

For the science and policy relationship to work, policy-makers have to challenge science to deliver on any investment it receives from the public purse. For their part, when target-setting, policy-makers must not look at aspirations only, but should define explicit goals including using scientific evidence as a guide to help define and achieve faster and better results. The Sustainable Development Goals are an example.

There is always an essential need for academic freedom within the parameters of any research question. Especially where public investment is involved, scientists must be held to account and challenged to demonstrate the relevance and effectiveness of their work. An example of this is the development and use of novel antibiotics. The responsibility of scientists does not end with the discovery or report of findings. The implementation of these findings, enshrining science in policy, needs to be a shared endeavour. The failure to report negative finding is in itself a perversion of science.

12. Policy-makers should be willing to justify decisions, particularly where they deviate from independent scientific advice:

Clarity and transparency are fundamentally important, particularly where policy deviates from independent scientific advice. Whether there is scientific consensus or not, it has to be clear, through disclosure of all sources of input, whenever non-scientific considerations or influencing factors are involved in decision-making. Policy-makers should also be brave and imaginative. A new spirit of innovation might have to out-weigh precaution. Opening up new opportunities should be a core responsibility of policy-makers, who must also give due attention to the need for global investment in education to provide the resources for our shared future.

13. Policy-makers should acknowledge the potential for bias and vested interests contrary to the scientific consensus:

Policy-makers should acknowledge all sources of input used in coming to decisions and be aware of the risks and dangers of pressure from commercial agencies or special interest groups including media bias, which can frequently lead public opinion. Where decisions are made that are contrary to the scientific consensus this should be made explicit and the considerations driving that decision should be transparent.

Input from those with a vested interest in the decision should be publicly acknowledged and, where possible, the nature of the advice should be made available. In order to minimise bias and inappropriate influence, a clear, reliable and transparent methodology for the whole life-cycle of policy-making should be defined.

SECTION 4:
WHAT WE EXPECT FROM THE PUBLIC, MEDIA, INDUSTRY AND INTEREST GROUPS

14. The public plays a critical role in influencing policy and must be included in the decision-making process

The public plays a critical role in determining what positions policy-makers will take. Unless science understands their 'nothing for us, without us' rights, then all sides of the equation will never truly balance out. Policy-makers are, by and large, elected and few will take a stance to support what the scientific evidence is telling us if this means going against the views of their electorate.

The emergence of social media plays an important role here. For while new media lends itself to the expression of strong emotion, it hardly facilitates the careful explanation of a research finding or a policy platform by elected policy-makers. Traditional media's capacity to explain the ins and outs of less tangible science-policy-making is equally limited, especially when scientific consensus may not exist.

In this context, scientists must learn to find transparent ways and means to make their voices heard. The scientific community must sharpen its message and engage the public. On their side, the public needs to better understand that societal problems are not necessarily solvable through science. Increasing science literacy is relevant in this regard.

Democracy is best served when citizens are comfortable with science and, by extension, science policy. However it is achieved, if the general public and their civil society actors are not included as fully as possible in decision-making by the scientific-political establishment, the consequences will be extremely damaging.

15. Industry is an investor in knowledge generation and science and has every right to have its voice heard:

Industry is not to be shunned when it comes to policy-making. As the largest investor in knowledge generation, technology and science, it has every right to have its voice heard. Indeed, society and the policy-making process greatly benefit from the participation of industry experts. This is especially true when it comes to newly emerging technologies, where experts from industry and academia alike tend to have the deepest understanding and the most thoughtful approach on how we should proceed.

Nevertheless, industry is too often perceived as suffering from fatal conflicts of interest and its views are therefore dismissed. In fact, commercial conflicts of interest are fairly easy to deal with if they are properly declared and the relationship between the science and the marketing made explicit. Ideological, personal or academic conflicts of interest, on the other hand, are much harder to detect or deal with.

Industry, in turn, must be better at disclosing its research methods, findings and interests and speak out more when its competitors or sector behave inappropriately. Equally, industry should speak out more when denied access to important policy-making or when its scientific research is poorly scrutinised or dismissed altogether. Yet, companies are too often constrained by their own competitive, secretive and hierarchical natures.

Spokespeople, not scientists, are deployed to engage with society. If greater trust is to be built, industry should empower its scientists to speak up. This will help industrial research to be seen to be underpinned by an inherent integrity and quality. Above all, industry should avoid a 'battle-ground' mentality and the promotion of public disinformation intended to muddle the scientific picture when competitors or policy-makers appear to be going in an unwelcome direction.

16. Interest groups similarly have every right to have their voice heard as guardians of the common good or legitimate sectoral interests:

Interest groups similarly have every right to have their voice heard as guardians of the common good or legitimate sectoral interests: interest groups are a crucial cog in the policy-making process. NGOs and legitimate grass roots groups represent a concerned citizenship. At the same time, policy-makers need to be conscious of the fact that interest groups are not necessarily defenders of the common good or promoters of robust science. For this reason, they must be transparent, accountable and responsible for the information and misinformation they disseminate.

When interest groups clearly get it right, both the scientific and policy-making community should give them credit. When they get it clearly wrong, they should learn to hold their hands up and contribute to dismantling the public myths about science that they have helped create.

17. Advice from any source to policy-making must acknowledge possible bias:

Transparency is key to science policy advice. Advice from any source must therefore acknowledge any possible bias (including any funding that may have influenced the advice). Scientists supported by government, academia, industry or special interest groups, including global institutions, must declare that support. Funding sources must be openly declared, also the various roles or associations, past and present, of those giving advice. It cannot be that when provided welcome advice it is called an 'input' and when unwelcome, called 'lobbying'.

The influencing of policy-makers is embedded in society, but this must not become the preserve of a privileged few. The majority of stakeholders, if not all, must be given an equal opportunity to exercise influence. It is essential that lobbying is transparent and accountable, and that it avoids any hint that it exerts an undue or even deceitful influence on decision-making.

SECTION 5:
WHAT NEEDS TO CHANGE: HOW SCIENTIFIC ADVICE & GREATER INCLUSIVITY NEED TO BE INTEGRATED MORE EFFECTIVELY

18. Scientific advice must be more involved in all stages of the policy-making process:

Knowledge institutions have multiplied. New players have joined. Think tanks and expert groups are manifest. Yet, few checks and balances are in place to contest when policies proposed by elite power circles are clearly not evidence-based. Therefore, from the anticipation and development of policy to its implementation, evaluation and reform, scientists need to be more readily involved in political circles, and integrated into the policy-making system. A variety of approaches to this can already be seen in the world today (science & society co-production in Asia or top-down advisory mechanisms in Europe etc.). A key impetus behind this is the fact that science-based issues are now so crucial to the conduct of foreign policy whether in the national, regional or global interest. Countries are expressing a clear interest in implementing science diplomacy through politics, a process which by its very nature demands a closer integration of science and politics. The same applies to global companies and institutions operating in a complex matrix of technical and relational challenges. But the reality is that scientists at the top of their profession are often kept away from policy-makers, particularly on emerging, controversial issues. The policy-making process must thus be self-critical and somewhat auto-correcting, rooting out its own inherent flaws and biases.

Recent moves towards the creation of science advisory posts at the top table of government and global institutions can only work if those appointed as important gatekeepers to power are permitted to actually listen and consult grass-root stakeholders more broadly. They must also have the courage to stand by what the consensus evidence is telling them. If as a society we recognise the benefits of increasing scientific input at all stages of the policy-making process, then we must all redouble our efforts to remove the political barriers that prevent science being heard.

19. Policy-making must learn to cope with the speed of scientific development and include greater foresight and policy anticipation:

Aspects of future risk and uncertainty are particularly complex and difficult for policy-makers to grapple with. Taking the Ebola virus as an example, some may choose to invest heavily in being prepared for even remote outcomes, others will prefer simply to respond whenever a crisis arises, if at all. Where there is scientific uncertainty, policy-making should be aware of the basis of that uncertainty. Science should be forthright in providing advice on the costs and benefits of action or inaction. Similarly, the precautionary principle must not be misused in a way that impedes technological progress towards reducing risk or public harms. It is clear that greater interaction between science and policy-making has great potential to bridge the fundamental divide, where scientists tend to think long-term, while policy-makers tend to address short-term, election-cycle concerns. Clearly the understanding of problems can be very different when viewed from different perspectives.

20. Societal investment in science will always require priority-setting; nevertheless, advances in public health deserve special attention:

The general public may be interested in investing their taxes in discovering life on Mars or the Higgs Boson, but they quite reasonably expect most tax-funded scientific research to be focused on issues of life and death. An increased focus on public health science and innovation or that which stresses food security and safety will help prevent disease and premature death and promote wellbeing worldwide. For this to be further established, there is a need to build trust between scientists, policy-makers and other societal actors through a long-term, sustained and participatory dialogue. Nobody should be excluded or left behind. There is a need for institutions that can serve as "brokers" and "interpreters" between the science and policy arenas. Global challenges need global solutions. In today's politics of science, it is therefore of the utmost importance to break with the past and already bankrupt world views to join efforts to provide the best possible scientific solutions for our time.

CONSULTATION EVENTS DETAILS & ATTENDEES

'Evidence-Based Policy Versus Policy-Biased Evidence: The Challenge Of Feeding Scientific Advice Into Policy-Making'
When science speaks to policy, politics and power because it has evidence

"Drugs have harmed many people but bad government policies have harmed many more"
Kofi Annan (GH) - *Global Commission on Drug Policy*

"Scientists should learn to stand up, shout up and when necessary, shut up. The voice of the rational middle ground should be louder"
Prof. Patrick Cunningham (IRL) - *former Irish Chief Science Adviser (2012 Participant)*

"We need to drag all stakeholders out of their silos and force them to work together"
Dr. Mary Baker MBE (UK) - *Immediate Past President, European Brain Council & European Federation of Neurological Associations (2014 Participant)*

"Only by systematically holding our leaders to account for the promises they make can we ever hope to tip the risks balance towards reduced harms and save lives"
Dr. Richard Horton (UK) - *Editor-in-Chief, The Lancet; Former First President of the World Association of Medical Editors (2012 Participant)*

CONSULATION EVENT DATES, LOCATIONS & THEMATIC TITLES

Consultation No 1: 29th June, 2012, South African Mission, Brussels
Case-study theme: **Harm Reduction Science**

Consultation No 2: 4th June, 2013, South African Mission, Brussels:
Case-study theme: **Substance Addictions And Their Brain Reward Systems**

Consultation No 3: 10th June, 2014, South African Mission, Brussels:
Case-study theme: **Ethics, Integrity And The Policy-Maker**

Consultation No 4: 18th June, 2015, South African Mission, Brussels:
Case-study theme: **Regulating Risk**

Consultation No 5: 24th July, 2016, Manchester Town Hall:
Case-study theme: **Towards Ethics & Principles Of Science Policy-Making**

Brussels Declaration Final Dialogue: 9th December, Pretoria:
Science Forum South Africa (SFSA)

Brussels Declaration Release: 17th February, Boston:
American Association for the Advancement of Science (AAAS)
Annual Meeting

THE BRUSSELS DECLARATION DRAFTING PROCESS

Chairpersons 2012 – 2016

Dr. Mary Baker MBE (British),
Past-President, European Brain Council; Consultant to the WHO; Universities of Oxford & London School of Economics.

Dr. Wilson Compton MD (American),
Deputy Director, U.S. National Institutes of Health, National Institute of Drug Abuse (NIDA).

Professor Patrick Cunningham (Irish),
Professor of Genetics, Trinity College Dublin; Former Chief Science Adviser to the Government of Ireland; Champion, EuroScience Open Forum (ESOF) 2012 Dublin.

Dame Professor Anne Glover (British),
Dean of International Relations, University of Aberdeen; Former Chief Science Adviser to European Commission President, José Manuel Barroso.

Professor Julian Kinderlerer (British & South African),
President, European Group on Ethics in Science and New Technologies (EGE); Professor of Intellectual Property Law, University of Cape Town.

Professor Michel Kazatchkine MD (French),
UN Secretary General's Special Envoy on HIV/AIDS in Eastern Europe and Central Asia; Member, Global Commission on Drugs Policy; Former Executive Director of the Global Fund to Fight Aids, Tuberculosis & Malaria.

In early May, 2016 our Consultation Event Co-Chairs, Professor Michel Kazatchkine and Professor Julian Kinderlerer took the Fifteen Principles & Recommendations arrived at following our first 2012 meeting as version 1.0. They revised them, adding five new principles reflecting a more robust ethical stance.

On 14th June, 2016 this version 2.0 was then sent to the four past Chairs for comment, namely Dame Anne Glover, Professor Patrick Cunningham, Dr. Wilson Compton and Dr. Mary Baker.

Based on their inputs, we arrived at our 3.0 version which was sent on 28th June, 2016 to the many past-participants unable to join the fifth and final Consultation Event in Manchester on 24th July, 2016, but who had asked explicitly to be kept in the loop and continue feeding-in to the process.

Taking into account their comments, we then sent a version 4.0 to all confirmed participants (see below), dividing them into five Pre-Working Groups with an assigned Discussion Lead who then steered the drafting process for their specific set of principles:

Working Group 1: Science and policy – a crucial relationship?

Discussion Lead: **Dr. David Budtz Pedersen** (Danish),
Associate Professor, Humanomics Research Centre, Department of Communication & Psychology, Aalborg University..

Working Group 2: What do we expect from the scientific community?

Discussion Lead: **Dr. Thomas Hartung** (German),
Professor and Chair for Evidence-based Toxicology, Director, Center for Alternatives to Animal Testing; Johns Hopkins University, Bloomberg School of Public Health, Dept. of Environmental Health Sciences.

Working Group 3: What do we expect from the policy community?

Discussion Lead: **Professor Roy Robertson M.D.** (British),
Center for Population Health Sciences, University of Edinburgh.

Working Group 4: What do we expect from the public, industry, media and interest groups?

Discussion Lead: **Professor Kathryn O'Hara** (Canada),
Professor of science broadcast journalism at Carleton University; former President of the Canadian Science Writers' Association; former Board Member, World Federation of Science Journalists.

Working Group 5: What needs to happen next?

Dr. Lidia Brito (Mozambique),
Director of Science Policy for Latin America & the Caribbean, UNESCO & former Minister for Science, Government of Mozambique.

On 24th July, 2016 at the Concluding Consultation Event, each Discussion Lead presented the specific text recommendations of their Working Group in open session at Manchester Town Hall, including further comments and suggested changes from the floor i.e. from all participants present.

Following this fifth and final Consultation Event, each Discussion Lead was tasked with continuing the dialogue and refining their texts for final submission to the Co-Chairs, which they did by end September, 2016.

Co-Rapporteurs Aidan Gilligan and Jan-Marco Mueller then worked with all Discussion Leads and Chairs to produce this final Brussels Declaration.

On 19th January, 2017 the Declaration was sent to all 2012 – 2016 Consultation Event participants for one final assessment, equally asking them to check their affiliations.

The initiative was announced in Nature Correspondence on 19th January, 2017 as being for public release at the Annual Meeting of the American Association for the Advancement of Sciences (AAAS) Boston on 17th February, 2017.

This scientific symposium panel announcing the Brussels Declaration includes:

> **Chair Professor Kinderlerer** presenting principles 1 – 4;
> **Chair Dr. Wilson Compton** presenting principles 5 – 8;
> **Chair Professor Michel Kazatchkine** presenting principles 9 – 13;
> **Discussion Lead Professor Kathryn O'Hara** presenting principles 14 – 17;
> **Participant Sir Peter Gluckman**, *Chief Science Adviser to the PM of New Zealand,* presenting principles 18 – 20; &
> **Grace Naledi Mandisa Pandor,** *South African Minister for Science & Technology,* joining as a Discussant.

In parallel, the Euroscientist journal and Elsevier released the principles to all publications in a global online campaign.

CONCLUDING CONSULTATION EVENT PARTICIPANTS, 24TH JULY, 2016 MANCHESTER TOWN HALL

Prof. Tateo Arimoto (Japanese),
National Graduate Institute for Policy Studies (GRIPS) & Japanese Science & Technology Agency (JST), Japan

Mr. Stephane Berghmans (Dutch),
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Professor Jean-Pierre Bourguignon (French),
President of the European Research Council (ERC)

Dr. Lidia Brito (Mozambique),
Director of Science Policy for Latin America & the Caribbean, UNESCO & former Minister for Science, Government of Mozambique

Dr. David Budtz Pedersen (Danish),
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Dr. Anne Cambon-Thomsen (French),
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Mr. Clive Cookson (British)
Research Editor, Financial Times

Mr. Francis P. Crawley (Belgian / American),
Executive Director, Good Clinical Practice Alliance & Member, Ethics Working Group of the European Academy of Paediatrics

Prof. Maria Da Graca Carvalho (Portuguese),
European Commission Cabinet Research Commissioner Carlos Moedas; Former Member of the European Parliament & Horizon 2020 Rapporteur, Former Minister for Science of Portugal

Mr. Conor De Lion (Irish),
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Mr. Nart Dohjoka (Jordanian),
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Professor Mark Ferguson (Irish),
Chief Science Adviser to the Government of Ireland & Director General, Science Foundation Ireland

Prof. Luke Georghiou (British),
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Mr. Aidan Gilligan (Irish),
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Professor Anne Glover (British),
Dean of International Relations, University of Aberdeen; Former Chief Science Adviser to European Commission President, José Manuel Barroso; Former Chief Scientific Adviser for Scotland

Professor Peter Gluckman (New Zealander),
Chief Science Adviser to the Prime Minister of New Zealand & Chairman, International Network on Government Science Advice (INGSA)

Mr. Patrice Goldberg (Belgian),
Science Editor RTBF (Belgian French-speaking Television)

Ms. Laura Greenhalgh (British),
News Editor, Research Europe (Observer)

Dr. Robin Grimes (British),
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President of Euroscience, Chairman, the Danish Nature Fund, Former Rector, Aarhus University

Dr. Rush Holt (American),
CEO, American Association for the Advancement of Science & Executive Publisher, Science Journals; Former U.S. Congressman for New Jersey

Mr. Toshiyasu Ichioka (Japanese),
Director, Japan Science & Technology Agency (JST) Paris Office (Observer)

Mr. Kazuyoshi Kashimida (Japanese),
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Iris Kisjes (Dutch),
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SUPPORTING ENGAGEMENT PANELS 2012 - 2016

Case-studies and presentations given at annual Consultation Events often formed the basis for participants coming together with further experts and groups to conceive and deliver high-level panels at global conferences. In addition, speakers and delegates often teamed up to generate novel thought-leader essays on specific topics of interest to them around scrutinising evidence-based policy-making.

This has generated a large body of work. These compendia and details of all below-mentioned high-level panels can be found under 'events' and 'publications' at www.sci-com.eu

July, 2012: EuroScience Open Forum Dublin (ESOF):

'Exploding myths about nuclear energy, GMO's and harm reduction science'
'Are science journalists doing their job?'

February, 2013: American Association for the Advancement of Science (AAAS) Boston:

'Clinical trial and error, beauty and the beast'
'Food, nicotine, and drug addictions: the latest research on brain reward systems'

26 November, 2013: World Science Forum Rio, Brazil:

'Leveraging the nexus between health science, policy & business: insights from the BRICS, USA & Europe'

February, 2014: American Association for the Advancement of Science (AAAS) Chicago:

'Addiction: our compulsions and brain reward systems'
'Building global partnerships: sharing discovery while protecting competition'
'Resolving our greatest public health challenges via science diplomacy'

July, 2014: EuroScience Open Forum (ESOF) Copenhagen:

'Unravelling addictions and brain reward systems'
'Building global partnerships, sharing discovery while protecting competition'
'Health science 2020: a jig-saw puzzle of global business clusters'
'Resolving our greatest public health challenges via science diplomacy'

February, 2015: American Association for the Advancement of Science (AAAS) San José:

'E-cigarettes: killing me softly or our greatest public health challenge?'
'Science diplomats tackling our lifestyle killers'

November 2015: World Science Forum Budapest:

'Mapping the brain, unlocking the mind'
'Fit for purpose global health policies'

February 2016: American Association for the Advancement of Science (AAAS) Washington D.C.:

'Neuroscience clues to the chemistry of addiction & their mood disorders'
'Statecraft & scalpel: regional & global health diplomacy'

July, 2016: Euroscience Open Forum (ESOF) Manchester:

'Evidence newcomers: revolutionising regional & global initiatives – should the 'old world' make more space?'
'Waging war on drugs doesn't work – applying harm reduction science does: key findings of the UN General Assembly 2016'
'The right to be forgotten versus the right to know'
'Toxicant detectives: the chemical innovation race, lifestyle risks & the role of animal experiments'
'Clinical trial and error: why narrowing the resources gap matters'

September, 2016: Latin American & Caribbean Open Science Forum (CILAC) Montevideo, Uruguay:

'Refining the open science paradigm shift - barriers, opportunities, infrastructure & open society'

November, 2016: Seoul, Korea (KOFAC):

'How good & bad innovation, ethics & policy-making shape our modern lives'

WHY ASKING THE DIFFICULT QUESTIONS MATTERS

Our annual consultation events brought unlikely bedfellows together. To help nudge some people out of their silos, to build bridges and to change mind sets, each year the Co-Chairs invited a select group of thought-leaders to write or to co-write opinion pieces.

CONTRIBUTING THOUGHT-LEADER ESSAY AUTHORS

Prof. Michel Kazatchkine

Prof. Julian Kinderlerer

Dr. Delon Human

Aidan Gilligan

Dr. Wilson Compton

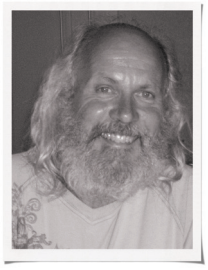
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Dr. Christopher Proctor

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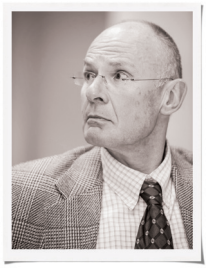
Prof. Philippe de Witte

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PHOTOS FROM THE CONSULTATION EVENTS

Consultation No 1: 29th June, 2012, South African Mission, Brussels
Case-study theme: **Harm Reduction Science**

CONSULTATION EVENT 2012

LIST OF PARTICIPANTS (Titles as of June 2012)**:** ▸ **1. Professor Michel Kazatchkine** (French), Professor of Immunology at Université René Descartes, Paris; Former Executive Director, The Global Fund to fight AIDS, Tuberculosis & Malaria (Panelist) ▸ **2. Dr. Peter Tindemans** (Dutch), Secretary General, Euroscience; High-Level Research Policy Consultant to the World Bank (Panelist) ▸ **3. Professor Klaus Bock** (Danish), Chairman of the Danish National Research Foundation (DNRF) and Champion, ESOF 2014 Copenhagen (Panelist) ▸ **4. Professor Riitta Mustonen** (Finnish), Vice President, Academy of Finland; (Panelist) ▸ **5. Professor Helmut Greim** (German), Chair of the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) (Panelist) ▸ **6. Dr. David Budtz Pedersen** (Danish), Strategic Adviser, Ministry of Science, Innovation & Higher Education; Bid Coordinator ESOF 2014 Copenhagen (Observer) ▸ **7. Professor Dr. Karl Fagherstrom** (Swedish), Founder, Society for Research on Nicotine and Tobacco; Former Editor-in-Chief, Scandinavian Journal for Behavioural Therapy; Director, Smokers Information Center (Panelist) ▸ **8. Dr. Bogosi Mogale** (South African), South African Mission to the European Union (Senior Health Representative to the EU, South African Department of Science & Technology) (Panelist) ▸ **9. Professor Jim Bridges** (British), Professor of Toxicology and Environmental Health and Dean for International Strategy at the University of Surrey, Guildford, UK; Chair of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), (Panelist) ▸ **10. Dr. Jan Marco Mueller** (German), Assistant to CSA Anne Glover (Rapporteur) ▸ **11. Mr. Alberto da Ponte** (Portuguese), President of The Brewers of Europe; Board of Directors of the European Foundation for Alcohol Research (Panelist) ▸ **12. Mr. Anders Olauson** (Swedish), President, European Patients Forum; Chairman and Chief Executive Officer of the Agrenska Centre (Panelist) ▸ **13. Mr. Pierre-Olivier Bergeron** (French), Secretary General, The Brewers Association of Europe (Observer) ▸ **14. Professor Anne Glover** (British), Chief Scientific Adviser to José Manuel Barroso, President of the European Commission (Convener) ▸ **15. Dr. Richard Horton** (British), Editor-in-Chief, The Lancet; Formerly First-President of the World Association of Medical Editors & Past-President of the US Council of Science Editors (Panelist) ▸ **16. Dr. Martin Seychell** (Maltese), Deputy Director General, European Commission, Health and Consumers (Panelist) ▸ **17. Mr. Daan Du Toit** (South African), Minister Counsellor (Science & Technology), South African Mission to the European Union (Senior S&T Representative to the EU, South African Department of Science & Technology), (Observer) ▸ **18. Mr. Aidan Gilligan** (Irish), Event Organiser & CEO, SciCom – Making Sense of Science (Rapporteur) ▸ **19. Dr. Wilson M. Compton** (American), Director, Division of Epidemiology, Services and Prevention Research, US National Institute on Drug Abuse (NIDA), (Panelist) ▸ **20. Mrs. Sophia Kuhn** (Swedish), Communications Manager at the European Food Information Council (EUFIC) (Observer) ▸ **21. Professor Martin Ingvar** (Swedish), Dean of Research, Professor of Integrated Medicine, Karolinska Institut (Panelist) ▸ **22. Dr. Delon Human** (South African), President & CEO, Health Diplomats; Secretary-General of the Africa Medical Association (AfMA); Formerly Secretary of the World Medical Association; Formerly Adviser to the WHO Director-General and UN Secretary-General (Panelist) ▸ **23. Dr. Susan Kentner** (American), Director of the Brussels Office of the Helmholtz Association of German Research Centres (Observer) ▸ **24. Mrs. Nathalie Moll** (British), Secretary General, EuropaBio (Panelist) ▸ **25. Professor Patrick Cunningham** (Irish), Chief Scientific Adviser to the Irish Government; Professor of Animal Genetics, Trinity College Dublin; Champion, ESOF 2012 (Chair) **MISSING FROM THE PHOTO:** ▸ **26. Dr. Theodoros Karapiperis** (Greek), Head of Unit, Scientific and Technical Options Assessment Panel (STOA), European Parliament (Panelist) ▸ **27. Mr. Frederik Wittock** (Belgian), Senior Director, Cross-Pharma R&D Communications, Johnson & Johnson Pharmaceutical Research & Development (Panelist)

Consultation No 2: 4th June, 2013, South African Mission, Brussels:
Case-study theme: **Substance Addictions And Their Brain Reward Systems**

CONSULTATION EVENT 2013

Dr. Wilson M. Compton, *Deputy Director, US National Institute on Drug Abuse (NIDA)*

Consultation Event delegates

Networking Event, Nicotine Addiction Panel

Professor Michel Kazatchkine, *United Nations Special Envoy for HIV/AIDS in Eastern Europe and Central Asia*

Professor Vittorio Prodi, *Member of the European Parliament*

Mr. Martin Dockrell, *Director of Research & Policy, Action on Smoking & Health (ASH)*

Consultation No 3: 10th June, 2014, South African Mission, Brussels:
Case-study theme: **Ethics, Integrity And The Policy-Maker**

CONSULTATION EVENT 2014

Event Co-Chair: Professor Julian Kinderlerer

Consultation Event Working Groups

Networking Cocktail

Professor Michel Kazatchkine & M.D. Delon Human

Dr. Didier Schmitt & Dr. Theo Karapiperis

Professor Didier Jayle & Dr. Mary Baker

Consultation No 4: 18th June, 2015, South African Mission, Brussels:
Case-study theme: **Regulating Risk**

CONSULTATION EVENT 2015

Professor Michel Kazatchkine

Consultation Event Working Groups

Networking Cocktail

Consultation Event Working Groups

Consultation Event Working Groups

Consultation Event Working Groups

Consultation No 5: 24th July, 2016, Manchester Town Hall:
Case-study theme: **Towards Ethics & Principles Of Science Policy-Making**

CONSULTATION EVENT 2016

Dr. David Budtz Pedersen

Consultation Event Working Groups

Professor Lidia Brito

Professor Anne Glover & Professor Michel Kazatchkine

Consultation Event Working Groups

Consultation Event Working Groups

HORIZON 2020

The New EU Framework Programme

for Research and Innovation

running from 2014 to 2020

Minimum standards

and

Guiding principles

for setting up systems of

National Contact Points

(NCP systems)

under Horizon 2020

Minimum standards and guiding principles

1. Context

A system of National Contact Points will be established for Horizon 2020, building on the experience of previous Framework Programmes. To promote equal and consistent support, this document provides a common reference for all participating countries.

2. Mission

Highly professional support services operating nationally will form an essential component of Horizon 2020 implementation. By spreading awareness, giving specialist advice, and providing on-the-ground guidance, they will ensure that the new programme becomes known and readily accessible to all potential applicants, irrespective of sector or discipline.

3. Key principles and minimum standards

For the national NCP systems:

a) The system of National Contact Points will be established, operated and financed under the responsibility of the Member States and countries associated to the programme. While acknowledging different national circumstances, the relevant national authorities will ensure compliance with these minimum standards and guiding principles.
b) The relevant national authority will alone be responsible for nominating NCPs, in line with the common structure.
c) A National NCP Coordinator will collaborate with the national authority in the operational management of that country's NCP system. In so doing the Coordinator will maintain an overview of the national system, to ensure overall operational consistency, and will liaise with the Commission coordinating services on any cross-cutting questions of operational policy, including training, and for horizontal objectives such as gender equality.
d) Each national authority will ensure that measures are in place for the smooth operation of the NCP system within the country concerned, including sufficient administrative capacity, performance monitoring, and compliance with the minimum standards.
e) Robust rules for ensuring confidentiality and for avoiding conflicts of interest should be established, in accordance with national law. In appointing NCPs, it is important to avoid situations that could later give rise to potential conflicts of interest, particularly where the host organisation of an NCP may itself become an applicant in a proposal.

f) If a host organisation does act as an applicant, mitigating measures should be established within the institution if necessary (eg. "firewalls" between the departments involved in submitting proposals, and those responsible for the NCP function)[1].

Clarifications in relation to points (e) and (f) above:

In all circumstances, NCPs must act to avoid any real or perceived conflict of interest. Special rules apply for the participation of an NCP in a proposal.

In this context "participation in a proposal" means a named NCP identified as either carrying out the R&I activities, or in an advisory or supporting role (e.g. project advisory board)*.

(i) An NCP must not participate in a proposal in relation to the work programme part where he or she provides NCP services, unless, in exceptional circumstances, the Commission allows such participation, due to the specific nature of a given call;

(ii) If an NCP intends to participate in a proposal where he or she provides NCP services, the official notification from the national authority announcing his or her withdrawal from NCP functions must be received by the Commission before the opening of the corresponding call;

(iii) It may be possible for an NCP to participate in a proposal in relation to a work programme part other than the one where he or she provides NCP services. In these cases the host organisation must:

- put in place measures to ensure that the NCP concerned does not receive confidential information from other NCPs;
- inform the Commission and the national coordinator of the intended involvement of the NCP, and describe the measures mentioned above;

(iv) NCPs, acting in that capacity, shall not provide letters of support or similar documents in relation to specific proposals;

(v) NCP national coordinators must draw these standards to the attention of the responsible hierarchy in every host organization.

* An NCP may participate in an advisory or supporting role in a project, once grant preparation has started.

[1] These concerns do not arise in the case of any calls for proposals targeted at NCPs themselves (e.g. transnational networks).

g) Cooperation with the Enterprise Europe Network will be set up in each country, taking into account national circumstances. This will include provisions for a one-stop-shop service for SMEs, particularly newcomers, directing potential applicants to the most appropriate service.
h) A Horizon 2020 web portal will be established by the relevant national authority in every country, building on existing web portals as appropriate. The portal will include relevant EU and Horizon 2020 visual identities, essential references, and clear links to all the relevant national support services (which may themselves be the subject of distinct web sites). The portal will provide a single point of entry for all participants, including SMEs, particularly those new to EU programmes. The Commission will establish a site on EUROPA that links directly to the national portals.
i) The Commission will facilitate the organisation and operation of the NCP network, provide coordination where necessary, and help ensure compliance with the minimum standards and guiding principles.
j) Third countries are also invited to nominate NCPs, in line with the common structure.

For each NCP [2]:

k) The work of NCPs will be guided by the principles of transparency and equal access to calls under Horizon 2020.
l) NCPs should be supported within their respective host organisations or by their national authorities in terms of staff and equipment (eg IT) to a level commensurate with the scope of the mandate, and the size of the potential constituency.
m) The NCP service should be accessible by e-mail and phone during working hours, with appropriate back-up arrangements in the case of absences. This should include a functional mailbox.
n) Every NCP should be fully conversant with the objectives, principles and content of that programme part for which they are the nominated specialist.
o) NCPs should be knowledgeable about all aspects of Horizon 2020, beyond their specialist area, thereby allowing effective signposting in line with the principle of 'no wrong door'.
p) NCPs should at least be aware of opportunities provided by related programmes (eg. COSME, ESIF), and be familiar with the relevant sources of advice in the country concerned (e.g., Managing Authorities).
q) All NCPs will establish mutually supporting relationships with the Enterprise Europe Network in their country, in accordance with the national arrangements.
r) NCPs should be good communicators, and be able to adapt methods as necessary, taking into account the diversity of actors that make up their constituency (eg. academia, industry, including SMEs, public authorities etc).

[2] Because of their specific role, not all provisions of this document apply to the NCPs for the Joint Research Centre. (See annex 1 for more details).

s) In line with the collaborative nature of EU programmes, and with the goals of the European Research Area, NCPs should be ready to participate actively in transnational networks. They may act as trainers or as trainees as appropriate.
t) In accordance with national law, systems should be in place to ensure that confidential information that comes into the possession of NCPs is treated accordingly.
u) NCPs must be free from conflicts of interest between their NCPs activities and the rest of their professional activities. NCPs will not be appointed as proposal evaluators in Horizon 2020.

4. Core functions of an NCP

Informing, awareness raising

- Circulate general and specific documentation on the Horizon 2020, including on conditions for participation, on possibilities and conditions for submission of proposals, and on project budgeting and reporting.
- Organise information and promotional activities – in liaison with the Commission services when appropriate- e.g. infodays, seminars, conferences, newsletters, web sites, fairs, etc.
- Raise awareness of:
    - the innovation activities in Horizon 2020, including the objective of enhanced participation of industry and SMEs.
    - funding opportunities offered through externalised measures, notably Articles 185 and 187 initiatives, and EIT KICs, within the scope of a specific NCP's mandate.
    - the interdisciplinary nature of Horizon 2020, especially with regard to the societal challenges.
    - the objectives to ensure gender balance in Horizon 2020, and of strengthening the link between science and civil society.
    - the activities of the Joint Research Centre, the in-house science service of the Commission, to relevant national stakeholders from the scientific community, industry and public authorities.
- Provide information as necessary on other European RTD-programmes in the field of research and innovation such as COSME, Eureka, COST, R&D related parts of European Structural and Investment Funds, and establish working links with the respective specialist support services.

Assisting, advising and training

- Assist researchers and organisations, in particular new actors and SMEs, with a view to increasing their participation in Horizon 2020.

- Assist in partner search activities notably by using internet based tools, co-operation networks, European Enterprise Network partnership services for SMES etc.
- Advise on administrative procedures, rules and issues (e.g. role and responsibilities of participants in a consortium, costs, rights and obligations of participants, ethical rules and for the principles laid down in the Commission Recommendation C(2005)576 on the European Charter for Researchers and the Code of Conduct for their Recruitment). Where necessary this will be in liaison with the specialist Legal and Financial NCPs.
- Advise participants, in particular smaller organisations and SMEs, on the setting up of appropriate management and legal structures in projects with large budgets and/or numerous participants.
- Explain the scope and the modalities of funding schemes to be used in Horizon 2020.
- Organise courses and training sessions on Horizon 2020 where appropriate, for intermediaries and information multipliers to ensure high quality of advice.
- Where appropriate, organise courses and training seminars for specific target groups (SMEs, universities, business organisations, women in science etc.) or on specific topics (legal aspects, modalities for participation, research and innovation areas covered by several specific challenges and programmes, financial rules etc.).

Signposting and cooperation

- Signpost to other business support network services those potential participants who require assistance, for example on general EU matters or matters relating to internal market, technology transfer, intellectual property rights (IPR) or regional development typically dealt with by these networks (e.g. EEN, EIB, Structural Funds, YourEurope, Solvit etc).
- Signpost to national funding services and programmes and to ERA Net Projects.

5. Cooperation between NCPs and Commission services

The Commission considers NCPs to be important partners in the implementation of Horizon 2020, and the main structure for providing practical information and assistance to potential participants.

Main interactions

The Commission will:

- Provide general and specialist information on Horizon 2020 related to the mandate of the NCPs.
- Invite NCPs to participate in information and awareness actions related to the activities that are organised by the Commission services, and reimburse their travel and subsistence costs, consistent with the Commission rules and policy.
- Invite NCPs to thematic conferences and seminars which the programme directorates organise and when possible reimburse their travel and subsistence costs, consistent with the Commission rules and policy.
- Provide information at the earliest possible time on work programmes and roadmaps, upcoming calls, changes in priorities or administrative procedures, particular provisions related to externalised bodies; statistics of calls and evaluations (including the externalised measures), relevant information on funded projects etc., striving for equally high quality of information flow throughout.
- Together with the national coordinators, periodically draw up a programme for general and specialist training courses across the NCP network, and coordinate and monitor its implementation.
- Inform NCPs about the results of any possible invitations to submit expressions of interest.
- Provide leaflets, brochures and other relevant information for further distribution by NCPs.
- Provide the data and information necessary for the proper performance of the NCPs. In particular, the EU and Associated Country NCP coordinators will receive, immediately after the Programme Committee has been informed, information on the outcome of proposal evaluations, in a similar form to that provided to the Programme Committee members.
- Where practicable, and consistent with the legal framework, NCPs in third countries will receive aggregated evaluation data, and selected data on proposals.

Practical modalities

The Commission will:

- Nominate contact persons for NCPs in the Commission services, mirroring the NCP structure.
- Identify a contact point for encouraging mutually supporting relationships between NCPs and EEN
- Establish and operate an NCP web area for supplying information and as a discussion forum.
- Support transnational networks of NCPs, as a means of stimulating European cooperation in research and innovation, and as a contribution to the realisation of the Innovation Union and the European Research Area.
- Ensure that NCPs are fully informed about the reimbursement rules for NCPs attending meetings, and any updates to these. These will again be spelled out with every invitation to an NCP.

- Where practicable, NCPs in third countries will be invited to participate in the activities and events mentioned above, but will in general not receive any financial support from the European Commission services unless specifically agreed otherwise.

Maintaining and improving quality

- The transnational networks mentioned above will, among other objectives, foster the minimum standards and enhance the competence of NCPs where needed.
- For the NCP system as a whole, the Commission will convene meetings of the national NCP coordinators to provide an opportunity to discuss the collaboration based on the minimum standards, share experience, to identify good practices and to address problems. The training programme mentioned above will be developed in this context.
- The meetings will include an invitation for national coordinators to describe lessons learned from the national monitoring exercises.
- When invited to do so by a particular national coordinator, one or more countries could undertake a "friendly peer review" of that country's NCP system, possibly through a transnational network project, with a view to benchmarking performance and making recommendations for further improvement. The approach to be used will be developed further at the meetings of the national NCP coordinators.

6. Nomination and recognition process

The names and contact details (address, telephone, email etc.) should be sent officially on behalf of the relevant national authorities. These notifications should be addressed to the Director-General of DG Research and Innovation, with a copy to the official in charge of coordination.

Any subsequent changes to the nominated persons should be communicated in the same way. However, simple changes of contact details (and not of the nominated persons) can be just sent to the Commission coordinating service.

The Commission will publish the nominated NCPs on its online NCP database, and refer to this database in the guides for applicants and in other information material.

If it becomes apparent that an NCP, or group of NCPs, is failing to comply with these minimum standards, the Commission services will raise the matter with the national NCP coordinator, or with the national authority, as appropriate. The aim will be to identify how best to improve the services, and to propose remedial actions.

If the problem persists, or in the case of grave misconduct, the Commission will inform the national authority (and/or Permanent Representation). If necessary, having first consulted the national authority, the NCP(s) in question will be "de-recognised" and the national authority concerned will be invited to nominate a replacement NCP.

"De-recognised" means that the NCP will be removed from the mailing lists and will no longer receive information directly from the Commission, including any confidential information. The NCP will no longer be listed on the relevant EU web site.

7. Confidentiality

A written declaration from the relevant national authority will be required by the Commission, confirming that the necessary measures are in place with regard to the handling of any confidential information, (e.g. the outcome of the evaluations).

Annex I: NCP Structure

1. National NCP Coordinator
2. Legal and Financial aspects
3. SMEs*
4. Access to Finance*
5. European Research Council
6. 'Future and Emerging Technologies';
7. 'Marie Sklodowska-Curie actions on skills, training and career development';
8. ‘European Research Infrastructures’;
9. 'Information and Communication Technologies (ICT)';
10. 'Nanotechnologies, advanced materials and advanced manufacturing and processing';
11. 'Space';
12. 'Health, demographic change and wellbeing';
13. 'Food security, sustainable agriculture, marine and maritime research and the bio-economy'; & 'Biotechnology';
14. 'Secure, clean and efficient energy';
15. 'Smart, green and integrated transport';
16. 'Climate action, resource efficiency and raw materials';
17. 'Inclusive, innovative and reflective societies';
18. Spreading excellence and widening participation
19. Science with and for Society
20. Secure societies
21. Euratom
22. Joint Research Centre**

** Task to be performed in liaison with Enterprise Europe Network, according to the national situation.*

*** As the in-house science service of the European Commission, the JRC is in charge of direct research under the Horizon 2020 framework programme. The JRC NCPs act as a key intermediaries and operational contact points between the JRC and the relevant stakeholders from the scientific community, industry and public authorities of the EU Member States and Associated Countries.*

The JRC NCPs' main missions are: to raise awareness about the JRC in their country; provide information about the JRC to relevant stakeholders in their country; advise and support relevant stakeholders regarding the practical modalities to collaborate with or work at the JRC; foster the contacts and collaboration between the JRC and scientific stakeholders in their country; act as a source of information and support for activities of the JRC in relation with their country.

Besides its close contacts with the special JRC NCPs, the JRC also liaises with and associates the thematic NCPs responsible for the 'societal challenges' priority under Horizon 2020 in its activities.

Annex II: Terminology

Client: Any potential applicant or other participant in Horizon 2020 seeking assistance from an NCP. (The term does not imply payment for services rendered.)

Commission coordinating service:

Official in charge of coordination of the network as a whole. Liaises primarily with the national NCP coordinators.

Commission NCP correspondent:

Officials in charge of exchanges with the individual NCP functions.

Host organisation: The legal entity (ministry, agency, research body, company etc) to which an NCP is affiliated.

National authority: The relevant government department responsible for the Horizon 2020 NCP system. NCP nominations are made officially on behalf of the national authority.

National Contact Point (NCP):

Individual officially nominated by the national authority to perform one or more of the NCP functions in line with the common structure.

National NCP coordinator: NCP in charge of coordinating the national system, and other horizontal tasks, and the main interlocutor with the Commission on operational policy questions.